



Laryngeal Soft Tissue Fixation Device



Ross Comer¹, Bryan Jepson¹, Christa Wille¹, William Zuleger¹

Advisor: John Webster¹, PhD Client: Seth Dailey², MD

Departments of Biomedical Engineering¹ and Surgery², University of Wisconsin-Madison

Motivation

- Damage or scarring to the vocal folds severely limits their pliability, inhibiting proper phonation⁹
- Asymmetric scarring of vocal folds can cause inconsistencies in closure
- Increased tension caused by scarring in one vocal fold can prevent proper closure of the medial fold edges leading to breathy phonation and vocal fatigue⁷
- Symptoms of scarring that affect daily life include:
 - Hoarseness
 - Thin, high-pitched voice
 - Poor volume and projection⁷

Background

Anatomy

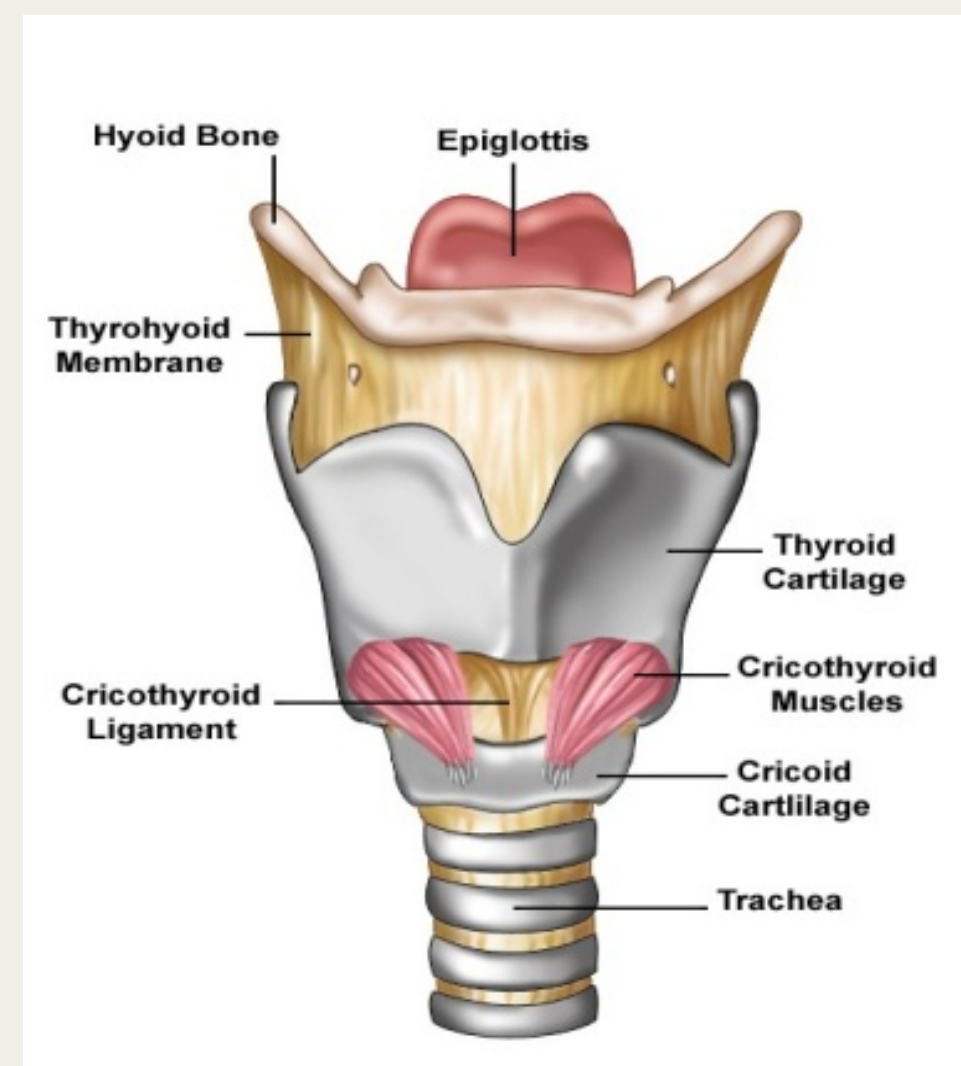


Figure 1. Anterior view of the larynx²

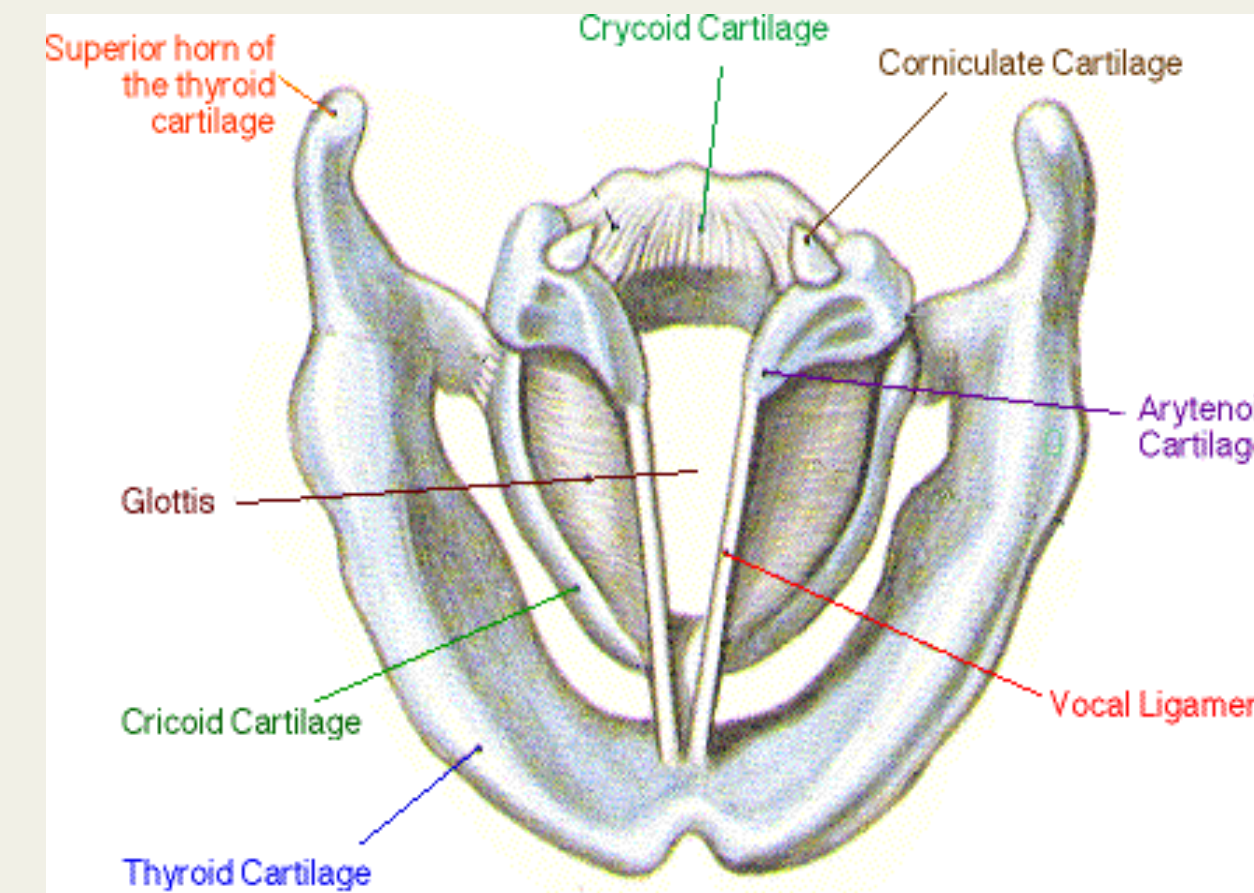


Figure 2. Transverse plane of the larynx viewed from above depicting the vocal folds anterior connection to the thyroid cartilage and posterior attachment to the arytenoid cartilage⁸

Vocal Fold Function

- Protect the airways
- Constrict airways for phonation

Phonation

- Positive air pressure from the lungs momentarily forces the vocal folds open
- The high velocity air causes a decrease in pressure, causing closure of the folds⁶
- The frequency of this repeated vibration cycle relies on the integrity of the superficial lamina propria⁹

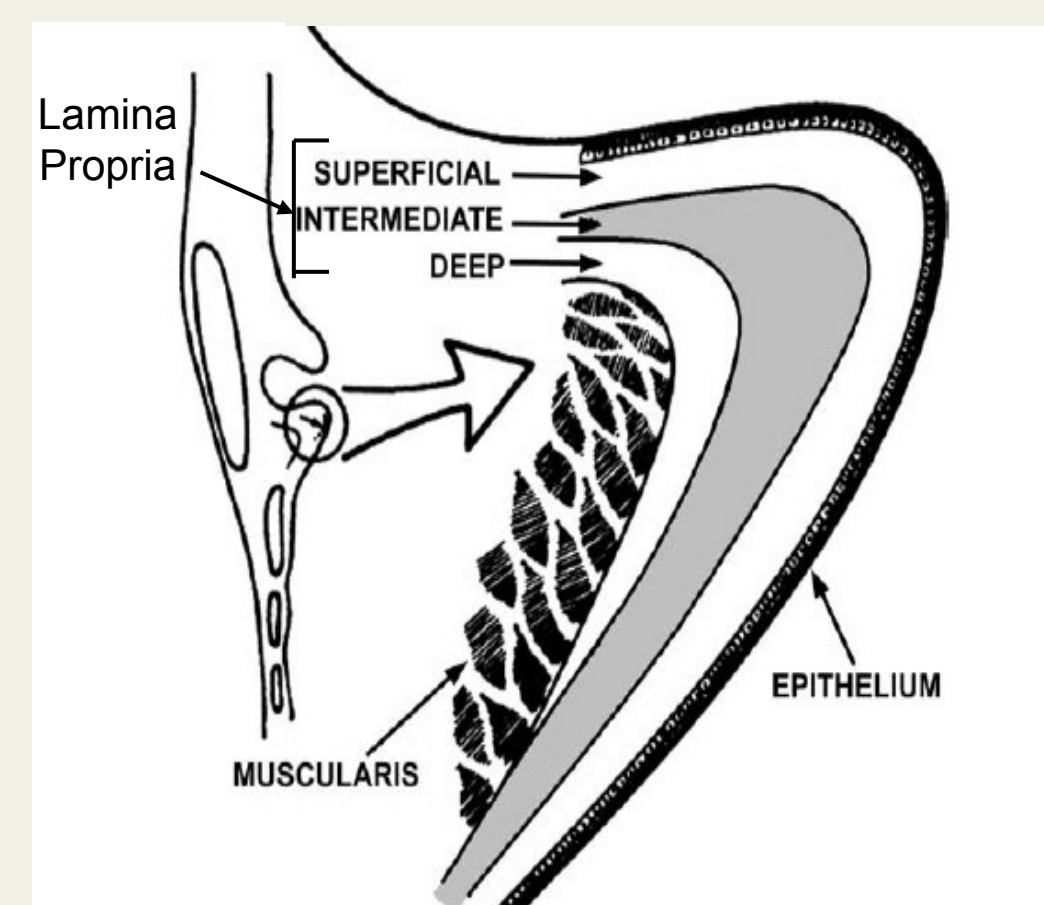


Figure 3. Coronal view of a vocal fold¹. The superficial lamina propria is critical for proper oscillation⁹

Problem Statement

- Our client has requested that we develop a device or a method to affix a soft tissue flap within the lamina propria of a scarred vocal fold.
- The implanted fat tissue of the flap will match the viscoelasticity of the lamina propria and, therefore, allow enhanced oscillation of the scarred or damaged vocal fold.

Acknowledgments

- McLean Gunderson, DVM
- John Noon, MD
- John Webster, PhD
- Tom Wirth
- Ben Bauer
- Mary Remley, RN BSN

Surgical Procedure

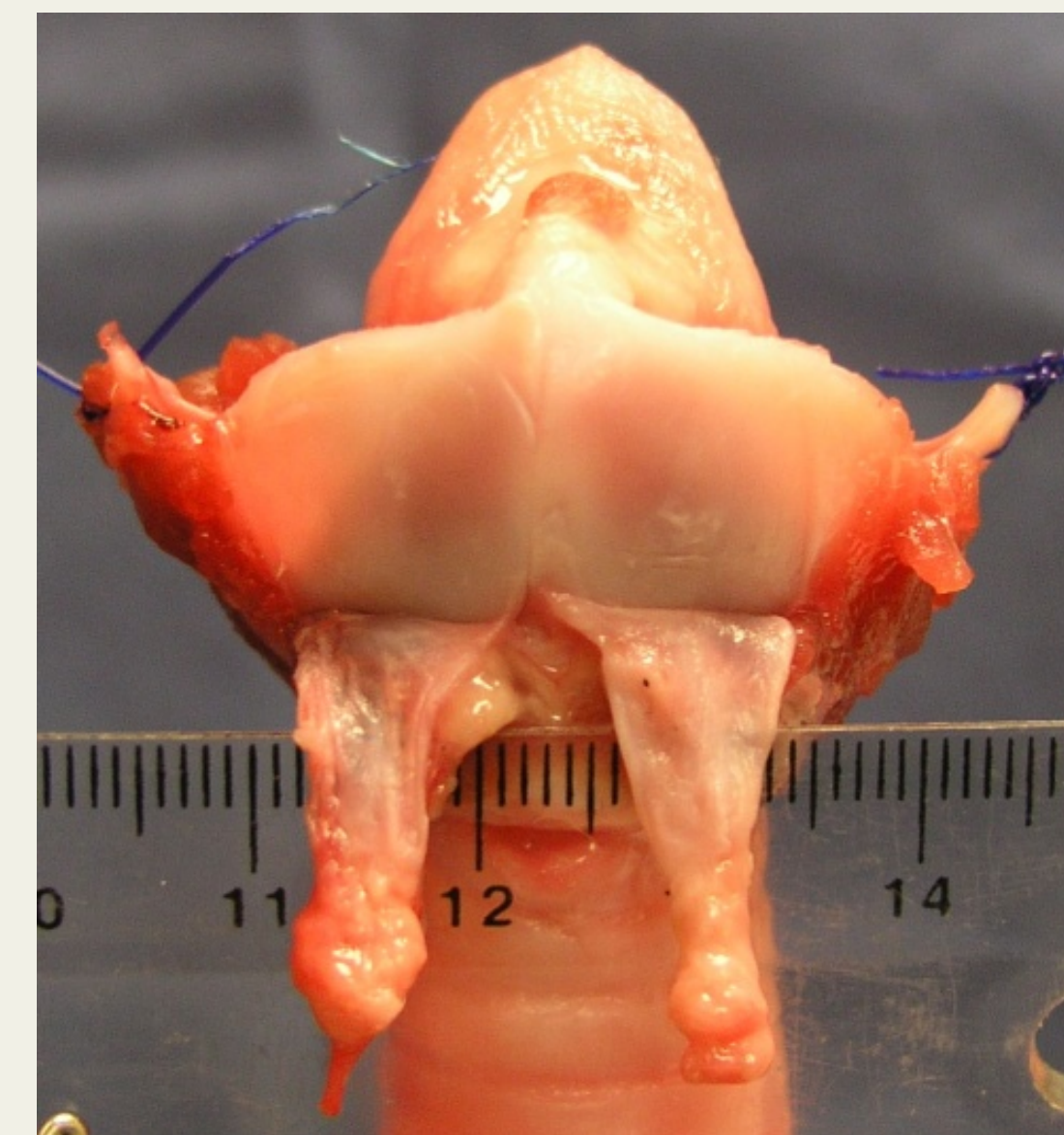


Figure 4. Formation of local, vascularized, perichondrial flaps from the surface of the thyroid cartilage with attached adipose tissue from the pre-epiglottic space³

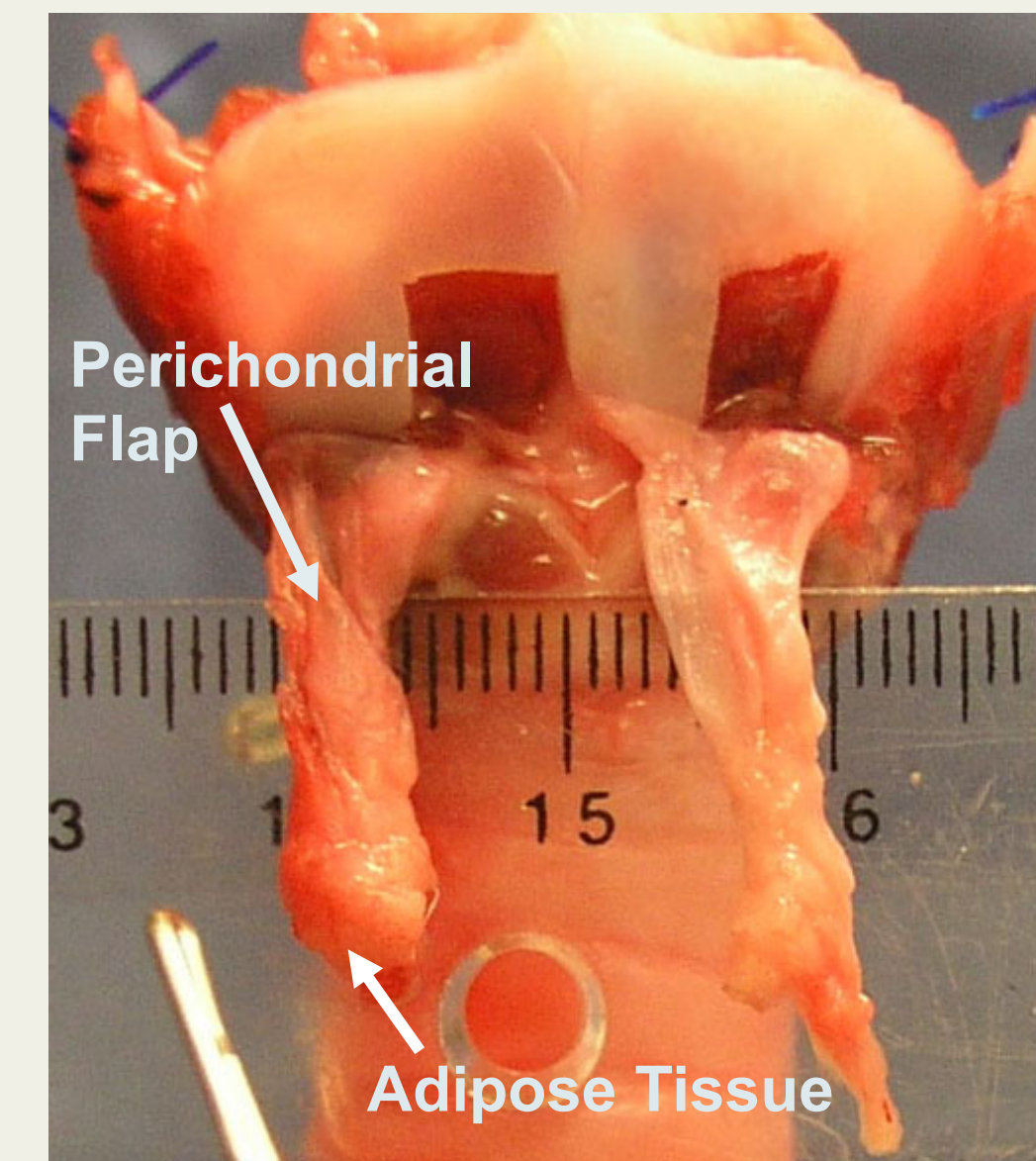


Figure 5. A depiction of a minithyrotomy, the procedure used to gain access to Reinke's space by creating a window through the thyroid cartilage to avoid incisions in the vocal fold epithelium^{3,5}

Adipose Tissue

- Matches the viscoelasticity of the lamina propria
- Serves to restore oscillatory function of the damaged or scarred vocal fold

Perichondrial Tissue

- Functions to vascularize the adipose tissue
- Provides increased surface area for fixation

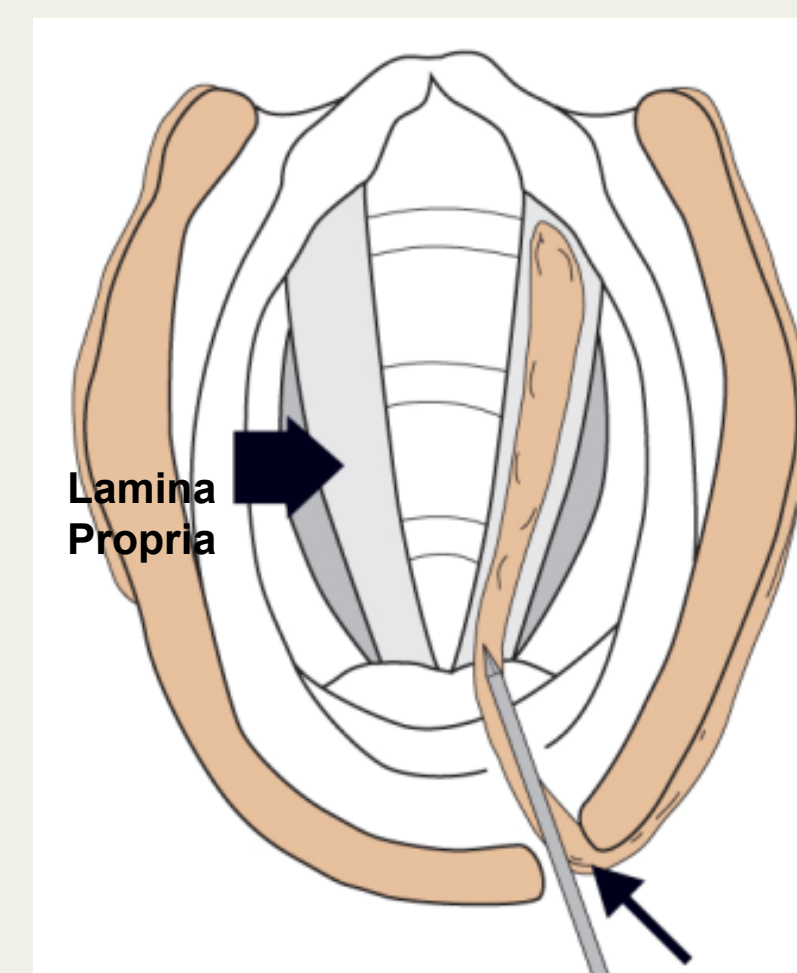


Figure 6. Insertion of the soft tissue flap (thin arrow) into the lamina propria (bold arrow)³.

Competition

Implants and Injections

- Collagen, Radiesse™, Adipose, Teflon, Gortex
- Do not directly address lamina propria deficiencies
- Complications include: high cost, extrusion and infections
- Improve medial displacement of the vocal fold

Alternative Design

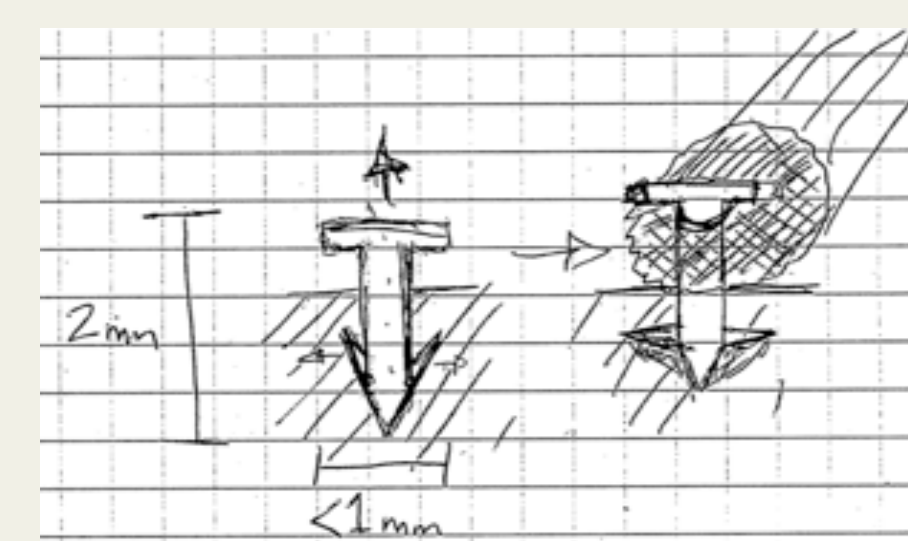


Figure 7. Barbed nail, may pull through arytenoid cartilage.

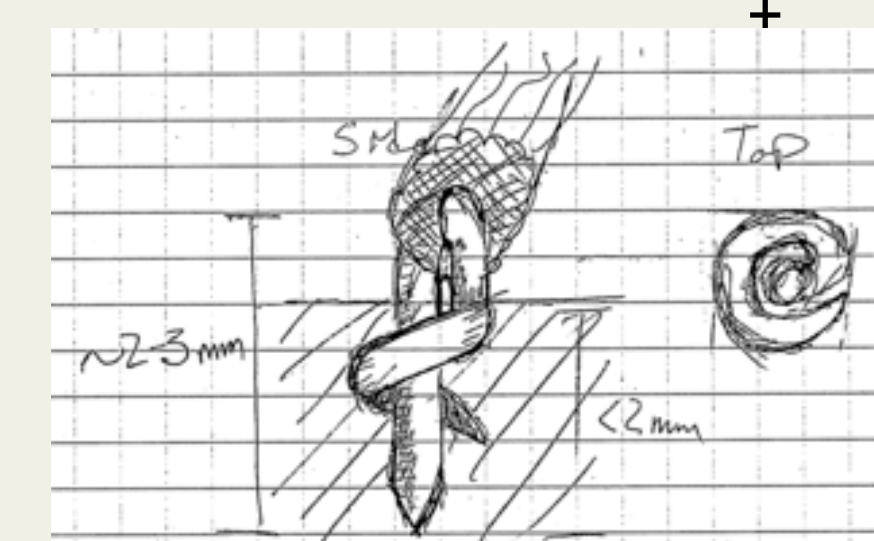


Figure 8. Screw nail combination, places unwanted twisting strain on flap

Design Criteria

- Overall strength of fixation
- Fixation maintained 1-2 weeks post-operative
- Biocompatibility
- Limited stress on tissue flap
- Must improve and not inhibit oscillation of vocal folds
- Short preparation time
- Ease of implantation

Final Design

Ethicon Evicel® Fibrin Sealant

- Composed of human fibrinogen and thrombin
- Begins clotting immediately after application, will be fully fixated within 2 min
- Works independently of patients' physiology
- Degrades to compounds found naturally in the body within 1-2 weeks



Figure 9. Delivery device used for the application of the Evicel surgical glue⁴.

Testing

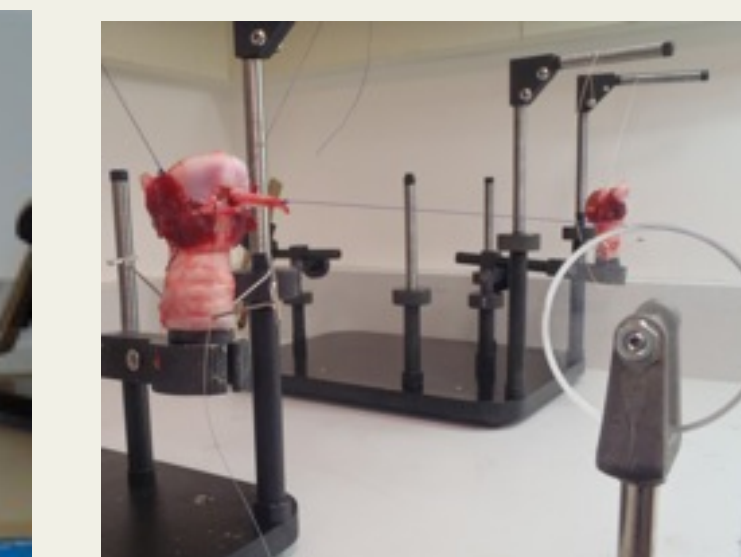
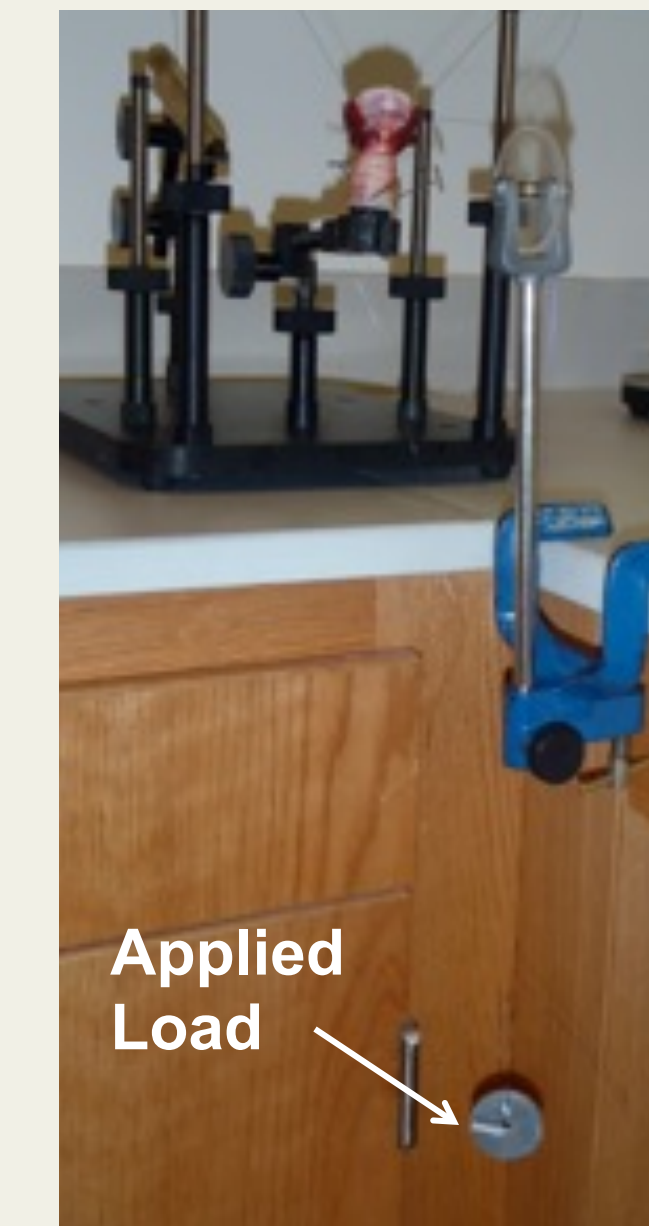


Figure 10. (left) Testing configuration to measure force needed to dislodge flap from vocal fold.

Figure 11. (top) Image of a larynx during testing. The flap is clearly in tension yet still in place.

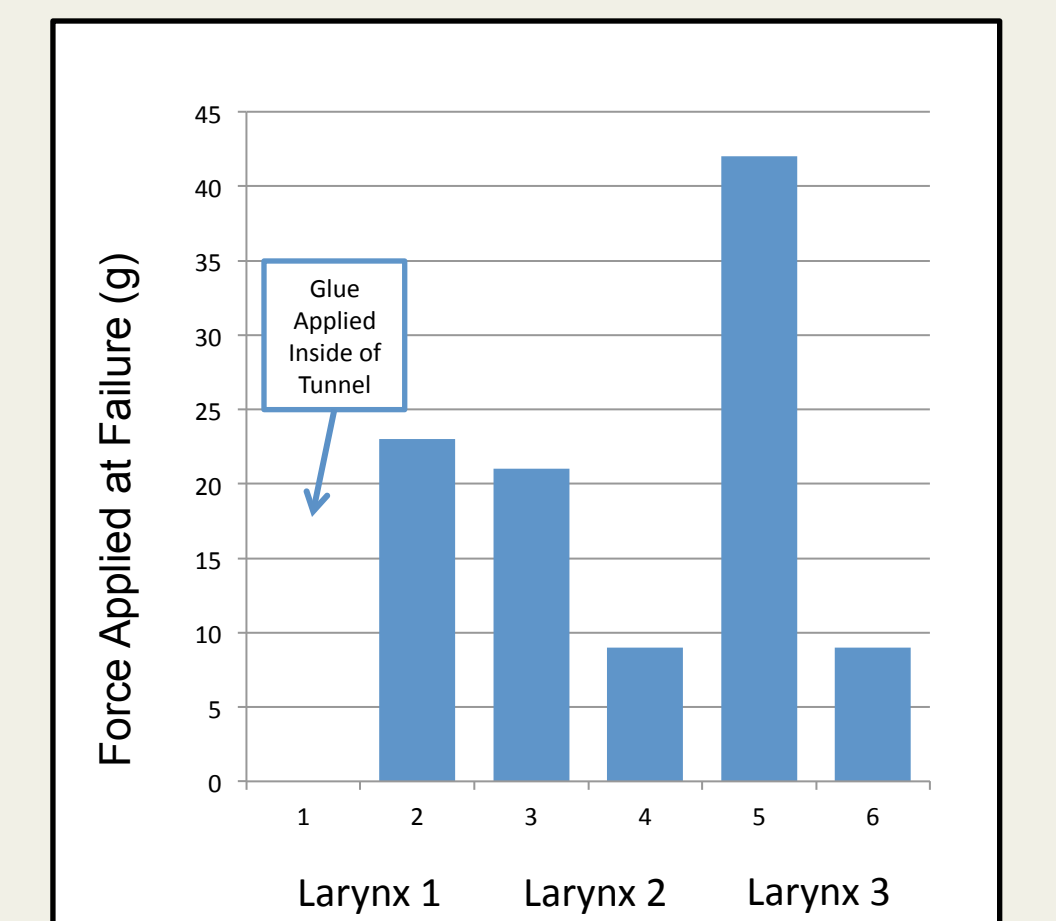


Figure 12. Force applied at failure (when the flap dislodged from the vocal fold) for the larynges tested. Each larynx was prepared and tested bilaterally.

Procedure and Results

- Procedures performed by client
- Flap 1 of Larynx 1: glue applied into the vocal fold after the flap was inserted
 - This method was concluded to contribute to failure even before a force was applied
 - Remaining tests performed by placing 1-2 drops of glue along the flap before insertion into the vocal fold.
- The maximum force applied at failure was 42 g
- This result is promising since the flap will likely not need to withstand loads any larger than those applied experimentally

Future Work

- Future testing of Evicel will reveal the most effective glue application method
- Variables that will be tested include:
 - Time of adhesion (2 or 5 min)
 - Applying pressure during adhesion
 - Types of tissue connected (perichondrium, cartilage, muscle, adipose)
 - Amount of glue applied (1 or 2 drops)
 - Application of glue before or after flap insertion
 - Field drying mechanism; Weck-Cel®
- This method will be integrated into the overall surgical procedure

References

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