Bonfils Endoscope: Intubation and Airway Assessment Device

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctor in Medicine

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Abstract

The Bonfils Intubation Endoscope is a rigid fibreoptic laryngoscope that facilitates the operator in placing a tracheal tube. It is intended for use in both routine and difficult intubations. The technique used is substantially different than traditional Machintosh laryngoscopy.

Its introduction into routine clinical practice is described herein. Sixty patients were studied. The intubation technique is explained in detail. The importance of creating space in the oropharynx and manipulating the epiglottis with both the endoscope and the operator's free hand is made clear. In the hands of inexperienced users, a consistent intubation time of <30 seconds is achieved after 25 intubations. An objective scoring system called the Bonfils Difficulty Score (BDS) can be used to grade endoscopy and intubation on a 0-12 scale and can be used to compare different intubations.

Bonfils Endoscopy and intubation is possible under the conditions of cricoid pressure application. 18/19 patients were successfully intubated. The pressure itself caused widespread and unpredicted levels of airway distortion and obstruction, this makes intubation more difficult.

Forty one patients with pharyngolaryngeal tumours were successfully intubated. Light anaesthesia with Remifentanil and Propofol infusion was adequate in most cases. The rigid nature of the Bonfils Endoscope was essential in at least 11 cases to push past the tumour partially obstructing the laryngeal inlet. The overall appreciation of the airway pathology was greatly enhanced in this difficult patient group.

A commercially produced airway manikin (Airsim®, Trucrop Ltd.) was used to examine Bonfils Endoscopy. It has the capability to progressively increase head flexion. It demonstrated that between 10° and 20° head flexion is the maximum the Bonfils Endoscope can operate.

Section 1

I. Preface

Failure to secure a patient's airway under anaesthesia can result in significant morbidity and mortality. In the USA problems of airway management are accountable for 30% of deaths associated with anaesthesia and more than 85% of respiratory closed-claim malpractice suits involve brain damage or death.[1] Difficult laryngoscopies have an incidence of between 0.3% and 20% depending on the patients studied[2, 3] Pre-operative tests predicting difficulty based on anatomical criteria such as mouth opening, Mallampati classification[4], ability to translate mandible and thyromental distance have low sensitivity and miss half of difficult cases[5, 6]. Difficult cases result in multiple attempts at laryngoscopy and can result in airway and dental trauma and in rare cases oxygen desaturation and neurological impairment[7]. Traditionally, blind nasal intubation or the use of airway adjuncts such as gum-elastic bougies or lighted stylets were the techniques employed when unexpected difficulty occurred. Rigid fiberoptic devices are now commercially available to assist with these intubations[8]. Few of these have undergone rigorous evaluation. This research details my experience and evaluation of the Bonfils Intubation Endoscope manufactured by Karl Storz GmbH & Co.,Tuttlingen, Germany.

Section 1

II. Introduction

Since the advent of tracheal intubation for airway maintenance and protection from aspiration during general anaesthesia, many devices have evolved to facilitate this seemingly straightforward but critical procedure. The Macintosh Laryngoscope is the established instrument to achieve this task. It has stood the test of time and been in use since the 1940's[9]. The anaesthetist uses the blade of the Macintosh to compress the tongue into the submandibular space; the tip of the spatula rests in the valleculum and lifts the hyoid bone and epiglottis, bringing the laryngeal inlet into the line of sight.

The Bonfils Intubation Endoscope uses fibreoptic technology to visualise the larynx. It is a rigid stainless steel optical stylet. It has a 40cm working length and is 5mm in diameter with a 40° anterior distal curve (Fig. 1).

Figure 1 Bonfils Intubation Endoscope

The use of rigid stylets within tracheal tubes to assist in intubation is not a new concept. Bowan in 1967 realised that in thoracic surgery when laryngoscopy (Macintosh) gave inadequate view of the vocal cords subsequently introduction of a straight bronchoscope was easy. His explanation was that the rigidity of the instrument displaced the tongue. He went on to adapt a number of straight rigid introducers; he stated they 'should be of rigid pattern and small bulk'. He also advised that 'using smaller endotracheal tube might be worth while'[10].

The background to the Bonfils Intubation Endoscope is rather obscure. Pierre Bonfils (University Hospital, Inselspital, Berne, Switzerland) wrote about the problems associated with difficult laryngoscopy and intubation over 25 years ago[11, 12]. His particular interest was the intubation of children with Pierre Robin Syndrome (mandibular hypoplasia with posterior displacement of the tongue). He advocates using a retromolar approach with a straight blade – he describes the 'straighter axis and shorter distance' to the larynx and also the 'appropriate bending of the tube with a stylet' to aid intubation[13]. Some years later a rigid endoscope based upon his philosophy of intubation was produced by Karl Storz GmbH & Co. Tuttlingen, Germany (about 200 km from Berne). Indeed it was originally called the "Bonfils Retromolar Intubating Fibrescope". I was unable to establish who actually designed it. There is nothing in the academic literature written by Dr Bonfils about the instrument that bears his name nor was anyone at Karl Storz Endoscopy (UK) Ltd. able to help.

My first introduction to the Bonfils Intubation Endoscope was in late 2001. A representative of the medical endoscope manufacturers Karl Storz Ltd., provided a Bonfils on a trial basis. Initially the device was received with some scepticism; it had the appearance of a surgical instrument rather than an anaesthetic laryngoscope. Its design was very simple. It was cold and hard with edges that were not smooth and could easily tear delicate mucosa[14]. It had the potential to cause a lot of trauma if used incorrectly[15]. Some of my more cynical colleagues likened it to swallowing a sword. A well produced booklet titled "Safe and Reliable Intubation using the Bonfils Retromolar Fibrescope" accompanied it. This illustrated a number examples of patients successfully managed with the Bonfils who were purportedly difficult intubations. Information on the intubation technique was not very detailed. It was written by Dr. Christian Rudolph MD, a German Anaesthetist (Klinik und Poliklinik fur Anasthesiologie und Intensivtherapie, Universitat Leipzig) for a German market and directly translated into English. Searching the internet for additional information revealed one publication on the PubMed database by Dr. Rudolph. This German article was an audit of one years experience using the Bonfils for 103 intubations, some of whom were difficult. However, there was no detailed description of how the device was used[13, 16]. At that time the Karl Storz website only had a photograph and a catalogue number.

The correct way to use the Bonfils is not intuitive. There were no references to the Bonfils in standard anaesthetic textbooks. The standard of Clinical Governance in the U.K. demands that users of new devices should familiarise themselves with them before clinical practice. The Karl Storz representatives had no knowledge of the whereabouts of Dr P Bonfils himself. Dr Rudolph seemed to be the only anaesthetist with any experience using the instrument. Dr. Peter Charters (Consultant Anaesthetist, University Hospital Aintree) and I went to Leipzig University Hospital in February 2002. Hospitals in the former German Democratic Republic had an extensive re-equipping in the early 1990's after German Reunification. Dr. Rudolph told us that he essentially rediscovered the then called 'Bonfils Retromolar Fibrescope' while browsing the Karl Storz catalogue. As far as I am aware he was the only anaesthetist using it regularly for about 10 years. I spent a day observing his intubation technique first hand and made meticulous notes. I saw it being used for routine and difficult cases. There were no special indications or contra-indications for its use. In addition to the theatre practice, I was shown a recording of its use in an awake patient. He also explained how initially his trainees found using the Bonfils difficult but once they became familiar with it, it became the instrument of choice. He tended not to use a camera and monitor system at that time and just used the eye-piece and often used a Macintosh laryngoscope to assist in placing it.

There are two adult Bonfils Endoscopes currently available. One has a 1.2mm working channel and 16,000 fibreoptic bundles (catalogue no.10330 B). The second does not have a working channel and therefore, has 35,000 bundles (catalogue no.10331 B). The proximal eye-piece can be connected to a video camera and there is a connector for the light source which can be either portable battery LED or fixed cold light cable. Tracheal tubes down to a size O.D. 5.5mm can be easily accommodated. The tracheal tube is held in position on the stylet by an adapter cone. This prevents slippage of the tracheal tube either forward off the stylet or backwards further on to the stylet. This is important because the tip of the stylet is positioned very carefully just within the lumen of the tracheal tube such that the view through the Bonfils is as if one is looking out of the end of the tracheal tube. The author prefers the leading edge of the bevel of the tracheal tube to be visible through the endoscope allowing very accurate placement.

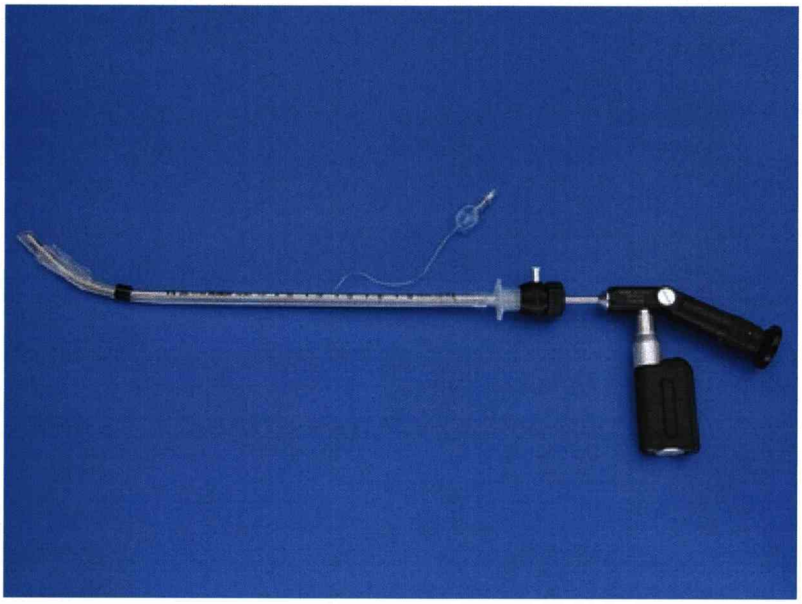

Figure 2 Bonfils Intubation Endoscope with tracheal tube loaded and portable LED light source

Returning to the U.K., I now had some insight into the potential of this rather unique instrument and the research project began to take shape. University Hospital Aintree NHS Trust like all large acute hospitals in the United Kingdom has a large elective and emergency case load. It also has one of the largest Head and Neck Oncology services in the European Union. It is also a principle anaesthetic training hospital for this region. The aims were to clarify what the Bonfils Intubation Endoscope would add to the management of routine and emergency patients in our institution, with special emphasis on Pharyngolaryngeal cancer treatment and to teach our trainees the indications and techniques of Bonfils intubation. The Bonfils Intubation Endoscope is now an integral part of a national difficult intubation course run quarterly from our hospital and is known as ADAM (Aintree Difficult Airway Management).

The first English publications regarding the Bonfils Intubation Endoscope were published by me in the *British Journal of Anaesthesia* in October 2002 and June 2003 as abstracts presentations to the Anaesthetic Research Society[17-19]. In these brief papers some basic data about intubation times, the concept of illustrating difficulty in instrument usage and learning curves were presented. Of note, there was a high success rate and a low intervention rate with rescue techniques such as jaw thrust. The median time to intubation was 33 s IQR (25-50 s). Another group from Guy's Hospital, London in correspondence in the *British Journal of Anaesthesia* in November 2003 did not enjoy such success[20]. They quoted a success rate of 31/36 (86%) and median time to intubation of 80s range (34-282 s). They encountered many difficulties none less than the issue of tissue distraction (i.e. making the airspace) which they found problematic in 28% of cases and serious fogging of the lens in 11%. It was suggested the Bonfils was a device for 'airway enthusiasts' rather than the regular anaesthetist. In reply, my greater success was put down to the use of camera and monitor system, better tissue distraction techniques and first hand demonstration by a competent user. One point that we were in full agreement on was the need for more well designed studies and peer reviewed research on new airway devices.

In November 2003, I published some of my work in the journal *Anaesthesia*. In this paper I described my experiences with the Bonfils Intubation Fibrescope. The intubations attempts (by two anaesthetists inexperienced using the device) of uncomplicated patients are examined. The techniques (slightly different for each anaesthetist) are carefully detailed. Observations made were success or failure, reasons for difficulty, complications, time to intubation and presence or absence of trauma. A learning curve was evident and for consistent intubation times of less than 30 seconds[21]. This paper is reproduced as part of the chapter one.

Section 2

I.

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A clinical evaluation of the Bonfils Intubation Fibrescope*

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Summary

The Bonfils Intubation Fibrescope is a rigid optical instrument for performing orotracheal intubation. We describe its introduction into our clinical practice in 60 patients with normal airways who required orotracheal intubation for elective surgery. Two anaesthetists each performed 30 attempts to intubate, in turn, in patients who received a standard general anaesthetic with neuromuscular blockade. Intubation was successful in 59 out of 60 cases. The median (IQR [range]) time to intubation was 33 s (24-50 [13-180] s). Median (IQR [range]) verbal rating score for difficulty was 2 (1-3 [0-10]). There was a significant correlation between the intubation times and the verbal rating score ($p < 0.01$). There was evidence of airway trauma in the single patient in whom intubation failed. The Bonfils Intubation Fibrescope is an effective instrument for orotracheal intubation in normal subjects.

Keywords: *Equipment*: Bonfils Intubation Fibrescope; endoscope. *Intubation,* tracheal.

The Bonfils Intubation Fibrescope is a rigid fibreoptic endoscope for performing orotracheal intubation, named after its designer Dr. P Bonfils (Inselspital Hospital, Bern, Switzerland). It has been available on a commercial basis since 1996 (Karl Storz Endoscopy Ltd.) but its use has been limited to a small number of centres [1*].

Our aim was to investigate the introduction of the device into our clinical practice in terms of efficacy, time to intubation, difficulties encountered and any evidence of airway trauma.

Figure 3 The Bonfils Intubation Fibrescope, with camera and light source attached, loaded with a tracheal tube

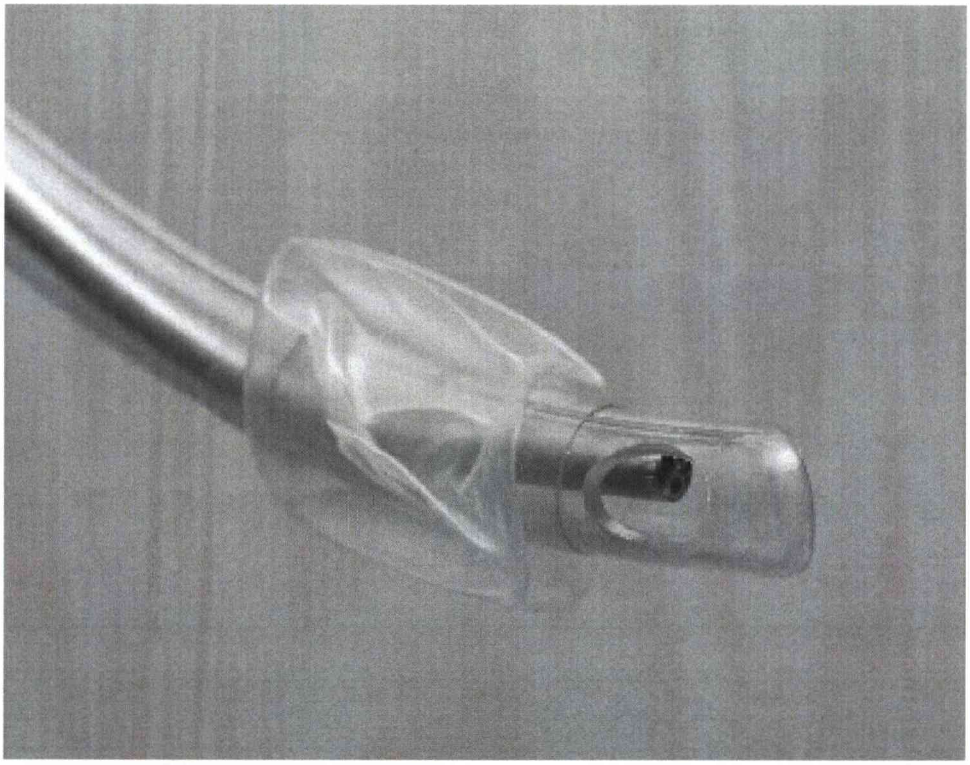

Figure 4 The tip of the Bonfils Intubation Fibrescope 0.5 cm within the lumen of the tracheal tube

Methods

The instrument has a long thin straight cylindrical body with a 40° curve a few centimetres from its distal end. The eyepiece is mounted at the proximal end and looks down fibreoptic bundles housed in the body (Figure 3). Illumination is via a connecting arm to a conventional light source or portable equivalent. A tracheal tube is loaded on to the body of the instrument and is pushed into a locking device that is adjusted so the distal end of the tube is just beyond the tip of the endoscope (Figure 4). As a result, the operator's effective view is looking out of the distal end of the tracheal tube. The shape of the instrument facilitates location of the laryngeal inlet. From this position, the operator advances the tube from the instrument through the vocal cords under direct vision. For this study, we chose to use a camera and video monitor system.

South Sefton Research Ethics Committee approved the study and all participants gave written, informed consent. Sixty patients requiring tracheal intubation for elective ear, nose and throat surgery were recruited. Exclusions were a history of difficult intubation, mouth opening < 3 cm and risk of gastric aspiration. The two authors performed all the intubations, the first 30 by MH and the second 30 by PC. All the subjects were interviewed and examined at the preoperative visit. Mallampati class as modified by Samsoon and Young [2*, 3*], interincisor distance (at maximum mouth opening) and the thyromental distance (at maximum neck extension) were recorded.

Since there is no recognised standard technique for using this instrument; we based our procedure on first-hand observation of a regular user of the instrument (Dr C Rudolph, University of Leipzig, Germany). Otherwise our exposure to the endoscope was deliberately limited before starting this study and we avoided practice attempts.

The patients were unpremedicated and received no antisialogogue. They lay supine with their heads in the neutral position on a small pillow. Standard monitoring including ECG, S_pO_2, non-invasive blood pressure, capnography and peripheral nerve stimulation were used. All patients were given intravenous midazolam 2 mg and pre-oxygenation performed for 3 min. Anaesthesia was induced with fentanyl 1 $\mu g.kg^{-1}$, Propofol 2.5 $mg.kg^{-1}$ and atracurium 0.5 $mg.kg^{-1}$. Thereafter their lungs were ventilated by hand using a Bain breathing system with Isoflurane 1.5% in oxygen for a further 3 min. When neuromuscular blockade was adequate as tested by train-of-four peripheral nerve stimulation, intubation was attempted.

A prepared endoscope with anti-fog solution on the lens and a tracheal tube loaded on the body was taken in the operator's right hand, and the left hand was used to open the patient's mouth and pull the mandible forward. The chin-lift manoeuvre used by MH was generally effective and usually able to raise the epiglottis to expose the laryngeal inlet; PC developed this further achieving a chin-and-tongue lift with his left thumb (Figure 5). The two authors used different techniques to advance the tip of the endoscope: MH used a midline approach using the uvula as a landmark and advanced staying in the midline until the epiglottis was reached, while PC employed a lateral approach advancing along the pharyngeal wall down to the level of the epiglottis. At the posterior pharyngeal wall the distal end was rotated in an anterior direction bring the epiglottis into view. The next step in the process was to advance the tip of the endoscope under the epiglottis (which may be adherent to the posterior pharyngeal wall). This was achieved by the following manoeuvres in a stepwise progression: chin lift; chin and tongue lift; external jaw thrust [4*]; jaw thrust with maximal neck extension; and finally assistance using the Macintosh laryngoscope. At this point the tube's tip was adjacent to the vocal cords and the release of the mandible did not alter this position. The left hand (now free) was then used to guide the tracheal tube onwards under vision. The correct position of the tube was confirmed in the usual manner.

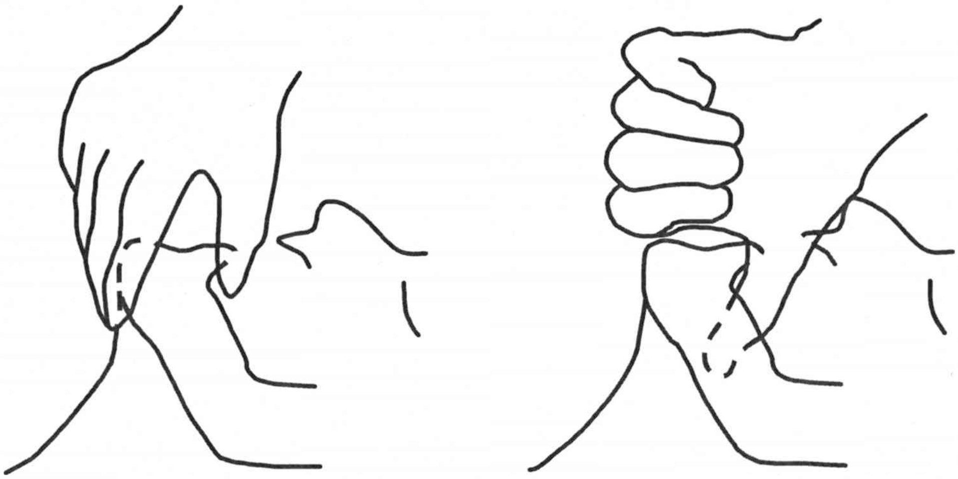

Figure 5 Schematic diagrams showing the difference in chin-lift (MH; left) and chin-and-tongue-lift (PC; right) manoeuvres.

The starting time of the intubation attempt was taken as the moment the instrument entered the subject's mouth. At 2 min, if there was no success, an assistant performed external jaw thrust by applying pressure at the angle of the mandible. Completed time to intubation was not recorded until it was confirmed by capnography. The maximum time allowed for each intubation attempt was 3 min. A fall of SpO_2 below 92% was a further criterion for abandoning the intubation attempt. Conventional laryngoscopy was used to check for the presence of bleeding or other injury when endoscopic intubation was successful, or to perform tracheal intubation in the case of failure.

We documented difficulty by means of a Verbal Rating Score (VRS; 0-10). This was influenced by patient factors, poor intubation technique and equipment factors. Freehand text notes were made at the time to explain these difficulties further. The relationship between the VRS and time to intubation was tested using the Pearson correlation coefficient.

Table 1 Characteristics of patients undergoing attempted orotracheal intubation using the Bonfils Intubation Fibrescope, by two different investigators (MH and PC). Values are mean (SD) or number (%).

	MH (n = 30)	PC (n = 30)
Age; years	33 (14)	37 (15)
Weight; kg	72.6 (15.5)	81.0 (14.4)
Sex; M:F	21:9	20:10
ASA Grade:		
1	26 (87%)	25 (83%)
2	4 (13%)	5 (17%)
>2	0	0
Mallampati Class:		
1	27 (90%)	23 (76%)
2	3 (10%)	5 (17%)
3	0	2 (7%)
4	0	0
Thyromental distance; cm	9.3 (1.5)	10.2 (1.2)
Interincisor distance; cm	5.1 (0.6)	5.2 (0.8)

Results

Characteristics of the patients studied are shown in Table 1. In all patients, SpO_2 remained satisfactory (> 92%) at all times. Endoscopic intubation was successful in 59/60 attempts, with median (IQR [range]) time to intubation for the 59 subjects 33 s (24-50 [13-180] s). The sequence of times taken for the individual anaesthetists is shown in Figure 6. Median (IQR [range]) time to intubation by MH in 30/30 was 44 s (32-55 [24-180] s) and by PC in 29/30 was 25 s (20-30 [13-86] s). The single failure was the only patient with any trauma to the airway. Minor difficulties, although frequent, were easily overcome and are summarised in Table 2. Median (IQR [range]) VRS for difficulty for the 60 subjects 2 (1-3 [0-10]). There was a significant correlation between intubation time and VRS ($p < 0.01$). External jaw thrust was used in three cases and gave an advantage in two.

Maximal neck extension was used on one occasion and was effective. The Macintosh laryngoscope was not required in any cases.

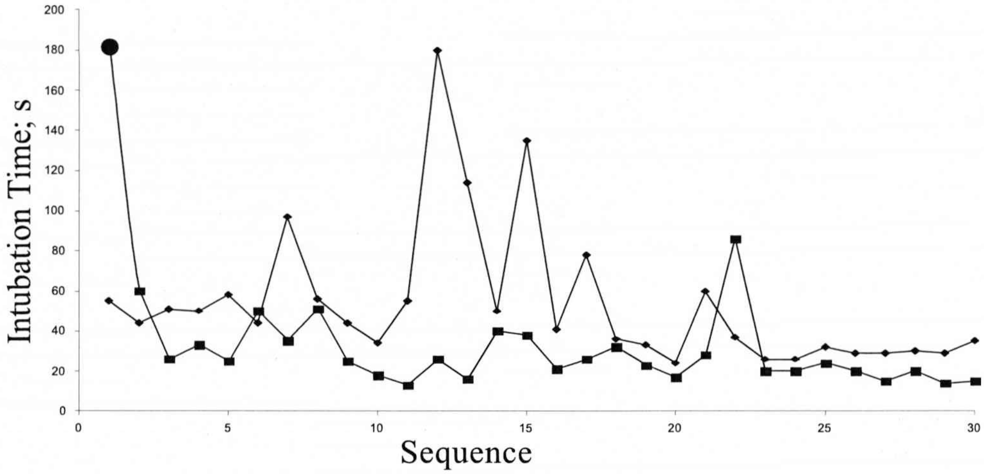

Figure 6 Intubation times for patients undergoing attempted orotracheal intubation using the Bonfils Intubation Fibrescope, by two different investigators: MH (♦) and PC (■) [nb in one patient (●) the attempt failed]

Discussion

In this small number of patients without anticipated difficulty, orotracheal intubation with the Bonfils Intubating Fibrescope was achieved in all but one. The relative ease in achieving intubation is reflected not only in the short intubation times but also in the low VRS for difficulty. It was clear however that the use of this endoscope is not intuitive and a learning process was evident from an early stage. Indeed, the failure with PC's first case supports this assertion. A previous report of these data looking at the intubation times suggested a learning experience of 20-25 cases [5*]. We have not attempted to compare the two authors' results formally because this was not planned as part of the initial protocol and the intubation techniques evolved during the course of the study. The second operator (PC) had the advantage of witnessing all of the first 30 attempts before commencing his 30 cases.

Creating space in the oropharynx for the instrument and lifting the epiglottis is an important aspect of its use. If the epiglottis is not lifted clear of the posterior pharyngeal wall, it is possible to use the endoscope as a rigid stylet, and sweep under the epiglottis and lift it forward to expose the laryngeal inlet. Similarly, it can be used to displace soft tissues such as large tonsils to one side as required.

Others have advocated the use of the Macintosh blade in combination with the endoscope in patients' whose tracheas are difficult to intubate [1*], although we did not use the Macintosh laryngoscope to assist us with any of our subjects.

Table 2 Difficulties encountered in 60 patients undergoing attempted orotracheal intubation using the Bonfils Intubation Fibrescope.

Patient factors:		
	Secretions reducing view	18 (30%)
	Difficulty getting scope tip under epiglottis	12 (20%)
	Heavy immobile mandible	4 (7%)
	Teeth; prominent incisors/crowns	3 (5%)
	Large tonsils reducing view	3 (5%)
	Edentulous; slight mandible	1 (2%)
Poor technique		
	Fogged lens* reducing view	7 (12%)
	Tube not loaded properly reducing view	3 (5%)
	Tangled light cable	2 (3%)
	Trolley too high	1 (2%)
	Camera loose	1 (2%)
	Incorrect hand grip	1 (2%)

*anti-fog solution used from n = 14 onwards

While it is possible to advance the endoscope some distance below the glottis into the trachea before releasing the tracheal tube, this is not recommended as it may be increase the risk of trauma, and was not practiced in this study. Upper airway trauma in normal patients after direct laryngoscopy with a Macintosh blade has been reported between 5% to 6.9% [6*, 7*]. Where a view of the glottis is limited, resulting in increased physical force and repeated intubation attempts, trauma is reported up to 17% [6*]. Difficult or awkward intubation represented approximately 4.3% of cases in one large Canadian study [8*]. Minimal trauma to the airway is one of the advantages claimed for the endoscope. This is supported by this study, as there was no evidence of bleeding or trauma other than in the one failed intubation (1.7%). Advancement of the tube under direct vision would be expected to avoid some of the complications associated with intubation using blind stylet devices [9*].

It is inevitable that some comparisons will be made with flexible fibreoptic laryngoscopes. It seems probable that the learning time for orotracheal intubation is shorter for the Bonfils endoscope than for fibreoptic nasotracheal intubation [10*]. The Bonfils scope is more robust and gives a larger and clearer image but with similar distortion. Although oral secretions were noted in 18/60 subjects (30%), the difficulty they caused was minor and they did not result in failed attempts; premedication with anticholinergic drugs is therefore unnecessary. Railroading of the tracheal tube is more straightforward than with the flexible fibreoptic laryngoscope [11*]. The instrument is however not suitable for nasal intubation. The configuration of its injection port and working channel does not allow a wire to be passed as a guide for catheters/tracheal tubes, as has been described for flexible fibrescopes [12*]. We have no experience using the endoscope for 'awake intubation but this is possible. [1*]

There are many other optical laryngoscopes and stylet intubation devices available. The Bullard laryngoscope has a curved blade that elevates the epiglottis directly and permits a view of the laryngeal opening. It has also been advocated for situations in which little or no neck movement is appropriate, for example in cases of cervical spine injury [13*]. The UpsherScope [14*] is somewhat similar to the Bullard but its blade's tip is placed in the valleculum, and the WuScope [15*] is a similar design concept. These laryngoscopes may feel familiar to anaesthetists because their blade incorporates the 'Macintosh curve' but difficulties have been noted when advancing tracheal tubes, largely because the view is 'off field' compared with the central of view obtained with the Bonfils device. Lightwands are similar in shape to the Bonfils endoscope but are blind intubating devices. Other fibreoptic stylets are designed for use with conventional laryngoscopes [16*].

The clinical role for the Bonfils endoscope, particularly in respect of difficult intubation, has yet to be determined, but some speculation based on our limited exposure is reasonable. We have become progressively more impressed with its effectiveness over time. The view from immediately above the glottis and into the subglottis is very impressive when compared with conventional laryngoscopy. Because less postural adjustment is necessary it may have advantages for patients with limited cervical spine movement. Others have suggested it may have a role in unanticipated difficult intubations [1*]. Finally, the authors believe that clinical experience with the device is critical and that training with currently available manikins is of limited use.

Section 2

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References for Section 2 (I) only.

Appendix B (I) for Data Collection Sheet

Section 2

III. Objective assessment of a Difficult Bonfils Intubation.

Defining what makes intubation difficult and comparing intubations on different patients has always been a problem for researchers[22]. The Bonfils Difficulty Score (BDS) is a proposed novel scoring system based on components associated with intubation difficulty. A post-hoc analysis concentrating on the patient factors (based on free-text comments) that contributed to the difficulty were identified and compiled. The presence or absence of airspace in the oropharynx and how that space is created is the first issue. Access to the epiglottis and how the epiglottis is negotiated is the second issue. The 4 components of these 2 issues are the basis of the score.

Each of the components of an intubation attempt and is scored as:

0 = No problem,

1 = A minor problem,

2 = A major problem and

3 = An impossible problem for the 'Bonfils' unaided to deal with.

By the summation of these parts a more objective score from 0 to 12 is calculated (table 3).

Table 3 Bonfils Difficulty Score. The sum of the four component scores gives the total.

Component		Score
Space available		
	Normal	0
	Minor reduction or easily improved	1
	Major reduction not easily improved	2
	No space (continuous red-out)	3
Manoeuvres required		
	Usual left hand techniques only	0
	Assisted jaw thrust	1
	Jaw thrust and maximal neck extension	2
	Macintosh blade assisted	3
Access to Epiglottis		
	No problem	0
	Minor (e.g. large tonsils)	1
	Major (e.g. generalised soft tissue excess)	2
	Impossible	3
Lifting of Epiglottis		
	No unusual manoeuvres required	0
	Minor Tube / scope flip adequate	1
	Major Tube / scope elevation required	2
	Impossible to lift epiglottis	3

The Bonfils Difficulty Score was validated for this data set by looking at the relationship with the established but subjective Verbal Rating Score. The relationship between VRS and BDS was plotted on a 'sunflower' scatter plot (SPSS, version 11.0) using number of 'petals' to represent cases. By comparison the median BDS was 0 (interquartile range [range]) (0-1[0-3]). These much lower values represent a more critical assessment of the intubating components contributing difficulty. The two measures were broadly comparable as demonstrated in the scatter plot (Fig. 7). Further assessment of the BDS looking at the relationship to time to intubation and other surrogate markers of difficulty is explored in Appendix B (III, IV).

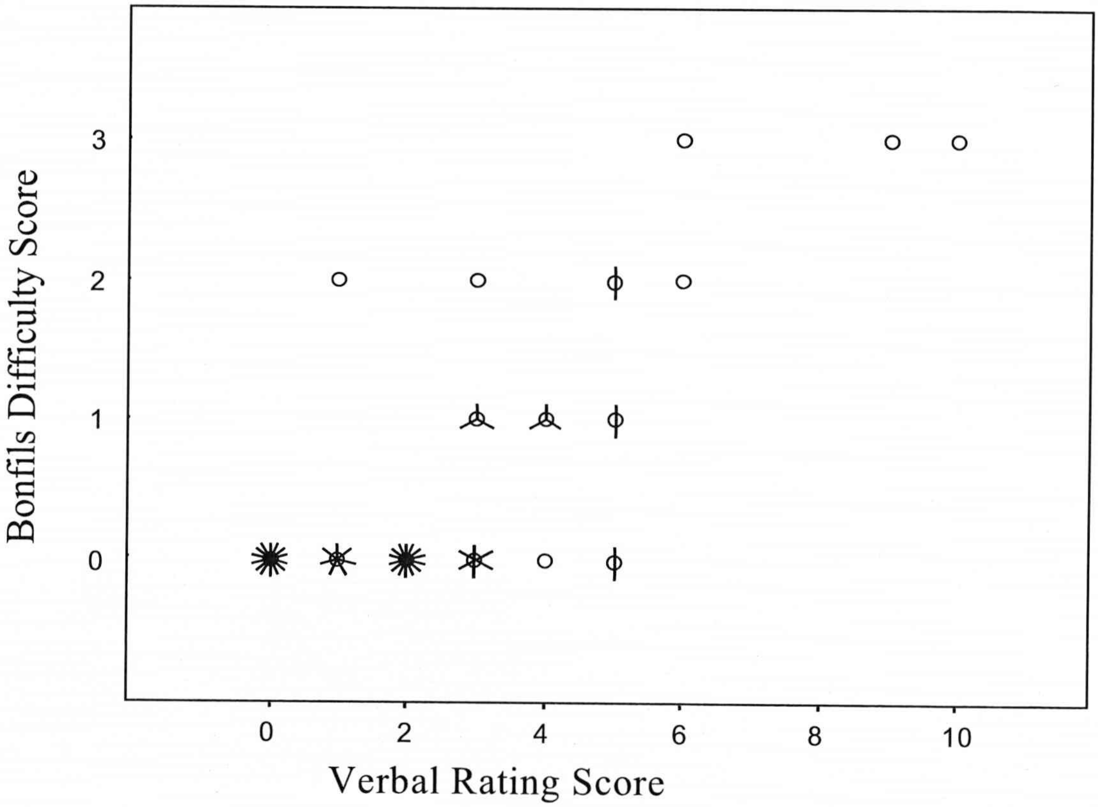

Figure 7 The relationship between VRS and BDS was plotted on a "sunflower" scatter plot (O represents a single subject and each petal the number otherwise)

The reason for creating the BDS was to compare objectively Bonfils intubations in a similar fashion to the Cormack and Lehane grade or Adnet's Intubation Difficulty Scale for direct Machintosh laryngoscopy[23, 24]. The BDS is used in chapter 2 and 3.

Section 3

I. Foreward

Experience and confidence with the Bonfils Intubation Endoscope was quickly acquired. The full potential and an insight into the boundaries of its effectiveness began to be realised. The views of the airway were far better than those seen in Macintosh and flexible fiberoptic laryngoscopy. Bonfils Endoscope displays a more panoramic view especially when used with camera and monitor systems. The ability to get within millimetres of your target is also achievable. The important manoeuvres were creating space in the airway and controlling the epiglottis. But what if there was a potentially interfering force? A clinical assessment of cricoid pressure would examine some of these issues. It would also be an opportunity to demonstrate the excellent optics and attain high quality images of the effect of cricoid pressure. Some of these findings were presented to the Difficult Airway Society (DAS) Meeting in Glasgow December 2003.

Section 3

II. Intubation and Endoscopy capabilities of the Bonfils Device with Cricoid Pressure applied.

The Bonfils Intubation Endoscope is a rigid fibreoptic laryngoscope that has been demonstrated to aid in the management of difficult intubations. Difficult intubations are more common in the emergency setting than the elective one[7]. It has been shown to be superior to the Macintosh laryngoscope in visualising the larynx in patient's immobilised with rigid cervical collars[25]. The Bonfils has many advocates for its use in the trauma setting[26].

Opening up the airway is the key for a successful Bonfils endoscopy and intubation. This is achieved by a combination of chin lift manoeuvres and traction on submandibular soft tissues. The ultimate result of this manipulation is to lift the epiglottis away from the posterior pharyngeal wall. This is a predominately upward force where as cricoid pressure is downwards and applied close by (figure 8). In the United Kingdom the application of cricoid pressure is standard anaesthetic practice if a patient is suspected of being at risk of aspiration of gastric contents[27]. It was imperative therefore that the Bonfils was examined under these conditions.

With the Bonfils good visualisation of the upper airway is possible with minimal tissue displacement. Consequently, it was considered a suitable instrument for the assessment of the effect on the airway of cricoid pressure. Previous attempts to do this could be criticised because many of the laryngoscopy methods put substantial forces on the tissues and laryngeal structures therefore influencing what was being observed[28].

Methods

Local Research Ethics Committee approved the study and all participants gave written, informed consent. Twenty patients requiring tracheal intubation for elective ENT surgery were recruited. Exclusions were a history of difficult intubation, mouth opening < 3 cm and risk of gastric aspiration. The author performed all the Bonfils intubations and these were observed by the second anaesthetist. All the subjects were interviewed and examined at the preoperative visit. Mallampati class[29], inter incisor distance and the thyromental distance were recorded. Patient details are shown in (table 4).

Table 4 Characteristics of patients undergoing attempted orotracheal intubation using the Bonfils Intubation Endoscope, with Cricoid Pressure Applied. Values are mean (SD) or number (%).

	(n = 20)
Age; years	32 (12)
Weight; kg	78 (14)
Sex; M:F	11:9
ASA Grade:	
1	18 (90%)
2	2(10%)
>2	0
Mallampati Class:	
1	18 (90%)
2	2 (10%)
3	0
4	0
Thyromental distance; cm	10.3 (1.8)
Interincisor distance; cm	5.1 (0.8)

The Bonfils Intubation Endoscope was prepared for use. The tracheal tube was loaded on to the body of the instrument so the end of the tracheal tube was slightly distal to the lens. As a result, the operator's effective view is looking out of the tracheal tube. For this study a camera and video monitor system were used. Anaesthesia was induced after a period of preoxygenation using midazolam 2mg, Fentanyl 1.5μg kg^{-1}, Propofol 2.5mg.kg^{-1} and Rocuronium 0.6 mg.kg^{-1} (or Mivacurium 0.2 mg.kg^{-1} for short procedures). Bag/mask ventilation with 1.5% Isoflurane in oxygen was continued until adequate neuromuscular blockade was confirmed by peripheral nerve stimulation (TOF). Two minutes was allowed for Bonfils Endoscopy and successful intubation. Reasons to abandon the procedure were: exceeding time limit, a drop in $SpO_2 < 92\%$ or any other safety issue. Cricoid pressure was to be removed and any other manoeuvres deeded helpful such as application of jaw thrust by a third party or duel laryngoscopy with Macintosh blade.

First a control endoscopy was recorded to observe the airway undisturbed. Four qualified Operating Department Personnel (ODP) with 2,3,10 and 15 years of experience respectively, were chosen to each perform their typical cricoid pressure technique on 5 patients. All stood on the patient's right side and used a right single-handed technique. They were blinded to the evaluations. These technicians were questioned as to the ease or difficulty of identifying the cricoid cartilage. The technician's hand was kept in position and the pressure was relaxed when the Bonfils had a view of each of the three assessment levels. This on/off/on sequence presented us with the opportunity to make 2 observations at each level, therefore ensuring consistency of the pressure effect (Fig 9).

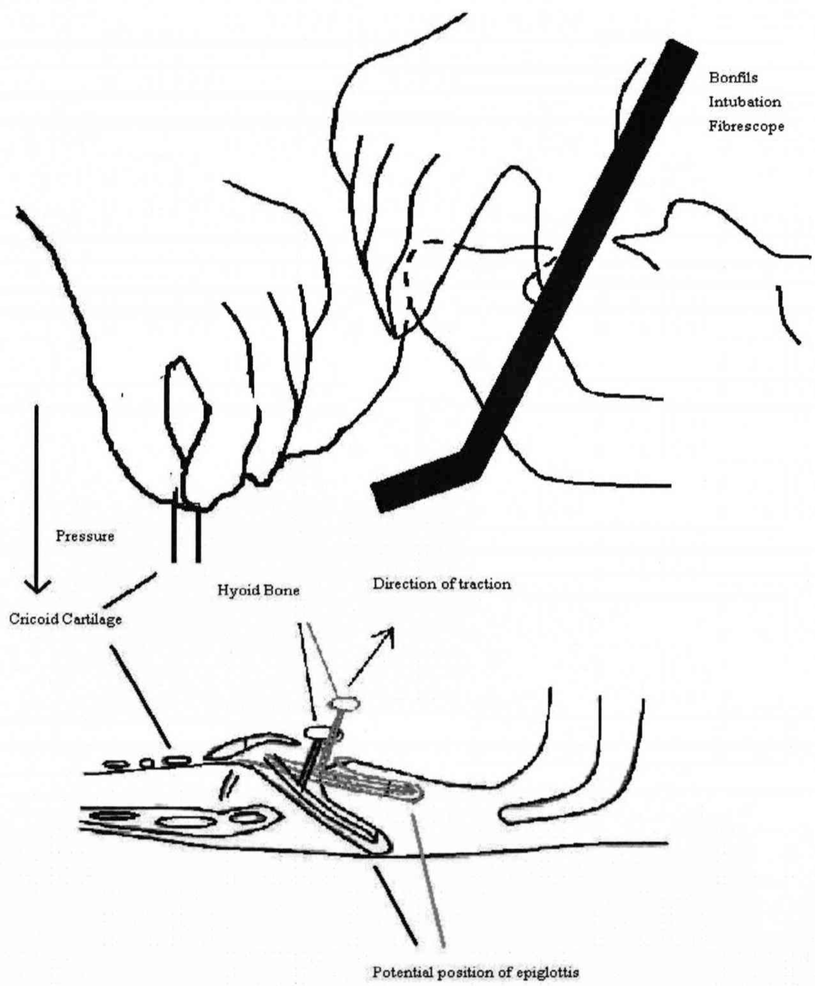

Figure 8 Anaesthetist's Left Hand provides chin lift and soft tissue traction while the technician's right hand performs cricoid pressure

Figure 9a Epiglottis without Cricoid Press

Figure 9b Epiglottis with Cricoid Pressure

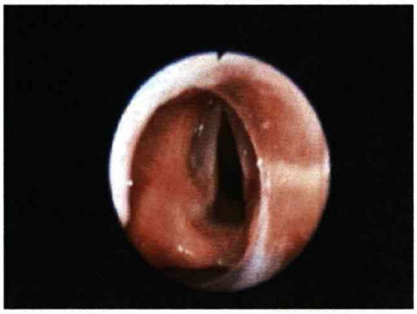

Figure 9c Laryngeal Inlet without Cricoid Pressure

Figure 9d Laryngeal Inlet with Cricoid Pressure

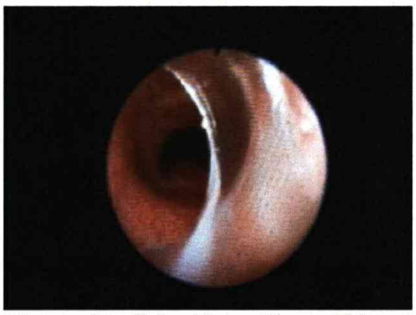

Figure 9e Cricoid cartilage without Cricoid Pressure

Figure 9f Cricoid Cartilage with Cricoid Pressure

Figure 9 Images captured from video recording of intubation show the effect of cricoid pressure on the airway

The Bonfils was advanced to the midline until a view of the epiglottis was achieved. This was the first assessment position. If the epiglottis was in close proximity to the posterior pharyngeal wall and proved difficult to negotiate a sideways manoeuvre was employed, the tip of the Bonfils was moved into a para-epiglottic position and 'flicked' to the midline. The second assessment position was a close up view of the laryngeal inlet. The third assessment position the view of the cricoid level having advanced the tracheal tube through the vocal cords. At this stage chin lift is no longer necessary and the tube is advanced off the Bonfils into the trachea by the left hand. Digital video (Sony DSR-20MDP, version 2.6.00) recordings were made and the data files downloaded to a laptop computer. Subjective observations were noted at the time during laryngoscopy. Numerical and motion descriptive analysis was performed at subsequent review of the video footage completed off-line with suitable software (Sony 'DVgate Motion'). The scoring scheme used was as indicated in Table 1.

Table 5 Measurement system via off-line video recordings

Level	Displacement	Scores	Details
Epiglottis	Rostral or Posterior	0, 1-5	0 = none; 1 = 1 - 20%; 2 = 21-40%, etc
Larynx	Inlet compression	0, 1-5	0 = none; 1 = 1 - 20%; 2=21-40%, etc
Cricoid	Cricoid compression	0, 1-5	0 = none; 1 = 1 - 20%; 2=21-40%, etc

The Bonfils Difficulty Score (BDS) was documented for the control endoscopy (No-Cricoid BDS) and again when cricoid pressure was applied (Cricoid BDS).

Once the real time and off line scoring were complete the data were classified and exported to SPSS v 13.0 for Windows (SPSS Inc., Chicago, IL, USA) for subsequent analysis.

Results

In two patients the pressure was relaxed, one because of the inability to get around the epiglottis (but reapplied once beyond epiglottis) the other was for safety reasons due to unexpected haemorrhage from a tonsillar tumour. Distortion of the airway as a result of cricoid pressure occurred at some level to some degree in all patients in whom this could be assessed (n=19). Another patient had minor contact bleeding from the left arytenoid cartilage which interfered with subglottic view. Therefore, we managed 19 epiglottic observations 19 inlet observations and 17 cricoid observations (2 bleeding, 1 fogged lens).

18 out of 20 (90%) patients were successfully intubated following the protocol. The mean (SD) for Bonfils Difficulty Score without cricoid pressure was 0.7 (1.8)

and with cricoid pressure applied 1.9 (2.1) this was significant $p<0.001$ Paired Samples t-test.

Movement of the epiglottis either against the posterior pharyngeal wall or rostrally towards the scope occurred in 8/19. The major influence in determining whether this occurred appeared to be the technician applying the cricoid pressure. Table 6 demonstrates scores for epiglottic displacement for each technician. If we look at mean epiglottic movement score for the ODPs; 1 scored 1.75 while the other 3 had an average score of 0.4. Friedman's test confirmed differences between ODPs (p=0.031).

Table 6. Displacement of epiglottis due to cricoid pressure per ODP (years experience) n=19.

Technician	Movement scores					
	0	1	2	3	n	Mean
ODP(2)	4	-	1	-	5	0.4
ODP(3)	3	2	-	-	5	0.4
ODP(15)	3	2	-	-	5	0.4
ODP(10)	1	-	2	1	4	1.75

Analysis of compression at the level of the laryngeal inlet and the cricoid cartilage are analysed individually and together and provide the some notable results. Compression at the level of the cricoid cartilage occurred in 15/17 observations and was greater than 80% airway occlusion in 4 patients. Compression at the level of the laryngeal inlet occurred in 15/19 observations and was greater than 80% airway occlusion in 6 patients. Near complete occlusion occurred in one patient at the cricoid cartilage and in two patients at the laryngeal inlet (fig. 10). Neither distribution was normal (Shapiro-Wilks test, p= 0.03 and p= 0.021 respectively). There was no correlation between compression at the cricoid and inlet (p=0.25).

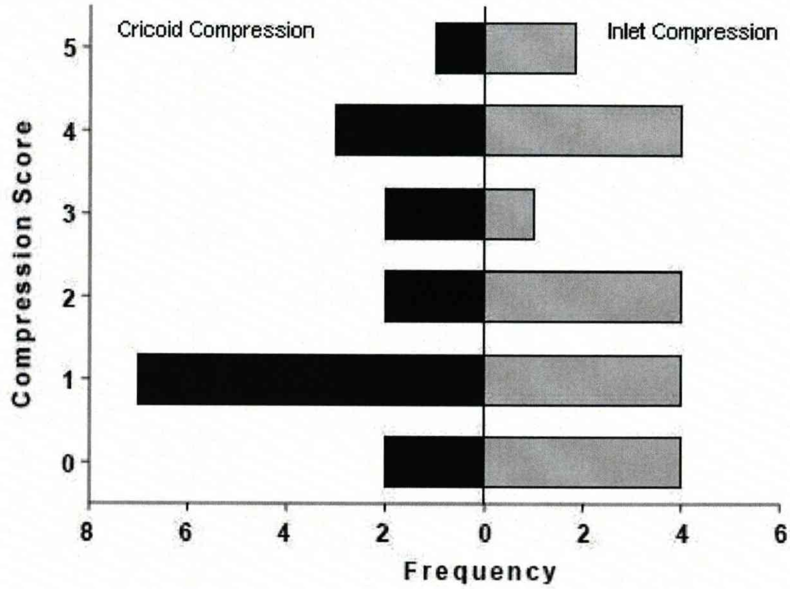

Figure 10 Cricoid (L) and Inlet (R) compression as a result of cricoid pressure. As this chart shows the effect is widespread and resulting obstruction is variable.

Supplement analysis of the effect of cricoid pressure is contained in Appendix C (III).

Discussion

There has been somewhat of an explosion in intubation and airway management equipment over the last decade[30]. Most of the new intubation equipment incorporates some optical technology to give the user an advantage visualising the larynx[8]. Experience with the use of these devices and the application of cricoid pressure is mixed Pandit and Popat et al were successful when they used the flexible fibrescope for orotracheal intubation[31]. Other have had limited success[32, 33]. There are also a number of supraglottic airways, which maintain a patent airway under anaesthesia by sitting above the laryngeal inlet. These devices although not strictly designed to maintain an airway when cricoid pressure is applied are often used as rescue devices for failed intubations[34, 35]. If we can appreciate the effect cricoid pressure has on the airway we will have a better insight into their performance[36-38].

There is no universal technique of application of cricoid pressure[39]. Controversy remains over single handed or bimanual technique, head and neck position, degree of force or the use of devices such as cricoid yokes[40-42]. All this goes to show how difficult it is to standardise cricoid pressure. It is also documented that anaesthetic assistants vary greatly in there knowledge and ability to apply cricoid pressure[43]. In this study we decide to err on the side of clinical realism. The only monitor of correct cricoid pressure was the ODP stating that they were 'happy' with their position and the observation of a consultant anaesthetist ensuring that the procedure appeared correct. There was no attempt to adjust their cricoid pressure based either on the video image obtained or any communication with the anaesthetist. The temporary release of pressure at each level before proceeding to the next worked well. The two observations of pressure applied at each level were always very similar.

The video images recorded were of very high quality especially the views of the subglottis and ensured detailed analysis. The incidence of airway distortion was high and the location was widespread, all 19 completed observations had some cricoid pressure effects at some level. Epiglottic movement to a less favourable position occurred in 8/19 (42%) of observations. In three of these it was > 60% closer to the posterior pharyngeal wall. In one attempt it proved too difficult to get around the epiglottis and the pressure had to be relaxed. The absolute failure rate was 10%, however, if we ignore the case abandoned due to bleeding the failure rate is halved to 5% which is somewhat more acceptable. The effects at the laryngeal inlet and at the cricoid cartilage are equally impressive as over 10 patients had >80% obstruction, which has implications for supraglottic airway devices.

The Bonfils Difficulty Score (BDS), not surprisingly, was significantly affected by cricoid pressure as it is based primarily on epiglottic access and manoeuvrability. Distortion at the level of the laryngeal inlet and cricoid cartilage although frequent, has less impact on Bonfils Endoscopy because of the rigidity of the instrument and the ability to push through narrow openings. This is not the case for flexible fibrescopes or large tracheal tubes.

The forces involved with Bonfils endoscopy are only a fraction of those employed during Macintosh laryngoscopy where the entire larynx is lifted forward and the base of the tongue is compressed into the submandibular space[44]. Any effect of cricoid pressure on the epiglottis or supraglottis in this generally speaking overcome by these forces. Any study on the airway distortion of cricoid pressure with Macintosh laryngoscopy can not be extrapolated to other airway devices[28].

Finally, the logical conclusion in the authors view is therefore to use a Macintosh Laryngoscope in combination with the Bonfils Endoscope when cricoid pressure is to be applied to enjoy the advantages of both instruments.

The Bonfils endoscopy skills necessary to overcome cricoid pressure were probably greater than anticipated in a few cases. This study gave me confidence to tackle patients with more challenging problems. Of course the problems caused by cricoid pressure were reversible, those caused by pathology such as tumours are not.

Appendix A Sample video (CD ROM)

Appendix C (I) Data Collection Sheet, Video Captures, and further analysis.

Section 4

I. Foreword

My experiences with the Bonfils Intubation Endoscope and the distortion caused by cricoid pressure were very helpful in the next study. Indeed two of the patients in the cricoid pressure effect study had airway tumours. Other similarities could be drawn, the distortion can be at any level, the epiglottis may be displaced to a less advantageous position, the glottis is frequently closed and requires a push through to enter the trachea and the subglottis needs to be visualised. Also high quality video footage would aid analysis. These exciting developments were published by me in the *British Journal of Anaesthesia* in April 2004 as an abstract for a presentation given to the Anaesthetic Research Society[45], and also presented as a free paper at the Difficult Airway Society (DAS) meeting in Leicester in November 2004. The use of the Bonfils in this difficult and potential very high risk clinical scenario was very successful.

Section 4

II. The Anaesthetic Management of Pharyngolaryngeal tumours using the Bonfils Intubation Fibrescope

The anaesthetic management of patients with pharyngolaryngeal tumours is a cause of great apprehension for anaesthetists[46]. Many authoritative reports and editorials have emphasised the need for senior help, use of the appropriate equipment and techniques and having an experienced surgeon on hand[47, 48]. The symptoms that these patients have are dependant on the size and location of the mass. In this study we came across the full range from totally asymptomatic, to partially obstructed upper airway with inspiratory stridor. The worst patients had difficulty lying supine. Many were very anxious and had co-morbidities associated with life long heavy smoking and alcohol consumption.

Pharyngolaryngeal tumours cause problems in a number of ways[49]. They are hard rigid structures which tend to destroy landmarks, cause localised oedema, fix surrounding tissues and distort the anatomy. They may obstruct the view of the laryngeal inlet. They tend to be very friable and bleed easily when disturbed. They may inhibit passage of a tracheal tube. These are often not straight forward cases and a high proficiency level is required no matter what technique is chosen.

It is suggested that the Bonfils Intubation Endoscope allows a non-traumatic, careful endoscopy followed by a precise positioning of the tip of the tracheal tube at the exact position that the airway opens[21]. The rigidity of the Bonfils may be required to push past the tumour if it encroaches on the laryngeal inlet. This study is designed to examine the merits of the Bonfils Intubation Endoscope and compare the view of the tumour and of the laryngeal inlet to that obtained by Macintosh laryngoscopy[23].

Figure 11 (a) Epiglottis

Figure 11 (b) Laryngeal Inlet

Figure 11 (c) Airway Opening

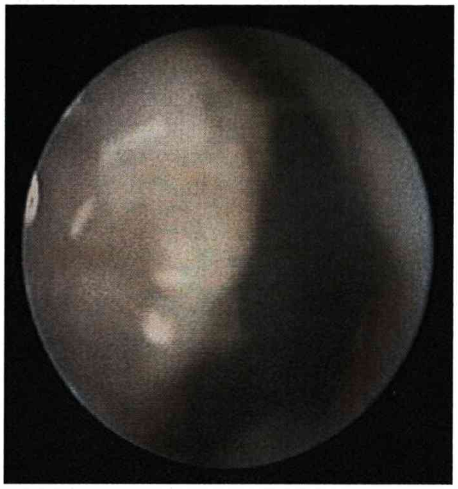

Figure 11 (d) Push Through Vocal Cords

Figure 11 Images [a,b,c,d] are taken sequentially from the same intubation video. They demonstrate the excellent view of the airway, the capacity to appreciate the tumour mass, to edge millimetres at a time seeking the airway opening, to avoid contact bleeding and the facility to push thought in the trachea

Methods

Local Research Ethics Committee approved the study and all participants gave written, informed consent. Forty-one patients (33 Male, 8 Female) with known Pharyngolaryngeal tumours were recruited. The median (IQR [range]) age was 58 y (46-70 [17-85] y). All cases were elective or semi-elective in nature. There were no particular exclusion criteria. All possible sources of information regarding the tumour were documented such as radiology reports, letters from other hospitals, and previous examinations under anaesthesia or awake out-patient nasendoscopy (Table 7). Any anticipated problems with airway maintenance and intubation were recorded.

Table 7 Breakdown of tumours by location.

General Position of tumour	N
Epiglottis, Base of Tongue, Piriform Fossa (Supraglottic)	13
Vocal Cords & Laryngeal Inlet (Glottic)	13
Bellow Vocal Cords (Subglottic)	1
Pharyngeal Wall and Tonsillar area	12
Extensive (Pharynx to Glottis)	1
No Tumour Visible	1

All the intubations were preformed by me. A second anaesthetist was also in attendance to administer the anaesthetic drugs and help with the video recording and equipment. Standard monitoring and a period of preoxygenation was used on all patients. The technique of choice was total intravenous anaesthesia without use of neuromuscular blockade (NMB) (n=32). The regime was Remifentanil 1μg.kg^{-1} bolus follow by an infusion of 0.15 g.kg^{-1}.min^{-1} and Propofol target controlled infusion to 4 ng.ml^{-1} over three minutes. The patients were oxygenated by gentle bag/mask ventilation during this time. Manipulation of the airway was commenced when the patient was deemed deep enough as judged by relaxation of Masseter muscle tone. Neuromuscular blockade was usually administered after intubation. In some of the younger and fitter patients who were generally asymptomatic NMB was administered before airway manipulation (n=6). Gas induction was given to three patients who had tracheostomies in situ.

Once under anaesthesia a Macintosh laryngoscopy was performed. The grade of Macintosh laryngoscopy was recorded as was the view of the tumour. If necessary, the oropharynx was cleared of secretions by suctioning. After brief bag/mask ventilation the Bonfils endoscopy and intubation was commenced. A systematic airway endoscopy was performed and the patient was intubated. Video recording were made of all the endoscopies for delayed re-analysis and research documentation. A subjective comparison was made of Macintosh and Bonfils Laryngoscopy for each patient, with emphasis on what could be seen and the likelihood a successful intubation. Difficulty with the Bonfils was scored using the Bonfils Difficulty Score and free text. All the many items of descriptive data were collected in spreadsheet, EXCEL (Microsoft, WA, USA), numerical data exported to SPSS v 13.0 for Windows (SPSS Inc., Chicago, IL, USA) for subsequent analysis.

Results

All 41 patients where successfully intubated using the Bonfils Intubation Endoscope. In one case a Macintosh laryngoscope had to be used with the Bonfils because it was impossible to lift the epiglottis from the posterior pharyngeal wall without assistance. Although the airway survey and intubation were not formally timed, no video was longer than three minutes the majority were between one and two minutes. In this difficult patient group the Machintosh struggled. A good view of the glottic opening Cormack and Lehane grade I or II was achieved in 27/41 patients (Table 8).

Table 8 Macintosh Laryngoscopy v Bonfils Intubation Endoscope view of laryngeal inlet

Glottis View †	Macintosh	Bonfils
C&L I	14	40
C&L II	13	0
C&L III	11	1*
C&L IV	3	0

† Cormack and Lehane grade view of glottis (where possible not taking tumour into account).

* Macintosh assistance required

Remifentanil and Propofol infusions were used in 32/41 cases. In six of these there was some difficulty in performing bag/mask ventilation, with one case of oxygen desaturation to 88%. It is impossible to say if this was as a result of inadequate anaesthesia or due to the location of the tumour but in four out of six cases the patient had a very large laryngeal or close-by tumour. There was no record of difficulty in the cases given NMB as part of their induction of anaesthesia. The Bonfils far out performed the Macintosh not only in the view of the Laryngeal inlet but in its overall appreciation of the pathology. In 17/41 (41%) cases the intubation would have been very difficult for a Macintosh laryngoscope. The Bonfils out performed the Machintosh in 30/41 (73%) of cases in this study

(Table 9). In many cases the unique features of the Bonfils were required for a successful intubation.

Table 9 Comparison of Macintosh and Bonfils Laryngoscopes in the management of patients with laryngopharyngeal tumours.

Comparsion	N	Comment
B=M	10* (25%)	Small vocal cord, tonsillar or pharyngeal, Small base of tongue tumours
B>M	13 (32%)	Advantage generally in tumour view rather than ability to intubate the patient
B>>M	17 (41%)	Mainly large tumours the involving the glottis, also patients who have had previous surgery or radiotherapy
M>B	1 (2%)	Small Vocal Cord tumour in 120kg man, Difficulty Bonfils under TIVA conditions
M>>B	0	

* In one case (a very large base of tongue tumour) the epiglottis couldn't be lifted without the assistance of a Macintosh Blade. View with the Macintosh alone was Grade 4.

B=M: Bonfils and Macintosh equally effective
B>M: Bonfils slightly better but both techniques feasible.
B>>M: Bonfils far superior, Macintosh intubation would be very difficult
M>B : Macintosh slightly better but both feasible
M>>B : Macintosh Far Superior. Bonfils would have been very difficult

The principle reasons for the superiority of the Bonfils was it's rigidity, its optics, the capacity to see the subglottis, the lack of trauma and bleeding and its ability to convert a usually difficult laryngoscopy, into a relatively easy one (Table 10). It was usually a combination of all these factors that supported use of the Bonfils.

Table 10 Principle reason for preferring Bonfils over Macintosh Laryngoscope

Cause	Cases No.	n	Comment
Rigidity	1,6,14,16,19,20,22,32,39,40	10	Large tumours partially obstructing laryngeal inlet, Push through required.
View	3,8,15	3	Tumour not well seen by Macintosh
Subglottis	13,27	2	Tumour in Subglottis
Bleeding	4,5,12	3	Macintosh caused bleeding
History	10,18,25,32,36,37,41	7	Difficult laryngoscopy previous surgery, radiotherapy or other

Although Bonfils intubation was successful it was not without difficulty in some cases. The median (IQR [range]) for Bonfils Difficulty Score was 0 (0-2 [0-10]) and Cormack and Lehane Grade was 2 (1-3 [1-4]). On closer analysis there was an association between BDS and C&L grades. Perhaps this is not surprising as both relay on space in the oropharynx. A large tongue pushing down the epiglottis or a tumour fixing the epiglottic position will make both modalities difficult.

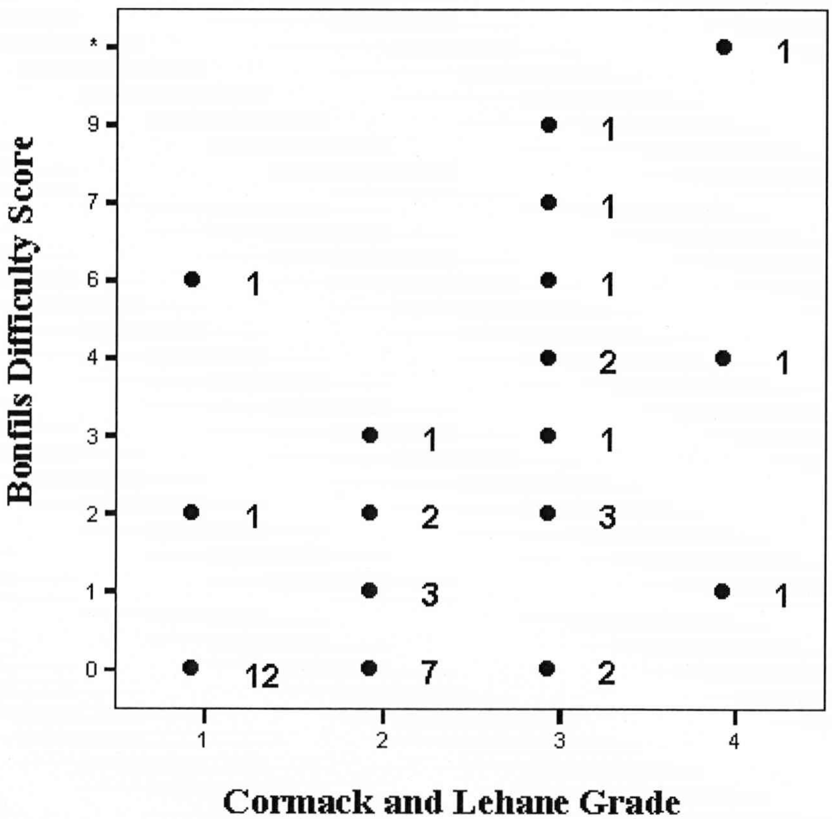

Figure 12 Comparison BDS versus C&L (Values represent number of cases) for 41 pharyngolaryngeal tumour patients. Difficult Macintosh laryngoscopies tended to be relatively more difficult Bonfils intubations.

C&L and BDS are correlated, F=17.792 (p<0.01). [BDS]= -1.385+ [C&L]*1.515

Discussion

A key message in the NCEPOD 1996/7 report section on head and neck surgery was that the management of the partially obstructed airway gave cause for concern[47]. It stressed the need for experienced anaesthetists and surgeons working together using the appropriate equipment. Considering the difficulties associated with the anaesthetic management of patients with pharyngolaryngeal tumours there are remarkably few studies in the literature[50, 51]. What is published is generally opinion rather than evidence based and there are many case reports[52]. Anaesthetists are inclined to have set ideas on how to handle these potentially difficult intubations and are unwilling to try new techniques which may be viewed as some what of a gamble. These patients tend to be treated in tertiary referral centres and are uncommon in other hospitals therefore, many anaesthetists don't have much experience dealing with them. There is a perception that these patients are difficult to recruit for studies although my experience was the very opposite. I didn't have any refusals; in fact the patients were reassured when the new approach was explained to them.

There are of course degrees of airway obstruction and few would disagree that the most critical cases require an awake tracheostomy performed by an experienced surgeon under local anaesthesia. These patients present with severe inspiratory stridor and respiratory distress. They are emergencies treated immediately with Heliox and brought straight to theatre. In less critical cases there is more debate about the appropriate treatment. There is some reluctance among surgeons for performing temporary tracheostomies particularly if further surgery is planned[53]. There is an incidence of tumour seeding at the tracheostomy site, there is the risk of tumour extending into the subglottic space and awake tracheostomy on an anxious distressed patient is difficult for surgeon and patient. Often a debulking of tumour is the treatment of choice[51]. The majority of patients present with partial obstructions rather than critical ones and there is time for preoperative investigations such as nasendoscopy and MRI scans. If intubation is the preferred method of securing the airway, the choice is between general anaesthetic and awake techniques. Awake fibreoptic intubation has the advantage of avoiding apnoea but is not without difficulty. A larger friable tumour can make the endoscopy very difficult. The landmarks that are so important for flexible endoscopy are often destroyed. Bleeding will cause a 'red out' and render the procedure impossible. The laryngeal inlet may be very narrow and not take the insertion cord of the scope. The tracheal tube may be impossible to railroad. Application of local anaesthetic may precipitate airway obstruction. However, there is very little lost by a quick endoscopy with a flexible fibrescope to get a real time visualisation of the mass and if possible proceed to intubation. General anaesthesia is achieved either by inhalational or intravenous induction. The case for an inhalational technique is that breathing is maintained and therefore, if the attempt fails the anaesthetic is easily and quickly reversed. It has many advocates and is recognised as the textbook answer to this problem[48]. Partial airway obstruction however, makes it difficult to deepen a patient and also hinders the blow off of anaesthetic gases necessary for awakening. It is easy to get caught at a level of anaesthesia where the patient is too light to attempt intubation but is apnoeic. These patients are very prone to experience laryngospasm and suffer arterial oxygen desaturation. The technique chosen for this study was the combination of Remifentanil and Propofol infusions. We argued that this gave us the most reliable depth of anaesthesia but could also be reversed if intubation failed[54-56]. We performed Bonfils endoscopy at a level of anaesthesia lighter than a typical bolus intravenous induction. We had a very low incidence of laryngospasm in this group of patients most of whom were COPD with reactive airways. Apnoea was a consequence of the technique and bag/mask ventilation was required. 6/32 infusion inductions proved difficult to hand ventilate and in two of these it was impossible. Whether this was due to the light level of anaesthesia or due to tumour about the larynx is difficult to tell. Of note is that when difficulty happened the response was to attempt Bonfils intubation which was always successful. However, I don't have sufficient confidence in the intravenous infusion technique to recommend it. There are new developments on the way that may change the way we anaesthetise these cases. Sugammadex is a new reversal agent for neuromuscular block induced by Rocuronium. It can be given immediately if necessary after Rocuronium and works in approximately one minute, thereby giving optimal intubating conditions with the option of quick reversal[57].

Patients were a mixture of major cases for definitive surgery such as laryngectomy or pharyngeal resection and minor diagnostic procedures. Others were urgent semi-elective cases requiring debulking of tumour causing partial airway obstruction. As a result of time constraints, decontamination of the Bonfils between cases and the making of the video recording only one or two patients were chosen from the operation list on any day. Patients weren't excluded from the study on the basis of anticipated difficulty, tumour size or location. However, this wasn't an emergency operating list therefore there were no patients in a critical condition. Three patients who had temporary tracheostomies in situ were recruited to the study, even though these patients had total laryngeal inlet obstruction the Bonfils endoscopy and attempted visualisation of the subglottis was feasible. It was still possible to push a tracheal tube past the tumour into the trachea in all three cases.

This was primarily a descriptive study and the results don't lend themselves to statistical analysis. The Machintosh laryngoscope performed relatively poorly in this study with 27/41 (65%) of patients being a grade I or II glottic view. The control laryngoscopy was performed at a level of anaesthesia somewhat less than optimal especially as there was no neuromuscular blockade used. The Macintosh laryngoscopy was performed first, so during the Bonfils endoscopy the patients were at a slightly deeper level of anaesthesia. The view with the Macintosh was frequently grade III or IV, it is reasonable to assume a lot of semi-blind bougie assisted intubations would have been necessary. The bougie may not have found entry into the trachea in some of the more diseased cases. Railroading the tracheal tube blindly into the larynx is fraught with difficulty if a large tumour blocks its path. It is possible there would have been one or two failed intubations. Macintosh laryngoscopy involves a lot of contact between the blade and the patients tongue and vallecula, if the tumour involves any of these areas it will interfere with intubation either by its sheer mass or because of bleeding. It also has the limitation that the right side of the oropharynx is much easier to see than the left side with a standard blade. It is designed for looking at the vocal cords and anything else seen is a bonus.

41/41 (100%) of cases were intubated using the Bonfils Intubation Endoscope. One case needed the assistance of the Macintosh blade to lift the epiglottis. This was a case of a large base of tongue tumour which displaced the epiglottis on to the posterior pharyngeal wall. The Macintosh view alone was grade IV in this case. The overall appreciation of the tumour, as it effected the airway, was much better with the Bonfils as compared to the Macintosh laryngoscope. This is important because it allows for a much more meaningful discussion with the surgeon about the benefits of debulking or performing a tracheostomy especially if there is subglottic extension. If the patient is extubated at the end of the procedure, information on the likelihood of re-obstruction and the difficulties of re-intubation will be much better understood. Comparisons between what was known about the tumour before induction and the impression when performing the airway assessment with the Bonfils vary. A MRI scan performed close to the procedure was always highly accurate. Occasionally, the Bonfils revealed more information particularly about the nature of the tumour; if it was friable or if there was evidence of subglottic involvement. The median (IQR [range]) for Bonfils Difficulty Score was 0 (0-2 [0-10]) and Cormack and Lehane was 2 (1-3 [1-4]).

The principle advantage of the Bonfils was the ability to push past the tumour encroaching on the laryngeal inlet by placing the bevel of the tracheal tube at the exact point that the airway opens up. Without these capabilities some of the patients would have been impossible to intubate. The other advantages were performing laryngoscopy on a patient with limited mouth opening or neck movement as a result of previous surgery and/or radiotherapy giving the user the ability to look around the corner and see the larynx. The avoidance of bleeding was another plus. It is probable that a number of temporary tracheostomies were avoided.

In conclusion the Bonfils Intubation Endoscope is a very effective tool for the intubation of patients with pharyngolaryngeal tumours. However, a high level of expertise is required. A patient may be too critically ill and require an awake tracheostomy. Emergency cannula cricothyroidotomy with jet ventilation can only be used as a rescue procedure if there is a patent expiratory route. Good communication with the surgeon is essential as an emergency tracheostomy or rigid bronchoscopy may be required if there is a failed intubation attempt.

Appendix A Sample Videos on CD ROM

Appendix A Data Spreadsheet

Appendix D (I) for Data Collection Sheet and sample videos

Section 5

I. Foreword

Assessing the operating boundaries of the Bonfils Intubation Endoscope was always going to be a challenge. Fortunately, true difficult intubations are rare therefore, recruiting patients to a clinical study is nearly impossible[58, 59]. Simulation of difficulty is often practiced in real patients but has its detractors[60]. The use of manikins for training purposes is well documented but was criticised by me in 2003[21, 61]. This was because the commercially available manikins at that time bore little similarity to true airway anatomy. Also the material they were made from didn't have the plasticity of human tissue. The chances of an intubation were very low and the risk of breaking a Bonfils was very high. In October 2004 an abstract of a presentation to the Anaesthetic Research Society was published in the *British Journal of Anaesthesia* concerning the use a physical model to explore the limitations of Bonfils laryngoscopy. I suggested the design of a manikin myself with exchangeable mandibles and moveable larynxes[62].

Then along came the Airsim® (Trucorp Ltd., Belfast, N Ireland) with their 'true to anatomy' manikin. It has many of the features first suggested in the 2004 abstract. The amount of robust clinical data that can be obtained from manikins studies is limited. It wasn't worth the effort and expense in developing a new manikin when an adequate commercial model was available.

Section 5

II. The physical limitations of Bonfils Endoscopy using the Airsim® Manikin.

It has been suggested that the Bonfils Intubation Fibrescope has some advantages over other forms of direct laryngoscopy[16]. Indeed, it has been reported as a rescue technique in the situation of failed Macintosh Laryngoscopy[63]. A successful Bonfils Intubation requires the user to get a straight on view of the laryngeal inlet and slide the tracheal tube off the stylet under direct vision.

The Bonfils is a rigid narrow calibre optical stylet with a gentle 40^{o} anterior curve; it is this curve that gives the user the advantage of 'seeing around the corner'. However, the curve is fixed and if the corner is too acute, visualisation of the inlet will be impossible. The only option open to the user is to change the 'angle of attack' and approach the airway from a more lateral or retromolar route.

The Airsim® (Trucorp Ltd. Belfast, N Ireland) is a commercially available, true to anatomy, airway training device. It has already been endorsed by other authors to test airway equipment[64-66]. The manikin has many features that make it particularly suitable for testing the Bonfils (table 11). These include the head, hinged on the neck, which can be secured in a range positions (fig 14 on page no. 45). The aim of this bench study was to find head position where Bonfils endoscopy became impossible for both the mid-line approach and the lateral approach to the laryngeal inlet. Further to this, we endeavoured to make intubation conditions more difficult by changing the configuration of the manikin.

Methods

The Airsim® Manikin was positioned on an adjustable height bench. A Bonfils Intubation Endoscope was prepared with 6.0-mm Mallinckrodt Microlaryngeal Tube, cold light source and camera video system. The line joining the supraorbital notch and the infraorbital foramen on the manikin were marked and used to indicate the orientation of the head. Accurate measurements were made of the manikin's head position relative to the horizontal, using an angle finder [67](fig. 13).

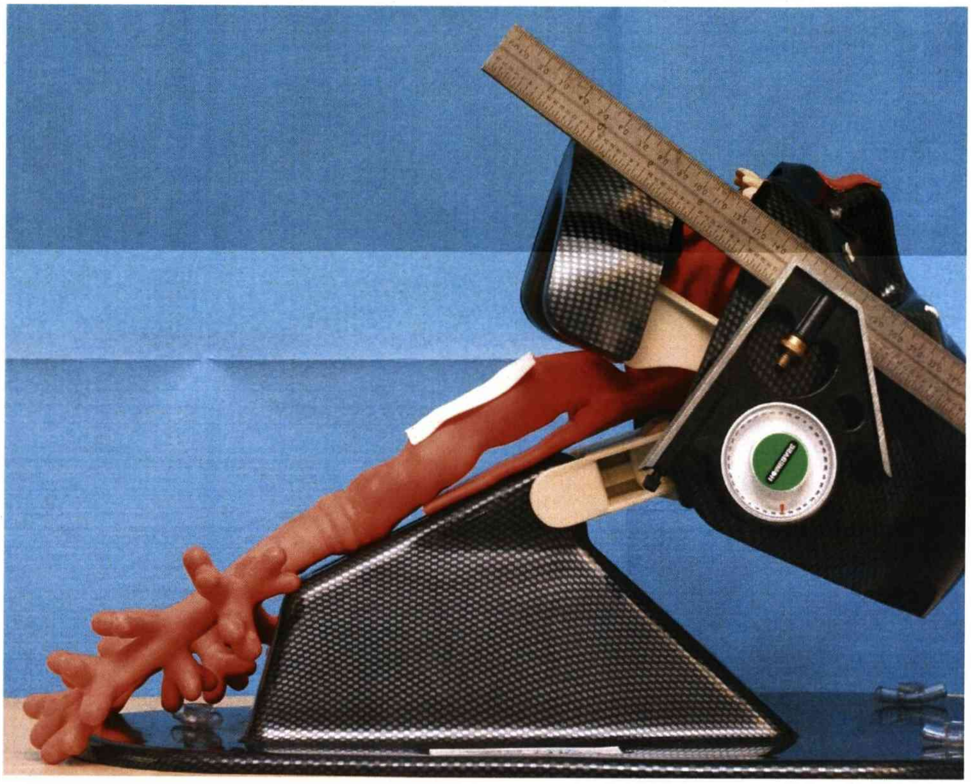

Figure 13 Angle finder measuring head position, the supraorbital notch and infraorbital foramen (white dots) are used as markers of head orientation.

Table 11 The Airsim® Manikin as an airway model for the Bonfils Intubation Endoscope

Advantages
The internal anatomy is highly accurate (tongue, epiglottis and laryngeal inlet)
Neck is fixed at 30° to the horizontal simulating standard intubation position
Head range of movement of 80° (40° extension to 40° flexion to horizontal)
The head position can be easily measured with appropriate equipment.
The mandible has a realistic range of movement including approx 1cm forward translation
The mouth opening with soft lateral cheek area allows a lateral approach to the airway
Upper incisor teeth are detachable when put under too much pressure
The tongue size can be increased to increase difficulty
Disadvantages
Friction between the rubberised mucosa and the instrument
It is not possible to pull submandibular soft tissues to influence the position of epiglottis
It only represents an average adult not extremes of size
The larynx is inclined to move too much with changes in head position

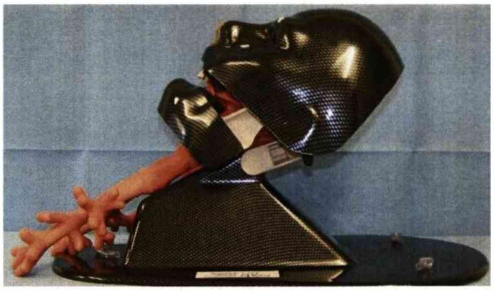

Figure 14a Airsim® manikin in full extension **Figure 14b Airsim® manikin in full flexion**

Bonfils endoscopy was attempted over a range of head positions (fig 15). The less favourable midline approach was initially used. The user was able to use a chin lift manoeuvre to pull the mandible forward and if necessary use their thumb to control the tongue. Intubation was attempted starting at full extension (- 40°) then 10° steps (-30°, -20°, -10°, 0°etc) until a point was reached when visualisation of the laryngeal inlet was no longer possible. This was termed the tipping point for that particular Bonfils Endoscopy approach.

Once the tipping point was arrived at, the user was allowed to employ the more favourable lateral or retromolar approach to the larynx. This is the approach advocated by Dr P Bonfils in his original publications on difficult intubations[13]. If any improvement in view was achieved it was recorded. The next step was to increase the amount of flexion still further until even this approach failed. This was the tipping point for the retromolar approach.

The affect of mouth opening and mandibular translation were tested. At the position of head flexion slightly more favourable than the tipping point the mouth opening was restricted to 1.5cm. This is just enough room for the user to place their thumb into the oropharynx. Bonfils endoscopy was again attempted and the results recorded. At the same level, mandibular translation or active chin lift manoeuvre was inhibited. (Fixing the position with tape) and Bonfils endoscopy attempted[68]. Finally, at the same position of head flexion and mouth opening the tongue was inflated with 30ml of air and a further endoscopy was attempted.

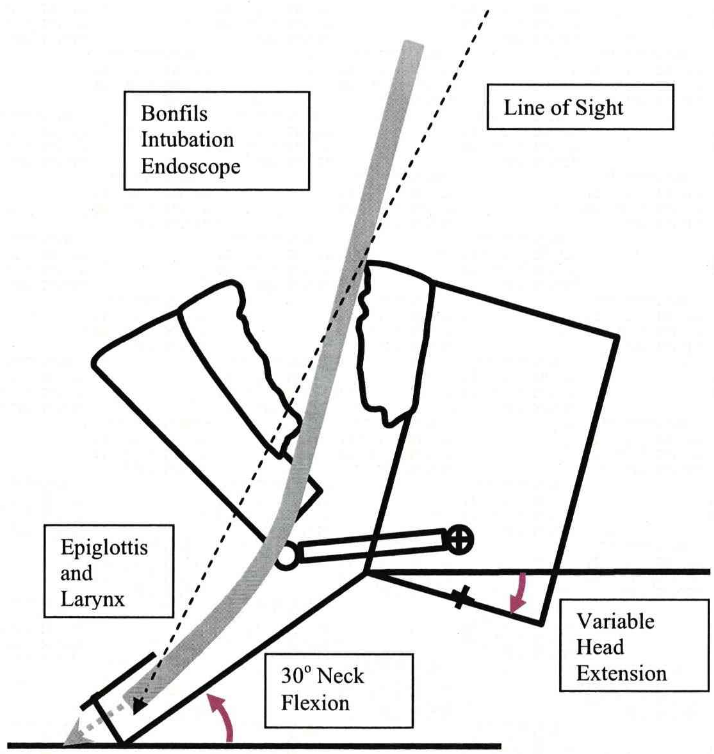

Figure 15a Bonfils endoscopy with head extension, (Line of sight view represents best direct laryngoscopy)

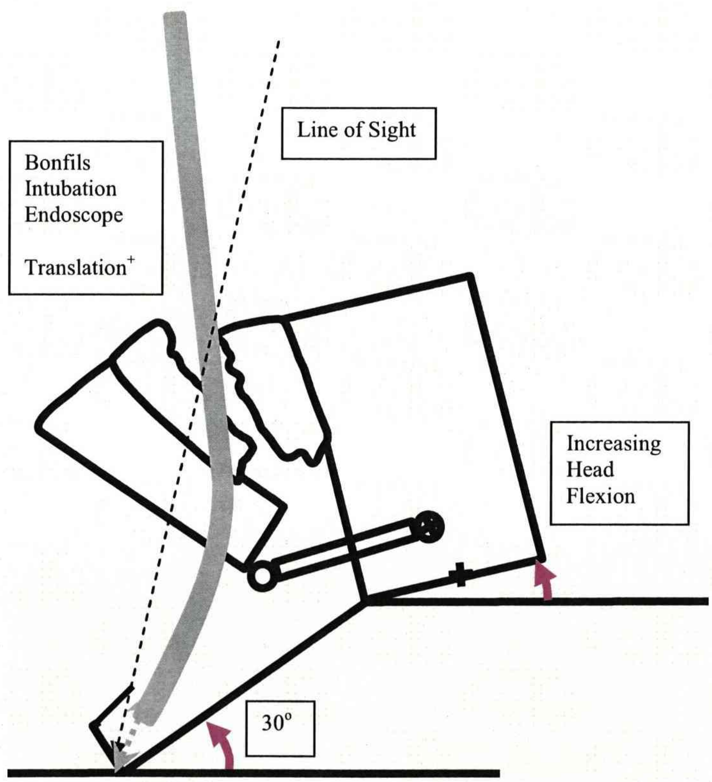

Figure 15b Bonfils endoscopy with head flexion. Increasing head flexion makes endoscopy more difficult and more mandible translation required.

Only reasonable force was applied to the manikin and the Bonfils to obtain a good view of the vocal cords and perform intubation. Any bending of the shaft of the Bonfils resulted in a negative result, any damage to the manikin or the manikin's teeth or any change in head position or further opening of the mouth due to the intubation procedure also resulted in a negative attempt.

Results

The Airsim® Manikin was easy to intubate in all positions of head extension. Using the midline technique the first failure was at a position 20° of head flexion. At this point it was impossible to see the laryngeal inlet of the manikin without unacceptable pressure on the upper incisors. The tipping point for the lateral or retromolar approach was a 20° head flexion (Table 12).

Table 12 The 'Tipping point', beyond which Bonfils Endoscopy is impossible

Bonfils Technique	Last Successful Position
Mid Line approach	10° Head Flexion
Lateral/Retromolar approach	20° Head Flexion

Adding in extra degrees of difficulty also had a negative effect on endoscopy. These extra manoeuvres were performed at a head flexion of 10° within the operating range of the Bonfils Endoscope and using the lateral approach (Table 13) (fig. 16).

Table 13 Changes in Manikin Configuration and effect on Bonfils Endoscopy

Extra Difficulty	Intubation	Comment
Mouth Opening 1.5 cm	Y	Restricted room to manoeuvre, Oesophageal pull back technique
Mouth Opening 1.5 cm and limited translation	N	Only Arytenoids seen
Mouth Opening 1.5 cm and enlarged tongue	N	Unable to get under epiglottis

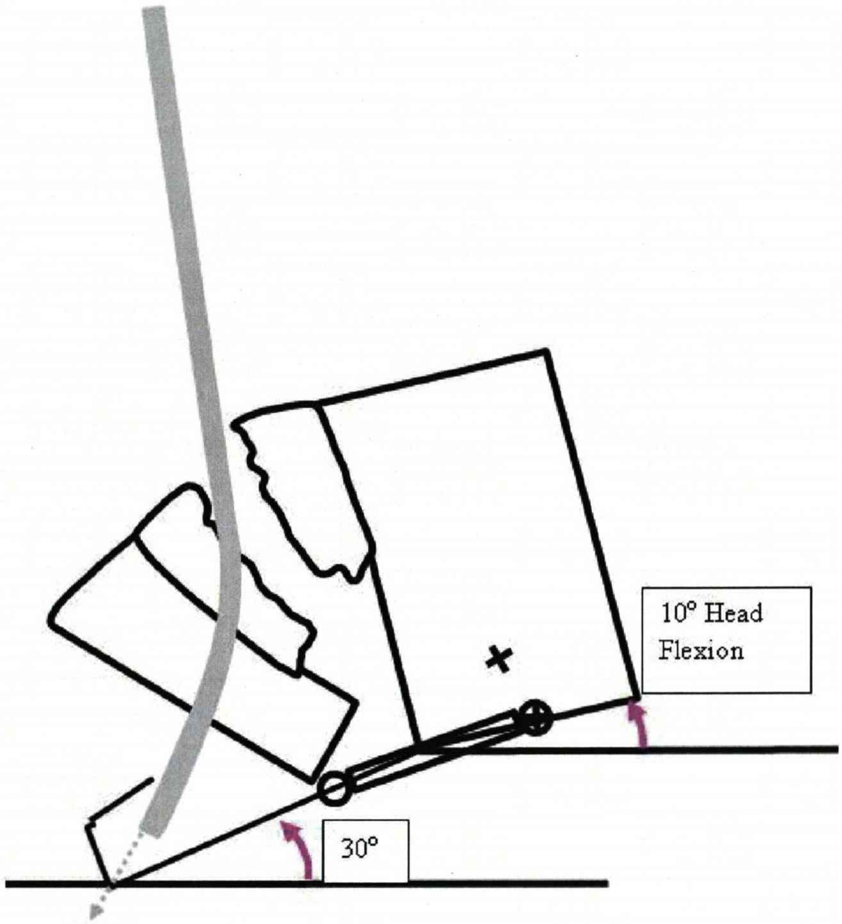

Figure 16 10° Head Flexion, 1.5cm Mouth opening and inhibited mandibular traction results in a failure to laryngeal inlet

Discussion

The Bonfils is an inflexible optical stylet with a distal curve. The view from the end of the tracheal tube is unique and it is far more manoeuvrable in the airway than is immediately evident. Commercial companies promoting a new device will focus on the positives and minimise the limitation of a product. Clinicians reporting their experiences tend to tell of their successes and not their failures. For this reason new devices can sometimes seem to be better and more versatile than they really are.

In this bench study we measure success or failure to intubate the Airsim® manikin; we did not record difficulty or time the intubation attempts. This study was looking for the point where Bonfils intubation became impossible. It would be difficult to construct a study in real patients were the aim was not to secure the airway.

It is demonstrated that increasing flexion of the head on the cervical spine eventually makes Bonfils endoscopy impossible. The Airsim® Manikin has a relatively easy to negotiate epiglottis which is often the 'Achilles' Heel' of Bonfils endoscopy. A difficult Bonfils endoscopy can happen in any patient but if you have another means of lifting the epiglottis such as a Macintosh Blade you chances of success are very high. However, if there is a flexion deformity greater than 20° with the Airsim® (or something similar in another patient), no matter what is used to control the epiglottis, a view of the laryngeal inlet will be impossible. This is why you should not throw away your gum-elastic bougie or flexible fibrescopes[69].

One can change the route to the laryngeal inlet and the advantage of the more lateral approach is easy to describe but difficult to assess. If a lateral approach is taken the final angle necessary to enter the trachea straight, is less acute. This is because our maxillas and hard palates are deeper than they are wide. Also, the bulk of the tongue can be avoided by this paraglossal route. In this manikin we only managed an extra 10° however, in real patients I suspect this would be better. The Manikin was well suited to performing this study but as intubating conditions deteriorated problems such as making space for the Bonfils and issues over the friction between the manikin and the instrument increased. The failed intubation attempts when mandible translation was inhibited and the tongue was enlarged show the importance of creating space in the airway as both these conditions increase the amount of tissue in an already confined space.

Teaching a new technique to trainees is always a challenge. If users have initial failure with the device they will soon discard it. It is important to be able to direct users to the more optimal intubation position. From this study we can advise users that extending the head and traction on the mandible are both shown to improve intubation conditions. Extra wide mouth opening doesn't improve your chances of visualising the laryngeal inlet however, restricted mouth opening makes manoeuvring very difficult. Restricted mouth opening is rarely an isolated event. It is usually associated with other pathology such as infection, trauma or surgery; careful consideration is required as there could be other impediments to intubation.

The question has to be asked would the Bonfils perform better if it were a different design. Some other similar devices are semi-malleable and may improve view of larynx but there could be other issues about the advancement of the tracheal tube if the curve is too acute. Other devices will require further studies.

Section 6

I. Closing Remarks and Literature Update

Interest in the Bonfils Intubation Endoscope has grown significantly over the last six years, since my first publications in *Anaesthesia* [21] and the *British Journal of Anaesthesia* [19]. Much of this is due to increased promotion by Karl Storz Endoscopy Ltd.

I have presented research, related to the Bonfils Intubation Endoscope at the Difficult Airway Society (DAS) meeting many times. It is the foremost meeting in the United Kingdom for Anaesthetists with an interest in new airway management devices.

I regularly demonstrate the Bonfils Intubation Endoscope at a number of difficult intubation workshops in both the U.K. (DAS, ADAM) and Ireland (Irish College of Anaesthetists Core Topic Meeting) up to five times per year.

There are now many papers published on the use of the Bonfils Intubation Endoscope. Many concern the management of difficult laryngoscopy and intubation and make comparisons with other devices [70]. Others tell of its use as a rescue technique after failed Macintosh attempt [63, 71]. There is also great interest of its use in trauma and particularly in the reduced cervical spine movement required for an intubation [26, 72-75]. Some of these have been written by Accident and Emergency specialists[76]. Some authors have described novel uses for the Bonfils, from placement of awkward double lumen tracheal tubes to monitoring of percutaneous tracheostomies in critical care medicine [77, 78]. It is also covered in review articles on new intubation devices [8, 79].

A recent check of the ISI Web of Knowledge [www.isiknowledge.com] (Thomson Reuters), reveals that the 2003 paper has been cited 14 times by other authors. And the abstracts have been quoted five times.

Section 6

II. Publications and Presentations: M Halligan

Halligan M, Weldon B, Charters P. A clinical appraisal of the Bonfils Intubating Fibrescope. Proceedings of the Anaesthetic Research Society Meeting, Cardiff Meeting, July 11-12, 2002. Br J Anaesth 2002; 89 (4):671-712

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Section 7

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Section 8

Appendices

Appendix A: Data spread sheets CD ROM (Attached to rear cover)

Appendix B-I

Data Sheet Study 1

Study Number: __________ Anaesthetist (initials): ________

Patient Information

Patient's Initials: ______ Chart Number: ________________

Sex: ______ Weight (kg): ________

Age (nearest year): _______ ASA classification: ________

Mallampati score: _______ Thyromental distance (cm): _______

Inter-incisor distance (cm): ________

Patient Information Free Text (Medical Conditions, Anxiety level, Airway Issues etc):
+Drugs given

Recorded Data

Size and type of Tracheal Tube: ______

Is the Epiglottis visible? (Yes/No): ______

Is the Epiglottis adherent to soft palate? (Yes/No): ________

Does an airway manoeuvre improve the view of the larynx? (Yes/No): _______

If yes what was the manoeuvre?____

Was there hang up on the vocal cords? (Yes/No) _________________________

Was the patient successfully intubated with the Bonfils? (Yes/No): __________

Time for Intubation (seconds): _________

Haemodynamics:

	Base Line	0	1 min	2 min	3 min	Post Int.
Sys						
Dia						
HR						
SpO_2						

Appendix B-I continued

Difficult with technique

Was the presence of secretions a cause of difficulty? (Yes/No): ______

Overall Difficulty with the procedure (0 = very easy, 10 = impossible)

Verbal Rating Score: _________

Range of verbal Rating Score (+ve Patient factors, -ve Instrument factors) : ________

e.g. VRS : 8 8,0 = very difficult entirely due to the patient

VRS : 5 0,-5=medium difficulty entirely due to the instrument

VRS : 5 2,-3= medium difficulty due to the instrument more than the patient

VRS : 2 1,-1= low difficulty equally due to the patient and the instrument

Difficulty Free Text:

Blood visible in oropharynx on direct laryngoscopy post intubation? (Yes/No): _____

Appendix B-II

Haemodynamic Data first 30 intubations all preformed by MH. Standard anaesthetic technique (Midazolam, Fentanyl, Propofol and Atracurium). Similar results have been demonstrated by other authors[80].

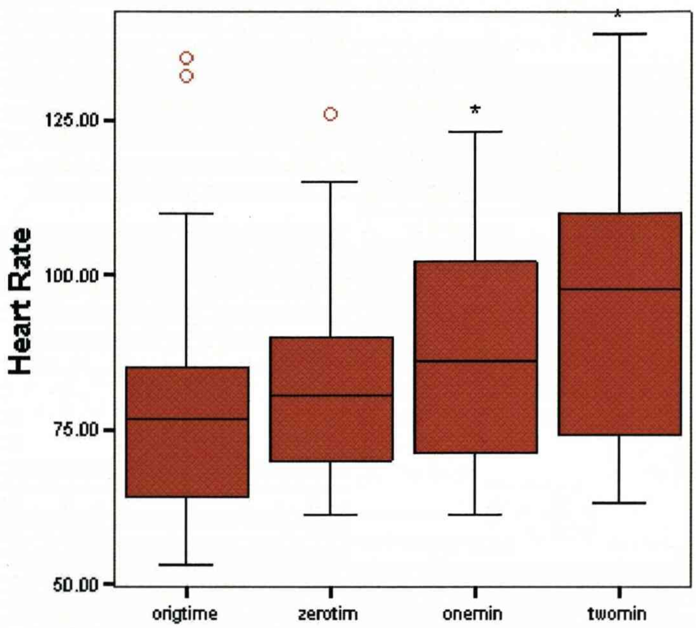


Figure B-i Increase in Heart Rate during and post intubation

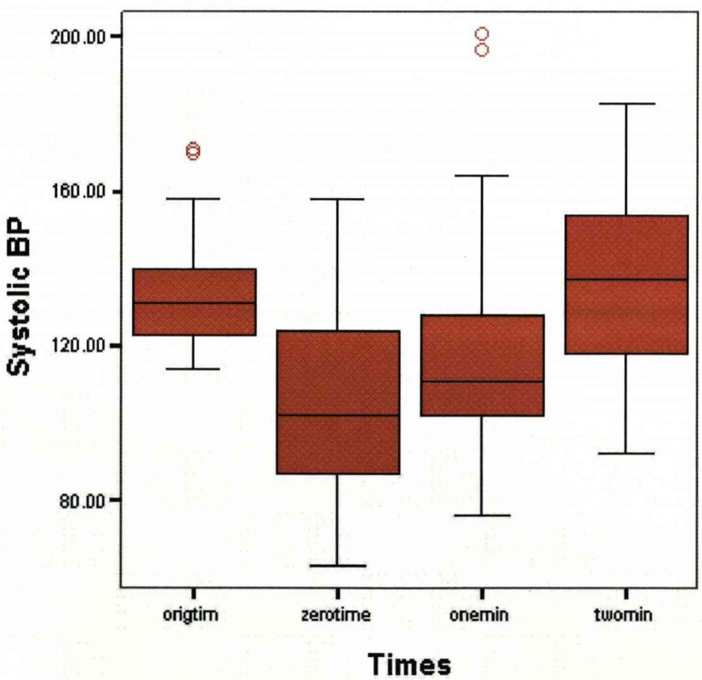


Figure B-ii No significant increase in systolic BP

Appendix B-III

Verbal Rating Score (VRS) [From Section 1]

- Original Verbal Rating Score VRS was broken down into patient factors versus others and represented as a "GRID"[19] presented at Anaesthetic Research Society in Cardiff June 2002..

- Maximum VRS was 10. A score of ≤ 2 could be considered trivial.

- 17/60 had scores greater than 2 for 'patient factors' (VRS-pat).

- 3/60 had scores greater than 2 for 'other factors' (VRS-oth).

- Using one-way ANOVA, intubation time related to VRS.

- Overall ($p<0.01$), significant.

- For VRS-pat ($p<0.01$), significant.

- For VRS-oth ($p>0.5$). not significant.

Appendix B-IV

Bonfils Difficulty Score (BDS): Background.

We used a post hoc analysis based on free-text comments (figure A-ii) at the time which we believe described and rationalised what made for patient difficulty. As described in Chapter 1 these are space available in oropharynx for endoscopy, manoeuvres required to make this space, access to epiglottis and negotiation around the epiglottis. A score of 0 to 3 is given to each category.

For each subject the total BDS was simply the sum of the various parts so that the total possible maximum was 12 and the minimum zero. In this study of normal subjects the highest value recorded was 5.

Score	Availible Space	Manoeuvres required	Ease of Access	Epiglottis lift
0	54	49	58	54
1	4	6	1	3
2	2	2	1	3
3	0	3	0	0

Table (B-i) Total Number of subjects in each category (n=60)

Table B-ii Summary of Free Text Comments Data Sheets Study 1

1. Edentulous maxilla
2. Water obscured the lens from cleaning. Required a wipe
3. Foggy lens / secretion
4. Very prominent teeth – noted pre-operatively
5. Lens fogged by secretions when manoeuvring the epiglottis; secretions heavy. No major improvement in view with soft tissue traction skin.
6. Secretions+. Light cable snagged on trolley while trying to remove tube.
7. Enlarged red beefy epiglottis. Difficulty getting under epiglottis – attempts x4. Scope cloudy.

8. Small immobile epiglottis. Foggy lens. Prominent incisors – noted pre-op.
9. Foggy view due to the presence of secretions.
10. Foggy view. Soft tissue traction – yes.
11. Epiglottis adherent to soft palate. Secretions+, thick, foggy view. Prominent incisors noted pre-op. Chin lift / soft tissue traction – yes
12. Heavy patient, soft tissue swelling++. Secretions+. Short light cable. Jaw thrust.
13. Secretions
14. Heavy mandible to lift. Anti-fog on lens.
15. Tip loaded too close to end of tube. Red-out against tongue. Secretions+. Difficulty getting under epiglottis. Jaw thrust.
16. Chin lift required for good view. Chin lift – yes.
17. Epiglottis adherent to soft palate. Slow in initiating chin lift. Chin lift – yes.
18. Very easy.
19. Not fully relaxed.
20. Very easy.
21. Heavy jaw and soft tissues.
22. Airway used for hand ventilation. Secretions+.
23. Easy.
24. Secretions+. Slightly cloudy view. Chin lift – yes.
25. Large patient. Secretions+. Soft tissue swelling.
26. Floppy epiglottis
27. Foggy view. Patient not totally relaxed. Chin lift – yes.
28. Secretions+.
29. Nil. Pre-op note – very anxious. Changed VRS scaling to include patient/ other allocation.
30. Easy.
31. Mallampati 3. Deceased pharyngeal space. Blood in airway. Tube not properly loaded tending to red-out. Jaw thrust. Decreased pharyngeal space.
32. Difficulty freeing tube from scope.
33. Very easy.
34. Epiglottis difficult to lift. Obese patient. Chin lift plus lifted with scope.
35. Large tonsils and epiglottis. Thumb to behind tongue (not floor mouth).

36. Copious secretions. Floppy epiglottis.
37. Copious secretions. Young, fit, nervous, could have taken more propofol.
38. Floppy epiglottis. Difficult to manoeuvre. Chin lift - yes.
39. Some secretions. Very easy.
40. Very easy. Chin lift –yes.
41. Very easy.
42. Cords not entirely relaxed.
43. Very easy.
44. Edentulous patient. Floppy epiglottis. Difficulty getting control of tongue. Tongue tended to be pushed down by left hand.

45. Camera rotating on eyepiece. Incorrect grip right hand grip. Chin lift – yes

46. Obese patient.
47. Epiglottis not easily moved. Secretions++. Epiglottis flicked up with scope

48. Very large tonsils. Secretions+. Chin lift – yes.
49. Some difficulty removing 'scope from tube as trolley a bit high.
50. Bleeding from right upper lip. (Thumb of operator.)
51. Oral secretions lead to slipping of left thumb. Chin lift – yes.
52. Difficult neck extension / crowns. Possible difficult intubation, not previously reported. Tube loaded too close to Murphy's eye. Secretions+. Neck extension – yes
53. Very easy
54. Easy.
55. Secretions++. Left thumb slipped.
56. Easy. Small lip bleed.
57. Very easy.
58. Prominent teeth. Chin lift – yes.
59. Easy
60. Easy

Colours: Red – change in practice from this point., Purple – complication note. , Green – pre-op. note. , Blue – other clinical note. , Orange – extra recorded data.

Appendix B-iv continued

The BDS was calculated without direct reference to the original VRS-pat. To contrast this scoring system with the original VRS-pat, we compared graphs of VRS-pat against BDS and also time to intubation versus BDS. They appear to be comparable.

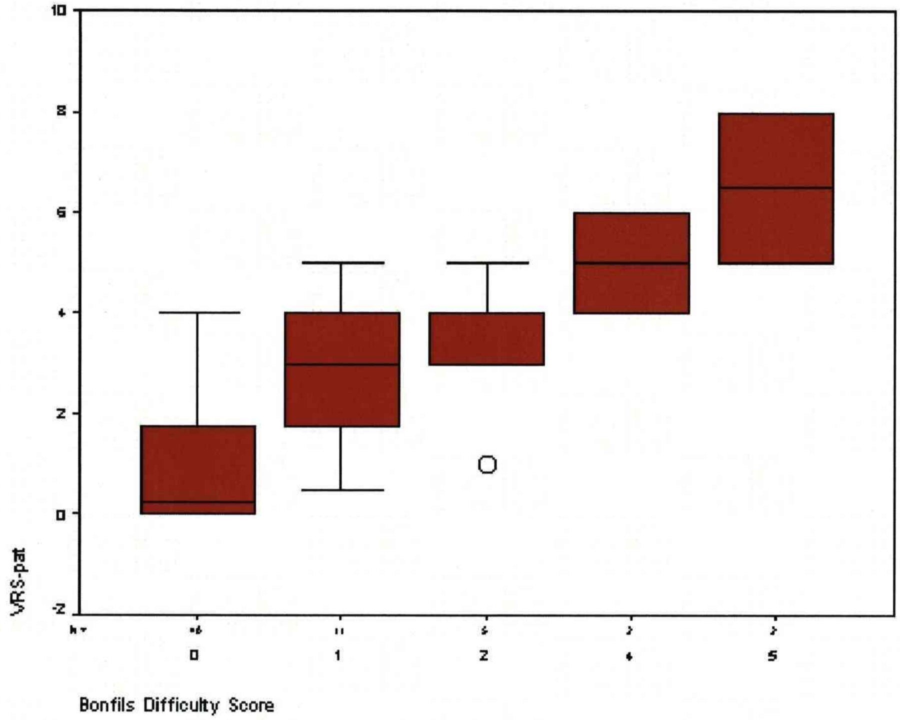


Figure B-iii VRS-pat v BDS

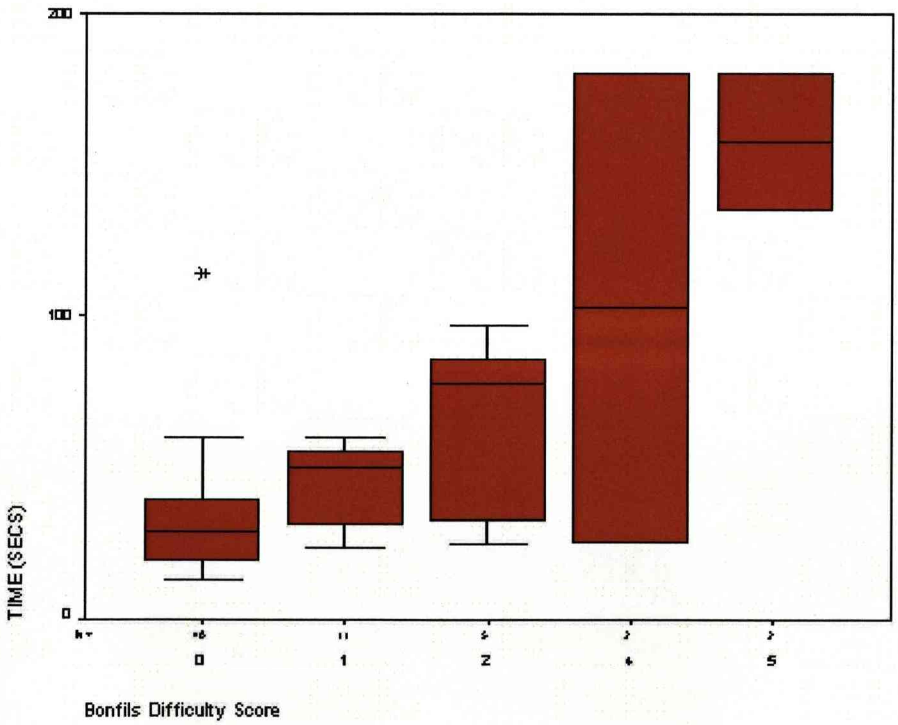


Figure B-iv Intubation time v BDS

Appendix B-iv continued

Learning curves and BDS

Because times for intubations were variable we used moving average (based on the last three cases) to show how each anaesthetist tended to improve over time. One this basis we suggest 20-25 cases is an expected learning time for the instrument. By dividing the 30 cases into three groups of ten, it was possible to show that this improvement was not simply due to easier cases over time, since the BDS was no different for each epoch for either anaesthetist (MH, p=0.09; PC, p=0.625).

Bonfils Difficulty Score related to Airway Assessment

	F-Ratio	Significance	
Mallampati	3.356	0.016	p<0.05
Thyromental	0.462	0.763	(N.S.)
Incisor gap	0.151	0.962	(N.S.)

Table B-iii Airway Assessment and BDS (one-way ANOVA)

Details of Assessment from Section 2; Table 1. Only Mallampati class was related to BDS. This is reasonable because no known difficult cases were included and both Thyromental and Incisor gap distances were all normal (just one thyromental distance was 6.0cm).

Appendix B-iv continued

Analysis of Verbal Rating Score of 'non-patient' or 'other factors' (VRS-oth) and BDS

Table B-iv Individual case device/user problems identified as important.

Problem	Intubation time	BDS
Difficulty releasing tube from scope	60 sec	0
Free rotation of camera on eyepiece	35 sec	0
Tube loading problem / difficulty with secretions	(Failed)	4
Tube loading problem / difficulty with secretions	135 sec	5
Tube loading problem / difficulty with secretions	86 sec	2

In the latter case, in addition to the BDS factor, the tracheal tube was loaded on the Bonfils scope with the tip too far back from the end. The effect was that the Murphy's eye came into play in that secretions not only clouded the view but bubbles formed at the Murphy's eye lumen, distorting the view. The problem occurred again on two other occasions where the BDS scores were greater than zero and the intubation times were prolonged.

No anti-fogging agent was used in the first 13 cases. The presence of fogging on the lens was never more than minor (11/60), but occurred in eight of the first 13 cases and only three of the remaining 47 (Chi-square, $p<0.001$). Secretions were described as either minor (14/60) or major (6/50) but not related to lens fogging (Chi-square, $p>0.5$).

Appendix C-I

Cricoid Pressure Data Sheet Study 2

Study Number: __________ Anaesthetist (initials): ____ODP (Years ex):_________

Patient Information

Initials		Number		Sex	
Weight (kg)		Height (m)		BMI:	
Age		ASA		MP	
TMD (cm)		I-C D (cm)		JT (+,-,0)	
Neck extension		ET type		ET size	

Patient Information Free Text (Medical Conditions, Anxiety level, Airway Issues etc):
+Drugs given

Recorded Data No Cricoid [NC], Cricoid Pressure[C] (post-hoc video)

Supraglottis

Difficulty entering oropharynx (Y/N) NC_______ CP ________

Epiglottis easily located? (Y/N): NC __________ CP _________

Laryngeal opening clearly visible? (Y/N): NC________________CP _____________

Glottis

Distortion of glottis? please comment NC _________________ CP_______________

Subglotttis

Subglottis visible? (Y/N): NC_________________ CP ________________________

Compression of trachea (%): ____

General

Was head extension useful? (Y/N/NA): NC ______________CP _________________

Was Jaw-thrust employed, was it helpful? (Y/N/NA): NC _________ CP __________

Hang-up on the vocal cords? (Yes/No) _____________________________

Was the patient successfully intubated with the Bonfils? (Yes/No): _______________

Difficult with technique

Any difficulty introducing the Bonfils into the patient's mouth? (Yes/No):______

Was the presence of secretions a cause of difficulty? (Yes/No): ______

Blood visible in oropharynx on direct laryngoscopy post intubation? (Yes/No): ____

Bonfils Difficult Score

Free Text

Intubation variables	Ease of overcoming variable	NC	C
Space available			
	Normal	0	0
	Minor reduction or easily improved	1	1
	Major reduction not easily improved	2	2
	No space (continuous red-out)	3	3
Epiglottis access			
	No problem	0	0
	Minor (e.g. large tonsils)	1	1
	Major (e.g. generalised soft tissue excess)	2	2
	Impossible	3	3
Manoeuvre required			
	Usual left hand techniques only	0	0
	Assisted Jaw thrust	1	1
	Jaw thrust and maximal neck extension	2	2
	Macintosh assist	3	3
Epiglottis lift			
	No unusual manoeuvres required	0	0
	Minor Tube / scope flip adequate	1	1
	Major Tube / scope elevation required	2	2
	Impossible to lift epiglottis	3	3
	Total BDS		

Appendix C-II

In this section selected still images captured from the videos of the Bonfils endoscopies are displayed. All 20 subjects are included.

The top row of images is the view from the endoscope without cricoid pressure applied. The second row is the images with cricoid pressure applied. It was from analysis of these videos that the measurement of the effect of cricoid pressure was estimated.

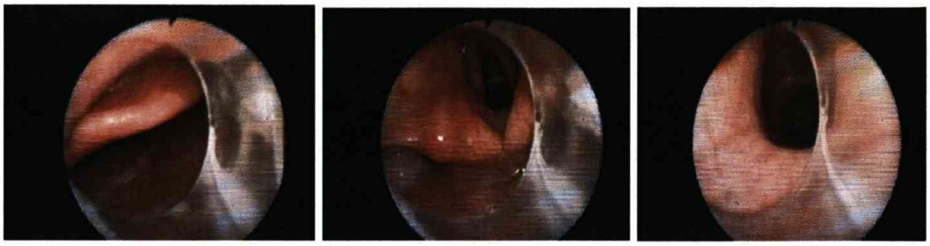
There is an assessment at three levels supraglottic or epiglottic column (i), glottic or laryngeal inlet column (ii) and subglottic or cricoid cartilage column (iii).

Sample video is included on CD see inside of rear cover.

Appendix C-II continued

Subject 1

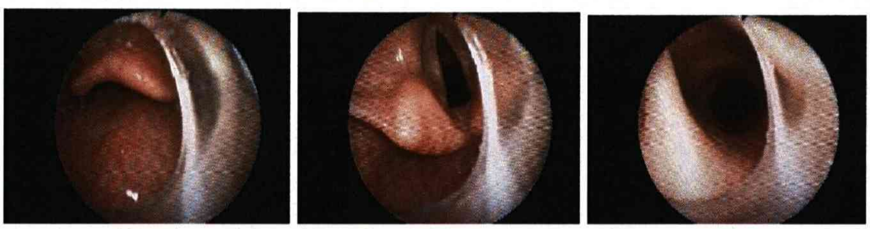
Normal (i) (ii) (iii)



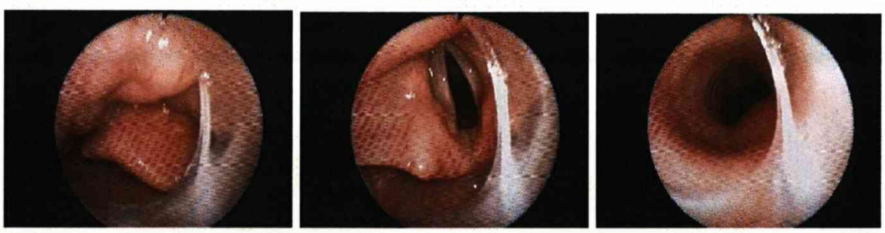
Cricoid pressure applied

Subject 2

Normal (i) (ii) (iii)



Cricoid pressure applied

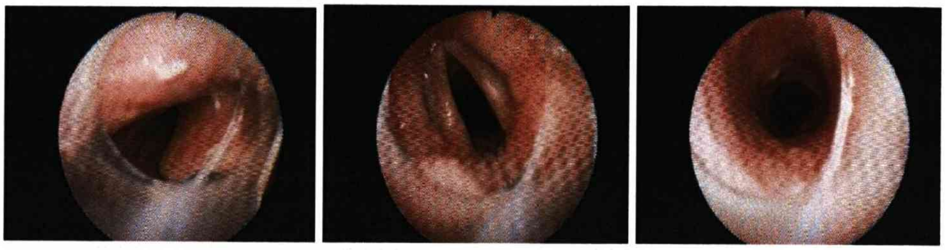


Appendix C-II continued

Subject 3

Normal (i) (ii) (iii)

Cricoid pressure applied



Subject 4

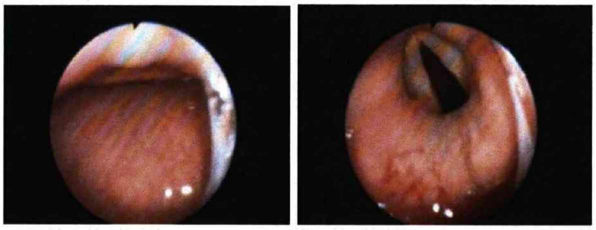
Normal (i) (ii) (iii)

Cricoid pressure applied

Subject 5

Normal (Blood in the supraglottic area)

(i) (ii)



Cricoid pressure abandoned

Subject 6

Normal (i) (ii) (iii)

Cricoid pressure applied

Appendix C-II continued

Subject 7

Normal (i) (ii) (iii)

Cricoid pressure applied

Subject 8

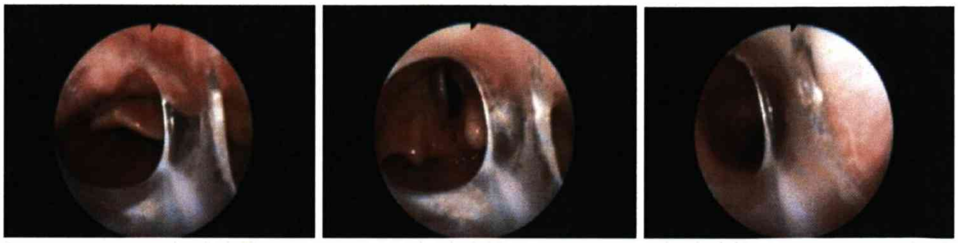
Normal (i) (ii) (iii)

Cricoid pressure applied

Appendix C-II continued

Subject 9

Normal (i) (ii) (iii)

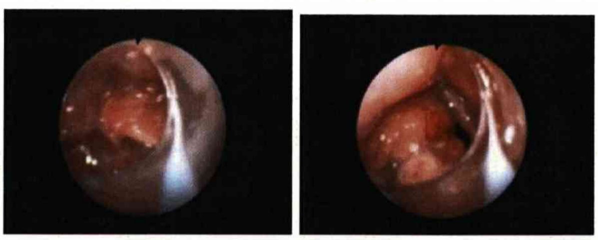


Cricoid pressure applied

Subject 10

Normal (i) (ii) (iii)

Cricoid pressure applied then released



Appendix C-II continued

Subject 11

Normal (i) (ii) (iii)

Cricoid pressure applied

Subject 12

Normal (i) (ii) (iii)

Cricoid pressure applied

Appendix C-II continued

Subject 13

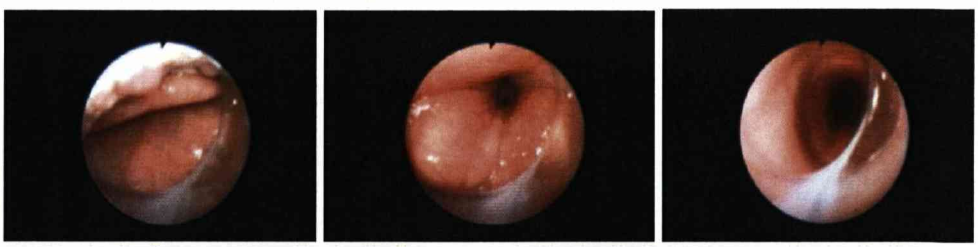
Normal (i) (ii) (iii)

Cricoid pressure applied

Subject 14

Normal (i) (ii) (iii)

Cricoid pressure applied



Subject 15

Normal (i) (ii) (iii)

Cricoid pressure applied

Subject 16

Normal (i) (ii) (iii)

Cricoid pressure applied

Appendix C-II continued

Subject 17

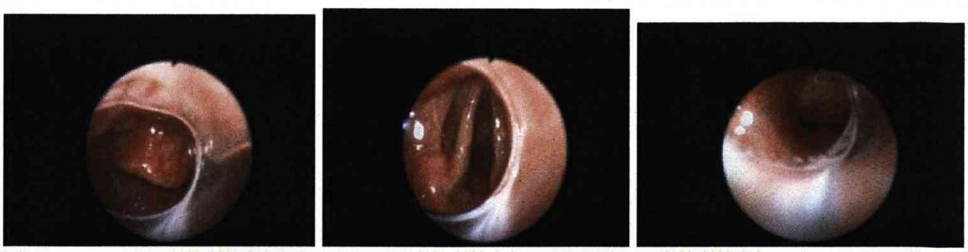
Normal (i) (ii) (iii)

Cricoid pressure applied

Subject 18

Normal (i) (ii) (iii)

Cricoid pressure applied



Subject 19

Normal (i) (ii) (iii)

Cricoid pressure applied

Subject 20

Normal

Cricoid pressure applied

Appendix C-III

Does the experience of the ODP or the gender of the patient affect the accuracy of cricoid pressure airway compression?

Experience of ODP

The Cricoid Pressure applied by the less experienced ODPs appeared to have a greater occlusion effect on the laryngeal inlet than the cricoid cartilage. For the three groups: [cricoid < inlet], [cricoid=inlet] and [cricoid > inlet], the percentage of less experienced ODPs applying the CP was 100% of 6, 33% of 3 and 27% of 8 respectively. There was a small group where the compression appeared to be similar.

Table C-i

Inlet Occlusion Score	Cricoid Compression Score 0	1	2	3	4	5
0		ODP(2), ODP(15)			ODP(15), ODP(10)	
1		ODP(3)	ODP(3)	ODP(2), ODP(10)		
2		ODP(3), ODP(3)*	ODP(10)			ODP(15)
3	ODP(2)					
4	ODP(2)	ODP(2), ODP(3)			ODP(10)	
5						

Table (C-i) shows relative compression at the cricoid level versus inlet level mapped for individual ODPs (years of experience) for the 17 complete observations. In the six incidents where Laryngeal inlet was more compressed than cricoid cartilage all the ODPs are less than three years qualified. In the eight incidents where more correctly cricoid compression is greater than laryngeal inlet compression only 3 are preformed by these less experienced ODPs. The 'old hands' were better. This Analysis by χ^2 (trend) = 5.2318 (1 dof, $p<0.05$) confirmed this result to be statistically significant.

Gender of Patient Table 4 shows, in sharp comparison the percentage of female patients for the three groups of cricoid versus inlet compression is now 17% of 6, 33% of 3 and 64% of 8 respectively. Being a female patient would therefore mean it more likely that cricoid compression would be greater than inlet compression. In this case, χ^2 (trend) = 3.025 ($p>0.05$ and $p<0.075$), so the result is not statistically significant. However, direct comparison of the two tables suggests that the difference is actually equivalent to a single case moving from the [cricoid < inlet] group to the [cricoid=inlet] group.

Table (C-ii)

Inlet Compression Score	Cricoid Compression Score: 0	1	2	3	4	5
0		F, F			M, F	
1		M	M	F, M		
2		M, M*	M			F
3	M					
4	M	M, F			F	
5						

Table (C-ii) shows relative compression at the cricoid level versus inlet level mapped for the gender of the patients.

Appendix D-I

Laryngeal Tumour Data Sheet

Study Number: __________ Date:________ Anaesthetist (initials):_____

Tumour assessment

Diagnosis (tissue):

TMN Classification:

CT Scan:

MRI Scan:

Out patient assessment (Nasendoscopy, Indirect laryngoscopy):

Previous MUA:

Photocopies of reports (including pathology):

Patient assessment

Initials		Number		Sex	
Weight (kg)		Height (m)		BMI:	
Age		ASA		MP	
TMD (cm)		I-C D (cm)		JT (+,-,0)	
Neck extension		ET type		ET size	

Patient Information Free Text (Co-morbidities, Anxiety level, Airway Issues etc): +Drugs given

Assessment of airway compromise (stridor or difficult anatomical features)

Percieved problem with airway maintenance?

Previous Anaesthetic? (Dates, technique used, intubation history)

Previous debulking?

Previous Radiotherapy?

This intubation

Type of Anaesthetic

TIVA Remi and propofol

Mixed Remi and isoflurane

Inhalational sevoflurane

Relaxant propofol and sux

Pre intubation Machintosh direct laryngoscopy and suction Cormack and Lehane:

Endoscopy Check list

- Uvela
- Base of Tongue
- Right piriform fossa
- Left Piriform fossa
- Valecullum
- Epiglottis
- Glottis
- Right vocal cord
- Left vocal cord
- Arytenoids
- Subglottic view

Recorded Data (post-hoc video)

Difficulty entering oropharynx (Y/N)

Supraglottis: Epiglottis easily located? (Y/N)

Glottis: Laryngeal opening clearly visible? (Y/N):

Subglottis visible? (Y/N):

What was seen

Comparsion of Bonfils view with Machintosh view:

Bonfils technique

1. Chin lift
2. Chin and tongue lift
3. Maximal head extension
4. Assisted jaw thrust
5. Machintosh Blade

Hang-up on the vocal cords? (Yes/No) ____________________________

Was the patient successfully intubated with the Bonfils? (Yes/No): ______________

Difficult with technique

Any difficulty introducing the Bonfils into the patient's mouth? (Yes/No):______

Was the presence of secretions a cause of difficulty? (Yes/No): ______

Blood visible in oropharynx on direct laryngoscopy post intubation? (Yes/No): ____

Intubation variables	Ease of overcoming variable	BDS
Space available	Normal	0
	Minor reduction or easily improved	1
	Major reduction not easily improved	2
	No space (continuous red-out)	3
Epiglottis access	No problem	0
	Minor (e.g. large tonsils)	1
	Major (e.g. generalised soft tissue excess)	2
	Impossible	3
Manoeuvre required	Usual left hand techniques only	0
	Difficulty making usual techniques effective	1
	Neck extension	2
	Jaw thrust	3
Epiglottis lift	No unusual manoeuvres required	0
	Minor Tube / scope flip adequate	1
	Major Tube / scope elevation required	2
	Impossible to lift epiglottis	3

CD ROM / Multimedia *(attached to inside of the rear cover)*

- **Appendix A:** Excel Spreadsheets Data collected.
- **Appendix B-IV**: Sample Video of Cricoid Pressure.
- **Appendix D-II:** Sample Videos of tumours x 3.

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