RE-DESIGN & FABRICATION OF SENSOR "GRIPPER" FOR USE IN MIDDLE EAR PROSTHESIS

Engineering Honors Program - Capstone Final Report

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ABSTRACT

Hearing loss is a significant problem globally. There are currently over 1.5 billion people that suffer from hearing loss, with this number projected to increase to over 2.5 billion by 2030 [1]. Sensorineural hearing loss occurs when the cochlea in the inner ear is damaged and cannot send signals corresponding to sound to the brain. Our main project focuses on replacing a cochlear implant, the current solution to severe sensorineural hearing loss. A piezo-MEMS (microelectromechanical systems) accelerometer is being developed to replace external components of a cochlear implant. The accelerometer measures middle ear ossicle bone vibrations and relays sound information to an internal processor. It holds the promise of giving more accurate sound information to the processor than current cochlear implant external microphones, increasing user safety, and removing the social stigma associated with wearing an audible prosthesis. For the accelerometer to function properly, an attachment mechanism, or a "gripper", must also be designed to attach the accelerometer to the incus bone in the middle ear. Here we show the gripper design process, which securely attaches to the incus but is not so tight as to damage the bone or cause necrosis. Included below is information about fabricating the gripper, including the initial fabrication methods brainstormed and the final fabrication method used, validation of the final gripper model, and recommended next steps for future teams. The results of the design process were promising, as the final gripper model successfully attached a Vesper's Disruptive PEBL™MEMS Technology VA1200 Bone Conductor Sensor - Analog Piezoelectirc MEMS Voice Accelerometer [2] to the incus bone, but methods should be developed to further validate the model.

Keywords: Sensorinueral Hearing Loss, Piezo-MEMS accelerometer, Gripper, Incus, Fabricate

PROJECT INTRODUCTION

Hearing Loss

There are two main types of hearing loss, conductive and sensorineural. Conductive hearing loss occurs when there is a problem with the abilities of the tympanic membrane and/or middle ear to transmit sound and convert it to mechanical vibrations due to an interference[3]. Interferences include but aren't limited to head/ear trauma, otosclerosis, and obstruction of the external canal by cerumen (ear wax), water, or another foreign body [3]. There are various ways to treat conductive hearing loss. For example, external auditory canal conductive hearing loss occurs when objects, such as cerumen, water, or other foreign bodies obstruct the external auditory canal. Treatment of external auditory canal hearing loss includes foreign body removal via surgery and antibiotics [3]. Another example is tympanic membrane conductive hearing loss, which is usually caused by head trauma. Head trauma can result in tympanic perforation, or a burst eardrum. The primary effect of tympanic perforation is that the eardrum can't vibrate as well as normal, resulting in hearing loss. If the membrane is unable to heal on its own, tympanic perforation is treated with surgery [3].

Sensorineural hearing loss “encompasses disorders that affect the inner ear and the neural pathways to the auditory cortex”[3] and generally occurs when the cochlea in the inner ear is damaged, or degraded as a result of aging, and cannot send signals corresponding to sound to the brain. Primary causes of sensorineural hearing loss include aging, illness, and loud noise exposure. The primary solutions to sensorineural hearing loss are hearing aids and cochlear implants.

Hearing Aids and Cochlear Implants

Hearing aids are electronic devices worn behind the ear and are typically used by people who suffer from mild to moderate hearing loss. They work by receiving sounds through a microphone that converts the sound to either an analog or discrete electrical signal, amplifying the signals using an amplifier, and sending the amplified signals to the inner ear using a speaker. Cochlear implants are much different. Cochlear implants bypass the damaged portions of the inner ear and directly stimulate the auditory nerve through a series of events. First, a microphone is used to pick up sounds, followed by the selection and arrangement of the sounds from the microphone using a speech processor. Then, using a transmitter and receiver, the signals from the speech processor are received and converted into electrical pulses. Finally, an electrode ray collects the electrical impulses from the stimulator and sends them to different regions of the auditory nerve [4]. Figure 1 below shows a graphic of a cochlear implant.

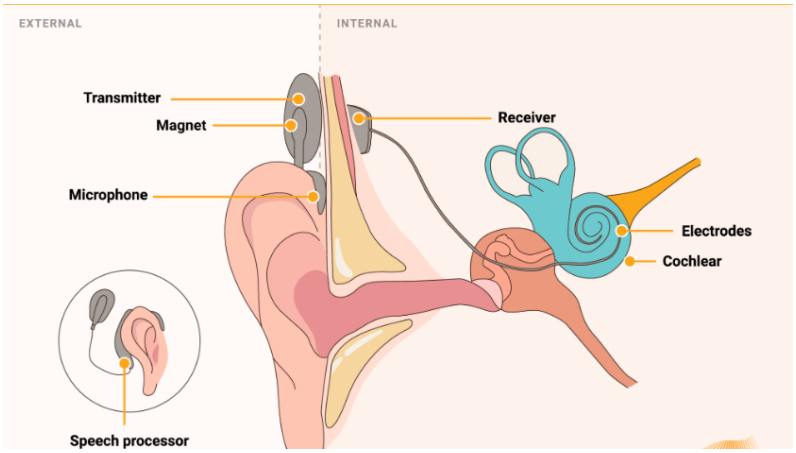

Figure 1. The figure shows the location of each component of a cochlear implant [5].

Although there are many benefits to current hearing aids and cochlear implants, there are also many drawbacks to them. One main drawback is the external components of both hearing aids and cochlear implants. External components create social stigma for users of hearing aids and implants. Because of this, people that would receive great benefit from the devices often choose not to wear them [6]. Additionally, external components limit the total time being able to hear because they can’t be worn all the time. Both sleeping and swimming are activities where a person can’t use their hearing device [7]. Finally, the geriatric population often struggles with adjusting their hearing devices and will often choose not to wear them over having them in and being able to hear [8]. Thus, there is a need for a totally implantable auditory prosthesis (TIAP) to reduce social stigma and enhance the safety and usability of the device.

PROJECT DESCRIPTION

In response to the need for a TIAP, Professor Grosh's research aims to diminish the need for external components in auditory prostheses. Currently, a TIAP is being developed that will fit in the tympanic membrane, or the middle ear space. Ideally, it will utilize an ultraminiature Piezo-MEMS (microelectromechanical systems) dual bandwidth accelerometer that will detect sound vibrations and send converted electrical impulses to the auditory nerve, allowing a person to hear. The design requirements for the Piezo-MEMS accelerometer [9] are listed below:

- Small (~ 2 mm x 2 mm x 1mm) and light (<15 mg)
- Frequency range to match current HAs/CIs (100 Hz - 8 kHz and higher)
- Noise floor commensurate to present microphones
- Biocompatible (for complete implantation) + MRI compatible
- Low power usage (0.05-0.5mW)

Following the design requirements, an early prototype of the accelerometer and its housing was developed and is shown in Figure 2 [10] below.

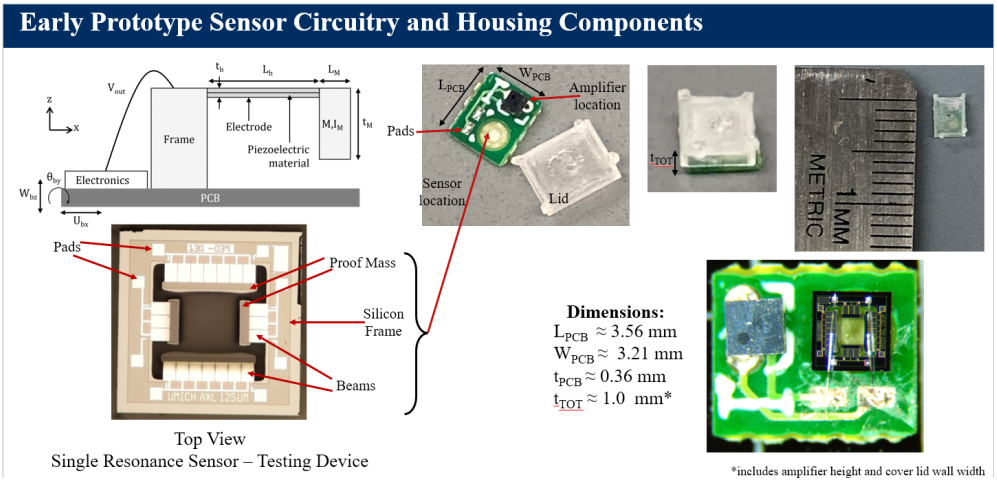

Figure 2. The figure shows the early-stage prototype for the accelerometer, including the materials and the current dimensions [10].

In addition to the initial design requirements of the accelerometer listed above, the TIAP has to fit into the middle ear space without damaging any of the ossiclular bones, ligaments, and nerves that lie in the space. The current early prototype has dimensions of about 3mm x 3mm x 3.6mm but it is anticipated that the final dimensions of the sensor are going to be about 1mm x 1mm x 1.4mm. In addition to the volume of the sensor, the sensor also must be tightly secured onto an ossicular bone so that when the bones vibrate in response to sound traveling through the ear, the exact vibrations of the ossicle bones are picked up by the accelerometer. Thus, the MEMS accelerometer must be packaged for implantation on the ossiclular bones. This packaging serves to protect the fragile structures of the sensor and also interfaces with or be an element of the gripping mechanism. However, the mechanism cannot secure the accelerometer too tight, as necrosis can occur if too much force is applied to an ossicular bone. There are several approaches to solving this complex design problem, and one potential solution could be using a similar competitor product and making modifications to its design to incorporate the accelerometer.

MED-EL Vibrant Soundbridge® and Short Process Coupler

MED-EL is one of the top competitors in the auditory prosthesis space and is a company that has been successful in developing and taking to market auditory prosthesis that are similar to what our team is trying to design. Specifically, MED-EL has developed the Vibrant Soundbridge® (VSB). The VSB is made up of an external audio processor (AP) and an implanted Vibrating Ossicular Prosthesis (VORP), which consists of a receiver coil, conductor link, and transducer [11]. The VSB functions by the AP first gathering sound and sending the information to the VORP. The transducer, also called the Floating Mass Transducer (FMT), then vibrates in a controlled way, specific to the user's hearing needs [11]. The FMT is located in the middle ear space and is attached by a coupler to the incus bone [12].

Currently MED-EL commercially sells two couplers that are of interest to our project. The Incus-SP-Coupler attaches the FMT to the short process of the incus and the Incus-LP-Coupler that attaches the FMT to the long process of the incus. The Incus-SP-Coupler is of the most interest to our project because it places the FMT in the antrum of the middle ear [12], where it avoids the facial recess and greatly reduces the risk of facial paralysis during surgery. The team was also interested in how Incus-SP-Coupler attached to the short process of the incus because it was able to hold the FMT, which has a much greater mass than the piezo-MEMS accelerometer, in place without having adverse effects on the incus.

Fall 2022 Gripping Mechanism Design and CAD

From August to December 2022, I worked with Professor Grosh and his team to design a Computer-Aided Design (CAD) model of a gripping mechanism that could attach the Piezo-MEMS accelerometer to the incus bone. Significant background reading was done to familiarize myself with Professor Grosh's overall project background, understanding the important components of the ear, and understanding the related experiments, models, and designs other institutions and companies had completed. Additionally, the team was able to view Dr. Emily Stucken, an Otolarygologist at Michigan Medicine working with Professor Grosh on the project, perform a mastoidectomy and posterior tympanotomy surgery, which is the surgery patients undergo when recieving a cochlear implant, to learn the optimal location for the gripper. From these experiences, we learned that the optimal location of the gripper would be the short process of the incus because the facial recess would be completely avoided, greatly reducing the risk of damaging the facial nerve, and therefore reducing the risk of facial paralysis [12]. As a result, a final CAD design for the gripper was created, and is shown below in Figure 3 [13]. The design is based on MED-EL's Incus-SP-Coupler and is made of Titanium Grade 5 (ASTM F136). The engineering drawing for the gripper is shown in Appendix A. The mechanism had a volume of $0.51mm^3$ and a surface area of $16.81mm^2$.

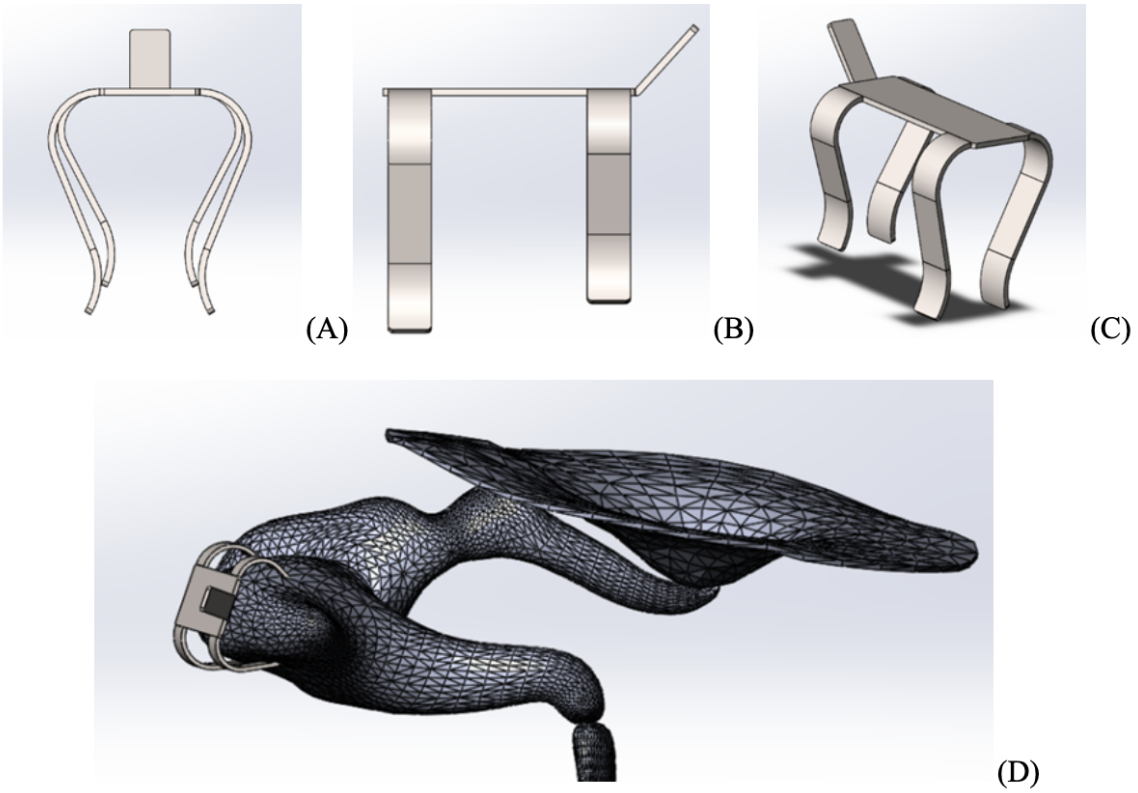

Figure 3. The figure shows the final CAD model design for the gripper during the Fall 2022 semester. It shows the front (A) and side (B) views of the design as well as how it will fit onto the SP of the incus (D). The material of the final design is Titanium Grade 5 (ASTM F136), which is the same as MED-EL's SP coupler [11].

The final CAD design showed promise to successfully attach the accelerometer to the incus bone. As such, the next steps for the project were to fabricate prototypes of the gripper and validate them by attaching them to incus bones obtained from cadavers at Michigan Medicine. Additionally, different methods for attaching the accelerometer to the gripper needed to be identified.

Clinical Indications Analysis

In addition to the complex engineering problems of creating a successful piezo-MEMs accelerometer and gripper, there is also an important business question that needs to be addressed: will the TIAP be adopted and how will it be successful in the market when it is complete? When complete, the TIAP will be a new technology in a highly regulated healthcare industry. So, in order to be successful in the market, a thorough explanation and proof of how TIAP is significantly better than current competitor products are needed. In order to answer how the TIAP will be adopted successfully, the acute need for the TIAP in the market needs to be found by defining the market, identifying meaningful trends in the market, and comparing the TIAP to the highest-performing existing technologies. In order to do this, a clinical indications analysis needs to be performed so that recommendations can be made for where the TIAP can intervene in the market.

GRIPPER MECHANISM FABRICATION

In order to fabricate the gripping mechanism, several steps were taken. The first step was contacting University of Michigan College of Engineering faculty with experience fabricating parts of a similar to size to the gripper. Conversations were held with Professor Jon Luntz and instructional lab manager Donald Wirkner to determine possible fabrication methods. The two most promising methods included metal 3-D printing and electrical discharge machining (EDM). Both methods were attempted before concluding that EDM was the best option. After the conclusion was made, the CAD model of the gripper was refined so it could successfully attach to a Vesper Disruptive PEBL™MEMS Technology VA1200 Bone Conductor Sensor - Analog Piezoelectirc MEMS Voice Accelerometer [2]. The accelerometer has dimensions of 2.90 x 2.76 x 0.90 mm^3 [2] and a mass of 8.124 mg (obtained from the VA1200 CAD model [2]) . The gripper was validated by using beeswax to attach the VA1200 to the gripper and using tweezers to attach the system to an incus bone.

Fabrication Methods

The two most promising methods for fabricating the gripper were metal 3-D printing and EDM. metal 3-D printing was initially considered the most promising method due to the feasibility of customization. Different models of the gripper could be 3-D printed and the models could then be compared. However, the main drawbacks with metal 3-D printing were the high cost of 3-D printing titanium gripper models and the resolution of a metal 3-D printer.

EDM was considered because of the team's past experience using the Knuth Machine Tools DEM 320A CNC (Computerized Numerical Control) EDM machine at the University of Michigan Engineering National Science Foundation (NSF) Research Center for Reconfigurable Manufacturing Systems. Training could be completed for the CNC EDM machine and many grippers of the same design could be produced. The EDM solution was more cost effective than 3-D printing, but had several drawbacks. The primary drawback was that the EDM could only produce a flattened gripper design because of its limited ability to cut in two directions, so additional methods were needed to bend the flattened gripper into its final shape

Metal 3-D Printing. The university did not have a metal 3-D printer with the capabilities of successfully fabricating the gripper. Each university metal 3-D printer considered could either not print with a fine enough resolution or could not print titanium, both of which were required for fabrication and validation. As such, the only viable option was to outsource the 3-D printing. Sculpteo® and i.materialise were the two companies considered after Professor Grosh and his team attended the Association for Research in Otolaryngology (ARO) Annual MidWinter Meeting 2023. The team met with subject matter experts in Otolaryngology and gained insight on the the 3-D printing companies that were most capable of fabricating our titanium gripper designs. The team also connected with representatives from Sculpteo® and i.materialise to better understand each company's capabilities. Following these conversations, three custom CAD models were developed to be 3-D printed. The designs and their unique components are shown in Appendix B. However, after further research had been conducted, it was found that the resolution of each companies' 3-D printers were not fine enough to print the gripper, as the Sculpteo® printer had a resolution of 1 mm and i.materialise printer had a resolution of 0.5 mm.

EDM. Since none of the 3-D printers considered had a fine enough resolution to fabricate the gripper, EDM was considered the only viable method for fabrication. The overall fabrication strategy was to use the the Knuth Machine Tools DEM 320A CNC EDM machine at the University of Michigan Engineering NSF Research Center for Reconfigurable Manufacturing Systems to cut a flat gripper model and then bend sections of the model into the correct shape. The CNC EDM setup is shown in Figure 4 below.

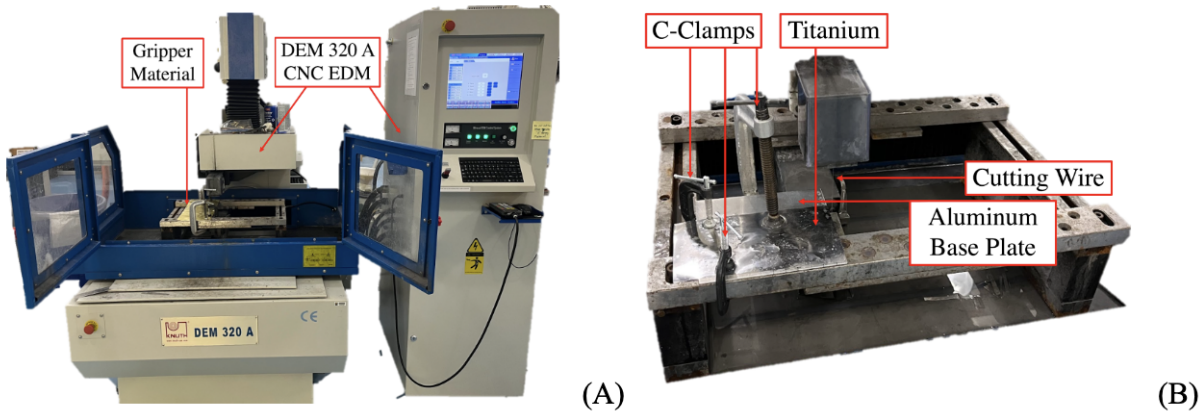

Figure 4. The figure shows the setup of the DEM 320 A CNC EDM machine used to cut the flat gripper model. (A) shows the entire setup and (B) shows a closeup of how the titanium material was set up relative to the 18μm diameter cutting wire. (B) also shows an Aluminum base plate that was used to increase the stiffness of the system, allowing for more consistent cutting.

Following EDM, the arms were bent around two 18-8 stainless steel dowel pins of diameters 1.0 mm and 0.8 mm [14], and the remaining sections were bent around the corners of the VA1200 accelerometer to ensure the accelerometer would be tightly secured to the gripper. The diameter of the pins were chosen to account for the springback of titanium [15][16] and the springback calculations can be found in Appendix C. The setup for bending is shown in Figure 5 below.

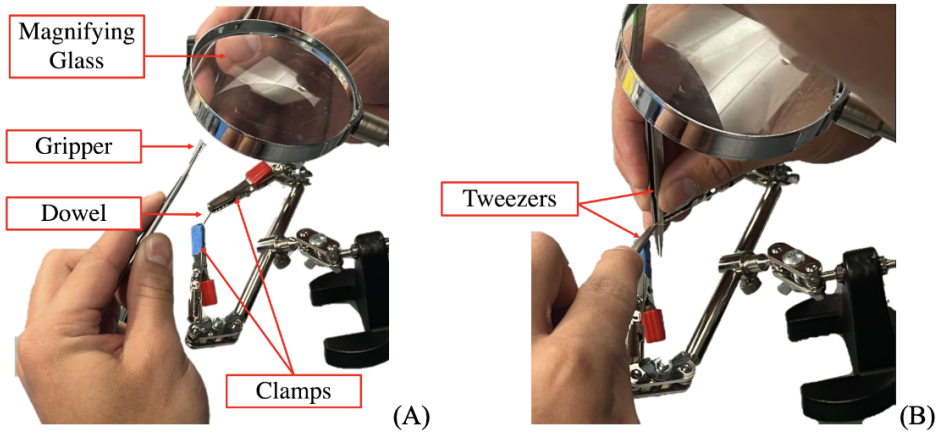

Figure 5. The figure shows the process of bending the gripper arms into their final shape by using tweezers to bend the the arms around a dowel. (A) shows two clamps holding the dowel in place. (B) shows two tweezers being used, one to firmly hold the gripper firmly in place and the

other to bend the arms. The bending process also involved looking through a magnifying glass for more accurate bending.

Overall, several fabrication trials were executed with several gripper designs. The reason for this was because during each trial, components of the gripper would often break during the EDM cutting and/or bending processes. Thus, the CAD model for the gripper needed to be modified after every trial until there was confidence that the gripper could be fabricated without components breaking during the fabrication process. Furthermore, initial trials were carried out using brass material instead of titanium, as brass was much less expensive and had a similar yield strength and ultimate tensile strength to titanium [17][18], and one gripper prototype was cut per trial to minimize waste. Finally, after there was confidence that the gripper could be fabricated successfully, Grade 5 titanium foil (ASTM B265) [19] was used in later trials and one gripper model prototype was created per trial.

Results

Using the CNC EDM machine, the flat gripper model was successfully fabricted and validated after several design modifications. Overall, ten brass gripper models and ten titanium gripper models were fabricated. The brass gripper models had a CNC run time of 30 ± 1 seconds and the titanium gripper models had a CNC run time of 131 ± 2 seconds. The large difference in run time was due to the presence of the alumninum base plate (show in Figure 4 on page 7) that was used while cutting the titanium prototypes. The brass gripper models were first used to practice bending the gripper arms around the dowels and several of the brass gripper models were bent into the correct shape without fracturing. As a result, the titanium grippers were then bent around the dowels, and one prototype successfully attached the VA1200 to the incus.

Final Gripper Design. The CAD model of the successful flat gripper design is shown in Figure 6 below.

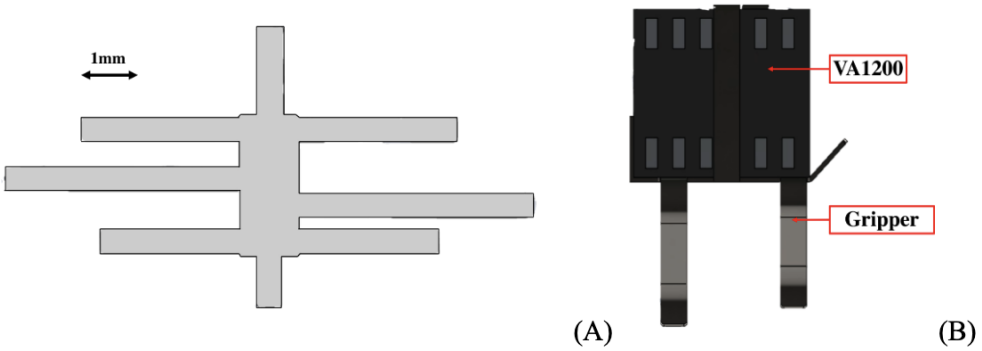

Figure 6. The figure shows the CAD model of the successful gripper design. The dimensions of the gripper were determined by using both the FA22 gripper CAD model shown in Figure 3 on page 5 as well as the dimensions of the VA1200 accelerometer. (A) shows how each corner in the design was filleted in Solidworks to reduce high local stress concentrations [20]. (B) shows the VA1200 in the system.

Fabricated and Validated Gripper. After a successful EDM and arm bending process, several gripper prototypes were attached to incus bones. They are shown in Figure 7 below.

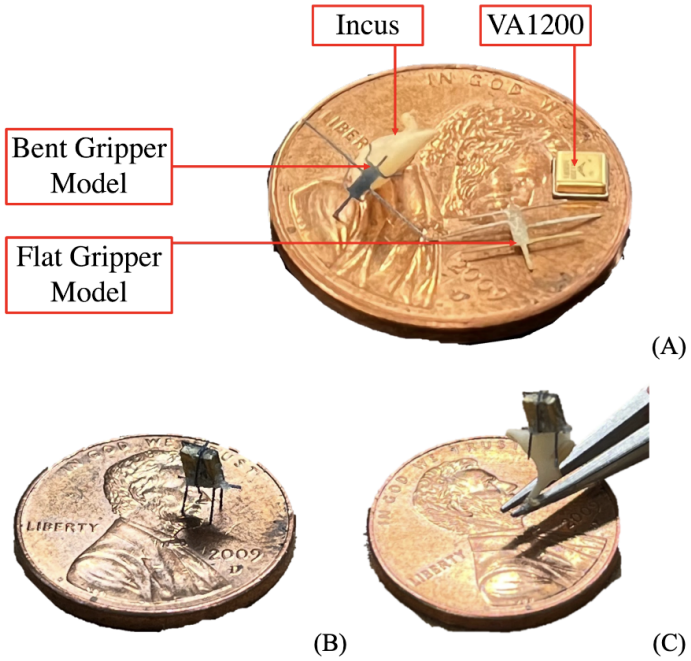

Figure 7. The figure shows a Titanium gripper bent around an incus bone. (A) shows the figure flat gripper model produced by the EDM and the VA1200 accelerometer. (B) shows VA1200 successfully attached to the gripper. (C) shows the gripper and accelerometer successfully attached ot the incus. A penny was used as background for each picture to convey the scale of the gripper.

Discussion and Recommendations

Following the completed design process, several future actions can be recommended. First, the fabrication process for the gripper should be standardized. Due to the current fabrication process requiring the gripper arms to be bent using tweezers, none of the final gripper models were exactly the same. Thus, the current fabrication process should be changed in a way to ensure less variance between final gripper models. Second, additional methods for validating the gripper/accelerometer system should be developed. Although the gripper was able to successfully attach the VA1200 accelerometer to the short process of the incus, no methods had been developed to analyze the accelerometer's performance while being subjected to movements corresponding to incus bone vibration over a range of sound frequencies. Additionally, methods should be developed to analyze the robustness and failure modes of the gripper. Finally, following the successful creation of the piezo-MEMS accelerometer, the gripper CAD model should be updated to incorporate the final dimensions of the accelerometer.

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CLINICAL INDICATIONS ANALYSIS

When the TIAP is successfully created, it will compete against all cochlear implants in the market. So, in order to assess where the TIAP could intervene in the market, the cochlear implant market needed to be defined and its important trends and drawbacks needed to be found. Additionally, the competitors excelling in the market needed to be found and compared to the TIAP. Finally, from the competitor analysis, recommendations for where the TIAP could intervene in the market could be made.

Market Definition - Global Cochlear Implants

Based on the current phase of the TIAP, our product market will be the global cochlear implants market. From technavio's *Global Cochlear Implants Market 2021-2025* report [21], this market was valued at $1,816 million in 2020 and has an anticipated compounded annual growth rate (CAGR) of 11.61% between 2022 and 2025. This market is accelerating due to the increasing prevalence of hearing loss, a rising geriatric population due to the increasing life expectancy around the world, and an increasing number of initiatives by companies promoting the awareness of hearing disabilities and improving access to cochlear implants. The market is segmented by both products, including unilateral and bilateral cochlear implants, and geography, including North America, Europe, Asia, and the rest of the world (ROW) [21]. In 2020, unilateral implants made up the largest segment of the product segment, and the market segment in North America was the largest geographic segment. It is projected that these will remain the top segments by 2025. However, it should be noted that between the present day and 2025, the cochlear implant market in North America is projected to be slow-growing compared to Asia and ROW [21]. To develop an understanding of how many cochlear implants are currently in use, at the end of 2019, about 736,900 cochlear implants had been implanted around the world, with about 183,100 of those being implanted in the United States [22]. It should be noted that the eventual goal for the TIAP is to be a disruptor in the global hearing aid market. The definition of the market can be found in Appendix D.

Market Trends, Drawbacks, and Top Competitors

Trends. There are two important trends in the Cochlear implant market that are helping drive the market's growth. First, there are currently many emerging technological innovations in this

space, including a reduction in the size of sound processors as well as the fact they can be connected to smartphones and televisions via a Bluetooth connection. An example of this is the Nucleus® 7 Sound Processor, a product created by Cochlear™. The Nucleus® 7 is "the world's first cochlear implant sound processor you can control and stream directly from your compatible smartphone" [23]. It is compatible with both Apple and Android devices and the user can manage their cochlear implant settings in the Nucleus® 7 app. The product also comes with different color options, which is an example of the second main market trend: an increase in focus on aesthetic appearance and customization of cochlear implants. The social stigma associated with the external components of a cochlear implant remains a significant pain point for users [6]. So companies are starting to create more customizable external components. These include external components whose color can match a user's skin tone or external components that can be uniquely designed by the user.

Drawbacks. There are also several drawbacks of cochlear implants that prevent market growth. First, the process of receiving a cochlear implant has a high cost. From technavio's *Global Cochlear Implants Market 2021-2025* report [21], the cost of receiving a cochlear implant is around $25000, with the devices themselves costing between $18000 and $20000 and hospital costs and surgery making up the rest. Dr.Emily Stucken, one of the University of Michigan otolaryngologists working on the TIAP project, even said that this was a low estimate and that the process of receiving a cochlear implant usually costs about $90000 for patients at the University of Michigan hospital. Second, cochlear implants have stringent regulations because the typical surgery for a cochlear implant is minimally invasive and implanted near the brain [21]. As such, it is a class III medical device by the US FDA. Thus, in order to bring a new product into the cochlear implants market, manufacturers "must submit studies and data to FDA scientists, who will review the information for safety and effectiveness" [24]. Finally, there are unfavorable reimbursement and insurance policies for cochlear implants [21]. Poor reimbursements for cochlear implants cause centers that provide cochlear implant services to restrict the number of patients that receive cochlear implants and sometimes cause centers to stop providing cochlear implant services completely. Additionally, from technavio's *Global Cochlear Implants Market 2021-2025* report, "Cochlear implants are not considered medically necessary to treat unilateral hearing loss [by Medicare]." Because of this, Medicare coverage for cochlear implants is limited [25]. This limits the number of people, especially those in the rising geriatric population who could greatly benefit from a cochlear implant, that can receive a cochlear implant.

Top Competitors. There are several key performers in the global and United States cochlear implant market. They are listed below [26][27]:

- MED-EL Medical Electronics
- Cochlear Limited
- Oticon Medical
- Advanced Bionics
- Demant A/S
- So nova

Each of these companies, among several others, have a significant share in the global cochlear implants market. Advanced Bionics, Cochlear Limited, and MED-EL themselves have an

estimated global market share of 95%. In the United States, the three companies offer a combined 16 different cochlear implant solutions and have 1802 US patents [27]. Several of the newest cochlear implants offer customizable external sound processors that have the ability to be controlled from a smartphone app [23]. These companies also have solutions that are segmented into adult and pediatric cochlear implants. With that said, all of the current solutions in the cochlear implant market have external components.

The Need for the TIAP

As previously mentioned, the main drawbacks of cochlear implants are their external components. Currently, even the top competitors in the market don't have a solution to get rid of the external components completely. That is where the TIAP has an advantage in the market.

TIAP Characteristics. The TIAP we are developing is initially set to target users who suffer from severe sensorineural hearing loss, or hearing loss between 61 to 80 decibels [28], and will be in the same market space as cochlear implants. The device is a processor that is completely implanted inside the user's middle ear membrane. Therefore, it would replace the current commercial cochlear implants, and in future TIAP phases, hearing aids, both of which are devices that use external microphone processors. The implanted processor comes with significant benefits over its external processor counterparts. These benefits are listed below:

1. Increase the range of possible activities the user can do while using their auditory prosthesis - External components of cochlear implants and hearing aids can limit the possible activities a user can do while using their auditory prosthesis. For example, it is recommended that a user take off the external component of their cochlear implant or hearing aid before taking a shower or swimming. External components are not waterproof; getting them wet can cause the prosthesis to malfunction. It is also recommended that the user take off the external component before sleeping, as the twisting and turning of the user during sleep could damage the device, causing it to malfunction. Both of these examples highlight the fact that the user cannot use their auditory prosthesis all the time, which is undesirable, as not being able to hear at all times can cause many problems for users. These problems include not being able to communicate as well with others and requiring additional assistance from others when not being able to use their cochlear implant or hearing aid. With the TIAP, a user will be able to hear at all times, getting rid of these problems.
2. Increase user safety - In addition to the increase in the range of possible activities, the TIAP will increase user safety because it allows the user to hear at all times. Currently, when a user has to remove the external microphone processor of their cochlear implant or hearing aid, like before they sleep or take a shower, they are not able to hear well or at all. This comes with significant safety concerns. For example, if a user is sleeping without their auditory prosthesis and a fire alarm goes off, the user wouldn't be able to hear the alarm. The TIAP solves this problem by allowing the user to hear at all times.
3. Ease of use - Removing external components before exercising, swimming, and sleeping can lead to damage to the prosthesis and theft or loss of the device. The TIAP solves this problem. Additionally, many hearing aids have to be adjusted by the user. With many users of hearing aids coming from the geriatric population, it becomes increasingly difficult for these users to adjust their hearing aids as they age. With the TIAP, the device works without the user having to make any adjustments.

4. Cosmetic benefits - There are many cosmetic benefits to not having external components. As previously mentioned, there is a social stigma associated with wearing an auditory prosthesis. This social stigma can have a significant negative impact on the users' mental health and overall well-being. With an implantable auditory prosthesis, this social stigma is removed because other people can't see it. Although there are an increasing number of solutions in the cochlear implant and hearing aid market that have customizable parts to reduce social stigma, there is not a solution that removes the social stigma entirely.

In addition to the benefits associated with the TIAP not having external components, an additional benefit of the TIAP is that it makes more use of the ear itself. The human ear is an amazing organ that can collect and amplify sound very well, much better than the external microphone of a cochlear implant. The TIAP uses the sound collected by the ear by receiving the vibrations of the ossicle bones and relaying very accurate sound information to the brain.

Clinical Indications Analysis

The TIAP is an innovation in the auditory prosthesis space. The TIAP's Piezo-MEMS accelerometer will outperform the external microphones of cochlear implants while increasing user safety and removing the social stigma associated with wearing an audible prosthesis. However, the path to market intervention is difficult. First, patent applications for all the TIAP's innovative technology must be submitted and approved. Both clinical and non-clinical laboratory testing should be done wherever necessary, and there should be statistical evidence that shows the TIAP as a successful solution to severe sensorineural hearing loss. Then, in order to start selling the TIAP commercially, it must obtain FDA approval. As previously mentioned, cochlear implants and the TIAP are Class III FDA medical devices [23]. In order to sell the TIAP, all of the general regulatory FDA regulatory controls, namely sections 501, 502, 510, 516, 518, 519, and 520 of the United States Federal Food, Drug, and Cosmetic (FD&C) Act needs to be followed and Premarket Approval (PMA) needs to be approved [29]. A more thorough explanation of these requirements can be found in Appendix E below. Assuming a business plan is created during the wait time for patent and FDA approval, once FDA approval is obtained and the TIAP is ready to enter the cochlear implants market, I suggest that the team use the University of Michigan Medicine connection to start offering the TIAP to patients looking for a solution to their severe sensorineural hearing loss. From the initial TIAP users, success stories should be used to help make the device more well-known. If there is enough evidence to show that the TIAP will be successful in performing better than cochlear implants, the TIAP could then start to be used in hospitals around the United States.

Conclusions and Recommendations

The global cochlear implant market is valued at nearly $2 billion. Three companies take up nearly 95% of the market [22], but our implantable prosthesis will perform better than their current solutions, as well as solves many problems that users have with the external components of their cochlear implants. It is critical to get the TIAP technology patented and FDA-approved so that University of Michigan hospitals can offer the TIAP to patients. For next semester, it is recommended that a more thorough reading is done on gaining FDA approval by looking at what competitors have done or are currently doing to get approval. Patents should also be looked into to make sure that the TIAP technology is novel.

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APPENDIX A:

Marked up drawing of MED-EL SP Coupler

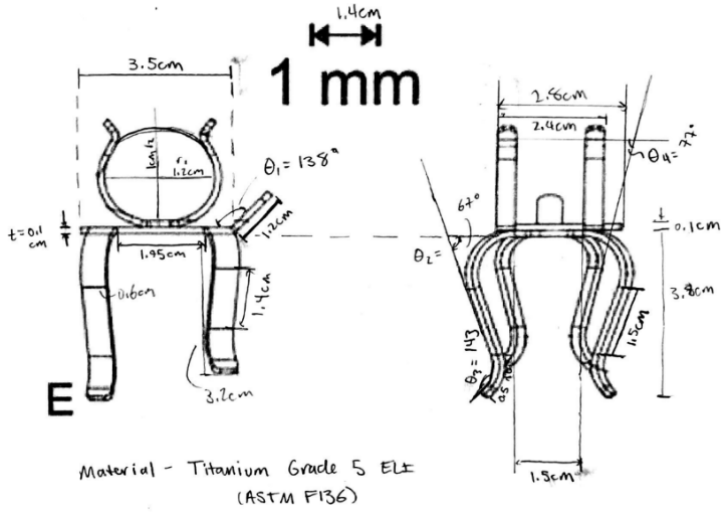


Figure A1. The figure shows how the dimensions of MED-EL's SP incus coupler were determined.

Engineering Drawing

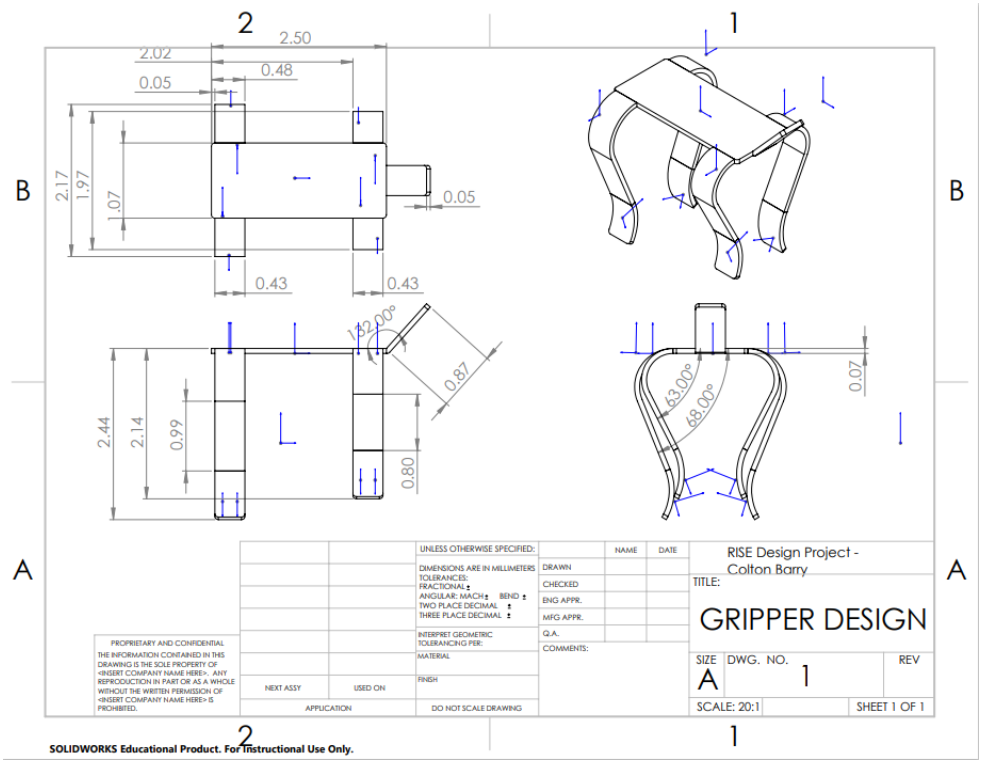


Figure A2. The figure shows the engineering drawing of the FA22 semester gripper CAD design based on MED-EL's SP Coupler. All dimensions are in millimeters and the material is Titanium Grade 5 ELI (ASTM F136).

APPENDIX B:

CAD Models for 3-D Printed Fabricaiton Method

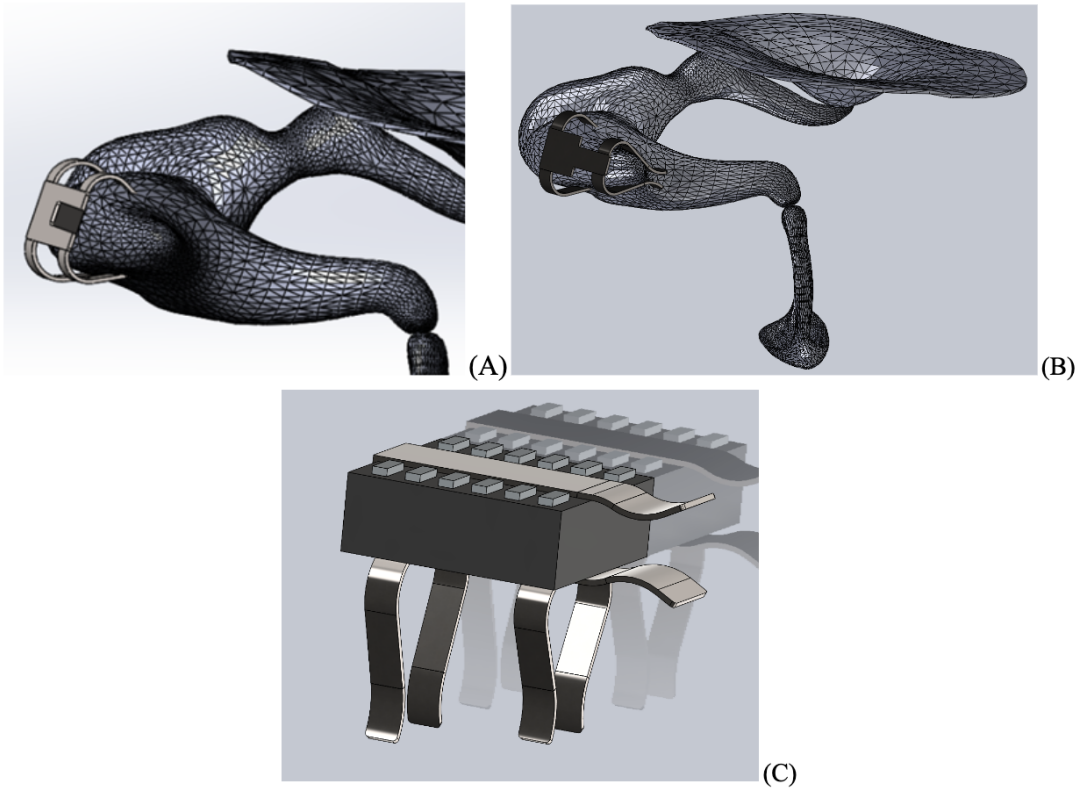
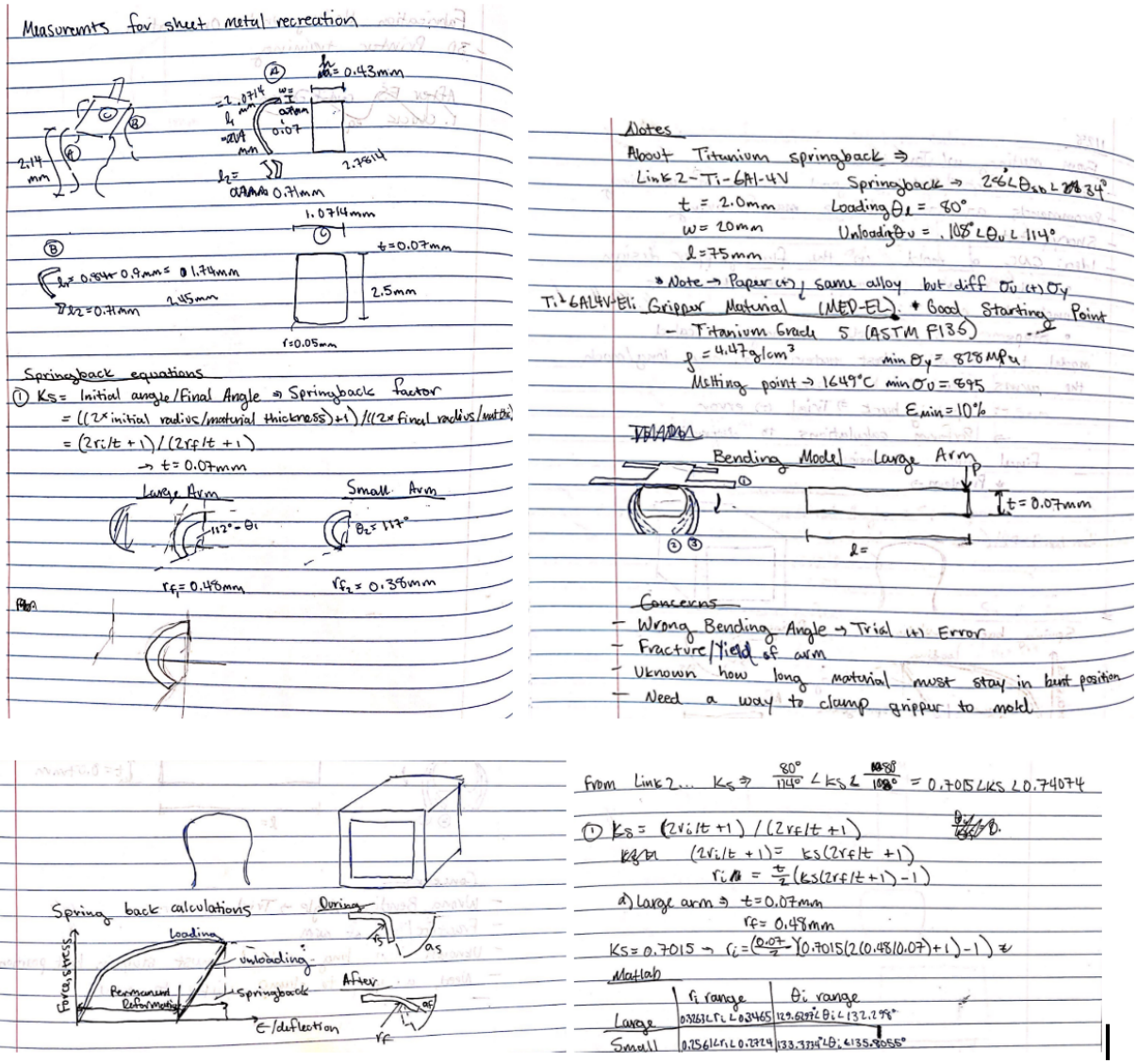


Figure B1. The figure shows three CAD models that were generated to be 3-D printed. (A) shows the final FA22 gripper model CAD design. (B) shows a modified gripper body to reduce material cost. (C) shows another modified gripper that allows for easy attachment and detachment of the Vesper VA1200 accelerometer.

APPENDIX C:

Springback Calculations to Determine Dowel Diameter [15][16]



APPENDIX D:

Global Hearing Aids Market. Although the global cochlear implants market is the market segment that the current phase TIAP is in, it is a relatively small market. This is because cochlear implants are only for users who suffer from severe sensorial hearing loss. Thus, the goal for further phases of the project is to enter into the global hearing aids market, which is significantly larger than the global cochlear implants market. From the *Global Hearing Aid Devices and Equipment Market Report 2022* [The Business Research Company, "Global Hearing Aid Devices And Equipment Market Report 2022" (published 08/2022)], the estimated global market size of hearing aids was $9,571.8 million, with a CAGR of 3.8% between 2016 and 2021. The market overall is much more segmented than the global cochlear implants market. It is segmented by product (five different types of hearing aids), distribution channel (clinics, pharmacies, online

sales, and soon to be over-the-counter), technology (analog and digital), patient age (pediatric, adults, elderly), and type of hearing loss (conductive and sensorineural). There are currently many innovations in hearing aid technology that are responsible for the growth of the market, including wireless hearing aids, AI powered hearing aids that can make changes automatically when different environments are detected, and Bluetooth capabilities to link hearing aids with other technology.

FDA approval info [29]
FD&C Act sections:

- 501: Adulterated devices
- 502: Misbranded devices
- 510: Registration of producers of devices
    - Establishment registration and device listing
    - Premarket Notification (510k)
    - Reprocessed single-use devices
- 516: Banned devices
- 518: Notifications and other remedies
    - Notification
    - Repair
    - Replacement
    - Refund
    - Reimbursement
    - Mandatory recall
- 519: Records and reports on devices
    - Adverse event report
    - Device tracking
    - Unique device identification system
    - Reports of removals and corrections
- 520: General provisions respecting control of devices intended for human use
    - Custom device
    - Restricted device
    - Good manufacturing practice requirements
    - Exemptions for devices for investigational use
    - Transitional provisions for devices considered as new drugs
    - Humanitarian device exemption

Premarket Approval (PMA):

PMA data requirements include technical sections that are usually divided into non-clinical laboratory studies and clinical investigations. Non-clinical laboratory studies section “includes information on microbiology, toxicology, immunology, biocompatability, stress wear, shelf life, and other laboratory or animal tests” [29]. Each study has to be conducted in accordance with the good laboratory practice for nonclinical laboratory studies. The clinical investigations section should “include study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints,

tabulations of data from all individual subjects, results of statistical analyses, and any other information form the clinical investigations" [29].