

# SHILEY™ FLEXIBLE ADULT TRACHEOSTOMY TUBES VERSUS SHILEY™ DCT AND FEN TRACHEOSTOMY TUBES

## PHONATION PERFORMANCE RESULTS

### INTRODUCTION

Tracheostomy can influence the work of breathing by introducing additional resistance to airflow through the native airway. In a 1996 study, Hussey and Bishop determined that the presence of a deflated cuff in the airway significantly increased the work of breathing and theorized that a lower profile cuff would introduce less resistance to airflow.<sup>1</sup> Hussey and Bishop also demonstrated that the presence of fenestration reduced the work of breathing. Interestingly, the authors noted that when they tested a cuffless No. 8 tube, the required inspiratory pressures remained below 1 cm of water at all flow rates. These findings suggest that the majority of the observed resistance to airflow for the cuffed tubes was due to the floppy, deflated cuff. In recent years, next-generation tracheostomy tubes with a taper-shaped cuff have been developed. Evidence to date suggests that a taper-shaped cuff provides a better seal against the tracheal wall at lower cuff pressures than a traditional cylindrical cuff, resulting in reduced fluid leak across the cuff and a lower potential for tracheal injury from excess pressure.<sup>2,3</sup> Given the influence of cuff shape and fenestration on tracheal airflow, the purpose of this analysis was to evaluate airflow around the tube for a range of Shiley™ tracheostomy tubes. More specifically, Shiley™ Flexible tracheostomy tubes with a taper-shaped TaperGuard™ cuff were compared to predicate tubes with cylindrical cuffs, with and without fenestration.

### METHODS

#### Test Product, Equipment and Procedure

Shiley™ Flexible adult tracheostomy tubes with TaperGuard™ cuff and disposable inner cannula (4CN65A, 6CN75A and 10CN10A), Shiley™ (DCT) tracheostomy tube cuffed with disposable inner cannula tubes (4DCT, 6DCT and 10DCT), and Shiley™ (FEN) tracheostomy tube cuffed with inner disposable cannula fenestrated (4FEN, 6FEN and 10FEN) were evaluated using a benchtop phonation test apparatus.

The test apparatus consisted of an acrylic cylinder connected to a Puritan Bennett™ PTS 2000 respiratory analyzer (Figure 1). Once the system airflow was calibrated and recorded with an empty cylinder, the test tracheostomy product or the unit under test (UUT) was inserted into the acrylic cylinder as shown in Figure 2. A speaking valve or white 15 mm cap was then attached to the 15 mm connector of the UUT. Once the UUT was ready for testing, the airflow around the UUT was recorded.

#### Statistical Analysis

Mean and standard deviation (SD) airflow around the cuff with the cuff deflated was determined for each of the test products. For each tube size, the airflow value for the Shiley™ Flexible adult tracheostomy tube with TaperGuard™ cuff and disposable inner cannula was compared to the mean airflow seen for the Shiley™ DCT tube or the Shiley™ FEN tube using a two-sample t-test.

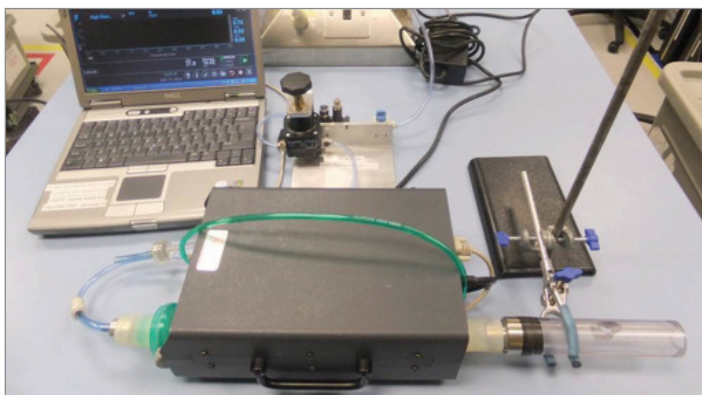


Figure 1.

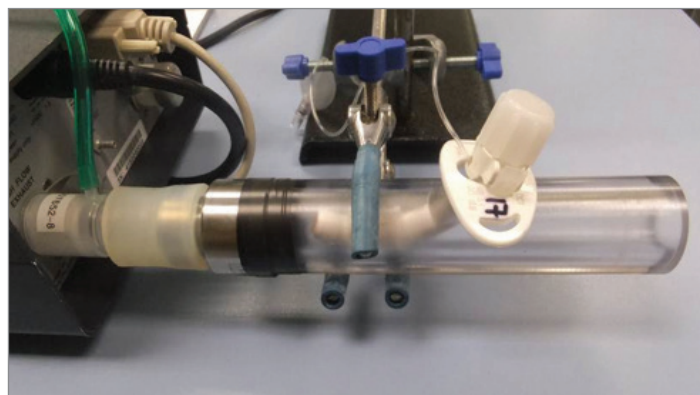


Figure 2.

## RESULTS

The measured airflows around the evaluated tracheostomy tubes with the cuffs deflated are presented in Table 1 and Figure 3. Airflow was significantly higher for the Shiley™ Flexible tubes with TaperGuard™ cuff than it was for the predicate Shiley™ DCT tubes at all evaluated tube sizes. Overall, the average airflow for the Shiley™ DCT tubes across tube sizes was 18.235 slpm, while the average airflow for the Shiley™ Flexible tubes was 62.464 slpm, representing a 242.55% increase in airflow with the TaperGuard™ cuff. As predicted, airflow was higher for Shiley™ FEN tubes compared to Shiley™ DCT tubes. Similar values were observed between the fenestrated tubes and the Shiley™ Flexible tubes across evaluated tube sizes. Airflow was slightly higher with the 4FEN tube than with the 4CN65A tube.

**Table 1.** Phonation Test Results

Shiley™ Flexible Tubes	Mean Airflow (slpm)	Shiley™ DCT Tubes	Mean Airflow (slpm)	Shiley™ FEN Tubes-Fenestrated	Mean Airflow (slpm)
4CN65A	41.270 [10.551]	4DCT	22.928 [7.260]	4FEN	51.950 [14.240]
6CN75A	47.235 [10.190]	6DCT	18.441 [12.594]	6FEN	50.892 [7.741]
10CN10A	98.883 [16.097]	10DCT	13.334 [2.780]	10FEN	98.578 [6.976]

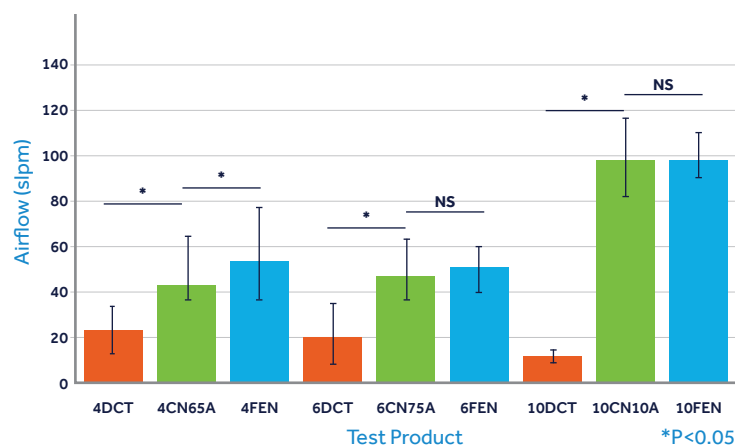
slpm = standard liters per minute

[ ] = standard deviation

## CONCLUSION

Overall, the mean airflow around the cuff with the cuff deflated was 242.55% higher for the Shiley™ Flexible adult tracheostomy tubes with TaperGuard™ cuff and disposable inner cannula than with the predicate Shiley™ DCT tubes. These results suggest that the lower profile TaperGuard™ cuff, when deflated, results in lower resistance to airflow than the deflated Shiley™ DCT cuff. Consistent with prior results, fenestrated tubes produced higher airflow rates than non-fenestrated tubes. However, airflow was similar between the fenestrated tubes and the Shiley™ Flexible tubes across evaluated tube sizes.

**Figure 3.** Phonation Test Results



## REFERENCES

- Hussey JD, Bishop MJ. Pressures required to move gas through the native airway in the presence of a fenestrated vs a nonfenestrated tracheostomy tube. *Chest*. 1996;110(2):494-497.
- D'Haese J, De Keukeleire T, Remory I, Van Rompaey K, Umbrain V, Poelaert J. Assessment of intraoperative microaspiration: does a modified cuff shape improve sealing? *Acta Anaesthesiol Scand*. 2013;57(7):873-880.
- Bassi GL, Xiol EA, Marti JD, et al. Assessment of cuff-induced tracheal injury by commercially available endotracheal tubes. *Crit Care Med*. 2012(12);40:443. (Abstract).

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