Trine University
Biomedical Engineering

Title: Cochlear Implant Pressure Relief

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Introduction and Motivation

Many individuals encounter hearing lose due to illness or injury where the use of Cochlear implants may improve their quality of life allowing the individual to hear. [1] Cochlear implants are either bilateral or single-sided depending on the individual needs. Cochlear implants are comprised with an external and internal components within the auditory system. [1]

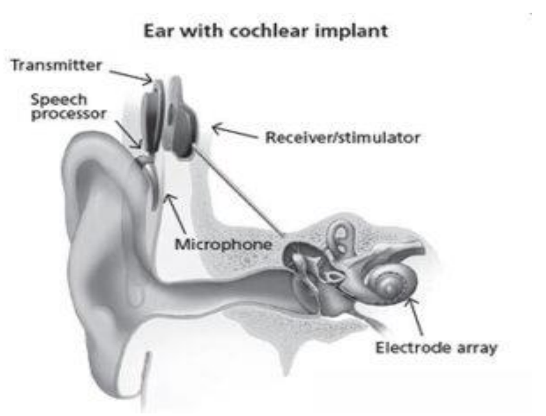


Figure 1: Cochlear Implant diagram within ear. [1] **Figure 2**: Components of Cochlear Implant. [2]

Many cochlear implant wearers enjoy spending time outside performing activities such as riding their bicycle. When riding a bicycle, standard safety precautions require the use of a helmet. Unfortunately, the helmet in a case with bilateral cochlear implants can cause pain during the ride due to consistent pressure being placed on the cochlear implant coils. The pain led to removal of the cochlear implants, potentially leading to safety concerns as this causes the inability to hear outside components during the bicycle ride.

Device Expectations

Customer requirements and technical specifications are as follows:

- Reduce pressure from the cochlear implant coil.
- Extend wear time from 20-30 miles to 100 miles
- Provide comfortability while device is in use.
- Processor is accessible to outside environment.
- Durability to withhold stress.
- Washable
- Aesthetically Appealing

Pressure Reduction on Coil | Headache Reduction | Extended Wear Time
Comfortable Fit | Accessible Processor | Sufficient Impact Protection
Aesthetic Appeal | Washable

Device Design

Design Iteration #1

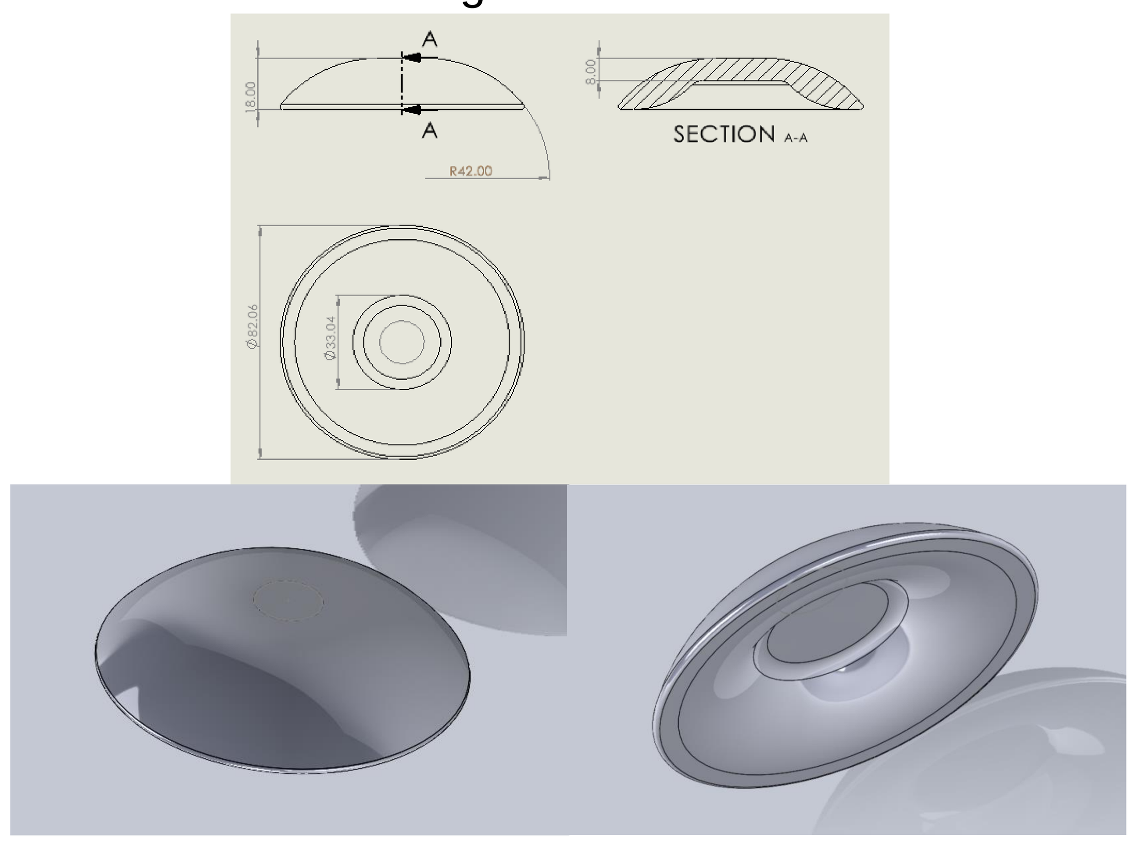


Figure 3: Dimensioned Drawing and Top/Bottom Views of 1st Iteration

Design Iteration #2

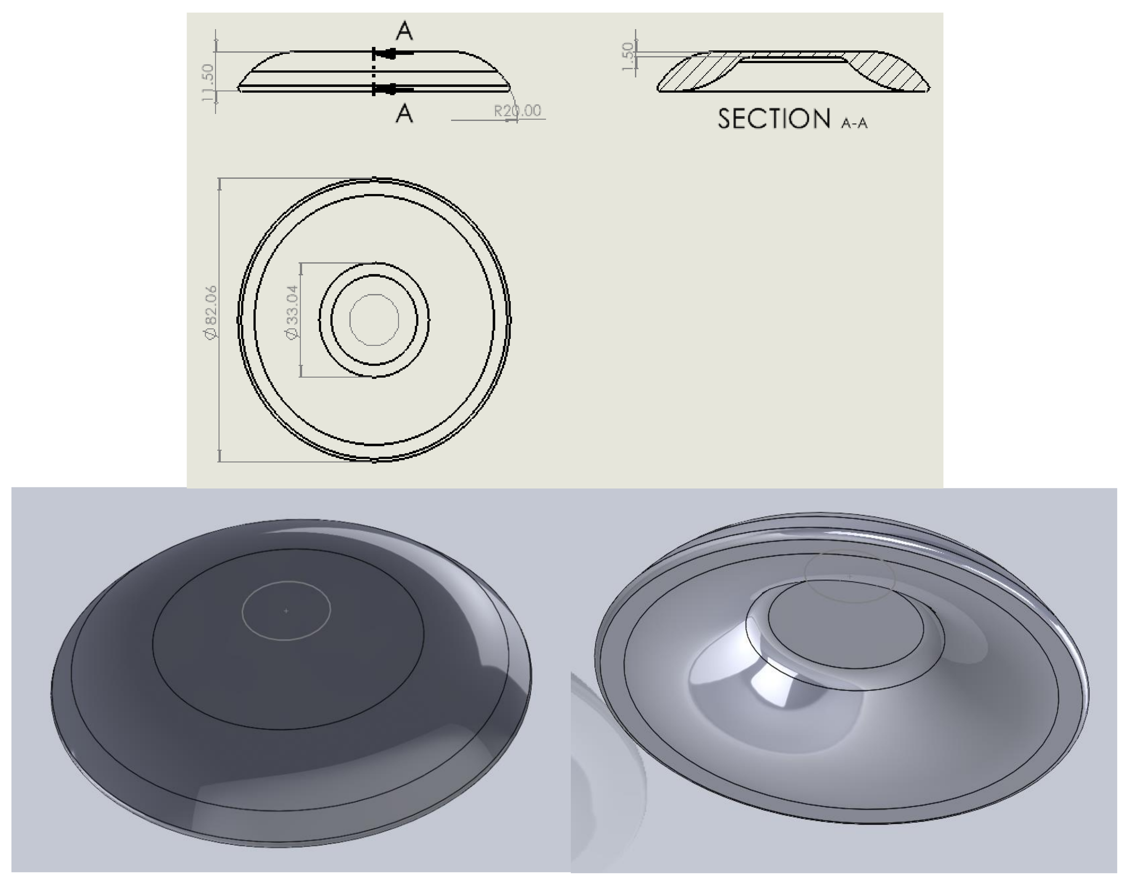


Figure 4: Dimensioned Drawing and Top/Bottom Views of 2nd Iteration

Design Iteration #3

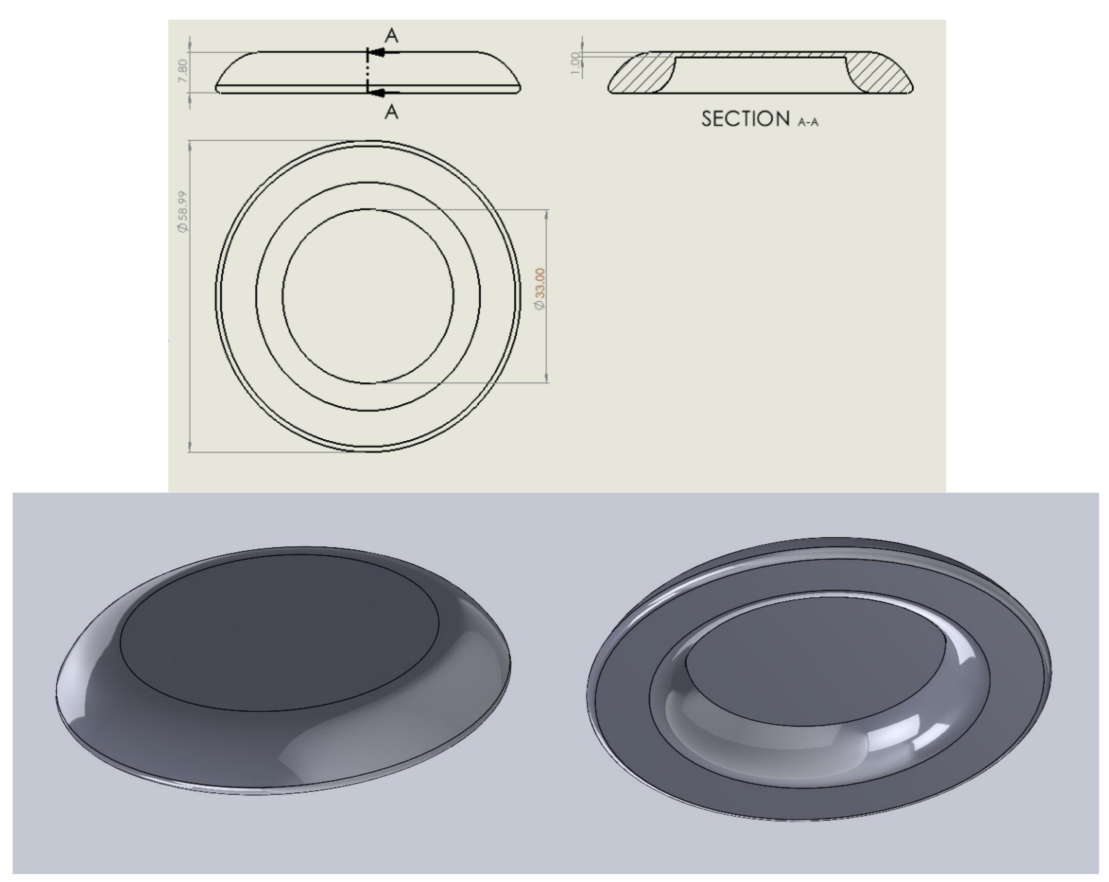


Figure 5: Dimensioned Drawing and Top/Bottom Views of 3rd Iteration

Testing and Validation

Material Testing:

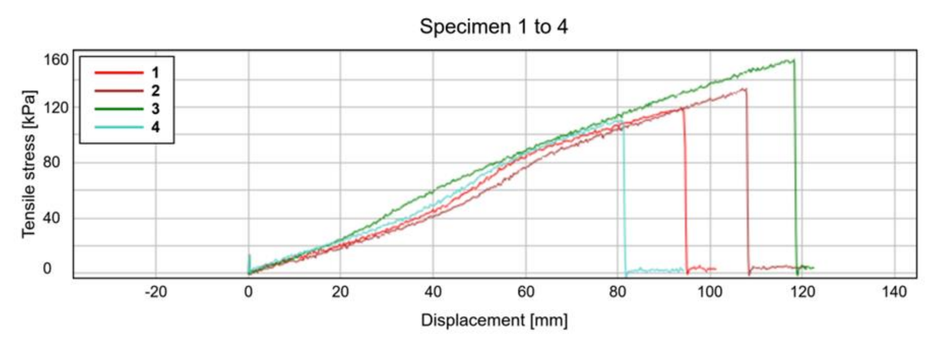
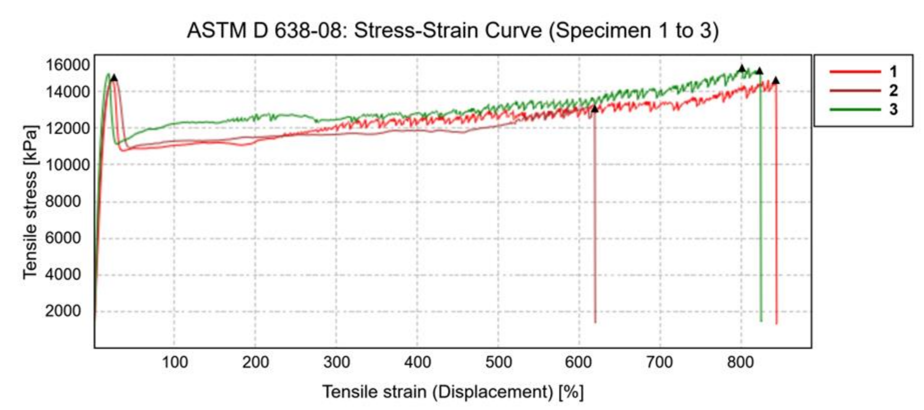


Figure 6: Stress vs. Displacement for Foam Samples



Material testing was conducted to determine the true properties of the materials being used for the padding and structural components. The graphs of data collected during those trials can be seen in Figure 6 and Figure 7.

Pressure Testing:

Performed using a pressure sensor on max pressure area with and without a cochlear implant. Statical analysis indicated that device significantly reduced the pressure on the coil of the implant. The maximum, minimum, and average forces recorded are displayed in **Table 1**.

Pressure (Kg)	Control(On coil without device)	On Device	Under Device(On coil with device)
Average	0.135	0.840	0.0847
Max	0.272	1.72	0.0812
Min	0.0811	0.272	0.102

Table 1: Pressure Test Results/Stats

Compression Testing:

Performed on the Instron machine conducting a compressive force causing device deformation, leveraging ASTM D695-15 [3]. The three tested device never reached fracture, highlighting the ductility of the polycaprolactone. The force vs displacement can be

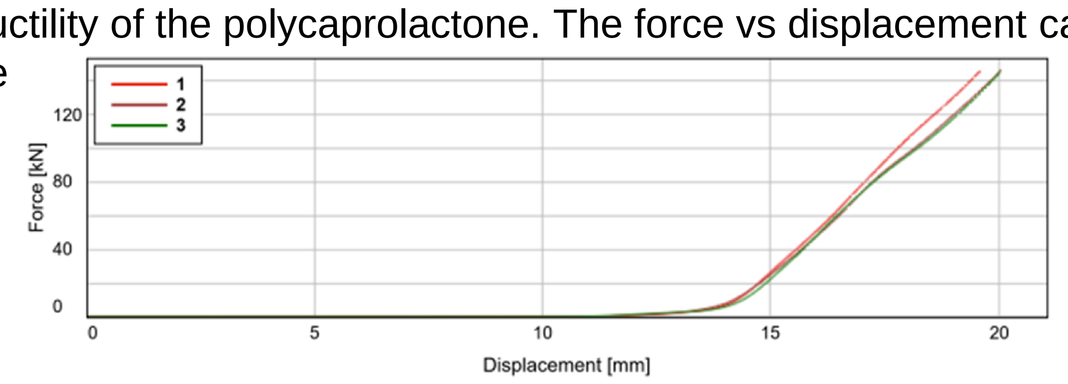


Figure 8: Compression test results highlighting the applied force and displacement.

Results indicated a compressive strength of 41.27 +/- 0.13 MPa, highlighting the devices' ability to withstand extreme compressive forces, without presenting additional risk to the user.

Customer Evaluation

The first device sent to the customer needed to be scaled down as it was interfering with the processor of the cochlear implant. The revised design securely covers and protects the cochlear implant coil, while avoiding contact with the processor.

Customer Questionnaire Results – 5-point Likert scale

- Overall comfortability – 4
- Ease of use – 4
- Helmet fit – 4
- Housing security – 5
- Pressure reduction – 4
- Likelihood to consistently wear the devices – 5
- No hindrance to the implant functionality

Conclusion

Wearing helmets can limit activities that improve quality of life for individuals with cochlear implants. The prolonged pressure of the helmet on the implant magnet can result in an external compression headache. The design team created a device to alleviate the pressure from the implant by dispersing the pressure around the coil rather than over it. Through testing and customer evaluation the team determined that the design was successful in alleviating the forces placed on the customer's implant by the bike helmet.

Literature Cited

[1] How the Cochlear Implant Works | Colorado Springs Ear Associates

[2] Rediscover the sounds you've been missing | Cochlear

[3] Standard Test Method for Compressive Properties of Rigid Plastics | ASTM D695-15

Acknowledgements

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