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The Parker Flex-Tip Tube versus *a Standard Tube for Fiberoptic Orotracheal Intubation*

A Randomized Double-blind Study

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Background: **During fiberoptic tracheal intubation, passage of the fiberscope itself to the trachea is often fairly easy, but passage of the tube into the trachea may be difficult or even impossible. A new type of disposable endotracheal tube, the Parker Flex-Tip tube, has a tip that reduces the gap between the fiberscope and the inside of the tube. Thus, theoretically, a smaller risk of impinging on laryngeal structures during insertion in trachea is expected.**

Methods: **Eighty patients scheduled for elective anesthesia using orotracheal intubation were randomized to either a Parker Flex-Tip tube or a standard (Portex) 7.5-mm-ID endotracheal tube. Blinding was obtained by having the tube premounted on the fiberscope (Olympus LF-1; diameter of fiberscope = 4 mm) and thereafter covered with a black opaque plastic bag. Difficulty in placing the tube was scored using an objective standardized grading system.**

Results: **Seventy-six patients completed the study. The use of the Parker Flex-Tip tube reduced the incidence of need for repositioning of the tube during insertion into trachea from 89% to 29% ($P < 0.0001$) when compared to the standard tube. The median time for passage of the tube into the trachea was reduced from 20 s to 7.5 s ($P < 0.0001$).**

Conclusions: **During oral fiberoptic intubation, the use of the Parker Flex-Tip tube is associated with greater incidence of initial success of passage of the tube into trachea when compared to a standard endotracheal tube.**

WHEN performing fiberoptic tracheal intubation, passage of the fiberscope itself to the trachea is often fairly easy, but passage of the tube into the trachea may be difficult or even impossible.[1–4] Difficulties are mainly due to the tube impinging on laryngeal structures.[2] The design and diameter of the endotracheal tube influences the success rate of tracheal intubation.[2,3,5–7] The endotracheal tubes that have been shown to be superior to a standard tube have either been prototypes not commercially available or expensive flexible tubes.[3,4,6,7] In this study, we compare a new disposable plastic endotracheal tube, the Parker Flex-Tip (PFT) tube, to a standard endotracheal tube for orotracheal fiberoptic intubation. The PFT tube has a tip pointing toward the center of the distal lumen of the tube and thus leaves a smaller gap between the fiberscope and the inner wall of the tube (fig. 1). The PFT tube is available in 6.5- to 8.0-mm sizes.

Materials and Methods

The study was approved by the Ethics Committee of Copenhagen and Frederiksberg, and all patients gave oral and written consent.

The two endotracheal tubes compared were a standard endotracheal tube (soft-seal cuff, 7.5-mm ID; Portex) and a PFT tube (7.5-mm ID; Parker Medical, Englewood, CO).

We used an Olympus LF-1 fiberscope (Olympus Optical, Tokyo, Japan), which has a 4-mm OD. The difficulty encountered when passing the endotracheal tube over the inserted fiberscope was objectively graded as suggested by Jones *et al.*[2] (table 1). As our primary effect variable, we chose the rate of the tube impinging on the glottis necessitating one or more manipulations before it could be passed into trachea (= grade 1 or 2).

We included patients scheduled for anesthesia in which orotracheal intubation was planned. Exclusion criteria were as follows: age younger than 18 yr; American Society of Anesthesiologists physical status greater than II; expected difficulty in ventilation or intubation and thus scheduled for awake intubation; patients not fasting; and patients with known pathology or previous surgery in the mouth, pharynx, or larynx.

The following items were preoperatively evaluated in all patients: the airway (by means of Mallampati score), ability to prognathe, head and neck movement, history, physical appearance, and weight.

Randomization and Blinding

The proximal connections of the two types of endotracheal tubes were replaced with identical connections to ensure that no difference could be felt when the blinded investigator touched the proximal end of the tubes. All tubes were then equipped with a piece of tape at the 20-cm mark. The pilot tubing was taped to the endotracheal tubes on the same side in all tubes. The patients were block-randomized to obtain an equal number of male and female patients in each group. Half of the tubes, half of each type, were placed in identical envelopes that hereafter were mixed and placed in cardboard boxes marked "male." Then, the procedure was re-

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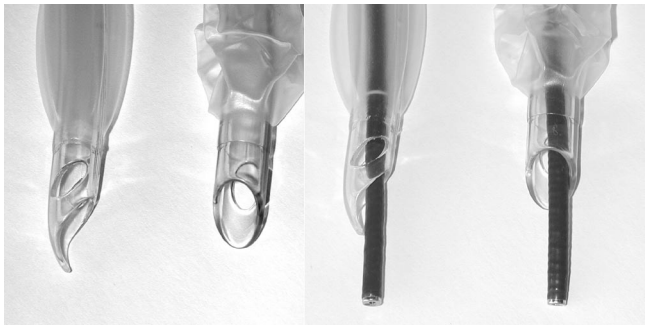

Fig. 1. The Parker Flex-Tip tube (*left*) has a flexible tip pointing toward the center of the distal lumen. The standard tube is seen second from the left. The Parker Flex-Tip tube (*second from the right*) leaves a smaller gap between the tube and the fiberscope than the standard tube (*right*) with the same ID.

peated with the other half of the tubes that were placed in a corresponding box marked "female." The following preparation was performed by an anesthesia nurse or assistant nurse on the day of the study: An envelope was drawn at random from the appropriate cardboard box. The tube was placed on the fiberscope lubricated with water-soluble gel. The tube was mounted onto the fiberscope with the concavity of the curvature facing the side of the maneuver lever. A black, opaque, plastic bag was placed over the fiberscope, allowing for the handle with the eye piece and control lever protruding from a hole in the bottom. The protruding handle was sealed to the plastic bag with tape. The other end of the plastic bag was wrapped around the fiberscope below the tip of the mounted tube and fixed with a clip. The distal end of the fiberscope thus protruded from the plastic bag. All patients were preoxygenated, and anesthesia was induced with fentanyl and propofol and maintained with propofol infusion. The patients were given a muscle relaxant (0.25 mg/kg mivacurium) and ventilated with oxygen *via* face mask until there was no response to train-of-four nerve stimulation. A bite block was placed between the incisors. To optimize the conditions for introducing the fiberscope, the anesthesia nurse then pushed the patient's jaw forward. The investigator took the fiberscope by the handle and by the free distal part and introduced it in the midline into the trachea until the tip was placed 1 to 2 cm above the carina. The investigator was standing on the patient's right side, facing the patient, and the fiberscope was kept in the midline in the sagittal plane during the whole procedure. The distal part of the plastic bag was unwrapped, by the helper, from the fiberscope so that it covered both the face of the patient and the fiberscope with the tube mounted to it. The investigator kept the handle of the fiberscope in the left hand and then passed the right hand up into the plastic bag and grasped the proximal end of the tube. A stopwatch was started, and passage of the tube was started. If resistance of the tube on its way into the trachea was met, a standardized action was taken: The first step was to withdraw the tube 5 cm, rotate it 90° counterclockwise, and then reinsert it. If the passage was still not successful, the tube was withdrawn 5 cm and turned 180° clockwise and then reinserted. If resistance was still encountered, external manipulation of the larynx and alterations in head and neck position were tried. A maximum of four attempts of tube passage were allowed. The tube was introduced until the tape placed at the 20-cm mark was felt with the fingers to be at the level of the bite block. This allowed the investigator to complete the intubation without knowing which tube was in use. The stopwatch was stopped, and the objective score (according to table 1) was noted by the anesthesia nurse. Before removing the blinding, the investigator gave an additional subjective score (scale of 1–10; 1 = easy, 10 = impossible) that was also noted by the anesthesia nurse. After this, the plastic bag was removed, the type of tube was noted on the chart, and tracheal placement of the tube was confirmed by capnometry and auscultation. The cuff pressure necessary to maintain an airtight seal when ventilating with a pressure of 20 cm H_2O was noted. After the operation, at the time of discharge from the postoperative recovery room, all patients reported sore throat and a new occurrence of hoarseness on a 100-mm visual analog scale. All data were stored without any analysis being made until the last patient had completed the study.

Table 1. Difficulties Encountered When Passing the Endotracheal Tube Over the Inserted Fiberscope

Grade	Difficulty
0	No holdup encountered
1	Holdup on initial attempt, relieved by 5 cm withdrawal and rotation of tube 90° counterclockwise followed by reinsertion
2	Holdup on initial attempt requiring more than one tube manipulation, alteration in head or neck position, or external laryngeal manipulation

Statistical Analysis

Sample size calculation was based on the following: We aimed at detecting a reduction in the incidence of glottis impingement of the tube, from 40% to 10%. Based on an α of 0.05 and a β of 0.2, 33 patients were estimated to be needed in each group. To compensate for patients not completing the study, we randomized 40 patients to each group. Rates were compared using the Fisher exact test. Other values were compared between groups using the Mann–Whitney test. Values are medians and quartiles.

Results

A total of 80 patients were randomized, of which 76 completed the study. The standard tube was used in 38 cases, and the PFT tube was used in 38 cases. When

Table 2. Difficulty of Passing the Endotracheal Tube into the Trachea during Fiberoptic Intubation

Grade of Difficulty	Parker Flex-Tip Tube, n	Standard Tube, n	*P**
0	27	4	<0.0001*
1	5	26	—
2	6	8	—

*Parker Flex-Tip tube compared with standard tube for grade 0 *versus* the combined grades 1 and 2.

using the standard tube, some manipulation was needed (grade 1 or 2) to pass the tube in 34 patients (89%). The corresponding number of patients for the PFT tube was 11 (29%) ($P < 0.0001$; table 2).

The four patients not completing the study (two from each group) were excluded *before* start of anesthesia. Two of these exclusions were due to canceling of surgery, one because the patient had previously had surgery of his pharynx and one because the blinding failed due to an inappropriate placing of the plastic bag used for the blinding. In one patient (randomized to a standard tube), the tube was easily advanced until it appeared to be in the appropriate position. However, after the plastic bag was removed, it was found that the tube had impinged on the laryngeal entrance and had made a curve in the mouth instead of having entered the trachea. This patient's data are included in the study, and the difficulty of intubation was graded as grade 1. In two patients, one in each group, intubation was abandoned in accordance with the protocol because four attempts were used without successful passage of the tube. Both patients' data are included in the study, and difficulty of passage of the tube for each patient was graded as grade 2. Both were successfully intubated fiberoptically after the blinding was relieved, making digital manipulation of the tip of the tube in the mouth possible.

Table 3. Demographic Data

	Parker Flex-Tip Tube	Standard Tube
Gender (M/F), n	18/20	19/19
Age, yr	39 (28–56)	50 (32–60)
Weight, kg	73 (64–83)	72 (62–78)
Height, cm	175 (167–183)	169 (163–180)

Values are median (quartiles).

No significant differences were found between the groups regarding sex, age, weight, height (table 3), or preoperative airway evaluation.

In the PFT group, the time for passing the tube into the trachea was significantly shorter, and the subjective difficulty score was lower, whereas a higher cuff pressure was needed in this group compared to the standard tube group (table 4).

Discussion

We found that during fiberoptic tracheal intubation, the use of the PFT tube led to a two-thirds reduction in the rate of resistance to passage of the tube into the trachea compared to a standard tube. We also found that the median time used for the procedure was more than halved when using the PFT tube.

In the current study, the initial rate of resistance when using the standard tube was at the high end, 89%, compared to what was found in other controlled studies (36–90%).[1,3,5,8,9] The reason for this relatively high initial failure rate probably is that in the majority of these previous studies, tubes with a smaller diameter (6.5 mm for females and 7.0 mm for males) or larger-diameter fiberscopes were used. One previous study used a combination of size of the tube and diameter of the fiberscope comparable to the ones used in the current study, and the investigators found an equally high failure rate of 90%.[8] Unlike in the current study, the person who did the intubation was not blinded to the type of tube in these other studies.

In our study, we used a challenging but clinically relevant combination: the placement of a relatively large endotracheal tube over a thin fiberscope *via* the oral route.

It is important to note that absolute rates of resistance to the tubes are difficult to compare between studies because of the use of different IDs of the tubes and different diameters of the fiberscope or even because of failure to report the diameter of the tube in use. The use of a fiberscope with a larger diameter reduces the incidence of resistance to passage of the endotracheal tube through the vocal cords.[10] Instead of the absolute rate, one can describe the relative reduction in the rate of

Table 4. Secondary Effect Parameters

	Parker Flex-Tip Tube	Standard Tube	*P*
Intubation time, s	7.5 (5–15)	20 (15–27)	<0.0001
Subjective difficulty score	1 (1–2)	2 (2–2.5)	<0.0001
Cuff pressure, cm H_2O	28 (25–30)	20 (16–22)	<0.001
Postoperative hoarseness (VAS), mm	9 (4.5–29)	7 (4–21)	0.35
Postoperative sore throat (VAS), mm	11 (1.5–23)	3 (0–13)	0.11

Values are median (quartiles).

VAS = Visual Analog Scale.

resistance to the tube. In our study, this relative reduction is more than two thirds (from 89% to 29%).

It is repeatedly described in the literature that even after trouble-free insertion of the tip of the fiberscope into the trachea, there is a considerable rate of resistance to passage of the tube into the trachea,[1–7] and that this is mainly due to the tube impinging on laryngeal structures (arytenoid cartilages and epiglottis).[2] When attempting intubation by passing a tube over a gum-elastic bougie placed with the tip in the trachea,[11] initial difficulty of passing the tube into the larynx was found in 92% of cases. When subsequently the tube was withdrawn 2 cm and rotated 90° counterclockwise and then reinserted, it went in in 78% of the cases in which it had initially failed. This maneuver was adopted and slightly modified (the tube was withdrawn 5 cm instead of 2 cm) by Jones *et al.*[3] for use when passing the tube over the fiberscope. In the current study and other studies, this maneuver proved to be effective in a large fraction of cases when oral fiberoptic intubation is performed[4,7]; however, for the nasal approach, it was not found to be efficient.[6]

Several studies have examined the possible benefits of alternative endotracheal tubes for fiberoptic intubation. Jones *et al.*[3] found, in a randomized but nonblinded study, that a specially manufactured endotracheal tube with a tapered tip was significantly more easy to pass over a fiberscope into the trachea than a standard tube; however, this endotracheal tube was never commercially available. A flexible wire-reinforced tube was found to be superior to a standard tube (rate of initial impingement of the tube upon entering the larynx being 1 in 20 *vs.* 13 in 20). The study was not blinded, and the cost of the flexible tube was 10–20 times that of the standard tube.[4] Subsequent studies have not found that flexible wire-reinforced tubes were the solution to the problem.[5] One endotracheal tube, the flexible silicone-tipped tube manufactured for intubation with the intubating laryngeal mask airway (*LMA-Fastrach™*; Laryngeal Mask Company Limited, Henley on Thames, Uxon, UK) has in two recent studies been found to be very well suited for fiberoptic intubation, reducing the rate of resistance to passing of the tube from 40–53% to 0–10%.[6,7] The major drawbacks of this tube are the high cost of the reusable tube and that it is only is available down to an ID size of 7 mm.

The use of a fiberscope with a larger diameter relative to the diameter of the tube reduces the incidence of resistance to passage of the endotracheal tube through the vocal cords,[10,12] whereas repeated attempts at passage may result in airway bleeding or swelling or damage to the arytenoid cartilages, making subsequent tracheal intubation attempts more difficult.

Many anesthesiologists have access to a flexible fiberscope, but they use it infrequently for performing fiberoptic intubation[13] and thus may not be familiar with the manipulations that lead to a successful intubation when the tube meets resistance during passage of the larynx. That also means that the tube passages that are categorized as "grade 1" in this study may lead to a difficult or impossible intubation in the clinical setting.

A possible solution to the problems with passage of the tube is to a use a fiberscope with the diameter suiting each size of endotracheal tube that is needed, but to most clinicians, this luxury is unlikely to be realistic. When one has to manage different sizes of patients and has access to a typical intubation fiberscope like the one used in this study, the use of a tube that minimizes the gap between the fiberscope and the tube and thus the need for repositioning of the tube are recommended.

The PFT tube needed higher cuff pressure to seal the trachea than the standard tube. This is a feature of the cuff that is shared with the *LMA-Fastrach™* tube and emphasizes the importance of maintaining the minimal cuff volume that seals the trachea.[14]

The differences in tube tip design did not lead to differences in the incidence of hoarseness or sore throat. The findings in this study are limited to patients with general anesthesia and may not be true in awake fiberoptic intubation.

In conclusion, during intubation with the use of a flexible fiberscope, the use of the PFT tube results in a significantly lower rate of repositioning and repeated attempts at passing the tube into the trachea, compared to a standard endotracheal tube. The use of the PFT tube is recommended for fiberoptic orotracheal intubation when a disposable tube is preferred and a fiberscope is used that is so slim that it leaves a gap between the scope and the tube.

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