



Developing a Scalable, Low-Cost Prosthetic Device for Below-Knee Amputations

Major Qualifying Project

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Abstract

In developing countries, transtibial amputees do not have the same access to high quality prostheses due to the high costs, low levels of prosthesis functionality, and long lead times. The most affordable prosthetics for these amputations typically cost thousands of dollars and the customization and fitting process for a prosthesis involves several visits with a prosthetist and can take weeks. The goal of this project was to design a low cost and easily reproducible prosthesis that has the ability to mimic the gait cycle of a person. The overall prosthesis design was broken down into three components: the socket, the pylon, and the foot. The designs of each of these components were modeled similarly to products currently in the global market and were altered to make them easier to manufacture. 3D printing was the main manufacturing technique for the three components, varying the machines and materials used for each based on necessary material characteristics. A four-bar linkage system was developed to evaluate the prosthesis's ability to mimic the locomotion of a typical gait cycle for a person. At the conclusion of this project, parametrized CAD models were developed to allow regeneration of prosthesis based on user measurements.

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Chapter 1: Introduction

Amputation is defined as the removal of all or part of an extremity, and is the result of surgery, trauma, or disease. There are numerous different types of amputations, ranging from minor amputations of digits to major amputations of arms or legs (Kenney Orthopedics, 2020). Transtibial amputations, or below-the-knee amputations (BKA), are the most common and account for about half of all major amputations (Stout, 2013). Their commonality has a direct correlation to their high rehabilitation rates. Studies have shown that more than 65% of patients with a BKA have ambulated with a prosthesis, while less than one-third of patients with an above-knee-amputation (AKA) “are likely to rehabilitate with the use of a prosthesis (Auliova, 2004). Other major leg amputations, such as hip disarticulations, transfemoral amputations, and knee disarticulations, are more complex surgeries and require a more rigorous rehabilitation period. The main reason for this is due to the fact the knee joint is removed, which adds complexity to not only the patient’s recovery but the prosthetic devices that counteract these surgeries. Figure 1 below depicts the different types of amputations that a leg can undergo.

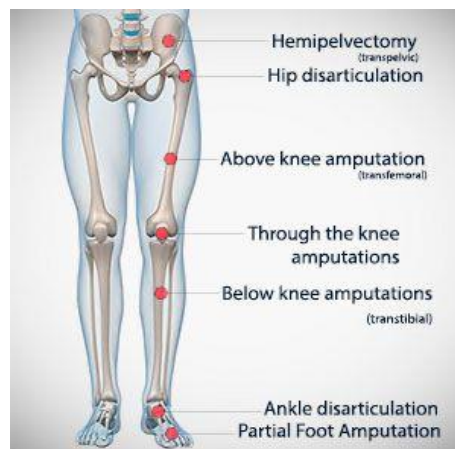


Figure 1: Lower Extremity Amputation Types Reproduces as from Lower Extremity Prosthetics. (2018). Retrieved from <https://www.cpousa.com/prosthetics/lower-extremity/>.

To assist with general life functions post-surgery, many amputees will use prostheses, or artificial devices designed to replace the missing body part. Numerous different types of prosthetic devices exist in the medical world today, ranging in price, functionality, and design. For example, the Jaipur foot is a simple design that is lower in cost due to its lack of electronics (Stout, 2013). Another example is the University of Michigan's bionic leg, an open source prosthetic platform that combines electronics and sensors with its metal apparatus. Prostheses can contain artificial joints if a user is missing them, be equipped with electronic sensors to mimic nerve function, and be designed to withstand vigorous activity, such as running, climbing, and walking on an incline. These factors all affect the price of the product, generally making them more expensive. They can be made from numerous different kinds of materials, such as metals, thermoplastics, silicones, and polymers and even be designed to look natural and life-like (Mota, 2017). Recent developments have been made to design and manufacture prosthetic devices through additive manufacturing, more commonly known as 3D printing.

Despite the range of prosthetic devices available, many amputees may not have feasible or desirable options available to them due to limitations such as insurance coverage, affordability, and geographical accessibility. Advanced prosthetic devices, ones equipped with sensors and electronics, like the University of Michigan's bionic leg, often correlate to an increase in price, while the cheapest prosthetic devices tend to have lower levels of functionality. The general cost of a cheap prosthetic is around \$5,000 and the lower levels of functionality fall under the K-levels one and two (Stout, 2013). Cheaper prosthetic devices may not accurately match natural human gait and can make walking appear unnatural or be uncomfortable (Physiopedia, 2020a). Additionally, the production time for developing a prosthesis for a user includes numerous scheduled fittings and appointments and can take anywhere from 6 months to a year (Amputee

Coalition, 2018). Additionally, advanced prosthetic devices also typically result in longer and more complex customization processes, as there is a more in-depth process of constructing the prosthesis with all of its sensors and electronics. Also, there is more of a learning curve for patients to get acclimated to the technology and assimilate its use into daily life, all the while making sure that it fits properly and is comfortable to use for long periods of time.

For regions around the globe that are underdeveloped, their medical facilities may not have access to complex customization tools for fitting prostheses or to advanced prosthetic devices. In order to reach out to the most amputees and aid in their recovery, a prosthetic device was developed that tackles the problems within the most common amputation type, transtibial amputations. As a result, an accessible and affordable prosthetic device was designed and developed for transtibial amputations.

1.1 Research Statement

The aim of this project was to develop a prosthetic prototype for transtibial amputees that:

- Is affordable
- Can accurately mimic the natural gait and locomotion of a user
- Can be quickly customized based on user requirements
- Has a lower production and fitting lead time
- Has interchangeable components.

This prosthetic device has been broken into three different components: a socket, a pylon, and a foot. These different parts were all designed to be customizable to a potential user's size and level of amputation. Different materials were investigated, and a multitude of designs were

developed and used in order to develop the most realistic prototype for a transtibial amputee, and iterations were tested to determine if the prosthesis accurately mimics human gait.

In this report, all background research for this project is in Chapter two. This research consists of lower limb amputations, including the anatomy and a focus on transtibial amputations, the causes and demographic information of amputations, and amputation mobility levels. This chapter also discusses lower limb prostheses: from simple to advanced designs, their costs, and their manufacturing processes. Lastly, Chapter two discusses 3D printing technology and how it applies in the manufacturing of prosthetic devices, including common materials and options. Chapter three outlines this project's objectives and leads to Chapter 4, which introduces the design of the prosthetic device and expands upon each individual component's design process. The manufacturing process of each component and the assembly is discussed in Chapter 5, with Chapter 6 reviewing the testing and analysis that took place. The project concludes with Chapter 7 and the social and the ethical implications of this project are examined.

Chapter 2: Literature Review

This chapter dives into all of the background information that would be needed to develop a low-cost prosthetic device. This chapter will begin by addressing lower limb amputations, discussing different types of lower limb amputations, the anatomy of below-knee amputations, the main causes for amputations, demographic information on amputees, and the varying levels of mobility that amputees can have. The next section of this chapter will examine current prostheses, including simple and complex designs, as well as the cost of these devices. The third section of this chapter will look at 3D printing technology, which includes the process of printing, commonly used materials, and the different options available based on printer size, and materials being used. Finally, we will analyze existing 3D printed prosthetics by addressing machines that are commonly used, customization and imaging used in the design and manufacturing process, and common issues that are encountered.

2.1 Lower Limb Amputation

Transtibial amputations are one of the most common amputation types, accounting for about half of all major limb amputations. (Kenney Orthopedics, 2020) They are often referred to as ‘below-the-knee’ or ‘BKA’ amputations and have very high physical rehabilitation success rates. No two amputations are exactly the same, but the process for both transtibial amputation surgery and physical therapy have been streamlined due to advances in technology. Transtibial amputations allow patients to keep their knee, a huge benefit, as prosthetic devices containing knee units give patients the bending motion of a knee but not the power (Stout, 2013). Knees contribute

a lot to maintaining balance, so surgeons will preserve the natural knee joint whenever possible. For transtibial amputations, the main challenge is therefore replacing the foot and ankle. Human feet adjust firmness levels throughout the gait cycle, always adapting as the amount of weight being put on the foot changes. Prosthetic foot designs can be made to be either soft or firm, but designs have yet to be made that more accurately mimic the natural gait cycle.

2.1.1 Anatomy of Transtibial Amputation

The human calf contains two different bones: the tibia, the larger of the two and positioned in the front of the leg, and the fibula, smaller and positioned further back, shown below in Figure 2. The two bones are joined at the top and bottom at the knee and ankle joints, respectively. The lower leg also contains four different muscle compartments and five major nerves.

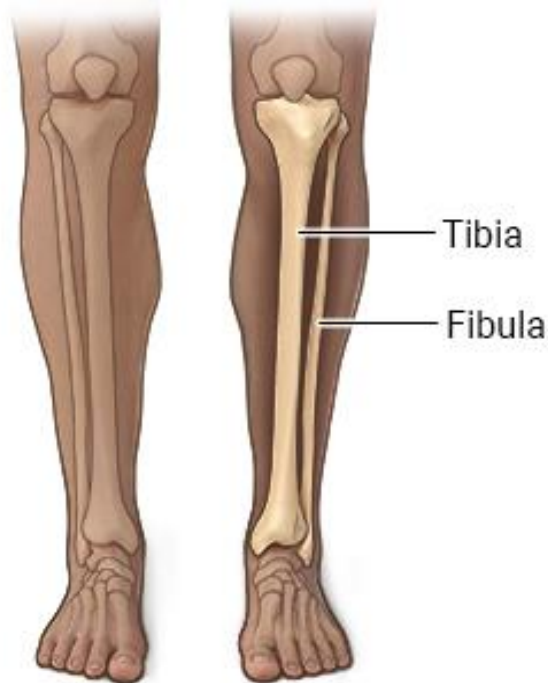


Figure 2: Lower limb anatomy showing tibia and fibula bones. Reproduced as is from Healthwise. (2020). Bones of the lower leg. Retrieved from <https://metrohealth.net/healthwise/bones-of-the-lower-leg/#>.

During amputation surgery, the tibia and fibula are cut, and a skin flap is preserved to cover the bottom of the stump, as shown in Figure 3 below.

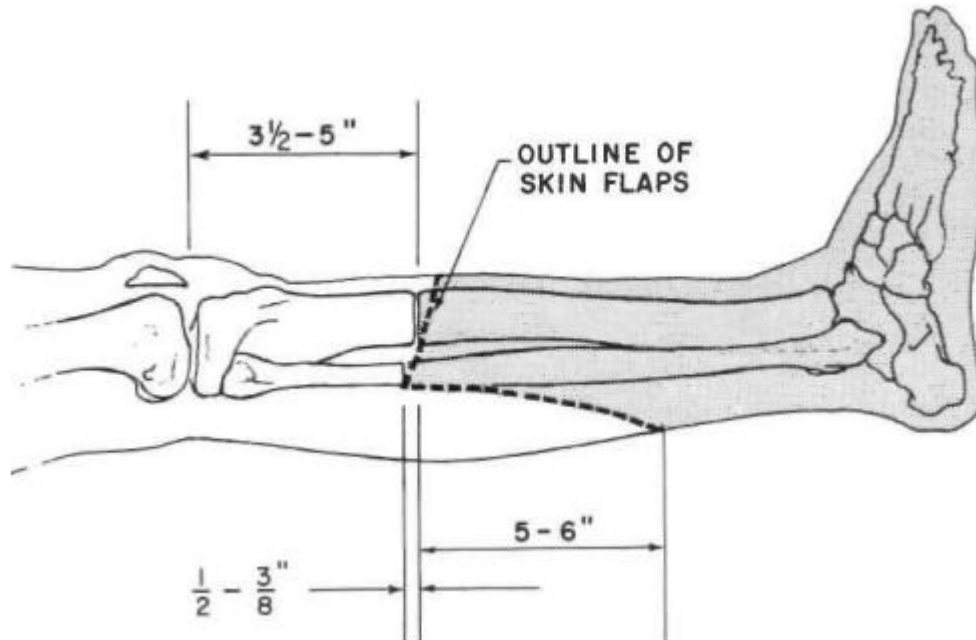


Figure 3: Transtibial amputation geometry, including range of residual limb length. Reproduced as is from Burgess, E., & Zetti, J. (1969). *Amputations Below the Knee*. *Artificial Limbs*, 13(1), 1–12. Retrieved from http://www.oandplibrary.com/al/pdf_raw/1969_01_raw.pdf

Bones are dissected using an oscillating saw, with optimum bone length being 12-17cm long. When the bones are cut, the tibia should be rounded to remove the sharp anterior edge, and the fibula is cut approximately 1-2cm shorter than the tibia, in order to avoid distal fibula pain (The Brigham and Women’s Hospital Inc, 2011). There are different styles and techniques to close the wound with the flap to create a functional and practical stump, and the technique is based on surgeon preferences (Physiopedia, 2020d).

Surgeons will attempt to preserve as much of the leg as possible; however, amputations in the lower third of the tibia are generally avoided. The front of the lower leg has almost no padding, so amputations in the lower portion of the tibia would leave the lower leg exposed and sensitive.

Additionally, areas with poor padding are difficult to fit a prosthetic device comfortably. When an amputation is performed, the tibia and fibula remain joined at the knee joint, but are no longer joined at the bottom. Some surgeons will attach a bone graft to the ends of the two bones to join them together, allowing reducing pinching and stress in the lower leg (Physiopedia, 2020b).

2.1.2 Causes

Currently in the United States, there are an estimated 2 million people living with an amputation (Ziegler, 2008). Each year that number grows, as 185,000 people receive an amputation (Owings, 1998). The epidemiology of amputations in the US is divided into three different categories. These categories are vascular diseases which accounts for 54% of amputations, trauma/accidents which accounts for 45%, and cancer which is responsible for less than 2% (Ziegler, 2008).

Vascular diseases account for 54% of all amputations that occur in the US. The main causes for these amputations are diabetes mellitus (Type II) and peripheral vascular disease (PVD). PVD is a vascular disease that is typically asymptomatic and has a relatively gradual onset but can progress quickly with serious implications. PVD affects the peripheral artery system (legs), when plaque builds up in the arteries, restricting blood-flow through the legs, potentially leading to blood clots (Physiopedia, 2020c). The other main vascular disease is diabetes mellitus. Diabetes is a common disease in the US, affecting roughly 29 million people (Physiopedia, 2020c). People with diabetes are at a 25% risk of getting a diabetic ulcer, which is typically located on the foot. These ulcers if not treated properly are prone to infection. As the infection progresses, it leads to the need for amputation, which is why approximately 84% of diabetics with an amputation had an ulcer before receiving their amputation (Physiopedia, 2020c).

2.1.3 Demographic Information

There is very little data regarding the number of people who have had amputations, but some trends can be seen across some demographics. Asians have a lower risk of lower limb amputation, while African Americans have a higher risk. The trends associated with these minority populations are not fully understood but seem to be independent of other risk factors commonly associated with minority status. Males are more likely to require amputation than females, as they are more likely to develop vascular diseases, which can lead to amputation (Esquenazi and Yoo, 2012). The risk of amputation due to trauma increases with age and is highest in individuals age 85 and older, for both males and females (NLLIC Staff, 2008).

2.1.4 Amputation Mobility Levels

Amputee mobility levels are measured using a rating system developed by Medicare, called Medicare Functional Classification Levels (MFCL), but more commonly known as K-Levels. This system ranges from 0-4, with function and mobility increasing as the level numbers increase. Medicare established this system to ensure that when Medicare pays for a prosthesis, a user will be able to use their device (Stout, 2013).

Level Zero indicates that a patient does not have the potential to move around safely, with or without assistance, and a prosthesis would not enhance their mobility levels. Level One indicates a patient has the ability to use a prosthesis on level surfaces at a fixed cadence and is common for individuals who are only moving around their home. Level Two indicates a patient has the ability to move about uneven surfaces and is commonly designated as the limited community ambulator. Level Three indicates a patient has the ability to move with varied cadence and traverse most barriers, requiring prosthetic use beyond simple movements. Level Four

indicates the patient has the ability to use a high functioning device that can withstand high impact, stress, and energy levels, and these devices are common in athletes (Stout, 2013).

Other mobility measurement systems exist to help determine a user's K-Level, but no one method is considered the gold standard for establishing K-Levels, so clinicians typically use a combination of assessments to determine the best fitting level (Ottobock, 2020). However, many individuals do not think that K-Levels are able to capture a patient's rehab potential. A patient's K-Level will impact the type of prosthesis they are likely to receive and will affect their level and intensity of physical therapy and rehabilitation.

2.1.5 Conclusion

As the most common major limb amputation, a wide range of data has been discovered regarding transtibial amputations. Surgical procedures for these amputations are standardized due to their commonality, resulting in stump geometry of users being relatively uniform. While no stumps will have the exact same geometry, stump topography tends to be similar between users. As a result, prosthesis designs for transtibial amputations can be similar in regard to socket designs and stump connections. Prosthesis designs will range in complexity and movement ability based on a user's K-Levels, price restrictions, and insurance coverage.

2.2 Lower Limb Prostheses

Based on the previously mentioned process of amputation and rehabilitation, a wide range of options for prosthetic devices is available for transtibial amputees. Transtibial amputees can have amputations performed close to their knee, while others may have amputations performed

closer to their ankle. Devices for these different amputations will be different, as patients with a longer residual limb may have a more secure socket to stump connection. This chapter will discuss the types of amputations for transtibial amputations, the customization process for prostheses, manufacturing processes, cost of prosthetics, and the customization and fitting process for prostheses.

2.2.1 Prostheses for Transtibial Amputation

Patients with lower K-Levels will typically have simpler prosthesis options, while individuals with higher K-Levels will have more complex prosthesis options. For lower K-Levels, and for individuals who cannot afford more expensive prostheses, common options are the Solid Ankle Cushion Heel (SACH) Foot and Jaipur Leg. These designs function well for low cost devices but may not fit a user perfectly or may not mimic human gait perfectly. For individuals with higher mobility levels, dynamic response feet and blade designs are common. These designs tend to be popular with athletes and users, as they naturally mimic expected human gait movement.

The SACH foot, seen in Figure 4, is described as the most basic prosthetic foot option (New Zealand Artificial Limb Service [NZALS], 2020b). They have no internal moving parts and provide no flex within the foot itself. The SACH foot is made of rubber materials, which flex, bend, and deform to provide a user with the desired movement. The main advantages of this type of device are its simple design and inexpensive price; the foot is lightweight, waterproof, and stable for users while being inexpensive. It is ideal for lighter weight users with low mobility levels (NZALS, 2020b). However, the design cannot be tuned to user requirements, as heel height is fixed and there are no flex components within the foot itself. While the foot will flex and deform under user loads, this flex motion is not designed to replicate natural biological foot flex and could

feel unnatural. Users with higher K-Levels and higher mobility levels will easily overpower the SACH foot, making the SACH foot a common option for those with lower K-Levels and for those that cannot afford more advanced devices. The SACH foot is attached to the pylon or bolt assembly, which is then attached to a socket, which serves as the main interface between a user's stump and the full prosthesis (Ottobock, 2019).



Figure 4: Example of a SACH Foot. Reproduced as is from Ottobock. (2019). SACH Foot Men 18mm Toes - Accessories. Retrieved from <https://shop.ottobock.us/Prosthetics/Lower-Limb-Prosthetics/Feet---Mechanical/SACH-Foot-Men-18mm-Toes/p/1S66>

The Jaipur Leg, seen in Figure 5, is similar to the SACH foot in that it is expensive and ideal for lower K-Levels, but does offer increased mobility. It is made primarily from rubber, plastic, and wood, similar to the SACH foot, but does contain hardware that allows for ankle articulation, making it superior to the SACH design (Science Museum, 2017). The ankle design contains a shorter keel and allows for flexion to create more life-like movement. The Jaipur Leg also has designs for above-knee amputations that contain an artificial knee joint; all prosthesis options are inexpensive and able to be manufactured for around \$45, and retail for \$80 (Science Museum, 2017, and Technology Exchange Lab, 2020). Users can perform more intense activities, like running, cycling, and hiking, than users with SACH foot designs, but are not ideal for highly strenuous or athletic activities.



Figure 5: Jaipur Leg. Reproduced as is from Bhagwan Mahaveer Viklang Sahayata Samiti, Jaipur. (2016). Below Knee Prosthesis. Retrieved from https://www.jaipurfoot.org/what-we-do/prosthesis/below_knee_prosthesis.html

Dynamic Response Feet, seen in Figure 6, are designed to mimic the foot's natural flex and movement to provide a natural option for users that have had amputations. They are typically made from stiff carbon fiber that elastically deforms when force is applied by a user, creating natural gait and flex similar to human movement. Dynamic response feet are often incorrectly classed as “energy storing” feet, as although the feet do not store energy, they return some of the energy developed during walking, resulting in lower overall energy expenditure (NZALS, 2020a). Advantages of dynamic response feet include their suitability for higher levels of mobility, natural shock absorption and adaptability to terrain, and lightweight characteristics. However, these designs are more expensive than multiaxial feet design and can be prone to failure if not cared for and used properly. Overall, dynamic response feet are ideal for higher K-level users, as they can be stiffer at low activity levels when not used as designed (Protosthetics, 2017).



Figure 6: Dynamic Response Foot. Reproduced as is from Protosthetics. (2017). Niagara Foot. Retrieved from <http://protosthetics.com/niagara-foot/>

Blade leg designs, seen in Figure 7, are similar to dynamic response feet and are ideal for higher K-Levels of mobility and are commonly used by athletes. Blades are usually made of carbon fiber and offer design variations for amputations both above and below the knee (Amputee Coalition, 2017). They are designed to mimic the phases of running and to absorb the stress typically felt by a user in their knee, hip, and back. Some individuals claim that blade leg designs offer users an unfair advantage to running over biological leg runners, but the design does have some flaws. The blade leg designs do not return the same amount of energy that a biological leg does when running. These leg designs are highly advanced in regard to their mobility potential, but do not have complex or electrical components (Amputee Coalition, 2017).



Figure 7: Blade Leg Design. Reproduced as is from Amputee Coalition. (2019, June 21). The Design and Controversy of Running Blade Prosthetics. Retrieved from <https://www.amputee-coalition.org/running-blade-prosthetics/>

Of the described prosthesis options in this chapter, they are all simplistic designs that do not contain electronic components. They range from low to high K-Levels, with designs that can be used only for basic mobility needs and designs that are commonly used by competitive athletes. The next section of this chapter will discuss options for individuals with amputations that are close to the ankle.

2.2.2 Prostheses for Ankle Amputation

Below the knee amputations also include ankle or through foot amputations. These are typically caused by diabetic foot ulcers and can lead to amputations of toes or even all the way up to removal of the entire foot at the ankle (Armstrong and Lavery, 2005). The other causes of ankle and foot amputations include “trauma, dvascular disease, congenital defects, and malignancy” (Ng and Berlet, 2010). Once these amputations are completed the doctors will work to select the correct prosthesis for the certain situation the patient is in. Whereas most of the amputations below the knee are transtibial there are still many that will be completed through the foot and some through the ankle. The range of lower limb amputations can be seen below in Figure 8.

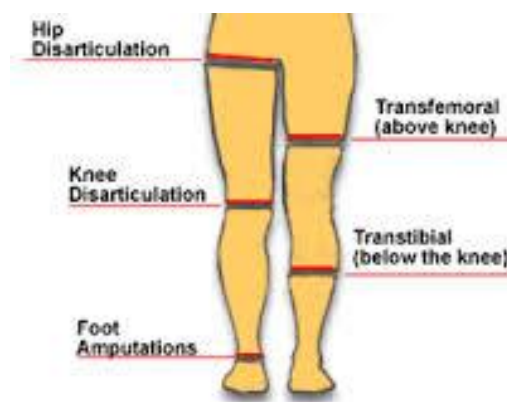


Figure 8: Lower Limb Amputation Locations. Reproduced as is from Nova Scotia Health Authority (2020). Lower Limb Amputations Categories. Retrieved from <http://www.cdha.nshealth.ca/amputee-rehabilitation-musculoskeletal-program/coping-your-amputation/lower-limb-amputations-categor>

While specific prosthetics are used for through the foot almost, similar to a slipper that slides over the foot, the prosthetics for through the ankle are very similar to those used for transtibial amputations, because they both use the same structure just at different sizes (Hofstad et. al, 2004). For prosthetics that are split into different sections and assembled, they can be easily transformed into either a prosthetic for transtibial amputations or through the ankle amputations.

2.2.3 Sockets for Transtibial Amputation

The different feet designs can all be combined with different socket and pylon configurations. The socket applies external forces to a user's stump, and designs typically vary based on the amount, location, and means of force application (Physiopedia, 2020b). If a socket does not fit properly, a user will likely walk incorrectly and be uncomfortable. The quality of the fit depends on a prosthetist's decisions, measurements, and K-Level evaluations (Physiopedia, 2020b). Prosthetists examine the quality of an amputation, and socket designs are constructed to apply force to pressure tolerant areas and not to pressure sensitive areas of a user's stump. A graphic of pressive tolerant and pressure sensitive areas can be seen below.

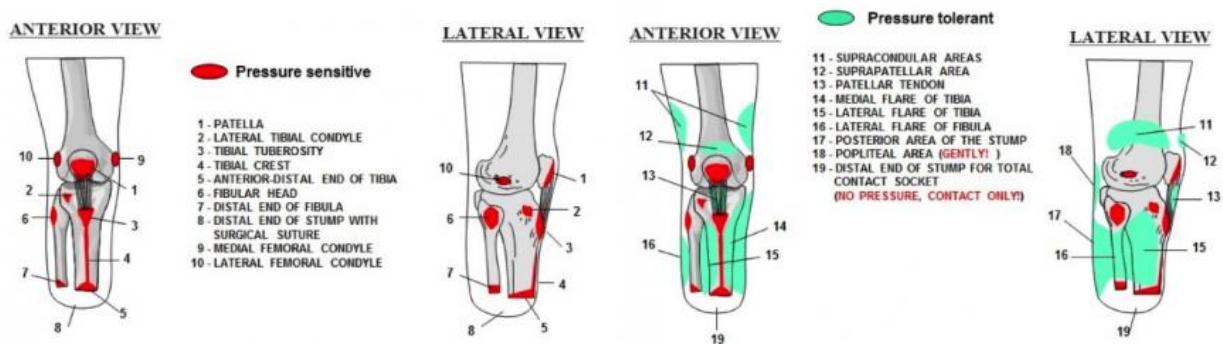


Figure 9: Pressure sensitive areas of residual transtibial limb and limb geometry. Reproduced as is from Physiopedia (2020). Lower Limb Prosthetic Sockets and Suspension Systems. Retrieved from https://www.physio-pedia.com/Lower_Limb_Prosthetic_Sockets_and_Suspension_Systems

Socket designs vary in their wearing bearing characteristics and are qualified as Patellar Tendon Bearing (PTB) or Total Surface Bearing (TBS) sockets. Patellar tendon bearing sockets bear weight on the patellar tendon and can be further classified by their suspension types. Patellar Tendon Bearing sockets (PTB) are accompanied by tension belts wrapped around the thigh to create suspension. These types of sockets can limit circulation and result in muscle atrophy over time. Patellar Tendon Bearing Supracondylar sockets (PTB SC) creates suspension along the medial and lateral areas of the femur and does not cause circulatory problems. This is the most basic design for prostheses. Patellar Tendon Bearing Supracondylar Suprapatellar (PTB SP SC) sockets are similar to PTB SC sockets in that suspension is generated at medial and lateral areas of the femur, but PTB SC SP sockets also create suspension above the patella and tend to surround the knee. These types of sockets are commonly used for individuals with shorter residual limbs (Physiopedia, 2020b). Total surface bearing (TSB) sockets apply weight and force over the entire stump, and suspension is created through tight adhesion and friction between the stump, socket, and any liners or socks used (Physiopedia, 2020b). Examples of all these socket designs can be seen in Figure 10 below, in respective order.

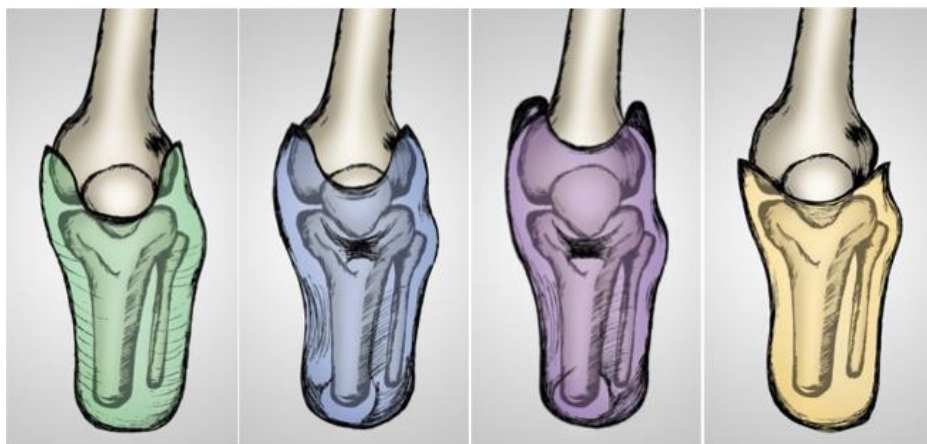


Figure 10: Patellar tendon bearing (PTB, PTB SC, PTB SC SP) and total surface bearing (TSB) sockets, respectively. Reproduced as is from Physiopedia (2020). Lower Limb Prosthetic Sockets and Suspension Systems. Retrieved from https://www.physio-pedia.com/Lower_Limb_Prosthetic_Sockets_and_Suspension_Systems

To determine the proper socket style for a user, a prosthetist will examine a user's residual limb length, potential volume changes of the stump, and K-levels of desired mobility. Sockets that contain more than one part are common as well, and can include straps, interfaces, liners, and more (AustPar, 2018). Total surface bearing sockets have a shorter production time, and enable higher activity levels, and sockets are crucial to patient comfort levels and prosthesis effectiveness (Stevens et al., 2019).

2.2.4 Manufacturing Prostheses

There are many different avenues that prosthetists can take to manufacture modern prosthetic devices, including utilization of many different materials. The range of materials that can be used increase the complexity of the device's designs as well as the customization levels. Typically, after the swelling on the residual limb goes down, a prosthetist casts a plaster mold, or a fiberglass cast to serve as a guide for the manufacturing of the prosthesis. After a positive mold is created from the original guide, the prosthesis creates a replica of the patient's residual limb to use during testing for the quality of fit (Hortonsopnew, 2015).

The range of materials that can be used in manufacturing prosthesis directly correlates to the complexity of the design, the needs of the patient, and the cost of the prosthesis. If a patient is more active and needs a more robust prosthetic device, then the materials used in manufacturing will reflect that. Acrylic resin, carbon fiber, thermoplastics, aluminum, titanium, and silicones are all the most common materials used in prosthetic manufacturing (Mota, 2017). Primarily, for the load bearing structures, metals, either pure or alloyed, such as titanium are used. Advantages of using titanium include its strength to weight ratio, strength to density ratio, corrosion resistance, and low density which makes prostheses lightweight. Additionally, it can be alloyed with other

metals, like aluminum, to improve its properties. Plastics are utilized primarily for the hard exterior for prosthetic limbs and make for easy sterilization and cleanup. Carbon fibers have high tensile strength and stiffness and high specific modulus and strength, making it perfect for amputees of all weights. Silicones are used to increase the comfort of the sockets for the patient by distributing the excessive pressure and shear stress that accumulates during the use of the device (Mota, 2017)

Two of the main leaders of the prosthetic industry are Otto Bock and DAW. Otto Bock's 44 subsidiaries and 63 equipment centers are dispersed in over 140 countries around the world, which allows them to be closer to any person who needs their services, regardless of geographical location. Their specialty is "tailor-made" products, which essentially means that they individualize each prosthetic device to each patient. They use an "athletic prosthesis technology" approach to make their prostheses innovative and of the highest quality (Limbs 4 Life, 2019). DAW is considered a perfect complement to Otto Bock because rather than manufacture prosthetics themselves, they produce prosthetic accessories that aid amputees. For example, DAW manufactures protective sheaths that provide additional comfort and increase the ease of assimilation to daily prosthesis use. Their products tackle the problems that arise for amputees when wearing their prosthetic devices. Considered like a second skin, DAW products improve the quality of life for all their customers all around the world (Limbs 4 Life, 2019).

There are also other institutions that are developing prosthetic devices that are changing the industry. For example, the University of Michigan developed a bionic leg that aims to rapidly advance the field of prosthetics. Through their open source platform, the University of Michigan is trying to tackle the issue of fragmented research and allow others to openly copy the programming and designs of the bionic leg. This bionic leg, shown in the figure below, is a prime

example of how simple prosthesis designs are being elevated through the use of sensors and other electronics (Beukema, 2019).

2.2.5 3D Printed Prostheses

A more modern technique of manufacturing prosthetic devices is through additive manufacturing, specifically 3D printing. This process is changing the face of medicine by hugely decreasing the rate and cost of production. Prosthetists are able to develop and design prostheses that are fully customized to the wearer and easily altered if need be (NIH, 2019). Also known as rapid prototyping, three-dimensional printing translates virtual models into reality. Specific to the manufacturing of prosthetics, digital imaging software can virtually replicate an amputee's stump to create the foundation of their individualized prosthetic. This virtual residual limb can be then used to create a design of a prosthetic that can fit the user's parameters (Bhatia, 2014).

Since rapid prototyping can manipulate a multitude of materials, all of the various components can be manufactured and processed in one place. This then cuts down on the time it takes for a prosthetic to be produced, as well as reduce the costs of production. Another caveat of rapid prototyping is that the materials used as filament are much cheaper than the same raw material used in other manufacturing processes. This is why manufacturing with 3D printing has such a great draw; the incentives of lowering costs are high (Reidel, 2019).

One such company that is a trailblazer in 3D printed prosthetics is e-NABLE. Specified in 3D printing hands, this global network of volunteers has an open-source library that can be accessed and perused per user needs. (Souder, 2019) All prosthetic hands developed through their platform are free, though the only fee the customer has to pay is the cost of materials. For example, their Raptor hand design material costs are \$35. This organization is spread out over 140 chapters

around the globe and works directly with trauma surgeons and other medical professionals to improve the quality of their product. There is an easy-to-follow reference document that will help a person pick which design that they would need printed and also connects users through their web of resources to 3D printers if they do not have one (Souder, 2019).

2.2.6 Cost of Current Prostheses

With constant advancements in modern prosthetics, the cost of prostheses can vary drastically based on the quality and functionality of the prosthesis. In many scenarios, the cost of prosthetics can be a financial burden for people. While the prosthetic device itself is very expensive, the additional costs of repetitive doctors' visits, fittings for the prosthetic(s), rehabilitation and repairs can become just as much of a burden to people.

The cost of a lower limb prosthetic for a trans-tibial amputee can cost from \$5,000-\$10,000 (McGimpsey, 2008). Due to the fact that a trans-tibial amputee retains their knee, the needed motion of the prosthetic is far cheaper than a trans-femoral amputation which can cost anywhere from \$5,000-\$50,000 (Mohny, 2013). For trans-tibial prosthetics, there are two different categories for the functionality of movement that they allow amputees. Patients who have a prosthetic in the \$5,000-\$7,000 range will be able to have a normal walking cycle on only flat ground (McGimpsey, 2008). In contrast, a \$10,000 prosthetic will allow the patient to move up and down stairs and traverse uneven surfaces (McGimpsey, 2008).

In the United States, the out of pocket cost of a prosthetic varies enormously based on the health insurance policy the patient has (Turner, 2018). There are a variety of factors that can vary on the amount of coverage that a person has and what they are allowed to get under their policy coverage. Coverage and plans can be dependent on the state that a person is living in and what their parity is (Turner, 2018). Prosthetic parity is a federal or state legislation that requires

insurance companies to pay on par or more than a federal program, which could be Medicare, Medicaid, or a program like Federal Employee insurance (Turner, 2018). According to the US Medicare website, Medicare will cover 80% of the Original Medicare which is the approved amount of money that Medicare will pay (Medicare.gov, n.d.). This amount can be less than the actual cost that a doctor charges leaving a patient to be responsible for their 20% of Original Medicare and whatever cost is left (Medicare.gov, n.d.). While this is the minimum coverage that patients are owed, insurance plans in some scenarios can cover much more (Turner, 2018). It is not uncommon for insurers to cover a prosthetic entirely, but there are limitations to how often one can replace their prosthetic and the frequency with how often repairs will be covered (Turner, 2018).

2.2.7 Conclusion

In this section, lower limb prostheses were discussed. When thinking of manufacturing a lower limb prosthetic device, it is important to recognize the importance of the anatomy of the patient and the science behind choosing the location of amputation. Manufacturing these devices can be accomplished with various techniques, either through traditional avenues or more modern ones like rapid prototyping, and with many different materials. However, depending on which materials or manufacturing processes used, the cost of the prosthetic devices is generally very expensive and limits the amount of accessibility to amputees all over the globe.

2.3 3D Printing Technology

Additive manufacturing and, more specifically, 3D printing is quickly becoming significantly more popular in many different fields including the medical industry. 3D printing is

now being used in multiple different domains, such as prosthetics, orthopedics, maxillofacial surgery, cranial surgery, and spinal surgery (Tack et al., 2016). There are many advantages in the shift towards using 3D printing including time reduction and improved medical outcomes. However, one of the main limitations that accompanies this method is the cost it takes to acquire and use 3D printers. This section will cover how this 3D printing technology is being incorporated into the design of prosthetics.

2.3.1 Process

There are components to the rapid manufacturing process, as seen in Figure 11 below.

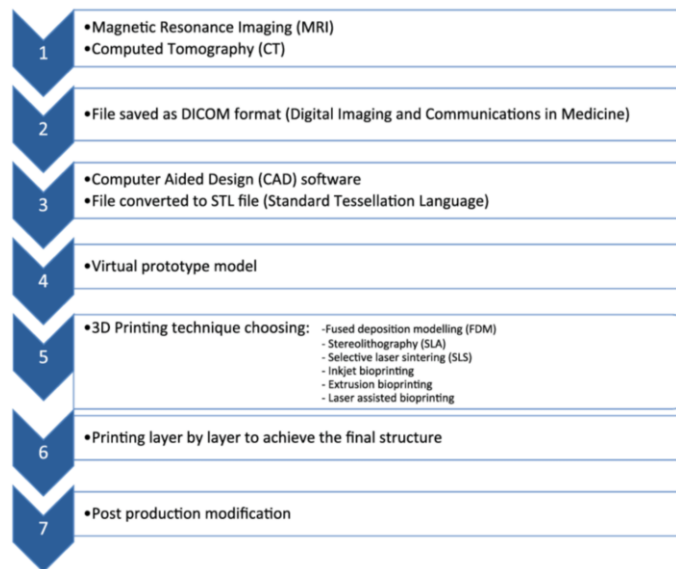


Figure 11: Flowchart of the 3D Printing Process. Reproduced as is from Aldaadaa, A. (2018, March 25). Three-Dimensional Printing in Maxillofacial Surgery: Hype vs. Reality. Retrieved May 17, 2020, from https://www.researchgate.net/publication/324672059_Three-dimensional_Printing_in_Maxillofacial_Surgery_Hype_versus_Reality

The process begins with the 3D modeling of the specific piece that is going to be made. This is typically done on software such as SolidWorks or Inventor Pro where the models are initially made (Gross et. al, 2014). The goal of this process is to produce a finished product that

can be immediately put into action. Many supporters of additive manufacturing believe that these processes will lead to toolless production of finished products that are individually customized to the consumer's needs. Once the design has been modeled and transferred to code as an ". stl" type file, also known as a stereolithography file, that the printer can read, the part is printed. However, some parts require rafts and supports so that the material being placed will stay in place and allow for everything to cool where it needs to be (Gross et. al, 2014). This is done by continuously solidifying material layer by layer on top of last (Gross et. al, 2014). When specific layers are added that may be floating or detached the printer will automatically add in support structures to connect the floating piece to the layers below. Typically, these support structures have to be removed by hand to finish the part off. This is known as the post processing, which includes the support removal along with potentially powder removal, cleaning, sanding, and so on. The post processing not only adds time to the build but also creates a need for human assistance, adding to the cost (Brocketter, 2020).

2.3.2 Materials

Additive manufacturing is quickly growing as a field by not only helping in many different industries but by also continuously finding new materials to print with. The materials that can be used have widened to metals, polymer powders, resins, and filaments (3D Printing Materials, 2020). However, many of the different machines can only print with specific materials. These materials are based off of the type of printer that is being used including Direct Metal Laser Sintering, Fused Deposition Modeling, Polyjet 3D, Stereolithography, Selective Laser Sintering, Binder Jetting, or Material Jetting (Xometry, 2020). Typically, PLA is known to be the most popular material for smaller printing jobs because it is very affordable and easy to print. Although, there are many substitutes for PLA, typically other filaments that act similarly and are also

affordable to acquire that have slightly different base properties once they are printed and hardened (3DPrinting.com, 2020). Another important concept when it comes to 3D printing is the price. There is a significant price difference between all of the materials that can be used, from roughly \$25 per kilogram for FDM (fused deposition modeling) filaments, to \$50-60 per kilogram of SLA (stereolithography) resin or SLS (selective laser sintering) powder (Brocketter, 2020).

2.3.3 3D Printing Options

There are many different options when it comes to deciding on what 3D printer to use. Usually the best choice is simple due to the parameters of what is being asked of the printer, whether it be the size of the print, the material that is being used, or the type of material being used, as seen in Figure 12 below.

	Typical build size
<u>FDM</u>	200 x 200 x 200 mm for desktop printers Up to 900 x 600 x 900 mm for industrial printers
<u>SLA/DLP</u>	145 x 145 x 175 mm for desktop Up to 1500 x 750 x 500 mm for industrial printers
<u>SLS</u>	300 x 300 x 300 mm (up to 750 x 550 x 550 mm)
<u>Material Jetting</u>	380 x 250 x 200 mm (up to 1000 x 800 x 500 mm)
<u>Binder Jetting</u>	400 x 250 x 250 mm (up to 1800 x 1000 x 700 mm)
<u>DMLS/SLM</u>	250 x 150 x 150 mm (up to up to 500 x 280 x 360 mm)

Figure 12: 3D Printing Materials and their Typical Build Sizes. Reproduced as is from Brocketter, R (2020). 3D Printing Geometry Restrictions. Retrieved from <https://www.3dhubs.com/knowledge-base/3d-printing-geometry-restrictions/>

These parameters also outline some of the main restrictions that accompany the use of additive manufacturing. These limitations include the physical size, water tightness, minimum wall thickness, curved surfaces, and post processing involvement (Brocketter, 2020). However, not everyone in every situation will be able to get access to all of the printers listed. The limitation to accessing these printers is not just due to the lack of availability in some areas but also the price that they cost.

2.3.4 Conclusion

When manufacturing a design through 3D printing, one must consider the desired material properties for their part, as well as potential financial restrictions. 3D printers range greatly in price, but high performing machines that can print specific materials, geometries, and material properties tend to be more expensive.

2.4 Testing

Before a prosthesis can be used by actual patients, it must be tested to ensure it will be both a safe and realistic alternative to a biological limb. Prostheses undergo structural testing and gait analysis during the design and development phases to determine if the device can withstand a patient's weight, activity, and motion. International standards and organizations exist for prosthetic devices to ensure that products are reliable and able to be used by patients and not be affected by patient weight and activity level. For gait analysis, many studies are done on prostheses to observe how accurately the prosthesis mimics natural human gait path.

2.4.1 ISO Standards for Prostheses

The International Standard for Organization (ISO) is an international standard-setting group containing representatives from different standards-based organizations (ISO, 2020). ISO publishes international standards to create safe and reliable products while improving productivity and product design. Since its establishment in 1946, ISO has released over 20,000 different standards covering almost all types of technology (ISO, 2020).

For prostheses, devices are tested using ISO 10328: Prosthetics - Structural Testing of Lower-Limb Prostheses. This document describes the ways in which to test lower limb prostheses, both transtibial and transfemoral, detailing test methods, set up, and more. The ISO Standard contains testing methods for a full prosthesis and for each individual component, describing cyclic, torsion, and static loading tests. The standard describes equipment set up, including force applications, references planes and axes, and machinery and attachments necessary to perform each test. The standard contains an entire chapter regarding compliance, describing exactly which tests and how many of each test must be performed in order for a prosthesis to claim compliance with the standard (International Organization for Standardization, 2016).

2.4.2 Gait Analysis

When developing a prosthesis, the device must be designed to mimic natural motion as accurately as possible. If a prosthesis deviates from natural human gait, discomfort, muscle weakness, altered gait path, and lowered confidence can all occur (Physiopedia, 2020a). Gait deviations can be caused by prosthesis malalignment and poor fitting sockets. Human gait is analyzed by observing an individual's profile and by tracking foot path while walking. Different points in the gait path require different movements and levels of energy as an individual swings

their leg, pushes off of a surface, and stands on their leg. The image below details these different stages as well as the proportion of time of each action in one full gait cycle.

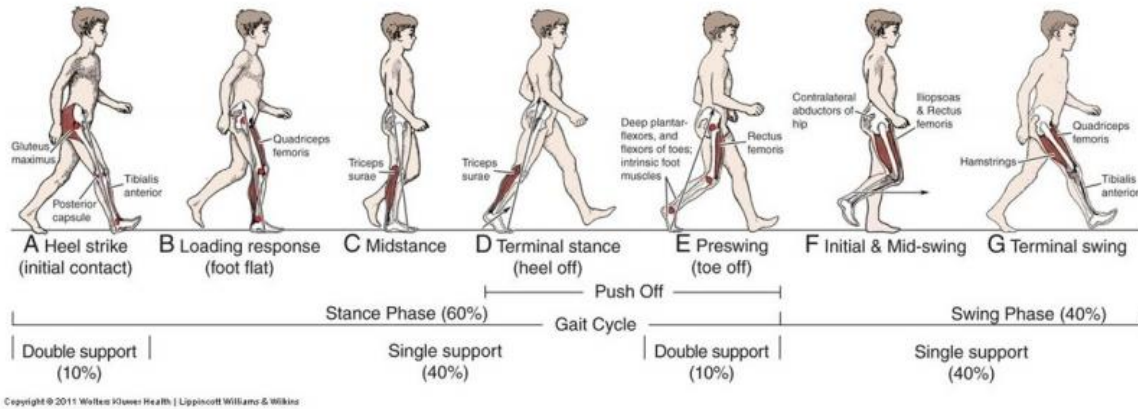


Figure 13: Human Gait from Side Profile. Reproduced as is from Physiopedia (2020). Gait in Prosthetic Rehabilitation. Retrieved from https://www.physio-pedia.com/Gait_in_prosthetic_rehabilitation

Many studies have also been completed to analyze the gait path of an individual's foot to determine natural human gait. When walking on a flat surface, human gait creates the same path. When examining the gait path, one can see that an individual spends approximately 60% of the gait cycle with their foot not touching the ground, which is compliant with the graphic above.

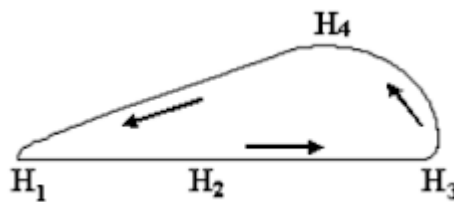


Figure 14: Projection of human gait path. Reproduced as is from Al-Araidah, O. Batayneh, W., Darabseh, T., and Banihani, S. (2011). Conceptual Design of a Single DOF Human-Like Eight-Bar Leg Mechanism. *Jordan Journal of Mechanical and Industrial Engineering*, 5(4), 285-289.

2.4.3 Conclusion

In the developmental stages of a prosthesis, before human testing can occur, a device undergoes standard-compliant testing to ensure safety and gait analysis to ensure effectiveness. International requirements and guidelines help designers and engineers to measure a prosthesis's ability to withstand a future user's weight and motion and determine a prosthesis's lifetime. Gait analysis is crucial in determining how life-like a prosthesis will act, as poor functioning prostheses can have detrimental effects on a patient's physical and mental health as well as a prosthesis's quality over time.

Chapter 3: Project Objectives

Based on background research and examination of current prosthetic devices and their development and customization processes, the following four objectives for our transtibial prosthesis: be made of interchangeable components, be quickly customized based on user requirements, have a lower production time, and be able to accurately mimic a user’s natural gait. The goal was to design a prototype of interchangeable parts for a transtibial prosthesis that is low cost and has a short production time while still being able to accurately mimic the human gait cycle. The flowchart below details how background research was conducted to help determine the project’s objectives. Based on background research and the objectives created, designs were created for each component. Designs were then manufactured using different materials that helped to aid in the function of the part. From here, designs were tested using a linkage system to determine if they could mimic a natural gait cycle.

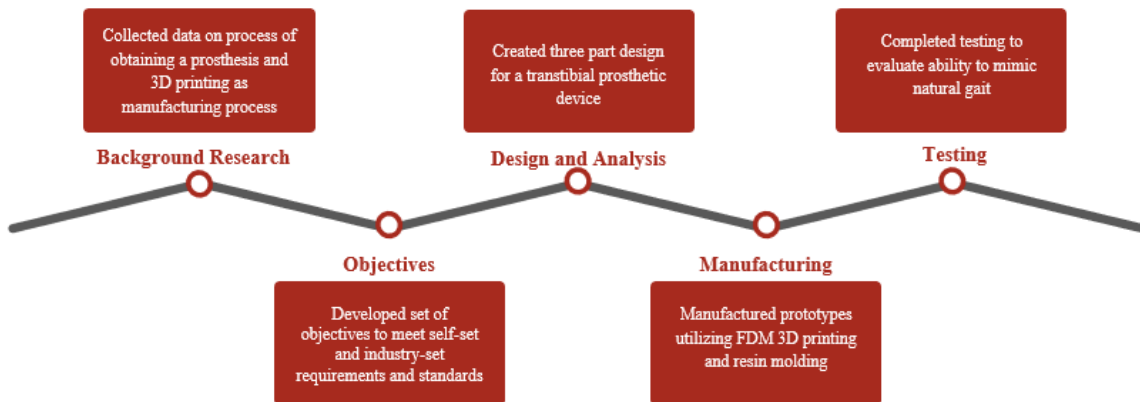


Figure 15: Project design process detailing flow of information and designs throughout the year

3.1 Objective 1: Interchangeable Components

The design was split into three components: a socket, a pylon, and a foot. The design was split into these different components due to the different required geometries and material properties for each part. The socket is the point of contact with a user, so it therefore must be able to stay on a user's stump and must be comfortable to use. The pylon is the portion of the prosthesis that structurally replaces the tibia, the main bone of the lower leg, and must be strong and sturdy to withstand a user's weight and activity while still being lightweight enough to move naturally. The foot also must be able to withstand a user's weight and activity, but also must be able to naturally mimic human movement and flexion.

3.2 Objective 2: Quickly Customized to User Requirements

One difficult aspect of acquiring a prosthesis is the customization process involved in fitting a patient to a device. Through background research, it was determined that patients can wait upwards of 6 months to receive a prosthesis after they get a prescription. One of this project's goals was to develop a prosthesis that has a lower lead time than other market competitors so that individuals can receive their device within a timely manner. The customization process for each part of the prosthesis was created in SolidWorks by using Global Variables for measurements, so users can input their measurements into each CAD file to generate the appropriately sized prosthesis. Additionally, a prosthesis preparation outline was created to detail how these measurements should be taken on a patient and how to input these measurements into the applicable SolidWorks equations. This manual also details how to assemble the prosthesis and

recommended accompanying sleeves and socks for a patient to use with their socket for a secure and comfortable fit.

3.3 Objective 3: Lower Production Time

Another objective for this project was a lower production time than competing prostheses. As previously mentioned, prostheses can take over six months to customize and develop. This is partially due to the complexity surrounding customization procedures but is also due to manufacturing and assembly techniques. Through research, it was determined that 3D printing could be an effective manufacturing technique that would lower production time significantly. 3D printing can be done in a wide range of materials, so each different component was created through 3D printing. 3D printing is also a relatively inexpensive manufacturing technique, as simple machines can be even under \$500. Material supplies for 3D printing can be inexpensive as well, depending on the material itself and the machine being used.

3.4 Objective 4: Accurately Mimic Natural Gait

During research of different types of prostheses available on the market today, all devices were measured on their abilities to naturally mimic human gait. The natural gait path of a user was discussed in Chapter 2.4, and this background information was used to determine the desired gait path that the prosthesis should be able to mimic. PMKS online software was used to develop a linkage system that closely recreates the projected human gait path, and this linkage system was created in SolidWorks (Andrews et. al, 2018). A system was designed to attach the prosthesis to

the bottom of the linkage system to determine if it can accurately mimic a user's gait path. When developing this design, the prosthesis and linkage system must have been able to move accurately throughout the path while also touching the floor to accurately mimic human gait. An initial prototype was constructed from laser cut acrylic, and the prosthesis was attached, and its path was analyzed. This system set-up was recreated in SolidWorks with the linkage system, full prosthesis, and mounting system all included. A motion study was performed on the prosthesis to confirm that it can mimic a user's natural gait path when being used.

Chapter 4: Component Design

Once the objectives had been established, the different prosthesis components were designed in SolidWorks. All parts were designed using global variables so users have the ability to input their measurements into the SolidWorks files to generate the appropriately sized design. Different manufacturing methods were used for each part based on desired characteristics and behaviors.

4.1 Foot

As one of the main components for the design, the foot was developed based on current prostheses. The main goals in the design of the foot were to provide stability during the stance phase of the gait cycle as well as flexion in the direction of walking to mimic the functionality of an ankle during the gait cycle.

4.1.1 Initial Design

Based on background research, it was decided that the best course of action would be to design a Dynamic Energy Response (DER) foot to account for users with higher k-levels of mobility. This means that the design needs to be able to absorb energy during the heel strike phase of the gait cycle and then flex forwards during the pre-swing phase. The flexion during the pre-swing phase is important to mimic the mobility of an ankle joint to help aid in recreating a normal gait cycle. With this being said an initial design was generated based on the concept of a DER foot, which is shown in the figure below.

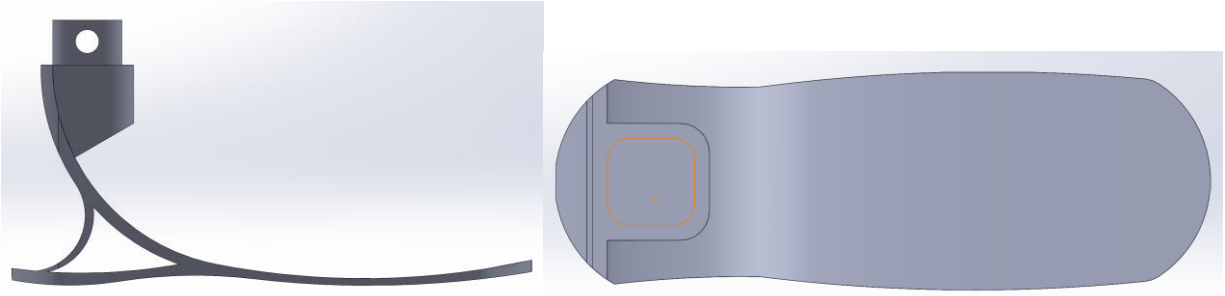


Figure 16: Front and Top Views of Initial DER Foot Design

The design followed a similar geometry of a normal foot to provide stability and balance, which widened in the forefoot to 7.45 cm, then caved in to 6.50 cm at the underfoot arch and then widened back to 7.0cm in the heel. . In the heel is a curvature of radius 2.5 to provide stability upon heel strike, while having the intended purpose of deforming to help with energy absorption during that phase of the gait cycle. Next, the forefoot was given a small radius to allow for energy transfer as the user moves from the stance phase through pre-swing to toe push off. This design was made to bend in the forefoot as well as in the ankle region to provide kinetic energy that would assist in initiating the swing phase of walking. The final aspect of this design was developing a way for the foot to connect to the pylon. It was determined as a team that the best approach to completing the objective for having interchangeable parts would be for the foot to insert into the pylon and be secured by a through bolt to prevent separation. For this, a connection was added that was made to fit into the pylon to secure both parts together. This initial design was printed in PLA due to its easy accessibility and usability for the team. After initial printing a number of design flaws were noticed. Flaws in this design were created by poor design for manufacturability, which was caused by the lack of a flat surface in the part that could be used as the foundation of the print.

4.1.2 Design Iterations

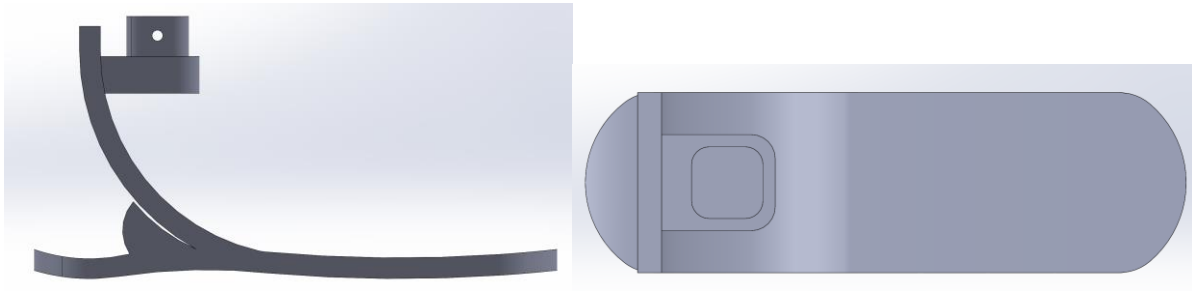


Figure 17: Front and Top Views of Second Design Iteration of the Foot

The second iteration of the design included five main changes, shown below in Figure 18: the curvature in the back of the heel was modified, the thickness was increased for manufacturing purposes, the sides were made flat for manufacturing purposes, a different material was used and tolerancing for the connector piece was modified to fit the pylon better.

Name of Dimension	Iteration 1 (cm)	Iteration 2 (cm)
Thickness	0.5	1.0
Heel Radius	2.5	2.06
Height From Ground to Connector	9.44	10.61
Forefoot Width	7.54	7.5
Forefoot Arch	6.5	7.5
Forefoot Heel	7.0	7.5
Length (Heel to Toe)	22.4	25.1

Figure 18: Change in Dimensions from Design Iteration 1 to Iteration 2

In this design iteration, the thickness was increased, and the sides of the foot were made flat. These design changes were made to provide a flat surface on the bottom of the part during printing, which was needed for it to be manufactured using the Markforged Mark 2 printer in the Rapid Prototyping (RP) Lab in WPI’s Higgins Laboratory, using Nylon filament (WPI Rapid

Prototyping Laboratory, 2020). The switch to Nylon was made because of its ability to bend while also providing some structural stability. The curve in the heel was changed to what is shown above from the original design to absorb some of the energy during heel strike but was not attached to the upper part of the foot so that it would not restrict or prevent the ankle area from flexing during pre-swing and toe push. In order to fit onto the print bed of the machine, the pylon connector was moved down. The big issues with this design were centered around the manufacturing process that was utilized. Even though the Markforged Mark 2 printer is a higher quality printer with a double nozzle that allows for carbon fiber and Kevlar reinforced parts, it was not able to successfully print the foot defect free due to the length of time it took to print the foot, which was 34 hours. The defects in the part were due to the bottom of the part rising up from the print bed which caused the path of the nozzle to shift to the side creating a raised surface throughout the entire part. Defects in areas where dimensions were not critical, such as a slightly raised surface in the forefoot was left on the foot, but a Dremel was used to shave down defects on the connection piece, where tolerancing is critical to fit into the pylon, and a drill was used to clean out the hole for the bolt.

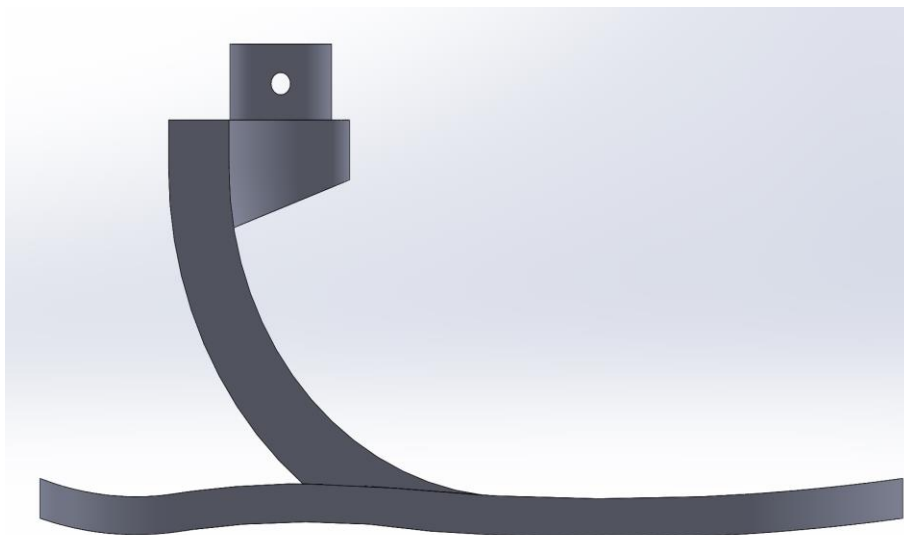


Figure 19: SolidWorks Model for the Third Design Iteration of the Foot

The third design iteration was made with a number of changes which includes, a different material, no curvature in the heel, the connector piece moved back up to its original spot and an increase in thickness of the ankle region.

Dimension	Iteration 2 (cm)	Iteration 3 (cm)
Thickness of Ankle	1.0	1.76
Thickness of Forefoot/Heel	1.0	1.01
Height from Ground to Connector	10.61	10.36

Figure 20: Change in Dimensions from Design Iteration 2 to Iteration 3 for a Model with the same Length

In the third iteration shown above in Figure 20, the thickness of the ankle portion of the foot was increased to add stability and to increase the amount of force needed to create flexion in the ankle region. The ankle portion was also moved up, to more accurately represent where the ankle is located in relation to the foot. This design was printed using TPU, a cheaper and more accessible filament with the ability to flex in a similar fashion to nylon and it has the ability to be printed using a printer that is less complex than the Markforged Mark 2 (Matterhackers, 2019, and WPI Rapid Prototyping Laboratory, 2020).



Figure 21: Three Part Design in ABS (Left) and Carbon Fiber Foot (Right)

Two separate design iterations were created using different materials and are pictured in the figure below. The blue foot shown in Figure 21 was based on the third design iteration discussed earlier.

This design was modified to be manufactured in three separate parts that could be attached via an adhesive. A three-part design would allow for a quicker manufacturing process and shorter lead time if there were three machines available to print a single part. This initial design was printed in ABS to investigate the tolerancing used and how well parts fit into one another. However, due to time working time working on this foot being cut short by COVID-19, adhesion testing for adhesives and design changes for the points of connection were not able to be made.

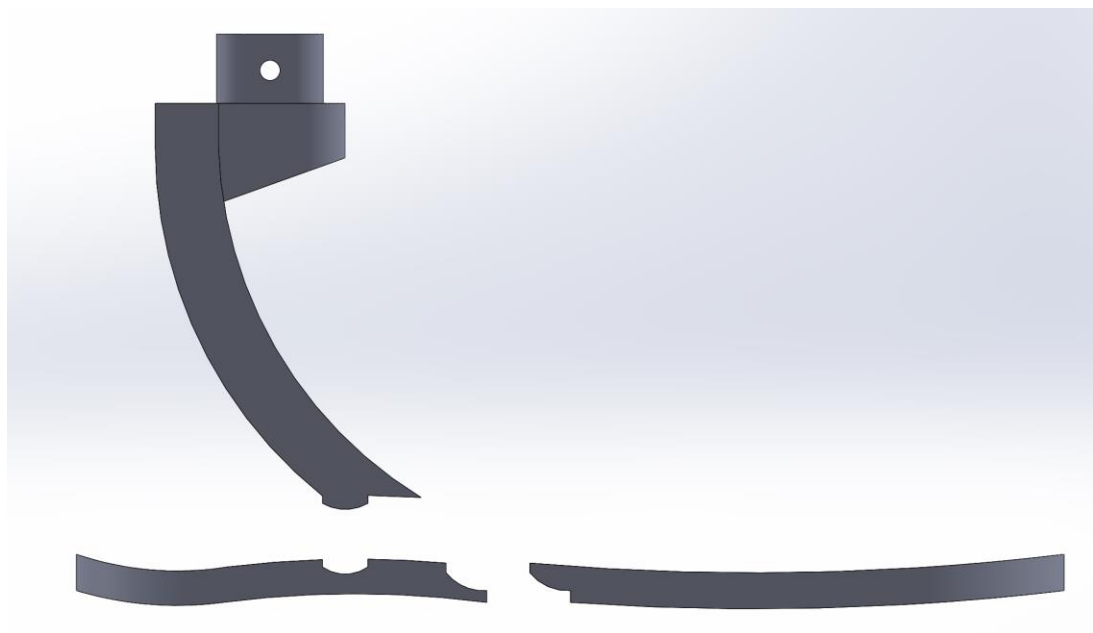


Figure 22: Exploded Front View of Three-Part Foot SolidWorks Model

The second foot shown in the figure above was manufactured using carbon fiber. This design was also based on the design of design iteration number three. 3D printed molds were developed based on the CAD model for design iteration three and were printed in the RP Lab. The

carbon fiber prepreg from Rockwest Composites, was cut using templates made from the mold and laid up layer-by-layer onto the mold. After being laid up onto the mold the mold was vacuum bagged and placed into an oven where the carbon fiber was left to cure at 275 degrees Fahrenheit for two hours, where it was then removed and left to cool overnight. A driving force for this design was the common use of carbon fiber in current prosthetics. A number of issues were present in this model. The main issue with this model was the brittleness of the carbon fiber used that prevented the needed flexion in the ankle region during toe push. As discussed in section 3.1.3.3, an adapter made out of ABS was added to the model and was secured to the foot using quarter inch bolts and hex nuts to allow for the foot to connect to the pylon.

4.1.3 Sizing and Parametrization

For design iteration three, the model was adjusted to have all dimensions vary based on the length from the “heel” to the “toe”. A global variable was made for length, and a relationship for all other dimensions was established with regards to length. The relationship for dimensions can be found in Figure 23 below.

Dimensions such as length and width were developed using anthropometric shoe size data. A general relationship was established for width, with regards to length of all adult US shoe sizes. The relationship for width to length was created by averaging the quotient from width divided by length. From here, a configuration was added to the CAD model in SolidWorks for each shoe men’s and women’s adult shoe size, which ranges from a women’s size 5.5 to a men’s size 14. This will allow for a foot to be easily printed for any potential user based on their shoe size.

Shoe Size	Length (cm)	Width (cm)	Foot/Heel Thickness (cm)	Ankle Thickness (cm)
W5	21.6	7.7112	0.864	1.512
W5.5	22.2	7.9254	0.888	1.554
W6	22.5	8.0325	0.9	1.575
W6.5	23	8.211	0.92	1.61
W7	23.3	8.3181	0.932	1.631
W7.5/M6	23.6	8.4252	0.944	1.652
W8/M6.5	24.1	8.6037	0.964	1.687
W8.5/M7	24.5	8.7465	0.98	1.715
W9/M7.5	24.9	8.8893	0.996	1.743
W9.5/M8	25.4	9.0678	1.016	1.778
W10/M8.5	25.8	9.2106	1.032	1.806
W10.5/M9	26.1	9.3177	1.044	1.827
W11/M9.5	26.7	9.5319	1.068	1.869
W11.5/M10	27.1	9.6747	1.084	1.897
W12/M10.5	27.5	9.8175	1.1	1.925
M11	27.9	9.9603	1.116	1.953
M11.5	28.3	10.1031	1.132	1.981
M12	28.6	10.2102	1.144	2.002
M12.5	29.2	10.4244	1.168	2.044
M13	29.5	10.5315	1.18	2.065
M13.5	30.2	10.7814	1.208	2.114
M14	31	11.067	1.24	2.17

Figure 23: Table of Dimensions Including Length, Width and Both Thicknesses for all Shoe Sizes Used.

4.2 Pylon

With the three parts laid out and their required characteristics set the pylon could be designed. Aiming to make a connection piece between the foot and the socket structural stability was the main aspect in creating the pylon.

4.2.1 Initial Design

The initial pylon design was strongly based around the structural design of the tibia bone that is in humans' legs and can be seen in Figure 24 below. This is because the typical procedure for below the knee amputations is the transtibial amputation. This being said the design began with making a wider top and bottom that slowly caved in towards the middle without losing too much width that it would become weak, but enough so that it would reduce the weight and size of the pylon.

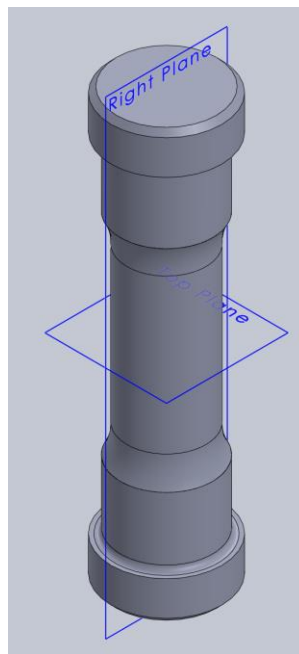


Figure 24: Initial Pylon Design

Once the initial pylon was made, the next step was finding the best way to connect the pylon to the other two main parts of the prosthetic. This was done by making the two ends of the pylon female ends so that the foot as well as the socket could have an insert piece to connect to the pylon as seen in Figure 25.

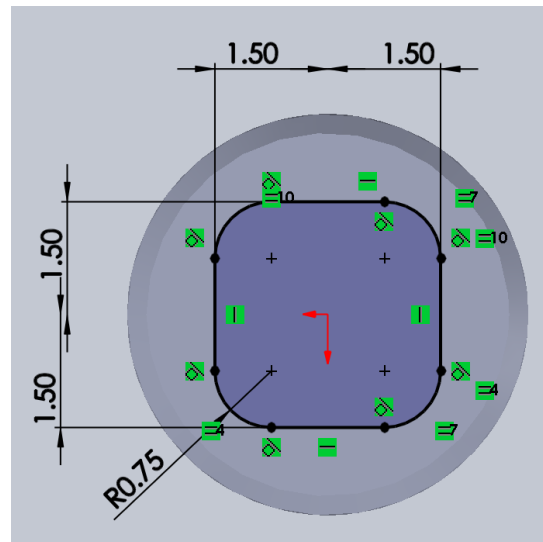


Figure 25: Pylon insert geometry

They would then be secured to each other using through-connector bolts with caps. These go all the way through both the pylon and the piece that it is connected to so that it would reduce the forces being applied to the bolts when weight is added. The initial material that was used for this part was PLA because it was easily accessible, acquirable, and usable. This was the original design idea, but it quickly adjusted to solve issues that the team found, which will be covered in 4.2.2.

4.2.2 Design Iterations

The second iteration of the pylon included three main changes: the use of a different material, adjusting the insert holes on the end and moving the side geometry up and down. The first change was to produce the pylons out of ABS plastic instead of PLA. This was because PLA

does not always hold up well in high temperatures that can be reached in many US states as well as many of the warmer countries around the world. ABS which has very similar properties but has a higher heat deflection temperature was a very easy substitution. The second main change was adjusting the insert holes on the ends so that they had a squarer shape to help reduce any chance of the socket, pylon or foot to rotate when a patient was wearing the prosthetic. They were not ninety-degree corners, they had more of a rounded shape to them to reduce the stress directly on that corner point, as seen in Figure 26.

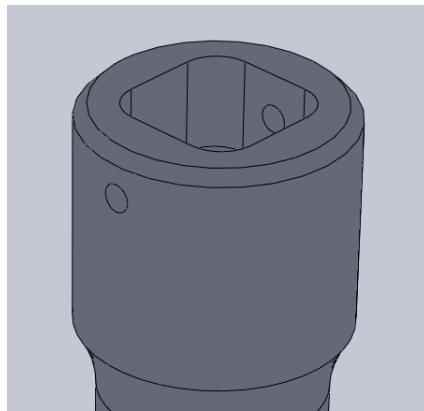


Figure 26: Rounded pylon design

The third change for this newer pylon was to adjust the side geometry along the pylon. This was caused by the team realizing that the shortest person that could use the pylon was four feet and ten inches tall. We wanted to be able to cover a larger array of people so the geometry on the sides had to be slid up so that it would not affect the connector holes when it was shrunk to smaller heights than it previously was. This also led up to the final adjustment we made of making all of the variables global.

4.2.3 Ankle

The design for the ankle amputation was strongly based off of the same design for the pylon. The two separate amputations have very similar needs for their general prosthetic: that being the socket, the foot, and the connector piece between the two. When it came to actually designing the piece that would connect the pylon and the socket for the ankle amputation, it is a very similar concept to that of the pylon. To design this piece, it was very simple in the fact it just needed to be able to connect the male end of the foot and the female end of the socket.

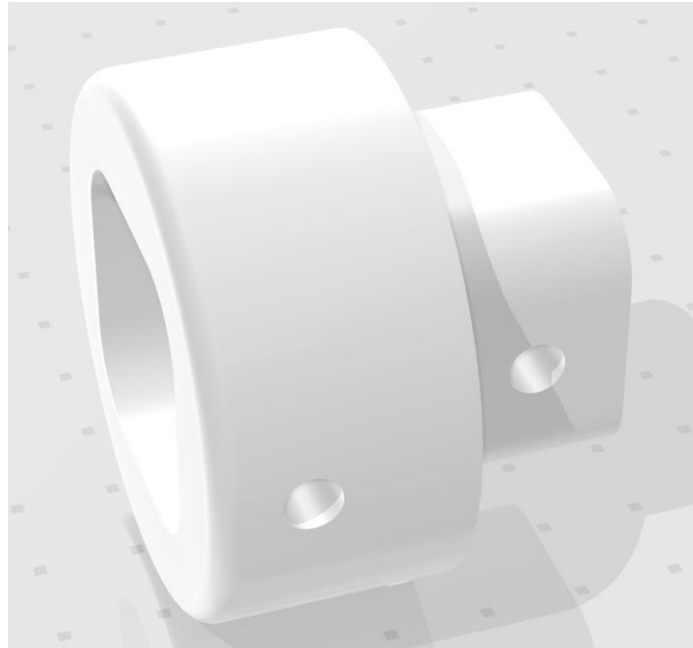


Figure 27: Ankle Connector Design

This design only had one iteration, as seen in Figure 27, due to the fact it was based so strongly off of the pylon. Similar to the pylon for the foot end it had the same female end that would fit the foot to fit perfectly inside allowing the bolts to connect the two parts. The other end is set up very similarly to the insert pieces that are designed for the socket that fits inside and then using adhesives is attached to the socket. This piece does not only adhere on the inside of the socket but also on the bottom flat surface to allow more contact area, making it less likely to pull

apart. These two end pieces are the same depth for the female end and length for the male end as the pylon so it could easily replace the pylon for the ankle amputations.

4.2.4 Sizing and parametrization

The initial pylon was designed to fit a male that is the average height for men in the United States, of 5'9". Then other variations were printed for a male in the 75th percentile for men in the United States along with the 50th percentile female in the United States. These global variables can be seen in Figure 28 here. These different products along with the ankle connector displayed the sizing and parameterization availability for the prosthetic as a whole.

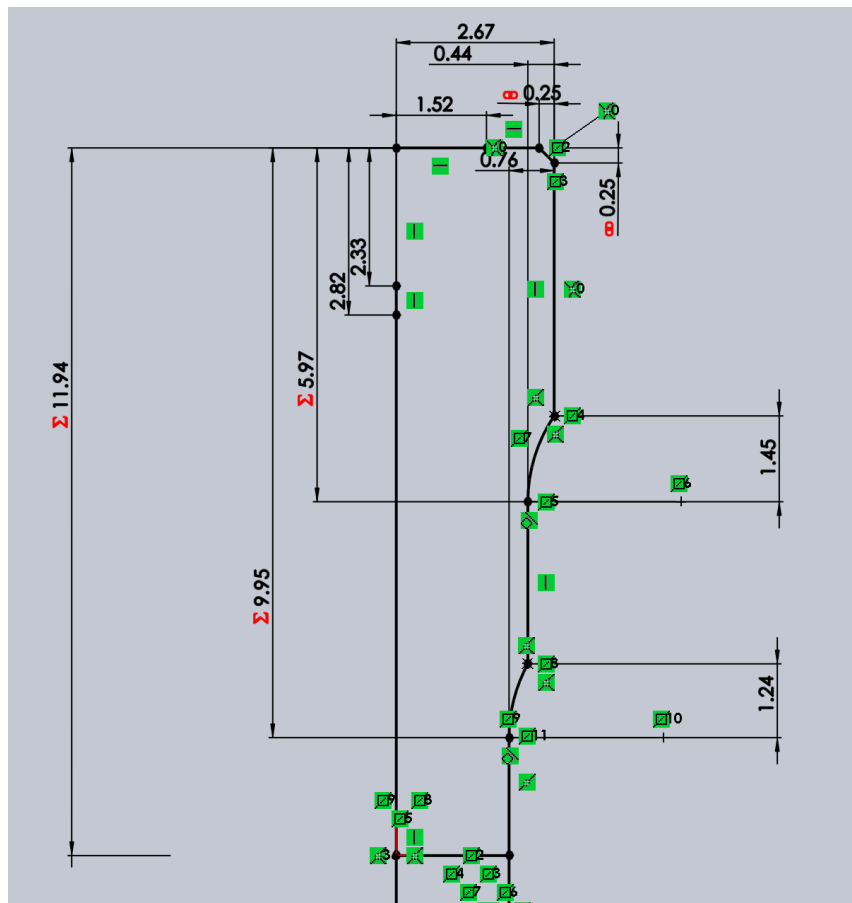


Figure 28: Sketch geometry of pylon showing global variables.

For the global variables on the full pylon, the main focus was to make sure every dimension would adjust correctly when the total height was changed. However, the way the pylon was designed it was mirrored around the x-axis so to adjust the total height, only half of the height of the pylon would need to be input, and the rest would correct itself. Once it was known that the minimum length for the pylon to be is 11.887 cm, it was easier to connect all of the rest of the dimensions to this length. This is because the only dimensions that would need to adjust for the pylon to fit to all length pylons is the total length of the side of the pylon.

Based on how tall the prosthetic needs to be to fit the specific person the ankle connector only has one global variable to adjust to the patient who needs it which can be seen in Figure 28. The variable is the length of the area in between the male and female ends. The spacer can be as small as adding zero extra length to the total height so that it is not affected by it being there, or it can be long as needed. This is adjusted to make sure however low the patient's stump goes the prosthetic can fit them.

4.2.5 Customization

The level of amputation is generally explained in the ankle pylon and foot sections of the Prosthetic Parts section. However, to be more exact, the prosthetic is designed to fit anyone that gets a below the knee amputation as long as they are taller than four feet tall. This is done by having both the pylon and the ankle connector piece. The ankle connector piece can be seen in Figure 27. This allows the prosthetic to be able to adjust to the level of amputation a patient has.

For both ankle and transtibial amputations, there are two main measurements to take for the height; how long the section of leg that is missing is and the foot size. The foot size is important because the height of the foot is proportional to how long the foot is similar to how it is on a

human body. Knowing that there is always roughly one centimeter of distance that will be dedicated to where the socket connects to the pylon and that the height of the foot part is variable to the foot size the whole prosthetic sizing can be found.

4.3 Socket

As the main interface with a user's body, the socket must be able to attach to both the user's stump and the rest of the prosthesis. Based on literature review in chapter 2, a total surface bearing socket design was constructed. These designs require less production time and are customized to fit around a user's stump and create suspension through tension and adhesion. This type of design also does not require suspension to be created around the thigh or surrounding the patella, so therefore requires less customization as well. When attaching to a user's stump, the socket must be comfortable to wear and securely stay on the stump. The socket must be able to properly fit a user, so one must be able to generate models based on their specific measurements and stump geometry. Generating different models must also be simple, as the objectives of this project included the ability to be customized to a user's requirements and to diminish production time. To satisfy these objectives, the socket was designed using global variables that signify different stump geometries. These geometries include stump length and diameter, to ensure that socket designs are not too small or large or too long or short. When selecting materials for the socket, ensuring a comfortable fit for an amputee was difficult, as this project did not have the ability to test or survey human subjects. For material selection, a flexible material was chosen in contrast to the pylon and foot's rigid, stiff materials. The final socket design was printed in a flexible resin material and designed to have a rigid insert to connect to the pylon. Concerns arose when considering if a

flexible material would be the best option for the socket to pylon connection, as it could be more likely to deform and fail. Therefore, 3D printed inserts were created and attached using adhesives.

4.3.1 Initial Design

The socket design began by examining geometry of amputee stumps and the amputation process. Residual limb length is typically 5-7in, as mentioned in Chapter 2 above, and stumps are constructed to taper at the bottom. The socket was constructed as a revolved sketch with different variables for a larger diameter, smaller diameter, and stump length. The socket was constructed in this manner due to the way stumps taper towards the bottom. The diameter of the socket should taper like a stump, for a proper fit; this desired geometry was discussed in Chapter 2.

The initial developed sketch was designed using linear geometry, which can be seen in Figure X below. The sides of the socket were straight and not curved, and the sketch consisted of radii for the large and small diameters, connected by a single straight line. This design resulted in a cup-like shape, creating corners and edges at the base near the pylon connection point.

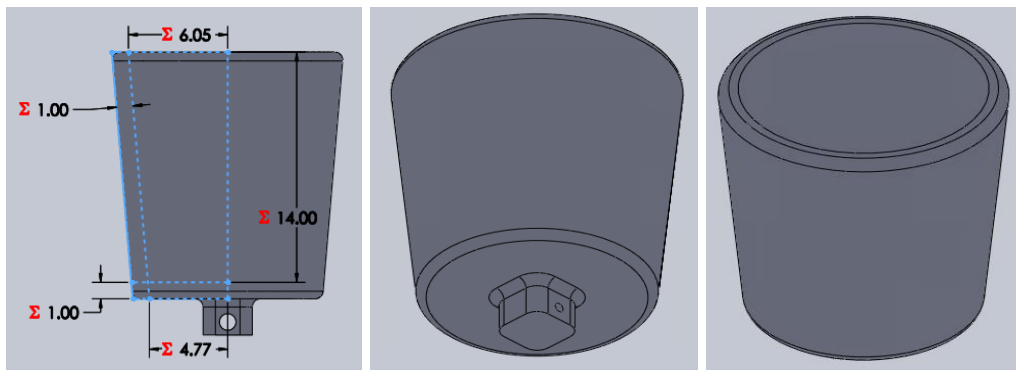


Figure 29: Preliminary Socket Geometry, shown in both sketch and isometric views

In Figure 29 above, the first image shows the global variable geometry used within the sketch. Of these dimensions, 14cm correlates to the stump length, 6.05 represents the large radius,

and 4.77 represents the small radius. The radius measurements are inputted as a diameter, as that is the manner in which a user would be taking the measurement, and radius values are calculated from diameter input. The global variables in SolidWorks can be seen below in Figure 30.

Name	Value / Equation	Evaluates to
[-] Global Variables		
"Lradius"	= 38cm / (2 * pi)	6.04789cm
"stumplength"	= 14cm	14cm
"Sradius"	= 30cm / (2 * pi)	4.77465cm
"thick"	= 1cm	1cm
<i>Add global variable</i>		

Figure 30: Global variables in Solid Works equations showing the radius calculations from diameter measurements.

4.3.2 Design Iterations

After creating the preliminary design for the socket, modifications were made. The previously mentioned linear geometry was determined to be unnatural. Approximations of stump geometries can be seen in Chapter 2, and the tapered and rounded characteristics should be noted. The preliminary socket design contains straight, rigid geometry, as seen in Figure 29 above, and does not mimic the rounded nature of an amputation in Chapter 2.

To improve the socket, the geometry was changed to be that of an ellipse, with the ellipse geometry being linked to the measurements of a user's large radius, small radius, and stump length.

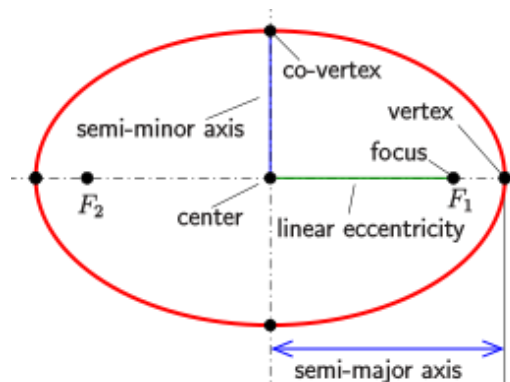


Figure 31: Ellipse Geometry showing vertex and co-vertex points. Reproduced as is from Ellipse (2020). In *Wikipedia*. Retrieved from <https://en.wikipedia.org/wiki/Ellipse>

The vertex of the ellipse is located at the origin, and the co-vertex of the ellipse is located at the point where the small radius and taper length intersect. In Figure 31 above, ellipse geometry can be seen and in Figure 32 below, the vertex of the ellipse is at Point A and the co-vertex of the ellipse is a Point B.

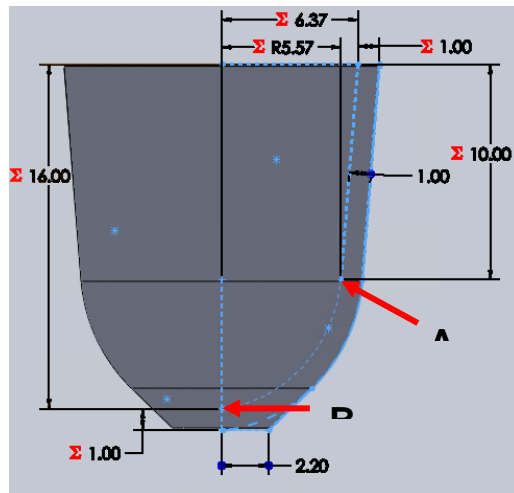


Figure 32: Ellipse Geometry in Socket Design

When the full prosthesis was assembled, changes to the socket design were made to make the prosthesis look more uniform. The socket had a universal thickness measurement that was the same in the whole socket, but when assembled, this resulted in a gap between the bottom of the socket and the top of the pylon that looked as if the pieces did not fit together, seen in Figure 33.

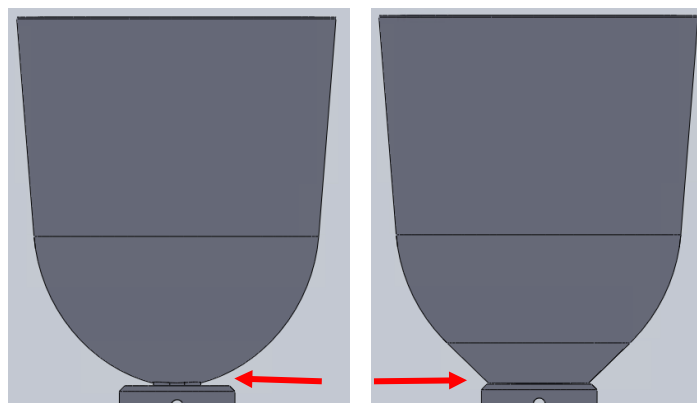


Figure 33: Socket design before and after showing non-uniform appearance and following adjustments.

Therefore, the socket thickness was adjusted at the bottom near the pylon connection to be thicker. The final socket design in assembly can be seen below in Figure 34.

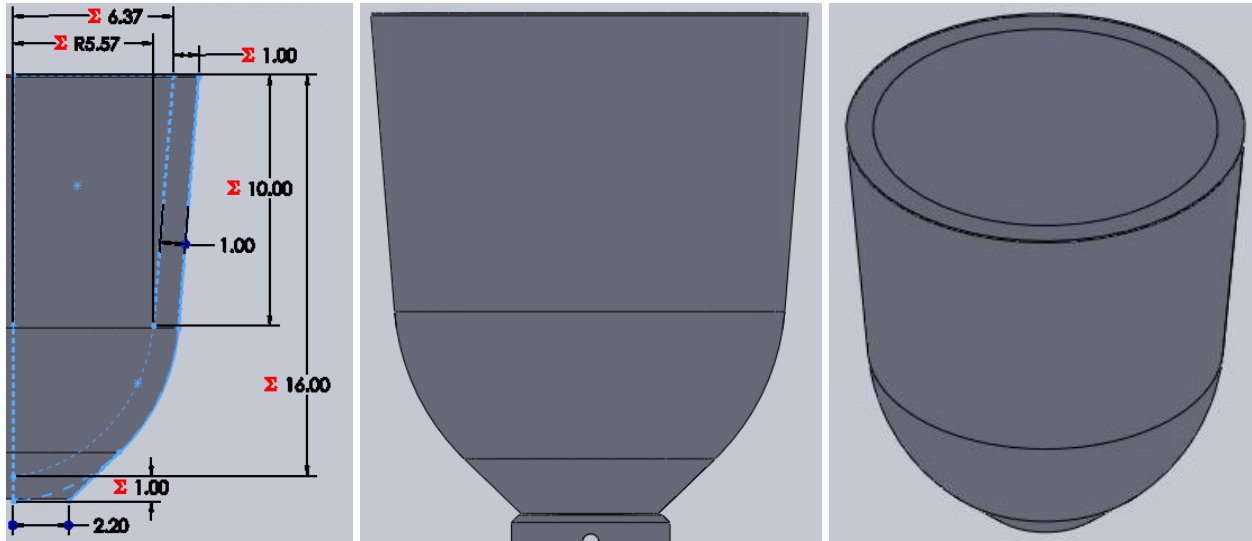


Figure 34: Final Socket Sketch Geometry, Isometric View, and in Full Assembly

4.3.3 ABS Inserts

The final socket design was printed in flexible resin materials, to ensure a comfortable fit while maintaining the desired geometries. For the connection point to the pylon, the team determined that a more rigid material would be a wiser material choice. When assembling the socket and attaching it to the pylon, the material at the connection point should not deform. Therefore, socket inserts were designed and developed to create a more stable connection point.

This design was based on already-existing pylon and ankle connector designs and constructed to have two male ends. One of these ends is inserted into a cutout in the socket, and the other is inserted into the pylon. The insert design can be seen below in Figure 35.

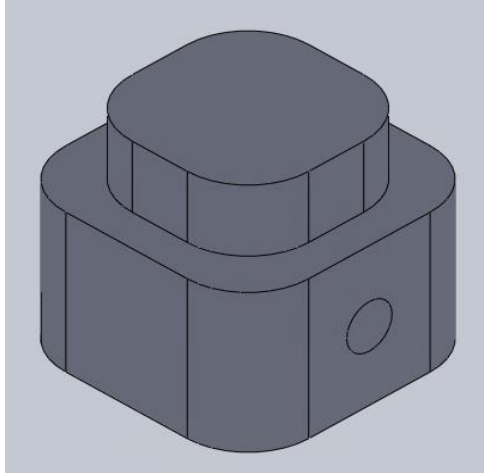


Figure 35: Socket insert in isometric view.

To connect the insert to the socket, adhesives were investigated to find a material that is strong enough to hold the parts together and is compatible with the materials for each part. After consulting with Dr. Erica Stults of the Rapid Prototyping Laboratory at WPI regarding material properties of the flexible resin the socket was printed in, different Marine Adhesives were investigated. Adhesives like superglue would peel off of the parts, and acrylic caulking could peel off with some effort (Stults, 2020). Dr. Stults recommended two marine adhesives, 3M4200 and 3M5000. 3M4200 is used on boats while 3M5000 is used on the waterline under boats. Based on this information, and preliminary testing observing effectiveness of acrylic caulk, 3M4200, and 3M5000, 3M5000 was determined to be the optimal choice for insert adhesion. Both 3M4200 and 3M5000 held the connection, while acrylic caulk separated slightly and did not adhere the parts effectively. Due to 3M5000's waterproof nature, it was determined to be the optimal option.

4.3.4 Customization

As mentioned above, the socket is designed as a revolved sketch that references different geometries of a user's stump: large diameter, small diameter, length, and taper length. The stump

length is the length from the back of a user's knee to the bottom of the stump. The larger diameter is the circumference of a user's leg directly below the knee. The smaller diameter is the circumference of a user's stump at the bottom of the stump, before it rounds off. The taper length is the length from the point at which the smaller radius is measured to the bottom of the stump. In the Prosthesis Preparation Outline, instructions on how to measure stump geometry was explained in detail. The following figures detail measurement specifications.

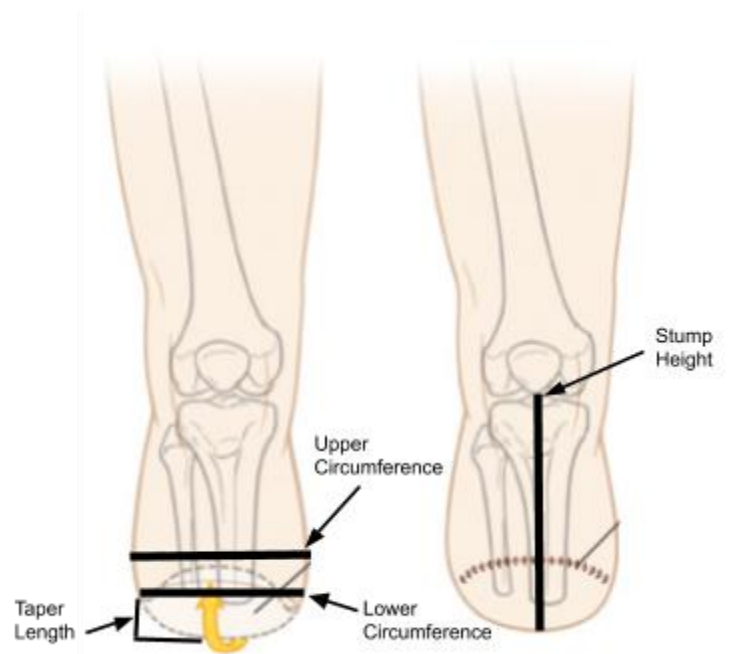


Figure 36: Stump Measurements from Prosthesis Preparation Outline

When inserting these measurements into the SolidWorks file, a user can generate the appropriately sized prosthesis based on their dimensions. Based on the ellipse geometry of the sketch, socket shape will change even if only one-dimension changes. In Figure 37 below, a socket for a user with a 12 cm socket and a socket for a user with a 16cm socket can be seen, while all other measurements remain the same. There is very little data regarding typical residual limb

geometry, so it is not possible to determine if the socket will be able to be used for every possible user.

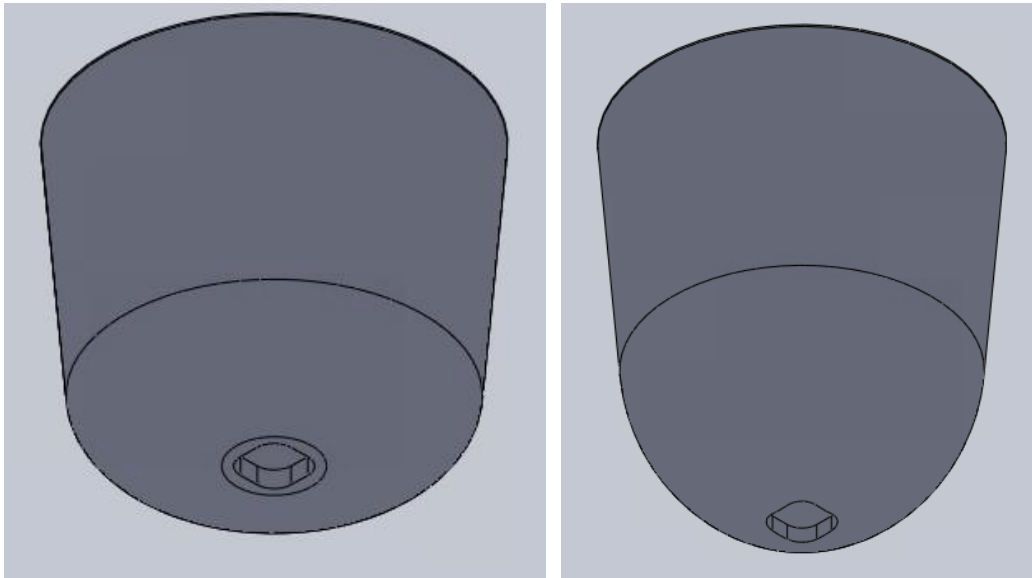


Figure 37: Socket designs with different stump lengths but all other measurements the same.

Chapter 5: Manufacturing and Assembly

Each component of this design was individually considered when manufactured. Within the parameters of this project, two different 3D printers were used: Creality CR-10s and Prusa MK3. When using the Creality printer, CURA slicing software was used. When printing with the Prusa machine, PrusaSlicer slicing software was used. In terms of materials, all initial designs were printed with polylactic acid (PLA) due to its commonality. As each design changed and requirements developed, the material selection also changed and reflected these needs.

5.1 Socket

The initial iterations of this design were printed with PLA. This was because a physical model was needed for analysis of the shape as well as the connections between components. Utilizing the PrusaSlicer slicing software, this component was sliced and printed with a 15% infill, a rectangular infill pattern, bed temperature of 60°C, extruder temperature of 200°C, and a general 30 mm/s speed. The socket was oriented on the bed facing upwards and support structures were used to solidify the foundation. After this part was printed, it was decided that this component needed a more flexible material. This is because per user requirements, comfort is one of this component's priorities as it comes into direct contact with the wearer's residual limb. PLA's rigidity is a problem in this case when considering comfort, so other materials were investigated for later iterations.

For the next iteration of the socket, it was decided to use silicone molding to try to get a more flexible result for the socket. The desired flexibility related to the socket's ability to stretch

and conform to a residual limb as well as not tear as the patient is taking the socket on or off. A mold was created using SolidWorks and was printed with PLA on the Prusa MK3 printer. The mold represented the residual limb fitting into the socket and was a positive mold of the socket design. After creating the mold, a release agent was sprayed on the PLA and silicone was poured into the mold and cured. Smooth-on Eco-Flex 00-10 silicon was used for this process due to its skin-safe properties, its elasticity, and its ratings in prosthetics. Specifications of this material can be found in Figure X. The reason behind choosing the 00-10 silicon rather than the other silicones in the Eco-Flex series was that its shore hardness was the lowest, so that the most flexible result would be obtained.

TECHNICAL OVERVIEW

	Mixed Viscosity (ASTM D-2393)	Specific Gravity (g/cc) (ASTM D-1475)	Specific Volume (cu. in./lb.) (ASTM D-1475)	Pot Life (ASTM D-2471)	Cure Time	Shore Hardness (ASTM D-2240)	Tensile Strength (ASTM D-412)	100% Modulus (ASTM D-412)	Elongation at Break % (ASTM D-412)	Die B Tear Strength (ASTM D-624)	Shrinkage (in./in.) (ASTM D-2566)
Ecoflex™ 5	13,000 cps	1.07	25.8	1 min.	5 min.	5A	350 psi	15 psi	1000%	75 pli	< .001 in./in.
Ecoflex™ 00-50	8,000 cps	1.07	25.9	18 min.	3 hours	00-50	315 psi	12 psi	980%	50 pli	< .001 in./in.
Ecoflex™ 00-30	3,000 cps	1.07	26.0	45 min.	4 hours	00-30	200 psi	10 psi	900%	38 pli	< .001 in./in.
Ecoflex™ 00-33 AF	3,000 cps	1.07	26.0	45 min.	4 hours	00-33	200 psi	10 psi	900%	38 pli	< .001 in./in.
Ecoflex™ 00-20	3,000 cps	1.07	26.0	30 min.	4 hours	00-20	160 psi	8 psi	845%	30 pli	< .001 in./in.
Ecoflex™ 00-10	14,000 cps	1.04	26.6	30 min.	4 hours	00-10	120 psi	8 psi	800%	22 pli	< .001 in./in.

*All values measured after 7 days at 73°F/23°C

Mix Ratio: 1A:1B by volume or weight	Useful Temperature Range: -65°F to 450°F (-53°C to 232°C)
Color: Translucent	Dielectric Strength (ASTM D-147-97a): >350 volts/mil

Figure 38: Overview of different Eco-Flex specifications. Reproduced as is from Smooth-On. (2019). Ecoflex™ 00-10 Product Information. Retrieved from <https://www.smooth-on.com/products/ecoflex-00-10/>

The advantages of using this material were that the final product was very elastic and could easily be applied to a wearer’s residual limb without breaking. The disadvantage was that there was a need to create an adapter piece that would be integrated into the silicone socket in order for the socket to attach to the pylon. If the connection was made using only silicone, the silicone would

most likely rip and wouldn't provide a safe connection for the patient. To eliminate this problem, a 3D printable material that was flexible was then chosen.

Another method that was tried during the manufacturing of the socket was Stereolithography, or SLA printing. In SLA, an object is created by selectively curing a polymer resin layer-by-layer using an ultraviolet (UV) laser beam (3DHubs, 2019). Utilizing the FormLabs Mark Two printer, a socket was made out of cured 'Flexible Resin'. The reason behind creating this resin socket was to investigate other flexible materials that can hold geometry and would not deform during use. In the end, the resin socket had both advantages and disadvantages. The main advantage of this manufacturing technique was that the material itself could be easily interchanged to alter the amount of flexion; the grade or amount of flexibility in the resins can be increased or decreased easily. The disadvantages of this method were that there was no clear ideal orientation that the socket could be cured in to get a quality surface finish, and that the connection between the socket and the pylon would create too much stress for the resin to withstand over the prosthesis's lifetime. As the socket was cured, there had to be an amount of support material either on the inside or outside of the socket, depending on the orientation set by the printer. After the socket was completed, one would have to cut out the supports, making it a tedious and messy process and resulted in a finish that would not be comfortable for the user if it came into direct contact with their skin. So, another flexible material was investigated for the final iteration of the socket.

In the socket's final iteration, thermoplastic polyurethane (TPU) was chosen. TPU is a flexible filament material that is resistant to abrasion, grease, and oil (Matterhackers, 2019). Due to its excellent rating in layer bonding and its flexibility, it was determined to meet our component requirements. When printing the socket with TPU, the temperatures of the bed and nozzle, the

printing speed, and infill were changed to result in the ideal socket. The bed temperature was set at 40°C while the nozzle temperature was set to 240°C. The print speed was lowered from 30mm/s to 20mm/s as this material needs the slow speed to get quality bonds between layers and reduce the risk of layer separation. The infill was printed using 10% infill but the infill pattern was altered from rectangular to cylindrical in order to achieve the desired level of flexibility and rigidity. Still unsatisfied with how this part was printed, it is recommended to continue printing with this material and settings but change the infill pattern to grid or cubic. A hollow socket printed with TPU is below. The bottom section of the socket where the stump will rest and connect into the pylon was found to have strength issues. Essentially, the material tore. Consequently, other methods of printing this component were investigated. For example, printing with multiple materials to strengthen that section while also providing flexibility and elasticity at the top, and different infill patterns and percentages applied to different cross-sections throughout the print are two such methods.

5.2 Pylon

Similar to the socket, the pylon was originally printed with PLA. Both printers, the CR-10s and the Prusa MK3, were utilized in the manufacturing of the socket due to its varying height. Initially, the nozzle temperature was set 215°C and the bed temperature was set at 50 °C. Every part printed with PLA used 30 mm/s speed and 15% infill, using rectangular infill patterns. PLA resulted in satisfactory rigidity as it can support the weight of any wearer and complex shapes can be created with it. Though, issues with this material arose when looking at its heat deflection temperature. If this prosthetic device is to be worn anywhere in the globe at any time of year, it

was found that in the hotter climate's PLA would warp and deflect under the extreme heat. Its heat deflection temperature is 49°C. For this reason, another rigid plastic was found.

Acrylonitrile butadiene styrene, or ABS, was chosen. Although ABS is less rigid than PLA, it is a stronger filament that is able to withstand extreme temperatures. Using the same print settings but different bed and extruder temperatures, as the PLA prototypes, ABS models were created. Other materials, such as carbon fiber reinforced nylon, Nylon X, and carbon fiber were investigated for the pylon, but they were not able to be completed due to time constraints.

5.3 Foot

The initial iterations of the foot were printed in PLA, and later ABS using the same print settings as the socket and pylon. Using the Creality CR-10s printer, the models were created and analyzed against the desired requirements. In this case, both plastics were found to be too rigid. This component needed to have a level of flexibility that creates an elastic deformation response. The foot needed to have a dynamic response in order for a person to walk comfortably on it. So, a material that can flex but was rigid enough to support the compression stress that the prosthetic device creates when in use was investigated.

In order to investigate different materials that were rigid that can flex when under pressure, carbon fiber was used. Making a foot out of carbon fiber was a complex process that included creating a 3D printed mold out of resin. The sheets of carbon fiber were then stuck to the mold in layers and then cured in an oven. This process was not a favorable one due to the emission of toxins as the carbon fiber was baking, so it was not a recommended manufacturing process. The resulting foot, however, was too rigid and would not be easily adapted to fit into the pylon.

Additionally, this process of making this foot was lengthy and not easily repeatable which directly contradicts one of the objectives of this project. As a result, a flexible material that was able to be 3D printed was needed.

Similar to the socket, TPU was used to print the foot. Using the same print settings of a bed temperature of 40 degrees Celsius, a nozzle temperature of 240 degrees Celsius, 20% infill, and a print speed of 20mm/s, a TPU foot was created. It was found that this material achieved the level of flexion that was desired yet was rigid enough to withstand the stress.

5.4 Prosthesis Assembly

After parts were manufactured and material selection was final, it was time to assemble the prototype. Considering that the pieces fit together naturally, the assembly is not only simple but quick. Fasteners were added at each of the connection points to secure the components together and make the prototype functional. A SolidWorks view of the full assembly is below.

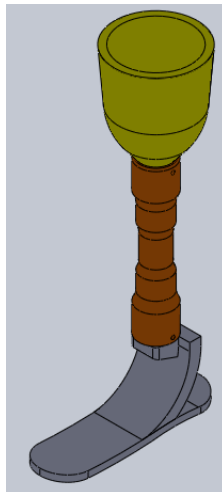


Figure 39: Assembly of all three components: stump, pylon, and foot

5.4.1 Assembly Hardware

While there were many different areas where hardware was thought to be needed in the final assembly of the product there was only one type of hardware outside of the main parts used. The final product is an assembly of three main parts. At the two connecting points between parts, through bolts were used to hold the assembly together as seen in the figure on the right. These bolts slide all the way through both of the connecting parts to hold them in place while the screw fits into the bolt so it could be one flat connection all of the way through both parts.



Figure 40: Assembly Hardware

The specific bolts are aluminum low profile binding barrels and screws. While they are not the strongest material the amount of surface area between the bolts and the parts allows for the connection to stay strong and if needed a stronger material could be selected.

5.5 Artificial Stump

To attach the prosthesis to the linkage system, a stump was manufactured from silicon. This stump was designed from the final socket file so their geometries match. A piece of PVC pipe was mounted in the middle of the stump and had holes drilled into it to attach to the bottom of the

linkage system. When manufacturing the stump, silicon was poured around the PVC pipe, which was clamped and mounted in the center of the stump mold.

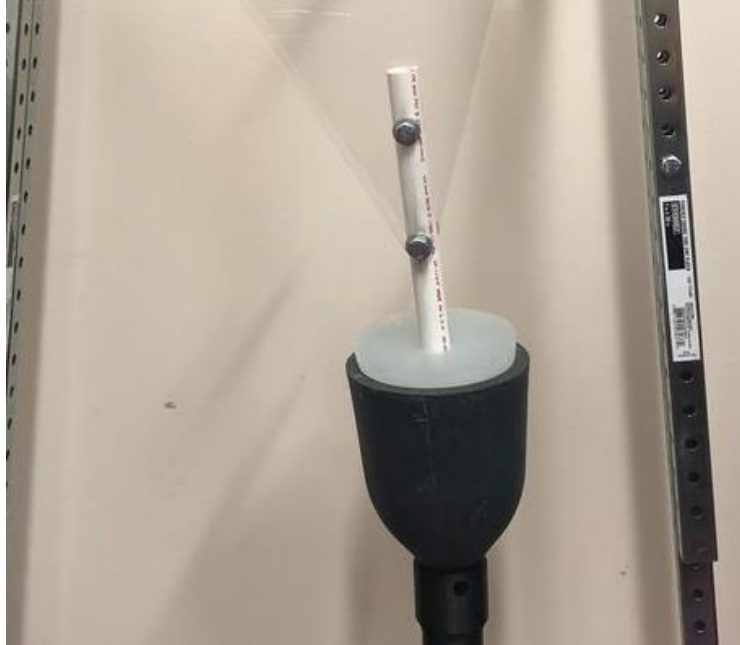


Figure 41: Close Up of Artificial Stump in Linkage Assembly

The silicone chosen for this residual limb replica was another Smooth-On product. This time, Eco-Flex 00-30 was used. Its shore hardness was in the moderate range which meant that it would still have an elastic and dynamic response but would have a more rigid feel. The reason for selecting this silicone was to replicate the feel and texture of human skin and flesh. Proving that the socket would be able to attach to a patient's stump and adhere for the duration of its use was an important test to the overall success of this prototype.

Chapter 6: Testing and Results

As this project did not have access to human test subjects to measure socket fit, gait analysis was measured through determining prosthesis alignment. Following research and examination of natural human gait path as discussed in Chapter 2, a linkage system that creates a path close to approximated human gait was created and developed using online software. The linkage system was developed in SolidWorks once the design was created. The fully assembled prosthesis was then attached to the linkage system and a testing assembly was created to observe the prosthesis's projected gait path. A physical preliminary test set-up was created and observed, and a full test set-up with the prosthesis was assembled in SolidWorks.

6.1 Linkage System Design

The linkage system was designed using Planar Mechanism Kinetic Simulator (PMKS) online to determine exact sizing and geometry of each component of the linkage system. The software used was developed by a team of WPI students in 2018, advised by Professor Pradeep Radhakrishnan, and their software was based on original work by Dr. Matthew Campbell at Oregon State University.

PMKS creates four-bar linkage systems and allows users to set which bars are grounded, adjust bar lengths, and view projected paths of each joint. To generate the path seen in Figure 14 in Chapter 2, the lengths and positioning of the bars of the linkage system were adjusted experimentally until the projected path mimicked that of human natural gait.

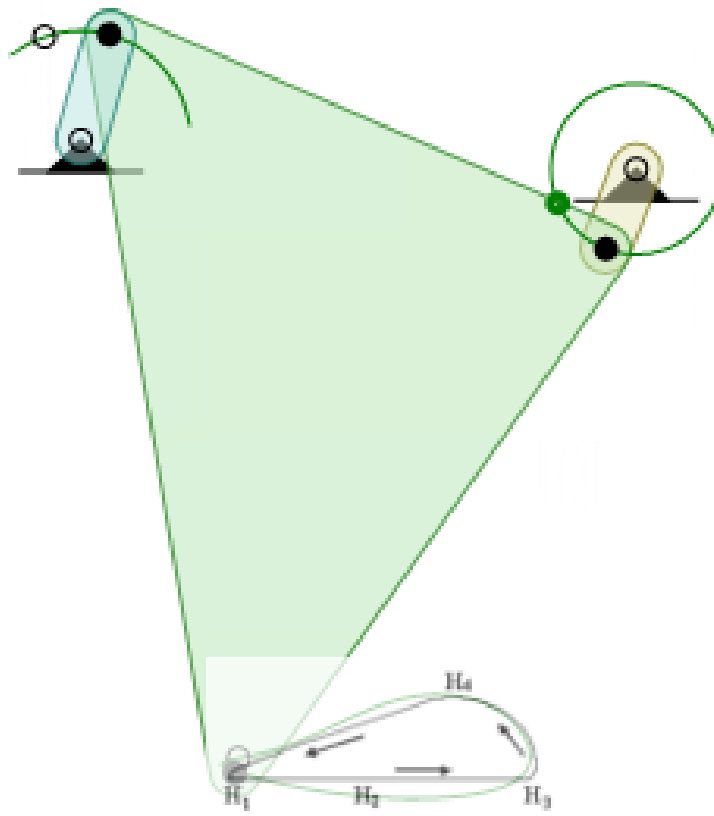


Figure 42: Generated Linkage System Design and Overlay of Desired Path from Chapter 2

In the figure above, the green path lines represent each path's projected motion. As the rightmost bar creates a full rotation, this point would be the articulation point for the entire linkage system. The two bars in the linkage system are each grounded point, so a mounting system was developed to ensure that those two points were mounted on level surfaces while still allowing free movement of the prosthesis and articulation of the rightmost bar. The prosthesis was attached to the lowest point on the triangle of the linkage system, as this is the point that generates the projected gait path. Exact coordinates for each part of the linkage system can be seen in Figure 43

below. Before constructing a physical prototype of the linkage system and attaching the prosthesis assembly, the linkage system was created in SolidWorks.

PMKS: Planar Mechanism Kinematic Simulator											User Manual
Open File	Save Configuration	Get as URL	Analysis				Edit Joints	Edit Forces			
Input	Links	Type of Joint	X Pos.	Y Pos.	Angle	P	V	A			
<input checked="" type="radio"/>	ground,input	R	34.874	36.297	25.000						
<input type="radio"/>	input,coupler	R	31.100	34.647	25.000	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="radio"/>	coupler,follower	R	6.448	42.642	0.000	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="radio"/>	follower,ground	R	8.194	37.690	0.000						
<input type="radio"/>	coupler	R	15.747	7.984	0.000	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Remove Row		Clear All Rows		Change Units		DOF = 1					

Figure 43: Joint descriptions of all parts of linkage system in PMKS software.

6.1.1 Physical Prototype

After developing the above linkage design, a preliminary prototype was created. The linkage system SolidWorks files were converted to AutoCAD Inventor files, as the different linkage system parts were made of laser cut acrylic. This design decision was made due to acrylic's low price and the accessibility of laser cutting machines on campus in Washburn Shops. As the laser cutting machine only reads Inventor files, the generated SolidWorks files needed to be converted to Inventor to generate the necessary parts.

When assembling the laser cut linkage system pieces, the pieces were very thin and weak, and the prosthesis was too heavy to be supported by the system. A second set of linkage system parts was cut and the assembly was modified to have each linkage joint be doubled up to create a sturdier prototype. The fully assembled linkage system and prototype was still not strong enough to articulate the prosthesis accurately, so a second iteration of the assembly was planned to be manufactured from plywood and be articulated by a motor. However, due to the current global

situation, these modifications were unable to be completed. Therefore, a full assembly and mounting system was developed in SolidWorks and gait analysis was conducted virtually.



Figure 44: Acrylic-Cut Linkage System for Gait Analysis

6.1.2 SolidWorks Assembly

Using the linkage system that was designed, the test setup was modified to be a free-standing structure that would allow for gait cycle analysis. A model, which is shown below, was developed in SolidWorks.

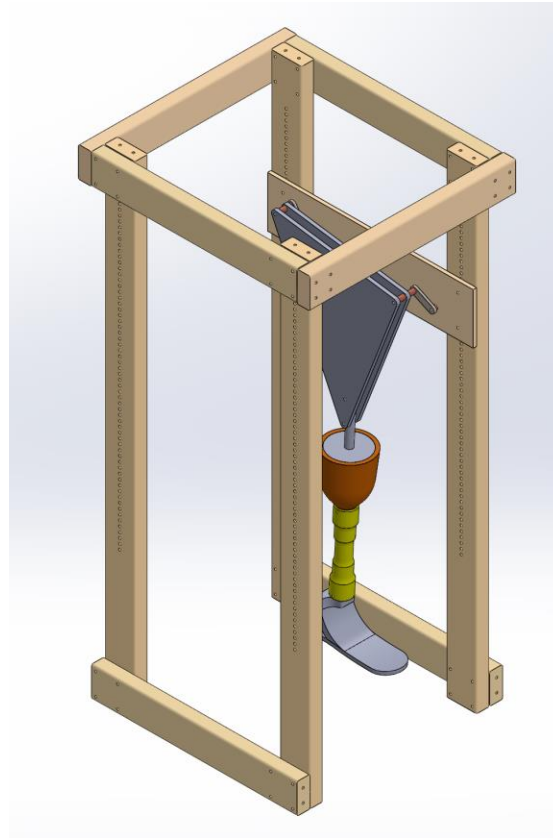


Figure 45: Second Design Iteration for Gait Analysis Test Setup

The frame uses 2x4 wood pieces that can be found at any home improvement or hardware store. Holes were added to the vertical 2x4's to allow for the linkage system to be moved up or down depending on the length of the prosthesis being used.

For this final test setup, the only adjustment made was the frame that holds the acrylic linkage system up. The same linkage system that was discussed in Section 6.1 is being used here as it was proven through the use of PMKS software to accurately mimic a natural gait cycle. A video simulation was run in SolidWorks to ensure that the linkage system was able to properly mimic the gait cycle, which proved to be true. However, this testing apparatus was never able to be manufactured and used to analyze the gait of the prosthesis due to COVID-19.

6.2 Discussion

This section will discuss whether or not objectives were met and what the contributing factors to meeting them are.

6.2.1 Interchangeable Components

The first main objective outlined by the team was to create a prosthetic with interchangeable components. This objective was met by designing and manufacturing each of the three individual components, which are the foot, pylon, and socket. A large part of this was to develop a way to connect the parts to each other. Connection between parts was achieved by creating an extruded surface on the CAD models of the foot and socket that was able to fit into inserts in the pylon. Then to ensure connection, through bolts were used to hold the components together. By using this connection that does not change with size, a component can easily be removed and replaced if it is the wrong size or breaks.

While the team was able to create a prosthesis with individual components, we were unable to test each component to ensure that it would be able to properly function. For the socket adhesion testing was unable to be performed due to restricted access to WPI's campus, due to the outbreak of COVID-19. Testing for the foot and the pylon to determine their weight bearing abilities was also not conducted due to a shift in project focus, to prioritize mimicking a natural gait cycle.

6.2.3 Quickly Customized to the User

The second main objective of this project was to design each component so that it could be easily customized to fit the user. This objective was completed as each model was parameterized to proportionally change based on established global variables. This is addressed earlier in Section

4.1.3 for the foot, which utilized a global variable for length to establish a configuration for each US adult men's and women's shoe size ranging from women's size 5.5 to men's size 14. For the pylon this is addressed in Sections 4.2.4 and 4.2.5, where it is mentioned that all pylon dimensions change based on the length of the pylon. Finally, Section 4.3.4 discusses the customization of the socket design and how the model can change based on two diameter measurements as well as two length measurements. A detailed procedure for how to customize each component to the user and how to take each measurement can be found in Appendix A.

6.2.4 Lower Lead Time

The third main objective of this project was to lower the lead time for a prosthetic to be manufactured and given to the user. In order to minimize the lead time, it takes to manufacture a prosthetic, the team uses 3D printing as the main form of manufacturing. By using 3D printing the lead time was able to be cut down drastically. In the end the production time for each part was as follows. The socket took approximately 24 hours to print. The pylon took 8-18 hours to print depending on size. Finally, the foot took 24-36 hours to print depending on size. By using 3D printing, the lead time if only one machine was being used could be as much as 78 hours and as little as 56 hours. If three machines were available, the lead time could range from 24-36 hours.

6.2.5 Mimic Gait

The final objective for this project was to create a prosthetic that could mimic the natural gait cycle of a person. Due to the fact that the team's time working on WPI's campus was cut short, an in-person gait analysis was not able to be completed. However, a test setup was developed in CAD where a simulation was successfully run, mimicking the natural gait cycle of a person. The test setup and gait cycle can be seen in Section 6.1.

Chapter 7: Conclusion

At the conclusion of this project, ideal material and design settings were determined for each part. For the socket, the best materials were 3D printed resin and TPU. These materials were slightly flexible and still able to hold the desired shape. For the pylon, ABS was the ideal material choice, as it is sturdy and has high heat deflection temperatures so it can be used in climates around the world. For the foot, printing in Nylon and TPU was the best option to allow for slight flex of the foot to mimic natural gait. A linkage test rig was designed in SolidWorks to test prosthesis gait path and compare it to that of biological human gait. To combat different measurements and user specifications, each part was designed using global variables to allow for rapid generation of customized parts, and a Prosthesis Preparation Outline was created detailing how to take each necessary measurement.

This project has many different ways to improve and expand before the prosthesis can be used by a patient to replace a biological limb. It does provide a clear goal to attempt to improve the quality of low-cost prostheses, especially those in developing countries, with the ability to customize specifications easily and produce prosthesis iterations quickly. The transtibial prosthesis developed throughout this project is a great starting point for others to continue building off of to create a market-ready product for amputees.

7.1 Social, Economic, Environmental, and Ethical Aspects

Through the background research of this project a number of issues in the prosthetic industry were identified. Long lead times and high costs create issues for amputees. It was the goal

of this project to create an impact on the cost of a prosthetic by manufacturing it via 3D printing as well as to use 3D printing and models based on global variables to shorten the lead time for an amputee to receive their prosthetic. The team felt that the financial burden that can be created through the need for a prosthesis to function daily was rather unethical. With this being said, the team felt an ethical obligation to work diligently to develop a prosthesis that could be affordable and easily accessible to those that cannot afford a more advanced prosthesis.

7.2 Personal Reflection

Throughout the process of this project the incorporation of many classes was considered. The preliminary design aspects were learned from the lectures of Computer Aided Design (ES1310). These lectures taught our team how to design all of our main parts as visual representations on the program of SolidWorks. These designs allowed us to 3-D print all of our parts to see how they all assembled and would form our final product. Along with this the analysis of the materials we would use to print all of our parts. This was made easier due to the knowledge all of us gained from our lectures in introduction to material science (ES 2001). This knowledge allowed for us to decide which materials would be best for the printing of each individual part. One extra lecture that would have also benefited our team would have been extra knowledge regarding linkage systems. Only one of the four of us took Kinematics of Mechanisms (ME 3310) which made it harder for the team to be able to develop and produce a linkage system so that we were able to test the gait cycle of our linkage system.

Although not everything regarding this project could be learned through lectures and classwork. This caused every member of the team to develop new skills to allow for the team to

reach its final goal of developing a lower limb prosthetic. This came through trial and error as well as experimenting with topics that were all new to the team. Not only did these skills allow for the team to complete the project but they also made the team grow as individuals.

7.3 Future Work

Through these discoveries, future recommendations can be made for continuation of this project to improve the prosthesis. Overall, the full prosthesis should undergo more extensive testing in compliance with the ISO Standards, such as fatigue cycle testing, and stress testing especially at joints. Other materials could be investigated for any and all parts, and other manufacturing techniques aside from 3D printing could be investigated as well. For the socket, creating designs in molded silicone or skin-safe foam could be developed. These designs may have the potential to be more form-fitting and easier to customize, as well as be able to provide a user with a more comfortable fit. For the pylon, more rigid materials could be investigated depending on ABS performance during more extensive testing. For the foot, developing designs that include flexible material inserts with a sturdy material frame that still allows for elastic deformation could improve energy response and gait outcomes. Additionally, customization processes for the entire prosthesis could be expanded upon, either through topographical imaging or through more uniform measurements. Lastly, the entire prosthesis could be tested on its ability to fit a user, through both pylon height and foot length and through socket to stump connection. Patient testing would require an IRB and likely partnership with a local hospital or rehabilitation center but would be very useful in determining the prosthesis's ability to be a successful design.

Data and analysis performed throughout this Major Qualifying Project will be used in two different projects and publications. One of the steps considered is the integration of this prosthesis with the open-source robot developed as part of The Poppy Project (Poppy Project, 2020). The analysis performed in this project regarding gait analysis and foot deflection could be useful in pre-existing or future Poppy projects. Additionally, analysis gathered through PMKS software for the linkage system design along with the parametric CAD assembly will be included in a future publication that will be completed by the team and the advisors.

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Appendix

Appendix A: Prosthetic Preparation Outline

Prosthetic Preparation Outline

To prepare a patient for their new prosthetic there are set measurements that need to be taken along with a certain order in which they relate to each other. The measurements that need to be taken for the socket include the upper circumference, the lower circumference of the stump, length of taper, and the total length of the stump taken from the back of the knee . These measurements can be seen in figure 1 and are input into the CAD files to automatically adjust all of the rest of the dimensions for the part to fit the patient as accurately as possible.

After the Socket is measured the length of the person's remaining foot is measured for length. This can also be based off of shoe size to find the length of the person's foot. This measurement can be seen in figure number 2 and is found by taking the total length from the bottom of a person's foot. When this length is input into the CAD file it adjusts the other measurements on the document. Using the height of this new foot size and how much extra space is needed for the socket the length of the pylon can be found.

The pylon's length is greatly based upon the height of the foot and the extra space needed for the socket. The total length of the prosthetic can be found by measuring from the bottom of the stump to the floor while the patient stands upright on their other foot. This measurement is also double checked by measuring the length of the other leg. This measurement is taken from the same point the length of the stump would be taken on the back of the knee down to the bottom of the foot. Then the length of the current stump would be subtracted from the length of the entire leg. Once the total length is found the height of the foot and the remaining height of the socket is subtracted to find the total length for the pylon. These measurements can be seen in figure 3. When inputting this length is put into the CAD file for the pylon the sketch where the dimension is adjusted is in the revolve task and the variable that is adjusted is half of the length of the total pylon and then it mirrors over the halfway point of the pylon. Then the rest of the geometry and dimensions will adjust accordingly.

For the patients that only get ankle amputations very similar methods are done to adjust the connector piece. However instead of using the initial assembly the doctor would have to use the second assembly which uses the connector piece instead of the pylon. For this piece once it is known how much room there is to work with 1 cm is dedicated to the socket. However much

height for the foot is needed is dedicated to that based off of the foot size. The remaining length is the only global variable on this CAD file and is simply the remaining height needed to make the prosthetic even with the persons' other foot.

For all of the parts the measurements that are shown are all of the specific global variables that need to be adjusted on the CAD files. For all of the specific parts the measurements will cause the parts of the CAD files to hopefully fit the patient to their specific needs. All of these parts can also be taken off and replaced if the size of someone's stump may change as time goes on or if one of the parts were to break.

Figure 1 (Socket Measurements)

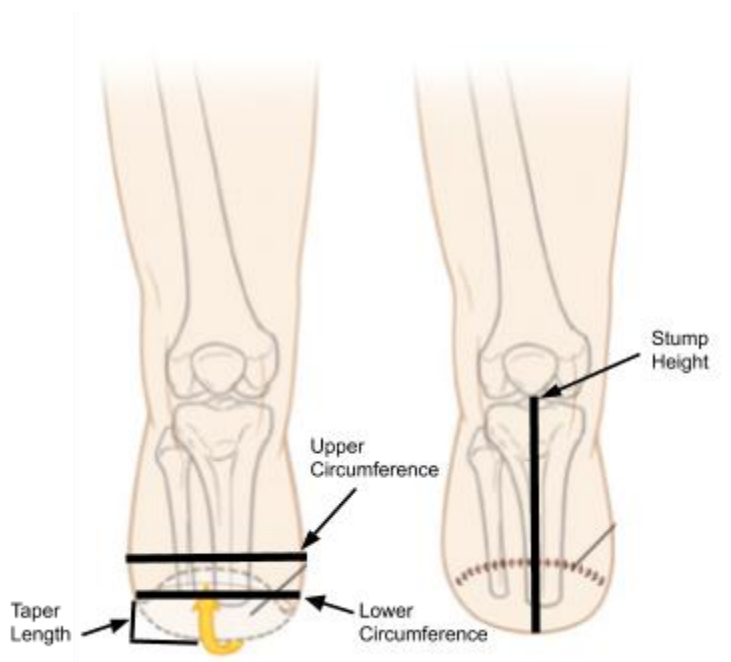


Figure 2 (Foot Measurements)



Figure 3a (Pylon Measurements)

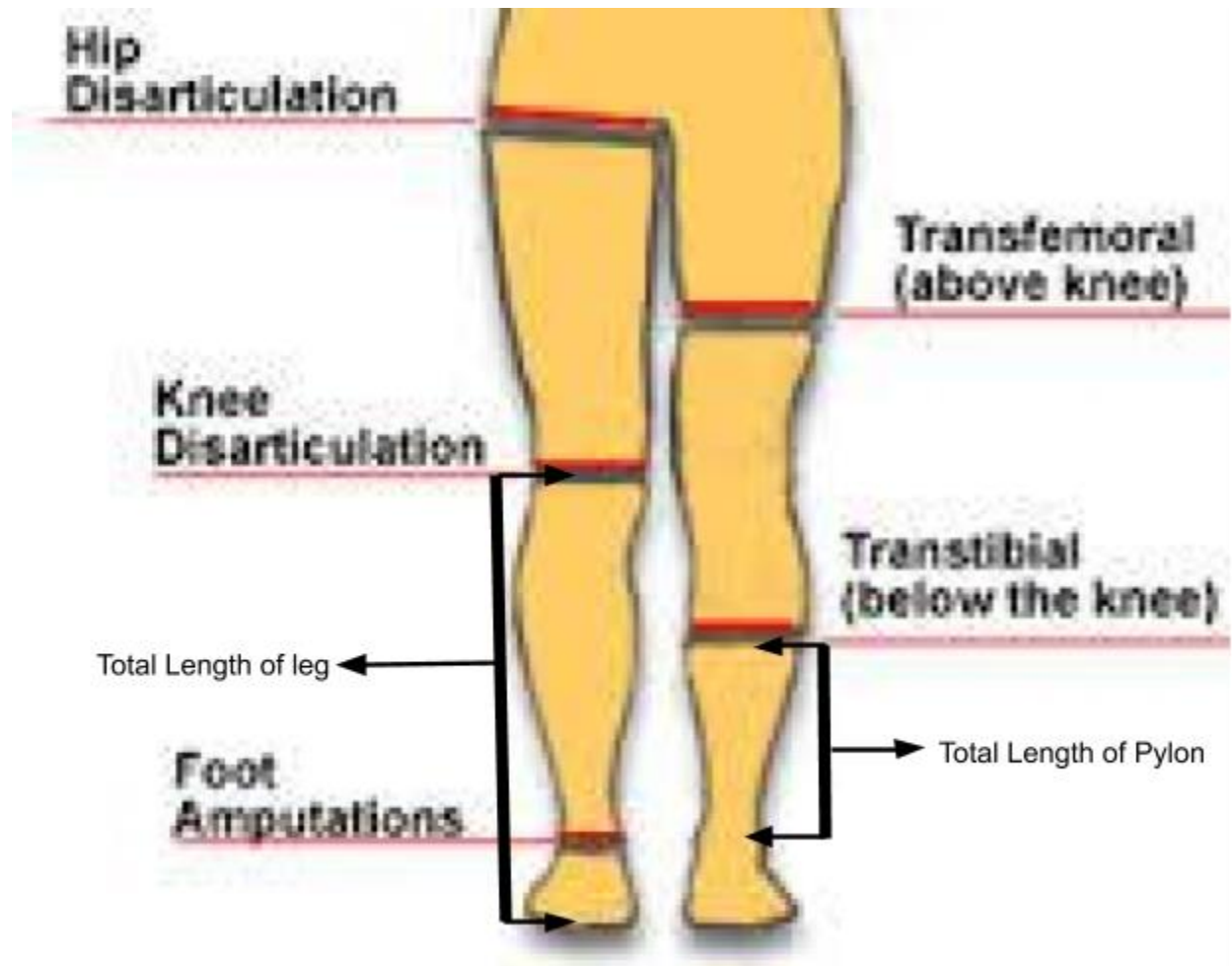


Figure 3b (Pylon measurement for stump)

Total Length
of prosthetic
below
amputation



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