Design and Stimulation of a Middle Ear Model to Aid with Otological Studies

A Major Qualifying Project

Submitted to the Faculty of
Worcester Polytechnic Institute
In partial fulfilment of the requirements for the
Degree in Bachelor of Science
In
Mechanical Engineering/Biomedical Engineering
By:
Sean Kane
Elleana Paradise
Arden Tanner
Theresa Torraca

Advisors:
Professor Sarah Wodin-Schwartz
Professor Zoe Reidinger

Submitted on: October 30, 2020

Tables of Contents

List of Figures

List of Tables

Acknowledgements

First and foremost, our team would like to thank our sponsor, Dr. Ivo Dobrev of UniversitätsSpital Zürich, for the unique educational opportunity he provided to us. His guidance was indispensable to our success as he ceaselessly provided encouragement and support to aid in the development of a successful project. We would like to specifically thank him for his flexibility in making this project possible to be completed remotely.

The success of this project was made possible thanks to our advisors, Dr. Sarah Wodin-Schwartz and Dr. Zoe Reidinger, who provided us with valuable feedback, guidance, and direction. We are especially grateful for everyone who was willing to be interviewed to help our team gain information on various aspects of the model. Specifically the team would like to thank: Peter Hefti for his advice on accelerometers, Dr. Stults and Mitra Anand for their advice on advanced 3D printing, Professor Sullivan for his advice on Arduino coding, and Dr. Jae Hoon Sim for his advice on how to model middle ear ligaments. Finally, we would like to extend our sincerest gratitude towards every individual that supported us through this process.

Abstract

The Universitätsspital Zürich expressed a need for a teaching model to enhance the understanding of sound mechanics, anatomy, and physiology of the middle ear. This project focused on replicating the middle ear and its surrounding components, as well as demonstrating the translation of vibrations in a healthy and abnormal middle ear. The model was acoustically stimulated, and accelerometers measured resulting vibrations. This model aids student understanding of the ear, and therefore in developing new options to address the challenges of hearing loss.

Chapter 1: Introduction

Hearing loss globally affects people of all ages, genders, and backgrounds. The World Health Organization projects that there are “466 million people in the world with disabling hearing loss” (WHO, 2020). While there are some technologies available that improve one’s hearing ability, such as hearing aids, research on a more advanced internal option is limited (NIH, 2016).

In order to further otology research, the anatomy and physiology of the ear must be understood. The anatomical ear is divided by depth into three sections; the outer, middle and inner ear. This project specifically focuses on the middle ear, which is tasked with transferring vibrations from the outer to the inner ear. The main parts of the middle ear are the tympanic membrane and ossicles. The ossicles are three small bones named the malleus, incus, and stapes, and are aligned in a chainlike formation, often referred to as the ossicular chain (The Middle Ear, n.d.). Various ligaments and joints connect the ossicles together, support them within the tympanic cavity, and hold them in their proper orientation (Nolan et al., 2013).

However, conditions such as otosclerosis can lead to temporary or permanent loss or impairment of the ear’s perception of sound (Otosclerosis, 2020). Treatments such as antibiotics, prostheses, and surgical procedures are available, but limited by an insufficient understanding of the ear and sound mechanics. Research on the middle ear at Universitätsspital Zürich is focused on hearing ability, vibrational changes due to chronic conditions or injuries, and optimizing prosthesis. For this reason, a representative and accurate model to visualize and further their understanding of the middle ear is crucial.

Based on these main ideas, the team developed the following objectives:

1. Replicate middle ear anatomy, tympanic membrane, and oval window at a 15:1 scale to show the anatomy of middle ear and surrounding features
2. Suspend the ossicles so that the alignment between components and location of ligament attachment to the ossicles is anatomically accurate
3. Design adjustable components to model an abnormal ear
4. Stimulate model acoustically or mechanically to demonstrate the translation of vibrations from the tympanic membrane, through the ossicular chain, and into inner ear
5. Analyze the vibrations of the model

Current models of the middle ear are unrepresentative of various ear conditions and lack the ability to show the movement of the middle ear (Hu, 2012). This project utilized various biomedical and mechanical engineering principles to address the inaccuracies and deficiencies of current teaching models of the ear. The model was made to be interchangeable and representative of various pathological conditions. Once the model was appropriately aligned and suspended according to the anatomy of the ear, the model was acoustically stimulated to show the translation of vibrations through the ear. Accelerometers were attached to the surrounding membranes to determine the input and output vibrations. The creation of this model has the ability to help students at the Universitätsspital Zürich further their understanding of the middle ear. Better knowledge of the middle ear has the potential to provide opportunities for future medical advancements and treatments for people with hearing loss or impairment.

Chapter 2: Background

2.1 Global Hearing Impairment

Hearing loss is worldwide and affects people of all ages and backgrounds. Whether the damage was caused via an event, infection, or birth defect, the World Health Organization estimates that, “there are 466 million persons in the world with disabling hearing loss” (WHO, 2020). This equates to approximately six percent of the entire world population. Hearing loss affects people of all ages, with 34 million being children, and can worsen through a person’s lifespan (WHO, 2020). Hearing loss can come about from continuous exposure to loud noises that are damaging to the ear structure. It can also be caused by the natural breakdown and weakening of the ear structure overtime. If scientific advances are not made to better protect the ear and treat hearing loss, “projections show that over 900 million people may be affected in 2050” (WHO, 2020). Hearing loss is not necessarily a genetic condition, as there are numerous people that develop hearing issues in their later years with no prior medical history. Further, a majority of newborns with hearing issues are born to hearing parents.

In addition to the numerous people that suffer from hearing damage or loss, there are approximately “28.8 million adults in the US that could benefit from using hearing aids" (NIH, 2016). Hearing aid devices have come a long way since they were first introduced as a technology to help hearing loss. The first hearing aids were “large unwieldy boxes that could be the size of a small suitcase” (The History of Hearing Aids, 2020). Current technology has created modern hearing aids that can sit or be implanted into the ear and allows the wearer to experience nearly perfect audio quality. However, even though this technology exists, it isn’t easily accessible to everyone that needs it. Hearing aids primarily help people improve “the hearing and speech comprehension of those who suffer from hearing loss” (Hearing Aids, 2017). As the ear becomes damaged due to an accident, old age, or disease, a hearing aid can “magnify the sound vibrations entering the year [to help] convert them into neural signals that are passed along to the brain” (Hearing Aids, 2017). It is important to continue to develop science and technology in relation to understanding the ear so that medical devices can continue to be innovated to help those that experience hearing loss.

2.2 Anatomy and Physiology of the Ear

The anatomy of the ear can be split into three main parts: outer, middle and inner ear. The outer ear is composed of the external part of the ear as well as the ear canal. The external part of the ear is used to funnel sound waves into the ear canal and towards the tympanic membrane. The middle ear starts at the tympanic membrane, or more commonly known as the eardrum and extends to the lateral wall of the inner ear. It contains three bones, or ossicles: the malleus, incus, and stapes (The Middle Ear, n.d.). The tympanic membrane is stimulated by sound waves causing the membrane to vibrate. The three ossicles work together to amplify this vibration so it can be transferred to the inner ear. The stapes bone delivers the final vibration to the inner ear at the oval window. The inner ear is composed of the cochlea, vestibule, and three semicircular canals. The cochlea is responsible for converting the mechanical vibrations into an electrical signal to be interpreted by the brain. Figure 1 depicts the outer, middle, and inner sections of the ear.

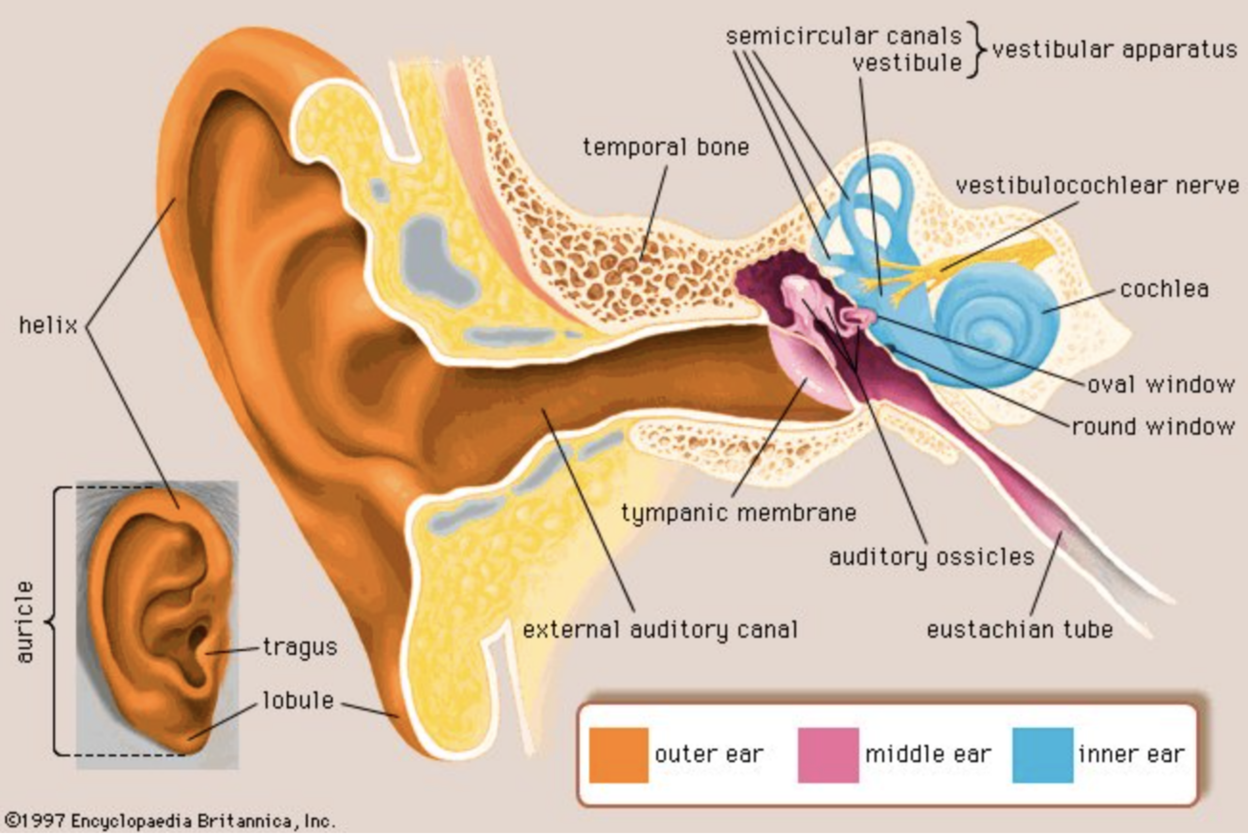


Figure 1: Anatomical Overview of the Ear (Vestibule, n.d.)

2.2.1 Anatomy and Physiology of the Tympanic Membrane

The tympanic membrane, also known as the eardrum, is a thin, circular layer of tissue. The average dimensions of the tympanic membrane are 0.1mm thick and 8-10mm in diameter (Team, 2018). While the membrane is a small, thin piece of tissue, it is very durable and flexible. The outer layer of the tympanic membrane is continuous with the skin in the external auditory canal. The inner layer of the tympanic membrane is continuous with the mucous layer lining the middle ear. In between these layers is a network of fibers that give the tympanic membrane its stiffness (Britannica, 2018). When sound waves strike the tympanic membrane, it causes the membrane to vibrate. The membrane is attached to the malleus bone which transfers this vibration throughout the middle ear.

2.2.2 Anatomy and Physiology of the Middle Ear

The middle ear is home to three small bones known as ossicles, and together they comprise the ossicular chain. In order from superficial to deep, they are the malleus, incus, and stapes. These three bones reside in the tympanic cavity of the middle ear, where fluid is normally produced in small amounts (Summit Medical Group, 2014). Each bone vibrates to send sound waves to the cochlea of the inner ear. Figure 2 shows an anatomical overview of the ossicles in the middle ear.

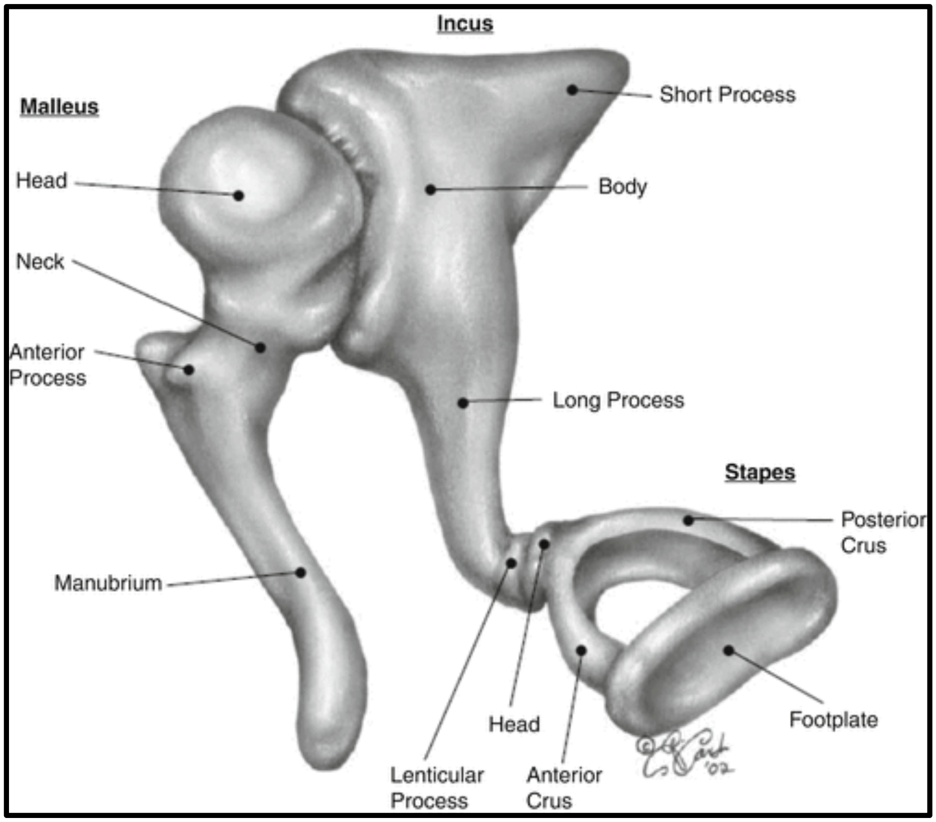


Figure 2: Anatomical Overview of Ossicles (Nolan et al., 2013)

The malleus is the largest and most superficial of the ossicle bones, and connects to the tympanic membrane by means of a soft tissue connection. The tympanic membrane oscillates in response to sound funneled through the external ear and sends those vibrations through the middle ear by its connection to the malleus. The head of the malleus articulates with the incus by means of a synovial joint called the incudomalleolar joint (IMJ) (De Greef et al., 2015). A synovial joint is a joint where each bone has a small lining of cartilage and then in between the cartilage there is synovial fluid. The joint is then surrounded by a fibrous connective tissue (Biga et.al., n.d.). There are three ligaments that suspend the malleus in place: anterior ligament of malleus (5), superior ligament of malleus (3) and lateral ligament of malleus (9). These ligaments can be seen as numbers 5, 3, and 9 respectively in Figure 3. The anterior ligament connects the neck of the malleus to the anterior wall of the tympanic cavity. The superior ligament connects the head of the malleus to the superior wall of the tympanic cavity. Lastly, the lateral ligament connects the head of the malleus to the posterior part of the tympanic notch (De Greef et al., 2015).

The incus is the middle ossicle and articulates with the stapes and malleus by synovial joints. The joint between the incus and stapes is referred to as the incudostapedial joint. There are two ligaments that suspend the incus in place: incus superior ligament and incus posterior ligament (1). These ligaments are shown as ligament number 1 and 8 respectively in Figure 3. The incus superior ligament attaches the body of the incus to the roof of the tympanic cavity. The incus posterior ligament attaches the short process of the incus to the posterior wall of the tympanic membrane (De Greef et al., 2015).

The stapes is the smallest ossicle as well as the most medial. It is also the smallest bone in the human body. The head of the stapes articulates with the incus in the incudostapedial joint. The footplate of the stapes joins with the oval window of the cochlea. The connection between the stapes and oval window is the tympanostapedial syndesmosis. The annular ligament of the stapes aids in the connection between the oval window and the base of the stapes (Nolan et al., 2013). When the vibration reaches the stapes, the stapes acts almost as a piston, and transfers the vibration to the oval window. The vibration is amplified enough by the middle ear ossicles to now be transmitted through a fluid in the inner ear. The inner ear converts this signal into electrical impulses, and it is then transferred through auditory nerves to the brain, where it is interpreted as sound (Ear Infection (Otitis Media), 2020).

There are two main muscles in the middle ear: tensor tympani muscle and stapedius muscle. The purpose of these muscles is to contract when the ear is exposed to loud noises in order to protect the ear from potential damage. The tensor tympani muscle attaches to the handle of the malleus. Due to the fact that the malleus is attached to the tympanic membrane, when the tensor muscle contracts, it tenses the membrane, effectively damping the vibrations. This reduces the intensity of the vibration on the inner ear. The stapedius muscle attaches to the neck of the stapes. When it contracts, it moves the stapes posteriorly effectively tightening the annular ligament. This tightening restricts the movement of the stapes effectively dampening the effect of loud noises (Osika, 2020). Therefore, the ear protects itself from loud noises in two ways by reducing the intensity of the vibration at the tympanic membrane and the stapes.

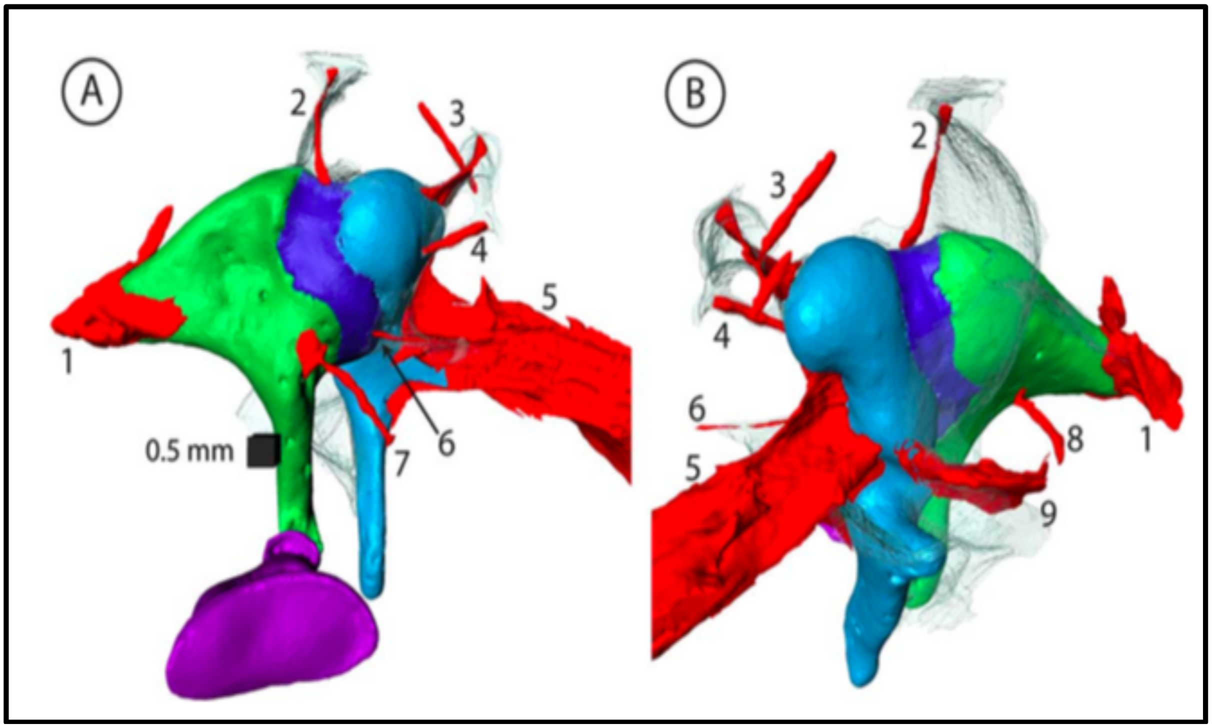


Figure 3: Ligaments in the Middle Ear. The ligaments are depicted in red and the joints are depicted in blue. For the ossicles, the stapes is purple, the incus is green, and the malleus is cyan. (De Greef et al., 2015)

2.3 Sound Mechanics

The ossicles in the middle ear, as discussed above, are able to communicate sounds to the brain by transferring vibrational disturbances in the air. Sound mechanics is the science behind how the human ear perceives sound. Sound is transferred by waves, or vibrations, travelling through and disrupting air. Waves are generated when energy is pushed through a medium such as air or water.

Sound waves are longitudinal waves. These waves displace medium particles parallel to the motion of the way (Russell, 1998). Sound waves are a special class of longitudinal waves that cause a sinusoidal pressure variation in the air as seen in Figure 4 (Nave, n.d.). This pressure change is dependent on the frequency of the sound wave.

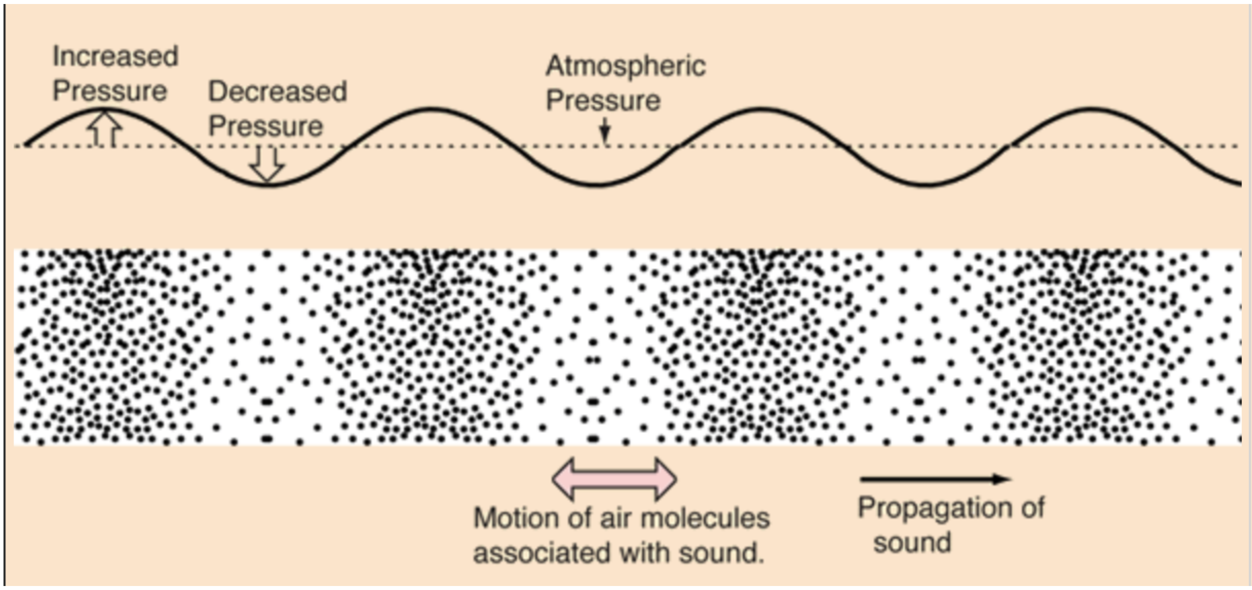


Figure 4: The resulting pressure variation and particle motion of a sound wave (Nave, n.d.)

In addition to being a longitudinal wave, sound waves can also be characterized as pressure waves. Sound waves behave in a repeating pattern of low and high pressure regions. The human ear detects these divergent pressures. When the ear detects a high pressure region, this signals a compression. A compression of the sound wave occurs when the medium particles are being pressed together (Sound Waves as Pressure Waves, n.d.). Following the compression, the ear would then notice a normal pressure and then a lower pressure. The lower pressure drop is called a refraction and occurs when the medium particles spread apart. These pressure changes repeat as the wave enters the ear. The fluctuations in pressure occur on regular time intervals called a period. The length of the wave is characterized by the distance between pressure drops and is frequently measured as the length between crests (high pressure points) and troughs (lower pressure points). One complete wave cycle is called the wavelength (Sound Waves as Pressure Waves, n.d.).

Hearing is the ability to recognize these changes in air pressure, or vibrations, through time. These vibrations travel as soundwaves through a surrounding medium. The human ear has the ability to discern both the frequency and amplitude of these waves.

Frequency is speed of the vibration per unit term. Higher frequencies are heard as a higher pitch and lower frequencies as a lower pitch, as seen in Figure 5. Humans have the ability to perceive waves with a frequency of 20-20,000 Hz. Amplitude is the strength of the waves. Bigger waves are perceived as louder sounds and smaller waves are heard as quieter sounds, as seen in Figure 6 (Amplitude and Frequency, 1997). The quietest audible sound for the human ear is approximately 10^{-12} W/m^2 or 0 dB. The loudest tolerable sound for the human ear is approximately $10^{12} W/m^2$ (OpenStax, n.d.).

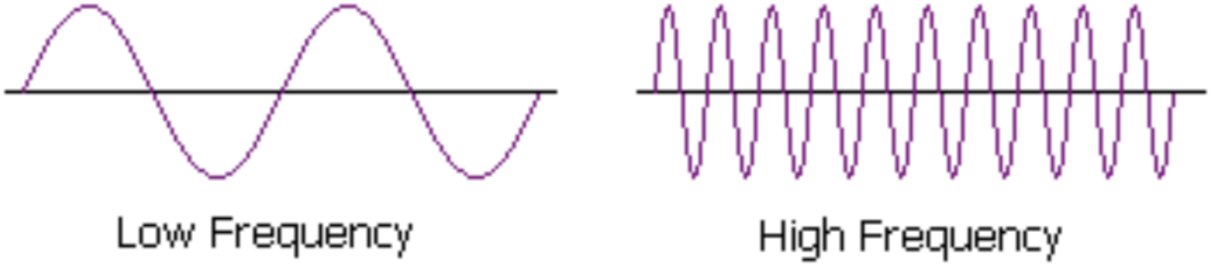


Figure 5: Comparison between high and low frequency of sound waves. (Amplitude and Frequency, 1997)

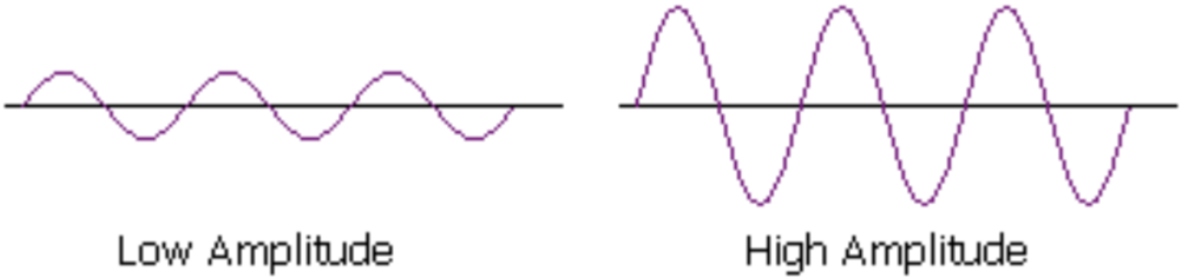


Figure 6: Comparison between a high and low amplitude of sound waves (Amplitude and Frequency, 1997)

2.4 Osteosclerosis

Otosclerosis is a condition where there is an abnormal excess of bone around the stapes bone in the middle ear (Leider, 2018). Changing the length or shape of any bone in the middle ear affects vibrations travelling through the ossicular chain (Otosclerosis, 2020). This causes conductive hearing loss or impairment. While causes for this condition are still undetermined, researchers have noted that it appears to be genetic with a 25% chance of expressing the condition if one parent has otosclerosis and a 50% chance if the condition is present in both parents (Otosclerosis, 2020).

While abnormal growth can occur in any one of the three ossicles, it appears most frequently in the stapes. Growth of the stapes fixes it in place, preventing or interfering with vibration transmission to the inner ear. The bone grows gradually and often goes unnoticed for a long period of time. When the growth begins to affect the patients' hearing, they first express difficulties hearing low noises and whispering. In most cases, otosclerosis is treated with a surgery called a stapedectomy, as discussed later in Chapter 2.5 (Otosclerosis, 2020).

2.5 Common Ear Prostheses

A stapedectomy is a surgical procedure that uses a prosthesis to treat the medical condition otosclerosis. This procedure removes part of the stapes and replaces it with a prosthetic piece. The patient goes under local anesthesia and the surgeon uses a microscope to make a small incision inside the ear canal. The eardrum is lifted and part of the stapes located near the incus is removed. A laser or drill is used to create a small hole in the footplate of the stapes (Otosclerosis & Stapedectomy, n.d.) One end of the prosthetic is threaded through the hole in the stapes footplate while the other end of the prosthetic is attached to the incus bone. This allows the prosthetic to move with the incus and deliver the vibrations to the inner ear in a similar manner to the stapes (Leider, 2018). The final product of this procedure can be seen in Figure 7 Diagram B.

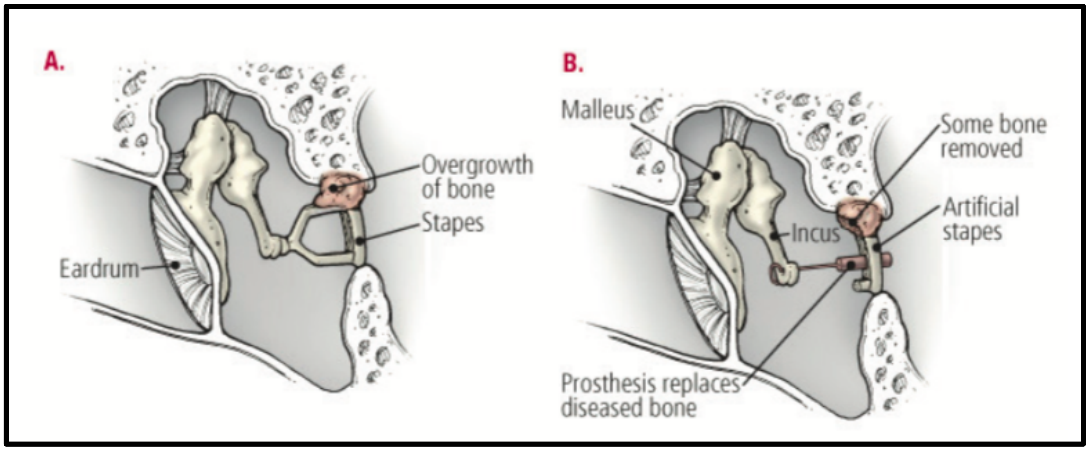


Figure 7: Stapedectomy, Diagram A: Before Procedure; Diagram B: After Procedure (Physicians Clinic of Iowa, n.d.)

Due to the vascularization of the incus, the prosthesis attachment to the incus is critical. If the prostheses is too tight it can lead to erosion and necrosis of the incus. If the attachment is too loose, it can shift and cause a deterioration in hearing (Ruckenstein and Nicolli, 2012). In Figure 8, the prostheses has a specialized connection where it applies pressure to the incus in limited locations to prevent necrosis.There are a variety of materials that the prostheses can be made of including: stainless steel, titanium, platinum, plastic, or wire (Rukenstein and Nicolli, 2012).

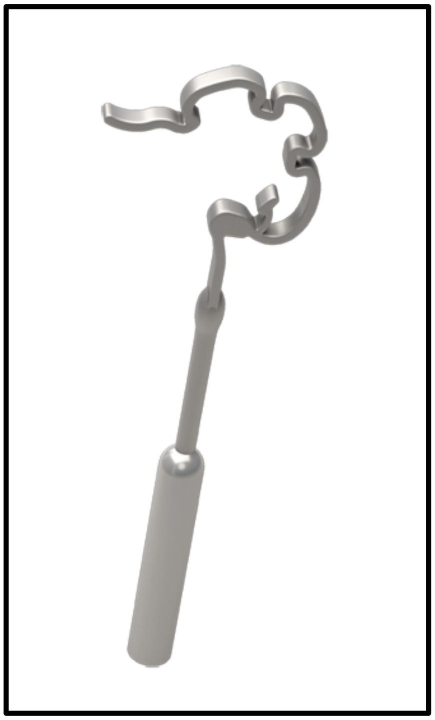


Figure 8: Stapedectomy Prostheses (Heinz Kurz GmbH Medizintechnik, n.d.)

2.6 Importance of Ear Models

Ear models serve as a way to give students or those looking to receive an education on the inner workings of the ear a way to see first hand what the different parts look like. Currently, there is "limited otolaryngology training in undergraduate and postgraduate medical education for primary care" (Hu, 2012). This is seen as a problem among the industry because as the need for medical treatment on the ear continues to rise, education in otology "may be the next opportunity to train our primary care providers" (Hu, 2012). Studies have shown that when students are exposed to something they can see first hand and interact with that they are more likely to retain and have a positive response to the information they are learning. For topics such as otology, it is critical to have accurate models because the slightest change in the middle ear can lead to damage and hearing loss. Oftentimes, these models show perfect microstructure that overlooks defects or damages that occur inside the ear. With a field as specific and detailed as otology, it is critical to have accurate depictions of the middle and inner ear, as the parts are often incredibly small and sensitive to work with so the models allow for exposure without fear of damaging a live subject. Currently, ear models are out of date in accordance with the information that is known about the ear, and do not provide enough variation to allow the students to recognize actual problems in the ear. A review of the current models available is described further in section 2.6.1. Up-to-date and interactive models are sought after in the industry as it allows for better scientific advances and proper education of students that will be working in the field in the future.

2.6.1 Current Ear Models and their Limitations

Medical practices often rely on anatomical models for education purposes in their practice. The current physical models available are a “puzzle piece” variation, which is a plastic model displaying the different parts of the ear in a larger scale for viewing purposes. This dates back to the 1950’s when plastic teaching models first came into use. It is critical to have interactive models that can show the response that the different structures of the ear have when it experiences frequencies and soundwaves. As seen in Figure 9, current otology ear models are clunky and static, which doesn’t give the educators the capability to show the numerous different functions of the ear when it is infected or damaged as well as its reactions to sound. The middle and inner ear have complex movements, such as how the ossicles move when sound enters the ear, and this plastic model does not have the capabilities to show this. It is critical to make an updated model to show these complexities and allow for better education on the subject.

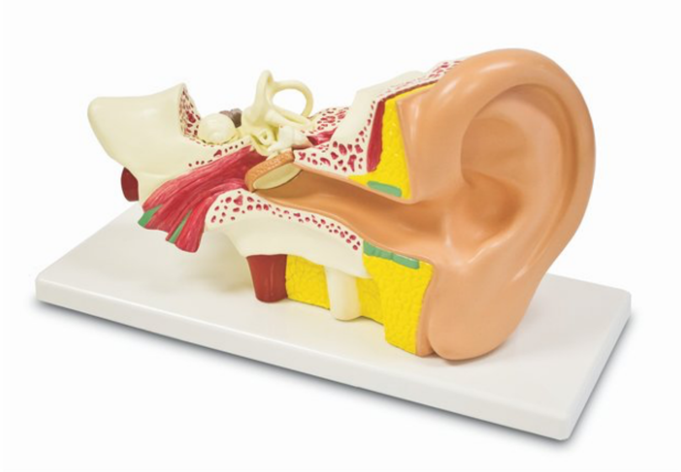


Figure 9: Current Anatomical Ear Model
(Walter Products 3-Part Ear Model, n.d.)

2.7 Universitätsspital Zürich

Universitätsspital Zürich is a research hospital with 43 departments designed diversely to be able to treat a multitude of ailments, as well as conduct cutting edge research, namely in otology. The projects they are currently working on in this field are focused on biomechanics of the middle and inner ear, as well as bone conduction as a form of hearing that sends vibrations straight to the cochlea.

2.7.1 Current Research at Universitätsspital Zürich

The first of the middle ear projects that the Universitätsspital Zürich researchers are currently working on is specifically focused on hearing ability and vibrational changes due to chronic conditions or injuries. Understanding the damage that occurs in the middle ear will improve both diagnosis and prognosis, which in turn makes possible a more direct, personalized therapy. A more accurate model of the middle ear could aid in understanding the anatomy and physiology of the middle ear. The second project in the middle ear region studies prosthetics. These studies are centered around achieving the optimal shape, weight, and coupling properties for both active and passive prostheses.

Their inner ear projects are centered around the cochlea. The first project studies the phenomena of residual hearing loss. When a patient experiences a type of hearing loss due to problems in the inner ear, on the anatomical level the cochlear hair cells are damaged and cannot respond to signals. When there are remaining functional hair cells, the patient is said to have residual hearing (Otology and Biomechanics of Hearing at UniversitätsSpital Zürich, n.d.). Residual hearing loss generally occurs before cochlear implant surgery, and although surgeons work to maintain this residual hearing during the procedure, it is sometimes lost after a delay of approximately four weeks from the time of the procedure. The reasons for this are not yet known and are sought after in this study. In the second inner ear project that the Universitätsspital Zürich researchers are working on, the aim is to better understand pressure fluctuations generated by the pressure waves in the inner ear fluid. They aim to create a pressure receiver to record these fluctuations and build it into a cochlear implant.

Lastly, the topic of bone conduction is under study. Bone conduction is a form of hearing that bypasses the eardrum and sends vibrations straight to the cochlea (Otology and Biomechanics of Hearing at UniversitätsSpital Zürich, n.d.). The bone conduction project aims to gain a better understanding of this hearing type in order to potentially build more powerful bone conduction hearing aids.

Aside from research and patient treatment, the Universitätsspital Zürich is also an instruction facility for the medical department of the University of Zurich. In the hospital they host labs and clinical trials that compliment the lectures taught at the main university.

2.7.2 The Need for a Better Model

Both students and professors of the Universitätsspital Zürich have voiced their needs for a more interactive middle ear model. Most students find that visual models improve learning and understanding. As described in section 2.6.1, current models show only ideal ear anatomy and are either in the form of a static model or a virtual simulation. Having a physical model that responds to stimuli and can be used to explain effects of pathological conditions would enhance student understanding.

Chapter 3: Objectives

3.1 Client Statement

To initiate the design process, the team gathered information from the sponsor Dr. Ivo Dobrev at Universitätsspital Zürich, regarding his desires for the functions of the model. He expressed a desire for a middle ear model that can be used as a visual aid to help students at the Universitätsspital Zürich gain a better understanding of the middle ear. He expressed his desire for an interactive model that can demonstrate the translation of vibration through the ossicular chain of the middle ear. Additionally, he stated that having a model that could represent various pathological conditions would aid in the ability to teach students. His goals for the model were used to create this project's objectives. He ranked his desired functions of the model by importance. The most desired functions ranked from most to least importance were:

1. Show motion of the model either optically or electronically
2. Have exchangeable parts to model abnormal conditions in the middle ear
3. Represent ear prostheses that corrects for abnormal conditions in the middle ear

3.2 Project Objectives

The goal of this project was to create a functional model of the middle ear that meets the desires of the project sponsor. To do this, the team created five main objectives. The team first wanted to create a model that could accurately represent the anatomy of the middle ear. The model is to be used as a visual teaching aid, so it is important that it accurately reflect middle ear anatomy and various mechanical properties of the middle ear components. This goal is reflected in objectives one and two. After an accurate visual model was created, the team wanted to have exchangeable parts so that various pathological conditions could be replicated. Being able to demonstrate various pathological conditions increases the value of the model as a teaching aid. Additionally, it allows for a comparison between the vibrational patterns of a standard, healthy ear to an ear with abnormal pathological conditions. This goal is reflected in objective three. After achieving these goals, the team then wanted to be able to stimulate the model so that the model could translate vibrations. This allows the model to not only be a visual model of the middle ear, but a dynamic model that can demonstrate the physiology of the middle ear. Then, the team wanted to find a way to quantitatively explain the vibrational patterns through the model. These objectives will be further explained in the next sections, but are listed here.

1. Replicate middle ear anatomy, tympanic membrane, and oval window at a 15:1 scale to show the anatomy of middle ear and surrounding features
2. Suspend the ossicles so that the alignment between components and location of ligament attachment to the ossicles is anatomically accurate
3. Design adjustable components to model an abnormal ear
4. Stimulate model acoustically or mechanically to demonstrate the translation of vibrations from the tympanic membrane, through the ossicular chain, and into inner ear
5. Analyze the vibrations of the model

3.2.1 Objective Descriptions

In accordance with our background research and discussions with our client, a set of objectives, as detailed above, were created. These objectives form a basis for which the design process was developed. The sub-objectives for each of these are shown in Figure 10. Further, a definition for each sub-objective in the context of this project is given in Table 1.

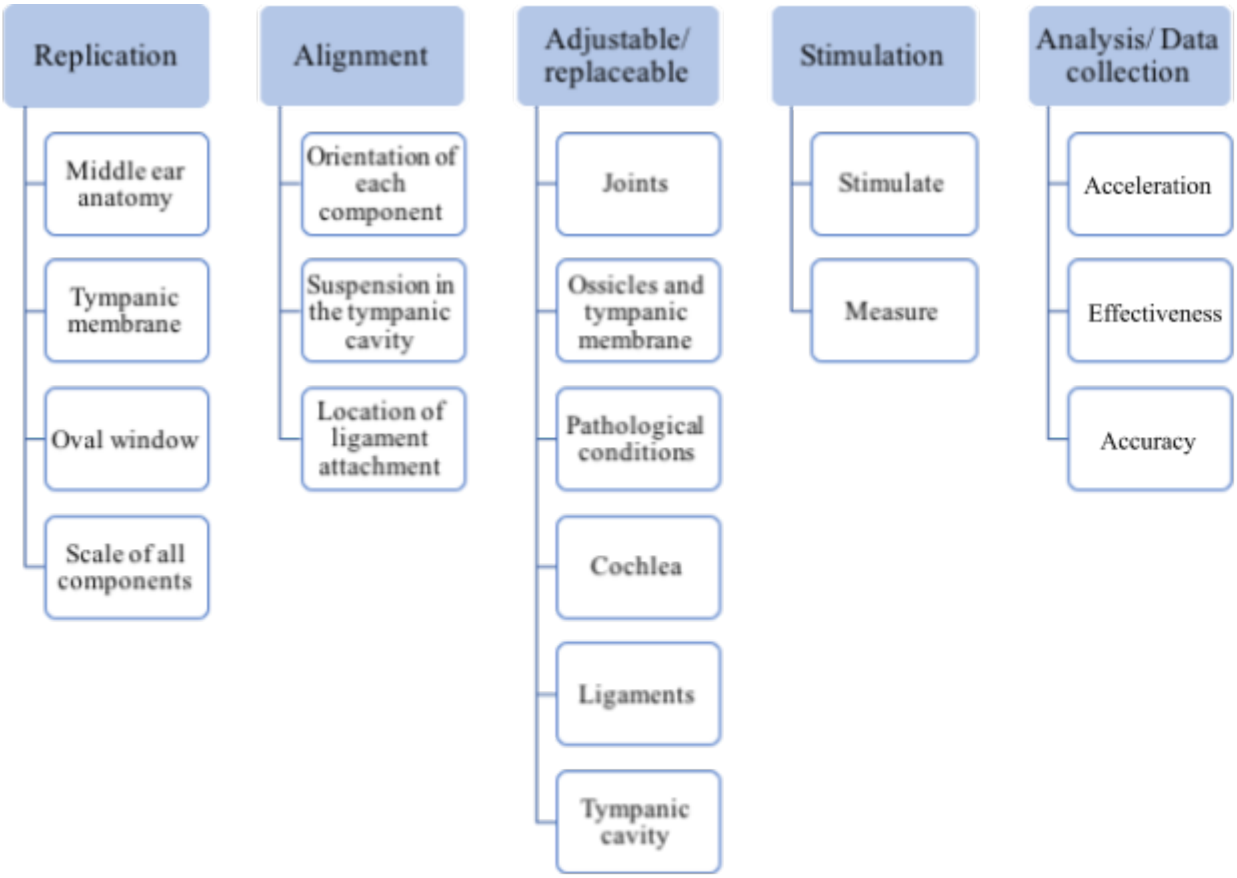


Figure 10: Objective and sub-objective overview and relationships

Table 1: Objective and Sub-objective definitions

Objective	**Sub-Objectives**	**Definition**
1. Replication: Replicate middle ear anatomy, tympanic membrane, and oval window at a 15:1 scale to show the anatomy of middle ear and surrounding features		
	Middle Ear Anatomy	The middle ear anatomy to be replicated consists of the ligaments and ossicles. The ossicles should have anatomically accurate dimensions. The ligaments must be replicated with material properties as similar as possible to those of human ligaments.
	Tympanic Membrane	The model should accurately display the shape, relative dimensions, and material properties to that of the human membrane
	Oval Window	The cochlea should be representative of the fluid filled human cochlea. It should also be able to visually show the resulting waves in the fluid when stimulated. Additionally, the cochlea needed to be attached to the stapes. It should also be large enough to accommodate full contact with the stapes footplate.
	Scale of All Components	The above components should be large enough to ensure visual observational potential by students, but small enough that stimulation and data collection is still

		possible
2. Alignment: Suspend the ossicles so that the alignment between components and location of ligament attachment to the ossicles is anatomically accurate		
	Orientation of Each Component	The three ossicles should be aligned so that the joints are an accurate representation of the joints in the middle ear. The tympanic membrane and cochlea should also be aligned at anatomically correct angles. The tympanic membrane and cochlear membrane should be parallel and in the same plane.
	Suspension in the Tympanic Cavity	The ossicles should be suspended so that the orientation of the ossicles remains anatomically accurate.
	Location of Ligament Attachment	The ligaments should attach to the ossicles in correct anatomical locations.
3. Adjustable/ Replaceable: Design adjustable components to model an abnormal ear		
	Joints	The joints need to be replaceable and removable from in between the ossicles. This serves the purpose of increasing the model's lifespan. Additionally, removability allows for different joint stiffness scenarios to be replicated by

		interchanging different joints.
	Ossicles and Tympanic Membrane	It is important that the ossicles in this model can be replaced and removed from the tympanic cavity and from each other. Further, the tympanic cavity needs to be removable from the frame and from the malleus. However, the tympanic membrane needs to be permanently adhered to the tympanic ring.
	Pathological Conditions	A prosthetic as well as an abnormal stapes need to be exchangeable with the normal ossicles mentioned above. Thus, they needed to be able to be easily removed and inserted into the model.
	Cochlea	The cochlea needs to be detachable from the stapes footplate and from the tympanic cavity. Additionally, the fluid in the cochlea needs to be easy to drain and refill.
	Ligaments	The ligaments need to be removable from the tympanic cavity. The ligaments also need to be easily replaced contingent upon wear and tear with use.
	Tympanic Cavity	The tympanic cavity needs to be easily broken down and shippable.
4. Stimulation: Stimulate model acoustically or mechanically to demonstrate the translation of vibrations from the tympanic membrane,		

through the ossicular chain, and into inner ear		
	Stimulate	The model should be stimulated where the frequency and amplitude can be modified.
	Measure	The motion of the model needs to be able to be quantified.
5. Analysis/Data Collection: Analyze the vibrations of the model		
	Acceleration	The acceleration of the membranes needs to be analyzed to determine the dynamic properties of the model.
	Effectiveness	How effectively the model can translate motion should be determined.
	Accuracy	How accurately the model can represent changes in vibrations due to anatomical changes should be analyzed. This will be determined by comparing the natural frequency of the healthy model to the model with abnormal pathological conditions.

Chapter 4: Design Process

This chapter entails the team's decisions for each component of the model. This includes the design process as well as the final decisions made. Additionally, this section further defines the objectives and sub objectives in the context of this project.

4.1 Replicate Middle Ear Anatomy, Tympanic Membrane, and Oval Window

The first objective of this project was to replicate the middle ear anatomy, tympanic membrane, and oval window at a 15:1 scale to show the anatomy of the middle ear and surrounding features. In order to create a model that could show motion optically or electronically, in accordance with the project sponsor's desires for the model, the team analyzed the material properties and anatomy of the components in the middle and surrounding ear.

Due to the observational and teaching potential of this model, all of the components needed to be large enough to be seen with the naked eye, but small enough that it was still able to respond to various stimuli. Thus, each component of the model was scaled by a factor of 15:1 to maintain visual observational potential. While this factor will most likely affect the measurable data, the goal of the project is to demonstrate similar, but not anatomically identical vibrations.

To address the second aspect of this objective, replicating the tympanic membrane, the team analyzed the anatomical ranges of various material properties of the membrane. From the team's research it was found that the known material properties of the tympanic membrane are: the Young's modulus, density, dimensions, and poisson's ratio. These values can be seen in Table 3. These properties were chosen in order to translate vibrations to the ossicles as similarly to the human ear as possible.

After comparing the material properties of the tympanic membrane to various materials, as seen in Table 2, the team subsequently determined silicone to have the most similar anatomical characteristics. As seen in Table 2, the materials were assigned a number from one to three where a one means it does not satisfy the criteria and a three means it does satisfy the criteria. A score of one in any row meant that the material had a property with a value that was far from that of the human tympanic membrane. For example, vinyl received a score of one when assessing young's modulus. This was because the young's modulus of vinyl is 3.72 GPa (MatWeb, n.d.). This value was more than 65 times that of the young's modulus of the human tympanic membrane. Thus, this material received a low score in the decision matrix.

Table 2: Decision map for tympanic membrane material
1 = does not satisfy, 2 = partially satisfies, 3 = satisfies

	Plastic wrap	Flexible plastic	Nylon	Vinyl	Silicone rubber
Young's Modulus	3	3	1	1	3
Density	2	2	2	3	3
Ability to cut into desired shape	3	3	2	2	3
Poisson's Ratio	2	2	2	2	3
Total	10	10	7	8	12

As seen in Table 2, silicone rubber had the closest material properties to the actual human tympanic membrane and therefore was chosen as the model's tympanic membrane material. To construct the model membrane, a silicone sheet was cut in an ellipse with the widest radius being 150 mm and smallest radius being 120 mm. These radii were fifteen times that of the human tympanic membrane. Comparable to the tympanic membrane, the silicone rubber had a thickness of 1 mm, which is just under fifteen times that of the human membrane. Further, the silicone also had material properties for the Young's modulus, density, compressive strength, and poisson's ratio that all fell within the range of those for a human ear. The ranges for the silicone properties compared to those of the humane tympanic membrane are cataloged below in Table 3.

In order to replicate the middle ear anatomy, it was necessary for the ossicles to be designed with appropriate dimensions that fell in a standard range of the human ear. The analyzed anatomical dimensions of the ossicles are listed in Figure 11.

Table 3: Material properties for the tympanic membrane and selected membrane material

	Human Tympanic membrane	Silicone Rubber (AZoM, 2001)
Young's Modulus	0.0341-0.0568 GPa (Luo, Dai, Gan, & Lu, 2009)	0.001-0.05 GPa
Density	1.75 Mg/mm^3(Healthline, 2018)	1.1-2.3 Mg/mm^3
Dimensions (ellipse)	Radius 1: 10 mm Radius 2: 8 mm Thickness: 0.1mm (Healthline, 2018)	Same as the human ear and scaled by a factor of 15: Radius 1: 150 mm Radius 2: 120 mm Thickness: 1 mm
Poisson's Ratio	0.5 (Aernouts, Soons, & Dirckx, 2009)	0.47-0.49

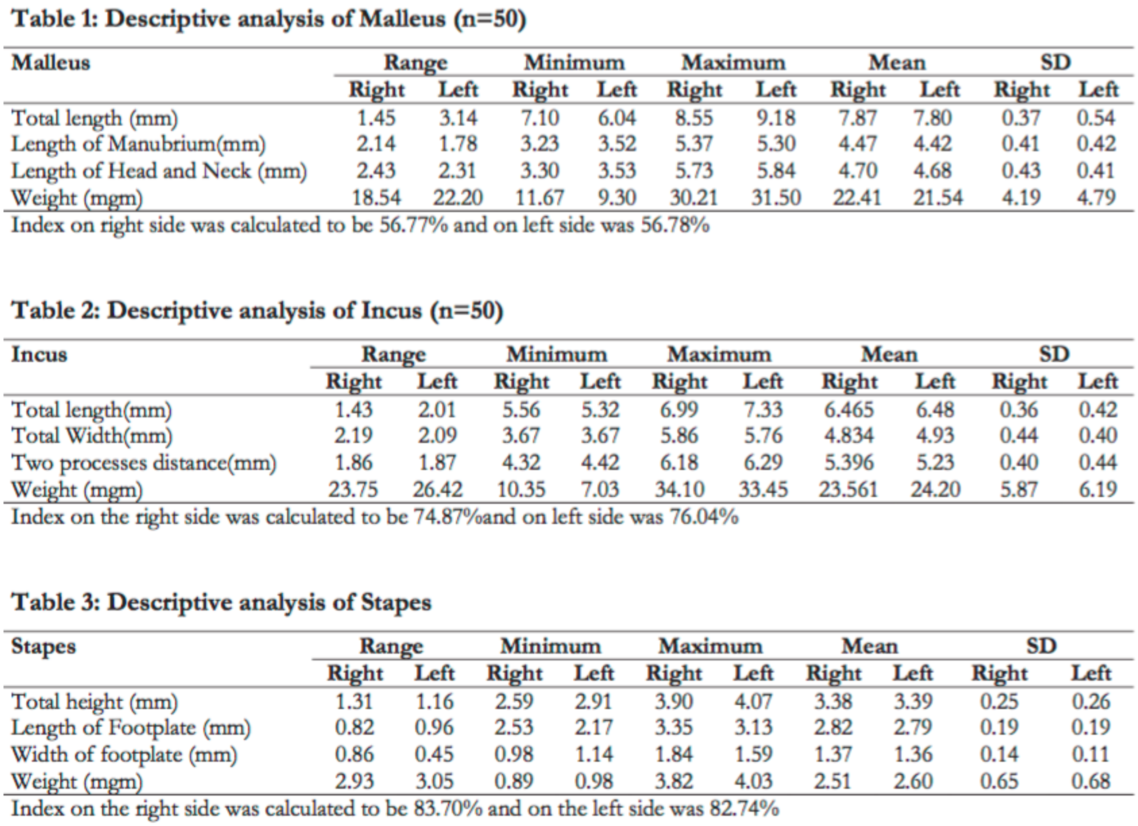


Table 1: Descriptive analysis of Malleus (n=50)

Malleus	Range		Minimum		Maximum		Mean		SD	
	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left
Total length (mm)	1.45	3.14	7.10	6.04	8.55	9.18	7.87	7.80	0.37	0.54
Length of Manubrium(mm)	2.14	1.78	3.23	3.52	5.37	5.30	4.47	4.42	0.41	0.42
Length of Head and Neck (mm)	2.43	2.31	3.30	3.53	5.73	5.84	4.70	4.68	0.43	0.41
Weight (mgm)	18.54	22.20	11.67	9.30	30.21	31.50	22.41	21.54	4.19	4.79

Index on right side was calculated to be 56.77% and on left side was 56.78%

Table 2: Descriptive analysis of Incus (n=50)

Incus	Range		Minimum		Maximum		Mean		SD	
	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left
Total length(mm)	1.43	2.01	5.56	5.32	6.99	7.33	6.465	6.48	0.36	0.42
Total Width(mm)	2.19	2.09	3.67	3.67	5.86	5.76	4.834	4.93	0.44	0.40
Two processes distance(mm)	1.86	1.87	4.32	4.42	6.18	6.29	5.396	5.23	0.40	0.44
Weight (mgm)	23.75	26.42	10.35	7.03	34.10	33.45	23.561	24.20	5.87	6.19

Index on the right side was calculated to be 74.87%and on left side was 76.04%

Table 3: Descriptive analysis of Stapes

Stapes	Range		Minimum		Maximum		Mean		SD	
	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left
Total height (mm)	1.31	1.16	2.59	2.91	3.90	4.07	3.38	3.39	0.25	0.26
Length of Footplate (mm)	0.82	0.96	2.53	2.17	3.35	3.13	2.82	2.79	0.19	0.19
Width of footplate (mm)	0.86	0.45	0.98	1.14	1.84	1.59	1.37	1.36	0.14	0.11
Weight (mgm)	2.93	3.05	0.89	0.98	3.82	4.03	2.51	2.60	0.65	0.68

Index on the right side was calculated to be 83.70% and on the left side was 82.74%

Figure 11: Ossicle Dimensions (NIH, 2016)

To ensure the anatomical accuracy of the ossicles as detailed above, the model's ossicles were printed and scaled appropriately from CT scans of a human middle ear. The ossicles were suspended within the tympanic cavity by ligaments. These ligaments are essential to the model's suspension and in holding the ossicles together, therefore contributing to the model's overall anatomical accuracy. Consequently, the team analyzed the ligaments' Young's modulus, density, poisson's ratio and shear modulus as seen in Table 4.

Upon initial evaluation of human ear ligaments, the team conducted an interview with Dr. Jae Hoon Sim. In this interview, Hoon revealed that the best material to model ligaments would be rubber. While having the capability to suspend the ossicles as well as hold the ossicles together, rubber bands had optimal material properties that were very similar to that of human ligaments. Additionally, a force test was performed to calculate the young's modulus and shear modulus of the rubber bands. The raw data for this test can be found in Appendix E. A plastic cup of known mass was suspended by a rubber band from a hook, as seen in Figure 12. Mass was added incrementally to the cup and the displacement of the rubber band was measured until the band broke. The material properties of human ligaments compared to those of the selected rubber are shown below in Table 4.

Table 4: Material properties of the human ear ligaments and of rubber

Material Properties	Human Middle Ear Ligaments	Rubber
Young's Modulus	0.10-3.2 MPa (Wang & Gan, 2016)	0.574 MPa*
Density	1 Mg/mm^3 (Wang & Gan, 2016)	1.1 Mg/mm^3 (EngineeringToolBox, 2009)
Dimensions	Width: 0.013-0.350	Width: 0.3175 mm
Poisson's Ratio	0.5 (Volandri, Di Puccio, Forte, & Carmignani, 2011)	0.47-0.49 (Koblar, Škofic, & Boltežar, 2014)
Shear Modulus	0.0333-1.231 MPa*	0.0003-0.02 MPa**

*Young's modulus was calculated from the above measured values using the equation;

$\frac{\sigma}{\epsilon} = \frac{F*L}{\Delta L*A}$ =E , where

- σ = stress
- ε = strain
- F = force
- L = length of the rubber band
- ΔL = displacement of rubber band
- A = area of the unstretched rubber band
- E = Young's modulus

**Shear modulus was calculated from the above known values using the equation;

$G = \frac{E}{[2(1+v)]}$, where

- G = shear modulus
- E = Young's modulus
- v = poisson's ratio

Figure 12: Force Test Setup

To address the sponsor’s intention of demonstrating the translation of vibrations through the ear, including a cochlear tube in the model was essential. The cochlear tube displayed the fluid motion caused by the stapes interaction with the inner ear: where the mechanical vibrations are translated into fluid motion. The properties of the cochlear tube chosen for analysis were only the dimensions dependent on the stapes. The cochlear tube was found to have a diameter of 2.82 mm, slightly larger than the footplate of the stapes. The cochlear tube was also found to be filled with endolymph (Hawkins et al., 2018), which is a liquid composed mostly of water. According to Dr. Ivo Dobrov, endolymph’s properties, such as viscosity, could be assumed to be equivalent to those of water for calculation purposes. Both fluids have a low resistance to stimulation by the stapes.

4.2 Suspend the ossicles

The second objective was to suspend the ossicles so that the alignment between components and location of ligament attachment to the ossicles was anatomically accurate. In the human ear, the tympanic membrane and cochlea are parallel and in the same plane, as seen in Figure 13.

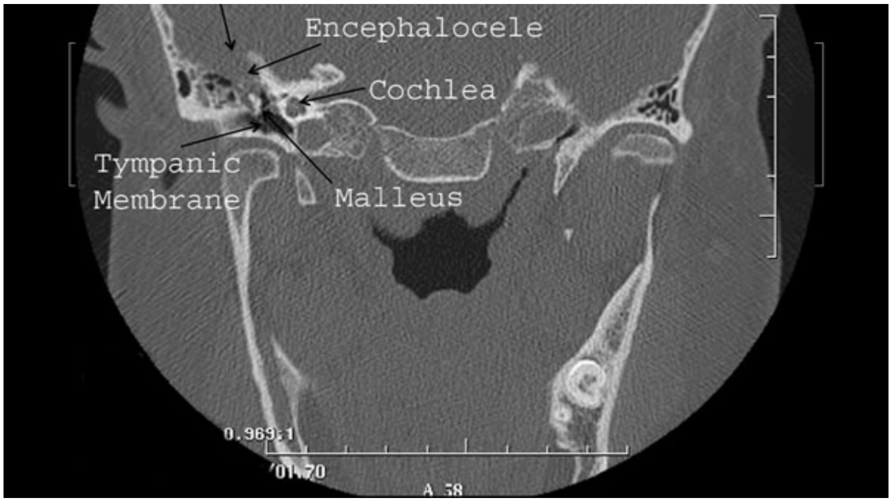


Figure 13: Tympanic membrane and cochlea orientation (Dallas Ear Institute, n.d.)

Due to the tympanic membrane's alignment in respect to the cochlea, it was initially assumed the tympanic membrane would be oriented vertically. However, it was discovered that in most individuals the tympanic membrane is oriented at an angle 55° to the horizontal (Epomedicine, 2013). As a result, the team compared an angled tympanic membrane to a vertical tympanic membrane. The angled membrane was found to aid in the accuracy of the ossicular chain orientation as well as aligning the stapes footplate with the cochlea. Thus, the angled orientation of the tympanic membrane was chosen due to its effect on the anatomically accuracy of the middle ear components.

A 3D printed ossicular chain was used to visualize the orientation of the individual ossicles from which the alignment and orientation was exactly replicated. In the human ear, the malleus is attached to the tympanic membrane along the manubrium by soft tissue. The manubrium is the part of the malleus that spans from the tip of the lateral process to the umbo. The stapes is attached to the oval window of the cochlea by the stapedial ligament. These connections were replicated in the model in order to create a visually accurate model of the middle ear.

It was discovered that the ligaments in the human ear vary greatly between individuals. The quantity, length, and orientation of ligaments is unique to each person. However, there are a few ligaments that appear frequently in individuals. Due to this discrepancy, the team interviewed Dr. Jae Hoon Sim, an expert in human ear ligaments. Dr. Jae Hoon Sim recommended that the model only represent the ligaments known to appear in at least ⅚ individuals (De Greef et al., 2015). While these common ligaments are oriented differently in individuals, they are all attached to the ossicles in a specific location. These locations can be seen in the compiled CT scan in Figure 14.

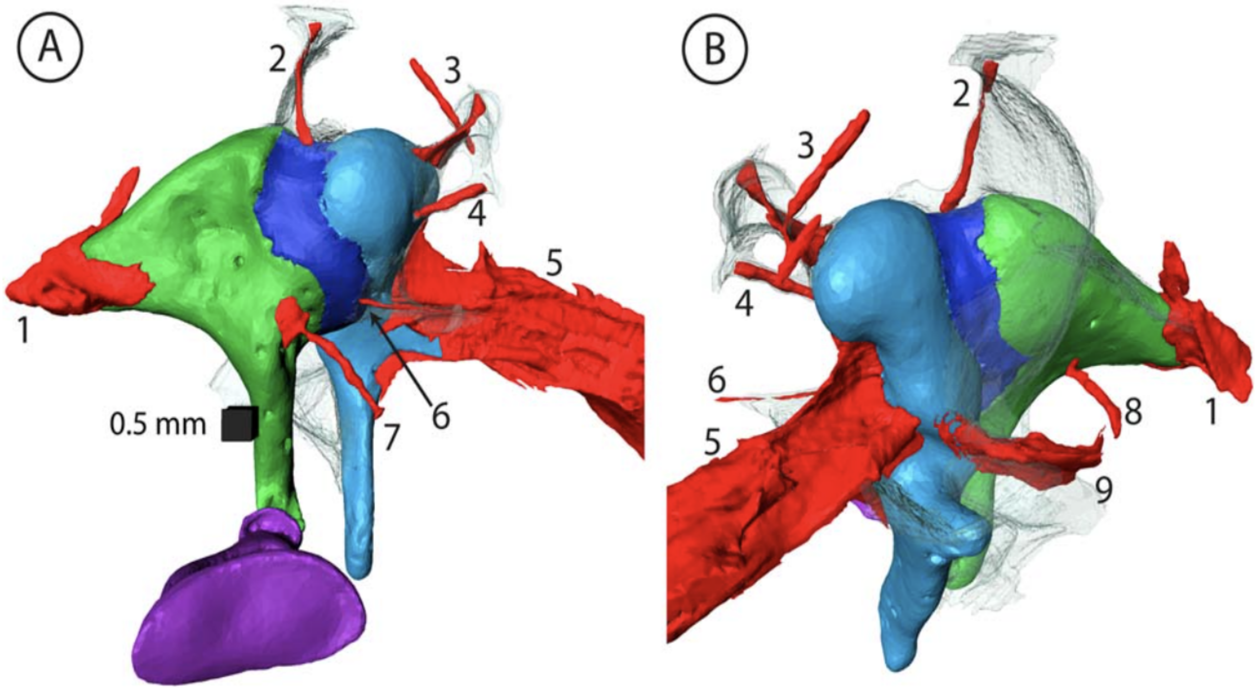


Figure 14: Compiled CT scan of the ligaments and ossicles (De Greef et al., 2015)

While attaching the chosen ligaments at the anatomically accurate points on the ossicles made the model more accurate, it increased the difficulty of suspending the ossicular chain in the tympanic cavity compared to the original design that involved no specific quantity or location of ligaments. Due to the educational purposes of this model, the anatomical accuracy of the ossicular chain, ligaments, and location of the ligament attachments to the ossicles were prioritized. In addition, the tensions and orientations of the represented ligaments were ignored due to the variance as well as the insignificance to the observational potential of the model.

4.3 Design adjustable components to model an abnormal ear

The third objective was to design adjustable components to model an abnormal ear. The primary goal of interchangeable parts was to allow abnormal pathological conditions to be replicated. However, additional advantages include the ability to replace any broken parts, and that the entire model can be disassembled for efficient and safe travel.

Removable joints allowed for the ossicles to be interchanged from the model. In addition to being removable, the joints had to maintain the particular orientation of the ossicles. Joint material was thus assessed based on their removability and ability to hold the ossicles properly. The team considered five different materials for the joint material including: snap fits, PDMS, flex paste, silicone and rubber bands, and silicone, foam and rubber bands. These materials are compared in Table 5 and are ranked on three different criteria. These criteria are: removability, ability to hold ossicles in correct orientation, and ability to account for diseased joint alteration. While differing joint materials was out of the scope of this project, the team wanted the joints to be interchangeable to allow for abnormal joints to be modeled in the future, as discussed in chapter 9.2. Each joint material was given a number between one and three based on how well it fit the criteria, three being the best.

Snap fits were discussed as a way to make the bones easily removable from each other. This design utilized a snap fastener as shown in Figure 15. Snap fits would result in easy removability and therefore were given a high value of a three for this criteria. However, snap fit joints resulted in poor anatomical accuracy. This was due to a lack of joint-like material between ossicles. The snap fits could be located very specifically to provide some anatomical accuracy, however it would have below average capabilities for what the team wants from a joint material. This reasoning is why it was given the value of two for orientation. Additionally, this option did not allow for joints with different stiffness to be interchanged. This caused snap joints to be rated a one for this criteria.

Figure 15: SolidWorks iteration of snap fastener joints

Another concept that was considered was polydimethylsiloxane (PDMS). The concept involved dipping bones in PDMS to create a joint that formed into the exact contours of the ossicles. Once dry, the PDMS would be removed from the ossicles and theoretically create a mold for the ossicles to be interchanged from. Additionally, the ratio of the two components that make up PDMS can be altered, creating different materials that could model abnormal joints. After an initial trial, the team found that PDMS was too brittle to remove from the ossicles without breaking apart. Its thin nature also prevented it from holding the ossicles in any orientation. Flex Paste, a rubber sealant, was far thicker and held the bones well. However, it was extremely thick which added weight to the bones. Additionally, the adhesiveness of the sealant made it irremovable from the part and thus was not reusable or replaceable.

In the last joint design considered, silicone was molded between the joints, and rubber bands were used to pull the bones back together. While this iteration was both removable and replaceable, the moldability of the material caused it to deform overtime therefore failing to maintain the orientation of the ossicles. Inserting foam between the silicone prevented the ossicles from reorienting themselves. The silicone on either side of this foam provided slight adhesion to sustain the ossicle’s alignment. Despite this adhesion, the silicone and foam combination, as well as the rubber bands, were easily removable from the model. Table 5 shows the different joint materials that were experimented with and are ranked on a scale from one to three where a one means it did not satisfy the criteria and a three means it did satisfy the criteria.

Table 5: Decision matrix for joint material
1 = does not satisfy, 2 = partially satisfies, 3 = satisfies

	Snap Fit	PDMS	Flex Paste	Silicone and Rubber bands	Silicone, Foam, and Rubber bands
Removability (and reusability)	3	1	1	2	3
Held ossicles in proper orientation	2	1	3	3	3
Accounts for diseased joint alteration	1	2	2	3	3
Total (out of 9)	6	4	6	8	9

In addition to joint material, ligament material was optimized to ensure the anatomical accuracy of the model. The ligaments needed to be removable, replaceable, and anatomically accurate. Thus, a decision matrix with these criteria was made to compare ligament materials: string, 12 lb fishing line and rubber bands. This decision matrix is outlined in Table 6. String and 12lb fishing line were not easily removed as they needed to be tied to the hooks on the frame. Additionally, these knots did not always hold. Due to these concerns, string and fishing line were given a ranking of two. Their inability to stretch also raised concerns for anatomical accuracy, resulting in the rank of a one. However, rubber bands are stretchable, removable, and replaceable. These interchangeable ligaments allow for abnormal pathological conditions to be demonstrated in the model. A decision matrix for ligament material in the context of the model's ability to be interchanged and removability of the components is detailed in Table 6. Rubber bands fit all the criteria described in Table 6 the best and therefore were used as the final ligament material for the model.

Table 6: Decision matrix for ligament material
1 = does not satisfy, 2 = partially satisfies, 3 = satisfies

	String	12 lb Fishing Line	Rubber Bands
Removability (and reusability)	2	2	3
Held ossicles in proper orientation	2	3	3
Anatomically Similar	1	1	3
Total (out of 9)	5	6	9

4.4 Stimulate model to demonstrate the translation of vibrations

The fourth objective of this project was to stimulate the model acoustically or mechanically to demonstrate the translation of vibrations from the tympanic membrane, through the ossicular chain, and into the inner ear. Two modes of stimulation were considered: acoustic and mechanical stimulation. In regards to mechanical stimulation, a micro midget vibration motor could be used. Figure 16 shows an example of this type of motor.

Figure 16: Micro Midget Vibration Motor (DZS Elec, 2020)

The vibration motor could be attached to the model directly to deliver the stimulus. These specific vibration motors, shown in Figure 16, have the ability to run at a maximum of 12000 rpm, which correlates to 200 Hz. This frequency is in an acceptable range for this project which is further described later in this section. Additionally, the vibration amplitude has the ability to change, with a minimum value of 0.8 Gs that can range up to 2.0 Gs. While the vibration motor has the ability to stimulate at the desired frequencies and has the ability to change amplitude, it does not provide a good visual representation of how the middle ear is stimulated in the actual human ear.

Acoustic stimulation involves stimulating the model with sound instead of mechanical stimulus. To generate a large enough amplitude to stimulate the model, a speaker could be used to control the amplitude of the sound. The frequency of the sound could also be controlled by downloading a frequency generator app. The team chose to stimulate the model acoustically instead of mechanically because while both modes of stimulation allow for variance in amplitude and frequency, acoustic stimulation is a more accurate representation of ear physiology. The model is being constructed as a teaching model, so having a more accurate representation of the stimulation was important.

The team decided to use a speaker to acoustically stimulate the model to create a large enough amplitude to move the model. To further increase the amplitude of the sound, the team decided to create a connection between the speaker and the tympanic membrane that would funnel the sound, thus acting as the ear canal. The increase in amplitude would result in a larger movement of the tympanic membrane and allow for easier measuring and a better demonstration of the translation of vibrations through the model. The team used an app called Sonic to stimulate the model at specific frequencies. These frequencies were checked by comparing them to another device playing the same frequency. The team decided that all frequencies would be played at the same speaker volume to maintain consistency in the data. However, even though a constant amplitude would be used, the team wanted the ability to change the amplitude of the stimulation to ensure that the method of stimulation would create motion in the model.

To measure the vibrations in the model, the team decided to use accelerometers to measure the acceleration of components in the model. Other methods of measuring the vibrations were looked into, including lasers, motion capture equipment, ultrasonic sensors, and pressure sensors as seen in the decision matrix in Table 7 (ranked on a scale 1-3 where a one means it does not satisfy the criteria and a three means it satisfies the criteria). These methods of measuring were given a value from one to three based on their ability to measure vibration and how accessible the item was to the team. For example, laser vibrometers are extremely accurate at measuring vibrations on a small scale. Therefore laser vibrometers were given the rating of a three for their ability to measure vibrations. While the laser vibrometers may have been the best of the team’s options for the ability to measure, the team had no way of accessing this technology. Thus, the laser vibrometers got a one for the accessibility of the item. The other options considered to analyze vibrations in the model were ultrasonic sensors, and motion capture systems. However, these technologies were not sensitive enough to measure the slight vibrations of the model.

Pressure sensors could have been placed inside the model’s cochlear tube to detect the changes in water pressure caused by the force the stapes exerted on the oval window. While pressure sensors are easily accessible, for this sensor to be effective, the cochlear tube would need to be filled completely with water. This would not allow for any visual representation of the vibrations as waves in the cochlear tube. Additionally, the pressure sensor still might not have been sensitive enough to measure the slight changes in water pressure.

Accelerometers are sensitive enough to detect very slight vibrations that would occur in the model. Additionally they are extremely easy to access. Due to this, the team decided to use accelerometers to measure the vibrations of the model.

Table 7: Decision matrix for measuring methods
1 = does not satisfy, 2 = partially satisfies, 3 = satisfies

	Lasers vibrometer	Ultrasonic sensors	Pressure sensors	Motion capture	Accelerometers
Ability to measure	3	1	3	2	3
Accessibility of the item	1	3	2	2	3
Total	4	4	5	4	6

The team decided to use specifically ADXL 335 three axis accelerometers. They were chosen because of their ability to measure motion in three directions. They also can be easily attached to various components in the model. The following section describes the specific calculations that were done with the accelerometers. The team came to the conclusion to measure the vibrations of the membranes in the model. A three axis accelerometer was needed to do this because the motion of the membrane is out of the plane of the surface of the accelerometer. Due to this, the acceleration needed to be measured in the Z direction, which required a 3-axis accelerometer. The ADXL 335 accelerometer can measure frequencies between 0-550 Hz in the Z direction. This range is acceptable because frequencies above 100 Hz were not tested on this model. The human ear can hear sounds from 20-20,000 Hz, however due to the larger size of the model compared to an actual middle ear, the model will have a lower resonance frequency than the human ear. This means that the model will more effectively vibrate at lower frequencies.

The team decided to use an Arduino to convert the data from the accelerometer. Another option considered was to use an oscilloscope to read the accelerometer data. However, the team had less experience working with oscilloscopes. Additionally, oscilloscopes have the ability to display data, but do not save the data externally. Arduinos have a high enough sampling rate to collect accurate data and they can export their data into various file types to be analyzed externally. Therefore, it was decided to use an Arduino to convert the data from an accelerometer.

The sampling rate of the Arduino was crucial for data collection on the model. The sponsor, Dr. Ivo Dobrev, recommended that the sampling rate for the data be between 2-5 times faster than the frequency being measured. The maximum frequency used to stimulate the model was 100 Hz due to the low resonance frequency of the larger scaled model. As a result, the sampling rate of the Arduino needed to be between 200-500 Hz. When creating the Arduino code, which can be found in Appendix A, the sampling frequency was 448 Hz, which was within the range for accurate frequency data.

4.5 Analyze the Vibrations of the Model

The fifth objective of this project was to analyze the vibrations transmitted through the model. The team initially decided to calculate the forces that the ossicles applied at the joints. This would be done by attaching accelerometers to each ossicle to measure their acceleration three dimensionally. Then, free body diagrams would be created to model the forces on each ossicle. The forces from the malleus could be compared to the forces of the stapes to analyze how the vibrations are translated through the model. However, due to the size of the accelerometers, they were not able to be aligned in the same way on each individual ossicle. This would create a need for a universal coordinate system. While this is possible, it requires a lot of intense and time consuming calculations.

The natural frequency of the middle ear is important to measure as natural frequency determines what frequencies can be heard. As the natural frequency changes, the frequencies at which a person can hear change as well. For example, consider that under standard conditions the first natural frequency occurs at 50 Hz, but then with a prosthetic, the first natural frequency occurs at 60 Hz. As a result, the person with the prosthetic will be unable to hear frequencies lower than 60 Hz. Understanding how the natural frequency changes when the components of the middle ear change allow the model to be a more effective teaching model, as it can demonstrate changes that can occur in hearing in the actual human ear.

The natural frequency of the model was also determined under standard conditions and with a prosthetic. Natural frequency is the frequency at which a system tends to oscillate without a driving force. To calculate the natural frequency of the model, plots of the average peak acceleration over frequency were generated. The average of all the positive peaks was calculated in excel for each individual frequency for the tympanic membrane under standard conditions, the cochlear membrane under standard conditions, and the cochlear membrane with the prosthetic. The natural frequency was identified as the maximum acceleration of the membrane at that frequency, which can be seen as a peak in the graph.

The team also considered analyzing the translation of vibrations through the model by analyzing the waves displayed in the clear cochlear tube. The amplitude of the waves and the frequency of the waves could be determined under standard conditions and then compared to the data with the prosthetic. However, this method does not allow for analysis of input vs output data in the model. Additionally, the waves were so fast and small to capture without proper equipment.

The team decided that the best way to collect and analyze data for the model was to attach the accelerometers to the membranes on each side of the model. Due to the fact that the membranes are aligned and parallel to each other, the accelerometers were aligned so that the axis on both accelerometers were in the same direction. The team taped the ADXL 335 accelerometers onto the membrane so that they could be easily removable. The acceleration in the z direction of each membrane was analyzed. A speaker played frequencies ranging from 30-100 Hz to stimulate the model. This range was determined by the speed of both the accelerometer and the Arduino, as discussed above in objective four. The team conducted initial tests by stimulating the model at the frequencies 30, 40, 50, 60, 70, 80, 90, and 100 Hz. Frequency was controlled by an app called “Sonic” on an iPhone which was connected by bluetooth to a speaker. The speaker played the frequency at a constant volume for all the tests.

Data was collected for three separate conditions: tympanic membrane under standard conditions, cochlear membrane under standard conditions, and cochlear membrane with a prosthetic. Standard conditions for this model are defined as the model with all healthy ear components. No abnormal pathological conditions are being modeled. These three sets of acceleration data were used to determine the translation of vibration through the model, and to compare natural frequencies of the model under healthy ear conditions to the natural frequency with a prosthetic. The tympanic membrane under healthy ear conditions was not compared to the tympanic membrane with the prosthetic because the prosthetic is located after the tympanic membrane in the model. Therefore, the vibration pattern of the tympanic membrane would not be affected by the prosthetic.

To collect data, the model was stimulated at the desired frequency and at a constant volume. The Arduino code collects data at a frequency around 448 Hz until it's memory fills with data, which takes a little over 0.5 seconds. To increase the sampling speed to 448 Hz, the final code only read and displayed the acceleration values in the z-direction. This was acceptable for the data collection because the membranes only moved in the z direction. This data is then exported into the serial monitor of the Arduino in four columns: data point number, time, raw acceleration value, acceleration value in milli-g's. The full Arduino code used can be found in Appendix A. This data was then converted into a .txt file and imported into excel. Once in excel, the data could be graphed and analyzed.

The tympanic membrane and cochlear membrane under healthy ear conditions were analyzed to determine the translation of vibrations through the model. The acceleration of the tympanic membrane was compared to the acceleration of the cochlear membrane. The average peak acceleration was calculated by averaging maximums in acceleration graphs versus time in excel. The average of the average peak acceleration over all the frequencies was taken. A ratio of the average peak acceleration over all frequencies for the tympanic membrane and cochlear membrane was taken. This gives a value that shows what percent of the acceleration from the tympanic membrane was transferred to the cochlear membrane. This is an important value to measure in the model because the purpose of the middle ear in the human body is to transmit and amplify vibrations from the outer ear to the inner ear. Understanding how much the model transmits vibrations allows for the model efficiency to be analyzed. Efficiency of the model would increase as the ratio of tympanic membrane acceleration to cochlear membrane increases.

Chapter 5: Prototypes

This chapter describes the two prototypes that preceded the final model. The prototypes were fabricated to achieve the design requirements that would allow for each of the five objectives to be considered successfully completed. These prototypes were then modified based on observed areas of needed improvement, including materials, anatomical accuracy, functionality, and visibility.

5.1 First Prototype

In the first prototype, the ossicles were 3D printed in standard polylactic acid (PLA), and scaled up to be 15 times larger than those in real human anatomy, as described in the first objective. The bone assembly was suspended using fishing wire to attach it to a wooden frame with dimensions 15 cm x 15 cm x 15 cm. The fishing wire was threaded through the holes that were drilled into the ossicles, and the fishing line tied around the frame. The attachments between bones were made of moldable silicone and rubber bands, as depicted in Figure 17. The intention of this first prototype was to provide a good visual of the middle ear. It allowed the group to have a better understanding of how the bones should be aligned and oriented when suspended as a complete set.

Figure 17: First rapid prototype involving 3D printed ossicles, moldable silicone joints, and rubber bands. The ossicles are as follows: grey = malleus; black = incus; red = stapes

5.1.1 First Iteration Tympanic Membrane

The first iteration of the tympanic membrane was composed of cling wrap and rubber bands, which were radially wrapped around the entire circumference of the mason jar lid. On top of the rubber bands, plastic wrap enclosed the entire structure so that mechanical and sound vibrations could be applied to it. As a first iteration tympanic membrane (seen in Figure 18) its purpose was to visualize how the membrane would interact with and alter the alignment of the ossicular chain.

Figure 18: First model iteration with the initial tympanic membrane addition

5.1.2 First Iteration Cochlea

The first creation of the cochlear tube was 3D printed in standard PLA with a diameter of 40 mm. This diameter was chosen based off of the length of the stapes footplate. This size was just large enough so that the full footplate contacted the oval window, as seen in real human anatomy. The ends of the cochlear tube were sealed with cling wrap and secured with rubber bands to hold water inside (Figure 19). This cochlear tube stood on its own as it was printed on a stand to hold it to the height of the stapes footplate as seen in Figure 20.

Figure 19: First 3D printed cochlea with transparent cling wrap ends

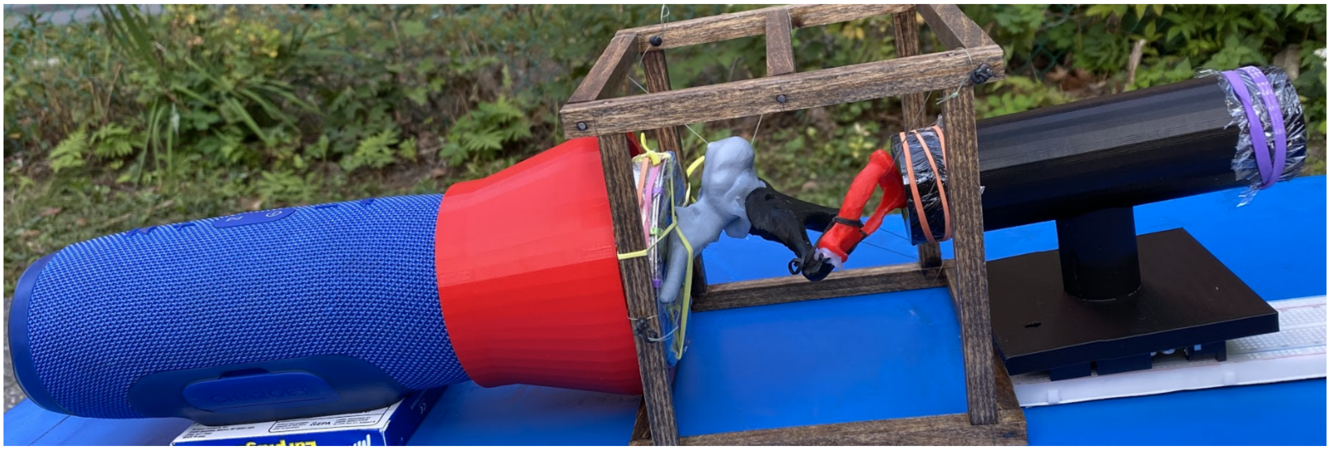


Figure 20: Initial cochlea print aligned with the first iteration prototype. The speaker, which is the blue, left most structure, was set up for acoustic stimulation.

5.1.3 First Iteration Ligaments

In the first iteration of the model, the ossicles were suspended using a 12 lb test fishing line. Fishing line held the ossicles in place by threading them through drilled holes in bones. This provided structural support in allowing them to suspend in the proper orientation and alignment, in accordance with objective two. Although it suspended the ossicles well for the purpose of viewing, the fishing line did not have other properties necessary for accurately replicating the ligaments, such as elasticity. Therefore, there was no intention to use the fishing line for purposes beyond the initial suspension of the first prototype.

5.1.4 First Iteration Joints

In the initial prototype, a moldable silicone was used to represent the joints between the ossicles. The silicone was pressed in between the ossicles and provided enough adhesion to keep the bones stable and in place .Rubber bands were also used to help stabilize the joint between the incus and the stapes. The first iteration joint material can be seen in Figure 21.

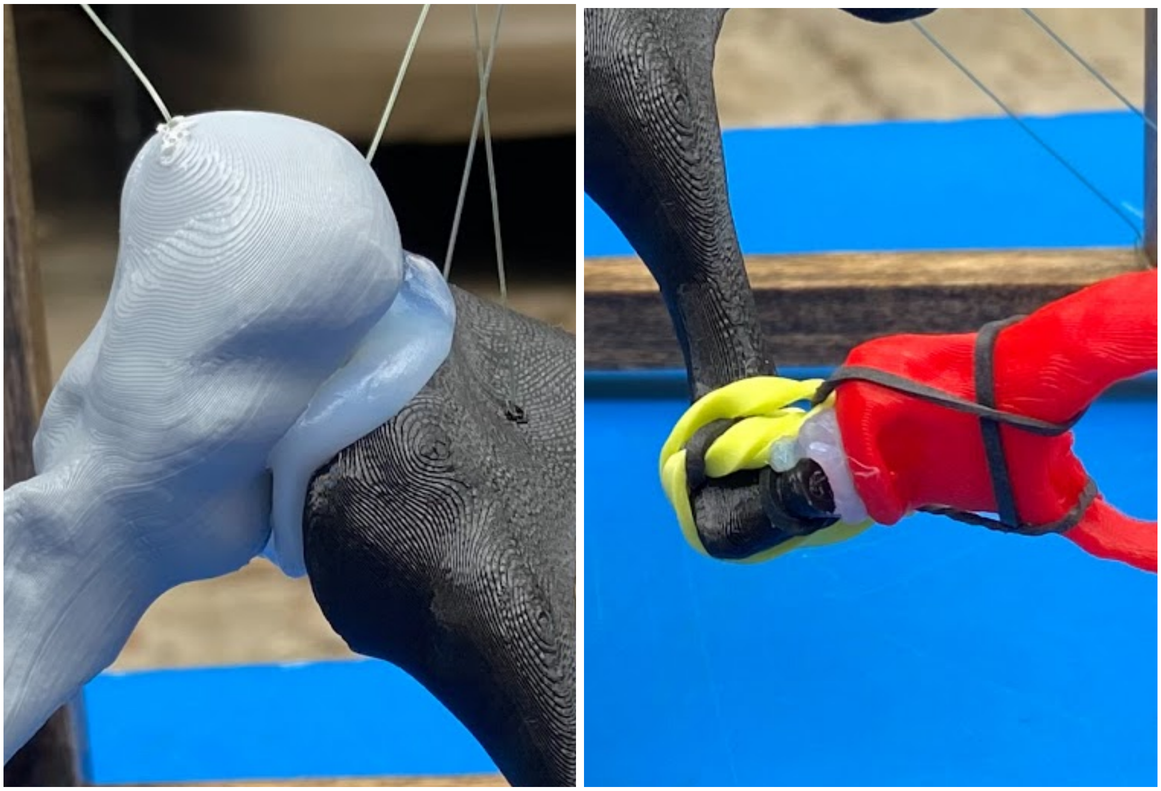


Figure 21: First Iteration Joints

5.1.5 First Iteration Strengths and Weaknesses

The first iteration served as a satisfactory visual for the middle ear. In this model, the proper scaling of the ossicles was determined so that it was large enough for visualization without making the ossicles too large, based on the recommendations of Dr. Ivo Dobrev. Additionally, the first design of the cochlear tube was able to stand without support from the frame. This made the addition or subtraction of the cochlea from the model very simple, adhering to objective three. The first model also contained a stable incudomalleolar joint attachment that did not deform over time. The joint material between the bones was also visually representative of human ear joints.

However, this model was unable to accurately represent the anatomical alignment of the ossicles and lacked the required support to suspend the stapes. In future models, the alignment and suspension system would need to be improved to satisfy the second objective. The first iteration of the cochlear tube was not clear or watertight. Thus, any stimulation that resulted in internal fluid movement would not be visible, and consequently immeasurable. Creating measurable vibrations is fundamental to completing objective five, and thus the cochlear tube needed to be made water tight and transparent. The tympanic membrane was not anatomically to scale, lacked similar material properties, and was not designed based on the actual human membrane's ellipse shape. Appropriate alterations to the membrane would need to be performed in the second prototype to satisfy objective one. The wooden frame was too small to fit the ear canal and would not fit a properly scaled up elliptical tympanic membrane. Therefore, to abide by the first objective and make the model more anatomically accurate, a second prototype would need to be fabricated.

This first model sped up the progression of the team's knowledge and understanding of the workings of the middle ear, but did not meet the design requirements necessary to make the model stimulatable, measurable, or anatomically accurate. Weaknesses addressed above were improved upon in the second prototype.

5.2 Second Prototype

In the second prototype, the alignment of the ossicles was improved to be more anatomically accurate to satisfy the second project objective. The tympanic membrane was also updated: its size and dimensioning was altered and 3D printed, and a silicone covering replaced the cling wrap and rubber band assembly from the first iteration. Additionally, the frame was enlarged to better fit all the components of the middle ear, and was created in a way such that it could be disassembled, satisfying objective three. The cochlear tube was replaced to be composed of transparent material to provide visuals of the waves propagating through the inner ear fluid, allowing objective five to be fulfilled.

5.2.1 Second Iteration frame

To finalize the model's suspension system, PVC pipes were chosen as an alternative to the initial wooden frame. The PVC pipes were attached by corner brackets to create the rectangular prism. A ten foot portion of ½ inch diameter PVC was purchased and cut down to the selected sizes. The size of the frame was increased to 10 x 10 x 12 inches (Figure 22) to allow for the updated model to easily fit within the frame. The PVC was spray painted black for aesthetic purposes. Holes were drilled into the frame at the points of desired ligament attachment. Hooks were screwed into these holes for the rubber bands hook on to. These modifications allowed for more efficient functionality for the final model in that the larger size allowed for the ear anatomy to be better fit and displayed, as well as stay in the correct orientation and alignment.

Figure 22: Final frame

5.2.1 Second Iteration Tympanic Membrane

The tympanic membrane (Figure 23) was modified from the initial prototype to be more functional and anatomically accurate. As seen in Table 3 in Chapter 4, the dimensions of the tympanic membrane were scaled up 15 times for the model and thus, the ellipse minimum radius was 120 mm and the maximum radius was 150 mm. It was 1.5 mm thick, and 3 mm in width. A thin silicone rubber sheet was fastened to the 3D printed tympanic ring using gorilla glue.

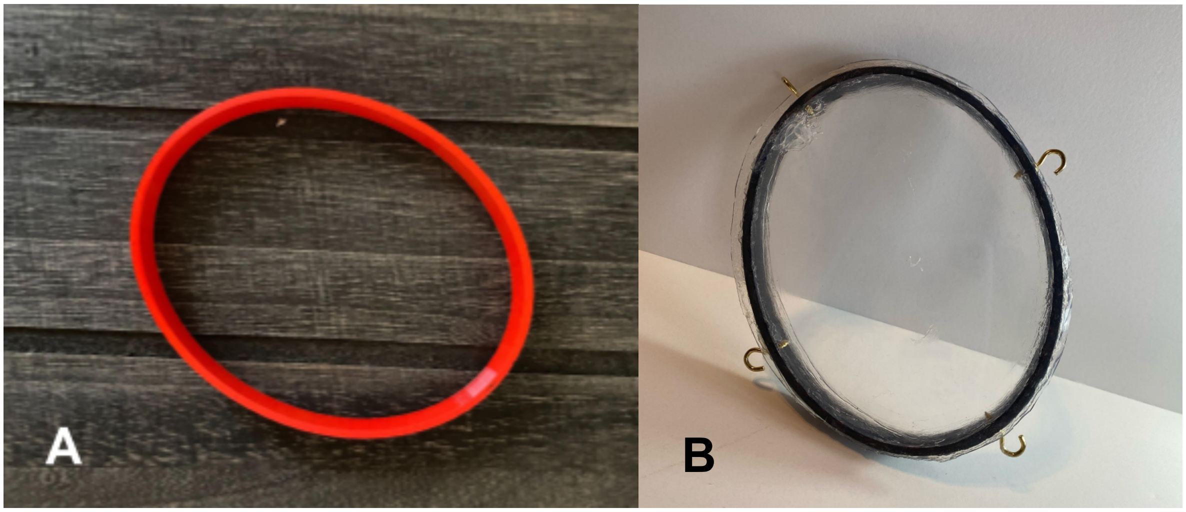


Figure 23: Tympanic membrane - A: 3D Printed Ring; B: painted ring with silicone membrane and hooks

5.2.2 Second Iteration Cochlea

The initial cochlea prototype, fabricated with an opaque material, was replaced in the second iteration with a clear plastic tube to facilitate visualization of the inner ear fluid. The cochlear tube was filled with blue stained water to further increase visibility. The tube was sealed on one end by a qwik cap and hose clamp as seen in Figure 24, and the other end was sealed with a removable silicone sheet and a hose clamp. The silicone end was aligned with the stapes footplate. The cochlear tube was placed on a stand to hold it at a height such that the geometric center of the stapes footplate interacted with the center of the oval window. It was inserted at a depth into the frame so that the two faces were coincident, as this would allow for optimal translation of the vibrations from the ossicular chain to the fluid of the inner ear.

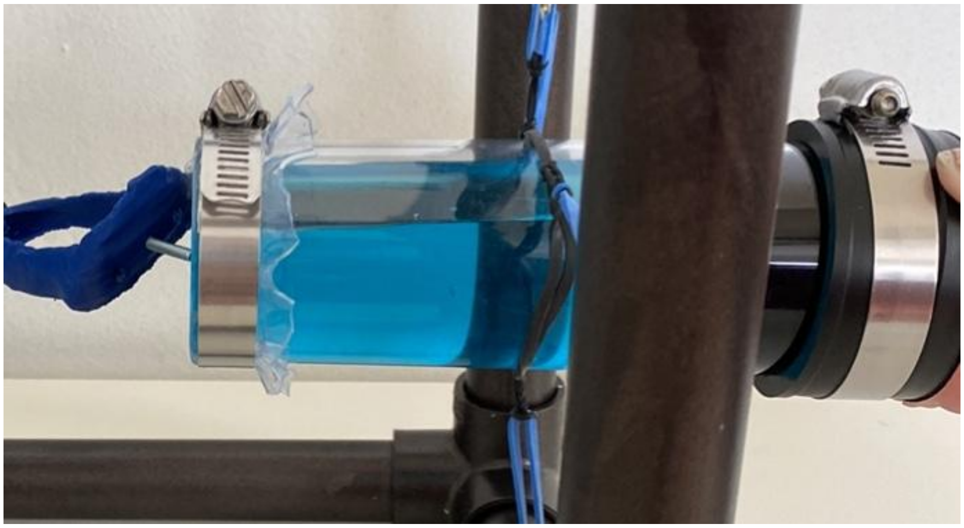


Figure 24: Second iteration of cochlea and internal fluid

5.2.3 Second Iteration Ligaments

To make the model's ligaments more realistic to those of the human ear, rubber bands were selected in the second version of the model. The rubber bands were either stabbed through the tack and into the ossicle, or hooked around the tack, depending on the angle of attachment to the ossicle. Ligaments were attached to the components in the frame with as much anatomical accuracy as possible. However, since the frame does not have the same spherical shape as the tympanic cavity, attachment angles and locations were not anatomically accurate. An example of these ligaments attachments are pictured in Figure 25.

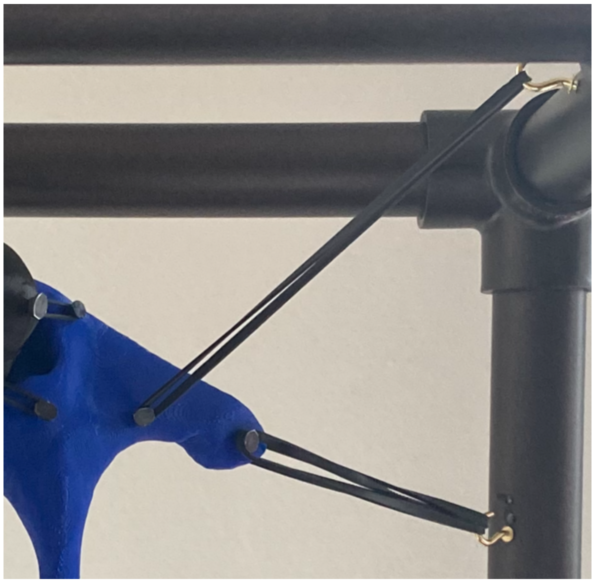


Figure 25: Second iteration ligament attachment

5.3.4 Second Iteration Joints

Joints in this iteration consisted of foam, silicon, and rubber bands. A layer of foam was cut to fit the joint, and two thin layers of silicon rubber were adhered to either side of the foam. This joint was inserted between the bones. Tacks paired with small black rubber bands worked in conjunction with the silicone to hold the joints together. The full joint assembly can be viewed in Figure 26.


Figure 26: Second iteration of joints

5.3.5 Second Iteration Strengths and Weaknesses

The second iteration improved the anatomical accuracy, functionality, and interchangeability of the model. The frame was made large enough to fit the scaled middle ear as well as its surrounding features inside. Further, the accuracy of the tympanic membrane was significantly improved by utilizing materials with similar properties to the middle ear, as well as creating it in the proper geometry of the real human ear. This helped to fulfill objective one.

The ossicles were properly oriented and the ligaments were attached and angled in accordance with CT scan data the team interpreted. The suspension orientation satisfied objective two. The accuracy of these ligaments was improved by using rubber bands, which had similar material properties to human ear ligaments. Rubber bands also allowed for all the ligaments and ossicles to be replaceable, in accordance with objective three.

The improved cochlea was made of a clear watertight polycarbonate tube filled with stained water. The transparency of the tube allowed for the translation of vibrations to the cochlea to be observed as fluid motion, assisting in the calculation portion of this project, listed in objective five. The cochlear tube's anatomical alignment in this iteration was also improved by positioning it in the same plane and parallel to the tympanic membrane.

However, in this iteration the tympanic membrane was not properly adhered to the tympanic ring, as gorilla glue is not compatible with silicone rubber, as seen in Figure 27. Additionally, the membrane did not mimic the conical aspect of the human membrane.

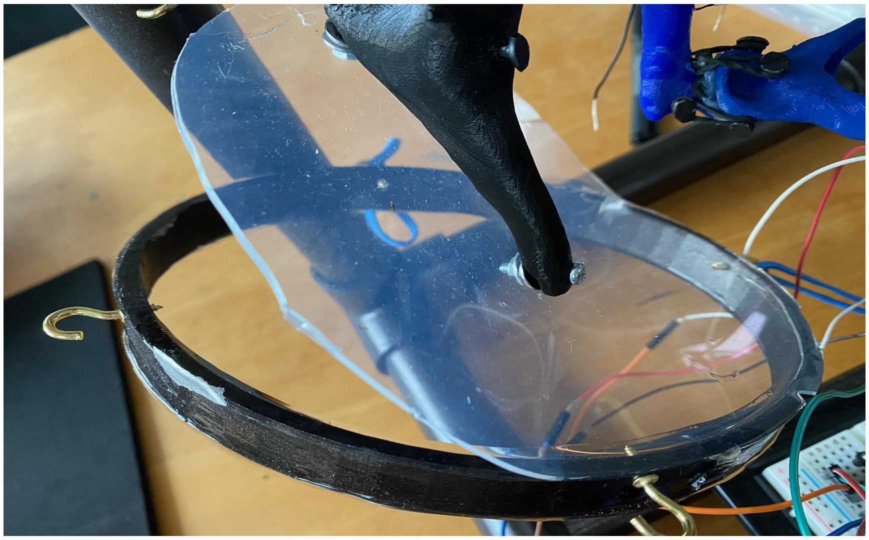


Figure 27: Peeling tympanic membrane

Another weakness of this iteration was that the ear canal was not at the proper height to be in contact with the tympanic membrane. The connection to the membrane was not airtight, and vibrations would not be transmitted well through it. The fluid in the cochlear tube was not able to be drained or replaced, as both end caps proved to be very difficult to remove and replace. Some of the rubber bands that had been impaled by the tacks ripped and fell off of their tacks.

This model also lacked the ability to analyze the vibrations through the model, a feature described in objective five. Accelerometers were not attached to the ossicles or the membrane to monitor the acceleration of these components. These shortcomings were addressed and alleviated in the final model.

Chapter 6: Final Model

The final model retained the joints, ligaments, and frame from the second prototype. However, the second iteration's weaknesses were addressed by evaluating the pre-existing cochlear tube, tympanic membrane, and ear canal. Changes were made to each of these components in order to make the parts more easily interchangeable, or anatomically accurate. Additionally, accelerometers were added to the model to monitor the acceleration of various components. These changes allowed for the model to satisfy project objectives one through five. The final model can be seen in Figure 28.

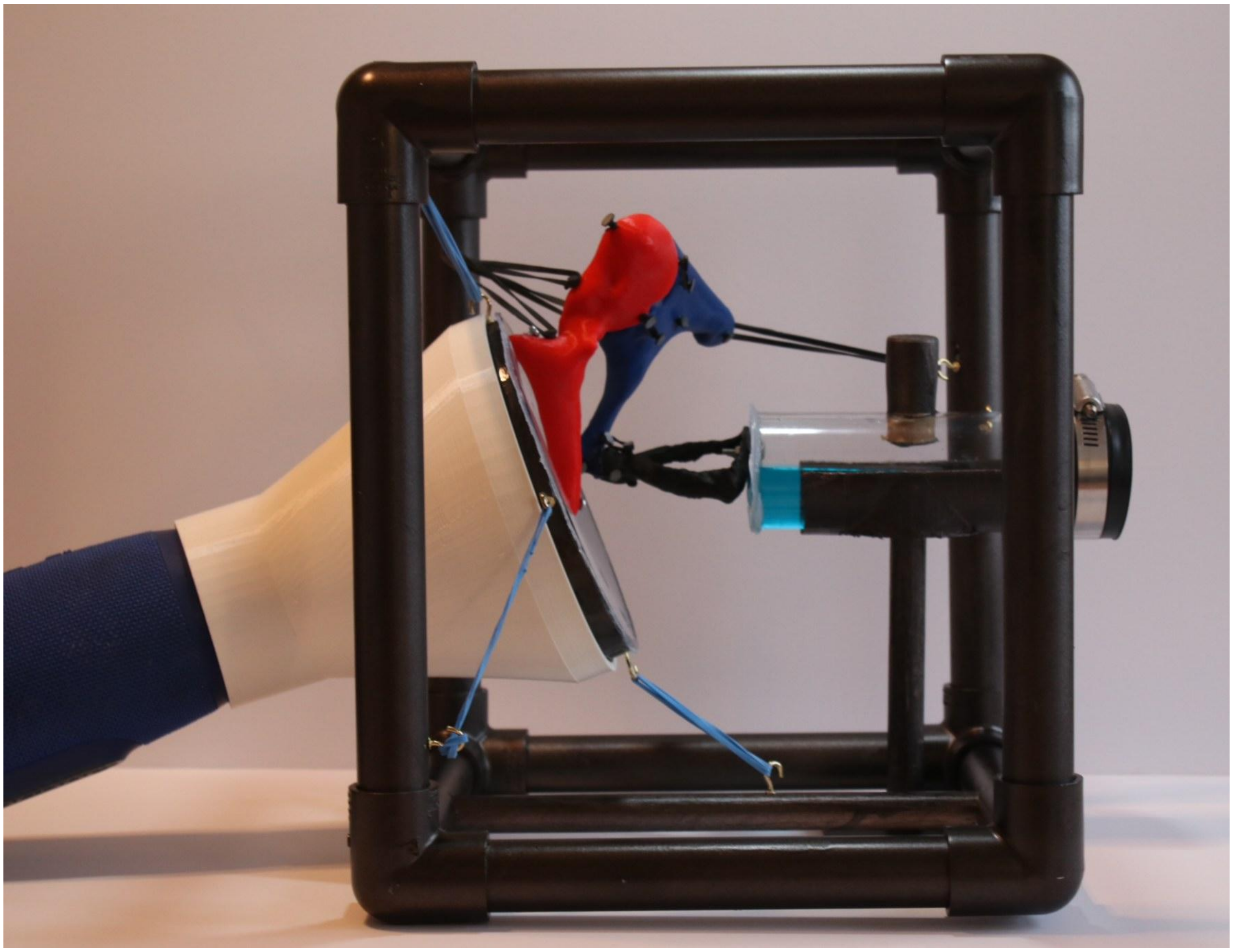


Figure 28: Final model

6.1 Final Cochlear Tube

In the final iteration of the cochlear tube, the team addressed the difficulty of unsealing the end of the tube to replace the fluid inside. The hose clamp took a sufficient amount of time and two people to reattach. Therefore, a hole was drilled into the top of the tube for easy drainage. When in use, a removable plug, following objective three: adjustable components, was used to keep the tube watertight. For the final model, a glue called Sil-poxy was used to adhere the cochlear membrane to the tube. Sil-poxy is a glue intended for bonding silicone to other substrates and is more permanent than the previously used gorilla glue. An accelerometer was also taped to the cochlear membrane so that the vibrations transmitted through the ossicles could be analyzed. The accelerometer wiring and Arduino code will be further explained in section 6.5.

The final cochlear tube satisfies project objective five, to analyze the vibrations of the model, and objective three, to have adjustable components. It satisfies objective five in two ways. First, by adhering an accelerometer to the membrane, it allows for the vibrations transmitted through the model to be measured and analyzed. Second, by being a clear tube, the waves in the water can be seen, and therefore potentially analyzed in future work. Additionally, the cochlear tube itself is removable from the model satisfying objective three on adjustable components. It is held up by a stand that is separate and removable from the frame. Additionally, the water in the cochlear tube is removable due to the addition of a plug on the top of the tube. The final iteration of the cochlear tube can be seen in Figure 29.

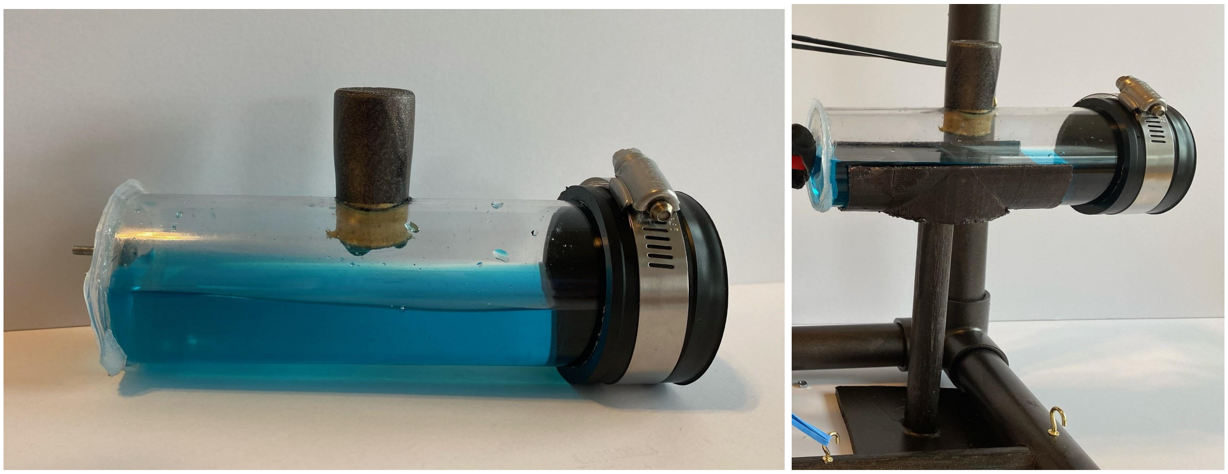


Figure 29: Final cochlear tube and cochlear stand

6.2 Final Tympanic Membrane

In the final model, the tympanic membrane was permanently adhered to the tympanic ring, unlike previous iterations. This new attachment allowed for vibrations caused by acoustic stimulation to be transmitted efficiently, satisfying objective four: to stimulate the model. This was done using the 3D printed ring from the second prototype, coupled with a layer of Sil-poxy, to attach the membrane to the ring. Sil-poxy is an adhesive designed to work on materials that have high elongation, specifically silicone. The durability of this adhesive allowed for the malleus to stretch the tympanic membrane to which it was bolted. Stretching made the membrane more taut and bolting it to the manubrium pulled it into a conical shape. This improved the anatomical accuracy of the model as the membrane in the human ear is a conical ellipse. Further, the membrane was made more anatomically accurate by angling it 55° to the horizontal, as seen in Figure 30. The tympanic membrane is oriented at this same angle in the human ear in order to correctly orient the stapes with the cochlea. This alignment is shown in Figure 32. An accelerometer was also added to the tympanic membrane so that the force applied to it could be analyzed, fulfilling objective five.

To address objective 2, the anatomical alignment of the model, the anatomical accuracy of the tympanic membrane was improved by connecting one point of the manubrium to the rim of the tympanic membrane and the other point to the center. This design choice was made based exactly on the human ear connection between the manubrium and the membrane. In the ear, soft tissue connects the entire length of the manubrium. However, the most critical contact points are those on either end of the manubrium (Dr. Ivo Dobrev, personal communication, 2020). Similarly to the connection between the tympanic membrane and the malleus, there is a stapedial ligament connection between the stapes and oval window (Dr. Ivo Dobrev, personal communication, 2020). Therefore, the cochlear tube was positioned so that it was in contact with the stapes as seen in Figure 31. Further, a screw was threaded through and permanently glued with Silpoxy to the cochlear membrane to secure the stapes in a removable way. The tube was oriented in the same plane and parallel to the tympanic membrane, just like that of the human ear (Figure 32).

Figure 30: Final tympanic membrane

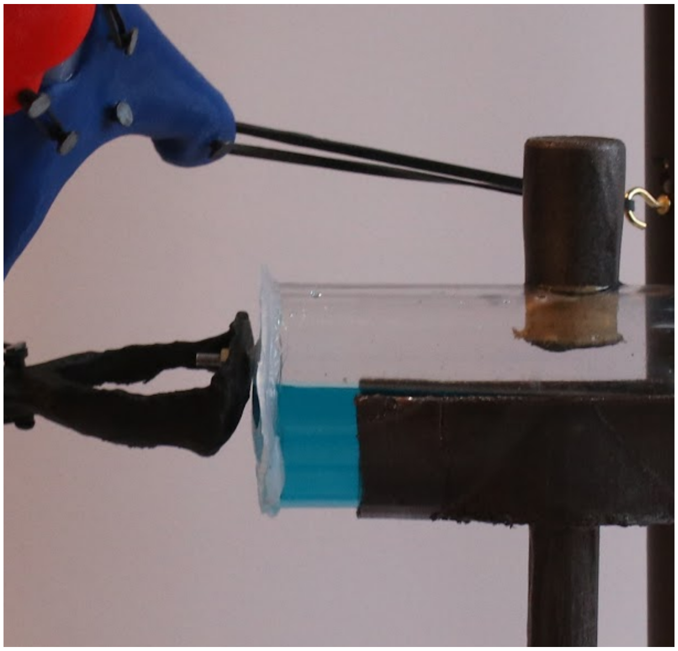


Figure 31: Stapes and cochlea connection

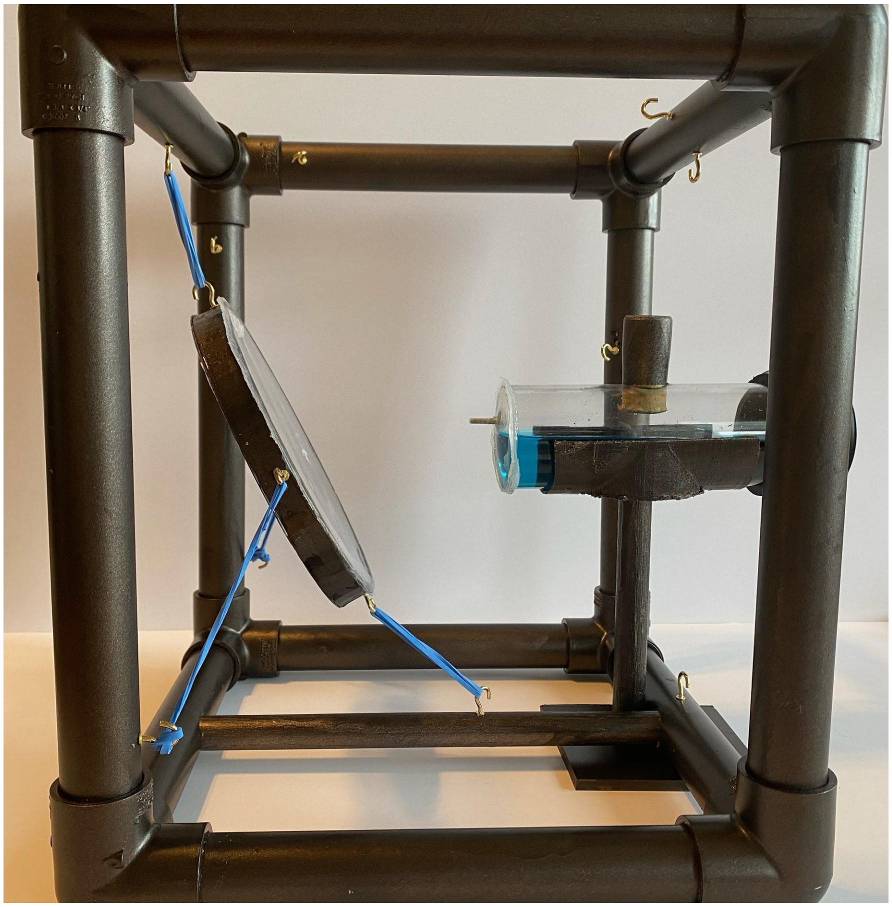


Figure 32: Tympanic membrane orientation in relation to the cochlear tube

The final tympanic membrane helps satisfy objectives one through five (replication, alignment, adjustable components, stimulation, and analysis). The membrane in the model is composed of silicone which has similar material properties to the human tympanic membrane. Additionally, the alignment of the tympanic membrane was adjusted to satisfy objectives one and two. The tympanic membrane is also easily removable from the model because it is attached by rubber bands to the frame, which helps satisfy objective three regarding adjustable components. Objective four of this project was to be able to stimulate the model acoustically. The silicone membrane's permanent adhesion to the previously 3D printed ring allows for the membrane to vibrate when stimulated acoustically.

Lastly, an accelerometer was taped to the center of the tympanic membrane to record data on the acceleration of the membrane. This was to address objective five regarding analyzing the vibrations through the model. The accelerometer wiring set up and Arduino code will be further addressed in section 6.5.

6.3 Final Ear Canal

The final ear canal was 3D printed using PLA. One side of the canal was designed to fit tightly around the tympanic ring with a tolerance of 2mm. The other end was a tight fit to the speaker. The canal was able to funnel the sound to the tympanic membrane from the speaker, to aid in the fulfillment of objective four. The ear canal was also designed to account for the new orientation and angle of the tympanic membrane. The final ear canal can be seen in Figure 33.

Figure 33: Final ear canal

The final version of the ear canal helps satisfy objectives three and four. The ear canal serves as a funnel between the speaker and the tympanic membrane. This increases the amplitude of the acoustic stimulation. This addresses objective four regarding stimulating the model acoustically. Additionally, the ear canal is removable from both the speaker and the tympanic membrane which helps satisfy objective three on adjustable components.

6.4 Abnormal Pathological Conditions

To address objective three on modeling abnormal pathological conditions, a modified stapes (Figure 34) and prosthesis were 3D printed, and can be interchanged into the model. As seen in Figure 35, the prosthetic can be easily hooked onto the incus, satisfying interchangeable requirements made in objective three.

Figure 34: 3D printed abnormal stapes

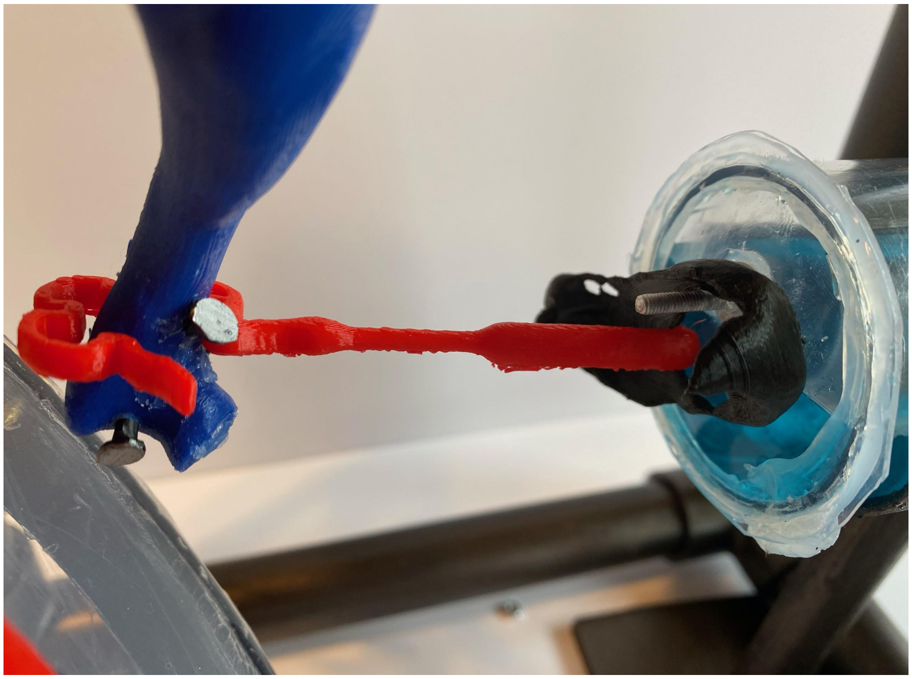


Figure 35: 3D printed prosthesis in red, 3D printed abnormal stapes in black.

Printing exchangeable parts that model various pathological conditions also helps satisfy objective five. Objective five was to analyze the vibrations of the model. The vibrations through the model can be analyzed with the abnormal ear parts and compared to the vibrations of the healthy ear.

6.5 Accelerometers

The final model contains two sets of ossicles: one set with accelerometers attached and one set without. The accelerometers were adhered to the ossicles by hot glue. This can be seen in Figure 36. Both sets of ossicles were printed at the same scale and with the same material as previous sets. These two sets of ossicles can be interchanged within the frame depending on whether accelerometer data or visualization of the ossicles is taking priority. Additionally, accelerometers were taped to the membranes to analyze the acceleration of both membranes.

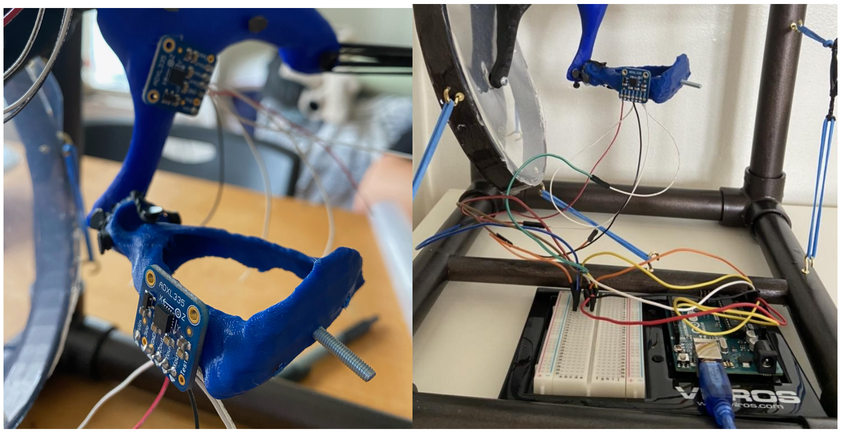


Figure 36: Left image: Accelerometer adhered to an ossicle. Right image: Accelerometer connection to Arduino Uno below.

To set up the accelerometers, wires were soldered onto the Vin, GND, Zout, Yout, and Xout pins. These pins can be seen in Figure 37. The wires were stripped and then threaded through the accelerometer pin from the bottom. Then, with the use of a soldering iron, solder was used to adhere the wire to the gold circle that defines each pin on the accelerometer. The wires were then cut and stripped on the other end.

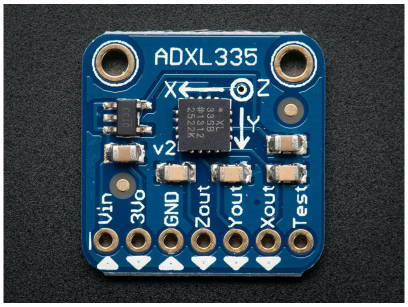


Figure 37: ADXL 335 Accelerometer (Buy Adafruit, 2020)

The accelerometer is attached to the Arduino by male to female wires, as seen in Figure 38. The female end of the wire is attached to the stripped end of the wire that is soldered onto the accelerometer. The male end of the wire is attached to the Arduino breadboard. The wiring setup for the Arduino can be seen in Figure 39. However, instead of the accelerometer being attached to the breadboard, wires connect the accelerometer to the Arduino breadboard.

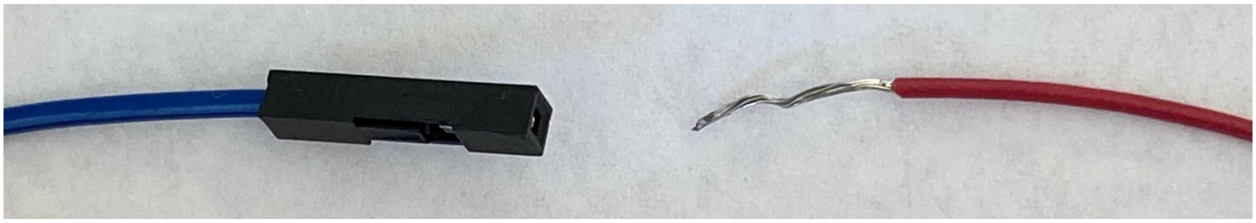


Figure 38: Female (left) and male (right) wires

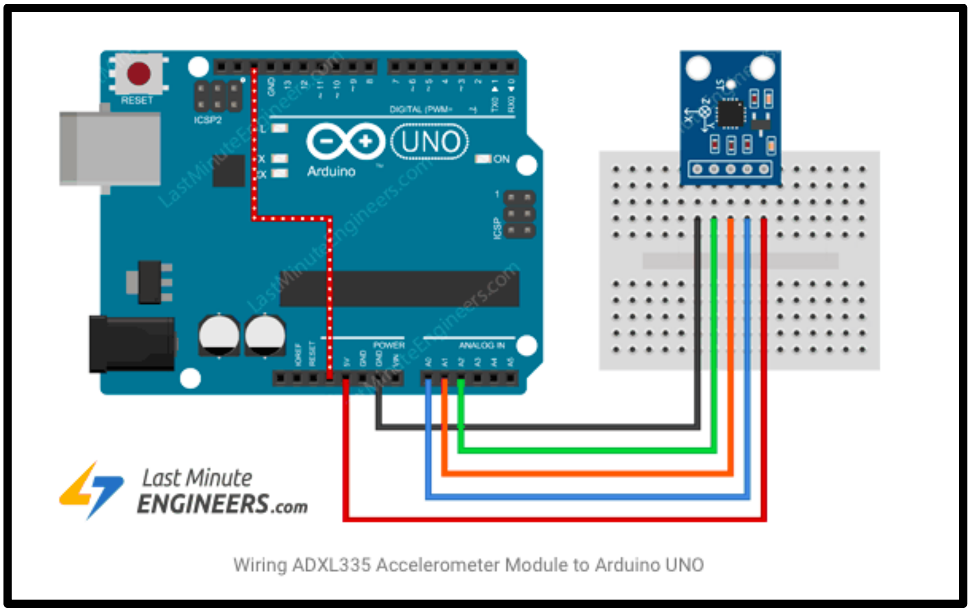


Figure 39: Arduino wiring setup (Last Minute Engineers, 2019)

The Arduino code is able to convert the raw data from the accelerometer into acceleration values in milli-g's. The raw value sent to the Arduino from the accelerometer is a number based on the voltage that the accelerometer sends to the Arduino pin. The arduino code then maps this number to the range of acceleration, -3g to +3g. Additionally, the time at which the acceleration occurred is recorded. The full Arduino code can be found in Appendix A.

6.6 Strengths and Weaknesses of the Final Model

The final model was updated to include more features in order to further the anatomical accuracy and function. This model also optimized features already included from previous iterations. The addition of the stand to the cochlear tube allowed for the oval window to be in contact with the stapes and aligned properly. This helped satisfy objectives one, two and three regarding anatomical accuracy, alignment, and exchangeability. The tympanic membrane was improved by aligning it at an anatomically accurate angle as well as permanently adhering it to the tympanic ring. This helped satisfy objective one and four by improving anatomical accuracy, and the ability for the model to be stimulated by sound. This model also attached the malleus to the membrane at the proper orientation and at the correct points. These improved contact areas increased anatomical accuracy and alignment, satisfying objectives one and two regarding anatomical accuracy and alignment.

Additionally, this iteration improved the interchangeability and replaceability of the model, adhering to objective three. The tympanic membrane was attached to the malleus with bolts, washers, and screws that could be removed and replaced. The cochlea was also attached to the stapes in this way. Further, the plug and hole addition to the cochlea allowed for the internal fluid to be drained and replaced with ease. In accordance with objective four, the new ear canal accounted for the new angle of the tympanic membrane. It also acted as a funnel, to funnel the sound from the speaker to the tympanic membrane, allowing vibrations to be better transmitted by the tympanic membrane. The vibrations transmitted by the model were also made measurable by attaching accelerometers to the tympanic and cochlear membranes. This allowed for calculations to be performed, satisfying objective five. These calculations can be found in Chapter 7.4.5.

The final model was able to successfully satisfy all five of the project objectives. The model was an anatomically accurate model, with proper alignment. The model had exchangeable and removable parts. Additionally, the model was able to be stimulated acoustically and the vibrations resulting from this stimulation were measured with accelerometers and an Arduino. While these objectives were satisfied, the team has additional recommendations for improving the model, which can be found in section 9.2.

Chapter 7: Testing and Analyzing the Model

The translation of vibrations through the model and the natural frequency of the model were analyzed to determine the model efficiency and accuracy. The efficiency of the model is described as how well the model is able to transfer vibrations through the model. The accuracy of the model is defined as how the natural frequency of the model changes due to abnormal pathological conditions demonstrated in the model. The analysis of the model described in this chapter satisfied objective five, which stated to analyze the vibrations of the model.

7.1 Design of Experiment

To test the model's efficiency and accuracy, as defined above, three experiments were conducted to obtain acceleration data of the membranes. The reasoning behind these parameters is to evaluate how well the model demonstrates actual middle ear physiology. More specifically, the physiological purpose of the middle ear is to transmit vibrations. Therefore, determining the model's efficiency, it's ability to transfer vibrations, was a key aspect in determining how well the model was mimicking middle ear physiology. Another key aspect of this model was to be able to portray abnormal pathological conditions in the middle ear. Determining the accuracy of these changes was crucial to understanding whether the model had the ability to portray differences in the physiology of the middle ear when anatomical changes occurred. The accuracy of the model was therefore evaluated by comparing the natural frequency of the model portraying a healthy ear, to the natural frequency of the model portraying an abnormal pathological condition. The natural frequency is a good indicator of the physiology of the middle ear because it determines the frequencies that can be heard in the ear. For example, if someone who has a healthy middle ear has their first natural frequency at 20 Hz, they will not be able to hear any frequencies below 20 Hz. However, if someone with an abnormal pathological condition has a first natural frequency at 50 Hz, they won't be able to hear any frequencies below 50 Hz. Demonstrating that the natural frequency of the model changes with changes in the anatomy, portrays accurate physiological behavior in the middle ear. The three experiments conducted to determine these parameters of the model were obtaining acceleration data at the tympanic membrane of a healthy ear, acceleration data at the cochlear membrane of a healthy ear, and acceleration data at the cochlear membrane with a prosthetic.

For each experiment as further detailed below, all sets of acceleration data were taken at the following frequencies: 30, 40, 50, 60, 70, 80, 90, and 100 Hz. The frequency was controlled by the iPhone App "Sonic" which played these specific frequencies through the speaker. The frequencies played by the app were checked against a computer playing the same frequency to validate this method.. Frequencies from the computer were played from a youtube channel called Sonic Electronix. To run each test, the model was placed on a table that was not touched during testing to ensure that the model was not vibrating due to an external force. Once the model was stable, which was determined by ensuring no water in the cochlear tube was moving, the frequency from the speaker was played. Then, the Arduino code, located in Appendix A, was uploaded to the Arduino. This ran the Arduino code, which collected the data from the accelerometer at a frequency of 448 Hz. The Arduino code ran until the storage in the Arduino was filled, which was 246 data points over the course of 0.55 seconds. The Arduino data was exported to the serial monitor in four columns: data number, time, raw acceleration value, and acceleration value in milli-g's. The frequency was stopped, the data was converted to a .txt file and then uploaded into excel. This process was repeated for all three sets of data for all of the frequencies. The data from these experiments is discussed in section 7.2.

For the first experiment, the team determined whether the model's tympanic membrane was responsive and representative to various stimuli. The membrane had to vibrate at frequencies relative to the input frequency. It also needed to show a relative change in vibration when it was stimulated with different frequencies. This would prove that our stimulation method and model is valid for demonstrating the translation of vibrations through the model from the tympanic membrane. This initial test was taken when with no prosthesis inserted into the model, therefore establishing a baseline for future comparative data. Additionally, this data would demonstrate the model's efficiency at transferring vibrations for healthy ear pathology. The malleus and stapes were screwed onto the tympanic and cochlear membranes respectively, and an accelerometer was taped to the center of the membrane near the contact points with the manubrium as seen in Figure 40. Wires connected the accelerometer to the Arduino below that was connected to a computer using a USB port. This is due to the fact that this contact point is where the membrane is most conical and is the point in which the translation of vibrations to the ossicles occur. This experiment then proceeded with the same testing and set up as described at the beginning of this section.

Figure 40: Accelerometer attachment to the tympanic membrane

After verifying the tympanic membrane's ability to receive and translate stimulation from the speaker, the team assessed the translation of vibrations through the ossicular chain to the cochlea. Following the setup earlier described, the model would be stimulated at various frequencies. Similar to the first experiment, the second experiment used the same healthy ear components with no inserted prosthetic. The malleus was screwed onto the tympanic membrane and the stapes was screwed onto the cochlear membrane. An accelerometer was taped onto the cochlear membrane adjacent to the membranes point of contact with the stapes footplate. Wires connected the accelerometer to the arduino below that was connected to a computer using a USB port. This test would first ensure that the model was able to show a difference in vibrations in response to different frequency inputs. Once this was verified, the acceleration at each frequency was compared with the data collected from experiment one. Using this comparison, the efficiency of the model in translating vibrations between membranes could be determined. A large difference between the membrane data was attributed to the scaling of the components.

The third experiment first involved determining the natural frequency of the healthy ear pathology for the tympanic and cochlear membranes using the data collected in the first two experiments. Natural frequency of the model was found by plotting average acceleration versus frequency. The natural frequency is identified by peaks on the graph. The graphs for each membrane would show what frequency the tympanic and cochlear membranes best resonate at. Once the natural frequency of the healthy ear model was established, the stapes was unscrewed from the cochlear membrane and removed from the incus. The healthy stapes was replaced with the abnormal stapes and the prosthetic was inserted into the model. An accelerometer was taped onto the cochlear membrane adjacent to the membranes point of contact with the prosthetic. Wires connected the accelerometer to the arduino below that was connected to a computer using a USB port. The model was then stimulated and data was collected exactly like that for experiments one and two, as described at the beginning of this section. The average acceleration versus frequency of the abnormal ear was plotted on the same graph as that of the healthy ear natural frequency plot. This was done to demonstrate the effect of the inserted prosthetic. As discussed in chapter 4.5, the natural frequency of the middle ear determines what frequencies can be heard and at which frequency sound is best heard. As the natural frequency changes, the frequencies at which a person can hear change as well. Therefore, by determining the natural frequency of the model, the effects of inserting the prosthetic or interchanging other parts in the future (as discussed in chapter 8) on a person's hearing could be demonstrated in the model.

7.2 Accelerometer Data

Figure 41 shows an example of the acceleration over time at 60 Hz for the tympanic membrane. All the acceleration over time plots can also be found in Appendix B, C, & D.

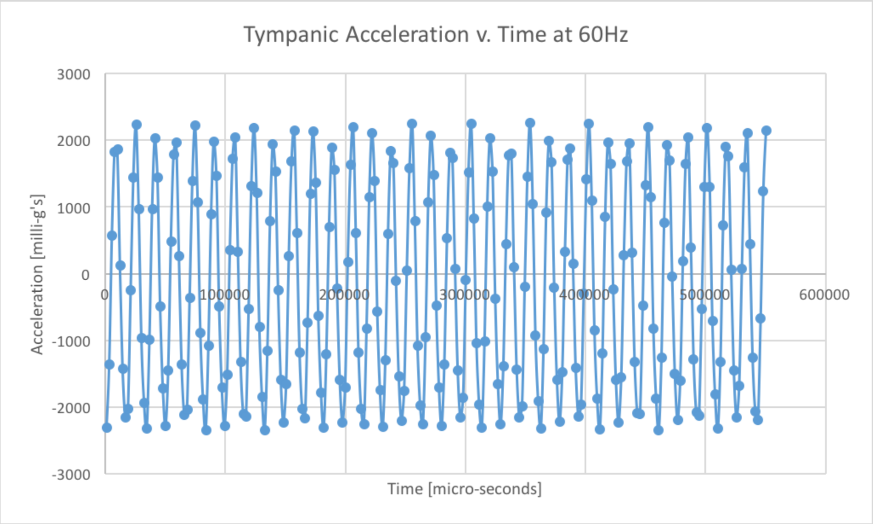


Figure 41: Graph of tympanic acceleration over time at 60 Hz

Figure 41 shows the magnitude of the acceleration of the tympanic membrane fluctuates between around +2000 and -2000 milli-g’s. This fluctuation is due to the oscillating pattern of the membrane. As the membrane changes directions of movement it experiences a maximum acceleration. As it passes the neutral position, no acceleration is occurring. Figure 42 shows this same pattern but between +60 and -60 milli-g’s for the cochlear membrane.

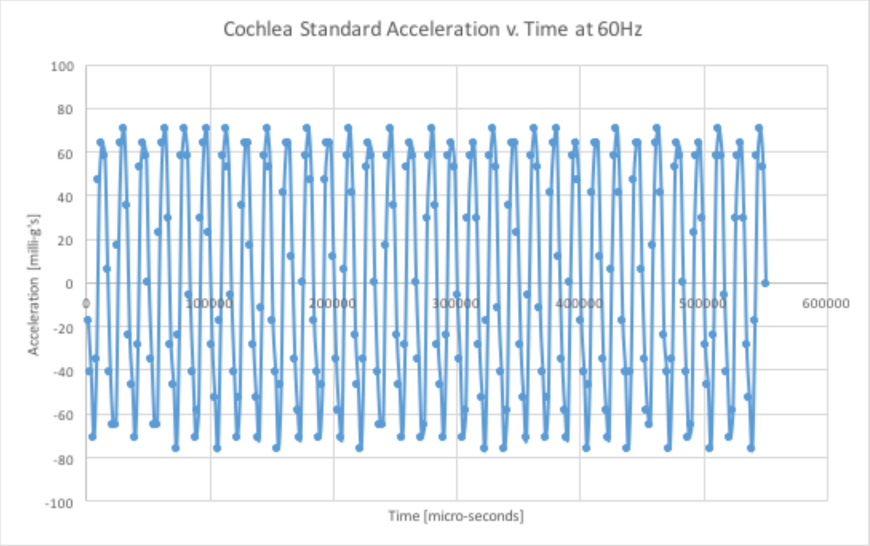


Figure 42: Graph of cochlear acceleration over time at 60 Hz

As can be seen in Figures 41 and 42, both the tympanic and cochlear membrane oscillated at about 60 Hz, which was the frequency the membranes were stimulated with. A frequency of 60 Hz should show approximately 30 peaks in 0.5 seconds. Figure 41 above shows approximately 31 peaks in 0.5 seconds and Figure 42 shows approximately 30 peaks in 0.5 seconds which both correlate to a frequency at about 60 Hz. Thus, these results provide verification for the data collection methods. However, while the data collection method was verified, the Arduino sampling rate of 448 Hz should be closer to ten times the speed of the highest frequency. This means that the ideal sampling rate would have been closer to 1000 Hz. This caused some slight discrepancies in the acceleration data which can be found in Appendices B, C, & D.

7.3 Analyzing Translation of Vibrations

In the human middle ear, the ossicles are able to amplify the vibrations received from the outer ear and transmit them into the inner ear. Due to the size of our model, and the materials used it was expected that the magnitude of the vibrations would instead decrease as they were transmitted across the model. Calculating the ratio of the acceleration of the tympanic membrane and cochlear membrane allows for the efficiency of the translation of vibrations of the model to be determined. Figure 43 shows the peak acceleration of the cochlear membrane and tympanic membrane over frequency for the healthy ear model. An example of the raw acceleration data can be seen in Figure 40 and 41. Figure 42 shows the averages of the maximum accelerations, which are located at the peaks in the raw data graphs, like Figure 41 and 42.

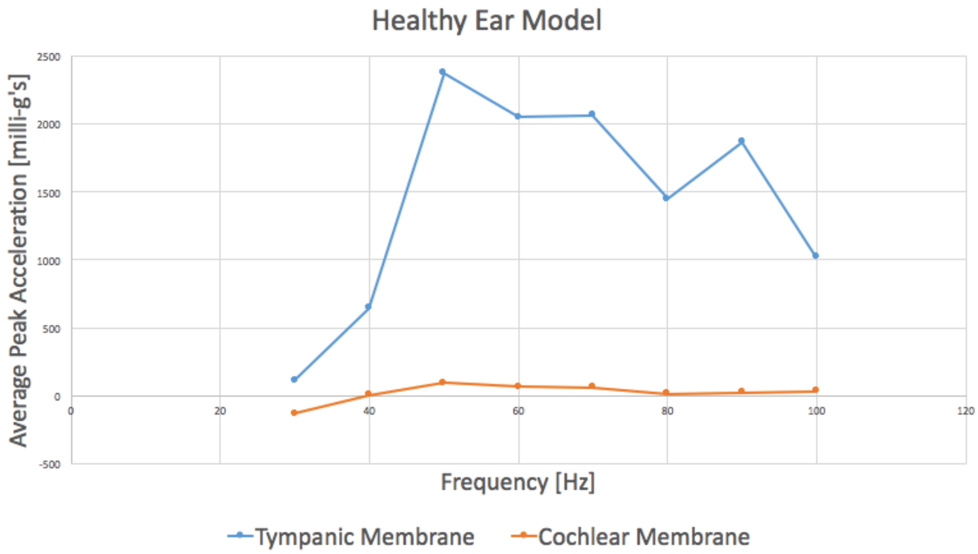


Figure 43: Acceleration of healthy ear model

Figure 43 shows that the magnitude of the acceleration of the tympanic membrane is much larger than the magnitude of the acceleration of the cochlear membrane. This means the amplitude of the vibrations is decreasing as it is transmitted through the model. Table 8 below shows the breakdown of what percent of the acceleration from the tympanic membrane was transmitted through the model to the cochlear membrane.

Table 8: Percent Acceleration Transmitted by Frequency

	30 Hz	40	50	60	70	80	90	100
Tympanic Membrane	112.5	645.45	2372.2	2051.5	2065.0	1449.5	1864.2	1021.1
Cochlear Membrane	-132.1	6	92.4	67.6	63.1	12	25.1	33.08
% Translated	-	0.93%	3.90%	3.30%	3.06%	0.83%	1.35%	3.24%

Table 8 shows that at between frequencies of 50 and 70 Hz the model was the most efficient at transmitting vibrations. The efficiency at these frequencies however was only around 3%. There were some discrepancies with this percentage. Some of the values of acceleration of the cochlear membrane were so small that the acceleration can probably be attributed to noise and therefore the percent transmitted isn't an accurate representation. Additionally, the frequency at 30 Hz for the cochlear membrane was negative, which could either be due to the accelerometer not being calibrated correctly, or that the motion of the membrane was so small that it was not detected well by the accelerometer. Overall, this data does show that the model has the ability to transfer vibrations, even though the efficiency of this translation is rather low. The ability of the model to transmit vibration satisfies the project objective number four. However, the percent acceleration translated is fairly low and could be improved to transmit vibrations more effectively, as discussed in Chapter 9.2.

7.4 Analyzing Model Accuracy

The natural frequency of the middle ear is important to measure as natural frequency determines what frequencies can be heard. Our model is able to demonstrate the theory that as conditions change in the ear, the natural frequency can change, ultimately affecting a person's ability to hear. The natural frequencies is the frequency at which the average peak acceleration is the largest. Figure 44 shows the plot of the tympanic peak acceleration over frequency.

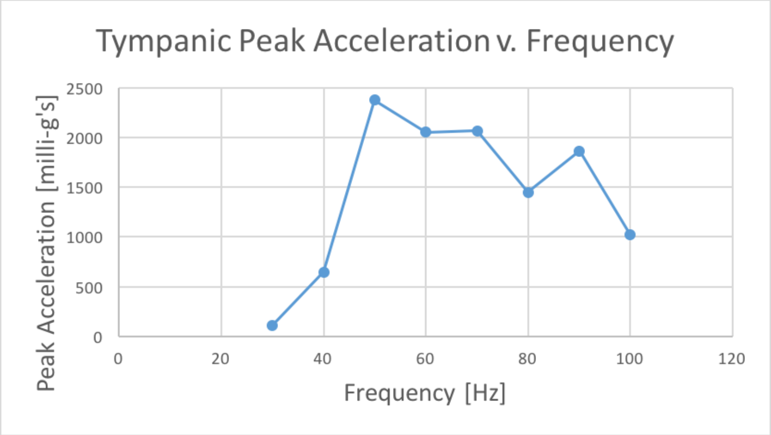


Figure 44: Tympanic membrane natural frequency plot

Figure 44 shows the average peak acceleration of the tympanic membrane over frequencies ranging from 30-100 Hz. The peak in this graph occurs at 50 Hz where the acceleration value is 2372.22 milli-g's. However, because the model is a multiple mass system, it will have multiple natural frequencies. While 50 Hz appears to be the first natural frequency, there appears to be a second natural frequency around 90 Hz.

The natural frequency of the cochlear membrane was analyzed by comparing the natural frequency of the healthy ear model to the model with the prosthetic. Figure 45 shows the cochlear membrane natural frequency of the healthy ear model to the natural frequency with the prosthetic.

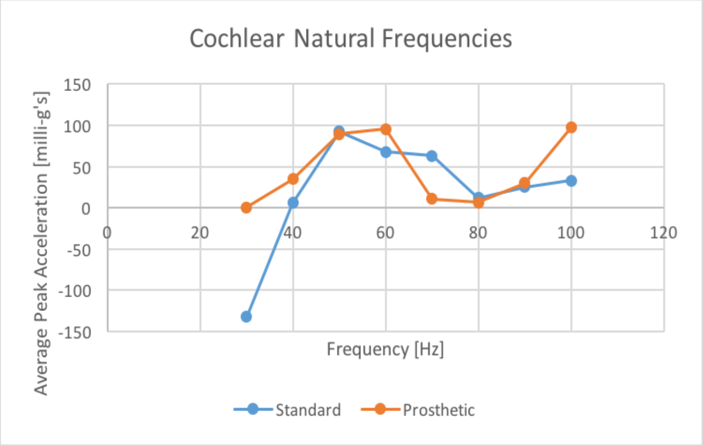


Figure 45: Cochlear membrane natural frequencies

Figure 45 shows the average peak acceleration of the cochlear membrane of the healthy ear model as well as with a prosthetic over frequencies ranging from 30-100 Hz. The peak of the cochlear membrane of the healthy ear model occurs around 50 Hz, which was the same as the tympanic membrane. The value of this acceleration is 92.4 milli-g's. The peak of the prosthetic plot occurs closer to 60 Hz where the peak acceleration value is 95.35 milli-g's. There are also additional peaks for the healthy ear conditions and prosthetic conditions around 100 Hz. The peak acceleration for the prosthetic at 100 Hz was 97.16 milli-g's and for the healthy conditions it was 33.08 milli-g's. The model is a multiple mass system so it is to be expected that there are multiple natural frequencies of the model. The acceleration values at lower frequencies on the cochlear membrane were so small that it was hard for the accelerometer to pick up. Therefore, the data around 30 and 40 Hz on the cochlear membrane can be attributed to noise in the data.

This natural frequency data is able to portray the accuracy of the model because it shows that the model has physiological change when there are anatomical changes. The natural frequency of the model changed from 50 Hz in a healthy ear, to 60 Hz in an abnormal ear. This means that the healthy ear model can hear frequencies above 50 Hz and the abnormal model could only hear frequencies above 60 Hz.

Chapter 8: Broader Impacts

8.1 Environmental Impact

The impact of this model on the environment is quite low. Some concerns that could arise are the use of spray paint contributing to air pollution, or the waste generated by replacing snapped and torn rubber bands. PLA is recyclable and biodegradable, and the team recommends recycling any broken or unnecessary printed material (Barrett, 2020). The spray painted PVC would be more difficult to recycle, but the frame is durable and large enough to encase potential future additions. The model requires small amounts of water to fill the cochlear tube. Added to this water, the team proposes adding food coloring for visual purposes, and salt to prevent bacterial and mold formation. Both food coloring and salt are non toxic and can be poured down the drain without detrimental impact. Electrical input is required for the Arduino. All of these effects were regarded as insignificant since this single model was made for the use of one institution.

8.2 Societal Influence

The middle ear model was manufactured specifically for the Universitätsspital Zürich to use as a teaching model during university lectures. It's potential to improve medical student's understanding of the middle ear could allow for innovative ideas and theories to provide treatment for people with middle ear abnormalities. Additionally, due to the model's potential to be used in research, it could aid researcher's understanding of the functionality of the middle ear. It could also allow them to test theories about how different conditions in the middle ear affect a person's ability to hear. This greater understanding could lead to more successful treatments for people with middle ear abnormalities. These treatments have the potential to improve the health of many individuals who experience some form of hearing loss.

Hearing research does raise concerns from the deaf community. There is a lack of trust in the medical industry by the deaf community, who feel deafness is a cultural identity rather than a disability (McKeer, Schlehofer, & Thew, 2013). Therefore, treatments to eliminate deafness in patients have been seen as insulting to the identity of members of the deaf community. Most of these concerns are rooted in "terminat(ing) pregnancies or select(ing) genetic engineering to avoid the birth of a deaf infant. The potential loss of future deaf individuals has major implications for the viability of the Deaf culture" (McKeer, Schlehofer, & Thew, 2013). However, the intention of this model is not to pose a threat to the deaf community but to educate medical students and professionals about the intricacies inside the middle ear.

8.3 Ethical Concerns

One ethical concern surrounding this model is that the anatomy used to replicate the middle ear is specific to one ear and is not a good representation of all middle ear anatomy. Everyone has slightly different anatomy in their middle ear, which could lead to discrepancies between the model and the middle ear of a specific individual. The model was created based on the CT of a specific person. It was not modified to be generalized for the public. Additionally, the model is a model of a left ear. So while the left and right ear tend to be symmetrical, there can be slight discrepancies between the two sides.

The model has the ability to portray various pathological conditions, but not all middle ear abnormalities can be replicated using this model. This brings up the question whether or not it is ethical for us to model some abnormal conditions in the ear and not others. By modeling some abnormalities, it can provide researchers and doctors with a better understanding of these conditions that could lead to potential treatments. While the conditions that cannot be modeled may not receive the same attention and therefore not have the same potential to be treated.

Another ethical concern about this model is if teaching the specific function and anatomy of the middle ear in an isolated model is the best way for students to be learning about the middle ear. Instead of learning only about the ear as a whole and how it connects with the rest of the body. This model specifically demonstrates the middle ear and doesn't portray the bigger picture of hearing mechanics.

However, even with these specific ethical concerns, the overall goal of the model is to improve researcher's & doctor's understanding of the human middle ear. A greater knowledge has the potential to lead to future treatments for individuals experiencing some form of hearing loss. This could be beneficial to over 37.5 million individuals in the United States alone who suffer from some form of hearing loss (NIH, 2016).

8.4 Manufacturability

The components of this model would be simple to manufacture. The STL files of the bones, tympanic membrane ellipse, and cochlear stand can easily be 3D printed, remembering to keep in mind that the bones need to be scaled 15:1 before printing. All other materials are very easily attainable: PVC pipes and PVC joints, spray paint, rubber bands, and metal hooks.

The assembly of these components requires more expertise, but this can be fixed by a proper labeling system of which hooks correspond to which ligaments.

No engineering or medical standards were used in the creation of this model, nor do they need to be applied to manufacturing this model. The model is to serve as a dynamic representation of the middle ear, and does not stand alone without proper instruction from the Universitätsspital Zürich's professors. No part of the model will be used in medical testing and is not intended to be used to further research. If the model were to be distributed for the purposes of medical and scientific education, it would need to be in accordance with ISO 9001:2015.

8.5 Sustainability

This model was designed to be able to undergo updates and changes, and therefore was designed with sustainability in mind. Due to the interchangeable parts system, all parts can be replaced if they become worn or broken. All STL files can be reprinted, rubber bands can be replaced, and all other used materials are easily attainable through either a local hardware store or ordered online. The team is unsure if high vibrations will cause the glue to separate from the silicone membrane and break the air tight seal, but in the case that it does, the tympanic membrane and cochlear tube can both be removed from the model in order to make the proper repairs.

Chapter 9: Conclusions and Recommendations

9.1 Conclusions

The goal of this project was to design and construct a more interactive teaching model for the UniversitätsSpital Zürich that could demonstrate the complex anatomy and physiology of the middle ear. The team developed five main objectives that focused on replicating healthy middle ear anatomy, aligning the components with anatomical accuracy, constructing removable parts to model abnormal pathological conditions, stimulating the model, and analyzing the translation of vibrations through the model. The outcomes of these objectives are discussed in detail below.

Objective one, to replicate the middle ear anatomy, tympanic membrane, and oval window at a 15:1 scale, was successfully completed. By utilizing research on the anatomical dimensions and material properties of the middle ear and surrounding features, the model was made to successfully represent accurate human anatomy. All components were scaled by a factor of 15:1 to ensure visual potential.

Objective two, to suspend the ossicles so that the alignment between components and location of ligament attachment to the ossicles was anatomically accurate, was also satisfied. CT scans as well as medical references were used to orient these components with anatomical accuracy. The ligaments were attached at correct anatomical locations on the ossicles, and the tympanic membrane was oriented at a proper angle and in the same plane as the cochlea.

Additionally, the team successfully fulfilled objective three, which was to design adjustable components in order to represent various abnormal pathologies through the use of interchangeable parts. All parts of the model including the joints, ossicles, prosthetic, abnormal stapes, ligaments, tympanic ring, cochlea, and components of the frame were removable. The model can be fully broken down and reassembled; Not only does this allow for the model to show an abnormal pathology and prosthetic, but also supports continuous improvement through adaptability to new parts and updates. Further, it allows the model to be repaired to increase its overall lifespan.

Objective four, to stimulate the model acoustically or mechanically to demonstrate the translation of vibrations through the ear, was successfully completed. The team chose to acoustically stimulate the model, as this is how the real human ear is most commonly stimulated. The team created an ear canal as well to recreate the sound funneling process into the middle ear to ensure accuracy in sound transmission to the tympanic membrane. The acoustic stimulation was proven successful through the fifth project objective.

Lastly, objective five, which encompassed analyzing the vibrations transmitted through the model, was satisfied. Since the model was responsive to acoustic stimulation, the vibrations could be measured and analyzed. Accelerometers were successfully connected to the tympanic membrane and oval window to record the translation of vibrations through the model. The data collected from the accelerometers was analyzed and graphed to demonstrate the model's response to various frequencies. The translation of vibrations was also analyzed when an abnormal stapes and prosthesis were interchanged into the model. This data was used to compare diseased ear function with that of a healthy ear.

The results of this preliminary data demonstrate the model's ability to depict physiological behaviors in the middle ear. The accelerometer data from the tympanic membrane showed that the membrane was vibrating at the same frequency as the input stimulus. This exhibits the effectiveness of our stimulation method and tympanic membrane design. The vibration of the cochlear membrane at the same specific frequencies was also analyzed. As expected, the team's dynamic movement analysis confirmed that the model did not amplify the vibrational waves like that of a human ear. However, the cochlea did vibrate differently at each frequency. Thus, our model translates acoustic vibrations and has the ability to demonstrate differences in movement at varying frequencies.

The data also showcases the model's ability to demonstrate hearing variabilities between a healthy ear and one with a prosthetic. As discussed in chapter 7.3, natural frequency plots revealed that the healthy ear had a lower natural frequency than that of an ear with a prosthetic. From this data, it can be concluded that people with this ear prosthetic cannot hear as low of frequencies as those without the prosthetic. This data is significant as it reveals the effect that this prosthetic has on an individual's hearing. Further, the interchangeability of our model allows for future parts or prosthetics to be inserted into the model. These newly inserted parts could then be similarly analyzed to show their effect on natural frequency and hearing.

Overall, these results demonstrate that the model accurately represents the middle ear and will provide a useful tool for educating students on the anatomy, sound mechanics, and physiology of the human ear. Future data collection, described the following section, describes how to continue to analyze the behavior of the model in more accurate ways.

9.2 Recommendations

While the model was able to satisfy each of the objectives discussed in chapter three, a few areas of improvement were identified for objectives one, three, four, and five. In regards to objective one, the anatomical accuracy of the model could be improved by better replicating the density of the ossicles. The fulfillment of objective three, the creation of interchangeable components, could be continued by creating abnormal joints. Lastly, objective four and five could be furthered by using more advanced measuring techniques and analyzing the output data. These improvements are further discussed below.

Based on background research and interviews with our sponsor, the ossicles were found to have a low density. In an attempt to show how the porous nature of bone affects the translation of vibrations through the ear and on natural frequency, ossicles with varying infills were 3D printed. The previously mentioned CT scans of a healthy ear malleus were printed with 15, 30, 60, and 90% infill PLA, with a 3D honeycomb infill geometry, as seen in Figure 46. Further, research revealed that wood is known to have one of the most similar porous internal structures to that of bone. After consulting with Mitra Anand and Dr. Stults, the team ordered a sample of Polywood PLA and 3D printed a malleus with this filament as seen in Figure 47. Due to time constraints, the effects of the infill and material density were not able to be tested. Thus, the team recommends that in order to further improve the accuracy of this model, the natural frequency and translation of vibrations through the model using different infills and wood material be evaluated. Further, using materials of a more accurate density could result in the translation of dynamic motion more efficiently than the current model, which is only translating about 3% of the motion, as discussed in chapter 7.2. When shipped to our sponsor, tacks and screws were added to their appropriate locations on the varying malleuses to ensure anatomical accuracy and ease of this recommended testing.

Figure 46: Malleus bones printed at various infills

Figure 47: Malleus 3D printed from Polywood PLA

Another recommendation to expand the demonstrational capabilities of this model is to replicate abnormal joints. The team originally planned on showing abnormal scenarios of both stiffer and looser than normal human ear joints. However, due to time constraints, the team was not able to analyze these cases. Thus, to increase the potential of the model the team recommends creating stiffer joints by increasing the amount of silicone between the ossicles and tightening the rubber bands of the joints. For looser joints, the rubber bands could be removed and the amount of silicone decreased. The natural frequency and translation of vibrations through the model could then be analyzed for the differing joints to show the effect of these pathological abnormalities. Further, the effect of joint stiffness on the proper orientation of the ossicles and surrounding elements could be observed. Demonstration of these scenarios to students could lead to a furthered understanding on the effect of various joint abnormalities on ear mechanics.

In accordance with the team's objective to create an interchangeable model, the cochlear tube, as earlier described, was drainable and refillable. For our analysis, the team aimed to assess the fluid waves in the cochlear tube. To achieve this, the tube would only be half filled with fluid so that waves could be visibly assessed. However, the team was not able to perform this analysis due to a lack of access to very high quality cameras or motion detection equipment. Analysis of the waves was attempted using a phone's slow motion video feature. It was also attempted using a quality Canon camera. Pictures on this camera were taken at a high shutter speed in an attempt to see the individual waves. However, video footage as well as the pictures were of too low quality to generate any conclusive results. Thus, the team recommends that slow motion capture cameras be used to measure the waves' amplitude and frequency under various stimuli. This method would be more accurate than visible observation or low quality camera data. Additionally, further analysis could be performed by filling the tube fully with liquid. A waterproof pressure sensor could then be inserted into the tube. The change in pressure in the cochlea due to the force on the cochlear membrane by the stapes could thus be measured. This pressure change could be analyzed for scenarios involving varying frequencies and for ear abnormalities.

As discussed in chapter 4.5, the team originally considered measuring the forces applied by each ossicle to demonstrate the translation of vibrations in the ossicular chain. This would be achieved through attaching accelerometers to each ossicle and measuring the acceleration. Force equations and free body diagrams would then be used to determine the forces. While the team decided to measure the translation of vibrations through the model as a whole by taking measurements at the cochlear and tympanic membranes, analyzing the forces at the ossicles could be beneficial. The team provided a set of ossicles with attached and soldered accelerometers so that future analysis on the individual ossicles could be performed. This analysis could supply students with a better understanding into the movement of the individual ossicles and their respective sound mechanics.

Similar to the team's attempt at visually analyzing the waves in the cochlea, trials for analyzing tympanic membrane movement were attempted. A metallic dot was placed on the membrane and photographs of the membrane for different frequencies were taken at a low shutter speed. The goal was to observe noticeable differences in the blurred movement of the dot in the pictures at different frequencies. Unfortunately, the camera used was not of high enough enough quality to show this blur, even at low shutter speed. Thus, the team again recommends the use of motion capture cameras to observe the vibrational movement of the tympanic membrane.

Another recommendation is to add strain gauges to the tympanic membrane. In the human ear, the force of sound vibrations cause the tympanic membrane and cochlea to stretch. Adding a strain gauge to the model would allow for displacement of the tympanic membrane and cochlear membrane to be measured. Additionally, the team recommends using more advanced technological sensors, such as a Laser Doppler Vibrometer. More advanced equipment would more accurately measure the vibrations of the ossicles under various frequencies and abnormal pathologies. Another way to improve the quality of the data would be to increase the sampling rate of the Arduino when using accelerometers. A sampling rate ten times faster than the input frequency is the ideal sampling frequency rate. These changes could improve the model's ability to demonstrate the physiology in addition to the anatomy of the middle ear.

Chapter 10: References

Aernouts, J., Soons, J. A., & Dirckx, J. J. (2009, September 17). Quantification of tympanic membrane elasticity parameters from in situ point indentation measurements: Validation and preliminary study. Retrieved September 30, 2020, from https://mrl.sci.utah.edu/papers/aernouts2009.pdf

Amplitude and Frequency. (1997). Retrieved August 30, 2020, from https://www.howmusicworks.org/103/Sound-and-Music/Amplitude-and-Frequency

AZoM. (2001, September 25). Properties: Silicone Rubber. Retrieved October 18, 2020, from https://www.azom.com/properties.aspx?ArticleID=920

Barrett, A. (2020, April 08). Is PLA Recyclable? Retrieved October 15, 2020, from https://bioplasticsnews.com/2020/04/05/is-pla-recyclable/

Biga, L., Dawson, S., Harwell, A., Hopkins, R., Kaufmann, J., LeMaster, M., . . . Runyeon, J. (n.d.). 9.4 Synovial Joints. Retrieved September 04, 2020, from https://open.oregonstate.education/aandp/chapter/9-4-synovial-joints/

Buy Adafruit ADXL335 - 5V ready triple-axis accelerometer (+-3g analog out) [ADA163] Online at Low Prices in India: Adafruit Reviews & Ratings. (2020). Retrieved October 22, 2020, from https://www.amazon.in/Adafruit-ADXL335-triple-axis-accelerometer-analog/dp/B00NAY2TUC

Conductive Hearing Loss. (n.d.). Retrieved August 30, 2020, from https://www.asha.org/public/hearing/conductive-hearing-loss/

Dallas Ear Institute. (n.d.). Encephaloceles and Cerbrospinal Fluid Leaks of the Ear. Retrieved October 23, 2020, from https://www.dallasear.com/conditions-encephalocele.html

De Greef, D., Buytaert, J. A., Aerts, J. R., Van Hoorebeke, L., Dierick, M., & Dirckx, J. (2015). Details of human middle ear morphology based on micro-CT imaging of phosphotungsticacid stained samples. *Journal of morphology*, *276*(9), 1025–1046.

DZS Elec. (2020). DZS Elec 12pcs Mini Vibration Motor. Retrieved 2020, from https://www.amazon.com/DZS-Elec-Button-type-Electronics-Appliances/dp/B07PHPK6SC/ref=asc_df_B07PHPK6SC/?tag=hyprod-20&linkCode=df0&hvadid=309803885710&hvpos=&hvnetw=g&hvrand=16215622921931942181&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9001847&hvtargid=pla-675863995091&psc=1

Ear Infection (Otitis Media): Symptoms, Causes, Prevention & Treatment. (2020, April 16). Retrieved August 30, 2020, from https://my.clevelandclinic.org/health/diseases/8613-ear-infection-otitis-media

Engineering ToolBox, (2009). *Density of Selected Solids*. Retrieved October 10, 2020, from https://www.engineeringtoolbox.com/density-solids-d_1265.html

Epomedicine, Says:, J., Says:, S., & Says:, N. (2013, November 16). Applied Anatomy of Tympanic Membrane. Retrieved October 16, 2020, from https://epomedicine.com/medical-students/applied-anatomy-of-tympanic-membrane/

Hawkins, J. E., Higgins, J., Lotha, G., Pallardy, R., M., Young, G., . . . Singh, S. (2018, October 25). Endolymph and perilymph. Retrieved October 1, 2020, from https://www.britannica.com/science/ear/Endolymph-and-perilymph

Healthline. (2018, January 22). Tympanic Membrane. Retrieved October 4, 2020, from https://www.healthline.com/human-body-maps/tympanic-membrane

Hearing Aids. (2017, March 6). Retrieved 29 August 2020, from https://www.nidcd.nih.gov/health/hearing-aids

Heinz Kurz GmbH Medizintechnik. (n.d.). NITIBOND STAPES PROSTHESIS. Retrieved August 30, 2020, from https://www.kurzmed.com/en/products/otologie/stapedioplasty/nitibond-stapes-prosthesis

Hu, A., Sardesai, M., & Meyer, T. (2012). A need for otolaryngology education among primary care providers. Medical Education Online, 17(1), 17350. doi: 10.3402/meo.v17i0.17350

Koblar, D., Škofic, J., & Boltežar, M. (2014, March 5). Evaluation of the Young’s Modulus of Rubber-Like Materials Bonded to Rigid Surfaces with Respect to Poisson’s Ratio. Retrieved October 9, 2020, from https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.831.7963

Last Minute Engineers. (2019, December 13). In-Depth: How Accelerometer works? Interface ADXL335 with Arduino. Retrieved October 08, 2020, from https://lastminuteengineers.com/adxl335-accelerometer-arduino-tutorial/

Leider, C. (2018, July 6). What is a Stapedectomy Surgery? (Indications, Procedure, Side Effects, and Recovery). Retrieved August 28, 2020, from https://www.houstonent.com/blog/what-is-a-stapedectomy-surgery-indications-procedure-side-effects-and-recovery

Luo, H., Dai, C., Gan, R. Z., & Lu, H. (2009, June). Measurement of young's modulus of human tympanic membrane at high strain rates. Retrieved October 2, 2020, from https://pubmed.ncbi.nlm.nih.gov/19449971/

MatWeb. (n.d.). Overview of materials for Vinyl Ester Sheet Molding Compound. Retrieved October 28, 2020, from http://www.matweb.com/search/datasheet_print.aspx?matguid=7ac4c12f06fe4ac19a437f4ef6a11bf8

McKeer, M., Schlehofer, D., & Thew, D. (2013, December). Ethical Issues in Conducting Research With Deaf Populations. Retrieved October 18, 2020, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3966694/

Nave, R. (n.d.). Transverse Waves. Retrieved August 30, 2020, from http://hyperphysics.phy-astr.gsu.edu/hbase/Sound/tralon.html

NIH. (2016, December 15). Quick Statistics About Hearing. Retrieved October 08, 2020, from https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing

Nolan J., Rivera A.L. (2013) Middle Ear Anatomy. In: Kountakis S.E. (eds) Encyclopedia of Otolaryngology, Head and Neck Surgery. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-23499-6_533

OpenStax. (n.d.). Physics. Retrieved August 30, 2020, from https://courses.lumenlearning.com/physics/chapter/17-6-hearing/

Osika, A. (2020, August 17). Auditory ossicles. Retrieved August 28, 2020, from https://www.kenhub.com/en/library/anatomy/auditory-ossicles

Otology and Biomechanics of Hearing at UniversitätsSpital Zürich. (n.d.). Retrieved August 29, 2020, from http://www.orl.usz.ch/forschung/seiten/otologie.aspx

Otosclerosis. (2020, May 14). Retrieved August 30, 2020, from https://vestibular.org/article/diagnosis-treatment/types-of-vestibular-disorders/otosclerosis/

Otosclerosis & Stapedectomy. (n.d.). Retrieved August 28, 2020, from http://www.michiganear.com/ear-services-otoscierosis-and-stapedectomy.html

Physics Tutorial: Sound Waves as Pressure Waves. (n.d.). Retrieved August 30, 2020, from https://www.physicsclassroom.com/class/sound/u11l1c.cfm

Ruckenstein, M.J. and Nicolli, E.A. (2012), Is there a “best” stapes prosthesis?. The Laryngoscope, 122: 2123-2124. doi:10.1002/lary.23353

Russell, D. A. (1998, August 26). Acoustics and Vibration Animations. Retrieved August 30, 2020, from https://www.acs.psu.edu/drussell/Demos/waves/wavemotion.html

Stapedectomy Post-Operative Instructions[Brochure]. (n.d.). Physician's Clinic of Iowa. Retreived from https://www.pcofiowa.com/files/5114/5314/8604/Stapedectomy_Post_Op.pdf

Summit Medical Group. (2014). Ear: Middle Ear Fluid. Retrieved September 21, 2020, from https://www.summitmedicalgroup.com/library/pediatric_health/hhg_earfluid/

Team, T. (2018, January 22). Tympanic Membrane Pictures, Function & Anatomy | Body Maps. Retrieved August 28, 2020, from https://www.healthline.com/human-body-maps/tympanic-membrane

The History of Hearing Aids. (2020). Retrieved 29 August 2020, from https://www.hear-it.org/lighter-smaller-and-better

The Middle Ear. (n.d.). Retrieved August 28, 2020, from https://teachmeanatomy.info/head/organs/ear/middle-ear/

The Editors of Encyclopaedia Britannica. (2018, June 20). Tympanic membrane. Retrieved August 28, 2020, from https://www.britannica.com/science/tympanic-membrane

University of Rochester Medical Center. (2020). Anatomy and Physiology of the Ear. Retrieved September 21, 2020, from https://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=90

Vestibule. (n.d.). Retrieved September 21, 2020, from https://www.britannica.com/science/vestibule-ear

Volandri, G., Di Puccio, F., Forte, P., & Carmignani, C. (2011, April 29). Biomechanics of the tympanic membrane. Retrieved October 7, 2020, from https://www.sciencedirect.com/science/article/abs/pii/S0021929011000224?showall=true

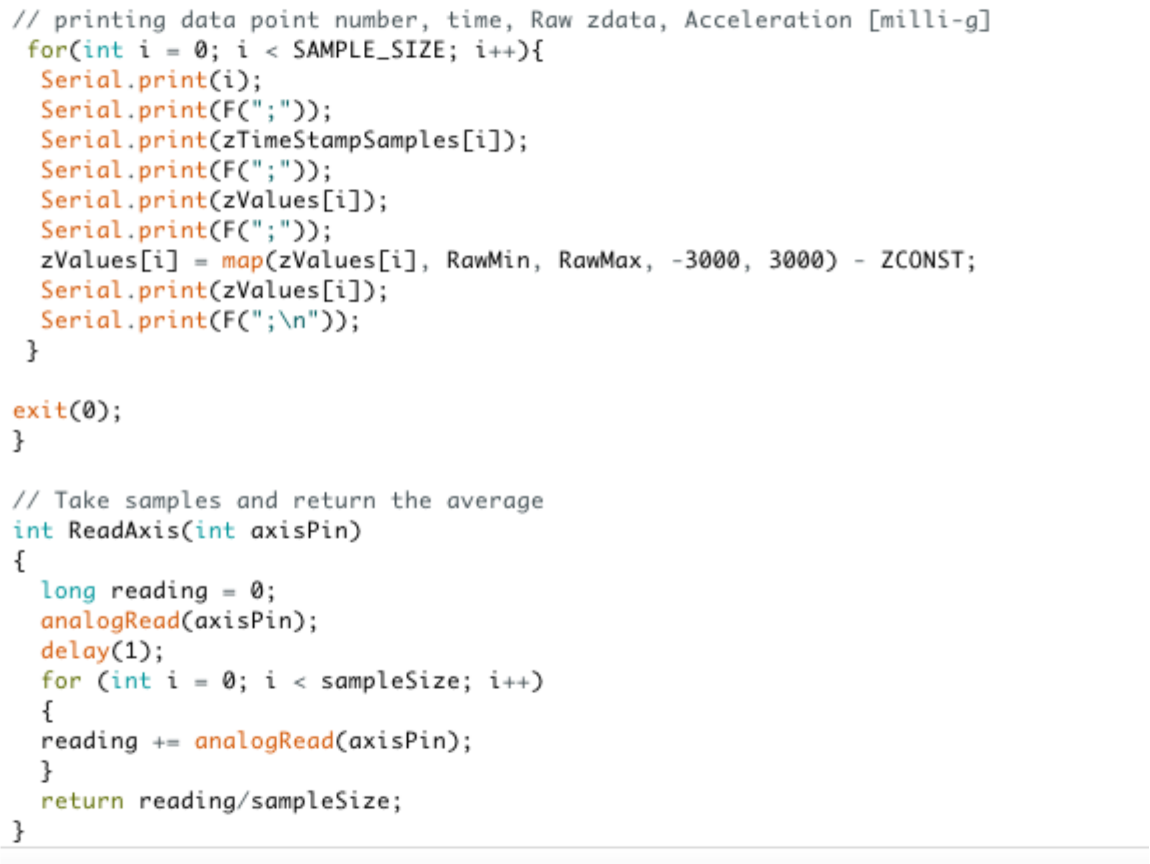
Walter Products 3-Part Ear Model - Teaching Supplies, Biology Classroom. (n.d.). Retrieved August 29, 2020, from https://www.fishersci.com/shop/products/walter-products-3-part-ear-model-3-part-ear-model/s07146

Wang, X., & Gan, R. Z. (2016, January 19). 3D finite element model of the chinchilla ear for characterizing middle ear functions. Retrieved October 18, 2020, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4955651/

World Health Organization (WHO). (2020). Estimates. Retrieved 29 August 2020, from https://www.who.int/deafness/estimates/en/

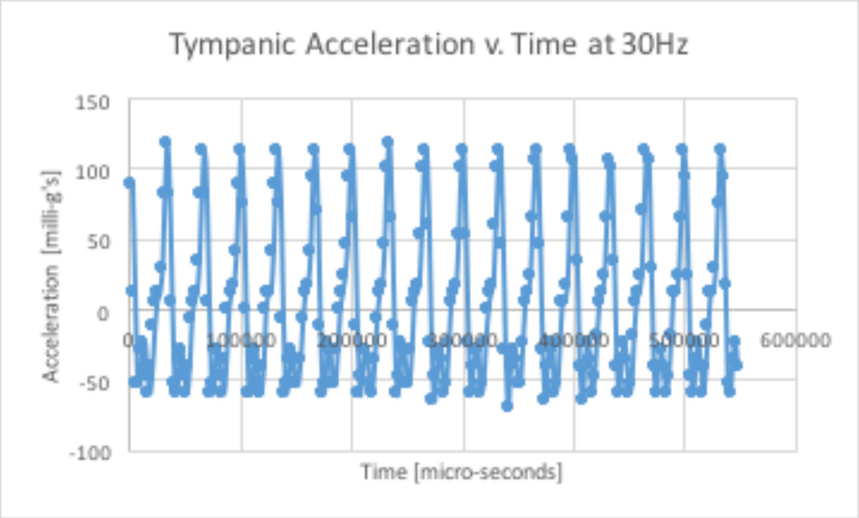
Appendix A: Arduino Code

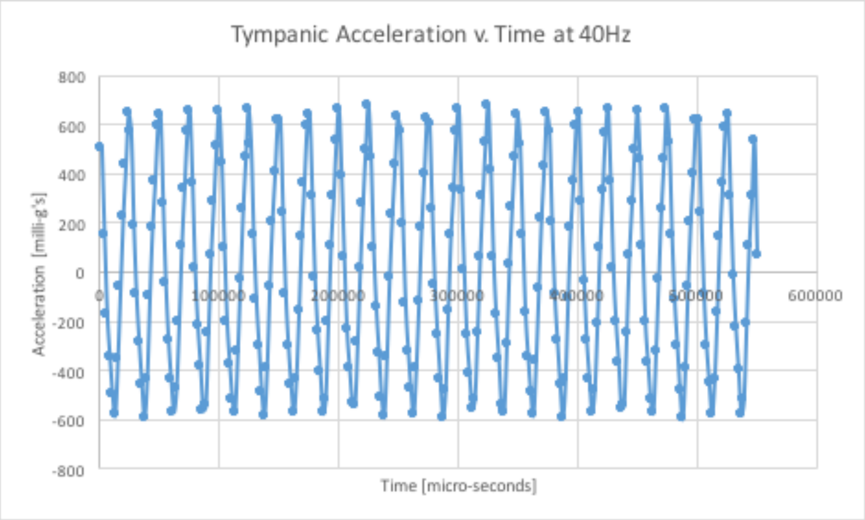
```
// define the pins used on Arduino
const int xInput = A0;
const int yInput = A1;
const int zInput = A2;

// initialize minimum and maximum Raw Ranges for each axis
int RawMin = 0;
int RawMax = 1023;

// Take 1 samples to increase smapling speed (there may be increased noise)
const int sampleSize = 1;


// define amount of data collected (size of the array)
const int SAMPLE_SIZE = 250;
unsigned long zTimeStampSamples[SAMPLE_SIZE];
signed short int zValues[SAMPLE_SIZE];

// the z value from accelerometer when it is not moving (used for calibration)
signed short int ZCONST = 618;


void setup()
{
  analogReference(EXTERNAL);
  Serial.begin(115200);
}

void loop()
{
▯
 // Creating an array of the raw zdata and time
 for(int i = 0; i < SAMPLE_SIZE; i++){

 unsigned short int zRaw = ReadAxis(zInput);
 unsigned long ztimestamp = micros();

 //zRawSamples[i] = zRaw;
 zValues[i] = zRaw;
 zTimeStampSamples[i] = ztimestamp;
 delay(1);
 }
```

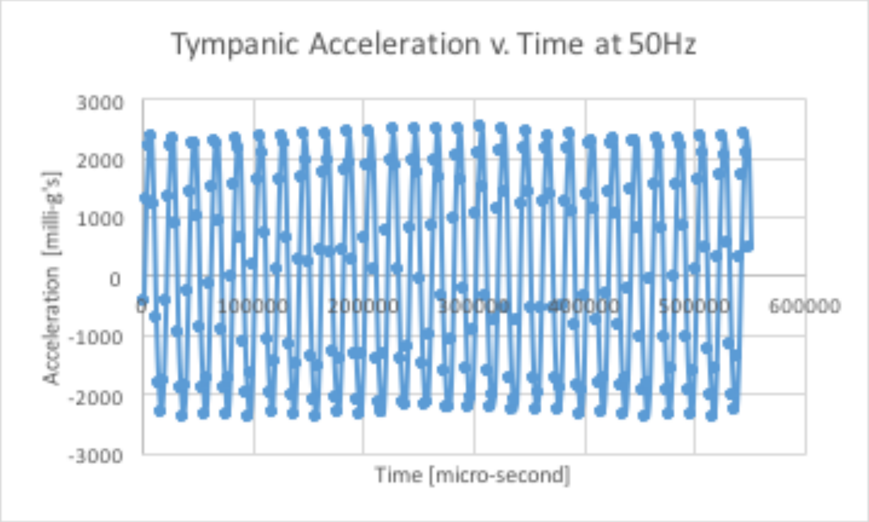


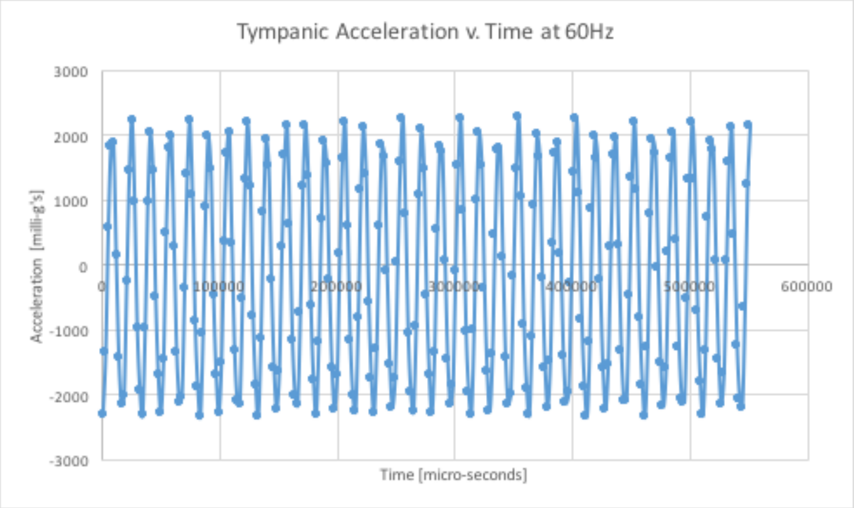
```
// printing data point number, time, Raw zdata, Acceleration [milli-g]
 for(int i = 0; i < SAMPLE_SIZE; i++){
  Serial.print(i);
  Serial.print(F(";"));
  Serial.print(zTimeStampSamples[i]);
  Serial.print(F(";"));
  Serial.print(zValues[i]);
  Serial.print(F(";"));
  zValues[i] = map(zValues[i], RawMin, RawMax, -3000, 3000) - ZCONST;
  Serial.print(zValues[i]);
  Serial.print(F(";\n"));
 }

exit(0);
}

// Take samples and return the average
int ReadAxis(int axisPin)
{
  long reading = 0;
  analogRead(axisPin);
  delay(1);
  for (int i = 0; i < sampleSize; i++)
  {
  reading += analogRead(axisPin);
  }
  return reading/sampleSize;
}
```

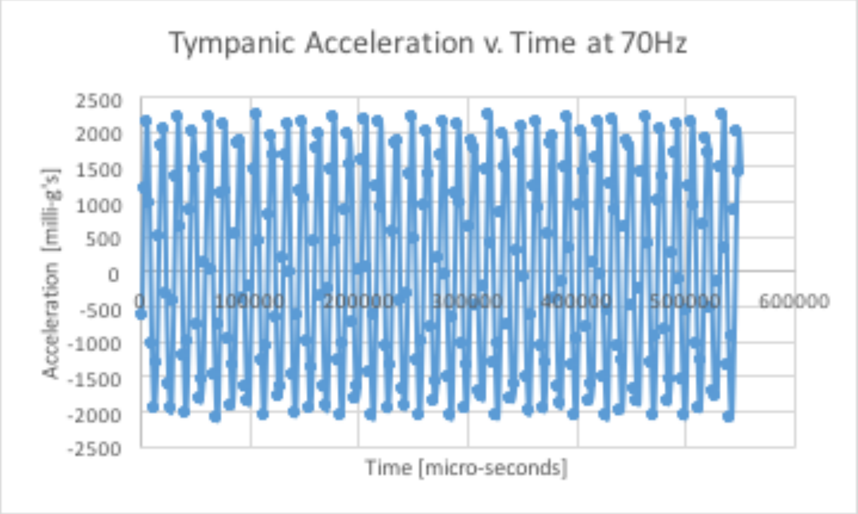
Appendix B: Tympanic Membrane Data

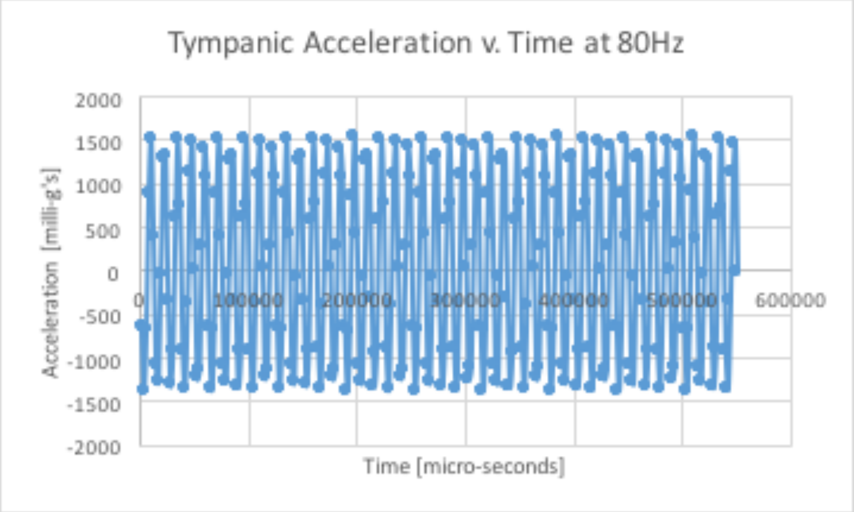


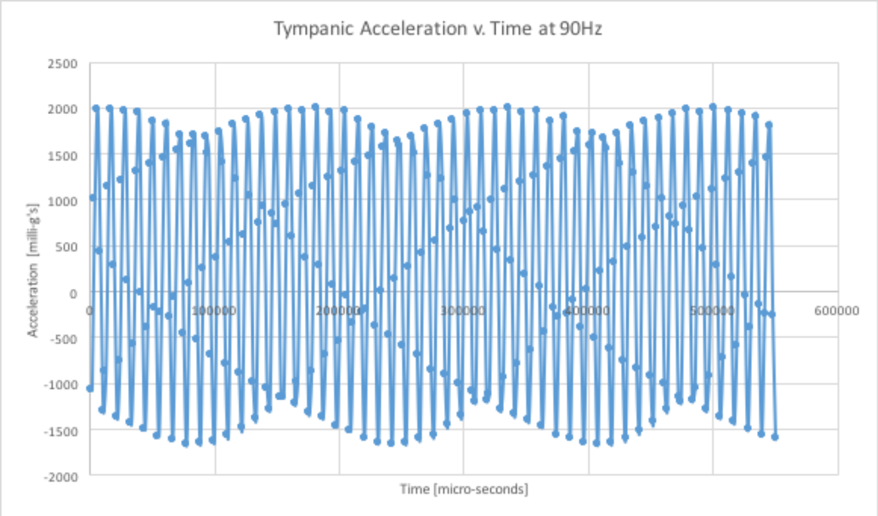


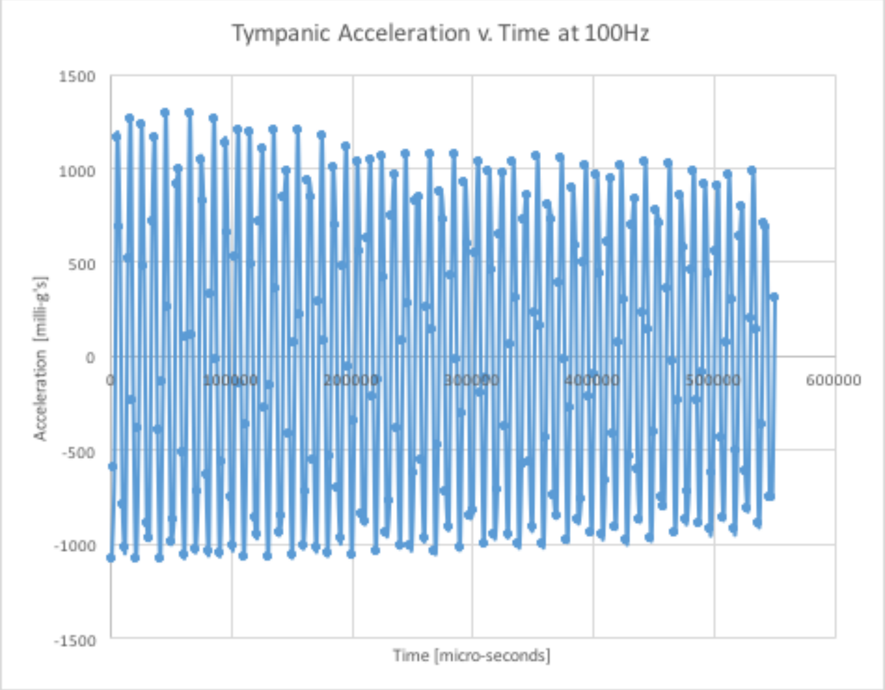



Tympanic Acceleration v. Time at 60Hz
3000
2000
1000
0
-1000
-2000
-3000
Acceleration [milli-g's]
0
100000
200000
300000
400000
500000
600000
Time [micro-seconds]

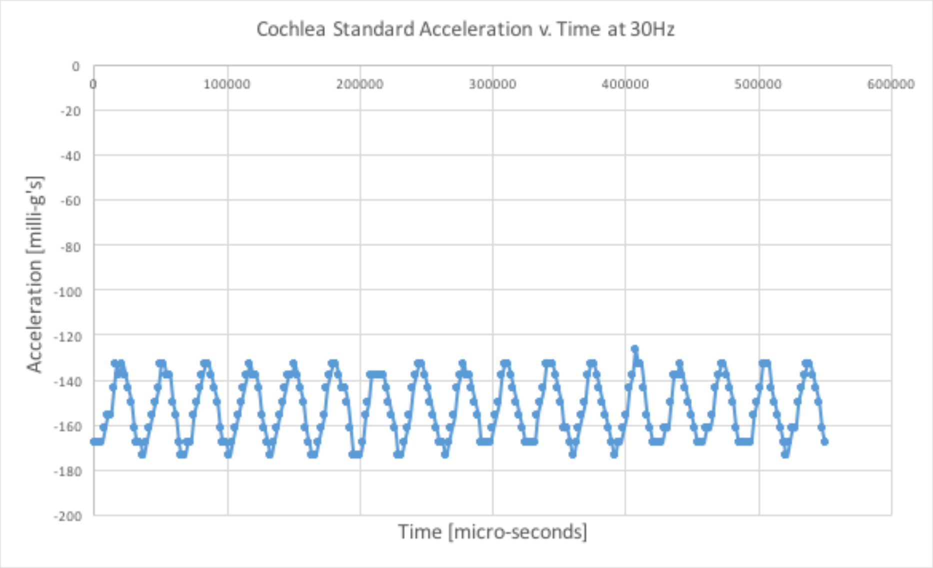

Tympanic Acceleration v. Time at 70Hz
2500
2000
1500
1000
500
0
-500
-1000
-1500
-2000
-2500
Acceleration [milli-g's]
0
100000
200000
300000
400000
500000
600000
Time [micro-seconds]

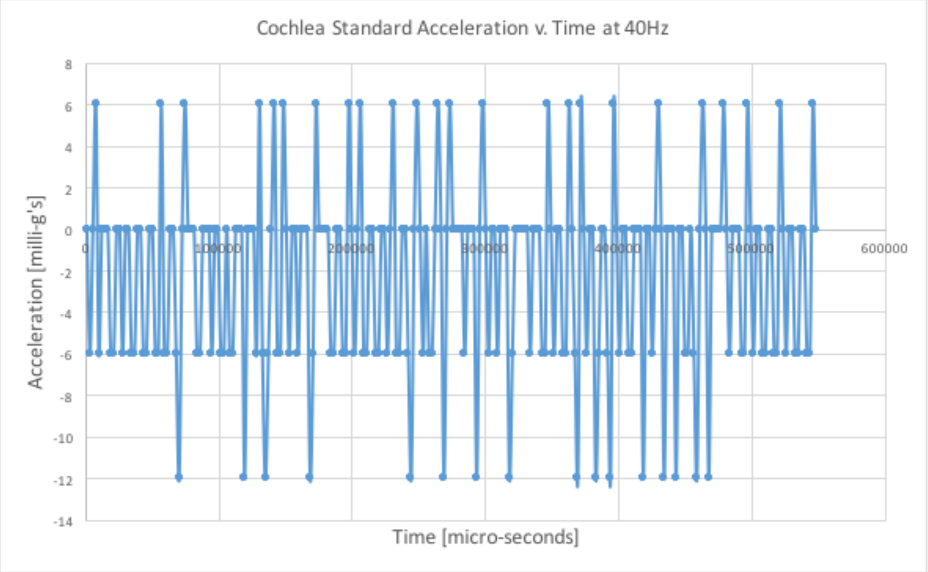

Tympanic Acceleration v. Time at 80Hz
2000
1500
1000
500
0
-500
-1000
-1500
-2000
Acceleration [milli-g's]
0
100000
200000
300000
400000
500000
600000
Time [micro-seconds]

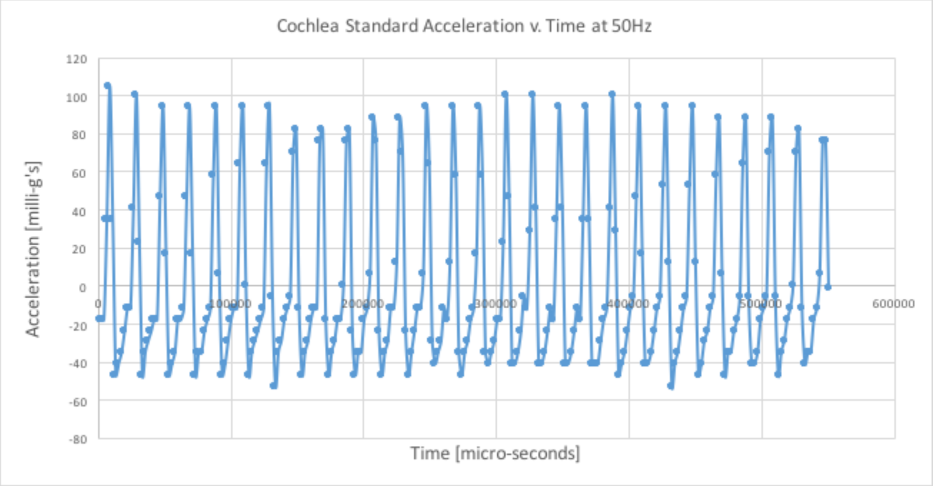

Tympanic Acceleration v. Time at 90Hz
2500
2000
1500
1000
500
0
-500
-1000
-1500
-2000
Acceleration [milli-g's]
0
100000
200000
300000
400000
500000
600000
Time [micro-seconds]

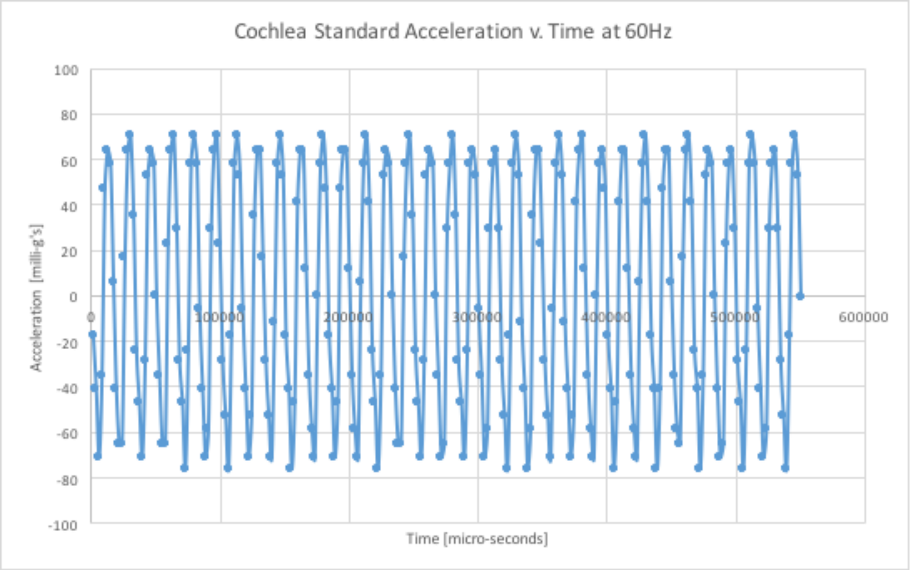

Tympanic Acceleration v. Time at 100Hz
1500
1000
500
0
-500
-1000
-1500
Acceleration [milli-g's]
0
100000
200000
300000
400000
500000
600000
Time [micro-seconds]

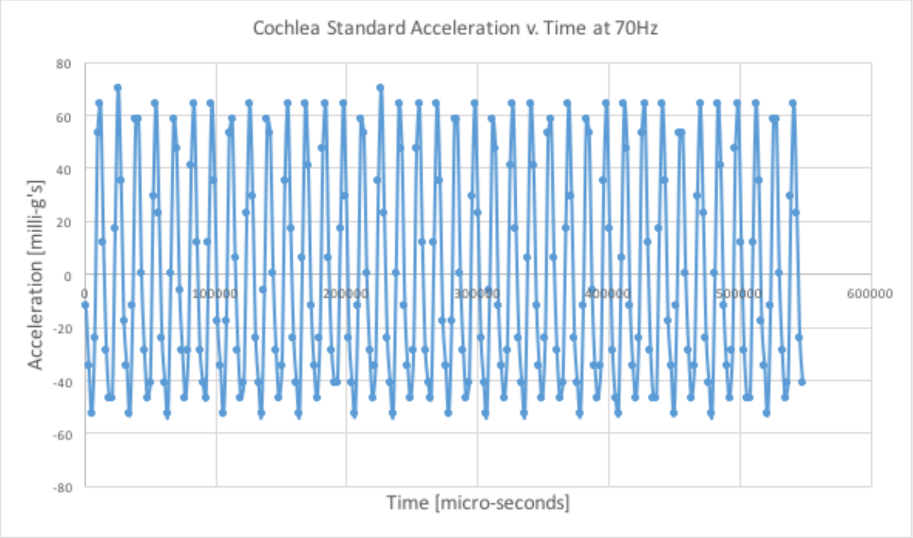
Appendix C: Healthy Cochlear Membrane Data

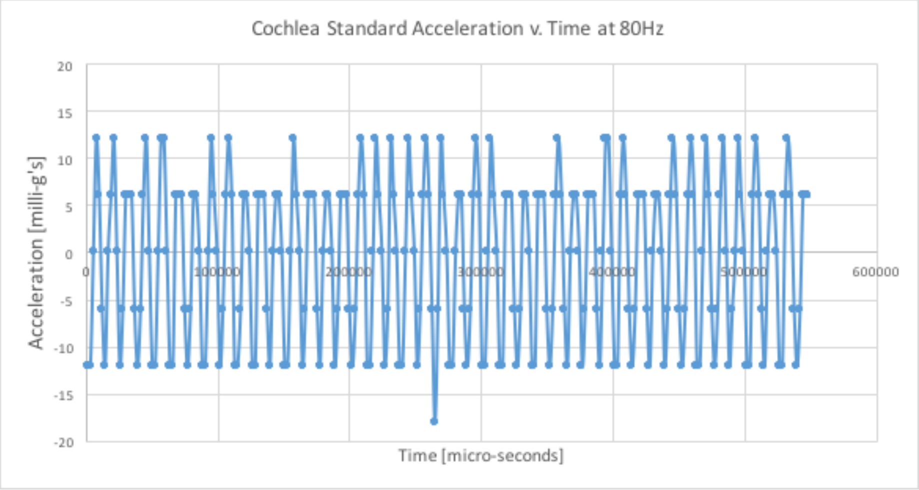


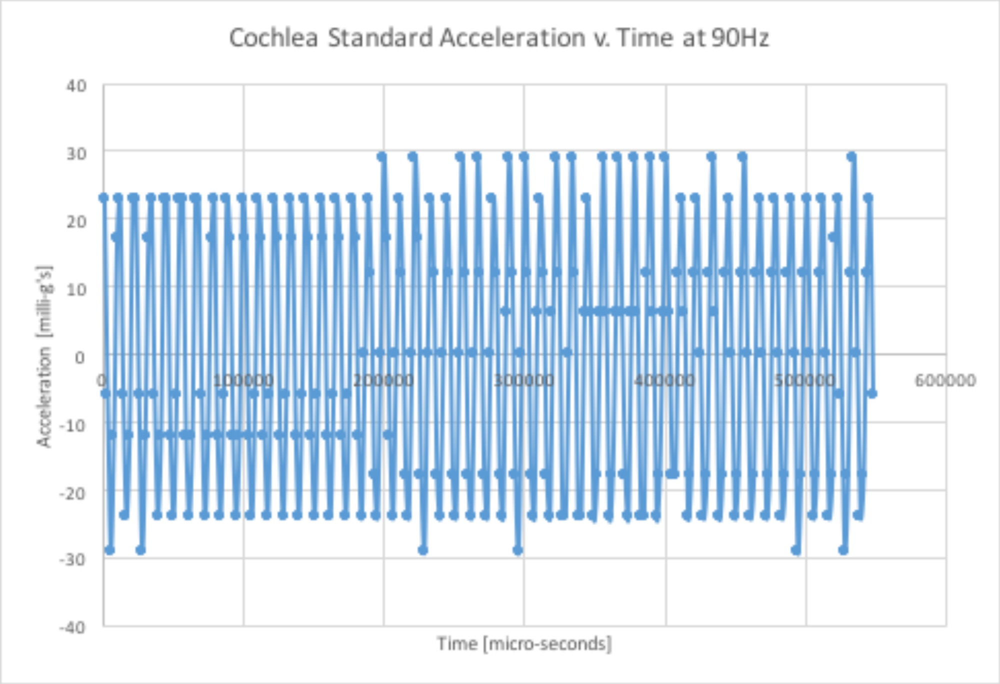


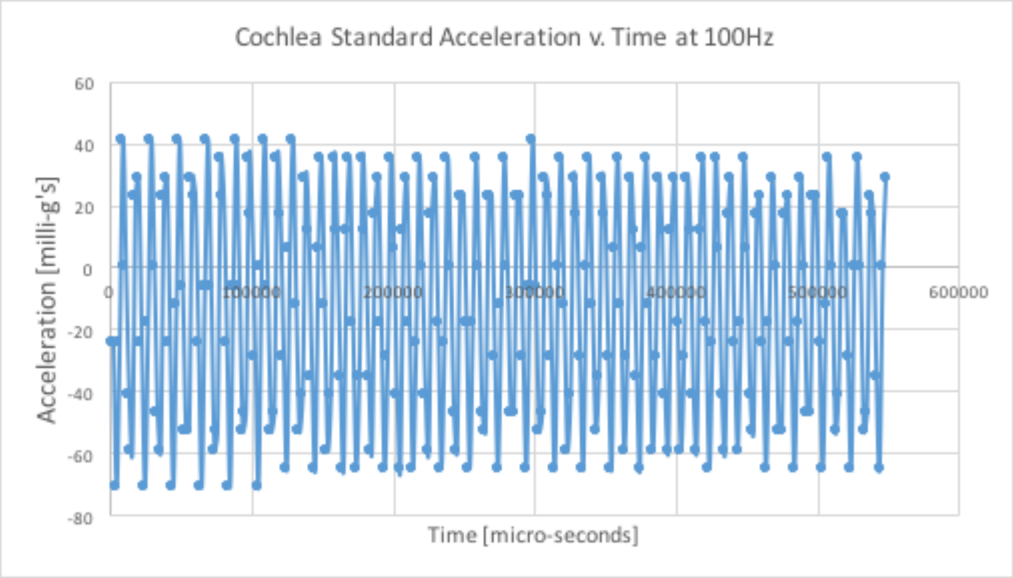



Cochlea Standard Acceleration v. Time at 60Hz
100
80
60
40
20
0
-20
-40
-60
-80
-100
Acceleration [milli-g's]
0
100000
200000
300000
400000
500000
600000
Time [micro-seconds]

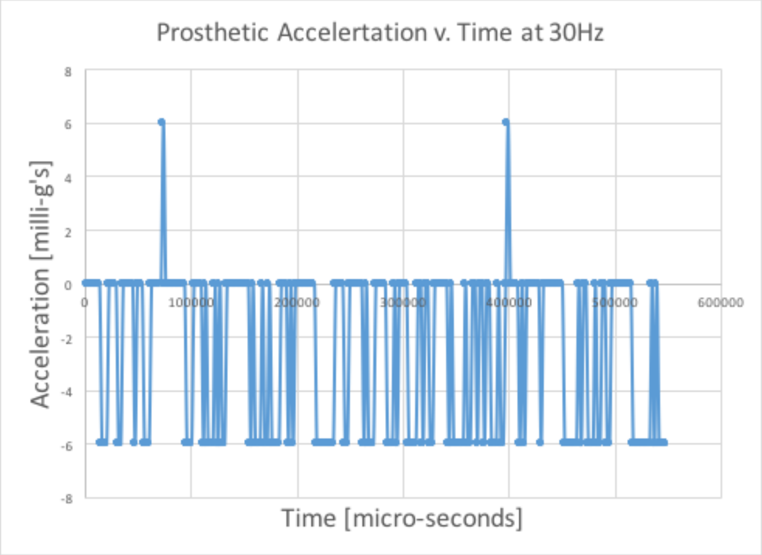

Cochlea Standard Acceleration v. Time at 70Hz
80
60
40
20
0
-20
-40
-60
-80
Acceleration [milli-g's]
0
100000
200000
300000
400000
500000
600000
Time [micro-seconds]

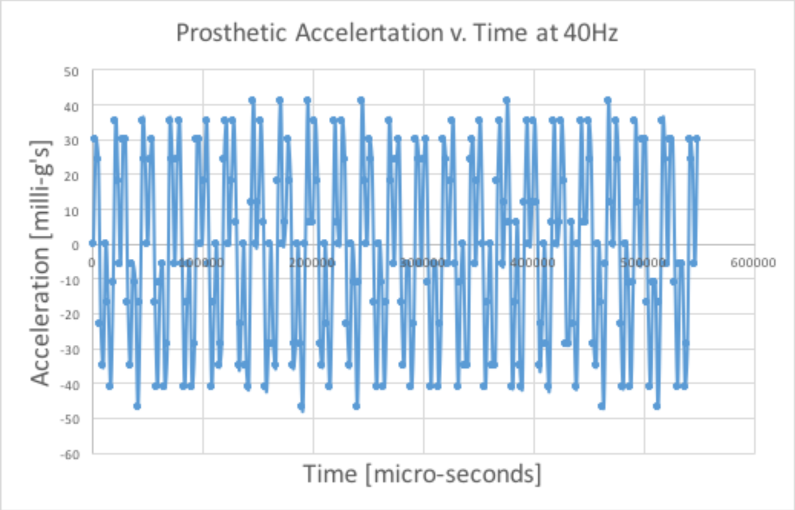

Cochlea Standard Acceleration v. Time at 80Hz
20
15
10
5
0
-5
-10
-15
-20
Acceleration [milli-g's]
0
100000
200000
300000
400000
500000
600000
Time [micro-seconds]

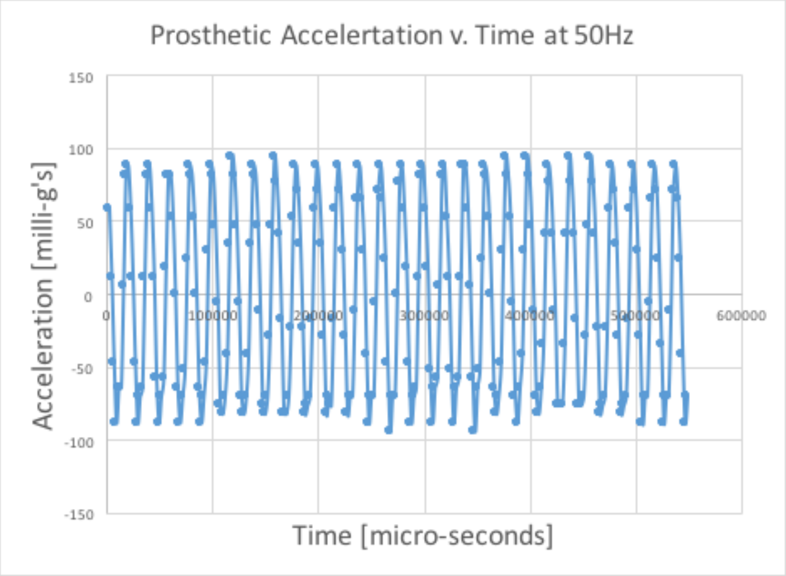

Cochlea Standard Acceleration v. Time at 90Hz
40
30
20
10
0
-10
-20
-30
-40
0
100000
200000
300000
400000
500000
600000
Acceleration [milli-g's]
Time [micro-seconds]

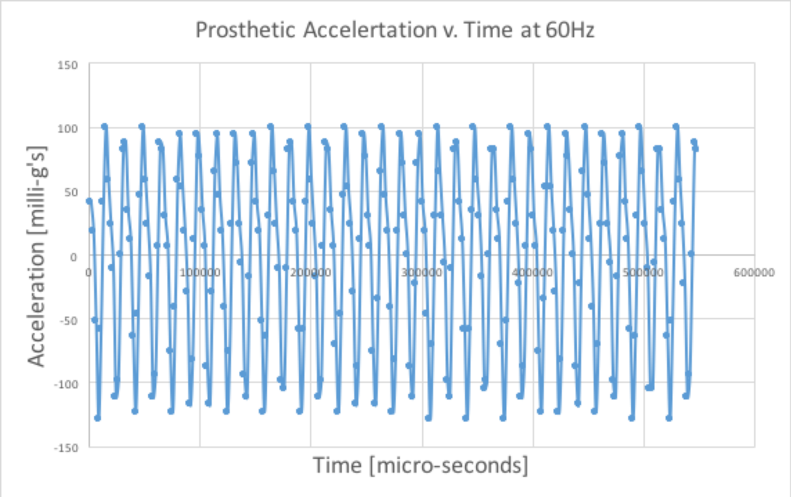

Cochlea Standard Acceleration v. Time at 100Hz
60
40
20
0
-20
-40
-60
-80
0
100000
200000
300000
400000
500000
600000
Acceleration [milli-g's]
Time [micro-seconds]

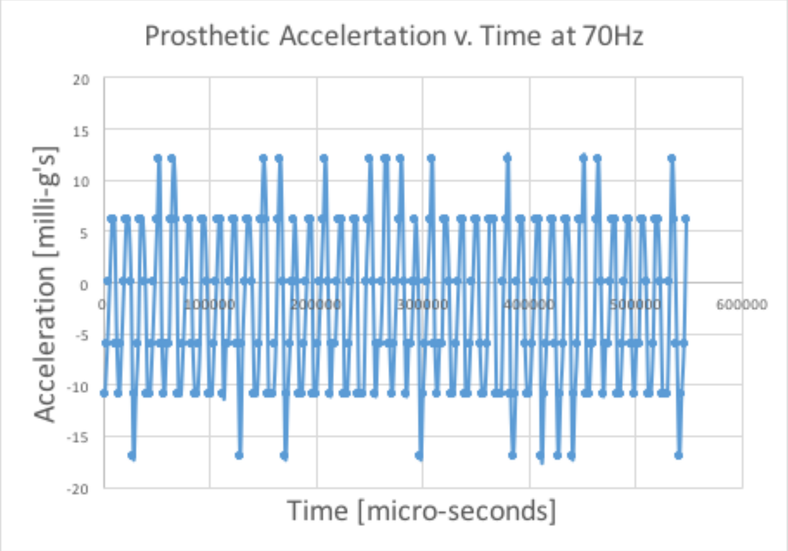
Appendix D: Prosthetic Cochlear Membrane Data

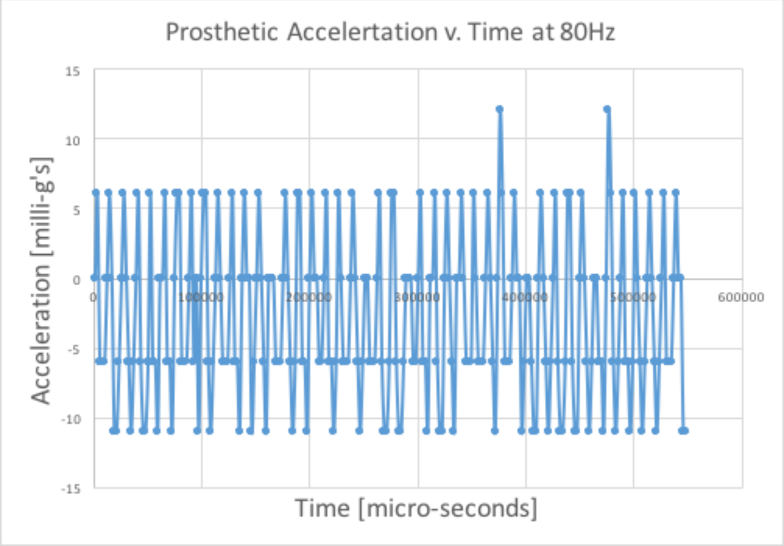


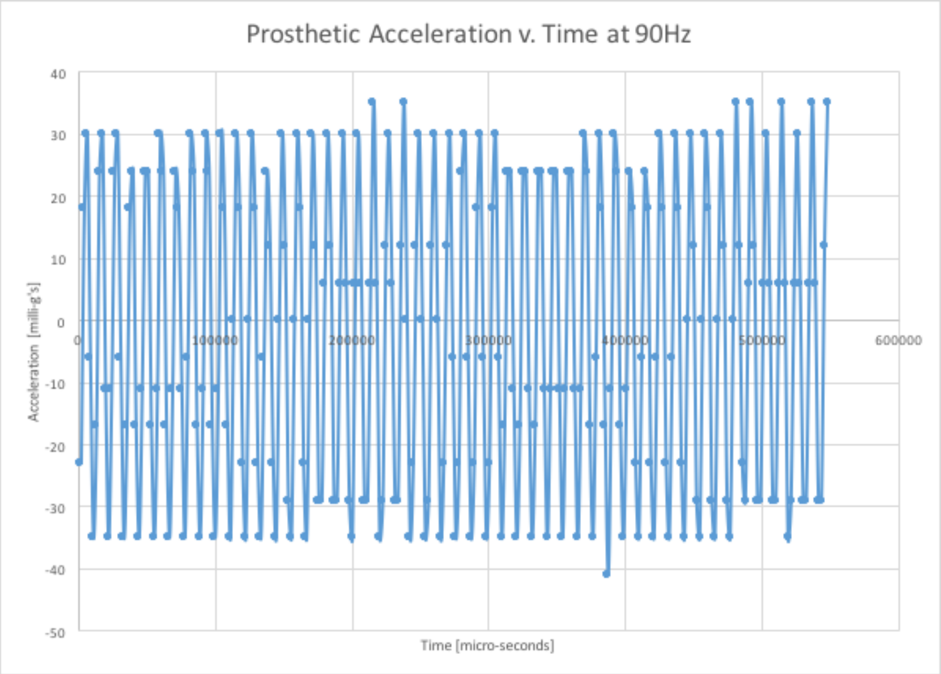




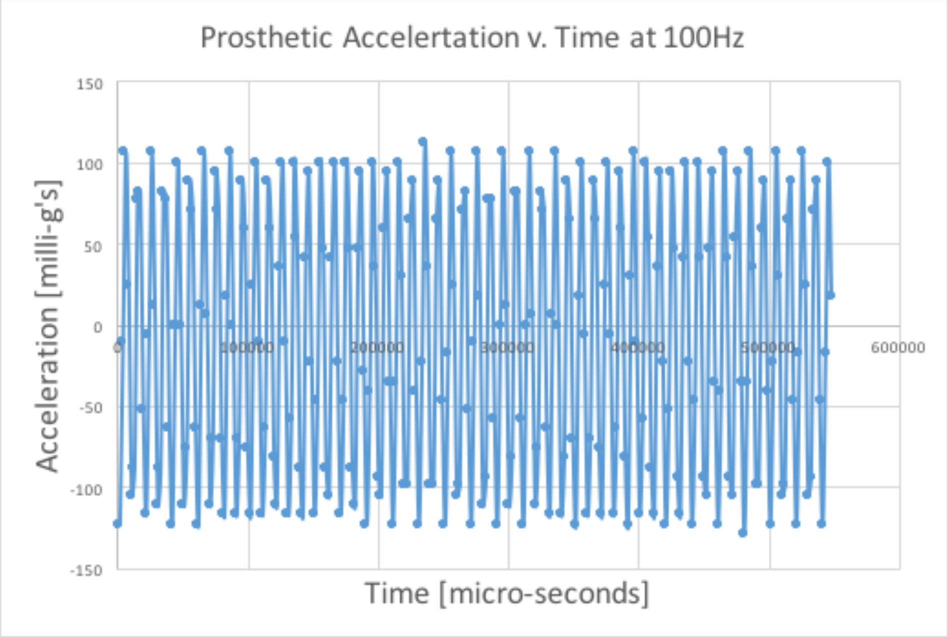

Prosthetic Accelertation v. Time at 60Hz


Prosthetic Accelertation v. Time at 70Hz


Prosthetic Accelertation v. Time at 80Hz



Prosthetic Acceleration v. Time at 90Hz



Prosthetic Accelertation v. Time at 100Hz

Appendix E: Force Test Raw Data

Mass applied (g)	ΔL (cm)
15 g	8.0
25	8.2
35	8.4
45	8.5
65	8.7
105	9.3
155	10.8
205	14.0
255	18.4
305	23.2
355	27.0
405	30.0
455	36.3
495	38.5
535	40.6
655	46.0
755	49.5
915	N/A

Appendix F: Model Assembly Instructions

Assembling the model will be simple and easy, and these instructions exist to help aid in the process. For the shipment of the model from Worcester, Massachusetts to Zurich, Switzerland, the entire design was deconstructed and packaged safely and securely into a box. Below is a list of materials included in the box:

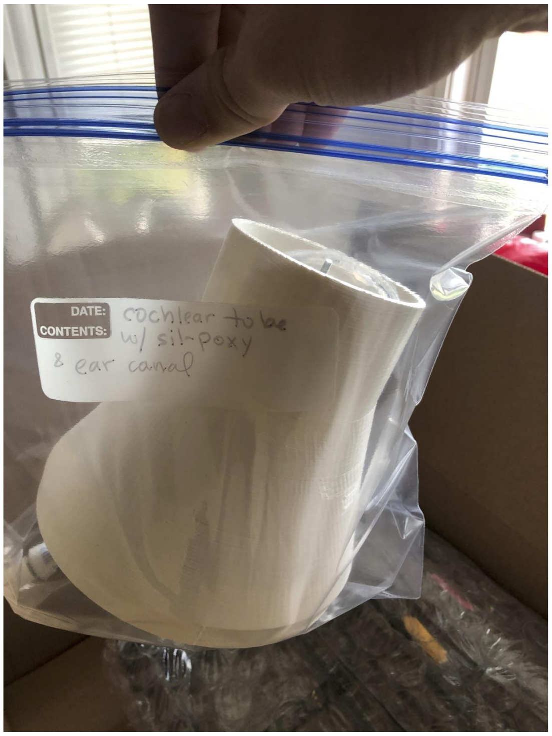
- The frame
    - Broken into 3 sections: top square, middle pillars, and bottom square
- The cochlear tube, ear canal, and additional silicone glue
- The cochlear tube stand
- Rubber bands to suspend the tympanic membrane
- Ligaments for the model
- Nuts and washers for the model
- The tympanic membrane
- A connected set of ossicles with joint material
- Malleus at 15 percent infill (x2)
- Malleus at 30 percent infill
- Malleus at 60 percent infill
- Malleus at 90 percent infill
- A set of ossicles with accelerometers attached
- Replacement Ligaments
- Replacement Joints
- Replacement tympanic membrane rubber bands
- Diseased stapes and prostheses
- Ossicular chain alignment
- Frame Hooks
- Replacements tacks for ossicles
- Replacement ossicle for membrane attachments

The Frame:

The two figures above show the frame with labels as it stands in its final configuration. One of the most important things when setting up the model is getting the correct rotational placement and locational placement of the different PVC pipes when assembling. The top and bottom squares of PVC were left intact as they easily fit into the box for shipping. They will clearly have labels, constructed using colored paper with tape folded over for easy and efficient removal, that show them as top and bottom.

These figures are all examples of how the labels look on the frame and how they relate to each other. The most important thing when setting up the frame is once all the PVC pipes are in the proper location, all the labels should be facing directly towards the person assembling the frame, as this will ensure proper orientation. The frame should be securely pushed together so that the model is stable and balanced when placed on flat surfaces. The frame has been bubble wrapped and placed into the box as shown in the figures below.

The Cochlear Tube, Ear Canal, and additional glue:

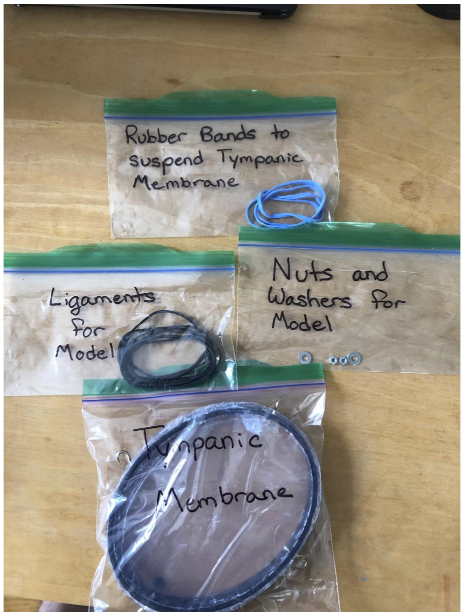


As shown in the figure above, the cochlear tube was packaged with the ear canal and additional sil-poxy. The cochlear tube rests in the cochlear tube stand, which will be discussed in the next chapter. To fill the cochlear tube with liquid, remove the cork and fill. Once filled, push the cork back into its original place to seal the tube. The ear canal, which is the white 3D printed part, connected to a speaker apparatus and the tympanic membrane. The additional sil-poxy was included in case either of the membranes peeled away from their attachments. Because the membranes are made from silicone rubber, a special glue was needed to allow the silicone to properly bond with substrates. Below will be a figure to show how this part was stored within the box.

The Cochlear Tube Stand:

The cochlear tube stand was a 3D printed apparatus that holds the cochlear tube in the proper place so that it is aligned with the stapes. The tube stands within the dimensions of the frame. Below is a figure to display how it was stored inside the box.

Rubber bands to suspend the tympanic membrane, ligaments, nuts, and the tympanic membrane:



The figures above show the different parts that were set out for the actual model. There are additional parts and replacement parts included in the package, but the group felt it was important to include a specific set that was counted out to be the exact number of parts to be used in the initial setup of the model. The blue rubber bands are used to suspend the tympanic membrane to the frame, which differ from the black rubber bands that are used to represent ligaments. There are four blue rubber bands to be used to suspend the tympanic membrane. The black rubber bands are used for the ligament attachments. The nuts and washers are used to connect the tympanic membrane and the cochlear membrane to the ossicles themselves. To connect the ossicles to the membrane, the order is bolt, washer, membrane, washer, and nut. This order is critical as the washers protect the membrane material from ripping or tearing. Finally, the tympanic membrane is a 3D printed ring with hooks drilled into it that allows it to attach to the frame. The tympanic membrane uses a silicone rubber material. All of these materials were wrapped in bubble wrap and placed into the box.

A connected set of ossicles with joint material:

Along with the materials above, the group provided a specific set of ossicles that are already connected that will be used in the initial setup of the model. The group chose to leave these ossicles connected to demonstrate the orientation and joint attachments to be easier for the initial user to set up. As this was one of the most delicate pieces in the box, it was bubble wrapped and set into the box as shown in the image below.

Malleus at varying infills:

One of the additional parts included in the box was a set of 3D printed malleus' at varying print infill. The specific infills are listed on the outside of the bags. As per the group's recommendations, these can be used to test different bone densities and the effects it has on the model. The figure below shows how they were placed inside the box.

A set of ossicles with accelerometers attached:

Above shows an image of additional ossicles that already have accelerometers attached that can be used to measure different vibrations throughout the model.

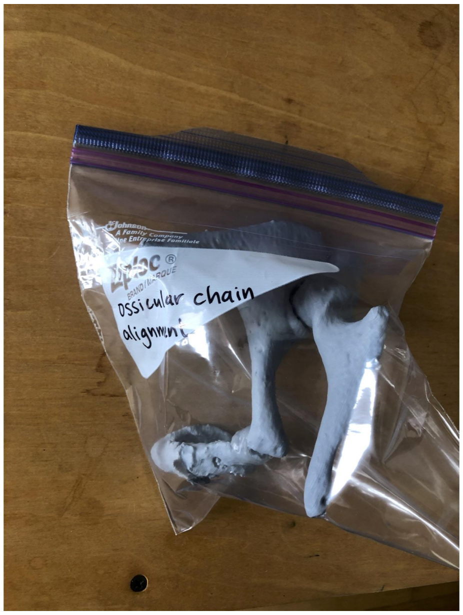
Replacement Parts:

The image on the left shows replacement tacks, hooks, and bolts. The tacks are used to hold the ligaments in place and these attach to the frame via the hooks. The bolts are used to screw the ossicles into the membranes. The image on the right shows replacement rubber bands, joints, and ligaments. The joints are wrapped in plastic wrap to keep them from sticking to each other.

Diseased stapes and prostheses:

The image above shows the diseased stapes and prostheses that are interchangeable within the model.

Ossicular chain alignment:



The image above shows the ossicular chain alignment that was used to set the three individual ossicles in the correct orientation. The group included it as an additional tool that could be used to help set up the model.

Finally, the images above show how the box and all the additional parts were packaged. They were wrapped totally with bubble wrap to protect the model during shipping.