Spring 2022

Cochlear Implant Training Model

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COCHLEAR IMPLANT TRAINING MODEL

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Final Report for 4600:402 Honor Design, Spring 2022

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Spring 2022

Abstract

Currently available training methods for cochlear implant surgeries such as cadavers and imaging systems are expensive and available for a limited number of training sessions. With the goal of decreasing risk factors associated with cochlear implant surgery, our team developed a cochlear implant training model prototype that is designed to provide a trial-and-error, tactile training method for developing force perception levels required to avoid causing damage to the cochlea. This model is designed to utilize a disposable material that ruptures when exposed to critical force levels. A material testing device was developed and utilized to test an assortment of easily accessible, thin materials that could be used by the training model. Further testing is still required before selecting the final material for the training model. An overview of potential material selection methods is given to improve future material testing results.

Contents

1. Introduction

Cochlear implant surgery involves one of the smallest bones in the human body. This surgery is performed by creating an incision behind the ear and inserting an electrode into the cochlea. The greatest challenge that surgeons are faced with through this process is ensuring that the electrode does not catch, and the membranes within the cochlea are not damaged. Currently, there are limited training options for cochlear implant surgery. The most common, and well-known method involves the use of a cadaver to practice, and an MRI scan to obtain feedback from the results. Problems with this method include delayed feedback as well as limited re-trials. A study performed with a sample size of over 1300 cochlear implants between 1987 and 2015 found an overall complication rate of 18.4% (Theunisse, Mulder, Pennings, Kunst, & Mylanus, 2018). With the goal of decreasing risk factors for patients, this project aims to develop a prototype that can serve as a readily available, trial-and-error, tactile method for trainees to experimentally develop force perception levels required to avoid damaging the cochlea during surgery. This paper will explore the methods and strategies our team used to develop a training model prototype.

2. Design

A study performed by Schuster et al. found that forces from 0.042 – 0.122N with a mean of 0.088N will cause translocation of the cochlear implant electrode array from the scala tympani to scala vestibuli with intracochlear damage (2015). The goal for this cochlear implant training model is to provide the users with feedback to train their force perception to avoid damage. Based on the study's lowest force value, the model should ideally train the user to avoid exceeding 0.042N of force. Schurzig et al. recommends that insertion forces be measured with a resolution of 0.005N (2012). Therefore, the force range for the training model should be between 0.037N and 0.047N. A study performed by Kratchman et al. reports the median force perception threshold for otolaryngologists who actively perform cochlear implant surgeries as 0.0223N with a maximum threshold of 0.0365N (2016). This suggests that using force perception as the method of training for forces between 0.037N and 0.047N can be achievable by trainees. For the training model prototype, our team decided to perform material testing to find a thin material that would consistently rupture within the targeted force range. Once found, the training model would utilize the selected material to give trainees feedback based on the post-insertion material condition. A ruptured material would indicate that critical force levels have been exceeded. Section 2.1 illustrates the device designed and used to test materials while Section 2.2 gives an overview of the cochlear implant training model prototype.

2.1 Material Testing Device

Our team designed the testing device shown in Figure 1. This design utilizes a NEWACALOX Digital Milligram Pocket Scale. This scale has 0.001g readability, 0.001g accuracy, and error range of ±0.005g (NEWACALOX, 2022). A design-stage uncertainty of ±0.00520g was calculated for this device. Converting mass to equivalent force using a gravitational acceleration of 9.81m/s^2, the force equivalent design-stage uncertainty is ±0.00005N, which is suitable to obtain data for the desired material rupture range. The electrode holding fixture shown in Figure 2 uses a 3D printed component to house the electrode substitute and a mini wooden clothespin to clamp it in place. An electrode substitute is used so that required force levels can be transmitted through its tip to puncture test materials. The electrode substitute is cut from bead stringing wire. For material testing, our team selected an assortment of easily accessible, thin materials such as paint films, papers, and plastics. Next, an overview of the testing procedure will be provided.

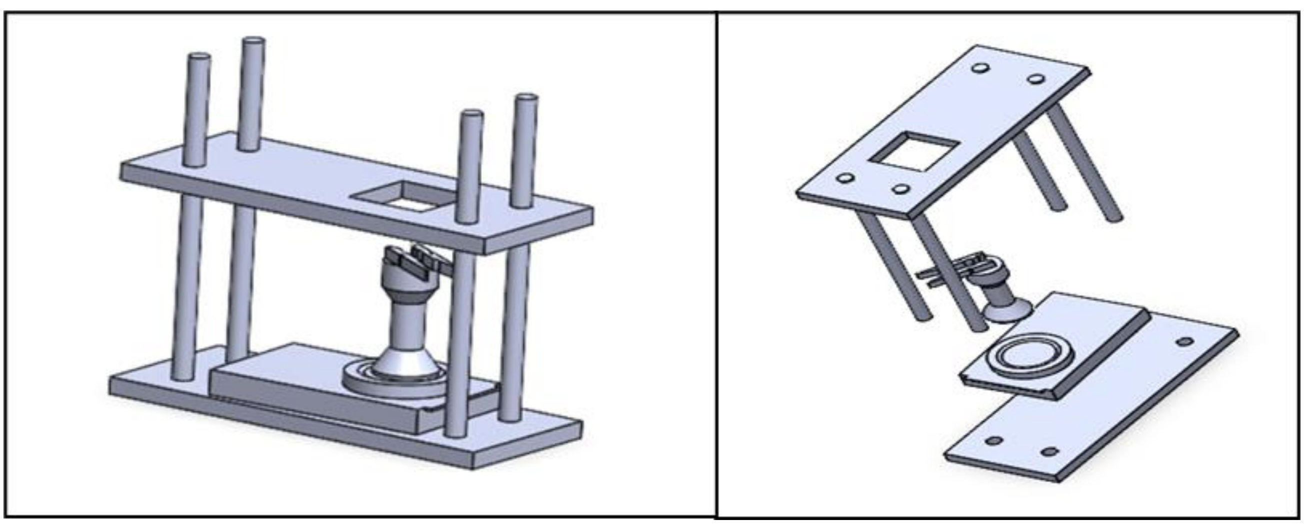

Figure 1. Material Testing Device 3D Model

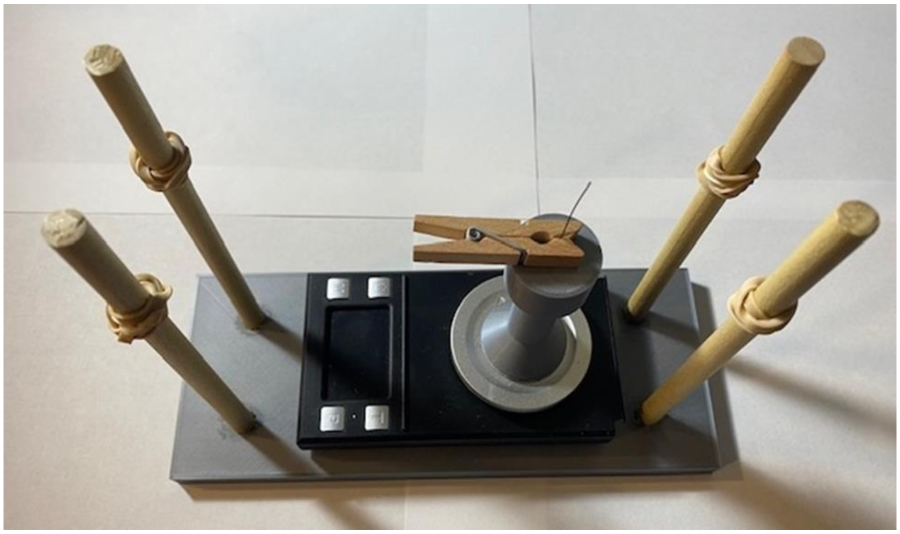

Figure 2. Electrode Holding Fixture

First the test material is placed in between two washers before two 32mm binder clips are used to clamp the washers together. The washers are then centered onto the window of the topmost platform and attached via another set of 32mm binder clips to become the platform assembly shown in Figure 3.

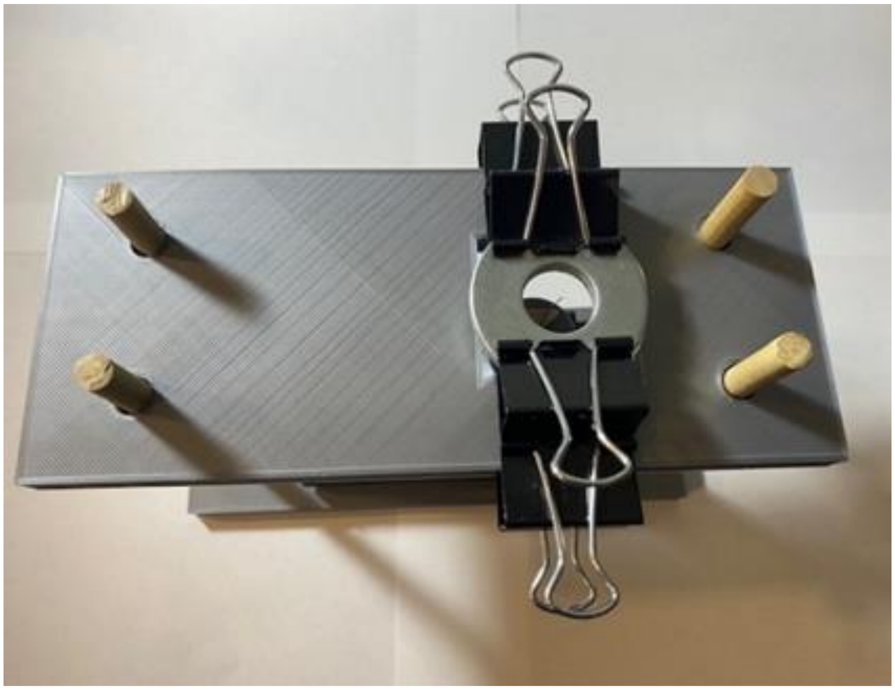

Figure 3. Platform Assembly

Next, video recording begins with the use of an iPhone 11's back camera with 1080p HD at 240fps. Utilizing the four dowel rods as guides, the platform assembly is slowly lowered onto the electrode substitute until a material rupture occurs. The camera footage is then reviewed to determine the digital milligram pocket scale's displayed reading at the moment of rupture. An example of this is shown in Figure 4. This reading is recorded before converting it to its equivalent force value in Newtons. If no material rupture has occurred, then the test is listed as having a rupture force outside of the testing setup's capabilities. It was found that the electrode substitute tends to buckle around a force of 0.112N, preventing the capture of rupture forces that exceed this value.

Figure 4. Example of Material Testing Process

2.2 Cochlear Implant Training Model Prototype

Figures 5 and 6 show the prototype for the cochlear implant training model. This device utilizes the same material clamping structure as the material testing device.

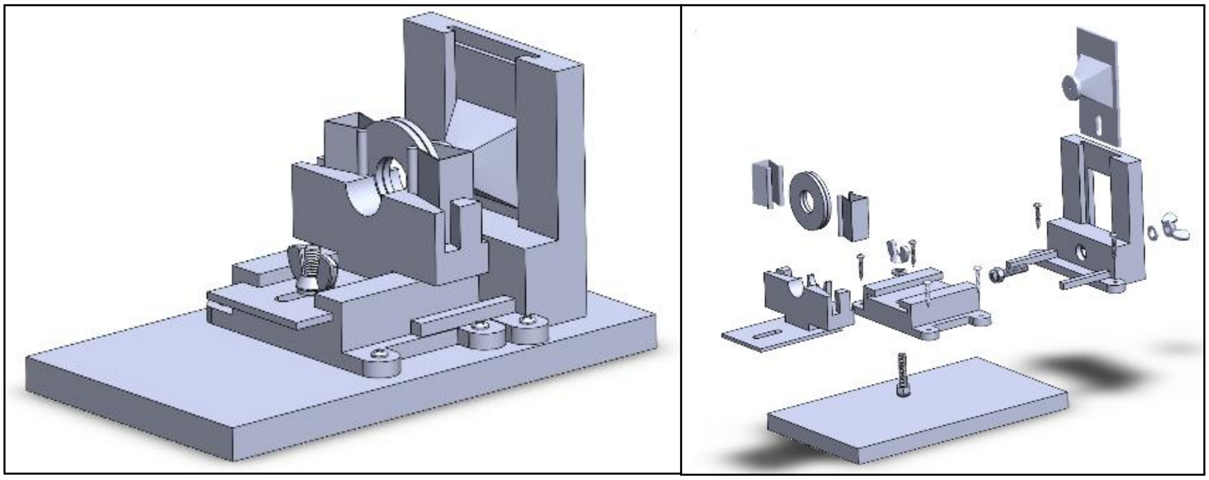

Figure 5. Cochlear Implant Training Model Prototype 3D Model

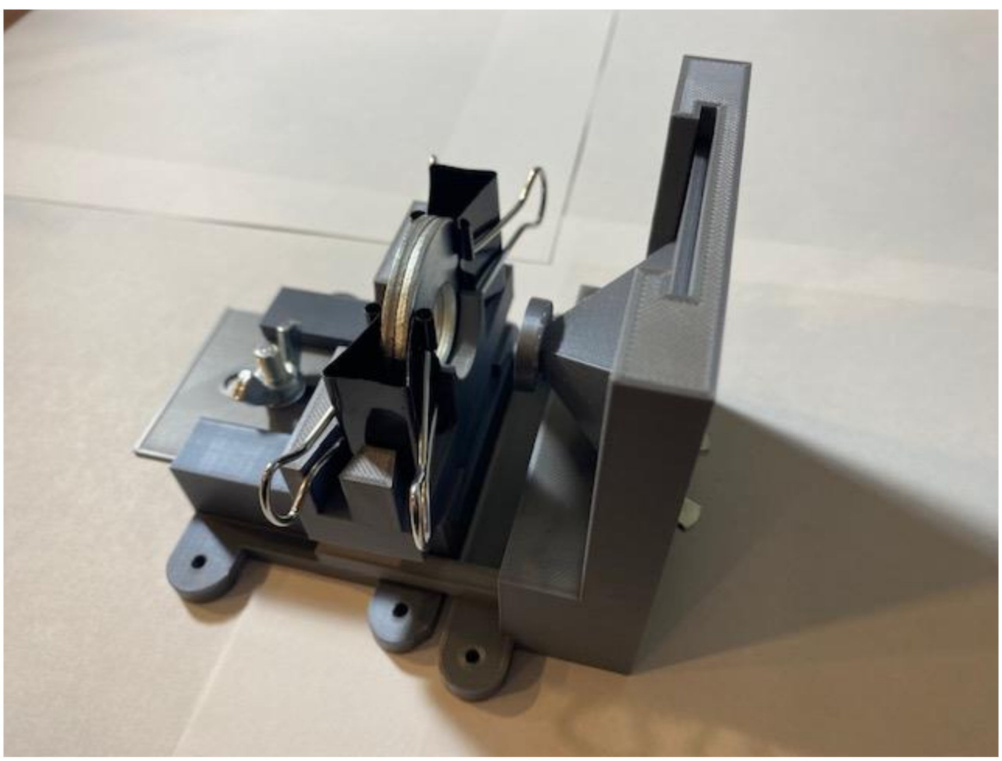

Figure 6. Cochlear Implant Training Model Prototype

The opening shown in Figure 7 represents the round window or “cochleostomy” that the surgeon inserts the electrode through during a cochlear implant surgery. The user may adjust the distance from the material to the window to account for varying insertion depths. This forces the trainee to rely solely on force perception as the training model blocks their vision of the electrode substitute’s position with respect to the material. Next, an overview of the training procedure will be provided.

Figure 7. Electrode Insertion Window

First, a new material is placed in between the two washers and clamped with two 32mm binder clips before being placed into the training fixture. This material should meet desired rupture force specifications. As shown in Figure 8, the training fixture can be adjusted to represent different insertion depths where the trainee may encounter resistance. This also ensures that the trainee is not able to predict when they will encounter resistance.

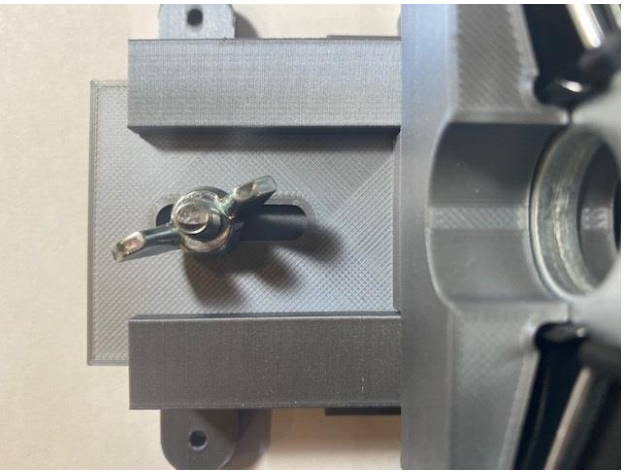

Figure 8. Adjustment Capabilities for Cochlear Implant Training Model Prototype

Next, they use forceps to insert the electrode substitute through the window as shown in Figure 9. The goal is for the trainee to identify when they encounter resistance and never exceed a force level that would rupture the material. Through training iterations and feedback from ruptured materials, the trainee will improve their force perception and learn to avoid critical force levels that can cause intracochlear damage. It is important to note that a camera and/or display showing the position of the electrode substitute with respect to the material can be utilized when live or recorded feedback of the training process is desired.

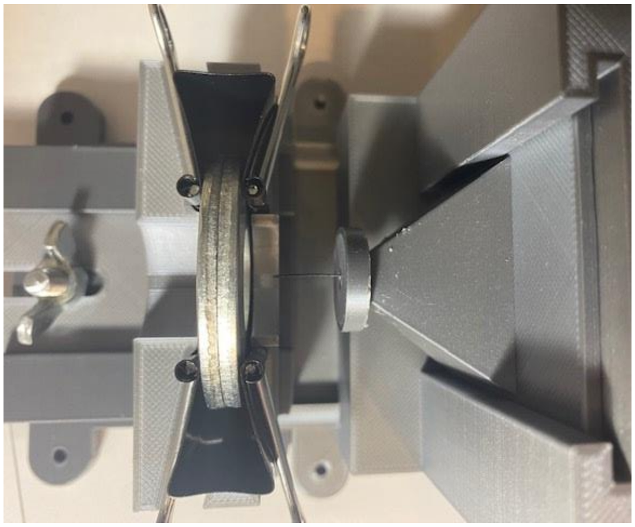

Figure 9. Example of Electrode Substitute Insertion

3. Verification

After all material tests were performed, none of the originally selected materials consistently ruptured within the defined force range requirements. Choosing materials for future testing will require better selection methods to improve testing results. Proposed tools for selecting future materials will be discussed in sections 3.1 and 3.2.

3.1 Static Structural Analysis with Ansys Workbench

The clamped material between two washers can be modeled by a disk with a fixed support along its entire perimeter. The diameter of this disk should be 18.1mm and its thickness can be defined by the user based on material thickness. A load is applied to a region in the center of the disk. This region is defined by the electrode substitute’s 0.4mm tip diameter. After the material’s Young’s Modulus of Elasticity and Poisson’s Ratio have been entered, a static structural analysis can be performed. Solution iterations with increasing applied loads are run until a solution occurs where the maximum stress in the disk is greater than the material’s ultimate strength. The load applied in this solution would provide a theoretical rupture force for the material. Utilization of Ansys Workbench software with several known material properties and initial conditions will provide theoretical results on materials that can be selected for future testing. Figure 10 gives an example of Ansys Workbench software being used to calculate total deformation and equivalent (von-Mises) stress.

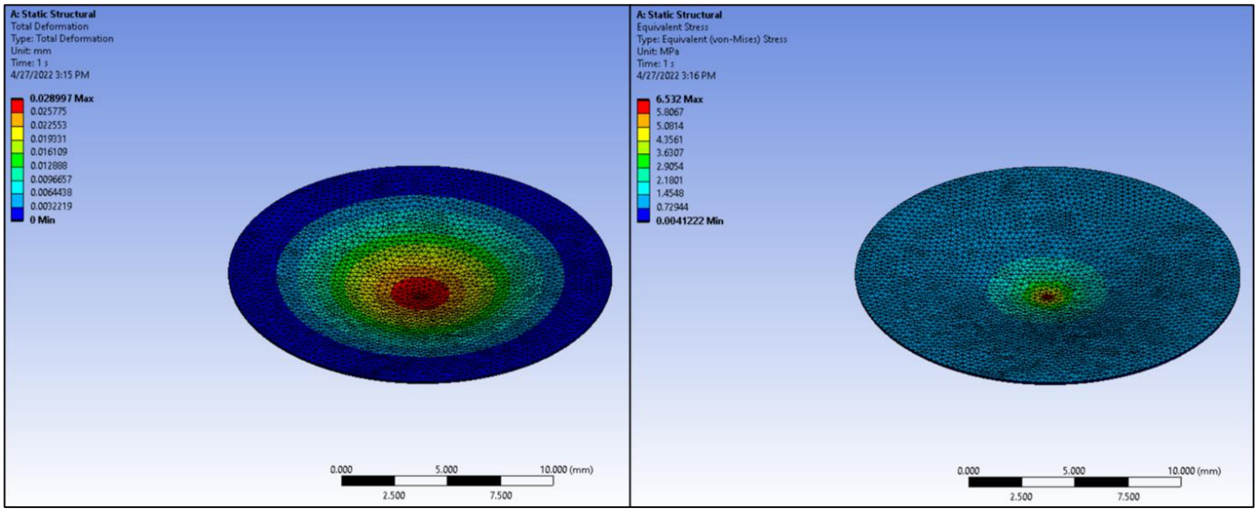

Figure 10. Ansys Workbench to calculate Total Deformation (left) and Equivalent Stress (right)

3.2 Solution for Elastic Membranes under a Central Load

The clamped material between the two washers can be modeled by the diagram shown in Figure 11.

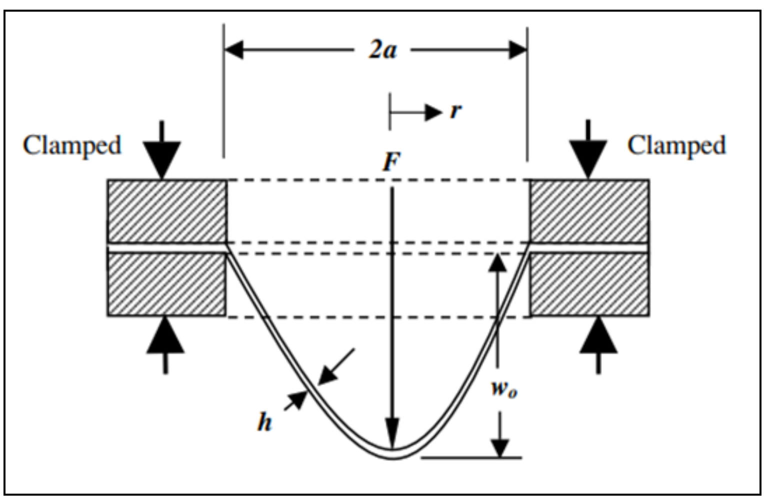

Figure 11. Sketch of a Circular Membrane Deformed by a Central Point Load

Note: Sketch of a circular membrane deformed by a central point load. Reprinted from "Characterization of the mechanical properties of microscale elastomeric membranes," by H. S. Khoo, K-K. Liu, and F-G Tseng, 2005, Measurement Science and Technology, 16, p. 656. 1999

Khoo et al. provides the following differential equation for elastically isentropic materials

$$\frac{d^3w}{dr^3} + \frac{1}{r}\frac{d^2w}{dr^2} - \frac{1}{r^2}\frac{dw}{dr} - \frac{N}{D}\frac{dw}{dr} = \frac{F}{2\pi Dr} \tag{1}$$

as well as the equation for flexural rigidity

$$D = \frac{Eh^3}{12(1 - v^2)} \tag{2}$$

where *E* is Young's Modulus of Elasticity, v is Poisson's Ratio, *h* is thickness, *F* is central load, *w* is displacement, and *N* is the average membrane stress (2005). It is reasonable to assume that the electrode substitute's tip can be treated as a point load because the diameter is much smaller than that of the material samples with a factor of approximately 1/2163. Utilization of Equation (1) and Equation (2) along with several known material properties and initial conditions through software such as MATLAB will provide theoretical results on what elastically isentropic materials can be selected for future testing.

4. Costs

The overall cost for this project is $8,936.85 USD. Figure 12 breaks down this cost. Labor costs account for $8,840.00 while material costs account for $96.85 USD.

Labor Costs	Staff	Hourly Salary	Total Man Hours	Cost	Sub Total	Overall Cost
	Engineer	$34.00	260	$8,840.00	$8,840.00	$8,936.85
Material Costs	Description	Model Number	Manufacturer	Cost	Sub Total	
	NEWACALOX Digital Milligram Pocket Scale	DH100G-2	JLX factory	$22.99	$96.85	
	5/8" x 1 3/4" Washers	31161800	HILLMAN	$0.94		
	6mm Metric Flat Washers	127074	HILLMAN	$2.28		
	M6-1.00 x 30 Metric Pan Phillips Machine Screws	127137	HILLMAN	$1.98		
	M6-1.00 Metric Wing Nuts	127089	HILLMAN	$1.98		
	M6-1.00 Metric Hex Nuts	127084	HILLMAN	$1.98		
	5/16" x 36" Dowel Rod	-	Waddell	$0.47		
	32mm Binder Clips	15351	Staples	$1.52		
	Mini Wooden Clothespin	88303E	On the Surface	$1.88		
	Size #32 Rubber Bands	2632A	Alliance Rubber	$0.67		
	Super Glue	1399965	LOCTITE	$3.48		
	Bead Stringing Wire	07575	Beadalon	$5.18		
	PLA 1.75 MM Real Grey Filament	PLA175RGY	SOLUTECH	$19.99		
	Assorted Test Materials	-	-	$31.51		

Figure 12. Project Cost Breakdown

Actual expenditures for this project came from purchased test materials as well as components required for the material testing device and cochlear implant training model prototype. An itemized list of materials required for each device are shown in Figure 13.

Device	Description	Model Number	Manufacturer	QTY
Material Testing Device	PLA 1.75 MM Real Grey Filament	PLA175RGY	SOLUTECH	1
	NEWACALOX Digital Milligram Pocket Scale	DH100G-2	JLX factory	1
	Mini Wooden Clothespin	88303E	On the Surface	1
	Super Glue	1399965	LOCTITE	1
	5/16" x 36" Dowel Rod	-	Waddell	1
	Size #32 Rubber Bands	2632A	Alliance Rubber	4
	5/8" x 1 3/4" Washers	31161800	HILLMAN	2
	32mm Binder Clips	15351	Staples	2
	Bead Stringing Wire	07575	Beadalon	1
Cochlear Implant Training Model Prototype	PLA 1.75 MM Real Grey Filament	PLA175RGY	SOLUTECH	1
	M6-1.00 x 30 Metric Pan Phillips Machine Screws	127137	HILLMAN	2
	6mm Metric Flat Washers	127074	HILLMAN	2
	M6-1.00 Metric Wing Nuts	127089	HILLMAN	2
	M6-1.00 Metric Hex Nuts	127084	HILLMAN	2
	5/8" x 1 3/4" Washers	31161800	HILLMAN	2
	32mm Binder Clips	15351	Staples	2
	Bead Stringing Wire	07575	Beadalon	1

Figure 13. Itemized List of Materials for Each Device

5. Conclusion

With the goal of decreasing risk factors associated with cochlear implant surgery, our team developed a cochlear implant training model prototype that is designed to provide a trial-and-error, tactile training method for developing force perception levels required to avoid causing damage to the cochlea. Our team also developed a material testing device that can experimentally determine material rupture forces. Utilizing this device, experimental results for an assortment of easily accessible, thin materials such as paint films, papers, and plastics were obtained. Lastly, selection methods for future material testing were explored.

5.1 Ethical Considerations

When considering materials for this training model, it was important to consider factors such as health and safety, replacement cost, and environmental impact. Due to the design of the training model, the materials will be continuously replaced after each use. As future materials are tested for this model, it is important to maintain these considerations as the final product must be safe to handle before, during, and after its intended training use. It is also critical to consider both ISO 13485:2016 and ISO 14971:2019 as they apply to medical devices. ISO 14971:2019 governs the application of risk management to medical devices while ISO 13485:2016 governs quality management systems and requirements for regulatory purposes.

5.2 Future work

More material testing is required before selecting the final material for this training model. When selecting materials, tools referenced in both Section 3.1 and Section 3.2 can be utilized to determine theoretical results before testing is conducted. Factors such as health and safety, replacement cost, and environmental impact are important considerations for the material that will be used in the final model. Upon successfully finding a material that consistently ruptures between 0.037N and 0.047N, this training model will go through testing with trainees to determine its ability to improve an individual's force perception to a value within this range.

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