pET Silicone Membrane

BMEN 3151 *Medical Device Practicum*

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Clinical Problem

The eustachian tube is an opening that connects the middle ear with the nasal-sinus cavity. This tube is necessary for Balancing pressure in the middle ear and draining fluid from the middle ear.

Patulous eustachian tube(pET) occurs when eustachian tubes are chronically opened, which allows too much sound through causing headaches, disorientation, and general discomfort. This is generally caused by loss of fat around the eustachian tube and weakening of the muscles that close the tube. This can be brought on by general aging or significant weight loss over a short period of time.

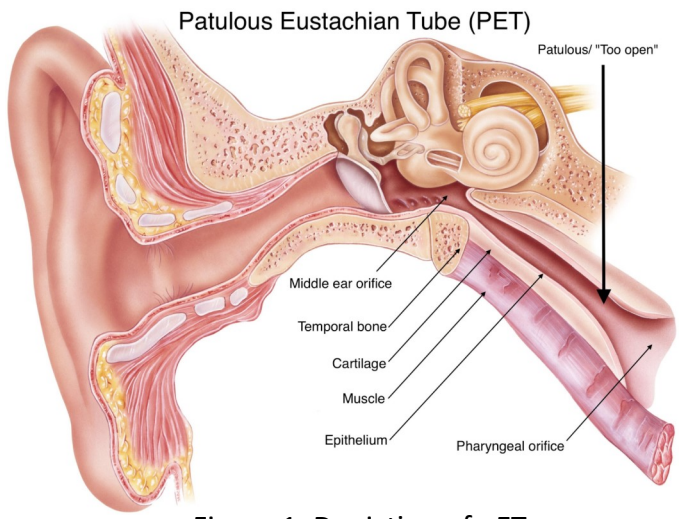

Figure 1: Depiction of pET

Current solutions include mucous thickening agents, self rinsing of saline solution, lifestyle changes (hydration), Tympanic membrane manipulation, and eustachian tube closure amongst many more which are relatively the same. All of these solutions are either a short term solution or involve invasive surgery. In many cases this causes the patient long lasting discomfort and autophony (feeling like you hear your own body).

Needs Statement

Create a device that enables a minimally invasive procedure for patients with pET, reducing the long term need for surgery in pET patients.

Market Analysis

There is nothing currently available that provides a partial blockage with long lasting effects. It affects every 1 in 10,000 people annually, so although somewhat uncommon, the current available treatments are not beneficial to the patients' long term health. Therefore the current market lacks competition but still has

Medical Device Solution

An implantable device that is situated in the middle ear which uses membranes with small perforations. This device needed to have membranes thick enough to block sound traveling through the middle ear but still allow air pressure to equalize reliably. Because this project is a continuation of another project, our group focused on creating a membrane which satisfies all of the requirements while being repeatable and precise with regards to manufacturing.

The solution that our group reached was a less rigid silicone gel that used a laser cutter to remove a specific amount of material. Although a to-scale model was not able to be produced due to time constraints, the large scale model worked adequately. The silicone used was craft-grade soft PDMS. This silicone had the attributes of being less rigid than an industrial grade silicone, and in our tests, it was evident that softer material handled the heat of the laser significantly better. It should be noted that the silicone and laser cutting process make the PDMS not up to medical device standards. Medical grade silicone and laser cutters exist but could not be afforded for this project. However, they are expected to yield the same results as shown in Figures 2 and 3.

Figure 2: Silicone casting with after 5 membranes have been laser cut out. 2 membranes have not yet been removed from the large mold following, but the 3 that were removed did not have any excess pieces being left. This shows promise for mass-production.

Figure 3: Images of silicone molds following laser cut step. A) Although the small holes are difficult to see, this piece was cleanly cut and able to be removed and overall shows promise for this methodology. B) This piece shows more damage caused by the laser, possibly suggesting the settings should be reassessed. However, it was still easily removed and the holes are present.

Team Photo

References

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