

Final Report

Middle Ear Prosthesis - The “Gripper”

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Team 17

Shanoli Kumar

Meng Shi

Edward Corralez

Won Kang

Adam Good

Instructor: Alex Shorter, PhD

Sponsor: Karl Grosh, PhD

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EXECUTIVE SUMMARY

Our sponsor, Karl Grosh PhD, requires a “gripper” mechanism that will secure a sensor (accelerometer) to the incus bone in the middle ear using shape metal alloys. Our product will be used to conduct various tests in the bigger scope of researching a completely implantable hearing aid that will revolutionize hearing loss correction much like LASIK does to correct vision.

The stakeholders involved in our project are Karl Grosh PhD, his graduate research assistant Panagiota Kitsopoulos, our contacts at Michigan Medicine Emily Stucken MD and Christopher Welch MD PhD, individuals with sensorineural hearing loss, and the environment and regulatory agencies. Our contributions and Dr. Grosh’s work as a whole seek to create a societal impact in reducing disadvantages and stigmas surrounding hearing loss.

With these factors in mind, the following stakeholder requirements were generated after multiple consultations with Dr. Grosh and extensive research into the project. The requirements and corresponding specifications are listed: Secure the accelerometer to gripper (High Priority); support a mass of 10 mg. Secure gripper to middle ear bone (H); apply a radial force between 1.0 and 10.0 N, withstand axial and shear forces > 1.0 N. Fit within the volume of the middle ear cavity (H); have a length < 5.0 mm, diameter < 2.0 mm, and fit inside a 5.0 X 5.0 X 10.0 mm cavity. Biocompatible (H); hold up to ASTM F2063 and ANSI 62366 standards. Implantable through ear canal (Low Priority); has cross sectional area < 38.5 mm² and a Surgical Difficulty score of 0-3. Adjustable (L); clamp to bones ranging from 0.55 to 0.75 mm diameter. Resistant to environment (L); withstand pH range of 6.0 to 8.0, temperature 20 to 50 °C. Lightweight design (H); mass of < 10 mg. Manufacturable (L); the prototyping cost $< \$2000$, no custom tooling required, and a lead time < 2 weeks. Simplicity (L); the assembly requires ≤ 3 parts and is made of only one material.

In planning our timeline, we expect bottlenecking and challenges in some areas. First, we believe our prototyping process may prove to be difficult. We are currently planning to use nitinol wire, a medical-grade metal using a wire EDM process. This process may be difficult given the small size of our device and our little experience with the EDM process. The size of the ear cavity has also posed an issue with our 3D printing process. Given the types of printers available for our use and the accuracy of these printers, we have run into issues creating a 3D model and are now planning on creating a scaled-up version of the ear cavity. In regards to the design challenges, we expect to have issues determining solutions for the passage of the device through the ear canal and ensuring that the device only touches one ossicle.

Consequently, our project plan and timeline were outlined. The initial benchmarking, research, stakeholder interviews, design context/process analysis, and problem domain analysis were complete as of February 17, 2022. Our concept generation, 3D CAD models, preliminary calculations, and acquisition of materials were complete as of March 10, 2022. Our prototyping and testing stage included creating scaled prototypes at 17.5:1 and 5:1 scales were completed as of April 14, 2022. To do this we started with 3D printed scale models, and then moved on to wire EDM of nitinol to create a more accurate representation of our final product.

PROJECT INTRODUCTION

How the Ear Works

The ear consists of 3 parts: the inner, outer and middle ear. The tympanic membrane, also known as the eardrum, is the barrier between the outer and middle ear. The middle ear houses the malleus, incus and stapes bones while the inner ear houses the cochlea. In order for electrical signals to be sent to the brain via auditory nerves, sound waves must travel through the ear canal, hit the tympanic membrane, and vibrate the middle ear bones [1]. As the vibrations travel towards the inner ear, they increase in force. This means that the malleus vibrates the most and the stapes vibrates the least when comparing the three middle ear bones. Although the Stapes does not vibrate as much as the malleus, the force in the bone increases as the sound wave is passed through the middle ear. This increase in force is needed to transfer the energy of the sound wave to the tissue at the end of the ear called the oval window. Finally, the force will leave the air-filled cavity of the middle ear and enter the fluid-filled cavity of the inner ear. The focus of our project is to utilize our knowledge of the middle ear to design a prosthetic which attaches to one of the middle ear bones: the malleus, incus, or stapes. It is important to note that our project must stay within the middle ear; if our prosthetic touches the underside of the tympanic membrane it could lead to a foreign body reaction and issues in the ear.

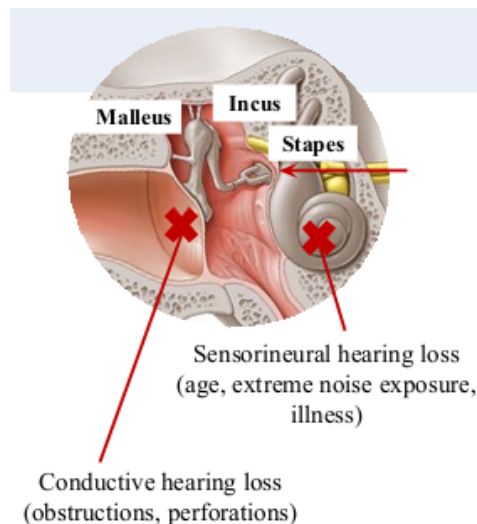


Figure 1. A labeled illustration of the outer, middle, and inner ear with associated hearing loss types [2].

Hearing Loss & Existing Solutions

An estimated 45 million adults are experiencing some form of hearing loss in the US alone [3]. There are two main types of hearing loss: conductive and sensorineural. Conductive hearing loss occurs when there is damage to the outer or middle ear. Sensorineural hearing loss is present due to damage in the cochlea. This sensorineural hearing loss can occur from age, extreme noise exposure, illness, and other issues.

Cochlear implants are the primary treatment for sensorineural hearing loss. They consist of internal and external components. External components include the microphone, battery, speech processor, external magnet, and transmitter antenna. The internal components include the internal magnet, antenna, receiver-stimulator, and electrode array. The way the implant works is the external microphone first picks up sound and converts it into an analog electrical signal. This signal is then sent to the sound processor which converts it from analog to digital. The digital signal is transmitted by radio frequency through the skin to the receiver-stimulator inside and is turned into rapid electrical impulses distributed to electrodes on an array implanted within the cochlea. The electrodes then stimulate nerve fibers in the cochlea which the brain processes as sound [4].

The main drawback to current cochlear implants is that they require external components which can cause social stigma, limit social activities (such as swimming), and limit the hearing period because they can't be worn while sleeping. These drawbacks motivate the need to develop a totally implantable cochlear implant (TICI), or a cochlear implant with no external components. There has already been some research done on implantable sensors for cochlear implants. For example, researchers out of Fudan University in Shanghai developed a floating piezoelectric microphone that attaches to the incus by clip and converts vibrations to electrical signals [5]. However, this microphone is too large to surgically implant; during testing, bones had to be removed from the cadaver to attach the sensor. Smaller sensors exist but have smaller bandwidths that limit hearing performance [6]. Thus, there is currently no microelectromechanical systems (MEMS) sensor that can both fit in the ossicular chain and pass all technical performance criteria. This is the problem that Dr. Karl Grosh, a professor of mechanical and biomedical engineering at the University of Michigan, hopes to tackle.

Nitinol (Shape Metal Alloy)

Nitinol (NiTi) is a shape metal alloy with “memory” temperatures ranging from room temperature up to 90°C depending on its composition. This makes it a useful alloy since extremely hot or cold temperatures are not required for restoring its “memory.” It has a wide range of applications including various biomedical uses including stents and implants [21] due to its low reactivity. Shape metal alloys “remember” their set shape due to the martensitic transformation they go through during the shape settling process. When a shape metal alloy is heated to the austenitic temperature (~500°C for nitinol), the shape is “remembered” or set in the crystal structure [22]. Then when it is cooled down to room temperature, the martensite phase can be manipulated into other shapes, but the crystal structure keeps its shape (crystal structure dimensions slightly change). At the instance enough energy is added (heat), the crystal structures restore back to their original dimensions, going back to the “memory” shape. The temperature required to restore memory varies as mentioned before.

Project Statement

The goal of Dr. Grosh's research is to develop a completely implantable middle ear sensor, utilizing MEMS technology to enhance auditory prosthesis by eliminating their external components without compromising hearing performance. This middle ear sensor package would couple an accelerometer to the force transmitting middle ear bones, having a miniscule volume

of 1 mm^3 , fitting entirely within the middle ear space without interfering with any structures such as the tympanic membrane. This is where the product's versatility comes into the picture. These vibrations must now be transmitted to the inner ear by some sort of driver in order to stimulate the nerves or amplify the sound, and depending on what the sensor is coupled with, this can be approached in multiple ways and solve multiple root causes of hearing loss [7]. In the case where the middle ear bones are functioning properly along with no obstructions within the middle ear, this sensor package can be linked with a cochlear implant to send auditory nerve implants and bypass any issue with a defunct cochlea, solving sensorineural hearing loss. On the other end, the cochlea can be in good condition, but particular middle ear bones can either be damaged or have experienced otosclerosis, an abnormal bone growth. In this case a hearing aid amplification can help deliver the amplified force onto the cochlear similar to how the middle stapes usually would. In addition to this versatility, this would allow for a much less invasive procedure, with surgeons being able to implant it directly through the ear canal.

This type of solution, if realized, would be similar to that of LASIK surgery for correcting vision disabilities. While LASIK is more invasive than traditional glasses, it can be used and adapted to solve multiple types of vision issues, such as near and farsighted vision, with ranging severity as well as providing a more permanent solution, providing continuous use and removing the maintenance issues that come with glasses or contact lenses. Similarly, the implantable sensor can be used for hearing loss with ranging severity while allowing continuous hearing and eliminating the inconveniences of an external device.

Thus far, the sensor package has been modeled and designed, and test protocols with commercial accelerometers have been verified. In order to proceed with accelerometer benchmarking, a robust way to secure the package to a middle ear bone is required. **The task given to us by our stakeholders is to design and fabricate a mechanism that will secure a $3.6 \times 3.2 \times 1.0 \text{ mm}^3$ accelerometer to the incus.** The design and manufacturing of tiny grips used in related ossicular replacement surgeries will be explored such as, as well as shape-memory alloys such as nitinol seen in Grace Medical's Megerian Nitinol Stapes Replacement Prosthetic (SRP) [4][7][8][9].

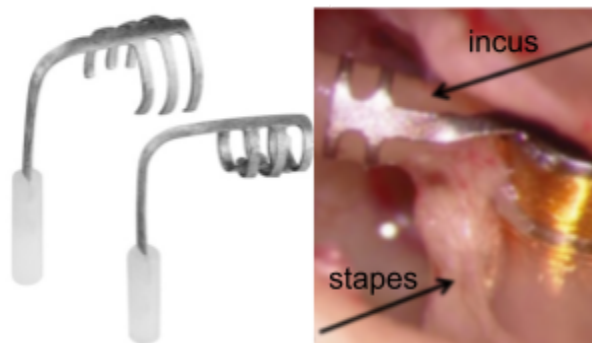


Figure 2. The Grace Medical Megerian SRP prosthesis shown in both open and closed configurations (left) and a similar implant secured onto the incus (right) [2].

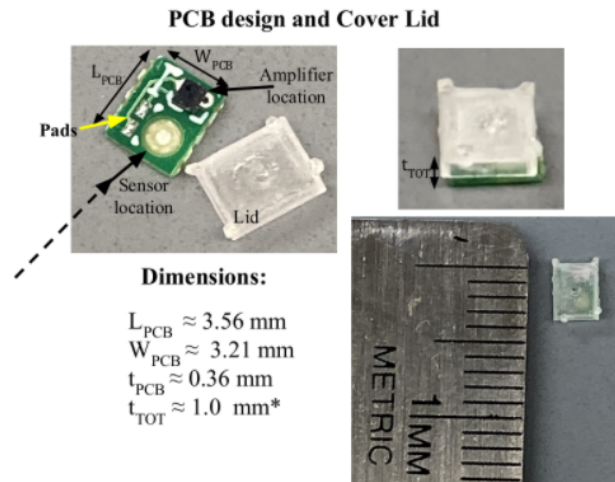


Figure 3. The sensor package (accelerometer) we need to secure onto the incus. The sensor is placed next to an incus sample and ruler for scale [2].

As laid out through communications with Dr. Grosh, a successful project would be a gripper that can attach itself to the surface of a middle ear while holding the accelerometer. Once secured, if the bone is excited by movement or vibrations, the gripper should also move faithfully with the bone without falling off. In addition, with the dimensions of the middle ear cavity in mind, it must be able to fit within these constraints as well.

Stakeholder Analysis

The broader implication of our project is the societal and health impact of improving the lives of individuals with hearing loss. According to the U.S. Department of Health and Human Services, an estimated 13% of all adults 18 and older suffer from some sort of hearing loss [2]. Our product will play a part in the overarching research to improve upon the current solutions for hearing loss such as external hearing aids. By talking with our project sponsor to better understand our project and using the Problem Definition learning block, we were able to make the stakeholder map which is shown below in Table 1.

Table 1. A stakeholder map visualization that outlines the different stakeholders based on their interest level and influence.

Stakeholder Interest	High	Keep Informed: <ul style="list-style-type: none"> ● Medical Faculty/ Surgeons ● Current solution manufacturers 	Manage Closely: <ul style="list-style-type: none"> ● People with sensorineural hearing loss ● Project Sponsor
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	Low	Minimal Contact: <ul style="list-style-type: none"> • Material suppliers (Nitinol producers) • Environment 	Keep Satisfied: <ul style="list-style-type: none"> • Regulatory agencies
		Low	High
		Stakeholder Influence	

As shown in the table above, there are many people and groups that have a stake in our project. The most important stakeholders for our project are people with sensorineural hearing loss and our project sponsor. People with sensorineural hearing loss are important stakeholders because they will ultimately be the end users for our product. Our project sponsor is an important stakeholder because they are the ones who are wanting to try to improve the existing solutions to sensorineural hearing loss and are who initially tasked us with creating the gripper between the middle ear bones and the accelerometer.

In addition to these important stakeholders, we will also need to consider the medical faculty, material suppliers, the environment and regulatory agencies whilst continuing with this project. It will be important to be in communication with the medical staff since our product will need to be surgically implanted, so we will need to make sure to keep them informed with how our device works in the human body. We will also need to consider the material suppliers. While this may not have a large impact on our design, it may affect the economic or environmental impact of our project. Lastly, we will have to consider regulatory agencies to make sure that our project is safe for use. Even though they may not have a vested interest in our specific project, the regulations in place may lead to large impacts on how we design our product.

One stakeholder who may be negatively affected could be companies that design and manufacture current hearing loss solutions. Companies that make currently used cochlear implants may be Supporters & Beneficiaries of the Status Quo. Since they are profiting off of the solutions that they already offer, they may not like a new solution being developed and offered to people with hearing loss. Even though this stakeholder group may be negatively impacted by our project, they will not impact our design since we believe this project has the potential to help a lot of people, even if it may impact the amount of business to a medical device company.

Intellectual Property

The intellectual property of this project belongs to the university and sponsor so that they can continue working on the project after this semester ends. This may impact the power dynamic between our project sponsor and our team if they are looking for a specific solution but we come up with an alternate solution. In that case, our sponsor may try to push us towards their solution so they can continue with the work after the semester ends. However, we don't anticipate this being an issue because of our good communication between our team and our sponsor, so we believe that we are in agreement with the direction of our project.

Design Process

The design process overview learning block introduced a large breadth of approaches in which we are implementing in order to reach the best design outcome. Structured design processes ensure the design best practices are incorporated to ensure high quality outcomes. While knowledge of the problem increases throughout the process, Design change cost and opportunities increase and decrease respectively.

From the ones provided, we chose to follow “The Design Process” provided in the Make: Magazine article [10]. Another major contribution to our thought process would be “The Waterfall Model of Medical Device Design” provided in the Models of Design chapter surveying a collection of design models, however it would be more apt to say we are following the iterative portions of it specifically, rather than focusing on user needs and medical device validation [11]. This is mostly due to the stage that the project is currently in; the user needs and overall problem have already been identified by our stakeholders, and the overall medical device and validation are still in preliminary stages. We are solely tasked with the fastening mechanism, so there is a focus on the iterative process of the design input, process output, and verification. With that in mind, back to “The Design Process”, with our specific problem identified, we will proceed to brainstorm and design potential mechanism solutions. From there we will build, validate, and redesign, continuing this iterative design until a final product is reached. With this being directly involved with a potential medical device, alongside the waterfall, another process we deemed as useful was “The Medical Device V-model”, once again focusing more on the validation in terms of needs and design constraints [11].

The introduction of the design process framework for ME 450 followed a similar trend to that of what was discussed of the waterfall model and Make’s design model. This framework begins with the need for identification and ends with the realization. However, these phases are usually out of scope. As mentioned in this project the need identification has already been given through stakeholder interviews, and while realization of the solution would be ideal, a high fidelity prototype that is validated may be the extent of progress. Make’s model itself similarly starts with problem definition and ends with an iterative framework. The waterfall model similarly has phases out of the scope of the work to be done within the timeline of the project, as benchmarking will proceed once this project delivers its solution. The major difference that comes up in the framework is the mindful incorporation of activities throughout each phase of the process. Some of these include stakeholder engagement, design best practices, context assessment, and inclusivity. These are important factors to consider and will be implemented in our design process in addition to the waterfall and Make model.

Following the concept generation and selection, the initial concepts will be narrowed down to a small selection of promising designs. From there we will apply our tailored design process made up from the discussed models, focusing on the iterative process. In practice, we will first finalize an accurate virtual model in order to validate the feasibility of the packaging and orientation of the remaining solutions. The best performing concept will then be used in a scaled up prototype to verify its performance according to our requirement and specifications. This process will be repeated in order to iterate to a final alpha design to be used in a high fidelity prototype.

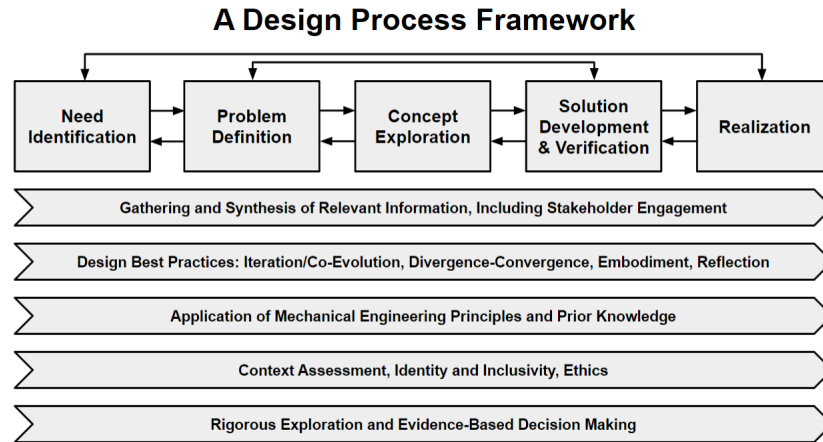


Figure 4. The ME 450 design process model.

Information Sources

At the beginning of the semester, our team met with librarian Joanna Thielen to help guide us in our approach to gathering information. We used library resources to help us to find credible sources about hearing loss, biomedical devices, and current solutions to sensorineural hearing loss. Our team decided to try and split up the work being done by assigning different areas for each member to research, and then sharing our findings with the rest of the team. Prior to meeting with the librarian, the sources we were finding were not as credible when we were doing our own research, so meeting with the librarian helped us to find better information to help guide our work.

STAKEHOLDER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

Based on the needs of our stakeholders and existing products, we developed the engineering requirements and specifications shown below in Table 2.

Table 2. List of our stakeholder requirements and corresponding engineering specifications ordered from most important (top) to least important (bottom) in each category. The high priority is highlighted in green, and the low priority is highlighted in yellow.

	Requirements	Specifications
Performance	1. Secure accelerometer to gripper	1a. Support accelerometer and housing combined mass of 10 mg
	2. Secure gripper to middle ear	2a. Can apply a radial force >50 mN 2b. Can withstand axial and shear force >

	bone	50 mN
Compatibility	3. Fit within volume of middle ear cavity	3a. Length < 5.0 mm 3b. Diameter < 2.0 mm 3c. Fit inside 5.0 X 5.0 X 10.0 mm ³ cavity
	4. Can be implanted through ear canal	4a. Cross sectional area < 38.5 mm ² 4b. Surgical Difficulty (SD) score of 0-3
	5. Adjustable	5a. Clamp to 0.55 < x < 0.75 mm diameter bones
Practicality	6. Lightweight	6a. Mass < 10 mg
	7. Manufacturable	7a. Prototyping cost < \$2000 7b. 0 custom tools 7c. Lead time < 2 weeks
	8. Simplicity	8a. Include ≤ 3 parts for assembly 8b. Made of 1 material

Performance

Both performance requirements, securing the accelerometer to the gripper and securing the gripper to the middle ear bone, are high priority. These requirements are important to our sponsor because they are trying to develop a way to secure their sensor to the middle ear bones. The specification about the radial force was created with a range because our product needs to be able to clamp hard enough to secure the accelerometer to the bone, but not so hard that it will damage the bone. Based on the tensile strength of the bones [13] and the dimensions of the incus bone [14], we determined that the maximum force that the bone could withstand would be about 40 N, so with a safety factor we hope to have our product grip with a force between 1.0 and 10.0 N. We developed the specification of being able to withstand an axial or shear force of greater than 1.0 N based on the pressure exerted on the ear by sound waves [15]. We were able to take the sound pressure level of the air waves and convert it into a pressure on the middle ear, and then we were able to find the force based on the area of the ear bones. In addition to being able to apply a 1.0 N force, our product also has to be able to support a mass of 10 mg since that is the mass of the accelerometer that our product will be attaching to the bone.

Compatibility

The three high priority requirements for compatibility are to fit inside the middle ear

cavity, biocompatibility, and implantation through the ear canal. Our product must fit in the operational space and must not have adverse effects to humans when implanted. Based on the size of the middle ear cavity and middle ear bones [16], we found that our final product should be smaller than 5.0 mm in length, 2.0 mm in diameter, and fit inside a 5.0 X 5.0 X 10.0 mm³ cavity. Our specifications to meet biocompatibility are outlined by two biomedical standards. ANSI/AAMI/IEC 62366 standard outlines guidelines and rules for designing and manufacturing medical devices. Specific guidelines of note to our product are identifying potential hazards, risk management, and intended use environment [18]. Our product also utilizes the use of medical grade nitinol which has standards outlined in ASTM F2063. The implant must be of specified chemical composition, metallurgical structure, and within a certain range of transformative temperature [19]. These standards were considered in defining our specifications to meet the stakeholder requirements. The specification to meet the ear canal implantation requirement is for the total cross sectional area to be less than the cross sectional area of the ear canal [16]. It must also have a surgery difficulty rating of 0-3.

The lower priority compatibility requirements are the ability to be implanted through ear canal, adjustability, and resistance to the environment. These are good design practices for the possible long term use of our product beyond our current scope. For the product to be adjustable, it must be able to clamp to a range of 0.55 to 0.75 mm. In terms of resistance to the human environment, the pH of different parts of the body can range from 6.0-8.0 pH [20] and the human body is always between 20-50 °C. Our product should be able to work inside that pH and temperature range.

Practicality

The high priority practical requirement for our project is to make our product lightweight. The incus is small and designed to only support minimal loads. In order to not cause discomfort to the user but enough to support the accelerometer, the mass of the product should be less than 10 mg. Another high priority item includes the manufacturability of the design. We would like to produce a true scale prototype, and we must be able to manufacture and assemble the product. Our project has a budget of \$2000 for the semester, so we should be able to create a wire prototype for less than that amount. In order to do that we are manufacturing the prototype ourselves and using a wire EDM process instead of using any custom tooling. In the future this should reduce the cost and improve the lead time.

A lower priority requirement includes the simplicity of the design. Since we only have a short time to work on this project, having a lead time of less than 2 weeks for all of our prototypes would be preferred. Also, we want to ensure that there are less than 3 parts for assembly and that our product consists of only 1 material.

Benchmarking

We also compared these requirements and specifications to already existing products. In particular, we looked at Megerian SRP. This product has a length ranging from 4-5 mm, and uses the same nitinol shape memory clamping that we plan to use in our project [20]. The SRP is a similar shape, performs a similar function, and abides by the same standards as our project so it

is a good baseline for our team to reference. The main difference between the SRP and our project is that we are trying to use the technology to attach an accelerometer to the incus as opposed to replacing the stapes. Even though the functions of the two products vary, the way they achieve their goals are similar.

Evolution of Requirements and Specifications

As we further explored the problem, coming across additional areas of concerns as well as getting a better idea about others, our requirements and specifications both shifted priority and saw additions. The sole addition was the requirement of being able to fit within the middle ear cavity. This is an extremely important consideration when moving into the concept generation phase, and was immediately added upon realization of its impact. Making sure that whatever the final design can fit within the middle ear cavity attached to the incus, without interfering or coming into contact with anything else is crucial. Impacts with the tympanic membrane for example is completely out of the question. Further exploring orientations and designs that could satisfy this became a huge priority initially and fueled the pursuit of virtual modeling.

After additions, the importance dynamic between the requirements were shifted a bit, still focusing on performance, but now highlighting the fit-focused compatibility requirements as well as manufacturability within the practicality category. This was to ensure a working concept with compromise to desired things such as a less invasive procedure or obstruction with other components, as opposed to the more secondary concerns of biocompatibility, since the material already satisfied that. Manufacturing came more into focus towards the end, as it became clearer that manufacturing and construction of the prototype was extremely difficult to do manually at the scale that had to be worked at.

CONCEPT GENERATION

Both the topic and sheer scale were unfamiliar to the team, so the application of tools and ideas introduced in the learning blocks used immediately upon brainstorming. Divergent thinking, the idea that there are multiple solutions to a problem that exist, was first used to emphasize coming up with a large number of ideas. Then the following guidelines for brainstorming were used: deferring judgment, encouraging wild ideas, building on the ideas of others, go for quantity, be visual. In this initial generation phase making sure that our critical filters were suspended in order to encourage out of the box ideas, ensuring quality over quantity was our main focus. While each concept may be obviously more apparent and feasible than others, on top of the fact that we were encouraged to follow the predetermined solution of shape memory alloys by our sponsors, we wanted to ensure that we gave every idea its due diligence in case something ended up being better. From this each team member came up with 20 concepts.

From there additional tools were used to generate another 20 individual concepts for a total of 40 each. First functional decomposition was used to better focus on generating concepts that directly addressed our most important issues. This decomposes the various functions and sub-functions of our product, and we took our problem statement as a base. Wanted to secure an accelerometer package to the incus through the ear canal, Figure 5 below shows how we broke it

down into our requirements for functions and specifications for sub-functions.

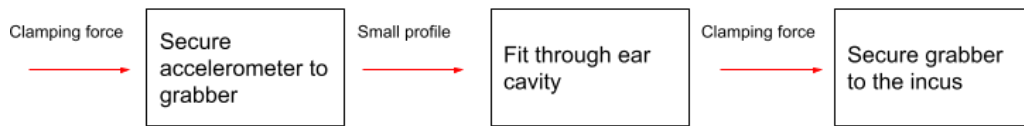


Figure 5. Function decomposition of our desired product

To top off our concept generation we then implemented design heuristics, a design ideation tool in order to further support variation and novelty in the concept generation. Design heuristics allow for rapid best guesses while not guaranteeing a determinate solution, promoting the generation of multiple, diverse ideas through repeated applications of different design heuristics. One that greatly influenced one of our final design choices was #76: utilizing opposite surfaces.

With all of these tools utilized, we generated a wide range of distinct concepts, mainly characterized by either the material or the method in which the mechanism fastened to the middle ear bones. The following five concepts regardless of their feasibility, from the appendix, highlight the variety of concepts generated.

1. A.2 Concept 5 Suction Cup: The accelerometer package is attached to a very small suction cup, which is stuck to the surface of the incus in order to secure the device.
2. A.2 Concept 8 Teeth Mechanism: The accelerometer package housing is modified in order to have a loop come out of it. Each end of the loop wraps around the bone, meeting and fastening through zip tie-like teeth allowing for one-way tightening.
3. A.1 Concept 9 Heat Shrink Sleeve: Place the accelerometer on the surface of the incus. Wrap and secure a biocompatible sleeve that is heat-treated and shrunk to proper tightness.
4. A.1 Concept 30 2 Piece Magnet: With the accelerometer package fastened to one of the two half circle pieces, the non ferrous pieces are attracted around the incus.
5. A.3 Concept 7 Glue: Simply using biocompatible glue in order to fasten the package directly to the surface of the bone.

With our 40 individual concepts generated, along with detailed and annotated sketches, we met as a group to highlight each of our top 10 concepts and further narrow down from there, starting with those initial 50 concepts.

CONCEPT SELECTION PROCESS

Taking our now 50 concepts, we categorized and separated our concepts into logical branches according to their materials. The main two branches were nitinol and non-nitinol materials. The nitinol branch was then further broken down into 3 subcategories depending on

the form type: wire, plate, and mesh. The non-nitinol branch was broken down into 2 subcategories based on attachment method: attach directly to bone or wrap around the bone. The following figure better visualizes the entire process documented in Appendix B.

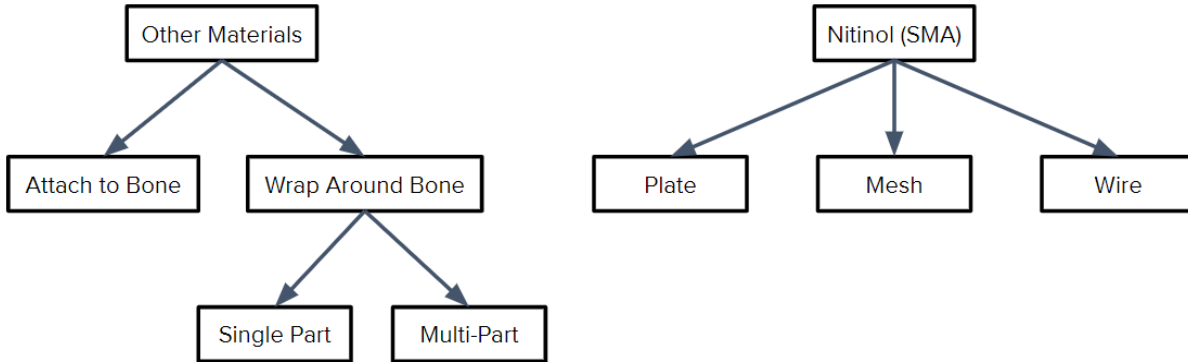


Figure 6. Classification tree used during design selection process.

Next, we combined, eliminated, and built off of similar ideas. Through this simple process, we were able to narrow down our concepts to about half of the original 50 ideas.

Finally, we evaluated each of the remaining designs on the basis of their ability to fulfill the stakeholder requirements. We realized that although some of the designs were very creative and unique, we were heavily constrained by the sheer miniature nature of our product. For example, all of the designs under the “other materials” branch had to be eliminated since they could not satisfy the requirement “implantable through ear canal” due to any manual crimping required. Other designs from the nitinol branch were eliminated on the grounds of not being able to satisfy the following requirements: “attach sensor to the gripper,” “attach gripper to bone,” “biocompatible,” “manufacturability,” and “simplicity.” We were left with 5 final designs- they are shown in the following figures.

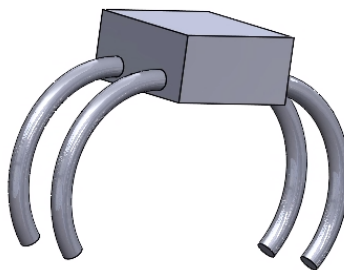


Figure 7. The “spider” design is made from nitinol wires. The legs are heated by the surgeon and close around the bone.

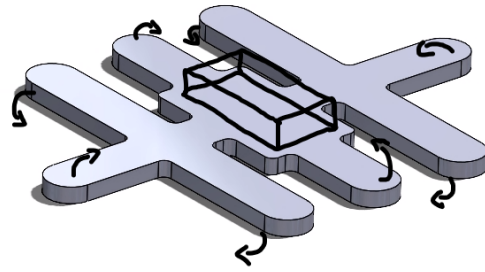


Figure 8. Gripper made from a nitinol plate (variation A). The legs are heated by the surgeon and close around the bone.

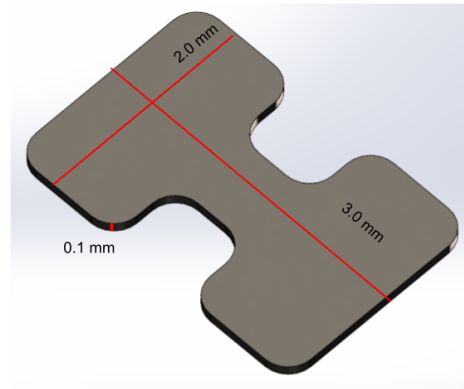


Figure 9. Gripper made from nitinol plate- simpler variation (variation B). The legs are heated by the surgeon and close around the bone.




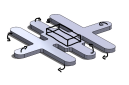
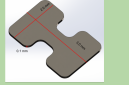


Figure 10. The “hook N’ loop” design is made from nitinol wire. The hook is threaded by a surgeon around the incus, then heated to close around the bone.



Figure 11. The mesh design is made from nitinol mesh. The mesh is heated by the surgeon and closes around the bone.

These designs were evaluated against important stakeholder requirements using a Pugh Chart.

Table 3. The Pugh Chart evaluates each of the designs based on functional requirements.

Requirement (weight)	“Spider” 	“Plate A” 	“Plate B” 	“Hook N’ Loop” 	“Mesh” 
Secure accelerometer to gripper (5)	0	-1	0	-1	-1
Secure gripper to middle ear bone (5)	0	1	0	0	0
Implantable through ear canal (4)	0	0	0	-1	0
Manufacturability (5)	0	-1	0	0	-1
Simplicity (3)	0	-1	0	0	0
Total	0	-8	0	-9	-10

As shown by the Pugh Chart, the “spider” design and the “plate B” design tied for the highest total score. The “spider” and “plate B” designs satisfy all the functional requirements with no major drawbacks. The “spider” design would be slightly easier to manufacture since

nitinol wire is more readily available and could be cut with wire cutters; the “plate B” design requires a rarer 0.1 mm thickness sheet and wire EDM machining. The “plate A” design would theoretically secure the gripper to the middle ear bone the best due to the multiple arm design, but its major drawback is that it would be impossible to manufacture given the size of our product. The “hook N’ loop” is the most unique design in that the surgeon has to thread the loop around the middle ear bone. Due to this feature, the downside is the difficulty of the surgery is increased (implantable through the ear canal). The “mesh” design will contour the shape of the middle ear bone the best. However, the mesh material for nitinol is hard to obtain at the fineness of the mesh required for the size of the product.

When we first started the project, we saw the industry example from Grace Medical (Figure 2) and imagined a design concept similar to our designs. Our final designs utilize the same principle of using a shape metal alloy “legs” to grab onto the middle ear bone. Our sponsor and our team did agree that a nitinol-based design would be a viable option since there was an industry example. This research space is very specific and working with a product of such miniscule size is difficult; the design selection process showed that a similar product to the existing solution was best.

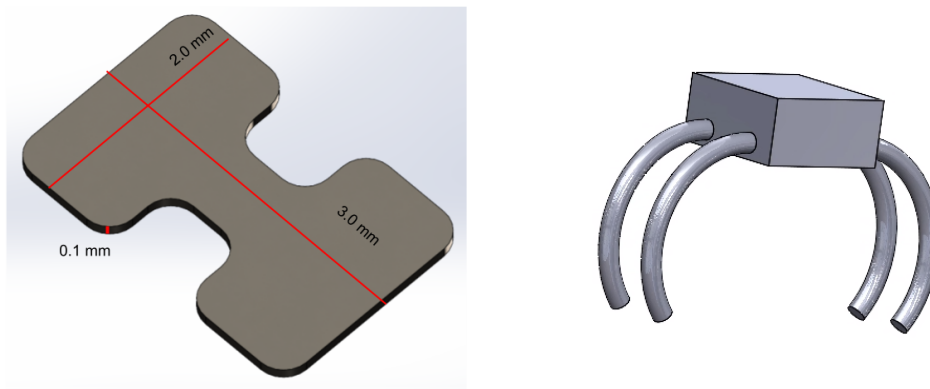


Figure 12. Two alpha designs with the “plate B” design on the left and the “spider” design on the right.

Plate Variation B Design

The “plate B” design is a 3.0 mm x 2.0 mm (± 0.05 mm) part made from 0.1 mm thick nitinol (45°C austenitic temp) sheet. The current plan is to manufacture the part using a wire EDM process. The product will then be formed around a 0.5 mm diameter stainless steel rod and set to a new memory shape in a furnace at 500°C. The gripper will then be carefully removed from the forming rod and glued with a biocompatible adhesive onto the accelerometer along its spine. Then the gripper will be installed on the incus by the surgeon using a cauterizer to heat and close the product around the bone. The following figure is a diagram of how the gripper functions.

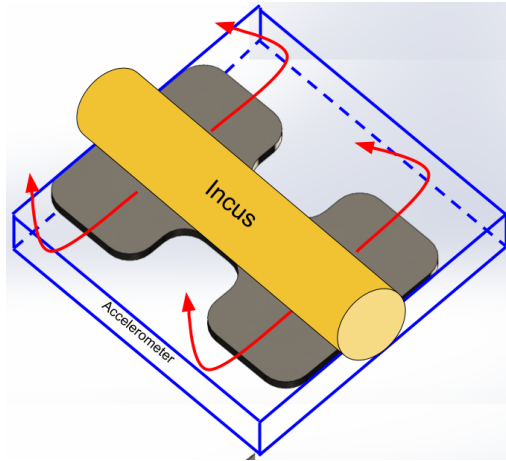


Figure 13. The “plate B” design secures the accelerometer to the incus.

Our sponsor did like this design, and they wanted a product that used shape metal alloys. Our objective selection process did consider other material designs, but all of them required manual crimping of some sort to secure the gripper. This is not feasible due to the small nature of the part; the non-nitinol designs were eliminated since they could not meet the stakeholder specifications. We were honest with our sponsor during our meeting, and we shared our concerns and logistics issues with the design. The design is well-defined with the material, thickness, diameter of curve, and dimensions on the CAD model. This will allow any FEA analysis to be performed for verification if needed.

The “Spider” Design

The “spider” design is composed of sets of “legs” made from 0.15 mm gauge nitinol wires. The number of “legs” can be varied, and further analysis will determine how many sets are required. The wires will be wrapped in a coil around a 0.5 mm diameter stainless steel rod and set to a new memory shape at 500°C. The wires will then be carefully removed from the rod and cut perpendicularly along the spiral so that circles with a cut would be created. These circles will then be glued with a biocompatible adhesive onto the accelerometer. Then the gripper will be installed on the incus by the surgeon using a cauterizer to heat and close the product around the bone. The following figure is a diagram of how the gripper functions.

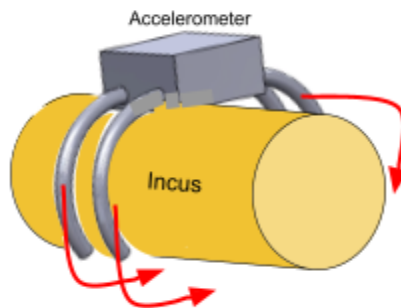


Figure 14. The “spider” design secures the accelerometer to the incus.

Our sponsor thought this was the most simple and creative design. Like mentioned before, the sponsor wanted the product made from shape metal alloys. Same with the previous design, we were honest with our sponsor with possible concerns and logistics issues with the design. This design is well defined with the gauge of the wire, diameter of the curve, and dimensions on the CAD model. This will allow any FEA analysis to be performed for verification if needed.

Concept Analysis and Iteration

Solid mechanics and material science are involved in the design of the gripper. The maximum strain the shape memory alloy can withstand is 5% before exhibiting plastic deformation. This, along with the required radius for the austenitic stage based on the incus diameter, dictates the required thickness of less than or equal to 0.15 mm needed for the gripper (Appendix C.1). Additionally, stress calculations will be necessary to ensure the stress the gripper exhibits will be below the yield strength of nitinol with a defined safety factor. Gripping force of the gripper onto the bone will also need to be calculated to ensure the gripper is stationary relative to the bone so the accelerometer performance will be as close to nominal as possible.

The quickest and easiest way to determine if the selected concept solution is likely to meet engineering specifications is to create a prototype of the gripper with representative dimensions and test how well the gripper stays on the bone (i.e. measure any rotational or translational movement relative to the original position). If there is movement, dimensional parameters will have to be adjusted until there is no movement.

FINAL CONCEPT DESCRIPTION

The final design is a three arm gripper machined out of stock nitinol plate. The total profile of the shape is 2x3mm. Each arm has a width of 0.5mm. The shape resulting from the machining process is highlighted below.

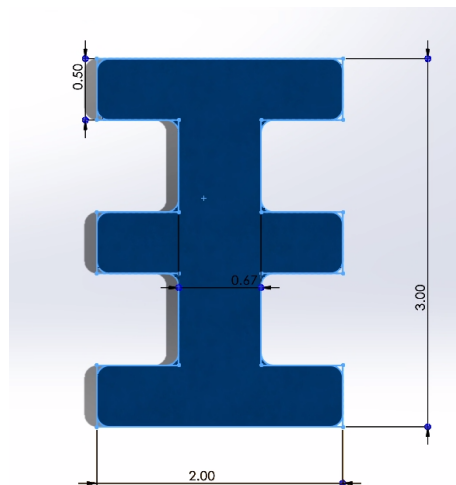


Figure 15. Three-arm gripper flat pattern machined out of nitinol plate.

After this stage of the manufacturing process is done, the piece will then go through heat treatments in order to set the new memory shape. This will be achieved by shaping and clamping the pattern onto a rod of a slightly smaller diameter of the average incus, 0.5mm. It will then cool and be unclamped, and slightly opened into a “relaxed” state.

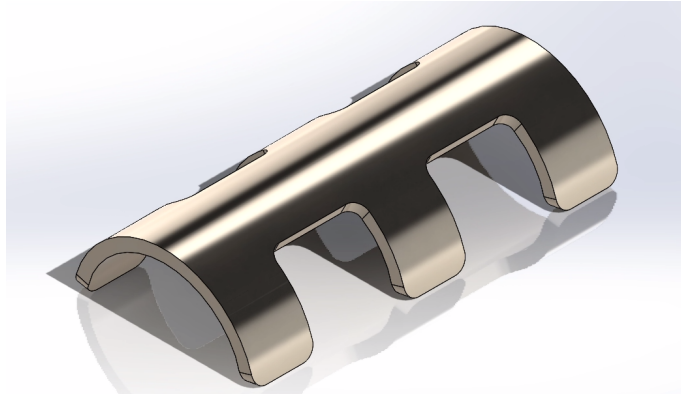


Figure 16. Heat treated three-arm gripper strained to a more open position.

The sensor package will then be secured to the back of the gripper through the use of biocompatible adhesive, ready for installation within the middle ear.

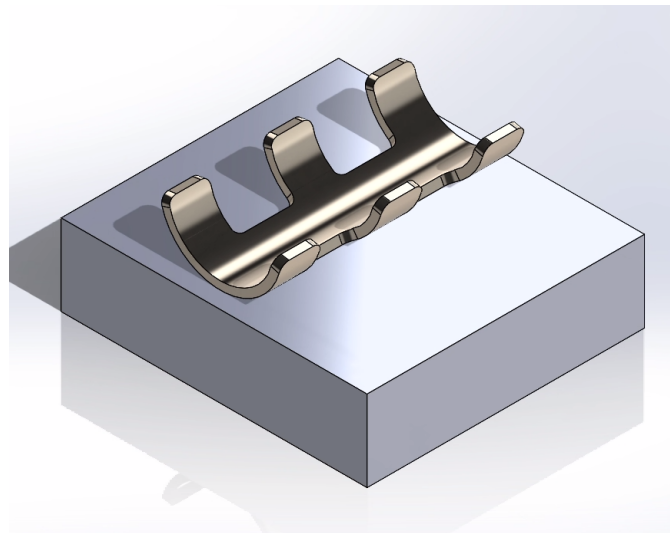


Figure 17. Heat treated three-arm gripper secured to the sensor package.

Finally, the gripper-sensor package is surgically implanted through the ear canal, following the movement of the tympanic membrane, into the middle ear cavity. The opened gripper will be fitted onto the lower, thin portion of the incus, and through the use of a cauterizer, the nitinol will be heated past its transition temperature. This will activate the memory shape of the gripper, closing tightly onto the surface of the incus, allowing for a secure and tight fit.

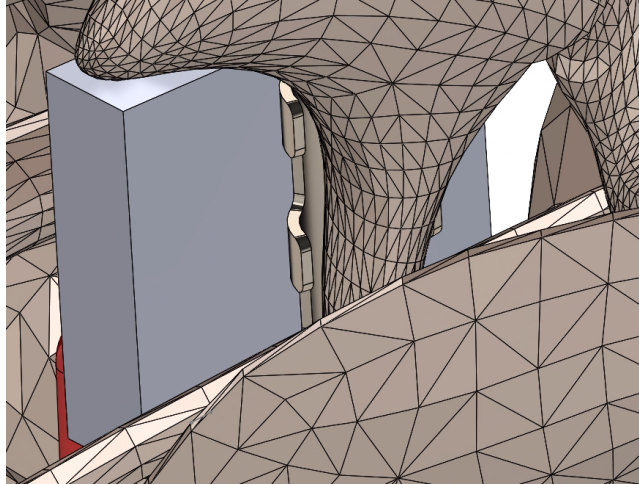


Figure 18. Three-arm gripper with sensor package placed around the diameter of the incus. Following the heat activation, it will securely grip around the surface of the bone, settling in the final orientation with the middle ear cavity.

The sensor will then be wired and coupled to a cochlear implant through the exposed side of the housing lid, as well as being connected to the power source. Moving faithfully with the incus, when sound hits the tympanic membrane and vibrations are sent down the middle ear bones, the sensor will accurately pick up those vibrations, and pass them along to the coupled device for processing in the inner ear.

ENGINEERING ANALYSIS

Our team has performed solid mechanics calculations, created 3D computer and printed models, and created physical prototypes in order to develop, evaluate, and refine our designs.

Maximum Thickness Calculation

We started our engineering analysis by performing solid mechanics calculations of the shape memory alloy to determine the required plate and wire thicknesses. Since nitinol can only undergo a 5% strain before it loses its shape memory, we needed to find a thickness that would allow for the metal to fully grip around the bone. The maximum thickness of the plate and wire was found to be 0.075mm and was determined from the calculations specified in Appendix C.1. We were able to use this calculation to guide our designs and material orders for the remainder of the project.

3D Virtual Modeling

After finding the thickness of the plate and wire, we updated the CAD 3D model of our designs. By creating our designs in CAD, we were able to then place the design into our model of the middle ear to make sure that it would fit within the space constraints of the middle ear without interfering with the rest of the ear.

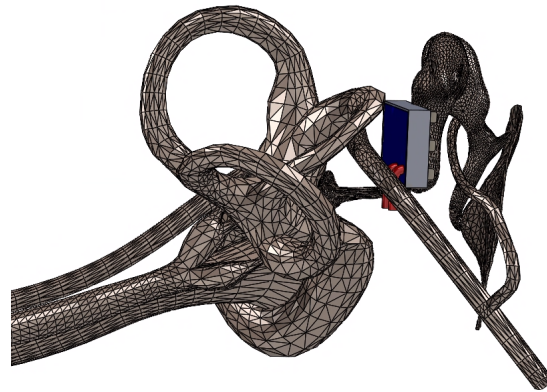


Figure 19. A 3D model of the middle ear testing the fitment of the package.

3D Physical Modeling

We then created a 3D printed version of the middle ear cavity and our design concepts that were all scaled up by X17.5. This allowed us to verify that our designs would be able to fit within the ear cavity, and support the accelerometer. By scaling the accelerometer along with our gripper designs, we were able to see that our designs are able to apply enough force to secure the accelerometer to the bone. Even though it was scaled up, we still believe that the experiment works as a good proof of concept of our designs before we moved to a 1:1 scale of our actual design. We then went on to create an actual 1:1 design to try and perform tests on the actual prototype. We formed the shape using wire EDM, heat treated the samples in a furnace, and attempted to form our final assembly. However, the nitinol samples fractured while we were bending it into its final shape. This fracturing was caused because the plate thickness that we had was greater than the thickness determined in the maximum thickness calculation. We were not able to order a thinner plate within our timeline or budget. We then moved on to a 5:1 scale model of our design so that our plate thickness would work. At this scale we were able to create a successful prototype that was able to be secured. While this prototype was still scaled up by X5, we still believe that a true 1:1 scale prototype would be successful if we had the correct materials.

FINAL DESIGN DESCRIPTION

Following the concept analysis narrowing down the selection to two alpha designs, we continued to iterate on both. Both initial alpha designs passed compatibility and practicality verifications utilizing virtual modeling and scaled modeling (physical experiment and analytical tests). The “spider” design utilizing nitinol wire was initially considered in a belief that it was simpler, however following the heat treatment process it was deemed too difficult to manually handle. The individual wire loops were too small to correctly position and adhere onto the back of the sensor housing. This led to the plate being set as the material to be used in the final alpha design, and was iterated into the final 3-Arm Grabber.

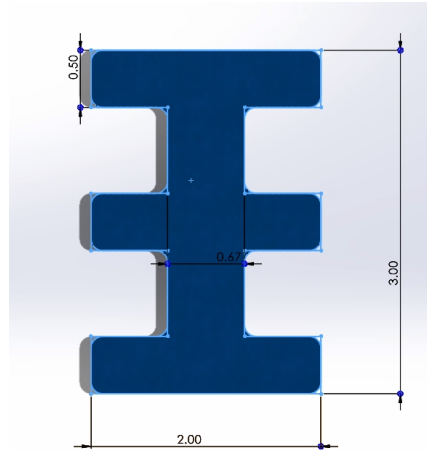


Figure 20. Final Design 3-Arm Gripper flat pattern design shown having a 2mmx3mm profile.

The final design takes on the pattern shown above in Figure 20, and it will grip onto the ear as shown in Figure 19. This piece will be machined out of our stock nitinol plate. It will then be heat treated around a rod with a diameter slightly smaller than the incus. The sensor package will be attached to the back of the gripper with biocompatible adhesive, and the arms will be slightly opened in order to fit and snap them over the incus. The tighter fit provides sufficient gripping force, of which we saw from the 7.5 scale prototype. We are confident that with how stiff the nitinol is, it will secure to the bone trying to return to its memory position, with us pursuing a to scale prototype in order to verify this assumption

With the minimum thickness for our use case calculated to be 0.075mm, the most feasible thickness we could obtain within the budget and timeline was 0.1mm. While this is greater than what our analysis yielded, we took a risk and attempted to continue with a to scale final prototype. Following the machining of the small grippers out our stock sheet, the pieces were taken to be formed around a steel rod slightly smaller than the average diameter of the incus. This process repeatedly failed as the flat gripper pattern would snap before it would fully conform around the rod.

Further iterations of the gripper introducing thinner and longer arms in an attempt to make the piece more malleable and withstand more deformation were machined, but none of these changes solved the issue. This was an anticipated challenge, and with our resources and tightening timeline, we made the final call that a 1:1 scale final prototype would not be possible.

We shifted our gears to a 2:1 scale prototype. This resulted in the same issue, so we shifted gears again to a 5:1 scale final prototype design. We were able to manufacture our design using 6-32 Stainless Steel nuts; we encased our prototype inside the stainless steel nuts in order for them to keep their shape when heated at 500°C. This resulted in a working prototype that we were able to validate. This prototyping process showed us that manufacturing a 1:1 scale prototype without custom tooling is not feasible. However, we also learned that wire EDM is a very successful way to create the shape of our gripper. In addition, the shape memory alloy of nitinol proved to be effective especially when tested in our verification stage.

We are confident that our final design prototype will work because there are a few currently existing devices that have similar concepts of gripping onto the bones with grippers. Ours is also using a biocompatible material. We underwent verification and validation testing to further determine if our design will work.

BUILD DESIGN

As shown in Figure 20, a CAD drawing was used to begin building our prototype. Depending on the prototype created, the measurements of the CAD were multiplied 2, 5, or 17.5 times. For the ear model, it was necessary for us to use a 3D printer. For the gripper prototypes, it was necessary for us to use a wire electrical discharge machining (EDM) machine, as shown in Figure 21. This design validated that the shape memory alloy property of nitinol could be useful in our gripper mechanism. It also showed the need for custom tooling and very precise prototyping instruments.

The final build design was a 5:1 scale prototype; this can not yet go into production, but it provides an informative insight on the design process and material properties of the future final prototype. Our build shows that the gripping mechanism works on a 5:1 scale. Due to the very small size of our design, we are confident that this will be able to translate to a 1:1 scale. Due to our build design, we are also able to understand that more consideration will need to be given to creating the bend in the prototype to enable the shape memory property of nitinol. We now understand that custom tooling is needed for this. In the future, to accurately represent the shape memory alloy property during surgery, a cauterizer will be needed to test a 1:1 prototype. Our build demonstrated the difficulty of such a small scale project and the necessary equipment needed in the future.

Bill of Materials

The table below highlights the materials that were used in order to create the 1:1, 2:1, 5:1, and 17.5:1 prototypes. This list also includes any items needed to aid in machining the prototype, such as the 6-32 Nuts. All of the prototypes were made in-house.

Table 4. Bill of Materials

Item Number	Item	Manufacturer	Part Number	Quantity	Cost Per Part (\$)	Total Price (\$)
1	0.1mm Nitinol Plate	KRL	P-NiTi-0.1-45	1	84.97	84.97
2	0.15 Nitinol Wire*	KRL	W-NITI-0.15-45	1	5.99	5.99
3	0.5mm Stainless Steel Rod*	Misumi	KRSSM0.5-50	1	68.33	68.33
4	Accura Xtreme White 200 SLA Material	NA	NA	1	0	0
5	Black PLA Material	NA	NA	1	0	0
6	6-32 Nuts	NA	NA	2	0	0
Total						159.29

Starred (*) items were not used in the final working prototypes.

Manufacturing Plan

The first step to fabricating a 5:1 scaled version of the plate gripper design is machining out the flattened shape. In this project, we used a wire electrical discharge machining (EDM) machine, as shown below in Figure 21.



Figure 21. Wire EDM machine.

Because the nitinol sheet maximum thickness is so thin, it needs to be sandwiched in between thicker plates to clamp into the EDM machine. Two 1.5 mm thick aluminum plates were used in this project, and the setup can be seen below in Figure 22.

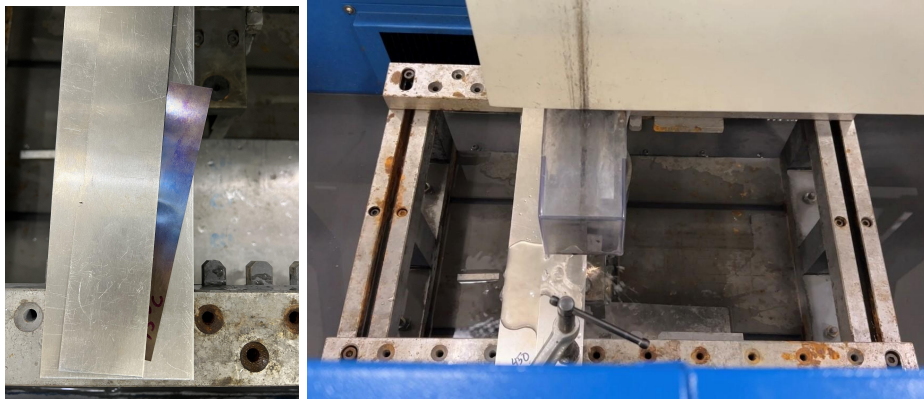


Figure 22. (Left) Nitinol sheet sandwiched in between two 1.5 mm aluminum plates. (Right) Nitinol edge lined up with aluminum edges and clamped down with a C-clamp and toe clamp (not pictured) during machining.

A DXF file of the flattened plate design was uploaded into the wire EDM machine using a USB drive. Then, the machine path was defined and the machining variables were set to 40 for TON (pulse on-time) and 200 for TOFF (pulse off-time), as shown in Figure 23 below. Finally, the cut was started, making sure the water stream was steady before enabling high frequency.

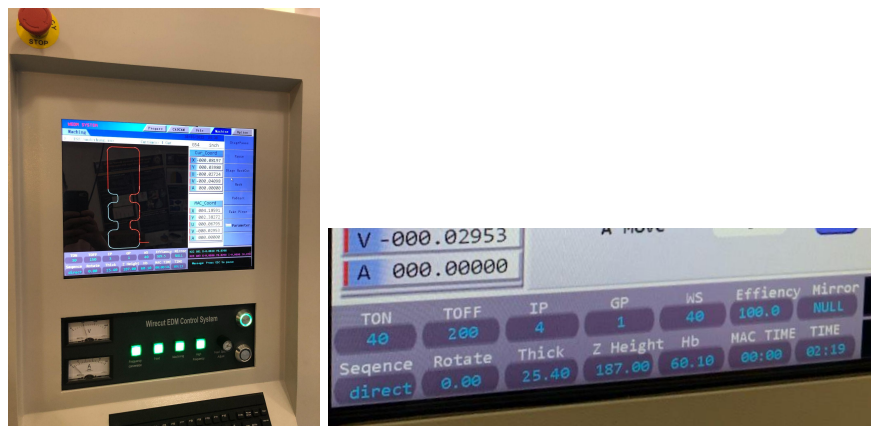


Figure 23. (Left) Machine path traced in red on EDM machine. (Right) Wire EDM machining settings.

After the gripper shape is machined from the nitinol sheet, the gripper needs to be formed and heat treated in its closed state. The nitinol was formed into its closed shape using the hole in 6-32 nuts, which had an inner diameter of about five times the diameter of an incus bone. In the past, alligator clips were attempted to form the gripper but were proven unsuccessful in sufficiently clamping the nitinol to a rod. After the nitinol was securely formed into its closed state, it was heat-treated to its austenitic phase at 500°C for 10 minutes in a heat furnace to memorize the shape. This process is visualized below in Figure 24.

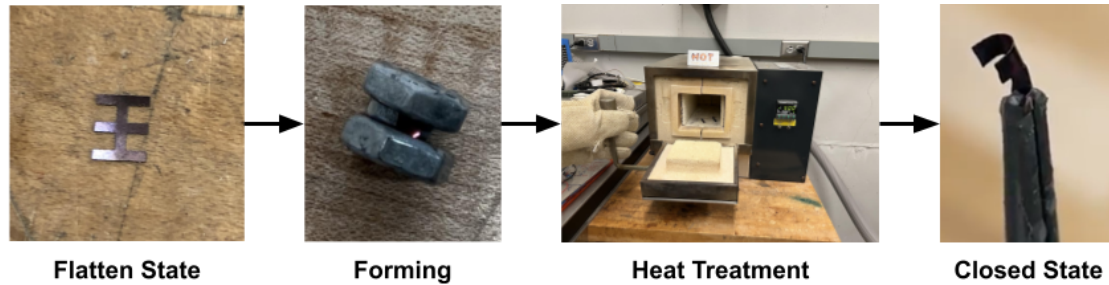


Figure 24. Forming and heat treating nitinol gripper.

After taking the nitinol out of the furnace, it was cooled down to room temperature before carefully opening the arms of the gripper using tweezers. Note that no more than 5% strain should be applied to the gripper for the preservation of the shape memory effect. A heat source at the transition temperature of 45°C can be used to reclose the gripper arms.

The final design and prototype differ in that the prototype is a five times scaled version of the final design. If the final design were to be produced, it recommended that custom tools to shape the nitinol into its closed state should be invested in due to the many difficulties of manually forming a 1:1 gripper.

VERIFICATION AND VALIDATION APPROACH

Our requirements and specifications were categorized into three groups: compatibility, practicality, and performance. Our verification and validation plans adhere to each of these three categories.

Compatibility Verification

Our compatibility verification ensures that the prototype fits within the confines of the middle ear cavity and ear canal. We utilized a virtual model to ensure that the gripper and sensor assembly fits in the middle ear cavity and that the gripper cross-section was smaller than the ear canal cross-section of 38.5 mm².

Practicality Verification

For practicality, we have created designs that are made of only one material and cost less than \$2000 to fully prototype. Additionally, a 1:1 scaled prototype will test the manufacturability of creating a gripper of this scale, which further supports Dr. Grosh’s research for the feasibility of totally internal ear implants. A 1:1 flattened version of the gripper was successfully machined out of a nitinol sheet, therefore demonstrating manufacturability at the 1:1 scale. However, forming the 1:1 scaled gripper proved to be difficult to do manually and was unsuccessful. Success in forming was found in a 5:1 scaled gripper.

Performance Verification

To verify and validate the performance, a 17.5:1 scaled 3D-printed prototype and a 5:1 scaled machined prototype was fabricated. The goal of the 3D-printed scaled prototype was to test whether or not the diameter of the gripper applied enough gripping force to secure the accelerometer to the incus with zero relative movement to the bone without having to worry about the difficulties of manufacturing. The average diameter of the incus is 0.6 mm and we had designed the gripper arms to form around a slightly smaller diameter of 0.5 mm for gripping force [16]. As shown below in Figure 25, we 3D printed a 17.5 times scaled model of an incus bone using Accura Xtreme White 200 SLA material and the gripper design in its closed position using PLA.



Figure 25. 17.5:1 scaled physical prototype of simplified plate design.

The scaled gripper was then snapped onto the scaled incus geometry and shook vigorously to check for movement. On the 17.5 scale, the gripper diameter was small enough to provide enough gripping force to successfully secure itself to the incus geometry without any movement.

The goal of the machined prototype is to test the gripper design with the representative material (nitinol) as close to the real scale as possible, which is limited by manufacturability. This build will test if the results seen from the 17.5:1 scaled printed prototype is translatable to the 5:1 scaled prototype with the same materials that will be used in industry. The gripper was placed on a rod with a diameter that is five times that of the incus and heated to its transition temperature to enable its closed shape. The same shaking test was then performed on the machined prototype. The machined prototype moved faithfully with the rod, therefore passing performance verification. This leads us to believe that a 1:1 scaled machined prototype will also pass performance verification.

Further Verification Testing

Due to limitations in time and resources, several of our specifications were not systematically tested and further verification testing is needed. For performance specification 1a, the 1:1 machined gripper prototype and accelerometer need to be weighed with a precise scale to determine if the combined mass is less than 10 mg. It should be noted that from the virtual model, the gripper only adds a mass of 0.003 mg. For performance specification 2a and 2b, FEA

analysis can be conducted to determine if the gripper assembly to an incus bone will withstand the specified radial, axial, and shear forces. Otherwise, a 1:1 prototype will need to be successfully fabricated for a physical test. For compatibility specification 5a, performance verification tests need to be conducted on varying diameter rods to ensure compatibility with different sized incus bones.

Validation

Design performance specifications in this project were drafted with load cases of the ear in mind but are certainly not extensive. As more quantitative information about ear load cases is made public, the specifications may need to be adjusted to ensure that the design problem is fully addressed. However, the same verification approach can be used for the adjusted specifications.

PROBLEM ANALYSIS

After completing our concept selection process, we have a couple of well defined concepts that we will continue working with to try to produce a working prototype. By the end of the semester we hope to develop a 2:1 scale working gripper that will be able to attach the accelerometer to a 1.3 mm diameter rod.

As discussed previously, our first attempts of manufacturing our prototypes quickly proved that manufacturing an actual size prototype was impossible with the 0.1 mm gauge nitinol on hand. According to calculations, a prototype at 2 times scale would be feasible.

Potential problems are bending the gripper into shape and securing the gripper in the furnace. To address this potential problem, we will 3D print a die that will shape the gripper around the 1.3 mm rod. With the die, more experience dealing with nitinol, and larger bend radius, we are confident in the 2:1 scale prototype.

Other notable concerns include making appropriate recommendations to the sponsor to successfully continue our project to its completion at actual size. Our documentation and information that was gathered will hopefully address this potential problem.

DISCUSSION

Initially the problem was straightforward to define, being clearly laid out in the project description, as well as in meetings with our stakeholders. However, after actually beginning work on the project, additional complexities were made aware to us. Some of them became deeply ingrained into our concept generation and design iterations, the most important being the sheer scale of the final product. With the design itself being about 3x3mm, it greatly impacted the approach we could take given the resources and time we had. Outsourcing proved way too expensive and time consuming, while the nitinol wire proved way too difficult to secure to both the incus and the sensor even though heat treating was simple. On the other hand, the nitinol plate was extremely difficult to heat treat, but once it was achieved, securing it was simple. In the end these defeats provided valuable information and we finally landed on our final build design,

One area that was another area that popped up in needing more attention was sensor orientation. Two main areas of interest for the sensor location came up during talks with the partnered medical faculty, as well as utilizing our virtual model. The simpler was just attaching directly on the back of where the gripper secures to the incus, while the other saw the addition of an underhang to the gripper in order to place the sensor below the stapes. The placement of the package relative to the gripper would have an impact on faithful movement relative to the bone, which is key for accurate results. In the end we chose the simpler solution due to time constraints, however having a better idea on orientations and the effect they have on sensor outputs would better define the problem going forward. The two main methods to do so would be experimental and FEA analysis. The experimental would see installations of the two approaches within cadavers, comparing sensor reading between each other as well as to some sort of baseline or just the input. The latter would see the use of our finite element model of the middle ear structure, running simulations and analysis on them, although the validity of the model may be in question.

Regarding the final design itself, the largest weakness from our personal experience was the sheer difficulty of handling and forming the nitinol. However, this was entirely due to not being able to secure the correct thickness of plate, forcing us to scale up the final build. So solve this, use the required maximum thickness of 0.075mm . In general, the main weakness is that the majority of the effort went into securing the gripper to the incus aspect, that the securing the sensor package to the gripper aspect was not as fleshed out. While biocompatible adhesive is a plausible approach on initial thought, it could be possible that the scale could again come into play, making it extremely difficult to do appropriately, especially in a surgical setting. That would have to be further explored, perhaps somehow ingrain the plate into the housing of the package somehow (such as a slot) or exploring some way to have additional nitinol structures enclose it.

The strengths of the design are seen in that more explored aspect, as the gripper is more than sufficient in securing to the incus, as shown in our results. If we had more time or could have a do over, we would strive to have more of a balance on addressing all parts of the problem. The material and scale of the problem proved more difficult to learn and make progress on than initially thought, forcing it to come to a time crunch at the end. However we are extremely satisfied with what we achieved and learned about machining and heat treating nitinol.

REFLECTION

Our product, the middle ear prosthetic “gripper,” is a piece of the bigger puzzle that aims to better hearing loss solutions and help individuals with hearing loss. Even though we will not be able to witness the fruits of our labors in seeing the final product (completely implantable hearing aids), we learned much about the hearing correction space and the medical advancements and research taking place. We are proud to have contributed in this exciting field with huge future implications to better lives.

Global, Social, and Economic Impact

Public health is at the forefront of our project- our product will improve the lives of hundreds of millions around the globe that are affected by hearing loss. With better solutions for corrective hearing, it will also enhance public safety by giving a sense of hearing for those who are hard of hearing.

In the global marketplace, our final product will compete with existing middle ear prosthetics. In the long run, the completely implantable hearing aids will revolutionize the hearing correction space much like LASIK has done to the vision correction space. The product will be one of its kind on the market and will be in high demand.

One of the biggest social issues that is addressed by our product is the social stigma around external hearing aids. With a completely implantable hearing aid, those who experience hearing loss can correct their hearing without any external indication that they have a disability.

The potential economic impact of our project is secondary; our primary focus is the positive societal impact. However, if our sponsor decides to patent the product and sell at a price in the market, there will be economic gains that follow. To analyze our potential societal, economic, and environmental impact we utilized the stakeholder map (see introduction) and the CES lifecycle report (Appendix D).

Culture, Privilege, Identity, and Stylistic Similarities

Our group represented a diverse background of cultures- we had a great representation of ethnic and gender minorities. This helped us consider better universality of our product since a teammate from a different cultural background could provide input on areas of inclusivity when that idea would not even cross the mind of another to consider due to different privileges and backgrounds. In terms of our stylistic similarities, many of us had interest in physical activities such as running, climbing, and tennis; we would keep spirits high with conversations about these topics during the down time. We also all preferred to divvy up the work in our meeting then complete the parts individually. This worked fairly well, but it had some shortcomings such as figure labeling issues and the like.

Our sponsor is an expert in the acoustic and biomedical space and therefore had significant influences in our design process. He suggested certain design possibilities and directed us to similar products used in industry.

Inclusion and Equity

In terms of power dynamics between team members, one or two people would take the lead on certain aspects of the project, but everyone's ideas were respected and heard. Certainly more members were more involved and dedicated to the project, but we tried to be equitable in the distribution of work and responsibilities. Our experiences and identities definitely influenced our perspective on the project since all our members did not

experience hearing loss. We could only be outsiders looking in, and we could not truly know what exactly the target audience would prioritize and want. The best we could do was follow our sponsor's guidance and requirements.

Our team incorporated everyone's ideas and viewpoints by hearing all ideas then voting on them as a group and moving forward with the majority. This was also the case for the ideas that our sponsor shared with us.

We prioritize the viewpoint of our stakeholders since it was their project, but we valued the input from our team and incorporated them in parts of the project. As a group, we decided on the ideas that best moved the project forward with the best interest for the success of the project at heart.

The cultural differences between our teammates did not play a significant role. We were mostly united in our interests for the project. There were certain instances where some members wanted the work done a certain way and another in a different way. Most of the conflicts were solved through conversation and did not lead to any complications. It was the same case with our sponsor- the cultural differences did not factor much.

Ethics

One significant ethical dilemma was when verification testing results failed, and we had to start over or find other ways. It would have been easy to take tests that barely failed and say they were successful. However, we knew that our product would eventually be used in biomedical applications, and we heard too many stories to risk any consequences even if it seemed insignificant at this stage of the project.

Personal ethics are based on personal values; professional ethics are based on the values of the company. The way to not have personal ethics conflict with professional ethics is to choose a company that has values that align with your personal values. Then, there is no chance for conflict of interest and can do personally meaningful work.

RECOMMENDATIONS

Our recommendation for our sponsor is to begin the 1:1 scale prototyping process. It is feasible with custom tooling, so reaching out to external suppliers is necessary. We would also recommend continuing to use a wire EDM machine as it was very effective. We believe that the next step in the design process would be to attach the gripper to an accelerometer using a biocompatible glue and verifying if the prototype still passes our requirements. It is also important to further work with surgeons to ensure that this device can truly be used during surgery.

CONCLUSIONS

Cochlear implants are the primary treatment for sensorineural hearing loss, a result of damage to the inner ear. The current cochlear implants in practice require external components

which set many limitations including social stigma, inability to participate in certain activities such as swimming, and discontinuous hearing from needing to take the external components off when sleeping. These limitations incentivize the need to develop a totally implantable cochlear implant with no external components. This would not only enhance the lives of people with serious hearing loss that require cochlear implants, but also provide the option of an invisible hearing device to people with less severe hearing loss.

Dr. Karl Grosh's research works toward this goal by developing an accelerometer that is to be implanted inside the middle ear and will pick up sound vibrations of different frequencies and send electrical signals to a driver that communicates with the cochlea. In order to test the sensor, a gripper needs to be designed to fasten the sensor to a middle ear bone, which is the scope of our project. To aid in our project development, we plan to follow "The Design Process" by Make. Through our work this semester, we have fabricated a 5:1 scaled shape memory alloy gripper mechanism that will secure Dr. Grosh's sensor to the incus and is also small, lightweight, adjustable, and resistant to the environment. Specifications for these requirements can be found in Table 2.

To create this 5:1 scale model we prototyped a 3D model of the middle ear, went through concept generation, created CAD models of a few designs, performed necessary calculations, and created physical models both at the 17.5:1 scale. All of these steps helped us to better understand our design problem, create our design, and to then create iterations on that design to help us to improve upon our design.

ACKNOWLEDGEMENTS

We thank Karl Grosh, Penny Kitsopoulos, Alex Shorter, John Shaw, Ryan Foster, Randy Cheng, Gregory Oberhausen, Emily Strucken, Chris Welch, and our colleagues from ME 450-005 for their continuous support and feedback throughout this project.

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APPENDICES

A. Individual Design Concepts

Appendix A.1. Won Kang's individual design concepts.

"Cripper" design

1. General Medical design
Small profile
Manufacturable
biocompatible

2. custom → available

3. Nitinol wire

4. about 1/2" in of piece
- sleek, malleable?
- elastic?
- other polymer?
- foil?

5. 1. Customized crimping
attaching
of mesh

6. Nitinol mesh

7. 8. Nitinol mesh

9. accel. inside sleeve
w/amp sleeve

10. Nitinol "band all"

11. Nitinol wire ID
accel.
cured in resin

12. Resin secured via
nitinol coil around
- electromagnetic resonance?

13. Nitinol mesh

14. Nitinol mesh - made from
wires
Sandwich design?

15. Nitinol mesh

16. accel. inside sleeve
w/amp sleeve

17. Nitinol mesh

18. "pinch band"
design
- around legs just
w/amp sleeve accel.

19. Nitinol mesh

20. Nitinol mesh

21. "Cripper" design
more fins to increase
contact

22. custom profile
to fit better

23. better
design →
suit hydrophilic
surface

24. different ID
pattern to
increase grip

25. Nitinol mesh

26. Nitinol mesh

27. clips
wires

28. Nitinol mesh

29. elastic
magnet
elastic material
stretch over box
attached via magnet

30. Nitinol mesh

31. Nitinol mesh

32. Nitinol mesh

33. Mesh cut into
shape for more
grip

34. Nitinol mesh

35. Nitinol mesh

36. clips

37. more space
efficient
design

38. soldered onto plate
no plastic - just
nitinol

39. plastic case
and mesh
sandwich
over the
case

40. "bar" design →
"basket" design

41. Nitinol wire
all the way
around

42. Nitinol mesh

43. Nitinol mesh

44. Nitinol mesh

45. Nitinol mesh

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96. Nitinol mesh

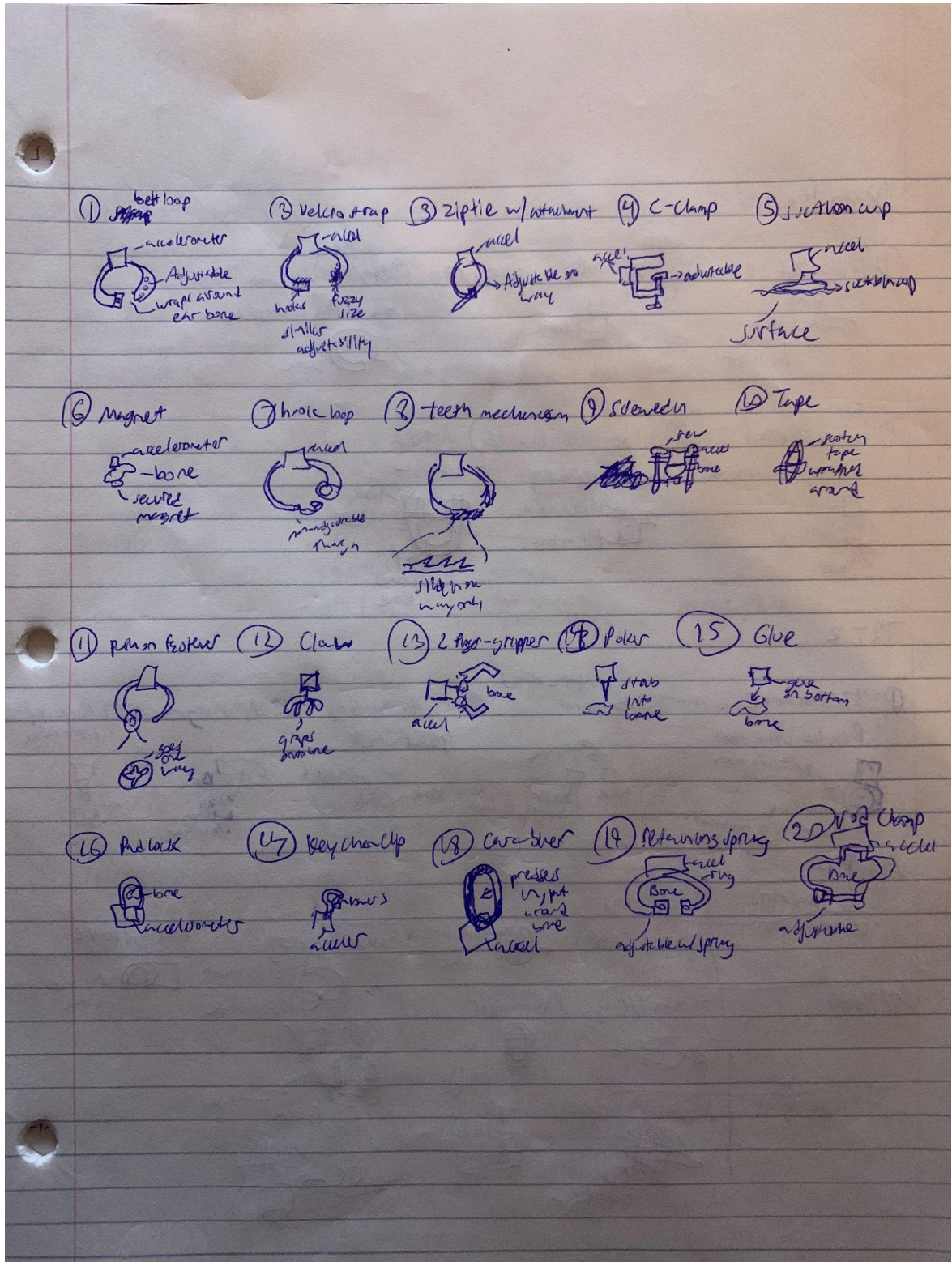
97. Nitinol mesh

98. Nitinol mesh

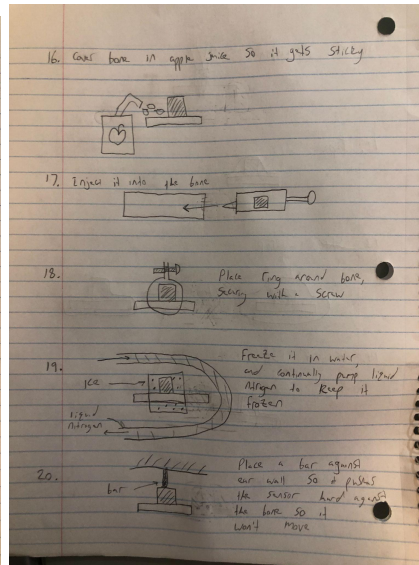
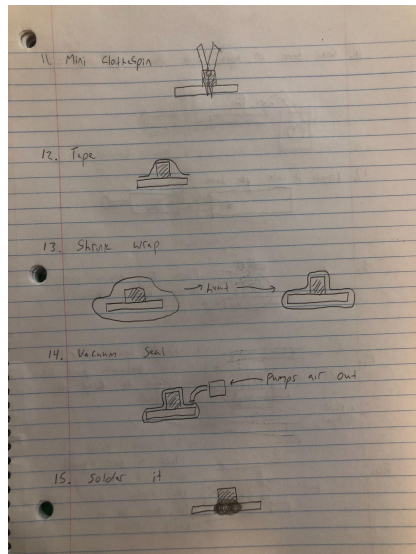
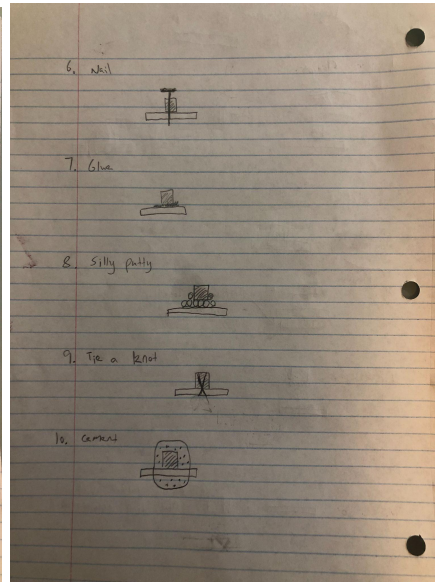
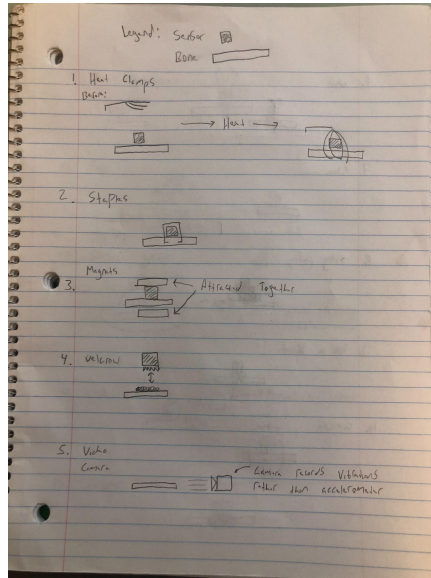
99. Nitinol mesh

100. Nitinol mesh

Appendix A.2. Edward Corralez's individual design concepts.



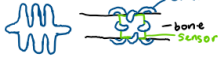
Appendix A.3. Adam Good's individual design concepts.



Appendix A.4. Meng Shi's individual design concepts.

PROBING, February 28, 2014 11:20 AM

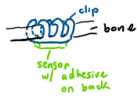
1) shape memory alloy claw (8 arms)



2) shape memory alloy claw (6 arms)



3) clip w/ adhesive



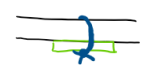
7) belt/ziptie



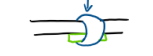
8) belt sensor to bone cross section view:



9) wire to tie sensor to bone



13) mold around bone/sensor



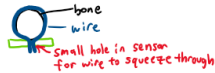
14) stitch band around bone/sensor



15) Velcro (hook/string) loop



19) friction



4) clip w/ sensor heat staked



5) clip w/ filled arms



6) hinged clip



10) stake sensor to bone



11) rivet



12) clamp



16) Carabiner



17) clasp



18) strap w/ pocket



20) Magnet



Requirements	Solutions →		
Secure accelerometer to middle ear bone	Pasteners (i.e. screw, clip, rivet)	adhesive (i.e. glue, tape, epoxy)	Straps
Adjustable	Elastic deformation (beam deflection, stretching of material)	manual (cut to length, physically set positions)	welding at position (i.e. ultrasonic, spot welding, electron beam welding)
			crimp at position

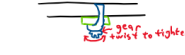
1) Strap/beam deflection



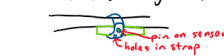
2) clip/beam deflection



3) gear-adjusted clamp



7) strap (physically set position)



8) sliding loop strap



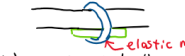
9) strap/crimp at position



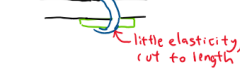
13) clip/crimp at position



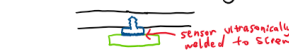
14) straps/stretching of material



15) straps/cut to length



19) screw/ultrasonic welding



20) clip/welding



4) screw/stretching of material



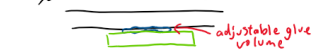
5) clip/stretching of material



6) rivet/stretching of material



10) glue/cut to length (adjustable volume)



11) tape/cut to length



12) epoxy/cut to length (adjustable volume)



16) straps/ultrasonic welding



17) Straps/spot welding



18) straps/electron beam welding



Appendix A.5. Shanoli Kumar's individual design concepts.

ME 450 - Brain Storming

1. Accelerometer 2-Pong
2. 1-Pong
3. 3-Pong
4. 3-Pong Bottom Hold
5. Gear Fit
6. Straight lock
7. Key-hole
8. One-sided 2-pong

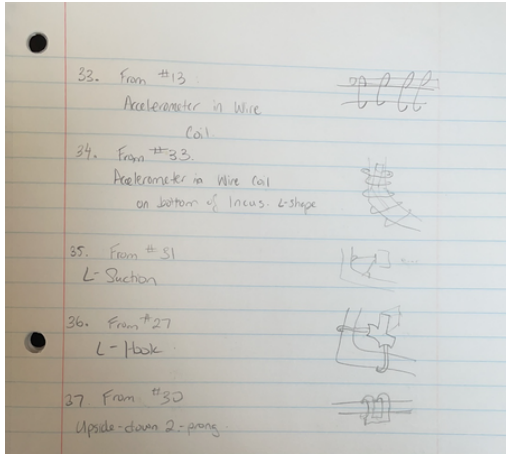
9. Plaid
10. Accordion
11. V-cup
12. U-cup
13. Slap bracelet "slap-on"
14. Snail Maze
15. 4-Port Diamond Clamp
* hinges on side
16. Snail Maze II
* loops through then tightens.

17. Section I one large cup
18. Section II 2 small cups
19. Tape
20. Velcro

Part II
- Concept Generation Tools & Design Heuristics, Morph Space (pace together parts), Quantity over quality theory
From what previous design

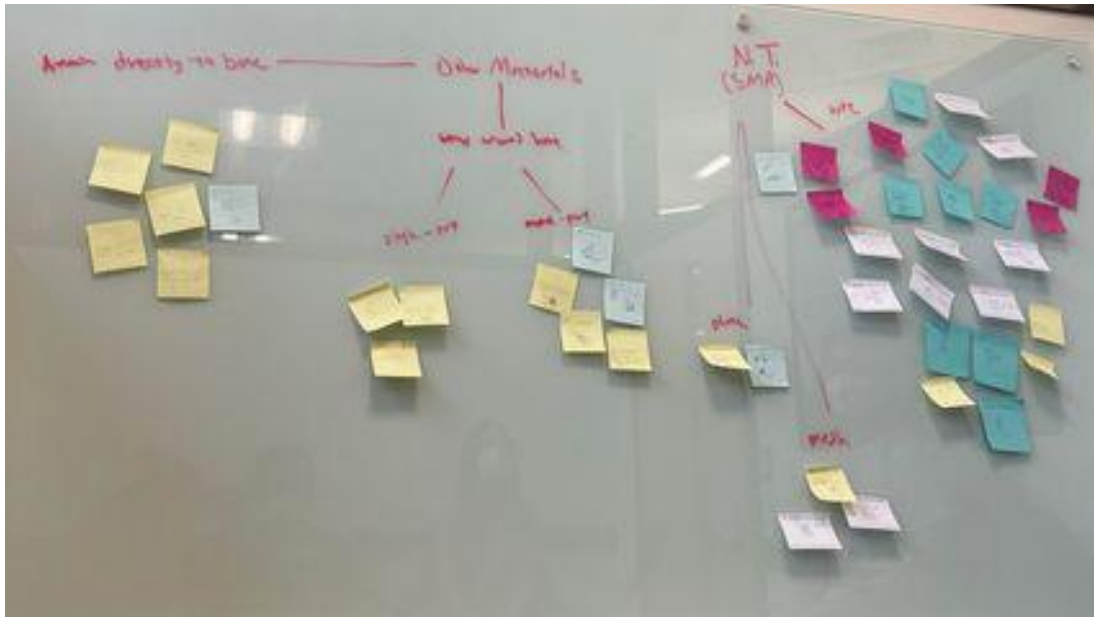
21. From #20 Buckle
22. From #12 Twist U-Cup
23. From #4 Small Hook
24. From #2 Push-in - Grab

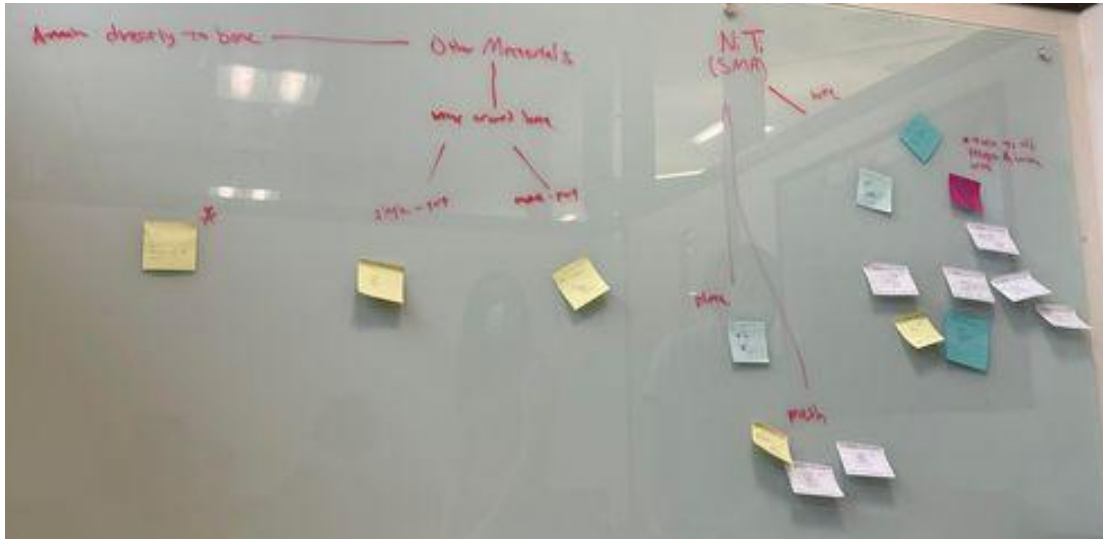
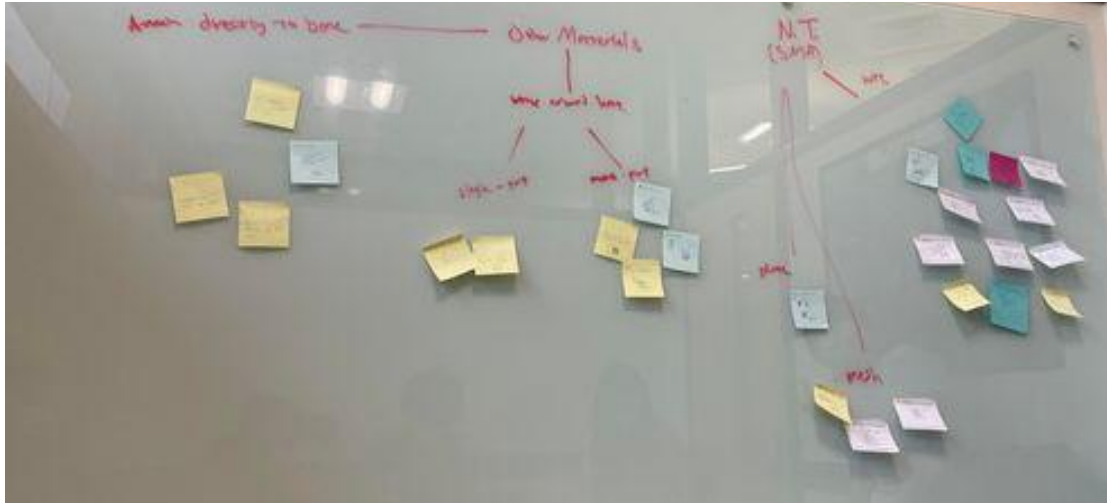
25. From #21 Zip tie
26. From #7 Hide hook w/ Notches
27. From #8 Hidden hook
28. From #12 Phone Charger
"plugs in" and fastens
29. From #15 Upside-down 4port Diamond Clamp
30. From #5 Upside-down one sided 3-pong
31. From #1 L-shape clip (on lower part)
32. From #13 Wire



B. Group Concept Evaluation

Appendix B.1-3. Group concept selection process.





C. Calculations

Appendix C.1. Calculation of the thickness/gauge of material



$K_{max} = \frac{1}{R_{max}}, K_{min} = \frac{1}{R_{min}}$, z is the distance from centerline of material to the edge of material thickness

$$\varepsilon = \Delta Kz = \left(\frac{1}{R_{min}} - \frac{1}{R_{max}}\right)z = \left(\frac{1}{R_{min}} - \frac{1}{R_{max}}\right)\frac{t}{2}$$

$$\varepsilon_{max} = 0.05 = \left(\frac{1}{R_{min}} - \frac{1}{R_{max}}\right)\frac{t}{2},$$

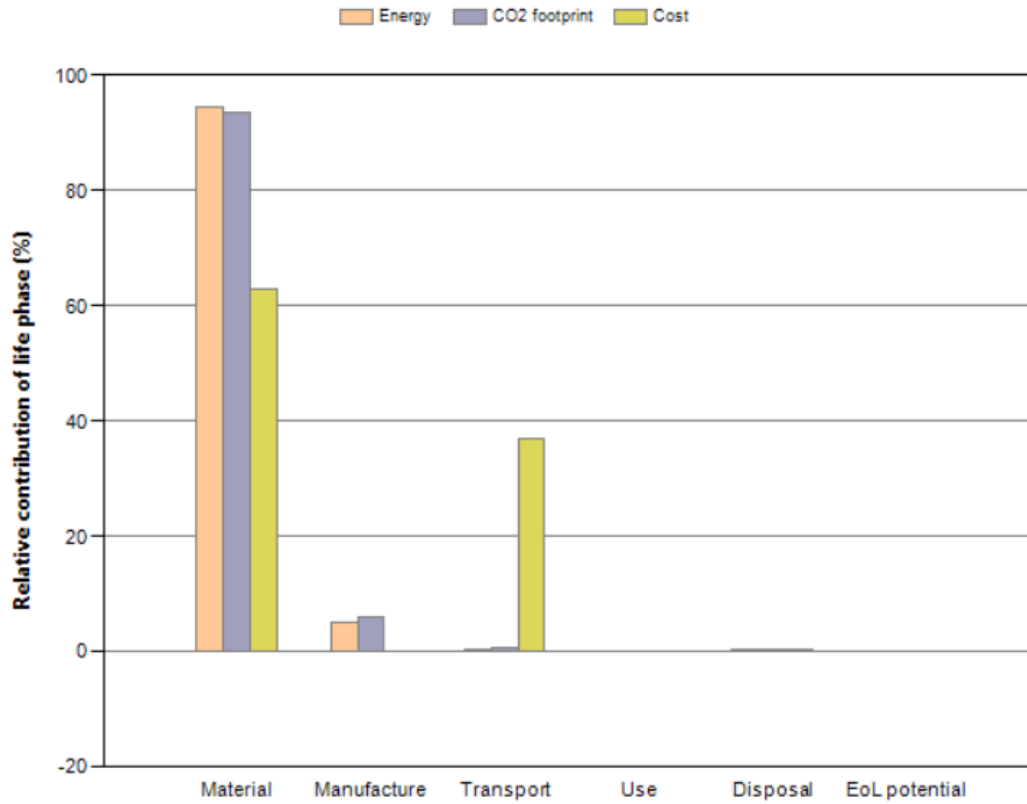
$$R_{min} \sim 0.3 \text{ mm}, R_{max} \sim 0.5 \text{ mm}$$

$$t_{max} = \frac{(2)(0.05)}{\left(\frac{1}{0.3E-3} - \frac{1}{0.5E-3}\right)} = 7.5 * 10^{-5} \text{ m} = 0.075 \text{ mm}$$

D. CES Report

Product name	Gripper
Country of manufacture	North America
Country of use	North America
Product life (years)	1

Summary:



[Energy details](#)

[CO2 footprint details](#)

[Cost details](#)

Phase	Energy (kcal)	Energy (%)	CO2 footprint (lb)	CO2 footprint (%)	Cost (USD)	Cost (%)
Material	612	94.6	0.351	93.5	0.175	63
Manufacture	32	4.9	0.0221	5.9	0	0
Transport	2.88	0.4	0.00191	0.5	0.103	37
Use	0	0.0	0	0.0	0	0
Disposal	0.325	0.1	0.00021	0.1	4.37e-05	0.0157
Total (for first life)	647	100	0.375	100	0.278	100
End of life potential	0		0			

BIO SKETCH



Won Young Kang (he/him)

Troy, MI

BSE Honors Mechanical Engineering 2023

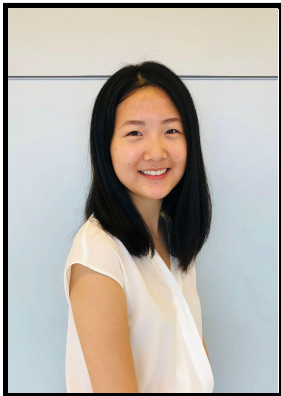
International Minor for Engineers

Interests: manufacturing, industrial and operations engineering

Future plans: Pursue Master's degree in IOE

Fun fact: I play tuba in the Michigan Marching Band!

I chose the project because I want to use my engineering skills to directly improve the lives of others. I also served on the ME DEI committee with Dr. Grosh and wanted to work with him again!



Meng Yian Shi (she/her)

Chicago, IL

BSE Mechanical Engineering 2022

Electrical Engineering Minor

Interests: product design, manufacturing, material science

Fun fact: I love rock climbing!

I chose this project because I am interested in designing something using shape memory alloys, something I've seen in the industry but have not had the opportunity to work with yet.



Edward Corralez (he/him)

Los Angeles, CA

BSE Mechanical Engineering 2022

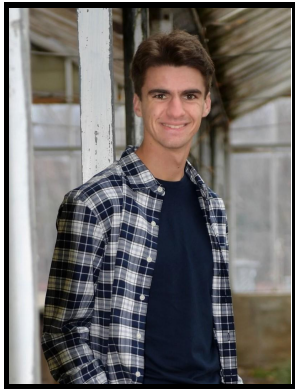
Electrical Engineering Minor

Interests: Manufacturing equipment and controls engineering

Future plans: Work in some sort of manufacturing engineering position

Fun fact: I played the bassoon!

I chose this project because I was interested in the opportunity to design something that is so small. Most of my previous experience is working on larger manufacturing equipment.



Adam Good (he/him)

Rochester Hills, MI

BSE Mechanical Engineering 2022

Electrical Engineering Minor

Interests: Manufacturing and Controls

Fun Fact: I'm the president of the running club on campus!

I chose this project because I've taken a few electives about acoustics and really enjoyed them. I also wanted to work on a project that would be able to help people.



Shanoli Kumar (she/her)

Novi, MI

BSE Mechanical Engineering 2022

Interests: Manufacturing and Product Design

Fun Fact: I'm the president of the club tennis team!

I chose this project because I've recently gained an interest in biomechanics and would love to be part of a project that could directly improve the lives of others. I also find it interesting to design a device so small.