Clinical Feasibility Trial of Transtracheal Stimulation for Vocal Fold Closure in Sensate Human Subjects

Elizabeth Hahn, Dustin Tyler, Nicole Maronion
Case Western Reserve University - Department of Biomedical Engineering
Case Western Reserve Medical Center – Department of Otolaryngology

Abstract

**Objective:**
- Apply transtracheal stimulation (TTS) of the recurrent laryngeal nerve (RLN) for vocal fold closure (VFC) in sensate humans.

**Methods:**
- Patients with chronic tracheostomies were selected for a “first-in-man” clinical trial to stimulate the RLN through transtracheal tissue for VFC. Subjects had no history of RLN stimulation.
- Device: The device consists of a custom-designed experimental stimulator and expand cuff, which was deployed into the trachea.

**Study Design:**
- 12 Lead “Modified” Endotracheal Tube Stimulation
- MicroPen
- VFC: 16.32
- VFC: 8.55

**Results:**
- Subject 2: Significant change in glottal angle with VFC and at angle thresholds for VFC of +20°. Cough reflex was seen after VFC stimulation for closure as seen on the right.

**Discussion:**
- This study demonstrates that transtracheal stimulation is effective in stimulating the RLN for closure. Avoiding the gag or cough response however is a significant obstacle to eliciting a full and effective glottal seal in some patients with a robust gag reflex. We witnessed full closure in most patients, but some experienced limited amplitude of closure secondary to this. Our findings suggest that to this cause, however, demonstrating that certain stimulation paradigms with different electrode positions, pulse widths, and pulse amplitudes have a varying effect on sensation while still eliciting vocal cord responses.

**Support & Acknowledgements:**
- Special acknowledgement is provided to Aaron Hadley, PhD who without his effort and dedication none of these would have been possible. He helped with data collection and consulted on various study design issues with his background in the preclinical trials that guided our device design.
- A special thank to MicroPen Inc. for their commitment to helping us produce a safe and reliable stimulation device.
- This research is supported by the Coulter Foundation, Medronic Inc., and UHCMC Department of Otolaryngology.

**References:**

**Device Development**
- RLN Anatomy
- Preclinical Studies
- Axon Physiology
- Preclinical Studies

**Summary of Conclusions**
- Transtracheal stimulation successfully initiated vocal fold closure in all subjects. Only one subject reached sensory thresholds before full closure was reached, but all patients had some sensory response that included coughing at higher amplitudes. None of the patients complained of unbearable pain. The highest level of discomfort was 2/10 on the FACS Pain Survey.