NTSP Podcast series

National Tracheostomy Safety Project

This month's top papers: April 2022

Welcome to the latest blog in the literature podcast from the NTSP. We try to bring you a quick roundup of what is hot in the world of tracheostomy and laryngectomy publications by scouring internationally recognised journals and media and bringing you the highlights.

The papers we will discuss this month are detailed below, along with an automated transcript of the podcast. Please note that the transcript is generated by AI and so may not be totally accurate.

You can find the links to the podcast on www.tracheostomy.org.uk and by searching for NTSP on your favourite podcast platform. Some of the podcasts are also uploaded to YouTube if you prefer to get your news that way. Check out the NTSP YouTube channel at https://www.youtube.com/c/NationalTracheostomySafetyProject. Please follow us and/or subscribe to keep up to date! https://x.com/NTSP_UK

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This month's top papers

- Characteristics, complications, and a comparison between early and late tracheostomy: A retrospective observational study on tracheostomy in patients with COVID-19-related acute respiratory distress syndrome.
- Clinical Outcomes of Early Versus Late Tracheostomy in Coronavirus Disease 2019 Patients: A Systematic Review and Meta-Analysis.
- Effect of Early vs Standard Approach to Tracheostomy on Functional Outcome at 6 Months Among Patients With Severe Stroke Receiving Mechanical Ventilation: The SETPOINT2 Randomized Clinical Trial.
- Indication Based Timing of Tracheostomy and its Effects on Outcome in the Pediatric Intensive Care Unit.
- Do tapered tracheostomy cuffs improve translaryngeal gas flow when compared to barrel cuffed fenestrated tubes: A laboratory study.

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Characteristics, complications, and a comparison between early and late tracheostomy: A retrospective observational study on tracheostomy in patients with COVID-19-related acute respiratory distress syndrome.

Lay Summary:

This study looked at the benefits and risks of performing a tracheostomy on patients with severe COVID-19. A tracheostomy is a procedure that creates an opening in the neck for a breathing tube, often needed for patients who are on a ventilator for a long time. Early in the pandemic, there was debate about whether this procedure should be delayed to protect healthcare workers from viral exposure.

Researchers reviewed the records of 117 patients in Sweden and divided them into two groups: those who received an "early" tracheostomy (within 7 days of being on a ventilator) and those who received a "late" one (after 7 days). They found that the early group had better outcomes:

- Shorter Ventilator Time: The early group was on a breathing machine for a shorter period.
- Shorter ICU Stay: They also had a shorter stay in the Intensive Care Unit (ICU).

The study found no difference in the death rate between the two groups. The most common complication was minor bleeding, but the overall rate of complications was higher in the late tracheostomy group. The authors suggest that performing a tracheostomy early is safe and could be beneficial for critically ill COVID-19 patients, but they recommend that this finding be confirmed with a larger, more rigorous study.

Summary for Healthcare Professionals:

This multicenter, retrospective observational study investigated the utility of tracheostomy in 117 patients with COVID-19-related acute respiratory distress syndrome (ARDS) in Jönköping County, Sweden. The study compared outcomes between an "early" tracheostomy group (≤7 days of invasive mechanical ventilation [IMV], n=56) and a "late" group (>7 days, n=61).

The study found that early tracheostomy was associated with several clinical benefits:

- **Shorter IMV Duration**: The early group had a shorter median duration of mechanical ventilation (7 days vs. 12 days, p = 0.001).
- **Shorter ICU Stay**: The early group also had a shorter median ICU length of stay (8 days vs. 14 days, p= 0.001).

There was no significant difference in all-cause mortality at 30 days between the early and late groups (10% vs. 11%, p>0.99). The most frequent complication was minor bleeding (22%), and the overall complication rate was 36%. The total complication rate was higher in the late tracheostomy group, but individual complication rates did not differ significantly between the groups. The authors note that the late group had a higher BMI and a higher incidence of immunosuppressant treatment, suggesting a selection bias towards patients with greater clinical complexity.

The authors conclude that early tracheostomy is safe and associated with a shorter time on IMV and a shorter ICU stay, indicating possible clinical benefits. They emphasize that these findings should be verified in a randomized controlled trial due to the retrospective nature of the study.

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Clinical Outcomes of Early Versus Late Tracheostomy in Coronavirus Disease 2019 Patients: A Systematic Review and Meta-Analysis.

Lay Summary:

This study is a review of multiple research papers to understand the benefits of performing a tracheostomy early versus late in critically ill COVID-19 patients. A tracheostomy is a procedure that creates an opening in the neck for a breathing tube, which is often needed for patients on a ventilator for a long time. Early in the pandemic, the timing of this procedure was a major concern.

By combining the results of 12 different studies with over 2,200 patients, the researchers found that performing a tracheostomy earlier has two main benefits:

- Shorter ICU Stays: The early tracheostomy group had a significantly shorter stay in the intensive care unit (ICU) compared to the late group.
- Less Time on a Ventilator: Patients who received an early tracheostomy spent less time on a mechanical ventilator.

However, the study found no difference in the death rate between the two groups. It also found that the time from the tracheostomy procedure to when the patient was taken off the ventilator was similar in both groups. The authors conclude that while the timing of the procedure does not affect survival, an early tracheostomy can help reduce the strain on hospital resources by getting patients out of the ICU and off ventilators sooner, which is very important during a pandemic.

Summary for Healthcare Professionals:

This systematic review and meta-analysis investigated the clinical and resource utilization benefits of early versus late tracheostomy in critically ill COVID-19 patients. The review included 12 observational studies published between January 2020 and December 2021, comprising 2,222 patients. Early tracheostomy was defined using cutoffs of 10 or 14 days post-invasive mechanical ventilation (IMV).

The meta-analysis found no significant difference in all-cause in-hospital mortality between the early and late tracheostomy groups (32.9% vs. 33.1%; OR=1.00; P=0.98). This finding remained consistent in sensitivity analyses using a 10-day or 14-day cutoff.

However, early tracheostomy was associated with several significant benefits related to resource utilization:

- ICU Length of Stay (LOS): The early group had a shorter ICU LOS (mean: 23.18 vs. 30.51 days; $P < 0.001$).
- IMV Duration: The early group had a shorter IMV duration (mean: 20.49 vs. 28.94 days; $P < 0.001$).
- Tracheostomy to Decannulation Time: The early group had a longer time to decannulation (mean: 23.36 vs. 16.24 days; P=0.02).

The authors conclude that early tracheostomy can significantly reduce ICU LOS and IMV duration without affecting mortality. They suggest these findings are crucial for managing healthcare resources, particularly in a resource-limited pandemic setting.

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Effect of Early vs Standard Approach to Tracheostomy on Functional Outcome at 6 Months Among Patients With Severe Stroke Receiving Mechanical Ventilation: The SETPOINT2 Randomized Clinical Trial.

Lay Summary:

This study, called the SETPOINT2 trial, investigated whether performing a tracheostomy (a breathing tube in the neck) early or later has a better long-term outcome for patients who have had a severe stroke. The trial included 382 patients who needed a breathing machine.

The patients were split into two groups:

- Early tracheostomy group: Received a tracheostomy within 5 days of being put on the breathing machine.
- Standard tracheostomy group: Continued with ventilator weaning and received a tracheostomy only if they still needed it after 10 days.

The main goal of the study was to see if an early tracheostomy led to better functional recovery, meaning less severe disability, at six months. The results showed that there was no significant difference in functional outcomes between the two groups. About 43.5% of the early group and 47.1% of the standard group survived without severe disability.

While the study found no clear benefit, the authors noted that the results were not precise enough to completely rule out a small benefit or harm. They also found that complications from the procedure were rare, with only a few cases in each group. The authors conclude that performing a tracheostomy early did not significantly improve long-term functional recovery for these patients.

Summary for Healthcare Professionals:

This randomized clinical trial, the SETPOINT2 trial, investigated whether an early tracheostomy strategy improved functional outcomes at 6 months for patients with severe stroke requiring mechanical ventilation. The trial enrolled 382 patients, who were randomized 1:1 to either an early tracheostomy group (≤5 days of intubation) or a standard tracheostomy group (tracheostomy if needed from day 10).

The primary outcome was functional status at 6 months, assessed using the modified Rankin Scale (mRS) score dichotomized to a score of 0-4 (survival without severe disability) versus 5-6 (severe disability or death). The results showed no significant difference in the proportion of patients who achieved an mRS score of 0-4 between the early tracheostomy group (43.5%) and the standard group (47.1%). The adjusted odds ratio (aOR) was 0.93 (95% CI, 0.60-1.42; P=.73).

Secondary outcomes, including mortality and ICU length of stay, also showed no significant differences between the two groups. The study found that complications related to tracheostomy were infrequent, with 5.0% of reported serious adverse events in the early group and 3.4% in the standard group being tracheostomy-related. The authors conclude that an early tracheostomy strategy did not significantly improve the rate of survival without severe disability at 6 months. However, they acknowledge that the wide confidence intervals mean that a clinically relevant benefit or harm cannot be excluded.

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Indication Based Timing of Tracheostomy and its Effects on Outcome in the Pediatric Intensive Care Unit.

Lay Summary:

This study looked at whether getting a tracheostomy (a breathing tube in the neck) earlier or later affects how a child recovers in the pediatric intensive care unit (PICU). The researchers reviewed the cases of 256 children and divided them into four groups based on why they needed a tracheostomy: for airway problems, neurological issues, cardiopulmonary problems, or neuromuscular disorders.

The study found that for all four groups, children who received an early tracheostomy had a shorter time on a breathing machine, a shorter stay in the PICU, and a shorter overall hospital stay compared to those who received a late tracheostomy. This was true even though the timing of "early" and "late" was different for each group, based on their specific condition.

The study also noted a few other points:

- Complications were similar in both groups, with the exception of airway anomaly patients, who had more early complications, and neuromuscular patients, who had more late complications.
- The timing of tracheostomy did not seem to affect survival.

The authors conclude that an early tracheostomy is beneficial for children with various medical conditions by reducing the time they spend on a breathing machine and in the hospital. They suggest that future research, such as randomized trials, is needed to further confirm these findings and understand the specific benefits for different types of patients.

Summary for Healthcare Professionals:

This retrospective analysis of prospectively collected data investigated the association between the timing of tracheostomy and clinical outcomes in 256 children admitted to a pediatric intensive care unit (PICU) from 2000 to 2018. Patients were divided into four groups based on their indication for tracheostomy: airways anomalies (AA), central neurological impairment (CNI), cardiopulmonary insufficiency (CPI), and neuromuscular disorders (NMD). Within each group, patients were categorized as either early tracheostomy (ET) or late tracheostomy (LT) based on the median duration of pre-tracheostomy mechanical ventilation (MV) for that specific indication.

The study found that for all four groups, ET was associated with significantly shorter durations of total MV, PICU stay, and hospital stay compared to LT ($p<0.01$ for all).

- In the AA group, ET patients had shorter post-tracheostomy MV duration, PICU stay, and hospital stay compared to the LT group.
- For CNI and NMD patients, post-tracheostomy MV duration was significantly shorter in the ET group.
- There was no significant difference in mortality between the ET and LT groups for any of the four indications.

Tracheostomy-related early complications were higher in the ET group for AA patients. Late complications were more frequent in the ET group for NMD patients. The authors conclude that ET, as defined by their indication-based median cutoff, has a beneficial association with a shorter duration of MV, PICU stay, and hospital stay. They recommend that future prospective randomized trials are needed to further elucidate the benefits of ET and establish optimal timing for different disease states in pediatric patients.

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

Lay Summary:

This study looked at how different types of tracheostomy tubes affect a person's ability to speak. A tracheostomy is a tube placed in the windpipe, and patients can often regain their voice if air is able to flow up past their vocal cords.

Researchers used a mechanical lung and a 3D-printed model of a windpipe to test two types of tubes:

1. Taper-cuffed tubes: These have a cuff that is designed to be less bulky when deflated.
2. Fenestrated tubes: These have small holes, or fenestrations, that are meant to allow air to pass through for speech.

The study found that the taper-cuffed tubes allowed significantly more airflow than the fenestrated tubes across all sizes tested. This is important because while fenestrated tubes are designed for speech, they have a number of potential complications, such as tissue growth in the holes. The authors believe that the tapered cuff design, which is less bulky when deflated, provides a better path for air to pass. The study concludes that this improved airflow could help patients regain their voice, though more research with actual patients is needed to confirm this.

Summary for Healthcare Professionals:

This comparative bench study investigated the translaryngeal gas flow capabilities of a taper-cuffed tracheostomy tube (Shiley™ Flexible) compared to a traditional fenestrated barrel-cuffed tube (Shiley™ FEN) of equivalent sizes. The study hypothesized that the deflated taper-cuffed design, with its less bulky profile, would allow for superior translaryngeal airflow compared to the fenestrated design.

The experiment used a mechanical lung and a 3D-printed tracheal model. Exhaled gas flow was measured as air passed through the model trachea and around the deflated cuffs of three sizes of tracheostomy tubes (Jackson 4, 6, and 10). The study's results showed that across all three sizes, the flexible taper-cuffed tracheostomy tube allowed for significantly more translaryngeal airflow than the fenestrated tracheostomy tube ($p<0.00001$ for sizes 4 and 10, and $p<0.0004$ for size 6). The largest difference was observed in the size 10 tubes, with mean air flow of 4.49±0.20 L/min for the flexible tube versus 3.28±0.25 L/min for the fenestrated tube.

The authors conclude that the taper-cuffed design provides significantly improved airflow past the cuff compared to fenestrated tubes. This improved airflow could have clinical implications for patient phonation and laryngeal rehabilitation, especially considering the potential complications associated with fenestrated tubes, such as granulation tissue formation. The study recommends that clinical studies are needed to further validate the use of this cuff design for phonation in patients.

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Scientific abstracts and references

Health Sci Rep. 2022 Apr 22;5(3):e595. doi: 10.1002/hsr2.595. eCollection 2022 May.

Characteristics, complications, and a comparison between early and late tracheostomy: A retrospective observational study on tracheostomy in patients with COVID-19-related acute respiratory distress syndrome.

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BACKGROUND AND AIMS: As the coronavirus disease 2019 (COVID-19) pandemic spread worldwide in 2020, the number of patients requiring intensive care and invasive mechanical ventilation (IMV) has increased rapidly. During the pandemic, early recommendations suggested that tracheostomy should be postponed, as the potential benefits were not certain to exceed the risk of viral transmission to healthcare workers. The aim of this study was to assess the utility of tracheostomy in patients with COVID-19-related acute respiratory distress syndrome, in terms of patient and clinical characteristics, outcomes, and complications, by comparing between early and late tracheostomy. METHODS: A multicenter, retrospective observational study was conducted in Jönköping County, Sweden. Between 14 March 2020 and 13 March 2021, 117 patients were included. All patients ≥18 years of age with confirmed COVID-19, who underwent tracheostomy were divided into two groups based on the timing of the procedure (≤/>7 days). Outcomes including the time on IMV, intensive care unit (ICU) length of stay, and mortality 30 days after ICU admission, as well as complications due to tracheostomy were compared between the groups. RESULTS: Early tracheostomy (<7 days, n = 56) was associated with a shorter median duration of mechanical ventilation (7 [12], p = 0.001) as well as a shorter median ICU stay (8 [14], p = 0.001). The most frequent complication of tracheostomy was minor bleeding. With the exception of a higher rate of obesity in the group receiving late tracheostomy, the patient characteristics were similar between the groups. CONCLUSION: This study showed that early tracheostomy was safe and associated with a shorter time on IMV as well as a shorter ICU length of stay, implicating possible clinical benefits in critically ill COVID-19 patients. However, it is necessary to verify these findings in a randomized controlled trial.

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Conflict of interest statement: The authors declare no conflicts of interest.

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Clinical Outcomes of Early Versus Late Tracheostomy in Coronavirus Disease 2019 Patients: A Systematic Review and Meta-Analysis.

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BACKGROUND: A significant proportion of Coronavirus Disease 2019 (COVID-19) patients require admission to the intensive care unit (ICU) and invasive mechanical ventilation (IMV). Tracheostomy is increasingly performed when a prolonged course of IMV is anticipated. OBJECTIVES: To determine clinical and resource utilization benefits of early versus late tracheostomy among COVID-19 patients. METHODS: Pubmed, Cochrane Library, Scopus, and Embase were used to identify relevant studies comparing outcomes of COVID-19 patients undergoing early and late tracheostomy from January 1, 2020, to December 1, 2021. RESULTS: Twelve studies were selected, and 2222 critically ill COVID-19 patients hospitalized between January to December 2020 were included. Among the included patients, 34.5% and 65.5% underwent early and late tracheostomy, respectively. Among the included studies, 58.3% and 41.7% defined early tracheostomy using cutoffs of 14 and 10 days, respectively. All-cause in-hospital mortality was not different between the early and late tracheostomy groups (32.9% vs. 33.1%; OR = 1.00; P = 0.98). Sensitivity analysis demonstrated a similar mortality rate in studies using a cutoff of 10 days (34.6% vs. 35.5%; OR = 0.97; P = 0.89) or 14 days (31.2% vs. 27.7%; OR = 1.05; P = 0.78). The early tracheostomy group had shorter ICU length of stay (LOS) (mean: 23.18 vs. 30.51 days; P < 0.001) and IMV duration (mean: 20.49 vs. 28.94 days; P < 0.001) than the late tracheostomy group. The time from tracheostomy to decannulation was longer (mean: 23.36 vs. 16.24 days; P = 0.02) in the early tracheostomy group than in the late tracheostomy group, but the time from tracheostomy to IMV weaning was similar in both groups. Other clinical characteristics, including age, were similar in both groups. CONCLUSIONS: Early tracheostomy reduced the ICU LOS and IMV duration among COVID-19 patients compared with late tracheostomy, but the mortality rate was similar in both groups. The findings have important implications for the treatment of COVID-19 patients, especially in a resource-limited setting.

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JAMA. 2022 May 4. doi: 10.1001/jama.2022.4798. Online ahead of print.

Effect of Early vs Standard Approach to Tracheostomy on Functional Outcome at 6 Months Among Patients With Severe Stroke Receiving Mechanical Ventilation: The SETPOINT2 Randomized Clinical Trial.

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IMPORTANCE: Many patients with severe stroke have impaired airway protective reflexes, resulting in prolonged invasive mechanical ventilation. OBJECTIVE: To test whether early vs standard tracheostomy improved functional outcome among patients with stroke receiving mechanical ventilation. DESIGN, SETTING, AND PARTICIPANTS: In this randomized clinical trial, 382 patients with severe acute ischemic or hemorrhagic stroke receiving invasive ventilation were randomly assigned (1:1) to early tracheostomy (≤5 days of intubation) or ongoing ventilator weaning with standard tracheostomy if needed from day 10. Patients were randomized between July 28, 2015, and January 24, 2020, at 26 US and German neurocritical care centers. The final date of follow-up was August 9, 2020. INTERVENTIONS: Patients were assigned to an early tracheostomy strategy (n = 188) or to a standard tracheostomy (control group) strategy (n = 194). MAIN OUTCOMES AND MEASURES: The primary outcome was functional outcome at 6 months, based on the modified Rankin Scale score (range, 0 [best] to 6 [worst]) dichotomized to a score of 0 (no disability) to 4 (moderately severe disability) vs 5 (severe disability) or 6 (death). RESULTS: Among 382 patients randomized (median age, 59 years; 49.8% women), 366 (95.8%) completed the trial with available follow-up data on the primary outcome (177 patients [94.1%] in the early group; 189 patients [97.4%] in the standard group). A tracheostomy (predominantly percutaneously) was performed in 95.2% of the early tracheostomy group in a median of 4 days after intubation (IQR, 3-4 days) and in 67% of the control group in a median of 11 days after intubation (IQR, 10-12 days). The proportion without severe disability (modified Rankin Scale score, 0-4) at 6

months was not significantly different in the early tracheostomy vs the control group (43.5% vs 47.1%; difference, -3.6% [95% CI, -14.3% to 7.2%]; adjusted odds ratio, 0.93 [95% CI, 0.60-1.42]; P = .73). Of the serious adverse events, 5.0% (6 of 121 reported events) in the early tracheostomy group vs 3.4% (4 of 118 reported events) were related to tracheostomy. CONCLUSIONS AND RELEVANCE: Among patients with severe stroke receiving mechanical ventilation, a strategy of early tracheostomy, compared with a standard approach to tracheostomy, did not significantly improve the rate of survival without severe disability at 6 months. However, the wide confidence intervals around the effect estimate may include a clinically important difference, so a clinically relevant benefit or harm from a strategy of early tracheostomy cannot be excluded. TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT02377167.

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Indication Based Timing of Tracheostomy and its Effects on Outcome in the Pediatric Intensive Care Unit.

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OBJECTIVES: The objective of study was to find an association between timing of tracheostomy with duration of mechanical ventilation (MV) and length of stay (LOS) in PICU and hospital. METHODS: The data was collected prospectively from 2000 to 2018 and was analysed retrospectively. Data included clinical diagnosis, indication and duration (days) of MV, LOS in PICU and hospital before and after tracheostomy. Patients who did not receive MV or underwent MV for <24 hours were excluded. According to indication of tracheostomy enrolled patients were divided into 4 groups - airways anomalies (AA), central neurological impairment (CNI), cardiopulmonary insufficiency (CPI), and neuromuscular disorders (NMD). Patients in each group were divided into early (ET) and late tracheostomy (LT) category based on the median (interquartile range IQR) days of pre-tracheostomy MV. RESULTS: 256 patients were analysed. The frequency and median [IQR] days of pre-tracheostomy MV were -AA 54 [7(3,16)], CNI 120 [12(9,16)], CPI 51 [25(16.5,30.5)] and NMD 31[12(8,16.5)]. In AA patients, median (IQR) durations of post-tracheostomy MV [2(1,5.2) vs. 3.5(2,12); P 0.032], PICU [7(5,8.2) vs.11(7,18); P 0.004] and hospital [12(9.7,21) vs. 21.5(12,28); P 0.027] stays were lower in ET as compared to LT group. Post-tracheostomy MV duration was significantly short in ET patients with CNI and NMD (P<0.005). The total days of MV, PICU and hospital stay were significantly lower in ET as compared to LT patients in all four groups (P<0.01). CONCLUSION: As compared to LT, ET patient had shorter durations of total MV and PICU and hospital stay. This article is protected by copyright. All rights reserved.

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

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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 translargyngeal 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.

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Conflict of interest statement: The authors are full time employees of Medtronic.