Low Cost Lower-Limb Prostheses For Amputees in Southeast Asia

By

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Thesis

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Abstract

According to the World Health Organization, there are 40 million amputees in developing countries. Of those, only 5% have access to a prosthetic device.[1] The lack of prosthetic accessibility is mainly a two-fold problem: the high cost of the prosthetic device, and the accessibility to hospitals that do prosthetic fittings. Most amputees do not have the time nor money required for a prosthetic leg. The goal was to streamline the fitting process with an adjustable, universal socket and a low-cost prosthetic knee while being less than $60 for production. The socket was designed to be adjustable in the circumferential and vertical directions. The socket prototype met the design criteria for circumferential adjustability but did not fully meet the set design criteria for pressure distribution and stability requirements. Next steps will involve testing the durability of the prototype through cyclic testing and improving on the adjustability component of the design. The prosthetic knee was designed to closely mimic natural gait using mechanical components. A four-bar linkage system was optimized through computer-aided design simulations to determine the kinematics. For design verification, the knee prototypes' positions were analyzed at initial swing and heel strike; prototypes were 3D-printed and tested using an able-bodied testing rig used to compare various prosthetic knee kinematics. Gait videos created of subjects using the rig were used to verify the torque experienced by the prosthetic knee during gait. This project demonstrated possible low-cost, sustainable prosthetic solutions for developing countries.

[1] M. Marino et al., "Access to prosthetic devices in developing countries:Pathways and challenges," in Proc. IEEE Annu. Global Humanitarian Technol. Conf., 2015, pp. 45–51.

1. Introduction

1.1 Author Contributions

Chapter 1: Introduction

- Matthew Lo wrote the introduction section including amputee statistics, components of a prosthetic, and challenges of current prosthetics.

- Justin Lee wrote the Master's project goals and achievements and author contributions sections.

- Luke Morales was responsible for critical review of these sections.

Chapter 2: Prosthetic Socket

- Matthew Lo contributed to the study concept and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript and critical revision. He wrote the background, outer socket, methods, results and discussion sections.

- Justin Lee contributed to the study concept and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript and critical revision. He wrote the current technologies, inner socket, methods, results, and discussion sections.

- Luke Morales contributed to the study concept and design and critical revision.

Chapter 3: Prosthetic Knee

- Matthew Lo contributed to the study concept and design, acquisition of data, analysis and interpretation of data and critical revision.

- Justin Lee contributed to the study concept and design and critical revision. He also wrote the competitor analysis sections.

- Luke Morales contributed to the study concept and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript and critical revision. He wrote every other section.

1.2 Amputee Statistics

According to the World Health Organization, there are 40 million amputees in the developing world and only 5% have access to prosthetic devices.[2] This low percentage of accessibility is largely due to the high cost of quality prosthetics and the long fitting process. A prosthetic leg is used to replace lost lower limbs, and they should mimic the natural leg as much as possible. In developed countries, healthcare and insurance programs make highly customized, computerized prosthetics widely available.[3] In many developing countries, such healthcare systems are not yet available and must use older prosthetic solutions.

In Southeast Asia, the main reasons for amputation are traumatic injury and severe arterial disease. Traumatic injury involves injury from war or remnants of war as well as motor vehicle accidents.[4] Unexploded land ordinances are still a major issue: "The International Committee of the Red Cross estimates that between 9 and 27 million landmines and bomblets remain embedded in Laotian soil and streams alone—relics of the huge load that U.S. forces

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[2] M. Marino et al., “Access to prosthetic devices in developing countries:Pathways and challenges,” in Proc. IEEE Annu. Global Humanitarian Technol. Conf., 2015, pp. 45–51.

[3] Shaffer, Erik. “The Prosthetic Knee.” The Prosthetic Knee, Amputee Coalition, Nov. 2008, www.amputee-coalition.org/resources/the-prosthetic-knee/.

[4] Clasper, Jon and Arul Ramasamy. “Traumatic amputations” British journal of pain vol. 7,2 (2013): 67-73.

dropped on Laos, Cambodia, and Vietnam between 1964 and 1973 and during the subsequent civil foment".[5] These explosions have lead to hundreds of thousands of deaths and amputations post war. In addition, lack of traffic regulations and the common use of motorcycles have been a main contributor to lower limb amputation. Roads are crowded with motorized scooters and bikes next to cars, with few traffic regulations. Inadequate care leads to the need for amputation. [6] In more recent years, there has been a rise in arterial disease in Southeast Asia, leading to a rise in diabetic complications resulting in lower limb amputations.[7] A rise in lifestyle changes with the lack of healthcare programs have contributed to this issue. There are over 200,000 amputees in Vietnam in a population of 95 million (1 in 475), while the average amputation is 1 in 1000 people.[8]

Amputation treatment has been shown to be inadequate in Vietnam. In a study by Matsen et al, amputees had about a 5-year delay before getting care for their amputated leg. Researchers noticed that the quality of care between veterans and regular citizens contrast dramatically; veterans received quicker care and received many legs and doctors visits, as programs covered these costs. In contrast, non-veterans averaged 1-2 legs in the same span of years. In addition, amputees living in areas further away from clinics tend to receive significantly less care.[9] The Matsen study mainly looked at government-funded prosthetics, but is one of the more in-depth studies done on the healthcare system relating to amputation. Due to inadequate healthcare, amputations and prosthetics are a long ordeal and are not available to all people who need them.

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[5] Nixon, Rob. 2007

[6] Staats, T.B. “The Rehabilitation of the Amputee in the Developing World: a Review of the Literature.” Prosthetics and Orthotics International, vol. 20, no. 1, 1996, pp. 45–50.

[7] Johannesson, Anton et al. “Incidence of lower-limb amputation in the diabetic and nondiabetic general population: a 10-year population-based cohort study of initial unilateral and contralateral amputations and reamputations” Diabetes care vol. 32,2 (2009): 275-80.

[8] Staats, T.B.1996

[9] Matsen, S L. “A Closer Look at Amputees in Vietnam: a Field Survey of Vietnamese Using Prostheses .” Prosthetics and Orthotics International, vol. 23, 1999, pp. 93–101., doi:10.3109/03093649909071619.

1.3 Components of a Prosthetic

A prosthetic leg for transtibial amputees consists of a prosthetic foot, pylon, prosthetic knee and socket (fig. 1). The foot is important for stability. It keeps the leg stable during stance phase and lets the prosthetic knee bend at proper times during walking phases. The foot base provides enough surface area for the amputee to stay balanced, but should be shaped similar to a foot so that the rest of the leg reacts during motion. Certain ankle mechanisms contain spring systems that uses potential energy to actively propel the leg forward during walking.[10] In developing countries, lower cost materials are used to create such energy return. Most of the time, these feet tend to have shorter lifespans due to its use and environment.[11] The pylon acts as a shin mimetic: it transfers motion and forces up and down the leg, providing stability during all phases of walking. Traditionally, and in developing countries, these pylons are made of hard metals, such as stainless steel or aluminum. Newer pylons use alloys and rubbers/carbon fiber to provide additional shock absorption. Additional add-ons help provide stability in multiple axes. Rotational adapters between the foot and pylon provide stability against torsional forces created

[10] J. Gardiner et al., "Transtibial amputee gait efficiency: Energy storage and return versus solid ankle cushioned heel prosthetic feet," J. Rehabil. Res. Develop., vol. 53, no. 6, pp. 1133–1138, 2016.

[11] Laferrier, Justin Z, et al. "A Review of Commonly Used Prosthetic Feet for Developing Countries: A Call for Research and Development." Journal of Novel Physiotherapies, vol. 08, no. 01, 27 Feb. 2018, doi:10.4172/2165-7025.1000380.

by out of plane motions. The pylon and foot act as the major stabilizing components that closely interact with ground reaction forces.

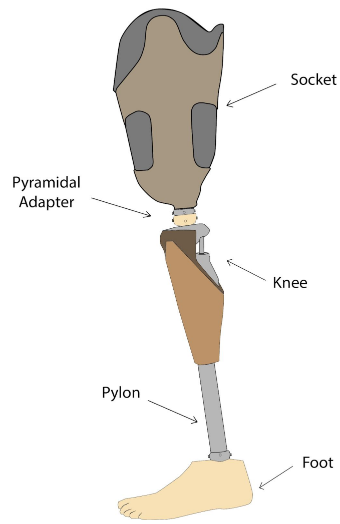

Figure 1.1: The parts of a transfemoral prosthetic leg are made to custom-fit the user and mimic a natural leg

The major parts of the prosthetic leg are the prosthetic knee and socket. The knee is the most expensive part of the leg, as it is the most complex component that ultimately determines the limb's structural integrity (fig. 1.1). The knee must mimic the natural joint and provide safe motion and support for all lower body motion. A natural knee has complex motions, as cartilage and tendons provide stability and motions in 6 degrees of freedom. It also provides major shock absorption. The knee motion is both translational and rotational. Most prosthetic knees focus on a select few motions and attempt to recreate them. Many new knees contain microprocessors that read the accelerations and movements of the leg and can react to closely mimic a natural leg in all situations. More traditional and affordable solutions are mechanical, using a four-bar linkage to approximately mimic the knee motion and a combination of spring and dampers to create human-like gait characteristics. The socket is the main interface between the residual limb and the prosthetic leg. Its main purpose is to provide comfort while closely reacting to the patient's movements. Sockets must be comfortable for days on end. Pressure distribution and snug fit are essential, as these are the main elements for prosthetic success.[12] Failure with the socket occurs when it loses its comfort. Most sockets are custom-fit to the amputee. An outer rigid exterior acts as a "volume container" that provides structural support, while the inner liner provides a snug fit and comfort. Traditionally, amputees will get a new custom-fit socket every time their previous one loses its fit or its comfort. Many healthcare systems cover such expenses. The combination of these parts create a prosthetic leg that is meant to closely mimic their leg pre-injury. Depending on the complexity of prosthetic devices and demographics, the costs of these prosthetic legs can vary drastically.

1.4 Challenges of Current Prosthetics

One major challenge arises is the cost for prosthetic devices. Current prosthetic legs can cost almost $100,000 for all the components. Current prosthetic knees-- the most expensive part of a prosthetic leg-- can range from $10,000 to $50,000 in a developed country.[13] The prosthetic ankle can cost upwards of $20,000. They can contain multiple microprocessors and use expensive materials to closely mimic leg motions. A traditional custom-fit socket can be upwards of $5,000, but the main costs come from the multiple hospital visits and fitting process, which can be over $30,000 in a lifetime.[14] More advanced sockets will cost even more and require a longer fitting process. Government programs and insurance are set in place so that

[12] Paterno, Linda, et al. "Sockets for Limb Prostheses: A Review of Existing Technologies and Open Challenges." IEEE Transactions on Biomedical Engineering, vol. 65, no. 9, 2018, pp. 1996–2010., doi:10.1109/tbme.2017.2775100.
[13] M. Marino et al. 2015
[14] Mahoney, Gillian. "The Cost of a New Limb Can Add up Over a Lifetime." Hospital for Special Surgery, 25 Apr. 2013, www.hss.edu/newsroom_prosthetic-leg-cost-over-lifetime.asp.

these sophisticated legs are accessible in developed countries, such to the United States. However, this price tag is not realistic for amputees in developing countries. Governments will issue low-cost solutions to amputees injured from war or government work.[15] However, amputees mainly need to pay out of pocket. Clinics will have higher quality components, but they are highly unaffordable for most of the population. There are low-cost solutions mainly for the knee prosthesis, but they are infamous for inconsistent quality, limited uses and are known to only last a few years.

A major challenge for amputees in obtaining a prosthetic leg is the long fitting process. A traditional fitting process involves a prosthetist making a mold out of the residual limb, creating a positive of that mold, then using a combination of polypropylene, polyethylene and carbon fiber to create a socket. Amputees need to return multiple times to get the socket molded correctly. The prosthetist may need to make multiple iterations of the socket before creating the one the amputee uses. This process takes at least one to two weeks. From there, the patients receive one rigid socket that is supposed to last them about 10 years.

There are many issues with this process. Most hospitals that do fittings are located in major cities; in Vietnam, all prosthetists are in either Ho Chi Minh City or Hanoi. Many amputees live in rural areas, sometimes hours from the city so it is a multiple day ordeal to get to these hospitals. As demonstrated by Matsen et al, amputees who live further away from clinics received far less treatment, and attributed it to lack of transportation means.[16] Once these patients get to the clinic, they need to stay for at least a week, forgoing that much in potential income as well as separation from family. The infrastructure in developing countries make it much more difficult to travel and stay. In addition, many of these amputees cannot afford both the fittings and the stay; a Vietnamese citizen makes an average of $1200 per year, and the

[15] T. R. Dillingham et al., “Use and satisfaction with prosthetic devices among persons with trauma-related amputations: A long-term outcome study,” Amer. J. Phys. Med. Rehabil., vol. 80, no. 8, pp. 563–571, Aug. 2001
[16] Matsen, S L. 1999

socket and prosthetic will cost over $5000 in hospital visits. To make matters worse, residual limbs change size over the course of years. The socket provided are custom fit to the amputee's residual limb at the moment they went to get the fitting. As a result, a socket may not fit the amputee comfortably within the year of having it and not practical to obtain.

There is a need for prosthetic devices that are affordable for amputees who do not have a strong healthcare system that can be adjusted to their needs.[17] We have designed, developed and tested a low-cost prosthetic knee from PLA plastic and an adjustable prosthetic socket that will streamline the overall fitting process.

1.5 Master's project goals and achievements

Given the current prosthetic landscape, we had clear goals for this year. The objective from first semester was to explore the possibility of creating an entire prosthetic leg for under $60. Mass availability of prosthetic parts is scarce in resource limited settings, so it would be ideal if we could package these components together to be sold as a single unit. This is why we divided our efforts into researching three main components: socket, knee and foot/pylon. We were interested in evaluating current solutions for each component and whether there was room for improvement with a new design or if we could adapt an already existing solution to meet our $60 benchmark for an entire leg. We determined that there was still room for improvement on existing low cost knee designs and that there did not yet exist a viable and sustainable solution for a low-cost socket, so we made ideating and prototyping on these designs a priority.

We have been working on iterations of this project for 2 years. We have done fields research in Vietnam, worked with local and foreign prosthetists, developed prototypes for the

[17] Andrysek, Jan. "Lower-Limb Prosthetic Technologies in the Developing World: A Review of Literature from 1994–2010." Prosthetics and Orthotics International, vol. 34, no. 4, 2010, pp. 378–398., doi:10.3109/03093646.2010.520060.

knee, socket and pylon, and have created a company. We won the Brown Hack Health competition for our design and testing of our first prosthetic socket iteration, and won the Dorris M. and Norman T. Halpin Prize for innovation and interdisciplinary thought. This year, we mainly focused on finishing and optimizing our prosthetic knee design as well as creating a more effective prosthetic socket through quantitative testing methods such as compression testing, fatigue testing and pressure loading.

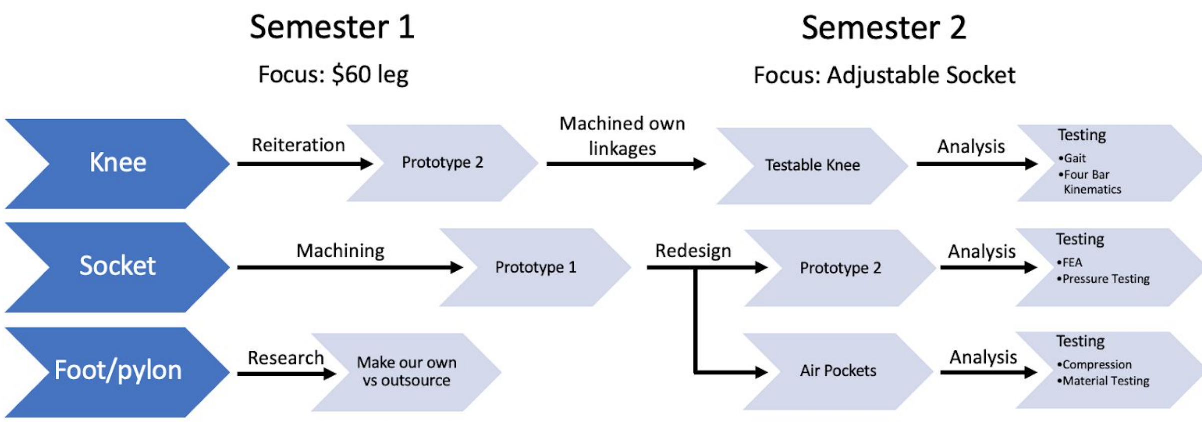

Figure 1.4: Timeline of achievements throughout Master’s

2. Prosthetic Socket

2.1 Background

2.1.1 What is a prosthetic socket?

The prosthetic socket is the main interface between an amputee's residual limb and the rest of the prosthetic leg. For an above knee (AK) amputee, this socket will fit over their quadriceps and hamstring muscles. It allows for a knee and ankle attachment to line up with the amputee's natural leg. The socket keeps the prosthetic devices in place throughout the day and transfer forces created by walking and standing from the body through the ground without concentrating pressure on the residual limb.[18] Its main role is to keep the rest of the prosthetic leg properly aligned and in place. The socket has been shown to be a key factor in the success of the overall prosthetic limb; as it directly contacts the amputee’s residual limb, it ultimately determines the comfort and overall experience of using these devices. This will allow the prosthetic leg to mimic a natural leg motion as closely as possible. It has been shown that misalignment of a prosthetic device causes an increase in hip extension moment during early stance phase and a decreased step length, creating an uneven gait pattern and imbalances during walking.[19]

[18] A. F. Mak et al., “State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: A review,” J. Rehabil. Res. Develop., vol. 38, no. 2, pp. 161–174, Apr. 2001.
[19] S. R.Koehler-McNicholas et al., “The biomechanical response of persons with transfemoral amputation to variations in prosthetic knee alignment during level walking,” J. Rehabil. Res. Develop., vol. 53, no. 6, pp. 1089–1106, 2016.

2.1.2 Components of a Prosthetic Socket

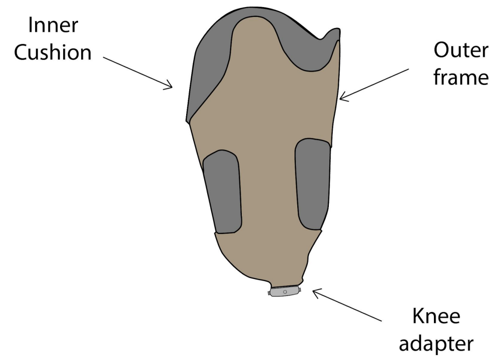

Figure 2.2: Components of a traditional socket

There are two main sections of a socket: the outer stiff frame that provides ample structural support and stability and the inner liner that allows for full control, fit and comfort (fig. 2.2). Outer sockets are traditionally made of a formulation of polypropylene, thermoplastic, carbon fiber or fiberglass. Depending on the amputee's lifestyle, different mixture of materials are used to maintain durability. Sockets are custom-molded so that it fits snugly on the residual limb, as residual limbs vary in shapes and sizes depending on the amputee and their lifestyle. The inner liner ensures the socket stays in place and provides proper comfort and breathability. This creates a suspension or suction system, which theoretically allows the socket to be completely reactive to the movements of the residual limb. This inner material acts as a cushioning system and prevents rubbing or "pistoning" from walking movements.[20] Reducing friction and providing proper cushioning are essential for making the socket comfortable for everyday use. The inner and outer materials must be optimized in order to create strong stability, comfort and ultimately long-term use by the amputee.[21] They interact closely together, and some inner materials work better with outer pieces.

[20] Ibid
[21] Paterno, Linda, et al. 2018

2.1.3 Cost of an Average Prosthetic Socket

The socket itself costs in the range of $1000-$2000 USD, but can be increasingly expensive based on the material selected. However, the main cost of the socket comes from the hospital visits for fitting and refitting. Sockets are typically made to last 5-10 years; however, residual limbs change sizes throughout the day due to swelling, and can permanently change shape over the course of a year. Skin lesions have been shown to develop in 63-82% of lower limb amputees, leading to poor comfort and low satisfaction levels with current socket solutions. [22] This is the main contributing factor to the 25-57% abandonment rate of prosthetics.[23] These numbers reflect studies done in developed countries (Netherlands), so we can only expect that the abandonment would be higher in developing countries, where prosthetic socket solutions are often times more crude. Old sockets that no longer properly fit, require amputees to go through the fitting process again to get a new one. The fitting process in itself is painstakingly long and requires many hospital resources. Such refittings and new materials can cost more than $30,000 USD over the course of a lifetime (cite the NEEDS slide fig. 1). In developing countries such as Vietnam, there are very few insurance or health care programs to make such fittings affordable.

2.1.4 Fitting Process for a Conventional Socket

Traditionally, sockets are formed around an amputee's residual limb through a molding process. Plaster is placed around the residual limb and hardens to the limb's unique shape. Using the negative created, a positive mold is created using another plaster, thus mimicking the

[22] T. R. Dillingham et al. 2001
[23] H. E. Meulenbelt et al., "Determinants of skin problems of the stump in lower-limb amputees," Arch. Phys. Med. Rehabil., vol. 90, no. 1, pp. 74–81, Jan. 2009.

shape of the residual limb. After smoothing and re-shaping, the mold is used for shaping an initial socket. Thermoplastic, such as polypropylene, is heated and shaped around the mold and allowed to settle. This shaping takes a few hours and must fit on the mold perfectly.[24] The patient is called back to the clinic where the thermoplastic socket is fit onto their residual limb. Any imperfections in the fitting are noted and a new socket is re-molded. This one process is repeated 3-4 times until a socket fits the patient comfortably. After the socket is finalized, a carbon fiber or fiberglass outer shell is shaped to provide extra protection and support. Inner cushioning or suspension straps are added to further provide support and comfort. This new iteration will again be fitted on the patient, and adjustments or re-fittings will be made. This process requires many resources and can take up to 2 weeks long. If the residual limb changes size and the socket does not fit anymore, this process must be repeated to get a new one. Each fitting requires multiple hospital visits, as the prosthetist needs to fit the socket on the residual limb multiple times since plaster does not accurately depict the soft tissues of the residual limb. [25] This is done prior to the fitting of the rest of the leg. The process is time consuming for both the patient and doctor. A lot of hospital resources are used to do these fittings. In the US, health insurance programs cover these overhead costs and create affordable payment options.

2.1.5 Issues with the fitting process in developing countries

In developing countries, accessibility to sockets are a multi-level systemic problem. The first issue is the accessibility to hospitals and clinics that do prosthetic fittings. In developing countries, only the main government hospitals do prosthetic fittings. These hospitals are few and far in-between, mainly found in city hubs. In Vietnam, most hospitals or clinics that do the

[24] Foort, J. "Socket Design for the above-Knee Amputee*." Prosthetics and Orthotics International, vol. 3, 1979, pp. 73–81.
[25] Sabolich, Scott. "Prosthetic Sockets." Amputee Coalition, Sept. 2006, www.amputee-coalition.org/resources/prosthetic-sockets/.

fittings are located in Ho Chi Minh City or Hanoi. However, many of the amputees are located throughout the cities and countryside. Landmines left over from the Vietnam war are still a large issue; Over 100,000 deaths have occurred from these remnants of war and has been one of the main contributors to amputations.[26] Motor vehicle accidents are the main source of amputations which usually result from poor infrastructure and lack of safety regulations. Many amputees are located in areas where they cannot get to major cities; and if they do have the means, travel and stay adds to the expenses of this process.

A second major issue in the fitting process is the time that it takes to get a socket properly fitted. A fitting takes about a week long but could last longer. During this time, patients need to find a place to stay and find travel back and forth from the hospital. Both are difficult, especially in countries that do not have infrastructure supporting handicap people. In addition, patients need to take time off of work. During that time, they will not be paid. If this is imperative to support a family, the fittings have larger repercussions. The time away from work and from family plus the money to stay around the hospitals outweigh the immediate benefit of a prosthetic fitting. They lose a weeks worth of income while having to pay for the stay and travel. As a result, the fitting process itself is a large deterrent from obtaining a prosthetic. There have been attempts to create lower-cost sockets with an easier fitting process. However, lack of training and knowledge of the fitting process led to only 37% of the fittings being successful.[27]

In our bottom-up research, we participated in prosthetic fittings and re-fittings in Vietnamese hospitals and clinics located throughout Ho Chi Minh City. One of the biggest issues was that amputees would not show up to their appointments, or would show up days later. Prosthetists waited on “stand-by” for their patients, as they knew transportation and

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[26] Nixon, Rob. "Of Land Mines and Cluster Bombs." Cultural Critique, vol. 67, 2007, pp. 160-174. Project MUSE, doi:10.1353/cul.2007.0031

[27] Jensen JS, Craig JG, Mtalo LB, Zelaya CM. “Clinical field follow-up of high density polyethylene (HDPE)-Jaipur prosthetic technology for trans-femoral amputees.” Prosthetics Orthotics International 2004;28(2):152–166.

hospital accessibility is an underlying issue. If the patient did show up, most of the time they could not stay for the whole appointment and fitting; prosthetists had to work on the fly to get a functional socket ready in their shortened time. The fitting process was too long, and the accuracy of the customized socket was compromised.

In our trip to Vietnam, we interacted with prosthetic clinics and hospitals to further understand the unresolved issues with prosthetics in their country. We participated in prosthetic fittings, re-fittings, alignments and tested new prototypes. We also interviewed many amputees and saw their lifestyle in a country that has few accomodations for the handicapped populations. One of the main challenges we noticed was that amputees could not make their appointments. One amputee travelled 8 hours for a knee re-fitting that lasted two hours. During this visit, we ran gait analysis on his deteriorating knee and compared it to a new one we gave him. The prosthetist also re-aligned the knee and ankle to stabilize his center of mass. After a quick interview, he then had to travel back home after the appointment to close up his coffee shop. He described how difficult it is to find time and modes of transportation to Ho Chi Minh City, the closest city with prosthetic clinics. We noticed a similar pattern with many of these amputees; patients would not make their appointments because of the time commitment and time away from work as well as the money necessary to make these appointments. All the socket fittings that had been scheduled during the two-week period we were assisting were cancelled or the patient’s never showed up. With some prior warning from the doctors and prosthetists, we learned many cannot make the long time commitment to get the socket fitted, and thus will ultimately have no prosthetic leg.

Lastly, the cost of the socket and the fitting process further reduces accessibility to a functional prosthetic. The traditional socket material costs about $70 USD, which is still a significant amount for a Vietnamese citizen. However, most of the expenses come from the fitting process. The process, especially the labor, can cost $2000 USD; the lack of regulation allows private or specialized clinics to charge even more.[28] Making a socket is intensive and requires a significant amount of adjustments from both the prosthetist and the patient. It also wastes hospital resources as thermoplastic materials cannot be reused. Re-fittings occur every few years as rigid sockets do not change with the amputee. As a result, the expenses due to socket fittings can skyrocket. A significant number of amputees will make their own solutions out of local resources, such as baskets or car parts, or stop using their prosthetics altogether. They cannot afford proper solutions, so the next best thing is to come up with their own solutions that will allow them to stand or walk. These DIY alternatives can sometimes even increase the risk of injury because many are not robustly designed.

2.1.6 Needs Statement

There are opportunities to make prosthetics much more accessible through the socket design. The fitting process is long, laborious and can lead to varying results. The fitting process is also the main reason amputees cannot access prosthetic limbs. There has been technology created to indirectly address these issues. Lim Prosthetics (San Francisco, CA) use a 3D scanning technique to get accurate measurements of the residual limb.[29] Other groups have used image splicing techniques to get accurate readings of a residual limb and use 3D printing to get custom sockets.[30] However, they require modern technology and a fitting process that is not ideal for the environment of a developing country. Current fitting processes also use a

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[28] Kahle, Jason T, and Jason Highsmith. “Practical Strategies for Reducing Prosthetic Costs.” Amputee Coalition, July 2011, www.amputee-coalition.org/resources/reducing-prosthetic-costs/.
[29] Burnard, George. “Introducing LIM Capture.” LIM Innovations, LIM Innovations Inc, 10 Sept. 2015, www.liminnovations.com/introducing-lim-capture/.
[30] Nayak, Chitresh. “Additive Manufacturing Society of India.” ResearchGate, Customised Prosthetic Socket Fabrication Using 3D Scanning and Printing, 2014, pp. 1–9.

significant amount of materials and resources. Each socket iteration is custom-molded, and has limited adjustability. In addition, the molds created for the amputee can only be used for a limited time until the amputee's residual limb changes shape. Thus, there is significant waste produced per fitting. There is a need to streamline the fitting process so that amputees do not need to sacrifice so much time and money while conserving hospital resources.

Lastly, amputees do not have much control over their prosthetics. Amputees must go to prosthetists to get their devices adjusted for better performance or greater comfort. Their residual limb changes shape throughout the day, and the size changes over time. However, their prosthetic— especially their socket— remains fixed. In a study tracking the success of a prosthetic leg over time, it was found that 52.4% of participants experiencing a fall, with 40% of those experience injury.[31] One focus is ensuring that the socket fits correctly on the residual limb to create optimal control. Adjustable sockets do exist and can be successful, but they are made for high performance and athletic uses; in those situations adjustability and comfort widely varies per person. There is an opportunity to create dynamic fittings that allow the amputee to have control over their socket. There is a need in developing countries for a prosthetic socket that requires a shorter fitting process that uses less materials and gives the amputee greater autonomy while providing the same support and strength as a traditional socket.

2.2 Current Socket Technologies

A traditional socket is highly effective because it is custom-fit to the amputee's residual limb. However, it requires a fitting process that takes multiple doctor appointments and is time consuming. It also requires easy access to hospital care. These custom molded sockets are stiff

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[31] Miller, William C., et al. "The Prevalence and Risk Factors of Falling and Fear of Falling among Lower Extremity Amputees." Archives of Physical Medicine and Rehabilitation, vol. 82, no. 8, 2001, pp. 1031–1037., doi:10.1053/apmr.2001.24295.

which allow it to provide strong structural support at the expense of comfort and versatility. Throughout daily activities, the volume and shape of a person’s residual limb fluctuates. These polypropylene sockets can become painful and lose their proper fit. Fluctuations differ between people and their physical activity levels.

The current market defines sockets that are “adjustable” as sockets that can be readjusted for comfort. They allow for micro-adjustments, such as changing the circumference at different areas of the socket. Adjustable sockets address the issue of small residual limb volumetric fluctuations. Amputees can adjust the socket so that it is comfortable to them. To our knowledge, no socket on the market addresses the need for large adjustments to allow for fitting of residual limbs of various sizes.

2.2.1 Martin Bionics - Socketless Socket

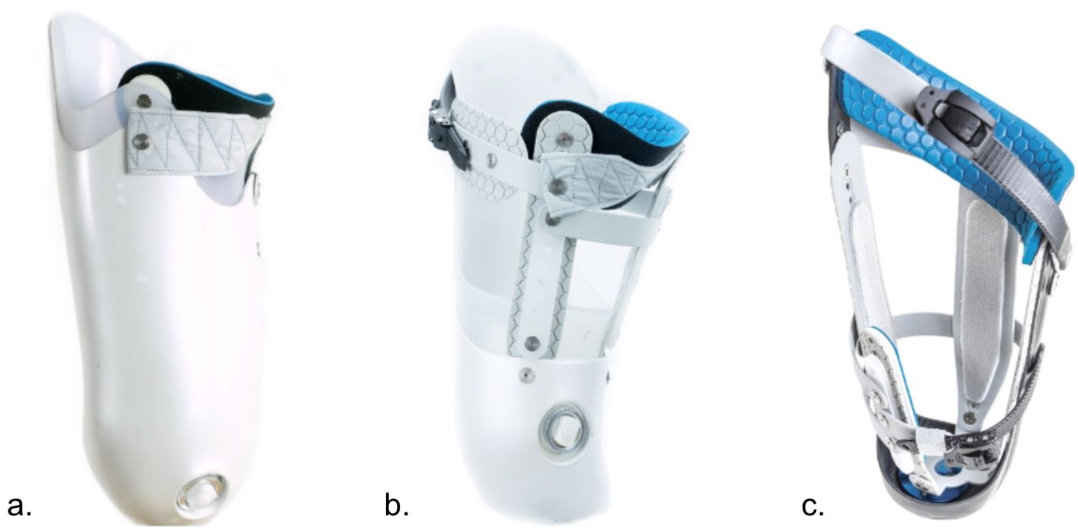

Figure 2.3: Martin Bionics limitless sockets come in increasingly adjustable designs. a) Swing brim attachment piece is an add-on for the conventional socket. b) cX-hybrid: is between a conventional socket design and the Martin Bionics socketless socket. c) Socketless socket cX: Martin Bionics' patented completely adjustable socket.

Martin Bionics (Oklahoma City, OK) created a line of sockets that are inspired by NASA's lightweight exoskeletons used by astronauts. The company prides itself in using as little material as possible, while providing exceptional support for all activities. Their Socketless Sockets come in three different designs, depending on the user and level of adjustability desired. It is 40% lighter than traditional sockets, and the strapping technologies resemble that of ski boots.[32] The material and manufacturing costs are proprietary information but from speaking with prosthetists in Rhode Island we have found that they sell for between $1000-$2000.

The Swing Brim (fig 2.3a) is an attachment piece meant to be an add-on for existing sockets. It is made of Martin Bionics patented "dynamic brim" material, which is softer than conventional socket material. The brim is attached to the top of an existing socket to allow for more comfort and flexibility, especially near the ischial seat. The idea behind this is to conform to the user's leg and fit "like a hammock, rather than a hard chair".

Their Socketless socket cX (fig. 2.3c), is the most progressive adjustable socket design. It includes the swing brim technology with the addition of four thin panels made of the same material attached to ratchet straps to encapsulate the limb. There is a rigid material in place at the distal cup to provide structural stability but almost every other part of the prosthetic is adjustable. The ratchet straps allow for micro adjustments during the day. It is also compatible with all types of limb suspension including lanyard, pin, vacuum, suction, and velcro suspension mechanisms.

Finally, the cX-hybrid (fig. 2.3b), merges Martin Bionics' socketless socket technology with a conventional socket design. The lower half is a custom molded polypropylene/polyethylene socket and the upper half has the swing brim and elements of the

[32] "Socket-less Socket" Martin Bionics. 2017. Accessed October 16, 2017. https://www.martinbionics.com/socket-less-socket-transfemoral/#1507848679404-decbcae6-85f0.

cX design. It is semi adjustable and a solid alternative for those who want some adjustability but also like the rigidity of their existing socket.

The main issue with implementing this solution in a low resource setting is that all three design's still require a custom-molding process. Even the most adjustable socket, the cX, has a bottom piece that is custom molded through conventional methods and each of the panels is a cutout from that mold. Thus, it would not resolve the issue of amputees having to make multiple trips to the prosthetist. The adjustability mechanism is novel and a robust solution for allowing micro-adjustability. For our design, we were inspired by the strapping mechanism because it is both a durable mechanism and easy to use. While conducting our own field research, we found that in practice there were some logistical concerns with this socket. Some prosthetists that had worked on fitting the socketless socket to patients found that putting it together was not intuitive. It comes completely disassembled and has many removable parts and attachments points that are not interchangeable so piecing it together was not always a simple task. We kept this design constraint in mind in engineering our own solution.

Figure 2.4: Lim Innovation's Adjustable Socket

2.2.2 Lim Innovations

Lim Innovations created the "world's most adjustable socket" (fig. 2.4) through their unique fitting process and high performance materials.[33] Lim Innovations wanted to account for all body fluctuations and create "natural comfort." The process to develop their socket is complex, but

[33] "Experience Freedom." LIM Innovations. 2017. Accessed October 13, 2017. https://www.liminnovations.com/

easy for the user. Using measurements and pictures of an amputee's residual limb, the company will create a 3D digital model of the residual limb. They will cut and mold four thermoplastic carbon fiber struts and attach to a customized base, providing structural support to the residual limb. The struts connect to a brim, which fan the four struts outward. The shape follows the specific contours of the user's residual limb up to their hip. The pieces are then covered with "high-tech" fabrics from shoe and apparel companies, making it as comfortable, durable and as high performance as possible. The amputee can choose the method for residual limb suspension, from suction to pin suspension.[34] The total turnaround time for manufacturing is about one week. The Lim socket is impressive due to its modular design and complete customization. Every part is custom molded to the amputee and matched to their preferences. The socket uses some of the most advanced materials to create extreme comfort. In addition, the tightness of the carbon struts can be adjusted around the residual limb, allowing for micro-adjustments from the fine teeth in the ski boot straps.

Constraints on this solution in a third world setting are much like those of the Martin Bionic socket. While being extremely adjustable, it still requires that initial step of a custom molding process. It does allow for the actual manufacturing of the molded socket to be done off site (taking advantage of digital 3D modeling). However, the modelling and molding processes take longer and require more specialized work causing it to take a longer time to fit. These sockets sell for at least $2,000 but often times much more.

[34] Hurley, Garrett Ray, and Jesse Robert Williams. Modular Prosthetic Sockets and Methods for Making Same. US Patent US9044349B2, filed November 7, 2013, and issued June 02, 2015.

2.2.3 Ottobock Revofit

The revofit adjustable socket (fig. 2.5) made by Ottobock (Minneapolis, MN), is the most similar in shape to conventional sockets. In 2015, Click Medical came out with this socket which offers day to day micro adjustability for conventional sockets. It is a regular socket, with three to four panels cut out at various spots around the limb. Each panel is tied together by a metal wiring system which all leads into a BOA dial, a plastic dial mechanism that allows for as small as 1mm adjustments. The benefit of the BOA tightening system is that it is very simple to use and very intuitive.

Figure 2.5: Ottobock Revofit

Since its inception, it seems that the revofit has not become widely used in the prosthetic world. After speaking with a local prosthetist, we found that some patient complained about localized pressure at the adjustment points. Since only the panels adjust inwards, they create pressure points when the socket is tightened. Additionally, the process for making this socket requires custom molding and is much more technically challenging because the BOA adjustment system must be integrated within the wall of the socket. Finally, the BOA mechanism, while novel, adds significantly to the cost of the socket. The raw materials for the BOA adjustment system as well as carbon fiber reinforcements are estimated to cost around $500. It is the cheapest adjustable socket to make of the ones available on the market today. A completed socket, however, gets reimbursed for as much $5,000, according to some of our informal discussions with Ottobock.

2.2.4 Mercer University

Mercer University wanted to reduce the cost of a socket by creating a “universal” socket that could be fit onto patients in Vietnam.[35] Their socket is made of an affordable thermoplastic. On the outside of the socket, there is a “V-cut” that flexes to the residual limb circumference. Along the edges of the cut, there are holes to string through lacing and velcro straps. Theoretically, you could adjust the circumference by tightening the lacing. However, the socket is a part of a patent that covers a whole transfemoral prosthetic leg. The overall prosthesis costs about $150 to manufacture, but does not cost the patient anything.[36] It is made of cheaper thermoplastics and metals; it does not function as highly as other leg prostheses, but they allow the patient to move independently. Our interviews with local prosthetists and amputees informed us that the idea of this product is good, but materials do not last a long time.

Since the prostheses are so cost effective, Mercer is partnered with the Vietnamese government to fit patients in more isolated areas in the northern part of the country. The largest issue with Mercer’s prostheses is that Mercer University doctors and students must do the fittings. Their sockets are fitted differently than traditional sockets, and are shaped using a heat gun. Mercer sends students and faculty every summer, and each fitting takes 2-3 hours. As a result, the demand for Mercer’s prostheses are much higher than the Mercer team can fit.

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[35] Vo, Ha Van. Prosthetic Devices and Methods of Making and Using the Same. US Patent US8870968B2, filed May 21, 2012, and issued October 28, 2014.

[36] Vo H.V., Nguyen B.N., Le T.T., McMahan C.T., O’Brien E.M., Kunz R.K. (2018) The Novel Design of the Mercer Universal Prosthesis. In: Vo Van T., Nguyen Le T., Nguyen Duc T. (eds) 6th International Conference on the Development of Biomedical Engineering in Vietnam (BME6). BME 2017. IFMBE Proceedings, vol 63. Springer, Singapore

2.2.5 Gaps In Current Solutions

There have been many attempts at creating an adjustable prosthetic socket and while some are promising designs they all suffer from the same drawback; they still require the custom molding/fitting process. In a resource limited setting, it may not be possible for an amputee to go through the entire molding process at the expense of potential income as well as time away from family. Lim, Martin Bionics, Ottobock and Mercer have all come up with adjustable sockets that accommodate daily fluctuations in residual limb size, but they all involve a custom molding process. Without eliminating the week long molding process, these adjustable solutions inadequate for a low resource setting. Data on cost for each of the sockets is proprietary information and varies per user, but from speaking to local prosthetists from Rhode Island we received estimates that all of the current adjustable sockets cost no less than $500 just the materials and then end up costing more than $2,000 for a completed unit.

Another drawback is that many of the designs are not modular and so if any component breaks, it would require an entirely new socket. The Ottobock Revo fit, for example, has the novel BOA fastening mechanism. While it provides extremely fine tuned adjusting capability, if the tightening wire or mechanism breaks, the entire unit would need to be replaced by a trained professional. Because of how unique the design is, there would not likely be many options for repairing the equipment.

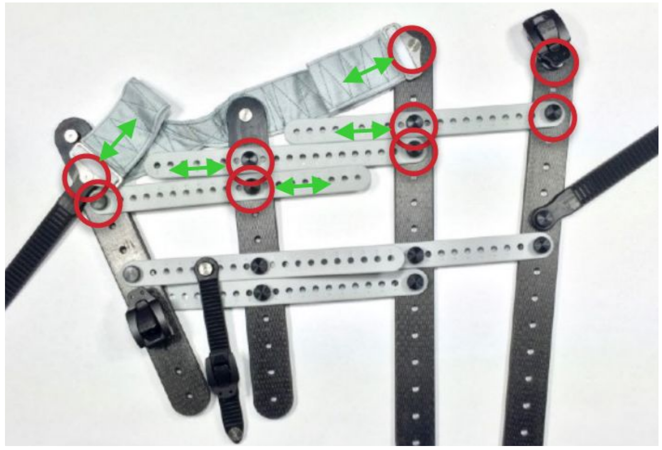

Figure 2.6: Diagram on connection and adjustability points from Martin Bionics Fitting guide shows many movable parts.

Along with being easily replaceable, the socket should also be fairly easy to assemble and intuitive to put on. The former condition will allow for minimal training and adaptation by the prosthetist and the latter condition allows for a user friendly design. The Martin Bionics socket offers some difficulties with this as there are many individual parts (figure 2.6). Additionally, we heard from a few prosthetists that the assembling instructions were not quite intuitive because of the various parts.

2.3 Design Ideation

2.3.1 Outer Socket

Our first ideations started at the 2018 Brown Hack Health Competition. We had returned from Vietnam a month prior to the event and saw this as an opportunity to ideate and receive feedback from engineers and professionals. This event was a weekend-long design sprint where we created products for populations in need. We had mentors, ranging from professors and doctors to CEOs of biotech companies. With our past experiences, we looked to address the need for a streamlined fitting process. We believed the way to do so was to design an adjustable socket. There had been previous exploration into developing new types of sockets, mainly to optimize performance and comfort. Newer techniques involved creating accurate measurements of the residual limb, rapid prototyping and Computer-Aided Design.[37] This method allows for force simulations before manufacturing actual products. We followed a similar design process.

We created the concept of a “one-size-fits-all” product that could be bought off the shelves at a local pharmacy. Based off pre-existing sockets and tightening mechanisms on snowboard boots, we created a first modular design (fig. 2.7).

[37] Torres-Moreno, R., et al. “Computer-Aided Design and Manufacture of an above-Knee Amputee Socket.” Journal of Biomedical Engineering, vol. 13, no. 1, 1991, pp. 3–9., doi:10.1016/0141-5425(91)90037-8.

Figure 2.7: Brown Hack Health drawing concept

It had three struts that came out of a cup, with each insert being the same “T-bone” shape so that it could hold on the residual limb. Two ratchet straps— similar to what is found on snowboard boots— wrapped around the socket to provide circumferential and vertical adjustment. We performed a rough Finite Element Analysis (FEA) to prove that our initial idea would withstand standing forces. We created a contact force between the socket and the base plate connected to the prosthetic knee. We assigned a 75-lb force on the socket, as that would be the theoretical force that goes through the socket while standing. We found that the maximum yield stress would be about 5.13 MPa. These were initial calculations done to understand possible force concentration and material optimization (fig. 2.8).

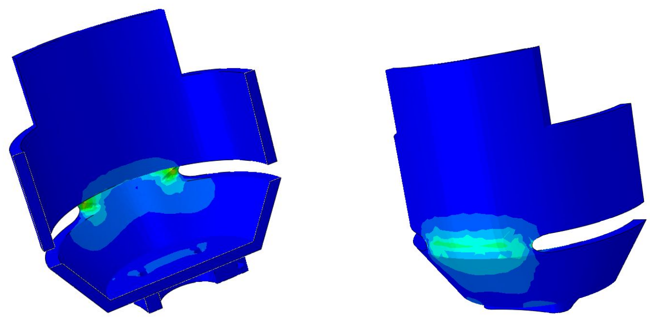

Figure 2.8: Initial FEA showing stress concentration

The socket was used mainly for proof of concept and to address a challenge in the developing world. We designed it using Computer-Aided Design (CAD) and had 3D-printed models; the socket had poor vertical and circumferential adjustment. However, this was the basis for our next iterations and designs. With this design, we won the Brown Hack Health Competition.

We looked to expand on our design through Brown's Biomedical Engineering capstone course, ENGN1930L Biomedical Engineering Design and Innovation. This course gave us a semester to develop the idea and create proof of concept prototypes. We received mentoring from local prosthetists and doctors while getting feedback from connections in Vietnam. We had design and testing critiques throughout this process.

From our initial design, we recognized the importance of circumferential adjustments and maintaining stability to attach the rest of the prosthetic leg to. Our challenges were creating a design that was modular and stable, choosing the right mechanisms and optimizing the material. We based our ideas on sneakers; we wanted the socket to "fit like a shoe". It needs to be comfortable throughout the day, conform to the residual limb and provide ample support. "Cages" on sneakers do something similar, where they keep the foot locked down onto the bottom sole. They conform to the liner interface and the foot without it providing discomfort.

Such cages are used on sneakers with sock-like uppers, such as the Adidas Ultraboost or Nike Air Presto.[38] We also used ski and snowboard boot mechanics as inspiration as they provide long-term locking and can be used to distribute pressure in a uniform manner, as we slightly thought through in our initial design. The Revofit Socket uses a BOA tightening system that is found on snowboard boots; thus, we decided to fully flesh out the ratchet bootstrap idea.

Our design was a three-ring, three section socket where each ring could have its circumference adjusted by tightening attached m2 ratchet straps (fig. 2.9). Each section connected to the other using one-way locks, allowing for macro vertical adjustments. At the base was a molded cup that was filled with packed Thermoplastic Polyurethane (TPU) beads that are used in sneaker cushioning. Our final prototype was made of a co-polymer of polyethylene and polypropylene, similar to that of a traditional socket. Our design was made to be heat-formed. We attached standard pieces to the socket that allows prosthetic leg attachment.

Figure 2.9: Initial socket with three ratchet straps and an adjustable backbone

We found that the circumferential adjustment was effective, but difficult to optimize when considering all three rings together. Since our rings were attached to one backbone, the center of each ring was not aligned when adjusted. The center alignment is lost as each ring is tightened. Residual limbs have a generalized conical shape, so the socket will lose its fit when it is adjusted. In addition, the vertical adjustment system using one-way locks hindered overall stability. Torque was concentrated at the interface

[38] Thorpe, Lucy. "The Story of Adidas Ultra Boost & How It Revolutionized Sneakers." Highsnobiety, Titel Media, 3 Dec. 2018, www.highsnobiety.com/p/the-story-of-adidas-ultra-boost/.

of the locks, which were prone to failure. It can be attributed to the prototype, but we understood there had to be significant reinforcement to these locks.

In our next iteration, we wanted to create stable vertical adjustments, as that was a major issue created by our previous design. We also wanted to address the challenge of maintaining a conical shape with circumferential adjustment. We used LIM Innovations as inspiration as they roughly tried to do something similar, but mainly focused on high performance and residual limb size fluctuations over a day. We also used the Martin Bionics idea of using vertical struts as the primary pieces of stability while using less material. We formulated this idea in the Brown Breakthrough Lab, a startup accelerator focused on developing the business and creating stronger connections with mentors and target users.

The new iteration was highly modular so that it could fit many different sizes and shapes. It had four struts connected to the bottom cup. The bottom cup comes in multiple sizes for different ends of the residual limb. The strut consists of a slide and an insert. The slide provides structural support and holds most of the downward forces from walking. The inserts supported the leg by providing an ischial seat, allowing the socket to fit comfortably around the socket. A pin allows the inserts to be fixed into place. Paracord between each strut allows for circumferential adjustments, and larger belts allow for macro adjustments. The socket was made of high density polyethylene, a material commonly used for prosthetic sockets (fig. 2.10).

Figure 2.10: Machined socket put together without inner cushioning

One major issue we had to address from our machined socket was the forces place on the cup-strut interface. With the paracord and belts pulling the struts closed, the stress is concentrated onto that interface. Even after redesigning the shape on CAD, the material properties placed too much tension throughout the socket. It also hindered the circumferential adjustments we could make as the base itself was stiff. In addition, outward stresses were placed on the strut bases, with a failing point becoming the outer cover of the base. This piece kept the strut inside its track, which is essential for long-term function.

Another issue that was brought up was the lack of surrounding materials and use of paracord. As found in previous sockets, the less material present means greater pressure concentration from the present material.[39] Traditional sockets are total surface bearing because all the pressure is distributed throughout all the material. [40] As this iteration had more material to

[39] Paterno, Linda, et al. 2018.
[40] J. T. Highsmith and M. J. Highsmith, "Common skin pathology in LE prosthesis users: The nature of state-of-the-art skin-prosthesis interface puts amputees who use prostheses at increased risk for these common dermatologic conditions," J. Amer. Acad. Phys. Assistants, vol. 20, no. 11, pp. 33–38, Nov. 2007.

distribute the loads, it also used paracord in high tension. This tension helped suspend the residual limb in the socket; however, the small surface area of the cords became an area of concern. Friction and pressure from the paracord can cause blood concentration and shear stresses creating ulcers.[41] As a result, we wanted to create a tightening system with greater surface area without increasing the cost. This will prevent any force concentration and make a more comfortable fit.

2.3.1.1 Masters Thesis Design

We recognized the poor circumferential adjustment, and wanted to optimize a mechanism that maintained both a stable shape and lockdown. Our first prototype functioned well to lock onto the prosthetic limb through strong circumferential adjustments, while the second focused on personal customization with low-cost materials. We attempted to address the major flaws of each design with the latest idea. We had used an Aircast boot as inspiration (fig 2.11). Aircast boots are used on lower extremity injuries to stabilize the area while providing comfort and breathability.

[41] H. E. Meulenbelt et al. 2009

Figure 2.11: The aircast boot works by providing a thin yet stiff outer shell with air pockets to suspend the foot and ankle in place

Similar to a prosthetic socket, they use a combination of polypropylene and High Density Polyethylene for an outer cast and a softer TPU and polyurethane cushioning. The materials are low-cost and easy to work with, especially through injection molding processes. The main adjustment system comes from strapping mechanisms and air pocket inflation; this allows for highly customizable comfort for different body shapes, as air will fill and compress around the foot.[42] These mechanisms provide the proper support we need for our socket while being low-cost and modular.

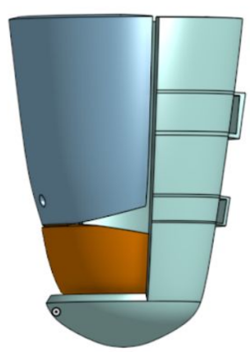

Figure 2.12: CAD mockup of the new design shows the three pieces that slide together for diameter adjustment

With this design, we created a three-piece outer shell from Low Density Polyethylene (fig. 2.12). The material was heat-molded to conform around residual limb molds, as this

[42] Johnson Jr, Glenn W; McVicker, Henry J. (1996) *US5577998A*. https://patents.google.com/patent/US5577998A/en?q=aircast&assignee=Aircast%2c+Inc.&page=1

material is a strong representation of a socket shell. One piece acted as the main backbone, connecting a cup to the ischial seat. The two secondary pieces were riveted together and provided lateral support. Similar to our first iteration, we used a ratchet strap system to create macro circumferential adjustments. The socket was originally made large so that material can be cut away to fit the amputee's limb length-wise. To create micro adjustments and better lockdown, the inner cushioning system is made of air pockets. These pockets are made of adhesive vinyl (Styletech, Tape Technologies, Green Cove Springs, FL) with a one-way valve to allow for air pumping without much loss. More detailed information on the air pockets can be found in the "Inner Socket" section. The new socket provides much more lockdown than our previous design while providing a strong outer shell to act as a strong volume container.

2.3.1.2 Prototype Manufacturing

We initially created cardboard prototypes (fig. 2.13), which allowed us to evaluate the interactions of the adjustable pieces. We were able to visualize different mechanism ideas to create vertical and circumferential adjustments. We created sample pieces that simulated individual mechanisms, then built them into a larger prototype. We sequentially added on mechanisms to understand how each would work with each other. The prototypes were the same size as what we wanted the product to be. As a result, we could get an understanding of how these ideas would work on an amputee while simulating different parts of the product. However, due to its pliability, cardboard does not work well to evaluate the realistic forces placed on the design.

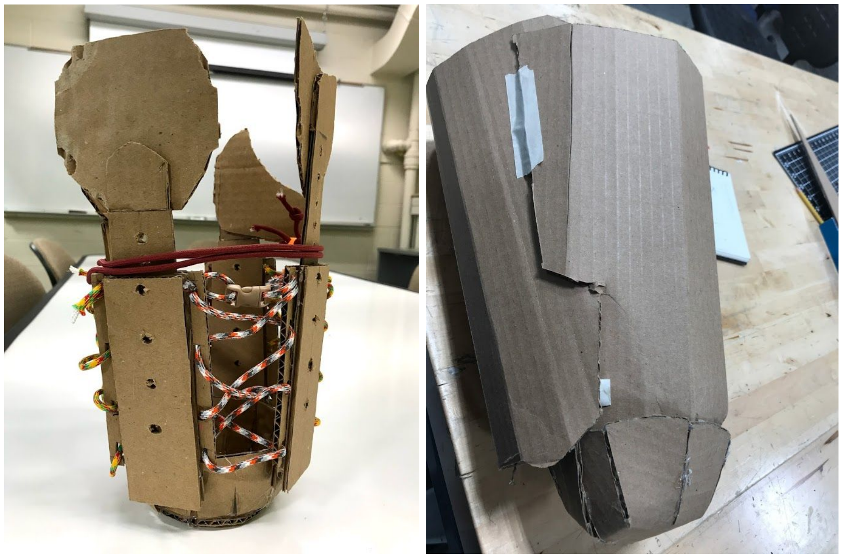

Figure 2.13: Cardboard prototyping was a method used to understand different mechanisms we wanted to explore

2.3.1.3 Computer Aided Design

Using these mechanical relationships, we created 3D models on Onshape (Onshape Inc, Cambridge MA). The online CAD software allowed us to design every piece of our product while allowing us to remotely collaborate and create branching versions off an initial design (fig. 2.14). We designed multiple iterations and created assemblies to understand how pieces fit into each other. These designs were then tested on FEA programs such as Abaqus (Dassault Systems, Vélizy-Villacoublay, France). FEA creates a mesh in the form of the socket design, and simulates forces placed on it in certain directions. Abaqus shows force concentrations at critical areas during certain forces, and will simulate failure. For our designs, force concentration occurred at points where the bottom cup joined vertical components. These areas are interfaces between two parts, indicating possible shearing and unaccounted torques. Once the parts were optimized, we converted the files for 3D printing. The prints were done on Makerbot Replicators

(Gen. 5, Brooklyn NY). These printers allowed us to rapidly print multiple variations of pieces to optimize the fit while understanding the full size of the design. In our first print, we recognized that there were issues with a “splayed” shape created by the socket-strut interface. Most of the shape was due to the cup shape. However, the paracord created strong tension that encapsulated a residual limb. We readjusted the angles and in-house machined the socket.

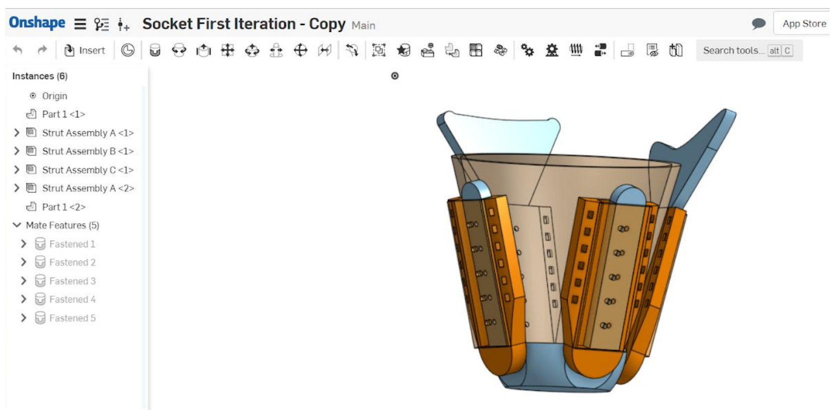

Figure 2.14: Using Onshape to design, simulate and assemble socket

2.3.1.4 Computer Aided Machining

Once we created a prototype that both met our design goals and withstood simulated forces without detriment to structural integrity, we transferred the Computer-Aided Design code to Computer-Aided Manufacturing (CAM) code through a STEP file (Fusion360, Autodesk, San Rafael CA). CAM allows us to create a step-by-step process to cut and carve material into desired shapes using a range of drill bits and cutting methods. CAM creates G-code, which directly controls the movements of the mill. In the software, we assigned the material as HDPE, as it is the polymer most traditional sockets are made of. We used a series of chip breaking, pocket formation and 3D contouring to make the struts and strut bases.

2.1.3.5 CAM Modeling

For each strut and its base, we would drill holes first, then create the assigned pockets and finish with 3D contouring and final cuts. Each setup created allowed us to re-calibrate the piece instead of continuously cutting. From our CAD design, each piece had a defined size and volume which was processed in Fusion360 to estimate the stock pieces necessary to machine. Starting with the strut bases, we assigned a stock piece that was slightly larger than the base so that there was space for the CNC to cut the specific shapes. We broke down the different cuts into two major sections: cuts to be done while being held clamped on a vice (interior cuts), then cuts where the piece needs to be screwed down to the base (perimeter cuts). From there, we had three major cut moves for all the pieces. The first cut move was hole drilling. The stock piece would be gripped down by a vice, and hole drilling would work well with keeping the piece held in place. These drill holes also act as a new method to hold the piece to the base, which is important when cutting any contours. The second cut move was inner contouring; for the strut base, the inner pocket was cut out. This is another cut that can be done while gripped on the base. Then, a pause was programmed so that we could screw the piece into the base as the final perimeter cuts would be made. The area that was being held by the vice was cut away. Lastly, the outer contouring, perimeter cut and smoothing actions were set to finalize the piece (fig. 2.15a). This method was applied to all non-cylindrical pieces. For a more detailed explanation of how to set the CAM for the strut base, see Appendix A.

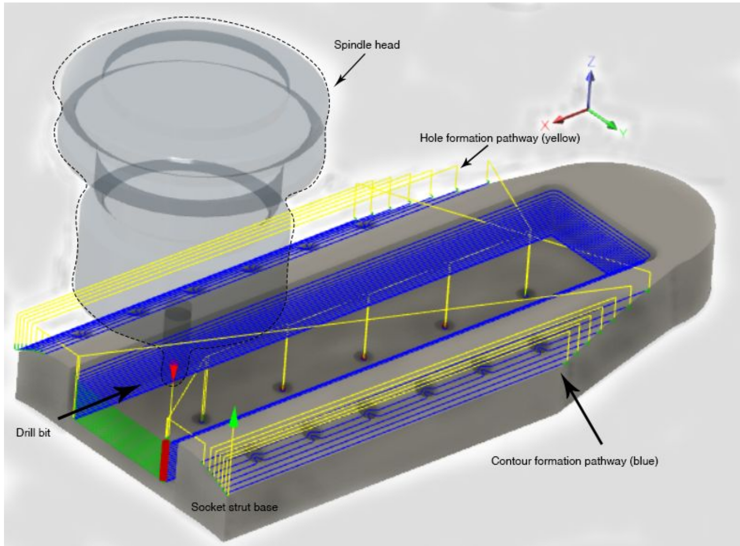

Figure 2.15a: Simulation on Fusion360 of how the strut base would be cut

The base cup was also programmed in Fusion360, but in cylindrical coordinates to be cut using lathing techniques in the Tormach 15L Slant Pro Lathe (Tormach Inc, Waunakee, WI). The lathe works by clamping the stock piece on a spinning chuck. As the piece is spun, a drill bit is brought into the piece, and moved around the spinning stock, creating a uniformly cut shape. Similar to the previous CAM model, a CAD model of the cup section was inserted. The CAM was made assuming that it will be cut out of stock material, identical to the lathing instructions. There were two main steps to be programmed. First, all inner cuts and contouring were performed. A drill was brought into the middle of the stock to create a ½" diameter hole. This set us up to perform the second boring step. The inner boring tool was brought into the hole, then moved outwards to create the inner cup shape. The third step was to use an outer boring tool to create the outer cup shape (fig. 2.15b). From there, we measured where each flat would be on the cup, as these were the locations where the strut bases attached. We manually milled the four flats until they were even.

We used a polyethylene polymer for the machined prototype. Most standardized sockets are molded by a copolymer of polyethylene and polypropylene, with an outer carbon fiber shell. The polymer gave us similar characteristics to a standard socket. In addition, polyethylene is a commonly machined material, making it easy to work with for an initial design. The pieces used for our prototype were thicker than what would be in a prosthetic socket so that we could test machining techniques and ensure proper support for the resulting socket.

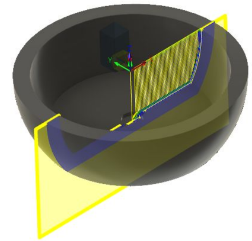

Figure 2.15b: The pathway of the inner and outer boring tools for the cup shape

2.1.3.6 Machining: CNC Milling

The CAM simulations directly control the actions done on the Tormach CNC mill (Tormach Inc, Waunakee, WI). The Tormach is a powerful subtractive manufacturing machine as it cuts a specified form from stock. A piece of stock is fixed at the bottom bed using a vice and a drill head is controlled to make different cutting moves. It allows us to create large, complex pieces from stronger, denser materials such as high density polymers and metals. However, this makes the pieces rather stiff and more difficult to create organic contours compared to additive techniques. In addition, it requires the use of excess material, which is not conducive to the actual manufacturing process.[43] Our purpose was to manufacture a stronger prototype that could be used for testing with the drawback that this prototype would be bulky.

[43] Staff, Creative Mechanisms. "Additive Manufacturing vs Subtractive Manufacturing."Creative Mechanisms Inc, 2014, www.creativemechanisms.com/blog/additive-manufacturing-vs-subtractive-manufacturing.

The CAM designed on Fusion360 was exported as G-Code, which directly controls the movements of the Tormach bed and drill bit. We separated the code into two sections: the inner contouring and the outer cuts. We mainly use a vice to clamp the stock onto the bed, and doing outer contouring would loosen that clamp. By separating the two into different steps, we could fix the pieces by screwing it into a template piece after the drill holes were created. Starting with the stock piece we inserted it into the vice clamp and assigned the bottom left corner as the zero point. Before any new cut, we had to reassign the zero point as well as calibrate the drillbit head using an edge finder and 3D taster. These tools ensured that the head of the CNC mill was directly over the zero point to serve as a reference for the height of the material. Each drill bit was assigned standardized offsets that aligned with each calibration so that they cut through the material properly.

First, a 13/64” drill bit was inserted into the spindle and locked into place. The first step ran, drilling holes that were shown in the CAD file. We then changed the drill bit to the ¼” flat end bit, which cut out the inner pocket of the strut base. Lastly, we changed the flat end to a ¼” ball end bit that cut away any curved contours in the design. Once all the inner cutting steps were finished, the CNC paused so that we could refix the piece using screws and recalibrate.

A template was made out of a 5” x 12” plank of aluminum, which allowed us to screw the stock onto the plank using the holes that were just drilled. After screwing it in, we clamped the aluminum to the vice. The stock piece was elevated about the vice, which allowed us to run the final steps. We re-attached the flat end bit into the spindle and ran an outer contouring step that cut away the excess material and shaved the top of the strut base smooth. These steps were repeated for every strut piece, including the inserts and covers (fig. 2.16).

2.3.1.7 Machining: CNC Turning

Figure 2.16: Struts, covers and inserts post machining

The CNC lathe is similar to the mill as it is a computerized subtractive manufacturing process that works by cutting away from a main piece of stock. However, it works by having the stock attached to a clamping chuck, which spins at desired speeds. A turret holds all the cutting tools at different positions, and is brought to the stock and cuts in a cylindrical fashion. Since all the cutting tools are already on the turret, there is no need to change the tool out. All the cutting programming and tooling is done on Fusion360, similar to the milling processes. The program creates G-code, which the lathe reads as commands to spin and cut the material.

Before the code was run, the stock was attached. The stock was 6in diameter and the cup would be 3in deep, so we created a 2in stub for the chuck to clamp onto. We manually milled the stub using a manual msc 951735 lathe (MSC Industrial Supply Co., Melville NY). This stub would be long enough to prevent application of high torques by the cutting tool being lowered into the material in the CNC lathe. Similar to the milled pieces, we used a high density polyethylene to create the cup.

As described in the CAM modelling section, the cuts were done from inner to outer cuts. We attached the inner boring tools at the first sections of the turret, as those tools would be used primarily. We then attached the outer boring tool in the fourth position of the turret. The G-code was set up to use each tool at a separate step, starting with the inner drilling tool and ending with the outer boring tool. The stock was zeroed at the center of the cylindrical outer face and the width of the stock was programmed in.

The first step drilled a ½” hole in the center of the stock. The stock was spun on the chuck and brought into the drill bit for 3in. This created room to fit in the inner boring tool. The boring tool was then rotated into position and brought into the stock. It cut by moving outward slowly to cut away from the hole that was created. This was done until the inner part of the stock resembled a cup. Next, the outer boring tool was rotated into place and brought into place. The outer boring tool was oriented perpendicular to the stock, which cut from the bottom to the top of the piece, following the curved contour set by the CAM. Lastly, we took the resulting piece and cut the stub away.

The cup required four flat surfaces to attach the strut bases. We took the cup to the CNC lathe, and angled the cup so that the outer surface was tangent to the flat end drill bit. We zeroed the piece to the bit, then cut down ¼” depth to create a flat surface. Using a hand drill, we drilled in two ¼” holes that were made on the strut bases and screwed into place. This was repeated 4 times. We then put together the pieces using m5 screws and ¼” screws. Each separate piece— excluding the strut inserts— were set into place using epoxy glues (Zap glue, Pacer Technology, Cucamonga, CA) to reinforce the screws. This made our socket strong against vertical forces and corresponding torques, but provided some elasticity in its adjustments.

2.3.1.8 Heat Molding

We used heat molding to create our first and our latest prototypes. Heat molding allowed us to use thinner, more dynamic materials than CNC machining. In addition, it created better representations of our designs, since it simulates an injection mold or traditional socket forming techniques. This technique works by heating a thermoplastic to close to its melting point, which turns the material soft and pliable. It is then pressed into a positive mold, where it takes the shape of the negative. Cooling the material sets it in that shape; this process can be repeated multiple times and shaped specifically to the positive.

We used ⅛" thick Low Density Polyethylene (LDPE) as the material for our heat-molded socket. LDPE has been used in the past to create custom-molded sockets, usually as a composite or co-polymer.[44] LDPE is a softer thermoplastic that has elastic properties. It has high impact strength while pure LDPE has poor tensile strength. Its low melting point (120 F) makes the material ideal for heat molding prototyping, as heating can be done quickly (fig. 2.17). The thermoplastic can be reheated multiple times and remolded to different shapes. However, if heated too much LDPE can burn and become brittle. If the melting point is reached, the plastic will melt and lose its original characteristics. It acts as a good physical, high resolution representation of such designs, and mimics characteristics similar to a socket that would be fitted onto a person. Testing can be done on this to determine how the design functions in more finalized materials. However, a finalized version would include a co-polymer mix with high density polyethylene and composite material.

[44] Lenka, Prasanna Kumar, and Amit Roy Choudhury. "Analysis of TransTibial Prosthetic Socket Materials Using Finite Element Method." Journal of Biomedical Science and Engineering, vol. 04, no. 12, 2011, pp. 762–768., doi:10.4236/jbise.2011.412094

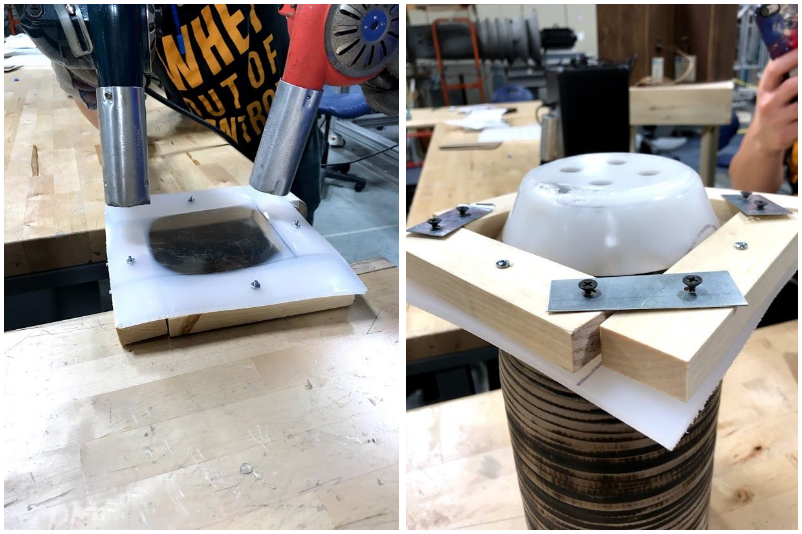

Figure 2.17: LDPE is heated with heat guns directly under its melting point and pressed onto positives to create specified shapes

The circumference of the residual limb mold was measured at six evenly spaced areas. Using half the arc of each section, the lengths were then measured on a 12” x 24” x ⅛” LDPE sheet. A square section was added at the end of the 13in. socket section for the cup mold. This backbone section was measured and cut in accordance to the measurements. Using heat guns, we heated the LDPE uniformly so that it reached between 100-110 F. We heated both the inner and outer sides of the material to allow the material to uniformly expand. As the material reached the melting point, the white polymer changed to a clear color and became pliable. We then pressed the materials firmly against the positive mold, causing the material to take that shape. This process was repeated multiple times until the LDPE held a curved shape that wrapped around the mold on its own. The same method was done to the two supporting pieces, as they will wrap around the residual limb mold. However, 3” of excess was added so that the supporting pieces would overlap and the circumference of the socket could be adjusted.

The second step was to create and attach the bottom cup. An 8” x 8” square of LDPE was cut for the cup, as there needs to be space to pull the heated polymer onto the end of a residual limb mold. 1” wooden handles were added around the perimeter of the square section to insulate the surrounding LDPE and allow us to handle the piece. Similar to the backbone section, we heated both sides of the sheet simultaneously until the material became clear and soft. The residual limb mold was fixed in a vertical position, and the material was pressed onto the end of the mold. It was pressed down 2.5” and held into place until the material cooled and returned to its solid state. All excess material was removed until only the cup remained.

Figure 2.18: Heat fusing the cup section with the backbone required reaching right below the melting point and pressing the two pieces together

To attach the cup, we aligned the bottom of the backbone and the corresponding section on the cup. We heated the two sections to 115 F as the material reaches a transition state between solid and liquid. In this state, both pieces can fuse to each other. Once heated, the two sections were pressed onto each other using the wooden holders and held together until it cooled. Once cooled, these pieces formed into one (fig. 2.18). This process was repeated multiple times to create a better fusion between the two pieces.

The two support sections were held together using a hammer rivet (McMaster-Carr, Elmhurst, IL). This allowed the two pieces to hold a rigid connection, but allowed them to independently bend. The two pieces insert into the backbone in a “weave” pattern, locking it into place around a residual limb. On the backbone, two m2 ratchet buckles (m2, Winooski, VT) were riveted at 4 inches above the base of the cup and 4 inches above the gap. These buckles created a one-way tightening mechanism while having a quick release option to loosen them.

Once inserted into place, the residual limb was measured to fit the socket, as the socket has extra material on the top end. We cut the extra LDPE so that it fit perfectly around the top side of the mold. The inner cushioning was then added to the socket prototype.

2.3.2 Inner Socket

Inspiration for a separate “inner socket” came after we assessed the shortcomings of our first socket prototype. There was not quite as much circumferential adjustability as we would have liked but allowing for additional adjustability would have compromised the structural support necessary to keep the residual limb in place. To address both issues, we looked to divide these design criteria into two pieces: the outer socket could be designed to provide the structural rigidity and the inner cushioning could be a more forgiving material that would allow for circumferential adjustment and comfort.

We investigated medical devices and equipment that had a similar purpose of having a stiffness constraint but also having to fit a wide variety of people. Roller blades came to mind as a prime example of fitting this need (fig. 2.19). They are composed of a hard plastic exterior shell that encases a softer shoe material, giving the user enough ankle support for high speeds while also a certain degree of comfort like a sneaker.

Figure 2.19: Design of a roller blade shows concept of outer shell for structural support and more comfortable inner shoe.

In the medical world, the AirCast (fig 2.10) serves a similar purpose. The exterior polyurethane/ polyethylene shell provides the general structural support for a person's sprained limb while inflatable air pockets fill the gaps in space created by the uneven topography of the limb and immobilize it. In general, the daily fluctuations in volume for a residual limb range from -11% to 7% of total volume, thus the inner socket would have to at least be able to be adjusted this much.[45] Studies suggest that a volume increase of 3-5% is enough to cause discomfort in a residual limb, indicating that the minimum adjustability increment would have to be no greater than 3%.[46]

Clinically, the inner socket should provide a secure interface between the socket and delicate tissue in the residual limb, allowing for an even distribution of pressure throughout the limb while walking.[47] Elasticity, stiffness, shear stress and thermal properties are all important factors to consider when choosing a proper liner. If the liner is too soft, there will be excess

[45] N. A. Abd Razak et al., 2015
[46] W. J. Board et al., "A comparison of trans-tibial amputee suction and vacuum socket conditions," Prosthetics Orthotics Int., vol. 25, no. 3, pp. 202–209, Jan. 2001.
[47] Pezzin, L. E., et al,, "Use and Satisfaction With Prosthetic Limb Devices and Related Services," Arch. Phys. Med. Rehabil., 85(5), 2004, pp. 723–729.

movement of the residual limb relative to the socket, leading to a “pistoning” effect. Pistoning is when the residual limb moves independently of the socket. This can degrade proprioceptive ability and then lead to gait instability increasing the likelihood of falling as well as unwanted chafing.[48] Having a high compressive elasticity in a material would be beneficial because it would concentrate pressure at desirable load bearing areas (like the patellar tendon). Lower compressive elasticity is preferred, however, for distributing pressure evenly and away from sensitive areas of the limb (eg. fibular head).[49] Thus, in determining the optimal liner, it was important to find a material that has a moderate compressive elasticity to be able to benefit from both sides of the spectrum.

2.3.2.1 Cardboard prototyping

Design iteration started with brainstorming materials that could serve as the inner cushioning). Based on the materials, we modelled different shapes and configurations that could provide adjustability. Emphasis was placed on creating a modular design that had easily removable components and could be easily replaced. Shown in figure 2.20 are a few examples of the modular designs. Each has the common theme that they are composed of repeating units, which would be useful for ease of manufacturing. We thought of using a variety of materials for the inner cushioning ranging from different types of foam in athletic equipment to rubber and air pockets.

[48] Miller, W. C., et al., “The Influence of Falling, Fear of Falling, and Balance Confidence on Prosthetic Mobility and Social Activity Among Individuals With a Lower Extremity Amputation,” Arch. Phys. Med. Rehabil., 82(9) 2001, pp. 1238–1244.
[49] Cagle, John C et al. “Development of Standardized Material Testing Protocols for Prosthetic Liners.” Journal of biomechanical engineering vol. 139,4 (2017): 0450011–04500112. doi:10.1115/1.4035917

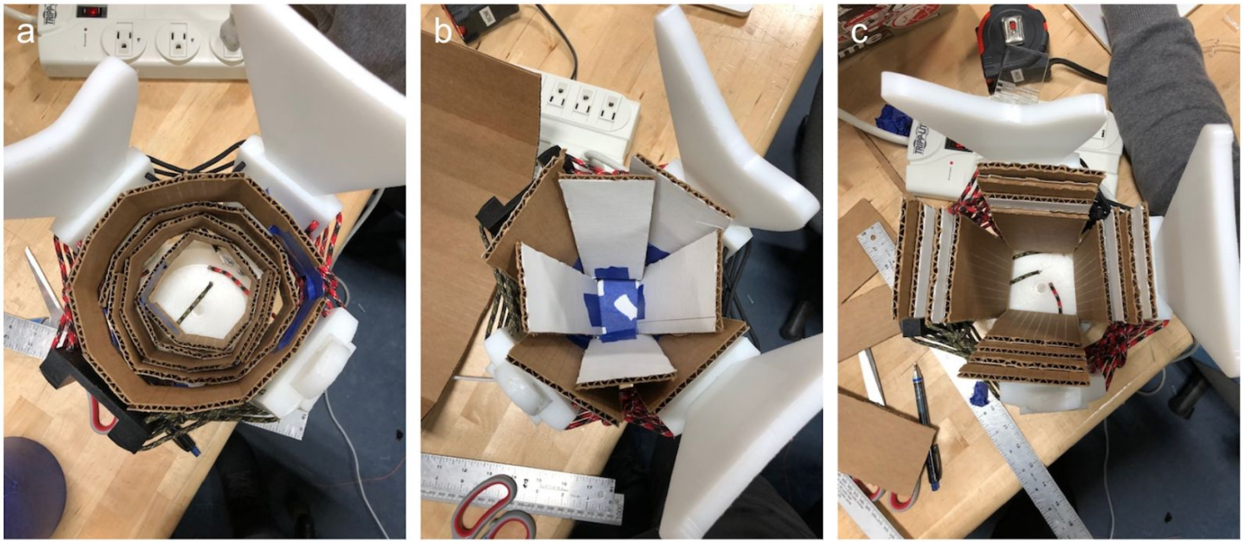

Figure 2.20: 3 ideas for modular inner cushioning layout. a) concentric ring design where each ring is its own separate unit. b) cushioning design as rectangular panels connected in sets of four. c) modification of the rectangular panel layout with each panel stacked directly on top of each other.

2.3.2.2 Method for Making Air Pockets

Our air-pockets were made by fusing vinyl sheets with pressure and heat. The adhesive vinyl was measured according to the dimensions of the outer socket frame (each strut was approximated to a 7”x 3” rectangle). A large roll of BDW plastic was laid out and the folded on itself, resulting in two sheets stacked on top of each other. The outline of the air pockets was drawn on the top sheet. To account for air expansion, the dimensions of each air pocket were extended by two inches on either side. The vinyl was then cut with a razor blade and excess material was discarded. A line was drawn outlining the entire air pocket approximately 1in from the cut edge to denote the boundary for the heat press. A strip of teflon was placed over the two sheets of plastic and an iron heated to approximately 300℉ was steadily pressed along the length of the plastic sheets. Care was taken to maintain a constant pressure and speed throughout the heat pressing process to create an even fusing between the plastic sheets. The teflon sheet helped to disperse the heat evenly throughout the plastic. Once all open sides were sealed, the air pocket was left to cool for at least 5 minutes. After cooling, a small opening was made on one face of the air pocket where a one way valve was again sealed to using the heat pressing technique (fig 2.21). One way valves and pumps were adapted from the AirCast models as a test for proof of concept.

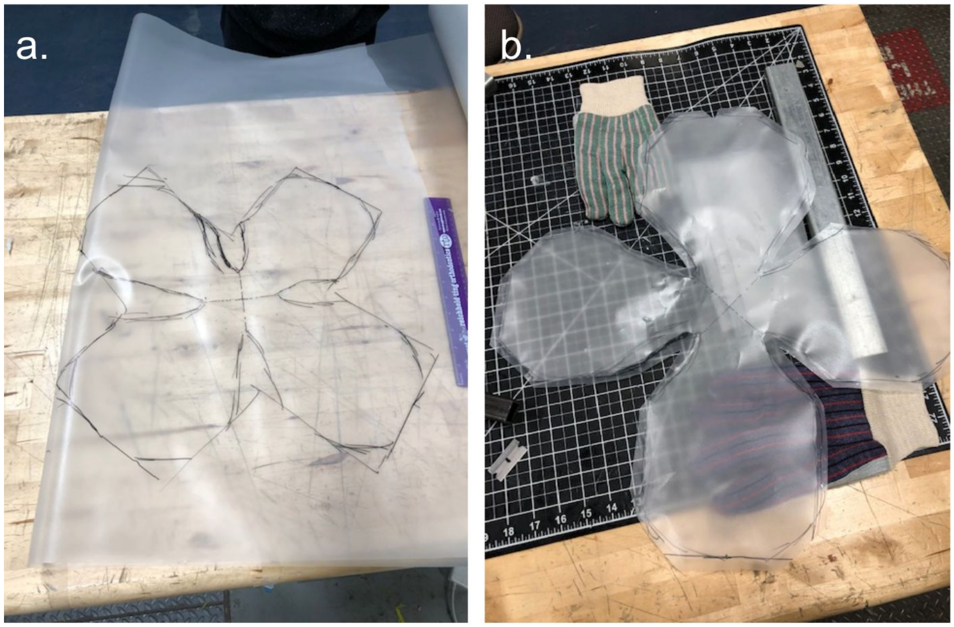

Figure 2.21: air pocket made using heat press. a) dimensions of air pockets drawn out on double layered plastic film. b) air pockets after being cut out and heat pressed to seal edges of the perimeter.

We also made a more modular set of air pockets consisting of even rectangular pockets 7”x 3”. The seal was made to be 0.5” thick around all sides to keep a consistent design (fig. 2.22).

Figure 2.22: 3 identical air pockets were created with the same method. The first air pocket has a one way valve fused in to allow inflation and deflation.

2.4 Methods

2.4.1 Design Goals and Requirements

Based on our measurements, considerations of amputees and prosthetists as well as pre-existing sockets, we created specific design goals and requirements we aimed to hit with our adjustable socket. They will ensure that the socket will perform under the necessary conditions for the associated amount of time. The requirements are listed out here:

Table 1: The goals and requirements for our prosthetic socket

	Goals and Requirements	Rationale
Performance:	SHALL allow the user to mimic 90% similarity gait performance compared to a standard custom-fit polypropylene/polyethylene socket	
	SHOULD be adjustable in <5 steps	
	SHOULD provide circumferential adjustment of at least +/- 1 inch	accounts for the daily average volume fluctuations of a residual limb (+/-10% volume) of an average male amputee[50]
	MUST be able to withstand a peak pressure of 300kPa	the residual limb can exert as much as 292kPa against the inner socket[51]
	MUST be able to withstand 4.5x the patient's body weight	The average body weight of males in Asia is 151.2lb. To have a safety factor of 2 the socket must withstand a human with body weight of 302.4lbs
	Tension tightening straps MUST withstand up to 550 N	m2 ratchet buckles have a safety limit of 550 N[52]
	MUST withstand torques from walking +/- 25 Nm[53]	Walking will create a torque upwards of 25 Nm according to Sup et al

[50] N. A. Abd Razak et al., "Comparison study of the prosthetics interface pressure profile of air splint socket and ICRC polypropylene socket for upper limb prosthetics," Biocybern. Biomed. Eng., vol. 35, no. 2, pp. 100–105, 2015.

[51] Jia X., Zhang M., Lee W.C.C. Load transfer mechanics between trans-tibial prosthetic socket and residual limb - dynamic effects J Biomech, 37 (2004), pp. 1371-1377

[52] "M2®Inc." M2® Ratcheting Buckles and Straps. Accessed November 07, 2017. https://www.ratchetingbuckles.com/engineering/.

[53] Sup, Frank et al. "Design and Control of an Active Electrical Knee and Ankle Prosthesis."IEEE/RAS-EMBS International Conference on Biomedical Robotics and Biomechatronics. October 19, 2008. Accessed November 07, 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2906131/.

	MUST be able to withstand the above forces for 7500 cycles per day	A person in a developed country averages around 3,000- 4,000 steps, thus doubling the cyclic load would provide a daily safety factor.[54]
Safety	No catastrophic failure: MUST be able to maintain 50% of optimal functionality if interface cracks or breaks	The socket must not fail under any forces or stresses that could possibly be put on by a user
Life in Service	SHOULD last at least 4 years of daily use (18 hours per day)	It must stay comfortable during daily use
	MUST operate in temperature range of 0 - 45°C	Daily temperature fluctuations plus body heat would create such operating temperatures
	SHOULD meet water resistance rating 50m- can be sprayed off with water	Easy to clean
Ergonomics	MUST be able to form to the limb with a radius of curvature 2.4 in +/- 0.5in	As residual limbs fluctuate in size drastically, this will be our baseline
	MUST weigh <10 lbs	No more than the traditional average socket weight of 10lbs[55]
Target Product Cost	MUST be less than $100; ideally less than $50 to produce	The fitting process can cost about $200 per fitting alone, so we look to streamline this total process so that the hospital fitting will be quicker and only require one day of fitting
Patient-related Concerns	SHOULD add less than 10% volume size to leg when compared to contralateral leg	Amputees in Southeast Asia care about fitting into their cultural views, and want to be able to fit pants over their leg to hide signs of amputation
	MUST have a sudden failure rate of less than 5% within designated product life	
	MUST have a comfort ranking of over 5 when ranked by the user on a scale of 1-10 (with 5 being current prosthetic solution)	
Client Requirements	Client: Amputee in Vietnam/ Thailand	

[54] Rieck, Thom. "10,000 Steps a Day: Too Low? Too High?" Mayo Clinic, Mayo Foundation for Medical Education and Research, 16 Mar. 2018, www.mayoclinic.org/healthy-lifestyle/fitness/in-depth/10000-steps/art-20317391

[55] "Answers to Frequently Asked Questions." Orthotic and Prosthetic Specialists. Accessed November 07, 2017. http://www.orthoticprostheticspecialist.com/faqs/.

Design variables/ parameters	Possible Materials: Extruded low density polyethylene, Low density polyethylene, High density polyethylene, Polypropylene, Copolymer	We were looking for a material that was durable, safe under cyclic loads, yet easy to work with and mold
Mechanisms	Height Adjustment: one-way vertical adjustment, telescoping mechanisms, threading	
	Width Adjustment: Velcro, ratchet straps, lacing, material shaping	

Table 2: The sizes of residual limbs that the socket must fit

Metric (in)	Base Measurement	Range (±)
Height	9.5	1.5
Width: Hip section	6.5	1
Width: Mid section	5	0.5
Width: Residual Limb end	4.5	0.5

2.4.2 Failure testing

First, the properties of the air pockets were measured to see if they met our design criteria. Jia et al found that the maximum pressure exerted by the residual limb on the socket during a gait cycle was 292kPa.[56] We tested our air pockets to failure by using an instron (3340 series single column) with a 500N load cell to apply a progressively greater load on the air

[56] Jia X., Zhang M., Lee W.C.C. Load transfer mechanics between trans-tibial prosthetic socket and residual limb - dynamic effects J Biomech, 37 (2004), pp. 1371-1377

pocket until the seal started to break. Both the 19mm diameter air pockets used for compression testing and the regular sized air pockets (7in x 3in) were tested to failure. The 19mm air pockets were tested with a progressive loading of 0.05% (1.8mm/min) strain per second until 100% strain or failure, whichever came first. The regular air pocket was tested at a progressive load rate of 5 mm/min until failure. Failure of the air pockets was characterized by popping of the air pocket which resulted in a steep decrease in pressure.

2.4.3 Compression Testing

Compression testing was performed on the various materials of the inner cushioning and air pockets according to a previously documented protocol on compression testing which was adapted from ASTM standards.[57] An arch punch was used to make a 19mm diameter and 6mm thick sample for the compression test. 19mm was the recommended specimen size because it closely matched the dimensions of the sensors used and cited in literature. A load rate of 0.5% strain per second was cited as the rate for the standing (quasi-static) loading condition. Each material was loaded to a maximum of 60% strain because it produced the stress that exceeded both the maximum measured pressure for elastomeric materials and the mean pressure for the standard liner used in the study.

2.4.4 Maximum Adjustability

To understand the success of our socket, we tested its adjustability. The main purpose of our design was to create a highly adjustable socket that could fit multiple sizes while being

[57] Cagle, John C et al. "Development of Standardized Material Testing Protocols for Prosthetic Liners." *Journal of biomechanical engineering* vol. 139,4 (2017): 0450011–04500112. doi:10.1115/1.4035917

adjustable to residual limb fluctuations. The first test was to understand the fit of the socket on residual limb molds. We accessed molds from Nunnery Orthotic and Prosthetic (North Kingston, RI). These molds varied widely in their circumference and their length, giving us a range of sizes we looked to accommodate (fig. 2.23). These molds were made of plaster and centered on a rod, allowing us to fix it into place while we fit the socket onto it.

Figure 2.23 We used two residual limb molds (Nunnery Prosthetics, North Kingston RI) to design our prototypes to fit

To test the adjustability of our air pocket design, the entire unit was deflated and positioned evenly in the base of the outer socket. The plaster residual limb molds were then inserted into the socket and the air pockets were inflated until they securely suspended the residual limb. We qualitatively determined how well secured the limb was in the socket. A quantitative assessment was done as part of the pressure testing protocol.

2.4.5 Pressure Testing

Jia et al. used FEA analysis to determine that the maximum pressures on the residual limb in a socket are localized at the distal end of the socket, near the knee interface. Bony landmarks such as the medial and lateral tibia and patellar tendon were the places that experienced maximum pressures in this study. In a trans-femoral residual limb we expected that maximum pressures would also occur at bony landmarks such as the medial and lateral femur. When developing our pressure testing protocol we attempted to strategically place six sensors in the locations that would experience the most pressure. These included the medial tibia (MT), lateral tibia (LT), near the popliteal depression (PD), the quadricep tendon (QT), at the distal end of the femur (D), and on any irregularity that would be load bearing. Six 101mm flexiforce Tekscan sensors were wired to separate channels on an arduino through a 100kΩ resistor as shown in fig. 2.24. Jia et al performed the analysis on an 81kg person to be able to compare the results to literature values. Given this body weight, it was determined that the maximum load on the residual limb would not exceed 400N while standing.

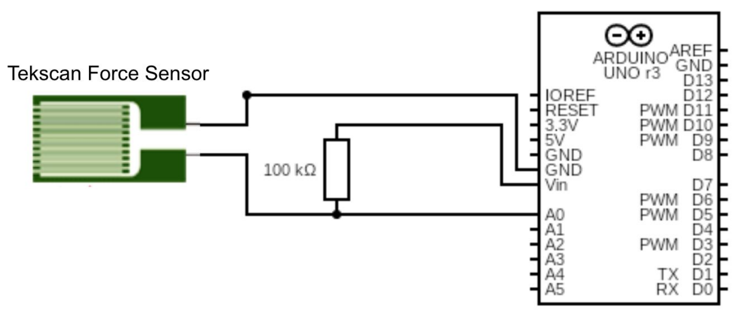

Figure 2.24: Circuit diagram of Tekscan flexi-force sensor connection to arduino. A total of six sensors were connected (A0-A5).

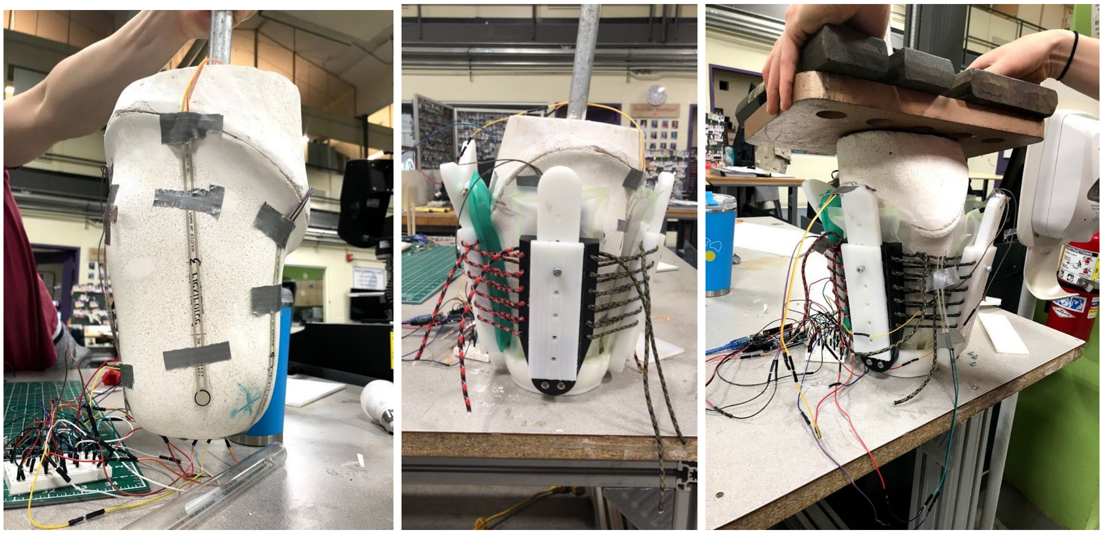

Figure 2.25 Pressure sensors were placed on the residual limb mold, then the socket was tightened around it. To simulate a person's weight, extra weight was added to the mold and the pressure was measured

We calibrated our force sensors at 5 different loads (50N, 100N, 150N, 200N, 300N) to determine the resistance and scaling factor necessary to get an accurate force output with a range of 0-400N. Measurements were taken 3 times at each load for repeatability (fig. 2.25). After placing the sensors on the residual limb mold, we placed it into our second socket iteration and tightened it until the limb was suspended inside the socket. The socket had air bladders for cushioning. Once tightened, the air pockets were inflated to its maximum inflation point and the pressure was recorded.

2.5 Results

2.5.1 Failure testing

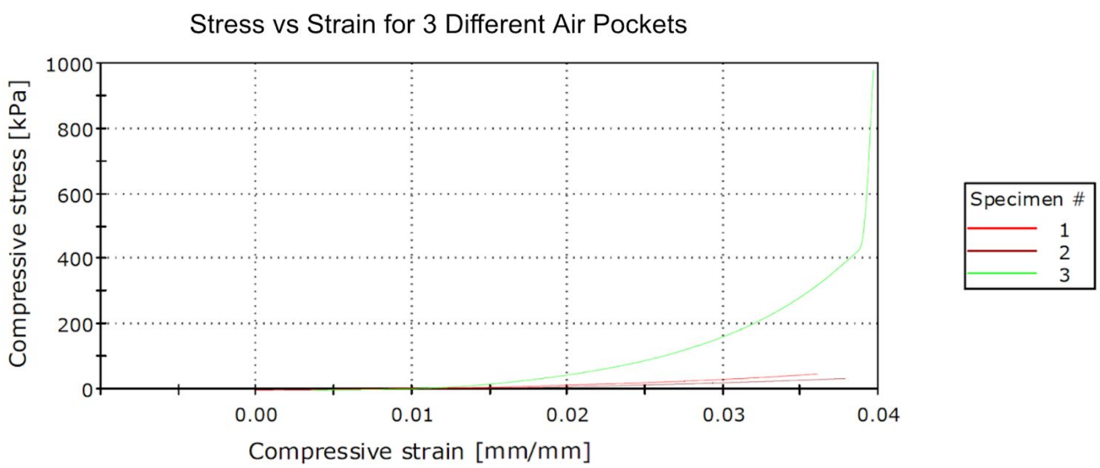

Figure 2.26: Shows the stress-strain curves of the same pockets. Specimen 1: height 7.18mm, radius 15mm. Specimen 2: height 10.66mm, radius 17.345mm. Specimen 3: height 4mm, radius 15mm.

Compression tests were run on three specimens of air pockets. These pockets were made to fit the compression area. Each were filled with slightly different amounts of air to observe their different reactions under compression (fig. 2.26). The compressive force was placed at 0.05% strain per second and compressed to 60% strain. Specimens 1 and 2 had similar Young's moduli, 400 KPa and 200 KPa. Specimen 3 had a Young's Modulus of 2000 KPa; the third specimen was filled with less air and could be displaced easier, which allowed for greater strain with less force. The sharp vertical section in specimen 3 occurred when the instron completely compressed the air pocket and pushed against the bottom plate.

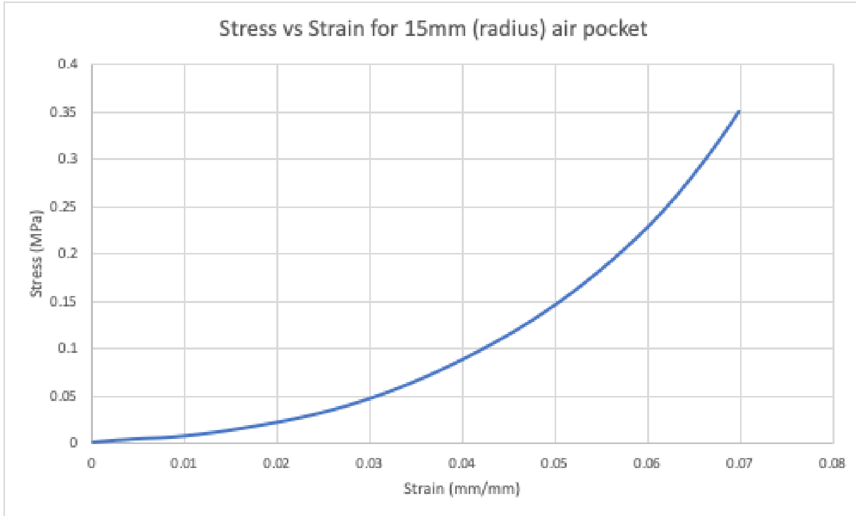

Figure 2.27: The stress-strain curve of specimen 1 when running compression to failure tests

After following the methods set up by Cagle et al., we ran compression failure testing. We pressed on the air pockets until they either failed or could not be compressed any more. This was done on specimen 1 (fig. 2.27) and it demonstrated a Young's modulus of 5 MPa. The same test was done on specimen 2 (fig. 2.28). The Young's modulus of the second specimen is roughly 4 MPa.

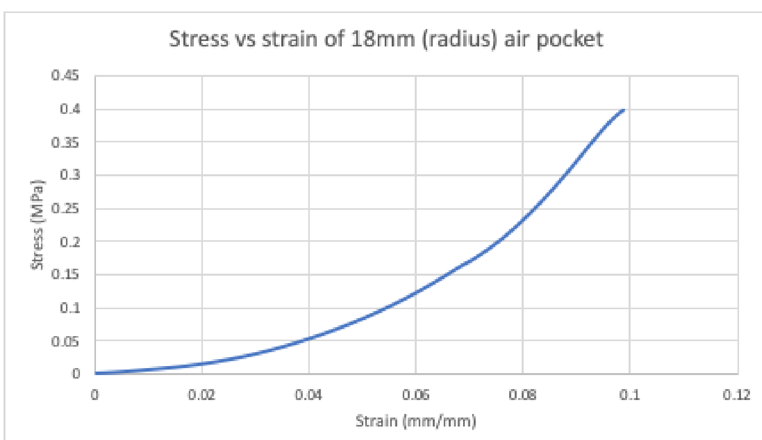

Figure 2.28: The stress-strain curve of specimen 2 under compression to failure testing

We noticed that the Young’s modulus changed depending on the tests and that the stress strain curves did not really have a consistent ramping phase. We believe this was due to the air compression. Air would become displaced as more pressure was placed onto the pocket. This displacement is difficult to account for in registering consistent readings because the instron surface area was smaller than the air pocket. However, the specimens show similar characteristics to each other. Specimens 1 and 2 were inflated a similar amount, and their Young’s moduli measurements were similar in both the first trial and the failure testing.

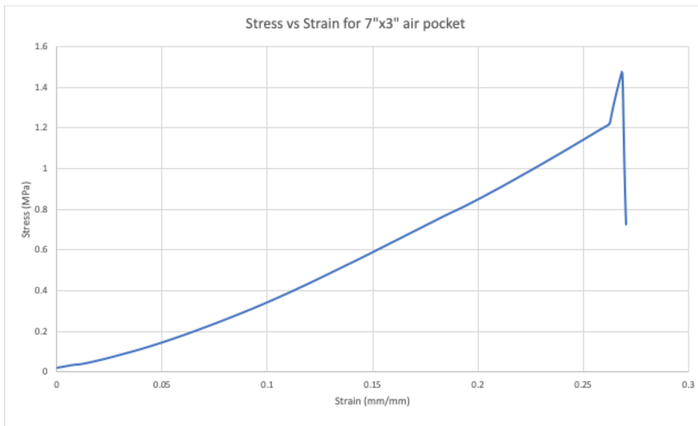

Figure 2.29: Compression testing to failure of a full air pocket, which fails at 1.2 MPa

Lastly, we ran compression tests on a full-sized air bladder (fig 2.29). Volume and surface area do not scale proportionally, thus it was important to determine compression of a full bladder. The compression head was only 8mm in diameter, so we set two pieces of HDPE on the top and bottom of the socket to distribute the force among the full pocket. As this was more effective, it still had localized pressure in the middle of the area. The Young’s Modulus was 4.8 MPa, similar to what was shown in our failure testing. After 1.2 MPa, there was a spike in stress over strain, creating plastic deformation and causing a leak to form. The larger air pocket demonstrated similar characteristics to that of a smaller one, though the larger hit a failure point.

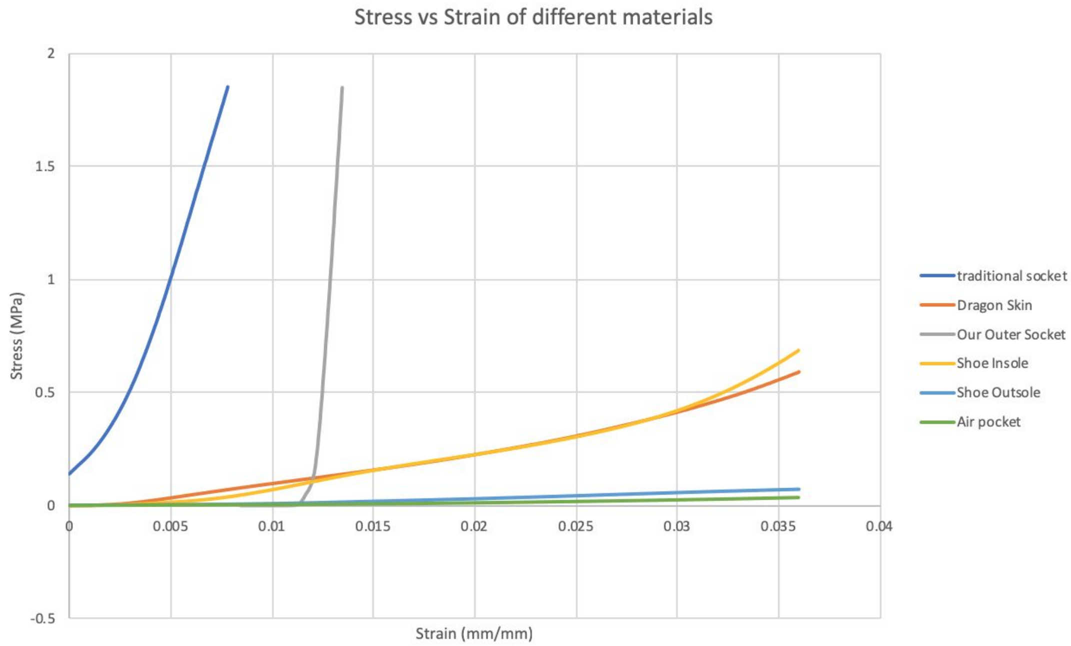

Figure 2.30: We ran compression tests on many different materials that undergo compression for a cushioning purpose; the air bladders demonstrate similar characteristics to a shoe cushion

We then compared the failure testing to other materials used in either the socket or related padding used in equipment (fig. 2.30). We saw how similar the materials reacted under an applied pressure. The air pockets acted similar to the sole of a shoe in terms of their Young's Modulus. Both have properties that allowed them to conform to the pressure being placed on them. However, the air pockets functioned by displacing the air while the sole material physically compressed.

2.5.2 Pressure Testing

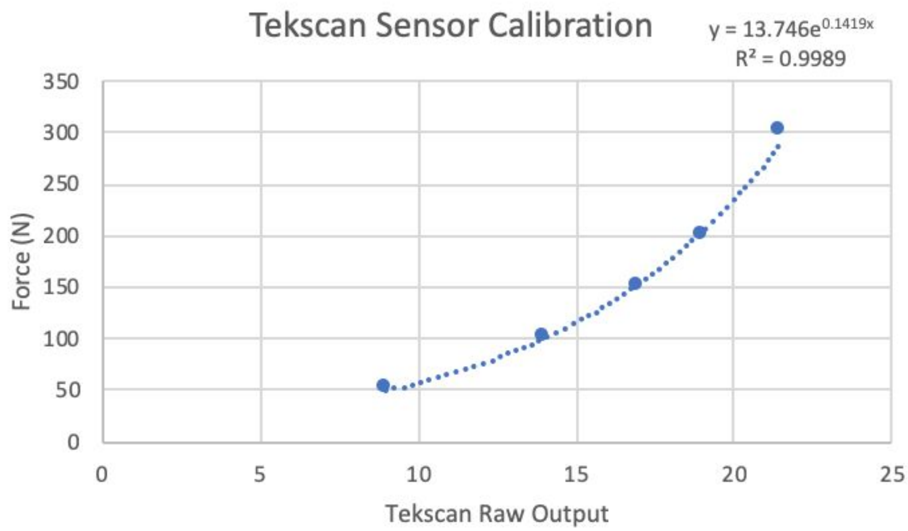

Figure 2.31: The pressure sensor was calibrated with an exponential line of best fit by comparing raw readout from the arduino with known loads placed on the sensor.

We first calibrated the six pressure sensors using the instron, and found that they followed an exponential curve shown in fig. 2.31. The raw output readings were mostly linear in the range between 100-200N. When we placed the residual limb inside the socket and tightened it, the pressure sensors registered very little force. We re-adjusted multiple times but with the same results. We are still in the process of reworking this set up.

2.6 Discussion

Table 3: How our socket compared to our goals

Requirement	Status (Y/N)
Circumferential adjustability +/- 1in	Yes
Withstand peak pressure of 300KPa	Yes
Fit femur length 18cm +/- 5cm	Yes
Fit thigh diameter 12cm +/- 3cm	Yes
Quickly adjustable (<5min)	Yes
Combined weight less than 10lbs	Yes
Tension straps withstand 550N	Yes
Water resistant parts	Yes
Withstand torque of +/-25Nm[3]	Not tested
Withstand 4.5x patient body weight	Not tested
Mimic 90% gait performance	Not tested
Withstand forces for 7500 cycles	Not tested

Operate in temperature range 0-45C	Not tested
Less than $50 socket	Unknown (depends on manufacturer)
Sudden failure rate of <5% within product life	Not tested
Thickness less than 1cm	No
Adds less than 10% volume to leg	No

2.6.1 Socket Adjustability

In our designs, the success of the socket comes from a successful outer shell and inner cushioning system. The two must account for a fit comparable to a customized socket. Thus, it was our goal to create this “fit” with non-customizable pieces and mechanisms. The outer shell’s main goal was to create a snug fit while being structurally supportive. However, it could only be so adjustable without compromising the integrity of the overall piece. To create the strong suspension and snug fit, we needed a inner cushioning system that would fill empty voids. We chose to use air pockets similar to those used in an AirCast boot system because the air effectively creates a “custom-fit” and suspend the foot in place. The boot moves with the foot because of the suspension created by the air bladders. We followed similar concepts to design our inner and outer socket pieces, as the outer was designed for support while the inner was for snug and comfortable fit.

The custom-mold socket works because of how well it is shaped around the residual limb, but is problematic because of the rigidity as the residual limb changes size. Lack of comfort has been attributed to why many amputees in developing countries stop using their prosthetics[58]. This rigidity also affects the longevity of the prosthetic, as changes over time may cause it to become unless. With our designs, we attempted to create both rigidity and adjustability through a non-custom molding fitting process. Our second socket iteration looked to provide maximum adjustability with reduced costs. However, the cup-strut interface made the socket much stiffer than anticipated. It was still able to hold a residual limb mold, but had limited circumferential adjustability. We attempted to resolve that through our latest design by adding air pockets, but further testing will be required to determine the viability of this prototype.

We have to account for different challenges than what is found in a custom socket, especially with air bladders as our inner cushioning system. The air bladders gave the socket significantly more adjustability, filling in the areas that the outer shell could not adjust to. It could successfully create a suspension system found in a custom socket. However, the pressure placed on the residual limb was different as the pressure is applied by air. Traditional sockets have a cushioning system that can suction the leg snug against it. The force created by the air looks to mimic just that. More testing and user testing would need to be done to fully compare the two inner cushioning systems.

2.6.2 Pressure Sensing

We looked to measure the pressure created by the air bladders in our socket design in hopes that it was comparable to that of a custom-molded socket. These measurements were done by Jia et al. in a transtibial socket; using similar methods we looked to compare the two. They recorded peak pressures at the middle patella tendon (292KPa), popliteal depression

[58] Smith DG, Burgess EM. “The use of CAD/CAM technology in prosthetics and orthotics-current clinical models and a view to the future.” J Rehabil Res Dev 2001;38(3):327–334.

(267KPa), lateral tibia (206KPa), and medial tibia (121KPa).[59] We would have expected our force sensors to register similar if, not slightly lower pressures at the bony landmarks of the femur and would have liked to compare these values accordingly. However, when the sensors made contact with the air bladders, no force reading was generated the sensors even though contact was made. We determined that the sensors functioned when there is a reaction force present from the applied pressure. We speculate that the air did not provide enough of a reaction force to get a sufficient measurement. To back this up, we fully inflated and fully deflated the air bladders and observed the measurements. When fully inflated, the air pockets provided some reaction force, but not enough to make significant forces. When we deflated and moved the mold around to apply extra pressure to areas, the sensors read those forces. We believe that our air bladders would be highly effective, but we needed a way to compare the air pressure and the pressure placed on the residual limb mold.

2.6.3 Limitations

The problem we were attempting to solve had multiple parts to create a viable solution. The socket was to circumvent the total fitting process while being adjustable in the vertical and circumferential directions, provide support comparable to a custom-fit socket, long-lasting and ultimately under $60. Each of our designs mainly focused on one or a few of these factors. Our very first design focused on circumferential adjustments while exploring the support required to hold the residual limb. However, it did not account for the full shape of the residual limb and was limited to very few sizes. Our second design was much more robust and attempted to resolve the vertical adjustment and stability problems. However, due to the machined nature and cup

[59] Jia et al. 2004

shape, the socket lost most of its circumferential adjustability. We had also switched from ratchet buckles to reduce costs, which added to the lack of adjustability. Our latest design attempted to solve both issues by having a circumferential adjustment mechanism similar to our first design, but also having extra material as an inner liner so that the socket could be shaped to an amputee's residual limb.

The difficult part of the product design was that every change in one parameter affected other parameters. The low-cost and long-lasting factors criteria limited us to what materials and production processes we could use. We had to manipulate simpler mechanisms that would stay under our budget. Ratchet buckles are good at holding tension and the desired shapes, but also were some of the most expensive pieces of the socket prototypes. Since they were interdependent, it was difficult to isolate one factor to optimize it without sacrificing something else.

As a result of interdependent factors and learning about new prosthetic mechanisms throughout the years, we also had a tendency to make drastic changes to all parts of a socket instead doing a more controlled change. For instance, when we realized paracord would not function properly for our second socket, we eventually changed to the full socket design.

Finally, controlling for varying residual limb sizes was challenging because it is hard to predict residual limb circumference for a given volume. Sanders et al did a comprehensive review on relevant transfemoral amputee studies through 2011 and looked at the relationship between limb circumference and volume and found that although limb circumference was positively correlated with residual limb volume, the variability was too great to accurately predict circumference solely based off of volume data.[60]

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[60] Sanders, Joan E, and Stefania Fatone. "Residual limb volume change: systematic review of measurement and management." *Journal of rehabilitation research and development* vol. 48,8 (2011): 949-86.

2.6.4 Applications to third world settings

With our designs, we looked to address the need for a low-cost prosthetic while streamlining the fitting process. Using the materials, mechanisms, and designs, we created effective proof of concept that this can be done. Our designs require additional optimization. We used materials that are readily available in Southeast Asia, and some are currently used for the custom-fitting process for the outer shell. Air pockets have been explored in the past because it uses available resources and can be adjusted for comfort. However, they are known to lose pressure over time.[61] We created a modular design that uses one-way valves and replaceable cushioning to limit such losses, as air bladders are cost-effective. Our prototypes and products show promise in creating an effective socket that does not require a long fitting process. This would tap a new section of the market, as these would be affordable for working-class amputees. The cost would be much more affordable, and they have the power to adjust their socket to their comfort levels. Replaceable parts will allow them to make their socket last longer, especially to combat the wear and tear of everyday use.

2.6.5 Future applications

Our socket will need some further testing to understand its effectiveness as a custom-fit replacement. We have run initial tests to determine pressure distribution and stress resistance, however we assumed a static equilibrium. Future tests should involve examining pressure distribution within the socket during gait or some kind of repetitive dynamic motion. We would also like to improve on our fatigue testing protocol for the air pockets and the buckles by

[61] J. E. Sanders, 2011

including a cyclic loading component to understand the longevity of our product. This would ultimately lead to patient testing, where amputees would wear our product and do motion capture to understand its performance. We would also want to know the comfort of the socket, both for short periods of time and day-long uses. These mechanisms and designs could be used in the future to create a modular socket that is readily available to more of the amputee population in developing countries.

3. Knee Chapter

3.1 Introduction

When first started this project, our goals were oriented solely on the design and manufacturing of a low-cost knee prosthetic. Since then, our design drivers have expanded to incorporate the design of many components of a prosthetic leg. Despite this expansion, our goals still include the development of a cheap, reliable prosthetic knee device. Our motivation for designing a knee is simple: Though there exist many variations of prosthetic knees, there are few that that are accessible to amputees in developing countries; of these prosthetic knees that are accessible, few reliably or accurately mimic natural human gait[62].

To this end, we have worked this year to further prototype and iterate the Koi knee which we have titled Mark 3 with the long term goal of creating an accessible, *quality* prosthetic device for impoverished amputees in the developing world.

3.1.1 Background

In the developing world there are 40 million amputees. Of these amputees, only 5% have access to a prosthetic device[63]. The source of these amputations vary from country to country, but follow a general theme. Often the cause is traumatic due to unexploded ordinances that are remnants of wars (i.e. landmines) or motor vehicle accidents[64]. The problem is then further compounded by the health care infrastructure present in the developing world. The standard of care in these countries is to opt for immediate amputation — even in cases in which

62 https://legworks.com/pages/impact
63 Matts citation
64 Sarvestani, Amene Sabzi, and Afshin Taheri Azam. “Amputation: A Ten-Year Survey.” Trauma Monthly, vol. 18, no. 3, 2013, pp. 126–129., doi:10.5812/traumamon.11693.

the distal end of the limb could be saved. The standard of care is often to amputate above the knee if it is a lower limb injury[65]. The motivation here is a simple supply and demand curve: there are few orthopedic hospitals that can handle the large number of patients that require surgical intervention. Because the surgery for amputation is faster and less resource intensive than a restoration surgery, the system is pressured towards efficiency[66].

This would be a more palatable solution if the orthotics and prosthetics (O&P) division of the hospital could keep up with the orthopedic amputations. However, the current O&P process is slow and cannot handle the influx of patients, making it the rate limiting step. There are many reasons for this issue, most of which revolve around the limitations in the process of fitting itself and the lack of trained personnel to expedite the process (Chapter 2 Background). However, another major limitation is the lack of affordable prosthetic devices. The hospital infrastructure is often corrupt and thus lets doctors and prosthetists greatly inflate prices of prosthetic devices that are already too costly without the extra markup[67]. This leaves many amputees in a limbo between surgery and prosthetic fitting, either trying to save money, or simply accepting the lower quality of life without any plan to attain a prosthetic device.

3.1.1.2 Culture

The amputees in the developing world are generally diverse in background. While some are wealthy and gain access to the prosthetic devices they need, many do not. This is largely due to financial barriers and lack of prosthetist ubiquity. However, there is also a cultural aspect that both contributes to problem definition and motivates some of the design drivers: cultural

[65] Interview citation
[66] Schirò, Giuseppe Rosario, et al. “Primary Amputation vs Limb Salvage in Mangled Extremity: a Systematic Review of the Current Scoring System.” BMC Musculoskeletal Disorders, vol. 16, no. 1, 2015, doi:10.1186/s12891-015-0832-7.
[67] Mackey, Tim K, and Bryan A Liang. “Combating Healthcare Corruption and Fraud with Improved Global Health Governance.” BMC International Health and Human Rights, vol. 12, no. 1, 2012, doi:10.1186/1472-698x-12-23.

requirements. This is a particularly difficult aspect of design to consider as cultures can vary drastically from country to country, and even from region to region within a country. Thus, we chose to focus a lot of our effort on the design of prosthetic devices for amputees in southeast Asia specifically. This narrowed our scope and allowed for better design decisions. Our primary focus has since moved to Thailand and Vietnam as the primary end user for our first product.

Figure 3.1: JaipurKnee initial cuboid design

The first requirement that cultural focus adds to the problem definition is an aesthetic constraint. In southeast Asia, amputees are often stigmatized and discriminated against[68]. This stigma can prevent the amputees from rejoining society and force a life of stagnation and house confinement upon the amputee. Therefore it is important to develop prosthetic devices that can be easily concealed if necessary and furthermore, are not egregiously dysmorphic when under a pant leg. For example, overly cuboidal prosthetic knees such as the first iteration of the Remotion Knee (San Francisco, CA) called the JaipurKnee (Figure 3.1) have since been remodeled in order to better meet this aesthetic cultural necessity [69]. Aesthetics don't strictly refer to the geometry of the prosthetic device. While it is important to have a semi-natural appearance in a static position, it is likewise important that the gait motion also appears semi-natural as well. Thus, a large focus was placed on the gait kinematics of the prosthetic device in order to better provide an aesthetically optimal knee during this iteration.

The second important cultural consideration is the functional requirements the device must be able to meet. In southeast Asia, two important functions of everyday life that are both

[68] "About Us." Penta, pentaprosthetics.com/about-us.
[69] "ReMotion Knee | D-Rev." D-Rev Design, D-Rev, d-rev.org/projects/mobility/?a=design.

Figure 3.2: Restroom squatting position common in Southeast Asia

documented in literature and that we observed through our own visitation to Vietnam was the importance of squatting[70]. People are expected to bend their knees past the expected range one might expect of a normal seated position which can occur during use of the bathroom (figure 3.2) or during use of motor bikes which are common modes of transportation in developing countries in Southeast Asia. The maximal range of knee flexion one can accomplish is about 150 degrees due to spatial limitation the calf and hamstring muscles put on knee rotation[71]. Since it is common our target end users to place themselves in this position frequently, the control of the prosthetic device in positions of high degrees of flexion must be considered.

3.1.2 Natural Gait and Lower Limb Physiology

Our goal during the development of the prosthetic knee device has always been to come as close to natural human gait as possible while using cost effective technology to do so. Often, amputees have a fully functional, natural lower limb contralateral to the side of amputation. While it is the prosthetists job to match the components of a prosthetic leg to the amputees natural leg, it is our job to match general physiology. Thus, a look at how the natural knee functions was imperative for design, and influenced many of our initial designs as well as major design drivers.

[70] Thambyah, Ashvin. “How Critical Are the Tibiofemoral Joint Reaction Forces during Frequent Squatting in Asian Populations?” The Knee, vol. 15, no. 4, 2008, pp. 286–294., doi:10.1016/j.knee.2008.04.006.
[71] Hemmerich, A., et al. “Hip, Knee, and Ankle Kinematics of High Range of Motion Activities of Daily Living.” Journal of Orthopaedic Research, vol. 24, no. 4, 2006, pp. 770–781., doi:10.1002/jor.20114.

3.1.2.1 Biomimicry

"First, do no harm."

-Hippocratic Oath

Our project has many medical components to it, and thus we feel that we must strive for the hippocratic oath, the goal of all physicians. To this end, we focused on the natural knee — with the goal that creation should come as close to that standard as possible.

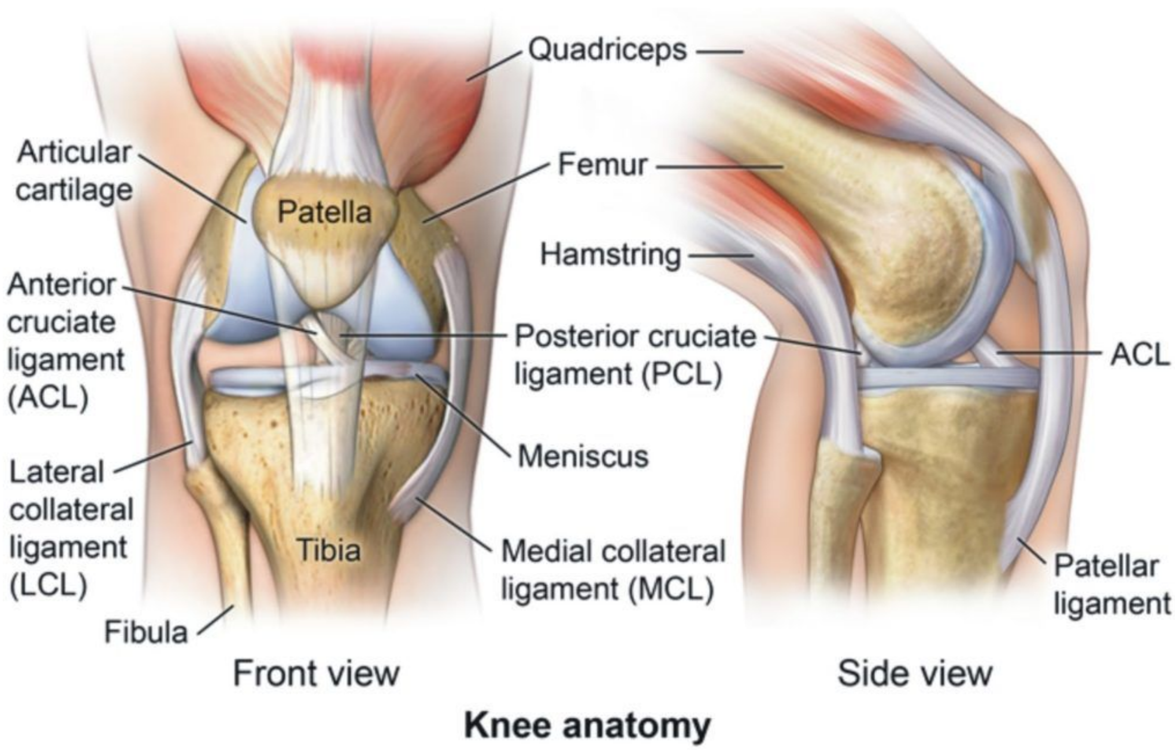

Figure 3.3: Soft tissue within the knee and general knee anatomy[72]

[72] "Ligament Injuries to the Knee." Comprehensive Orthopaedics, 25 Jan. 2017, comportho.com/knee/ligament-injuries-to-the-knee/.

As figure 3.3 shows, the natural knee is quite a complex joint. The knee makes use of a network of soft tissue including ligaments and tendons in order to afford control of the distal end of the limb as well as stability in the coronal, sagittal, and transverse body planes. The anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) cross within the interior of the knee joint capsule within the intercondylar notch and in conjunction with the hamstring tendon, patellar ligament and patellar tendon regulate flexion and extension motion in the sagittal plane. The lateral collateral ligament (LCL) and the medial collateral ligament (MCL) are important in the stabilization of the knee in the coronal plane of rotation, which play a major role in walking on uneven surfaces. Finally, the meniscus is important in the cushioning and lubrication of the knee as it rotates throughout flexion. During our design process, we took particular interest in the roles of the LCL, MCL and meniscus. Based on their role in medial-lateral stabilization when walking over uneven surfaces — something that is a very common occurrence in underdeveloped countries that lack pervasive infrastructure or paved roads.

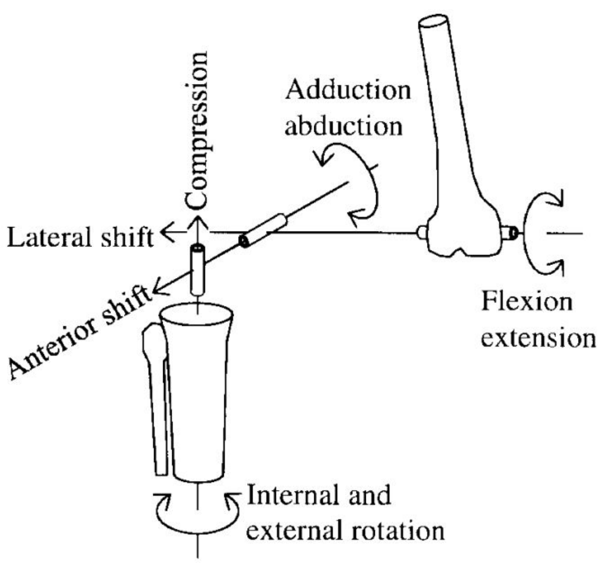

Figure 3.4: Screw-Home moment of the knee joint during flexion

Although described as a hinge joint, the knee is more complex than a simple hinge as there is no single axis or rotation through knee flexion [73]. Rather, the knee rotation can be

[73] Ruiz-Diaz, Fd, et al. "External Knee Prosthesis with Four Bar Linkage Mechanism." 2016 13th International Conference on Electrical Engineering, Computing Science and Automatic Control (CCE), 2016, doi:10.1109/iceee.2016.7751263.

considered a screw-home motion[74]. Figure 3.4 demonstrates this type of motion and is taken from Piazza *et al.*. This motion is based on the natural knee's slight internal rotation in the transverse plane throughout its rotation during flexion in the sagittal plane. This means that in order to fully mimic natural gait, a prosthetic knee must allow for minimal, yet controlled rotation in the sagittal plane[75].

3.1.2.2 Gait

Termial Swing	Mid Swing	Initial Swing	Pre Swing	Terminal Stance	Midstance	Loading Response	Heel Strike	Gait Phase
87-100%	73-87%	60-73%	50-60%	30-50%	10-30%	0-10%	0%	% of Gait
Single Leg	Single Leg	Single Leg	Double Leg	Single Leg	Single Leg	Double Leg	Double Leg	Type of Support

Time

Stance Phase
Swing Phase

Figure 3.5: Gait cycle

Gait analysis is often used by prosthetists in order to evaluate the efficacy of a prosthetic device used in locomotion[76]. This methodology is used to gather data on a subjects specific gait pattern and cadence, power output, and in the case of amputees, degree of natural gait deviance. Figure 3.5 shows the sequence that natural gait follows during standard walking movement. Gait is measured in cycles, which are comprised of the events between the heel

[74] Piazza, Stephen J., and Peter R. Cavanagh. "Measurement of the Screw-Home Motion of the Knee Is Sensitive to Errors in Axis Alignment." Journal of Biomechanics, vol. 33, no. 8, 2000, pp. 1029–1034., doi:10.1016/s0021-9290(00)00056-7.
[75] Bull, A M J, and A A Amis. "Knee Joint Motion: Description and Measurement." Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, vol. 212, no. 5, 1998, pp. 357–372., doi:10.1243/0954411981534132.
[76] Troje, Nikolaus F. "Decomposing Biological Motion: A Framework for Analysis and Synthesis of Human Gait Patterns." Journal of Vision, vol. 2, no. 5, 2002, p. 2., doi:10.1167/2.5.2.

strike of one leg and the subsequent heel strike of the same leg. There are 8 specific landmarks of gait that happen within one gait cycle, the first 5 landmarks comprise the stance phase of gait and are sequentially: Heel Strike, Loading Response, Midstance, Terminal Stance, Preswing. The stance phase of gait takes about 60% of the entire gait cycle, and each landmark of gait occurs at discrete intervals of the total percentage. The stance phase is followed by the swing phase of gait, in which the reference leg lifts off the ground at a point named *toe off*. The 3 landmarks that comprise the swing phase are Initial Swing, Mid Swing, and Terminal Swing[77].

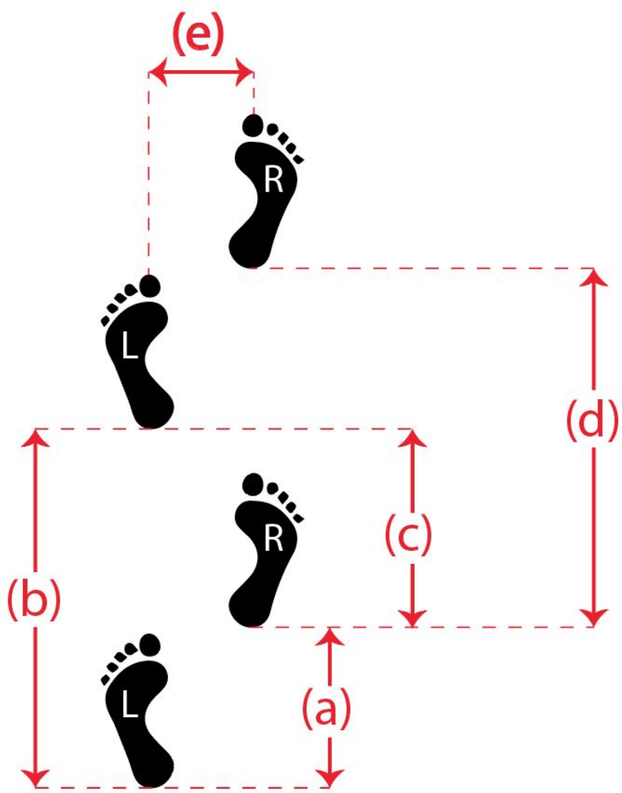

Figure 3.6: a) Right step length b) Left stride length c) Left step length d) Right stride length e) stride width

Figure 3.5 shows gait analysis in the sagittal view. It is important to analyze gait from all 3 body planes, and thus a second way to visualize gait deviance is through analysis of the transverse plane. Figure 3.6 shows a complete gait cycle for both legs from the transverse plane perspective. Analysis from this perspective can show internal or external foot rotation, straddle distance from midline, and step length. In standard gait, one would expect that all values measured in this perspective would be equal bilaterally. However, it is common for these values to be unequal if the subject has sustained a lower limb injury, or wears an ill-fitting prosthetic device.

[77] "Phases of the Gait Cycle: Gait Analysis » ProtoKinetics." ProtoKinetics, 23 Jan. 2019, www.protokinetics.com/2018/11/28/understanding-phases-of-the-gait-cycle/.

Since the focus of our project is the knee, it is important to characterize gait based on knee-specific landmarks as well. Another factor gait analysts use is joint angles, which describes the relative flexion of a joint by measuring the angle created by the distal and proximal long bones that the joint of interest connects. In this case, the important long bones would be the femur and the tibia. Figure 3.7a shows the flexion as a function of the gait cycle.

A second important measure is the torque that the knee experiences throughout gait (Figure 3.7b). Throughout natural gait, human exert moment forces on distal end of the lower limb to either positively or negatively accelerate it to prepare for the next stage of gait. This is especially important in the swing phase of gait and the loading response.

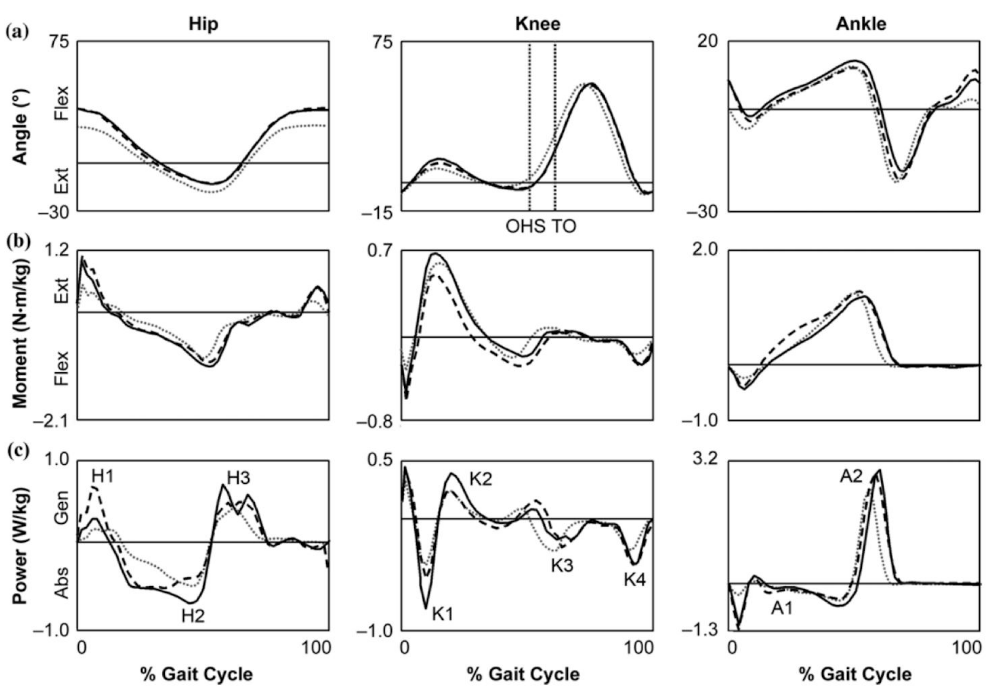

Figure 3.7: Angles, moment, and power of the hip, knee, and ankle joints throughout the duration of one gait cycle[78]

[78] Segal, Ava D., et al. "Kinematic and Kinetic Comparisons of Transfemoral Amputee Gait Using C-Leg and Mauch SNS Prosthetic Knees." The Journal of Rehabilitation Research and Development, vol. 43, no. 7, 2006, p. 857., doi:10.1682/jrrd.2005.09.0147.

Without large negative torques placed on the knee during these portions of gait, humans would either topple over during the loading response, or continuously snap their leg into full extension during swing. Both of these outcomes would be unhealthy with respect to the connective tissue within the joints of the leg as well as visually unnatural.

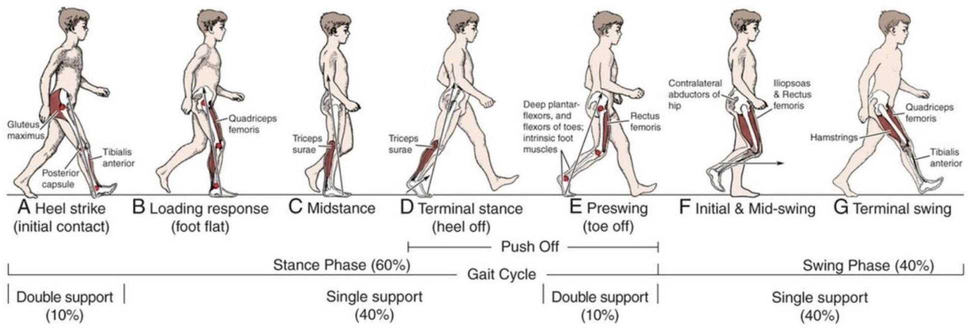

Figure 3.8: a) Visual representation of the muscle activation pattern of a single leg throughout one cycle of gait.[79]

Throughout locomotion, humans have a specific activation pattern of muscles in order to create the desired movement. Figures 3.8 & 3.9 show visually and graphically the pattern of muscle activation of able bodied individuals during gait. The important muscles during this pattern of muscle activation in anatomically descending order are the iliopsoas, gluteus maximus, gluteus medius, semitendinosus, vastus lateralis, vastus medialis, Bicep femoris, rectus femoris, gastrocnemius lateralis, gastrocnemius medialis, tibialis anterior, and soleus[80].

When an able bodied individual walks, all of the muscle groups from the hip down contribute at different points of the gait cycle. When an amputee walks, they only have the muscle in between the hip and above the point of amputation. In a transfemoral amputee, which is our target population, there is limited force generation on the quadricep and the hamstring muscles because the connection point to the knee no longer exists and thus, there is

[79] "Gait in Prosthetic Rehabilitation." Physiopedia, www.physio-pedia.com/Gait_in_prosthetic_rehabilitation.
[80] Arnold, E. M., et al.

no distal position to exert a force on.

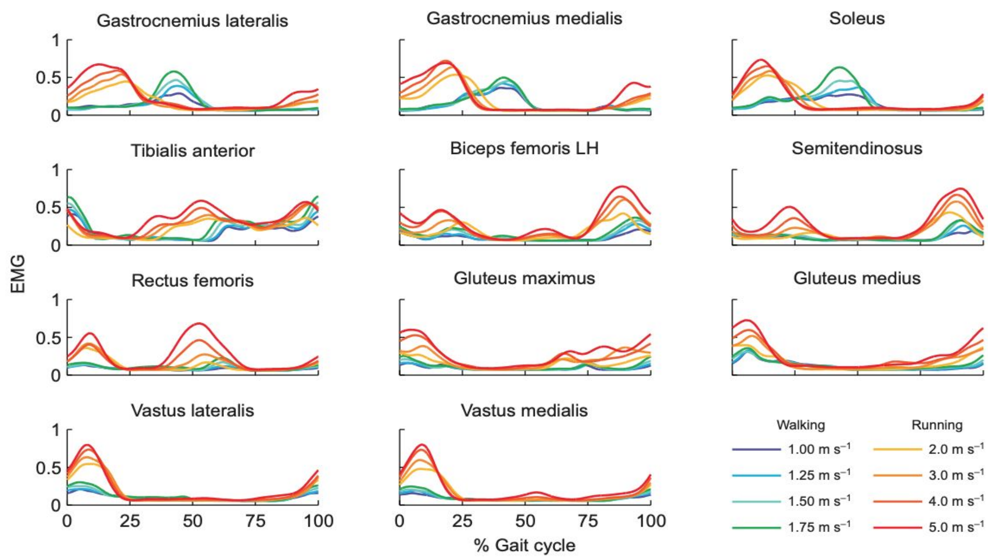

Figure 3.9: EMG data of the various lower limb muscles throughout one gait cycle. one complete gait cycle[81].

Thus, only the hip flexors, gluteus maximus and gluteus medius will exert a force similar to natural gait[82]. This poses a significant challenge since the torque and power generation needed to mimic natural gait is heavily dependent on the synchronised activation patterns of the rest of the missing muscles.

3.1.3 Prosthetic Knee

3.1.3.1 Axis of rotation

A prosthetic knee is simply various approximations of knee joint kinematics. One such kinematic parameter is the center of rotation since the knee acts as a pivot between two rigid

[81] Arnold, E. M., et al. “How Muscle Fiber Lengths and Velocities Affect Muscle Force Generation as Humans Walk and Run at Different Speeds.” Journal of Experimental Biology, vol. 216, no. 11, 2013, pp. 2150–2160., doi:10.1242/jeb.075697.
[82] Raya, Michele A., et al. “Impairment Variables Predicting Activity Limitation in Individuals with Lower Limb Amputation.” Prosthetics and Orthotics International, vol. 34, no. 1, 2010, pp. 73–84., doi:10.3109/03093640903585008.

bodies: the shank/foot and the residual limb. As mentioned above, the knee's movement is actually more complex than a simple hinge. However, many affordable prosthetic devices use a simple hinge as the mechanism by which the prosthetic knee rotates[83]. Although a reasonable approximation, this misses an important action of the natural knee which is leg shortening[84]. The natural knee uses a screw-home movement, which means that during extension the knee joint rotates and translates simultaneously. Thus, the length of distance between distal and proximal part of the leg is less than would be expected if the knee were replaced with a simple hinge. If a prosthetic knee is made using a single hinge, the prosthetic leg would be prone to dragging on the ground during the swing phase of gait.

A better mechanical approximation of the knee is to use a polycentric knee which is defined as a knee that has more than one center of rotation[85]. This type of knee is the more common and almost exclusively used in expensive and computerized knee as it has been found to better mimic natural gait. There are many ways to create a mechanical joint that mimics natural knee kinematics, yet the most common form is a linkage mechanism comprised of multiple discrete linkages used to transmit power in discrete geometries.

Linkage mechanisms are defined as any two or more rigid bodies that are connected by a lower pair that allows rotation[86]. These mechanisms are useful in transferring power between individual rigid bodies as well as for generating torque throughout a strictly defined rotational geometry. Linkage mechanisms have a wide variety of applications and are often desirable for their simplicity, light weight, and low prices[87]. Virtually any desired motion or geometry can be

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[83] "Prosthetic Knee Systems." Amputee Coalition, www.amputee-coalition.org/resources/prosthetic-knee-systems/.
[84] Arnold, E. M., et al.
[85] Radcliffe, C W. "THE KNUD JANSEN LECTURE Above-Knee Prosthetics ." Prosthetics and Orthotics International, 1977, doi:10.3109.
[86] Hunt, K. H., Kinematic Geometry of Mechanisms, Oxford University Press, New York, 1978.
[87] Freudenstein, Ferdinand. "Approximate Synthesis of Four-Bar Linkages." Resonance, vol. 15, no. 8, 2010, pp. 740–767., doi:10.1007/s12045-010-0084-7.

attained with the addition of more linkages to the linkage mechanism, with more additions yielding less error with respect to the ‘optimal’ or desired geometry. However, the addition of unnecessary linkages can only create more complexity due to the increasing degrees of freedom the system would have. Therefore linkage mechanisms present an interesting optimizing problem between complexity and reasonable error.

3.1.3.2 4-Bar Mechanism

While linkage systems can come in various orientations, one orientation of interest is the cyclic orientation in which the bars connect to form closed geometries. The simplest of these linkage mechanisms is the 4-bar linkage mechanism. A 4-bar linkage system is comprised of 4 linkages connected in a quadrilateral arrangement by rotational joints. The synthesis of even a 4 bar linkage mechanism is quite complicated and can require significant equation manipulation.

Figure 3.10: various 4-Bar linkage prosthetic knees: (from left to right) Remotion Knee, Medi OH5/KH5, Ottobock Titan Knee, Koi Knee.

It is common to see 4 bar mechanisms in prosthetic knees. Figure 3.10 shows four different prosthetic knee devices that employ 4 bar linkage mechanisms. These are chosen as the rotational mechanism for prosthetic knees due to the high stability in the medial-lateral anatomical direction that prevent rotation of the distal end relative to the proximal end.

Interestingly, there is a hint of biomimicry that is at play. The natural knee is often approximated as a 4-bar mechanism . In this natural 4-bar (Figure 3.11), the linkages are crossed instead of open as it has been in the previous figures. The anterior and posterior linkages are the ACL and PCL while the top and bottom linkages are the done between anchoring points of the ligaments on the femur and the tibia, respectively. This natural 4-bar system provides some support for the use of it in the design of prosthetic devices although it is important to note that it is limited to 2D flexion-extension motion.

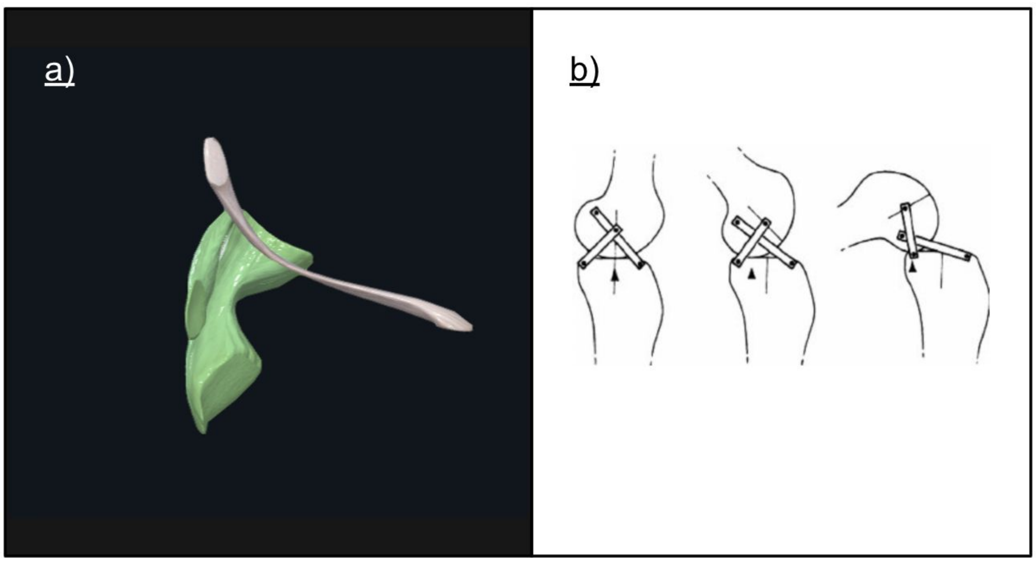

Figure 3.11: a) PCL (green) and ACL (white) in anatomical rendering demonstrating a 4-bar linkage mechanism b) drawing of the 4 bar linkage system in the natural knee

3.2 Competitor Analysis

3.2.1 Remotion Knee

The Remotion Knee is the third iteration of one of the first commercially available low cost prosthetic knees to enter the knee prosthetic space (the Jaipur knee). It was specifically designed for amputees in resource limited settings, and was meant to provide a more streamlined prosthetic solution at the similar low cost point. The remotion knee consists of a basic four bar mechanism with two acetal housing units connected by stainless steel linkages. It is lightweight (400g), water resistant and costs approximately $80 USD. While it is one of the first low cost prosthetic knees and has been fitted on over 600 patients in 32 countries, there are many improvements that can be made on it. Most importantly, the knee does not have an active component, which is an integral part of creating a biomimetic knee. An active mechanism mimics the function of various muscles to help kick out the leg during the initial phases of gait. It is also the force that dampens the extension right before lockout to prevent hyperextension and excessive tension. Without this active component, amputees are forced to compensate with an extra swing in their hip (circumduction) or compensation with the contralateral limb which leads to early fatigue of these muscles and increased risk of falling. These gait abnormalities, over time can compound into various health issues such as injury to overworked limbs and increased risk of falling.

3.2.2 LIMBS International Knee

Limbs International is a non profit organization based in Texas that also sought to design and distribute a cost effective prosthetic knee for developing countries. Its design is similar to Remotion in that it it uses a four bar mechanism but it brands itself as being different from other knees in that it "enables a more normal gait pattern and easier swing without significant loss of stability".[88] They started their efforts in 2006 and since then have fitted 200 patients in 8 partnered clinics around the world. The price point set for the Limb knee is $60, slightly below the Remotion knee. The Limb prosthetic knee suffers some of the same drawbacks as Remotion as it does not have an active component.

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[88]"Technology Development." LIMBS International,www.limbsinternational.org/technology-development1.html.

3.3 Methods & Results

3.3.1 Computer Aided Design

3.3.1.2 Onshape

In order to coordinate with many of the designs, we used the cloud functionality of the computer aided design program Onshape. Both branches and component configurations were used to create new workspaces of the various parts used for the prosthetic knee. Branches were used to vary large design changes while configurations were used to vary dimensions of the changes.

3.3.2 Able Bodied Human Testing Rig

In order to test any of our prosthetic creations on able bodied humans, we have designed a mechanical rig that would allow someone with both legs to artificially mimic the experience of a prosthetic device wearer. This type of testing has been done in prior device design[89]. The rig (Figure 3.12) was designed using 1.25in thick plywood as the base on which the distal end of the lower limb is rested. The plywood was covered with Baseball helmet lining in order to provide comfort to the wearer. Velcro straps were attached to both medial and lateral sides of the base such that the limb could be secured to the base. To secure the rig to wearer's proximal lower limb (thigh), a previous iteration of our adjustable socket (Chapter 2 Design Ideation Outer Socket) was repurposed and attached to the base of the rig. This socket used a ratchet strap mechanism in order to circumferentially adjust to the proximal lower limb of the wearer and allow for hip moments to propagate through the artificial leg. The cup portion of the

[89] Ghosh, Shramana, et al. "Geometric Design of a Passive Mechanical Knee for Lower Extremity Wearable Devices Based on Anthropomorphic Foot Task Geometry Scaling." Volume 5B: 39th Mechanisms and Robotics Conference, 2015, doi:10.1115/detc2015-46499.

socket was cut at the base to allow for the distal limb of the leb to rest stabily on the base of the rig. Additional helmet cushion was added as needed at the point of contact between the wearer's knee and the cup. Directly underneath the cup of the rig, 4 holes were drilled in the base of the board to secure a knee attachment component which is often found under the base of the socket itself.

Separately, a knee, a foot, and a shank combination were prepared. The foot and shank used were always a standard aluminum pylon from Bulldog and a foot manufactured by the Jaipur team in India. The pylon was inserted into correct portion of the prosthetic knee (distal end) that was desired for testing. The knee was then inserted into the connection piece using the 4-point pyramidal adjustment mechanism and the appropriate allen wrench to tighten the connection on all 4 sides. Foot orientation was matched to the opposing foot as best as possible using visual comparison.

Figure 3.12: Able Bodied Human Testing Rig

The position of the knee located under the base was a design choice to combat some limitations exhibited in previous iterations of our rig. Prior to the changes made, the prosthetic knee attachment point was adjacent to the natural knee shown in Figure 3.12. At this attachment point, the knee would show natural kinematics with respect to height as it matched the natural knee in a way an amputee would experience. However, due to the lateral displacement of this position, the prosthetic knee was subject to significant shearing forces and based on our testing showed compensation and unnatural movement. Thus, we decided to move the attachment point to underneath the leg to prevent these unnatural movements at the expense of correct height kinematics. We believe that if the kinematics are to work for the incorrect height, this would be translatable to correct height and more representative of correct gait.

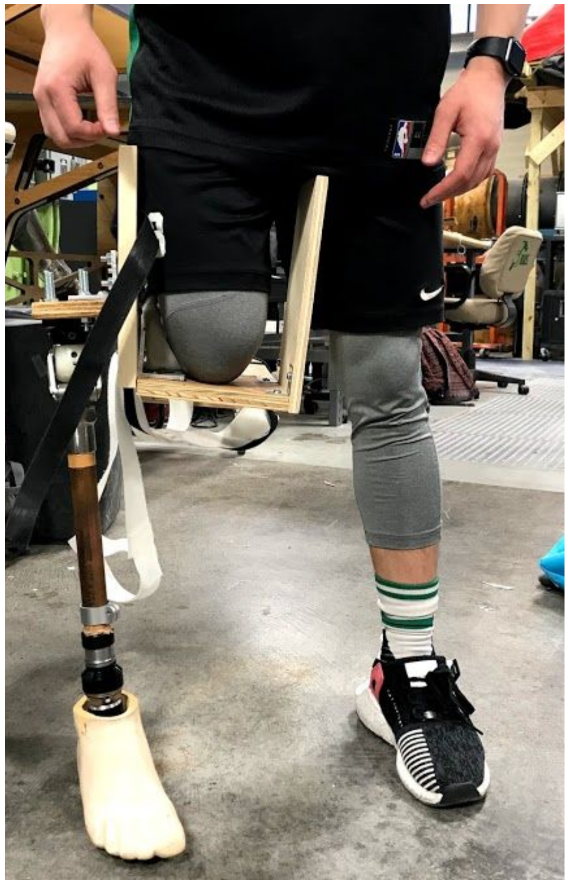

Figure 3.13: Able Bodied Human Testing Rig — Initial Design

3.3.3 Manufacturing

3.3.3.1 Manual Mill Prototyping

A Series 1 Bridgeport manual mill (Hardinge Inc., Berwyn, PA) was used to prototype linkage models. Part drawings from Onshape were used to guide the milling process. A 0.25in drillbit was used to create the holes in the linkages at points made in accordance with the CAD models and part drawings. Drawings can be found in the Appendix B. The Metal used during all machining processes was Aluminum 6061 which was selected for its versatility and ease of machining.

3.3.3.2 Machine Belt Sanding

A Wilton 52421-0 machine belt sander (Wilton Tools, La Vergne, TN) was used to complete the rounded edges of the linkage model. This methodology was selected for prototyping purposes because the design of the linkages would be a complex geometry to machine, and not easily accomplished without specialized equipment that the workshop itself lacked. After pieces had been cut with a bandsaw and holes were drilled, the linkages were held to the sander for approximately 30 second intervals and cooled in tap water in between sanding intervals in order to prevent overheating. The radius of curvature of the rounded edges was compared to the mechanical drawing until satisfactory results were achieved. Figure 3.14 shows the machined linkage juxtaposed with the CAD counterparts.

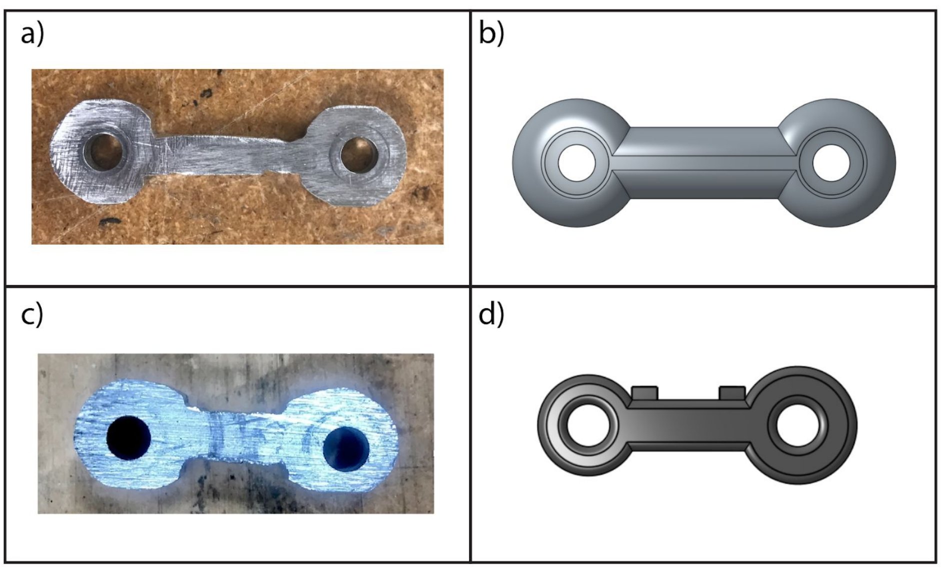

Figure 3.14: a) machined anterior linkage b) CAD model of the anterior linkage c) machined posterior linkage d) CAD model of posterior linkage

3.3.3.3 3D Printing Prototyping

An M2 Makerbot PLA extrusion based 3D printer (Makerbot Industries, Brooklyn, NY) was used to iterate on prosthetic knee design and both qualitatively and quantitatively test the movement of the knee. The Makerbots were set to extrude at 215° C with a 20% triangular infill pattern. Parts were printed on a non-heated bed, thus glue was applied to the bed to prevent warping and ensure raft adherence.

3.3.4 Kinematic calculations

3.3.4.1 ICR

Figure 3.15: ICR of a 4-Bar Knee (Ottobock Titan)

The instant center of rotation (ICR) is the point on or about a rigid body that is undergoing rotational and/or translational movement that exhibits zero velocity[90]. While a simple hinge knee prosthetic has a single point of rotation throughout its entire gait cycle, the 4-bar linkage knee will have a varying instant center of rotation throughout the gait cycle.

For 4-bar mechanisms the instant center of rotation is calculated using the anterior and posterior linkages, as guide traces. As shown in figure 3.15, the centers of the holes drilled in the linkages are connected and extended upwards away from the floor. The point at which the lines drawn from either linkage intersect is the instant center of rotation.

In order to iterate and evaluate different geometries, we made use of CAD configurations to change hole orientation on the two components of the Knee or length of the linkages themselves. Many of our models were made in Onshape, which was convenient to take advantage of because the CAD rendering was easy to change to different configurations, and has the origin point marked on the top component of the design. Thus, the ICR was made to be a point with respect to that origin using the perpendicularly incident view on the sagittal plane of the prosthetic knee.

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[90] Anderst, William, et al. "Motion Path of the Instant Center of Rotation in the Cervical Spine During In Vivo Dynamic Flexion-Extension." Spine, vol. 38, no. 10, 2013, doi:10.1097/brs.0b013e31828ca5c7.

3.3.4.2 Torque & Moment

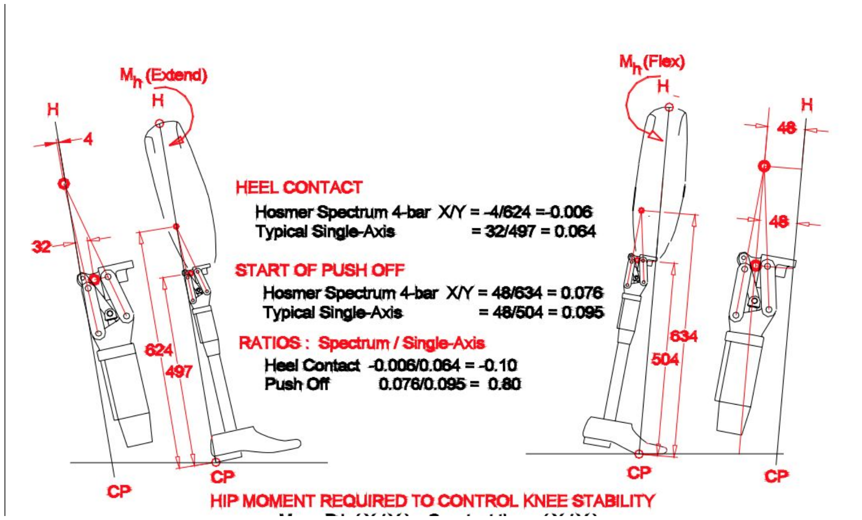


Figure 3.16: calculations of geometric values and hip moment for a 4-Bar Knee

Hip moment was calculated based on the position of the ICR relative to the center of pressure. The following equation was used to calculate the necessary hip moment that amputees place on their prosthetic limb during heel contact and during toe off[91].

$$M = PL\left(\frac{x}{y}\right) \qquad Equation\ 1.$$

Based on this equation, the Moment is dependent on the Force propagating down the center of the limb P, the length of the load line measured from hip joint to the center of pressure L, the horizontal perpendicular distance to the load line x, and the vertical parallel distance to the distal end of the load line on the y. The distal end of the load line, the center of pressure CP, was either the heel or the ball of the foot based on the point in the gait cycle analyzed.

[91] Radcliffe, C W. "Biomechanics of Knee Stability Control with Four-Bar Prosthetic Knees."

3.3.4.3 Voluntary Zone of Stability

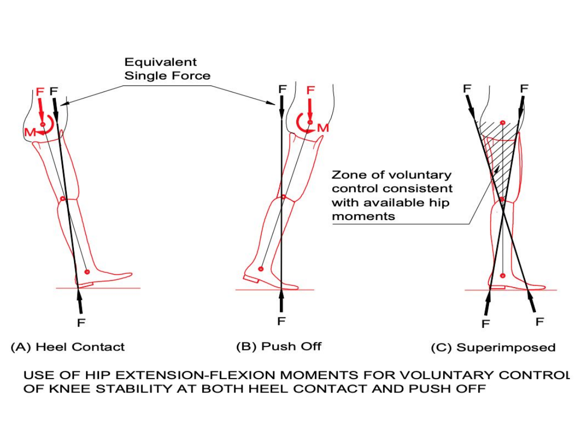


Figure 3.17: a) Force propagation from heel strike b) Force propagation from toe off c) superimposed force lines on static leg with no knee flexion[92]

The voluntary zone of stability was calculated using similar landmarks as the moment calculations. Using video taken of the subject walking through multiple gait cycles, still frames were selected at both toe off and heel strike. At either position, the center of pressure was drawn from point of contact with the floor and traced through the knee up to an equivalent height as the hip, as shown in figure 3.17 a and b. These lines were then superimposed onto an image of the limb in an upright standing position with no knee flexion Figure 3.13 c. The shaded zone in this figure shows the zone of voluntary stability. If the Knee's ICR was located within this zone, the amputee can exert a hip moment to straighten then leg.

3.3.5 Anthropometric calculations

All dimensions not explicitly calculated were found in anthropometric tables and did not need to be manipulated. [93,94]

[92] Radcliffe, C W. "Biomechanics of Knee Stability Control with Four-Bar Prosthetic Knees."
[93] United States Military. Weight, Height, and Selected Body Dimensions of Adults, United States, 1960-1962; Age and Sex Distributions for Weight, Height, Erect Sitting Height, Normal Sitting Height, Knee Height, Popliteal Height, Elbow Rest Height, Thigh Clearance Height, Buttock-Knee Length, Buttock-Popliteal Length, Elbow-to-Elbow Breadth, and Seat Breadth. 1965.

3.3.5.1 Average Leg Length

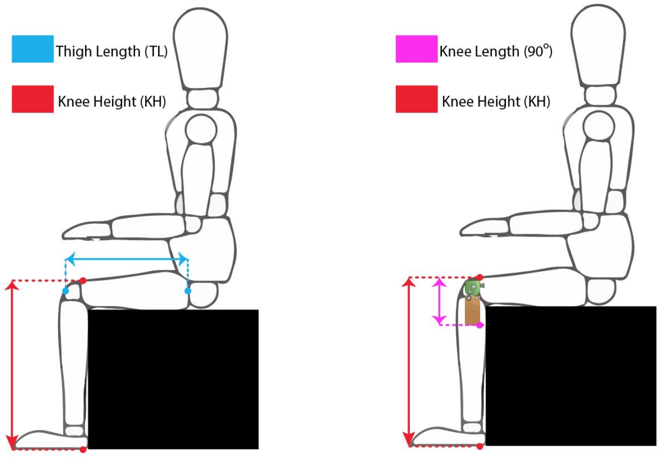


Figure 3.18: a) Knee Height (KH) and Thigh Length (TL) measurement criteria b) KH with prosthetic knee superimposed with difference representing foot/shank

In order to complete simulated gait analysis, the average lengths of the long bones in the legs were calculated. Known values of knee height (KH) and thigh length (TL) were used to calculate the average lengths of sockets, and foot+shank combinations based on standards set forth by for landmark placement. Using the KH and TL values (figure 3.18A) we then superimposed a model of our prosthetic knee onto the seated figure (Figure 3.18B). Since both the natural leg dimensions, and prosthetic leg dimensions were known, anthropometric data of residual limb length and pylon/shank length could be calculated through simple ratios and subtraction

$$avg\ KH\ =\ 21.6\ in\,;\ avg\ TL\ =\ 15.8\ in\,;\ KL_{90}\ =\ 6.07\ in$$

Thus, the average length of the prosthetic shank/foot combinations was calculated to be 15.53in and the average above knee prosthetic socket length was calculated to be 15.8in. A

[94] Anthropometric Reference Data for Children and Adults: United States, 2007-2010. U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, 2012.

correction ratio of the average vietnamese male height to the average US male height was determined to be 0.937. The above values when multiplied by this correction ratio to give the average length of a shank/foot to be 14.55in and the average socket length to be 14.8in. These measurements were then used in moment and stability calculations

3.3.5.2 Average Foot Length

There was no known source of average foot lengths. However, average foot:height ratios have been shown to be 0.15[95]. The average height of a vietnamese citizen is found to be 65.748in. Using that ratio, the average vietnamese foot length was determined to be 9.862in.

3.3.6 Gait Analysis

3.3.6.1 Filming

An iPhone 7s Plus was used to record all video footage. This camera has 12MP resolution and dual cameras to better perceive depth. The iphone was placed on a stool with level spacers placed as needed such that the camera was at the hip height of the individual being tested. In order to standardize, a yard stick was placed in frame such that the known distance could be used to calculate other measurements with respect to pixel values.

3.3.6.2 Still Image Measurement

ImageJ was used to measure distances or lengths taken from filmed video or still images. ImageJ is based on pixel counts, and thus requires the known length or distance of some objects in the images in order to create a pixel:inch coefficient. The known distance or length is measured using ImageJ line segments 3 times. Each of the 3 line measurements is

[95] "Height-to-Foot-Size Ratio." LIVESTRONG.COM, Leaf Group, www.livestrong.com/article/491821-height-to-foot-size-ratio/.

recorded using the ImageJ measure function and averaged to determine the pixel count to inches coefficient. This ratio is dependent on the computer used to analyze the images.

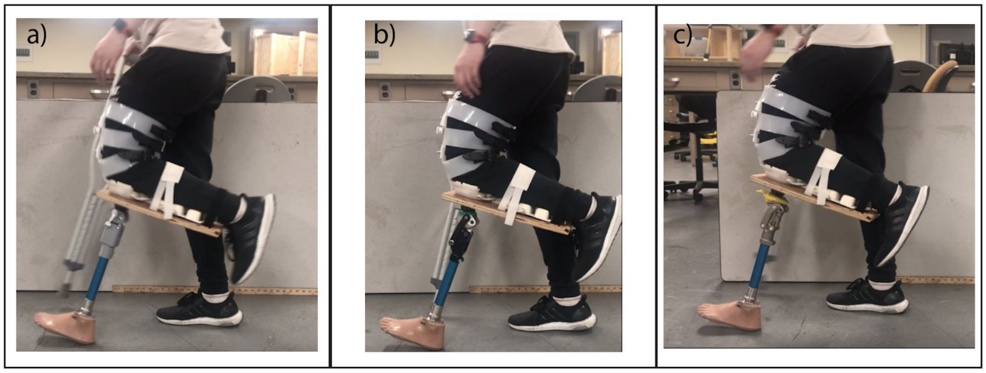


Figure 3.19: Still images of Heel Strike taken from gait analysis testing of 3 different knees with yard stick in frame as reference for sizing. a) Koi Mark 3 b) Ossur Balance Knee c) Medi OH5/KH5 knee

3.3.6.3 Adobe Illustrator Analysis

ICR, Zone of Voluntary Stability analysis, and X/Y ratio analysis were all accomplished in Adobe Illustrator. Images or drawings used during this analysis were all converted into vectors using Image Trace and grouped accordingly. Corresponding lines of importance such as the CP line (Figure 3.16) or medial line were drawn in Illustrator. The images for X/Y ratio and moment analysis were all made on a 1:3 scale in adobe Illustrator and all distances calculated from the illustrator measuring system were multiplied by 3 to yield the correct dimensions.

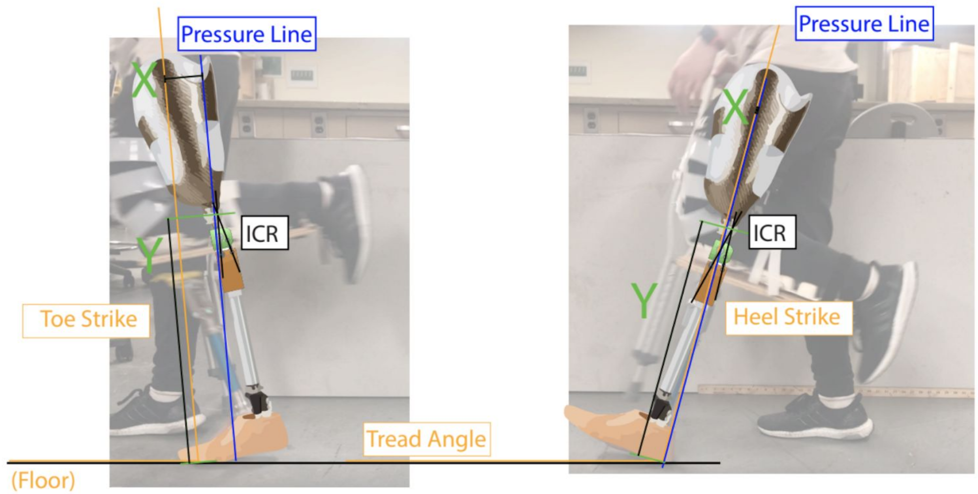


Figure 3.20 : Illustrator set up for Torque Calculations as well as voluntary zone of stability calculations

3.3.7 Onshape movement simulations

In order to qualitatively evaluate 4-bar linkage geometry, CAD assembly animations were used to visually inspect the potential success of a discrete set of 4 linkage lengths and 4 hole positions. Part Configurations were used as the main means of varying assembly geometry.

Each part was redesigned to make a more simplistic model that would cut out any confounding variables and make visualization focused solely on the 4-bar geometry. Sketches were made such that relevant dimensions were all in one sketch and extruded cuts were performed based on these dimensions. The important dimensions for the linkages was the distance between the holes on either end. The important dimensions for the distal piece were the holes distance from the back of the knee, the top part of the piece itself, and from each other. Similar logic was used for the proximal piece in that the relevant hold distances were from the back of the knee, the bottom of the piece itself and from each other. These can be seen in Appendix C1 and C2.

All parts were brought into an assembly on Onshape and then made to animate around a revolute mate. The animations were set such that the linkages were capable of revolving around the holes present on the proximal and distal pieces of the prosthetic knee. Proximal part of the prosthetic leg was set to be fixed at the origin of the CAD space such that the only moving pieces were the linkages, and the distal piece of the Knee. This is a common type of analysis called foot/shank rotation analysis[96].

The animations were set to step between 100-300 times between the angles of 0^{o} and 90^{o} of knee flexion. Continuous playback was toggled on or off depending on the desired motion: sequential gait cycles or one half cycle.

Part configuration data can be found in Appendix C1-4. The process used for optimization for this dissertation was a simple change one variable at a time and then visualize. All of the iterations were put through the animation sequence described above and evaluated qualitatively based on smoothness of rotation. We then selected 5 that were the most promising and calculated the Torque of those 5 iterations. The table in Appendix D shows the tables of different iterations. The 5 highlighted columns are the combinations chosen for calculation. Table 3.1 show the moment calculations of the selected assembly configurations. Part combinations are based on the configuration tables found in Appendix C.

Table 3.1: 5 Chosen Configurations and Moment Calculation Results

Assembly Build					Moment Calculation -- Toe Off				Moment Calculation -- Heel Strike			
version	Posterior Linkage	Anterior Linkage	Top Piece	Bottom Piece	x (in)	y (in)	x/y	M = x/y * P * L	x	y	x/y	M = x/y * P * L
1	2	2	1	10	1.131	6.619	0.1708717329	0.492246972	0.245	6.504	0.03766912669	0.1085171505
2	6	4	1	8	1.153	6.748	0.1708654416	0.4420271888	0.307	6.654	0.04613766156	0.1193576691
3	6	4	1	15	1.147	6.689	0.1714755569	0.4435421787	0.276	6.566	0.04203472434	0.1087278767
4	8	6	11	1	1.217	7.202	0.1689808387	0.4275344015	0.483	7.114	0.06789429294	0.1717777361
5	9	7	12	1	1.095	6.292	0.1740305149	0.4293766696	0.138	6.2	0.02225806452	0.05491619454

[96] Radcliffe, C W. “Biomechanics of Knee Stability Control with Four-Bar Prosthetic Knees.”

3.4 Discussion

Our first priority with the design of the prosthetic knee was to generate physical models and iterate based on these models. Mark 2 — our design from last year's capstone course — was solely a CAD model and thus had very little verification. Thus, we began by bringing the model into the physical world through 3D printing. The first challenge we faced was the methodology to generate tight rotational joints about which the linkages in the 4-bar linkage mechanism could rotate.

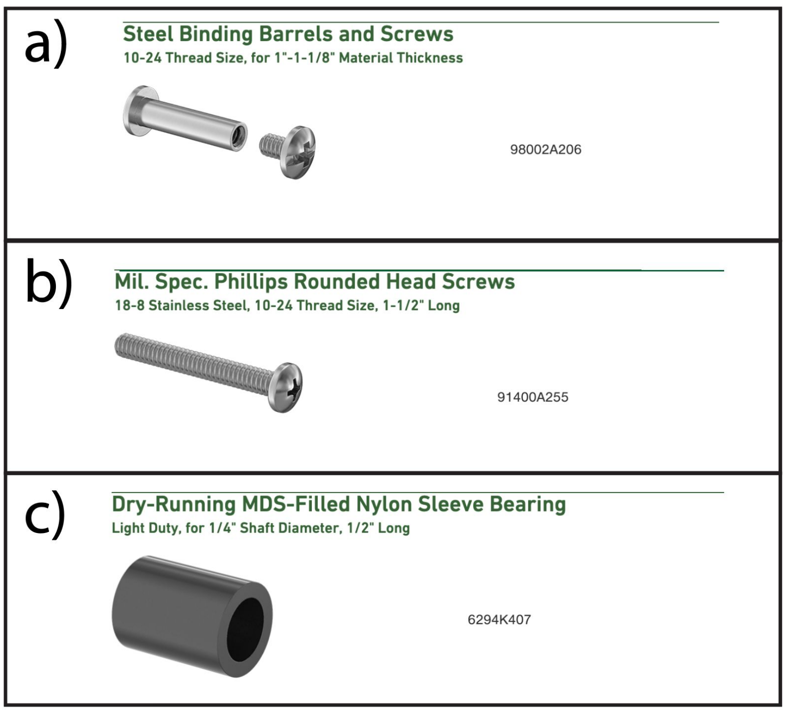


Figure 3.21: a) 10-24 thread binding barrels were used as the rotation pins that secured the linkages to the body of the Knee b) 10-24 thread screws used to mate the female component of the binding barrel c) Nylon bushing to reduce friction during rotation

Prior to this design, we had used simple threaded rods with nuts on either side of the linkage to clamp the bars into place. However, we wanted a tighter junction and a more sustainable solution with better stress mechanics and a smooth surface to rotate over. We chose to go with a steel 10-24 thread binding barrel (Figure 3.21A) from McMaster Carr (part number 98002A206) to serve as the rotational joint. Binding barrels were chosen for the large heads on either side that allow for easy insertion and removal of the rod, as well as their smooth steel surface which provided a better interface to rotate over. Next, in order to get more lubricated motion during the swing phase of gait, we selected MDS filled nylon bushings (Figure 3.21C) from McMaster Carr (part number 629K407) to act as extra lubrication between the plastic body of the knee and the steel binding barrels. Because the binding barrels are sold with their female and male components, some of the male mating ends were too short to fully connect areas of the knee that require rods of lengths greater than 2 inches. We ordered 18-8 stainless steel threaded screws of 1 inch in length (Figure 3.21B) from McMaster Carr (part number 91400A255) to compensate.

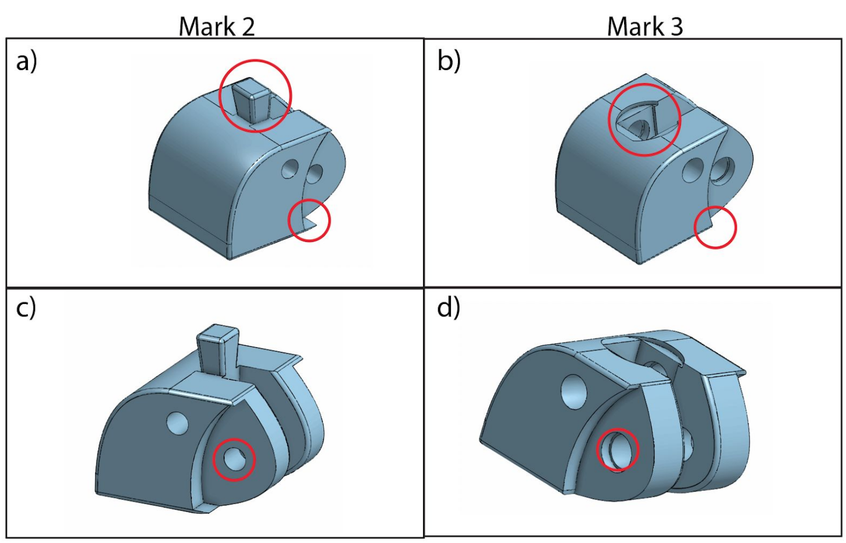


Figure 3.22: a,c) Proximal Piece of Mark 2 prototype prior to changes. Red circles indicate position of change. b,d) Proximal Piece of Mark 3 after changes. Red circles indicate position of change

After settling on the linkages, we began to iterate on the Proximal Piece of the prosthetic knee. The major functional aspects of this piece that were changed were the linkage-rod interface and the knee-socket interface (pyramidal connector). There were also aesthetic changes made in order to keep in line with our goal to make the least anatomically dysmorphic device. As mentioned above, the linkage interface in Mark 2 was flat and relied on a threaded rod with nuts to clamp the linkages in place. For this iteration, we recessed the holes and expanded them such that the nylon bushings could sit inside of the PLA body, and the binding barrel heads could fit flat with the rest of the body (Figure 3.20 c,d).

Figure 3.23: Metal Pyramidal Connector insert for the proximal piece

The Pyramidal Connector was changed from the Mark 2 plastic version to a metal version in Mark 3 (Figure 3.22 a,b top circles). This connector is a crucial piece for any prosthetic knee because it is what connects the prosthetic socket to the prosthetic knee and the rest of the limb. The metal piece was taken from the Remotion Knee by D-Rev for prototyping purposes, but is a standard connector common to most knee prosthetic devices and will be outsourced in future iterations. We decided to switch to metal instead of molded plastic due to its durability and ease of repair. If the connecting piece were kept as a plastic and happend to break due to the stresses placed on it during normal gait, the entire knee would cease to be functional and could not be repaired by a prosthetist. Plastic is not as durable as metal, so this is a true risk that staying with plastic would pose. Thus, even though the metal would be slightly more expensive than the plastic pieces, it would save cost in the long run.

Finally, some of the overhung features that were left over from prior CAD designing (Figure 3.22 a, bottom circle) were cleaned up and removed to allow better rotation of the linkages as well as a more sleek physical appearance (Figure 3.22 b, bottom circle)

Next, we worked on iterating the more distal component of the prosthetic knee, which we call the Distal Piece. In Mark 2, we had a similar linkage interface for both the Distal and Proximal Pieces and thus iterated on these in a similar fashion. The recessed pieces for the binding barrel heads and the expansion to fit nylon bushings was done throughout the PLA body of the knee (Figure 3.24 c,d).

The two major changes to the bottom component were the iteration of the the closing mechanism for the Pylon and the additional gap on the top of the proximal face of the Distal Piece. The closing mechanism at the bottom of the Distal Piece in Mark 2 was designed to be a looks like model more than a functional piece. The way this mechanism works is through the tightening of screws and their complement bolt on opposite sides of the slit in order to decrease the circumference of the hole in the distal end of the knee and thereby increase the friction the plastic body has on the metal pylon that connects to the foot more distally. In order to allow this mechanism to be tested, we created a T-Shaped slit (Figure 3.24 b bottom circle). This slit allowed for the most distal cylindrical section to have a changing radius without propagating large quantities of stress throughout the rest of the Distal Piece.

Next, an additional gap on the proximal face of the Distal Piece was added as a housing for a cushion — most likely rubber — intended to muffle the sound of any clicking the knee will have when quickly snapping out into full extension during gait. The reasoning behind this addition comes from our interviews with amputees in Vietnam as well as qualitative testing of the Remotion Knee: It has a loud snapping sound during normal gait, and it can be annoying as well as an auditory indicator that someone is wearing a prosthetic device. We included this physical change to continue with our desire to make all aspects of this prosthetic device concealable should the amputee desire.

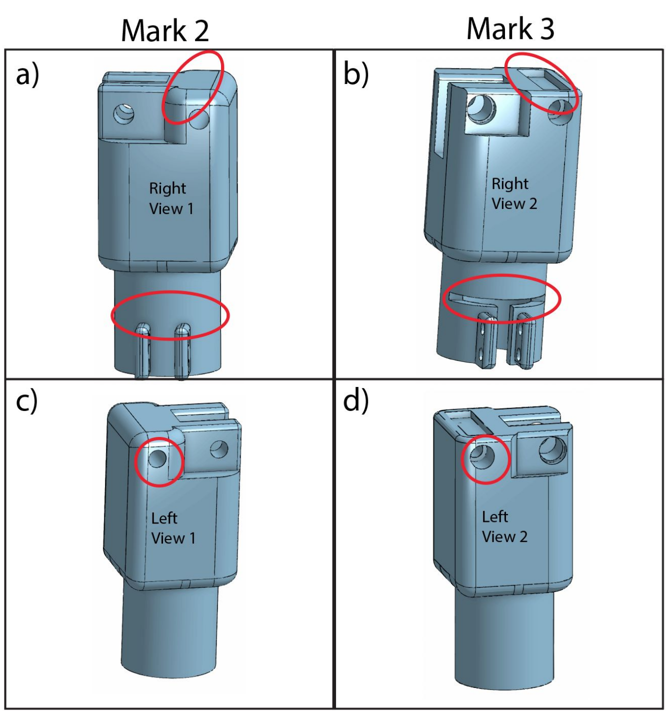


Figure 3.24: a,c) Distal Piece of Mark 2 prototype prior to changes. Red circles indicate position of change. b,d) Distal Piece of Mark 3 after changes. Red circles indicate position of change

The next pieces we iterated on were the linkages themselves. The posterior linkage had the largest functional makeover of the entire knee with respect to the Mark 2 to Mark 3 transition. In Mark 2, the posterior linkage was used as a cam device that would compress a spring housed in the interior of the bottom piece (figure 3.22 a). However, for Mark 3, we moved away from the active component. The decision to cut out the active component was based on our ultimate goal to design a $60 prosthetic leg with all components included. Though we know an active component is integral to maximally accurate knee torque, we felt that the goal of a $60 leg would not be unattainable with an active component. Since the goal to allow amputees to return to autonomy is dependent on a complete prosthetic leg and not just a single functional knee, we opted to make a passive knee the design standard. Thus the need for a cam system was lost. With this change, the geometry of the linkage shifted to more of a traditional linkage. We added another rubber housing to the anterior portion of the Posterior Linkage (Figure 3.22 b) as a means of further dampening the reported clicking sound during rapid knee extension.

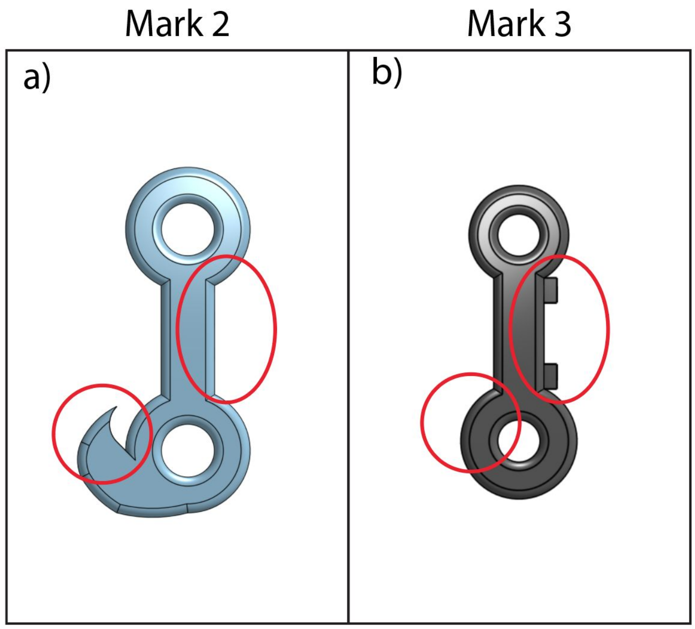


Figure 3.25: a) Posterior Linkage of Mark 2 prototype prior to changes. Red circles indicate position of change. b) Posterior Linkage of Mark 3 after changes. Red circles indicate position of change

Lastly, the Anterior Linkage was changed minimally with only the addition of recessed holes where the heads of the binding barrels would attach. The motive for this is the same as the aforementioned motives of maintaining a more streamlined aesthetic.

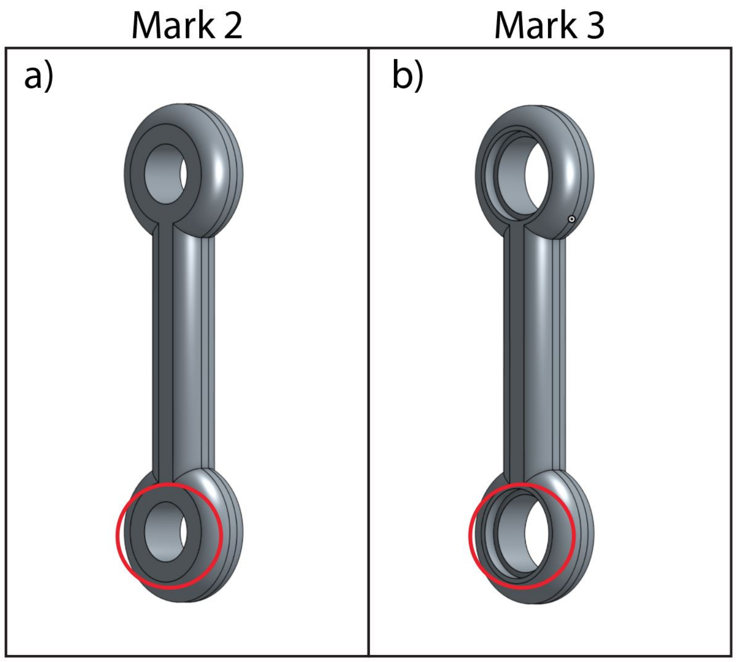


Figure 3.26: a) Anterior Linkage of Mark 2 prototype prior to changes. Red circles indicate position of change. b) Anterior Linkage of Mark 3 after changes. Red circles indicate position of change

After completing the 3D printing prototypes, we wanted to move into gait analysis in order to verify our design. Prior to gait testing, the able bodied human testing rig which we had used in prior work was revisited (Figure 3.12 and 3.13). We moved the attachment point of the prosthetic knee on the rig from a position directly lateral to the natural knee to directly beneath the natural knee. The point of this move was to allow the knee to more accurately experience the forces that a prosthetic knee would experience in natural gait. One of the main reasons we initially chose a 4-bar mechanism was to help with stabilizing any medial lateral rotation. Thus to properly evaluate the stability of our knee, the prosthetic would need to experience similar forces to what it would in practice. A second change we made prior to the gait testing was creating metal linkages for Mark 3 as opposed to the PLA ones we had been using. This step was important because metal on metal interactions are quite different from metal on PLA interactions. Thus, as shown in Figure 3.14, Linkages were machined to similar specifications as that of the CAD models. Figure 3.27 shows the assembled Mark 3 Knee device used for testing with metal linkages

Figure 3.27: assembled Mark 3 with metal linkages

We followed the gait analysis specifications described in the methods section (3.3.6) in order to conduct gait analysis with the 3 different knees: Mark 3, Medi OH5/KH5, and the Ossur Balance Knee. Our first method of testing was ICR location and voluntary zone of stability calculation. We chose this first because it was the simplest means of quantitatively determining whether the Mark 3 was stable based on industry standards. After collecting the data during multiple gait cycles and superimposing the CP lines onto a still image of the rig, we quickly realized that this methodology would not work for our analysis. The figure on the left shows our calculation of both the ICR and the voluntary zone of stability superimposed onto a still image of the able bodied testing rig. We suspected that the ICR would be somewhat outside of the voluntary zone of stability, but not by how much it was. The image shown here is our test with the Ossur Balance Knee. There could only be two explanations for this much of a deviance from expected results: the knee is significantly unstable or the test itself is not an accurate test of stability. Since this is a prosthetic knee that is commercially sold and often prescribed by doctors, the only possible explanation is that the test itself is faulty.

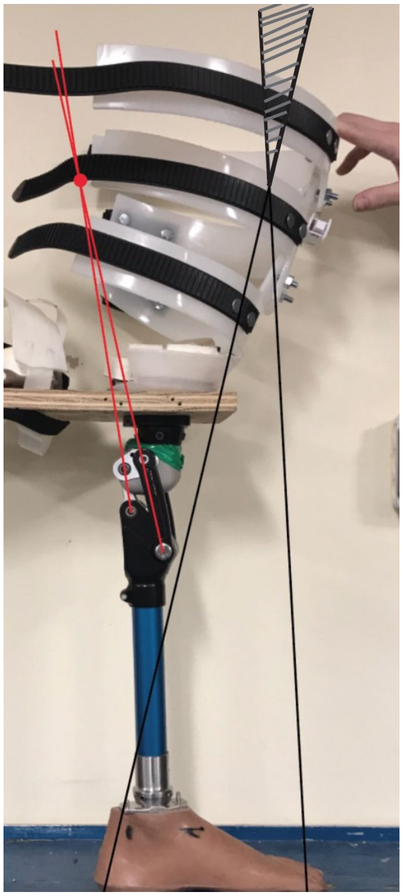


Figure 3.28: ICR (red lines) mismatched with voluntary Zone of Stability (Black Lines)

Thus, we decided to focus on another aspect of prosthetic devices that measures stability: the hip moment that the amputee exerts on the leg during heel strike and toe off. Figure 3.16 demonstrates the moment calculation for both landmarks of gait. We wanted to approach changes to this prototype more quantitatively than we had the previous prototype. To this end, we began to use simulations with Onshape to drive the design iterations. We used part configurations for each piece as illustrated in Appendix C and D. The parts were then put into an assembly configuration in which the anterior faces of each piece were held to be parallel to mimic the position that should occur during complete knee extension. 5 Geometries were selected correlating with the 5 rows shown in Table 3.1 and shown in figure 3.29.

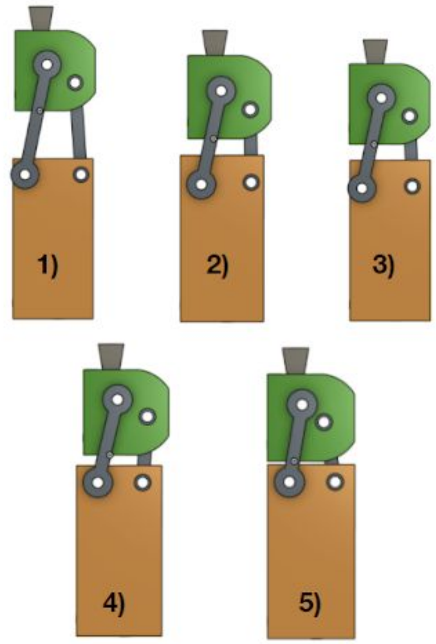


Figure 3.29: the 5 linkage and hole geometries used for Onshape simulation and moment calculation

These 5 were chosen based on their varying geometries a well as generally good vertical alignment between the top and bottom pieces at 0^{o} of flexion. These 5 knees were then imported into adobe illustrator and the moments were calculated. We expected to see agreement with the calculated moments at both Heel Strike and Toe-Off with respect to the knee geometry used for calculations. However, Table 3.1 shows that the knee geometry with the highest Heel Strike moment actually had the lowest Toe-Off moment. This was surprising to us because we thought that a knee would exhibit stability on both ends of the stance phase if it was a superior geometry. However, this shows that the optimization methodology that we followed for this technique actually requires significantly more computational work because the true minima may lie somewhere in the middle between lowest moment at both ends of stance phase.

3.4.1 Limitations

One of the largest limitations we have as a group is the lack of actual testing on amputees. Ready access to amputees would give us significant advantages in the design process as we would be able to continually iterate on the design with readily available and reliable feedback. Ultimately, we need to allow our products to be fit onto patients, even if it is more of a back of the envelope testing situation.

Another limitation our methodology has is the bias inherent in using ImageJ and Illustrator as the main methods of simulation assessment. These two programs are quite powerful, however, they require the user to make judgements as to what pixel values are based on the naked eye. Therefore, there is bias in the measurements of lines and angles as well as bias in the accuracy of any of the grouping constructs.

3.4.2 Next Steps

The next steps for this project are quite clear: continue the optimization of the 4-bar mechanism using the torque analysis, and then repeat gait testing. The 4-bar optimization will take quite some time, as there are a vast number of permutations for each piece geometry as well as combination of said permutations in assembly configurations. One potential approach for minimizing the moments could be a graphical approach in which trends can be analyzed and predicted. A second method could be to sum the moment at both toe off and heel strike and find an equation to minimize this sum.

After this, able bodied human gait testing must be done again, this time with more angles of filming: namely from more than one body plane. Not only should testing be conducted on a walkway, but other methodologies such as treadmill gait testing or force plate gait testing could be used. Upon completion of that analysis, testing should next be conducted on humans in order to complete the product design.

4.1 Conclusion

Though we have made significant progress in terms of designing universal prosthetic solutions, there still exists a significant gap between where our suite of products is currently, and the ultimate goal of providing low cost devices to the developing world. Based on research, communication with other prosthetic groups, and experience facing difficult design challenges during this project, we can safely conclude that this is not an easy problem. This thesis has served as the culmination of almost 2 years of work in the field of low-cost prosthetic devices. As we have continued to iterate on our designs and rework our problem statements, solutions have turned into more questions and ‘a-ha’ moments have turned into new lenses through which we can gaze upon the problem.

Our pivot as a group came soon after visiting Vietnam. We traveled with the goal of optimizing and testing our prosthetic knee on patients, and left with the realization that the problem was deeper than a single product design could solve. After returning to the US, we began to design other components of a prosthetic leg with a heavy focus on the adjustability and universality of the product itself. After pushing the design for a prosthetic knee, socket, and pylon, our next pivot came which was the focus on the socket solely.

Our choice to focus on the socket came from our realization that the bottleneck of prosthetic fittings wasn't solely the lack of access to cheap prosthetics, but rather was significantly impacted by the slow process of traditional custom molded sockets. We spent a lot of time working on how to make a socket universally adjustable without compromising the integrity the socket needed to uphold. We have come up with a few designs for adjustability in our air pocket and strap designs and have quantified our design metrics with initial compression testing, material testing, and static load bearing. Future study will involve dynamic as well as cyclic testing. Given our current work, we hope to inspire future iteration on this idea of creating a more universal solution. As the three barriers to technology suggest, a technology very well might exist but may not be accessible to those who need it most.

Yet, after all of the pivots and adjustments to the design drivers and goals — all of the prototypes and products, we still felt the humbling dissatisfaction with our solution: it was incomplete. It took some time, but while this thesis represents many of our design iterations and pivots, it also represents our growth as a group. No individual socket, knee, pylon, or any other single product would drastically affect the lives of amputees in developing countries. We've realized that a product that is simply thrust into a broken system will not create major change. Rather a product that is built both for the end user that allows for the system to change around it will bring the change necessary. With this mindset, we hope to continue to iterate on the suite of prosthetic products we are working on such that the products can help both amputees *and* the medical infrastructure in developing countries.

Acknowledgements

And so it concludes! We've been grinding on this project for a couple years now; to have it finally come to a conclusion as the gem at the top of our academic careers is nothing short of surreal! The ebbs and flows of this project have been euphoric at times and crushing at others but we can only look back fondly at all we have done and how far we have come as engineers, as designers, and most importantly as people.

What would a project be without the support and advice. First and foremost we have to thank Brown University for providing a space for a group of engineering youngbloods to tackle a global problem — the encouragement and support that we have felt from the school has been nothing short of astounding. The Brown University School of Engineering & especially the Brown Center for Biomedical Engineering have provided invaluable resources towards the progress of our project! From Money to machines, from counseling to publicity, we can't possibly express the full magnitude of our appreciation for the things you've given — the support of our intellectual curiosity was tangible throughout the process and a cornerstone of what our project is built upon.

To our advisor Dr. Celinda Kofron, where do we even begin! You've played many roles for us throughout this process: Mentor, Advisor, Teacher, sometimes spirit guide? We can't thank you enough for the time you spent organizing our scrambled thoughts, and teaching us how to do sound science. Most of all, we are truly humbled by the amount of autonomy you gave us and the inherent trust that came with that. From fledgling undergraduates to soon to be Masters Degree holders, you've helped to pave a path for us that afforded maximal growth as scientists and as designers.

A big shout out to the rest of the faculty from Brown University who have played a role in the advising. Dr. Chris Bull for showing us the ropes of CNC machining and advising some of our prototyping decisions; Dr. Braden Fleming for advice regarding the physiology of the knee and for reading our thesis and serving on our committee; Dr. Anubhav Tripathi for teaching us the value of engineering innovation.

Trang Duong and Victor Wang from Penta Prosthetics! Thank you for being the Nick Fury to the Koi Prosthetics Avengers. You both had a vision of affordable prosthetic devices and we were lucky to be chosen to help you realize that vision. We have immeasurable gratitude for the experiences you have provided for us and the knowledge/insight you have bestowed in terms of designing for the developing world. You took our interest in an engineering problem and kindled that flame to turn it into a genuine passion to help the underserved and to look to the betterment of tomorrow. It all love from our end, thank you!

Dr. Jason Harry, Jonas Clark and the whole Breakthrough Lab team, thank you for showing us the value of business development. We gained so much by our weekly meetings last summer and now have a true appreciation for how important a business plan can be in the follow through of an engineers dream. As we move into the next phase of prosthetic development and user testing we will continue to hold onto the lessons you taught us and eventually make good on our goal to deliver the products to the end user.

To our entire Koi Prosthetics team, Thank You for hanging with us as we learned and grew with you all! Alex Lo, Claire Sise and Matty B, thank you for helping us get this whole thing started in Spring of our Junior year! From late night facetimes to our trips to Vietnam we really hustled at the start of this project! Was a true honor working with such great minds to design and build in a field we were all beginners in. Whether it was Koi bubble tea or koi fish, we made it together and that unity can never be taken away. Franklin Tarke! Tarketron! Thank you

for joining us our senior year as we ventured into new ground with the socket and pylon development, and thank you for always bringing that “work hard yeah, play hard yeah” attitude! We miss you on the east coast but hope you’re still Infiltrating the dealer and finding the supplier out there in the D school!

To our very own younglings —Eric DuBois, Emily Esposito, & Madison Frye — you all gave us a spark of youth and a fresh take this past year that helped us push this project from new angles. Madi you killed it on the business team and brought some new attention to Koi. Eric, man your prototyping skills are second to none and we learned a lot from you this year. The future of this project will fall heavily on both of your shoulders and I know we picked some great and talented designers to take the mantle.

Part of the Journey is the end. What a ride this has been and while this isn’t the end for our time with Koi, it is for our prosthetic device work at Brown. We’re ready to take that step out of the university space. So to all of our supporters, our advisors, and maybe even a couple of fans, one last thank you for all you’ve done for us, and look out for some of of the noise we’ll make in the coming years.

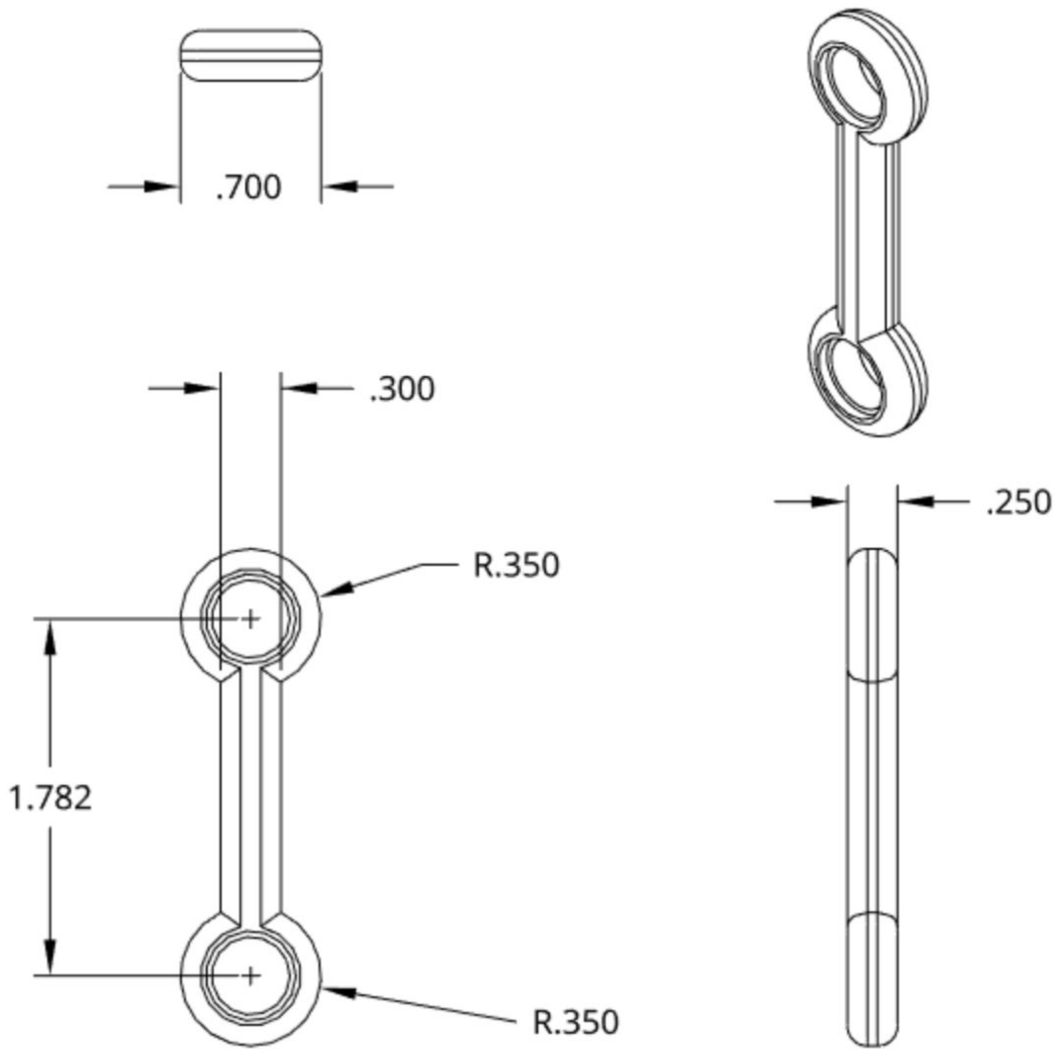
- Justin, Matt & Luke

Appendix A: CAM Preparation

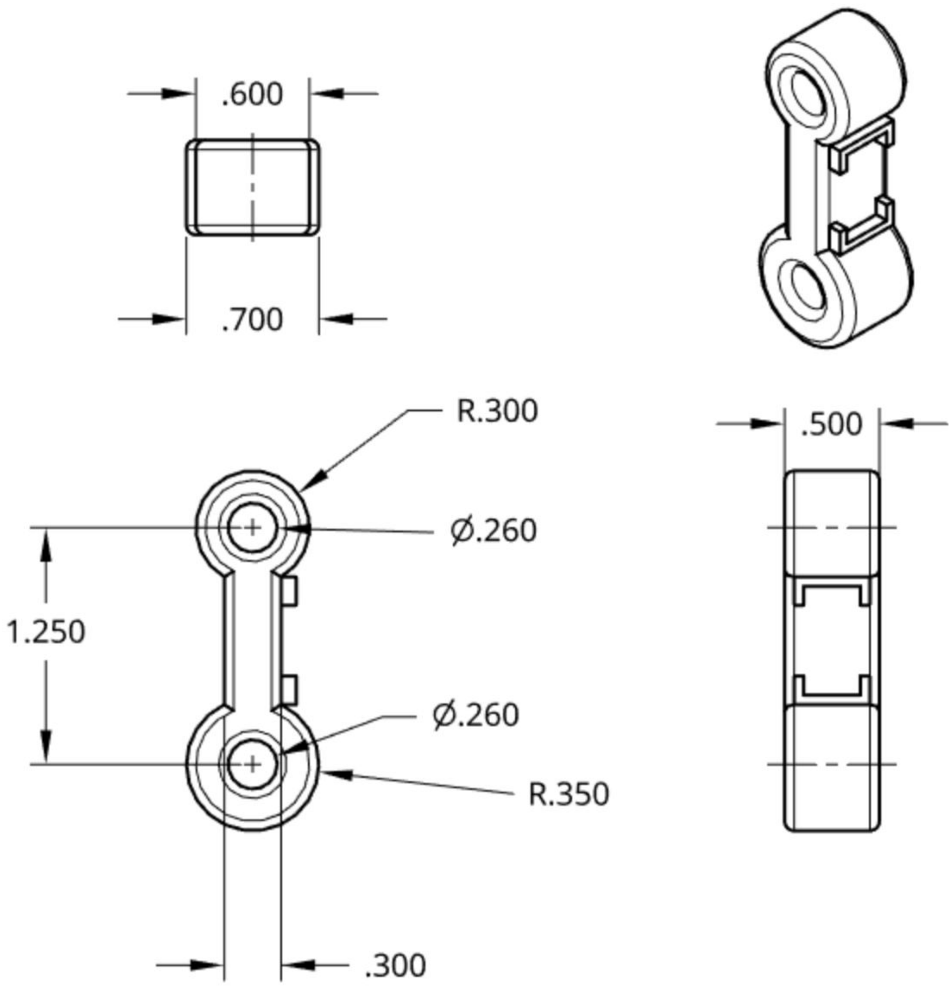
Starting with the strut bases, we assigned a stock that was 7.01in x 3.16in x 0.72in. We then assigned the origin at the bottom right corner of the piece, as the origin was on stock instead of the actual piece. In the first setup, we drilled the holes and created the inner pocket. The stock would be clamped using a vice. Fusion360 could read where holes were located. For the first step, we used the drill function to insert pilot holes. We assigned a 1/8" center drill with a spindle speed of 5000 rpm, surface speed of 163 ft/min, and a retract feed rate of 40 in/min. These settings were repeated in the over steps because the the settings are assigned specifically for the material being cut. Under the heights tab, we assigned how deep each hole should be made in the stock. Given that we were creating pilot holes, we assigned the bit to go into the stock 0.125in. Our next step was to use these pilot holes to create the drill holes. We programmed a 13/64" drill bit the same way we did with the center drill, except we ensured the drill pressed through until -0.1in through the bottom of the stock. The action was changed from rapid out to chip breaking; the bit would drive in halfway then retract to clear debris and then finish the cut. Next step was to program the pocket. We selected the 2D pocket, which cuts away planes at a time. We selected the pocket created in the CAD and assigned a 1/4" flathead bit for the cut. For each plane that was cut, we programmed the bit to cut away 0.125in of stock until it reached the final height created by the CAD model. Next, a second setup was created. The exterior would be cut away to finish the strut base. We used a template to screw the base on, and clamped the metal template with the vice; this gave us the freedom to cut away stock on the edges of the piece. The base had two slanted edges, which were cut by a 1/4" round bit with a 3D contour move. Using a similar method as the pocket, we ran the cut multiple times to shave away left over stock without putting too much stress on the bit. For the final outline cut, we used a 2D contour move and used the 1/4" flathead bit. The same method was repeated for the inserts and strut covers, as both required holes to be cut and 2D contouring to get the specific shapes.

For the cup section, a CAD model was inserted into the CAM. The CAM is made assuming that it will be cut out of stock material. Thus, we set the stock to have a 6” diameter and 3” deep. We created a setup and programmed the operation to be “turning”. Fusion then assumes the cuts will be done on a lathe. The stock piece is spun on an axis, then the cutting tool is inserted into the stock to make the cylindrical cuts. The first step to the CAM was a chip breaking operation with a ¼” diameter drill bit, followed by a ½” diameter bit. This hole allows the inner boring tool to fit inside the stock material. The boring tool is used to clear the middle of the cup and create the circular contours. To create the inner contours, a boring tool was selected and adjusted to the proper ½” diameter. The turning mode was selected to be “inner profiling”, which read the 3D model and simulated the boring cut. The surface speed was set to 300 ft/min with a maximum spindle speed of 1000 rpm and a cutting feed per revolution of 0.005 in. The speeds were set to adjust for the stock plastic, and was used in the other steps of the cutting process. Lastly, an outer profiling turning mode was added to create the outer contour. The tool was set to be a standardized right-handed facing tool, as it would cut by approaching tangent the outer edge of the cup. The same settings were set for the outer cut as the inner profiling tool.

Appendix B: Mechanical Knee Drawings

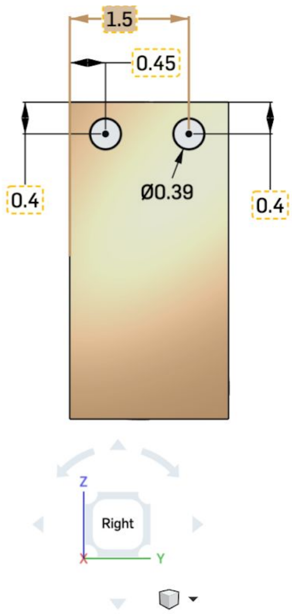


Appendix B1: Anterior Linkage Mechanical Drawings



Appendix B2: Posterior Linkage Mechanical Drawings

Appendix C: Onshape Part Configuration

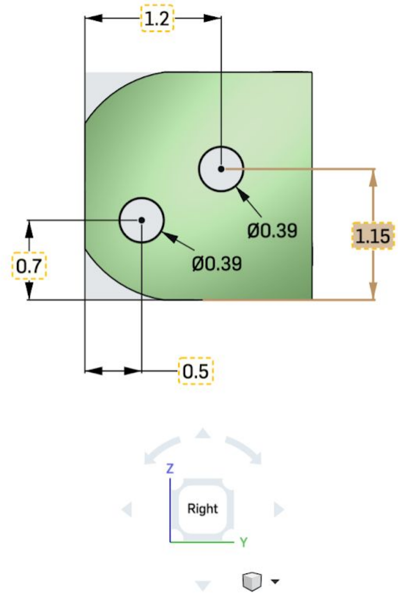


Configurations | Configured part properties

Configuration | + Configure features

Name	Sketch 3 Distance	Sketch 3 Distance	Sketch 3 Distance	Sketch 3 Distance
1.0	**0.45 in**	**0.4 in**	**0.4 in**	**1.5 in**
2.0	0.3 in	0.4 in	0.4 in	1.5 in
3.0	0.45 in	0.65 in	0.4 in	1.5 in
4.0	0.3 in	0.65 in	0.4 in	1.5 in
5.0	0.45 in	0.4 in	0.7 in	1.5 in
6.0	0.3 in	0.4 in	0.7 in	1.5 in
7.0	0.45 in	0.65 in	0.7 in	1.5 in
8.0	0.3 in	0.65 in	0.7 in	1.5 in
9.0	0.45 in	0.4 in	0.4 in	1.7 in
10.0	0.3 in	0.4 in	0.4 in	1.7 in
11.0	0.45 in	0.65 in	0.4 in	1.7 in
12.0	0.3 in	0.65 in	0.4 in	1.7 in
13.0	0.45 in	0.4 in	0.7 in	1.7 in
14.0	0.3 in	0.4 in	0.7 in	1.7 in
15.0	0.45 in	0.65 in	0.7 in	1.7 in
16.0	0.3 in	0.65 in	0.7 in	1.7 in

Appendix C1: Distal Piece part configuration list with sketch changes

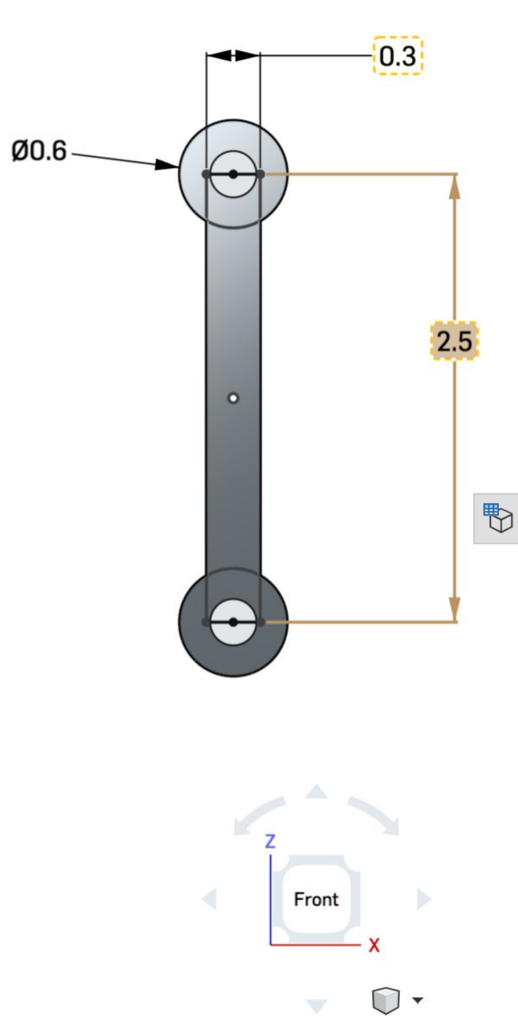


Configurations | Configured part properties

Configuration | + Configure features

Name	Sketch 3			
	Distance	Distance	Distance	Distance
1.0	**0.5 in**	**0.7 in**	**1.2 in**	**1.15 in**
2.0	0.7 in	0.7 in	1.2 in	1.15 in
3.0	0.5 in	0.9 in	1.2 in	1.15 in
4.0	0.7 in	0.9 in	1.2 in	1.15 in
5.0	0.5 in	0.7 in	1.0 in	1.15 in
6.0	0.7 in	0.7 in	1.0 in	1.15 in
7.0	0.5 in	0.9 in	1.0 in	1.15 in
8.0	0.7 in	0.9 in	1.0 in	1.15 in
9.0	0.5 in	0.7 in	1.2 in	1.3 in
10.0	0.7 in	0.7 in	1.2 in	1.3 in
11.0	0.5 in	0.9 in	1.2 in	1.3 in
12.0	0.7 in	0.9 in	1.2 in	1.3 in
13.0	0.5 in	0.7 in	1.0 in	1.3 in
14.0	0.7 in	0.7 in	1.0 in	1.3 in
15.0	0.5 in	0.9 in	1.0 in	1.3 in
16.0	0.7 in	0.9 in	1.0 in	1.3 in

Appendix C2: Proximal Piece part configuration list with sketch changes

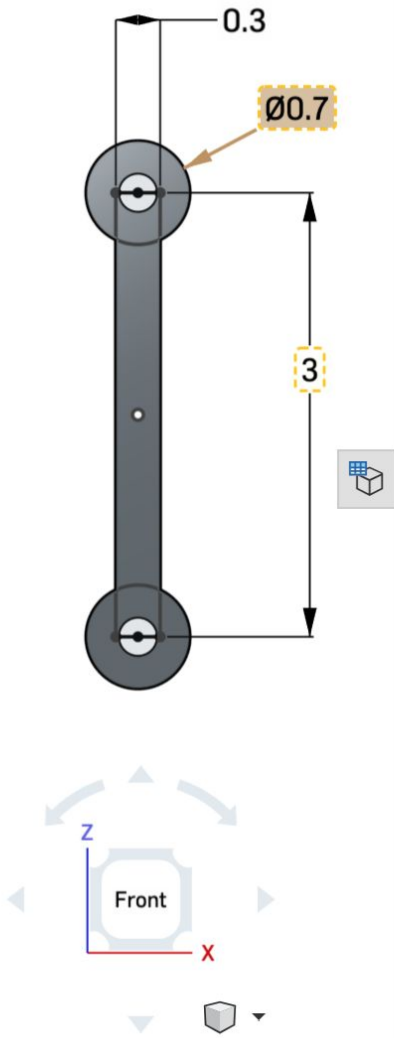


Configurations | Configured part properties

Configuration | + Configure features

Name	Sketch 1 Length	Sketch 1 Length
1.0	**0.3 in**	**2.5 in**
2.0	0.3 in	2.3 in
3.0	0.3 in	2.2 in
4.0	0.3 in	2 in
5.0	0.3 in	1.8 in
6.0	0.3 in	1.75 in
7.0	0.3 in	1.6 in
8.0	0.3 in	1.55 in
9.0	0.3 in	1.4 in
10.0	0.3 in	1.3 in
11.0	0.3 in	1.25 in
12.0	0.3 in	1 in
13.0	0.3 in	0.9 in
14.0	0.3 in	0.8 in
15.0	0.3 in	0.7 in
Name		

Appendix C3: Posterior Linkage part configuration list with sketch changes



Configuration

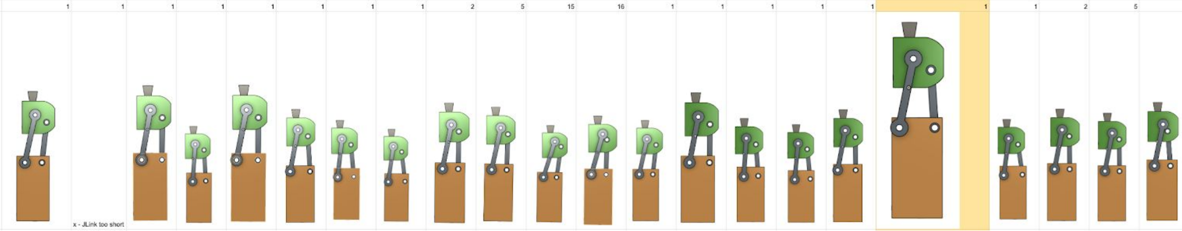
+ Configure features

Name	Sketch 1	
	Length	Diameter
1.0	3 in	0.7 in
2.0	2.8 in	0.7 in
3.0	2.5 in	0.7 in
4.0	2.3 in	0.7 in
5.0	2.1 in	0.7 in
6.0	2 in	0.7 in
7.0	1.8 in	0.7 in
8.0	1.75 in	0.7 in
9.0	1.65 in	0.7 in
10.0	1.55 in	0.7 in
11.0	1.4 in	0.7 in
12.0	1.2 in	0.7 in
Name		

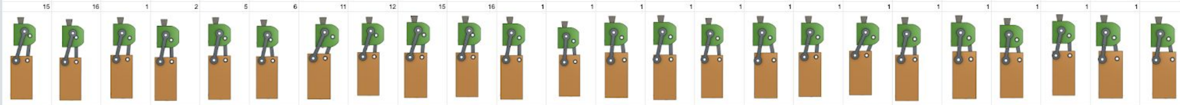
Appendix C4: Anterior Linkage part configuration list with sketch changes

Appendix D: Onshape Assembly Configuration Table

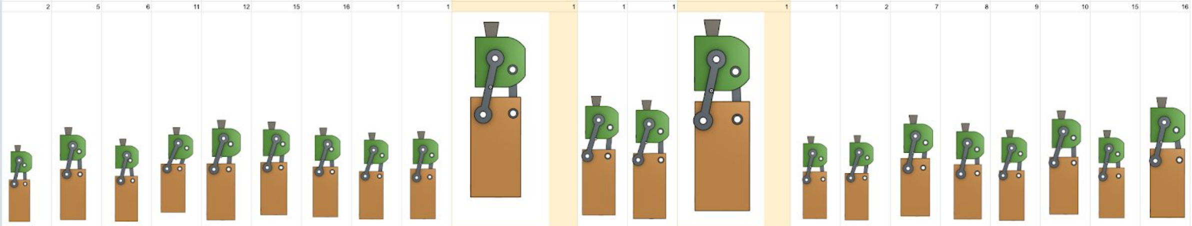
Anterior Link	1	1	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2
Posterior Link	1	2	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2
Bottom piece	1	1	2	8	9	10	15	16	1	1	1	1	1	2	7	8	9	10	16	1	1	1
Top Piece	1	1	1	1	1	1	1	1	2	5	15	16	1	1	1	1	1	1	1	2	5	6
Image		x - JLink too short																				



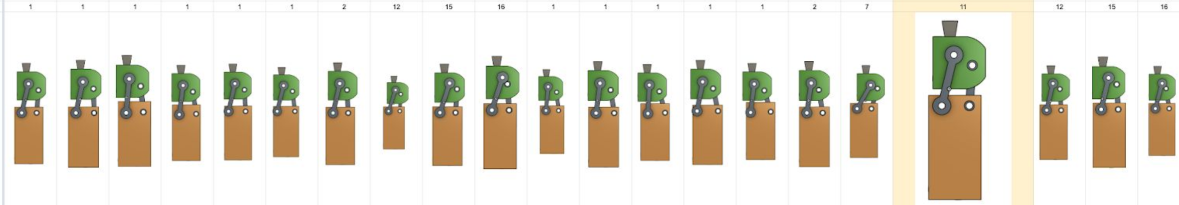
Anterior Link	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4
Posterior Link	2	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	5	6	5	5	5	5	5	5
Bottom piece	1	1	1	1	1	1	1	1	1	1	2	7	8	9	10	16	1	1	2	7	8	9	15	16
Top Piece	15	16	1	2	5	6	11	12	15	16	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Image																								



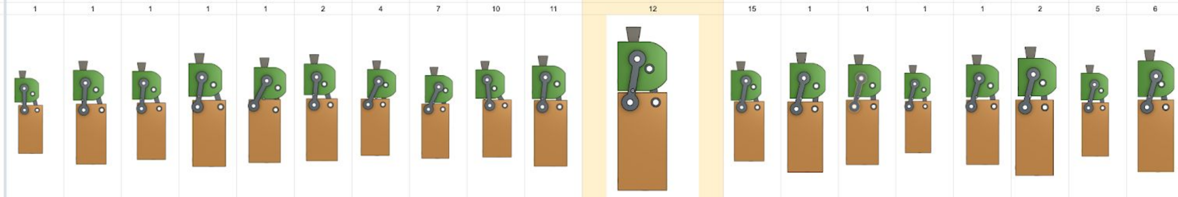
Anterior Link	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Posterior Link	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6
Bottom piece	1	1	1	1	1	1	1	2	7	8	9	10	15	16	1	1	1	1	1	1	1
Top Piece	2	5	6	11	12	15	16	1	1	1	1	1	1	1	2	7	8	9	10	15	16
Image																					



Anterior Link	5	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6
Posterior Link	7	7	7	7	7	7	7	7	7	7	8	8	8	8	8	8	8	8	8	8	8
Bottom piece	1	2	7	8	9	10	1	1	1	1	1	2	8	10	16	1	1	1	1	1	1
Top Piece	1	1	1	1	1	1	2	12	15	16	1	1	1	1	1	2	7	11	12	15	16
Image																					



Anterior Link	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
Posterior Link	9	9	9	9	9	9	9	9	9	9	9	9	10	10	10	10	10	10	10
Bottom piece	1	2	9	10	12	1	1	1	1	1	1	1	1	2	9	10	1	1	1
Top Piece	1	1	1	1	1	2	4	7	10	11	12	15	1	1	1	1	2	5	6
Image																			



Anterior Link	8	8	8	8	8	8	8
Posterior Link	10	10	10	10	10	10	10
Bottom piece	1	2	9	10	1	1	1
Top Piece	1	1	1	1		2	5
Image