# Feasibility and Safety of the AEBLscope in Routine Tracheostomy Tube Exchanges

USC Tina and Rick Caruso Department of Otolaryngology Head and Neck Surgery

**Ella Prebel Jackert BS**[1] ,Roger Boles MD[2] ,Karla Odell MD[2]

[1]Keck School of Medicine of USC [2]USC Caruso Department of Otolaryngology – Head and Neck Surgery

## Introduction

- Airway exchange procedures (AEPs) are common but can be dangerous in complex cases.
- Airway exchange catheters (AECs) are used in these cases, but standard instruments only permit blind insertion of these devices, which can cause serious complications including esophageal intubation, tension pneumothorax, gastric perforation, and airway trauma.[1,2]
- Airway-Exchange Bronacholaryngoscope (AEBLScope) developed that combines bronchoscope and AEC into a single instrument, allowing for use of both with visualization of the AEC placement to prevent complications.[3,4]
- This study is the first clinical use of the AEBLScope for AEPs through an early feasibility clinical trial.

## Methods

- Ten chronically tracheostomy-dependent adult patients were recruited and enrolled.
- Study conducted at routine in-office tracheostomy tube exchange visits.
- Inclusion criteria: chronic tracheostomy dependence defined as presence of tracheostomy for greater than one month with at least one prior tube exchange, no required ventilatory support or supplemental oxygen.
- Exclusion criteria: tubes with inner diameter less than 6.0mm, patients who could not be orotracheally intubated, active pulmonary pathology, unable to provide informed consent.

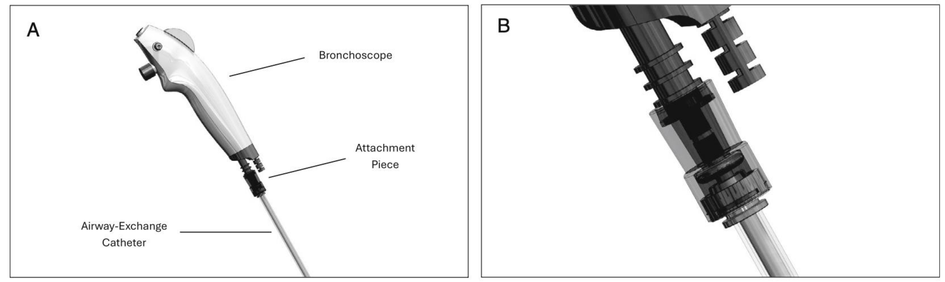



**Figure 1. SolidWorks design for airway-exchange broncholaryngoscope.**
(A) Assembled device comprising the bronchoscope, the attachment piece, and the airway-exchange catheter. (B) Details of attachment piece including the translucent view of 3D-printed parts.[3]

## Results

**TABLE 1. Baseline Participant Characteristics (n=10)**
**(Values indicate number of participants unless otherwise stated)**

| Characteristic | n |
|---|---|
| Age, years, mean (SD) | 53.9 (14.1) |
| Sex | |
| Female | 4 |
| Male | 6 |
| Indication for Tracheostomy | |
| Postsurgical (head and neck cancer) | 3 |
| Prolonged intubation | 3 |
| Neurofibromatosis | 1 |
| Facial trauma | 1 |
| Bilateral true vocal fold immobility | 1 |
| Caustic ingestion | 1 |
| Tracheostomy Duration, months, median (IQR) [range] | 26 (3-69) [2-300] |
| Tracheostomy Tube Manufacturer | |
| Shiley | 7 |
| Bivona | 3 |
| Tracheostomy Tube Inner Diameter (mm) | |
| 6.0 | 7 |
| 7.0 | 1 |
| 8.0 | 1 |
| 8.5 | 1 |
| Abbreviations: SD, standard deviation; IQR, interquartile range. | |

**TABLE 2. Airway-Exchange Procedure Outcomes**
**(Values indicate mean and standard deviation unless otherwise stated)**

| Outcome | Mean (SD) |
|---|---|
| Procedure Time, seconds | 52.3 (7.4) |
| Oxygen Saturation | |
| Starting SpO2, % | 98.6 (1.5) |
| SpO2 Nadir, % | 97.3 (2.5) |
| ΔSpO2, % | -1.3 (1.3) |
| First Pass Success Rate, n (%) | 10 (100) |

Abbreviations: SpO2, peripheral capillary oxygen saturation



**Figure 2. In-office AEBLScope exchange.**

- AEBLScope used to perform ten tracheostomy exchanges with 100% first-pass success rate.
- No procedural complications.
- Mean procedure time was 52.3s.
- Average decrease of 1.3% $SpO_2$ from baseline.

## Discussion

- All 10 exchanges successfully performed on first attempt with accurate placement in airway across multiple tracheostomy tube types and sizes.
- Confirms feasibility assessed during preclinical testing.
- Mean procedural time less than one minute, enhancing this instrument's clinical application in acute airway management.
- No periprocedural complications observed.
- Patient population for this study was for routine exchanges, intended use is in the high-acuity setting.
- Did not evaluate exchange endotracheal tubes.
- Expanded feasibility study underway to evaluate AEBLScope in this intended patient population.

## Conclusion

- AEBLScope demonstrated favorable safety profile and high procedural success rate for in-office tracheostomy tube exchange.
- This device has potential to improve acute airway management by enabling safer and more efficient airway exchange procedures.

## Contact

Ella Prebel Jackert
Keck School of Medicine of USC
jackert@usc.edu

## References

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