British Journal of Anaesthesia **105** (4): 538–43 (2010)
Advance Access publication 3 August 2010 · doi:10.1093/bja/aeq202
BJA

RESPIRATION AND THE AIRWAY

Effect of tracheal tube cuff shape on fluid leakage across the cuff: an *in vitro* study

M. H. Dave*, A. Frotzler, N. Spielmann, C. Madjdpour and M. Weiss

Department of Anaesthesia, University Children's Hospital, Steinwiesstrasse 75, CH 8032 Zurich, Switzerland

* Corresponding author. E-mail: mital.dave@kispi.uzh.ch

Key points

- Optimizing tracheal sealing is of clinical interest: fluid leakage past the tube cuff plays an important role in the pathogenesis of VAP.
- Tapered shaped tube cuff offering a sealing zone with reduced folds and channels is a new strategy to minimize fluid leakage past the tracheal tube cuff.
- Tracheal tube cuffs made from PVC show much more and faster fluid leakage than cuffs made from PU in a simulated artificial model.
- Tracheal sealing with tapered shape PU tube cuff is as efficient as the conventional cylindrical PU tube cuff in smaller tracheal diameters and more efficient at higher tracheal diameter with regard to tracheal sealing against fluid leakage.

Background. This study compared the fluid leakage in the new 'tapered' shaped against the classic 'cylindrical' shaped tracheal tube cuffs when placed in different sized tracheas.

Methods. The 7.5 mm internal diameter (ID) tracheal tube cuffs—Tapered Seal Guard (TSG), Standard Seal Guard (SSG), Hi-Lo, Microcuff, Ruesch, and Portex Profile—were compared in an *in vitro* apparatus. Vertical artificial tracheas with 16, 20, and 22 mm ID were intubated, 5 ml clear water was applied above the unlubricated tube cuffs, and fluid leakage was measured up to 60 min. Data of tapered *vs* non-tapered tube cuffs (16 observations) were compared for each tracheal diameter using the Mann–Whitney test.

Results. Median (range) fluid leakage (ml) at 60 min was 2.14 (0.05–4.88), 1.14 (0.00–4.84), and 0.13 (0.00–1.32), respectively, for 16, 20, and 22 mm tracheas in the TSG tube studies when compared with 4.58 (0.44–4.88), 2.21 (0.00–4.81), and 0.00 (0.00–4.81) in the SSG tube and 4.54 (1.54–4.82), 0.90 (0.00–4.49), and 4.85 (4.40–4.99) in the Microcuff tube studies. Leakage in all polyvinylchloride (PVC) tube cuffs was almost complete (5 ml) within 5 min ($P<0.001$).

Conclusions. The tapered PU tube cuff was as effective as the cylindrical PU cuffs in smaller tracheal diameters and was more efficient than the cylindrical Microcuff PU tube cuff in larger tracheal diameter in preventing subglottic fluid leakage across the tube cuff tested in this *in vitro* study. PVC tube cuffs leaked much more and faster than PU cuffs.

Keywords: airway; tracheal tube

Accepted for publication: 5 June 2010

When high volume–low pressure cuffs (HVLP) are inflated in the trachea to achieve a seal, the excess material folds over itself, developing channels and thus allowing leak.[1–4] There is clear evidence that leakage of subglottic contaminated secretions past the tracheal tube cuff plays a major role in the development for ventilator-associated pneumonia (VAP).[5] It is now widely accepted that VAP is an important cause of morbidity and mortality in critically ill patients and also a major killer in intensive care medicine.[6] Critically ill adults receiving mechanical ventilation have an incidence of VAP between 20% and 60% and an associated mortality reported at 27%.[7]

The recently introduced tapered-shaped tracheal tube cuff made from polyurethane (PU) (Tapered Seal Guard Tracheal Tube, Covidien, Athlone, Ireland) represents a new strategy to reduce fluid leakage across the cuff (Fig. 1). The tapered cuff design ensures that there is always a 'sealing zone' where the outer cuff diameter corresponds to the internal tracheal diameter.

The object of this study was to compare the tapered-shaped PU tracheal tube cuff with different cylindrical tracheal tube cuffs for fluid leakage when placed in different sized tracheas in an *in vitro* model.

Methods

In an *in vitro* apparatus, we investigated the efficacy of six different commercially available tracheal tubes with an internal diameter (ID) of 7.5 mm (Table 1) in preventing fluid leakage past the tube cuff. We chose conventional tracheal tube cuffs with PU and polyvinylchloride (PVC) cuff material that are currently most widely used in Europe.

Artificial PVC tracheas with 16, 20, and 22 mm ID corresponding to a wide range of human tracheal size[8 9] were vertically placed and intubated with tracheal tubes without cuff wall lubrication. The range of the human adult tracheal diameter varies from 1.5 to 2.5 cm.[9] Tracheal

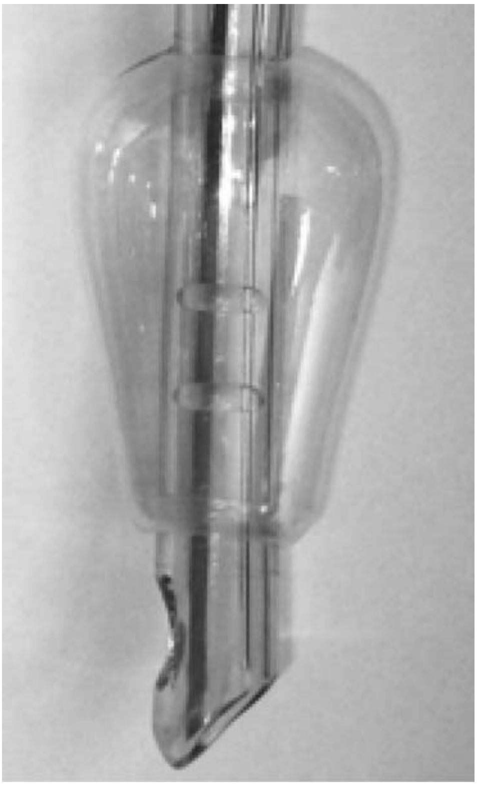

Fig 1 TSG tracheal tube (Covidien, Athlone, Ireland) inflated to 25 cm H_2O cuff pressure.

anteroposterior and transverse diameter range in females is 12.7–23.8 and 17.3–27.8 mm, respectively.[10] A 7.5 mm ID tracheal tube is used for female patients and hence we considered 16, 20, and 22 mm ID artificial trachea appropriate for testing.

The tube cuff was inflated to 25 cm H_2O cuff pressure and continuously monitored by a digital automated cuff pressure manometer (VBM Cuff Controller, VBM Medizintechnik GmbH, Sulz a.N., Germany). The tube was positioned with its lower cuff border 2.5 cm above the lower tracheal edge.

At room temperature of 20–22°C, 5 ml of clear water was applied above the tube cuff and fluid leaking past the cuff was collected in a container below the model and weighed using an electronic balance (AG 204-Delta-Range®, Mettler Toledo, Schwerzenbach, Switzerland; sensitivity 0.0001 g). Fluid leakage was measured at 0, 0.5, 1, 2, 3, 4, 5, 10, 15, 30, and 60 min in this static setup. Measurements were discontinued when we did not see any fluid level above the top of the cuff if earlier than 60 min. The end time and fluid amount was noted in each trial. We chose 1 h as an endpoint as already studied in similar benchtop studies.[3 11 12] We intentionally did not ventilate the tracheas since PEEP and positive pressure ventilation are known to protect against cuff leakage and hence differences between sealing characteristics of various tubes might remain concealed.[13]

We calculated the cross-sectional area (CSA) of a given tracheal tube cuff from its outer diameter (OD) (mm) as provided by the manufacturer. Similarly, internal CSA of a given trachea was calculated and a percentage ratio was obtained by dividing the abovementioned areas. For the TSG tube, a similar ratio was obtained over a range.

Table 1 HVLP tracheal tube cuffs investigated (all ID 7.5 mm). CSA, cross-sectional area; ID, internal diameter; OD, outer diameter

Tubes tested	Product reference number	Tube ID (mm)	Tube OD (mm)	Cuff material	Cuff OD (mm)	Cuff CSA (mm^2)	% of cuff CSA (mm^2)/200 mm^2 (internal CSA of 16 mm trachea)	% of cuff CSA (mm^2)/314 mm^2 (internal CSA of 20 mm trachea)	% of cuff CSA (mm^2)/379 mm^2 (internal CSA of 22 mm trachea)
TSG (Covidien, Athlone, Ireland)	109875	7.5	10.2	PU	20–27	314–572	157–286	100–182	82–150
SSG (Covidien, Athlone, Ireland)	109675	7.5	10.2	PU	26	530	265	168	139
Microcuff tracheal tube (Kimberly Clark, Zaventem, Belgium)	35125	7.5	10	PU	22	379	189	120	100
Hi-Lo tracheal tube (Covidien, Athlone, Ireland)	109-75	7.5	10.2	PVC	30	706	353	224	186
Portex Profile Soft Seal (SIMS Portex Ltd, Hythe, UK)	100/199/075	7.5	10.3	PVC	30	706	353	224	186
Rüschelit Super Safety Clear (Rüsch GmbH, Kernen, Germany)	112480	7.5	10	PVC	26	530	265	168	139

Experiments were performed twice using eight different tracheal tubes from each manufacturer in a randomized order (thus 16 observations) with three different artificial trachea models (48 observations per tube brand). Tracheal tube cuffs were inflated and checked by inspection before each test. Between experiments, the model was cleaned and dried.

Statistics

The amount of fluid leakage at 5 and 60 min in each cylindrical tube cuff was compared with that of the tapered-shaped tube cuff in all the three different sized tracheal models tested, using a separate non-parametric Kruskal–Wallis test for each tracheal diameter. When statistical significance was obtained, we proceeded with planned pairwise comparisons using the Bonferroni-corrected Mann–Whitney *U*-tests comparing fluid leakage (ml) in the TSG tube with that of all the other five tracheal tubes included in this study. Again, to assess the effect of cuff material, a similar planned pairwise Mann–Whitney *U*-test was done between the PVC and the PU groups of tracheal tube cuffs. The level of significance was set at $\alpha=0.007$ after the Bonferroni correction. SPSS version 16.1 (SPSS Inc., Chicago, IL, USA) was used for this purpose.

Results

Fluid leakage (ml) at 5 and 60 min is described in Table 2. Overall sealing characteristics of the new tapered-shaped TSG tube cuff were superior to all other tube cuffs tested at both 5 and 60 min time point (Fig. 2) in different dimensions of trachea tested. The fluid leakage past the tube cuff was less with the TSG tube when compared with five other tubes of different cuff shape and material in both 16 and 22 mm trachea, and the difference was found to be statistically significant ($P<0.001$, Mann–Whitney *U*-test with the Bonferroni correction, Table 2) for all PVC tube cuffs.

When considering the PU cuff material, the Microcuff tracheal tube cuff was not able to seal the 22 mm ID trachea, although there was no significant difference between this tube and the TSG tube when tested in the 16 and 20 mm tracheal models (Table 2).

Tracheal tube cuffs made from PVC allowed a considerably higher fluid leakage than those made from PU ($P<0.001$) (Table 2). Fluid leakage across cylindrical PU cuffs was faster and higher in parallel with the percentage ratio of tube cuff to artificial trachea CSA (Table 1; Fig. 3).

Discussion

This *in vitro* study compared the ability of a 'tapered' shaped cuff design to the conventional 'cylindrical' cuff design for the prevention of tracheal fluid leakage in three different sized artificial tracheas. The main finding was that the tapered-shaped cuff was effective in preventing cuff leakage in the three different sized tracheas tested and that cuffs made from PU were superior to those made from PVC.

Folds and channels in HVLP tube cuffs leading to silent aspiration of secretions into the trachea to date remain a challenging problem awaiting a scientifically advanced solution. Numerous attempts have been made by researchers in the past to design a cuff that would provide a more effective seal without leakage at lower transmitted cuff pressures.[11 14–19]

One such novel concept to reduce the folds in the HVLP tube cuff comes from Zanella and colleagues.[17] They proposed wrapping the standard HVLP cuff with a low protein latex rubber supported by gel lubrication between the two layers to ensure an even surface without folds. It claimed effective sealing at low transmitted pressures to the tracheal wall in static *in vitro* models. They also described a 'no-pressure' laryngeal seal design that uses a series of compliant gills rather than a cuff in an attempt to prevent the leakage from subglottis into the trachea and to minimize airway injury.[19 20] Low volume–low pressure tubes introduced by Young and colleagues[21] have a highly compliant silicone cuff wall and preliminary *in vitro* testing showed excellent sealing characteristics.

Recently, tracheal tube cuffs made from PU have been shown to reduce microaspiration and the rate of postoperative nosocomial pneumonia.[12 22] The introduction of

Table 2 *In vitro* fluid leakage (ml) measured in HVLP tracheal tube cuffs (ID 7.5 mm). Cuffs inflated to 25 cm H_2O cuff pressure. Data represented in median (range). *$P<0.001$, Mann–Whitney *U*-test (Bonferroni's correction); PU, polyurethane; PVC, polyvinyl chloride

Tracheal ID	Cuff material	Fluid leakage (ml) in artificial trachea at 5 min			Fluid leakage (ml) in artificial trachea at 60 min		
		16 mm	20 mm	22 mm	16 mm	20 mm	22 mm
TSG	PU	0.59 (0.00–2.74)	0.11 (0.00–0.82)	0.00 (0.00–0.06)	2.14 (0.05–4.88)	1.14 (0.00–4.84)	0.13 (0.00–1.32)
SSG	PU	1.62 (0.00–4.84)	0.18 (0.00–1.74)	0.00 (0.00–4.81)	4.58 (0.44–4.88)	2.21 (0.00–4.81)	0.00 (0.00–4.81)
Microcuff tracheal tube	PU	1.17 (0.32–4.56)	0.03 (0.00–0.35)	4.85 (4.40–4.99)*	4.54 (1.54–4.82)	0.90 (0.00–4.49)	4.85 (4.40–4.99)*
Ruesch tracheal tube	PVC	4.67 (4.34–4.89)*	4.55 (3.14–4.98)*	4.66 (2.28–4.97)*	4.67 (4.34–4.89)*	4.69 (4.39–4.98)*	4.75 (4.39–4.97)*
Portex tracheal tube	PVC	4.61 (4.45–4.83)*	4.27 (0.04–4.92)*	4.65 (4.01–4.97)*	4.61 (4.45–4.83)*	4.68 (1.24–4.92)*	4.65 (4.01–4.97)*
Hi-Lo tracheal tube	PVC	4.64 (4.45–4.89)*	4.43 (0.04–4.99)*	4.71 (4.22–4.97)*	4.64 (4.45–4.89)*	4.69 (1.24–4.99)*	4.71 (4.22–4.97)*

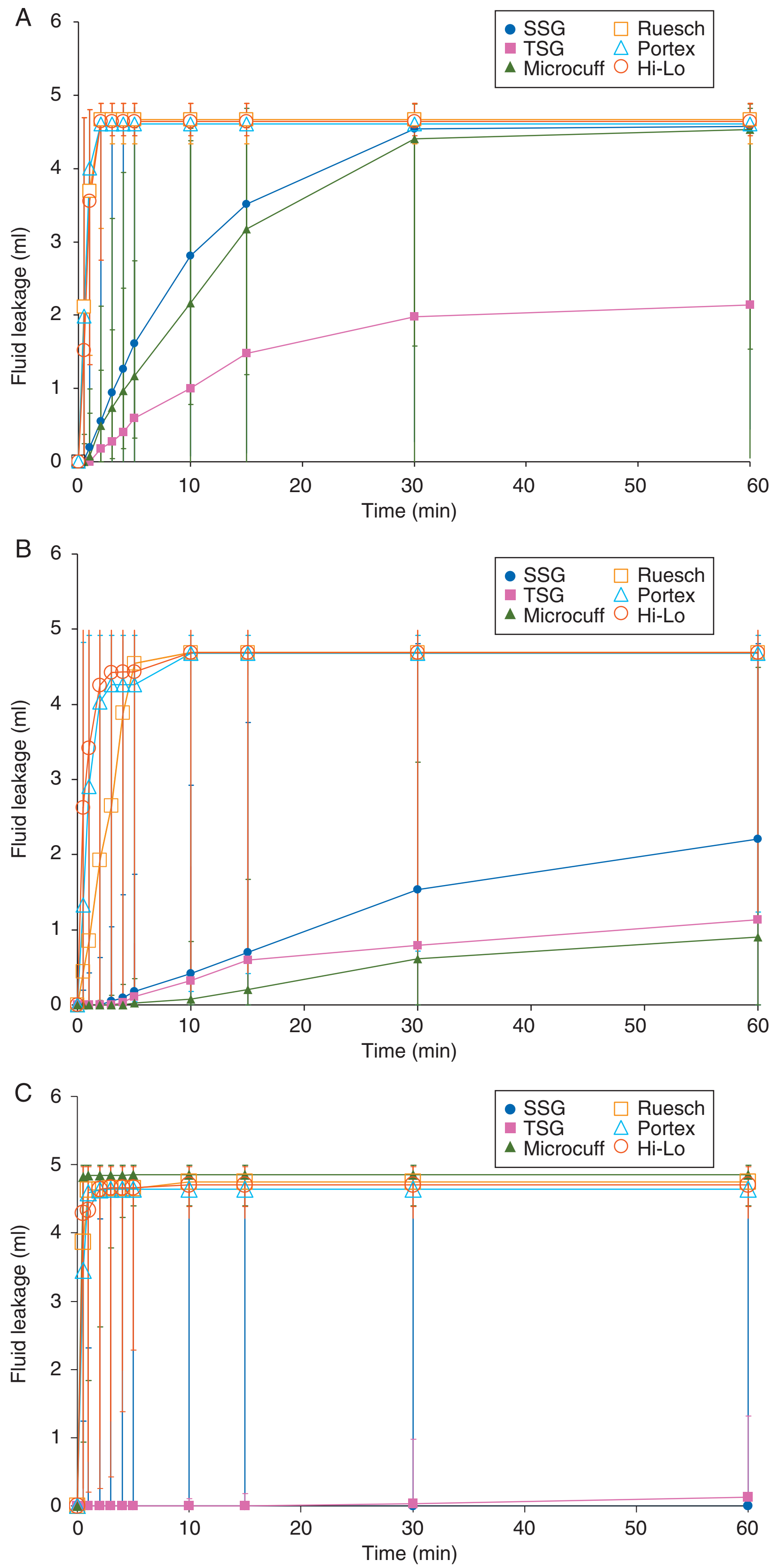

Fig 2 Fluid leakage across the tracheal tube cuff in (A) 16, (B) 20, and (C) 22 mm ID artificial trachea (cuff pressure 25 cm H_2O, 16 measurements per tube brand). Data presented as median (range).

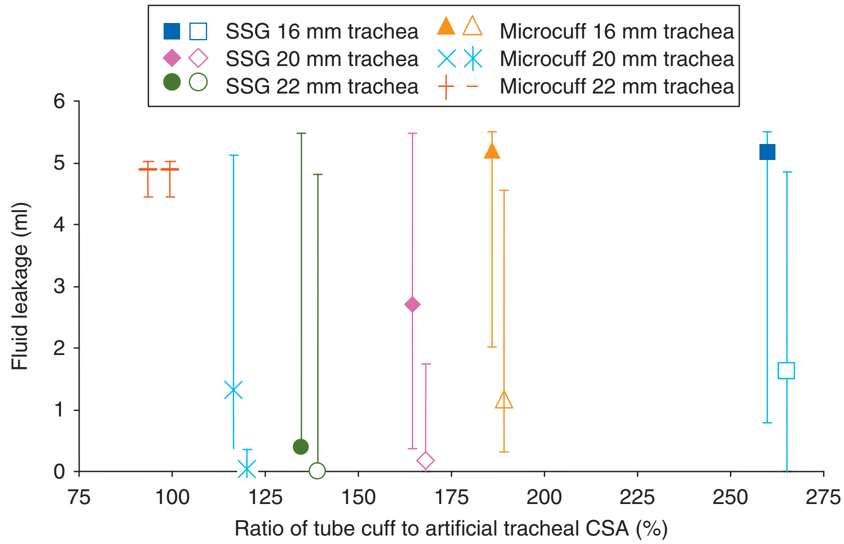

Fig 3 Comparison of fluid leakage (ml) in median (range) and the percentage ratio of tube cuff to artificial trachea CSA in PU tube cuffs. Fluid leakage at 60 and 5 min, respectively. Data points have been offset for clarity. Data for the TSG tube are not shown because the tapering shape of the tube cuff means that a single value for the ratios of the CSA cannot be calculated.

ultrathin wall PU cuff membrane technology seems to be a major step forward providing cuffs with improved tracheal air and fluid sealing characteristics[3 16 23 24] as confirmed by the present study, which, to the best of our knowledge, is the first study comparing three PU and three PVC tracheal tube cuffs in an *in vitro* setup. Poelaert and colleagues[22] have shown that the PU cuff can reduce the frequency of early postoperative pneumonia in cardiac surgical patients and compared the SSG tube with the Hi-Lo tube in their study. Similarly, Lucangelo and colleagues[12] showed that the SSG tube with PU cuff is much more resistant to leak when compared with the Hi-Lo tube.

The tapered-shaped tracheal cuff represents a further step in improving sealing characteristics of PU cuffs by the proposed mechanism of accommodating natural variations in the size of the trachea. On the basis of our findings, the TSG tube cuff showed overall efficient protection against cuff leakage in all the three diameters tested up to 60 min. The SSG tracheal tube which has a cylindrical PU cuff decreased the fluid leak in all the tracheal diameters, but the measured leak was more than the TSG tracheal tube at all time points in all the three different tracheal diameters tested, although this difference did not achieve statistical significance.

The Microcuff tracheal tube cuff sealed equally well in 16 and 20 mm diameter tracheas but completely failed to prevent fluid leak in the 22 mm diameter trachea. On the basis of Table 1 for a given 7.5 mm ID tracheal tube cuff, the Microcuff tracheal tube has the smallest cuff diameter and is not a true HVLP cuff. Hence, the cuff seals very well in a 20 mm trachea where a small outer cuff diameter results in fewer longitudinal folds and hence better sealing. The smaller cuff diameter is then too small to cover larger trachea (22 mm) and hence the tube allows a large leak in this model. Comparisons between Microcuff and TSG should be done with caution as the Microcuff tube cuff does not function as a real HVLP cuff in a 22 mm trachea. If the Microcuff tube had a larger cuff diameter sealing in the smaller tracheas would be expected to be worse, as fluid leakage was more in the 16 mm compared with the 20 mm ID artificial trachea (Table 1).

Another interesting observation was that a percentage ratio of the CSA of the tracheal tube cuff to the artificial trachea of more than 150% facilitated excessive longitudinal cuff fold formation that allowed rapid fluid leak (Fig. 3). In contrast, a percentage ratio of CSA of between 120% and 140% favoured better sealing and less fluid leakage. The 'dynamic sealing area' of the TSG tube provided a wide range for this ratio for the three different tracheas tested and thus exhibits efficient sealing over a range of tracheal sizes (Table 1).

In the near future, a tapered-shaped tube cuff may offer greater advantage in paediatric patients where the natural variation in tracheal diameter is considerable from birth to adolescence.[8] The new cuff design is likely to reduce cuff length of paediatric tracheal tube cuffs and to seal the paediatric airway at lower cuff pressures.[16 25]

Our study model of an intubated trachea did not attempt to simulate the surface of contact between the tracheal mucosa and the cuff, the static or dynamic properties of the tracheal and extra-tracheal tissues during ventilation, and the properties of different consistencies of secretions or the effect of mucus on the cuff–tracheal interface. *In vivo*, the posterior tracheal wall is compliant and dynamic and our rigid cylindrical model trachea cannot simulate this. A vertical model at room temperature does not mimic the real-life situation and a re-evaluation is required in the supine position and at body temperature. However, the model used here allowed testing the new cuff shape in a standardized and comparable way under 'stringent' conditions (no lubrication and no positive pressure ventilation) which might otherwise mask differences in fluid leakage past the tracheal tube cuff due to design and cuff material.

In conclusion, the tapered PU tube cuff was as effective as the cylindrical PU cuffs in smaller tracheal diameters and was more efficient than the cylindrical Microcuff PU tube cuff in larger tracheal diameter in preventing subglottic fluid leakage across the tube cuff tested in this *in vitro* setup. The tapered-shaped cuff offers a sealing zone with reduced folds and channels along a wide range of diameters and thus is capable of sealing different sized tracheas. However, clinical studies are needed to confirm the protective effect of the tapered-shaped cuff design in prevention of fluid leakage, intraoperative aspiration, and VAP.

Conflict of interest

The tracheal tubes tested were ordered from the local distributors. Prof. M.W. was involved in the development and evaluation of new cuffed tracheal tubes in co-operation with Microcuff GmbH, Weinheim, Germany, and Covidien, Athlone, Ireland.

Funding

This study was supported by departmental resources.

References

1 Young PJ, Rollinson M, Downward G, Henderson S. Leakage of fluid past the tracheal tube cuff in a benchtop model. *Br J Anaesth* 1997; **78**: 557–62

2 Oikkonen M, Aromaa U. Leakage of fluid around low-pressure tracheal tube cuffs. *Anaesthesia* 1997; **52**: 567–9

3 Dullenkopf A, Gerber A, Weiss M. Fluid leakage past tracheal tube cuffs: evaluation of the new Microcuff endotracheal tube. *Intensive Care Med* 2003; **29**: 1849–53

4 Seegobin RD, van Hasselt GL. Aspiration beyond endotracheal cuffs. *Can Anaesth Soc J* 1986; **33**: 273–9

5 Young PJ, Ridley SA. Ventilator-associated pneumonia. Diagnosis, pathogenesis and prevention. *Anaesthesia* 1999; **54**: 1183–97

6 Chawla R. Epidemiology, etiology, and diagnosis of hospital-acquired pneumonia and ventilator-associated pneumonia in Asian countries. *Am J Infect Control* 2008; **36**: S93–S100

7 Fagon JY, Chastre J, Hance AJ, Montravers P, Novara A, Gibert C. Nosocomial pneumonia in ventilated patients: a cohort study evaluating attributable mortality and hospital stay. *Am J Med* 1993; **94**: 281–8

8 Chandler M, Crawley BE. Rationalization of the selection of tracheal tubes. *Br J Anaesth* 1986; **58**: 111–6

9 Mehta S, Myat HM. The cross-sectional shape and circumference of the human trachea. *Ann R Coll Surg Engl* 1984; **66**: 356–8

10 Kamel KS, Lau G, Stringer MD. In vivo and in vitro morphometry of the human trachea. *Clin Anat* 2009; **22**: 571–9

11 Young PJ, Blunt MC. Improving the shape and compliance characteristics of a high-volume, low-pressure cuff improves tracheal seal. *Br J Anaesth* 1999; **83**: 887–9

12 Lucangelo U, Zin WA, Antonaglia V, *et al.* Effect of positive expiratory pressure and type of tracheal cuff on the incidence of aspiration in mechanically ventilated patients in an intensive care unit. *Crit Care Med* 2008; **36**: 409–13

13 Dave M, Koepfer N, Madjdpour C, Frotzler A, Weiss M. Tracheal fluid leakage in benchtop trials. Comparison of static versus dynamic model with and without lubrication. *J Anesth* 2010; **24**: 247–52

14 Young PJ, Ridley SA, Downward G. Evaluation of a new design of tracheal tube cuff to prevent leakage of fluid to the lungs. *Br J Anaesth* 1998; **80**: 796–9

15 Young PJ, Basson C, Hamilton D, Ridley SA. Prevention of tracheal aspiration using the pressure-limited tracheal tube cuff. *Anaesthesia* 1999; **54**: 559–63

16 Dullenkopf A, Gerber AC, Weiss M. Fit and seal characteristics of a new paediatric tracheal tube with high volume-low pressure polyurethane cuff. *Acta Anaesthesiol Scand* 2005; **49**: 232–7

17 Zanella A, Cressoni M, Epp M, Stylianou M, Kolobow T. A double-layer tracheal tube cuff designed to prevent leakage: a bench-top study. *Intensive Care Med* 2008; **34**: 1145–9

18 Kolobow T, Berra L, DeMarchi L, Aly H. Ultrathin-wall, two-stage, twin endotracheal tube: a tracheal tube with minimal resistance and minimal dead space for use in newborn and infant patients. *Pediatr Crit Care Med* 2004; **5**: 379–83

19 Kolobow T, Tsuno K, Rossi N, Aprigliano M. Design and development of ultrathin-walled, nonkinking endotracheal tubes of a new 'no-pressure' laryngeal seal design. A preliminary report. *Anesthesiology* 1994; **81**: 1061–7

20 Reali-Forster C, Kolobow T, Giacomini M, Hayashi T, Horiba K, Ferrans VJ. New ultrathin-walled endotracheal tube with a novel laryngeal seal design. Long-term evaluation in sheep. *Anesthesiology* 1996; **84**: 162–72, discussion 27A

21 Young PJ, Pakeerathan S, Blunt MC, Subramanya S. A low-volume, low-pressure tracheal tube cuff reduces pulmonary aspiration. *Crit Care Med* 2006; **34**: 632–9

22 Poelaert J, Depuydt P, De Wolf A, Van de Velde S, Herck I, Blot S. Polyurethane cuffed endotracheal tubes to prevent early postoperative pneumonia after cardiac surgery: a pilot study. *J Thorac Cardiovasc Surg* 2008; **135**: 771–6

23 Dullenkopf A, Schmitz A, Frei M, Gerber AC, Weiss M. Air leakage around endotracheal tube cuffs. *Eur J Anaesthesiol* 2004; **21**: 448–53

24 Weiss M, Doell C, Koepfer N, Madjdpour C, Woitzek K, Bernet V. Rapid pressure compensation by automated cuff pressure controllers worsens sealing in tracheal tubes. *Br J Anaesth* 2009; **102**: 273–8

25 Ho AM, Aun CS, Karmakar MK. The margin of safety associated with the use of cuffed paediatric tracheal tubes. *Anaesthesia* 2002; **57**: 173–5