REDESIGN OF SENSOR "GRIPPER" FOR USE IN MIDDLE EAR PROSTHESIS

RISE - Fall 2022

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ABSTRACT

Hearing loss is a significant problem around the world. There are currently over 1.5 billion people that suffer from hearing loss globally, 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 the 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 design process of developing the gripper, which securely attaches to the incus but is not so tight as to damage the bone or cause necrosis. Included below is information about the background research conducted, initial design requirements and designs, key experiences and learnings, and a final design that will be used for finite element analysis (FEA) in winter 2023. Additionally, below is a clinical indications analysis for our prosthesis that includes recommendations for how it can intervene in the global cochlear implant market.

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[2]. 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 [2]. 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 [2]. 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 [2].

Sensorineural hearing loss "encompasses disorders that affect the inner ear and the neural pathways to the auditory cortex"[2] and generally occurs when the cochlea in the inner ear is damaged 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 [3]. Figure 1 below shows a graphic of a cochlear implant.

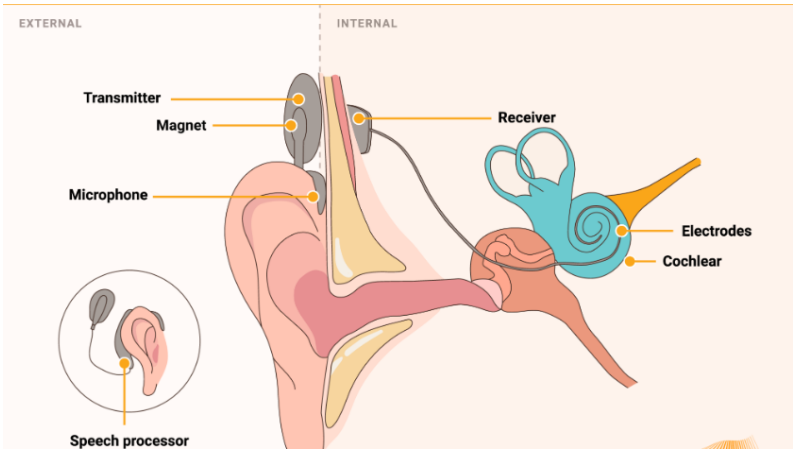


Figure 1. The figure shows the location of each component of a cochlear implant [4].

Although there are many benefits to current hearing aids and cochlear implants, there are also many drawbacks to them. The 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 [5]. 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 [6]. 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 [7]. 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 [8] 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 [9] below.

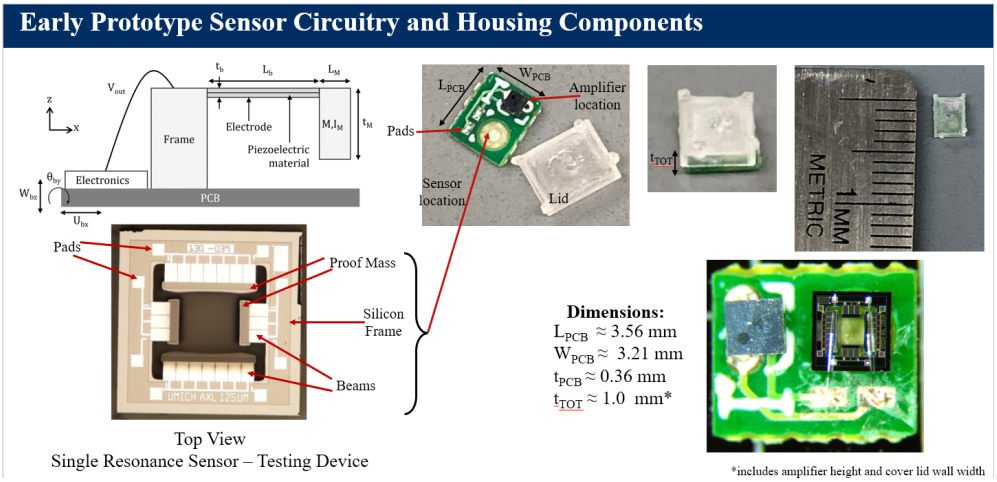


Figure 2. The figure shows the early-stage prototype for the accelerometer, including the materials and the current dimensions [9].

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 ossicle 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 ossicle 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 ossicle 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 ossicle bone. There are several approaches to solving this complex design problem, and one potential solution could be to use the biocompatible Nickel and Titanium (NiTi) alloy [10] Nitinol.

Nitinol

Nitinol belongs to the Shape Memory Alloy (SMA) family because it has the ability to undergo martensitic transformation. At the typical austenitic temperature for Nitinol, around 500℃ [11],

Nitinol can take a strong and permanent crystalline structure and shape. Then, as Nitinol is cooled it undergoes a martensitic transformation, where the crystalline structure of the Nitinol changes and it can easily deform into a new shape [12]. Finally, the Nitinol can be reheated to the austenitic temperature where it will return to its original permanent crystalline structure. Because of its biocompatibility and shape memory properties, Nitinol is used in many biomedical applications. And depending on the proportions of Nickel in the alloy, the temperature at which the martensite-to-austenite transformation occurs varies [13].

Current Nitinol Gripper Design

In the winter 2022 semester, a student-project Mechanical Engineering 450 (ME450) team worked on developing a gripper using Nitinol. The gripper designed would initially be a flat Nitinol piece that when heat treated, would curl around the Long Process (LP) of the incus and attach tightly to the bone. The images of their CAD model and final manufactured gripper are shown in Figure 3 below:

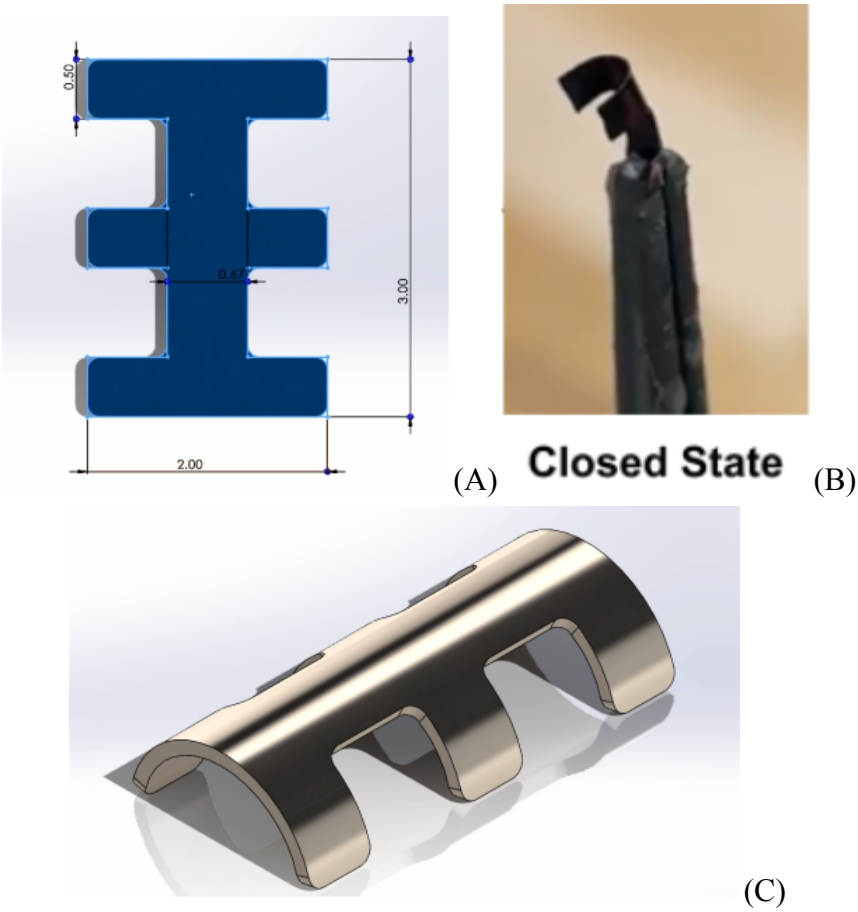


Figure 3. The figure shows the final CAD design (A)(C) and heat-treated prototype (B) of the ME450 team's nitinol gripper [14].

The ME450 team's final 5:1 prototype successfully attached a scaled accelerometer to a scaled incus bone. However, while the final design showed promise that Nitinol was a potential solution for the gripper, there were several design flaws. First, the design doesn't have a successful way of attaching the gripper to the accelerometer. Trying to attach a box-shaped accelerometer onto a curved surface would be very difficult. In addition, the design has the accelerometer directly attached to the top surface of the gripper. This would restrict the surgeon's view of where and how the gripper attaches to the incus, making surgery difficult or impossible. Because of these design flaws, a redesign of the gripper that builds on the past ME450 team's work is needed.

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 RE-DESIGN

After looking at the design constraints for the gripper, evaluating the strengths and weaknesses of the ME450's nitinol gripper design, reviewing the existing middle ear transducer grippers, and attending several meetings with Professor Grosh and his research team, a design process for re-designing the gripper mechanism was completed.

Gripper Design Requirements

The design requirements set for the new gripper are shown below in Table 1.

Table 1. The table shows the design requirements for the gripper/accelerometer system. It also includes the target that should be achieved by the end of the project.

Requirements	Description	Target
Biocompatible	The chosen material of the gripper mechanism must be biocompatible and safe for the patient	Biocompatible: Nitinol, Titanium, Platinum
MRI safe	The chosen material must be able to work when a patient gets an MRI	MRI safe: Nitinol, Titanium, Platinum
Width of System	The gripper must allow for the accelerometer to fit in the middle ear space	Minimum Gripper + Sensor Width $<$ 1mm

Sensor attachment and detachment	The entire accelerometer and gripper system should attach and detach from the incus as one piece	Sensor can easily be attached, detached, and/or replaced easily via surgery
Ease of Surgery	To make surgery possible, the surgeon's view of where the gripper attaches to the ossicle cannot be blocked by the accelerometer	Accelerometer offset from gripper
Accelerometer Movement	The system should limit the movement of the accelerometer so Ossicle vibration/movement only	System only moves as bone vibrates

Initial Gripper Designs

At the beginning of the design process, a lot of background reading was done to get caught up on the project background, understanding the locations of the important components of the ear, understanding the related experiments/models/designs other institutions and companies have completed, as well as to find several objects not related to the design problem that could potentially serve as inspiration for a unique solution. Afterward, I was able to brainstorm many ideas and create sketches which can be found in Appendix A. From the sketches, I created an initial four gripper CAD designs in Solidworks. They are shown in Figure 4 below.

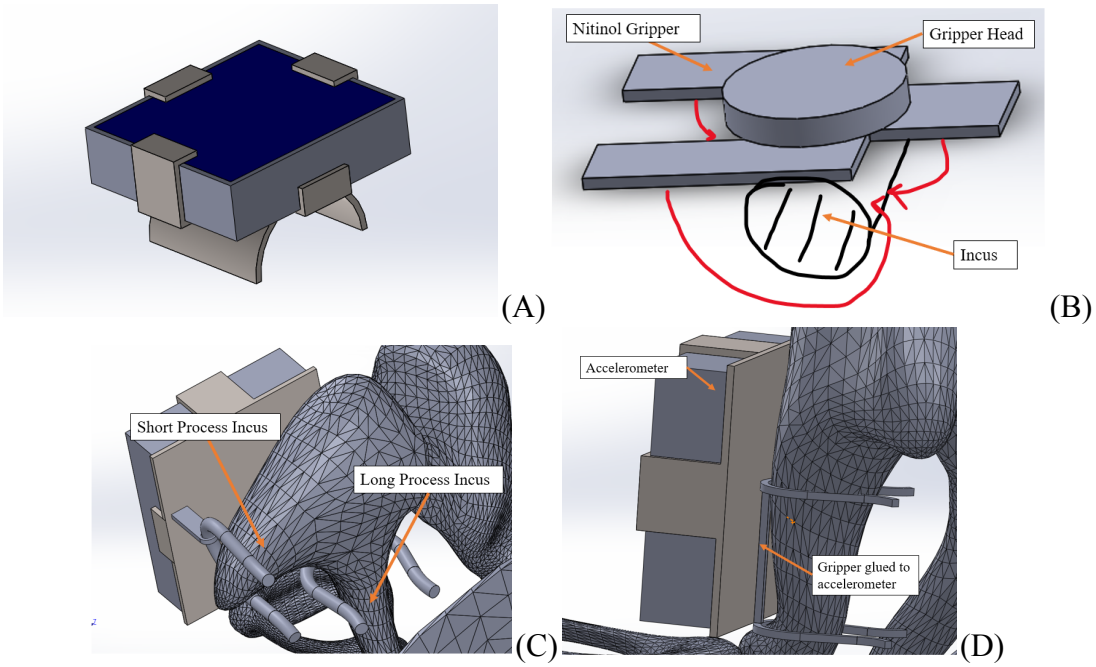
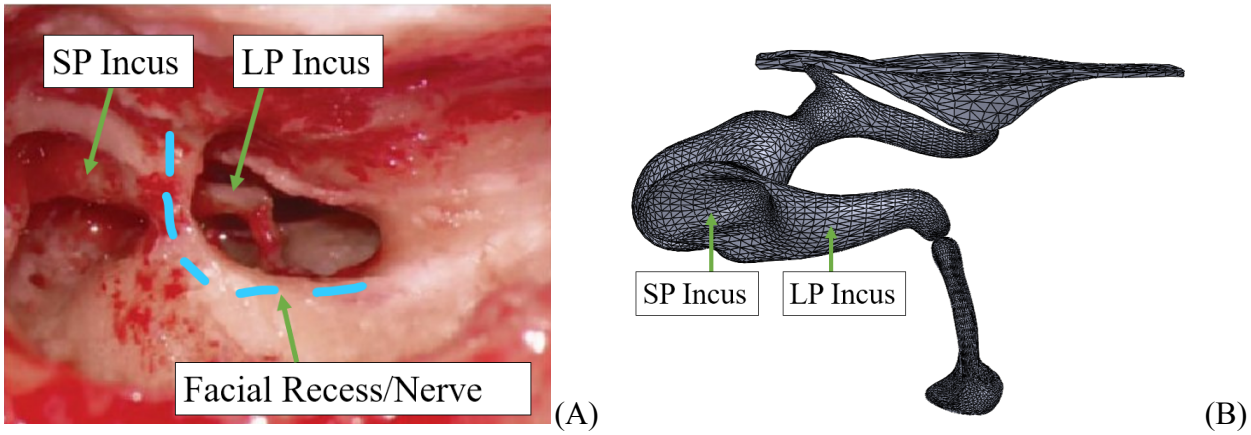


Figure 4. The figure shows the initial four designs after the brainstorming and background reading process.

Findings. Appendix B includes a detailed explanation of each of the initial designs and a Pugh chart evaluation comparing each design. The greatest design strength was the clips that attach to the incus. The clips should be able to slide onto the incus and the ends could be tightened using a crimper, securely attaching the gripper to the incus but not so tight as to cause necrosis. On the

other hand, the main limitation that occurred in every design was that the “ease of surgery” design requirement was not being met. To help with mastoidectomy and posterior tympanotomy, the typical cochlear implant surgery, should be used going forward to create new gripper designs. Figure 5 shows a surgeon’s view of a mastoidectomy and posterior tympanotomy, as well as the CAD model of the same view.



(A) (B)

Figure 5. The figure shows a surgeon’s view of a mastoidectomy and posterior tympanotomy [15](A) as well as the CAD model of the middle ear with the same view (B).

Figure 5 shows the view a surgeon has while performing a cochlear implant surgery. This was concluded after the research team watched Dr.Stucken perform a mastoidectomy and posterior tympanotomy. Also concluded from the surgery, the gripper should attach to the **short process** of the incus because there is significantly less risk of damaging the facial nerve. During a cochlear implant surgery, the surgeon inserts the electrodes of the cochlear implant into the cochlear by going through the facial recess [16], shown to the right of the dashed lines in Figure 3(A). The facial nerve lies just underneath (into the page) the dotted blue lines in Figure 3(A) and it’s crucial that the surgeon doesn't hit/damage the nerve because it can result in total facial paralysis [17]. So, by attaching the gripper to the short process of the incus, the facial recess is avoided completely and there is significantly less risk of causing facial paralysis.

It should be noted that before conclusions were made from the cochlear implant surgery, the team thought that the best place to insert the gripper onto the incus was on the long process, as there was more space. Two additional designs were created before the surgery occurred. They are shown in Figure 6 below and detailed explanations of each design are in Appendix C.

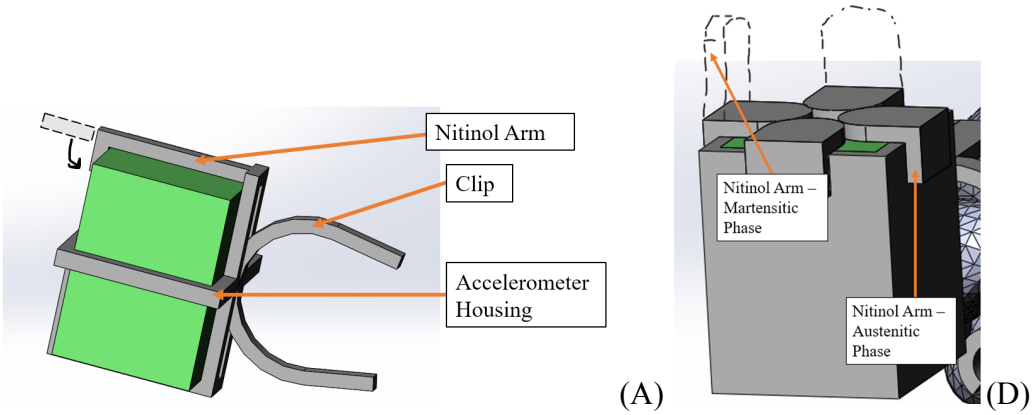


Figure 6. The figure shows two further gripper designs that would attach to the LP. They both utilize Nitinol and should be re-looked at for accelerometer casing design next semester.

Final Gripper Design

Based on the findings, the final design was modeled after the Med-EL short process coupler [18], including the material. In order to obtain appropriate dimensions, a study about the coupler's performance was found [19] and important dimensions were measured using a ruler and a protractor. The final design is shown in Figure 7 below. The engineering drawings with the important dimensions of the design can be found in Appendix D.

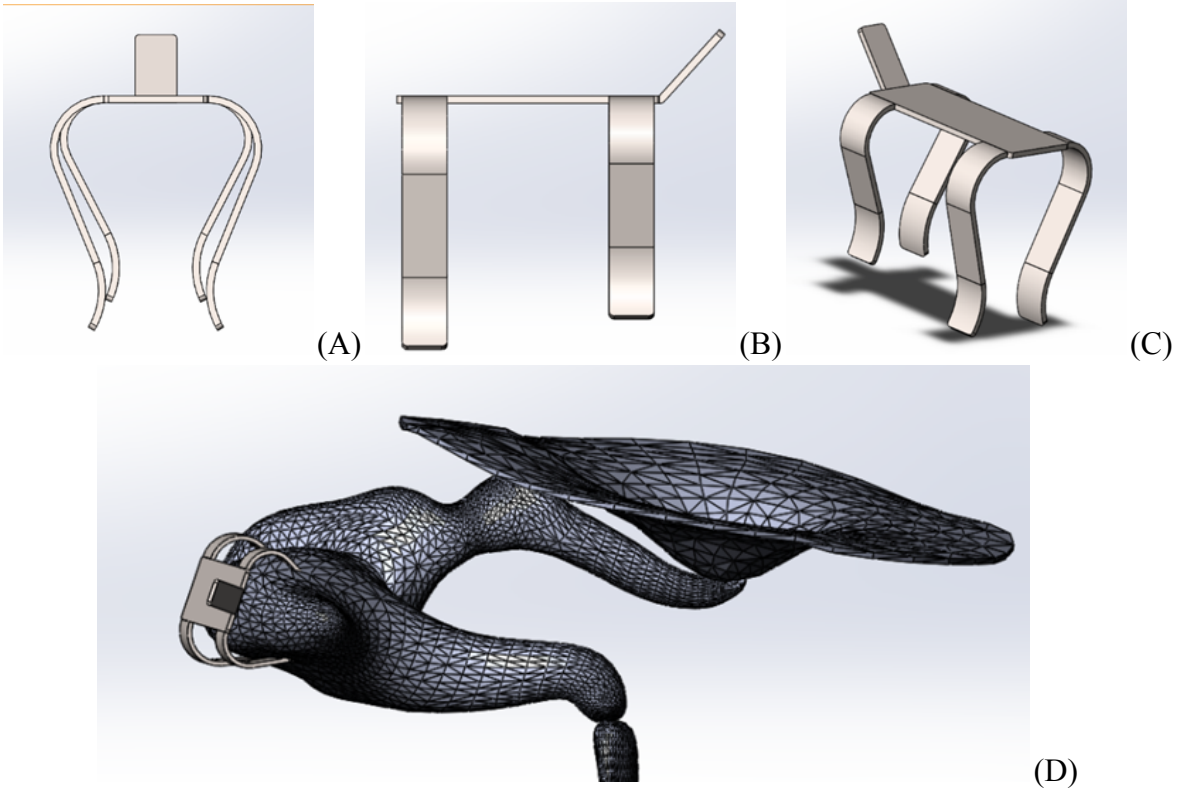


Figure 7. The figure shows the CAD model of the final design. It shows the front (A) and side (B) views of the design as well as how it will fit onto the SP of the incus (D). The material of the final design is Titanium Grade 5 (ASTM F136), which is the same as MED-EL's SP coupler.

Discussion and Recommendations

Following this project, several recommendations can be made for the Winter 2023 semester. First, different orientations for the accelerometer in the middle ear need to be considered. Because the incus vibrates differently depending on the frequency of the sound being transmitted through the tympanic membrane, the optimal location of the accelerometer is unknown, which is why the accelerometer was not shown in the final model. So, finite element analysis (FEA) should be done to determine if the accelerometer needs to be offset from the gripper and if so, where the gripper should be placed inside the middle ear. Second, the design of the accelerometer case needs to be finalized. The gripper design with the nitinol arms showed promise, so further background reading and modeling, specifically measuring the stress and strain of the nitinol during the forming process, should be conducted to determine the feasibility of fabricating the design. Finally, after modeling is complete, several gripper prototypes should be created so that future teams can conduct lab testing.

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 [20], 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) [20]. 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 [20]. 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 [21]. 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 E.

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" [22]. 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 [5]. 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 [20], 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 [20]. 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" [23]. Finally, there are unfavorable reimbursement and insurance policies for cochlear implants [20]. 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 [24]. 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 [25][26]:

- 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 [26]. Several of the newest cochlear implants offer customizable external sound processors that have the ability to be controlled from a smartphone app [22]. 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 [27], 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 [28]. 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 [21], 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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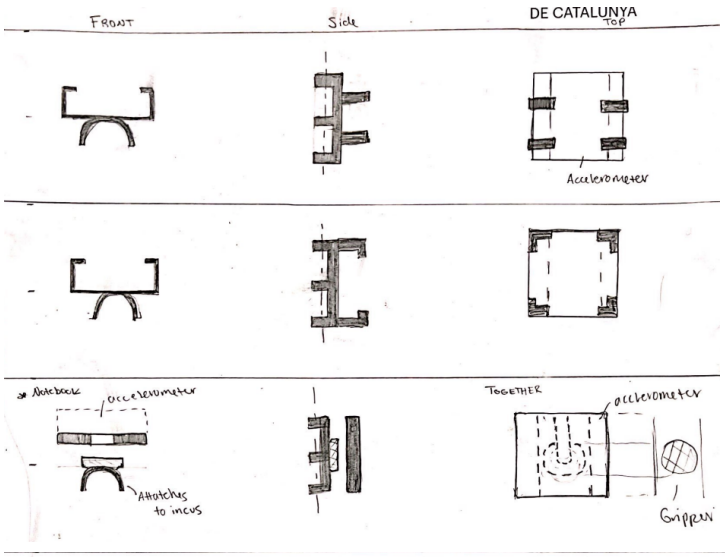
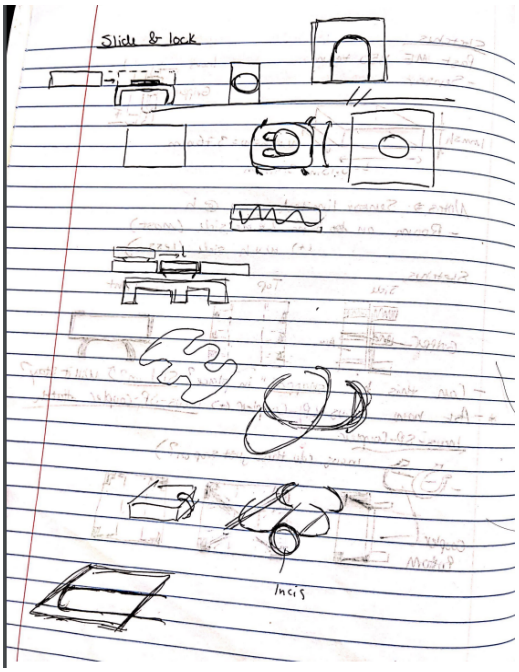
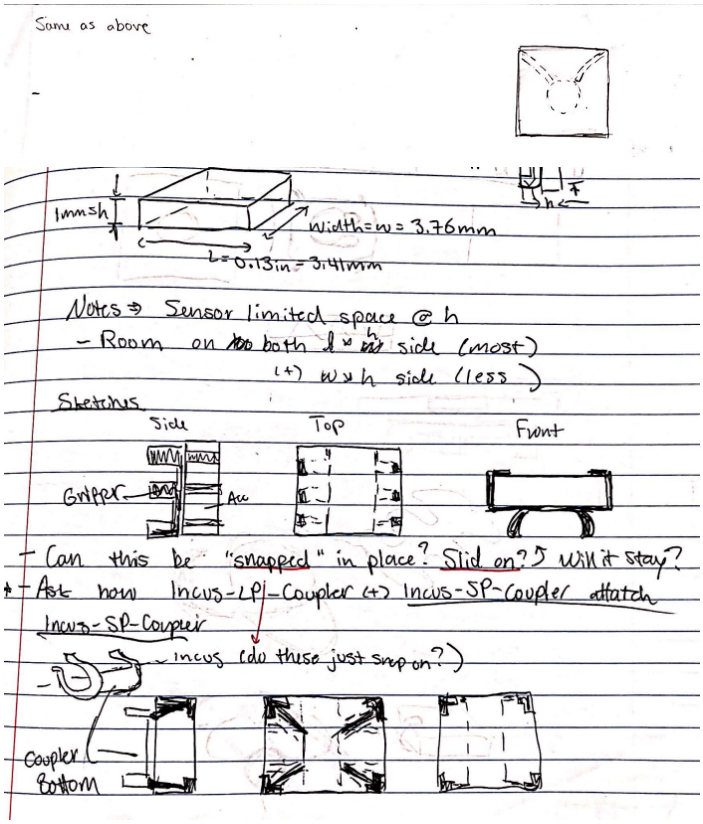
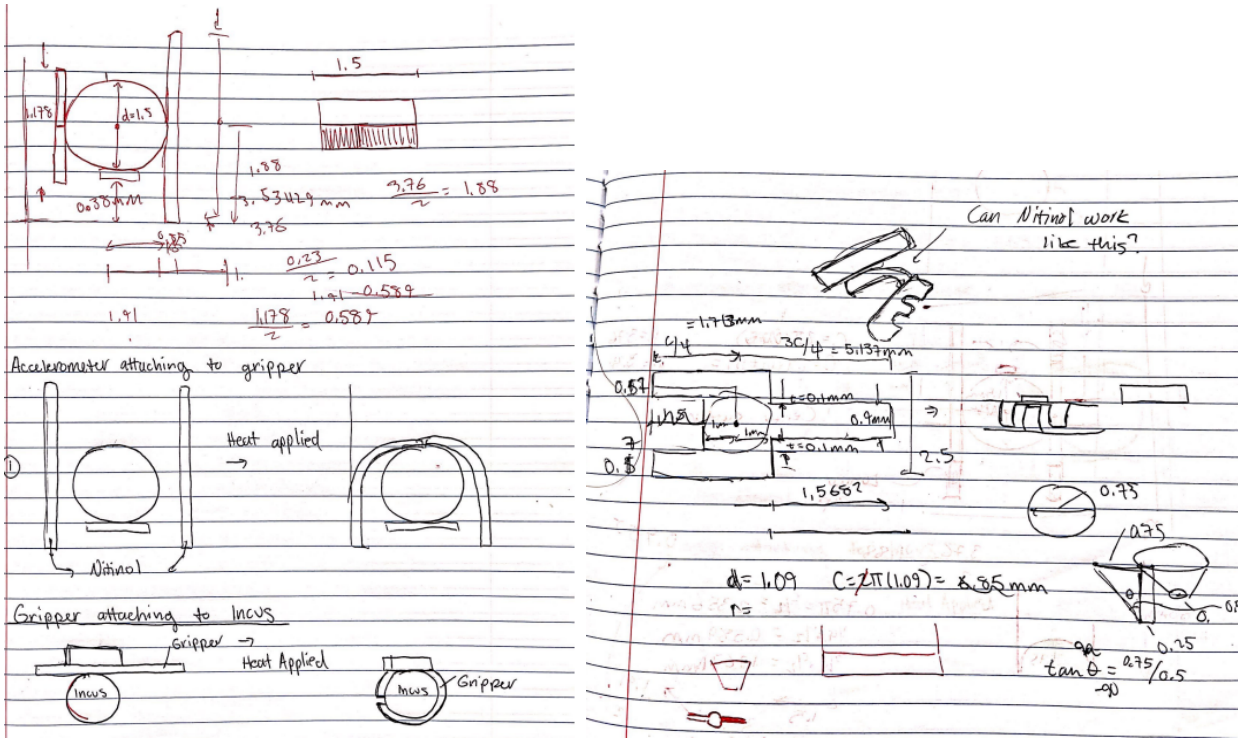
APPENDIX A: Sketches for concept generation









APPENDIX B: Initial Four Designs and Pugh Chart Evaluation

Design 1. The idea behind this design is that a biocompatible adhesive (Look this up) will be administered to the Platinum gripper before the accelerometer is placed into it. Surgically, the gripper would first be attached to the LP of the incus without the accelerometer using a crimper. The accelerometer would then be placed inside of the gripper as shown below in Figure 1. The gripper would be biocompatible and MRI compatible, being made of Platinum, which is flexible for easy attachment and detachment of the gripper, and it also will limit the movement of the accelerometer to the ossicle vibrations alone.

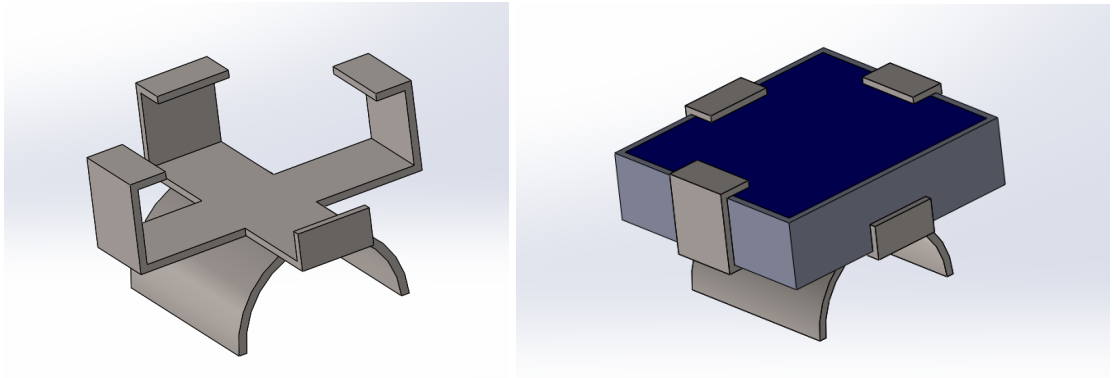
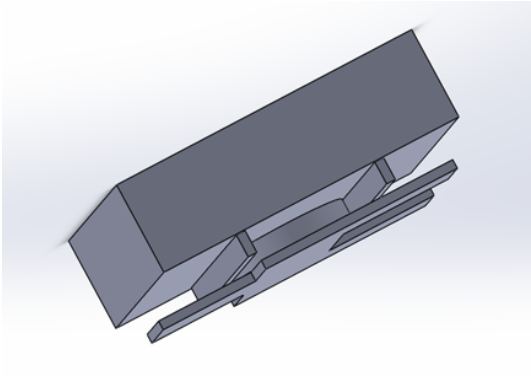
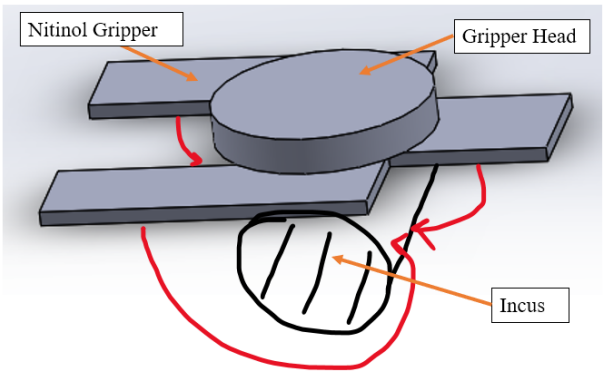


Figure X. The figure shows design 1 with and without the accelerometer. The curved section of the design will be crimped onto the LP of the incus.

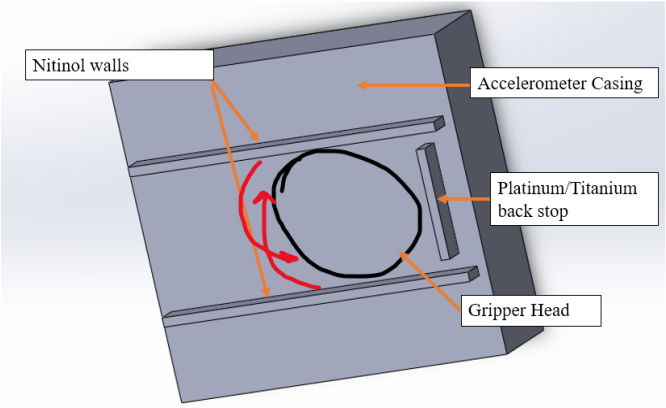
Design 2. This design takes advantage of Nitinol's shape memory property. As shown in Figure X (A) below, there are two components of this gripper/accelerometer system. As shown in Figure X (B), the first component is a Nitinol gripper that has a unique cylindrical head. Shown by the red arrows, after heat treatment, the Nitinol will wrap around the Incus in three places. As shown in Figure X (C), the second component contains the accelerometer with a unique casing that has a Platinum/Titanium backstop as well Nitinol walls. After the gripper is attached to the Incus, the head of the gripper will slide until it hits the backstop. Then the system can be heat treated again and the Nitinol walls will lock the whole gripper/accelerometer system into place.



(A)



(B)



(C)

Figure X. The figure shows design 2. (B) shows how the gripper will attach onto the incus and (C) shows how the accelerometer will slide onto the gripper head and will be attached using Nitinol's shape memory property.

Design 3. The third design, shown in Figure X below, shows a gripper that will attach to both the LP and SP of the Incus. Shown in Figure X, there are two clips that will attach to the bone, and these clips will be attached to the accelerometer. These clips can be made from Titanium or Platinum, where they would be crimped onto the LP and SP, or they can be made from Nitinol, where they can be heat treated to latch onto the LP and SP.

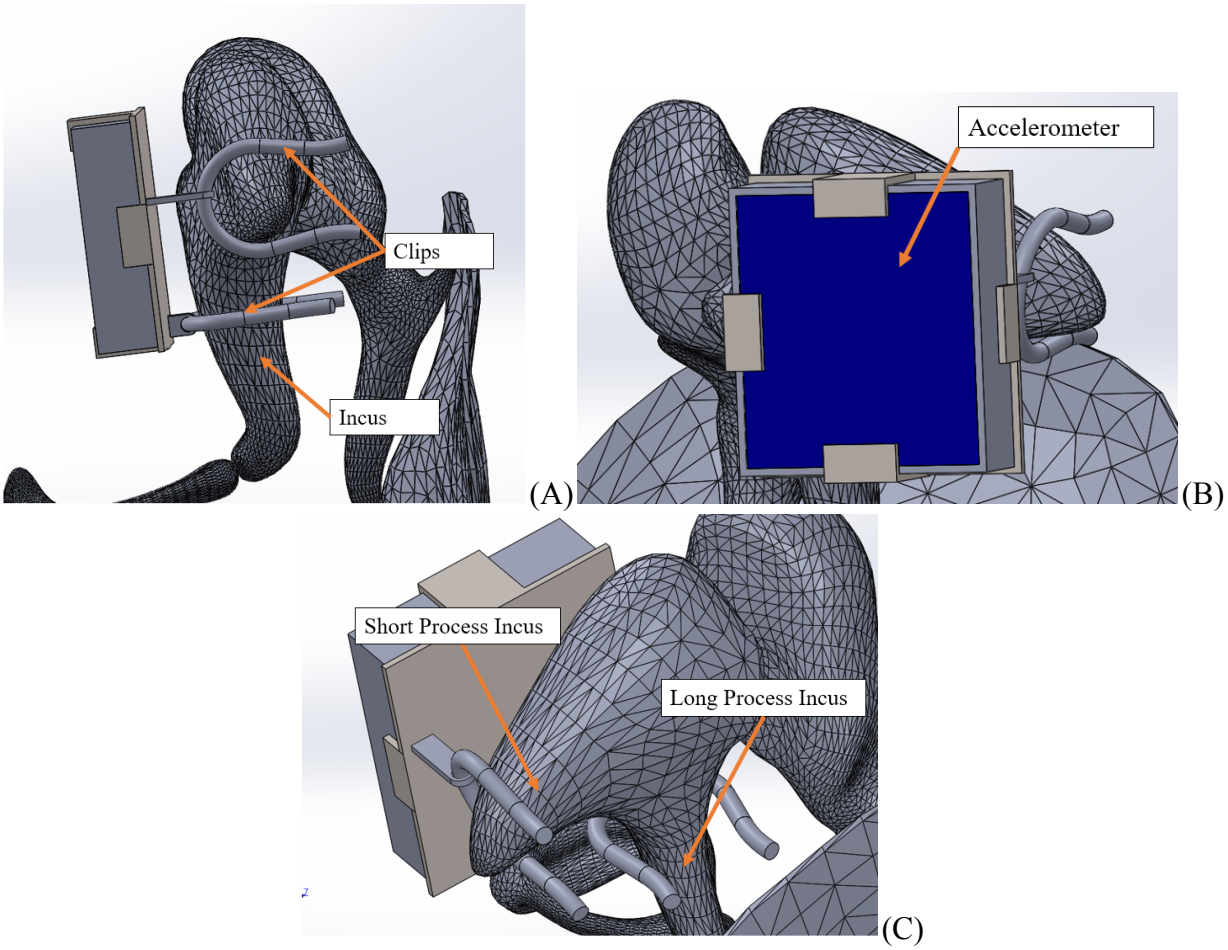
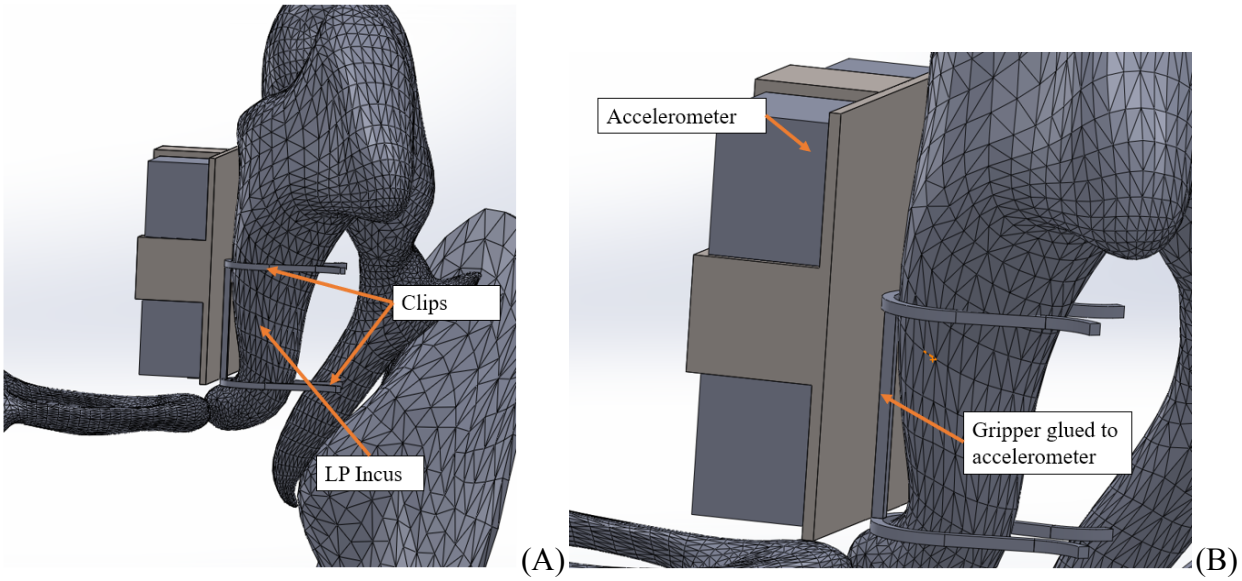


Figure X. The figure shows the unique clip design that attaches to both the LP and SP of the incus, limiting the movement of the accelerometer

Design 4. The fourth design, shown in Figure X, also utilized two clips. The clips will both be attached to the LP of the incus. Compared to Design 3, this design has a square cross section that makes the gripper easier to attach to the accelerometer casing. The idea behind surgery with this design is that the clips will first be attached to the LP without the accelerometer so the surgeon has a view of where the gripper and bone are attached. Then the accelerometer can be glued in. afterwards. The clips can be made from Titanium or Platinum, where they would be crimped onto the LP, or they can be made from Nitinol, where they can be heat treated to latch onto the LP.



(A) (B)

Figure X. The figure shows a unique clip design that easily attaches the gripper to the accelerometer, while limiting the movement of the accelerometer, as the bottom clip uses the angle between the incus and the stapes.

Pugh Chart. Following the creation of the initial four design concepts, I created a Pugh Chart to evaluate each design. The goal of the Pugh chart was to determine what aspects of each design worked well and which ones did not. The weights of the requirements range from 1 to 5, with 5 being the most important. The Pugh chart is shown below in Table 2.

Table 2 - The table shows the Pugh chart comparing my initial 4 designs.

Objective	Weight	Design 1	Design 2	Design 3	Design 4
Material	1	0	-1	-1	-1
Width of System	4	0	-1	0	0
Sensor attachment and detachment	2	0	-1	+1	+1
Gripper pressure on the Incus	4	0	-1	0	0
Ease of Surgery	5	0	-1	0	+1
Total		**0**	**-16**	**+1**	**+7**

The design requirement and their weights are explained below:

1. Material - The material of the gripper was weighted a **1** because each design was biocompatible and MRI compatible and using a combination of materials doesn't matter as much to the overall project, just as long as the gripper works. However, I gave lower

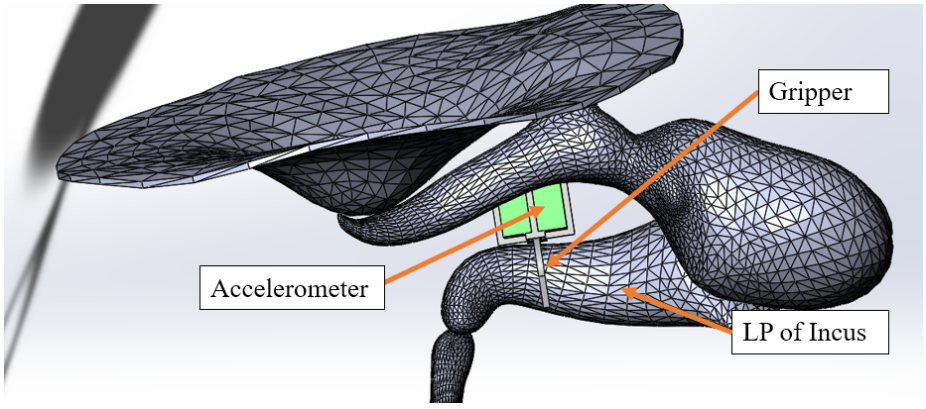
scores to designs using multiple materials, as they would be more difficult to manufacture.

2. Width of System - The width of the system was weighted a **4** because it is highly important that the accelerometer can fit in the middle ear space. If the width condition is not met, a new design for the gripper or sensor would be required.
3. Sensor attachment and Detachment - This requirement was weighted a **2** because although it would be beneficial for the TIAP to attach and detach easily so a patient could have their TIAP replaced, it is not as important as other design requirements. Ideally the TIAP will work for the user's lifetime so it would only need to be attached to the user once.
4. Gripper Pressure on Incus - This requirement was weighted a **4** because it is highly important that the gripper doesn't cause incus necrosis. If the gripper causes incus necrosis, then the TIAP is doing more harm than good for the patient.
5. Ease of Surgery - This requirement was weighted a **5** because it is of the greatest importance that the TIAP can be implanted via surgery. The surgeon needs to know where and how the gripper is attaching to the incus. If they can't determine where the gripper is attached, then the surgery can't be completed and the patient would not be able to use the TIAP.

APPENDIX C:

Before the team was able to attend a live cochlear implant surgery, two additional designs were created attaching the gripper to the **long process** of the incus. Before the surgery**,** the team had thought that attaching the gripper to the long process was the best option, as we thought

Design 4. This design utilizes one clip that will attach to the LP of the incus. It is made from Titanium or platinum and will first slide onto the LP. Then, the ends of the clip can be crimped to tightly secure the accelerometer to the LP. The housing for the accelerometer is a combination of platinum or titanium and nitinol. In order to secure the accelerometer inside the housing, nitinol arms can be heat treated to firmly lock the accelerometer into place. Figure X below shows the CAD model of this design to explain how it works.



(A)

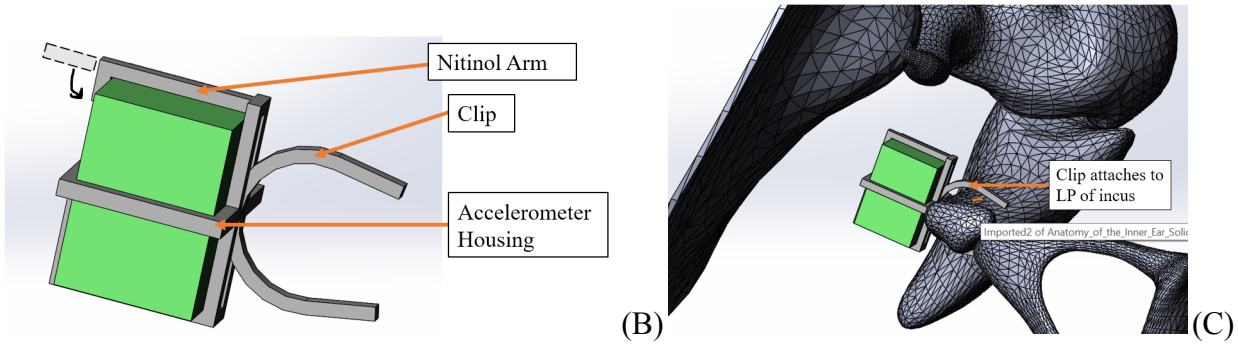
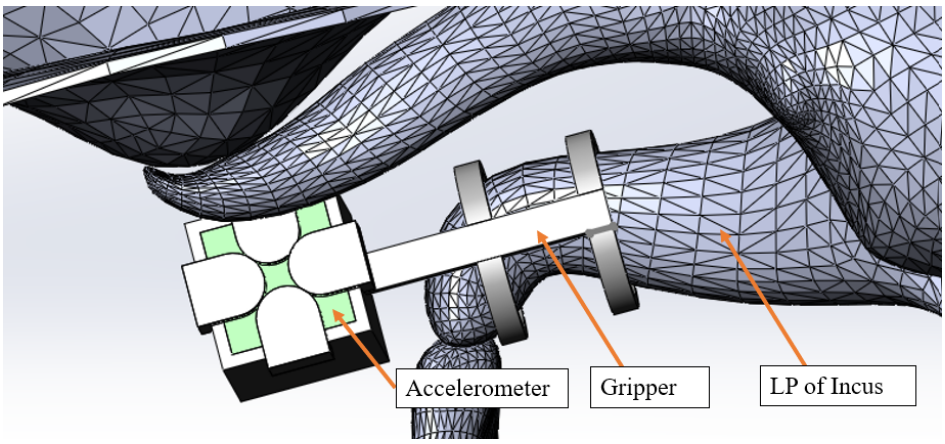
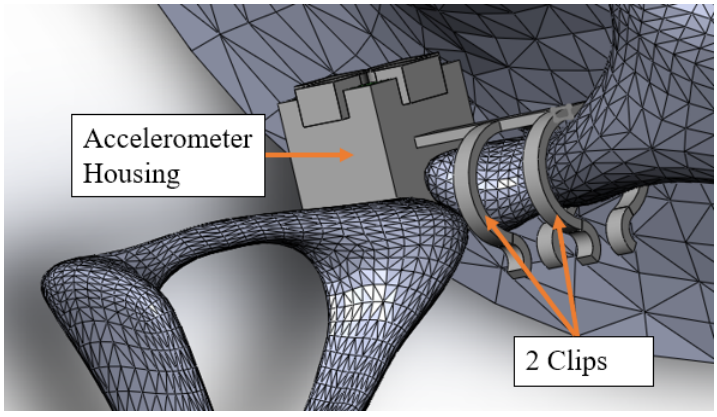
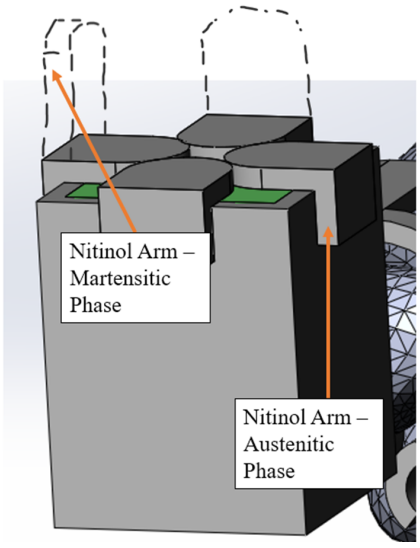


Figure X. The figure shows the first final design. The heat treatment of the nitinol arm (B) will be used to secure the accelerometer into its housing, made of titanium or platinum.

Design 5. This design utilizes two titanium/platinum clips that can be crimped onto the LP of the incus. There is also titanium/platinum housing offsets the accelerometer from the incus so a surgeon could see how the gripper is being attached. The housing also has four nitinol arms that when heat treated, can bend and unbend so the accelerometer can be firmly locked into place as well as be removed from the housing as needed. Figure X shows the CAD model of this design to help clarify how it works.





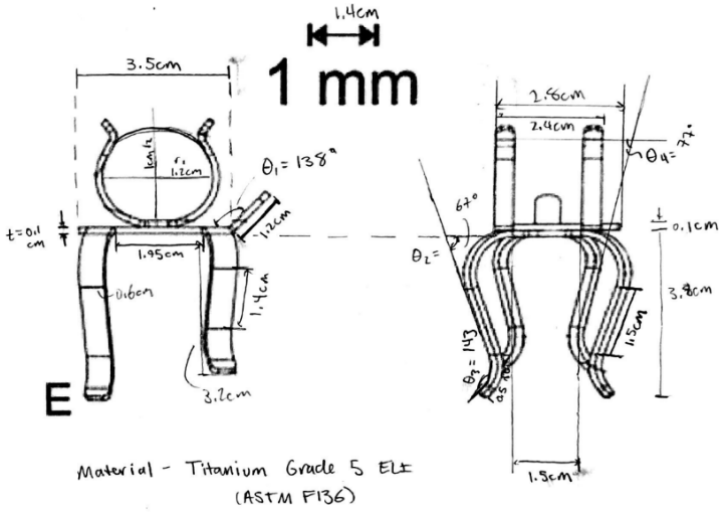
(B)


(C)

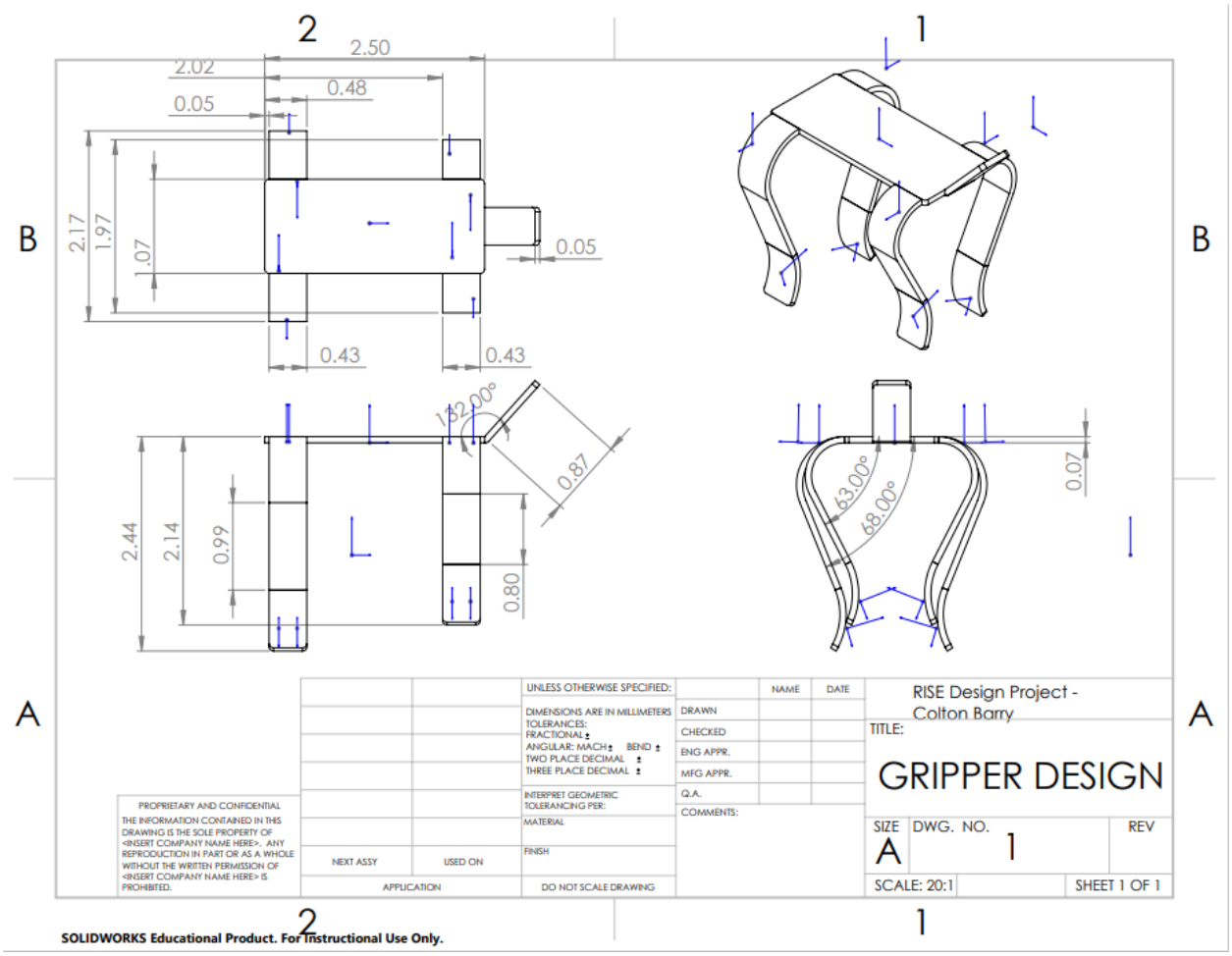
Figure X. The figure shows the second final design. Two clips can be crimped onto the LP of the incus using a crimper (B). Heat treatment of the nitinol arms (C) can secure the accelerometer into place and if needed, the nitinol can be cooled so the arms can be bent up so the accelerometer can be removed.

APPENDIX D: Engineering Drawing of Final Design

Marked up drawing of MED-EL SP Coupler



Engineering Drawing



***All dimensions are in millimeters (mm)**

- Material: Titanium Grade 5 ELI (ASTM F136)

APPENDIX E:

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 [28]
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” [28]. 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” [28].