

ORIGINAL RESEARCH

Do tapered tracheostomy cuffs improve translaryngeal gas flow when compared to barrel cuffed fenestrated tubes: A laboratory study

Ulf Borg BS  | Katie Bull MSN, Ed.D, RN

Department of Medical Affairs, Medtronic
Minimally Invasive Therapies Group, Boulder,
Colorado, USA

Correspondence

Ulf Borg BS, Medtronic, 6135 Gunbarrel
Avenue, Boulder, CO 80301, USA.
Email: ulf.borg@medtronic.com

Funding information

Medtronic

Abstract

Objective: The benefits of tracheostomy are well documented and include improved comfort and a reduction in sedative requirements that may facilitate more rapid ventilation weaning. A stable airway established with tracheostomy allows pulmonary toilet that may help in addressing aspiration. It is postulated that it may also increase translaryngeal airflow and allow phonation. We hypothesized that taper-shaped cuffed tracheostomy tubes have less bulk upon cuff deflation, and on this basis, gas flow past the deflated tapered cuff is better than non-tapered barrel cuffs and equal to gas flow in equivalent-sized fenestrated versions.

Methods: This comparative bench study measured exhaled gas flow of Shiley™ Flexible taper-cuffed tracheostomy and Fenestrated Shiley™ FEN tubes of equivalent sizes. Three sizes of Shiley™ tracheostomy tubes were used in printed 3D model tracheas, Jackson sizes 4, 6, and 10 (6.5, 7.5, and 10 mm ISO sizes). A standard ventilator provided tidal volumes to mechanical lungs. Because expiratory volume was the focus, the mechanical lungs exhaled through the model trachea and only the air exiting the model trachea, representing exhalation, was measured.

Results: Across three sizes, the Shiley™ Flexible tracheostomy tube allowed significantly more translaryngeal airflow compared to the tracheostomy tube with fenestrations.

Conclusion: This bench study showed significantly improved air flow past the cuff compared to fenestrated tubes. Improved airflow may help the phonation ability of patients. Clinical studies are required to elucidate use of this cuff design to allow phonation in patients with a tracheostomy.

Level of evidence: NA.

KEYWORDS

cuff design, fenestration, phonation, tracheostomy

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2022 The Authors. *Laryngoscope Investigative Otolaryngology* published by Wiley Periodicals LLC on behalf of The Triological Society.

1 | INTRODUCTION

The indications for tracheostomy vary depending upon the clinical scenario. In the context of otolaryngology, one indication is laryngeal obstruction whether due to tumors, trauma, infection, or stenosis. Tracheostomy procedures performed in the intensive care unit are

more likely to be required because of prolonged ventilation and the need for ongoing airway toilet.¹⁻⁴ Placement of tracheostomies in this context will be more comfortable for patients, allow rapid weaning of sedation, and shorten the duration of mechanical ventilation.^{5,6}

Lighter levels of sedation and improved comfort can improve the patient's ability to communicate.⁷ Translaryngeal airflow is possible with

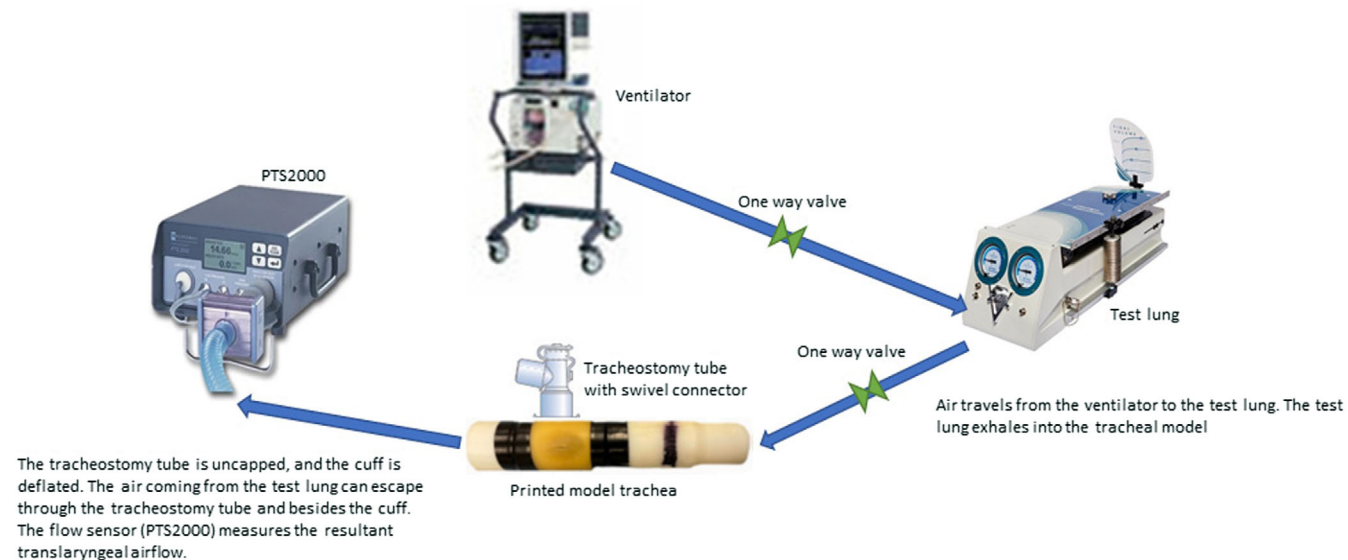


FIGURE 1 Schematic of experimental setup to measure translaryngeal airflow around tracheostomy tubes

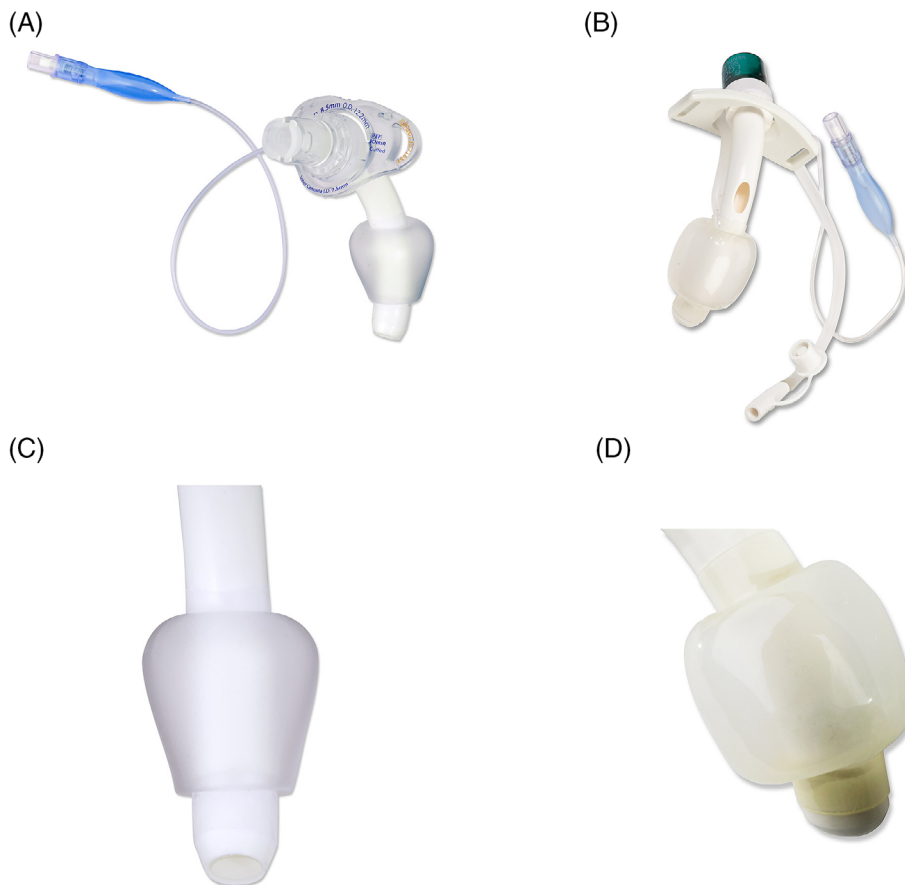


FIGURE 2 Tracheostomy tubes used in bench study, including (A) the Shiley™ Flexible tracheostomy tube and (B) the traditional Shiley™ Fenestrated tracheostomy tube. (C) Close-up view of the inflated taper-shaped cuff on the Shiley™ Flexible tracheostomy tube. (D) Close-up of the inflated barrel shaped cuff on the traditional Shiley™ tracheostomy tube Source: ©2021 Medtronic. All rights reserved. Used with the permission of Medtronic

cuff deflation. While this is the ideal situation, oversized tracheostomies may lead to intrinsic end-expiratory pressure due to breath-stacking, and render speech impossible. Even where the tracheostomy size is ideal, speech may be difficult due to breath-stacking. Long-term lack of translaryngeal airflow may lead to atrophy of the upper airway muscles, difficulties in swallowing, and longer times to decannulation.⁸⁻¹⁰ Therefore, the correct size of tracheostomy and an emphasis on translaryngeal airflow around the deflated tracheostomy cuff may improve outcomes.

Previous evidence has suggested that reducing fluid leakage around the cuff and into the lungs may reduce ventilator-associated pneumonia. For example, one benchtop model demonstrated that intermittent or continuous suction above the inflated cuff of the Portex Blue Line Ultra Suctionaid tracheotomy tube significantly reduced the mean volume of saliva that passed the cuff.¹¹ Similar results were observed using the Voyager tracheostomy tube, which contains a subglottic suction port (Medtronic, Boulder, USA).¹² The 4-h porcine study included suctioning every 15 min, and resulted in no secretions detected below the cuff.¹² Furthermore, Ledgerwood et al reported that patients who receive suction-above-the-cuff tracheotomy tubes had a significantly lower incidence of ventilator-associated pneumonia.¹³ This may be due to a reduction in the quantity of normal flora and pathogens in the subglottic space in the presence of a tracheotomy tube with above-the-cuff suction capabilities.¹⁴

A tracheostomy tube (Shiley™ Flexible Tracheostomy Tube, Medtronic, Boulder, USA) was developed with a tapered shaped cuff that may offer advantages in terms of incidence of ventilator-associated pneumonia compared to barrel shaped cuffs lacking above-the-cuff suctioning capabilities. Tracheostomy tubes with tapered cuffs were introduced for their potential benefits in reducing microaspiration. For example, one ex vivo model found that cuff sealing performance was significantly better in endotracheal tubes with tapered cuffs, compared to spherical cuffs. This included significantly lower microaspiration volumes when using a taper-shaped cuff.¹⁵ In addition, when deflated, the tapered cuff rests tighter to the tracheostomy outer cannula, reducing bulk when compared to the older barrel shaped cuffs.

Fenestrated tracheostomy tubes with cuffs are used in patients requiring positive pressure ventilation in an attempt to

promote phonation. There are several problems with secretion accumulation and ingrowth of tissue in the fenestrations. Therefore, we hypothesized that the gas flow around the less bulky deflated taper shaped cuff would be equal to the gas flow through fenestrations. A bench study was performed to test this hypothesis.

2 | METHODS

Three sizes of fenestrated and flexible tracheostomy tubes were used (Jackson 4/ISO 6.5 mm, Jackson 6/ISO 7.5 mm, and Jackson 10/ISO 10 mm) without an inner cannula. These sizes were selected as a representative sample of tube sizes, encompassing the smallest tube (Jackson 4), the most commonly used tube (Jackson 6), and the largest tube (Jackson 10). Since many patients in the weaning phase of ventilation need a cuff to maintain positive pressure ventilation intermittently, we compared cuffed fenestrated and flexible tracheostomy tubes but not uncuffed fenestrated tubes that are employed for long-term use. Three different 3D model tracheas were printed, each specifically sized to represent the trachea of a patient that would be expected to use each size of the tracheostomy tubes (18.5 mm ID for the size 4/6.5 mm tubes, 21.3 mm ID for the size 6/7.5 mm tubes and 23.2 mm ID for the 10/10.0 mm tubes).⁹ A standard ventilator (Puritan Bennett™ 840, Medtronic, Carlsbad, USA) was utilized to provide tidal volumes to the mechanical lungs.

Since expiratory volume was the focus of the study, the mechanical lungs exhaled through the model trachea where the tracheostomy tube was placed (Figure 1). The tracheostomy tubes were uncapped, and the cuffs on both types of tracheostomy tubes were deflated, hence allowing air to escape through the fenestration, if applicable, and around the tubes (Figure 2). We measured only the air exiting the model trachea, representing a normal exhalation (PTS 2000, Medtronic, Carlsbad, USA) and captured the data on BreathLab (Medtronic, Carlsbad, USA). Three different tidal volumes (Table 1) based on the size of tracheostomy tube were used for a total of 375 breaths per tracheostomy tube tested. As a laboratory study not involving patients nor animals, ethics approval was not required for this study.

TABLE 1 Volume controlled ventilation settings

Size	Size 4/6.5 mm	Size 6/7.5 mm	Size 10/10 mm
Tidal volume (ml)	175	500	800
Respiratory rate	15	15	15
Peak flow (L/min)	4.2	24	35
Plateau (s)	0.5	1.5	1.5

3 | RESULTS

In all sizes tested, the flexible tracheostomy tube allowed significantly more air flow around the cuff compared to the air flow through the

TABLE 2 Results of translaryngeal airflow around the Shiley™ Flexible and Shiley™ Fenestrated tracheostomy tubes

Tracheostomy tube size	4 (6.5 mm ISO)		6 (7.5 mm ISO)		10 (10 mm ISO)	
Tracheostomy tube style	Flexible	Fenestrated	Flexible	Fenestrated	Flexible	Fenestrated
Mean air flow (L/min)	1.59	1.41	4.26	3.8	4.49	3.28
Standard deviation	0.03	0.07	0.04	0.26	0.20	0.25
p-Value	<.00001		<.0004		<.00001	

fenestrated tracheostomy tube (Table 2). For example, the size 4 flexible tracheostomy tube had mean air flow of 1.59 ± 0.03 L/min, whereas the size 4 fenestrated tracheostomy tube had mean air flow of 1.41 ± 0.07 L/min ($p < .00001$). Similarly, the size 6 flexible tracheostomy tube had significantly higher mean air flow than the same sized fenestrated tracheostomy tube (4.26 ± 0.04 vs 3.8 ± 0.26 L/min, $p < .0004$). The largest difference between paired tracheostomy tubes was observed between the size 10 flexible and fenestrated tracheostomy tubes, which had mean air flow 4.49 ± 0.20 vs 3.28 ± 0.25 L/min, respectively ($p < .00001$).

4 | DISCUSSION

Phonation can often improve quality of life (QoL) for tracheostomized patients and can be accomplished with a variety of devices.^{16,17} A fenestrated tracheostomy tube can be used to help facilitate speech and has proven valuable in certain situations.³ However, complications such as granulation tissue formation around the site of fenestration, subcutaneous edema, tracheal stenosis, and tracheomalacia have limited their use.¹⁸⁻²⁰ Additional challenges with fenestrated tubes include the ability to suction and perform adequate airway toilet since fenestrations may collect mucous that may be hard to remove. The suction catheter can also get caught in the fenestrations, hence a non-fenestrated inner canula is recommended during suctioning.²⁰

In this study, we tested a tracheostomy tube with a taper-shaped cuff. The taper-shaped cuff has been shown to protect against fluid leaks up to 96% more efficiently compared to barrel shaped cuffs.²¹ The surface of the tapered shaped cuff contacting the tracheal wall is smaller compared to that of the barrel shaped cuff. As a result of less contact area with the taper-shaped cuff, the force affecting the tracheal wall is lower by 18.9% overall.²²

The results of this study may be applicable in the clinical setting. The Taperguard cuff design presents less bulk compared to the traditional barrel shaped cuff, since the barrel shaped cuff has a resting cuff diameter at 30 cm H₂O that is 50% greater than the tracheal diameter, whereas the taper shaped cuff is only 15% greater. When both cuffs are deflated, the excess material of the barrel shaped cuff occupies a significantly larger volume in the trachea hence reducing the available space for air to pass. It has been reported in the literature that the peak flow rate for phonation in women is approximately 0.07 L/s or 4.2 L/min,²³ which matches the flow rate around the deflated taper shaped cuff measured during this bench study.

5 | CONCLUSION

In conclusion, this bench study demonstrated significantly increased translaryngeal airflow with the Taperguard cuff when compared with equivalent sized fenestrated barrel cuffed tubes. Further clinical studies are required to fully elucidate the use of this new cuff design to allow phonation in tracheostomized patients.

ACKNOWLEDGMENTS

Role of the Funder/Sponsor: Medtronic was involved in the design and conduct of the study and contributed to the collection and management of the data; it reviewed and approved the manuscript to ensure legal and regulatory policy compliance. The authors, who are Medtronic employees, were responsible for analysis and interpretation of the data, preparation, review, and approval of the manuscript, and the decision to submit the manuscript for publication.

CONFLICT OF INTEREST

The authors are full time employees of Medtronic.

AUTHOR CONTRIBUTIONS

Ulf Borg designed and organized the study, analyzed the data, and authored the manuscript. Katie Bull managed study execution, audited and confirmed study data, and edited the manuscript.

ORCID

Ulf Borg  <https://orcid.org/0000-0002-2743-2300>

REFERENCES

- Cipriano A, Mao ML, Hon HH, et al. An overview of complications associated with open and percutaneous tracheostomy procedures. *Int J Crit Illn Inj Sci*. 2015;5(3):179-188.
- Cox CE, Carson SS, Holmes GM, Howard A, Carey TS. Increase in tracheostomy for prolonged mechanical ventilation in North Carolina, 1993-2002. *Crit Care Med*. 2004;32(11):2219-2226.
- Hess DR, Altobelli NP. Tracheostomy tubes. *Respir Care*. 2014;59(6):956-971. discussion 971-973.
- Diehl JL, El Atrous S, Touchard D, Lemaire F, Brochard L. Changes in the work of breathing induced by tracheotomy in ventilator-dependent patients. *Am J Respir Crit Care Med*. 1999;159(2):383-388.
- Khammas AH, Dawood MR. Timing of tracheostomy in intensive care unit patients. *Int Arch Otorhinolaryngol*. 2018;22(4):437-442.
- Combes A, Luyt CE, Nieszkowska A, Trouillet JL, Gibert C, Chastre J. Is tracheostomy associated with better outcomes for patients requiring long-term mechanical ventilation? *Crit Care Med*. 2007;35(3):802-807.
- Whitmore KA, Townsend SC, Laupland KB. Management of tracheostomies in the intensive care unit: a scoping review. *BMJ Open Respir Res*. 2020;7(1):1-9.
- Ten Hoorn S, Elbers PW, Girbes AR, Tuinman PR. Communicating with conscious and mechanically ventilated critically ill patients: a systematic review. *Crit Care*. 2016;20(1):333.
- Adam SI, Srinet P, Aronberg RM, Rosenberg G, Leder SB. Verbal communication with the Blom low profile and Passy-Muir one-way tracheotomy tube speaking valves. *J Commun Disord*. 2015;56:40-46.
- Davydow DS. Posttraumatic stress disorder in critical illness survivors: too many questions remain. *Crit Care Med*. 2015;43(5):1151-1152.
- Coffman HMS, Rees CJ, Sievers AEF, Belafsky PC. Proximal suction tracheotomy tube reduces aspiration volume. *Otolaryngol Head Neck Surg*. 2008;138(4):441-445.
- Borg U, Cobb C, Bull K. Performance characterization of a new tracheostomy tube with subglottic suction port. Paper presented at: ESICM LIVES 2020.
- Ledgerwood LG, Salgado MD, Black H, Yoneda K, Sievers A, Belafsky PC. Tracheotomy tubes with suction above the cuff reduce the rate of ventilator-associated pneumonia in intensive care unit patients. *Ann Otol Rhinol Laryngol*. 2013;122(1):3-8.

14. Rabach L, Siegel MD, Puchalski JT, et al. Use of the blom tracheotomy tube with suction inner cannula to decontaminate microorganisms from the subglottic space. A proof of concept. *Ann Am Thorac Soc*. 2015;12(6):859-863.
15. Monsel A, Le Corre M, Deransy R, et al. Modification of tracheal cuff shape and continuous cuff pressure control to prevent microaspiration in an ex vivo pig tracheal two-lung model. *Crit Care Med*. 2017;45(12):e1262-e1269.
16. Breatnach E, Abbott GC, Fraser RG. Dimensions of the normal human trachea. *Am J Roentgenol*. 1984;142(5):903-906.
17. Freeman-Sanderson AL, Togher L, Elkins M, Kenny B. Quality of life improves for tracheostomy patients with return of voice: a mixed methods evaluation of the patient experience across the care continuum. *Intensive Crit Care Nurs*. 2018;46:10-16.
18. Ford DW, Martin-Harris B. I miss the sound of your voice: earlier speech in tracheostomy patients. *Crit Care Med*. 2016;44(6):1234-1235.
19. Orme RM, Welham KL. Subcutaneous emphysema after percutaneous tracheostomy—time to dispense with fenestrated tubes? *Anaesthesia*. 2006;61(9):911-912. Reply 912.
20. Morris LL, Bedon AM, McIntosh E, Whitmer A. Restoring speech to tracheostomy patients. *Crit Care Nurse*. 2015;35(6):13-27. Quiz 28.
21. Li Bassi G, Ranzani OT, Marti JD, et al. An in vitro study to assess determinant features associated with fluid sealing in the design of endotracheal tube cuffs and exerted tracheal pressures. *Crit Care Med*. 2013;41(2):518-526.
22. Lichtenthal P, Borg U, Lockett W. Does endotracheal tube design affect cuff seal, safety and subglottic suction performance: an in-vitro study? *Int J Anesthesiol Res*. 2015;3(10):166-171.
23. Zhuang P, Sprecher AJ, Hoffman MR, et al. Phonation threshold flow measurements in normal and pathological phonation. *Laryngoscope*. 2009;119(4):811-815.

How to cite this article: Borg U, Bull K. Do tapered tracheostomy cuffs improve translaryngeal gas flow when compared to barrel cuffed fenestrated tubes: A laboratory study. *Laryngoscope Investigative Otolaryngology*. 2022;7(2):494-498. doi:10.1002/liv.2.783