Peak Stress Reduction in Below-Knee Amputation

A Major Qualifying Project submitted to the faculty of
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Abstract

Transtibial amputation, or below-the-knee amputation, is a surgical procedure performed in the area between the ankle and the knee. Residual limb pain is experienced by 60% of the patients after surgery, often caused by infection, nerve damage (neuromas), and high stresses between the bone-ending and soft tissue due to excessive loading at the amputation site. Our team collaborated with Dr. John J. Wixted, who specializes in orthopedic surgery, and Dr. Arthur Graham, who specializes in prosthetics, to develop an implant that enhances load distribution and minimizes peak stress on the soft tissue near the bone ending in transtibial amputations. The team developed four implant designs, flat, turtle, muffin, and mushroom, for the weight-bearing end. Each of these designs was tested through the Ansys finite element analysis (FEA) model and Fujifilm Instron Testing to determine the effectiveness of the device designs. This included factors such as reducing stress between bone ending and soft tissue, reducing skin irritation, biocompatibility, stable interface, and reducing soft tissue used as a cushion. The outcomes from the FEA analysis presented the mushroom design proved most effective at decreasing the peak muscle ending stresses by 23%, 18%, and 30% for heel strike, standing, and heel-off loading states. The findings from the Fujifilm analysis supported those of the FEA analysis, indicating that the mushroom design was the most effective due to its uniform pressure distribution and consistent low-pressure reading across its surface. Overall, the implant incorporates a mushroom-shaped end structure designed to maximize load distribution, through the increased surface area, resulting in at least a 25% reduction in Peak Von Mises Stress originating from the residual bone near the soft tissues. The mushroom end is connected to a biocompatible Titanium alloy rod through Morse taper, which is then press-fit into the patient’s bone to facilitate osseointegration.

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Chapter 1: Introduction

1.1 Problem Definition

Amputation is the process of removing a part of the body. They can be congenital, traumatic, or surgical [25]. In the United States, approximately 150,000 patients undergo a lower extremity amputation per year [22]. Transtibial amputation, or below-the-knee amputation, is a surgical procedure performed in the area between the ankle and the knee. It involves the detachment of the foot, ankle joint, distal tibia, fibula, and corresponding soft tissue structures. The predominant causes of limb amputations include lower limb ischemia, peripheral arterial disease, and diabetes, followed by secondary cause trauma [21].

Following the amputation, about 60% of patients experience residual limb pain [26]. Post-surgical complications such as infection, neuromas, and stresses between the bone-ending and soft tissue are the primary causes of the pain [12]. Individuals with lower-limb amputation experience limitations in performing daily activities due to the loading at the amputation site causing high stress between the bone ending and soft tissue. The excessive stress, over time, can cause long-term discomfort by weakening the residual limb and causing damage to the soft tissue and socket interface [3]. Additionally, the limited surface area between the bone and soft tissue causes high pressure at the amputation site resulting in residual limb pain. There are limited

solutions available that help reduce the stresses patients experience between the bone ending and soft tissue. Current devices used to help reduce residual limb pain are exterior padding between the limb and prosthetic socket. However, these devices have many limitations as they cannot change the surface area of the bone ending in contact with the soft tissue.

For our project, we intend on designing an implant that will reduce the stress placed on the soft tissues at the amputation site by increasing the surface area between the rigid load bearing structure and the soft tissue. While increasing the surface area, we intend that the implant also creates a better fit between the limb and prosthetic socket. Furthermore, creating a better fit for the limb and socket should reduce common skin irritations caused from the prosthetic socket.

Chapter 2: Literature Review

2.1 Amputation Screening Process

2.1.1 Patient Screening Process

Surgeons go through a screening process with amputation patients to determine limb salvage and the best fitting surgery for that specific patient. Screening of the patient's nerve injury, soft-tissue and muscle damage, vascular injury, psychosocial factors, bone injury, and medical history are all considered for amputation patients. Depending on these factors the medical team determines the best fit for the patient [24]. Surgeries are categorized based on the location of the amputation. Figure 1 shows the various locations of the different amputation locations and types.

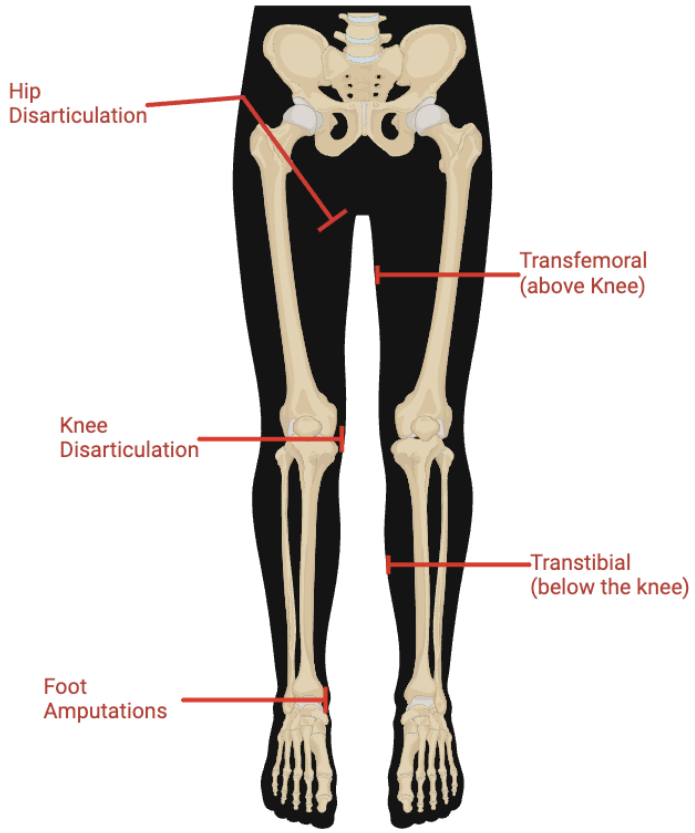

Figure 1. *Different Locations of Amputations. Created in BioRender by Gabriella Rios*

Partial foot amputations involve removing part of the foot and vary in types of specific surgeries depending on the amount of residual limb remaining. Ankle disarticulation involves removing the foot by separating it at the ankle joint. Transtibial amputations are made below the knee and cut at the lower leg (cutting the tibia and fibula) and remove the remaining lower leg. Knee disarticulation removes the entire lower leg by removing it at the knee joint. Transfemoral amputations are made above the knee and remove part of the thigh (cutting the femur) and remove the remaining lower leg. Hip disarticulation removes the totality of the leg at the hip joint. Lastly, pelvic amputation (hemipelvectomy) is the removal of the entire leg with removal of part of the pelvis [25].

2.1.2 Surgery Strategies

Although each type of leg amputation has specific strategies and procedures, there are common principles that surgeons use when performing an amputation. These principles are described in *General Principles of Amputation Surgery* by Douglas G. Smith, M.D [28] Maximizing the success of an amputation depends on the management of the skin, soft tissue cuts and stabilization, nerves, hemostasis, bones , and postoperative care. The common strategies behind managing these specific factors were investigated.

During the amputation process surgeons consider the incisions made to the skin and the wound closure process. The goal of surgeons is to Figure out a plan that allows for the skin to have the least amount of residual scar tissue and most amount of pliability. Picking the location of the incisions made to the skin is important to minimize the amount of damage and pain caused by scarring.

Surgeons perform certain techniques on soft tissues and muscles to retain the most amount of tissue and muscle function. The goal of surgeons is to produce an amputation with, " *a muscular, well-padded and balanced residual limb,"* which can be defined as having , "*effective strength, size, shape, circulation, metabolic exchange and proprioception* [28].

Surgeons consider all of these factors and come up with the best operation plan that accomplishes these factors to the best of their ability. One key practice that assists amputees is the process of muscle stabilization. Muscle stabilization is the process of securing the muscle to either itself (myofascial closure), around the bone to the corresponding and opposite muscle (Myoplasty), directly to the bone (myodesis), or attaching the remaining tendon to the bone (tenodesis).

Surgeons must also consider the management of the nerves in the residual limb of an amputee. Out of all the functions considered during an amputation, nerves and the adverse effects are the hardest to mitigate. Methods to mitigate these issues include cauterizing nerve endings chemically or thermally, enclosing the nerve in the bone, encasing the nerve in some sort of foreign material, ligating the nerve, or chemical injection. Surgeons try to place the nerve away from areas of pressure, pulsating vessels, and scarring. Practices such as nerve ligation. In general this is an area that can see improvement of care for the patient.

Management of the cardiovascular systems in the residual limb is of top priority for surgeons. This is because issues of low blood supply can cause serious consequences and can require additional removal of the residual limb and more surgery. It is common practice to double ligate large arteries while cauterization is used only for smaller bleeds during procedure. For central arteries such as for large nerves may need the additional procedure of using an absorbable suture. Surgeons will also use suction drainage to manage the blood during surgery. Surgeons attempt to limit the amount of damage made to the blood vessels, subcutaneous tissue, and skin to minimum to preserve hemostasis.

Surgeons must consider the forces and stresses that the residual limbs bone is exposed to when performing amputations. The amount of remaining bone length is determined by the ability (length and structural integrity) of the remaining soft tissues. Surgeons also attempt to create the best shape (rounded edges) of the residual bone to prevent future pain. Doctors will remove irregular shapes in the residual bone to reduce complications but try to keep the amount of bone removal to a minimum. Another component that doctors consider is sealing the end of the bone. Just as bones naturally are sealed in the body, during an amputation doctors may use osteo-periosteal bone cap techniques.

Postoperative care is as specialized as the amputation procedure itself. Depending on the need of the patient, some amputee patients may require staged amputations or revision

amputations. In these cases there are additional surgeries required that go through the same considerations of the different systems involved in an amputation. In general, postoperative care involves management of wound closure, determining the type of prostheses required (may be multiple different prostheses at different healing points), and rehabilitation plans.

Overall, specific procedure techniques and protocol are outside of the realm of this research. An overview of the different components of an amputation surgery and the common goals of surgeons is important in understanding the problem at hand.

2.2 Surgical Process

2.2.1 Common Transfemoral Amputation

To start surgery the surgeon will make incisions on marks drawn on the patient's thigh. These incisions will be different depending on the type of skin flaps that will be used to close the wound. There are different closures including fish mouth closure, lateral skin flap closure, or medial skin flap closure. In trauma cases these closures will be decided based on the amount of visible tissue remaining. Prior to the incision a tourniquet will be placed above the surgery site to reduce bleeding. Electrocautery will be used throughout surgery as well. Muscles are then transected about 1-2 inches below the bone ending. Next the femoral artery and vein are dissected and ligated. Additionally the sciatic and saphenous nerves are located and transected to help reduce formation of neuromas. Finally the bone is cut using an oscillating saw. Two drill holes are made in the lateral and posterior bone that's left. The abductor magnus tendon is sewn to the lateral drill hole at 5 to 10 degrees of abduction. The quadriceps muscle is then wrapped around the bone and sewn into the posterior drill hole with the hip at full extension. Lastly, the remaining skin flaps are sewn to close the wound [23].

2.2.2 Common Transtibial Amputation

Transtibial surgery also starts with the surgeon making various markings on the leg. There is a mark made about 10-15 cm below the tibial tubercle and marks for the anterior and posterior skin flaps. A tourniquet is inflated before the first incision is made. Next muscles are separated and divided into the tibia and fibula. Nerves are then dissected and separated to avoid neuromas. After separation, each nerve is ligated to help lower the risk of neuromas. The tibia and fibula are then cut and a hole is placed in the distal tibial bone. The skin flap is then sewn into the tibia [21].

2.3 Post Surgery Complications

2.3.1 Infections

Following surgery, infection occurs in 21-42% of patients. Infections ultimately delay the rehabilitation process and most of the time lead to additional surgeries. Most infections occur

within 6 weeks of the surgery. Hematomas can cause infections by weakening the wound and limiting blood supply due to the pressure at the amputation site [12]. There are 2 types of infections that can occur, Superficial Incisional Infection and Deep Incisional Infection. Superficial infections are between the skin and tissues around the incision. Deep infections occur in the deep soft tissues and can occur up to a year after surgery [25, 35]. Infections are very important to catch post surgery however they are not normally a cause for long term residual limb pain.

2.3.2 Nerve Damage

Nerve damage is another leading cause of residual limb pain. Neuromas are bundles of nerve endings that can be very sensitive to pressure. Neuromas can develop anywhere from 8 days to 10 years following surgery. Pain due to neuromas is often caused from contraction of surrounding scar tissues or pressure from the prosthetic [9]. Additional surgery can be required to fix severe cases but some non-medical treatments include ultrasound, massage, vibration, and nerve stimulation. Prosthetic limb sockets can also be altered to take pressure off the area of the neuroma [30].

2.3.3 Soft Tissue & Bone Ending

Contact between the bone ending and soft tissue can lead to residual limb pain in patients. Following surgery the bone ending experiences a lot of load across a small surface area, resulting in high stresses. This stress on the soft tissue from the bone ending can lead to residual limb pain. Additionally, formation of bone spurs at the bone ending can trigger high stresses across small areas in the soft tissue which can lead to residual limb pain [12]. Younger patients are at a larger risk of developing heterotopic bone. This is the formation of additional bone which can lead to poor prosthetic fit. This can change the load distribution between the socket and bone ending and cause pain [30]. Stresses between soft tissue and bone endings can lead to long term residual limb pain.

2.4 Current Devices

Lower limb prosthetics have had much progress in recent years. advancements focus on improved comfort, stability, and functionality. The main developments are in socket casting, positive mold creation, and rectification, to ensure a precise and customized fit for patients.

Socket casting is the first step and main step in the prosthetic design. The socket is the interface between an amputee's residual limb and the prosthetic device. The socket has to be fitted precisely, because the fit determines stability and control, balanced load distribution, and prevents skin-related complications. The process of socket casting starts with the collection of measurements and the creation of a negative cast of the residual limb. The negative cast is then filled with plaster to create a positive mold, which essentially replicates the shape of the limb. The positive mold goes through a rectification process, fine-tuning its contours to optimize the socket's fit and comfort. The final socket is crafted by laminating the mold with materials such as

carbon fiber, fiberglass, or nylon. In this process precise rectification is essential to distribute forces evenly and mitigate pressure points, thus preventing discomfort, skin irritation, and the compromise of prosthetic functionality.

Along this important process many advancements and alternatives have emerged in the realm of prosthetics. Polypropylene technology developed by the International Committee of the Red Cross (ICRC) has gained worldwide use, especially in resource-limited settings, offering a cost-effective and durable alternative to traditional socket laminating. The Modular Socket System by Ossur is time efficient by directly creating a socket on the patient's residual limb, but has a higher cost [20]. CAD and 3D printing technologies have also been widely used, it can give a precise design and provides easier manufacturing. Adjustable sockets like the RevoFit2 are gaining popularity for their customization features [32]. These advancements have provided a significant improvement in the quality of lower limb prosthetics, enhancing the lives of amputees by providing more comfort and functionality [48]

2.4.1 Osseointegration

Osseointegration is the process of fusing residual bone to metal. This process is a newer development in amputation strategies and is relevant for the scope of this project. Osseointegration is not widely practiced due to the new nature of these procedures, the cost of the procedure, and the associated risks involved with the surgery. Current research into osseointegration is being conducted at Johns Hopkins Medicine by Jonathan Foresberg, M.D, Ph.D. Dr. Foresberg describes his excitement about this procedure in the research article *Will Osseointegration Change the Future of Prosthetics?* Dr. Forsberg states that,

" Osseointegration as an orthopedic field is still in its infancy. Several companies worldwide are developing osseointegrated implants, but only one of them has data beyond 10 years. Given the unique challenges, there are many areas that are ripe for research [34]."

Areas of research include ideal patient population, implant types, bone health, skin health, ethics, and costs. Although there is more research needed for these types of procedures promising results have been seen. In the article *Walking without pain: How a new surgical procedure is giving hope to some amputees* by Marcy Cuttler of CBC News, the story of Jason Simunic, an above the knee amputee who had an osseointegration procedure, is described [36]. In the article, Jason described his personal story of residual limb pain that he had to deal with when using traditional prostheses options and how this factored into him getting the surgery. Jason described what went into his decision to get the operation and what it came down to was the possibility of an increase to his quality of life it had to offer. Although the surgery provides an opportunity of reduced pain, acioperception (ability to feel the sensations of different surfaces under foot), and less skin irritation, the surgery is not perfect. Cost is a major factor in the unavailability to osseointegration as it is not a widely accepted surgery and insurances will likely not cover it. Another consideration is that not all amputees are suitable candidates for the current surgery. People who have lost their limb due to blood circulation are not currently able to get this

surgery and is reserved for amputee patients from trauma or cancers. There are also dissenting views on the surgery due to the increased risks of infections and residual limb fractures.

An overview of current osseointegration devices was defined in the research article *Osseointegration for Amputees Current Implants, Techniques, and Future Directions* in 2020 [5]. One of the leading osseointegration device companies is Integrum. Integrum has the OPRA Implant System which is a set of osseointegrated prosthesis. Other osseointegration types include the percutaneous osseointegrated prosthesis which is still under development. Overall Osseointegration is a promising new technology but due to the limiting factors such as cost, not being applicable for infection prone patients, and the limited amount of accessibility there is a need for another alternative.

2.5 Socket Designing Process

2.5.1 Development of the Socket

A prosthetic socket allows the mechanical coupling between the residual limb and the prosthetic limb. The development of a patient-specific socket is a labor-intensive, time-consuming, and iterative process. Patients with limb amputation have indicated socket fit to be one of the most crucial parts of the prosthesis. If the socket does not fit well with the patient's residual limb or the prosthesis itself, challenges will arise for the patients while performing day-to-day activities. Various factors like moisture lockage, humidity, volume fluctuation, muscle deterioration, joint fit, and surrounding tissues need to be considered during the design process. Volume fluctuations in the residual limb affects the adaptability of the prosthetic socket and lead to interface pressure mismatch. Any inconvenience in the design could cause physical restrictions for the amputee like lower back pain, osteoporosis, and osteoarthritis [3]. To check for the effectiveness of the socket, multiple models of the socket shape and volume are tested. Lack of knowledge and consistency exists in manufacturing comfortable sockets and desirable alignment for patient-specific amputees.

Designing the socket starts with Magnetic Resonance Imaging (MRI) of the patient's stump. A geometric model of the socket is designed in SolidWorks or any designing software, using the patient's stump model for reference [14]. A Computed tomography (CT) image of the patient's stump is uploaded to the 3D software used to develop the stump model, which is then used as a reference to develop the socket model [3]. An issue with the technical approach of developing the stump model could be the time involved in getting the model validated and making sure it is the right fit for the user. However, additive manufacturing (AM) technologies are known for developing sockets with good fit, adequate strength, and stability [39].

Once the stump model is developed, the design then goes through a finite element analysis (FEA). Evaluating the static structural and explicit dynamics analysis of the socket is

crucial to determining its mechanical functioning and understanding the stump-socket interface [3]. Various technologies like Spiral X-ray Computer Tomography (SXCT), MRI, and Ultrasound can be used to provide internal and external limb information to help design multiple 3D models of a residual limb. MRI is known for its ability to detect soft tissue, bone dimension, and volume measurement to help estimate residual limb morphological information of different tissues. After all the testing necessary to approve the socket functions properly, the Computer-Aided Design (CAD) of the socket is 3D printed [14].

Casting is another way the prosthetists manually develop the model of the residual limb. The process involves using a Plaster of Paris (POP), a wet plaster bandage, is manually wrapped by the prosthetist over the patient's residual limb or the liner covering the residual limb to create a negative cast model. During the drying process, the prosthetists manipulate the mold by squeezing the plaster with their hands to capture the anatomy of the user's residual limb [39]. A positive mold is then made by pouring plaster into the negative cast mold, which develops the patient's socket model. However, mistakes are often made during this procedure because of human error. This could result in the patient having to send the socket back to the manufacturer to perfect the fit of the socket. In addition, the patient may be asked to come to the lab multiple times to get the casting redone, which can be time-consuming and push the socket development [39].

2.5.2 Analytical Process

The use of 3D modeling of the residual limb to study the interaction between the socket and the limb is becoming common in the field of prosthetics and orthopedics. Finite Element Analysis is used to study the interaction between the stump and the socket while under loading. Following this, the fabrication of the socket is 3D printed [3]. Various design approaches have been introduced to improve the socket shape. The basic goal of the socket design is to uniformly distribute the load throughout the stump to allow comfort and mobility for the amputee. However, excessive interface pressure and shear force can result in soft tissue damage and skin irritation [41].

A further understanding of the biomechanical consequences like the pressure distribution between the stump and the socket will allow the designers to evaluate and elevate the quality of socket fitting. Experimentally measuring the pressures and shear stress applied to the surface of the residual limb can only be accessed at specific sites. This makes it difficult to access the load transfer of the socket interface for the whole affected area [41]. However, numerical analyses through the use of computational models can facilitate a systematic model of the biomechanical principles behind the prosthetic socket design. The load transfer biomechanics of the residual limb-socket interface can be predicted through CAD technology.

Finite element analysis (FEA), is a commonly used method for computational modeling that provides understanding of the various magnitudes and load distribution about the socket

model. The MRI scans are used to develop the FEA model. It is used to understand stress in the tissues and prosthesis, determine the load transfer mechanism, and identify biomechanical behaviors between the limb-socket interface. All forces and moments between the body and the prosthesis through the residual limb skin [3]. Developing a socket with a good fit requires an understanding of biomechanical concepts involving socket pressure, friction, tissue response to external loads, etc. To detect tissue damage, FEA was conducted to stimulate the load-bearing conditions of the patient. Internal strains, strain energy density, and stresses in muscle flaps were analyzed to get a better sense of deep tissue injury. The analysis further concluded that friction between the bone and soft tissue affects the stress-strain predictions .

Elevated temperatures, humidity, presence of moisture, grease, and sweat on the surface of the skin were some of the issues mentioned about the limb-socket interface. High humidity can also soften skin and increase cellular permeability resulting in an increased chance of skin irritation [3]. Through the FEA, the effects of the thermal conductivity of the liner's ability to handle heat can be evaluated. The analysis concluded that thermal conductivity affected the temperature of the residual limb's skin [17]. Moreover, the FE analysis is used to determine the effects of material properties, thickness, and size to examine the stiffness of the design. The various factors analyzed through this process provide a way to determine the performance of the socket/prosthesis, ways to advance it, and finalize the model [39].

2.5.3 Manufacturing Process

Once the socket model is designed and analyzed through the FEA, the geometric socket design is ready to be a 3D-printed multi-material socket. Additive Manufacturing (AM) technologies will help develop a better socket fit with adequate strength. To manufacture the socket, a 3D printer based on the Fused Decomposition Modelling (FDM) technology is used [39]. It is used to fabricate a physical model of prototypes and functional parts in engineering plastics, layer-by-layer. A variety of plastic filaments can be used to print the prototypes, but some of the most commonly used plastics for socket models in FDM are PLA (Polylactic acid), PP (Polypropylene), CF (Carbon Fiber Reinforced PLA), or ABS (Acrylonitrile butadiene styrene).

The traditional fabrication technique involves manually casting a model of the residual limb through a negative cast first, and then pouring the plaster in to make a positive mold of the limb. The prosthetic socket itself is made as the thermoplastic sheets are heated and vacuum-formed onto the positive plaster mold, and left to cool off to adapt to its shape. The patient then goes through a fitting process to make sure the socket is a good fit, easy to move in, and comfortable [17]. The traditional process is known to work the best as it is able to capture almost the exact anatomy of the patient's stump, allowing the socket to fit the patient properly.

Although this process works well, the introduction of AM technologies opens new opportunities. The designer has control over the infill ratio, internal geometric structure, material

composition, and behavior of the 3D socket model, which is later 3D printed [39]. Through the use of FEA, mechanical characteristics and functional performance of the socket design through AM technology are known to have the ability to improve the material distribution while the design maintains its stiffness. In addition, products can be manufactured using multi-material components, minimal time, low labor cost, etc. Developing a socket design using multi-material components, helps in terms of stiffness, functionality, and environmental adaptation for the product [17].

However, the difference in material may cause issues with the difference in thermal expansion, contraction, and release of the product. In addition, a lack of quantitative and qualitative evidence that compares the socket models developed through an additive manufacturing approach to a standard manufacturing approach exists. Therefore, AM is a disruptive technology since it is still in the works of developing as issues exist with trying to develop a socket model that is both comfortable and functions properly [17].

2.6 Limitations

Lower limb amputations have many challenges that impact their day to day lives. obtaining a comfortable and stable interface between the residual limb and the prosthetic socket is one of the main achievements for doctors, the main issues are due to discomfort and pressure sores. Lower limb prosthetics have the difficulty of fully replicating the natural biomechanics of a human leg, this impacts mobility and energy efficiency [38]. The lack of sensory feedback in lower limb prosthetics restricts the patient's ability to perceive changes in terrain and maintain balance [11]. Lower limb amputees also have many skin irritations, these can cause great discomfort [37]. Psychosocial factors, like body image and self-esteem issues, are another factor that aren't talked about as much. Lower limb amputees often struggle with body image, self-esteem, and social acceptance, which can impact their overall well-being [38]. Cost and accessibility are another limitation for some amputees. Access to high-quality lower limb prosthetic devices can be limited by their cost, creating disparities in access to prosthetic care for individuals with limited financial resources [11]. Maintenance and durability are practical concerns. Prosthetic devices often require regular maintenance and may have limited durability. Frequent repairs or replacements can also be costly[40]. Addressing these and developing relieving solutions to improve lower limb prosthetic care is important to improve the quality of life of patients.

2.6.1 Skin Damage Due to Pressure Points

A study done by Dudek et al. (2005) highlights the important issue of skin irritation in lower limb amputees due to skin pressure under high mechanical loads. The research included 828 lower-extremity amputations, and was aimed to determine the likelihood of various factors being associated with the presence of skin problems [37]. Approximately 40.7% of the 828

residual limbs had at least one recorded skin problem, such as ulcers, irritations, inclusion cysts, calluses, verrucous hyperplasia, and more [37]. These skin problems were mainly linked to the mechanical pressures exerted by amputated limbs, especially in cases where the residual skin was not adapted to withstand such forces. They showed that the type of prosthetic socket and suspension mechanisms did not affect the results for both transtibial and transfemoral residual limbs [37]. Amputation location was shown to be of great importance with transtibial residual limbs being four times more likely than transfemoral residual limbs to have skin problems [37]. This heightened risk in transtibial amputations could be attributed to factors such as the presence of bony prominences and increased prosthetic use due to higher activity levels.

The findings provide a strong need in addressing the pressure distribution in lower limb amputations. Focusing on improving design and development to distribute pressure from amputated limbs in a socket can help address many of the limitations and overall comfort of patients.

2.7 Patent Search

We conducted a patent search using the resources of the WPI Gordon Library. The patent databases used include; USPTO (United States Patent and Trademark Office), Google Patents, ESpace (European Patent Office), and Nexis Uni. For each of these patent databases, search terms were identified and used to execute the patent searches. Table 1 shows the results for the different search terms and a summary of the devices.

Table 1. *Patent Search*

Patent Number	Search Term(s) Used	Summary of Patent Contents
1. DE102018132918A1	"Amputation" AND "Liner"	1. This patent is for a liner designed for amputation stumps, providing cushioning and ease of use for prosthetic limbs. It has the integration of an electrode system that generates dielectrically impeded plasma discharge. The liner also includes a dielectric cover with raised areas mainly around the electrode system, creating gas spaces for the plasma discharge. This design overall simplifies the attachment of prosthetic limbs to amputation stumps.
1. US7374577B2 - Implant device for osseointegration to	"Osseointegration" AND "Amputation"	1. This implant device is an osseointegration implant device that focuses on load distribution by creating a load dispersing adaptor with a cap shape with a wider diameter than the residual bone.

endure weight - Google Patents [8] 2. https://patents.google.com/patent/US20080200995A1/en [16] 3. https://patents.google.com/patent/US20090005820A1/en [1] 4. US20110190907A1 - Transdermal Intraosseous Device - Google Patents [13]		2. This patent is for an implant connection device for osseointegration. The device consists of a metal stem that is tapered to fit into residual bone and skin is extended over the outer surface through a suture ring with an external protrusion. 3. This implant device describes an end cap to the bone that is able to be used as an anchor of the bone to an external prosthetic system. The cap mounts onto a fixator pin between the prosthesis and the soft tissue of a residual limb. The cap includes an antibacterial agent that closely overlays the tissue interface of the skin to prevent infections. Created for easy removal and for cleaning and to replenish the antimicrobial agent. 4. This implant device is an osseointegration device that connects the residual bone to an external socket.
No Relevant Patents	"Insert" AND "Amputation"	For this search the patents that came up were referring to joint replacement rather than limb amputations.
1. US9056023B- Limb volume accommodation in people with limb amputation [15] 2. JP5068302B2-Prosthetic leg with drive source for patients with upper limb amputation [19]	"Socket" AND "Amputation"	1. This patent covers a prosthetic sock monitoring system comprising a storage device and a data collection unit. The data collection unit. The data collection unit gathers data from sensors on a patient's prosthetic sock and stores it. The prosthetic sock itself is designed for a better limb fitting and may include features like a sock identification unit and a force sensing device. The system aims to enhance prosthetic limb comfort and performance by collecting sensor data from the sock. 2. This patent is for an improved prosthetic leg with a drive source, which includes a knee member, socket, crus member, artificial foot, and a linear actuator. This design aims to enhance functionality and comfort, offering a greater energy efficiency and improved mobility for amputees.
No Relevant Patents	"Amputation" AND "Residual Limb"	For this search the patents that came up are referring to the use of electrical stimulation on the residual limb to help with pain relief and non-relevant socket measurements.

Chapter 3: Project Strategy

3.1 Initial Client Statement

The initial client statement involved designing an “end cap” piece that could fit into the bone of a residual limb to increase comfort during weight-bearing activities / within a prosthetic socket. In addition, we had to consider aspects of tissue stress, blood flow, biocompatibility, and other issues involved with the development of our device.

3.2 Design Requirements

3.2.1 Design Objectives

As we determined our client statement we began to formulate design objectives to be associated with the goals for the design. Once the client statement was finalized, a pairwise comparison chart was created to define our design objectives and determine the most important design requirements (See Table 2. below) .

Table 2. *Pairwise Comparison Chart*

REQUIREMENTS	REDUCE STRESS BETWEEN BONE ENDING AND SOFT TISSUE	REDUCE SKIN IRRITATION BY CREATING A BETTER FIT INTO SOCKET	BIOCOMPATIBLE AS AN INSERT IN THE BODY	RIGID INTERFACE BETWEEN INSERT AND BONE	SMOOTH INTERFACE BETWEEN SKIN AND INSERT	LIGHT WEIGHT	REDUCE SOFT TISSUE/ MUSCLES USED AS CUSHION	TOTAL
REDUCE STRESS BETWEEN BONE ENDING AND SOFT TISSUE	X							
REDUCE SKIN IRRITATION BY CREATING A BETTER FIT INTO SOCKET		X						
BIOCOMPATIBLE AS AN INSERT IN THE BODY			X					
RIGID INTERFACE BETWEEN INSERT AND BONE				X				
SMOOTH INTERFACE BETWEEN SKIN AND INSERT					X			
LIGHT WEIGHT						X		
REDUCE SOFT TISSUE/ MUSCLES USED AS CUSHION							X	

3.2.2 Design Functions

Our design consists of a rod and a weight bearing end. The rod is for stability and fixation, and the end piece is connected to the stem, allowing better load distribution along the bone ending and soft tissue interface. To guide our design process design specification and constraints were considered:

We considered what materials could be used and how these materials would interact with the body. After conducting extensive research on what predicate devices currently use, such as femoral stems, we decided on using a Ti alloy (ie.: some type of surface treated Ti6Al4V) rod for the stem, and a Highly cross linked polyethylene for the cushion bottom. Ti alloys present high corrosion resistance, good biocompatibility, and good mechanical properties [7]. We specifically looked at Styker's Restoration® Modular Ti6Al4V ELI stem, used in THA [45]. Styker's femoral stem is circumferentially plasma sprayed with commercially pure titanium and then over-sprayed with PureFix® hydroxyapatite, and have proven through their clinical trials to improve biocompatibility [49]. Another biomaterial we looked at, for the cushion end, was Zimmer's Vivacit-E® Vitamin E Highly Crosslinked Polyethylene, used in acetabular cup systems for THA, and in liners for partial or total knee replacements. This material is compatible with Ti alloy (including Styker's material), prevents oxidation, has a 95% wear reduction over conventional polyethylene, and has bearing technologies [47].

Through our research for material selection, we found that following materials that were already widely used in the market would be most beneficial for our device. As specified we selected Strykers restoration modular titanium alloy stem as a predicate for our rod, and Zimmer's Vitamin E injected highly cross linked polyethylene as a predicate for our weight bearing end. The devices met our material criterias for each part, these criterias are specified in Table 3 and Table 4.

Table 3. *Stryker Restoration Modular Stem Material Objectives*

1	Biocompatible
2	Osseoinigration
3	Lightweight
4	Imageable with x-ray
5	Long Lifetime (10 millioin Cycles)
6	Low oxidation
7	Wear Resistance
8	Corrosion resistance
9	Fatigue strength

Stryker Restoration® Modular

Table 4. *Zimmer's Vivacit-E Material Objectives*

1	Biocompatible
2	Lightweight
3	Imageable with x-ray
4	Long Lifetime (100 Million Cycles)
5	Low oxidation
6	Wear Resistance

Vivacit-E® Vitamin E Highly Crosslinked Polyethylene

Stryker's stem has better biocompatibility and osseointegration compared to other devices in the market because it has plasma spray titanium and a hydroxyapatite overs spray. Its taper junction exceeds ISOs testing standards (517 lbs), being tested at 10 million cycles (the

average load on an implant over a 10 year period) at 1,00 lbs. It also undergoes a shot peening process which has proven to improve Ti-6Al-4V alloy fatigue strength by approximately 10% - 15%. By having improved fatigue strength it also enhances the material's corrosion resistance, and the stem goes through other surface hardening treatments that improves its corrosion resistance [45].

Zimmer's vitamin E injected polyethylene met all our criterias for material selection. It is biocompatible, has lower oxidation than conventional polyethylene due to the graft of vitamin E directly to the polyethylene chain. It was tested at accelerated aging for 33 weeks and showed no decline in material properties, which is important due to oxidation being the primary aging mechanism of polyethylene. It has ultra low wear rates compared to conventional polyethylene. The vitamin E also provides it with improved strength and retained mechanical strength.

Using a Ti alloy stem also allows for better osseointegration. This is specially important because the stem would be tapered into the patient's bone, and we need the stem to osseointegrate and anchor onto the bone for better stability.

While designing our device we had to consider the shape of each part and how it would fit. The weight bearing end had to be just a little bigger than the tibia, not too big where it would cause pressure points and not too small, where it would create more stress on the limb.

To determine the mechanical properties of our design and select the suggested materials, we first researched different orthopedic alloys and compared each to the cortical bone properties. The properties of cortical bone were determined in the Tables below.

Table 5. *Cortical Bone Mechanical Properties.*

Material	Poisson's Ratio	Density	Compressive Strength
Bone (Cortical Bone)	0.15 - 0.45	1.6-2g/cm^3	20-193 MPa

Tensile strength (Ultimate)	fatigue Strength	Young's modulus
52-133 MPa	7-40 MPa at 10^7 cycles	4-30 GPa

The Figure shows a screenshot of the excel sheet created by the team that presents the mechanical properties of the cortical bone. All measurements were taken from source: [27].

Table 6. *Cortical Bone Measurements*

Cortical Bone		**Average**
Breadth of upper extremity	7.45cm	
Width (Top part of tibia)	68.9-80.4mm	75.1 +/- 3.4mm
Diameter (Middle of tibia)	**1.7-3.7cm**	
Thickness	2.07 - 8.92mm	
Surface area		
Length (Max)	35.2-43.6cm	39.9 +/- 2.2cm
Length (trans-tibial amputee)	**12.5-17.5cm**	
	^ less than 12.5cm would be less efficient	

The table above is a screenshot from the team's excel sheet that presents the measurements of the cortical bone. All data was taken from the sources: [5, 6, 10]. The measurements and properties in the Figures above were used by us as a reference and basis to our designs.

3.3 Standards for Design Requirements

3.3.1 510(K) Pathway

If our device were to go into the market we would follow a 510(k) pathway. The pathway is a submission made to the U.S Food and Drug Administration (FDA) for medium-risk devices that have a predicate on the market. The predicate should be able to prove the safety and effectiveness of the device and show that the device is substantially equivalent (SE) to other legally marketed devices [46].

For our device we would use 2 predicates. One for the stem and another for the weight bearing end. The stem is similar to femoral stems used in total hip arthroplasty (THA). The weight bearing end is similar to liners used in acetabular cups for THA, and liners used in total knee replacements. Both predicates are widely used in the market and have been around for decades, giving us many options for predicate devices.

3.3.2 ISO Standards

International Organization for Standardization (ISO) standards are a set of internationally recognized guidelines developed to ensure the products used by consumers are safe, reliable, and of high quality. The product we developed is a cutting-edge implant aimed at enhancing load distribution and minimizing peak stress on the soft tissue near the bone ending in transtibial amputations. During the development of this product, we considered the following ISO standards to address quality assurance, compatibility, risk management, continuous improvement, regulatory requirements, and manufacturing [29].

1. **ISO 5832-3: 2021 -** Implants for surgery - Metallic materials - Wrought Titanium 6-Aluminum 4-Vanadium alloy
    - The following standard addresses the characteristics of the Ti-6Al-4V alloy for use in the manufacture of surgical implants. It makes sure the alloy used for the surgical implant meets specific biocompatibility, mechanical, and functional properties [29].
2. **ISO 8548-2: 2020** - Prosthetics and orthotics - Limb deficiencies
    - The following standard addresses the method of describing lower-limb amputation stumps [29].
3. **ISO 21065: 2017** - Prosthetics and orthotics
    - The following standard addresses the terminology involved in the description of the phases of treatment and rehabilitation for people with lower limb amputation [29].
4. **ISO 10993-1: 2018 -** Biological evaluation of medical devices
    - The following standard addresses guidelines for biological safety of medical devices when in contact with the human body. It emphasizes the significance of risk management, material selection, and clinical evaluation while developing a medical device. In addition, factors of biocompatibility such as cytotoxicity, irritation, sensitization, material-mediated pyrogenicity, and acute systemic toxicity [29].
5. **ISO 11607-1/2: 2019 -** Packaging for terminally sterilized medical devices
    - The following standard addresses the requirements and test methods for materials, sterile barrier systems and packaging systems to maintain sterility of terminally sterilized medical devices until the point of use [29].
6. **ISO 13485: 2016 -** Medical devices - Quality management systems
    - The following standard addresses the requirements for quality management systems in the development of medical devices to consistently fulfill the needs of customer and regulatory requirements [29].
7. **ISO 14630: 2012** - Non-active surgical implants - General requirements
    - The following standard addresses the safety requirements, intended performance level, and quality of non-surgical implants. Some requirements include design attributes, materials, manufacture, and sterilization [29].
8. **ISO 14971: 2019 -** Application of risk management to medical devices
    - The following standard addresses the hazards manufactures may encounter while developing a medical device. The hazards may include risks with biocompatibility, usability, moving parts, etc. This is a guide that allows manufacturers to evaluate, control, and monitor the risks associated with the medical device [29].

3.4 Revised Client Statement

Develop an implant aimed at enhancing load distribution and minimizing peak stress on the soft tissue near the bone ending in transtibial amputations. The primary objective is to mitigate peak stresses originating from the bony ending, utilizing a press-fit Titanium alloy rod for osseointegration. The design incorporates an end structure designed to maximize load distribution, through the increased surface area, resulting in at least 25% reduction in Peak Von Mises Stress transmitted to the soft tissue from the residual bone.

3.5 Management Approach

3.5.1 Term Breakdowns

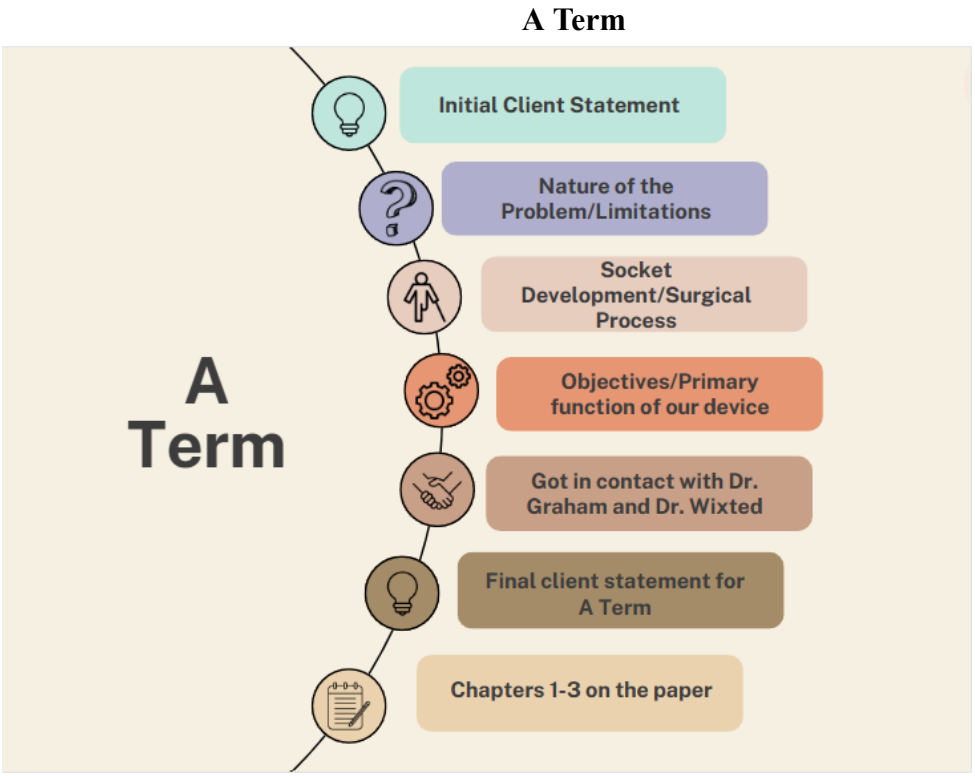

Figure 2. *Work breakdown from A Term*

The primary focus during this term was project definition. This included getting a deeper understanding of our project topic through background research, getting in contact with our colleague who is an amputee himself, and forming connections with orthopedic professionals. The initial project interest was to design an “end-cap” piece that could fit into the bone of a residual limb to increase comfort during weight-bearing activities and provide a better fit for a prosthetic socket. However, the project became more defined as the client statement was altered over the course of the term.

The team was able to get in contact with our colleague Douglas, to get a better understanding of the limitations he faces with his current prosthetic system and what he believed should be our main focus for this project. Refer to Appendix B for Douglas' interview transcript. From this interview we understood more about the skin irritations and day to day limb pains that Douglas experiences. Through the help of our advisor, the team was able to form connections with Dr. John Wixted, who is a trauma amputation surgeon . Dr. Wixted connected us with his prosthetist, Dr. Arthur Graham. We scheduled bi-weekly meetings with them to send updates on our progress and receive feedback. With the support and expertise of these parties, we were able to understand the various aspects of the main issues faced by people with lower-limb amputation. During this term, the team was able to solidify a list of objectives to incorporate into our design, prioritize the functions for the design, as well as narrow down our client statement. At the beginning of the term our team created a work breakdown chart that we would use as a guideline throughout the term, seen in Figure 2. The chart was then revisited at the end of the term to see the progress that was made, during A term we were able to complete all the tasks.

B Term

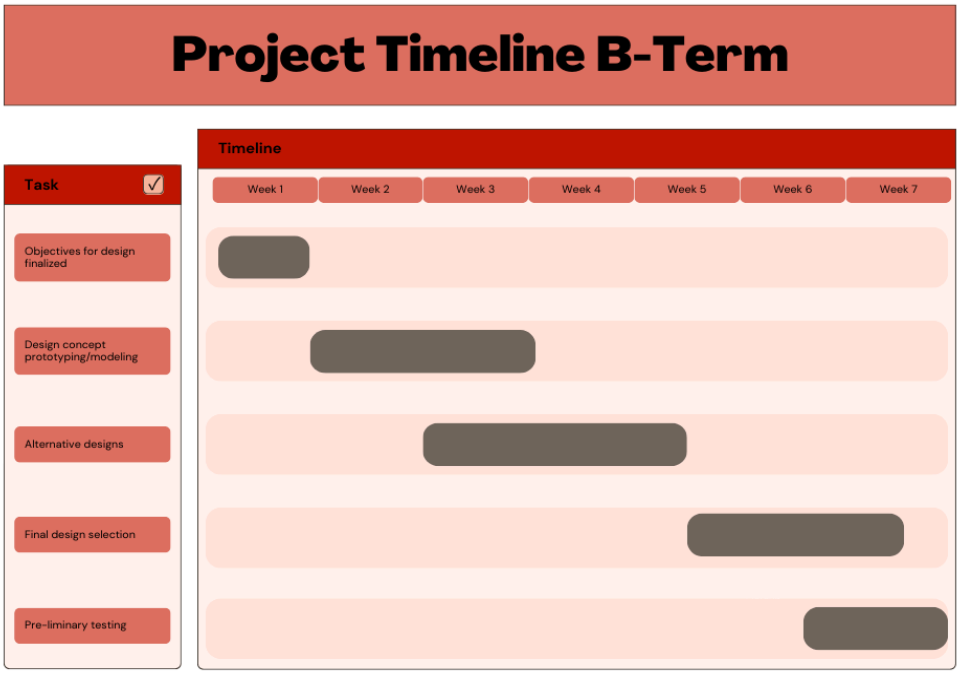

Figure 3. *Gantt Chart from B Term*

The primary focus during this term was design concept prototyping. This included solidifying the design objectives and developing preliminary designs for the various components of the device (stem, weight-bearing, and cushion end). These ideas were shared with Dr. Wixted and Graham during our bi-weekly meetings and the professor throughout the term. The feedback from these meetings allowed us to move forward with the design process.

In the beginning of the term, the team was able to connect with Dr. Ian Gray and Kelsey Wielhouwer, from Next Step Bionics & Prosthetics, Worcester, MA. Dr. Ian was able to show us the system used for developing a patient-specific socket, where the casting takes place, and the various socket and prosthetics designs currently being used by their patients. In addition, the team had the opportunity to observe Dr. Ian cast Kelsey, which helped us understand the casting process that leads to socket development. Through this visit we were also able to gain more understanding on the main issues faced by amputees, and further validate our own research.

During this term, the team was able to solidify a list of materials, design CAD models of the device, and develop a 3D model through Solidworks and started looking into ANSYS static structural simulation, for future testing of our designs. Various material properties were determined through research which was necessary for designing the device and applied to the 3D model. Our team created a gantt chart at the beginning of the term to outline our timelines and expectations, seen in Figure 3. The chart was visited at the end of the term to evaluate our progress, this term achieved some of our objectives, and realized the last two objectives, final design selection and preliminary testing, was an overreach.

C Term

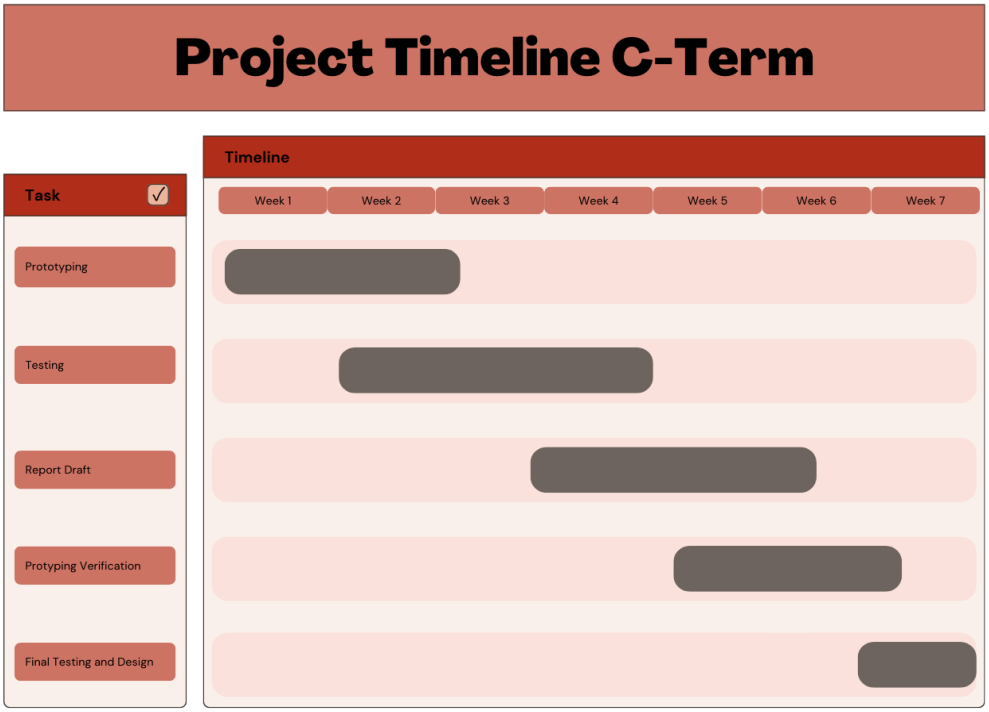

Figure 4. *Gantt Chart from C Term*

The primary focus for this term was finalizing our designs, design prototype testing, and verification. This included using the 3D simulation model to test all four of the load-bearing device prototypes under various conditions to determine its effects on the residual limb and socket. The implant prototypes we designed on Solidworks include tibia shaped (flat),

mushroom, turtle, and circular faced (muffin). Through the 3D model, each of the design's stress and strain distributions were displayed through a mesh that shows where and how the stresses are applied across the socket/residual limb.

In addition to the 3D model, we conducted mechanical tests through Instron on 3D printed prototypes to validate the results from the 3D model. The testing involved using Fujifilm, which is a sheet of paper that measures pressure between any two surfaces that touch, through making an indent. A piece of steak was used as a surface for the prototype to be pushed against, as it mimics the soft tissue, while conducting compression tests. The results from the film were then analyzed to determine how well the pressure is distributed by each of the designs.

Over the course of the term, we conducted bi-weekly meetings with Dr. Wixted and Dr. Graham to update them on our progress. Additionally, we received help from Professor Adriana Hera to assist with the development of the 3D model. Feedback from the doctors and our advisor, allowed us to move forward with our design and testing process. The gantt chart for this term can be seen in Figure 4, our team created realistic timelines and expectations this term. We were able to achieve all of our set goals, except for finalizing testing. We still had one more round of instron testing left.

D Term

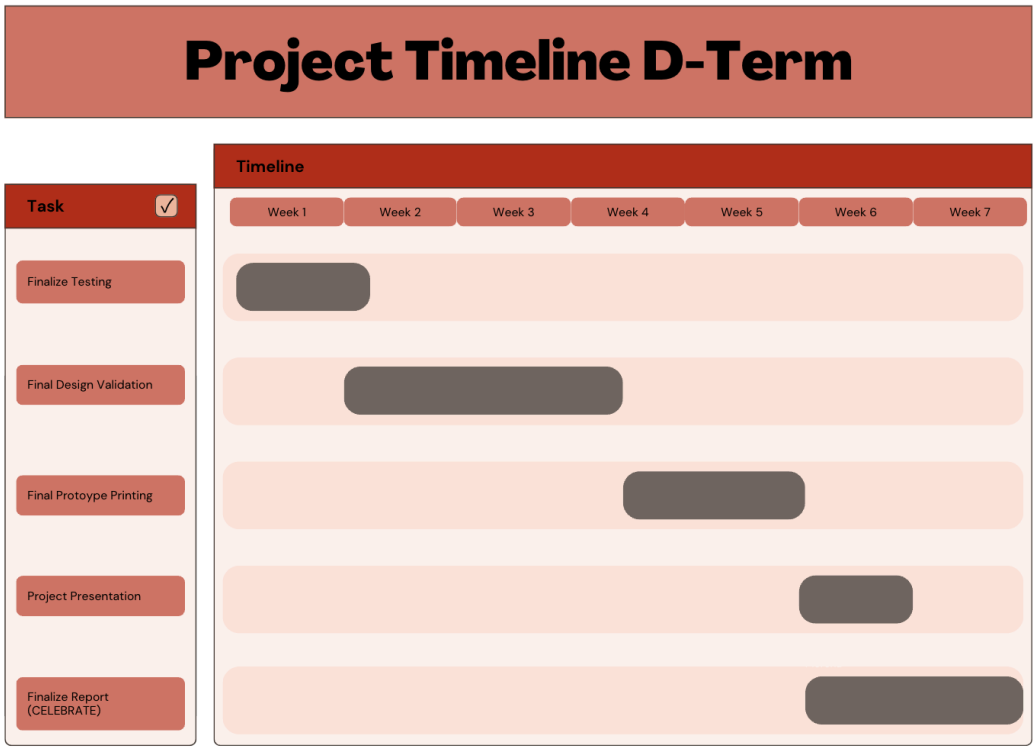

Figure 5. *Gantt Chart from D Term*

The primary focus for this term was finalizing the 3D model, CAD designs, materials, testing, and data analysis. The 3D model was finalized as different loading conditions (toe-off load, standing load, and heel-off load) were added to understand the distribution of Von-Mises

stresses for each design under those conditions. The model shows the percentage decrease in total muscle stress peak and under bone muscle stress peak for the various designs.

Through Dr. Wixted and Dr. Graham's guidance, we were able to solidify four different designs for the implant: tibia shaped (flat), mushroom, turtle, and circular face (muffin). We discussed the implant would be made of Zimmer's Vivacit-E® Vitamin E Highly Crosslinked Polyethylene, a highly crosslinked polyethylene, for the cushion end and Styker's Restoration® Modular Ti6Al4V ELI for the stem. During the term we were able to get in contact with workers at Zimmer, who were able to send us a sample of their highly crosslinked polyethylene. This allowed us to get a better sense of the type of material we would be using for our cushion end.

In addition, the Fujifilm prints collected from the Instron testing conducted on the various designs were analyzed for the pressure distributed along the film through ImageJ. The analysis from the testing was then compared to the results from the FEA to determine which of the designs are successful at enhancing load distribution and minimizing peak stress on the soft tissue near the bone ending in transtibial amputations. This final term gantt chart can be seen in Figure 5, our team completed all our goals in the correct time-line. The charts helped us make sure we stayed on track throughout the year.

Chapter 4: Design Process

4.1 Needs Analysis

About 60% of patients with limb amputations have experienced residual limb pain following surgery [25]. Post-surgical complications such as infection, nerve damage (neuromas), and stresses between the bone-ending and soft tissue are the predominant causes of the pain [12]. Lower-limb amputees experience limitations in performing simple daily activities due to the loading at the amputation site causing high stress between the bone ending and soft tissue. The excessive stress, over time, can cause long-term discomfort by weakening the residual limb and causing damage to the soft tissue and socket interface [3]. As a result of these complications, there is a need to develop a device that enhances socket fit and addresses not only physical comfort but also physiological and functional aspects, allowing for successful rehabilitation after surgery.

The implant design needs to have an increased surface area at the amputation site for a better fit of the socket and distribution of the load between the bone ending and soft tissue interface. The uniform distribution of load will prevent concentration of stress in a particular area at the amputation site and limit the transfer of pain to the residual limb. This will enhance socket-prosthetic comfort and prevent complications with stress-shielding. In addition, the implant design needs to be biocompatible when press-fit into the residual limb to prevent post-surgery complications like infection. Therefore, looking into commonly used materials in the orthopedic market for implants is crucial to develop the stem and weight-bearing end of the device. The stem needs to be able to press-fit into the bone, therefore, the stem must contain

porous parts to allow for better osseointegration. The weight-bearing end needs to be able to handle heavy loads, while also including a surface area big enough to distribute the load evenly across the stump.

4.2 Design Concept Prototyping

To begin prototyping our group began with rough sketches. In these sketches our group focused on how we planned on connecting the implant to the bone and designing an interface to reduce stress concentrations in the soft tissue.

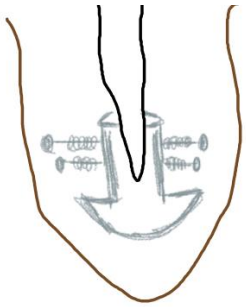

Figure 6. *Design to attach implant using collar around bone*

Figure 6 shows an initial design that would allow the implant to be connected to the bone. This design uses a collar that would wrap around the bone. The collar would then be pinned into the bone as shown in the Figure. However it was decided that any form of connection that wrapped around the bone would damage the periosteum. Damaging or covering the periosteum would cause the bone not to heal correctly following any fractures or damage to the bone. In conclusion our team determined that the implant must be connected using a rod that goes into the bone.

Figure 7. *Design to attach implant to bone using osseointegration*

Figure 7 features a design that uses a rod that is inserted into the bone to attach the implant. Very similar to total hip implants, the bone will be drilled out to a certain diameter and then a rod will be hammered into the bone with the same diameter to create a press fit. The rod will be coated in hydroxyapatite, a ceramic coat, that will allow the bone to grow onto the implant rod. This method of connecting an implant to the bone has already been widely practiced in medicine and is the best option for connecting our implant to the tibia. Using a rod that goes into the bone allows a solid anchor for our implant while not disrupting the periosteum on the outside of the bone.

The team then started to create different designs to maximize surface area and reduce peak stresses. One design idea featured a cup shape implant with a cushion liner on the bottom. An issue with this design is that the creases between the cups could result in high stress concentrations. The team decided that our design should be a smooth surface instead.

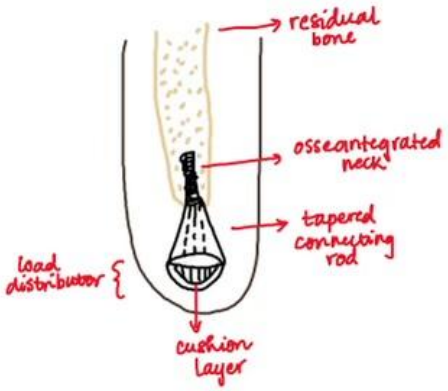

Figure 8. *Cup Shaped with Cushion Liner*

Another design the team considered was a cup shaped implant, seen in Figure 8, with an exterior cushioned liner. When we had a meeting with the doctors aiding the team they recommended using materials that were not rigid due to fatigue and deterioration over time. The implant is intended to maintain shape and function over long periods of time; Therefore our team decided not to go with a cushion at the face of the implant.

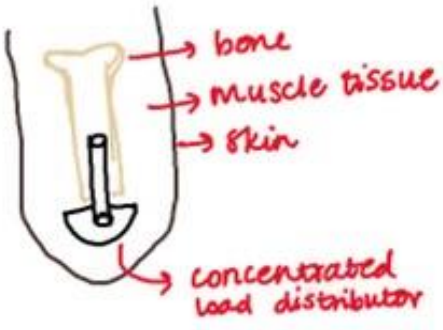

Figure 9. *Cup Shape design with no liner*

Figure 9 shows a very similar to the previous design however it does not have a cushion. The implant will be made using a biocompatible metal that will not deteriorate or fatigue over time. The only issue we found with this design is the gap between the implant and the bone. Our team determined that the implant should be flush to the bone to avoid sharp edges at the bone ending that could result in high stress concentrations.

Following all of our sketches the team began to build models using CAD software. These designs incorporate the positive aspects of the preliminary designs and leave out all of the issues the team found in our initial drawings.

4.3 Alternative Designs

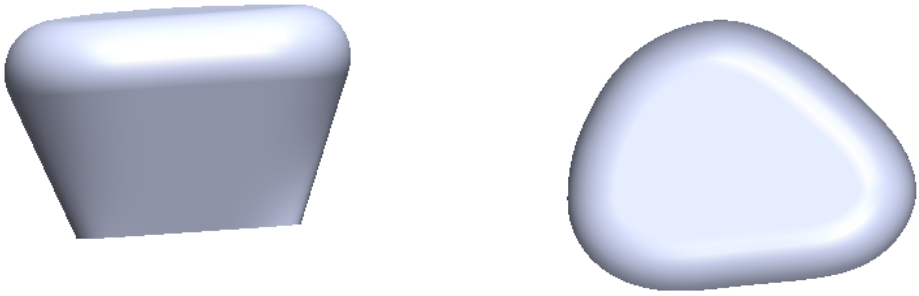

Figure 10. *Flat Tibia Shaped Implant*

Our tibia-shaped implant, seen in Figure 10, maintains the shape of the tibia however becomes larger at the face to increase surface area. The base of the design is tibial shaped and will sit on the tibia to avoid any sharp edges from being exposed. The implant becomes larger at the face that will be in contact with soft tissue to increase the surface area and reduce the stress

concentrations. The edges at the face are rounded off to avoid any sharp edges. This design only had one iteration as the team felt there were not any changes to be made to even out stress distributions.

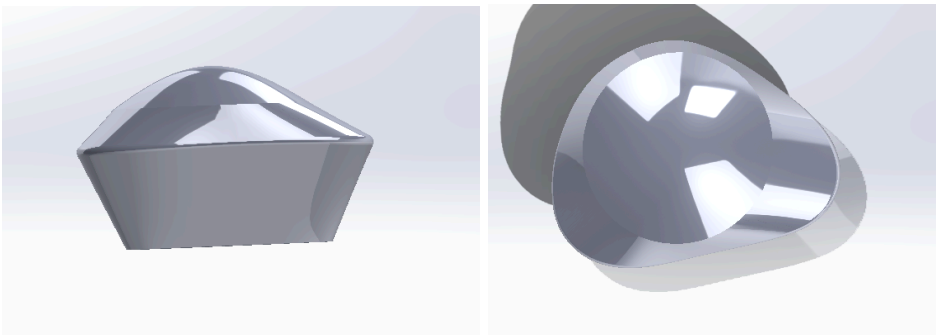

Figure 11. *Initial Turtle Shaped Design*

The turtle shell-shaped implant, seen in Figure 11, is very similar to the tibia-shaped implant, however, it includes a dome at the face to increase surface area every more. The doctors who have been helping our team liked the dome shape because it would create a good fit between the limb and the socket of the prosthetic. However, this design has sharp edges that the doctors did not like. The sharp edges could cause high-stress concentrations in those areas. For this reason, the design was altered to create rounder edges.

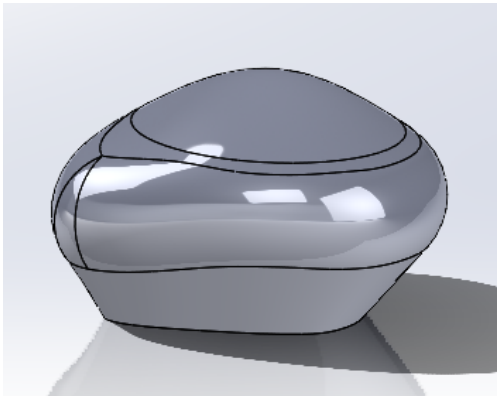

Figure 12. *Turtle Shaped Implant with Rounder Edges*

Figure 12 shows the second iteration of the Turtle Shaped design. By rounding the edges this design distributes stress more evenly throughout the soft tissue. The doctors liked this design a lot more with the round edges compared to the previous design.

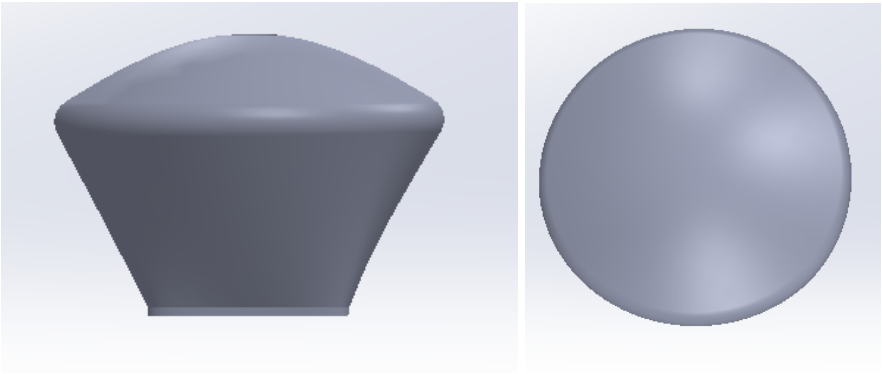

Figure 13. *Muffin Faced Implant*

The circular-faced implant design, featured in Figure 13, is tibia-shaped only at the very bottom for connecting it to the bone. The face of this design is circular with a dome at the top of it. The benefit of this design is that it will fit into the socket very well since it is circular like the sockets used in prosthetic legs. However, like the previous turtle design, our team was worried about the edges not being very round. We also found that this design was too tall and used a lot of unnecessary space that would make it more difficult for the doctor to wrap the soft tissue around.

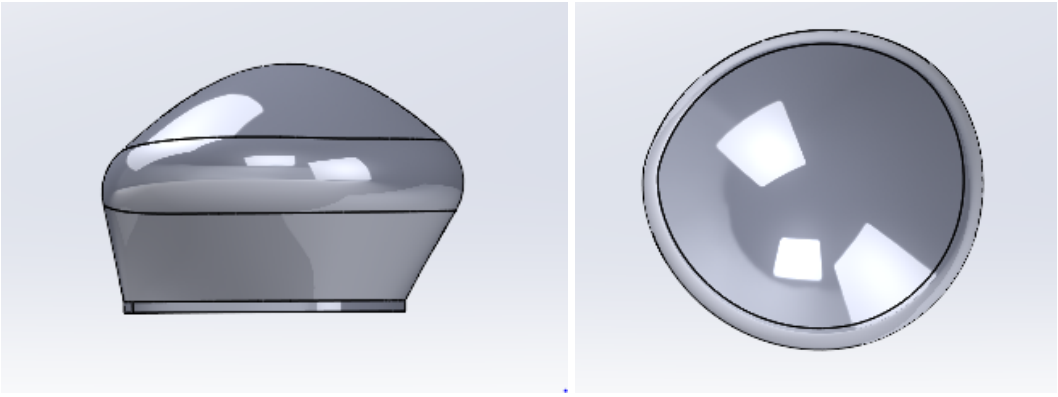

Figure 14. *Muffin Face Implant Iteration 2*

Figure 14 shows the second version of the circular implant features rounder edges and is also much shorter than the previous version. The sizing of the new design will make it easy for the doctors to wrap the existing soft tissue around. Rounding the edges will reduce peak stresses caused by this design. Additionally, this design will also be attached to the bone the same as the previous three using a morse taper.

4.4 Final Design Selection

Our final design selection is called the mushroom cap design. This was selected for our final design because of a combination of testing results as well as expectations from industry experts. Our two verification tests, finite element analysis and Instron testing using fuji film showed this design to distribute stress more evenly and reduce peak stresses more than any other design. Additionally, the two doctors we worked with for this project both expected this design to perform the best compared to all other designs.

The mushroom design is a spherical shell that goes around the bone ending. This design also uses a morse taper to attach the rod that will be implanted into the bone.

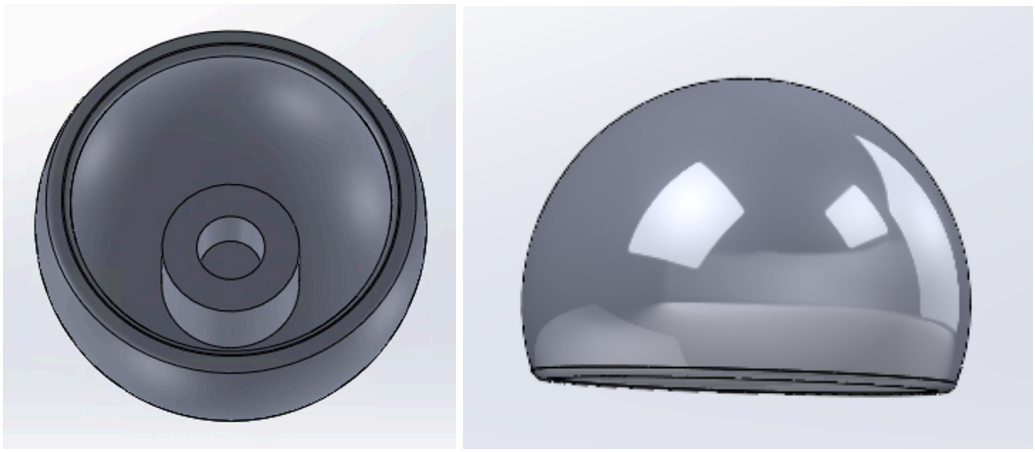

Figure 15. *Mushroom Cap Implant*

The design seen in Figure 15, was determined out best design through our testing methods found in Chapter 5. This design allows the bone ending to sit inside of it which reduces any small edges from overhang that the other devices may experience. We expected that this design will create a better fit between the limb and the socket as the ends of sockets have a similar shape.

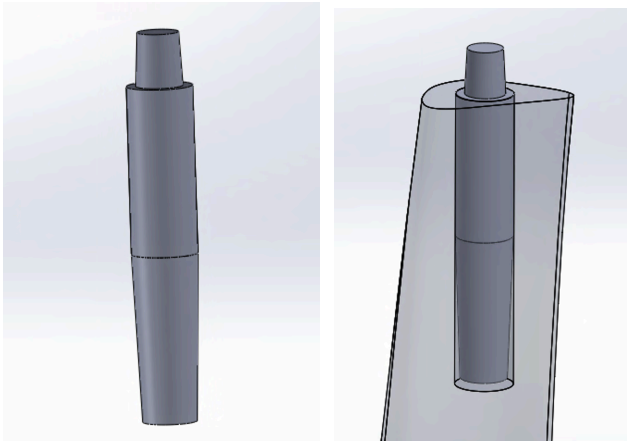

Figure 16. *Implant Rod CAD and Implant Assembled into the Tibia*

Our final design for the rod, seen in Figure 16, will anchor the implant to the bone and is 40mm long. We tested 3 different rod sizes at 40, 60, and 80mm using finite element analysis to determine the best length for the rod. It was determined the 40mm rod caused the least amount of internal forces and stresses on the bone. This rod has a 2 degree draft at the end and will be hammered into the bone. The diameter of the rod at the top half is 8mm which will match the hole drilled into the bone. At the very top of the rod is a morse taper that is 8mm tall with a draft of 3 degrees. This is where the implant will be attached to the rod. Morse taper is commonly used to connect two separate parts in medical implants by press fit. Since it is widely used in practice this is another aspect of our design that will allow us to follow the 510(k) pathway.

Chapter 5: Design Verification

5.1 Problem Description

To evaluate design validation and verification, our team used two parallel approaches to test our designs. The first method is using 3D modeling and FEA (Finite Element Analysis) to evaluate the differences in Von Mises Stress that the end cap piece causes on the muscle tissue. It was also used to validate the proper length that the stem of the device should be. In addition to the virtual testing, we developed a physical instron test method to verify the results seen in the FEA analysis. The effects of load-distributing devices on an amputated tibia, a model needs to be created to show the differences in Von Mises Stress, on the surrounding soft tissues with and without a device. Von Mises Stress is used to indicate the yield and failure of a material based on the combination of its shear and normal stresses. This provides comparable values for our models to show the differences in stress and stress concentrations.

5.2 3D Model Approach

When creating the model for our study, we wanted to use a case study to base our finite element analysis. In the research paper *Full Body musculoskeletal model for simulation of gait in persons with transtibial amputations,* a case study of a 75 kg and 170 cm tall male was used to simulate the gait of a person with a 50% tibia amputation [18]. The tibia model that was used in this study, Figure 17, was downloaded and used for our model.

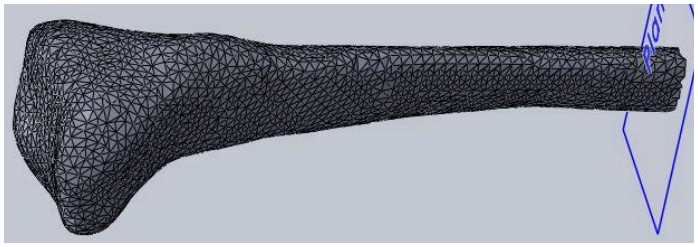

Figure 17. *Tibia Model*

The next step in creating the 3D model was to simplify the shape of the tibia for ease of computation. To do this an assumption was made that a 100mm cut of the tibia and a simplified geometry of the shape would be satisfactory for our FEA analysis. To simplify the geometry, the bottom face of the tibia was used to create a splined sketch that was then extruded 100mm (shown in Figure 18).

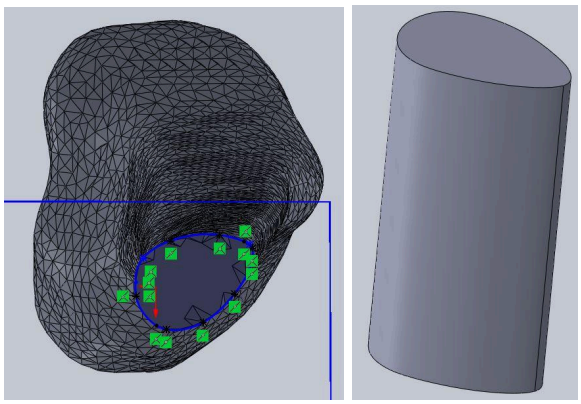

Figure 18. *Spline Sketch (left) and Simplified Extrude of Tibia (right)*

After the bone shape was simplified, the surrounding muscle was created. The shape and placement of the muscle were approximated based on the expert opinion of Dr. Wixted. The distance from the front edge of the tibia and the front face of the muscle is 6mm and can be seen below (Figure 19).

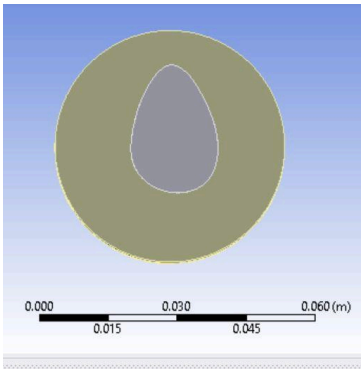

Figure 19. *Muscle Model Top View*

The muscle body has a 20mm muscle ending after the bone with a total length of 120mm. Finally, a model of a socket and an assembly of all the parts was created. It is assumed that the muscle and bone have direct contact at all points and that the bottom surface of the muscle is tangent to the socket. In Figure 20 below a sliced image of the model can be seen.

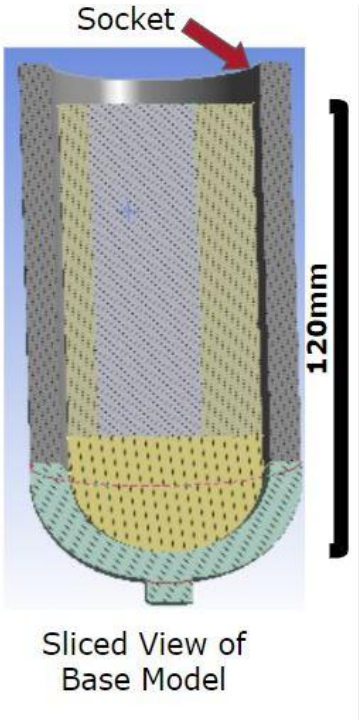

Figure 20. *Cut View of Final Model Assembly*

5.3 Finite Element Analysis Modeling

For the FEA Analysis, additional parameters needed to be added to the CAD model and used in ANSYS Static Structural application. The first step in this process was creating a new material library that included bone and muscle material properties. For bone the material properties were set with a .45 Poisson's Ratio and 17000 MPa Young's Modulus. For muscle, the material properties were set with a .49 Poisson's Ratio and a 1 MPa Young's Modulus (See Section 4.4.1 Materials). Once these properties were added to a library they were then assigned to the specific parts that they corresponded with. For simplification of the models, all medical device bodies (socket, load distributing cap, and rod) were given the material assignment of stainless steel.

Once this was done, meshing was automatically generated using ANSYS and the contacts were defined. The contacts were all defined as rigid except for the contact between the socket and the muscle which was defined as a frictionless contact. For the boundary conditions of the model, there was a cylindrical support condition used on the muscle to prevent movement in transversal direction (z-direction). Additionally, a fixed support condition was used on the bottom face of the socket to stimulate the ground reaction force of a step. Different loading conditions were set to simulate the forces of a step. The load for each study state was placed on the anterior half of the tibia. An image of this loading condition can be seen below in Figure 21.

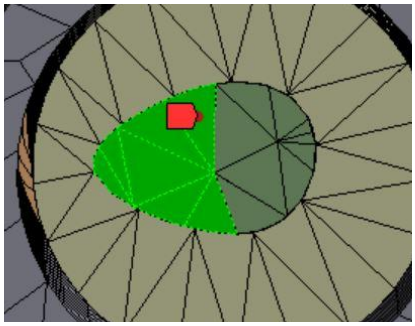

Figure 21. *Location of Force Applied on Tibia Highlighted in Green*

Three conditions were studied for these forces. The first condition had all force in the negative y-direction to simulate the standing state. A load of 735N was used to simulate the weight of a 75 kg individual. Two additional loading conditions were conducted to simulate the heel-strike and toe-off phases of the gait-cycle. For these cases the loads were evenly split in the y-direction and x-direction (negative x-direction for heel-strike and positive x-for toe-off). These study states can be seen below in Figure 22.

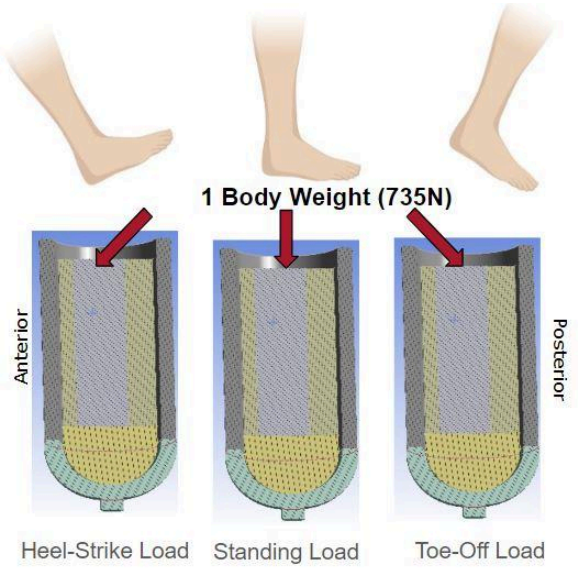

Figure 22. *Gait Cycle Graphic with Associated Load States*

This process was repeated with the mushroom, circular face, and turtle shaped designs comparing the peak Von Mises stresses to make conclusions about the devices effectiveness. Figure 23 shows the models of the top three device designs.

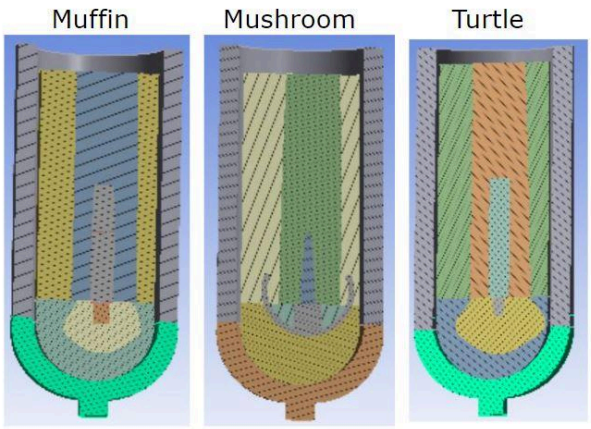

Figure 23. *Top Three Device Models*

5.4 FEA Results

The results of the FEA modeling were used to compare the percent change in peak Von Mises stress in the muscle body of the model. There were two different stress analyses done for each condition. The first analysis included the entire muscle body of the 120mm model. This analysis was used to make conclusions about the effects of the device on the muscle body as a whole and see if there were any unforeseen stress increases in the muscle body. The second analysis was done only on the muscle end because the focus of the device is to reduce stress concentrations in this specified region. Using the results from the FEA modeling it was able to determine the best design to move forward with. The total muscle peak Von Mises stresses and the muscle ending peak Von Mises stresses were analyzed. The scale of the stresses ranges from 0 KPa to 600 KPa. The results for the heel-strike load state for each model can be seen below (Figure 24).

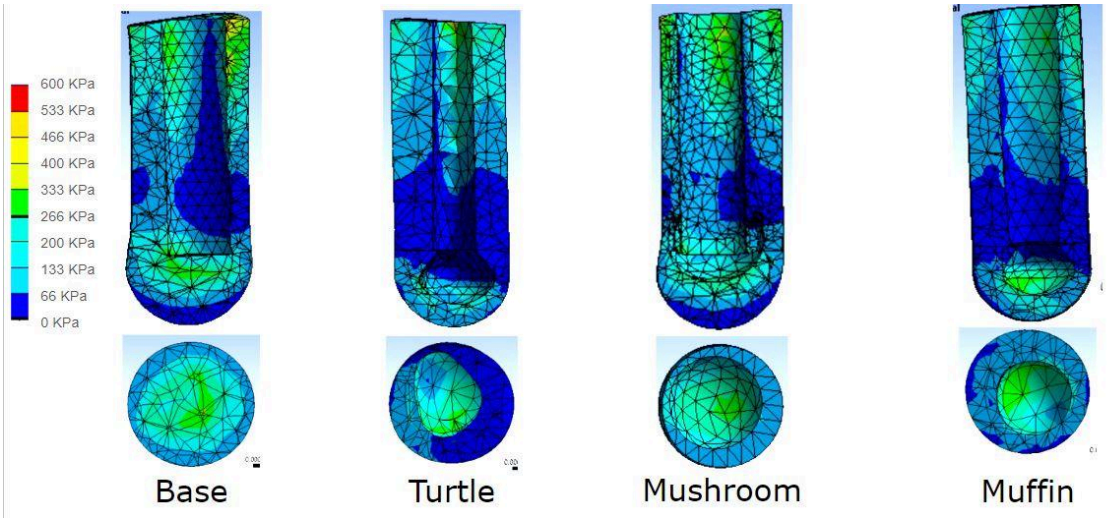

Figure 24. *Heel-Strike Models' Results*

The base model showed peak Von Mises stresses outlining the muscle directly under the bone ending which is indicative of the root cause of the peak stresses in the muscle ending. All three devices showed reduced stress in the muscle ending with the mushroom design showing the best results of 23% reduction. This stood true for the standing model as well. The mushroom showed a 18% reduction in peak Von Mises stress in the muscle ending and the results for all models can be seen in Figure 25.

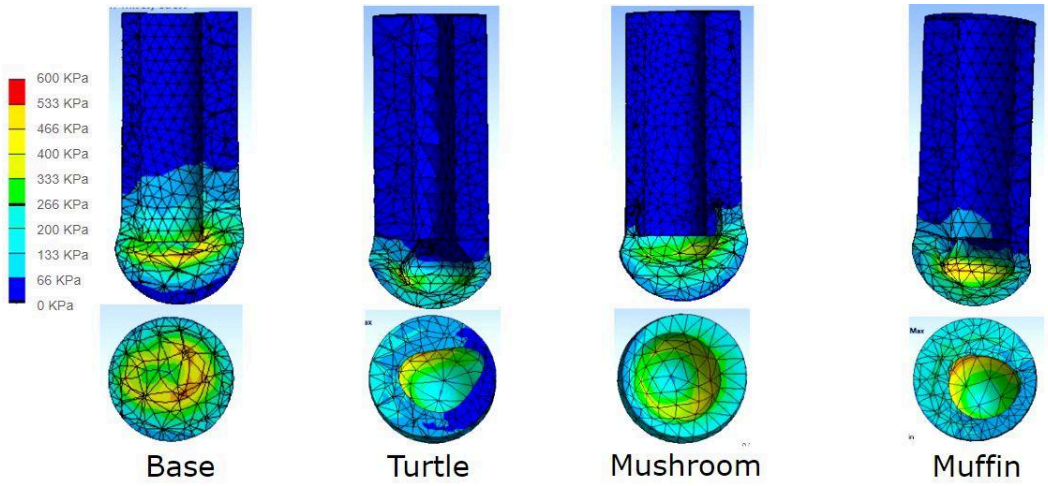

Figure 25. *Standing Models' Results*

The toe-off models showed similar results to the heel-strike and standing load phases. The mushroom design showed the best reduction in peak Von Mises stresses with a 30% reduction. Figure 26 shows the results for the toe-off load phase.

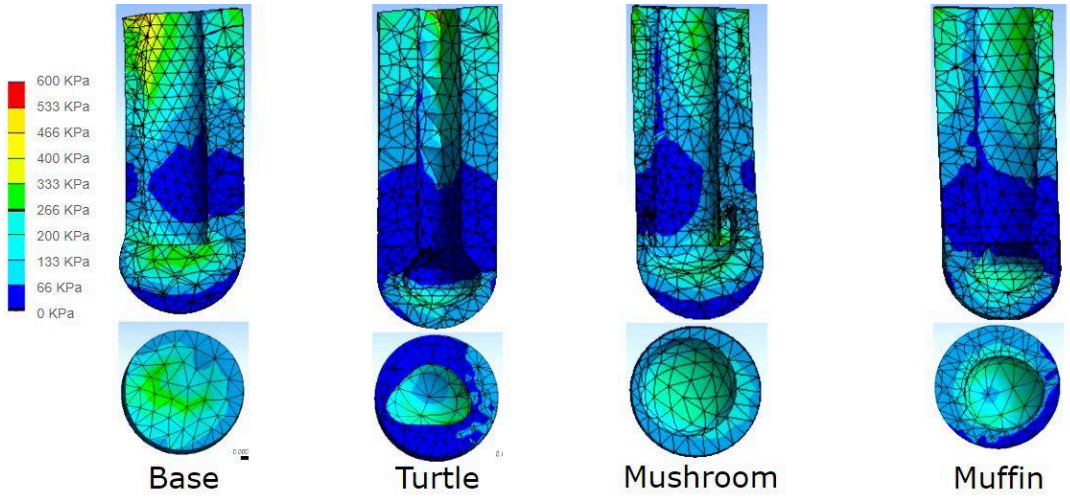

Figure 26. *Toe-off Models' Results*

Through all three load phases, the mushroom design showed the best reduction in peak Von Mises stresses in the muscle ending. The average reduction in peak Von Mises stress in the muscle ending by the mushroom design was 24% reduction. The peak stresses for each study instance and the percent reduction compared to the base model can be seen below in Table 7.

Table 7. *FEA Modeling Results*

Model	Study State	Total Muscle Von-Mises Peak Stress (Kpa)	Percent Change Compared to Base Model	Muscle Ending Von-Mises Peak Stress (Kpa)	Percent Change Compared to Base Model
Base Model	Heel-Strike	551.83	N/A	362.26	N/A
	Standing Phase	584.27	N/A	567.84	N/A
	Heel-Off	582.12	N/A	350.69	N/A
Mushroom Design	Heel-Strike	375.62	32%	280.82	☆ 23%
	Standing Phase	463.34	☆ 21%	463.34	☆ 18%
	Heel-Off	402.54	31%	247.22	☆ 30%
Muffin Design	Heel-Strike	320.82	☆ 41%	309.93	21%
	Standing Phase	528.46	10%	528.46	7%
	Heel-Off	371.07	☆ 36%	277.7	14%
Turtle Design	Heel-Strike	489.95	11%	300.59	17%
	Standing Phase	531.18	17%	531.18	6%
	Heel-Off	518.72	11%	329.56	6%

The stars in the table indicate the most reduction in each load case. As discussed before the mushroom showed the best percent reduction in peak Von Mises stresses in all three load states for the muscle ending. It also showed the best percent reduction in the total muscle for the standing phase. The muffin design did show a slight edge in percent reduction for the heel-strike and toe-off phases for the total muscle analysis but this is not the primary objective for our design. Figure 27 is a bar graph showing the differences in percent reduction for the muscle ending for each device type.

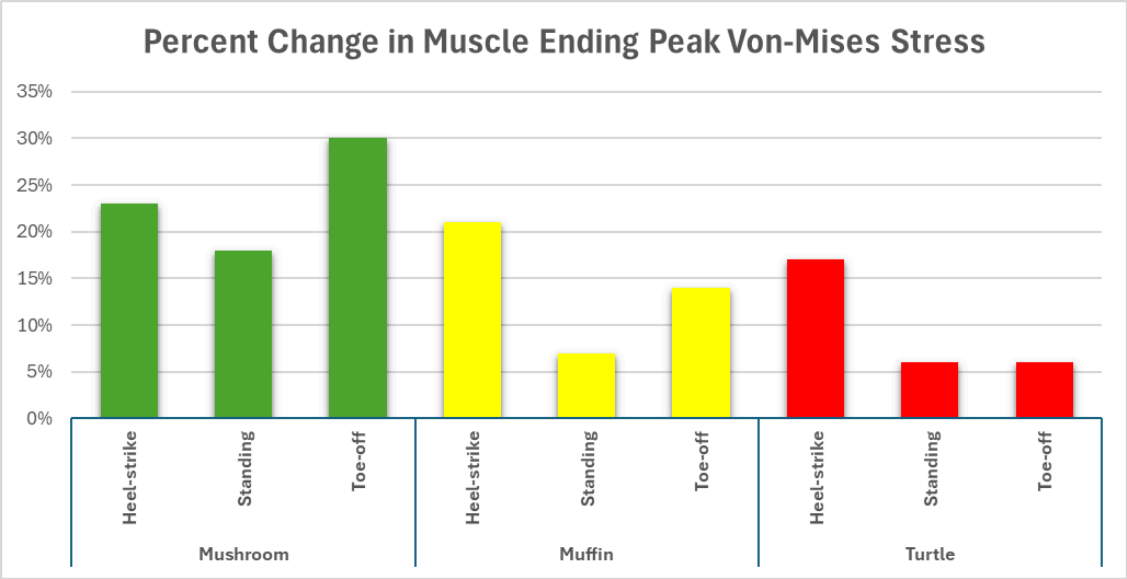

Figure 27. *Percent Change in Muscle Ending Peak Von-Mises Stress*

Through these results it was determined that the mushroom design was the most effective at reducing the peak Von Mises stresses at the muscle ending of transtibial amputations.

5.5 Instron Test Method

Evaluation of Pressure Distribution Using Fujifilm Prescale

1. Objective:

The objective of this test method is to evaluate the pressure distribution exerted by our 3D printed devices on a soft surface using Fujifilm Prescale, and an Instron universal testing machine. Fujifilm is a one time use pressure sensitive film that stains in red when pressure is applied to its surface. The red colored stain has different intensities that correspond to the amount of pressure on the film's surface. Using this method we were able to analyze the stains and determine the 2D surface pressure distribution of each 3D printed prototype and a 3D printed tibia.

2. Materials and Equipment:

- Instron universal testing machine with appropriate grips
- Fujifilm Prescale pressure-sensitive film super low pressure
- 4 3D printed prototypes an 3D printed tibia attached to blocks
- Supermarket-bought steak
- Saran Wrap
- Scissors

3. Preparation:
- Prepare the Instron machine according to Lab instructions.
- Prepare the steak by wrapping it tightly with plastic wrap to ensure a smooth surface.
- Label each device with their number, F (front), and B (Back).
- Attach the 3D printed devices to the Instron grips.ensuring they are securely fastened and aligned.
- Cut square pieces of Fujifilm Prescale slightly larger than the contact area of the 3D printed devices.

4. Test Setup:
- Place wrapped steak onto the lower Instron plate.
- Position the cut pieces of Fujifilm Prescale on top of the soft surface, directly under each 3D printed device.
- Ensure that the surface of the film is smooth and free from wrinkles or creases.

5. Test Procedure:
- Initiate the Instron test method programmed to apply a force of 100N.
- Lower the upper Instron crosshead to make the 3D printed devices be closer to the steak surface and activate the test.
- Once the instron reaches 100N, let the machine hold for 5 seconds before removing the load.
- Jog the upper grip, with the devices attached, back to the top.
- Carefully remove the Fujifilm Prescale from the steak.
- Repeat for each device.

5.6 Instron Testing Results

The results obtained from the Instron testing provided a comprehensive surface pressure analysis of our preliminary devices. Utilizing Fujifilm Prescale super low pressure, we evaluated how each 3-D printed device distributed pressure. To ensure accuracy, each device underwent 3 to 4 trials.

In some trials, slits were carefully cut into the Fujifilm to mitigate potential wrinkling during the application of force. Following the completion of each test, the films were arranged based on the sequence of testing and categorized according to their respective devices. We then took digital photographs using a flash to facilitate image processing in ImageJ. Refer to the image below for visual representation.

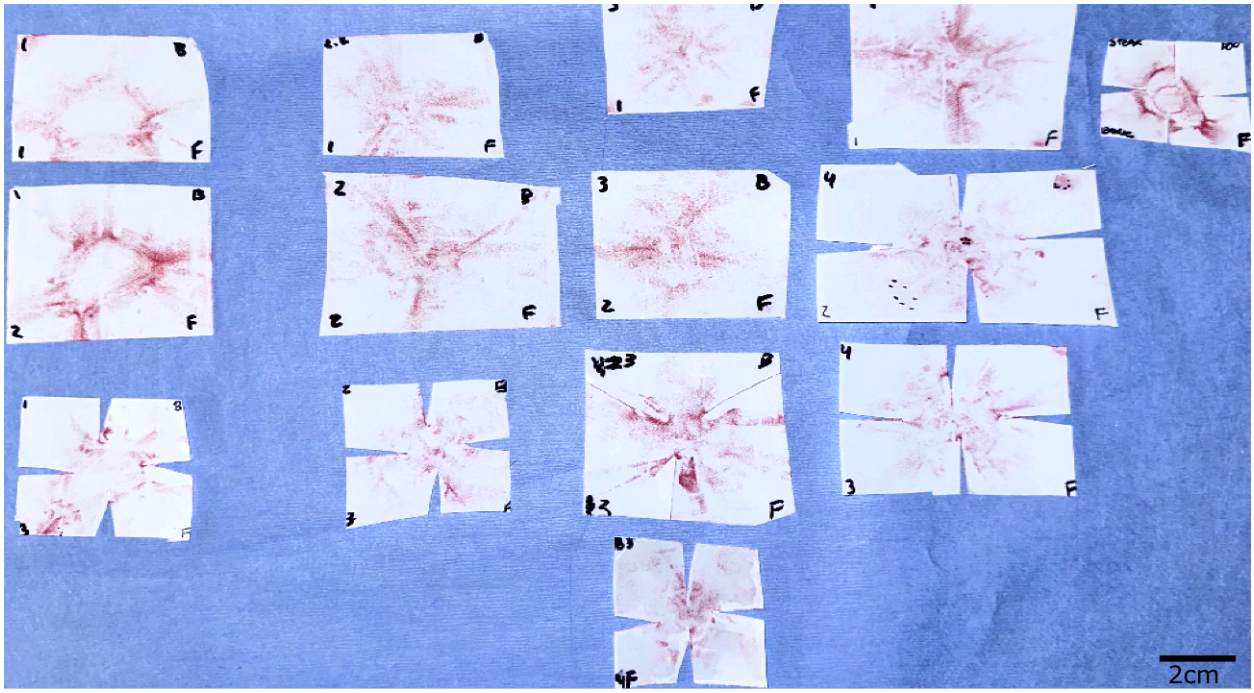

Figure 28 . *Fujifilm Results*

The picture was taken on an Iphone using flash. From left to right the films are laid out as flat, turtle, muffin, mushroom, and tibia.

The initial steps in quantifying our test results was to upload the image seen in Figure 28, along with a picture of the standard color sample provided with the Fujifilm prescale (Figure 29), onto imageJ. In imageJ we applied the 'Smoothe' effect and the 'Gaussian Blur' filter to selected sections of each film test. This was done to reduce speckling and to have smoother images, for better analysis. After that we converted both the 'Fujifilm Results' and the 'Standard Color Sample' to 8-bit, this transformed the images into a black and white picture. After that we used the 'rectangle' select tool to choose an area in each color. In the selected area, we obtained the 'measurements', which provide us the mean pixel intensity of each of the 8 colors. With the mean intensity of each color, we established a range of +/- 5 of the mean for each standard density. This enabled us to assign upper and lower bounds for the black and white thresholds.

For each design, we identified the most suitable Fujifilm test and cropped them individually for analysis. Using the 'rectangle tool', we selected specific parts of the image that were irrelevant and removed them using the 'remove outliers' option under the 'remove noise' tool. This ensured they wouldn't affect our analysis when applying the threshold. We then entered the minimum and maximum values into the threshold tool for each standard color sample. Table 8 shows the mean of each density and their respective ranges. This process outlined in black only the pressure associated with that particular standard color. We repeated this with each color that was appropriate for analysis.

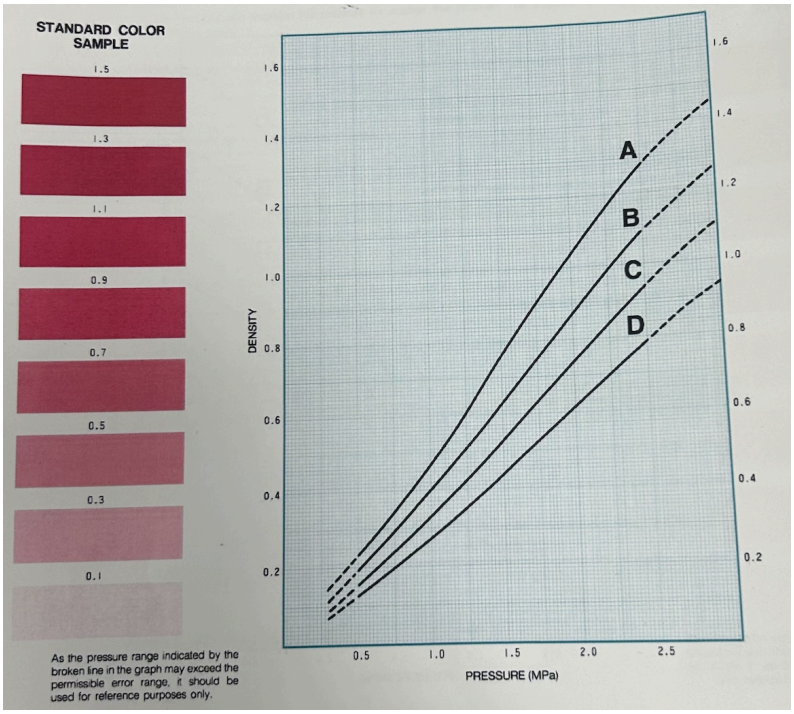

Figure 29. *FujiFilm Standard Color Sample and Pressure Chart*

The color sample (right) was used to interpret the pressure measurements obtained from our Instron testing. By referencing the color standards and their given density, we were able to approximate the pressure in MPa using the pressure chart (left). The lines A,B,C,D are different temperatures and humidity conditions, our group used line B.
The images below show each analyzed image corresponding to its respective threshold range.

Table 8. *Mean Pixel Intensity and Threshold Range*

Gray Scale	Mean	Range +	Range -	MPa
0.1	153.667	158.667	148.667	0.25
0.3	131.159	136.159	126.159	0.825
0.5	110.97	115.97	105.97	1.225
0.7	96.921	101.921	91.921	1.525
0.9	88.813	93.813	83.813	1.825
1.1	83.428	88.428	78.428	2.125
1.3	80.373	85.373	75.373	2.625

This table was created on Excel. The Gray Scale column shows all the standar color's given density. The Mean column is the pixel intensity mean for each standard in grayscale. The Range + column is the mean plus 5. The Range - column is the mean minus 5. The MPa column is the pressure in MPa for each standard color, it was found using the graph in Figure 29 (above).

For the tibia shaped flat design we performed a total of 3 instron tests. We selected test number 2 as the best for the ImageJ analysis. The results from the flat device show an uneven distribution in surface pressure across the flat device. There was high pressure mainly concentrated on the back right side, with moderate seen on the back left and front side. By analyzing the imageJ threshold images in Figure 31 (a), we observe a pressure of 0.25 in the black outlined regions, which highlights an uneven pressure distribution. The back and front edges also present a pressure of approximately 0.825MPa, as seen in Figure 31 (b). In Figure 31 (c) we see the pressure at 1.1225 MPa, and we can observe a concentration mostly in the back edges of the device. There are some regions in the outermost edges that have a pressure of 1.525MPa seen in Figure 31 (d). The Fujifilm results overall highlight an uneven pressure distribution, with a concentration on the back side of the flat design.

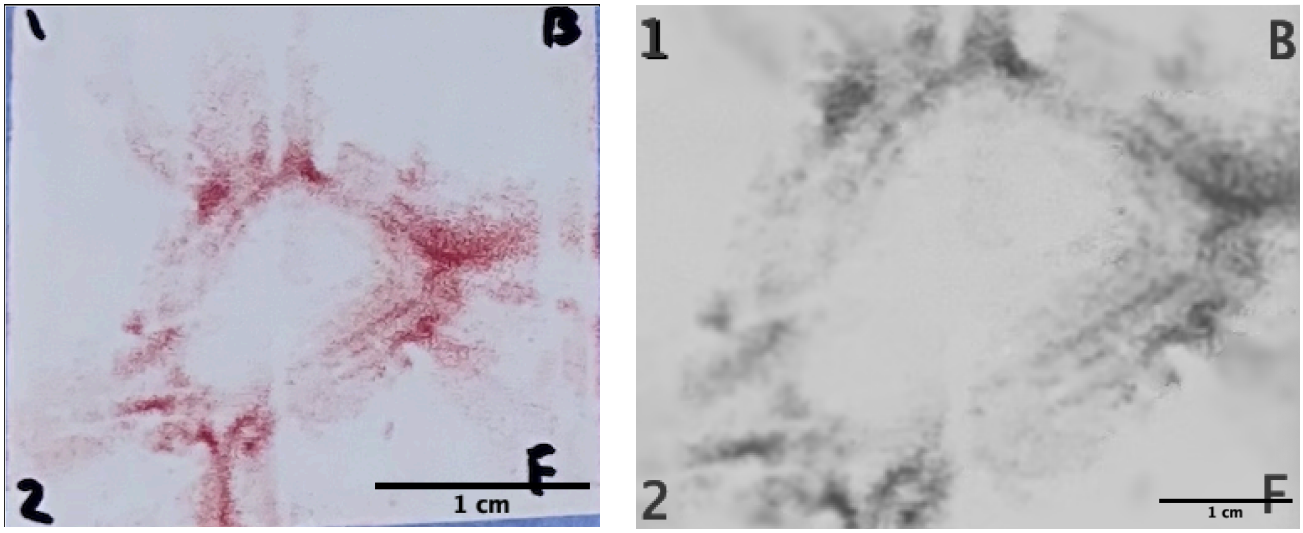

Figure 30. *Flat Design, Test 2, Original Picture and ImageJ Picture*

The picture on the left displays the original Fujifilm test image, cropped from the digital photo captured after testing. On the right is the same image converted to bit-8, filtered and edited on ImageJ. The label B and F stand for front and back, these were marked so the group could distinguish the position in which the device was loaded onto the Instron.

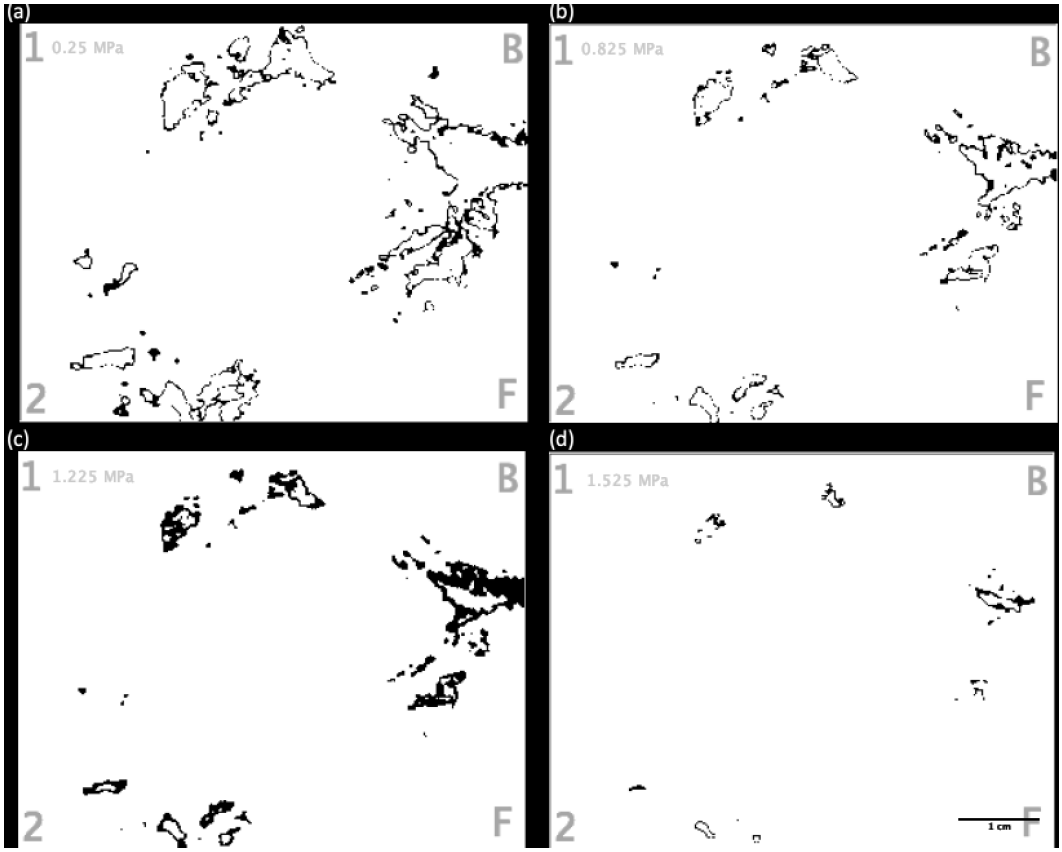

Figure 31. *Flat Design , Test 2, ImageJ.*

In ImageJ we set different thresholds that corresponded to each standard color pixel intensity. (a)This image had a minimum and maximum black and white threshold of 158 and 148, respectively. These thresholds outline in black all the pressures present in the film at 0.25 MPa. (b) This image had a minimum and maximum black and white threshold of 126 and 136, respectively. These thresholds outline in black all the pressures present in the film at approximately 0.825 MPa. (c) This image had a minimum and maximum black and white threshold of 105 and 115, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.225 MPa. (d) This image had a minimum and maximum black and white threshold of 91 and 101, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.525 MPa.

The turtle designs had a total of 3 Instron tests, and we selected test number 3 for analysis. The design exhibits a relatively even surface pressure distribution, with a minor concentration seen on the bottom front edge. In Figure 33 (c) and (d) we can see minimal black outlines corresponding to pressures at 1.225 MPa and 1.525MPa. Figure 33 (a) presents distributions in all 4 corners, with some distribution in the middle at 0.25MPa. In Figure 33 (b) we can observe a higher pressure predominantly on the right side, measured at 0.825MPa. This

higher pressure is on the middle, top and bottom edges. The analysis shows an overall better pressure distribution with a small concentration on the front right side of the turtle design.

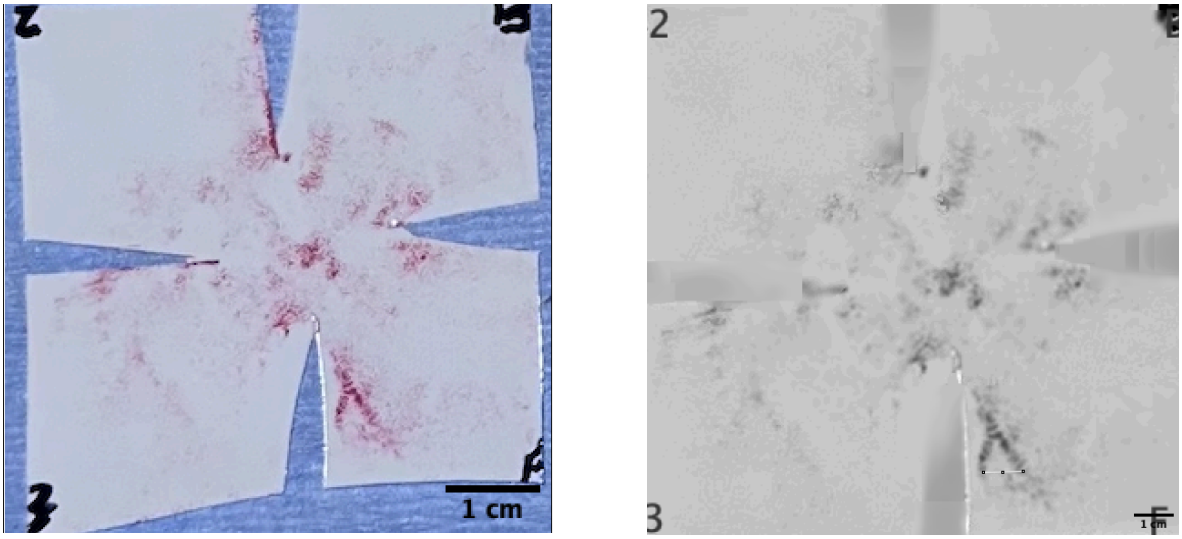

Figure 32. *Turtle Design, Test 3, Original picture and ImageJ Picture*

The picture on the left is the original Fujifilm that was cropped from the digital photo taken after testing. On the right is the Fujifilm image that was converted to 8-Bit, filtered, and smoothed out on ImageJ.

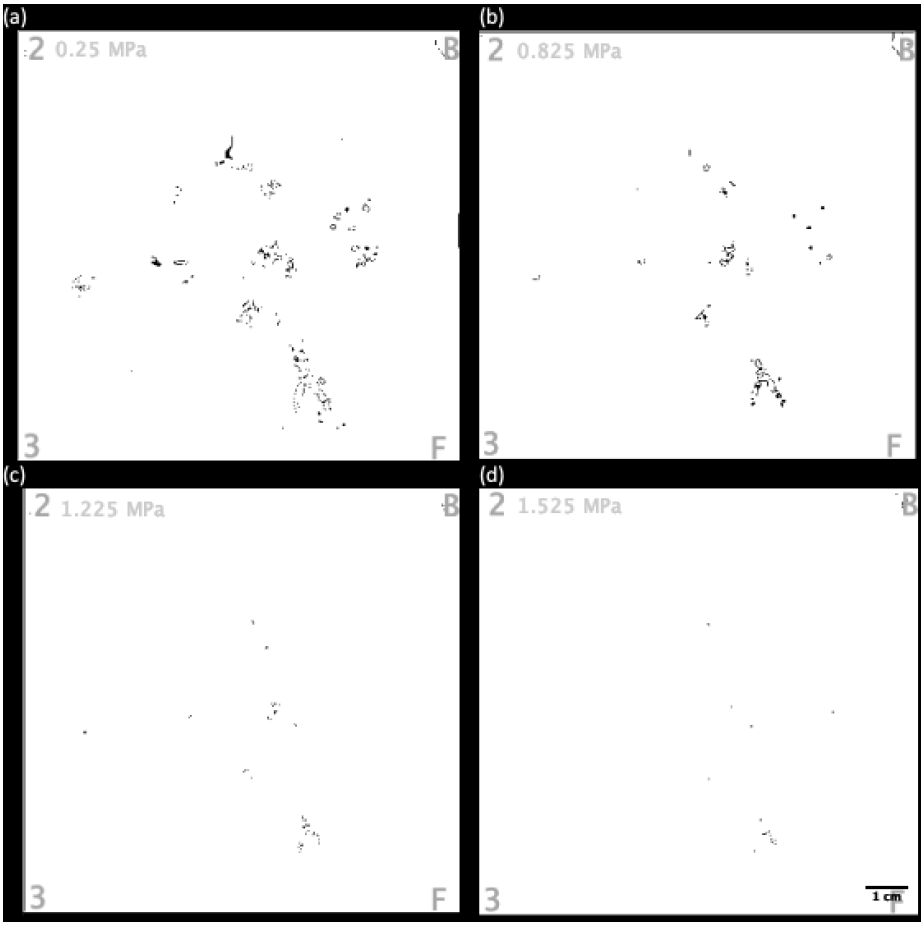

Figure 33. *Turtle Design, Test 3, ImageJ*

In ImageJ we set different thresholds that corresponded to each standard color pixel intensity (a)This image had a minimum and maximum black and white threshold of 158 and 148, respectively. These thresholds outline in black all the pressures present in the film at 0.25 MPa. (b) This image had a minimum and maximum black and white threshold of 126 and 136, respectively. These thresholds outline in black all the pressures present in the film at approximately 0.825 MPa. (c) This image had a minimum and maximum black and white threshold of 105 and 115, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.225 MPa. (d) This image had a minimum and maximum black and white threshold of 91 and 101, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.525 MPa.

We performed 4 Instron tests for the muffin design, with the 4th test being the optimal one for analysis. The design presents a significantly uneven pressure distribution with higher concentration on the back, but it does present low pressures. In Figure 35 (a), a high pressure distribution at 0.25MPa is evident mainly on the back edge of the device, with minimal outlines seen in the front. In Figure 35 (b) we observe less outlines, although some remain prominent

along the back edge, particularly on the back right, reaching 0.825MPa. In Figure 35 (c) there are less outlines but some on the middle and back corresponding to approximately 1.225MPa. In Figure 35 (d) minimal outlines are seen, just a few on the back edge with pressures peaking 1.525MPa. The data presents overall an uneven pressure distribution pattern for the muffin design.

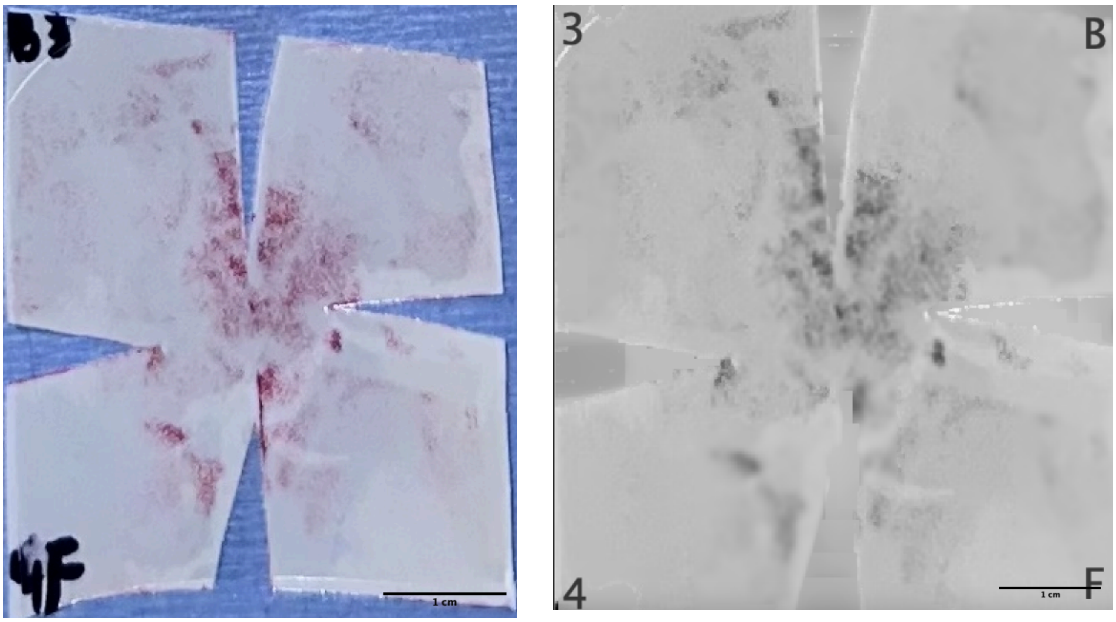

Figure 34. *Muffin Design, Test 4, Original picture and ImageJ Picture.*

The picture on the left is the original Fujifilm that was cropped from the digital photo taken after testing. On the right is the Fujifilm image that was converted to 8-Bit, filtered, and smoothed out on ImageJ.

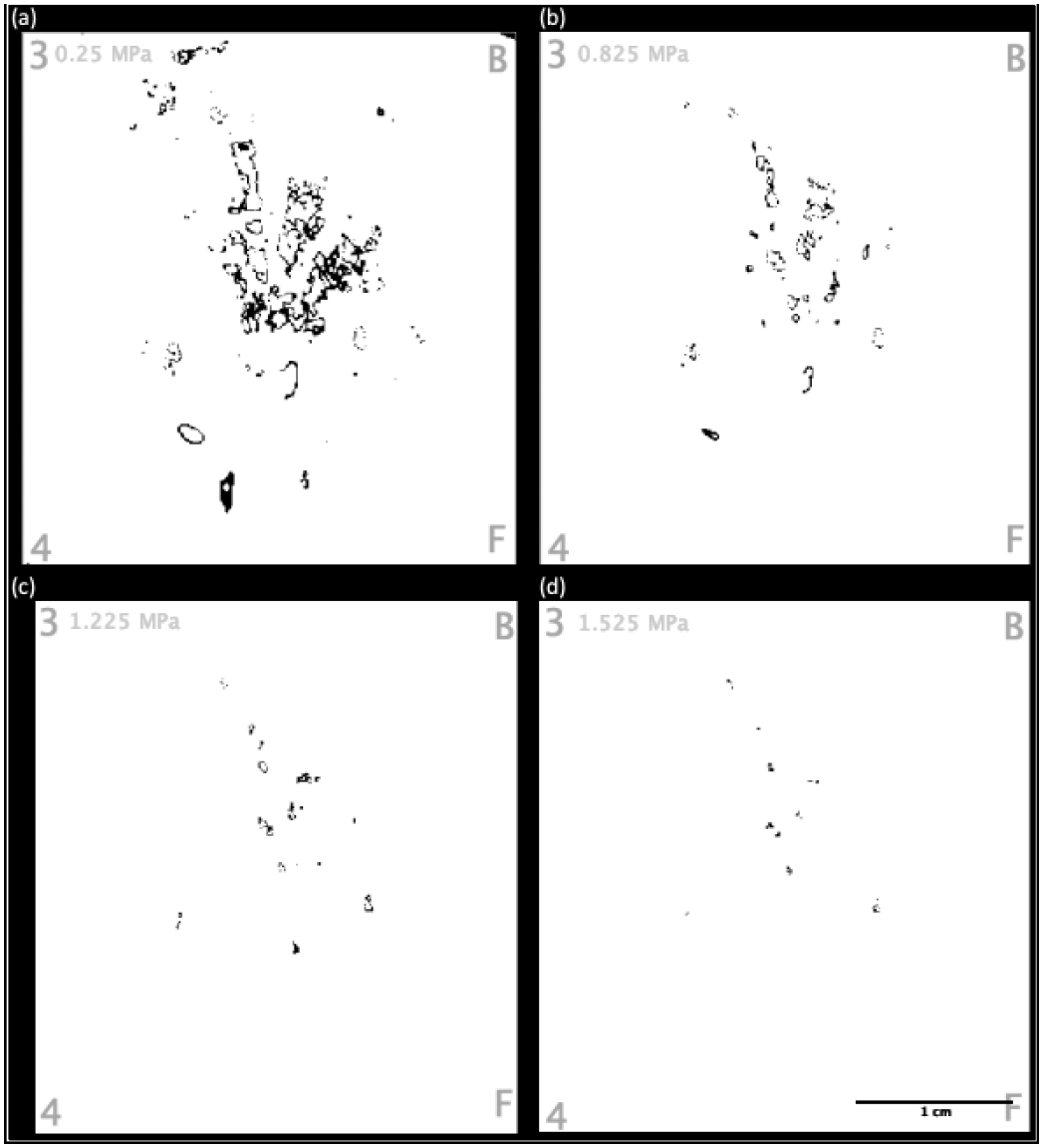

Figure 35. *Muffin Design, Test 4, ImageJ*

In ImageJ we set different thresholds that corresponded to each standard color pixel intensity (a)This image had a minimum and maximum black and white threshold of 158 and 148, respectively. These thresholds outline in black all the pressures present in the film at 0.25 MPa. (b) This image had a minimum and maximum black and white threshold of 126 and 136, respectively. These thresholds outline in black all the pressures present in the film at approximately 0.825 MPa. (c) This image had a minimum and maximum black and white threshold of 105 and 115, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.225 MPa. (d) This image had a minimum and maximum black and white threshold of 91 and 101, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.525 MPa.

The mushroom device had a total of 3 tests, and we used results from the 3rd test for analysis. reveals a remarkably even distribution of pressure, with low pressure readings across the surface. In Figure 37 (a) we observe pressures at 0.25MPa, with uniform distribution in all four areas and the middle region. A slight concentration of pressure is noticed on the right side. Figure 37 (b) shows minimal outline visible at pressures of approximately 0.825MPa. These outlines exhibit an even distribution throughout the surface, with no concentration. In Figure 37 (c) and (d) the outlines are nearly absent, with specks being seen in each area for pressures at approximately 1.225MPa and 1.525 MPa. Overall Fujifilm data presents an evenly distributed pressure pattern for the mushroom device.

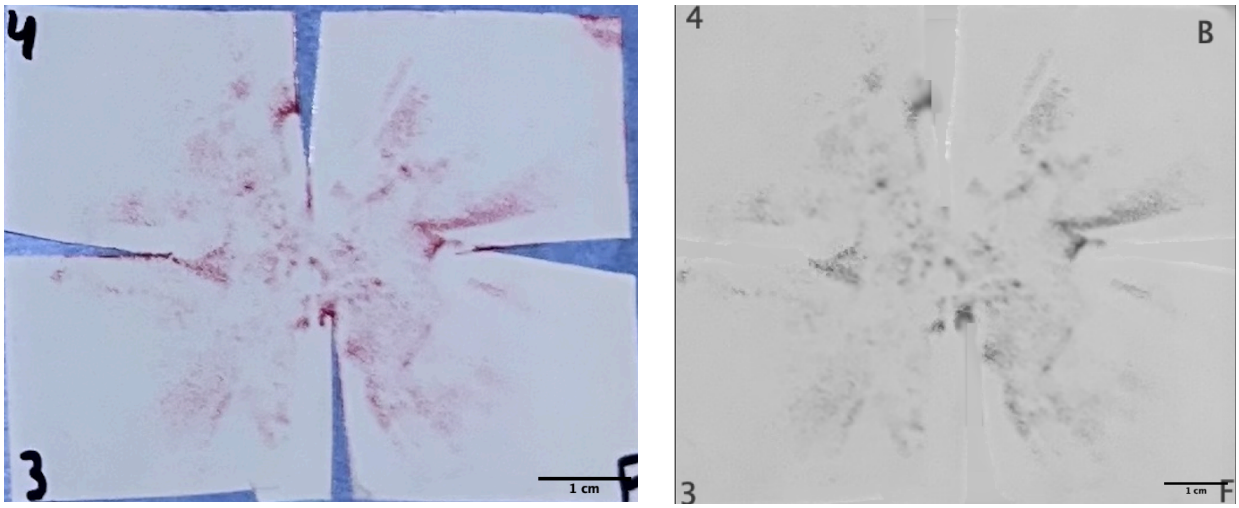

Figure 36. *Mushroom Design, Test 3, Original picture and ImageJ Picture*

The picture on the left is the original Fujifilm that was cropped from the digital photo taken after testing. On the right is the Fujifilm image that was converted to 8-Bit, filtered, and smoothed out on ImageJ.

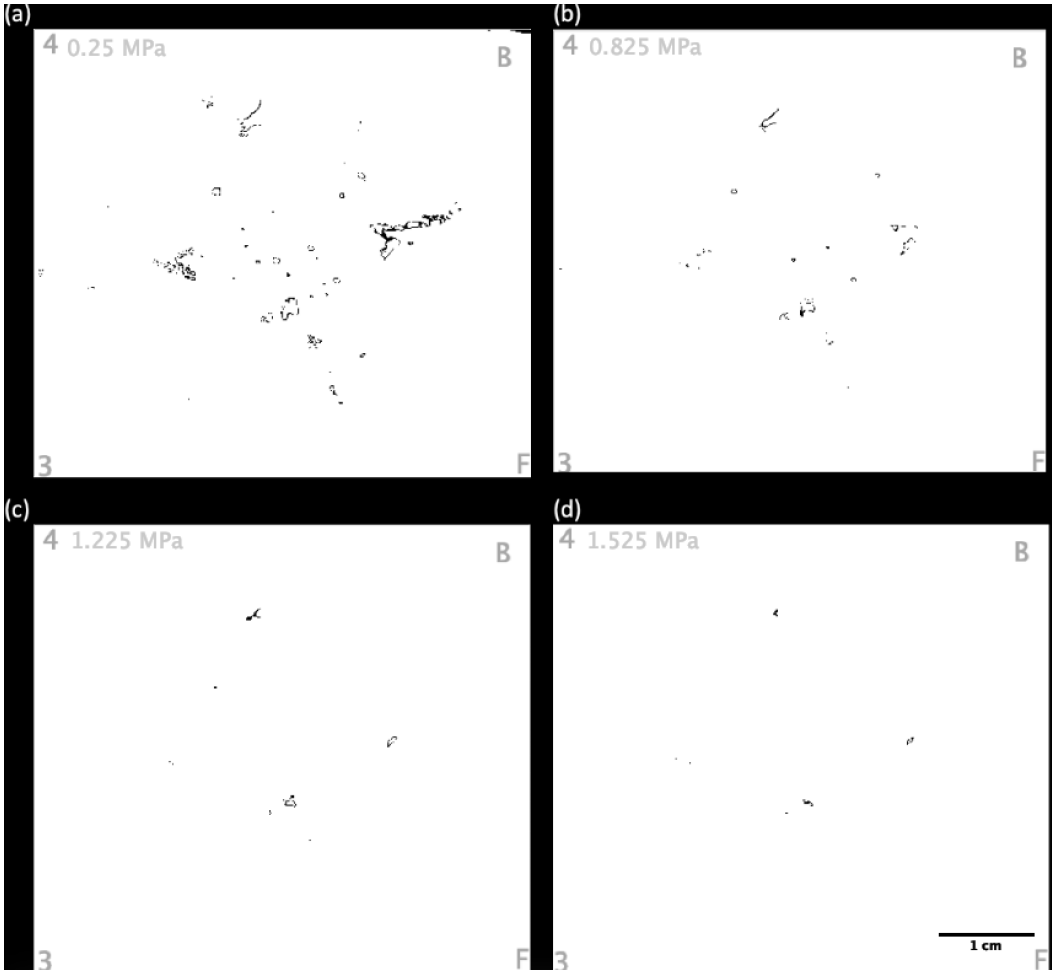

Figure 37. *Mushroom Design, Test 3, ImageJ*

In ImageJ, we set different thresholds that corresponded to each standard color pixel intensity (a)This image had a minimum and maximum black and white threshold of 158 and 148, respectively. These thresholds outline in black all the pressures present in the film at 0.25 MPa. (b) This image had a minimum and maximum black-and-white threshold of 126 and 136, respectively. These thresholds outline in black all the pressures present in the film at approximately 0.825 MPa. (c) This image had a minimum and maximum black-and-white threshold of 105 and 115, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.225 MPa. (d) This image had a minimum and maximum black-and-white threshold of 91 and 101, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.525 MPa.

We 3-D printed a tibia, using the same tibia from the case study mentioned in chapter 5.2 [18]. In the Fujifilm analysis, we can observe a non-symmetrical pressure distribution across the tibia. Figure 39 (a) outlines are seen in the corners and side edges, showing pressures 0.25MPa, with a particular focus on the front end of the bone. In Figure 39 (b), similar outlines are seen at

the same edges, with pressures at approximately 0.825MPa. Figure 39 (c) shows a continuation of the uneven distribution, with outlines persisting at the edges, and the concentration on the front edge at a pressure of approximately 1.225 MPa. Figures 39 (d) (e) (f) and (g) also display outlines on the front, back, and left areas, with that focus still on the front edge, with pressures increasing at 1.525 MPa, 1.825 MPa, 2.125 MPa, and 2.626 MPa. The Instron results reveal the uneven pressure distribution, with an extra concentration on the front edge of the tibia.

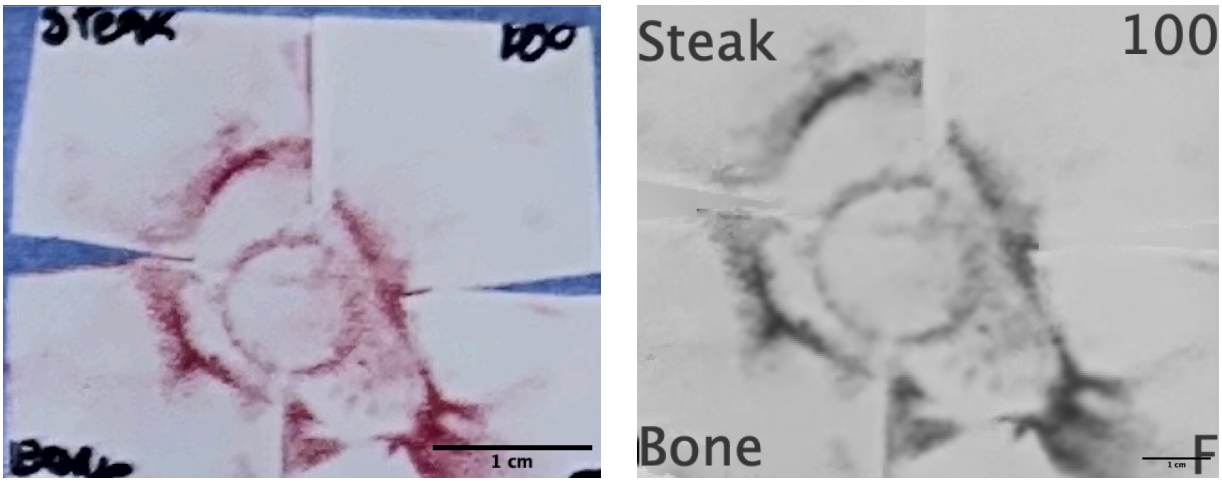

Figure 38. *Tibia 3-D Print Original picture and ImageJ Picture*

The picture on the left is the original Fujifilm that was cropped from the digital photo taken after testing. On the right is the Fujifilm image that was converted to 8-Bit, filtered, and smoothed out on ImageJ. The label 100 represents the 100N force used with the instron.

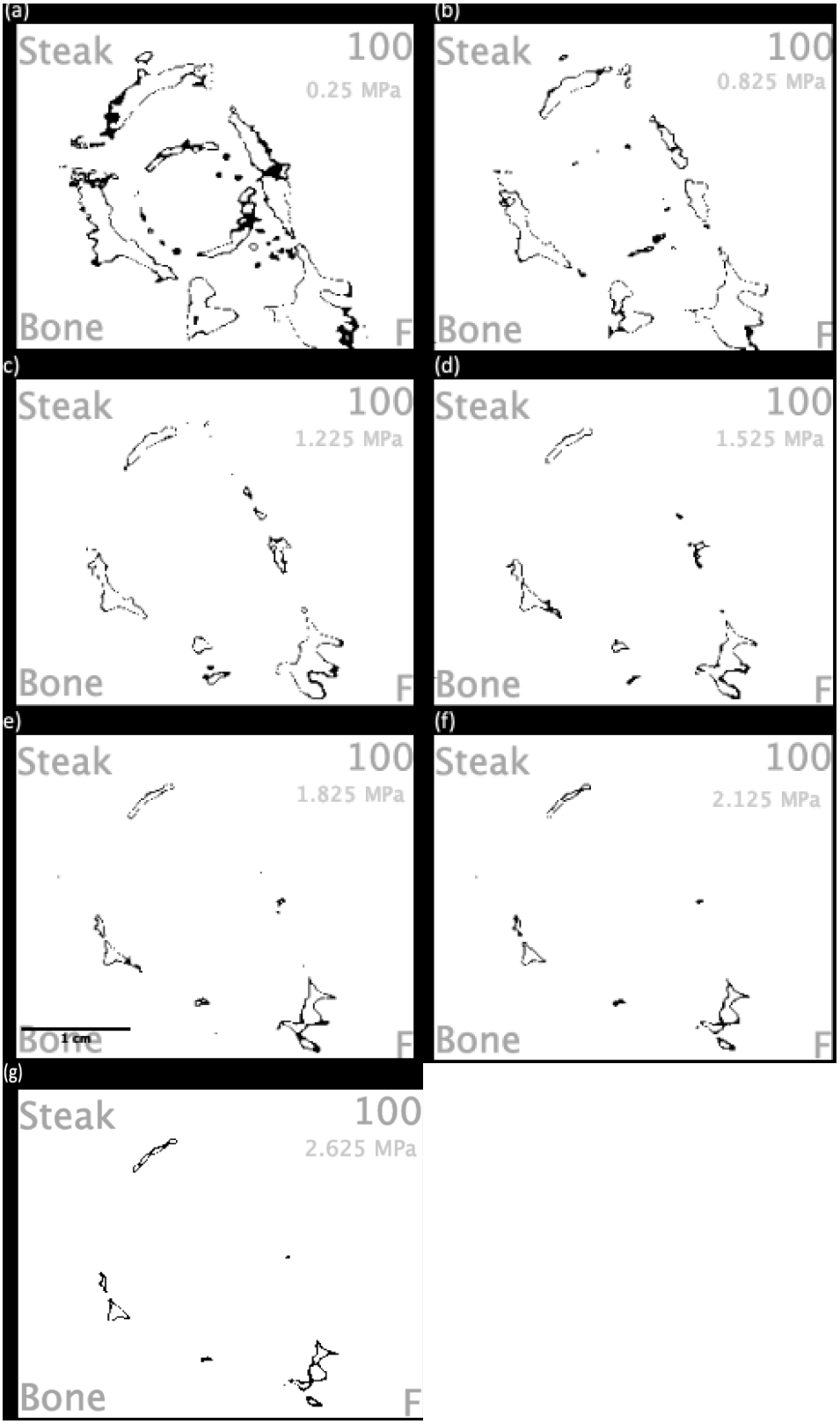

Figure 39. *Tibia 3-D Print ImageJ*

In ImageJ we set different thresholds that corresponded to each standard color pixel intensity. (a) This image had a minimum and maximum black and white threshold of 158 and 148, respectively. These thresholds outline in black all the pressures present in the film at 0.25 MPa. (b) This image had a minimum and maximum black-and-white threshold of 126 and 136, respectively. These thresholds outline in black all the pressures present in the film at approximately 0.825 MPa. (c) This image had a minimum and maximum black and white threshold of 105 and 115, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.225 MPa. (d) This image had a minimum and maximum black and white threshold of 91 and 101, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.525 MPa. (e) This image had a minimum and maximum black and white threshold of 83 and 93, respectively. These thresholds outline in black all the pressures present in the film at approximately 1.825 MPa. (f) This image had a minimum and maximum black and white threshold of 78 and 88, respectively. These thresholds outline in black all the pressures present in the film at approximately 2.125 MPa. (g) This image had a minimum and maximum black and white threshold of 75 and 85, respectively. These thresholds outline in black all the pressures present in the film at approximately 2.625 MPa.

To further analyze the surface pressure distributions we used the area tool in imageJ to find the total area of each Fujifilm result. Figures 40, 41, 42, 43, below shows the results of each design and the printed tibia in each standard pressure.

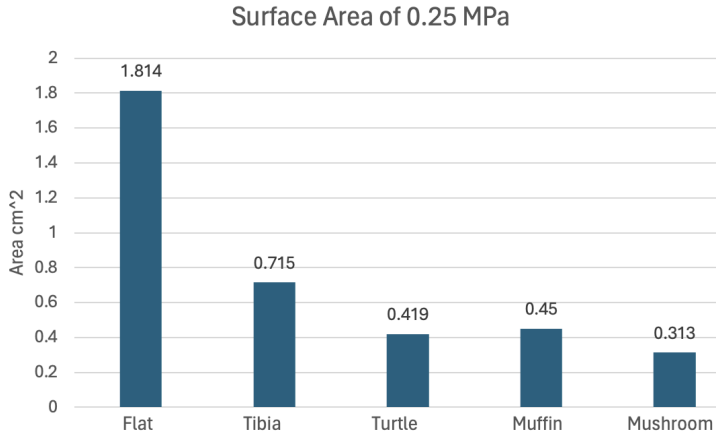

Figure 40. *Surface Area in 0.25 MPa*

The graph shows the results of the area measured in each fujifilm result at 0.25 MPa. The x-axis is labeled as each design and the y-axis is the area in cm^2. The flat design had the largest area by a significant gap with 1.814cm^2, the tibia had the second largest with a total area of 0.715 cm^2. The turtle and the muffin had similar areas with 0.419 cm^2 and 0.45 cm^2. The mushroom had the smallest area overall.

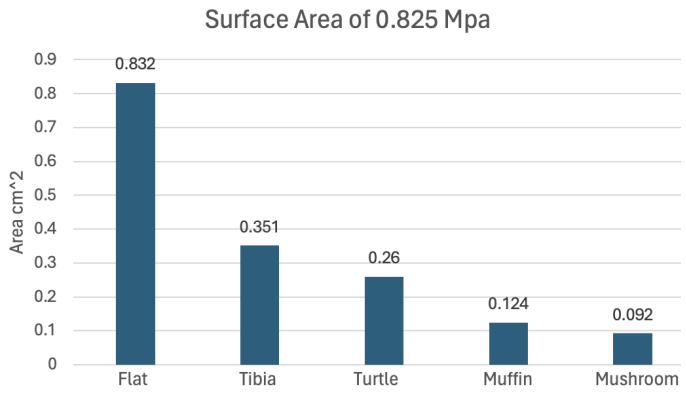

Figure 41. *Surface Area in 0.825 MPa*

The graph shows the results of the area measured in each fujifilm result at 0.825 MPa. The x-axis is labeled as each design and the y-axis is the area in cm^2. The flat design had the most significant area, measuring 1.814cm^2. Following that, the tibia had 0.351 cm^2, and the turtle had a total area of 0.26. The muffin and the mushroom had the smallest areas at 0.124 cm^2 and 0.92 cm^2. The mushroom had the smallest area overall.

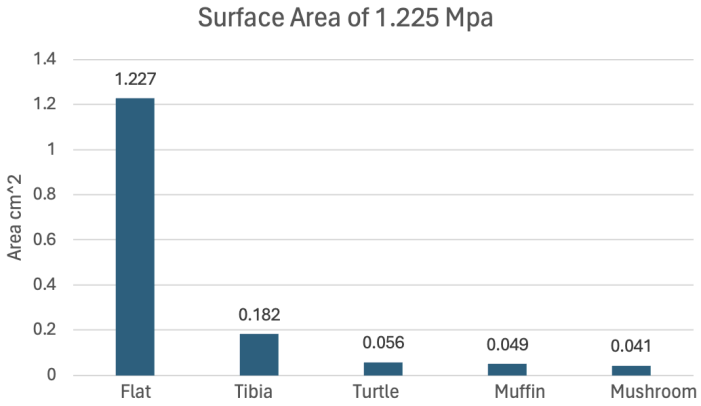

Figure 42. *Surface Area in 1.225 MPa*

The graph shows the results of the area measured in each fujifilm result at 1.225 MPa. The x-axis is labeled as each design and the y-axis is the area in cm^2. The flat design had the largest area by a significant amount, measuring 1.227 cm^2. The tibia was the second largest at 0.182 cm^2. The turtle, muffin and mushroom had significantly smaller areas at 0.056 cm^2, 0.049 cm^2 and 0.041 cm^2. The mushroom had the smallest area overall.

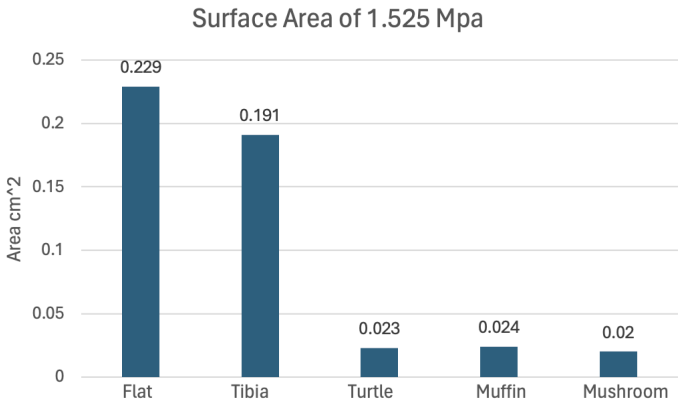

Figure 43. *Surface Area in 1.525 MPa*

The graph shows the results of the area measured in each fujifilm result at 1.525 MPa. The x-axis is labeled as each design and the y-axis is the area in cm^2. The flat design and the tibia had the largest areas by a significant gap at 0.229 cm^2 for the flat design and 0.191 cm^2 for the tibia. The turtle, muffin and mushroom had significantly smaller areas at 0.023 cm^2, 0.024 cm^2 and 0.02 cm^2. The mushroom had the smallest area overall.

Our analysis of the fujifilm prescale results further guided us to choosing the mushroom as our final design. Our findings revealed that the pressure distribution across the surface area of the mushroom design results were notably more uniform, with the smallest surface area in each standard pressure which suggests consistent low pressure readings. In contrast, the flat design showed us uneven surface pressure distributions, with the largest surface area across all standard pressures.

Chapter 6: Final Design Validation

6.1 Final Design Selection

Based off of the FEA, instron, and trauma surgeon survey results the mushroom design was chosen as the final design for our project. A survey was conducted with four trauma surgeons ranging from 2-25 years of experience and averaged 5-7 amputations a year. Each design was shown in the survey and questions about the ability of the device to distribute load were asked. The mushroom design had promising results and the survey and its results can be seen in the Appendix B. The FEA analysis showed the best percent reduction in peak Von Mises stresses in the muscle ending in all three load states. Similarly, the instron testing showed the best distributed load on the fujifilm and showed the least amount of area in the peak stress thresholds. This data showed that both physical testing and simulation modeling resulted in the

mushroom design showing the most effective load distribution of the stresses on the muscle ending under the bone.

Additionally, expert opinions on the survey conducted with trauma surgeons showed that surgeons believed that the mushroom design would be the most effective option. All surgeons voted for the mushroom design as the design they liked the best of our top three designs. Through our physical testing, modeling simulations, and expert opinions we came to the decision to go with the mushroom design.

6.2 Ethical Impacts

6.2.1 Economics

In the development of our device, we followed ethical principles that emphasize economic considerations and the well-being of individuals with an amputation. Advancements in medical technology and innovative implants, like our mushroom implant, can improve one's quality of life. Therefore, the team considered ethical aspects during our implant designing and development process to elevate the experience of people with a lower-limb amputation. We commit to minimizing disparities in accessing our device and making it affordable for a diverse range of individuals, regardless of socioeconomic status. In addition, encouraging insurance providers to prioritize the medical necessity of these implants and provide adequate coverage will help enhance one's life. We plan to market our device with all the information necessary for our consumers to understand the process that goes into the development of the product.

6.2.2 Environmental

Acknowledging the environmental ethics problems associated with the production and utilization of medical implants, we aim to minimize the ecological footprint throughout our implant's life cycle. In anticipation of future challenges, our design can incorporate materials and processes that align with responsible waste management and recycling practices. Our decision-making process includes a practical cost/benefit analysis, wherein we prioritize sustainability by promoting osseointegration with a press-fit Titanium alloy rod. This not only reduces the need for frequent replacements but also minimizes the environmental impact associated with prosthetic production. Furthermore, our device addresses healthcare disparities by being versatile and accessible, catering to a diverse patient demographic with four different sizes.

6.2.3 Social

Acknowledging the social ethics problems associated with the impact our mushroom implant can have on individuals with transtibial amputations and society, we followed ethical principles to ensure a responsible and equitable deployment of our device. An important initial

step to the equitable deployment of these implants is making them accessible and affordable to a broad range of individuals, regardless of their socioeconomic status. Our design process for the device is inclusive as we consider different demographics, anatomies, and health conditions. This is accomplished by developing different sizes for the implant, making it accessible for various groups. In anticipation of future challenges, we will inform individuals about the implant procedure, potential risks, and benefits, ensuring their decision is based on thoroughly understanding the process. In addition, we recognize that healthcare resources should be distributed evenly across different groups.

6.2.4 Global

Access to advanced prosthetic solutions represents a current global ethics problem characterized by disparities. Our design addresses this disparity by offering a solution to prosthetic fits, making a more affordable and accessible prosthetic option. In addressing the contribution to global healthcare disparities, our implant provides versatility and accessibility, catering to diverse needs and minimizing potential disparities in advanced prosthetic care on a global scale.

Chapter 7: Discussion

7.1 Accomplishments

The overall goal of this project was to develop an implant that addresses residual limb pain often experienced by individuals after receiving transtibial-amputation surgery. The implant is designed to enhance load-distribution and minimize peak stresses on the soft tissue near the bone ending in transtibial amputation. The team constructed a list of design objectives necessary to meet the goals of our implant design. The objectives to be met by the final implant design include the following:

1. Reduce stress between the bone-ending and soft tissue.
2. Reduce skin irritation by creating a better fit into the socket.
3. Biocompatible as an implant in the body.
4. Rigid interface between implant and bone.
5. Smooth interface between implant and skin.
6. Lightweight.
7. Reduce soft tissue/muscle used as cushion.

While developing our design prototypes, we wanted our implant to be constructed of two parts: a metal stem and a weight-bearing end. The metal stem will be inserted into the patient's bone using a press fit, promoting bone-growth into the stem. The stem will have a Morse taper that hangs out of the bone ends, allowing the weight-bearing end to be attached to it through a negative Morse taper. The implant will be made of biocompatible materials, fulfilling objective

3. The materials include using Styker's Restoration® Modular Ti6Al4V ELI, for the stem and Zimmer's Vivacit-E® Vitamin E Highly Crosslinked Polyethylene, for the weight-bearing (cushion) end.

Titanium alloy is known for its good biocompatibility, high corrosion resistance, and exceptional mechanical properties [7]. They also promote osseointegration, as it is press-fit into the patient's bone allowing for bone to grow into the implant, creating a rigid interface between the implant and bone (objective 4). Zimmer's Vivacit-E® is known for its compatibility with Titanium alloys, exceptional oxidative stability, ultra-low wear, and mechanical strength. This material will reduce the amount of soft tissue/muscle used as cushion (objective 7) near the bone-ending and promote a smooth surface between the implant and skin (objective 5). In addition, the lightweight nature (objective 6) of this material helps prevent skin irritation and minimizes further stresses at the amputation site, thus promoting successful rehabilitation following implantation. All the designs we brainstormed for the implant involved the use of the materials discussed above.

The weight-bearing (cushion) end was our primary focus because excessive stress between the bone ending and soft tissue causes long-term discomfort through weakening residual limb and damaging the soft tissue and socket interface. We created four implant designs (flat, turtle, muffin, and mushroom) with different surface areas to determine how surface area affects the load distribution and peak stress at the amputation site. The designs must have rounded off edges to prevent further pain, stress concentration, and allow for better socket fit (objective 2). In addition, the press-fit aspect of the implant allows for minimal skin irritation and infections due to improved comfort and stability. Each of the designs were tested through the Ansys FEA model and Fujifilm Instron testing.

The FEA model was used to compare the peak Von Mises stresses for each design to a base model (without the device) to determine the design's effectiveness at reducing stress between the bone-ending and soft tissue (objective 1). The peak Von Mises stress was analyzed for both the total muscle and specifically the muscle ends. The base model had a total muscle Von-Mises peak stress of 551.83 kPa, 584.27 kPa, and 582.12 kPa and a muscle ending Von-Mises peak stress of 362.26 kPa, 567.84 kPa, and 350.69 kPa for heel-strike, standing, and heel-off loading states. The Fujifilm Instron testing was used to determine the design with the best surface pressure distribution. The results from the tests were analyzed through ImageJ to identify the values of the pressures distributed by the various designs. Furthermore, the designs were ranked based on the number of design requirements they fulfilled to achieve the project's goal.

The flat design has a surface area of 1316 mm^2 and resembles the shape of a tibia. Due to the design having the smallest surface area, we concluded that it will not be able to enhance load distribution or reduce stress between the bone-ending and soft tissue. Therefore, we did not develop a FEA model of the tibia design to determine the effectiveness of the device. However, we conducted a Fujifilm Instron test on the 3D printed model to confirm our assumption about the ineffectiveness of the design. The findings from the test validated our assumption since the

tibia design had uneven pressure distribution across its surface. In addition, it presented high-pressure reading of 1.225MPa at the back edges of the device as seen in Figure 31 (Flat Design , Test 2, ImageJ). In summary, the tibia-shaped design is unable to fulfill objective 1, which is the primary goal of the project: to reduce stress between bone-ending and soft tissue.

The turtle design has a surface area of 2021 mm^2 and resembles the flat design, but includes a dome at the face to increase surface area. The outcomes from the FEA model presented the turtle design as the least effective at decreasing peak total muscle and muscle-ending stress compared to muffin and mushroom design. The results of the design compared to the base model displayed a 11%, 9%, 11% decrease in peak total muscle stress and 17%, 6%, 6% decrease in peak muscle-ending stress for heel strike, standing, and heel-off loading stances. This demonstrates how the turtle design is unable to fulfill objective 1, due to the minimal decrease in Peak Von Mises stress compared to the other designs. The findings from the Fujifilm analysis indicated relatively even pressure distribution for the turtle design. The design exhibited a low pressure reading of 0.25MPa in all four corners and a concentrated pressure reading of 0.825MPa on the right side as seen in Figure 33 (Turtle Design, Test 3, ImageJ). Despite the exceptional pressure distribution properties of the design, the FEA tests revealed the design's inability to decrease Peak Von Mises stress between the muscle-ending. Consequently, the turtle design fails to alleviate residual limb pain, eliminating it from being considered the final design.

The muffin design has a surface area of 1469 mm^2 and has a circular face to allow improved load distribution. The outcomes from the FEA model revealed that the muffin design decreased peak total muscle stress by 41%, 10%, 36%, as well as peak muscle-ending stress by 14%, 7%, 21% for heel-strike, standing, and heel-off loading states. These results show the effectiveness of increasing the surface area of the design, as it helps distribute the load, resulting in a decrease in peak Von Mises stresses. However, the findings from the Fujifilm analysis displayed significantly uneven pressure distribution, with high concentrations of 0.25MPa in the middle and 0.825MPa in the rear edges. The design expressed minimal presence of high pressures measuring 1.225MPa and 1.525MPa as seen in Figure 35 (Muffin Design, Test 4, ImageJ).

The mushroom design is a spherical shell with a surface area of 3330 mm^2. The outcomes from the FEA model presented the mushroom design as the most effective at decreasing peak muscle-ending stress by 23%, 18%, and 30%, as well as peak total muscle stress by 32%, 21%, and 31% for heel strike, standing, and heel-off loading states. The findings from the Fujifilm analysis supported those of the FEA analysis, indicating that the mushroom design was the most effective due to its uniform pressure distribution and consistent low-pressure reading of 0.25MPa across its surface. The design barely expressed any readings in 1.225MPa and 1.525 MPa as seen in Figure 37 (Mushroom Design, Test 3, ImageJ), further validating the results from the FEA model about the device’s ability to enhance load distribution and decrease peak Von Mises stresses. Although the muffin design had decreased peak total muscle stress better than the mushroom design, the main focus of our project primarily targeted the reduction

of peak muscle ending stress, as it is responsible for residual limb pain and skin irritation. The mushroom design demonstrated an average reduction of 24% peak stress on the muscle ending, making it the most effective option everall. Table 9 below summarizes how the mushroom design accomplishes the majority of our project objectives compared to the tibia, turtle, and muffin design.

Table 9. *Various Designs Compared to Objectives Achieved*

Project Objectives	Tibia	Turtle	Muffin	Mushroom
Reduce stress between the bone-ending and soft tissue	X	X	X	✔
Reduce skin irritation by creating a better fit into the socket	X	X	X	X
Biocompatible as an implant in the body	✔	✔	✔	✔
Rigid interface between implant and bone	✔	✔	✔	✔
Smooth interface between implant and skin	✔	✔	✔	✔
Lightweight	✔	✔	✔	✔
Reduce soft tissue/muscle used as cushion	✔	✔	✔	✔

The table above shows the objectives that were accomplished by each of the designs were marked with a "✔", while the objectives that the designs were not accomplished were marked with an "X". Out of the four designs, it is clear that the mushroom design was able to fulfill most of the objectives compared to the other designs. The mushroom design was not able to accomplish objective 2, reduce skin irritation by creating a better fit into the socket, since the team had time constraints to conduct tests on that aspect of the objective. However, our mushroom design is the most effective design compared to tibia, turtle, and muffin design due to the results from the FEA model and Fujifilm Analysis (see Chapter 5 for FEA model and Fujifilm testing and results).

7.2 Limitations

For the project, we tested all four of the designs, tibia, turtle, muffin, and mushroom, through our finite element analysis (FEA) and Instron testing analysis. Although the results from both the FEA model and Instron testing confirmed the mushroom design to be the best at

enhancing the load distribution and reducing peak stresses along the soft tissue, additional testing is encouraged to further validate its effectiveness. Our team started the project in August and had to finish it by mid April. Due to our limited time frame of 9 months and the fact that most team members were full-time students with additional full-time jobs, we faced significant time constraints. Consequently, we had to prioritize tasks and focus on efficiency. As a result, we were only able to complete compression Instron testing to validate our results from the FEA model. Rigorous mechanical testing such as fatigue, torsion, tensile testing, can help assess the structural integrity, durability, and performance of the implant in realistic scenarios, and we suggest these tests to be done in the future.

We tested the 3D printed model for all four designs in the Instron, instead of testing the recommended material the implant would be constructed off. The material used for the weight-bearing end, Zimmer's Vivacit-E® Vitamin E Highly Crosslinked Polyethylene, did not arrive on time during our testing period, preventing us from collecting data that validates the materials for our device. It is imperative to test the cushion end is necessary to monitor the strength, durability, and wear resistance of the material, ensuring a smooth interface between the implant and the soft tissue. Similarly, due to logistical limitations, we were unable to obtain Styker's Restoration® Modular Ti6Al4V ELI, for testing purposes. Testing the rod is necessary to monitor the osseointegration properties, providing a stable interface between the implant and the bone. Exploring alternative material options for the weight-bearing end may be beneficial in enhancing our mushroom implant.

We were unable to explore various sizing options for the implant due to time constraints, as we were focused on developing a working 3D model for FEA testing and physical testing to validate our FEA results. Additionally, we could not conduct tests to fulfill our second objective of reducing skin irritation by achieving a better fit into the socket. Since the project primarily focused on reducing peak stresses between the bone ending along the soft tissue, we needed more time to test the implants compatibility with the socket. Ensuring the socket interface is compatible with our mushroom implant design is necessary for the effectiveness of the device. This validates the impact of our device and the potential benefits for individuals with transtibial amputation once it is approved and available to the public.

Chapter 8: Conclusions and Recommendations

8.1 Conclusions

The overall goal of this project was to develop an implant aimed at enhancing load distribution and minimizing peak stress on the soft tissue near the bone ending in transtibial amputations. Our design incorporates a press-fit Titanium alloy (Ti-6Al-4V) rod connected to an highly cross-linked polyethylene end structure that maximizes load distribution, through an increased surface area. Styker's Restoration® Modular Ti6Al4V ELI is biocompatible and provides a rigid interface between the bone and implant, promoting osseointegration. Zimmer's

Vivacit-E® Vitamin E Highly Crosslinked Polyethylene is biocompatible, lightweight, provides smooth interface between the implant and skin, and reduces soft tissue used as cushion at the bone ending.

The team developed four different designs for the implant using the CAD software. They include tibia (flat), turtle, circular-faced (muffin), and mushroom. The primary focus while developing these designs included incorporating a larger surface area to allow for uniform load distribution at the amputation site. In addition, the design must allow for a good fit between the limb and the socket of the prosthetic. To evaluate which one of the designs allowed for an improved load distribution and minimized peak stress on the soft tissue, FEA modeling and Instron testing were used.

The 3D model created with and without the devices showed the difference in peak Von Mises stress surrounding the soft tissue. The base model (without device) was used to compare how effective the designs are in fulfilling our goal of enhancing load distribution and minimizing peak stress on the soft tissue. Each of the designs were analyzed under various loading states: toe-off, standing, and hell-off, allowing us to visualize the difference in peak total muscle stress and peak under bone muscle stress. The results from the FEA model recommended the mushroom as the best design for the implant compared to the other designs: tibia, turtle, and muffin. In the toe-off loading state, the mushroom design displayed a 32% decrease in total muscle stress peak and 23% decrease in under bone muscle stress peak. In the standing loading state, the mushroom design displayed a 21% decrease in total muscle stress peak and 18% decrease in under bone muscle stress peak. In the heel-off loading state, the mushroom design displayed a 31% decrease in total muscle stress peak and 30% decrease in under bone muscle stress peak.

We developed a testing method for compression tests on the Instron 5544 to further validate and verify the designs' data from the FEA model. Fujifilm captured the prints of how the pressure is distributed by the various designs. The results from the Fujifilm analysis indicated the mushroom design to be the most effective due to its uniform pressure distribution and consistent low-pressure reading of 0.25 MPa across its surface. Consequently, the analysis confirmed that the mushroom design is able to fulfill the primary objective of improving load distribution and minimizing peak stresses on the soft tissue at the amputation site.

During surgery, the mushroom device will be press-fit to the tibia as the stump is closed over the implant, unlike the osseointegration procedure where the implant is integrated into the bone. The press-fit method allows for faster healing since the amputation site remains closed, preventing risk for infection, implant failure, soft tissue complications, stress shielding, and the need for revision surgery. The porous surface of the Titanium alloy stem promotes bone growth. The rod includes a 8mm tall Morse taper extending from the bone ending, where the mushroom design (weight-bearing end) is fixed to the stem through a negative Morse taper within the mushroom. Overall, the mushroom design successfully accomplished all of our design objectives except reducing skin irritation by creating a better fit into the socket, as this aspect was not tested.

8.2 Future Work & Recommendations

Throughout the process of our project we were able to create a design that successfully reduced the peak stresses between the bone ending and the muscle tissue below based on FEA modeling results and instron testing. With that being said there is still further testing and simulations that could be run to better understand our product and optimize the design. For example a good step would be to do fatigue testing/ simulations using the specific material properties that we plan on using for our device. Additionally, we recommend that optimization testing is done that changes small aspects such as the thickness of the mushroom wall to see what these effects would have on weight and ability to reduce peak stresses. Eventually if this product were to go to market there would need to be proof that we did diligence to create a product that is as effective and safe as possible and pointing towards further testing would allow for this to happen.

It is also recommended that if our product could be optimized that we could bring it eventually to market. The overall goal of this project was to help transtibial amputation patients with pain they experience in their muscle ending and this can not be done without the product coming to market. To do this it is recommended to follow the 510(k) pathway and produce the appropriate documentation for the device to become approved.

Lastly, it is also recommended to look at the possibility of creating another device that would pair with our device. During our research it became apparent that there is also a market need for improvements in liner design. The current liners are not breathable and cause complications such as skin irritation and infection. It is recommended that a liner be developed that innovates a way to reduce these complications while also modeling the shape of our device. The goal of modeling the liner to mirror the shape of our device would be to create a pair of devices that when working together create an innovative way to reduce the most amount of post amputation complications as possible.

Appendix:

A. Douglas Interview

Interview with Douglas Transcript
September 18, 2023

Team
00:00:04
So our first question was just kind of about the process of you choosing a prosthetic and then most importantly, more specifically about choosing your interface.

Douglas
00:00:14
Okay, so I have a couple of things. So if I'm talking about like the actual process of what it takes to go through building one, actually just recently, like this is brand new for me. Like I just received this one. So Most of the time It's not the actual user that gets to choose the design or the specifications of a prosthetic. Most of the time it's up to the prosthetist himself or that self. And that's mainly just because most of the time their experience is always going to trump your ability to really understand what goes into making a prosthetic. you know, as far as like, when it comes to finding and like searching for a prosthetist, like I've always stuck with the same person. I've been with the same guy for I think over 14 or 15, you know, like long time like over a
decade basically and You know, he just he knows me really well, I know him very well There's
like a trust that goes on and he also very much understands like what needs to go into
the design of the prosthetic so They start off by obviously they start off with casting
Casting is still very commonly used as much as you know new technology comes out like with
3d scanning and molding and like printing things as far as that goes like it's still a really
expensive process it's a high upfront investment and in terms of like actual accuracy it's debatable because what ends up happening is with the 3D modeling you will get a more accurate to like in terms of measurement of the limb but you have no moldability in like your hands right? one of the biggest things that I think that my prosthetist does really well is he's able
to create the cast and then as it's starting ,to harden, right, because as the cast cools
down it starts to harden, he's able to shape the mold in a way that I'm able to stand on
it and feel supported and comfortable. So it's not just about creating an outer layer outside
of this, it's about creating like bottom where I can bear weight, right? Also avoiding like,
avoiding like bigger spots in here. So for me, like I have a really sharp bone that runs
down the right side here. So if I have any kind of weight on it, it actually hurts a lot.
So to avoid that, they're able to create the mold to be able to like fit around it essentially,
and that's a really big deal. Also as far as like knee, You have like, basically it's not
just covering the knee, it has to support the knee as well. So the knee needs like pressure
points here essentially. And they can do that when they use the calves with the thumb. And
so they can mold around the knee and create more accurate casts essentially. And so that's
one of the main things that I've gone to appreciate the most you know, technology isn't always gonna be the best for people. And I think that it shows just because you also have like the craftsmanship, like, you know, the whole factor as well. That you have to consider when you come to building a prosthetic, right? Not everything is gonna be about numbers. Most of it is actually just about feel. So that's like a really big

deal for me. And then as far as like... Like design goes, again, like I said earlier, it's really up to the prosthetist, but it also comes down
to what you're looking to do with it. If it's for daily wear, active wear, I mean we have
like swim legs now, like waterproof ones, like iit really comes down to that. Right. And so based on those parameters, as well as, you know, you also have limb length too. I happen
to have like a lot of my shin. So when it comes to that, I have very limited space to create
an interface between my socket and my foot. Right. So I can't actually, so some people,
if they have a higher up, if they're amputated higher up, they'll have space for like, I don't
know, like, I guess you could call it like kind of like, suspension where you it'll piston
up and down and start mitigating force you'll set rotators so people who like need help like
walking or if they play a sport in which they need to twist like oh there's a lot of torque
going into the ground it actually helps them like really load into the right side and use
the right side as much as they can or in my case the right side into the prosthetic side
so like a lot like those are just some of the factors that I think are the main factors that come into when
you're building a prosthetic. And then after that, it's basically all hands off. They create a check socket out of usually plastic fiberglass. They'll test fit it. And then they'll mold it into the first carbon fiber model. And then just so you can put some weight onto it and test it out if any adjustments need to be made in terms of how flat your feet
line kind of thing. For me, it's always beena little bit more difficult because I've had the limited space. It's been harder to adjust. Like I need to like be pretty spot-on from earlier on to be able to adjust like how my foot is oriented So that I put the a good amount of force and it doesn't affect my gait So like if it's built incorrectly sometimes what will happen is when you take a step It'll push your knee inward, which is not really good. You want it to stay in line as best you can It's just things like that. Yeah And yeah, the whole process, I think on average, takes about a couple of months to really get the whole thing through. I'm like really picky too, so... Yeah. Mine usually takes a little longer. I always try to send it back.

Team
00:06:54
How many times do you like send it back?

Douglas
00:07:00
On average for me, this one took an unbelievably long amount of time. Just because I kind of got lucky, my last prosthetic I actually had since high school. And even though I outgrew it, it was built... so well that it actually still fits me and so it was like really comfortable and like it was
really hard for me to like get into prosthetic with a new one and like feel comfortable yeah
it was very you know it's a weird concept but like when it comes to like familiarity and things
like that that's also really important as well yeah I mean the other challenge was this is
also a new design for me so my last prosthetic was an interface that came from the bottom,
right? So it would attach directly to the bottom and then I have the foot basically come out
of the bottom more like a traditional sense. This one is a posterior mounted prosthetic foot.
So the main reason why we went to this model, this design for the new one, or the main reason
why I wanted to try it is because I kept breaking my last prosthetic. So the carbon fiber foot,
I have so much shin that there's actually alot of leverage when I push into the ground.

So if I'm playing sports, I actually have a tendency to split the carbon fiber in the foot.
And I think I've done that around five times in the last two years, which gets really expensive
because those feet are not cheap and like, you know, insurance obviously isn't really happy
with it. So I and for me as well, like, you know, I've when you play a sport, Like you can
tell the difference in the force and as it degrades over time it becomes very inconsistent
Over time and that's also something that you want to avoid as well because it'll affect how
you walk You know your gait like randomly like sometimes I'll feel like pain in my right hip
and I won't know why Until I realize well, it's just the reaction I'm getting from the
foot isn't the same as it was a couple months ago, right? And that's also really hard to gauge
as well. Yeah, right. And yeah, that's mainly a couple of things that
I would say are really important. As far as how often I have to replace it goes, from when I was a kid to I think it goes up to when I'm 18 or 20, you get by insurance standards you
get a new one every year. I probably replaced mine. close to every year during like middle
school and early high school and then until I had gotten the one that I really liked and
then I didn't even replace it for I think I guess four or five years. I've had that one
for a really long time and uh. Well there is a difference in like replacing the type of prosthetic
and then like you said you broke a few times dude that's not including the break it or. So when you when
you break it they usually will just send you a replacement part or you can
get like a part. that would work better with the foot. So eventually I kept breaking them.
So we switched to like a stiffer one, essentially. One that wouldn't break as much. And that worked out for
a little while, but obviously eventually like I started breaking them again. And so that's really tough to
control though. That's realistically out of, it's out of the manufacturer's control and it's out of my control.
Because it comes down to how aggressive you are, amount of force that you're putting into it also like
over time like over a year you know I'm putting in
like well hundreds maybe even more miles on it right so thousands of miles even possibly
just walking on it so like it's going to break eventually and like that's like but you want
you want it to like be as long as possible between the great breaks.

Team
00:11:17
specifically to the interface so interface how often would you replace that and then also what is it is that
the same as like the process or your doctor's just chooses your interface for you do you go through like a
selection so by interface?

Douglas
00:11:24
I'm assuming you mean like the liner itself this part like what goes on my skin and what goes, because
this is a socket yes I'm assuming you're between the sock yeah so prosthetic
liners come in like two different types two main types you of customs and like basically like pre-made
ones right? Pre-made ones are cheaper, insurance will cover every six months,
once every six months and they tend to obviously pros and cons right? So for me I've had both.
The nice part about the pre-made ones is they're really easy to replace and like I will go through
them really fast, but at the same time I can get them replaced really fast, which is super

nice. And they have tons of different kinds, right? I mean, because everyone's limb is slightly

different. So they account for that by creating basically form-fitting ones, and general sizes in terms of width, length. whether it's upper or lower LIM amputees. So depending on that, it will change. So I'd say if I have a non-custom one, I replace it every six months as often as I can basically. This one is a custom one. This is made of polyurethane on the inside and then a really common theme is to have fabric on the outside sewn on and that's to make it easier to slide on and off. The problem with polyurethane is it likes to stick to itself so sliding it on really isn't an option. Lubricant or lotion to be able to put it on which is just another hassle that you have to deal with yeah which is why i prefer the fabrics but the hard part about customs is like sometimes like the manufacturer like will not like get it right the first time so you have to like
send it back and get it revised and things like that Yeah, I mean, there's a- the main issue has always been with the liner across like everyone. No one, almost no one has a problem with like
socket making, you know, like everyone agrees, like if it's custom, like it feels good. The
problem is always with the liners because, you know, you sweat, right? And when they're
especially active, these are not breathable issues especially for new amputees you know
I see a lot of the time like new amputees you know they take it off because they're uncomfortable they have to dry it off and then put it back on I've had it my whole life so I'm super used to it doesn't really affect me it doesn't really bother me but I will still to this you know
I will still get like rashes or you know like blisters. Traveling for tournaments like and I'm on a plane for a long period of time. It gets super uncomfortable. Yeah And and the hard part about like amputated limbs is you don't realize how much your limbs like swell up and Like especially if you're like flying Because it because it's a lower pressure so all your fingers and joints
they tend to swell up So it's really hard to like keep it on it just gets really uncomfortable.
Right. And like that's where I think like, well, potentially liners have the potential
to like mitigate that as well by having cushion. So if there's like a certain threshold where
you could compress the liner and it still wouldn't push back on you, I think that is one of the solutions to that. But again, like it totally depends on like what you're, what you're trying
to achieve with it. it too. Like obviously a liner like that isn't gonna last very long
if you're playing basketball or soccer.

Team
00:15:57
Our project is focused towards the liner and our advisor refers to it as an interface. It's a materials issue.

Douglas
00:16:04
Yeah it's a materials issue.

Team
00:16:11
And ours would be for like a more or what we would hope is a more long-term use. Have you used it all
or like no one has used it in the in search of current devices on the market,
there's some gel pads. Have you ever used anything like that?

Douglas
00:16:24
I haven't used anything like that. I also haven't heard of it. I don't know what that is, but.

Team
00:16:29
You wanna pull that up? Yeah, I can pull it up right now.

Team
00:16:39
Thank you so much for, you like hit a lot of the points already that we even were gonna ask you so thank you so much. skimmed through the questions.

Douglas
00:16:48
Yeah, I kinda skimmed through the questions. I had a pretty good idea of what you guys needed.

Team
00:17:01
Yes, there's like these gel cups and socket pads and volume management pads that like certain companies will have But yeah, it sounds like you haven't tried it yet.

Douglas
00:17:10
Yeah, I mean Most of those devices I think would be targeted toward newer people, trying to get adjusted. In terms of when it comes to that, it's very difficult for me to understand just because I've been on it since I was a kid. I don't really know anything different. I just know what feels bad and what feels good and what feels bad. For me, in general, I have a pretty good understanding. Yeah, I mean like as far as like liners go, I know there's like they've been talking about using like aerogels and things for a really long time just because of its like moisture wicking capabilities. That's a huge, like if someone could come up with a material for a liner that like is actually like breathable and comfortable, A, I think it lasts way longer. B, it would just be, it'd be a huge breakthrough because it'd be so much more comfortable

Team
00:18:35
So that makes a lot of sense. So I just want to like reiterate, your main point, for you, you would say your main challenges with the liner would be more of like a long-term discomfort, like you said, like sitting in an airplane for too long.

Douglas
00:18:48
Yeah, exactly. And then this moisture.

Team
00:18:53
when you're playing, because I know you're a golfer, when you're playing is there a lot of discomfort at all?

Douglas
00:19:03
Um, when I play I don't really notice it and I think that's also the case for other Paralympic athletes as well, but It's definitely noticeable after the fact. You cannot, you can see the bruising that happens from like You know ideally there wouldn't be any bruising, but it does happen. Right. Um, but the biggest thing is usually you can see like the, like the sweat rash that happens all the time, especially if you're somewhere hot. Yeah. You know, I've been, I go to Florida all the time, Florida, like Arizona. And like, that's where it's usually the worst just because like it gets really hot. Carbon fiber also gets really hot. Um. Yeah, it's not ideal, but like, you know, there aren't many ways around it besides taking it off. So like, it really comes down to like, just like caring for the limb at that point. But like ideally, you want to be able to like manage the moisture a lot easier or a lot better. That's what I think.

Team
00:20:17
And then in terms of still the interface, how satisfied would you say you are with the current one that you have?

Douglas
00:20:22
Current one that I have is I think pretty good. This is the first custom liner I've been wearing for the past year I guess. I was a pretty big fan of the Polyurethane ones. But I think I have a picture somewhere that I could probably send you, but unfortunately I threw it out because it was gross, but the polyurethane, another problem with it is that it will absorb some of the moisture, so over time you know, like you really just have to like wash it, and like after six months or eight months depending on how active you are, you literally just, it's unbearable, like you have to throw it out, like it's just not effective, like start to break down like and like those are those are kind of like the main problems I think with liners.

Team
00:21:18
That makes sense. Yeah. And what is the name of the company that makes it?

Douglas
00:21:26
Autobot makes most custom liners I think they call it the Bueno series. That's the one that I'm wearing right now. The one that I was wearing literally up until like last week was a pre-made one by Willowwood. It was the 12mm thickness liner. It was green or something. They make very good pre-made liners. I really like those ones.

Team

00:22:02
I'm just reading through the questions and see if we got all of them. I guess we didn't really talk much about, but like on the day to day, just like going to class and doing your day to day activities and stuff, like what would you say was the most challenges and like what works, what does not work?

Douglas
00:22:27
I think when it comes to just like the liner itself, if it's like... If the fabric is like, cause this is relatively new. Yeah. So it's like still kind of stiff. Like I haven't really worked it in very well. So when it comes to that, like putting it on is kind of a hassle. Yeah. Just cause like you have to like kind of stretch it over it. It was even more annoying without the fabric one because then you would have to have like a lotion nearby to try and slide it on. That makes sense. And yeah, I mean that's as far as really the kind of limitations go on a day to day basis. I wouldn't necessarily really call it a huge problem. Yeah, it's just a hassle you'd have to deal with.

team
00:23:23
What do you really like about this one that you have right now? And then what do you really like about the other one?

Douglas
00:23:28
I think that the... benefit to this, Well, the custom fitting ones are really nice because they like actually do fit really well. Like anywhere that you, it's similar to the socket anywhere that you would need like. anywhere that you would need support, like you have it. And it is literally just a perfect copy of like your limb. So that it, so like for me, like my shin kind of gets like really skinny and then like, it'll be like a little bit rounded at the end, just cause like the end of the bone is there. And so like the trouble is always finding a liner that will be able to like be, stay compressed in the, in the, in like the middle. section but also like be able to like stretch over like my knee and things like that. So like when you have a custom one you know it's gonna fit well. And if obviously if you find the right like pre-made ones like those fit pretty good too as far as form fitting goes they just don't last as long. That's just a main problem. Yeah. With that one.

Team
00:24:40
That makes sense. It seems like moisture is kind of the main issue.

Douglas
00:24:47
Yeah. I would put that at the top, like 100%. Like a good margin. Yeah. I think a lot of people have always been trying to, it's to this day still the number one problem with prosthetics.

Team
00:25:01

Do you have any issues in terms of stresses on your residual limb, like your muscle or your body itself having pain in that?

Douglas
00:25:10
For me, I've never had any issues like that. And that, I think, comes mainly from a really well-built socket. Any issues that comes with on the muscle or the bone usually is a structural problem. It's not so much of an interface issue. Yeah, that makes sense. And I've, again, I have a really great prosthetist. So he just builds them great for me. And I've never had any issues when it comes to that. OK. Yeah, like if I were to tell a story that I had, I guess like in the middle school, what can sometimes happen is like the end of the bone will develop something called a bursa. Yeah. And that's like really painful, like it's kind of like just a giant blister almost. Right. And it happens because the bone inside the limb is hitting on the inside of the skin. Yeah. And then it causes it to like really inflame. It gets exponentially worse because you're wearing the prosthetic all the time. So it gets tighter and tighter because it's becoming more inflamed. I've had that at one point and it was relieved because we were able to open space inside the prosthetic to let the inflammation run its course almost. And then as it goes down, you can re-add the padding and then make sure that it doesn't happen again and things like that.

Team
00:26:43
And then last question really. Do you have any like company contact or like people that you have contact that you think would be helpful for us?

Douglas
00:26:56
Yeah I think, so I've been with New England Orthopedics for a really long time. There's a younger prosthetist,she works like literally 10 minutes from here at New England Orthopedics. I probably talked to her, I can't remember her name because I only went to her a couple times. But they're a really good company, I really like them. And I was with them up until my guy moved companies.So he moved to the Hanger Clinic. And he's based all the way in Easton. So he was actually originally closer to New York to me. He was in Stanford originally. And then he moved to Easton, Massachusetts. So that's where I go now. And like, you know, like... I think I would probably reach out to New England Orthopaedics. I think they're really good. They're a great company, very local. They take care of a lot of people. More mass production wise, like I think you have like Hanger Clinic is like the biggest clinic in the United States, possibly in the world as far as I'm aware. They have really great prosthetists as well. I just don't know too many. Yeah. I'm not too familiar with the company just because I switched over to them recently. But as far as like, as far as I'm aware, the labs that actually end up building the prosthetic sockets, all are basically the same. Like they have multiple labs throughout the US. They're all like basically private practices essentially. And... offices will send them jobs to do and then they mold the prosthetic and then they send it back.

Team
00:29:03

I think we covered everything.If you have anything that comes to your mind after or anything you feel like would be helpful to share with us, you can feel free to reach out to me or anyone. I think that basically covers it.

260
00:29:12,702 --> 00:29:20,085
I mean, my main point is always talking about moisture management. I can't stress that enough. That was one of my research topics in high school. But there just really aren't any good solutions to that right now. It ends up becoming more of a... more of like a materials problem i think but when it comes to like i think there could be like design things that could come into it um like more like perforated prosthetic liners or something like that right like that could potentially be explored but again like i have no idea.

Team
00:30:39
Thats it for us, so Well, thank you so much for taking yeah Like this is basically everything I got from you is everything I got from the six peer Review Yeah, thank you so much.

Douglas
00:31:03
Hope your project goes well. We need it. So funny how you guys knew the face, probably the only guy with a prosthetic on campus. I don't know anyone else. I don't know, yeah. I don't know anyone else. I've never seen anyone.

B. Trauma Surgeon Survey

1. How long have you worked as a surgeon?

4 Responses

ID ↑	Name	Responses
1	anonymous	20 years
2	anonymous	2 years
3	anonymous	21 yrs
4	anonymous	20 years

2. On average how many leg amputations do you perform a year?

4 Responses

ID ↑	Name	Responses
1	anonymous	3
2	anonymous	3-5
3	anonymous	10
4	anonymous	5

3. Considering load distribution and stress reduction, rank the designs based on which you think exhibits the most increase in surface area effectively, from most to least effective....

4 Responses

ID ↑	Name	1st	2nd	3rd	4th	Result
1	anonymous	Flat ×	Turtle ×	Muffin ×	Mushroom ×	×
2	anonymous	Turtle ×	Muffin ×	Mushroom	Flat ×	×
3	anonymous	Turtle ×	Muffin ×	Mushroom	Flat ×	×
4	anonymous	Muffin	Turtle ×	Flat ×	Mushroom ×	×

4. Rank the designs based on which you think features the most favorable shape to optimize the fit between the current sockets and the residual limb for transtibial amputations, fro...

4 Responses

ID ↑	Name	1st	2nd	3rd	4th	Result
1	anonymous	Muffin	Turtle ×	Mushroom	Flat ×	×
2	anonymous	Flat ×	Turtle ×	Muffin ×	Mushroom ×	×
3	anonymous	Mushroom ×	Turtle ×	Muffin ×	Flat ×	×
4	anonymous	Muffin	Mushroom ×	Flat ×	Turtle	×

5. In terms of patient comfort during daily activities, rank the designs based on which you think is expected to provide the highest level of comfort, from most to least...

4 Responses

ID ↑	Name	1st	2nd	3rd	4th	Result
1	anonymous	Muffin	Turtle ×	Mushroom	Flat ×	×
2	anonymous	Mushroom ×	Turtle ×	Muffin ×	Flat ×	×
3	anonymous	Turtle ×	Muffin ×	Mushroom	Flat ×	×
4	anonymous	Muffin	Mushroom ×	Flat ×	Turtle	×

6. In terms of impact on adjacent tissues or structures, rank the designs based on which you think minimizes potential adverse effects the most, from least impact to most...

4 Responses

ID ↑	Name	1st	2nd	3rd	4th	Result
1	anonymous	Muffin	Turtle ×	Mushroom	Flat ×	×
2	anonymous	Flat ×	Turtle ×	Muffin ×	Mushroom ×	×
3	anonymous	Turtle ×	Mushroom ×	Muffin ×	Flat ×	×
4	anonymous	Muffin	Mushroom ×	Turtle ×	Flat ×	×

7. In your opinion what is the largest dimensions (diameter and length) that can be implanted beneath the bone in a trans-tibial amputation?

4 Responses

ID ↑	Name	Responses
1	anonymous	5 cm x 5 cm or so
2	anonymous	5cm diameter, length dependent on level of amputation and tissue available.
3	anonymous	3x5 cm
4	anonymous	6 inches, 18 inches

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