Parker Flex-Tip™ are not superior to polyvinylchloride tracheal tubes for awake fibreoptic intubations

[Les tubes Parker Flex-Tip™ ne sont pas supérieurs aux tubes trachéaux de polychlorure de vinyle utilisés pour les intubations fibroscopiques vigiles]

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Purpose: Difficulty can be encountered during advancement of the tracheal tube (TT) over the bronchoscope after successful endotracheal bronchoscopy due to impingement on laryngeal structures. A new TT, the Parker Flex-Tip (PFT), has been shown to be superior to polyvinylchloride (PVC) TTs in anesthetized, paralyzed patients with normal airways. However, no study to date has shown the superiority of the new tapered tip design in patients with difficult airways during awake fibreoptic intubations (AFOI). The purpose of this study was to compare the PFT with PVC TTs for AFOI in patients with difficult airways or unstable c-spines.

Clinical features: In this prospective observational study, 111 patients with predicted or documented difficult airways, or unstable c-spines were assessed for ease of TT advancement during AFOI. First attempt success rates were 91% for PFT TTs and 84% for PVC TTs (P = NS). Resistance to TT advancement was none to mild and similar in both groups. Advancement without the need to rotate the TT 180° was also similar in both groups (57% *vs* 53%).

Conclusion: For AFOI in patients with difficult airways, the PFT is not superior to conventional PVC TTs.

Objectif : *Il peut être difficile d'avances le tube endotrachéal (TET) le long du bronchoscope lors d'une intubation fibroscopique à cause d'un contact avec des structures laryngées. Un nouveau TET, le Parker Flex-Tip (PFT), s'est révélé supérieur aux TET de polychlorure de vinyle (PCV) chez les patients anesthésiés et paralysés aux voies aériennes normales. Mais aucune étude à ce jour n'a montré la supériorité de ce tube à pointe effilée dans les cas de problèmes de voies aériennes pendant l'intubation fibroscopique vigile (IFOV). Notre étude compare le PFT avec les TET de PCV pour l'IFOV en cas d'anomalies des voies aériennes ou d'instabilité de la colonne cervicale.*

Éléments cliniques : *Notre étude observationnelle prospective a évalué 111 patients avec des problèmes de voies aériennes prévus ou documentés ou une instabilité de la colonne cervicale, quant à la facilité d'avancer le TET pendant l'IFOV. Les succès du premier essai ont été de 91 % pour le TET PFT et de 84 % pour le TET de PCV (P = NS). La résistance à l'avancement du TET a été de nulle à légère dans les deux groupes. L'avancement sans nécessité de rotation de 180° du TET a aussi été comparable dans les deux groupes (57 % vs 53 %).*

Conclusion : *Pour l'IFOV chez les patients qui ont des problèmes de voies aériennes, le PFT n'est pas supérieur au TET de PCV traditionnel.*

FIBREOPTIC bronchoscopy (FOB) is used routinely to perform awake fibreoptic intubation (AFOI) in patients with predicted or documented difficult airways. However difficulty can be encountered during advancement of the tracheal tube (TT) over the bronchoscope after successful endotracheal bronchoscopy due to impingement on laryngeal structures.[1] This can lead to airway trauma or failed tracheal intubation (TI).

It has been shown previously that the TT tip and bevel design can affect the probability of successful TI in anesthetized, paralyzed patients with normal airways.[2–4] A new commercial TT, the Parker Flex-Tip™ (PFT; Parker Medical, Englewood, CO, USA), has been specially designed with a contoured, tapered tip

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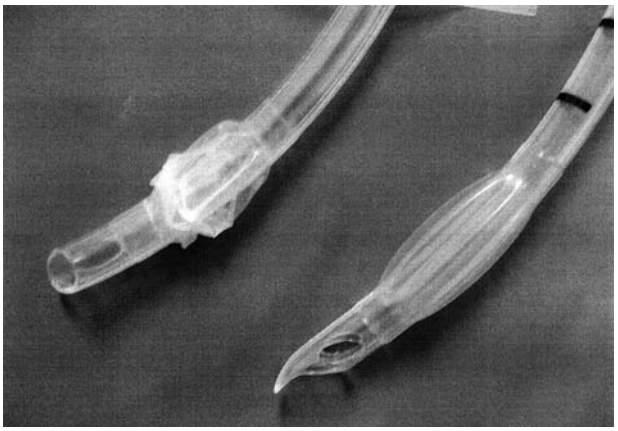

FIGURE 1 Tip of Mallinckrodt Hi-Lo™ polyvinylchloride and Parker Flex-Tip™ tracheal tubes.

for ease of advancement into the trachea during FOB assisted TI (Figure 1). The PFT TT has been shown to have higher success rates with easier passage when compared to a conventional polyvinylchloride (PVC) TT in anesthetized, paralyzed patients with normal airways.[5] However, no study to date has shown the superiority of the tapered tip designed TTs in patients with difficult airways during AFOI.

The purpose of this study was to compare the conventional PVC TT with the PFT TT for success and ease of TT advancement during AFOI in patient with difficult airways after airway topicalization.

Methods

After Institutional Research Ethics approval, consecutive patients scheduled for daytime surgery were enrolled in the study. Patient consent was not required by the local Ethics Board as the study was a prospective non-randomized observational study. Patients requiring AFOI for a difficult airway, previously failed TI or unstable c-spine were enrolled. Mode of airway topicalization was performed at the discretion of the attending anesthesiologist. The type of TT and the size of TT were also chosen by the attending anesthesiologist based on patient characteristics and personal preference. Patients were excluded if the first time TI attempt was made with a TT size < 7.0 mm or > 8.0 mm in order to limit extreme sizes which are not representative of routine clinical practice. The PFT TT was inserted without any rotation as per the manufacturer's suggestions. The Mallinckrodt Hi-Lo™ (Mallinckrodt, Hazelwood, MO, USA) PVC TT was inserted with a 90°clockwise rotation such that the bevel was facing up as is practice in our hospital to facilitate insertion by preventing impingement on the epiglottis. A 4.5-mm diameter FOB diameter was used in all cases. Either TT was rotated, up to 180°, during TI to increase success rates, when required. All subjective grading of difficulty of TT insertion over the FOB were performed by research personnel who were not involved with primary patient care. Grading for resistance to tube insertion was defined as follows:

None: no resistance;
Mild: resistance which did not affect TT insertion;
Moderate: resistance which required force to insert the TT into the trachea;
Severe: resistance that resulted in failure of passage into the trachea.

Sample size calculation was not performed as this was a non-randomized observational study. Parametric data were analyzed using an unpaired student's t test. Non-parametric data were analyzed using the Mann Whitney Rank Sum test. Categorical data were analyzed using the Chi-square test. A two-tailed P value of < 0.05 was considered significant.

Results

During the period between December 2001 to December 2003, 111 patients were included in the study. Patient demographics show that there were no differences between groups (Table I). There were no differences between the two groups with respect to success rates. First attempt success rates were 91% for the PFT TTs and 84% for the PVC TTs ($P = 0.40$). Ease of TT insertion was also similar between groups ($P = 0.24$; Figure 2). The need to rotate the TT, up to 180°, was also similar in both groups at 57% for the PVC group *vs* 53% for PFT group ($P = 0.47$). Characteristics of patients with failed first attempt intubations are shown in Tables II and III.

Discussion

Many studies have shown the benefits of tapered TTs for FOB assisted TI.[3,5–7] However, all of these studies were performed on patients with normal airways, under general anesthesia with muscle paralysis. The results of past studies may not be applicable to clinical situations when patients are awake and breathing spontaneously. For example, it has been advocated by the American Society of Anesthesiologists' that patients with difficult airways or unstable c-spines have their airways secured while they are still awake with spontaneous ventilation.[8]

The results of our study suggest that there is no benefit of using the PFT TT *vs* a conventional PVC

TABLE I Patient demographics

	Parker Flex-Tip TT (n = 56)	*Polyvinylchloride TT (n = 55)*	*P value*
Age 55 ± 16	57 ± 16	0.57	
Sex M:F	36:20	32:23	0.64
Height (cm)	167 ± 10	165 ± 10	0.39
Weight (kg)	80 ± 22	84 ± 22	0.32
Reason for AFOI			
Difficult airway	41	34	0.28
Unstable c-spine	15	21	
Fibreoptic route			
Oral	54	53	1.00
Nasal	2	2	
Midazolam dose (mg)	2.5 (1.2-4.0)	2.0 (1.1-3.0)	0.20
Fentanyl dose (μg)	50.0 (0-100)	50.0 (0-87)	0.34
Mode of airway topicalization			*0.35*
Nebulized/spray	55	50	
Gargle/pledget	27	37	
Transtracheal	5	8	
Superior laryngeal block	2	7	
Lidocaine via FOB	28	31	
Optimal patient cooperation	52 (93%)	51 (93%)	0.98
Median initial tracheal tube size (mm)	7.5 (7.0-8.0)	7.5 (7.0-8.0)	0.48
Tracheal tube sizes (mm)			
7.0	18	22	
7.5	21	7	
8.0	17	26	

TT= tracheal tube; AFOI = awake fibreoptic intubation; FOB = fibreoptic bronchoscopy. Data expressed as mean ± SD or median (range).

TABLE II Failed intubation - Parker Flex-Tip

Patient no.	*Sex*	*Age*	*BMI*	*Route*	*Reason for AFOI*	*Initial TT size*	*No. of attempts*	*Type and size of tube at success*
4	M	70	28	Oral	Difficult airway	8.0	2	8.0 Parker
5	F	30	25	Oral	Difficult airway	7.5	2	7.5 Parker
33	F	68	34	Oral	Difficult airway	7.0	2	7.0 Parker
46	M	62	42	Oral	Difficult airway	8.0	2	7.0 Parker
51	M	42	27	Oral	Difficult airway	8.0	2	8.0 PVC

BMI = body mass index; TT = tracheal tube; PVC = polyvinylchloride.

TT for AFOI. There may be many reasons why the results of our study are different from previous studies performed under general anesthesia. Firstly, the lack of paralysis may have altered the dynamics of resistance on the impinging structures such as the arytenoids cartilages and the epiglottis. Secondly, the orientation and rotation of the PVC TT on insertion may have improved success rates. Our hospital practice is to insert PVC TTs with a 90°clockwise rotation to prevent impingement on the epiglottis. If TI is not successful with this maneuver, the PVC TT is rotated 180° such that the bevel is facing posterior. Previous reports have demonstrated that a 90°counterclockwise rotation with a posterior facing bevel increases success rates when compared to no rotation.[1,7]

A previous study by Kristenson showed that the PFT TT was easier to insert than a PVC TT, with an initial success rate of 89% *vs* 29% in the PVC group.[5] However, the major limitation of that study was that the PVC TT was inserted without any rotation, thus leading to a potential advantage for the PFT TT. Another limitation of their study was that they used patients with normal airways under general anesthesia with paralysis. Finally they used a 4.0-mm FOB while we used a 4.5-mm FOB. A previous study by Hakala showed that a larger FOB (5.0 *vs* 3.7 mm) results in less resistance to TT passage.[9] The study by Kristenson, therefore, may not represent clinical scenarios when fibreoptic guided TI is performed on patients with difficult airways in the awake state, with a larger FOB.

TABLE III Failed intubation - PVC

Patient no.	*Sex*	*Age*	*BMI*	*Route*	*Reason for AFOI*	*Initial TT size*	*No. of attempts*	*Type and size of tube at success*
12	F	73	36	Oral	Unstable c-spine	8.0	2	8.0 PVC
14	M	37	37	Oral	Difficult airway	8.0	3	8.0 PVC
16	F	24	24	Oral	Difficult airway	7.0	2	6.5 Parker
19	M	66	37	Oral	Difficult airway	8.0	2	8.0 PVC
24	F	72	25	Oral	Difficult airway	7.0	2	6.5 Parker
25	M	86	30	Oral	Unstable c-spine	8.0	2	7.5 Parker
40	F	49	22	Oral	Difficult airway	7.0	2	6.5 Parker
47	M	69	28	Oral	Difficult Airway	8.0	3	8.0 PVC
54	F	50	34	Oral	Unstable c-spine	8.0	2	7.0 PVC

PVC = polyvinylchloride; BMI = body mass index; AFOI = awake fibreoptic intubation.

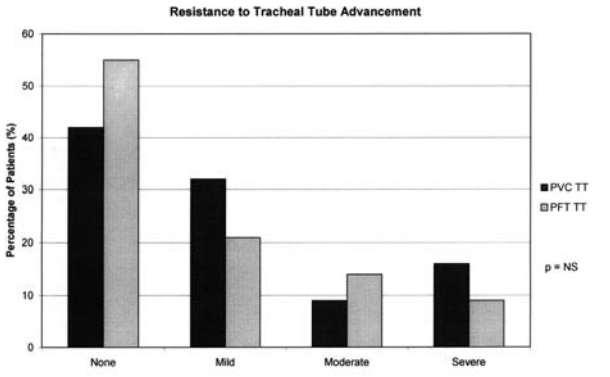

FIGURE 2 Resistance to tracheal tube advancement.

The current study has limitations. The study was not randomized, not blinded, and the airway topicalization was not standardized. We chose a prospective observational study type so that we could enroll the maximal number of patients given that patients with difficult airways requiring AFOI are encountered infrequently. With the large number of patients coming in for same day surgery, having emergency surgery and having AFOI immediately after failed laryngoscopy, we felt that we could not enroll an adequate number of patients if the study was to be randomized and controlled. Considering the mean difference in successful tube insertion, the possibility exists for a type 2 error as the power was only 0.18. However, even if a type 2 error occurred, the difference in success rates may still be marginal at 84 *vs* 91%, and not clinically significant.

The mode and effectiveness of topical anesthesia may affect success with AFOI. In our study, there was a trend toward an increased number of anesthetic blocks (transtracheal and superior laryngeal blocks) performed in the PVC group. However, more blocks do not necessarily correlate with more effective anesthesia. Topical anesthesia was performed by tertiary care anesthesiologists, to the best of their ability until they felt that the patients were adequately blocked.

Finally, study design may have contributed to bias. However, we expected the bias to favour the PFT TTs due to its novelty, previous reports of superiority and higher expectations, as it was specifically designed for FOB TI. The fact that we did not see differences in resistance or success rates suggests that bevel design may not be the most important variable when the TTs are used for AFOI. Other factors such as patient anatomy and difference in size between FOB and TT may play a more important role in determining success.[9,10]

In conclusion, we found that both the regular PVC TT and the specifically designed PFT TT are suitable for use for FOB TI. The PVC TT should not be replaced with the PFT until more convincing evidence of its superiority is published. PVC TTs are currently cheaper and still more readily available for FOB TI. Ideally, a randomized controlled study on awake patients with difficult airways should be performed to provide a more definitive answer.

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References

1 *Katsnelson T, Frost EA, Farcon E, Goldiner PL.* When the endotracheal tube will not pass over the flexible

fiberoptic bronchoscope (Letter). Anesthesiology 1992; 76: 151–2.
2 *Greer JR, Smith SP, Strang T.* A comparison of tracheal tube tip designs on the passage of an endotracheal tube during oral fiberoptic intubation. Anesthesiology 2001; 94: 729–31.
3 *Hakala P, Randell T, Valli H.* Comparison between tracheal tubes for orotracheal fibreoptic intubation. Br J Anaesth 1999; 82: 135–6.
4 *Lucas DN, Yentis SM.* A comparison of the intubating laryngeal mask tracheal tube with a standard tracheal tube for fibreoptic intubation. Anaesthesia 2000; 55: 358–61.
5 *Kristensen MS.* The Parker Flex-Tip tube versus a standard tube for fiberoptic orotracheal intubation: a randomized double-blind study. Anesthesiology 2003; 98: 354–8.
6 *Connelly NR, Kyle R, Gotta J, et al.* Comparison of wire reinforced tubes with warmed standard tubes to facilitate fiberoptic intubation. J Clin Anesth 2001; 13: 3–5.
7 *Jones HE, Pearce AC, Moore P.* Fibreoptic intubation. Influence of tracheal tube tip design. Anaesthesia 1993; 48: 672–4.
8 *Benumof JL.* Management of the difficult adult airway. With special emphasis on awake tracheal intubation. Anesthesiology 1991; 75: 1087–110.
9 *Hakala P, Randell T.* Comparison between two fibrescopes with different diameter insertion cords for fibreoptic intubation. Anaesthesia 1995; 50: 735–7.
10 *Makino H, Katoh T, Kobayashi S, Bito H, Sato S.* The effects of tracheal tube tip design and tube thickness on laryngeal pass ability during oral tube exchange with an introducer. Anesth Analg 2003; 97: 285–8.