Implementing Smart Materials And Technologies For Medical Emergency Airway Access Devices

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ABSTRACT

Airway management and intubation procedures continue to challenge anaesthetists daily. Failure to secure the airway with an endotracheal tube in a timely manner upon induction of anaesthesia can lead to serious complications, including death or disability. Most anaesthetists consider endotracheal tube introducers (bougies) as essential equipment; however, there are many different types with relatively little performance data to help anaesthetists make an informed choice. Standard bougies have a requirement to be reshaped multiple times in an attempt to create the desired navigation path of the endotracheal tube. Manoeuvring within the trachea presents significant navigation and control challenges whilst attempting to minimise trauma. Improvements in airway management care is often facilitated by the introduction of new or improved airway management equipment, however understanding their physical properties is imperative for the development of an improved device. This research addresses the development of a new emergency airway access device; the *steerable bougie* has been designed to enhance device control and improve the speed and the safety of bougie guided endotracheal intubation.

Initial work focussed on assessing the case of need for the development of an improved bougie, in addition to identifying design criteria and specifications. A number of anaesthetists were surveyed and identified increased manoeuvrability in-situ, improved shape retention and steerable control as desirable device attributes. Initial design, development and testing explored the feasibility of actuators and smart materials capable of replicating a steerable movement. Initial prototyping and testing demonstrated that flexible steerable tips controlled by Flexinol® actuator wires could effectively control the navigation of the tip.

Understanding the physical properties of bougies is fundamental to patient safety, device operation and ultimately equipment procurement decisions. Accurate and reliable bougie safety performance data, including perforation forces, bougie tip pressures and shape retention is not available. Equipment evaluations often fail to consider key testing criteria including testing equipment specifications. Tip pressure studies conducted identified current equipment weaknesses with airway trauma, including significant mucosa damage and perforation easily achieved by low tip pressure forces. The *steerable bougie* demonstrated significantly lower tip pressure forces compared to commercially available bougies. Repeatability testing conducted assessing tip pressure performance identified variable degradation over time for all commercially available bougies; the developed steerable bougie presented limited degradation over time.

Anaesthetists define shape retention as a critical performance characteristic for a bougie. To match the curvature of a patient's airway multiple bougie shaping iterations are usually required, however bougies often return to their original shape within seconds of being manipulated. All bougies present initial snap back and shape loss. To identify bougies with optimal shape retention, an innovative *Shape Retention Testing System* (SRTS) was designed and built to test shape retention characteristics. Testing demonstrated that bougies with dual or multi-lumened structures provided the highest level of shape retention hold. The steerable bougie outperformed the commercially available bougies at most shaping distances, demonstrating limited shape loss.

Utilising the accumulated bougie performance data, a steerable bougie with improved shape retention, reduced tip pressures and reduced likelihood of causing airway trauma has been developed. The steerable bougie is connected to an ergonomically designed controller attached to a laryngoscope that can also be easily attached/detached and sterilised.

This research has demonstrated that a steerable bougie with augmented physical properties can be developed that not only provides medical professionals with a device that has increased steerability and usability for time critical procedures but will also reduce the likelihood of patient airway trauma.

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DECLARATION

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Additional Declaration Notes

The development for the OTPPS and RTMS software presented in Chapter 7 has been completed in collaboration with Mr Paul Watts (Software Developer, Medical Design Research Group, Nottingham Trent University, UK). Mr Watts contribution to the production of the OTPPS and RTMS software package has been acknowledged within this thesis and in all of the resulting publications through his co-authorship.

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CHAPTER 1 – INTRODUCTION & RESEARCH CONTEXT

1.1 Introduction

When the NHS was formed on July 5th 1948 it set out with the model that good healthcare should be available to everyone regardless of the wealth of the person (Choices N.H.S, 2013). The NHS set out with three key principles and values, to meet the needs of everyone, to be free at the point of delivery and to be based on clinical need and not ability to pay.

The NHS Consortium for England later in 2015 set out seven key principles to guide the NHS in all it does (Gov.uk, 2015), these include:

1. The NHS provides a comprehensive service, available to all.
2. Access to NHS services is based on clinical need, not an individual's ability to pay.
3. The NHS aspires to the highest standards of excellence and professionalism.
4. The patient will be at the heart of everything the NHS does.
5. The NHS works across organisational boundaries.
6. The NHS is committed to providing best value for taxpayers' money.
7. The NHS is accountable to the public, communities and patients that it serves.

In the modern era of the NHS finds itself under severe financial pressure. Robertson, Appleby and Evans, (2018) report that NHS overall public satisfaction was 57% in 2017, a six-percentage point drop from the previous year; yet dissatisfaction increased by seven percentage points to 29%. Patient satisfaction is a critical factor in all health care services; this is no different for anaesthesia. Heidegger et al., (2002), Heidegger, Saal and Nübling (2013), Walker et al., (2016) all present studies on patient satisfaction within anaesthesia specialisms suggesting satisfaction in the UK is high, however, improvement is still required. Factors such as information, communication, emotional relationships, and post-operative complications because of operator or equipment error/misuse are all factors that affect patient satisfaction.

The NHS is under severe pressure to deliver performance targets which are not achievable within the current economic climate; these challenges are likely to continue for the foreseeable future. To lessen the burden of ill health on the population and healthcare financial strain, the NHS finds itself striving towards a forward-thinking approach by implementing an innovation into action plan. The NHS Five Year Forward View (England.nhs.uk, 2015) desires greater ambition in the transformation of healthcare services

by 2020. The challenge however is how to accelerate innovation safely and effectively to enable the NHS to seek the benefits from this model.

To accelerate the uptake of high-impact innovations, the innovation into action concept requires application across all disciplines; however, medical professionals cannot do this alone. Multidisciplinary teams will be required to not only innovate, design and manufacture new systems and interventions but also provide significant advancements in technology development for optimum success.

Innovation within equipment design is one of the many areas where innovation can improve practice. Within airway management, Hinkelbein et al., (2017) has recently stressed the importance of innovation but has placed an emphasis on quality not quantity. Innovation within airway management has been documented for many years with one of the most prominent innovations in recent times being the introduction of video laryngoscopes.

Difficult airway management has and will continue to result in serious incidents, however improvement in practice, technique, equipment and guidelines aims to reduce this. If an airway is not secured quickly, serious consequences including disability or death are possible. Improvement in equipment presents an opportunity to increase the safety and efficiency of procedures within anaesthesia, especially within emergency airway management.

The research presented within this thesis focuses on the development of a device entitled the “Steerable Bougie”. Bougies are long, flexible, relatively narrow rods that have some intrinsic “memory”. They can be shaped and directed into the trachea more easily than an endotracheal tube when the laryngeal view is limited. Bougies are commonly used during endotracheal intubation to help guide the insertion of an endotracheal tube into the trachea. They are particularly useful with the management of difficult intubations but must be used with caution to prevent injury.

Bougies are manually manipulated prior to use to match the curve of the patient’s airway. If the bougie does not retain its shape whilst in situ and it cannot be adjusted, it must be removed and reshaped, this can be a time-consuming process. Airway management procedures are often time-critical, therefore improving the standard bougie through the incorporation of smart materials and technologies to improve the speed, safety and efficiency of the procedure would be an innovative step forward.

There are many steerable devices that currently exist on the market within many medical specialism, especially within cardiovascular and minimally invasive surgery; however, these

are often expensive to manufacture, purchase and maintain. The complexity of the equipment used in practice can contribute to many complex issues within anaesthetic practice; these include slow set up for use in emergencies, pre-procedure planning, anticipation of patient anaesthetic care difficulties and refreshing and maintaining equipment training.

At Nottingham University Hospitals Trust, Queens Medical Centre, approximately two thousand bougies a year are used; these are purchased at 10-30 GBP (2017) per unit dependant on the brand and manufacturer. Prices are however significantly higher when purchased outside of the NHS supply chain; for example, the Reusable Tracheal Tube Introducer (Eschmann/Portex Gum Elastic Bougie) currently costs 28.89 GBP per unit (2018) within the NHS supply chain, however outside of this supply chain prices are in excess of 70.00 GBP (2018).

Marshall and Pandit (2016), suggest that the original gum elastic bougie (GEB) is still considered the gold standard device for use; the GEB performs significantly better in comparison to the cheaper single use bougies currently available for use within practice. These perform poorly in comparison and generate higher tip pressures.

It can be argued whether a stylet or bougie should be utilised in practice when a difficult airway is presented. In an emergency setting, quick and effective intubation is required and equipment choice is critical. Gregory et al., (2012) highlighted that it is possible to achieve quicker intubation times with a stylet rather than a bougie. Nielsen, Hope and Bair (2010) however argues when using a GlideScope video laryngoscopy there was no benefit when considering the speed or ease of intubation when comparing the use of the bougie over a standard stylet. Conversely, recent research conducted by Driver et al., (2018) identified that within an emergency department setting, using a bougie compared to the use of an endotracheal tube and stylet resulted in significantly higher first-attempt intubation success among patients undergoing emergency endotracheal intubation.

Based on the issues identified, this research will focus on the design and development an emergency airway access device for medical professionals through the implementation of smart materials and technologies to improve tracheal intubation procedures.

1.2 Research Context and Scope

Complications with airway management procedures have been documented for many years. Airway management procedures continue to challenge anaesthetists daily, with serious

consequences including death or disability, trauma to the airway, cardiac arrest and hypoxemia all a reality (Gannon, 1991).

Airway management can be split into two categories, basic airway management techniques and advanced airway management techniques. The basic techniques include the use of oral airway devices, nasal airway devices and ventilation. Advanced airway management techniques include the use of supraglottic techniques (nasopharyngeal, oropharyngeal, supraglottic), infraglottic techniques (tracheal intubation) and surgical methods (cricothyroidotomy and tracheostomy).

The two most common airway management techniques used are face mask ventilation and tracheal intubation. El-Orbany and Woehlck (2009) identifies that mask ventilation is a fundamental skill in airway management however difficult mask ventilation (DMV) can often occur. Tracheal intubation is the procedure used to place a flexible plastic tube (endotracheal tube) into the trachea to maintain an open airway.

Airway management complications causing temporary patient harm are common; severe injury is rare (Cook and MacDougall-Davis, 2012). Hypoxia, the lack of oxygen provided to the body is one of the most common causes of airway related deaths (Cook et al., 2011b). Safely securing a difficult airway successfully is a significant issue that has medical professionals, researchers and medical device designers constantly striving for improvements.

Airway management is a critical part of emergency airway access care provided by anaesthesiologists, irrespective of the type of anaesthetic administered (Berkow, 2004). It is widely accepted that there is no one standard definition for a difficult airway, mainly due to the numerous airway assessment and management techniques that exist.

The most appropriate definition of a difficult airway is provided by Apfelbaum et al., (2013) as the clinical situation in which a conventionally trained anaesthesiologist experiences difficulty with facemask ventilation of the upper airway, difficulty with tracheal intubation or both. Berkow (2004) describes four categories for which a difficult intubation can be classified. The four categories were then expanded to five as defined by the American Association of Anaesthesiologists in the 2013 Practice Guidelines for Management of The Difficult Airway, these are described by Apfelbaum et al., (2013) as:

1. Difficult facemask or supraglottic airway (SGA) ventilation (e.g., laryngeal mask airway [LMA], intubating LMA [ILMA], laryngeal tube).

2. Difficult SGA placement.
3. Difficult laryngoscopy.
4. Difficult tracheal intubation.
5. Failed intubation.

Successful anaesthetic care commences with the correct application of airway management techniques which aims at reducing the complications associated with anaesthetic procedures. To avoid complications and failure of airway management, the expectation is to apply the recommendations presented by the United Kingdom's Difficult Airway Society (DAS) Guidelines (Frerk et al., 2015) and the supporting intubation guidance. Airway complications are more frequent when a patient presents a difficult airway; however, complications occur regularly in patients who have been deemed to have an easy airway (Cook and MacDougall-Davis, 2012).

There are many methods of overcoming the complications encountered during anaesthesia; however, this can often be daunting in a time critical procedure. Often this requires the anaesthetist to *"STOP AND THINK"* (Frerk et al., 2015) however other actions such as assessing the airway management techniques applied and selecting the optimum equipment and device for safe practice are just as important.

When difficult airways are presented, the use of additional equipment to aid the guidance of tube placement to improve procedure success is often required. Several equipment options are presented, the most common being the bougie (long flexible rod), which is used to allow correct placement of an intubation tube. Other more complex equipment is available to aid intubation and an assessment of this equipment should be made in relation to a patient's physical status. However, the vast majority of the equipment used can often be significantly expensive for only a small increase in improved functionality.

Crawley and Dalton (2015) suggests that airway assessment must go beyond carrying out a series of bedside tests; problems must be identified in each facet of airway management and these should be incorporated logically into an appropriate strategy. Factors that should be considered when generating any airway intubation strategy, include anatomical variations, airway pathology and assessing previous strategies undertaken.

Before any anaesthesia procedure takes place, it is important to consider the risks, benefits, and consent. Hardman, Moppett and Aitkenhead (2009) provide a detailed review of consent within adults and the necessary procedures that should be put in place and adhered to. Cook

et al., (2011a), Crawley and Dalton (2015), and Cook and MacDougall-Davis (2012) all provide a comprehensive review of risks and major complications of airway management. Crawley and Dalton (2015) suggests that the anaesthetist should be able to answer the following key questions before completing any procedure:

1. Will I be able to mask ventilate?
2. Will I be able to perform laryngoscopy, directly or indirectly?
3. Will I be able to intubate this patient?
4. Is there a significant aspiration risk?
5. If I predict difficulty, should I secure the airway awake?
6. Can I access the cricothyroid membrane if needed?
7. How will the airway behave at extubation?

Emergency airway management procedures are not only performed as routine procedures but often performed on patients in poor physical or critical condition. Several factors need considering which influence successful decision making for patient survival (AirwayCam, 2011), these are:

1. The dynamic deterioration of the clinical situation; assessment will be required on how quick a medical procedure needs to be completed to ensure patient survival.
2. The patient status and whether they are cooperative or non-cooperative; considerations include patient consciousness, pain severity and medical history.
3. Respiratory and ventilatory compromise, apnea times (whether these are extremely short and safe), and impaired oxygenation.
4. Oxygenation impairment and the assessment of how quickly a procedure must be completed to secure the airway.
5. Patient's starvation status i.e. does the patient have a full stomach increasing risk of regurgitation, vomiting or aspiration.
6. Patient's secretions, blood loss, vomitus.
7. Anatomical status and impairments, i.e. distorted anatomy.

The Fourth National Audit Project by the Royal College of Anaesthetists (NAP4) conducted by Woodall and Cook (2010), presents data collected from 309 UK hospitals indicating that the number of general anaesthetic procedures reported in the two-week period analysed was 114,904. Extrapolated, this suggests an estimated 2.9 million anaesthesia procedures

are conducted annually. One of the key findings discussed by Woodall and Cook (2010) suggests that the primary airway management device used for general anaesthesia was a supraglottic airway (56.2%) followed by, a tracheal tube (38.4%) and facemasks (5.3%). The total number of intubations performed nationally per year is estimated at over a million, suggesting a large target market.

When attempting to guide a tracheal tube within the trachea, the most common equipment utilised includes the use of a laryngoscope and a bougie or stylet (or another appropriate adjunct). Visualization of the larynx by direct or indirect methods is referred to as laryngoscopy; the aim of this procedure during airway management is to complete the passage of a tracheal tube. (Collins, 2014). Laryngoscopy is typically conducted for tracheal intubation and airway management and critical care practice; it is also extremely common in trauma situations.

Video laryngoscopy is increasingly used and has been proposed as the recommended standard; prior to this, direct laryngoscopy was the sole method used by anaesthesiologists to insert a tracheal tube into the trachea (Zaouter et al., 2014). Video laryngoscopy has many benefits compared to conventional laryngoscopy. A video laryngoscope utilises a camera at the distal end of the instrument, allowing the larynx to be visualized even when it is impossible to obtain a straight line of sight. Even if an increased view is achieved, greater control of the adjunct (i.e. bougie, stylet) is still desirable, as problems can still be encountered during device manoeuvrability in-situ.

A recent systematic review completed by Lewis et al., (2016) analysing video laryngoscopy versus direct laryngoscopy for adult patients requiring tracheal intubation, identified thirty-eight studies that suggest the use of a video laryngoscope demonstrated significantly fewer failed intubations. In some patients even when the video laryngoscope allows a good view of the larynx to be obtained, this can still present its challenges due to the angles involved within an intubation (Nielsen, Hope and Bair, 2010).

Unlike many products, medical devices have two fundamental user perspectives, the user/operator perspective and the patient perspective. Martin et al., (2012) argues that for a medical device to be considered ‘well-designed’ firstly it must be clinically effective and safe; however, it must also meet the needs of the user and the patient. The design and manufacture of any new medical device is a complex task that considers a large spectrum of factors.

One of the common misconceptions is that once the problem has been identified by a clinical or medical expert and passed over to the design team or manufacturer, it is the sole responsibility of the designer or manufacturer to ensure this product makes it to the market and becomes a commercial success. The utilisation of multidisciplinary design and development teams are fundamental to success; medical and clinical experts must be able to work with design engineers and device manufacturers and vice versa. Eberhardt et al., (2016) describes the development of multidisciplinary team-based learning environments in undergraduate and graduate engineering curricula, suggesting many positive outcomes that are focused on medical device design due to a global shift in the teaching methodology of science and engineering toward multidisciplinary, team-based processes.

Sterck (2017) also suggests that multidisciplinary project teams are a necessity for successful medical device development. Involving the required various disciplines at the beginning of a project enables the creation of the desired synergy to manage a project effectively. Utilising a multidisciplinary team through the design, development and implementation of smart materials and technologies for the development of an emergency airway access device will be essential.

1.3 Research Aim & Objectives

The aim of this research is to design and develop an emergency airway access device for medical professionals through the implementation of smart materials and technologies to improve tracheal intubation procedures.

To ensure the overall aim of this research is achieved a set of objectives have been generated:

1. Investigate the incorporation of smart materials and technologies into the fabrication of emergency airway access devices with the aim of increasing the success rates of airway access procedures whilst combatting the safety concerns and associated medical risks.

2. Develop a conceptual framework to depict the design development process for an emergency airway access device.

3. Design and develop iterative prototypes of the steerable bougie considering the usability and ergonomic issues associated with intubation procedures.

4. Design and manufacture accurate testing solutions/systems to validate the development of an emergency airway access device constructed during TRL stages 1-5.

5. Design and apply testing protocols and procedures for designed emergency airway access devices and testing systems to validate design construction and device accuracy.

1.4 Problem Statement

When in use the standard bougie requires reshaping whilst inside and outside of the patient to allow the desired navigation of the endotracheal tube. This results in a time-consuming process of reshaping and if a patient's airway is rapidly closing this becomes a significant issue. The longer time a patient's airway is blocked the patient becomes oxygen deprived and this could result in further complications. By producing an emergency airway device similar to a bougie which allows the operator to manoeuvre inside the body in one motion will speed up the intubation procedure. The development of a mid-tier emergency airway device capable of being used in a similar manner to a standard bougie should be designed focusing on a steerable application. Initial designs for the proposed steerable bougie have been created (Hughes, 2013); however, the device requires significant development to become a viable product.

1.5 Original Design Brief

The programme of the work has been designed around the development of a device entitled "The Steerable Bougie". The original design brief set by Nottingham University Hospitals Trust must be considered:

"The scope of this project will be to develop a steerable endotracheal bougie targeted to replace current disposable bougies. QMC uses approximately 200-300 per year at a cost of £11 per unit. The alternative is to use a GlideScope, Airtraq or an optical stylet each of which has a number of disadvantages including disposability, cost per use and lack of the versatility of a traditional bougie.

The product should be compatible for use with both conventional and video laryngoscopes used in QMC. It should be similar in flexibility to the existing bougie and be easy to shape whilst in surgery. It should display similar or better shape retention than the existing bougie and should be compatible with the whole range of adult sized intubation tubes. The final

manufactured product should cost no more than £17 so as to be competitive within the existing market. All parts that come into direct contact with the patient must be disposable."

Dr James Armstrong (Consultant Anaesthetist, Nottingham University Hospitals Trust (QMC)

1.6 Alterations To The Original Design Brief

Alterations to the original design brief were deemed necessary based on device development and consultation with the external anaesthetic consultant's in addition to advice given when in attendance of the Difficult Airway Society (DAS) Conference 2015. The project team soon realised that rather than the steerable bougie being a device, which should be used if the original bougie/stylet proves ineffective; the device should be used as a two in one device but only if the price point is suitable. The steerable bougie must be able to function as not only an ordinary bougie but also a steerable device.

The biggest change is therefore to ensure that the redesign of the bougie attempts to relinquish the need for the sole use of a standard single use bougie. The airway device market has many devices all completing the same functional task. By introducing increased steerability and shape retention capabilities in a bougie, this would demonstrate a significant improvement. However, the price point for this device should be comparative or only add a small additional cost compared to a single use/disposable bougie.

1.7 Thesis Structure

A schematic overview of the thesis is presented (Figure 1.1) demonstrating how the research activities link; a brief description of each of the further seven chapters is presented below:

Chapter 2: Literature Review: The literature review covers several topics ranging from design, engineering, methodology, testing techniques and anaesthesia. Emergency airway access devices, techniques and problems are reviewed in addition to design and research methods that will inform the conceptual framework presented in Chapter 3. Finally, literature is reviewed focussing on the assessment of the physical characteristics of bougies with the review also focused on the quality of current methods used.

Chapter 3: Conceptual Framework: The conceptual framework presented focuses on the development of new emergency airway devices considering the theories and models discussed in Chapter 2. The generation of the main structure of conceptual framework is based upon Technology Readiness Levels, Soft Systems Methodology, Design and Engineering Methods and feedback actions.

Chapters 4 & 5: Designing/Developing The Steerable Bougie: The initial concept of the steerable bougie is presented based on the case of need survey, product design specification and assessment of suitable mechanisms for the steerable bougie including a review of Nitinol, Flexinol® and artificial muscles as a method of creating a cost-effective steerable control mechanism. The performance of the selected mechanism for incorporation requires a high level of control to accurately steer a device within the human airway; this information is presented, analysed and published.

Chapter 6: Analysing Physical Properties Of Bougie Introducers and Product Development: Chapter 6 focuses on the physical properties of bougie introducers. Airway perforation and tissue damage is a well-documented risk. Testing protocols focused on equipment analysis are presented within this chapter and considers factors including force testing, repeatability testing, tip pressure forces and perforation Forces. Repeatability testing, tip pressure studies and porcine airway perforation testing activities are all conducted.

Chapter 7: Shape Retention Testing System (SRTS): This chapter describes the development of the Shape Retention Testing System (SRTS). The SRTS has been constructed to allow bougies to be assessed within a standardised, calibrated testing system. This system aims to inform anaesthetists on the comparative device performance and shape retention characteristics of bougies and inform professional societies and academics on the optimal device for use.

Chapter 8: The Steerable Bougie (Design Verification): Chapter eight presents the development of the steerable bougie and its initial construction based on the information and data presented within Chapters 4, 5 and 6. The design considers the overall design and usability of the steerable bougie and makes recommendations for future use.

Chapter 9: Discussion & Conclusions: A review of the methods undertaken to complete the development of the steerable bougie and the associated testing systems are discussed highlighting the generation of new knowledge. The completed testing studies have contributed to the development of the steerable bougie but also provide clinical comparison within the greater context of the anaesthesia product market. The conclusions discussed within this chapter identify how the aims and objectives of the PhD have been met. Future work recommendations and a discussion on the recommended commercial device for use in practice is presented

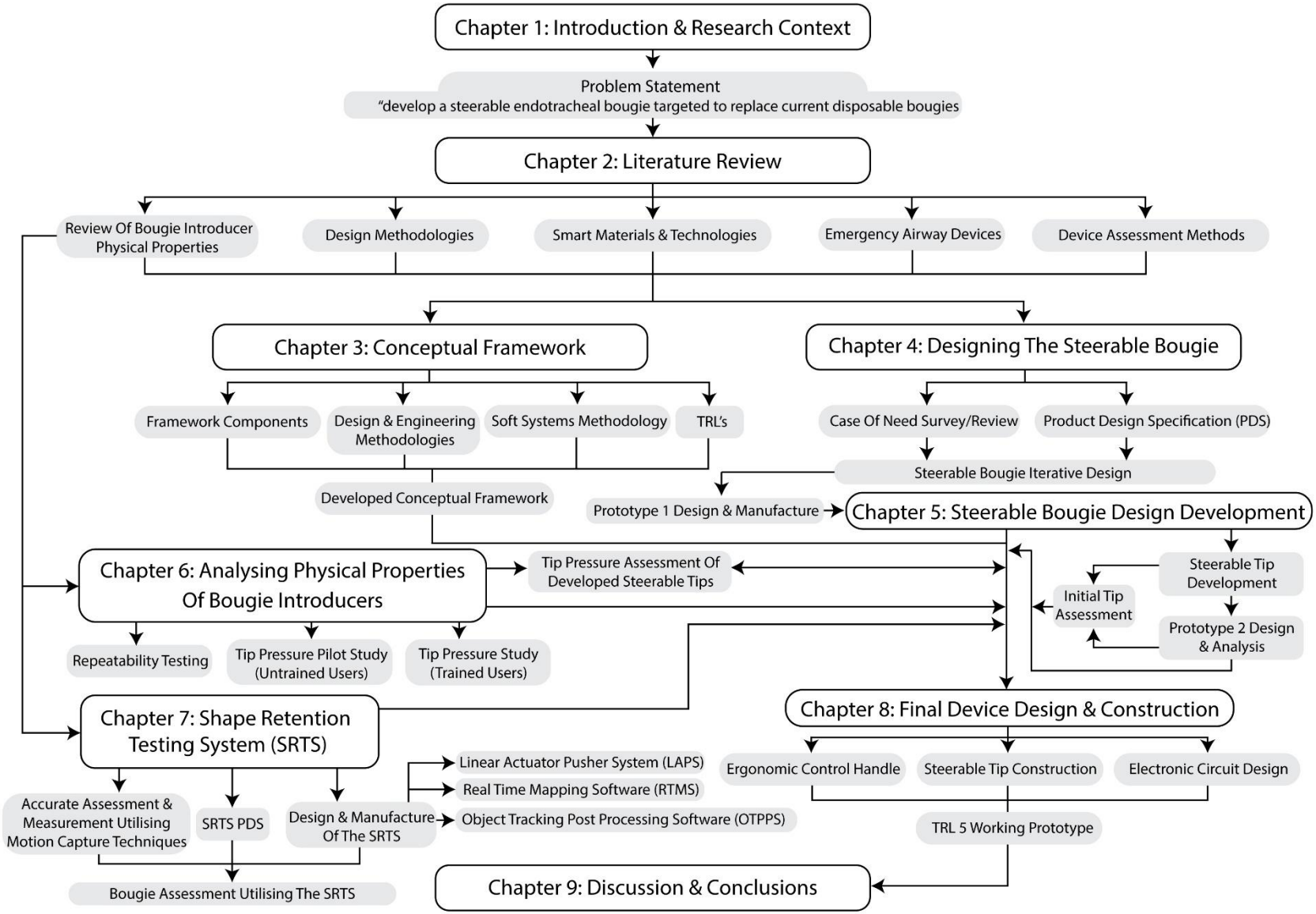


Figure 1.1: Schematic Overview Of The Thesis.

CHAPTER 2 – LITERATURE REVIEW

2.1 Introduction

The literature review presented aims to review the key themes derived from the multidisciplinary approach required for the research and design of a new novel emergency airway access device. Focus will be placed on reviewing airway assessment and management techniques, existing devices, medical device regulations, design and engineering methods and assessing the physical properties of bougie introducers. By reviewing these topics, it has been possible to not only identify key design criteria for the development of a new emergency airway access device i.e. the steerable bougie, but also dictate the research path, identifying suitable research and design methodologies to validate key design outcomes. Fundamental to this research is understanding the intubation process.

2.2 Securing A Patients Airway - Intubation

To conduct an intubation, firstly pre-oxygenating the patient with bag and mask ventilation is required. Standing behind the patient, their head must be manoeuvred into an optimum position for endotracheal intubation, this is described as the "sniffing the morning air position"; this position is superior to all the other head positions recognised (Hafiizhoh and Choy, 2014; El-Orbany, Woehlck and Salem, 2011; Adnet et al., 2001; Magill, 1926; Magill, 1930). For obese patients the ramped position should be used (Collins et al., 2004).

Next, the laryngoscope blade is inserted into the patients mouth over the right side of the tongue and displaced upwards and to the left (Figure 2.1a). The laryngoscope is then advanced until the tip of the epiglottis can be seen posterior to the back of the tongue. The anaesthetist must optimise the position of the laryngoscope blade tip in the vallecula and once accurately positioned, the laryngoscope is lifted up and away at approximately forty-five degrees in an attempt to lift up the tongue and epiglottis to enable a view of the vocal cords and laryngeal opening (Figure 2.1b).

Next, the endotracheal tube (ET tube) is inserted from the right-hand side of the mouth between the cords before passing into the trachea; the anaesthetist must ensure the cuff on the ET tube passes the cords. To place the ET in the trachea this can be completed in combination with an adjunct; the two most common are stylets or bougies in combination with the railroading of an ET tube (Figure 2.1c). The Difficult Airway Society Guidelines 2015 (Frerk et al., 2015) recommend using an adjunct where required; one of the most common devices used is the gum elastic bougie (GEB), especially when a grade 2 or 3 view of the larynx

is presented (Latto et al., 2002). Once the ET tube is in position, the adjunct and laryngoscope should be carefully removed from the patient's mouth leaving the ET tube in-situ (Figure 2.1d). Finally, the cuff of the ET tube should be inflated to prevent air leaking during ventilation.

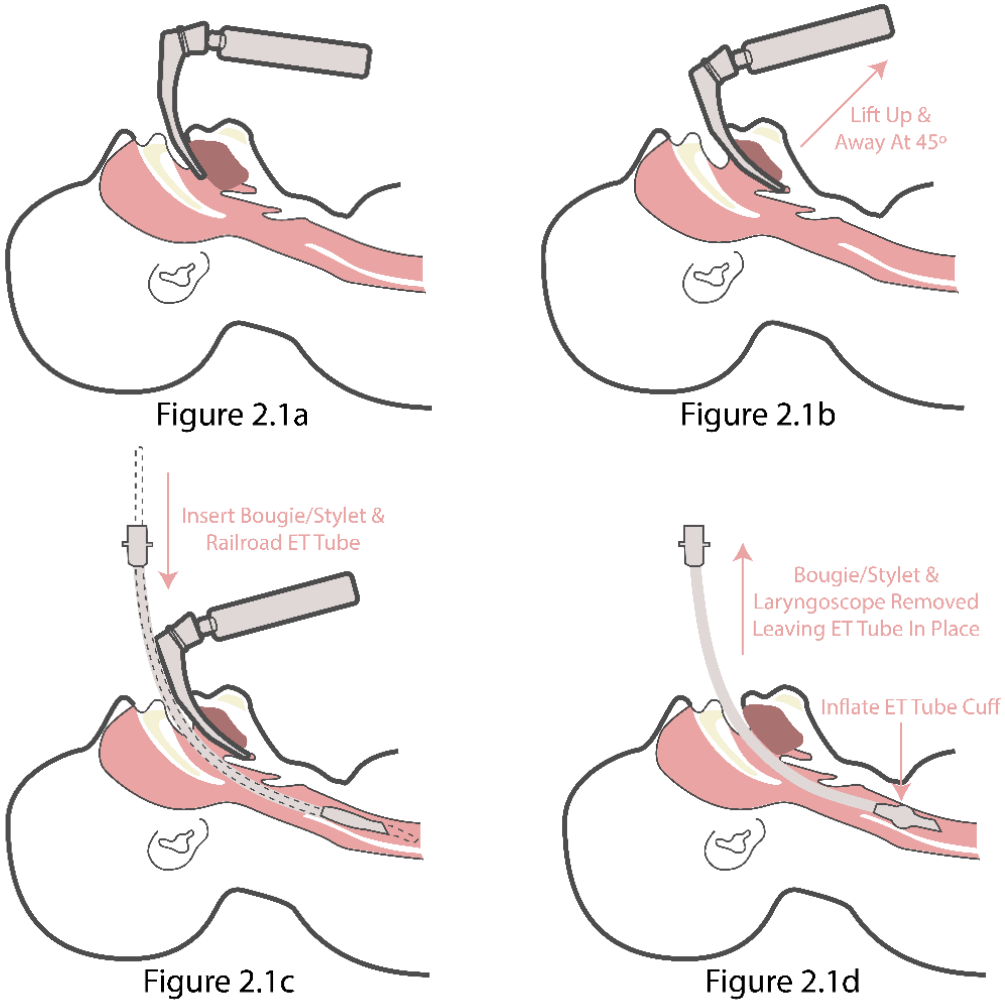


Figure 2.1 a-d: Step-By-Step Tracheal Intubation Procedure.

2.2.1 Summary Of Key Airway Management Techniques/Methods

The research presented within this thesis focuses on tracheal intubation; understanding the DAS 2015 algorithm is imperative and the associated techniques used in combination with tracheal intubation. The DAS 2015 guidelines for management of unanticipated difficult intubation in adults (Frerk et al., 2015) presents various strategies; the key techniques relevant to this research are summarised in Sections 2.2.1.1 – 2.2.1.3.

2.2.1.1 Face Mask Ventilation

Facemask ventilation (FMV) is recognised as one of the most important skills and even though it appears to be a simple task to perform, doing so correctly and effectively is extremely challenging (Hart et al., 2013; Han et al., 2014). Holland and Donaldson (2015) identifies FMV as an integral skill for all anaesthetists; this airway management method acts as a starting point of most general anaesthetics and often occurs prior to tracheal intubation; FMV is the essential fall-back technique for maintaining oxygenation.

There are three main FMV techniques based on the hand positioning used during the ventilation process, these are the one-handed E-C technique, two handed C-E technique and the VE technique (Hart et al., 2013). Joffe, Hetzel and Liew (2010) identified the two-handed jaw-thrust technique is superior to the one-handed E-C technique, yet Umesh et al., (2014) identified an E-O technique that is claimed to be superior to the E-C technique. Irrespective of the technique used, it is vital that the proper position of the head and neck is secured after which the manual opening of the airway with the jaw thrust manoeuvre should be completed. The use of oral and nasopharyngeal airways should also be considered when completing difficult mask ventilation (DMV) (Frerk et al., 2015).

Studies completed by Kheterpal et al., (2006) and Kheterpal et al., (2009) reviewed over 26,000 and 50,000 anaesthetic procedures suggesting an incidence rate of 1.4% for DMV and 0.15-0.16% for impossible FMV. These studies considered variables including neck radiation, patient gender, sleep apnoea, Mallampati grades 3-4, and the presence of facial hair. Han et al., (2014) identifies that definitions are required to identify the various stages of difficulty similar to the Cormack and Lehane grading system (Cormack and Lehane, 1984). Holland and Donaldson (2015) and Han et al., (2014) suggest that for FMV the following grading categories and methods should be used:

- Grade 0 - Ventilation by mask not attempted.
- Grade 1 - Ventilated by mask.
- Grade 2 - Ventilated by mask with oral airway or other adjunct.
- Grade 3 - Difficult MV (inadequate, unstable, or two-person technique).
- Grade 4 - Unable to mask ventilate.

2.2.1.2 Tracheal Intubation

Tracheal intubation is the process of placing an ET tube into the trachea to secure the airway and ensure patient oxygenation (Ambrose and Taylor, 2004). Thomas and Moss (2010)

describes tracheal intubation as the placement of a tube into the trachea; this is the gold standard procedure for airway protection and ensures the trachea and lungs are protected from aspiration of the stomach contents that could potentially cause a difficult airway.

The placement of an ET tube is not solely used for ventilation, it is also used to allow the removal of carbon dioxide from the body and aid the delivery of drugs when required (i.e. anaesthetic agents). The ET tube when correctly inserted ensures the trachea and lungs are isolated from oesophageal soiling (Thomas and Moss, 2010).

The correct placement of an ET tube is extremely important, if a failed intubation is not recognised and not correctly positioned in the trachea, this could result in the ET tube being incorrectly placed within the oesophagus. If an ET tube is not recognised as being located within the oesophagus instead of passing through the laryngeal opening and cords, this could be potentially fatal due to incorrect and failed oxygenation (Thomas and Moss, 2010).

Indications for emergency airway management are multifactorial (Mort, 2004). Ambrose and Taylor (2004), and Grover and Canavan (2007) present several indications and situations where tracheal intubation is required; these indications are split into two categories. Depending on the type of injury or situation presented, different equipment will be required, i.e. different adjuncts (stylets or bougies) or direct or indirect visualisation equipment etc.

Anaesthetic & Surgical Indications & Considerations

- Restricted access to the patient's airway (e.g. Maxillofacial Surgery).
- Restricted access to the patient (e.g. Neurosurgery).
- Necessary to secure the airway (e.g. Airway obstructions or burns).
- Protection against soiling of the airway in order to maintain a clear and unobstructed airway (e.g. high risk of aspiration, vomitus, blood in the pharynx, pregnancy, etc.).
- Intermittent positive pressure ventilation required during respiratory issues.
- Requirement for muscle relaxation (e.g. during surgical procedures).

Non-Anaesthetic Indications & Considerations

- Respiratory failure which requires intermittent positive pressure ventilation.
- Respiratory failure as a result of chest or head injuries.
- Cardiopulmonary resuscitation.
- Airway protection in patients with Glasgow Coma Scale < 9.
- Facial burns and inhalation injury.

- Airway obstructions which cannot be resolved through basic manoeuvres.
- Prolonged intermittent positive pressure ventilation.
- Uncooperative patients requiring further examination and investigation.

Although tracheal intubation procedures are common and are often daily tasks, even for the most experienced/trained professional, anticipating a difficult airway is challenging. Tracheal intubations often take place outside of the hospital setting and are conducted by pre-hospital physicians (i.e. paramedics); this is often completed in an emergency setting when a patient exhibits trauma. Emergency tracheal intubation in the pre-hospital setting is an accepted definitive procedure for airway management (Ridgway et al., 2004) and is vital for treatment of patients who are critically ill.

Lockey et al., (2014) presents an observational study on the success rates of intubation and failed intubation airway rescue techniques by pre-hospital physicians and concludes that success rates of 99.3% are achieved; this was consistent with other studies that presented high success rates (Lossius, Røislien and Lockey, 2012). Lockey et al., (2014) identified that non-anaesthetists were twice as likely to be required to perform a rescue airway intervention. It is critical to practice and prepare for every eventuality and have an appropriate plan of action in place.

2.2.1.3 Laryngoscopy

Laryngoscopy is a procedure which is performed to obtain a view of the vocal cords under direct or indirect vision; this is often completed using direct laryngoscopy or indirect laryngoscopy. Optimal patient positioning improves the likelihood of success for both types of laryngoscopy and tracheal intubation (Frerk et al., 2015).

Direct laryngoscopy is defined by the American Association of Anaesthetists task force as the inability to visualise any part of the vocal cords despite multiple attempts at conventional laryngoscopy methods (Berkow, 2004). An indirect laryngoscopy is performed when there is no possible visual line of sight of the patient's vocal cords; this requires the use of additional equipment such as video laryngoscopes, bronchoscopes or fibreoptic stylets to obtain a clear view. Indirect laryngoscopy equipment is significantly more expensive; repeated use can reduce the associated costs. Interestingly, indirect laryngoscopy uses a small hand-held mirror to aid the visualisation process of the glottis (Thomas and Moss, 2010).

Laryngoscopy is the main method utilised for placing an ET tube during airway management in many different clinical situations. Technology development within the anaesthesia

product category is constantly driving improvement in practice; various devices and technologies have been developed throughout the history of the procedure (Collins, 2014).

Equipment used in practice varies based on the operators skillset/training. The type of equipment used varies based on the complexity of the clinical situation; this is reflected in equipment costs. Devices range from inexpensive with limited functionality i.e. stylets and bougies, to sophisticated and expensive i.e. video laryngoscopes and fibreoptic scopes.

Video laryngoscopes, e.g. GlideScope® and C-MAC™, use a remote camera and present a display to the anaesthetist which allows them to obtain an improved view of the larynx. The initial setup costs for these devices require a significant investment; regular servicing and maintenance is required. This may be a deterrent for some hospital trusts regardless of the recommendations made by professional societies.

Frerk et al., 2015 identifies that the type of laryngoscope used can influence success rates of tracheal intubation. Video laryngoscopes offer improved views in comparison to the direct laryngoscopy equipment; there have been many reviews analysing the pros and cons between indirect and direct laryngoscopy with a consensus championing the use of video laryngoscopes (Andersen, Rovsing and Olsen, 2011; Aziz et al., 2012; Griesdale et al., 2012; Mosier et al., 2013; Niforopoulou et al., 2010). Video laryngoscopes are the preferred choice of equipment; several different video laryngoscopes are available on the market. Anaesthetists must be competent on at least two types and therefore anaesthetist experience and training must be considered (Frerk et al., 2015).

In severe cases, fibreoptic scopes are used Yumul et al., (2016) and Kaufmann et al., (2013); fibreoptic scopes offer significantly improved views of the larynx in certain clinical situations. These are expensive to buy and maintain; in some situations, these enable a view to be obtained which is not possible with other equipment.

Conversely, they are slow to set up and their use in an emergency often requires the operator to have a high degree of skill and experience to ensure procedural success. A high degree of training is required; often the skill retention of these devices is less. Video laryngoscopes offer advantages over the flexible fibreoptic scopes including shorter intubation times, the time required to obtain glottic view and successful placement of the tracheal tube. Improving the functionality of less expensive equipment such as adapting a stylet or bougie into a mid-tier steerable device utilising inexpensive smart materials, would help improve the efficiency of laryngoscopy procedures.

2.2.2 DAS Difficult Intubation Guidelines

The Difficult Airway Society (DAS) published a set of guidelines (Frerk et al., 2015) continuing the work of Henderson et al., (2004), providing a strategy to manage unanticipated difficulty with tracheal intubation; the guide algorithms are presented in Figures 2.2 – 2.4.

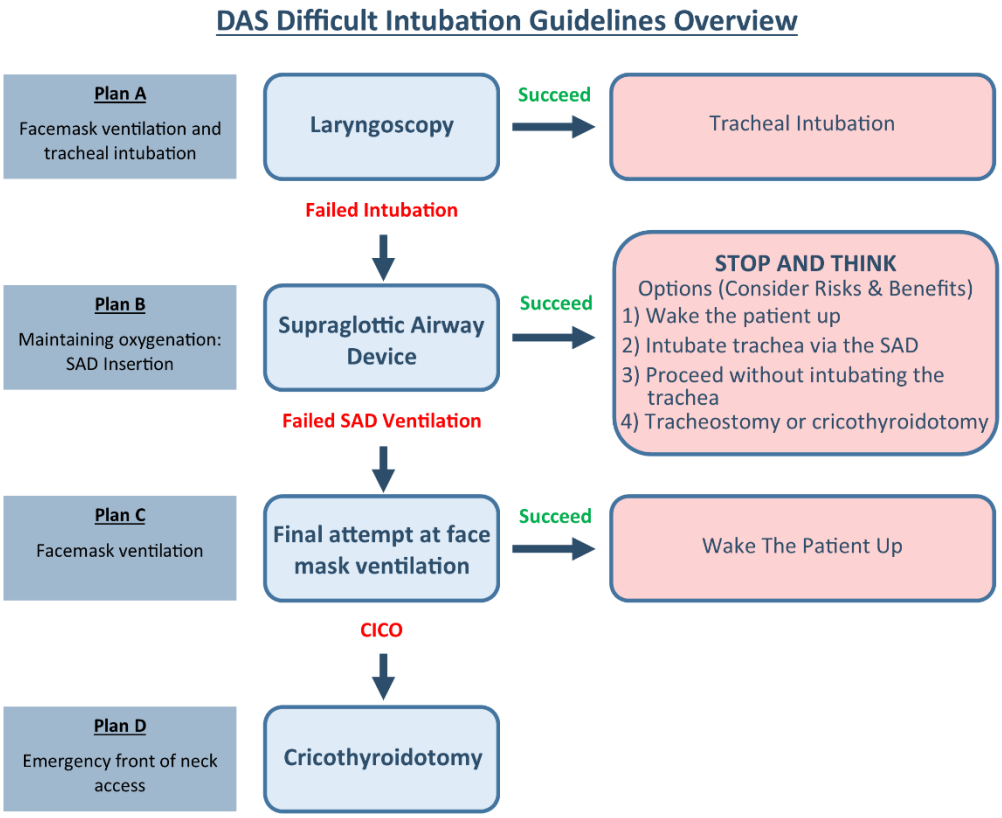


Figure 2.2: DAS Difficult Intubation Guidelines 2015 Overview

Reproduced from: Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults. C. Frerk, V. S. Mitchell, A. F. McNarry, C. Mendonca, R. Bhagrath, A. Patel, E. P. O'Sullivan, N. M. Woodall and I. Ahmad, Difficult Airway Society; Intubation guidelines working group; British Journal of Anaesthesia, 115 (6): 827–848 (2015) doi:10.1093/bja/aev371

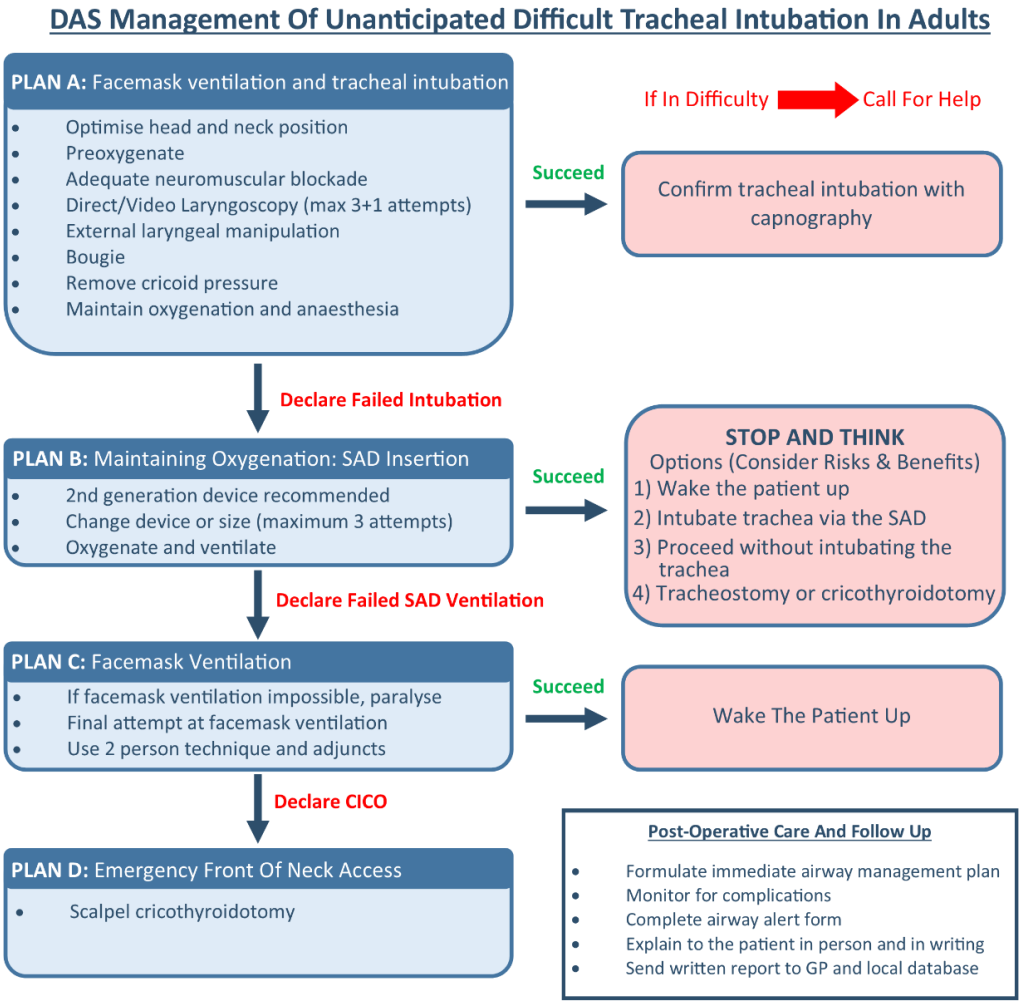


Figure 2.3: Management Of Unanticipated Difficult Tracheal Intubation In Adults

Reproduced from: Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults. C. Frerk, V. S. Mitchell, A. F. McNarry, C. Mendonca, R. Bhagrath, A. Patel, E. P. O'Sullivan, N. M. Woodall and I. Ahmad, Difficult Airway Society; Intubation guidelines working group; British Journal of Anaesthesia, 115 (6): 827–848 (2015) doi:10.1093/bja/aev371

The DAS 2015 guidelines are based on expert opinions and identify several updated and critical recommendations for best practice, including placing emphasis on assessment, preparation, positioning, pre-oxygenation, maintenance of oxygenation, and minimizing trauma from airway interventions (Frerk et al., 2015). Limiting the number of airway interventions is advised; in addition, blind techniques using a bougie or a supraglottic device are recommended to be superseded with video or fibre-optically guided intubation. Scalpel cricothyroidotomy is the recommended rescue technique and should be utilised in accordance with the DAS algorithm presented in Figure 2.4.

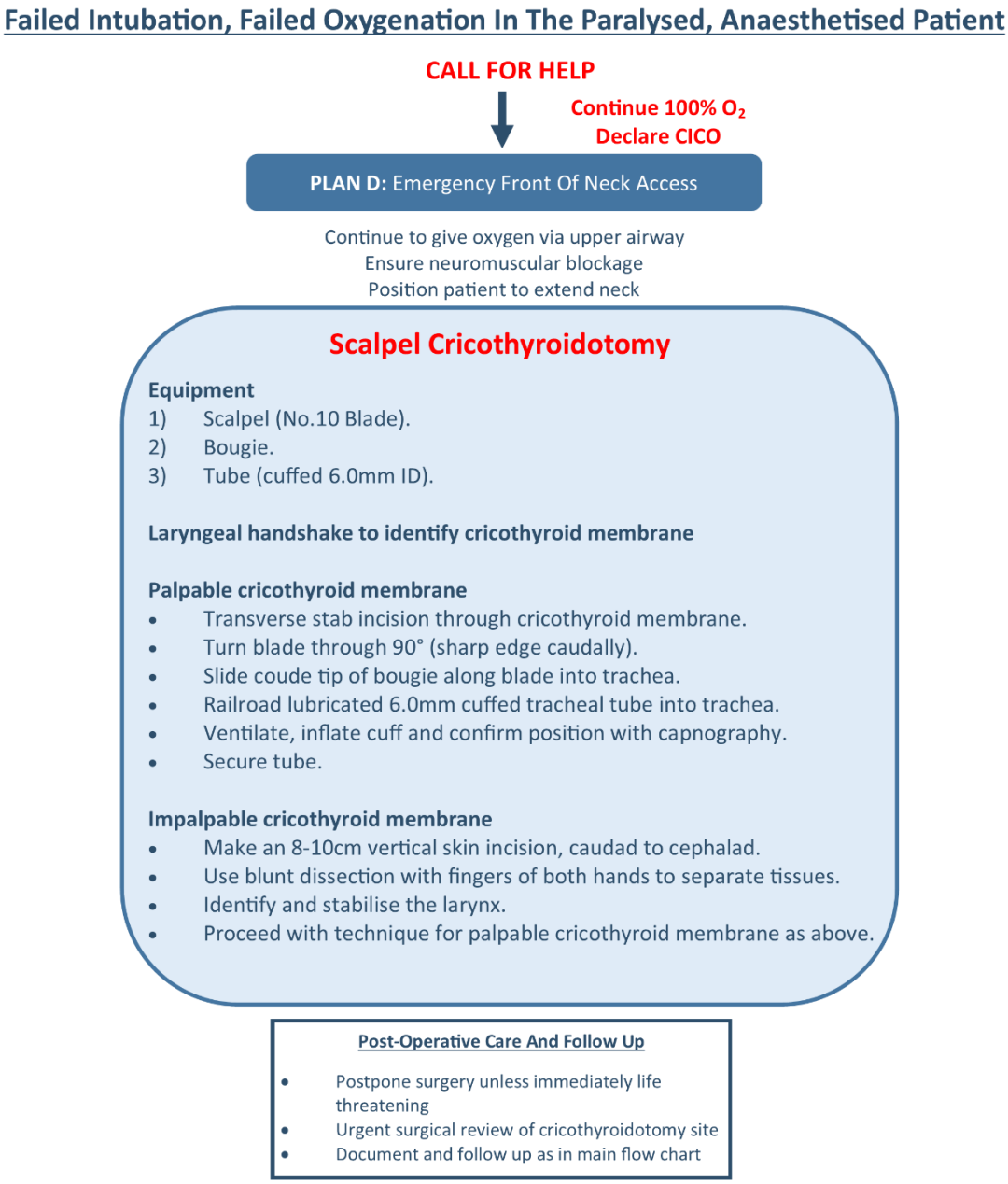


Figure 2.4: Failed Intubation, Failed Oxygenation In The Paralysed, Anaesthetised Patient

Reproduced from: Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults. C. Frerk, V. S. Mitchell, A. F. McNarry, C. Mendonca, R. Bhagrath, A. Patel, E. P. O'Sullivan, N. M. Woodall and I. Ahmad, Difficult Airway Society; Intubation guidelines working group; British Journal of Anaesthesia, 115 (6): 827–848 (2015) doi:10.1093/bja/aev371

Equipment design and implementation is critical to successful practice. For the development of the steerable bougie a review of the physical properties of the current devices is necessary to identify design requirements. Feedback will need to be collected for suggested design improvements; suitably designed surveys identifying this information will be required.

2.2.3 Airway Assessment & Management Considerations

Airway management is a critical part of emergency airway access care provided to patients irrespective of the type of anaesthetic administered (Berkow, 2004). Berkow (2004) identifies three phases of airway management, including airway evaluation, management of the airway and extubating of the airway.

Securing the airway in a safe and timely manner is imperative; this applies to both routine and difficult intubations. Effective airway management is vital in the treatment of critically ill patients. The incidence of a difficult intubation is estimated to be between 3 – 18% (Ambrose and Taylor, 2004). Difficult airways are often associated with a considerable number of serious complications such as hypoxemia, awareness, trauma to the airway and aspiration of gastric contents, amongst others; these issues need to be considered during patient assessment tasks (Ambrose and Taylor, 2004).

When evaluating an airway, a review of the patient's medical history supported by a physical examination is required (Berkow, 2004). Performing these two tasks will allow the anaesthetist to predict potential difficult ventilation or intubation issues. Performing a physical examination will help identify potential risks that need to be considered, for example, pregnancy severely effects the difficulty level of an intubation. In cases where physical deformities i.e., Noma disease (Marck, 2013; Maley, Desai and Parker, 2015) are exhibited this presents significant airway management challenges.

Most difficult airways can be assessed clinically through preoperative assessments, but false positive results can contribute to further complications. If combined with the Mallampati screening test and thyromental distance considerations, the majority of difficult intubations can be anticipated (Ambrose and Taylor, 2004). Clinical evaluation of an airway, especially in a preoperative environment is critical; anaesthetists must develop sensible strategies (Pearce, 2005). Zambouri (2007) and Kitts (1997) identify the following primary goals of preoperative evaluation and preparation:

- Documentation of the condition(s) for surgery.
- Patient's overall health status assessment.
- Identification of hidden or undiagnosed conditions that could cause problems both during and after surgery.
- Identifying perioperative risks.

- Optimisation of the patient's medical condition to reduce the patient's surgical and anaesthetic perioperative morbidity or mortality.
- Development of a perioperative care plan.
- Identification of critical information to discuss with a patient about surgery, anaesthesia, intraoperative care, postoperative pain treatments and obtain patient consent and alleviate concerns.
- Reduce the costs associated with the shortening of in-hospital care.

Pearce (2005) highlights several questions which must be considered when assessing a patient preoperatively, these include:

- Is airway management necessary?
- Which airway device should be used to provide the necessary protection and maintenance of the airway?
- After induction of anaesthesia will facemask/laryngeal mask ventilation be possible?
- Will direct laryngoscopy and tracheal intubation be difficult?
- What are the aspiration risks?
- Can the patient tolerate a period of apnoea?
- Is the cricothyroid membrane available for emergency access and oxygenation?

Difficult airways can be predicted clinically through bedside testing when considering the Mallampati score, thyromental distance, mouth opening, neck extension, mandibular subluxation and sternomental distance (extended head and neck to mouth closed distance) (Thomas and Moss (2010). Preoperative assessment is required before anaesthetising a patient this should include a review of a patient's full history with focus placed on the patient's anaesthetic records (Thomas and Moss, 2010). This further reinforces the recommendations made by Kitts (1997), Ambrose and Taylor (2004) and Zambouri (2007). The Mallampati classification system contributes to the assessment of a patient during airway evaluation; this is split into four classification grades (Mallampati et al., 1985):

- Class 1 - Glottis (including anterior and posterior commissures) could be fully exposed.
- Class 2 - Glottis could be partly exposed (anterior commissure not visualized).
- Class 3 - Glottis could not be exposed (corniculate cartilages only could be visualized).
- Class 4 - Glottis including corniculate cartilages could not be exposed.

Conversely, Samsoon and Young (1987), Berkow (2004) and Ambrose and Taylor (2004) describe the modified/updated four classifications based on observed structures (Figure 2.5):

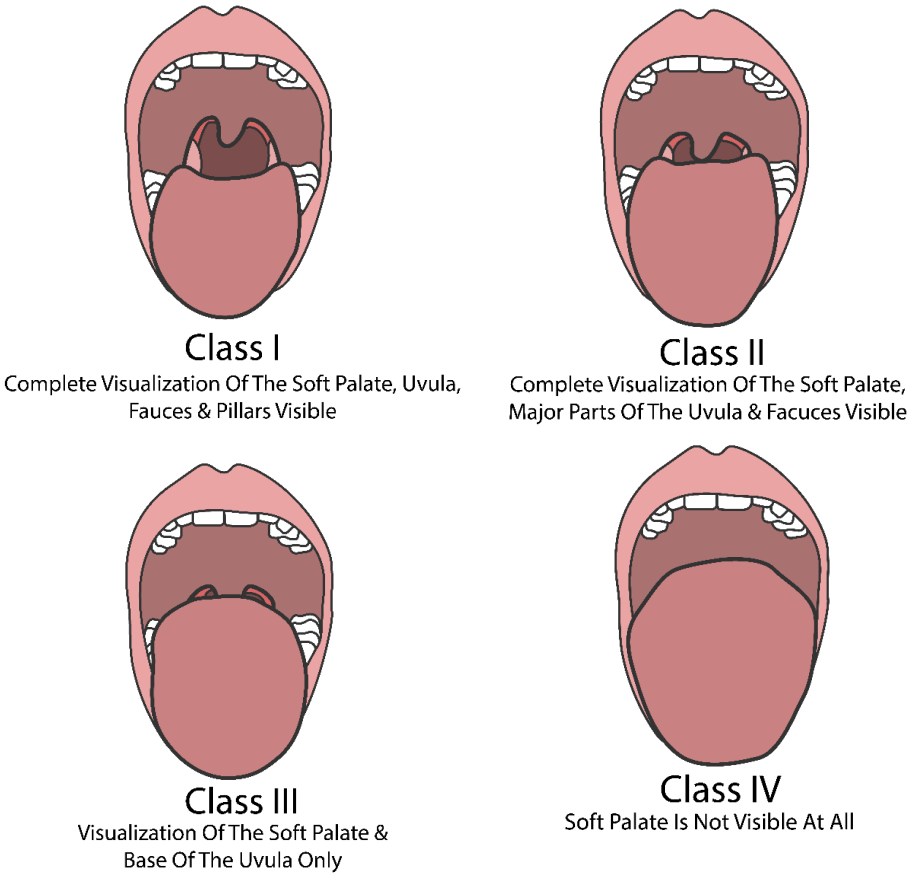


Figure 2.5: Modified Mallampati Score Classifications

One of the most universally accepted grading/classification systems used in practice is the Cormack and Lehane system (Cormack and Lehane, 1984); only grades three and four are recognised by anaesthetists as difficult airways to intubate. The Cormack and Lehane grading system is split into four classifications (Figure 2.6); Cormack and Lehane (1984), Berkow (2004), Ambrose and Taylor (2004), Krage et al., (2010) describe these as:

- Class/Grade I – The entire glottis or most of the glottis is visible.
- Class/Grade II – Only the posterior portion of the glottis can be seen.
- Class/Grade III – Only the epiglottis can be seen, and no part of the glottis is visible.
- Class/Grade IV – The epiglottis is now not visible.

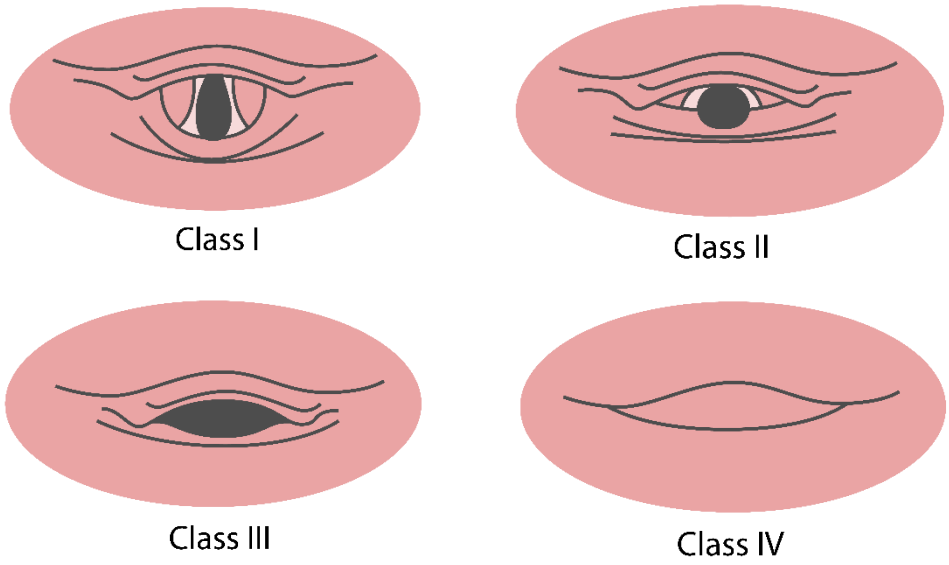


Figure 2.6: Cormack and Lehane Grading System Diagrams

Pearce (2005) identified several factors that can have an effect on an intubation including, patient history, Mallampati score, thyromental and sternomental distances, obesity, trauma, burns, swelling, infections, tongue dimensions, anatomical construction of the pharynx, larynx, trachea or neck amongst others. These factors vary based on the type of patient presented (critical or non-critical) and could alter depending on the type of airway management procedure being conducted.

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) identify within their safety guidelines that equipment for managing anticipated or unexpected difficult airways must be available and checked regularly in accordance with departmental policies (AAGBI, 2009). Ambrose and Taylor (2004) identifies a list of equipment that should always be readily available within the difficult airway trolley (DAT) when procedures are being performed:

- Laryngoscopes (variety of sizes and shapes).
- Face masks and breathing circuits.
- Syringes for cuff inflation.
- Tracheal tubes (Variety of sizes).
- Tracheal tube introducers (GEB, stylets).
- Oral and nasal airways.
- Cricothyroidotomy set.
- Suction equipment.
- Laryngeal mask airways (LMAs).

Ambrose and Taylor (2004) and Grover and Canavan (2007) also recommend the use of the Cook catheter or Aintree intubation catheter, Combitube, ProSeal LMA, McCoy Laryngoscope, Intubating LMA and fibre-optic laryngoscope. Equipment use is however subjective to training and purchase decisions made by individual hospital trusts. The NAP4 report published by Cook et al., (2011a) identifies the importance of a suitably stocked difficult airway trolley; DAS therefore developed recommendations for equipment use for Plan A-D and recommendations for setting up a DAT (Difficult Airway Society, 2014).

With any medical procedure there are risks; errors often result in the filing of a liability claims. Liability claims due to complications with respiratory events have gradually decreased since the 1980's (42%), by the 1990's this had decreased further (Cheney, 2002). The American Association of Anaesthesiologists Committee on Professional Liability Closed Claims Project recognises that there has been a significant decrease in the claims over the past decade, however, claims due to respiratory events still need to decrease further as they represent 32% of all claims. Within the UK, anaesthesia-related claims account for 2.5% of all claims and this equates to 2.4% of the value of all claims made (Cook, Scott and Mihai, 2010). By developing medical devices that improve safety and increase procedure efficiency, this will contribute to reducing liability claims.

The examination of a patient is considered an essential activity in the management of a patient's airway. Airway management requires the careful selection of equipment with the use of no one single piece of equipment deemed an effective solution (Ross and Ball, 2009). Appropriate preoperative planning and identified back up plans in emergency airway access contributes to procedure success rates.

Airway management often requires a wide variety and a combination of equipment to successfully complete a procedure (Jackson and Cook, 2007); training is a key element to correct use in practice. Each piece of equipment requires a different operative skillset; training must constantly be refreshed. The skill retention of multiple techniques and equipment is challenging but this is extremely important as equipment varies at each hospital trust. Seamless transition and equipment interchangeability between different plans and stages of airway management is crucial.

2.3 Review Of Airway Devices, Steerable Medical Devices & Control Systems

To potentially introduce an element of steerable control into a bougie, it is imperative to investigate existing devices and the mechanisms utilised within similar products. Research into control mechanisms will direct the research conducted in relation to the materials and mechanism practical investigations.

2.3.1 Existing Steerable Medical Devices & Control Systems

Advancements in steerable medical devices over the past few decades have pushed the medical device industry to investigate new and novel methods of creating mechanical and automated control instruments that can be manipulated and monitored externally whilst the surgical instrument is manoeuvred internally of small orifices. Due to rapid development, there are now a plethora of medical devices that can be steered and controlled; many of these often rely on large control systems to power or manipulate the mechanisms. Mechanisms such as pull wires, cables, springs, shape memory alloys amongst others, are often utilised. A significant challenge is miniaturising these devices and maintaining the desired level of control; this becomes increasingly difficult for smaller medical devices especially needles and catheters. Often steerable medical devices have a diameter of <5mm and this is due to the orifice they are to be manipulated within; this can create a significant design challenge.

Dankelman, Grimbergen and Stassen, (2007) identify that with the introduction of modern technologies, more complex surgical and interventional procedures can be performed at an increased level of accuracy. Dankelman, Grimbergen and Stassen, (2007), identify two categories of technologies:

1. Technology that improves manipulation by a device that is controlled by the surgeon, with a focus placed on minimally invasive procedures, including tele-operated surgical robots, surgical assistants, and other augmented devices.
2. Technology that enhances precision and focuses on preoperative planning, image guidance, including autonomous robots.

For many steerable devices, inspiration can be drawn from biomimetic applications. A notable example is the manufacture of the steerable endoscope that was inspired by squid tentacles (Breedveld et al., 2005). Fan, Dodou and Breedveld, (2013) identifies that there are several scenarios where minimal access approaches benefit from steerable devices including, laparoscopic surgery, flexible endoscopy, gastroscopy, catheter interventions and pathway

surgery. The literature review presented by Fan, Dodou and Breedveld, (2013) identified several manoeuvrable approaches and their controls, categorising these as single segment control devices, single deflection control (SDC), dual deflection control (DDC), triple motion control (TMC), multiple segment control, parallel single segment control (PSSC), serial single segment control (SSSC) and integrated single segment control (ISSC).

There are a considerable number of devices that utilise one of the above-mentioned control mechanisms and methods to function, whether this be an ablation device, videoscope, endoscope etc. Fan, Dodou and Breedveld, (2013) suggest the most promising development focuses on multi-segmented manoeuvrable instruments, but these are still in their infancy. Some of the most prominent suppliers of steerable medical devices are presented in Table 2.1.

Manufacturer	Example Product Range	Reference
Boston Scientific	Blazer™ Steerable Temperature Ablation Catheter Range & Fathom ™ Steerable Guidewire	(Bostonscientific.com, n.d.) (Bostonscientific.com, 2016)
SJM Global (St Jude Medical):	FlexAbility™ Ablation Catheter Range Livewire TC Ablation Catheter Range	(Sjmglobal.com, 2016) (Sjmglobal.com, 2013)
Olympus Europe	Olympus VideoScope Range (IPLEX & Series C)	(Olympus-ims.com. n.d.)
Medtronic	SILS™ Hand Instrument Range	(Medtronic.com, n.d.)
Teleflex Medical OEM	Coronary interventions and guidewires product category including: Guideliner V3 Catheter, Twin-Pass Dual Access Catheters, Pronto V4 Extraction Catheter	(Teleflex.com, 2018)
DePuy Synthes/ Johnson & Johnson:	Agility Steerable Guidewire and ENVOY® DA Distal Access Guiding Catheter	(Depuysynthes.com, n.d.)

Table 2.1: Sample Of Steerable Devices Product Range

Innovation within steerable medical devices is a focus for the BITE Bio-Inspired Technology Group (Delft University of Technology (TU Delft)). BITE have developed several devices that can either be steered, controlled or manoeuvred within small orifices of the body, the most prominent devices developed include:

- DragonFlex Micro and Macro: smart steerable laparoscopic instruments (Jelínek, Pessers and Breedveld, 2013; Jelínek and Breedveld, 2015).
- VOLT 3D Printed bi-polar laparoscopic grasper (Sakes et al., 2018).
- Helixflex: A squid like motion by helical steering for skull base surgery (Gerboni et al., 2015).
- Ovipositor Needle I and II (WASP Project): Self propelling and steerable needle (Scali et al., 2017).
- EndoPeriscope I, II and III: Steerable endoscope for laparoscopic surgery (Breedveld et al., 2005).

Henselmans et al., (2017) has developed an alternating memory mechanism that was incorporated and tested into a proof of concept system called the "MemoSlide". This mechanism allows the control of surgical instruments to move along curved paths in endoscopic surgery and offers device control memory where an identified path needs to be followed.

There are many advantages to the increased control exhibited by steerable devices. Loeve, Breedveld and Dankelman, (2010) identify that flexible devices, especially flexible endoscopes are used because their flexibility enables them to negotiate difficult trajectories. Although with endoscopes the ability to steer is increased, functions such as pulling forces may manipulate the device into orientations that the operator does not want. Forces applied to any device, even the soon to be developed steerable bougie will need to be considered; bougie tip pressures and bougie shaft resistance are two factors that could force an uncontrolled directional movement.

2.3.1.1 Design Criteria Considerations For The Steerable Bougie

There are many systems and devices that utilise steerable mechanisms; many of these have overcome miniaturisation and accurate degree of movement issues. The brief review of steerable devices presented identified several key design criteria points that must be factored into the design of the steerable bougie, including:

1. Suitable construction and assembly methods must be utilised to allow device shape integrity, thus contributing to mechanism manoeuvrability internally of the outer structure.
2. Degrees of freedom (DOF) for operative actuation must be established to ensure the steerable function (i.e. mechanical pull wires, SMA's etc.) can be integrated and perform as required.
3. Outer sheath design must ensure the devices shape integrity can be maintained and consider the forces exhibited when the device is used both internally and externally of the patient.
4. Device segments should be stacked where required and securely connected to the rigid section of the device (if this approach is utilised).
5. Forces applied to the outer structure and tip, preventing uncontrolled shaping and device manoeuvrability must be considered; reduced forces will result in reduced trachea mucosa damage.

2.3.2 Existing Intubation Adjuncts and Laryngoscopes

There a wide variety of intubation adjuncts and visualisation devices that are used in practice, many of which have been described within Section 2.2. Within the category of endotracheal intubation, the four most common intubation adjuncts and visualisation devices used are stylets, bougies, laryngoscopes and video laryngoscopes.

2.3.2.1 Stylets

Stylets (Figure 2.7) are preloaded within an ET tube for use to give it a predefined shape that aids the navigation of the ET tube within the trachea. Stylets are available from various manufacturers within the UK's NHS supply chain including Smiths Medical International Ltd, Intersurgical Ltd, ConvaTec Inc, Proact Medical Ltd, Teleflex Medical, Flexicare Medical Ltd, Healthcare 21 UK Ltd, P3 Medical Ltd, Armstrong Medical amongst others.

Figure 2.7: Endotracheal Stylet

Traditionally the construction of a stylet is based on a malleable aluminium rod with a PVC sheath (typically ranging from 6ch/fr - 14ch/fr) and are shaped within the ET tube. Articulating stylets are now becoming more common as they give the anaesthetist the opportunity to manually manipulate the stylet and ET tube whilst in-situ. Although the use

of a stylet typically ensures an intubation is performed quicker compared to a bougie (Batuwitage et al., 2015; Kovacs et al., 2007), the potential forces created with rigid stylets can be significantly greater than with bougies.

2.3.2.2 Tracheal Tube Introducers/Exchangers/Guides/Bougies

Table 2.2 presents a comprehensive list of tracheal tube introducers, exchangers and guides identified by the Difficult Airway Society, (2018); these bougies require further experimental evaluation to understand their physical properties. Adjuncts are often assessed based on their speed and success rates in addition to their usability whether this be a single use or reusable device (Marfin et al., 2003; Hodzovic, Wilkes and Latto, 2004; Hames et al., 2005; Whitcombe, Strang and Reay, 2005).

Introducers/Exchangers/Guides	**Manufacturer**
Aintree Intubation Catheter	Cook Group Incorporate©, Indiana, USA.
Arndt Airway Exchange Catheter Set	
Cook Airway Exchange Catheter (Soft Tip)	
Cook Airway Exchange Catheter	
Eschmann Tracheal Tube Introducer (Gum Elastic Bougie)	Eschmann© Holdings Ltd, West Sussex, UK & Smiths Medical International Ltd, Kent, UK.
Frova Single Use Introducer	Cook Group Incorporate©, Indiana, USA.
Gliderite Stylet	Verathon Inc./ Roper Technologies, Seattle, Washington, USA.
Marshall Single-Use Bougie (Straight Tip)	Marshall Airway Products Ltd, Radstock, UK.
Marshall Vented Intubating Introducer	
Portex Intubation Stylet	Smiths Medical International Ltd, Kent, UK.
Portex Single-Use Bougie (Straight Tip)	
Portex Single-Use Bougie (Angled Tip)	
Pro-Breathe Single-Use Introducer	Proact Medical, Corby, UK.

Table 2.2: List Of Introducers/Exchangers/Guides

Within the UK, bougie introducers are commonly available from twenty-three different suppliers listed within the NHS supply chain (Q1 2018). The most commonly available outside

of those listed in Table 2.2 include the SunMed Introducer Bougie (SunMed, Grand Rapid, USA), InterGuide Tracheal Tube Introducer Bougie (Intersurgical Ltd, Wokingham, UK), AviAir Intubating Bougie (Armstrong Medical, Coleraine, Northern Ireland), P3 Medical Tracheal Tube Introducer (Bristol, UK) amongst others. The original Eschmann Tracheal Tube Introducer "Gum Elastic Bougie" (Eschmann Holdings Ltd, West Sussex, UK) is still considered the gold standard bougie for use. Bougies are often used instead of stylets as they are easily manipulated and are easier to control within the dimensional restrictions of the trachea.

Bougies are available in various shapes and sizes (ranging from 500 – 800mm in length and 5ch/fr – 15ch/fr) (Figure 2.8). Straight tip and coude tip bougies (Figure 2.9) are also available for use, however, coude tip bougies are more commonly used as they are associated with increased success rates when utilised within a difficult intubation setting (Hodzovic, Wilkes and Latto, 2003). Bougies also have depth markings applied to the side to allow the user to gauge distance; recent developments have shifted toward colour coded shafts to gauge depth (Paul et al., 2014).

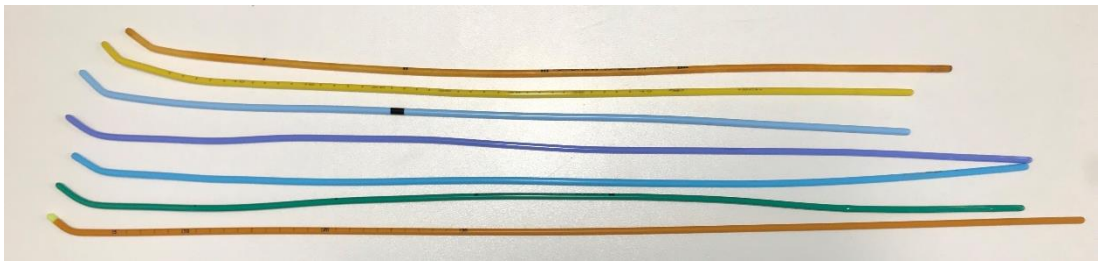


Figure 2.8: Sample Of Bougies Available Within The UK

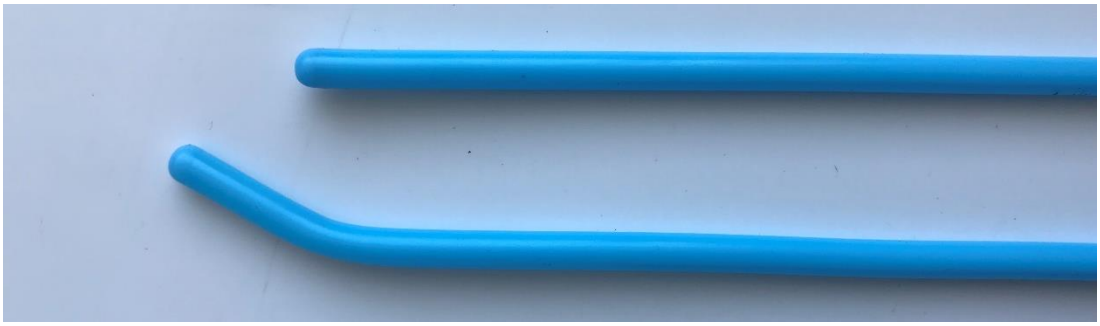


Figure 2.9: Straight Tip Bougie & Coude Tip Bougie

Bougies are also available in vented formats (Figure 2.10) with oxygen connectors to allow patient oxygenation. The through lumen design is often exhibited with one or two distal side ports to allow adequate airflow. One major drawback with bougies is their shape retention characteristics; this is often due to the internal construction of bougies (Figure 2.11) and the materials used.

Figure 2.10: Vented Bougie/Introducer

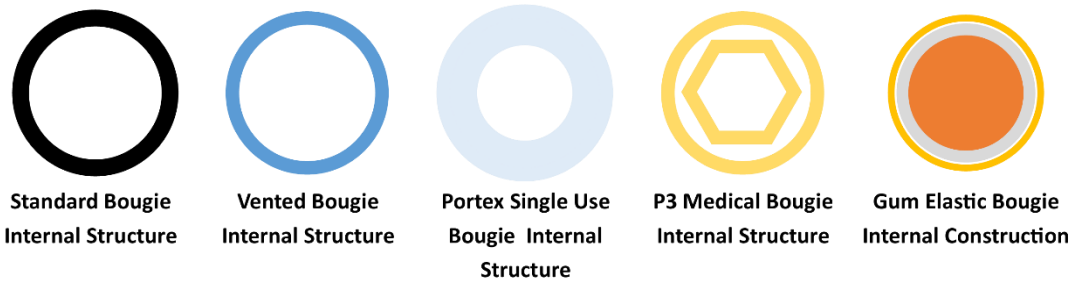


Figure 2.11: Example Of Various Internal Constructions Of Bougies

Recent developments have been presented in the form of a flexible tip bougie (2013) and an articulating introducer (2016). Little information is available on the development of the articulating introducer (ttcmed.com, n.d.), however, this mechanical device appears to function similar to articulating ET tube stylets and only has one direction of movement control. The flexible tip bougie developed by Construct Medical (Melbourne, Australia) (Figure 2.12) is also a mechanically driven bougie. This utilises a central core metal pull wire and uses push and pull movements to generate two directions of control.

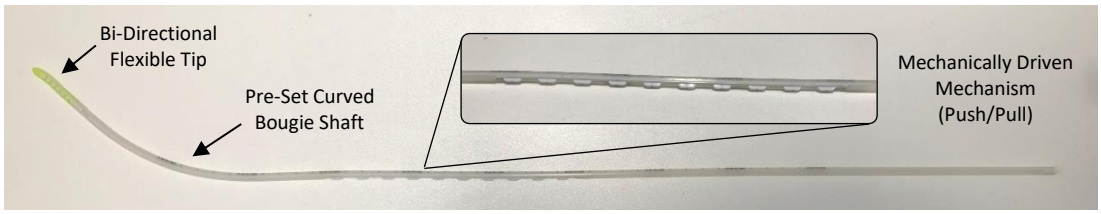


Figure 2.12: Construct Medical Flexible Tip Bougie

The flexible tip bougie requires the operator to utilise a slightly adjusted grip position which may feel unnatural to the operator. A more stable grip position is required to successfully operate the steerable mechanism (Figure 2.13); it is hypothesised that this has the potential to generate increased tip and extubation forces; this requires further investigation. Early prototypes of the steerable mechanism were only available for operation within the 15cm-

25cm range; this has now been extended up to the 35cm distance held which covers the wider spectrum of bougie distance held locations (Hodzovic, Wilkes and Latto, 2004).

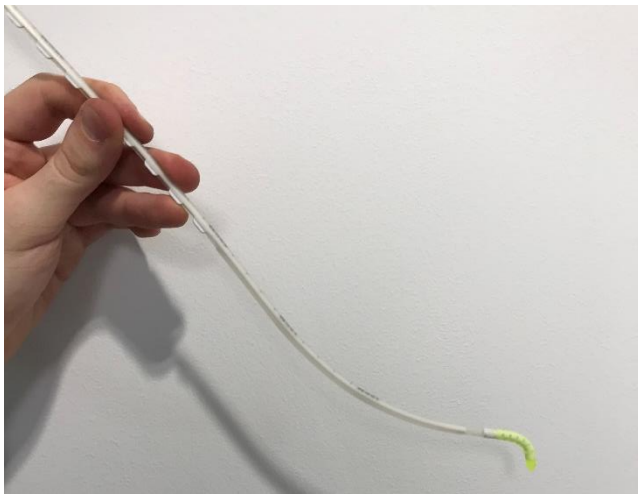


Figure 2.13: Construct Medical Flexible Tip Bougie Example Grip Position

The flexible tip bougie has several issues; restricted reshaping of the bougie is exhibited due to a rigid main shaft, thus limiting the bougies to use in situations where the curvature of the bougie shaft matches the curvature of the patient airway. Bending of the bougie will distort and damage the flexible tip mechanical mechanism. Once railroading of the ET tube has occurred, it is impossible to adjust the bougie whilst in-situ, thus requiring complete removal of the ET tube for device adjustment. Figure 2.14 demonstrates the inability to manipulate the bougies tip once the bougie has been inserted 30cm into a standard 7mm diameter ET tube. The above identified issues should be factored into the design of the steerable bougie.

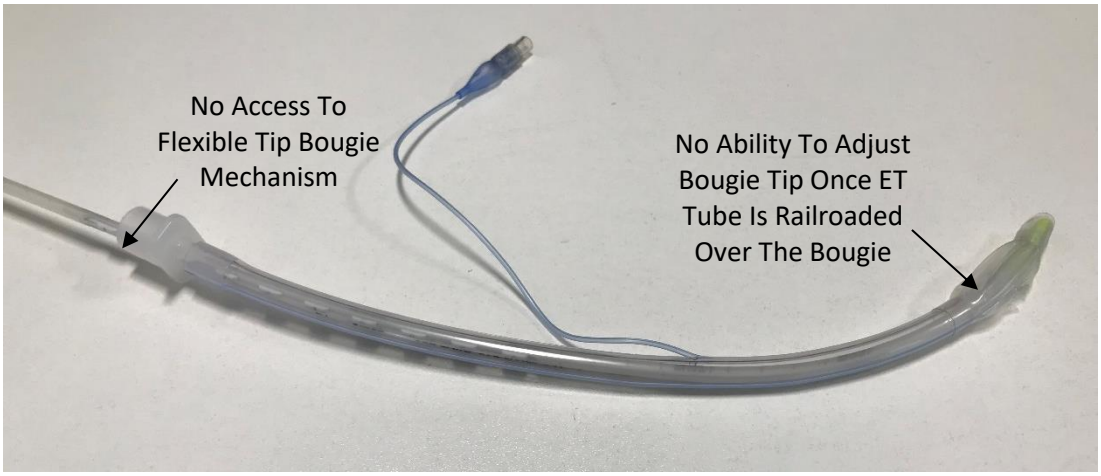


Figure 2.14: Construct Medical Flexible Tip Bougie & Railroaded 7mm ET Tube

2.3.2.3 Laryngoscopes & Video Laryngoscopes

Airway adjuncts are often used in combination with a laryngoscope (Figure 2.15) or video laryngoscope to complete a direct or indirect laryngoscopy; these are available in both single use and multiple use setups. The use of a laryngoscope and video laryngoscope are discussed in Sections 2.2 and 2.2.1.3.

Figure 2.15: Example Of A Laryngoscope

Several conventional laryngoscopes are available on the market varying in length and diameter. Standard handles are typically 25-30mm in diameter, however various other handles exist to accommodate the variability of patients. The most commonly used blades are the McCoy, Magill and Macintosh (Magill, 1926; Macintosh, 1943; Cook and Tuckey 1996). The blades used on conventional laryngoscopes are available in both straight and curved formats; curved laryngoscope blades typically vary between 70^{O}-100^{O} (Levitan et al., 2011; Marks, Hancock and Charters, 1993; McIntyre, 1989). Laryngoscopes often need to withstand a significant amount of force during operation. Recently plastic single use and multi-use laryngoscopes have entered the market; however plastic blades are often assessed as being inferior both when considering intubation speed and forces observed (Evans et al., 2003).

Video laryngoscopes are an alternative to the conventional laryngoscopes used for direct laryngoscopy. The popularity of video laryngoscopes has dramatically increased in recent years (Chemsian, Bhananker and Ramaiah, 2014); with video laryngoscopy recognised as a key feature within Plan A (Frerk et al., 2015). The improved view offered by a video laryngoscope compared to conventional direct laryngoscopy equipment often results in this

method being an anaesthetist's first choice (Frerk et al., 2015). Video laryngoscopes are available in many forms, the most common device used being the GlideScope (Verathon Inc. USA). The GlideScope is available in both single use (Figure 2.16) and multiple use formats, with recent additions made in portable systems.

Figure 2.16: Example Video Laryngoscope Blades and Covers

Alternatives include The Storz C-Mac (KARL STORZ Endoscopy Ltd, Tuttlingen, Germany), McGrath Laryngoscope (Medtronic, Minnesota, USA), King Vision® (Ambu, Copenhagen, Denmark). Video laryngoscopes are available in many shapes and sizes; they have been ergonomically designed to ensure optimal operational comfort and use. Attaching devices to a video laryngoscope is possible, however due to the vast array of shapes and sizes available a one size fits all approach may be difficult.

2.3.3 Patent Search Review - Steerable & Flexible Bougies/Stylets

A patent search was completed to assess the current state of the art and the niche market for a steerable bougie. The search terms input on Espacenet are presented below with the number of results presented in brackets; this search was maintained until June 2018:

- Flexible AND Bougie (50)
- Flexible AND Stylet (519)
- Steerable AND Bougie (0)
- Steerable AND Stylet (70)

The search results were filtered based on the assessment of the patent title and abstract to ensure that the searches were relevant to anaesthesia. Results related to steerable catheters with stylets were often combined into the same prior art to maximise coverage. Appendix B presents a brief descriptive summary of twenty-two key patents linked to steerable bougies and stylets. Many of the patents presented in the summative table in Appendix B are duplicated by other inventors with minor alterations to the type of mechanical or actuator driven mechanism utilised. It is common that the same operative task is described using the same approaches with minor alterations made to ensure the patent can be granted; these patents have been omitted from the summative table to present a summary of key mechanisms and approaches used.

Variations on video control, mechanical or electronic driven mechanisms were observed; most applications have permanent control devices attached to the top of the bougie or stylet and are controlled/driven from this point; this alters the bougie/stylet grip position. Only one patent (AU2010205892 (A1)) was noted to specifically state the use of a shape memory alloy as the fundamental method of control; this is not unexpected as several steerable catheters and ablation devices utilise shape memory alloys both for finite movement and steerable control but also for deploying stents. A bougie with a manually controlled tip is also a recent invention as depicted in patent US20160279365A1.

After consultation with patent lawyers (Barker Brettell), it has been established that it would be extremely difficult to acquire a patent for a device in this field due to the extensive previous prior art and existing body of work. It is important to focus on the operative control and design of the steerable bougie to ensure maximum uptake, this in turn could result in a licence agreement with a major manufacturer being acquired.

2.3.4 Bougie Introducer Airway Trauma

Airway trauma can occur due to several factors including the inaccurate pre-operative assessment, the patient status presented, anaesthetist inexperience, etc. A common cause of airway trauma is incorrect selection or incorrect use of equipment. The NAP4 audit (Cook et al., 2011a) presents several lessons for airway management, including the identification of recommended equipment and techniques for use. Cook et al., (2011b), Cook, Scott and Mihai (2010) and Peterson et al., (2005) identified that both in the UK and America, trauma during airway management reported in litigations included major trauma caused by adjuncts during intubation, including tracheal perforation which can lead to death.

One of the most commonly used adjuncts is the bougie. Many argue whether multiple or single use bougies should be used in practice. Multiple use bougies are perceived to be the most appropriate device for use, this is evidenced in many studies as documented within the literature review.

Phelan (2004) reports that difficult intubations are an uncommon occurrence and reports that within the United States there are no universally accepted techniques or devices, whereas in the UK, the bougie has been adopted as standard equipment. Phelan (2004) identifies that bougie placement is associated with relatively few complications; those that are reported often relate to perforations which are caused by an over aggressive approach because of railroading the ET tube over the bougie. There are many other situations when perforations can occur due to an over aggressive approach, including the initial guidance of the bougie; this is based on evidence presented by Smith (1994) and Kadry and Popat (1999).

Although soft tissue trauma is rare, there are a few rare cases reported with the use of GEB (Hodzovic, Latto and Wilkes, 2003), however, these occur more often with single use devices. Prabhu et al., (2003) reports a “critical incident” that involves the use of a multiple-use GEB due to trauma caused within the airway; this was noted to be a rare complication, especially when the insertion of the bougie and railroading of the ET tube has been successful at the first attempt.

Single use bougies can cause significant airway injury; Staikou, Mani and Fassoulaki (2009) present a case where blood was exhibited within the endotracheal tube and was linked to the difficulty attempting to remove the Portex single use tracheal tube introducer as this became stuck inside the ET tube. Withdrawal was eventually achieved by removing it gradually and as gently as possible. After this incident, the anaesthesiologists within the Department of Anaesthesiology (Aretaieio Hospital) decided to no longer use single-use introducers in their practice citing the need for improvements in device quality. Although this was an extreme reaction, it highlights the importance of improvements needed within the single use device market.

Many anaesthetists argue that single use bougies require further re-evaluation before they replace the GEB, none more so than Mushambi et al., (2016). Higgs and Goddard (2009) argue that many people believe single-use devices are not like-for-like replacements for Eschmann introducers. Hodzovic et al., (2004) has documented differences in physical properties between single and multiple use bougie introducers.

Higgs and Goddard (2009) argue that trauma is most likely to occur when an ET tube is firmly railroaded over the bougie and not when the distal hold-up sign is used to place the perceived stiff single use bougies; trauma is noted to be caused when the bougie is removed from the trachea. Arndt, Cambray and Tomasson (2008) describe a very rare airway injury created by an intubation bougie resulting in the perforation of the posterior tracheal mucosa located distal to the glottis. This trauma was created due to the presentation of a false lumen dissecting under the cervical membranous trachea after positive pressure ventilation with an ET tube.

Gardner and Janokwski (2002) report a case where a fit, ASA I, 42-year-old woman who was initially orally intubated without any problem using a 5-mm micro-laryngoscopy tube was later discovered to present a tumour in the right piriform fossa; trauma was caused by the use of a GEB. As the bougie used for this intubation was withdrawn, it was discovered that the GEB tip was no longer attached and upon inspection of the trachea the GEBs tip was lodged above the bifurcation. Based on this incident, Gardner and Janokwski (2002) recommend that bougies (especially the GEB) should be periodically checked to confirm device integrity to ensure no loss of strength around the tip is observed. The point at which the bougie curves is also identified as a potential area of weakness (Gardner and Janokwski, 2002). Further evaluation of the physical properties of bougies relating to tip pressure could provide performance informed data, thus affecting equipment purchase decisions.

Trauma caused by equipment is not limited to UK manufactured equipment. Tacquard et al., (2014) reports a case of tracheal rupture after intubation using a Boussignac bougie supplied by Vygon™ (Ecouen, France). Shah et al., (2011) presents a brief report on the difficulties observed with GEB intubation in an academic emergency department in New York recognising multiple case reports of soft tissue trauma and bleeding.

Trauma caused by airway equipment is not solely limited to the trachea; Smith (1994) presents a case where a Haemopneumothorax was presented following a bougie-assisted tracheal intubation when using a neoplex bougie. Although the case presented by Smith (1994) is quite dated, it demonstrates yet another hazard possible within bougie-assisted intubation. This case identifies a need for caution when using a bougie that is pre-inserted into the trachea followed by the railroading of an ET tube over a bougie.

Anaesthetists often choose to use a stylet preloaded into an ET tube instead of a bougie. A stylets construction promotes shape retention, a property that many bougies lack;

conversely, increased tip pressures are likely. Lim et al., (2012) identifies that tracheal rupture is a rare but serious complication can occur during endotracheal intubation and presents several cases where tracheal rupture was identified as a possible cause of injury by a stylet or an endotracheal tube tip.

O'Neill, Giffin, and Cottrell (1984) report several cases of oesophageal or pharyngeal perforation that can occur within the operating room. In two cases presented, a rigid stylet was utilised and when inserted beyond the lumen of the ET tube, trauma occurred. Similar to Lim et al., (2012), incorrect use of the rigid stylet can cause trauma, even when used by an experienced operator. O'Neill, Giffin, and Cottrell (1984) however identified that inexperienced operators who complete procedures are more likely to cause trauma or perforation.

Finally, Bisgard and Kerr (1949) presents three cases where perforation situations occurred in the cervical portion of the oesophagus, including one situation where a child exhibited a perforation because of the forces generated by a bougie. Although this case is historic, this demonstrates the issues related to bougie trauma over an extended period. With many arguments still debated within modern literature relating to optimum equipment for use, this suggests further product development work is still required. Accurate assessment methods based on device performance would add significant value to the industry and could influence professional society recommendations and hospital trust purchase decisions.

2.4 Overview Of Smart Materials and Artificial Muscle Technologies

Over the past few decades within the field of engineering and material science, the development of smart materials and artificial muscles have demonstrated significant promise in the accurate control of products and systems. Fairweather (1999) classifies smart materials into two categories, active and passive. Active materials are those that have the capabilities to modify their geometric shape or physical properties through a stimulus. Passive materials act as sensors rather than actuators or transducers.

Smart materials are often associated with robotic applications due to their potential to be intelligent and responsive, thus mimicking muscle memory. The use of a smart material or smart system to control a mechanism as a method of steering a medical device would be a suitable solution for the development of the steerable bougie. The use of a smart material activated by a thermal or electronic stimulus would be an adequate solution to gain accurate control compared to mechanically driven alternatives.

Smart materials and artificial muscles have been used in many sectors such as structural engineering, nuclear industries, health and wellbeing, aerospace and defence amongst others (Kamila, 2013). The use of smart materials and system technologies has dramatically increased within the medical device sector with electronic and ionic Electroactive polymers (EAPs), Shape Memory Alloys (SMAs) and low cost artificial muscles all demonstrating significant promise. Nitinol grade materials are the most prominent example and their use in medical devices is expected to increase by 11% between 2017 and 2021 (Wire, 2017).

2.4.1 Shape Memory Alloys (SMAs)

A shape memory alloy (SMA) refers to the ability of certain grades of alloys (split into two categories) that can remember their thermomechanical treatments. Certain grades of materials are usually subjected to traction, torsion, flexion etc., to generate controllable actuation (Lexcellent, 2013), these include:

- Copper-based materials – Cu-Al (ZN, Ni, Be etc.)
- Nickel-titanium materials (Ni-Ti) in addition to small proportions of (Fe, Cu, Co etc.)

SMAs can undergo large strains and can recover to their original shape after undergoing spontaneous deformation or residual deformation by temporary heating (Schwartz, 2009; Lexcellent, 2013). SMAs can be heated to remember a previously set shape before being deformed to simulate a pre-set movement. For an SMA such as Nickel Titanium (Nitinol) to exhibit shape memory and super elasticity, Nitinol undergoes a phase transformation in its crystalline structure when cooled from the stronger, high temperature form (Austenite) to the weaker, low temperature form (Martensite) (Breedon and Vloeberghs, 2009).

SMAs are solely related to “solid to solid” phase transformation which is often thermal, or stress induced but this can also be electrically driven or heated; this makes SMAs suitable for a wide variety of applications due to their small size. One of the most common shape memory alloys, Nitinol, has been used in a variety of aerospace and medical applications, but the control of the material can be difficult. Nitinol can be manufactured in a variety of forms including sheets, wires, ribbons, springs etc. Nitinol springs are commonly utilised in soft robotic applications; examples include the development of soft robotic systems using micro artificial muscle fibres creating NiTi springs (Kim et al., 2009) and an earthworm-like micro robot using shape memory alloy actuators (Kim et al., 2006).

Nitinol is often controlled by an electrical or thermal stimulus input for actuation, this is often exhibited as geometrical alteration or shrinking. One of the drawbacks with the use of the

various grades of Ni-Ti SMAs such as Flexinol® (Dynalloy.com., n.d.). are their vulnerability to failure if the parameters are not carefully controlled. The application of a pulse width modulation (PWM) system can regulate and control these parameters, therefore reducing hysteresis. Similar results are highlighted and achieved by Breedon and Vloeberghs (2009) when integrating Nitinol wire into a facial nerve paralysis system. Morgan and Broadley (2004) also identified concerns relating to Nitinol's increased brittleness displayed after a period of use.

The use of SMAs within the medical sector has dramatically increased over the past two decades with championed applications including stents (Stoeckel, Pelton and Duerig, 2004; Kapoor, 2017), interventional radiology (Rabkin, Lang and Brophy, 2000), catheter guidewires (Morgan, 2004) amongst other applications. Morgan (2004) and Machado and Savi (2003) provide insight into the use of shape memory alloy applications within the medical sector and identified clinical instruments as a prominent area for SMA applications. Duerig, Pelton and Stöckel (1999) and Stoeckel (2000) provide insight on Nitinol medical applications with a focus on how its deployment has steadily driven the medical industry towards less invasive procedures.

2.4.2 Active Polymers

Active polymers are alternatives to SMAs with shape memory polymers (SMPs) the most recognised; SMPs are mechanically activated polymers that change shape based on an external stimuli (Kim and Tadokoro, 2007; Safranski and Griffis, 2017). SMPs are commonly thermally induced (Kim and Tadokoro, 2007); many other stimuli can be used (Hu, 2007) including visible light (Jiang, Kelch, and Lendlein, 2006), magnetic fields (Vialle et al., 2009), current (Liu et al., 2009) etc., which can result in actuation; the construction of the material defines the movements created and manipulated.

There are a greater number of SMPs available compared to SMAs and these present a variety of different properties that can be utilised in a wider scope of applications. Polymers provide designers with significant scope for development; Gurunathan et al., (1999) highlights their immense potential and reviews the state of the art and ability to be used as a cost-effective solution in a wide variety of applications. Progress in the development of SMPs has been rapid and subsequently has gained significant interest within both industrial and academic applications due to the increased functionality displayed (Liu, Qin and Mather, 2007).

Within the active polymers category, Electroactive Polymers (EAPs) demonstrate the greatest potential for integration into steerable medical devices. EAPs have many uses due to their cost effective small size and weight ratio forms. EAPs are polymers that change shape or size when influenced or exposed to a stimulus, most commonly an electric field. EAPs can sustain large forces while undergoing high deformation (Lakhtakia and Martin-Palma, 2013) and are one of several emerging technologies that promote biomimetic applications (Bar-Cohen et al., 2007).

Electronic EAPs include electrostrictive, electrostatic, piezoelectric and ferroelectric materials and are driven by Coulomb law/forces; these materials can hold their induced displacement when controlled by a DC voltage stimulus (Bar-Cohen et al., 2007). Conversely, ionic EAPs are materials that involve transporting ions and typically comprise of two electrodes and an electrolyte (Bar-Cohen et al., 2007). EAPs are often split into two categories (ionic and electronic) based on their activation methods. Kim and Tadokoro, (2007) list several leading EAP's including:

Electronic EAPs	**Ionic EAPs**
– Dielectric EAP – Electrostrictive graft elastomers – Electrostrictive paper – Electro-viscoelastic elastomers – Ferroelectric polymers – Liquid crystal elastomers (LCE)	– Ionic polymer gels (IPG) – Ionic polymer metal composites (IPMC) – Conducting polymers (CP) – Carbon Nanotubes (CNT)

Table 2.3: Leading EAPs (Kim and Tadokoro, 2007)

Reproduced from: Kim, K. and Tadokoro, S., 2007. Electroactive Polymers For Robotic Applications: Artificial Muscles and Sensors. London: Springer Science, pp 3.

Carpi et al., (2011) identifies that certain EAPs such as dielectric elastomers have significant performance advantages compared to other muscle like technologies, this is due to their large strain, high work densities, good frequency responses and high degree of electromechanical coupling. Conversely, supplying high voltage to the material and designing the pre-straining mechanisms are a few of the practical issues that must be considered. Carpi et al., (2011) highlights that although SMAs have several drawbacks, they are unmatched in work density with dimensional changes exhibited between 1-8% and when compared to EAPs their performance generally exceeds the majority of EAPs.

2.4.3 Low Cost Artificial Muscles – Sewing Thread & Fishing Line

Over the past few decades, significant advancements have been made in the development of artificial muscles, especially within the use of pneumatic and electronic controlled actuation systems. There are several performance and efficiency issues associated with high powered artificial muscles including high manufacturing costs, large stroke rates and high stresses (Haines et al., 2014) thus limiting their application in portable devices. Haines et al., (2014) has developed a low-cost artificial muscle solution using monofilament fishing lines and sewing threads, which replicate the performance of high cost powerful artificial muscles.

Research conducted by Haines et al., (2014) has shown that through the application of twist insertion using inexpensive high-strength polymer fibres such as fishing line and sewing threads, this has allowed them to be transformed into fast, scalable, nonhysteretic, long-life tensile and torsional muscles. The experimental setup utilised is simple and uses extreme twisting procedures resulting in coiling and the creation of the muscle by stimulus activation. By applying heat to the coiled muscles, loads can be lifted over 100 times heavier than those a human muscle is capable of lifting when considering a muscle of the same length. When heated the threads can contract by almost 2% and expand in diameter by 5% (Madden and Kianzad, 2015). Other plastics including polyethylene also demonstrate similar levels of actuation/response (Madden and Kianzad, 2015).

Heat application is the primary actuation of the sewing thread/fishing line artificial muscles but the use of hot water, warm air, electric current etc., is also possible. Accurate positional control can be achieved as demonstrated by Arakawa et al., (2016) and the muscles can be driven by joule heating (Mirvakili et al., 2014).

The development of this low cost artificial muscle has been applied to various applications, including the development of high performance robotic muscles using conductive nylon sewing thread (Yip and Niemeyer, 2015). The yarn twisting principles and techniques have also been applied to the development of electrochemically powered energy-conserving carbon nanotube artificial muscles (Lee et al., 2017).

2.4.4 Smart Materials & Their Application To The Steerable Bougie

After identifying several smart materials and suitable materials/mechanisms that can be directionally controlled or shaped, suitable applications need to be identified for the development of the steerable bougie. Based on the summary of literature presented and the criteria presented within the initial design brief, several of the above-mentioned materials should be practically assessed.

Within the initial design brief, the response time of the steerable function to be developed is imperative. The device operative control requires a fast and positive movement with reaction and relaxation times of 1-2 seconds, to ensure the device can be utilised within the desired environment. A high level of control will be required in addition to key criteria including fast, scalable and high work density abilities. Based on this criteria, several of the reviewed materials have been selected for further investigation, including the low cost artificial muscles (fishing line and sewing thread developed muscles) and SMAs (Nitinol/Flexinol).

2.5 Medical Device Regulations & Standards

Equipment selection is often based on an operator's personal preference, the availability of equipment within the NHS supply chain and selection of hospital-designated suppliers. Ideally any new or existing device should conform to the United Kingdom's Difficult Airway Society's ADEPT principles (Pandit et al., 2011); many devices have not undergone any formal testing in accordance these recommendations.

ADEPT has formulated advice underlining evidence-based principles, defining minimum evidence requirements to inform purchasing and selection decisions. The ADEPT guidance protocol concludes:

> *"All airway-related equipment under consideration must fulfil the minimum criterion that there exists for it at least one source of 'Level 3b' trial evidence concerning its use, published in peer-reviewed scientific literature."* (Pandit et al., 2011).

The most important aspect of any medical device is to conform to the Medical Device Directive 2007/47/EC (Ec.europa.eu, 2007). The Medical Device Directive defines a medical device as:

> *Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to*

be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means." (Ec.europa.eu, 2007).

In addition to the Medical Device Directive 2007/47/EC it is imperative that medical devices conform to the guidance and approval processes set by the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA assess the risks associated with medical devices and the likelihood of adverse events and as such the necessary technical file documentation is required for device approval.

For anaesthetic devices it is important to consider the guidance set out by AAGBI within the Safe Management of Anaesthetic Related Equipment, AAGBI Safety Guidelines (AAGBI, 2009). Wilkes (2017) provides a summary of international standards that relates to anaesthetic equipment, Table 2.4, presents the relevant standards. In addition to the international standards and regulations considered by Wilkes (2017), it is also important to consider the following UK and international standards presented in Table 2.5, which also relates to risks associated with medical devices and the accurate labelling, packaging and disposal of equipment.

Regulation/Standard ID Number	Title
IEC 60601-1	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.
ISO 14971	Medical devices – application of risk management to medical devices.
ISO 13485	Medical devices – quality management systems – requirements for regulatory purposes.
1SO 10993-1	Biological evaluation of medical devices.
ISO 5356-1	Anaesthetic and respiratory equipment – conical connectors – part 1: cones and sockets.
ISO 11712	Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.
ISO 5366-1	Anaesthetic and respiratory equipment. Tracheostomy tubes. Tubes and connectors for use in adults.
ISO7376	Anaesthetic and respiratory equipment – Laryngoscopes for tracheal intubation.
ISO 80601-2-13	Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation.

Table 2.4: Anaesthetic Equipment International Standards

Reproduced from: Wilkes, A. 2017. Equipment in Anaesthesia. In: Hardman, J.G. ed., 2017. Oxford textbook of anaesthesia. Oxford University Press. pp. 410.

Regulation/Standard ID Number	Title
BS EN 60601-1	Medical Electrical Equipment and Systems.
BS EN ISO 15223 and BS EN 980	Medical Device Labelling, Standards and Symbols.
2012/19/EU	The Waste Electrical and Electronic Equipment Directive (WEEE Directive).
BS EN ISO 11683	Packaging: Tactile warnings of danger - requirements.
BS EN 1041: 2008	Information supplied by the manufacturer of medical devices.

Table 2.5: Medical Equipment International Standards

Within the context of this research it is important to consider the regulations identified, with TRL 5 targeted for the developed device, this suggests that focus should be placed on design development, technology validation, prototype fabrication and prototype and component validation within the relevant environment. The development process must consider medical device regulations, however TRL 6 onward is where medical device regulations become the most prevalent as creating pre-series devices that conform to the required standards are necessary to acquire the required approvals for clinical trials.

2.6 Design & Engineering Methodologies

Design and engineering methodologies are used to solve complex problems with the aim of creating tangible products or outcomes. There are many types of design and engineering methodologies used in practice that vary based on the type of application or product being designed. The product development process is often factored into a design or engineering methodology with the purpose of describing individual or groups of activities. Within product design, there are a significant number of methodologies and product development models; several influential models have been identified. Within medical product design a number of the key themes and activities identified in standard product development models can be utilised. Problem definition identification tasks, task exploration, product design specification activities, creative phases and detail design stages are essential.

2.6.1 Pugh's Total Design Activity Model

The Total Design Activity Model (Pugh, 1991) is a systematic activity model that encompasses tasks which range from identifying the market/user need, selling of the successful product to satisfy the need and focused activities that encompasses products, processes, people and organisations. Using a central core of activities imperative to the design process, the Total Design Activity Model utilises product design specifications (PDS), component design specifications (CDS's), concept design, detail design and manufacturing processes. The use of PDS's and CDS's align themselves with other design analysis and evaluative tools such as design weighted matrices that provide an unbiased evaluation of a product and/or a design.

2.6.2 The 'Double Diamond' Design Process Model

The 'Double Diamond' design process model (Council, 2005a) is simple and visual design process methodology split into four distinctive stages (Council, 2015) to navigate the process of problem identification to solution output:

- Discover: The first element of the project requires a designer try to look at the world in a fresh way in an attempt to notice new things and gather new insights (Council, 2005b). Initial activities such as observational research strategies, brainstorming, and surveys can all be used.
- Define: The second element requires the designer try to attempt to make sense of identified opportunities identified in the first stage. Key questions that should be addressed include: Which matters most? Which should we act on first? What is feasible? After completing the tasks within this stage, a clear creative brief that frames the fundamental design challenge must be constructed.
- Develop – The third element requires the solution or concepts to be created, prototyped, tested and iterated through trial and error methods.
- Delivery – The final stage is a delivery stage, where the resulting project outcomes are finalised, produced and launched.

2.6.3 Cross's Eight Stages Of The Design Process Model

Cross's eight stage model first developed in 1984 (Adams, 2015), has developed into an updated model presented in Engineering Design Methods (Cross 2008). This model integrates procedural and structural aspects of design problems and focuses on the visualisation of larger design problems that can be split up into sub problems and sub solutions to create a final total solution. The eight elements that construct the model include, identifying opportunities, clarifying objectives, establishing functions, setting requirements, determining characteristics, generating alternatives, evaluating alternatives and improving details (Cross 2008).

2.6.4 French's Model Of The Design Process

French's block diagram of the design process (French, 1998) focuses on four key themes, these include an analysis of problems, conceptual design, embodiment of schemes and detailing. The process starts by identifying a need and an initial statement of the need which should cover three elements, a statement of the design problem, limitations placed on the solution and the criteria of excellence to work towards. The conceptual design process focuses on developing broad solutions focusing on areas of improvement. The embodiment of schemes follows this, where the initial concept solutions are developed further into a final solution set. The final stage focuses on the detailing of the small but essential points that are yet to be addressed.

2.6.5 Asimov's Seven-Phase Linear Chronological Structure

The Asimov Seven-Phase Linear Chronological Structure methodology created by Morris Asimov (Asimov, cited in Adams 2015), focuses on seven stages which are split into two categories, the design phases (phases I-III) and the production and consumption cycle phases (phases IV – VII). Beginning with the identification of the need, feasibility design, preliminary design and detailed design activities are undertaken; these are followed by construction planning, distribution planning, consumption planning and retirement planning activities.

2.6.6 Archer's Three Phase Summary Model Of The Design Process

A notable prescriptive model developed by Archer based on John Chris Jones early systematic design methodology (Archer, cited in Cross 2008) focuses on six types of activities, programming, data collection, analysis, synthesis, development and communication. Although this prescriptive model may fall slightly outside the remit of product design development, the key themes relating to the inputs and outputs are still relevant. These six activities are separated within the three-phase model and grouped into the analytical phase, creative phase and executive phase.

2.6.7 Pahl and Beitz,'s Model Of The Design Process

Phal and Beitz (Pahl and Beitz, cited in Cross 2008) presents a clear design process methodology that is more expansive than the previously discussed models. This methodology uses the general structure of many design process models but adds fine details and numerous tasks within the practical design work stages. The stages used within this model include task classification, conceptual design, embodiment design and detail design. The subtasks identified in each of the sections focus on tasks, specifications, concept development, preliminary layouts, definitive layouts, documentation and the solution, with many individual task capable of being set within each subtask. A key task set within the model is the use of evaluation activities that focus on the technical and economic criteria.

2.6.8 Application To Emergency Airway Devices

The use of design and engineering methodological approaches and processes will be critical to the development of new emergency airway devices. Task identification activities, concept and development activities and specification identification tasks are all critical aspects of the design process and these must be implemented to ensure the successful design of a new product. Within the category of emergency airway devices, many activities must be considered including system methodologies (used for healthcare system management and protocols). Systems methodologies must be considered and combined where appropriate.

One of the most prominent methodologies focused on system design is Soft Systems Methodology developed by Checkland (1989); this offers great promise within action research and has been used within the healthcare environment.

2.7 Soft Systems Methodology (SSM)

Soft System Methodology (SSM) is an approach created by Checkland (1989) and Wilson (2001). The emergence of SSM was established as result of the rethinking of systems ideas described by Checkland (1981; 1984) and Wilson (1984). Shah (2011) notes that this system is based upon action research conducted by Checkland and Scholes, (1990). SSM has been recognised as having potential in many different sectors, including military applications (Staker, 1999), health service management (Lehaney and Paul, 1996), analysing and managing learning environments (Hardman and Paucar-Caceres, 2011) and it has even been used by Shah (2011) as a method of integrating user involvement into medical device development. Checkland (2000) notes that the NHS have adopted some of SSM's initial ideas. SSM's most common application relates to systems thinking and system practice applications (Checkland, 1981).

The concept of SSM was presented by Checkland (1989) as an alternative to systems engineering. SSM was born from research conducted on applying system engineering approaches to solve management and business problems (Burge, 2015), i.e. attempting to apply hard system approaches to fix business related problems. It was discovered that this often failed at the first steps when focusing on problem definitions; this was due to the various numbers of stakeholders involved in the process, all of which had conflicting views. This is often a common issue within medical device design as healthcare professionals often have conflicting views on the use of different equipment, approaches and techniques.

Within medical device design there are several key activities that must take place; these must revolve around the patient and the user of the medical device. User involvement, human factor considerations, ergonomic design processes are all critical elements to successful medical device design. Shah (2011) has developed a theoretical framework based upon SSM's structure and draws upon the importance of user requirements research factoring this into the medical device development process.

Burge (2015) presents an overview of SSM and the notion that SSM is more than just a process but an approach which offers a set of tools to help users carry out the various steps

within the methodology. The extensive literature available on SSM results in small variations of the definitions of the seven stages of SSM:

1. Enter the situation considered as problematic.
2. Expressing the problem situation.
3. Formulating root definitions of relevant systems of purposeful behaviour/activity.
4. Building a conceptual model of human activity systems named in the root definitions.
5. Compare models with real-world actions.
6. Define possible changes that are both desirable and feasible.
7. Take action to improve the problem situation.

Presley, Sarkis and Liles (2000) analyses the concept of SSM in relation to product and process innovation, recommending its use as a tool for scientifically evaluating complex environments such as organizational processes and products delivered by organisations. One common use of SSM and its soft problem assessment processes include, providing insight into complex questions such as how can health services delivery be improved? Placing this in the context of emergency airway devices, topical questions can be analysed such as; how can device adoption be influenced, or how does academic and professional society validation affect procurement?

2.7.1.1 The Seven Stages Of Soft Systems Methodology (SSM).

SSM can be traced back as far the 1970's (Burge, 2015), with many adaptions presented. Although SSM is most aligned to systems thinking, these principles can be applied to many other subject areas such as product design and engineering. The adaption of the seven SSM stages described below has occurred due to various stakeholders adding to and adapting the methodology to suit; the key stages and themes however remain. The seven stages ensure even the messiest of arguments can be structured. These stages take place in two theoretical realms. Stages one, two, five six and seven take place within the "real world" whereas stages three and four take place in the "systems thinking world" which is based on thinking about the real world.

Stage 1 - Enter the situation considered as problematic: The first stage focuses on gathering information and viewpoints about the situations that are deemed problematic. To discover the problem situation, there must be a universal agreement that there is some scope for improvement; this leads to the completion of basic research. The research to be conducted

focuses on identifying the problem situation context, content and activities such as interviews, surveys and observations.

Stage 2 - Expressing the problem situation: It is important at this stage that the communication and validation of the investigator's ideas about the problem situation are clearly defined. There any many tools which can be used to express the problem situation, one of the most common, was developed by Checkland et al., (1989) is based on the "rich picture technique" allowing the capture of various perceptions. Shah (2011) notes that the rich picture technique is used to construct formal annotations of the problem.

Stage 3 - Formulating root definitions of relevant systems of purposeful behaviour/activity: Formulating the root definitions based on human activities can be completed in many ways, the two most common are through using input output transformation diagrams (Bergvall-Kåreborn, Mirijamdotter and Basden, 2004) or through the traditional CATWOE system (Checkland, 1989). Checkland (1989), Burge (2015), Bergvall-Kåreborn, Mirijamdotter and Basden, (2004) and Gasson (1995) discuss the stages of CATWOE and define these as:

> [C] The Customer: Who would be victims/beneficiaries of the purposeful activity?
>
> [A] The Actors: Who/What individuals will do the activities?
>
> [T] The Transformation: What is the purposeful activity expressed as a transformation of input to output.
>
> [W] Weltanschauung: What are the views of the world that make the definitions generated meaningful?
>
> [O] Owner: Who could stop this activity? Who is the wider system decision maker who is concerned with performance?
>
> [E] Environmental Constraints: What key constraints exist outside the system boundary that are significant to the system?

Stage 4 - Building a conceptual model of human activity systems named in the root definitions: This stage focuses on conceptualising the system defined within the root definitions and what they will do (Shah, 2011). For each of the definitions defined a conceptual model can be created. This is an extremely useful task for designers especially within medical devices where multiple systems need to collaborate to complete the desired activity or action.

Stage 5 - Compare models with real-world actions: The fifth stage is where the methodology returns to the real world and compares the reality experienced with the information captured in the models Burge (2015). This stage is critical to ensure discussions on the proposed improvements are conducted; this is an imperative task for a designer and usually is clarified in working documents such as the design brief, product design specification etc. Shah (2011) suggests that stage five should result in a list of recommendations. From the perspective of a designer, the recommendations defined within SSM could be the design criteria or proposed project outputs.

Stage 6 - Define possible changes that are both desirable and feasible: Stage six analyses the proposed changes that are both desirable and feasible. Ideally all the recommendations suggested should be implemented. Burge (2015) suggests that because SSM was developed as a human activity systems it is necessary to recognise that people involved in potential change could hold conflicting views. A tool recommended for use at this stage is the ease benefit matrix; weighted matrices could also be of used at this stage.

Stage 7 - Take action to improve the problem situation: The final stage is where action can now be taken. It is important at this stage not to try and change everything at once. Consider the scenario of the creation of a new conceptual medical device, implementing this and trying to change practice immediately would not be possible; incremental changes should ideally be targeted.

2.7.1.2 SSM's Potential Within Medical Device Design

The potential for SSM's integration into medical device design practice has already been demonstrated by Shah (2011); however, there are many factors that have yet to be considered. The design and manufacture of any new medical device is a complex task that requires considering a large spectrum of factors. A common misconception in medical device development is that once the problem has been identified by a clinical or medical expert it is passed over to the design team or manufacturer to complete the necessary work.

Problem identification as demonstrated within SMM is not a simple task; there are many complex tasks demonstrated within the SSM activities. Various stakeholders must be involved in this process. Integrating SSM as an approach that should be completed alongside design activities would not only ensure that accurate problem identification and action research can be completed, but the action itself in the form of design tasks can be conducted. Integrating design tasks alongside SSM activities in the form of a conceptual model would

help depict this process; other elements such as technology readiness levels could be integrated to ensure that the entire research and design process is depicted.

2.8 Physical Properties Of Bougie Introducers

The use of single and multiple use bougies has been debated for many years due to the risk of infection and microbial issues identified with multiple use bougies (Annamaneni et al., 2003 and Cupitt, 2000). Reusable bougies are commonly manufactured from a polyester based resin, whereas single use disposable bougies are commonly manufactured out of suitable polymers (e.g. polyurethane, polyethylene etc.,) that have optimal material properties and exhibit the desired physical properties defined by the manufacturer. Single use bougies often demonstrate increased resistance, especially when removing them from ET tubes (Jackson, Bartlett and Yentis, 2009). Manufacturers often recommend the use of lubricants when using a bougie (Staikou, Mani and Fassoulaki, 2009).

Complications due to bougie related trauma, especially significant mucosa damage and perforations, typically occur due to aggressive placement and excessive pushing of the ET tube within the trachea, causing ET tube and bougie resistance (Dumanli Özcan et al., 2017, Phelan et al., 2004). There have been several reviews into the forces generated by bougie introducers (Hodzovic et al., 2004; Hodzovic, Wilkes, and Latto, 2004; Janakiraman et al., 2009) indicating single-use bougies present higher tip pressures when compared to multiple-use bougies. Marson et al., (2014) has identified that airway trauma can be created with forces as low as 0.8N; many of the above-mentioned studies highlight tip pressures that are significantly higher with various bougies. The testing equipment utilised in these tests does not compare to modern force gauges, thus the confidence in this data can be questioned; bougie stiffness is also reviewed by Bowman and Renwick (2012).

Interestingly, Frova et al., (2005) criticise many of these studies as it is suggested that no evidence exists that the peak force tests are correlated with the clinical outcome in any meaningful way. Bougie tip pressures can have significant effect on the level of mucosa damage exhibited in difficult intubations; in addition, tip pressure and resistance can also be generated during the railroading of the ET tube, removal of the bougie from the ET tube (Bartlett, Jackson and Yentis, 2009; Jackson, Bartlett and Yentis, 2009) and the withdrawal of the bougie when repositioning in-situ.

Trauma due to railroading resulting in blood being present on the bougie tip has been reported by Higgs and Goddard (2009). Although it may be obvious to state that stiffer

bougies create more tip pressure, this needs to be quantified in the context of a porcine airway study, but also be related to the design of the bougie tip; the worst-case scenario must always been planned for.

Although the DAS guidelines recommend preloading a bougie when using an AirTraq, some anaesthetists still railroad bougies when using video laryngoscopy. John and Ahmad, (2015) highlight a potential hazard whereby when using a bougie in combination with an Airtraq, the bougie tip is capable of traversing through the Murphy's eye of the ET tube, which could generate significant trauma to the trachea. Due to the physical properties of some bougies, this can be more common as the bougies shape can be altered more easily.

Although cases of difficult intubations are rare, there are cases reported where trauma is observed (Hodzovic, Latto and Henderson, 2003). Marson et al (2014) has also presented results that demonstrate significantly greater peak tip pressure forces for the Frova single-use bougie compared to the Eschmann re-usable bougie; this demonstrates greater likelihood for trauma. To further quantify this, Hodzovic and Latto (2007) presented airway trauma cases including two fatality cases that were identified as being more common with single use devices; although the number of cases reported was minimal.

Other cases include studies presented by Prabhu et al., (2003), Kadry, and Poppat (1999). Dumanli Özcan et al., (2017) discusses a case of an obese patient that presented with a difficult intubation; intubation with a bougie was attempted due to Grade 2–3 view of larynx under direct laryngoscopy and lubricant facilitated sliding the ET tube over the bougie; however, injury occurred due to excessive force exerted on the bougie.

Paul et al., (2014), has investigated the aesthetics of bougie introducers through the creation of a traffic light bougie that indicates depth of insertion. This study conducted on a manikin significantly reduced the depth of bougie placement both on initial insertion and following railroading of the ET tube. The results from this study highlighted that the use of the traffic light bougie can help reduce dangerous practice of inserting bougies too far and will help reduce airway complications. The location of the coloured distances on the bougie shaft will need further consideration due to the bespoke nature of patients. Campbell (2014) suggests that the traffic light bougie requires further design work to include a green/safe zone sandwiched between two red zones to account for insufficient and too great of insertion depth.

Grape and Schoettker, (2017), identifies that the physical characteristics of bougies will affect the choice of a specific tracheal tube introducer in a clinical situation. Their size, length, structure, stiffness, hollow or solid core, shape, type of distal end will all affect the choice of device for use. Nevertheless, hospital trusts also consider factors such as single-use or reusable and soft versus hard tip as this affects the price of the bougie and their purchase decisions. Robbins (1995) and Latto (1999) suggests that bougies should be inspected before use; if greater quality control and testing is completed this may not be necessary.

A principal factor operative factor that must be considered for bougies is their shape retention capabilities. Shaping a bougie has been proven to significantly increase the likelihood of successful placement when faced with a Grade 3 Cormack and Lehane laryngoscopic view; superiority is noted in curved coude (angled) tip GEBs in simulated difficult intubations (Hodzovic, Wilkes, and Latto, 2003).

There are a limited number of studies that analyse the shape retention characteristics of bougie introducers. Grape and Schoettker, (2017), identifies several products that have different levels of memory, this often depends on whether they are a bougie, introducer or stylet. Nolan and Wilson (1992) identified that the Eschmann introducers (gum elastic bougies) often retain a new shape when bent; this often is not the case for single use bougies (Xue et al., 2018; Annamaneni et al., 2003). Jackson and Cook (2007), even go as far as suggesting that plastic single-use bougies, show poorer performance characteristics when compared with the GEB and cannot be recommended for use in practice; Mushambi et al., (2016) recommends further evaluation is required of single use bougies before replacing the GEB.

Although shape retention is a critical physical characteristic for a bougie, reshaping a bougie multiple times can result in device failure due to main shaft or tip fracture (Latto, 2002). Sterilisation and cleaning of reusable bougies has been noted to affect the physical properties of bougie introducers (Cuppit, 2000; Cummings et al., 2013; Dawes and Ford, 2011); this has led to manufacturers of the GEB recommending that the GEB be used no more than five times. Mingo et al. (2008) has reviewed the effect temperature has on bougies; it is suggested that bougies are kept in a refrigerated environment as temperature has been shown to have a significant effect on the performance on bougies with concerns raised on the high ambient temperatures exhibited in anaesthetic rooms. Ghei et al., (2010) and Woollard, Hodzovic and Latto, (2009) suggests that temperature does not have a significant

effect on the success rates of introducers but importantly identifies that cooling tracheal introducers doubles the peak forces exerted at the tip thus increasing bougie stiffness.

There are several recent developments within the airway device market relating to the alteration of the physical properties of bougies, introducers and stylets; many of these are identified in the patent search in Appendix B. Two interesting development in recent years relating to managing or altering the shape characteristics of bougie introducers are presented by Gao, Gao and Gao, (2017) and Construct Medical Pty, Ltd.

Gao, Gao and Gao, (2017) presents a device that allows medical personnel to grip and stabilise a bougie inside an apparatus which can maintain the curve of the bougie during intubation. This device temporarily alters and controls the bougie curvature and allows O2 ventilation; the preloading of the ET tube appears to be incorrect/backwards as per the figures presented in patent US20170157349A1. Construct Medical Pty, Ltd in 2016 released a flexible tip bougie that has a manually manipulated and controllable tip having proximal and distal ends; the proximal end of the movable tip is connected to the distal end of the main shaft; as discussed in Section 2.4.2.2, there are several fundamental performance issues with this bougie.

The review presented by Grape and Schoettker, (2017) identified that currently the ideal intubation aid does not exist; this assessment is valid based on the evidence discussed thus far within the literature review. Grape and Schoettker, (2017) identified a criteria for the optimal gold standard intubation aid (listed below); many of these recommendation are impractical for a low/mid cost single use intubation device as the technologies required for integration are expensive.

- Inexpensive, readily available and single use.
- Easy to store and transport.
- Straightforward to handle.
- Firm enough to maintain its shape after bending (memory effect).
- Soft enough not to cause airway trauma.
- The tip should be soft and curved for easy (blind) positioning under the epiglottis.
- The intubation aid should provide visual feedback of proper placement.
- Allow emergency oxygenation.
- Compatible for use with video-assisted laryngoscopy and allow movement of the tube’s extremity under direct visualisation.

2.8.1 Key Equipment Assessment Studies

Section 2.8 highlighted many studies that have considered factors that can influence the physical properties of bougie introducers; it is important to review a few of the key published examples in more detail and identify the methods used for the measurement and assessment of bougie performance and efficiency that can cause trauma. Appendix C presents a summary of results from a sample of key studies that analyse physical properties, equipment performance, efficiency and safety. The selection of this sample of studies is based on several key publications cited within the field of equipment assessment.

Many of the issues identified within the summative table (Appendix C) can be factored into the design of any new airway device including the re-design of bougie tips, success and speed of intubation considerations, bougie bend and shaping and the forces associated during use (intubation and extubation). The studies conducted by Braude et al., (2009), Jackson, Bartlett and Yentis, (2009), Hodzovic et al., 2004, Hodzovic, Wilkes and Latto, (2004), Annamaneni et al., (2003), Marson et al., 2014, Janakiraman et al., (2009) and Hodzovic et al., (2008) review the operational uses of bougies and use various measurement criteria. The equipment and experimental setups utilised for the studies where measurement of forces were captured are not necessarily the best approaches and do not always account for key measurement and data acquisition considerations such as calibration and accuracy.

2.8.1.1 Measurement Inaccuracies

The studies identified in Section 2.8.1 and Appendix C present several cases where the correct selection of testing equipment has not always been identified. Selecting the correct type of testing equipment is imperative to ensure that the results collected are accurate and quantifiable rather than comparable thus limiting their wider application. To ensure accurate measurement during procedural testing, it is important that the correct specification of hardware be used. Inaccurate testing protocols can result in data only being deemed comparable rather than accurate.

Within any force gauge there is always an element of error that will ultimately limit the application of the load cell; thus, it is important to ensure that the load cells accuracy and resolution are accurately defined and specified. Ensuring the load cell is calibrated and rated to an accurate scale is extremely important; otherwise, this affects the measuring range that can be accurately recorded. With any force gauge or load cell, Figure 2.17 presents the expected performance of a standard force gauge load cell:

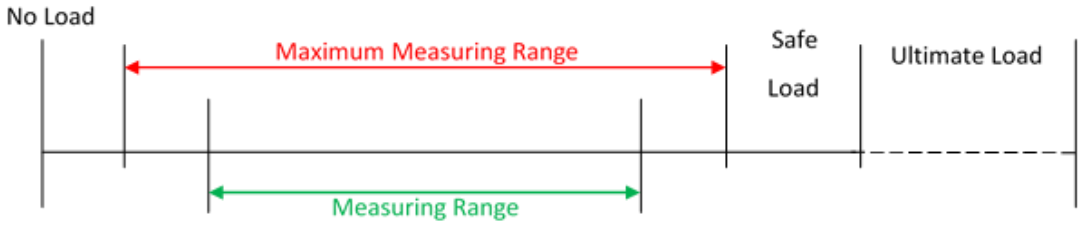


Figure 2.17: Load Cell Accuracy in Relation to the Conditions of Use

Applying too much load/pressure to a load cell, thus going beyond the ultimate load limit will permanently damage this and therefore provide false positive results. This may not be obvious to the naked eye as the load cell will still be functional, however, the data recorded will no longer be accurate. Ensuring the correct protective stops are preprogramed on the device will ensure the maximum load is not exceeded. Applying too much load to the load cell is not the only problem that exists. Collecting accurate data in the lower end of the load cell can be extremely difficult and variable. If the wrong type of device is selected with a specification that is not correctly rated to experiment parameters, the data collected will not be accurate, but only comparable to itself.

Studies conducted by Marson et al., (2014), Hodzovic et al., (2004), Hodzovic, Wilkes and Latto (2004) and Janakiraman et al., (2009) that evaluate emergency airway equipment unfortunately fall into the category of collecting data at the bottom end of the load cell which has too significant a range, therefore this fails to consider the full-scale deflection accuracy of the data collection. The force gauges utilised do not fall within the correct specification to collect accurate data; only comparable data has been collected.

Hodzovic et al., (2004), Hodzovic, Wilkes and Latto (2004) and Marson et al., (2014) use a Mecmesin PFI200N force gauge rate at 0-200N. After consultation with Mecmesin, it was identified that the resolution of the Mecmesin PFI200N is 1:5000, therefore the PFI200N resolution equates to 0.04N. The accuracy of the Mecmesin PFI200N, which reads from 0-200N, is only 0.5% full scale deflection (FSD) which equates to +/- 1 N. With data collected in this study as low as 0.7N and the accuracy of the force gauge rated at +/- 1N this unfortunately means that the accuracy of the data is only comparable. The data collected in the lower range of the tests for example at 1N would therefore read at +/- 1N which would result in the testing data collected being validated anywhere between 0 and 2N.

The study completed by Janakiraman et al., (2009) uses a Mecmesin PFI500N. Again, after consultation with Mecmesin, it was identified that the resolution of the Mecmesin PFI500N

is 1:5000, therefore the PFI500N resolution equates to 0.1N. The accuracy of the Mecmesin PFI500N, which reads from 0-500N, is again only 0.5% FSD which equates to +/- 2.5 N.

To collect data at a lower range as required, ideally a force gauge rated a 50N or lower with a 0.5% FSD should be used. A force gauge with this level of accuracy that has a maximum measurement range of 50N or lower would ensure accurate data can be collected. If a force gauge with an FSD of 0.5%-1% is available for a 0-50N force gauge this would ensure the data is accurate within +/- 0.25N – 0.50N; if an FSD of 0.5%-1% is available for a 0-20N force gauge this would ensure the data is accurate within +/- 0.1N - 0.2N.

2.9 Discussion

This chapter has reviewed five key themes; the review of literature suggests that medical device development is a complex task requiring the involvement of a wide variety of stakeholders. Every manufactured medical device available on the market today will have followed a form of development process however there is a gap for a medical device design framework focused on emergency airway devices. Every medical device must be designed in a unique way due to the bespoke nature of medical procedures. Combining engineering and design methodologies to create a suitable framework for device development, specific for the product category, would help inform future design of emergency airway devices.

This literature review has discussed several areas that clearly demonstrate the case of need for a new difficult airway device that could increase the safety and efficiency of intubation procedures. As with all new medical devices, uptake and effective use is a key issue when hoping to penetrate the medical device market. For the steerable bougie to be successful, an increase in procedure speed and safety is desirable. It is hoped that a reduction in required training compared to alternatives and increased skill retention can be demonstrated through the introduction of the steerable bougie. Device uptake relies not only on evidence of efficacy but also effective marketing and distribution. Uptake in the UK and the NHS can potentially be encouraged by creating an evidence file for the NICE (National Institute for Health and Clinical Excellence) device appraisal route. MHRA and the related technical documentation are required during device development to achieve the necessary certification.

Shortcomings have been identified in relation to existing emergency airway devices and their safety and efficient use. Problems associated with the current anaesthetic intubation procedures relating to the safety and efficiency of procedures performed and the equipment

utilised have identified device design improvement considerations that can be implemented into a product design specification. The safety and efficiency of difficult airway management must be continuously improved; management protocols, national surveys teaching techniques, procedure best practice and equipment all must be periodically reviewed to ensure optimum approaches to practice. Typically, this appears to be only updated when new guidelines or national surveys are published, or new equipment is introduced into practice, both of which are infrequent and subjective to personal preference and training.

New devices should only be allowed to penetrate the market and implemented into practice if clinical assessment is conducted and demonstrates a significant improvement compared to current practice. The market currently has several low-cost equipment solutions i.e. mass-produced bougies, which although provide useful in some cases, do not demonstrate the same performance level as the gold standard devices available; Mushambi et al., (2016) also raised this as a concern in a recent national survey. New emergency airway access devices should conform to the below criteria to be deemed useful for integration into practice:

1. Improving procedure safety and device safe use thus reducing patient complication risks and reducing the likelihood of incorrect device operation.
2. Improving the efficiency of the procedure though improved and better designed devices i.e. reducing the length of time to intubate a patient safely.
3. Improving overall device performance resulting in greater success rates for first pass intubation.

Safety issues and the efficient use of emergency airway access devices are not solely related to equipment design and use. Teaching and learning strategies related to complex task learning and team dynamics can contribute to the success or failure of undertaken procedures. Teaching strategies can improve both learning and engagement as proven in other education studies. Different instructional approaches result in various levels of engagement and knowledge retention (Deslauriers, Schelew and Wieman, 2011). Importantly human tutoring is widely believed to be the most effective form of instruction, as described in the experimental study by Bloom (1984). Consideration can be made to the design of teaching/tutorial methods, the design of the teaching space, and the interaction behaviours within this space (Vanlehn, 2006).

Finally, the inaccurate equipment and methods used to analyse the physical properties of bougie introducers requires addressing. When designing bespoke testing systems,

equipment calibration and repeatability must be taken into consideration. It is proposed that accurate testing systems and protocols are designed to review existing bougies and future devices produced for the market. By doing so, this would allow the following knowledge to be generated:

1. Contribution to testing data that informs the likelihood of successful device operation, providing recommendation for optimum equipment selection.
2. Inform users of product ranges that offer improved intubation efficiency.
3. Ensure manufacturers avoid producing poorly designed, higher risk devices; i.e. devices with increased tip pressures influenced by material selection.
4. Increase overall performance and safe use of devices within the sector, contributing to increased procedure success rates for first time intubation.

Considering the above four points' three testing systems/protocols will be created:

1. Tip Pressure Testing Protocol: evaluating the forces applied at the bougie tip, considering the grip location.
2. Tip Pressure Repeatability System: assessing bougie tip deformation through repeated tip pressure tests.
3. Shape Retention Testing System: tracking and accurately measuring the shape retention capabilities of bougies; considering bend location, angle of bend and position vs time tracking.

The next chapter will focus on the development of a conceptual framework which will review the process of medical device development focusing on emergency airway access devices. Focus will be placed on integrating the Soft Systems Methodology created by Checkland (1989) alongside design and engineering models including the Total Design model developed by Pugh (1991). Shah (2011) highlights that collaboration of knowledge across disciplines would benefit the successful understanding and involvement of users in a healthcare system and suggests that the use of the soft systems methodology approach would provide a foundation in the construction of a framework that is both logical and flexible for a problem situation. Shah and Alshawi, (2010) identifies a number of key themes within medical device development which require integration with specific focus placed on user requirements research. Key themes such as collaborative design approaches, user involvement, ergonomic design considerations, regulatory considerations and technology assessment are required.

CHAPTER 3 – CONCEPTUAL FRAMEWORK

3.1 Introduction

The development of medical device is a complex task requiring the involvement of a wide variety of stakeholders. Every manufactured medical device available on the market today will have followed a form of medical device development process. There are many definitions for a medical device, but these often differ based on country and associated regulator bodies as presented in Appendix A.

Medical device development processes are not straightforward due to the extensive range of factors that can influence their design, development and manufacture. Thorough research and design development strategies must be applied to the development of any new device whilst incorporating and implementing a structured methodological approach. No one medical device is identical and so the research and design development strategies associated with the medical device design must be tailored accordingly. There are many common themes within the design process for medical devices, but every product is unique. Developing a framework for a product development category rather than an individual product may provide an approach for a common working method. This chapter describes the construction of a conceptual framework that is appropriate for the development of a new emergency airway device considering the theories and models discussed in Chapter 2.

3.2 Context

The design and manufacture of a new medical device is a complex task that requires consideration to a large spectrum of factors. One of the common misconceptions in medical device development is that once the problem has been identified by a medical professional and handed over to the design team or manufacturer, it is the sole responsibility of the designer or manufacturer to ensure this product is implemented into market and is a success. The question that is yet to be answered is what approach should be taken to ensure the medical device design process that is being undertaken is suitable in order to design and manufacture a device to its optimum potential; one of the key factors is the use of multidisciplinary development teams. Medical professionals must be able to collaborate with design engineers and device manufacturers and vice versa. The utilisation of a multidisciplinary development team approach must extend beyond than the sole relationship between medical professional and the design engineers and device manufacturers. A wider scope of the ideal team of contributors is depicted in Figure 3.1.

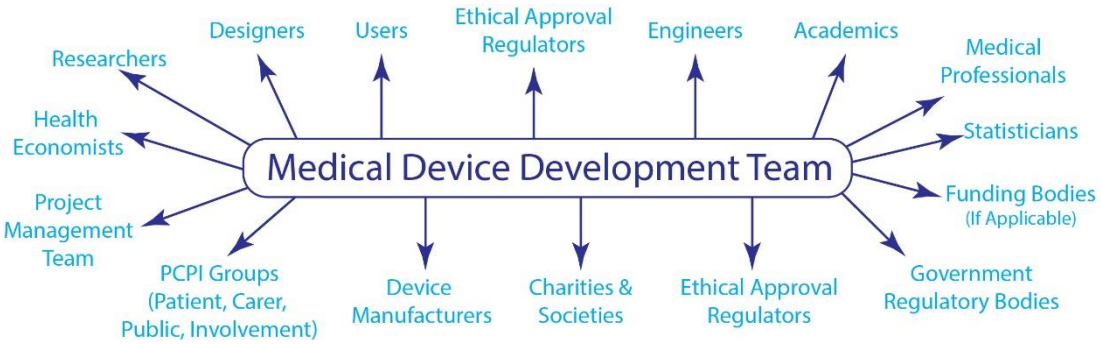


Figure 3.1: Proposed Medical Device Development Team

The World Health Organization (2010) acknowledges that a significant body of stakeholders are involved in the innovation process; these are split into two categories, users and other stakeholders. The World Health Organization (2010) does breakdown the category of medical professionals into subcategories including, general practitioners, specialists, allied health professionals and professional societies. To create the conceptual framework focussing on developing of a new emergency airway access device, the elements presented in sections 3.2.1 – 3.2.8 summarise several key considerations:

3.2.1 Medical Device Regulations

Medical device regulations fundamentally influence the design, manufacture and implementation of medical devices. As medical device regulations are regularly and cyclically updated, an adaptive multi-dimensional approach is required. Manufacturers not only have to be aware of the current legislation but also have foresight to plan for future changes; this may result in device amendments. The current changes to the EU medical device regulations were implemented on 25th May 2017 and fully apply in EU Member States from 26 May 2020 (The EU Regulation on Medical Devices 2017/745) and 2022 respectively (The EU Regulation on In Vitro Diagnostic Medical Devices 2017/746) (GOV.uk, 2017).

Changes in the medical device regulations have occurred for many years based on the original Council Directive 93/42/EEC of 14 June 1993. The purpose of creating the Medical Device Directive was to provide a co-ordinated regulatory environment where medical devices are to be sold within the European Economic Area. Products that need to conform to the Medical Device Directive must conform to certain essential safety and administrative criteria and must be CE marked to demonstrate compliance. Using a bougie introducer as an example, the manufacturer has an obligation to ensure all of the necessary labelling is provided on the products packaging, provide a manufacturer's product code, the supplier name, product description, instructions for use and storage, distribution details, date of manufacture and used by date.

Since its inception, the Medical Device Directive has undergone many revisions and updates to ensure that the latest updates within medical practice are considered; the revisions of the Medical Device Directive include:

- Directive 93/68/EEC [CE Marking].
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma.
- Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 amending Council Directive 93/42/EEC concerning medical devices.
- Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

The Medical Device Directive dictates the requirements of the four classifications of medical devices; this encompasses many of the old regulations into one. Jefferys (2001) discusses the history and development of device regulations in the UK and Europe and how older regulations and procedures from regulatory bodies such as the Scientific and Technical Board (STB) of the Department of Health and the Manufacturers Registration Scheme (MRS) were established to improve the quality and safety of medical equipment, and as such influenced the Medical Device Directive.

It is also important to highlight that since the introduction of the Medical Device Directive; administration bodies have been created to help implement and regulate the acceptance of medical devices. The Medicines and Healthcare Products Regulatory Agency (MHRA) is a government body that brought together the functions of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA). Depending on the classification of the device, the level of control, supervision and the content of data that is required to support products differs based on their assessed risk.

Medical device manufacturers are now forced to take an integrated approach to design and validation of medical devices to ensure that their products are reliable and fit for purpose;

this is also noted by Alexander and Clarkson (2000a; 2000b) who states that good design practice encourages an integrated approach while ensuring fitness for purpose within commercial reality.

3.2.2 User Perspectives

Unlike many products, medical devices have two fundamental user perspectives, the user/operator perspective and the patient perspective:

1. **User/Operator Perspective:** The safe use and operation of the medical device from the user's perspective to treat a patient whether this completed by the vast range of potential device operators (doctor, surgeon, emergency responders, first aider, etc.,), which is also dependant on the procedure to be completed.
2. **Patient Perspective:** The medical device must be capable of safely completing the diagnosis, prevention, monitoring, treatment or alleviation of the clinical situation associated with the patient to ensure improvement in their health and wellbeing.

The user/operator and patient perspective can sometimes be the same or have the same objectives; however, they should ideally be considered as two separate entities initially. The patient perspective is increasingly perceived as a fundamental element of health innovation research and medical device development. It is therefore important to get the viewpoints of patient and public involvement groups (where appropriate) and medical professionals. Many research-funding bodies now demand that patient and public involvement (PPI) is integrated as a fundamental part of the research. The importance of PPI feedback cannot be underestimated; there are many positives that can be achieved by fully integrating PPI throughout product development, for example acquiring clinically accurate feedback through the involvement of PPI groups. Some hospital trusts have even created their own groups such as the Young Person Advisory Groups (YPAG) who have also been assembled to help support research in children. The viewpoint of carers and responsible adults should also be considered during this process, especially when considering medical conditions which require emotional and (or) physical support for the remainder of a patient's life.

Mockford et al., (2011) suggests that patient and public involvement (PPI) is an integral part of health care as it places emphasis on including and empowering individuals and communities in the shaping of health and social care services. Mockford et al., (2011) also identifies that there is still significant development required for the PPI evidence base particularly around guidance for the reporting of user activity and impact.

3.2.3 User Involvement

The importance of user involvement feedback cannot be underestimated; many positives can be achieved by fully integrating user involvement throughout research. Acquiring clinically accurate feedback through the involvement of users and patient groups is now perceived as a fundamental element to many funding bodies' application processes. Ghulam Sarwar Shah and Robinson (2006) suggest that medical device users are one of the principal stakeholders of medical device technologies with user involvement in medical device technology development and assessment central to the stakeholder's requirements. The literature review presented by Ghulam Sarwar Shah and Robinson (2006) based on user involvement in medical device development and assessment provides a detailed list of studies that have considered user involvement principles.

The use of user involvement also extends beyond medical devices and can often be found in literature relating to health services research. Grocott, Weir and Bridgelal Ram (2007) present a paper that addresses three topical themes: user involvement in health services research; determining the value of new medical technologies in patient care pathways and furthering knowledge related to quality in health and social care. Grocott, Weir and Bridgelal Ram (2007) identifies many of the key elements required for medical device development, such as the design team, end users, testing and exploratory trials, health economic evaluations, dissemination and post market surveillance, amongst others.

Within the development of the conceptual framework presented in this chapter, many of the considerations that Ghulam Sarwar Shah and Robinson (2006) and Grocott, Weir and Bridgelal Ram (2007) consider are integrated. However, design and engineering methods and additional theoretical considerations such as TRLs are combined to present an integrated approach using soft system methodology and design and engineering methods in combination with design process activities for medical device development, specifically for emergency airway devices.

3.2.4 Influencing Device Adoption

Device adoption is a complicated matter due to the considerable number of factors that can affect this. Regulations, pricing strategies, reimbursement of new technologies, global policy changes, coverage, economic constraints, amongst many other factors can prohibit device adoption. Carlfjord et al., (2010) suggests that device adoption is positively influenced when perceptions of the innovation being compatible with existing routines is perceived advantageous.

Technology transfer and implementation is another factor that can influence medical device adoption, Roback et al., (2007) identified three explanatory variables for medical devices including, the subjective expected value of the device, information and learning, and the innovativeness of the adopting unit. Dramatic increases in health expenditures have led to a substantial number of regulatory interventions in the European market (Schreyögg, Bäumler and Busse, 2009); balancing these adoption considerations against affordability to facilitate device uptake and deployment is imperative.

There are many factors that influence device adoption; two of the key elements that are particularly relevant for emergency airway devices are academic/clinical validation and professional society validation. Societies often provide guidelines or recommendations for gold standard devices, techniques etc; this information is then often utilised by hospitals and trusts for procurement justification. Academic literature, case studies, critical reviews and laboratory reports all also have a significant impact on device adoption. In the context of tracheal intubation devices in the emergency airway device equipment assessment studies highlighted in Chapter 2 Section 2.7 must be considered.

The studies conducted by Annamaneni et al., (2003), Braude et al., (2009), Hodzovic et al., 2004, Hodzovic, Wilkes and Latto, (2004), Hodzovic et al., (2008), Jackson, Bartlett and Yentis, (2009), Janakiraman et al., (2009), Marfin et al., (2003) and Marson et al., 2014, review the operational uses of bougies and use various measurement criteria.

Evaluations on different types of bougie introducers are presented within the literature with a variety of recommendations made with regards to the performance and optimum approaches for utilising the devices. It is therefore not a surprise that many papers acknowledge the reusable/multiple use gum elastic bougie (GEB) as the gold standard device and suggest that further re-evaluation of single-use devices is still required. The recommendations of the GEB as the gold standard device is also reinforced by Pandit et al., (2011) who also suggests that some hospitals, for reasons of cost alone, have tried to replace the gum elastic bougie with alternative equipment which has not undergone any form of formal testing in accordance with DAS' ADEPT principles.

3.2.5 Causes of Commercial Failure of Medical Devices

Commercial success and failure can be linked to wide variety of factors; a medical products lifecycle is a defining factor which is imperative to its success or failure. The Global Alliance on Healthcare Technology initiative run by the World Health Organisation suggests that a

medical devices life span perspective should run from design to disposal. There are many examples of product lifecycles relating to medical devices including those presented by Gutiérrez-Ibarluzea, Chiumente and Dauben, (2017), World Health Organization (2011), Morrison et al., (2017) and the FDA (Total Product Life Cycle). Fundamentally all products follow a generic product lifecycle. Lidwell, Holden and Butler (2010) states:

> *"All products progress sequentially through four stages of existence: introduction, growth, maturity and decline"*

Day (1981) argues that the simplicity of the product life cycle makes it vulnerable to criticism identifying five basic issues that must be faced in any meaningful application of a concept include:

- How should the product-market be defined for the purpose of life cycle analysis?
- What are the factors that determine the progress of the product through the stages of the life cycle?
- Can the present life cycle position of the product be unambiguously established?
- What is the potential for forecasting the key parameters, including the magnitude of sales, the duration of the stages, and the shape of the curve.
- What role should the product life cycle concept play in the formulation of competitive strategy?

Failure to understand the theory behind the product life cycle and its appropriate application will inevitably result in product failure. Within the medical device industry this is no different; there is a significantly larger scope of problems that extend beyond simply understanding the risks associated with the product market.

Santos (2013) provides a comprehensive list of potential causes for commercial failure of medical devices including failure to meet a need, insufficient device testing, poor design or performance, poor material selection, ethical issues, lack of evidence to support device use, device obsoleteness or alternative treatments, legislation modifications, noncompliance to regulatory requirements, misunderstanding the acquisition process, improper reimbursement code, high price/insufficient pricing strategy, inadequate reimbursement level, poor marketing and inexperienced management. Despite the comprehensive list provided by Santos (2013), two key factors have been overlooked. Patient benefit and clinical needs to be established; if there is no patient benefit to a new or existing product and there is no clinical need, the device will ultimately fail.

3.2.6 Soft Systems Methodology (SSM)

The emergence of SSM was established as result of the rethinking of systems ideas described by Checkland (1981; 1984) and Wilson (1984). The concept of SSM was presented by Checkland (1989) as an alternative to Systems Engineering. Shah (2011) reports that SSM has significant applications to user involvement in medical device development. Shah (2011) also notes that SSM's basis comes from action research carried out by Checkland in the 1990's (Checkland and Scholes, 1990). Burge (2015) presents an overview of SSM and the notion that SSM is more than just a process but also an approach which offers a set of tools to help users carry out the various steps within the methodology, including the rich picture technique, conceptual model, CATWOE and formal systems model. SSM has already been recognised as having potential within the NHS with some of its initial ideas having already been applied (Checkland, 2000).

Using SSM within the development a conceptual framework for an emergency airway device is imperative due to the multi-dimensional approach required to develop a device of this kind. The simplest products still require deep level thinking, for example when analysing a bougie introducer, product factors such as tip pressure, internal structure (hollow or solid) shape retention, surface finish, product colour, guidance measurement lines, tip design amongst many other factors all influence the user's perception as to whether the device is suitable for their practice. The wide range of elements that can be considered within SSM such as social sciences, psychology, business, human factors, risk analysis, legislation, design, amongst others, can allow a multidimensional approach to be taken whilst considering the ever-changing arena that is medical device development.

3.2.7 Design & Engineering Methodologies

There any many design and engineering models and methodologies presented within literature. Adams (2015) suggests that there are many unique engineering design methodologies, frameworks, and models that have evolved to provide the structural framework for applicable design processes, methods, and techniques. Pugh (1986) provides a perspective suggesting that without a structured approach to design, there is no way that the user-need situation will ever be satisfied. Pugh (1986) stipulates that the discipline of systematic working should also allow for variations, whilst retaining discipline and imparting comprehensiveness. Within the literature review in Chapter 2, many design process and design and engineering methodologies/models have been reviewed, the key methodologies include:

- Pugh's Total Design Activity Model (Pugh, 1991)
- The 'Double Diamond' design process model (Council, 2005a).
- Seven-phase linear chronological structure (Asimov, cited in Adams 2015).
- Cross's Eight stages of the design process (Cross and Roy, 1989).
- French's block diagram of total design (French, 1998).
- Archer's three phases summary model of the design process (Archer, cited in Cross 2008)
- Pahl and Beitz,'s model of the design process (Pahl and Beitz, cited in Cross 2008).

The use of Pugh's Total Design Activity Model (Pugh, 1991) and Cross's Eight stages of the design process (Cross and Roy, 1989) will be fundamental to the designed conceptual framework as discussed in section 3.3. The use of the design activity model ensures that the iterative stages and approaches utilised can be adopted and amalgamated within the developed framework.

3.2.8 Technology Readiness Levels (TRLs)

TRLs are a systematic metric/measurement system which allows the assessment of the maturity of technologies or concepts compared to the maturity between different types of technologies (Mankins, 1995). TRLs have notably been utilised by NASA space technology for many years; Mankins (1995) summarises TRLs into nine different levels, as described below:

- **TRL 1** - Basic principles observed and reported.
- **TRL 2** - Technology concept and/or application formulated.
- **TRL 3** - Analytical and experimental critical function and/or characteristic proof-of concept.
- **TRL 4** - Component and/or breadboard validation in laboratory environment.
- **TRL 5** - Component and/or breadboard validation in relevant environment.
- **TRL 6** - System/subsystem model or prototype demonstration in a relevant environment (ground or space).
- **TRL 7** - System prototype demonstration in a space environment.
- **TRL 8** - Actual system completed and "flight qualified" through test and demonstration (ground or space).
- **TRL 9** - Actual system "flight proven" through successful mission operations.

TRLs have since been adopted by various organisations and government bodies who have adapted the different stages to suit different applications. Mankins (2009) notes that TRLs

have been embraced by the U.S. Congress' General Accountability Office (GAO) and adopted by the U.S. Department of Defence (DOD). Other notable users include the Oil and Gas Industry, European Space Agency, The European Commission, US Department of Energy (DOE) and the Federal Aviation Administration.

The use of TRLs has most recently been suggested for integration into pharmaceutical and medical device development. (Heterogeneous Technology Alliance, 2014, cited in Morales, 2015, p.29). Tierney, Hermina and Walsh, (2013) also presents examples of the use of TRLs within the pharmaceutical technology landscape. It is proposed that TRLs should be integrated into the measurement and assessment of medical technology and device design.

3.3 Conceptual Framework & Theoretical Justification

Throughout sections 3.3 and 3.4 the developed conceptual framework and theoretical justification discussion will be presented. The literature review completed in Chapter 2 presents the argument that medical device development is a bespoke process. Bergsland, Elle and Fosse (2014), Bridgelal Ram, Grocott and Weir (2008), Martin et al., (20012), Money et al., (2011) and Shah (2011), identify various issues that include the lack or over use of user involvement, adoption issues, ethical barriers, manufacturing constraints, design limitations etc., that can affect the product development process. The concept of user involvement and patient and public involvement (PPI) is perceived now to be a necessity in medical device development. An isolated approach during the development of medical device development will ultimately result in failure; integrating user involvement and PPI involvement will inevitably improve the chances of successful device development and adoption. Mockford et al., (2011) reports that the impact of patient and public involvement on UK NHS health care requires significant development; a PPI evidence base is often required in particular when information on guidance for the reporting user activity is required when the impact of this is still not fully understood.

The conceptual framework presented (Figure 3.2) was constructed by combining several theories and ideas identified during the literature search and review. Soft Systems Methodology (SSM), Design and Engineering Methods (D&EM) and Design Processes (DP) have provided the fundamental structure to the conceptual framework.

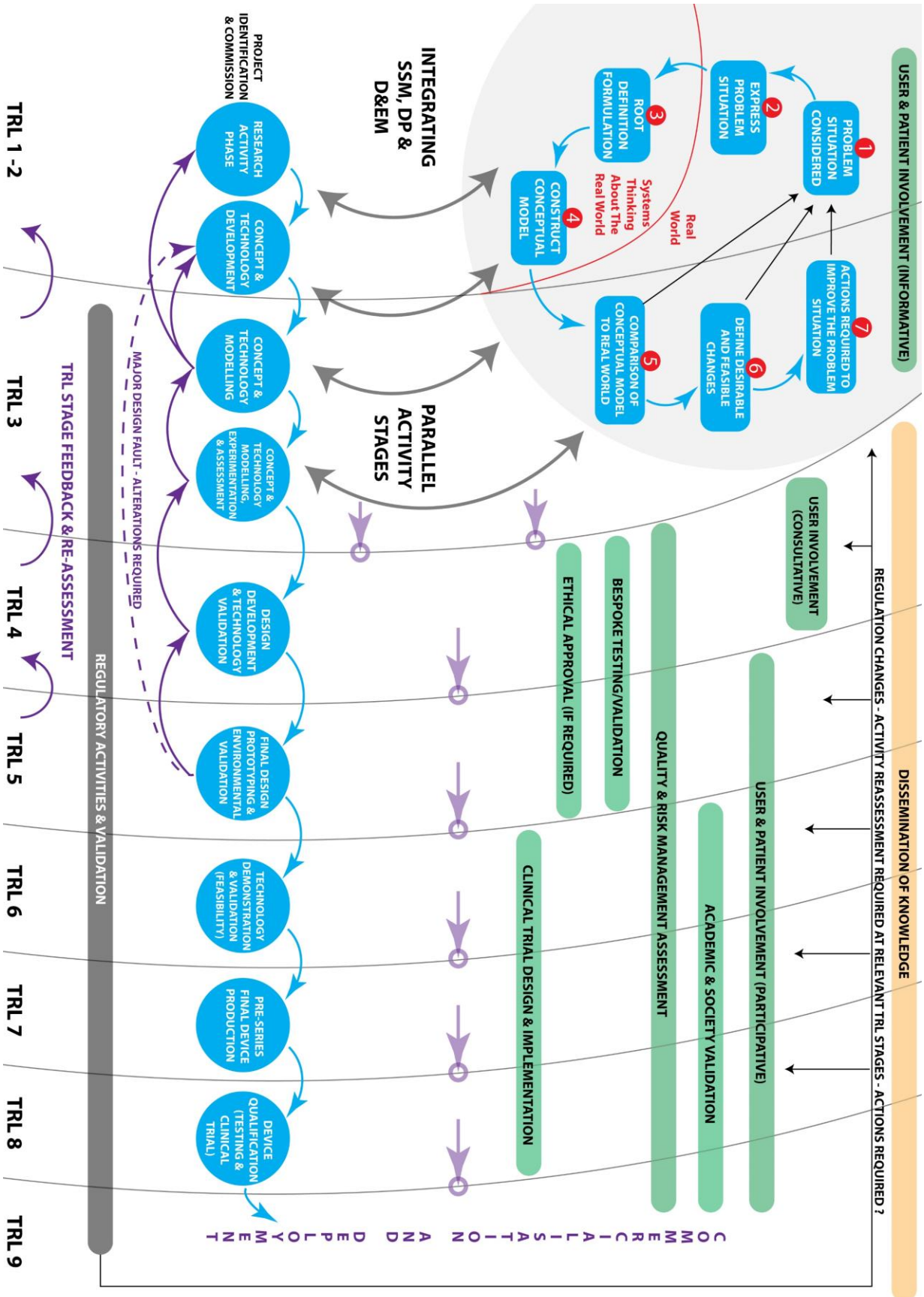


Figure 3.2: Initial Conceptual Framework For Emergency Airway Device Development

The use of Total Design Activities presented by Pugh (1991) is also directly linked to D&EM. In addition, TRL stages have been designed specifically for the development of emergency airway access devices whilst considering authors such as Mankins (1995) and European Commission (2014). TRLs have been used to provide the backbone to the framework. Using TRLs to breakdown tasks into different readiness level categories, ensures that activities and processes can run in parallel throughout. Critical processes and activities relevant to the key methods have been integrated into the framework, such as regulatory activities, user involvement, dissemination, clinical trial activities and academic/society validation.

The literature search presented many arguments for the use of Soft Systems Methodology as a dynamic approach to medical device development. SSM has been presented as an alternative to systems engineering methods used for the development of medical devices and is championed by Shah (2011) in relation to user involvement in medical device development. Shah (2011) utilises SSM as a starting point, and then adds different elements such as ergonomics design methods to each stage to create a conceptual framework.

The soft and free approach of SSM is especially useful within the initial stages of medical device development due to the extensive range of research and development activities that can be undertaken. As the construction of a medical device prototype progresses beyond the testing and validation stages, environment testing, feasibility trial and clinical trial activities require a more structured approach. Checkland (1989) suggests that 'Hard' systems thinking need to start with a carefully-defined objective; this starting point in systems engineering, systems analysis and classical research can create a structured approach.

Checkland (1989) observes that systems engineering methodology is concerned with achieving objectives, whereas SSM is deemed a learning system which is an approach which articulates the process of inquiry leading to action. With the end goal of SSM defining actions to improve the problem situation, integrating a more structured approach beyond this stage is required. The detailed design work, validation, clinical trials, regulatory considerations etc., are a pivotal part of any medical device development framework, however, these elements needs to be controlled by hard system thinking approaches, whereas the initial research and conceptual stages requires a soft system approach to be able to consider the wider context of information. There are many positives and negatives to both hard systems thinking and soft system methods; integrating these together is critical to encompasses the dynamic nature of medical device development.

The developed conceptual framework utilises the freedom of SSM within TRL 1-3 utilising an integrative approach with design engineering methods. Progressing beyond TRL 3, a structured approach consisting of design engineering methods and involvement and validation stages is required to ensure the detailed development of medical devices can result in the desired end outcome of commercialisation and deployment.

3.3.1 Conceptual Framework Breakdown

The conceptual framework (Figure 3.2) has many actions depicted throughout, to ensure the actions and processes depicted within the methodology can be fully understood, a conceptual framework key is presented (Figure 3.3). The symbols presented within the conceptual framework key provide action descriptors which inform the reader of the activities, processes and stages involved.

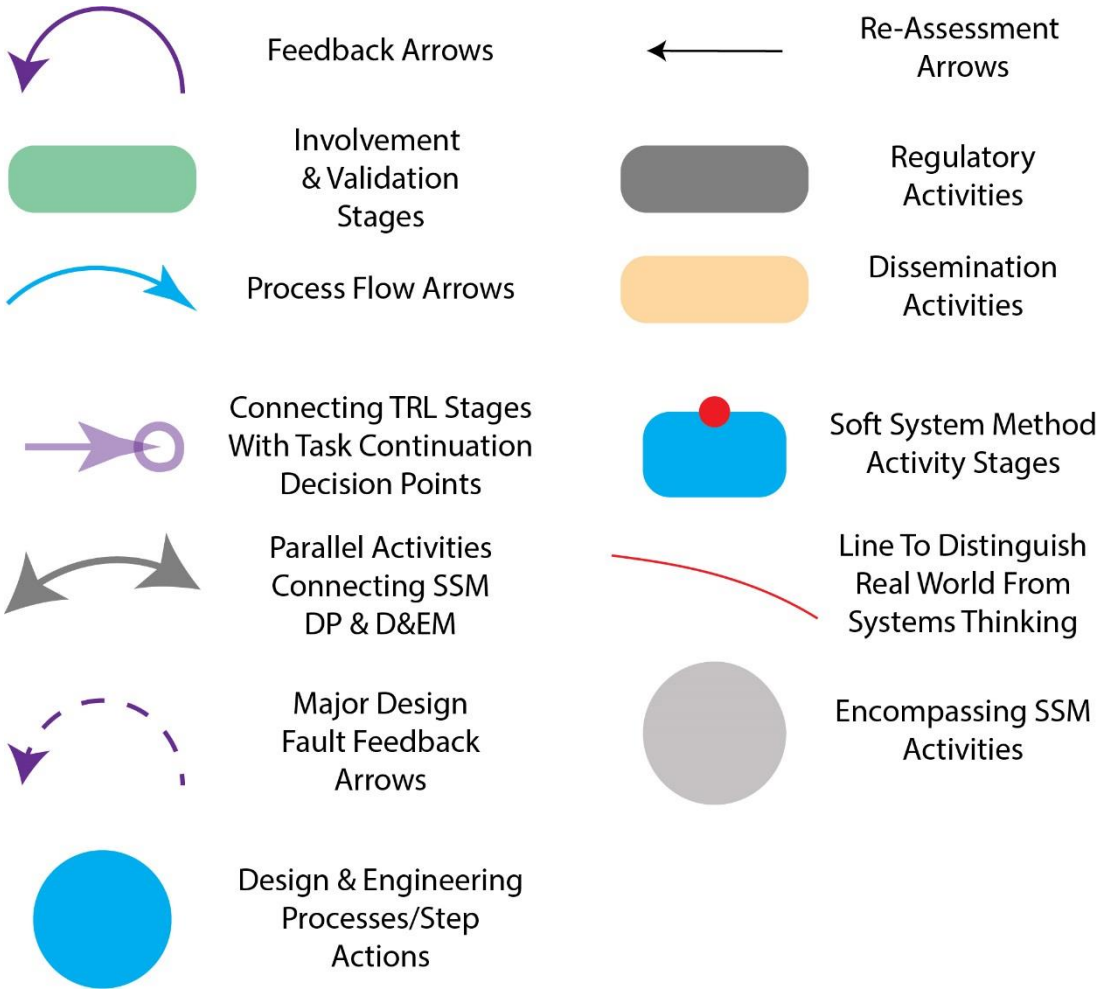


Figure 3.3: Conceptual Framework Key

3.3.2 Technology Readiness Level's (TRL) Definitions

One of the key elements to the developed conceptual framework is the integration of TRLs throughout, with activities appropriately grouped to ensure the successful design development of an emergency airway device. As such, it is important to define the classifications of the TRLs utilised. Various TRL definitions have been considered including those presented by Mankins (1995), Mankins (2009), Heterogeneous Technology Alliance, 2014, cited in Morales (2015) and Tierney, Hermina and Walsh (2013). The European Commission (2014) TRL descriptors relating to research and innovation have also been reviewed. The TRL scale created relating to the development of emergency airway access devices is presented in Table 3.1; the supporting definitions for each TRL level are also defined.

TRL ID	**Definition**
TRL 1	Basic principles and initial concept generation.
TRL 2	Technology formulation and application assessment.
TRL 3	Analytical and experimental assessment to confirm proof of concept.
TRL 4	Design development and validation of technology to be integrated.
TRL 5	Prototype fabrication and validation in relevant environment.
TRL 6	Promote feasibility study/trial: Technology demonstration and device validation.
TRL 7	Pre-series prototype demonstration in operational environment.
TRL 8	Complete system/pre-series device qualification through testing and clinical trial.
TRL 9	Device evidenced and deployed for integration into practice.

Table 3.1: Technology Readiness Levels (TRLs) Definitions

3.4 Conceptual Framework Construction

The construction of the conceptual framework is based upon the combination of many different theories and activities. A detailed description of each of the elements can be found in sections 3.4.1 – 3.4.8; a description and justification of the activities are discussed.

3.4.1 TRL Feedback Steps

Integrating TRL stages into the conceptual framework was completed to provide a progressive backbone structure where tasks and approaches can be grouped and linked together. Developing an emergency airway access device requires the integration of medical

technologies and systems to formulate a final commercial product for deployment. Hicks et al., (2009) provides insight into some of the limitations of utilising TRLs, such as the "blurring" of various characteristics within development phases leading to implementation difficulties. The purpose of utilising TRL stages within this conceptual framework is to ensure that the technology development is accurately measured considering the maturity of the technology being developed but also providing continuation assessment point/milestones to assess whether the technology being developed should continue or be discontinued. Within the TRL stages, the breakdown of methods and activities ensures that Hicks criticisms of TRLs are overcome.

Figure 3.4 presents the structure of TRL stages within the developed conceptual framework. TRL definitions have also been created specifically for the category of emergency airway device development (Table 3.1). The use of TRL stages has also been deemed imperative for this framework; the use of TRLs have been increasingly used by funding bodies to justify technology development and maturity, thus this presents a clear need for integration into this framework.

Figure 3.4: TRL Stage Feedback & Re-Assessment

Within the TRL stages developed, feedback and reassessment loops connecting the early TRL stages have been incorporated. The reassessment and feedback loops provide opportunities to move backwards within the different TRL stages; the ever-changing nature of the medical field sometimes requires backward steps to reassess or redo tasks that will contribute to optimum medical device development and success, for example, regulatory changes may force a manufacturer into completing further documentation or compliance.

The opportunity to move backwards in the TRL stage outline stops at TRL 5. Once prototype fabrication and validation have been achieved, the feedback loops returning to TRL stages 2-5 end, as re-design and technology formulation redesign and reassessment is no longer required, and the sole focus should be placed on progressing towards clinical trial and commercialisation.

3.4.2 Progression Through TRL Stages

Progressing through TRL Stages TRL 3-9 requires assessment as to whether the activities completed justify the technology development level and activity progression. The arrow symbols with circular nodes represent the reassessment points at each of the TRL stages, but also act as a go/no go decision point used to decide whether the project development should continue. This task decision point is imperative for funded medical device development projects; if the delivery of the objectives are not achieved, funding withdrawal is a possibility at this stage or product development termination can occur.

3.4.3 Soft Systems Methodology (SSM)

The developed conceptual framework utilises SSM during TRL 1-3. As discussed earlier within this chapter, the use of SSM within the conceptual framework for the development of an emergency airway device is imperative due to the multi-dimensional approach required to develop a device within this sector.

The use of SSM also provides the opportunity to assess the information presented by multiple stakeholders in relation to medical device development. The seven stage SSM construction (Checkland, 1989), is utilised for the SSM elements within this conceptual framework as it is more appropriate than the four-stage model developed by Checkland and Scholes (1990). Baskerville, Pries-Heje and Venable (2009) believes that the seven-stage model is more accessible to the novice, with more specific activities stipulated in the stages and less generalised iteration; this is a viewpoint the author also shares.

The stakeholders involved in the device development phase will all have different desirable objectives and actions that need to be implemented. Within SSM there are two main modes:

1. Real world.
2. Systems thinking about the real world.

The systems thinking element of SSM uses concepts of hierarchy, communication, control, and emergent properties in an attempt to identify 'relevant systems' that can provide useful insights (Institute for Manufacturing, 2016). SSM is based on seven key stages all of which have been integrated within this section of developed conceptual framework (Figure 3.5).

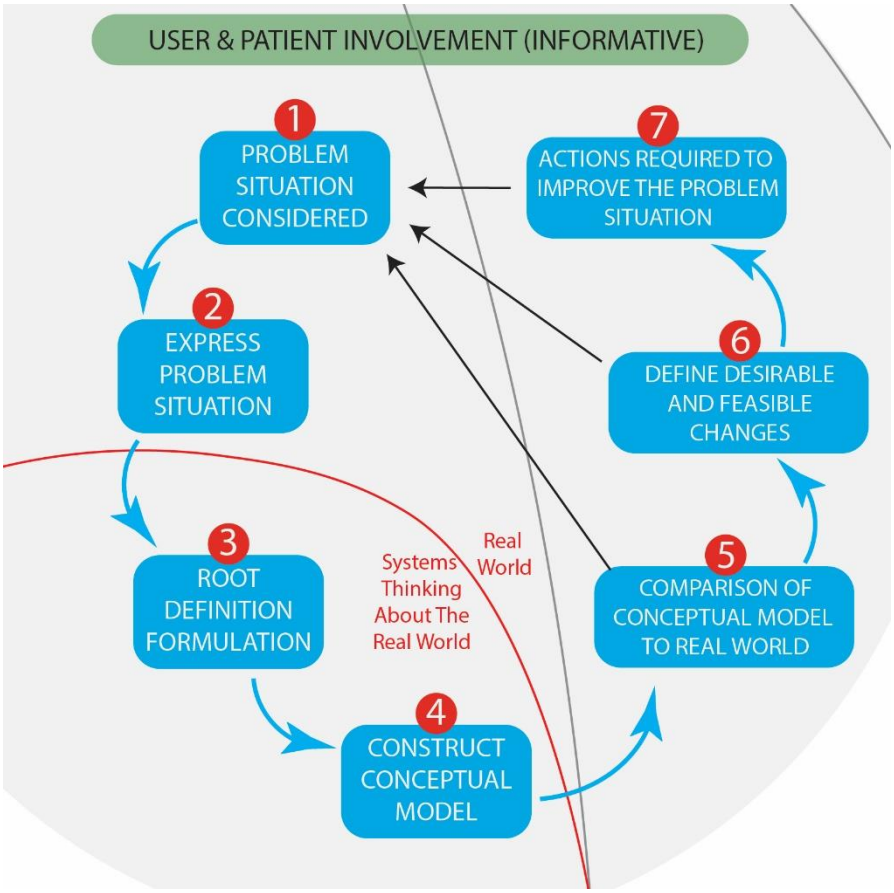


Figure 3.5: Soft Systems Methodology Elements

Shah (2011) who utilises SSM within the context of user involvement for medical device development uses the seven stages as a starting point, and then adds ergonomics design methods to each of the stages, but often additional information and methods are required dependent on the design problem. Shah (2011) also considers other elements that become inbuilt including user centred design methods, psychology methods and design methods. Within the developed conceptual framework user and patient involvement is integrated into TRL 1-3 which covers the entire scope of the SSM stages and the design engineering activities.

The parallel activities and processes considered within these TRLs stages are used as a method of providing a bigger picture that does not end with a prototype system or device being manufactured. SSM can provide attempts to foster learning to gain a level of appreciation for the problem situation between stakeholders rather than set out to solve a pre-defined problem (Institute for Manufacturing, 2016).

From TRL 4-9 the conceptual framework considers activities that can result in device assessment, experimentation, validation, deployment and commercialisation. Involvement and validation processes are then strategically positioned throughout the framework rather than being solely positioned to the tasks relating to SSM.

One of the key elements to the SSM stages is the CATWOE stage. CATWOE is a checklist that can be used to stimulate thinking about problems and solutions (Checkland, 1989). Checkland (1989), Burge (2015), Bergvall-Kåreborn, Mirijamdotter and Basden, (2004) and Gasson (1995) discuss the stages of CATWOE and define these as:

> [C] The Customer: Who would be victims/beneficiaries of the purposeful activity?
>
> [A] The Actors: Who/What individuals will do the activities?
>
> [T] The Transformation: What is the purposeful activity expressed as a transformation of input to output.
>
> [W] Weltanschauung: What are the views of world the make the definitions generated meaningful?
>
> [O] Owner: Who could stop this activity? Who is the wider system decision maker who is concerned with performance?
>
> [E] Environmental Constraints: What key constraints exist outside the system boundary that are significant to the system?

One of key additions to the SSM phase within the developed conceptual framework is the introduction of re-assessment arrows that link back to stage one from stages five, six and seven. Shah (2011) suggests that process iteration should occur between stages five and two, however, upon re-entering the real world at stages five, six and seven it is necessary to identify action problems, if these exist, returning to stage one to examine this problem situation is required.

3.4.4 Design & Engineering Methods

The design and engineering methods within the conceptual framework run in parallel to the soft systems methodology elements which occur in TRL 1-3. The structure of the design and engineering methods can be found in Figure 3.6. These processes have been inspired by the Total Design Activity Model and integrated product design engineering approaches adopted by Pugh (1991), in addition to many of the strategic engineering design approaches presented by Cross and Roy (1989). These two sets of product design and engineering approaches have been reviewed and appropriately combined to create the design and engineering methods suitable for developing an emergency airway accesses device. The core design activities presented within the design engineering methods also directly link to the

TRL stages and definitions presented (Table 3.1). Sections 3.4.4.1 – 3.4.4.9 below will provide further detail with regards to the activities within the TRL stages.

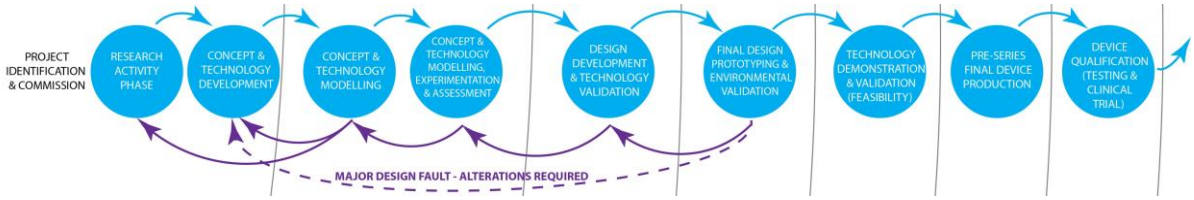


Figure 3.6: Design Engineering Process (TRL Stages 1-9)

3.4.4.1 Research Activity Phase

The research activity phases are the first activities to commences after project identification and commissioning. The phase is used to capture the problem and assess the initial research tasks that need to be undertaken. In the context of the design engineering processes, this is reliant on information acquisition. Sourcing information from both primary and secondary sources is important to capture all the problems identified. Competition analysis, market analysis, user requirements amongst many other factors are all required to identify the sub problems within the research activity stage.

Sub problems can be used to clarify the design objectives for the next elements of the design engineering process. Project dependant tasks can also be incorporated into the research activity phases such as material assessment tasks and function analysis. Using the rich picture concept from the SSM elements (Checkland et al., 1989), themes can be identified for sub task research activities. The research activity phase runs in parallel to the SSM activities and encompasses elements from the real world and elements from the systems thinking that relate to the real world. Further detail on the parallel activity phase is provided in section 3.4.5.

Within the research activity phase, many different research tasks can be completed. These research tasks will provide valuable information to SSM stages 1-7. Depending on the type of device being developed within the category of emergency airways, acquiring the right type of information is important. The key research activities that can be undertaken are split into three main categories, (technology, user and patient); the capturing and use of this information will determine product development.

User: Brainstorming, Workshops, User Environment Analysis, Surveys, Medical Procedure Observation, Clinical Case Study/Literature Review, Customer/Client Review, Expert Groups,

Academic Society Input/Feedback, Service Provider Analysis, Advisory Panels Feedback, PDS/CDS Generation.

Patient: Brainstorming, Workshops, User Profile Analysis, Focus Groups, Interviews, Surveys, PPI Steering Groups, PPI Feedback, Clinical Case Study/Literature Review, PDS/CDS Generation.

Technology: Technology Reviews, Surveys, Equipment Assessment, Usability Analysis, Regulation Review, Concept Modelling, Formulation Of Detail Design Activities For Validation, PDS/CDS Generation, Competitor Analysis.

3.4.4.2 Concept & Technology Development

The first element of concept and technology development is to combine the research requirements into a product design specification (PDS). A PDS is document that is created during and in conclusion of the research activity phase to detail the requirements that must be met for the successful creation of a product or process. It is necessary to formulate a PDS to identify the design and manufacture needs of a product. Pugh (1991) emphasises that a PDS is a dynamic document that requires updating as more information is presented within a project. This is encapsulated by Pugh (1991) as the establishment and evolution of the product design specification (PDS), due to it acting as a mantle enveloping the entire core activity. Predefining a methodology/framework mapped to the specification promotes an optimum total design activity, ensuring successful design and manufacture activities.

Pugh (1991) suggests that design cores with additional inputs from technology disciplines and sources can be integrated within the design process too. A variety of other design activities from the disciplines such as ergonomics can be integrated as described in the literature review. Critically it is important to reflect on the user requirements and understand the how the application of the technology and design could be integrated to develop the desired product. Integrating the SSM constructed root definitions and conceptual models into the design process ensures that the design problem and situation can be considered in detail; further detail on this parallel activity is discussed in Section 3.4.5.

Using these key design principles and following an iterative design approach which allow various sources of information to applied during the design process, technologies and products can be developed with the outcome being a tangible product that can be realistically developed into a commercial product.

Kim and Tadokoro (2007) suggests technological advancements in conventional materials and new material technologies enable designers to produce bespoke small sized, cost effective solutions. This relates to the experimental research design process/approach which is desired; Kumar (2014) highlights that the nature of experimental and non-experimental research needs controlling to ensure meaningful data analysis. The use of experimental research design approaches is critical due to the several unknown factors within any project.

3.4.4.3 Concept & Technology Modelling

The concept and technology modelling stage is based upon the initial concept and technology development activities and the methods in which this can be translated into a real world initial model(s). These model(s) can be analysed and experimented with for proof of concept. This integrates with the SSM activity phase of comparing the conceptual model to the real world. Typically, the SSM elements would be solely a theoretical comparison to identify tasks or approaches to move forward; however, within the developed conceptual framework, using theoretical elements to compare and analyse the real-world elements (i.e. the developed models) provides a good method for product analysis.

Comparison to the PDS to identify the criteria achieved and the elements that still require further work is necessary. A PDS matrix or a form of design weighted matrix (i.e. Combinex® Value Analysis (Fallon, 2005) can be utilised for concept or technology evaluation. Considering the TRL stages and feedback loops that have been integrated into the model (Figure 3.7), if significant issues are identified that require redesign, it is necessary at this point to move backwards within the design engineering process. The feedback loop provides the opportunity to instigate re-designs or investigate new technology development options due to initial failure. By moving backwards to conduct a process again, additional information can be utilised to allow a valid solution to be created and progress beyond the concept and technology modelling experimentation and assessment phase.

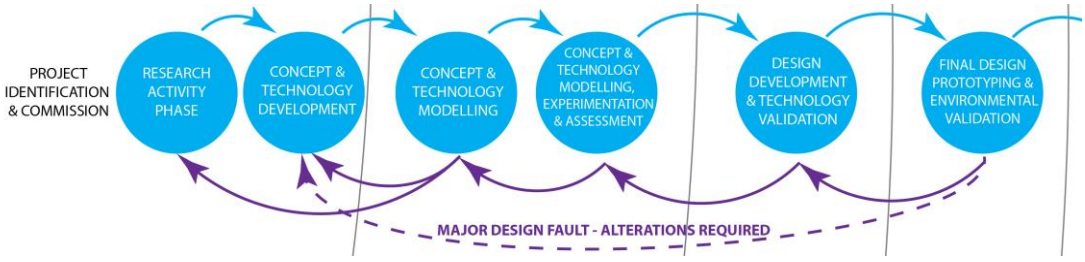


Figure 3.7: Design Engineering Process (TRL Stages 1-5)

3.4.4.4 Concept & Technology Modelling Experimentation & Assessment

Once concept and technology modelling has been completed, experimentation and assessment is required to ascertain whether this is fit for purpose or whether further development is required. The feedback loops linking the activities in TRL 3 provide the opportunity to move backwards within the framework to correct any problems encountered. It is important to setup and follow a specific experimentation plan and refer to the PDS formulated earlier within the design engineering process. Feedback from the user and patient involvement activity that takes place within TRL 3 should also be considered and ideally linked to the actions derived from the SMM activities.

Technology modelling, experimentation and assessment may also require the analysis of materials for device integration. In the context of the development of the steerable bougie, this is required, especially for the assessment of smart materials and systems to be integrated into the device and the testing systems. If the concept and technology developed is approved at this stage, progression to TRL 4 is required. As progression to TRL 4 occurs, the actions derived from the SSM activities must be adopted to direct design and technology development to achieve validation. Alongside product design specifications, component design specification (CDS) may need generating, especially if multiple technologies are to be integrated into a device that are reliant upon each other.

Pugh (1991) denotes that CDS's may cover a wide variety of components in general terms with varying performance characteristics. Actions defined by the SSM activities will likely provide context and detail to the specific requirements to be stipulated in the CDS's. Crnkovic et al., (2006) also utilises a component-based approach during development processes to build systems from pre-existing components.

To put this in to context, using an example from the research conducted thus far, accurate assessment of devices and technologies to justify clinical use of the bougies has been conducted by Annamaneni et al., (2003), Hodzovic et al., (2004), Hodzovic, Wilkes and Latto (2004), Jackson, Bartlett and Yentis (2009), Janakiraman et al., (2009) and Marson et al., (2014). Although a number of these authors have attempted to look at the comparative performance of bougies they often failed to assess relevant absolute performance due to inaccuracy in equipment use or the adoption of testing techniques that lacked reproducibility and objectivity. This would result in an action requirement being created for technology validation and as such would require the development of accurate testing equipment and

testing methods to justify device development. The development of appropriate testing protocols and testing techniques will be discussed at a later stage in this thesis.

3.4.4.5 Design Development & Technology Validation

Once the concept and technology modelling experimentation and assessment has been completed the conceptual framework progresses to the tasks within TRL 4. User involvement at its consultative level, quality risk management, planning of bespoke testing and ethical approval are all required at this stage to ensure that design development and technology validation tasks can be completed. The detail design processes discussed by Pugh (1991) can now commence and can be integrated at this stage. At this stage of the design process, Cross (2008) suggests that weighted objectives and value engineering methods should be utilised to improve detail.

Technology validation should be achieved by providing measurable data that validates the research questions and capturing desirable measurables that be analysed. Often at this stage industrial testing equipment is utilised to confirm product or technology validity; it is not uncommon in the medical device field that bespoke testing systems are to be designed, manufactured and calibrated to capture clinically relevant data to assess technology validation. An example of this will be presented later in Chapter 7 in relation to the design, manufacture, calibration and testing of the Shape Retention Testing System which is used to asses bougie shape retention.

3.4.4.6 Final Design Prototyping & Environment Validation

The final design prototyping stage is utilised to finalise all the detail design work required for the developed technology and medical product. At this stage user and patient involvement in the form of participative activities are integral. Ergonomic and anthropometric considerations are also imperative to ensure the technologies and devices are not only safe for use but also comfortable to operate.

The use of industry standard manufacturing techniques is fundamental to successful device manufacture. Pugh (1991) suggests that the use of the PDS and CDS documentation is regularly referred to during the detail design stage. The use of the PDS and CDS documentation is often utilised in combination with various other methods to assist the design core activities. Customer requirement and product characteristic matrixes, quality control plans, failure mode and effect analysis (FMEA), process planning, and a wide range

of functional cost analysis tools should be utilised. Once the final design prototype has been manufactured the appropriate validation in a relevant environment should be completed.

Considering emergency airway devices, validation in manikins with simulated difficult airways would pose as suitable environment for validation to be confirmed. If successful repeated intubation can be achieved, TRL 5 can be verified. At this point the product design development phases of the framework now switch focus to technology validation within the clinical context of feasibility and clinical trials.

3.4.4.7 Technology Demonstration & Validation (Feasibility)

Upon completion of the final design prototyping which considers the detailed design processes presented by Pugh (1991), the technology and developed device must now be demonstrated and validated within the feasibility environment; most likely this will be in a feasibility study or pilot study. Pilot studies are preliminary studies that inform a main study and are run to test whether the components of a main study can function (National Institute For Health Research, 2017). Feasibility studies are an assessment of the practicality of a proposed plan or method. The National Institute For Health Research (2017) defines a feasibility study as a piece of research completed prior to a main study to answer the question “Can this study be done?”. They are used to estimate important parameters that are needed to design the main study. The development of the technology developed, and its construction will also dictate whether the device to be tested will be suitable for pilot or feasibility testing. Bowen et al., (2009) proposes that there are eight general areas of focus addressed by feasibility studies, a summative explanation of these eight areas is presented below:

1. Acceptability: Participant reaction to interventions.
2. Demand: Estimated use of interventions/data collection.
3. Implementation: Likelihood of intervention implementation.
4. Practicality: Practical assessment of intervention implementation.
5. Adaption: Assessment of system change for changes to procedures.
6. Integration: Assessment of system change for new programs.
7. Expansion: potential success of existing intervention in various locations and populations.
8. Limited Efficacy Testing: Feasibility study using convenience samples.

Any feasibility study completed is in preparation for full-scale research and clinical trial and therefore careful assessment of the information to be collected is critical. Upon completion of a feasibility or pilot study which has positive outcomes, progression to the next TRL stage is desirable. The next stage relates the preparation and manufacture of the pre-series final device which would be used in clinical trial.

3.4.4.8 Pre-Series Final Device Production

The production of the pre-series final device is in effect the production of a commercial standard product with the necessary regulatory validation completed. All the quality risk management documentation should be complete for the device. At this stage of the design and engineering process, final decisions are made in relation to the mass manufacture, material construction, technology construction and packaging of the device. It is possible that minor changes to the pre-series device will be made after TRL 8 in preparation for commercialisation and adoption. These changes usually relate to minor alterations required because of clinical trial outcomes or the addition of the symbols and/or labelling of the product packaging after achieving the desired standards.

3.4.4.9 Device Qualification (Testing & Clinical Trial)

The device qualification step located within the final TRL stage (Figure 3.8) is an essential stage of medical device development. Integrating this in the design and engineering methods is an essential process to ensure device verification is achieved before commercialisation and deployment. Device qualification is necessary to ensure that the created product or service can be provided accurately within the clinical setting. The World Health Organization (2018), defines a clinical trial as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials can involve a wide range of interventions, including the assessment of biological products, cells, drugs, surgical procedures, radiological procedures, equipment, preventive care, etc; thus complying to ADEPT evidence levels 1a and 1b.

In the context of emergency airway access devices, clinical trials would be utilised for device qualification and validation. Assessment routes must be considered based on the classification of the device. Carrying out clinical trials also provides the opportunity to present a clinical investigation case that demonstrates device conformity with the Medical Device Directive and other associated regulations. Carrying out a conformity assessment will ensure that the necessary markings can be applied to the device, i.e. CE Marking. CE marking shows that the device is fit for its intended purpose and meets legislation relating to safety.

The CE marking also show the product can be freely marketed anywhere in the European Union. (GOV.UK, 2018)

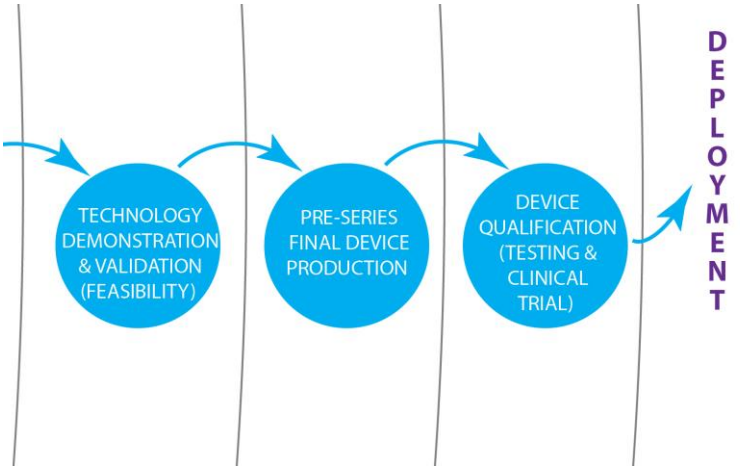


Figure 3.8: Design Engineering Process (TRL Stages 6-9)

3.4.5 Integrating SSM, DP & D&EM Parallel Activities

Figure 3.9 presents one of the key components to this conceptual framework in the form of integrating both approaches during TRL 1-3. There are many activities within the Soft Systems Methodological approach that can be interlinked with the design and engineering methods and design process. The SSM rich picture and human activity systems provide freedom for conceptual thinking during the initial stages of the research and development phases. Once the opportunity to consider SSM, DP & D&EM as parallel activities finish, a hard system thinking approach is required to ensure development, validation testing, commercialisation and adoption can be achieved.

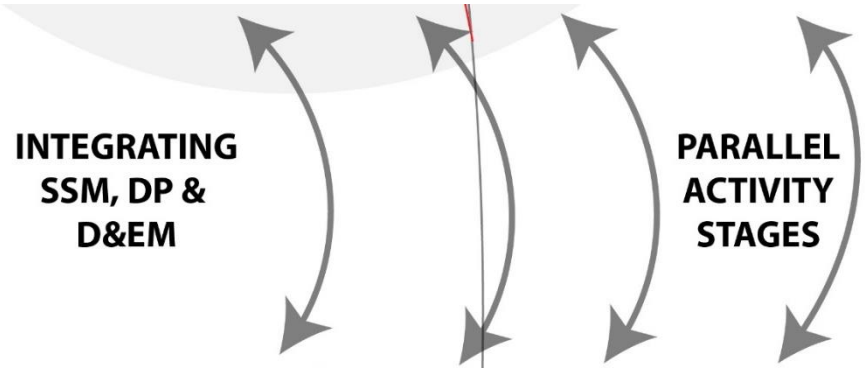


Figure 3.9: Linking SSM To DP & D&EM

Within TRL 1-2 is the research activity phase (discussed in section 3.4.4.1); this activity phase is perfectly positioned to be integrated alongside the SSM stages which exist both within the

real world and systems thinking about the real-world. The initial research activities that are placed within the D&EM elements co-align with stage 1 - 3 of SSM which relates to the problem situation and definition formulation.

Burge (2015) states that the first element of SSM concerns the real world and gathers information and views about situations that are considered problematic to establish the scope for improvement. The research activity phase uses the captured problem and assesses this against the initial research tasks undertaken within the context of design engineering processes. Checkland (1989) also discusses how it will not be possible for any would-be problem solver, whether this be an outsider or part of the problem situation, to simply 'find out' about the situation in a neutral manner. Integrating the design engineering research activities, alongside the SSM activities will ensure that a balanced integrated approach can be taken.

The concept and technology development phase of the design engineering elements (TRL 1-2) can be aligned with the SSM stage 3-4 activities. It is important at this stage to ensure the CATWOE checklist is completed and is used as an analysis tool for visualisation and verification of the root definitions as previously discussed in section 3.4.3.

The formulation of root definitions of relevant systems of the purposeful behaviour and construction of a conceptual model of human activity systems links to the conceptual nature of the design tasks. Using an example presented by Burge (2015) within SSM stage 4 relating to a BHM Marketing System, tasks such as identifying potential and current customers, reviewing product/service portfolios and developing new products and services are all tasks which relate to the research design and development aspects of design engineering thinking.

As the transition from TRL 1-2 shifts to TRL 3, the parallel activity stages link in relation to the real-world activities. Within SSM this is where there is a return to the real world and comparison is made to the experiences captured in the model(s) created in SSM phase 4 and 5. The transition between the real world and systems thinking about the real world is one of the key advantages to SSM. This transition enables us to consider the activities that need to be completed, whilst also considering how this can be completed as part of the problem, whereas with a design and engineering hard system approach focus on finding the systematic way of achieving the needs and objectives.

At SSM stage 6, definitions are created relating to changes that are both desirable and feasible. This provides an opportunity to compare the concept and technology modelling

against the desirable and feasible changes required. If these do no coalesce, the feedback loops can be used to move backwards within the framework to make the required changes. At this point, some of the required hard system thinking approaches must be integrated, i.e. regulatory consideration. It is not until the end of the SMM stages that multiple hard thinking elements and design engineering methods must work in unison.

At SSM phase 7, based on the definitions created for changes that are both desirable and feasible, it is at this point the actions to improve the problem situation can be taken. These actions are demonstrated in the design engineering process as the concept and technology modelling experimentation and assessment activities. As clear actions have been defined and are now being addressed by the design engineering processes, the SSM processes and parallel activity stages now conclude and allow a hard system and structured approach to be taken as progression into TRL 4 occurs.

3.4.6 Involvement & Validation Processes

The involvement and validation processes that exist within this conceptual framework consider various elements (Figure 3.10). The integration of involvement and validation processes throughout TRL 1-9 is designed to ensure that all of the stakeholders that are required to provide input or feedback have the capacity to do so. User involvement is split into three elements, informative (TRL 1-3) consultative (TRL 4) and participative (TRL 5-9). The informative elements ensure that the user can provide clinical context and feedback throughout the initial stages of the product development. The use of SSM ensures that the user can provide the context of the problem, the real-world considerations and the human systems and factors feedback.

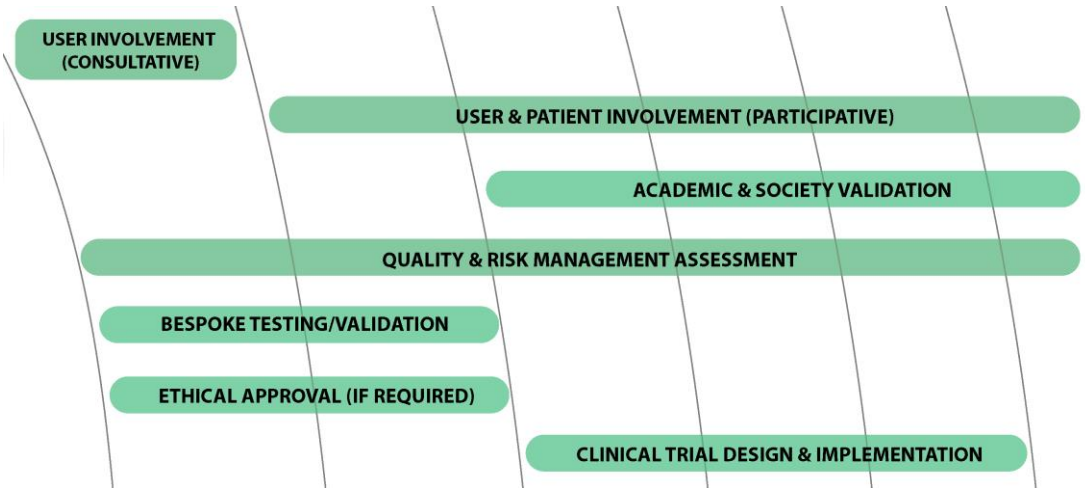


Figure 3.10: Involvement & Validation Processes

Within the engineering design processes, clinical context and assessment of key design considerations are imperative to the feedback integration elements. The consultative element of the user involvement tasks are typically formed in activities such as PPI/PCPI where steering groups provide feedback through various sources both as individuals and as a group. The participative stage again would usually involve a PPI/PCPI group but would also include trial participants for feasibility and clinical trials.

Ethical approval processes are often one of the most time-consuming tasks and involve many different stakeholders with varying skillsets to provide the necessary information for approval. This is an essential validation process for any medical device and as such requires the involvement of both stakeholders directly and indirectly involved in this process. It is often that the bespoke testing/validation processes and the clinical trial design and implementation processes must be planned in advance to ensure that the necessary ethical approval is sought.

Quality and risk management processes are imperative for medical devices; many organisations including the European Medicines Agency, European Commission, MHRA etc., require detailed technical file documentation and risk management information which should include the following information:

- Medicine or medical device safety profile.
- Information on how the risks will be prevented or minimised in patients.
- Details on the plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine.
- Information on the approaches to be taken for measuring the effectiveness of risk-minimisation measures.

Academic and professional society validation that is linked to the dissemination activities which are discussed in section 3.4.8 is another significant barrier that needs to be overcome for any medical device. Scrutinisation is inevitable with any medical device; there are many competitive devices and medical device manufacturers who all want a proportion of the market and as such comparative studies and clinical trials to assess the comparative effectiveness is often disseminated in academic literature in an attempt to prove the device in question is the gold standard device for use.

Societies often provide guidelines or recommendations for gold standard devices, techniques etc. This information is then often utilised by hospitals and trusts for

procurement justification. Using difficult airway equipment as an example, specifically bougie introducers, the Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults (Frerk et al., 2015) acknowledges that Gum Elastic Bougie's physical properties and performance are better than the single use bougies. This recommendation is based on clinical effectiveness information and is referenced in many scholastic articles which provide comparative results relating to tip pressures, shape retention, hold up forces (Annamaneni et al., 2003, Marfin et al., 2003, Marson et al., 2014).

All the above-mentioned activities link within the TRL stages throughout the conceptual framework; often these activities overlap and as such this suggests that information collected within these activities are required to be shared to ensure progression to the ultimate target of commercialisation and deployment. There are many other activities that loosely connect to the involvement and validation activities, such as education activities and marketing activities, however, these are only small elements of the bigger picture within medical device development and as such, these are often considered within TRL 8-9 in preparation and anticipation of deployment.

3.4.7 Regulatory Activities & Re-Assessment Phase

To achieve device adoption and market penetration any medical device must conform to the vast and strict medical device regulations and documentation requirements. All medical devices must conform to the Medical Device Regulation (EU) 2017/745. It is also imperative to have the relevant technical file documentation in place, this includes following strict document and certification procedures put in place by MHRA and NICE. It is therefore important to embed this process throughout TRL 3-9 to ensure the necessary information is logged and submitted for approval.

Once the developed medical device has entered the market, medical regulations are notorious for regular updates and as such, any developed medical device may require recertification or reassessment to ensure that it conforms to any updated standard. This reassessment and revalidation process has been integrated into the conceptual framework. The feedback and reassessment loops ensure that the product can be reassessed at any stage of the TRL process and is followed through to product deployment and commercialisation again.

3.4.8 Embedding Dissemination Activities

Embedding dissemination activities throughout the conceptual framework is an essential element of validation and verification within the medical product design field. Dissemination runs throughout TRL 4-9 due to the various activities that are undertaken, some of which are described briefly below:

1. **Dissemination to Patients & Users:** It is important to disseminate both the research and information collated throughout the research and design process to the patient and user to ascertain feedback, this will help improve the case of need for the device when it enters the market.
2. **Feasibility and Clinical Trial:** Publication and assessment of feasibility, pilot and clinical trial data to help inform the academic and medical profession community on adjustments to practice.
3. **Professional Society Validation:** In the emergency airway field, validation and feedback from the Difficult Airways Society is vital for device adoption. To become a gold standard device, DAS must approve of the device and this must be used by the wider anaesthetic community.
4. **Dissemination to Regulators:** It is important to disseminate trial data and performance data of the developed medical device to regulators. Providing information of efficacy, evidence of improvements within safety, amongst other factors, will ensure the required certification can be achieved.

3.4.9 TRL Definition Justification

The use of TRLs throughout this framework is viewed as a measurement system that supports the maturity assessment of the medical technology or device being developed. It is important to provide a descriptive discussion of each technology readiness level describing how this has been generated. Table 3.2 and 3.3 provides a comparison of three different Technology Readiness Level definitions; these are compared to the author generated TRL stages and definitions for emergency airway device development.

TRL ID	Author	Definition
TRL 1	Mankins (1995)	Basic principles observed and reported.
	European Commission (2014)	Basic principles observed.
	HTA (2014) /Morales (2015)	Early concept stage.
	Proposed Description	**Basic principles and initial concept generation.**
TRL 2	Mankins (1995)	Technology concept and/or application formulated.
	European Commission (2014)	Technology concept formulated.
	HTA (2014) /Morales (2015)	Early concept stage.
	Proposed Description	**Technology formulation and application assessment.**
TRL 3	Mankins (1995)	Analytical and experimental critical function and/or characteristic proof-of concept.
	European Commission (2014)	Experimental proof of concept.
	HTA (2014) /Morales (2015)	Early concept stage.
	Proposed Description	**Analytical and experimental assessment to confirm proof of concept.**
TRL 4	Mankins (1995)	Component and/or breadboard validation in laboratory environment.
	European Commission (2014)	Technology validated in lab.
	HTA (2014) /Morales (2015)	Design development.
	Proposed Description	**Design development and validation of technology to be integrated.**
TRL 5	Mankins (1995)	Component and/or breadboard validation in relevant environment.
	European Commission (2014)	Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)
	HTA (2014) /Morales (2015)	Prototype fabrication.
	Proposed Description	**Prototype fabrication and validation in relevant environment.**

Table 3.2: Comparison Of Technology Readiness Levels (TRLs) Definitions (Stages 1-5)

At TRL 1, the basic principles are observed for the initial concept generation tasks that are fundamental at this stage. Considering the SSM elements, the problem situation must be considered at this stage and adequately expressed. By formulating root definitions for the tasks to be completed by the proposed emergency airway device, purposeful behaviour/activities can be assessed and considered. Considering the conceptual model and associated human activities, the root definitions can be implemented into the design process, initial research activities and technology maturation assessment.

For TRL 2, technology formulation/application assessment is conducted. At this stage, it is important to develop upon the basic principles and problems identified through design and technology formulation processes. It is important to remain focused on the practical applications of the proposed emergency airway device to be 'invented' or identified. At this stage, the SSM elements integrated includes comparing existing models with real-world actions and in doing so definitions of possible changes that are both desirable and feasible can be created for action points. These action points influence technology formulation and the design of the proposed emergency airway device, with key considerations such as performance, safety and proof of concept critical for the successful generation of technology and design concepts ready for TRL stage 3.

Once the initial concepts have been assessed, the activity progresses to TRL stage 3 which is based on the analytical and experimental assessment of the technology to confirm proof of concept. At TRL 3 the framework focuses on the active research and development (R&D) elements, however, feedback loops still provide opportunities to return to TRL 1 and 2 if required. Technology assessment at this stage will ensure the correct design development direction is taken.

Utilising analytical studies at this stage to set the technology into an appropriate context is important. Typically, laboratory-based studies are used to physically validate the technology and design of an initial emergency airway device would help ensure analytical predictions can be confirmed or denied. Medical device regulations should now be considered at this stage; technology confirmation and validation may also be driven by key regulations such as the Medical Device Directive.

Once proof of concept has been achieved, the work progresses into TRL 4, which is based on design development and validation of technology to be integrated. During this stage the emergency airway device being developed in individual components thus far will now be

assembled together with the basic technological elements to establish whether all the components can function together to achieve the desired outputs stated during the SSM root definition and identification of desirable and feasible changes. The technology and designs produced must demonstrate trustworthiness to confirm product validation.

TRL ID	**Author**	Definition
TRL 6	Mankins (1995)	System/subsystem model or prototype demonstration in a relevant environment (ground or space).
	European Commission (2014)	Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies).
	HTA (2014) /Morales (2015)	Promote clinical trials.
	Proposed Description	**Promote feasibility study/trial: Technology demonstration and device validation.**
TRL 7	Mankins (1995)	System prototype demonstration in a space environment.
	European Commission (2014)	System prototype demonstration in operational environment.
	HTA (2014) /Morales (2015)	Device pre-series.
	Proposed Description	**Pre-series prototype demonstration in operational environment.**
TRL 8	Mankins (1995)	Actual system completed and "flight qualified" through test and demonstration (ground or space).
	European Commission (2014)	System complete and qualified.
	HTA (2014) /Morales (2015)	Device pre-series.
	Proposed Description	**Complete system/pre-series device qualification through testing and clinical trial.**
TRL 9	Mankins (1995)	Actual system "flight proven" through successful mission operations.
	European Commission (2014)	Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space).
	HTA (2014) /Morales (2015)	Multicentric clinical trials.
	Proposed Description	**Device evidenced and deployed for integration into practice.**

Table 3.3: Comparison Of Technology Readiness Levels (TRLs) Definitions (Stages 6-9)

At TRL 5 prototype fabrication is completed and validation is now required for the manufactured device in the relevant clinical environment. Fidelity and reliability must increase significantly compared to the earlier assessments. Technological elements are expected to achieve a standardised repeatability and reliability standard. Testing validation

at this stage may still be required, this will be achieved utilising bespoke testing systems and protocols. Validation of device performance must be achieved in a suitably assessed realistic environments with component-level, sub-system level, or system-level tests completed and/or simulated. Reassessment and feedback may still be required at this level and backtracking to TRL 4 still possible; this is the last opportunity to loop back. Once device performance is achieved and the design and manufacturing activity progresses beyond TRL 5, future TRL stages focus on device validation and preparation for market penetration.

Progression to TRL 6 ensures that feasibility trials can now be undertaken to validate the technology/device. At TRL 6, management confidence in the developed emergency airway device must be achieved. Demonstrations conducted must represent an actual system application. Academic validation and professional society feedback should be sought at this point also. The Difficult Airways Society has strict intubation guidelines and for any new device to be recommended for use, society and academic backing is required. Parallel to this, initial device documentation should be generated and submitted to the relevant government bodies for review, i.e. NICE, MHRA.

TRL 7 is one of the most significant steps taken within the framework; at this stage the developed emergency airway device must be at the pre-series prototype stage and be demonstrated in its operational environment. Academic validation and society feedback at this stage is imperative; should this not be achieved device uptake could be significantly affected. The patient and user involvement at its participative stage achieved at TRL 5 is now imperative for demonstration purposes in the operational environment; this may also be connected to clinical trial activities.

At TRL 8, a complete system or final device must be achieved. Validating the complete system through clinical trials is imperative. Comparisons must be drawn against the pre-series device and device improvement or procedural success must be qualified through testing and clinical trial. Successful clinical trials and testing will confirm true system achievement for the technology elements. Academic and society validation/recommendations are critical in preparation for device commercialisation and market penetration. Successful clinical trials should aspire to capture the required evidence to achieve relevant regulatory approval, i.e. CE Marking, FDA approval etc. At TRL 9 the developed emergency airway device has been fully evidenced and final regulatory approval has been achieved. Ideally academic and society approval has also been achieved; this does not necessarily stop commercialisation. Without society validation, adoption could be significantly affected resulting in limited device sales.

Deployment and commercialisation is now achieved and the device ready for integration into practice. It is not uncommon that small fixes and amendments are made to the commercialised product at this stage as manufacturing parameters can change. Regular reassessment and device evidence is still required after achieving commercialisation. Academic scrutiny and competitor analysis is expected. Regulatory changes are also expected; accurate records of sales must be kept. Future regulatory feedback and reassessment loops have been integrated at the activity level of the TRL stages to ensure regulatory validation and confirmation.

3.5 Conceptual Framework Adjustments & Theoretical Justification

Upon review, the ergonomic activities described within the theoretical justification and analysis of the framework were not accurately portrayed. Adjustments are to be made to ensure that the ergonomic activities considered during the SSM and D&EM processes are integrated and adequately represented during TRL stages 1-3.

Minor adjustments were also made to the wordings of the design engineering actives within TRL 3. Modelling and assessment of concepts and technologies are critical before experimentation can occur; in the initial framework presented (Figure 3.2), assessment and experimentation were linked together into one task. Both experimentation and assessment should still take place in TRL 3 as described within the developed TRL descriptors; they should be undertaken as separate tasks. To provide an example, technology assessment of technical specifications of both hardware and software should be considered before the purchase and experimentation of the technology explored; thus, providing a cost-effective approach. The organisational ergonomics considerations that relate to the regulatory activities were not clearly defined and as such the links between the ergonomics, regulatory considerations and involvement/validation processes are not clearly aligned. Considering these two issues, minor modifications to the conceptual framework are required.

The two ergonomic elements that have been added to the framework firstly relate to the parallel ergonomic processes and the second relates to organisational ergonomic considerations. The parallel ergonomic processes (Figure 3.11) are integrated into the parallel activity stages that link the SSM, DP and D&EM processes. Ergonomic considerations are exceptionally important during the design development process whether this be technology application or physical modelling.

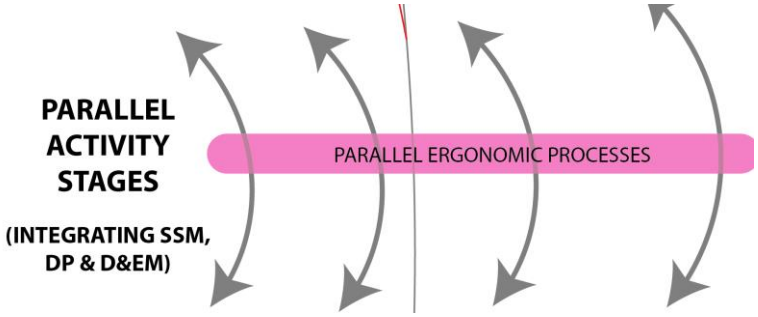


Figure 3.11: Linking Ergonomic Processes Throughout SSM To DP & DEM

The addition of organisational ergonomics (Figure 3.12) within the framework is heavily linked to the regulatory considerations that are pivotal to medical device development. Within organisational ergonomics, tasks relating to system ergonomics, participatory ergonomics, policies and task allocation can be considered. Policy adoption is a crucial element within emergency airways, whether this be from societies or hospital trusts.

To achieve optimum device uptake, validation must be achieved with increased benefits demonstrated to both the patient and clinical outcomes. Implementing organisational ergonomics alongside the validation and prototyping stages of the TRLs in addition to the regulatory considerations provides the opportunity to re-evaluate the necessary issues to ensure optimum device design and increased likelihood of device adoption. Organisational ergonomic considerations relating to team dynamics and optimum device operation processes would also need to be considered during technology validation.

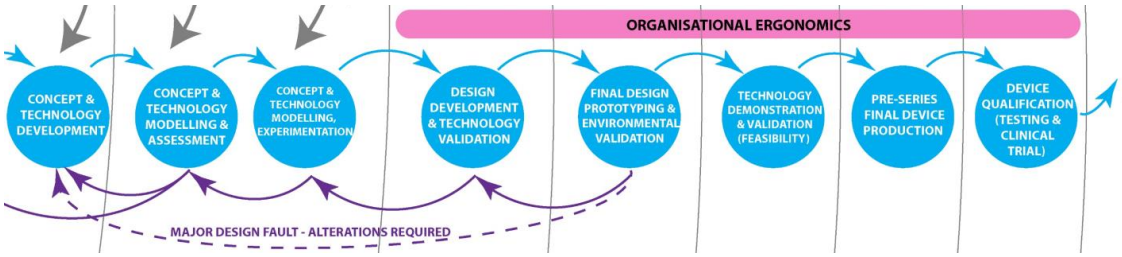


Figure 3.12: Linking Organisational Ergonomics To Regulatory Activities

The integration of organisational ergonomics during TRL stages 4-9 is critical to activities such as organisational processes, resource management, policies and functions such as communication in the workplace. Integrating these factors at the earliest possible stage will help improve the likelihood of device adoption. Consider TRL 8 (Complete system/pre-series device qualification through testing and clinical trial) as an example; the communication and organisational resource management required for the clinical trial of an emergency airway access device would be heavily reliant on ensuring the correct policies are in place thus ensuring validation can be achieved. Minor alterations have been made to the involvement

activities (Figure 3.13). Although quality and risk management activities were described previously within the framework, it was deemed necessary to split this up into two stages. The introduction of a systematic assessment phase for quality and risk management earlier in the framework ensures that there is clear distinction between initial assessments and a full risk management activity.

The addition of the MHRA technical file application activity (Figure 3.13) was also imperative. The generation of this technical file is a requirement of the device manufacturer and requires approval before any clinical trials can be completed. The creation of the technical file documentation is a lengthy process and often requires information generated during the research, design, validation and initial testing activities. The introduction of the technical file activity has therefore been introduced during TRL stages 5-6.

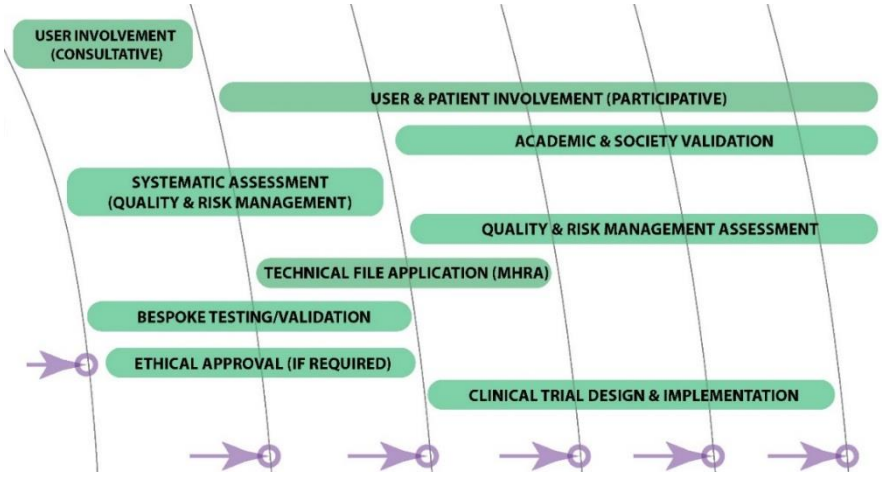


Figure 3.13: Involvement & Validation Activity Amendments

The final conceptual framework is presented in Figure 3.14. The additions made include adjustments to the parallel activity stages with specific reference made to the ergonomic processes and the organisational ergonomics. In addition, minor amendments to the descriptions of the design and engineering methodological processes have been made to improve clarity ensuring the tasks encompassed are suitable within the context of the descriptors. Technical file activity stages and systematic assessment activities have been introduced to provide further clarity to the framework. The parallel ergonomic processes and organisation ergonomics stems from additional literature considered. Alur (2010) describes how organisational ergonomics deals with interaction of users in the organizational environment in addition to the impact this has within medical device standards and human factors. User involvement and regulatory considerations are a fundamental aspect of the developed conceptual framework and failure to consider the ergonomic factors that can

influence these activities would be naive. Shah (2011) also presents valid arguments for the need to incorporate ergonomics and user involvement activities such as user analysis/profiling, contextual inquiry and user requirement analysis.

Ergonomics that are relevant to medical and surgical practice and to healthcare in general are identified by Stone and McCloy (2004) identifying a number of issues that must be considered. Stone and McCloy (2004) present a range of human centred issues relevant to the ergonomic design of equipment or systems in addition to consideration relating to design and training, these include:

- Body size (anthropometry)
- Motion and strength capabilities (biomechanics).
- Sensory-motor capabilities i.e. vision, hearing, haptics (force and touch) and dexterity.
- Cognitive processes and memory (including situational awareness).
- Training and current knowledge relating to equipment, systems, and practices.
- Training and current knowledge of medical conditions (including emergency conditions).
- Operation of equipment and the expectations and cultural stereotypes.
- General health, age, motivation, stress levels, mental fatigue, performance under drug treatment.

To develop an emergency airway device, many of the above-mentioned points must be considered. The user and patient who encounter these devices are the most important parameters. Integrating ergonomic and anthropometric data is critical and sources such as Bodyspace (Pheasant and Haslegrave, 2016) are resources that can influence design work. Utilisation of these resources especially during TRL 1-3 and the parallel ergonomic processes will be imperative. Fairbanks and Wears (2008) present the notion that technologies often fail to deliver their promised benefits especially when they are not designed to match the needs, cognitive processes, and environments of the intended users. This can be a significant barrier for device adoption and suggests hospital trusts are initially hesitant to invest in new equipment unless validation has been achieved and verified by academic rigor and effective clinical trial outcomes. This type of organisational ergonomic consideration is imperative to the qualification and production of any new device. Fairbanks and Wears (2008) also discovers that purchasers (e.g., hospital supply officials) and end users are often naive about the role that device design can play in enhancing safe and effective performance; Johnson et

al., (2007) suggests that health care employers still put too much emphasis on the traditional view of blaming and retraining the user.

Ergonomic design activities and organisational ergonomic considerations are fundamental to successful device design, these methods should influence a change the blame and retrain culture. Blaming and retaining users on equipment best practice is often completed because of the perception of inadequate device operation during challenging cases. Devices successfully designed to ensure simple, intuitive operation using universally accepted techniques may help the shift towards clinical situation assessment and problem solving.

Vincent, Li and Blandford (2014) discusses the importance of integrating human factors and ergonomics during medical device design and development process. Reference is made to the importance of communication and for the acceleration of the integration of human factors and ergonomics in patient safety. Gurses, Ozok and Pronovost (2011) considers human factors, engineering principles and techniques as imperative to medical device design and development, identifying five recommendations to better integrate human factors and ergonomics within patient safety improvement efforts.

Finally, a small amendment was made to the dissemination of knowledge activity to the framework. Originally, this was scheduled to begin at TRL 4, however, dissemination of knowledge should arguably start at TRL 3. Disseminating knowledge to the user and patient involvement groups at an early stage would validate the initial conceptual and technology development work completed; this information can also be disseminated to the wider academic community. Shah (2011) suggests that users need to feel sufficiently notified if not involved in any developments of their healthcare delivery; this type of information can be disseminated to the potential user groups and within the wider context of the academic field.

Marriott, Palmer and Lelliott (2000) also presents the same viewpoint but in a clinical setting suggesting dissemination as an essential, often overlooked component of quality improvement; this can provide essential links between research and policy which in turn can influence best practice and delivery. It is important to recognise the characteristics of the individuals, or groups of individuals, who need to be made aware of key information and the earlier this takes place in the development of innovative technologies and devices for emergency airway access devices, better and safer practice can be influenced.

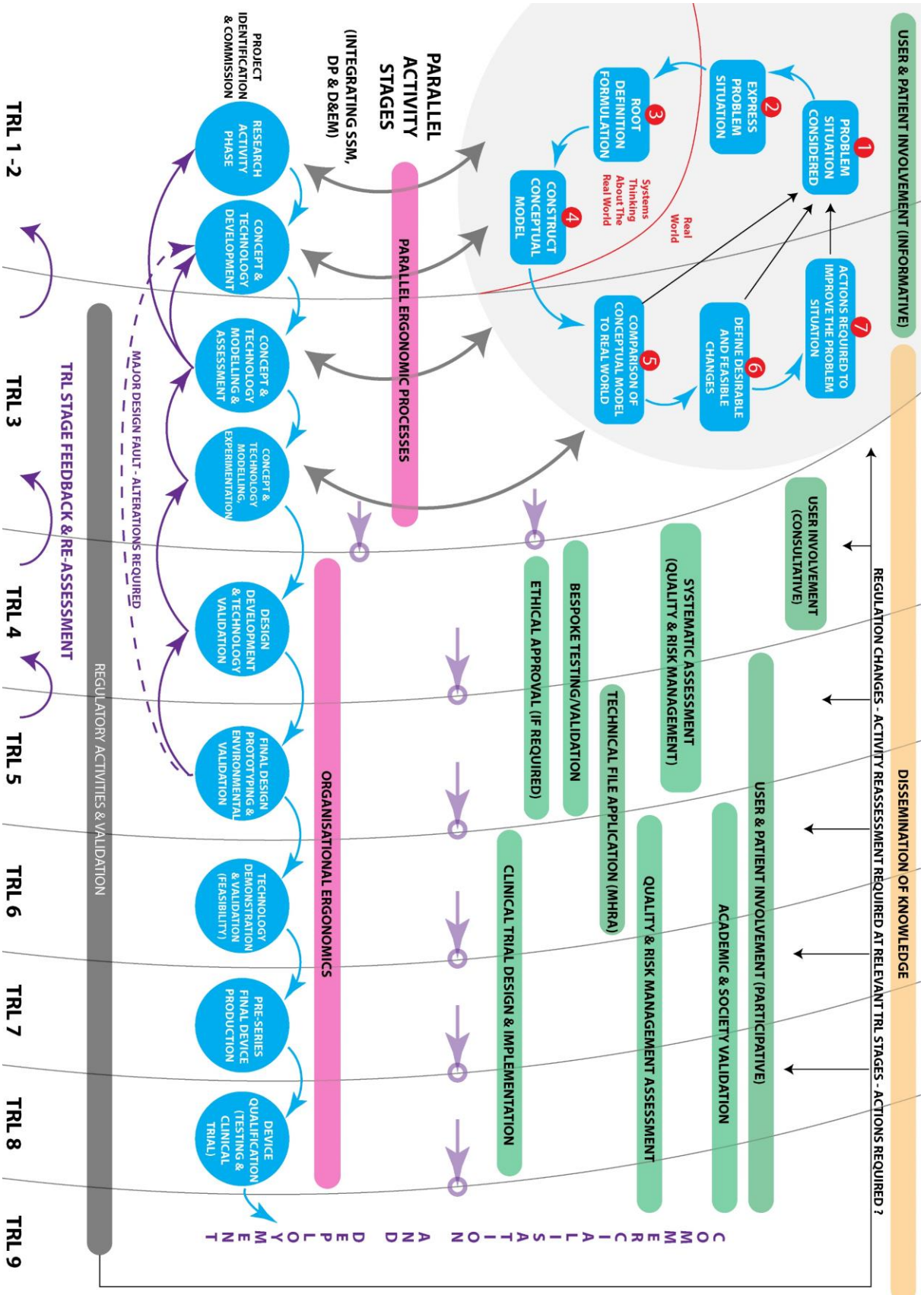


Figure 3.14: Final Conceptual Framework For Emergency Airway Device Development

CHAPTER 4 – DESIGNING THE STEERABLE BOUGIE

4.1 Introduction

This chapter begins with a description of the methods and techniques utilised to inform the design of the steerable bougie. These methods and techniques co-align with the developed conceptual framework and the design and engineering methods discussed within the literature review. A case of need survey is presented identifying key design criteria informed by the literature review. These tasks inform the generation of the product design specification (PDS).

The on-line case of need survey was created by the research team with the aim of defining the user defined design improvements; the results will inform the design of the steerable bougie. An initial design criteria is generated based on an assessment of the product market and influences other research activities, for example a practical assessment of technical capabilities of materials and mechanisms. Identifying key criteria will ensure a PDS can be constructed. Developing a PDS is a fundamental activity for any iterative design process or total design activity, Pugh (1991, p.5) states:

> *"From the statement of the need – often called the brief – a product design specification (PDS) must be formulated – the specification of the product to be designed. Once this is established, it acts as the mantle or cloak that envelopes all the subsequent stages in the design core. The PDS thus acts as the control for the total design activity, because it places the boundaries on the subsequent designs." (Pugh, 1991, p.5)*

A practical assessment of the suitable materials and mechanism identified is completed and considers product specific criteria identified within the PDS. Results collected from the practical assessment influences the iterative design process. Initial design work of the steerable bougie is completed utilising iterative design process tasks identified within the conceptual framework and based on the Total Design Activity described by Pugh (1991). Individual component design is completed including the CAD design and manufacture of the first iteration model.

Finally, the research conducted within this chapter has been published in the Australasian Medical Journal (Siena et al., 2016) and has validated the methods utilised for the design and manufacture of the steerable bougie.

4.2 Methods

Throughout this chapter numerous research methods and techniques are utilised to achieve the desired objectives. Sections 4.2.1 – 4.2.4 describe the methods utilised to conduct the case of need survey, a practical assessment of suitable materials and mechanisms, approaches undertaken for constructing a PDS and the design methods undertaken for the design of the steerable bougie.

4.2.1 Case Of Need Survey

To be able to ascertain the requirements for the design of the steerable bougie, a PDS must be created. To be able to create a PDS, first the design problem must be fully understood and defined. Utilising the SSM and design engineering processes presented within the TRL 1-2 stages of the conceptual framework, initial research activities are conducted. The research team decided to undertake a case of need survey to establish the key design considerations and areas for improvement based on expert opinions. The creation of the on-line survey utilising surveymonkey.com was completed. The survey was distributed to anaesthetists of varying grades at Nottingham University Hospitals Trust to identify and answer the following questions:

1. How commonly video laryngoscopy is used in practice?
2. Type of video laryngoscopy device used.
3. Types of adjuncts used to aid intubation when using a video laryngoscope without a guided channel.
4. Experience of difficult or impossible intubation situations encountered despite having a good laryngoscope view and the prevalence of this situation.
5. Preferred new design features and increased functionality desired for a new device to assist successful intubation when using a video laryngoscope.

4.2.2 Generation of a PDS

Developing a PDS is a critical activity for any iterative design process or total design activity and is a fundamental element to product lifecycle management. There are many models and tools that can be used to construct a PDS, for example Hosnedl et al., (2010) presents a design specification and evaluation tool for design engineering and its management using a software support tool. However, one of the most internationally recognised is the Total Design methodology constructed by Pugh (1991).

To facilitate the generation of a PDS for the design of the steerable bougie, Pugh's Total Design approach is utilised. Pugh's approach for a PDS utilises over thirty elements, however not all these elements are specific to every project. Before generating the PDS for the steerable bougie, a selection process of the specification points is undertaken as shown in Table 4.1.

Time Scale	X	Competition	✓	Materials	✓
Customer	✓	Packaging	✓	Ergonomics	✓
Processes	X	Quality/Reliability	✓	Standards	✓
Size	✓	Shelf Life Storage	✓	Aesthetics	✓
Shipping	✓	Patents	✓	Installation	✓
Company Constraints	X	Environment	✓	Life In Service	✓
Disposal	✓	Testing	✓	Performance	✓
Manufacturing Facility	X	Safety	✓	Product Cost	✓
Politics	✓	Legal/Legislation	✓	Quantity	✓
Market Constraints	✓	Documentation	✓	Product Life Span	✓
Weight	✓	Maintenance	✓		

Table 4.1: Selection Of PDS Elements

The excluded criteria identified four areas within Table 4.1 where the design specification points were deemed not necessary. The rationale for their exclusion is as follows:

Time Scale: The objective to design and develop the steerable bougie within the context of this PhD is to achieve TRL4/5 status and this should be achieved within the PhD timescale. However, the timescale for the overall design, manufacture, testing, clinical trial and commercialisation of the steerable bougie is too complicated to predict, hence this topics exclusion.

Processes: Pugh (1991) defines the processes element of a PDS as in-house process specifications as opposed to manufacturing techniques; however, special processes must be considered for manufacture. For this PDS, when considering the design of the steerable bougie, identifying specific processes for wiring specifications, shaft manufacture etc., are not feasible until the design of the device is completed; after the design of the steerable bougie has been produced, device specific processes can be considered.

Manufacturing Restrictions: Although there are several manufacturing restrictions that can be identified such as size limitations which will in turn affect tooling constraints, as the PDS being generated is focusing on the design and development of the steerable bougie within

the context of this PhD research, the device will not be professionally manufactured until post PhD.

Company Constraints: Within the context of this PhD there are no company constraints as the steerable bougie will be designed and tested up to TRL 5 and not involve external companies for licencing or commercialisation.

There are many methods of producing a PDS document which can be distributed between all the stakeholders. Pugh (1991) suggests utilising a tabulated format that considers descriptors and a variety of parameters to record accurately the progress made. However, interestingly when consulting with the medical specialists and several other stakeholders, many of which had not heard or used a PDS before, this version of PDS documentation and reporting was not deemed an appropriate method due to the unfamiliar terminology use. To allow full communication within the project team and to ensure all the stakeholders can assess the designs against measurable outcomes reported in the PDS, an itemised descriptive PDS will be created.

4.2.3 Material and Mechanism Investigation

To identify suitable materials and mechanisms to be integrated into any new device an initial material assessment was conducted within the literature review. The materials and mechanisms reviewed were based on the design brief generated in collaboration with the project team. The initial design brief stipulated that the steerable bougie should be a new steerable device capable of completing an intubation in thirty seconds to one minute with the intention of increasing the speed, efficiency and safety of current intubation procedures. The new device is expected to perform in a comparable manner to the gold standard device i.e. gum elastic bougie, but with increased steerable functionality within the standard dimensions and restrictions of existing devices which in the case of a bougie is a 500mm – 800mm length shaft which is 5mm in diameter.

The design brief also stipulates the response time of the steerable function, which should be fast and positive with reaction and relaxation times of one second or less. The importance of speed and efficiency of intubation procedures cannot be underestimated; however, intubation safety cannot be compromised. Blanda (2000) identifies the need to complete an intubation within thirty seconds and highlights the importance of securing a patient's airway in the management of acutely life-threatening illnesses and injuries.

A review of materials and mechanisms within the literature review identified several materials and applications for SMAS many of which have been integrated into small steerable medical devices. Duerig, Pelton and Stöckel (1999) and Stoeckel (2000) provide overviews on nitinol medical applications with a focus on how its deployment has steadily driven the medical industry towards less invasive procedures.

Flexinol® actuator wire (nickel-titanium) (Dynalloy.com, n.d.) is a shape memory alloy (SMA) actuator wire that has been utilised within a variety of applications. There are several examples within the literature including Dutta and Chau (2003) who present a feasibility study on the use of Flexinol® as a primary actuator in a prosthesis hand. Black et al., (2014) reviews the use of Flexinol® for its application within an SMA guidewire system related to optically actuated active needles for guided percutaneous surgery and biopsy procedures. Pappafotis et al., (2008) describes an application relating to the design and fabrication of miniature MRI compatible robots.

Boston Scientific also have several registered patents including US8795348B2 relating to Flexinol's application in medical devices and related methods (Weber, Holman and Schewe, 2014). Other patents that utilise Flexinol® within their application include US20090076597A1, which is a system for mechanical adjustment of medical implants (Dahlgren and Gelbart, 2009), US9737427B2, medical device delivery systems (Gunderson, 2017) and US8372033B2, a catheter that has a proximal heat sensitive deflection mechanism and related methods of use and manufacturing (Kronstedt and Grasse, 2014).

The identification of suitable materials used in existing mechanisms ensured a material property analysis could be conducted using a material selection database (CES Granta Design©). Within this material selection process, the performance objectives highlighted in the design brief were critical to material selection considerations which included a cost versus performance analysis. Additional performance analysis charts were analysed based on design requirements utilising material screening, however it was also important to consider the bougie geometric limitations and design constraints which affected the potential outcomes. The material selection process identified the need to further analyse shape memory alloys, shape memory polymers and artificial muscles as viable solutions.

4.2.4 Designing The Steerable Bougie

As identified within Chapter 3, the design and manufacture of a new medical device is a complex task that requires consideration of a large spectrum of factors. With medical device design it is important to undertake iterative design processes to ensure that product development process results in a functional product that fits within the case of need and resolves the problem identification definitions.

For the development of the steerable bougie, implementation of the developed conceptual framework is undertaken. By utilising the developed conceptual framework which includes SSM, DP & D&EM and parallel activities, both a soft and a hard system thinking approach can be undertaken dependant on the iterative design process. This ensures development, validation testing, commercialisation and adoption can be achieved.

There are three key elements within the conceptual framework which are imperative for the successful design of the device, especially at the initial concept phase. Firstly, the use of the SSM elements incorporated into the conceptual framework, based on the work completed by Checkland (1981; 1984; 1989), Wilson (1984) and Shah (2011), are imperative to ensure the defined problem and root definitions are translated into feasible designs.

Secondly the iterative design process approach which considers key elements from Pugh's Total Design Activity Model (Pugh, 1991) and Cross's eight stages of the design process (Cross and Roy, 1989) ensures that feedback, whether this be quantitative or qualitative data, can direct the design development process. Finally, the parallel ergonomic design processes and technology assessment activities, which are directed by the material and mechanism investigations, direct the design restrictions and technology feasibility assessment of any designed product.

4.3 Case of Need Survey

The online survey constructed by the research team was distributed to approximately 150 anaesthetists of all grades, at Nottingham University Hospitals, UK. This survey was completed by 52 anaesthetists as shown in Figure 4.1 and Table 4.2 representing a >30 percent response rate. The majority of the respondents (83 percent) were either consultants or senior trainees with over four years specialty experience.

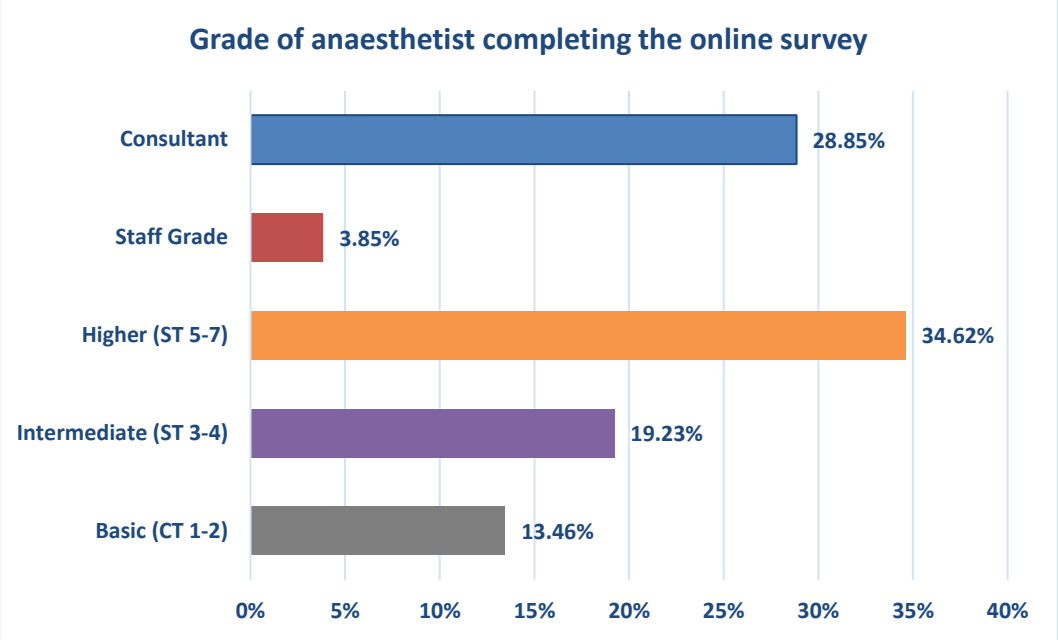


Figure 4.1: Grade Of Anaesthetist Responding To Survey

Grade of Anaesthetist Completing The Survey		
Grade	**Responses**	**Percentage**
Basis (CT 1-2)	7	13.46%
Intermediate (ST 3-4)	10	19.23%
Higher (ST 5-7)	18	34.62%
Staff Grade	2	3.85%
Consultant	15	28.85%
Total No of Respondents	52	-

Table 4.2: Responses: Grade Of Anaesthetist Responding To Survey

Figure 4.2 and Table 4.3 suggests that over ninety-two per cent utilise video laryngoscopy within their practice with the majority of respondents stating that they were familiar with devices both with and without a guided channel. Figure 4.3 and Table 4.4 identifies the choice of device used by anaesthetists when conducting video laryngoscopy. This question did not limit the respondent to one response thus ensuring that the full range of preferred equipment use could be captured.

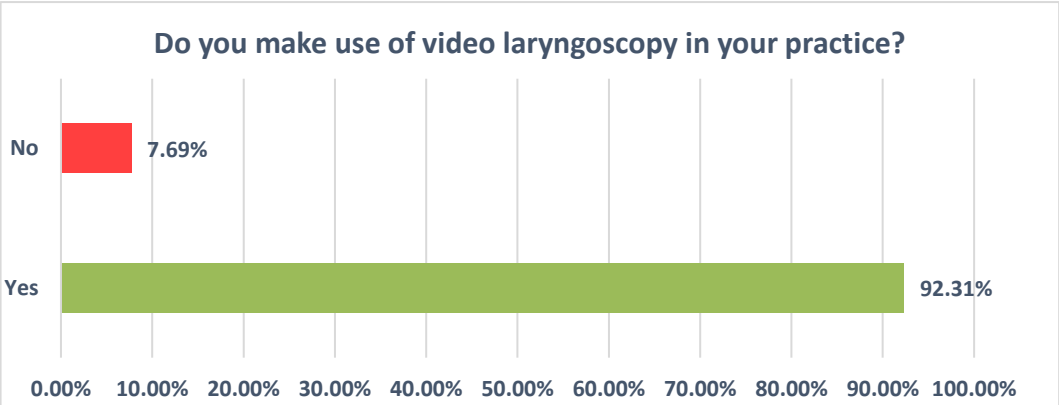


Figure 4.2: Use of video laryngoscopy in Practice

Use of video laryngoscopy in practice		
Answer	**Responses**	**Percentage**
Yes	48	13.46%
No	4	19.23%
Total No of Respondents	52	-

Table 4.3: Responses: Use of video laryngoscopy in Practice

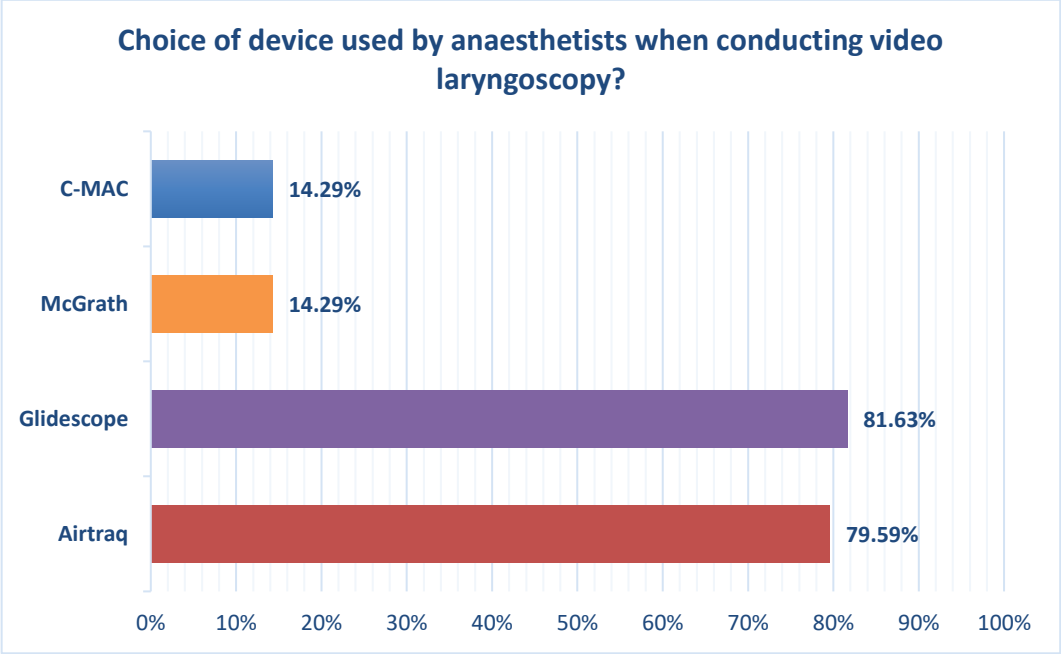


Figure 4.3: Choice of video laryngoscopy device?

Choice of device used by Anaesthetists when conducting video laryngoscopy		
Device Type	**Responses**	**Percentage**
Airtraq	39	79.59%
Glidescope	40	81.63%
McGrath	7	14.29%
C-MAC	7	14.29%
Total No of Respondents	49	-

Table 4.4: Responses: Choice of video laryngoscopy device?

Respondents reported a range of adjuncts used with the video laryngoscopes to aid endotracheal intubation, as shown in Figure 4.4 and Table 4.5; the bougie and manufacturer stylet proved to be the most popular within the score-based system. Interestingly a sizeable number of the respondents also reported not utilising an adjunct when conducting video laryngoscopy without a guided channel.

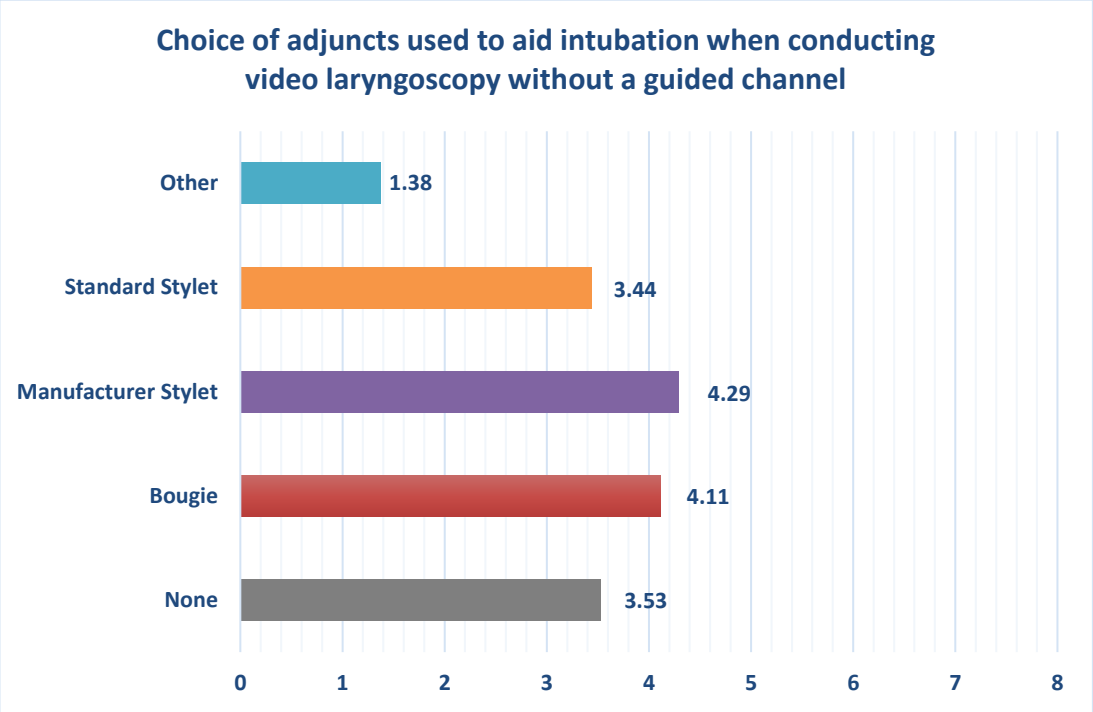


Figure 4.4: Choice of adjunct during video laryngoscopy

Choice of adjuncts used to aid intubation when conducting video laryngoscopy without a guided channel (Ranked in Order Of Preference)							
Answer	**1st**	**2nd**	**3rd**	**4th**	**5th**	**Total**	**Score**
None	46.67%	6.67%	6.67%	33.33%	6.67%	N/A	3.53
Number of Respondents	7	1	1	5	1	15	N/A
Bougie	32.43%	45.95%	21.26%	0.00%	0.00%	N/A	4.11
Number of Respondents	12	17	8	0	0	37	N/A
Manufacturer Stylet	51.61%	32.26%	12.90%	0.00%	3.23%	N/A	4.29
Number of Respondents	16	10	4	0	1	31	N/A
Standard Stylet	28.00%	16.00%	28.00%	28.00%	0.00%	N/A	3.44
Number of Respondents	7	4	7	7	0	25	N/A
Other	0.00%	0.00%	12.50%	12.50%	75.00%	N/A	1.38
Number of Respondents	0	0	1	1	6	8	N/A
Total No Of Respondents	42						

Table 4.5: Responses: Choice of adjunct during video laryngoscopy

Figure 4.5 and Table 4.6 identified that 75 per cent of anaesthetists still reported being familiar with the situation whereby despite having a good view, they were unable to intubate due to encountering a difficult/impossible intubation; a third of respondents indicated this was a common finding; this is also consistent with the findings presented by Nielsen, Hope and Bair (2010).

Nielsen, Hope and Bair (2010) also identify that among novice users of the GlideScope® video laryngoscope for simulated difficult airway management, no benefit was found using the bougie over the standard stylet; this suggests that the mixed preference of adjuncts utilised as presented in Figure 4.4 and Table 4.5 is not unexpected. Assessing the similar device properties and combining these together to create a combined product poses an exciting avenue to explore.

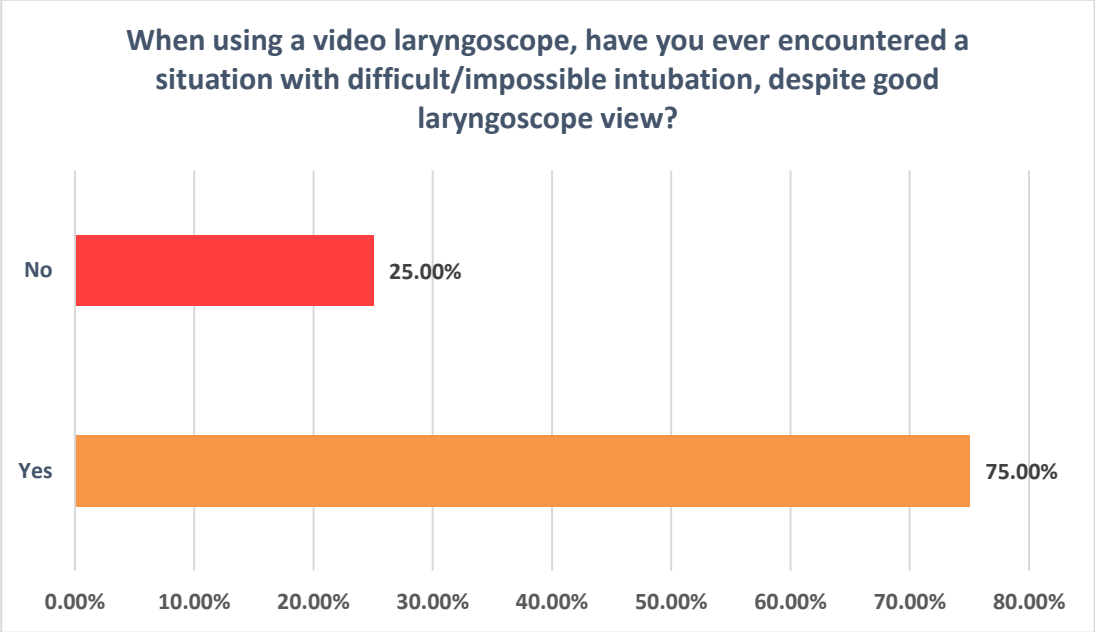


Figure 4.5: Difficult/Impossible Intubation Encountered

Difficult/Impossible Intubation Encountered		
Answer	**Responses**	**Percentage**
Yes	36	75.00%
No	12	25.00%
Total No of Respondents	48	-

Table 4.6: Responses: Difficult/Impossible Intubation Encountered

In response to the previous question, if the respondent answered the question with the answer "Yes", a follow up question aimed to identify the perceived frequency of encountered difficult or impossible intubation; these results are presented in Figure 4.6 and Table 4.7. The findings are also consistent with the findings presented by Russo et al., (2007). Russo et al.,

(2007) reports that there was a high variation of frequency of an experienced difficult airway. Forty five of the forty-eight respondents (92%) stated that they had experienced a difficult airway situation during the previous six months. Thirty-seven (77%) respondents described difficult mask ventilation; thirty-six (75%) of respondents stated they had experienced difficult laryngoscopy; thirty-seven respondents (77%) experienced a difficult intubation, ten respondents (21%) encountered impossible intubation and three respondents (6%) encountered a cannot intubate, cannot ventilate situation.

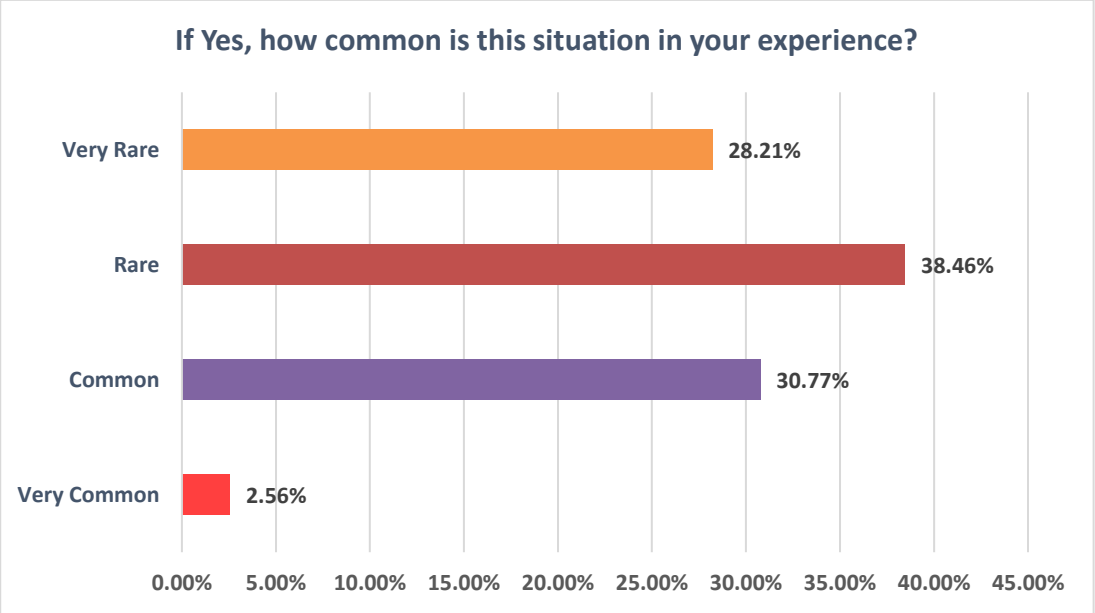


Figure 4.6: Frequency Of Difficult/Impossible Intubation Encountered

Frequency Of Difficult/Impossible Intubation Encountered		
Answer	**Responses**	**Percentage**
Very Rare	1	2.56%
Rare	12	30.77%
Common	15	38.46%
Very Common	11	28.21%
Total No of Respondents	39	-

Table 4.7: Responses: Frequency Of Difficult/Impossible Intubation Encountered

The data collected and presented in Figure 4.7 and Table 4.8 identifies that 64% of respondents recognised that device shape retention improvements is an essential area where design improvement is required, with only introduction of a steerable function receiving a greater response rate of 68%. The most desired new function or improvement to a bougie is improved tip flexibility and control, suggesting a device with increased steerability is necessary to help improve the success rates of procedures and help improve patient safety.

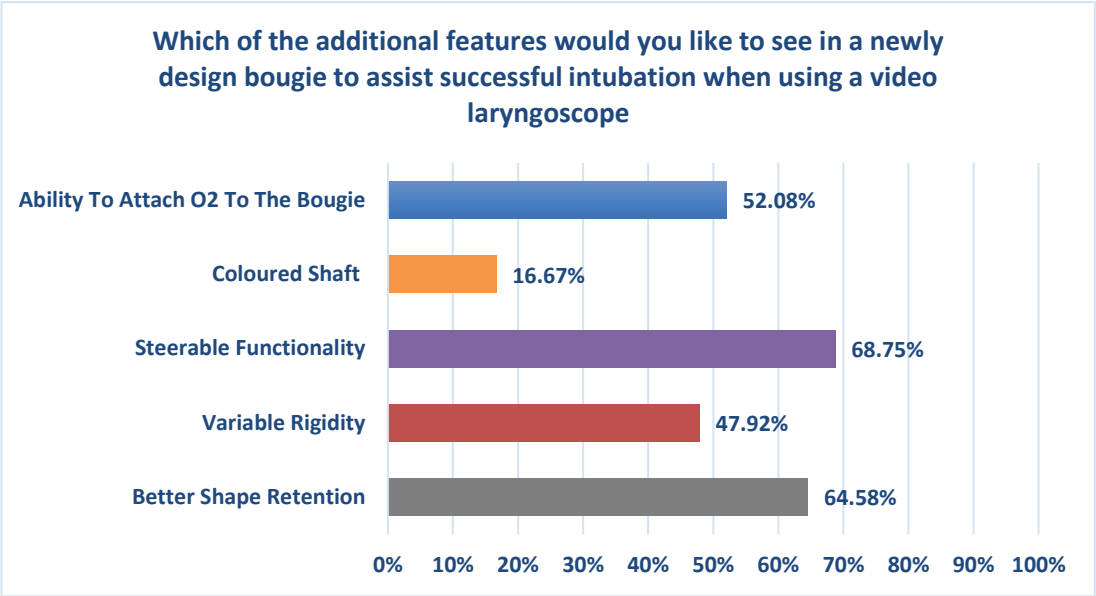


Figure 4.7: New Bougie Design Features

Which of the following features would you like to see on a newly designed bougie to assist in successful intubation when using a video laryngoscope?		
Answer	**Responses**	**Percentage**
Better Shape Retention	31	64.58%
Variable Rigidity (More Flexible Tips)	23	47.92%
Steerable Functionality (To Allow Shape Change With Device In Situ)	33	68.75%
Coloured Shaft (To Guide Insertion Depths)	8	16.67%
Ability To Attach O2 To The Bougie	25	52.08%
Total No of Respondents	48	-

Table 4.8: Responses: New Bougie Design Feature

4.4 Product Design Specification (PDS)

The development of the PDS is based on the original PDS's developed by Hughes (2013) based on consultations with Dr James Armstrong, Dr Andrew Norris and Dr Kristopher Inkpin from Nottingham University Hospitals. This PDS has been significantly developed, however parts of the PDS remain the same based on the original design requirements set by Hughes (2013) during the initial project work. After analysing the literature and a review of the project outcomes, this resulted in a few minor changes to the performance outcomes expected for the device.

The main changes from the original PDS and design brief were agreed upon with the project team and have been incorporated into the performance criteria presented in section 4.4.1. The main alterations to the PDS were based upon the clarification of the performance criteria

and after further consultation the PDS was approved. A summative version of the PDS is presented below; for reference to the full PDS, refer to Appendix D:

Performance

- The device should act as a steerable emergency airway access device and exhibit similar or greater physical properties to bougie introducers currently available on the market. The original bougie/stylet should be capable of acting as both a standard and steerable device instead of being a replacement device with increased steerable functionality which is sought when initial induction of anaesthesia fails.
- The procedure should take no longer than thirty seconds to one minute.
- The device is to be used on patients who are either unconscious or unable to breathe on their own, therefore preventing suffocation or airway obstruction.
- Reduce the need of surgical airway access and improve the safety of the procedure over existing emergency airway access devices.
- Prevent oxygenation depravation to the patient ensuring an unobstructed airway is maintained.
- The bougie should be capable of bending 120° in the sagittal plane, 60° in each direction.
- The response of the device should be fast and positive with the necessary reaction and relaxation times of one second.
- The device should be able to hold by itself in the bent position with sufficient strength until the controls are relaxed.
- The bougie should still be capable of being manually bent and be capable of retaining its shape as well as, or better than, the current gold standard bougie.
- The bougie should still be capable of being manually bent should the steerable function fail.
- The device should be compatible with intubation tubes with an internal diameter between 7mm and 9mm.
- The device should be capable of being used in conjunction with standard laryngoscopy equipment and video laryngoscopy equipment currently utilised in practice.

Environment

- 22 °C Ambient Temperature.
- Temperature Range ± 6 °C.
- The steerable device is to be used in direct contact with a patient's airways and open lesions.
- The steerable bougie is to be used by anaesthetists, intensive care and emergency room physicians during endotracheal intubation. The disposable bougie part is to be stored in a sealed packet until required.
- Selected materials must be safe to use during device operation whilst inside the human body, without causing a reaction to human tissue.
- The human body normal temperature (37 °C) must not affect device performance and material manipulation.
- The reusable grip is to be subjected to cleaning and sterilisation between uses.
- The reusable grip is to be stored in a clean environment; ideally the difficult airway trolley, until required.

Maintenance

- The disposable steerable bougie parts should require no servicing.
- The reusable grip should not require any servicing during its lifespan (five years).
- The device must have minimal or zero maintenance other than battery maintenance and sterilisation procedures.
- The steerable bougie component is to be designed and used for a single operation and disposed after detachment from the reusable controller. The disposal of components must comply with Health & Safety Legislation, European Union Directives and Waste Electrical and Electronic Equipment (WEEE) Legislation.
- A battery indicator must be incorporated to ensure the notification of low battery after periods of device inactivity.
- The steerable bougie component must be capable of constant operation for a period of ten minutes with a maximum of forty moves per operation with a mean average of twenty-five moves ±20 per cent.

Size

- The bougie length should be a total of 700mm long including a 50–60mm steerable tip.
- The bougie shaft diameter should be no greater than 5mm and must continue to retain or improve bougie shape retention.
- The detachable power connector located at the base of the bougie shaft should be no greater than 6mm in diameter and be of a suitable weight that will not hinder or impede the intubation procedure.

Product Cost

- The steerable bougie part should cost no more than £18-£20 GBP to manufacture.
- The steerable bougie should be profitable at £25-£30 GBP selling price.
- The reusable grip should cost no more than £100 GBP to manufacture.

Ergonomics

- The device should be suitable for single hand operation.
- The device should be optimised for use by male and female adults considering the 5th and 95th percentile hand dimensions presented by Pheasant and Haslegrave, (2016).
- The grip should be easily detachable from the bougie mid-operation.
- The device should be easy to pass between operators during operation.
- The controls should be intuitive and easy to operate.

Safety

- The steerable bougie must reduce the need of surgical airway access and improve the safety of standard bougie related procedures based on the use of existing emergency airway access devices.
- The device must conform to the necessary medical safety guidelines and regulations; consideration must be made to Medical Device Directive 2007/47/EEC.
- The materials used for construction must minimise the chance of damage to airway soft tissues.
- The forces generated by activation of the device must not be capable of damaging airway tissue.

Customer

The customer targeted is anaesthetists of all grades; anaesthetists will use the product in the following situations and may involve a wide user base:

- During emergency airway access procedures.
- During practical demonstrations of the procedure.
- Teaching opportunities for trainee anaesthetists.

Politics/Legislation

- The product should comply with CE Mark and ideally FDA regulations to ensure that the product can be sold internationally.
- For successful operative integration, the device must adhere to the applicable medical regulations and pass clinical trials, providing proof of increased usability and safety in comparison to existing devices available on the market.
- All materials and systems incorporated require the necessary medical approval and must conform to the appropriate medical legislation, i.e., Medical Device Directive 2007/47/EC, CE Mark Legislation and MHRA Medicines and Medical Device Regulations.

4.5 Materials and Mechanisms Investigation

To define a suitable material mechanism to be incorporated into the steerable bougie, an analysis of potential suitable mechanisms is required. Within the literature review conducted, various smart materials, sensors and artificial muscles have been reviewed ranging from electronic EAP'S, Ionic EAP's, Nitinol wire, artificial muscles, amongst others. A substantial number of these are deemed not be suitable for incorporation within the steerable bougie due to their size limitation and actuation methods; a small number require further investigation. Nitinol wire, artificial muscles manufactured from monofilament fishing line and sewing threads developed by Haines et al., (2014) are also to be tested.

4.5.1 Experimental Setup

The testing of artificial muscles was completed to ascertain the suitable mechanism for integration into the steerable bougie. This was conducted by testing the contraction and relaxation timings of artificial muscles through observational recordings utilising physical markers. The movement of physical markers was monitored against a pre-measured setup, this allowed data to be collected based on the actuation observed. Initial pre-testing of

artificial muscles suggests that a reduction of 2.8 - 3% of the total length of the material would provide enough contraction to steer a bougie tip. This value was calculated considering the manufacture of a simplified initial model of the bougie shaft.

A 650mm piece of reinforced PVC tubing, 5mm in diameter, was used to simulate the bougie shaft and a 50mm section of hollow Tygon tubing was used to simulate the flexible tip; these were bonded together using a two-part epoxy glue. At the tip of the shaft, wire was mounted and threaded down the central shaft of the tubing; this wire can now be pulled by hand to force the tip to bend to the desired angle. Using a CAD drawn angle grid depicting changes of ten-degree increments, the tip is monitored until the desired sixty-degree tip movement is achieved (Figure 4.8, position A and B). Using a visual marker attached to the base of the pull wire (Figure 4.8, position C); the distance moved (Figure 4.8, position D), is measured from the base of the tubing to the visual marker using a set of Vernier callipers. The full initial setup is depicted in Figure 4.8.

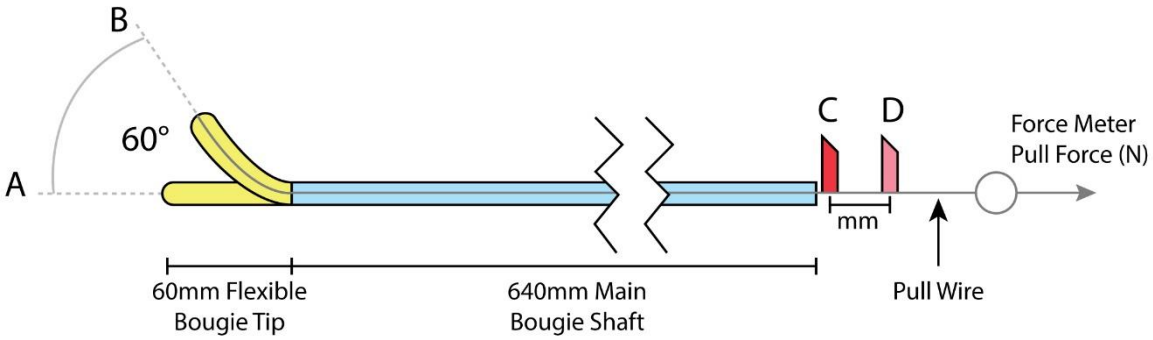


Figure 4.8: Calculating The Required Reduction In Actuator Length

The pull wire was then manoeuvred axially five times to collect results. The results collected are presented in Table 4.9. Based on the values collected, a range of 2.8-3% reduction in total length measurements defined the location of the measurement markers.

Test ID No.	Distance Moved (mm)	Percentage (%) Distance Moved
#1	19.95	2.85
#2	19.81	2.83
#3	20.58	2.94
#4	20.37	2.91
#5	20.16	2.88
Average	20.17	2.881

Table 4.9: 60 Degree Tip Movement

Due to manufacturing restrictions identified during production of initial samples of the fishing line muscles, all the materials and mechanisms tested were conducted on 500mm lengths, this was due to facility limitations capable of producing the fishing line and sewing thread artificial muscles at a length of 700mm. To produce fishing line muscles of 700mm in length an initial length in excess of 2.5 metres was required prior to coiling, thus making 700mm length artificial muscles impossible to manufacture. 500mm lengths required significantly less coiling of an initial length. The manufacture of the fishing line and sewing thread muscles required the coiling of a length of thread suspended from a clamped motor as shown in Figure 4.9. The coiling of the line/thread was held tight at the base of the line/thread by a small weight, this is used to promote the coiling process as described by Haines et al., (2014).

To produce fishing line and sewing thread muscles of 500mm in length, up to 2m line/thread had to be used, therefore to produce 700mm muscles, lengths exceeding 2.5m would be required and with facility ceiling height restrictions this makes 700mm muscles impossible to manufacture. To produce the desired pulling action, thermal contraction of the fishing line and sewing thread muscles is necessary; a heat gun is used to heat the muscle to generate the contraction/pulling forces, but also to pre-set the muscle movement. The heat applied could be no greater than 240°C otherwise the reversible thermal contraction would no longer be possible due to artificial muscle failure.

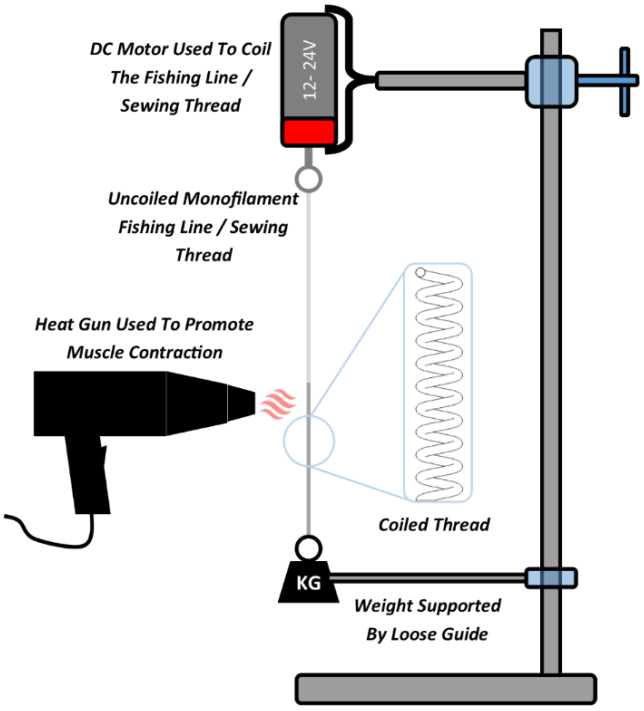


Figure 4.9: Artificial Muscles Manufacture Setup

To select a small number of manufactured artificial muscles to be compared against Nitinol setups, it was important to ascertain which types of fishing line and threads would generate the desired contraction and pulling action. The manufacture of several types of artificial muscles was completed and are to be assessed as to whether they can create the desired pulling actuation required. Proof of concept testing with several types of fishing line and threads was conducted using a heat gun or a DC power supply (depending on the input required for artificial muscle activation), this ensured that movement and can change in length can be achieved. The following threads and fishing lines were assessed:

- Maxima Monofilament 4lb, 6lb, 8lb, 12lb, 15/16lb Fishing Line.
- Sufix Superior Shock Leader – 60lb Fishing Line.
- Berkley Trilene XL 8lb and 12lb Fishing Line.
- Sneak Camouflage Monofilament 8lb Fishing Line.
- Nylon Monofilament Sewing Thread 0.24mm diameter.
- Conductive Sewing Thread.

After manufacturing artificial muscles out of the above-mentioned materials, the artificial muscles that were deemed to show the most promise were the Maxima Clear Monofilament 4lb and 6lb fishing lines and the nylon monofilament sewing thread (0.24mm diameter). A small sample of a 6lb Maxima Clear Monofilament fishing line artificial muscle can be seen in Figure 4.10 alongside a 60lb fishing line artificial muscle.

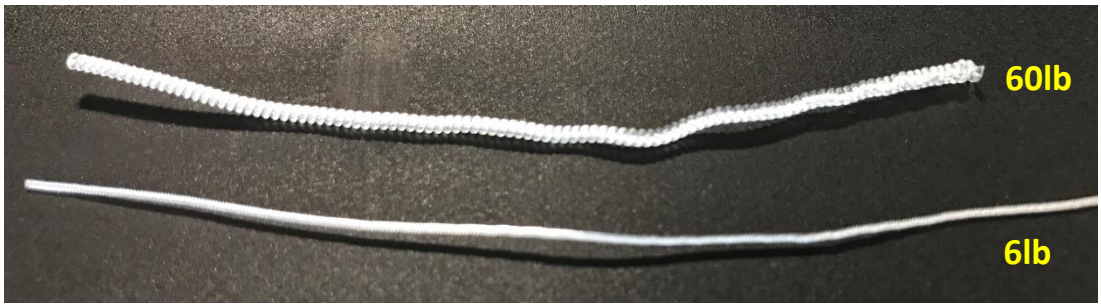


Figure 4.10: Sample of Manufactured Artificial Muscles

The 60lb artificial muscles (seen in Figure 4.10) demonstrates the coiling due to the larger surface area. The 4lb and 6lb fishing lines and the nylon monofilament sewing thread provided the most significant visual actuation and can now be taken forward and included in the side by side comparison against the Nitinol and Flexinol wire setups; the experimental setup for this side by side comparison is depicted in Figure 4.11.

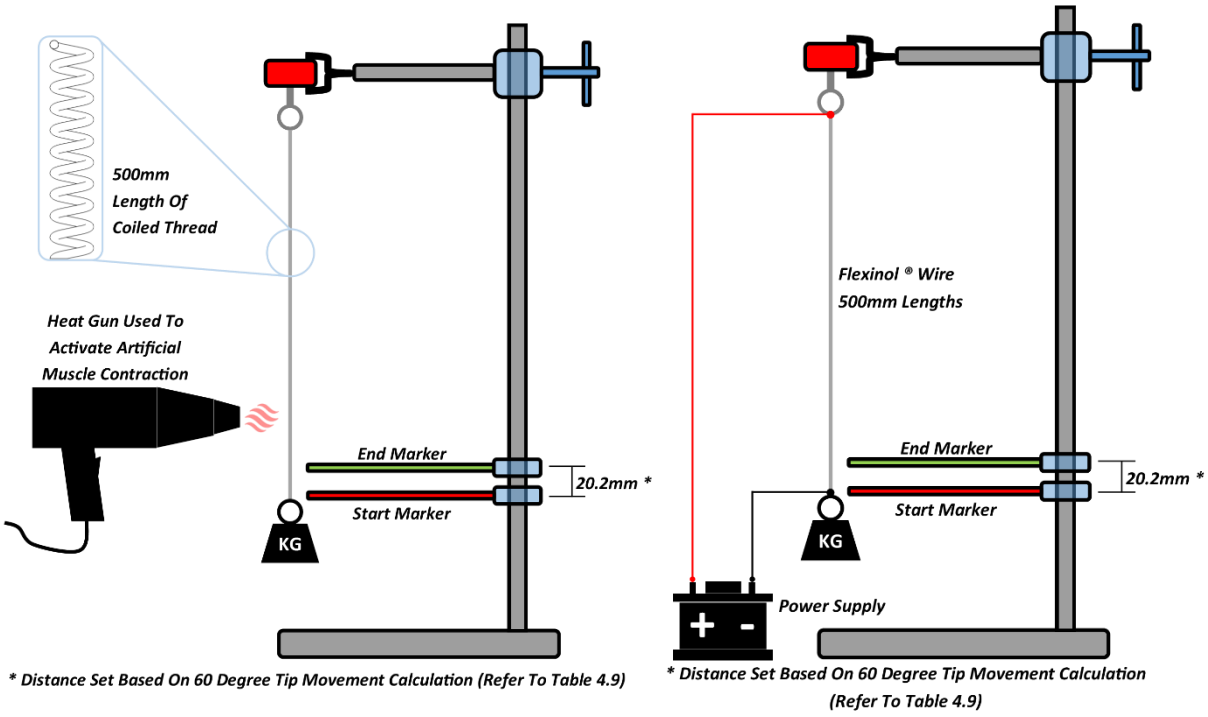


Figure 4.11: Final Experimental Setup

4.5.2 Materials and Mechanisms Testing Results & Discussion

Table 4.10 presents the data collected from testing completed for the fishing line and sewing thread artificial muscles alongside data collected from a Flexinol wire setup and a NiTi spring and pull wire mechanism setup. The PDS previously discussed, states a mechanism reaction time of one second is required to meet the procedure time constraints.

Smart Material/Artificial Muscle Type	Reaction Time 1 (Seconds)	Reaction Time 2 (Seconds)	Reaction Time 3 (Seconds)	Average/Mean Reaction Time (Seconds)	Price Per Metre
Maxima Clear Monofilament Fishing Line 4lb	3.2	2.8	3.4	3.133	£0.044
Maxima Clear Monofilament Fishing Line 6lb	2.0	1.8	2.1	1.966	£0.044
Nylon Monofilament Sewing Thread Clear 0.24mm Diameter	1.9	1.8	2.1	1.933	£0.0012
40mm NiTi Spring Plus Attached Pull Wire	6.8	6.4	7.1	6.766	£1.23
Flexinol 150 Wire - 150 µm	0.45	0.48	0.46	0.463	£1.61

Table 4.10: Smart Material & Artificial Muscle Reaction Times (500mm Length)

The results presented in Table 4.10 identify Flexinol® muscle wire as the most efficient and suitable mechanism for use (based on reaction times). Even though Flexinol® is the most expensive solution, this still conforms to the approved price plan. The data presented in Table 4.10 clearly demonstrates a superior mechanism. A mean reaction time of 6.76 seconds for the NiTi spring and pull wire mechanism is not suitable as the time taken to replicate the 2.8-3% reduction in length is too long.

The fishing line muscles created out of Maxima clear monofilament 4lb fishing line do not meet the PDS requirements due to a mean reaction time of 3.06 seconds. The Maxima clear monofilament 6lb fishing line and the nylon monofilament sewing thread present quicker reactions times, however with mean reactions times of 1.966 and 1.933 seconds, this still does not meet the PDS requirements.

Far superior to all the other mechanisms tested was the 150 µm Flexinol wire, this presented a mean reaction time of 0.463 seconds and is superior to all the other mechanisms trialled;l this also fits comfortably within the PDS requirements. However, with the requirements set for a 700mm bougie, it was necessary to analyse the reaction times of a 700mm length of 150µm Flexinol wire to ensure that the suitable reaction times can be observed.

The Flexinol wire is the most expensive actuator to purchase per metre in comparison to the other actuators assesed, however if the device is mass produced this will significantly reduce the cost of purchase. Table 4.11 presents test data collected comparing the reactions times of 500mm and 700mm lengths of 150µm Flexinol wire. Immediately it is noticeable that the reaction times are longer for the 700mm length compared to the 500mm length to generate the 2.8-3% reduction in length. However, with a mean reaction time of 0.763 seconds, this still fits comfortably within the set requirements highlighted in the PDS.

Smart Material/Artificial Muscle Type	**Reaction Time 1 (Seconds)**	**Reaction Time 2 (Seconds)**	**Reaction Time 3 (Seconds)**	**Average/Mean Reaction Time (Seconds)**
Flexinol 150 Wire - 150 µm – 500mm Length	0.45	0.48	0.46	0.463
Flexinol 150 Wire - 150 µm – 700mm Length	0.80	0.73	0.76	0.763

Table 4.11: Comparison Of Flexinol® Wire Lengths

The Flexinol® wire control mechanism appeared the best choice for inclusion; however, there are multiple different grades of Flexinol® available with different control parameters. Based on the data provided by Dynalloy.com (n.d.) the heating pull force (grams) will determine the exact diameter of Flexinol® wire to be used, this cannot exceed a wire that has a diameter greater than 0.25mm due to the cooling time specifications.

One of the concerns with the use of Flexinol® is its vulnerability to failure if the parameters are not carefully controlled. The integration of a pulse width modulation system to help control these parameters is desirable, therefore reducing hysteresis; however, miniaturising these electronics into the control panel may be problematic. With the identification of Felxinol® wire as the optimum mechanism for inclusion into the steerable bougie, this now needs to be incorporated into the design.

As discussed within the literature review, Nitinol is available in wire, sheet, foil and ribbon format; it is actively used within a wide variety of different applications within medical applications, most commonly with vascular stents and dental applications. The use of SMAs in medical devices will inevitably increase as new devices are designed and manufactured, and the popularity of the material increases. In addition, as the material becomes more regularly used, this also sets a precedent within the medical device regulations for its acceptable use and as such regulatory approval becomes easier to achieve. SMA's, especially Nitinol do however have some significant drawbacks; the key factors are described by Morgan and Broadley (2004). These specifically relate to increased brittleness displayed after a period of use, repeatability and reliability constraints and the required power consumption. This issue becomes less of an issue if the developed device is "single use" therefore reducing the operative time period the device is use for.

It is proposed that Nitnol/Flexinol® wire is used as the control mechanism for the steerable bougie. The steerable component of the proposed system is single use, therefore, repeatability and over use of the mechanism will not be an issue, however as the products are sometimes infrequently used, it will be essential to ensure the product is adequately packaged and the Nitnol/Flexinol® wire mechanism does not become brittle and non-functional after a sustained period of inactivity.

4.6 Steerable Bougie Design – Iteration 1

The initial design of the steerable bougie was created by Hughes, 2013 and was based on the initial design of a low cost steerable endotracheal stylet for improving success rates of intubation in difficult airways. The initial feasibility work completed ensured that the initial design of the steerable bougie was created (Figure 4.12,) however the initial work completed only considered a limited number of the key design criteria highlighted in the PDS.

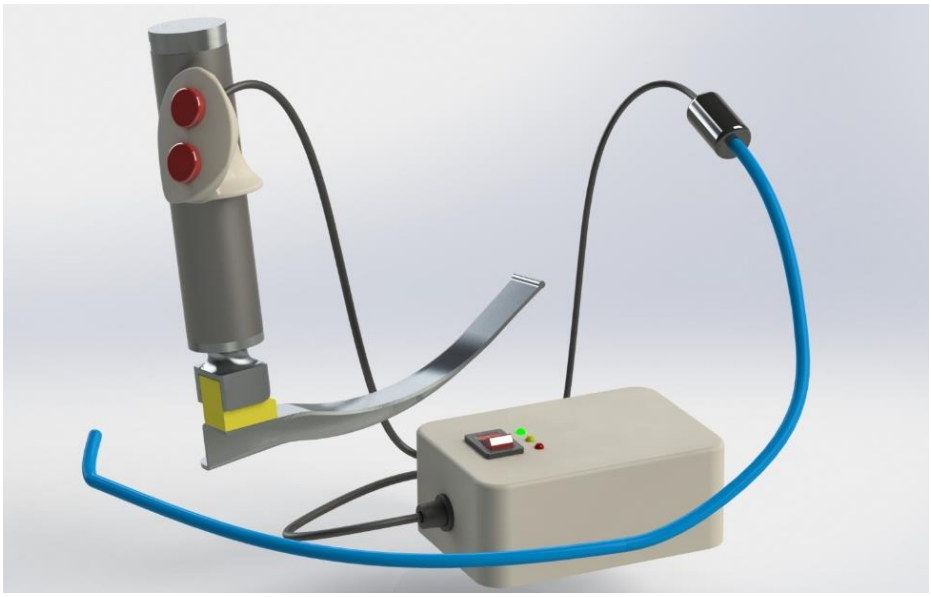


Figure 4.12: Initial Concept of Steerable Bougie – Remastered Image
(Credit: Initial Design Development by Mr Alexander Hughes)

The initial design utilised control wires threaded down the internal profile of the bougie shaft. The control wires are crimped together at the tip; currently the location and mounting of this internal feature has limited development. A major flaw with the design is the hollow flexible distal tip end of the bougie that allows for the crimp to be inserted. The forming of a crimp and top hat connection ensures the control wires are inset and individually controllable however when the tip flexes 60^{o} in each direction this results in the control wires touching due to a non-segmented tip thus creating a circuit short resulting in device failure.

The Polytetrafluoroethylene (PTFE) bougie adaptor is also more than twice the size of the bougie shaft diameter and the ability for this to be disconnected easily by the anaesthetist one handed is questionable. A quick release system will be required rather than screwing the connections on and off. Finally, it is important to note that the first iteration of the designed steerable bougie was never manufactured and only a mechanism proof of concept model was created (Figure 4.13). The setup of the proof of concept model was significantly larger than the 5mm diameter bougie shaft, therefore the miniaturisation of this design is a priority.

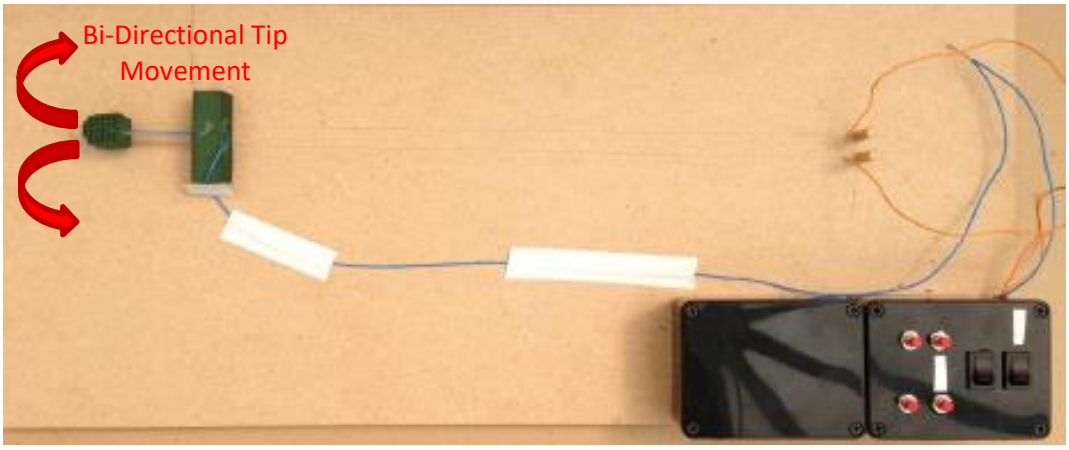
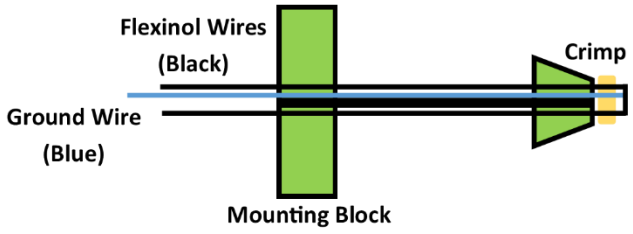
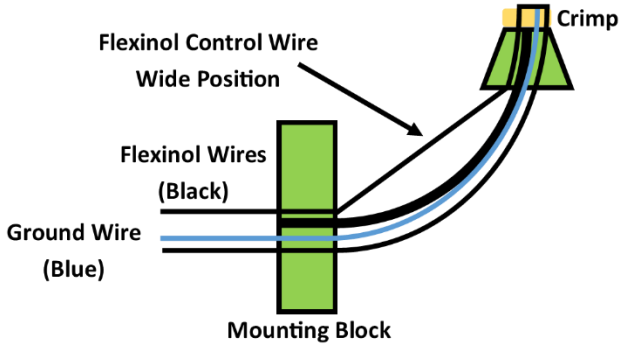


Figure 4.13: Mechanism Proof Of Concept Model

When experimenting with the proof of concept model it was apparent the control wires when powered move significantly wider at the mounting point as depicted in (Figure 4.14), this occurs as there is currently no method of housing the wires which results in a failure to fully control the wire directional movement. The control wires must be able to function within the 5mm diameter bougie shaft and create the 120-degree tip movement when inset.



A) In-Active Control Wire Setup



B) Active Control Wire Setup (Electric Current Applied)

Figure 4.14: Mechanism Schematic

A mounting block, in a miniaturised form, would also be located at the base of the main bougie shaft; this requires further development to be safely independently housed. Running a free moving control wire the length of the bougie and mounting this only at the distal end of the connector could potentially solve this internal design feature issue.

4.7 Steerable Bougie Design – Iteration 2

The second iteration of the steerable bougie focuses on two areas where significant development was required, the bougie tip and the detachable connector. The redesign of the bougie tip (Figure 4.15) is based on the use of a hollow flexible tip which will promote tip flexibility and directional control and separated along the main shaft by multi lumen tubing. A crimp is used to anchor the control wires; these are threaded through the bougie tip and mounted to a crimp which is then covered by a soft outer sheath.

Figure 4.15: Design Iteration 2 Steerable Bougie Main Shaft

The bougie tip redesign, presented in Figure 4.16, depicts the miniature exterior thread points; once the control wires and ground wires are threaded through they are mounted using a miniature crimp. The internal tip structure also has a base mounting block which allows the threaded wires to be looped around, therefore ensuring that the threaded wires are separated. One area for improvement that is required for the tip design is a dedicated mounting point slot for the ground wire to be threaded through, this would ensure the ground wire has its own dedicated slot and does not interfere with the control wires.

Figure 4.16: Tip Outer & Internal Structure

Figure 4.17 presents the design of the bougie connector which is located at the base of the bougie shaft. The connector is designed to slot over the main bougie shaft and secured into position; the control wires are threaded through to the base of the connector and mounted to the connector holders. One of the key issues with this design is that there is no dedicated mounting point for the ground wire, but also the connectors are not positioned in the optimum position to allow the wiring to be extracted out of the connector and relocated to the bougie controller placed on the laryngoscope.

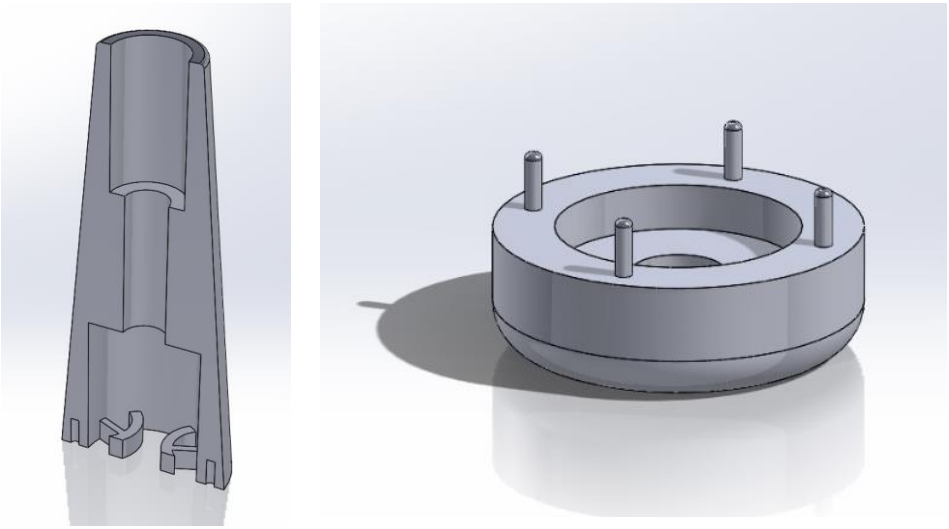


Figure 4.17: Bougie Connector Internal Cross Section (Left), Connector Lid (Right)

The detachable connector lid also has a key design flaw. The location pins which allow for the lid to be taken off are extremely small and will be fragile once manufactured. These pins could easily snap off and should be replaced by mounting screws which can be countersunk into the base. The next iteration of the design needs to solve the issues identified but also consider the tolerances for assembly, especially when considering screw insertions.

4.8 Steerable Bougie Design – Iteration 3

The third iteration of the steerable bougie is based on resolving the issues identified in section 4.7. Figure 4.18 presents the amendment made to the tip external and internal structure (left and centre) and the bougie connector (right). The internal structure of the bougie tip has been amended to incorporate a channel for the ground wire. This ground wire requires an outer insulation sheath but can now be inserted and threaded through the tip without interfering with any control wires. To incorporate the channel for the ground wire, the thickness of the sections has been increased thus reinforcing the channel wall thickness and enabling the part be 3D printed at either 16 or 25 microns.

The bougie connector has also been redesigned to incorporate countersunk screws, however after consideration, the wall thickness of the connector does not appear to be adequate for M2 screws with 0.4mm clearance from the exterior wall of the feature is too little without increasing the overall diameter of the connector which is not an option. An alternative solution would be to have snap fit connectors which would also increase ease of access.

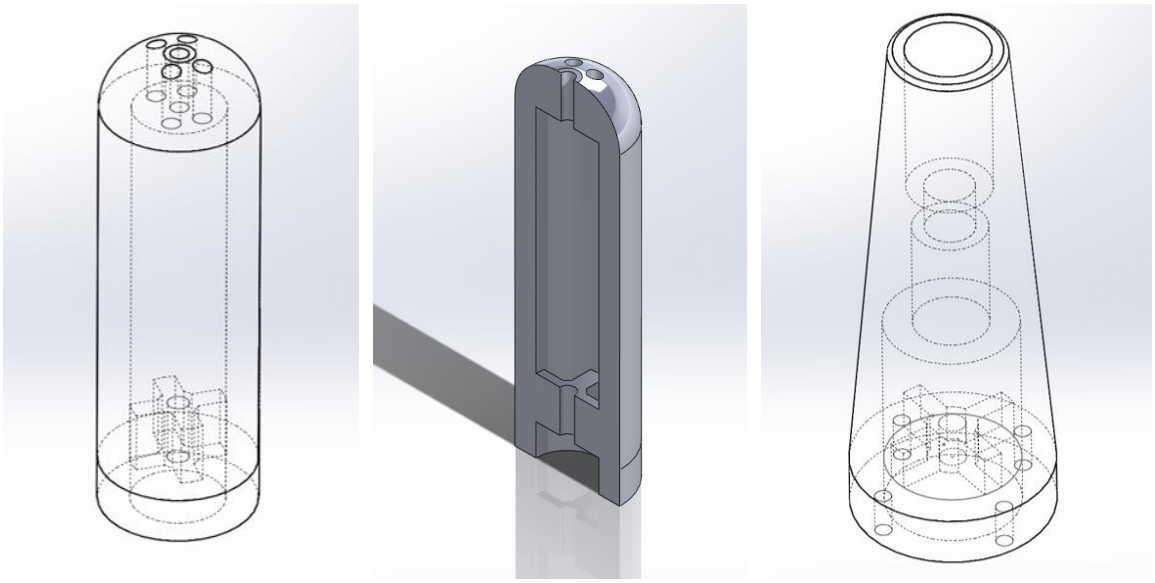


Figure 4.18: Tip Structure (Left), Cross Section Of The Tip Internal Structure (Centre), Bougie Connector Redesign (Right)

After further investigation into internal connection sizes, it is also clear that for practical experimentation it will not be possible to miniaturise these features; as such, external connectors to the base of the bougie will be trialled. Butt crimp connectors for clip on wires could also be utilised. Concern is also raised with regards to the tapered connector and the ability for an endotracheal tube to be railroaded over the bougie connector or removed if adjustment in situ is necessary.

Although this is only 6.5mm in diameter at the base, this is arguably too large and restricts the use of the product when an endotracheal tube of 6mm internal diameter can be used although a standard ET tube size for an adult is 7mm. A solution to this would be to have a 5mm connector at the base of the bougie shaft which then connects via a mechanism such as a push fit or twist lock.

4.9 Steerable Bougie Design – Iteration 4

Design iteration 4 focuses on the development of the 5mm connector at the base of the bougie shaft, which will be capable of being connected by a push fit and connector locators that slot together. Figure 4.19 presents the overall image of the bougie; the bougie tip has not changed significantly from design iteration 3 other than some minor tolerance changes for prototyping using a 16-micron accuracy 3D printer.

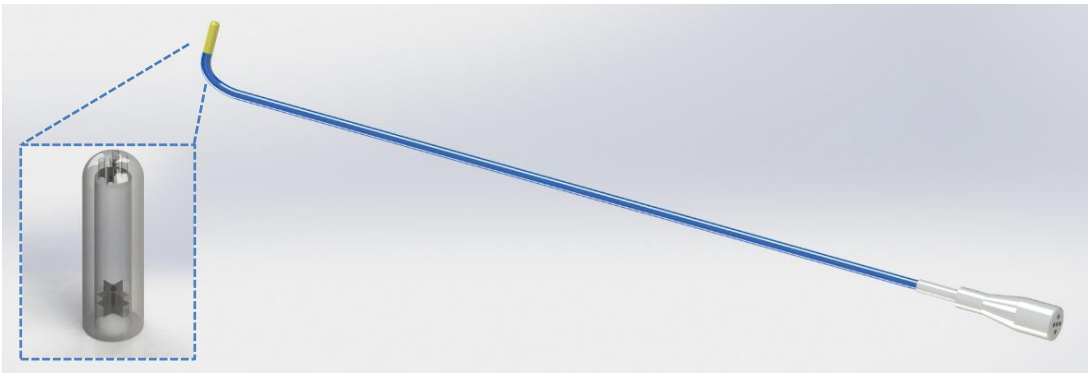


Figure 4.19: Design Iteration 4 Steerable Bougie Main Shaft

Figure 4.20 presents the bougie shaft connector and holder. The concept of the bougie shaft connector is to enable a quick release through the push fit system to allow the endotracheal tube to be easily railroaded over the top of the bougie. Most importantly the taper has been removed from the connector on the bougie which prevented the removal of the endotracheal tube when in-situ should complications occur.

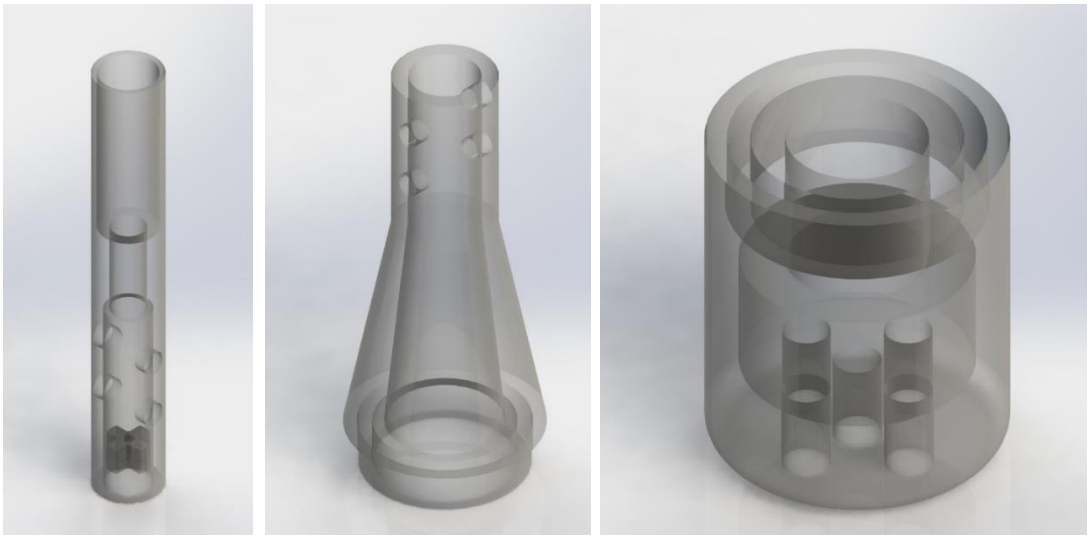


Figure 4.20: Bougie Shaft Connector (Left), Bougie Shaft Holder (Centre), Bougie Shaft Snap On Lid (Right)

The bougie shaft holder contains the electronics with a snap on lid with push pin connectors. In section 4.10 there are several issues with the design that are identified which need rectifying; specifically, the speed at which the connections can be removed and reattached should there be a requirement to reuse or readjust the bougie whilst in situ. The setup of this connector is also rather temperamental and requires colour coded wiring to ensure the control wires and ground wires have the required power or non-power source. Ideally the device should be self-explanatory during assembly and use; preventing this issue is a priority.

4.10 Steerable Bougie Design Iteration 4 Manufacture & Design Review

Figure 4.21 presents the first working model of the steerable bougie based on design iteration 4 of the steerable bougie. It is immediately noticeable that the manufactured version of the steerable bougie is significantly larger than the CAD model of the steerable bougie described in section 4.9.

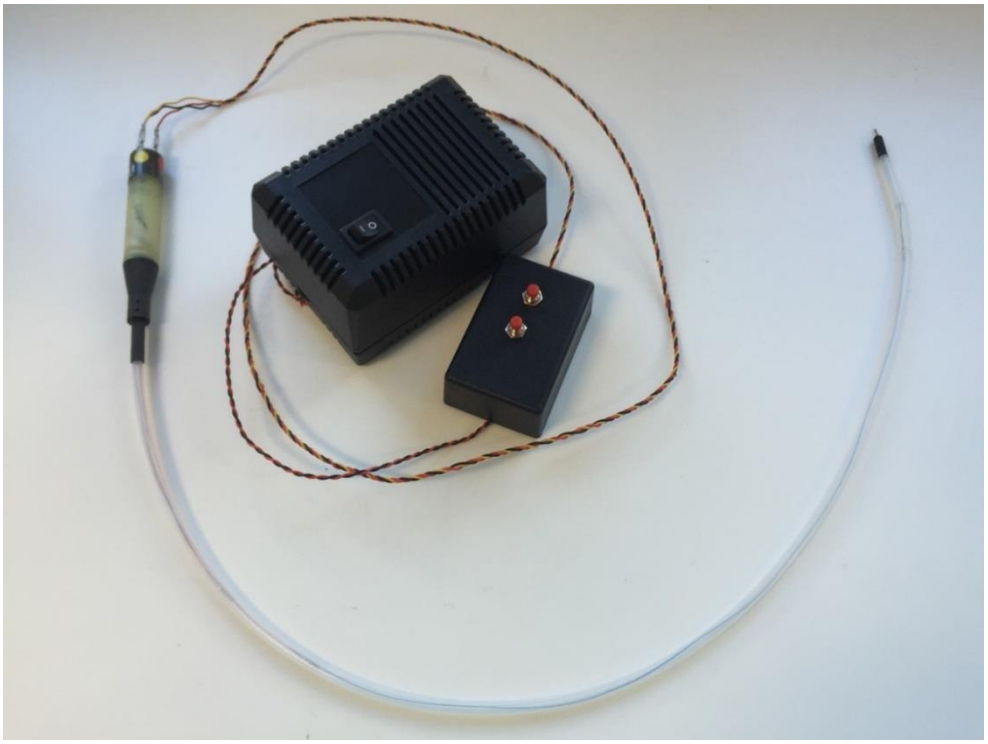


Figure 4.21: Steerable Bougie Working Prototype

The bougie shaft size is 4.8mm in diameter which is slightly smaller than the standard single use and multiple use bougie which are 5mm in diameter; this ensures an endotracheal tube with a 5mm internal diameter and above can be threaded over the top of the bougie. However, the main area where the device is significantly larger is the power pack and the connections between the bougie and the power supply. The control handle at this stage has not been fully manufactured, as ensuring the bougie mechanism functionality was achievable was the main priority for this proof of concept model.

Miniaturising the wiring created some unexpected issues during the manufacture of the device; this resulted in an additional component being added to the connector design to allow the adequate storage room for electronic components to be independently isolated; the additional component in its 3D printed format is shown in Figure 4.22.

Figure 4.22: Bougie Shaft Holder Extension Piece

Figure 4.23 presents the assembly of the bougie shaft and the connector. Immediately it is obvious from the image that failure to miniaturise the wiring created the need for the bougie shaft extension piece. The connectors here are colour coded to ensure correct assembly, but threading wires through the shaft holder is a challenging and a time-consuming task; this is time that an anaesthetist does not have when performing an emergency intubation. The push fit connection between the bougie shaft and the holder are an extremely tight fit and although in theory this was an ideal solution, the tight tolerance fit does mean this connection does cause a friction jam down the shaft. As a result of these issues, an alternative connection is desirable; alternatives include push fits similar to those exhibited on headphones or alternatively a bayonet twist lock connection could be utilised; this would also resolve the issues of incorrect wires being connected together which create shorts within the circuitry.

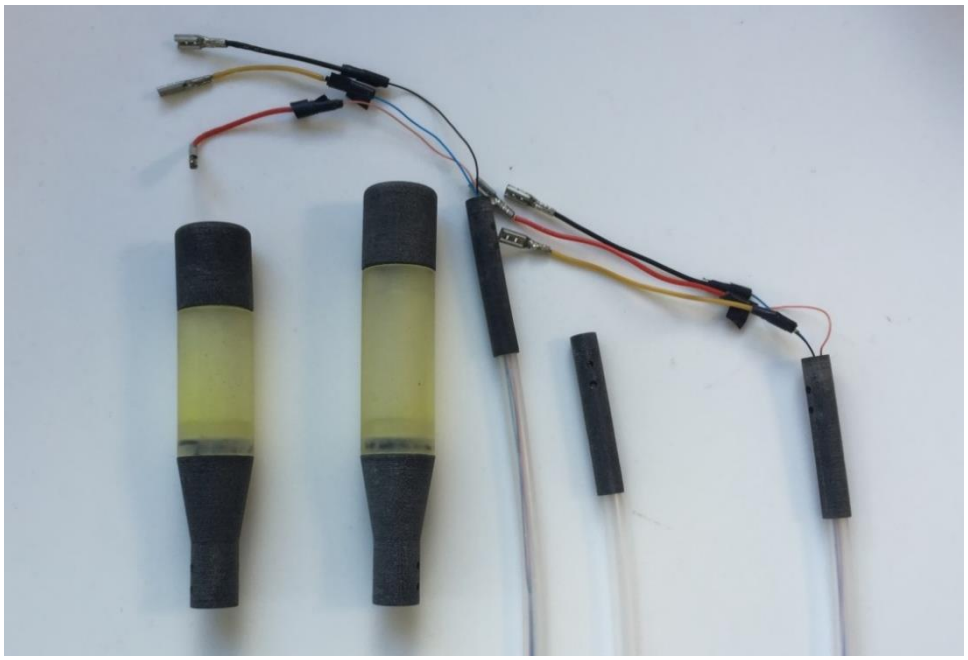


Figure 4.23: Steerable Bougie Internal Connections

Comparing design iteration 4 and the manufactured model against the performance criteria within the PDS, this highlights several design issues that still need resolving. The designed device in its current form can act as a steerable intubation aid during an emergency airway access procedure. The device can perform tasks similar to the original bougie/stylet and currently demonstrates some steerable movement; however, initial testing shows this is only 60 degrees in one direction (Figure 4.24 Position B) and 20 degrees in the opposite direction (Figure 4.24 Position C) due to construction issues (Figure 4.24). Therefore, the steerable bougie in its current form is not fully capable of bending 120° in the sagittal plane, i.e. 60° in each direction.

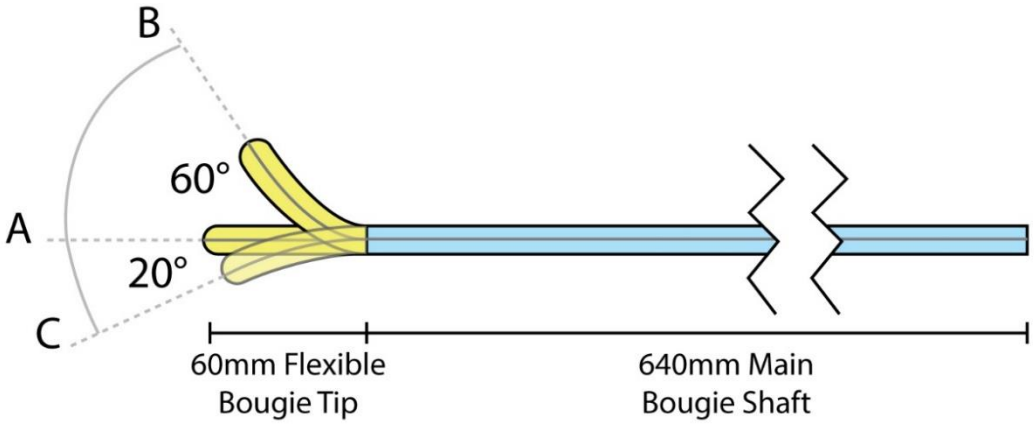


Figure 4.24: Bougie Tip Control Movement Diagram

Due to the extreme flexibility of the current steerable tip, this requires reinforcing to ensure the tip is capable of being inserted into the trachea without kinking; at this current time the procedure therefore takes longer than one minute due to accommodating the kinking issues. If this is overcome the intubation time can be achieved. With a softer tip that demonstrates reduced tip pressures, this will contribute to the reduction of a need for surgical airway access due to improved safety within the procedure over existing emergency airway access devices. The response of the device is fast and positive as demonstrated in section 4.5; the necessary reaction and relaxation times of one second or less are achieved.

The device is also capable of holding itself in the bent position with sufficient strength until the controls are relaxed. The steerable bougie is also capable of being manually bent should the steerable function fail. Finally, the bougie is still capable of being manually bent and can retain its shape as well as or better than the current bougie. Shape retention analysis of commercial and developed bougie introducers will be fully analysed in Chapter 7. Further development is however required to ensure the device is capable of being used in conjunction with standard laryngoscopy equipment currently utilised in practice.

4.10.1 User Feedback

To formally analyse the manufactured iteration of the steerable bougie, user feedback was collected. A small user feedback group which consisted of the three consultant anaesthetists who serve as external advisors to this PhD research were invited to a meeting where they were presented with the first working prototype of the steerable bougie. Each of the consultant anaesthetists experimented with the steerable bougie, the collated feedback provided is summarised below:

- All three users identified the increased weight exhibited at the base of the bougie where the connector is located as a significant drawback. The extension connector applied to the bougie means that this is too heavy, and the users felt that this made the bougie difficult to control and impractical to use.
- The connector design significantly reduced the operative control of the device; the gained increased control of the bougie tip was counteracted by the time required for extra manipulation control to shape the bougie.
- The bougie tip insert (which was 3D printed) was perceived to be too hard and the external outer sheath needed to be softer to prevent tracheal wall damage or damage at the hold-up sign point.
- The lack of markings on the bougie to gauge insertion depth/distance was noted along with the colour of the bougie. These design considerations are crucial factors to consider, for the initial model manufacture these were impractical to incorporate due to manufacturing restrictions. Distance markings and an accepted bougie colour are key design considerations that require further deliberation, especially if the product is to be used in some instances with video laryngoscopes where a view can be difficult to achieve.
- The unclipping of wires was highlighted a major design fault; it was explained to the user group for initial modelling purposes it was impractical to create automated push fit internal connectors due to issues with the wiring miniaturisation. It was therefore suggested an alternative connection should be utilised to ensure a plug and go scenario could be achieved.
- The connector design which utilised push pins was deemed too complicated and unintuitive. Alternatives were discussed, and bayonet twist connections or snap fit connections were perceived as the most likely to promote device adoption.

- The power pack requires significant miniaturisation; attaching this to the top of the laryngoscope or within the internals of the laryngoscope was deemed as an appropriate location.
- Although the control buttons are an adequate solution, the users suggested investigating other controls used within other airways devices, therefore alleviating device unfamiliarity if a recognised control movement is used. The roller switch controls used on the Ambu fibreoptic scope was identified as an acceptable control mechanism that is universally accepted within this type of device.
- To promote an optimum grip position, inspiration could be taken from the traffic light bougie. The traffic light bougie study (Paul et al., 2014), found that by using the pre-determined grip positions and by being able to identify insertion depth, this significantly reduced the depth of bougie placement both on initial insertion and following railroading of the tracheal tube. The traffic light bougie was deemed to help prevent the dangerous practice of inserting bougies too far and as a direct result reduced associated airway complication (Paul et al., 2014). However, it is also important to consider the concerns and recommendations highlighted by Campbell (2014) who suggests improvements to the traffic light bougie that include a green/safe zone sandwiched between two red zones alerting the operator to insufficient insertion depth, and the proximal zone which is identified as too great an insertion depth.

4.10.2 Design Improvements

One of the key issues identified with the manufactured steerable bougie model was reliability. Due to the small diameter of the tubing stipulated in the design brief and PDS, the control and steerable wires are extremely difficult to keep isolated once the ground wire was integrated and therefore this created several areas within the bougie where the electronics would either short out or create unreliable movements within the device.

As discussed, multi lumen tubing was sought to isolate each wire to allow an improvement in reliability. A potential solution identified was to use an integrated copper core ground wire inset within the multi lumen tubing which would not only increase shape retention properties of the bougie, but also isolate each of the wires within their own lumen and provide a wire capable of acting as a ground wire. Quotations were sought on the following criteria based on the engineering drawings provided in Figure 4.25:

- 660mm lengths - Minimum order of one hundred lengths.
- Outer Tube Diameter: 5mm.
- Diameter of lumens approximately 0.6-0.8mm in diameter dependant on the resolution of the extrusion machinery used for manufacture. The lumens would have to be close to the OD wall and equally separated.
- Material: Medically accepted material, ideally a material that exhibits the material properties of Low-Density Polyethylene (LDPE).
- The material must be capable of bending and flexing of up to 60 degrees in each plane on an X and Y Axis to allow the bougie shaft to match the curve of the patient's airway.
- Three or four central lumens dependant on mechanism construction and number of directional control wires.
- The tolerances for the parts are as follows:
    - 660mm Cut Length +/- 2mm.
    - 5mm Diameter OD +/- 0.05mm.
    - 0.8mm Diameter Lumen +/- 0.05mm.

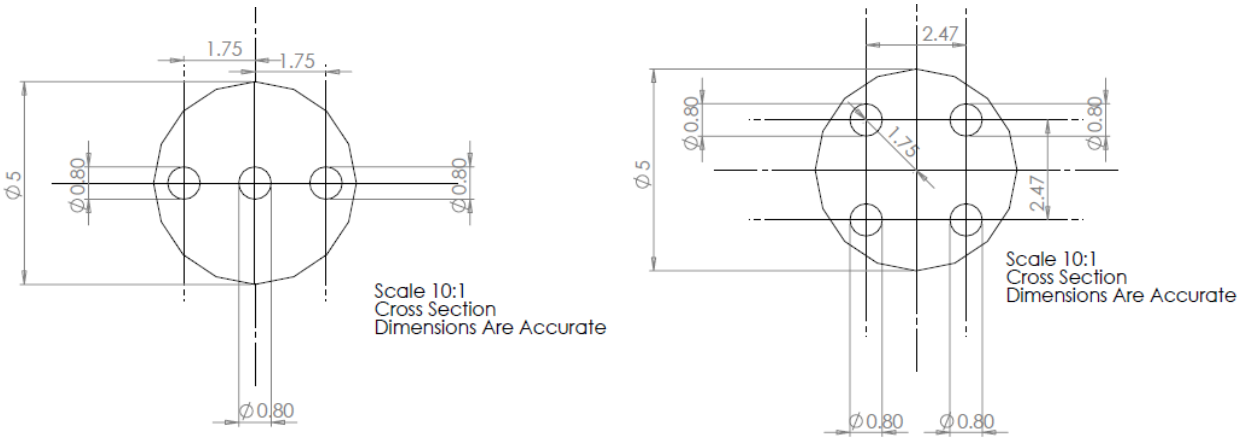


Figure 4.25: Cross Section Drawings Of Multi-Lumen Tubing

Quotations received ranged from $2500 to $6500 for an individual order of 50-100 units of the multi-lumen tubing, this was due to specialised tooling costs required to create the die for the plastic multi lumen extrusion. Several of the manufacturers of medical grade tubing offered complete development services to develop the steerable bougie further, however with the lowest quote provided costing £300,000, this was not a feasible option.

Due to the unrealistic quotations and limited budget available for product development for the initial model development, an alternative multi lumen tubing that was non-medical grade but has similar construction and shape retention properties was sourced to complete prototype development.

Another key area requiring significant design development was the tip of the bougie. Even though the 3D printed tip promoted wiring spacing and directional control movement, the hollow bougie tip also caused most of the failures within the electronic circuitry. As a result of this key design flaw for the bougie tip, an alternative method of manufacturing the flexible bougie tip will be explored.

Casting the bougie tip around the inset control wires would appear to be one of the most sensible approaches and this is explored in section 4.11. The ideal solution would be to create an initial mould where the wires connected by a crimp can be cast inset and held in position, this would allow this pre-cast to then be inserted into an outer tip mould and cast around, thus creating a solid body with miniature channels for control wire movement.

CHAPTER 5 – STEERABLE BOUGIE DESIGN DEVELOPMENT

5.1 Introduction

This chapter begins by presenting the design development improvements made to the steerable bougie based on the recommendations presented Sections 4.10.1 - 4.10.2. The design development processes and methods utilised co-align with the developed conceptual framework and the design and engineering methods discussed within the literature review. Ergonomic design considerations are implemented into the individual component designs, this is detailed throughout the development process of the steerable bougie components.

The product development of the steerable bougie also focuses on silicone casting techniques and the development of numerous bougie tips in an attempt to reduce the tip pressure forces produced compared to existing bougies on the market. Manufacturing methods and initial modelling is completed considering several detail design parameters and functional requirements for the steerable bougie. These bougies are then tested and the results reviewed with areas of improvements discussed.

Finally, an assessment of the technical specifications of suitable force gauges and pressure sensors is presented based on improving the accuracy and validity of the data collected from the initial sampling. By increasing the accuracy and resolution of the data captured from the initial testing of the bougie tips this will ensure that a larger equipment assessment study can be conducted.

5.2 Design Improvements – Steerable Bougie Iteration 5

Based on the user feedback collected and presented in Chapter 4, significant design revisions were required to the steerable bougie; this mainly related to the connector and the unsuitable control box placed in between the controller and the bougie. The fifth iteration of the steerable bougie is shown in Figure 5.1.

The large control box has been removed; the power supply has been connected to the device controller and is attached by a tolerance seal fit to the outer diameter of the laryngoscope. It was initially proposed that the power supply/battery connector could be built within the laryngoscopes, however due to the various types of laryngoscopes used in practice and the variable size and shape, the sensible approach is to have this connect to the existing laryngoscope.

In addition, by incorporating an additional power supply within the hollow section laryngoscope, this would also require the laryngoscopes certification documentation and CE marking to be reviewed to ensure conformity to the necessary standards due to housing a larger power supply than stated within its technical file documentation.

To ensure this is not a weighty addition to the laryngoscope, button cell batteries or AAA batteries will be utilised to power the controller, however, upscaling the voltage will be required to ensure that adequate voltage supply to the control wires to ensure functionality is achieved. To ensure the battery clip and the controller stay connected and can be powered using the same power supply an extendable adjustable slider has been incorporated into the controller.

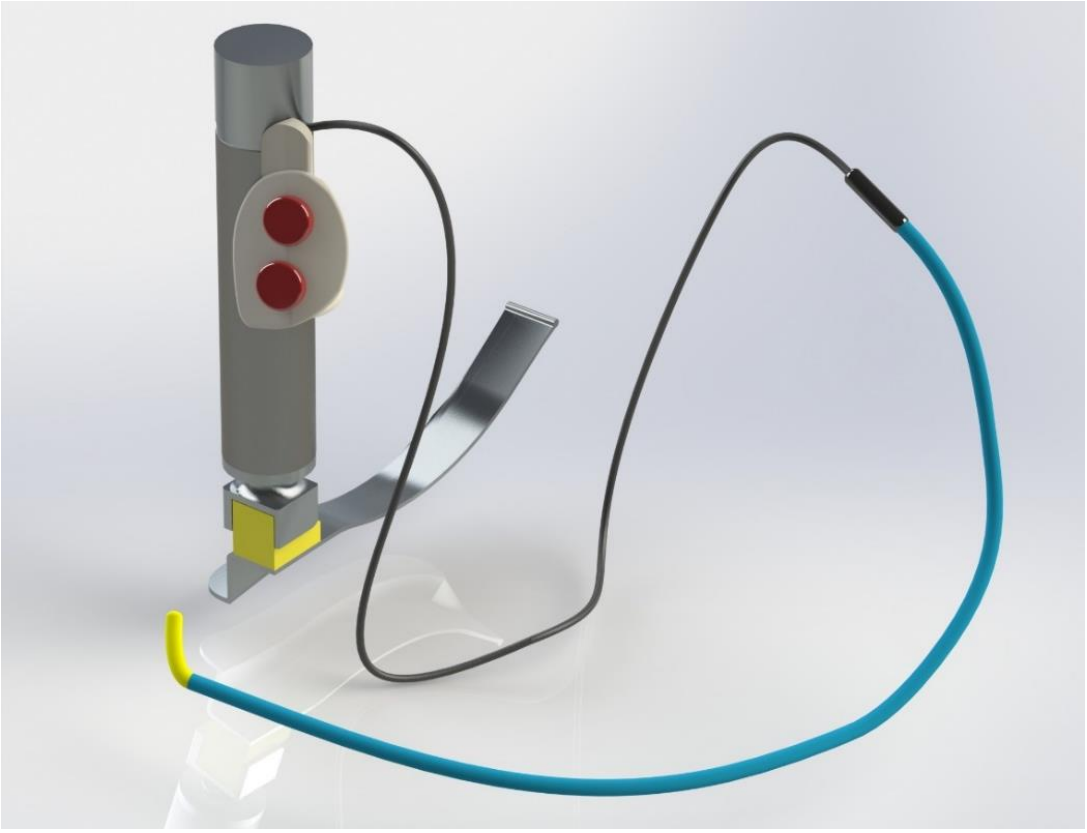


Figure 5.1: Steerable Bougie Design Iteration 5 Assembly

Upon reflection and review of the design of the controller, the location of the directional control buttons that are offset from the centre axis of the laryngoscope cause the user to stretch further with their thumb, which will affect the devices ease of use and its perceived comfort. After review from the project advisors (consultant anaesthetists) it was decided that further redesign work would be necessary for the controller as it was suggested that a joystick ball joint mechanism or a roller switch control system should be used.

The original design proposed by Hughes (2013) identifies that the steerable bougie should incorporate a new adaptor (Figure 5.2) to allow the control wires to be connected to and disconnected from when railroading of the endotracheal tube. Alternative connectors have been explored during the initial design process; finding a solution to avoid the expensive manufacturing costs associated with miniature connector development must be solved.

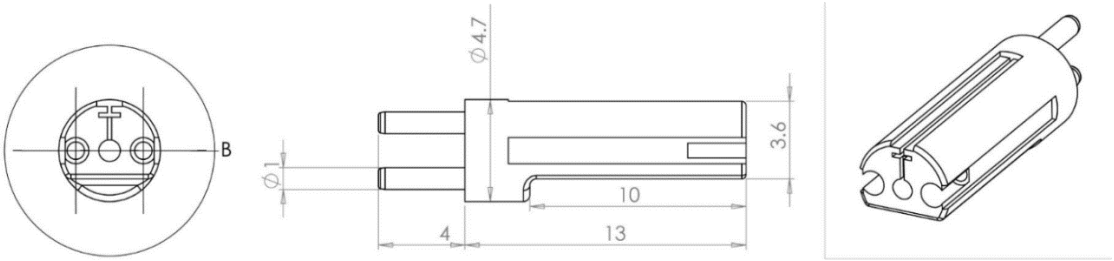


Figure 5.2: Control Adaptor Original Design (Credit – Hughes, 2013)

The manufacture of the connector presented in Figure 5.2 would be a complex and expensive task due to the small-scale detail design and injection moulding processes required. In addition, this would add more expense to the steerable bougies manufacturing cost and the product's subsequent resale value would be more expensive, making this less likely to be used in practice. After further investigation, the use of a 3.5 mm cable mount stereo jack adaptor and socket, which is a readily available part at most electronic outlets and is low cost (<£1.00), is an appropriate alternative. Not only does this type of connector have the required number of connection mounting points, but the quick release mechanism and push fit connections would be simple to operate single handed. Typically, 3.5mm cable mount stereo jacks, even with the outer protective insulation sheath, range between 5-7mm in diameter. Railroading an endotracheal tube over the top of this would not be an issue, however a stable mounting point will be required.

The rating of the connector and the cabling however will require some consideration, especially due to the control wires required power supply, for example, when considering Flexinol® actuator wire which is 0.15mm in diameter, this has a maximum resistance of 55 ohms per meter and an approximate current for one second contraction of 410mA (Dynalloy.com, n.d.). Using Ohms Law, this therefore suggests that when using a one metre length of 0.15mm diameter Flexinol® actuator wire, this will require a 22.55V power supply to adequately activate the control wires. Integrating a pulse width modulation setup would significantly increase the working life span of the Flexinol® actuator control wires; this has proven to add greater control and multi-step actuation to many shape memory alloy actuator applications as highlighted by Ma and Song (2003) and Lee et al., (2006). Further development of design iteration 5 will be described in section 5.3; this focuses on the

development of the tip and the casting method utilised to investigate and achieve different grades of tip flexibility.

5.2.1 Controller Handle Re-Design

As discussed in section 4.10.1 there are several areas of the original design that require further development, one of these being further development of the controller handle. One of the most intriguing points highlighted within the user feedback, was that the controllers directional control buttons had an element of unfamiliarity due to this being button based, which is not a common feature on many emergency airway control devices. To alleviate device unfamiliarity within the controllers directional control movement, it was suggested that a joystick ball joint system or a roller switch control system similar to that of an Ambu fibreoptic scope should be utilised.

For the controller movement, it is also imperative to consider the size of the vast number of different users that can use the device, both male and female and as such the level of comfort using the device is imperative. The user's hands and the potential size of the handle must therefore be taken into consideration during the re-design of the controller. As this controller is to be mounted to the laryngoscope, the manufacturers of these devices stipulate the size of the handle, this cannot be altered. However, considerations can be made concerning the comfort and usability of the controller when attached to the laryngoscope. One of the most essential elements to consider is the users thumb length (a), thumb breadth (b) (measured at the interphalangeal joint) and the users thumb thickness (c) (measured at the proximal interphalangeal joint) Pheasant and Haslegrave, (2016) (Refer to Figure 5.3)

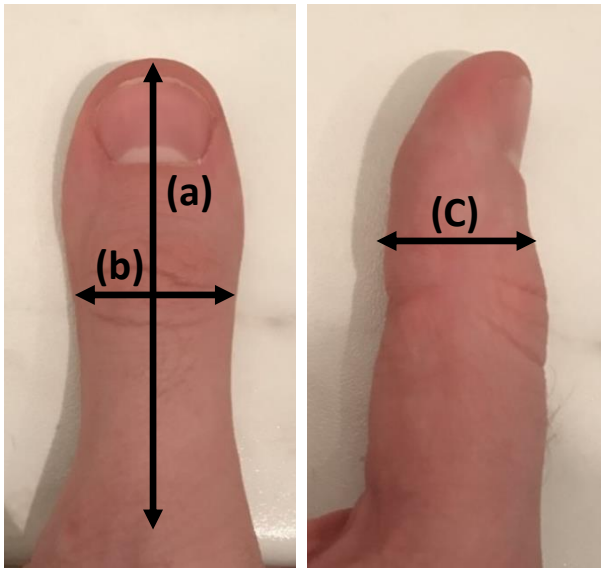


Figure 5.3: Thumb Measurement Locations

Pheasant and Haslegrave, (2016) provide anthropometric estimates for the hand for both males and females based on these measurements; the following data must therefore be considered when designing the control handle lever for men:

- Male Thumb Breadth 5th%ile: 20mm.
- Male Thumb Breadth 50th%ile: 23mm.
- Male Thumb Breadth 95th%ile: 26mm.
- Male Thumb Thickness 5th%ile: 19mm.
- Male Thumb Thickness 50th%ile: 22mm.
- Male Thumb Thickness 95th%ile: 24mm.
- Male Thumb Length 5th%ile: 44mm.
- Male Thumb Length 50th%ile: 51mm.
- Male Thumb Length 95th%ile: 58mm.

The following data must be considered when designing the control handle lever for women:

- Female Thumb Breadth 5th%ile: 17mm.
- Female Thumb Breadth 50th%ile: 19mm.
- Female Thumb Breadth 95th%ile: 21mm.
- Female Thumb Thickness 5th%ile: 15mm.
- Female Thumb Thickness 50th%ile: 18mm.
- Female Thumb Thickness 95th%ile: 20mm.
- Female Thumb Length 5th%ile: 40mm.
- Female Thumb Length 50th%ile: 47mm.
- Female Thumb Length 95th%ile: 53mm.

Based on the above-mentioned dimension considerations, the following dimensions have been stipulated for the design of the controller. The controller must be no higher than 40mm from the top of the outer diameter of the laryngoscope; this is based on the smallest user thumb size which is female thumb length/reach of 40mm. This will ensure users with the smallest and largest of thumb lengths do not have to over stretch their thumb to use the controller. However, it is imperative to ensure that the controller can be moved further away from the user if necessary for those users who have large thumb reaches, which would suggest that a controller button distance too close to the user would be uncomfortable.

Considering thumb dimension and anthropometric data presented by Pheasant and Haslegrave, (2016), dimensions for the button/slider/roller have been defined as requiring a minimum width of 30mm. The 30mm minimum button slider dimension ensures that users with the smallest of thumbs or the largest of thumbs still have a large enough surface area to place their thumb on the button and comfortably manipulate this to steer the steerable bougie accurately. Figure 5.4 presents the CAD model of the re-designed controller/adaptor.

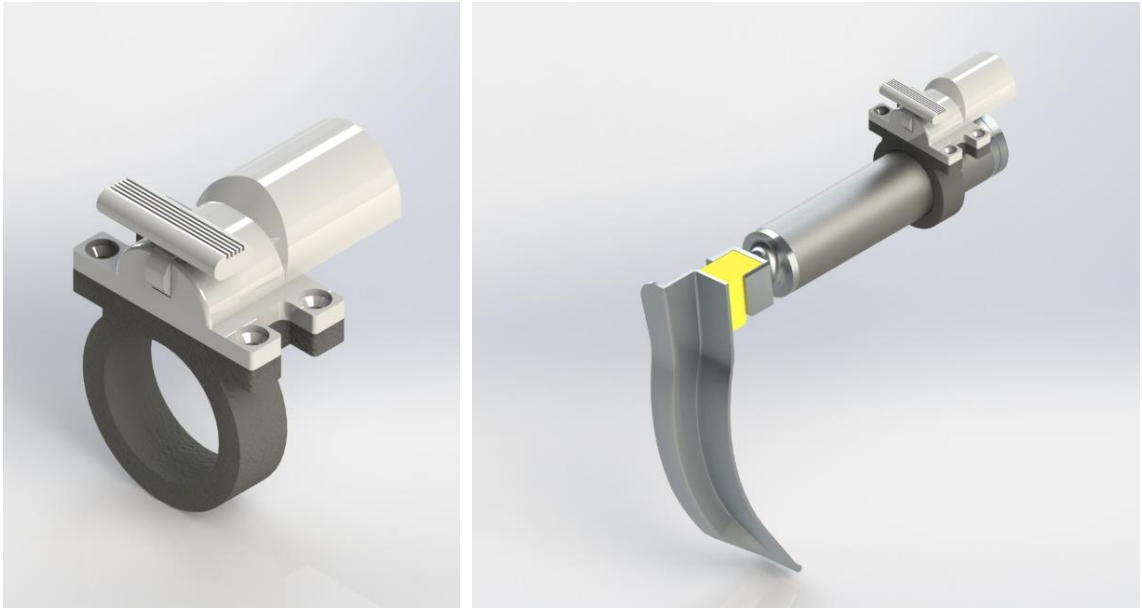


Figure 5.4: Re-Designed Controller Adaptor (Left), Re-Designed Controller Adaptor Attached To Laryngoscope (Right)

The controller design presented in Figure 5.4 has been prototyped utilising a Form 2 3D printer and constructed using two different materials (Figure 5.5). The support that encompasses the laryngoscopes shaft outer diameter was manufactured out of the Form 2's Flexible Resin that is recommended for the production of handles, grips and over moulds and has excellent material properties that help simulate the effects of soft-touch materials in addition to adding ergonomic features to multi-material assemblies (Formlabs.com, 2016).

In addition, the compression characteristics (0.40% compression set) and 75-87% elongation at failure, suggests that this material is suitable for creating parts that can act as custom grips (Formlabs.com, 2016). The controller itself where the batteries are encapsulated is manufactured using the standard black rapid prototyping resin that allows for precise concept modelling at an affordable cost.

Figure 5.5: Manufactured Form Model Of The Control Adaptor Attached To A Proact Laryngoscope.

The modelling of the controller has identified a few areas that require design improvement and will be resolved in the final design development work to be completed:

1. To allow full integration and use on the wide variety of laryngoscopes and video laryngoscopes, the controller adaptors O-Ring support should be manufactured similar to that of a watchstrap with a simple hook or clip connection to lock this tightly into place. Manufacturing this out of a medical grade rubber, medical grade silicone or thermoplastic polyurethane (TPU) material would also ensure that this could be reused and sterilised repeatedly when disconnected from the steerable bougie main shaft.
2. Although the control switch that currently uses a roller switch connection is a suitable solution, to ensure future proofing of the product should the steerable bougie be further developed to allow four directions of movement, a thumb joystick similar to that of a PlayStation controller could be used; however, this will still allow the device to solely run on two directions of movement. The design of the controller thumb locator will however be integrated into the thumb joystick top ensuring that the design considerations and ergonomic/anthropometric features are combined.

3. The battery storage area of the controller is too small. This was initially designed to allow multiple button cell batteries (type C) to be placed in parallel, however with an increased power supply unit required and integration of pulse width modulation via a control board necessary, based on this alone, a larger controller body with greater storage space will be required to allow all the internal electronics to be stored. Increasing this size but also considering the weight ratio applied to the laryngoscope will require equal distribution of weight to ensure any additional weight doesn't restrict operative control.
4. The controller also fails to adhere to one of the critical product design specification criteria stating that a battery indicator is required. This battery indicator must be a visual indicator for low power if the batteries require changing to ensure the steerable bougie can be controlled throughout the procedure. The changing of batteries must be done easily and quickly especially if this process needs to be completed prior to airway management. Induction charging/rechargeable batteries are another alternative; however, this requires an extra task for the user to complete and will rely on best practice for this to be completed. Simply changing the batteries is the simpler and more reliable option.

5.3 Steerable Bougie Design – Iteration 5 Development

As described in section 4.10.2, pre-inserting the control wires using a casting approach was to be explored as an alternative modelling and manufacturing method for the bougie tip design. Utilising a casting approach will negate the need for the reproduction of expensive high micron miniature 3D printed parts with detailed internal features. Manually casting the bougie tips would allow an investigation to take place into the design of the bougie tip but also the material properties including crucially the shore hardness of the bougie tip which will correlate to the bougie tip pressure.

Due to inexperience with silicone casting, training on silicone casting was undertaken. Due to inexperience of mould design, initial moulds were designed in conjunction with the Medical Engineering Unit at Queens Medical Centre, Nottingham, UK; this provided insight into the design process for moulding and will ensure that future mould designs can be completed independently. Figures 5.6 and 5.7 present the initial moulds designed; these were then 3D printed using a MakerBot 2 Experimental Replicator. The designed moulds represent a two-part casting process, the smaller mould creating a precast for the mechanism wires to be anchored around a crimp which will then be cast inside the larger moulds to create the steerable tip which is bonded to the multi lumen tubing main shaft.

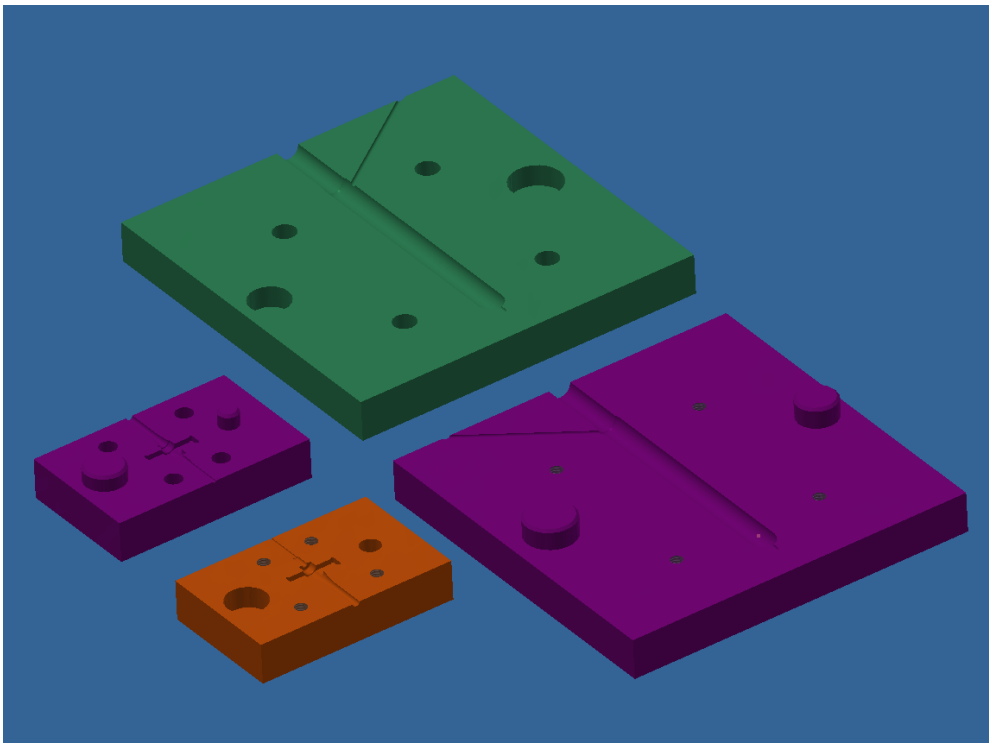


Figure 5.6: Initial Casting Mould Designs for Steerable Bougie Tips

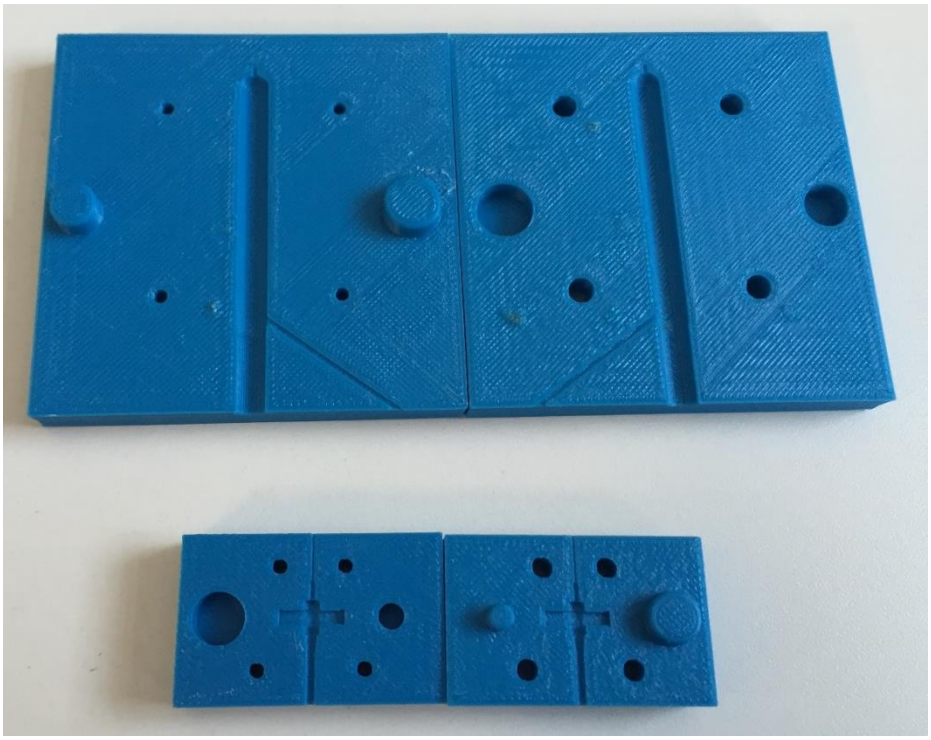


Figure 5.7: 3D Printed Casting Moulds for Steerable Bougie Tips

Figure 5.8 presents an initial trial cast utilising the 3D printed moulds to establish whether the designed mould can produce an accurate part. Appendix F presents the risk assessment for this process). Using a standard silicone with a shore hardness of 20A, it was clear that adjustments to the mould were required. The mould required an injection point with a greater diameter and needed relocating to allow for the part to fill up from the bottom up, thus ensuring that any bubbles or air pockets within the mould could be reduced. A second higher quality 3D printed mould was created as shown in Figure 5.12 with adjustments made to the injection and air escape funnels as well adjusting the mould connections to allow a tighter bond to be created.

Figure 5.8: Casting Trial Of Flexible Bougie Tip Utilising Green Silicone (Shore Hardness 20)

Utilising a redesigned version of the 3D printed trial moulds, several tips were manufactured, these are shown in Figures 5.9 and 5.10. These tips were cast using several different methods including injection casting, pour casting, two-part casting including the use of bonding agents, etc. From the initial trial casts, it was established that a silicone with a shore hardness of 30-60A presented a level of stiffness that would allow for adequate tip control but would still provide enough shape retention required during intubation procedures for manual insertion. Further testing on the tip pressures associated with solid tips with shore hardness's of 30-60A will be required and presented in Chapter 6.

Figure 5.9: Flexible Tip Cast Out Of Medical Grade Silicone

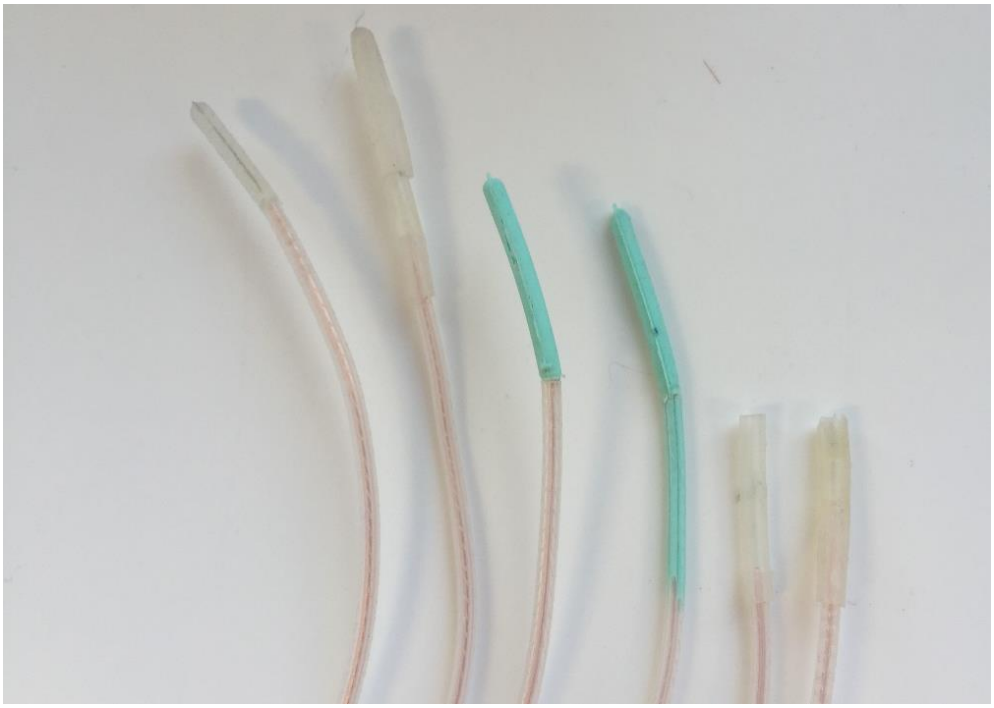


Figure 5.10: Produced Flexible Tips Cast Using Different Techniques

After completing the trials casts, final alterations to the bougie moulds were required; these revisions are shown in Figure 5.11. The original dimensions ensured that the tip mould would be 50mm in length and 5mm diameter, however this was altered and an additional length of 20mm was added to the mould. This ensured that the lumen tubing could be inserted at different depths allowing various tip lengths to be produced for testing.

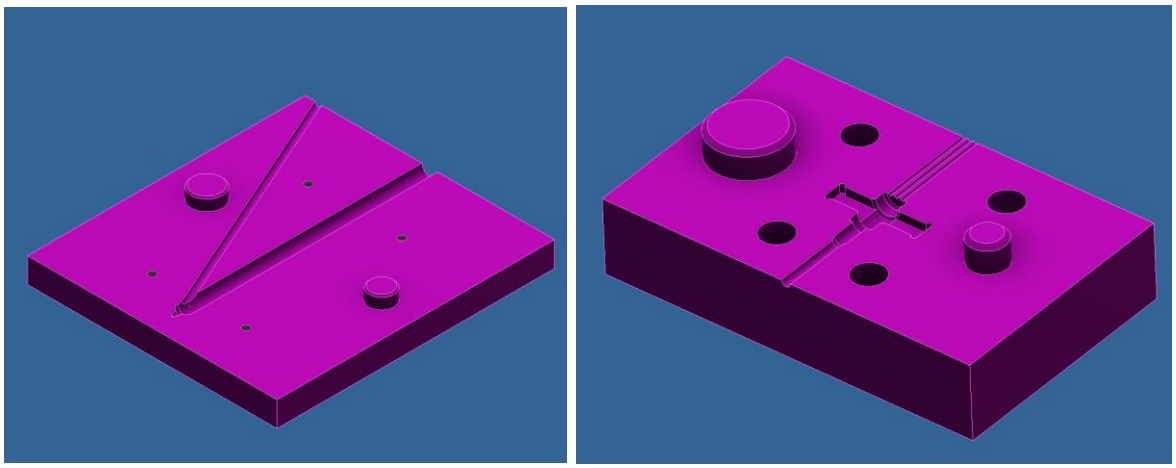


Figure 5.11: Altered Casting Moulds Based on Tip Casting Trials

One of the key redesigns is the injection point, this has been modified in position to the base of the mould but located around the bolt points to ensure air pockets do not get stuck within the problematic areas of the mould. Additionally, the pre-cast mould has been edited to ensure that the pre-inserted wires cannot bond together; individual wire locators have been added to the mould as shown in Figure 5.12.

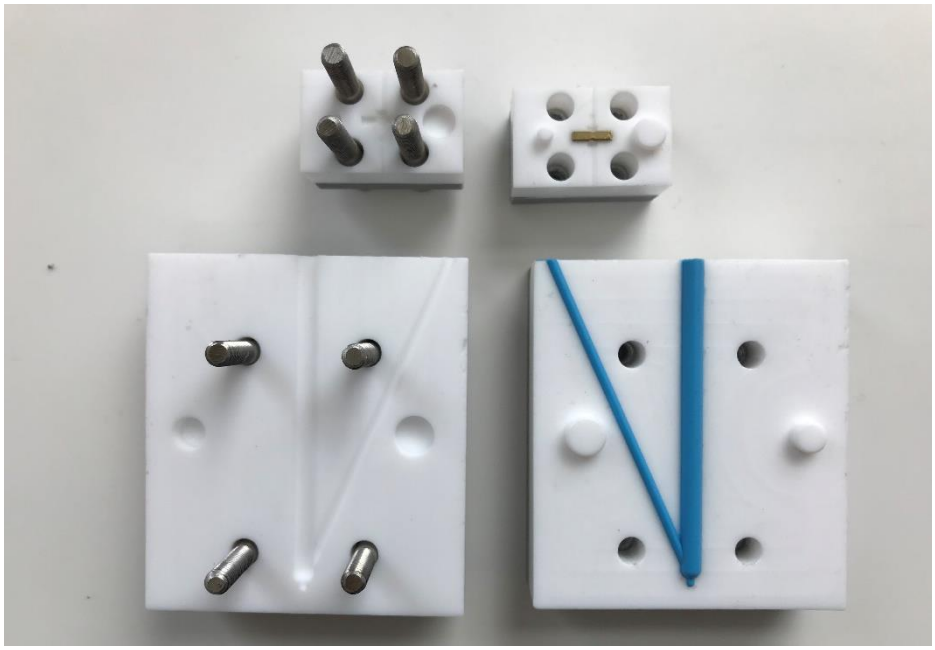


Figure 5.12: Manufactured Moulds

Finally, an outer support for the moulds to secure the multi lumen tubing and wiring is to be manufactured; the final casting rigs are presented in Figure 5.13.

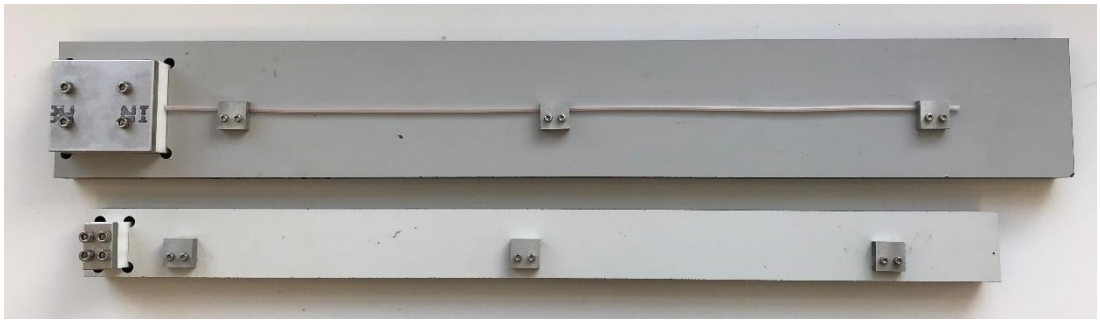


Figure 5.14: Manufactured Moulds & Supporting Structure

Chapter 6 presents a detailed analysis of the physical tip pressure properties of the manufactured steerable bougie tips; however, Chapter 5 section 5.4.3 presents the initial tip pressure testing. Upon receiving delivery of the manufactured silicone casting moulds, nine different silicones were used to create a sample of trial bougies ranging from shore hardness values of OO to 10A – 50A. The silicones used were as follows:

- Smooth-Sil 935 (Light Blue).
- Smooth-Sil 940 (Pink).
- Smooth-Sil 950 (Mild Blue).
- Transil 40-1 (Clear).
- Transil 20 (Yellow).
- Platsil Gel-25 (Orange).
- Platsil Gel 10 (Red).
- Platsil Gel 00 (Green).
- BlueSil RTV 3428 (White).

Once the sample bougies had been manufactured (see Figure 5.14), these bougies were presented to the small user feedback group which consisted of the three consultant anaesthetists. Individually and under no influence, they were asked to select their top three bougies based on three criteria points:

1. Perceived ability to be used as a steerable tip and capable of being controlled within the trachea.
2. Hardness/Stiffness - Perceived Tip Pressure.
3. Texture.

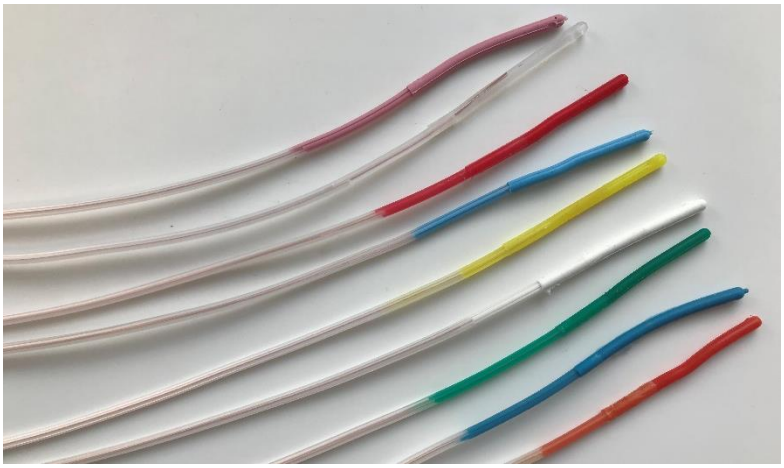


Figure 5.14: Sample Of The Initial Manufactured Cast Bougies

Each of the anaesthetists selected three bougies which were to be used to manufacture a larger sample of bougies for future testing. All three anaesthetists selected the same three bougies without any ranking; they were then asked collectively to rank the bougies. The rankings were as follows: Rank 1: Smooth-Sil 950, Rank 2: Smooth-Sil 935 and Rank 3: Smooth-Sil 940. Based on this ranking the following bougies were manufactured to be used for full comparative tip testing which is presented in Chapter 6:

- Smooth Sil 950 – 15mm Wire Indent, 10 mm Mould Indent (60mm Straight Tip) – 11 Bougies @ Original + 5% Increments of Hardener Up To 50%.
- Smooth Sil 950 – 25mm Wire Indent, 20 mm Mould Indent (35mm Straight Tip) – 11 Bougies @ Original + 5% Increments of Hardener Up To 50%.
- Smooth Sil 935 – 15mm Wire Indent, 10 mm Mould Indent (60mm Straight Tip) – 11 Bougies @ Original + 5% Increments of Hardener Up To 50%.
- Smooth Sil 935 – 25mm Wire Indent, 20 mm Mould Indent (35mm Straight Tip) – 11 Bougies @ Original + 5% Increments of Hardener Up To 50%.
- Smooth Sil 940 – 15mm Wire Indent, 10 mm Mould Indent (60mm Straight Tip) – 4 Bougies @ Original + Hardener (Original, 10%, 30% & 50%).
- Smooth Sil 940 – 25mm Wire Indent, 20 mm Mould Indent (35mm Straight Tip) – 4 Bougies @ Original + Hardener (Original, 10%, 30% & 50%).

In addition to the above mentioned bougies, eight additional bougies with Coude tips were also manufactured at two-degree incremental angles with the following material and component variations in-order to investigate the effects coude tips could have on silicone cast bougie tips:

- Smooth Sil 935 – 25mm Wire Indent, 20 mm Mould Indent (35mm Straight Tip).
- Smooth Sil 935 – 25mm Wire Indent, 20 mm Mould Indent (35mm Straight Tip) + Hardener (Original, 10%, 30% & 50%).

The Coude tip moulds as shown in Figure 5.15 had to be developed; the production of the CAD designed moulds incorporated casting design considerations concerning demoulding, degassing, air bubble extraction, locator pins and injection points.

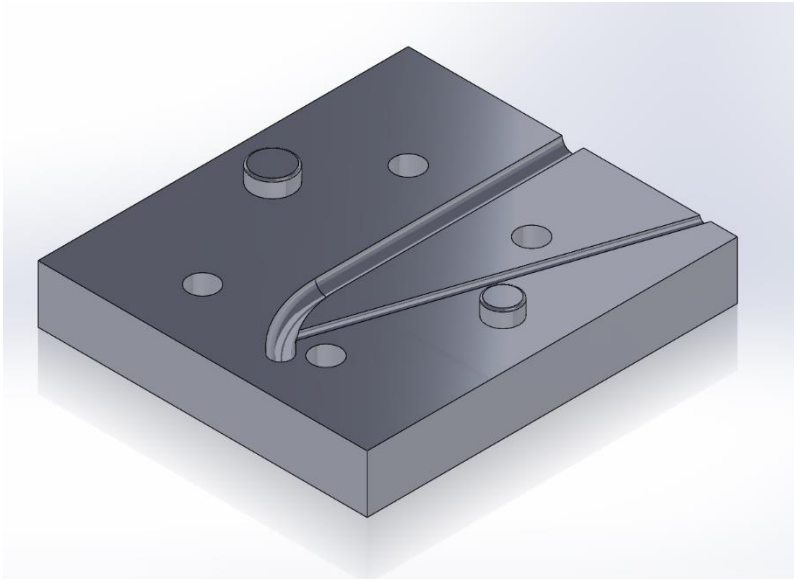


Figure 5.15: Coude Tip Mould

Due to the cost of the CNC routered moulds presented earlier in Figure 5.12, high accuracy 3D printing was to be used to manufacture the coude tip moulds due to their low volume part manufacture requirements. To replicate the accuracy of the CNC routered moulds, a 3D Systems ProJet 3500HD Max medical grade 3D printer capable of producing parts up to 16 microns in accuracy was utilised. After 3D printing the parts, the standard post processing of melting away the wax support in a sunflower oil solution was conducted at a temperature of 80^{o}C. The parts once removed from the sunflower oil solution required cleaning and sterilisation ready for the casting process to be undertaken; the 3D printed moulds are presented in Figure 5.16.

After completing the casting process several times, the Smooth Sil 935, 940 & 950 material refused to set inside the mould and this continued to occur regardless of the significant sterilisation and cleaning processes that were undertaken. After reviewing the technical data specification of Smooth-Sil silicone material, it was discovered that the silicone was reacting with the wax-based surface of the mould and when it was capable of setting this was tripling

the cure time of the material from twenty-four hours to seventy-two hours in the cases when multiple sterilisation processes were conducted.

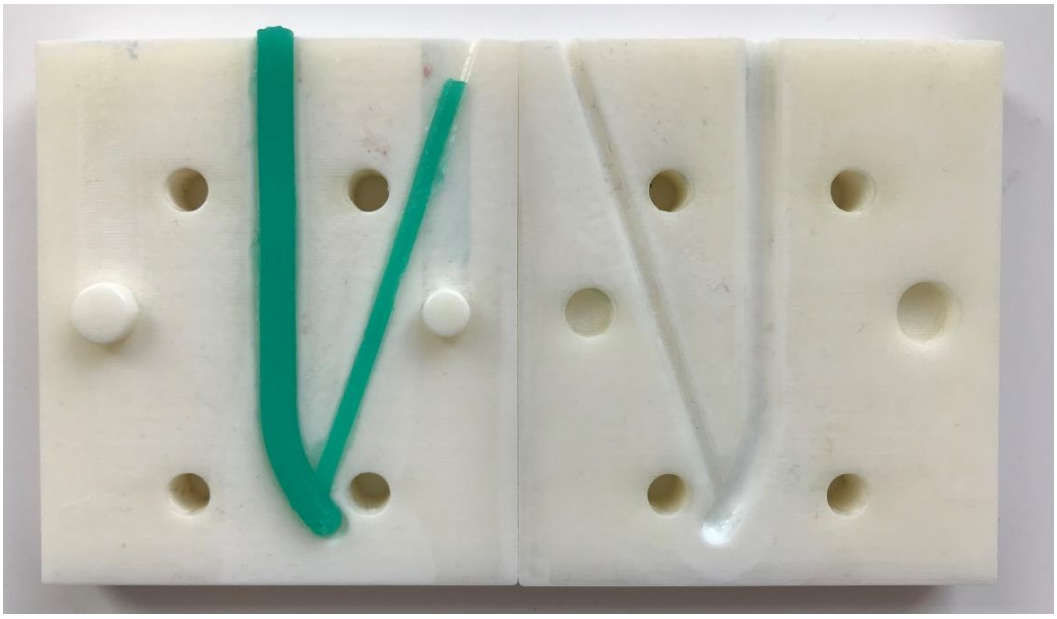


Figure 5.16: 3D Printed Coude Tip Mould

The recommended solution to ensure the material reacted in the desired manner was heating the moulds once the casting process was completed. Unfortunately, heating the part to instigate the catalytic reaction for the curing and hardening process was not possible as the mould and bougie insert would not fit in the oven due to the 750mm length setup; as result of this, other options needed to be investigated.

To prevent the waxy wall finish reacting with the Smooth Sil material, an extra demoulding agent was applied to the surface of the mould (Vaseline). The demoulding agent again did not coat the moulds outer surface sufficiently to alleviate the wax coating and allow the material to cure, so other alternatives were to be explored.

The next option investigated was to sweat the moulds to reduce the waxy surface of the mould. To sweat the moulds and capture the excess wax and water exposed to the surface of the mould, the moulds were placed in an oven at 100^{o}C and covered with extra absorbent crystals. After sweating the moulds for one hour, the casting process was attempted again; this again failed. A second mould was sweat for two hours, however, again this casting process failed.

Finally, to further post process the moulds; a light coating of spray on lacquer was applied to the moulds in two layers. The two-layered lacquer adequately sealed the waxy surface of the mould and provided an optimal surface finish that allowed the bougies to be cast with the

desired Smooth Sil 935, 940 and 950 materials. To accommodate the spray on lacquer the dimensions of the 3D printed parts were altered because of the surface finish; reprints of the moulds were then required. The eight bougies were then cast, an example of one of the coude tip bougie sets is presented in Figure 5.17.

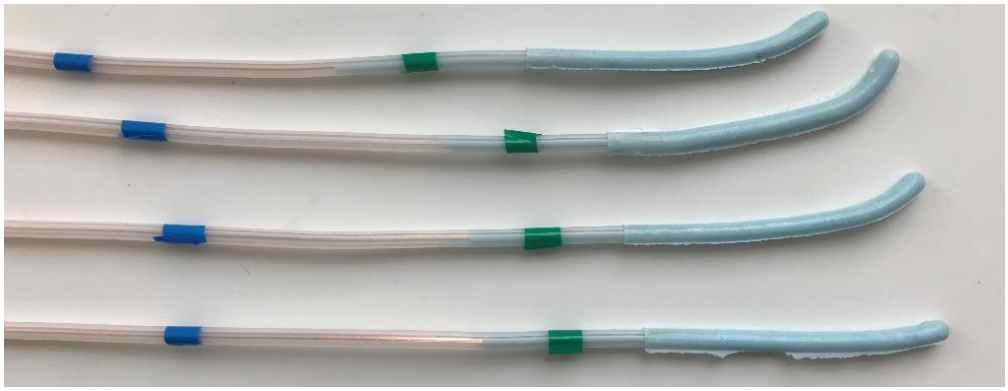


Figure 5.17: Cast Coude Tip Bougies

5.4 Initial Tip Pressure Testing

The correct selection and safe use of optimally designed equipment is just one aspect of difficult airway management; recent equipment improvements have been shown to improve airway management success and safety rates, however these devices have not all been tested against DAS's ADEPT guidelines (Pandit et al., 2011). It is imperative that any equipment used is fit for purpose; causing further complications because of device failure during airway management procedures must be avoided.

Testing of intubation introducers and bougies tip pressures is required utilising suitable equipment to help inform device manufacture and selection. The purpose of this initial tip pressure testing is to assess the constructed testing setup and a sample of the bougies manufactured. Upon completing this testing an application to Nottingham Trent University's Joint Inter College Ethics Committee will be submitted to complete this study within a hospital environment to assess the designed steerable bougie against a selected set of commercial bougies.

Considering the measurement methods inaccuracies discussed in Chapter 2, which was specifically related to equipment use in experiments conducted by Marson et al., (2014) and the use of a Mecmesin PF 500N and Hodzovic et al., (2004) and Janakiraman et al., (2009) use of a Mecmesin PFI200N, an alternative force gauge or pressure sensor with the required resolution and accuracy was to be sourced and used. After reviewing several force gauges and pressure sensors a SingleTact capacitive force sensor was identified (SingleTact, 2016).

The SingleTact sensor can be provided in both an uncalibrated format ($15.00 + $23.00 I2C board) and can be used with free Arduino data acquisition software or in the form of a calibrated sensor ($74.95 complete set).

The calibrated sensor was purchased after reviewing the technical specification of the product, the standard uncalibrated sensors was described as non-linear whereas the calibrated sensor linearizes the output and ensures that the full-scale output matches full-scale input (SingleTact, 2017). To ensure the data can be captured within the optimum range and considering any inaccuracies with the bottom end of load cell and force gauge readout, a SingleTact 45N sensor was to be utilised. The use of the SingleTact 45N sensor considers the data range presented within the studies completed by Marson et al., (2014), Hodzovic et al., (2004) and Janakiraman et al., (2009). As the SingleTact 45N sensor also has a force resolution of <0.2% of the full-scale deflection (FSD) this equated to an accuracy of +/- 0.09N which is significantly more accurate than the equipment used in the aforementioned studies.

To ensure that the testing could be conducted utilising the SingleTact 45N sensors, a small testing setup was required to be manufactured (Figure 5.18). Utilising white standard resin from the Form 2 3D printer, a shell to encapsulate the sensor was manufactured and mounted to a laser cut Perspex board which displays 10cm incremental markings to inform the participants of the distance from the tip of the bougies they will be asked to hold as they press it against the sensor.

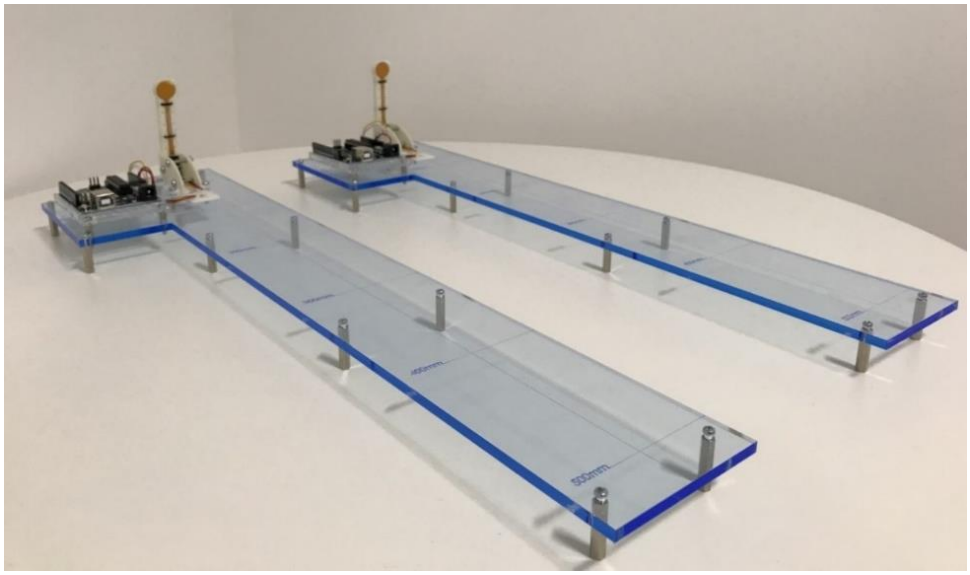


Figure 5.18: SingleTact 45N Tip Pressure Testing Setup

5.4.1 Method

The purpose of this initial testing is to compare the tip pressures generated based on a sample of the cast bougies. Initially, two consultant anaesthetists within the project team were recruited to assess the testing equipment and a commercially available bougie. Force/pressure readings are recorded as the anaesthetists press the bougies against the SingleTact sensor and are repeated at 10cm intervals from the tip with the aim of discovering the optimum grip position that exhibits the lowest tip pressures.

An example of the testing environment/data acquisition setup can be seen in Figure 5.19. The operator of the bougies is instructed to press the bougies and generate a maximum tip pressure when pressed against the force sensor where the data acquisition software will collect data and plot graphs.

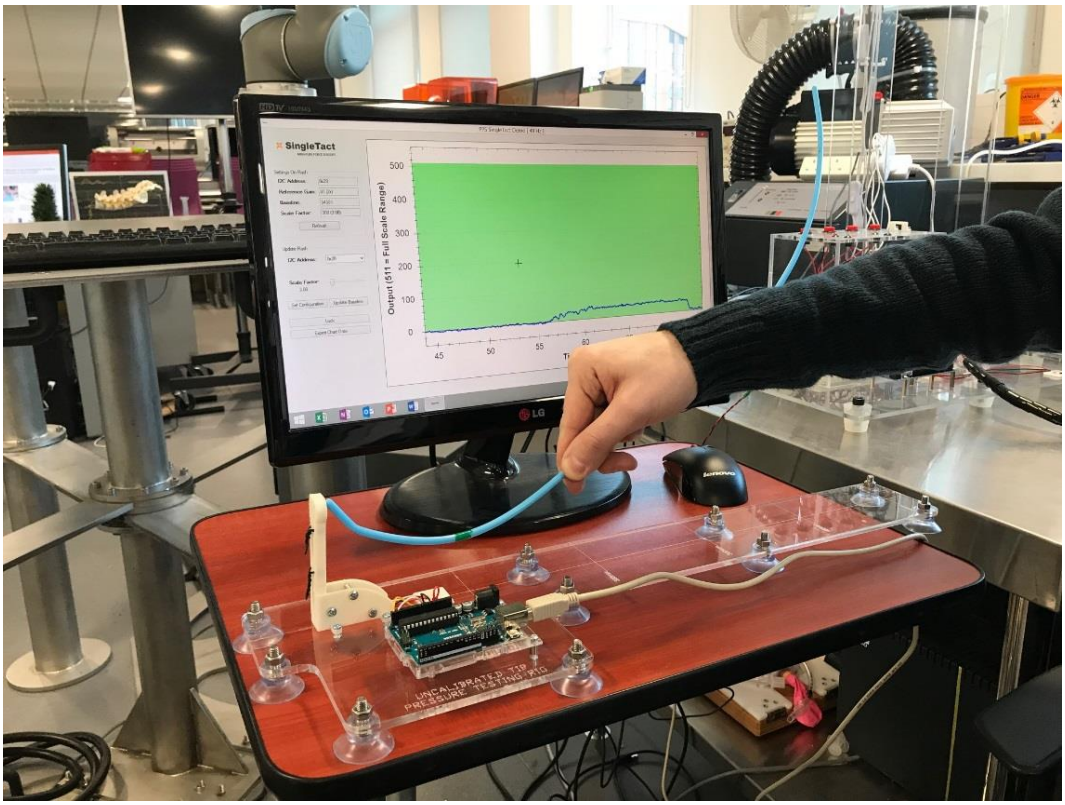


Figure 5.19: Testing Setup & Data Acquisition Software

As forty-four bougies had been manufactured for initial assessment, to reduce the testing time during for this initial trial, both anaesthetists, separately and under no influence, were provided with a set of eleven bougies manufactured from Smooth Sil 950 and eleven bougies manufactured from Smooth Sil 935 with a 15mm wire indent and a 10 mm mould Indent (60mm Straight Tip). Each bougie was graded from the original mix with incremental 5% increases of hardener up to 50%. Each bougie was given a colour coded tip in a random order,

both of which were different for each type of Smooth Sil. They were instructed to select four bougies from each set of eleven based on feel, haptic tip pressure feedback and texture.

Both participant one and two selected the exact same bougies which equated to the 30 – 45% increment range. Participant one also stated that the dark brown tipped bougie (Smooth Sil 950 +25% hardener) was of a suitable texture, however they were concerned with its perceived floppiness and its ability to be navigated down the trachea without kinking; for this reason, this bougie was excluded. Before the initial testing commenced, both participants were instructed on the protocol for the testing (Figure 5.21) and the participants acknowledged and confirmed this was clear and that they understood the testing instructions.

To ensure standardisation of grip position, each of the bougies was individually measured and markers were placed on the bougies at 10cm intervals from the bougie tip (as shown in Figure 5.20)

Figure 5.20: Bougie Grip Positions

Finally, the participants were notified that the bougies they had selected would also be compared to the most commonly available bougie utilised within practice at Nottingham University Hospitals Trust (QMC) that was the Sun-Med 15FR x 700m and is available for use on most difficult airway trolleys.

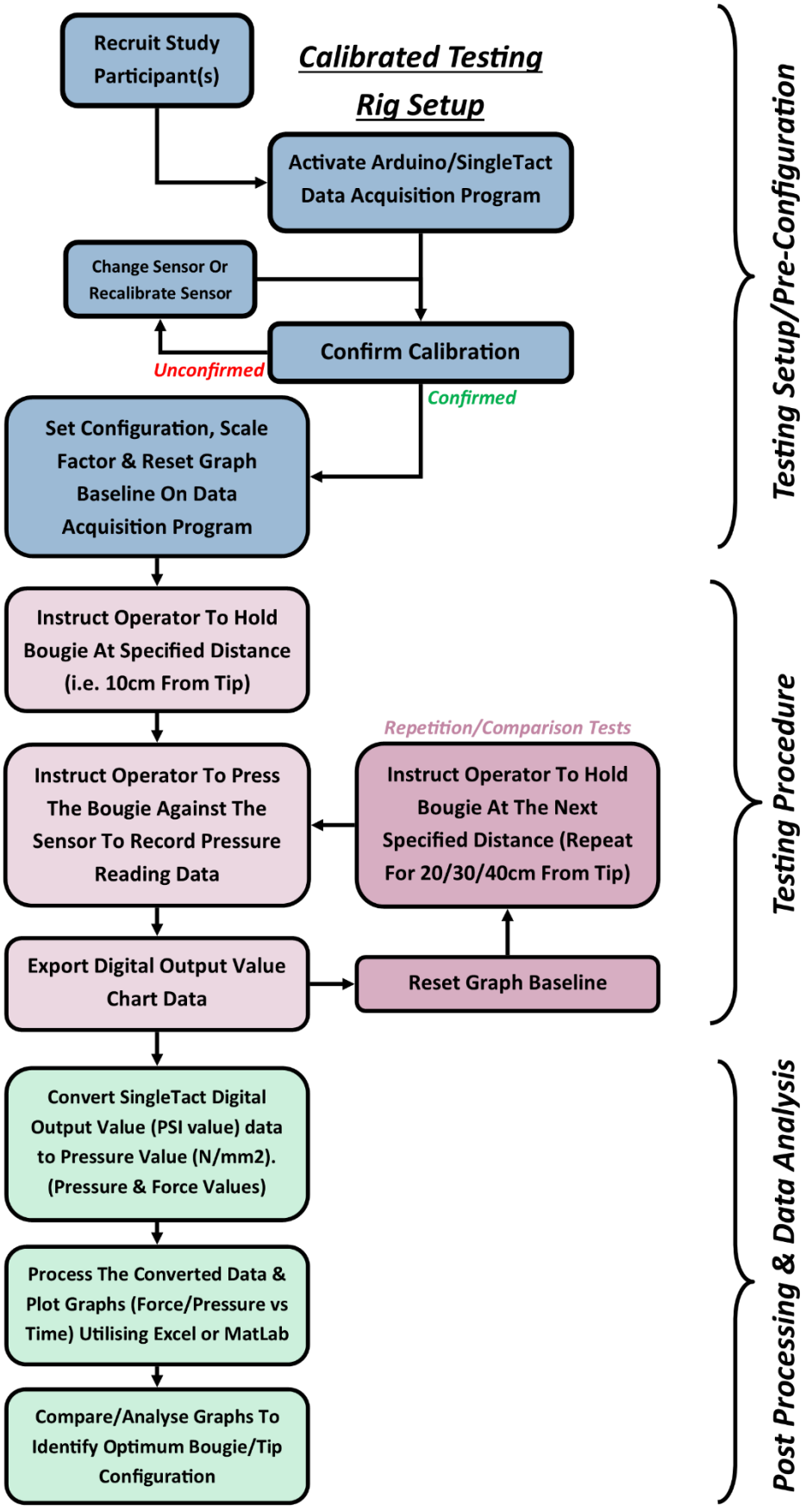


Figure 5.21: SingleTact Tip Initial Pressure Testing Protocol

5.4.2 Results

Upon collating the results, it is evident that the data presents several trends similar to those presented by Marson et al., (2014) and Hodzovic, Wilkes and Latto (2004). Typically holding the bougie 10cm from the tip of the bougie presented the highest tip pressures; however, within Tables 5.1, 5.2, 5.3 and 5.4 there is a significant amount of data which doesn't correlate to the expected trends; this data is highlighted in pink. Initial assessment of the data suggests that although the selection of the SingleTact sensor based on the TDS data was a sensible choice, the number of unexpected trends suggests there are other inaccuracies that require further consideration.

The tip pressures captured should be at their highest when the bougies are held at 10cm from the tip, this should then decrease significantly when 20cm from the tip and then decrease again when held 30cm from the tip. When held at 40cm from the tip, the tip pressures are usually similar to those exhibited when a bougie is held at 30cm from the tip.

Anderson, Hodzovic and Wilkes, (2011) also present a similar trend when tip pressures are analysed in relation to the force exerted when simulating pressure at the hold-up sign. Anderson, Hodzovic and Wilkes, (2011) discovered that the Frova introducer exerted significantly greater force during hold-up compared to the BreatheSafe or Eschmann introducers. Forces exerted by the introducers increased (after the initial drop) as the distance from the incisors to tip increased to more than 35 cm suggesting an optimum grip position of 30-35cm from the tip of the bougie.

Participant 1 - 60mm Straight Tips				
Bougie Tip Construction	**10cm**	**20cm**	**30cm**	**40cm**
Smooth-Sil 935 + 30% Hardener	0.351	0.176	0.351	0.264
Smooth-Sil 935 + 35% Hardener	0.351	0.527	0.088	0.088
Smooth-Sil 935 + 40% Hardener	0.264	0.351	0.176	0.264
Smooth-Sil 935 + 45% Hardener	0.351	0.264	0.088	0.088
Smooth-Sil 950 + 30% Hardener	0.615	0.264	0.351	0.088
Smooth-Sil 950 + 35% Hardener	0.791	0.264	0.351	0.264
Smooth-Sil 950 + 40% Hardener	0.615	0.351	0.264	0.264
Smooth-Sil 950 + 45% Hardener	0.615	0.703	0.351	0.264

Table 5.1: Participant 1 – 60mm Straight Tip Pressure Data

Participant 2 - 60mm Straight Tips				
Bougie Tip Construction	**10cm**	**20cm**	**30cm**	**40cm**
Smooth-Sil 935 + 30% Hardener	0.176	0.351	0.264	0.264
Smooth-Sil 935 + 35% Hardener	0.351	0.351	0.351	0.351
Smooth-Sil 935 + 40% Hardener	0.351	0.351	0.264	0.176
Smooth-Sil 935 + 45% Hardener	0.351	0.264	0.351	0.176
Smooth-Sil 950 + 30% Hardener	0.615	0.615	0.527	0.439
Smooth-Sil 950 + 35% Hardener	0.703	0.351	0.351	0.264
Smooth-Sil 950 + 40% Hardener	0.703	0.439	0.351	0.236
Smooth-Sil 950 + 45% Hardener	0.791	0.615	0.527	0.527

Table 5.2: Participant 2 – 60mm Straight Tip Pressure Data

Considering the data in Table 5.1, the tip pressure forces generated by the bougies for participant one was almost double when comparing the values for Smooth Sil 935 and 950. Although this is to be expected due to a significant difference in shore hardness values, a balance between pressure created by the tip and potentially damaging the trachea due to bougie tip pressure must be considered.

Upon reviewing the tip pressures demonstrated by participant one when testing the bougies with a 35mm straight tip (Table 5.3), again the data collected follows no trend in places and is very random. With an increased amount of hardener added to the mixes, the tip pressures should increase on an incremental basis, however this either stays at the same value in the case of Smooth-Sil 935 +35%, 40% and 45% hardener or fluctuates up and down.

Participant two's data for the 35mm straight tip (Table 5.4) does however present some of the trends expected. For Smooth-Sil 950, as the hardener increases, typically the values increase, this is most noticeable when the bougie is held at 10cm from the tip and the hardness value increases. When reviewing the data collected for the Smooth-Sil 935, Smooth-Sil 935 + 30% hardener and Smooth-Sil 935 + 45% hardener they exhibit higher tip pressures than Smooth-Sil 935 + 35% hardener and Smooth-Sil 935 + 40% hardener. This is to be expected for Smooth-Sil 935 + 45% hardener but not Smooth-Sil 935 + 30% hardener.

Participant 1 - 35mm Straight Tips				
Bougie Tip Construction	**10cm**	**20cm**	**30cm**	**40cm**
Smooth-Sil 935 + 30% Hardener	0.264	0.264	0.264	0.264
Smooth-Sil 935 + 35% Hardener	0.527	0.351	0.351	0.439
Smooth-Sil 935 + 40% Hardener	0.527	0.439	0.351	0.351
Smooth-Sil 935 + 45% Hardener	0.527	0.527	0.088	0.264
Smooth-Sil 950 + 30% Hardener	0.351	0.351	0.439	0.351
Smooth-Sil 950 + 35% Hardener	1.055	0.439	0.527	0.527
Smooth-Sil 950 + 40% Hardener	0.879	0.615	0.351	0.351
Smooth-Sil 950 + 45% Hardener	1.142	0.527	0.527	0.527

Table 5.3: Participant 1 – 35mm Straight Tip Pressure Data

Participant 2 - 35mm Straight Tips				
Bougie Tip Construction	**10cm**	**20cm**	**30cm**	**40cm**
Smooth-Sil 935 + 30% Hardener	0.703	0.527	0.527	0.264
Smooth-Sil 935 + 35% Hardener	0.527	0.351	0.351	0.264
Smooth-Sil 935 + 40% Hardener	0.351	0.264	0.176	0.351
Smooth-Sil 935 + 45% Hardener	0.967	0.264	0.439	0.176
Smooth-Sil 950 + 30% Hardener	0.527	0.879	0.351	0.351
Smooth-Sil 950 + 35% Hardener	0.791	0.439	0.527	0.439
Smooth-Sil 950 + 40% Hardener	0.879	0.527	0.527	0.351
Smooth-Sil 950 + 45% Hardener	1.055	1.055	0.615	0.351

Table 5.4: Participant 2 – 35mm Straight Tip Pressure Data

The data collected in Tables 5.1 – 5.4 have been plotted into charts presented in Figures 5.22 – 5.25. Figure 5.22 presents the chart for participant one tip pressures for the 60mm straight tip, this visually demonstrates that there is no obvious incremental tip pressure change trend as expected when the shore hardness values of the tips increase, this is especially obvious for Smooth-Sil 935 + 40% hardener (Green) and Smooth-Sil 935 + 35% hardener. However, Figure 5.23 presents data for participant one's 35mm tip pressure tests and shows a more uniform set of results. The data collected for the tip samples when held 20cm from the tip of the bougie for Smooth-Sil 950 + 30% hardener (Green) and Smooth-Sil 950 + 35% hardener do not exhibit the expected trend within the relevant category. Greater control of the bougies appears to be achieved with a shorter flexible tip.

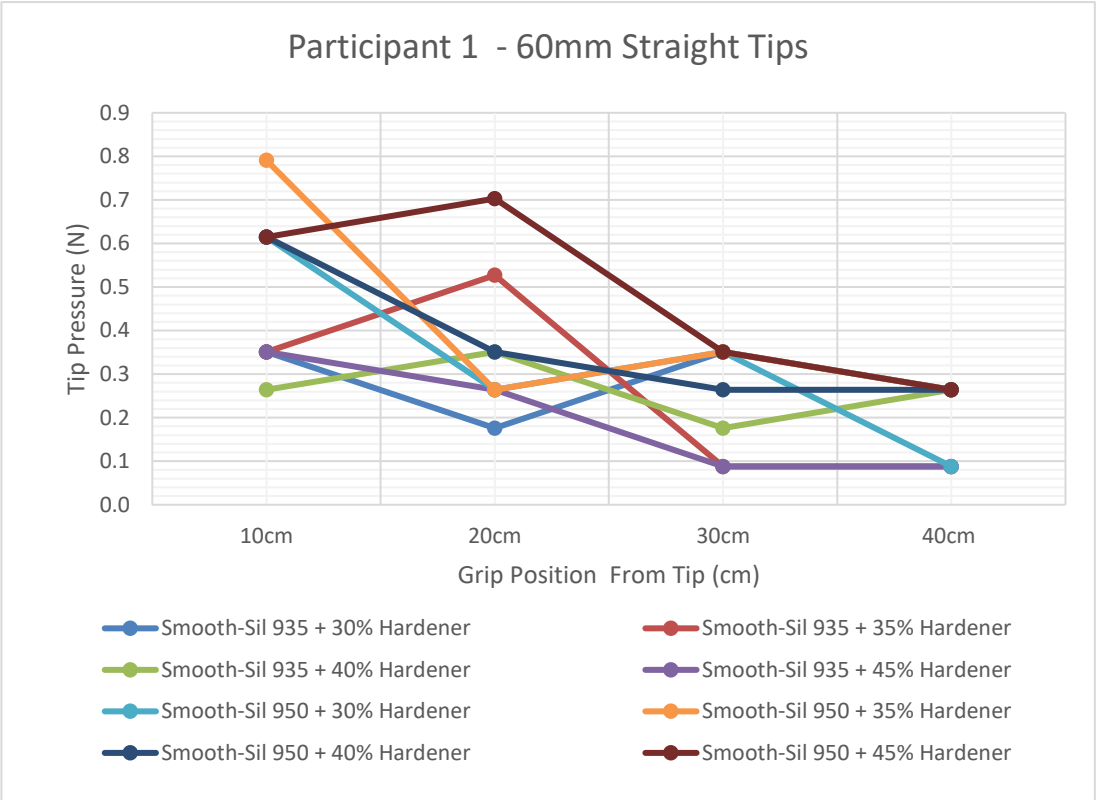


Figure 5.22: Participant 1 – Tip Pressures 60mm Straight Tip

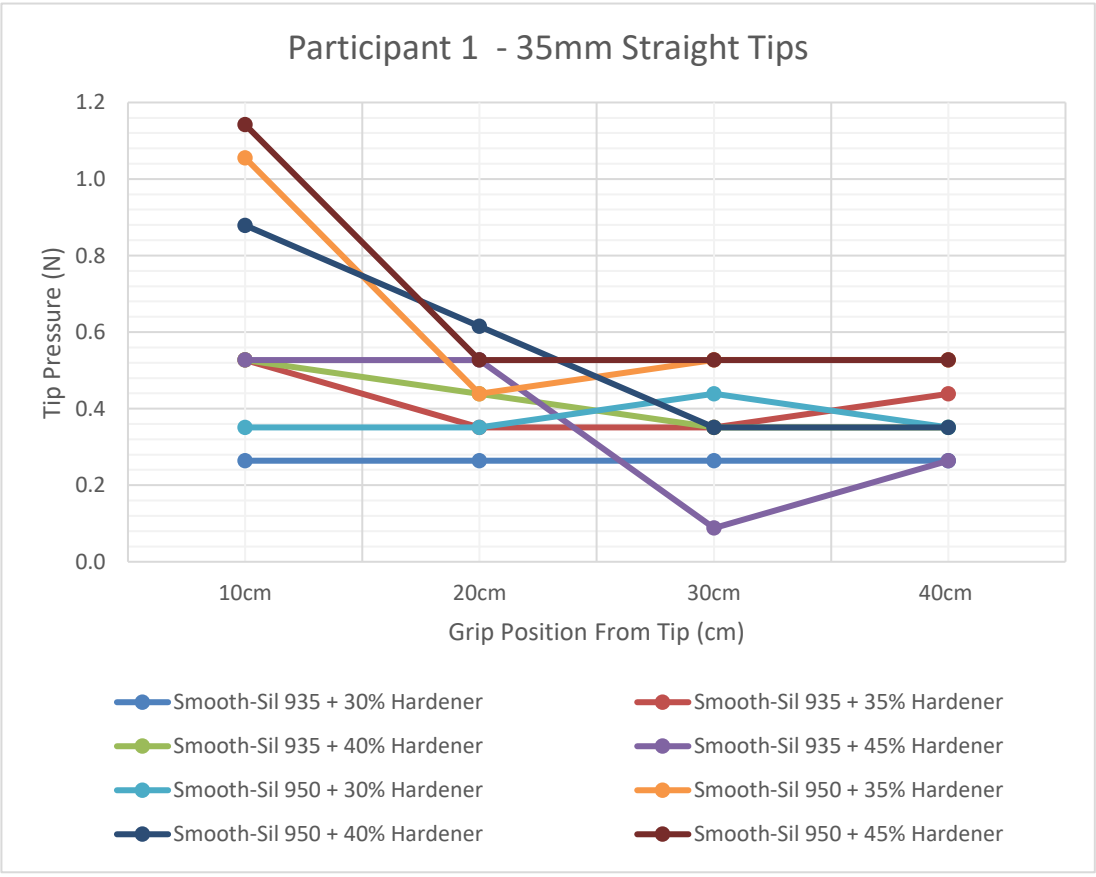


Figure 5.23: Participant 1 – Tip Pressures 35mm Straight Tip

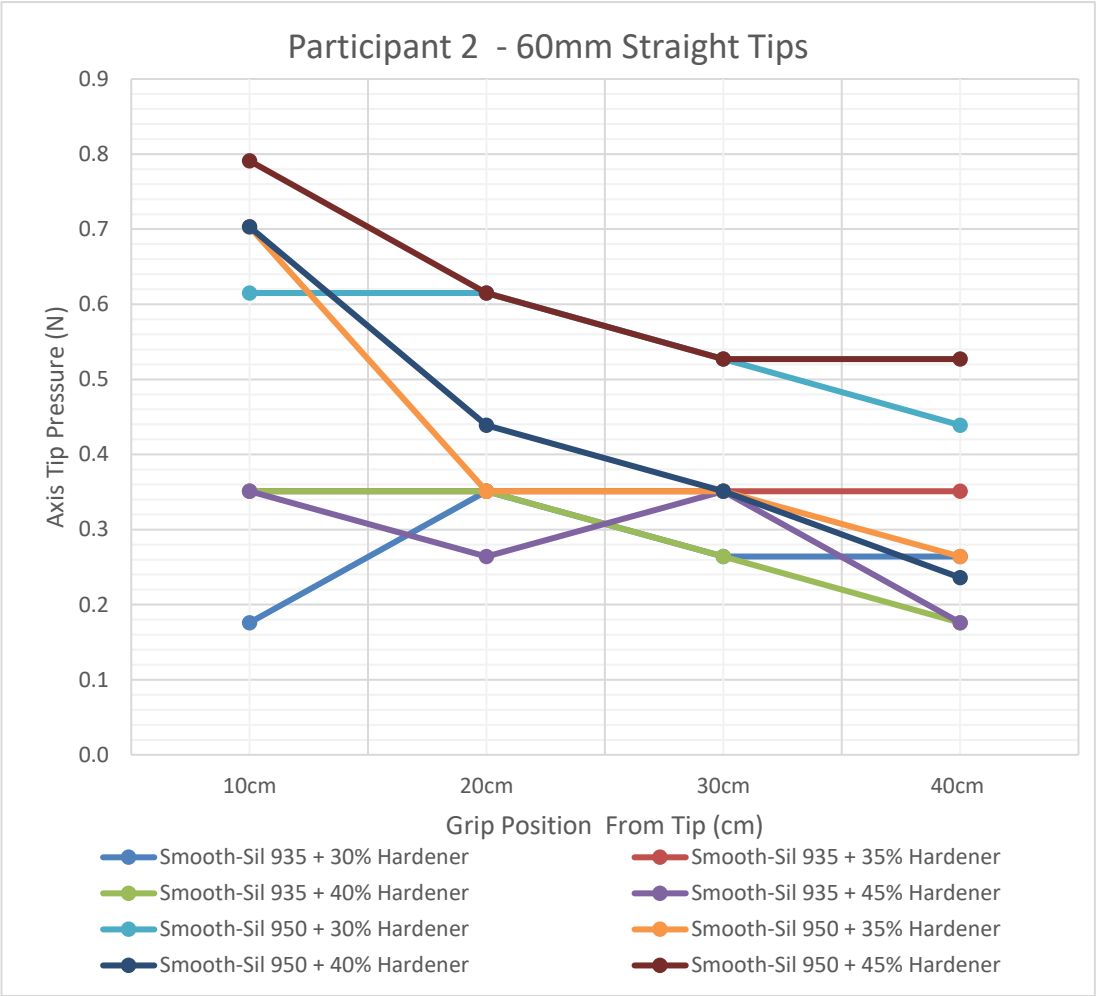


Figure 5.24: Participant 2 – Tip Pressures 60mm Straight Tip

Figures 5.24 and 5.25 presents the chart for participant two tip pressures for the 60mm and 35mm straight tips, these clearly demonstrate that the Smooth-Sil 950 graded tips create higher tip pressures than the Smooth-Sil 935 graded tips. This also keeps in line with the results from participant one's tests. However, Figure 5.25 below presents data which highlights unexpected results for tip pressures for the Smooth-Sil 950 + 30% hardener when held at 10cm from the bougie tip and Smooth-Sil 935 + 45% hardener when the bougie is held 20cm from the tip. A factor that could have affected these results could be the bougie tip slipping off the sensor earlier than expected, therefore not generating data sets for a long enough period that can be captured by the data acquisition software. A force gauge with a higher sampling rate would enable the capture of an increased data set. A cup or anti-slip depression disk could also be integrated to prevent bougie tip slippage.

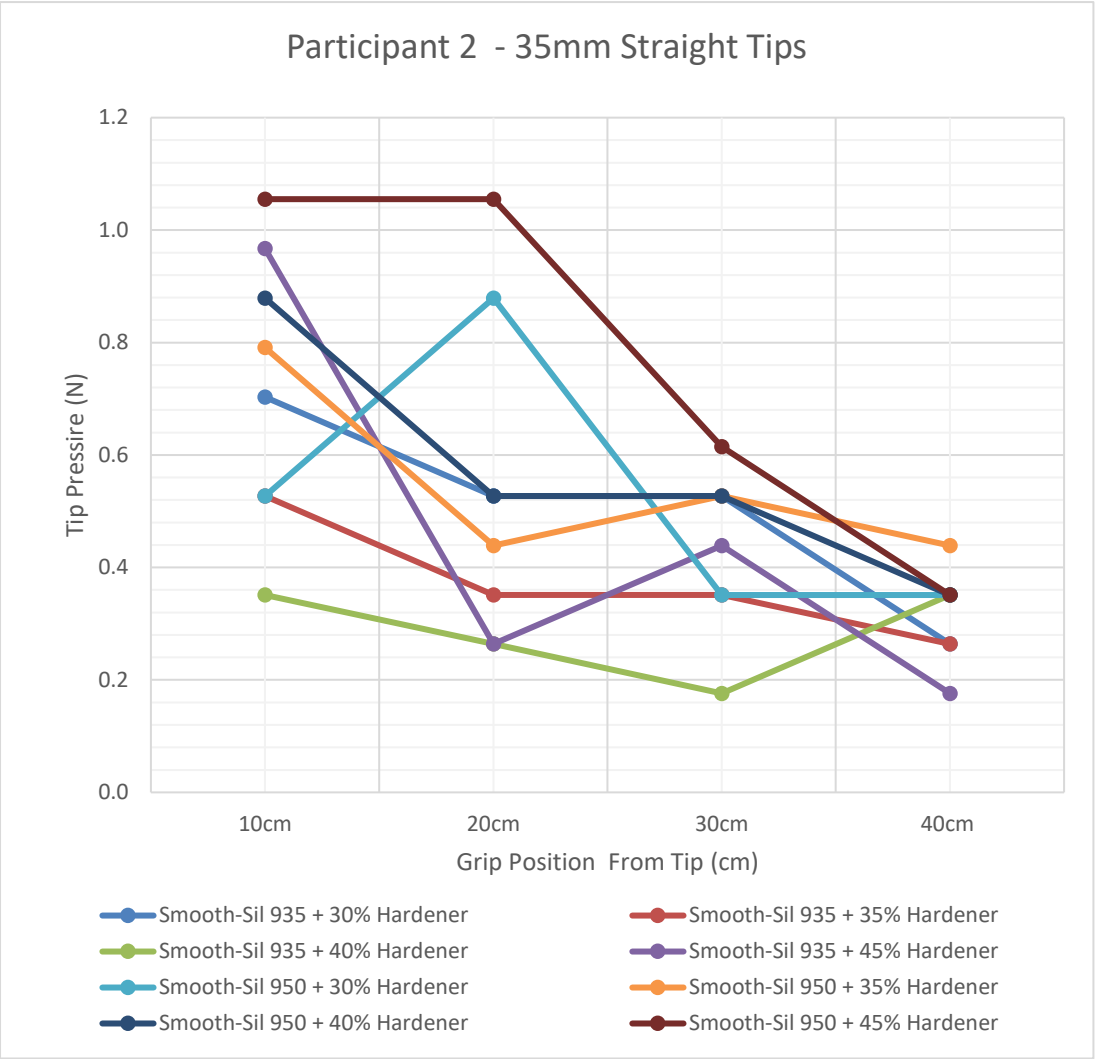


Figure 5.25: Participant 2 – Tip Pressures 35mm Straight Tip

Due to the random nature of several data sets collected and plotted in Figures 5.22 – 5.25 there is also significant concern in the ability for the data acquisition software to start on the base line after further review of individual data sets. Figures 5.26 and 5.27 present two charts, one for each participant with regards to the tip pressure tests conducted when holding the Smooth-Sil 950 bougies 10cm from the tip of the bougie. It is immediately noticeable that there are several data points that drop below the base line “zero” or the base line beings above calibrated “zero” base line. This again brings into question the ability for the SingleTact sensors to accurately capture the required data. Ensuring the baseline is reset must also be a focal point in any future protocol design for tip pressure testing. By resetting the baseline before each individual test, this will ensure that small data fluctuations do not occur, thus affecting the accuracy of the data collected.

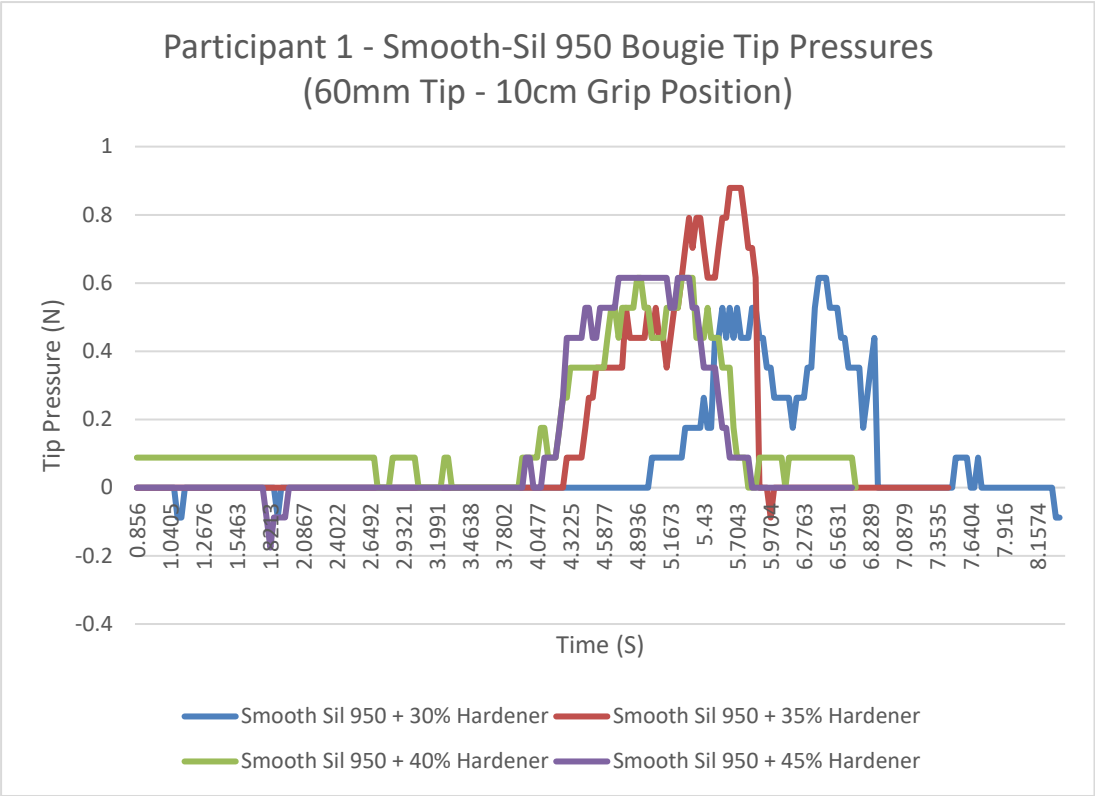


Figure 5.26: Participant 1 – Smooth Sil 950 Tip Pressures (60mm Tip – 10mm Grip Position)

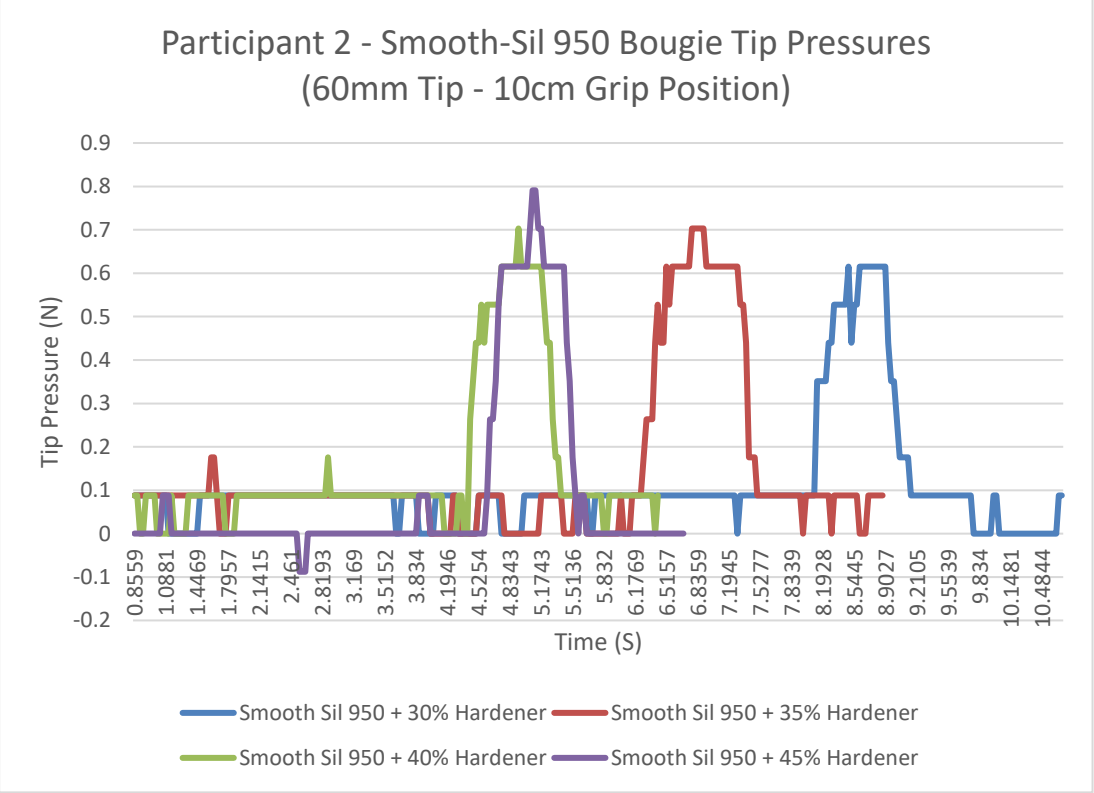


Figure 5.27: Participant 2 – Smooth Sil 950 Tip Pressures (60mm Tip – 10mm Grip Position)

Data presented in Table 5.5 and Figure 5.28 presents testing conducted on the Sun-Med 15FR x 700mm bougie which does not have a flexible or soft tip. As expected this presents tip pressures that are significantly higher. Although these are higher when compared to the Smooth-Sil cast bougies, the data collected does not compare to the tip pressures collected in the study completed by Hodzovic, Wilkes and Latto (2004) where the Portex Single Use Bougie presents a mean of 8.3N tip pressure and the Frova Single Use Bougie presents a mean of 6.6N tip pressure, both of which are competitors of the Sun-Med bougie introducer product range. This calls in to question the accuracy of the sensor being used or the method in which the sensor is being utilised.

Participant	**10mm**	**20mm**	**30mm**	**40mm**
Participant 1 - Sun-Med 15FR x 700mm	3.516	2.725	2.109	1.582
Participant 2 - Sun-Med 15FR x 700mm	1.406	3.252	3.076	2.725

Table 5.5 SunMed Bougie Tip Pressures

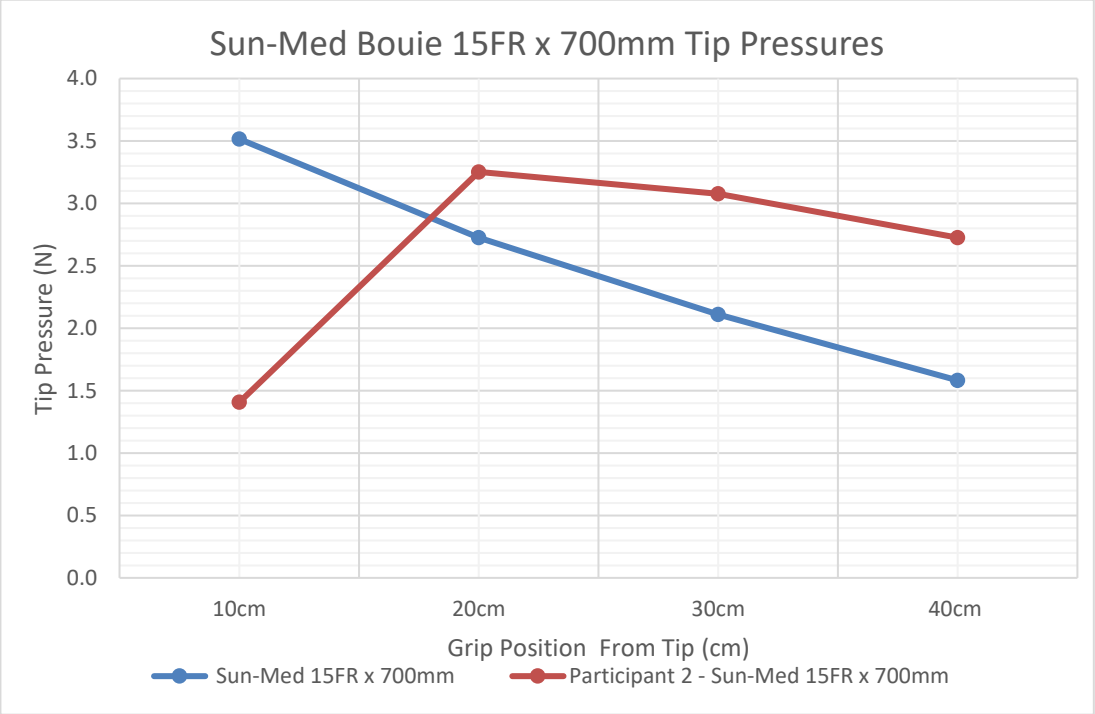


Figure 5.28: Participant 2 – SunMed Bougie Tip Pressure Comparison

In conclusion the data collected from this initial tip pressure study ultimately presents a set of data that demonstrates a few of the expected trends, however the data is not of much use due to the perceived inaccuracies of the SingleTact sensor or the methods used. It is therefore clear that an alternative force gauge or pressure sensor with a higher level of accuracy and sampling rate must be acquired to allow the desired testing to be completed.

5.4.3 Initial Tip Pressure Testing Analysis

Due to the significant variance in the collected data from the initial bougie tests, further analysis of the technical specification of the SingleTact sensors was required to ascertain the reason why the sensors are not providing the expected data in a linear format as presented within the study by Hodzovic, Wilkes and Latto (2008) regardless of the inaccuracies in their force gauge selection. After reviewing the performance documentation for the calibrated sensor, it was discovered that the specification data provided assumes that the whole sensor is uniformly loaded. SingleTact (2017) however elsewhere within their forums describe four experimental scenarios that highlight the key performance considerations of the sensors, these are depicted in Figure 5.29.

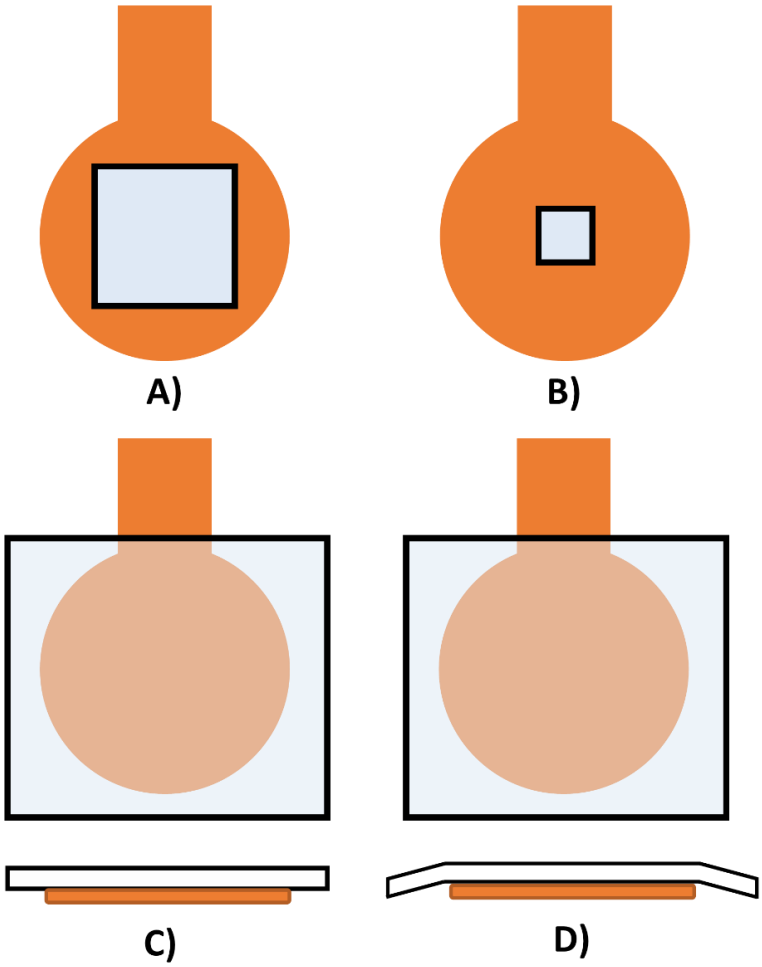


Figure 5.29: Single Tact Sensor Contact Area Performance

Image Reproduced from: SingleTact. (2017).

In scenario a), the load applied to the sensor is slightly smaller than the sensing area, this ensures that a good estimate of the applied force is achieved. In scenario b) the load applied to the sensor is significantly smaller than the sensing area; as the load contact area is reduced to a value smaller than the sensor expects, the sensors performance deteriorates from the

documented specification (SingleTact, 2017). When the load is larger than the sensing area, as depicted in scenarios c) and d), the sensor will perform as designed and report the correct forces, unless, the load is resting on a test surface as depicted in scenario d); this may report artificially low results. To achieve to optimum results, SingleTact (2017) suggests utilising a load distribution fixture as depicted in Figure 5.30. Due to the size of the bougies, the testing conducted is aligned with scenario b); this explains the variation and inaccuracy in the collected results.

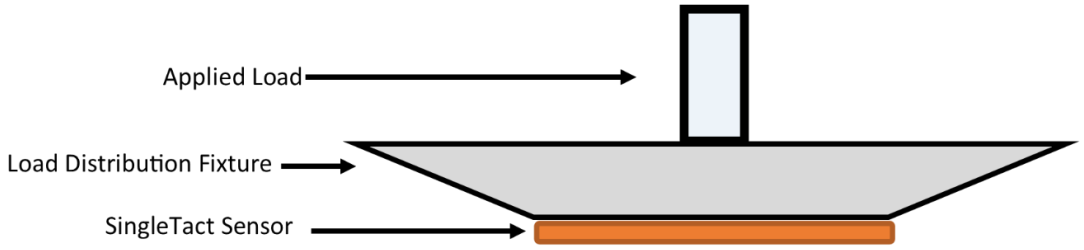


Figure 5.30: Single Tact Sensor Contact Area Optimum Performance Setup

Image Reproduced from: SingleTact. (2017).

Any adaption of testing equipment is risky as this can create scenarios where inaccuracies and lack of standardisation can result in data anomalies. After reviewing this documentation and considering the data collection issues encountered within the initial bougie comparison testing, an alternative force gauge is to be purchased to allow accurate data collection and to limit adaption of the testing equipment to achieve accurate results. The force gauges reviewed are presented in Table 5.6.

Criteria	Sauter FK25	Sauter FH 20	OMEGA's DFG35	Mecmesin AFG 25	Mecmesin AFG 50
Data Sampling Rate (HZ)	1000	2000	2000	5000	5000
Accuracy (%)	+/- 0.5 FSD	+/- 0.5 FSD	+/- 0.3 FSD	+/- 0.1 FSD	+/-0.1 FSD
Overload Protection	Yes	Yes (150%)	Yes (150%)	Yes (150%)	Yes (150%)
Measurement Range (N)	25	20	20	25	50
Readout (N)	0.01	0.01	0.1	0.005	0.01
Price (GBP)	£185.00	£335.00	£510.00	£995.00	£995.00
Data Acquisition Software Price (GBP)	£110.00	£110.00	Included	£495.00	£495.00
Testing Stand Price (GBP)	£180.00	£180.00	No	£545.00	£545.00
Calibration Certification Available	Yes	Yes	No	Yes	Yes

Table 5.6: Force Gauge Specification

As discussed in Chapter 2 to collect data in the lower spectrum of a force gauges load cell as required, ideally a force gauge rated a 25N or lower with a 0.5% FSD should be used. Considering this, the most cost-effective force gauge for purchase when considering the accuracy and measurement range and the price point would be the Sauter FH 20. With a 20N data capture range and a 0.5% FSD this equates to +/- 0.1N and therefore will provide a higher accuracy with significantly less uncertainty compared to the studies completed by Marson et al., (2014) who uses a Mecmesin PF 500N and Hodzovic et al., (2004) and Janakiraman et al., (2009) who use a Mecmesin PFI200N. This is also only +/- 0.01 different to the SingleTact sensors that although is of the correct resolution it does not have a suitable sampling rate. Upon taking delivery of the Sauter FH 20, the testing setup was again adapted for future testing (Figure 5.31).

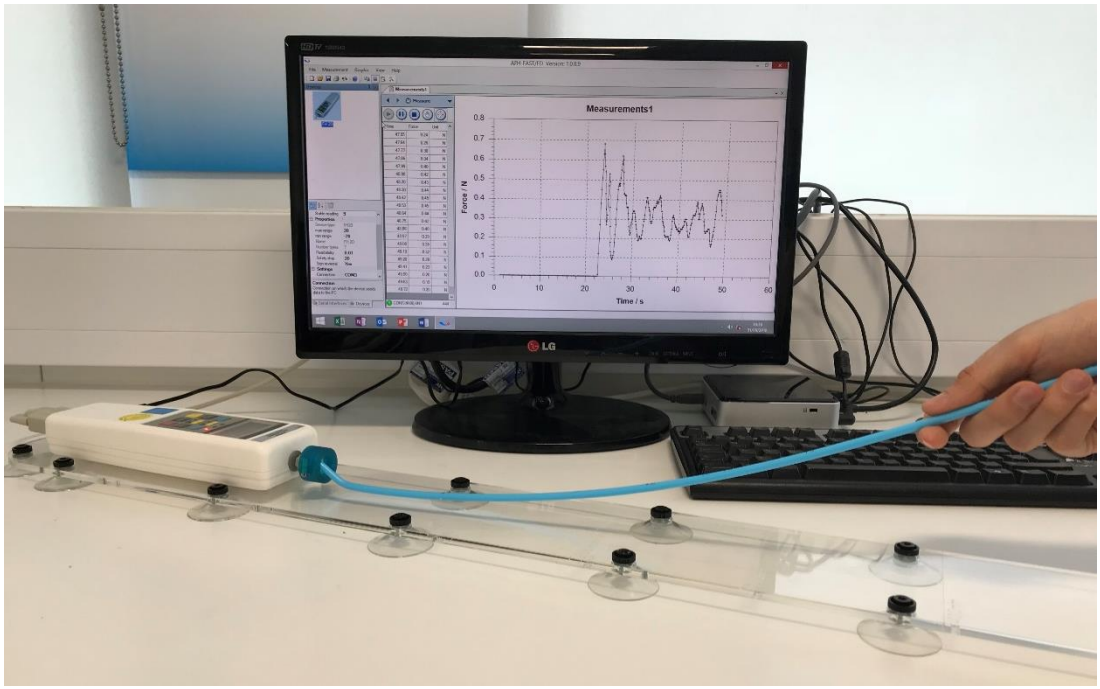


Figure 5.31: Testing Setup & Data Acquisition Software (Sauter FH 20 & AFH Fast Software)

By utilising the Sauter FH 20, the results collected utilising the AFH Fast data acquisition software are expected to follow the expected trend and initial validation of the sensor suggests this is likely to be the case. The next stage of this element of the research is to provide an accurate assessment of the tip pressures generated by all the bougies manufactured and a large sample of commercially available bougies. A full assessment of all these bougies will now be completed and presented in Chapter 6.

CHAPTER 6 – ANALYSING THE PHYSICAL PROPERTIES OF BOUGIE INTRODUCERS & DESIGN DEVELOPMENT

6.1 Introduction

Following the initial development of the steerable bougie, this chapter explores the analysis methods of the physical properties of the constructed bougies thus resulting in further product development and validation. To ensure that the developed bougies are superior in performance to the commercial rivals, a comparative analysis tasks will be completed identifying shortcomings in the designed and manufactured. A full analysis of the physical properties of bougie introducers is necessary to ensure design justification and validation can be achieved. The testing equipment and data acquisition system identified as being suitable for use was the Sauter FH 20 Digital Force Gauge and the AFH Fast Software which has a higher accuracy, resolution and full-scale deflection compared to the force gauges used by Hodzovic et al., (2004), Janakiraman et al., (2009) and Marson et al., (2014).

This chapter will therefore focus on the testing approaches and results based on an analysis of several key physical properties of bougies and will utilise a variety of testing techniques to identify not only the optimum bougie for use based on the commercial bougies currently available, but act as a comparative assessment tool to influence the development of the steerable bougies final setup. The tasks to be conducted and discussed within this chapter are as follows with the aim of proving the final design of the steerable bougie will be superior to the products currently available on the market:

- **Initial Manufactured Bougies Analysis:** Tip pressure testing will be completed by an untrained user. This will allow the identification of bougies that are either suitable or unsuitable for the use. Tip pressures will be compared against existing bougies tested. The developed bougies will tested for successful intubation in a manikin (TruCorp AirSim Advance X) to validate their use as a single use bougie.
- **Shore Hardness Testing:** The shore hardness testing to be conducted will identify the shore hardness “A” values of the sample disks cast for each of the graded bougie materials used for casting the tips; thus identifying critical material property data.
- **Steerable Tip Development:** The steerable tip development section describes improvements in techniques used and alternative manufacturing processes investigated to ensure the final design of the steerable tip can be produced. Tip pressure testing and mechanism validation will be completed.

- **Overcoming Silicone Cure Inhibition:** Various silicones cast within the designed 3D printed moulds present signs of cure inhibition. To overcome cure inhibition, controlled heating of the moulds to promote silicone curing is required. Due to contamination issues with existing heating equipment available, a heat chamber with ambient, mould and plate temperature monitoring was designed and manufactured in collaboration with Mr Paul Watts (Software Developer, Medical Design Research Group, Nottingham Trent University, UK). The design of a heat chamber to promote curing of the silicones is discussed alongside casting process issues encountered during the steerable tip development.
- **Repeatability Testing:** Repeatability testing will be conducted to ascertain the material degradation of the bougies over a defined timescale when regulated and repeated force is applied to a bougies tip. This data will also validate the methods used within the tip pressure studies.
- **Tip Pressure Studies:** The untrained user study will be completed at Nottingham Trent University, UK and will involve the tip pressure force analysis of six selected bougies. The trained user study will be completed at Nottingham University Hospitals Trust (QMC). A testing protocol and equalised randomisation will be utilised. Data acquisition software will collect and plot tip pressure force graphs with the aim of discovering the force that can be generated by untrained and trained users but providing an insight into the optimum grip position and the identification of the bougie that demonstrates the least amount of tip pressure thus limiting mucosa damage.
- **Tip Pressure Study Survey:** The tip pressure study survey aims to validate the data collected within the survey presented in Chapter 4. Questions will be posed to the twenty-four anaesthetists in the trained user testing to identify current habits and preferences related to equipment use.
- **Airway Perforation Tests**: Testing equipment inaccuracies identified in the studies completed by Marson et al., (2014), Hodzovic, Wilkes and Latto, (2004) and Janakiraman et al., (2009) has highlighted a gap in the literature relating to airway perforation forces. An experimental setup is designed/manufactured; porcine airways will be purchased for testing. Perforation forces created by bougie introducers at a location identified as most likely to result in significant airway damage i.e. the split of the bronchus located near the carina, will be investigated.

6.2 Methods

Throughout this chapter numerous research methods and approaches have been utilised to achieve the desired objectives. Sections 6.2.1 – 6.2.8 describe the methods utilised and are categorised within the developed conceptual framework within TRL 2-5:

6.2.1 Manufactured & Commercial Bougie Analysis

Utilising the experimental and testing setup presented in Chapter 5 (Figure 5.31) the developed bougies described in Chapter 5, Section 5.4 are tested. Figure 6.1 presents the manufactured bougies tip pressure analysis protocol. Using an untrained user, the bougies are held at 10cm from the tip of the bougie. The user then presses the bougies against the force gauge until the tip pressure does not increase further. Once this peak value has been reached, the user removes the bougie and repeats this until five readings have been recorded. This process is repeated with the bougies held 20cm, 30cm and 40cm from the tip of the bougie. When the five values are recorded for each of the bougies, the arithmetic mean is calculated in addition to the standard deviation and standard error.

Based on the initial samples manufactured, an assessment of these bougies was conducted by Dr James Armstrong, Dr Kristofor Inkpin and Dr Andrew Norris. Three materials identified and tested were suitable for use based on the texture, material stiffness and perceived tip flexibility. These were ranked in order of preference for further testing; Rank 1: Smooth-Sil 950, Rank 2: Smooth-Sil 935 and Rank 3: Smooth-Sil 940.

Once each of the manufactured bougies are tested, a comparative analysis is completed. For this comparative analysis to be placed into the correct context, the bougies must also be compared to bougies currently available on the market; an analysis of the tip pressures of commercially available bougies has also be completed using the same protocol. Each of the developed bougies are also used during an attempted intubation on a TruCorp AirSim Advance X Manikin to ascertain whether the developed bougies can be operated as a standard bougie (minus the steerable control wires). If the bougie tips kink or curl back upon themselves or provide significant resistance, they are deemed not fit for purpose.

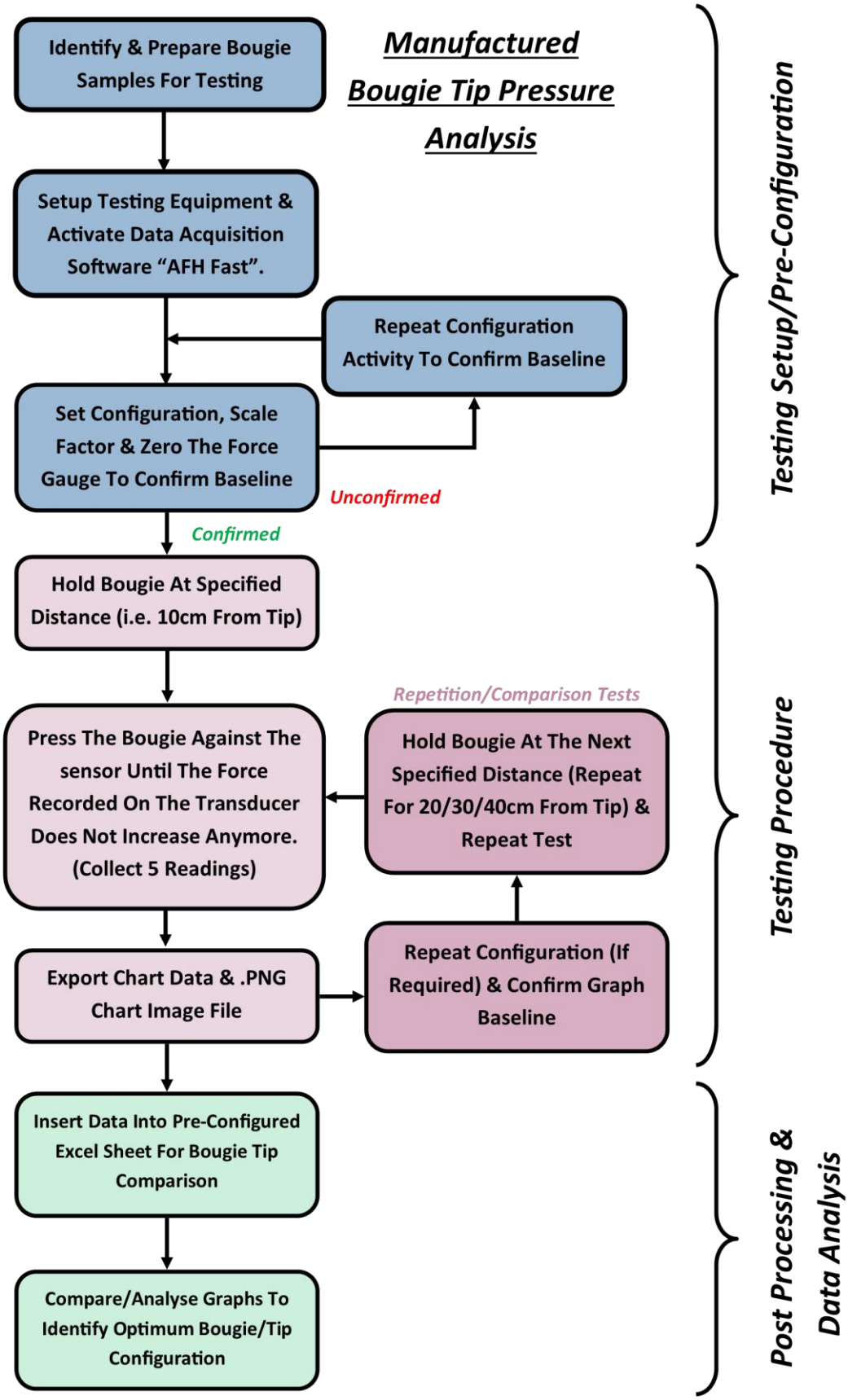


Figure 6.1: Manufactured Bougies Tip Pressure Analysis Protocol

Completing the tip pressure analysis of the bougies and attempting to accurately place the bougies in the trachea of the manikin, it is possible to identify the bougie that has the optimum construction when considering tip flexibility and tip pressures generated. It may be necessary to compromise by identifying a bougie that has an adequate construction to ensure kinking inside the trachea does not occur, yet at the same time display the lowest possible tip pressures. The kinking of the bougie will correlate to the stiffness or flexibility of the bougie tip and finding an adequate compromise will be necessary. The developed bougies are also to be compared to samples of commercially available bougies sources from manufacturers and suppliers around the UK.

The developed bougies would ideally be compared to a large sample commercially available bougies however the cost implications of this would be significant. Several of the bougies are also extremely difficult to source and can only be sourced in boxes of ten at a price which exceeds £100.00 per box (2018). Additionally, the Eschmann re-usable bougie (gum elastic bougies) cost £28 each (2018) and can only be purchased with a minimum order of ten units.

6.2.2 Shore Hardness Testing Method & Experimental Setup

There are two testing approaches reported within ASTM_D2240-03; Manual (Hand Held) Operation of Durometer and Operating Stand Operation (Type 3 Operating Stand Required for Type M). It is also imperative to consider BS ISO 7619-12010 rubber, vulcanized or thermoplastic - determination of indentation hardness, durometer method (Shore hardness) (ISO, 2010) and ISO 868:1978 Plastics - Determination of indentation hardness by means of a durometer (Shore hardness) (ISO, 1981). To obtain accurate and reliable shore hardness test results, conformity to shore hardness protocols (ASTM International, 2003) is required; the key considerations are set out in Appendix M.

During the manufacture of the sample bougies, as presented in Chapter 5, Section 5.3, a sample disk was also cast to allow shore hardness “A” testing to be conducted. The sample disks cast are a minimum of at least 6.0 mm in thickness, otherwise a recast of the sample disk was required. The shore hardness “A” tests are conducted utilising the manual operation (hand held) method due to the limited availability of suitable equipment. To avoid variation in collected data and conform to the regulations, a 1kg mass was securely affixed to the durometer and centred on the axis of the indenter as depicted in Figure 6.2.

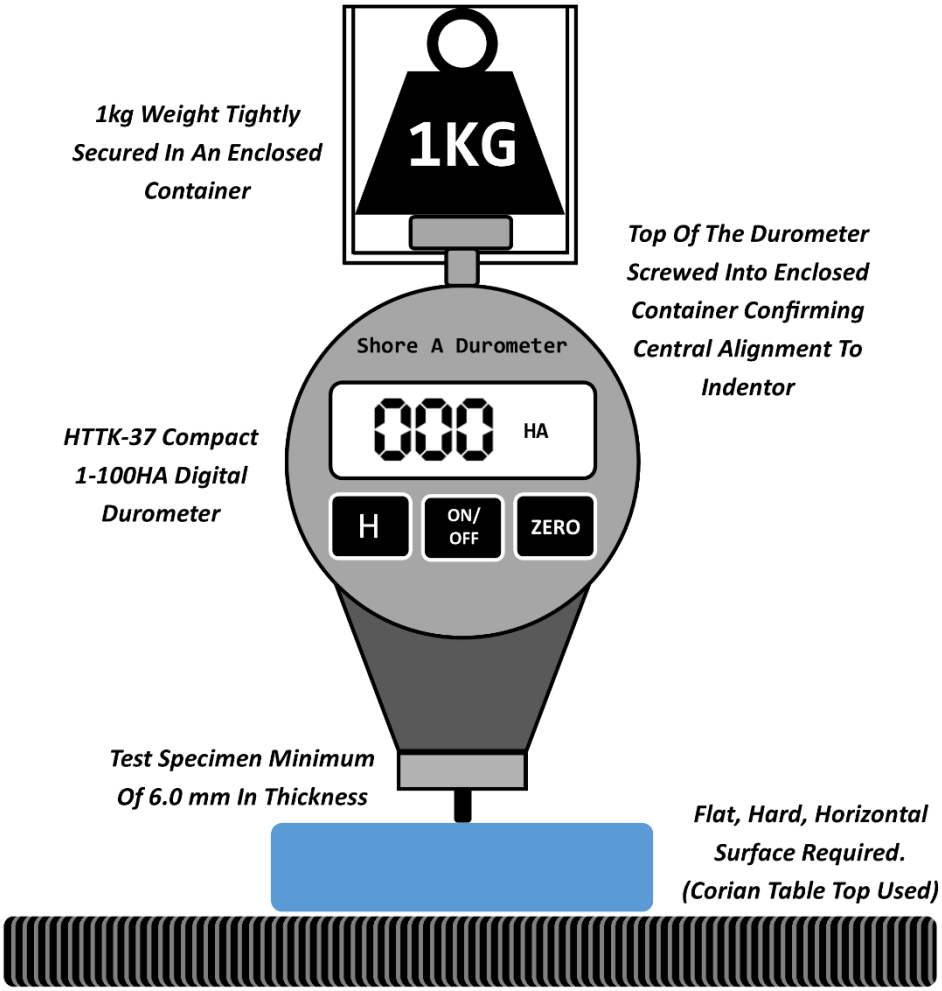


Figure 6.2: Durometer Testing Setup

The HTTK-37 Compact 1-100HA Digital Durometer used is a Shore A digital hardness tester and is used to measure the hardness of rubber and plastics according to ASTM D2240, DIN53505, ISO 868-1986 and ISO 7619. Although the durometer does not come supplied with a calibration certificate, this is not necessary as this is solely being used to provide measurements for comparative analysis of the manufactured parts and act as sample disks for future comparative assessment. The HTTK-37 Compact 1-100HA Digital Durometer has passed and conforms with ISO 868-1986 & ISO 7619 international standards as required for Type A durometers and can be used to test the penetration medium hardness of rubber, plastic, leather, multi-grease, wax, amongst other materials. As per D2240-03, article 9.4, to complete the manual method of testing, five determinations of hardness at different positions on the specimen are required at least 6.0 mm (0.24 in.) apart; the arithmetic mean is then calculated to determine the samples shore hardness value. To ensure testing uniformity across all the samples, a test location template was created identifying a set position and testing order to be used across all the samples (Figure 6.3).

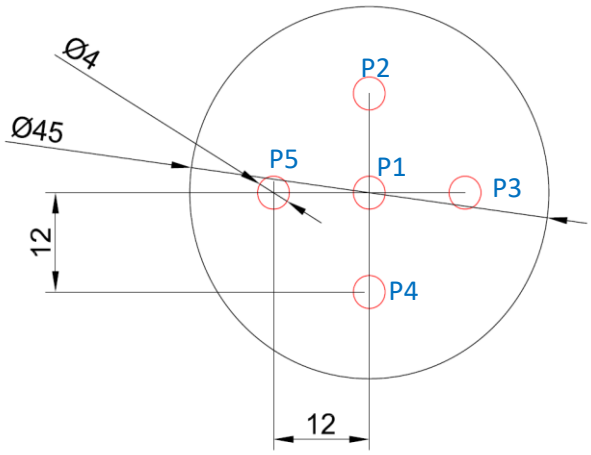


Figure 6.3: Durometer Test Locations Template

6.2.3 Steerable Tip Development

The steerable tip will inevitably need further development work based on the results collected from the initial tip pressure analysis and bougie placement activities. Using the developed conceptual framework, the feedback loops are used to move backwards within the TRL stages to complete re-design development work and re-complete the design and technology validation tasks based on the bespoke testing and validation tasks already completed (Figure 6.4).

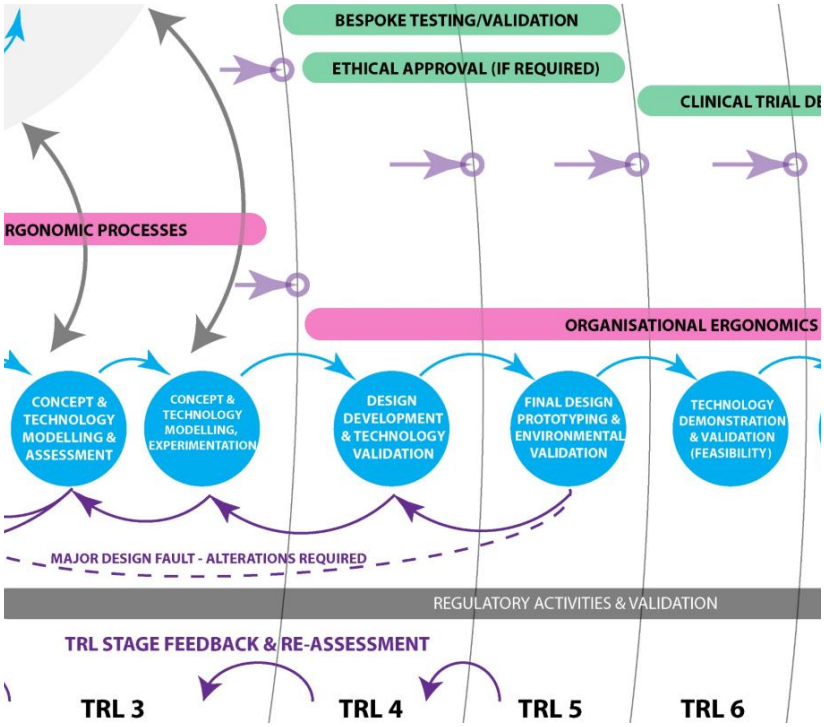


Figure 6.4: TRL 4-5 Development & Re-Design Stage

Upon completing the redesign of the steerable tips, validation testing is again required. Using the methods described in Section 6.2.1 and 6.2.2 the data collected determines whether the developed tip is fit for purpose. Conversely, if the tip pressure studies determine yet again that further development work is required, it will be necessary to move backwards within the conceptual framework from TRL 5 activities and return to TRL 3/4 design development activities, thus ensuring a successful steerable bougie is designed and manufactured.

6.2.3.1 Overcoming Silicone Cure Inhibition - Heat Chamber Design & Manufacture

During the further development of the steerable tips described in Section 6.6, it became evident that cure inhibition was an issue due to the dimensions of the part being cast (0.5mm wall thickness. Cure inhibition is not uncommon with addition-cure silicone rubbers and when this does occur this usually is due to certain contaminants being present on the mould being used. Cure inhibition can be displayed in many forms, for example, the part may not cure properly resulting in tackiness or it may completely fail to cure throughout the mould leaving the silicone in its liquid form. Some of the most common issues that cause cure inhibition are due to the surface of the mould being contaminated by latex, tin-cure silicone, sulfur clays, epoxy or urethane rubber etc. Identifying cure inhibition can often be recognised if the rubber is gummy or uncured after the recommended cure time has passed; an example of this is presented in Figure 6.5.

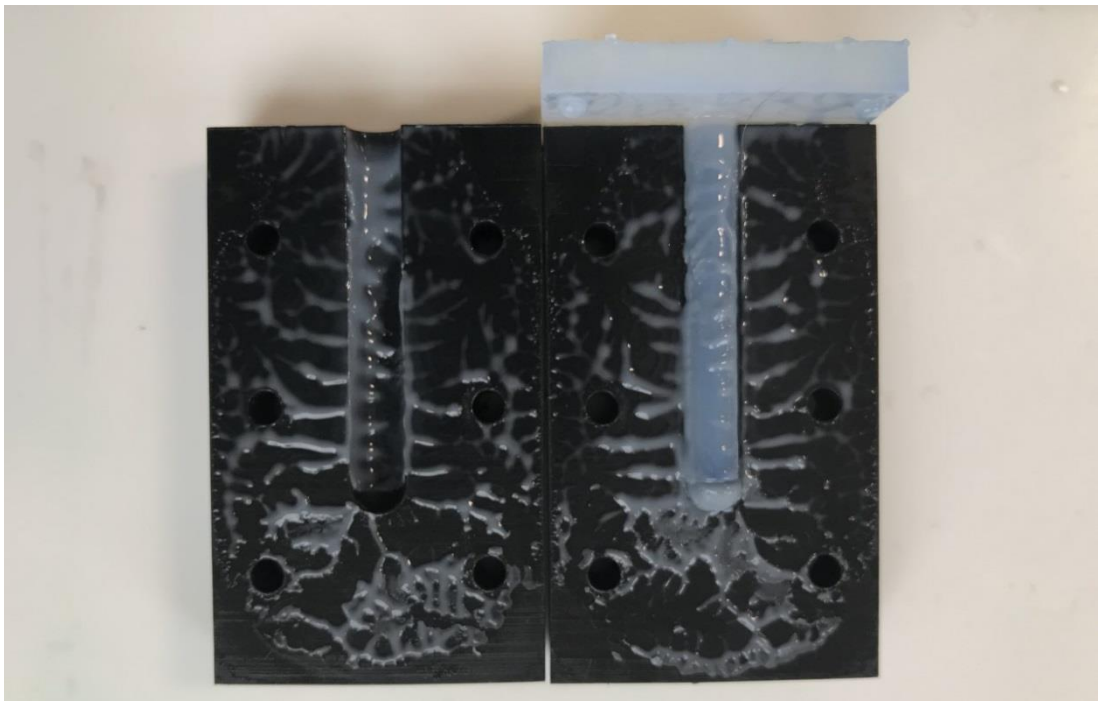


Figure 6.5: Example of Cure Inhibition

Cure inhibition can also occur with some silicones and rubbers if there is insufficient material/part wall thickness. After experimentation this has been identified as the issue for the cure inhibition for the mould presented in Figure 6.5. To promote curing, the technical data sheets provided identify that heating of the moulds to promote curing at an increased rate is required. Curing and post curing Smooth-Sil Series Silicone can be completed at 176°F/80°C for two hours or 212°F/100°C for one hour (Smooth-on.com, n.d.a).

To cure the silicones for two hours at 176°F/80°C or 212°F/100°C for one hour, the utilisation of a suitable heat source is required. Identifying a suitable heat source was a challenge due to the silicone being used and the specified recommended temperatures. The low heat ovens and autoclaves available within the facilities at Nottingham Trent University are either incompatible for the low temperatures required or contain solvents and fluids (i.e. sunflower oil) that promotes cure inhibition. Domestic ovens installed within a household are also unsuitable due to their inability to function at the desired low temperatures.

Based on these factors, it became evident that the construction of a heat chamber would be required. Utilising off the shelf components including a 3D printer heated build plate, the heat chamber was constructed, this is presented in Section 6.6.2. To ensure optimum low-level heat control and monitoring, the heat chambers control was completed utilising Arduino open source software. Multiple temperature sensors (Grove Sensors) were integrated into the system including the use of ambient temperature sensors, a thermistor (to control the temperature of the heated plate) and an additional temperature sensor that is to be slotted into the interior of the mould to monitor its temperature (Figure 6.6). The developed program code for the heat chamber is presented in Appendix O.

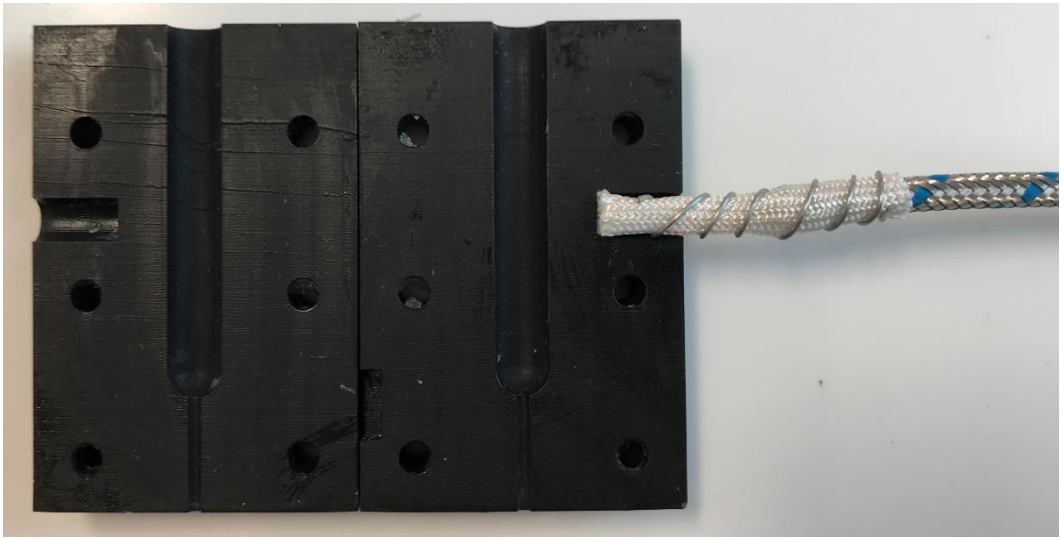


Figure 6.6: Re-Designed Mould For Grove Temperature Sensor Integration

To validate the heat chambers Grove Sensors, the ambient temperature readings displayed were compared to the ambient temperature recorded by a Thandor TH31 Digital Thermometer that is capable of recording temperatures within a range of -50^{O}c to 750^{O}c utilising a "Type K thermocouple". To confirm comparative validation, temperature readings were collected in five minutes intervals of a thirty-minute period. The comparative results confirming the Grove Sensors accuracy is presented in Table 6.1.

- Date of Validation Test: 5/5/2018.
- NG1 Postcode UK Met Office Official Recorded Temperature: 22^{O}c Issued at 14:00.
- Comparative Test Time: 14:30 – 15:00.
- Location: Nottingham Trent University, Maudslay Building, Room 214.

Time (24hrs)	**Grove Sensor Ambient Temperature (^{O}c)**	**Thandor TH31 Digital Thermometer**
14:30	22.98	23
14:35	22.69	22
14:40	22.54	22
14:45	22.46	22
14:50	22.83	22
14:55	22.55	22
15:00	22.43	22

Table 6.1: Grove Sensor Temperature Validation

The designed and manufactured heat chamber has now been used to resolve the cure inhibition issues described. The data collected from the heat chamber can also be exported from the program code and plotted into charts to depict the heating of the mould and the level of heat control exhibited within the heat chamber.

6.2.4 Repeatability Testing

Every bougie will present a level of deformation after repeated pressure is applied to the tip. This level of degradation will therefore determine how many uses a bougie is capable of withstanding before it requires being disposed of (in the case of multiple use bougie); this data will also inform how many times the bougies to be assessed within the described tip pressure studies can be utilised before a new set is required. For the tip pressure studies, it has been determined within the project team that once the tip pressures exhibited by the bougies have degraded by more than 10% of the original exhibited tip pressure, this bougie set needs to be replaced within the studies.

It was also noted that testing the bougie at the location where the tip pressure exhibits the highest tip pressures based on existing literature (Hodzovic, Wilkes and Latto, 2004) would also represent the worst-case scenario. Repeated straightening or reshaping of the bougie back to its original tip shape, especially for a coude tip bougie, can ensure the tip pressures do not fall below this 10% bracket for a longer period. It will be good practice to replace the bougies after a repeated and standardised number of uses within the trial based on the initial repeatability testing conducted; this takes away the need to rely upon reshaping of the bougies repeatedly.

As repeatability testing of bougie tip pressures does not currently exist within published literature, a testing rig must be created to capture this data. The testing rig that has been designed and constructed (Figure 6.7) and utilises Festo pneumatic and electrical automation equipment. By altering the starting position of the piston, the starting bougie tip pressure can be determined. Once this value has been set, the testing apparatus is run at a set speed for a defined period to collect 250 repetitions of the bougie tip pressures. The data acquisition software automatically plots a graph over the defined period, an example can be found in Figure 6.8.

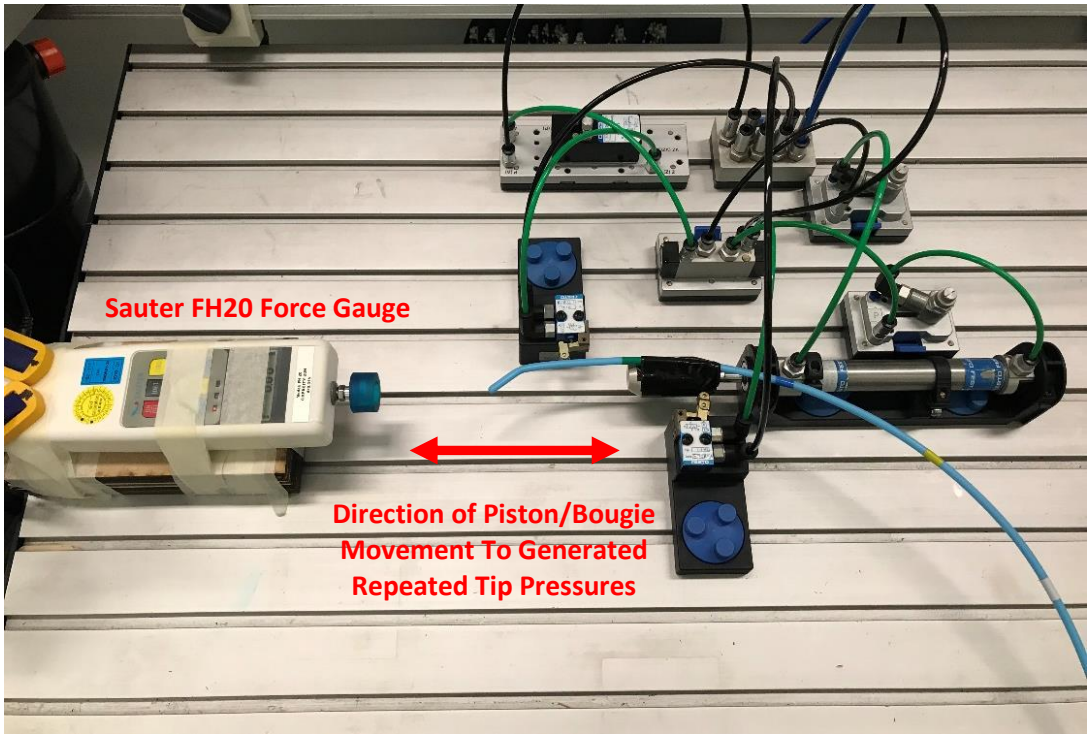


Figure 6.7: Bougie Tip Pressure Repeatability Testing Experimental Setup

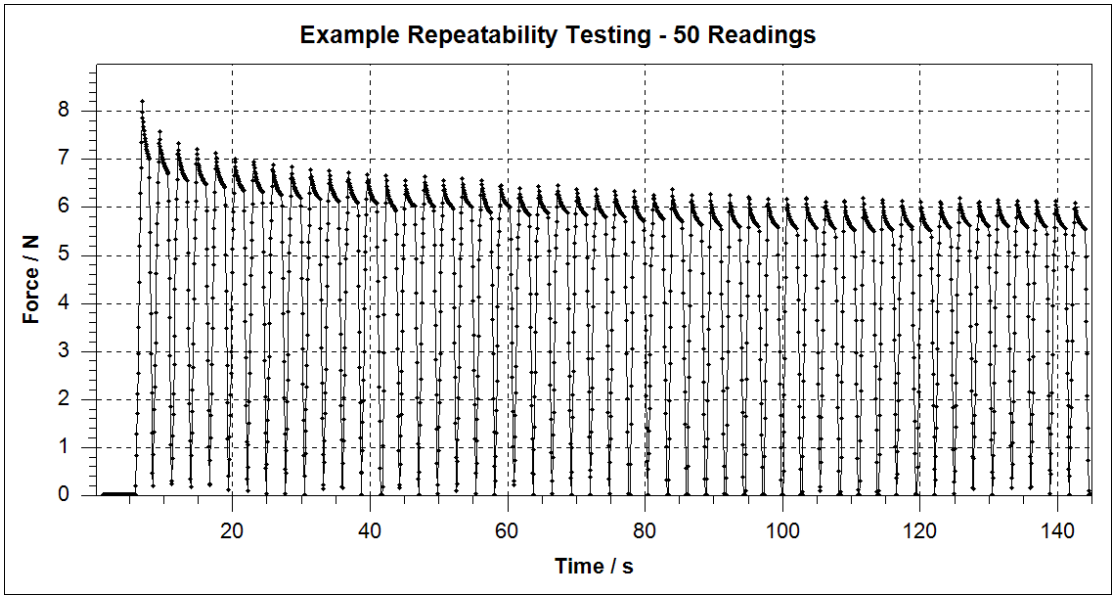


Figure 6.8: Example Tip Pressure Repeatability Testing Chart (50 Readings)

After initial experimental testing of the developed testing setup, it became evident that securing the bougie with a permanent fixture along the central axis of movement would be required. Initially attaching the bougie in a set position with a cable tie was acceptable; after repeated testing, this caused unexpected rotation of the bougie on the piston and rotation of the piston itself, therefore securing the bougie in position was required. To alleviate this problem three 3D printed parts were manufactured to not only keep the bougie aligned in the central axis but also to prevent piston rotation; this setup is demonstrated in Figure 6.9.

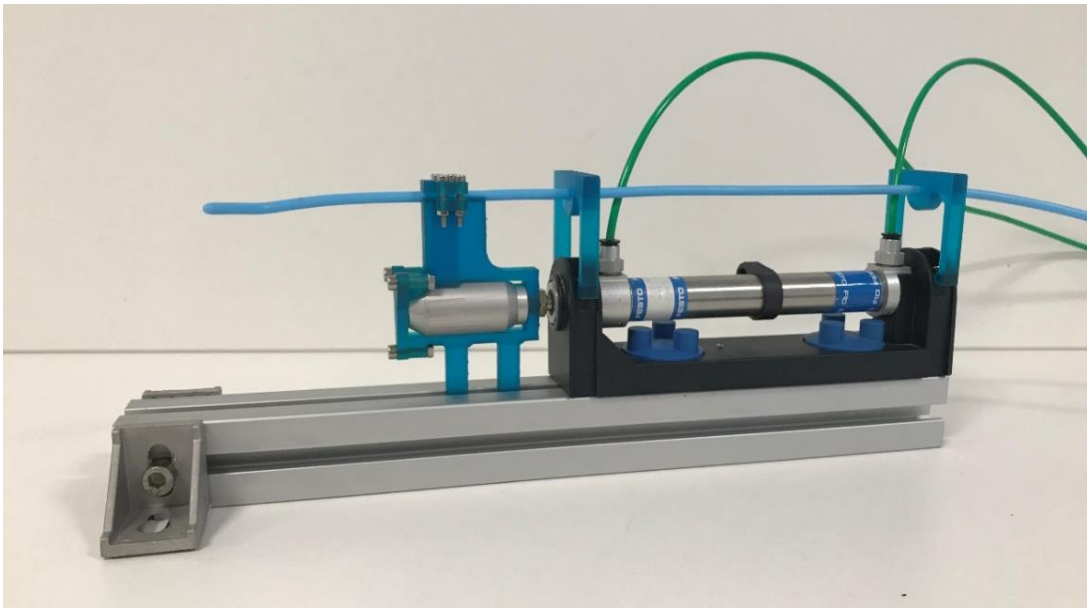


Figure 6.9: Modified Piston Setup (Bougie Central Axis Alignment)

Finally, prior to testing, it was necessary to find out the starting tip pressure to be set for each bougie. Twenty readings are collected for each bougie when manually pressed against the force gauge when held by an operator at 10cm from the tip. The arithmetic mean is calculated for each bougie and the determined value is the pre-set tip force generated for the first reading taken during the repeatability testing.

6.2.5 Tip Pressure Studies (Untrained Users and Trained Users)

The purpose of the user tip pressure study is to assess bougie tip pressures generated by trained operators i.e. anaesthetists based at Nottingham University Hospitals Trust (QMC) in addition to untrained users with no medical experience. Both participant sets will require the recruitment of twenty-four participants. The experimental setup has previously been presented in Chapter 5, Section 5.4.3 (Figure 5.31) based on the use of a Sauter FH 20 Digital Force Gauge and AFH Fast Data Acquisition Software.

The participants are required to hold six different bougies at intervals of 10, 20, 30 and 40cm from the tip. The participant was then instructed to press the bougies individually against the force sensor until the force generated increases no further. The data acquisition software collects the data and plot graphs; this will be repeated three times per bougie per participant at all four distances starting with the 40cm distance held location. The data is then transferred to a pre-configured SPSS spreadsheet where a full statistical analysis of users and equipment is completed.

A photograph of the participants hand and grip position is also captured during one of the tests as per the ethical clearance acquired (presented in Appendix E). It may be necessary to analyse whether grip position affects the amount of force generated when pushing the bougie against the force gauge.

To ensure there is no learning bias within the data collection, an equalised randomisation approach (Appendix L) is used to ensure that all the bougies are tested the same number of times and used, first, second, third, fourth, fifth and sixth an equal number of times. This will reduce the likelihood that a learning bias will affect the data. Importantly, the equalised randomisation is based on a factor of six and therefore and must correlate to the number of participants recruited. The protocol for both the trained and untrained user study is presented in Figure 6.10. To complement the full study, a short survey is also conducted alongside the testing as described in Section 6.2.6.

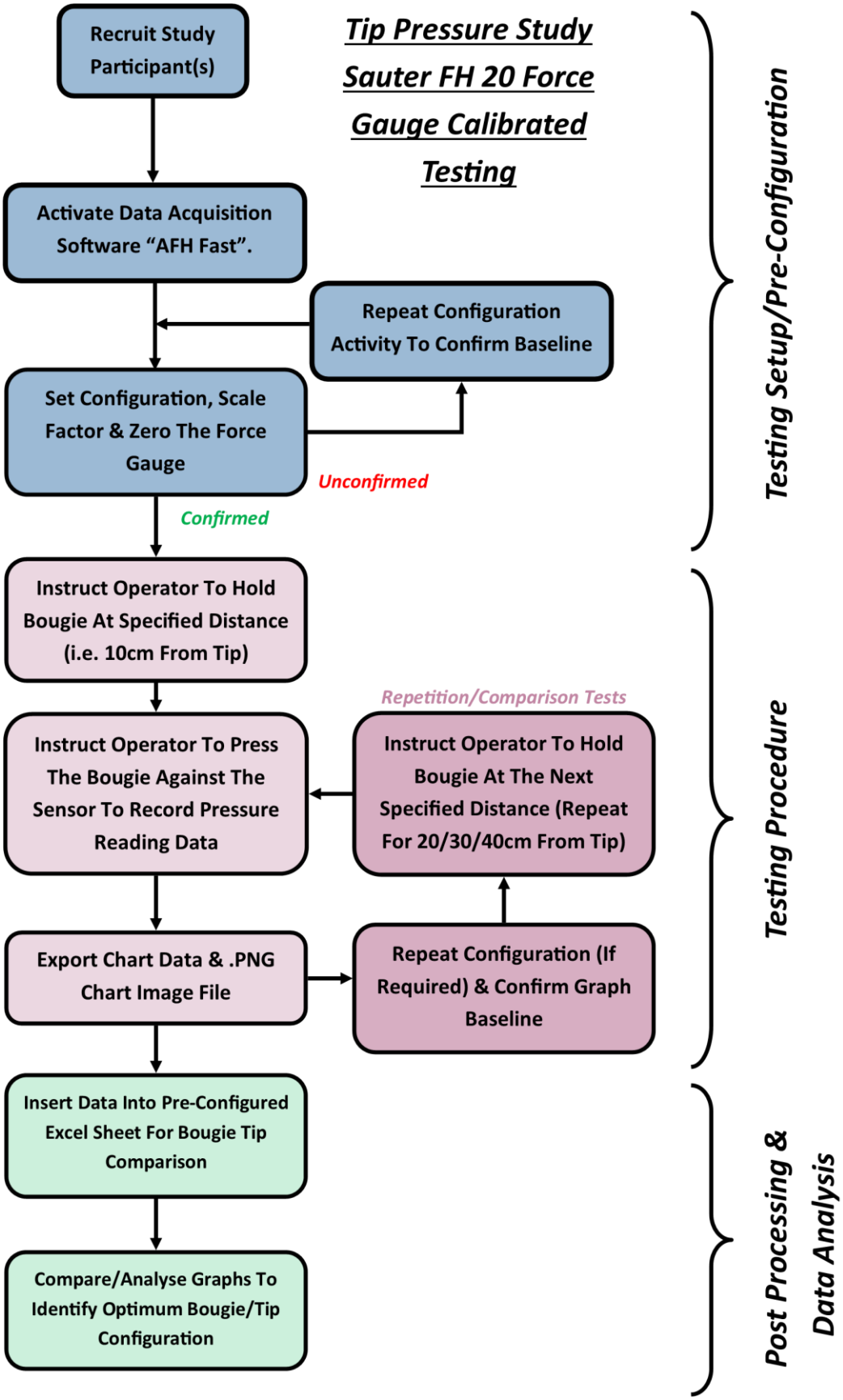


Figure 6.10: Tip Pressure Studies Protocol

6.2.6 Trained User Tip Pressure Study Survey

Alongside the tip pressure study to be completed at Nottingham University Hospitals Trust (QMC) the recruited participants are also asked to complete a short paper survey consisting of nine questions with the aim of understanding their habits and preconceptions when using a bougie. The questions asked within the survey are also directed towards defining the preferred new design features desired for a new bougie; this will also validate the questions previously asked within the online survey completed two years earlier.

The questions asked within the survey are all multiple-choice questions and are processed within an excel spreadsheet that automatically generates comparative charts. It is important within that this survey does not to have any open-ended questions, as the purpose of the survey is to determine current habits rather than identify areas for discussion or debate.

The grade of the anaesthetist and number years the anaesthetist has been using a bougie must be ascertained. Next, questions are posed that relate to the type of bougie the participant utilises; there are only a few variations available (SunMed, Frova, GEB). The distance from the tip that the participant most commonly uses the bougie is to be ascertain by measuring the held distance on an unmarked bougie.

The participants are asked to identify their preferred choice of bougie introducer from the samples provided. This will not only evaluate whether the participants are aware of what is currently available on the market, but also whether they are aware of the recommendations made by the Difficult Airways Society relating to the use of gold standard devices. Finally, questions relating to future device improvements and aesthetics are posed.

6.2.7 Airway Perforation Testing

The purpose of airway perforation testing is to establish the forces required to generate perforation when pressure is applied using a bougie to an area of the bronchus located near the carina. Porcine airways are the closest alternative to a human airway; this has been previously validated to provide similar tissue elasticity and airway anatomy (Young and Blunt and 1999; Patel, Ferguson and Patel, 2006). For this testing adequate risk assessment was necessary (Appendix G). It is expected that the design of bougies and the shape of their tip will influence the forces required to perforate porcine airway tissue. Due to the limited availability of the Flexible Tip Bougie, only one of each of the following bougies is to be tested:

- Eschmann Reusable Bougie 15CH 60cm (Smith Medical, Ashford, UK).
- SunMed Introducer Bougie 15FR 70cm (Coude) (Fannin, Wellingborough, UK).
- SunMed Introducer Bougie 15FR 70cm (Straight) (Fannin, Wellingborough, UK).
- Frova Introducer 14FR 70cm (Cook Medical, Hitchin, UK).
- Portex Single Use Bougie 15FR 70cm (Smith Medical, Ashford, UK).
- Flexible Tip Bougie (Construct Medical, Melbourne, Australia).
- Developed Steerable Bougie (Nottingham, UK).
- P3 Medical Tracheal Tube Introducer 15CH 60cm (Coude Tip).

For the study, twelve porcine airway samples (Figure 6.11) have been sourced from a local abattoir. Before the study could commence, the tongue, larynx and lungs were removed from each of the samples leaving the trachea and bronchus intact. The trachea and bronchus were then sliced vertically to create two cross sections (Figure 6.12) thus allowing each bougie to be tested a minimum of two times; each bronchus branch on each trachea can then be utilised where sufficient tracheal wall width is available.

The porcine airways were collected from the abattoir two hours prior to the testing being completed and were not refrigerated after collection to ensure that the airways tissue composition was not altered. The processed porcine airway is attached to the designed Perspex board with 3D printed fixings to replicate the trachea based on human trachea dimensions (Breatnach, Abbott and Fraser, 1984); the experimental setup is presented in Figure 6.13.

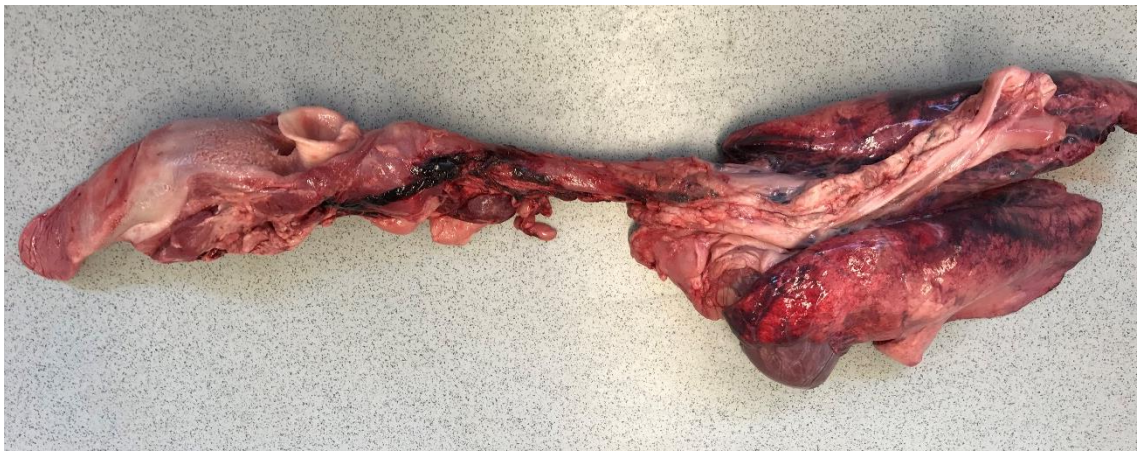


Figure 6.11: Porcine Airway Collected From A Local Abattoir

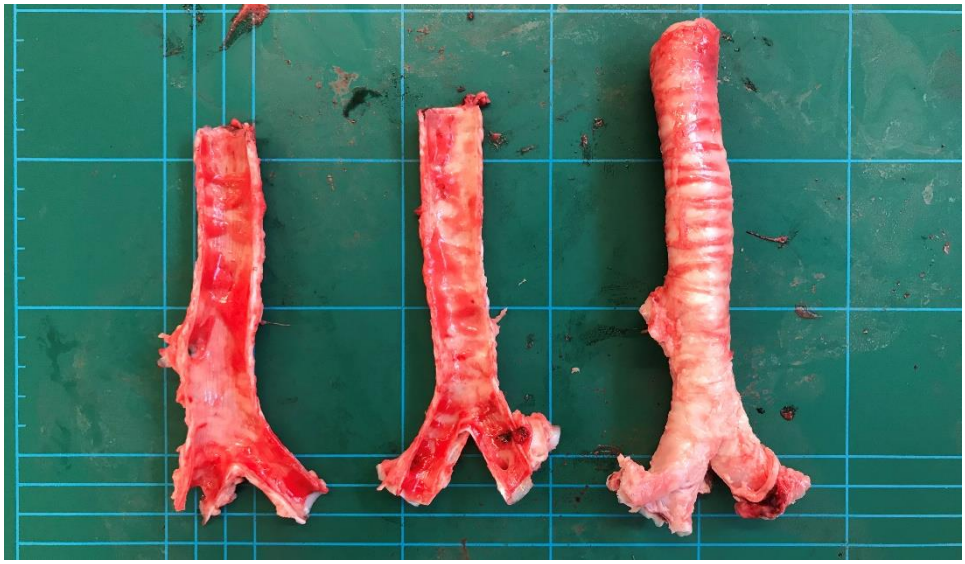


Figure 6.12: Porcine Trachea & Bronchus Cross Section

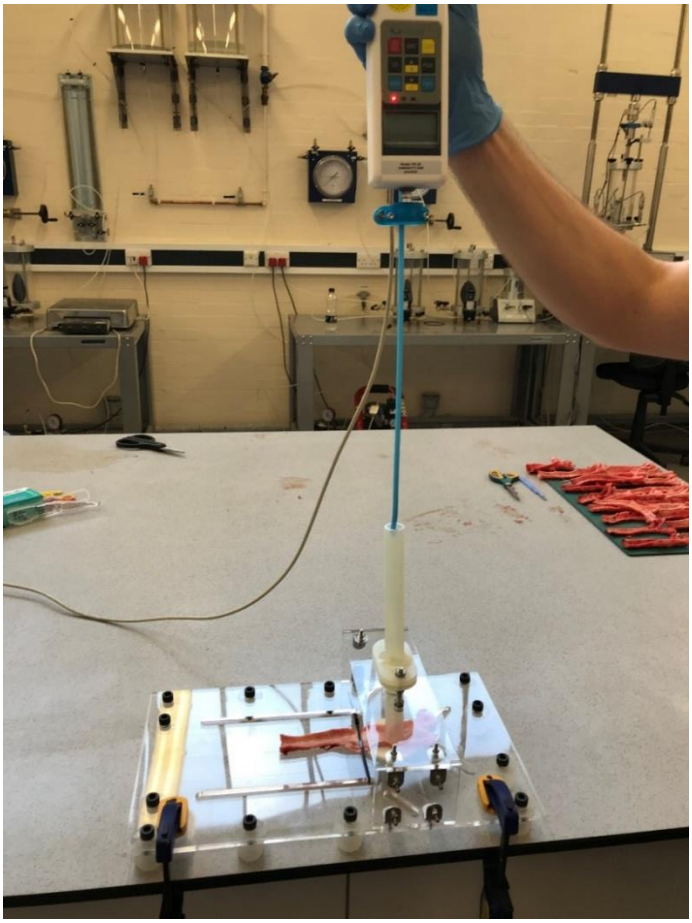


Figure 6.13: Porcine Airway Perforation Testing Experimental Setup

The bougies are attached to the Sauter FH 20 force gauge and positioned 30cm away from the bougie tip using a specially designed grip that encompasses the pressure pad tip of the force gauge. The designed bougie grip attachment (Figure 6.14) allows the bougie position to be altered if required.

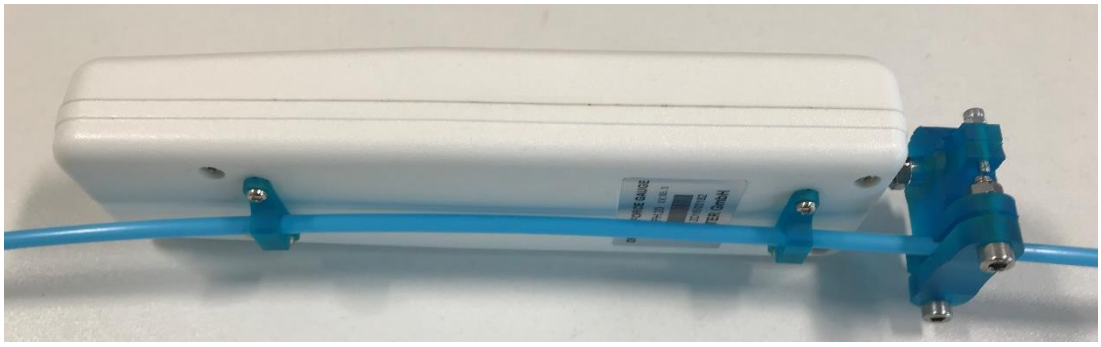


Figure 6.14: Porcine Airway Perforation Testing – Bougie Grip Setup

The testing process conducted is to push the bougie through the 3D printed fixing (designed to replicate the trachea) onto each of the bronchus branches as close to the carina as possible. The operator then keeps pushing the bougie through the 3D printed component until airway perforation is achieved or until the force gauge maximum load limit is reached (20N), at which point the porcine specimen is examined.

In the study completed by Marson et al., (2014), perforation was defined as the force required to produce airway damage when the bougie is positioned snugly in a bronchiole by gradually increasing the applied force. This was also recognised as the sudden give or appearance of the tip of the introducer in the subpleural tissue.

Within the study completed by the project team, airway perforation is defined as the bougie placing a hole through the tracheal wall, therefore perforating the trachea completely when located at the carina/start of the bronchus branch. The testing location used is perceived by the project team as the most likely location when perforation damage would occur. All measurements were completed by two trained anaesthetist operators with the control of data acquisition software and experimental setup managed by the author of the thesis.

This study has not been randomised or blinded due to the low number of tests being completed. The study by Marson et al., (2014) focusing on the Frova and Eschmann re-usable bougie also suggests that randomisation and blinding was unlikely to have significant effect on the forces exerted at the tip in the experimental setting. Blinding of the study would also require altering the mechanical qualities of the bougies by masking the bougies from the operator.

6.3 Manufactured Bougies - Tip Pressure Results & Analysis

Utilising the protocol presented in Figure 6.1, the sixty manufactured bougies have been tested. To begin with, the bougies were manufactured from nine different silicones which have varying shore hardness values; the material specifications and technical data information is presented in Tables 6.2 and 6.3.

	Material			
Physical Properties	**Platisl Gel 00**	**Platisl Gel 10**	**Platisl Gel -25**	**Transil 40-1**
Mix Ratio (Weight)	1A:1B	1A:1B	1A:1B	10A:100B
Shore Hardness	OO30	10A	25A	40A
Pour Time (Min)	6	6	5	110
Demould Time (Min)	30	30	60	1440
Cured Colour	Milky White	Milky White	Milky White	Translucent
Mixed Viscosity (cP)	15,000	15,000	15,000	35,000
Specific Volume (in^3/lb)	25	25	25	-
Specific Gravity (g/cc)	1.1 @25°C	1.1 @25°C	1.1 @25°C	-
Shrinkage (%)	Nil	Nil	Nil	< 0.1
Tear Strength (KN/m approx.)	56	810	146	>0.000018
Elongation At Break (%, approx.)	1275	970	385	280

Table 6.2: Silicone Material Technical Data

	Material				
Physical Properties	**Smooth-Sil 935**	**Smooth-Sil 940**	**Smooth-Sil 950**	**Transil 20**	**BlueSil RTV 3428**
Mix Ratio (Weight)	100A:10B	100A:10B	100A:10B	1A:1B	10A:100B
Shore Hardness	35A	40A	50A	20A	28A
Pour Time (Min)	45	30	45	4	60
Demould Time (Min)	1440	1440	1080	35	960
Cured Colour	Blue	Pink	Blue	Translucent	White
Mixed Viscosity (cP)	40,000	35,000	35,000	7000	-
Specific Volume (in^3/lb)	23.5	23.4	22.3	-	-
Specific Gravity (g/cc)	1.18@25°C	1.18@25°C	1.24@@25°C	-	-
Shrinkage (%)	<0.01	<0.01	<0.01	< 0.1	< 0.1
Tear Strength (KN/m approx.)	-	-	-	15	20
Elongation At Break (%, approx.)	300	300	320	500	600

Table 6.3: Silicone Material Technical Data

Each of the above mentioned bougies have been cast into a steerable bougie which for the purpose of this initial testing is set at a flexible tip length of 40cm. Each of the bougies are

tested and pressed against the force gauge five times at 10cm intervals from the bougie tip; the arithmetic mean is then calculated; the results of the assessment of the nine initial bougie are presented in Table 6.4 and Figure 6.15.

	R1-5 = Distance Held / Mean (N) SE = Standard Error							
Bougie Tip Material Construction	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Smooth-Sil 935	0.750	0.009	0.234	0.006	0.176	0.004	0.142	0.004
Smooth-Sil 940	0.954	0.012	0.392	0.006	0.284	0.004	0.244	0.007
Smooth-Sil 950	1.514	0.048	0.916	0.012	0.876	0.009	0.790	0.016
Transil 40-1	3.304	0.090	2.528	0.038	1.562	0.030	0.928	0.009
Transil 20	1.196	0.017	0.848	0.031	0.630	0.021	0.430	0.011
Platsil Gel -25	1.314	0.012	0.762	0.032	0.678	0.023	0.470	0.013
Platsil Gel 10	0.464	0.019	0.274	0.013	0.278	0.015	0.162	0.016
Platsil Gel 00	0.138	0.007	0.134	0.010	0.084	0.007	0.066	0.005
BlueSil RTV 3428	1.110	0.035	0.496	0.007	0.402	0.024	0.400	0.015

Table 6.4: Initial Bougie Construction Material Assessment Collated Data

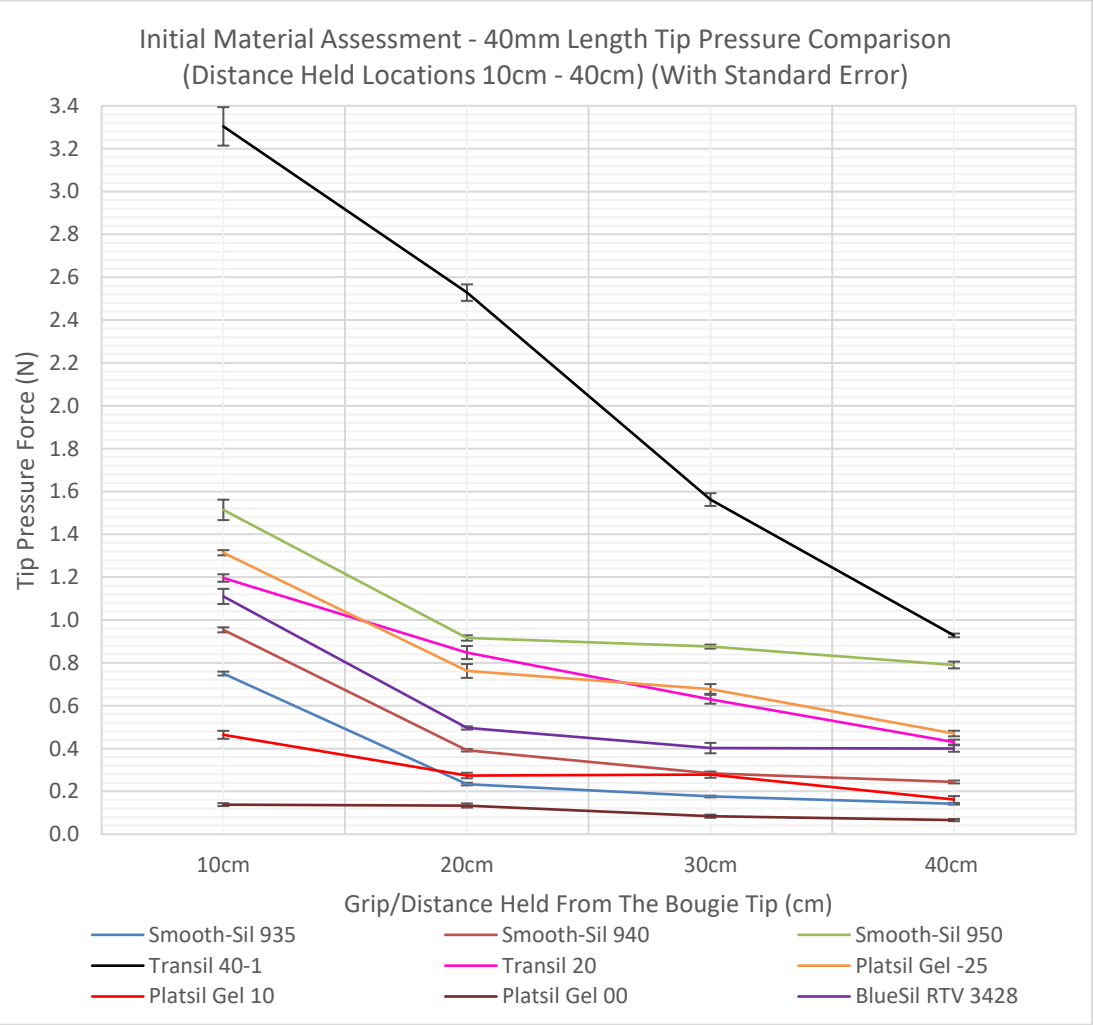


Figure 6.15: Initial Bougie Construction Material Assessment Chart

The results collected across the nine bougies present a standard deviation of <0.1 apart from the readings captured at a distance of 10cm from the tip of the bougie for Smooth-Sil 950 and Transil 40-1 where standard deviations of 0.107 and 0.201 are presented. These two standard deviation values are not unexpected, as the Smooth-Sil 950 and Transil 40-1 are the two bougies that exhibit the highest tip pressures and therefore the range of pressures capable of being generated are higher and more variable due to their significantly higher hardness values compared to the other seven bougies. Interestingly, the Transil 40-1 material exhibits significantly higher tip pressures compared to the other materials. Several of the materials that have similar material properties exhibit lower tip pressures; the tip pressures presented by the Transil 40-1 bougie therefore do not follow the expected trend.

All the bougies including the three bougie materials selected by the anaesthetists (Smooth-Sil 935, 940) follow the trend of reducing tip pressures as the distance held from the tip is increased; the range between these three bougies is noticeable on the graph. As the shore hardness values of the material increase the tip pressures increase.

Each of the Smooth-Sil materials will now have several bougies developed using incremental hardness added to the material composition; flexible tips of 35mm and 60mm are manufactured for comparative review. Tables 6.5 and 6.6 and Figures 6.16 and 6.17 present the tip pressure test results collected for the Smooth-Sil 935 and 950 flexible tips of 60mm.

	R1-5 = Distance Held / Mean (N) SE = Standard Error							
Bougie Tip Material Construction	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Smooth-Sil 935	0.272	0.009	0.168	0.010	0.070	0.004	0.070	0.004
Smooth-Sil 935 + 5% Hardener	0.334	0.009	0.236	0.009	0.098	0.004	0.094	0.006
Smooth-Sil 935 + 10% Hardener	0.348	0.008	0.300	0.012	0.122	0.004	0.104	0.004
Smooth-Sil 935 + 15% Hardener	0.382	0.009	0.262	0.006	0.134	0.002	0.148	0.004
Smooth-Sil 935 + 20% Hardener	0.536	0.025	0.308	0.012	0.146	0.007	0.128	0.008
Smooth-Sil 935 + 25% Hardener	0.546	0.009	0.286	0.012	0.136	0.002	0.122	0.002
Smooth-Sil 935 + 30% Hardener	0.508	0.016	0.340	0.016	0.144	0.004	0.114	0.002
Smooth-Sil 935 + 35% Hardener	0.516	0.010	0.274	0.006	0.168	0.006	0.120	0.007
Smooth-Sil 935 + 40% Hardener	0.576	0.020	0.274	0.004	0.142	0.002	0.142	0.002
Smooth-Sil 935 + 45% Hardener	0.544	0.018	0.302	0.012	0.256	0.014	0.136	0.007
Smooth-Sil 935 + 50% Hardener	0.668	0.017	0.330	0.004	0.198	0.006	0.164	0.012

Table 6.5: Smooth Sil-935 (60mm Straight Tip) Data

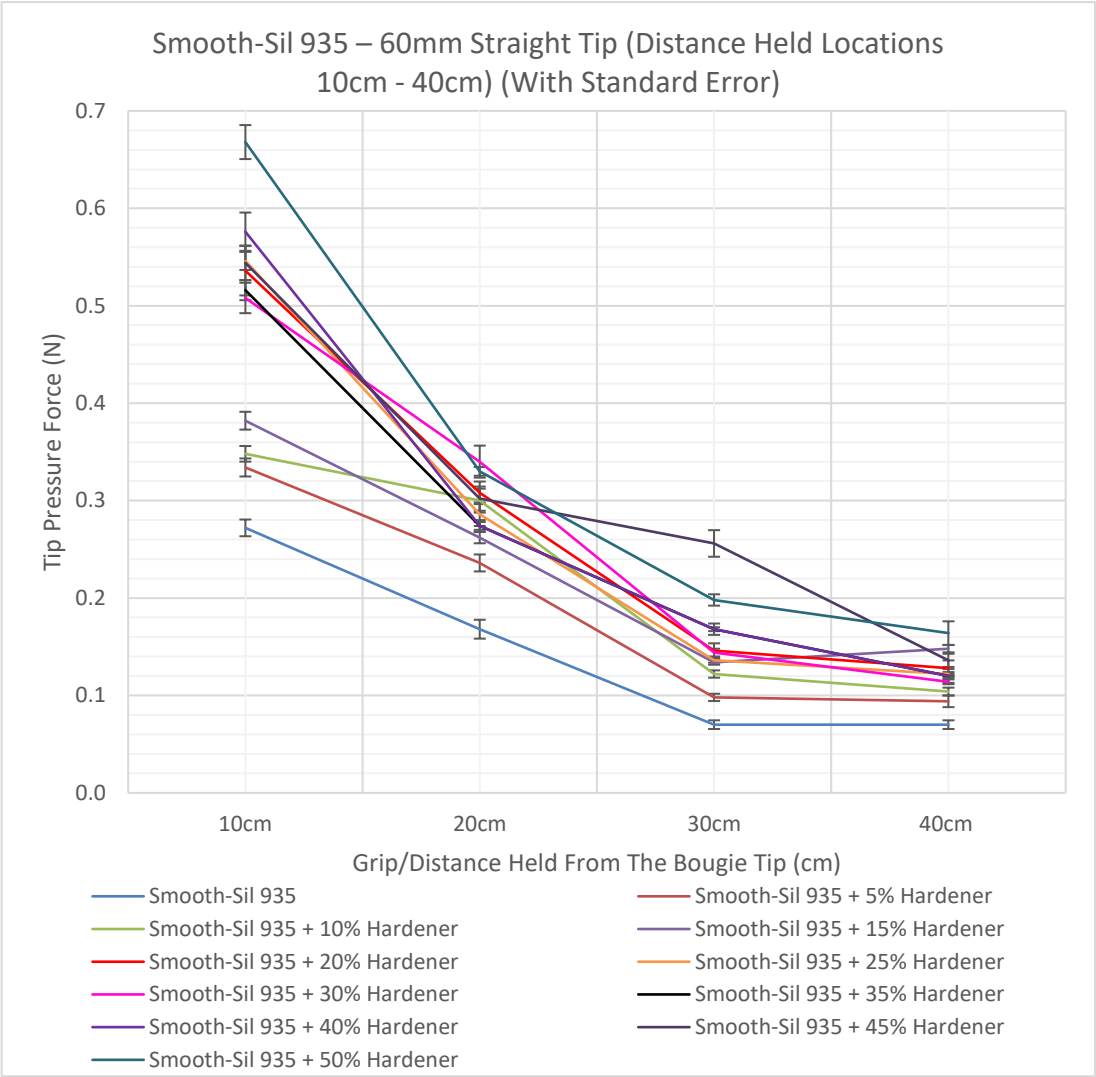


Figure 6.16: Smooth Sil-935 (60mm Straight Tip) Chart

	R1-5 = Distance Held / Mean (N) SE = Standard Error							
Bougie Tip Material Construction	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Smooth-Sil 950	1.078	0.036	0.460	0.010	0.240	0.009	0.214	0.013
Smooth-Sil 950 + 5% Hardener	0.978	0.021	0.396	0.012	0.222	0.006	0.188	0.007
Smooth-Sil 950 + 10% Hardener	0.984	0.037	0.478	0.007	0.190	0.008	0.208	0.004
Smooth-Sil 950 + 15% Hardener	0.772	0.012	0.364	0.016	0.196	0.004	0.148	0.004
Smooth-Sil 950 + 20% Hardener	1.116	0.032	0.430	0.006	0.278	0.006	0.222	0.005
Smooth-Sil 950 + 25% Hardener	1.250	0.025	0.436	0.002	0.262	0.009	0.236	0.013
Smooth-Sil 950 + 30% Hardener	1.114	0.019	0.418	0.019	0.224	0.009	0.166	0.004
Smooth-Sil 950 + 35% Hardener	1.088	0.010	0.366	0.012	0.242	0.007	0.206	0.010
Smooth-Sil 950 + 40% Hardener	1.228	0.015	0.426	0.007	0.280	0.005	0.262	0.007
Smooth-Sil 950 + 45% Hardener	1.256	0.028	0.494	0.011	0.316	0.007	0.264	0.007
Smooth-Sil 950 + 50% Hardener	1.308	0.028	0.416	0.005	0.268	0.009	0.236	0.005

Table 6.6: Smooth Sil-950 (60mm Straight Tip) Data

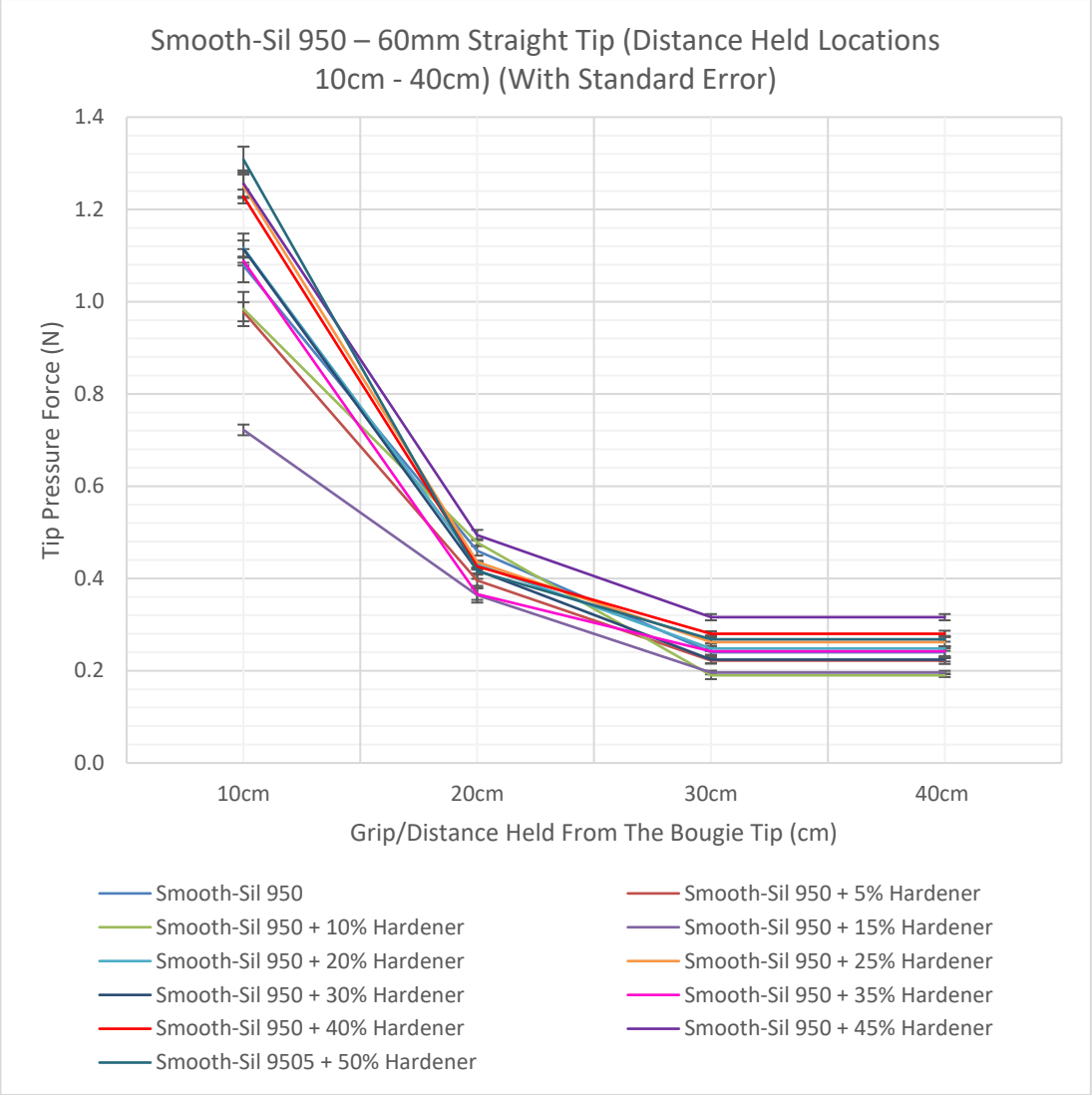


Figure 6.17: Smooth Sil-935 (60mm Straight Tip) Chart

The two data sets again present charts that follow the expected trend of reducing tip pressures as the distance held from the bougie tip is increased. All the data collected presents standard error of mean values of <0.040 suggesting an accurate set of results has been collected with very little deviation. When the Smooth-Sil 935 and 950 bougies were held at 20, 30 and 40 cm from the bougie tip, the results typically clustered and represent approximately 0.1-0.15N of variable tip pressure force across the data set; this is a minimal change. When the bougies are held at 10cm from the tip, the tip pressures generated are significantly higher and are also more widespread (Smooth Sil 935: 0.272 – 0.668N, Smooth-Sil 950: 0.722 – 1.308N); the values are almost double when the shore hardness differs by 15A. One of the obvious issues with the bougies is the floppiness exhibited; shortening the bougie tips is therefore required. As the bougie tips are made shorter from 60mm to 35mm, the tip pressures become more widespread (0.1 – 1.8N) as demonstrated in Tables 6.7, 6.8 and 6.9 and Figures 6.18, 6.19 and 6.20.

	R1-5 = Distance Held / Mean (N) SE = Standard Error							
Bougie Tip Material Construction	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Smooth-Sil 935	0.774	0.026	0.324	0.009	0.214	0.013	0.184	0.004
Smooth-Sil 935 + 5% Hardener	1.038	0.029	0.468	0.016	0.294	0.009	0.252	0.014
Smooth-Sil 935 + 10% Hardener	1.052	0.020	0.414	0.008	0.296	0.006	0.180	0.004
Smooth-Sil 935 + 15% Hardener	1.076	0.025	0.342	0.015	0.174	0.002	0.146	0.004
Smooth-Sil 935 + 20% Hardener	1.024	0.019	0.372	0.009	0.212	0.007	0.172	0.007
Smooth-Sil 935 + 25% Hardener	1.360	0.021	0.476	0.014	0.320	0.011	0.296	0.006
Smooth-Sil 935 + 30% Hardener	1.390	0.047	0.822	0.036	0.428	0.011	0.362	0.012
Smooth-Sil 935 + 35% Hardener	1.402	0.049	0.394	0.013	0.310	0.012	0.266	0.013
Smooth-Sil 935 + 40% Hardener	1.536	0.039	0.472	0.013	0.374	0.021	0.354	0.013
Smooth-Sil 935 + 45% Hardener	1.600	0.052	0.522	0.008	0.482	0.024	0.390	0.014
Smooth-Sil 935 + 50% Hardener	1.766	0.030	0.948	0.038	0.658	0.022	0.528	0.033

Table 6.7: Smooth Sil-935 (35mm Straight Tip) Data

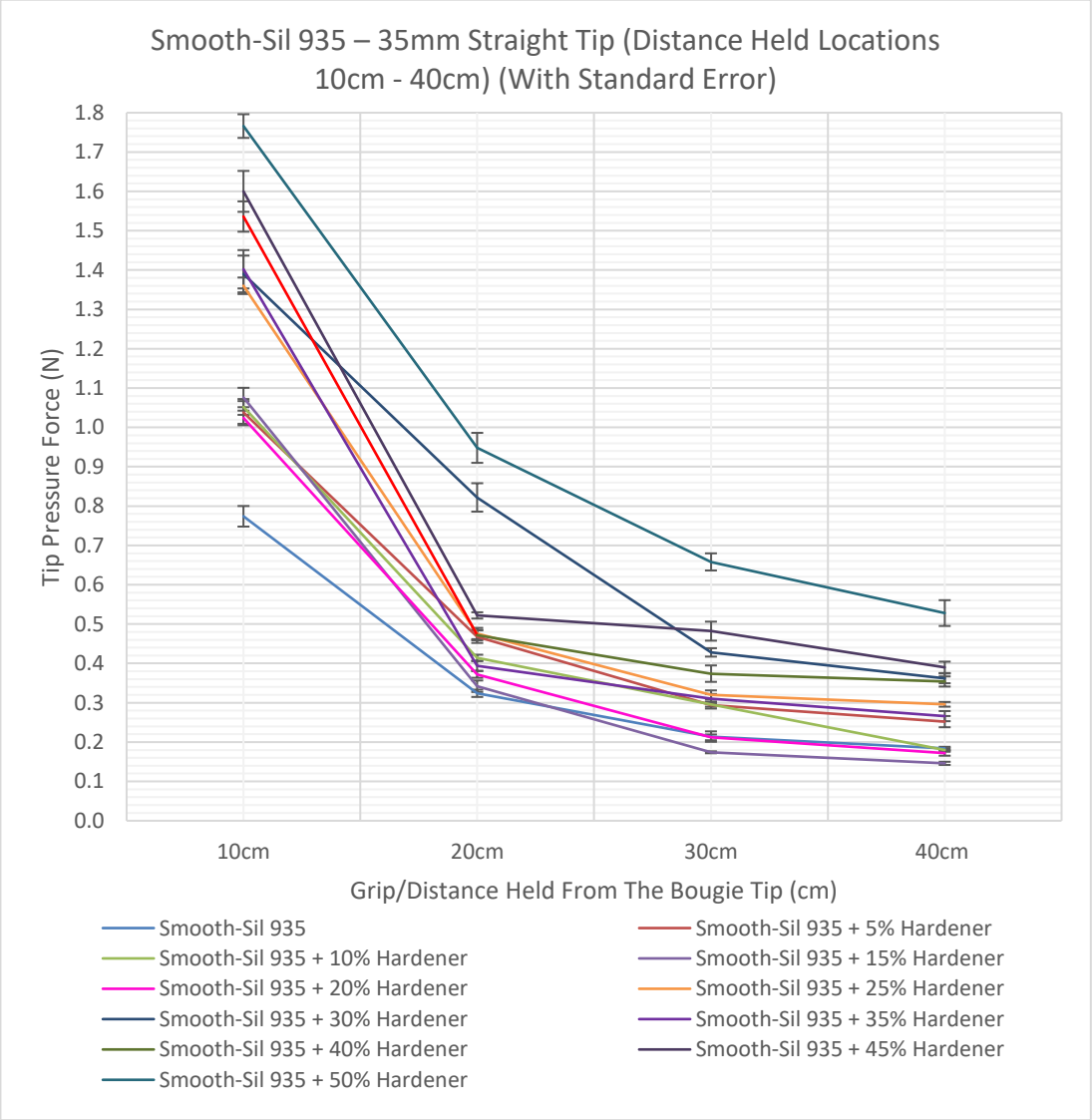


Figure 6.18: Smooth Sil-935 (35mm Straight Tip) Chart

	R1-5 = Distance Held / Mean (N) SE = Standard Error							
Bougie Tip Material Construction	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Smooth-Sil 950	1.050	0.022	0.512	0.025	0.442	0.004	0.382	0.015
Smooth-Sil 950 + 5% Hardener	1.312	0.031	1.058	0.020	0.708	0.009	0.548	0.024
Smooth-Sil 950 + 10% Hardener	1.444	0.037	0.782	0.020	0.598	0.022	0.498	0.022
Smooth-Sil 950 + 15% Hardener	1.448	0.027	0.788	0.027	0.582	0.029	0.374	0.017
Smooth-Sil 950 + 20% Hardener	1.438	0.039	0.822	0.019	0.730	0.031	0.456	0.007
Smooth-Sil 950 + 25% Hardener	1.402	0.039	0.754	0.020	0.598	0.012	0.514	0.017
Smooth-Sil 950 + 30% Hardener	0.680	0.029	0.372	0.015	0.236	0.014	0.242	0.016
Smooth-Sil 950 + 35% Hardener	1.424	0.025	0.806	0.013	0.654	0.023	0.572	0.019
Smooth-Sil 950 + 40% Hardener	1.488	0.050	0.534	0.014	0.378	0.005	0.354	0.015
Smooth-Sil 950 + 45% Hardener	1.700	0.016	0.850	0.020	0.622	0.007	0.470	0.010
Smooth-Sil 950 + 50% Hardener	1.672	0.016	1.072	0.037	0.702	0.023	0.558	0.028

Table 6.8: Smooth Sil-950 (35mm Straight Tip) Data

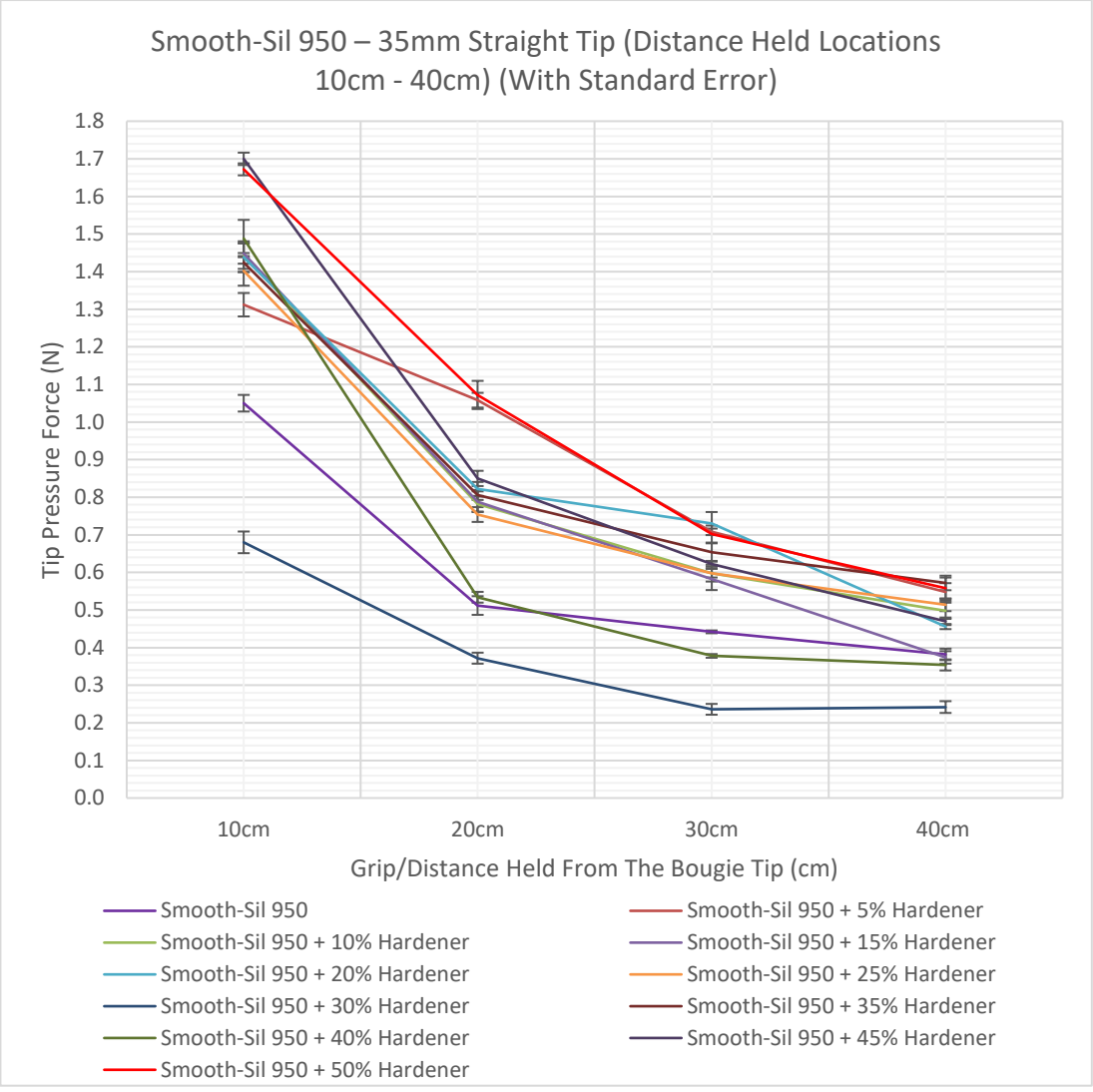


Figure 6.19: Smooth Sil-950 (35mm Straight Tip) Chart

For many of the readings collected, a gradual increase in the tip pressures is presented. Interestingly, the maximum tip pressure readings collected stay within the same range for both material compositions and it is the length of the tip as hypothesised that alters the tip pressure readings. When comparing the 35mm and 60mm bougie tips, it is immediately noticeable the user has greater control with the 35mm bougie tips; the 35mm bougie tips are less floppy and easier to place, guide, rotate and operate; this contributes to the increased tip pressures generated.

One observation made for the Smooth Sil-950 (35mm Straight Tip) is the unexpected lower readings for the bougie tips constructed when 30% and 40% hardener is added to the mix; this does not conform to the expected trend of increased tip pressures because of increased hardener. Upon closer inspection of the bougies, manufacturing defects were observed, including splitting at the connection point between the tip and multi lumen shaft (Smooth-Sil 950 + 40% hardener) and fracture of the ground wire within the bougie tip for the Smooth-Sil 950 + 30% hardener tip.

As a result of this discovery, the two bougies need recasting and retesting. Table 6.9 and Figure 6.20 present the retest data and the integration of the retest data into the comparative chart. It is immediately obvious within Figure 6.20 that the retest data fits into the expected trend and again the data clusters into sections within the relative grip distance categories.

The data collected again presents the standard error of mean values of <0.040 suggesting an accurate set of results has been collected with very little deviation; higher standard error of mean values were exhibited in the failed testing data, this also added suspicion that an error in the construction of the bougies was present as all of the data was clustered suggesting significant deformation of the material or tip.

	R1-5 = Distance Held / Mean (N) SE = Standard Error							
Bougie Tip Material Construction	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Smooth-Sil 950 + 30% Hardener	0.680	0.029	0.372	0.015	0.236	0.014	0.242	0.016
Smooth-Sil 950 + 30% Hardener (Re-Test)	1.404	0.043	0.788	0.030	0.520	0.008	0.376	0.014
Smooth-Sil 950 + 40% Hardener	1.488	0.050	0.534	0.014	0.378	0.005	0.354	0.015
Smooth-Sil 950 + 40% Hardener (Re-Test)	1.422	0.012	0.762	0.016	0.578	0.008	0.452	0.014

Table 6.9: Smooth Sil-950 (35mm Straight Tip) Re-Test Data

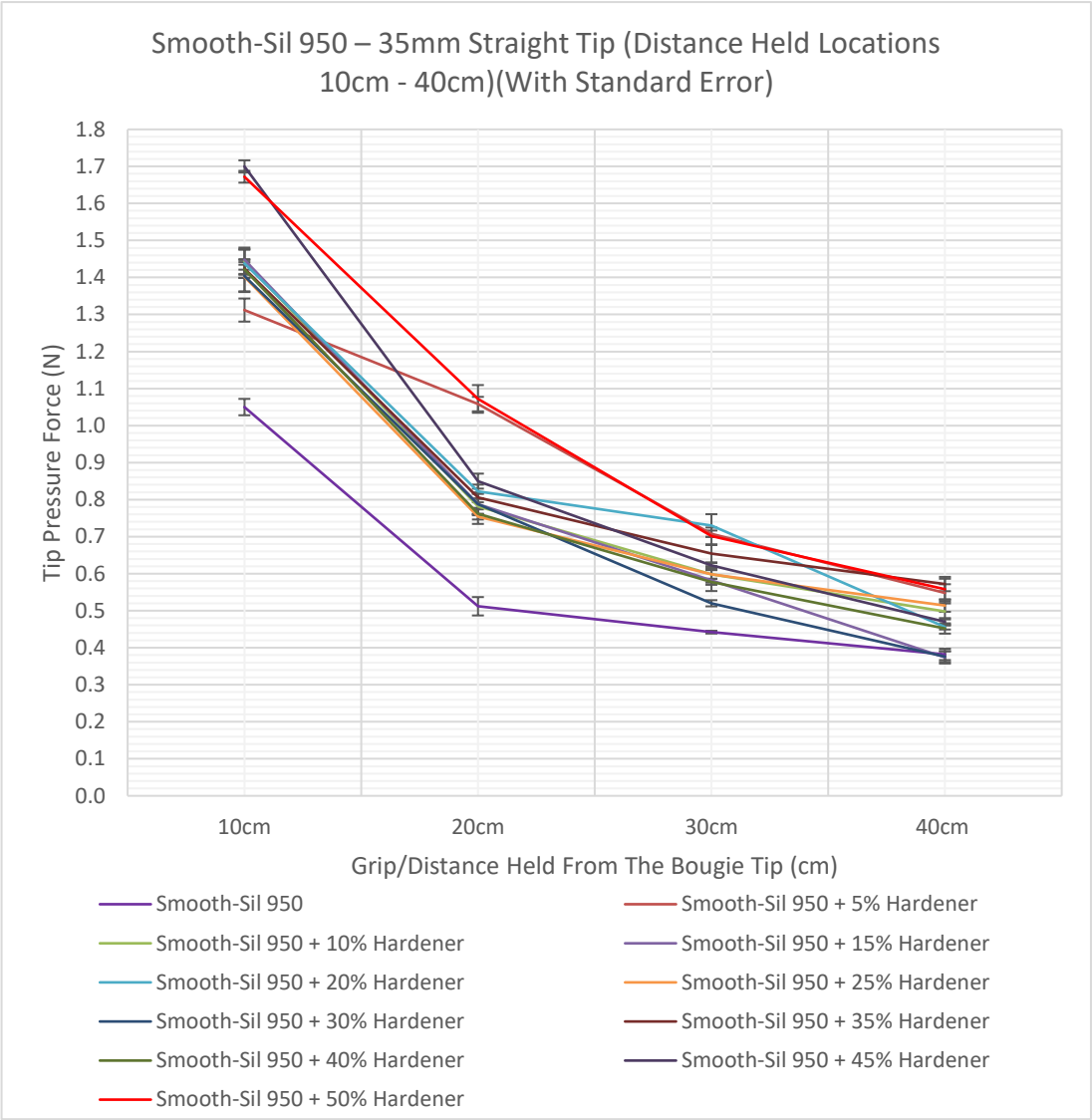


Figure 6.20: Smooth Sil-950 (35mm Straight Tip) - Re-Test Data Chart

To investigate the observed trends further, bougies are constructed with 35mm and 60mm flexible tips using Smooth Sil 940 (the 3rd ranked material by the anaesthetists). Tables 6.10 and 6.11 and Figures 6.21 and 6.22 present these results. Upon review of the results, the expected trends are yet again observed; the results typically cluster when the readings collected are lower and the distance held is increased. The more hardener added to the mix the tip pressures typically increase; in the case of the 60cm flexible tips the Smooth-Sil 940 + 10% hardener and Smooth-Sil 940 + 30% hardener, the values recorded for the 10cm distance held tests are lower. No obvious manufacturing defects are exhibited so this can only be attributed to user control or inability to control the device adequately with a longer, flexible tip.

For the 35mm flexible tips, the expected trends are presented; the readings collected at 20cm from the bougie tip Smooth-Sil 940 + 30% hardener drop lower than expected. It is not

uncommon for a couple of anomalies to be presented within the data as the bougie tip may slip off or out of the depression plate/cup. It is also interesting to discover that in the case of the Smooth-Sil 940 bougie tips the increase in tip pressures between the 60mm and 35mm tips is not as significant as the level of hardener added increases; in the cases of Smooth-Sil 935 and 950 typically the tip pressure forces, especially at the 10cm distance doubles, with Smooth-Sil 940 this is below double.

	R1-5= Distance Held / Mean (N) SE = Standard Error							
Bougie Tip Material Construction	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Smooth-Sil 940	0.662	0.025	0.228	0.004	0.124	0.002	0.086	0.002
Smooth-Sil 940 + 10% Hardener	0.598	0.017	0.276	0.015	0.116	0.002	0.100	0.003
Smooth-Sil 940 + 30% Hardener	0.604	0.019	0.224	0.012	0.130	0.005	0.084	0.002
Smooth-Sil 940 + 50% Hardener	0.804	0.017	0.464	0.028	0.184	0.007	0.158	0.006

Table 6.10: Smooth Sil-940 (60mm Straight Tip) Data

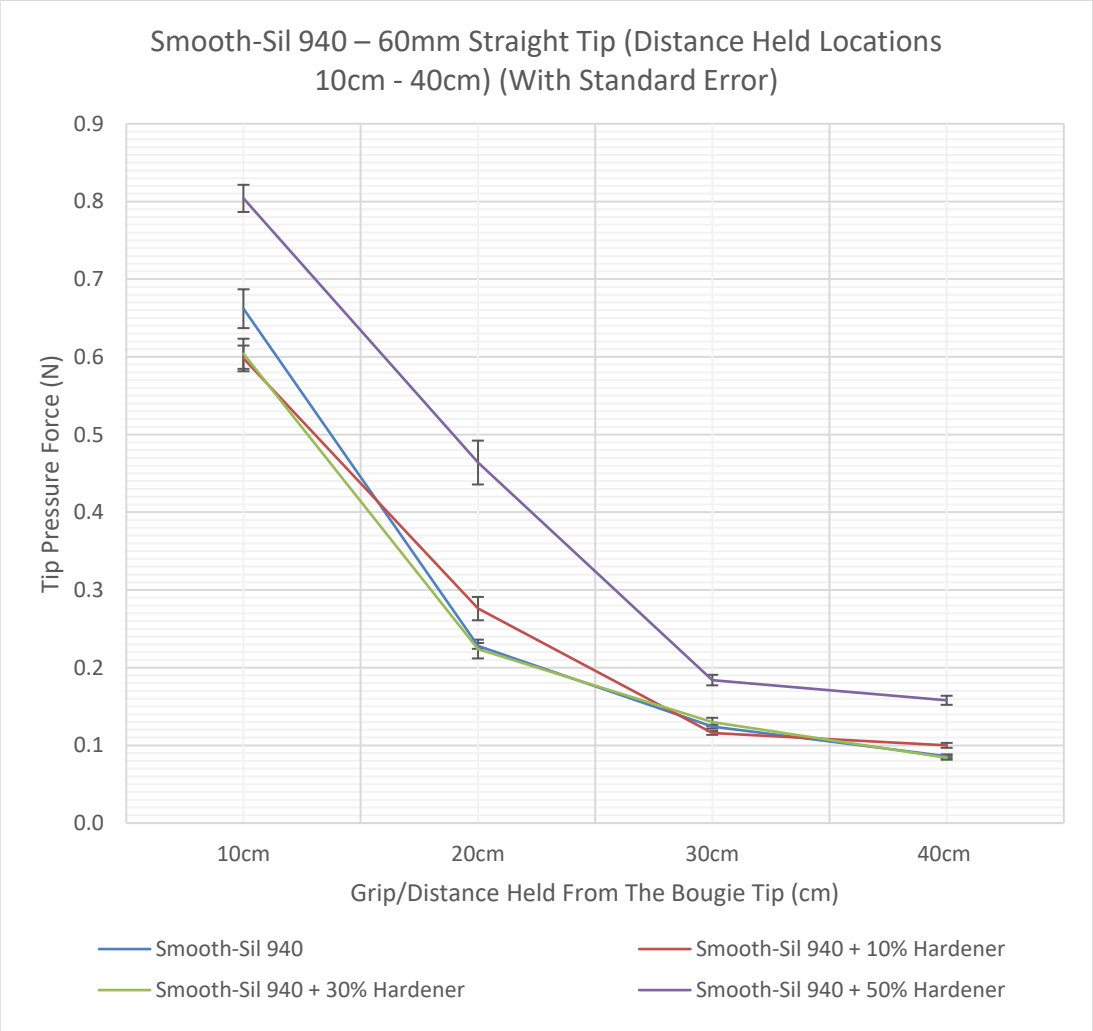


Figure 6.21: Smooth Sil-940 (60mm Straight Tip) Chart

	R1-5= Distance Held / Mean (N) SE = Standard Error							
Bougie Tip Material Construction	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Smooth-Sil 940	1.094	0.055	0.424	0.016	0.242	0.008	0.224	0.018
Smooth-Sil 940 + 10% Hardener	1.074	0.038	0.438	0.023	0.302	0.012	0.252	0.008
Smooth-Sil 940 + 30% Hardener	1.036	0.032	0.280	0.003	0.314	0.011	0.222	0.005
Smooth-Sil 940 + 50% Hardener	1.292	0.039	0.518	0.017	0.350	0.019	0.306	0.016

Table 6.11: Smooth Sil-940 (35mm Straight Tip) Data

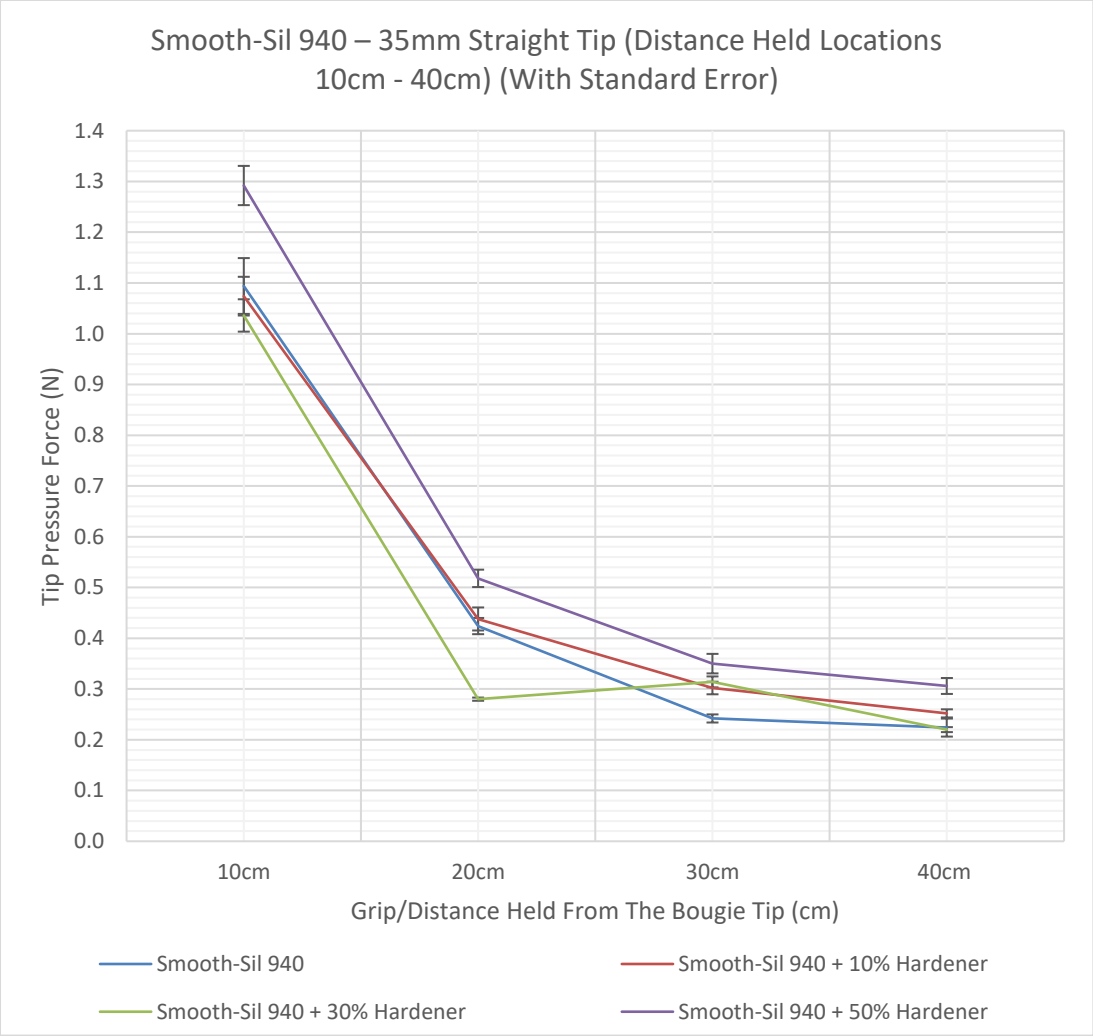


Figure 6.22: Smooth Sil-940 (35mm Straight Tip) Chart

Typically, most of the commercially available adult bougies have a coude tip and do not use straight tips, this is because the tip pressures for coude tip bougies are less (as presented in Section 6.4) but also coude tips act as a useful feature for intubating an anterior larynx. For the development of the steerable bougie, the coude tip could be both a positive and negative feature. The coude tip would provide a curve for the anaesthetist to utilise, the use of the straight tip which can be controlled to bend in two directions as required takes away the

need for the coude tip. It could be argued that a slight “S” bend to the bougie would increase the steerable functionality to the device, this could result in the lodging of the bougie tip within the trachea if not accurately controlled.

Table 6.12 and Figure 6.23 present the data and chart for the 35mm coude tip bougies constructed using Smooth-Sil 935 plus incremental hardener. The standard error of the mean is slightly higher for this set of data (<0.050) compared to the straight tip bougies (<0.040) as the coude tip adds an element of greater variability when pressing the tip of the bougie onto the force gauge. As expected the trend presented within the results is the incremental increase of the tip pressures at the 10cm and 20cm distance held locations and the clustering of the readings at the 30cm and 40cm distance held readings; the 50% hardener bougie as expected presented the highest tip pressure readings.

Another variable which must be considered is the degree of angle of the coude tip; Table 6.13 and Figure 6.24 review the incremental increase of the angle of the coude tips ranging from 3-9^{o}. Upon reviewing the data, when the bougies are held 10cm away from the tip of the bougie, the greater the angle of the coude tip results in greater tip pressures exhibited, this may be due to the increase surface area that is pressed up against the force gauge due to the angle of the bougie. Reviewing the data collected for the bougies held 20cm, 30cm and 40cm away from the tip, the 3^{o} and 5^{o} bougies exhibit less pressure than the 7^{o} and 9^{o} degree coude tip bougies.

The 3^{o} and 5^{o} coude tip bougies tip pressure values remain below 0.45N; when the 7^{o} and 9^{o} coude tip bougies are held at 20cm from the bougie tip they present tip pressure values of 0.488N and 0.556N; these values continue to drop for the 30cm and 40cm distance held positions. When comparing the material composition alterations through the addition of hardener or the alteration of the coude tip angle, both cause the gradual increase of tip pressure.

Regardless of the tip pressures generated, with the aim for these to be as low as possible, if the devices cannot be used to aid the intubation of the patient, then the activity of developing a flexible tip bougie is pointless. Each of the bougies will require a bougie placement validation test to ascertain whether they are fit for purpose; this will also help define the final bougie tip construction, whether this should be a longer floppier flexible tip or whether this should be shorter and stiffer. Other factors such as a straight tip versus coude tip and soft tip versus hard tip can also be debated.

	R1-5= Distance Held / Mean (N) SE = Standard Error							
Bougie Tip Material Construction	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Smooth-Sil 935	1.064	0.019	0.430	0.012	0.358	0.008	0.340	0.005
Smooth-Sil 935 + 10% Hardener	1.134	0.033	0.388	0.010	0.324	0.015	0.280	0.014
Smooth-Sil 935 + 30% Hardener	1.204	0.045	0.556	0.013	0.478	0.022	0.412	0.008
Smooth-Sil 935 + 50% Hardener	1.278	0.038	0.488	0.007	0.346	0.009	0.334	0.008

Table 6.12: Smooth Sil-935 (35mm Coude Tips) Data

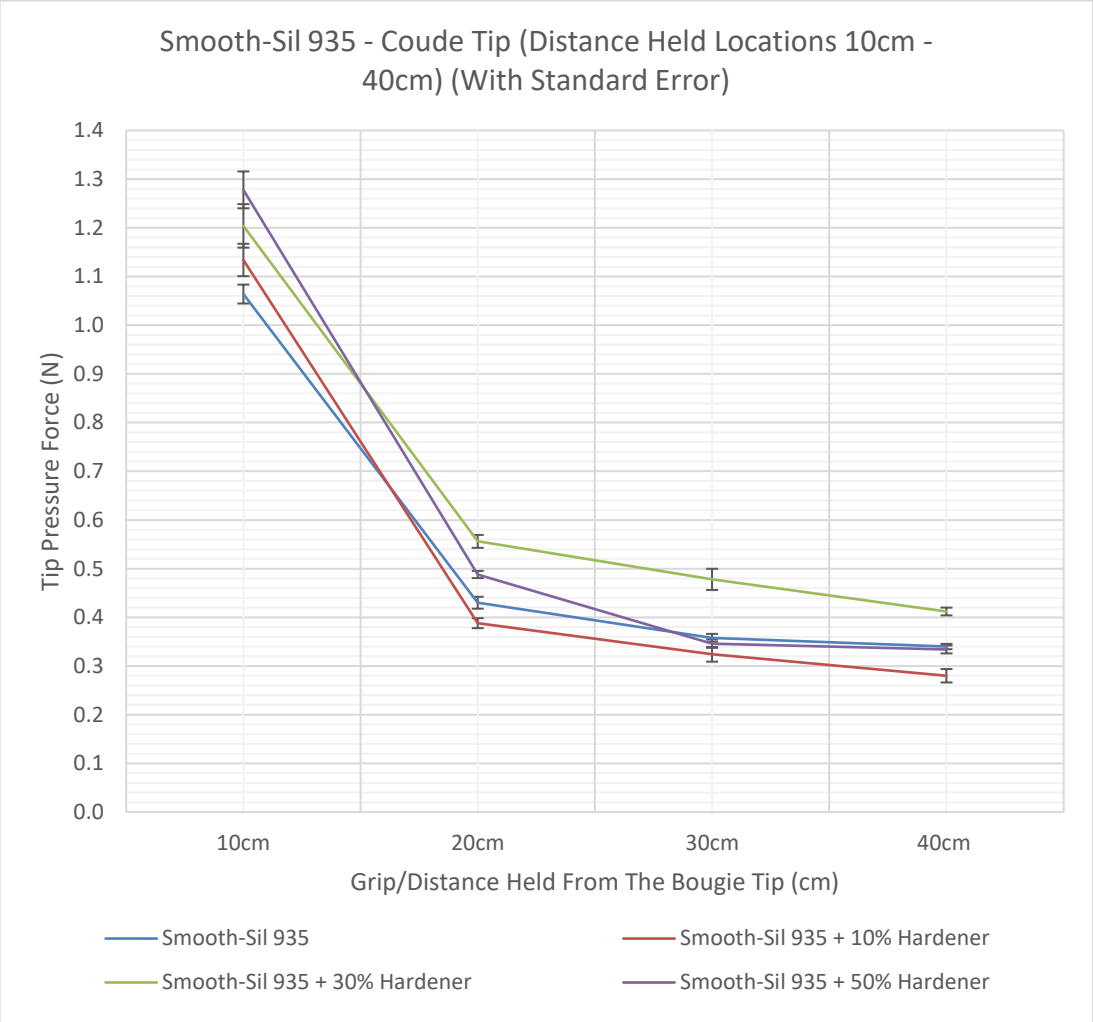


Figure 6.23: Smooth Sil-935 (35mm Coude Tips) Chart

	R1-5= Distance Held / Mean (N) SE = Standard Error							
Bougie Tip Material Construction	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Smooth-Sil 935 Coude Tip 1 (3°)	1.014	0.034	0.294	0.013	0.270	0.011	0.248	0.004
Smooth-Sil 935 Coude Tip 2 (5°)	1.062	0.019	0.404	0.012	0.318	0.006	0.266	0.010
Smooth-Sil 935 Coude Tip 3 (7°)	1.016	0.018	0.456	0.006	0.318	0.007	0.240	0.003
Smooth-Sil 935 Coude Tip 4 (9°)	1.122	0.029	0.500	0.009	0.222	0.004	0.216	0.007

Table 6.13: Smooth Sil-935 (35mm Variable Angle Coude Tips) Data

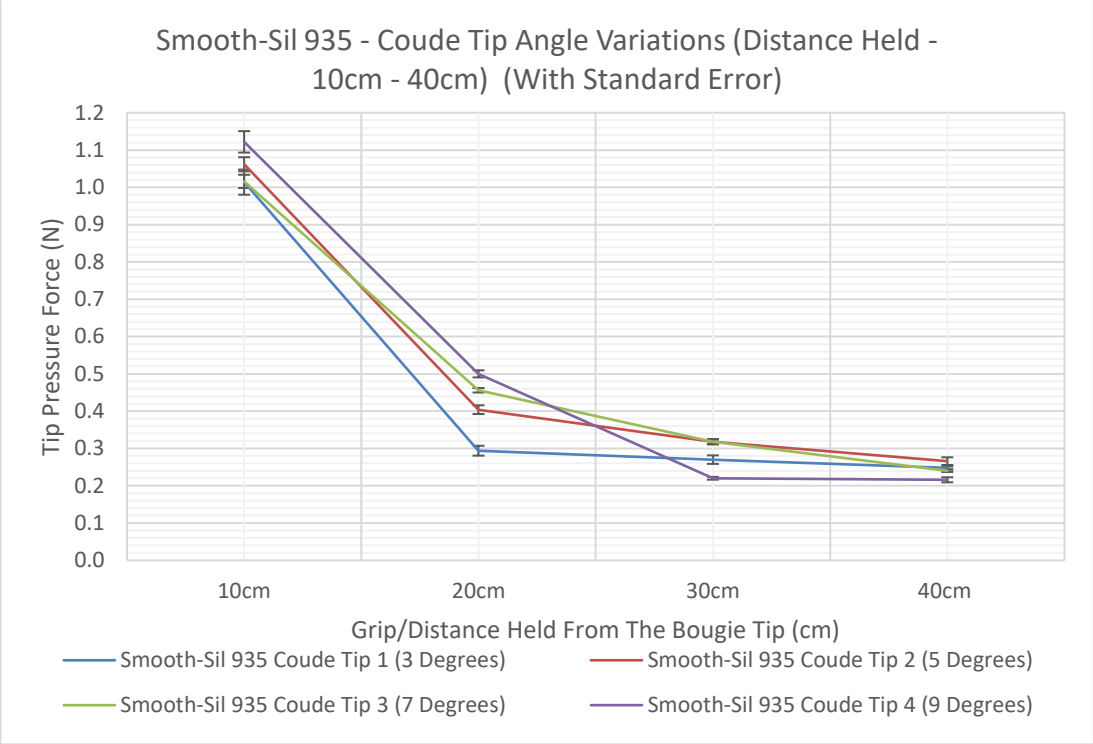


Figure 6.24: Smooth Sil-935 (35mm Coude Variable Angle Tips) Chart

When comparing the original Smooth-Sil 935 straight tip bougie to the developed coude tip bougies (Figure 6.25) constructed out of the basic Smooth-Sil 935 mix, surprisingly the straight tip bougie provides the lowest tip pressures. It is therefore hypothesized that for certain material compositions a straight tip flexible tip bougie is the optimal construction option, this is the opposite when compared to the commercially available rigid bougies as they all typically have coude tips. Straight tip bougies currently available on the market often display significantly higher tip pressures.

Figure 6.26 presents a comparison of the coude tip bougies and straight tip bougies with incremental values of hardener added to the material mix. When reviewing the chart, the two bougies that demonstrate the highest tip pressures are both straight tip bougies, although the tip pressures presented are significantly lower than the commercial bougies tip pressures presented in Section 6.4. From the comparative analysis completed, the 35mm smaller tips provide greater control; these often exhibit higher tip pressures than the 60mm tips. The 35mm tip bougies still require further development. Shortening the tips to 30mm would provide even greater control and this would allow a softer tip to be cast instead. The use of a silicone that is approximately 50A in shore hardness also provides the greatest level of control but does unfortunately generate higher tip pressures than a 35-40A shore hardness tip. Further development of the steerable tip is required to ensure a realistic compromise can be found.

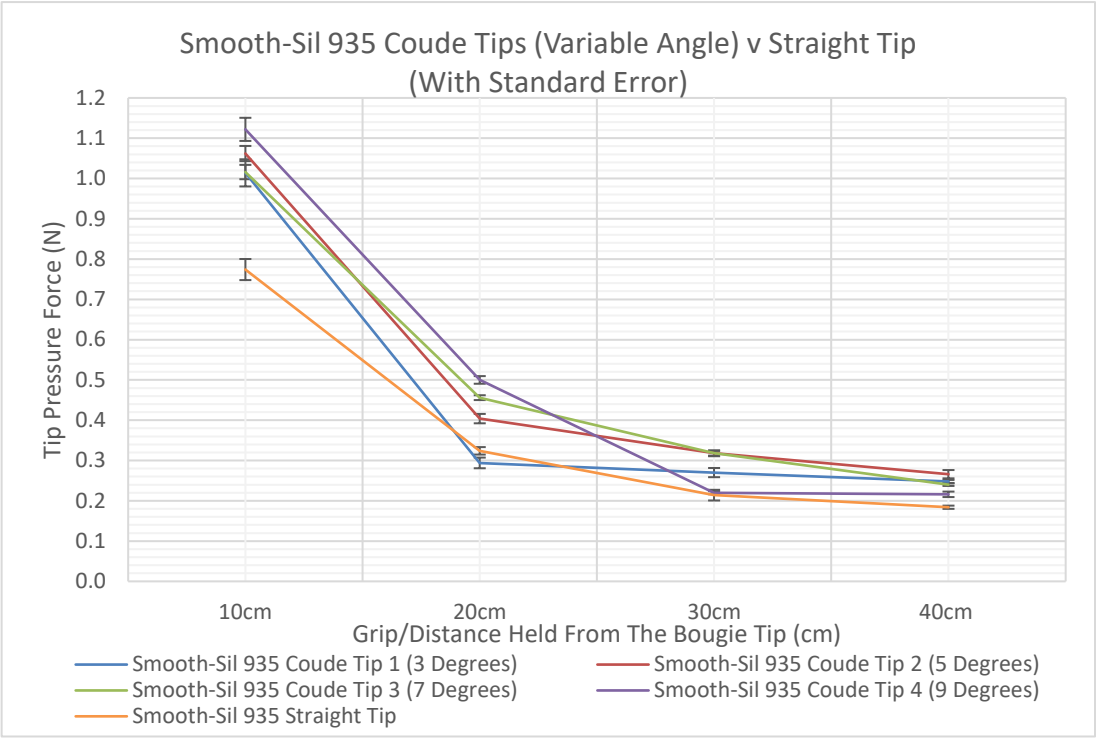


Figure 6.25: Coude Tip Angle Variations vs Straight Tip Chart

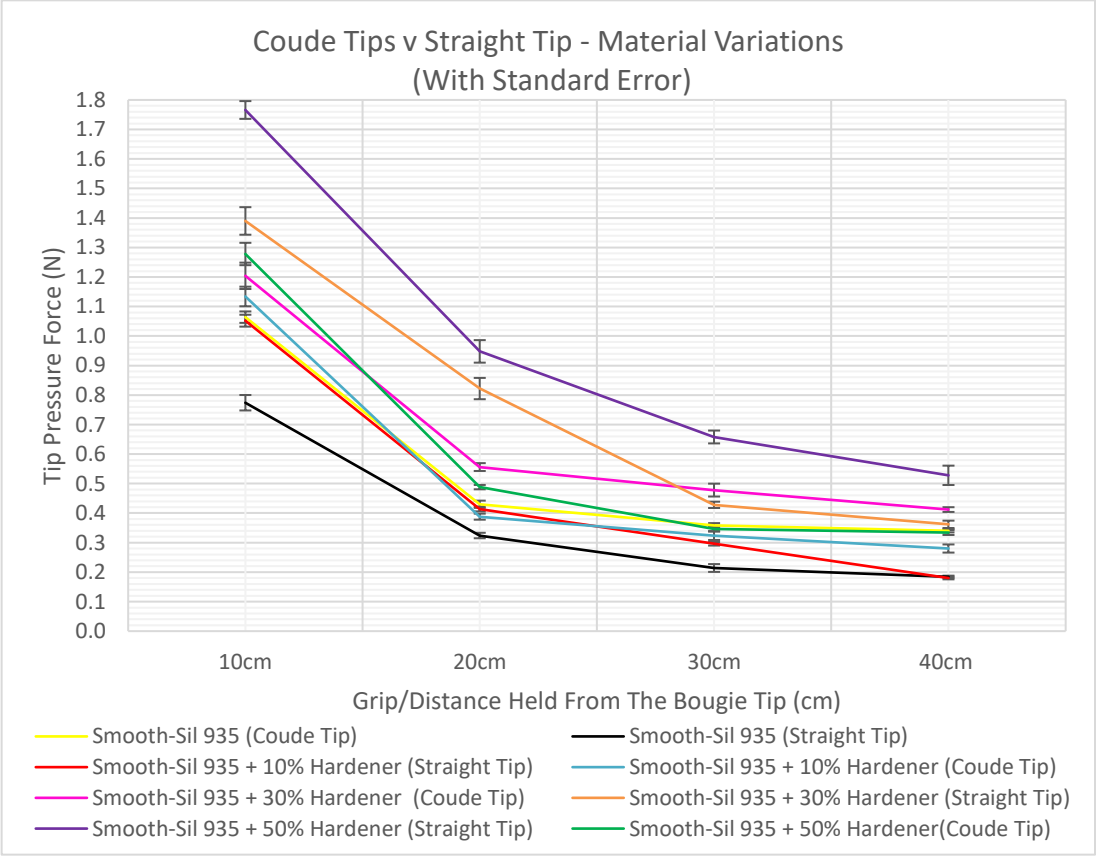


Figure 6.26: Coude Tip vs Straight Tip (Material Variations) Chart

The initial manufactured bougies have demonstrated that from the considerable number of bougies manufactured and analysed, greater tip control and reduced tip pressures can be achieved. Further development of the bougies is still required; after testing the Smooth-Sil

950 + 40 hardener bougie with the control wires, the 60-degree bi-directional movement is still not fully achieved in both directions (Figure 6.27). Promoting the bending of the steerable tip still requires further development.

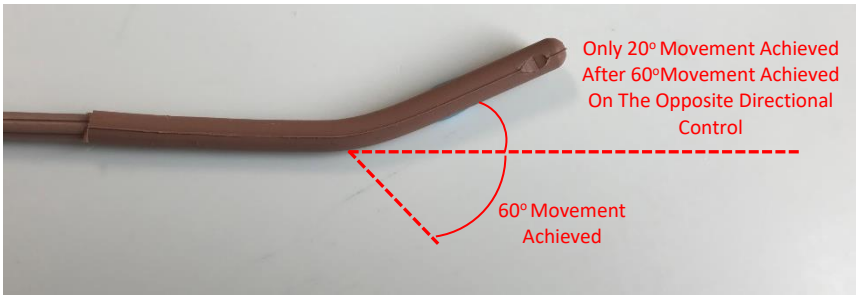


Figure 6.27: Bougie Tip Control Movement Development

6.3.1 Bougie Placement Results

As described earlier in Section 6.3, the developed bougies require validation to ascertain whether they are fit for purpose. To ascertain this, a bougie placement test is completed; each of the developed sixty bougies use are tested both unlubricated and lubricated with an intubation procedure completed on a TruCorp AirSim Advance X Manikin as depicted in Figure 6.28. By establishing whether the bougies can be placed accurately in the trachea or not, will help identify the future development criteria for the steerable bougies flexible tip.

Figure 6.28: Bougie Placement Experimental Setup

The results captured during the bougie placement experiment are simply defined as successful or unsuccessful placement (i.e. Yes or No); if the placement is unsuccessful, a coded comment is provided using the failure descriptors key presented in Table 6.14. Each of the developed bougies is tested both with and without lubricant.

Key Code	Failure Descriptors
R	Resistance experienced resulting in a loss of bougie movement.
K	Kinking or curling of the bougie tip experienced.
@10	10cm bougie insertion depth before failure.
@15	15cm bougie insertion depth before failure.
@20	20cm bougie insertion depth before failure.
LC	Loss of bougie control exhibited.
FPE	Failure to pass the epiglottis.
PA+	Bougie placement achieved but failure occurred due to issues encountered during placement. (Additional descriptors are to be provided)

Table 6.14: Smooth-Sil 940 Bougie Placement (60mm Tips)

Tables 6.15 - 6.22 present results from bougie placement tests. The developed bougies consisting of various material mixes, dimensions and shape are analysed with results on successful placement (no issues encountered) or unsuccessful placement (with coded failure comments) provided:

	Without Lubricant		With Lubricant	
Bougie Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
Smooth-Sil 935 (Original Mix)	No	K FPE LC	No	K FPE LC
Smooth-Sil 935 + 5% Hardener	No	K FPE LC	No	K FPE LC
Smooth-Sil 935 + 10% Hardener	No	K FPE LC	No	K FPE LC
Smooth-Sil 935 + 15% Hardener	No	K FPE LC	No	K FPE LC
Smooth-Sil 935 + 20% Hardener	No	K FPE LC	No	K FPE LC
Smooth-Sil 935 + 25% Hardener	No	K FPE LC	No	K FPE LC
Smooth-Sil 935 + 30% Hardener	No	K FPE LC	No	K FPE LC
Smooth-Sil 935 + 35% Hardener	No	K FPE LC	No	K FPE LC
Smooth-Sil 935 + 40% Hardener	No	K FPE LC	No	K FPE LC
Smooth-Sil 935 + 45% Hardener	No	K FPE LC	No	K FPE LC
Smooth-Sil 935 + 50% Hardener	No	K FPE LC	No	K FPE LC

Table 6.15: Smooth-Sil 935 Bougie Placement (60mm Tips)

	Without Lubricant		With Lubricant	
Bougie Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
Smooth-Sil 940 (Original Mix)	No	K FPE	No	K FPE
Smooth-Sil 940 + 10% Hardener	No	K FPE	No	K FPE
Smooth-Sil 940 + 30% Hardener	No	K FPE	No	K FPE
Smooth-Sil 940 + 50% Hardener	No	K FPE	No	K FPE

Table 6.16: Smooth-Sil 940 Bougie Placement (60mm Tips)

	Without Lubricant		With Lubricant	
Bougie Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
Smooth-Sil 950 (Original Mix)	No	R K @10	No	R K @15
Smooth-Sil 950 + 5% Hardener	No	R K @10	No	R K @15
Smooth-Sil 950 + 10% Hardener	No	R K @10	No	R K @15
Smooth-Sil 950 + 15% Hardener	No	R K @15	No	R K @15
Smooth-Sil 950 + 20% Hardener	No	R K @15	No	R K @20
Smooth-Sil 950 + 25% Hardener	No	R K @20	No	R K @20
Smooth-Sil 950 + 30% Hardener	No	R K @20	No	R K @20
Smooth-Sil 950 + 35% Hardener	No	R K @20	No	R K @20
Smooth-Sil 950 + 40% Hardener	No	R K @20	No	R K @20
Smooth-Sil 950 + 45% Hardener	No	R K @20	No	R K @20
Smooth-Sil 950 + 50% Hardener	No	R K @20	No	R K @20

Table 6.17: Smooth-Sil 950 Bougie Placement (60mm Tips)

	Without Lubricant		With Lubricant	
Bougie Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
Smooth-Sil 935 (Original Mix)	No	PA+ R K	No	PA+ K
Smooth-Sil 935 + 5% Hardener	No	PA+ R K	No	PA+ K
Smooth-Sil 935 + 10% Hardener	No	PA+ R K	No	PA+ K
Smooth-Sil 935 + 15% Hardener	No	PA+ R K	No	PA+ K
Smooth-Sil 935 + 20% Hardener	No	PA+ R K	No	PA+ K
Smooth-Sil 935 + 25% Hardener	No	PA+ R K	No	PA+ K
Smooth-Sil 935 + 30% Hardener	No	PA+ R K	No	PA+ K
Smooth-Sil 935 + 35% Hardener	No	PA+ R K	No	PA+ K
Smooth-Sil 935 + 40% Hardener	No	PA+ R K	No	PA+ K
Smooth-Sil 935 + 45% Hardener	No	PA+ R K	No	PA+ K
Smooth-Sil 935 + 50% Hardener	No	PA+ R K	No	PA+ K

Table 6.18: Smooth-Sil 935 Bougie Placement (35mm Tips)

	Without Lubricant		With Lubricant	
Bougie Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
Smooth-Sil 940 (Original Mix)	No	PA+ K @20	No	PA+ K @20
Smooth-Sil 940 + 10% Hardener	No	PA+ K @20	No	PA+ K @20
Smooth-Sil 940 + 30% Hardener	No	PA+ K @20	No	PA+ K @20
Smooth-Sil 940 + 50% Hardener	No	PA+ K @20	No	PA+ K @20

Table 6.19: Smooth-Sil 940 Bougie Placement (35mm Tips)

	Without Lubricant		With Lubricant	
Bougie Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
Smooth-Sil 950 (Original Mix)	No	K R @20	No	K R @20
Smooth-Sil 950 + 5% Hardener	No	K R @20	No	K R @20
Smooth-Sil 950 + 10% Hardener	No	K R @20	No	K R @20
Smooth-Sil 950 + 15% Hardener	No	K R @20	No	K R @20
Smooth-Sil 950 + 20% Hardener	No	K R @20	No	K R @20
Smooth-Sil 950 + 25% Hardener	No	K R @20	No	K R @20
Smooth-Sil 950 + 30% Hardener	No	K R @20	No	K R @20
Smooth-Sil 950 + 35% Hardener	Yes	N/A	Yes	N/A
Smooth-Sil 950 + 40% Hardener	Yes	N/A	Yes	N/A
Smooth-Sil 950 + 45% Hardener	Yes	N/A	Yes	N/A
Smooth-Sil 950 + 50% Hardener	Yes	N/A	Yes	N/A

Table 6.20: Smooth-Sil 950 Bougie Placement (35mm Tips)

	Without Lubricant		With Lubricant	
Bougie Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
Smooth-Sil 935	No	R @20	No	R @20
Smooth-Sil 935 + 10% Hardener	No	R @20	No	R @20
Smooth-Sil 935 + 30% Hardener	No	R @20	No	R @20
Smooth-Sil 935 + 50% Hardener	No	R @20	Yes	N/A

Table 6.21: Smooth-Sil 935 Bougie Placement (Coude Tip)

	Without Lubricant		With Lubricant	
Bougie Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
Smooth-Sil 935 Coude Tip 1	No	R K @20	No	R K @20
Smooth-Sil 935 Coude Tip 2	No	R K @20	No	R K @20
Smooth-Sil 935 Coude Tip 3	No	R K @10	No	R K @10
Smooth-Sil 935 Coude Tip 4	No	R K @10	No	R K @10

Table 6.22: Smooth-Sil 935 Bougie Placement (Coude Tip Variable Angles)

All of the Smooth-Sil 935 bougie placement tests for the 60mm tips were a complete failure. A complete loss of control of the bougie tips was observed. The tips floppiness and lack of rigidity ultimately prevented the bougies passing the epiglottis with the tips curling back on themselves; the addition of lubricant only made the curling worse. The same issues were observed with the Smooth-Sil 940 60mm tips.

Bougie placement was achieved for the Smooth-Sil 935 35cm tips, however, the tests were deemed a failure due to the significant levels of resistance observed during the intubation process with kinking of the bougie also exhibited. This required minor withdrawal of the bougie to re-straighten the bougie tip then allow reinsertion. When completed with lubricant resistance was not observed, the lubricant instead encouraged the bougie tip to kink. The Smooth-Sil 940 60mm tip tests all result in successful placement of the bougie, but these were deemed failed tests as kinking was observed when the bougie was inserted 20cm; no change was observed with the addition of lubricant.

The Smooth-Sil 935 coude tip bougies with variable angle coude tips again resulted in unsuccessful placement results. The limited hardness values exhibited by the Smooth-Sil 935 material prevents the bougies from having enough tip rigidity to achieve successful placement; significant resistance and kinking was observed when the bougie was inserted either 10-20cm into the trachea depending on the angle of the coude tip. When the 3^{o} coude tip bougie has hardener added to the mix, most of the cases resistance is exhibited at 20cm during bougie placement; when 50% hardener is added to the mix and lubrication is added to the bougie, successful placement is achieved. From this it can be deduced that bougie placement can be achieved if the material mix achieves a shore hardness value of 45A and the bougie tip is shorter with a coude tip (i.e. 35mm in length). Straight length tips will likely

need a higher shore hardness value to achieve bougie placement as the straight tip will likely curl and kink much more easily. For the Smooth-Sil 950 bougies of 60mm in length, bougie placement was a complete failure. Various levels of resistance and kinking were exhibited depending on the levels of hardener added to the material mixture, the harder the steerable tip, the greater depth the bougie insertion was able to achieve before kinking and resistance was observed. The addition of lubricant made no difference to the 60mm length bougie tips.

The Smooth-Sil 950 35mm length tips presented several bougies that allowed successful placement. It was therefore expected that the majority of the bougies would be successful. The bougies with up to 30% hardener added to the mixture failed as kinking and resistance was observed when the bougie was inserted to a depth of 20cm. When a value of 35% hardener or greater is added to the Smooth-Sil 950 mixture, successful placement is achieved. For straight tip bougies, it is deduced that a shore hardness value of 55A or greater is required for successful intubation. The shore hardness values referred to within this analysis are based on the results presented in Section 6.5.

6.4 Commercial Bougie – Initial Tip Pressure Results & Analysis

Utilising the methods described in Section 6.2.1, eleven commercially available bougies have been analysed using the tip pressure testing protocol. Ideally more than one of each bougie would be tested; due to the limited availability of the bougies and the cost implications of purchasing eleven boxes of ten bougies, one sample bougie of each type has been sourced and tested. The results of the commercial bougie tip pressure testing can be found in Table 6.23 and Figure 6.29. The full data collection can be found in Appendix J and K.

Considering the results presented by Marson et al., (2014) on bougie related airway trauma where forces as small as 0.8 and 1.1 N caused airway perforation in porcine lung model, tracheal mucosa damage can be produced very easily when a bougie is held close to the tip. An anaesthetist is very unlikely to hold a bougie at 10cm from the tip; the forces generated by all the bougies at this grip position are >2.5N. The Eschmann re-usable bougie (Smiths Medical, UK) exhibits the lowest tip pressure when held at 10cm from the bougie tip with a mean bougie tip pressure of 4.746N; the Construct Medical bougie exhibits even lower tip pressure forces, this is designed to be a flexible tip bougie and has a hollow insert to allow this flexibility to be achieved. All the other bougies exhibit significantly higher tip pressure forces when held at this distance.

One of the most concerning discoveries relates to the SunMed Introducer Bougie 15FR 70cm (Coude Tip) which is the single use bougie used in practice at Nottingham University Hospitals Trust (QMC). The SunMed bougie introducer displays the highest tip pressure values of all the coude tip bougies when held at all four distances. The recommended bougie grip position is located at 30cm – 40cm from the tip of the bougies, for the SunMed coude tip bougie, mean tip pressure values at these two distances are 3.604N and 2.034N, which is both triple and double the airway trauma values reported by Marson et al., (2014). The only bougie to display higher tip pressure forces than the SunMed coude tip bougie is the SunMed straight tip bougie; this is only the case for the 10cm and 20cm distance held positions.

	R1-5= Distance Held / Mean (N) SE = Standard Error							
Bougie	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Eschmann Re-Usable Bougie 15CH 60cm	4.746	0.162	1.868	0.078	0.952	0.024	0.694	0.024
Portex Single Use Bougie 15FR 70cm (Coude Tip)	5.550	0.094	3.096	0.052	1.788	0.051	1.070	0.017
Frova Introducer 14FR 70cm (Coude Tip)	8.196	0.165	3.598	0.037	1.876	0.024	1.228	0.019
P3 Medical Tracheal Tube Introducer 15CH 60cm (Coude Tip)	10.632	0.107	5.946	0.045	2.998	0.013	1.710	0.039
SunMed Introducer Bougie 15FR 70cm (Straight Tip)	14.638	0.153	6.458	0.167	3.136	0.137	2.044	0.056
SunMed Introducer Bougie 15FR 70cm (Coude Tip)	10.808	0.187	6.038	0.041	3.604	0.038	2.304	0.026
AviAir Intubating Bougie 15CH, 75cm (Coude Tip)	8.696	0.221	5.308	0.072	3.094	0.033	1.744	0.071
Pro Breathe Premium ET Tube Introducer 15FR 70cm (Coude Tip)	4.328	0.101	2.238	0.091	1.608	0.059	0.800	0.014
InterGuide Tracheal Tube Introducer Bougie 15FR 70cm (Coude Tip)	5.568	0.061	3.444	0.105	2.098	0.042	1.208	0.029
Flex-Guide Endotracheal Tube Introducer 15FR 60cm (Coude Tip)	7.168	0.090	3.944	0.047	2.104	0.028	1.232	0.004
Construct Medical (Flexible Tip Bougie)	2.514	0.099	1.642	0.049	1.242	0.046	1.046	0.037
Construct Medical (Flexible Tip Bougie) * Grip Position 2	N/A	N/A	2.092*	0.039	1.568*	0.038	N/A	N/A

Table 6.23: Commercially Available Bougies Tip Pressure Force Analysis

**Alternative Grip Position Due To Bougie Mechanism*

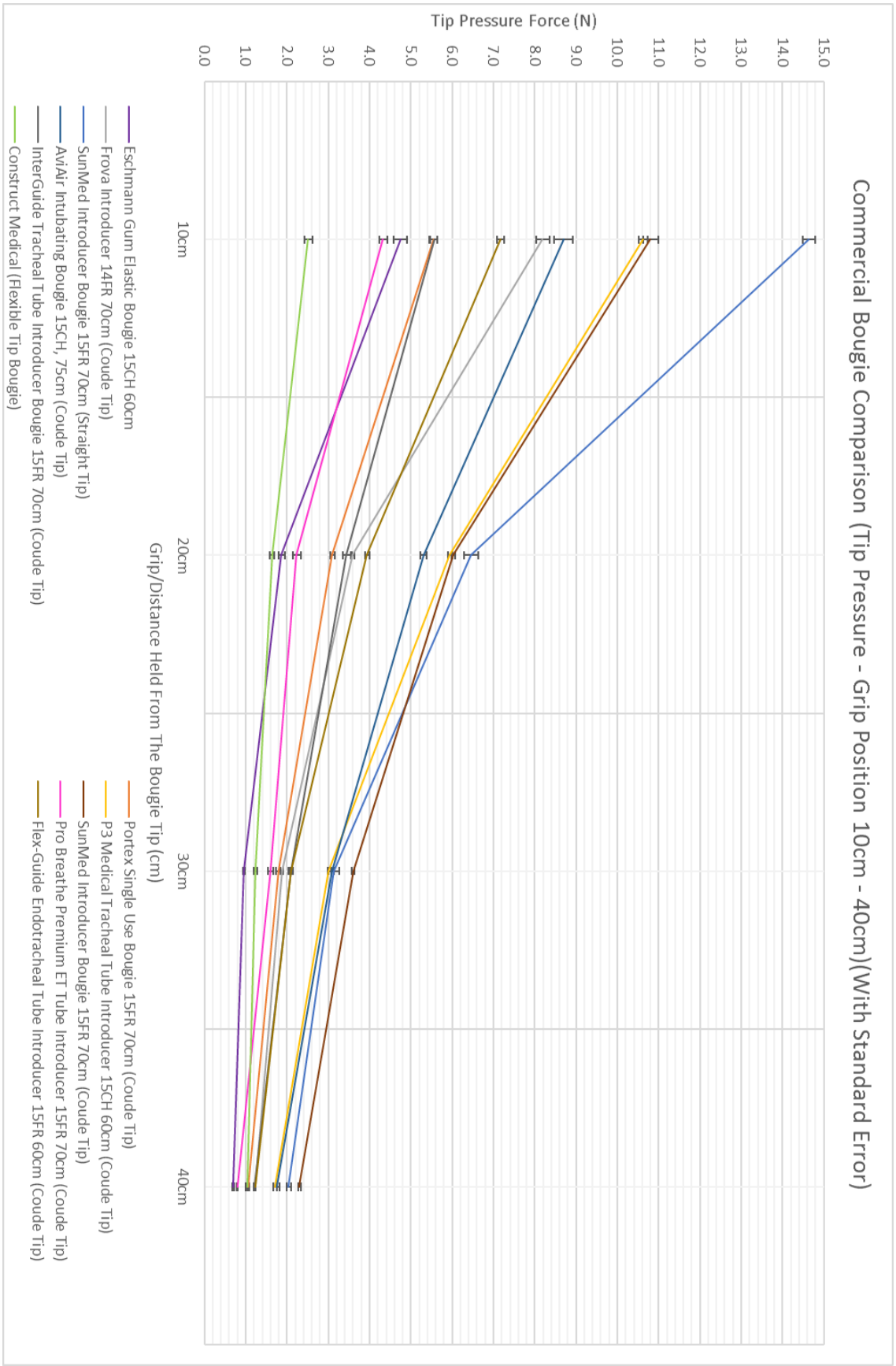


Figure 6.29: Commercial Bougie Tip Pressure Comparison

The comparative commercial bougie tip pressure chart presented in Figure 6.29, clearly demonstrates that the Gum Elastic Bougie (GEB) (Smith Medical, Ashford, UK) is the optimal bougie of choice due to exhibiting the lowest tip pressure forces at the 30cm and 40cm distance held locations. Numerous studies including Mushambi et al., (2016) propose that newer single-use tracheal tube introducers require urgent further evaluation before they are deemed acceptable alternatives for the GEB; the evidence supplied by this short commercial bougie analysis clearly emphasises why there is widespread concern. This also re-emphasises the point that simply reproducing the single use bougie using similar manufacturing methods and materials will reproduce similar results (Pandit et al., 2011).

Single use bougies often perform poorly in comparison to multiple use bougies, studies by Annamaneni et al., (2003), Hames et al., (2003), Marfin et al., (2003) and Hodzovic, Wilkes and Latto (2004) all suggest this. The use of single use bougies continues to increase. Rowley and Digwall (2007) also identify growing concern about the quality and efficacy of some single-use devices, leading to several clinicians questioning the safety of using these devices.

Upon further review of Figure 6.29, the expected trend of reduced tip pressures as the grip position increases in distance from the tip of the bougie is presented. As the tip pressure readings collected reach the 30cm distance, there become two clear clusters of bougie tip pressure readings. The first cluster where readings of 3N or higher are presented, includes the SunMed, P3 and AviAir bougies. The second cluster where values of 1N – 2.5N are presented contain the remaining single use bougies and the multiple use GEB. It is important to highlight that the GEB used in this review was brand new and was not taken from the clinical environment where the reuse or sterilisation process may have altered the material composition of the bougie.

Aside from the GEB, the other two bougies most commonly used in practice according to Mushambi et al., (2016) are the Frova introducer and Portex single use bougie. The tip pressures recorded at the 30cm distance held for these bougies are 1.788N and 1.876, this is still in excess of 0.6N of the bougie related trauma observed by Marson et al., (2014). This review highlights current issues with many of the bougies; many manufacturers are attempting to gain a portion of the bougie market yet fail to produce a suitably safe and compliant product regardless of the approvals they have acquired. The development of the steerable bougie will consider these discoveries and ensure that these issues are factored into the design development process. The steerable bougie will also be compared to the commercially available bougies once full development has been completed.

6.5 Shore Hardness Testing

The bougies tested in Section 6.3 were constructed from three-materials, Smooth-Sil 935, 940 and 950 with incremental hardener added to the mix. During the manufacture of these tips, sample disks were created and are now to be tested using a durometer to identify their shore hardness values.

To conduct the shore "A" hardness tests accurately, the testing must conform to the ASTM_D2240-03 standard test method for rubber properties utilising a durometer (ASTM International, 2003). The D2240-03 shore hardness test standard describes twelve types of rubber hardness measurement devices known as durometers for Types A, B, C, D, DO, E, M, O, OO, OOO, OOO-S, and R. This testing procedure is utilised to determine the indentation hardness of substances classified as thermoplastic elastomers, vulcanized (thermoset) rubber, elastomeric materials, cellular materials, gel-like materials and some plastics (ASTM International, 2003). The method used to complete this testing is set out in Section 6.2.2.

6.5.1 Shore Hardness Test Results

Date Of Test: 21.04.2018 **Relative Humidity:** 54% **Ambient Room Temperature:** 22°C

Durometer Manufacturer/Model: HTTK-37 Compact 1-100HA Digital Durometer

Material Composition	Time Of Test	Reading 1	Reading 2	Reading 3	Reading 4	Reading 5	Mean
Smooth-Sil 935 (Original Mix)	16:15	34.5	34.5	36	34	35.5	34.9A
Smooth-Sil 935 + 5% Hardener	16:17	35.5	36.5	36	35.5	36	35.9A
Smooth-Sil 935 + 10% Hardener	16:18	36.5	37.5	36	36.5	36.5	36.6A
Smooth-Sil 935 + 15% Hardener	16:19	37.5	37	36.5	36.5	37	36.9A
Smooth-Sil 935 + 20% Hardener	16:21	37	37.5	36	37	38.5	37.2A
Smooth-Sil 935 + 25% Hardener	16:23	38	40.5	39.5	40.5	38.5	39.4A
Smooth-Sil 935 + 30% Hardener	16:25	41	42.5	40.5	42	41.5	41.5A
Smooth-Sil 935 + 35% Hardener	16:26	42.5	41.5	42	40.5	42.5	41.8A
Smooth-Sil 935 + 40% Hardener	16:28	42.5	44	43	43	43.5	43.2A
Smooth-Sil 935 + 45% Hardener	16:30	43	42.5	43.5	43.5	43.5	43.2A
Smooth-Sil 935 + 50% Hardener	16:31	43.5	43.5	43.5	44	43	43.5A

Table 6.24: Smooth-Sil 935 Shore "A" Hardness Tests

Date Of Test: 21.04.2018 **Relative Humidity:** 54% **Ambient Room Temperature:** 23°C

Durometer Manufacturer/Model: HTTK-37 Compact 1-100HA Digital Durometer

Material Composition	Time Of Test	Reading 1	Reading 2	Reading 3	Reading 4	Reading 5	Mean
Smooth-Sil 950 (Original Mix)	14:40	49.5	50.5	50	49.5	50	49.9A
Smooth-Sil 950 + 5% Hardener	14:42	49.5	50	50.5	50	50.5	50.1A
Smooth-Sil 950 + 10% Hardener	14:43	50.5	52	50	51.5	52	51.2A
Smooth-Sil 950 + 15% Hardener	14:44	51.5	51	52.5	51	50	51.2A
Smooth-Sil 950 + 20% Hardener	14:46	51.5	52	52	52	51.5	51.8A
Smooth-Sil 950 + 25% Hardener	14:48	51.5	52	52	53	52	52.1A
Smooth-Sil 950 + 30% Hardener	14:50	53	52.5	52.5	54	53	53A
Smooth-Sil 950 + 35% Hardener	14:52	52	54	51.5	52	53	52.5A
Smooth-Sil 950 + 40% Hardener	14:53	52.5	54	54	54	53.5	53.6A
Smooth-Sil 950 + 45% Hardener	14:55	52.5	53.5	54.5	55	54	53.9A
Smooth-Sil 950 + 50% Hardener	14:57	54	53	54	56	55	54.4A

Table 6.25: Smooth-Sil 950 Shore “A” Hardness Tests

Date Of Test: 21.04.2018 **Relative Humidity:** 54% **Ambient Room Temperature:** 23°C

Durometer Manufacturer/Model: HTTK-37 Compact 1-100HA Digital Durometer

Material Composition	Time Of Test	Reading 1	Reading 2	Reading 3	Reading 4	Reading 5	Mean
Smooth-Sil 940 (Original Mix)	15:15	40.5	39.5	39.5	41	40	40.1A
Smooth-Sil 940 + 10% Hardener	15:17	41.5	39.5	41	40.5	41.5	40.8A
Smooth-Sil 940 + 30% Hardener	15:19	42.5	41	43	41.5	42.5	42.1A
Smooth-Sil 940 + 50% Hardener	15:21	46.5	44	45	46	45	45.3A

Table 6.26: Smooth-Sil 940 Shore “A” Hardness Tests

Based on the feedback collected from the anaesthetists in Chapter 5, Smooth-Sil 935 and 950 of ranges between 30-45% hardener was the most liked based on the tactile feedback presented. The shore hardness values for these material compositions range between 40A and 55A and as such this range must be adhered to when amendments are to be made during the steerable tip development stages presented in Section 6.6.

6.6 Steerable Tip Development

Based on the analysis of the developed steerable tips presented in Section 6.3, further developments are still required. The steerable tip is now capable of bending in two directions due to the multi-channel approach; it is still not possible to achieve the full 120^{o} required movement. To further develop the steerable tip, inspiration is to be drawn upon from flexible materials such as bendable MDF, whereby slots are placed in the material to replicate the required curves. Using this approach, increasing the shore hardness of the materials used will be required.

6.6.1 Development of the Steerable Tip

Figure 6.28 presents the first iteration of the developed 30mm flexible tip with slots. The internal insert designed will be supported by an outer sheath which slots over the top of the internal insert; the outer sheath design is described in Section 6.6.1.1. The internal insert designed (Figure 6.30, Left) is designed to slot over the outer edge of the bougie shaft with the internal wires threaded through the middle of the internal insert.

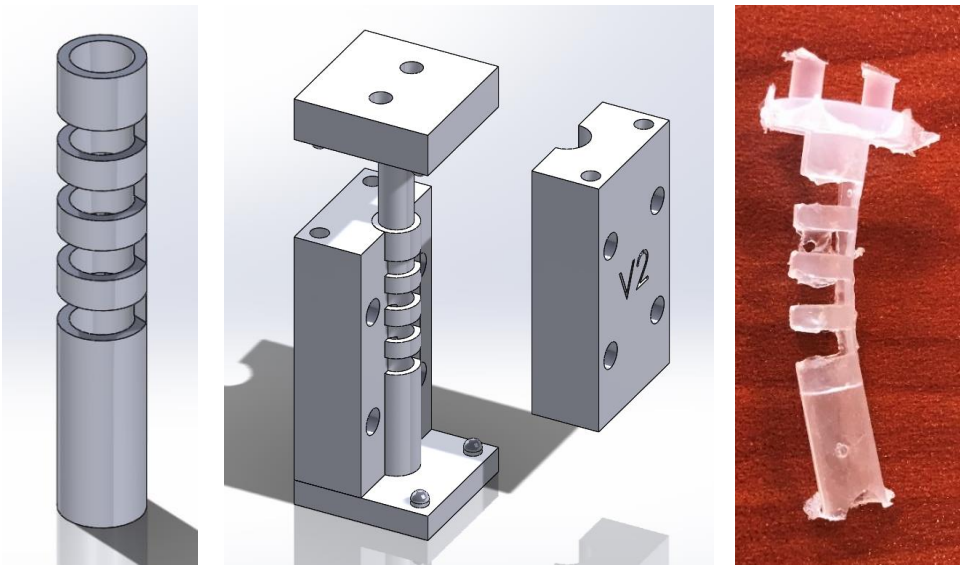


Figure 6.30: Steerable Tip Insert Development Iteration 1 (Left), 3D Printed Mould (Centre), Cast Part (Right)

The internal insert will need to be adapted further to ensure that the internal wires can be separated accordingly to prevent electrical shorting; the purpose of this design is to test the

functionality of the concept. The internal insert is to be cast using the designed 3D printed mould (Figure 6.30, Centre) using Transil 55 which is a silicone rubber with a shore hardness of 55A; this is an increase on the shore hardness values exhibited by the Smooth-Sil Series material but exhibits a similar texture. Ideally the Smooth-Sil series would be utilised, however the shore hardness values are too low once the internal tips structure is hollowed out further as per the redesign. Even when using Transil 55 the cast part (Figure 6.30, Right) is too flexible due to the thin wall thickness, but as hypothesised, the part is capable of bending in two directions; further development is required.

Figure 6.31 presents the next three iterations of the bougie insert. Iteration 2 presents an increased wall thickness and slots on both sides of the tip with a solid section present down each side of the part. Cast out of silicone rubber with a shore hardness of 43A, this part added greater strength to the insert, but was still too soft; a central wall is required to add greater rigidity to the part. Iteration 3 resolves this issue by placing a central wall in the part, with slots for the wire, however, the level of detail required for these elements cannot be achieved using silicone rubber casting due to material viscosity of 40000 – 80000 mPa.s. To overcome this issue, amendments were made to design iteration 4 to allow the wires to be threaded though the main body of the shaft. The moulds for design iteration 4 were manufactured and again silicone rubber with a shore hardness of 43A and viscosity of 40000 – 80000 mPa.s was utilised. Although casting the part was not an issue this time as many of the detailed small diameter loops had been removed, the part was still too flexible. In addition, cure inhibition was often observed due to the lack of wall thickness (<0.5mm), therefore resulting in double length cure times, or a complete lack of part curing.

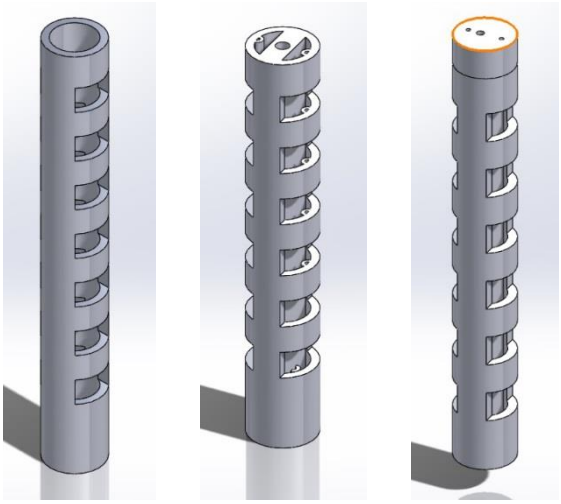


Figure 6.31: Steerable Tip Insert Development Iteration 2 (Left), Iteration 3 (Centre), Iteration 4 (Right)

To overcome cure inhibition issues exhibited with the silicone rubbers used and the inability to accurately cast detailed parts, the next avenue of experimentation focuses on casting the parts using EpoxAcast® 690 which is a UV resistant clear casting epoxy. Although in its original form this will create a solid part, it is possible to make this epoxy semi rigid with the addition of a Flexer® Epoxy Flexibilizer; the casting process for this is more complex and the cure time to achieve full shore hardness attributes can take up to seven days (Smooth-on.com, n.d. b).

To develop steerable tip iteration 5 (Figure 6.32, Left), using the epoxy resin casting approach, silicone moulds must be created instead of 3D printed moulds. Negatives of the moulds (Figure 6.32, Right) are created using CAD software and are 3D printed. Once assembled an addition cure silicone rubber is poured into the mould and left to cure; once demoulded, the silicone rubber moulds (Figure 6.33) are ready to be used.

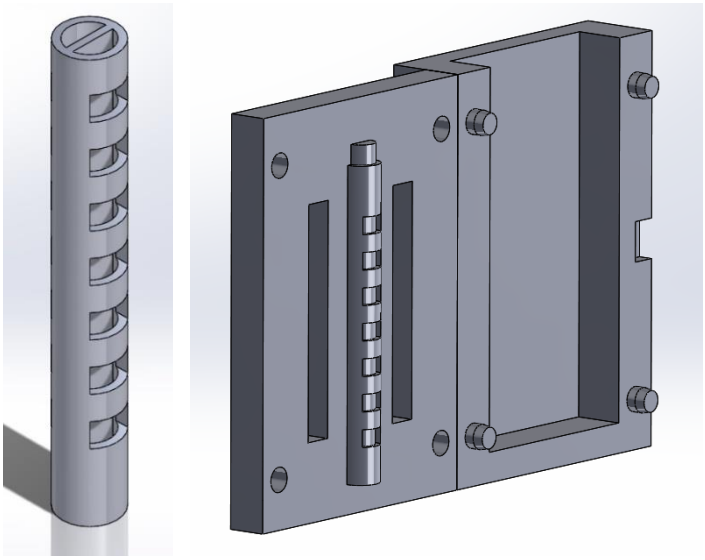


Figure 6.32: Steerable Tip Insert Development Iteration 5 (Left), Mould Negatives (Right)

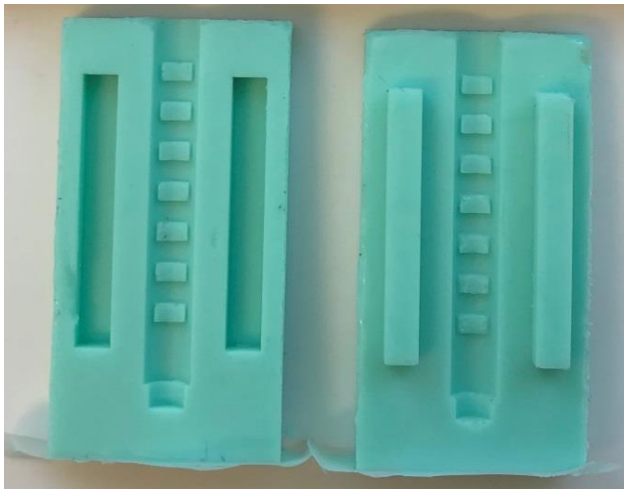


Figure 6.33: Steerable Tip Insert Development Iteration 5 Silicone Mould

Using the developed moulds and a solid 3D printed part to create the internal wall features, using a pour mould technique, a tip was cast using the EpoxAcast® 690 + 10% Flexibilizer. Although the part appears to be successfully cast (Figure 6.34), the part has permanently adhered itself to the insert. To overcome this issue, a melt away wax insert will be developed using a combination of candle wax and bees wax. The development of this wax insert is created using the mould presented in Figure 6.35.

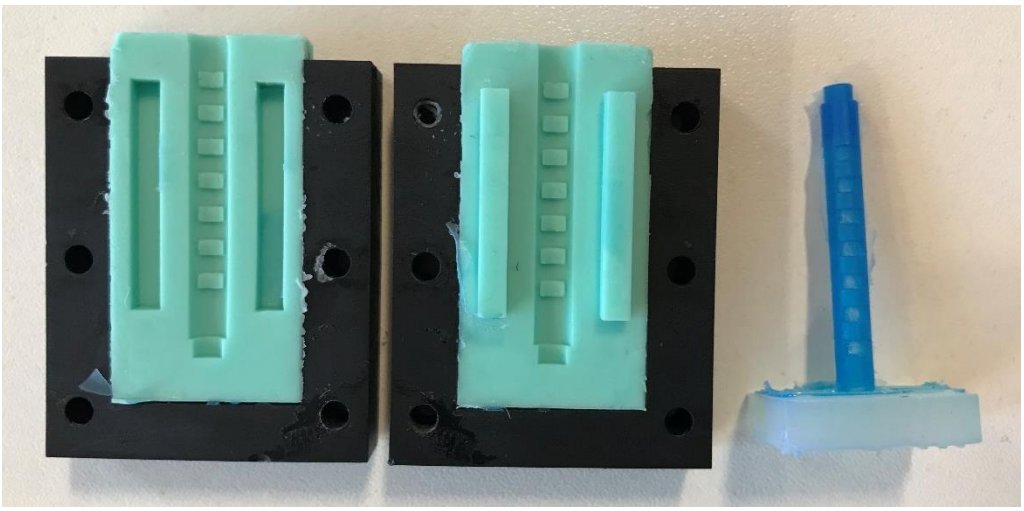


Figure 6.34: EpoxAcast® 690 + 10% Flexibilizer Cast Tip Insert

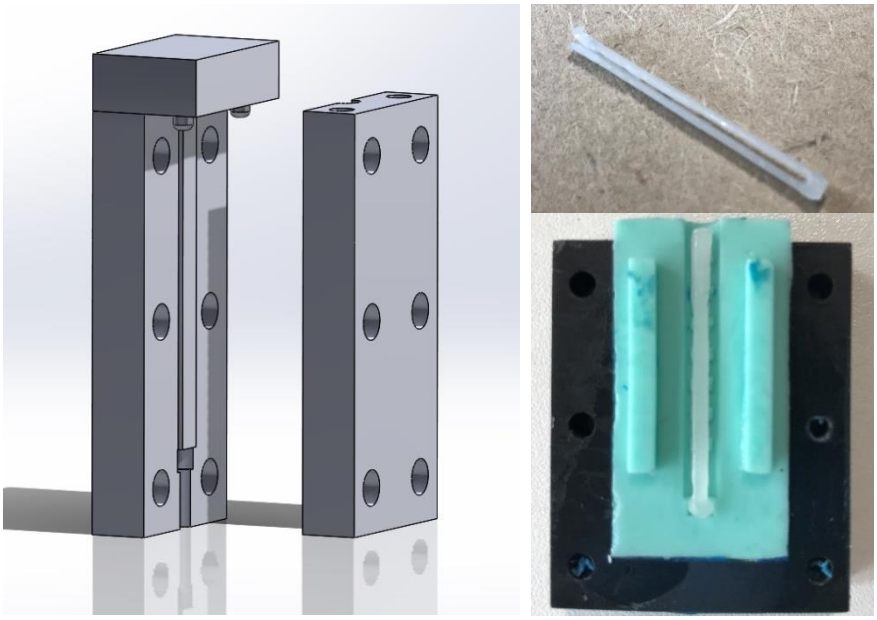


Figure 6.35: Wax Insert Mould (Left) & Developed Wax Insert (Right)

After attempting to recast the flexible tip insert, this was initially a success. Upon attempting to melt away the wax insert using warm water and squeezing the wax out of the insert, it became apparent that the fragile nature of the wax insert (<0.5mm wall thickness) caused the insert to have solid sections down the tip shaft. Failure to control the wax inserts on multiple occasions resulted in another alternative needing to be explored.

Using the developed moulds for the wax insert, a low viscosity silicone rubber with high tear resistance was cast to create an alternative insert; this was completed using a syringe injection moulding technique. The cast part (Figure 6.36, Left) was then removed from the mould, sterilised and then placed in the silicone moulds with a large amount of demoulding agent. The EpoxAcast® 690 + 10% Flexibilizer cast was then attempted again with the successful result presented in Figure 5.36 (Right); the silicone insert can easily be removed due to the demoulding agent. Further developments were also made to the moulds to allow for syringe injection casting of the epoxy resin mixture rather than pour casting, this alleviates several material degassing issues (Figure 6.37).

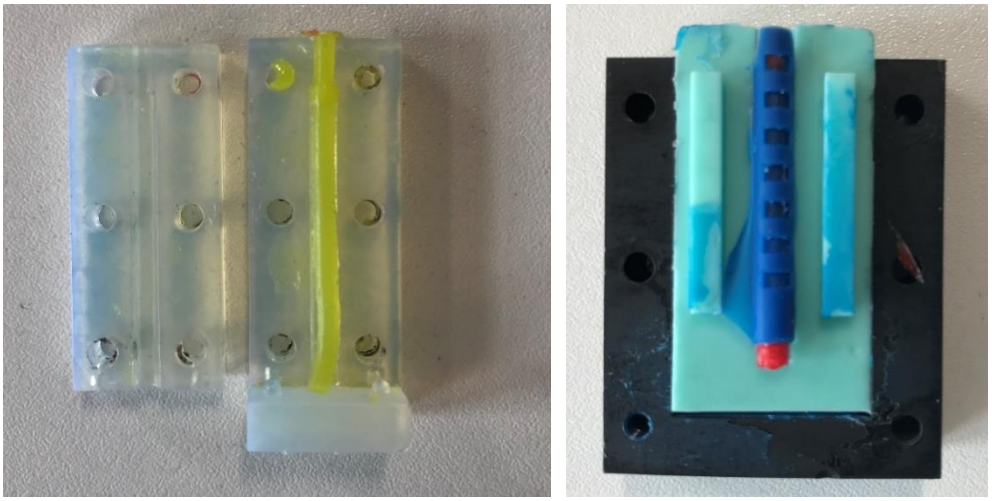


Figure 6.36: Cast Rubber Insert (Left) & Successful EpoxAcast® 690 + 10% Flexibilizer (Right)

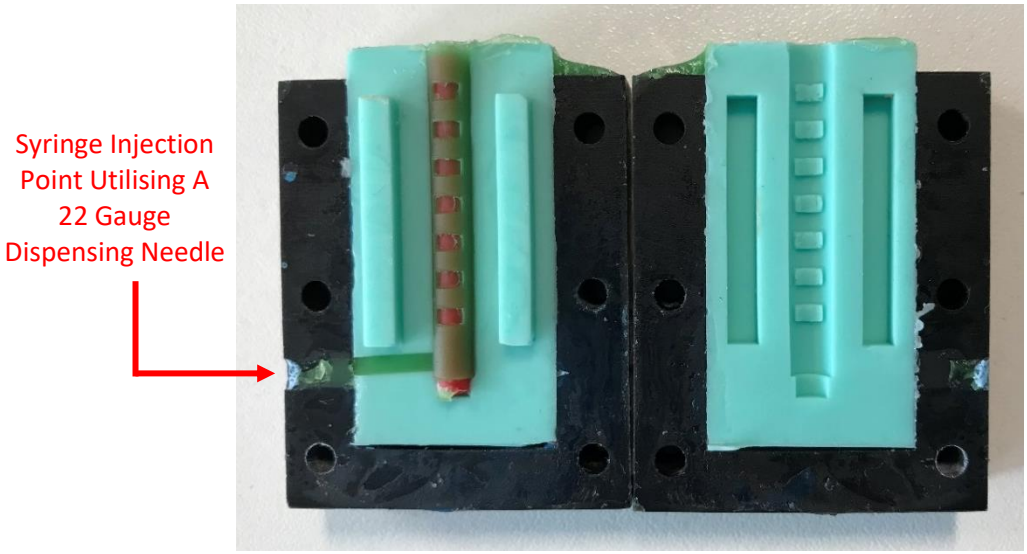


Figure 6.37: Amended Mould For Syringe Injection Casting

For the development of the flexible steerable tip inserts, five mix ratios were completed, these are presented in Table 6.27. The cast tips are demoulded at 48 hours and then reanalysed after seven days when full cure has been achieved (Figure 6.38).

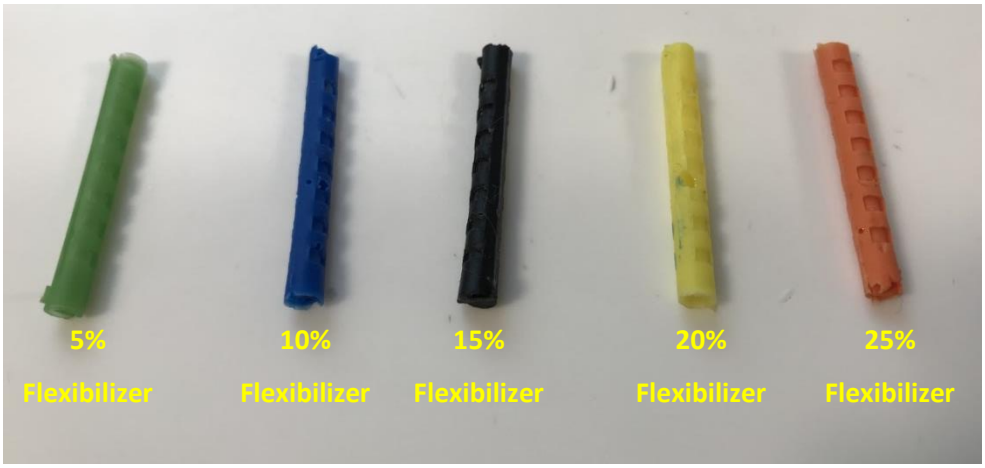


Figure 6.38: EpoxAcast® 690 + Flexibilizer Cast Tips

	Part A (100)	Part B (30)	Flexibilizer
Green Tip	4.0g	1.2g	5% (0.26g)
Blue Tip	4.0g	1.2g	10% (0.52g)
Black Tip	4.0g	1.2g	15% (0.78g)
Yellow Tip	4.0g	1.2g	20% (1.04g)
Orange Tip	4.0g	1.2g	25% (1.30g)

Table 6.27: EpoxAcast® 690 + Flexibilizer Mix Ratios

After 48 hours of curing, the demoulding process is completed; all the parts are still tacky, however, the silicone insert can easily be removed with a set of tweezers. All the parts demonstrate enough flexibility to function as a steerable tip. After leaving the parts for the maximum seven days to fully cure, upon bending the tips it became apparent the material was not fit for purpose due to tensional stress deformation occurring as a result of the tips being shaped and bent after several repetitions (Figure 6.39).

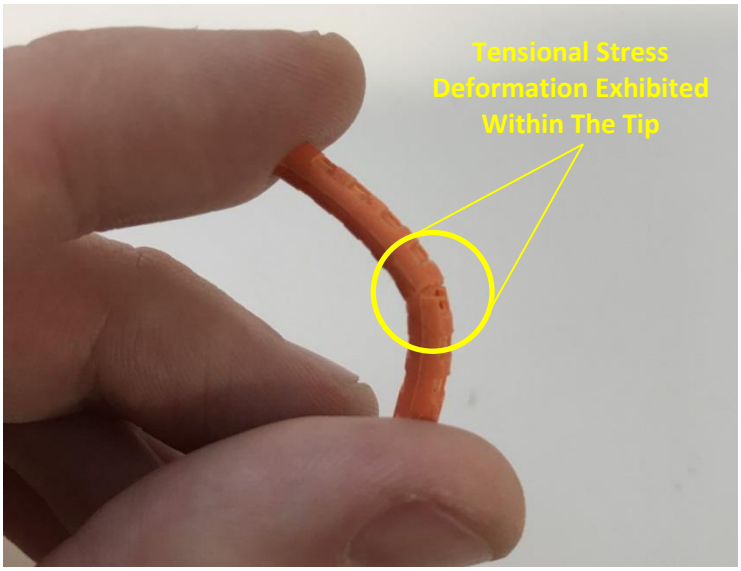


Figure 6.39: Tensional Stress Deformation Exhibited On EpoxAcast® 690 + Flexibilizer Cast Tips

Development iteration 6 presents two successful manufacturing methods for the steerable tips. The first method presented in Figure 6.40 often presents cure inhibition issues and part deformities (Figure 6.40, Right) if casting material selection is not carefully controlled. Using the moulds presented in Figure 6.40 (Left), the syringe injection casting method is used. To overcome cure inhibition and extending curing times, the parts are heated utilising the heated chamber where needed as described in Section 6.6.1.1.

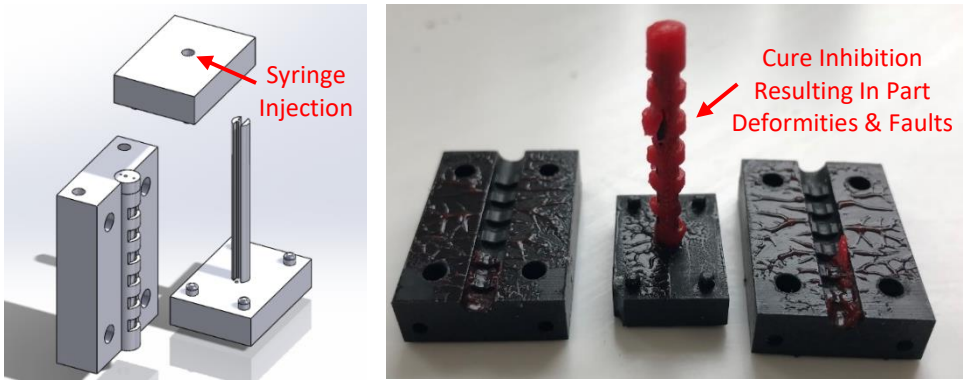


Figure 6.40: Developed Mould (Left) & Failed Silicone Casting: Cure Inhibition & Part Faults (Right)

After numerous failed attempts to silicone cast the designed tip using the syringe injection technique, tips were eventually constructed utilising Easy Composites Silicone Rubber (SR), SR + 50% Hardener, Transil 55, Transil 55 + 50% Hardener and Smooth-Sil 960 in addition to the use of the designed heat chamber. Upon initial review by the project team, the tips with a shore hardness of 55A or higher were deemed suitable.

The second method was the 3D printing of the steerable tips using a Form 2 Desktop Stereolithography 3D Printer and flexible resin (F2F) which simulates 80A shore hardness; this can be used to manufacture parts that can bend and compress after UV post curing (Formlabs.com, 2016). Using manually planned support structures (Figure 6.41, Left), the parts are 3D printed and post processed by IPA bathing and UV curing (Figures 6.41, Right).

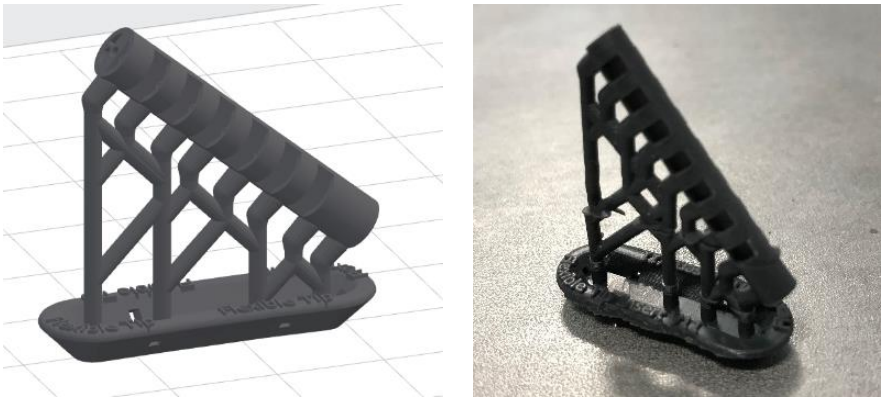


Figure 6.41: Manual Support Structure Generation (Left), Printed Part (Right)

Manufacturing the tips using the above described methods, validation of the bi-directional control movement was now required. Manual pull wires were mounted internally at the top of the manufactured flexible tips and threaded down the bougie multi-lumen tubing. Figure 6.42 demonstrates the setup, resulting in the accurate curling of the flexible tip proving 60° bi-directional tip movement can be achieved.

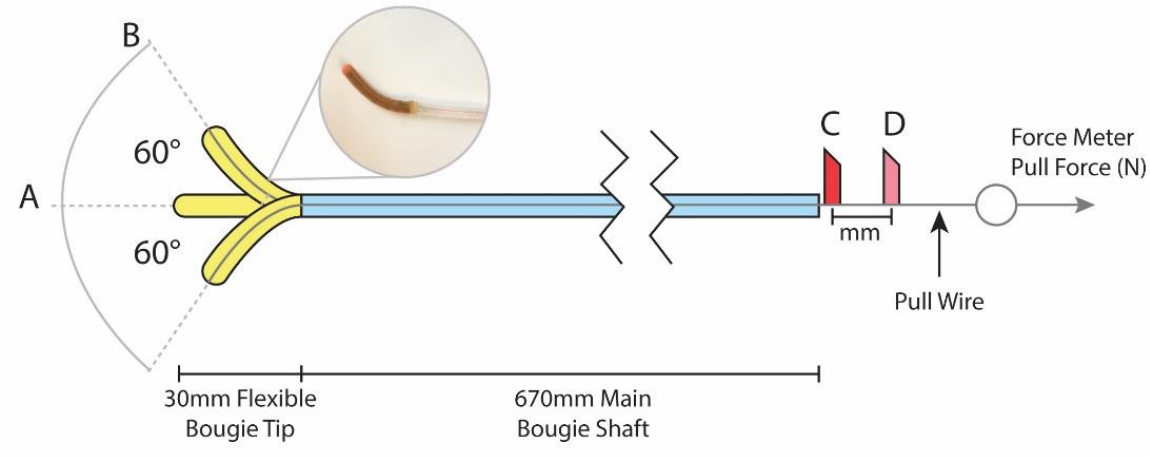


Figure 5.42: Flexible Tip 60° Bi-Directional Tip Movement

6.6.1.1 Outer Sheath Design/Manufacture & Heat Chamber

Although the design of the outer sheath for the steerable tip appears simple, this is complicated due to the 0.5mm wall thickness of the part; the steerable tip assembles as demonstrated in Figure 6.43.

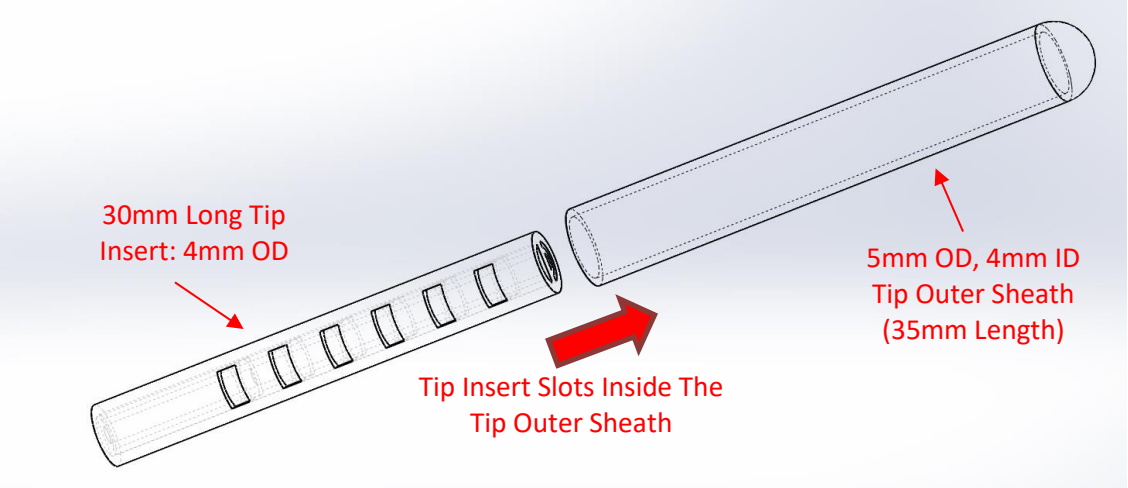


Figure 6.43: Proposed Steerable Tip Assembly

To manufacture the tip outer sheath, a three-part 3D printed mould was designed and manufactured. Using the syringe injection moulding method, the silicone tip was cast. After numerous casting attempts, the part failed to cure because of cure inhibition (Figure 6.44, Left). It was deduced that the silicone failed to cure due to the small wall thickness of the part and a lack of heat to initiate the curing process. To successfully manufacture the part

(Figure 6.44, Right), heating the mould in a controlled environment is required where no contaminants can be exposed to the silicone.

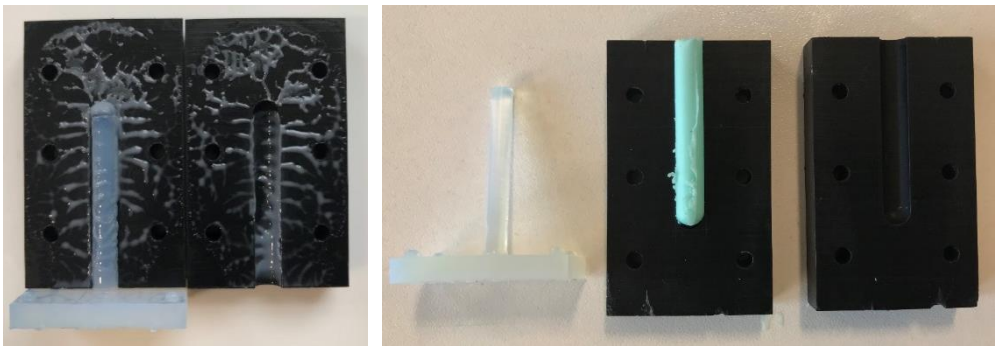


Figure 6.44: Unsuccessful Outer Sheath Cast (Left) Successful Outer Sheath Cast (Right)

Heating the 3D printed moulds in a controlled environment without exceeding the materials melting point (130^{o}c) is achieved by using a 3D printer hot plate to conduction heat the mould. A heated chamber was designed and manufactured (Figure 6.45). Using portable grove sensors, the ambient temperature of the heated chamber and internal temperature of the 3D printed mould is monitored.

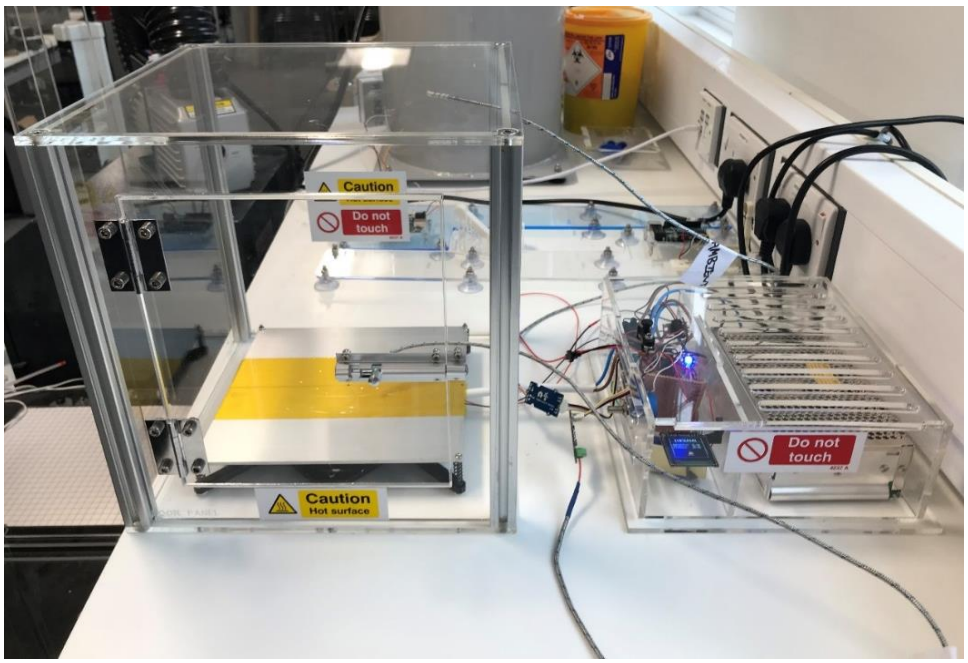


Figure 6.45: Manufactured Heat Chamber

The heat chamber is programmed using Arduino and controlled by an Arduino Uno microcontroller, two grove temperature sensors and a heat plate mounted thermistor. The target mould temperature settings are adjusted using a potentiometer. The heat plate thermistor is used to regulate temperature of the mould and the cast material from being overheated. Analysing the thermistor temperature, this switches off the heat plate when the temperature reaches 90^{o}C, thereby avoiding the melting point of the mould. A grove sensor

is mounted internally within the mould allowing the temperature to be analysed to achieve the target temperature set by the potentiometer. Once the mould achieves the set temperature, the heat plate is turned off. The mould temperature is then regularly monitored checking for a drop within a tolerance of 2°C.

When the mould temperature drops below the target temperature (minus 2°C of the pre-set), the heat plate switches back on until the target temperature is achieved again; it is therefore possible to maintain a constant temperature with a tolerance of 2°C. An OLED display on the heat chamber control box allows the user to visually check the current temperature status of the heat chamber along with the current target temperature set. The temperature readings can also be exported from the serial monitor within the program to a .csv file.

Due to the large capacity of the heat chamber, pre-heating can take a significant period of time. To reduce this, an additional feature is utilised within the heated chamber. Aluminium foil lined expanded polystyrene domes are used to encapsulate the moulds to reduce the heat escape and heated area capacity (Figure 6.46); this reduces the time taken for the heated area to reach a suitable ambient temperature.

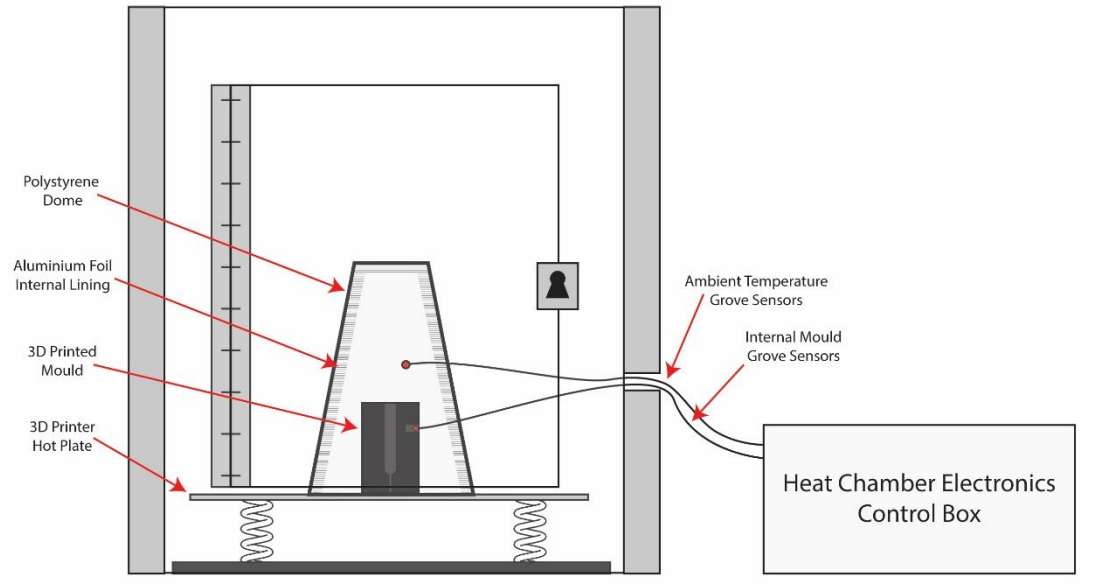


Figure 6.46: Heat Chamber Setup

Using the manufactured heated chamber, the cure inhibition issues are overcome. The programmed heated chamber has the capacity to monitor the temperature control; an example of this is demonstrated in Figure 6.47.

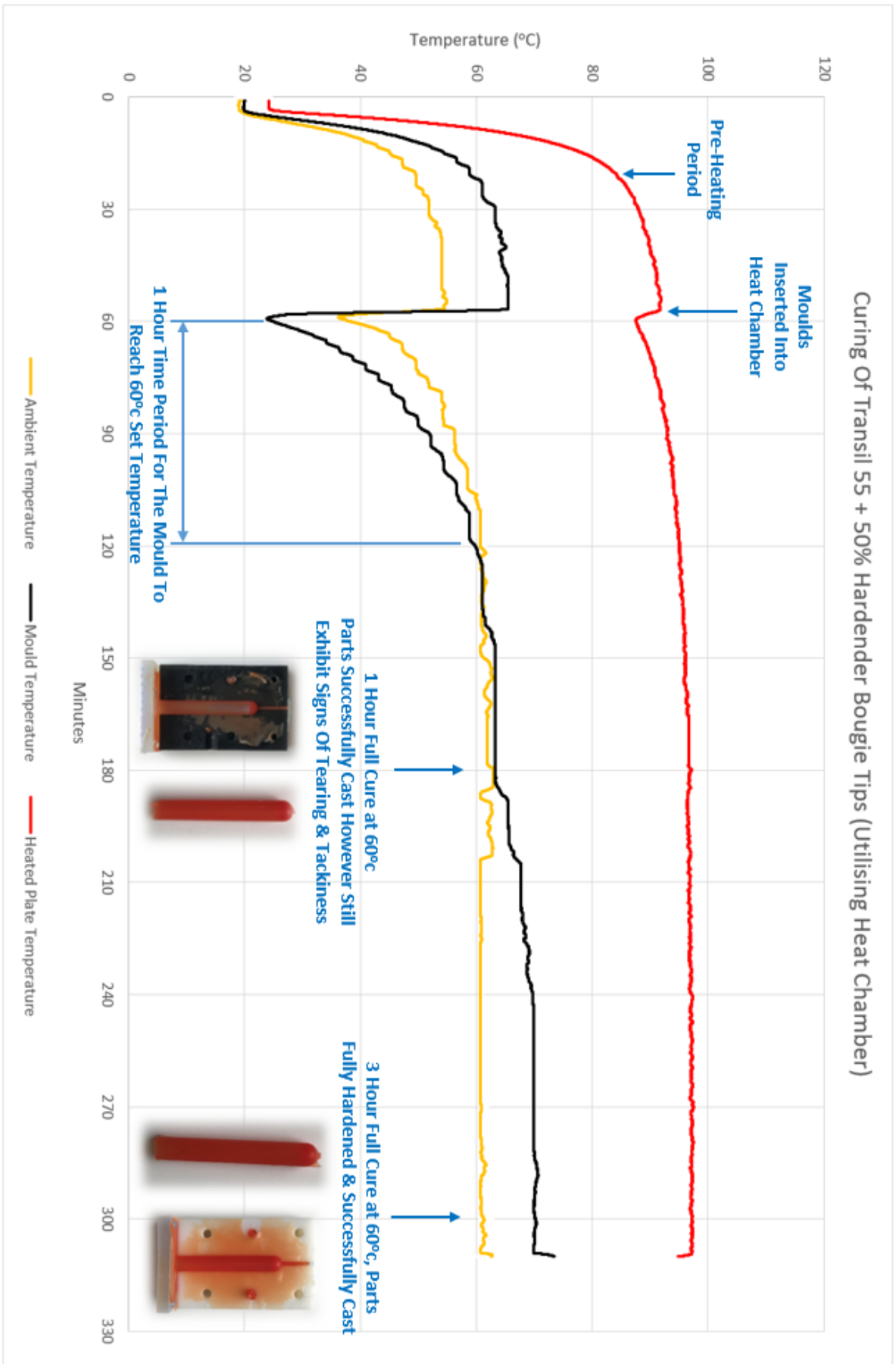


Figure 6.47: Monitoring Of Temperature Sensors Within The Heated Chamber

6.6.2 Development Bougies Results & Analysis

The development bougies constructed were manufactured from numerous different silicones and resins; shore hardness testing has been completed to confirm the hardness values of the mixes used.

Date Of Test: 30.05.2018 **Relative Humidity:** 93% **Ambient Room Temperature:** 15ºC

Durometer Manufacturer/Model: HTTK-37 Compact 1-100HA Digital Durometer

Material Composition	Time Of Test	Reading 1	Reading 2	Reading 3	Reading 4	Reading 5	Mean
Form 2 Flexible Resin	19:00	80	79.5	80	80	81	80.1A
Silicone Rubber	19:03	41	42	42.5	41	42	41.7A
Transil 55	19:05	54.5	55	55	56	55	55.1A
Transil 55 + 50% Hardener	19:07	60	61	61.5	60	60.5	60.6A
Smooth-Sil 960	19:10	60.5	61	59	59.5	60	60A
Silicone Rubber + 50% Hardener	19:12	50.5	51	50.5	51	51.5	50.9A

Table 6.28: Development Bougie Materials - Shore "A" Hardness Test Results

Table 6.28 presents the results from the shore hardness testing. Both silicone rubber compositions are too soft based of the minimum 55A shore hardness values required. The developed tips constructed each had 0.5mm wall thickness and seven 1.5mm slots. These were tested using the tip pressure testing protocol described in Section 6.2.1; the results are presented in Table 6.29 and Figure 6.48.

	R1-5 = Distance Held / Mean (N) SE = Standard Error							
Bougie	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
Inner: F2F Outer: T55	1.208	0.029	0.692	0.023	0.498	0.021	0.490	0.037
Inner: SR Outer: T55	0.720	0.026	0.472	0.018	0.530	0.004	0.330	0.010
Inner: SR+50H Outer: SR+50H	0.824	0.016	0.602	0.016	0.598	0.006	0.394	0.014
Inner: T55+50H Outer: T55	0.818	0.024	0.404	0.005	0.354	0.021	0.342	0.013
Inner: SS960 Outer: T55+50H	0.860	0.034	0.738	0.039	0.524	0.016	0.452	0.017
Inner: T55+50H Outer: T55+50H	1.146	0.046	0.536	0.010	0.362	0.018	0.284	0.002
Inner: T55 Outer: T55	0.788	0.013	0.612	0.027	0.470	0.008	0.496	0.011

Table 6.29: Development Bougies Tip Pressure Test Results

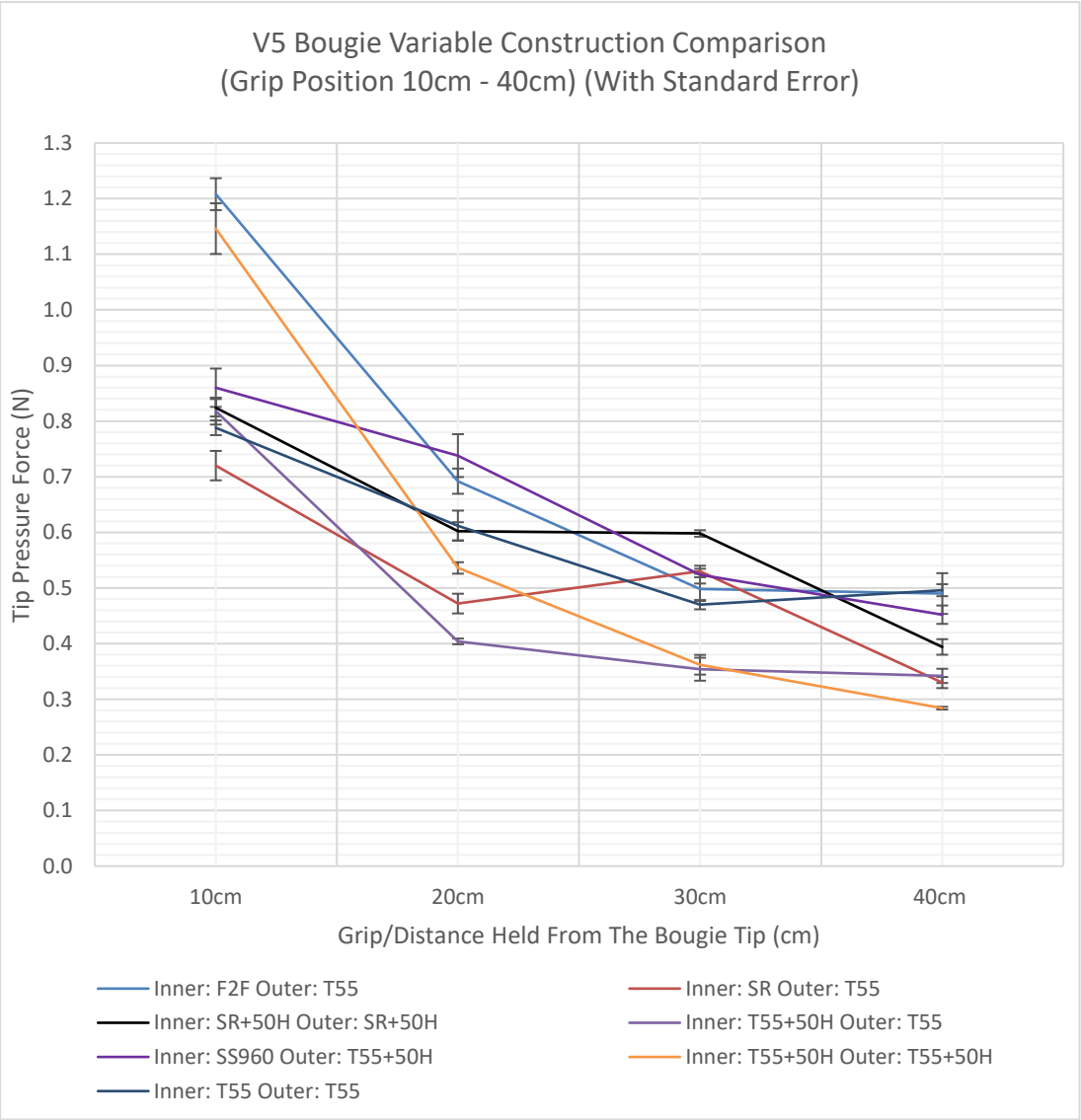


Figure 6.48: Development Bougie Tip Pressure Comparison Graph

All the bougies mean peak tip pressures are <0.8N at 20cm and 30cm bougie grip position; this is below the tip pressure forces capable of generating airway trauma (Marson et al., 2014). After presenting these bougies for tactile assessment to Dr Armstrong, it was suggested the bougie tips created were too soft. If the bougie with the Form 2 3D printed internal and Transil 55 outer sheath was reinforced slightly, this would be suitable. Each of the manufactured bougies were also tested using the methods described in Section 6.3.1; the results are presented in Table 6.30.

	Without Lubricant		With Lubricant	
Bougie Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
Inner: F2F Outer: T55	Yes	N/A	Yes	N/A
Inner: SR Outer: T55	No	K @20	Yes	N/A
Inner: SR+50H Outer: SR+50H	No	K @20	Yes	N/A
Inner: T55+50H Outer: T55	No	K @20	Yes	N/A
Inner: SS960 Outer: T55+50H	Yes	N/A	Yes	N/A
Inner: T55+50H Outer: T55+50H	No	R @20	Yes	N/A
Inner: T55 Outer: T55	No	R @20	Yes	N/A

Table 6.30: Development Bougies Placement Test Results

The results confirm Dr Armstrong's observations that the majority of the bougies were unusable when used without lubricant, but also confirms his observations that the Form 2 3D printed internal and Transil 55 outer sheath bougie could be suitable for use if improved. Further development of the material composition was required; another variable considered possible for tip reinforcement was reducing the height of the slots that promote bougie curling. Amendments were made to the models; each tip now has a Transil 55 + 50% hardener outer sheath and a Form 2 internal with variable slots increased by 0.25mm height increments. The amended bougies are assembled, and tip pressure testing completed; the results are presented in Table 6.31 and Figure 6.49.

	R1-5 = Distance Held / Mean (N) SE = Standard Error							
Bougie Revision 1	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
1mm Slots (Height)	1.192	0.046	0.832	0.040	0.766	0.026	0.452	0.012
1.25mm Slots (Height)	1.040	0.022	0.552	0.024	0.566	0.025	0.456	0.018
1.5mm Slots (Height)	0.864	0.013	0.638	0.031	0.596	0.022	0.408	0.016
1.75mm Slots (Height)	0.866	0.030	0.552	0.037	0.516	0.026	0.404	0.023
2mm Slots (Height)	0.798	0.015	0.602	0.005	0.516	0.023	0.426	0.014

Table 6.31: Development Bougie Revision 1 Tip Pressure Test Results

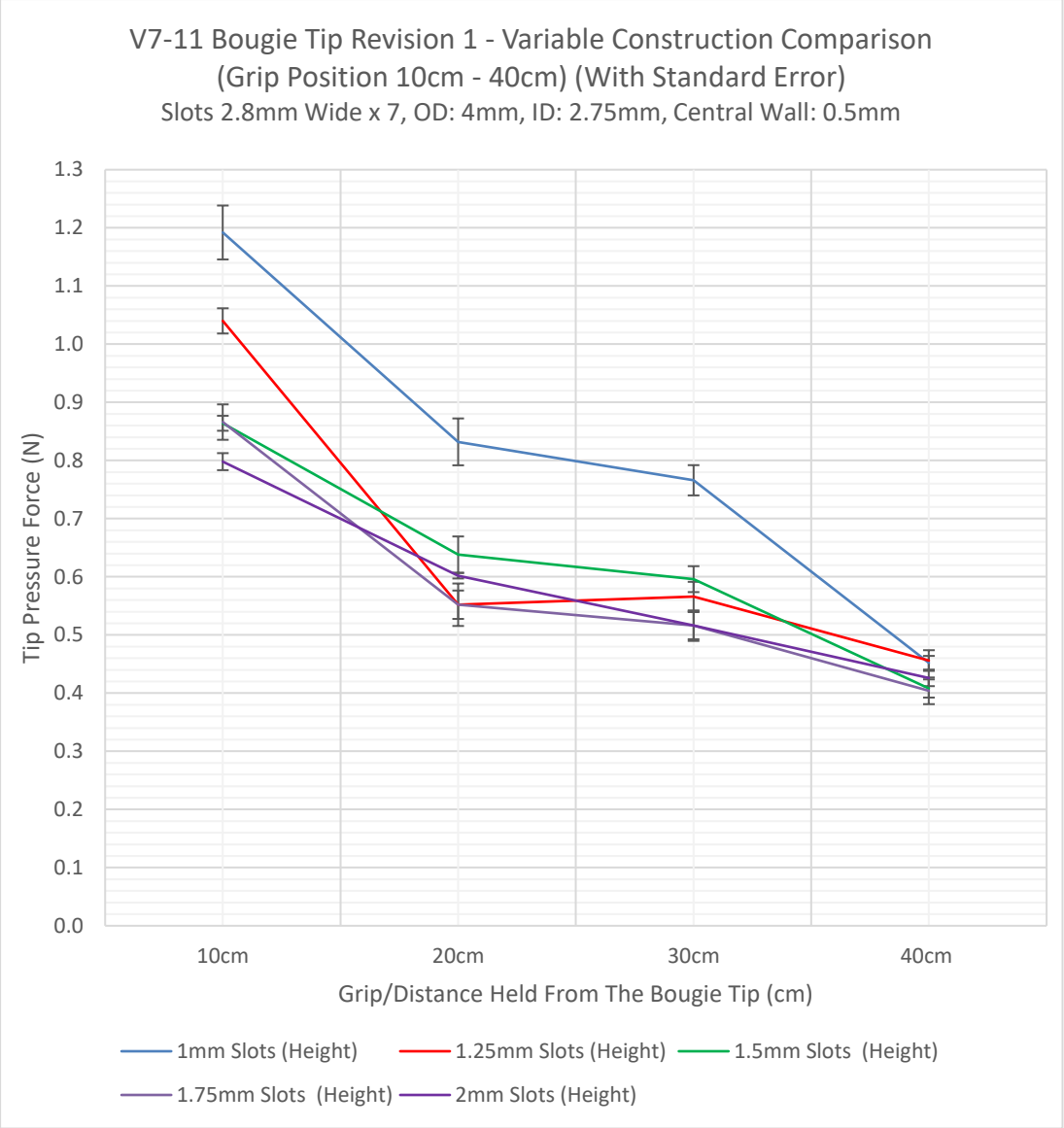


Figure 6.49: Bougie Revision 1 Comparison (Material Composition: Internal – F2F, Outer – Transil 55 + 50% Hardener)

The results present mean tip pressures <0.9N at the recommended 20cm-30cm grip position; these tip pressures have increased slightly. Dr Armstrong's review of the bougies suggests that although these bougies are suitable for use, the tactile feedback exhibited by the tips is still a little too soft. Table 6.32 presents results from the bougie placement testing and confirms Dr Armstrong's feedback that the bougies are suitable for use.

	Without Lubricant		With Lubricant	
Bougie Revision 1 Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
1mm Slots (Height)	Yes	N/A	Yes	N/A
1.25mm Slots (Height)	Yes	N/A	Yes	N/A
1.5mm Slots (Height)	Yes	N/A	Yes	N/A
1.75mm Slots (Height)	Yes	N/A	Yes	N/A
2mm Slots (Height)	Yes	N/A	Yes	N/A

Table 6.32: Development Bougie Revision 1 – Bougie Placement Test Results

To add further rigidity to the steerable tips, the central wall of the designed tips was increased from 0.5mm to 1.5mm; the five bougies were again manufactured and tested. The results are presented in Tables 6.33 and 6.34 in addition to Figure 6.50.

The increased wall thickness resulted in increased tip pressures being exhibited at the 10cm, 20cm and 40cm distance held locations; the tip pressures remained within a similar range at the 30cm distance held location with a minor increase of 0.1N. All the bougies were capable of being utilised as standalone bougies without the control mechanism and were all successfully placed within the trachea of the manikin.

	R1-5 = Distance Held / Mean (N) SE = Standard Error							
Bougie Revision 2	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
1mm Slots (Height)	1.504	0.049	0.968	0.024	0.764	0.020	0.758	0.015
1.25mm Slots (Height)	1.054	0.027	0.694	0.013	0.690	0.019	0.654	0.015
1.5mm Slots (Height)	0.920	0.020	0.844	0.012	0.638	0.012	0.482	0.012
1.75mm Slots (Height)	0.692	0.015	0.764	0.024	0.700	0.019	0.470	0.006
2mm Slots (Height)	0.720	0.022	0.684	0.030	0.650	0.019	0.592	0.017

Table 6.33: Development Bougie Revision 2 Tip Pressure Test Results

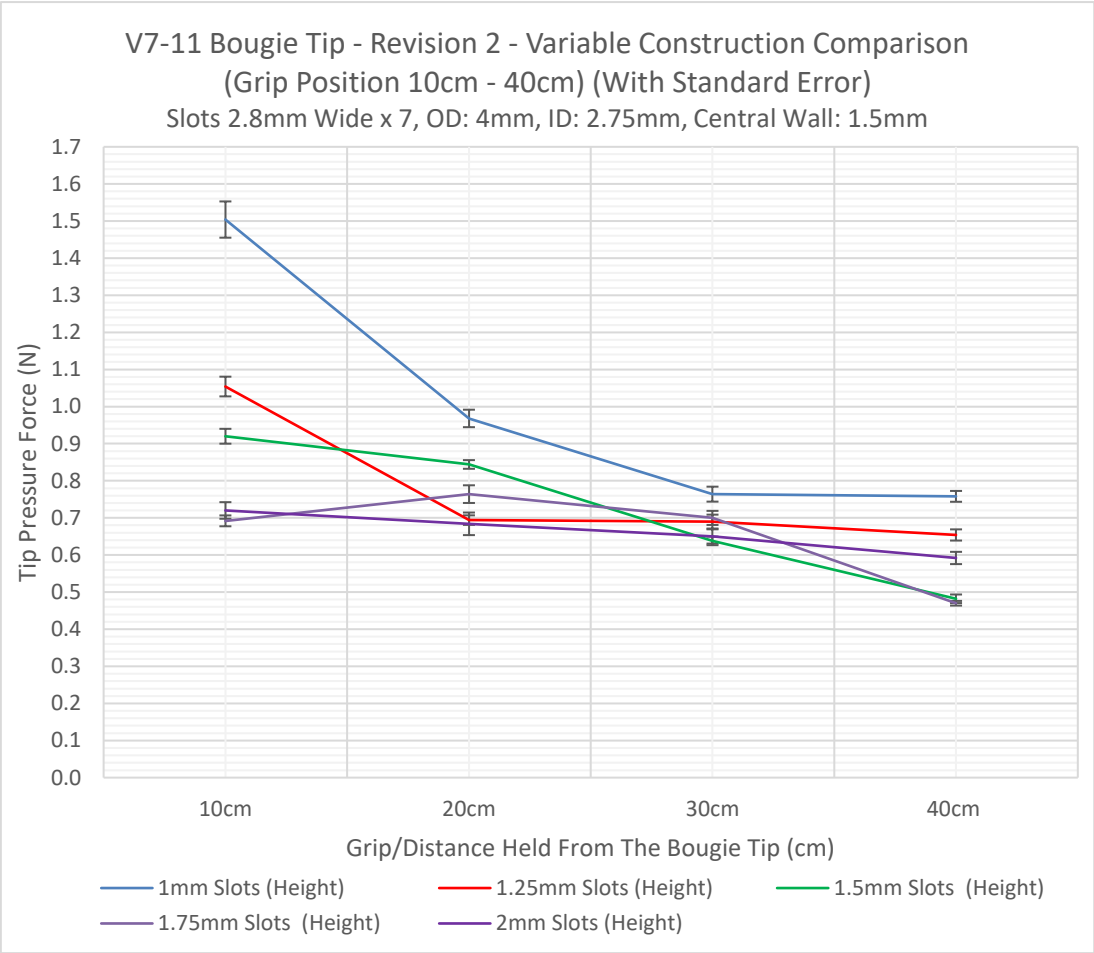


Figure 6.50: Development Bougie Revision 2 Comparison Graph

	Without Lubricant		With Lubricant	
Bougie Revision 2 Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
1mm Slots (Height)	Yes	N/A	Yes	N/A
1.25mm Slots (Height)	Yes	N/A	Yes	N/A
1.5mm Slots (Height)	Yes	N/A	Yes	N/A
1.75mm Slots (Height)	Yes	N/A	Yes	N/A
2mm Slots (Height)	Yes	N/A	Yes	N/A

Table 6.34: Development Bougie Revision 2 – Bougie Placement Test Results

To further investigate the parameters of the designed steerable tips, the tips were also developed with thinner slots (all 1.2mm wide), therefore adding further rigidity to the bougie tip. The results from the testing are presented in Tables 6.35 and 6.36 in addition to Figure 6.51.

	R1-5 = Distance Held / Mean (N) SE = Standard Error							
Bougie Revision 3	**R1-5 10cm**	**SE of Mean**	**R1-5 20cm**	**SE of Mean**	**R1-5 30cm**	**SE of Mean**	**R1-5 40cm**	**SE of Mean**
1mm Slots (Height)	1.362	0.017	1.162	0.019	0.844	0.008	0.544	0.017
1.25mm Slots (Height)	1.098	0.024	0.906	0.017	0.770	0.015	0.806	0.012
1.5mm Slots (Height)	1.148	0.035	0.958	0.027	0.816	0.010	0.810	0.030
1.75mm Slots (Height)	0.936	0.015	0.772	0.018	0.594	0.007	0.580	0.018
2mm Slots (Height)	1.042	0.026	0.874	0.016	0.804	0.019	0.590	0.018

Table 6.35: Development Bougie Revision 3 Tip Pressure Test Results

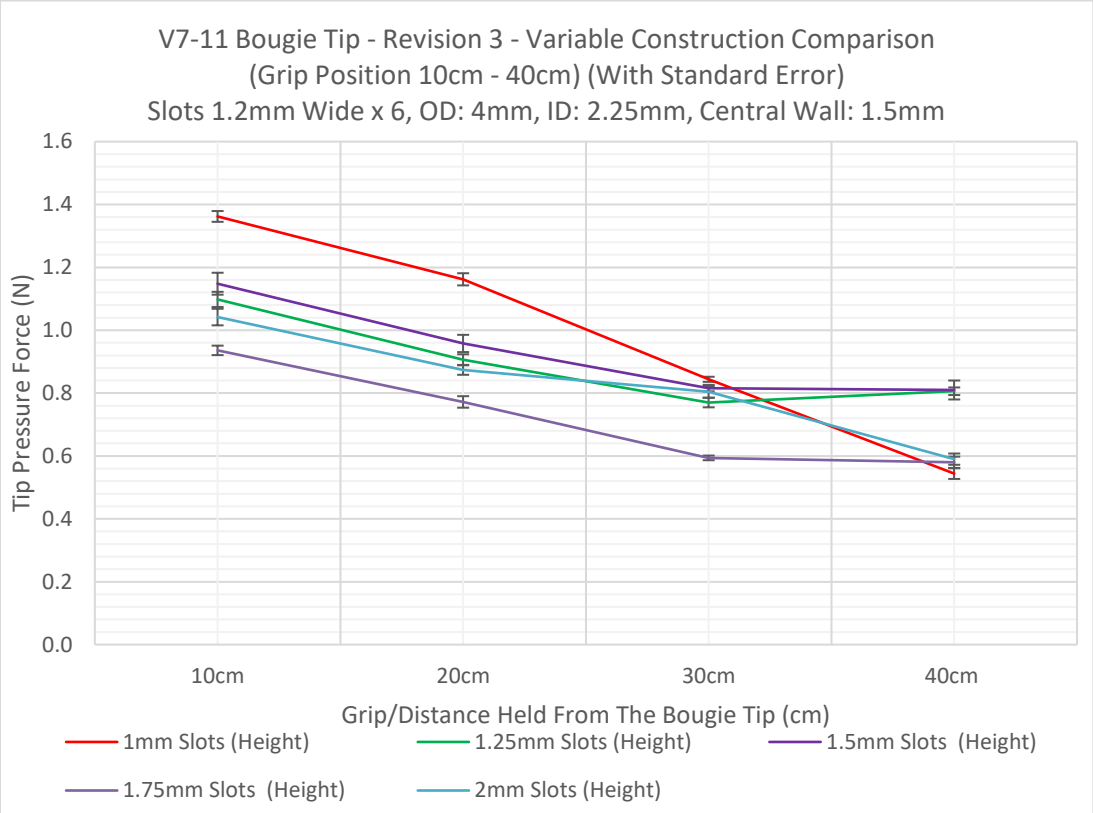


Figure 6.51: Development Bougie Revision 3 Comparison Graph

	Without Lubricant		With Lubricant	
Bougie Revision 3 Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
1mm Slots (Height)	Yes	N/A	Yes	N/A
1.25mm Slots (Height)	Yes	N/A	Yes	N/A
1.5mm Slots (Height)	Yes	N/A	Yes	N/A
1.75mm Slots (Height)	Yes	N/A	Yes	N/A
2mm Slots (Height)	Yes	N/A	Yes	N/A

Table 6.36: Development Bougie Revision 3 – Bougie Placement Test Results

Upon presenting this set of bougies to Dr Armstrong, this was deemed the preferred set based on the tactile feedback. The tip pressures although higher are still within a manageable range and should not cause trauma; the tips have a level of rigidity especially at the 1mm and 1.25mm slots range allowing improved use as a bougie with no additional functionality. This was also the consensus for development set 2, however, the tactile feedback was a little less responsive. Unfortunately, upon validating the tips with the pull forces exhibited by the wires, development set 3 was deemed unsuitable for use; this is explained in detail in Section 6.6.3. Based on these findings, final design development will be constructed using development bougie set 2 parameters.

6.6.3 Steerable Mechanism Validation For Developed Steerable Tips

The feedback collected from Dr Armstrong suggests bougie development sets 2 and 3 with slot heights of 1mm and 1.25mm are suitable. The tip pressures presented by these bougies are low enough to prevent trauma to the airway when held at 30cm or 40cm distances; when held at 10cm or 20cm the tip pressures are significantly lower than all the commercially available bougies but could still cause minor trauma. Testing of the bougies with pull wires will validate their capability for use. Testing will be performed as per the methods described in Chapter 4, Section 4.5, with the aim of achieving the 60° flexible tip angle as per Figure 6.52; the results are presented in Tables 6.37 – 6.40.

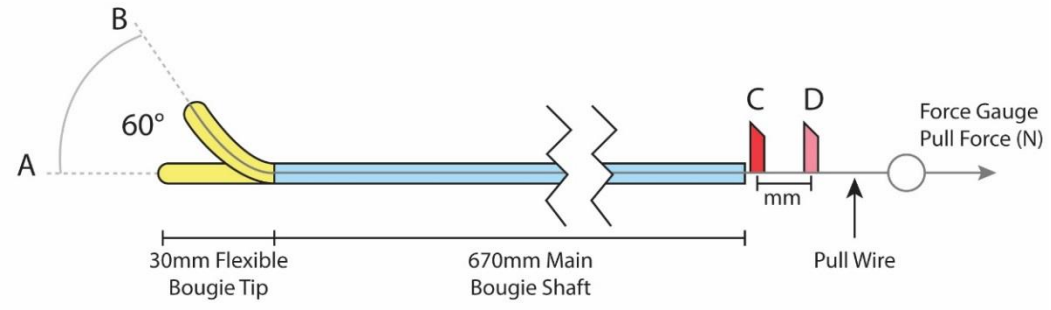


Figure 6.52: Experimental Setup To Achieve 60° Flexible Tip Angle

Test ID No.	Applied Pull Force(N)	Pull Wire Distance Moved (mm)	Angle Of Bend Achieved (Degrees)	Percentage (%) Distance Moved
#1	2.96	30.57	60	4.37
#2	3.01	31.02	60	4.43
#3	2.92	30.93	60	4.42
#4	3.12	31.22	60	4.46
#5	2.84	30.85	60	4.41
Mean	2.97	30.91	60	4.42

Table 6.37: Development Bougie Revision 2 – Slots 1mm Tall 2.8mm Wide x 7, OD: 4mm, ID: 2.75mm, Central Wall: 0.5mm

Test ID No.	Applied Pull Force(N)	Pull Wire Distance Moved (mm)	Angle Of Bend Achieved (Degrees)	Percentage (%) Distance Moved
#1	2.63	30.02	60	4.29
#2	2.76	29.77	60	4.25
#3	2.79	30.10	60	4.30
#4	2.82	30.03	60	4.29
#5	2.74	29.84	60	4.26
Mean	2.74	29.95	60	4.28

Table 6.38: Development Bougie Revision 2– Slots 1.25mm Tall 2.8mm Wide x 7, OD: 4mm, ID: 2.75mm, Central Wall: 1.5mm

Test ID No.	Applied Pull Force(N)	Pull Wire Distance Moved (mm)	Angle Of Bend Achieved (Degrees)	Percentage (%) Distance Moved
#1	4.21	51.63	40	7.23
#2	4.38	51.03	40	7.29
#3	4.28	51.29	40	7.33
#4	4.42	50.75	40	7.25
#5	4.58	51.50	40	7.36
Mean	4.32	51.04	40	7.29

Table 6.39: Development Bougie Revision 3 – Slots 1mm Tall, 1.2mm Wide x 6, OD: 4mm, ID: 2.25mm, Central Wall: 1.5mm

Test ID No.	Applied Pull Force(N)	Pull Wire Distance Moved (mm)	Angle Of Bend Achieved (Degrees)	Percentage (%) Distance Moved
#1	4.05	39.43	60	5.63
#2	4.26	39.86	60	5.69
#3	4.22	39.56	60	5.65
#4	4.15	39.51	60	5.64
#5	4.18	39.40	60	5.63
Mean	4.17	39.55	60	5.65

Table 6.40: Development Bougie Revision 3 – Slots 1.25mm Tall, 1.2mm Wide x 6, OD: 4mm, ID: 2.25mm, Central Wall: 1.5mm

In Chapter 4, Section 4.5.2, it was identified that the reaction times of a 700mm length of 150µm Flexinol® wire can reduce by 2.8-3% in length to achieve the desired tip movement (for a hollow tip). Small diameters of Flexinol® wire can contract typically within a range of 2% - 5% of their length dependent on the voltage applied (Dynalloy.com, n.d.). Tables 6.39 and 6.40 present mean percentage distance moved values of 7.29% and 5.65% which are not within the required range; these tips are deemed too stiff. Development tip revision 3 with

1mm slots also failed to achieve the 60-degree angle required. Tables 6.37 and 6.38 presents the mean percentage distance moved values of 4.42% and 4.28% for development tip revision 2, both are within the 2-5% range.

Further refinement of development tip revision 2 is required to ensure that the stress placed on the control wires is reduced, this will also reduce the percentage change in wire length. The design revisions made included reducing the central wall thickness to 0.7mm but adding a central loop wall of 0.35mm for the ground wire. By reducing the number of slots to six but spreading them evenly and linearly, it is expected that tip curvature should be achieved with less control wire contraction required. These tips were 3D printed and tested; the results are presented in Tables 6.41 and 6.42.

Test ID No.	Applied Pull Force(N)	Pull Wire Distance Moved (mm)	Angle Of Bend Achieved	Percentage (%) Distance Moved
#1	2.91	29.99	60	4.28
#2	3.02	29.52	60	4.22
#3	2.99	29.70	60	4.24
#4	2.96	30.08	60	4.30
#5	2.91	30.01	60	4.29
Mean	2.95	29.86	60	4.27

Table 6.41: Bougie Final – Slots 1mm Tall 2.8mm Wide x 6, OD: 4mm, ID: 2.75mm, Central Wall: 0.7mm + Central Loop Wall 0.35mm

Test ID No.	Applied Pull Force(N)	Pull Wire Distance Moved (mm)	Angle Of Bend Achieved	Percentage (%) Distance Moved
#1	2.72	26.62	60	3.80
#2	2.78	26.82	60	3.83
#3	2.76	26.98	60	3.85
#4	2.85	26.22	60	3.75
#5	2.79	26.89	60	3.84
Mean	2.78	26.70	60	3.82

Table 6.42: Bougie Final – Slots 1.25mm Tall 2.8mm Wide x 6, OD: 4mm, ID: 2.75mm, Central Wall: 0.7mm + Central Loop Wall 0.35mm

Tables 6.41 and 6.42 demonstrate that the percentage distance moved can be reduced by altering the internal construction of the central wall; this has had no effect on the tip pressures generated. Based on the results collected the bougie with slots of 1.25mm in height and 2.8mm wide will be used for the final bougie construction. The final construction bougies passed the bougie placement test (Table 6.43); this further validates the use of the bougie with 1.25mm slots.

	Without Lubricant		**With Lubricant**	
Bougie Final Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
1mm Slots (Height)	Yes	N/A	Yes	N/A
1.25mm Slots (Height)	Yes	N/A	Yes	N/A

Table 6.43: Final Bougie Construction – Bougie Placement Test Results

6.6.4 Final Bougie Tip Construction & Validation

The final 3D printed structure for the bougie tip was generated (Figure 6.53); minor adjustments to the tip have been completed to allow for the successful 3D printing of the tip with minimal supports. Internal amendments including the depth of the ground wire indent have been necessary to allow for 100% 3D printing viability, ensuring support minima errors are reduced.

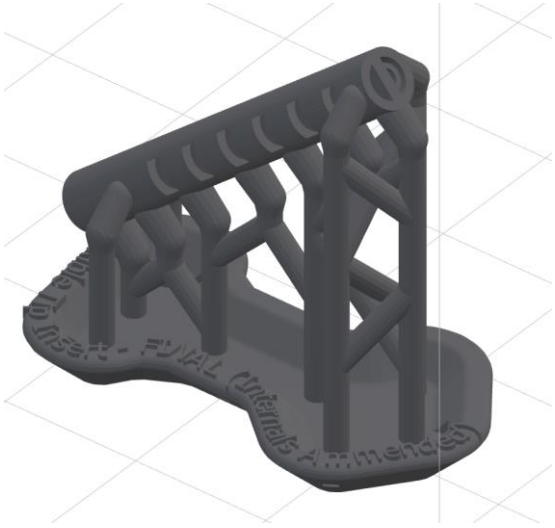


Figure 6.53: 3D Printed Support Generation For Final Bougie Tip

Due to the minor amendments made to the tip, validation was again required. The results are presented in Table 6.44. The minor adjustments made have resulted in a reduced mean percentage distance moved value (3.511%); this value will now be used to validate the Flexinol® wire proposed for use within the steerable bougie.

Test ID No.	Applied Pull Force (N)	Pull Wire Distance Moved (mm)	Angle Of Bend Achieved	Percentage (%) Distance Moved
#1	2.62	24.56	60	3.51
#2	2.56	24.38	60	3.48
#3	2.59	24.89	60	3.56
#4	2.48	24.29	60	3.47
#5	2.61	24.76	60	3.54
Average	2.572	24.576	60	3.511

Table 6.44: Bougie Final Construction – Pull Wire Testing Results

The Flexinol® wire selected for use is 0.15mm in diameter; the maximum safe stress for this wire is 321g heating pull force (3.15N) (Dynalloy.com, n.d.), for a 1 second contraction based on a current of 410(mA). This wire has an approximate cooling time of 1.7 seconds to 2 seconds. To validate the 0.15mm diameter wires suitability, this will also be compared to the 0.20mm diameter wire, which has increased pulling force tolerance but an increased approximate cooling time (2.7-3.2 seconds). Reaction times of 1 second or less are required to meet the PDS requirements. The experimental setup used is similar to the testing described in Chapter 4, Section 4.5.1; this experimental setup has been adjusted and is presented in Figure 6.54. The results from the testing are presented in Table 6.45.

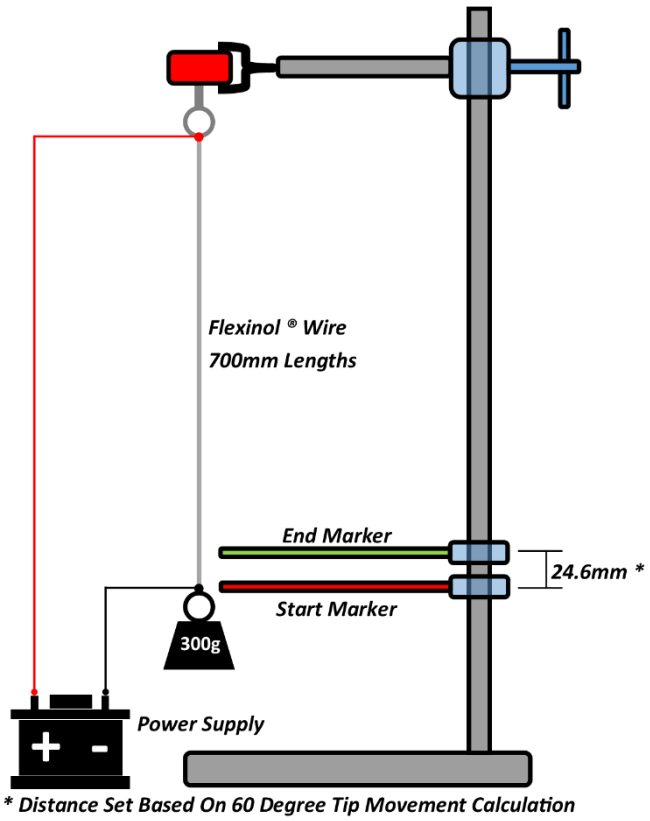


Figure 6.54: Flexinol® Wire Validation Experimental Setup

	0.15mm Diameter Flexinol® Actuator Wire x 700mm	0.20mm Diameter Flexinol® Actuator Wire x 700mm
Reading No.	**Reaction Time (Seconds)**	**Reaction Time (Seconds)**
#1	1.12	1.03
#2	1.06	1.08
#3	1.16	1.12
#4	1.15	0.98
#5	1.18	1.00
#6	1.06	1.06
#7	1.13	1.11
#8	1.15	1.12
#9	1.05	1.13
#10	1.03	1.06
Mean	**1.109**	**1.069**

Table 6.45: Comparison Of Flexinol® Wire (700mm Length) Contraction Reaction Times

Both wires present mean reaction times slightly outside of the 1 second reaction time target set within the PDS. Although the mean reaction times are 0.109 and 0.069 outside of the targeted reaction time, the reaction times are still deemed suitable. Most importantly, both Flexinol® wire setups demonstrated that they can generate the desired pull force in a suitable timescale. The choice of the 0.15mm diameter wire is still necessary due to the superior cooling times exhibited.

With the final design of the steerable bougie tip confirmed and validated with the bougie placement test (Table 6.46), this bougie can now be compared against the commercially available bougies.

	Without Lubricant		With Lubricant	
Bougie Final & Internal Features Construction	**Successful Placement (Yes/No)**	**Comments**	**Successful Placement (Yes/No)**	**Comments**
1.25mm Slots (Height)	Yes	N/A	Yes	N/A

Table 6.46: Final Bougie With Internal Features – Bougie Placement Test Results

6.6.5 Developed Steerable Bougie vs Commercially Available Bougies Results

After successfully developing the steerable bougies tip, the steerable bougie must now be compared against commercially available bougies utilising the data captured in Section 6.4, this is compared to the data captured for the final bougie; a comparative chart is presented in Figure 6.55.

The steerable bougie presents significantly lower tip pressures at all four distances held when compared to the commercially available bougies. The steerable bougie is superior when compared to the GEB (Figure 6.56). When operating the steerable bougie at the 20cm and 30cm distance held locations, this is lower than the airway trauma values exhibited in the research experimentation conducted by Marson et al., (2014). The SunMed and Frova bougies, the two most commonly used at Nottingham University Hospitals Trust (QMC), display significantly higher tip pressure forces compared to the steerable bougie at all four distances held. The force generated by the SunMed bougie could be capable of causing significant trauma to the airway if used incorrectly; replacing this with the steerable bougie could be a suitable solution.

To validate the results collected it is important to demonstrate that the steerable bougie is significantly better when individually compared to all the commercial bougies. The use of a Mann-Whitney U test compares the differences between two independent groups when the dependent variable is either ordinal or continuous, but not normally distributed.

The results from the Mann-Whitney U tests are presented in Tables 6.47-6.57. The results collected are significant across all forty-four Mann-Whitney U tests with <0.009 p-values demonstrating the steerable bougies superiority with lower peak tip pressure forces. In the trained and untrained user testing to be completed it is expected that the p-values recorded should be lower when an increased sample size is used.

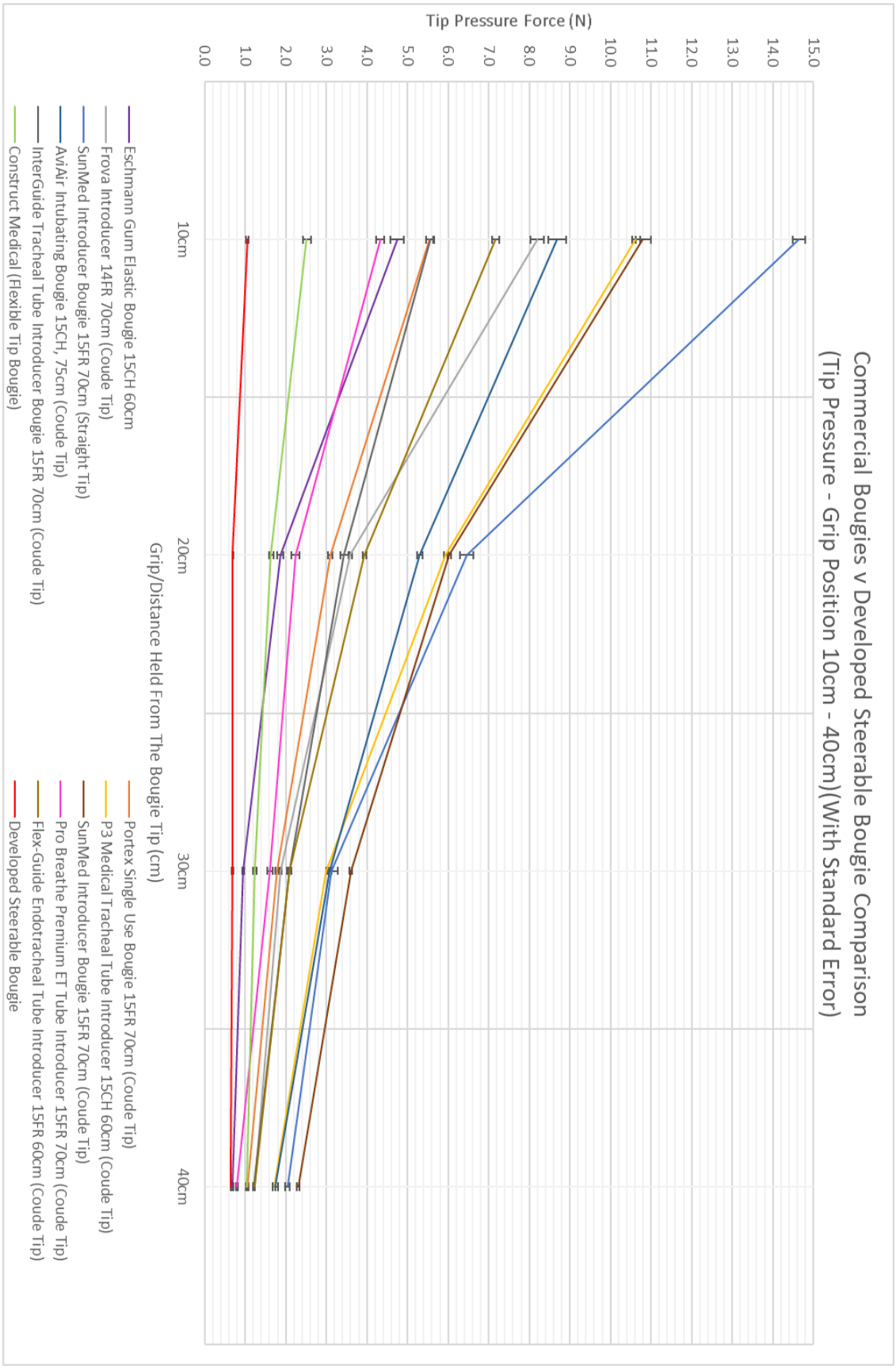


Figure 6.55: Developed Steerable Bougie vs Commercially Available Bougies Chart

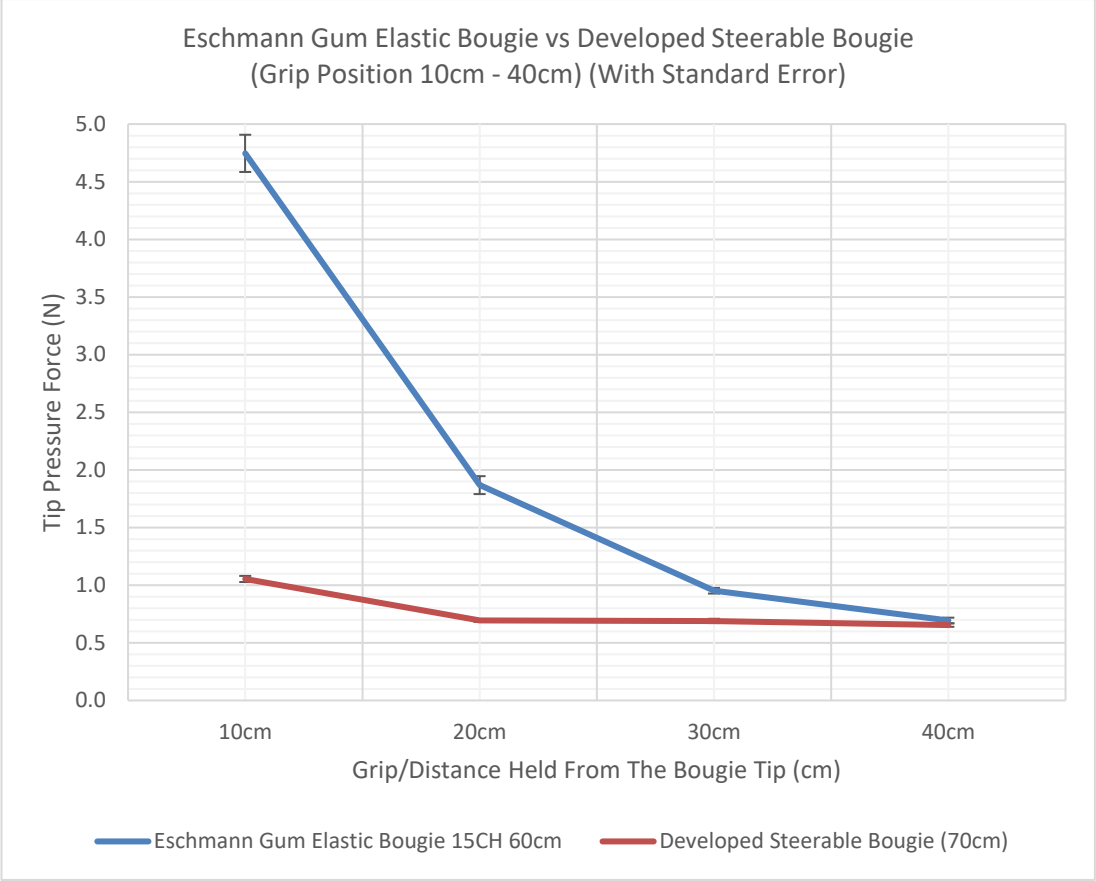


Figure 6.56: Developed Steerable Bougie vs Eschmann Re-usable Gum Elastic Bougie (GEB)

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**Eschmann Gum Elastic Bougie**	**Developed Steerable Bougie**	**p-value**
10	4.746	1.194	< 0.009
20	1.868	0.769	< 0.009
30	0.952	0.726	< 0.009
40	0.694	0.666	< 0.009

Table 6.47: Mann-Whitney U-test: Eschmann Gum Elastic Bougie vs Developed Steerable Bougie

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**Portex Single Use Bougie**	**Developed Steerable Bougie**	**p-value**
10	5.550	1.194	< 0.009
20	3.096	0.769	< 0.009
30	1.788	0.726	< 0.009
40	1.070	0.666	< 0.009

Table 6.48: Mann-Whitney U-test: Portex Single Use Bougie vs Developed Steerable Bougie

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**Frova Introducer**	**Developed Steerable Bougie**	**p-value**
10	8.196	1.194	< 0.009
20	3.598	0.769	< 0.009
30	1.876	0.726	< 0.009
40	1.228	0.666	< 0.009

Table 6.49: Mann-Whitney U-test: Frova Introducer vs Developed Steerable Bougie

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**P3 Medical Tracheal Tube Introducer**	**Developed Steerable Bougie**	**p-value**
10	10.632	1.194	< 0.009
20	5.946	0.769	< 0.009
30	2.998	0.726	< 0.009
40	1.710	0.666	< 0.009

Table 6.50: Mann-Whitney U-test: P3 Medical Tracheal Tube Introducer vs Developed Steerable Bougie

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**SunMed Introducer Bougie (Straight Tip)**	**Developed Steerable Bougie**	**p-value**
10	14.638	1.194	< 0.009
20	6.458	0.769	< 0.009
30	3.136	0.726	< 0.009
40	2.044	0.666	< 0.009

Table 6.51: Mann-Whitney U-test: SunMed Introducer Bougie (Straight Tip) vs Developed Steerable Bougie

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**SunMed Introducer Bougie (Coude Tip)**	**Developed Steerable Bougie**	**p-value**
10	10.808	1.194	< 0.009
20	6.038	0.769	< 0.009
30	3.604	0.726	< 0.009
40	2.304	0.666	< 0.009

Table 6.52: Mann-Whitney U-test: SunMed Introducer Bougie (Coude Tip) vs Developed Steerable Bougie

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**AviAir Intubating Bougie**	**Developed Steerable Bougie**	**p-value**
10	8.696	1.194	< 0.009
20	5.308	0.769	< 0.009
30	3.094	0.726	< 0.009
40	1.744	0.666	< 0.009

Table 6.53: Mann-Whitney U-test: AviAir Intubating Bougie vs Developed Steerable Bougie

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**ProBreathe Premium ET Tube Introducer**	**Developed Steerable Bougie**	**p-value**
10	4.328	1.194	< 0.009
20	2.238	0.769	< 0.009
30	1.608	0.726	< 0.009
40	0.800	0.666	< 0.009

Table 6.54: Mann-Whitney U-test: ProBreathe Premium ET Tube Introducer vs Developed Steerable Bougie

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**InterGuide Tracheal Tube Introducer**	**Developed Steerable Bougie**	**p-value**
10	5.568	1.194	< 0.009
20	3.444	0.769	< 0.009
30	2.098	0.726	< 0.009
40	1.208	0.666	< 0.009

Table 6.55: Mann-Whitney U-test InterGuide Tracheal Tube Introducer vs Developed Steerable Bougie

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**Flex-Guide ET Tube Introducer**	**Developed Steerable Bougie**	**p-value**
10	7.168	1.194	< 0.009
20	3.944	0.769	< 0.009
30	2.104	0.726	< 0.009
40	1.232	0.666	< 0.009

Table 6.56: Mann-Whitney U-test: Flex-Guide ET Tube Introducer vs Developed Steerable Bougie

	Mean Peak Force(N)		Mann-Whitney U-test
Distance Held From The Tip (cm)	**Construct Medical Flexible Tip Bougie**	**Developed Steerable Bougie**	**p-value**
10	2.514	1.194	< 0.009
20	1.642	0.769	< 0.009
30	1.242	0.726	< 0.009
40	1.046	0.666	< 0.009

Table 6.57: Mann-Whitney U-test: Construct Medical Flexible Tip Bougie vs Developed Steerable Bougie

6.7 Repeatability Testing

As described in Section 6.2.4, a Festo pneumatic and electrical automation system has been constructed to allow the repeatability testing of ten bougies in addition to the developed steerable bougie. The repeatability testing of the Construct Medical Flexible Tip Bougie is not possible, as securing the bougie in the testing setup without fracturing the bougie mechanism within the internal shaft of the device is deemed not possible.

Prior to conducting the repeatability testing, the system required performance validation to ensure the accurate collection of the desired data. By running an initial test using a used Frova bougie, immediately it became apparent that the anti-slip depression cup/disk designed for the force gauge was not fit for use. As the bougie is pressed up against the force gauge by the retractable pneumatic piston setup, the bougie curls and causes the tip to dislodge from the anti-slip cup. This slippage results in the side of the bougie being pressed up against the force gauge (Figure 6.57) and not the tip as required.

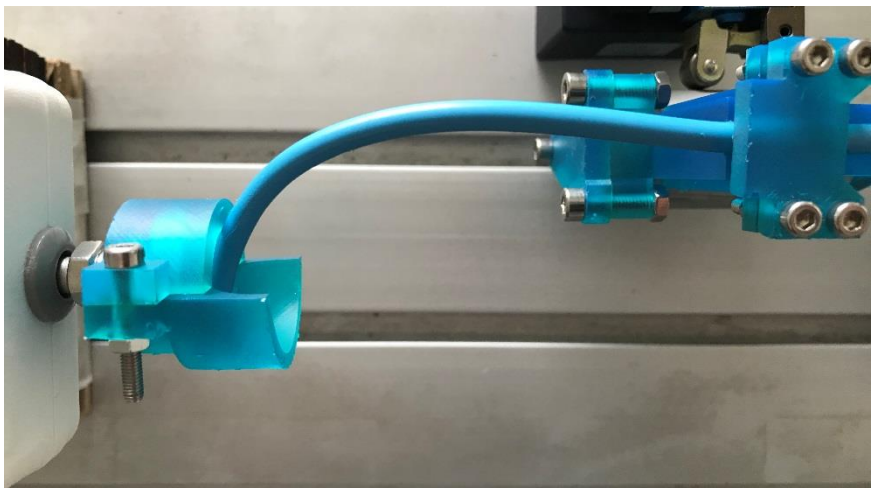


Figure 6.57: Repeatability Testing Failure Issue

Another observation made is that as the bougie inevitably bends, it will do so outside of the normal operating environment which will be within the internal diameter of the human trachea, typically this ranges from 15-22cm in diameter (Breatnach, Abbott and Fraser, 1984). With the bougie bending outside of the normal operating environment, the repeated tip pressure readings collected will not be an accurate representation of how the bougie deforms in the standard operative environment. To overcome this, an attachment that replicates the diameter of a human trachea was developed. This attachment must also prevent the bougie tip from slipping and curling. The designed attachment is presented in its CAD format in Figure 6.58.

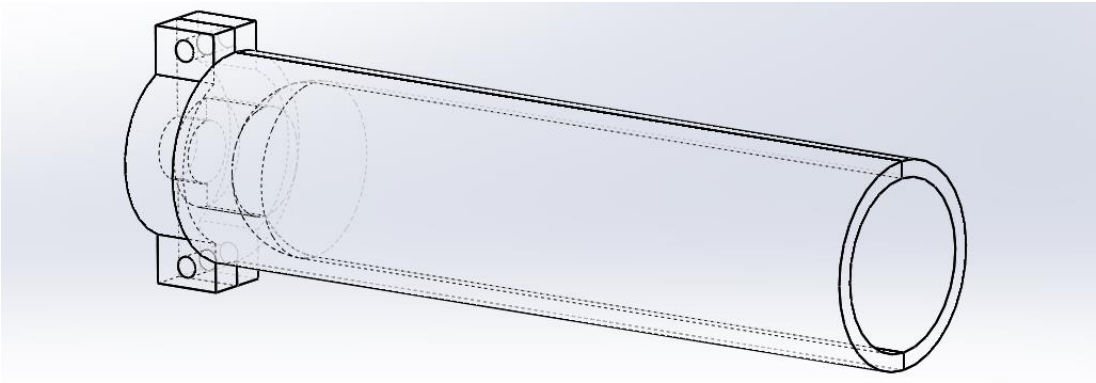


Figure 6.58: Trachea Force Gauge Attachment

Although the attachment presented in Figure 6.58 is an improvement on the current setup, there are two issues that require the attachment to have further amendments made. As the piston attempts to push the bougie into the trachea attachment, the tip does not reach the internal pressure plate; a reduction of the attachment length by 20mm is required. The second issue relates to the retractable piston lodging against the side of the attachment. The attachment needs altering to allow the piston to move without being impeded. The alterations to the attachment in its manufactured form are presented in Figure 6.59.

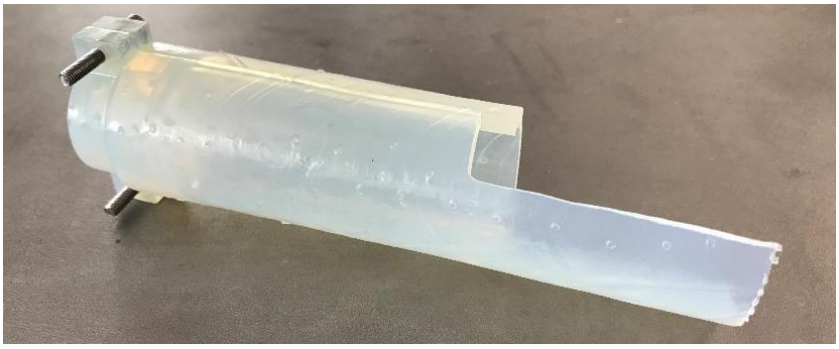


Figure 6.59: Amended Trachea Force Gauge Attachment

Prior to testing, the starting tip pressure force must be defined. The tip pressure force for each of the bougies to be tested was defined by capturing twenty hand generated peak tip forces and calculating the arithmetic mean (Table 6.58). Prior to the testing commencing, each of the bougies are placed into the bougie grip holder attached to the piston, the piston location was then measured at 10cm and temporarily locked into position. The piston was then moved forward into a position allowing the bougie to be pressed up against the force gauge; once the required tip pressure value defined in Table 6.58 for the bougie being tested was achieved, the bougie was locked into position. It is important to note that the starting value was not always 100% accurate to the figures defined in Table 6.58 due to the variables involved in the setup. Where an exact tip pressure could not be achieved, starting tip pressure values were exceeded by approximately 0.2-0.3N.

Bougie	GEB	Portex	Frova	P3/Insight	InterGuide	ProBreathe
Tip Type	**Coude**	**Coude**	**Coude**	**Coude**	**Coude**	**Coude**
R1	4.76	6.07	7.50	8.92	7.43	6.41
R2	5.11	6.68	7.81	8.96	7.92	6.42
R3	4.98	6.26	7.59	9.46	8.40	5.82
R4	4.96	6.68	7.88	9.97	8.44	6.07
R5	4.78	5.94	8.08	8.98	8.16	6.04
R6	5.15	6.32	8.32	8.64	8.05	6.02
R7	4.87	5.94	7.63	9.56	7.41	5.78
R8	5.11	6.08	7.49	9.11	7.94	5.69
R9	4.80	6.46	7.86	8.77	7.29	5.68
R10	4.66	6.19	7.32	8.94	7.26	5.40
R11	4.87	6.08	8.21	9.24	7.25	6.19
R12	4.78	6.29	7.29	8.65	7.26	6.26
R13	5.13	6.08	7.50	8.69	7.13	5.46
R14	5.15	6.25	7.46	9.16	7.21	5.60
R15	4.79	5.99	7.05	9.31	7.19	5.12
R16	5.13	6.20	6.95	8.93	7.29	5.29
R17	4.96	6.30	7.29	8.73	7.22	5.78
R18	4.58	6.38	7.32	8.61	6.99	5.85
R19	5.13	6.37	7.77	9.77	7.00	5.10
R20	4.98	6.11	7.83	9.89	6.72	5.05
Mean	4.93	6.23	7.61	9.11	7.48	5.75

Bougie	SunMed		AviAir	FlexGuide	Steerable Bougie
Tip Type	**Coude**	**Straight**	**Coude**	**Coude**	**Straight**
R1	10.35	14.70	9.77	7.65	1.14
R2	10.21	14.52	9.69	7.35	1.15
R3	10.35	14.62	10.12	8.09	1.17
R4	11.00	15.04	9.71	7.40	1.19
R5	10.60	14.14	9.56	7.80	1.19
R6	10.07	15.30	9.24	8.20	1.05
R7	9.74	14.49	9.69	8.17	1.19
R8	10.07	15.35	9.21	8.50	1.24
R9	10.14	14.56	9.83	8.06	1.19
R10	10.97	14.67	10.22	8.51	1.15
R11	10.52	14.82	9.68	8.04	1.26
R12	10.04	15.35	9.18	7.65	1.16
R13	10.70	15.51	9.51	7.55	1.20
R14	11.20	14.95	9.33	7.78	1.22
R15	10.32	15.16	9.50	8.02	1.22
R16	9.76	15.43	9.48	8.29	1.25
R17	10.15	14.88	9.51	8.48	1.15
R18	10.53	14.89	9.40	8.40	1.24
R19	10.90	15.36	9.26	8.45	1.20
R20	10.20	15.44	10.09	8.35	1.15
Mean	10.39	15.01	9.60	8.04	1.18

Table 6.58: Mean Bougie Tip Pressures (20 Readings)

6.7.1 Repeatability Testing Results & Analysis

The repeatability testing results collected are combined into one chart for comparative analysis after being plotted onto individual charts during testing (Figure 6.62). Each bougie was pressed against the force gauge 250 times by the pneumatic piston at a pre-set speed, with a short pause programmed to ensure the piston did not immediately retract when pressing up against the force gauge. The peak forces (N) exhibited are captured by the data acquisition software and automatically plotted (Figure 6.60). The peak force readings plotted over time demonstrate the bougie tips degradation as the tip pressure forces reduce.

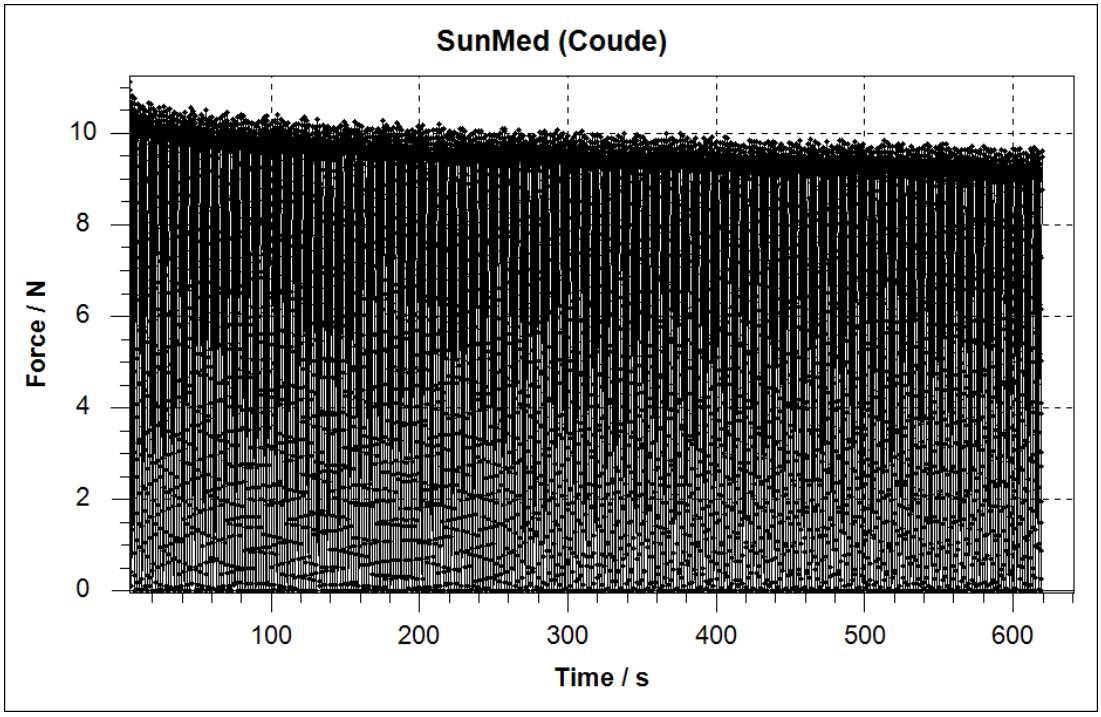


Figure 6.60: Example Live Data Capture Of Tip Pressure Readings

As each of the bougie testing processes are repeated, there are inevitable peaks and dips in the data collected as the bougie deforms and recovers (Figure 6.61). As each of the bougies are constructed using a variety of materials and internal setups, degradation occurs at different rates.

Upon review of Figure 6.62, the majority of the bougies over 250 repetitions reduce in tip pressures by approximately 1N; the SunMed straight tip bougie, Portex single use bougie (coude tip) and the InterGuide bougie deform quicker than the others assessed. The project team have set the target value of 10% bougie degradation before the bougie would be deemed unusable as it has deformed past its perceived optimal operating specification. This 10% cut off will define when the bougie sets will be changed within the tip pressure studies.

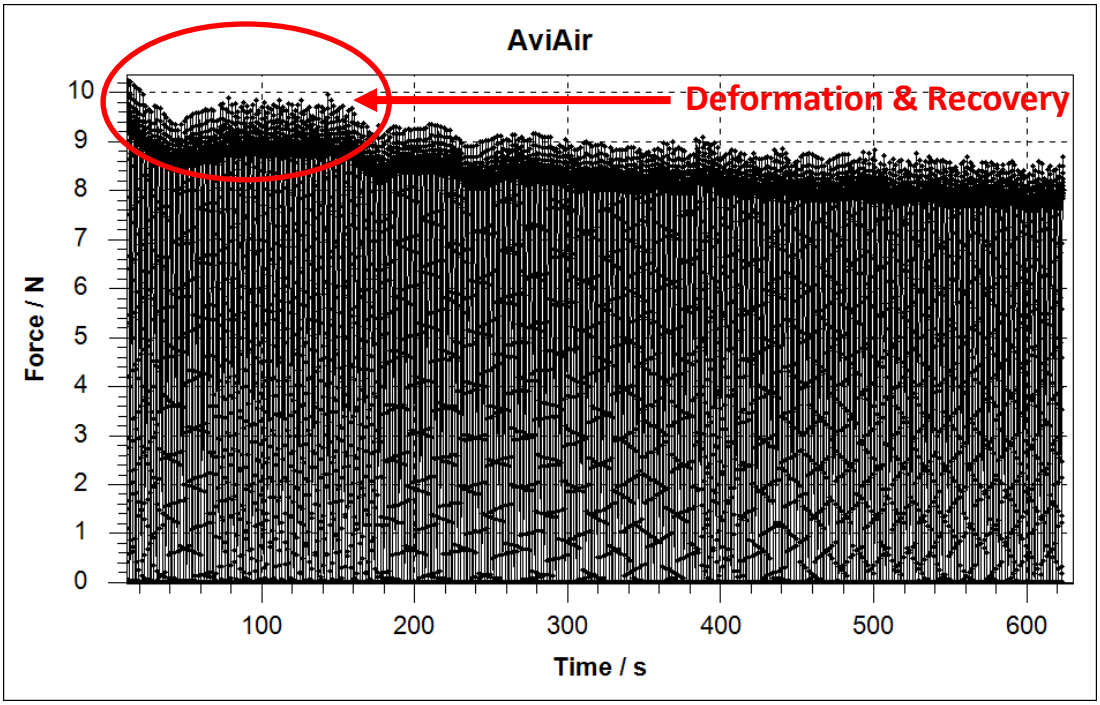


Figure 6.61: Example Of Bougie Deformation & Recovery

One of the most promising results presented is by the developed steerable bougie; no deformation occurs over the 250 readings as the bougie utilises a flexible tip and is designed to be shaped. The tip pressures encountered do not drop other than on the odd occasion where lower tip pressures are temporarily observed as the retractable pistons speed did not allow the bougie tip to fully straighten/recover before attempting to press the bougie tip against the pressure plate again. Interestingly a slight increase in tip pressure is observed over the 250 readings, however this is only by 0.1N.

After initially being placed under strain, recovery before permanent deformation can occur; a good example of this recovery is demonstrated by the AviAir bougie (Figure 6.61), Interguide bougie and SunMed straight tip bougie.

Figure 6.63 presents the repeatability testing comparison chart which focuses on a 10% degradation cut off; this cut off accounts for the first time a 10% cut off tip pressure reading is observed. The steerable bougie, GEB, Portex bougie, FlexGuide bougie and InterGuide bougie all present a 10% cut off value recorded with a reading number of <50. Assessing the bougies 10% cut off on the first reading is an unfair method of assessment, as the bougie may recover especially if the pressure reading collected is because of a small bougie tip slip on the force gauge depression disk/cup. To overcome this, the cumulative force for each of the bougies is calculated and then the average force is defined based on the cumulative force readings; the average force deformation cut off chart is presented in Figure 6.64.

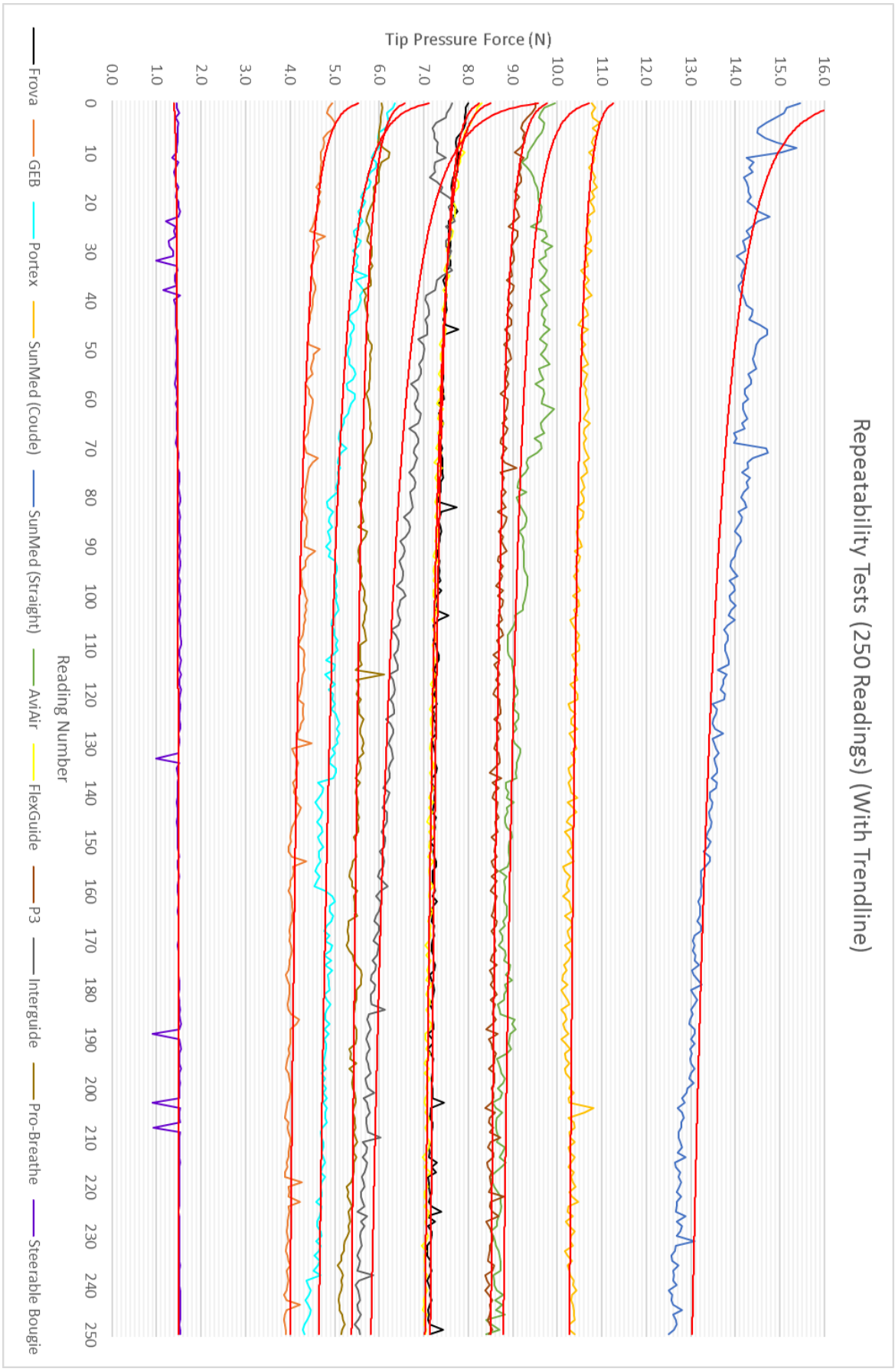


Figure 6.62: Repeatability Testing Comparison (With Trend Lines)

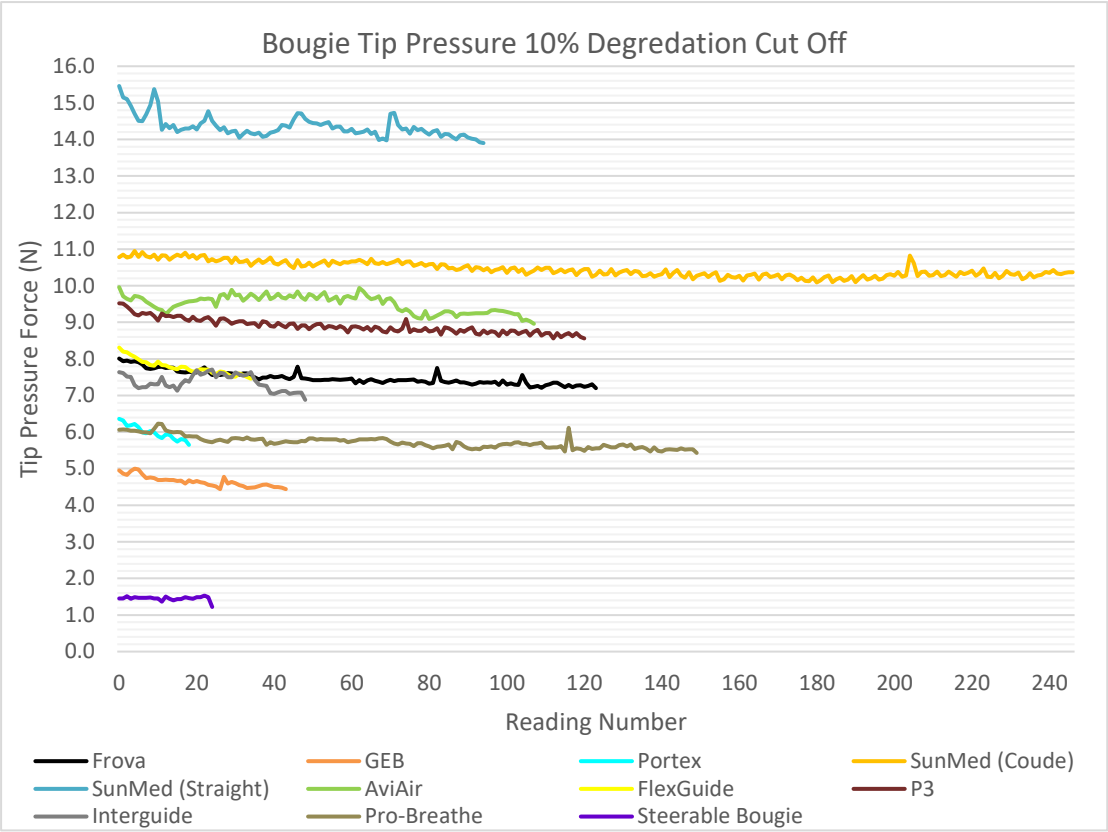


Figure 6.63: Repeatability Testing Comparison (10% Degradation Cut Off Point)

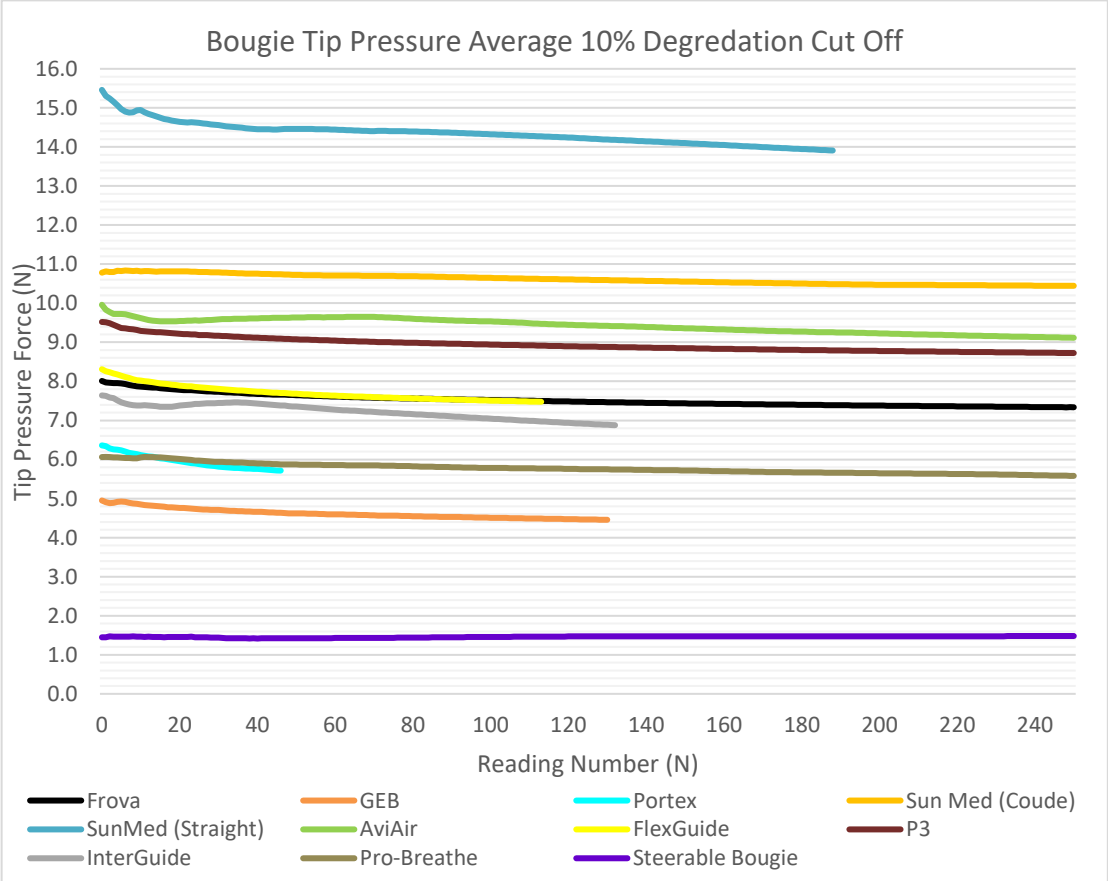


Figure 6.64: Repeatability Testing Comparison (10% Average Degradation Cut Off Point)

Table 6.59 presents the reading number at which the 10% degradation is achieved, this is based on the calculated average force reduction. The reading numbers are then translated as shown in Figure 6.65, this presents the final repeatability testing comparison chart based on a 10% average degradation cut off point.

Bougie	Original Force	10% Degradation Force Value	Reading Number Of 10% Degradation
Frova	8.01	7.21	250+
Eschmann Gum Elastic Bougie	4.95	4.46	130
Portex	6.36	5.72	47
SunMed (Coude Tip)	10.78	9.70	250+
SunMed (Straight Tip)	15.46	13.91	188
AviAir	9.96	8.96	250+
FlexGuide	8.31	7.48	113
P3	9.52	8.57	250+
InterGuide	7.64	6.88	132
ProBreathe	6.06	5.45	250+
Steerable Bougie	1.45	1.31	250+

Table 6.59: Average Force Reading Number Of 10% Degradation

The results presented in Table 6.59 and Figure 6.65, demonstrate that two of the most commonly used bougies in the UK (GEB and Portex) (Mushambi et al., 2016), degrade at a faster rate than the majority of the other bougies assessed. The Frova bougie, which is the second most popular bougie used within UK practice does not degrade by the 10% defined cut off within 250 readings. Interestingly, the bougies that display higher tip pressure readings do not typically degrade within 250 repetitions. Stiffer bougies often result in slower degradation, conversely these bougies have higher mean peak tip pressures resulting in increased likelihood of airway trauma.

During intubation procedures, bougies are not placed under this level of repeated significant strain to achieve 10% degradation, this testing demonstrates that all the bougies are capable of being utilised for a significantly longer period than they are designed for. Adequate factors of safety considerations are clearly in place for each of the bougies, this is especially important for the gum elastic bougie which is the only re-usable bougie analysed; further testing to consider sterilisation is required. This testing has also validated the methods for the tip pressure studies presented in Section 6.8. Each of the bougies can be used for a minimum of 40 readings when held 10cm from the tip of the bougie before the bougies sets are to be replaced.

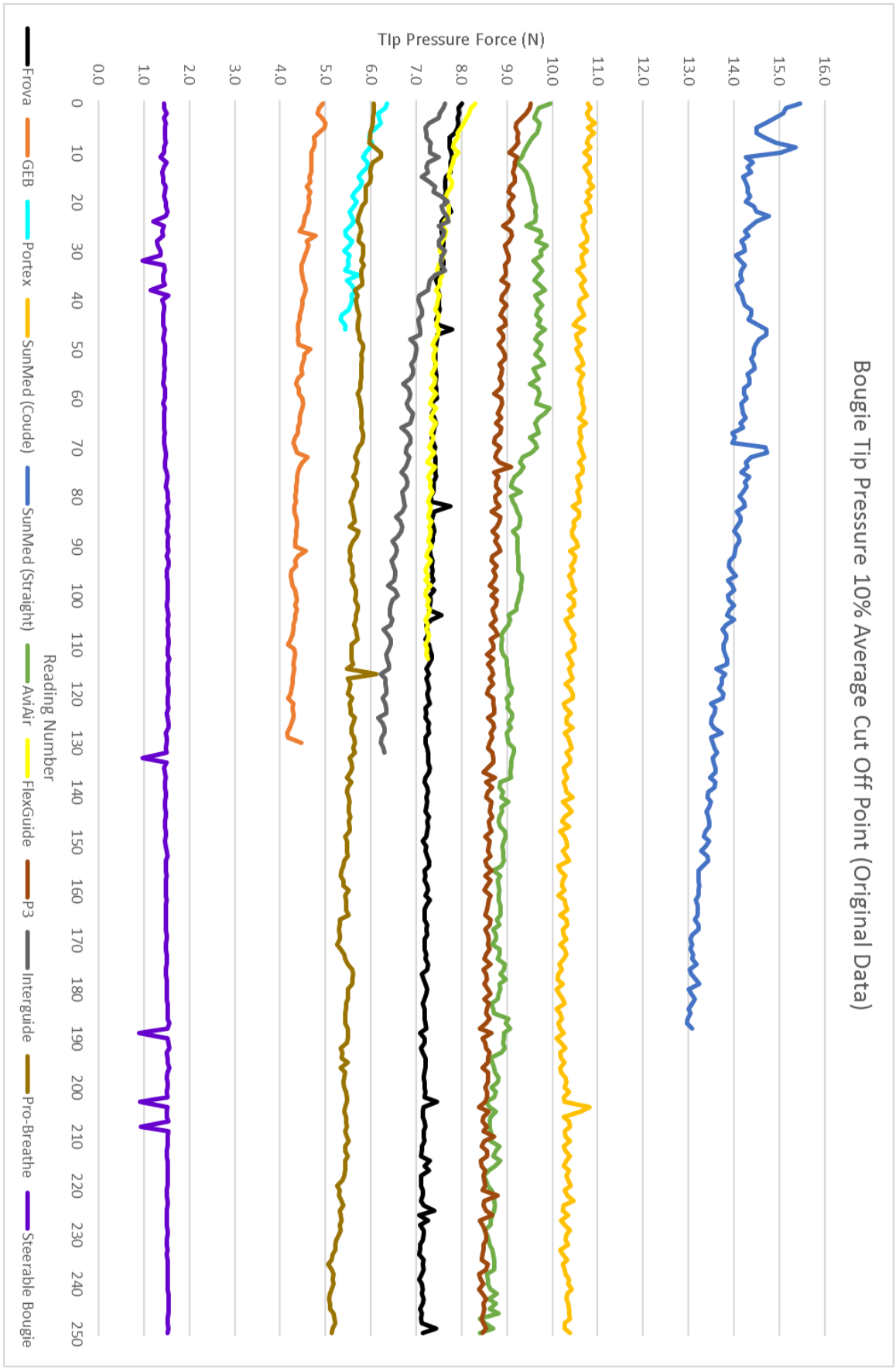


Figure 6.65: Repeatability Testing Comparison (10% Average Degradation Cut Off Point)

To add a further level of analysis to the bougie degradation testing, twenty-four hours after the repeatability testing was completed, each of the bougies were again tested twenty times by a hand-held operator with the peak tip pressure forces recorded. The purpose of this testing was to confirm that a level of permanent deformation had occurred in all the bougies. It is important to note there is an element of variability with a hand-held operator as they are not able to perform the same axial movements accurately compared to the pneumatic piston, but conversely a human operator will likely be able to generate more tip pressure with the bougies due to variable device control. Tables 6.60 and 6.61 present the results from the second operator tests.

Upon review of the data, a level of permanent deformation has occurred in all the bougies. This is significant in all the bougies other than the SunMed straight tip bougie where a 0.07% change is exhibited; this bougie has appeared to recover. It is hypothesised that the straight tip bougie has recovered as it has not reached a permanent level of deformation unlike all the coude tip bougies where this degradation is amplified due to the increase of the angle of the coude tip. For all the other bougies the percentage tip pressure force change reduced by >2.5%.

Bougie	**Mean Tip Pressure (N) Before Repeatability Testing**	**Mean Tip Pressure (N) After Repeatability Testing**	**% Tip Pressure Force Change**
Frova	7.61	7.27	4.47
Eschmann Gum Elastic Bougie (GEB)	4.93	4.67	5.27
Portex	6.23	5.91	5.14
SunMed (Coude Tip)	10.39	10.08	2.98
SunMed (Straight Tip)	15.01	15.00	0.07
AviAir	9.60	8.87	7.19
FlexGuide	8.04	7.76	3.48
P3	9.11	8.87	2.66
InterGuide	7.48	6.17	17.51
ProBreathe	5.75	5.13	10.78
Steerable Bougie	1.18	1.11	5.93

Table 6.60: Before & After Repeatability Testing % Deformation – Operator Generated Readings

Bougie	GEB	Portex	Frova	P3/Insight	InterGuide	ProBreathe
Tip Type	**Coude**	**Coude**	**Coude**	**Coude**	**Coude**	**Coude**
R1	4.48	6.02	6.85	9.04	6.23	5.64
R2	4.27	5.93	7.49	8.80	6.08	5.15
R3	4.29	5.84	7.03	9.10	6.61	5.60
R4	4.23	6.38	7.17	8.87	6.78	5.53
R5	4.29	5.77	6.93	8.82	6.30	4.87
R6	4.25	5.48	6.94	9.08	6.13	4.81
R7	5.30	5.46	7.45	9.01	6.02	5.13
R8	4.96	6.23	7.48	9.16	6.45	4.76
R9	4.57	5.79	7.27	8.72	5.96	5.14
R10	4.46	5.66	7.36	8.60	6.19	5.28
R11	4.78	6.30	7.42	8.96	6.04	5.08
R12	5.19	5.65	7.22	9.17	5.88	5.34
R13	4.35	5.72	7.33	8.60	5.90	4.73
R14	4.59	5.76	7.45	8.72	5.96	5.02
R15	5.25	6.40	7.42	8.43	6.08	5.21
R16	5.20	6.10	7.33	8.40	6.66	5.35
R17	5.11	5.91	7.51	9.17	6.44	5.00
R18	4.86	6.03	7.22	8.60	5.76	5.19
R19	4.64	5.84	7.42	8.91	5.77	4.99
R20	4.52	5.99	7.24	9.30	6.28	4.95
Mean	4.67	5.91	7.27	8.87	6.17	5.13

Bougie	SunMed		AviAir	FlexGuide	Steerable Bougie
Tip Type	**Coude**	**Straight**	**Coude**	**Coude**	**Straight**
R1	9.73	15.13	9.09	8.15	1.05
R2	10.29	14.89	9.42	7.58	1.09
R3	10.31	15.43	9.24	8.43	1.13
R4	10.30	14.97	8.54	7.62	1.13
R5	10.04	14.74	8.58	7.58	1.11
R6	10.42	14.55	9.22	7.66	1.19
R7	10.11	13.37	8.75	7.79	1.05
R8	9.81	15.28	8.68	7.31	1.09
R9	10.35	15.12	8.50	7.72	1.05
R10	9.83	15.52	8.47	8.05	1.05
R11	10.12	14.61	8.65	7.62	1.16
R12	9.86	15.76	8.68	7.32	1.23
R13	10.50	14.70	9.05	7.66	1.19
R14	9.89	15.45	8.75	7.75	1.19
R15	9.93	15.40	9.09	7.75	1.01
R16	10.05	14.75	9.20	7.80	1.06
R17	9.93	14.63	8.59	8.27	1.05
R18	10.17	15.12	8.96	8.02	1.20
R19	10.11	15.24	9.40	7.66	1.02
R20	10.04	15.44	9.38	7.57	1.19
Mean	10.08	15.00	8.91	7.76	1.11

Table 6.61: Bougie Tip Pressures After Repeatability Testing (20 Readings)

Although 10% degradation has been deemed an acceptable margin of deformation for the trained and untrained user study, to place the bougies under a higher level of scrutiny, a 5% bougie tip pressure degradation cut off will be analysed. The same process of data analysis will be used as the 10% degradation; the three result charts are presented in Figures 6.66, 6.67 and 6.68. Based on Figure 6.68, Table 6.62 presents the reading number at which the 5% degradation is achieved based on the calculated average force reduction.

Bougie	Original Force	Target 5% Degradation Force Value	Reading Number Of 5% Degradation
Frova	8.01	7.61	61
Eschmann Reusable Gum Elastic Bougie (GEB)	4.95	4.70	32
Portex	6.36	6.04	15
SunMed (Coude Tip)	10.78	10.24	250+
SunMed (Straight Tip)	15.46	14.69	17
AviAir	9.96	9.46	117
FlexGuide	8.31	7.89	20
P3	9.52	9.04	62
InterGuide	7.64	7.26	63
ProBreathe	6.06	5.76	122
Steerable Bougie	1.45	1.38	250+

Table 6.62: Average Force Reading Number Of 10% Degradation

As Table 6.62 suggests, the two bougies that do not degrade within the 5% cut off are the SunMed coude tip bougie and the steerable tip bougie. The SunMed coude tip bougie used at Nottingham University Hospitals Trust (QMC) continues to perform well in the repeatability testing and does not show significant signs of degradation; to counteract this positive result, this is the bougie that exhibits the highest mean peak tip pressure readings.

The majority of the other bougies degrade within <100 readings before the 5% cut off is reached. Interestingly the GEB and Portex single use bougies degrade quickly before reaching the 5% cut off, only lasting 32 and 15 readings respectively. The testing completed utilising the pneumatic and electronic system setup has identified the rate at which the bougies degrade at when held 10cm from the tip. Identifying these values has allowed a defined point to be set for the bougie sets to be replaced within the tip pressure studies. By completing this repeatability testing and creating the testing system, this will allow a full analysis of all the bougies at 10, 20, 30 and 40cm to be completed as future work; an adequate number of unused bougies will need to be sourced to replicate high volume testing.

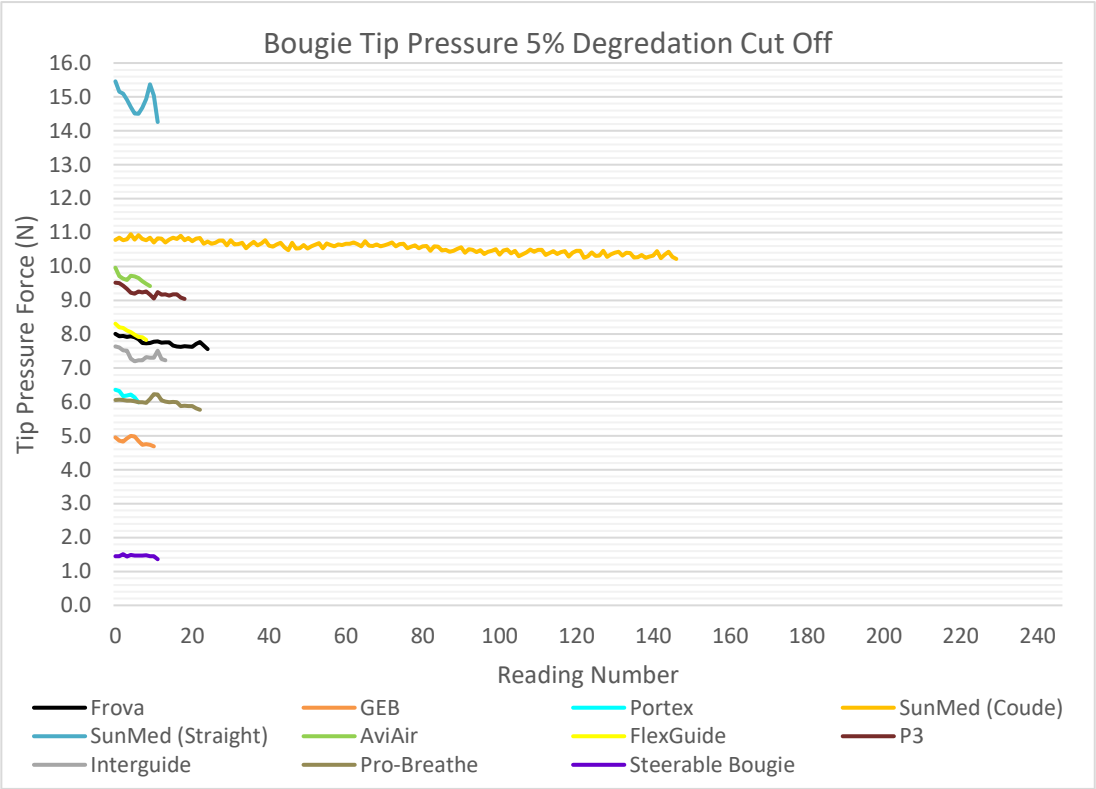


Figure 6.66: Repeatability Testing Comparison (5% Degradation Cut Off Point)

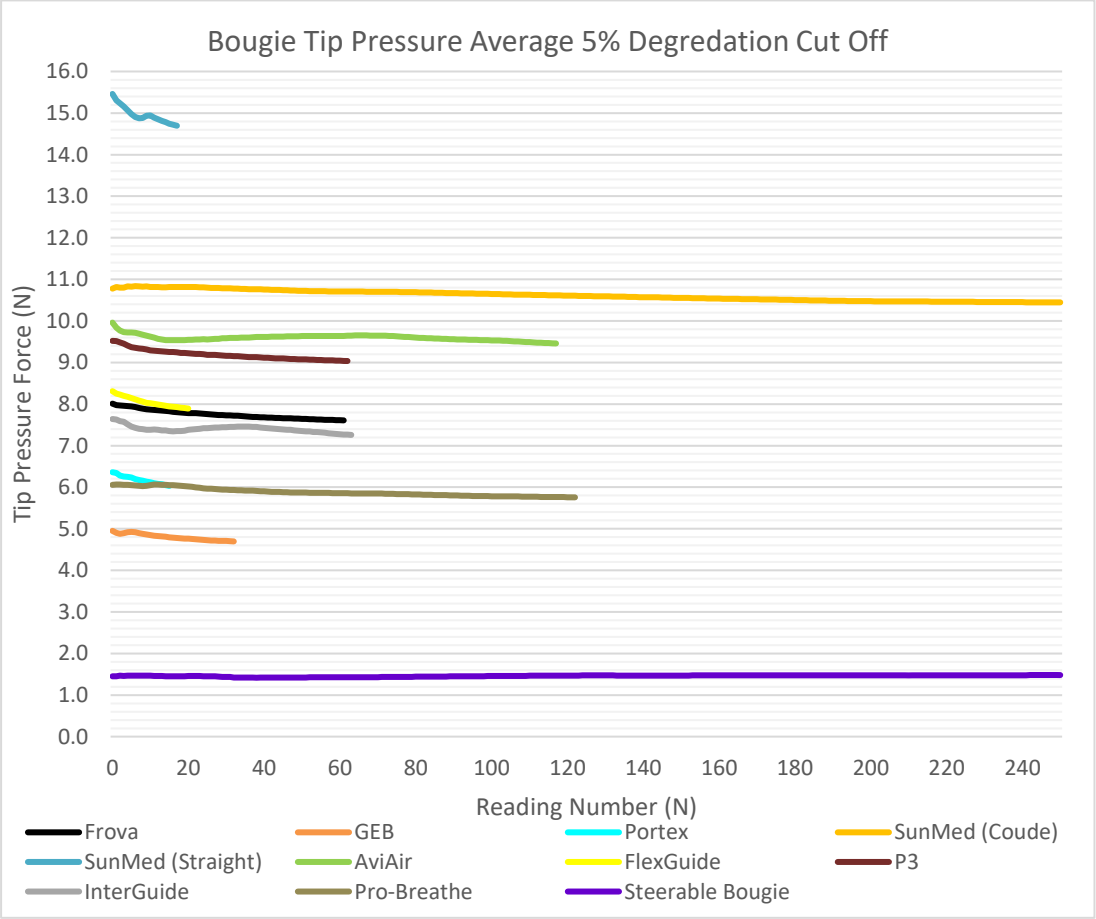


Figure 6.67: Repeatability Testing Comparison (5% Average Degradation Cut Off Point)

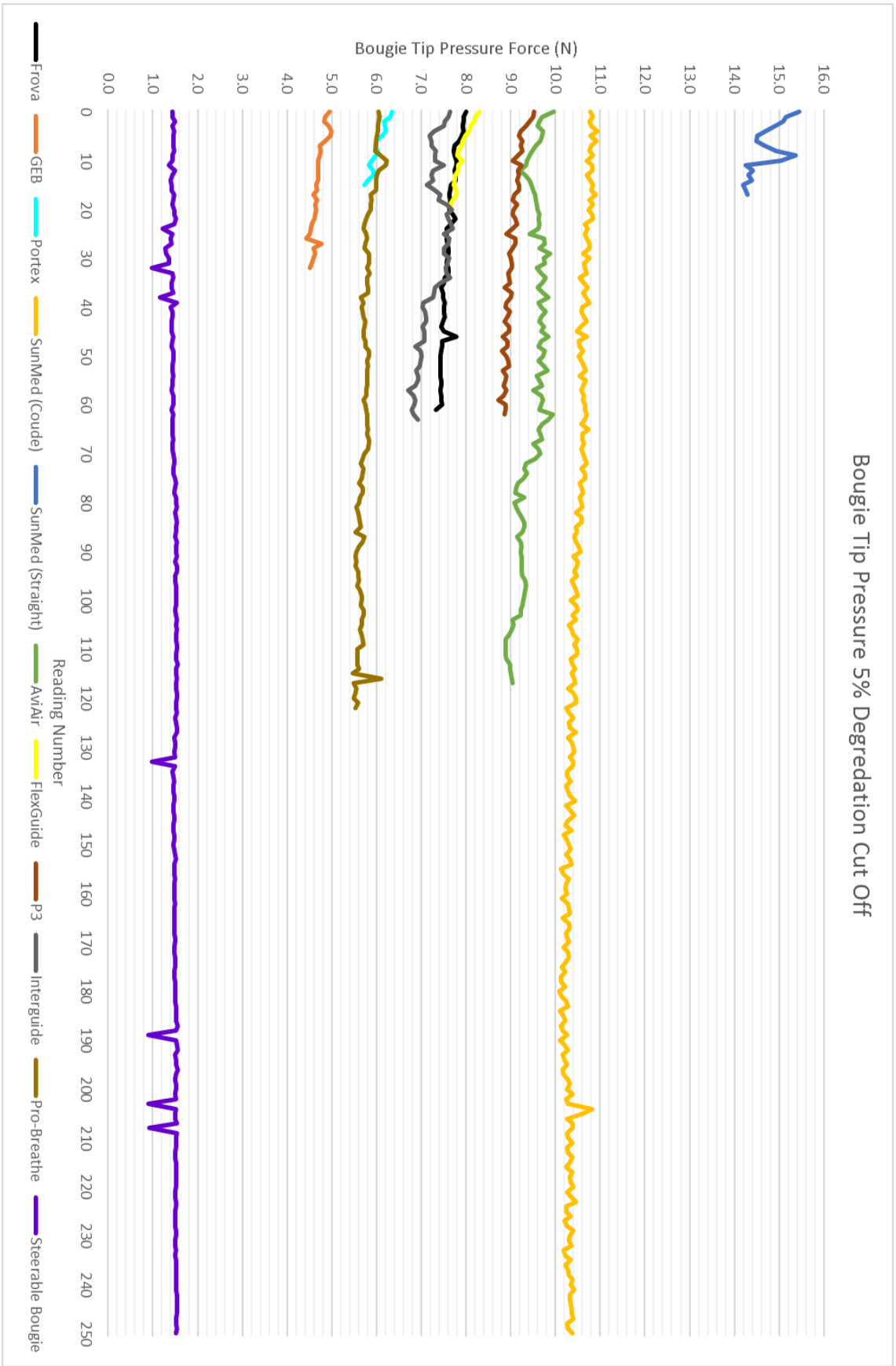


Figure 6.68: Repeatability Testing Comparison (5% Average Degradation Cut Off Point)

6.7.2 Validating The Tip Pressure Study Method – Repeatability Testing

To fully validate the testing protocol and the number of readings collected by each bougie in the tip pressure study, a set of six bougies to be tested in the tip pressure study will be analysed. Each bougie is held at 40cm, 30cm, 20cm and 10cm from the bougie tip (in the listed order) and three readings are collected at each distance held. This is then repeated until six sets of data for all six bougies are collected. The mean tip pressures of the first and last set (i.e. Data Set 1 (DS1) and Data Set 6 (DS6)) at each distance are compared and the percentage change calculated.

As described in Section 6.7.1, when held at 10cm from the bougie tip, the highest tip pressure forces are generated. The point at which 10% degradation for each of the bougies sets has been defined is due to the Portex single use bougie degrading by 10% after 47 readings. Within the designed testing protocol, the bougies will only be used 18 times at this distance before the bougie sets are changed, therefore ensuring the 10% degradation cut off does not become a factor. The bougie can be used as many times as required at the other distances also, as maximum bougie deformation cannot be achieved as significant forces cannot be generated. Using this method, the results from this validation repeatability testing are presented in Table 6.63 and 6.64.

The results presented in Table 6.64 show the percentage change of the mean peak tip pressures of the readings taken between DS1 and DS6 at each recorded distance. Immediately it is obvious there is an element of variability within the readings, interestingly, the distance that presents the least amount of variability is the 10cm distance held where the most severe amount of degradation is likely to be recorded; greater control is however achievable.

Although the bougies have degraded, surprisingly in some cases tip pressure forces have increased. The greater control of the bougie when held at a shorter distance has resulted in a less than 5% change. Conversely the tip pressure readings recorded at the 40cm and 30cm distance held locations provide the greatest variability; this is not because the tip pressure exhibited at these distances are high, it is because the bougies bend easier when held further away from the tip and user control is lower. The majority of the readings collected for all of the bougies and distances held represent a change of +/- 10% between data set one and six mean values; there are a few data set mean values that fall outside of this bracket, most notably the 20.51% increase at 30cm held with the P3 bougie and a 16.91% decrease in tip pressure at 40cm held for the Eschmann GEB.

		Data Set 1				Data Set 2				Data Set 3			
		40cm	30cm	20cm	10cm	40cm	30cm	20cm	10cm	40cm	30cm	20cm	10cm
Portex	R1 (N)	0.90	1.73	4.36	6.65	1.05	1.97	3.94	7.25	0.88	2.07	4.00	7.44
	R2 (N)	0.94	1.76	5.05	6.59	1.09	1.54	4.49	6.93	1.06	2.02	4.19	6.07
	R3 (N)	1.05	1.68	4.39	7.11	1.03	1.88	4.64	7.13	1.02	1.98	4.19	7.34
	Mean (N)	0.963	1.723	4.600	6.783	1.057	1.797	4.357	7.103	0.987	2.023	4.127	6.950
GEB	R1 (N)	0.96	1.60	2.47	5.04	0.65	1.17	2.74	4.83	0.88	1.36	2.63	5.22
	R2 (N)	0.89	1.39	2.30	4.69	0.68	1.14	2.74	5.55	0.77	1.39	2.78	4.92
	R3 (N)	0.87	1.39	2.23	5.19	0.73	1.21	2.47	4.82	0.78	1.37	2.68	5.01
	Mean (N)	0.907	1.460	2.333	4.973	0.687	1.173	2.650	5.067	0.810	1.373	2.697	5.050
SunMed	R1 (N)	2.22	3.51	6.08	13.67	2.34	3.13	6.38	13.33	2.11	3.46	5.99	14.02
	R2 (N)	2.07	3.35	5.93	15.19	1.95	3.30	6.14	14.95	2.14	3.23	5.54	15.29
	R3 (N)	1.98	3.22	5.48	15.05	2.05	3.02	6.75	14.77	1.96	2.64	5.99	15.90
	Mean (N)	2.090	3.360	5.830	14.637	2.113	3.150	6.423	14.350	2.070	3.110	5.840	15.070
Frova	R1 (N)	1.73	2.46	4.15	9.81	1.82	2.32	4.56	10.37	1.89	2.74	4.40	9.79
	R2 (N)	1.67	2.34	4.09	10.48	1.70	2.23	4.63	10.33	1.84	2.57	4.41	10.39
	R3 (N)	1.57	2.41	3.05	10.25	1.73	2.08	4.57	10.49	1.67	2.56	4.35	10.70
	Mean (N)	1.657	2.403	3.763	10.180	1.750	2.210	4.587	10.397	1.800	2.623	4.387	10.293
P3	R1 (N)	2.09	3.42	6.21	11.70	1.81	3.11	5.67	12.04	1.76	2.72	6.50	12.59
	R2 (N)	2.01	3.03	6.05	11.53	1.64	2.98	5.61	12.04	1.71	2.88	5.71	12.17
	R3 (N)	2.05	2.97	5.56	11.37	1.86	2.80	5.17	10.97	1.75	2.72	6.14	12.39
	Mean (N)	2.050	3.140	5.940	11.533	1.770	2.963	5.483	11.683	1.740	2.773	6.117	12.383
Steerable Bougie	R1 (N)	0.65	0.66	0.77	1.24	0.65	0.69	0.79	1.18	0.63	0.74	0.74	1.22
	R2 (N)	0.63	0.65	0.78	1.17	0.69	0.67	0.76	1.15	0.68	0.69	0.68	1.10
	R3 (N)	0.62	0.64	0.79	1.22	0.67	0.65	0.78	1.15	0.69	0.73	0.81	1.23
	Mean (N)	0.633	0.650	0.780	1.210	0.670	0.670	0.777	1.160	0.667	0.720	0.743	1.183
		Data Set 4				Data Set 5				Data Set 6			
		40cm	30cm	20cm	10cm	40cm	30cm	20cm	10cm	40cm	30cm	20cm	10cm
Portex	R1 (N)	1.10	1.95	3.44	7.29	1.14	1.91	3.64	8.01	1.04	1.87	4.02	6.82
	R2 (N)	1.03	2.04	3.65	7.67	1.07	1.86	4.11	7.77	0.97	1.92	3.99	7.33
	R3 (N)	1.04	1.86	3.65	7.65	1.02	1.84	3.69	7.76	1.05	1.85	3.94	7.07
	Mean (N)	1.057	1.950	3.580	7.537	1.077	1.870	3.813	7.847	1.020	1.880	3.983	7.073
GEB	R1 (N)	0.92	1.45	2.53	5.12	0.75	1.33	2.32	4.88	0.66	1.22	2.29	4.59
	R2 (N)	0.84	1.64	2.44	5.05	0.72	1.22	2.54	4.20	0.74	1.29	2.65	5.06
	R3 (N)	1.03	1.22	2.77	5.07	0.80	1.32	2.47	5.03	0.86	1.35	2.58	5.22
	Mean (N)	0.930	1.437	2.580	5.080	0.757	1.290	2.443	4.703	0.753	1.287	2.507	4.957
SunMed	R1 (N)	2.12	2.37	6.66	14.16	2.20	3.62	6.63	14.79	2.22	3.89	7.27	15.63
	R2 (N)	1.81	3.21	6.84	15.58	2.07	3.43	6.41	15.48	1.98	3.82	7.00	15.32
	R3 (N)	1.89	3.24	6.93	15.26	2.14	3.29	6.02	15.22	2.04	3.49	7.09	14.84
	Mean (N)	1.940	2.940	6.810	15.000	2.137	3.447	6.353	15.163	2.080	3.733	7.120	15.263
Frova	R1 (N)	1.64	2.34	4.26	9.42	1.63	2.15	4.35	10.68	1.73	2.48	4.37	9.14
	R2 (N)	1.54	2.59	4.18	10.86	1.50	2.19	4.54	11.01	1.61	2.62	4.41	10.33
	R3 (N)	1.83	2.41	4.19	10.87	1.64	2.18	4.34	10.39	1.76	2.37	4.33	11.00
	Mean (N)	1.670	2.447	4.210	10.383	1.590	2.173	4.410	10.693	1.700	2.490	4.370	10.157
P3	R1 (N)	1.50	2.76	5.39	10.98	1.78	2.33	5.47	11.79	1.85	2.79	5.06	11.38
	R2 (N)	1.86	2.62	5.88	11.92	1.78	2.49	5.20	11.76	1.91	2.74	5.30	12.29
	R3 (N)	1.82	2.37	5.65	12.04	1.58	2.69	4.90	12.28	1.81	2.88	5.63	12.43
	Mean (N)	1.727	2.583	5.640	11.647	1.713	2.503	5.190	11.943	1.857	2.803	5.330	12.033
Steerable Bougie	R1 (N)	0.68	0.72	0.74	1.14	0.63	0.61	0.76	1.16	0.63	0.85	0.86	1.17
	R2 (N)	0.66	0.65	0.70	1.20	0.67	0.79	0.72	1.21	0.74	0.77	0.86	1.28
	R3 (N)	0.65	0.70	0.73	1.28	0.67	0.71	0.79	1.29	0.67	0.73	0.72	1.17
	Mean (N)	0.663	0.690	0.723	1.207	0.657	0.703	0.757	1.220	0.680	0.783	0.813	1.207

Table 6.63: Tip Pressure Force Study Method Validation (Repeatability Testing – Operator Controlled)

	40cm			30cm			20cm			10cm		
Bougie	DS1 Mean (N)	DS6 Mean (N)	% Change Of Mean	DS1 Mean (N)	DS6 Mean (N)	% Change Of Mean	DS1 Mean (N)	DS6 Mean (N)	% Change Of Mean	DS1 Mean (N)	DS6 Mean (N)	% Change Of Mean
Portex	0.963	1.020	5.88%	1.723	1.880	9.09%	4.600	3.983	-13.41%	6.783	7.073	4.28%
GEB	0.907	0.753	-16.91%	1.460	1.287	-11.87%	2.333	2.507	7.43%	4.973	4.957	-0.34%
SunMed	2.090	2.080	-0.48%	3.360	3.733	11.11%	5.830	7.120	22.13%	14.637	15.263	4.28%
Frova	1.657	1.700	2.62%	2.403	2.490	3.61%	3.763	4.370	16.12%	10.180	10.157	-0.23%
P3	2.050	1.857	-9.43%	3.140	2.803	-10.72%	5.940	5.330	-10.27%	11.533	12.033	4.34%
Steerable Bougie	0.633	0.680	7.37%	0.650	0.783	20.51%	0.780	0.813	4.27%	1.210	1.207	-0.28%

Table 6.64: Percentage Change Of Mean Between Data Sets 1 & 6

Although the variability of the readings collected at some of the distances is quite high, when closer attention is taken upon review of the raw data, it appears that the variability is down to rogue readings within the data sets that cause the mean of an individual data set to appear much higher. This can also be attributed to the small number of readings collected in each data set. When the studies are completed (Section 6.8) using the increased number of participants and equalised randomisation this will provide a significantly greater sample of data. It is expected that the variability exhibited in this validation test will be nullified or become less significant.

6.8 Tip Pressure Study Results & Analysis (Untrained & Trained Users)

The tip pressure study results presented are split into three sections; first a review of the results collated from the untrained user testing is presented (Section 6.8.1), followed by the results and analysis of the trained user testing (Section 6.8.2) and a comparative analysis of the untrained and trained users (Section 6.8.3).

6.8.1 Untrained User Results & Analysis

Utilising the methods described in Section 6.2.5, the results were collated and input into SPSS; the full data collection can be located in Appendix N. The mean tip pressure forces generated by the twenty-four untrained participants were calculated alongside the standard deviation and standard error; a summative table of the results is presented in Table 6.65.

	Mean Peak Tip Pressure Forces Untrained Participants (N) & Distance Held From The Bougie Tip (cm) * SE = Standard Error							
Bougie Type	**10cm**	**SE of Mean**	**20cm**	**SE of Mean**	**30cm**	**SE of Mean**	**40cm**	**SE of Mean**
Frova	8.582	0.389	4.194	0.148	2.337	0.096	1.641	0.097
Eschmann Reusable Gum Elastic Bougie	4.908	0.247	2.007	0.070	1.137	0.041	0.838	0.067
P3 Medical	9.824	0.419	4.826	0.150	2.651	0.130	1.770	0.106
Portex	8.959	0.390	3.488	0.103	1.854	0.047	1.331	0.089
Steerable Bougie	1.575	0.079	0.999	0.045	0.843	0.032	0.679	0.190
SunMed (Coude)	12.015	0.644	6.261	0.285	3.325	0.120	2.303	0.065

Table 6.65: Untrained Users Mean Tip Pressure Forces (N) 10-40cm Distance Held From The Bougie Tip

The results presented in Table 6.65 are displayed in Figure 6.69; upon review it is immediately apparent which of the six bougies reviewed generates the most significant tip pressures (SunMed coude tip) and which generates the least (developed steerable bougie).

Latto et al., (2002) identifies that if the bougie is held near the proximal end, it will not transmit very much force to the distal tip as it will bend easily; the results presented match this finding. The results also confirm Hodzovic, Wilkes and Latto's (2008) findings that the position at which the bougie is held influences the maximum force measured at the tip, although the results collected by the project team are more accurate due to the methods and the testing equipment used. Latto et al., (2002) also suggests that if the bougie is grasped more distally, much more force can be generated at the tip and trauma may occur; again, these findings match the results collected as the tip pressures generated at the 30cm and 40cm distance held locations are significantly lower.

Hodzovic, Wilkes and Latto (2008) identify that holding the bougie at 30cm may cause the least trauma; the results presented suggest that holding the bougie at 30cm or 40cm from the tip of the bougie will generate significantly less tip pressure than compared to the bougie being held at 10cm or 20cm. Hodzovic, Wilkes and Latto (2008) identify that the participants prefer to hold the bougie at 20cm as this makes placement easier and greater equipment control is exhibited. Conversely, Marson et al., 2014 identifies that airway trauma as low as 0.8 and 1.1 N caused airway perforation in a lung model, yet the results collected from untrained users suggests tip pressure forces up to 2N at the 20cm distance can be generated with the gold standard equipment for use (GEB). Single use devices can generate significantly more tip pressure when held at 20cm.

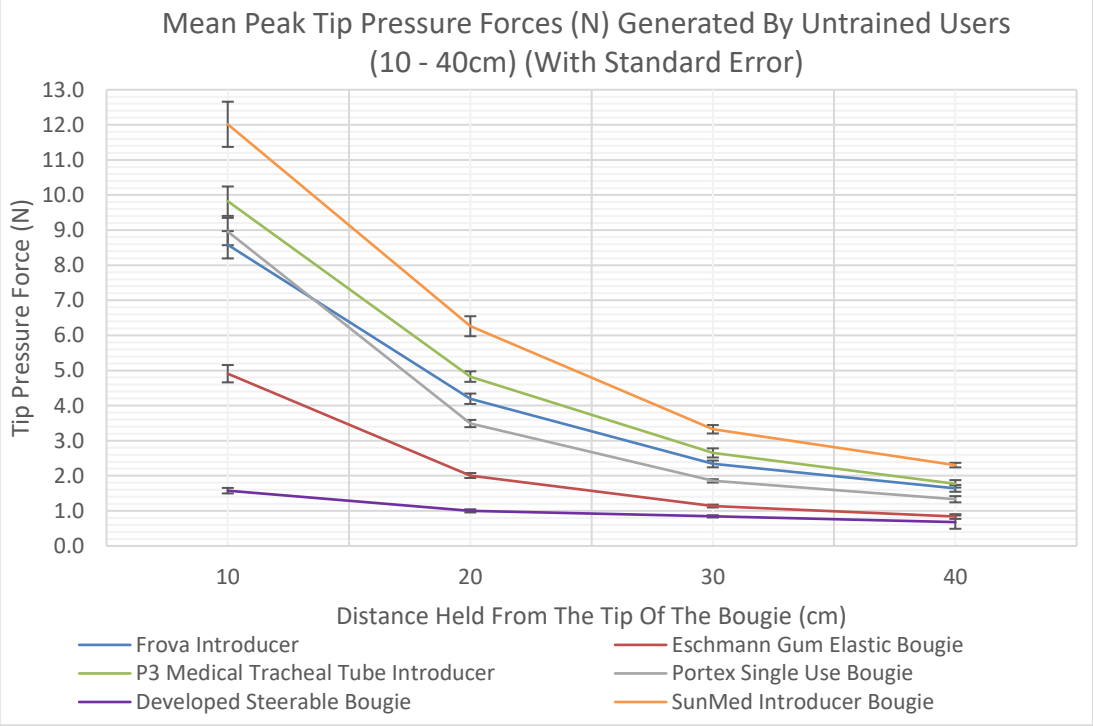


Figure 6.69: Untrained Users Mean Tip Pressure Forces (N) 10-40cm Distance Held From The Bougie Tip

Untrained users (i.e. simulating new medical students), should be trained to hold the bougie as close to the 30cm distance where optimal control can be achieved to ensure that even when a difficult airway occurs, the likelihood that airway trauma can occur is reduced; this reduces the chance that the overzealous use of the bougie can cause trauma.

The results collected also validate the findings by the plethora of literature previously cited, stating the GEB is the gold standard device for use of all the equipment currently available on the market. The SunMed coude tip bougie used at Nottingham University Hospitals Trust (QMC) generates over four times the amount of tip pressure at the recommended 30cm distance than the 0.8N airway trauma values noted by Marson et al., (2014). The Frova introducer (the other single use bougie available for use at QMC) also generates double the amount of tip pressure compared to the GEB at the 30cm distance held location; the GEB also generates 1.13N of pressure as exhibited by untrained users which is also within the airway trauma range.

Significantly, the developed steerable bougie is superior to the GEB at all four distances held when tested by the untrained users. To validate the results collected from the untrained user study, Friedman tests were completed; this tests for differences between groups when the dependent variable being measured is ordinal. The results of the Friedman tests are presented in Table 6.66 and with p-values of <0.0001 this suggests the peak tip pressure forces recorded for each bougie are significantly different to each other.

Figure 6.67 clearly presents the developed steerable bougie with the lowest mean tip pressures; this needs validating to ensure that a large group of data outliers don't skew the results. To compare the steerable bougie against the other five bougies at all four distances held, Wilcoxon signed-rank tests are completed.

The Wilcoxon signed-rank tests are used to compare two sets of scores that come from the same participants or groups; this is suitable for the validation of the results as the Wilcoxon signed-rank test does not assume normality in the data. The results of the Wilcoxon signed-rank tests completed are presented in Table 6.67. The results provide p-values of <0.0001, demonstrating significant results; the only exception is when comparing the steerable bougie against the GEB at the 40cm distance held location; with a p value of <0.020, this is still a significant result.

	Median Peak Tip Pressure Forces (N) [Interquartile Range]			
	Distance Held From The Bougie Tip (cm)			
Bougie	**10**	**20**	**30**	**40**
Frova	8.841 [9.755-7.545]	4.108 [4.482-3.724]	2.306 [2.545-2.183]	1.538 [1.639-1.379]
Eschmann Reusable Gum Elastic Bougie	4.526 [5.635-4.099]	2.025 [2.257-1.770]	1.160 [1.243-0.947]	0.750 [0.872-0.654]
P3 Medical	10.378 [11.333-8.228]	5.006 [5.422-4.187]	2.558 [2.760-2.360]	1.671 [1.819-1.505]
Portex	8.756 [10.358-7.957]	3.556 [3.784-3.057]	1.776 [2.000-1.687]	1.208 [1.305-1.124]
Steerable Bougie	1.471 [1.790-1.370]	0.958 [1.165-0.835]	0.820 [0.948-0.730]	0.666 [0.730-0.615]
SunMed (Coude)	11.880 [14.692-10.262]	6.375 [6.805-5.661]	3.301 [3.789-3.055]	2.255 [2.514-2.118]
Friedman Test p-value	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**

Table 6.66: Friedman Test Results (Untrained Users)

	Wilcoxon Signed Rank Tests: Steerable Bougie vs Commercial Bougies Peak Tip Pressures Compared At Distance Held Locations (cm)			
Bougie	**10**	**20**	**30**	**40**
Steerable Bougie vs Frova	<0.0001	<0.0001	<0.0001	<0.0001
Steerable Bougie vs Eschmann Reusable Gum Elastic Bougie (GEB)	<0.0001	<0.0001	<0.0001	<0.020
Steerable Bougie vs P3 Medical	<0.0001	<0.0001	<0.0001	<0.0001
Steerable Bougie vs Portex	<0.0001	<0.0001	<0.0001	<0.0001
Steerable Bougie vs SunMed (Coude)	<0.0001	<0.0001	<0.0001	<0.0001

Table 6.67: Wilcoxon Signed Rank Test Results (Untrained Users)

Figures 6.70 – 6.73 present box and whisker plots for comparison of the bougies at each of the held distances. The purpose of these charts is to review the distribution and variability of the data collected. The variability in the data, or potential lack of it in some cases, will also indicate how variable the feedback exhibited in the devices is, this in turn may affect a

person's training or use of the device, thus affecting device acceptability and uptake; a difficult to operate bougie could increase the likelihood of airway trauma.

At all four distances held, the steerable bougie presents the least amount of variability; this is closely followed by the GEB. This further reinforces the GEB's superiority over all commercially available devices and most importantly single use devices when operated by an untrained user. The SunMed coude tip bougie presents significant variability in the readings collected and often presents outliers in the data collected. The mid-tier single use devices (Portex, Frova and P3), present a large amount of variability in the readings collected, this variability does reduce as the distance held increases.

Overall, Figures 6.70 – 6.73 present the steerable bougie and GEB's superiority in patient safety, design and usability, as these two devices offer the least variability in tip pressures and the lowest tip pressures; this should equate to reduced levels of airway trauma.

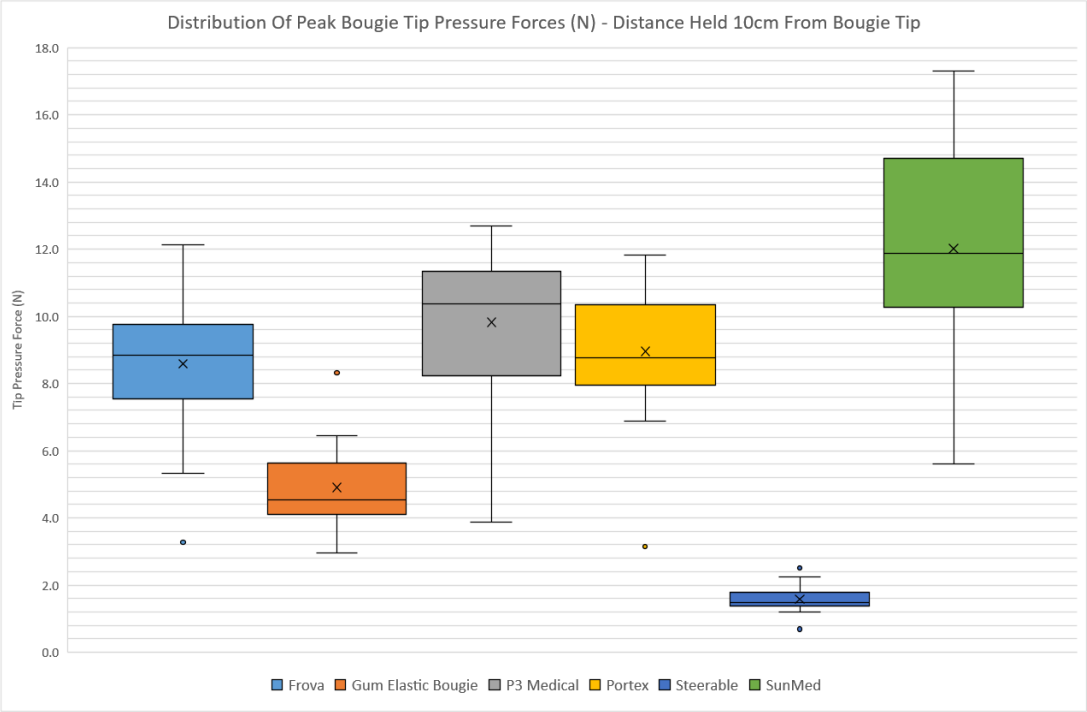


Figure 6.70: Distribution Of Peak Tip Pressure Forces Generated By Untrained Users (Bougie Distance Held: 10cm)

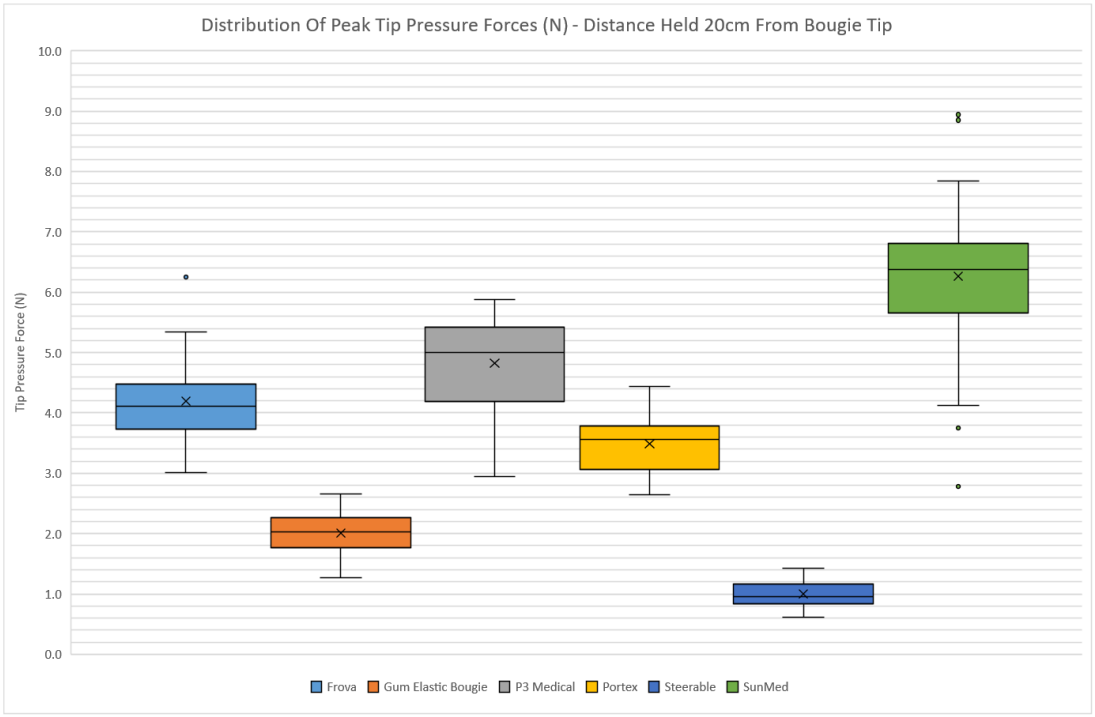


Figure 6.71: Distribution Of Peak Tip Pressure Forces Generated By Untrained Users (Bougie Distance Held: 20cm)

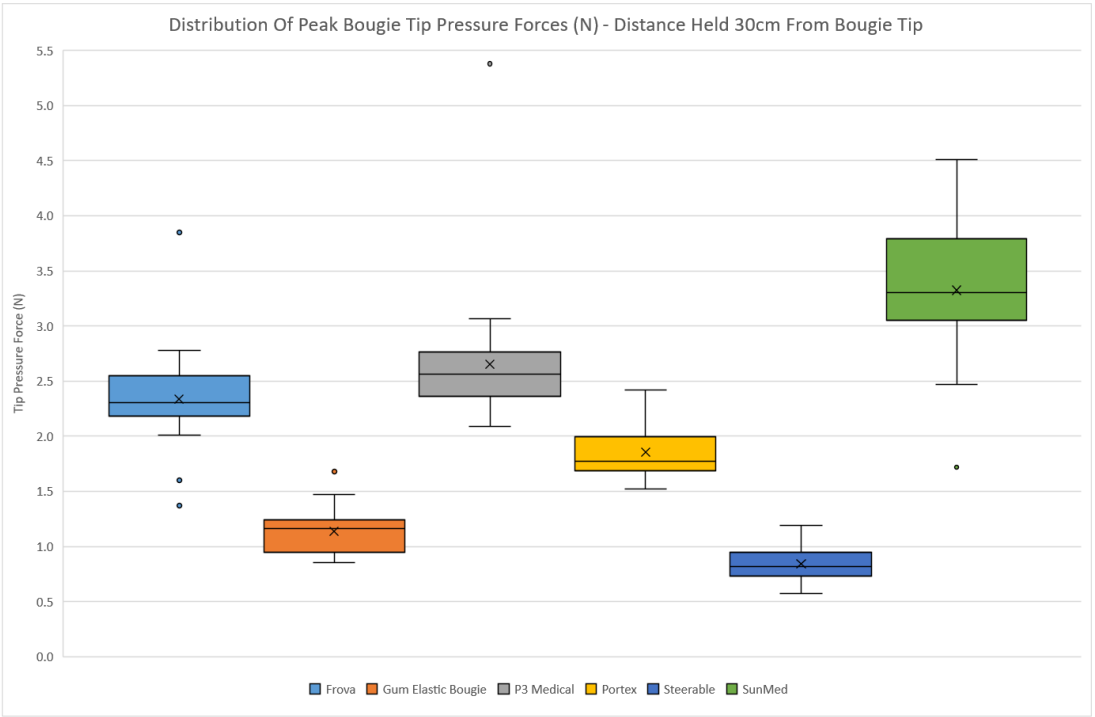


Figure 6.72: Distribution Of Peak Tip Pressure Forces Generated By Untrained Users (Bougie Distance Held: 30cm)

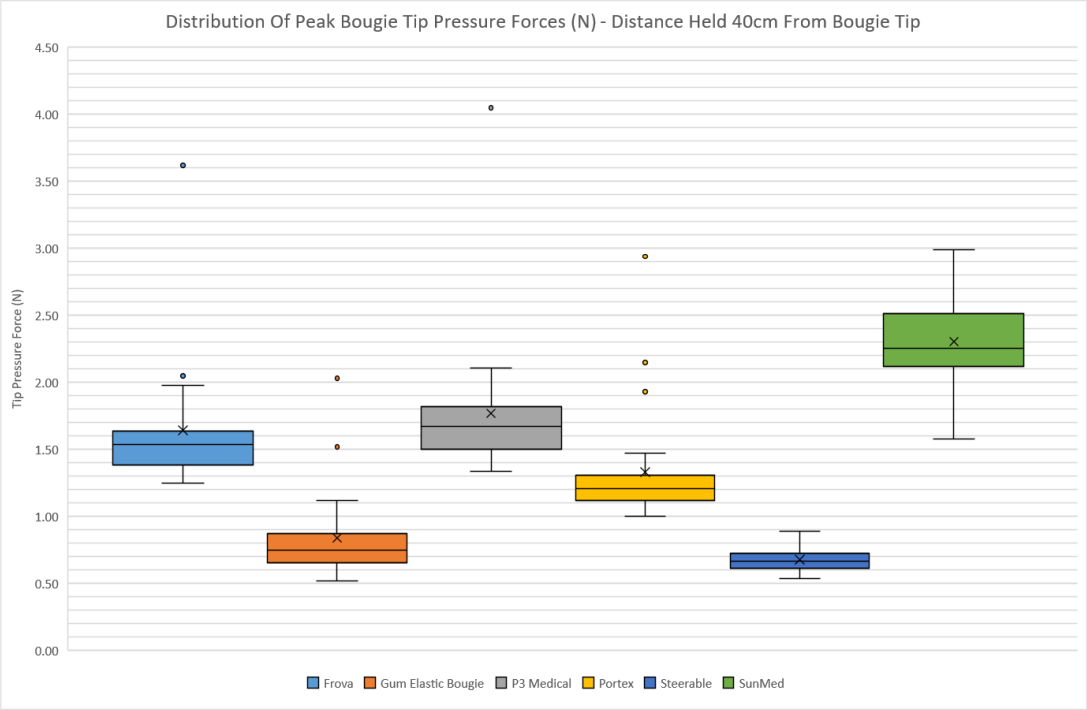


Figure 6.73: Distribution Of Peak Tip Pressure Forces Generated By Untrained Users (Bougie Distance Held: 40cm)

A review of the untrained users grip positions is presented in Tables 6.68, 6.69 and 6.70. The tracheal intubation procedure was described to the participants and no visual demonstration was used. Purposefully no instruction was given to the participants as an appropriate method of holding the bougie to complete the study.

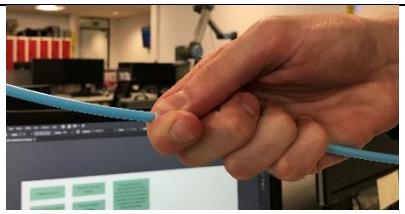
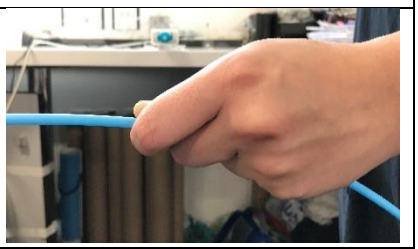
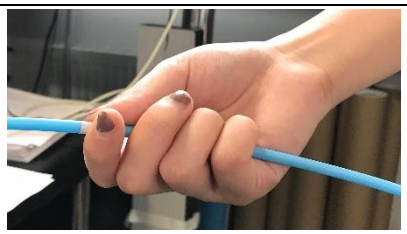
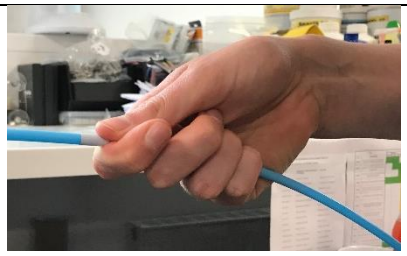
Participant ID	Bougie Grip	Participant ID	Bougie Grip
#1		#4	
#2		#5	
#3		#6	

Table 6.68: Untrained Participant 1 -6 Bougie Grip

Participant ID	Bougie Grip	Participant ID	Bougie Grip
#7		#14	
#8		#15	
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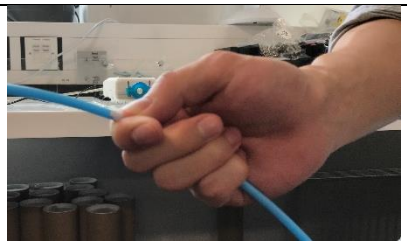
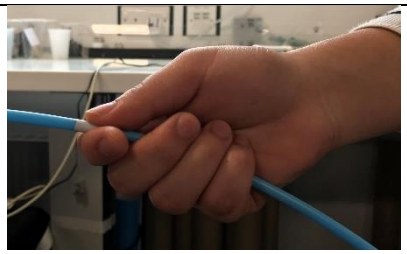
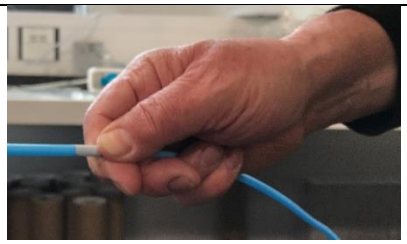
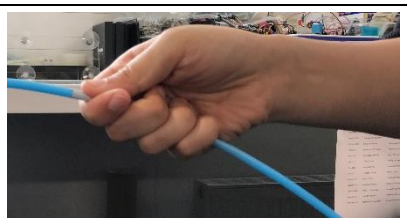
#10		#17	
#11		#18	
#12		#19	
#13		#20	

Table 6.69: Untrained Participant 7 - 20 Bougie Grip

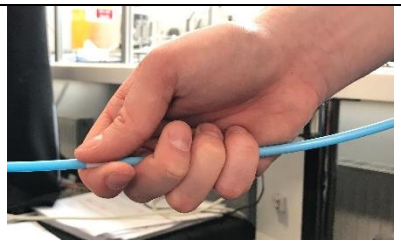
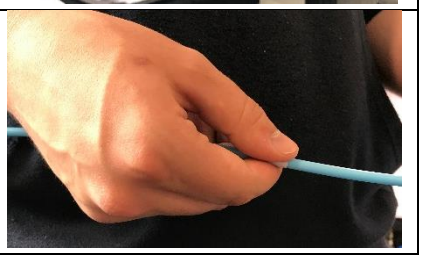
Participant ID	Bougie Grip	Participant ID	Bougie Grip
#21		#23	
#22		#24	

Table 6.70: Untrained Participant 21 -24 Bougie Grip

Only one participant chose to use two hands during the testing (participant 17) and only two participants chose to use their left hand (participant 5 and 15). Interestingly participant 5 noted that they did not use their dominant hand during the testing. Upon reviewing the raw data, surprisingly the participants that used their left hand or both hands were not responsible for any data outliers presented on the box and whisker charts (Figures 6.70 – 6.73). No untrained user naturally used an accepted bougie grip taught in practice for endotracheal intubation; it is hypothesised that the untrained user will present increased mean tip pressures when compared to trained users.

6.8.2 Trained User Results & Analysis

The mean tip pressure forces generated by the twenty-four trained participants were calculated alongside the standard deviation and standard error; a summative table of the results is presented in Table 6.71 and Figure 6.74. The results from the trained users follow the same trend as the untrained user testing, the main difference observed was the use of a different grip position which results in lower mean peak tip pressures. The full data collection can be located in Appendix N.

Of the six bougies reviewed, the SunMed single use bougie again generates the highest tip pressures, whereas the developed steerable bougie presents the lowest tip pressures. As identified for the untrained user results, Hodzovic, Wilkes and Latto (2008) suggest that holding the bougie at 30cm may cause less trauma; the results presented again suggest that holding the bougie at 30cm or 40cm from the tip of the bougie will generate significantly less tip pressure than compared to the bougie being held at 10cm or 20cm. With optimum control

established to be closer to 20cm (Hodzovic, Wilkes and Latto, 2008) tip pressure forces increase with the majority exceeding the 0.8N trauma value identified by Marson et al., (2014), the only exception being the developed steerable bougie.

	Mean Peak Tip Pressure Forces Trained Participants (N) & Distance Held From The Bougie Tip (cm) * SE = Standard Error							
Bougie Type	**10**	**SE of Mean**	**20**	**SE of Mean**	**30**	**SE of Mean**	**40**	**SE of Mean**
Frova	7.513	0.370	3.393	0.164	1.911	0.073	1.309	0.035
Eschmann Reusable Gum Elastic Bougie	4.285	0.288	1.800	0.153	0.974	0.057	0.650	0.032
P3 Medical	8.398	0.465	3.955	0.155	2.256	0.090	1.533	0.078
Portex	7.662	0.385	3.233	0.175	1.664	0.061	1.108	0.041
Steerable Bougie	1.329	0.051	0.756	0.031	0.615	0.029	0.582	0.035
SunMed (Coude)	10.425	0.509	4.880	0.207	2.731	0.090	1.852	0.048

Table 6.71: Trained Users Mean Peak Tip Pressure Forces (N) 10-40cm Distance Held From The Bougie Tip

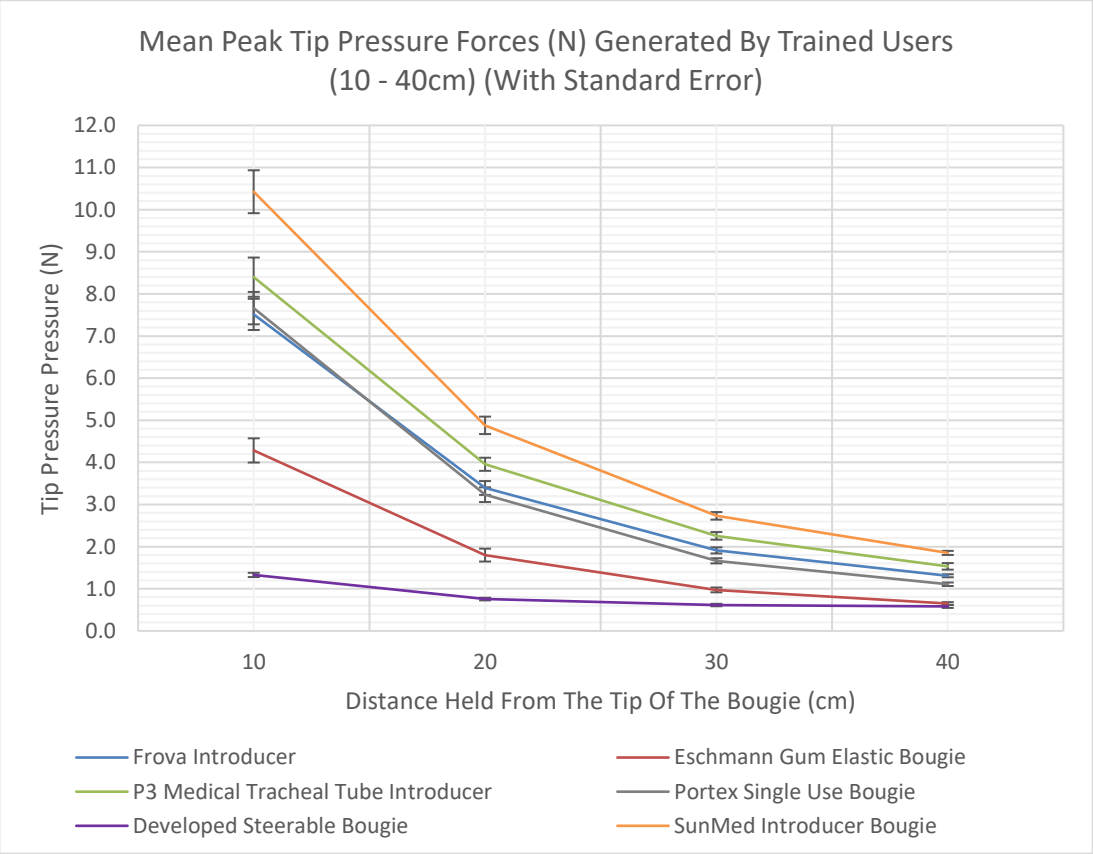


Figure 6.74: Trained Users Mean Peak Tip Pressure Forces (N) 10-40cm Distance Held From The Bougie Tip

To validate the results collected from the trained user study, Friedman tests are completed; the results are presented in Table 6.72 and with p-values of <0.0001 this suggests the peak tip pressure forces results collected are significantly different to each other.

	Median Peak Tip Pressure Forces (N) [Interquartile Range]			
	Distance Held From The Bougie Tip (cm)			
Bougie	**10**	**20**	**30**	**40**
Frova	7.585 [8.905-6.087]	3.220 [3.963-2.980]	1.808 [2.189-1.660]	1.266 [1.509-1.203]
Eschmann Reusable Gum Elastic Bougie	4.190 [4.896-3.403]	1.615 [2.016-1.395]	0.953 [1.098-0.737]	0.608 [0.788-0.513]
P3 Medical	8.851 [9.756-6.939]	3.955 [4.688-3.420]	2.113 [2.440-1.992]	1.461 [1.672-1.366]
Portex	7.760 [8.844-6.084]	3.080 [3.468-2.835]	1.606 [1.737-1.484]	1.088 [1.197-0.957]
Steerable Bougie	1.335 [1.542-1.129]	0.753 [0.849-0.653]	0.603 [0.683-0.494]	0.565 [0.657-0.460]
SunMed (Coude)	10.155 [12.700-8.974]	4.700 [5.311-4.367]	2.685 [3.021-2.422]	1.915 [2.005-1.674]
Friedman Test p-value	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**

Table 6.72: Friedman Test Results (Trained Users)

Figure 6.74 presents the developed steerable bougie with the lowest mean tip pressures; these need validating to ensure that a large group of data outliers don't skew the results. To compare the steerable bougie against the other five bougies at all the four distances held, Wilcoxon signed-rank tests are completed. The results of the Wilcoxon signed-rank tests are presented in Table 6.73. The results provide p-values of <0.0001, demonstrating significant results and identifying significant differences between the peak forces recorded. One exception to this is the Wilcoxon signed-rank test comparing the steerable bougie against the GEB at the 40cm distance held location; with a p-value of <0.081 this is deemed not significant. visually there is a clear difference in the results collected indicating the steerable bougies superiority at this distance too.

	Wilcoxon Signed Rank Tests (p-values): Steerable Bougie vs. Commercial Bougies Tip Pressures Compared At Distance Held Locations (cm)			
Bougie	**10cm**	**20cm**	**30cm**	**40cm**
Steerable Bougie vs. Frova	<0.0001	<0.0001	<0.0001	<0.0001
Steerable Bougie vs. Eschmann Reusable Gum Elastic Bougie (GEB)	<0.0001	<0.0001	<0.0001	<0.081
Steerable Bougie vs. P3 Medical	<0.0001	<0.0001	<0.0001	<0.0001
Steerable Bougie vs. Portex	<0.0001	<0.0001	<0.0001	<0.0001
Steerable Bougie vs. SunMed (Coude)	<0.0001	<0.0001	<0.0001	<0.0001

Table 6.73: Wilcoxon Signed Rank Test Results (Trained Users)

Similar to the untrained user testing, the collected results also validate the findings of the plethora of literature previously cited, that the GEB is the gold standard device for use of all the equipment currently available on the market. The results for the trained users when testing the SunMed coude tip bougie also follows the same trend as untrained user testing but with slightly reduced tip pressures due to the grip position used. The SunMed bougie still generates over four times the amount of tip pressure at the 30cm distance than the 0.8N airway trauma values noted by Marson et al., (2014).

The Frova introducer (the other single use bougie available for use at QMC) also generates double the amount of tip pressure compared to the GEB at the 30cm distance held location. Overall, the results highlight the gum elastic bougies superiority of the commercially available bougies and validate the concerns highlighted in published research that suggests single use bougies still require improvement before replacing the gum elastic bougie in practice.

Figures 6.75 – 6.78 present box and whisker plots for comparison of the bougies at each of the held distances. At all four distances held, the steerable bougie presents the least amount of variability; this is closely followed by the GEB. This further reinforces the GEB's superiority over all commercially available devices and most importantly single use devices. Like the untrained user results, the SunMed coude tip bougie presents significant variability in the readings collected; this is common in single use devices with the Portex and P3 bougie also presenting large variability.

Overall, Figures 6.75– 6.78 present the steerable bougie and GEB's superiority in patient safety, design and usability, as these two devices offer the least variability in tip pressures and the lowest peak tip pressures. One factor that does need to be considered for these two

bougies is their rigidity and ability to hold their shape especially when a Grade 3 Cormack and Lehane laryngoscopic view is presented where more control over the bougie is required to navigate within a limited area.

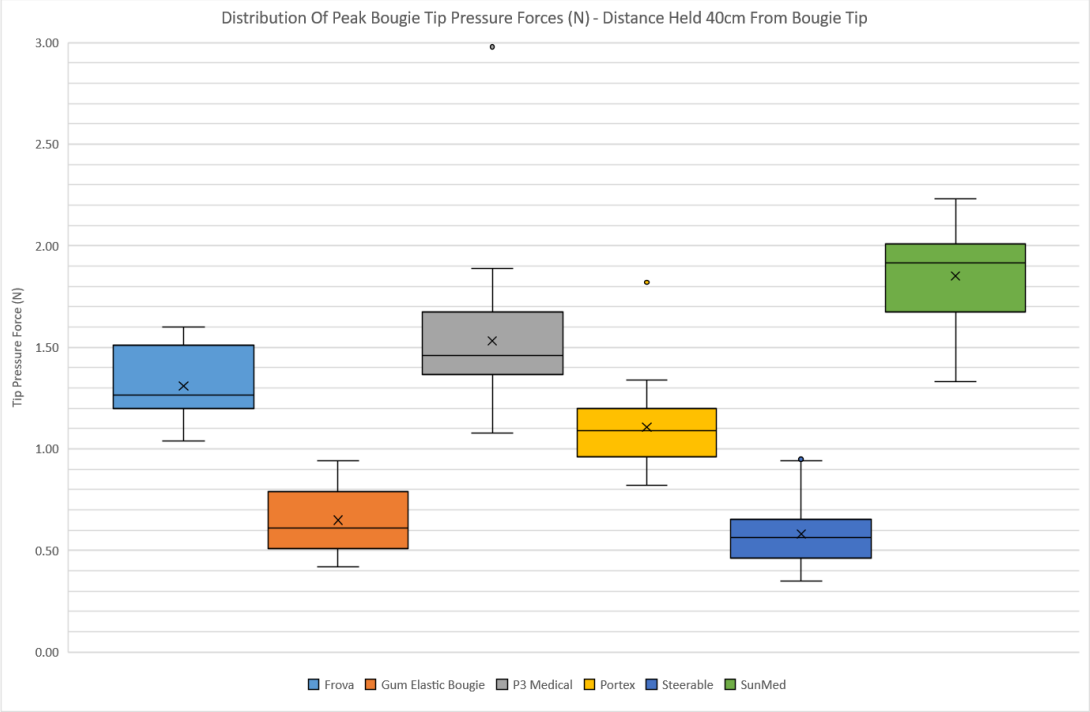


Figure 6.75: Distribution Of Peak Tip Pressure Forces Generated By Trained Users (Bougie Distance Held: 40cm)

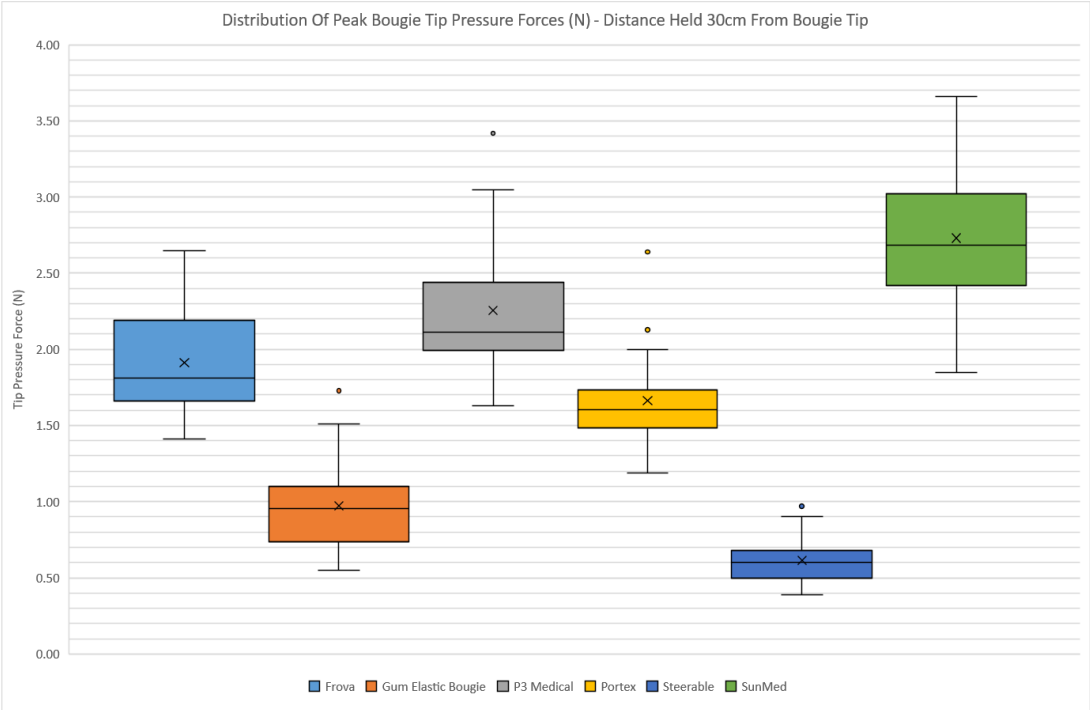


Figure 6.76: Distribution Of Peak Tip Pressure Forces Generated By Trained Users (Bougie Distance Held: 30cm)

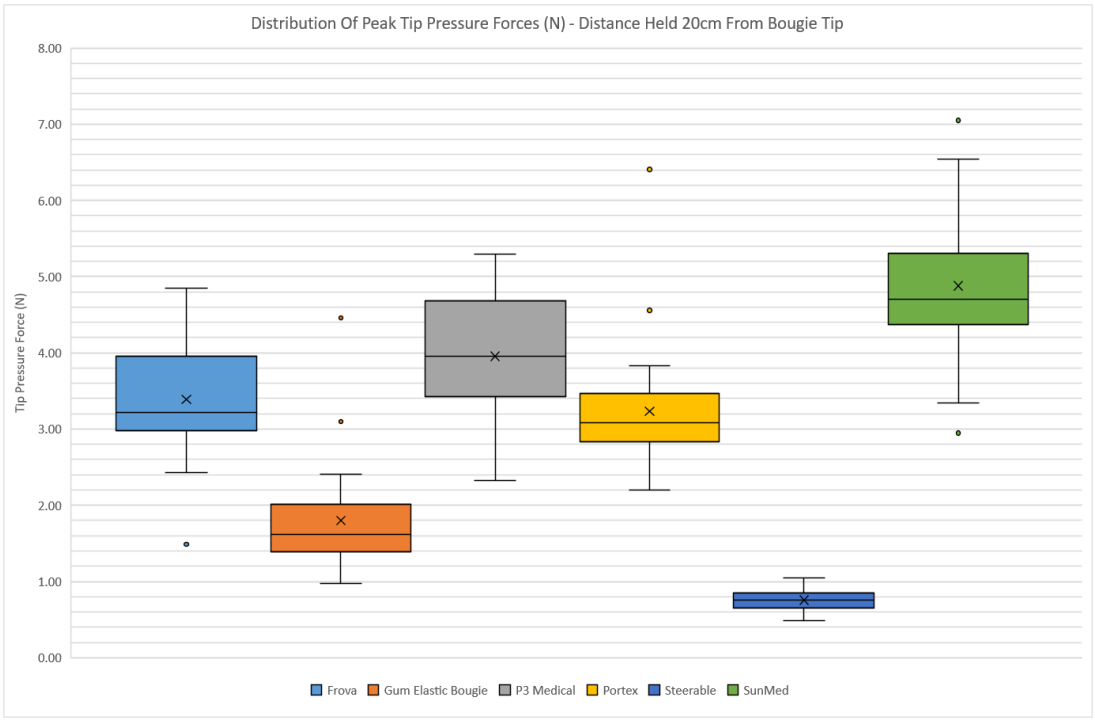


Figure 6.77: Distribution Of Peak Tip Pressure Forces Generated By Trained Users (Bougie Distance Held: 20cm)

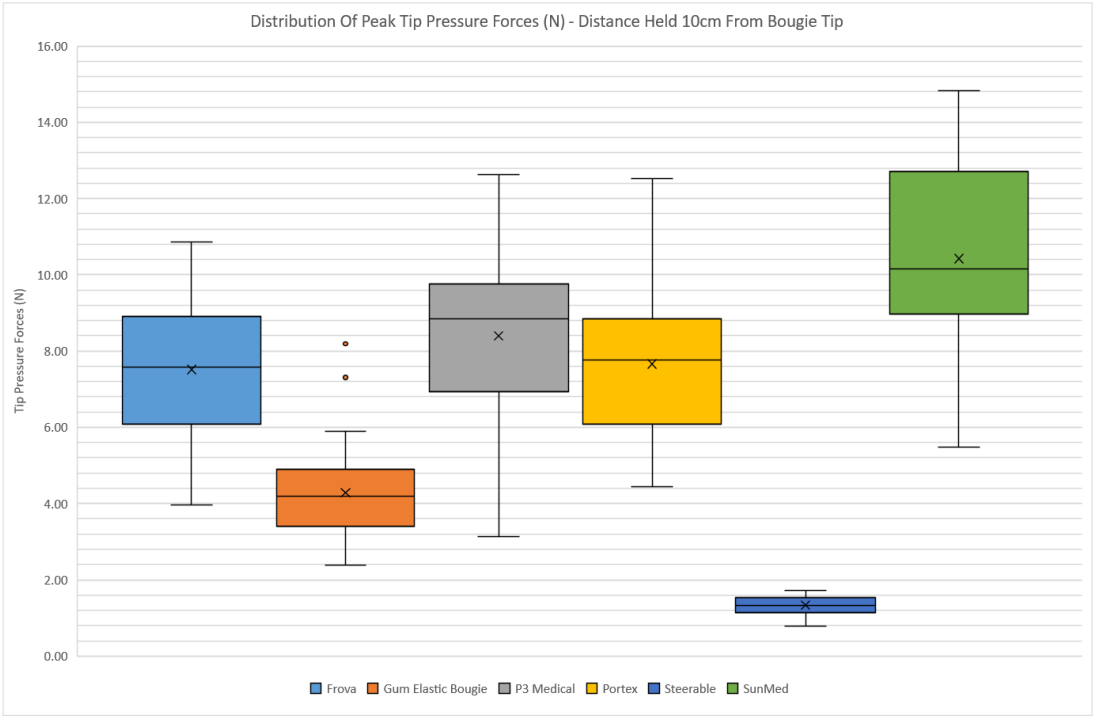
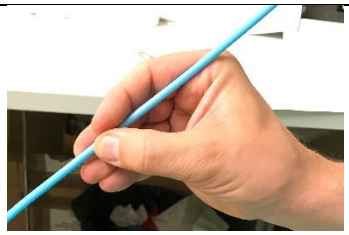


Figure 6.78: Distribution Of Peak Tip Pressure Forces Generated By Trained Users (Bougie Distance Held: 10cm)

A review of the trained users bougie grip position is presented in Tables 6.74 and 6.75. Immediately it is obvious that the grip positions used by the trained users are different to the untrained users with a pen like grip position adopted. Although this may be less stable than the untrained user grip position adopted, this offers greater control; it is also hypothesised that this is the reason why the tip pressures exhibited are lower.

Participant ID	Bougie Grip	Participant ID	Bougie Grip
#1		#7	
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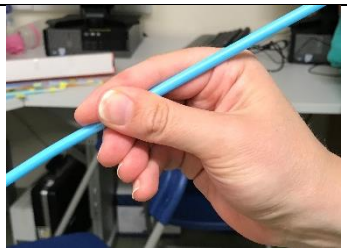
#4		#10	
#5		#11	
#6		#12	

Table 6.74: Trained Participant 1 -12 Bougie Grip

Participant ID	Bougie Grip Position	Participant ID	Bougie Grip Position
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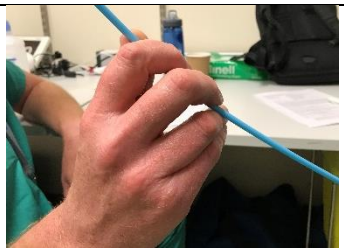
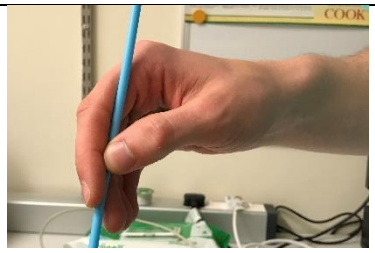
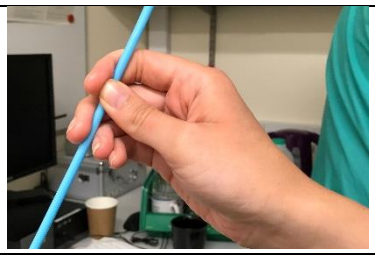
#14		#20	
#15		#21	
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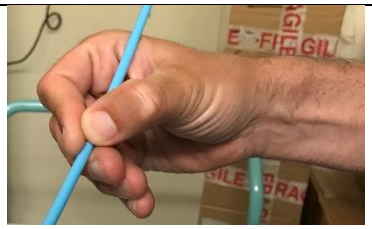
#17		#23	
#18		#24	

Table 6.75: Trained Participant 13 -24 Bougie Grip

6.8.3 Comparative Analysis Of Trained & Untrained Users - Tip Pressure Study

The results collected in Sections 6.8.1 and 6.8.2 have been collated; Table 6.76 and Figures 6.79 - 6.82 present the results. At all four distances held, trained users present lower mean peak tip pressure forces (reduction range of 8-37%). The steerable bougie consistently

displays lower tip pressure forces at all four distances held when compared to the commercially available bougies.

Excluding the steerable bougie, of the current bougies commercially available, the gum elastic bougie displays the lowest tip pressures; single use bougies display significantly higher tip pressures. Rigid bougies perceived to be more easily shaped and in some cases display increased shape retention characteristics present the highest tip pressures, increasing the likelihood of airway trauma. This data reinforces the research conclusions presented by Hodzovic et al., (2004) and Janakiraman et al., (2009), however, the data collected is more accurate due to the data acquisition equipment used.

Bougie	Distance Held From Bougie Tip (cm)	Untrained Mean Peak Tip Pressure Force (N)	Trained Mean Peak Tip Pressure Force (N)	Mean Peak Tip Pressure Force (N) Difference	% Peak Tip Pressure Force Difference
Frova	10	8.882	7.513	1.369	18%
	20	4.194	3.393	0.801	24%
	30	2.337	1.911	0.426	22%
	40	1.641	1.309	0.332	25%
Reusable Gum Elastic Bougie	10	4.908	4.285	0.623	15%
	20	2.007	1.800	0.207	12%
	30	1.137	0.974	0.163	17%
	40	0.838	0.650	0.188	29%
P3 Medical	10	9.824	8.398	1.426	17%
	20	4.826	3.955	0.871	22%
	30	2.651	2.256	0.395	18%
	40	1.770	1.533	0.237	15%
Portex	10	8.959	7.662	1.297	17%
	20	3.488	3.233	0.255	8%
	30	1.854	1.664	0.190	11%
	40	1.331	1.108	0.223	20%
Developed Steerable Bougie	10	1.575	1.329	0.246	19%
	20	0.999	0.756	0.243	32%
	30	0.843	0.615	0.228	37%
	40	0.679	0.582	0.097	17%
SunMed Introducer Bougie (Coude Tip)	10	12.015	10.425	1.590	15%
	20	6.261	4.880	1.381	28%
	30	3.325	2.731	0.594	22%
	40	2.303	1.852	0.451	24%

Table 6.76: Comparing Untrained and Trained Users Mean Peak Tip Pressure For Bougies and Grip Position Location

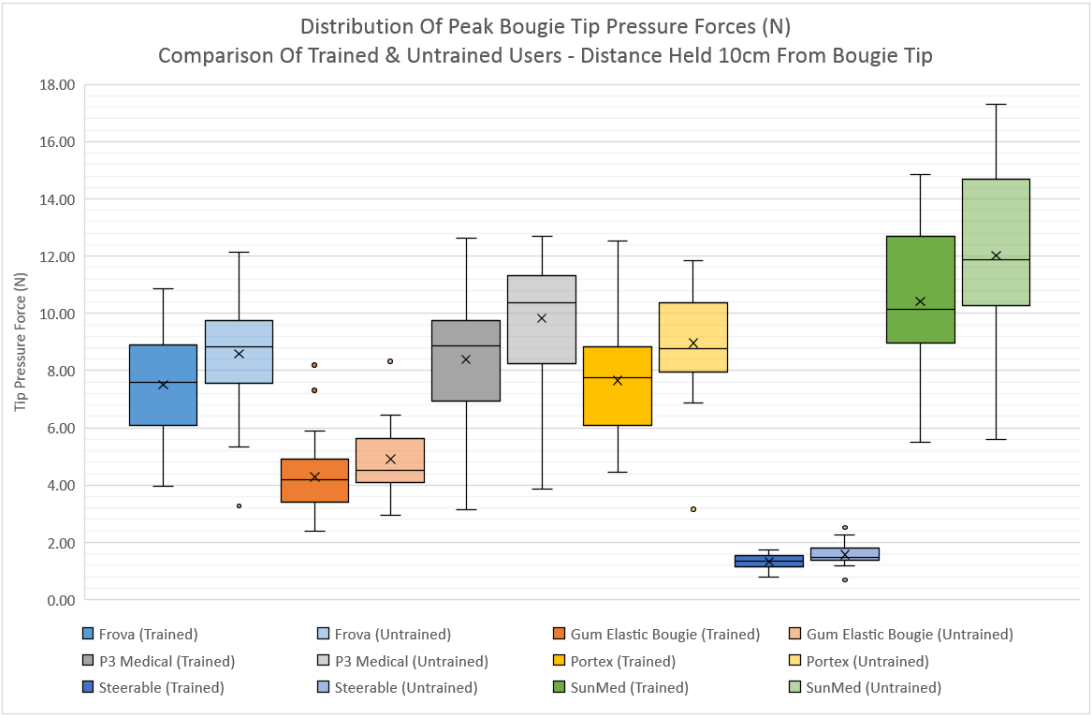


Figure 6.79: Comparison Of Trained & Untrained Users Peak Tip Pressure Forces Generated (Bougie Distance Held: 10cm)

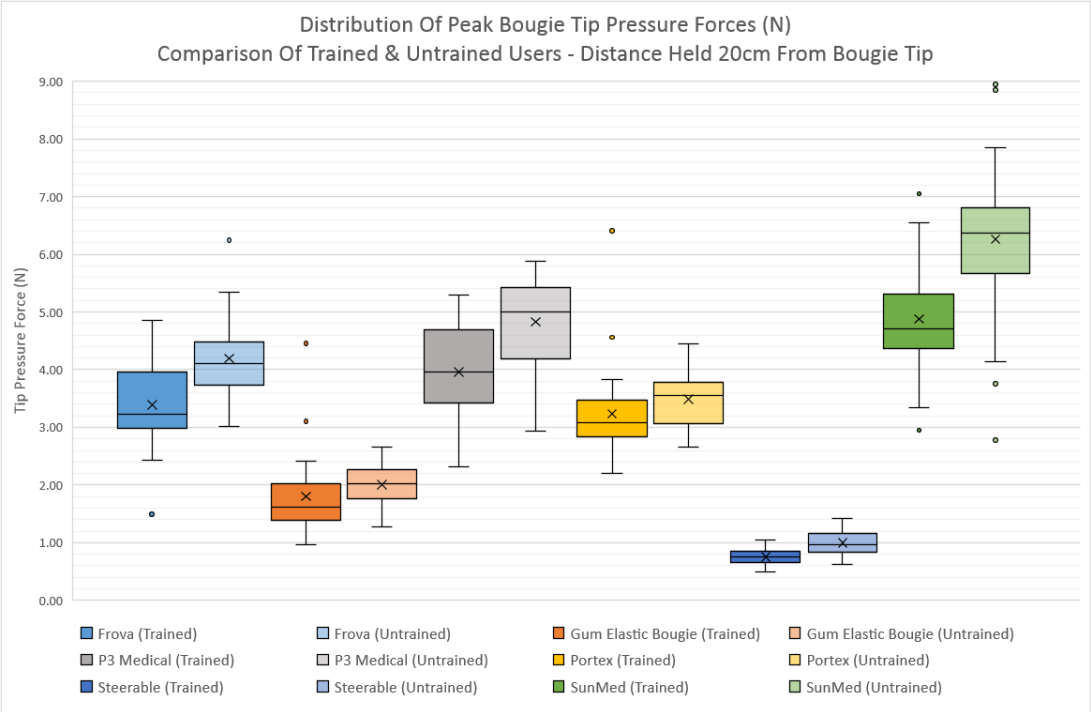


Figure 6.80: Comparison Of Trained & Untrained Users Peak Tip Pressure Forces Generated (Bougie Distance Held: 20cm)

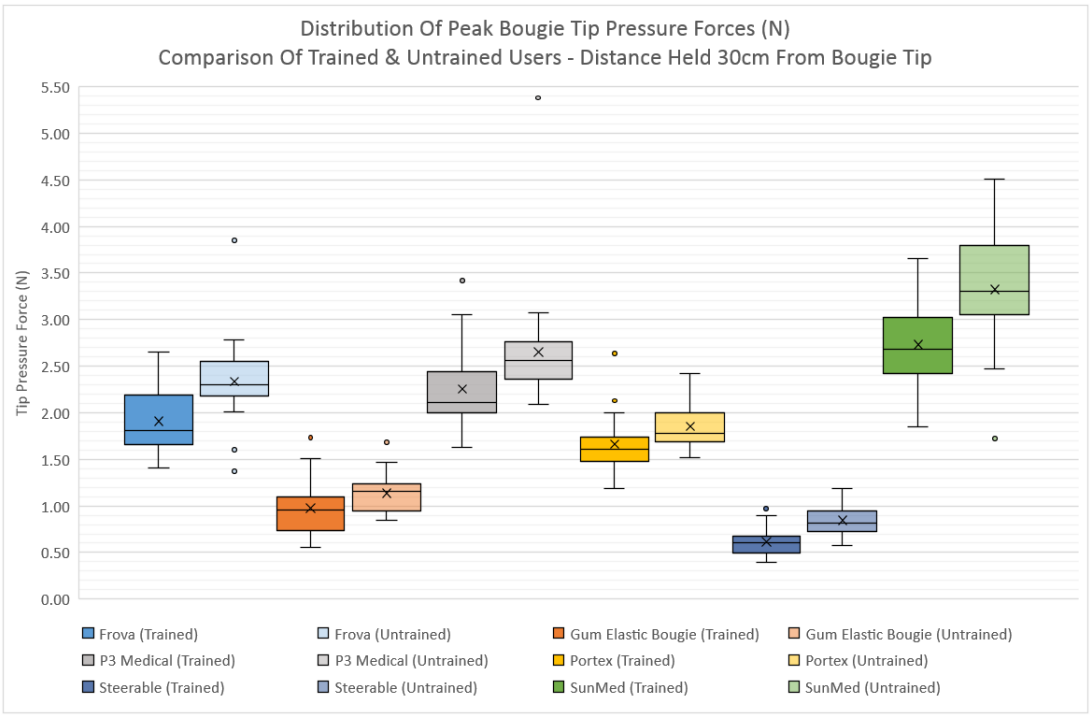


Figure 6.81: Comparison Of Trained & Untrained Users Peak Tip Pressure Forces Generated (Bougie Distance Held: 30cm)

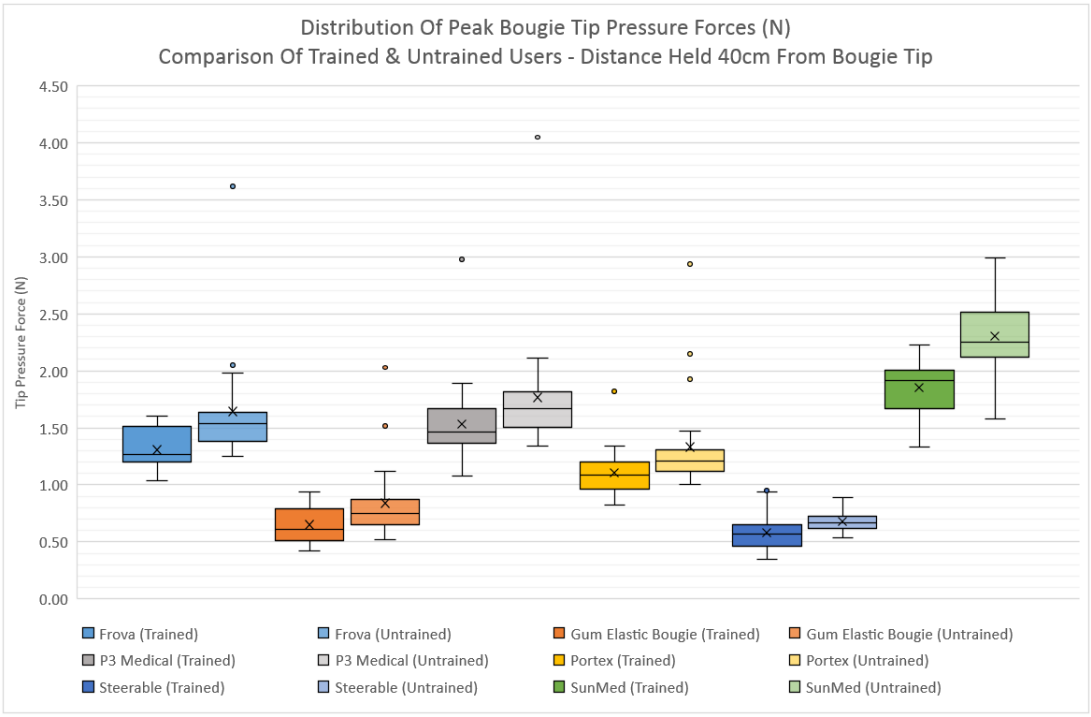


Figure 6.82: Comparison Of Trained & Untrained Users Peak Tip Pressure Forces Generated (Bougie Distance Held: 40cm)

Friedman tests were conducted for each bougie at all four grip positions to assess whether there was a significant difference between the variability of tip pressure feedback presented regardless of the grip position used. The results presented in Table 6.77 indicates that the grip position from the trained and untrained users does affect the level of variability of the

tip pressure results collected; significant p-value results are presented in most scenarios. The results from the Friedman tests demonstrate that the steerable bougie is no worse or no better than the commercial bougies available when considering the grip position; the materials in combination with the type of grip position used clearly have an effect on the performance of the bougies.

	Friedman Test (p-value): Trained vs Untrained Average Peak Tip Pressure Compared At Distance Held Locations (cm)			
Bougie	**10**	**20**	**30**	**40**
Frova	<0.004	<0.0001	<0.014	<0.014
Re-Usable Gum Elastic Bougie	<0.102	<0.0001	<0.004	<0.102
P3 Medical	<0.041	<0.0001	<0.004	<0.014
Portex	<0.041	<0.0001	<0.014	<0.014
Steerable Bougie	<0.014	<0.0001	<0.004	<0.041
SunMed (Coude Tip)	<0.102	<0.0001	<0.014	<0.0001

Table 6.77: Friedman Test Comparing Untrained and Trained Users Peak Tip Pressure For Bougies and Grip Position Location

Based on the results presented in Section 6.8.3, the steerable bougie consistently presents lower tip pressures at all four distances held, independent of the level of skill of the user or the type of grip position used; this further reinforces the success of the design development processes undertaken and reported in Chapter 4, 5 and 6. The reusable gum elastic bougie is the optimum bougie for use of the commercially available bougies assessed when considering peak tip pressures exhibited.

Single use bougies present significantly higher mean peak tip pressures. The use of the SunMed single use coude tip bougie is rather concerning, with mean peak tip pressures recorded over four times the recorded airway trauma values presented by Marson et al., (2014) when held at the 20-30cm grip locations. When considering mean peak tip pressures, single use bougies increase the likelihood of airway trauma; this reinforces the concerns highlighted by Hodzovic et al., (2004), Marson et al., (2014), Mushambi et al (2016) amongst other documented reports within the literature. Finally, training on the correct use and grip position of bougie introducers clearly has a significant impact; untrained users who hold a bougie in a non-traditional yet more secure grip present increased peak tip pressure forces ranging from 8-37% increases across the assessed bougies and distance held locations. A less stable grip utilised by the trained operators reduces bougie tip pressures, however, this does result in a bigger range of readings collected for the stiffer single use bougies.

6.9 Tip Pressure Study Survey Results & Analysis (Trained Users)

Twenty-four anaesthetists were recruited for the trained user study (including twelve consultants, two basic (1-2) grades, three intermediate (ST 3-4) grades, four higher (ST 5-7) grades, two associate specialists and one senior fellow, all of whom completed the survey; all participants had a minimum of one year's use of a bougie in practice. The participants using a blank unmarked bougie were asked to hold the bougie where they would commonly hold this in practice; the results are presented in Figure 6.83. The findings are similar to the distance held survey results presented by Hodzovic et al., (2004) where 68% of participants identified that they would hold the bougie in the region of 20-30cm; however, this focused on the distance held when a Grade 3 Cormack and Lehane laryngoscopic view is presented.

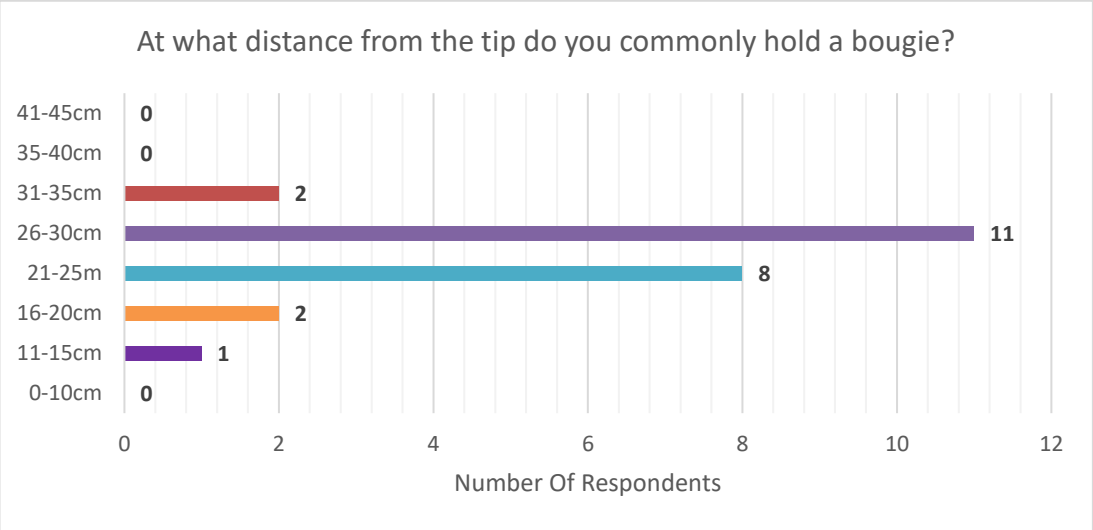


Figure 6.83: Distance Held Survey Results

Most of the participants (23/24) identified that they currently use the single SunMed Introducer Bougie 15FR 70cm (Coude Tip) during daily practice; the sole participant who uses the gum elastic bougie stated they were from another hospital within Nottingham University Hospital Trust (City Hospital) where an alternative bougie is used. The majority of the surveyed participants stated they were happy with the current choice of bougie (20/24). Single use bougies are not the recommended gold standard device for use (Hodzovic et al., 2004; Marson et al 2014; Mushambi et al., 2016). Braude et al., (2009) demonstrates that some single use bougies, including the SunMed provide higher success rates and intubation speeds in simulated difficult airways. Conversely, the tip pressure study results suggest the SunMed is the worst bougie for increased tip pressures, increasing the likelihood of trauma.

The participants were then presented with a sample of ten different bougies sourced from different suppliers and manufacturers within the UK; the participant was given the opportunity to assess these. Only four participants (17%) stated they would still choose to use the SunMed bougie as their preferred bougie for use after assessment. The most popular selection was the gum elastic bougie (8/24, 34%) with all but the P3 medical bougie selected at least once (Figure 6.84).

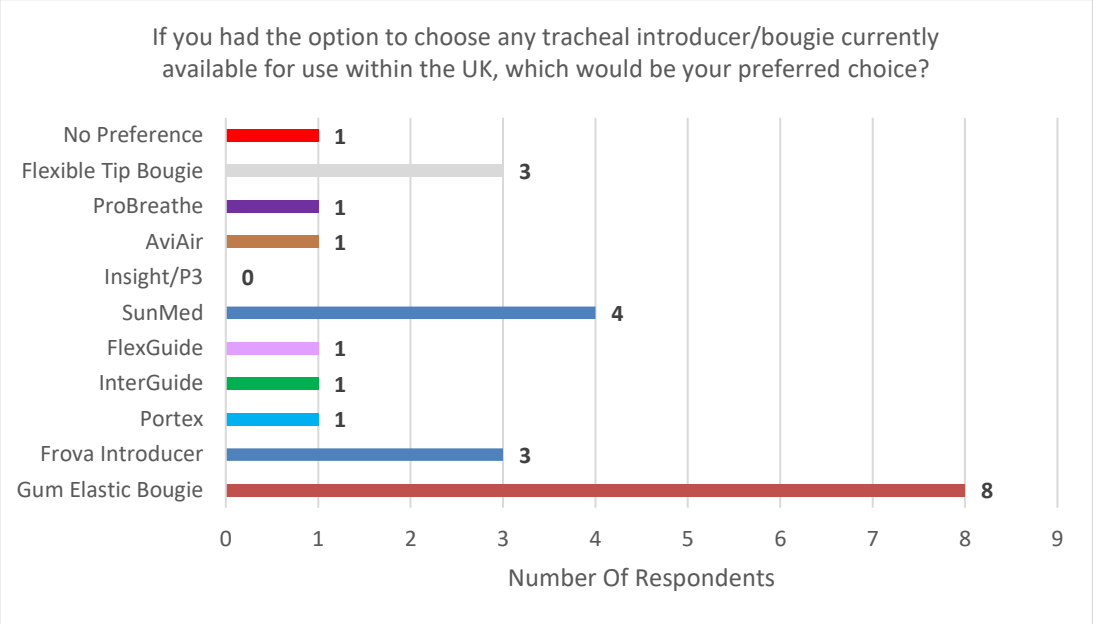


Figure 6.84: Distance Held Survey Results

Participants were asked to identify any additional features they would like to see introduced into a new bougie (Figure 6.85). The results are similar to those presented in Chapter 4 in a survey conducted two years earlier. This demonstrates that there is still a demand for a bougie with increased shape retention capabilities with steerable functionality.

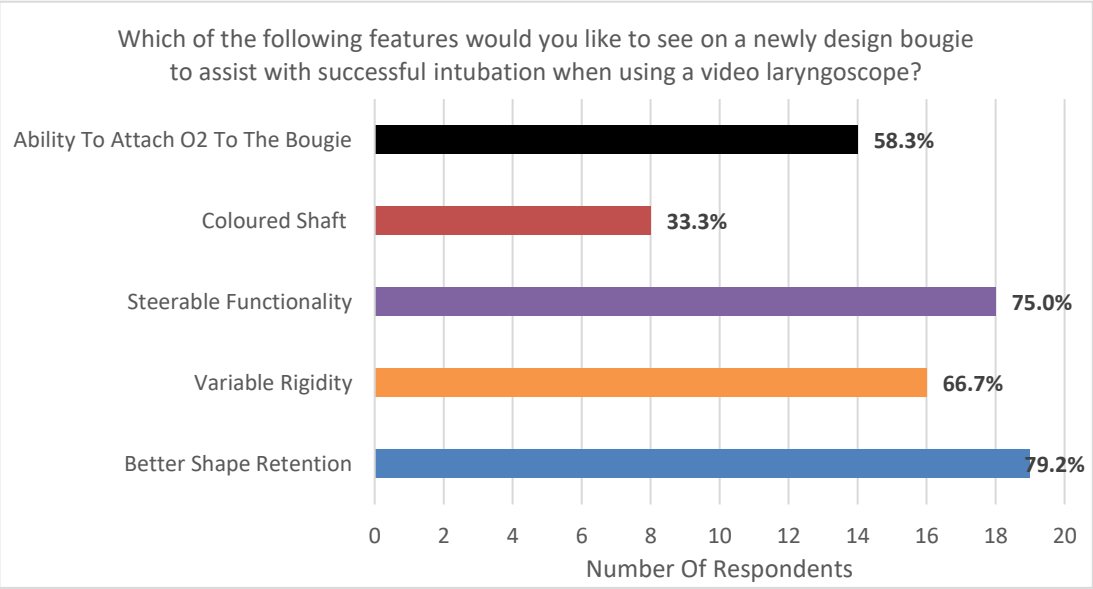


Figure 6.85: Identified Desirable Features In A New Bougie

Bougie aesthetics were also considered with participants asked to identify a colour choice as this could help increase the visibility during use; there was no consensus on an appropriate colour with a larger proportion of participants having no preference (Table 6.78).

Preferred Colour Of Bougie		
Bougie Colour	**Responses**	**Percentage (%)**
Red	1	4.17
Orange	0	0.00
Yellow	3	12.50
Green	1	4.17
Brown	0	0.00
Light Blue	6	25.00
Dark Blue	3	12.50
Pink	1	4.17
Purple	0	0.00
Black	1	4.17
No Preference	8	33.33
Total Number Of Respondents	**24**	**100**

Table 6.78: Preferred Colour Of A Bougie

Finally, the participants were asked whether they would use a bougie with a colour-coded shaft to guide them on depth of insertion; research conducted on the development of a traffic light bougie (Paul et al., 2014), looked at implementing this type of solution on a single use bougie. The majority of the respondents (19/24) identified that they would use a bougie of this construction; those who stated they would not, identified concerns similar to Campbell (2014). Concern was also raised in relation to the variance in patient airway dimensions, especially patients who are obese.

6.10 Porcine Airway Perforation Testing Results

The results from the airway perforation testing are presented in Table 6.79. Initially it was intended that six readings would be collected for each of the bougies tested. Many of the bougies failed to fully perforate the tracheal wall and many of the readings collected reached the maximum 20N force gauge limit without presenting any perforations. Mucosa damage of a varying degree was noted and bougie construction failure also occurred on numerous occasions, whether this be main shaft failure or mechanism damage.

Bougie	Reading Number	Perforation (Y/N)	Perforation Force (N)	Notes/Observations
SunMed Introducer Bougie 15FR 70cm (Coude Tip) (Single Use)	R1	Y	17.91	N/A
	R2	Y	15.25	N/A
	R3	Y	16.62	N/A
	R4	Y	15.54	N/A
	R5	Y	16.88	N/A
	R6	Y	9.56	Trachea appeared smaller with a thinner wall thickness.
SunMed Introducer Bougie 15FR 70cm (Straight Tip) (Single Use)	R1	N	N/A	20N pressure, no perforation, significant mucosa damage presented.
	R2	N	N/A	
	R3	Y	18.62	N/A
	R4	N	N/A	20N pressure, no perforation, significant mucosa damage presented.
	R5	N	N/A	
	R6	N	N/A	
Eschmann Reusable Gum Elastic Bougie 15CH 60cm (Coude Tip) (Multiple Use)	R1	N	N/A	20N pressure applied, no perforation, mucosa damage presented. Significant bending occurred at 30cm grip location.
	R2	N	N/A	
	R3	N	N/A	
	R4	N	N/A	20N pressure applied, no perforation, mucosa damage presented. Cracking at coude tip angle presented.
	R5	No further readings taken due to the alteration of the bougies physical construction/characteristics.		
	R6			
Frova Introducer 14FR 70cm (Coude Tip) (Single Use)	R1	N	N/A	20N pressure applied, no perforation, mucosa damage presented. Frova presented considerable damage (cracking and bending) at grip location making bougie unusable.
	R2	No further readings taken due to bougie failure.		
	R3			
	R4			
	R5			
	R6			

Bougie	Reading Number	Perforation (Y/N)	Perforation Force (N)	Notes
Construct Medical Flexible Tip Bougie (Single Use)	R1	N	N/A	20N pressure applied, no perforation, however significant mucosa damage presented.
	R2	N	N/A	
	R3	No further readings could be taken due to bougie mechanism failure.		
	R4			
	R5			
	R6			
Portex Single Use Bougie 15FR 70cm (Coude Tip)	R1	N	N/A	20N pressure applied, no perforation, mucosa damage presented.
	R2	N	N/A	
	R3	N	N/A	
	R4	No further readings taken due to non-perforation.		
	R5			
	R6			
Developed Steerable Bougie 70cm 5mm Diameter (Straight Tip) (Single Use)	R1	N	N/A	Maximum force able to be generated was 10.68N, the bougie kinked and curled back on itself resulting in reduced tip pressures. No mucosa damage was presented.
	R2	N	N/A	Maximum force able to be generated was 11.80N, the bougie kinked and curled back on itself resulting in reduced tip pressures. No mucosa damage was presented.
	R3	N	No further readings were taken due to the observation of the bougie tip kinking and curling back on itself when a maximum of 10-12N of pressure that could be generated is applied.	
	R4			
	R5			
	R6			
P3 Medical Tracheal Tube Introducer 15CH 60cm (Coude Tip) (Single Use)	R1	N	N/A	20N pressure, no perforation, significant mucosa damage presented.
	R2	Y	13.99	N/A
	R3	Y	10.65	N/A
	R4	Y	17.84	N/A
	R5	N	N/A	20N pressure, no perforation, significant mucosa damage presented.
	R6	N	N/A	20N pressure, no perforation, significant mucosa damage presented.

Table 6.79: Airway Perforation Testing Results

6.10.1 Porcine Airway Perforation Analysis

The SunMed Introducer Bougie 15FR 70cm (coude tip) and SunMed Introducer Bougie 15FR 70cm (Straight Tip) both presented results of tracheal wall perforation (Figure 6.86). In all six attempts, the SunMed coude tip bougie perforated the tracheal wall. Significant mucosa and submucosa damage was also observed around the perforation hole. The SunMed straight tip bougie only perforated the tracheal wall once at 18.62N. The other five attempts resulted in the 20N maximum force load being reached and no perforation occurring. It was observed that the mucosa and submucosa showed considerable damage but the bougie was unable to perforate the hyaline cartilage.

Based on the observations and comparisons made during the testing, it is hypothesised that the coude tip bend provides a greater surface area and acts as a leverage point when pressed directly onto the tracheal wall membrane, thus allowing greater amounts of damage to be created at a lower force.

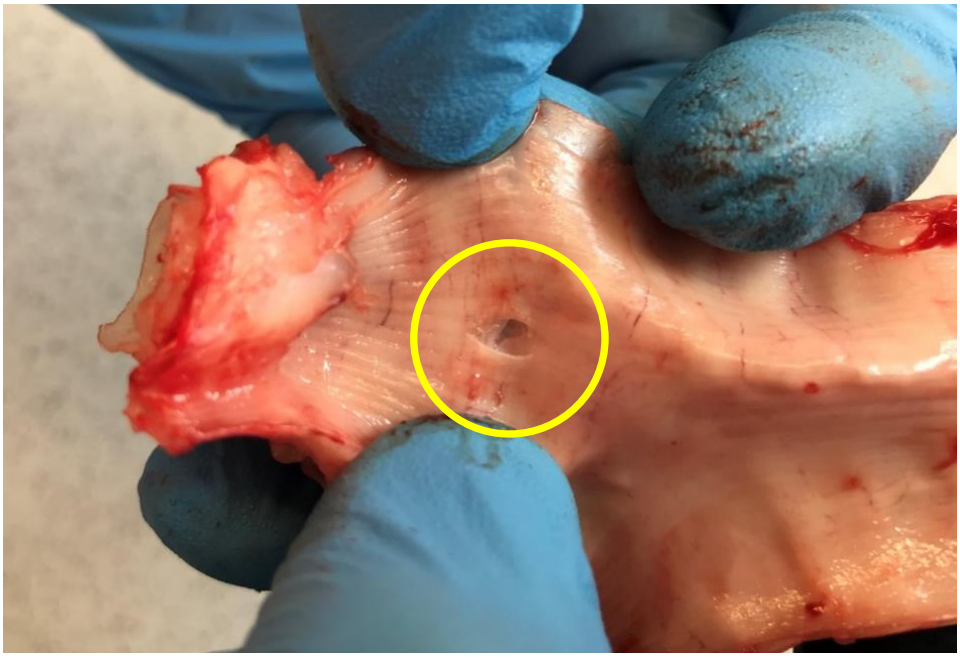


Figure 6.86: Tracheal Wall Perforation – SunMed Bougie Introducer

The first five readings collected for the SunMed coude tip bougie presented perforation forces of 17.91N, 15.25N, 16.62N, 15.54N and 16.88N resulting in a mean perforation force of 16.44N. The sixth reading collected unexpectedly presented a perforation force of 9.56N. No experimental setup or procedural change was noted; the only difference observed was the size of the trachea used; upon visual inspection the tracheal wall thickness was slightly thinner.

If this testing was repeated again in the future, the measurement of airway wall thickness should be integrated in the data collection process and compared to the perforation values recorded to check for any obvious trends. Measurement of the airway wall thickness using a non-destructive technique can be extremely difficult as noted by Lee et al., (2014). There are many factors that can affect the airway metrics, anatomy and growth of reared pigs as noted by McClendon et al., (2013); controlling the source of the pigs for future studies would be difficult but would add another element of standardisation to the testing protocol.

The re-usable gum elastic bougie (GEB) 15CH 60cm (coude tip) was tested four times; the first three attempts to perforate the tracheal wall with the GEB resulted in the 20N maximum force load being reached and no perforation occurring. It was observed that as the force was increased, significant bending occurred at the grip location which was set at 30cm from the bougie tip. Upon inspection of the tracheal wall (Figure 6.87), it was observed that the mucosa showed some initial splitting; the submucosa and the hyaline cartilage had not been perforated.

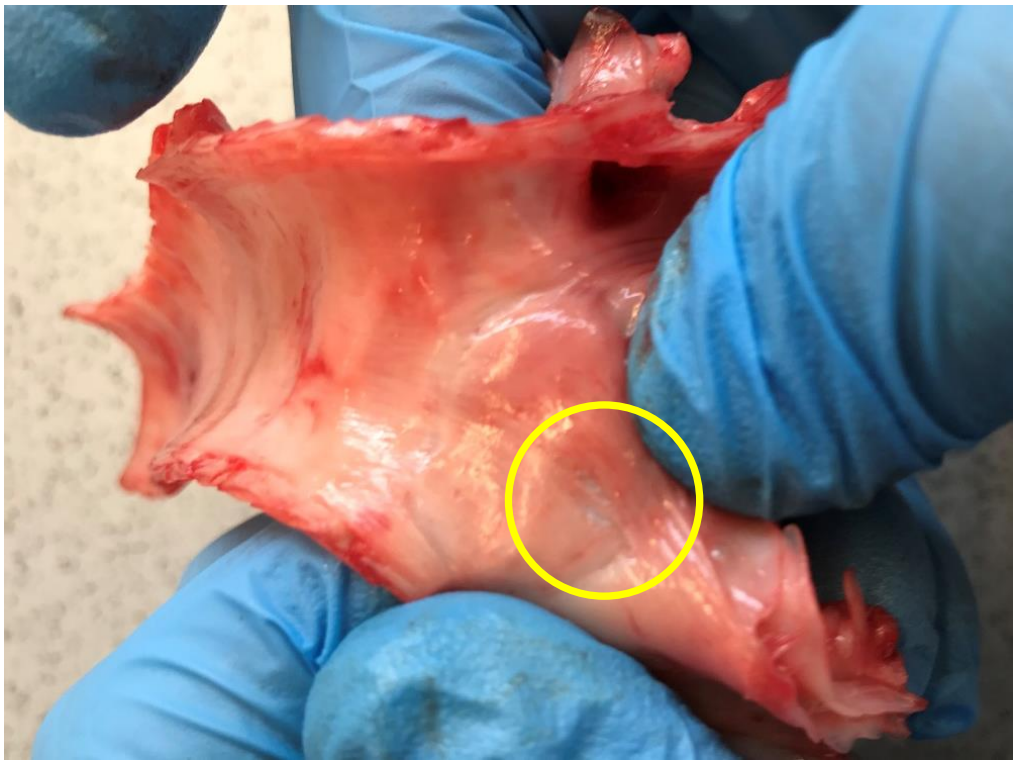


Figure 6.87: Minor Mucosa Damage On Tracheal Wall Using A Eschmann Re-Usable GEB

After the fourth attempt to perforate the trachea with a GEB, which again was unsuccessful, it was deemed that the GEB was not capable of perforating the tracheal wall unless the perfection force was increased past 20N. Upon closer inspection of the GEB, there was a noticeable crack at the coude tip (Figure 6.88). Repeated tip pressure applied at 20N had

resulted in the initial cracking of the outer coating of the GEB, which if repeated use continued and had gone unnoticed this could result in the tip snapping and being dislodged. This is an issue highlighted by Gardner and Janokwski (2002) who observed a rare case where the GEB tip became detached and lodged above the bifurcation/carina.

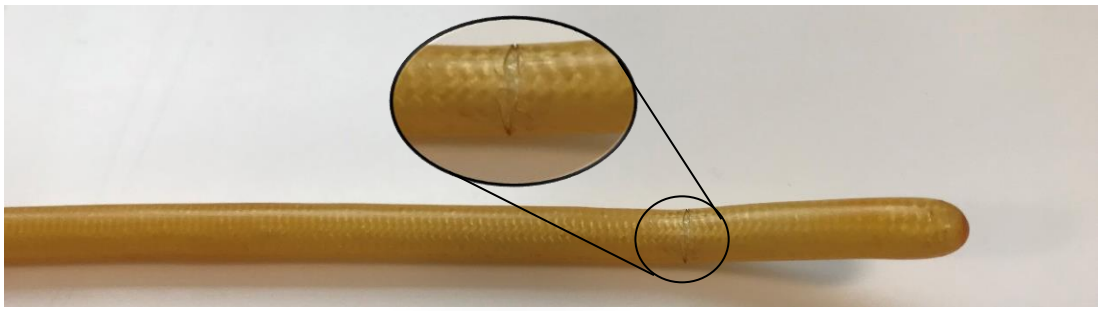


Figure 6.88: Coude Tip Cracking On A Reusable Gum Elastic Bougie

Bougie failure due to cracking or severe alteration of the physical properties was also noted in the Frova bougie and the Flexible Tip Bougie. The first attempt to perforate the tracheal wall with the Frova bougie, 20N pressure was again reached, with no perforation observed; mucosa damage was present. After a single test, the bougie was deemed unusable again due to a significant kinking at the grip location as shown in Figure 6.89. The hollow nature of the vented Frova bougie resulted in this failure, a thicker wall thickness would prevent this from occurring, conversely, this would result in the bougie becoming more rigid and thus create increased tip pressures and reduce the open lumen capacity for ventilation.

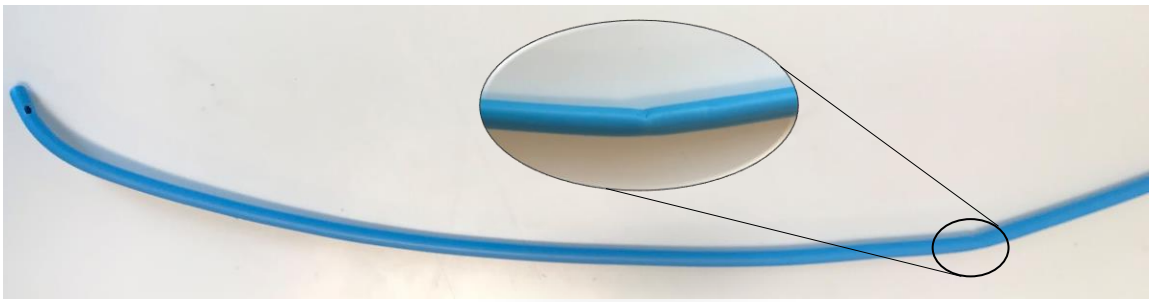


Figure 6.89: Kinking On A Frova Introducer

The Flexible Tip Bougie developed by Construct Medical was used twice before the mechanism stretched causing the device to fail; this was a result of the maximum of 20N pressure being applied; no perforation was observed. Significant mucosa and submucosa damage is presented as demonstrated in Figure 6.90.

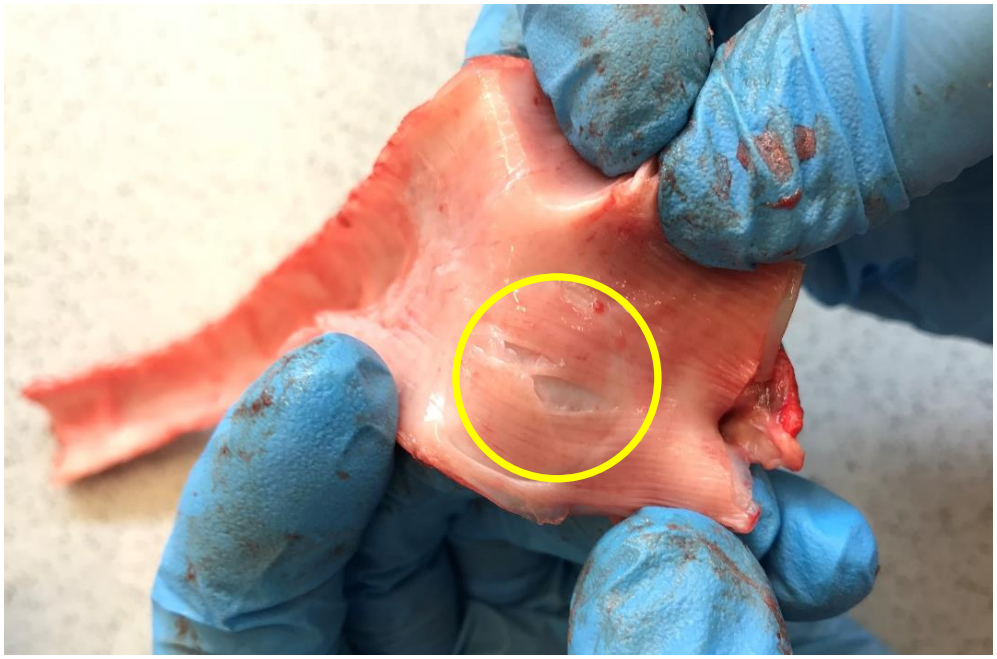


Figure 6.90: Significant Mucosa and Submucosa Damage (Flexible Tip Bougie, Construct Medical)

In contrast to the Flexible Tip Bougie, the Portex Single Use Bougie 15FR 70cm (Coude Tip) presents significantly less mucosa damage as observed in Figure 6.91. The Portex bougie failed to perforate the tracheal wall on all three attempts conducted, with only small amounts of mucosa damage observed; this was a result of the maximum of 20N pressure being applied and no perforation observed. Due to the Portex bougie presenting no sign of perforating the tracheal wall with no damage to the submucosa observed, no further readings were collected.

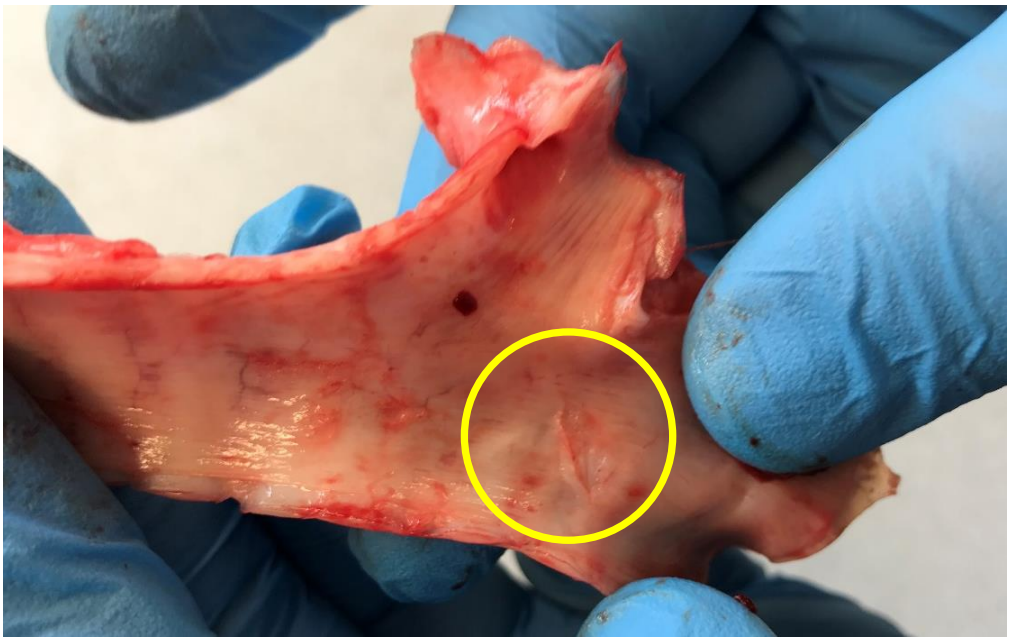


Figure 6.91: Mucosa Damage (Portex Single Use Bougie)

The single use P3 Medical Tracheal Tube Introducer 15CH 60cm (coude tip) presented a set of unexpected results. As the SunMed bougie (coude tip) had already been tested and presented six perforations, it was expected the P3 Medical bougie (coude tip) which exhibits similar peak tip pressure values would also do the same. After completing six tests, three perforations were exhibited (an example presented in Figure 6.92) and three non-perforations were presented as the 20N maximum applied force was reached.

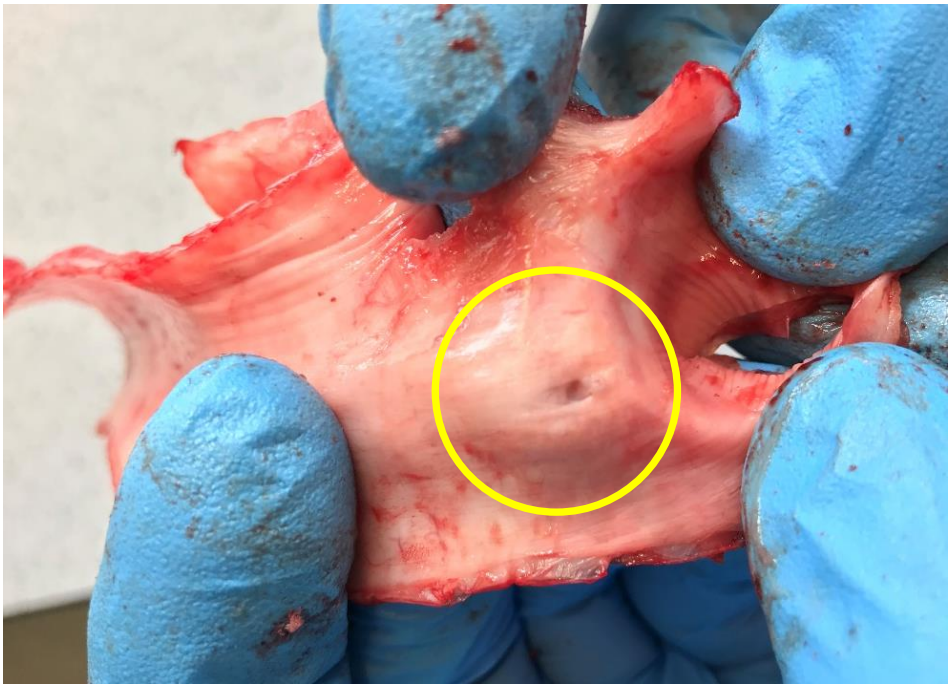


Figure 6.92: P3 Medical Single Use Bougie (Perforation Observed)

The perforation values were also extremely varied with perforation values recorded at 10.65N, 13.99N and 17.84N. The SunMed bougie and P3 Medical bougie presented in Figure 6.93 do exhibit slightly different manufactured setups which may offer some insight into the different perforation force values.

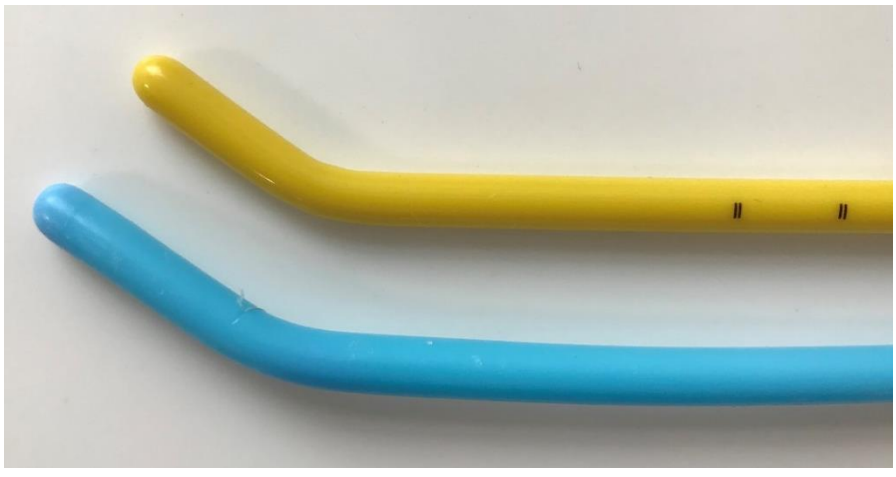


Figure 6.93: SunMed Bougie (Blue), P3 Medical Single Use Bougie (Yellow)

The SunMed bougie used during testing measured at 5.1mm in diameter with a 25mm coude tip and a bend of 40^{o} that begins 25mm from the bougie tip. The P3 Medical bougie used measured at 4.9mm in diameter with a 20mm coude tip and a bend of 35^{o} that begins 20mm from the bougie tip. These small dimensional differences could result in the variance in perforations/non-perforations but also the perforation forces exhibited. The thicker SunMed bougie which has a slightly larger coude tip length and bend angle, may provide greater leverage for perforation; the P3 Medical bougie which has a slightly less rounded tip, if axially lined up, could provide perforation at a lower value in a worst-case scenario due to a more targeted application of force.

Considering the commercially available bougies reviewed, the majority of the bougies failed to perforate the tracheal wall; mucosa and submucosa damage appears to be common. The softer bougies clearly need more than 20N to perforate the trachea, whereas the single use bougies that are rigid by design demonstrate perforation values of 10N or greater. The bougies that have resulted in perforations are bougies that have presented high tip pressures as demonstrated in the tip pressure testing completed.

After reviewing the commercially available bougies, the last bougie to be analysed was the developed steerable bougie. The readings collected suggest it was impossible to generate 20N of tip pressure; the maximum tip pressure force generated was 11.80N at which point significant bending of the main shaft of the bougie was noticed at the base of the grip (Figure 6.94).

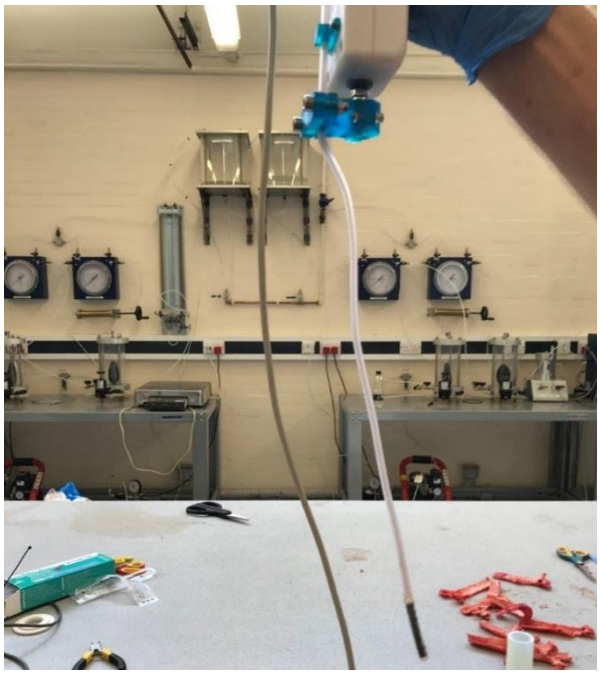


Figure 6.94: Steerable Bougie Main Shaft Bend

After the first couple of readings were collected, it was not necessary to collect further readings as the bougie was not capable of generating tip pressures over 10-12N. When the 10-12N of tip pressure was created, the flexible tip presented significant kinking and curling back on itself therefore creating a larger surface area with no protruding edge capable of creating a perforation, this is demonstrated in Figure 6.95.

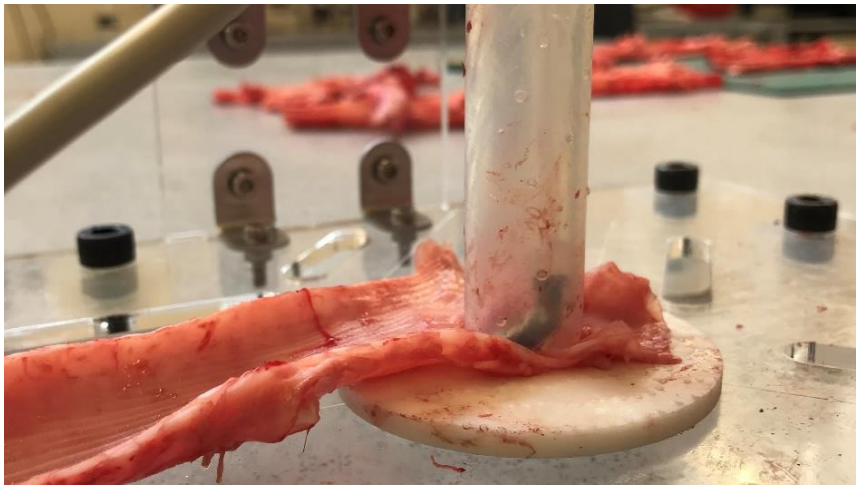


Figure 6.95: Steerable Bougie Curling Inside 3D Printed Trachea Component

The most significant result presented, regardless of the tip pressures generated by the steerable bougie, was no evidence of tracheal wall or mucosa damage (Figure 6.96). This lack of tracheal wall damage presented, highlights that the steerable bougie is the optimal device for use based upon its current construction. The steerable bougie was the only bougie tested that does not present any form of tracheal wall damage.

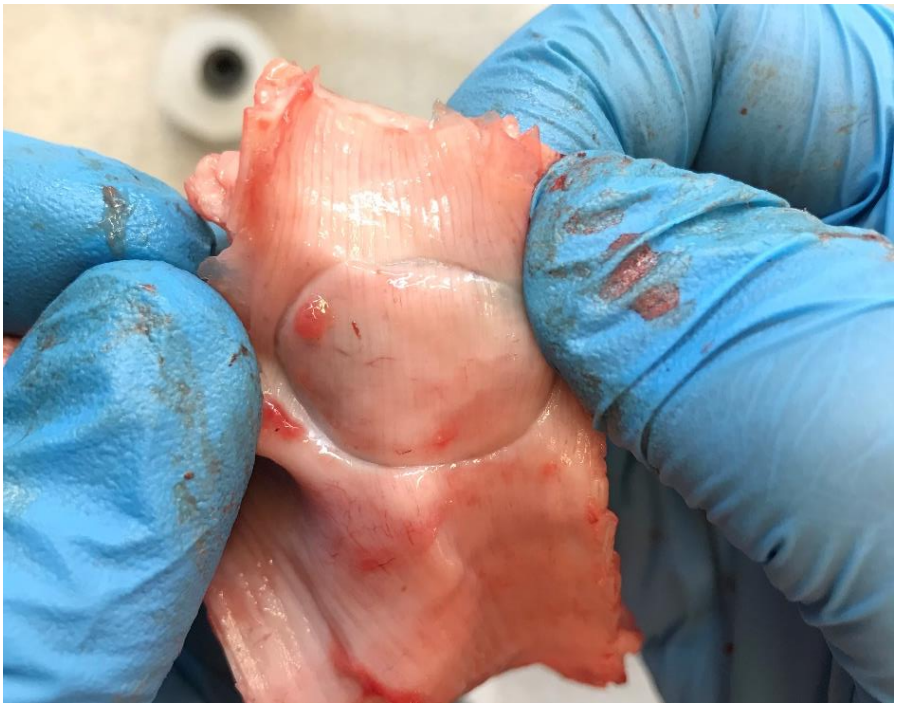


Figure 6.96: No Mucosa Damage Created By Steerable Bougie

Finally, an additional test was conducted utilising one of the Sauter Digital Force Gauge FH-S standard attachments. The use of the rounded tip spike attached to the force gauge (Figure 6.97) was used to apply 1N increments of force to the tracheal wall. As demonstrated in Figure 6.98, 5N of force presents splitting of the mucosa layer of the tracheal wall with a rounded spike; indentations can be observed at 3N and 4N. Although this is a worst-case scenario example, this highlights the importance of the bougie tip design, identifying a need for a rounded tip with no sharp or focused points that could increase the likelihood of mucosa damage.

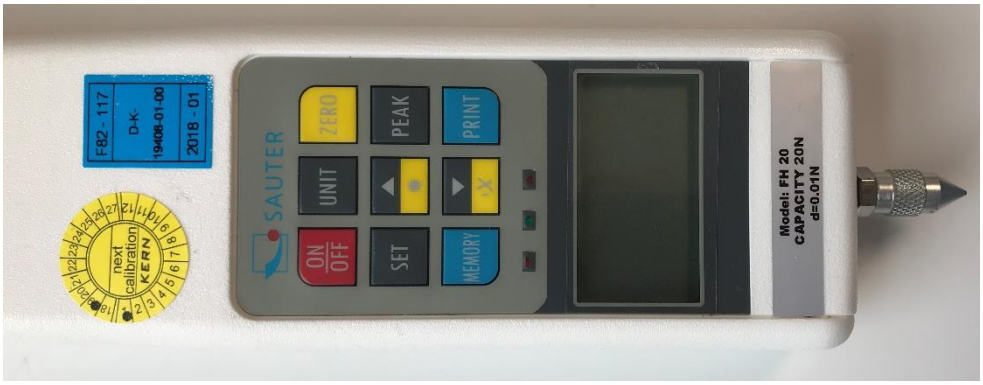


Figure 6.97: Force Gauge With Rounded Tip Spike

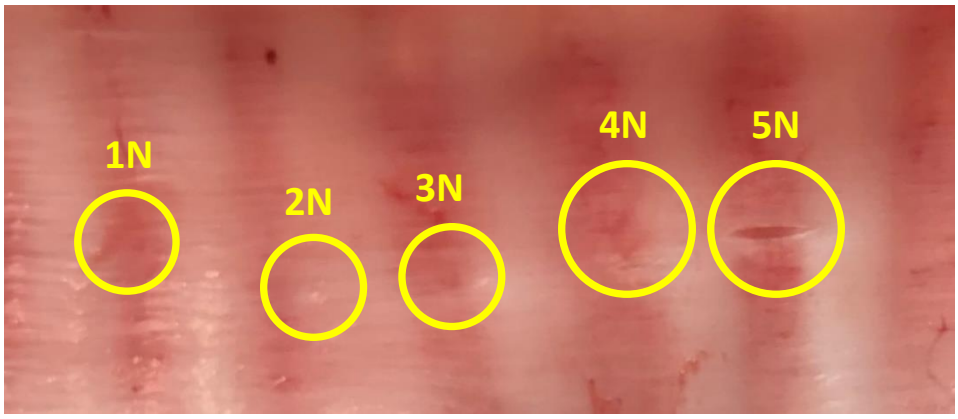


Figure 6.98: Splitting Of The Mucosa With Increased Forces

CHAPTER 7 - SHAPE RETENTION TESTING SYSTEM (SRTS)

7.1 Introduction

Shape retention is a critical performance property for bougies. The ability to shape a bougie to match the curvature of a patient's airway contributes to the first pass success rate. This chapter focuses on the design, development, manufacture, validation and testing of the newly developed Shape Retention Testing System (SRTS). The shape retention system utilises motion detection, object tracking and image processing to assess the relative performance of bougie introducers thus identifying the bougie with the greatest shape retention capabilities.

Research is limited in the area assessing the shape characteristics of bougie introducers, notable studies include a brief review of the effects of shaping on placement of multiple and single-use bougies (Annamaneni et al., 2003), a shape study conducted by Hodzovic, Wilkes and Latto, (2003) and Mingo et al's., (2008) study on the effect of temperature on bougies: a photographic and manikin study. A comparison of the Levitan FPS Scope^{TM} against single use bougies in a simulated difficult intubation also identified that the inability to maintain the desired shape of a bougie was a main cause of intubation failure (Greenland et al., 2007). As previously discussed, device selection appears to be solely reliant on an operator's personal preference, the availability of equipment within the NHS supply chain and selection of hospital-designated suppliers; due to the variance in bougie diameter, length, tip design and material construction these variables will affect the shape retention performance of a bougie.

The GEB is universally accepted as the gold standard device for use, however single use devices are becoming more common. Mushambi et al., (2016) proposes that newer single-use tracheal tube introducers require urgent further evaluation, especially before they are considered as suitable replacement devices for the re-usable GEB. Whitcombe, Strang and Reay (2005) however argue that the Frova is a viable long-term replacement; but the Frova should not be utilised with the hold-up sign (Marson et al., 2014). Hold up is part of the DAS's guideline recommendations. Assessing the shape retention of the product range would provide objective data to identify the optimal bougie for shaping.

Physical properties can significantly influence the performance of a bougie introducer as previously demonstrated in Chapter 6 and in published literature (Hodzovic et al., 2004; Janakiraman et al., 2009). As discussed, single use bougies have been documented to provide

increased tissue trauma (Evans, Hodzovic and Latto, 2010; Hodzovic et al., 2008; Hodzovic and Latto, 2007; Umesh and Jasvinder, 2008). Hodzovic, Wilkes and Latto, (2003) also propose that the improved design of a bougie might incorporate a moderately rigid proximal end and a flexible, soft distal end to maintain desirable bougie characteristics, as the GEB is recognised as being too soft and floppy (Cormack, 1985). Hodzovic, Wilkes and Latto, (2003) also identified an optimal shape for a bougie for when faced with a Grade 3 Cormack and Lehane laryngoscopic view; a CAD analysis review of the publication imagery has identified four distinct curved angles as 5^{o}, 23.5^{o}, 52^{o} and 95^{o}, all 20cm from the proximal tip.

As discussed in Chapter 2 there is a lack of standardised testing and the variance in bespoke experimental studies completed requires urgent assessment. It is imperative that any new or existing devices conform to the United Kingdom's Difficult Airway Society's ADEPT principles (Pandit et al, 2011); however, many devices have not undergone any of this formal testing; whether this be tip pressure testing as described in Chapter 6, shape retention testing, skill retention testing etc. It is therefore important that accurate, repeatable and reliable testing systems and protocols are utilised to help inform device selection and usage decisions. The testing of the shape retention capabilities to date has not been completed in a comparative study to identify the optimum device.

When designing and constructing testing equipment it is important to consider how this affects the devices being tested in relation to technology readiness levels (TRL's), but also where the constructed testing system fits into the TRL landscape. By implementing a design brief and a focused design approach in relation to TRL's, a detailed PDS can be generated. PDS's are not just utilised for the design of products, they can also be utilised for the design of systems and technology applications too; the tasks identified in the conceptual framework will be utilised. A PDS for the SRTS has been produced and discussed within this chapter in addition to the key criteria and detailed design requirements.

Behringer and Kristensen (2011) concludes that new intubation equipment can play an important role in advanced airway management and identifies the importance and responsibility of both clinicians and manufacturers to complete sufficiently powered, thoughtfully designed, and well conducted studies. Suitably designed testing equipment is required to be designed and manufactured to assess the relative performance data for bougie introducers.

7.2 System Design Method (Focused Design Approach)

Many designers fail due to a lack of focused approach during the design of everyday products. The design and testing phases are two of the most fundamental aspects to a focused design approach. Following a structured design methodology throughout the design process is extremely important and formulating a product design specification (PDS) and in some cases a component design specification (CDS) is a critical task. During the design of the SRTS, activities within Pugh's Total Design Activity Model (Pugh, 1991) were considered to compliment the use of the conceptual framework.

As discussed in Chapter 3, Pugh (1986) stipulates that the discipline of systematic working should allow for variations, whilst retaining discipline and imparting comprehensiveness. Variations within the design parameters will be imperative to ensure that the variable length, diameter, colour, and shape of the bougie introducers is taken into consideration during the design process of the SRTS.

Planning and utilising a focused design and testing approach ensures that variables that can affect accuracy of results can be both predicted and overcome. To improve validity of collected data in future studies, it is necessary to design new testing systems that accurately record and track various elements simultaneously. It is therefore important to consider the following issues:

- Calibration and repeatability of standard testing parameters to allow the accurate evaluation of equipment.
- Regulating/standardising the amount of pressure or applied movement input to shape the bougie.
- Repeatability of positional tracking (analysis of bougie bend angle and orientation).
- Adaptability of the testing system ensuring accurate and statistically relevant testing data can be collected regardless of device brand.

Finally, utilising a focused design approach within the conceptual framework described in Chapter 3 has ensured necessary design and research tasks have been completed. Research tasks include the assessment of motion capture technologies, PDS development and the identification of a design brief based on the requirements set out in the literature search etc.

7.3 SRTS Concept

To achieve the successful design and implementation of the SRTS a design criteria must be generated. The generation of a PDS comprises of quantitative statements that stipulate design requirements indicating key criteria. The PDS for the SRTS presented below also identifies the problem definitions for the activities and identifies elements of technology required for consideration based on initial research conducted, thus ensuring that all relevant factors are planned for and all stakeholder's requirements are considered.

7.3.1 Design Brief

The programme of the work for the construction of the SRTS has been designed around assessing the shape retention properties of bougie introducers to provide statistically relevant quantitative data that will demonstrate how bougie introducers perform in relation to their shape retention. The design brief for the SRTS is as follows:

"To design and manufacture a standardised, calibrated testing system that can provide comparative quantifiable data on the shape retention performance of bougie introducers. The testing system must be capable of accurate tracking and measuring the shape retention capabilities of bougies; considerations include bend location, angle of bend and position vs time tracking. Regulating and standardising the amount of pressure applied to shape the bougie, repeatability of positional tracking of a bougie, measurement of angle and orientation of the bend of the bougie are key measurables. The system must be adaptable based on equipment dimensions and material properties to ensure data can be collected regardless of the bougie introducer manufacturer/brand."

7.3.2 Patient Benefit & Clinical Need

Ensuring anaesthetists and Hospital Trusts have objective information will help identify optimum equipment selection for use/purchase, thus ensuring measurable improvements in clinical outcomes and success rates. The design of the testing system has the potential to be of benefit to patients by:

- Identifying devices with the greatest shape retention, thus ensuring procedures are quicker and more efficient with reduced need for multiple intubation attempts.
- Reduce the risk of airway injury, particularly perforation of the airway due to excessive tip pressures.

- Reduce the risk of damage occurring to the teeth because of the anaesthetist trying to obtain a view due to not being able to manipulate the bougie in situ because of poor malleability.
- Teaching/tutoring methods can be improved as training could be standardised for a set of approved equipment, thus reducing equipment operator experience factors.

7.3.3 Motion Capture Technologies

Motion capture technologies provide a repeatable and accurate method of measuring motion. The rapid development of 3D camera technologies has resulted in a market with numerous options, all with varying strengths and weaknesses. Motion capture and tracking technologies can be utilised within a variety of industries such as television and film making, sports technology, health and wellbeing, computer gaming and industrial vision amongst others. In this section, the technical capabilities of several low-cost motion capture technologies are reviewed and discussed with the aim identifying technical parameters to inform the SRTS PDS and identify a suitable motion capture device for integration. There are many types of motion capture devices available of the market, the most effective, yet cost effective are often utilised within the computer gaming platforms. Most motion capture devices utilised within the gaming industry are capable of 3D motion capture. 3D motion sensing cameras are often sold in combination with game consoles such as the X-Box 360, X-Box One and Playstation 3 and 4. Many other camera technologies and motion sensing devices exist that also have the capabilities to accurately track and measure data points.

Initial research suggests that the Microsoft Kinect gaming platforms (Microsoft Corp., Redmond, Washington, USA), Intel® RealSense™ camera range (Intel Corp., Santa Clara, CA, USA), PlayStation Camera (Sony Corporation, Minato, Tokyo, Japan), Leap Motion (Leap Motion Inc., San Francisco, California, USA), CREATIVE® SENZ3D camera range (Creative Technology Ltd., Jurong East, Singapore) and Xtion Pro Live (Asus, Beitou District, Taipei, Taiwan) have the greatest potential for motion capture and tracking. All these motion capture cameras have been utilised extensively within the development of healthcare applications and have the capabilities of tracking various features. Many of the above-mentioned motion capture camera technologies utilise versatile Software Development Kits (SDKs) which allow the bespoke development opportunities.

A full assessment and review of motion capture technologies within various areas has been completed, for further information refer to the published outputs (Breedon et al., 2016; Siena et al., 2018) (Appendix U).

Upon reviewing several motion capture devices, the most feasible and readily available cameras have been compared for their potential implementation. Table 7.1 provides a brief comparative review of the technical capabilities of the Microsoft Kinect v2.0 (Microsoft Corp., Redmond, Washington, USA), the Intel® RealSense™ SR300 and D435 (Intel Corp., Santa Clara, CA, USA) and the CREATIVE® BlasterX SENZ3D (Creative Technology Ltd., Jurong East, Singapore). The Leap Motion, Playstation Camera, CREATIVE® SENZ3D, Kinect 360 v1.0 and Xtion Pro Live have all been dismissed due to their inferior technical specification and availability for purchase. The Intel F200 and R200 have also been dismissed due to their application and availability for purchase; the ZR300 has also been ruled out due to its reduced depth camera capabilities in comparison to the SR300 and D400 range.

Specification/ Function	**Intel® RealSense™ SR300**	**Intel® RealSense™ D435**	**Microsoft Kinect® v2.0**	**CREATIVE® BlasterX SENZ3D**
RGB Camera (Pixel)	1080 at 30 FPS, 720 at 60 FPS	1920 x 1080 at 30 FPS	1920×1080 at 30 FPS	720p at 60 FPS, 1080p at 30 FPS
Depth Camera (Pixel)	Up to 640 x 480 at 60 FPS	Up to 1280 x 720 at 90 FPS	512×424 at 30 FPS	Up to 640 x 480 at 60 FPS
Range (m)	0.2-2	0.11 - 10	0.7-6	0.2-1.5
Connectivity (USB)	3.0	3.0	3.0	3.0
Release Date	Q1 2016	Q1 2018	Q4 2013	Q4 2016
Latest SDK Update	Q3 2016	Q1 2018	Q4 2014	Q3 2016
Approximate Price (GBP)* Feb 2018	80	130	20	190

Table 7.1: Comparison Of Camera Specifications (Colleen, 2016; Pagliari and Pinto, 2015; Software.intel.com., 2016; Software.intel.com., 2018a; Software.intel.com., 2018b).

These four 3D camera modules are commonly used, however, the Microsoft Kinect Sensor V2/2.0 manufacture has now ceased, potentially signalling the end of Microsoft's involvement in this technology sector (Good OS, 2017); the old SDK and limited technical support suggests this is not a viable option. The CREATIVE® BlasterX SENZ3D is a viable option but it is the most expensive camera available for purchase and utilises the same SDK as the Intel SR300. This suggests the Intel RealSense camera range is ideal for use. The D435 may appear to be the most suitable camera for use due to its new SDK. The camera itself is a pre-order device and would not be available for use until Q2 2018, therefore the SR300 which has the second best technical specification, is the most appropriate device for use and allows the user to select the appropriate camera feed suitable for their application.

7.3.4 Constructing The SRTS PDS - Method

As discussed in Chapter 4, a structured approach to constructing a PDS is imperative to ensure all the design criteria is considered. To facilitate the generation of a PDS for the design of the SRTS, Pugh's Total Design approach will again be utilised. Pugh's approach for a PDS utilises over thirty elements, however not all these elements are specific to every project. Before generating the PDS for the SRTS a selection process of the specification points is undertaken as shown in Table 7.2

Time Scale	✓	Competition	✓	Materials	✓
Customer	✓	Packaging	X	Ergonomics	X
Processes	X	Quality/Reliability	✓	Standards	✓
Size	✓	Shelf Life Storage	X	Aesthetics	X
Shipping	X	Patents	X	Installation	✓
Company Constraints	X	Environment	✓	Life In Service	✓
Disposal	✓	Testing	✓	Performance	✓
Manufacturing Facility	X	Safety	✓	Product Cost	X
Politics	X	Legal/Legislation	✓	Quantity	✓
Market Constraints	✓	Documentation	X	Product Life Span	✓
Weight	✓	Maintenance	✓		

Table 7.2: Selection Of PDS Elements

The excluded criteria from the PDS as presented in Table 7.2 identified several areas where the design specification points were deemed not necessary. The rationale for their exclusion is documented in Appendix P along with the full PDS.

7.3.5 Summative SRTS PDS

The summative PDS presented has been generated after considering the existing literature with regards to assessment methods for bougie introducers. With a clear gap in knowledge on the physical properties of bougie introducers, especially the shape retention capabilities, the PDS defines the design criteria for the manufacture of an accurate, repeatable and calibrated testing system. The full PDS is presented in Appendix P.

Performance

- Repeatable logic-based programming testing system utilising open source software (i.e. Arduino) with a protocol of pre-configured variables (i.e. actuators

programmable for set movements). The system must provide a protocol of standard movements, reset protocols and adaptable parameters.

- Requires an accurate camera capable of recording and capturing the required data within the specified field of view (FOV) i.e. 3D Depth Camera. This must be connected to accurate camera/video tracking data acquisition software capable of recording at a fixed frame rate, within an FOV thus allowing tracking of bend angles, tip movements, speed of movement and shape retention.
- Interchangeable angle measurement grids capable of complimenting the recording of different measures over clinically relevant ranges. The grids must be measured based on pixels to ensure calibration can be achieved.
- LED lighting system used to reduce the effects of ambient light to standardise the testing environment.
- Interchangeable components to standardised system setup regardless of the assessed equipment's diameter and length i.e. adaptable bend location points, adjustable grip chuck, adjustable bougie support beam, interchangeable linear actuator location points and motor bed location points.
- A quick speed, retractable bed, used to prevent bougie interference; lock points/brakes will also be required to prevent inaccuracies with data acquisition.
- Live real time object tracking (bougie movement mapping) and post processing assessment software is required to analyse bougie characteristics and suitability.

Installation

- The SRTS is required to be semi-permanent and collapsible for transportation if required.
- Interchangeable grids are to be inserted into the designated slot; they must have a standardised origin and grid spacing to allow confirmation of calibration. Coloured grids will be required based on the variance of bougie colours.
- The lighting system must be installed to standardise the ambient light. This system should also aim to reduce the shadowing recorded on the interchangeable grids.
- The SRTS will require various power sources dependant on the equipment utilised; PC/Laptop (Mains Plug), Intel RealSense Camera (USB Powered), Linear Actuator (12V DC), Geared DC Motor (12V DC) and Brake System (5V DC Solenoid).

Testing

- Regulate and standardise the forces/pressures applied to shape the bougie. (This will vary based on bend location and distance from the bougie tip).
- The SRTS must be capable of conducting repeatable tests for several types of bougies/introducers yet still conform to standardised positional tracking.
- Accurately record and post-process the measurement of the bougie bend angle and orientation.
- The SRTS must be adaptable to allow the real-time data acquisition software to accurately map bougie movement and collect accurate and statistically relevant data regardless of the equipment assessed.
- Post processing software is required to track data points and monitor bougie shaping and loss of shape thus defining outputs including distance moved, angle variation, starting angle and speed.

Legislation

- The SRTS must be capable of producing quantifiable data that can inform the Difficult Airway Society (DAS) Guidelines and the DAS ADEPT Guidelines (Pandit et al., 2011).
- The system must be capable of contributing information to the DAS guidelines for management of unanticipated difficult intubation 2015, data collected must inform positive change for best practice.
- The SRTS should conform to the testing requirements set out by the MHRA and Medicines and Medical Device Regulations.

7.4 Design & Manufacture Of The SRTS

7.4.1 System Design

Based on the generated PDS discussed and fully presented in Appendix P the SRTS (Figure 7.1) has been designed as a standardised, calibrated testing system that can provide quantifiable data on the performance of airway equipment and bougies. The purpose of the SRTS is to inform individual and departmental equipment usage decisions which in turn can inform guidelines for best practice. Currently no testing system exists for assessment of bougies. The research team first presented the concept of the SRTS as a system aimed at helping standardise equipment assessment (Siena et al., 2017). These systems must be adaptable, calibrated to collect relevant, reliable and accurate testing data, and function alongside interchangeable components to standardise system setup regardless of the assessed equipment's diameter and length. Creating a logic-based programming setup with a protocol of standard movements also aids the manufacture of a standardised testing system with calibrated home and reset functions.

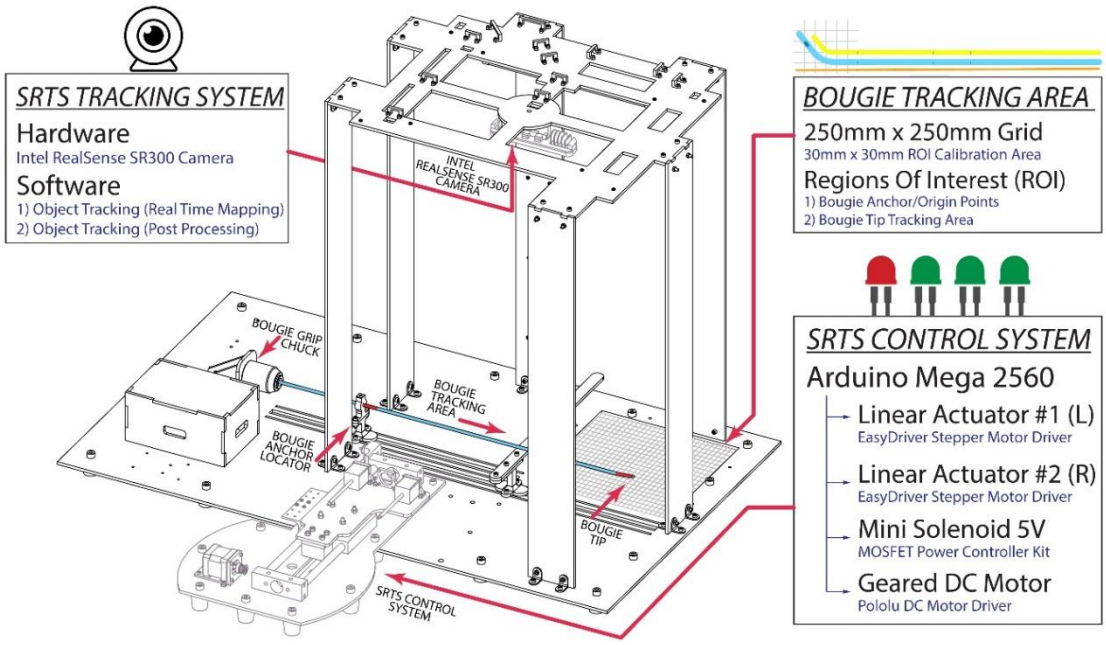


Figure 7.1: Shape Retention Testing System (SRTS)

*** Note** The development for the OTPPS and RTMS software that compliments the SRTS has been completed in collaboration with Mr Paul Watts (Software Developer, Medical Engineering Design Research Group, Nottingham Trent University, UK). Mr Watts contribution to the production of the OTPPS and RTMS software package has been acknowledged within this thesis and in the resulting publications.*

The SRTS has been designed as a repeatable logic-based programming testing system that utilises open source software (i.e. Arduino) with a protocol of pre-configured variables (i.e. actuators programmable for set movements/distances). The system provides a protocol of

standard movements to shape the bougie (Figure 7.2), reset protocols and adaptable parameters all of which can be adjusted within the program code if required.

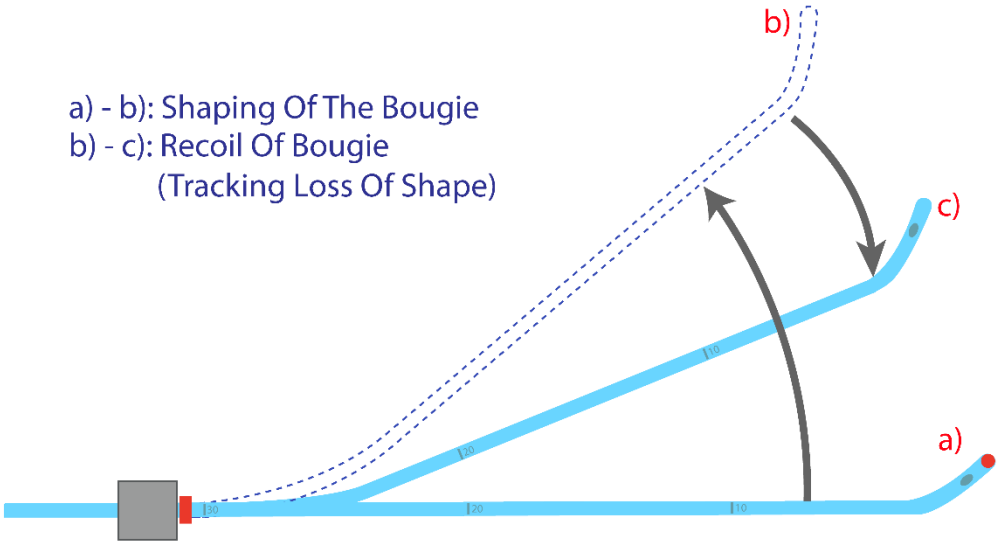


Figure 7.2: Shaping Of The Bougie

Utilising an Intel RealSense SR300 camera provides the SRTS with an accurate camera module capable of recording and capturing the required video within the specified FOV that can be processed for data analysis. This is linked to the accurate camera/video tracking data acquisition software package capable of recording at a fixed frame rate, within an appropriate FOV thus allowing tracking of bend angles, tip movements, speed of movement and shape retention. The use of interchangeable angle measurement grids provide a suitable visual gauge to assess bougie movement but also provide a system of calibration.

An LED lighting system is used to reduce the effects of ambient light to standardise the testing environment; this works in conjunction with a black out hood which is placed over the top of the SRTS's frame. The SRTS utilises a variety of interchangeable components to ensure that only one system is required creating a standardised system setup yet also ensures that the assessed equipment's diameter and length can be supported. Adaptable bend location points, an adjustable chuck, adjustable bougie support beam and interchangeable linear actuator location points and motor bed location points provide this adjustability.

The SRTS has a linear actuator pusher system (LAPS) integrated and used to push and shape the bougies based on input distances. This also acts as a fast, retractable carrier, used to prevent bougie interference (Figure 7.3). The lock points/brakes integrated also prevent

inaccuracies with data acquisition. Live real time object tracking (bougie movement mapping) and post processing assessment software is used to analyse the bougies.

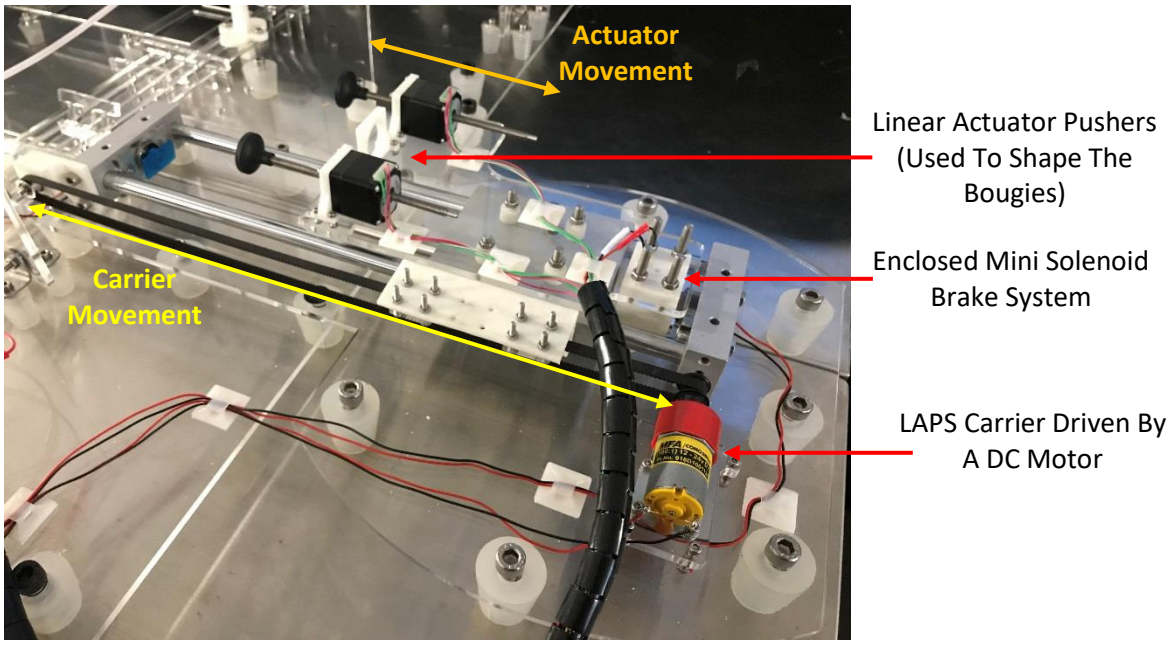


Figure 7.3: Linear Actuator Pusher System (LAPS)

The SRTS uses real-time data acquisition software to accurately map bougie movement and collect accurate data regardless of the equipment assessed. In addition, the post processing software tracks data points and monitors bougie shaping and loss of shape to defining outputs including distance moved, angle variation, starting angle and speed. Within the PDS it was defined that the SRTS is required to be semi-permanent to ensure this is collapsible for transportation if required. The collapsible frame and interchangeable components ensures that this PDS point is met. The interchangeable grids use standardised origins and grid spacing to allow confirmation of calibration. The use of programmable regions of interest (ROI) within the software packages has ensured that targeted tracking is utilised. The interchangeable grids also allow the use of coloured grids to be inserted when required based on the variance of bougie colours.

The SRTS requires various power sources due to the variance of equipment utilised to achieve the desired control; PC/Laptop (Mains Plug), Intel RealSense Camera (USB Powered), linear actuator or other suitable retractable actuator (12V DC), Geared DC Motor (12V DC) and brake system (5V DC Solenoid).

The SRTS can regulate and standardise the distance of the actuator to shape the bougie through programmable speed changes of the linear actuator pusher system. This will vary based on bend location and distance from the bougie tip. The SRTS has also been designed

to be capable of conducting repeatable tests for several types of bougies/introducers yet still conform to standardised positional tracking. The system overview diagram (Figure 7.4) depicts how the SRTS functions.

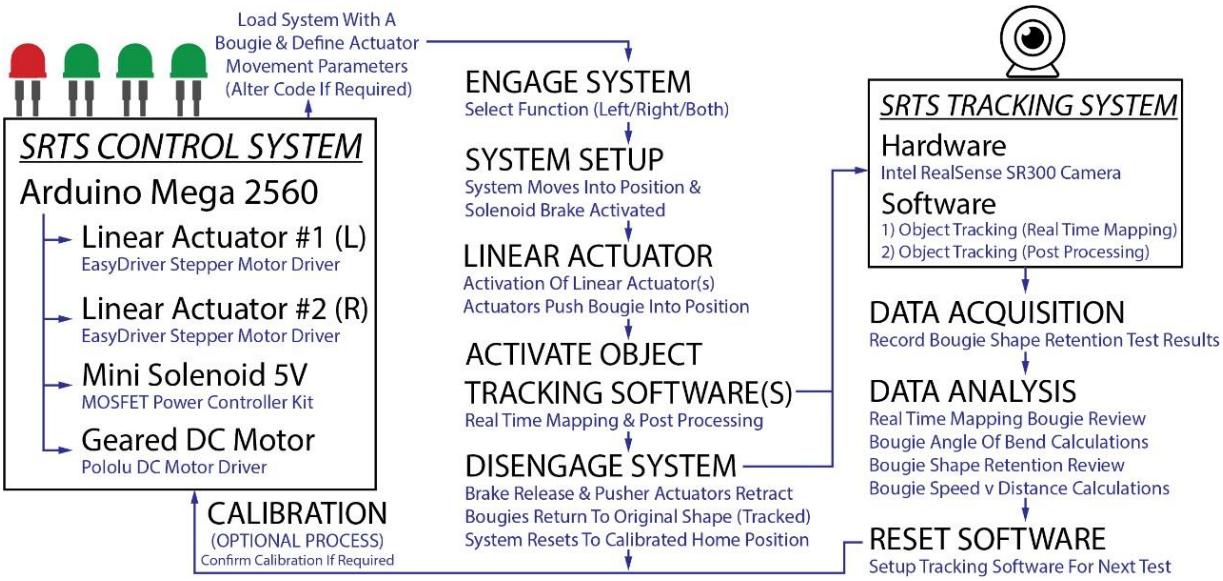


Figure 7.4: Overview of Shape Retention Testing System (SRTS) Functions

After initially testing the SRTS and its mechanism it was discovered that the 5V LAPS system was ineffective and failed to engage consistently to shape the bougies. To overcome this, improvements to the LAPS system were made using NEMA 17 linear actuators with higher torque, these were placed under tension using threaded bars to ensure consistent forward and backward motion; 3D printed end caps were also used. (Figure 7.5). Further design improvements were also made to prevent the bougies from slipping from the pushers (Figure 7.6); these are interchangeable depending on the size and shape of the bougie being tested.

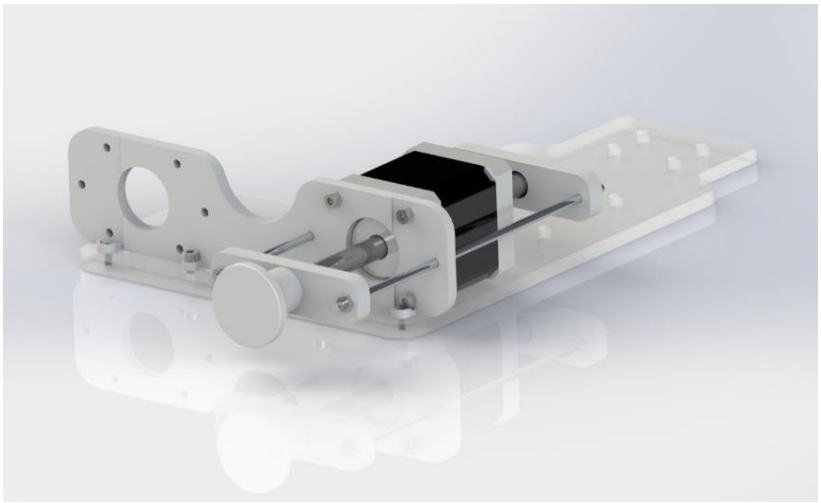


Figure 7.5: Linear Actuator Pusher System V2

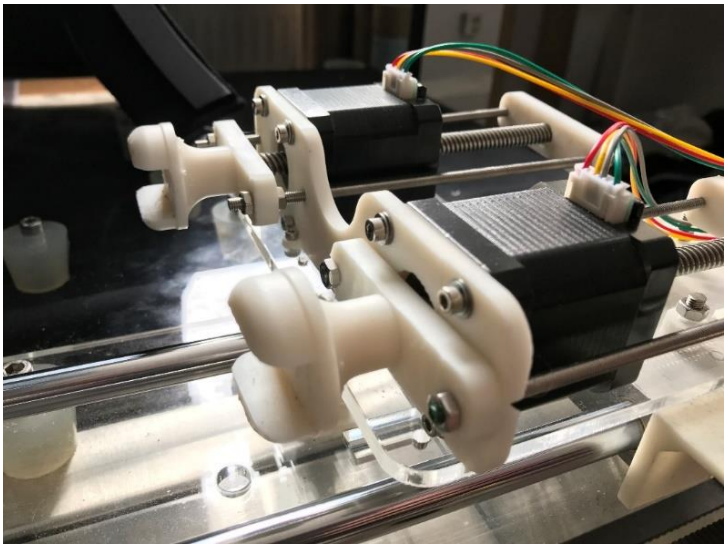


Figure 7.6: Improved Linear Actuator Pusher System V2 (Replaceable End Caps)

7.4.2 Utilisation Of Software

The SRTS uses two software packages that have been combined into one application to complete the accurate assessment of bougie shape retention parameters. The Real Time Mapping Software (RTMS), utilises a live feed recorded video and object colour tracking to map the bougie tip movements. The Object Tracking Post Processing Software (OTPPS) as described in full below tracks the change in shaping of the bougie whilst tracking the changes in angles, timings and distance. The Real Time Mapping Software (RTMS) is developed to function in a similar manner to an open source object tracking C# program that utilises a live camera video feed to assess the colour and size of objects (Gupta, 2013) and is used to detect movement of coloured objects being tracked (Figure 7.7). This is then plotted onto a chart to map the bougie tip positional movements.

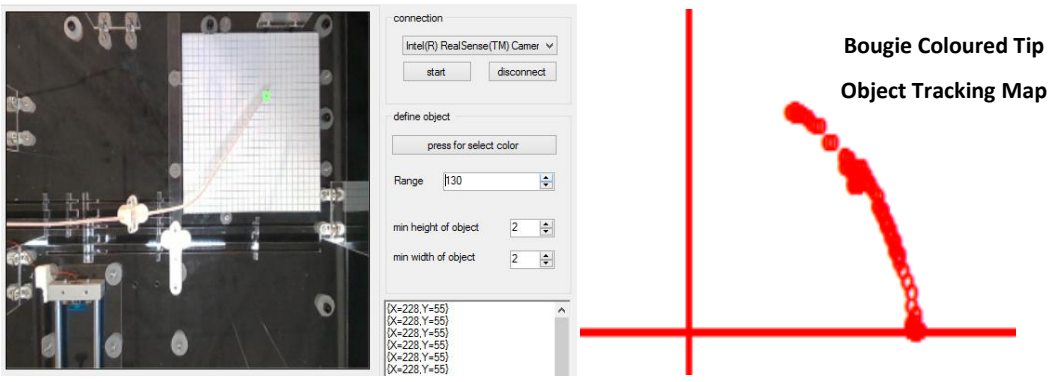


Figure 7.7: Tracking Live Feed (Left), Bougie Tip Tracking Map (Right)

The RTMS identifies coloured objects and tracks their positional movement based on the captured co-ordinate data. The X and Y co-ordinate data is plotted onto a position-tracking map as the object is moved providing a mapped image (Figure 7.8).

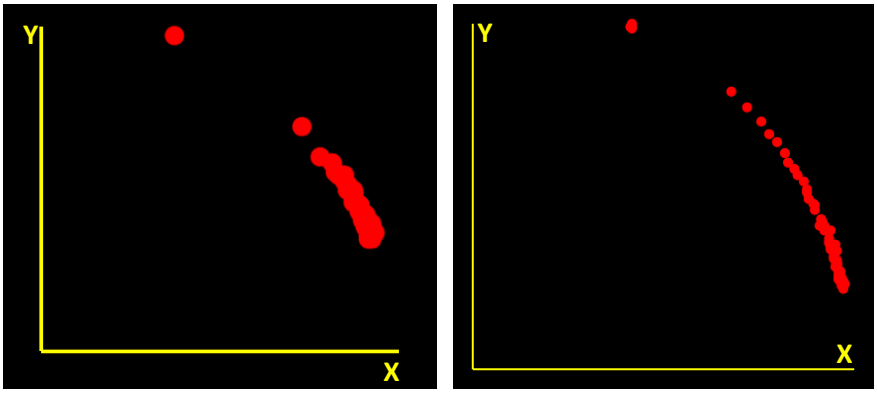


Figure 7.8: Example Bougie Tracking Plot Maps

The OTPPS analyses a recorded video of the bougie introducer movements. The software processes the video collected and calculates the starting angle (degrees), change in angle (degrees), the distance moved (mm) and the speed of movement recorded in millimetres per second (mm/s).

The OTPPS tracks the bougie tip movements over a set number of frames considering the two defined points, the anchor/origin location and the tip of the bougie. Data points are then monitored as the bougie attempts to return to its original shape after the LAPS withdraws and the bougie manipulation has been completed. The RTMS & OTPPS have been combined into one software package (Figure 7.9), which can be operated utilising a packaged executable file or operated directly from Visual Studio. Further detail on the individual package elements are described below.

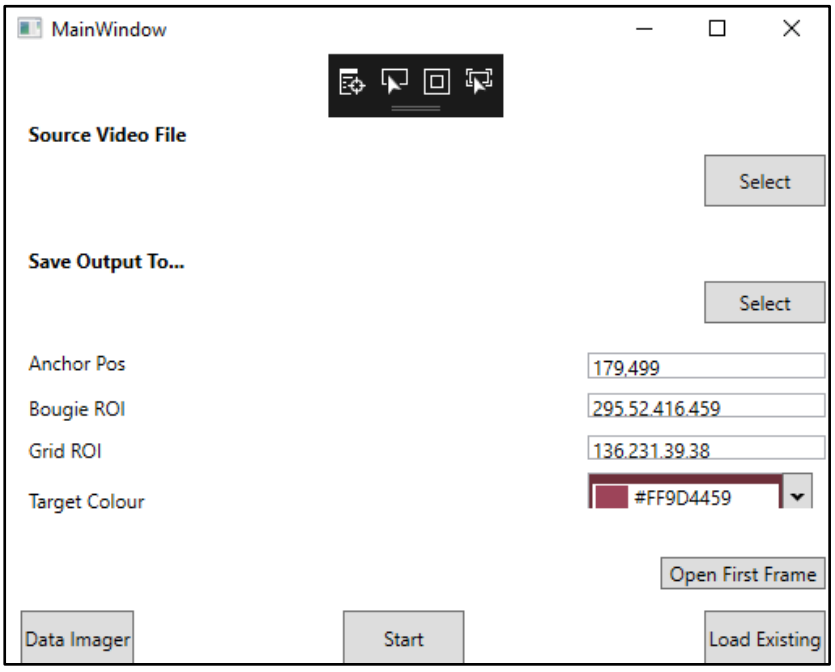


Figure 7.9: SRTS Tracking Application Package

Before any tracking can be completed a video of the bougie shaping and shape retention loss must be recorded. To do so the SRTS must be engaged utilising the power control box, the LAPS controlled by the geared DC motor moves forward until the front switch on the carrier is pressed. Upon hitting the front switch, the operator activates the actuator(s) required to shape the bougie, these are pre-set distances that can be altered within the system program code. After the completion of the programmed movements, the disengage button is then pressed on the control box and the video recording software records the bougie movements; simultaneously the LAPS retracts until hitting the back switch at which point the LAPS is reset to its calibrated home position.

Object Tracking Post Processing Software (OTPPS)

The OTPPS is the data processing system used to calculate the defined measurables identified in the SRTS PDS. The OTPPS processes captured videos of bougie movement; however, this requires several input parameters to function correctly. Regions of interest (ROI) are used to target specific areas of the recorded bougie shaping videos (Figure 7.10).

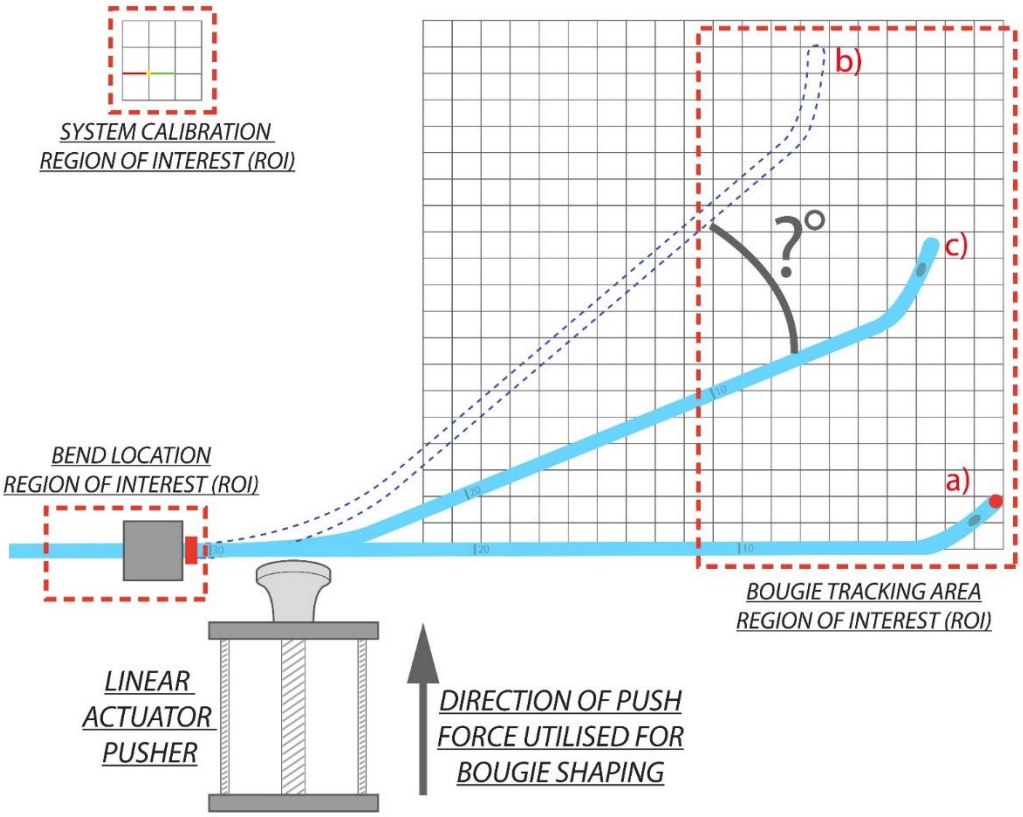


Figure 7.10: SRTS Tracking Application Package

The coloured tip of the bougie is identified as the main target; a colour marker is also used to track the bend location, however for accuracy and standardisation this is then fixed. The

use of ROI's reduces the area that the system will need to search and this speeds up the data processing; this also reduces the likelihood of rogue objects identified being tracked causing incorrect tracking. Once a video is captured of the bougie movement, the OTPPS software processes this.

The OTPPS software breaks down the video into individual video frames. Through extracting the pixel data from each frame and isolating the pixels of the target, a digitised array is created that the computer searches for (Figure 7.11). The pixel data is extracted from the source image and converted into a digitised map (Figure 7.11, Left) which is then converted into a digitised image which is numerically converted (Figure 7.11, Right). Once the system receives the numerically converted image, it isolates the centre of the tracked object and uses these reference points to capture the coordinates for measurement.

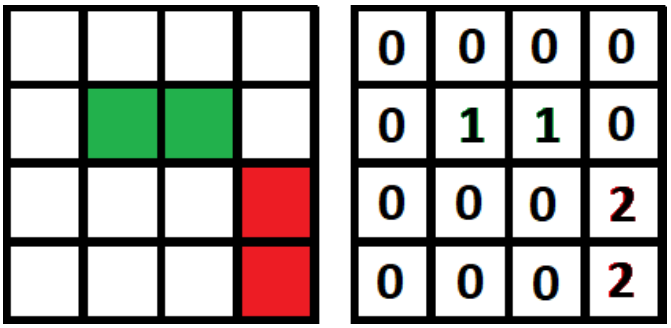


Figure 7.11: Original Image In Pixels (Left) Digitised Map Of The Pixel Image (Right)

For the SRTS to function as desired, two targets are required to be tracked to calculate the angle change and speed of a bougie. The first target is located at the base of the bougie where it will be bent; this is a fixed anchor point and will not move during the test. The second target location is the tip of the bougie (Figure 7.10a); when the bougie is shaped this will move and will be tracked (Figure 7.10b, c).

As the OTPPS processes the recorded video and tracks the bougies movement over a set number of frames considering the origin/anchor location and the bougie tip, these data points are monitored during bougie manipulation and as the bougie attempts to return to its original shape. The captured video is then processed and broken down into frame-by-frame images; the OTPPS then analyses each image for the location of the anchor marker and the bougie tip marker. The tracked points are converted into X, Y coordinates based on the pixel location at the centre of each of the tracked markers. This data is then stored into an array with an item in the array for each frame of the video; this data is then timestamped.

Using this data array, it is now possible to query the data to find out where the markers were at any given time in the video feed. Using trigonometry, the angle between the two points from each frame can be calculated. By subtracting one angle from the other, the difference between the two angles can be identified and it can be established how far the bougie has moved within a selected time frame. Dividing this value by the time that has elapsed between the frames, the average speed of the bougie movement can be calculated.

To achieve calibration and the correct scale, the number of pixels in the image per centimetre must be calculated. This is achieved by placing a small grid in a separate ROI under an observed area (Figure 7.10) and using this grid within each image the OTPPS calculates the distance between the lines; the number of pixels located between the lines provides the scale in pixels per centimetre. Using this value, the distance between any two points within the image frame can be calculated.

As the video runs at a fixed frame per second (FPS) rate as defined in the PDS, it is possible to calculate exact timestamps for each frame and a set of coordinates thus making it possible to calculate the movement of the target points between two specified timestamps. By calculating the angle between the anchor and the bougie tip for each of the two frames and subtracting the first angle from the second, the amount of rotation that has occurred within the specified timeframe is calculated, thus defining the shape retention loss.

To calculate the distance moved, the bougie tip start frame is subtracted from the bougie tip end frame; this defines the distance in pixels between the two points. By dividing this new value by the number of pixels per mm, it is possible to discover the number of millimetres moved by the bougie tip between the start and end frame.

The analysis of video frames is a processor intensive task therefore optimising this image-processing task was important; this was completed by allowing the processing of video frames to run in parallel, thereby utilising all the cores available on the computer/workstation. Further detail on optimising the image processing system is available in the published research listed (Siena et al., 2018).

Real Time Mapping Software (RTMS)

The RTMS identifies the coloured tip and tracks the positional movement creating an output plotting map or comparison of bougie movements. The captured videos processed by the OTPPS are then again processed by the data imager command setup within the software (Figure 7.10). Before this feature was integrated into the developed software package, a

standalone software developed by Gupta (2013) was trialled; this required a significant amount of setting up and could not be run in parallel with the OTPPS unless a virtual camera was in operation.

The RTMS makes use of the collected data captured and processed by the OTPPS system to generate a visual representation of the bougie movement over time. The RTMS system uses the .csv file and assess the data at intervals of 10 frames; this is then plotted onto an image that presents a representation of bougie movement. The system detects the furthest bend point within the captured data and uses this as a starting plot point and continued to plot each point until the end of the video or stipulated recording time scale. The system draws each point as a red circular marker to show the curve of the bougie over time. In an attempt to limit the size of the output image and to remove unused areas of the video frame the system calculates the region of interest using the further points of the bougie tip and anchor point throughout the video capture, this then scales the image dimensions accordingly.

SRTS Validation

To validate the OTPPS and the SRTS, an initial bougie shape retention test was conducted. Using the LAPS to shape the bougie, once released, a video of the bougies movement/shape retention is recorded. This video is then processed within the OTPPS to track the change between the start and end points defined (Figure 7.12). Once processed, the OTPPS opens the dialogue box which presents all the tracking data collected. The number of frames analysed based on the input time-scale (milliseconds) can be altered to calculate the required results.

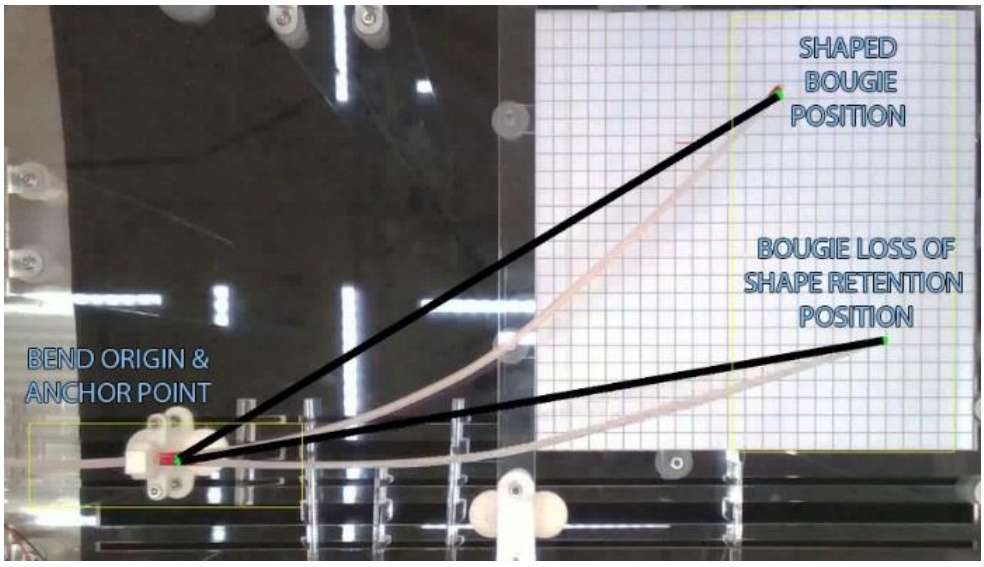


Figure 7.12: Post Processing Software: Shape Retention Bougie Test – Start & End Position

As shown in Figure 7.13, the number of frames that the operator chooses to analyse is input; for the test these are set between 0 and 1000; this however can be any time range based on the captured video length. Once the image processing is completed and the results are calculated, a results dialogue box appears stating the starting angle position (degrees), the distance moved (mm), angle variation (degrees) and the speed of the bougie movements (mm per second). For the validation test completed (Figure 7.13), the bougie was shaped to a starting angle of 121.2 degrees, the bougie then moved 149.27mm from the shaped position to the loss of shape retention position, thus demonstrating movement and loss of shape retention. The angle variation observed was 21.31 degrees and the speed of movement was calculated at an average of 3.04 mm/s.

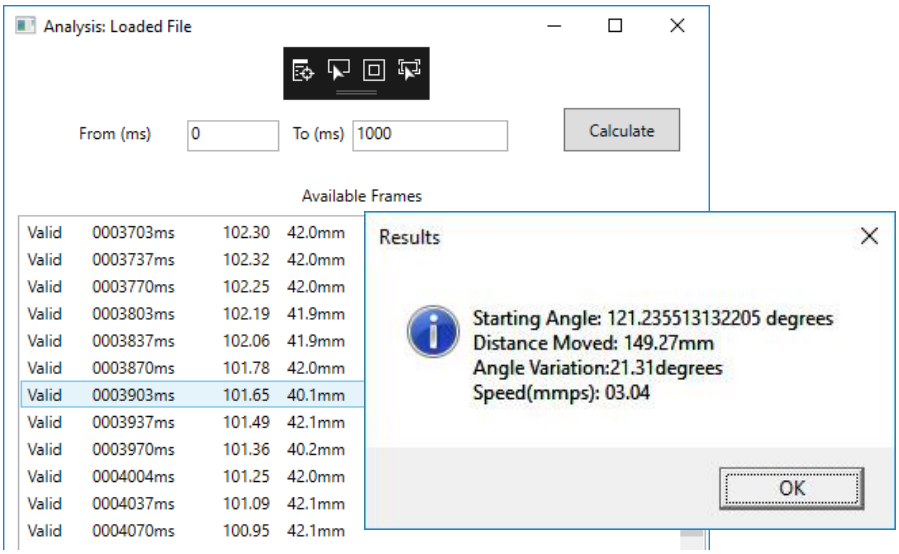


Figure 7.13: Validation Test Data Acquisition & Results Dialogue Box

Although the system has successfully tracked and shaped the steerable bougie tested, after testing each of the bougies within the SRTS, the SunMed and P3 bougies failed to successfully shape due to their increased stiffness compared to the other bougies; this resulted in the LAPS system locking up.

7.4.3 Design Improvement Considerations

As the SunMed and P3 bougies have failed to be shaped by the LAPS, to ensure the correct purchase of an alternative motor with sufficient torque to shape the bougies, compressive testing was completed to identify the approximate forces required to shape the bougies to a 90^{o} angle (Figure 7.14).

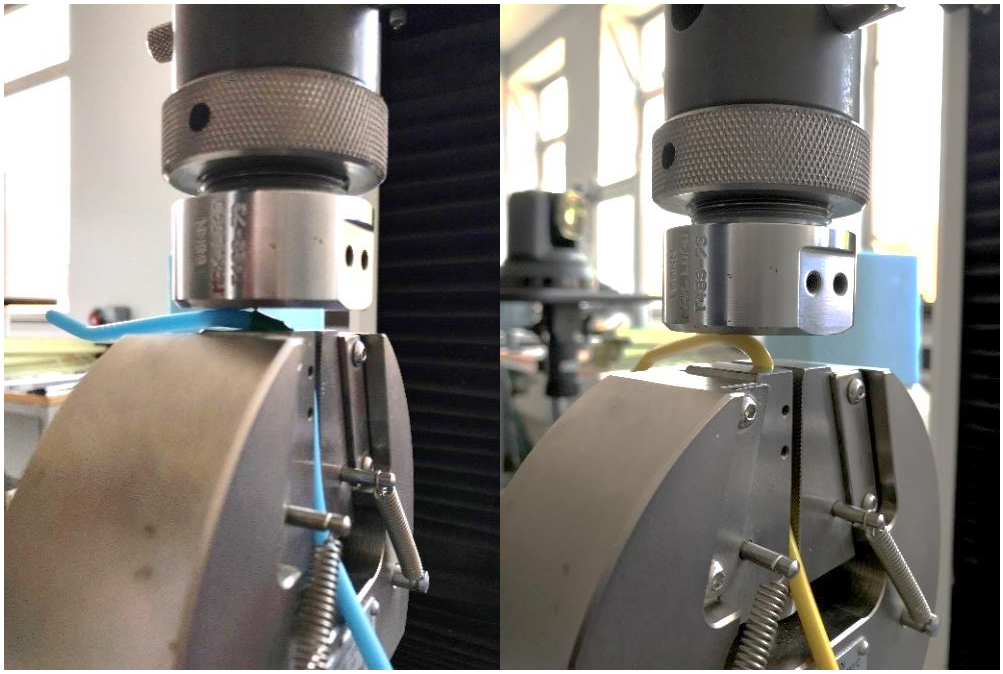


Figure 7.14: Compressive Force Testing Of The Stiffest Bougies (SunMed & P3 Medical)

The testing completed identified that the SunMed Bougie required 15.45N of compressive force and the P3 bougie required 25.90N of compressive force to be shaped to 90° (Figure 7.15 – 7.16).

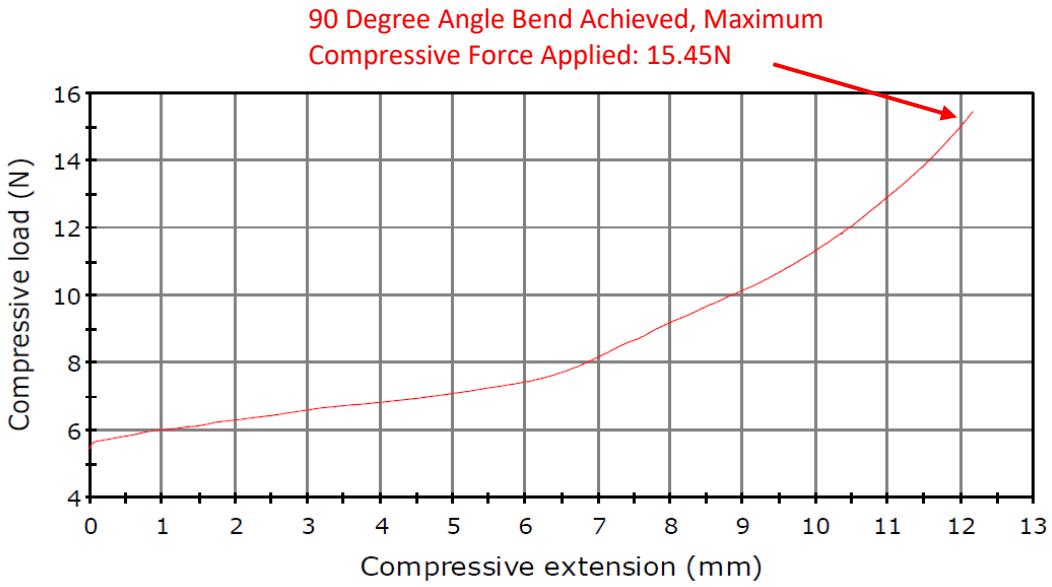


Figure 7.15: SunMed Coude Tip Bougie (70cm) – Compressive Force Required To Produce A 90° Bougie Bend Angle

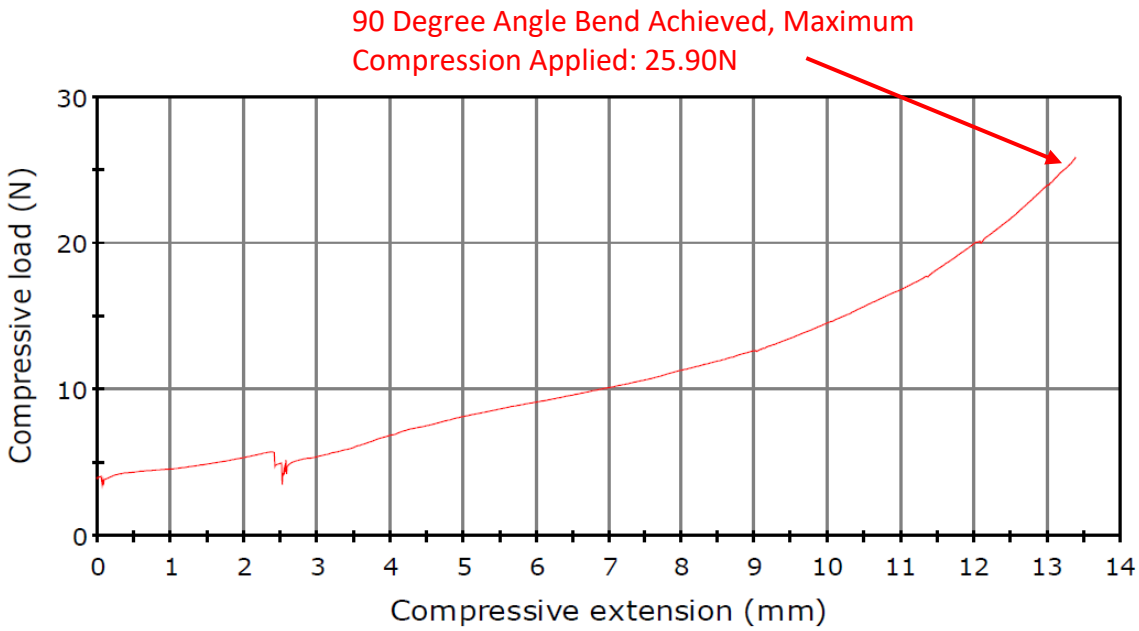


Figure 7.16: P3 Medical Coude Tip Bougie (60cm) – Compressive Force Required To Produce A 90° Bougie Bend Angle

Based on the testing completed, the stiffer single use bougies require significantly greater levels of compressive load to shape the bougies to 45-90° than previously anticipated. Improvements to the LAPS system was required. After assessing the market for appropriate linear actuators that have accurate position control and appropriate force capabilities, an Actuonix P16 Series mini linear actuator with a planetary gearbox, will be used as this offers not only speed and position control but higher forces and repeatable long-term service; this requires an alternative linear actuator control board.

7.4.4 SRTS & LAPS Further Development

The introduction of the Actuonix linear actuators into the LAPs has resulted in several amendments being required to reinforce the SRTS due to the increased torque and compressive forces generated. The Easydriver control boards have been removed and the LAC boards introduced; alterations to the power supply were required. The Actuonix linear actuators required a new mounting plate to be designed in addition to new pusher handles (Figure 7.17). Minor alterations to the solenoid braking system location were also required.

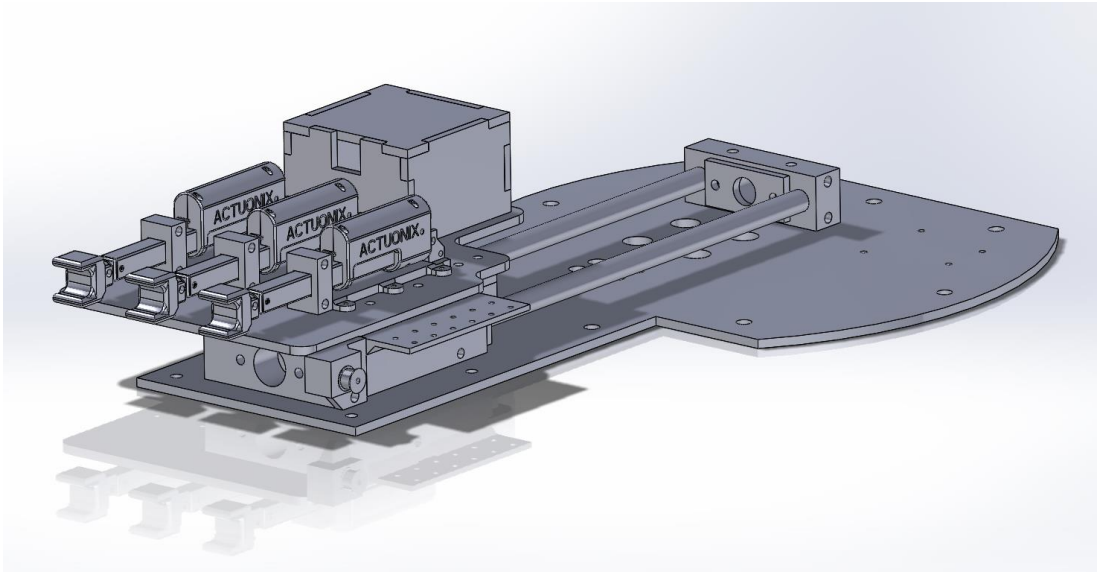


Figure 7.17: Amended Shape Retention Testing System (SRTS) LAPS Carrier

Due to the new LAPS systems increased force output, the SRTS requires reinforcement, the following changes have been made to the SRTS's base/structure (Figure 7.18):

1. The sliding adjustable gripper bend location and support bar holders have been removed and replaced with 16 possible set locations on the SRTS base.
2. Interchangeable support bar holders have been developed and can be added and removed as required (subject to bougie location and support requirements).
3. The bougie chuck holder has been provided with four possible positions to accommodate 60cm and 70cm bougies.
4. The electronics control box has been removed from the base and now located as a separate unit.
5. The calibration ROI has been moved to an alternative location to prevent interference with other components.
6. The interchangeable grids have increased in size to accommodate the larger scale of bougie bends/shapes.

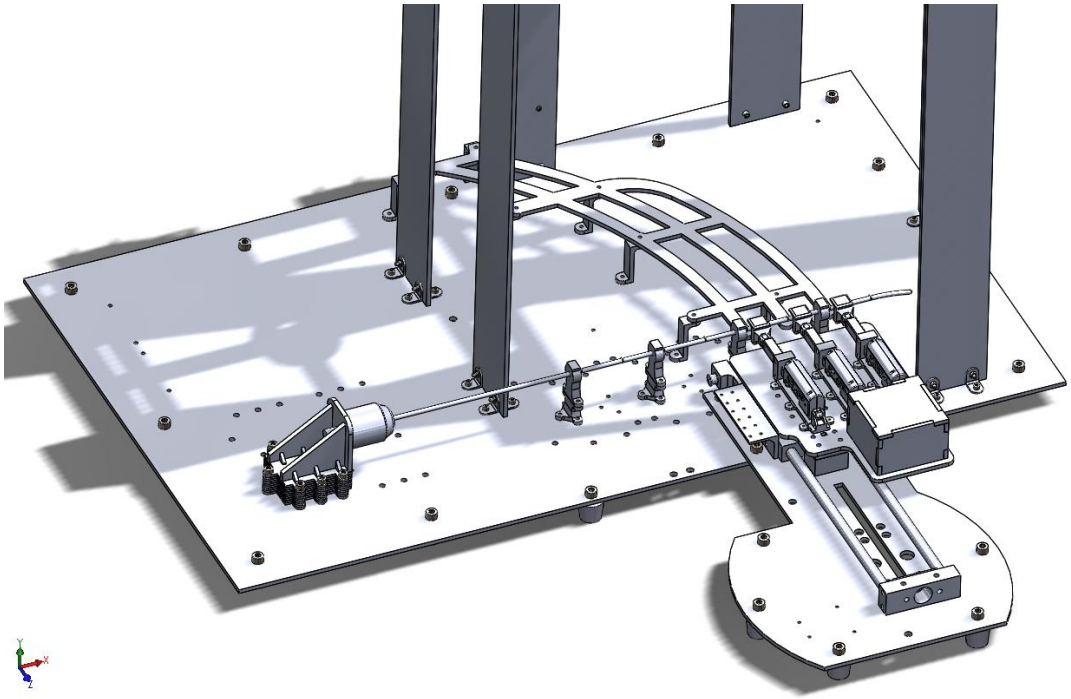


Figure 7.18: Amended Shape Retention Testing System (SRTS) Base

From Figure 7.4, the improvements made to the SRTS construction has resulted in minor alterations being made to the SRTS's functionality, an updated system overview is presented in Figure 7.19.

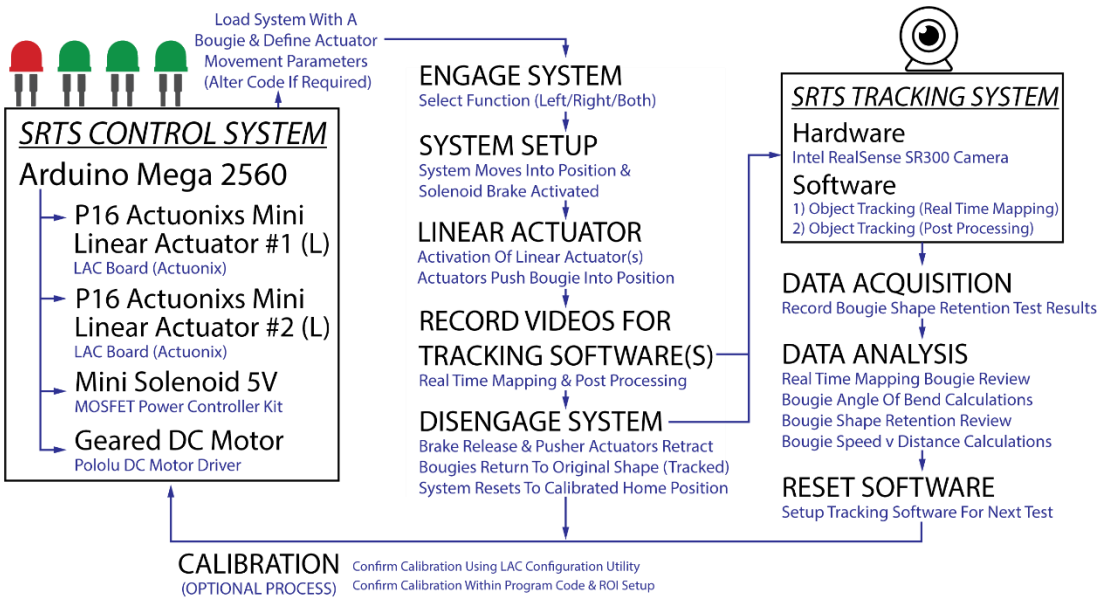


Figure 7.19: Overview Of The Shape Retention Testing System (SRTS) Functions

7.5 Bougie Shape Retention Testing

Based on the shape study conducted by Hodzovic, Wilkes and Latto, (2003) the SRTS will be used to replicate a number of the curvature angles presented. Using 15mm and 7.5mm extensions of the linear actuators, the LAPS generates this approximated angle. Within Hodzovic, Wilkes and Latto, (2003) shape study, the majority of bougies are bent, curved or angled within the first 20cm, however for study completeness an assessment of bougie shape retention will be analysed at 10cm intervals up until 40cm. Sections 7.5.1 – 7.5.2 presents the experimental protocol, methods, results and key findings.

7.5.1 Experimental Protocol & Method

The experimental protocol for the bougie shape retention testing is presented in Figure 6.20. By collecting data on the starting angle position (degrees), the distance moved (mm), angle variation (degrees) and the speed of the bougie movements (mm per second) it is possible to assess the shape retention characteristics of bougie introducers.

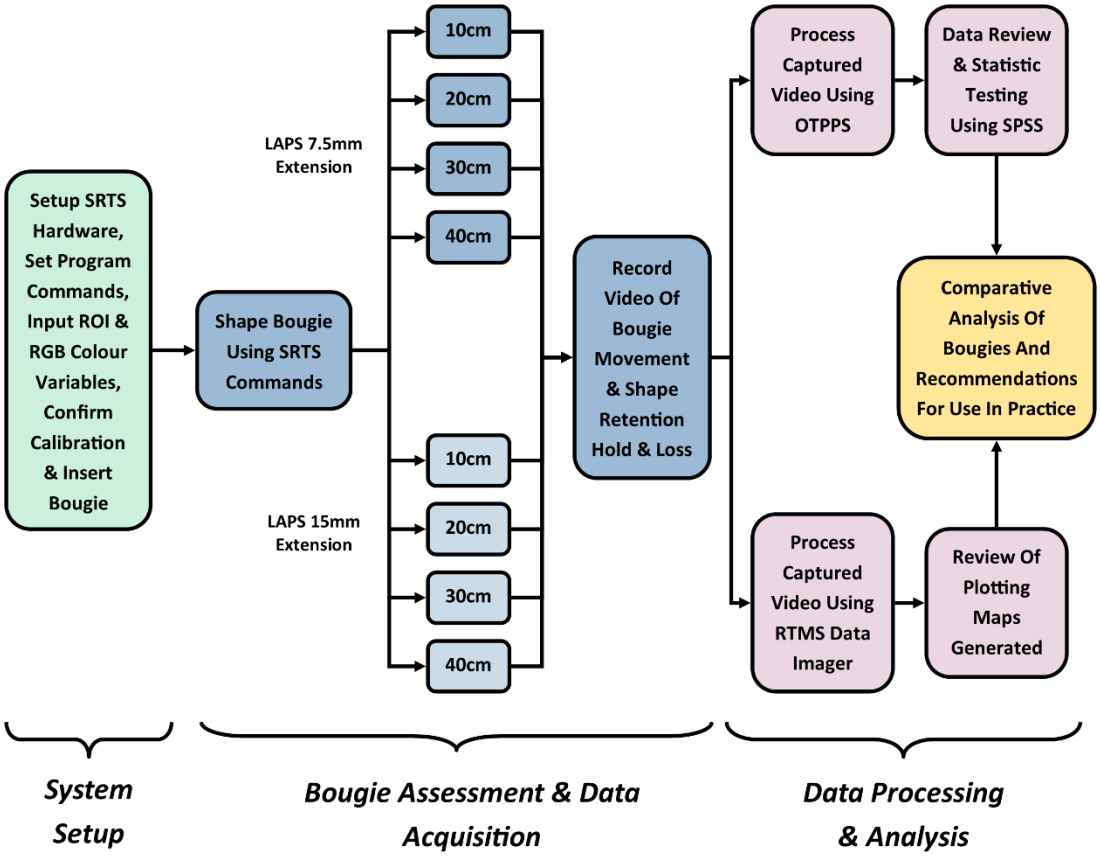


Figure 7.20: Bougie Shape Retention Testing Experimentation Protocol

Nine bougies listed below were assessed using the SRTS; one of each bougie was shaped five times at the four predefined locations and their shape retention monitored and assessed for twenty seconds after release of shaping hold. The arithmetic mean, standard deviation and standard error are then calculated. This was repeated with two different linear actuator shaping distances. After each of the shaping procedures, the bougies are straightened before being tested again.

- Re-Usable Gum Elastic Bougie 15CH 60cm (Coude Tip)
- Portex Single Use Bougie 15FR 70cm (Coude Tip)
- Frova Introducer 14FR 70cm (Coude Tip)
- P3 Medical Tracheal Tube Introducer 15CH 60cm (Coude Tip)
- SunMed Introducer Bougie 15FR 70cm (Coude Tip)
- Pro Breathe Premium ET Tube Introducer 15FR 70cm (Coude Tip)
- InterGuide Tracheal Tube Introducer Bougie 15FR 70cm (Coude Tip)
- Flex-Guide Endotracheal Tube Introducer 15FR 60cm (Coude Tip)
- Developed Steerable Bougie (70cm)

Prior to testing, a red marker is applied to the tip of each of the bougies to act as a tracking mark, this is a distinct colour that can be used for all the bougies. Due to the variance of each bougie, the applied marker will vary slightly in colour which will affect the input parameter of the colour to be tracked. To identify this colour, the bougies are placed in the testing rig and a single frame photo is taken and placed into a GNU Image Manipulation Program (GIMP) where a colour picker tool is used to identify each bougie tip RGB colour code. The RGB colour codes to be tracked (Table 7.3) are then input into the OTPPS for image processing.

Bougies	**Coloured Tip RGB Codes**
SunMed, Portex, Steerable Bougie, Flexguide and GEB	157,68,89
Frova	145,67,86
InterGuide	150,62,76 or 161,82,104
Pro-Breathe	157,68,89 or 156,67,86
P3 Medical	157,68,89 or 158,51,60

Table 7.3: Bougie Coloured Tip Tracking - RGB Colour Codes

To standardise the testing environment to be assessed, ROI's have been predefined and utilised for all the bougies at the assessed bougie bend locations (Table 6.4); the anchor point ROI is also fixed at each location to ensure standardisation.

Bougie Bend Location	Anchor Point ROI Pixel Co-Ordinates	Bougie Tracking Area ROI Pixel Co-Ordinates
10cm	554,500	558,356,157,171
20cm	430,500	449,225,292,278
30cm	306,499	331,68,386,442
40cm	179,499	295,52,416,459

Table 7.4: ROI Tracking Area Setup Co-Ordinates

Use Of Software For Data Collection

As previously described the RTMS and OTPPS is used to collect the data and process the videos collected from the testing of the bougies. After video capture of the bougie shaping, the OTPPS processed videos will be output. Through assessment of the loaded file dialogue box, the start and end frame number at the points where the bougie moves from point “b” to point “c” (Figure 7.10) will need to be input. Due to the initial snap back of the bougie, the OTPPS displays this initially as invalid tracking (Figure 7.21) before reconnecting and fully tracking the bougie movement. The frame prior to this initial snap back will need inputting into the image processing calculator followed by the end frame “x” number which will be a set number of milliseconds within the testing protocol.

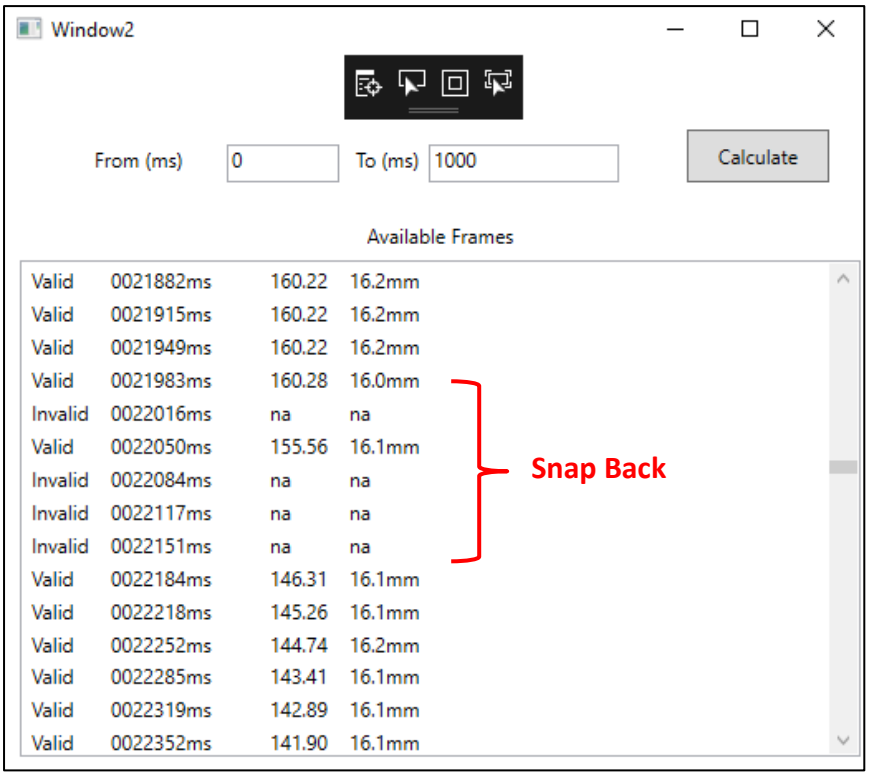


Figure 7.21: Invalid Bougie Tracking Due To Initial Bougie Snap Back

The built in RTMS will be used to collect plotting maps of the shaped bougies. As each bougie is pushed by the LAPS, X, Y coordinates are collated and saved as .csv files. Using the X, Y co-ordinates these are processed by the data imager and plotting maps are generated. As the testing will be completed on the bougies multiple times at the same location, only a sample of the plotting maps are presented as typically the plotting maps for each bougie are similar in behaviour. Every time the location changes a plotting map will be recorded and presented.

Data Assessment

Assessment of the shape retention of bougies is be based around two key variables, the change in angle (degrees) and the speed of change (mm/s). The arithmetic mean of the five-readings collected at each distance are compared; therefore, a suitable statistical analysis test comparing the means between two unrelated groups on the same continuous, dependent variable must be utilised. Before a suitable statistic test can be used to compare the bougie introducer range against the designed steerable bougie, it is important to assess the normality of the data collected and whether a parametric of non-parametric test should be utilised. Depending on the outcome of the normality test, an independent t-test will be utilised, however, if non-parametric data is collected the Mann-Whitney U Test will be used.

The plotting maps collected and processed by the RTMS will be visually compared to assess the levels of shape retention loss within two stages these being the initial snap back followed by the gradual loss of shape. Full assessment of the RTMS plotting maps is an entirely new study and will be completed as further work; these RTMS plotting maps require individualised detailed analysis of over 300 charts at different stages with the assessment of angle variations and heat maps plotted.

7.5.2 Results & Analysis

After completion of the video capture and data processing, the results from the image processing and statistical analysis are presented below. The use of statistical analysis tests is used to compare the assessed bougies versus the steerable bougie, comparative levels of significance can be assessed to validate the steerable bougies design and structure which aims to promote improved shape retention characteristics. For detail on the full data collection and a comprehensive sample of the bougie plotting maps for each bougie at all distances, refer to Appendix S.

Shaping Of Bougies - 15mm Linear Actuator Extension

Utilising the SRTS's LAPS to shape the bougies with 15mm linear actuator extension, this typically shapes the bougies to an angle of 65-80° at the 10cm and 20cm distances and 50-70° at the 30cm and 40cm distances. Upon review it is immediately obvious that the steerable bougie and P3 medical introducer bougie demonstrates significantly less shape retention loss compared to the other bougies (Figure 7.22). These two bougies utilise an internal lumened structure which clearly helps reduce the amount of shape retention loss. The Flexguide bougie performs poorly compared to all the bougies; this bougies increased rigidity results in a high degree of angle loss. This bougie therefore requires even greater initial shaping to ensure the curvature required by the anaesthetist can be achieved after considering shaping loss. Also, the GEB's soft and floppy structure does not promote shape retention hold and this also performs poorly at the 10cm and 20cm shaped distances.

Many of the middle of the range bougie introducers such as the ProBreathe, InterGuide and Frova bougie present a similar pattern of shape retention hold and loss across the four distances, with shape retention loss becoming less as the bougie shaped distance moves further away from the tip. The SunMed bougie also presents this pattern at the 30cm and 40cm distances, but its increase of shape retention loss is unexplained at the 20cm shaping distance; this is the only bougie that performs in this manner at the first two shaping distances.

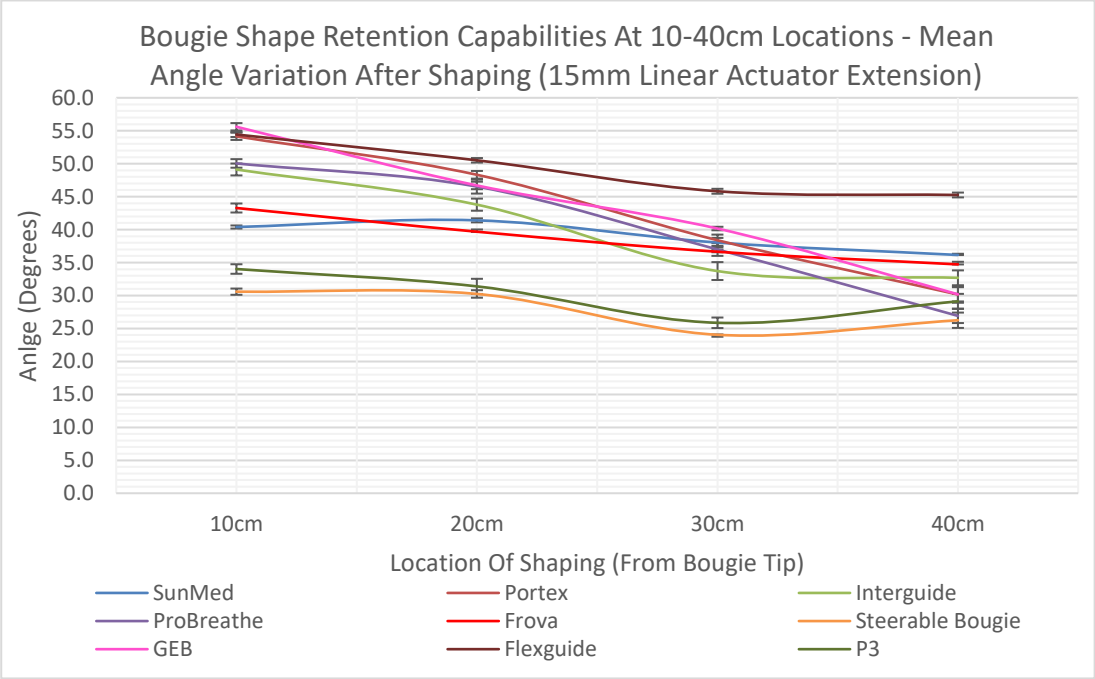


Figure 7.22: 15mm Extension - Bougie Shape Retention Angle Variation

The speed of shape retention loss (Figure 7.23) can be linked to the rigidity of the bougie introducers. The Flexguide which is the stiffest of all the bougies presents the highest mean speed of shape retention loss of all the bougies. The initial snap back of this bougie is quick and as the bougie loses a large proportion of its shaping, this speed change is amplified.

The GEB interestingly performs poorly in this category also. Although the GEB displays a limited initial snap back, its consistent progressive shape loss at a constant speed contributes to this bougie being one of the worst performing; this does level out at 40cm but again the likelihood of a need to shape bougies at this distance is not often required.

As with mean angle variation (Figure 7.22), there are two distinct groupings of the data with the steerable bougie and P3 Medical bougie presenting significantly lower values at the 10cm, 20cm and 30cm shaped distances. Again, due to their lumened internal structures, this helps slow the speed of shape retention loss down, however it is important to note that due to a level of main bougie shaft stiffness required to achieve this, the initial snap back of these bougies can be quite significant. Typically, the bougies either hold or only lose a small amount of shaping over the recorded period.

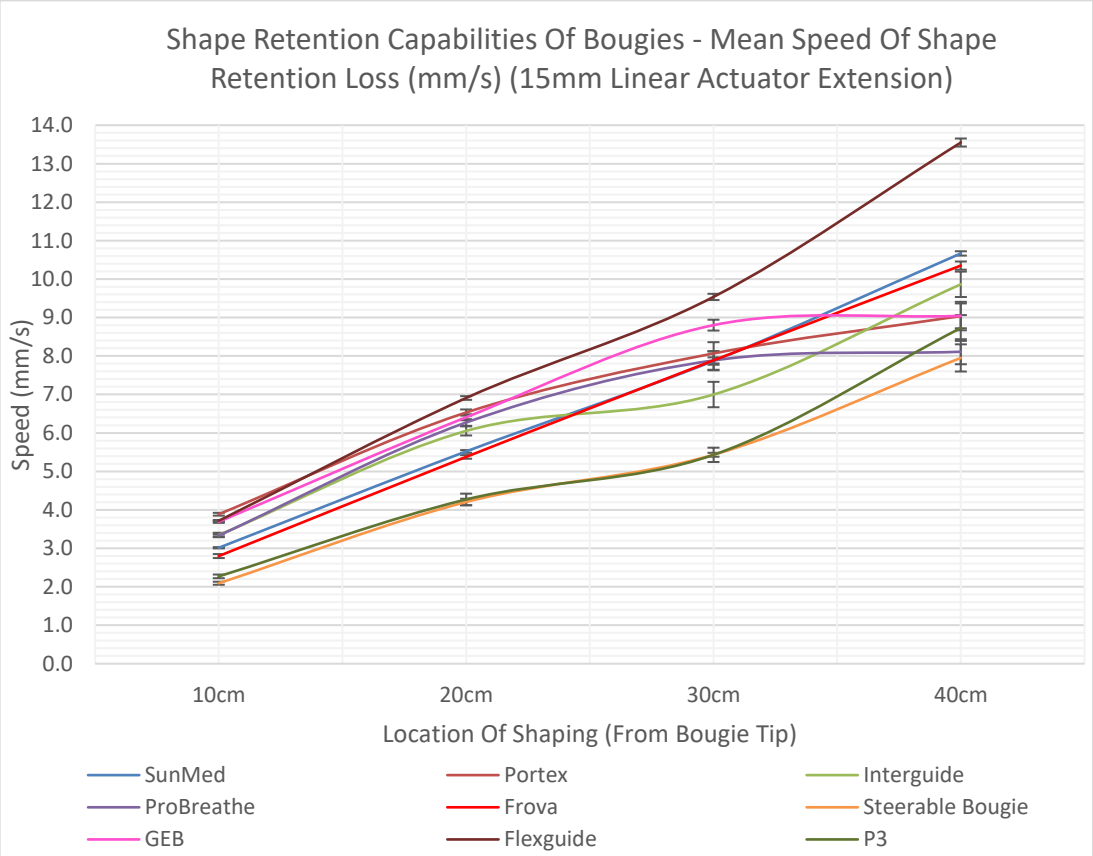


Figure 7.23: 15mm Extension - Bougie Mean Speed Of Shape Retention Loss

Before deciding on the statistic test to be used to compare the steerable bougie against the other assessed bougies, it is necessary to test for normality within the data sets. Testing for normality using SPSS, the data collected has been confirmed as being normally distributed across all the data sets recorded. As such the independent t-test will be used for comparative assessment as this compares the means between two unrelated groups on the same continuous dependent variable (Statistics.laerd.com, n.d.). Tables 7.5 – 7.12 present the results from the independent t-tests for comparative analysis of shape retention loss/angle variation and the speed of shape retention loss.

When comparing the steerable bougie to the other eight bougies using the independent t-tests, for the 10cm, 20cm and 30cm shaping distances, statistically significant results are presented in favour of the steerable bougie apart from the P3 Medical bougie. When comparing the steerable bougie against the P3 Medical bougie, the steerable bougie is still superior at these distances but the independent t-test demonstrates a lesser degree of significance. The steerable bougie speed of shape retention loss is similar to the P3 Medical bougie at 20cm and is outperformed at 30cm (Table 7.12). When considering the 40cm shaped distance, the steerable bougies out performs all the bougies, however, superior data significance not always achieved.

	Comparison Of Bougie		**Independent t-test**
Distance Held From The Tip (cm)	**SunMed Introducer Bougie (Coude Tip)**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	40.398 [0.233]	30.586 [0.472]	<0.0001
20	41.410 [0.305]	30.240 [0.569]	<0.0001
30	38.040 [0.703]	24.046 [0.297]	<0.0001
40	36.154 [0.185]	26.252 [1.162]	<0.001
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	3.014 [0.016]	2.092 [0.039]	<0.0001
20	5.518 [0.036]	4.204 [0.085]	<0.0001
30	7.872 [0.025]	5.432 [0.051]	<0.0001
40	10.666 [0.056]	7.950 [0.353]	<0.001

Table 7.5: SunMed Introducer Bougie v Steerable Bougie: 15mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**Portex Single Use Bougie**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	54.158 [0.550]	30.586 [0.472]	<0.0001
20	48.324 [0.582]	30.240 [0.569]	<0.0001
30	38.994 [0.855]	24.046 [0.297]	<0.0001
40	30.152 [1.245]	26.252 [1.162]	<0.051
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	3.886 [0.037]	2.092 [0.039]	<0.0001
20	6.530 [0.080]	4.204 [0.085]	<0.0001
30	8.066 [0.294]	5.432 [0.051]	<0.001
40	9.038 [0.370]	7.950 [0.353]	<0.066

Table 7.6: Portex Single Use Bougie v Steerable Bougie: 15mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**InterGuide Tracheal Tube Introducer**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	49.126 [0.901]	30.586 [0.472]	<0.0001
20	43.790 [0.920]	30.240 [0.569]	<0.0001
30	33.713 [1.355]	24.046 [0.297]	<0.0001
40	32.690 [1.130]	26.252 [1.162]	<0.004
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	3.346 [0.057]	2.092 [0.039]	<0.0001
20	6.052 [0.118]	4.204 [0.085]	<0.0001
30	6.998 [0.330]	5.432 [0.051]	<0.008
40	9.864 [0.331]	7.950 [0.353]	<0.004

Table 7.7: Portex Single Use Bougie v Steerable Bougie: 15mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**Pro Breathe Premium ET Tube Introducer**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	50.044 [0.650]	30.586 [0.472]	<0.0001
20	46.530 [1.062]	30.240 [0.569]	<0.0001
30	39.990 [0.973]	24.046 [0.297]	<0.0001
40	26.916 [1.091]	26.252 [1.162]	<0.688
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	3.332 [0.030]	2.092 [0.039]	<0.0001
20	6.270 [0.086]	4.204 [0.085]	<0.0001
30	7.884 [0.243]	5.432 [0.051]	<0.0001
40	8.110 [0.325]	7.950 [0.353]	<0.748

Table 7.8: Pro Breathe Premium ET Tube Introducer v Steerable Bougie: 15mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**Frova Introducer**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	43.284 [0.682]	30.586 [0.472]	<0.0001
20	39.686 [0.341]	30.240 [0.569]	<0.0001
30	36.648 [0.338]	24.046 [0.297]	<0.0001
40	34.726 [0.396]	26.252 [1.162]	<0.001
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	2.798 [0.052]	2.092 [0.039]	<0.0001
20	5.376 [0.047]	4.204 [0.085]	<0.0001
30	7.886 [0.079]	5.432 [0.051]	<0.0001
40	10.350 [0.107]	7.950 [0.353]	<0.002

Table 7.9: Frova Introducer v Steerable Bougie: 15mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**Re-Usable Gum Elastic Bougie**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	55.608 [0.556]	30.586 [0.472]	<0.0001
20	46.706 [0.569]	30.240 [0.569]	<0.0001
30	40.166 [0.267]	24.046 [0.297]	<0.0001
40	30.184 [1.080]	26.252 [1.162]	<0.038
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	3.690 [0.028]	2.092 [0.039]	<0.0001
20	6.406 [0.078]	4.204 [0.085]	<0.0001
30	8.802 [0.141]	5.432 [0.051]	<0.0001
40	9.044 [0.323]	7.950 [0.353]	<0.052

Table 7.10: Re-Usable Gum Elastic Bougie v Steerable Bougie: 15mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**Flex-Guide Endotracheal Tube Introducer**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	54.430 [0.379]	30.586 [0.472]	<0.0001
20	50.518 [0.342]	30.240 [0.569]	<0.0001
30	45.822 [0.373]	24.046 [0.297]	<0.0001
40	45.258 [0.367]	26.252 [1.162]	<0.0001
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	3.716 [0.020]	2.092 [0.039]	<0.0001
20	6.908 [0.048]	4.204 [0.085]	<0.0001
30	9.536 [0.081]	5.432 [0.051]	<0.0001
40	13.550 [0.105]	7.950 [0.353]	<0.0001

Table 7.11: Flex-Guide Endotracheal Tube Introducer v Steerable Bougie: 15mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**P3 Medical Tracheal Tube Introducer**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	34.024 [0.722]	30.586 [0.472]	<0.005
20	31.392 [1.151]	30.240 [0.569]	<0.387
30	25.864 [0.801]	24.046 [0.297]	<0.079
40	29.116 [1.139]	26.252 [1.162]	<0.116
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	2.270 [0.048]	2.092 [0.039]	<0.021
20	4.270 [0.151]	4.204 [0.085]	<0.715
30	5.430 [0.186]	5.432 [0.051]	<0.992
40	8.728 [0.335]	7.950 [0.353]	<0.149

Table 7.12: P3 Medical Tracheal Tube Introducer v Steerable Bougie: 15mm LAPS Extension – Independent t-test Results

Shaping Of Bougies - 7.5mm Linear Actuator Extension

A shorter linear actuator extension test was also conducted to assess the less severe angles/curvatures sometimes required for bougie introducers. The same protocol and data processing methods have been utilised as with the 15mm linear actuator extension testing. Utilising the SRTS's LAPS to shape the bougies with 7.5mm linear actuator extension, this typically shapes the bougies to an angle of 20-35^{o} at the 10cm and 20cm distances and 15-30^{o} at the 30cm and 40cm distances.

Upon review it is immediately obvious that a similar trend is observed as with the 15mm linear actuator extension testing with the steerable bougie demonstrating significantly less shape retention loss compared to the other bougies at 10cm, 20cm and 30cm shaping distances (Figure 7.24). Interestingly this is not the case with the P3 Medical bougie as this has grouped this time with the other single use rigid bougies. The minimal shaping has not allowed the lumened core of this bougie to be shaped enough to generate a satisfactory level of shape retention hold.

The Flexguide bougie again performs poorly compared to all the bougies; this bougies increased rigidity results in a high degree of angle loss therefore requiring greater initial shaping. Interestingly the GEB, Portex, Flexguide and SunMed all increase in the amount of shape retention loss at 20cm before decreasing again. These four bougies are either solid or hollow core bougies and are at either end of the scale of rigidity.

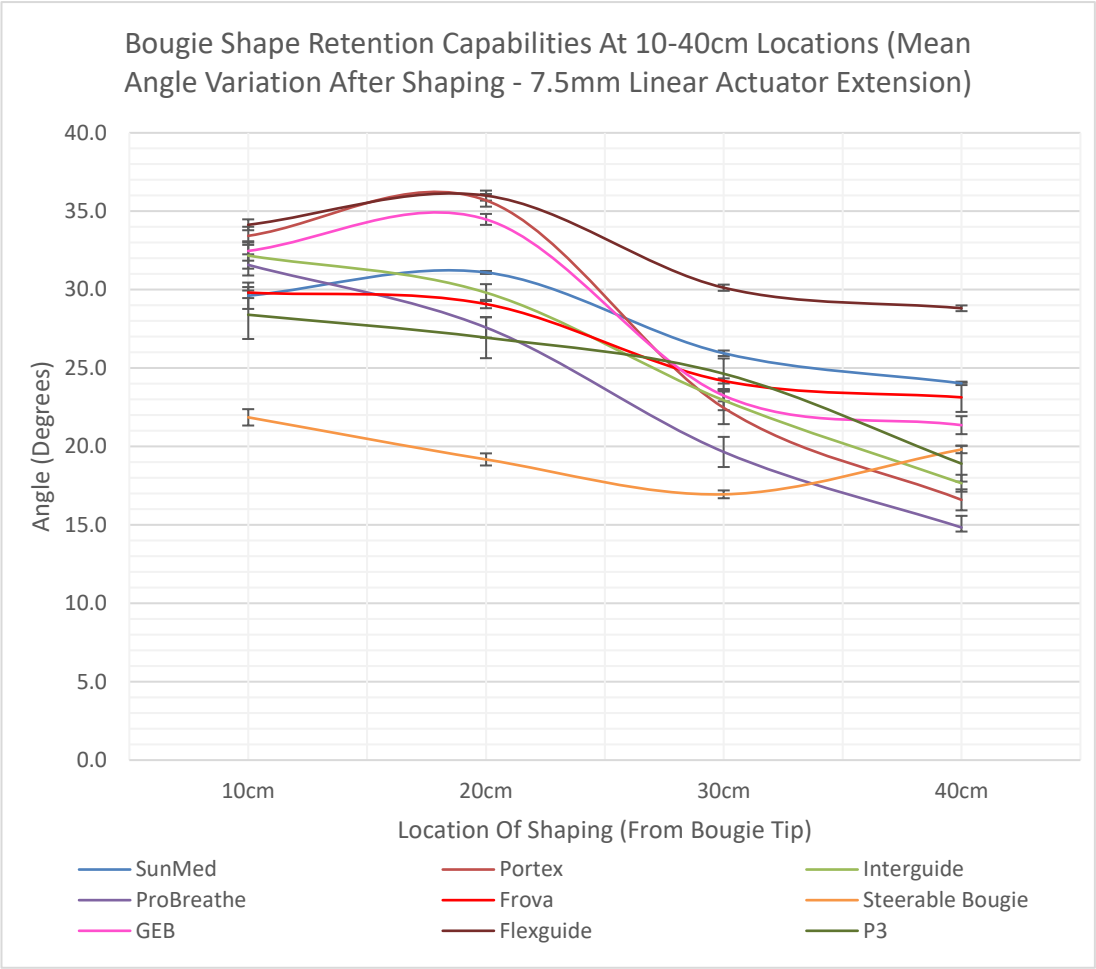


Figure 7.24: 7.5mm Extension - Bougie Shape Retention Angle Variation

The speed of shape retention loss (Figure 7.25) can again be linked to the rigidity of the bougie introducers. When comparing the speed of shape retention loss between 15mm and 7.5mm linear actuator extension tests, a 2-4 mm/s reduction is noticed, this is ultimately down to the distance travelled and the time this takes. Many of the bougies follow a similar pattern as the 15mm linear actuator extension test, however there is a noticeable peak for the Portex and GEB at the 20cm bend location.

Again, due to the lumened internal structure and copper wire core, the steerable bougie has the lowest speed of shape retention loss at 10cm, 20cm and 30cm distances. However, the 40cm shaping location has an increased mean speed of shape retention loss compared to four other bougies, this is due to the steerable bougie increasing in mean angle variation at 40cm.

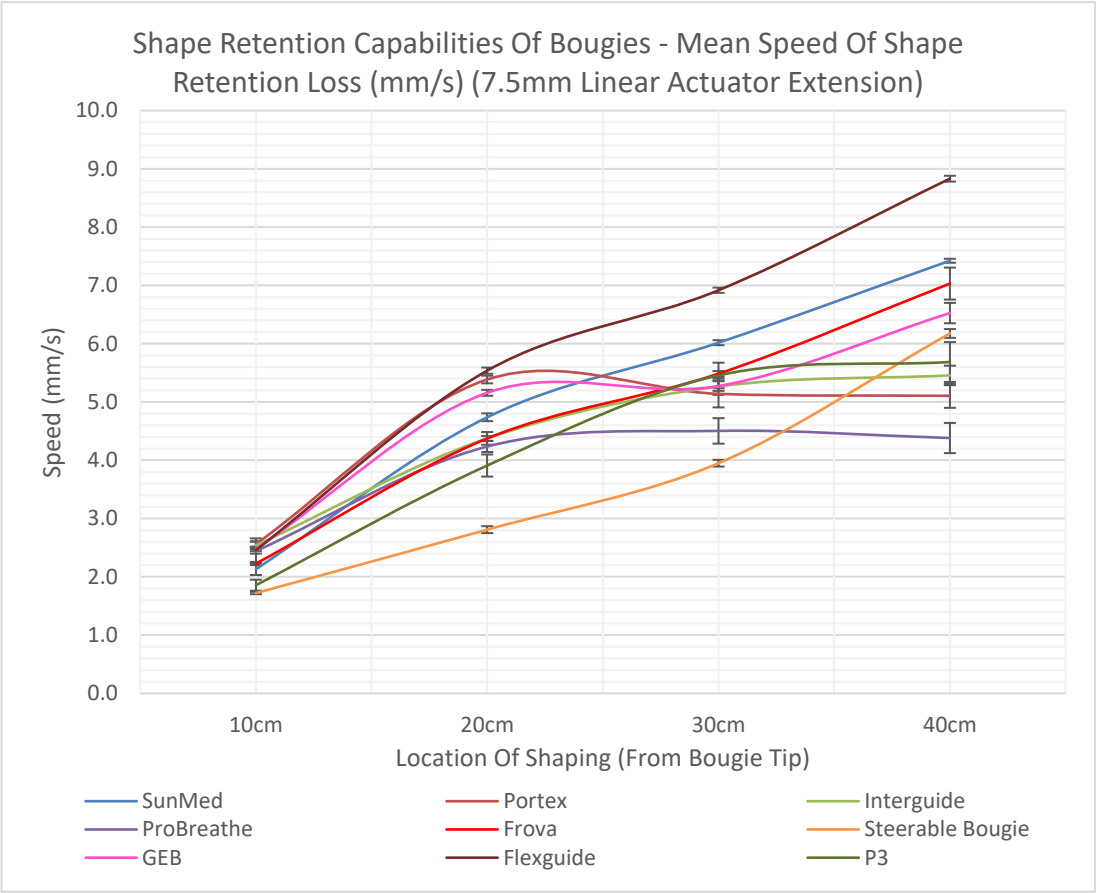


Figure 7.25: 7.5mm Extension - Bougie Mean Speed Of Shape Retention Loss

Tables 7.13 – 7.20 present the results from the independent t-tests for comparative analysis of shape retention loss/angle variation and the speed of shape retention loss for the 7.5mm extension tests. When comparing the steerable bougie to the other eight bougies using the independent t-tests, statistically significant results are presented in the favour of the steerable bougie at the 10cm, 20cm and 30cm bend locations, apart from the P3 Medical bougie at the 10cm shaping location. The lumened structure and stiffness of the P3 Medical bougie although different to the steerable bougie contributes to making the proximal end of the shaft stiffer thus this variable becomes less of an influence as the shaping location moves further away from the bougie tip.

Considering the mean speed of shape retention loss, the independent t-tests present statistically significant results for all the bougies at 10cm, 20cm and 30cm bend locations, with the exceptions being the P3 Medical bougie at 10cm and ProBreathe at 30cm. At the 40cm bend location distance, the Frova, SunMed and FlexGuide present statistically significant results in favour of the steerable bougie; this also out performs the GEB but a p-value of <0.156 does not present significance. The other four bougies out perform the steerable bougie at the 40cm location.

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**SunMed Introducer Bougie (Coude Tip)**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	29.612 [0.840]	21.858 [0.522]	<0.0001
20	31.098 [0.094]	19.174 [0.386]	<0.0001
30	25.944 [0.176]	16.948 [0.249]	<0.0001
40	24.024 [0.079]	19.808 [0.237]	<0.0001
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	2.132 [0.101]	1.722 [0.020]	<0.014
20	4.738 [0.067]	2.810 [0.060]	<0.0001
30	6.018 [0.043]	3.950 [0.058]	<0.0001
40	7.424 [0.019]	6.176 [0.075]	<0.0001

Table 7.13: SunMed Introducer Bougie v Steerable Bougie: 7.5mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**Portex Single Use Bougie**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	33.432 [0.578]	21.858 [0.522]	<0.0001
20	35.696 [0.404]	19.174 [0.386]	<0.0001
30	22.462 [1.037]	16.948 [0.249]	<0.005
40	16.596 [0.464]	19.808 [0.237]	<0.006
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	2.562 [0.046]	1.722 [0.020]	<0.0001
20	5.386 [0.066]	2.810 [0.060]	<0.0001
30	5.140 [0.233]	3.950 [0.058]	<0.006
40	5.106 [0.104]	6.176 [0.075]	<0.004

Table 7.14: Portex Single Use Bougie v Steerable Bougie: 7.5mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**InterGuide Tracheal Tube Introducer**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	32.172 [0.834]	21.858 [0.522]	<0.0001
20	29.812 [0.539]	19.174 [0.386]	<0.0001
30	22.942 [0.629]	16.948 [0.249]	<0.0001
40	17.656 [0.281]	19.808 [0.237]	<0.012
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	2.540 [0.065]	1.722 [0.020]	<0.0001
20	4.376 [0.109]	2.810 [0.060]	<0.0001
30	5.266 [0.144]	3.950 [0.058]	<0.0001
40	5.456 [0.064]	6.176 [0.075]	<0.009

Table 7.15: InterGuide Tracheal Tube Introducer v Steerable Bougie: 7.5mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**Pro Breathe Premium ET Tube Introducer**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	31.578 [0.674]	21.858 [0.522]	<0.0001
20	27.586 [0.649]	19.174 [0.386]	<0.0001
30	19.650 [0.961]	16.948 [0.249]	<0.046
40	14.834 [0.430]	19.808 [0.237]	<0.001
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	2.442 [0.044]	1.722 [0.020]	<0.0001
20	4.236 [0.095]	2.810 [0.060]	<0.0001
30	4.504 [0.219]	3.950 [0.058]	<0.063
40	4.382 [0.098]	6.176 [0.075]	<0.002

Table 7.16: Pro Breathe Premium ET Tube Introducer v Steerable Bougie: 7.5mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**Frova Introducer**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	29.814 [0.351]	21.858 [0.522]	<0.0001
20	29.082 [0.265]	19.174 [0.386]	<0.0001
30	24.180 [0.164]	16.948 [0.249]	<0.0001
40	23.132 [0.073]	19.808 [0.237]	<0.021
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	2.226 [0.023]	1.722 [0.020]	<0.0001
20	4.374 [0.041]	2.810 [0.060]	<0.0001
30	5.486 [0.045]	3.950 [0.058]	<0.0001
40	7.032 [0.020]	6.176 [0.075]	<0.033

Table 7.17: Frova Introducer v Steerable Bougie: 7.5mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**Re-Usable Gum Elastic Bougie**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	21.855 [0.619]	21.858 [0.522]	<0.0001
20	34.480 [0.350]	19.174 [0.386]	<0.0001
30	23.244 [0.366]	16.948 [0.249]	<0.0001
40	21.358 [0.164]	19.808 [0.237]	<0.052
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	2.478 [0.038]	1.722 [0.020]	<0.0001
20	5.158 [0.051]	2.810 [0.060]	<0.0001
30	5.274 [0.083]	3.950 [0.058]	<0.0001
40	6.526 [0.037]	6.176 [0.075]	<0.156

Table 7.18: Re-Usable Gum Elastic Bougie v Steerable Bougie: 7.5mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**Flex-Guide Endotracheal Tube Introducer**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	34.136 [0.347]	21.858 [0.522]	<0.0001
20	35.996 [0.320]	19.174 [0.386]	<0.0001
30	30.124 [0.198]	16.948 [0.249]	<0.0001
40	28.812 [0.089]	19.808 [0.237]	<0.0001
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	2.458 [0.202]	1.722 [0.020]	<0.0001
20	5.538 [0.053]	2.810 [0.060]	<0.0001
30	6.918 [0.045]	3.950 [0.058]	<0.0001
40	8.832 [0.020]	6.176 [0.075]	<0.0001

Table 7.19: Flex-Guide Endotracheal Tube Introducer v Steerable Bougie: 7.5mm LAPS Extension – Independent t-test Results

	Comparison Of Bougie		Independent t-test
Distance Held From The Tip (cm)	**P3 Medical Tracheal Tube Introducer**	**Developed Steerable Bougie**	**p-value**
	Shape Retention Loss/Angle Variation (Degrees) (Mean [Standard Error])		
10	28.400 [1.545]	21.858 [0.522]	<0.011
20	26.940 [1.311]	19.174 [0.386]	<0.003
30	24.638 [0.974]	16.948 [0.249]	<0.001
40	18.906 [0.436]	19.808 [0.237]	<0.480
	Speed Of Shape Retention Loss (mm/s) (Mean [Standard Error])		
10	1.856 [0.095]	1.722 [0.020]	<0.203
20	3.910 [0.190]	2.810 [0.060]	<0.003
30	5.456 [0.219]	3.950 [0.058]	<0.002
40	5.686 [0.098]	6.176 [0.075]	<0.228

Table 7.20: P3 Medical Tracheal Tube Introducer v Steerable Bougie: 7.5mm LAPS Extension – Independent t-test Results

RTMS Plotting Maps

For each test completed, an RTMS plotting map was captured; a sample of one from each distance recorded for each bougie is presented in Appendix S. The RTMS plotting maps depict two pieces of information that can inform the user on the behaviour of a bougie. Every bougie has an initial snap back which the tracking system presents when the mechanism that

shapes the bougie has been removed, this is then followed by a gradual loss of shape over a sustained period (Figure 7.26).

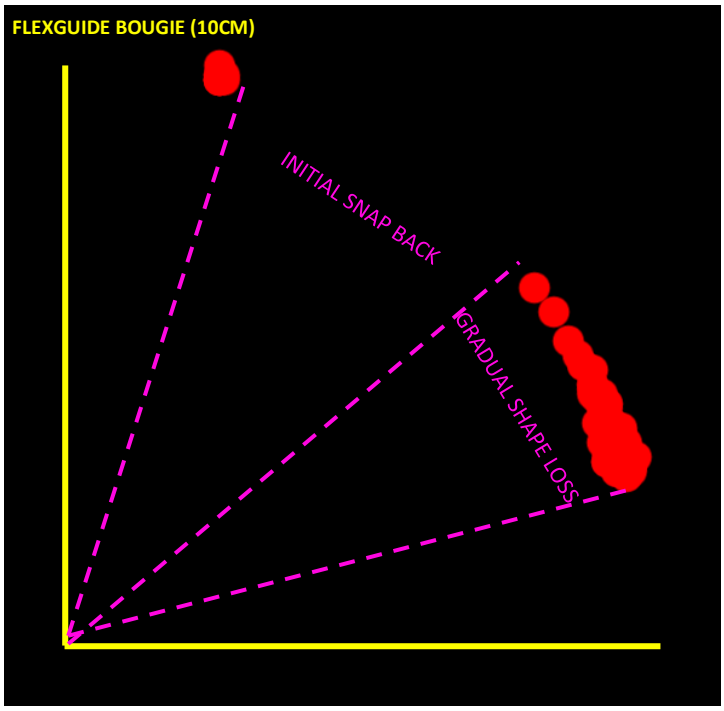


Figure 7.26: Bougie Shaping Behaviour – RTMS Plotting Map

The initial snap back and gradual shape loss varies depending on the amount of shaping/angle of bend applied to the bougie, the material properties and the physical characteristics. When considering the RTMS plotting maps, the bougies can typically be split into three distinct categories.

1. Soft Solid or Soft Hollow Core Bougies (GEB and Portex) – Typically present a small snap back and longer gradual shape retention loss.
2. Rigid Bougies (Flexguide, InterGuide, SunMed, Frova and ProBreathe) – Typically present larger snap backs than soft core bougies with progressive gradual shape retention loss depending on bougie shaft rigidity.
3. Lumen Core Bougies (P3 and Developed Steerable Bougie) – Typically present a large initial snap back with minimal gradual shape loss afterwards.

Table 7.21 presents a sample of the plotting maps for the SunMed bougie (rigid bougie), the GEB (soft core bougie) and the developed steerable bougie for the 15mm & 7.5mm extension test. The full of plotting maps for all the bougies assessed are presented in Appendix S for both the 15mm and 7.5mm extension tests.

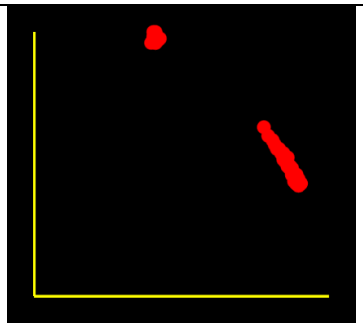
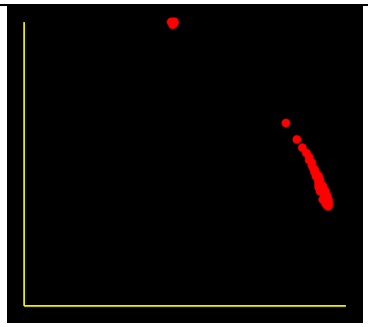
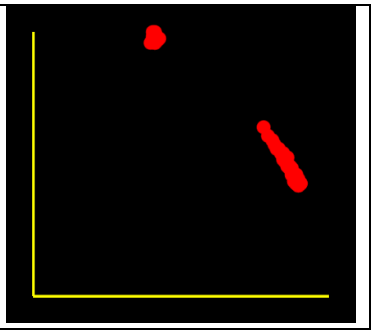
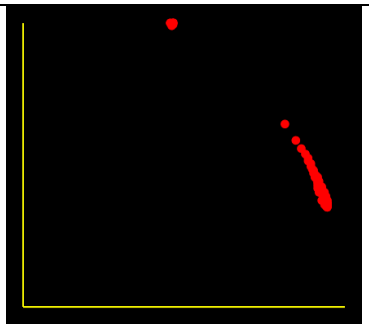
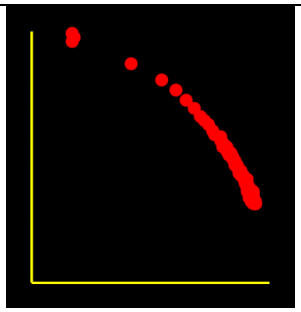
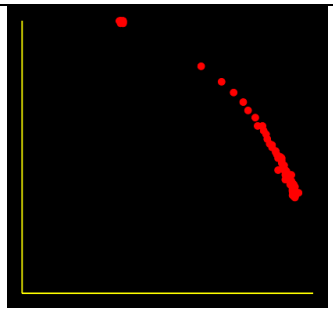
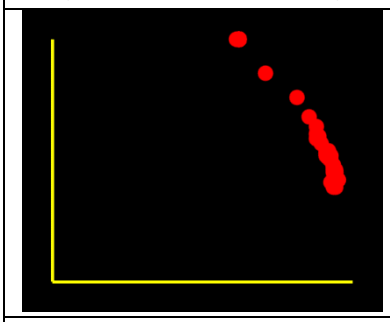
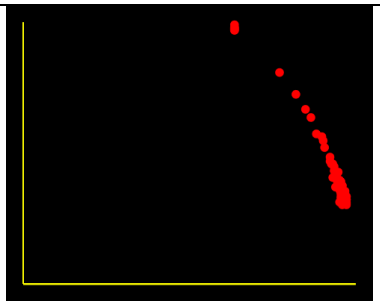
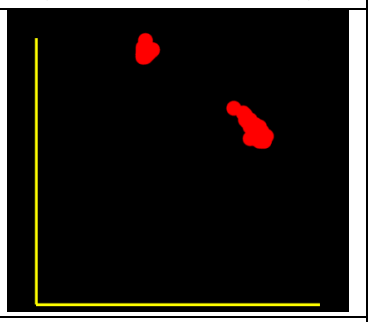
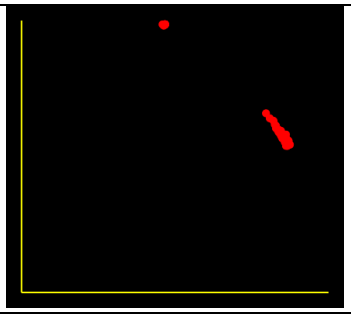
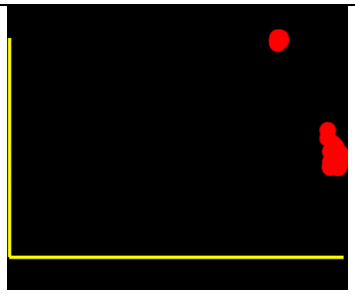
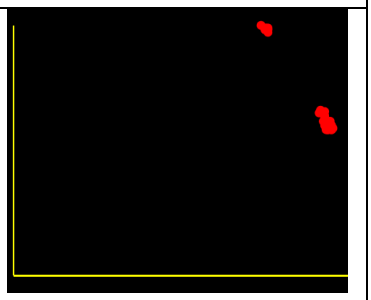
		
SunMed - 10cm Bend Location (15mm Extension Test)	SunMed 20cm Bend Location (15mm Extension Test)	SunMed 10cm Bend Location (7.5mm Extension Test)
		
SunMed 20cm Bend Location (7.5mm Extension Test)	GEB 10cm Bend Location (15mm Extension Test)	GEB 20cm Bend Location (15mm Extension Test)
		
GEB 10cm Bend Location (7.5mm Extension Test)	GEB 20cm Bend Location (7.5mm Extension Test)	Steerable Bougie 10cm Bend Location (15mm Extension Test)
		
Steerable Bougie 20cm Bend Location (15mm Extension Test)	Steerable Bougie 10cm Bend Location (7.5mm Extension Test)	Steerable Bougie 20cm Bend Location (7.5mm Extension Test)

Table 7.21: Sample Of The RTMS Plotting Maps

The SunMed bougie (rigid bougie) typically demonstrates large initial snap back and progressive gradual shape retention loss. This is typical for both the 15mm and 7.5mm linear actuator extension tests, with the main difference being the starting angle. The progressive shape loss does appear to be less on the 7.5mm extension tests, however with reduced shaping this also presents an overall shallower angle of bougie bend.

The GEB (soft core bougie) presents a significantly smaller snap back compared to the rigid single use bougies, the initial snap back does however increase as the shaped distance is further increased from the bougie tip but not to the degree of any single use bougie. This variance is not noted with the rigid core bougies.

The steerable bougie has been designed to provide a greater level of shape retention compared to devices currently available on the market. This level of improvement has been statistically proven. This is also visually demonstrated as shown in Table 7.21 where the snap back and shape loss is clearly reduced. A short initial snap back is observed at the 10cm bend location, but larger snap backs are observed for the remaining bend locations; this is consistent across both the 15mm and 7.5mm LAPS extension parameters. The P3 Medical bougie also demonstrates a similar trend in shape retention snap back and gradual shape loss, however with this bougie being more rigid than the steerable bougie, the overall shape retention loss is greater at 10cm, 20cm and 30cm bend locations but less than the steerable bougie at 40cm; this is only the case when less sharp curvature angles are created.

7.6 Discussion: Bougie Use Considerations - Shape Retention vs Tip Pressure

The experiments conducted utilising the SRTS have demonstrated that the type of internal construction of bougie introducers has a significant effect on the performance of the shape retention characteristics of bougie introducers. Figure 7.27 presents the internal structure of the range of bougie introducers assessed. The two bougies that demonstrate the least amount of shape retention loss (Steerable Bougie and P3 Medical Bougie) have internal structures that promote shape retention shaping and hold through the use of central or multi lumens.

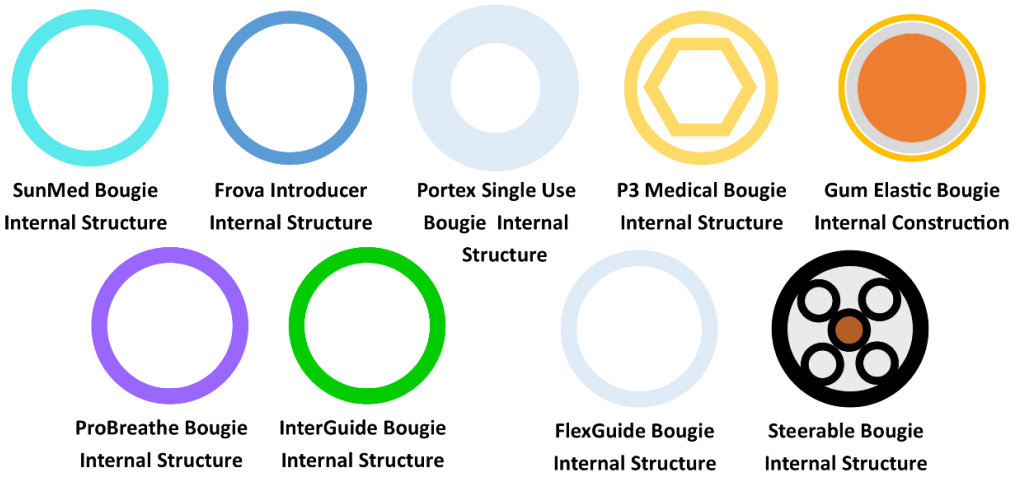


Figure 7.27: Bougie Internal Construction

Although the re-usable GEB has an internal solid woven structure, this fails to compare to the other two bougies that have internal structures due to its soft inner core rather than rigid structure. Softer internal structures are optimal for reducing tip pressure but conversely the this can make the GEB too floppy and soft to hold shape retention. The steerable bougie is not as rigid as the P3 Medical bougie; the steerable bougies uses a copper central core wire to promote shape retention whereas the P3 uses a rigid extruded hexagonal polymer structure. The shape retention of the hollow single use bougies varies between manufacturers due to the variance in bougie wall thickness (Table 7.22) and their material choice which ultimately affects their rigidity and shape hold.

Bougie/Introducer	Bougie Extrusion Wall Thickness (mm)
Portex Single Use Bougie 15FR 70cm	1.50
Frova Introducer 14FR 70cm	0.90
P3 Medical Tracheal Tube Introducer 15CH 60cm	1.00
SunMed Introducer Bougie 15FR 70cm	1.60
Flex-Guide Endotracheal Tube Introducer 15FR 60cm	1.10
Pro Breathe Premium ET Tube Introducer 15FR 70cm	0.75
InterGuide Tracheal Tube Introducer Bougie 15FR 70cm	0.80

Table 7.22: Single Use Bougies Extrusion Wall Thickness

One of the key findings from the testing completed using the SRTS is the identification that the steerable bougie is superior to all the bougies when shaped at 10cm, 20cm and 30cm from the bougie tip. Although the steerable bougie has an initial snap back that is larger than some of the bougies, this is still smaller than most of the single use bougies available. The reusable GEB's snap back is however less but its overall shape loss is more significant. Figure 7.28 demonstrates that internal structures significantly reduce the snap back and overall shape retention loss.

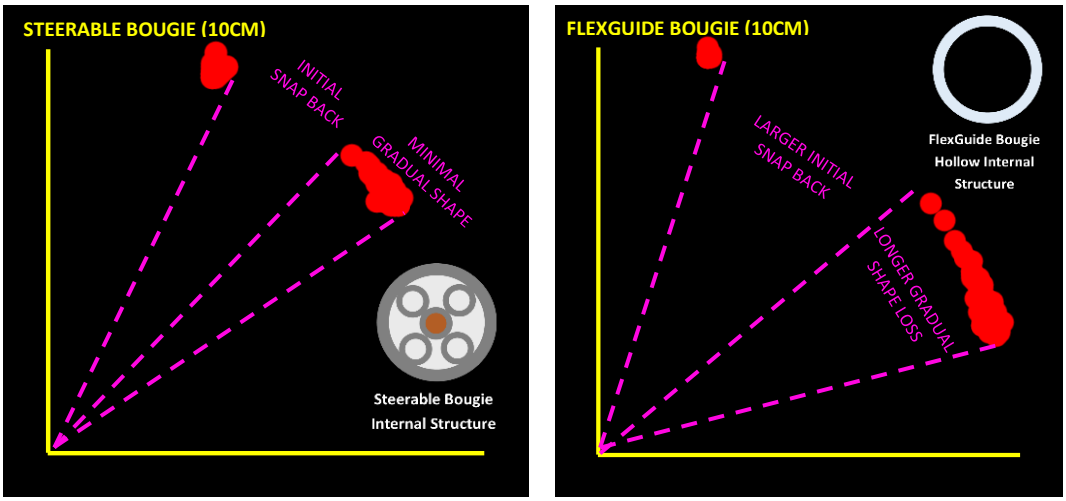


Figure 7.28: Comparison Of Initial Snap Back & Gradual Shape Loss Between Hollow and Internal Featured Bougie Introducers

The steerable bougies shape retention is however out performed when shaped at 40cm from the bougie tip compared to the ProBreathe, Portex Single Use, GEB and P3 Medical bougies. This is not of concern as the likelihood of a bougie being shaped at 40cm for insertion into a patient of a depth of 40cm or even being held at 40cm by an anaesthetist is extremely rare; the distance held survey conducted (Chapter 6, Section 6.9) and the distance held survey results presented by Hodzovic et al., (2004) also confirm this.

Based on the testing completed within the SRTS study and considering the tip pressure testing conducted in Chapter 6, it is now possible to rank the bougies in order based on two criteria, shape retention and tip pressure. The 40cm grip and shaping location is excluded from this comparison as anaesthetists typically do not shape bougies at the 40cm distance and do not hold bougies at this distance either. Using equalised weighting for importance, a cumulative rank is calculated (Table 7.23). Interestingly the gold standard GEB does not rank well overall. Although this ranks 2nd behind the steerable bougie with the least amount of tip pressure generated, its shape retention performance is poor ranking 9th, 7th and 8th out of 9 assessed bougies at the 10cm, 20cm and 30cm distances, thus affecting its overall rank.

Bougie	Distance Held & Shaped	Mean Tip Pressure (N)	Mean Shape Retention Loss (15mm Extension) (Degrees)	Combined Comparative Rank *	Overall Rank
Re-Usable Gum Elastic Bougie 15CH 60cm	10cm	4.746	55.608	7th	6th
	20cm	1.868	46.706	= 2nd	
	30cm	0.952	40.166	= 5th	
Portex Single Use Bougie 15FR 70cm (Coude Tip)	10cm	5.550	54.158	= 5th	7th
	20cm	3.096	48.324	= 5th	
	30cm	1.788	38.394	7th	
Frova Introducer 14FR 70cm (Coude Tip)	10cm	8.196	43.284	= 5th	3rd
	20cm	3.598	39.686	= 2nd	
	30cm	1.876	36.648	= 3rd	
P3 Medical Tracheal Tube Introducer 15CH 60cm (Coude Tip)	10cm	10.632	34.024	= 3rd	5th
	20cm	5.946	31.392	= 5th	
	30cm	2.998	25.864	= 5th	
SunMed Introducer Bougie 15FR 70cm (Coude Tip)	10cm	10.808	40.398	7th	8th
	20cm	6.038	41.410	8th	
	30cm	3.604	38.040	8th	
Pro Breathe Premium ET Tube Introducer 15FR 70cm (Coude Tip)	10cm	4.328	50.044	2nd	2nd
	20cm	2.238	46.530	= 2nd	
	30cm	1.608	36.990	2nd	
InterGuide Tracheal Tube Introducer Bougie 15FR 70cm (Coude Tip)	10cm	5.568	49.126	= 3rd	4th
	20cm	5.568	43.790	= 5th	
	30cm	1.608	33.716	= 3rd	
Flex-Guide Endotracheal Tube Introducer 15FR 60cm (Coude Tip)	10cm	7.168	54.430	9th	9th
	20cm	3.944	50.518	9th	
	30cm	2.104	45.822	9th	
Developed Steerable Bougie (70cm)	10cm	1.194	34.024	1st	1st
	20cm	0.769	31.392	1st	
	30cm	0.726	25.864	1st	

Table 7.23: Bougie Tip Pressure (N) Versus Shape Retention Loss (Degrees) – Equal Weighted Ranking

**Rank is calculated at each distance by ranking the bougies in ascending order based for each criteria, the sum of the two criteria rank score provides the overall score, the lowest score equates to the highest ranked bougie, the highest score equates to the lowest ranked bougie.*

When considering equalised weighted rankings, the ProBreathe and Frova bougie introducers are the two commercially available bougies that rank highly after the developed steerable bougie. When double factored weightings are used for the two criteria's (Table 7.24) the 2nd and 3rd place ranked bougies alter; the steerable bougie still ranks 1st regardless.

Bougie	Equal Weighted Rank	Tip Pressure Double Weighted Bias Ranking	Shape Retention Double Weighted Bias Ranking
Re-Usable Gum Elastic Bougie 15CH 60cm (Coude Tip)	6th	**3rd**	7th
Portex Single Use Bougie 15FR 70cm (Coude Tip)	7th	5th	8th
Frova Introducer 14FR 70cm (Coude Tip)	3rd	6th	=5th
P3 Medical Tracheal Tube Introducer 15CH 60cm (Coude Tip)	5th	7th	**2nd**
SunMed Introducer Bougie 15FR 70cm (Coude Tip)	8th	9th	6th
Pro Breathe Premium ET Tube Introducer 15FR 70cm (Coude Tip)	**2nd**	**2nd**	=5th
InterGuide Tracheal Tube Introducer Bougie 15FR 70cm (Coude Tip)	4th	4th	**3rd**
Flex-Guide Endotracheal Tube Introducer 15FR 60cm (Coude Tip)	9th	8th	9th
Developed Steerable Bougie (70cm)	**1st**	**1st**	**1st**

Table 7.24: Bougie Tip Pressure (N) Versus Shape Retention Loss (Degrees) – Varied Weighted Rankings

Overall, this comparison identifies that anaesthetists and health care professionals must be clear on the physical properties of bougie introducers they require and how important each of these are in rank order. If a bougie with low tip pressure is required to reduce the likelihood of trauma, the GEB is the device to use, however, its poor shape retention will ultimately mean the anaesthetist may have to reshape the bougie multiple times. If shape retention is purely the focus, then the P3 medical bougie is the optimum choice, however, this bougie can generate significant levels of tip pressure as previously highlighted in Chapter 6. The ProBreathe ET tube introducer and InterGuide bougies provide the user with a happy medium in terms of physical properties, however first pass success rates and simulated intubation study data must also be considered, for example the ProBreathe's success rate for tracheal placement is significantly lower compared to the Portex single use bougie, Frova and GEB (Janakiraman et., 2009). If a study on the success rates of simulated intubations for all nine of the tested bougies could be added to this comparison, this would add further value and contribute to the definition of the optimum bougie for use.

CHAPTER 8 – THE STEERABLE BOUGIE: DESIGN VERIFICATION

8.1 Introduction

The development of the steerable bougie has considered a substantial number of parameters as described throughout the first seven chapters. Based on the successful identification of operational parameters and safety factors, the final design development of the steerable bougie has now been completed. This chapter presents the assembly of all the individual components developed to construct the steerable bougie, this is based on incorporating the user feedback collected from the anaesthetists within the project team. The steerable bougie has been developed to comply with TRL 5, however to commercialise this product, further development and verification work is required within TRL 6-9. Sections 8.2 and 8.3 describe the two main components of the steerable bougie, the bougie shaft with steerable tip and the controller.

8.2 Steerable Bougie: Bougie Shaft & Steerable Tip

The developed steerable bougie presented in Figure 8.1 has been designed to be 600mm in length and 5mm in diameter to ensure that the device can be utilised with endotracheal tubes of 7mm in diameter or greater. Originally as per the PDS, the bougie was to be 700mm in length, however user feedback during the tip pressure study suggested that the greater shape retention of the device left the user wanting a shorter bougie due to the excess length obstructing their operative control, hence the length of the steerable bougie now being set at 600mm.

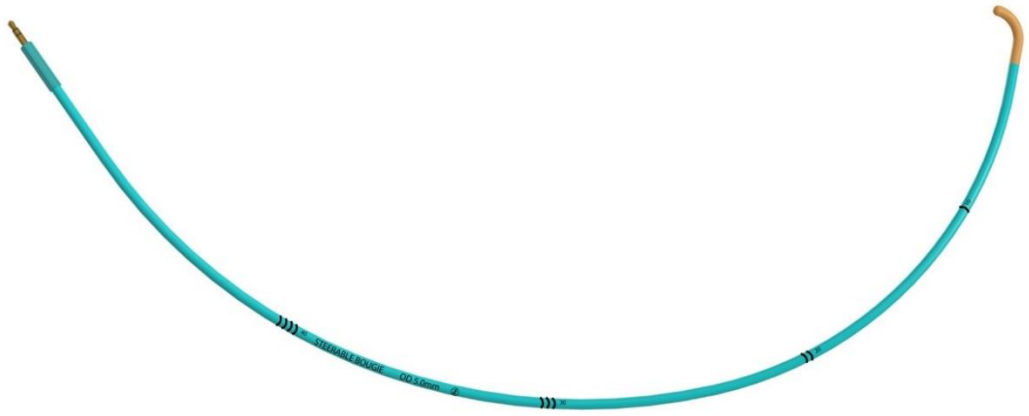


Figure 8.1: Steerable Bougie

The steerable bougie consists of three main parts, a flexible steerable tip, the multi lumen main shaft (with central core wire to promote bougie shape retention) and a stereo jack connector that connects to the steerable bougie controller by a stereo jack port.

The stereo jack connector attached to the steerable bougie multi lumen shaft (Figure 8.2), is 3mm in diameter and is housed within a 6.5mm diameter case attached to the bougie shaft, thus providing enough tolerance to allow the railroading of an ET tube over the steerable bougie. The internal construction of the casing allows the two control wires (Flexinol® 0.15mm) and the two ground wires to be individually separated and connected to crimps that are then soldered to the stereo jack connector. This connector is then attached to the stereo port/hub (Figure 8.3) which is fastened to the steerable bougie controller by the operator thus providing the power supply to the control wires that are individually activated and drive the directional control of the bougie tip.

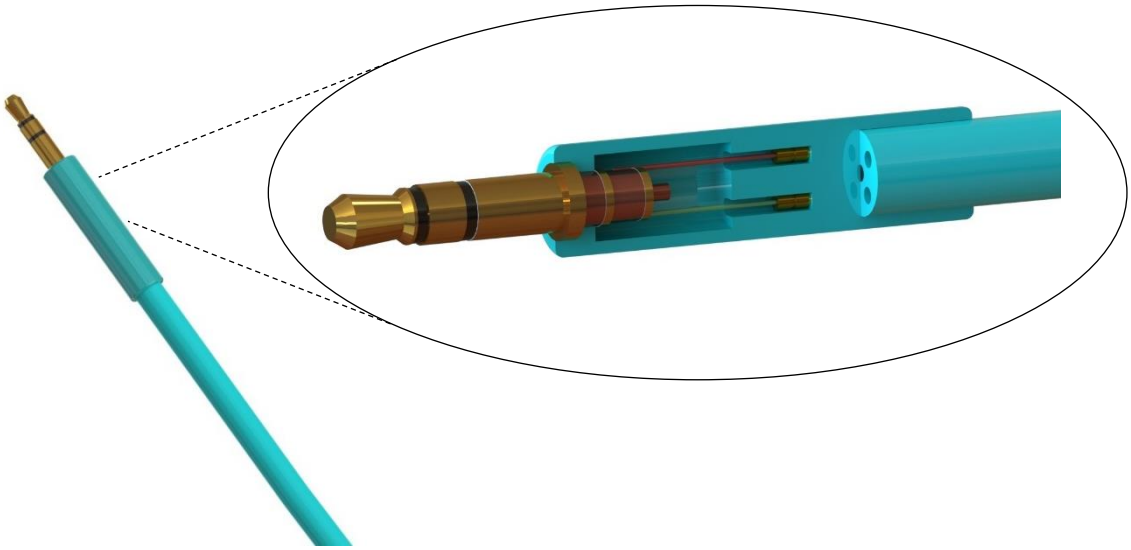


Figure 8.2: Cross Section Of Steerable Bougie Stereo Jack Casing

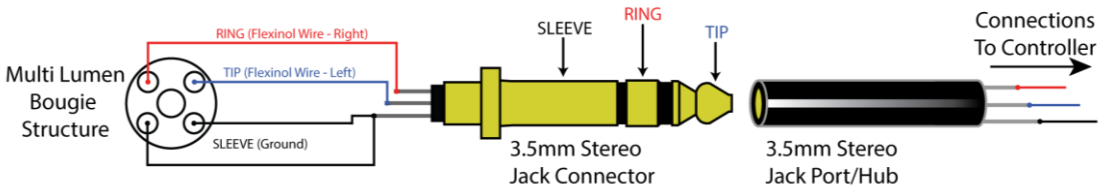


Figure 8.3: Connection Of Stereo Jack & Port To Bougie Shaft & Control Wires

As the steerable bougie has developed, the use of a multi lumen tubing structure has ensured shape retention has been improved compared to existing bougies available on the market. Due to the expense required to produce the tooling and availability of the multi lumen tubing during the development process, readily available six-lumen tubing has been utilised for modelling; one of the lumens consisted of the central copper core to help promote shape retention. The designed steerable bougie however only requires a five-lumen structure, including the central copper core wire (Figure 8.4).

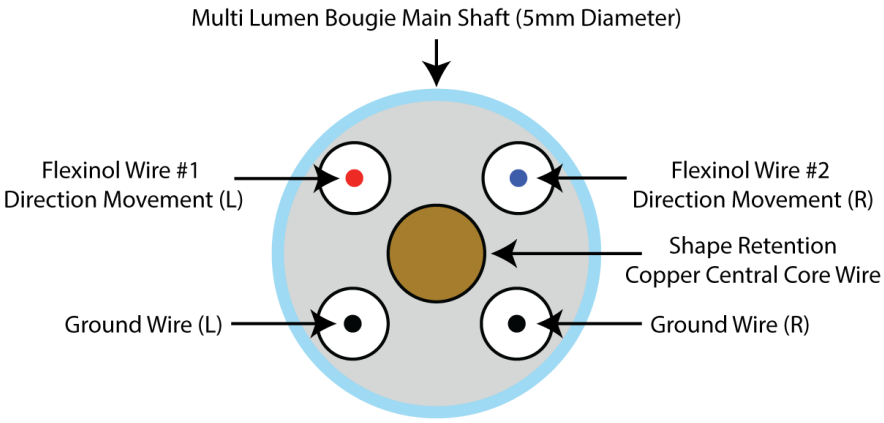


Figure 8.4: Steerable Bougie Shaft Cross Section

Four of the lumens house the two ground wires and two control wires that are crimped throughout the device (Figure 8.5). Originally, the central copper core wire was to act as the ground wire but to ensure the device does not rely on the copper central wire remaining a complete structure, this will now solely be used as a shaping wire to promote shape retention. Concerns were raised after the repeated shaping of the steerable bougie regarding the structural integrity of this wire, whereas free and loose ground wires can be threaded through the lumens.

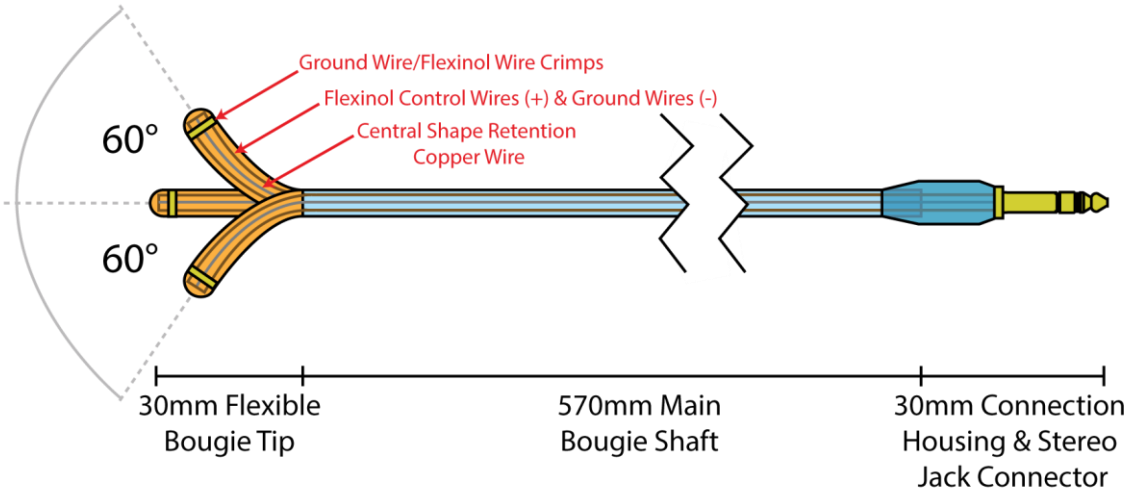


Figure 8.5: Steerable Bougie Shaft Setup

The recommended material used for the steerable bougies main shaft structure is a medical grade of polyethylene (PE) which is often used within bougies and similar medical devices and is approved for short-term contact with the human body. PE is a commonly used material utilised within other medical devices such as catheters, feeding tubes, drainage tubes and surgical instruments (Hcltech.com, 2013).

Minor amendments have been made to the steerable tip internal construction previously presented within Chapter 6. The amendments have resulted in the addition of isolated slots for the control wire and ground wire crimps located within the tip of the bougie (Figure 8.6). The tip has also seen a deeper slot for the shape retention central core wire integrated to allow for a sturdier connection during the modelling phase.

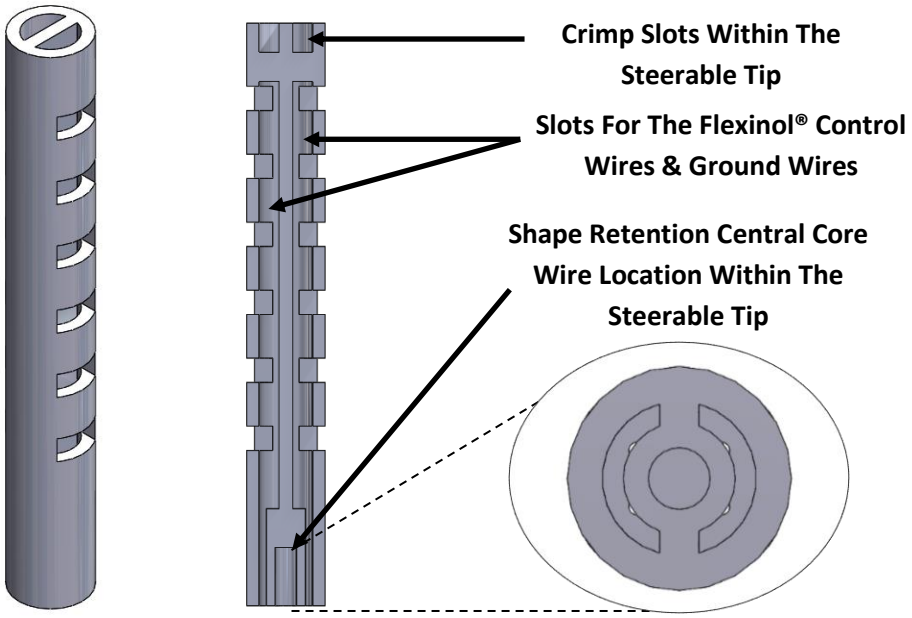


Figure 8.6: Steerable Tip Internal Construction

The crimps located within the steerable tip and the stereo jack connector (Figure 8.7) are fundamental to the directional control of the steerable tip. The control wires must be tight to ensure that when contracted the steerable tip flexes in the desired direction, this is promoted by the slots within the steerable tip insert (Figure 8.6).

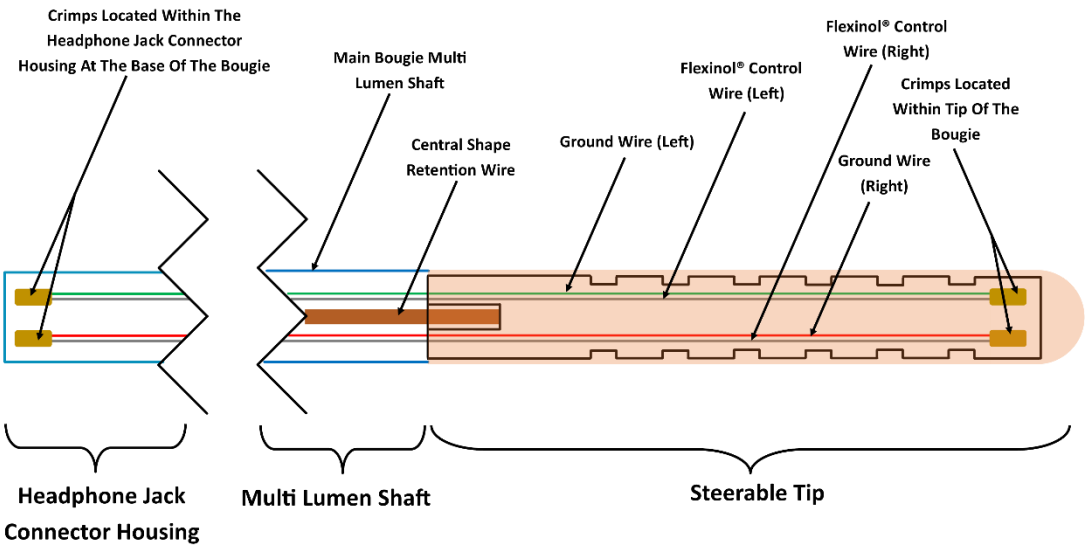


Figure 8.7: Internal Construction & Layout Of The Control & Ground Wires Within The Steerable Bougie

As further minor amendments have been made to the steerable tips internal structure, it is important to again validate the tip pressure generated by the newly developed tip to confirm that no significant increases in tip pressure have occurred. The amended tip has been tested in accordance with the protocols set out in Chapter 6 with the results presented in Figure 8.8. This has been compared to the tip pressure study results from the skilled and un-skilled user testing. Figure 8.8 demonstrates that no significant difference has occurred with tip pressure results demonstrating that the steerable bougie still has the lowest tip pressure of all the bougies compared.

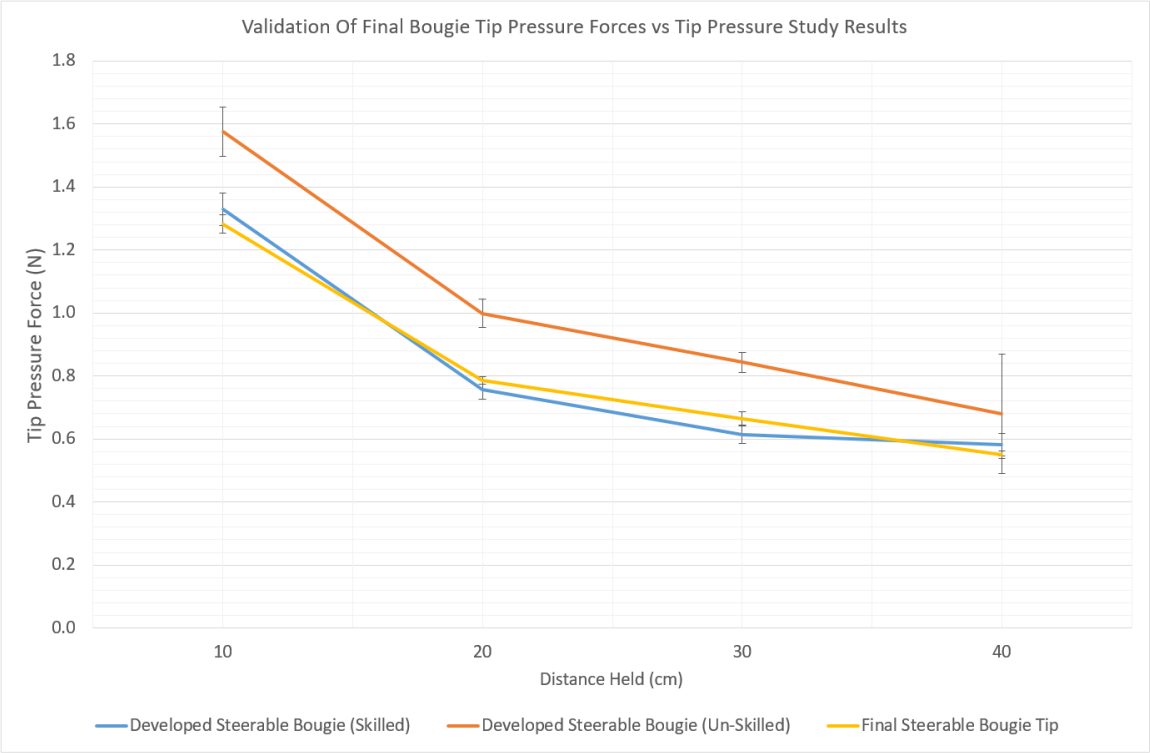


Figure 8.8: Tip Pressure Forces Of Adjusted Steerable Tip Compared To Tip Pressure Studies

8.3 Steerable Bougie Control Handle

The final element of the steerable bougie design is the development of the controller handle. The controller connects to the steerable bougie using the headphone jack and socket connection, however the size of the controller is ultimately dictated by the electronic components required to ensure the device is functional. As previously described, the steerable bougie tip movement is controlled using individual Flexinol wires crimped at the top and bottom of the bougie. Using Ohms law and the technical data information provided by the manufacturer, it is possible to calculate the required voltage input necessary to drive the Flexinol wires:

Calculating Voltage Using Ohms Law (Solution)

I = 410 (mA) V = ??

R = 55 Ohm/Meter (600mm Flexinol Wire Lengths = 33 Ohms)

V = 410mA x 33 Ohms

= 13.53V

To achieve the required voltage input from a single cell Li-Po battery or array of button cell batteries used to power the controller, it will be necessary to boost the input voltage from 3.3V to the required 13.53V. A power boost convertor module will be used to complete this function; a power control switch will also be integrated within this element of the circuit. An AdaFruit Feather is utilised as a control module to provide pulse width modulation to the Flexinol wires which turns the current on and off to the Flexinol wire very quickly, thus preventing the wire from overheating and failing.

A sliding potentiometer has been used to provide variable input values based on its position that will dictate the amount of Flexinol contraction thus affecting the directional control movement of the steerable tip. The MOSFET power control units linked to the AdaFruit module provides a logic signal that switches the signal and voltage input on and off to the Flexinol wires. Finally, an LED is connected to an analogue pin and indicates when the battery supply to the control module is running low or needs recharging. This functions by assessing the voltage input value and checks when this drops below a certain tolerance, once this tolerance is exceeded the LED indicator will illuminate indicating device charging or swapping of the batteries is required. Considering the defined components and their dimensions, these will define the shape and size of the controller. The controller wiring setup is presented in Figure 8.9.

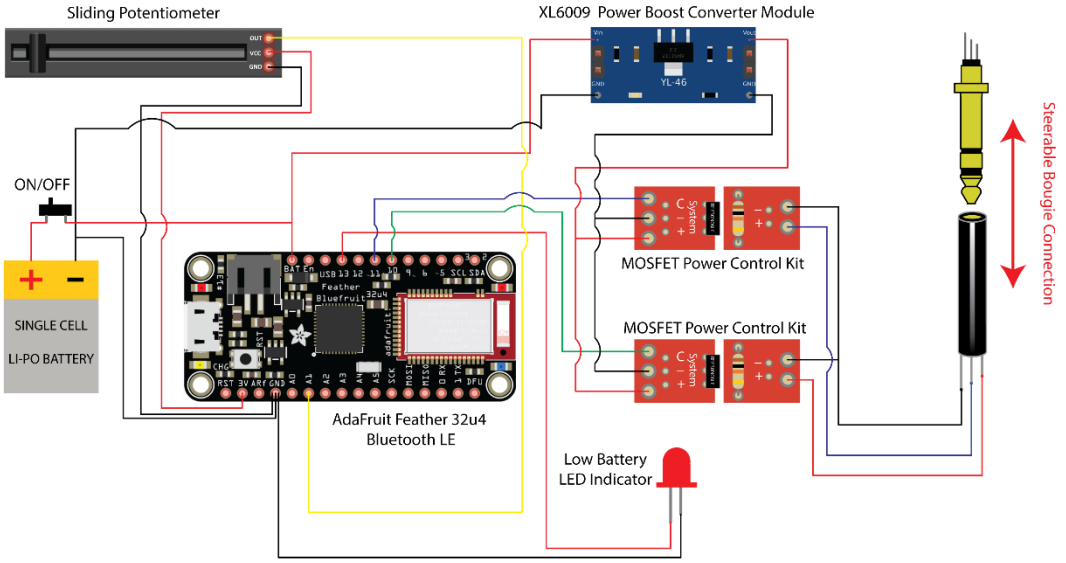


Figure 8.9: Controller Electronic Wiring Setup

Based on the feedback collected in Chapter 4, 5 and 6, the controller required further development to ensure this could be adjustable and attached based on the type of laryngoscope used. Ideally, this should also consider video laryngoscopes, however due to the location of the video laryngoscope connector ports this may not always be possible, as the device would fail to be ergonomic and thus make the video laryngoscope unusable. Three final development controller concepts have been created (Figure 8.10 a, b and c) and utilise three different attachment methods:

1. Laryngoscope encompassing plastic wings operated by a ratchet mechanism and quick release button that allows the clips to encompass the laryngoscope (Figure 8.10a).
2. A watchstrap styled button system with a curved wing to encompass the laryngoscope to add grip (Figure 8.10b).
3. A stretchable rubber strap and hook system similar to a tourniquet (Figure 8.10c).

The controller shape and size has been dictated by the sliding potentiometer control board and the electronic power control module boards required to drive the steerable bougie control wires. Inevitably, as the electronic boards are combined onto printed PCB's there is potential that this size could decrease further. In addition, the sliding potentiometer used could be further reduced, however this is dependent on the potentiometer track size.

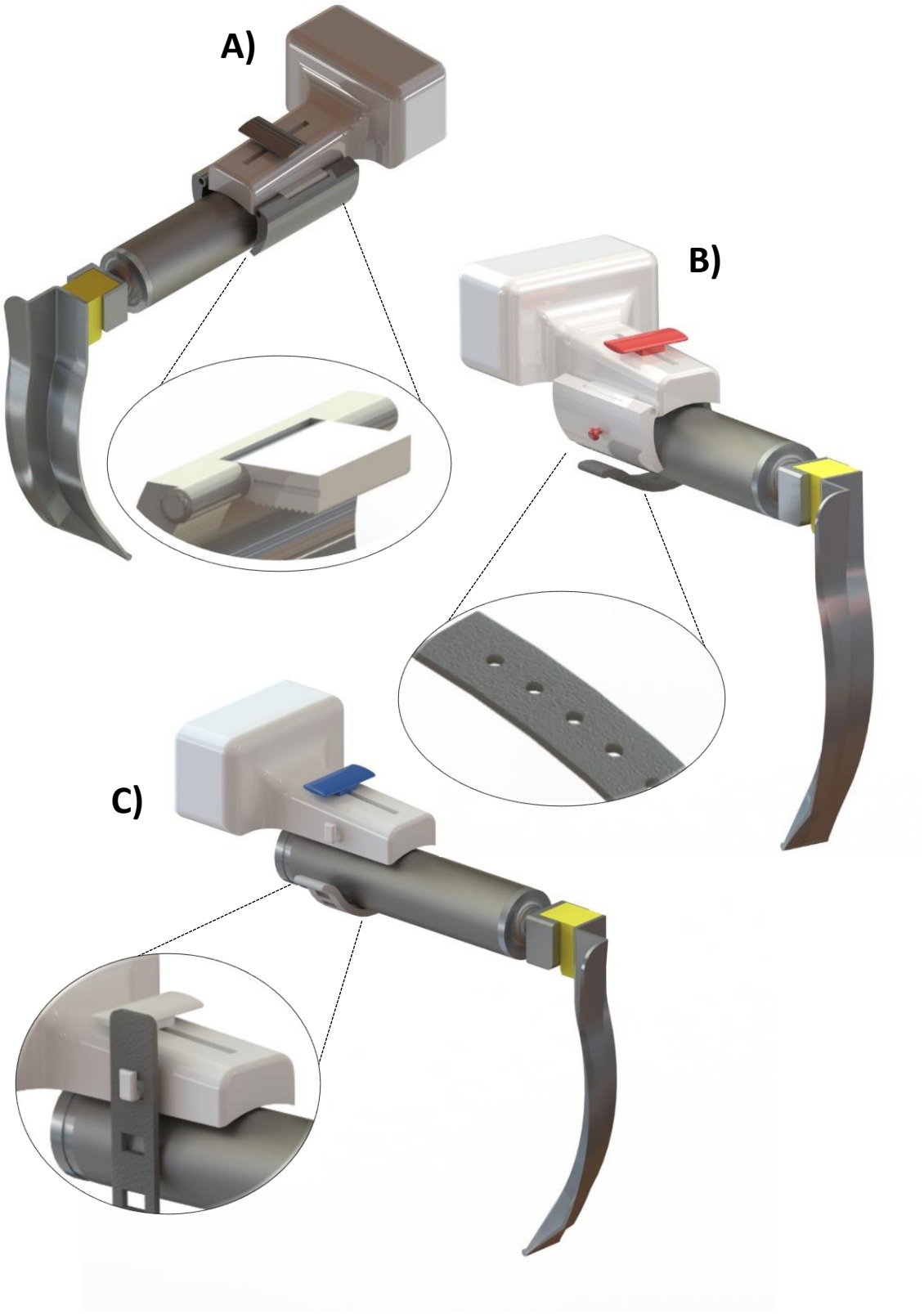


Figure 8.10: Controller With Ratchet Clamps (a), Watchstrap Styled Controller With Button Plug Connector (b), Controller With Tourniquet Inspired Hook Strap (c)

Upon review of the three attachment methods to secure the controller to the laryngoscope, the use of the tourniquet inspired hook strap provides the greatest adaptability and form matching of the three development concepts. Further development of the controller with a

tourniquet inspired hook strap has been completed and is presented in Figure 8.11. The use of an elastic rubber strap that tightly secures the controller in place on the laryngoscope is ideal for sterilisation. One improvement made is the hook-on system used. The previous version (Figure 8.10c) had limited control of the excess strap which could obstruct the operation of the controller slider, this therefore required further improvement. To overcome this issue, a two-part hook strap has been designed and allows the excess strap to be manoeuvred away from the operating area of the controller and away from the laryngoscope to prevent this impeding the anaesthetists view. To allow the form of the controller to adapt to multiple laryngoscopes, a rubber insert has been attached to the base of the controller which will provide extra grip whilst forming around the different laryngoscope sizes as the controller strap is tightened around the handle of the laryngoscope. Finally, a low battery indicator and on/off control switch have been integrated into the controller as required and stated in the PDS.

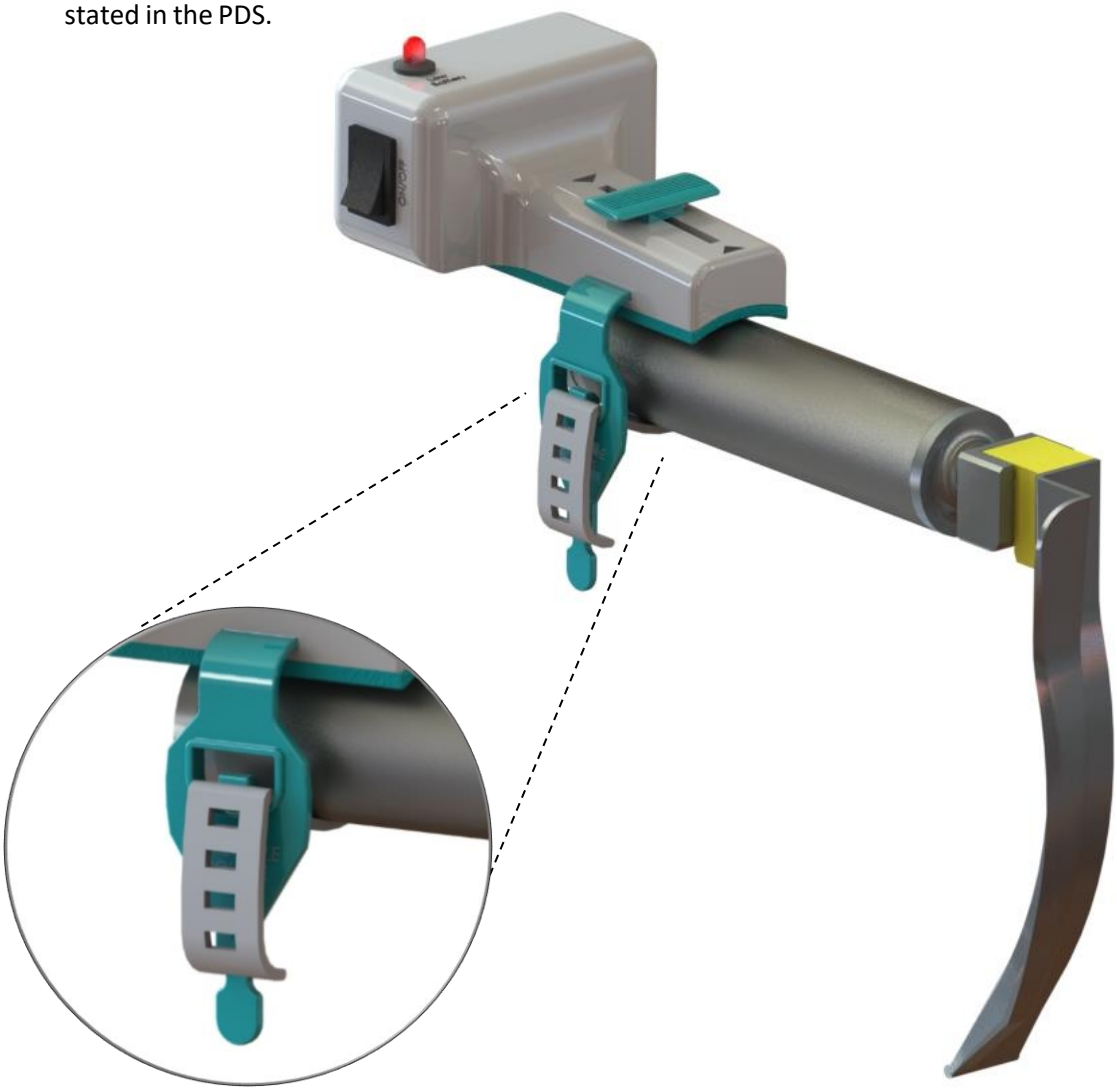


Figure 8.11: Visualisation Of The Steerable Bougie Controller Attached To A Laryngoscope

8.4 Operating The Steerable Bougie & Controller

The developed steerable bougie is presented in Figures 8.12 and 8.13. Sections 8.2 and 8.3 have presented the individual components of the steerable bougie and described how these elements function and have developed. The steerable bougie has been designed based on feedback collected from anaesthetists and the analysis of the physical properties of currently available bougies to enable the safest but also most functional device to be developed.

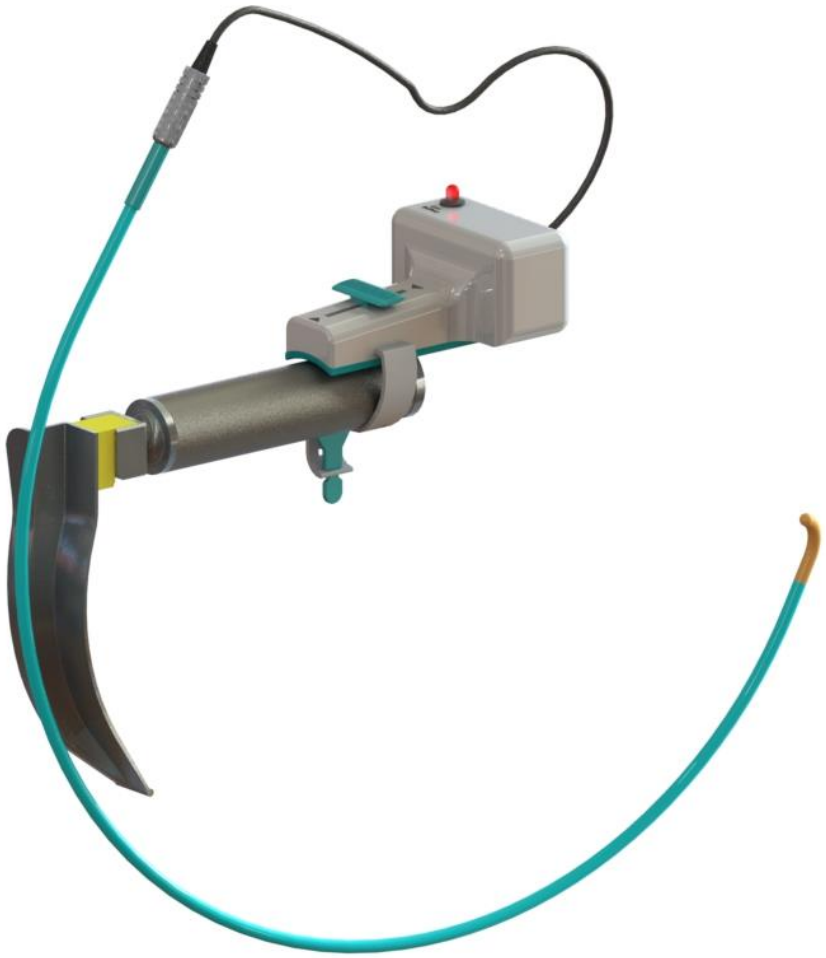


Figure 8.12: Final Visualisation Of The Steerable Bougie

The step by step operation of the steerable bougie is presented in Figure 8.14 a-h. Critically the steerable bougie does not require preloading and can still be used as per standard bougie intubation procedures. Using the detachable headphone jack connection which is only 6.5mm in diameter, this allows any endotracheal tube with a 7mm internal diameter or greater to be used. Unlike other mechanical steerable devices currently available (i.e. Flexible Tip Bougie), the steerable bougie can be adjusted in situ due to the use of the external controller. The steerable bougie has been designed to be used for both emergency and non-emergency situations and provides the anaesthetist with greater control of the bougie. With increased shape retention characteristics and the ability to steer the tip of the

bougie, this allows the anaesthetist to perform quicker, safer and more controlled intubations. The steerable bougie has also been designed to ensure the device can be operated as an ordinary single use bougie should the steerable functionality fail; therefore, this will not increase the time taken to complete the intubation procedure by requiring the anaesthetist to switch equipment should operative control failure occur.

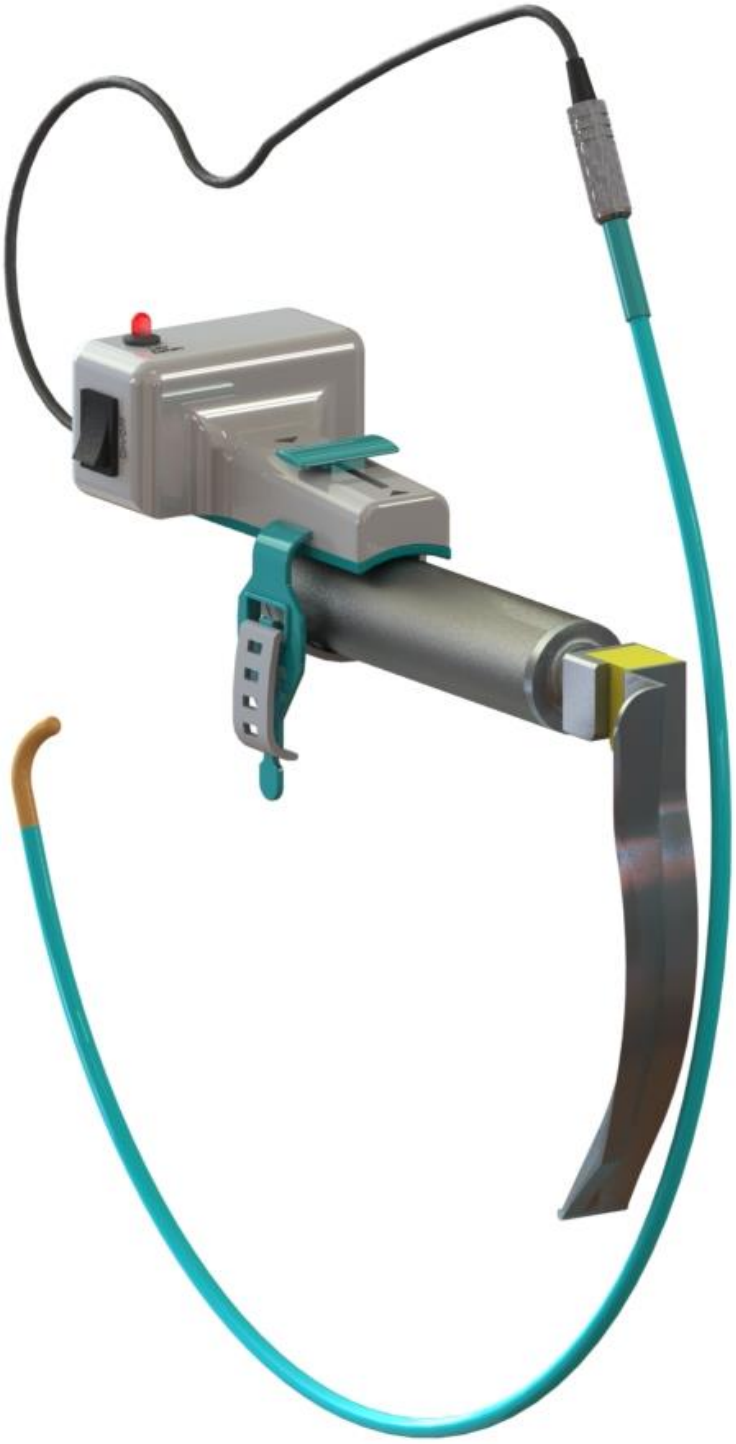


Figure 8.13: Final Visualisation Of The Steerable Bougie

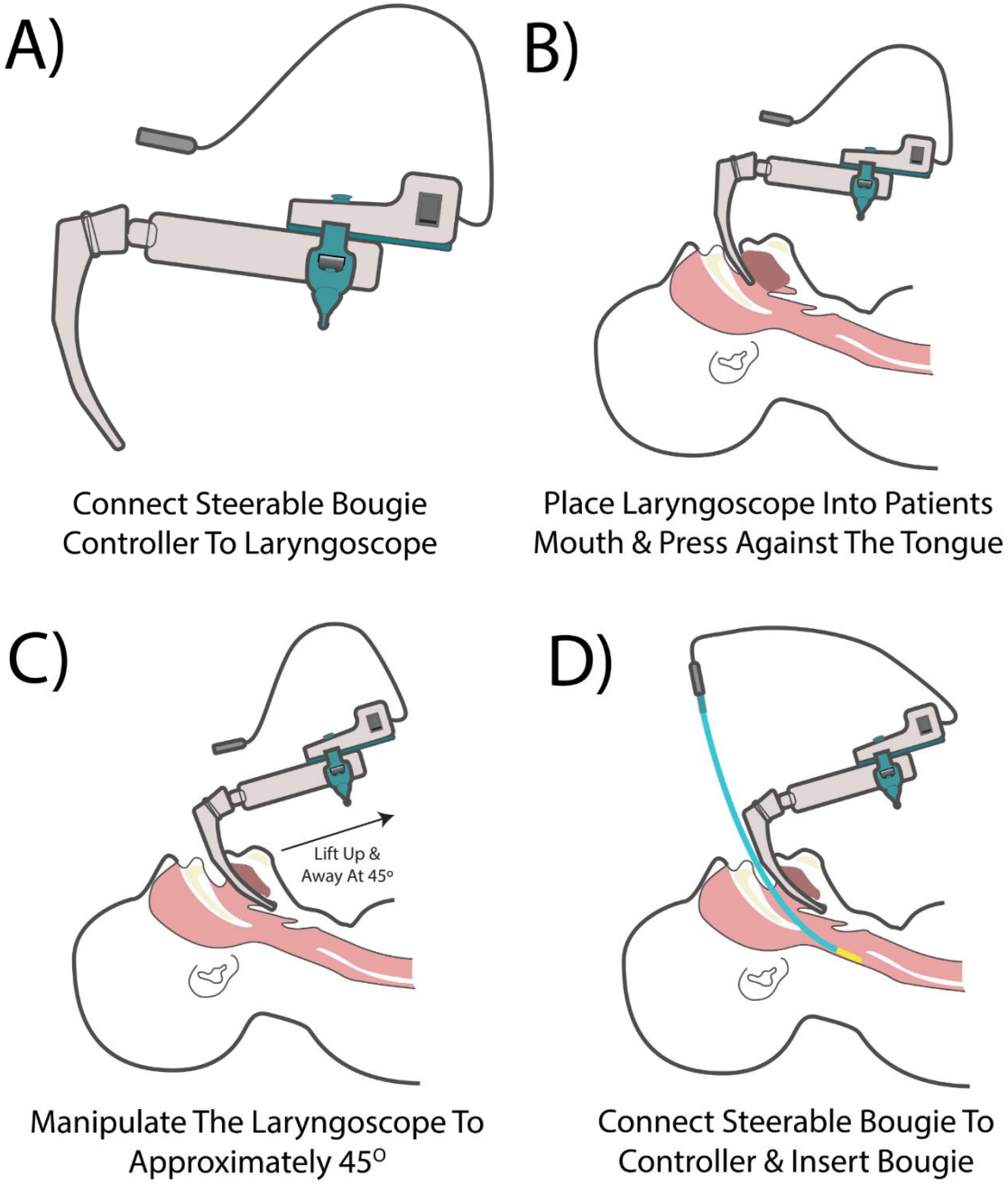


Figure 8.14 a-d: Step-By-Step Tracheal Intubation Procedure Using The Steerable Bougie

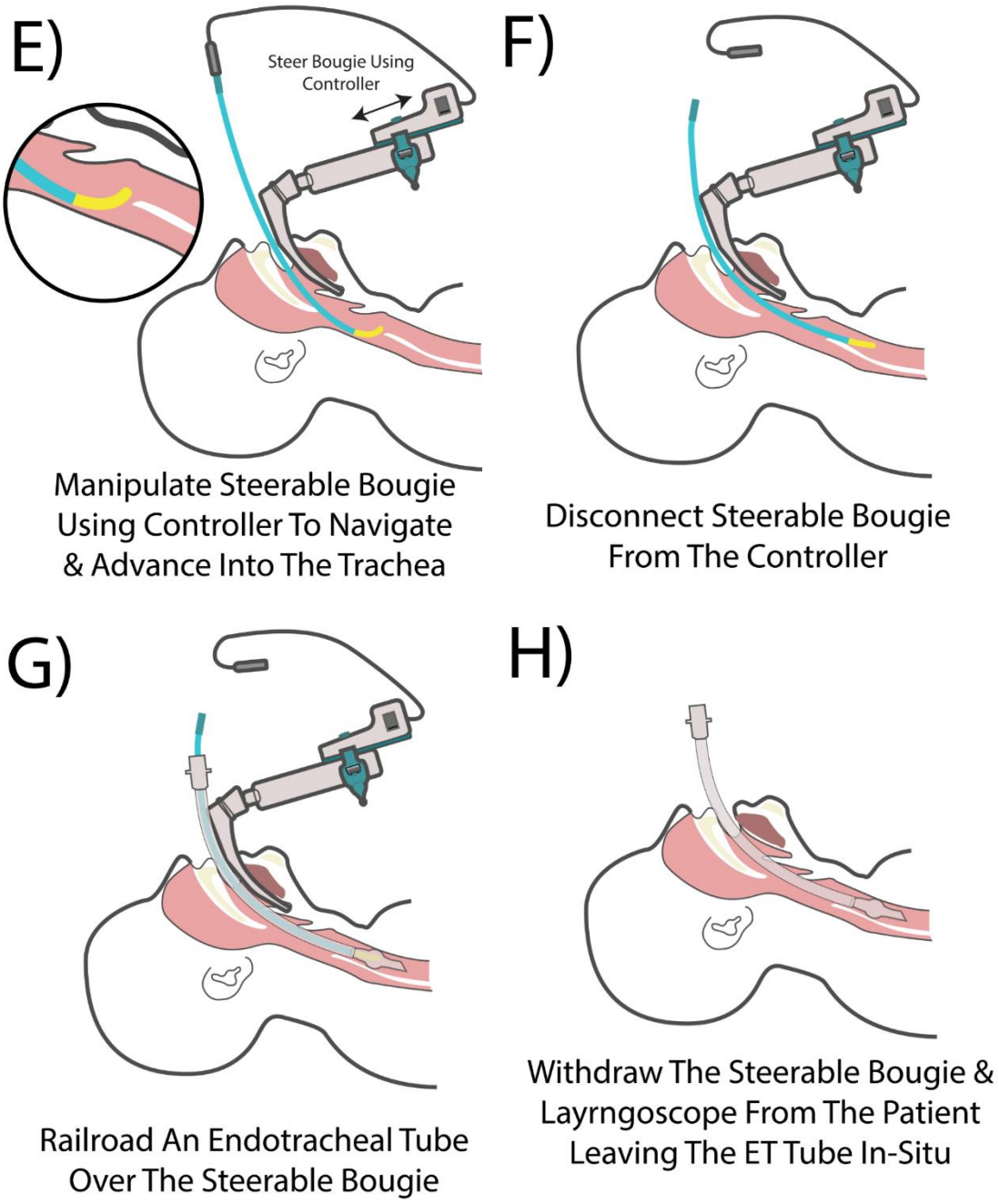


Figure 8.14 e-h: Step-By-Step Tracheal Intubation Procedure Using The Steerable Bougie

8.5 Evaluation Of The Steerable Bougie Against The PDS

An important aspect of reviewing the final design of any product is comparing the products acceptability against the PDS. A review of the steerable bougie against the full PDS set out in Appendix D is presented in Table 8.1 below. This assessment is based on the devices current developed state at TRL 5. As the device progresses through TRL 6-9, the PDS criteria currently not attained will be addressed during pre-series development and manufacture.

PDS Criteria Category	PDS Criteria No.	Conformity Y/N/N/A	Comments
1.0 Performance	1.1	Y	-
	1.2	Y	Initial usability testing of the device demonstrates this is achievable, further testing required for full validation.
	1.3	Y	-
	1.4	Y	-
	1.5	Y	-
	1.6	Y	Development of the steerable tip and ability to achieve 60° of movement in two directions is presented in Chapters 4-5.
	1.7	N	The response of the bougie is fast and positive, however, this does not fully conform to the 1-second target, as the reaction time of the devices movement has been calculated to 1.1 seconds.
	1.8	Y	-
	1.9	Y	-
	1.10	Y	-
	1.11	Y	Largest bougie diameter dimension set at 6.5mm.
	1.12	Y	Designed controller strap can attach to a wide variety of products.
2.0 Environment	2.1	N/A	Standard operating parameters; reference information only.
	2.2	N/A	
	2.3	Y	-
	2.4	N	Packaging still requires development.
	2.5	Y	-
	2.6	N/A	Requires testing to confirm.
	2.7	Y	-
	2.8	N/A	DAT storage location to be defined.
3.0 Patents	3.1	Y	-
	3.2	N	Submitted patent was not acquired based on advice from a patent attorney who indicated prior art in other devices would make achieving a patent unlikely.
	3.3	Y	-

Table 8.1: Conformity Of The Steerable Bougie Against The Full PDS

PDS Criteria Category	PDS Criteria No.	Conformity Y/N/N/A	Comments
4.0 Shelf Life Storage	4.1	N/A	Until final device manufacture has occurred, these PDS points cannot be considered.
	4.2	N/A	
	4.3	N/A	
	4.4	N/A	
5.0 Quality & Reliability	5.1	N/A	-
	5.2	Y	Components tested using the 1m drop test and do not display signs of fracture or failure; full testing required for the assembled steerable bougie.
	5.3	N/A	Range of motion not affected based on usability assessment when used as a standard bougie; validation required in simulated intubations to conform to PDS.
	5.4	Y	1m drop test completed, no adverse effects noted, 5m and 10m drop tests deemed unnecessary.
	5.5	N/A	Not achievable to test within research remit.
	5.6	N/A	Full compliance and assessment to be completed when device enters commercial manufacturing stage.
6.0 Maintenance	6.1	Y	-
	6.2	Y	Switching batteries or charging required only.
	6.3	Y	-
	6.4	Y	-
	6.5	Y	Further development required based on user feedback.
	6.6	Y	Specification of components indicates this is achievable.
7.0 Size	7.1	N	The steerable bougie is now set at 600mm with a 30mm steerable tip based on feedback collected and performance assessment research completed.
	7.2	Y	-
	7.3	N	Connector is 6.5mm in diameter not 6mm; device is still usable at this size.
8.0 Product Cost	8.1	Y	Prototype manufacture costs suggest this is achievable, however full manufacture costs still needs to be compiled.
	8.2	Y	
	8.3	Y	
9.0 Ergonomics	9.1	Y	Based on ergonomic data used and feedback received, early indications suggest these PDS points have been achieved; formal validation required.
	9.2	Y	
	9.3	Y	
	9.4	Y	
	9.5	Y	

Table 8.1 *Continued*: Conformity Of The Steerable Bougie Against The Full PDS

PDS Criteria Category	PDS Criteria No.	Conformity Y/N/N/A	Comments
10.0 Product Life Span	10.1	Y	Based on testing conducted and materials identified for use within the manufacture of the steerable bougie, this can be achieved. Formal testing required during TRL 6-9 to confirm these requirements.
	10.2	Y	
	10.3	Y	
	10.4	Y	
	10.5	Y	
	10.6	Y	
11.0 Quantity	11.1	Y	-
	11.2	N/A	Initial sales targets will need amending based on the demand identified after formal evaluation of market share and product interest based upon feedback collection from the anaesthesia community.
12.0 International Standardisation	12.1	Y	The design and development of the steerable bougie has considered the international standardisation PDS points and relevant regulations throughout the development process. Although conformity is not currently possible due to the TRL4/5 models created, the selection of materials and components for use would make this achievable upon final product manufacture.
	12.2	Y	
	12.3	Y	
	12.4	Y	
	12.5	Y	
	12.6	Y	
	12.7	Y	
	12.8	Y	
	12.9	Y	
	12.10	Y	
13.0 Shipping & Packaging	13.1	N/A	No packaging development work currently completed.
	13.2	N/A	
	13.3	N/A	
14.0 Materials	14.1	Y	Materials and components utilised within the design and development of the steerable bougie have been utilised in various medical device products globally thus setting a precedent. The identified materials and components will therefore meet the requirements set out in the relevant material standards relating to medical device development.
	14.2	Y	
	14.3	Y	

Table 8.1 *Continued*: Conformity Of The Steerable Bougie Against The Full PDS

PDS Criteria Category	PDS Criteria No.	Conformity Y/N/N/A	Comments
15.0 Documentation	15.1	N/A	Documentation for the steerable bougie has yet to be produced, however many of the diagrams utilised throughout this thesis can be utilised for step by step instructions.
	15.2	N/A	
	15.3	N/A	Instruction on disposal procedures have yet to be written, however the materials proposed for use will enable the device to conform to the relevant regulations relating to disposal of the device using the correct medical waste disposal units in the hospital or clinical based environment.
16.0 Disposal & Eco Constraints	16.1	Y	-
	16.2	Y	-
	16.3	N/A	Final manufactured device will be capable of conforming to this standard, however specific manufacturing techniques will fully define this.
	16.4a	Y	Markings are available on each of the devices/components to inform the user.
	16.4b	Y	-
	16.4c	N/A	No metal components accessible for the user. Flexinol® wire will be required to be removed from the bougie shaft upon delivery to waste disposal plants.
17.0 Customer	17.1	Y	-
	17.2	Y	-
	17.3	Y	-
18.0 Politics & Legislation	18.1	N	PDS criteria not currently attained, however CE marking and Medical Device Directive 2007/47/EEC conformity will be attained during pre-series manufacture and TRL 6-9.
	18.2	N	
	18.3	N	
19.0 Installation	19.1	Y	-
	19.2	Y	-
	19.3	Y	-
	19.4	Y	-
	19.5	Y	-

Table 8.1 *Continued*: Conformity Of The Steerable Bougie Against The Full PDS

PDS Criteria Category	PDS Criteria No.	Conformity Y/N/N/A	Comments
20.0 Aesthetics	20.1	Y	-
	20.2	Y	-
	20.3	Y	Main shaft coloured blue, steerable tip coloured orange.
	20.4	Y	Connector coloured a different shade of blue but in keeping with the aesthetic style utilised.
	20.5	Y	-
	20.6	Y	-
	20.7	Y	-
21.0 Safety	21.1	Y	Increased operative control achieved.
	21.2	N	Although the design of the steerable bougie has considered Medical Device Directive 2007/47/EEC, this has not been achieved at TRL 5, TRL 6-9 will allow regulatory approval to be achieved.
	21.3	Y	Improved physical properties presented in Chapters 4-7.
	21.4	Y	Porcine airway testing in Chapter 6 ensures this has been achieved.
	21.5	Y	Reduced tip pressures documented.
	21.6	Y	Improved shape retention documented.
	21.7	Y	-
	21.8	Y	-
	21.9	Y	-
	21.10	Y	-
	21.11	N	Proof of concept conformity has been achieved, however regulatory conformity with regards to safety will be achieved during TRL 6-9 tasks where the necessary documentation will be created. Evidence-based assessment tasks to be completed resulting in device improvements to achieve MHRA approval.
	21.12	N	
	21.13	N	
	21.14	N	
	21.15	N	
	21.16	N	
	21.17	N	
	21.18	N/A	
	21.19	N	
	21.20	N	

Table 8.1 *Continued*: Conformity Of The Steerable Bougie Against The Full PDS

PDS Criteria Category	PDS Criteria No.	Conformity Y/N/N/A	Comments
22.0 Testing	22.1	Y	-
	22.2	Y	-
	22.3	N	Initial device repeatability achieved, larger scale repeatability testing required to achieve the necessary regulatory approval.
	22.4	Y	-
	22.5	N	Simulated intubation verification trial required to be undertaken to prove this. Theoretical improved first pass intubation is discussed and is capable of being achieved based on the development of a device with increased functionality.
23.0 Competition	23.1	N/A	Commercial devices not assessed.
	23.2	N/A	
	23.3	N/A	
	23.4	N/A	
	23.5	Y	Device superiority achieved with regards to physical properties as presented in Chapters 4-6.
	23.6	Y	
	23.7	N/A	Commercial device not assessed.
	23.8	Y	Device superiority achieved with regards to physical properties as presented in Chapters 4-6.
	23.9	N/A	Commercial devices not assessed.
	23.10	N/A	
	23.11	N/A	
	23.12	Y	Device superiority achieved with regards to physical properties as presented in Chapters 4-6.
	23.13	Y	

Table 8.1 *Continued*: Conformity Of The Steerable Bougie Against The Full PDS

PDS Criteria Category	PDS Criteria No.	Conformity Y/N/N/A	Comments
24.0 Weight	24.1	Y	-
	24.2	Y	-
	24.3	Y	-
25.0 Market Constraints	25.1	Y	Device superiority achieved with regards to physical properties as presented in Chapters 4-6.
	25.2	Y	
	25.3	Y	
	25.4	Y	
	25.5	Y	
	25.6	Y	
	25.7	Y	
	25.8	Y	
	25.9	Y	
	25.10	Y	
	25.11	Y	
	25.12	N/A	Products not assessed.
26.0 Life In Service	26.1	Y	-
	26.2	N/A	Requires testing and MHRA approval for life in service recommendations to be acquired.

Table 8.1 *Continued*: Conformity Of The Steerable Bougie Against The Full PDS

8.6 Future Developments – Increasing The Usability Of The Steerable Bougie

As with any product development process for a medical device, there are always potential areas for future development work to be completed based on the demands of the market. Potential future developments are briefly described in Sections 8.6.1 - 8.6.4.

8.6.1 Controller LCD Information Screen

The designed steerable bougie controller has been designed to be simple in operation and intuitive for the user to use whilst considering a low price point target, however with the increased use of the technology within difficult airway equipment, an argument could be made to provide the user greater information on the control parameters of the device. One of the key parameters that may be useful for the operator to be aware of is the amount of steerable tip movement used which may affect bougie shaping processes. To visually display this, the integration of an LCD screen would be required to compliment the potentiometer. Potential designs for a simple LCD screen are presented in Figure 8.15; alteration of the displays graphics would be based on the values output from the sliding potentiometer. Figure 8.16 demonstrates a possible location for an LCD screen on the designed controller.

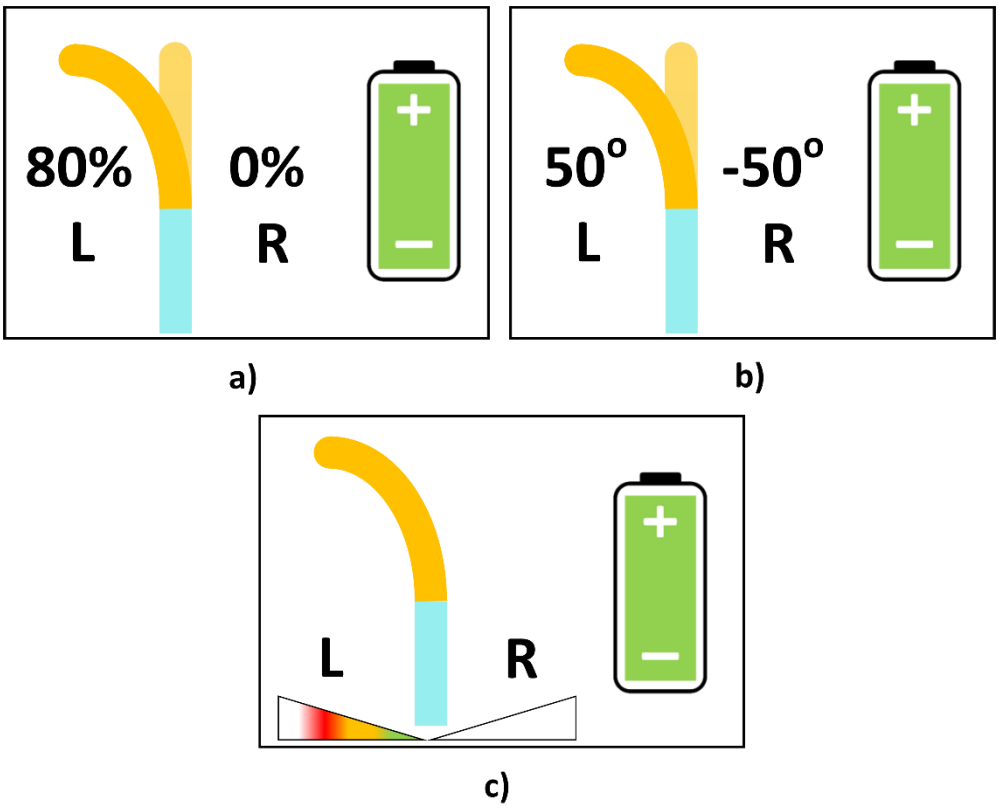
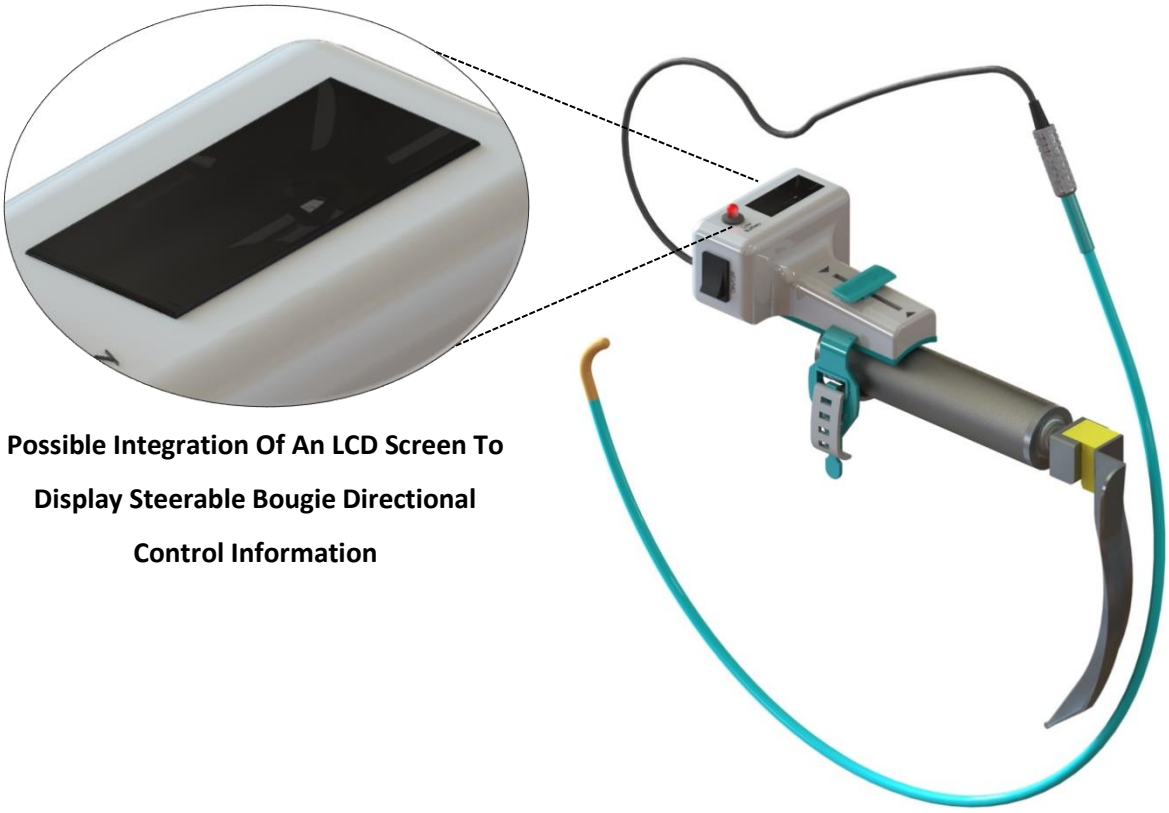


Figure 8.15 a-c: LCD Screen Bougie Movement Display Screen Concepts



Possible Integration Of An LCD Screen To Display Steerable Bougie Directional Control Information

Figure 8.16: Steerable Bougie & Controller With LCD Screen

Although a low battery indicator has been incorporated into the controller using a coloured LED indicator, providing the user with a percentage value or colour coded symbol displayed on the LCD screen could ensure that the maintenance of the device is adequately managed. Figure 8.17 presents possible designs for the battery indicator graphics for a controller LED screen. If this route is to be further explored, it will be important to review literature on semiotics and the interpretation of battery graphics; consideration should also be made to systems used on existing control devices such as video laryngoscopes.

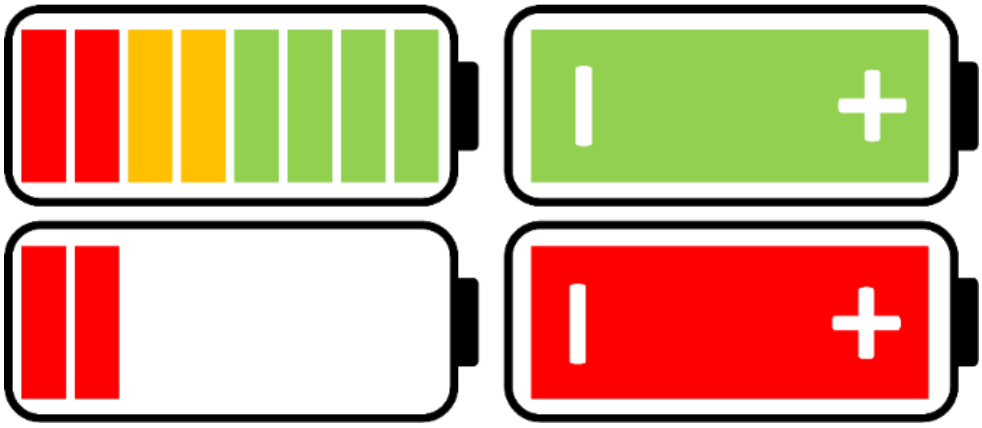


Figure 8.17: Possible LCD Screen Battery Indicator Symbols

The incorporation of an LCD must be carefully considered as to whether there is need for this information as this will ultimately increase the cost of the controller. Further research on the inclusion of further technology into the controller is required through design development and user analysis.

8.6.2 Steerable Bougie Range - Variable Tip Hardness For Different Clinical Situations

The development work completed in Chapter 6 identified that the 0.15mm diameter Flexinol® wire was the optimum wire for use based on the construction of the steerable tip. This provided positive contraction and relaxation times thus meeting the points set out within the PDS. Many anaesthetists may decide that for the steerable bougie to be implemented within their practice they would prefer to choose from a range of steerable bougies with various levels of bougie tip hardness (softer or harder) based on the clinical situation presented; this will affect the control wires utilised.

Providing a range of steerable bougies with graded tip hardness's can be achieved by increasing or decreasing the steerable bougies internal inserts OD wall thickness, slot height, width and depth in addition to increasing or decreasing the central wall thickness (Figure 8.18). By altering these variables this will affect the tip pressures generated by the bougie tips. Based on the results presented in Chapter 6, Section 6.6.2, this demonstrates that tip

pressures generated by harder steerable tips are still superior when compared to all the commercially available bougies; small increases do result in tip pressures exceeding the 0.8N values recorded by Marson et al., (2014) on trachea trauma.

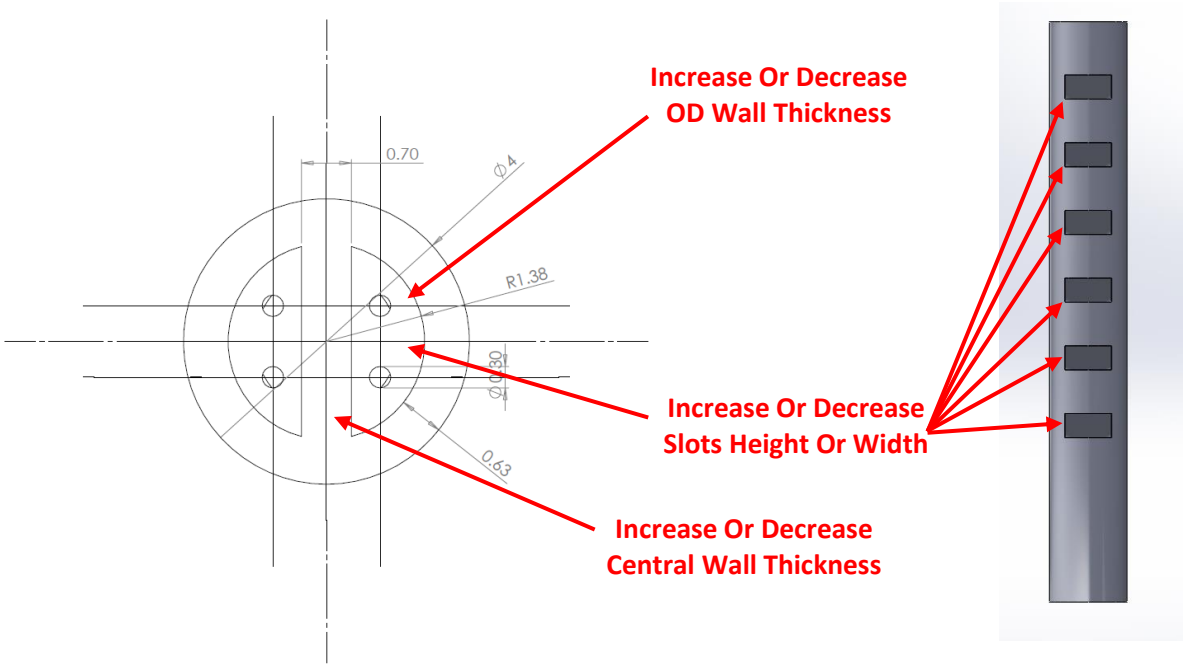


Figure 8.18: Adjustable Variables To Increase Or Decrease Bougie Hardness

In addition to the risks of increasing tip pressures generated, to ensure the steerable bougie is functional with tips of higher hardness and stiffness, Flexinol® Actuator Wire (Dynalloy.com., n.d.) with increased heating pulling force must be used. Using wire with an increased diameter will result in greater pulling forces being achieved, but the contraction and cooling time of the wire increases thus exceeding the reaction and relaxation times identified within the PDS and in some cases this can be greater than five times slower than the performance criteria set out. This is not a problem for routine intubations but for time critical and emergency situations this is not acceptable.

8.6.3 Colour Coded Bougie Shaft

The use of a colour-coded shaft has been discussed throughout this thesis based on the work conducted by Paul et al., (2014). Survey results collected suggest that users would be prepared to be guided by a colour coded system, however further assessment on the depths and parameters of the colour coded sections requires further work and must consider the criticisms highlighted by Campbell (2014). Every patient is bespoke so accurately categorising depth requires a significant level of clinical evaluation and consideration before integration; further literature and user consultation is required.

8.6.4 Integrated Steerable Bougie Controller/Laryngoscope

As with many of the devices currently available on the market such as the video laryngoscopes, manufacturers are continually expanding the product range by providing single use and multiple use devices. Currently the steerable bougie can be utilised in combination with the majority of laryngoscopes and a number of video laryngoscopes as the controller can be easily detached, sterilised and reused. It is proposed that if device uptake is achieved and a need is identified, the steerable bougie controller could be integrated into a single use laryngoscope or video laryngoscope thus taking away the need for sterilisation processes after intubation procedures have been completed.

8.6.5 Anaesthetists Review Of Product Development Process

The following anaesthetist review of the product state is presented by Dr James Armstrong (Consultant Anaesthetist, Nottingham University Hospitals Trust (QMC):

"When I suggested the idea of a 'steerable bougie' to the team at Nottingham Trent University I had no idea the path it would lead us down. Asking for a solution to a clinical problem seemed, with a non-engineering brain, to be a relatively straightforward task and certainly not one that would take too long to solve. Over the last few years of Luke's PhD I have become inducted into the world of smart materials, material performance specifications and product design. I am constantly amazed as to the elegant and highly novel techniques that the team have come up with to develop our wished-for device.

I am extremely impressed with the final product that has resulted from Luke's work. The material testing and classification that has been done on the basic structure of the bougie itself could potentially lead to a huge improvement in what we currently use, in terms of device functionality and patient safety. Added to this, the ability to add the desired steerable function could lead to a highly useful and potentially game changing device. The development of accurate and reproducible testing techniques will also aid in the development of other new devices, all of which should function better and be safer for the patient than anything we have at the moment".

CHAPTER 9 – DISCUSSIONS, CONCLUSIONS & RECOMMENDATIONS FOR FURTHER WORK

9.1 Summary

Difficult airway management continues to challenge anaesthetists daily with serious implications including death and disability. Current equipment does not always provide an optimum solution; continued improvement in practice, technique, equipment and guidelines is required.

This research set out with the aim of developing a novel steerable bougie based on a design brief and problem statement; however, the research developed into a variety of research streams, many of which can continue to expand into additional research projects.

As with any design project, a structured design and research methodology was required to ensure successful product development. The development of a medical device is a complex task requiring the involvement of a wide variety of stakeholders all contributing to solve a wide array of design issues. Chapter 1 highlights the common misconceptions in medical device development identifying that medical professionals and design teams must work collaboratively together and with other stakeholders.

Chapter 3 attempts to resolve the issues identified in the first two chapters to ensure airway device design development can follow as structured approach. A conceptual framework underpinned by Soft Systems Methodology, design and engineering principles and TRL stages aims to structure this process; one of the most important activities described was the use of feedback loops.

The literature review conducted in Chapter 2 discusses a variety of topics including airway assessment and management methods, existing devices, medical device regulations, design and engineering methodologies, smart materials and technologies, physical properties of bougies amongst other topics. The correct use of testing equipment for accurate measurement of data outputs is a key element of any research conducted. Significantly, inaccurate assessment and measurement of measurables was identified in several published studies. Studies conducted by Marson et al., (2014), Hodzovic et al., (2004) and Janakiraman et al., (2009) are good examples where testing equipment (i.e. force gauges) are not used within the correct scale, resulting in only comparable data being collected rather than accurate data.

A key section of the literature review focuses on the physical properties of bougie introducers, this helped identify key design criteria for the PDS and development activities. This review identified several issues related to device performance and safety, including issues relating to bougie tip pressures, airway trauma, shape retention characteristics of bougies, extubation forces amongst others. The patent search completed also identified the methods previously explored by medical device professionals and designers; information regarding bougie construction and operation was reviewed.

The UK market currently has many single use solutions that do not demonstrate the same performance attributes as the gold standard devices on the market; national surveys however suggest the gold standard devices are becoming less common with an increased use of single use devices. Further assessment of devices was required (Mushambi et al., 2016); this PhD has addressed this.

New emergency airway access devices as a minimum should conform to the below criteria to be deemed useful for integration into practice:

1. Improving procedure safety and device safe use thus reducing patient complication risks and therefore reducing the likelihood of incorrect device operation.
2. Improving the efficiency of the procedure through improved and better designed devices i.e. reducing the length of time to intubate a patient correctly.
3. Improving overall device performance resulting in greater success rates for first pass intubation.

The impact of medical device regulations within the product development process cannot be underestimated; these regulations influence the design, manufacture and implementation of medical devices and ultimately dictate whether a product can be commercialised or not. However, when designing the steerable bougie conforming to the regulations has been an extremely challenging task. The medical device regulations have been under constant review and updated regulations were originally due for implementation in 2016, then 2017, and now these regulations are due for implementation during 2018 with full implementation required by 2020. Conforming to these regulations during TRL 1-5 has been challenging and not always successful as there have been many questions that could not be answered due to these changes; conformity from TRL6 onwards is however required to prove clinical viability.

Chapters 4, 5, 6 and 7 describe the design and main experimental sections of the work completed within this thesis; these experimental activities have not only contributed to the

development of the steerable bougie, but the research activities have also focused on the design and manufacture of accurate testing systems and the accurate assessment of bougie introducers physical properties. Several key factors had to be considered including:

- Repeatability and degradation properties of bougies.
- Accuracy of equipment used to record data i.e. maximum measurement ranges, load cell capabilities and full-scale deflection accuracy (%FSD).
- Regulating/standardising the amount of pressure applied to shape the bougie.
- Repeatability of positional tracking of a bougie.
- Angle and orientation of the bend of the bougie.
- Adaptability of the testing systems ensuring accurate and statistically relevant testing data can be collected regardless of the device manufacturer and model.

Further analysis of the testing systems is reviewed separately in the topical sub-sections described in Section 8.3. Finally, Chapter 8 presents the final design for the steerable bougie based on the testing data collected during Chapters 4-7, ultimately leading to the design validation of the steerable bougie. Chapter 8 also considers the overall design and usability of the steerable bougie.

9.1.1 Achieving The Project Aims & Objectives

The aim of this research was to design and develop an emergency airway access device for medical professionals through the implementation of smart materials and technologies to improve tracheal intubation procedures. The design of the steerable bougie has ensured that the overall aim of the PhD has been completed. Using a shape memory alloy (Flexinol®), this has been integrated into the steerable bougie as the main method of actuation control; this was linked to the design of the flexible tip which underwent considerable development and validation.

The investigation and incorporation of smart materials and technologies into the fabrication of emergency airway access devices with the aim of increasing the success rates of airway access procedures whilst combatting the safety concerns and associated medical risks was a complex objective to achieve. Integrating the smart materials and technologies was achieved and demonstrated in numerous aspects of the research including the design development of the steerable bougie and designed testing systems. By improving the control and hence the usability of bougie introducers based on the criteria defined by the case of need survey, increased shape retention and device steerability has been achieved. It can be deduced that

by improving the mechanical properties of bougies and increasing the functionality of the product, faster and safer procedures can be completed. This needs fully validating in the clinical setting to conform to TRL 6-7 activities; further work focusing on this element is therefore required.

Developing a conceptual framework to depict the design development process for an emergency airway access device was presented in Chapter 3; the conceptual framework combines numerous approaches including Soft Systems Methodology, design and engineering approaches and technology readiness levels to create a structured approach.

The design and development of iterative prototypes of the steerable bougie considering usability and ergonomic issues was yet another key objective for the project and was demonstrated through the development of numerous individual components of the steerable bougie, many of which are depicted in Chapters 4-5.

The design and manufacture of accurate testing solutions/systems to validate the development of an emergency airway access device could have been split into multiple sub objectives due to the extensive amount of work conducted in this area as presented in Chapters 4-6. The development of the following testing systems and protocols has been completed:

- **Tip Pressure Testing Protocol:** Evaluating the forces applied at the bougie tip, considering the grip position. Although this experimental setup was relatively simple, the sourcing of an accurate force gauge with the desired resolution, accuracy, full scale deflection and data acquisition software required a significant amount of research including numerous conversations with suppliers. Suppliers of testing equipment also confirmed inaccuracy of data collected in the published studies identified within the literature review.
- **Shape Retention Testing System (SRTS):** The SRTS was constructed to improve upon the methods used within published literature for analysing the shape properties of bougies. Creating a system capable of tracking and accurately measuring the shape retention capabilities of bougies was a complex task to ensure factors such as bend location, angle of bend and position vs time tracking could be monitored.
- **Repeatability Testing**: Using pneumatic and electronic control equipment supplied by Festo, a retractable pneumatic piston system was constructed in combination

with the sourced force gauge to assess the degradation of bougies based on their tip pressures.

- **Porcine Airway Perforation:** The airway perforation setup was designed to define the forces required to perforate a porcine airway or generate trauma; although this testing was successful in identifying several key discussion points, further amendments are required as discussed in Section 9.3.4.

The use of the above-mentioned testing systems using the designed testing protocols and procedures has allowed for the accurate assessment of not only the steerable bougie but also the testing and evaluation of a variety of commercially available bougies. By assessing the devices currently available on the market, greater insight can be provided to health professionals and the academic community on the optimal devices for use.

9.2 Conceptual Framework

The construction of the conceptual framework was based on the premise that simply following a design methodology such as Pugh's Total Design Activity Model (Pugh, 1991) or the 'Double Diamond' design process model (Council, 2005a) could not guarantee successful medical device development and commercial success. Chapter 3 identified the complex contextual nature of medical device development, identifying that a wider selection of activities was needed that go beyond simply using design development and manufacturing techniques.

The healthcare sector is a complex and dynamic arena which is always evolving; simply integrating new equipment into this practice cannot and will not happen quickly; creating a level of demand and overcoming early adoption resistance will be necessary. To overcome this, research was conducted into integrating a systems development model alongside design development processes to ensure the relevant stakeholders can identify a need for improvements in the product category. Soft System Methodology (SSM) was deemed a suitable dynamic model which could be integrated into the initial stages of project and product development. Through the literature search, SSM was recognised as having potential in many different sectors, including military applications (Staker, 1999), health service management (Lehaney and Paul, 1996), analysing and managing learning environments (Hardman and Paucar-Caceres, 2011) and was even used by Shah (2011) as a method of integrating user involvement into medical device development.

Combining SSM with design and engineering approaches into one model requires a framework structure to be monitored. To achieve this, TRL stages are used to formulate the basis of the framework allowing tasks and approaches to be grouped and linked together. The task identification activities used in SSM stages for the development of the steerable bougie included utilising literature searches, patent searches, design criteria identification activities and a survey which confirmed that steerability and shape retention were key areas for device improvement.

Within the conceptual framework there were several key actions implemented. TRL definitions were developed specifically for emergency airway devices; these TRL definitions allow activities to be defined specifically for the product range. Feedback is a critical part of the conceptual framework; identifying feedback review points within the product development process has ultimately allowed re-design activities to be built into the framework. Re-design processes are common within the design industry both during and after product development. This was no different during the development of the steerable bougie as several iterative design development activities have been undertaken as presented in Chapters 4, 5, 6 and 7 based on feedback collected.

Although there are many positives to the developed conceptual framework, including providing the user with a structured approach, it would be naive to ignore some of the limitations. Although user and patient involvement has been integrated into the framework, the level of involvement will vary based on the product being developed; this will be dependent on the type of user and patient. Inevitably, there may be resistance to change and therefore recruiting open minded users to provide feedback can be challenging. The users of emergency airway devices go far beyond the operating room environment, this can be extended to first responders, medical practitioners etc. Factoring in larger user groups of varying skill can be challenging. Another limitation of the framework is the early task identification activities that must be completed within the SSM and design engineering activities; these will be further complicated if and when team dynamics become a factor.

9.3 Analysing The Commercial Bougie Market

Within the UK market, there are currently a considerable number of bougie introducers that can be sourced within the NHS supply chain. It was hypothesised that there was a large degree of variability in the product range which needed assessing to ensure the design of the optimum steerable bougie. The conclusions and recommendations set out in Sections 9.3.1 - 9.3.5 present key considerations for the bougie introducer product range:

9.3.1 Bougie Tip Pressures

Bougie tip pressure testing completed throughout the project acted as a design validation assessment tool for the developed tips for the steerable bougie. Using this process, over eighty bougies were manufactured using different material compositions and constructions. Balancing limited tip pressures and successful intubation testing utilising a manikin has been a fundamental task for the successful development of the steerable bougie. As a measure of success, the developed steerable bougie is compared to the majority of bougie introducers available in the UK. When considering tip pressure as a critical design criteria, the tip pressure testing conducted has not only identified the GEB as the optimal device for use of the existing bougies available of the market, but this has also set the benchmark for the steerable bougie. Based on the results presented in Chapter 6, the steerable bougie consistently outperforms the commercially available bougies; this has been validated in the trained and untrained user testing, repeatability testing and the statistic tests performed (Mann-Whitney U Tests, Friedman Tests, Wilcoxon Signed Tests etc.) all of which present significant results for the majority.

The final device comparison of the bougie tips presented in Sections 6.6 – 6.10 have proven that the steerable bougie tip is superior to that of the GEB which is currently perceived as the gold standard. The tip pressure testing completed also validates the findings that re-usable bougies are superior to single use bougies in the context of tip pressure relating to physical property performance.

The trained user testing identified that the optimal position to hold a bougie is located between 20cm – 30cm. The further away from the tip the bougie is held, it is perceived that lower control is exhibited. Conversely, the closer to the tip the bougie is held, the peak tip pressures exhibited increase. There is no definitive solution to where a bougie should be held, as this can also vary due to the patient presented; however, a bougie should ideally never be held outside of the 20 – 30cm range as the variability in control and tip pressures could cause trauma to the patient.

Grip position has a significant affect on the tip pressures generated; this is clear when comparing the skilled and unskilled user testing grip positions and peak tip pressure forces generated. Untrained users who held the bougie in a non-approved technique, exhibited increased tip pressures ranging between 8%-37% across the assessed bougie range. A less rigid and stable grip position as presented by the trained participants dramatically reduces peak tip pressures. Further analysis is required based on the variation of trained user grip

positions to assess if this has a significant impact on mean peak tip pressure; this would also need to be validated within a simulated intubation study to compare the speed and accuracy of a difficult intubation versus the tip pressure exhibited with the grip position used.

9.3.2 Repeatability Testing

The repeatability testing identified several interesting trends. Firstly, the softer, more malleable bougies degrade significantly faster than the rigid alternatives. The GEB, FlexGuide bougie and Portex single use bougie, degrade after 130, 47 and 113 repeated peak tip pressures. The other bougies all degrade >150 repeated tip pressure uses with the majority of the bougies not degrading by 10% within the 250 readings recorded with the InterGuide Bougie the exception to this trend.

The degradation of the bougies, especially re-usable bougies is a crucial factor to consider; the manufacturer of the GEB recommends this should not be used more than five times due to sterilisation affecting the material properties of the bougie. Rowley and Dingwall (2007) suggest that the re-use of single use devices is becoming more common; the re-use of single use bougies is untested and although the completed repeatability testing suggests that a number of the bougies assessed will cope with re-use, sterilisation as a variable has not been assessed.

Within the repeatability testing completed, this was restricted to the analysis of one of each type of bougie; this is due to the cost implications of purchasing a considerable number of bougies. This repeatability testing therefore needs to be completed on a larger scale to be able to definitively state the mean degradation levels, but clear assumptions can be made from the testing completed. Interestingly, the rigid bougies typically do not degrade within the 10% cut off which suggests based on this review criteria the products are superior; conversely, the majority of the bougies degrade within a 5% tolerance very quickly. The steerable bougie is unique as it consistently presents low tip pressure values and no degradation within the repeatability testing; this is due to the use of a rubber flexible tip which requires significant deformation before failure.

9.3.3 Shape Retention Capabilities Of Bougies

Chapter 7 presented the development of the Shape Retention Testing System (SRTS) for the accurate assessment of the shape retention characteristics of bougie introducers. When using a bougie during an intubation, matching the curve of a patient's airway is critical. One of the main complaints by anaesthetists is that bougies do not hold their shape; this is a

common trait for all bougies due to the type of material used for their manufacture. Data on this shape loss has up until now not been explored.

After shaping the bougies at various locations, it has been observed that the typical movements include an initial large snap back that is then followed by a sustained gradual shape loss; plot maps of these movements have been recorded and presented in Chapter 7. The stiffer the bougie the more severe the snap back is; softer bougies that are more malleable typically have a less severe snap back but often have increased shape retention loss over a sustained period.

Several of the preferred bougies used by anaesthetists including the reusable GEB and Portex single use bougie, demonstrate some of the worst shape retention capabilities when comparing the change of angle observed during a 20 second period (Figure 9.1). Utilising the SRTS, bougie angle loss has been observed to be between 24-56°, this equates to 42-78% loss of shaping. The designed steerable bougie demonstrates the least amount of shape loss of all the bougies, this is closely followed by the P3 Medical bougie.

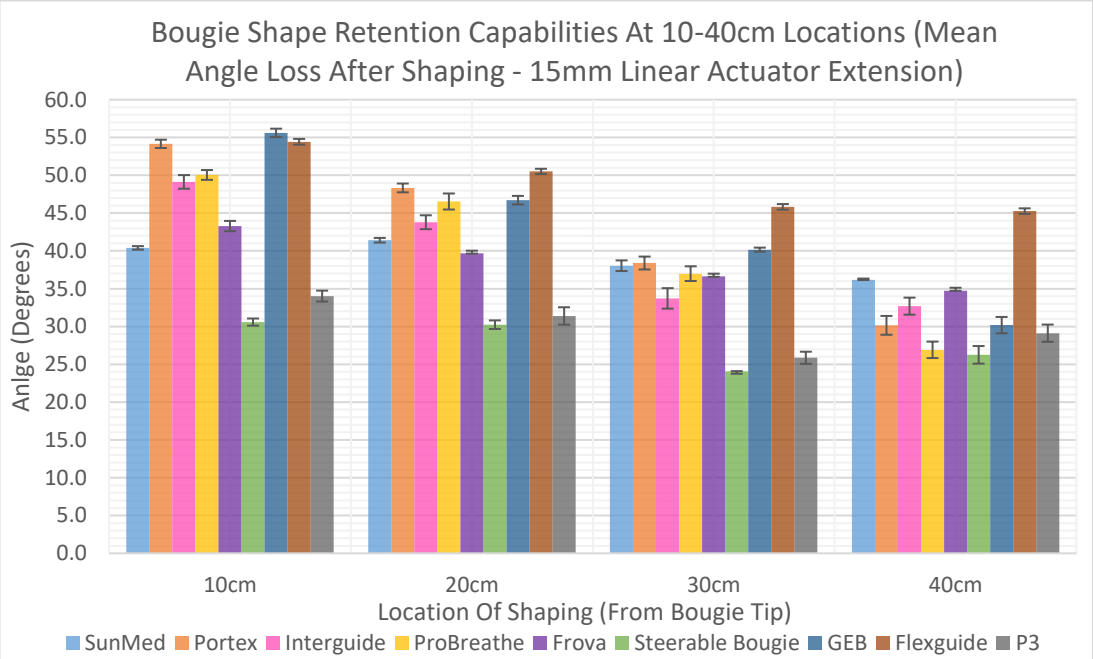


Figure 9.1: Bougie Shape Retention Capabilities – Angle Variation

Based on the observations made during the testing and data analysis, the bougies that have internal structures demonstrate the best shape retention characteristics, thus promoting shape retention. Future designs of bougies should implement an internal structure that promotes shape retention hold rather than simply extruding a hollow tube that has limited functionality in an attempt to make a low cost product with higher-income return. The

majority of the bougies available do not have internal structures, whereas the designed steerable bougie uses a multi lumen structure with a copper central wire to promote shape retention; this presents the best shape retention of all the bougies analysed.

9.3.4 Porcine Airway Perforation

The porcine airway perforation experiment provided insight in to the forces required to achieve tracheal wall perforation. Initially, it was intended that six readings would be collected for each of the bougies being tested; however, many of the bougies failed to perforate the tracheal wall due to the maximum 20N load being reached on the force gauge without presenting any perforations.

For the SunMed coude tip bougie, perforations were achieved in all six trials; perforations were also achieved with the SunMed straight tip bougie and P3 medical bougie. Perforation forces ranged from 9 – 18N. It is however hypothesised that the bougies that have a rigid construction would perforate the tracheal wall at forces just above 20N, therefore a force gauge with a greater capacity is required. Conversely, the softer, more malleable bougies such as the GEB and Portex single use bougie may never perforate a healthy trachea unless significant force is generated, resulting in the curling of the bougie within the trachea thus providing a greater leverage point. Mucosa damage is however exhibited at various levels depending on the forces generated.

The main positive outcome from the porcine airway testing was establishing that the developed steerable bougie was not capable of producing mucosa damage. The soft, flexible tip structure with rounded tip prevents significant force being generated as demonstrated in the testing results in Chapter 6.

9.3.5 Equipment Use Recommendations

Once device acceptability and skill retention are proven, the obvious recommendation is to suggest that the developed steerable bougie be manufactured and integrated into practice due to its reduced tip pressures and increased shape retention characteristics. The increased safety considerations and improved usability attributes demonstrate that the steerable bougie has a place in the airway market.

Regardless of the microbial contamination issues of the gum elastic bougie identified by Cupitt (2000) and the effects of sterilisation on the plasticity of multi-use Eschmann gum elastic bougies identified by Dawes and Ford (2011), the GEB should continue to be defined as the optimal bougie for use in practice as this presents the lowest levels of mucosa trauma

and bougie tip pressures. Tip pressures exhibited by the GEB are significantly lower than single use bougies. The lower tip pressures exhibited are likely to contribute to the reduced incidence of airway trauma; even when 20N of pressure is applied to the GEB, this presents the lowest level of mucosa damage other than when compared to the steerable bougie.

Single use devices currently available on the market do not match the standards of the re-usable GEB when considering tip pressures and potential to cause trauma; hospital trusts must factor the pros and cons to using a re-usable bougie compared to a single use bougie. A considerable drawback to the use of the GEB is its poor shape retention characteristics compared to most single use devices. Single use bougies exhibit higher peak tip pressures compared to re-usable bougies with some single use bougies demonstrating quicker intubation speeds (Braude et al., 2009). If shape retention is the defining factor for intubation procedures, the P3 Medical introducer bougie should be utilised, however limited literature currently exists on the success rate of this bougie within simulated intubation studies. It is however important to note that the P3 Medical introducer bougie does present high bougie tip pressure which can cause significant trauma and perforation if incorrectly used.

Considering the tip pressure data, shape retention characteristic data, the literature on success rates in simulated intubations and factoring in the importance of reduced airway trauma, it is recommended that the GEB should remain the gold standard device for use. This however should only be the case until a suitable single use device can be manufactured that exhibits significantly lower bougie tip pressure similar to the GEB and maintains superior shape retention. Internal extrusion features present the most promising solution to achieve this as demonstrated within the P3 Medical bougie and steerable bougie. More care must however be taken with regards to the use of multiple use bougies with adequate inspection procedures necessary to ensure defects are identified. The steerable bougie which is intended to be a single use device is expected to challenge the GEB as the gold standard device for use once acceptability is proven as this presents superior shape retention, reduced tip pressures and improved control functionality.

9.4 Design & Manufacture Of The Steerable Bougie

The design, development and manufacture of the steerable bougie has been completed throughout Chapter 4, 5, 6 and 7 with several steps validating the developed bougie. Progress has been made in the iterative design processes and activities utilised within the conceptual framework with technology and design validation taking place at several stages. This also included several redesign processes documented throughout the thesis to ensure

the shape memory alloy (Flexinol®) wires were capable of bending the steerable tip to the desired angle; these validation tests are documented within Chapter 6.

The reaction times required for the steerable bougie mechanism were set at one second in order to achieve the desired tip angle. During the validation tests conducted in Chapter 6, the mean reaction times for the control wire to shape the bougie tip were identified as 1.1 seconds. Although this does not fully meet the criteria set within the PDS, this is still acceptable to the project team. This reaction time could be decreased by applying a higher voltage to the control wires, however, this would reduce the operational working lifetime of the control wires thus affecting the products factor of safety.

The construction of the steerable bougie which utilises a multi-lumen tubing shaft to isolate the control wires also contains a central copper wire. The use of the copper core wire is used to increase the shape retention capabilities of the steerable bougie which ensures its shape retention characteristics are greater than the majority of its competitors.

Finally, the design of the ergonomic controller has developed much further than originally envisaged at the start of the research process. The designed controller utilises a fastening strap, this allows it to be attached to the majority of laryngoscopes, and a select number of video laryngoscopes, ensuring the device can be used in a greater number of procedures. However, due to the variety of video laryngoscopes available on the market, the attachment of a controller is extremely difficult for certain models, especially the GlideScope® due to the shape of the laryngoscopes and the location of the video output cables/connectors (Figure 9.2a, b). To design a handle for these devices a different controller mechanism would be required; rather than a sliding action, a roller switch action would be required due to the location of the thumb used to control the device. (Figure 9.2c, d).

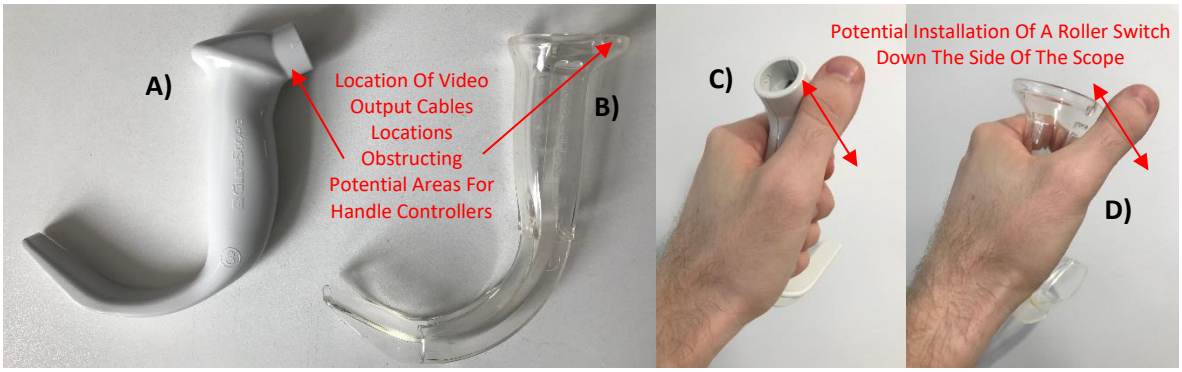


Figure 9.2 a-d: Video Laryngoscope Controller Handle Further Considerations

9.5 Further Work

As the PhD research inevitably expanded during the research journey, a wide array of future work has been identified that can be conducted:

9.5.1 Bougie Tip Pressures – Non-UK Products

Rowley and Dingwall (2007) highlights that there is growing concern about the quality and efficacy of some single-use devices, which has led a number of clinicians to question the safety of using these devices at all, let alone contemplating their reuse. Bougie introducers within the UK vary in cost (£10-£80 per bougie deepening on their source within or outside of the NHS supply chain), however there are many suppliers outside of the UK market, especially in the Asia and Americas where bougies can be purchased from as low as $2 per bougie where the physical properties of the bougies are untested.

Numerous health organisations around the world are facing financial constraints resulting in cost saving exercises. To save costs, the use of low-cost disposable tracheal tube introducer bougies has become more common. Using the developed testing systems, an assessment of the quality and use of these low-cost disposable tracheal tube introducer bougies can be completed.

9.5.2 Shape Retention Testing

The shape retention testing completed in Chapter 7 using the SRTS has provided significant insight into the shape retention characteristics of several bougie introducers. Further testing using a larger pool of bougie introducers is desirable. Unfortunately, due to cost limitations, a limited number of bougies were assessed in Chapter 7; if money was no barrier, a minimum sample of 10 different bougies would be compared. The SRTS system however has significant potential to be used for other airway equipment including paediatric and infant bougies, stylets, catheters, amongst others.

Further amendments to the LAPS system could also be made to allow more complex curves to be generated providing more variables that can be tested including shaping the bougies at multiple different angles; this may require a second LAPS system to be integrated into the SRTS for individual control.

9.5.3 Repeatability Testing

The repeatability testing experiment setup provides several opportunities for further bougie assessment to be completed. A full analysis of a wide variety of bougies using a minimum sample size of five units of each bougie would be ideal. Assessing the repeatability and

degradation of the bougies should be extended to capturing repeated use measurements at 10, 20, 30 and 40cm when an adequate number of unused bougies can be sourced to replicate the high volume of testing required.

9.5.4 Airway Perforation Testing

As described in Chapter 6, several recommendations were made to further improve the airway perforation testing completed; re-running the experiment factoring in the following recommendations would ensure the dissemination of the results would reach a wider audience with greater impact:

1. Utilise a greater number of bougies from the same manufacturer thus increasing the sample data.
2. Complete the testing using a force gauge with a maximum load cell value of 50N instead of 20N. By increasing the load cell capacity perforation should be achieved for a greater number of boguies.
3. Add further variables to the experiment including the grip location. Marson et al., (2014) utilised bougie grip locations of 25cm – 45cm.
4. Collect data on the porcine airway dimensions.
5. Utilise an automated test stand to push the bougie introducers at a constant rate, rather than using a human operator to gradually push the bougie.

Measurement of the airway wall thickness using a non-destructive technique is essential, methods adopted by Lee et al., (2014) and McClendon et al., (2013), could be used to add greater context to the results collected.

9.5.5 Paediatric Bougie Assessment

Over the course of the research project several protocols and testing systems have been designed and/or manufactured, these include the tip pressure testing protocol, shape retention testing system, repeatability testing system and the porcine airway perforation setup. These testing systems can now be utilised to perform an assessment of paediatric bougies including 5FR, 5CH, 10FR and 10CH bougies; however, sourcing of the paediatric bougies will be required to perform this assessment. The testing systems could also be extended to the assessment of emergency airway equipment sold within the veterinary market also.

9.5.6 Skill Retention Study

During the PhD research time scale, originally the research team intended to complete a skill retention study with the aim of establishing the skill retention of unskilled practitioners using the steerable bougie over a set period of time when compared to existing devices. However, as the product development process expanded, it became apparent that validating the bougie design was more complex than originally envisaged, it was therefore decided that the skill retention study for the steerable bougie would be completed at a later date as further work. Completion of the device development work and physical property justification was a fundamental aspect to the PhD which could affect the results of the skill retention study. The full plan and rationale for the skill retention study is presented in Appendix T.

9.5.7 Integration Of The Controller Into A Video Laryngoscope

A possible extension to the development of the controller for the steerable bougie is integrating the controls of the steerable bougie into a single use laryngoscope or video laryngoscope. As previously discussed the controller has been designed to be as ergonomic and comfortable as possible considering this is an add on component and is aimed at minimising additional costs, however integrating a power control unit, a connection to the steerable bougie and the controller driver (i.e. sliding potentiometer) is possible. This would require a slight redesign of the single use laryngoscope shape. For a video laryngoscope, this would also involve moving the video output connection location to ensure a control mechanism can be installed into a position comfortable for the user. This would inevitably increase costs, but this may make the user more comfortable and promote device uptake. By designing and providing the anaesthetist community with a range of options and surveying this response, this could identify a market gap that could be exploited.

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APPENDICES

Implementing Smart Materials And Technologies For Medical Emergency Airway Access Devices

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APPENDIX A – SUMMARY OF MEDICAL REGULATION

DEFINITIONS

Regulation	Definition
Medical Device Directive 2007/47/EC (Ec.europa.eu, 2007).	*Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:* – *diagnosis, prevention, monitoring, treatment or alleviation of disease,* – *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,* – *investigation, replacement or modification of the anatomy or of a physiological process,* – *control of conception,* *and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."*
US Food & Drug Agency (FDA) (U.S. Food and Drug Administration, 2018).	*an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:* – *recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,* – *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or* – *intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and* *which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).*

Therapeutic Goods Act 1989 (Australia) (Federal Register of Legislation, 2017)	*(1) A medical device is:* *(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:* *i. diagnosis, prevention, monitoring, treatment or alleviation of disease;* *ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;* *iii. investigation, replacement or modification of the anatomy or of a physiological process;* *iv. control of conception;* *and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or* *(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or (ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or (b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).*

APPENDIX B – SUMMATIVE PATENT SEARCH

Patent/Application Number	Applicant	Priority Date	Summarised Description
WO2018094015 (A1)	Steven Venicinque	17/09/2016	Mechanical hollow stylet with a handle and a flexible bougie contained at least partially within the hollow stylet, manually controlled guidance of a hollow preloaded endotracheal tube.
US2017246410 (A1)	Richard Levitan	17/09/2014	An introducer for tracheal tube intubation that has a proximal section connected to a distal section having an angled bougie tip. Use as a bougie (can be railroaded), use as a stylet (pre-loaded). The flexible/malleable sections have directional bending such that the sections bend in roughly the same plane as the angled bougie tip; manually manipulated.
GB2547017 (A)	Intersurgical	04/02/2016	An intubation aid that is utilised in like a stylet or bougie, for insertion into an endotracheal tube. The bougie has a cross-sectional shape having at least one vertex defining a longitudinally extending edge; the intubation aid also has malleable sections and portions to be manually manipulated; no mechanism or electronic control.
USD752213 (S)	Lothian Health Board (GB)	13/09/2013	Flexible tracheal intubation bougie and catheter with color-coded depth indicators; manually manipulated, no mechanism or electronic control included.
CA2816265 (A1)	Kiani Mehrdad	05/08/2013	Smartphone enabled bougie with handle adjustability; assists with endotracheal intubation and includes a malleable guidewire which is mechanically controlled; device must be preloaded with the endotracheal tube.
GB2504581 (A)	Xograph Technologies Ltd.	29/05/2012	Deflectable bougie tip with recommendations for shore hardness and length of manually deflected bougie tips based on insertion forces; no mechanism or electronic control included.

Patent/Application Number	Applicant	Priority Date	Summarised Description
US5718666 (A)	BioentriCS Corp (US)	29/02/1996	Trans-illuminating bougie consisting of an elongated flexible member which can be operated with a light source from the proximal end of the bougie to the distal portion. No steerable function, light source illuminates the hollow core provided an increased view.
US5624432 (A)	Jean P Angelchik	07/10/1991	Illuminating bougie and methods for diagnostic, therapeutic and surgical procedures; no steerable mechanism control included; A socket for attaching a light-transmitting end of a fibre optic bundle is provided at the proximal end of the bougie.
WO2018005776 (A2)	Brio Device LLC	01/07/2016	Intubation stylet with video feed; stylet assembly has a steering shaft that carries a flexible distal tip at one end and is attached to a handle at the other end; steerable stylet is mechanically controlled via applied forces.
US2017095234 (A1)	Intuitive Surgical Operations (US)	02/04/2014	Devices, systems, and methods using a steerable stylet and flexible needle; the patent focuses on a steerable needle but covers the use of a steerable stylet. A description is provided on mechanical and sensor actuator driven needle system that is either mechanically controlled or acts as a teleoperation medical system with retracting mechanical wires or manual actuators. Rotating handle is utilised for the steering of the device and in the case of the stylet a preloaded ET tube is required. Embodiment covers the steering of the flexible portion that can be controllable by the actuator.
WO2017076654 (A1)	Peter Desatnik and Mats Christensson	06/11/2015	Endotracheal intubation device that acts as a flexible tip stylet requiring preloading over an ET tube. Mechanically driven flexion mechanism; no electronic components.

Patent/Application Number	Applicant	Priority Date	Summarised Description
US2014275772 (A1)	Michael Robert Chuda	29/03/2009	Trigger controlled steerable video intubation device referred to as a stylet which has firming and bending tendons controlled by a trigger for controlled anatomic shaping and anatomically accurate steerage.
US2014200405 (A1)	Univ Rutgers (US)	15/11/2012	An extendable Intubation stylet that includes a trigger mechanism connected to a handle which can be manoeuvred into the trachea with a retracted position and an extended position.
US4244362 (A)	Charles Anderson	13/01/1981	Magnetically controllable stylet; a magnet placed on the exterior of the patient's neck as the device is inserted in the trachea. The magnets are manipulated to manoeuvre the device in position.
US2010108060 (A1)	Thripjatek Inc Ltd.	05/06/2010	Hand operated articulated intubation stylet with a link at its distal end, a L-shaped lever with a downward depending handle for manipulating a flexible wire to flexing the link into a flexed positioned to form a hook-like configuration in the stylet member's side view; manually controlled device.
WO2007146496 (A1)	Parker Medical Inc (US)	21/12/2007	A flexible articulating stylet for an endotracheal tube that is manipulated with a ratchet mechanism with a preloaded ET tube.
US5058577 (A)	Gary Six (US)	22/10/1991	Handle operated manual steerable stylet, using a spring-operated handle device to facilitate the insertion of an ET tube into the larynx and vocal cords of a patient regardless of any obstructing physical characteristics.

Patent/Application Number	Applicant	Priority Date	Summarised Description
US2011270169 (A1)	Medtronic Inc	03/11/2011	Steerable stylet with a guidewire tip controlled by a pull wire located at the proximal end and coupled to the handle and a pull wire at the distal end comprising a guidewire tip thus creating a steerable control.
US2011137309 (A1)	Bruce David Ogle and Matthew Partlett	09/06/2011	A steerable stylet assembly that utilises a tubular control structure with manual actuator pull wires to manipulate the two bending angles on the steerable stylet, one at the tip of the stylet and one at the half way mark.
AU2010205892 (A1)	Cathrx Ltd	21/07/2011	A steerable stylet with a controlled tip based on a control device attached to the top of the stylet. The bend region (i.e. steerable tip) is constructed by an array of longitudinally spaced slots. An actuator that could be a shape-memory alloy is to be pre-formed within a loop shape or be a material to bent into the desired shape prior to use.
US2015258295 (A1)	John Stocking and Francis Duque	13/12/2013	Described as a device for introducing and airway tube into the trachea utilising a telescoping guide member that is operator drive. Patent provides no detail as to whether this is mechanical or electronic drive, however describes control as operator to manoeuvre guided with the finger or fingers of the hand supporting the introducer.
US5766202 (A)	Pilling Weck Inc. (US)	21/01/1997	Wire-guided oesophageal bougie; hollow bougie that allows a guidewire to be threaded down the main shaft, no mechanism or electronic control included.
US20160279365A1	Construct Medical Pty, Ltd.	06/11/2013	A manually manipulated bougie with controllable movable tip having proximal and distal ends, the proximal end of the movable tip is connected to the distal end of the main shaft.

APPENDIX C – SUMMARY OF A SAMPLE OF STUDIES CONSIDERING EQUIPMENT PERFORMANCE, EFFICIENCY AND SAFETY

Reference	Bougies, Introducers, Stylets Analysed	Methods/Measurement	No. Trial Participants	Overview Of Results & Findings
Jackson Bartlett and Yentis, (2009)	1. Portex Venn reusable tracheal tube introducer. 2. Portex Single Use Bougie (coude tip). 3. Portex extra-long tracheal tube stylet. 4. Portex single use exchange guide. 5. Portex tracheal intubation stylet. 6. Frova airway intubating catheter.	*Part 1:* An examination of the differences between six different bougies and the forces required to remove them from a standard tracheal tube. *Part 2:* An examination of the force required to remove a standard bougie from four different tracheal tubes (Portex Ivory, Portex Clear, Hudson RCI/Sheridan and Rusch (7.0mm).	N/A	– *Part 1:* The forces recorded that were required to remove the bougies varied between the six difference bougies tested ranging from 5N to 31N. The extra-long TT stylet could not be pulled from the tracheal tube without altering the testing setup. Removal was noted to be easier when the bougies were lubricated; however this was not significantly when corrections were made for the multiple comparisons. – *Part2B:* The forces required to remove gum elastic bougie from the four tracheal tubes varied significantly regardless of the use of lubrication; forces recorded ranged from 4N to 24N. Removal of the bougie was noted to be easier when lubricated; significant differences were only noted between the two Portex tracheal tubes.

Reference	Bougies, Introducers, Stylets Analysed	Methods/Measurement	No. Trial Participants	Overview Of Results & Findings
Hodzovic, Wilkes and Latto (2004)	1. Mutiple-Use Eschmann Gum Elastic Bougie (Tracheal Tube Introducer) 2. Portex Tracheal Tube Introducer.	50 anaesthetists recruited to and asked to place a multiple-use bougie in the trachea of a manikin with grade three laryngoscopic view simulated. 20cm and 30cm bougie distance held locations were used. An analysis on the effect of holding bougies at different distances was completed; bougie placement success rates were also recorded. A distance held survey was completed. A force study to analyse bougie tip pressures when held at different distances was also completed.	50	– *Distance Held Survey:* Twenty anaesthetists identified that they would hold the bougie at 20 cm from the tip; other participants identified they would hold the bougie within the range of 10- 40 cm; 11 were not being able to specify a set standard distance they would hold the bougie at. – *Effects Of Distance Held On Placement:* The mean (SD) time taken when holding the bougie at the 20 cm distance held location placement was significantly shorter with compared to the 30 cm location with successful intubation recorded at 20 and 30 cm distance from the tip were 68 and 62%. Holding the bougie at either 20 or 30 cm distance from the tip did not influence success rates significantly ($p = 0.55$). – *Force Study:* Single use bougies were two/three times greater compared to multiple use bougies.
Annamaneni et al., (2003)	1. Single Use & Multiple Use Bougies	This study is a randomised cross-over study consisting of 20 anaesthetists who attempted to place a multiple or single-use bougie in the trachea of a manikin, setup to a cormack and lehane grade 3 laryngoscopic view. Each anaesthetist made two attempts at placement with each bougie and were blinded to success (tracheal placement) or failure (oesophageal placement).	20	– Success rates for the first attempt placement with the multiple and single-use bougies were 85% and 15%. – The success rates for second attempts with the multiple and single-use bougies were similar success rates recorded for the first time placement attempts. – Single use bougies present an increased risk of failure for successful first time intubation placement; consideration must be made to the argument of successful placement vs cross infection from multiple use bougie.

Reference	Bougies, Introducers, Stylets Analysed	Methods/Measurement	No. Trial Participants	Overview Of Results & Findings
Marson et al., (2014)	1. Eschmann Reusable Bougie 2. Frova Bougie	*Part 1:* A study was setup to record the maximum force that could be exerted at the tip of a bougie during tracheal placement i.e. identifying the hold-up force. *Part 2:* Airway perforations force assessment (i.e. the force required to produce airway trauma on a porcine airway model). Airways were simulated utilising a manikin that has a bronchial extension to analyse the hold-up force and porcine lung models were used to analyse airway perforation forces. Forces were recorded utilising a force transducer at the end of the manikins airway or at the distal end of the tray utilised for the porcine airway.	N/A	– Peak forces measured with the Frova bougie ranges from 4.7–6.3 N (mean). The Frova bougie presented forces four times greater than those measured with the Eschmann bougoe (0.6– 1.4 N(mean)). – The mean force required to produce airway perforation was 0.9 N with the Eschmann bougie and 1.1 N with the Frova bougie. P values of <0.11 highlights significant results. – The mean hold-up forcea (for airway lengths over the range 25–45 cm) recorded were 1.0 and 5.2 N for the Eschmann and Frova bougies; p value of <0.001 inidicats the results are significant. – The study recommends that the holdup sign should no longer be used when utilising single use bougies. – Airway trauma that is associated with the use of the hold up sign could be minimised if the bougie is gently advanced with the tip facing anteriorly during tracheal placement with the operator feeling for clicks as the tip of the bougie slides over tracheal cartilage rings. – Hold up sign airway trauma could be avoided if the inserted bougie is retracted by a few centimetres before railroading the tracheal tube. – The assistant should be asked to hold the bougie during railroading if the patient has a small airway to minimize the risk of airway trauma.

Reference	Bougies, Introducers, Stylets Analysed	Methods/Measurement	No. Trial Participants	Overview Of Results & Findings
Hodzovic et al., (2004)	1. Eschmann Multiple Use Introducer Bougie 2. Frova Single Use Introducer Bougie 3. Portex Single Use Introducer Bougie	An analysis of 48 anaesthetists who attempted to place a Frova single-use introducer, an Eschmann multiple-use introducer and a Portex single-use introducer in the trachea of a manikin set up to simulate a grade 3 laryngoscopic view. A force study to analyse bougie tip pressures of the three bougies when held at different distances was also completed (10-40cm).	48	– Successful placement for the Frova introducer (65%, 50–77%) and Eschmann introducer (60%, 46–73%) was significantly more likely than the Portex introducer (8%, 3–20%). – Peak forces exerted by the Frova Bougie and Portex Introducers were two to three times greater compared to the Eschmann Introducer. In all the force tests, p values of < 0.05 indicated significant results. – Mean (SD) force (Newtons) exerted when holding the introducer at various distances presented that 40cm from the tip exhibited the least amount of tip pressure. The peak forces decreased significantly as distances increased away from the tip. – Single-use introducers are more likely to cause tissue trauma during placement.
Hodzovic et al., (2008)	1. Frova Single Use Introducer Bougie	A prospective observational research study was used to evaluate the clinical effectiveness of the Frova single-use tracheal tube introducer. Forms were to be completed and placed in a transparent folder with data collected relating to the patient and the procedure completed.	203	– Successful placement was achieved in the trachea in 194 ⁄ 203 (96%) of patients when two attempts at placement were achieved by the first clinician. Failure to complete successful placement by the first clinician was noted in six (3%) and ten (5%) of the 203 patients. Airway trauma was observed in 11 ⁄ 203 (5%) patients. – The success rate achieved by the first clinician was significantly influenced by the laryngeal view obtained during the procedure undertaken. – Although the Frova introducer has a high success rate for tracheal placement however there is evidence to suggest there the incidence for airway trauma is noteworthy where are the Eschmann introducer has a low association with airway trauma.

Reference	Bougies, Introducers, Stylets Analysed	Methods/Measurement	No. Trial Participants	Overview Of Results & Findings
Janakiraman et al., (2009)	1. Eschmann Multiple Use Introducer Bougie 2. Pro Breathe 3. Frova Single Use Introducer Bougie 4. Portex Single Use Introducer Bougie	A randomised cross-over study analysing 72 anaesthetists attempting to place Pro-Breathe, Portex, and Frova single-use tracheal tube introducers and an Eschmann multiple-use introducer in the trachea of a manikin set to simulated a grade 3 laryngeal view. A force study to analyse bougie tip pressures of the four bougies when held at different distances was also completed (10-40cm).	72	– Successful placement was achieved with the Frova (78%, 67–86%) and Eschmann introducer (64%, 52–74%) compared to the Pro-Breathe (4%, 1–12%) or the Portex introducer (13%, 7–22%). (proportion, confidence interval). The difference between the Frova and Eschmann bougie di not present significant results (<0.08). – Peak forces could be exerted by the Pro-Breathe, new Portex and Frova single-use introducers were between three to six times greater compared to the Eschmann introducer. Results were significant (p values of <0.0001). – The study suggests the the Pro-Breathe and new Portex single-use introducers are inferior to the Frova single-use and Eschmann multiple-use introducers which are more commonly used in practice. The Pro-Breathe and Portex single use bougies should ideally not be used for the management of grade 3 laryngeal view airways.
Braude et al, (2009)	1. Sunmed Bougie. 2. Portex Bougie. 3. Greenfield Bougie. 4. Eschmann Bougie.	Randomized study of four different gum elastic bougies (Sunmed, Portex, Greenfield, and Eschmann) Measurements were recorded on a simulated difficult airway model. Success, time to intubation, and personal preferences were recorded for each participant within the study.	34	– Success rates of 88% (Sunmed), 68% (Portex), 88% (Greenfield) and 79% (Eschmann) were observed. – Participants were more likely to be successful when using Sunmed or Greenfield Gum Elastic Bougies compared to other equipment. – Success rates differed significantly based on the specialty of the operator. The emergency medicine physicians were successful in 60/84 (71%) intubations compared to anaesthetists 50/52 (96%). – No overall differences were observed in speed on intubations for the participant groups.

APPENDIX D – STEERABLE BOUGIE PRODUCT DESIGN SPECIFICATION (PDS) FULL VERSION

1.0 Performance

1. The device should act as a steerable emergency airway access device and exhibit similar or greater physical properties to bougie introducers currently available on the market. The original bougie/stylet should be capable of acting as both a standard and steerable device instead of being a replacement device with increased steerable functionality which is sought when initial induction of anaesthesia fails.
2. The procedure should take no longer than thirty seconds to one minute.
3. The device is to be used on patients who are either unconscious or unable to breathe on their own, therefore preventing suffocation or airway obstruction.
4. Reduce the need of surgical airway access and improve the safety of the procedure over existing emergency airway access devices.
5. Prevent oxygenation depravation to the patient ensuring an unobstructed airway is maintained.
6. The bougie should be capable of bending 120° in the sagittal plane, 60° in each direction.
7. The response of the device should be fast and positive with the necessary reaction and relaxation times of one second.
8. The device should be able to hold by itself in the bent position with sufficient strength until the controls are relaxed.
9. The bougie should still be capable of being manually bent and be capable of retaining its shape as well as, or better than, the current gold standard bougie.
10. The bougie should still be capable of being manually bent should the steerable function fail.
11. The device should be compatible with intubation tubes with an internal diameter between 7mm and 9mm.

12. The device should be capable of being used in conjunction with standard laryngoscopy equipment and video laryngoscopy equipment currently utilised in practice.

2.0 Environment

1. 22 ^{o}C Ambient Temperature.
2. Temperature Range ± 6 ^{o}C.
3. The steerable device is to be used in direct contact with a patients airways and open lesions.
4. The steerable bougie is to be used by anaesthetists, intensive care and emergency room physicians during endotracheal intubation. The disposable bougie part is to be stored in a sealed packet until required.
5. Selected materials must be safe to use during device operation whilst inside the human body, without causing a reaction to human tissue.
6. The human body normal temperature (37 degrees) must not affect device performance and material manipulation.
7. The reusable grip is to be subjected to cleaning and sterilisation between uses.
8. The reusable grip is to be stored in a clean environment; ideally the difficult airway trolley, until required.

3.0 Patents

1. Patent searches should be completed and investigated for new steerable technologies which could be applied or allow additional patents to be registered for steerable devices.
2. Ensure the development of the device and project runs in alignment with the submitted patent application, especially during the manufacture of the device.
3. Monitor registered patents over a three-year time-period to monitor potential competition.

4.0 Shelf Life Storage

1. The bougie is to be used within a two-year time scale from the manufacture completion date.
2. The control grip must start to be used in service within two years of manufacture.
3. Products must be stored at room temperature and conform to ISO 11607-1:2006: Packaging for terminally sterilized medical devices (International Standards Organisation. (2006).
4. Re-shelving costs and processes may need factoring into the shelf life storage and inspection of products.

5.0 Quality/Reliability

1. The reusable grip should display no more than one minor fault in one thousand uses and no failures under simulated or normal use in the testing phase.
2. 1m drop test should not affect reliability of the reusable grip.
3. The disposable bougie components should display no more than a 20% reduction in range of motion should failure occur in simulated normal use trials; no catastrophic failures should occur.
4. 1m, 5m and 10m drop test should not affect reliability of the steerable bougie device.
5. The mean time before failure for the reusable controller should be no less than six years.
6. The steerable bougie must conform to ISO 13485 - Quality management system for the design and manufacture of medical devices.

6.0 Maintenance

1. The disposable steerable bougie parts should require no servicing.
2. The reusable grip should not require any servicing during its lifespan (five years).
3. The device must have minimal or zero maintenance other than battery maintenance and sterilisation procedures.

4. The steerable bougie component is to be designed and used for a single operation and disposed after detachment from the reusable controller. The disposal of components must comply with Health & Safety Legislation, European Union Directives and Waste Electrical and Electronic Equipment (WEEE) Legislation.

5. A battery indicator must be incorporated to ensure the notification of low battery after periods of device inactivity.

6. The steerable bougie component must be capable of constant operation for a period of ten minutes with a maximum of forty moves per operation with a mean average of twenty five moves ±20 per cent.

7.0 Size

1. The bougie length should be a total of 700mm long including a 50–60mm steerable tip.

2. The bougie shaft diameter should be no greater than 5mm and must continue to retain or improve bougie shape retention.

3. The detachable power connector located at the base of the bougie shaft should be no greater than 6mm in diameter and be of a suitable weight that will not hinder or impede the intubation procedure.

8.0 Product Cost

1. The steerable bougie part should cost no more than £18-£20 GBP to manufacture.

2. The steerable bougie should be profitable at £25-£30 GBP selling price.

3. The reusable grip should cost no more than £100 GBP to manufacture.

9.0 Ergonomics

1. The device should be suitable for single hand operation.

2. The device should be optimised for use by male and female adults considering the 5th and 95th percentile hand dimensions presented by Pheasant and Haslegrave, (2016).

3. The grip should be easily detachable from the bougie mid-operation.

4. The device should be easy to pass between operators during operation.

5. The controls should be intuitive and easy to operate.

10.0 Product Life Span

1. The reusable controller should have a total lifespan of five years, after which it must be disposed of.

2. The bougie will have a maximum shelf life of two years after which the bougie must be recycled or disposed of.

3. The bougie is to be designed and used for a single operation.

4. The reusable controller will be used with the steerable bougies for a maximum number of 250 operations per year.

5. The bougie is required to perform a maximum of forty moves per intubation procedure and a mean average of twenty-five.

6. Maximum use of the controller will therefore be 31,250 movements ± 20%.

11.0 Quantity

1. Manufactured bougies are to be individually packaged and supplied in boxes of ten.

2. Initial quantities per hospital trust should be targeted at 300 disposable units per annum and ten reusable grips. With successful adoption these volumes should be increased based on demand.

12.0 International Standardisation

The developed steerable device must be fully compliant with the following standards:

1. Medical Device Directive (2007/47/EEC).

2. ISO 13485;2003 – Medical Device Quality Systems.

3. EN 60601 – Electrical Safety.

4. IEC 60601-1-2 – EMC Emissions.

5. IEC 61000-4-1 – EMC Immunity.

6. EN 980 – Use of Symbols on Medical Labelling.

7. ISO 14971 – Medical Device Risk Management.

For the product to be sanctioned for sale within the UK market, the product must be compliant with the following directives:

8. 2002/96/EC – Waste Electrical & Electronic Equipment (WEEE).

9. 2011/65/EU – Restriction of Hazardous Substances (RoHS).

10. (EC)1907/2006 – Regulation - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

13.0 Shipping/Packaging

The steerable device should be supplied in sterile packets and should remain intact during distribution to allow for the immediate use. Packaging should conform to the following standards and regulations:

1. BS EN 868-(2 to 10):2009: “Packaging for terminally sterilized medical devices. Sterilization wrap. Requirements and test methods”.

2. BS EN ISO 11607-1:2009: “Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems”.

3. BS EN ISO 11607-2:2006: “Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes”.

14.0 Materials

The materials used should conform with the following material standards:

1. BS EN ISO 10993-12:2009: “Biological evaluation of medical devices. Sample preparation and reference materials”.

2. BS EN ISO 10993-18:2009: “Biological evaluation of medical devices. Chemical characterization of materials”.

3. DD ISO/TS 10993-19:2006: “Biological evaluation of medical devices. Physico-chemical, morphological and topographical characterization of materials”.

15.0 Documentation

The production of the required operative documentation will cover the following issues:

1. Operation of use instructions are required to be supplied with each box of ten of the devices.

2. Legal and medical legislation information must be provided and clearly stated on packaging where required.

3. Disposal information and recycling instructions need to be provided to the operator either on the individual product packaging or grouped box packaging.

16.0 Disposal & Eco-Constraints

1. The disposable bougie components must be disposed of ensuring the necessary recyclable parts can be separated and recycled.

2. The reusable grip should be disposed of after a five-year lifetime with only minor dismantlement of the device required i.e. removal of the electronic components from the controller's outer shell.

3. Manufactured elements of the steerable device must be compliant with the Restriction of Hazardous Substance and Waste Electrical & Electronic Equipment directives.

4. When disposing of the device the following eco-constraints must be considered:

    a. Individually mark each individual component so that the user knows which components can be recycled.

    b. Identify the components via the relevant logo to ensure the user recycles the components utilising the correct medical waste disposal units in the hospital or clinical based environment.

    c. Suitably mark for disposal the sharp and metal components of the internal controller mechanism (if applicable) which should be placed in sharps boxes once used.

17.0 Customer

The customer targeted is anaesthetists of all grades; anaesthetists will use the product in the following situations and may involve a wide user base:

1. During emergency airway access procedures.
2. During practical demonstrations of the procedure.
3. Teaching opportunities for trainee anaesthetists.

18.0 Politics/Legislation

1. The product should comply with CE Mark and ideally FDA regulations to ensure that the product can be sold internationally.
2. For successful operative integration, the device must adhere to the applicable medical regulations and pass clinical trials, providing proof of increased usability and safety in comparison to existing devices available on the market.
3. All materials and systems incorporated require the necessary medical approval and must conform to the appropriate medical legislation, i.e., Medical Device Directive 2007/47/EEC, CE Mark Legislation and MHRA Medicines and Medical Device Regulations.

19.0 Installation

Device installation and setup for procedural use must consider the following criteria:

1. The design of the device must enable the steerable bougie to be easily assembled/installed into one device to ensure quick operation during an emergency.
2. The device must be battery powered and have the ability for the battery to be changed quickly should the battery indicator display a low charge, thus making the device non-operational.

Installation into the clinical setting, i.e. within the difficult airway trolley, the following must be considered:

3. The steerable bougie should be located in the difficult airway trolley (DAT) and must be stocked in a logical sequence, and clearly labelled so that it is easily identifiable.

4. The steerable bougie should be located in the side container of the difficult airway trolley in accordance with the Difficult Airway Society (DAS) recommendations.

5. The re-usable controller is to be stored in draw one (i.e. Plan A) of the difficult airway trolley.

20.0 Aesthetics

The following aesthetic design requirements must be adhered to for the design of the steerable bougie main shaft:

1. The colour of the steerable bougies main shaft must conform to a colour accepted by anaesthetists; common colours include, light blue, yellow, orange, purple and green.

2. The main shaft must have markings on to depict the distance from the tip; markings 10cm, 20cm, 30cm and 40cm from the tip are required.

3. The steerable tip must be a distinctly different colour to the main shaft of the bougie.

4. The connector at the top of the steerable bougie must also be a different colour to the main shaft and the steerable tip to ensure that the operator can distinguish where the connector is located for quick release.

The following aesthetic design requirements must be adhered to for the design of the re-useable control device connected to the laryngoscope:

5. The re-useable control device must be of a contrasting colour to the laryngoscope to be easily identifiable.

6. The control device must also be of a contrasting colour and must consider the safety apparatus worn by the anaesthetist, i.e. surgical gloves.

7. The controller must be an easily identifiable, distinguishable colour and clearly depict the directional control.

21.0 Safety

1. The steerable bougie must reduce the need of surgical airway access and improve the safety of standard bougie related procedures based on the use of existing emergency airway access devices.

2. The device must conform to the necessary medical safety guidelines and regulations; consideration must be made to Medical Device Directive 2007/47/EEC.

3. The materials used for construction must minimise the chance of damage to airway soft tissues.

4. The forces generated by activation of the device must not be capable of damaging airway tissue.

The following safety considerations must be accounted for when designing and manufacturing the steerable bougie:

Design & Manufacturing Considerations

5. The steerable bougie must be capable of reducing the tip pressures exhibited within the tracheas in comparison to competitor products..

6. The bougie must be capable of holding its formed shape i.e. curved form, to ensure the bougie can be adequately inserted after safely passing the vocal cords and resistance or hold-up is achieved.

7. The steerable bougie must be capable of having an endotracheal tube railroaded over the top of the main shaft and tip whilst it is in-situ.

8. The operator of the steerable bougie must be able to securely hold the bougie when either unlubricated or lubricated; the safety apparatus worn must also be considered in this scenario.

9. The bougie shaft and steerable tip must seamlessly integrate to ensure that no ridges are evident, and the endotracheal tube can seamlessly pass over the bougie when in-situ.

10. As far as possible all components must be fail safe with regards to their performance and conform to performance repeatability requirements.

Electrical Safety

11. Any electronic components must conform to the standards set out within the Medical Device Directives 2007/47/EEC.

12. All electronic components must conform to IEC 60601-1-1 General requirements for basic safety and essential performance.

13. All MHRA risk management regulations must be considered including ISO 14971 – Risk management for medical device safety.

14. Medical Electrical Safety Tests (MEST) may be required; specialist medical equipment safety testers which are programmed according to IEC 62353 standards will have to be utilised.

15. IEC 60601:The device must pass the following tests in accordance with IEC 60601 (International Electrotechnical Commission, 2012):

    - Visual Check.
    - Earth Continuity.
    - Earth Leakage.
    - Enclosure/Touch Leakage.
    - Patient Leakage.
    - Patient Auxiliary leakage.
    - Patient Type F Leakage.

16. IEC 62353:(International Electrotechnical Commission, 2014) defines the requirements for electrical safety testing of medical electrical (ME) equipment and systems during routine intervals and must include the following tests:

    - Visual Check.
    - Earth Continuity.
    - Equipment Leakage.

- Applied Part Leakage.

17. IEC 61010: In the case that the steerable bougie is to be tested by testing lab equipment, this equipment must conform to IEC 61010 (International Electrotechnical Commission, 2010). This includes:
    - Visual Check.
    - Earth Continuity.
    - Touch Voltage.
    - Enclosure Leakage (if required).

General Medical Device Safety Considerations

18. All re-useable medical equipment is subject to regular preventative maintenance to comply with manufacturer guidelines as a minimum.
19. The steerable bougie must comply with the MHRA recommendations on Single-use medical devices: implications and consequences of reuse (MHRA, 2013).
20. The steerable bougie must comply and consider the recommendations set out by the MHRA with regards to managing medical devices (MHRA, 2015).

22.0 Testing

During the product development phase of the steerable bougie, the following characteristics must be tested to confirm improved functionality and operative control; bespoke testing systems may need constructing to test these characteristics:

1. Improved shape retention.
2. Control mechanism repeatability testing.
3. Device operation repeatability testing.
4. Tip pressure testing.
5. Simulated intubation verification.

23.0 Competition

There are a considerable number of products that will rival the steerable bougie. Within the UK, the product range is reviewed extensively within literature, with a significant body of work completed on comparable and bespoke studies which inform regulation and professional body recommendations and publications. The Difficult Airway Society (2018) provides a comprehensive list of tracheal tube introducers, exchangers and guides, these include the following:

1. Aintree Intubation Catheter.
2. Arndt Airway Exchange Catheter Set.
3. Cook Airway Exchange Catheter (soft tip).
4. Cook Airway Exchange Catheter.
5. Eschmann Tracheal Tube Introducer (Gum Elastic Bougie).
6. Frova Single Use Introducer.
7. Gliderite Stylet.
8. Marshall Single-Use Bougie (straight tip).
9. Marshall Vented Intubating Introducer.
10. Portex Intubation Stylet.
11. Portex Single-Use Bougie (straight tip).
12. Portex Single-Use Bougie (angled tip).
13. Pro-Breathe Single-Use introducer.

Outside of the UK there are a sizeable number of products available on the market, however, many of these have not undergone formal testing to achieve their CE marking. However, the Asian market, especially China, Japan and Indonesia mass produce lower quality products which have FDA approval and can be sold at a lower price point. The physical properties and performance attributes of these products are noted to be lower and do not conform to the ADEPT guidelines.

24.0 Weight

1. The steerable bougie should weigh no more than 15g; this figure is set based on the average weight calculated from a sample of existing single used bougies.
2. The controller connector must not add significant weight to the bougie or affect its operative control.
3. The controller must be lightweight and must not hinder the use of the laryngoscope when attached for use.

25.0 Market Constraints

The UK market for bougie introducers is limited due to the market size and the suppliers approved by the NHS Supply Chain. For the steerable bougie to be successful, the product must be designed to ensure that it can be sold within the NHS supply chain. The steerable bougie must be able to be sold by an NHS approved supplier or be sold by a company that can become an NHS approved supplier and listed on the NHS supply chain. The steerable bougie must be superior in performance in order to take advantage of the market constraints and must be able to compete with products sold by the following suppliers:

1. Armstrong Medical Ltd, Coleraine, Northern Ireland, UK.
2. Cook Group Incorporate©, Indiana, USA.
3. Eschmann© Holdings Ltd, West Sussex, UK & Smiths Medical International Ltd, Kent, UK.
4. Fannin UK Ltd, Swadlincote, UK.
5. Intersurgical©, Berkshire, UK
6. Insight Medical, Tetbury, UK.
7. Proact Medical, Corby, UK.
8. P3 Medical, Bristol, UK.
9. Marshall Airway Products Ltd, Radstock, UK.
10. Smiths Medical International Ltd, Kent, UK.
11. SunMed, Grand Rapids, Michigan, USA.
12. Verathon Inc./ Roper Technologies, Seattle, Washington, USA.

26.0 Life In Service

1. The steerable bougie is to be designed based on the procedure length. Operative life in service is based around the device being a single use bougie and as such must be capable of being utilised within this time scale. Once operative use has been completed, disposal of the bougie is required.

2. The controller should complete a minimum of two years life in service before being replaced with a mandatory five years life in service; changing of power source i.e. replaceable batteries, may extend this minimum life in service.

APPENDIX E – JICEC ETHICS APPLICATION

Appendix 1 - Joint Inter College Ethics Committee Ethical Clearance Checklist

JOINT INTER COLLEGE ETHICS COMMITTEE

ETHICAL CLEARANCE CHECKLIST

College of Art, Architecture, Design and Humanities; College of Science and Technology; and the Centre for Academic Development and Quality (CADQ)

(TO BE COMPLETED FOR ***ALL*** INVESTIGATIONS INVOLVING PARTICIPANTS)

All staff and PGR students wishing to conduct an investigation involving participants in order to collect new data in either their research projects or teaching activities are required to complete this checklist before commencement. It may be necessary after completion of this form to submit a full application to the Joint Inter College Ethics Committee (JICEC). Collecting primary data in the absence of ethical approval, or in the face of an adverse ethical opinion, may constitute a disciplinary offence.

If, after receiving ethical approval, factors beyond your control change your project such that the information provided in this form no longer holds, the approval will automatically become void, and you should re-apply for ethical approval. The approval process should take no longer than one month.

If your research is being conducted off campus and ethical approval for your study has been granted by an external Ethics Committee, Please send details to the professional support research team for consideration by the chair. you will be expected to provide evidence of approval from the external Ethics Committee and the terms on which this approval has been granted.

IF YOUR RESEARCH IS TRANSFERRING INTO NOTTINGHAM TRENT UNIVERSITY AND APPROVAL WAS OBTAINED FROM YOUR ORIGINATING INSTITUTION, THERE IS A REQUIREMENT ON THE UNIVERSITY TO ENSURE THAT APPROPRIATE APPROVALS ARE IN PLACE.
If you believe either of these statements applies to your research, please contact the Professional Support Research Team AHDResearchteam@ntu.ac.uk **with evidence of former approval and the terms on which this approval has been granted.**

It is the responsibility of INDIVIDUAL investigators AND/OR SUPERVISORS to ensure that there is appropriate insurance cover for their investigation.
If you are at all unsure about whether or not your study is covered, please contact the Finance & Planning Manager in your Finance team to check.

Name of Applicant:		**Francesco Luke Siena (ADB3SIENAF & N0527590)**	
School:		**Architecture, Design & The Built Environment**	
Title of Investigation:		**Evaluation Of Intubation Introducers & Bougies**	
STAFF	☒	**Student**	☒(*if student, please complete)

Research	☒	**Consultancy**	☐

Degree Title and Level*:	**PhD**
Supervisor (List Lead supervisor first)	**1.Professor Philip Breedon** **2. Dr Phillipa Marsh** **3. Professor Bob Stevens**
Names of co-investigators (CIs) (If any of the CIs are not employed at NTU, please give the name of their organisation)	Dr James Armstrong (NuH) Consultant Anaesthetist Dr Andrew Norris (NuH) Consultant Anaesthetist & Honorary (Clinical) Associate Professor Dr Kristopher Inkpin (NuH) Consultant Anaesthetist
Project start date	**Jan 2018**
Estimated end date of the project	**Feb 2018**
Who is funding the project? Has funding been confirmed?	No Funding Required. NTU PhD Funding (VC Bursary)

Briefly outline the objectives of the research. [75 words]

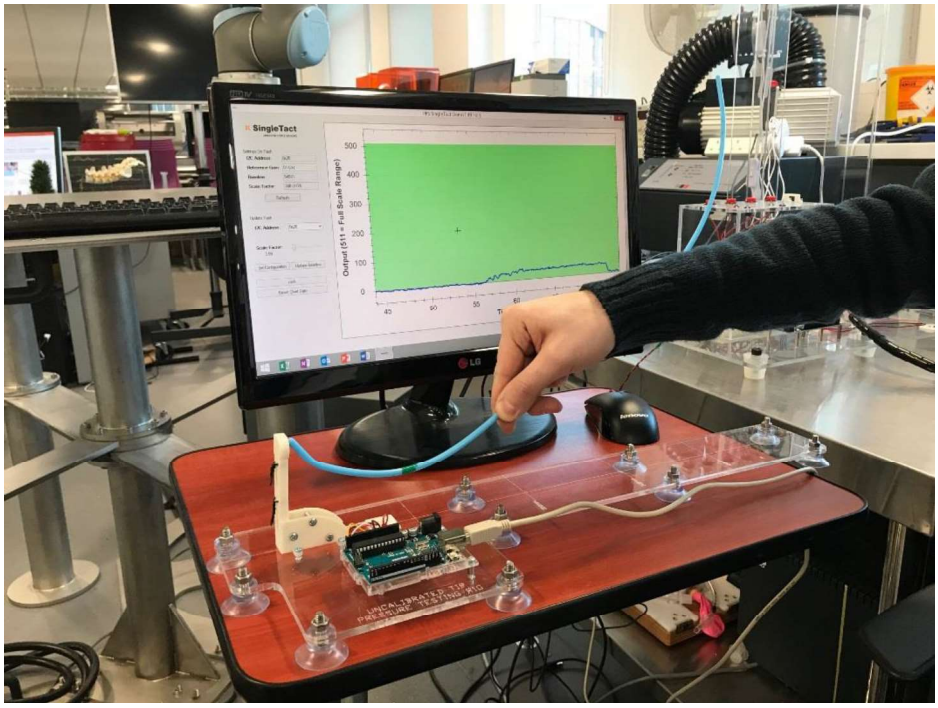
The correct selection and safe use of optimally designed equipment is just one aspect of difficult airway management; recent equipment improvements have been shown to improve airway management success and safety rates however these devices have not all been tested against DAS's ADEPT guidelines. It is imperative that any equipment used is fit for purpose; causing further complications because of device failure during airway management procedures must be avoided. Testing of intubation introducers and bougies tip pressures is required utilising suitable equipment to help inform device manufacture and selection.

An JICEC application has been completed in order to request a statement/letter that states that no ethics is required which can be passed onto the Nottingham University Trust to allow testing to take place within the anaesthesia department. External advisors from Nottingham University Hospitals Trust (NuH) have advised that no ethical approval is required for this testing to be conducted, however a statement from NTU stating this is required for participation/approval.

Briefly describe the principal methods, the sources of data or evidence to be used, and the number and type of research participants who will be recruited to the project. [150 words]

The purpose of this study is to compare different intubation introducers and bougies; a force/tip pressure study will be completed by a minimum of 20 anaesthetists and up to a maximum of 50

dependant on recruitment. Force/pressure readings will be recorded as anaesthetists press the bougies against the sensor (type/software may vary) and will be repeated at 10cm intervals from the tip with the aim to discover optimum grip position in relation to tip pressures. An example of the testing environment/data acquisition setup can be seen below:



There are many bougies on the market, but little information is available to make informed decisions regarding device selection. Many of the devices complete the same procedural tasks, although little evidence supports their selection other than personal preference or designated hospital suppliers. Many devices have not undergone any formal testing in accordance with the Difficult Airway Society's ADEPT principles. High/increase tip pressures are noted in many journal articles however, published testing from other researchers has been deemed inaccurate due to measurement equipment selection.

Do you intend to use questionnaires, scales, psychometrics, vignettes, etc. that someone else has published?

NO

If YES, complete the next 3 questions

If NO, proceed 4 questions

Have you included with this application a full electronic copy or link to the above?

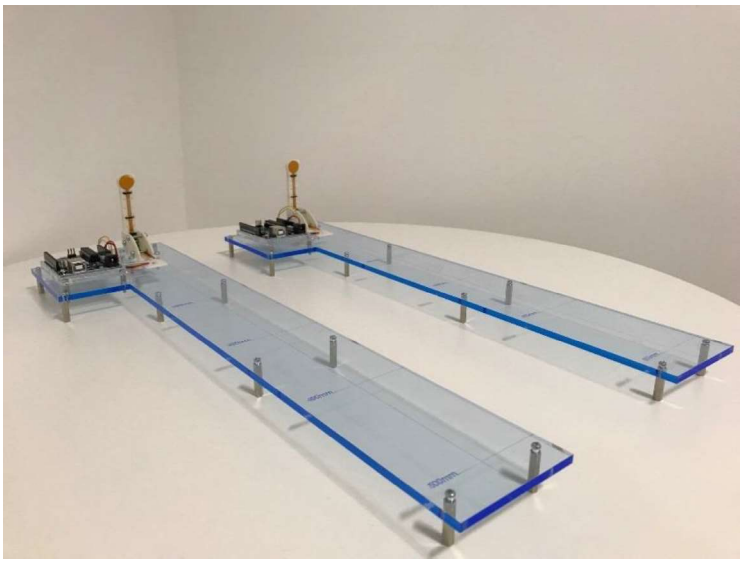
N/A

If you are using published the above, do you have permission to use them in the way that you intend to use them?

N/A

What steps will be taken to ensure compliance with the requirements of copyright rules for the use of published scale? **N/A**
Are you developing your own research resources/instruments to collect data? **NO – Forces sensors have been purchased from Single Tact & DMV UK & secured onto a laser cut acrylic base with Arduino controller as instructed by the manufacturer. This system has been adapted with suction cup feet to ensure testing system rigidity. (Please see Figure 1)** If YES, complete the questions below. If NO, proceed to the next section.
Briefly describe the research resources/instruments you are developing. [50 words] • Study Participation Consent Form • Risk Assessment • Force/Pressure Testing Equipment Setup • Purchase of Bougie's (4-6 different types) + Manufacture Of Research Group Developed Bougie. • Data Acquisition Software & PC/Laptop
If applicable, please include an electronic copy of your own bespoke/self-developed research instrument(s) that you will use to collect data with this application. **N/A**

Figure 1: Example Testing Rig Setup*



*Setup/Data Acquisition Software may alter slightly depending on the sensor used to capture data.

A. **Familiarisation with policy -** Please answer *as appropriate*			
Please confirm if you are fully acquainted with the policies for guiding ethical research named below:			
NTU research ethics policy, and the procedures for ethical approval	Yes ☒	No☐	N/A☐
The guidelines for ethical research promulgated by a professional association, as appropriate	Yes ☒	No☐	N/A☐
NTU Data Management Policy	Yes ☒	No☐	N/A☐
The Regulations for the Use of Computers (*see* NTU website)	Yes ☒	No☐	N/A☐
Guidelines for Risk Assessment in Research	Yes ☒	No☐	N/A☐
If you answered **NO** to any of these questions, please note that you must study these guidelines and regulations before proceeding to complete the remainder of this form.			

B. **External Ethical Review –** *Please answer as appropriate*			
Has a favourable ethical opinion already been given for this project by any other external research ethics committee[1]? ****Clinical experts have suggested no ethical approval is required however require a NTU Statement/Headed Letter to confirm this.** An external research ethics committee means any research committee *other* than those at Nottingham Trent University. Submission of this form is *not* a submission to an external research ethics committee.	Yes ☐ **	No☐	N/A ☒

Will this project be submitted for ethical approval to any other external research ethics committee[2]? An external research ethics committee means any research committee *other* than those at Nottingham Trent University. Submission of this form is *not* a submission to an external research ethics committee.	Yes☐	No ☒	N/A☐
If you answered **YES** then sign the declaration and submit with the letter of confirmation to the Research Office to keep on file.			

C. **Investigators**			
Do investigators have previous experience of, and/or adequate training in, the methods employed?		Yes ☒	No**☐
If involved will junior researchers/students be under the direct supervision of an experienced member of staff?	Yes ☒	No**☐	N/A☐
If involved will junior researchers/students be expected to undertake physically invasive procedures (not covered by a generic protocol) during the course of the research?	Yes**☐	No ☒	N/A☐
Are researchers in a position of direct authority with regard to participants (e.g. academic staff using student participants, sports coaches using his/her athletes in training)?	Yes**☐	No ☒	N/A☐
** If you select ANY answers marked **, please submit your completed Ethical Clearance Checklist accompanied by a statement covering how you intend to manage the issues (indicated by selecting a ** answer) to the JICEC.			
D. **Participants**			
Clarify whether or not your research involves any do the following vulnerable groups.			
Children under 18 years of age (please refer to published guidelines)		Yes*☐	No ☒
People over 65 years of age		Yes*☐	No ☒

Disabled people	Yes*☐	No ☒
People with mental illness	Yes*☐	No ☒
Prisoners/Detained persons	Yes*☐	No ☒
1. Is a DBS/Overseas Police Check required?	Yes☐	No ☒
2. If required, do you have a DBS/Overseas Police Check? 3. *Please contact NTU Disclosures, details can be found on the address book.*	Yes☐	No ☒
What actions will you take to ensure the safety of yourself and the participants?		
How will you recruit your participants?		
Have you completed a risk assessment form? Please attach to the application.	Yes* ☒	No☐
Risk		
4. To the best of your knowledge, please indicate whether the proposed study:		
Involves procedures likely to cause psychological, social or emotional distress to participants	Yes*☐	No ☒
Is designed to be challenging psychologically in any way	Yes*☐	No ☒
Exposes participants to risks or distress greater than those encountered in their normal daily life	Yes*☐	No ☒
E. **Special Risks**		
Does the project involve access to websites normally prohibited on university servers, for example pornography or sites of organisations proscribed by the UK Government.	Yes*☐	No ☒
Does the project involve access to investigation into extremism or radicalisation.	Yes*☐	No ☒
Does the project involve accessing and using data of a potentially damaging nature which has been obtained from a source which may not have the requisite authority to provide it. Here, potentially damaging can mean anything from information on cases of domestic abuse to data on international spy networks. In case of uncertainty please	Yes*☐	No ☒

consult the Research Support Office or your School Associate Dean for Research.		
Does the project involve the acquisition of security clearances, including the Official Secrets Act.	Yes*☐	No ☒

If you responded yes to any of these questions then this is classified as 'Special Risk Research' please refer to the guidance in Appendix B and ensure that these items are covered in the Risk Assessment (Appendix A). Please note that your application must be approved by your School Associate Dean for Research. This applies to both members of staff and Postgraduate Research Students.

Is there any foreseeable risk that your project may lead to:

Physical harm to participants or researchers?	Yes*☐	No ☒
Significant psychological or emotional distress to participants • i.e. Is designed to be challenging psychologically in any way • Exposes participants to risks or distress greater than those encountered in their normal daily life	Yes*☐	No ☒
Harm to the reputation of participants, or their employers, or of any other persons or organisations?	Yes*☐	No ☒

Chaperoning Participants
If appropriate, e.g. studies which involve vulnerable participants, taking physical measures or intrusion of participants' privacy:

5. Will participants be chaperoned by more than one investigator at all times?	Yes☐	No*☐	N/A ☒
6. Will at least one investigator of the same sex as the participant(s) be present throughout the investigation?	Yes☐	No*☐	N/A ☒
7. Will participants be visited at home?	Yes*☐	No ☐	N/A ☒

If you have selected N/A please provide a statement in the space below explaining why the chaperoning arrangements are not applicable to your research proposal:

No vulnerable participants are involved in the study.

If you have selected any of the * answers for any question in section E please explain/confirm:

- Explain why it is necessary to conduct the research in such a way as to qualify it as Special Risk research

- If applicable, confirm that access to websites which may be proscribed by the UK Government or may be subject to surveillance by security services will be undertaken using the University network
- Explain what, if any, steps will be taken, in addition to those listed in Section 6, to ensure that data obtained during the research project will be stored securely
- If applicable, confirm that the transmission of data obtained during the research project to any co-investigators outside of the University network will be in encrypted format and using Zend, which encrypts files during transmission.
- If applicable, explain why the transportation of research data or materials is required and that an encrypted memory stick will be used where such transportation is necessary or unavoidable

If the answer to <u>any</u> of the remaining questions is YES, please explain:

- the nature of the risks involved, and why it is academically necessary for the project to incur them
- how you propose to mitigate them
- the arrangements by which you will ensure that participants understand and consent to these risks
- any arrangements you will make to refer participants to sources of help, if they are seriously distressed or harmed as a result of taking part in the project
- your arrangements for recording and reporting any adverse consequences of the research

N/A

Advice to Participants following the investigation

Investigators have a duty of care to participants. When planning research, investigators should consider what, if any, arrangements are needed to inform participants (or those legally responsible for the participants) of any health related (or other) problems previously unrecognised in the participant. This is particularly important if it is believed that by not doing so the participants well-being is endangered. Investigators should consider whether or not it is appropriate to recommend that participants (or those legally responsible for the participants) seek qualified professional advice, but should not offer this advice personally. Investigators should familiarise themselves with the guidelines of professional bodies associated with their research.

Observation/Recording – *Please answer: yes or no*

Does the study involve data collection, or the observation or recording of participants?	Yes ☒	No☐

Note that data collection includes the re-use of material originally collected for a non-research purpose (e.g. client or student data already in your possession) and includes anonymous data		
Will those contributing to the data collected (or being observed or being recorded), or the appropriate authority, be informed that the data collection, observation or recording will take place?	Yes ☒	No☐
If you have answered **NO** to question to the first question in section E, because you are not undertaking empirical work, proceed to the declaration at the end of this form. If you have answered **NO** to question the second question, an application for ethical approval needs to be made to the JICEC.		
Consent and Deception – *Please answer: yes or no*		
Informed Consent & Data Withdrawal Will participants, or the appropriate authority, be fully informed of the objectives, and of all other particulars of the investigation (preferably at the start of the study, but where this would interfere with the study, at the end)?	Yes ☒	No☐
1. Will participants, or the appropriate authority, be fully informed of the use of the data collected (including, where applicable, ownership of any intellectual property arising from the research)?	Yes ☒	No☐
2. For detained persons, members of the armed forces, employees, students and other persons who may not be in a position to give fully independent consent, will care be taken over the gaining of freely informed consent?	Yes ☒	No☐
If your research involves children under the age of 18 or participants who have impairment of understanding or communication: **NOT APPLICABLE**		
- will consent be obtained (either in writing or by some other means)?	Yes☐	No*☐
- will consent be obtained from parents or other suitable person?	Yes☐	No*☐
- will they be informed that they have the right to withdraw regardless of parental/ guardian consent?	Yes☐	No*☐
3. For investigations conducted in schools, will approval be gained in advance from the Head-teacher and/or the Director of Education of the appropriate Local Education Authority?	Yes☐	No*☐
4. For detained persons, members of the armed forces, employees, students and other persons judged to be under duress, will care be taken over gaining freely informed consent?	Yes☐	No*☐
5. Will participants, or the appropriate authority, be informed of their right to withdraw from the investigation at any time (or	Yes☐	No*☐

before a specific deadline) and to require their own data to be destroyed?		
Deception		
1. Is deception part of the study? 2. If the answer is no, proceed to section G	Yes☐	No* ☒
3. If yes, please explain the rationale and nature of deception (50-75 words): 4. **N/A**		
5. Will participants be de-briefed and the true object of the research revealed at the earliest stage upon completion of the study?	Yes☐	No*☐
6. Has consideration been given on the way that participants will react to the withholding of information or deliberate deception?	Yes☐	No*☐
G. Storage of Data and Confidentiality		
Please see University guidance on https://www.ntu.ac.uk/intranet/policies/legal_services/data_protection/16231gp.html. If you are a member of NTU staff you can obtain direct access to this with your staff username and password. If you are not a member of NTU staff, please request of copy from your supervisor or course leader.		
Does the funder of your research require you to comply with policy around data management planning and access to publically funded research (RCUK funders, Horizon 2020, Wellcome Trust, etc). If yes, please attach your data management plan (please use https://dmponline.dcc.ac.uk/ to design your plan based around your funder's requirements. If you have any queries or require support please email: LIBResearchTeam@ntu.ac.uk).	Yes☐	No ☒
Will all information on participants be treated as confidential and not identifiable unless agreed otherwise in advance, and subject to the requirements of the law of the relevant jurisdiction?	Yes ☒	No☐
Will storage of data comply with the Data Protection Act 1998 and the law of any non-UK jurisdiction in which research is carried out?	Yes ☒	No☐
Will any video/audio recording of participants be kept in a secure place and not released for use by third parties?	Yes ☒	No☐
Will video/audio recordings be destroyed within six years of the completion of the investigation?	Yes ☒	No☐
If your study involves video/photography please ensure that participants have completed a release form.		

Have you taken steps to ensure full security and confidentiality of any personal or confidential data collected for the project.	Yes ☒	No☐
I confirm that any data will be stored in line with the University Data Management Policy. Files will be stored in a password protected computer with data coded and anonymised appropriately.	Yes ☒	No☐
H. Incentives		
1. Have incentives (other than those contractually agreed, salaries or basic expenses) been offered to the investigator to conduct the investigation?	Yes**☐	No ☒
2. Will incentives (other than basic expenses) be offered to potential participants as an inducement to participate in the investigation?	Yes**☐	No ☒
** If you select ANY answers marked **, please submit your completed Ethical Clearance Checklist accompanied by a statement covering how you intend to manage the issues (indicated by selecting a ** answer) to the JICEC.		
The design of the participant information sheet/consent form and of any research instrument (including questionnaires, sampling and interview schedules) that will be used, have been discussed with my supervisor(s).		
Compliance with Ethical Principles If you have completed the checklist to the best of your knowledge and selected an answer marked with * or ** your investigation you will need to seek full formal approval from the JICEC. Please return to completed Ethical Approval Checklist with the following documents as necessary to the Research Team, Arkwright 204, City Campus, or via email AHDresearchteam@ntu.ac.uk: • A copy of the research tool you are using • Consent Form (if necessary) • Data Management Policy (if necessary) • Risk Assessment (if necessary) Please note that the ethics form does not abrogate your need to complete a risk assessment		

Declaration

☒I have read the Ethics & Governance Statement https://www.ntu.ac.uk/research/research-at-ntu/research-integrity . I confirm that the above named investigation complies with published codes of conduct, ethical principles and guidelines of professional bodies associated with my research discipline.

☒ I have read this form and confirm that appropriate steps have been taken to mitigate the special risks associated with the proposed project.

☒ I agree to notify the Research Office of any changes or modification that may have an influence on ethical approval.

Appendix 2 - Joint Inter College Ethics Committee – Risk Assessment

NOTTINGHAM TRENT UNIVERSITY

Task or Activity Description	Location:	Queens Medical Centre – Nottingham University Hospitals Trust (Department of Anaesthesia)
Bougie/Introducer Tip Pressure Study Participants will be asked to hold 4-6 different bougies in 10cm intervals from the tip. You will then be instructed to press the bougies against the force sensor where data acquisition software will collect and plot graphs. The participant will then be asked to repeat this test at 10cm intervals from the bougie tip with the aim of discovering optimum grip position in relation to tip pressures.		

Persons at Risk - Affected Groups:	
A – Recruited Participant	B – Operator (F.L.Siena)
C – Study Co-Investigators	D -
E –	F -

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
Study Protocol & Supervision Of Study	Study protocol has been approved by the co-investigators and clinical specialists at NuH Trust (QMC). The clinical co-investigators will monitor the study where appropriate.	Low	Clinical Co-Investigators have approved in advance.
Location Of Study	The study will take place at Queens Medical Centre – Nottingham University Hospitals Trust (Department of Anaesthesia). A suitable room/office will be used during the study. The study will be supervised by one of the clinical co-investigators	Low	Clinical Co-Investigators will organise prior to the study date.
First Aid	Although this study does not pose any risk of physical harm, if a first aider is required, directions to an approved first aider will be supplied by the clinical co-investigators.	Low	Clinical Co-Investigators will advise on site.

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
Fire Alarm/Emergency Exits	As a quest at Queens Medical Centre – Nottingham University Hospitals Trust (Department of Anaesthesia) the operator and lead of the study will be supervised on-site. Notification of the fire exits, drills, meeting points etc., will be advised upon arrival at the study location.	Low	Clinical Co-Investigators will advise on site.
Operation Of Equipment (PC/Laptop + Data Acquisition Sensor)	All electrical equipment will have the necessary electrical safety test certificate and PAT testing completed prior to arrival at Queens Medical Centre – Nottingham University Hospitals Trust (Department of Anaesthesia).	Low	Evidence to be provided if required. NTU Electrical safety test certificate and PAT testing completed for each piece of equipment on a rolling cycle, PC equipment completed/updated Dec 17.
Trip Hazards	With numerous wires for the data acquisition equipment and portable pc equipment, suitable cable location and tidying is required to prevent any trip hazards.	Low	N/A
Lone Working	If a clinical emergency occurs where the clinical co-investigators are required to leave the operator alone to work, clinical staff write provide details in and give a contact number to an office based member of staff for contact in emergencies.	Low	Contact details to be provided.
Consent/Withdrawal	All study participants are required to complete a consent form prior to taking part in the study. Contact details, anonymity an withdrawal details all provided in the consent form.	Low	Additional information can be added to the consent form if the clinical investigators request this to be done.

This risk level has been reduced as low as is reasonably practicable			
Assessor's Signature:		**Date:**	
Manager's Signature		**Date:**	

	1st Review	2nd Review	3rd Review	4th Review	5Th Review
Assessors Name:					
Managers Name:					
Date of Review:					

Appendix 3 – Tip Pressure Study Consent Form

NOTTINGHAM TRENT UNIVERSITY
Proforma: Research Consent Information Sheet

Protocol Title	Evaluation and testing of the physical properties of intubation introducers and bougies.
Principal Investigator:	Mr Francesco Luke Siena
Project Group	Mr Francesco Luke Siena Professor Philip Breedon Dr James Armstrong (NuH) Dr Kristopher Inkpin (NuH) Dr Andrew Norris (NuH)
Supported By	Dr Phillipa Marsh & Professor Bob Stevens (PhD Supervisor Team)

What is the purpose of this study?

The correct selection and safe use of optimally designed equipment is just one aspect of difficult airway management; recent equipment improvements have been shown to improve airway management success and safety rates however these devices have not all been tested against DAS's ADEPT guidelines. It is imperative that any equipment used in practice is fit for purpose; causing further complications because of device failure during airway management procedures must be avoided. Testing of intubation introducers and bougies physical properties such as tip pressures is required. A tip pressure testing study will be completed utilising suitable equipment to help inform device manufacture and thus inform optimum device selection for procedures.

What are we asking you?

The purpose of this study is to compare different intubation introducers and bougies; a force/tip pressure study will be completed by a minimum of 20 anaesthetists and up to a maximum of 50 dependant on recruitment.

We require you to take part in the force/tip pressure study. You will be asked to hold 4-6 different bougies in 10cm intervals from the tip. You will then be instructed to press the bougies against the force sensor where the data acquisition software will collect and plot graphs. We will require you to and will be repeated at 10cm intervals from the tip with the aim to discover optimum grip position in relation to tip pressures.

Video and/or photos of participant completing one of the tests/procedure (tip pressure study to analyse grip position of the bougie/introducer. This will solely consist capturing the ***hands/body only.***

How we would like to use the information provided

The information/result collected will be utilised and disseminated in the following ways:

1. Data will be utilised in Mr Francesco Luke Siena's PhD Thesis, specifically in chapters relating to the design, manufacture and analysis of existing bougies and new bougies.

2. Data will be analysed with the intention of publishing the results in an international journal i.e. Anaesthesia
3. Data collected will be analysed and protocol insights will contribute to a conference paper submission for at ICDVRAT 2018 (International Conference On Disability, Virtual Reality and its Associated Technologies)
4. Any video/photos captured of ***hands/body only,*** during the tests/procedures may be used within the publication of journal articles (if required) in relation to discussion about grip position. Videos/photos may also be used during conference presentations to illustrate methods and results collected.

Compliance with the Research Data Management Policy
Nottingham Trent University is committed to respecting the ethical code of conducts of the United Kingdom Research Councils. Thus, in accordance with procedures for transparency and scientific verification, the University will conserve all information and data collected during your interview in line with the University Policy and RCUK Common Principles on Data Policy (http://www.rcuk.ac.uk/research/datapolicy/) and the relevant legislative frameworks. The final data will be retained in accordance with the Retention Policy. All data will be anonymised and made available to be re-used in this form where appropriate and under appropriate safeguards.

What are the possible risks or discomforts?
Your participation does not involve any risks other than what you would encounter in daily life. If you are uncomfortable with any of the questions and topics, you are free not to answer.

What are my rights as a research participant?

- You have the right to withdraw your consent and participation at any moment: before, during, or after the interview. If you do wish to withdraw your consent please contact me using my contact details as above by **22nd June 2018.**

- You have the right to remain anonymous in any write-up (published or not) of the information generated during this interview.

- You have the right to refuse to answer to any or all of the questions you will be asked.

- You also have the right to specify the terms and limits of use (i.e. full or partial) of the information generated during the interview.

- You have the opportunity to ask questions about this research and these should be answered to your satisfaction.

If you want to speak with someone who is not directly involved in this research, or if you have questions about your rights as a research subject, contact Professor Michael White, Chair for the Joint Inter-College Ethics Committee (JICEC) at Nottingham Trent University. You can call him at 0115 848 2069 or send an e-mail to michael.white@ntu.ac.uk.

What about my Confidentiality and Privacy Rights?
Participation in this research study may result in a loss of privacy, since persons other than the investigator(s) might view your study records. Unless required by law, only the study investigator, members of NTU staff and the sponsoring

organisation [details] have the authority to review your records. They are required to maintain confidentiality regarding your identity.

Results of this study may be used for teaching, research, publications and presentations at professional meetings. If your individual results are discussed, then a code number or a pseudonym will be used to protect your identity.

Audio/visual recordings
Permission to use audio or visual recordings of your participation, for presentations in the classroom, at professional meetings or in publications, is requested below, as this may be necessary to understand and communicate the results. Any recorded data will be kept confidential and in a secure place in line with the Research Data Management Policy and destroyed in line with the current RCUK/University Guidelines.

Video and/or photos of participant completing one of the tests/procedure (tip pressure study. This will solely consist capturing the ***hands/body only.***

Who should I call if I have questions or concerns about this research study?

Mr Francesco Luke Siena

Medical Design Research Group

Nottingham Trent University

50 Shakespeare Street

Maudslay Building

Nottingham

NG1 4FQ

Phone: +44 (0) 1158 484 790

Phone: +44 (0) 7906 221 425

E-Mail: luke.siena@ntu.ac.uk

CONSENT FORM PROFORMA

Dear Research Participant

By agreeing to take part in this short force/tip pressure study, you will be asked to hold 4-6 different bougies in 10cm intervals from the tip and be instructed to press the bougies against the force sensor where data acquisition software will collect the tip pressure data and plot graphs. We will require you to repeat this at 10cm intervals from the bougie tip across 4-6 bougie types, with the aim of discovering optimum grip position in relation to tip pressures. Video and/or photos

of participant completing one of the tests/procedure (tip pressure study. This will solely consist capturing the ***hands/body only.***

There are many bougies on the market but little information is available to make informed decisions regarding device selection. Many of the devices complete the same procedural tasks, although little evidence supports their selection other than personal preference or designated hospital suppliers. Many devices have not undergone any formal testing in accordance with the Difficult Airway Society's ADEPT principles. High/increase tip pressures are noted in many journal articles however, published testing from other researchers has been deemed inaccurate due to measurement equipment selection.

The purpose of this study is to compare different intubation introducers and bougies; this force/tip pressure study will be completed by a minimum of 20 anaesthetists and up to a maximum of 50 dependant on recruitment. Force/pressure readings will be recorded as anaesthetists press the bougies against the sensor and will be repeated at 10cm intervals from the tip with the aim to discover optimum grip position in relation to tip pressures.

All participation in the project is voluntary. If do you agree to be part of the project, we would like to use the information to develop a range of content including research papers, conference contributions and a PhD thesis; but your name and identity will remain anonymous. If you decide at any stage, you no longer want to be part of the project, please let us know by 22nd June 2018 and we will make sure any information you have given us is destroyed.

This project has been reviewed by, and received ethics clearance through, the Nottingham Trent University Joint Inter College Ethics Committee.

Please read the following statements:

I have read the above project description, and had an opportunity to ask questions about the research and received satisfactory answers to any questions.
I have had sufficient information to decide whether or not you wish to take part in the study.
I understand that I am free to withdraw from the research by 23rd February 2018 by informing the researcher of this decision.
I understand that the information I give will be treated in the strictest confidence.
I agree to take part in the study.
I agree that this interview can be recorded.
I understand that quotations, which will be made anonymous, from this interview may be included in material published from this research.
I am willing to participate in an interview as part of this research project.
I understand that anonymized data may be used in other studies in line with the University Research Data Management Policy

I confirm that data obtained from the study can be used in the final research report. I understand that the data will be used anonymously: names, places and identifying details will be changed.

Full Name _____

Signature _____

Date _____

If you have any questions please contact:

Mr Francesco Luke Siena
Medical Design Research Group
Nottingham Trent University
50 Shakespeare Street
Maudslay Building
Nottingham
NG1 4FQ

Phone: +44 (0) 1158 484 790
Phone: +44 (0) 7906 221 425
E-Mail: luke.siena@ntu.ac.uk

In line with the Research Data Management Policy, requests may be made to use data from this study for other projects. If you do not wish your anonymized data to be used for future studies please tick here ☐

APPENDIX F – CASTING RISK ASSESSMENT

Risk Assessor's Name:	Francesco Luke Siena	**Accountable Managers Name:**	Phillip Breedon	**Planned Review Date**	January 2019

Task or Activity Description	**Location:**	**Future Factory Research & Consultancy Centre (Nottingham Trent University - Maudslay 214)**
Casting of Medical, Food, Modelling Grade Polymers into a designed casting rig (Transil, BlueSil, Smooth-Sil, Silicone Rubber) utilising Luer Lock Syringes, Needles & A Vacuum Degassing System for the manufacture of models. **Persons at Risk: A** – Main Operator of Luer Lock Syringes, Needles & Vacuum Degassing System. **Persons at Risk: B** – Additional Main Operators of Vacuum Degassing System for other project work. **Persons at Risk: C, D, E, F & G** – Additional Operators or person working in vicinity of Vacuum Degassing System. Training of future operators is only possible once the necessary training is provided for safe operation.	**Persons at Risk - Affected Groups:**	
	A – Luke Siena	B – Chris Forbes (Qualified First Aider)
	C – Mark Golab (PepsiCo RF)	D – Philip Breedon
	E – NTU Technical Support Staff	F – MDRG Group Members
	G – UG/PG Students	H - Invited Visitors Into M214

Potential Hazard	**Existing Controls**	**Risk level with controls**	**Additional Controls or Required Action & Date**
Medical Grade Polymers Material Preparation	Material preparation will be done so utilising the previous provided PPE. Eye protection to avoid eye contact. As with any work involving the risk of contamination, cover any exposed cuts or grazes with waterproof dressings. Ensure hands are thoroughly washed with hot water and an appropriate anti-bacterial soap before and after contact with the material.	Low	The safe use and control of the material used is the responsibility of the user/operator. The materials in use may cause eye and skin irritation and material data sheets advise that in case of eye or skin irritation that washing with soap and plenty of water is sufficient. If this occurs a first aider will also be notified so that this can be logged accordingly.

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
	Gloves are to be worn to avoid skin contact. In addition, clear vinyl (GN65) powder free examination gloves will be available to be worn when handling the materials to prevent skin irritation and material contamination (allergy considerations) Suitable hand sanitizer must be available. Suitable Clothing Protection (Lab Coat or Apron) must be worn at all times. Appropriate ventilation is provided within the testing room if required. The materials in question have been recommended for use by Richard Arm/Ryan Young (Casting Experts & Current NTU Technical Staff) and are materials which have already been approved as safe for use at NTU.		
Degassing Material	A Vacuum Degassing System will be used for the degassing of the material in use. The Vacuum Degassing System will have the necessary NTU electrical safety test and PAT test to ensure the device is in safe working order. The same Vacuum Degassing System is currently utilised in other facilities within the School of Art & Design and does not require hearing protection for operation, and does not require any form of ventilation.	Low	This is the responsibility of the user/operator of the Vacuum Degassing System and they must follow the provided instruction for safe use and operation. If in the future ventilation is required, the appropriate re-assessment procedure will be followed. PAT & Electrical Safety Test Updated – Dec 2017 An improved Bofa Fume Extraction is now in operation with replaceable filters.
Insertion Of Material Into Syringe	Once the material has been degassed it may need to be inserted into a syringe and needle system. If so the material will be poured into the syringe with no needle attached to ensure that the skin cannot be penetrated during the material loading phase. Once the material is loaded the needle will be attached with the safety cap still in place. Once the needle is locked into position the safety cap will be removed and the needle immediately used. Needles without bevels will be used	Low	This is the responsibility of the user/operator. If a needle at any point perforates the skin of the operator a first aider will need to be notified so that this can be assessed and logged accordingly.

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
	in all cases unless these are not available for in the required size.		
Refilling Material Into Syringe	When material is being reloaded in the syringes, the needle will be need to be safely detached with the necessary safety cap re-attached. Once the needles safety cap is in place at this point the needle can be unlocked, removed and immediately stored. If there is material still loaded in the needle and the safety cap cannot be used, the needle shall be inserted into a block of blue foam as a temporary measure before syringe reattachment or disposal, following the necessary guidelines previously described.	Low	This is the responsibility of the user/operator to ensure the safe handling and operation of the syringes and temporary detachment and safe storage of the needles. If a needle at any point perforates the skin of the operator a first aider will need to be notified so that this can be assessed and logged accordingly.
Safe Handling Of Needles for Casting Procedures	When needles are being utilised the previous described procedures and safety considerations must be applied. Needles will only be used once a syringe has been loaded with material and not prior to this point, the needle will be need to be safely attached or detached with the necessary safety cap in place. Once the needles safety cap is in place at this point the needle can be unlocked and removed and immediately stored. If there is material still loaded in the needle and the safety cap cannot be used, the needle shall be inserted into a block of blue foam whilst being detached as a temporary measure before syringe reattachment or disposal, following the necessary guidelines previously described.	Low	If a needle at any point perforates the skin of the operator a first aider will need to be notified so that this can be assessed and logged accordingly.
Disposal of Needles	Any needles used and no longer required for use must be disposed of in a provided sharps bin.	Low	A Sharps Bin Is Located in the Future Factory Research & Consultancy Centre (Maudslay 214) for safe disposal. Jez Keeling will organise the disposal of the bin once full. If a needle at any point perforates the skin of the operator during disposal a first aider will need to be notified so that this can be assessed and logged accordingly.

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
Disposal of Syringes	General waste bins are located in the Future Factory Research & Consultancy Centre (Maudslay 214) and will be utilised once all of the material has been discarded from the syringes. Additionally the syringes will be dismantled into two parts and the two parts will be disposed of on separate days to ensure that the syringes cannot be reused for other activities.	Low	Any syringes that have needles still attached and are unable to be dismantled and must be disposed of utilising a provided sharps bin.
University Environment (Technical Staff Support)	Staff supporting any of the casting procedures will be advised to remain at a safe distance from the casting area when not directly involved in the casting process. They will be advised not to touch any of the syringes or needles unless instructed to do so in a safe manner considering the sharps procedures and regulations specified in The Health and Safety at Work Act 1974, The Control of Substances Hazardous to Health Regulations (COSHH) 2002 and The Management of Health and Safety Regulations 1999.	Low	If the situation is not safe, the user will ask everyone to step back from the controlled area and the equipment in use will be disposed of safely utilising the provided sharps bin before any further work can be conducted. If a needle at any point perforates the skin of the operator a first aider will need to be notified so that this can be assessed and logged accordingly.
University Environment (Observation)	Staff and Students walking past and observing any of the casting procedures will be advised to remain at a safe distance from the casting area and not to touch the syringes or needles.	Low	If the situation is not safe, the user will ask everyone to step back from the controlled area at which point the sharps equipment involved in the procedure will be disposed of utilising the designated sharps bin. If a needle at any point perforates the skin of the operator a first aider will need to be notified so that this can be assessed and logged accordingly.
Storage of Needles & Syringes	Storage of Needles & Syringes when not in use will be done so by utilising one of the secure lockers or desk draws which can only be accessed through the use of the individual specific locker/draw key. Needles will be stored in the provided medically approved packaging box (provided at shipment). Additionally all of the	Low	Secure Lockers and Desk Draws are provided by NTU and will be used accordingly in the Future Factory Research & Consultancy Centre (Maudslay 214). This room is swipe card activated and is only available for use to a select number of academic staff and researchers in addition to technical support staff. Special swipe card access rights have to be approved to gain

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
	needles will have been packaged into medically approved packaging in addition to being supplied with the necessary safety cap.		entry to this research facility (Maudslay 214) and can only be requested by select staff members via card services. If any needles or syringes are stolen, this will be immediately reported to Maudslay Reception & NTU security. If future safety concerns are highlighted, additional security may be provided by NTU upon re-assessment.
Additional Hazardous Material (If Required In Future)	Additional materials with hazardous substances can be utilised within the Vacuum Degassing System. If this is to occur the system will be relocated to a suitable extraction system or enclosed extraction chamber before use.	Medium	Material Use/Safe Handling and Risk Re-assessment will be required before use if the system is relocated for extraction system attachment or for use within an enclosed extraction chamber.
Vacuum Degassing System Training	All individuals that will use the Vacuum Degassing System will require training on the appropriate use and health and safety requirements before first time operation.	Low	Observation of first time operation introduced to ensure student/operator confidence for sole operation whilst trained member of staff is still present in the room for support if required.
Use Of 3D Printed Mould	Casting into 3D printed moulds utalising pour casting or syringe injection casting introduced. Mould design and appropriate safe operation of equipment in relation to the mould is assessed by F.Siena or C.Forbes before 3D printing and subsequent casting. F.Siena & C.Forbes have experience in mould design and suitability.	Low	Casting material suitability assessed as to whether this will react to 3D Printed Mould Material. Additional controls include suitable design of the moulds to ensure safe removal of cast parts without damaging the moulds which has an extremely low risk of operator injury (cuts/scratches) if mould fractures/breaks.
Sterilisation & Cleaning Of Moulds	Standard cleaning of moulds includes the use of washing up liquid and warm water. Ronsol Lighter Fluid is also used in ***rare cases*** to completely sterilise 3D printed moulds. Gloves and goggles are worn to prevent eye and skin contamination. The first aid measures in place for this fluid include: **General**: NOTE! Keep affected person away from heat, sparks and flames!Promptly wash eyes with copious amounts of water while lifting the eyelids. Get medical attention	Low	Storage of Lighter Fluid reserves is done so in the fire safe/resistant storage cabinet located in Maudlsay 114. Suitable extraction system located in working area.

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
	immediately. Continue to rinse. **Skin**: Remove affected person from source of contamination. Promptly remove clothing. If penetrated and flush the skin with water. **Inhalation**: Move the exposed person to fresh air at once. When breathing is difficult, properly trained personnel may assist affected person by administering 100% oxygen. Keep the affected person warm and at rest. Get prompt medical attention. **Ingestion**: NEVER MAKE AN UNCONSCIOUS PERSON VOMIT OR DRINK FLUIDS. If vomiting occurs, the head should be kept low so that stomach vomit doesn't enter the lungs. **(See Supporting MSDS)**		

This risk level has been reduced as low as is reasonably practicable			
Assessor's Signature:	Francesco Luke Siena	**Date:**	**11/01/2018**
Manager's Signature		**Date:**	

	1st Review (Nov 16)	2nd Review (Jan 18)	3rd Review	4th Review	5Th Review
Assessors Name:	Francesco Luke Siena	Francesco Luke Siena			
Managers Name:	Philip Breedon	Philip Breedon			

APPENDIX G - TRACHEA PERFORATION TESTING RISK ASSESSMENT

Risk Assessor's Name:	Francesco Luke Siena	**Accountable Managers Name:**	Phillip Breedon	**Planned Review Date**	January 2019

Task or Activity Description	**Location:**	**Nottingham Trent University - Maudslay 112**
Porcine Airways & Trachea will be purchased from a local abattoir for the purpose of testing the bougie introducer perforation forces associated with airways and tracheas. Bougies & force sensors will be pressed on the airway until perforated in order to record perforation forces.	**Persons at Risk - Affected Groups:**	
Persons at Risk: A – Main operator of testing equipment.	A – Francesco Luke Siena	B – Visiting Clinical Expert (Dr James Armstrong, Dr Kris Inkpin, Dr Andrew Norris
Persons at Risk: B– Co-Operator/Observer of testing being conducted.	C – NTU Technical Support Staff	D – Philip Breedon
Persons at Risk: C, D & E – Additional Observer Of Testing Being Completed.	E – Other Approved Testing Observers (If Any.)	F –
	G -	H -

Potential Hazard	**Existing Controls**	**Risk level with controls**	**Additional Controls or Required Action & Date**
Safe Handling Of Porcine Airways & Tracheas	Eye protection to avoid eye contact. As with any work involving the risk of contamination, cover any exposed cuts or grazes with waterproof dressings. Ensure hands are thoroughly washed with hot water and an appropriate anti-bacterial soap before and after contact with the material. Gloves are to be worn to avoid skin contact. (Powder Free Gloves Available if required.) Suitable hand sanitizer must be	Low : There have been no ill health effects reported whilst using this product with the current controls at other institutions & facilities.	N/A

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
	available. Suitable Clothing Protection (Lab Coat or Apron) must be worn at all times. Appropriate ventilation is provided within the testing room if required. Up to date Information, Technical Data are available from Local Abattoir if required.		
Storage Of Porcine Airway & Tracheas	Collection & Transport of Porcine Airway will be completed utilising private transport ensuring that no member of public is exposed to the porcine/offal. Storage of the product will be in the containers provided by the local abattoir. Testing will be immediately completed upon arrival to the university therefore removing the need for storage of the porcine.	Low	N/A
First Aid	First Aid must be made available if required. No sharps or dangerous activities will be used/undertaken, however suitable first aid must be available for any unexpected incident.	Low	Pre-Identification Of First Aiders available on the testing date.
Testing Procedure & Control Measures	Utilising various bougies (Long Plastic Rods – Approx. 700mm Length/5mm Diameter) the porcine airways will be perforated (surface punctured). No excess residue is expected. On the end of the bougie a small pressure sensor will be attached to record the readings which will be linked to a portable data acquisition PC. Once the bougies are removed, the sensor will be cleaned and re-attached to the next bougie and the testing repeated. Suitable cable covers will be applied to the sensor to minimise contact with the Porcine Airway & Tracheas.	Low	N/A
Purchase Of Porcine	The purchase of porcine airways from the local abattoir must conform to Category 3 Food grade Inspection Processes. Confirmation from the local abattoir is required.	Low	
University Environment (Technical Staff Support)	Staff supporting/supervising any of the testing procedures will be advised to remain at a safe distance from the area when not directly involved. They will be advised not to touch any of the testing equipment or porcine airway unless instructed to	Low	If the situation is not safe, the user will ask everyone to step back from the controlled area and the equipment and porcine airway use will be disposed of safely.

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
	do so in a safe manner ensuring that the necessary PPE is in use and consideration is made to The Health and Safety at Work Act 1974, The Control of Substances Hazardous to Health Regulations (COSHH) 2002 and The Management of Health and Safety Regulations 1999.		
University Environment (Observation)	Staff and Students observing any of the porcine airway testing procedures will be advised to remain at a safe distance from the working area and not to touch any of the equipment unless instructed to do so (approval must be granted prior to the testing being conducted). The necessary PPE must be worn.	Low	If the situation is not safe, the user will ask everyone to step back from the controlled area and the equipment and porcine airway use will be disposed of safely.
Disposal Of Porcine Airway & Trachea	Once the testing has been completed, the porcine airway and tracheas will be placed back in their original packaging or opaque polythene bags and sealed. These will then be disposed of utilising the correct bins. (The necessary records will be kept as per Appendix 1 & 2) Once the dissection or experiment has taken place all remains must be double bagged in opaque polythene (e.g. autoclave bags) and disposed of via the establishment's waste disposal system. This must be accordance with the Animal by-product categories, site approval, hygiene and disposal guidance documentation. https://www.gov.uk/guidance/animal-by-product-categories-site-approval-hygiene-and-disposal As the waste is classed as a category 3 animal by product, the waste is fit for anaerobic digestion. Utilising NTU food waste stream, which is sent for anaerobic digestion, the product must be disposed of using the food waste wheelie bin in Maudslay yard (WasteCycle). The food waste wheelies have a grey base	Low	N/A

Potential Hazard	Existing Controls	Risk level with controls	Additional Controls or Required Action & Date
	and red lid and labelled as food waste. Accurate logs of acceptance of ingoing and outgoing Animal By-products will be kept as per Appendix 1 & 2.		
Cleaning Procedures (Environment)	Suitable cleaning products will be utilised to cleaning the worksurfaces where the testing will be completed on. All cleaning products, cloths etc., once used will be placed in bin liner and disposed of utilising provided bins. Antibacterial cleaning spray must be utilised on all work surfaces.	Low	N/A
Sterilisation Of PC Equipment (Post Testing If Required)	Suitable antibacterial cleaning products will be utilised to cleaning the PC equipment once the testing has been completed. All cleaning products, cloths, wipes etc., once used will be placed in bin liner and disposed of utilising the provided bins.	Low	N/A

This risk level has been reduced as low as is reasonably practicable			
Assessor's Signature:	Francesco Luke Siena	**Date:**	**11/01/2018**
Manager's Signature		**Date:**	

	1st Review	**2nd Review**	**3rd Review**	**4th Review**	**5Th Review**
Assessors Name:	Francesco Luke Siena				
Managers Name:	Philip Breedon				

Record of Outgoing Animal By-products Consignments

Date of Despatch	Description of material including category	Weight/ Volume / Quantity	Place of destination
24th May 2018	Porcine Airway (Food Grade)	12 (Total Weight 30Kg)	Disposed in Food Waste Bins (NTU) – Further Details Provided By Waste Management Company If Required.

Record of Incoming Animal By-products Consignments

Date of Receipt	Description of material including category	Weight/ Volume / Quantity	Place of origin
24th May 2018	Porcine Airway (Food Grade)	12 (Total Weight 30Kg)	Sourced From: Cleaver Meats Ltd.

APPENDIX H – INITIAL BOUGIE TIP PRESSURE DATA

Appendix 1 - Initial Material Assessment – 60mm Straight Tip

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Smooth-Sil 935 *(Light Blue)*	10cm	0.76	0.74	0.73	0.74	0.78	0.75	0.020
	20cm	0.24	0.21	0.24	0.24	0.24	0.234	0.013
	30cm	0.18	0.18	0.18	0.18	0.16	0.176	0.009
	40cm	0.15	0.14	0.14	0.15	0.13	0.142	0.008
Smooth-Sil 940 *(Pink)*	10cm	0.92	0.94	0.99	0.96	0.96	0.954	0.026
	20cm	0.39	0.41	0.40	0.38	0.38	0.392	0.013
	30cm	0.28	0.29	0.29	0.29	0.27	0.284	0.009
	40cm	0.22	0.25	0.25	0.26	0.24	0.244	0.015
Smooth-Sil 950 *(Mild Blue)*	10cm	1.60	1.50	1.60	1.34	1.53	1.514	0.107
	20cm	0.91	0.89	0.94	0.89	0.95	0.916	0.028
	30cm	0.86	0.87	0.88	0.91	0.86	0.876	0.021
	40cm	0.74	0.81	0.83	0.77	0.80	0.79	0.035
Transil 40-1 *(Clear)*	10cm	3.03	3.38	3.50	3.45	3.16	3.304	0.201
	20cm	2.60	2.59	2.48	2.57	2.40	2.528	0.086
	30cm	1.56	1.58	1.66	1.48	1.53	1.562	0.066
	40cm	0.92	0.96	0.92	0.93	0.91	0.928	0.019
Transil 20 *(Yellow)*	10cm	1.20	1.20	1.19	1.14	1.25	1.196	0.039
	20cm	0.85	0.84	0.74	0.89	0.92	0.848	0.068
	30cm	0.57	0.60	0.69	0.65	0.64	0.63	0.046
	40cm	0.43	0.46	0.45	0.40	0.41	0.43	0.025

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Platsil Gel -25 *(Orange)*	10cm	1.31	1.36	1.29	1.31	1.30	1.314	0.027
	20cm	0.68	0.82	0.69	0.83	0.79	0.762	0.072
	30cm	0.66	0.71	0.69	0.60	0.73	0.678	0.051
	40cm	0.43	0.47	0.51	0.48	0.46	0.47	0.029
Platsil Gel 10 *(Red)*	10cm	0.46	0.41	0.50	0.51	0.44	0.464	0.042
	20cm	0.26	0.30	0.25	0.31	0.25	0.274	0.029
	30cm	0.23	0.29	0.32	0.27	0.28	0.278	0.033
	40cm	0.12	0.20	0.19	0.17	0.13	0.162	0.036
Platsil Gel 00 *(Green)*	10cm	0.14	0.13	0.12	0.14	0.16	0.138	0.015
	20cm	0.10	0.16	0.14	0.13	0.14	0.134	0.022
	30cm	0.07	0.09	0.08	0.07	0.11	0.084	0.017
	40cm	0.06	0.07	0.07	0.08	0.05	0.066	0.011
BlueSil RTV 3428 *(White)*	10cm	1.13	1.22	1.09	1.11	1.00	1.11	0.079
	20cm	0.49	0.47	0.51	0.50	0.51	0.496	0.017
	30cm	0.45	0.42	0.45	0.33	0.36	0.402	0.054
	40cm	0.40	0.36	0.45	0.41	0.38	0.4	0.034

Appendix 2 - Smooth-Sil 935 – 60mm Straight Tip

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Smooth-Sil 935 *(Light Blue)*	10cm	0.27	0.24	0.28	0.28	0.29	0.272	0.019
	20cm	0.16	0.15	0.18	0.15	0.20	0.168	0.022
	30cm	0.06	0.06	0.08	0.08	0.07	0.07	0.010
	40cm	0.06	0.06	0.08	0.07	0.08	0.07	0.010
Smooth-Sil 935 + 5% Hardener *(Red)*	10cm	0.31	0.32	0.35	0.36	0.33	0.334	0.021
	20cm	0.21	0.25	0.23	0.26	0.23	0.236	0.019
	30cm	0.11	0.09	0.09	0.10	0.10	0.098	0.008
	40cm	0.11	0.08	0.10	0.10	0.08	0.094	0.013
Smooth-Sil 935 + 10% Hardener *(Yellow)*	10cm	0.32	0.36	0.36	0.34	0.36	0.348	0.018
	20cm	0.27	0.34	0.30	0.28	0.31	0.3	0.027
	30cm	0.12	0.11	0.12	0.13	0.13	0.122	0.008
	40cm	0.10	0.09	0.11	0.11	0.11	0.104	0.009
Smooth-Sil 935 + 15% Hardener *(Orange)*	10cm	0.38	0.40	0.35	0.38	0.40	0.382	0.020
	20cm	0.24	0.27	0.27	0.27	0.26	0.262	0.013
	30cm	0.14	0.13	0.13	0.14	0.13	0.134	0.005
	40cm	0.14	0.15	0.14	0.15	0.16	0.148	0.008
Smooth-Sil 935 + 20% Hardener *(Pink)*	10cm	0.59	0.47	0.50	0.60	0.52	0.536	0.057
	20cm	0.30	0.27	0.34	0.32	0.31	0.308	0.026
	30cm	0.16	0.15	0.12	0.16	0.14	0.146	0.017
	40cm	0.14	0.12	0.14	0.14	0.10	0.128	0.018
Smooth-Sil 935 + 25% Hardener *(Purple)*	10cm	0.52	0.56	0.53	0.55	0.57	0.546	0.021
	20cm	0.27	0.25	0.32	0.29	0.30	0.286	0.027
	30cm	0.14	0.14	0.13	0.13	0.14	0.136	0.005
	40cm	0.12	0.13	0.12	0.12	0.12	0.122	0.004
Smooth-Sil 935 + 30%	10cm	0.45	0.53	0.54	0.51	0.51	0.508	0.035
	20cm	0.36	0.28	0.33	0.36	0.37	0.34	0.037

Hardener *(Dark Blue)*	30cm	0.13	0.14	0.15	0.15	0.15	0.144	0.009
	40cm	0.12	0.11	0.12	0.11	0.11	0.114	0.005
Smooth-Sil 935 + 35% Hardener *(Dark Green)*	10cm	0.52	0.49	0.52	0.50	0.55	0.516	0.023
	20cm	0.28	0.28	0.28	0.28	0.25	0.274	0.013
	30cm	0.19	0.16	0.16	0.16	0.17	0.168	0.013
	40cm	0.11	0.14	0.13	0.12	0.10	0.12	0.016
Smooth-Sil 935 + 40% Hardener *(Light Green)*	10cm	0.50	0.58	0.61	0.60	0.59	0.576	0.044
	20cm	0.26	0.28	0.28	0.27	0.28	0.274	0.009
	30cm	0.15	0.14	0.14	0.14	0.14	0.142	0.004
	40cm	0.14	0.14	0.14	0.14	0.15	0.142	0.004
Smooth-Sil 935 + 45% Hardener *(Brown)*	10cm	0.57	0.52	0.49	0.59	0.55	0.544	0.040
	20cm	0.29	0.28	0.29	0.35	0.30	0.302	0.028
	30cm	0.25	0.24	0.24	0.31	0.24	0.256	0.030
	40cm	0.13	0.16	0.14	0.12	0.13	0.136	0.015
Smooth-Sil 935 + 50% Hardener *(Grey)*	10cm	0.63	0.69	0.72	0.67	0.63	0.668	0.039
	20cm	0.33	0.32	0.32	0.34	0.34	0.33	0.010
	30cm	0.19	0.19	0.20	0.19	0.22	0.198	0.013
	40cm	0.15	0.16	0.21	0.14	0.16	0.164	0.027

Appendix 3 - Smooth-Sil 950 – 60mm Straight Tip

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Smooth-Sil 950 *(Mild Blue)*	10cm	1.06	0.95	1.15	1.14	1.09	1.078	0.080
	20cm	0.42	0.46	0.47	0.48	0.47	0.46	0.023
	30cm	0.22	0.22	0.24	0.26	0.26	0.24	0.020
	40cm	0.22	0.25	0.19	0.18	0.23	0.214	0.029
Smooth-Sil 950 + 5% Hardener *(Light Blue)*	10cm	0.98	0.98	0.98	0.91	1.04	0.978	0.046
	20cm	0.38	0.42	0.37	0.43	0.38	0.396	0.027
	30cm	0.21	0.23	0.21	0.24	0.22	0.222	0.013
	40cm	0.16	0.20	0.19	0.20	0.19	0.188	0.016
Smooth-Sil 950 + 10% Hardener *(Turquoise)*	10cm	1.03	0.85	1.07	0.99	0.98	0.984	0.083
	20cm	0.45	0.49	0.49	0.48	0.48	0.478	0.016
	30cm	0.18	0.19	0.22	0.17	0.19	0.19	0.019
	40cm	0.21	0.22	0.20	0.21	0.20	0.208	0.008
Smooth-Sil 950 + 15% Hardener *(Dark Green)*	10cm	0.80	0.74	0.78	0.75	0.79	0.772	0.026
	20cm	0.33	0.34	0.38	0.42	0.35	0.364	0.036
	30cm	0.19	0.21	0.20	0.19	0.19	0.196	0.009
	40cm	0.14	0.15	0.15	0.14	0.16	0.148	0.008
Smooth-Sil 950 + 20% Hardener *(Light Green)*	10cm	1.09	1.15	1.11	1.02	1.21	1.116	0.071
	20cm	0.41	0.42	0.44	0.44	0.44	0.43	0.014
	30cm	0.26	0.28	0.29	0.29	0.27	0.278	0.013
	40cm	0.24	0.22	0.22	0.21	0.22	0.222	0.011
Smooth-Sil 950 + 25% Hardener *(Dark Brown)*	10cm	1.29	1.32	1.25	1.18	1.21	1.25	0.057
	20cm	0.44	0.43	0.43	0.44	0.44	0.436	0.005
	30cm	0.28	0.23	0.27	0.26	0.27	0.262	0.019
	40cm	0.28	0.20	0.22	0.24	0.24	0.236	0.030
Smooth-Sil 950 + 30%	10cm	1.06	1.17	1.12	1.13	1.09	1.114	0.042
	20cm	0.49	0.41	0.41	0.40	0.38	0.418	0.042

Hardener *(Purple)*	30cm	0.23	0.19	0.23	0.23	0.24	0.224	0.019
	40cm	0.16	0.16	0.18	0.16	0.17	0.166	0.009
Smooth-Sil 950 + 35% Hardener *(Maroon)*	10cm	1.10	1.10	1.06	1.11	1.07	1.088	0.022
	20cm	0.38	0.38	0.39	0.36	0.32	0.366	0.028
	30cm	0.27	0.24	0.24	0.23	0.23	0.242	0.016
	40cm	0.19	0.18	0.20	0.23	0.23	0.206	0.023
Smooth-Sil 950 + 40% Hardener *(Light Brown)*	10cm	1.21	1.23	1.23	1.28	1.19	1.228	0.033
	20cm	0.44	0.43	0.41	0.41	0.44	0.426	0.015
	30cm	0.29	0.28	0.26	0.28	0.29	0.28	0.012
	40cm	0.27	0.24	0.28	0.26	0.26	0.262	0.015
Smooth-Sil 950 + 45% Hardener *(Dark Blue)*	10cm	1.21	1.26	1.34	1.18	1.29	1.256	0.063
	20cm	0.46	0.49	0.50	0.49	0.53	0.494	0.025
	30cm	0.33	0.33	0.30	0.30	0.32	0.316	0.015
	40cm	0.26	0.28	0.25	0.25	0.28	0.264	0.015
Smooth-Sil 950 + 50% Hardener *(Grey)*	10cm	1.25	1.29	1.27	1.41	1.32	1.308	0.063
	20cm	0.40	0.41	0.42	0.43	0.42	0.416	0.011
	30cm	0.28	0.24	0.26	0.27	0.29	0.268	0.019
	40cm	0.24	0.23	0.25	0.22	0.24	0.236	0.011

Appendix 4 - Smooth-Sil 935 - 35mm Straight Tip

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Smooth-Sil 935 *(Light Blue)*	10cm	0.76	0.81	0.68	0.83	0.79	0.774	0.059
	20cm	0.36	0.31	0.32	0.32	0.31	0.324	0.021
	30cm	0.25	0.17	0.23	0.21	0.21	0.214	0.030
	40cm	0.19	0.19	0.19	0.18	0.17	0.184	0.009
Smooth-Sil 935 + 5% Hardener *(Red)*	10cm	1.00	1.03	1.05	1.14	0.97	1.038	0.065
	20cm	0.47	0.47	0.52	0.42	0.46	0.468	0.036
	30cm	0.28	0.28	0.32	0.31	0.28	0.294	0.019
	40cm	0.27	0.26	0.29	0.23	0.21	0.252	0.032
Smooth-Sil 935 + 10% Hardener *(Yellow)*	10cm	1.09	1.01	1.02	1.03	1.11	1.052	0.045
	20cm	0.39	0.41	0.42	0.41	0.44	0.414	0.018
	30cm	0.29	0.29	0.31	0.28	0.31	0.296	0.013
	40cm	0.19	0.17	0.19	0.18	0.17	0.18	0.010
Smooth-Sil 935 + 15% Hardener *(Orange)*	10cm	1.04	1.08	1.04	1.05	1.17	1.076	0.055
	20cm	0.32	0.39	0.31	0.33	0.36	0.342	0.033
	30cm	0.17	0.18	0.17	0.17	0.18	0.174	0.005
	40cm	0.14	0.14	0.15	0.16	0.14	0.146	0.009
Smooth-Sil 935 + 20% Hardener *(Pink)*	10cm	1.05	1.04	1.04	1.04	0.95	1.024	0.042
	20cm	0.36	0.35	0.38	0.37	0.40	0.372	0.019
	30cm	0.20	0.23	0.19	0.22	0.22	0.212	0.016
	40cm	0.18	0.17	0.15	0.17	0.19	0.172	0.015
Smooth-Sil 935 + 25% Hardener *(Purple)*	10cm	1.43	1.30	1.35	1.35	1.37	1.36	0.047
	20cm	0.50	0.46	0.48	0.51	0.43	0.476	0.032
	30cm	0.30	0.31	0.30	0.33	0.36	0.32	0.025
	40cm	0.31	0.28	0.29	0.31	0.29	0.296	0.013
Smooth-Sil 935 + 30%	10cm	1.38	1.28	1.52	1.30	1.47	1.39	0.104
	20cm	0.76	0.86	0.92	0.85	0.72	0.822	0.081

Hardener *(Dark Blue)*	30cm	0.44	0.43	0.40	0.46	0.41	0.428	0.024
	40cm	0.41	0.35	0.35	0.34	0.36	0.362	0.028
Smooth-Sil 935 + 35% Hardener *(Dark Green)*	10cm	1.31	1.54	1.33	1.33	1.50	1.402	0.109
	20cm	0.37	0.39	0.37	0.44	0.40	0.394	0.029
	30cm	0.31	0.34	0.30	0.27	0.33	0.31	0.027
	40cm	0.23	0.24	0.28	0.29	0.29	0.266	0.029
Smooth-Sil 935 + 40% Hardener *(Light Green)*	10cm	1.40	1.63	1.58	1.55	1.52	1.536	0.086
	20cm	0.46	0.47	0.50	0.43	0.50	0.472	0.029
	30cm	0.39	0.36	0.40	0.30	0.42	0.374	0.047
	40cm	0.32	0.36	0.37	0.33	0.39	0.354	0.029
Smooth-Sil 935 + 45% Hardener *(Brown)*	10cm	1.48	1.51	1.77	1.59	1.65	1.6	0.116
	20cm	0.51	0.53	0.55	0.51	0.51	0.522	0.018
	30cm	0.52	0.42	0.50	0.43	0.54	0.482	0.054
	40cm	0.34	0.39	0.43	0.39	0.40	0.39	0.032
Smooth-Sil 935 + 50% Hardener *(Grey)*	10cm	1.75	1.70	1.72	1.87	1.79	1.766	0.067
	20cm	1.06	0.86	0.88	0.93	1.01	0.948	0.085
	30cm	0.63	0.67	0.60	0.66	0.73	0.658	0.049
	40cm	0.47	0.62	0.44	0.57	0.54	0.528	0.073

Appendix 5 - Smooth-Sil 950 - 35mm Straight Tip

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Smooth-Sil 950 *(Mild Blue)*	10cm	1.01	1.01	1.06	1.13	1.04	1.05	0.049
	20cm	0.46	0.57	0.46	0.50	0.57	0.512	0.055
	30cm	0.43	0.44	0.45	0.45	0.44	0.442	0.008
	40cm	0.35	0.34	0.41	0.41	0.40	0.382	0.034
Smooth-Sil 950 + 5% Hardener *(Light Blue)*	10cm	1.42	1.29	1.25	1.34	1.26	1.312	0.070
	20cm	1.04	1.00	1.12	1.07	1.06	1.058	0.044
	30cm	0.73	0.68	0.71	0.70	0.72	0.708	0.019
	40cm	0.57	0.47	0.52	0.58	0.60	0.548	0.053
Smooth-Sil 950 + 10% Hardener *(Turquoise)*	10cm	1.45	1.44	1.52	1.50	1.31	1.444	0.082
	20cm	0.82	0.84	0.74	0.75	0.76	0.782	0.045
	30cm	0.63	0.64	0.53	0.56	0.63	0.598	0.050
	40cm	0.50	0.44	0.54	0.46	0.55	0.498	0.048
Smooth-Sil 950 + 15% Hardener *(Dark Green)*	10cm	1.37	1.41	1.52	1.49	1.45	1.448	0.060
	20cm	0.72	0.80	0.83	0.86	0.73	0.788	0.061
	30cm	0.52	0.67	0.54	0.63	0.55	0.582	0.065
	40cm	0.34	0.43	0.34	0.38	0.38	0.374	0.037
Smooth-Sil 950 + 20% Hardener *(Light Green)*	10cm	1.37	1.40	1.37	1.57	1.48	1.438	0.086
	20cm	0.77	0.83	0.79	0.87	0.85	0.822	0.041
	30cm	0.70	0.72	0.70	0.68	0.85	0.73	0.069
	40cm	0.45	0.48	0.44	0.46	0.45	0.456	0.015
Smooth-Sil 950 + 25% Hardener *(Dark Brown)*	10cm	1.35	1.48	1.39	1.29	1.50	1.402	0.088
	20cm	0.72	0.83	0.75	0.73	0.74	0.754	0.044
	30cm	0.59	0.58	0.57	0.63	0.62	0.598	0.026
	40cm	0.50	0.47	0.50	0.53	0.57	0.514	0.038
Smooth-Sil 950 + 30%	10cm*	0.72	0.68	0.73	0.57	0.70	0.68	0.064
	20cm*	0.37	0.37	0.40	0.32	0.40	0.372	0.033

Hardener *(Purple)*	30cm*	0.21	0.20	0.28	0.25	0.24	0.24	0.032
	40cm*	0.20	0.26	0.26	0.21	0.28	0.28	0.035
Smooth-Sil 950 + 35% Hardener *(Maroon)*	10cm	1.40	1.38	1.37	1.48	1.49	1.424	0.057
	20cm	0.84	0.82	0.82	0.78	0.77	0.806	0.030
	30cm	0.69	0.62	0.59	0.72	0.65	0.654	0.052
	40cm	0.52	0.54	0.57	0.61	0.62	0.572	0.043
Smooth-Sil 950 + 40% Hardener *(Light Brown)*	10cm*	1.39	1.58	1.39	1.63	1.45	1.488	0.111
	20cm*	0.53	0.52	0.56	0.49	0.57	0.534	0.032
	30cm*	0.38	0.38	0.36	0.39	0.38	0.378	0.011
	40cm*	0.32	0.38	0.39	0.32	0.36	0.354	0.033
Smooth-Sil 950 + 45% Hardener *(Dark Blue)*	10cm	1.75	1.72	1.70	1.67	1.66	1.7	0.037
	20cm	0.90	0.84	0.89	0.79	0.83	0.85	0.045
	30cm	0.62	0.63	0.64	0.60	0.62	0.622	0.015
	40cm	0.44	0.50	0.48	0.46	0.47	0.47	0.022
Smooth-Sil 950 + 50% Hardener *(Grey)*	10cm	1.64	1.70	1.68	1.63	1.71	1.672	0.036
	20cm	1.09	1.00	1.15	0.97	1.15	1.072	0.084
	30cm	0.67	0.70	0.64	0.77	0.73	0.702	0.051
	40cm	0.52	0.58	0.51	0.66	0.52	0.558	0.063

Appendix 6 - Smooth-Sil 940 - 60mm Straight Tip

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Smooth-Sil 940 *(Pink)*	10cm	0.68	0.73	0.64	0.58	0.68	0.662	0.056
	20cm	0.22	0.24	0.23	0.22	0.23	0.228	0.008
	30cm	0.12	0.13	0.13	0.12	0.12	0.124	0.005
	40cm	0.09	0.08	0.08	0.09	0.09	0.086	0.005
Smooth-Sil 940 + 10% Hardener *(Dark Blue)*	10cm	0.54	0.64	0.61	0.61	0.59	0.598	0.037
	20cm	0.23	0.26	0.28	0.29	0.32	0.276	0.034
	30cm	0.12	0.12	0.12	0.11	0.11	0.116	0.005
	40cm	0.10	0.10	0.11	0.10	0.09	0.1	0.007
Smooth-Sil 940 + 30% Hardener *(Purple)*	10cm	0.58	0.64	0.64	0.54	0.62	0.604	0.043
	20cm	0.19	0.24	0.26	0.22	0.21	0.224	0.027
	30cm	0.13	0.13	0.11	0.14	0.14	0.13	0.012
	40cm	0.08	0.08	0.08	0.09	0.09	0.084	0.005
Smooth-Sil 90 + 50% Hardener *(Red)*	10cm	0.84	0.76	0.78	0.79	0.85	0.804	0.039
	20cm	0.40	0.55	0.51	0.43	0.43	0.464	0.063
	30cm	0.17	0.18	0.18	0.18	0.21	0.184	0.015
	40cm	0.17	0.17	0.14	0.15	0.16	0.158	0.013

Appendix 7 - Smooth-Sil 940 - 35mm Straight Tip

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Smooth-Sil 940 *(Pink)*	10cm	1.20	1.19	1.03	0.91	1.14	1.094	0.123
	20cm	0.43	0.45	0.46	0.37	0.41	0.424	0.036
	30cm	0.23	0.26	0.22	0.24	0.26	0.242	0.018
	40cm	0.17	0.23	0.28	0.23	0.21	0.224	0.040
Smooth-Sil 940 + 10% Hardener *(Dark Blue)*	10cm	1.11	1.17	0.95	1.03	1.11	1.074	0.085
	20cm	0.49	0.49	0.38	0.40	0.43	0.438	0.051
	30cm	0.32	0.29	0.34	0.27	0.29	0.302	0.028
	40cm	0.26	0.24	0.24	0.24	0.28	0.252	0.018
Smooth-Sil 940 + 30% Hardener *(Purple)*	10cm	1.01	1.04	1.09	0.93	1.11	1.036	0.071
	20cm	0.27	0.28	0.29	0.28	0.28	0.28	0.007
	30cm	0.30	0.28	0.32	0.33	0.34	0.314	0.024
	40cm	0.22	0.21	0.22	0.24	0.22	0.222	0.011
Smooth-Sil 90 + 50% Hardener *(Red)*	10cm	1.23	1.32	1.22	1.43	1.26	1.292	0.086
	20cm	0.53	0.49	0.50	0.58	0.49	0.518	0.038
	30cm	0.35	0.28	0.35	0.38	0.39	0.35	0.043
	40cm	0.27	0.35	0.32	0.27	0.32	0.306	0.035

Appendix 8 - Smooth-Sil 935 – 60mm Tip (Coude Tip Design)

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Smooth-Sil 935 *(Light Blue)*	10cm	1.10	1.04	1.10	1.00	1.08	1.064	0.043
	20cm	0.41	0.44	0.43	0.47	0.40	0.43	0.027
	30cm	0.33	0.36	0.38	0.36	0.36	0.358	0.018
	40cm	0.35	0.34	0.32	0.35	0.34	0.34	0.012
Smooth-Sil 935 + 10% Hardener *(Yellow)*	10cm	1.18	1.01	1.20	1.15	1.13	1.134	0.074
	20cm	0.38	0.42	0.38	0.40	0.36	0.388	0.023
	30cm	0.34	0.28	0.37	0.32	0.31	0.324	0.034
	40cm	0.32	0.27	0.27	0.30	0.24	0.28	0.031
Smooth-Sil 935 + 30% Hardener *(Dark Blue)*	10cm	1.15	1.17	1.34	1.09	1.27	1.204	0.100
	20cm	0.53	0.57	0.53	0.55	0.60	0.556	0.030
	30cm	0.51	0.51	0.51	0.40	0.46	0.478	0.049
	40cm	0.43	0.43	0.41	0.39	0.40	0.412	0.018
Smooth-Sil 935 + 50% Hardener *(Grey)*	10cm	1.13	1.31	1.29	1.32	1.34	1.278	0.085
	20cm	0.47	0.50	0.51	0.48	0.48	0.488	0.016
	30cm	0.32	0.34	0.37	0.34	0.36	0.346	0.019
	40cm	0.36	0.31	0.33	0.33	0.34	0.334	0.018

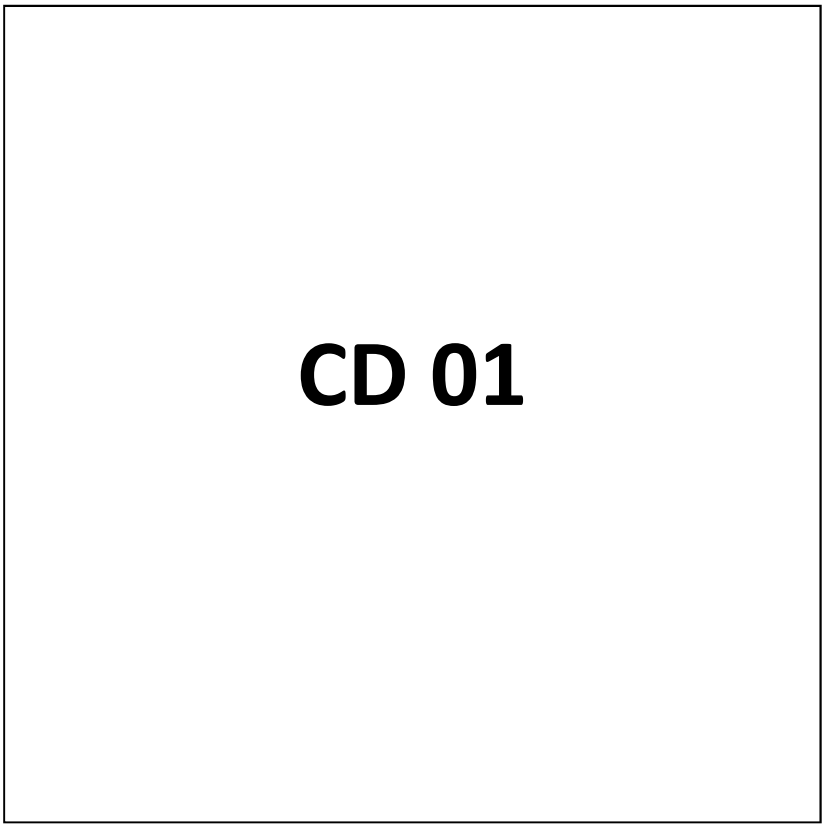
Appendix 9 - Smooth-Sil 935 - 60mm Tip (Coude Tip Design)

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Tip 1 (3° Bend) Smooth-Sil 935	10cm	0.94	1.10	1.04	0.93	1.06	1.014	0.075
	20cm	0.28	0.26	0.33	0.28	0.32	0.294	0.030
	30cm	0.29	0.29	0.23	0.28	0.26	0.27	0.025
	40cm	0.26	0.24	0.24	0.25	0.25	0.248	0.008
Tip 2 (5° Bend) Smooth-Sil 935	10cm	1.00	1.11	1.09	1.06	1.05	1.062	0.042
	20cm	0.39	0.40	0.43	0.43	0.37	0.404	0.026
	30cm	0.31	0.33	0.33	0.32	0.30	0.318	0.013
	40cm	0.28	0.23	0.27	0.26	0.29	0.266	0.023
Tip 3 (7° Bend) Smooth-Sil 935	10cm	0.99	1.04	1.01	1.07	0.97	1.016	0.040
	20cm	0.45	0.47	0.45	0.47	0.44	0.456	0.013
	30cm	0.30	0.34	0.31	0.31	0.33	0.318	0.016
	40cm	0.24	0.23	0.24	0.24	0.25	0.24	0.007
Tip 3 (9° Bend) Smooth-Sil 935	10cm	1.13	1.21	1.07	1.15	1.05	1.122	0.064
	20cm	0.47	0.49	0.52	0.52	0.50	0.5	0.021
	30cm	0.22	0.22	0.21	0.23	0.23	0.222	0.008
	40cm	0.21	0.22	0.21	0.20	0.24	0.216	0.015

APPENDIX I – INITIAL TIP PRESSURE TESTING CHARTS & RAW DATA FILES

The CD attached provides digital copies of the raw data and graphs collected for the tip pressure testing reading taken during the initial development stages. Each folder as listed below contains the incremental mixture testing charts and raw data as described within Chapter 5.

- Smooth-Sil 935 - 15W10I (60mm Tip)
- Smooth-Sil 935 - 15W10I (60mm Tip)
- Smooth-Sil 935 - 15W10I (60mm Tip)
- Smooth-Sil 935 25W20I (35mm Coude Tip Variations)
- Smooth-Sil 940 - 15W10I (60mm Tip)
- Smooth-Sil 940 - 25W20I (35mm Tip)
- Smooth-Sil 950 - 15W10I (60mm Tip)
- Smooth-Sil 950 - 25W20I (35mm Tip)



APPENDIX J – INITIAL COMMERCIAL BOUGIE TIP PRESSURE DATA

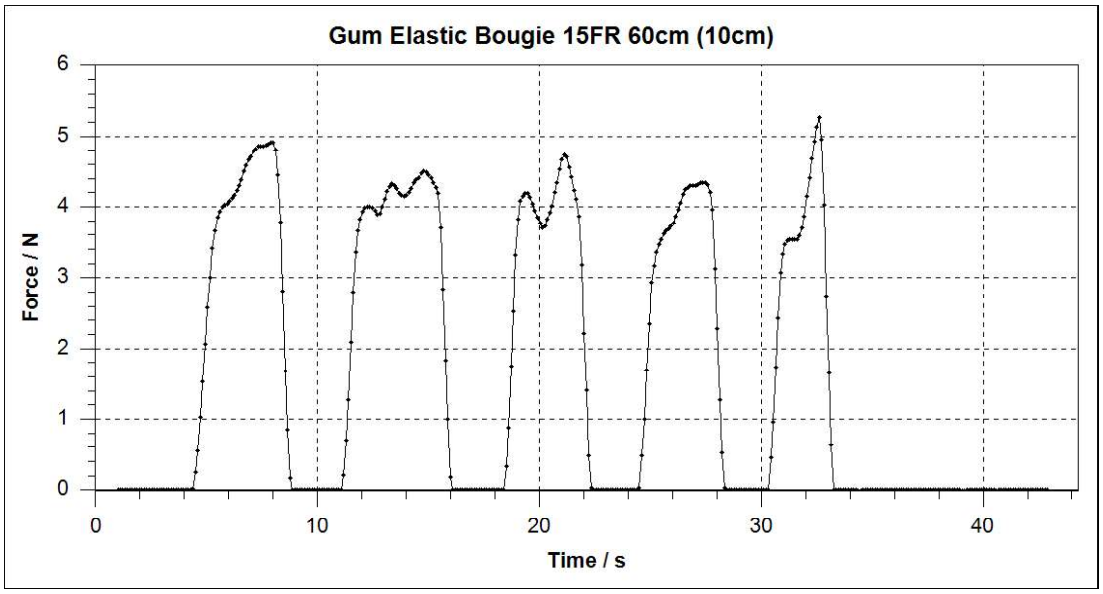
Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean (N)	SD
Eschmann Gum Elastic Bougie 15CH 60cm (Coude Tip)	10cm	4.91	4.49	4.73	4.34	5.26	4.746	0.323
	20cm	2.08	1.75	1.70	1.78	2.03	1.868	0.156
	30cm	1.04	0.94	0.95	0.89	0.94	0.952	0.049
	40cm	0.78	0.70	0.68	0.68	0.63	0.694	0.049
Portex Single Use Bougie 15FR 70cm (Coude Tip)	10cm	5.44	5.65	5.80	5.61	5.25	5.550	0.189
	20cm	3.27	3.02	3.13	3.09	2.97	3.096	0.103
	30cm	1.86	1.91	1.70	1.64	1.83	1.788	0.101
	40cm	1.12	1.10	1.04	1.06	1.03	1.07	0.035
Frova Introducer 14FR 70cm (Coude Tip)	10cm	8.48	7.92	8.70	7.89	7.99	8.196	0.331
	20cm	3.71	3.49	3.64	3.59	3.56	3.598	0.074
	30cm	1.93	1.90	1.86	1.79	1.90	1.876	0.048
	40cm	1.19	1.19	1.25	1.22	1.29	1.228	0.038
P3 Medical Tracheal Tube Introducer 15CH 60cm (Coude Tip)	10cm	10.48	10.63	10.87	10.32	10.86	10.632	0.214
	20cm	5.97	6.09	5.84	5.86	5.97	5.946	0.090
	30cm	2.96	2.99	3.00	3.04	3.00	2.998	0.026
	40cm	1.85	1.69	1.67	1.62	1.72	1.710	0.077
SunMed Introducer Bougie 15FR 70cm (Straight Tip)	10cm	14.31	15.01	14.54	14.34	14.99	14.638	0.306
	20cm	6.94	6.53	6.62	6.24	5.96	6.458	0.334
	30cm	3.57	3.02	2.78	3.00	3.31	3.136	0.275
	40cm	2.26	2.04	1.99	1.96	1.97	2.044	0.111

Material	Distance	R1 (N)	R2 (N)	R3 (N)	R4 (N)	R5 (N)	Mean	SD
SunMed Introducer Bougie 15FR 70cm (Coude Tip)	10cm	10.96	11.41	10.74	10.66	10.27	10.808	0.375
	20cm	6.01	6.11	6.08	6.10	5.89	6.038	0.082
	30cm	3.68	3.64	3.64	3.60	3.46	3.604	0.076
	40cm	2.35	2.37	2.30	2.27	2.23	2.304	0.051
AviAir Intubating Bougie 15CH, 75cm (Coude Tip)	10cm	8.70	8.80	8.94	7.87	9.17	8.696	0.442
	20cm	5.56	5.36	5.26	5.22	5.14	5.308	0.145
	30cm	3.13	3.05	3.01	3.08	3.20	3.094	0.066
	40cm	1.94	1.76	1.52	1.83	1.67	1.744	0.143
Pro Breathe Premium ET Tube Introducer 15FR 70cm (Coude Tip)	10cm	4.33	4.62	4.01	4.43	4.25	4.328	0.201
	20cm	2.07	1.99	2.35	2.30	2.48	2.238	0.181
	30cm	1.82	1.58	1.63	1.54	1.47	1.608	0.118
	40cm	0.82	0.78	0.84	0.80	0.76	0.800	0.028
InterGuide Tracheal Tube Introducer Bougie 15FR 70cm (Coude Tip)	10cm	5.66	5.50	5.55	5.39	5.74	5.568	0.122
	20cm	3.61	3.63	3.56	3.08	3.34	3.444	0.209
	30cm	2.20	1.96	2.13	2.15	2.05	2.098	0.084
	40cm	1.30	1.21	1.23	1.17	1.13	1.208	0.057
Flex-Guide Endotracheal Tube Introducer 15FR 60cm (Coude Tip)	10cm	7.08	7.18	7.51	7.01	7.06	7.168	0.180
	20cm	4.02	3.80	4.07	3.92	3.91	3.944	0.094
	30cm	2.10	2.09	2.18	2.14	2.01	2.104	0.057
	40cm	1.24	1.22	1.23	1.23	1.24	1.232	0.007
Construct Medical (Flexible Tip Bougie)	10cm	2.35	2.23	2.71	2.54	2.74	2.514	0.199
	20cm	1.71	1.55	1.70	1.50	1.75	1.642	0.098
	30cm	1.24	1.10	1.22	1.26	1.39	1.242	0.093
	40cm	1.06	1.01	1.08	0.93	1.15	1.046	0.073
	20cm*	2.20	2.04	2.09	1.98	2.15	2.092	0.078
	30cm*	1.60	1.52	1.48	1.70	1.54	1.568	0.077

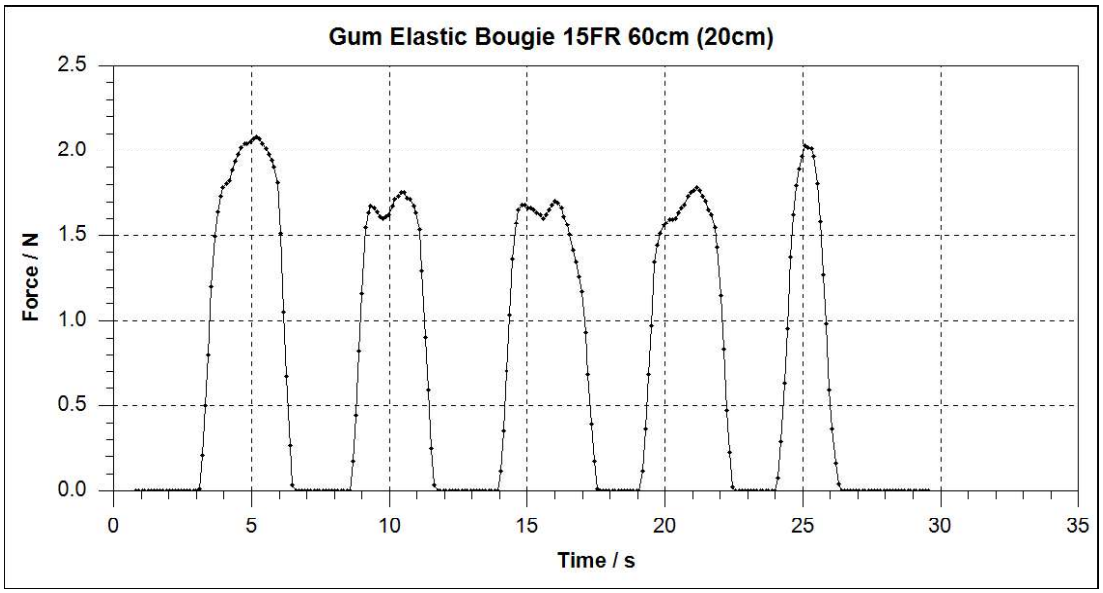
APPENDIX K – COMMERCIAL BOUGIE INITIAL TIP PRESSURE TESTING CHARTS

Appendix 1: Gum Elastic Bougie 15CH 60cm (Coude Tip) - Tip Pressure Graphs

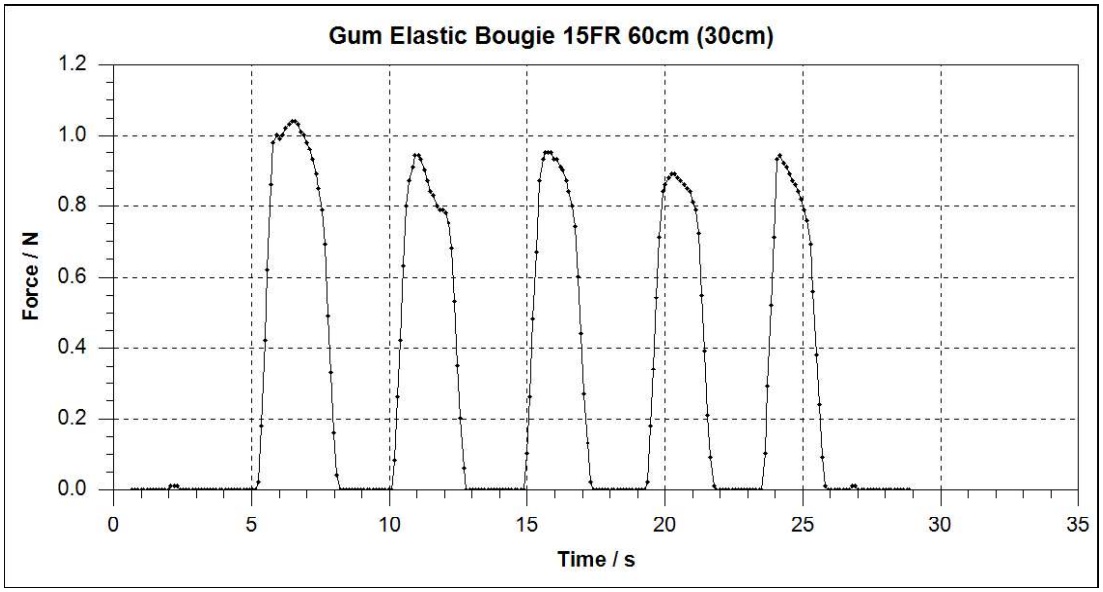
Appendix 1a - Gum Elastic Bougie (10mm)



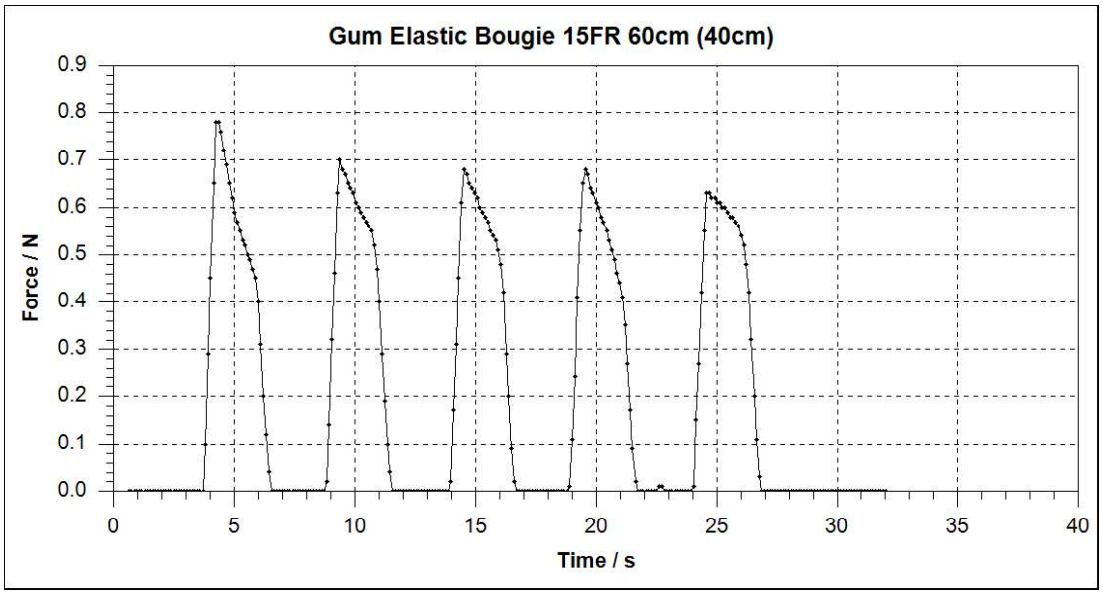
Appendix 1b - Gum Elastic Bougie (20mm)



Appendix 1c - Gum Elastic Bougie (30mm)

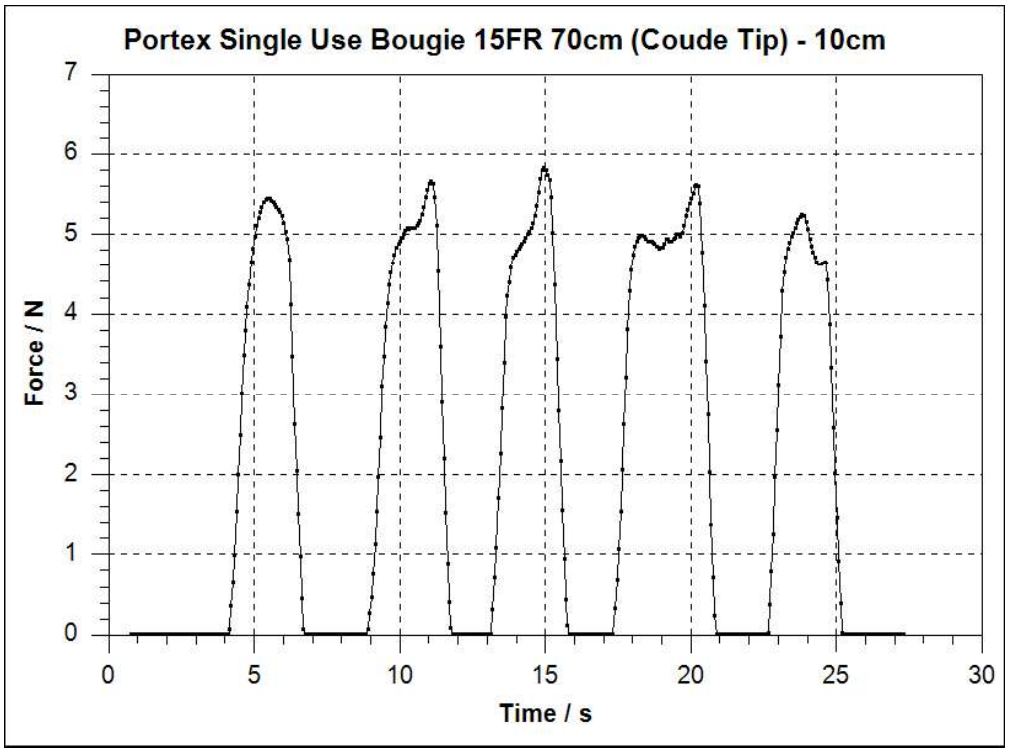


Appendix 1d - Gum Elastic Bougie (40mm)

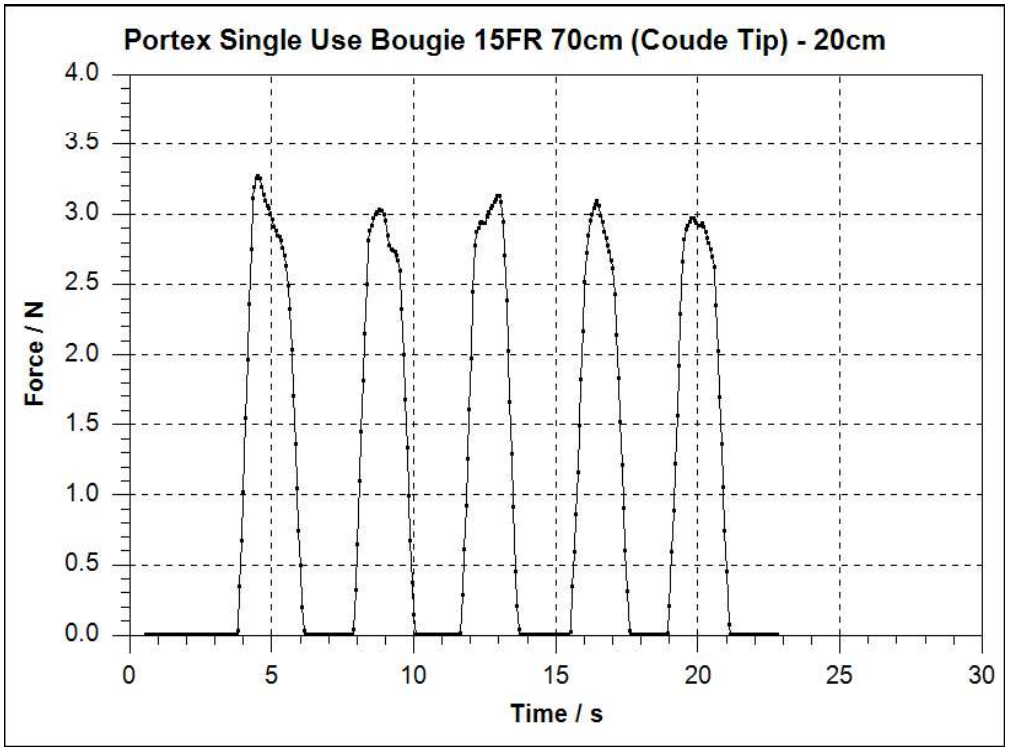


Appendix 2: Portex Single Use Bougie 15FR 70cm (Coude Tip) - Tip Pressure Graphs

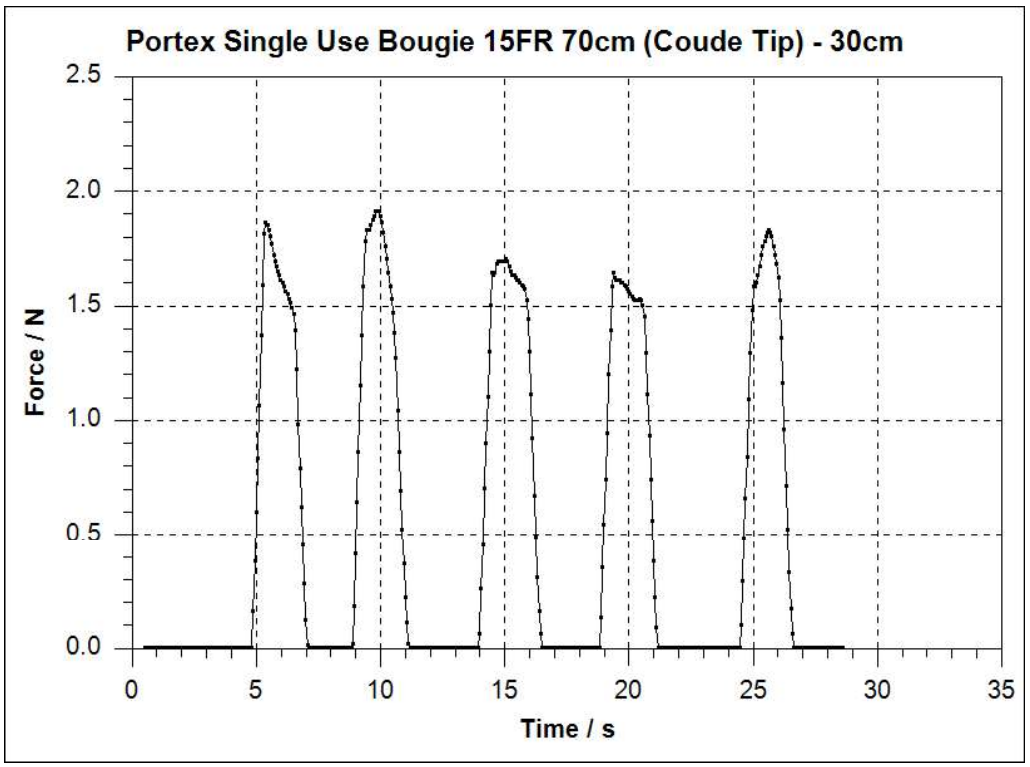
Appendix 2a - Portex Single Use Bougie (10mm)



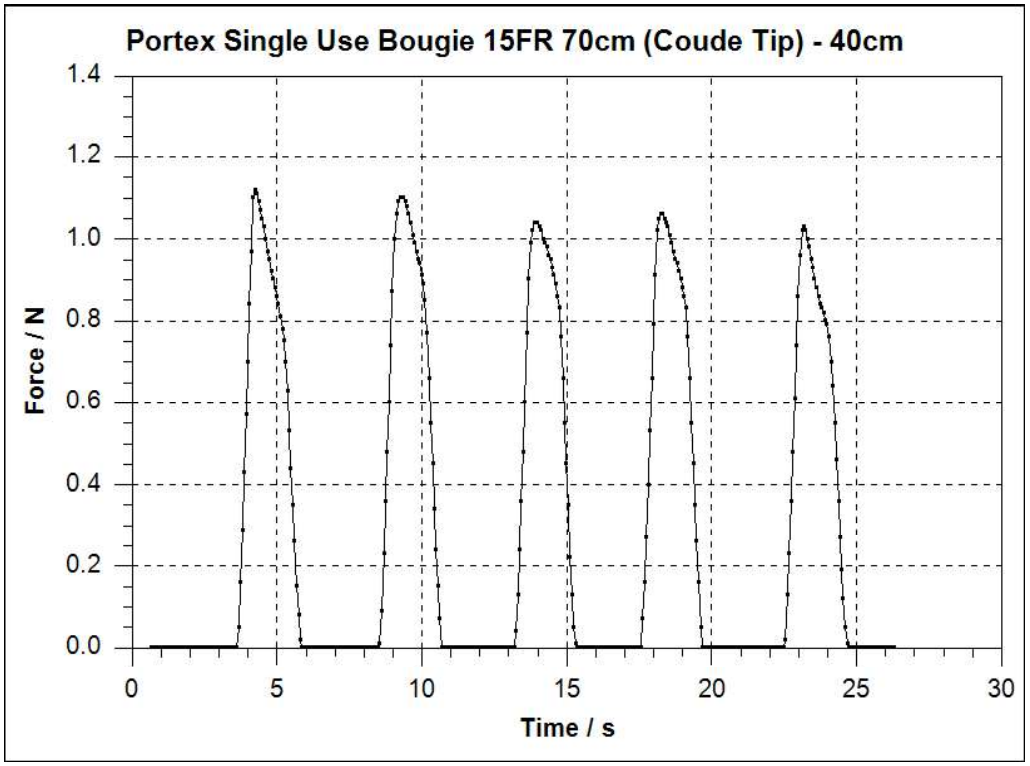
Appendix 2b - Portex Single Use Bougie (20mm)



Appendix 2c - Portex Single Use Bougie (30mm)

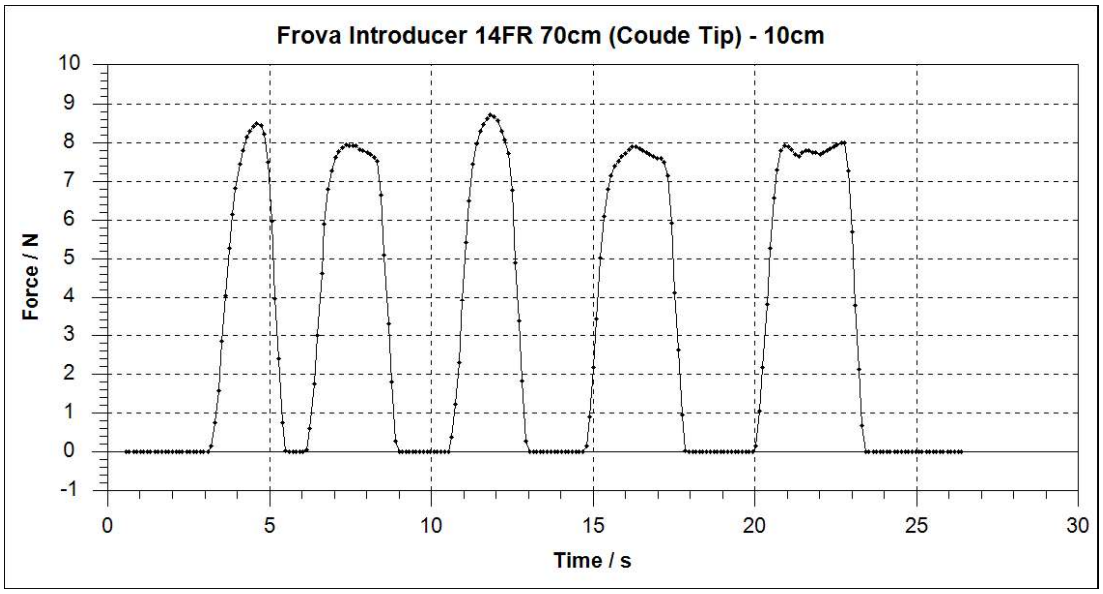


Appendix 2d - Portex Single Use Bougie (40mm)

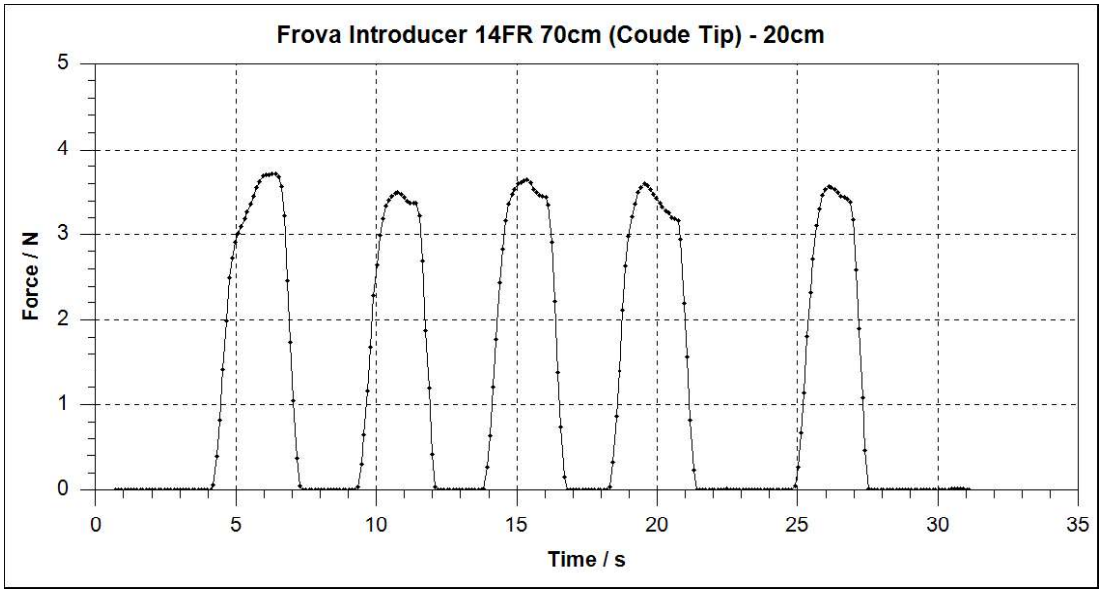


Appendix 3: Frova Introducer 14FR 70cm (Coude Tip) - Tip Pressure Graphs

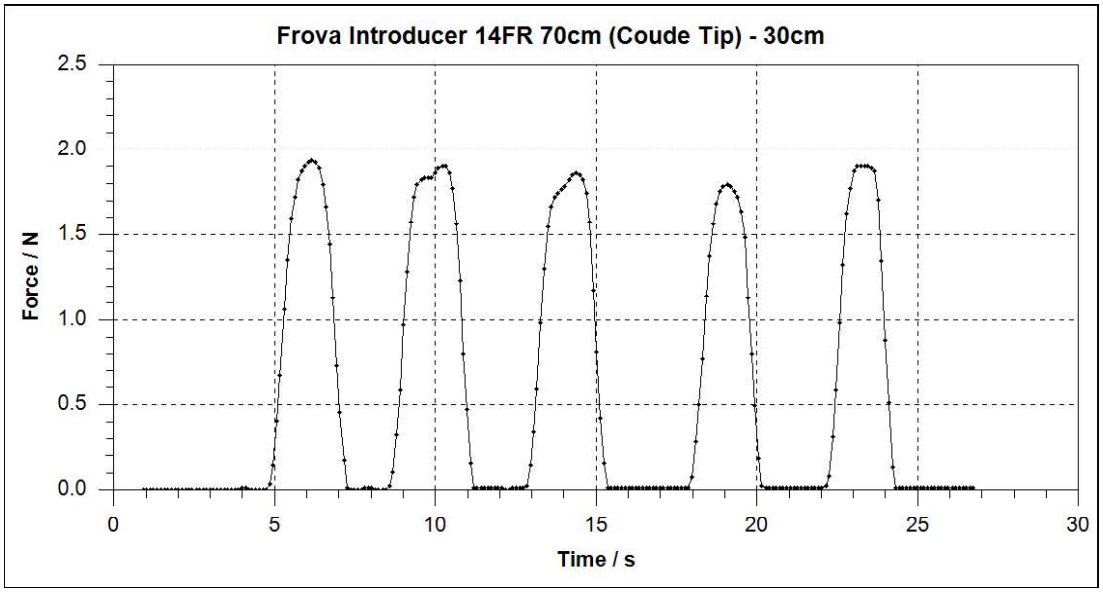
Appendix 3a - Frova Introducer (10mm)



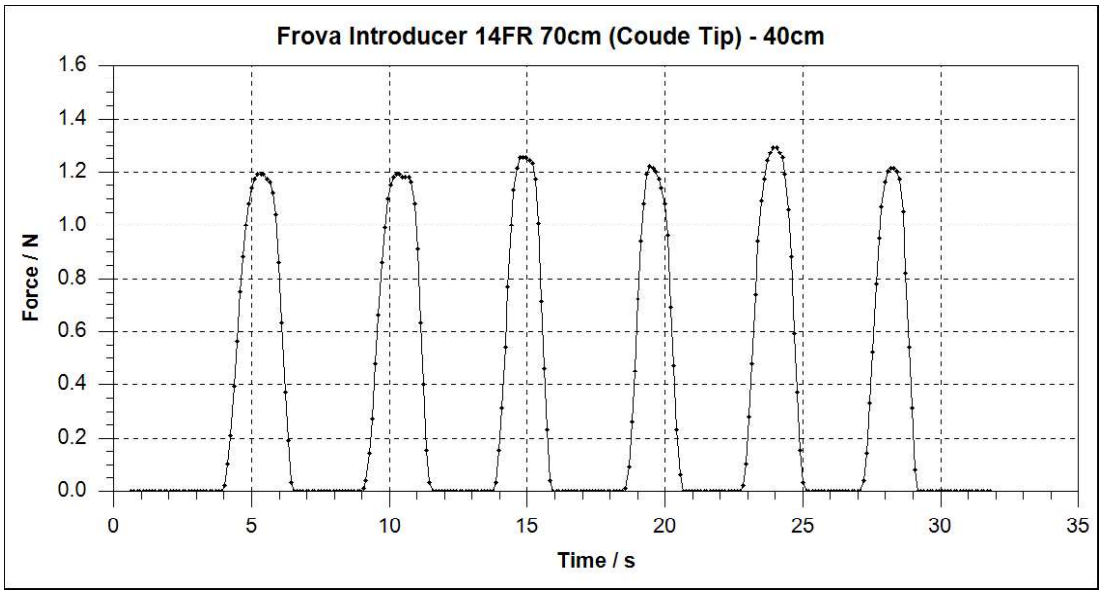
Appendix 3b - Frova Introducer (20mm)



Appendix 3c - Frova Introducer (30mm)

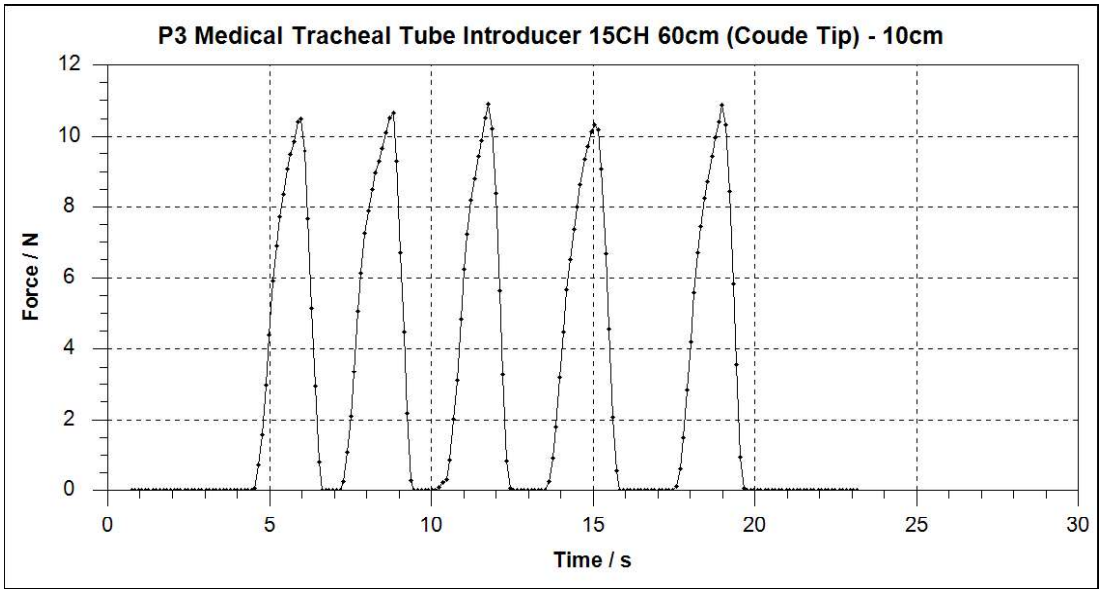


Appendix 3d - Frova Introducer (40mm)

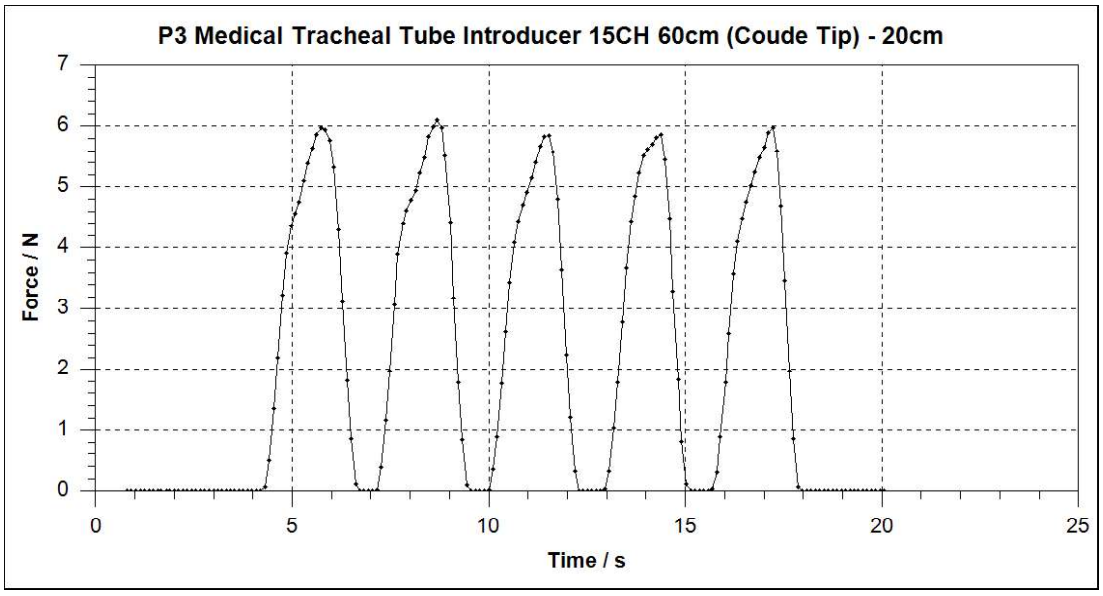


Appendix 4: P3 Medical Tracheal Tube Introducer 15CH 60cm (Coude Tip) - Tip Pressure Graphs

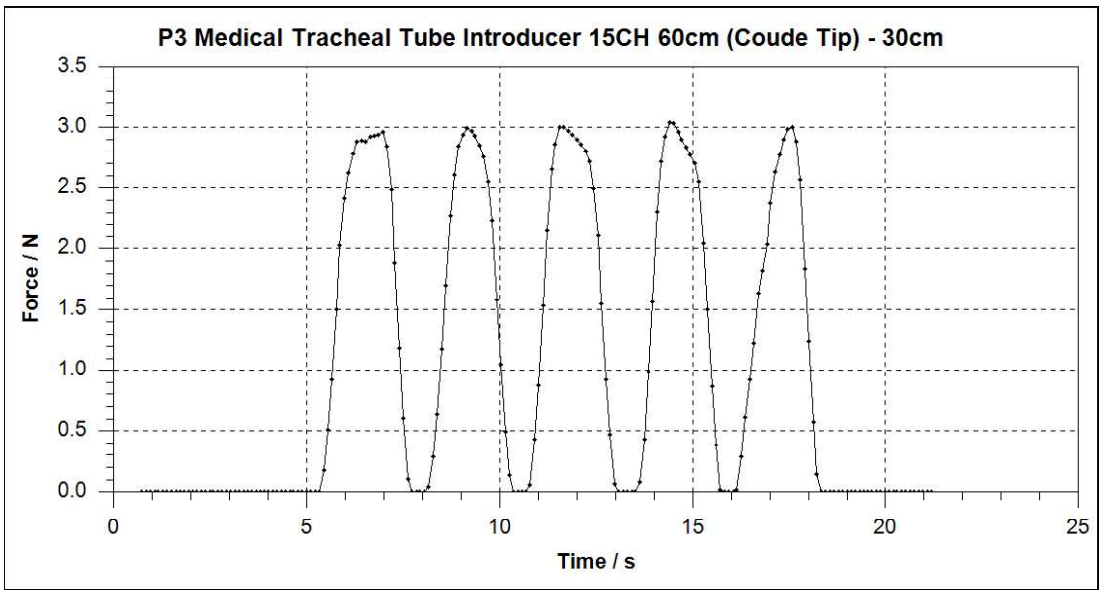
Appendix 4a - P3 Medical Tracheal Tube Introducer (10mm)



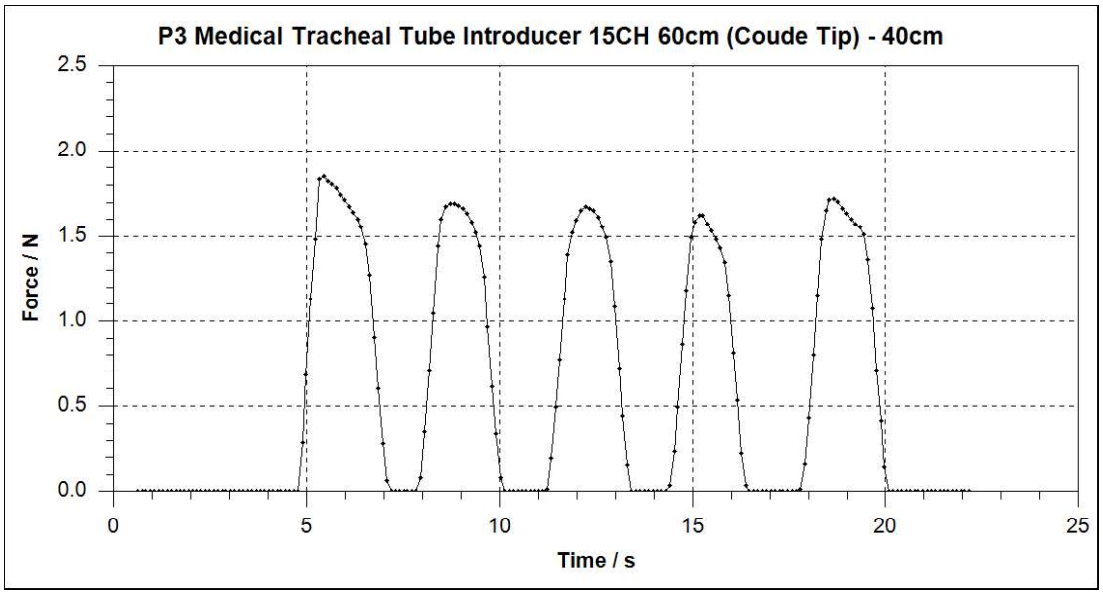
Appendix 4b - P3 Medical Tracheal Tube Introducer (20mm)



Appendix 4c - P3 Medical Tracheal Tube Introducer (30mm)

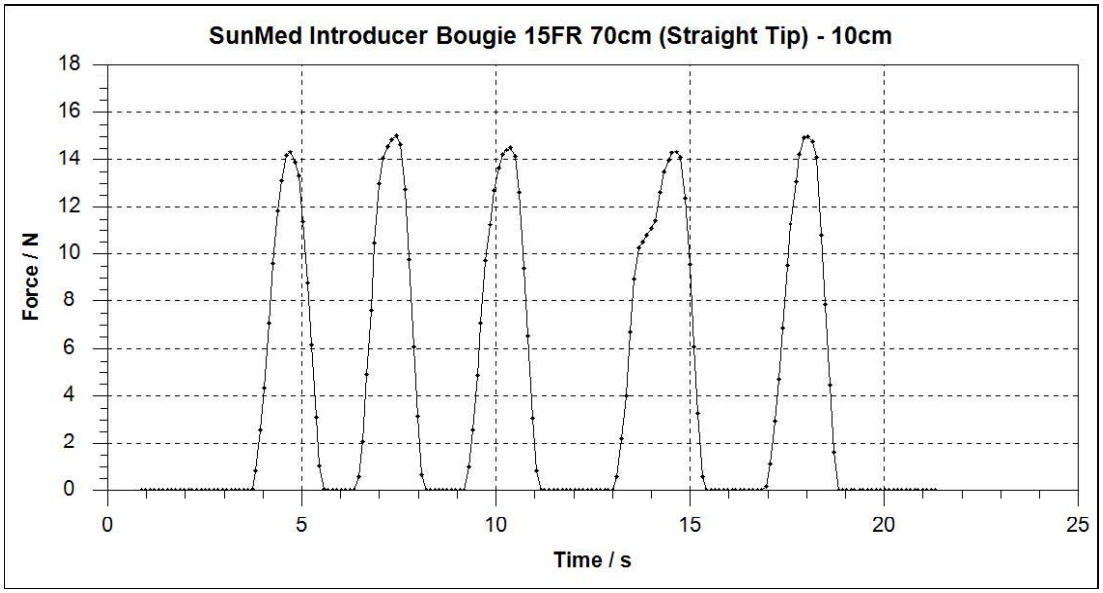


Appendix 4d - P3 Medical Tracheal Tube Introducer (40mm)

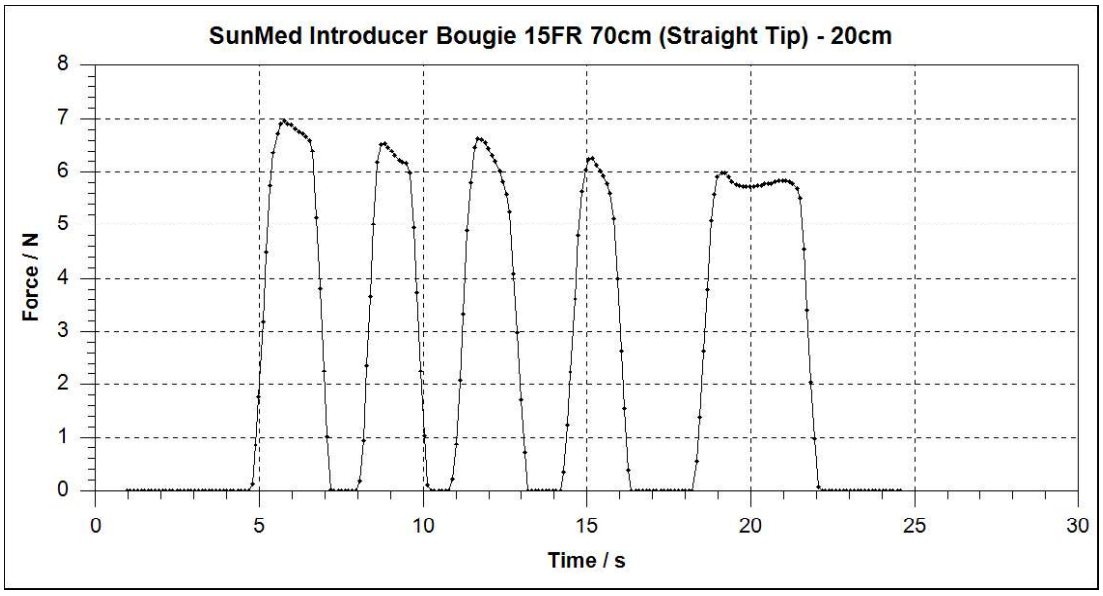


Appendix 5: SunMed Introducer Bougie 15FR 70cm (Straight Tip) Tip Pressure Graphs

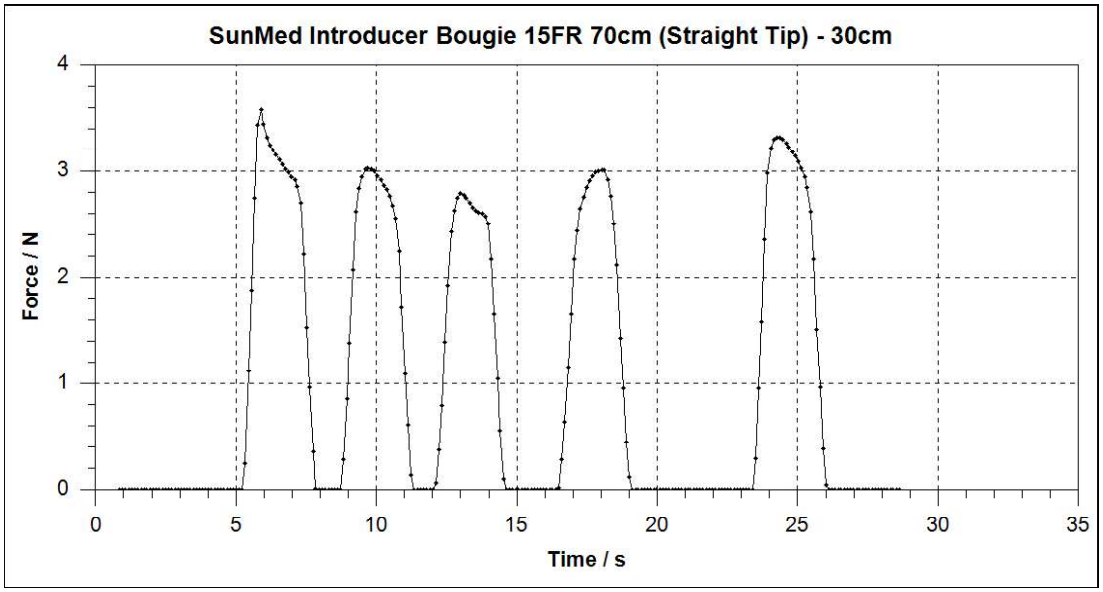
Appendix 5a - SunMed Introducer Bougie – Straight Tip (10mm)



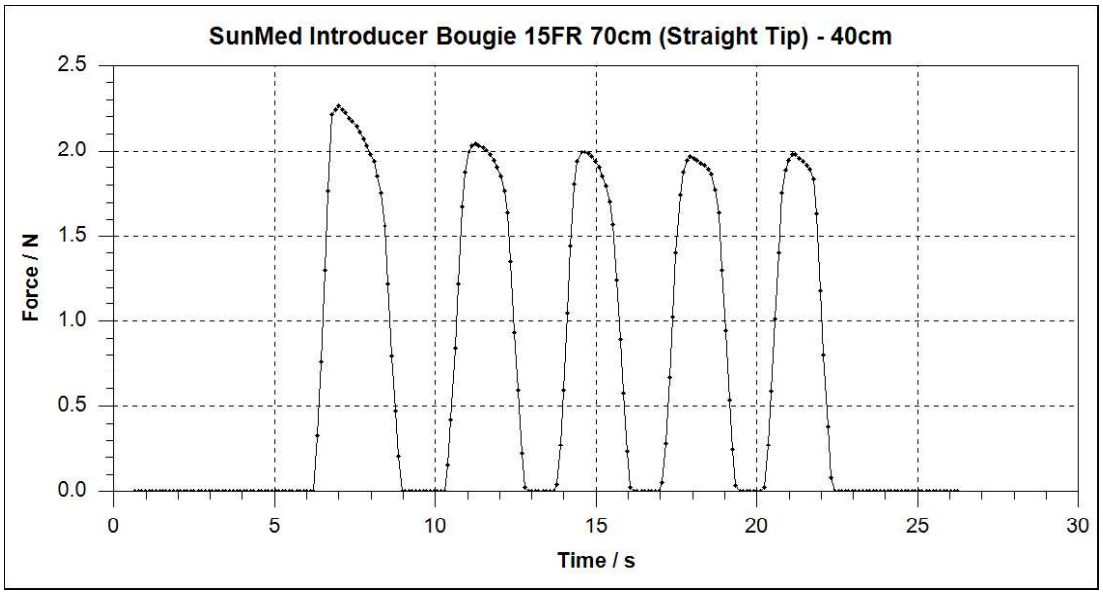
Appendix 5b - SunMed Introducer Bougie – Straight Tip (20mm)



Appendix 5c - SunMed Introducer Bougie – Straight Tip (30mm)

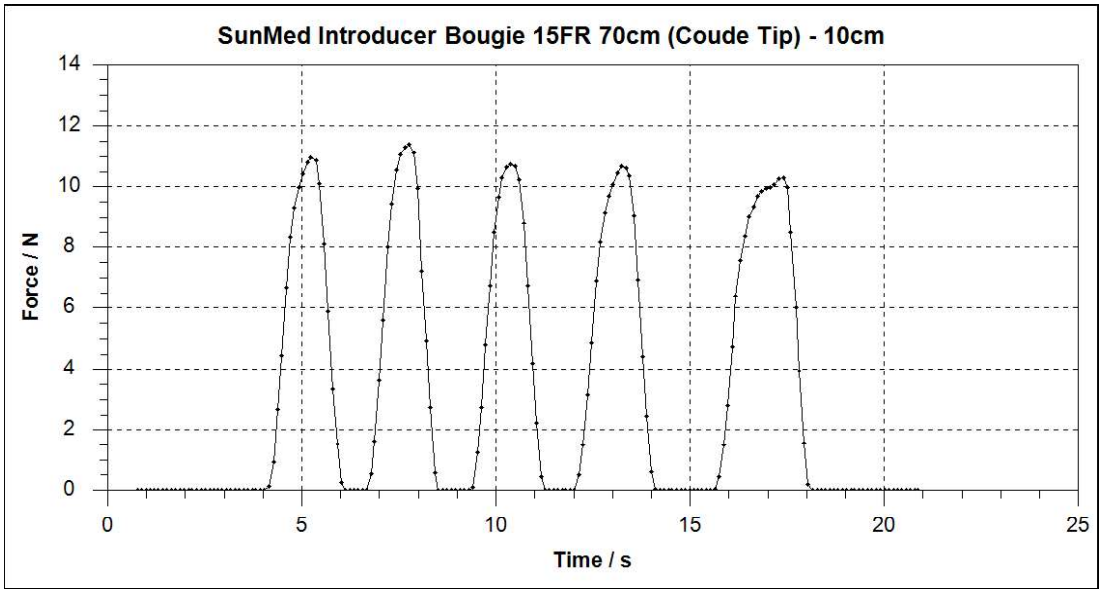


Appendix 5d - SunMed Introducer Bougie – Straight Tip (40mm)

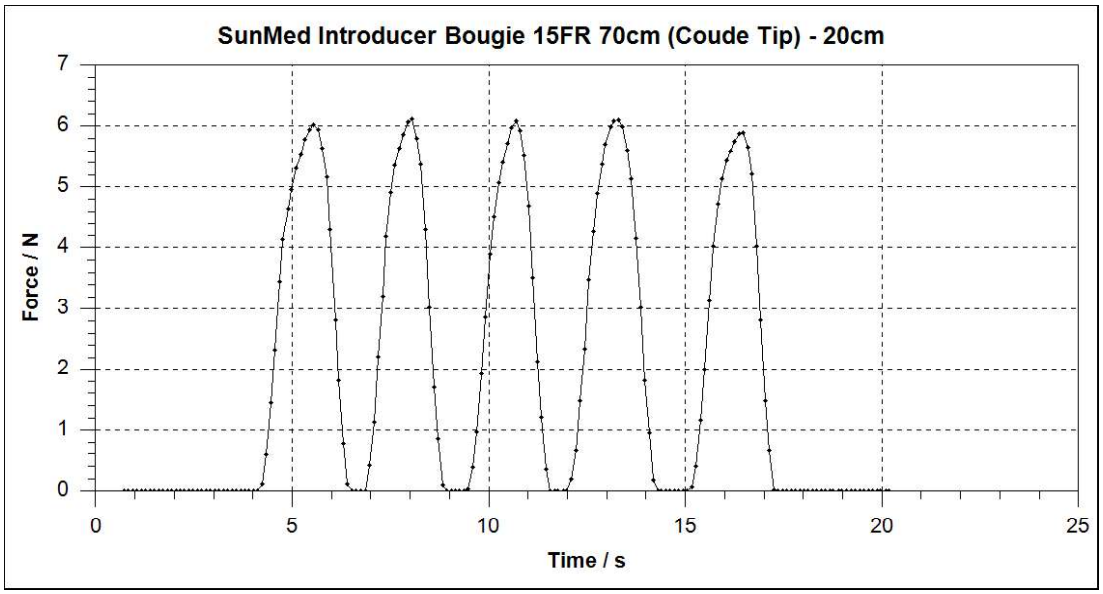


Appendix 6: SunMed Introducer Bougie 15FR 70cm (Coude Tip) - Tip Pressure Graphs

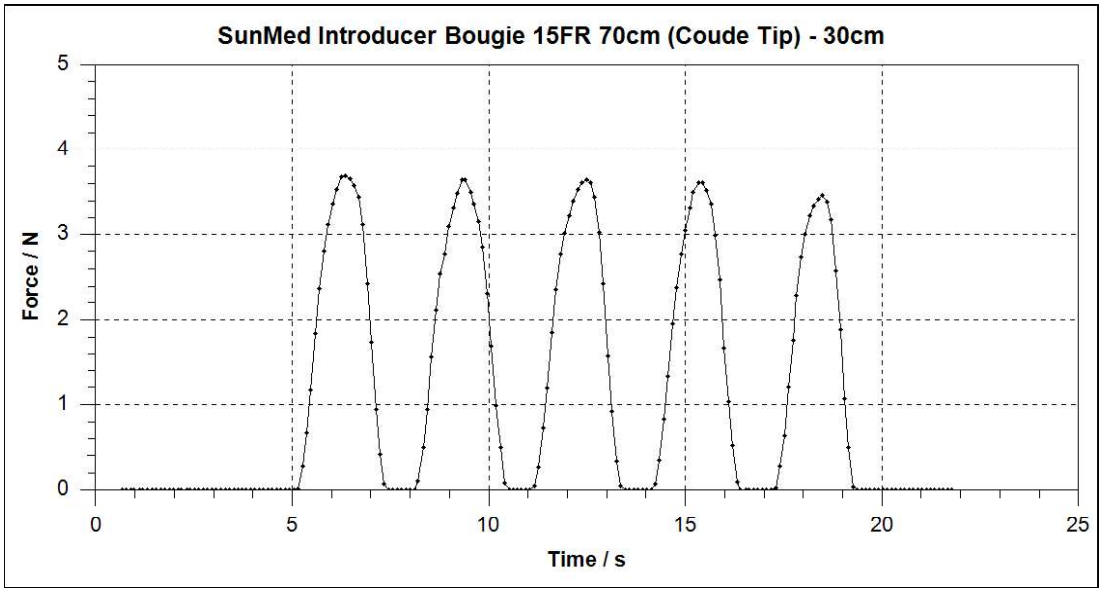
Appendix 6a - SunMed Introducer Bougie – Coude Tip (10mm)



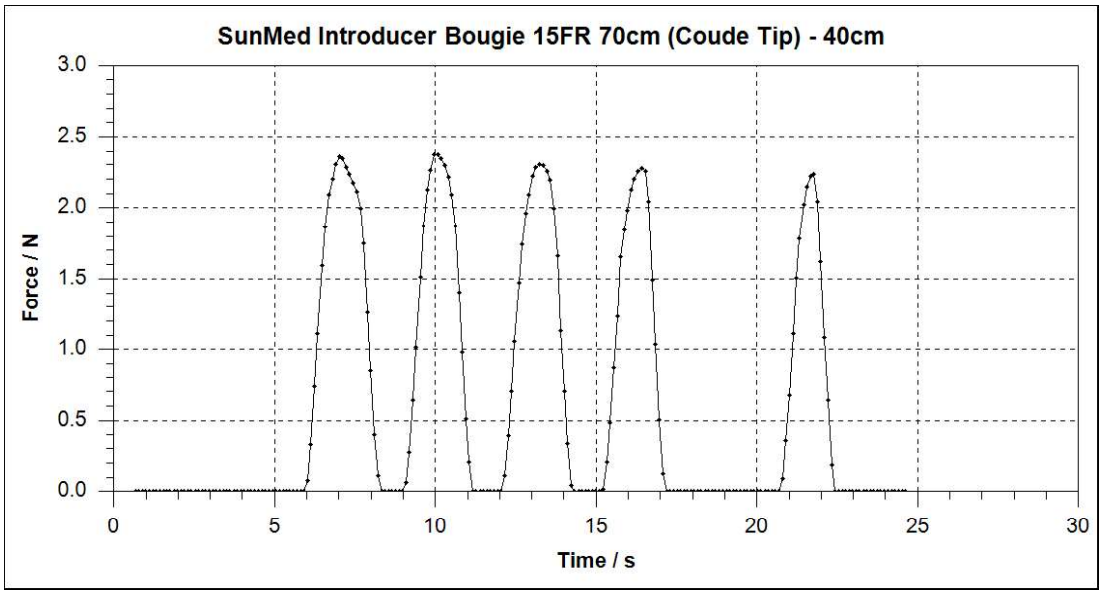
Appendix 6b - SunMed Introducer Bougie – Coude Tip (20mm)



Appendix 6c - SunMed Introducer Bougie – Coude Tip (30mm)

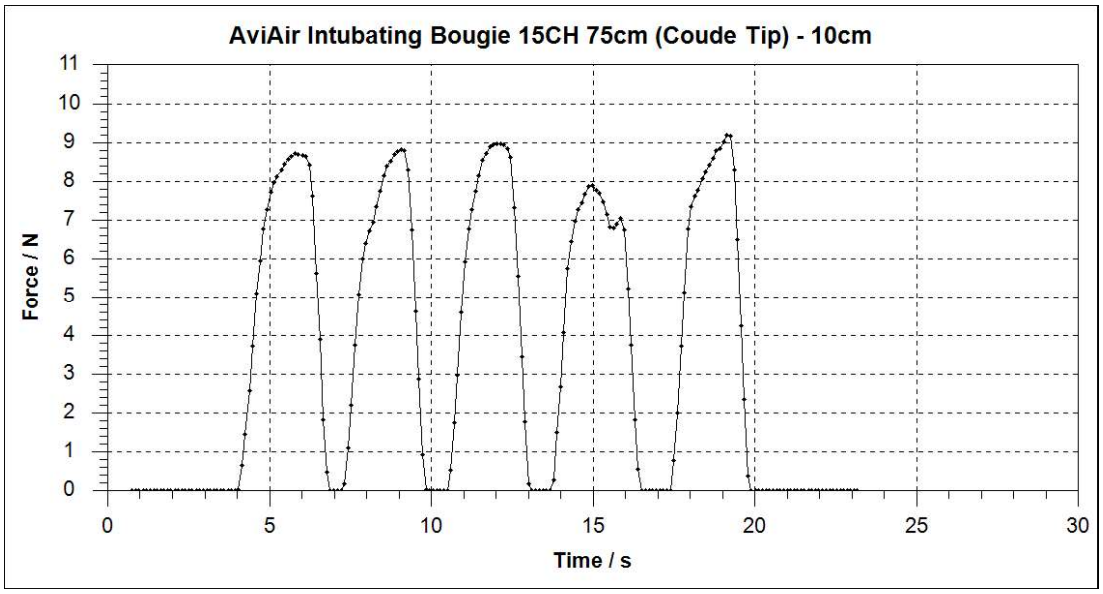


Appendix 6d - SunMed Introducer Bougie – Coude Tip (40mm)

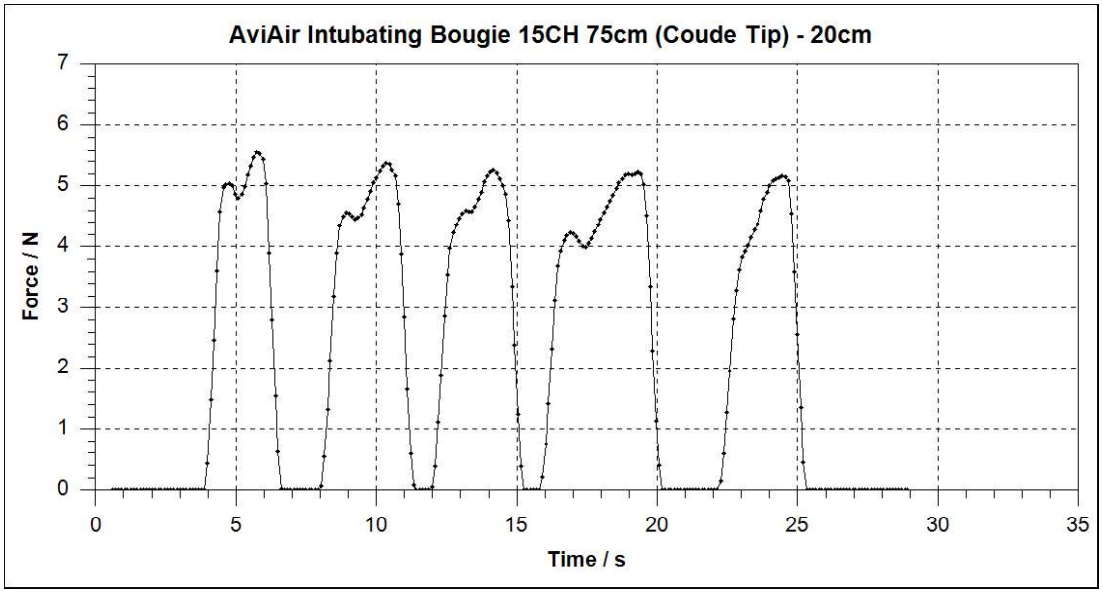


Appendix 7: AviAir Intubating Bougie 15CH, 75cm (Coude Tip) - Tip Pressure Graphs

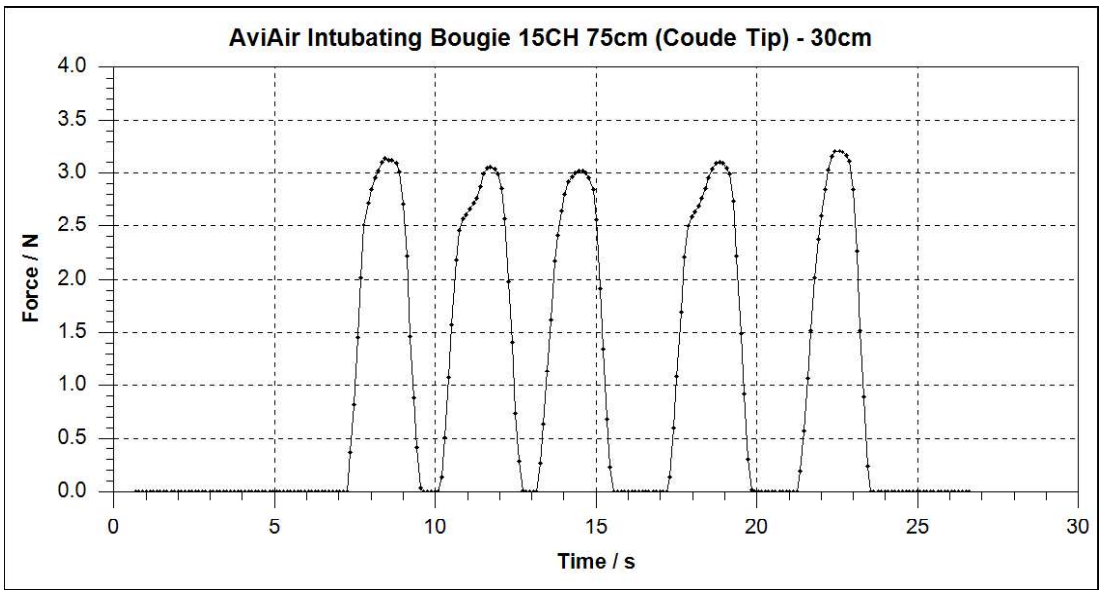
Appendix 7a - AviAir Intubating Bougie (10mm)



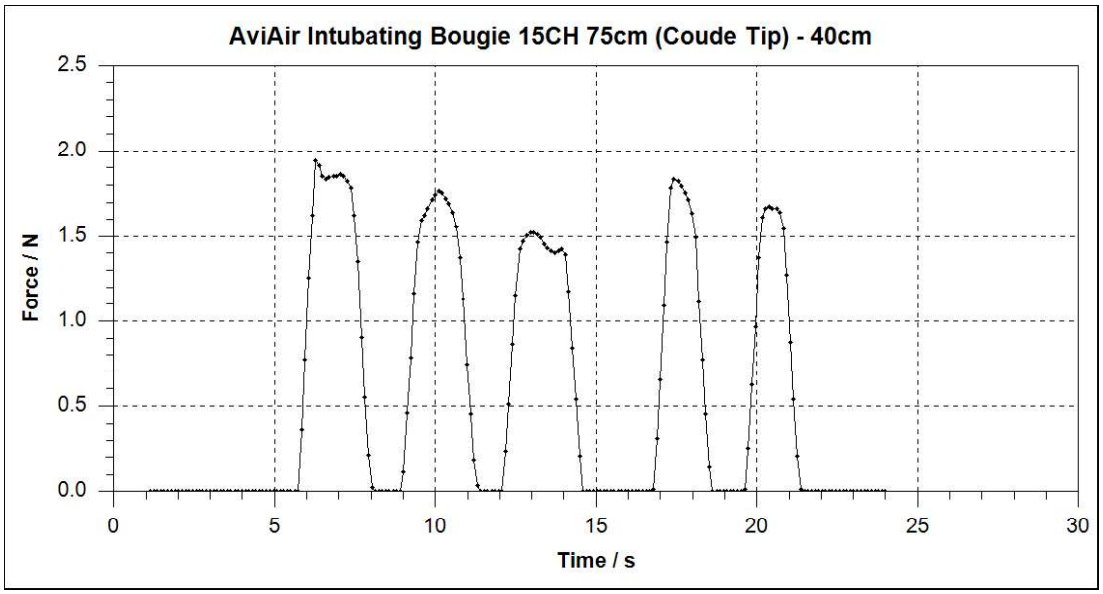
Appendix 7b - AviAir Intubating Bougie (20mm)



Appendix 7c - AviAir Intubating Bougie (30mm)

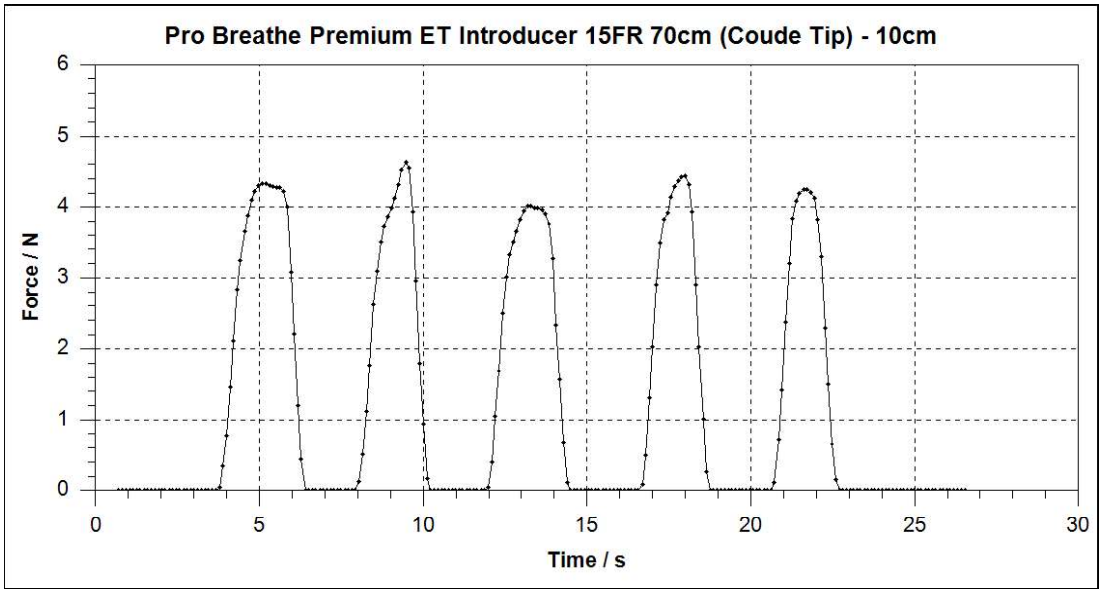


Appendix 7d - AviAir Intubating Bougie (40mm)

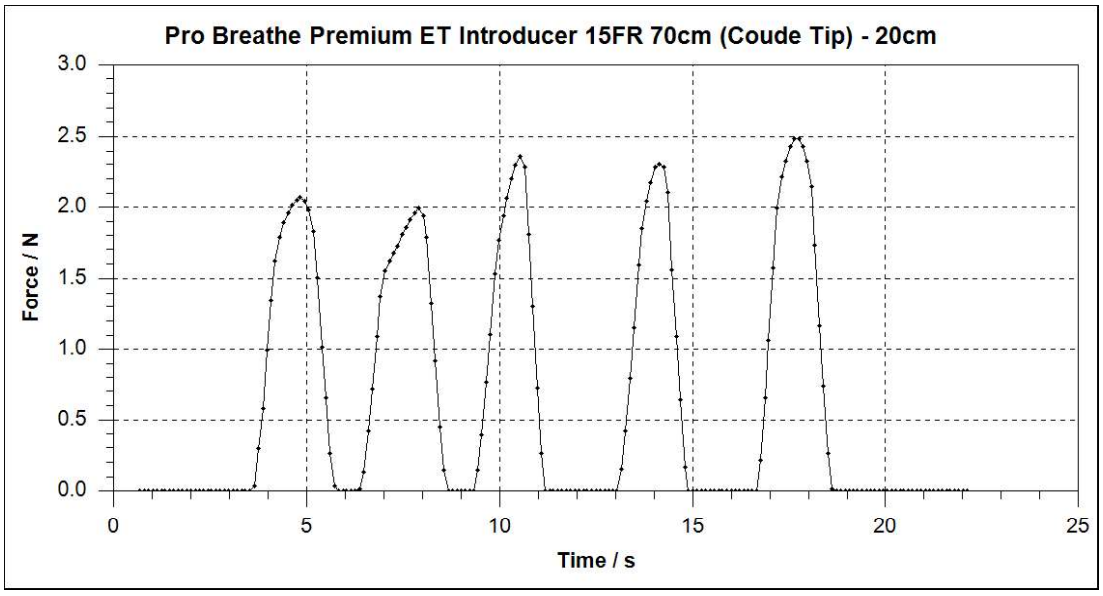


Appendix 8: Pro Breathe Premium ET Tube Introducer 15FR 70cm (Coude Tip) - Tip Pressure Graphs

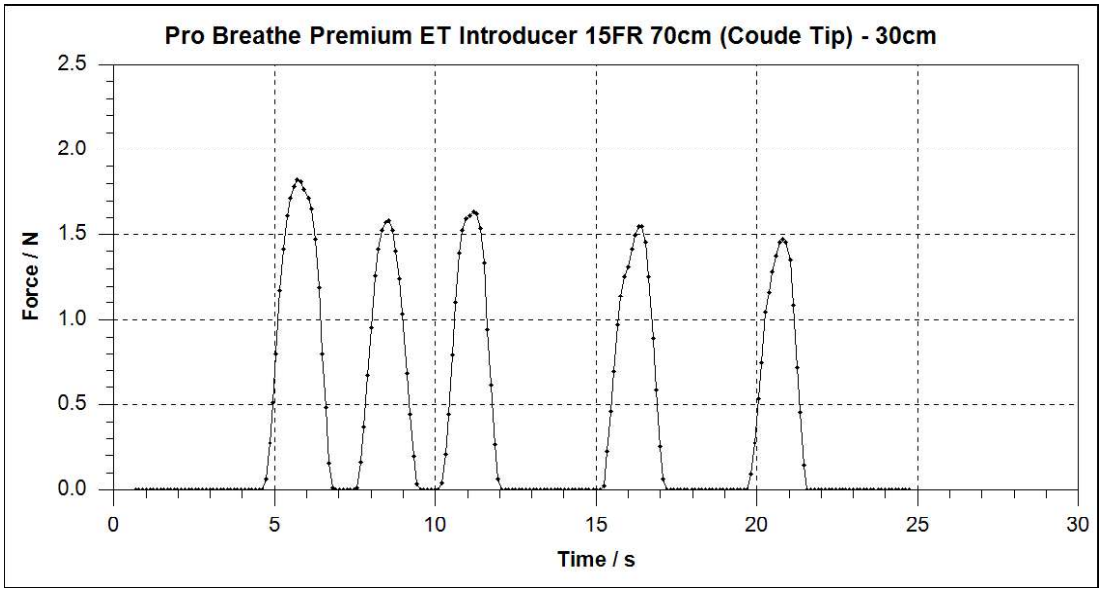
Appendix 8a - Pro Breathe Premium ET Tube Introducer (10mm)



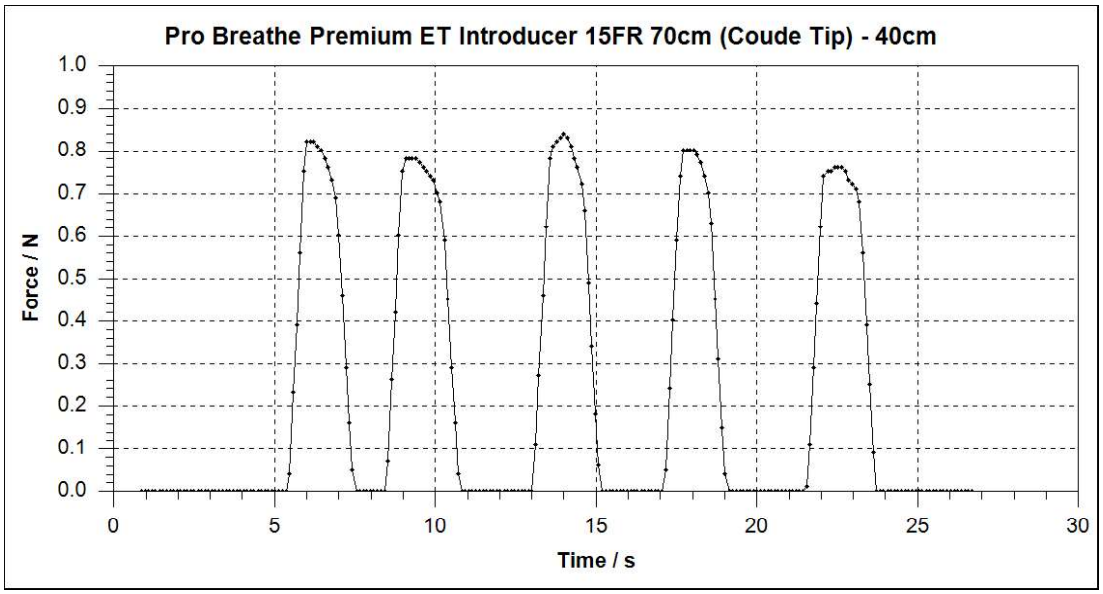
Appendix 8b - Pro Breathe Premium ET Tube Introducer (20mm)



Appendix 8c - Pro Breathe Premium ET Tube Introducer (30mm)

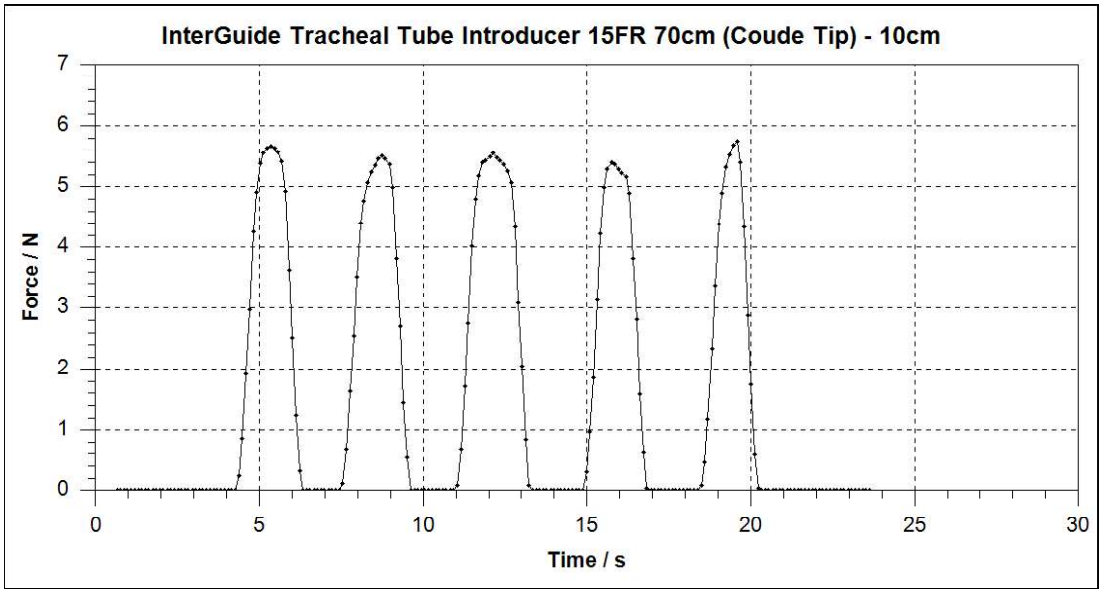


Appendix 8d - Pro Breathe Premium ET Tube Introducer (40mm)

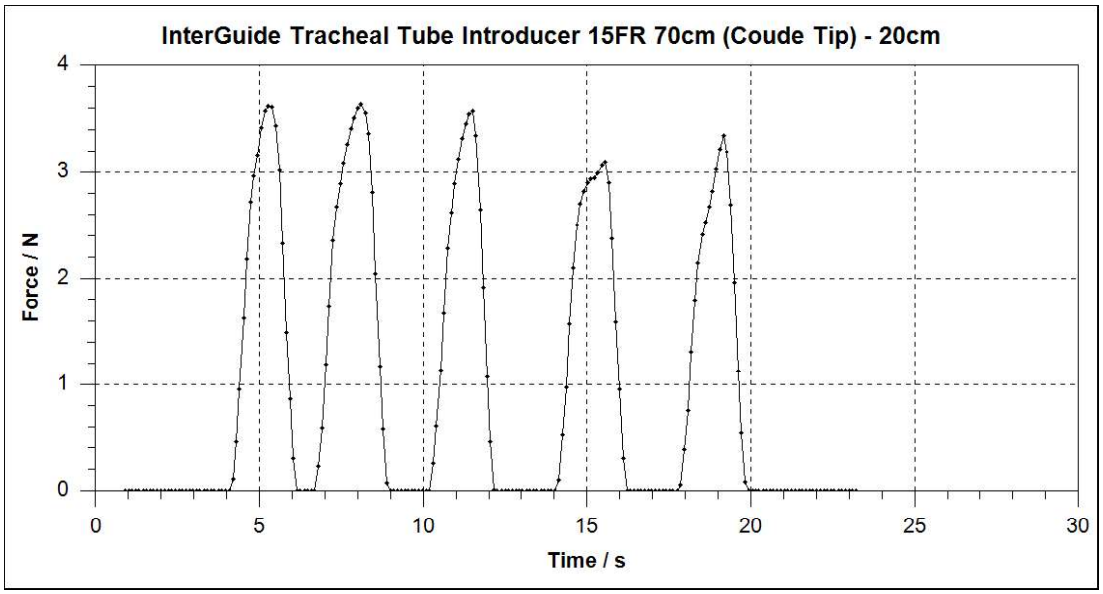


Appendix 9: InterGuide Tracheal Tube Introducer Bougie 15FR 70cm (Coude Tip) - Tip Pressure Graphs

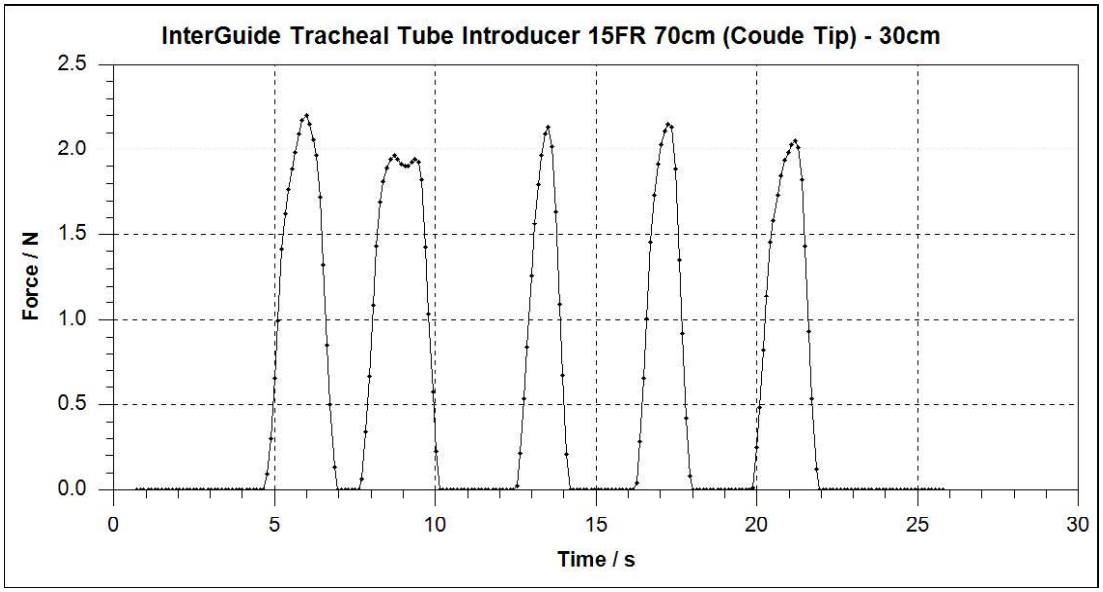
Appendix 9a - InterGuide Tracheal Tube Introducer Bougie (10mm)



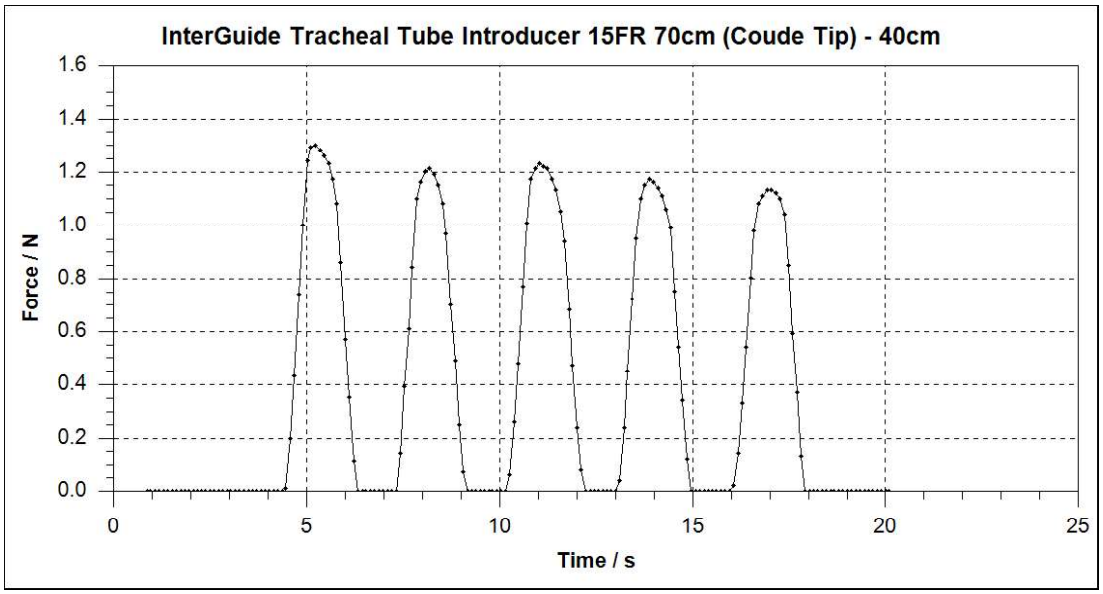
Appendix 9b - InterGuide Tracheal Tube Introducer Bougie (20mm)



Appendix 9c - InterGuide Tracheal Tube Introducer Bougie (30mm)

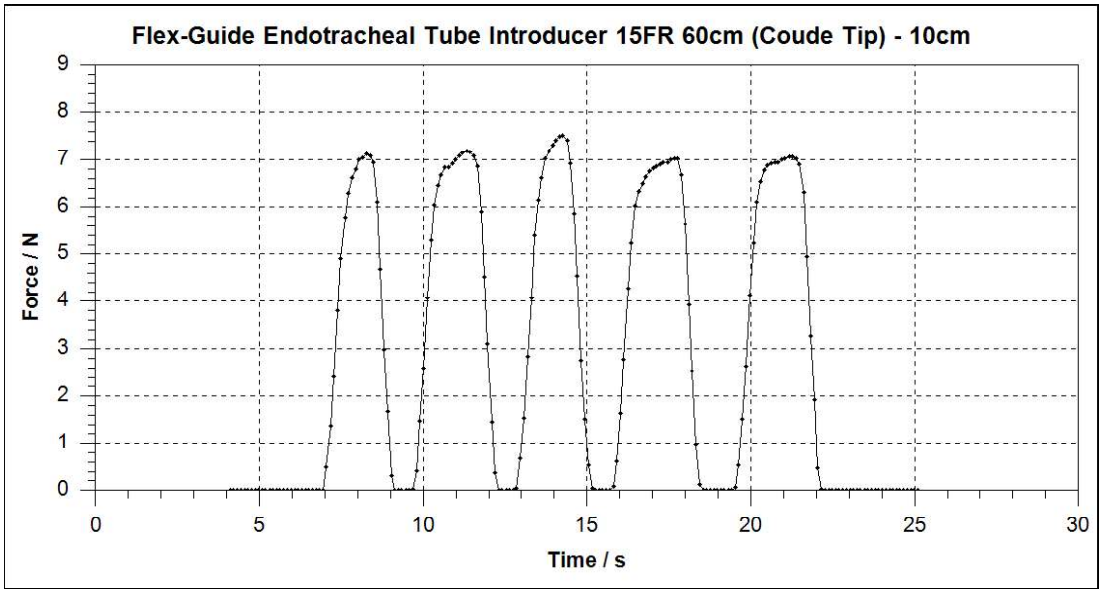


Appendix 9d - InterGuide Tracheal Tube Introducer Bougie (40mm)

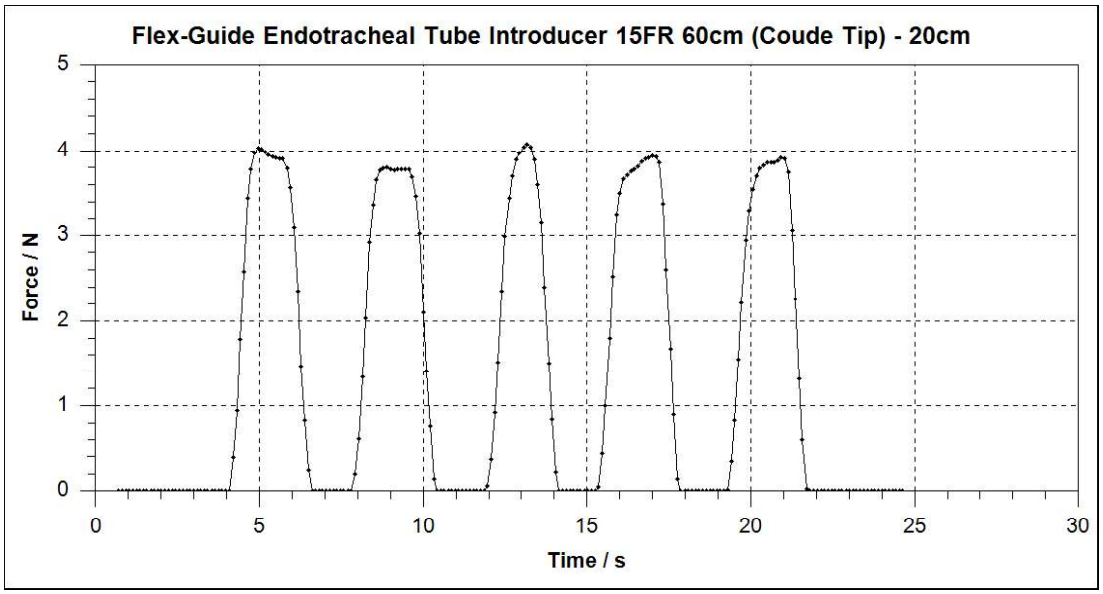


Appendix 10: Flex-Guide Endotracheal Tube Introducer 15FR 60cm (Coude Tip) - Tip Pressure Graphs

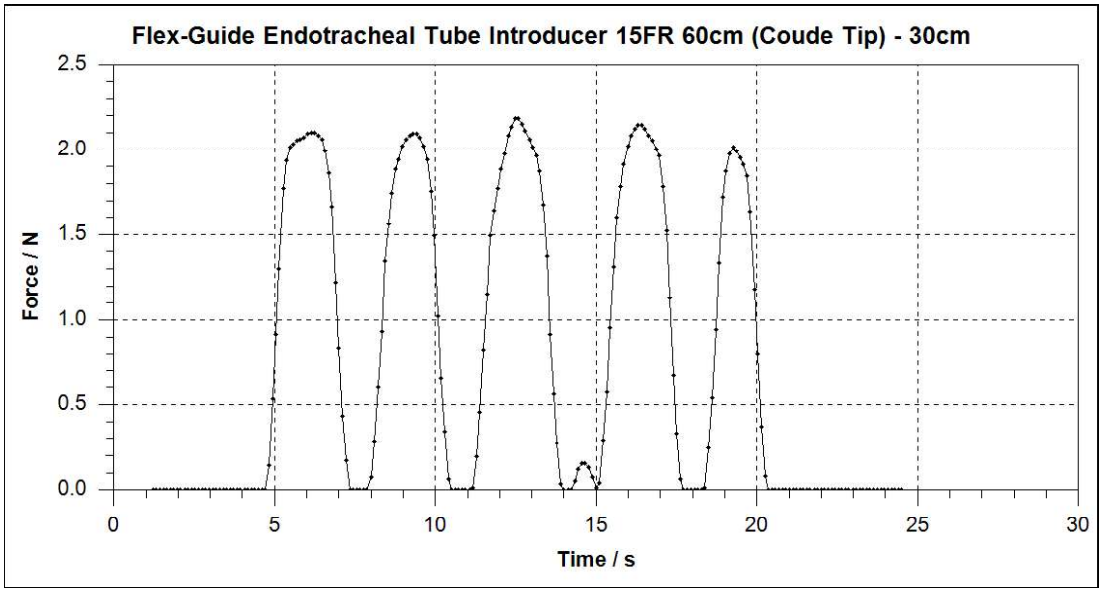
Appendix 10a - Flex-Guide Endotracheal Tube Introducer (10mm)



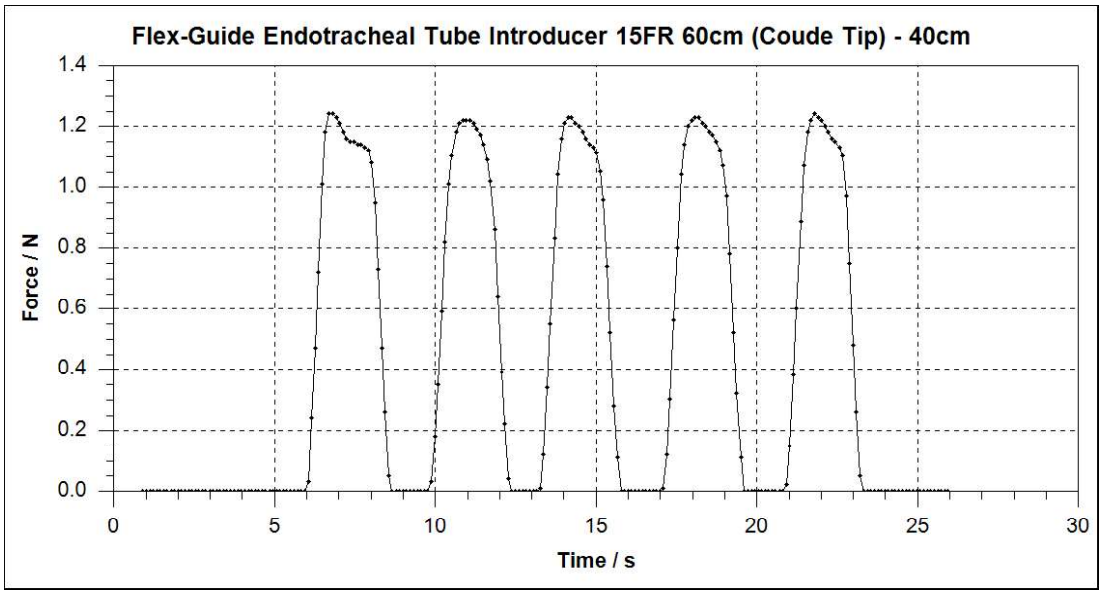
Appendix 10b - Flex-Guide Endotracheal Tube Introducer (20mm)



Appendix 10c - Flex-Guide Endotracheal Tube Introducer (30mm)

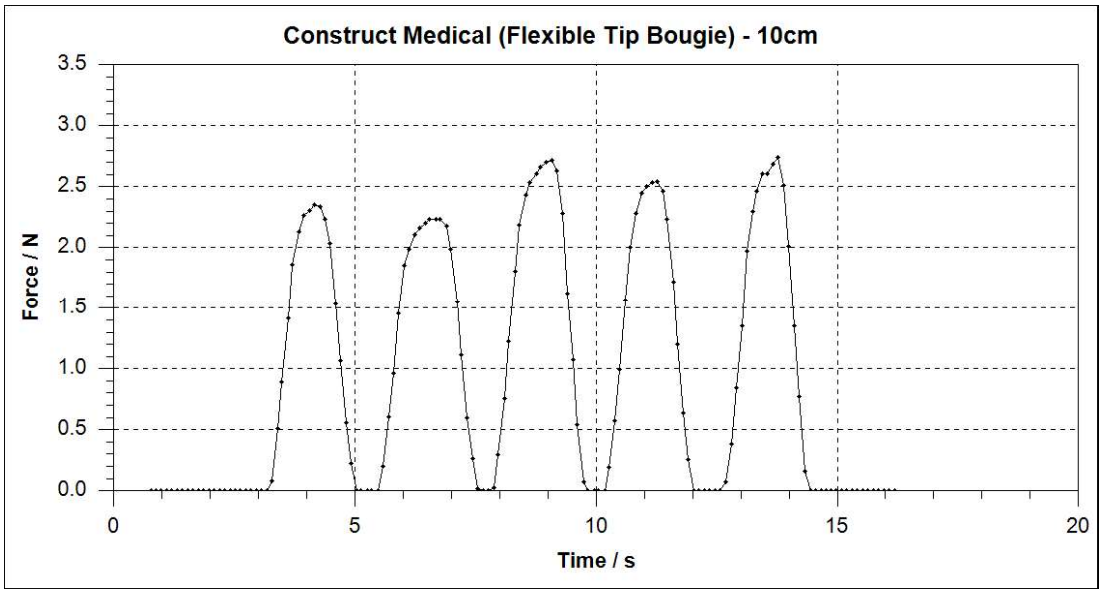


Appendix 10d - Flex-Guide Endotracheal Tube Introducer (40mm)

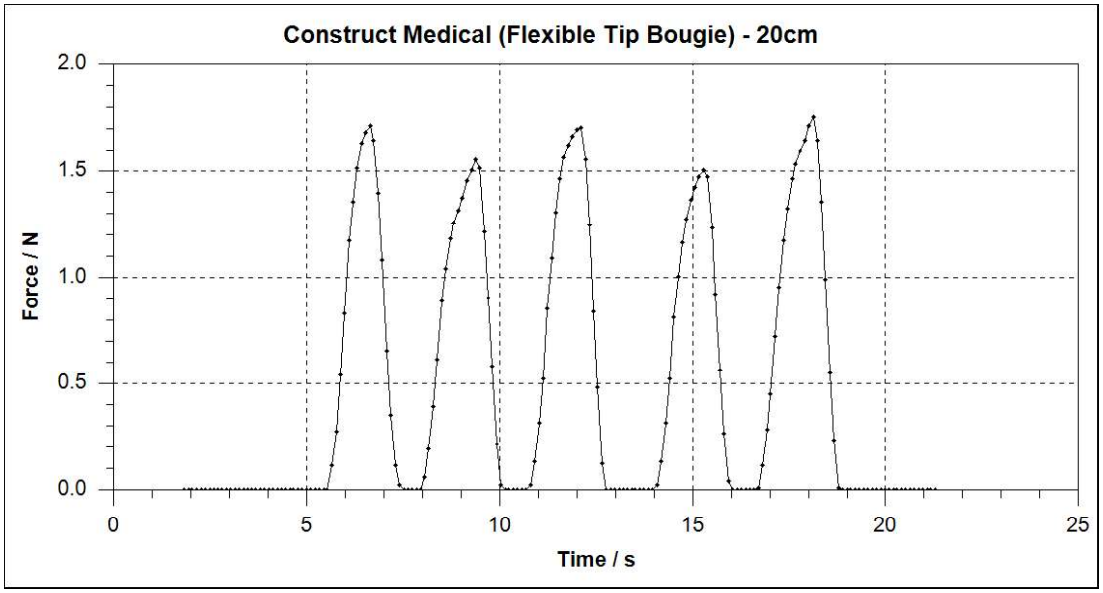


Appendix 11: Construct Medical (Flexible Tip Bougie) - Tip Pressure Graphs

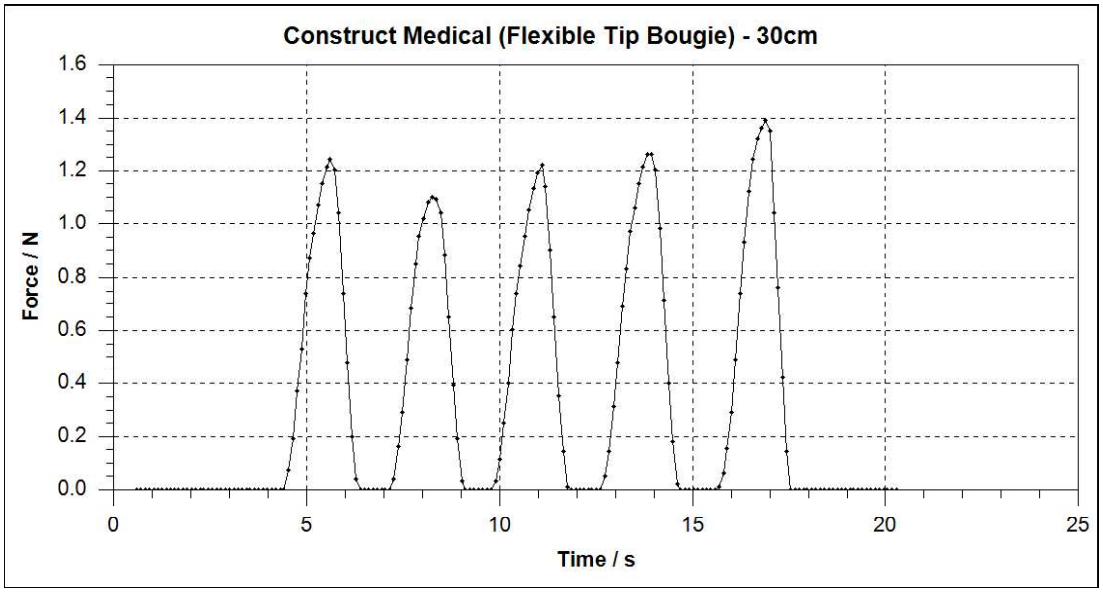
Appendix 11a - Construct Medical - Flexible Tip Bougie (10mm)



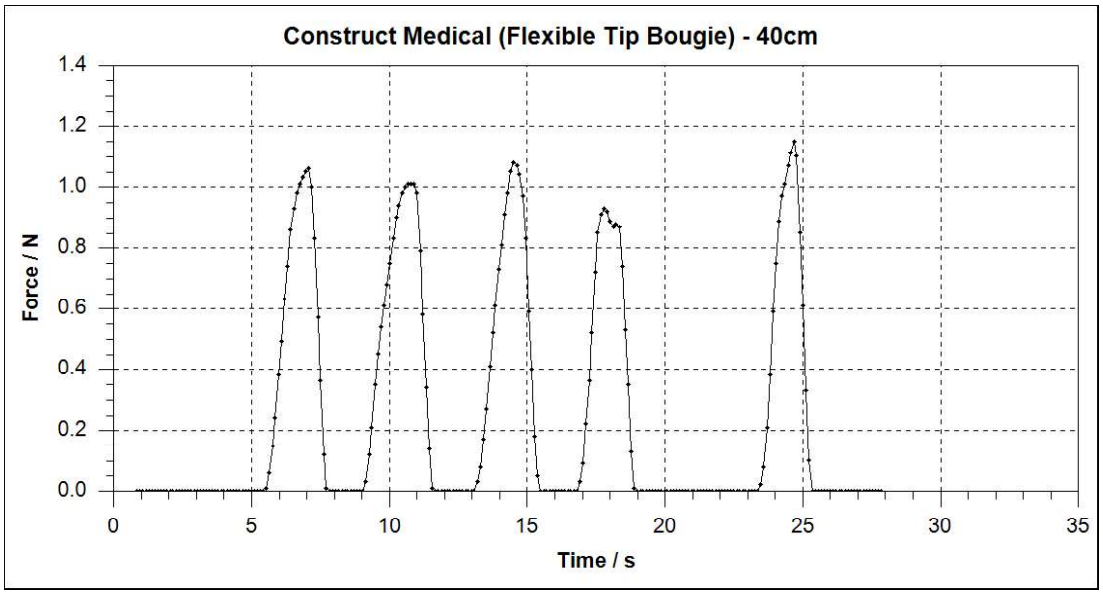
Appendix 11b - Construct Medical - Flexible Tip Bougie (20mm)



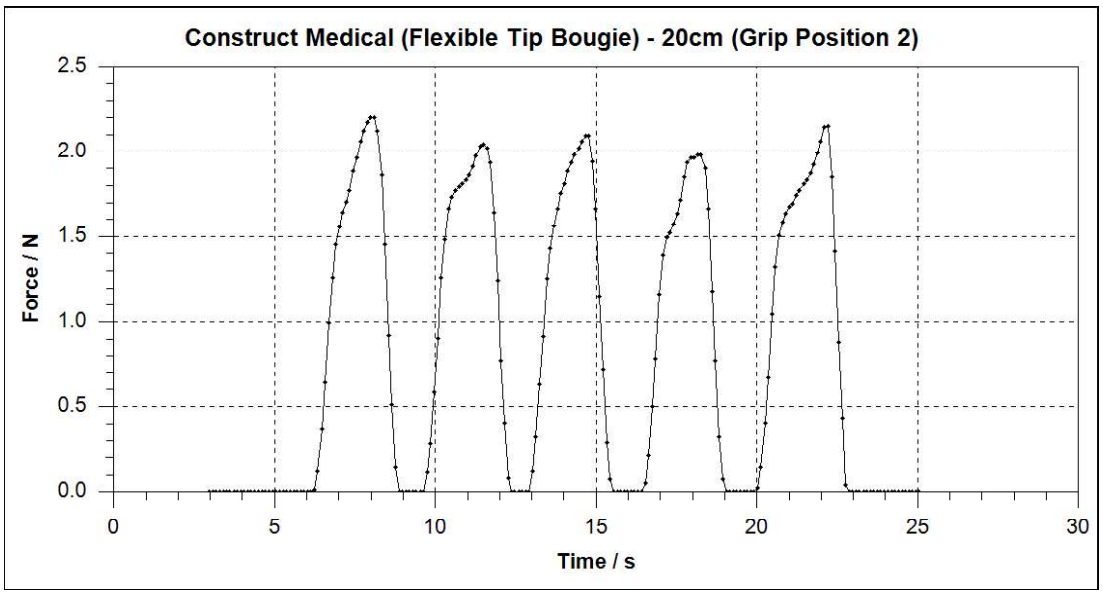
Appendix 11c - Construct Medical - Flexible Tip Bougie (30mm)



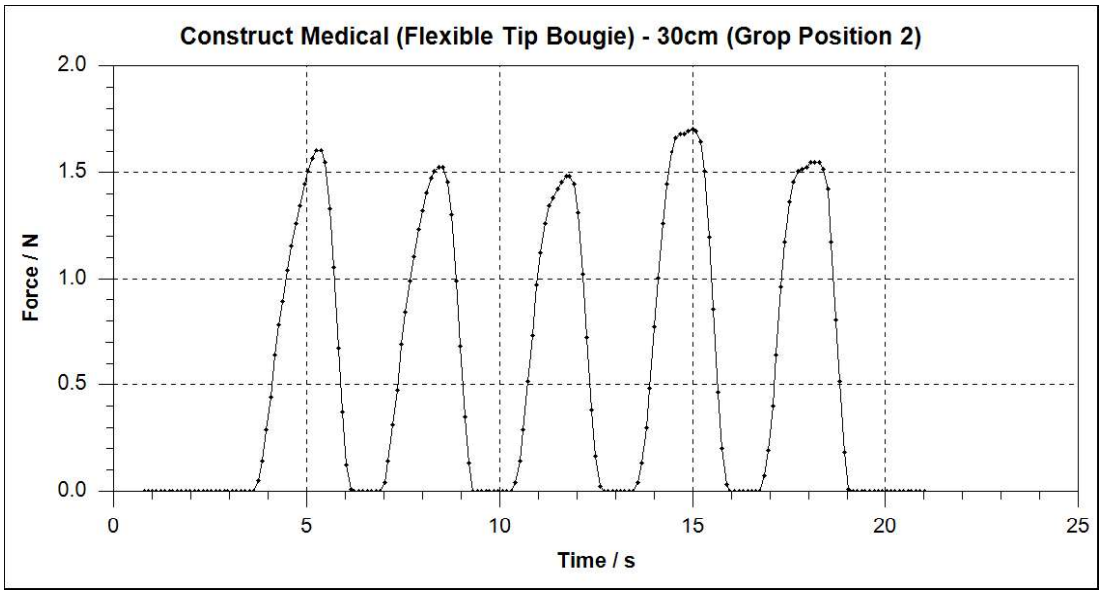
Appendix 11d - Construct Medical - Flexible Tip Bougie (40mm)



Appendix 11e - Construct Medical - Flexible Tip Bougie (20mm) – Grip Position 2



Appendix 11f - Construct Medical - Flexible Tip Bougie (40mm) – Grip Position 2



APPENDIX L – EQUALISED RANDOMISATION

Bougie Tip Pressure Study - Equalised Randomisation						
Participant No	**Frova**	**Sun-Med**	**Gum Elastic**	**Portex**	**PRO-Breathe**	**Steerable Bougie**
1	1	2	3	4	5	6
2	6	1	2	3	4	5
3	5	6	1	2	3	4
4	4	5	6	1	2	3
5	3	4	5	6	1	2
6	2	3	4	5	6	1
7	1	3	4	5	6	2
8	2	1	3	4	5	6
9	6	2	1	3	4	5
10	5	6	2	1	3	4
11	4	5	6	2	1	3
12	3	4	5	6	2	1
13	1	4	5	6	2	3
14	3	1	4	5	6	2
15	2	3	1	4	5	6
16	6	2	3	1	4	5
17	5	6	2	3	1	4
18	4	5	6	2	3	1
19	1	5	6	2	3	4
20	4	1	5	6	2	3
21	3	4	1	5	6	2
22	2	3	4	1	5	6
23	6	2	3	4	1	5
24	5	6	2	3	4	1
25	1	6	2	3	4	5
26	5	1	6	2	3	4
27	4	5	1	6	2	3
28	3	4	5	1	6	2
29	2	3	4	5	1	6
30	6	2	3	4	5	1
31	1	2	4	5	6	3
32	3	1	2	4	5	6
33	6	3	1	2	4	5
34	5	6	3	1	2	4
35	4	5	6	3	1	2
36	2	4	5	6	3	1
37	1	2	5	6	3	4
38	4	1	2	5	6	3
39	3	4	1	2	5	6
40	6	3	4	1	2	5
41	5	6	3	4	1	2
42	2	5	6	3	4	1
43	1	5	6	3	4	2
44	2	1	5	6	3	4
45	4	2	1	5	6	3
46	3	4	2	1	5	6
47	6	3	4	2	1	5
48	5	6	3	4	2	1

24 Participants							
	1st	2nd	3rd	4th	5th	6th	Total
Frova	4	4	4	4	4	4	24
Sun-Med	4	4	4	4	4	4	24
Gum Elastic	4	4	4	4	4	4	24
Portex	4	4	4	4	4	4	24
Pro Breathe	4	4	4	4	4	4	24
Steerable	4	4	4	4	4	4	24

36 Participants							
	1st	2nd	3rd	4th	5th	6th	Total
Frova	6	6	6	6	6	6	36
Sun-Med	6	6	6	6	6	6	36
Gum Elastic	6	6	6	6	6	6	36
Portex	6	6	6	6	6	6	36
Pro Breathe	6	6	6	6	6	6	36
Steerable	6	6	6	6	6	6	36

48 Participants							
	1st	2nd	3rd	4th	5th	6th	Total
Frova	8	8	8	8	8	8	48
Sun-Med	8	8	8	8	8	8	48
Gum Elastic	8	8	8	8	8	8	48
Portex	8	8	8	8	8	8	48
Pro Breathe	8	8	8	8	8	8	48
Steerable	8	8	8	8	8	8	48

APPENDIX M – SUMMARY OF SHORE HARDNESS TESTING REQUIREMENTS

Regulation	No.	Description
BS ISO 7619-1:2010	3.0	When using durometers, the scale should be chosen as follows: for values less than 20 with a type D durometer: type A; – for values less than 20 with a type A durometer: type AO; – for values over 90 with a type A durometer: type D; – for thin test pieces (less than 6 mm thick): type AM.
BS ISO 7619-1:2010	5.3	The other dimensions of the test piece shall be sufficient to permit measurements at least 12 mm away from any edge for types A and D, and 15 mm and 4,5 mm away from any edge for type AO and type AM, respectively. The surface of the test piece shall be flat and parallel over an area sufficient to permit the pressure foot to come into contact with the test piece over an area having a radius of at least 6 mm from the indentor point for types A and D, 9 mm for type AO and 2,5 mm for type AM. Satisfactory hardness determinations cannot be made on rounded, uneven or rough surfaces using durometers. However, their use in certain specialized applications is recognized, e.g. ISO 7267-2 for the determination of the hardness of rubber-covered rolls. In such applications, the limitations to their use shall be clearly identified.
BS ISO 868:1978	8.1	Place the test piece on a hard, horizontal, plane surface. Hold the durometer in a vertical position with the point of the indentor (4.2) at least 12mm from any edge of the test piece. Apply the presser foot (4.1) to the test piece as rapidly as possible, without shock, keep the foot parallel to the surface of the test piece. Apply just sufficient pressure to obtain form contact between presser foot and test piece. Read the scale of the indicating device (4.3) after 15 +/- s. If an instantaneous reading is specified read the scale within 1s after the presser foot is in firm contact with the test piece.
D2240-03	9.2.1	Care shall be exercised to minimize the exposure of the instrument to environmental conditions that are adverse to the performance of the instrument, or adversely affect test results.
D2240-03	9.2.2	Place the specimen on a flat, hard, horizontal surface. Hold the durometer in a vertical position with the indentor tip at a distance from any edge of the specimen as described in Section 6, unless it

		is known that identical results are obtained when measurements are made with the indentor at a lesser distance.
D2240-03	9.2.3	Apply the presser foot to the specimen, maintaining it in a vertical position keeping the presser foot parallel to the specimen, with a firm smooth downward action that will avoid shock, rolling of the presser foot over the specimen, or the application of lateral force. Apply sufficient pressure to assure firm contact between the presser foot and the specimen.
D2240-03	9.2.4	For any material covered in 1.1, after the presser foot is in contact with the specimen, the indicated reading shall be recorded within 1 +/- 0.1 s, or after any period of time agreed upon among laboratories or between supplier and user. If the durometer is equipped with a maximum indicator, the maximum indicated reading shall be recorded within 1 +/- 0.1 s of the cessation of initial indentor travel. The indicated hardness reading may change with time.
D2240-03	9.2.5	Make five determinations of hardness at different positions on the specimen at least 6.0 mm (0.24 in.) apart and calculate the arithmetic mean, or alternatively calculate the median. The means of calculating the determinations shall be reported according to Section 10.2.8.
D2240-03	9.3	It is acknowledged that durometer readings below 20 or above 90 are not considered reliable. It is suggested that readings in these ranges not be recorded.
D2240-03	9.4	Manual operation (hand held) of a durometer will cause variations in the results attained. Improved repeatability may be obtained by using a mass, securely affixed to the durometer and centred on the axis of the indentor. Recommended masses are 1 kg for Type A, B and O durometers, 5 kg for Type C, D and DO durometers, and 400 g for Type OO durometers. Further improvement may be achieved by the use of a durometer operating stand that controls the rate of descent of the durometer presser foot to the test specimen and incorporates the masses described above.
D2240-03	10.2.8	Hardness value obtained and method of calculation, either arithmetic mean or alternatively, the median.

APPENDIX N – UNSKILLED & SKILLED BOUGIE TIP PRESSURE TESTING RAW DATA

Please find attached a CD copy of the Unskilled and skilled bougie tip testing raw data; this CD provides the individualised data for all 48 participants and is split up into to participant numbers and skilled and unskilled users:

APPENDIX O – HEAT CHAMBER ARDUINO PROGRAM CODE

The heat chamber and the supporting program was developed in collaboration with Mr Paul Watts (Software Developer – Medical Design Research Group, Nottingham Trent University, UK). The following code also utilises the Adafruit_GFX.h, Adafruit_SSD1351.h, High_Temp.h and High_Temp.cpp plugins and have been adapted accordingly.

Luke_Inferno Tab

```
#include <Adafruit_NeoPixel.h>

#include "High_Temp.h"
#include "Graphics.h"

class SmoothingList
{
  private:
    float vals[5] {0,0,0,0,0};
    int _index = 0;
    bool _isfull = false;

  public:

    void AddValue(float value)
    {
      // Increment
      vals[_index] = value;
      _index++;
      if(_index > 4)
      {
        _index = 0;
        _isfull = true;
      }
    }

    float GetSmoothValue()
    {
      int max = 5;
      if(!_isfull)
      {
        max = _index;
      }

      float accum = 0;
      for(int x =0; x < max; x++)
      {
        accum += vals[x];
      }

      return (accum / max);
    }
};

SmoothingList _platesmoother = SmoothingList();
SmoothingList _ambientsmoother = SmoothingList();
SmoothingList _mouldsmoother = SmoothingList();

HighTemp ambient(A4, A5);
HighTemp _mouldtemp(A2, A3);
const int POT_PIN = A0;
const int ThermistorPin = A1;
const int Thermistor_R1 = 10000;
const int MAX_TEMP = 90;
const int HEATING_SWITCH_PIN = 7;
const int NEO_PIXEL_PIN = 6;
bool _forcedcooling = false;
bool _forceblinking = false;

GraphicsModule videoscreen = GraphicsModule();
```

```
//0 = Initialising
// 1 = Heating
// 2 = At Temperature
// 3 = Cooling
// 4 = ALERT Overtemperature
int status = 0;

int refreshscreen = 0;

Adafruit_NeoPixel pixels = Adafruit_NeoPixel(1, NEO_PIXEL_PIN, NEO_GRB + NEO_KHZ800);

float c1 = 1.009249522e-03, c2 = 2.378405444e-04, c3 = 2.019202697e-07;
void setup() {
  // put your setup code here, to run once:
  Serial.begin(9600);
  ambient.begin();
  _mouldtemp.begin();
  pinMode(POT_PIN, INPUT);
  pinMode(ThermistorPin, INPUT);
  pinMode(10, OUTPUT);
  pinMode(HEATING_SWITCH_PIN, OUTPUT);
  pixels.begin();
  pixels.setPixelColor(0, pixels.Color(0, 255,255));
  pixels.show();

  videoscreen.begin();
  videoscreen.setDisplayScreen(0);

  // Wait two seconds before starting (Give time to switch off if a mistake)
  delay(2000);

  videoscreen.setDisplayScreen(1);
}

void loop() {
  // Get Values
  _platesmoother.AddValue(ThermistorTemperatureCelsius());
  _ambientsmoother.AddValue(ambient.getThmc());
  _mouldsmoother.AddValue(_mouldtemp.getThmc());

  Serial.print(millis() / 1000);
  Serial.print(",");
  Serial.print(_ambientsmoother.GetSmoothValue());
  Serial.print(",");
  Serial.print(_mouldsmoother.GetSmoothValue());
  Serial.print(",");
  Serial.print(_platesmoother.GetSmoothValue());
  Serial.println("");

  /*
  Serial.print("Ambient Sensor Temp\t");
  Serial.print(_ambientsmoother.GetSmoothValue());

  Serial.print("Mould Sensor Temp\t");
  Serial.print(_mouldsmoother.GetSmoothValue());

  int pot = analogRead(POT_PIN);
  Serial.print("\tTemp Dial: ");
  float scale = (MAX_TEMP / 1023.0);
  Serial.print(scale * analogRead(POT_PIN));

  Serial.print("\tThermistor: ");
  Serial.println(_platesmoother.GetSmoothValue());
  */

  WriteScreen();

  OvenSwitch();
  delay(200);
}

void WriteScreen()
{

}
```

```
float ThermistorTemperatureCelsius()
{
  float logR2, R2, T;
  int Vo = analogRead(ThermistorPin);
  R2 = Thermistor_R1 * (1023.0 / (float)Vo - 1.0);
  logR2 = log(R2);
  T = (1.0 / (c1 + c2*logR2 + c3*logR2*logR2*logR2));
  T = T - 273.15;
  //T = (T * 9.0)/ 5.0 + 32.0;

  return T;
}

void OvenSwitch()
{
  // What are we aiming for?
  int target = float(MAX_TEMP / 1023.0) * analogRead(POT_PIN);
  float platetemp = _platesmoother.GetSmoothValue();
  float ambienttemp = _ambientsmoother.GetSmoothValue();
  float mouldtemp = _mouldsmoother.GetSmoothValue();

  videoscreen.updateTemperature(ambienttemp, platetemp, target, mouldtemp);

 if(_forcedcooling)
 {
  if(platetemp < MAX_TEMP - 2)
  {
    _forcedcooling = false;
  }
  else
  {
    if(_forceblinking)
    {
       pixels.setPixelColor(0, pixels.Color(128,0, 0));
    }
    else
    {
       pixels.setPixelColor(0, pixels.Color(0,0, 0));
    }

    // Invert
    _forceblinking = !_forceblinking;
  }
 }
 else
 {
   if(platetemp > MAX_TEMP)
   {
      Serial.println("Heating Plate At Max! Emergency switch off");

     // SWITCH OFF!!
     digitalWrite(HEATING_SWITCH_PIN, 0);

    // Overheat
     status = 4;

    // Show Flame
    videoscreen.updateGraphic(2);

     // RED
     pixels.setPixelColor(0, pixels.Color(128,0, 0));
     pixels.show();

     _forcedcooling = true;
   }
   else
   {
      if(mouldtemp < target)
      {
        Serial.println("Heating Plate To Temperature");

        // SWITCH ON
        digitalWrite(HEATING_SWITCH_PIN, 1);

        // Show Flame
```

```
        videoscreen.updateGraphic(0);

        status = 1;

        pixels.setPixelColor(0, pixels.Color(0, 0, 128));
        pixels.show();
      }
      else
      {
        // Ensure relay is off
        digitalWrite(HEATING_SWITCH_PIN, 0);

        if(mouldtemp > target + 5)
        {
          status = 3;
          // Hold
          Serial.println("Over Temperature.");


          // Draw Idle
          videoscreen.updateGraphic(3);

          // OverTemp
          pixels.setPixelColor(0, pixels.Color(128 ,64, 0));
          pixels.show();
        }
        else
        {
          status = 2;

          // Draw Idle
          videoscreen.updateGraphic(1);

          // Hold
          Serial.println("At Temperature.");

          pixels.setPixelColor(0, pixels.Color(0, 128, 0));
          pixels.show();
        }
      }
    }
  }
}
```

Graphics.CPP Tab

```
#include "Graphics.h"

GraphicsModule::GraphicsModule()
{

}

void GraphicsModule::begin()
{
    // Start the screen
  tft.begin();
  tft.fillScreen(BLACK);
}

void GraphicsModule::drawSplash()
{
  tft.fillRect(0,0,tft.width(), tft.height(), BLACK);

  tft.setTextColor(YELLOW);
  this->drawText(40, 24, 2, "LUKES");
  this->drawText(25, 54, 2, "INFERNO");
  this->drawText(25, 84, 2, "MACHINE");
  this->drawText(80, 120, 1, "NTU 2018");
}

void GraphicsModule::drawRunningBackground()
{
  // Clear old
  tft.fillRect(0,0, tft.width(), tft.height(), BLACK);
```

```
  tft.drawLine(3,3,tft.width() -6, 3, WHITE);
  tft.drawLine(tft.width() -6, 3, tft.width() -6, tft.height() - 6, WHITE);
  tft.drawLine(tft.width() - 6, tft.height() - 6, 3, tft.height() - 6, WHITE);
  tft.drawLine(3,tft.height() - 6, 3, 3, WHITE);

  tft.setTextColor(WHITE);
  this->drawText(20, 10, 2, "INFERNO");
  tft.drawLine(3, 25, tft.width() - 6, 25, WHITE);

  this->drawText(10, 40, 1, "Ambient(c): ");
  this->drawText(10, 50, 1, "Target(c): ");
  this->drawText(10, 60, 1, "Plate(c): ");
  this->drawText(10, 70, 1, "Mould(c): ");
  this->drawText(10, 80, 1, "Run Time: ");

  this->drawText(80, 40, 1, this->ambientTemp);
  this->drawText(80, 50, 1, this->targetTemp);
  this->drawText(80, 60, 1, this->probeTemp);
  this->drawText(80, 70, 1, this->mouldTemp);
  this->drawText(70, 80, 1, "00:00:00");
}

void GraphicsModule::setDisplayScreen(int screen)
{
  if(this->screen != screen)
  {
    // Update
    this->screen = screen;

    switch(screen)
    {
      case 0:
        // Splash
        this->drawSplash();
        break;

      case 1:
        // Main
        this->drawRunningBackground();
        break;
    }
  }
}

void GraphicsModule::drawText(int x, int y, int size, char *text)
{
    tft.setCursor(x, y);
    tft.setTextSize(size);
    tft.print(text);
}

void GraphicsModule::drawText(int x, int y, int size, float text)
{
    tft.setCursor(x, y);
    tft.setTextSize(size);
    tft.print(text);
}

void GraphicsModule::drawText(int x, int y, int size, int text)
{
    tft.setCursor(x, y);
    tft.setTextSize(size);
    tft.print(text);
}

char * TimeToString(unsigned long t)
{
 static char str[8];
 int h = t / 3600;
 t = t % 3600;
 int m = t / 60;
 int s = t % 60;
 sprintf(str, "%02d:%02d:%02d", h, m, s);
 return str;
}
```

```
void GraphicsModule::updateTemperature(float ambient, float probe, float target,
float mouldtemp)
{
  if(this->screen == 1)
  {
    // Check for changes in ambient (Reduce flicker on no change)
    if(this->ambientTemp != ambient)
    {
      // Update
      tft.setTextColor(BLACK);
      this->drawText(80, 40, 1, this->ambientTemp);

      // Write new temp
      tft.setTextColor(WHITE);
      this->ambientTemp = ambient;
      this->drawText(80, 40, 1, this->ambientTemp);
    }

    if(this->probeTemp != probe)
    {
       // Update
      tft.setTextColor(BLACK);
      this->drawText(80, 60, 1, this->probeTemp);

      // Write new temp
      tft.setTextColor(WHITE);
      this->probeTemp = probe;
      this->drawText(80, 60, 1, this->probeTemp);
    }

    if(this->targetTemp != target)
    {
       // Update
      tft.setTextColor(BLACK);
      this->drawText(80, 50, 1, this->targetTemp);

      // Write new temp
      tft.setTextColor(WHITE);
      this->targetTemp = target;
      this->drawText(80, 50, 1, this->targetTemp);
    }

    if(this->mouldTemp != mouldtemp)
    {
      // Update
      tft.setTextColor(BLACK);
      this->drawText(80, 70, 1, this->mouldTemp);

      // Write new temp
      tft.setTextColor(WHITE);
      this->mouldTemp = mouldtemp;
      this->drawText(80, 70, 1, this->mouldTemp);
    }

    tft.fillRect(70,80, (tft.width() / 2) - 12, 10, BLACK);

    char *text = TimeToString(millis() / 1000);

    this->drawText(70, 80, 1, text);

  }
  else
  {
    // Store values
    this->ambientTemp = ambient;
    this->probeTemp = probe;
    this->targetTemp = target;
    this->mouldTemp = mouldtemp;
  }
}

void GraphicsModule::updateGraphic(int graphic)
{
  switch(graphic)
  {
    case 0:
```

```
      // HEATING
      drawFlame();
      break;

     case 1:
      // Plate Off
      drawIdle();
      break;

     case 2:
      // Critical
      drawCriticalTemp();
      break;

     case 3:
      // Draw too hot
      drawTooHot();
      break;
  }
}

void GraphicsModule::drawImage(int posx, int posy, int g[][5], int width, int height)
{
  for(int x = 0; x < width; x++)
  {
    for(int y = 0; y < height; y++)
    {
      if(g[x][y] == 1)
      {
        tft.fillRect(posx + (x * 4), posy + (y * 4), 4,4, YELLOW);
      }
      if(g[x][y] == 2)
      {
        tft.fillRect(posx + (x * 4), posy + (y * 4), 4,4, RED);
      }

      if(g[x][y] == 3)
      {
        tft.fillRect(posx + (x * 4), posy + (y * 4), 4,4, WHITE);
      }

      if(g[x][y] == 4)
      {
        tft.fillRect(posx + (x * 4), posy + (y * 4), 4,4, BLUE);
      }
    }
  }
}

void GraphicsModule::drawFlame()
{
  tft.fillRect(54, 90, 20, 20, BLACK);

  int graphics[5][5];

   graphics[0][4] = 1;
      graphics[1][4] = 2;
      graphics[2][4] = 2;
      graphics[3][4] = 2;
      graphics[4][4] = 1;

      graphics[0][3] = 0;
      graphics[1][3] = 1;
      graphics[2][3] = 2;
      graphics[3][3] = 1;
      graphics[4][3] = 0;

      graphics[0][2] = 0;
      graphics[1][2] = 1;
      graphics[2][2] = 2;
      graphics[3][2] = 1;
      graphics[4][2] = 0;

      graphics[0][1] = 0;
      graphics[1][1] = 1;
      graphics[2][1] = 1;
```

```
      graphics[3][1] = 1;
      graphics[4][1] = 0;

      graphics[0][0] = 0;
      graphics[1][0] = 0;
      graphics[2][0] = 1;
      graphics[3][0] = 0;
      graphics[4][0] = 0;
  switch(this->frame)
  {
    case 0:
      break;

    case 1:
      graphics[2][0] = 0;
      graphics[3][0] = 1;
      graphics[2][2] = 1;
      break;

    case 2:
      // centre again
      break;

    case 3:
      graphics[2][0] = 0;
      graphics[1][0] = 1;
       graphics[2][2] = 1;
      break;
  }

  // Draw
  this->drawImage(54,90, graphics, 5, 5);

  this->frame++;
  if(this->frame > 3)
  {
    this->frame = 0;
  }
}

void GraphicsModule::drawIdle()
{
  tft.fillRect(54, 90, 20, 20, BLACK);

  int graphics[5][5];

   graphics[0][4] = 4;
   graphics[1][4] = 4;
   graphics[2][4] = 4;
   graphics[3][4] = 4;
   graphics[4][4] = 4;

   graphics[0][3] = 0;
   graphics[1][3] = 0;
   graphics[2][3] = 0;
   graphics[3][3] = 0;
   graphics[4][3] = 0;

   graphics[0][2] = 0;
   graphics[1][2] = 0;
   graphics[2][2] = 0;
   graphics[3][2] = 0;
   graphics[4][2] = 0;

   graphics[0][1] = 0;
   graphics[1][1] = 0;
   graphics[2][1] = 0;
   graphics[3][1] = 0;
   graphics[4][1] = 0;

   graphics[0][0] = 0;
   graphics[1][0] = 0;
   graphics[2][0] = 0;
   graphics[3][0] = 0;
   graphics[4][0] = 0;
```

```
  // Draw
  this->drawImage(54,90, graphics, 5, 5);

  this->frame++;
  if(this->frame > 3)
  {
    this->frame = 0;
  }
}

void GraphicsModule::drawTooHot()
{
  tft.fillRect(54, 90, 20, 20, BLACK);

  int graphics[5][5];

   graphics[0][4] = 2;
   graphics[1][4] = 2;
   graphics[2][4] = 2;
   graphics[3][4] = 2;
   graphics[4][4] = 2;

   graphics[0][3] = 0;
   graphics[1][3] = 0;
   graphics[2][3] = 0;
   graphics[3][3] = 0;
   graphics[4][3] = 0;

   graphics[0][2] = 0;
   graphics[1][2] = 0;
   graphics[2][2] = 0;
   graphics[3][2] = 0;
   graphics[4][2] = 0;

   graphics[0][1] = 0;
   graphics[1][1] = 0;
   graphics[2][1] = 0;
   graphics[3][1] = 0;
   graphics[4][1] = 0;

   graphics[0][0] = 0;
   graphics[1][0] = 0;
   graphics[2][0] = 0;
   graphics[3][0] = 0;
   graphics[4][0] = 0;

  // Draw
  this->drawImage(54,90, graphics, 5, 5);

  this->frame++;
  if(this->frame > 3)
  {
    this->frame = 0;
  }
}

void GraphicsModule::drawCriticalTemp()
{
  tft.fillRect(54, 90, 20, 20, BLACK);

  int graphics[5][5];

   graphics[0][4] = 2;
   graphics[1][4] = 2;
   graphics[2][4] = 2;
   graphics[3][4] = 2;
   graphics[4][4] = 2;

   graphics[0][3] = 0;
   graphics[1][3] = 0;
   graphics[2][3] = 2;
   graphics[3][3] = 0;
   graphics[4][3] = 0;

   graphics[0][2] = 0;
   graphics[1][2] = 0;
```

```
    graphics[2][2] = 0;
    graphics[3][2] = 0;
    graphics[4][2] = 0;

    graphics[0][1] = 0;
    graphics[1][1] = 0;
    graphics[2][1] = 2;
    graphics[3][1] = 0;
    graphics[4][1] = 0;

    graphics[0][0] = 0;
    graphics[1][0] = 0;
    graphics[2][0] = 2;
    graphics[3][0] = 0;
    graphics[4][0] = 0;

  // Draw
  this->drawImage(54,90, graphics, 5, 5);

  this->frame++;
  if(this->frame > 3)
  {
    this->frame = 0;
  }
}
```

Graphics.h Tab

```
#include <SPI.h>
#include <Adafruit_GFX.h>
#include <Adafruit_SSD1351.h>

// Color definitions
#define  BLACK           0x0000
#define BLUE            0x001F
#define RED             0xF800
#define GREEN           0x07E0
#define CYAN            0x07FF
#define MAGENTA         0xF81F
#define YELLOW          0xFFE0
#define WHITE           0xFFFF
#define ORANGE          0xFD20

// SCREEN
// You can use any (4 or) 5 pins
#define sclk 12
#define mosi 11
#define dc   5 //10
#define cs   9
#define rst  8

class GraphicsModule
{
  private:
    Adafruit_SSD1351 tft = Adafruit_SSD1351(cs, dc, rst);

    int screen = -1;
    void drawSplash();
    void drawRunningBackground();
    void drawText(int x, int y, int size, char *text);
    void drawText(int x, int y, int size, float text);
    void drawText(int x, int y, int size, int text);

    // Animations
    void drawFlame();
    void drawIdle();
    void drawTooHot();
    void drawCriticalTemp();

    void drawImage(int posx, int posy, int g[][5], int width, int height);
    float ambientTemp;
    float probeTemp;
    float targetTemp;
```

```
    float mouldTemp;

    int frame;

  public:
    GraphicsModule();
    void begin();
    void setDisplayScreen(int screen);
    void updateTemperature(float ambient, float probe, float target, float
mouldtemp);
    void updateGraphic(int graphic);
};
```

High_Temp.h Tab

```
/*
  High_Temp.h

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  Loovee
  2013-4-14

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  License along with this library; if not, write to the Free Software
  Foundation, Inc., 51 Franklin St, Fifth Floor, Boston, MA  02110-1301  USA
*/
#ifndef __HIGH_TEMP_H__
#define __HIGH_TEMP_H__

class HighTemp{

public:

    HighTemp(int _pinTmp, int _pinThmc);

    float getRoomTmp();                       //
    float getThmc();

    void begin();


private:

    int pinRoomTmp;                           // pin of temperature sensor
    int pinThmc;                              // pin of thermocouple

    float tempRoom;                           // room temperature
    float tempThmc;                           // thermocouple temperature

public:

    int getAnalog(int pin);
    float K_VtoT(float mV);                   // K type thermocouple, mv->oC
    float getThmcVol();                       // get voltage of thmc in mV
};


#endif
```

High_Temp.cpp Tab

```
/*
  High_Temp.cpp

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```

```
  Loovee
  2013-4-14

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*/

#include <Arduino.h>
#include "High_Temp.h"


const float VOL_OFFSET = 350;                       // offset voltage, mv
const float AMP_AV     = 54.16;                     // Av of amplifier


const float Var_VtoT_K[3][10] =
{
    {0, 2.5173462e1, -1.1662878, -1.0833638, -8.9773540/1e1, -3.7342377/1e1,
    -8.6632643/1e2, -1.0450598/1e2, -5.1920577/1e4},
    {0, 2.508355e1, 7.860106/1e2, -2.503131/1e1, 8.315270/1e2,
    -1.228034/1e2, 9.804036/1e4, -4.413030/1e5, 1.057734/1e6, -1.052755/1e8},
    {-1.318058e2, 4.830222e1, -1.646031, 5.464731/1e2, -9.650715/1e4,
    8.802193/1e6, -3.110810/1e8}
};


HighTemp::HighTemp(int _pinTmp, int _pinThmc)
{

    pinRoomTmp = _pinTmp;
    pinThmc    = _pinThmc;


}

void HighTemp::begin()
{

    tempRoom   = getRoomTmp();

    Serial.print("tempRoom = ");
    Serial.println(tempRoom);

    delay(10);
    Serial.print("pinRoomTmp = ");Serial.println(pinRoomTmp);

    delay(10);
    Serial.print("pinThmc = ");Serial.println(pinThmc);
}

float HighTemp::getThmc()
{
    float vol  = getThmcVol();

    tempThmc = K_VtoT(vol) + tempRoom;

    return tempThmc;
}


int HighTemp::getAnalog(int pin)
{
    long sum = 0;

    for(int i=0; i<32; i++)
```

```
    {
        sum += analogRead(pin);
    }

    return ((sum>>5));                                              // 3.3V supply
}


float HighTemp::getRoomTmp()
{
    int a = getAnalog(pinRoomTmp)*50/33;                                    // 3.3V
supply
    float resistance=(float)(1023-a)*10000/a; // get the resistance of the sensor;
    float temperature=1/(log(resistance/10000)/3975+1/298.15)-273.15; // convert to
temperature via datasheet ;


   // Serial.print("a = ");Serial.println(a);
    //Serial.print("resistance = ");Serial.println(resistance);
   // Serial.print("temperature = ");Serial.println(temperature);

    tempRoom = temperature;
    return temperature;
}


float HighTemp::getThmcVol()                                                // get
voltage of thmc in mV
{
    float vout = (float)getAnalog(pinThmc)/1023.0*5.0*1000;
    float vin  = (vout - VOL_OFFSET)/AMP_AV;
    return (vin);
}


float HighTemp::K_VtoT(float mV)
{
    int i = 0;
    float value = 0;

    if(mV >= -6.478 && mV < 0)
    {
        value = Var_VtoT_K[0][8];

        for(i = 8; i >0; i--)
        value = mV * value + Var_VtoT_K[0][i-1];
    }
    else if(mV >= 0 && mV < 20.644)
    {
        value = Var_VtoT_K[1][9];

        for(i = 9; i >0; i--)
        {
            value = mV * value + Var_VtoT_K[1][i-1];
        }
    }
    else if(mV >= 20.644 && mV <= 54.900)
    {
        value = Var_VtoT_K[2][6];

        for(i = 6; i >0; i--)
        value = mV * value + Var_VtoT_K[2][i-1];
    }

    return value;
}
```

APPENDIX P – SRTS PDS & CRITERIA EXCLUSION

PDS Exclusion Criteria & Rationale

Shipping: Due to the bespoke nature of the testing system, initially only one testing system will be manufactured, therefore there is no need to consider shipping within the PDS. However, one of the main aims of the system is to ensure it has an element of portability, therefore the transportation of the system will need to be considered during the design process to ensure the system is semi collapsible.

Company Constraints: Within the context of this PhD there are no company constraints as the SRTS will be designed for assessing and testing the shape retention capabilities of bougie introducers. The product is not intended for commercialization as the SRTS will initially be a one-off product that is being designed for a specific application.

Manufacturing Facility: As the PDS generated focuses on the design and modelling of the SRTS within the context of this PhD thesis, the system will not be professionally manufactured until post PhD, if this is deemed necessary. As such, manufacturing restrictions such as size limitations will be placed into suitable categories and highlighted for design integration accordingly. Manufacturing restrictions in relation to the modelling of the system will be in the context of the workshop facilities and technical support staff skills available within the School of Architecture, Design and The Built Environment at Nottingham Trent University.

Politics: Within the context of a PDS, the politics descriptor is utilised to list or discuss political factors such as regulatory body regulations, European and Worldwide regulatory approval processes and governmental legislation requirements placed on products. As the SRTS is to be designed as bespoke testing system, this will have to take into consideration recommendations made by the MHRA and other regulatory bodies. Data collected by the SRTS may force the manufacturers to attempt to improve the physical properties of their products if recommendations are made in relation to the device with the optimum shape retention characteristics.

Packaging: The SRTS will not be sold as a commercial product and therefore packaging the SRTS for sale will not be required. The SRTS may be shipped if required to test laboratories however, the proposed semi detachable and flat pack design will ensure that the shipping of the system will be achievable.

Patents: After completing an initial patent search with regards to protected designs for testing systems relating to the assessment of the physical properties of bougie introducers, the results from the patent search provided no existing systems that complete this assessment task. The patent search provided an extensive number of active and expired patents on bougie introducer devices and devices that assess the clinical situation of an airway, but no systems are testing devices that assess the physical properties of bougie introducers.

Documentation: When designing and manufacturing a product for sale the production of a set of operative documentation is produced covering factors such as the operation of use instructions are required to operate the product, legal and medical legislation information and disposal information and recycling instructions. However, as the SRTS is to be design for use solely by the Medical Design Research Group, no documentation for operation is required due as training can be provided by the designers and software developers involved in the design and manufacture of the device.

Ergonomics: There are no ergonomic considerations required for the design and manufacture of the SRTS; the system is being produced based around the dimension variables set out by the camera module and the bougie introducers.

Aesthetics: As the testing system to be produced will be solely be for the purpose of testing bougie introducers, the aesthetic of the product is not a focus, whereas the function of the testing system is essential; as such aesthetic considerations are not factored into the PDS.

Product Cost: The product has no target cost as it is not expected to be sold for profit or reproduced in large quantities. The development of the system should be produced at the lowest achievable cost with a development budget set for £400 for materials; components recycled from testing systems and machinery will be utilised where possible to ensure the system is produced at the lowest achievable cost.

Full SRTS PDS

Time Scale

- The design and manufacture of the SRTS is to take place during the months of June through to September 2017.
- The SRTS must be operational and available for testing from October 2017 onwards.

- Dissemination of the data collected by the SRTS will commence from December 2017 in the form of academic publications and documentation.

Customer

The customer targeted is anaesthetic product manufacturers, specifically those who supply bougie introducers and stylets. However, anaesthetists will still be informed by the product as this would help inform anaesthetists of comparative device performance, providing evidence for device selection and purchase and generating evidence for societies and academics to inform their guidelines for best practice.

Size/Dimensions

The dimensions of the SRTS are defined by two key factors; the dimension of bougie introducers and the technical specification of the camera system used to track the bougie movements.

The dimensions required for consideration for the bougie introducers are as follows:

- Bougie's length vary between 500mm – 750mm in length.
- Bougie's vary at the distal end; straight and coude tips are available.
- The bougie shaft diameter vary from 1mm - 5mm in diameter depending on application for adults, children or babies.

The dimensions of the SRTS frame must consider the following technical specification points for the Intel® RealSense™ Camera (SR300) which will be integrated for use:

- RGB Camera (Pixel): 1080p at 30 FPS
- Depth Camera (Pixel): 640 x480 resolution at 60 FPS
- RGB Colour Field Of View: 77°x43°x70°
- Infrared Field Of View: 70°x46°x59°
- Effective Range: 0.4m to 2.8m

Disposal

- The design of the testing system must ensure that the product can be dismantled and allow the necessary recyclable parts to individually be separated and recycled.
- Manufactured elements of the SRTS must be compliant with the Restriction of Hazardous Substance and Waste Electrical & Electronic Equipment directives.
- When disposing of the device the following eco-constraints must be considered:
    - Individually mark each individual component so that the user knows which components can be recycled.
    - Identify the components via the relevant logo to ensure the user recycles the medical aspects utilising the medical waste disposal units in hospitals.
    - Suitably mark for disposal the sharp and metal components which should be placed in sharps boxes once used.

Market Constraints

The UK market for bougie introducers is restricted due to the available market share and the suppliers approved by the NHS Supply Chain. The following manufacturers are available within the NHS supply chain and supply products to NHS trusts:

- Armstrong Medical Ltd, Coleraine, Northern Ireland, UK.
- Cook Group Incorporate©, Indiana, USA.
- Eschmann© Holdings Ltd, West Sussex, UK & Smiths Medical International Ltd, Kent, UK.
- Fannin UK Ltd, Swadlincote, UK.
- Intersurgical©, Berkshire, UK
- Insight Medical, Tetbury, UK.
- Proact Medical, Corby, UK.
- P3 Medical, Bristol, UK.

- Marshall Airway Products Ltd, Radstock, UK.
- Smiths Medical International Ltd, Kent, UK.
- SunMed, Grand Rapids, Michigan, Usa.
- Verathon Inc./ Roper Technologies, Seattle, Washington, USA.

The SRTS will assess products sold by the above manufacturers and provide statistically relevant data through academic dissemination to the customers of the products. By assessing the physical properties of bougie introducers, this many force manufacturers to alter their product range and their products construction to compete with competitor products who offer greater physical properties that are desirable by the market sector.

Weight

- The weight of the overall product must not exceed the 5-10kg range to ensure an unassembled SRTS can be transported.

Competition

After an initial patent search with regards to protected designs for testing systems relating to the assessment of the physical properties of bougie introducers, the results from the patent search provided no existing systems that complete this task; therefore, there are no competitors within the design and manufacture of testing systems for bougie introducers. However, there are a considerable number of products that rival each other for market share. Within the UK the product range is reviewed extensively within literature with a significant body of work completed on comparable and bespoke studies which inform regulation and professional body recommendations and literature; however, many of these tests have failed to consider key design considerations such as the repeatability, accuracy and calibration of the equipment selected for assessing bougie introducers. By creating a comparative assessment system to analyse the physical properties of bougie introducers this could potentially signal changes in the requirements manufacturers set for their products. The products available within the UK market as highlighted by The Difficult Airway Society (2018) include the following:

- Aintree Intubation Catheter
- Arndt Airway Exchange Catheter Set

- Cook Airway Exchange Catheter (Soft tip)
- Cook Airway Exchange Catheter
- Eschmann Tracheal Tube Introducer (Gum elastic Bougie)
- Frova Single Use Introducer
- Gliderite Stylet
- Marshall Single-Use Bougie Straight tip)
- Marshall Vented Intubating introducer
- Portex Intubation Stylet
- Portex Single-Use Bougie (Straight tip)
- Portex Single-Use Bougie (angled tip)
- Pro-Breathe Single-Use introducer

Outside of the UK there are a sizeable number of products available on the market, many of these devices if they can be sourced can also be assessed and compared to the equipment available in the UK; thus, highlighting the device that is the gold standard based on shape retention properties.

Quality & Reliability

- The designed system must not deform the bougies past their values of operational use. Deforming the bougie past the deformation point will result in false results being presented.
- The system must be capable or repeating the same operative control movement for over 1000 repetitions, thus ensuring full data capture.

Environment

The testing environment for the SRTS will be the Future Factory Research and Consultancy Centre based in the Maudslay Building, Nottingham Trent University, Nottingham, UK.

The following environmental conditions must be factored into the design of the SRTS:

- Ambient Temperature (°C)
- Lighting Conditions (lx)
- Background Image (Available in FOV of 3D Depth Camera)

Testing

- Regulate and standardise the forces/pressures applied to shape the bougie. (This will vary based on bend location and distance from the bougie tip).
- The SRTS must be capable of conducting repeatable tests for several types of bougies/introducers yet still conform to standardised positional tracking.
- Accurately record and post-process the measurement of the bougie bend angle and orientation.
- The SRTS must be adaptable to allow the real-time data acquisition software to accurately map bougie movement and collect accurate and statistically relevant data regardless of the equipment assessed.
- Post processing software required to track data points and monitor bougie shaping and loss of shape to defining outputs including distance moved, angle variation, starting angle and speed.

Safety

- The testing system must have suitable operative control to ensure the power can be cut from the system when required in case on an emergency.
- All moving components must be safe enough to be manually operated if required to allow the manual reset of the system.
- The device must conform to the necessary medical safety guidelines and regulations; consideration must be made to Medical Device Directive 2007/47/EEC.
- The materials used for construction must ensure no risk of harm can occur should the device fail.

Legislation

1. The SRTS must be capable of producing quantifiable data that can inform the Difficult Airway Society (DAS) Guidelines and the DAS ADEPT Guidelines (Pandit et al., 2011).

2. The system must be capable of contributing information to the DAS guidelines for management of unanticipated difficult intubation 2015, if data collected informs positive changes for best practice.

3. The SRTS should conform to the testing requirements set out by the MHRA Medicines and Medical Device Regulations.

Maintenance

- The system must enable the end user to easily control the device without risk. All surfaces must be clear of sharp edges that can cause harm.

- The linear actuators must be interchangeable should any of the control system elements fail.

- The camera must be easily attached and detached to allow for suitable cleaning procedures to be conduct in accordance with the manufacturer recommendations.

- The electronics controls must be easily accessible to ensure components such as fuses and capacitors that have a limited lifespan can be replaced when required.

- The bougie gripper i.e. chuck holder, must be lubricated periodically to ensure manual operative control can be achieved.

- The brake system to be designed must ensure a suitable locking mechanism can be replaced when operative control fails.

- Wiring within the system control box should use male and female connectors where possible to allow for interchangeable components to be used ensuring components can be replaced when required.

- Any lighting control included within the device must be easily replaced when inevitable lighting source failure occurs after repeated use.

Materials

- The SRTS frame must be constructed of a suitable material to allow for device structural integrity.
- Materials utilised within the SRTS system must be capable of being manufactured both using traditional and automated control methods.
- Rubber feet must be integrated into the system frame and base to ensure the SRTS remains grounded at all times.
- 3D printed parts manufactured for the system should be constructed out of suitable standard and engineering photopolymer resin.

Standards

The developed system must be fully compliant with the following standards if the system is to be manufactured for resale:

- Medical Device Directive (2007/47/EEC).
- ISO 13485;2003 – Medical Device Quality Systems.
- EN 60601 – Electrical Safety.
- IEC 60601-1-2 – EMC Emissions.
- IEC 61000-4-1 – EMC Immunity.
- EN 980 – Use of Symbols on Medical Labelling.
- ISO 14971 – Medical Device Risk Management.

For the product to be sanctioned for sale within the UK market, the product must be compliant with the following directives:

- 2002/96/EC – Waste Electrical & Electronic Equipment (WEEE).
- 2011/65/EU – Restriction of Hazardous Substances (RoHS).

- (EC)1907/2006 – Regulation - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

It is however proposed the system would not be made available for resale due to the limited market potential.

Installation

- The SRTS is required to be semi-permanent, however collapsible for transportation if required.
- Interchangeable grids are to be inserted into the designated slot; however, they must have a standardised origin and grid spacing to allow confirmation of calibration. Coloured grids will be required based on the variance of bougie colours.
- The lighting system must be installed to standardise the ambient light. This system should also aim to reduce the shadowing recorded on the interchangeable grids.
- The SRTS will require various power sources dependant on the equipment utilised; PC/Laptop (Mains Plug), Intel RealSense 3D Depth Camera (USB Powered), Linear Actuator (12V DC), Geared DC Motor (12V DC) and Brake System (5V DC Solenoid).

Life In Service

- The system must have a life in service of a minimum of two years to allow for data collection and assessment of device both during and post PhD.

Performance

The following performance design requirements have been defined as the minimum implementation recommendation when designing and manufacturing the SRTS:

- Adaptable system, calibrated to collect reliable and accurate testing data.
- Interchangeable components standardising system setup regardless of the equipment's diameter and length.
- Repeatable testing system with pre-configured variables adaptable for the bespoke product range.

- Recordable accurate camera tracking with interchangeable angle measurement grids to record different measures over clinically relevant ranges.
- Accurate camera/video tracking with fixed frame rates and appropriate field of view (FOV) to track bend angles, tip movements, speed of movement, and shape retention.
- LED lighting to reduce the effects of ambient light.
- Logic-based programming system ensuring that the testing system is reset to a home position, providing a protocol of standard movements.
- Post-processing capabilities to re-analyse data and adjust into alternative formats.

Quantity

- One SRTS will be manufactured for the purpose of the PhD Research.
- The manufacture of the SRTS can be scaled up if a market for the product is defined where low volumes of the product can be sold.

Product Life Span

- The minimum product life span is 1 year.
- The maximum life span of the product is 2 years before components will require maintenance, servicing or replacing.
- The 3D camera technology integrated into the SRTS (Intel® RealSense™ Camera (SR300)) will need updating when superior camera technology becomes available.
- The product will require decommissioning within a 5-10-year time scale as new innovative technology supersede the system capabilities.

APPENDIX Q – SRTS FINAL ARDUINO PROGRAM CODE

The heat chamber and the supporting program was developed in collaboration with Mr Paul Watts (Software Developer – Medical Design Research Group, Nottingham Trent University, UK). The developed code has been designed either use standard linear acutators controlled by easydriver boards, or Actuonic linear acutators powered by the LAC board. Either control mechanism can be lined in or out for control depending on the electronics wiring setup.

LUKE_RIG_NEW Tab

```
#include "BasicStepperDriver.h"
#include "Servo.h"

#define IDLE_BACK 0
#define MOVE_IN 1
#define IDLE_FRONT 2
#define LA_ENGAGING 3
#define MOVE_OUT 4
#define LA_RESET 5

#ifdef REFRESH_INTERVAL
  #undef REFRESH_INTERVAL
  #define REFRESH_INTERVAL 10000
#endif

// Carrier Detection Switches - PINS Relate To The Pins On The Arduino Mega
int BACK_SWITCH_PIN = 12;
int FRONT_SWITCH_PIN = 13;

// Linear Actuators
int LA_LEFT_BUTTON_PIN = 8;
int LA_RIGHT_BUTTON_PIN = 7;
int LA_ALL_BUTTON_PIN = 4;
int LA_ANALOG_PIN = 11;

int SOLONOID_PIN = 2;
int MASTER_BUTTON_PIN = 30;

int MOTOR_PIN1 = 10;
int MOTOR_PIN2 = 9;

int _currentstate = 0;
int _actuatorindex = 0;

int _lawaiting = 0;
int _accumlsteps = 0;
int _accumrsteps = 0;
bool _laset = false;

int stepDelay = 10000;

#define LA_WAIT_TIME 5000; // Wait/Delay Time
#define LA_LEFT_MOVE 1000 // 200 * 5 = 5mm - Length Of Time Left Linear Acutators Are
Switched On For
#define LA_RIGHT_MOVE 1000 // 200 * 5 = 5mm - Length Of Time Right Linear Acutators
Are Switched On For

#define LA_LED_LEFT 52 // LED Activation PIN Number On Arduino Mega
#define LA_LED_RIGHT 50 // LED Activation PIN Number On Arduino Mega
#define LA_LED_BOTH 48 // LED Activation PIN Number On Arduino Mega

// 2-wire basic config, microstepping is hardwired on the driver
//BasicStepperDriver rightactuator(200, 53, 5);
//BasicStepperDriver leftactuator(200, 11, 6);
Servo LAServo;

void setup() {
  // put your setup code here, to run once:
```

```
  _currentstate = 0;

  pinMode(BACK_SWITCH_PIN, INPUT);
  pinMode(FRONT_SWITCH_PIN, INPUT);
  pinMode(MASTER_BUTTON_PIN, INPUT);

  pinMode(MOTOR_PIN1, OUTPUT);
  pinMode(MOTOR_PIN2, OUTPUT);

  pinMode(SOLONOID_PIN, OUTPUT);

  Serial.begin(9600);
  Serial.println("Starting...");

  pinMode(LA_LED_LEFT, OUTPUT);
  pinMode(LA_LED_RIGHT, OUTPUT);
  pinMode(LA_LED_BOTH, OUTPUT);

  // New Linear Actuator
  //pinMode(LA_ANALOG_PIN, OUTPUT);
  LAServo.attach(LA_ANALOG_PIN);
  LAServo.writeMicroseconds(1000);
  delay(stepDelay);

  Serial.println("ready to go!");
}

void loop() {
  // put your main code here, to run repeatedly:

  switch(_currentstate)
  {
    case IDLE_BACK:
      // Check Switch To Begin
      IdleBack();
      break;

    case MOVE_IN:
      MoveIn();
      break;

    case IDLE_FRONT:
      IdleFront();
      break;

    case MOVE_OUT:
      MoveOut();
      break;
  }

  // Repeat every 50 ms
  delay(1);
}

void MoveOut()
{
  int pin = digitalRead(BACK_SWITCH_PIN);
  if(pin == 1)
  {
    _currentstate = LA_RESET;
    Serial.println("Back Stop Reached resetting actuators");

    digitalWrite(MOTOR_PIN1, 0);
    digitalWrite(MOTOR_PIN2, 0);
    // Engage the Brake
    digitalWrite(SOLONOID_PIN, 0);

     // Reverse
     LAServo.writeMicroseconds(1000);
     delay(stepDelay);

     //analogWrite(LA_ANALOG_PIN, 0);

     // Wait to prevent collisions
     //delay(2000);
```

```
      digitalWrite(LA_LED_LEFT, 0); // Switch Off LED
      digitalWrite(LA_LED_RIGHT, 0); // Switch Off LED
      digitalWrite(LA_LED_BOTH, 0); // Switch Off LED

      // Reset the reset value
      _accumlsteps = 0;
      _accumrsteps = 0;

      _laset = false;

     _currentstate = IDLE_BACK;
     Serial.println("System Reset");

  }
}

void IdleFront()
{
  int pin;

  if(!_laset)
  {
    // Check the switches
    pin = digitalRead(LA_LEFT_BUTTON_PIN);
    if(pin == 1)
    {

           digitalWrite(LA_LED_LEFT, 1);

           // Extend the new LA
          // double volt = 180 * 0.8; // 0.2 = 20%, 0.3 = 30% etc., i.e 100mm /100 *
20 = 20%
          // Serial.print("Volts: ");
          // Serial.println(volt);

          // New Linear Actuator engage
          //analogWrite(LA_ANALOG_PIN, (int)volt);
           LAServo.writeMicroseconds(1150);// 2000 max 1000 min
          // Wait to prevent collisions
          Serial.println("starting extension");
          delay(stepDelay);
          Serial.println("done extension");

          Serial.println("Engaging Linear Actuator");

          _laset = true;

          // Start Both
          Serial.println("Actuators Positioned, Going Idle");
          _currentstate = IDLE_FRONT;

    }
    else
    {
      pin = digitalRead(LA_RIGHT_BUTTON_PIN);
      if(pin == 1)
      {
          digitalWrite(LA_LED_RIGHT, 1);

           // Extend the new LA
          // double volt = 180 * 0.8; // 0.2 = 20%, 0.3 = 30% etc., i.e 100mm /100 *
20 = 20%
          // Serial.print("Volts: ");
          // Serial.println(volt);

          // New Linear Actuator engage
          //analogWrite(LA_ANALOG_PIN, (int)volt);
           LAServo.writeMicroseconds(1250);// 2000 max 1000 min
          // Wait to prevent collisions
          Serial.println("starting extension");
          delay(stepDelay);
          Serial.println("done extension");

          Serial.println("Engaging Linear Actuator");

          _laset = true;
```

```
          // Start Both
          Serial.println("Actuators Positioned, Going Idle");
          _currentstate = IDLE_FRONT;

        }
        else
        {
          pin = digitalRead(LA_ALL_BUTTON_PIN);
          if(pin == 1)
          {
            digitalWrite(LA_LED_BOTH, 1);

             // Extend the new LA
            // double volt = 180 * 0.8; // 0.2 = 20%, 0.3 = 30% etc., i.e 100mm /100 *
20 = 20%
            // Serial.print("Volts: ");
            // Serial.println(volt);

            // New Linear Actuator engage
            //analogWrite(LA_ANALOG_PIN, (int)volt);
             LAServo.writeMicroseconds(2000);// 2000 max 1000 min
            // Wait to prevent collisions
            Serial.println("starting extension");
            delay(stepDelay);
            Serial.println("done extension");

            Serial.println("Engaging Linear Actuator");

            _laset = true;

            // Start Both
            Serial.println("Actuators Positioned, Going Idle");
            _currentstate = IDLE_FRONT;
          }
        }
      }
    }

    pin = digitalRead(MASTER_BUTTON_PIN);
    if(pin == 1)
    {
      _currentstate = MOVE_OUT;

      // Release the brake
      digitalWrite(SOLONOID_PIN, 1);
      delay(2000);
      Serial.println("Moving Back");


      analogWrite(MOTOR_PIN1, 0);
      analogWrite(MOTOR_PIN2, 64);
    }
}

void IdleBack()
{
  // Check Start Button
  int start = digitalRead(MASTER_BUTTON_PIN);

  if(start == 1)
  {
    _currentstate = MOVE_IN;

    Serial.println("MOVING IN");
  }
  else
  {
    // Engage the brake
    digitalWrite(SOLONOID_PIN, 0);

    // Stop the motor
    analogWrite(MOTOR_PIN1, 0);
    analogWrite(MOTOR_PIN2, 0);
  }
}
```

```
void MoveIn()
{
  // Run Motor Forwards
  int input = digitalRead(FRONT_SWITCH_PIN);

  if(input == 1)
  {
    // STOP, FRONT IDLE
    _currentstate = IDLE_FRONT;

    // Stop Motor
    analogWrite(MOTOR_PIN1, 0);
    analogWrite(MOTOR_PIN2, 0);

    // Engage Solonoid (Brake On)
    digitalWrite(SOLONOID_PIN, 0);

    Serial.println("Front Detected, FRONT IDLE");
  }
  else
  {
    // Ensure Brake (Solonoid) is dissengadged
    digitalWrite(SOLONOID_PIN, 1);

    // RUN MOTOR FORWARD
    analogWrite(MOTOR_PIN1, 64);
    analogWrite(MOTOR_PIN2, 0);
  }
}
```

BasicStepperDriver.cpp Tab

```
/*
 * Generic Stepper Motor Driver Driver
 * Indexer mode only.

 * Copyright (C)2015-2017 Laurentiu Badea
 *
 * This file may be redistributed under the terms of the MIT license.
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LICENSE.
 *
 * Linear speed profile calculations based on
 * - Generating stepper-motor speed profiles in real time - David Austin, 2004
 * - Atmel AVR446: Linear speed control of stepper motor, 2006
 */
#include "BasicStepperDriver.h"

/*
 * Basic connection: only DIR, STEP are connected.
 * Microstepping controls should be hardwired.
 */
BasicStepperDriver::BasicStepperDriver(short steps, short dir_pin, short step_pin)
:motor_steps(steps), dir_pin(dir_pin), step_pin(step_pin)
{}

BasicStepperDriver::BasicStepperDriver(short steps, short dir_pin, short step_pin,
short enable_pin)
:motor_steps(steps), dir_pin(dir_pin), step_pin(step_pin), enable_pin(enable_pin)
{}

/*
 * Initialize pins, calculate timings etc
 */
void BasicStepperDriver::begin(short rpm, short microsteps){
    pinMode(dir_pin, OUTPUT);
    digitalWrite(dir_pin, HIGH);

    pinMode(step_pin, OUTPUT);
    digitalWrite(step_pin, LOW);

    if IS_CONNECTED(enable_pin){
        pinMode(enable_pin, OUTPUT);
        digitalWrite(enable_pin, HIGH); // disable
```

```
    }

    this->rpm = rpm;
    setMicrostep(microsteps);

    enable();
}

/*
 * Set target motor RPM (1-200 is a reasonable range)
 */
void BasicStepperDriver::setRPM(short rpm){
    if (this->rpm == 0){        // begin() has not been called (old 1.0 code)
        begin(rpm, microsteps);
    }
    this->rpm = rpm;
}

/*
 * Set stepping mode (1:microsteps)
 * Allowed ranges for BasicStepperDriver are 1:1 to 1:128
 */
short BasicStepperDriver::setMicrostep(short microsteps){
    for (short ms=1; ms <= getMaxMicrostep(); ms<<=1){
        if (microsteps == ms){
            this->microsteps = microsteps;
            break;
        }
    }
    return this->microsteps;
}

/*
 * Set speed profile - CONSTANT_SPEED, LINEAR_SPEED (accelerated)
 * accel and decel are given in [full steps/s^2]
 */
void BasicStepperDriver::setSpeedProfile(Mode mode, short accel, short decel){
    this->mode = mode;
    this->accel = accel;
    this->decel = decel;
}

/*
 * Move the motor a given number of steps.
 * positive to move forward, negative to reverse
 */
void BasicStepperDriver::move(long steps){
    long next_event;
    startMove(steps);
    do {
        next_event = nextAction();
        microWaitUntil(micros() + next_event);
    } while (next_event);
}
/*
 * Move the motor a given number of degrees (1-360)
 */
void BasicStepperDriver::rotate(long deg){
    move(calcStepsForRotation(deg));
}
/*
 * Move the motor with sub-degree precision.
 * Note that using this function even once will add 1K to your program size
 * due to inclusion of float support.
 */
void BasicStepperDriver::rotate(double deg){
    move(calcStepsForRotation(deg));
}

/*
 * Set up a new move or alter an active move (calculate and save the parameters)
 */
void BasicStepperDriver::startMove(long steps){
    long speed;
    if (steps_remaining){
        alterMove(steps);
```

```
    } else {
        // set up new move
        dir_state = (steps >= 0) ? HIGH : LOW;
        steps_remaining = abs(steps);
        step_count = 0;
        switch (mode){
        case LINEAR_SPEED:
            // speed is in [steps/s]
            speed = rpm * motor_steps / 60;
            // how many steps from 0 to target rpm
            steps_to_cruise = speed * speed * microsteps / (2 * accel);
            // how many steps are needed from target rpm to a full stop
            steps_to_brake = steps_to_cruise * accel / decel;
            if (steps_remaining < steps_to_cruise + steps_to_brake){
                // cannot reach max speed, will need to brake early
                steps_to_cruise = steps_remaining * decel / (accel + decel);
                steps_to_brake = steps_remaining - steps_to_cruise;
            }
            // Initial pulse (c0) including error correction factor 0.676 [us]
            step_pulse = (1e+6)*0.676*sqrt(2.0f/(accel*microsteps));
            break;

        case CONSTANT_SPEED:
        default:
            step_pulse = STEP_PULSE(rpm, motor_steps, microsteps);
            steps_to_cruise = 0;
            steps_to_brake = 0;
        }
    }
}
/*
 * Alter a running move by adding/removing steps
 * FIXME: This is a naive implementation and it only works well in CRUISING state
 */
void BasicStepperDriver::alterMove(long steps){
    switch (getCurrentState()){
    case ACCELERATING: // this also works but will keep the original speed target
    case CRUISING:
        if (steps >= 0){
            steps_remaining += steps;
        } else {
            steps_remaining = max(steps_to_brake, steps_remaining+steps);
        };
        break;
    case DECELERATING:
        // would need to start accelerating again -- NOT IMPLEMENTED
        break;
    case STOPPED:
        startMove(steps);
        break;
    }
}
/*
 * Brake early.
 */
void BasicStepperDriver::startBrake(void){
    switch (getCurrentState()){
    case CRUISING:  // this applies to both CONSTANT_SPEED and LINEAR_SPEED modes
        steps_remaining = steps_to_brake;
        break;

    case ACCELERATING:
        steps_remaining = step_count * accel / decel;
        break;

    default:
        break; // nothing to do if already stopped or braking
    }
}
/*
 * Return calculated time to complete the given move
 */
long BasicStepperDriver::getTimeForMove(long steps){
    long t;
    switch (mode){
        case LINEAR_SPEED:
```

```
            startMove(steps);
            t = sqrt(2 * steps_to_cruise / accel) +
                (steps_remaining - steps_to_cruise - steps_to_brake) *
STEP_PULSE(rpm, motor_steps, microsteps) +
                sqrt(2 * steps_to_brake / decel);
            break;
        case CONSTANT_SPEED:
        default:
            t = STEP_PULSE(rpm, motor_steps, microsteps);
    }
    return t;
}
/*
 * Move the motor an integer number of degrees (360 = full rotation)
 * This has poor precision for small amounts, since step is usually 1.8deg
 */
void BasicStepperDriver::startRotate(long deg){
    startMove(calcStepsForRotation(deg));
}
/*
 * Move the motor with sub-degree precision.
 * Note that calling this function will increase program size substantially
 * due to inclusion of float support.
 */
void BasicStepperDriver::startRotate(double deg){
    startMove(calcStepsForRotation(deg));
}

/*
 * calculate the interval til the next pulse
 */
void BasicStepperDriver::calcStepPulse(void){
    // remainder to be fed into successive steps to increase accuracy (Atmel DOC8017)
    static long rest;

    if (steps_remaining <= 0){  // this should not happen, but avoids strange
calculations
        return;
    }

    steps_remaining--;
    step_count++;

    if (mode == LINEAR_SPEED){
        switch (getCurrentState()){
        case ACCELERATING:
            if (step_count == 1){     // first step, initialize rest
                rest = 0;
            }
            step_pulse = step_pulse - (2*step_pulse+rest)/(4*step_count+1);
            rest = (step_count < steps_to_cruise) ? (2*step_pulse+rest) %
(4*step_count+1) : 0;
            break;

        case DECELERATING:
            step_pulse = step_pulse - (2*step_pulse+rest)/(-4*steps_remaining+1);
            rest = (2*step_pulse+rest) % (-4*steps_remaining+1);
            break;

        default:
            break; // no speed changes
        }
    }
}
/*
 * Toggle step and return time until next change is needed (micros)
 */
long BasicStepperDriver::nextAction(void){
    if (steps_remaining > 0){
        /*
         * DIR pin is sampled on rising STEP edge, so it is set first
         */
        digitalWrite(dir_pin, dir_state);
        digitalWrite(step_pin, HIGH);
        unsigned m = micros();
```

```
        long pulse = step_pulse; // save value because calcStepPulse() will overwrite
it
        calcStepPulse();
        m = micros() - m;
        // We should pull HIGH for 1-2us (step_high_min)
        if (m < step_high_min){ // fast MCPU or CONSTANT_SPEED
            DELAY_MICROS(step_high_min-m);
            m = step_high_min;
        };
        digitalWrite(step_pin, LOW);
        // account for calcStepPulse() execution time
        return pulse - m;
    } else {
        return 0; // end of move
    }
}
enum BasicStepperDriver::State BasicStepperDriver::getCurrentState(void){
    enum State state;
    if (steps_remaining <= 0){
        state = STOPPED;
    } else {
        if (steps_remaining <= steps_to_brake){
            state = DECELERATING;
        } else if (step_count <= steps_to_cruise){
            state = ACCELERATING;
        } else {
            state = CRUISING;
        }
    }
    return state;
}

/*
 * Enable/Disable the motor by setting a digital flag
 */
void BasicStepperDriver::enable(void){
    if IS_CONNECTED(enable_pin){
        digitalWrite(enable_pin, LOW);
    }
}

void BasicStepperDriver::disable(void){
    if IS_CONNECTED(enable_pin){
        digitalWrite(enable_pin, HIGH);
    }
}

short BasicStepperDriver::getMaxMicrostep(){
    return BasicStepperDriver::MAX_MICROSTEP;
}
```

BasicStepperDriver.h Tab

```
/*
 * Generic Stepper Motor Driver Driver
 * Indexer mode only.
 *
 * Copyright (C)2015-2017 Laurentiu Badea
 *
 * This file may be redistributed under the terms of the MIT license.
 * A copy of this license has been included with this distribution in the file
LICENSE.
 */
#ifndef STEPPER_DRIVER_BASE_H
#define STEPPER_DRIVER_BASE_H
#include <Arduino.h>

// used internally by the library to mark unconnected pins
#define PIN_UNCONNECTED -1
#define IS_CONNECTED(pin) (pin != PIN_UNCONNECTED)

/*
 * calculate the step pulse in microseconds for a given rpm value.
 * 60[s/min] * 1000000[us/s] / microsteps / steps / rpm
 */
```

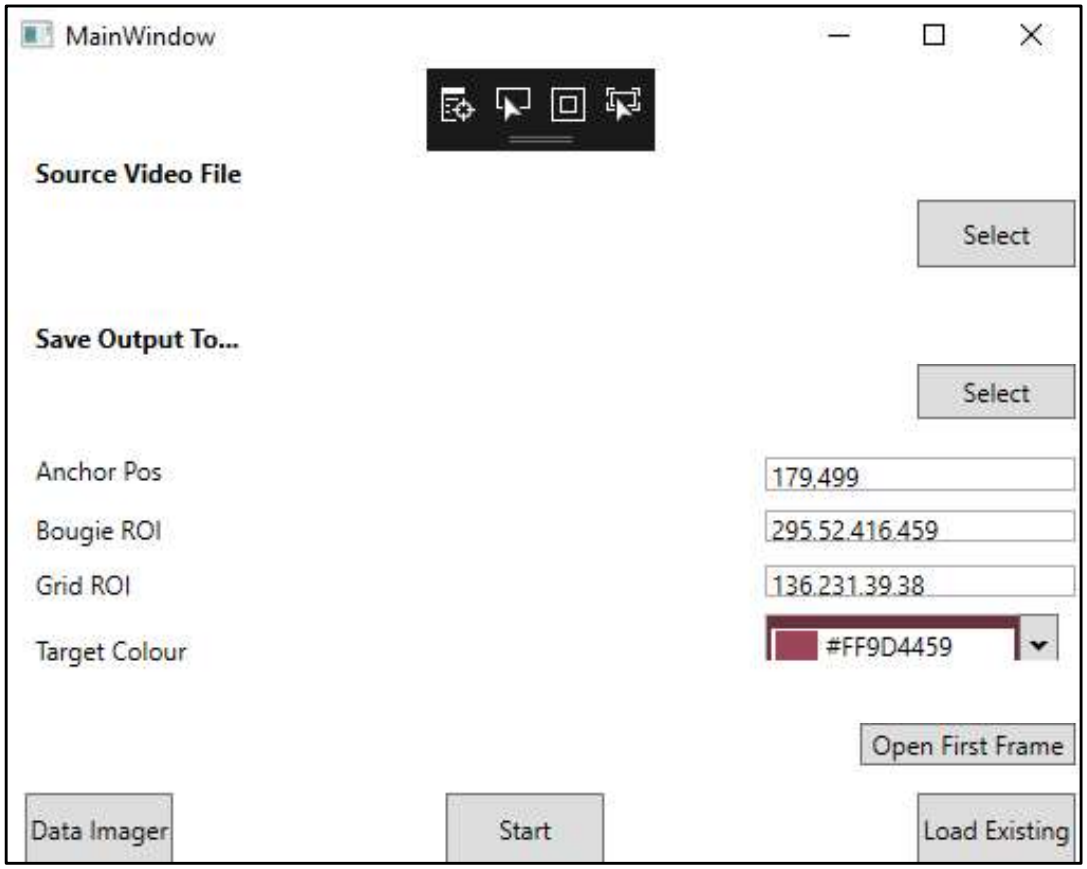
```
#define STEP_PULSE(steps, microsteps, rpm) (60*1000000L/steps/microsteps/rpm)

// don't call yield if we have a wait shorter than this
#define MIN_YIELD_MICROS 25
inline void microWaitUntil(unsigned long target_micros){
    if (target_micros - micros() > MIN_YIELD_MICROS){
        yield();
    }
    while (micros() < target_micros);
}
#define DELAY_MICROS(us) microWaitUntil(micros() + us)

/*
 * Basic Stepper Driver class.
 * Microstepping level should be externally controlled or hardwired.
 */
class BasicStepperDriver {
public:
    enum Mode {CONSTANT_SPEED, LINEAR_SPEED};
    enum State {STOPPED, ACCELERATING, CRUISING, DECELERATING};

protected:
    /*
     * Motor Configuration
     */
    short motor_steps;           // motor steps per revolution (usually 200)
    short accel = 1000;     // maximum acceleration [steps/s^2]
    short decel = 1000;     // maximum deceleration [steps/s^2]

    /*
     * Driver Configuration
     */
    short dir_pin;
    short step_pin;
    short enable_pin = PIN_UNCONNECTED;
    // Get max microsteps supported by the device
    virtual short getMaxMicrostep();
    // current microstep level (1,2,4,8,...), must be < getMaxMicrostep()
    short microsteps = 1;
    // tWH(STEP) pulse duration, STEP high, min value (us)
    static const int step_high_min = 1;
    // tWL(STEP) pulse duration, STEP low, min value (us)
    static const int step_low_min = 1;
    // tWAKE wakeup time, nSLEEP inactive to STEP (us)
    static const int wakeup_time = 0;

    short rpm = 0;

    /*
     * Movement state
     */
    Mode mode = CONSTANT_SPEED;
    long step_count;        // current position
    long steps_remaining;   // to complete the current move (absolute value)
    long steps_to_cruise;   // steps to reach cruising (max) rpm
    long steps_to_brake;    // steps needed to come to a full stop
    long step_pulse;        // step pulse duration (microseconds)

    // DIR pin state
    short dir_state;

    void calcStepPulse(void);

    // this is internal because one can call the start methods while CRUISING to get
here
    void alterMove(long steps);

private:
    // microstep range (1, 16, 32 etc)
    static const short MAX_MICROSTEP = 128;

public:
    /*
     * Basic connection: DIR, STEP are connected.
     */
    BasicStepperDriver(short steps, short dir_pin, short step_pin);
```

```
    BasicStepperDriver(short steps, short dir_pin, short step_pin, short enable_pin);
    /*
     * Initialize pins, calculate timings etc
     */
    void begin(short rpm=60, short microsteps=1);
    /*
     * Set current microstep level, 1=full speed, 32=fine microstepping
     * Returns new level or previous level if value out of range
     */
    virtual short setMicrostep(short microsteps);
    /*
     * Set target motor RPM (1-200 is a reasonable range)
     */
    void setRPM(short rpm);
    short getRPM(void){
        return rpm;
    };
    short getCurrentRPM(void){
        return (short)(60*1000000L / step_pulse / microsteps / motor_steps);
    }
    /*
     * Set speed profile - CONSTANT_SPEED, LINEAR_SPEED (accelerated)
     * accel and decel are given in [full steps/s^2]
     */
    void setSpeedProfile(Mode mode, short accel=1000, short decel=1000);
    /*
     * Move the motor a given number of steps.
     * positive to move forward, negative to reverse
     */
    void move(long steps);
    /*
     * Rotate the motor a given number of degrees (1-360)
     */
    void rotate(long deg);
    inline void rotate(int deg){
        rotate((long)deg);
    };
    /*
     * Rotate using a float or double for increased movement precision.
     */
    void rotate(double deg);
    /*
     * Turn off/on motor to allow the motor to be moved by hand/hold the position in
place
     */
    void enable(void);
    void disable(void);
    /*
     * Methods for non-blocking mode.
     * They use more code but allow doing other operations between impulses.
     * The flow has two parts - start/initiate followed by looping with nextAction.
     * See AccelTest example.
     */
    /*
     * Initiate a move over known distance (calculate and save the parameters)
     * Pick just one based on move type and distance type.
     */
    void startMove(long steps);
    inline void startRotate(int deg){
        startRotate((long)deg);
    };
    void startRotate(long deg);
    void startRotate(double deg);
    /*
     * Toggle step and return time until next change is needed (micros)
     */
    long nextAction(void);
    /*
     * Optionally, call this to begin braking (and then stop) early
     */
    void startBrake(void);
    /*
     * State querying
     */
    enum State getCurrentState(void);
```

```
    /*
     * Return calculated time to complete the given move
     */
    long getTimeForMove(long steps);
    /*
     * Calculate steps needed to rotate requested angle, given in degrees
     */
    long calcStepsForRotation(long deg){
        return deg * motor_steps * (long)microsteps / 360;
    }
    long calcStepsForRotation(double deg){
        return deg * motor_steps * microsteps / 360;
    }
};
#endif // STEPPER_DRIVER_BASE_H
```

APPENDIX R – SRTS IMAGE PROCESSING APPLICATION

Please find attached a CD copy of the SRTS image processing application developed in conjunction with Mr Paul Watts (Software Developer, Medical Design Research Group, Nottingham Trent University, UK).



CD 03

APPENDIX S – SRTS FULL DATA COLLECTION

Appendix 1 - Shaping Of Bougies - 15mm Linear Actuator Extension

	10CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
SUNMED 1	154.61	64.61	60.34	40.17	24.44	-62.2%	3.01
SUNMED 2	155.22	65.22	59.91	40.21	25.01	-61.7%	2.99
SUNMED 3	156.17	66.17	60.82	40.58	25.59	-61.3%	3.04
SUNMED 4	157.38	67.38	61.34	41.20	26.18	-61.1%	3.06
SUNMED 5	157.95	67.95	59.51	39.83	28.12	-58.6%	2.97
PORTEX 1	163.38	73.38	78.72	54.95	18.43	-74.9%	3.93
PORTEX 2	164.78	74.78	79.68	55.49	19.29	-74.2%	3.98
PORTEX 3	164.78	74.78	78.27	54.49	20.29	-72.9%	3.91
PORTEX 4	164.89	74.89	76.85	53.44	21.45	-71.4%	3.84
PORTEX 5	164.89	74.89	75.44	52.42	22.47	-70.0%	3.77
INTERGUIDE 1	162.75	72.75	70.25	51.76	20.99	-71.1%	3.51
INTERGUIDE 2	162.75	72.75	68.39	50.25	22.50	-69.1%	3.42
INTERGUIDE 3	162.75	72.75	66.99	49.18	23.57	-67.6%	3.35
INTERGUIDE 4	163.34	73.34	65.66	47.84	25.50	-65.2%	3.27
INTERGUIDE 5	162.30	72.30	63.72	46.60	25.70	-64.5%	3.18
PROBREATHE 1	164.18	74.18	68.88	52.48	21.70	-70.7%	3.44
PROBREATHE 2	163.98	73.98	66.99	50.28	23.70	-68.0%	3.35
PROBREATHE 3	164.57	74.57	65.60	49.11	25.46	-65.9%	3.29
PROBREATHE 4	164.82	74.82	66.51	49.36	25.46	-66.0%	3.31
PROBREATHE 5	164.45	74.45	65.16	48.99	25.46	-65.8%	3.27
FROVA 1	156.60	66.60	59.39	45.81	20.79	-68.8%	2.97
FROVA 2	156.60	66.60	56.57	43.60	23.00	-65.5%	2.83
FROVA 3	156.13	66.13	54.69	42.03	24.10	-63.6%	2.65
FROVA 4	156.60	66.60	55.17	42.49	24.11	-63.8%	2.76
FROVA 5	156.60	66.60	55.17	42.49	24.11	-63.8%	2.78
STEERABLEBOUGIE 1	154.30	64.30	43.21	31.40	32.90	-48.8%	2.16
STEERABLEBOUGIE 2	157.19	67.19	43.33	31.58	35.61	-47.0%	2.17
STEERABLEBOUGIE 3	156.11	66.11	42.68	31.05	35.06	-47.0%	2.13
STEERABLEBOUGIE 4	156.48	66.48	40.68	29.52	36.96	-44.4%	2.03
STEERABLEBOUGIE 5	156.73	66.73	39.46	29.38	37.35	-44.0%	1.97

	10CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
GEB 1	169.90	79.90	75.20	57.10	22.80	-71.5%	3.75
GEB 2	170.38	80.38	74.86	56.67	23.71	-70.5%	3.74
GEB 3	170.15	80.15	74.26	55.34	24.81	-69.0%	3.71
GEB 4	169.99	79.99	72.98	54.74	25.25	-68.4%	3.65
GEB 5	169.43	79.43	72.04	54.19	25.24	-68.2%	3.60
FLEXGUIDE 1	164.70	74.70	74.99	55.37	19.33	-74.1%	3.75
FLEXGUIDE 2	164.94	74.94	75.44	55.17	19.77	-73.6%	3.77
FLEXGUIDE 3	164.82	74.82	74.08	54.16	20.66	-72.4%	3.70
FLEXGUIDE 4	164.82	74.82	74.08	54.16	20.66	-72.4%	3.70
FLEXGUIDE 5	164.82	74.82	73.19	53.29	21.53	-71.2%	3.66
P3-1	163.85	73.85	49.06	36.59	37.26	-49.5%	2.45
P3-2	163.85	73.85	46.17	34.57	39.28	-46.8%	2.28
P3-3	162.21	72.21	42.19	32.54	39.67	-45.1%	2.21
P3-4	164.32	74.32	44.56	33.18	41.14	-44.6%	2.23
P3-5	164.05	74.05	44.58	33.24	40.81	-44.9%	2.18

	20CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
SUNMED 1	152.11	62.11	112.38	42.22	19.89	-68.0%	5.61
SUNMED 2	153.65	63.65	112.71	42.08	21.57	-66.1%	5.60
SUNMED 3	154.20	64.20	108.92	40.81	23.39	-63.6%	5.44
SUNMED 4	153.65	63.65	109.40	40.90	22.75	-64.3%	5.47
SUNMED 5	153.98	63.98	109.43	41.04	22.94	-64.1%	5.47
PORTEX 1	154.93	64.93	135.22	50.04	14.89	-77.1%	6.76
PORTEX 2	155.35	65.35	133.27	49.18	16.17	-75.3%	6.65
PORTEX 3	156.20	66.20	129.33	47.70	18.50	-72.1%	6.42
PORTEX 4	156.95	66.95	126.85	46.71	20.24	-69.8%	6.31
PORTEX 5	156.95	66.95	130.19	47.99	18.96	-71.7%	6.51
INTERGUIDE 1	156.18	66.18	129.70	47.08	19.10	-71.1%	6.48
INTERGUIDE 2	155.96	65.96	121.63	44.03	21.93	-66.8%	6.05
INTERGUIDE 3	157.41	67.41	121.15	43.69	23.72	-64.8%	6.06
INTERGUIDE 4	155.75	65.75	115.96	41.81	23.94	-63.6%	5.80
INTERGUIDE 5	156.49	66.49	117.38	42.34	24.15	-63.7%	5.87
PROBREATHE 1	155.45	65.45	135.80	50.20	15.25	-76.7%	6.79
PROBREATHE 2	154.49	64.49	129.14	47.50	16.99	-73.7%	6.45
PROBREATHE 3	156.96	66.96	121.30	44.18	22.78	-66.0%	6.05
PROBREATHE 4	154.79	64.79	124.74	45.39	19.40	-70.1%	6.22
PROBREATHE 5	155.32	65.32	124.67	45.38	19.94	-69.5%	6.14
FROVA 1	152.46	62.46	110.94	40.98	21.48	-65.6%	5.55
FROVA 2	152.46	62.46	108.03	39.77	22.69	-63.7%	5.40
FROVA 3	151.92	61.92	106.24	39.27	22.65	-63.4%	5.31
FROVA 4	151.92	61.92	106.24	39.27	22.65	-63.4%	5.31
FROVA 5	151.92	61.92	106.19	39.14	22.78	-63.2%	5.31
STEERABLEBOUGIE 1	151.74	61.74	90.52	32.35	29.39	-52.4%	4.53
STEERABLEBOUGIE 2	151.74	61.74	85.35	30.54	31.20	-49.5%	4.20
STEERABLEBOUGIE 3	152.06	62.06	82.60	29.42	32.64	-47.4%	4.13
STEERABLEBOUGIE 4	152.37	62.37	82.16	29.47	32.90	-47.3%	4.11
STEERABLEBOUGIE 5	152.37	62.37	81.21	29.14	33.23	-46.7%	4.05

	20CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
GEB 1	160.21	70.21	133.42	48.72	21.49	-69.4%	6.67
GEB 2	158.94	68.94	127.75	46.75	22.19	-67.8%	6.44
GEB 3	158.86	68.86	126.85	46.19	22.67	-67.1%	6.35
GEB 4	160.21	70.21	127.82	46.62	23.59	-66.4%	6.38
GEB 5	158.63	68.63	124.00	45.25	23.38	-65.9%	6.19
FLEXGUIDE 1	156.58	66.58	141.87	51.81	14.77	-77.8%	7.09
FLEXGUIDE 2	155.63	65.63	138.62	50.40	15.23	-76.8%	6.91
FLEXGUIDE 3	156.58	66.58	138.04	50.48	16.10	-75.8%	6.88
FLEXGUIDE 4	156.80	66.80	136.97	50.01	16.79	-74.9%	6.85
FLEXGUIDE 5	156.15	66.15	137.10	49.89	16.26	-75.4%	6.81
P3-1	150.94	60.94	96.20	35.46	25.48	-58.2%	4.81
P3-2	152.02	62.02	87.21	32.19	29.83	-51.9%	4.36
P3-3	152.02	62.02	82.50	30.44	31.58	-49.1%	4.14
P3-4	152.25	62.25	82.04	30.04	32.21	-48.3%	4.10
P3-5	152.24	62.24	78.83	28.83	33.41	-46.3%	3.94

	30CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
SUNMED 1	149.61	59.61	175.87	40.27	19.34	-67.6%	8.79
SUNMED 2	149.61	59.61	156.91	38.50	21.11	-64.6%	7.85
SUNMED 3	149.33	59.33	154.16	37.81	21.52	-63.7%	7.70
SUNMED 4	149.61	59.61	146.77	35.91	23.70	-60.2%	7.33
SUNMED 5	149.47	59.47	154.02	37.71	21.76	-63.4%	7.69
PORTEX 1	152.38	62.38	183.64	41.31	21.07	-66.2%	9.17
PORTEX 2	151.52	61.52	159.96	38.56	22.96	-62.7%	8.00
PORTEX 3	151.66	61.66	150.41	36.23	25.43	-58.8%	7.46
PORTEX 4	154.50	64.50	159.84	38.64	25.86	-59.9%	7.99
PORTEX 5	154.35	64.35	154.20	37.23	27.12	-57.9%	7.71
INTERGUIDE 1	150.54	60.54	148.58	35.60	24.94	-58.8%	7.43
INTERGUIDE 2	152.03	62.03	156.60	37.44	24.59	-60.4%	7.83
INTERGUIDE 3	150.99	60.99	138.62	33.02	27.97	-54.1%	6.91
INTERGUIDE 4	150.71	60.71	139.12	33.10	27.61	-54.5%	6.96
INTERGUIDE 5	149.00	59.00	123.52	29.42	29.58	-49.9%	5.86
PROBREATHE 1	146.91	56.91	158.80	38.03	18.88	-66.8%	7.91
PROBREATHE 2	148.06	58.06	174.80	39.33	18.73	-67.7%	8.74
PROBREATHE 3	147.34	57.34	158.80	38.07	19.27	-66.4%	7.94
PROBREATHE 4	147.77	57.77	142.46	33.96	23.81	-58.8%	7.41
PROBREATHE 5	146.83	56.83	148.46	35.56	21.27	-62.6%	7.42
FROVA 1	149.66	59.66	156.34	37.83	21.83	-63.4%	7.81
FROVA 2	149.66	59.66	152.47	36.84	22.82	-61.7%	7.62
FROVA 3	149.74	59.74	162.35	36.57	23.17	-61.2%	8.07
FROVA 4	150.01	60.01	159.76	36.07	23.94	-60.1%	7.98
FROVA 5	150.01	60.01	159.23	35.93	24.08	-59.9%	7.95
STEERABLEBOUGIE 1	146.04	56.04	113.69	25.19	30.85	-45.0%	5.62
STEERABLEBOUGIE 2	146.57	56.57	107.15	23.61	32.96	-41.7%	5.38
STEERABLEBOUGIE 3	146.83	56.83	106.63	23.32	33.51	-41.0%	5.34
STEERABLEBOUGIE 4	146.87	56.87	107.07	23.75	33.12	-41.8%	5.36
STEERABLEBOUGIE 5	147.34	57.34	109.09	24.05	33.29	-41.9%	5.46

	30CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
GEB 1	157.06	67.06	183.89	41.13	25.93	-61.3%	9.19
GEB 2	156.92	66.92	178.86	39.94	26.98	-59.7%	8.75
GEB 3	158.37	68.37	167.69	40.34	28.03	-59.0%	8.32
GEB 4	157.99	67.99	177.01	39.67	28.32	-58.3%	8.85
GEB 5	157.84	67.84	178.07	39.75	28.09	-58.6%	8.90
FLEXGUIDE 1	151.26	61.26	194.90	46.74	14.52	-76.3%	9.74
FLEXGUIDE 2	152.03	62.03	193.25	46.35	15.68	-74.7%	9.65
FLEXGUIDE 3	152.52	62.52	191.63	46.00	16.52	-73.6%	9.57
FLEXGUIDE 4	150.83	60.83	185.75	44.62	16.21	-73.4%	9.28
FLEXGUIDE 5	151.96	61.96	188.89	45.40	16.56	-73.3%	9.44
P3-1	148.16	58.16	119.77	28.89	29.27	-49.7%	5.98
P3-2	148.35	58.35	115.66	26.12	32.23	-44.8%	5.78
P3-3	148.51	58.51	103.26	24.83	33.68	-42.4%	5.13
P3-4	148.60	58.60	102.78	24.69	33.91	-42.1%	5.13
P3-5	148.21	58.21	102.78	24.79	33.42	-42.6%	5.13

	40CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
SUNMED 1	145.15	55.15	216.57	36.61	18.54	-66.4%	10.82
SUNMED 2	146.67	56.67	214.64	36.37	20.30	-64.2%	10.72
SUNMED 3	147.27	57.27	214.46	36.33	20.94	-63.4%	10.71
SUNMED 4	147.60	57.60	211.81	35.87	21.73	-62.3%	10.58
SUNMED 5	147.80	57.80	210.11	35.59	22.21	-61.6%	10.50
PORTEX 1	147.78	57.78	204.94	34.20	23.58	-59.2%	10.24
PORTEX 2	148.63	58.63	186.42	31.07	27.56	-53.0%	9.31
PORTEX 3	148.26	58.26	181.87	30.24	28.02	-51.9%	9.08
PORTEX 4	148.26	58.26	162.13	26.92	31.34	-46.2%	8.10
PORTEX 5	149.37	59.37	170.21	28.33	31.04	-47.7%	8.46
INTERGUIDE 1	148.67	58.67	218.79	36.33	22.34	-61.9%	10.93
INTERGUIDE 2	149.35	59.35	207.28	34.35	25.00	-57.9%	10.35
INTERGUIDE 3	148.09	58.09	189.45	30.80	27.29	-53.0%	9.31
INTERGUIDE 4	148.55	58.55	188.94	31.26	27.29	-53.4%	9.44
INTERGUIDE 5	148.15	58.15	185.96	30.71	27.44	-52.8%	9.29
PROBREATHE 1	143.92	53.92	181.63	30.13	23.79	-55.9%	9.07
PROBREATHE 2	144.28	54.28	167.98	27.82	26.46	-51.3%	8.39
PROBREATHE 3	145.23	55.23	165.81	27.52	27.71	-49.8%	8.28
PROBREATHE 4	144.11	54.11	143.99	23.80	30.31	-44.0%	7.19
PROBREATHE 5	144.80	54.80	152.61	25.31	29.49	-46.2%	7.62
FROVA 1	144.69	54.69	214.44	36.04	18.65	-65.9%	10.71
FROVA 2	145.42	55.42	209.61	35.20	20.22	-63.5%	10.47
FROVA 3	145.42	55.42	202.13	33.86	21.56	-61.1%	10.13
FROVA 4	145.23	55.23	204.92	34.20	21.03	-61.9%	10.24
FROVA 5	145.68	55.68	204.14	34.23	21.45	-61.5%	10.20
STEERABLEBOUGIE 1	145.76	55.76	185.39	30.55	25.21	-54.8%	9.26
STEERABLEBOUGIE 2	147.96	57.96	159.61	26.35	31.61	-45.5%	7.97
STEERABLEBOUGIE 3	147.96	57.96	157.09	25.93	32.03	-44.7%	7.85
STEERABLEBOUGIE 4	148.35	58.35	148.54	24.47	33.88	-41.9%	7.42
STEERABLEBOUGIE 5	148.43	58.43	145.10	23.96	34.47	-41.0%	7.25

	40CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
GEB 1	149.90	59.90	197.02	32.87	27.03	-54.9%	9.84
GEB 2	150.63	60.63	189.41	31.60	29.03	-52.1%	9.46
GEB 3	148.69	58.69	182.88	30.45	28.24	-51.9%	9.13
GEB 4	149.64	59.64	177.28	29.50	30.14	-49.5%	8.86
GEB 5	148.16	58.16	159.60	26.50	31.66	-45.6%	7.93
FLEXGUIDE 1	149.89	59.89	278.86	46.50	13.39	-77.6%	13.93
FLEXGUIDE 2	150.15	60.15	268.63	44.80	15.35	-74.5%	13.42
FLEXGUIDE 3	149.07	59.07	272.28	45.63	13.44	-77.2%	13.60
FLEXGUIDE 4	148.53	58.53	266.85	44.42	14.11	-75.9%	13.33
FLEXGUIDE 5	149.31	59.31	269.58	44.94	14.37	-75.8%	13.47
P3-1	142.53	52.53	199.14	33.29	19.24	-63.4%	9.96
P3-2	142.56	52.56	177.81	29.67	22.89	-56.4%	8.88
P3-3	144.02	54.02	168.74	28.04	25.98	-51.9%	8.44
P3-4	142.39	52.39	165.99	27.73	24.66	-52.9%	8.29
P3-5	144.40	54.40	161.34	26.85	27.55	-49.4%	8.07

10CM - ANGLE VARIATION									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	40.17	40.21	40.58	41.20	39.83	40.398	0.521	1.290	0.233
PORTEX	54.95	55.49	54.49	53.44	52.42	54.158	1.230	2.270	0.550
INTERGUIDE	51.76	50.25	49.18	47.84	46.60	49.126	2.015	4.101	0.901
PROBREATHE	52.48	50.28	49.11	49.36	48.99	50.044	1.453	2.903	0.650
FROVA	45.81	43.60	42.03	42.49	42.49	43.284	1.526	3.525	0.682
STEERABLE BOUGIE	31.40	31.58	31.05	29.52	29.38	30.586	1.056	3.451	0.472
GEB	57.10	56.67	55.34	54.74	54.19	55.608	1.244	2.237	0.556
FLEXGUIDE	55.37	55.17	54.16	54.16	53.29	54.430	0.848	1.558	0.379
P3	36.59	34.57	32.54	33.18	33.24	34.024	1.613	4.742	0.722
10CM - SPEED (MM/S)									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	3.01	2.99	3.04	3.06	2.97	3.014	0.036	1.210	0.016
PORTEX	3.93	3.98	3.91	3.84	3.77	3.886	0.082	2.111	0.037
INTERGUIDE	3.51	3.42	3.35	3.27	3.18	3.346	0.128	3.831	0.057
PROBREATHE	3.44	3.35	3.29	3.31	3.27	3.332	0.067	2.018	0.030
FROVA	2.97	2.83	2.65	2.76	2.78	2.798	0.116	4.163	0.052
STEERABLE BOUGIE	2.16	2.17	2.13	2.03	1.97	2.092	0.088	4.200	0.039
GEB	3.75	3.74	3.71	3.65	3.60	3.690	0.064	1.725	0.028
FLEXGUIDE	3.75	3.77	3.70	3.70	3.66	3.716	0.044	1.182	0.020
P3	2.45	2.28	2.21	2.23	2.18	2.270	0.107	4.714	0.048
10CM - % SHAPE RETENTION LOSS									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	62.2%	61.7%	61.3%	61.1%	58.6%	60.98%	0.014	2.288	0.006
PORTEX	74.9%	74.2%	72.9%	71.4%	70.0%	72.68%	0.020	2.761	0.009
INTERGUIDE	71.1%	69.1%	67.6%	65.2%	64.5%	67.50%	0.027	4.050	0.012
PROBREATHE	70.7%	68.0%	65.9%	66.0%	65.8%	67.28%	0.021	3.148	0.009
FROVA	68.8%	65.5%	63.6%	63.8%	63.8%	65.10%	0.022	3.390	0.010
STEERABLE BOUGIE	48.8%	47.0%	47.0%	44.4%	44.0%	46.24%	0.020	4.340	0.009
GEB	71.5%	70.5%	69.0%	68.4%	68.2%	69.52%	0.014	2.053	0.006
FLEXGUIDE	74.1%	73.6%	72.4%	72.4%	71.2%	72.74%	0.011	1.566	0.005
P3	49.5%	46.8%	45.1%	44.6%	44.9%	46.18%	0.020	4.426	0.009

20CM - ANGLE VARIATION									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	42.22	42.08	40.81	40.90	41.04	41.410	0.682	1.648	0.305
PORTEX	50.04	49.18	47.70	46.71	47.99	48.324	1.302	2.695	0.582
INTERGUIDE	47.08	44.03	43.69	41.81	42.34	43.790	2.056	4.696	0.920
PROBREATHE	50.20	47.50	44.18	45.39	45.38	46.530	2.375	5.103	1.062
FROVA	40.98	39.77	39.27	39.27	39.14	39.686	0.763	1.921	0.341
STEERABLE BOUGIE	32.35	30.54	29.42	29.42	29.47	30.240	1.273	4.209	0.569
GEB	48.72	46.75	46.19	46.62	45.25	46.706	1.270	2.719	0.568
FLEXGUIDE	51.81	50.40	50.48	50.01	49.89	50.518	0.764	1.513	0.342
P3	35.46	32.19	30.44	30.04	28.83	31.392	2.573	8.197	1.151
20CM - SPEED (MM/S)									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	5.61	5.60	5.44	5.47	5.47	5.518	0.080	1.458	0.036
PORTEX	6.76	6.65	6.42	6.31	6.51	6.530	0.179	2.742	0.080
INTERGUIDE	6.48	6.05	6.06	5.80	5.87	6.052	0.265	4.371	0.118
PROBREATHE	6.49	6.45	6.05	6.22	6.14	6.270	0.193	3.074	0.086
FROVA	5.55	5.40	5.31	5.31	5.31	5.376	0.105	1.949	0.047
STEERABLE BOUGIE	4.53	4.20	4.13	4.11	4.05	4.204	0.190	4.518	0.085
GEB	6.67	6.44	6.35	6.38	6.19	6.406	0.174	2.719	0.078
FLEXGUIDE	7.09	6.91	6.88	6.85	6.81	6.908	0.108	1.567	0.048
P3	4.81	4.36	4.14	4.10	3.94	4.270	0.337	7.893	0.151
20CM - % SHAPE RETENTION LOSS									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	66.0%	66.1%	63.6%	64.3%	64.1%	64.82%	0.012	1.777	0.005
PORTEX	77.1%	75.3%	72.1%	69.8%	71.7%	73.20%	0.029	4.020	0.013
INTERGUIDE	71.1%	66.8%	64.8%	63.6%	63.7%	66.00%	0.031	4.740	0.014
PROBREATHE	76.7%	73.7%	66.0%	70.1%	69.5%	71.20%	0.041	5.776	0.018
FROVA	65.6%	63.7%	63.4%	63.4%	63.2%	63.86%	0.010	1.549	0.004
STEERABLE BOUGIE	52.4%	49.5%	47.4%	47.3%	46.7%	48.66%	0.023	4.817	0.010
GEB	69.4%	67.8%	67.1%	66.4%	65.9%	67.32%	0.014	2.030	0.006
FLEXGUIDE	77.8%	76.8%	75.8%	74.9%	75.4%	76.14%	0.012	1.525	0.005
P3	58.2%	51.9%	49.1%	48.3%	46.3%	50.76%	0.046	9.100	0.021

30CM - ANGLE VARIATION									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	40.27	38.50	37.81	35.91	37.71	38.040	1.572	4.132	0.703
PORTEX	41.31	38.56	36.23	38.64	37.23	38.394	1.912	4.981	0.855
INTERGUIDE	35.60	37.44	33.02	33.10	29.42	33.716	3.031	8.988	1.355
PROBREATHE	38.03	39.33	38.07	33.96	35.56	36.990	2.177	5.884	0.973
FROVA	37.83	36.84	36.57	36.07	35.93	36.648	0.757	2.064	0.338
STEERABLE BOUGIE	25.19	23.61	23.63	23.75	24.05	24.046	0.663	2.758	0.297
GEB	41.13	39.94	40.34	39.67	39.75	40.166	0.598	1.488	0.267
FLEXGUIDE	46.74	46.35	46.00	44.62	45.40	45.822	0.833	1.818	0.373
P3	28.89	26.12	24.83	24.69	24.79	25.864	1.790	6.923	0.801
30CM - SPEED (MM/S)									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	8.79	7.85	7.70	7.33	7.69	7.872	0.548	6.957	0.245
PORTEX	9.17	8.00	7.46	7.99	7.71	8.066	0.656	8.137	0.294
INTERGUIDE	7.43	7.83	6.91	6.96	5.86	6.998	0.739	10.557	0.330
PROBREATHE	7.91	8.74	7.94	7.41	7.42	7.884	0.542	6.879	0.243
FROVA	7.81	7.62	8.07	7.98	7.95	7.886	0.176	2.227	0.079
STEERABLE BOUGIE	5.62	5.38	5.34	5.36	5.46	5.432	0.115	2.109	0.051
GEB	9.19	8.75	8.32	8.85	8.90	8.802	0.315	3.581	0.141
FLEXGUIDE	9.74	9.65	9.57	9.28	9.44	9.536	0.181	1.894	0.081
P3	5.98	5.78	5.13	5.13	5.13	5.430	0.417	7.676	0.186
30CM - % SHAPE RETENTION LOSS									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	67.6%	64.6%	63.7%	60.2%	63.4%	63.90%	0.027	4.152	0.012
PORTEX	66.2%	62.7%	58.8%	59.9%	57.9%	61.10%	0.034	5.522	0.015
INTERGUIDE	58.8%	60.4%	54.1%	54.5%	49.9%	55.54%	0.042	7.490	0.019
PROBREATHE	66.8%	67.7%	66.4%	58.8%	62.6%	64.46%	0.037	5.765	0.017
FROVA	63.4%	61.7%	61.2%	60.1%	59.9%	61.26%	0.014	2.304	0.006
STEERABLE BOUGIE	45.0%	41.7%	41.0%	41.8%	41.9%	42.28%	0.016	3.692	0.007
GEB	61.3%	59.7%	59.0%	58.3%	58.6%	59.38%	0.012	2.012	0.005
FLEXGUIDE	76.3%	74.7%	73.6%	73.4%	73.3%	74.26%	0.013	1.710	0.006
P3	49.7%	44.8%	42.4%	42.1%	42.6%	44.32%	0.032	7.202	0.014

40CM - ANGLE VARIATION									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	36.61	36.37	36.33	35.87	35.59	36.154	0.414	1.144	0.185
PORTEX	34.20	31.07	30.24	26.92	28.33	30.152	2.784	9.233	1.245
INTERGUIDE	36.33	34.35	30.80	31.26	30.71	32.690	2.527	7.730	1.130
PROBREATHE	30.13	27.82	27.52	23.80	25.31	26.916	2.439	9.063	1.091
FROVA	36.04	35.20	33.86	34.30	34.23	34.726	0.884	2.547	0.396
STEERABLE BOUGIE	30.55	26.35	25.93	24.47	23.96	26.252	2.599	9.899	1.162
GEB	32.87	31.60	30.45	29.50	26.50	30.184	2.415	8.001	1.080
FLEXGUIDE	46.50	44.80	45.63	44.42	44.94	45.258	0.821	1.813	0.367
P3	33.29	29.67	28.04	27.73	26.85	29.116	2.547	8.747	1.139
40CM - SPEED (MM/S)									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	10.82	10.72	10.71	10.58	10.50	10.666	0.126	1.181	0.056
PORTEX	10.24	9.31	9.08	8.10	8.46	9.038	0.827	9.148	0.370
INTERGUIDE	10.93	10.35	9.31	9.44	9.29	9.864	0.740	7.499	0.331
PROBREATHE	9.07	8.39	8.28	7.19	7.62	8.110	0.727	8.967	0.325
FROVA	10.71	10.47	10.13	10.24	10.20	10.350	0.238	2.302	0.107
STEERABLE BOUGIE	9.26	7.97	7.85	7.42	7.25	7.950	0.790	9.939	0.353
GEB	9.84	9.46	9.13	8.86	7.93	9.044	0.723	7.990	0.323
FLEXGUIDE	13.93	13.42	13.60	13.33	13.47	13.550	0.234	1.725	0.105
P3	9.96	8.88	8.44	8.29	8.07	8.728	0.750	8.591	0.335
40CM - % SHAPE RETENTION LOSS									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	66.4%	64.2%	63.4%	62.3%	61.6%	63.58%	0.019	2.935	0.008
PORTEX	59.2%	53.0%	51.9%	46.2%	47.7%	51.60%	0.051	9.890	0.023
INTERGUIDE	61.9%	57.9%	53.0%	53.4%	52.8%	55.80%	0.040	7.181	0.018
PROBREATHE	55.9%	51.3%	49.8%	44.0%	46.2%	49.44%	0.046	9.347	0.021
FROVA	65.9%	63.5%	61.1%	61.9%	61.5%	62.78%	0.020	3.134	0.009
STEERABLE BOUGIE	54.8%	45.5%	44.7%	41.9%	41.0%	45.58%	0.055	12.032	0.025
GEB	54.9%	52.1%	51.9%	49.5%	45.6%	50.80%	0.035	6.850	0.016
FLEXGUIDE	77.6%	74.5%	77.2%	75.9%	75.8%	76.20%	0.012	1.621	0.006
P3	63.4%	56.4%	51.9%	52.9%	49.4%	54.80%	0.054	9.899	0.024

Appendix 2 - Shaping Of Bougies – 7.5mm Linear Actuator Extension

	10CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
SUNMED 1	134.67	44.67	44.24	30.21	14.46	-67.6%	2.21
SUNMED 2	135.00	45.00	44.48	30.42	14.58	-67.6%	2.21
SUNMED 3	135.64	45.64	44.74	30.43	15.21	-66.7%	2.24
SUNMED 4	138.62	48.62	34.57	26.27	22.35	-54.0%	1.73
SUNMED 5	135.62	45.62	45.39	30.73	14.89	-67.4%	2.27
PORTEX 1	137.94	47.94	54.51	35.56	12.38	-74.2%	2.73
PORTEX 2	137.94	47.94	51.33	33.57	14.37	-70.0%	2.57
PORTEX 3	137.94	47.94	50.72	33.13	14.81	-69.1%	2.54
PORTEX 4	138.59	48.59	49.14	32.21	16.38	-66.3%	2.46
PORTEX 5	137.94	47.94	50.12	32.69	15.25	-68.2%	2.51
INTERGUIDE 1	137.84	47.84	55.73	35.32	12.52	-73.8%	2.78
INTERGUIDE 2	137.84	47.84	51.50	32.32	15.52	-67.6%	2.57
INTERGUIDE 3	137.84	47.84	49.74	31.53	16.31	-65.9%	2.48
INTERGUIDE 4	138.14	48.14	48.38	30.71	17.43	-63.8%	2.42
INTERGUIDE 5	138.14	48.14	49.14	30.98	17.16	-64.4%	2.45
PROBREATHE 1	135.62	45.62	48.31	32.91	12.71	-72.1%	2.41
PROBREATHE 2	135.64	45.64	51.57	33.02	12.62	-72.3%	2.58
PROBREATHE 3	136.88	46.88	49.88	31.75	15.13	-67.7%	2.49
PROBREATHE 4	136.88	46.88	48.28	30.76	16.12	-65.6%	2.41
PROBREATHE 5	136.88	46.88	46.42	29.45	17.43	-62.8%	2.32
FROVA 1	128.95	38.95	46.05	30.89	8.06	-79.3%	2.30
FROVA 2	129.25	39.25	45.05	30.26	8.99	-77.1%	2.25
FROVA 3	128.95	38.95	43.45	29.03	9.92	-74.5%	2.17
FROVA 4	129.32	39.32	43.45	29.78	9.54	-75.7%	2.22
FROVA 5	128.95	38.95	43.76	29.11	9.84	-74.7%	2.19
STEERABLEBOUGIE 1	127.22	37.22	34.50	21.28	15.94	-57.2%	1.73
STEERABLEBOUGIE 2	128.18	38.18	35.77	22.12	16.06	-57.9%	1.79
STEERABLEBOUGIE 3	132.78	42.78	37.06	23.00	19.78	-53.8%	1.70
STEERABLEBOUGIE 4	128.10	38.10	33.57	20.78	17.32	-54.5%	1.67
STEERABLEBOUGIE 5	127.83	37.83	34.50	21.35	16.48	-56.4%	1.72

	10CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
GEB 1	142.76	52.76	50.57	32.74	20.02	-62.1%	2.53
GEB 2	140.01	50.01	51.31	33.78	16.23	-67.5%	2.56
GEB 3	142.76	52.76	51.15	33.59	19.17	-63.7%	2.48
GEB 4	142.40	52.40	49.15	31.79	20.61	-60.7%	2.48
GEB 5	142.40	52.40	46.75	30.43	21.97	-58.1%	2.34
FLEXGUIDE 1	135.00	45.00	53.42	34.22	10.78	-76.0%	2.67
FLEXGUIDE 2	137.91	47.91	53.30	34.31	13.60	-71.6%	2.66
FLEXGUIDE 3	135.97	45.97	50.96	32.81	13.16	-71.4%	2.55
FLEXGUIDE 4	137.54	47.54	54.39	34.82	12.72	-73.2%	2.72
FLEXGUIDE 5	137.23	47.23	53.78	34.52	12.71	-73.1%	2.69
P3-1	137.58	47.58	43.64	33.91	13.67	-71.3%	2.18
P3-2	137.12	47.12	38.45	29.00	18.12	-61.5%	1.93
P3-3	135.71	45.71	35.69	27.28	18.43	-59.7%	1.78
P3-4	137.86	47.86	35.50	27.19	20.67	-56.8%	1.77
P3-5	134.64	44.64	32.36	24.62	20.02	-55.2%	1.62

	20CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
SUNMED 1	136.28	46.28	96.40	31.09	15.19	-67.2%	4.82
SUNMED 2	136.93	46.93	97.38	31.46	15.47	-67.0%	4.86
SUNMED 3	136.93	46.93	89.75	31.02	15.91	-66.1%	4.48
SUNMED 4	136.93	46.93	95.79	30.95	15.98	-65.9%	4.78
SUNMED 5	137.44	47.44	95.10	30.97	16.47	-65.3%	4.75
PORTEX 1	138.77	48.77	110.25	36.81	11.96	-75.5%	5.37
PORTEX 2	138.63	48.63	107.67	35.73	12.90	-73.5%	5.38
PORTEX 3	139.60	49.60	108.65	35.96	13.64	-72.5%	5.43
PORTEX 4	139.77	49.77	107.81	35.68	14.09	-71.7%	5.39
PORTEX 5	139.60	49.60	103.14	34.30	15.30	-69.2%	5.16
INTERGUIDE 1	134.02	44.02	91.30	31.65	12.37	-71.9%	4.57
INTERGUIDE 2	135.00	45.00	93.73	30.24	14.76	-67.2%	4.69
INTERGUIDE 3	135.32	45.32	85.99	29.63	15.69	-65.4%	4.30
INTERGUIDE 4	135.48	45.48	83.31	28.92	16.56	-63.6%	4.19
INTERGUIDE 5	135.32	45.32	82.54	28.62	16.70	-63.2%	4.13
PROBREATHE 1	134.18	44.18	90.81	29.70	14.48	-67.2%	4.54
PROBREATHE 2	134.51	44.51	87.35	28.41	16.10	-63.8%	4.37
PROBREATHE 3	134.18	44.18	82.93	27.01	17.17	-61.1%	4.15
PROBREATHE 4	134.51	44.51	81.59	26.59	17.92	-59.7%	4.08
PROBREATHE 5	134.67	44.67	80.72	26.17	18.50	-58.6%	4.04
FROVA 1	130.16	40.16	89.76	29.82	10.34	-74.3%	4.48
FROVA 2	130.04	40.04	89.15	29.47	10.57	-73.6%	4.45
FROVA 3	129.98	39.98	87.52	29.14	10.84	-72.9%	4.37
FROVA 4	129.68	39.68	85.95	28.56	11.12	-72.0%	4.29
FROVA 5	129.50	39.50	85.61	28.42	11.08	-71.9%	4.28
STEERABLEBOUGIE 1	133.58	43.58	60.54	20.51	23.07	-47.1%	3.03
STEERABLEBOUGIE 2	132.92	42.92	53.43	18.18	24.74	-42.4%	2.67
STEERABLEBOUGIE 3	134.21	44.21	57.17	19.37	24.84	-43.8%	2.80
STEERABLEBOUGIE 4	134.05	44.05	55.84	19.00	25.05	-43.1%	2.79
STEERABLEBOUGIE 5	134.04	44.04	55.12	18.81	25.23	-42.7%	2.76

	20CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
GEB 1	140.16	50.16	106.00	35.44	14.72	-70.7%	5.29
GEB 2	140.97	50.97	104.00	34.61	16.36	-67.9%	5.20
GEB 3	141.77	51.77	104.03	34.85	16.92	-67.3%	5.20
GEB 4	141.44	51.44	102.23	34.14	17.30	-66.4%	5.11
GEB 5	140.82	50.82	99.84	33.36	17.46	-65.6%	4.99
FLEXGUIDE 1	134.51	44.51	114.37	37.05	7.46	-83.2%	5.72
FLEXGUIDE 2	134.67	44.67	111.48	36.22	8.45	-81.1%	5.57
FLEXGUIDE 3	134.67	44.67	109.89	35.74	8.93	-80.0%	5.49
FLEXGUIDE 4	135.00	45.00	110.25	35.87	9.13	-79.7%	5.51
FLEXGUIDE 5	134.67	44.67	108.02	35.10	9.57	-78.6%	5.40
P3-1	133.11	43.11	91.67	31.57	11.54	-73.2%	4.58
P3-2	133.10	43.10	80.89	27.83	15.27	-64.6%	4.04
P3-3	133.45	43.45	75.83	26.10	17.35	-60.1%	3.78
P3-4	133.45	43.45	73.01	25.09	18.36	-57.7%	3.65
P3-5	132.62	42.62	70.08	24.11	18.51	-56.6%	3.50

	30CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
SUNMED 1	128.99	38.99	122.99	26.58	12.41	-68.2%	6.14
SUNMED 2	128.99	38.99	122.04	26.57	12.42	-68.1%	6.10
SUNMED 3	128.65	38.65	119.49	26.05	12.60	-67.4%	5.97
SUNMED 4	128.65	38.65	119.15	25.85	12.80	-66.9%	5.95
SUNMED 5	128.78	38.78	118.51	25.67	13.11	-66.2%	5.92
PORTEX 1	126.83	36.83	117.93	25.80	11.03	-70.1%	5.89
PORTEX 2	126.40	36.40	98.70	21.55	14.85	-59.2%	4.93
PORTEX 3	126.83	36.83	109.28	23.89	12.94	-64.9%	5.48
PORTEX 4	126.74	36.74	93.25	20.31	16.43	-55.3%	4.66
PORTEX 5	127.39	37.39	95.21	20.77	16.62	-55.5%	4.76
INTERGUIDE 1	128.63	38.63	114.04	24.82	13.81	-64.3%	5.70
INTERGUIDE 2	128.63	38.63	108.29	23.62	15.01	-61.1%	5.41
INTERGUIDE 3	129.21	39.21	106.06	23.08	16.13	-58.9%	5.30
INTERGUIDE 4	129.52	39.52	101.01	21.97	17.55	-55.6%	5.05
INTERGUIDE 5	129.40	39.40	94.54	21.22	18.18	-53.9%	4.87
PROBREATHE 1	128.73	38.73	107.02	23.38	15.35	-60.4%	5.35
PROBREATHE 2	129.38	39.38	82.32	17.96	21.42	-45.6%	4.11
PROBREATHE 3	129.28	39.28	86.42	18.81	20.47	-47.9%	4.32
PROBREATHE 4	130.60	40.60	89.19	19.43	21.17	-47.9%	4.46
PROBREATHE 5	130.38	40.38	85.63	18.67	21.71	-46.2%	4.28
FROVA 1	125.22	35.22	111.55	24.71	10.51	-70.2%	5.57
FROVA 2	125.04	35.04	110.31	24.38	10.66	-69.6%	5.61
FROVA 3	124.78	34.78	107.41	23.78	11.00	-68.4%	5.37
FROVA 4	124.93	34.93	108.71	23.98	10.95	-68.7%	5.43
FROVA 5	125.21	35.21	109.08	24.05	11.16	-68.3%	5.45
STEERABLEBOUGIE 1	123.69	33.69	82.42	17.66	16.03	-52.4%	4.12
STEERABLEBOUGIE 2	124.24	34.24	80.82	17.35	16.89	-50.7%	4.04
STEERABLEBOUGIE 3	124.66	34.66	78.58	16.86	17.80	-48.6%	3.93
STEERABLEBOUGIE 4	125.34	35.34	77.31	16.57	18.77	-46.9%	3.86
STEERABLEBOUGIE 5	125.21	35.21	76.05	16.30	18.91	-46.3%	3.80

	30CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
GEB 1	131.45	41.45	111.36	24.54	16.91	-59.2%	5.57
GEB 2	131.55	41.55	106.69	23.51	18.04	-56.6%	5.33
GEB 3	131.33	41.33	101.92	22.46	18.87	-54.3%	5.10
GEB 4	131.55	41.55	103.51	22.82	18.73	-54.9%	5.18
GEB 5	131.43	41.43	103.88	22.90	18.53	-55.3%	5.19
FLEXGUIDE 1	127.69	37.69	140.22	30.48	7.21	-80.9%	7.01
FLEXGUIDE 2	127.91	37.91	140.60	30.66	7.25	-80.9%	7.03
FLEXGUIDE 3	127.91	37.91	137.96	30.05	7.86	-79.3%	6.90
FLEXGUIDE 4	128.01	38.01	136.93	29.84	8.17	-78.5%	6.85
FLEXGUIDE 5	127.91	37.91	135.99	29.59	8.32	-78.1%	6.80
P3-1	124.48	34.48	122.42	27.59	6.89	-80.0%	6.12
P3-2	125.07	35.07	114.61	25.92	9.15	-73.9%	5.73
P3-3	125.45	35.45	108.42	24.40	11.05	-68.8%	5.42
P3-4	124.58	34.58	102.62	23.18	11.40	-67.0%	5.13
P3-5	125.16	35.16	97.78	22.10	13.06	-62.9%	4.88

	40CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
SUNMED 1	127.67	37.67	148.86	24.05	13.62	-63.8%	7.44
SUNMED 2	127.97	37.97	148.86	24.11	13.86	-63.5%	7.44
SUNMED 3	128.15	38.15	150.13	24.29	13.86	-63.7%	7.51
SUNMED 4	127.90	37.90	148.53	24.04	13.86	-63.4%	7.43
SUNMED 5	127.72	37.72	145.98	23.63	14.09	-62.6%	7.30
PORTEX 1	123.78	33.78	115.99	18.86	14.92	-55.8%	5.80
PORTEX 2	123.81	33.81	106.07	17.21	16.60	-50.9%	5.30
PORTEX 3	124.16	34.16	93.60	15.19	18.97	-44.5%	4.68
PORTEX 4	124.07	34.07	100.32	16.30	17.77	-47.8%	5.01
PORTEX 5	124.62	34.62	94.88	15.42	19.20	-44.5%	4.74
INTERGUIDE 1	125.18	35.18	120.44	19.48	15.70	-55.4%	6.02
INTERGUIDE 2	125.92	35.92	111.81	18.07	17.85	-50.3%	5.59
INTERGUIDE 3	126.31	36.31	104.49	16.89	19.42	-46.5%	5.22
INTERGUIDE 4	126.98	36.98	108.02	17.49	19.49	-47.3%	5.40
INTERGUIDE 5	126.57	36.57	101.01	16.35	20.22	-44.7%	5.05
PROBREATHE 1	129.09	39.09	106.95	17.10	21.99	-43.7%	5.34
PROBREATHE 2	128.93	38.93	79.35	13.82	25.11	-35.5%	3.93
PROBREATHE 3	128.93	38.93	89.75	15.63	23.30	-40.1%	4.48
PROBREATHE 4	129.07	39.07	83.98	13.65	25.42	-34.9%	4.20
PROBREATHE 5	129.50	39.50	78.59	13.67	25.83	-34.6%	3.93
FROVA 1	124.53	34.53	137.79	22.61	11.92	-65.5%	6.89
FROVA 2	130.18	40.18	162.31	26.79	13.39	-66.7%	8.11
FROVA 3	124.50	34.50	136.49	22.44	12.06	-65.0%	6.82
FROVA 4	124.69	34.69	132.00	21.67	13.02	-62.5%	6.60
FROVA 5	124.69	34.69	134.90	22.15	12.54	-63.9%	6.74
STEERABLEBOUGIE 1	126.09	36.09	129.37	20.71	15.38	-57.4%	6.46
STEERABLEBOUGIE 2	126.09	36.09	123.62	19.78	16.31	-54.8%	6.18
STEERABLEBOUGIE 3	127.39	37.39	122.39	19.61	17.78	-52.4%	6.11
STEERABLEBOUGIE 4	127.55	37.55	122.39	19.62	17.93	-52.3%	6.11
STEERABLEBOUGIE 5	127.71	37.71	120.51	19.32	18.39	-51.2%	6.02

	40CM						
	STARTING ANGLE	**ADJUSTED STARTING ANGLE**	**DISTANCE MOVED**	**ANGLE VARIATION**	**ANGLE AFTER SHAPE LOSS**	**% SHAPE RETENTION LOSS**	**SPEED (MM/S)**
GEB 1	129.22	39.22	139.38	22.80	16.42	-58.1%	6.96
GEB 2	130.80	40.80	138.92	22.70	18.10	-55.6%	6.94
GEB 3	130.11	40.11	124.09	20.29	19.82	-50.6%	6.20
GEB 4	130.37	40.37	126.67	20.70	19.67	-51.3%	6.33
GEB 5	131.04	41.04	124.09	20.30	20.74	-49.5%	6.10
FLEXGUIDE 1	127.21	37.21	178.57	29.14	8.07	-78.3%	8.90
FLEXGUIDE 2	127.63	37.63	179.42	29.23	8.40	-77.7%	8.96
FLEXGUIDE 3	127.63	37.63	177.17	28.87	8.76	-76.7%	8.85
FLEXGUIDE 4	127.54	37.54	175.80	28.59	8.95	-76.2%	8.78
FLEXGUIDE 5	127.54	37.54	173.56	28.23	9.31	-75.2%	8.67
P3-1	123.72	33.72	140.22	23.31	10.41	-69.1%	7.00
P3-2	123.26	33.26	113.74	18.88	14.38	-56.8%	5.68
P3-3	123.52	33.52	106.38	17.66	15.86	-52.7%	5.31
P3-4	123.86	33.86	107.02	17.76	16.10	-52.5%	5.35
P3-5	124.31	34.31	101.90	16.92	17.39	-49.3%	5.09

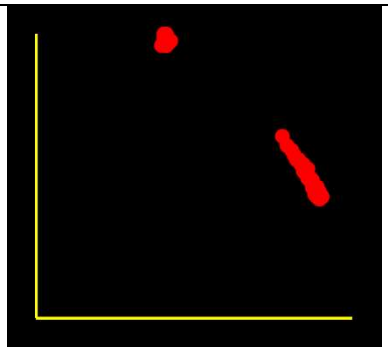
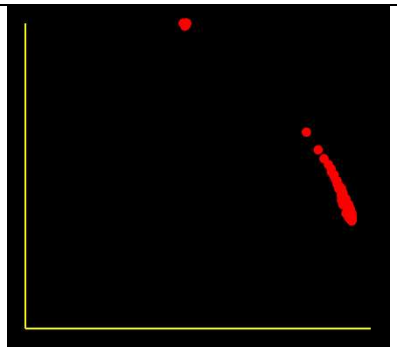
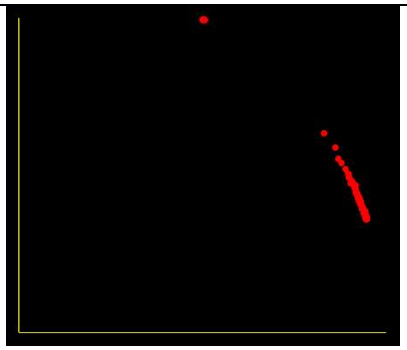
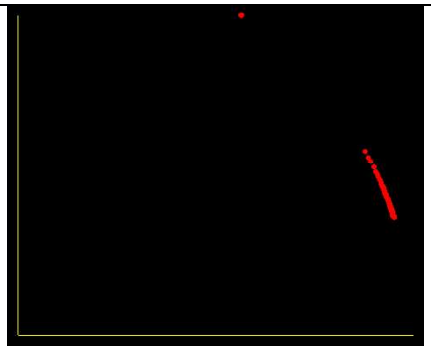
10CM - ANGLE VARIATION									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	30.21	30.42	30.43	26.27	30.73	29.612	1.877	6.340	0.840
PORTEX	35.56	33.57	33.13	32.21	32.69	33.432	1.293	3.866	0.578
INTERGUIDE	35.32	32.32	31.53	30.71	30.98	32.172	1.864	5.795	0.834
PROBREATHE	32.91	33.02	31.75	30.76	29.45	31.578	1.507	4.771	0.674
FROVA	30.89	30.26	29.03	29.78	29.11	29.814	0.786	2.635	0.351
STEERABLE BOUGIE	21.28	22.12	23.76	20.78	21.35	21.858	1.166	5.336	0.522
GEB	32.74	33.78	33.59	31.79	30.43	32.466	1.384	4.264	0.619
FLEXGUIDE	34.22	34.31	32.81	34.82	34.52	34.136	0.776	2.274	0.347
P3	33.91	29.00	27.28	27.19	24.62	28.400	3.454	12.163	1.545
10CM - SPEED (MM/S)									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	2.21	2.21	2.24	1.73	2.27	2.132	0.226	10.605	0.101
PORTEX	2.73	2.57	2.54	2.46	2.51	2.562	0.102	3.994	0.046
INTERGUIDE	2.78	2.57	2.48	2.42	2.45	2.540	0.145	5.726	0.065
PROBREATHE	2.41	2.58	2.49	2.41	2.32	2.442	0.098	4.006	0.044
FROVA	2.30	2.25	2.17	2.22	2.19	2.226	0.051	2.304	0.023
STEERABLE BOUGIE	1.73	1.79	1.70	1.67	1.72	1.722	0.044	2.578	0.020
GEB	2.53	2.56	2.48	2.48	2.34	2.478	0.084	3.405	0.038
FLEXGUIDE	2.67	1.66	2.55	2.72	2.69	2.458	0.451	18.338	0.202
P3	2.18	1.93	1.78	1.77	1.62	1.856	0.212	11.408	0.095
10CM - % SHAPE RETENTION LOSS									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	67.6%	67.6%	66.7%	54.0%	67.4%	64.66%	0.060	9.234	0.027
PORTEX	74.2%	70.0%	69.1%	66.3%	68.2%	69.56%	0.029	4.217	0.013
INTERGUIDE	73.8%	67.6%	65.9%	63.8%	64.4%	67.10%	0.040	5.997	0.018
PROBREATHE	72.1%	72.3%	67.7%	65.6%	62.8%	68.10%	0.041	6.061	0.018
FROVA	79.3%	77.1%	74.5%	75.7%	74.7%	76.26%	0.020	2.606	0.009
STEERABLE BOUGIE	57.2%	57.9%	53.8%	54.5%	54.4%	55.56%	0.019	3.335	0.008
GEB	62.1%	67.5%	63.7%	60.7%	58.1%	62.42%	0.035	5.617	0.016
FLEXGUIDE	76.0%	71.6%	71.4%	73.2%	73.1%	73.06%	0.018	2.519	0.008
P3	71.3%	61.5%	59.7%	56.8%	55.2%	60.90%	0.063	10.361	0.028

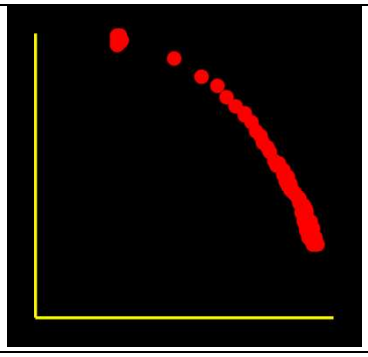
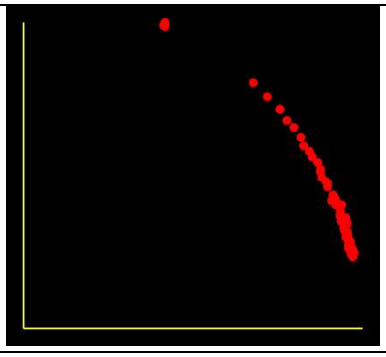
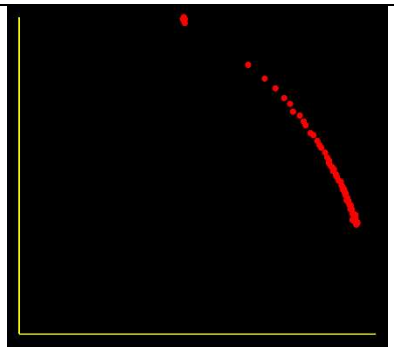
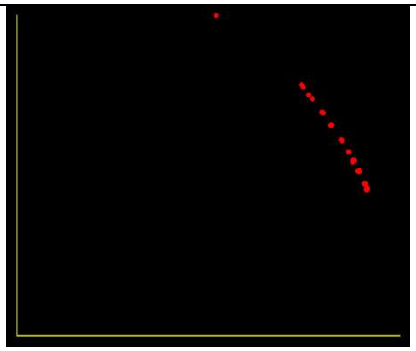
20CM - ANGLE VARIATION									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	31.09	31.46	31.02	30.95	30.97	31.098	0.209	0.674	0.094
PORTEX	36.81	35.73	35.96	35.68	34.30	35.696	0.903	2.529	0.404
INTERGUIDE	31.65	30.24	29.63	28.92	28.62	29.812	1.205	4.043	0.539
PROBREATHE	29.70	28.41	27.06	26.59	26.17	27.586	1.451	5.260	0.649
FROVA	29.82	29.47	29.14	28.56	28.42	29.082	0.594	2.041	0.265
STEERABLE BOUGIE	20.51	18.18	19.37	19.00	18.81	19.174	0.862	4.497	0.386
GEB	35.44	34.61	34.85	34.14	33.36	34.480	0.782	2.268	0.350
FLEXGUIDE	37.05	36.22	35.74	35.87	35.10	35.996	0.715	1.987	0.320
P3	31.57	27.83	26.10	25.09	24.11	26.940	2.931	10.880	1.311
20CM - SPEED (MM/S)									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	4.82	4.86	4.48	4.78	4.75	4.738	0.150	3.167	0.067
PORTEX	5.57	5.38	5.43	5.39	5.16	5.386	0.147	2.737	0.066
INTERGUIDE	4.57	4.69	4.30	4.19	4.13	4.376	0.243	5.564	0.109
PROBREATHE	4.54	4.37	4.15	4.08	4.04	4.236	0.212	5.015	0.095
FROVA	4.48	4.45	4.37	4.29	4.28	4.374	0.091	2.074	0.041
STEERABLE BOUGIE	3.03	2.67	2.80	2.79	2.76	2.810	0.133	4.741	0.060
GEB	5.29	5.20	5.20	5.11	4.99	5.158	0.113	2.199	0.051
FLEXGUIDE	5.72	5.57	5.49	5.51	5.40	5.538	0.119	2.142	0.053
P3	4.58	4.04	3.78	3.65	3.50	3.910	0.424	10.839	0.190
20CM - % SHAPE RETENTION LOSS									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	67.2%	67.0%	66.1%	65.9%	65.3%	66.30%	0.008	1.192	0.004
PORTEX	75.5%	73.5%	72.5%	71.7%	69.2%	72.48%	0.023	3.201	0.010
INTERGUIDE	71.9%	67.2%	65.4%	63.6%	63.2%	66.26%	0.035	5.329	0.016
PROBREATHE	67.2%	63.8%	61.1%	59.7%	58.6%	62.08%	0.035	5.575	0.015
FROVA	74.3%	73.6%	72.9%	72.0%	71.9%	72.94%	0.010	1.414	0.005
STEERABLE BOUGIE	47.1%	42.4%	43.8%	43.1%	42.7%	43.82%	0.019	4.352	0.009
GEB	70.7%	67.9%	67.3%	66.4%	65.6%	67.58%	0.020	2.887	0.009
FLEXGUIDE	83.2%	81.1%	80.0%	79.7%	78.6%	80.52%	0.017	2.164	0.008
P3	73.2%	64.6%	60.1%	57.7%	56.6%	62.44%	0.068	10.818	0.030

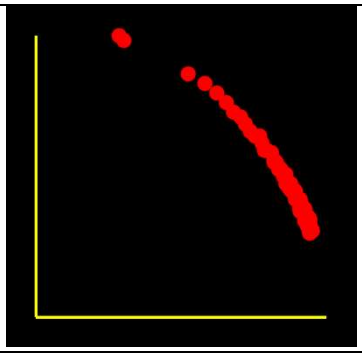
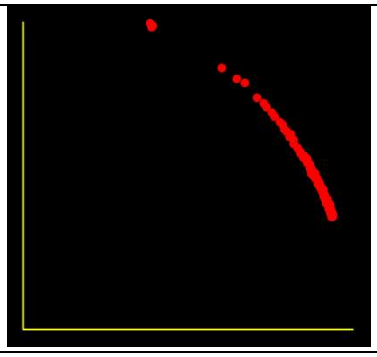
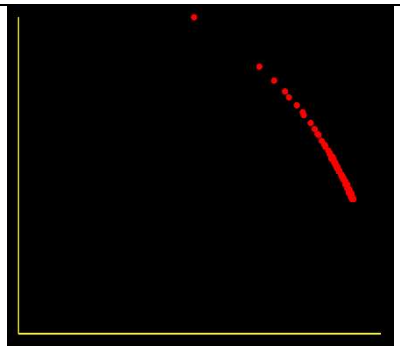
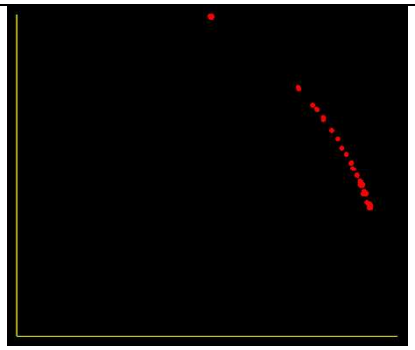
30CM - ANGLE VARIATION									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	25.58	26.57	26.05	25.85	25.67	25.944	0.394	1.517	0.176
PORTEX	25.80	21.54	23.89	20.31	20.77	22.462	2.320	10.328	1.037
INTERGUIDE	24.82	23.62	23.08	21.97	21.22	22.942	1.407	6.132	0.629
PROBREATHE	23.38	17.96	18.81	19.43	18.67	19.650	2.150	10.940	0.961
FROVA	24.71	24.38	23.78	23.98	24.05	24.180	0.367	1.516	0.164
STEERABLE BOUGIE	17.66	17.35	16.86	16.57	16.30	16.948	0.557	3.284	0.249
GEB	24.54	23.51	22.45	22.82	22.90	23.244	0.818	3.521	0.366
FLEXGUIDE	30.48	30.66	30.05	29.84	29.59	30.124	0.443	1.471	0.198
P3	27.59	25.92	24.40	23.18	22.10	24.638	2.178	8.842	0.974
30CM - SPEED (MM/S)									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	6.14	6.10	5.97	5.96	5.92	6.018	0.096	1.596	0.043
PORTEX	5.89	4.93	5.46	4.66	4.76	5.140	0.521	10.127	0.233
INTERGUIDE	5.70	5.41	5.30	5.05	4.87	5.266	0.322	6.107	0.144
PROBREATHE	5.35	4.11	4.32	4.46	4.28	4.504	0.489	10.859	0.219
FROVA	5.57	5.61	5.37	5.43	5.45	5.486	0.100	1.830	0.045
STEERABLE BOUGIE	4.12	4.04	3.93	3.86	3.80	3.950	0.130	3.301	0.058
GEB	5.57	5.33	5.10	5.18	5.19	5.274	0.185	3.508	0.083
FLEXGUIDE	7.01	7.03	6.90	6.85	6.80	6.918	0.100	1.443	0.045
P3	6.12	5.73	5.42	5.13	4.88	5.456	0.489	8.957	0.219
30CM - % SHAPE RETENTION LOSS									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	68.2%	68.1%	67.4%	66.9%	66.2%	67.36%	0.008	1.245	0.004
PORTEX	70.1%	59.2%	64.9%	55.3%	55.5%	61.00%	0.064	10.497	0.029
INTERGUIDE	64.3%	61.1%	58.9%	55.6%	53.9%	58.76%	0.042	7.109	0.019
PROBREATHE	60.4%	45.6%	47.9%	47.9%	46.2%	49.60%	0.061	12.345	0.027
FROVA	70.2%	69.6%	68.4%	68.7%	68.3%	69.04%	0.008	1.197	0.004
STEERABLE BOUGIE	52.4%	50.7%	48.6%	46.9%	46.3%	48.98%	0.026	5.236	0.011
GEB	59.2%	56.6%	54.3%	54.9%	55.3%	56.06%	0.019	3.474	0.009
FLEXGUIDE	80.9%	80.9%	79.3%	78.5%	78.1%	79.54%	0.013	1.653	0.006
P3	80.0%	73.9%	68.8%	67.0%	62.9%	70.52%	0.066	9.372	0.030

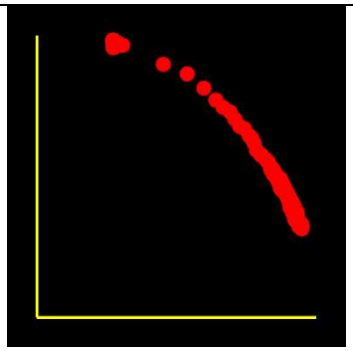
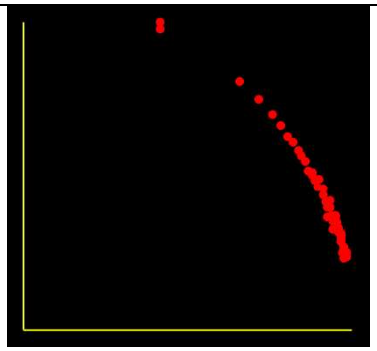
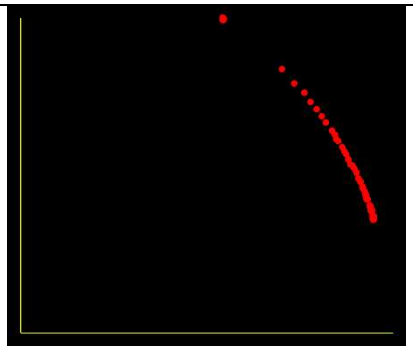
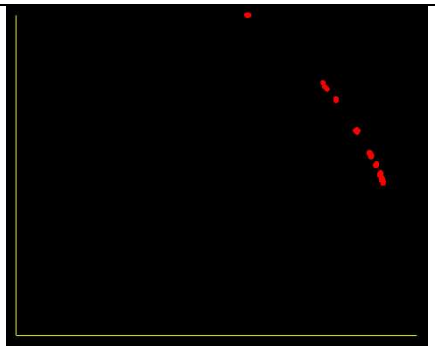
40CM - ANGLE VARIATION									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	24.05	24.11	24.29	24.04	23.63	24.024	0.242	1.007	0.108
PORTEX	18.86	17.21	15.19	16.30	15.42	16.596	1.496	9.013	0.669
INTERGUIDE	19.48	18.07	16.89	17.49	16.35	17.656	1.206	6.831	0.539
PROBREATHE	17.40	13.82	15.63	13.65	13.67	14.834	1.659	11.181	0.742
FROVA	22.61	26.79	22.44	21.67	22.15	23.132	2.076	8.973	0.928
STEERABLE BOUGIE	20.71	19.78	19.61	19.62	19.32	19.808	0.531	2.680	0.237
GEB	22.80	22.70	20.29	20.70	20.30	21.358	1.282	6.002	0.573
FLEXGUIDE	29.14	29.23	28.87	28.59	28.23	28.812	0.410	1.424	0.184
P3	23.31	18.88	17.66	17.76	16.92	18.906	2.560	13.538	1.145
40CM - SPEED (MM/S)									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	7.44	7.44	7.51	7.43	7.30	7.424	0.076	1.028	0.034
PORTEX	5.80	5.30	4.68	5.01	4.74	5.106	0.459	8.996	0.205
INTERGUIDE	6.02	5.59	5.22	5.40	5.05	5.456	0.374	6.856	0.167
PROBREATHE	5.34	3.96	4.48	4.20	3.93	4.382	0.579	13.223	0.259
FROVA	6.89	8.11	6.82	6.60	6.74	7.032	0.612	8.706	0.274
STEERABLE BOUGIE	6.46	6.18	6.11	6.11	6.02	6.176	0.169	2.730	0.075
GEB	6.96	6.94	6.20	6.33	6.20	6.526	0.391	5.987	0.175
FLEXGUIDE	8.90	8.96	8.85	8.78	8.67	8.832	0.112	1.269	0.050
P3	7.00	5.68	5.31	5.35	5.09	5.686	0.764	13.440	0.342
40CM - % SHAPE RETENTION LOSS									
	R1	**R2**	**R3**	**R4**	**R5**	**MEAN**	**SD**	**SD% OF MEAN**	**STANDARD ERROR**
SUNMED	63.8%	63.5%	63.7%	63.4%	62.6%	63.40%	0.005	0.748	0.002
PORTEX	55.8%	50.9%	44.5%	47.8%	44.5%	48.70%	0.048	9.812	0.021
INTERGUIDE	55.4%	50.3%	46.5%	47.3%	44.7%	48.84%	0.042	8.575	0.019
PROBREATHE	43.7%	35.5%	40.1%	34.9%	34.6%	37.76%	0.040	10.596	0.018
FROVA	65.5%	66.7%	65.0%	62.5%	63.9%	64.72%	0.016	2.468	0.007
STEERABLE BOUGIE	57.4%	54.8%	52.4%	52.3%	51.2%	53.62%	0.025	4.641	0.011
GEB	58.1%	55.6%	50.6%	51.3%	49.5%	53.02%	0.037	6.909	0.016
FLEXGUIDE	78.3%	77.7%	76.7%	76.2%	75.2%	76.82%	0.012	1.593	0.005
P3	69.1%	56.8%	52.7%	52.5%	49.3%	56.08%	0.077	13.819	0.035

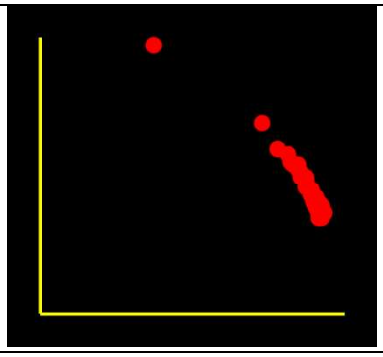
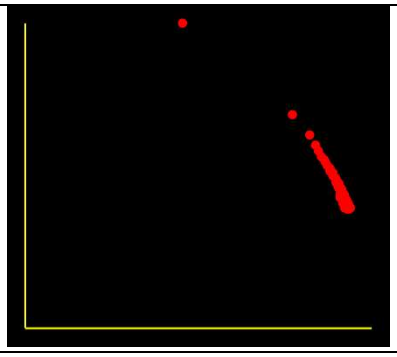
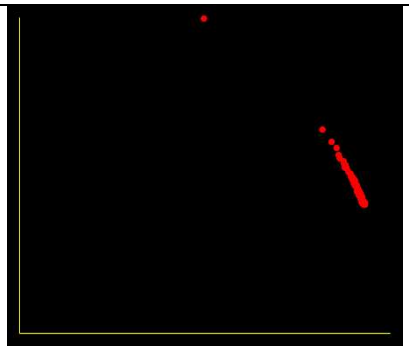
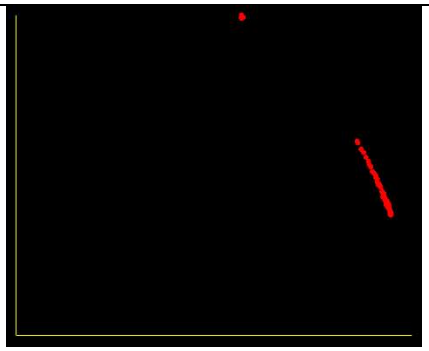
Appendix 3 - 15mm Linear Actuator Extension – Sample Of Plotting Maps

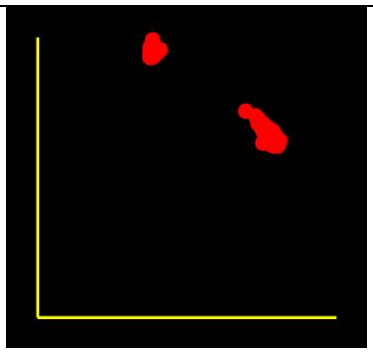
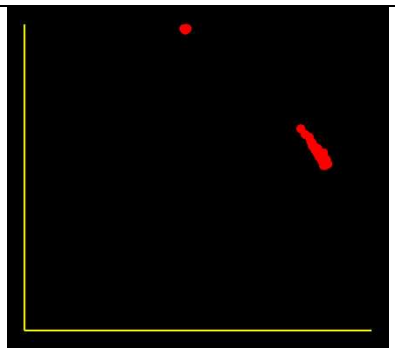
SunMed Introducer Bougie 15FR 70cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

Portex Single Use Bougie 15FR 70cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

InterGuide Tracheal Tube Introducer Bougie 15FR 70cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

Pro Breathe Premium ET Tube Introducer 15FR 70cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

Frova Introducer 14FR 70cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

Developed Steerable Bougie (70cm) – Plotting Maps	
	
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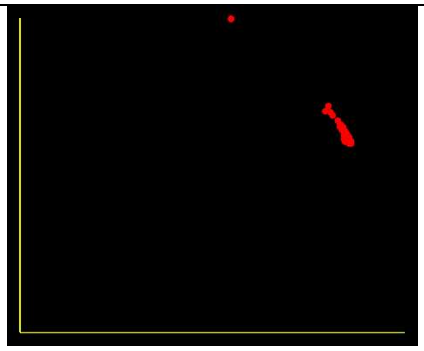
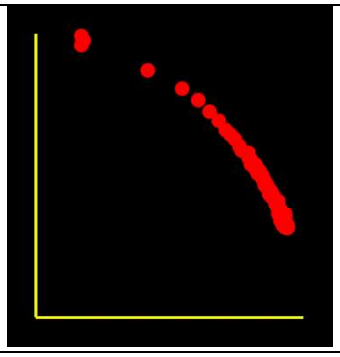
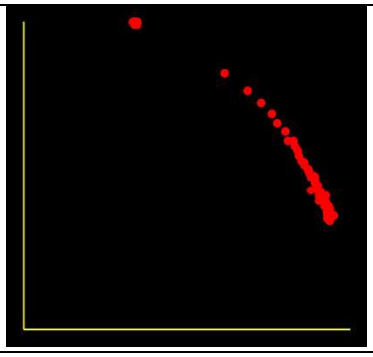
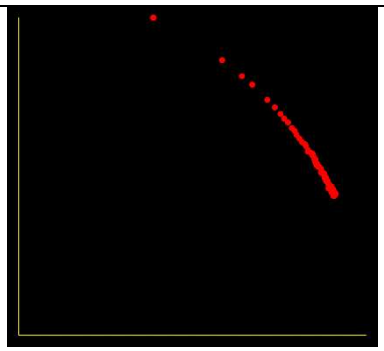
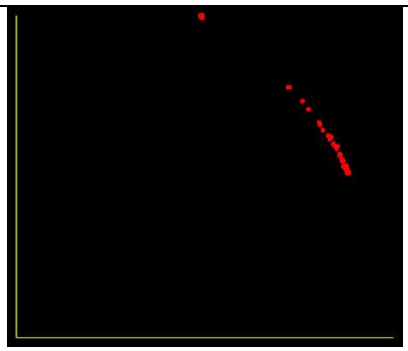
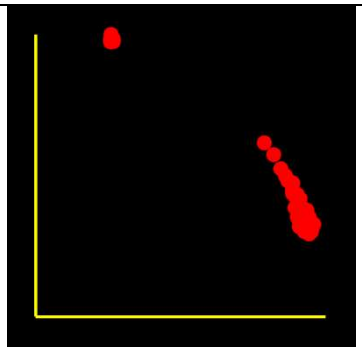
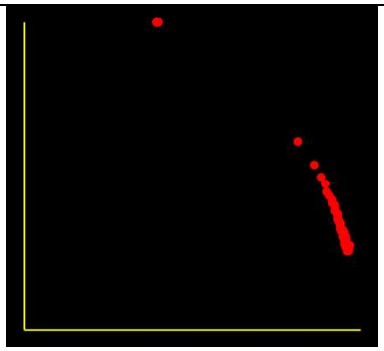
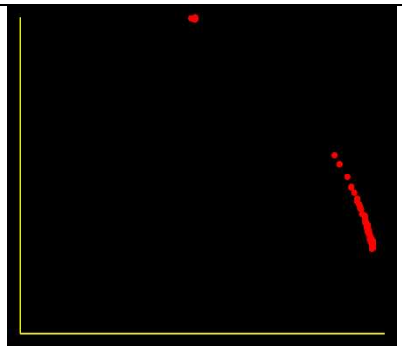
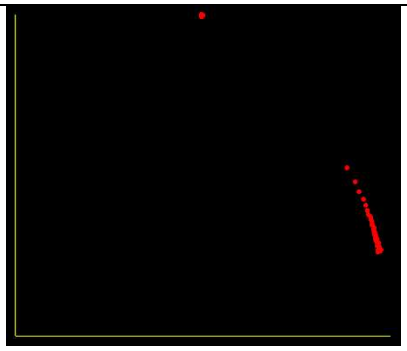
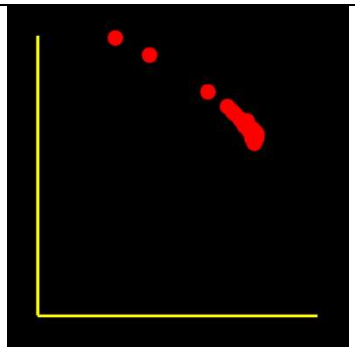
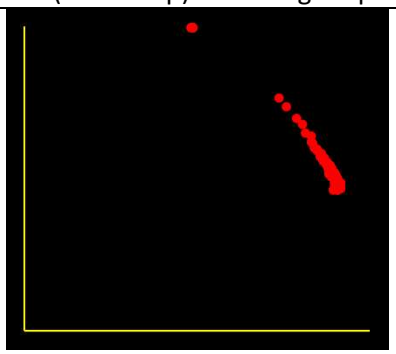
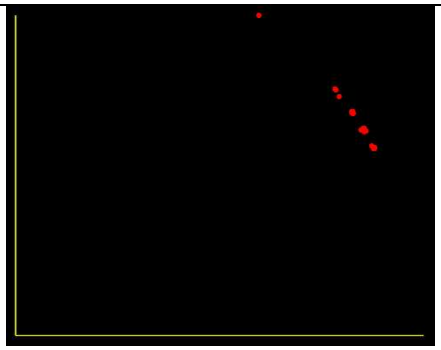
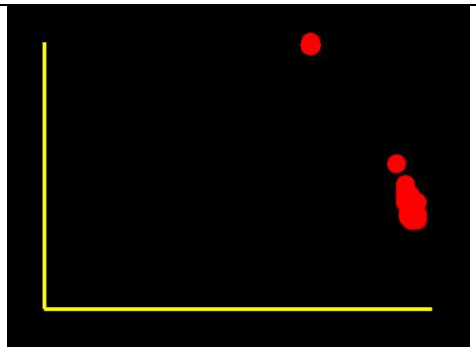
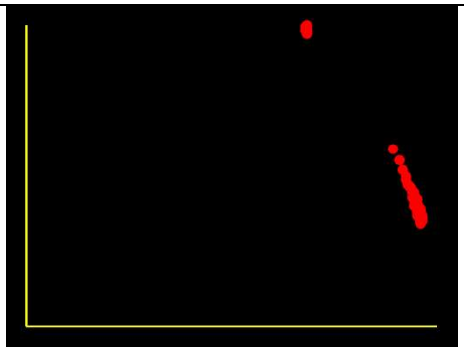
	
30cm Bend Location	40cm Bend Location

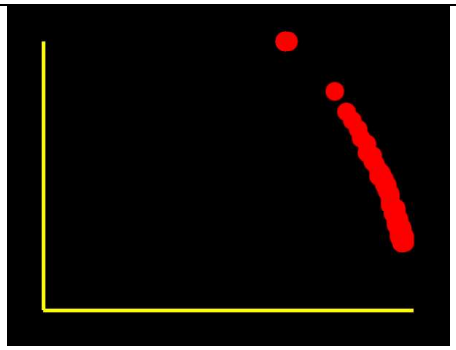
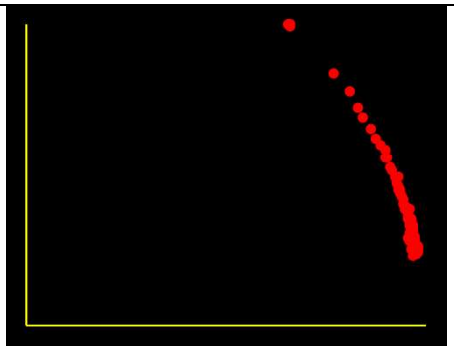
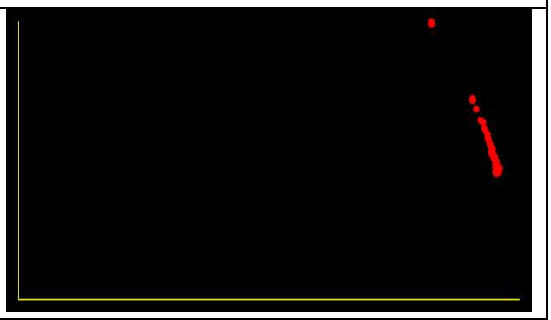
Reusable Gum Elastic Bougie 15CH 60cm – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

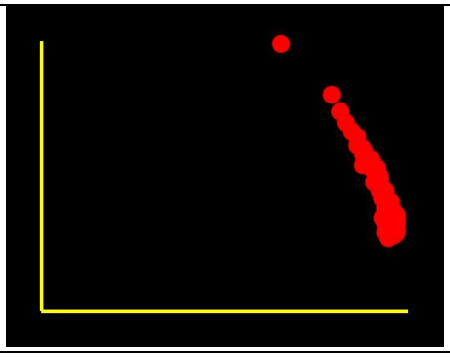
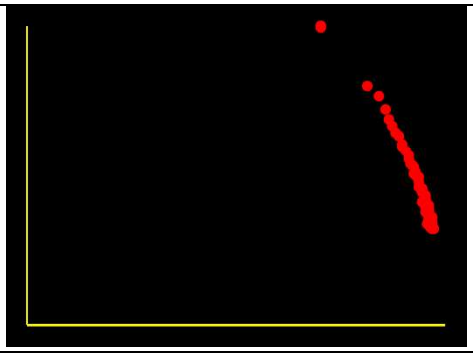
Flex-Guide Endotracheal Tube Introducer 15FR 60cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

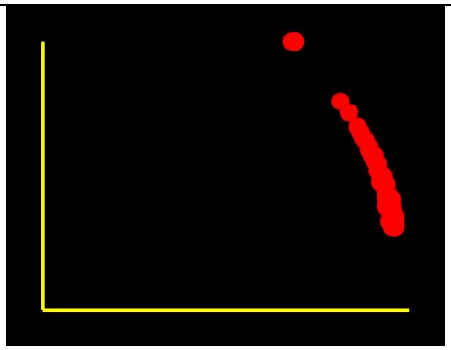
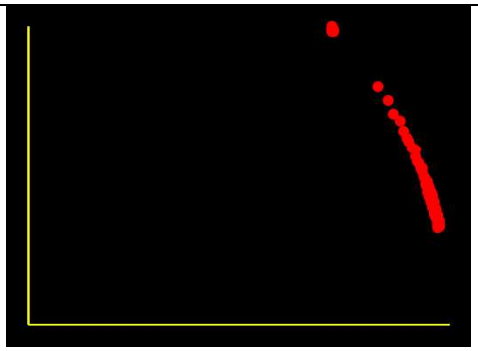
P3 Medical Tracheal Tube Introducer 15CH 60cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

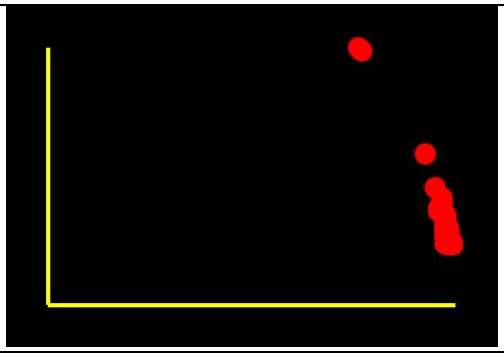
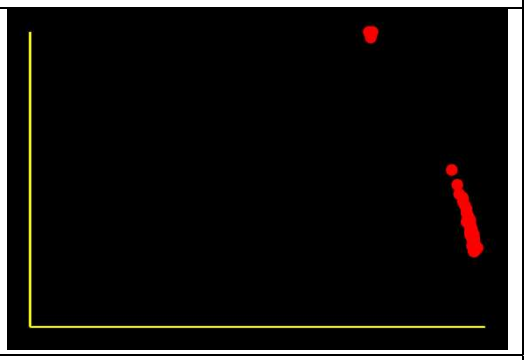
Appendix 4 - 7.5mm Linear Actuator Extension – Sample Of Plotting Maps

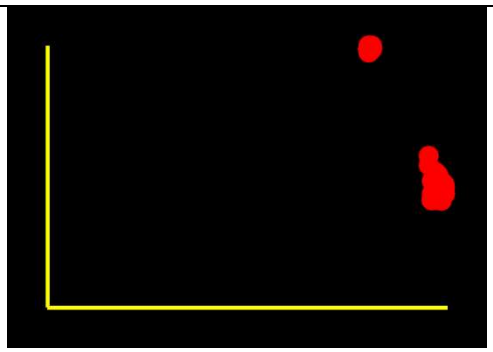
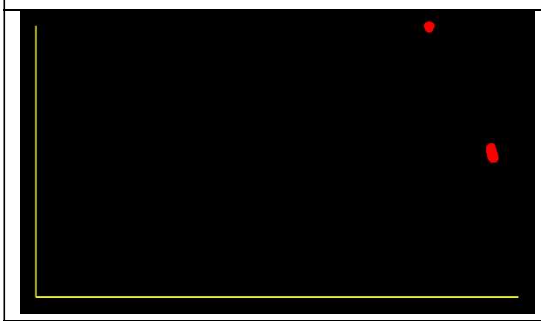
SunMed Introducer Bougie 15FR 70cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

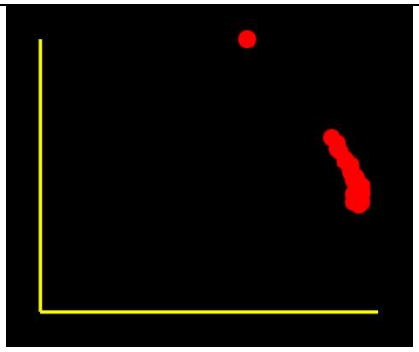
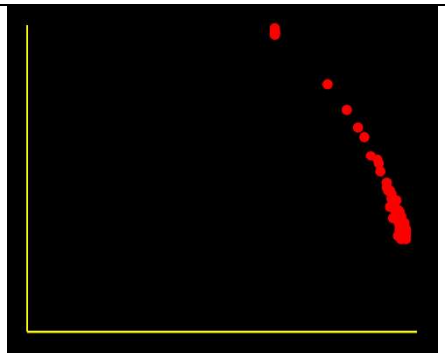
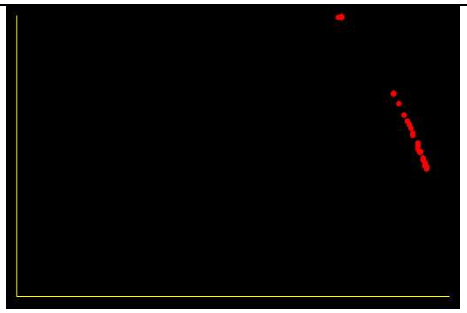
Portex Single Use Bougie 15FR 70cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

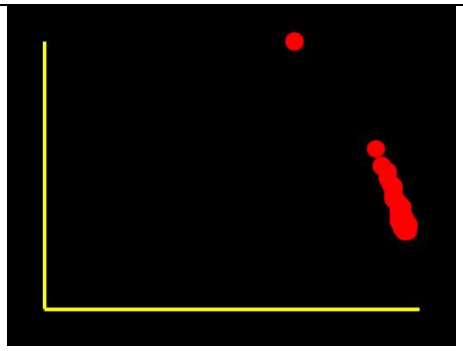
InterGuide Tracheal Tube Introducer Bougie 15FR 70cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

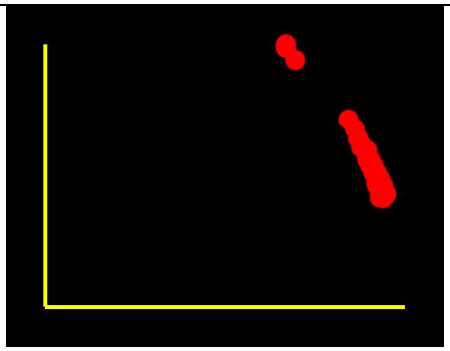
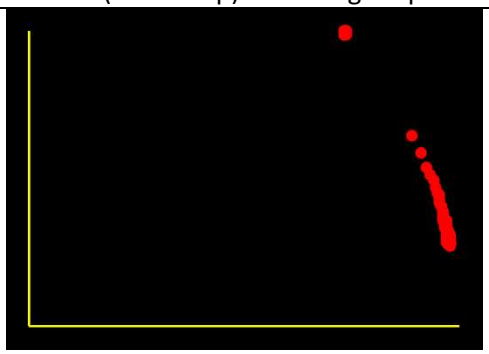
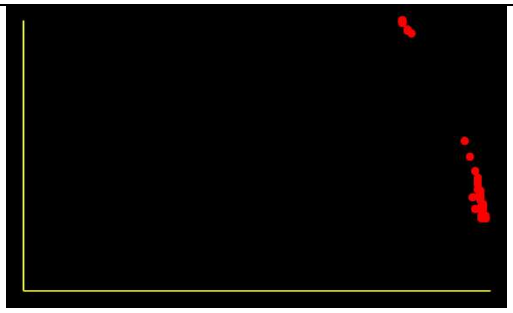
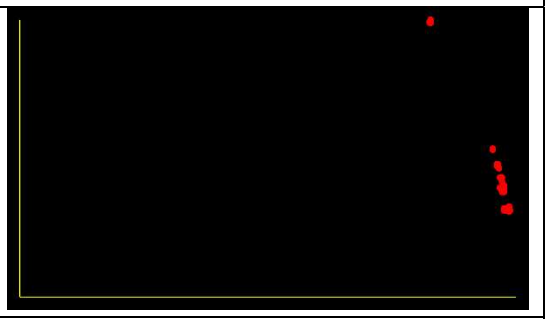
Pro Breathe Premium ET Tube Introducer 15FR 70cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

Frova Introducer 14FR 70cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

Developed Steerable Bougie (70cm) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

Reusable Gum Elastic Bougie 15CH 60cm – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

Flex-Guide Endotracheal Tube Introducer 15FR 60cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

P3 Medical Tracheal Tube Introducer 15CH 60cm (Coude Tip) – Plotting Maps	
	
10cm Bend Location	20cm Bend Location
	
30cm Bend Location	40cm Bend Location

Appendix 5 – SRTS Image Processing & Recorded Videos

Please find attached below a digital copy of the SRTS Image Processing & Recorded video available for viewing on the provided DVD's, the following data folders are

- 7.5mm Extension Tests
    - 10cm Tests
    - 20cm Tests
    - 30cm Tests
    - 40cm Tests
- 15mm Extension Tests
    - 10cm Tests
    - 20cm Tests
    - 30cm Tests
    - 40cm Tests

CD 04

CD 05

CD 06

CD 07

APPENDIX T – SKILL RETENTION STUDY PLAN (FURTHER WORK)

Skill Retention Study Background

During the PhD research time scale, originally the research team intended to complete a skill retention study. However, as the product development process expanded, it became apparent that validating the bougie design was more complex than originally intended, it was decided that the skill retention study for the steerable bougie would be completed as further work after the PhD research was completed. The plan for the skill retention study is based on the following context provided below.

Integrating a new medical device into the market is an extremely challenging task; validating this however to promote device adoption through evidence is however difficult. If suitable performance or safety improvement evidence is not provided the success or failure of the device could be affected. After the manufacture of the steerable bougie has been completed, it is necessary to ensure the target market approve of the device; The device uptake relies not only on evidence of efficacy but also effective marketing and distribution.

The uptake of the steerable bougie in the UK and the NHS can potentially be encouraged by creating an evidence file for NICE (National Institute for Health and Clinical Excellence) device; the skills retention study would add significant value to this documentation and would also add further value to MHRA documentation produced for the device.

Proving the novelty of the steerable bougie and its increased functionality compared to the vast commercial product range that currently exists is critical to its success. Skill retention and ease of learning the skill is paramount to device success or failure. Learning a new practical procedure takes time to master, however to be competent on device use can be established after 15 – 200 attempts as discussed by Tarasi et al. (2011) and Kestin (1995).

Safety issues and the efficient use of emergency airway access devices are not solely related to equipment design and use; but also linked to how the devices are used, how teaching methods on device operation are delivered and skill acquisition and retention. Teaching and learning strategies related to complex task learning and team dynamics contribute to the success or failure of undertaken procedures. Teaching strategies can improve both learning and engagement as proven in other education studies; different instructional approaches result in different levels of engagement and knowledge retention (Deslauriers, Schelew and

Wieman, 2011). Importantly human tutoring is widely believed to be the most effective form of instruction, and the experimental work described by Bloom (1984) confirms that utilising expert human tutors can produce large learning gains; this can also contribute to skill retention. The skill retention study aims to resolve the skill uptake questions surrounding the steerable bougie.

Skill Retention Study Setup

With the help of the external advisors, recruitment of unskilled operators of medical devices will be necessary; it is proposed that medical students with no prior intubation experience would prove suitable participants. Forty medical students with no airway training will be recruited and instructed how to intubate using the steerable bougie. Once the skill is learnt, the time to successful intubation will be noted on a simulated difficult intubation. After a one-month gap, the forty medical students will be recalled to re-complete the difficult intubation task again and the same data will be recorded. By analysing this data skill retention or loss of skill retention, the acceptability of the steerable bougie can be calculated. The plan is to carry out the test, using unskilled practitioners, to evaluate skill acquisition and retention with the 'steerable' bougie, compared with a regular bougie. The outcome measures for this test are:

1. Time to successful intubation in each attempt.
2. Appropriate Scoring System.
    a. Visual Analogue Score: used to establish ease of use of the device.
    b. NASA Task Load Index: A subjective, multidimensional assessment tool used to score workload, assess a task, system, or team's effectiveness or other aspect of performance.
3. Global rating scale for procedure (although this might be better used in the expert practitioners in the next phase).

Outcome Measurables and Key Considerations

The key outcome measurables and considerations assessed by Dr James Armstrong and Dr Kristofor Inkpin are as follows. Firstly, demonstrating equivalence or greater acceptability when using the steerable bougie when compared to the standard bougie is important to establish. This will need to be completed in the setting of an uncomplicated airway (when

the control device for the steerable bougie is not used) and when steerable function used. Success of intubation within a pre-defined time could be a suitable property to do this, as could average time to intubation.

Secondly assessing the ease of intubation will also contribute to device acceptability. Demonstrating that the steerable bougie provides overall an easier intubation in the clinical setting is better or at least equivalent is important. The steerable bougie should ideally be used in combination with a standard MAC blade and a video laryngoscope (such as GlideScope). The case of need survey completed by the project team and presented in Chapter 4 already demonstrates that the anaesthetists commonly use standard bougies within their practice and that video laryngoscopy technique often used. However, the standard MAC blade however is the most common piece of airway management equipment and factoring this into the setup will be important.

Critically, the skill retention study needs to convey that through the addition of the steerable function, increased benefit and performance can be attributed. It is hoped that by using a simulated difficult airway. This information could be analysed and demonstrated using a Visual Analogue Scale (VAS) or a NASA Task Load Index (NASA-TLX). Finally, demonstrating the skill retention or intuitive nature of device is fundamental to success. The aim is to achieve this by getting the same participants to repeat the tasks at a later date using a crossover study approach.

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Tarasi MD, P.G., Mangione MD, M.P., Singhal, S.S. and Wang MD MS, H.E., 2011. Endotracheal intubation skill acquisition by medical students. Medical education online, 16(1), p.7309.

APPENDIX U – PUBLISHED JOURNAL & CONFERENCE ARTICLES

The following journal and conference papers have been published or accepted for publication; copies of the papers are provided in the subsequent pages.

Journal Articles

SIENA, F.L., BREEDON, P., ARMSTRONG, J., INKPIN, K. and NORRIS, A., 2016. The development of a novel steerable bougie to assist in airway management. Australasian Medical Journal, 9 (5), pp. 124-137. ISSN 1836-1935.

BREEDON, P., SIENA, F. and ARMSTRONG, J., 2017. Tracheal intubation: improving first pass success with smart material solutions. The Journal of Health Design, 2 (3), pp. 15-18. ISSN 2206-785X Item not available from this repository.

SIENA, F., BREEDON, P., ARMSTRONG, J., MARSH, P. and WATTS, P., 2017. Performance analysis for difficult airway equipment: Standardising for success. Journal of Health Design, 2(4), pp.39-41.

SIENA, F.L., BYROM, B., WATTS, P. and BREEDON, P., 2018. Utilising the Intel RealSense Camera for Measuring Health Outcomes in Clinical Research. Journal of Medical Systems, 42(3), p.53.

SIENA, F.L., BREEDON, P., ARMSTRONG, J., WATTS, P., INKPIN, K. and NORRIS, A., 2018. Performance Analysis System For Endotracheal Tube Introducers: Standardising For Success. Journal of Health Design, 3(3).

Conference Proceedings

SIENA, F.L., BREEDON, P., ARMSTRONG, J., WATTS, P., INKPIN, K., NORRIS, A. and MARSH, P. 2018. Utilising Object Tracking For The Performance Analysis Of Difficult Airway Equipment - A Shape Retention Testing System (SRTS). Proceedings of the 12th International Conference on Disability, Virtual Reality and Associated Technologies (ICDVRAT 2018), Nottingham, UK, 4-6 September 2018.

SIENA, F.L., BYROM, B., WATTS, P. and BREEDON, P., 2018. Usability Assessment Of Facial Tracking For Use In Clinical Outcomes. Proceedings of the IADIS International Conference: Interfaces and Human Computer Interaction 2018, Madrid, Spain, 18-20 July 2018. [Madrid]: IADIS (International Association for Development of the Information Society).

SIENA, F.L., BREEDON, P., ARMSTRONG, J., WATTS, P., INKPIN, K. and NORRIS, A., 2018. Mechanical Performance Assessment System For Endotracheal Tube Introducers Using Motion Detection And Object Tracking. Proceedings of the IADIS International Conference: Computer Graphics, Visualization, Computer Vision and Image Processing 2018, Madrid, Spain, 18-20 July 2018. [Madrid]: IADIS (International Association for Development of the Information Society).

BREEDON, P., BYROM, B., SIENA, L. and MUEHLHAUSEN, W., 2016. Enhancing the measurement of clinical outcomes using Microsoft Kinect. In: Proceedings of the 2016 International Conference on Interactive Technologies and Games (iTAG 2016), Nottingham, 26-27 October 2016. Los Alamitos, CA: Institute of Electrical and Electronics Engineers, pp. 61-69. ISBN 9781509037384.