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DESIGN INSIGHT

# Performance analysis system for endotracheal tube introducers: Standardising for success

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**SUMMARY**
Equipment design and selection can contribute to the success or failure of difficult airway management. The design of medical devices/testing systems completed by multidisciplinary design teams that include healthcare professionals can significantly influence device success or failure. This paper presents an overview of the design tasks used to develop the Shape Retention Testing System (SRTS) for the assessment of bougie introducers. By using a multidisciplinary design team that includes healthcare professionals, critical design tasks such as design criteria generation, product design specification (PDS) generation, focused design approaches, and iterative design processes have ensured essential feedback is collected to influence the SRTS's design and manufacture.

**Key Words**
Airway management; bougie introducers; difficult airway; focused design approach; shape retention testing system

## INTRODUCTION & BACKGROUND

Endotracheal intubation is fundamental to safe anaesthetic practice. Failing to secure the airway with an endotracheal tube (ET tube) quickly on induction of anaesthesia can lead to serious complications.[1] Various adjuncts can be used to complete a successful endotracheal intubation, the most common being the bougie. Bougies are long, flexible, relatively narrow rods that have some intrinsic "shape memory" and are used when the view is limited, making direct placement of the ET tube difficult. Bougies are manually shaped to match the curve of the patient's airway and act as a physical guide over which the ET tube can be placed. Understanding the physical properties of bougie introducers is crucial; different manufacturers' bougies exhibit extremely variable physical properties and shape retention characteristics.

A recent United Kingdom (UK) national survey of tracheal tube introducers and associated complications[2] identified numerous bougies used in UK hospitals and recognised the re-usable Eschmann Tracheal Tube Introducer "Gum Elastic Bougie" (GEB) as the gold standard device due to its superior tracheal placement success rate. However, single-use bougies have a significantly lower price point; that, alongside infection control concerns, typically results in their use instead of the GEB.[2] Further evaluation of single-use devices and optimization of their performance is required before they completely replace the GEB.[2] Any testing of bougies should conform to the UK's Difficult Airway Society's ADEPT principles.[3]

To date, no performance assessment systems capable of formally assessing bougie shape retention properties exist. The authors recently presented the concept of accurate testing systems, including developing a Shape Retention Testing System (SRTS) capable of accurately measuring shape retention characteristics.[4] The SRTS aims to resolve issues identified from previous studies that fail to fully consider issues such as reliability, measurement accuracy, standardisation of applied pressures, calibration, data acquisition equipment accuracy, and repeatability of positional tracking.

## SUMMARY

Many medical device designs fail due to lack of a focused design approach during concept, development, and testing phases of product development. To ensure the successful design and manufacture of the SRTS, Pugh's Total Design Activity Model[5] was used. Fundamentally, critical tasks that must be completed include iterative design processes, manufacturing tasks, and the generation of accurate testing protocols; these tasks must not solely be completed by the design teams but must involve healthcare professionals, software developers, statisticians, technologists, etc. The experience of healthcare professionals (ie, consultant anaesthetists) influenced the SRTS's design by ensuring clinically relevant measurables were identified and integrated into the operative control functions. Feedback from healthcare professionals collected during multidisciplinary team meetings and problem identification tasks ensured that a product design specification (PDS) performance criteria could be generated. The PDS performance criteria included:

1. Production of an adaptable, calibrated system capable of collecting accurate shape retention data of bougie introducers that vary in diameter, length (500mm–800mm), and are available either hollow or solid with a straight and coude tip.
2. Interchangeable components are required to standardise system setup regardless of bougie diameter, length, and bend location (anaesthetists defined bend locations of 10cm–40cm from the tip).
3. Repeatable testing commands with preconfigured variables adaptable for the bougie product range.
4. Recordable accurate motion capture tracking used in combination with angle measurement grids to record various measures:
    a. Shaped bougie angle (degrees).
    b. Change in distance (mm).
    c. Variation in angle (degrees); ie, shape retention loss.
    d. Average speed of movement (mm/s).
5. Accurate camera/video tracking with fixed frame rates and appropriate field of view (FOV).
6. Calibration regions of interest (ROI) that do not interfere with data capture.
7. LED lighting and blackout covers to standardise ambient lighting.
8. Logic-based programming system that allows the testing system to reset to a calibrated home position thus providing a protocol of standard movements.
9. Post-processing capabilities to re-analyse data and adjust output formats.

Considering this performance criteria, the SRTS was designed and manufactured (Figure 1). The SRTS functions by shaping the bougie using the linear actuator pushers (LAPS) using pre-set movement commands. The LAPS pushers shape the bougie by manipulating it from position "A" to shaped position "B" (Figure 2). Once LAPS retracts, the bougie's loss of shape retention is measured as demonstrated by position "C" (Figure 2).

The recorded video, monitoring the return to original position, is processed by an image processing system providing results, including bougie starting angle (position "B") (degrees), change in angle (position "C") (degrees), distance moved (mm), and speed of movement recorded in millimetres per second (mm/s). A SRTS validation test (Figure 3) presents a set of results collected over the clinically defined ranges identified by the healthcare professionals. Completing a side-by-side analysis of various bougies from different manufacturers, the bougie with optimum shape retention characteristics can be identified.

**Figure 1: Shape Retention Testing System (SRTS) setup**

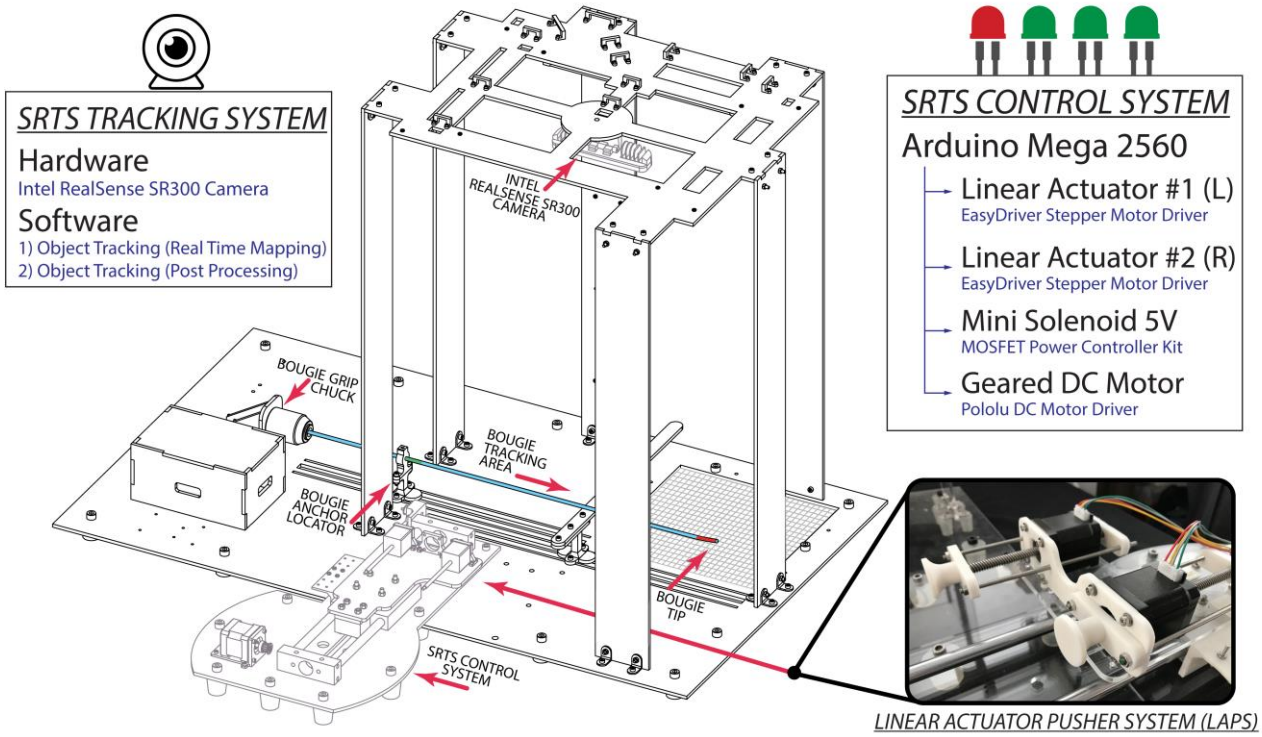



**Figure 2: SRTS object tracking functionality**

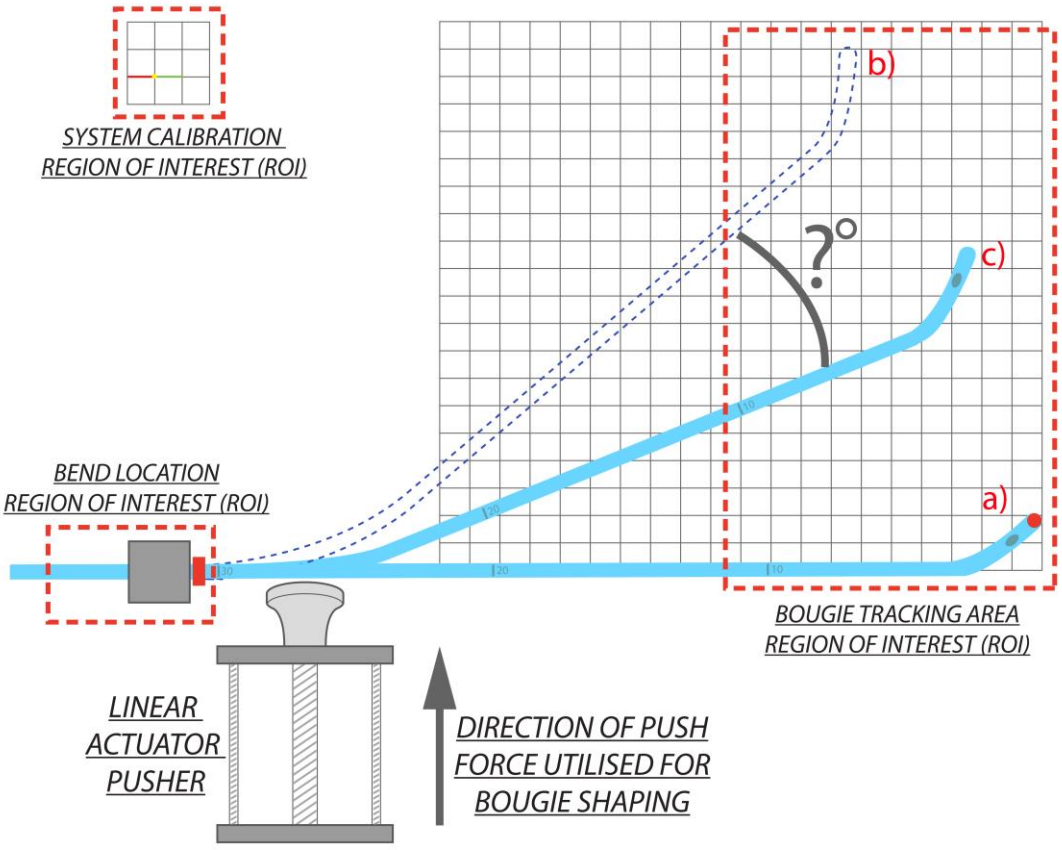
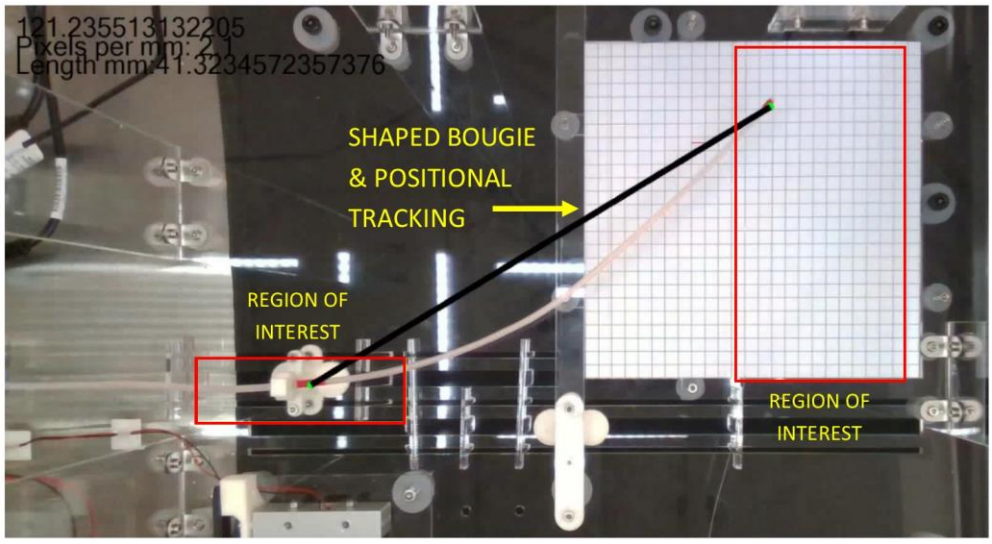
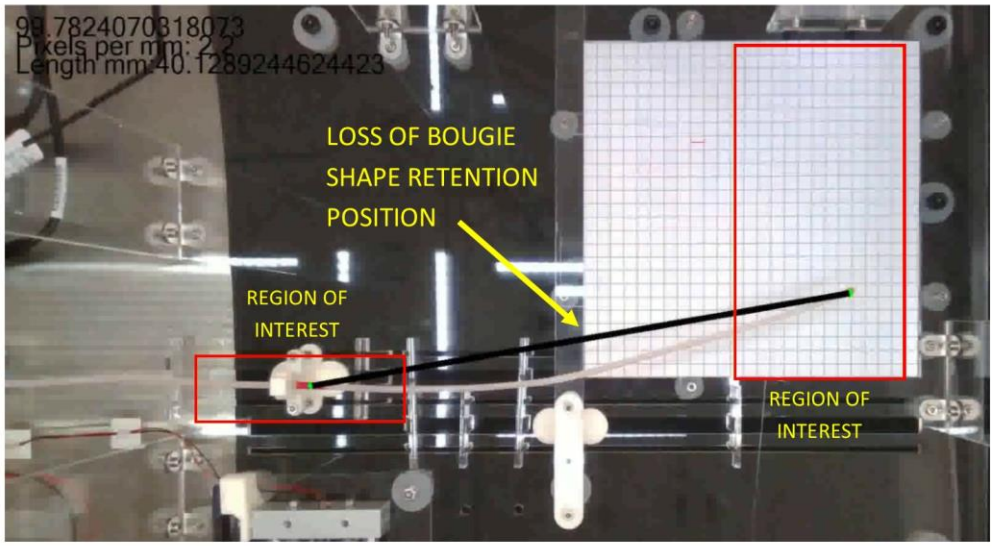


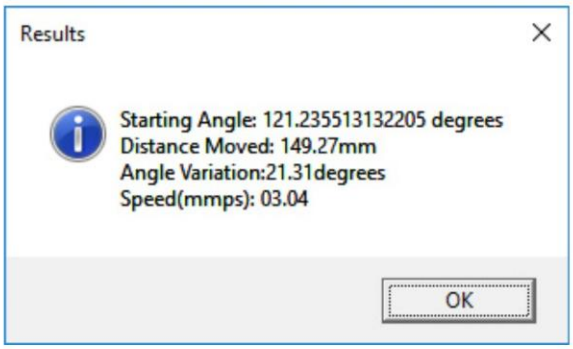
**Figure 3: SRTS data acquisition validation**




A) Shaped Bougie Position: Tracking Begins




B) Bougie Loss Of Shape Retention Position: Tracking Ends




C) SRTS Image Processing Results Dialog Box: Validation Test Results

## LEARNING FROM EXPERIENCE

The importance of using a multidisciplinary design team during the design process cannot be overstated. Generating design criteria identified by multidisciplinary teams can significantly influence device success or failure by identifying accurate problem definitions and design improvement criteria. Products or testing systems endorsed as designed and tested by healthcare professionals and/or professional societies usually influences equipment usage or purchase

decisions due to recommendations relating to improved usability and practice safety.

Using a multidisciplinary design team to design the SRTS has demonstrated that an accurate, repeatable, and reliable testing system can be manufactured to provide anaesthetists and professional societies with a system capable of analysing performance data to inform device selection. Once a full assessment of bougie introducers is completed using the SRTS, the comparative data should influence equipment adoption and purchase decisions. Identifying and using the identified optimum equipment during a procedure has significant patient benefit by improving procedure safety and reducing the risk of complications from incorrect equipment selection and use.

It is strongly recommended the use of multidisciplinary design teams are adopted when designing new medical devices and testing systems. The inclusion of healthcare professionals, and where necessary patients, will add a greater knowledge base to the design process. This will ultimately improve the iterative design process due to accurate identification of problem definitions, accurate design criteria identification, and feedback incorporation from expert customer/user bases.

## DESIGN INSIGHT

Great approach to medical product development! As a practicing industrial designer and ID educator, I am excited to see this implementation of the design process presented. Using this form of human-centered design generally results in products that better meet user needs—not just for the end user (in this case the healthcare professional), but for other stakeholders as well (which here includes the patient as well as the engineering design team).

The authors discuss the value of the multidisciplinary approach encompassing different professional disciplines that are involved in the physical design, engineering, testing, and manufacturing along with end users of these medical products. Overlaying real user feedback with the disciplinary knowledge points towards what a successful product outcome would be. Each of these stakeholders have ownership of the product at various points, but a siloed approach to development where disciplines perform in a segmented or sequential manner generally leads to products that meet no one's needs.

Collecting, sharing and processing disciplinary information, knowledge and needs across the team is the first step of the process. When these various disciplines meld into an interdisciplinary team that *synthesises* the approaches from *all* disciplines from the *start* of the project, talking with each other and not at each other, sharing, learning, reflecting, and collaborating is where the magic happens. It is more complex, but ultimately makes the team of multiple disciplines more powerful, timelier, and adds greater value to the product outcome.

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## PEER REVIEW

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## CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

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## ETHICS COMMITTEE APPROVAL

Not Required