

APPARATUS

Evaluation of Frova, single-use intubation introducer, in a manikin. Comparison with Eschmann multiple-use introducer and Portex single-use introducer*

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Summary

In a randomised cross-over study, 48 anaesthetists attempted to place a Frova single-use introducer, an Eschmann multiple-use introducer and a Portex single-use introducer in the trachea of a manikin set up to simulate a grade 3 laryngoscopic view. The anaesthetists were blinded to success (tracheal placement) or failure (oesophageal placement). Successful placement (proportion, 95% confidence interval) of either the Frova introducer (65%, 50–77%) or the Eschmann introducer (60%, 46–73%) was significantly more likely than with the Portex introducer (8%, 3–20%). There were no significant differences between the success rates for the Frova and the Eschmann introducers. A separate experiment revealed that the peak force exerted by the Frova and Portex introducers was two to three times greater than that which could be exerted by the Eschmann introducer, $p < 0.0001$, indicating that the single-use introducers are more likely to cause tissue trauma during placement.

Keywords *Manikins. Equipment, intubating introducers. Intubation, intratracheal.*

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Three intubating introducers (bougies) (Fig. 1) are available in the UK. The Eschmann multiple-use introducer (Eschmann Healthcare Tracheal Tube Introducer, SIMS Portex, Hythe, Kent, UK) is widely used in clinical practice in the United Kingdom as an aid during difficult intubation [1,2]. However, concerns have been raised about the possibility that multiple-use devices transfer between patients the prions thought to be responsible for causing variant CJD [3]. This is because of the difficulty in ensuring that all microbial and proteinaceous contamination of the device has been removed during cleaning and sterilisation [4,5]. The guidelines of the Association of Anaesthetists of Great Britain and Ireland state that 'single use intubation aids' should be used where possible [6]. This has led to a clear move in clinical practice in favour of single-use devices.

The Eschmann multiple-use introducer (Fig. 1) was brought into clinical practice in 1973 [7]. It is due to be renamed the Portex Venn Introducer (Cedric Russell, Portex Limited, personal communication). The Portex single-use introducer (Portex Tracheal Tube Introducer, SIMS Portex) became available in 1997. The Frova single-use introducer (Frova Intubating Introducer, Cook (UK) Limited, Letchworth, Hertfordshire, UK) was brought into clinical practice in 1998. Both single-use devices appear to be significantly different in design and physical characteristics from the Eschmann multiple-use introducer.

Success rates are known when using the Eschmann introducer for intubation in difficult cases [2,8]. The Portex single-use introducer is more rigid [9] and is thus more likely to cause trauma [10]; it does not maintain a curved shape when bent [9] and it has a significantly

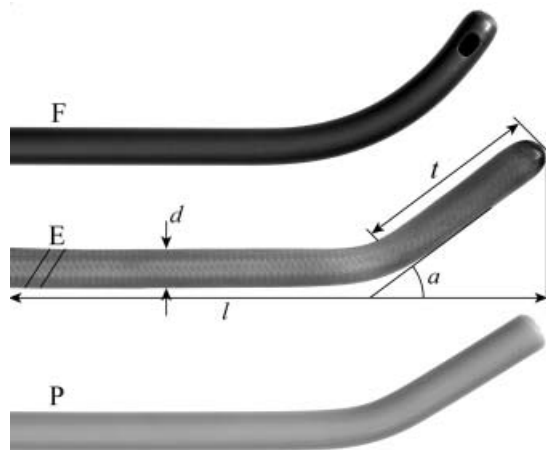


Figure 1 Currently available tracheal tube introducers. F = Frova single-use introducer (Cook), polyethylene, length (l) = 650 mm, diameter (d) = 4.7 mm, tip length (t) = 20 mm, angle of the tip (a) = 65° . E = Eschmann multiple-use introducer (Portex Ltd), resin-coated polyester, l = 600 mm, d = 5 mm, t = 25 mm, a = 40° . P = Portex single-use introducer (Portex Ltd), polyurethane, l = 600 mm, d = 5 mm, t = 25 mm, a = 40° (manufacturers' specified dimensions).

lower tracheal placement rate in simulated grade 3 laryngoscopy both in a manikin [9] and *in vivo* [11].

The Frova single-use introducer appears to be able to maintain the desired curvature – a feature shared with the Eschmann multiple-use introducer. However, the clinical performance of the Frova has yet to be tested. There are data on the forces exerted by the tips of the Portex single-use introducer and Eschmann multiple-use introducer [10] but not of the Frova single-use introducer.

We therefore decided to compare the success rates of the Frova, Eschmann, and Portex introducers for tracheal placement in simulated grade-3 laryngoscopy in a manikin [8,12]. The forces exerted by the tips of the three introducers when held at different distances from the tips were also investigated in the laboratory.

Methods

The Local Research Ethics Committee considered that ethical approval for this study was unnecessary. Anaesthetists present in the Department at the time of the study were invited to participate. They were informed what the study entailed and were given the choice not to participate. None declined. Forty-eight anaesthetists (26 consultants, 19 trainees of various grades and 3 Associate Specialists) who had at least one year's experience of using intubating introducers were invited to take part.

A Rouilly airway management trainer (Scopin, Adam Rouilly Limited, Sittingbourne, UK) was arranged, to simulate a Grade 3 laryngoscopic view, so that only the tip

of the epiglottis could be seen [8,12]. The laryngoscope blade (Macintosh size 3, Penlon Ltd, Abingdon, UK) was fixed into position using a retort stand and a clamp. Each of the 48 anaesthetists attempted to place the three introducers into the manikin's trachea. The introducers were presented to the anaesthetists in a random order. The order was balanced, so that equal numbers of anaesthetists attempted to place each type of introducer first, second or third. An Excel spreadsheet (Microsoft Office '97, Microsoft Corporation, Redmond, USA) running on a PowerMac Macintosh (Apple Computer Ltd, Cork, Ireland) was used to generate the randomisation code.

The anaesthetists were not allowed to manipulate the laryngoscope, alter the head position or apply external laryngeal pressure. The investigator held each introducer at the end and passed it to the anaesthetist. After assessing the view of the larynx, the anaesthetist was asked to shape the introducer and to hold it according to their everyday practice.

With the Frova and Portex single-use introducers, a new one was used for each intubation attempt. The Eschmann multiple-use introducer was used five times, as per the manufacturer's recommendation. A stopwatch was started when the anaesthetist took the introducer and stopped at introducer placement. Intubation over the bougie was not attempted. The anaesthetist placing the introducer was blinded to the site of placement. This was noted by the investigator.

In a complementary study, the peak force exerted by pressing five samples of each device, held at distances of 10, 20, 30 or 40 cm from the tip, against a disc attached to a force transducer (Mecmesin PFI200N; resolution 0.1 N; Mecmesin, Newton House, Slinford, West Sussex, UK) was measured. Each test on each of the five samples of the three different introducers was repeated three times. All the introducers used in this experiment were brand new. The introducers were not shaped prior to testing.

A depression in the disc prevented the tip of the introducer from slipping as the device bent during the test. Introducers were pressed progressively until the force recorded by the force transducer did not increase anymore (Fig. 2). The peak force for each test was recorded.

Statistical analysis

The Cochran Q -test was used to determine whether successful placement depended on which device the anaesthetists used.

The effect of the type of introducer used on the time to placement was determined using a repeated measures analysis of variance (ANOVA).

Repeated measures analysis of variance was also used to determine whether the type of introducer used affected the force that could be exerted on the force transducer.

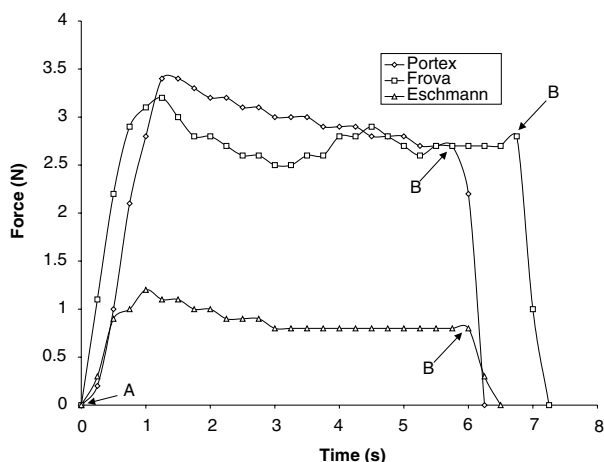


Figure 2 Force against time as the introducer was pressed against the force transducer when held at 20 cm distance from the tip. A – introducer pressed against the force transducer. B – introducer removed.

The standard deviations of the peak force for each introducer were not the same at each distance but approximately proportional to the mean values. Therefore values of log (peak force) were used in the analysis. ‘Introducer type’ (Frova single-use, Eschmann multiple-use and Portex single-use) was added as the ‘between-devices’ effect and ‘attempt’ (first, second and third) and ‘distance’ (10, 20, 30 and 40 cm) were added as ‘within-devices’ effects. In all tests, $p < 0.05$ was considered to indicate a significant effect.

Statview version 5 was used to carry out the ANOVA tests. Confidence Interval Analysis version 2.0.0 was used to obtain the 95% confidence intervals [13].

Results

Tracheal placement

The success rates for the Frova, Eschmann and Portex introducers are shown in Table 1 and Fig. 3. The Cochran

Table 1 Tracheal placement and time to placement by 48 anaesthetist for the Frova single-use, Portex single-use and Eschmann multiple-use introducers. Values are number (proportion, 95% confidence interval) and mean (SD), respectively.

	Introducers			p-value
	Single-use		Multiple-use	
	Frova	Portex	Eschmann	
Tracheal placement	31 (65%, 50 to 77%)	4 (8%, 3 to 20%)	29 (60%, 46 to 73%)	<0.0001
Time to placement (s)	14.3 (5.6)	13.3 (5.6)	14.9 (7.2)	0.38

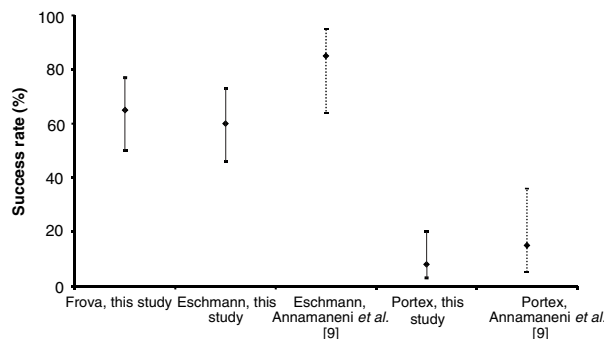


Figure 3 Success rates (95% confidence intervals) of tracheal placement when the anaesthetists used the three introducers, with a comparison against success rates from a previous study [9] (broken lines).

Q-test, gave $p < 0.0001$, indicating that the type of tracheal introducer used significantly affected whether correct placement occurred. The 95% confidence intervals for the success rates with the introducers (Fig. 3) make it clear that the $p < 0.0001$ is mainly due to the success rate with the Portex introducer being much less than those for the Eschmann or the Frova. The 95% confidence interval for the difference in the success rates in our study (Eschmann minus Frova) was -13 to $+21\%$, indicating no statistically significant difference between them, but also a small probability that the Eschmann might be about 20% more successful (or about 10% less successful) than the Frova (in so far as our 48 anaesthetists are a representative sample of anaesthetists in the UK). Success rates varied between anaesthetists: nine anaesthetists could not succeed with any of the introducers, three succeeded with all three. Of the remaining 36, roughly half could make both Frova and Eschmann introducers work; half could make either Frova or Eschmann introducer work but not both (Table 2).

Time to tracheal placement

There was little difference in the time to placement for the three devices (Table 1). The repeated measures

Table 2 Tracheal placement of the introducers in the manikin.

Tracheal placement	Number of anaesthetists
No successes with any bougie	9
One success out of three	17
Frova single-use only	9
Eschmann multiple-use only	8
Portex single-use only	0
Two successes out of three	19
Frova single- and Eschmann multiple-use	18
Frova single-use and Portex single-use	1
Eschmann multiple- and Portex single-use	0
Three successes out of three	3
Total	48

Table 3 Mean (SD) force (Newtons) that could be exerted when holding the introducer at various distances. Five samples of each introducer were each used three times, giving $n = 15$ for each cell in the table.

Bougie	Mean (SD) force (Newton) that could be exerted when holding bougie at			
	10 cm	20 cm	30 cm	40 cm
Eschmann multiple-use	3.2 (0.5)	1.1 (0.1)	0.6 (0.1)	0.4 (0.1)
Frova single-use	6.6 (0.6)	3.2 (0.4)	1.9 (0.3)	1.2 (0.2)
Portex single-use	8.3 (1.1)	3.2 (0.2)	1.8 (0.2)	1.1 (0.1)

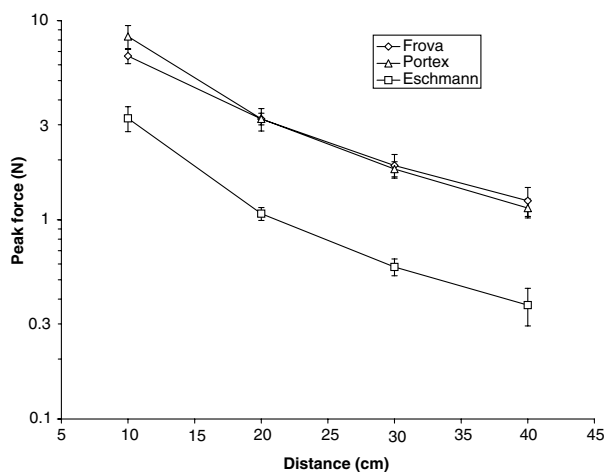


Figure 4 Peak force (on a logarithmic scale), mean (SD), against distance held from the tip for each bougie.

ANOVA gave a p -value of 0.38, indicating that the type of introducer did not have a significant effect on the time to tracheal placement. The mean (95% confidence interval) difference (Frova minus Eschmann) in the time to place the introducers was -0.6 s (-3.0 to $+1.9$ s).

Force

The forces that could be exerted by the introducer varied significantly between introducer type ($p < 0.0001$) and with the position of holding ($p < 0.0001$) (Table 3, Fig. 4)

For all three introducers the peak force decreased steeply as distances increased. At all distances the force that could be exerted using the Eschmann introducer was much less than that using either the Frova or the Portex introducer, which showed very similar forces (Fig. 4).

Discussion

The principal finding of this study is that, in a manikin, the success rate for tracheal placement with the Frova

single-use introducer (65%) was similar to that of the multiple-use Eschmann (60%), and that the success rate for the Portex single-use introducer was very much less (8%). It remains to be seen whether the similarity in success rate between the Frova and the Eschmann is confirmed in patients.

The pattern of our results may be mainly because the Eschmann performs best when it is curved [14] and, like the Eschmann, the Frova retains any curvature well, whereas the Portex rapidly straightens [9]. However, differences in construction materials and slight differences in dimensions (Fig. 1) may also be relevant.

The Eschmann introducer is generally regarded as the gold standard because the high success rate is combined with only rare instances of airway trauma during placement [15]. Therefore the Frova does not represent the ideal single-use alternative: although it has a high success rate it can, like the Portex, exert 2–3 times greater force than the Eschmann; so it is more likely to cause airway trauma.

Potential signs of correct placement of the introducer are, in sequence: introducer seen to pass through the vocal cords, cough in an inadequately paralysed patient, ‘clicks’ as it passes along the tracheal rings, and ‘distal hold up’ as it reaches the small bronchi [16–18]. Recommendations (based on only the Eschmann introducer) can be summarised as ‘continue advancing the introducer until one sign is detected’. Therefore the ‘distal hold-up’ sign should be used only as a last sign of tracheal placement. We are not aware of any cases of tissue trauma, following ‘distal hold-up’ with an Eschmann introducer [19,20].

‘Clicks’ are sensed as minor fluctuations in the resistance to advancement of the introducer, whereas entering a small bronchus causes a much greater increase in resistance. Therefore, it seems likely that the risk of tissue trauma is much greater with ‘distal hold up’ than with ‘clicks’, especially with introducers that can exert large forces. Therefore, we recommend that ‘distal hold-up’ should not be sought with Portex and Frova introducers. These introducers should not be advanced beyond 25 cm, as the ‘distal hold-up’ sign occurs at between 24 and 40 cm in tracheal intubations [17].

Once advancement of the introducer is stopped after a positive indication of placement, the tracheal tube should be passed over the introducer and its position established with capnography during manual ventilation. With the Frova, in the absence of signs of tracheal placement, a tracheal tube can still be passed over the device. Confirmation of placement can then be established with capnography. Alternatively, the Frova, which is a hollow tube and is supplied with a ‘Rapi-Fit’ Luer lock connector, can itself be attached to a CO₂ analyser.

However, we would advise caution with this approach: the 'Rapi-fit' connector may not be immediately available and the procedure is likely to be time consuming for an inexperienced operator.

Placement of a tracheal tube over the introducer was not attempted in our study. However, one of the authors (IH) has noticed, while using Frova introducers in patients, that advancing the tracheal tube over the introducer can often prove difficult. This is because the proximal end of the Frova has a sharp edge, which can impact on the blunt end of the tracheal connector inside the tracheal tube (Fig. 5). We recommend that the design of the Frova introducer be modified: when faced with difficult intubation it is vital that the tracheal tube slides easily over the introducer.

The reliability of our results is enhanced by the use of a cross-over design and an unaltered manikin position throughout the study. However, our anaesthetists were able to use both hands to shape the introducers before placement and this does not resemble normal clinical practice. Therefore, if the use of two hands helps to achieve optimum curvature (well retained by the

Eschmann and Frova introducers) this may have biased our results in favour of those introducers against the Portex. However, the success rates of Annamaneni *et al.* [9] for the first attempt at placement of the Eschmann and Portex in a manikin (85% and 15%, respectively) were similar to our 60% and 8% (all 'first attempts'). Higher success rates have been reported in patients [12]: 94% and 56%, respectively, for the Eschmann and Portex introducers; but the difference (Eschmann minus Portex) of 38% is nearly as large as in our study ($60\% - 8\% = 52\%$).

The Eschmann multiple-use and Portex single-use introducers are very similar in appearance so the devices can be easily confused. The length, size and the angle of the tips of the two introducers are specified to be the same. The assistant might therefore hand to the anaesthetist a Portex single-use introducer when the anaesthetist wishes to use an Eschmann multiple-use introducer. If an introducer is needed urgently for an unexpected difficult intubation, confusing the Portex introducer for the Eschmann introducer is unacceptable. The Frova, on the other hand, is made of blue polyethylene and is easily distinguishable from the other introducers.

From the foregoing it is clear that the Eschmann introducer has the highest success rate [9,11] and least likelihood of causing trauma [10,15] and has reliable and clinically tested signs of confirmation of tracheal placement [2,17,18]; therefore it is generally the introducer of choice. However, if a single-use introducer is deemed essential, the Frova is to be preferred to the Portex because of the much higher success rate with similar risk of trauma. The Frova may also be useful if the anaesthetist encounters difficulty with the Eschmann because about a third of our anaesthetists succeeded with one and not the other (Table 2). However, there is no information on the incidence of trauma in clinical practice with this device. The use of the Portex single-use introducer as an intubation aid seems inappropriate.

There is a move towards single-use devices in the UK. Caution however, should be used before the tried and tested Eschmann multiple-use introducer is rejected in favour of single-use devices. It seems illogical not to use an effective multiple-use introducer when multiple-use LMAs and surgical tools continue to be in common use. If money were no object we would be using Eschmann multiple-use introducer, but only once. What is needed in the future is an effective, atraumatic and cheap single-use tracheal introducer.

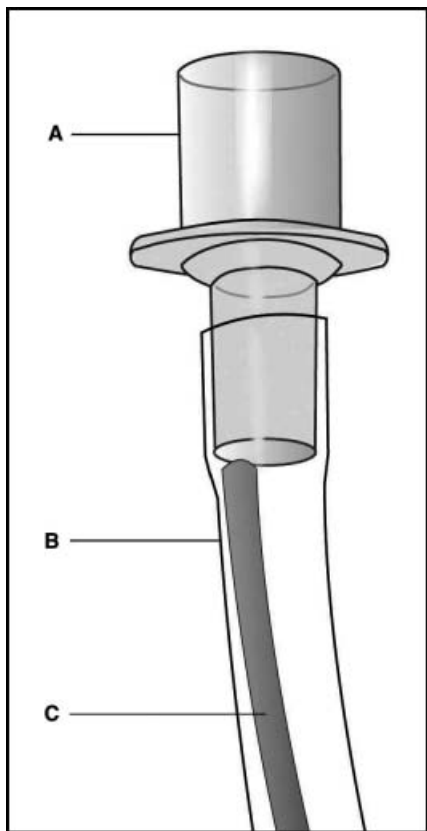


Figure 5 The Frova introducer caught on the tracheal connector during 'railroading' of the tracheal tube. A = Tracheal tube connector. B = Tracheal tube. C = Frova introducer.

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