



# Towards a Novel Solution for Patulous Eustachian Tubes: Multi-Layered Membrane Prototype Device Design

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## Introduction

Eustachian Tubes (ETs) connect a person's middle ear to their nasopharynx. ETs are closed at baseline and insulate the middle ear from noises in the nasopharynx such as breathing, swallowing, and speaking. They also provide pressure relief periodically. However, when patulous, ETs are unable to close properly and patients suffer with autophony and middle ear discomfort.

Current solutions available to providers are difficult to implement and often inhibit ventilation (Ward et. al.). Thus, adults with patulous eustachian tubes (pET) need a safe and effective solution to block internal body sounds from traveling to the middle ear via the ETs without inhibiting middle ear ventilation.

Figure 1: Open ET opening.



## Methods

### Prototyping

- All 3-D modeling in FreeCad software
- 3-D printing with AnyCubic Photon Resin Printer
- Membrane holes drilled out with 0.3mm micro drill bits on drill press
- Hook fashioned out of chrome plated 0.8mm thick steel wire

### Ventilation Testing

- A tube was set up with a prototype device sealed on one end and a motorized plunger on the other end. Honeywell ASDX pressure transducer put in parallel. The end of the device open to external air was sealed with putty and the tube's volume shrunk to increase the pressure gradient across the prototype device to 500 Pa. Volume held for 5 seconds. A decrease of less than 100 Pa indicated a good seal. The putty was then removed from the open air end and volume shrunk to that which previously created the pressure gradient of 500 Pa. Volume held for 5 seconds. Volume returned to previous value and held for 5 seconds. Repeated at least 3 times. Approximately 1 teaspoon of ketchup evenly spread across the end of the device to simulate mucus.

### Sound Testing

- Buzzer inserted on one side of silicone pET models based upon studies by Janzen-Senn et. al. and Yoshida et. al. Sound level measured in dB with Brüel & Kjær Hand-held Analyzer Type 2250-L. dB level of buzzer sound at opening of model first measured with a small ~2 cm square foam piece placed a few cm into the ET, then with and without a prototype device inserted deep and shallow into the silicone model. Insertion with needle driver and hook clamped into silicone with needle driver.

### Cadaver Testing

- A single cadaver was prepared following experimental protocol approval by anatomy and bequest program lab team at the University of Minnesota (Jackson Hall). 5 prototype devices with different length hooks ranging from 5cm to 15cm of extension past the prototype base to hook top were attempted to be implanted into the bilateral ET via the nasal passage. Tools used included a blakesley forceps, 45 deg frontal sinus curette, stryker rigid nasal endoscope and associated tower. Video records of the procedure were obtained for further analysis.

## Results

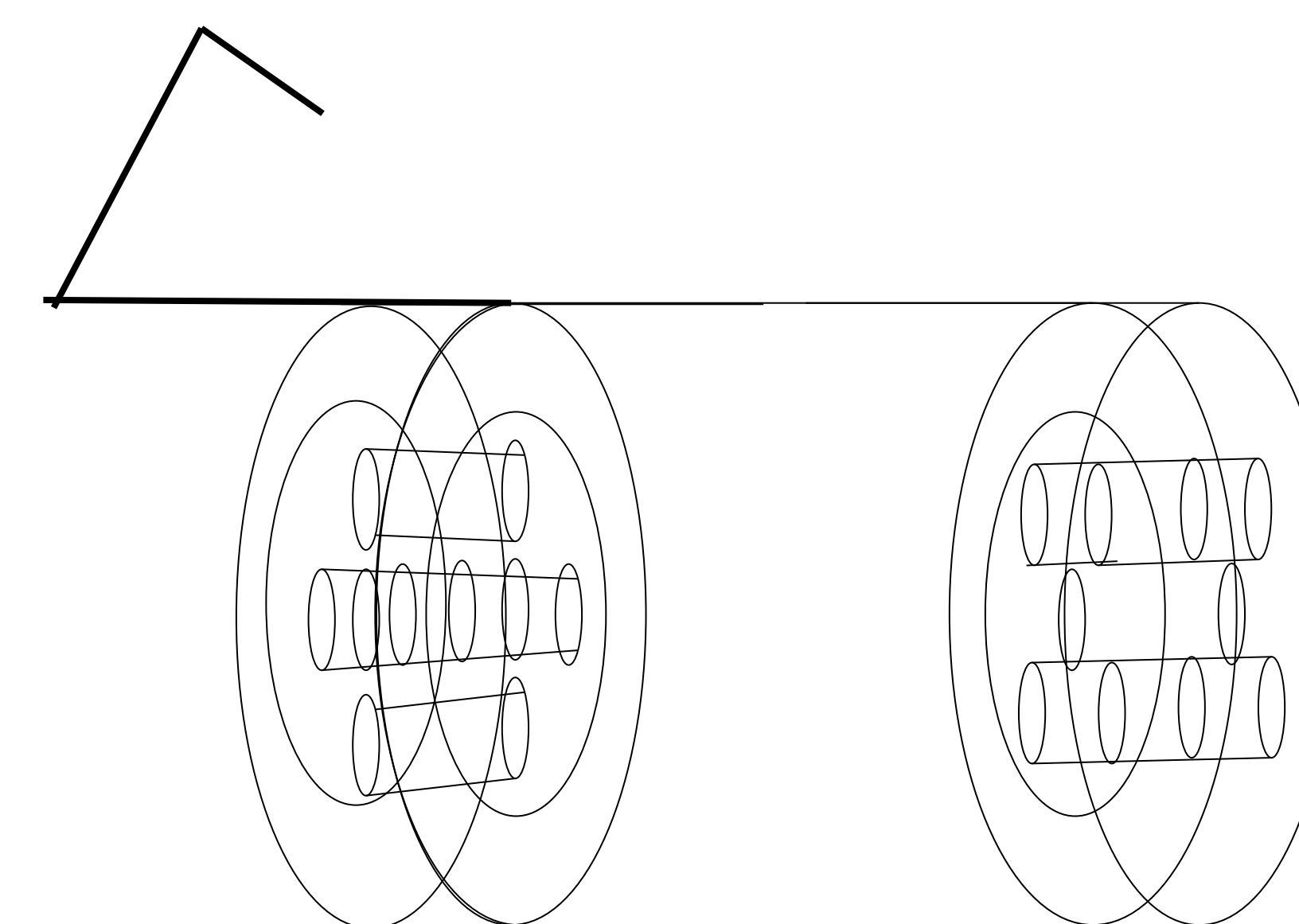


Figure 2: Prototype. Hook holds it in place. Membranes ventilate, but block sound.

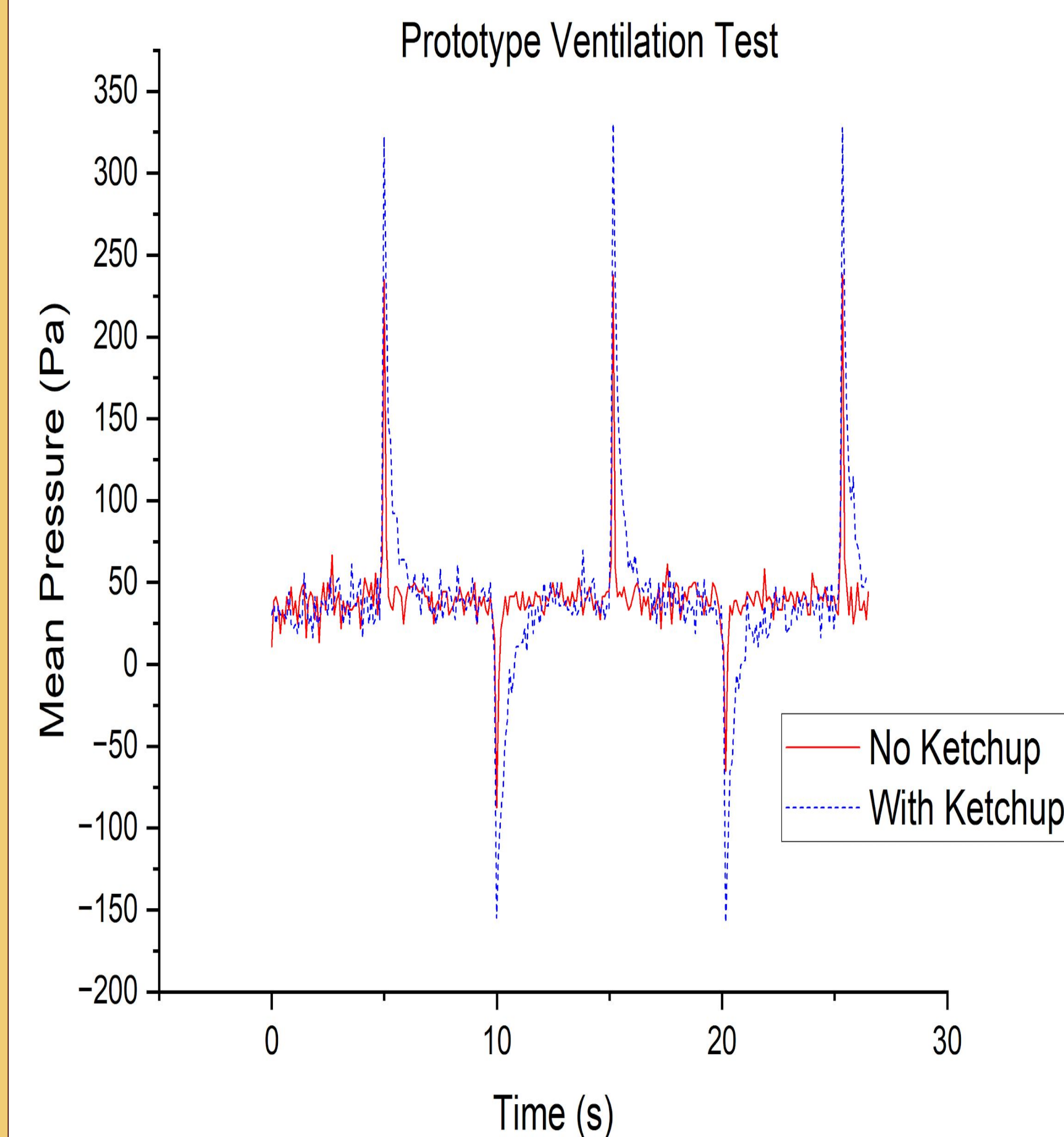


Figure 4: Ventilation testing per protocol in methods.

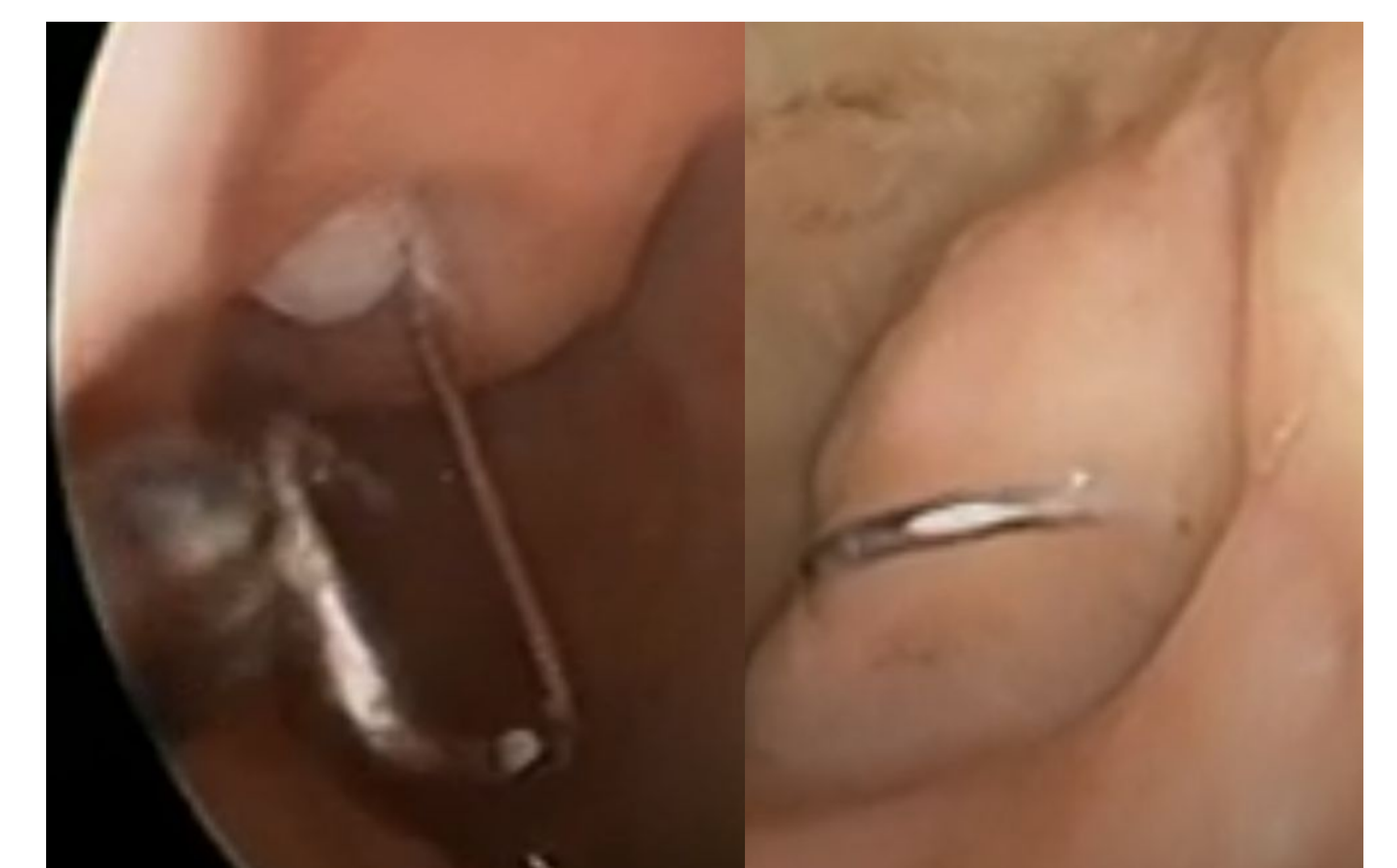


Figure 3: Images from partially (L) and fully inserted/clamped (R) devices in cadaver ET.

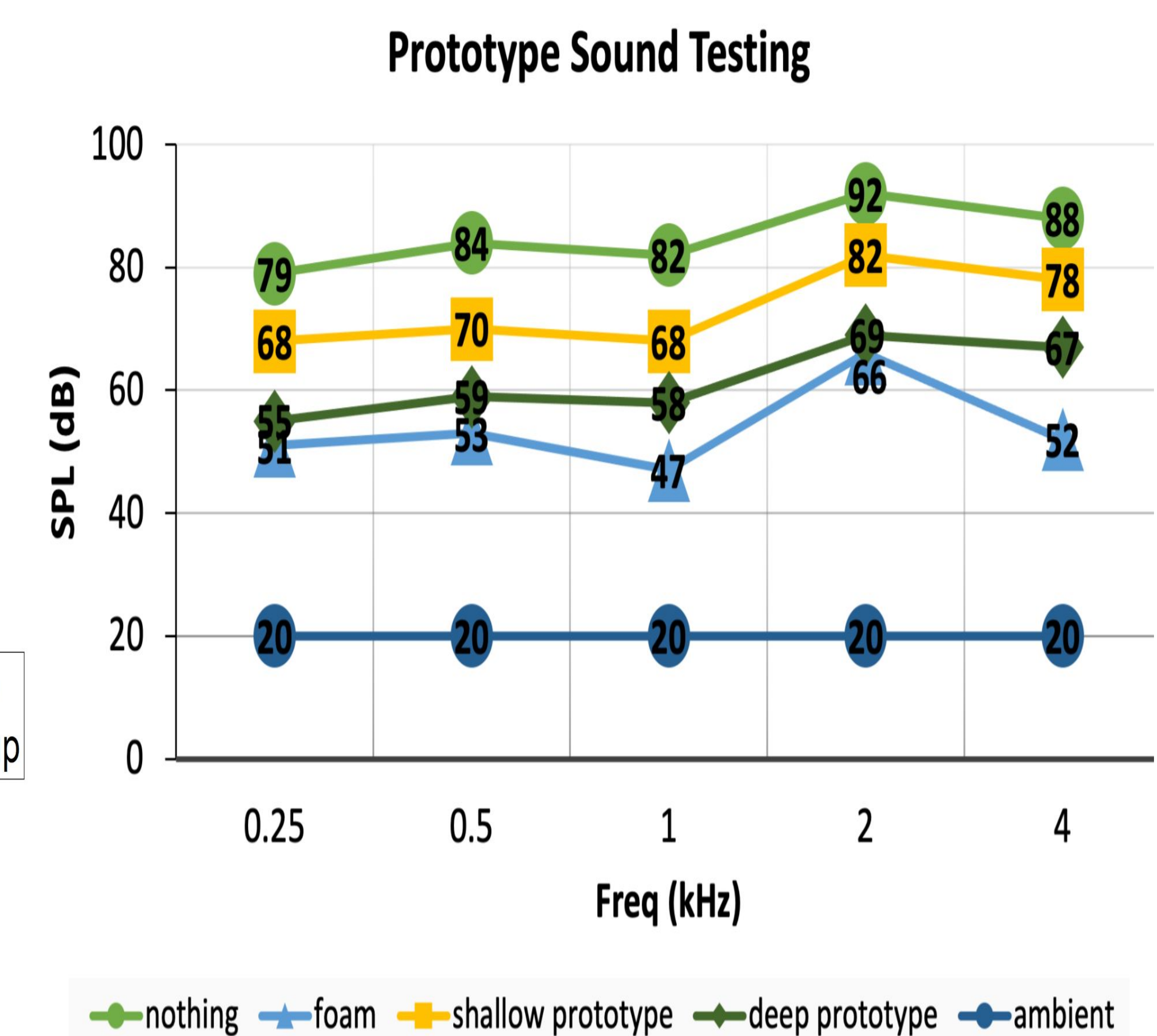


Figure 5: Sound testing per protocol in methods.

## Discussion

- Device shows promise for providing safe and effective solution to block internal body sounds from traveling to the middle ear via the eustachian tube without inhibiting middle ear ventilation.
- Ex vivo study limits strength of conclusions - need either cadaver studies with pressure and sound testing or human testing
- Plan for additional cadaver studies prior to commercialization.
- US patent application filed with UMN Tech Comm Office.

## References

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- Janzen-Senn I, Schuon RA, Tavassol F, Lenarz T, Paasche G (2020) Dimensions and position of the Eustachian tube in Humans. *PLoS ONE* 15(5): e0232655. <https://doi.org/10.1371/journal.pone.0232655>
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