Design of Cadaveric Temporal Bone Sample Holders for Otological Research

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Abstract

The goal of this project was to design a bio-sample holder for temporal bone that will withstand the forces applied during research at the UniversitätsSpital Zurich, while only allowing less than 1 millimeter of deflection. The current bio-sample holder used by the USZ was not suitable for a variety of bone sample sizes, creating difficulties when researchers attempted to collect data. A design needed to be created that would allow variable sizing for different bones, as well as specific user requirements required by the researchers. This goal was achieved through designing, prototyping, and testing several designs in order to recommend the best option to the USZ team. The final design recommendation was a drill fixture design which allows a quick setup time, with minimal deflection from the bone when maximum force was applied. This device will aid the research teams in collecting data which will be used to create a fully implantable cochlear implant.

Chapter 1: Introduction

The Otology and Biomechanics of Hearing team at UniversitätsSpital Zurich (USZ) conducts otological research on biological samples of various shapes and sizes. The focus of their research is the investigation and understanding of the basic science of hearing, including the study of the mechanics of the middle ear, the hydrodynamics of the cochlea and the complex fluid-solid interaction of bone conduction. The research also encompasses collaboration with the commercial sector, such as the development of novel implantable acoustic receivers. These acoustic receivers are cutting edge due to their ability to be fully implanted in the cochlea [12]. Most of the velocity data from the middle ear is collected using Laser Doppler Vibrometers, or custom miniature hydrophones which can quantify the mechanical and hydrodynamic vibrations that occur during the process of hearing, either due to air or bone conduction stimulation.

In many research cases, the temporal bone sample needs to be resized using a surgical drill to help in this data collection. In order to successfully conduct this research, the various biological samples must be fixed in specific positions and orientations using bio-sample holders. As illustrated in Figure 1, the temporal bone is held by 3 screw-in clamps, allowing various angles of access for the convenience of the medical researchers.

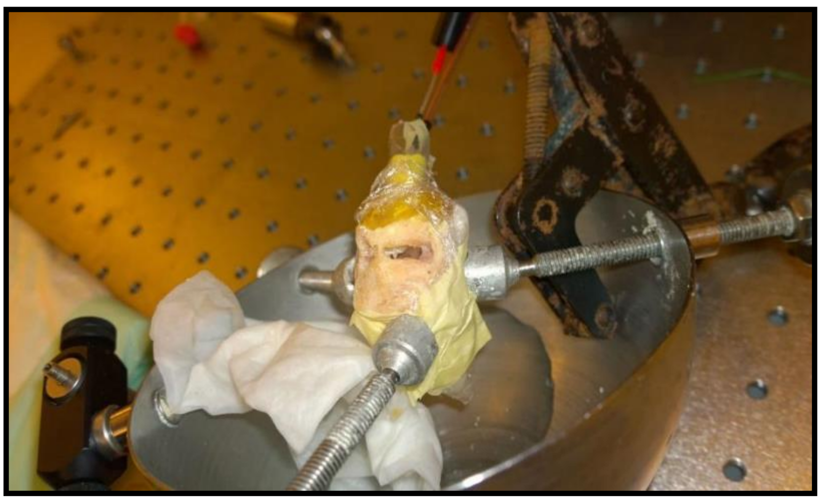


Figure 1: Temporal Bone Fixed Using Bio-Sample Holder

USZ has come across multiple issues when collecting data due to the ineffective bio-sample holders that are currently available on the market [12]. The PhD students at USZ introduced some aspects of current bio sample holders that could be improved including:

- Fixing the sample rigidly in place
- Positioning the sample so data can be collected
- Moving the sample to different workstations and locations
- Allowing multiple angles of access

The issues with current bio-sample holder lead to inaccurate data, results, and prolonged time to set up and perform experiments.

To address these areas of improvement, a bio-sample holder needs to be designed with specific criteria taken into consideration based on the needs of each PhD students' research. The project designed and implemented new design ideas, which satisfied the specific set of requirements for use with the USZ's research. The proposed designs mitigated the issues listed above so that the USZ can collect data and perform dissections for their otological research.

Chapter 2: Background

2.1 Conductive Hearing Loss

As of 2018, it was reported that 48 million Americans deal with hearing loss [28]. Conductive hearing loss takes place when sound energy cannot be delivered to the cochlea, which is in the inner ear. This can happen for a multitude of reasons including, canal blockage, an issue with the small bones inside the ear, or fluid that can build up between the eardrum and cochlea [5]. Specifically, for the USZ, the researchers are focused on the small bones within the middle ear and the reaction they have to vibrations and variations of forces applied to them.

2.1.1 Current State of Research at USZ

The Otology and Biomechanics of Hearing research team of UniversitätsSpital Zurich (USZ) focuses their research on the basics of hearing as well as the development of devices and therapy that aids hearing-impaired patients [31]. The team at the USZ is dedicated to the development of middle ear implants with the goal of creating a cochlear device that would be fully applicable in the middle ear of the patient. Cochlear implants work by directly stimulating the auditory nerve, compared to hearing aids which amplify noise through the damaged parts of the ear [4]. The research being conducted requires in depth analysis on all aspects of the ear as well as the entire head. There are 4 PhD students that are working in this lab, all studying the normal functions of the ear and potential pathologies to hearing loss. These cochlear implants function to stimulate the nerves directly, thus bypassing the whole ear completely.

The PhD students are working with various sizes of temporal bone, completing a range of experiments and measurements to gather data. The students store these temporal bones in a refrigerator located in the lab, and often store them overnight as they are completing days of testing. The samples are moved from cleaning stations, laser testing stations, and mounting stations to either drill through or cut the bone down to a smaller size.

Birthe Warnholtz researches the changes in the motion of the middle ear under high (or low) static pressure, commonly occurring during elevator rides, air travel, and swimming. A laser aimed through a narrow gap in the temporal bone is utilized to measure the small vibrations that take place in the middle ear [2]. Merlin Schär, another PhD student, researches the middle ear as well. Mr. Schär focuses his research on the stapes, which is the bone in the middle ear that is directly involved in sound conduction from the middle ear to the inner ear [14]. Mr. Schär studies a similar topic to Ms. Warnholtz, but his sample sizes are much smaller and more specific, as the samples Mr. Schär uses are approximately 3 cm in width, compared to Ms.Warnholtz who uses samples around 20-30 cm.

Both Mr. Schär and Ms. Warnholtz are focusing more on the protection that the ear provides to the hearing functions. Their research centers around anatomically based ear protection rather than optimizing sound conduction. Damage to ossicles in the middle ear can result in hearing loss or permanent damage, giving protection a vital role. Their research starts by analyzing the force it takes to rupture individual parts of the middle ear, including the stapes. From there, they can draw conclusions regarding the responsibility of these parts of the ear in executing hearing protection.

Nuwan Liyanage conducts research focused on the fluid pressure inside the cochlea. The vibrations that take place inside the cochlea cause the hair cells to vibrate, which in turn generates nerve impulses that support hearing [4]. Mr. Liyanage has different study constraints due to his focus of the fluid inside this organ [16].

Tahmine Farahmandi's research is slightly different than the rest of the students as she is focused on the entire head. Her scans demonstrate movement of the entire head (both with or without the brain) and the effect of its vibrations that travel through the skull. Ms. Farahmandi emphasized that her research benefits from a head that can move in order to replicate real human movement that would take place if the sample was not a cadaver [29]. This student's research includes a dynamic element, while the other students' research is strictly static.

This research being conducted by UniversitätsSpital Zurich can only be executed properly if the research team has the correct tools and devices that allow them to gather the data they need with accuracy. The PhD students working in the lab are handling a variety of samples of different shapes and sizes, which all require different standards when it comes to the devices, they are using to complete their research. While there is no universal solution for a holder that will fit all samples, it is important that there is an option for all research being done as "otologic procedures require meticulous bone drilling, which demands a high degree of precision and skill in order to avoid complications" [17]. Samples need to be fixed in place firmly, while allowing for the device to be cleaned and transported easily, and to provide numerous angles of access to the sample.

2.1.2 Anatomy of the Ear related to Cochlear Implants

The ear is an organ that functions by perceiving sound vibrations in the environment. The human ear collects and interprets high frequency vibrations of air [15]. Ear research involves a variety of complex studies that deal with the 3 major parts of the ear. In order to understand cochlear implant research conducted by the USZ, the anatomy of the human ear should be understood and visualized.

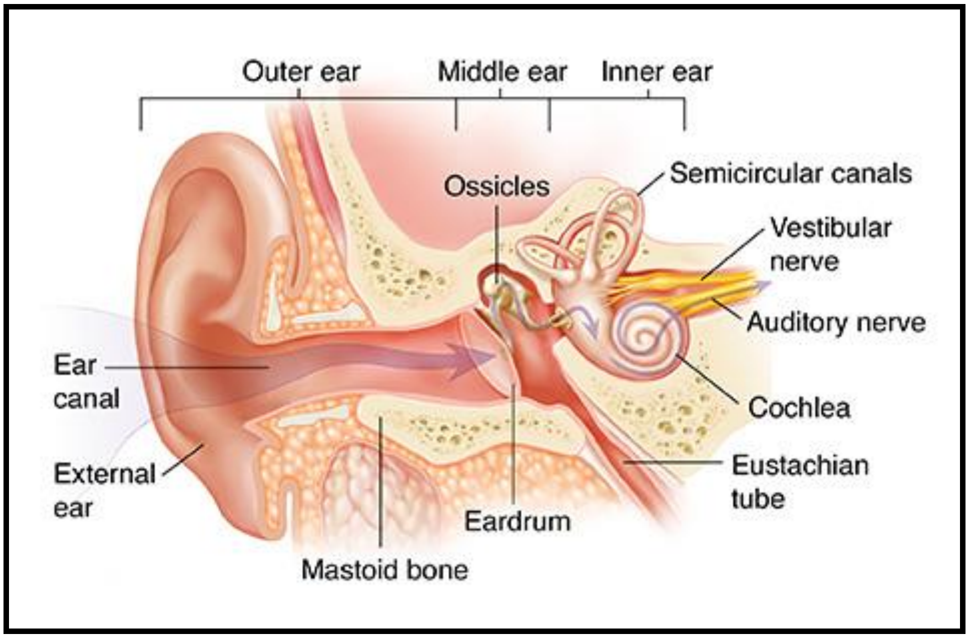


Figure 2: Human Ear Anatomy. Adapted from "Anatomy of the Ear "by Medcor,2017 [17]

The middle and inner ear anatomy are the most important to the Otology and Biomechanics of Hearing team at USZ [17]. The diagram in Figure 2 depicts the middle and inner sections of the ear with a clear representation of the anatomy [28].

The main function of the middle section of the ear is converting sound waves in air to the vibration of cochlear fluid. Sound waves in the ear canal vibrate the tympanic membrane, and this motion is transmitted to the cochlea via the middle ear ossicular chain [28]. At the end of the chain, the sound vibrations are pushed through the inner ear, where the stapes interfaces with cochlear fluid and the vibrational motion of the middle ear ossicular chain is converted into fluid vibrations.

Once through the middle ear, the inner section is where the cochlea and 3 semicircular ducts are present. The cochlea is filled with fluid and hair cells that are extremely sensitive to vibrations [17]. When these hair cells are bent, due to vibration of the cochlea fluid, the bending of these cells causes proteins, called mechanically gated ion channels to open. These electromagnetic signals are carried to the cochlea nerve and result in sensory signals to the brain. It is within the cochlea that the transition from the mechanical systems to the electrochemical systems take place [28].

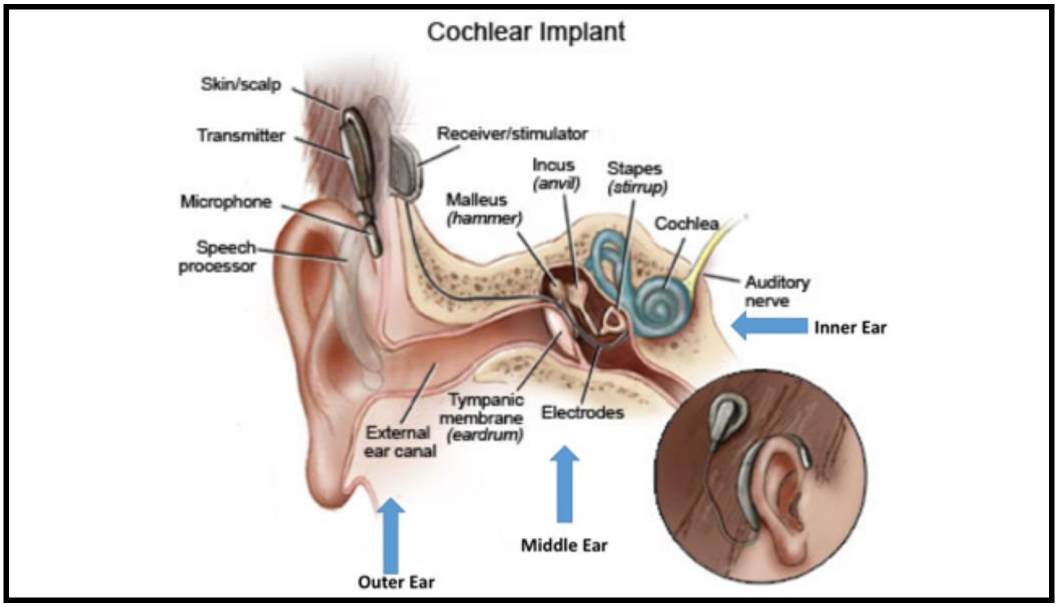


Figure 3: Ear with Cochlear Implant [5]

Cochlear implants target senso-neural hearing loss, where the mechanical parts of the ear could be completely functional, but the hair cells themselves have failed. There are 4 main parts to a cochlear implant that interacts directly with the ear, each is illustrated in Figure 3.

The first part of the implant is the microphone which rests on the mastoid bone and outer ear to pick up sounds from the environment [5]. Hearing through the microphone of the cochlear implant does not replace normal hearing but instead gives a useful representation of sounds in the environment to help understand speech.

The next part of the implant is known as the speech processor and this selects and arranges sound picked up by the microphone [5]. The processor is located outside the skin resting on the mastoid bone behind the ear.

The third part of the implant is known as the transmitter and receiver/stimulator which serves to receive signals from the speech processor and convert them into electric impulses [5]. This component is surgically inserted behind the ear and is then secured to the skull in that designated area.

The final part of the implant is called the electrode array, which is a group of electrodes that collects the impulses from the stimulator and sends them to the different regions of the auditory nerve [5]. A surgeon must make a cut behind the ear to open the mastoid bone and facial nerves to access the cochlea. The cochlea is then opened, and the electrodes are inserted inside.

The research taking place at the USZ is working towards moving an entire cochlear device into the ear. The researchers focus on different areas of the inner and middle ear that the implant will affect, which involves complex research that requires precise accuracy in order to gather the best data. Figure 3 depicts a future cochlear implant and where the implant will interface with the outside and inside of the ear. The devices supporting these samples must withstand forces that may be applied for drilling purposes, while still allowing full access to the sample. There are many requirements that are necessary for a researcher to complete testing, but the student's must be equipped with the tools that will fit their needs and allow proper studies to be completed. The bio-sample holder will aid the researchers to better work on the sample and eventually reach the goal of a fully implantable cochlear implant.

2.2 Bio-Sample Holders

A bio-sample holder can be defined as a device that is used to fix a biological sample in place for the purpose of research, training, or any need that a medical technician might have. Medical research and training are done on biological samples to obtain information or practice for real scenarios; the sample that is being examined must be rigid to ensure accuracy. Bio-sample holders are very common when performing temporal bone and cadaver dissections for a plethora of medical purposes. An article overviewing the pitfalls of the modern bio-sample holder states that the "ideal temporal bone holder should remain stable in multiple orientations but also adjust easily. It should not obstruct the surgical view and should simultaneously provide adequate drainage of bony debris" [23].

2.2.1 Current Designs

Bio-sample holders are widely available for purchase online around the world. For the USZ's applications, only a small subsection falling under the definition of bio-sample holder will be useful. Numerous options of bio-sample holders are being sold by different brands, but most of them follow the same ineffective design for temporal bone research. They all contain a metal bowl with either 3 or 4 holes near the top that allow for threaded bolts to pass through and screw in to clamp the sample. They also have a base that allows for small amounts of rotation for the bowl, so that the sample can be viewed at different angles. In addition to these features, there are small deviations between brands, but nothing that will fit the needs of the current research taking place at the USZ. An example of a device that is currently used at the USZ can be found in Figure 4.

Figure 4: Bio-Sample Holder from Anthony Products, Inc [2]

2.2.2 Bio-Sample Holder Use in Research at USZ

There are a handful of variations of bio-sample holders currently being used by the Otology and Biomechanics of Hearing Team at UniversitätsSpital Zurich. This includes both commercial designs and custom designs made by the team for specific requirements. The various designs hope to address the needs of the individual research projects, yet there are many notable flaws in each design.

Commercial Design 1

The first bio-sample holder utilized by the research team at the USZ was procured using miscellaneous pieces from surgical rooms and purchased parts from Acumed Instruments. This sample holder is a rather basic design featuring the bowl-assembly that many commercial bio-sample holders have. The bowl has 3 holes around the circumference with a threaded bolt fed through each one. There is a machined holding piece on the end of each bolt that has teeth to grip the sample being observed and there is a handle to tighten or loosen the grips on the opposite end. A stone is placed at the bottom of the bowl to act as a counterweight and to position the bowl at the orientation of choice on top of a rubber donut. This design can be observed in Figure 5 and Figure 6.

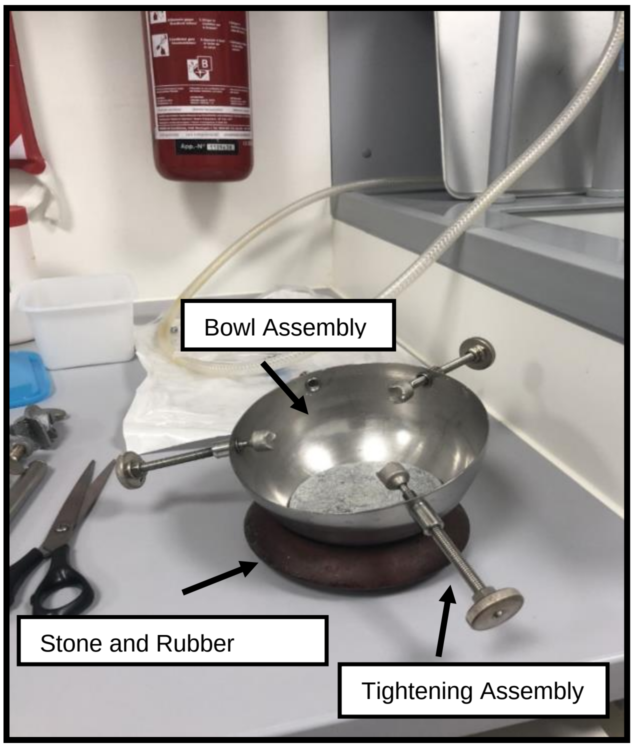


Figure 6: Current Bio-Sample Holder Assembly

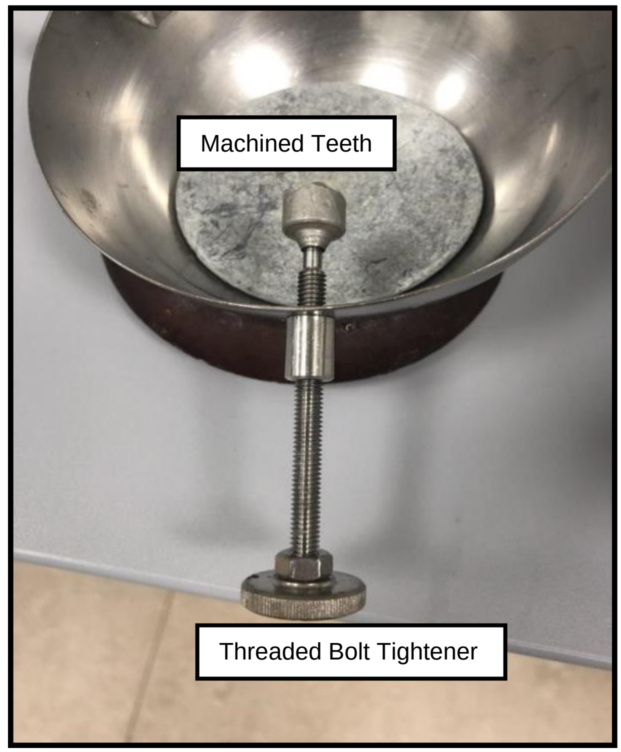


Figure 5: Threaded Bolt Assembly

Commercial Design 2

The second bio-sample holder that the research team at USZ utilizes is very similar to the one shown in Figures 5 and 6 and was also procured using miscellaneous parts from surgical rooms and Acumed Instruments. This holder features a bowl assembly with threaded bolts and gripping teeth to fixture the sample over the bowl. There are 3 threaded bolts and handles to tighten or loosen them at the opposite end. The main difference in this sample holder is the ball-bearing joint at the base of the bowl which allows the user to vary the orientation by turning the bowl rather than adjusting the stone at the bottom of the bowl. This design can be observed in Figure 7 and Figure 8.

Figure 8: Ball Bearing Joint Bottom View

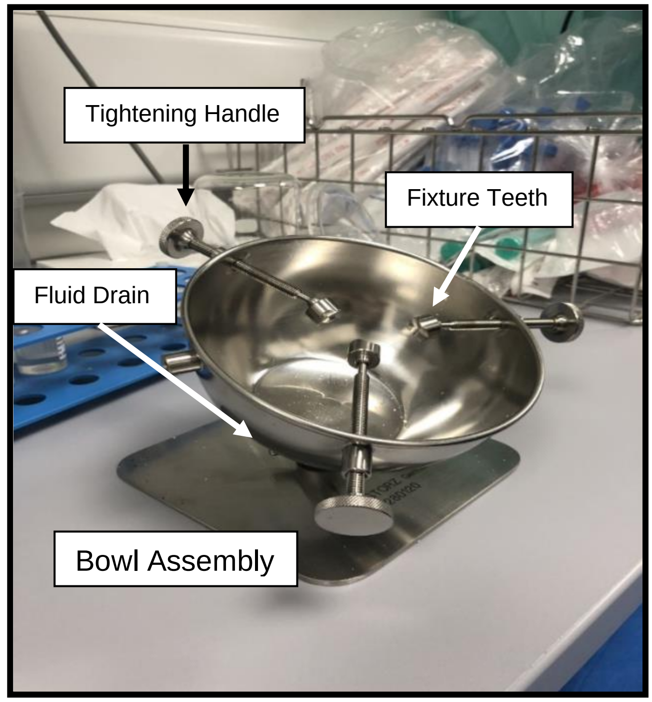


Figure 7: Current Bio-Sample Holder Used

2.2.3 Forces Placed on Bone

Throughout preparation and experimentation of the middle ear, the bone experiences a range of forces from different angles. The PhD students must cut or drill the bone to reveal the area of the middle ear they are most interested in. The drilling that takes place is most often a downward force that is executed at an angle, but with most of the force in the vertical direction only [12]. The forces placed on the bone from the semicircular drill come from the blade rotation which is perpendicular to the normal face of the bone [12]. A visualization of the forces applied to the bone during experimentation can be seen in Figure 9. Bio-sample holders used to support this bone must withstand worst-case force scenarios without the device breaking or the bone slipping out of position and skewing the data being collected. Additionally, Dr. Dobrev indicated that drilling can be less precise than the experimentation, and that a maximum sample displacement of 1 millimeter would be acceptable. If the sample exceeds this maximum displacement, it will need to be repositioned. Through discussions with Dr. Dobrev and the PhD students regarding research, the worst-case scenario was explained to be when a maximum force is applied in both the X and Y directions on the bone. While completing research on newly designed holders, it will be important to take this discussion into account and test the designs under worst-case conditions.

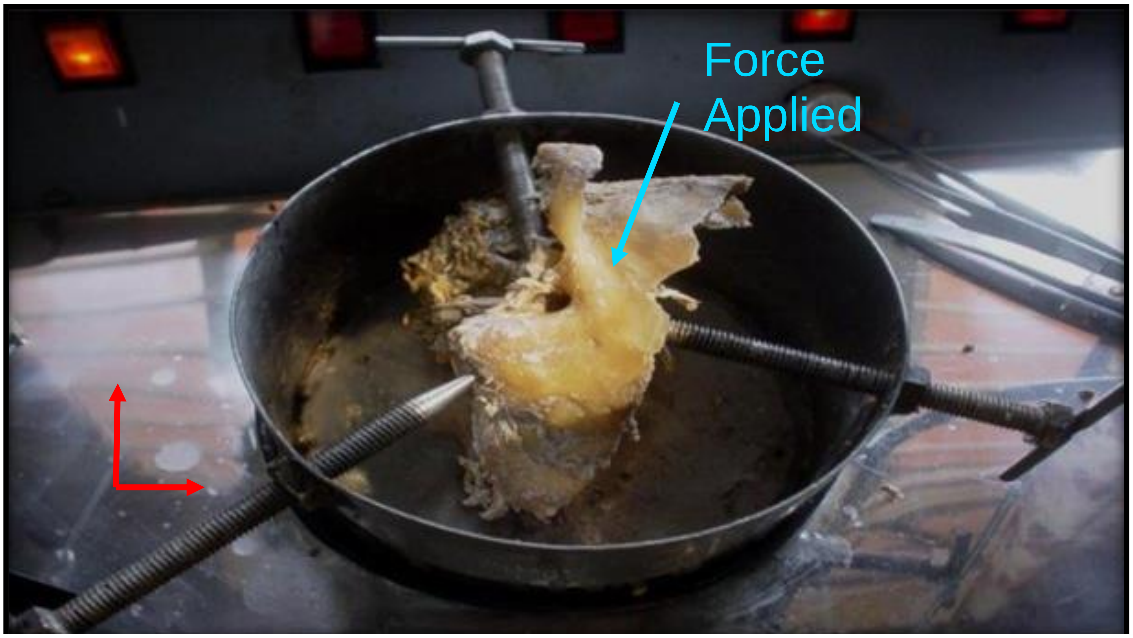


Figure 9: Forces Applied to Bone [12]

2.2.4 Issues with Bio-Sample Holders

Dr. Ivo Dobrev and the 4 PhD students completing otology research explained the issues they were having when using bio-sample holders while performing their experiments. Although each of their experiments are different, there were many similarities in the application of the bio-sample holders and consequent issues that they were experiencing. In order to design a new bio-sample holder, the drawbacks of the previous holders needed to be analyzed. Table 1 summarizes the overall research and specific needs expressed by the PhD students.

Ms. Warnholtz uses large pieces of the temporal bone for fixing purposes during her experiments, yet she only focuses on a small area of the inner ear [2]. The issue Ms. Warnholtz has with the current bio-sample holder is that it takes too long to set it up and hold the sample. The sample's shape is also irregular which further adds to the difficulty in setting up the experiment. During her experiments, Ms. Warnholtz must move the sample and the sample holder around to different stations. The experiments Ms. Warnholtz conducts require a steady hand and concentration, so she struggles with a holder that is not low to the table. Lastly, she expressed the difficulty researchers have when realigning the sample, sample holder and measurement system, to keep the velocity measurements at consistent orientation and position [2].

Due to the small size, Mr. Schär's samples are easy to break while being cut if not held rigid. His example lined up with Ms. Warnholtz that it is counterproductive to have the piece move while it is being held. Specifically, for Mr. Schär, the sample needs to be securely fixed in place when he is extracting the stapes and footplate from the temporal bone via standard and customized surgical drilling procedures [16]. When testing, Mr. Schär glues the small piece to a metal MakeBlock plate and fixes that to the bio-sample holder; he would like to find a more efficient way to fixture without gluing the sample down to a plate [16].

Mr. Liyanage clamps the same large cut out of temporal bone for his experiments that Ms. Warnholtz does for her sample, so there are similar issues he faces. He once again mentioned the time it took for him to secure his samples in place [22]. Among other new features, a design that can clamp the sample quickly and easily would be very beneficial for the USZ.

Dr. Dobrev and Ms. Farahmandi's research is based around the whole head and neck area. To get the most realistic scenarios, the neck needs to be fixed so it will imitate the biological aspects of a head attached to its body. This is because the sample is much larger than the temporal bone, so the clamps must be tightened to give the sample a proper hold. They noticed that one of them could clamp the head tighter than the other, and that the difference in the force that the clamps were exerting on the neck skewed the data [29]. Ms. Farahmandi expressed that a bio-sample holder that held the sample by the spine would give the most realistic results [29]. Dr. Dobev touched upon the further need to allow the cadaveric sample to move dynamically while fixed, however this is a requirement to investigate if time persists [12].

Table 1: PhD Student Design Requirements

Student	**Area of Research**	**Design Requirements Identified**				
Birthe Warnholtz	Middle Ear	Low to Table	Mobility	Easy to Clean	Short Setup Time	Stability
Merlin Schär	Stapes	Clamps That Will Not Damage Sample	Ability to Withstand Force of Drilling	Easy to Clean	Short Setup Time	Stability
Nuwan Liyanage	Cochlea	Access to Various Angles	Mobility	Easy to Clean	Short Setup Time	Stability
Tahmine Farahmandi	Head	Allows for Dynamic Testing	Access to Various Angles	Easy to Clean	Short Setup Time	Stability in Spine

The bio-sample holder that the PhD students at the USZ currently use, is a mass-produced product that is available worldwide. The issues that the students had with this device are issues that are affecting researchers outside of the USZ. For example, one group of researchers studying mastoidectomies stated that “during drilling, care was taken not to move the temporal bone holder” [23]. This means that the design did not have the base rigidly in place, which could allow for the sample to slip. If the base were to slip out during the research at the USZ, it could completely corrupt the data or the sample, making it necessary to restart the whole procedure.

Currently, all the students are being given access to the same bio-sample holders, which is one basic shape, making it hard to adapt to drastically different sample shapes. The current device is not a viable option for many researchers, and there needs to be a better option available for the PhD students. The team aims to design a device that will help meet requirements at the USZ specifically. Often, research on different parts of the body cannot be completed using the same device, because there are many different requirements that will be necessary for proper research to be completed. The device created by the team will be for temporal bone research for researchers in the lab, not a universal bio-sample holder for a range of research.

Chapter 3: Design Development

The main goal of this project is to design a bio-sample holder that will help alleviate the issues that current researchers at the USZ encounter while performing research. While there is no universal temporal bone bio-sample holder currently available that will please all the researchers, the following section highlights the steps for design requirements, design creation, testing, and final designs. To reach this goal, the team must take into account the different opinions and research that each student is focusing on in order to design a device that can be used by all researchers, while offering variable aspects that allow the device to adapt to more specific research. An outline of the design process that was followed is illustrated in Figure 10.

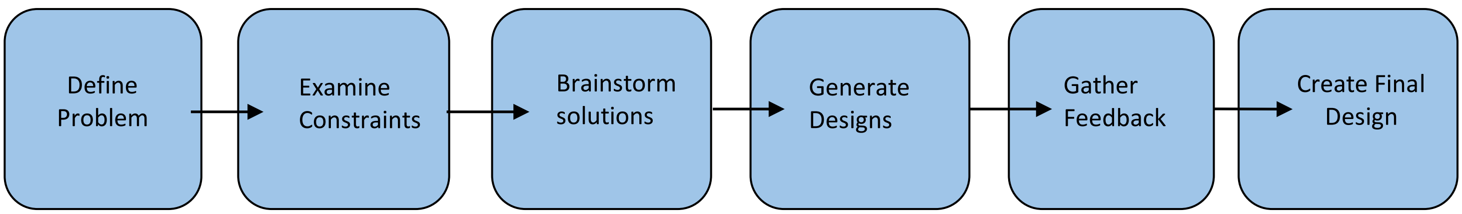


Figure 10: Design Development Process

3.1 Design Requirements

For the team to create a bio-sample holder that will effectively aid research being done at the USZ, it is important to gather all opinions and suggestions that the researchers can provide. The researchers will be the primary users of these holders every day, and therefore can give the team the best feedback and recommendations. Using this information from the researchers, design requirements were identified and ranked in order of importance. Before the brainstorming of designs, engineering standards were researched and discussed. Engineering standards are a critical aspect of every design process and must be considered when creating a new device.

3.1.1 Personal communication with researchers

To fully understand the issues with current designs of bio-sample holders, the team talked to each of the researchers who use the holders daily. To ensure responses that were uninfluenced by other researchers, each student was consulted individually to understand the design requirements that they alone believed would be most beneficial to their work. Each researcher gave a quick 5 to 10-minute summary about the research they focus on and then transitioned to the functionality and issues with the current bio-sample holders in use. All the PhD students researching temporal bone are given the same bowl-assembly bio-sample holder represented in Figure 4. The researchers expressed some overlapping issues that occurred, but also unique issues they have with the sample holder based on their specific research. This investigation technique gave the team a broad range of issues that the team was able to break-up into design requirement categories. Once all the researchers were interviewed, the team used the collected observations to group similar terms into single design requirements. For example, “sanitary” and “easy to clean” were grouped into one category to avoid repetition of identical requirements under different nomenclature. The 9 design requirements include: allowing for easy rotation, being low to the table, being portable, holding the sample rigidly, being variable, being easy to clean, being easy to access the sample, being durable, and being easily re-attachable to previous positions. In addition to the preliminary design issues discussed in this section, there are several secondary requirements addressed as well in the previous section of 2.2.3. By narrowing the list of design requirements, there was a better understanding of the categories that that could be used to organize the issues. Following this sorting, the team ranked requirements in order of importance, and provided a weighting scale for comparison purposes.

3.1.2 Identified Design Requirements

Before creating design options, the team created in-depth explanations that clarify what each design requirement entails for future steps. The description of each requirement is based on the discussions with the PhD students, focusing on how they discussed the following terms.

Holds Sample Rigid

Middle and inner ear research often requires measurements of small vibrations taking place in specific areas of the ear. It is extremely important that the temporal bone is held rigid while necessary forces are being applied with minimal deflection, allowing the measurement of smaller sections of the ear. To achieve this, the bio-sample holder must have a rigid hold that withstands the drilling and cutting forces the researchers apply to the bone sample. It was indicated to the team by Dr. Dobrev and the PhD students that the largest forces placed on the sample occur during drilling and preparation, and that the sample must not displace or deflect more than a millimeter during this process.

Easy to Access the Sample

While there are multiple ways to hold a sample rigid, the team needs to consider the area the fixtures surrounding, in order to not take away from the easy access to the sample. For example, more contact points would allow a more secure hold on the bone but would restrict the access points for the researchers. The average temporal bone sample measures around 12 square inches, meaning the fixturing device must be designed much smaller, to avoid blocking the area of interest. The holder should allow multiple access points for the user when attached to the sample while also holding the sample secure in a fixed position.

Allows for Easy Rotation

A temporal bone is not a uniform piece of bone, but instead has small crevasses and areas that need to be seen from different angles in order to gather accurate data. It is important that the bio-sample holder being created always allows for different angles of rotation to be easily accessed for testing and observation purposes. The bio-sample holder having rotational capabilities allows the researchers to properly examine the irregular three-dimensional shape that is the temporal bone.

Easy to Clean

For sanitation purposes in the lab, as well as the international engineering standards set by The International Organization for Standardization (ISO), it is important that the team focuses on allowing an easy clean for the holder. The sterilization process that the device must follow is the EN ISO 17664 for the sterilization of the holder. This process details that any part that will be contacting different cadaver bones must be made of materials that can be disinfected and cleaned with the chemicals in the lab. This also requires that the temporal bone can detach from the holder to facilitate ease of cleaning.

Variable

The bio-sample holder must be adaptable to different sizes and shapes of temporal bone. Each PhD student has some aspect to their sample that is different from another and requires the sample holder to change to their certain bio-sample situation. Some aspects of adaptability include adjustable fixture size and adjustable fixture placement. The bones that make-up a human head is never uniform from person-to-person and will result in the need to hold the bone from completely different angles in order to see the same areas of interest. While the device must be easy to change in size and placement, it must also be a quick and easy process to change from constraints of one bone to the next.

Re-attachable

The next category of the design that the sample holder must satisfy is the ability to return to the previous position of clamping after being used. The PhD students require the holder to be re-attachable after removing the sample. A researcher may be working on a certain aspect and need to move the sample to a different station in order to gather data. After, the researcher would like to return the sample to the original station while keeping it in the same orientation that was used before. If the device is not reattach-able, this adds time into the researcher's experiment which may cause issues when certain samples must be submerged into water after set amounts of time to keep the sample moist.

Low to Table

Another characteristic that the bio-sample holder needs to satisfy is the ability to be low to the table for comfort purposes. After talking with some of the students, the team realized that work on the bio-sample holder can take long hours and often feel uncomfortable due to the size of the current holder. Resting their elbows on the table allows for more stability when examining small aspects of the ear as well. This holder should be low enough to the table so that the user's elbows can rest comfortably in a 90-degree angle while sitting down.

Portable

Often, many of the bio-sample holders are moved around to different stations within the lab. The design of the new holder should be easy to carry and built for travel within the lab. Current bio-sample holders vary in size, sometimes being too large to carry easily. The new design should allow only one person to move the device without exerting too much energy or worrying about dropping the sample.

Durable

The last category of design that the holder should satisfy is that the structure should be compact and durable. The design of the structure should use materials that do not break easily or weaken with multiple uses. Many pieces of the holder will be cleaned daily, so it is critical that the metal material can withstand this. In the event the holder is dropped with the sample, the holder should be able to withstand the impact and remain together in one piece.

3.1.3 Ranking Requirements

After categorizing all requirements into 9 areas, a survey was distributed to the researchers to gain a better understanding of which requirements were most important in future designs. The survey contained 9 different design requirements that the researchers could rank on a numerical scale from 1 to 9. Each of the 6 responses the team received provided helpful insight on the most important design requirements that should be addressed. For each of the requirements listed on the survey, the total score each requirement received was summed and averaged based on number of respondents. The requirements with the largest average scores were deemed the most important in comparison to one another. This method of analysis took into consideration the input of the researchers while providing numerical data to consolidate the requirements.

The results of the survey from the 6 respondents indicated that the most important requirement was the holder's ability to fixture the sample rigid enough to withstand applied forces with minimal deflection less than 1 millimeter. This finding was consistent with our individual conversations as well. Conversely, the survey indicated that the least pertinent of the 9 requirements was the durability and portability of the holder's new design. It is important to note that the bio-sample holders are being used for a range of applications, meaning certain requirements may be more applicable from researcher to researcher. Although not all the design requirements were ranked among the researchers as important, they were still mentioned during personal communications, so they would be implemented if it could be done within the 9-week period.

The User Design Requirements Comparison chart, illustrated in Figure 11, depicts a box and whisker chart of the data collected from the design requirement survey. The different colored boxes are the representatives of the 9 design requirements the team surveyed the researchers on. The relative size of the box, or the span of the first standard deviation, demonstrates the variation between respondents. For example, the requirement "holding the sample rigid" can be observed as very compact, meaning that most respondents did not deviate from ranking this requirement around 10. The requirement "easily able to attach back to previous position" in comparison was more spread out, indicating that the respondents' answers varied greatly between values of 4 and 9. This chart gave the team a visual representation of the importance of each design requirement.

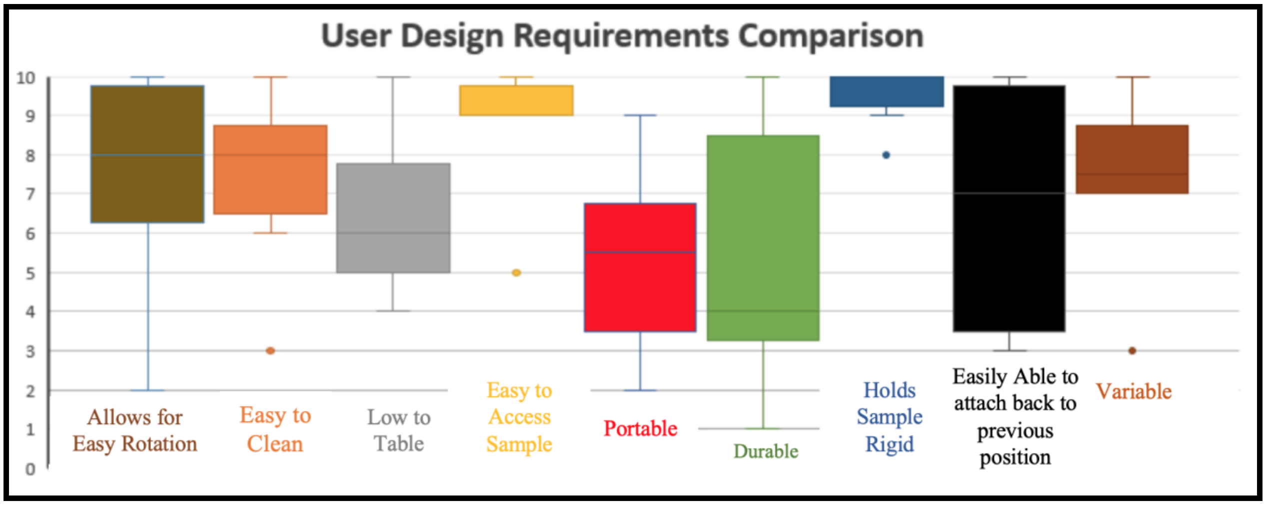


Figure 11: User Design Requirements Comparison Chart

3.1.4 Engineering Standards

The device will follow certain standards to ensure both the safety of the user and the safety of the sample. As the team will not be manufacturing a final design to be used in the lab directly, it is unlikely that the current standards will play a direct role. Although, it is important for the team to be aware and take all applicable standards into account before creating final designs.

The ISO standards should be followed during the manufacturing process of the design before it is implemented at the USZ. These standards cover processes including mechanical designing, bioprocessing, and manufacturing. These standards are given to manufacturers by the organization so that they can follow the proper guidelines in creating their products. The international standards apply to the entire design process of the project. The team will utilize relevant standards implemented by the organization when considering bioprocessing and the mechanical design of the device.

EN ISO 17664 is a standard that applies to medical devices that are intended for multiple uses and require sterilization after each use. This standard specifies requirements in which the medical device manufacturer needs to provide information about the device that requires cleaning followed by sterilization so it can be processed safely and continue to meet performance specifications [8]. Some requirements that are specified for processing consist of: preparation at the point of use, preparation with cleaning and disinfection, drying, inspection with maintenance and testing, packaging, sterilization, and storage [8]. Medical companies are required to provide instruction on each of these activities for the user so that they can replicate these procedures accurately. This standard is important when considering the bio-sample holder due to the hospital's continuous use of temporal bones in research. There are a handful of experiments that occur daily within the Otology and Biomechanics of Hearing department that consistently use bio-sample holders to secure the bone samples, which will cause contaminant bacteria to be left behind on the sample holder after one use. The team's sample holder design will require specific parts to be cleaned in accordance to ISO 17664. These parts include: the steel bracket, washers and screws, clamps, and the FISSO metal arm. Each one of these parts will have similar cleaning instructions to properly neutralize all contaminants. It is important to include instructions on the proper cleaning process for the medical device in order to get rid of all bacteria that would affect data and would allow continued use of the holder for more experiments. The USZ has a special dishwasher containing specific sterilizing chemicals where these parts will be cleaned and ready for another use.

Quality management systems and specifications help ensure that the device will be maintained and utilized properly. These standards are part of the ISO 9000 family, a collection of engineering standards relating to the quality control of processes. The specific standard relating to medical devices within this family is ISO 13485.

ISO 13485, Medical devices – Quality management systems – Requirements for Regulatory Purposes, is a standard that sets the requirements for a quality management system specific to the medical device industry [13]. The ISO 13485 certification should be considered when designing the device because this standard requires the quality of the product to be maintained and regulated. Over time the bio-sample holder will require maintenance and need certain parts swapped out for new ones such as the screws and washers and the metal fixture bracket. Planned regulatory maintenance should be conducted on the holder to ensure that it is performing to its specifications. This is so the quality of the device does not affect the data being collected by the students. Before the device can be used for in-lab research purposes, the device will need to pass Quality Control tests to ensure that all manufacturing of the product is standardized.

3.1.5 Design Matrix & Design Objective Tree

Table 2 compares the received design requirements based upon the survey that was distributed to the research team and can be found in Appendix A. There are 9 criteria that have been compared, each scored against one another regarding relative importance to the final design. In comparing the various requirements, a 1 is assigned to a requirement that is more important than the one it is being compared to. Conversely, a 0 is assigned to a requirement that is not as important as the one it is being compared to, and a 0.5 is assigned to 2 requirements that are equally important. The data being illustrated in this design matrix is consolidated from the results of the survey distributed to the PhD students, the primary users of the bio-sample holder. This matrix provides an easier to understand visual to demonstrate the relative importance of the requirements. This design matrix can be read vertically, starting with the requirement "Holds Sample Rigid" being compared to "Easy to Access Sample". The totals at the bottom indicates the numerical importance of the requirements.

Table 2: Design Requirements

Importance (9 = Most Important, 1 = Least Important)		Design Requirements	1 Holds Sample Perfectly Rigid	2 Easy to Access Sample	3 Allows For Easy Rotation	4 Easy to Clean	5 Variable	6 Easily Able to Attach Back to Previous Position	7 Low to Table	8 Portable	9 Durable
	1	Holds Sample Rigid		0	0	0	0	0	0	0	0
	2	Easy to Access Sample	1		0	0	0	0	0	0	0
	3	Allows For Easy Rotation	1	1		0.5	0.5	0	0	0	0
	4	Easy to Clean	1	1	0.5		0.5	0	0	0	0
	5	Variable	1	1	0.5	0.5		0	0	0	0
	6	Easily Able to Attach Back to Previous Position	1	1	1	1	1		0	0	0
	7	Low to Table	1	1	1	1	1	1		0	0
	8	Portable	1	1	1	1	1	1	1		0.5
	9	Durable	1	1	1	1	1	1	1	0.5	
		Totals	8	7	5	5	5	3	2	0.5	0.5

Figure 12 depicts an objective tree for the design of an effective bio-sample holder. When starting the design process, the team considered the highest scoring requirements based upon the Design Requirements Matrix. These five requirements are the most important design specifications that the holder needs to satisfy. Each requirement is followed by 3 individual options or points of interest that the team will keep in mind while designing bio-sample holders. These options were generated by the group, and then implemented in different combinations through early brainstorm sketching. Some of the options may be used in conjunction with each other, while some may prevent others from being considered in the design. This tree was used as a preliminary research tool to brainstorm the different attributes that may assist the researchers with their current issues. Before creating full designs, the team started with discussions of individual components.

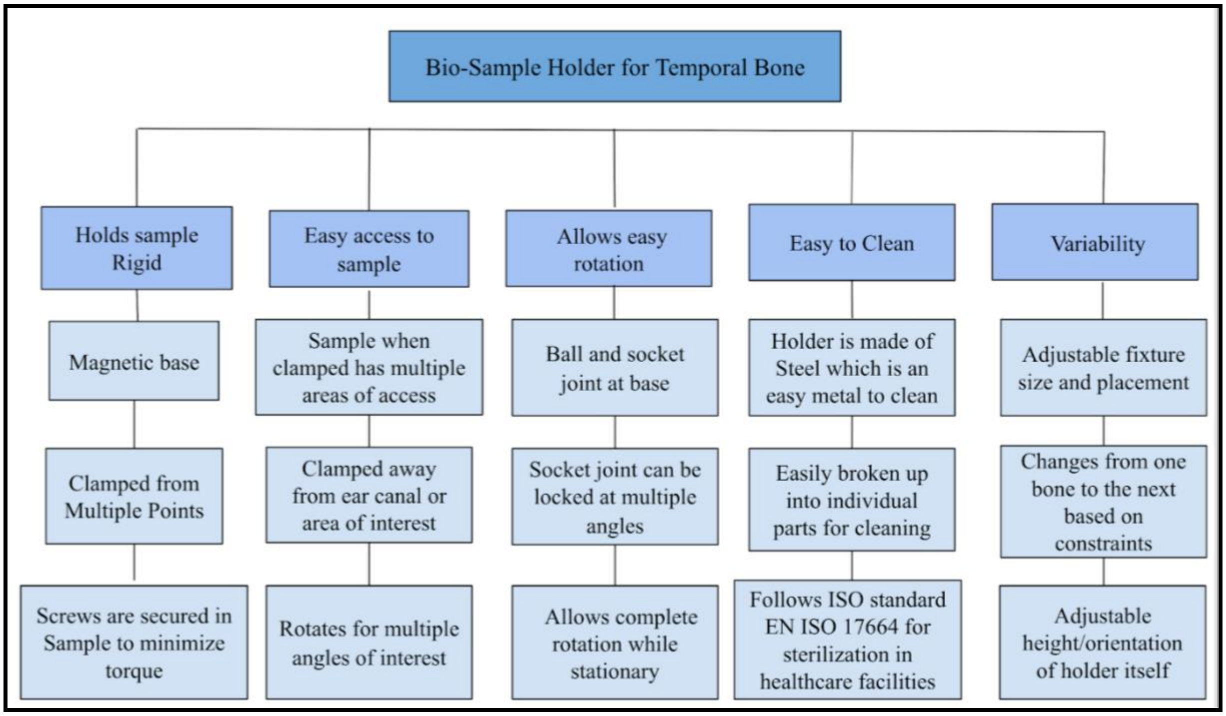


Figure 12: Design Objective Tree for Sample Holder

3.2 Preliminary Brainstorming and Creation of Designs

After interviews with the researchers, the design process continued by implementing the top requirements in preliminary sketches. Individual and group brainstorming allowed the team to create a variation of different designs that included a broad range of components and different fixturing options. The goal of this design process was to create and recommend one design to Dr. Dobrev and the USZ team at the end of the 9 weeks.

3.2.1 Individual Design Sketching

The team used the design criteria described in Chapter 3.1 as a starting point to create preliminary designs. Together, the team discussed the Design Requirements Matrix and Design Objective Tree, highlighting the areas that would be consistent and which aspects could be designed variable in order to assist the most researchers. Each member individually sketched multiple designs of different combinations of design requirements that could work for the USZ. The team discussed pros and cons of each sketch while comparing them to the design criteria developed. For example, a design with multiple points of contact establishes a rigid hold, but may block surface area, which does not allow easy access to the sample. The individual sketches allowed no influence of differing opinions on the team, which gave different options of variability for future designs. The team came up with different options of clamping/drill methods in order to keep the sample rigid. As the team had previously ranked this as the top design requirement, it was important to focus heavily on the fixing method from the beginning of the brainstorming sessions. While these sketches would not be used for the final design, brainstorming was effective in furthering the design process and led to collaboration and the culmination of ideas to create full design options.

3.2.2 Collaborative Design

Utilizing ideas from 3.2.1, sketches were created to help visualize the components of the designs. Below are 8 sketches that the team created, starting with 4 sketches of individual components, and then 4 sketches of full design options combining the individual components.

Design Component 1

Design Component 1, shown in Figure 13, illustrates 3 different options of clamping systems. Option 1 is a one-screw bracket with a needle-point screw contacting the bone. This option fixtures the bone with 1 point of contact from the screw and is supported by a plane of contact on the opposing end. This component would allow clamping of samples that vary in thickness as well as allowing easy access to the sample because of the small contact area of this clamp. Option 2 is more secure, as it follows a very similar idea to Option 1 but has 2 focused points of contact. Like Option 1, this clamp would also allow the securing of samples with a range of widths. Option 3 is a tooth vice grip along with a bolt lock. The teeth at the top of the clamp would add numerous points of contact, and the vice-grip would allow a tight hold to ensure the sample is kept fixed.

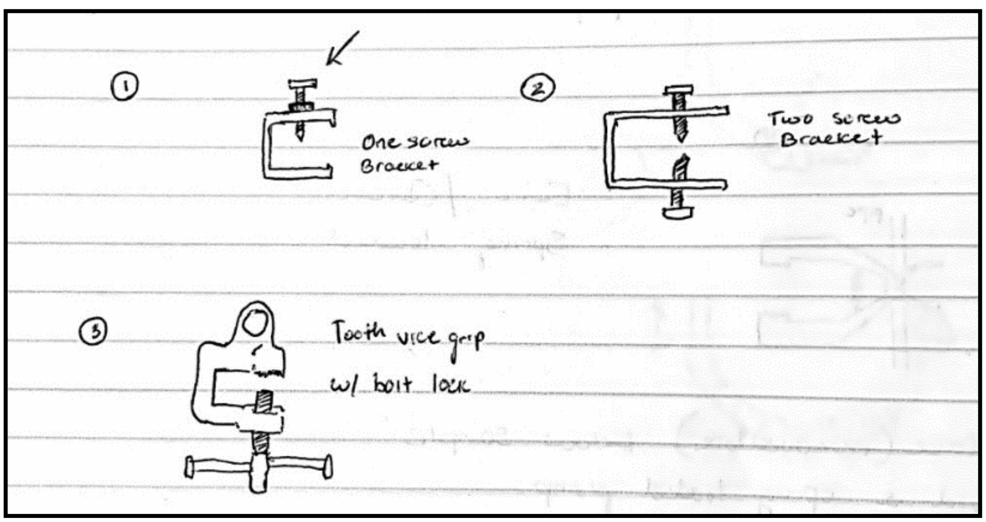


Figure 13: Isolated Clamp Sketch

Design Component 2

Design Component 2 takes a different approach to the fixture technique as compared to previous design options. For temporal bone samples, the PhD students informed the team that there is normally 7-9 centimeters of bone left around the area of interest, shown in Figure 14.

This area of the bone allows a screw to be drilled without the risk of damaging the rest of the sample. This design uses a screw that goes through a clearance hole that is drilled through the bone during the sample's preparation. This screw will also hold 2 plates with teeth that when tightened will prevent the bone from tilting or rotating and will provide more stability to the sample overall. 2 screws attached to a 3x3 L-Bracket support the free end of the bone opposing the ear canal. The minimal contact allows easy access to any part of the sample that needs to be researched, and screws directly fixing to the bone address the rigidity design requirement that is most important for the PhD students. In order to support the petrous region of the sample, an optional industrial ratchet strap could be attached to the bracket in order to avoid deflection when force is added.

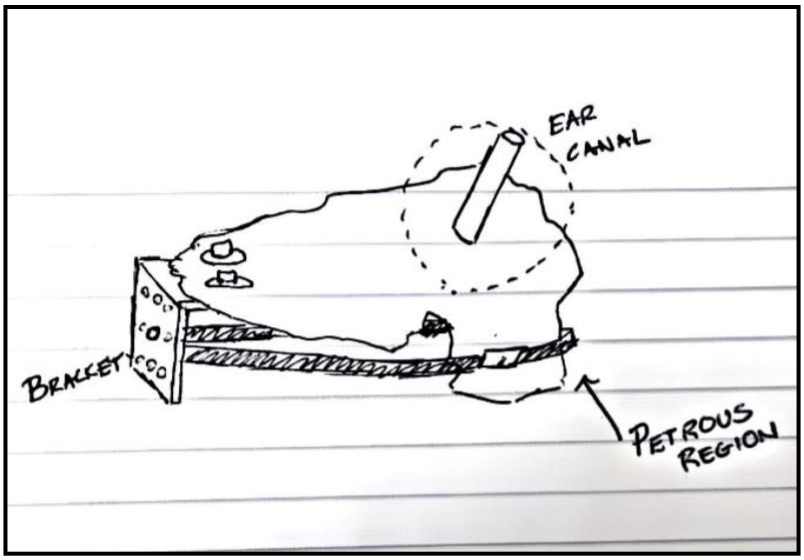


Figure 14: Design Component 2

Design Component 3

Illustrated in Figure 15 is Design Component 3, which is the top half of a design. The clamps are metal plates with small, sharp teeth that would clamp to the bone. The clamps would contact the side edges of the sample in 2 areas. Attached to these metal plates are rods that slide horizontally and vertically in order to allow the holder to adapt to different sized samples. The magnetic base would ensure portability throughout the lab, as researchers could move the sample and attach it to any other location with a magnetic base. Due to the 2 points of contact, which may prevent the bone from being held rigid, and the non-variable clamping system, this top-half design was no longer considered in the design process.

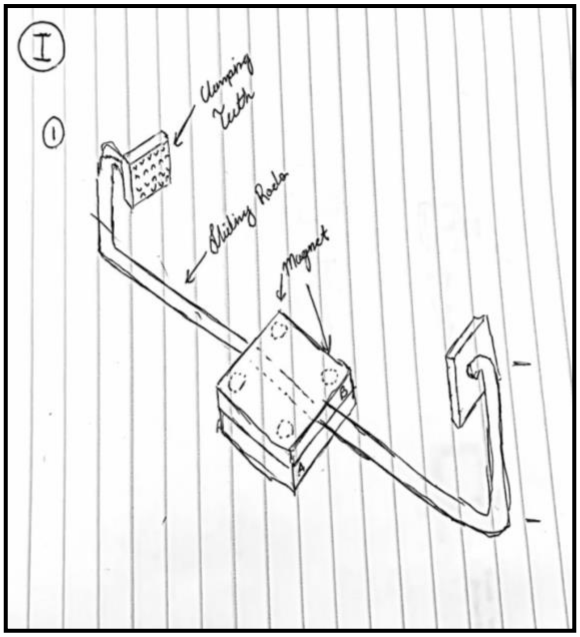


Figure 15: Vise-Grip Adjustable Arm Design Component

Design Component 4

Design Component 4, shown in Figure 16, is an illustration of the bottom half of a holder that would allow for security and easy rotation of the bone. Starting from the bottom up, 2 screws would be fixed into the table, securing the device into a stable position and eliminating the possibility of the entire device sliding when force is applied. This fixturing device helps to make the holder more rigid. The ball-in-socket joint would allow the researchers to rotate the device about the 3 axes while maintaining the ability to lock the ball at a desired angle. The ball device then attaches to a magnetic base, which will be paired with a second magnetic base that is attached to the part of the bio-sample holder that fixtures the sample. The magnets give the researcher the option to move their sample without having to disassemble it entirely because it is fully reattach-able. This allows for higher precision when repeating tests and data collection.

After the analysis of the individual components, full designs were created using

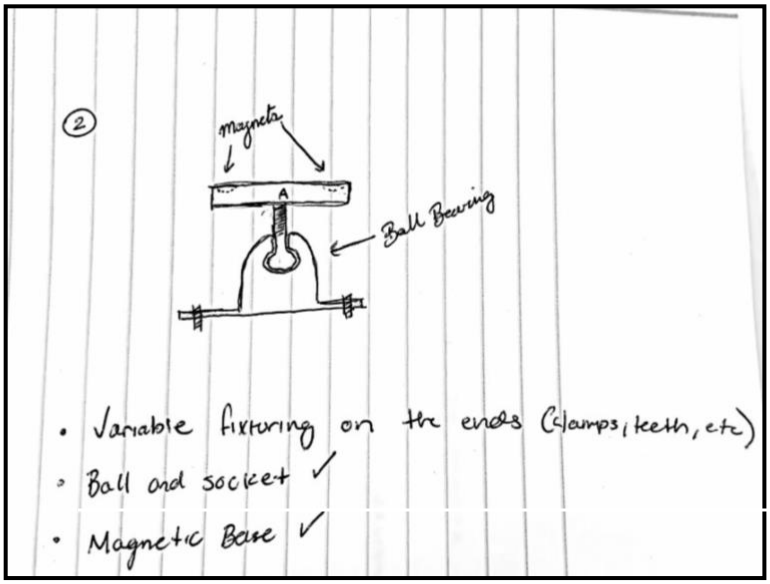


Figure 16: Ball and Socket Joint

combinations of these components that would best fulfill the design requirements.

Bracket Clamp Design

The Bracket Clamp Design, shown Figure 17, focuses on keeping the sample as rigid as possible by utilizing a clamping system with threaded bolts. This design combines Option 1 of Design Component 1 with the base that was explained in Design Component 4. The clamping system is attached with 3 perpendicular metal bars that are secured into the base cylinder of the holder by 3 metal bolts. At the top of each bar there are 3 metal threaded screws that are screwed in with the clamping mechanism attached at each end. These threaded screws can be adjusted to the size of the sample accordingly, which provides flexibility for the shape and size of the sample. The 3-individual c-clamps effectively fit around the sample and the sharpened screws hold the sample in place. The user may have trouble accessing the sample from multiple angles as the clamps surround the sample.

The magnetic base allows the structure to stay rigid when being used. Using a magnetic base allows the ball-in-socket joint to rotate freely while staying rigid. To fully analyze the design, the team came up with pros, cons, and future improvements to break down the different design features and relate them back to design requirements. Some pros of this design include a rigid structure and rotation while some cons are that the ball-in-socket joint is not easily machined, and the clamping mechanism could take longer to secure. This holder has many complex parts, meaning that it would not be easy to clean. Future improvements for this design would be to add handles at the clamping screw and threaded rod so it would take less time to secure.

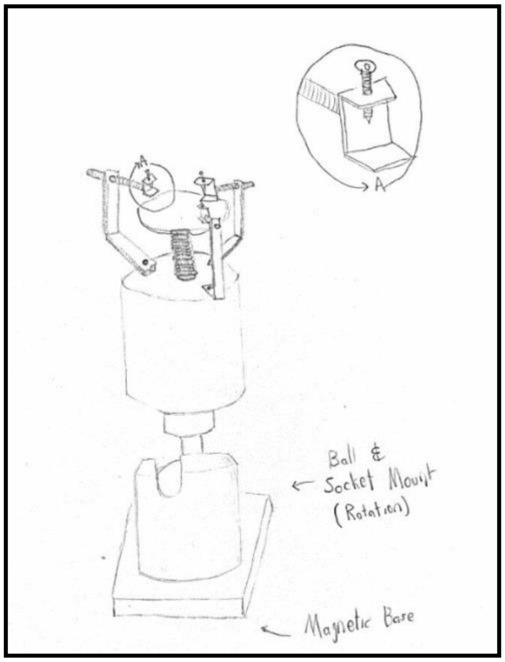


Figure 17: Full Clamp Design Sketch 1

Semi-Circle Clamp Design

The Semi-Circle Clamp Design, sketched in Figure 18, illustrates a complete bio-sample holder. Starting with a magnetic base, the holder leads to a ball-in-socket joint that allows for complete rotation, which was explained in Design Component 4. This component is then connected to a breadboard that leads to 3 threaded rods. 3 steel rods connect the breadboard to the half-ring, which holds 3 vice grips that are attached to threaded rods. At the end of these threaded rods is a needle-point screw clamping system. The clamping system shown here utilizes aspects of Design Component 1, the one screw bracket, but combining this with a U-shape device that would be attached to the half-circle rod.

This design satisfies multiple design requirements that an effective bio-sample holder should meet. The Semi-Circle Clamp design has a rigid magnetic base attached directly to a ball-in-socket joint to provide easy rotation and a rigid structure. This sketch also shows a wide area to access the sample due to the semi-circular tube that can also provide variability with clamp placement, but the clamp will only allow a certain range of sample widths. Some pros to this design include multiple variable clamp contact points for different angles of access to sample and the magnetic base allows portability for re-attachment. A con with this design is that the design is not easily assembled and disassembled so cleaning would be difficult. Another con that can be seen from the sketch is that the half-circle rod is not easily manufactured using stainless steel. Future improvements can be made to this design by making the clamps and clamp arms on a slider track so that the arms can be moved easier and faster instead of screwing. Another improvement that can be made to the 3 threaded rods, would be making them smooth with a lock and pin mechanism to move them up and down faster.

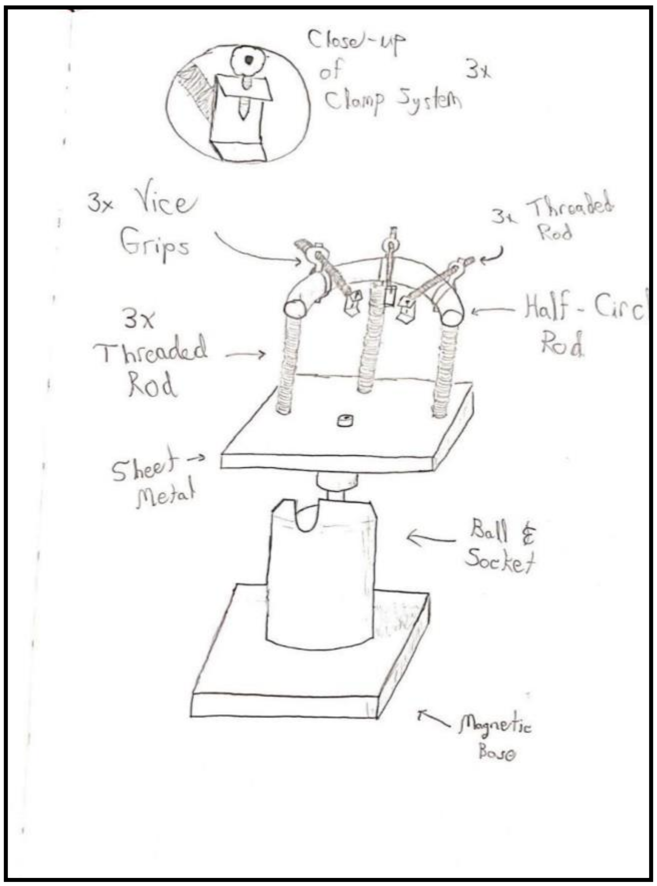


Figure 18: Full Clamp Assembly Sketch 2

Drill and Bracket Fixture

The Drill and Bracket Design, depicted in Figure 19, takes inspiration from Design Component 2 as well as Design Component 4. The drill and fixture technique allow minimal bone to by impacted which supports easy access for the researchers. The researchers will have a standardized drill design template that can be used as a guide for where to drill and what size drill to use for inserting the screws. This screw will be threaded into a horizontal post that attaches to an adjustable arm to give it the clearance necessary from the ground while keeping it low to the ground in order to ensure comfort for the researcher. The arm has a ball-in-socket base as well as a ball-in-socket head which can be fixed into place using a rotational knob which allows for the arm to be adjusted in any direction. This vertical post will be threaded into a magnetic plate. The base used follows a very similar design to that discussed in Design Component 4, with the same magnetic base which allows for the holder to be re-attachable, but the ball-in-socket joint is a part of the adjustable arm instead of being a separate attachment to the holder.

The full design depicted below varies from the previous 2 designs and uses different elements to secure the sample. This sketch shows variability at 3 different locations in the top and bottom ball-in-sockets and at the adjustable knob. These 3 adjustable points give a 360-degree rotational view at both joints and a knob to adjust the angle of the metal arm as well. This design fulfils multiple design criteria that the bio-sample holder should have including a portable and easy to clean design. Some pros of this design are that the drill-in bracket fixture secures a rigid hold with minimal contact areas. Another pro about the design is that the arm is manufactured as one piece, as opposed to the previous designs where the arm mechanisms had to be constructed of multiple parts. A con about Figure 19 is that the bracket cannot align exactly with the curvature of the bone resulting in reduced hold with a small open area in between the component and the bone. Another con of this sketch is that the bracket would need to be custom manufactured out of steel which can be difficult to obtain in a timely manner. Future improvements can be made to this design by installing a rubber interface in between the curvature of the bone and bracket to increase rigidness.

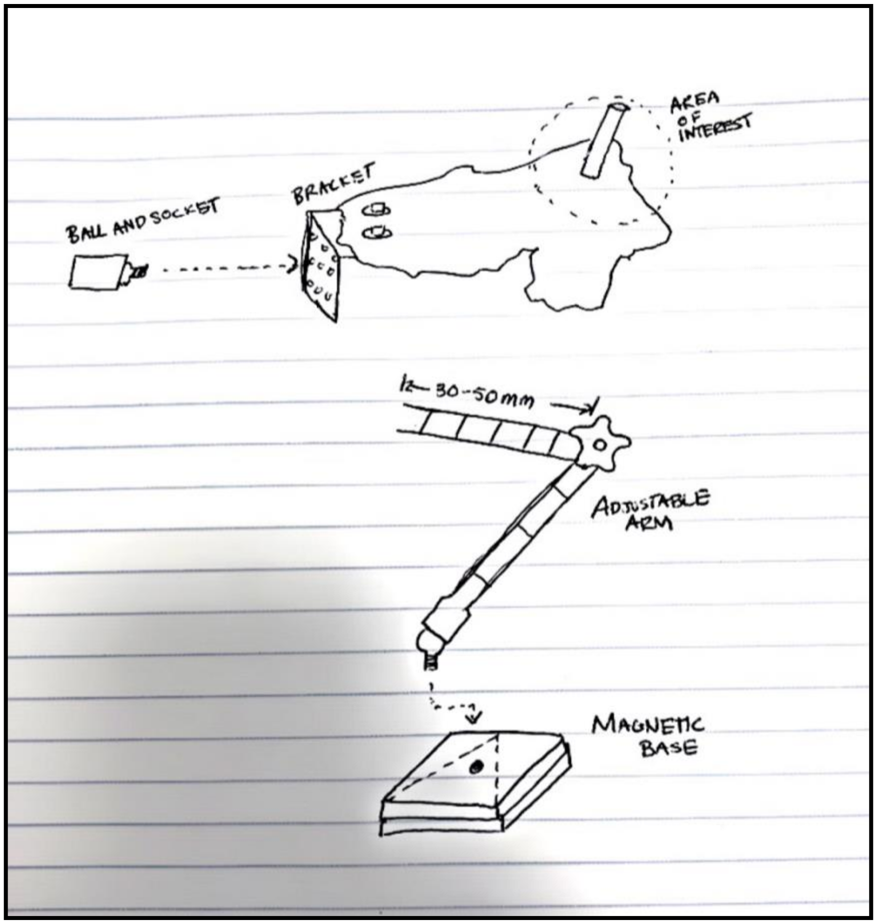


Figure 19: Drill and Fixture Sketch 1

Three Arm C-Clamp Design

The final full design, shown in Figures 20 and 21, utilize the C-clamp design discussed in Design Component 1 along with the base of Component 4. Three C-clamps will attach to the free area of the sample, allowing easy access to the area of interest. Each clamp contacts the bone on the top and bottom, holding the bone with 6 points of contact total. The 6 points of contact around the bone will keep the sample rigid when forces are applied in order to minimize any deflection from the bone. The clamps used will have a maximum span larger than an average temporal bone width, and the screw will be adjusted to ensure a rigid hold on a sample of any width, making this design variable. This design will require no prior setup time to drill into the bone but will take 10-15 minutes to adjust all 3 clamps into a rigid hold if one researcher is working on the preparation. An adjustment that would be added to this design would be the addition of a ball-in-socket joint which will make the entire device re-attachable and portable when it needs to be moved around the lab.

While this design is like what is depicted in the Semi-Circle Clamp Design, the clamping mechanisms that attach at 3 separate points on the sample will apply different forces. The team believed that both designs could be viable options for the researchers, but additional designing and initial testing needed to take place to gain a full understanding of the mechanisms created. It is important that the sample being held by these clamps has enough area of free bone as seen in Figure 21, or the clamps will be forced to intrude on the area of interest and the sample would not be easy to access. The device is easy designed to be easy to clean, as the clamps separate from the bone and can be detached from the arms themselves.

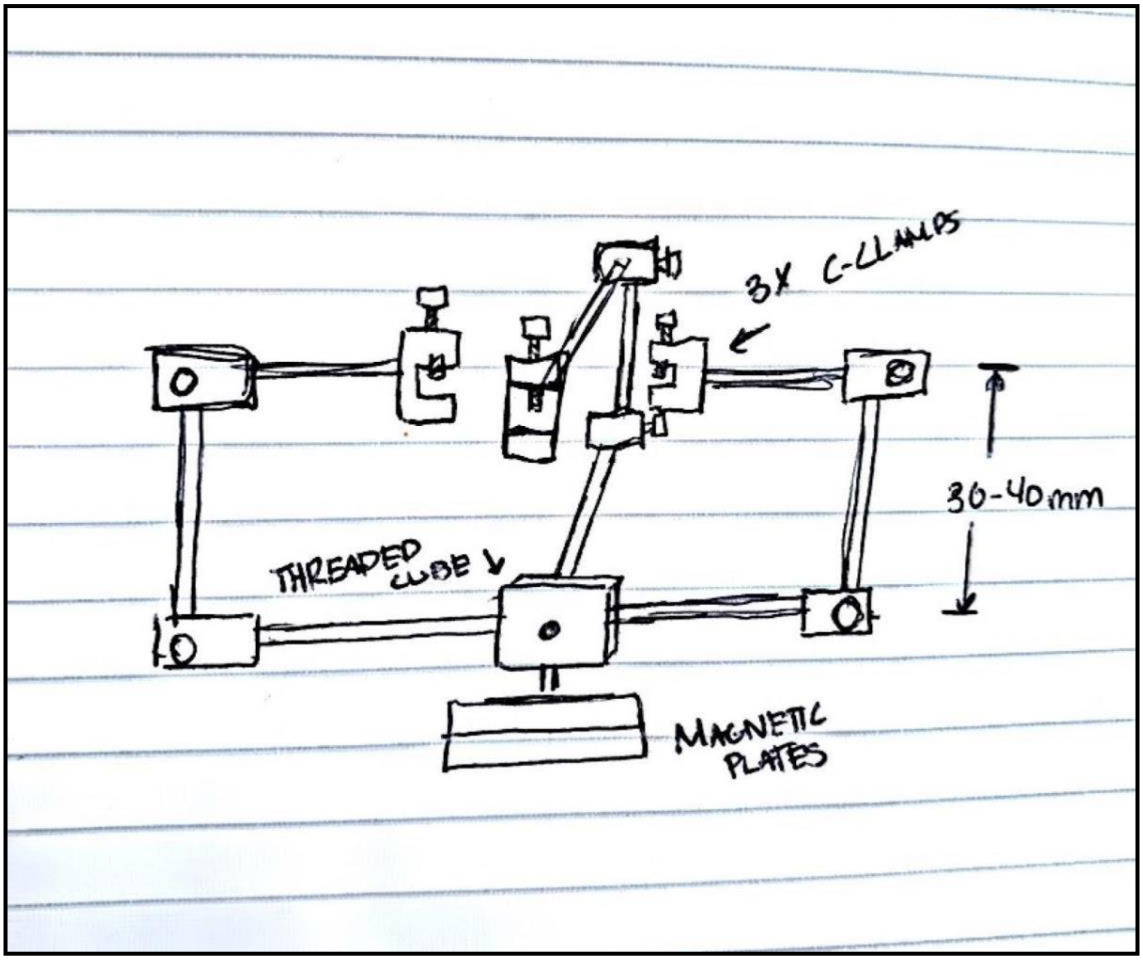


Figure 20: Three Arm Clamp Sketch

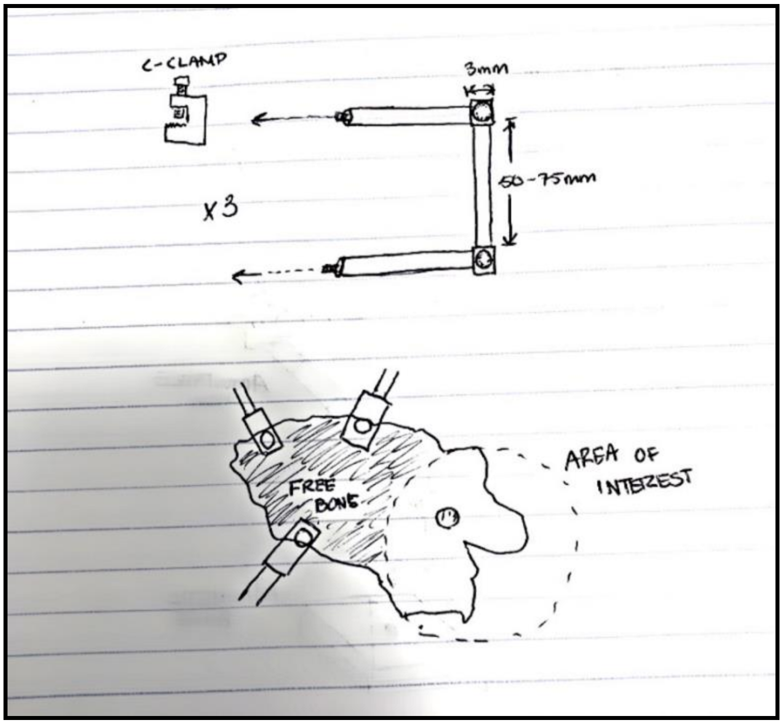


Figure 21: Clamp, Arm and Clamping Location Sketch

Analysis of Sketches

All the sketches were created with the goal to address the design requirements that were initially discussed in 3.1.3. Each Full Design is a combination of different components, some fulfilling more design requirements than others. Shown in Table 3 is a visualization of the 4 Full Design options compared on Design Requirements.

Table 3: Design Requirement Comparisons

	Bracket Clamp	Semi-circle Clamp	Drill and Bracket Fixture	Three Arm C-Clamp
Holds Sample Rigid	✓	✓	✓	✓
Easy to Access Sample	X	✓	✓	✓
Allows for Easy Rotation	✓	✓	✓	✓
Easy to Clean	X	X	✓	✓
Variable	X	X	✓	✓
re-attachable	✓	✓	✓	✓
Low to Table	X	X	✓	✓
Portable	✓	✓	✓	✓
Durable	✓	✓	✓	✓

After comparison of the design options, the team modeled The Drill and Bracket Fixture design and the Three Arm C-Clamp Design in SolidWorks. The team decided to utilize SolidWorks as the next step in the design process because this computer software is a tool that will allow a 3-D visualization of the 2-D sketches. After assessing the design requirements of the sketches, SolidWorks will allow precise designing in terms of geometry and assembly, as well as identifying areas of improvement that were overlooked in the sketching process.

3.2.3 3-D Modeling of Top Designs

Once the team concluded the brainstorming and sketching phases, the next step in the design process was to create 3-D designs. The team wanted to visualize the scale and functionality of the considered designs, which can be difficult to do from preliminary sketches. Assemblies were created in SolidWorks using custom-made parts and exported parts from known suppliers such as ThorLabs. Each design can be broken down into multiple sections which describes the different geometries and functional properties that aim to fulfill different design criteria. Creating models through SolidWorks worked to finalize the designs and analyze how the designs will move when assembled as one device.

Drill and Fixture Assembly

The first assembly modeled in SolidWorks was the drill and fixture assembly. A 3-D design of the assembly can be seen in Figure 22. A magnetic base is attached to a ball-in-socket joint, which joins to an adjustable arm which can be tightened at the midpoint to hold the arm rigid. The two ball-in-socket joints in this design were located at either end of the dynamic arm. The attachable arm has a tightening knob at the midpoint which makes the device easier for the researcher to tighten, needed no assistance with a screwdriver or wrench. This magnetic base works to ensure the holder is re-attachable and can be moved around the lab to different stations if necessary. The top half of the adjustable arm attaches to a bracket, which will then attach to the bone through a drilling method. This design utilizes only the blue bracket to secure to the bone, leaving the area of interest on the sample completely free for research. Each of the major parts of the assembly will be discussed in detail in the following sections

below.

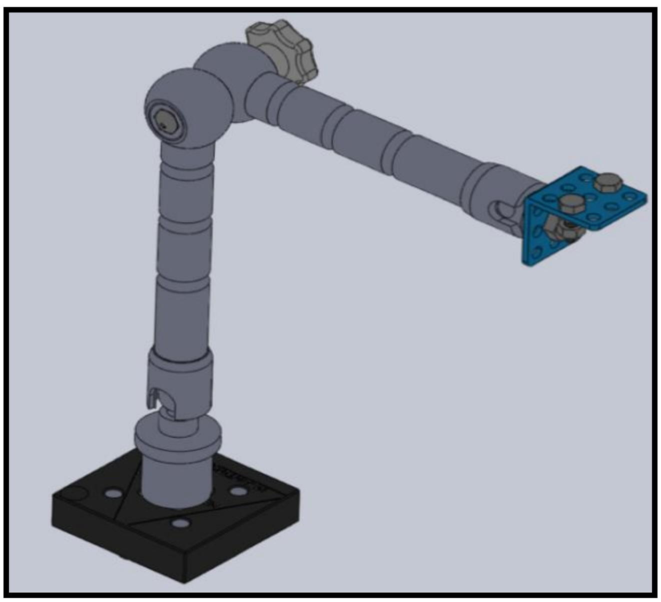


Figure 22: Isometric Drill and Fixture SolidWorks Design

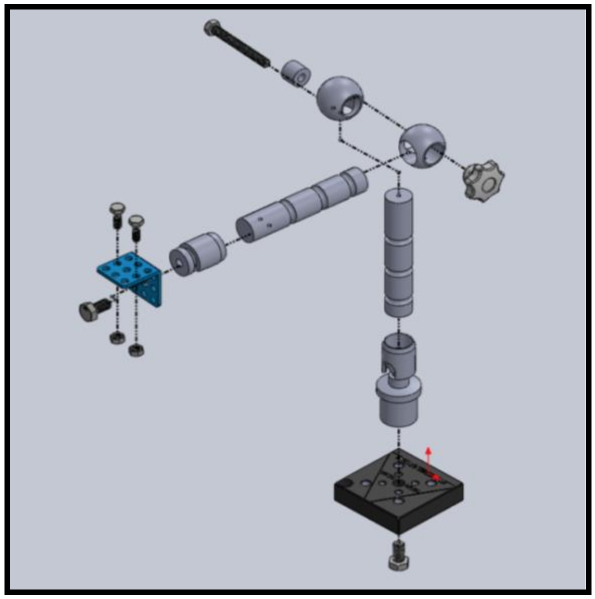


Figure 23: Exploded Assembly Drill and Fixture SolidWorks Design

Magnetic Plates

At the base of the Drill and Fixture assembly were the magnetic plates, shown in Figure 23, that helped create a stable base for the assembly. The magnetic plate model that the team used is the 50 mm by 50 mm KB2X2 [20]. The exact dimensions can be seen in Figure 24. The top mounting plate and bottom base plate are coupled using 2 pairs of high strength magnets which provides a holding force of 6.25 pounds [20]. The holding force benefits the overall design by providing a rigid hold at the base of the structure that keeps the magnets together if moved. The top plate has a ball and V-groove design which allows the plate to be inserted and removed repeatedly [20]. The top plate has a central M6 counterbore that can be used to attach a 25-millimeter post [20]. Also, the KBT2X2 top plate features four M6 tapped holes and four M4 tapped holes to provide flexible mounting options. The KBT2X2 has the option to have the top and bottom plates be fastened by a 3-millimeter hex head cap screw for tip prevention that can be used to prevent the 2 plates from separating while in use [20]. The magnetic plates contain key features that benefit the rigidness of the clamp design. The holding force and hex cap screw ensure that the 2 plates will not separate while the rest of the assembly is mounted on top of the plates.

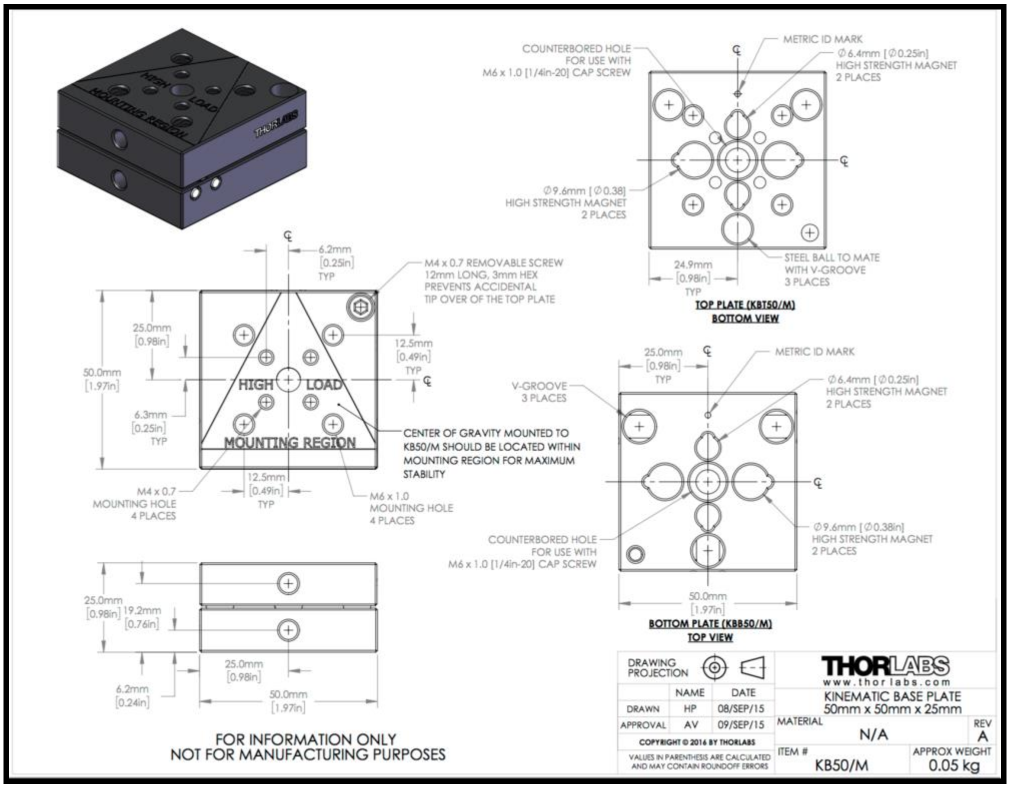
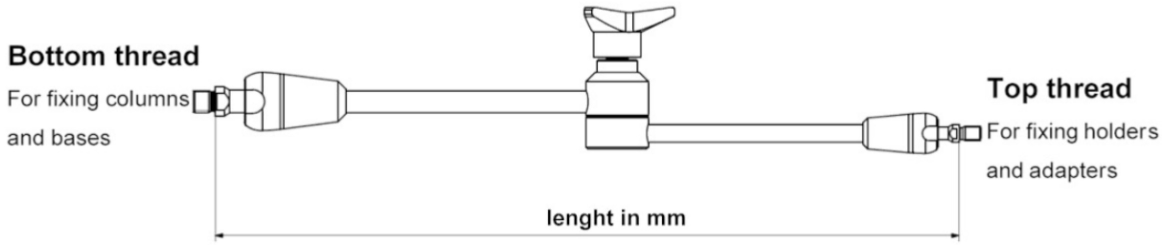


Figure 24: Magnetic Plates [20]

Dynamic Arm

The next component of the drill fixture design is the dynamic arm. The dynamic arm is manufactured by FISSO and comes in multiple lengths. In Figure 25, the proper dimensions of the arm in millimeters are modeled to visualize its geometry [19]. The dynamic arm has 2 ball-in-socket joints at the base and the top of the arm [19]. This allows rotational movement around the top axis and bottom axis of the arm. There is also an adjustable knob at the middle of the arm to allow translational movement between the 2 arms [19]. To attach the arm to the magnetic base and bracket there are M6 threaded holes that allow screws to be inserted in the design [19].



Length mm	Bottom thread	Top thread	Knob	Weight kg
130	M6	M6	stainless steel	0.24

Figure 25: FISSO Arm and Specifications [19]

Drill Bracket

The MakeBlock blue bracket, shown in Figure 26, is a 3 hole by 3-hole aluminum bracket that can be seen with its proper dimensions. The right-angle shaped bracket is used to support to attach the FISSO arm and bone sample together. The center hole on the perpendicular plate was widened using a 5.5 mm drill in order to clear a M6 threaded insert. M4 screws thread through the top of the bracket to secure the bone to the bracket.

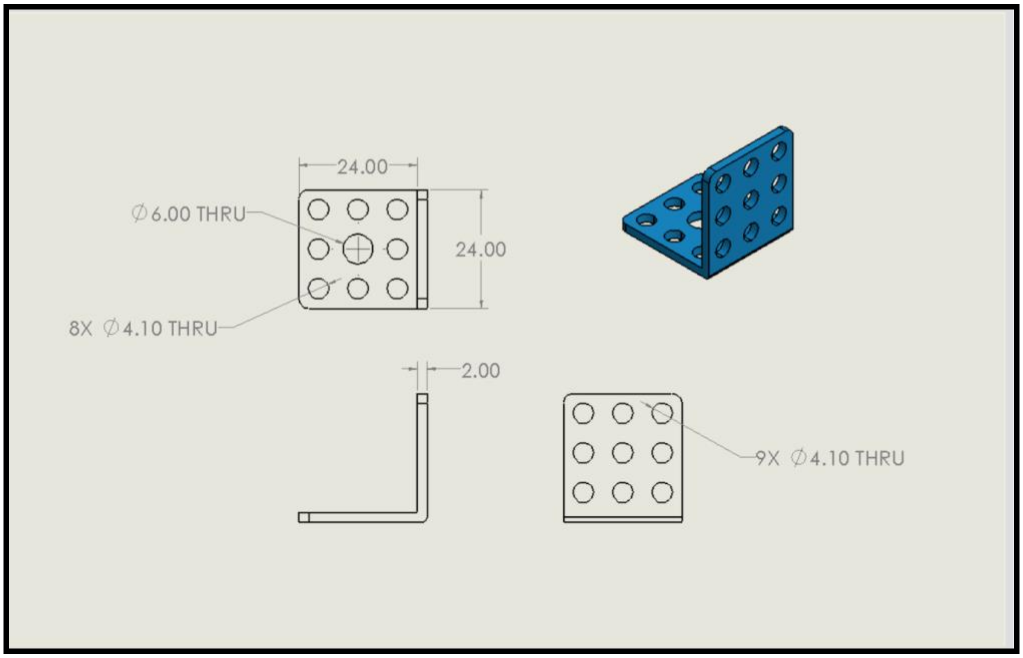


Figure 26: Drill Bracket

Analysis of Drill and Fixture SolidWorks Model

After modeling the team’s designs and components, an assessment of the designs was conducted based on the researcher's requirements. It was important to once again compare and evaluate these full designs to the Design Requirements listed in Chapter 2, to ensure an accurate interpretation of the previous sketches. Starting with sketches in the previous section and then translating them to a 3D SolidWorks drawing gave further insight on how each of the designs could work. The major requirements that this design meets can be seen in Table 4. Specifically, this design satisfies the top 2 requirements of holding the sample rigid and easy access. Due to the success of this model, it was created in the prototyping section.

Table 4: Drill and Fixture Preliminary Analysis

Design Requirement	✓ or X?
Holds Sample Rigid	✓
Easy to Access Sample	✓
Allows for Easy Rotation	✓
Easy to Clean	✓
Variable	✓
re-attachable	✓
Low to Table	✓
Durable	✓

Three Arm C-Clamp Assembly

Using SolidWorks, the team modeled an assembly of the C-clamp design, which can be observed in Figure 27 and 28. This clamping design features a ball-in-socket base for dynamic motion which are attached to 2 magnetic plates for easy repositioning. Attached to the magnetic plates are 3 adjustable arms which are connected to the 3 C-clamps that fix the bone.

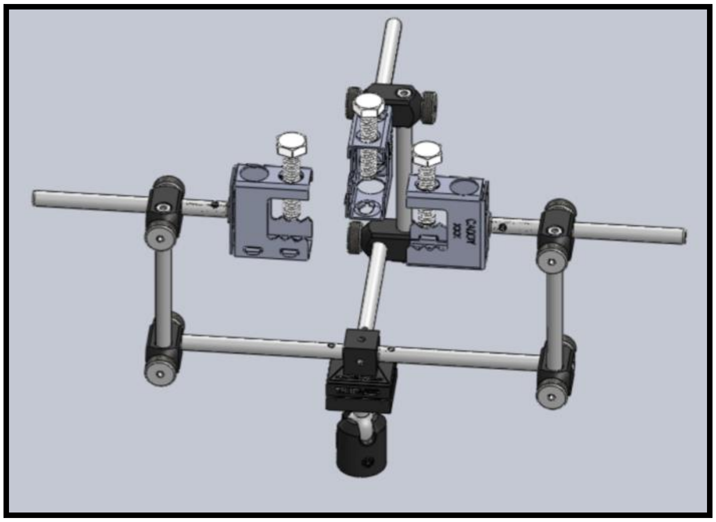


Figure 27: Clamp Assembly SolidWorks Design

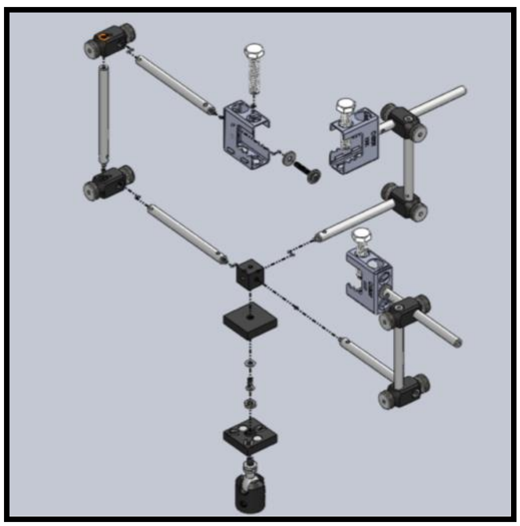


Figure 28: Exploded View Clamp Assembly SolidWorks Design

Ball and Socket Base

The ball-in-socket base is a mechanism that allows the mounting surface to be positioned anywhere within a 50° cone [20]. There are 3 cutouts in the base that allows the mounting surface to be positioned at a 90° angle with respect to the mount's base [20]. The team used the TRB2 version of the ball-in-socket because this version was the most available in the lab. The dimensions of the TRB2M ball-in-socket mount features a Ø11.2-millimeter mounting surface with a M6 threaded stud [20]. A key aspect of the ball-in-socket joint is that the mounting surface can be locked in place using any of the 3 locking screws. The bottom of the base contains a hole with the same tap as the threaded stud which makes these mounts ideal for working with optical posts. The ball-in-socket component of this design provides an increased range of rotation for assembly which can be seen in the CAD model in Figure 29. The software allowed the team to see a 3D representation of rotation at the different joints which the sketches did not illustrate.

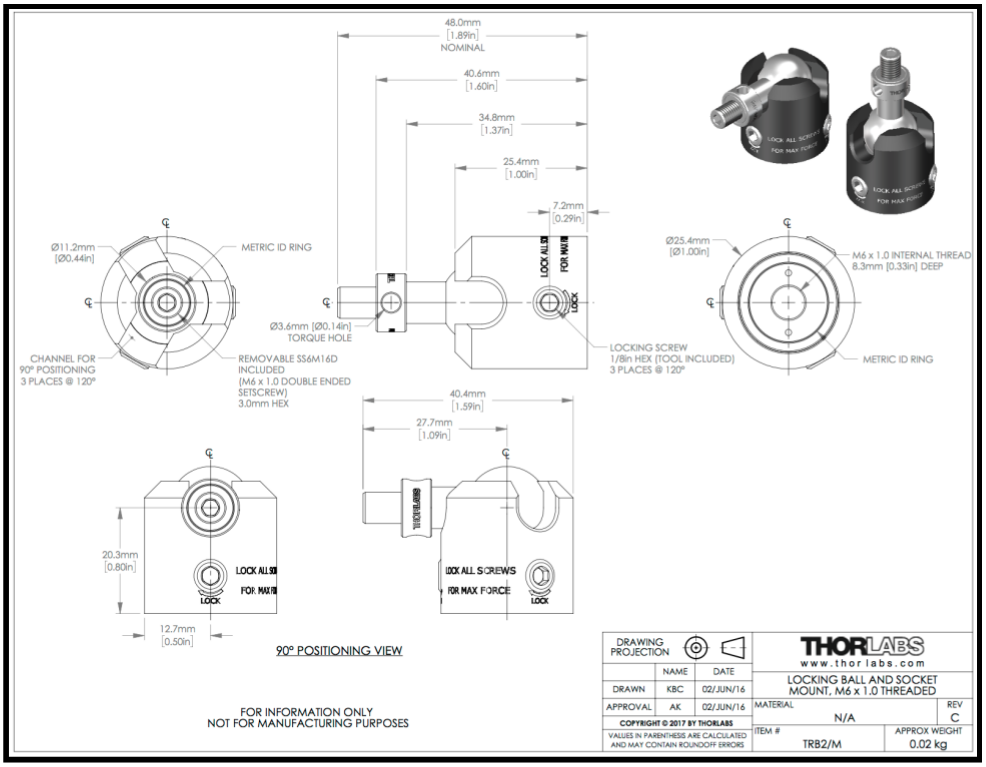


Figure 29: Locking Ball-in-Socket Mount [20]

Magnetic Plates

The next major component of the 3 Arm Clamp is the magnetic base that was previously discussed for the Drill and Fixture design. The magnetic plates still serve the same purpose as before to provide a rigid base for the assembly. The model of the magnetic plate that the team used is the 50 mm by 50 mm KB2X2, which are the same dimensions used for the drill assembly [20]. Visuals and full dimensions can be seen in Figure 24. The major difference in the use of the magnetic plates in this design was its assembly within the full device. For this model the magnetic plate is secured to the ball and socket joint at the bottom and to the assembly cube.

Adjustable Clamping Arm Components

There are 3 adjustable arms in the clamp design which creates variability for clamp placement. The SolidWorks assemblies of these arm components are shown in Figures 30 and 29. The arms are constructed using Ø12 millimeter stainless steel optical posts and Ø12 millimeter to Ø12 millimeter right angle post clamps. The optical post is a basic building block in the team’s assembly and in most rigid structures and is available in lengths ranging from 20 millimeters to 300 millimeters [20]. The post is 12 millimeters in diameter and is 75 mm in length. One end has an M6 tapped hole, while the other end has a removable M4 threaded set screw [2 mm hex] [20]. The other aspect of the arm is the right-angle post clamp, which serves to adjust the lengths and angles of the optical posts. These clamps allow for fixed angles as well as 360° continuous adjustments. The holes of the clamps are double bored to provide 2 lines of stable contact for the optical post [20]. Additionally, there are aluminum thumb screws that secure the posts in place while inserted into the right-angle clamp. These 2 parts make up the rigid arms of the clamp design which provides variability and rigidness to the design.

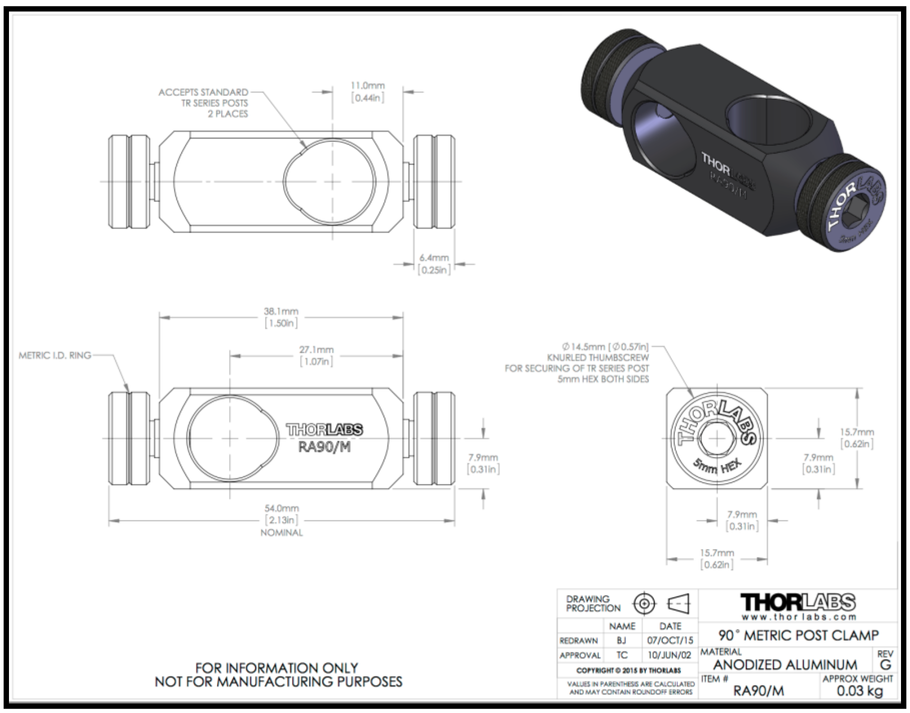


Figure 30: Locking Ball-in-Socket Mount [20]

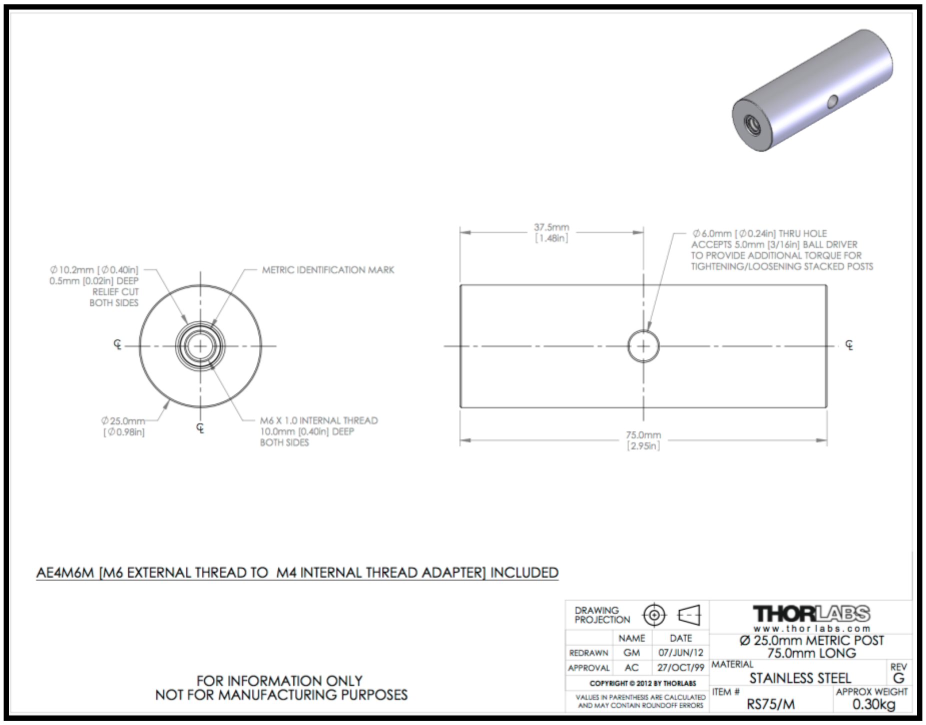


Figure 31: Optical Post [20]

C-Clamps

The final component of the clamp design is a metal clamp with teeth and a pointed screw. In Figure 32 the proper dimensions in millimeters are shown for the entire clamp and screw [7]. The clamp uses an M6 threaded screw fitting through a 10.5 mm hole into the clamp [7]. The M6 pointed screw can easily thread through the clamp and into the bone to have a rigid hold on the bone.

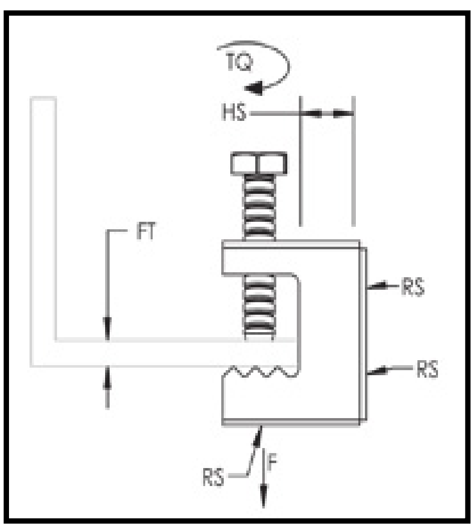


Figure 32: C-Clamp Drawing [7]

Table 4: C-Clamp Dimensions and Specifications [7]

Rod Size [RS]	M6
Hole Size [HS]	10.5 mm
Flange Thickness [FT]	16 mm Max
Torque [TQ]	3 N-m
Static Load [F]	450 N

Analysis of C-Clamp SolidWorks Model

The Drill and Fixture SolidWorks model was created referencing the sketches in 3.2.2. In order to determine if the design requirements had been translated to 3D models with all intended design elements, an analysis was conducted, visualized in Table 5. This Three Arm C-Clamp design met all 9 requirements and was a clear adaptation of its sketches.

Table 5: Drill and Fixture Preliminary Analysis

Design Requirement	✓ or X?
Holds Sample Rigid	✓
Easy to Access Sample	✓
Allows for Easy Rotation	✓
Easy to Clean	✓
Variable	✓
re-attachable	✓
Low to Table	✓
Durable	✓

After the design process, prototyping was the next step to finalizing designs and recommendations for the USZ team. The sketches and SolidWorks models gave the team a clear visualization of the designs that would then be prototyped using standard parts found in the lab. With the geometries and dimensions analyzed in SolidWorks, the team then could confidently begin building devices that would be tested. While not all parts used in the SolidWorks models would be available at the USZ team, custom parts could be created for timely testing to be completed.

Chapter 4: Prototyping Process

Following the design process, prototypes were created utilizing the sketches and SolidWorks models. Prototyping brought an interactive understanding of the entire design setups and were able to display any issues that sketches, and modeling software could not demonstrate to the team. The final product would take weeks to manufacture and lead times would need to be taken into consideration. The final design would be manufactured with custom parts as well as standard parts that would need to be ordered specifically for the device. Due to time constraints, prototyped designs were built and tested using only the parts available in the lab. Testing, analyzation, and final conclusions were generated with the prototypes and would give the WPI and the USZ team results that would only be improved if the final recommendations were followed correctly. Based on the testing results and design recommendations of this project, the USZ would then decide if a fully manufactured device was an investment they wanted to make, or if more research was necessary before relying on this holder.

Dr. Dobrev supplied the team with a range of components that were in the lab and recommended companies that would quickly ship parts needed for assembly. A prototype that the researchers could visualize and evaluate would give the team constructive feedback and recommendations for future steps. This step of the design process provided the team with designs that would be tested and analyzed to form recommendations for a final design.

4.1 Lab-Available Parts

Dr. Dobrev allowed the team full access to any materials in the lab that would be used to execute tests and produce a prototype. All parts used to design prototypes were created using standard parts found in the USZ lab. With these parts, such as ball-in-socket joints, magnetic bases, various plates, pole and base fixtures, and miscellaneous hardware, the team was able to gain a better understanding of full designs being procured. While not all standard parts would be ideal for a final device, the hands-on aspect of experimenting with these parts, and understanding their functionality, was helpful. Most of the parts originated from ThorLabs and MakeBlock, 2 common suppliers of both the laboratory and robotic parts.

Ball-In-Socket Joint

Shown in Figure 33 is an adjustable ball-in-socket joint that enables rotation of the holder in three 90° positions. The small hole on the bottom of the base is threaded, allowing the ball to be locked when the device is in the desired location. This part allows easy rotation of the sample during research, rigidity when the base is locked, and easy access to view all necessary angles.

Figure 33: ThorLabs Ball and Socket Base

Magnetic Base

Magnetic bases, shown in Figures 34 and 35, are used for mounting the sample quickly, and in the exact position it was mounted before. The 3 magnetic spheres, circled in Figure 35, ensure precision when the 2 plates are matched together. Magnetics plates allow the device to be easily re-attachable to previous positions and portable when moving to stations around the lab.

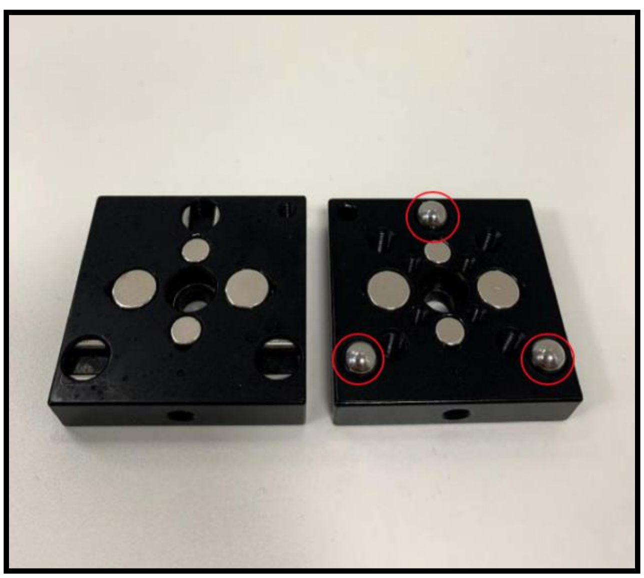


Figure 35: Magnetic Base (Bottom View)

Figure 34: Magnetic Bases (Connected)

U-Shape and C Brackets

The brackets shown in Figure 36 and 37 are used as structural support for most builds in the lab. These parts are made of aluminum, which was not an ideal material for a final product for the USZ but gave a good representation of parts available on the market and worked for prototyping purposes. The U-Shape brackets were found to be useful in clamping the magnetic base plates together when large forces were being applied. The C-bracket was used in some prototypes to fixture the bone to the rest of the assembly.

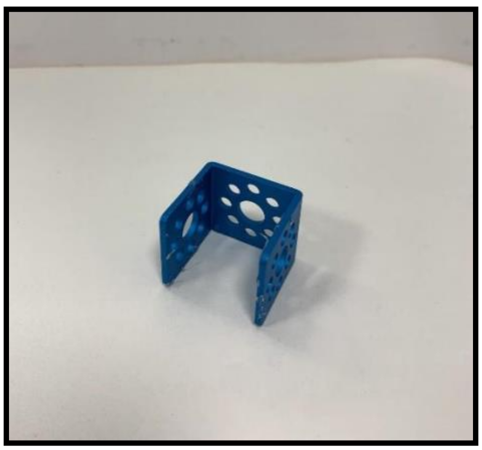


Figure 36: U-Bracket

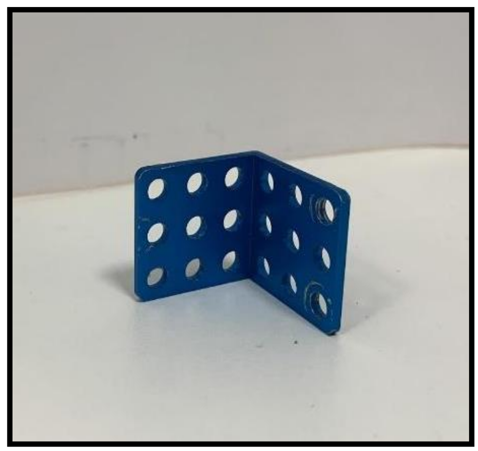


Figure 37: C-Bracket

Optical Post & Post Holder

An optical post and an optical post holder are shown in Figures 38 and 39. Optical posts are the basic building blocks required in most rigid structures and come in a variety of different lengths for construction. The optical post is made of stainless steel and is compatible with the post holder in Figure 38. The post holder simplifies the task in mounting an optical post on a breadboard. These post holders incorporate a swiveling base for rotational purposes and magnets on the bottom of the base to aid in alignment to the breadboard.

Figure 38: Optical Post

Figure 39: Optical Post Holder

Dynamic Arm

Figure 40 shows a PS3 adjustable arm that comes in a variety of sizes for medical applications. The height is adjustable, which allows the arm to be low to the table, and it can be fixed at certain points with the knob. Each arm rotates perpendicular to each other to provide rotation at different heights and the arm contains ball-and-socket joints at the end of each arm. The PS3 arm provides rotational and variable capabilities for mounting different assemblies on the arm. This is useful for changing positions, so that the samples can be accessed in the prototypes.

Figure 40: PS3 Dynamic Arm

Angle Post Clamp and Spring-loaded Thumb Screws

Figure 42 depicts a right-angle post clamp that connects optical posts at a 90-degree angle. These clamps fasten at a variety of different angles to one another and a range of fixed angles as well providing variability to the design. The team used 90-degree angle clamps for optical post assemblies for testing and prototyping. The range of motion from this clamp allowed easy access to the sample and easy rotation.

Figure 43 shows a pair of aluminum spring loaded thumbscrews for right-angle clamps. The screws provide enough force on a post to hold the right-angle clamp in place. While they hold the posts rigid, they also allow for easy rotation, which is helpful because changing the angle of the holder is a quick process for the researcher.

Figure 42: Angle Post Clamp

Figure 41: Spring Loaded Thumb Screws

4.1.3 Artificial Temporal Bone

In addition to the parts given to the team, there was also a replica of a temporal bone, shown in Figure 43. These replicas are used by researchers to practice tests and surgeries before using a real temporal bone. These artificial bones are procured by PHACON, a manufacturer of various medical devices, replicas, and instruments. These replicas are molded from real patients and created using a ceramic material very similar to real bone. The bones can be drilled into, cut, and represent proper anatomy. The bone model gave the team a better understanding of the shape and size that the holder would need to support. As this project is engineering-based, none of the team members had the background or experience that would allow testing with real bones, so these replicas were a suitable option to give a realistic understanding of the interaction between real bone and the prototyped bio-samples holders.

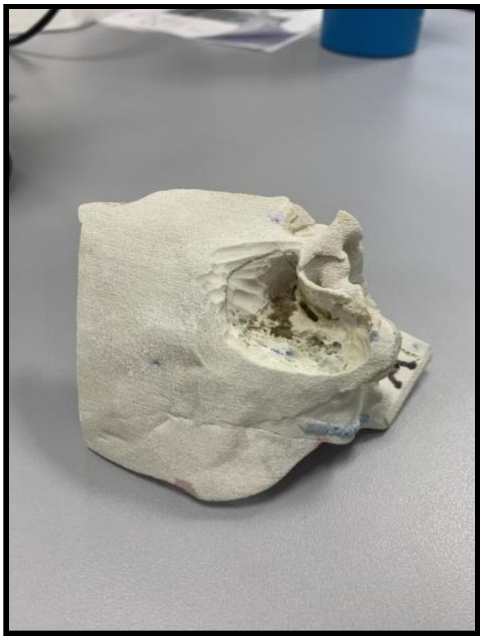


Figure 43: PHACON Artificial Temporal Bone

Using the parts detailed in 4.1.2 and 4.1.3, the team was able to begin the next stage of the design process: prototyping. These parts allowed the team an interactive understanding of the sketches and SolidWorks models that had been created up until this time. Prototyping would permit a full insight of parts working together and enabling more feedback from researchers, who would have a better understanding for a device they may be using in the future.

4.2 Creating Prototypes

Utilizing the parts mentioned in 4.1, full designs were produced, referencing sketches and SolidWorks models. A parts list was attached to each prototype, allowing easy evaluation of all parts used to assemble the designs. Once the designs were constructed, all 3 devices were analyzed through comparison of benefits and drawbacks. Following that process, each design was compared to the Design Requirements that were previously established in Chapter 2.

4.2.1 C-Clamp Design

Construction

The clamping prototype is seen in Figures 44. Given the parts available in the lab, the team was able to incorporate the ball-in-socket mount and magnet connection at the bottom of the design. The clamps were able to be fixtured to the model using one M6 screw to attach them to the Thorlabs posts. The top magnet uses a second M6 screw to fixture itself to the ThorLabs cube that provides 6 threaded holes that will be utilized throughout the rest of the assembly process. Using a combination of 9 ThorLabs posts and 6 ThorLabs 90-degree angle clamps, the team was able to assemble the framework of the bio-sample holder that would give it the maneuverability to clamp onto the bone at a variety of angles. Lastly, the team attached 3 C-clamps to the end of the top posts, which gave the design 6 main points of contact to rigidly fasten the temporal bone sample.

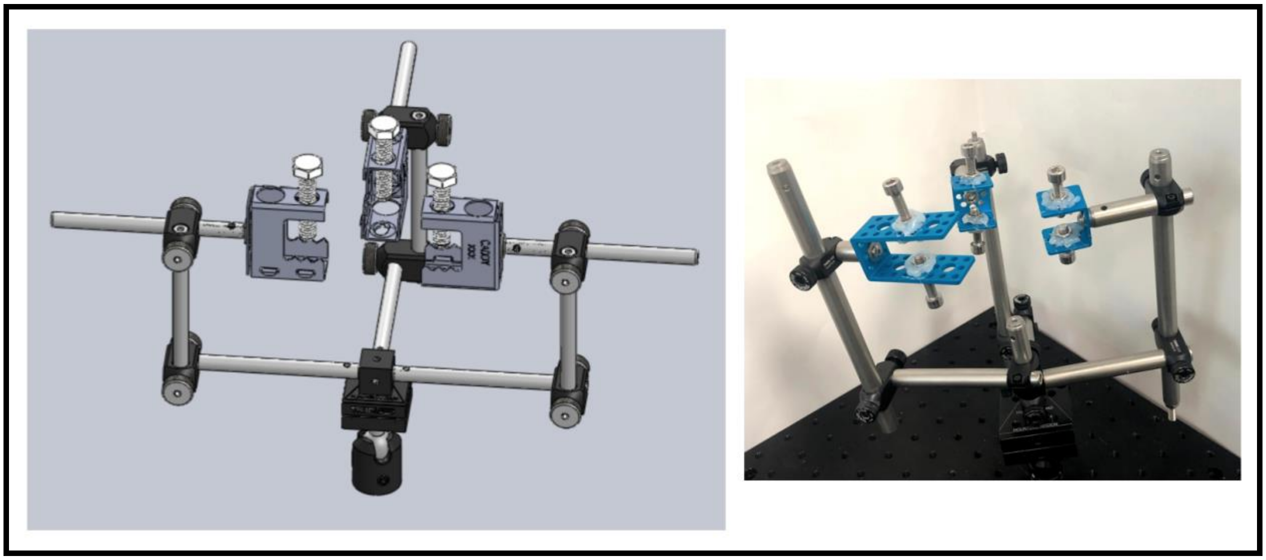


Figure 44: Clamp Prototype to Design Comparison

Table 6: C-Clamp Design Iteration 1 Parts List

Design Iteration 1			
Supplier	Part Number	Item	Quantity
ThorLabs	RM1F/M	25mm Construction Cube with M6 Tapped Holes	2
ThorLabs	TR75/M	12.7 mm Optical Post	9
ThorLabs	RA90	Right-Angle Clamp	6
ThorLabs	KB2X2	Kinematic Base	1
ThorLabs	TRB1	Locking Ball and Socket Mount	1
Misc.	N/A	M6 Socket Head Screws	2
Misc.	N/A	0.5” C-Clamps	3

Discussion

Once constructed the design was evaluated based on the benefits and drawbacks that the team brainstormed in Table 7. The analysis of the design requirements that this design iteration meets or fails to meet is expressed in Table 8. The 3 clamps used in this design were created using standard parts in the lab to give a secure hold to the bone keeping it rigid. In addition, the top half of this design was heavy, which could cause more strain on the ball-in-socket mount. These drawbacks directly related to the design requirements of holding the sample rigid, and do not allow a secure hold under all conditions. While the ball-in-socket joint allows 180 degrees of rotation, the pole structure only allows 90 degrees of rotation, not satisfying the “Allows for Easy Rotation” design requirements. The magnetic base is a benefit because it ensures that the entire device will be re-attachable at specialized positions.

Table 7: C-Clamp Design Iteration 1 Benefits and Drawbacks

Design Iteration 1	
Benefits	Drawbacks
○ 6 points of contact with the bone ○ Standard parts used ○ Ball-in-socket provides 180 degrees of rotation ○ Magnetic base allows for easy removal ○ No special preparation of bone needed	○ Rigid pole structure (90 degrees) ○ Top heavy (More stress on the base) ○ Clamps are missing a sharp edge ○ Difficult to adjust pole assembly ○ Difficult to find piece-part suppliers ○ Long setup time when securing bone

Table 8: Design Requirements for C-Clamp Design Iteration 1

Design Requirement	✓ or X?
Holds Sample Rigid	✓
Easy to Access Sample	✓
Allows for Easy Rotation	X
Easy to Clean	X
Variable	✓
re-attachable	✓
Low to Table	✓
Durable	X

4.2.2 Drill and Fixture Designs

Iteration 1

Construction

The first iteration of the drill and fixture design was derived from the preliminary drill and fixture sketch and SolidWorks iteration. A visual of this prototype can be found in Figure 45. Having 4 points of contact, this iteration attempts to improve upon the current drill and fixture method used by the PhD students. The artificial temporal bone is tapped using a 3.6 mm drill in 2 places based on the geometry of the MakeBlock 3x3 Bracket. M4 screws were utilized to thread through the top of the bone to the MakeBlock Bracket fixed on the bottom side of the artificial bone. Washers were used to extend the point of contact on the top side of the artificial bone, and M4 nuts were used to fasten the M4 screws tightly in place. The center hole on the perpendicular plate of the MakeBlock Bracket was widened using a 5.5 mm drill in order to clear an M6 threaded insert. Two 12-millimeter ThorLabs Stainless Steel Optical Posts of 75 millimeters in length are attached perpendicularly to each other using a ThorLabs Right Angle Clamp and are fastened to the MakeBlock Bracket in the widened M6 hole. The opposite side of the post assembly is fastened to two 50 millimeters by 50-millimeter Kinematic Bases which in turn are fastened to a ball-in-socket mount.

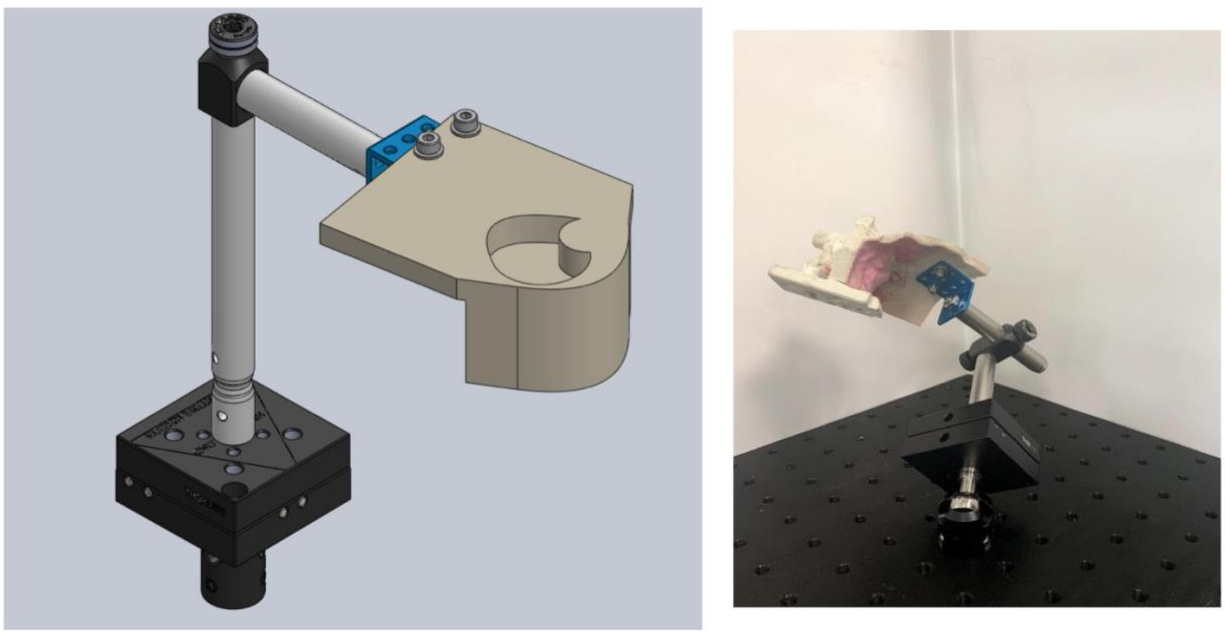


Figure 45: Drill and Fixture Prototype to Design Comparison

Table 9: Design Iteration 1 Part List

Design Iteration 1			
Supplier	Part Number	Item	Quantity
PHACON	TF-br	Temporal Bone Patient "Schmidt"	1
MakeBlock	N/A	Stainless Steel Nut 4 mm	2
MakeBlock	N/A	Stainless Steel Socket Cap Screw 4mm - 14mm	2
ThorLabs	N/A	Stainless Steel Washer	2
ThorLabs	TR75/M	12.7 mm Optical Post	2
ThorLabs	RA90	Right-Angle Clamp	1
ThorLabs	KB2X2	Kinematic Base	1
ThorLabs	TRB1	Locking Ball and Socket Mount	1

Discussion

In Drill and Fixture Iteration 1, there were multiple outlined benefits that would meet the design requirements of the researchers. Design requirements that were met consist of easy access to sample, variable, and low to the table. The requirement of the device being variable was supported by the multiple contact points created by the drilled in bracket. The ball-in-socket joint allows for increased rotation which results in easy access to samples at different angles and makes the assembly low to the table. The aluminum material that the bracket is manufactured out of is not as rigid as an ideal steel bracket for this design, which may result in deformation. Table 10 and Table 11 conceptualize the benefits, drawbacks, and design requirements of this Drill and Fixture Design Iteration 2.

Table 10: Design Iteration 2 Benefits and Drawbacks

Design Iteration 2	
Benefits	Drawbacks
○ Multiple points of contact with the bone ○ Easy to fixture ○ Standard parts used ○ Ball-in-socket provides 180 degrees of rotation ○ Magnetic base allows for easy removal	○ Rigid pole structure (90 degrees) ○ Weak MakeBlock bracket material ○ Top heavy (non-uniform weight distribution) ○ No precise template for drilling locations ○ Difficult to adjust pole assembly

Table 11: Design Requirements for Design Iteration 2

Design Requirement	✓ or X?
Holds Sample Rigid	✓
Easy to Access Sample	✓
Allows for Easy Rotation	X
Easy to Clean	✓
Variable	✓
re-attachable	✓
Low to Table	✓
Durable	✓

Iteration 2

Construction

The second iteration of the drill and fixture design was focused on the variability the ball-in-socket joints allow. This design continues to use the preliminary drill and fixture method to secure the temporal bone with a rigid hold as seen in Figure 46. The temporal bone was drilled into with a 3.6-millimeter drill in two separate places, based on the specific geometry of the bracket. These holes were matched up with a 3x3 MakeBlock bracket that fits securely within the bottom geometry of the temporal bone. Once the bracket was in place with the holes, M4 screws were used to thread through the top of the bone into the bracket and out through the bottom side of the bone where M4 nuts were used to secure the screws in place. Washers were used to extend the surface area at the top of the bone. The center hole on the bracket was widened using a 5.5-millimeter drill in order to create an M6 clearance hole for the threaded insert of the arm. The arm originated from the medical device supplier, FISSO, and consists of a double-jointed structure with a ball-in-socket joint at the top and bottom of the arm. The top ball-in-socket joint is inserted through the bracket and fastened with an M6 nut. The arm is adjustable in 3 places, 2 of which are the ball-in-socket joints and the other is an adjustable knob that connects 2 arms together. This knob can loosen to let the arm move perpendicular to the temporal bone adding adjustability to this structure.

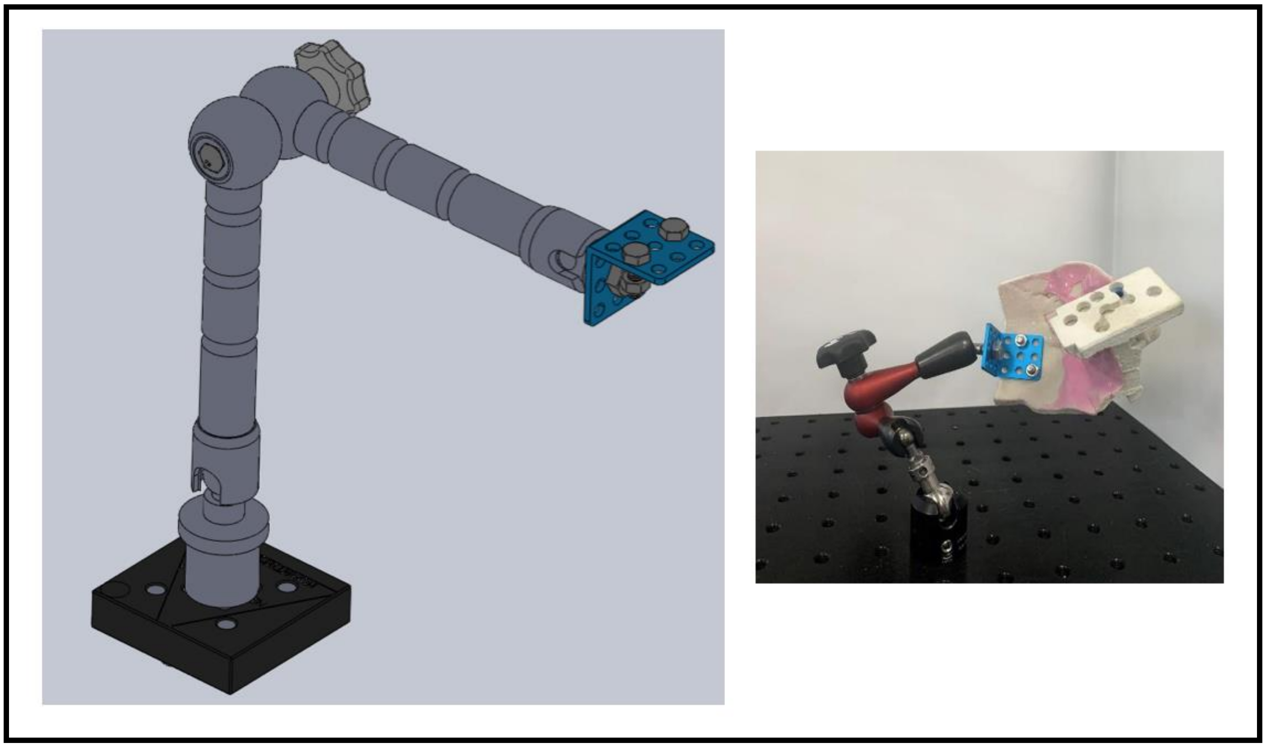


Figure 46: Drill and Fixture Prototype to Design Comparison

Table 12: Design Iteration 1 Part List

Design Iteration 1			
Supplier	Part Number	Item	Quantity
PHACON	**TF-br**	Temporal Bone Patient "Schmidt"	1
MakeBlock	N/A	Stainless Steel Nut 4 mm	2
MakeBlock	N/A	Stainless Steel Socket Cap Screw 4mm - 14mm	2
ThorLabs	N/A	Stainless Steel Washer	2
MakeBlock	MB-61500	MakeBlock Blue Bracket 3x3	1
FISSO	XS-13	FISSO Dynamic Arm	1
ThorLabs	TRB1	Locking Ball and Socket Mount	1

Discussion

The second iteration improved upon the first iteration and allowed the team to further brainstorm the different positive and negative aspects in Table 13. The benefits and drawbacks can directly relate to the design requirements and if the design meets or does not meet the criteria. A table visualizing how this design correlates to the Design Requirements is shown in Table 14. A notable benefit that this design had is that the assembly can rotate in 3 different areas which are the base, the bracket attachment, and the adjustable arm knob. This benefit satisfies the requirement for variability in accessing the sample and keeping the sample low to the table. Design iteration 2 also has some drawbacks that would affect the 9 design requirements. The dynamic arm needs to be locked in 3 different locations to be completely rigid, which would affect the setup time and create a high chance of deflection. The FISSO arm tends to slip when a large moment arm is applied which would affect the rigidness of the structure as well.

Table 13: Benefits and Drawbacks of Design Iteration 2

Design Iteration 2	
Benefits	Drawbacks
○ Allows 3 different areas of rotation: at the base, bracket attachment, and connecting the 2 metal arms ○ Increases mobility with horizontal and vertical movement ○ Bracket assembly connected to ball-in-socket joint allows for relative rigidness	○ Needs to be locked in 3 different locations for relative rigidness ○ Fisso Arm tends to slip when strong moment arm is applied ○ MakeBlock bracket material is not ideal ○ No precise location for drilling template

Table 14: Design Requirements for Design Iteration 2

Design Requirement	✓ or X?
Holds Sample Rigid	✓
Easy to Access Sample	✓
Allows for Easy Rotation	✓
Easy to Clean	✓
Variable	✓
re-attachable	✓
Low to Table	✓
Durable	✓

After the team successfully built multiple prototypes and compared them to the design requirements, the next step in the design process was to gain feedback on the prototypes from the USZ research group.

4.3 In-Progress Reception and Feedback

The team had the chance to attend a mid-project meeting with the Otology and Biomechanics of Hearing team. These meetings were attended by each person on the team and were intended to keep everyone up to date on all the different projects being worked on in the lab. Before the team began the testing of the holders, it was pertinent that feedback from the entire team was gathered to ensure no areas were overlooked or would be difficult to use in the lab.

4.3.1 USZ Team Meeting

After the C-Clamp and Drill and Fixture prototypes had been built and analyzed, they were presented in a weekly meeting to the USZ team. Feedback was given to the WPI team regarding the C-Clamp Design discussed in 4.2.2, as well as Iteration 2 of the Drill and Fixture prototype. A summary of the most important discussion points is featured in Table 15.

Table 15: Feedback from 9/19/19 Meeting

Feedback	Changes and Adaptations

• Team supports drill design, which was a new idea to them
• Believes clamp design may be more stable if drill design does not support the Petrous
• Recommended that the team investigate a way to fixture the Petrous in addition to drilling to stabilize the moment arm due to the bone's weight.
• Urged the team to investigate the stability of the magnetic base was when a moment is was applied.
	• Team investigated possible options to add this Petrous support
	    o Strap supports the bone's weight, which would increase the rigidity when force is applied about minimize deflection
	• Researched the magnetic base and ways to stabilize when moment arm is added
	    o Added 2 C-clamps on opposite sides of the base which solve the issue of the magnet sliding or coming apart
	    o Easy application and deconstruction, not adding time to set-up process

The research team was overall pleased with the designs that had been created and were interested in the testing results each would collect. The USZ team suggested research into a support system implemented to reinforce the opposing end to the temporal bone for the Drill and Fixture design, and a more stable magnetic base.

Solutions that were discussed for extra support included incorporating a secondary point of contact at the Petrous, eliminating the cantilever effect of fixing the sample at one end. Additionally, the team was inspired by the functionality of industrial ratchet straps which had been discussed in Chapter 3 as extra support and reflected on incorporating nylon straps to the drill design. These straps would secure to the bracket and wrap around the Petrous. This can be observed in Figure 47. The straps necessary for proper support would need to be specially designed for the temporal bone. After discussions with the USZ team and research into the strap solution, the team decided that additional research and designing would be necessary if this was a design feature that would be added. Due to the timeline of the project, testing was conducted without the strap, but the additional strap would become a recommendation for the USZ team if the Drill and Fixture design were to be used or if this project were to continue in the future.

While focusing on the issue of the magnetic plates, the team identified a threaded bolt that effectively fixed the 2 magnetic plates together. The issue with this solution was that the bolt location was outside of the loading section of the plates and acted against the force of the magnets. MakeBlock brackets were used as a temporary solution, vising the 2 plates together. During testing, the magnetic base would be tested with and without the MakeBlock brackets, which would support or disprove the clamps as a solution to avoiding the magnetic base coming apart while a moment arm is applied.

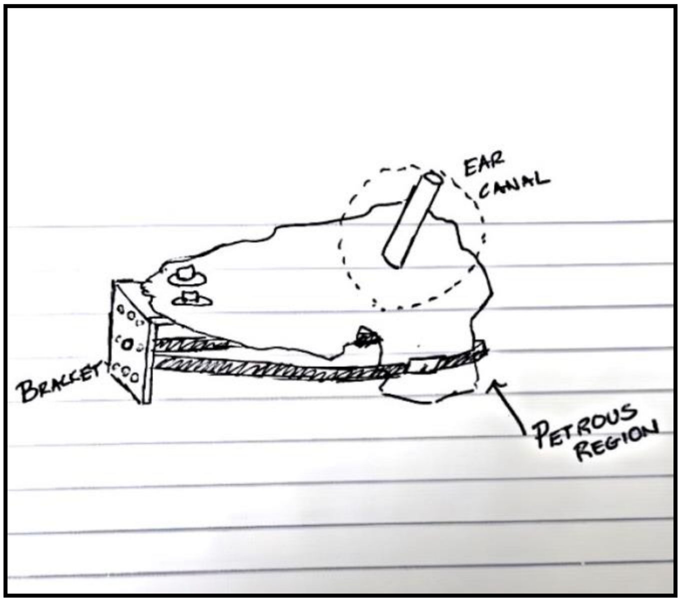


Figure 47: Petrous Support Strap Sketch

Feedback from the team at the USZ was just as important as the data that would be collected during the tests of the bio-sample holders. If the researcher's saw a problem that could be fixed or a feature that needed to be added to make the design usable, it was critical that the team adapt the designs before completing final testing. The team aimed to recommend new ideas that brought viable solutions to the issues they had, which would only be possible with meetings and analysis from those who will be working with the devices.

Chapter 5: Testing and Analyzing Designs

Following the prototype stage of the project, tests were designed to analyze the rigidity of the prototypes and their components. Throughout experimentation and preparation, the sample experiences various forces while it is fixed to the sample holder. The goal of the testing was to determine if the designs could withstand worst-case force scenarios that may take place during lab research, with less than 1 millimeter of deflection. To obtain a maximum force value to test the designs against, the team created a drill force test. Following this, the team created and validated static force tests to replicate the drilling force observed in the drill force testing. Table 16 describes the experimental flow of data collection.

Table 16: Testing Outcomes

Test	Outcome
Drill Force Testing	Range of forces applied by researchers
Control Static Testing	Validation that test setup yields accurate deflection data
Prototyped Design Testing	Deflection results of full designs and individual components

5.1 Drill Force Testing

In order to determine if the designs would survive the maximum forces placed on it throughout experimentation and preparation, the team needed to determine a range of maximum forces. The forces that are placed on the sample consist of drilling, minimal vibrating in certain experiments, and contacting the bone. During preparation, the raw temporal bone is cut and drilled to reveal the area of interest. For the PhD students, this process can take between 2 and 3 hours, while practiced surgeons can prepare the sample in 20 minutes [2]. The PhD students told the team that drilling is the maximum force that is placed on the temporal bone [12]. As previously detailed in Chapter 2, Dr. Dobrev stated that the sample could deflect a maximum of 1 millimeter while drilling.

The purpose of analyzing the vertical force that drilling places on the temporal bone is to understand the maximum force that the sample holder must support. The team wanted to obtain data from the 3 PhD students that regularly prepare temporal bone samples for experimentation. Ms. Warnholtz, Mr. Schär and Mr. Liyanage were asked to participate in this experiment because they use temporal bone holders often. Obtaining a wide range of data from each of the 3 PhD students would ensure that a true maximum range of forces was obtained before testing the designs.

5.1.1 Test Setup

The team designed an experiment to determine the force placed on the temporal bone during drilling. This was done by fixing an artificial temporal bone to scale and observe the force applied to the sample during a set period of drilling. After talks with the USZ team, it was determined that most of the force that they drill with is in the downward direction. As a result, the team strictly focused on the vertical force of drilling placed on the sample. This force would then be assumed to be a worst-case scenario for the horizontal force as well, since the likelihood of the horizontal force surpassing the vertical would be minimal. For later testing, a resultant force of the 2 directions would be used to represent the worst-case force for drilling.

The PHACON artificial temporal bone features a flat ceramic plate on the bottom side of the bone which the team identified as an ideal horizontal plane to fix to the scale. The team fastened an M6 nut to this horizontal plate and utilized a M6 set screw to fasten the plate to a ThorLabs 12-millimeter diameter post extending vertically upwards. This post was fastened to a horizontal ThorLabs 12-millimeter diameter post with identical perpendicular posts on either side. A scale with 5-kilogram maximum allowance was placed under this assembly, and the assembly posts were fastened to a ThorLabs 300 millimeter by 300-millimeter breadboard. This ensured that when the students drill down into the sample, the vertical applied force was observed by the scale. This setup can be seen in Figure 48 and 49.

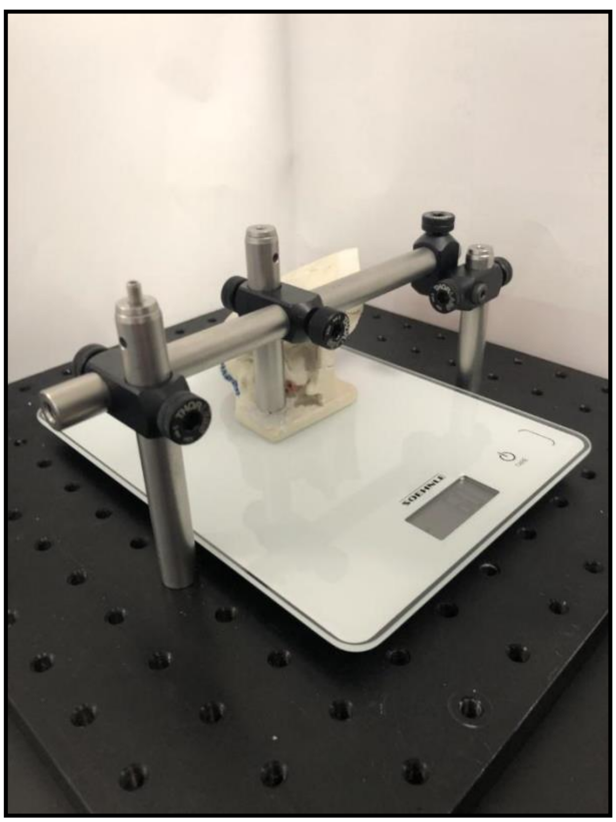


Figure 48: Drill Force Test Setup

Figure 49: Drill Force Test Setup (2)

Each PhD student drilled into the fixed artificial temporal bone for 5 seconds, repeating this process five times. One team member took a video recording of the 5 second drill period, and the maximum applied force for each trial was recorded. The PhD students utilized surgical drills that are regularly used during typical preparation of the sample. Figure 50 demonstrates a PhD student participating in the team's test, while one team member records the weight results.

5.1.2 Data and Interpretation

Figure 50: PhD Student Drilling into Artificial Bone

Table 17: Drill Force Test Data

	Ms. Warnholtz	Mr. Liyanage	Mr. Schär
Trial 1	335	105	77
Trial 2	421	120	337
Trial 3	370	124	104
Trial 4	312	121	277
Trial 5	466	87	349
Maximum Mass [g]	466	124	349
Maximum Force [N]	4.57	1.22	3.42

The output of the data received during the testing can be observed in Table 17. Of the 3 PhD students, Ms. Warnholtz placed the largest force on the sample of 4.57 Newtons. This occurred during her fifth trial, with comparable masses of 421 grams and 370 grams being observed during trials 2 and 3. Mr. Liyanage produced the least force when drilling into the sample, with his maximum mass being observed as 124 grams or 1.22 Newtons. Mr. Liyanage produced comparable values to his maximum in trials 3 and 4, with the scale observing 124 grams and 121 grams respectively. Finally, Mr. Schär's trials produced forces that between the maximum and minimum values of the other 2 PhD students, with his maximum reading being 349 grams during his fifth trial, or 3.42 Newtons of force. Comparable values to Mr. Schär's maximum were observed to be 337 grams and 277 grams, in his second and fourth trial respectively. This will assist in the replication of drilling forces on the team's prototypes in later testing.

Throughout this procedure, there were areas in which error could affect the data collection including the reading of the scale measurements, improper fixing of the sample to the scale, slight horizontal sliding of the bone while drilling, and the inaccuracy of the scale. Due to the researchers completing 5 trials each, the team was able to see a wide range of drilling force values, which would mitigate the room for error.

5.2 Control Static Testing

Given the range of maximum forces that were obtained in the drill force testing, the team designed a static force analysis system, so that the deflection of certain components under these maximum forces could be measured. This system replicates the vertical force placed on the sample through drilling. With a numerical value for applied force, the team designed a system that would evaluate the displacement of any given assembly or part. In order to verify that this system would produce accurate deflection results, the team had to perform a control test. The data obtained during this control test was compared with a simulation conducted using SolidWorks software. This simulation was verified by hand calculations carried out by the team. The purpose of the control static testing was to confirm that the testing setup, which would be used on the full designs and individual components, was outputting accurate data. If the tests were first run on the designs, there would be no way to confirm that the testing setup was outputting valid data to draw conclusions from. A visual that helps explain the static testing process is shown in Figure 51.

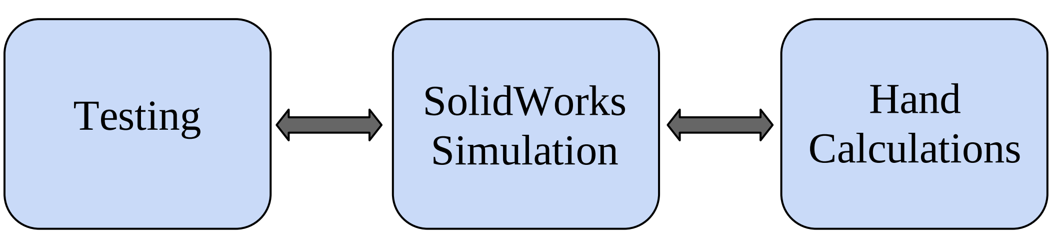


Figure 51: Static Testing Process Validation

5.2.1 Static Force Test Setup Verification

The first step to complete Static Testing was creating a test that would measure deflection. The team designed a method of simulating a force being applied to any given location of the design using a pulley apparatus. This would consist of a prototype assembly, or a specific part being fixed at one end, and attaching a string to the opposite end to be threaded through a minimal-friction pulley. The team utilized the applied force and observed deflection to compare the stiffness of relative designs and finite elements.

The team designed a control test to analyze the accuracy of this system to measure deflection. Utilizing a Euler cantilever beam model would be a viable method to test the deflection of a beam against the SolidWorks simulation apparatus using the same test conditions. In order to verify the accuracy of the SolidWorks simulation, the team modelled a basic beam and performed numerous simulations of varying forces. These deflection results were then validated by hand calculations carried out by the team.

System Setup and Verification

Dr. Dobrev identified that an effective method to observe the deflection of the assembly or part would be to use an optical camera. The Otology and Biomechanics of Hearing Team had numerous optical camera setups readily available, making this method a viable option to analyze deflection. Using a target system that can be observed in Figure 53, it was possible to focus the optical camera and measure the number of pixels per millimeter through a screenshot. The area surrounded in a red box in Figure 53 demonstrates the target that the camera focused on. The target in question provides a scale of millimeters and can be observed in Figure 52. Using Microsoft Paint, the team chose 2 points that are between 1 and 5 millimeters apart in distance indicated by the target and recorded the pixel location of each. Microsoft Paint allowed the team to see the pixel locations through a cartesian coordinate system. Once the team had the distance in number of pixels from this coordinate system, the pixel value was divided by the number of millimeters that they were apart to get pixels per millimeter. This method calibrated the camera, making the conversion from pixels to millimeters seamless during testing. This calibration varied between tests because it needed to be recalibrated every time the camera was repositioned. One point was selected on the part or assembly in question, and screenshots were taken before and after loading to examine the deflection in pixels [12]. The calibration set up can be observed in Figure 53.

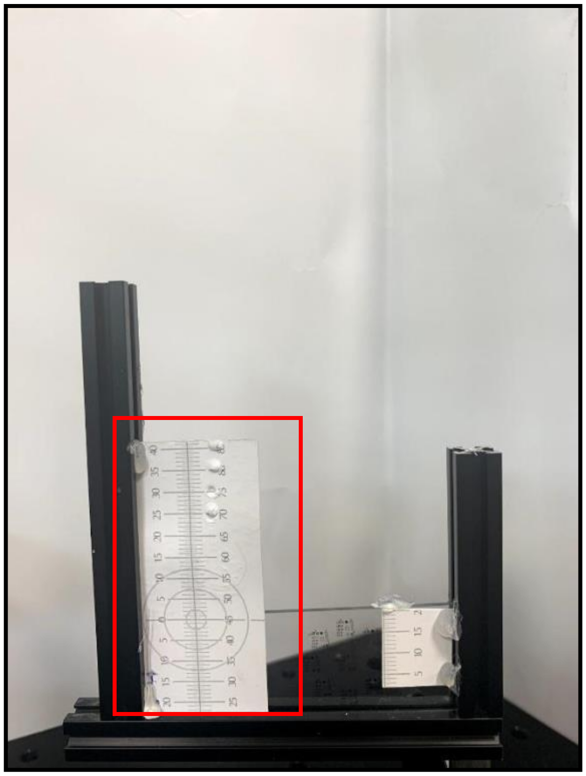


Figure 53: Pixel to Millimeter Conversion Target

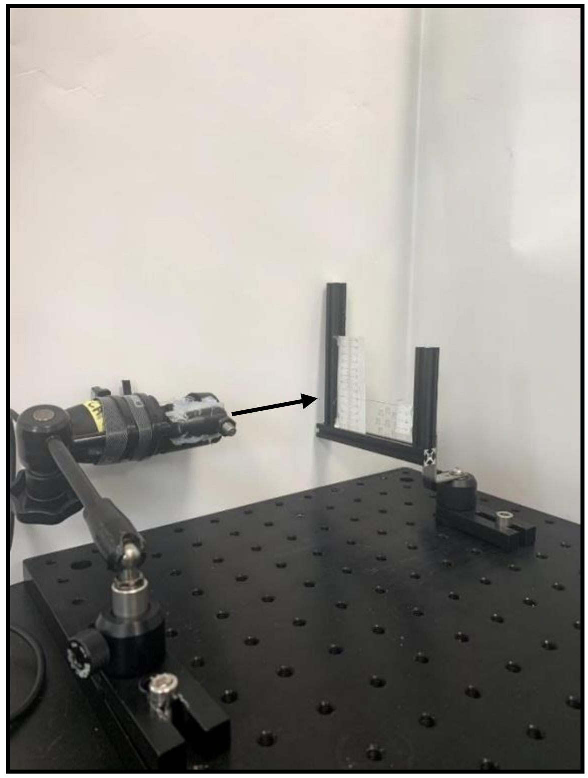


Figure 52: Calibration Setup

The team proceeded with the control testing to determine if the optical camera and pulley system would be an effective method in measuring deflection for given applied forces. A beam was selected from the standard parts available in the laboratory and fixed in an upright position. The beam utilized was manufactured from MakeBlock and featured the following conditions and dimensions shown in Table 18. This beam has a non-uniform cross section and a complex geometry. The non-uniform beam can be seen in Appendix C. The beam was fixed to a horizontal ThorLabs 12-millimeter diameter post with an M4 set-screw and nut, and the post was fastened to the breadboard. The top of the beam was pulled by a string that was fed through a minimal-friction pulley, and weights were tied to the opposite end of the string.

Table 18: MakeBlock Beam Dimensional Information

Beam Thickness (m)	**0.0018**
Beam Width (m)	**0.00775**
Beam Length (m)	**0.1085**
Aluminum 6061 Young's Modulus (Gpa)	**68.9**
Pixels per Millimeter	**45.621**

Initially, a screenshot was taken of the fixed beam with no added weight to the opposite end of the pulley. This would act as a starting position for the beam to compare the relative deflection to and can be observed in Figure 54. The point of focus is the within the red box.

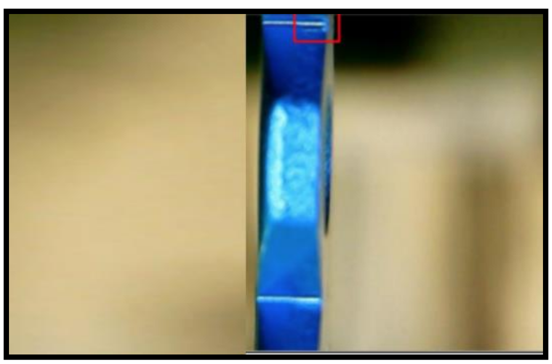


Figure 54: Beam Pre-Loading Screenshot

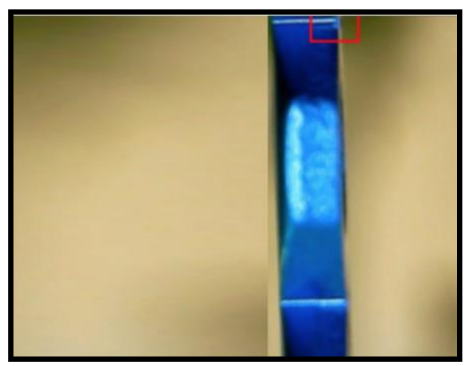


Figure 55: Beam Post-Loading Screenshot

Next, weight was added to the pulley in increments of four washers. Once the motion had ceased, a new screenshot was taken using the microscopic camera, which can be observed in Figure 55. A small amount of movement was noticed within the red boxes in the two images.

Before the next increase of weight was added to the system, a screenshot was taken when the sample had no weight applied, acting as a recalibration for the next data point. 3 trials of loading the 5 specified forces were completed to ensure accuracy. The experimental setup can be observed in Figures 56 and 57. The relative location of the selected point in pixels was identified using Microsoft Paint for both the initial and the loaded positions. Since the beam was being pulled horizontally, the deflection in the vertical direction was minimal and was ignored. The deflection in pixels in the horizontal direction was compared to the initial starting position, then converted to millimeters using the calibration method. The deflection can be observed in Table 19.

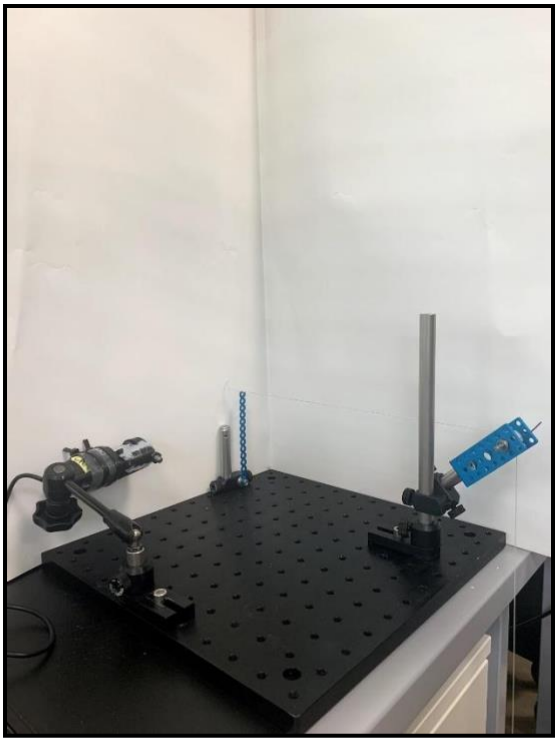


Figure 56: MakeBlock Beam Static Test Setup

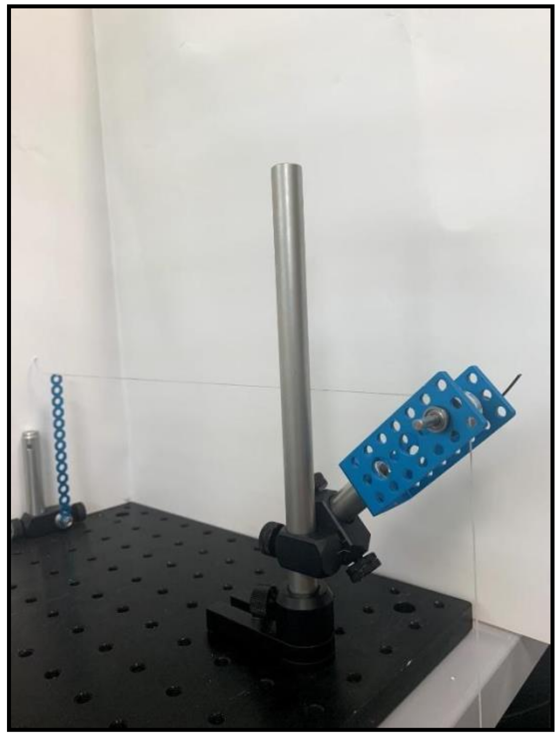


Figure 57: MakeBlock Beam Static Test Setup (Pulley and Beam)

Table 19: Beam Deflection Output

	Weight (g)	Force (N)	Y Pre-Loading (Pixels)	X Post-Loading (Pixels)	Deflection (Pixels)	Deflection (mm)
	29.57	0.29	380	342	38	**0.83**
	58.71	0.58	382	307	75	**1.64**
	88.35	0.87	383	267	116	**2.54**
Trial 1	118.22	1.16	383	224	159	**3.49**
	29.87	0.29	383	346	37	**0.81**
	59.01	0.58	384	307	77	**1.69**
	88.58	0.87	384	274	110	**2.41**
Trial 2	118.23	1.16	383	226	157	**3.44**
	29.55	0.29	385	344	41	**0.9**
	59.42	0.58	385	310	75	**1.64**
	88.81	0.87	385	270	115	**2.52**
Trial 3	118.27	1.16	385	236	149	**3.27**

In order to validate the accuracy of this system, finite element analysis was performed on the MakeBlock beam in question. The team created the geometry of the beam in SolidWorks, including material, and set the simulation up to represent the experiment. The beam was fixed at the far bottom hole and the force was applied to the very top hole, which was the location in which the string was tied. The actual beam can be observed in Figure 58, and the 3D model created by the team can be observed in Figure 59.

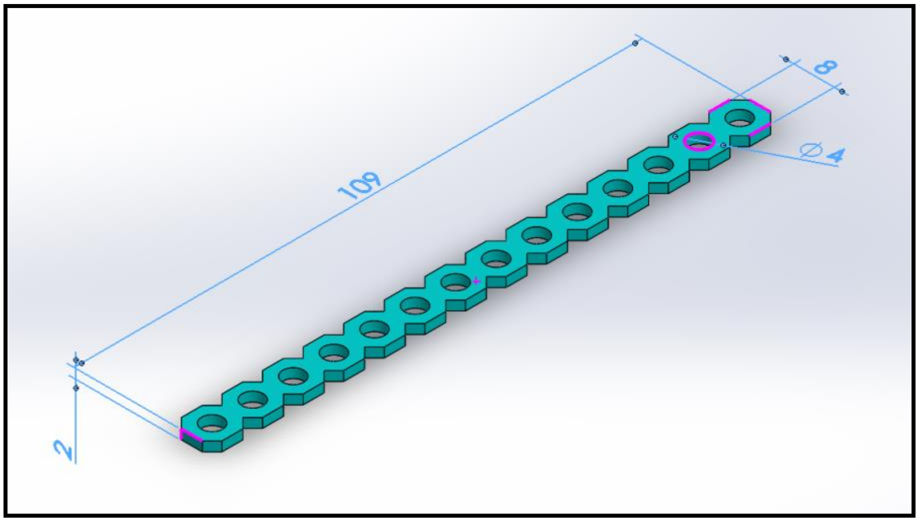


Figure 59: SolidWorks Model of MakeBlock Beam

Figure 58: MakeBlock Beam Fixed

When selecting the mesh size for the simulation, the team analyzed mesh values ranging from 2.0 millimeter to 0.3 millimeter, with 0.3 millimeter being the finest quality. In Figure 61, it can be observed that the mesh begins to converge to more precise values. With this observation, the team decided to utilize 0.5 millimeters as a mesh value. This would ensure that throughout trials, the data received from the simulation would remain precise, as any mesh value below 0.5 millimeters produces very similar data outputs. Figure 60 demonstrates the mesh convergence to the value of 0.5 millimeters.

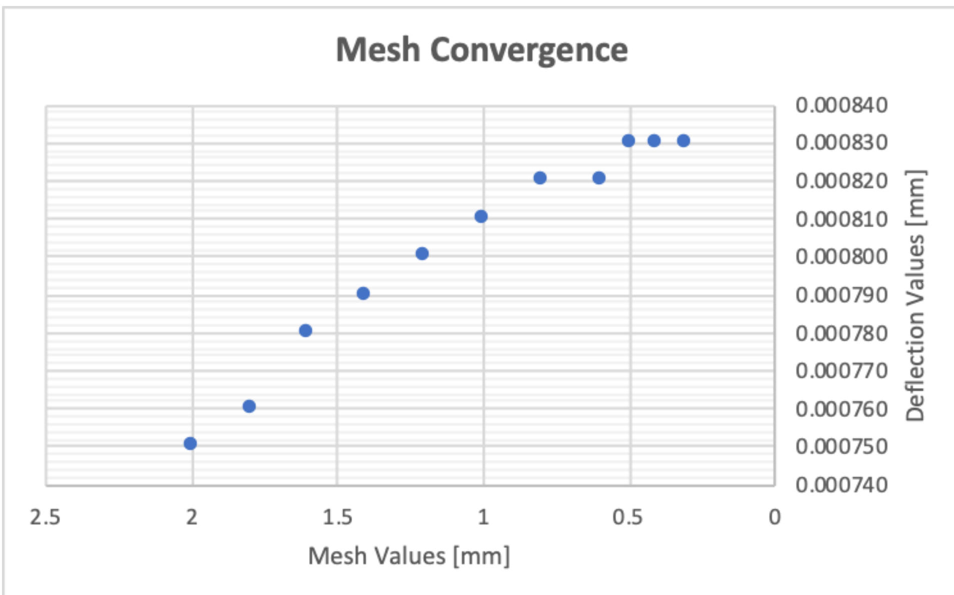


Figure 60: Mesh Convergence

Using the mesh value of 0.5 millimeters, the team ran finite element analysis on the MakeBlock beam for numerous iterations of force. The simulation set up can be observed in Figure 61 and the comparison of results can be observed in Table 20.

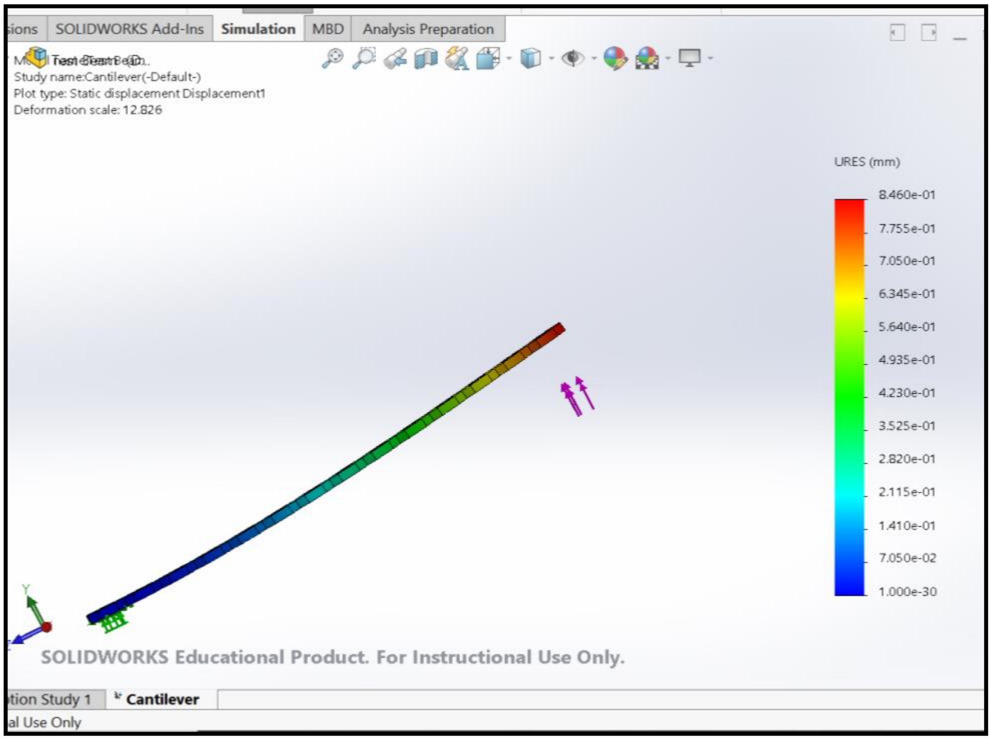


Figure 61: MakeBlock Beam Finite Element Analysis

Table 20: Deflection of Beam Comparison Simulation and Experimental

	Weight (g)	Force (N)	X Pre-Loading (Pixels)	X Post-Loading (Pixels)	Deflection (Pixels)	Deflection (mm)	SolidWorks Simulation Deflection (mm)	Percent Error (%)
	29.57	0.29	380	342	38	**0.83**	**0.83**	0.00
	58.71	0.58	382	307	75	**1.64**	**1.64**	0.00
	88.35	0.87	383	267	116	**2.54**	**2.54**	0.22
Trial 1	118.22	1.16	383	224	159	**3.49**	**3.38**	3.11
	29.87	0.29	383	346	37	**0.81**	**0.83**	2.41
	59.01	0.58	384	307	77	**1.69**	**1.64**	3.05
	88.58	0.87	384	274	110	**2.41**	**2.54**	4.96
Trial 2	118.23	1.16	383	226	157	**3.44**	**3.38**	1.82
	29.55	0.29	385	344	41	**0.85**	**0.83**	2.41
	59.42	0.58	385	310	75	**1.64**	**1.64**	0.00
	88.81	0.87	385	270	115	**2.52**	**2.54**	0.64
Trial 3	118.27	1.16	385	236	149	**3.27**	**3.38**	3.37

As can be observed in Table 20, the percent error between the SolidWorks simulation and the experimental data gathered by the control static testing had the value of 5.73 %. Possible sources of error would include small values of friction occurring because of the low-friction pulley, as well as locating the exact point of measurements in the screenshots analyzed by Microsoft Paint. Due to multiple trials of each force iteration, the team proceeded with this method of static testing and deflection data collection. The team was confident that the testing setup would accurately represent the deflection of the assemblies and their components.

SolidWorks Deflection Simulation

The team used a SolidWorks feature to perform static testing on the designs to further verify the testing results. Due to complex geometries of elements of the team's tests and designs, it was important to verify SolidWorks simulations are an accurate form of data collection as it was efficient to model these geometries in the software. Using a basic beam, the team developed a 3D model and simulated static testing. Modelling the 2-D theoretical evaluation, the beam was fixed at one end, and a force was applied perpendicular to the cross-section at the opposite end of the beam. A mesh value of 0.5 millimeters was used for this simulation. The set up for this simulation can be observed in Figure 62.

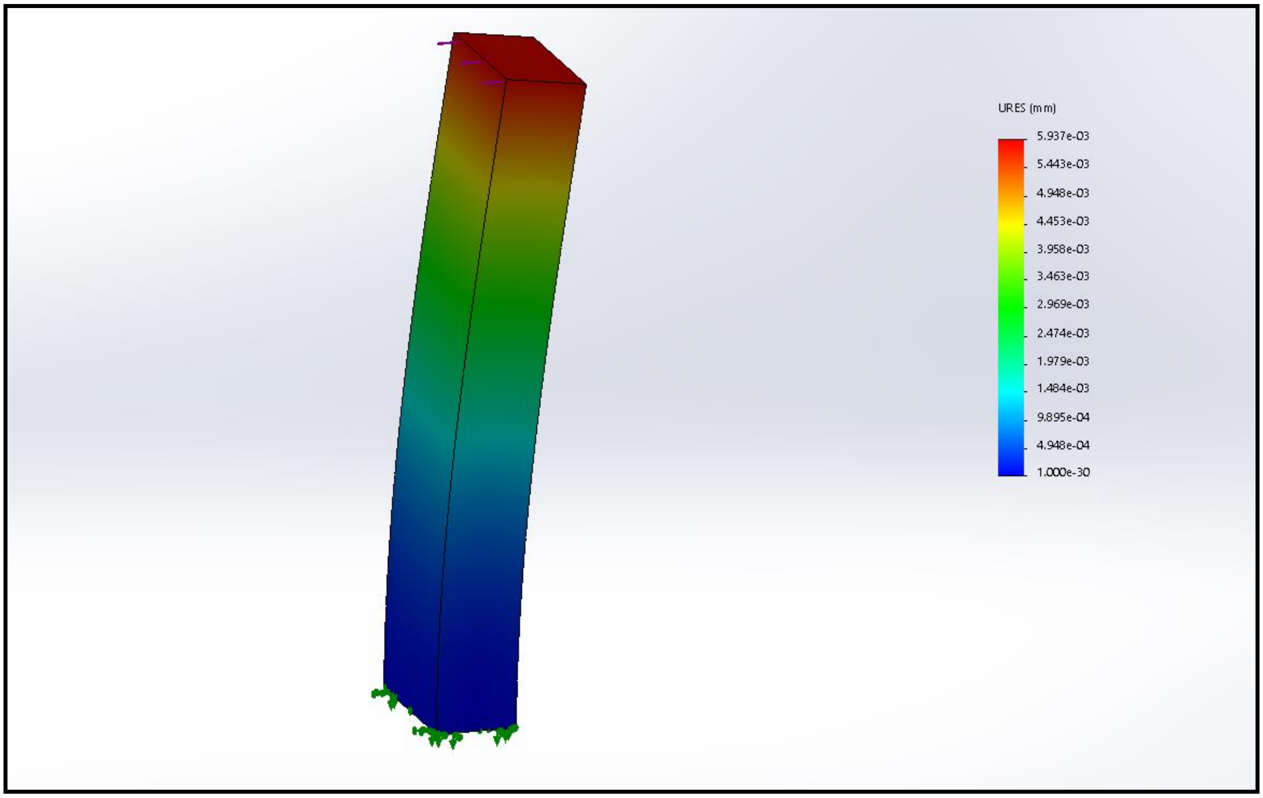


Figure 62: Basic Beam SolidWorks Finite Element Analysis

Table 21 displays the results obtained from finite element analysis in SolidWorks. Figure 62 shows the deformation that SolidWorks simulated in this situation. Next, the team performed theoretical hand calculations to verify this SolidWorks simulation feature's accuracy.

Table 21: Basic Beam SolidWorks Simulation Data

Theoretical Beam	
Force [N]	SolidWorks Simulation Deflection [mm]
1	0.00594
2	0. 01187
3	0.01781
4	0.02395
5	0.0297

Euler Beam Deflection

A Euler cantilever beam model would allow the team to produce accurate hand calculations to compare to the results of the simulation. The Euler-Bernoulli model provides a method to calculate the deflection of a beam fixed at a point that is exposed to a force perpendicular to its cross-section. In this case, the beam was fixed on the face of one end, and the vertical force was applied to the face on the opposite end. This theoretical representation can be observed in Figure 63.

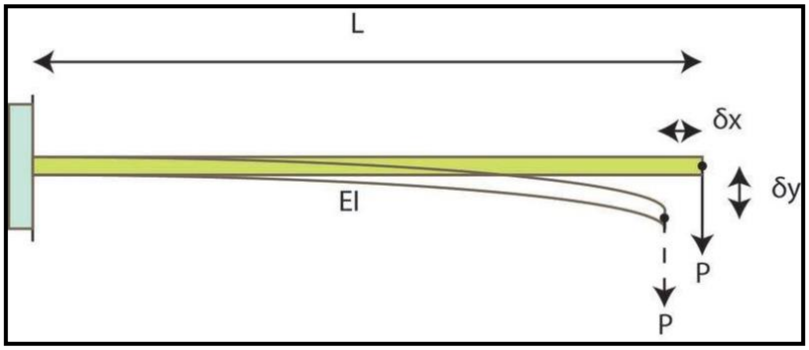


Figure 63: Euler Beam Deflection Diagram [11]

Specific for this application, the applied force is not large enough to produce plastic deformation of the Aluminum material beam. For the team's specific boundary conditions, the equation relating to the deflection of a fixed beam based upon a point force is as follows:

$$\text{Euler Beam Deflection} = \frac{F\,l^3}{3\,E\,I}$$

Using a theoretical beam with the following dimensions and made of Aluminum Alloy 6061, the team was able to follow through with calculations to determine the moment of inertia, and theoretical deflection for an applied vertical force. Table2 was generated to compare the deflection values from this theoretical model to the SolidWorks simulation model to ensure accuracy.

Length = 20 mm [0.02 m]
Thickness = 2.5 mm [0.0025 m]
Width = 5 mm [0.005 m]
Modulus of Elasticity = 68.9 GPa

Area Moment of Inertia = $(1/12)\,wt^3$
Area Moment of Inertia = $6.51 * 10^{-12}$

Table 22: Basic Beam Data Comparison

Basic Beam				
Force [N]	Theoretical Deflection [mm]	SolidWorks Simulation Deflection [mm]	Mesh Value [mm]	Percent Error (%)
1	0.00594	0.00592	0.5	0.34
2	0.01188	0.01183	0.5	0.42
3	0.01782	0.01775	0.5	0.39
4	0.02376	0.023661	0.5	0.42
5	0.0297	0.02958	0.5	0.41

Due to the extremely low value of percent error in the comparison between hand calculations and SolidWorks simulation, the team determined that SolidWorks is a viable software to use to verify the static testing setup. As mentioned previously, verifying the accuracy of the SolidWorks software allows the team to model complex geometries. With the low percent error, the team confidently moved to the next step of testing: testing of the prototypes.

5.3 Prototyped Design Testing

To verify that the designs the team prototyped would be able to withstand the 4.57 Newton force that was measured as the maximum value during the drill force testing, the team performed static testing on each design along with individual components from the designs.

The static test system was verified to produce accurate results in the control stage, so the team proceeded using the same setup. The static tests each measured increasing increments of Newtons ranging from 1 to 10 being loaded onto the part. This was done because only 3 researchers were recorded during the drill force testing, meaning there is a possibility that other researchers could surpass the maximum measured value.

The team decided to perform testing on the individual components of the 2 designs, then perform testing on the full assemblies. All static tests of individual components had loads applied that would replicate the vertical drilling force applied by the researchers. For the full designs, the force was applied at a 45-degree angle, replicating a worst-case scenario the replicated drilling force was created for each test using either one or 2 low-friction pulleys.

Using the same optical camera that was used during the control static test, the team carried out the calibration process and displayed the images of the initial and displaced parts on a laptop. The displacement values taken from the end of the temporal bone or component were then able to be converted from the number of pixels to millimeters. Given this conversion, it could be determined whether the design was able to meet the maximum of 1 millimeter of displacement when the researchers were drilling on the temporal bone.

5.3.1 Individual Component Static Testing

To begin static testing, the team performed finite element analysis on various components of each design. This was necessary because it gave the team insight into the possible sources of major deflection, other than the assembly. If one component had significantly larger deflection than the other, the team knew that an adaptation needed to be made. For individual components, common ThorLabs optical posts were used to raise and fixture the parts being tested. To ensure that there was minimal error in using these poles, deflection for given forces was calculated for various lengths of the optical posts. This can be seen in Table 23.

Table 23: ThorLabs Optical Post Deflection Validation

Theoretical Deflection for Given Lengths					
Force [N]	0.025 m	0.050 m	0.075 m	0.100 m	0.125 m
1	0.000	0.003	0.011	0.026	0.051
2	0.001	0.007	0.022	0.052	0.102
3	0.001	0.010	0.033	0.079	0.154
4	0.002	0.013	0.044	0.105	0.205
5	0.002	0.016	0.055	0.131	0.256
6	0.002	0.020	0.066	0.157	0.307
7	0.003	0.023	0.077	0.183	0.358
8	0.003	0.026	0.088	0.210	0.409
9	0.004	0.029	0.099	0.236	0.461
10	0.004	0.033	0.111	0.262	0.512

Isolated Clamp Arms

The most important aspect of the clamp design would be the clamping arms that consist of the clamps and the Thorlabs posts that are attached to the back end of the clamps. The test was designed to see the deflection of the clamp design without the ball-in-socket mount or the magnetic base. In order to isolate these clamp arms, the team utilized standard ThorLabs parts and the prototyped clamps seen in Chapter 4. To begin the setup, the 75-millimeter ThorLabs posts were screwed into the breadboard using an M6 screw, fixing it in place. Right-angle post clamps were used to attach the clamp prototypes to the vertical posts. The vertical posts and post clamps are assumed to be part of the testing, as these are the same materials the team used in the full prototype. Next, the artificial temporal bone was clamped by the holder.

Once clamped in place, running the static test on this design required 2 low-friction pulleys. The force was applied using a force-spring scale and string that was attached to the artificial temporal bone in the area where the researchers would be drilling into their samples. The string was attached to an M6 screw that was drilled through the area of interest. The force-spring scale was pulled at the opposite end of the string by a team member until desired iterations of various forces were read. To try and minimize deflection caused by the artificial temporal bone sliding from the clamps, the string pulled the sample in the vertical direction. Later, when the full assemblies were tested, the team pulled the string from a 45-degree angle to test for the worst-case scenarios.

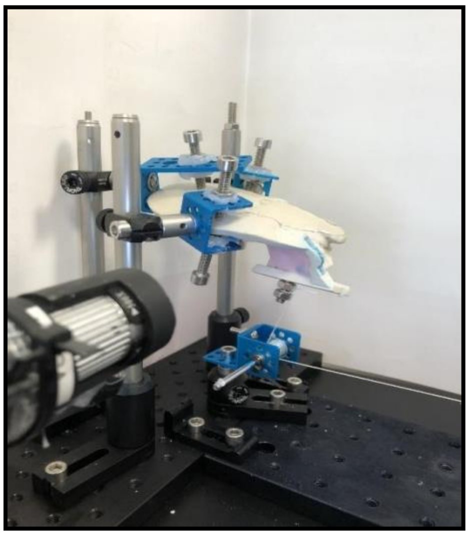


Figure 65: Isolated Clamp Static Testing

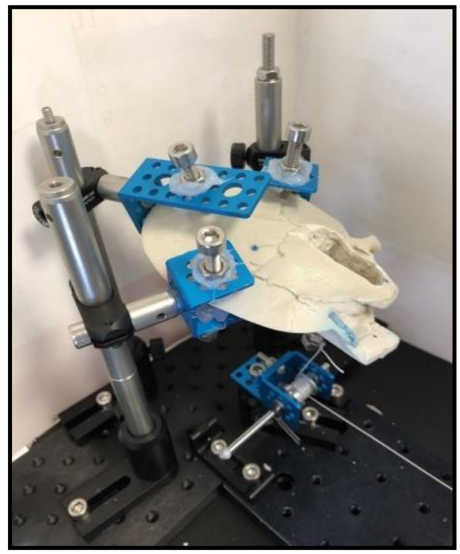


Figure 64: Isolated Clamp Static Testing (2)

Table 24: Calibration Data (Isolated Clamps)

	Position	X	Y
Calibration	**Initial**	302	386
	1 mm Distance	301	413
	Pixels Per Millimeter	27.02	

Table 24 shows the data from the initial calibration that was used in converting pixels to millimeters. This calibration was used throughout all 3 trials because the camera was not moved, and the measurements were taken from the same distance away from the camera.

3 trials were completed on these components. At 5 Newtons, which is just slightly higher than the maximum force measured during the drill force testing, the maximum displacement was 0.96 millimeters between the 3 trials. This was a successful rigidness for the bio-sample holder

given the maximum allowance of 1 millimeter when drilling. This would allow the researcher to exceed the maximum value of vertical force with minimal deflection of the bone. The rest of the measurements taken during the clamp components' static testing can be seen in Appendix D. The data differed between trials because of inconsistent pulling when applying the force. Another error could have been the sample loosening in the bio-sample holder that caused different deflections for each trial. Lastly, with the possibility of a 5% error calculated in the simulation, the deflection could be 0.96 ± 0.05 millimeters, which could cause it to surpass the 1-millimeter limit.

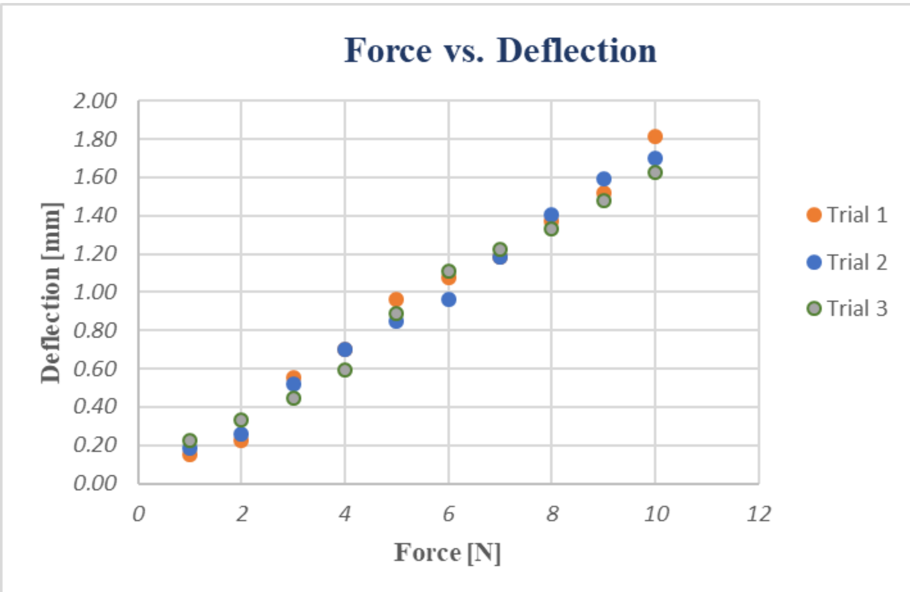


Figure 66: Force vs Deflection (Isolated Clamps)

Drill Bracket Part

The bracket was tested for deflection, as well. The team thought that its thin, aluminum material might not be strong enough to withstand the drilling forces. Testing was performed to see if the bend in the aluminum would cause deflection between the 2 surfaces. To fixture this bracket, a 50-millimeter ThorLabs post was fastened to the bracket using an M6 screw. This pole was fastened to the breadboard using a ThorLabs 12-millimeter Post Holder. Pulling from Table 23, the error value for additional deflection per Newton is between 0.00 and 0.003 millimeters. Only one pulley was used for this test. The string that applies the force was tied around the center of the 2 points that fix the bracket to the bone. The force was once again applied by having a team member pull the force-spring scale to the predefined force values. This setup can be seen in Figure 67 and 68.

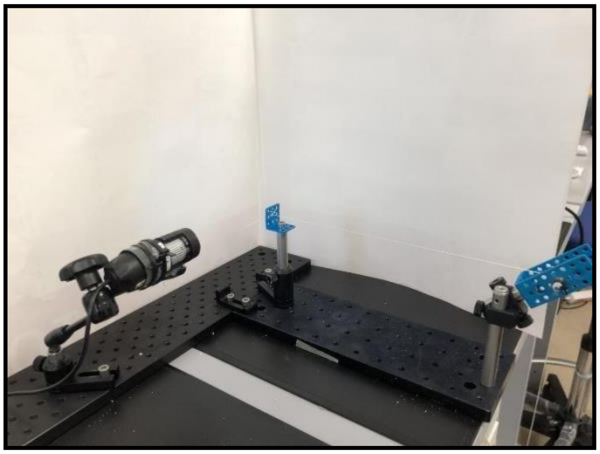


Figure 68: Bracket Static Testing Setup

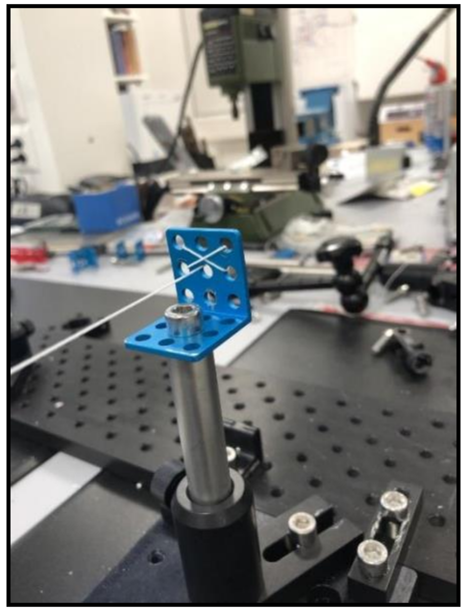


Figure 67: Bracket Static Testing Setup (2)

Table 25: Calibration Data (Bracket)

	Position	**X**	**Y**
Calibration	**Initial**	387	321
	5 mm Distance	393	142
	Pixels Per Millimeter	35.82	

The team ran 3 trials on the bracket. Each trial only had five measurements taken this time because of time constraints on testing numerous many parts. The measurements were taken in 2 Newton intervals from 2 to 10 Newtons. Based off the data the team collected, the bracket was very rigid. The team found that the deflection observations between the different forces being applied in each trial were too small for the optical camera to pick up on. Given the calibration data, it was determined that for every pixel that there was a ±0.028-millimeter error during each recorded measurement. With the data staying between approximately 0 and 0.08 millimeters, this error was found to be too high for accurate numerical deflection values during this testing. Even so, because the deflection values were not going to exceed approximately 0.11 millimeters with the maximum error, it could be assumed that the deflection caused by the bracket was minimal and therefore would not be the source of most of the deflection for the drill and fixture assembly. The calibration information can be observed in Table 25, and the tabulated data can be observed in Appendix D. The large percent error in between trials could have been due to misreading the exact position of deflection on the pixel coordinate system or not pulling with the same force between each trail.

Figure 69: Force vs Deflection (Bracket)

Artificial Temporal Bone

The artificial temporal bone was made of a softer material that the metal components, so the team ran experiments on the isolated bone to gather data on how the bone would deflect under specific loads. To set up this static testing, a 75-millimeter Thorlabs post was screwed into the breadboard, fixing it to the system's base. Pulling from Table 23, the error value for additional deflection per Newton is between 0.00 and 0.003 millimeters. There was a predrilled hole in this artificial temporal bone, which was used to thread an M6 screw through that was fastened to the ThorLabs post. Since the hole was drilled in the same location as the drill and fixture design, the team decided it would provide an accurate representation of the deflection that should be expected when testing a full assembly. The bone was suspended parallel to the base of the system and required 2 pulleys to replicate the vertical drilling force that would be applied on it. Only the vertical force was used during this test, because the team believed that the flexibility of the artificial bone would be more apparent while being pulled in this direction, since the research team expressed that the vertical force was the strongest. The forces were applied using the same setup as the 2 full assemblies, where there was a screw through the main drilling area which the string got tied to. Once again, a team member pulled the force-spring scale to apply different forces to the artificial temporal bone.

Table 26: Calibration Data (PHACON)

	Position	X	Y
Calibration	**Initial**	187	341
	5 mm Distance	335	234
	Pixels Per Millimeter	36.53	

2 trials were recorded, each having ten increments of 1 Newton. At the 5 Newton measurement which is a representation of a likely maximum force, both trials indicated that the bone deflected 0.19 millimeters. Even after 10 Newtons of force was applied, the bone only reached a maximum deflection of 0.36 millimeters. The remaining data for the artificial temporal bone can be seen in Figure 71. The calibration information can be observed in Table 25, and the tabulated data can be observed in Appendix D.

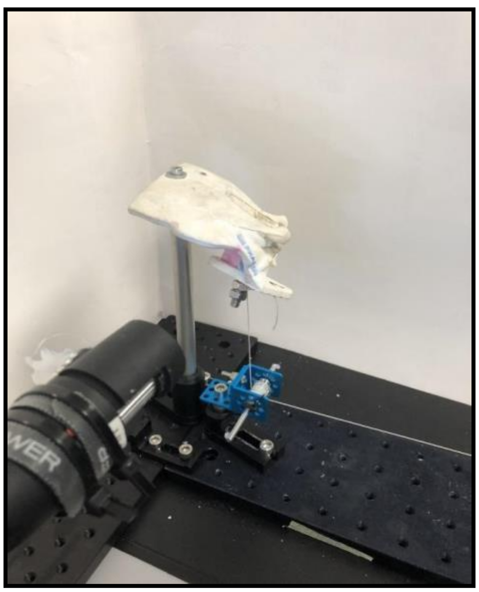


Figure 70: PHACON Static Testing Setup

Figure 71: Force vs Deflection (PHACON)

This data allowed the team to assume that the artificial temporal bone was not the primary cause of the displacement for the drill and fixture design or clamp design, although it could produce a source of error. Additionally, this data allowed the team to recommend additional support to the petrous region of the temporal bone to further stabilize the sample.

Dynamic Arms

The last major component that the team investigated was the dynamic arm. The dynamic arm has numerous joints and fixtures, allowing for areas of potential deflection. This setup went back to measuring the vertical force that replicated the drilling force. Initially, the PS3 dynamic arm was fixed directly to the breadboard using the M6 thread that was already on the bottom of it. The PS3 dynamic arm was then positioned in a 90-degree angle and tightened. This positioning represents the worst-case scenario for loading while the researchers drill. This is because the researchers would not likely drill in a position where the arm is at an angle greater than 90 degrees. They would most commonly want the bone to be low to the table, so the drilling would occur at an angle much less than 90 degrees for most of the time. A 2-pulley system was used, and the string was tied to the free end of the PS3 dynamic arm. The spring-scale was used to apply the force at the opposite end of the string. This setup can be seen in Figure 72.

Table 27: Calibration Data (PS3)

	Position	X	Y
Calibration	**Initial**	280	249
	5 mm Distance	498	226
	Pixels Per Millimeter	43.84	

The PS3 dynamic arm was tested over 2 trials of ten increments each. At 5 Newtons of force, the arm was experiencing a maximum of 0.59 millimeters of displacement and a minimum displacement of 0.48 millimeters. The displacement values kept increasing to just below 2 millimeters by the time 10 Newtons of force was being applied. It is worth noting that the PS3 dynamic arm experienced a drastic deflection of 2.21 millimeters at 8 Newtons of applied force during trial 2. This data point was removed from the plot seen below due to the fact that it was an apparent outlier. This occurred due to the arm slipping out of initial position from excessive applied force. This data led the team to believe that this specific dynamic arm was not a reliable component to be used in the drill and fixture assembly. The full data table from the PS3 dynamic arm static tests can be seen in Appendix D. The calibration information can be observed in Table 27.

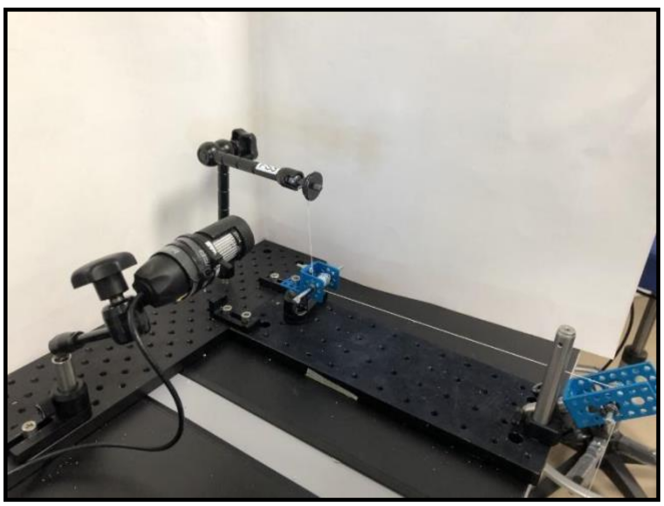


Figure 72: PS3 Dynamic Arm Static Testing

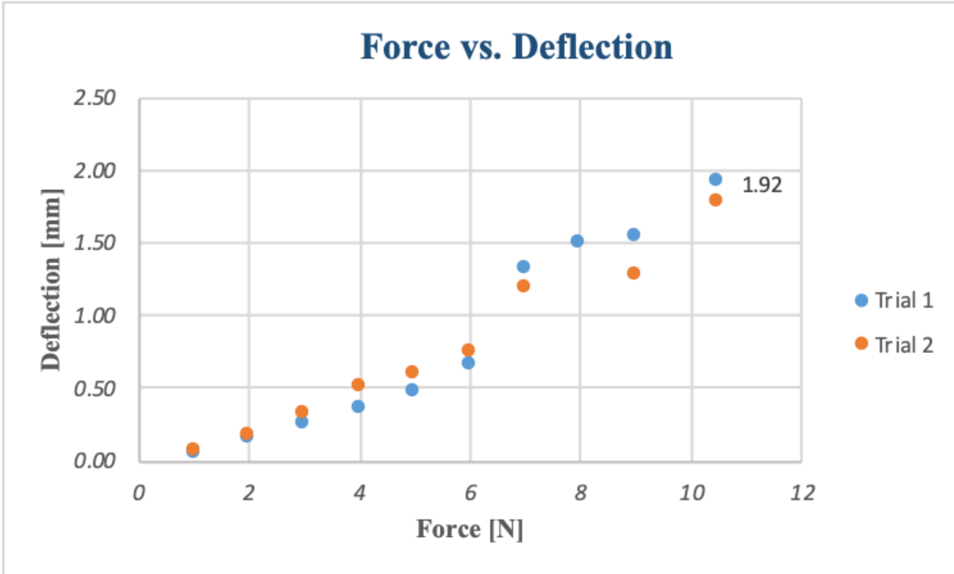


Figure 73: Force vs Deflection (PS3)

Once the team determined that a relatively high value for deflection was caused by the PS3 dynamic arm, it was apparent that a new component needed to be found. After seeing how the moment arm caused the magnetic base to separate with a relatively small force, the team decided that the distance from this joint would be a factor in the overall deflection. As a result, a more compact arm was found and tested.

Table 28: Calibration Data (FISSO)

Calibration	**Position**	X	Y
	Initial	90	305
	5 mm Distance	275	275
	Pixels Per Millimeter	37.48	

The FISSO dynamic arm was readily available in the USZ lab, and it was more compact than the PS3 dynamic arm, so the team ran the same test on it. The arm was once again set to a 90-degree angle to replicate a worst-case scenario and the string where the force is applied was tied to the end. This string was threaded through 2 pulleys, and a team member applied the force at the opposite end using the force-spring scale. The only difference for this test was that the FISSO dynamic arm was screwed into a 50-millimeter Thorlabs post rather than the breadboard because the arm was shorter and needed space for the first of the 2 pulleys beneath it. Pulling from Table 23 the error value for additional deflection per Newton is between 0.00 and 0.003 millimeters. The FISSO dynamic arm setup can be seen in Figure 74.

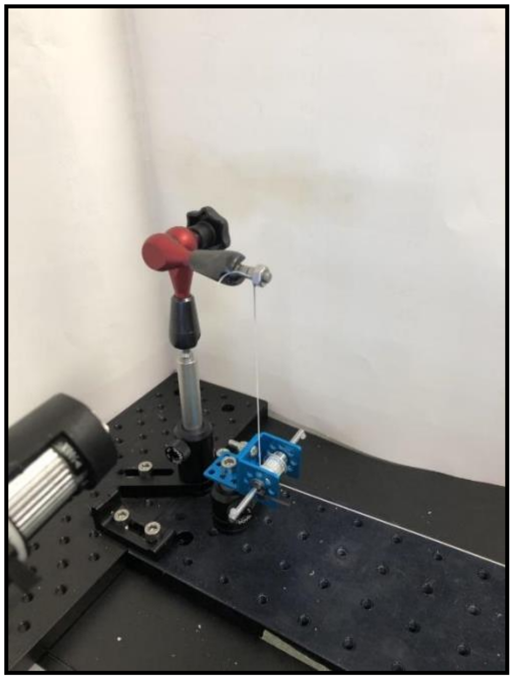


Figure 74: FISSO Dynamic Arm Static Testing

The team repeated the testing procedure that was used during the PS3 dynamic arm testing, completing 2 trials of ten intervals. The FISSO dynamic arm deflection measurements were very small. Similarly, to the drill bracket, the optical camera was unable to accurately measure the deflection because of the pixels having too much error for the small deflection values being recorded. The data being measured was smaller than the tolerance of the experiment. Given the calibration data, every pixel had an error of ±0.027 millimeters. Even with the high errors, it can be assumed that the FISSO arm was well within the deflection restraints set by the team at the USZ. Since the deflection of the FISSO arm was too small to accurately be measured, it could be assumed that its deflection was much smaller than that of the PS3 arm. This difference validated our decision in including the FISSO dynamic arm in a full assembly of the drill and fixture design for testing. The full data table for the FISSO dynamic arm's deflection can be seen in Appendix D. The calibration information can be observed in Table 28. With the deflection measurements being only hundredths of a millimeter for this testing, the changes in deflection using pixels were sometimes hard to pick up on, which resulted in some of the data being horizontal in the plots.

Figure 75: Force vs Deflection (FISSO)

5.3.2 Full Assembly Static Testing

When static testing the full assemblies of the 2 designs, the team wanted to replicate the forces that would be the worst-case scenarios when drilling into the bone. After talking to Dr. Dobrev and the PhD students, the team concluded that the researchers applied more vertical drilling force than horizontal drilling force [11]. The assumption was then made that by setting both the vertical and horizontal forces to the maximum value that the team recorded during the vertical drilling force test, it would give a resultant force that could represent a worst-case drilling scenario. To replicate this force in a static test, a string was attached to the temporal bone's area of interest and stretched at a 45-degree angle around a pulley, which then continued as all the other static tests had. The force that was needed to be applied to the pulley system was calculated using the Pythagorean theorem. The team used 7 different force measurements setting both the horizontal and vertical forces to 1 Newton through 7 Newtons, so that they would have the same magnitude in both directions. When calculating the resultant forces, this gave us 7 force values ranging from 1.4 Newtons to 9.9 Newtons. The team ran 3 trials each at three different orientations for each design. Each orientation was rotated 90 degrees clockwise from the initial position. The 180-degree position could not be done due to interference from the bio-sample holders in both designs. The test setups and data for each design are shown below.

After the team ran testing on the full assemblies, the data was analyzed and used to draw conclusions regarding which design would be best for the team at the USZ. The data demonstrated whether the designs met the requirements set for both deflection and drift. For a successful bio-sample holder, the displacement would be as small as possible and less than 1 mm, and the drift would be as close to zero as possible. From this, the team was able to see different applications that would be most advantageous for each design. For example, a design that had a smaller deflection, but a higher drift would be more useful for drilling than a design that had more deflection, but less drift.

Clamp Design

Using a 2-pulley system again, the team tested the prototyped clamp design. This was completed to measure the deflection of the temporal bone when a force was applied, as well as the drift in position. The drift measures the distance that the initial position varies between each trial. It shows whether the assembly is elastic and will return to the initial position after a load is applied. Identical to the previous iteration of testing, 3 different orientations were tested to attempt to more closely replicate the force of drilling. The test set up was identical to the drill and fixture static test; a string attached to the temporal bone is threaded through one pulley at a 45-degree angle and then threaded through another pulley at a 90-degree angle. 7 measurements

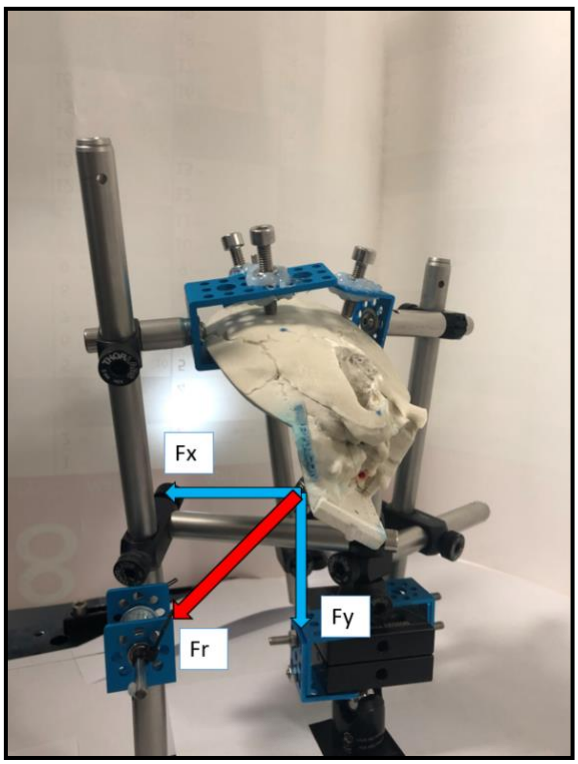


Figure 77: Clamp Assembly Static Testing (Force Vectors)

Figure 76: Clamp Assembly Static Testing

were taken at 7 different forces attached to the opposite end of the string. The test setup can be observed in Figure 77 and 78.

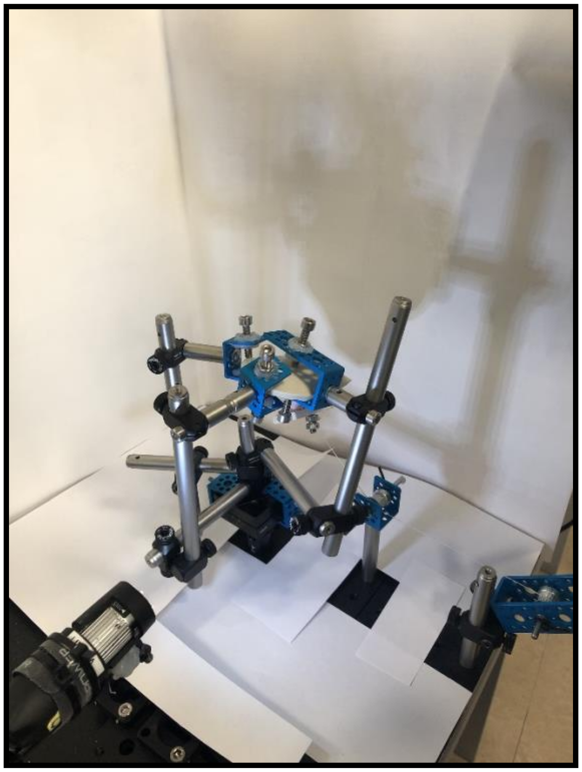


Figure 79: Clamp Assembly (Back View)

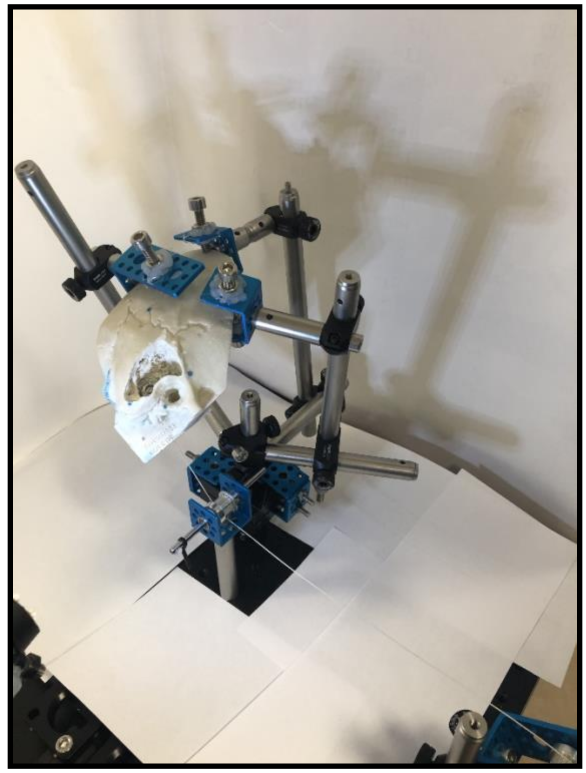


Figure 78: Clamp Assembly (Side View)

Once the setup was complete, the optical camera was calibrated for the conversion from pixels to millimeters. This was done using the target and calibration method previously mentioned in this chapter. The initial and loaded positions were considered by tracking one point on in the camera's focus on the temporal bone. Initial positions for every iteration were measured to evaluate the drift after every loading.

Figure 79 shows that when the force was being applied from the front position at 0 degrees, it was at 0.68 millimeters of deflection during the 7.1 Newtons force being applied. Once again, the 7.1 Newtons be the likely worst-case scenario when drilling is occurring. When the orientation was at 90 degrees, so that the force was being applied to the side of the clamp bio-sample holder, the deflection was 0.18 millimeters at 7.1 Newtons. At the 270-degree orientation, the deflection was 0.38 millimeters when 7.1 Newtons of force were applied. All three orientations had deflections well under the 1-millimeter restriction. The drift for the 2 side positions were relatively low with a maximum of 0.11 millimeters at 7.1 Newtons of force. At the same force for the front position, the drift measured 0.14 millimeters.

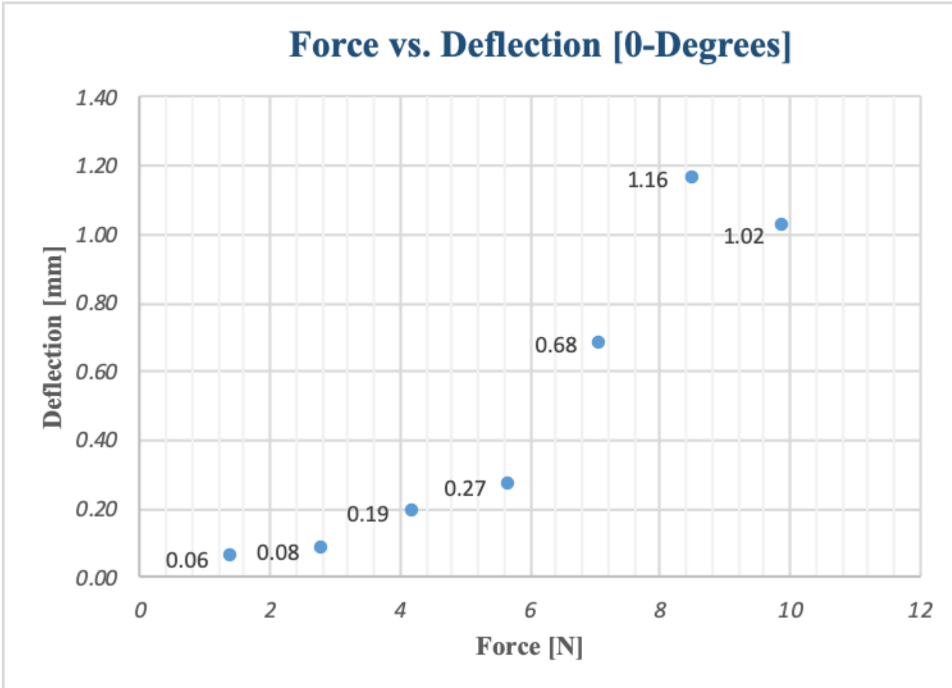


Figure 80: Force vs Deflection (0-Degrees)

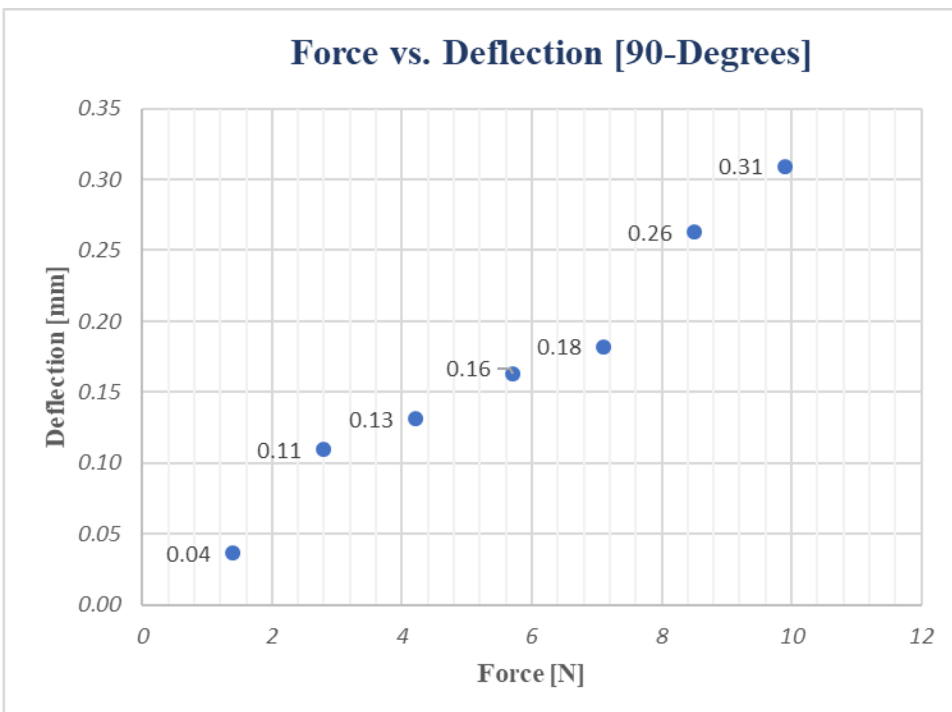


Figure 81: Force vs Deflection (90 Degrees)

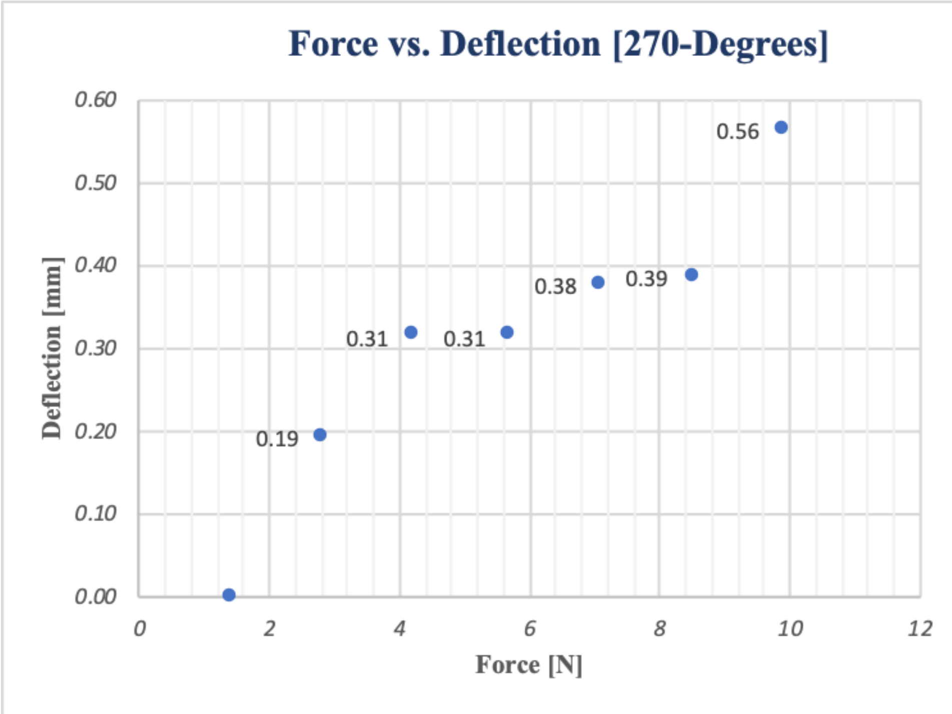


Figure 82: Force vs Deflection (270 Degrees)

Clamp Assembly Analysis

During the clamp assembly testing, all 3 of the orientations gave results with low deflection. The maximum deflection amongst the 3 trials at 7.1 Newtons was 0.68 millimeters, which makes all 3 positions ideal in terms of deflection for drilling. When looking at the drift, the 90 degree and the 270-degree positions were able to keep their final positions within 0.11 millimeters from their initial positions at 7.1 Newtons. The 0-degree position had a drift of 0.14 millimeters at 7.1 Newtons, but after more force was applied, the ball-in-socket joint was unable to hold the combined weight and force being distributed on it. This resulted in a 1.35-millimeter drift at 9.9 Newtons. Overall, the clamp assembly was not as successful at retaining its initial position as the drill and fixture assembly. It did, however, have smaller deflections when forces were applied. Lastly, it was observed during the testing that to fixture the bone in place after the whole assembly is put together took approximately 15 minutes.

Table 29: Clamp Assembly Test results

Orientation Angle	Force Applied	Deflection	Drift
0°	7.1 N	0.68 mm	0.14 mm
90°	7.1 N	0.18 mm	0.00 mm
270°	7.1 N	0.38 mm	0.07 mm

Drill and Fixture Design

The team tested the drill and fixture design by using a 2-pulley system to measure the deflection of the temporal bone. The drift was also measured again, representing the change in initial positions after each force has been applied to the temporal bone. The test consisted of 3 trials, each at a different orientation. The different orientations were tested to account for the various directions by which the researchers might drill from. The team accounted for drilling to come from the front position and both side positions because the drill and fixture design's geometry was not symmetric, so drilling from a different side could have different effects on the deflection of the temporal bone. The dynamic arm was positioned in the ideal position for drilling for accurate deflections on the bone in the position the researchers will likely be using. This position is ideal because it is low to the table, which will allow the researchers to rest their elbows on the table, aiding in keeping a steady hand. When setting up the static testing, the string that ran from the pulley was attached to the bone so that it would pull it at a 45-degree angle. For each trial, 7 measurements were taken at 7 different forces. The forces were applied the same way as all the other static tests with a team member pulling the spring scale to the predetermined force values. This spring scale was tied to the end of the string that was opposite of the temporal bone. This test setup can be seen in Figure 83.

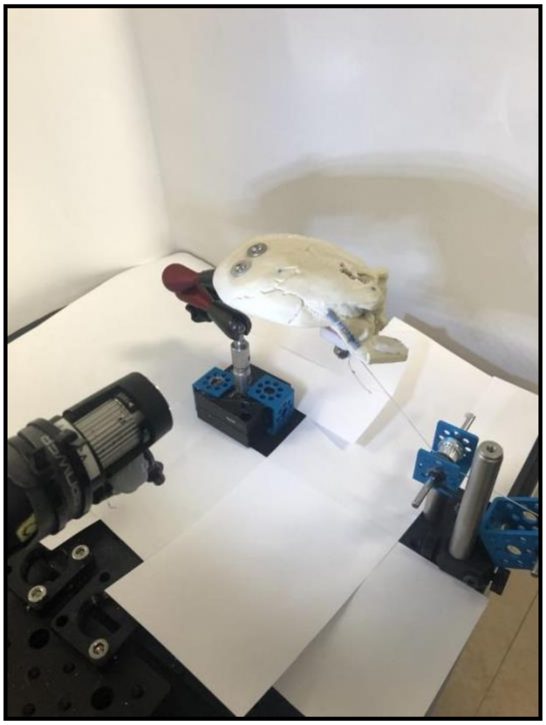


Figure 85: Drill and Fixture (0 Degrees)

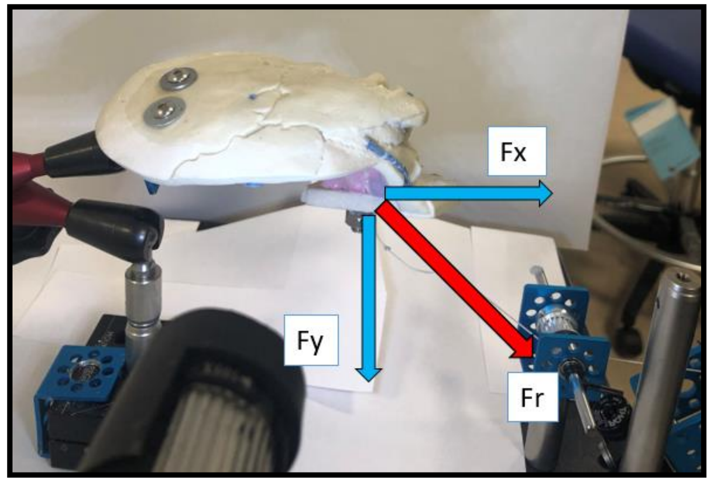


Figure 86: Drill and Fixture Force Vectors

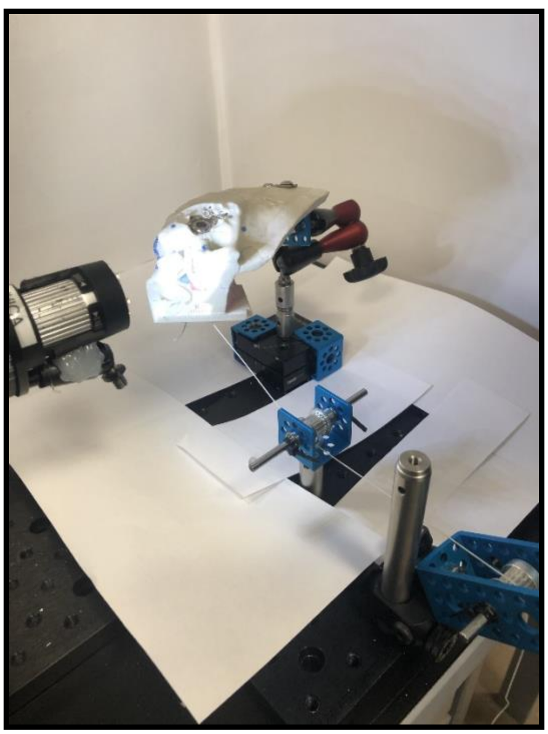


Figure 84: Drill and Fixture (90 Degrees)

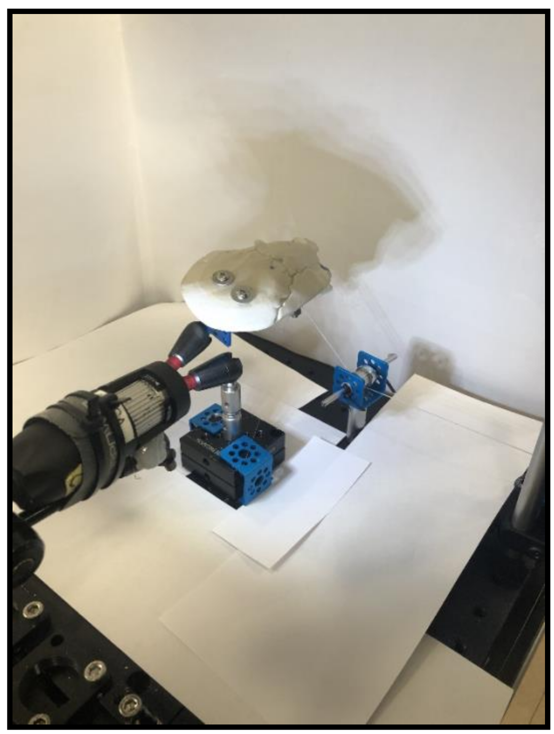


Figure 83: Drill and Fixture (270 Degrees)

Once setup, the 7 different values of forces were applied to the temporal bone and the deflection was observed and recorded for each through the optics camera. To view the deflection, a marked point was chosen on the temporal bone, and followed on the pixel coordinate system that would later have the displacements be converted to millimeters. The initial position of this mark was also measured in between when each force was applied. This allowed for the drift to be found. When switching the orientation, the camera was recalibrated to ensure that the measurements would still be accurate.

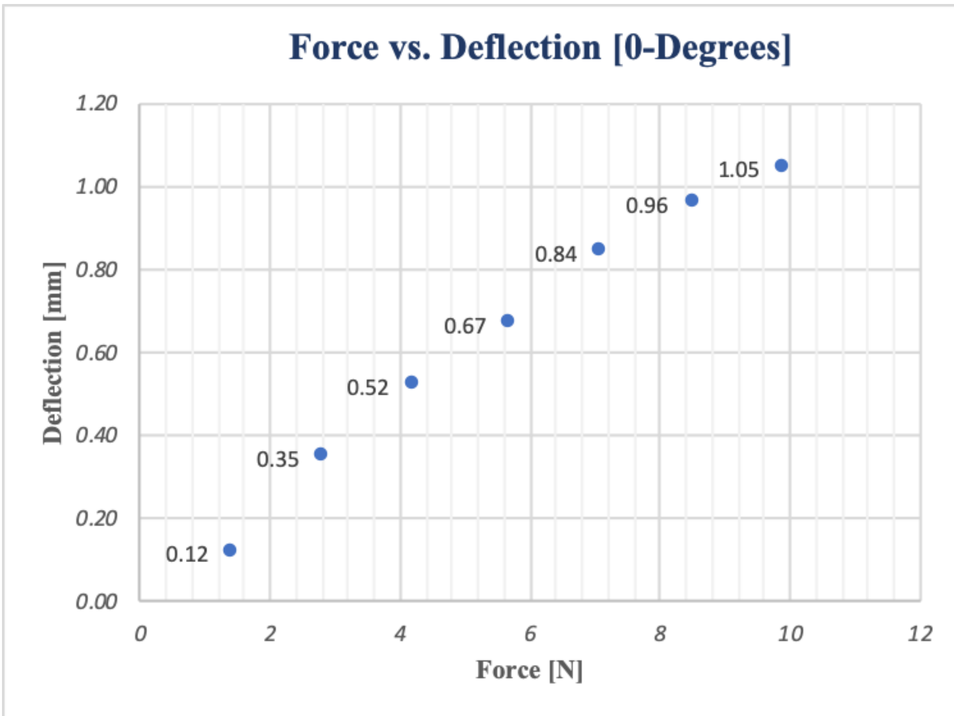


Figure 87: Force vs Deflection (0 Degrees)

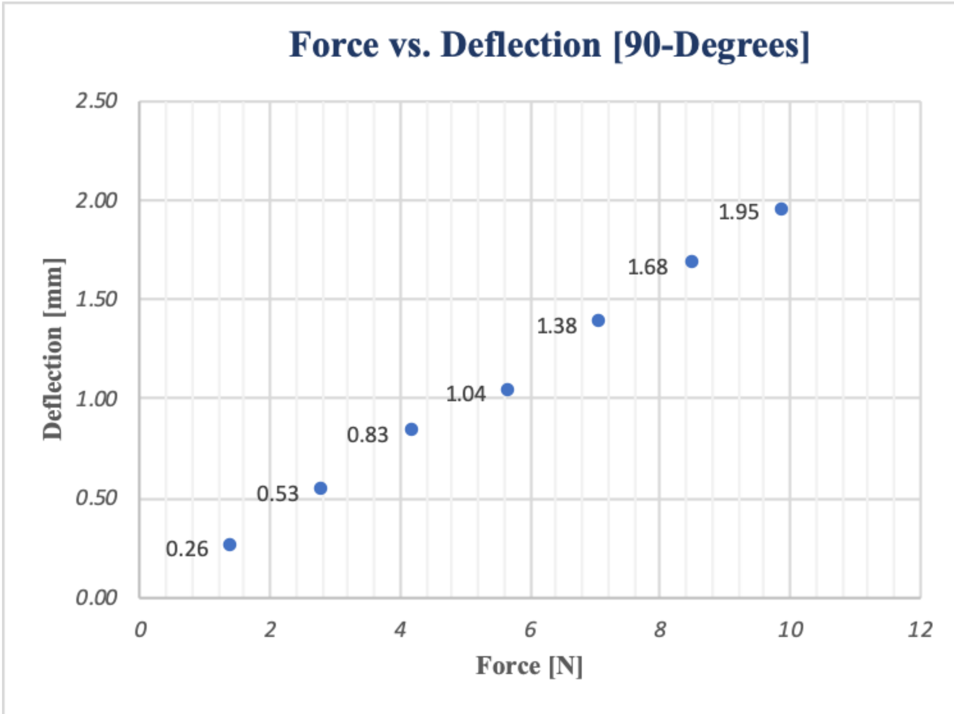


Figure 88: Force vs Deflection (90 Degrees)

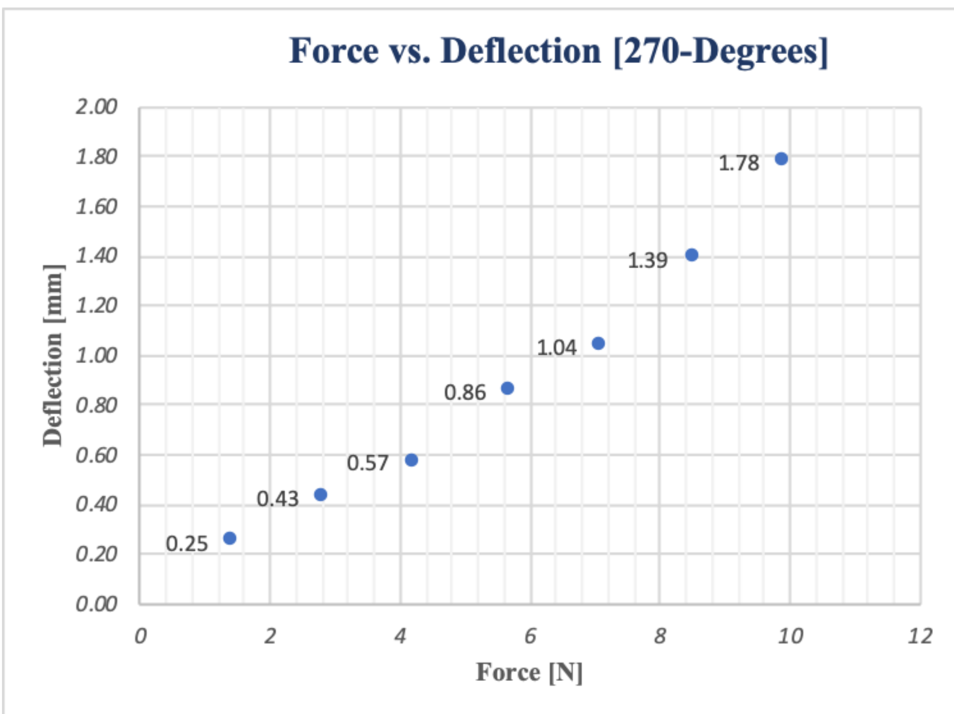


Figure 89: Force vs Deflection (270 Degrees)

When the force was being applied from the front position at 0 degrees, it was at 0.65 millimeters of deflection when 7.1 Newtons of force were being applied. Based off the team's drill force measurements, the 7.1 Newtons be the likely worst-case scenario when drilling is occurring. The 0.84 millimeters of deflection at this force is well under the 1-millimeter restriction. When the orientation was rotated 90 degrees clockwise so that the force was being applied to the side of the drill-in bio-sample holder, the deflection was 1.38 millimeters at 7.1 Newtons. This was the weakest side for the force to be applied from on this design. Lastly, the drill and fixture design got rotated another 180 degrees, so that it was positioned 270 degrees clockwise from the starting position. At 7.1 Newtons of force, this orientation only saw 1.04 millimeters of deflection. The drift throughout all 3 of these trials showed the final position after all the forces had been applied and then removed below 0.1 millimeters from the initial position of the temporal bone marker.

Drill and Fixture Assembly Analysis

During the drill and fixture assembly testing, the 3 orientations where data was collected yielded different results. The orientation position that remained the stiffest was at 0 degrees of rotation. At 7.1 Newtons, which is the force that applies 5 Newtons in both the horizontal and vertical directions, the deflection was only 0.84 millimeters. The force applied at that value is well above the measurements taken during the drill force testing, and the deflection is well below the 1-millimeter goal. The 90-degree orientation had the worst results with the deflection being 1.38 millimeters at 7.1 Newtons. This demonstrates that the 90-degree orientation should be avoided when drilling if this less than 1 millimeter of deflection is critical. The 270-degree orientation was at 1.04 millimeters at 7.1 Newtons, making it an ideal position for drilling. The team also noted the drift for each orientation. All 3 orientations had this value below 0.07 millimeters at 7.1 Newtons, which means they had elastic properties that make the design ideal when going back to the starting position is critical. The time it takes to setup these devices is significant to the researchers and was also noted during the testing that after the assembly was together, it only took 5 minutes to drill through the bone and fixture it to the bracket.

Table 30: Drill and Fixture Test Results

Orientation Angle	Force Applied	Deflection	Drift
0°	7.1 N	0.84 mm	0.06 mm
90°	7.1 N	1.38 mm	0.01 mm
270°	7.1 N	1.04 mm	0.00 mm

5.3.3 Additional Testing

In addition to the static testing and the drill force testing, the team was asked to investigate a problem with the magnetic bases. This had to be tested using a different method than the two previously used.

Magnetic Base

The magnetic base was tested differently than the rest of the parts and assemblies. The downward drilling force would not have any effect on the magnets regarding displacement, so the team decided to test the stability of the magnets using a moment arm. When the magnet bases are in use, it is possible to accidentally disconnect them when a perpendicular force is applied to the bio-sample holder, acting as a moment arm [12]. The setup started with the base magnet being fixed to the breadboard with an M6 screw. The top magnet has a 75-millimeter ThorLabs pole acting as a moment arm fixed using an M6 screw. The ThorLabs pole was approximately the same height as a bio-sample holder would be during drilling, so the team believed it was an accurate representation. The magnets were then connected. The string was tied to the top of the ThorLabs pole to complete the moment arm. The string was drawn out over one pulley and the force was once again applied by the spring scale.

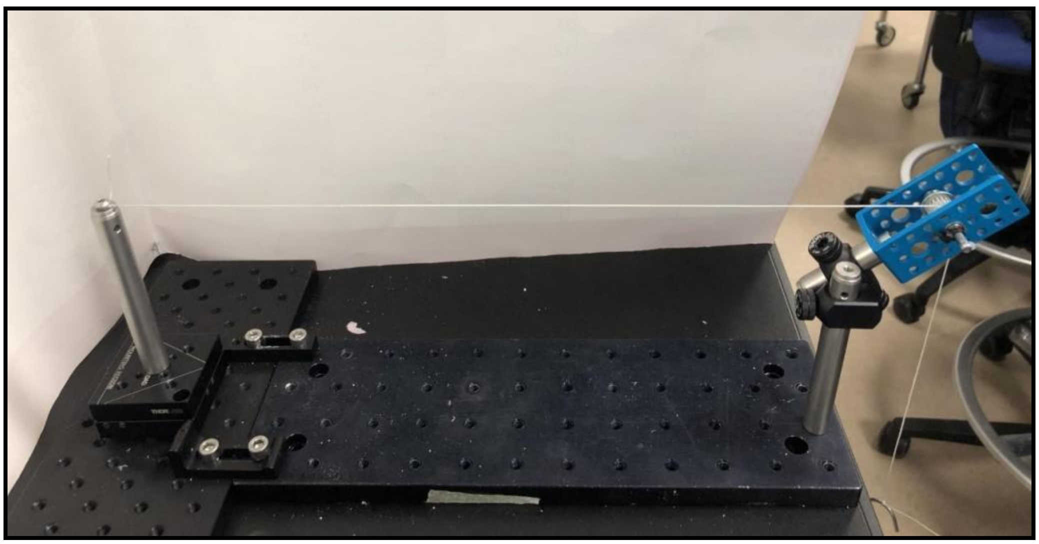


Figure 90: Magnetic Base Static Testing

The team ran 6 trials for the magnets; 3 of the trials were the magnets alone, and 3 of the trials had 2 C-brackets around the outside. The addition of the brackets around the magnetic bases were a potential solution to the issue at hand. The general setup can be seen in Figure 89.

For both setups, the team increased the force until the magnetic bases separated from each other or until they reached 20 Newtons. 20 Newtons was the maximum force that was tested to ensure that the C-brackets would not snap or become plastically deformed. During the trials without the C-brackets, the magnets separated at 8 Newtons twice and 7 Newtons the other time. The C-brackets were then added and during the 3 trials they reached 20 Newtons without coming apart. Given this information, the team determined that adding the C-brackets significantly improved the magnetic base and would be added to the final design. The team also determined that the magnet was not the cause of the displacement of the full drill-in design assembly. The full data table from the testing can be seen in Appendix D.

5.6 Project Impact

Before data was analyzed and a single design was recommended to the USZ, it was important to consider the impacts that these holders would have economically, environmentally, socially, and ethically. While the research being done by the USZ was hearing research at the base, the team believed it was discussing the long-term impacts that these bio-sample holders would have in numerous aspects.

5.6.1 Economic and Environmental

The bio-sample holders for the temporal bone that the team creates will have a small economic impact on the USZ. Otology and Biomechanics of Hearing research team have a set budget for ordering different parts and completing research each year and this project is factored into the amount they are given. There is no environmental concern regarding the bio-sample holder, except for manufacturing. The device being created is made of mostly metal, allowing it to be reused after proper sanitation.

The bio-sample holders created by the team are specific to the research and needs of the USZ team. It is unlikely that these devices would ever be mass produced as a medical device on the European market, but there would be many steps the team at the USZ would go through to finalize that process. Firstly, a manufacturing company would take the responsibility of producing these bio-sample holders. Most countries have different laws regarding custom-made medical devices, meaning a device created in Switzerland may not be able to be sold in other countries unless proper research is completed, and all guidelines are followed [1]. The research that these holders are created for is specific to the temporal bone or samples of similar size. A profit would be possible only if the device came in a variation of sizes, which would require plenty of testing and research to ensure this device can adapt to a multitude of tests [1]. Overall, choosing to mass produce these holders would not be a recommended next step for the USZ, based on the economic impact that it would have on the team's yearly budget. While the devices would be reusable, manufacturing of any kind is known to generate pollution and carbon emissions that harm the environment. It is recommended that the team at the USZ only produces the number of holders that will be necessary in the lab for the research the holders were created for.

A positive social impact would be reducing the time that it takes the researchers to secure their samples in order to perform testing. This device aims to make the research process easier for the Otology and Biomechanics of Hearing PhD students and should help them perform their testing in a safer and quicker process.

5.6.2 Societal and Ethical

Cochlear implants are widely popular as they assist the deaf community with an opportunity to hear. Many deaf people who will benefit from this implant will end up getting the surgery that utilizes this device. However, there is a current controversy within the deaf community who do not support cochlear implants because they are a technological "cure" rather than giving the deaf community a choice. A cochlear implant is not a sudden cure-all for deaf people, but instead it is the start of a long journey to understand how the device works and what it allows each patient to do. Just because a patient has a cochlear implant, does not mean they have perfect hearing or speech, which many people believe takes place as soon as the surgery is complete (22). There is a debate regarding cochlear implants throughout the deaf community, with some arguing that cochlear implants should not be used, others arguing this is child-abuse if a parent does not allow their child the implant. The deaf community wants others to understand that cochlear implants are "not the only way a deaf person can ever be happy with themselves" (21). Overall, there is no one solution that can assist the deaf community, and it is up to that community to choose whether they would like to receive a cochlear implant or not. The research being completed by the Otology and Biomechanics of Hearing research team works to discover more about human hearing and hearing loss, and this information is then utilized by companies who create cochlear implants.

In addition to the societal impact of cochlear implants, the ethical considerations of these implants need to be discussed as well. The ethics around these implants directly correspond to the child being operated on and their consent to do so (18). In most cases, the parents are under the pressure of when to choose the best option for their child. The consent of a child to want these implants is a key ethical debate in the child's right to choose for themselves. Legally and ethically, it is accepted that the parents can provide consent for the child in this medical treatment (18). In many court settings when the situation is life threatening, the court can override the parent's refusal to provide consent. Additionally, when the situation is not life threatening, they are asked to provide consent (18).

Another ethical issue surrounding cochlear implants is if a patient meets or does not meet the criteria for a cochlear implant. Companies have the right to refuse parents that want these implants for their kids that do not meet the audiological and neurological requirements (18). The reason these companies refuse some cases is because there is an increased amount of risk when the implant could be incompatible with the patient. There are many qualifications that must be considered when recommending these implants and companies do not want to run the risk of their product potentially harming the patient. Even when a patient is deemed unfit to undergo surgery and implantation, parents and patients will often fight these companies on their decision and request that the surgery is completed without approval. This push often takes place because to many, a cochlear implant is seen as one of the best chances to help a deaf person reach their full potential of hearing. The ethical issues of consent and cochlear implants are a continued debate within the deaf community and will continue to affect the children and parents who are considering these implants.

Chapter 6: Conclusions

The Design of Cadaveric Temporal Bone Sample Holders for Otological Research MQP created designs and a testing process that aimed to recommend the team at the USZ with a new design for a bio-sample holder that would better aid in their research needs. Previously, the USZ team was utilizing devices that could not withstand the forces applied during proper research, causing skewed data and longer setup times to gather data. The MQP team brainstormed, designed, prototyped, and tested full design options as well as individual components in order to collect data that supports the use of the new bio-sample holders.

The holders created through this project are specific to the research being conducted on the middle ear using cadaver temporal bone. The ideal testing outcomes would prove that the designed holders withstand worst-case scenario force testing with a deflection less than 1 millimeter and drift close to 0 millimeters. Once all tests had been concluded, and the results were analyzed, the final designs were compared based on test performance and satisfaction of design requirements in a Decision Matrix. In addition to design requirements, additional factors, such as the time it takes to fixture the bone to the fully assembled devices, were also considered while completing analysis.

6.1 Decision Matrix

Following the testing period and discussion of project impact, the designs were then compared to each other in order to choose one design that would better fit the needs of the USZ. The final designs that were being analyzed were the C-Clamp Design and Drill and Fixture assembly featuring the FISSO dynamic arm.

Testing results for assemblies and components, as well as project impact and design requirements were considered in evaluating both designs. To evaluate the designs, the team developed a decision matrix that would justify which design would be recommended for future use. The decision matrix took all the design requirements that had initially been chosen, along with 2 requirements that were determined to be necessary during the project and weighted them based on their overall importance. The more important the design requirement was, the higher its weighted value would be. This was determined based on the initial survey results from the PhD students, as well as conversations with the researchers, which was discussed in Chapter 2. For example, holding the sample perfectly rigid had the highest weighted value because it was the most important design requirements for both the researchers and the team. The deflection data gathered for the 2 designs was translated into a value for “Holds Sample Rigid”, so that it could be considered along with all other requirements.

Table 31: Decision Matrix

Decision Matrix					
Design Requirments	**Weight**	**External Clamping Fixture (1-5)**	**Weighted Score**	**Drill and Fixture (1-5)**	**Weighted Score**
Holds Sample Rigid	0.20	4	0.8	4	0.80
Easy to Access Sample	0.16	3	0.48	5	0.80
Allows for Easy Rotation	0.11	2	0.22	5	0.55
Easy to Clean	0.11	3	0.33	4	0.44
Variable	0.11	3	0.33	4	0.44
Reattachable	0.06	4	0.24	4	0.24
Low to Table	0.04	3	0.12	4	0.16
Portable	0.01	2	0.02	4	0.04
Durable	0.01	3	0.03	3	0.03
Additional Requirements					
Set up Time	0.13	2	0.26	4.5	0.59
Relative Size	0.06	2	0.12	4.5	0.27
	Score		2.83		4.09
	Rank	**2nd**	**2.83**	**1st**	**4.09**

Once the testing was complete, the team understood the extent that each of the proposed designs either met or failed to meet each design requirements previously mentioned. The designs were ranked on each design requirement using a scale from 1-5 with 5 being that it meets the requirement without issue. Once the score was determined for each of the designs, it was multiplied by the weight to obtain the weighted value. After all the weighted values were summed for each design requirement, the total summation of all weighted values outputted each of the designs' overall score.

As can be observed in Table 30, the Drill and Fixture design out-scored the Clamp design by a score of 4.09 to 2.83, respectively. It was also the only design that met all the design requirements, as discussed in Chapter 4.2.2. The WPI MQP team recommends that the UniversitätsSpital team continue with the Drill and Fixture design, based on combined testing results and comparison based on the design requirements that the researchers found most important. This design, combined with recommendations in Chapter 7, would be the best option for a bio-sample holder that secures a temporal bone with minimal deflection while meeting design needs.

Chapter 7: Recommendations

To further improve the Drill and Fixture and C-Clamp designs, the team created a list of suggestions that were given to the UniversitätsSpital Zurich research team. By implementing the following recommendations, the 2 designs would prove more beneficial to the researchers and result in smaller deflections.

7.1 Drill and Fixture Recommendations

- Replace the current aluminum bracket with one made of steel, as pictured in Appendix E. This will decrease the deflection from the total design because steel is stiffer than aluminum.
- Machine the template drawn in Appendix F to ensure the drilling locations are consistent each time drilled through the bone.
- Retighten the dynamic arm after each use to ensure minimal deflection.
- For the highest stiffness, drill while the dynamic arm is in a compressed position. An example of this position can be seen in Appendix G.
- Add a support strap that would secure the Petrous region.
- Clean the 2 holes in the temporal bone after drilling to guarantee no interference when threading the nuts on.

7.2 C-Clamp Recommendations

- Order steel clamps specified in Appendix H to ensure a more rigid clamping system. The nVent clamps were the ideal clamping method for this design but were unattainable due to long lead times paired with the project time constraint.
- Utilize mini-series ThorLabs poles and joints, instead of the standard sized parts used in final prototypes. The smaller parts will result in a smaller weight, allowing more force to be applied to the system.

7.3 Recommendations for Both Designs

- Use a breadboard as a mounting surface to attach the magnetic base to. This will establish a secure hold from the base surface.
- Put the 2 C-brackets around the magnetic base for minimal deflection.

- When screwing the bottom half of the magnetic base into the breadboard, put 2 M6 washers underneath it to leave space for the C-brackets that clamp the magnetic base together.

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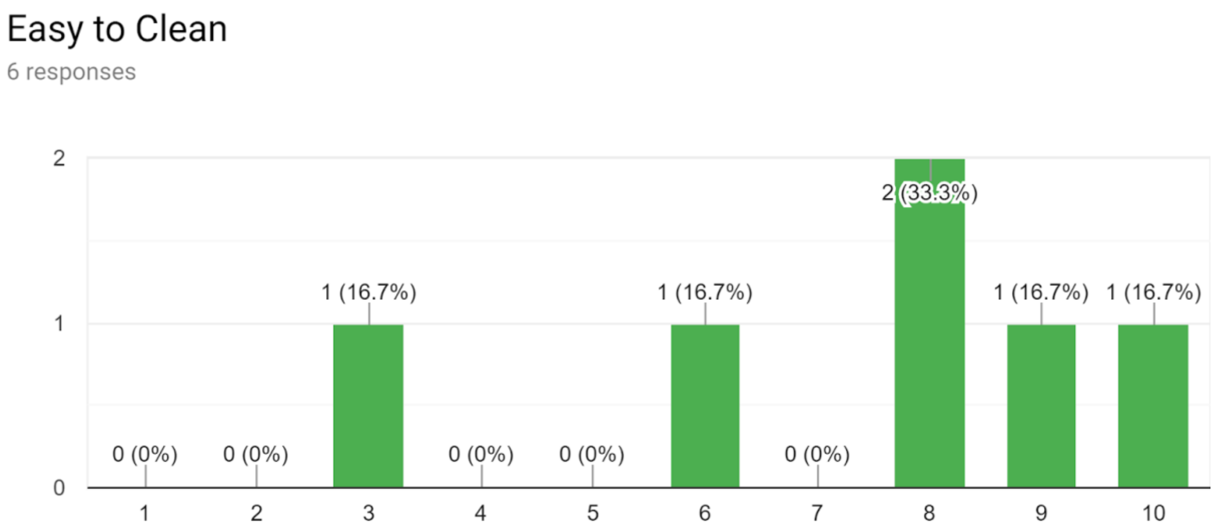
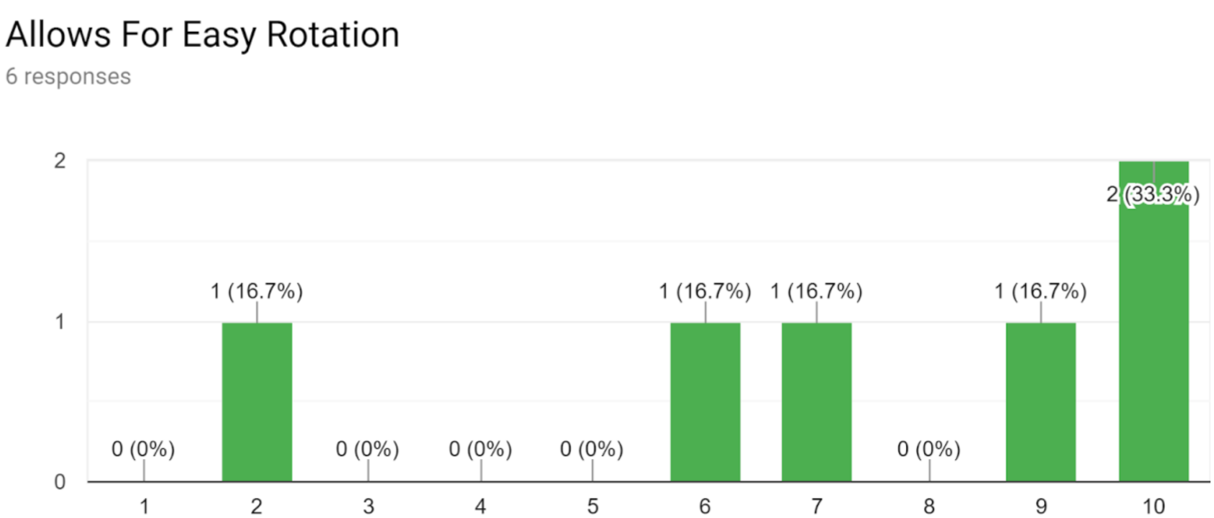
Appendix A: PhD Student Survey Response

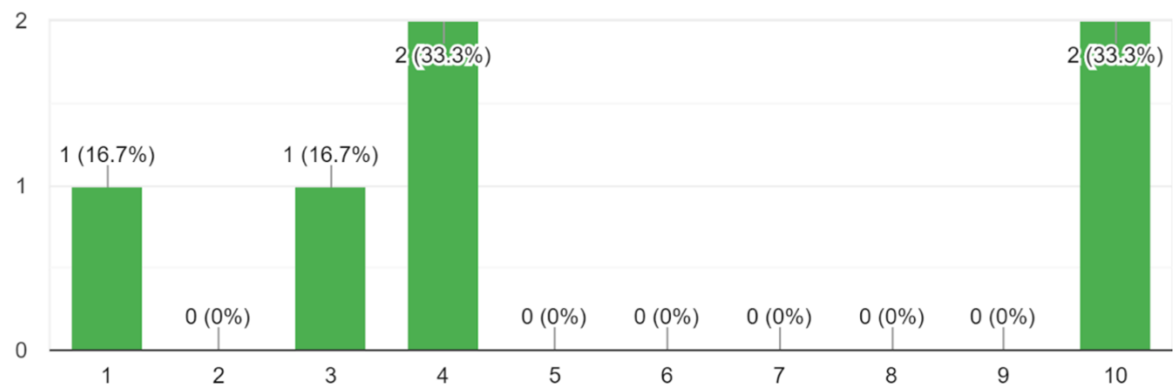
Appendix A includes the raw data results from the survey discussed in Chapter 3.1.3. This survey was used to rank the Design Requirements in terms of importance after the 9 requirements were chosen. 6 Researchers responded to the survey and their results are shown in a bar chart form for a clear comparison of results.





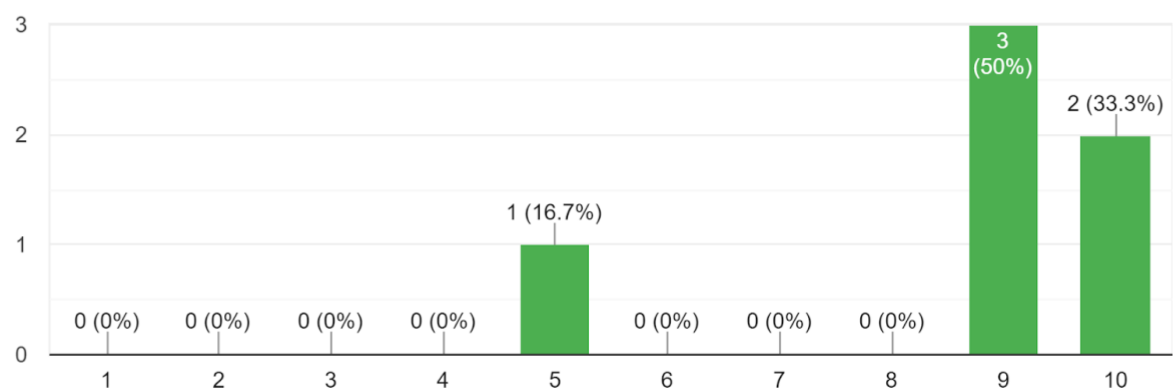
Durable (Can Withstand Drilling Force Without Moving)

6 responses



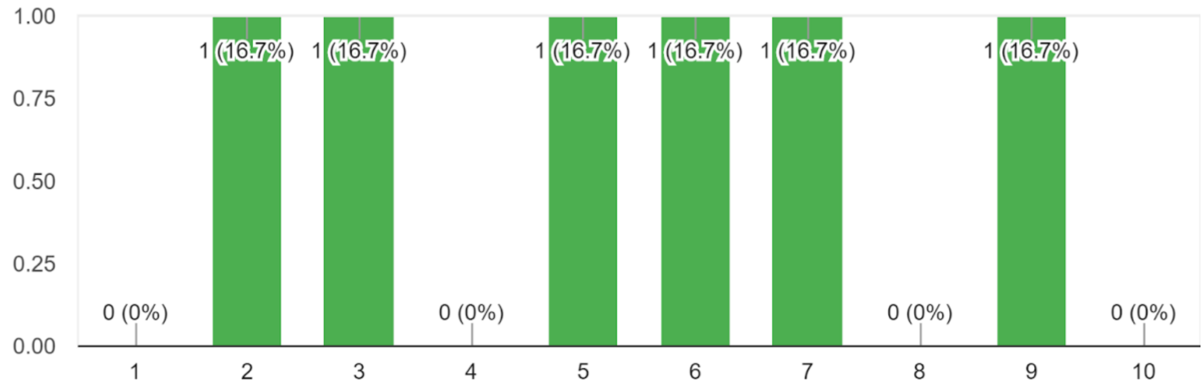
Easy to Access the Sample

6 responses



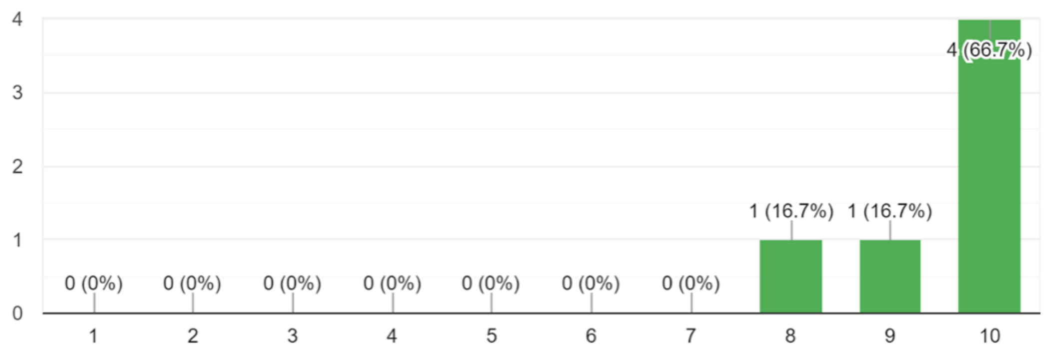
Portable (Easy to Move to Different Stations)

6 responses



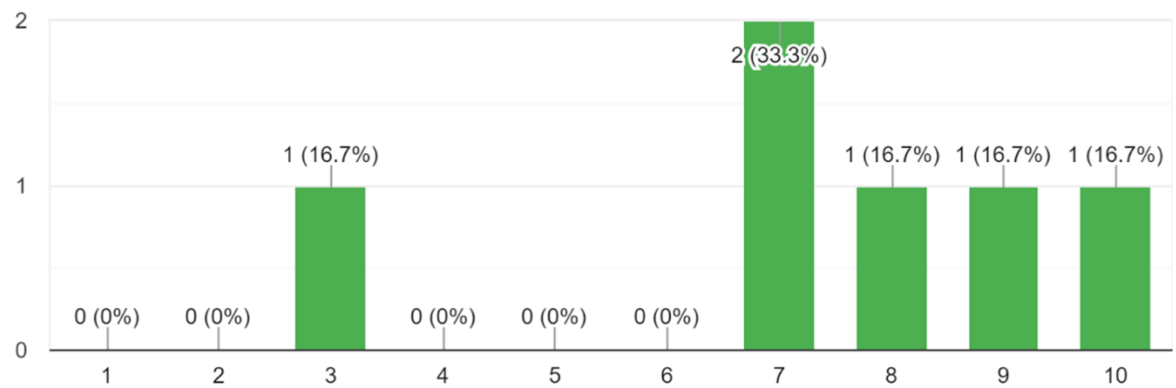
Holds Sample Rigid

6 responses



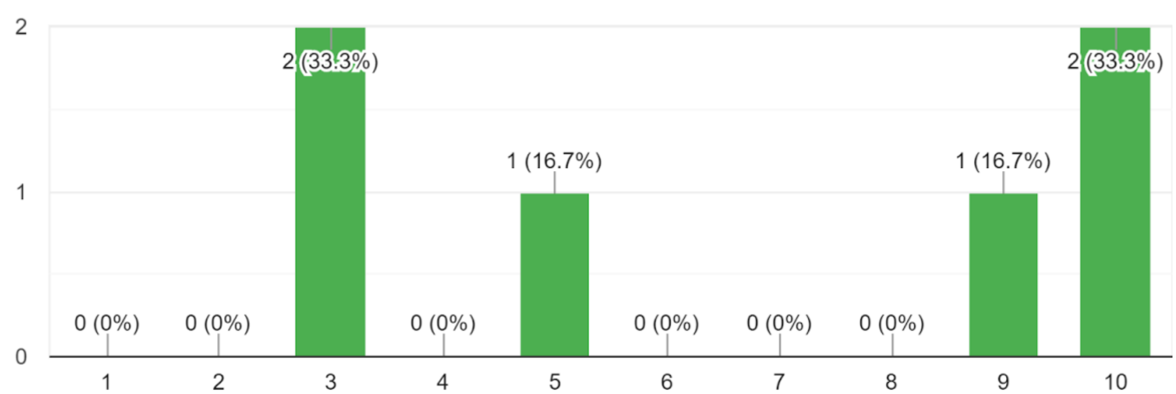
Variable (One Design Will Work for Most Samples)

6 responses



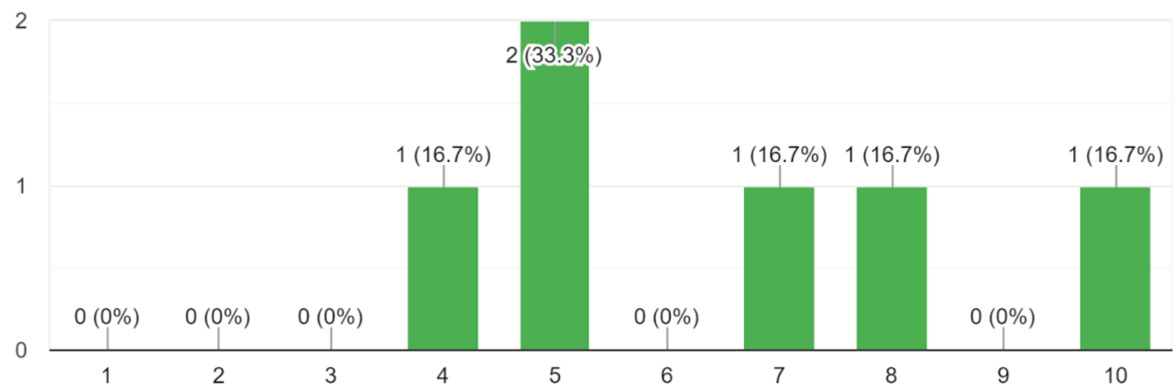
Easily Able to Attach Back to Previous Position

6 responses



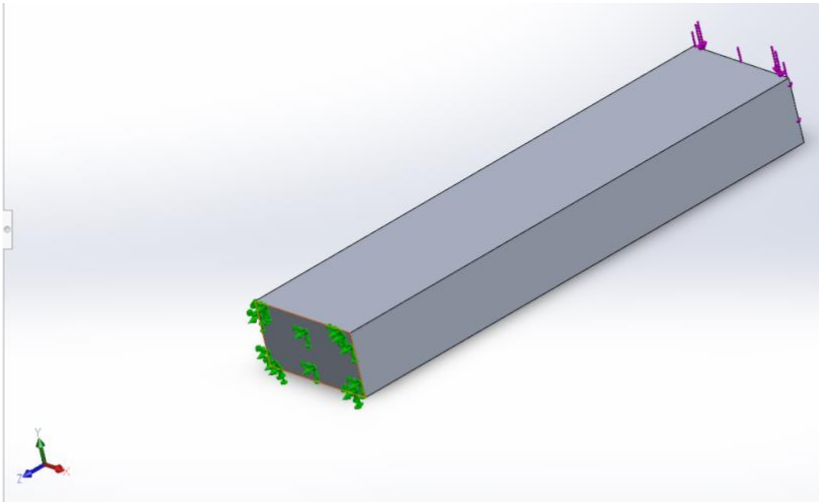
Low to Table (Comfortable to Use)

6 responses



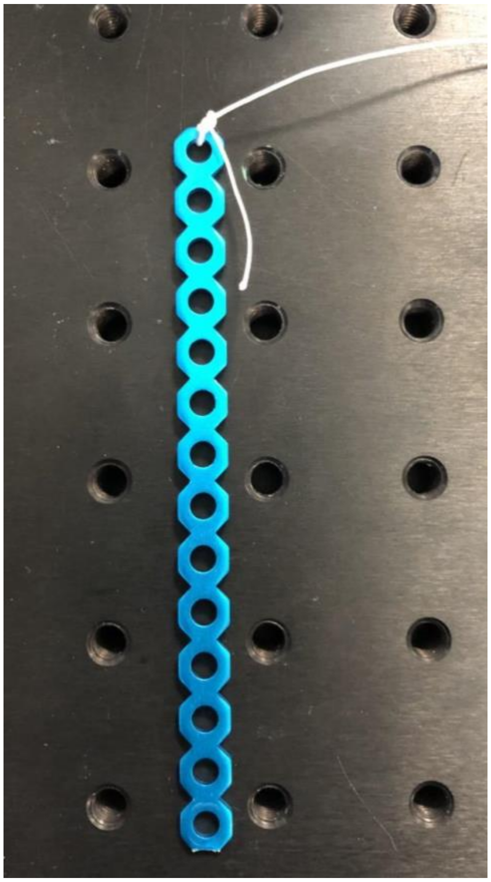
Appendix B: Static Testing

Appendix B shows the fixed location of the theoretical beam (green arrows in SolidWorks) and the location of the force being applied (purple arrows in SolidWorks) for the static testing.



Appendix C: Non-Uniform Beam for Control Tests

This beam was used to validate the static testing system. It was created in SolidWorks, so that a simulation could be run, and the simulation could be compared to the actual testing.



Appendix D: Static Testing Data Tables

Appendix D includes all raw data for the Static Testing. Labeled below, this appendix includes data for isolated clamp arms, the bracket, the artificial bone, the PS3 Arm, and the FISSO arm. Also included is the data for the full designs, the C-Clamp and Drill and Fixture.

Isolated Clamp Arms

Force [N]	Weight [g]	Position	Y [Pixels]	X [Pixels]	Deflection [mm]
1	101.9	Initial	399	244	
		Deflected	395	244	0.15
2	203.9	Initial	399	244	
		Deflected	393	244	0.22
3	305.8	Initial	399	244	
		Deflected	384	244	0.56
4	407.7	Initial	399	244	
		Deflected	380	244	0.70
5	509.7	Initial	399	244	
		Deflected	373	244	0.96
6	611.6	Initial	399	244	
		Deflected	370	244	1.07
7	713.6	Initial	399	244	
		Deflected	367	244	1.18
8	815.5	Initial	399	244	
		Deflected	362	244	1.37
9	917.4	Initial	399	244	
		Deflected	358	244	1.52
10	1019.4	Initial	399	244	
		Deflected	350	244	1.81

Force [N]	Weight [g]	Position	Y [Pixels]	X [Pixels]	Deflection [mm]
1	101.9	Initial	412	258	0.19
		Deflected	407	258	
2	203.9	Initial	412	258	0.26
		Deflected	405	258	
3	305.8	Initial	412	258	0.52
		Deflected	398	258	
4	407.7	Initial	412	258	0.70
		Deflected	393	258	
5	509.7	Initial	412	258	0.85
		Deflected	389	258	
6	611.6	Initial	412	258	0.96
		Deflected	386	258	
7	713.6	Initial	412	258	1.18
		Deflected	380	258	
8	815.5	Initial	412	258	1.41
		Deflected	374	258	
9	917.4	Initial	412	258	1.59
		Deflected	369	258	
10	1019.4	Initial	412	258	1.70
		Deflected	366	258	

Force [N]	Weight [g]	Position	Y [Pixels]	X [Pixels]	Deflection [mm]
1	101.9	Initial	394	253	0.22
		Deflected	388	253	
2	203.9	Initial	394	253	0.33
		Deflected	385	253	
3	305.8	Initial	394	253	0.44
		Deflected	382	253	
4	407.7	Initial	394	253	0.59
		Deflected	378	253	
5	509.7	Initial	394	253	0.89
		Deflected	370	253	
6	611.6	Initial	394	253	1.11
		Deflected	364	253	
7	713.6	Initial	394	253	1.22
		Deflected	361	253	
8	815.5	Initial	394	253	1.33
		Deflected	358	253	
9	917.4	Initial	394	253	1.48
		Deflected	354	253	
10	1019.4	Initial	394	253	1.63
		Deflected	350	253	

Isolated Bracket

Force [N]	**Weight [g]**	**Position**	**Y [Pixels]**	**X [Pixels]**	**Deflection [mm]**
2	203.9	Initial	339	299	
		Deflected	340	299	0.03
4	407.7	Initial	339	299	
		Deflected	341	299	0.06
6	611.6	Initial	339	299	
		Deflected	342	299	0.08
8	815.5	Initial	339	299	
		Deflected	342	299	0.08
10	1019.4	Initial	339	299	
		Deflected	342	299	0.08

Force [N]	**Weight [g]**	**Position**	**Y [Pixels]**	**X [Pixels]**	**Deflection [mm]**
2	203.9	Initial	339	298	0.00
		Deflected	339	298	
4	407.7	Initial	339	298	0.03
		Deflected	340	298	
6	611.6	Initial	339	298	0.03
		Deflected	340	298	
8	815.5	Initial	339	298	0.03
		Deflected	340	298	
10	1070.3	Initial	339	298	0.06
		Deflected	341	298	

Force [N]	**Weight [g]**	**Position**	**Y [Pixels]**	**X [Pixels]**	**Deflection [mm]**
2	203.9	Initial	339	298	0.00
		Deflected	339	298	
4	407.7	Initial	339	298	0.03
		Deflected	340	298	
6	611.6	Initial	339	298	0.03
		Deflected	340	298	
8	815.5	Initial	339	298	0.06
		Deflected	341	298	
10	1070.3	Initial	339	298	0.06
		Deflected	341	298	

Artificial Temporal Bone

Force [N]	Weight [g]	Position	Y [Pixels]	X [Pixels]	Deflection [mm]
1	101.9	Initial	378	233	
		Deflected	377	233	0.03
2	203.9	Initial	378	233	
		Deflected	375	233	0.08
3	305.8	Initial	378	233	
		Deflected	373	233	0.14
4	407.7	Initial	378	233	
		Deflected	372	233	0.16
5	509.7	Initial	378	233	
		Deflected	371	233	0.19
6	611.6	Initial	378	233	
		Deflected	370	233	0.22
7	713.6	Initial	378	233	
		Deflected	370	233	0.22
8	815.5	Initial	378	233	
		Deflected	368	233	0.27
9	917.4	Initial	378	233	
		Deflected	368	233	0.27
10	1019.4	Initial	378	233	
					0.30

Weight [N]	Weight [g]	Position	Y [Pixels]	X [Pixels]	Deflection [mm]
1	101.9	Initial	353	259	0.03
		Deflected	352	259	
2	203.9	Initial	353	259	0.05
		Deflected	351	259	
3	305.8	Initial	353	259	0.11
		Deflected	349	259	
4	407.7	Initial	353	259	0.14
		Deflected	348	259	
5	509.7	Initial	353	259	0.19
		Deflected	346	259	
6	611.6	Initial	353	259	0.22
		Deflected	345	259	
7	713.6	Initial	353	259	0.25
		Deflected	344	259	
8	815.5	Initial	353	259	0.27
		Deflected	343	259	
9	917.4	Initial	353	259	0.30
		Deflected	342	259	
10	1019.4	Initial	353	259	0.36
		Deflected	340	259	

PS3 Dynamic Arm

Force [N]	Weight [g]	Position	Y [Pixels]	X [Pixels]	Deflection [mm]
1	101.9	Initial	424	414	
		Deflected	422	414	0.05
2	203.9	Initial	424	414	
		Deflected	417	414	0.16
3	305.8	Initial	424	414	
		Deflected	413	414	0.25
4	407.7	Initial	424	414	
		Deflected	408	414	0.36
5	509.7	Initial	424	414	
		Deflected	403	414	0.48
6	611.6	Initial	424	414	
		Deflected	395	414	0.66
7	713.6	Initial	420	414	
		Deflected	362	414	1.32
8	815.5	Initial	387	424	
		Deflected	321	454	1.51
9	917.4	Initial	350	430	
		Deflected	283	463	1.53
10	1070.3	Initial	317	437	
					1.92

Force [N]	Weight [g]	Position	Y [Pixels]	X [Pixels]	Deflection [mm]
1	101.9	Initial	522	386	
		Deflected	519	386	0.07
2	203.9	Initial	522	386	
		Deflected	514	386	0.18
3	305.8	Initial	522	386	
		Deflected	508	386	0.32
4	407.7	Initial	522	386	
		Deflected	500	404	0.50
5	509.7	Initial	516	386	
		Deflected	490	409	0.59
6	611.6	Initial	507	394	
		Deflected	474	416	0.75
7	713.6	Initial	498	396	
		Deflected	446	424	1.19
8	815.5	Initial	472	402	
		Deflected	375	436	2.21
9	917.4	Initial	407	410	
		Deflecte	351	442	1.28

		d			
10	1070.3	Initial	384	414	
					1.78

FISSO Dynamic Arm

Force [N]	Weight [g]	Position	Y [Pixels]	X [Pixels]	Deflection [mm]
1	101.9	Initial	180	244	
		Deflected	180	244	0.00
2	203.9	Initial	180	244	
		Deflected	179	244	0.03
3	305.8	Initial	180	244	
		Deflected	179	244	0.03
4	407.7	Initial	180	244	
		Deflected	178	244	0.05
5	509.7	Initial	180	244	
		Deflected	178	244	0.05
6	611.6	Initial	180	244	
		Deflected	178	244	0.05
7	713.6	Initial	180	244	
		Deflected	177	244	0.08
8	815.5	Initial	180	244	
		Deflected	177	244	0.08
9	917.4	Initial	180	244	
		Deflected	177	244	0.08
10	1070.3	Initial	180	244	
		Deflected	176	244	0.11

Force [N]	**Weight [g]**	**Position**	**Y [Pixels]**	**X [Pixels]**	**Deflection [mm]**
1	101.9	Initial	180	244	
		Deflected	180	244	0.00
2	203.9	Initial	180	244	
		Deflected	180	244	0.00
3	305.8	Initial	180	244	
		Deflected	179	244	0.03
4	407.7	Initial	180	244	
		Deflected	179	244	0.03
5	509.7	Initial	180	244	
		Deflected	179	244	0.03
6	611.6	Initial	180	244	
		Deflected	178	244	0.05
7	713.6	Initial	180	244	
		Deflected	178	244	0.05
8	815.5	Initial	180	244	
		Deflected	177	244	0.08
9	917.4	Initial	180	244	
		Deflected	177	244	0.08
10	1070.3	Initial	180	244	
					0.08

Clamp Assembly

Trial [0 Degrees]									
Force [N]	Position	Y [Pixels]	X [Pixels]	Deflection Y [mm]	Deflection X [mm]	Overall Deflection	Drift Y	Drift X	Overall Drift
1.4	Initial	368	186						
	Deflected	368	188	0.00	0.06	0.06	N/A	N/A	N/A
2.8	Initial	368	187						
	Deflected	366	189	0.06	0.06	0.08	0.00	0.03	0.03
4.2	Initial	369	187						
	Deflected	363	190	0.17	0.09	0.19	0.03	0.03	0.04
5.7	Initial	367	188						
	Deflected	359	193	0.23	0.14	0.27	0.03	0.06	0.06
7.1	Initial	365	190						
	Deflected	349	208	0.45	0.51	0.68	0.09	0.11	0.14
8.5	Initial	357	201						
	Deflected	329	231	0.79	0.85	1.16	0.31	0.43	0.53
9.9	Initial	341	225						
	Deflected	311	245	0.85	0.57	1.02	0.77	1.11	1.35

Trial [90 Degrees]									
Force [N]	Position	Y [Pixels]	X [Pixels]	Deflection Y [mm]	Deflection X [mm]	Overall Deflection	Drift Y	Drift X	Overall Drift
1.4	Initial	415	295						
	Deflected	416	295	0.04	0.00	0.04	N/A	N/A	N/A
2.8	Initial	416	293						
	Deflected	416	296	0.00	0.11	0.11	0.0364614	0.0729228	0.08
4.2	Initial	415	295						
	Deflected	412	297	0.11	0.07	0.13	0	0	0.00
5.7	Initial	418	295						
	Deflected	414	297	0.15	0.07	0.16	0.1093842	0	0.11
7.1	Initial	415	295						
	Deflected	412	299	0.11	0.15	0.18	0	0	0.00
8.5	Initial	414	293						
	Deflected	410	299	0.15	0.22	0.26	0.0364614	0.0729228	0.08
9.9	Initial	415	296						
	Deflected	409	302	0.22	0.22	0.31	0	0.0364614	0.04

Trial [270 Degrees]									
Force [N]	Position	Y [Pixels]	X [Pixels]	Deflection Y [mm]	Deflection X [mm]	Overall Deflection	Drift Y	Drift X	Overall Drift
1.4	Initial	211	200						
	Deflected	211	200	0.00	0.00	0.00	N/A	N/A	N/A
2.8	Initial	211	200						
	Deflected	207	199	0.19	0.05	0.19	0	0	0.00
4.2	Initial	210	200						
	Deflected	204	197	0.28	0.14	0.31	0.04680261	0	0.05
5.7	Initial	210	199						
	Deflected	204	196	0.28	0.14	0.31	0.04680261	0.0468026	0.07
7.1	Initial	210	199						
	Deflected	202	198	0.37	0.05	0.38	0.04680261	0.0468026	0.07
8.5	Initial	209	199						
	Deflected	201	201	0.37	0.09	0.39	0.09360522	0.0468026	0.10
9.9	Initial	209	201						
	Deflected	197	202	0.56	0.05	0.56	0.09360522	0.0468026	0.10

Drill and Fixture Assembly

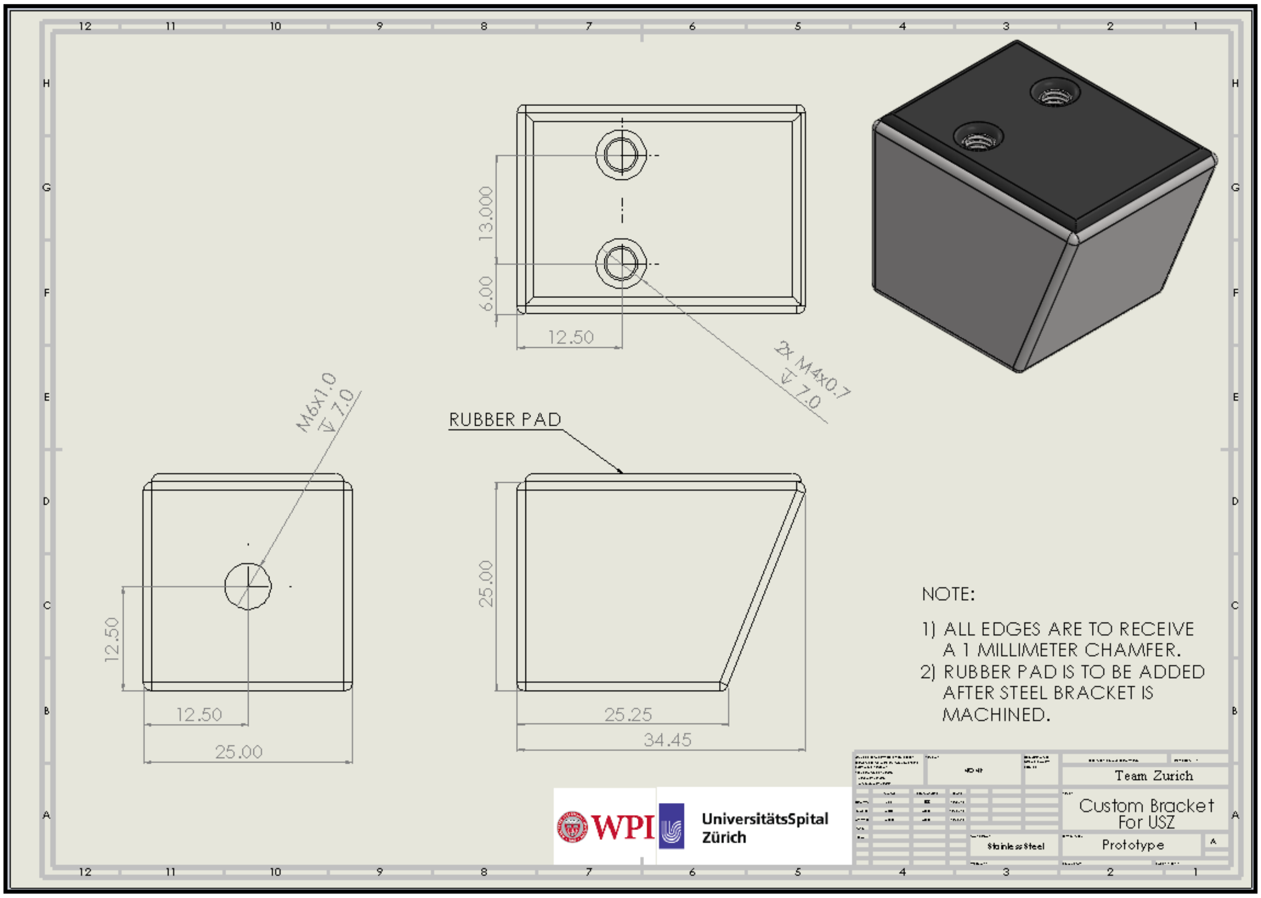
Trial [0 Degrees]									
Force [N]	Position	Y [Pixels]	X [Pixels]	Deflection Y [mm]	Deflection X [mm]	Overall Deflection	Drift Y	Drift X	Overall Drift
1.4	Initial	286	380						
	Deflected	282	380	0.12	0.00	0.12	N/A	N/A	N/A
2.8	Initial	286	380						
	Deflected	276	386	0.30	0.18	0.35	0.00	0.00	0.00
4.2	Initial	285	380						
	Deflected	268	384	0.51	0.12	0.52	0.03	0.00	0.03
5.7	Initial	284	380						
	Deflected	262	384	0.66	0.12	0.67	0.06	0.00	0.06
7.1	Initial	284	380						
	Deflected	256	383	0.84	0.09	0.84	0.06	0.00	0.06
8.5	Initial	283	380						
	Deflected	251	382	0.96	0.06	0.96	0.09	0.00	0.09
9.9	Initial	283	380						
	Deflected	248	381	1.05	0.03	1.05	0.09	0.00	0.09

Trial [90 Degrees]									
Force [N]	Position	Y [Pixels]	X [Pixels]	Deflection Y [mm]	Deflection X [mm]	Overall Deflection	Drift Y	Drift X	Overall Drift
1.4	Initial	457	169						
	Deflected	440	170	0.25	0.01	0.26	N/A	N/A	N/A
2.8	Initial	457	170						
	Deflected	422	175	0.52	0.07	0.53	0	0.014994	0.01
4.2	Initial	457	170						
	Deflected	403	181	0.81	0.16	0.83	0	0.014994	0.01
5.7	Initial	457	170						
	Deflected	390	187	1.00	0.25	1.04	0	0.014994	0.01
7.1	Initial	457	170						
	Deflected	368	193	1.33	0.34	1.38	0	0.014994	0.01
8.5	Initial	457	171						
	Deflected	349	200	1.62	0.43	1.68	0	0.029989	0.03
9.9	Initial	454	171						
	Deflected	330	210	1.86	0.58	1.95	0.045	0.029989	0.05

Trial [270 Degrees]									
Force [N]	Position	Y [Pixels]	X [Pixels]	Deflection Y [mm]	Deflection X [mm]	Overall Deflection	Drift Y	Drift X	Overall Drift
1.4	Initial	434	353						
	Deflected	427	354	0.25	0.04	0.25	N/A	N/A	N/A
2.8	Initial	434	353						
	Deflected	422	355	0.43	0.07	0.43	0	0	0.00
4.2	Initial	434	353						
	Deflected	418	355	0.57	0.07	0.57	0	0	0.00
5.7	Initial	434	353						
	Deflected	410	356	0.85	0.11	0.86	0	0	0.00
7.1	Initial	434	353						
	Deflected	405	357	1.03	0.14	1.04	0	0	0.00
8.5	Initial	434	354						
	Deflected	395	357	1.39	0.11	1.39	0	0.035529	0.04
9.9	Initial	434	354						
	Deflected	384	358	1.78	0.14	1.78	0	0.035529	0.04

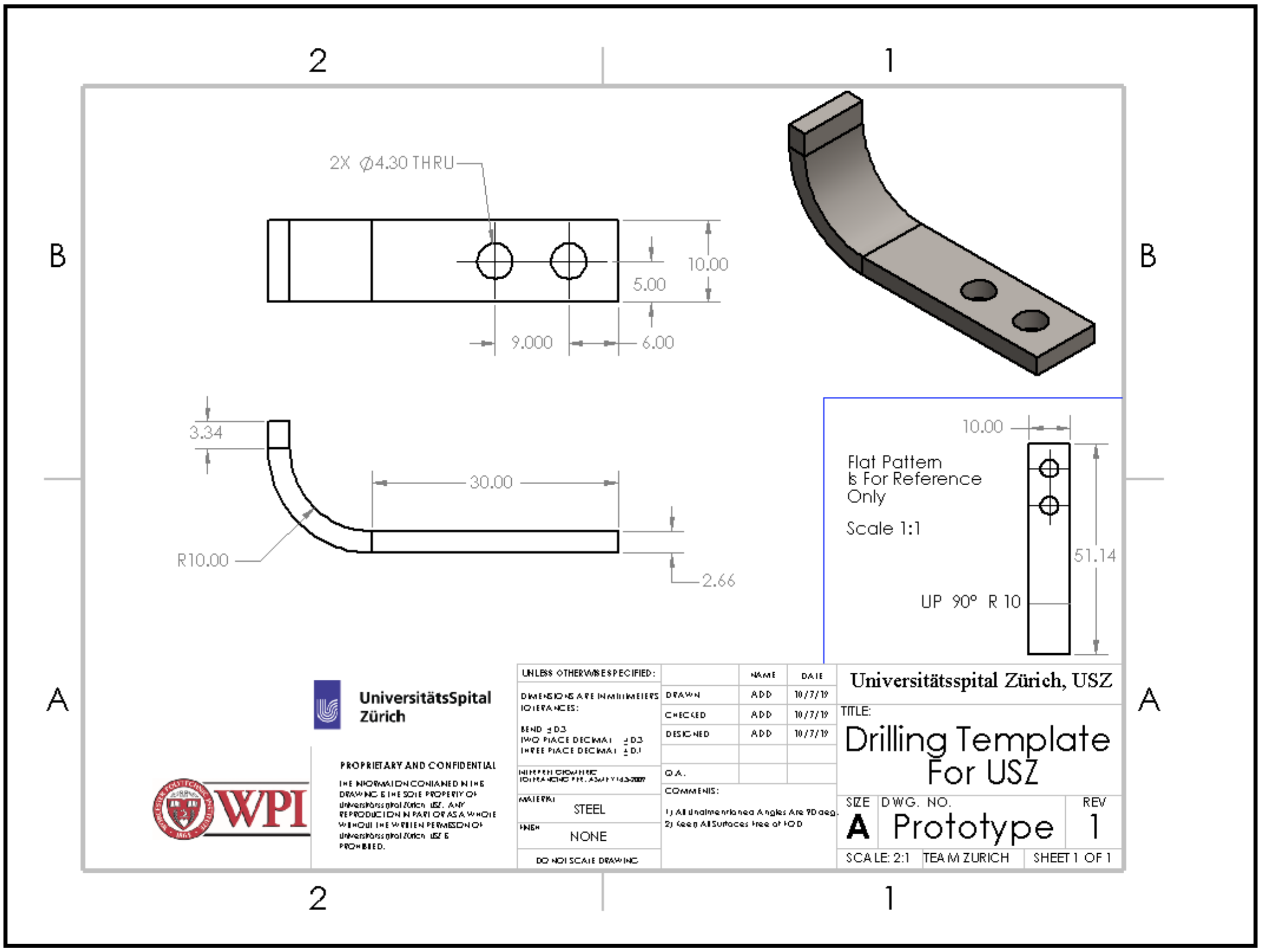
Appendix E: Steel Bracket Recommendations

Appendix E shows a steel bracket that the team designed to better suit the holder. The C-Clamp prototype uses clamps made of aluminum standard parts that were found in the lab. The team recommends that a clamp of the following dimensions be used instead. Steel is a stronger material than aluminum and would cause less deflection when force is applied, and the threaded holes would place a more secure hold on the bone from the screws.



Appendix F: Drilling Template for Drill Fixture Design

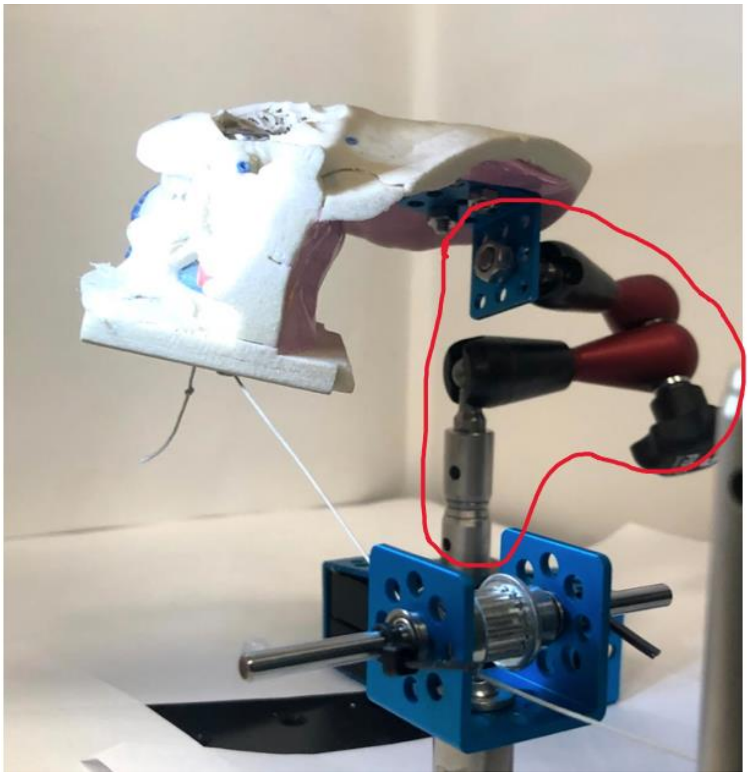
Appendix F is a SolidWorks drawing of a part designed to be manufactured to ensure consistent drilling locations for the Drill and Fixture design. This device will save researchers



time while they are preparing the samples and ensure a secure fit on each bone.

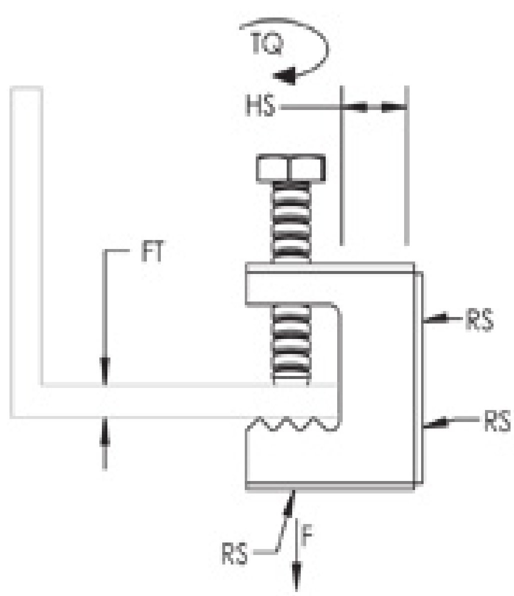
Appendix G: Arm Position for Highest Stiffness

Appendix G shows the position of the dynamic arm when it will have the highest stiffness. When the arm is most compact, the stiffness is at its maximum because of the smaller moment.



Appendix H: Clamp Recommendations

The clamps shown in Appendix H are a recommendation for the C-Clamp Design. The team planned to order these clamps, but due to time constraints, the clamps would have not arrived in time to complete testing and analysis. These are the ideal clamps for this design, and the steel would cause less deflection than the aluminum brackets used in the prototype.



nVent CADDY EBC BEAM FASTENER: https://www.erico.com/part.asp?part=EBCSP25