

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

Samuel Newell, MS & Holly Boyer, MD

University of Minnesota Medical School Department of Otolaryngology - Head and Neck Surgery

Introduction

Eustachian Tubes (ET) connect a person's middle ear to their nasopharynx. ET 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 a patulous eustachian tube (pET) need a safe and effective solution to block internal body sounds from traveling to the middle ear via the eustachian tube 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.

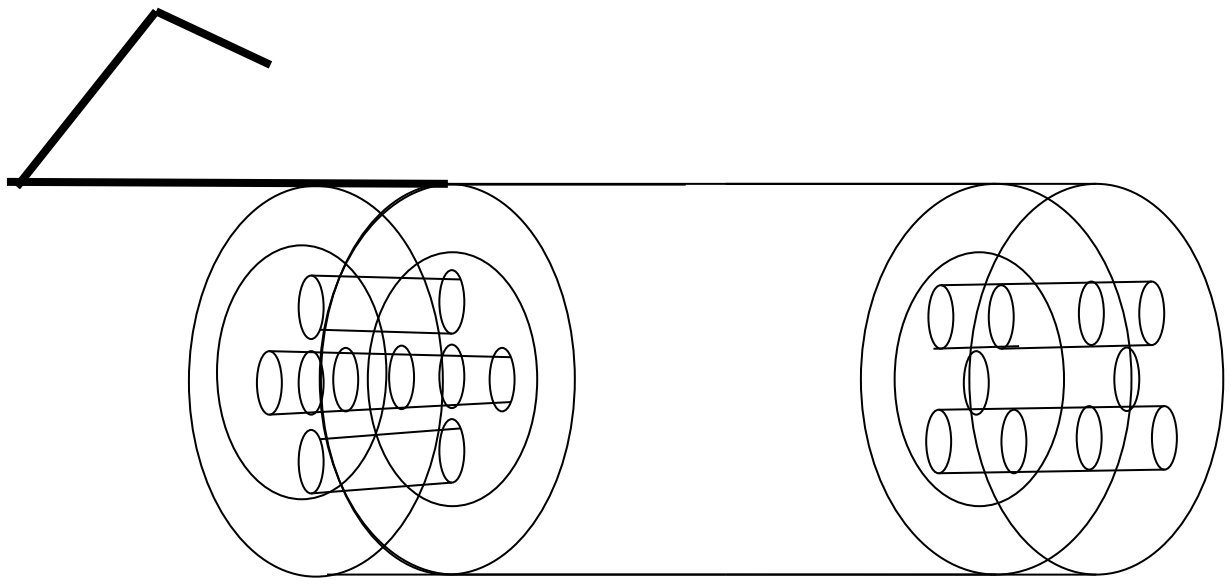


Figure 2: Prototype. Hook holds it in place. Membranes ventilate, but block sound.

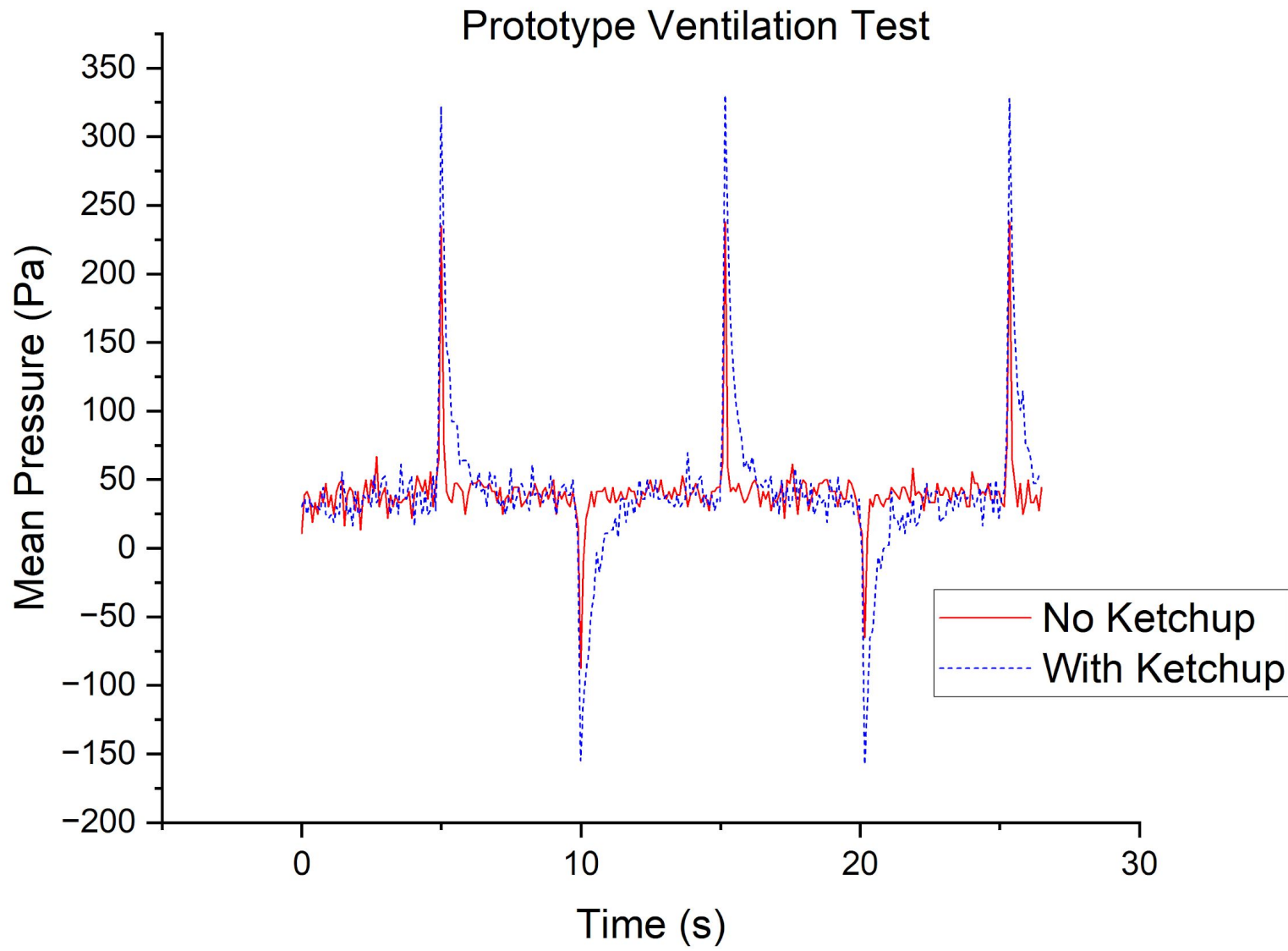


Figure 4: Ventilation testing per protocol in methods.

Results

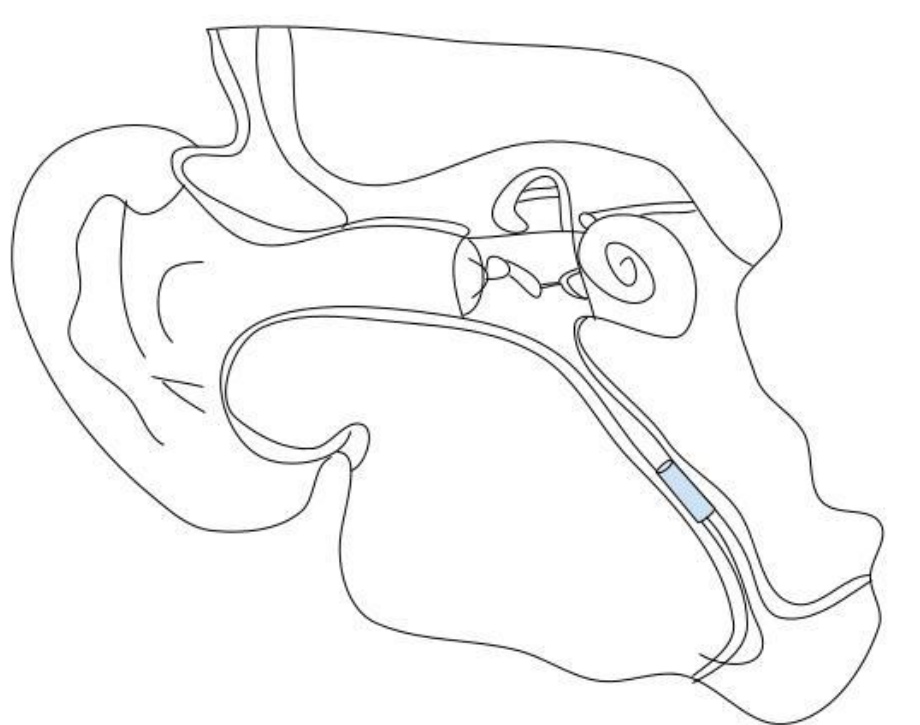


Figure 3: Anatomical diagram with inserted prototype.

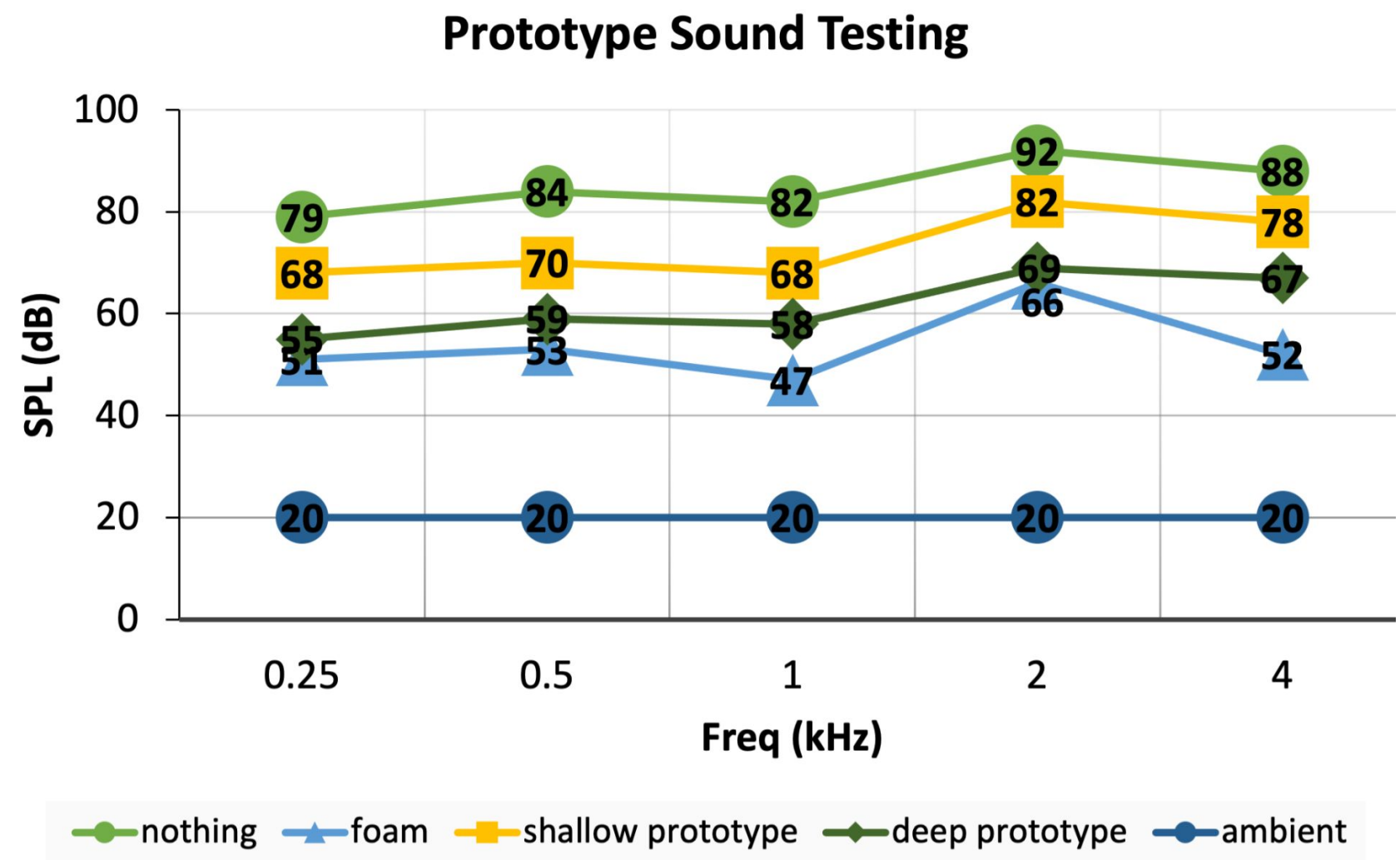


Figure 5: Sound testing per protocol in methods.

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 cadaver and human studies for stronger conclusions.
- US patent application filed with UMN Tech Comm Office.

References

- B. K. Ward, W.-C. Chao, G. Abiola, K. Kawai, Y. Ashry, T. Rasooly, and D. S. Poe, "Twelve-month outcomes of Eustachian tube procedures for management of patulous Eustachian tube dysfunction," *The Laryngoscope*, Jan-2019. [Online]. Available: <https://www.ncbi.nlm.nih.gov/pubmed/30325505>.
- 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>
- Haruo Yoshida, Toshimitsu Kobayashi, Kenji Takasaki, Haruo Takahashi, Hideki Ishimaru, Minoru Morikawa & Kuniaki Hayashi (2004) Imaging of the patulous eustachian tube: high-resolution CT evaluation with multiplanar reconstruction technique, *Acta Oto-Laryngologica*, 124:8, 918-923, DOI: 10.1080/00016480410017422