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Redesign Of A Volume Adjustable Transtibial Prosthetic Socket

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REDESIGN OF A VOLUME ADJUSTABLE TRANSTIBIAL PROSTHETIC SOCKET

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Master’s Program in Systems Engineering

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Dedication

Dedicated to my parents, Enrique Terrazas and Priscila Quezada; my brothers Enrique L. Terrazas and Joaquin Terrazas. Father, thank you for always driving me to work hard and to never give up, to your financial aid during the difficult days and for teaching me to enjoy the little things in the middle of the storm. Mama, thank you for your great life advice, for your kind support during my calls when I was so stressed, and for your teachings in caring for others. Brothers, thank you for always cheering me up, and for lifting my courage up in the moments of weakness.
REDESIGN OF A VOLUME ADJUSTABLE TRANSTIBIAL PROSTHETIC SOCKET

by

SAMUEL TERRAZAS QUEZADA, BS

THESIS

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Finally, to God, for whom I live and for who I do what I do.
Abstract

Recent research and development in prosthetics have aimed at improving socket designs and components to mimic more efficiently the human body. One such innovation is the Aperture Socket, a low-cost volume adjustable prosthetic socket. During the validation stage of its development, the Aperture Socket successfully demonstrated that it could compensate for volume changes, but various improvements on use and comfort were identified. This project develops and tests a redesign of the Aperture Socket previously developed for amputees in developing countries and subsequently patented and licensed to LIMBS International, Inc.

The first phase of this study was the creation of various prototypes to improve the existing mechanism for adjusting the prosthetic socket. The adjustment system was redesigned to improve ease of use and provide a more stable coupling between the socket and the remaining prosthetic components. The second phase consisted of creating a new socket wall design that implements struts with a flexible inner socket. The new socket system was designed to provide greater support to the residual limb, to improve user comfort, to simplify the manufacturing process, and to lengthen the lifecycle of the product. The third phase was experimentally testing the prototype with mechanical compression machines, following guidelines dictated by the ISO 10328:2006, and user feedback. One experienced transtibial amputee rated at the K3 activity level was selected to validate comfort, volume adjustability, and ease of adjustment of the redesigned Aperture Socket while performing the L-Test of functional mobility [7].

The results of the ISO 10328 ultimate strength test showed that the socket design struts are not capable of supporting the ultimate load applied during the late stages of the gait cycle (P5 level, condition II). However, the axial load test of the ultimate strength force was successfully passed, which shows that the socket system is capable of withstanding the ultimate strength force of 4025N. The results from the subject trial concluded that the socket redesign was successful in adjusting its volume in a friendly manner while providing a comfortable fit and natural gait.
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Chapter 1: Introduction

1.1 Significance

Losing a limb is a major physical and psychologically overwhelming event that can happen to a person. Limb loss, also known as an amputation, not only causes major deformity, but it also reduces people’s mobility and increases the risk of loss of independence [1]. Although limb loss can severely affect functional abilities, prosthetic rehabilitation, through the use of an artificial limb, has the potential to increase amputee quality of life by restoring patients’ function.

Despite advances in medicine and biomechanics, amputations continue to be a large and rapidly growing problem worldwide that impacts millions of individuals. The American Diabetes Association (ADA) reported, in 2010 alone, an estimated 73,000 lower limb amputations (LLA) were performed on adults aged 20 years or older. Of all LLA reported in the United States (US), 60% occur in adults diagnosed with diabetes. By 2034, amputations will increase even more since the number of people living with diabetes is expected to reach 44 million individuals [2].

The reasons for needing an amputation differ between developed and developing countries. In developed countries, such as the US, 82% of the amputations are due to complications of diabetes and peripheral vascular diseases [2], whereas, in developing countries, the same cause represents only 50.5% of amputations and trauma (accidents or injuries) account for 38.4%. LLA in both developed and developing countries are more frequent than upper limbs amputations (ULA) and are most commonly caused by vascular diseases, followed by trauma. A recent study of 162 patients in developing countries showed that 86.4% of amputations performed LLA while ULA are only 13.6%, giving a lower to upper limb amputation ratio of 6:1 [3].

Amputations worldwide are becoming a pervasive problem due to its growing prevalence and the consequences it brings. Despite these causes, a solution in prosthetic
rehabilitation, for both LLA and ULA, is the use of prosthetic limbs. A prosthetic limb consists of three basic components: the socket, the shank, and an artificial foot/hand. The socket is the interface between the limb and the mechanical support system. The shank replaces the length of the lost limb and also incorporate a knee/elbow joint if the amputation is above the knee/elbow [62].

1.2 BACKGROUND

Lower limb prostheses have been a favorable option for restoring mobility and independence for people living with an amputation. However, if the socket, the interface between the residual limb and the prosthesis, is inappropriately designed or improperly fitted, the comfort can deteriorate and directly affect function and prosthesis use for people with amputations [5-6]. Even if an appropriate design and a good prosthetic fit is achieved, current sockets still need to be replaced regularly. This is because most socket designs are custom fitted to the individual and made out of rigid materials that cannot compensate for the degree of volume change experienced by amputees during the day and over time. Therefore, the socket can become improperly fitted which can increase shear stress between the socket and the residual limb [4]. As a result, inappropriately manufactured sockets, thermal discomfort, and volume fluctuations can negatively affect prosthesis use, activity level, and quality of life. Additionally, they cause pain, skin maceration, skin irritation, friction blisters, infection, unpleasant odor, and an environment for bacterial invasion to hair follicles of the residual limb [5-6].

This project is intended to redesign an existing volume adjustable socket. The volume adjustable socket builds upon the current volume adjustable Aperture Socket design prepared by Dr. Kendall and licensed to LIMBS International, Inc. [8]. Likewise, new redesign improvements will potentially reduce the many struggles that lower limb amputees encounter when using a conventional non-adjustable prosthetic socket, according to current issues in prosthetic sockets found in the literature review [9]. The improvements
on the redesign include the development of a user-friendly adjustment mechanism for end users. Also, a more simplified and efficient manufacturing process is sought to reduce time and resources.

1.2.1 Types and Causes of Lower Limb Amputations

An amputation is defined and categorized depending on the part of the body amputated. It can happen to any of the body’s extremities and limbs.

A lower limb amputation ranges from partially removing a toe to fully removing a leg and part of the pelvis. Most of the lower limb amputations are due to vascular diseases (54%, diabetes, and peripheral arterial disease), trauma (45%), and cancer (less than 2%) [10]. The different types of lower limb amputations include partial foot amputation, ankle disarticulation (disjointed), transtibial amputations, knee disarticulation, transfemoral amputations, hip disarticulation, and hemipelvectomy. These type of amputations are defined and listed below:

- **Partial Foot Amputation (PFA)**
  
PFA is the most common type of amputation performed in industrialized countries. It affects about 2 out of every 1000 individuals in such countries [10]. The primary cause of this amputation is diabetes. The second most common are complications due to advanced vascular disease. Foot injuries, infections, and congenital disabilities are also causes of PFA. Post-amputation solutions for PFA include the use of insoles or toe fillers that help relieve pressure from sensitive areas or, in some cases, restore the effective foot length [10].

- **Ankle Disarticulation**
  
Amputations that are performed through the ankle joint are also known as Syme’s amputation technique or Syme’s ankle disarticulation. James Syme first suggested ankle disarticulation in 1843 with the purpose of providing
a less risky procedure to patients than a transtibial amputation, theorizing that it would provide a more comfortable and functional amputation for the residual limb. Current literature and evidence support his observations, but this amputation level has not gained full acceptance by the prosthetic community [11]. Advantages of this type of amputation are: patients can walk short distances, can put weight on the distal end of the foot, and stand in the shower, among others, without being assisted with by prosthesis. Disadvantages include that is harder to build an appealing cosmetic prosthesis, and the options available for a prosthetic foot are limited [13].

- Transtibial Amputations
A transtibial surgery is an amputation of the leg below the knee (BK). Performed through the tibia, this style of amputation retains the knee joint. The most common reason for a BK amputation is when an individual has a severe infection in his/her limb or has a severe injury that cannot be healed using conventional means. Other reasons for a below knee amputation include non-healing ulcers, congenital disabilities, chronic pain, and tumors. A below knee amputation is the most common amputation worldwide. It represents 71% of dysvascular amputations and is expected to increase to 47% between 1995 and 2020 [5]. Patients with a BK amputation have the option to use an artificial leg, also called a prosthesis that can allow them to walk and restore mobility [13].

- Knee Disarticulation
The Knee Disarticulation (KD) style of amputation is performed by amputating the limb between the bones in the knee joint instead of cutting through either bone. This kind of amputation is most commonly done after a tumor resection or when an individual has suffered a severe trauma. KD represents less than 2% of the annual amputations performed in lower
extremities in the United States [6]. Similar to a below knee amputee, a patient with a KD amputation has the possibility of regaining mobility with the use of a custom-made prosthesis [14].

- **Transfemoral Amputation**

  A Transfemoral Amputation occurs through the femur and is performed by removing the lower-limb above the knee joint when the limb has suffered a severe trauma or has been severely damaged by a disease. The most common conditions that result in the need for a transfemoral amputation include diseases such as peripheral vascular, diabetes, tumors or cancer, and infections that cause gangrene. Individuals who have suffered an above knee amputation also have the possibility of regaining mobility and to walking again by using a prosthesis [14].

- **Hip Disarticulation**

  Hip disarticulation is the amputation of the whole lower extremity through the hip joint [15]. This surgery is frequently elected due to a malignant bone or soft tissue tumors below the lesser trochanter of the femur. In the 1970s hip disarticulation was traditionally performed due to osteosarcomas of the distal femur before the application of chemotherapy. Therefore hip disarticulation was the most common operation for distal femoral sarcomas [16]. Currently, along with the use of adjuvant chemotherapy (preoperative radiation therapy for soft-tissue sarcomas), the procedure for saving a limb from distal femoral and diaphyseal tumors are extremely successful. Now, less than 5-10% of individuals with such complications require an amputation, and hip disarticulation is considered a poor oncological operative procedure. The primary purpose of such amputation is for failed vascular procedures that have followed multiple lower-level amputations, or due to a severe trauma with crush injuries to the lower extremity.
Fortunately, the use of a new prosthesis is acceptable and can provide mobility to the amputee with intensive physical therapy and psychological rehabilitation [16].

- Hemipelvectomy

A transpelvic amputation (Hemipelvectomy) consists of removing half of the pelvis to treat localized tumors, and, rarely, cancer that has metastasized on the area. Hemipelvectomy can be classified as internal or external. An internal hemipelvectomy consists of removing the bones of the pelvis and the amputation of the leg of the same side. An external hemipelvectomy removes only the diseased bones and tissues but avoids the amputation by sparing the lower limb [17]. Individuals who have undergone an internal hemipelvectomy amputation and lost their leg have the possibility to regain mobility and walk again with the use of a prosthesis [17].

1.2.2 Impact of a Lower Limb Amputation

Regardless of the nature of the loss, an individual who has suffered an amputation is impacted in a variety of areas. Almost every amputee is likely to feel depressed immediately after an amputation surgery. For others, who have suffered pain on their leg(s) for quite a while, the loss may be perceived as a relief and as a positive step [18]. The most common areas in which they experience challenges are psychological, medical, social, and economical.

**Psychological Impacts**

A report of consequences of an amputation has shown that the quality of life on amputees is directly related to the psychology of the amputees and their physical well-being [19]. Sadly, many people have reported that losing a limb causes feeling and emotions such as grief and bereavement, emotions akin to experiencing the death of a loved one. In many situations, people do not have the time to mentally prepare for the amputation
if they have had an emergency surgery. These negative feelings and emotions are akin to the five stages of grief [20]. These include denial and isolation, anger, bargaining, depression, and acceptance, which may last up to 2 years [20].

**Medical Impacts**

Like any other type of surgery, an amputation represents a risk for the individual. These risks are driven by different factors, such as the age of the amputee, the type of amputation, and the current health status. The medical complications that are commonly presented after an individual has undergone an amputation are [19]:

- Residual and phantom limb pain
- Heart complications
- Deep vein thrombosis (DVT)
- Wound infections and slow wound healing
- Pneumonia

Sometimes, additional surgery may be needed to help amputees alleviate problems that had been caused by the amputation. For instance, if the amputee is being affected by thickened nerve tissue (neuromas), the affected set of nerves may need to be removed [46].

A crucial aspect of improving outcomes after an amputation is to provide appropriate care to address the physical and psychological needs. One of the key factors to rehabilitation and recovery phases of many amputees is the use of a prosthesis and proper training on their use. The more an amputee uses a prosthesis, the more likely they will be to return to employment [22], increased the quality of life [23], decreased phantom pain [23], and lower levels of psychiatric symptoms [24].

**Social impacts**

A third aspect that could be affected by amputation is the amputee’s social life. It has been reported that social discomfort and body-image anxiety has been found among amputees and are directly affected by physical restrictions limiting their performance of regular life activities and due to depression [20]. However, social support, having a greater
time with an amputation, and better prosthesis satisfaction are some of the positive aspects that help amputees in adjusting to their limb loss.

**Economic impacts**

Returning to work has become a pervasive problem for people who have undergone an amputation. Factors vary by the age, gender, educational level, and the type of job to be performed. However, research has shown that the rate of returning to work is about 66% of which only 22 to 67% of these subjects retained the same occupation (many may need to change jobs or work only part time) [25].

In addition to the reduced earning potential if an amputee has difficulty in returning to employment, the costs of surgery and rehabilitation have to be covered in the early stages after the amputation. On average, the first two-year costs of amputation exceed $90,000 [26]. Moreover, lifetime estimated expenses that an amputee will need to cover a range from $345,000 to closely $600,000, depending on prosthetic replacements and the age of the amputee at the time of getting the amputation [26]. Further, a single lower-limb prosthesis can fluctuate its cost from $3,000 to $100,000 which, no matter how advanced they are, require replacement every two to five years [27].

Prosthetic and Rehabilitation expenses are outside most amputees’ financial capabilities. Therefore, insurance providers come into play to cover most of these costs. Depending on the insurance type, amputees might get from very basic prosthetic components to high-end prosthetic technology and services. Also, insurance providers such as Medicare, cover expenses on components and on the different type of prosthesis depending on the ability of the patient to rehabilitate as determined by a prosthetist and the physician’s prescription.
1.3 Amputation Rehabilitation Options

1.3.1 Prosthetics Definition

Whatever the cause of an amputation, a solution for alleviating the negative impacts of amputation, for both lower limb and upper limb amputations, is the use of prosthetic (artificial) limbs. Prostheses help patients to decrease the physical limitations resulting from their amputation and regain their mobility and independence.

A typical prosthetic limb consists of four essential components: the socket (Figure 1), the suspension system, the shank or pylon, and an end effector [10]. The socket is the interface between the residual limb and the rest of the prosthesis. The suspension system prevents the socket from falling off the residual limb. The shank replaces the length of the lost limb and also incorporates a knee joint if the amputation is above the knee. Lastly, the end effector is a device at the end of the prosthesis, designed to interact with the environment.

The socket, with its suspension system, is the main component of a prosthetic limb that provides structural coupling, control, and proper transfer of forces at the interface with the residual limb [11]. Most sockets are custom fitted to the individual and made out of rigid and expensive materials, such as carbon fiber, and need to be replaced regularly; this is because amputees experience residuum volume changes during the day and over time, therefore, the fit of their sockets may vary [24]. For many patients, the first prosthesis may last only 3-6 months because of shrinkage from surgery. Even after this significant volume reduction, amputees typically need a replacement every 2-4 years [13].
1.3.2 Types of Prosthesis

Many types of prostheses had been developed with the purpose of replacing a lost part of the body. In theory, a prosthesis can be used to replace anything from an ear to a finger or toe. In the prosthetic practice, four categories of prosthetic limbs have been identified for the four most common amputation levels. These are Transtibial and Transfemoral (Figure 2), and Transradial and Transhumeral (Figure 3).
Regardless of the type of amputation, there are current solutions to substitute any lost limb, i.e. upper and lower limb. However, technology and development fluctuate on demand. Although a transtibial amputation has higher statistical rates (86% LLA, 14% ULA), in developed and developing countries, development has been overcome by advancements in upper limb technology [14].

1.3.3 Benefit of Prosthetic Solutions for Amputees

Multiple advantages make a prosthesis the best option to regain mobility for people with lower limb amputations. However, everyone reacts differently to an amputation; some are anxious to get fitted with a prosthesis, others are more comfortable with slower approaches. Most of these factors depend upon the needs of the amputees and their psychological and physical health. Despite the decision of getting a prosthesis or not, evidence have shown that positive aspects, more than negatives, impact amputees in their quality of life if they choose this path.
Mobility

Some people with a bilateral amputation (both limb amputation) may opt to use a wheelchair instead of a prosthetic leg. Even individuals with a single amputation prefer the use of wheelchairs because of the comfort they provide [14]. However, a wheelchair ends up being a more complicated device to use when it comes to going up stairs or traversing areas where a wheelchair is not accessible. As a result, a prosthesis may not provide the cushion and the comfort that a wheelchair provides, but it does provide a greater sense of independence [30].

Energy

The Atlas of Limb Prosthetics: Surgical, Prosthetic, and Rehabilitation Principles [30] study examined the energy that a unilateral (single limb amputation) amputee spends when walking with crutches and with their prosthesis. The results showed that amputees walking with a prosthesis had a lower rate of energy expenditure, heart rate, and O2 cost than using a three-point crutch-assisted. Amputees performing the study met the following criteria: Young and healthy at the time of testing, had worn their prosthesis for at least six months, and did not utilize crutches [29].

Psychological

People who use a prosthesis have a better ability to blend in better in the crowd. According to the Amputee Coalition of America, this feeling helps amputees have less discomfort with their conditions when wearing a prosthetic leg.

Many other advantages have demonstrated that an artificial limb is by far the best option for amputees who want to regain mobility and return to their usual daily activities. Despite this statement and evidence, some of the amputees prefer to use alternative solutions, such as crutches and wheelchairs. For example, one amputee interviewed explained that, during her pregnancy, she was using a wheelchair rather than an artificial limb because it gave her a more secure feeling when moving around and the greatest ability to stay independent [30]. Other example and cases include senior people who prefer to get
around using crutches or wheelchairs because handling a prosthesis may be tough and they do not want or are cognitively limited, to learn how to walk again. Although these are particular cases, the promising solution of prostheses fails to succeed on any amputee, being limited to a certain population.

As Prosthetist Chris Kort stated, “The faster, lighter, cheaper, and more efficient that science can make prostheses, the better it will be for everyone. Without researchers pushing the boundaries of prosthetics, users will be stuck with the same systems forever” – and he finished by adding – “Prosthetic technology has advanced, but it is nowhere close to mimicking human function yet” [52].

1.3.4 Current Prosthetic Socket Solutions: Non-Adjustable Socket

Before proceeding with prosthetic rehabilitation and fitting, the residual limb must have healed any wounds, swelling caused by edemas must be resolved, and the residual limb maturation (shape) should be achieved [1]. For a new amputee, this recovery time after surgery usually takes from 4 to 6 weeks [24]. If the full healing process has been achieved, as determined by a physician, a prosthetist and the insurance company or other payer will determine when the right time to fit the amputee with a new prosthesis. The process above, which determines if a patient is ready to be equipped with a prosthesis may take up to 6 months from the healing date [2].

Once an amputee is ready for a prosthesis, he or she will enter the rehabilitation phase where he will be fitted with the first prosthesis, called a preparatory prosthesis. This preparatory prosthesis helps amputees reduce the volume of their residual limb to a more stable, definitive state. The time a person wears a preparatory prosthesis prior to being fitted with the final prosthesis varies from person to person. These variable factors include the cause of amputation, body type, the level of activity, among others. The duration can fluctuate between two to six months or longer.
Current solutions for lower limb amputations are prosthesis made of rigid materials such as carbon fiber and plastic (see Figure 4) that does not adequately mimic the functionality of the lost limb and has limited adaptability to limb volume fluctuations. Prosthesis made of such materials have been shown to lead to pain and skin damage that further complicates the condition of the patient’s residual limb. [32].

![Rigid Carbon Fiber Transtibial Prosthesis](image.png)

**Figure 4. Rigid Carbon Fiber Transtibial Prosthesis**

**1.3.5 Current Prosthetic Socket Solutions: Adjustable Socket**

There have been various attempts in the prosthetic industry to treat volume fluctuations on the residual limb by improving prosthetic sockets. These solutions include:

1. The use of adding layers of socks to compensate for the volume loss of the residual limb [33]
2. The use of vacuum as a suspension system to generate negative pressures able to maintain the desired limb volume for short periods of time [33]
3. The use of volume adjustable prosthetic sockets that can adapt to changes in volume during a day and throughout time [34].
The use of the aforementioned technologies varies according to the user needs, current physique, and financial capabilities of the amputee. Moreover, these solutions (ply of socks, vacuum suspension system and volume adjustable sockets) are available in developed countries and limited for developing countries.

The advancement of prosthetic socket technology has demonstrated different levels of effectiveness upon each amputee. For example, socks are made of different fabric and affordable materials, such as wool, cotton, and synthetic fibers. Their simplicity and low cost make socks available for a wider amputee population. Socks are commonly used for lower limb amputees because the volume of their residual limb changes during the day, affecting the fit of their prosthesis. They effectively compensate daily volume changes but fail in compensating volume changes for longer periods of time. Also, the use of socks increases the temperature and moisture on the residual limb that further lead to skin problems and uncomfor ting fit that eventually lead amputees to stop using their prosthesis. Therefore, socks are good for compensating immediate low volume changes at an affordable cost.

A vacuum suspension system is a high-end technique that helps to maintain the residual limb inside the prosthetic socket by creating negative pressure with a mechanical or electronic vacuum pump, generally attached outside the prosthetic socket. This suspension system is recommended by most of the prosthetic practitioners, also called prosthetists, for lower limb amputees. The benefits include not only reducing limb volume loss during the walk (generally 6.5% with a non-vacuum suspension system) but gaining volume with an average of 3.7% [3]. However, acquiring a vacuum suspension system is a bit complicated. Due to the high-end manufacturing process and cost, amputees require having substantial justification (defined by a prosthetist and a physician) and financial capabilities to afford a vacuum suspension system.

Volume adjustable sockets for lower limb amputees have been introduced in the market in the past years. Amputee testimonies and literature review has demonstrated high
efficiency in reducing and potentially eliminating issues with prosthetic fit due to daily and throughout time residual limb volume loss. However, their availability has been limited because, anecdotally, some prosthetic engineering companies have yet to agree with insurance providers to accept these trends under their reimbursement policies. Also, prosthetic clinics are still questioning the use of adjustable prostheses and their effectiveness. Hence, some clinics do not adopt the process of manufacturing these or providing off-the-shelf designs.

**Volume adjustable prostheses**

Some companies have succeeded in receiving approval from insurance providers to reimburse their volume adjustable sockets for amputees who will be fitted with their products. Unfortunately, prosthetists who are willing to provide and prescribe this kind of prostheses still need complete a series of certifications and trainings offered by supplier companies if they are to build or even fit an off-the-shelf prosthesis.

LIM Innovations® (San Francisco, CA) and Martin Bionics (Oklahoma City, OK) are companies that have engineered prosthetic sockets with volume adjustability for lower limb amputees and whom have had certain products approved by insurance providers and are currently available in the market. Both companies provide above and below knee volume adjustable sockets. For above-knee amputees, Martin Bionics and LIM Innovations® have introduced the Socket-less Socket Transfemoral™ (Figure 5, Left) and the Infinite TF™ prosthetic socket (Figure 6, Left), respectively. Also, in 2016, both companies developed prosthetic devices for below-knee amputees. These are the Socket-less Socket Transtibial™ (Figure 5, Right) by Martin Bionics and the Infinite TT™ (Figure 6, Right) by LIM Innovations®. Unfortunately, the latter sockets for below the knee amputees from Martin Bionics and LIM Innovations® have not yet been approved by the insurance providers under their reimbursement policies [41].
Figure 5. Socket-less Socket™ Transfemoral (Left) and Socket-less Socket™ Transtibial (Right)

Figure 6. Infinite TF™ (Left), and Infinite TT™ (Right)

**Advantages**

*Adjustability and adaptability*

One of the benefits of adjustable sockets such as the Socket-less Sockets™ and the Infinite Sockets™ is their adaptability to daily volume changes. Both sockets can be adjusted by the end user in various and simple forms. For example, both Socket-less
Sockets™ (Transtibial and Transfemoral) had been designed with a flexible clothing approach implementing familiar mechanisms such as belt buckles, shoe laces, and buttons from shirts that allow users to take control over the fit of their prosthetic socket, i.e., they can loosen or tighten as desired.

Similarly, the Infinite Socket TT™ and Infinite Socket TF™ allow volume adjustments of prosthetic sockets as desired by the end user (amputee). Its modular design allows amputees to adjust not only size but also the alignment of the prosthetic device. The most recent Infinite Socket TT™ has been integrated with a Boa© closure system to reduce pressure by providing anterior and posterior adjustability, it also has been combined with air bladders to improve pressure distribution and protect sensitive areas. Other features added in the Infinite Socket TT™ were re-moldable thermoplastic materials to provide structure and a custom anatomical fit and a flexible outer cover that protects user’s clothes and provides an aesthetically pleasing finish.

Health

It has been documented that patients who wear a prosthesis during early stages after the amputation present a better control of edema, however, many amputees are not treated this way for several reasons, mostly economic [42]. Without early ambulation, amputee can develop edematous on the residual limb, which is expected to shrink over time by using elastic bandages or shrinker socks. Several provisional prosthetic sockets in successively smaller sizes ought to be fabricated to properly manage this until no further volume reduction is expected. In addition to the high expenses of this process, uncomfortable fit arises because a more definitive fit happens only for short periods of time within each provisional socket. This condition is directly related to the activity of the newly fitted patient. Therefore, volume adjustable sockets ought to come into play to help patients in having a better fit from early stages of the amputation by accommodating the gradual volume change in the residual limb [42].
Disadvantages

User performance

Technology and engineering in prosthetic has been shown previously to be a promising solution for people who have undergone lower limb amputation(s) to regain mobility and restore their previous lifestyle before suffering such a traumatic event, or for individuals who wanted to increase their quality of life if their loss is congenital. However, this promising solution has demonstrated limited applicability for people whose amputation cause is due to vascular diseases or have suffered cognitive impairments. Prosthetic practitioners prescribe and build prostheses based on the patient’s ability to handle an artificial limb. This is important because some deficiencies, such as weakness of the non-amputated leg because of circulatory insufficiencies or neuromuscular conditions that can affect their balance and their ability to walk, become evident once amputees begin wearing preparatory or provisional legs. Although most of these new volume adjustable prosthetic technologies have been developed with light-weight materials, their complexity to use and handle is still considered a limitation for people whose cognitive ability has been affected severely by vascular diseases and diabetes that consequently causes cerebral arteriosclerosis [28].

Economic feasibility

Based on feedback from multiple personal interviews described later, the process of acquiring a prosthesis in developed countries, like the United States, is quite complicated, especially for those who do not have health insurance. For fortunate amputees who do have health insurance, being fitted with a prosthesis is becoming more complicated than it was five years ago when only a prescription from a certified prosthetist was necessary. Reimbursement policies dictated by some insurance providers have become more stressful for prosthetic practitioners because of the long list of requirements they need to fulfill to get a refund approved or to at least maintain the approval and not have it revoked if an audit is performed. Significant amounts of paperwork, a very detailed justification
prescribed by a physician, history records of the patient, are some of the requirements that prosthetists are required to have upfront before fitting a patient with a prosthesis if they want to get any reimbursements or at least get paid. These requirements are needed even if a patient is to wear a prosthesis with the simplest design and components available in the market.

Annecdotally, amputees with health insurance typically end up paying 10% of 50% of the total cost of a prosthesis, which ranges from around $10,000 for a basic prosthetic leg up to $70,000 for a more advanced version (computerized and controlled by muscle movements). These prices must be covered 100% by the amputee who does not have insurance. These costs depend on the level of the amputation (above and below the knee). For instance, per the Worcester Polytechnic Institute from the Bioengineering Institute Center for Neuroprosthetics, a basic transtibial (below knee) prosthesis that allows amputees to walk on flat ground has a cost of $5,000 to $7,000, while a prosthetic leg that provides the ability to walk up the stairs could cost $10,000. These costs only represent the device themselves and do not include medical care such as physical therapy ($50 to $350 per session) and occupational therapy ($50 to $400 per session), which help amputees in their process of learning the fundamentals of walking with their new prosthesis and to perform daily tasks at home or work [43]. Additionally, prosthetic costs need to be repeatedly covered if a replacement is required, which typically occurs several times during a patient’s lifetime. A study reported by the Department of Veterans Affairs revealed that the average lifetime expenditures for prosthetics and medical care for a veteran of the Afghanistan or Iraq wars with a single lower limb amputation were more than 1.4 million US dollars [43]. As can be seen, the costs are extremely high and the probability of acquiring a prosthesis for an amputee, who does not have health insurance, is low, especially for amputees whose income is low and are the main economic providers in their families.
On the other hand, volume adjustable sockets could have the potential to reduce the number of replacements needed over time. However, even if the number of replacements is reduced, the cost of a single volume adjustable prosthetic socket could end up becoming harder to cover than a conventional non-adjustable prosthesis. Typically, prosthetic engineering companies and manufacturers work closely with prosthetic clinics to provide the most efficient service when it comes to designing, manufacturing, and shipping an adjustable volume prosthesis. Costs of design, manufacturing, and shipping are now added to new prosthesis. Usually, an adjustable prosthesis such as the Infinite Socket TT™ results in an extra cost of ~$3600 over the final price of only the prosthetic socket. These additional costs decrease the acquisition probability of these technologies for amputees with no insurance coverage and increase the difficulty to provide the justification needed for a reimbursement or coverage for amputees who have the benefit.

*Geographical impediments*

Another identified limitation for cutting-edge technology in volume adjustable prosthesis is its current limited availability for amputees in developing countries where the need is greatest [44]. Current prosthetic companies, whose market includes volume adjustable sockets, have a limited market size only for developed countries such as the United States. Material availability, low-income rates, and underdeveloped technologies in developing countries have shown to be some of the reasons why companies have not yet expanded their market in the developing world.
Developing countries: Volume adjustable prostheses

Advantages and disadvantages

The major need for an adjustable prosthesis in the developing world is the fit related issues from residual volume changes during the early stages of rehabilitation. Along with this problem, the poor training of prosthetic practitioners and technicians in developing countries have produced fit problems for amputees when they are fitted with low-quality custom-made sockets [20]. A volume adjustable socket introduces an opportunity to achieve early ambulation for lower limb amputees whose quality of fit could be compromised by the technician’s ability, as well as reducing the need for recurrent replacements and thus, potentially decreasing costs.

Various non-profit organizations, universities, and startup companies have recently started developing affordable solutions for lower limb amputees from developing countries. The most recent volume adjustable socket of low-cost was designed by graduate students from Penn State University in the first quarter of 2016. They have deployed their design through AMPARO (Figure 7), a startup company also founded by students from Penn State University [24]. Their design is one of the first pre-assembled prosthetic sockets available for lower limb amputees, i.e., a non-custom socket, whose thermoplastic materials allow prosthetic designers and technicians to thermoform the shape of the prosthetic socket to universally fit patients according to their residual limb shape. Its advantages include a more simple process in which patients can be fitten with a prosthesis during their first visit to the prosthetic clinic. Also, a ratcheting system has been included so users can adjust the fit themselves as desired. Its challenges include the limited size of its design. As it has been designed as a one-size-fits-all socket, it is difficult to fit every patient due to the vast volume and shape range of the amputee population [30].
Another socket design was developed by the Johns Hopkins University in 2014. Invented by Nicholas Flower et al. [20], the RightFit socket (Figure 8) has also been developed for below knee amputees with the primary purpose of reducing cost and fitting time. The more important aspect of the RightFit socket is the modularity of its design that allows components to be replaced and remolded in warm water as a result of its thermal material properties. Overall, qualitative analysis of prosthetist and user feedback has demonstrated that the RightFit socket complies with the minimum requirements to fit patients with amputations below the knee. However, further quantitative analysis on comfort, fit, and strength of the RightFit socket has not been proved.
1.3.2 The Aperture Socket

There is therefore still a need for a low-cost prosthesis that can accommodate the constant volume changes that are present in residual limbs, particularly for amputees in developing countries. The presence of such a need is becoming stronger due to the steady growth of the amputee population. This need has been addressed in the design of the Aperture Socket, a low-cost volume adjustable socket, patented and licensed to LIMB International, Inc. This technology is named after its adjustment feature that is based on the analogous rotational movement of a camera aperture [8].

The design of the Aperture Socket is focused on addressing the needs of amputees in developing countries. Its primary design feature is its ability to provide radial volume adjustment. To achieve volume adjustment, the socket design includes an adjustment mechanism anchored to different socket walls which are sectioned into longitudinal plates (Figure 10). This adjustment mechanism also helps to maintain alignment while the device is being adjusted [8]. Also, an adjustment spacer is connected to the socket sections to control the radial displacement (Figure 9).
The entire assembly (Socket walls and adjustment mechanism) are secured and adjusted with fasteners that connect the plate and the spacer. A +/- 15% volume can be achieved in the socket by rotating the mechanism, which consequently causes the socket wall plates to expand or contract as desired (Figure 11).
Manufacturing of the Aperture Socket

The Aperture Socket was designed for deployment through LIMBS International. Therefore, components and parts were designed and chosen per the existing materials that LIMBS Int. regularly use on their LIMBS Knee. These include:

- Delrin® material thickness of 5/8”
- Stainless steel 5/16” fasteners
- Bolt clearance of 0.332 in

The Aperture Socket can be manufactured for preparatory stages (Figure 12), i.e. check sockets to validate proper fitting of the prosthesis on the residual limb, or for the definitive stage, i.e. the final deliverable product. For the first one, different conventional plastics can be chosen, as desired by the prosthetist, to manufacture the socket. It is important to mention that not all plastics can be used to manufacture a prosthetic socket, special treatments and materials have been developed for the prosthetic industry, and they must be utilized (e.g. VIVAK®, Orfitrans, etc.). For the second one, carbon fiber has been chosen as the default material to manufacture the definitive version of the Aperture Socket.
The definitive version of the Aperture Socket (Figure 13) consists of a two-stage laminated socket. Typically, for a definitive non-adjustable prosthetic socket only one lamination is needed. However, in the Aperture Socket design, a second lamination is needed. This is because, during the first lamination, the first set of socket sections are obtained. Therefore the second set of sections is obtained in the second lamination by overlapping the first set of sections during the lamination process.
To keep the four sections of the socket in place, two customized Velcro straps are then attached, one on the proximal end of the socket and the second one on the distal end of the socket. Also, these Velcro straps are used to secure the socket after it has been adjusted, i.e. keeps the adjusted volume fixed.

**User Feedback and Gait Analysis of the Original Aperture Socket: A Review**

A multi-step verification procedure was used to assess the strength capabilities of the Aperture Socket before fitting individuals with the socket. A mechanical strength test was performed based on a modified version of the ISO 10328:2006 standard for structural testing of lower limb prostheses [39]. Results showed that the strength of the socket is appropriate for use on humans for further trials [8].

Figure 13. Aperture Socket – Definitive Version [8]
Furthermore, after proving the strength capabilities of the Aperture Socket, the device was validated on three individuals with unilateral transtibial amputations. The validation phase consisted of validating overall comfort, strength, and fit by comparing the Aperture Socket with the participant’s current socket. Techniques for validating such parameters were the L Test of Functional Mobility [49], in-socket pressure distributions, and gait analysis. After the trials, analysis of the data showed that little difference was detected in gait parameters values between the sockets during the ambulatory tests. However, some of the participants reported discomfort while using the Aperture Socket during trials, which shows that for a longer gait duration, results might become more variable. As a result from the gait trials, participants liked the socket design, and they have demonstrated that it provides the necessary volume adjustments, but future improvements in the device design are sought.
Chapter 2: Design Methodology

With the redesign opportunity identified in Chapter 1, the methodology implemented to develop potential and final solutions are presented and discussed in this chapter. The design methodology follows the process depicted by the Waterfall Process Model in Figure 14. Various requirements were determined from the previously analyzed future work of the original Aperture Socket [8], plus a complementary list of user needs is presented from newly discovered conditions.

![Figure 14. Design Methodology: Waterfall Process Model.](image)

2.1 Identification of the Need

Various design improvements were identified during the validation phase of the product lifecycle of the Aperture Socket. Quantitative data showed little variations when comparing the Aperture Socket vs. the current participant’s socket, but qualitative data gathered from the participant’s feedback showed another perspective on the Aperture Socket design.
2.1.1 Possible Redesign Opportunities Based on Initial User Feedback

Results from the gait study and feedback from participants showed that improvements on the Aperture Socket were needed [8]. These redesign opportunities, published in the designer’s dissertation, are shown and listed below:

- Reduce wear between the adjustment mechanism plates
- Minimize stretch in the adjustment straps
- Optimize location of the socket sections
- Reduce socket straps adjustment complexity
- Increase stability of the socket: plates need to tighten and secure because they move slightly and they could be loosening up over time.
- Reduce cost

Furthermore, different key activities were defined during the exploratory research, this helped to characterize the solution space, and the translation of stakeholder needs to system requirements. These activities consisted of the identification, clarification, and documentation of the stakeholders’ conceptual operation of the prosthesis across the different stages of use and their intended environment of use. To do this, a local prosthetic clinic was visited and the first interview took place with the prosthetist onsite. The interviewed prosthetist has 40+ years of experience in prosthetic practice with a major focus on working with lower limb amputees. A semi-structured interview utilizing an open-ended question format was performed to identify all the possible user needs. After the 2-hour interview with the local prosthetist, the data collected was analyzed and compared against the redesigned avenues identified on for the Aperture Socket.

Based on the responses from the onsite interview, a set of customer needs were identified. These are:

- Protect bony prominences at all times
- Compensate volume loss
• Keep it simple. Amputees must wear components that they can understand due to cognitive impairments
• Vacuum and suction suspension systems help patients in having a more sense of secureness while using their prosthesis
• Keep design and technology cheap
• Increase the effective usability time on sockets by providing a longer comfortable lifespan
• Keep it light

2.2 Elicitation of System Requirements

The basis of the system design and its development consist of the definition of the system requirements. The objective is to transform the stakeholder and user-oriented view of desired capabilities into a more technical view of a solution that should meet the needs of the user in an operational manner. It is, therefore, crucial that a complete set of requirements be defined and established by stakeholders and users in the early project life cycle.

The characteristics of the system are specified by the requirements, attributes, functions, and performance desired to meet the stakeholder demands. Requirements definition is both iterative and recursive, according to the ISO/IEC/IEEE 29148 Requirements Engineering (2011), and includes the activities of preparing for system requirements definition, and defining system requirements.

2.2.1 Prepare for System Requirements Definition

In this stage, the preparation of tools and resources to gather the system requirements is set and defined. To begin the definition of requirements for the redesign of the Aperture Socket, various techniques for requirements elicitation are implemented. These techniques are literature review, interviews, and simulation tools.
**Literature Review.** A literature review was conducted to define the problem space. The results of this literature review are reflected throughout this thesis.

**Interviews.** A total of 23 stakeholders were interviewed to gather the minimum requirements of the system. The interviews were conducted face-to-face (20), via skype (2), and via phone call (1). Each interview was conducted in a free-form format, but also included a set of 10 open-ended questions prepared in advance (See *Stakeholder Interview* in Appendix I for more details). The responses gathered from these interviews aided in understanding the current state of the art of the prosthesis, the process of prescribing a prosthesis for lower-limb amputees, building process of the prosthetic sockets, and the current boundaries and limitations according to the state of health, physical capabilities, and financial capabilities of the amputee.

Later, interviews were also conducted during the participation of the I-CORPSTM program, a commercialization program sponsored by the National Science Foundation. During the program, more than a 100 stakeholders were interviewed across the country. Also, while interviewing and gathering data, many benchmark opportunities were presented in which prosthetists and patients showed many different solutions that are being under development in the present days. Feedback from experts in the matter was compiled, and a new design iteration emerged.

**Simulation tools.** Technical requirements were gathered and defined by analyzing the stakeholder’s requirements using simulation tools. These include the use of CAD, preliminary prototypes using a 3D printer MakerBot Z18, and paper drawings. Ideas generated as a result of interviews and group meetings were tested using these simulation tools. As a result, technical requirements were identified during these tests to improve the feasibility and capabilities of the redesign opportunities.
2.2.2 Define System Requirements

The definition of the system requirements consist of first identifying system functions and then articulating system constraints, limitations, and critical quality characteristics. As a result from the elicitation activities, requirements were defined and categorized as system functions, constraints and limitations, and quality characteristics.

Table 1. Redesign System Requirements

<table>
<thead>
<tr>
<th>Requirement ID</th>
<th>Requirement Description</th>
<th>Type of Redesign Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The socket should be custom made per each amputee’s residual limb</td>
<td>System Function</td>
</tr>
<tr>
<td>2</td>
<td>The socket should provide support to the entire residual limb</td>
<td>System Function</td>
</tr>
<tr>
<td>3</td>
<td>The socket should have special points of support for bony prominences (tibia, fibula head, etc.)</td>
<td>System Function</td>
</tr>
<tr>
<td>4</td>
<td>The socket should not increase pressure on bony prominences at any time</td>
<td>System Function</td>
</tr>
<tr>
<td>5</td>
<td>The adjustment system should be user-friendly</td>
<td>System Function</td>
</tr>
<tr>
<td>6</td>
<td>Adjustment mechanism should use prosthetic conventional hardware/tools</td>
<td>System Function</td>
</tr>
<tr>
<td>7</td>
<td>The socket should be adaptable to pin-lock and suction suspension system</td>
<td>System Function</td>
</tr>
<tr>
<td>8</td>
<td>The socket should be able to adapt to daily volume changes of 15%</td>
<td>System Function</td>
</tr>
<tr>
<td>9</td>
<td>The socket should be compatible with the adjustment mechanism</td>
<td>System Function</td>
</tr>
<tr>
<td>10</td>
<td>Vacuum suspension system might not be available for the adjustable socket system</td>
<td>Limitations and Constraints</td>
</tr>
<tr>
<td>11</td>
<td>A socket made out of polypropylene might not be adaptable to the adjustment mechanism</td>
<td>Limitations and Constraints</td>
</tr>
<tr>
<td>12</td>
<td>Long residual limbs might not be suitable for the adjustable socket due to the thickness of the adjustment mechanism. A certain length is needed for the rest of the prosthetic components to be attached (Pyramid, pylon, foot, etc.)</td>
<td>Limitations and Constraints</td>
</tr>
<tr>
<td>13</td>
<td>Some level of expertise and manufacturing training is necessary prior manufacturing the socket</td>
<td>Limitations and Constraints</td>
</tr>
<tr>
<td>14</td>
<td>Specific machinery is needed to manufacture the adjustment mechanism</td>
<td>Limitations and Constraints</td>
</tr>
<tr>
<td>15</td>
<td>Cognitively impaired users might not perform efficiently the adjustment capabilities of the system</td>
<td>Limitations and Constraints</td>
</tr>
<tr>
<td>16</td>
<td>The system should successfully pass the safety norms per ISO 10328:2006 for structural testing of lower-limb prostheses</td>
<td>Quality Characteristics</td>
</tr>
<tr>
<td>17</td>
<td>Users should have training in using the adjustment system</td>
<td>Quality Characteristics</td>
</tr>
<tr>
<td>18</td>
<td>The system should provide comfort and protection on sensitive bony zones</td>
<td>Quality Characteristics</td>
</tr>
</tbody>
</table>
2.3 Development Stage

The development of the full prosthetic system was segmented in two subsystems: the adjustment mechanism and the adjustable socket. The first subsystem to be developed was the adjustment mechanism followed by the adjustable socket. Various design iterations of both subsystems are further defined in Chapter 3.

The resultant concepts of the Adjustment Mechanism were modeled and analyzed using Siemens NX 10.0. Further analyzed concepts were then prototyped with additive manufacturing techniques (3D Printing) using a MakerBot Z18 and Computer Numerical Control (CNC). The resultant concepts of the socket redesigns were prototyped using typical vacuum forming techniques for prosthetic sockets. Prototyped concepts are defined and described in more details in Chapter 3. The prototypes were then verified using Interface Testing to validate the adaptability of the socket design with the adjustment mechanism.

2.4 Testing Stage

After verifying the functionality of the system components, the process then proceeds to verify and validate the design based on system requirements and design criteria defined in early stages of the product development. Verification procedures include the volumetric, weight, and strength analysis of the redesign, described in Chapter 4.
Chapter 3: Redesign of the Aperture Socket

The redesign of the Aperture Socket has been prototyped based on the translated user needs to technical requirements described in Chapter 2. The specific design criteria and specifications, along with the different iterations prior manufacturing the detailed design are discussed in this chapter. Further verification and validation stages from mechanical strength tests are described in Chapter 4. The redesign adjustable prosthesis system has been divided into two main subsystems: The adjustment mechanism and the adjustable socket.

3.1 THE ADJUSTMENT MECHANISM

One of the key aspects in adjusting the volume of the socket is its adjustment mechanism. The primary focus in improving the redesign of the Aperture Socket is the application of engineering to the development of a mechanism able to adjust the socket in the most efficient manner while complying with the redesign avenues identified during the analysis of the socket redesign. Therefore, the first conceptual redesign version for the adjustment mechanism was developed based on the original adjustment mechanism from the Aperture Socket [8].

The design criteria for the adjustment mechanism has been derived from improvements identified during the validation stage of the original Aperture Socket and from the requirements derived from the elicitation process described in section 2.2
Table 2. Design Criteria for the Redesign Adjustment Mechanism

<table>
<thead>
<tr>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must be able to adapt to the adjustable socket</td>
</tr>
<tr>
<td>2. Radial translation of the guide screw needs to produce a volume change of ±15%</td>
</tr>
<tr>
<td>3. Must be able to provide stability on the socket sections</td>
</tr>
<tr>
<td>4. Mechanism should be able to remain still at the desired adjustment</td>
</tr>
<tr>
<td>5. Minimize thickness area such as to include its adaptability for short residual limbs</td>
</tr>
<tr>
<td>6. Weight less than 300g</td>
</tr>
<tr>
<td>7. Should be able to manufacture using basic machinery</td>
</tr>
<tr>
<td>8. Must be able to withstand the ultimate strength test from ISO 10328</td>
</tr>
</tbody>
</table>

3.1.1 Conceptual Design – Version 1

The first concept was developed to meet the design criteria listed in Table 2. It consists of a set of disks; one named the rotational disk (Figure 15) and the second one the transfer disk (Figure 16). The round design of the disks mimics the distal end design of a prosthetic socket (Specification 1). This is with the purpose of providing stability and consistency in the socket design (Specification 2), as well as to be adaptable to the distal end of any particular custom-made socket. The slots of both disks are used to guide the screw that is going to be attached to each socket section during expansion and contraction. The transfer disk has four straight slots that allow the guide screw to move inwards and outwards based on the input torque. This inward and outwards movement is caused by the curved slots of the rotary disk which pushes in and out the guide screw as it is rotating clockwise or counterclockwise, also based on the input torque. Four slots have been selected which correspond to the number of sections of the original Aperture Socket.
Figure 15. Rotational disk v1.0 (Left, top view; Right, Isometric view)

Figure 16. Transfer disk (Top L, Top view; Top R, Isometric top view; Down L)
For a better understanding of the concept, a full CAD assembly of the system was designed (Figure 17), including the socket, the adjustment mechanism and the pylon connector (pyramid).

![Assembly diagram](image)

**Figure 17. Assembly – Second redesign iteration of the adjustment mechanism**

To successfully transfer the four socket sections along the radial direction, a transfer guide screw is needed, one that serves as a connector of the socket sections onto the rotational and transfer disk. The most important functionality of the transfer guide screw is to translate the sections of the socket in a +/- volume range, i.e. collapse and expands the sections to increase or decrease the volume of the socket. Figure 18 shows the transfer guide screw that is to be placed in each of the four sections of the socket.
Figure 18. Assembly - Second redesign iteration of the adjustment mechanism with transfer guide screws.

After designing the full system of the first design iteration of the adjustment mechanism, the system was verified using the modeling software NX 10.0. To do so, the system components were designed independently and put together on a full system assembly with their proper constraints between the components to complete a realistic simulation. These constraints consisted on fixing the transfer disk; allowing only rotation on the Yc axis (as shown in Figure 19) for the rotational disk; and allowing translation of the guide screws only along the guide slots of the transfer disks, i.e. translation over the Zc axis.

3.1.1.1 Results

The simulation of the adjustment mechanism system on CAD successfully demonstrated that by rotating the rotary disks, the transfer guide screws would collapse and expand while following the path of the transfer slots of the transfer disk, as shown in Figure 19. Further, once the concept was validated, the engineering process begun to develop the adjustment system based on the Design Criteria from Table 2 and the Technical Requirements listed in Table 1.
3.1.2 Preliminary Design of the Adjustment Mechanism – Version 2

Given the defined design criteria and technical requirements, the analysis of the adjustment mechanism design was made with the proper calculations for each statement using paper and simulations in NX 10.0 (See Design calculations on Appendix IV). Siemens was used to simulating and prove the precision of the estimates. Any changes and improvements were made using CAD tools to better increase the accuracy of the functionality of the adjustment system.

As a result, the first preliminary design of the adjustment mechanism is shown below:
Initial parameter values based on the design concept for the adjustment mechanism are summarized in Table 4. To continue deploying this redesign adjustment mechanism alongside the LIMBS prosthetic components, as the original Aperture Socket does, the concept was designed to allow the use of conventional millimetric flat headed hex screws and Delrin® material a Polyoxymethylene chemical compound known as an acetal homopolymer resin. Its low cost, mechanical and thermal properties made Delrin®
the best plastic candidate to replace the PLA material used in the previous dummy design (see Table 3).

Table 3. Delrin Property Values (SDSPlastics, 2017)

<table>
<thead>
<tr>
<th>Properties</th>
<th>ASTM Test Method</th>
<th>Units</th>
<th>Delrin 150</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density</td>
<td>D792</td>
<td>lb/in³</td>
<td>0.0513</td>
</tr>
<tr>
<td>Tensile Strength</td>
<td>D638</td>
<td>Psi</td>
<td>9,000</td>
</tr>
<tr>
<td>Tensile Modulus</td>
<td>D639</td>
<td>Psi</td>
<td>350,000</td>
</tr>
<tr>
<td>Heat Deflection Temperature</td>
<td>D648</td>
<td>°F</td>
<td>336</td>
</tr>
<tr>
<td>@66 psi</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@264 psi</td>
<td>D648</td>
<td>°F</td>
<td>257</td>
</tr>
</tbody>
</table>

Initial parameter values of the technical concept of the adjustment mechanism are summarized in Table 4.
Table 4. Initial Parameter Values for the Preliminary Adjustment Mechanism Design

<table>
<thead>
<tr>
<th>#</th>
<th>Description</th>
<th>Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Rotary Disk</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>Angle of rotation</td>
<td>20</td>
<td>Deg</td>
</tr>
<tr>
<td>B</td>
<td>Disk diameter</td>
<td>83.3</td>
<td>mm</td>
</tr>
<tr>
<td>C</td>
<td>Disk thickness</td>
<td>10</td>
<td>mm</td>
</tr>
<tr>
<td>D</td>
<td>Curve slot hole diameter</td>
<td>6</td>
<td>mm</td>
</tr>
<tr>
<td>E</td>
<td>Outer curve slot diameter</td>
<td>14.2</td>
<td>mm</td>
</tr>
<tr>
<td>F</td>
<td>Inner curve slot diameter</td>
<td>8.2</td>
<td>mm</td>
</tr>
<tr>
<td>G</td>
<td>Inner latching slot diameter</td>
<td>73.5</td>
<td>mm</td>
</tr>
<tr>
<td>H</td>
<td>Outer latching slot diameter</td>
<td>78.5</td>
<td>mm</td>
</tr>
<tr>
<td>I</td>
<td>Roughing latching depth</td>
<td>1</td>
<td>mm</td>
</tr>
<tr>
<td></td>
<td><strong>Transfer disk</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J</td>
<td>Disk diameter</td>
<td>83.3</td>
<td>mm</td>
</tr>
<tr>
<td>K</td>
<td>Disk thickness</td>
<td>10</td>
<td>mm</td>
</tr>
<tr>
<td>L</td>
<td>Radial adjustment at 15%</td>
<td>11.2</td>
<td>mm</td>
</tr>
<tr>
<td>M</td>
<td>Inner transfer slot hole diameter</td>
<td>6.5</td>
<td>mm</td>
</tr>
<tr>
<td>N</td>
<td>Inner transfer slot length</td>
<td>17.60</td>
<td>mm</td>
</tr>
<tr>
<td>O</td>
<td>Outer transfer slot hole diameter</td>
<td>12</td>
<td>mm</td>
</tr>
<tr>
<td>P</td>
<td>Outer transfer slot length</td>
<td>17.63</td>
<td>mm</td>
</tr>
<tr>
<td>Q</td>
<td>Inner latching slot diameter</td>
<td>74</td>
<td>mm</td>
</tr>
<tr>
<td>R</td>
<td>Outer latching slot diameter</td>
<td>78</td>
<td>mm</td>
</tr>
<tr>
<td>S</td>
<td>Latching extrusion</td>
<td>1</td>
<td>mm</td>
</tr>
</tbody>
</table>
Figure 22. Initial parameter values for the rotary disk
Figure 23. Initial parameter values for the transfer disk.

Figure 24. Rotation parameter values for the first concept assembly design
3.1.2.1 Prototyping of the Preliminary Design

Various versions of the adjustment mechanism were prototyped using additive manufacturing techniques. The 3D models were printed in a MakerBot Z18 using Polyactic Acid plastic (PLA) as the filament material.

The first step of the preliminary design stage consisted in 3D printing a simulated socket base that can replicate a section of it. The objective of this stage is to simulate the translation of the socket sections along with the adjustment mechanism to verify by demonstration its overall performance, detect any defects injected in the design, and to identify any opportunities for improvement.

Figure 25 depicts the assembly of the first preliminary design stage.

![Socket base assembly with adjustment mechanism](image)

Figure 25. Socket base assembly with adjustment mechanism

Furthermore, the mentioned design assembly was prototyped and verified using demonstration techniques described below. Various defects in the design were detected and a second version of the adjustment mechanism was designed and prototyped (Section 3.1.2.2)

3.1.2.2 Verification and Validation of Preliminary Designs

After prototyping the first assembly, it was found that the slots of the transfer disk were designed without considering the radius of the guide screw head after translating it to the fullest, i.e. the screw was not fully translated because the head was obstructing. Second,
it was found that the diameter of the curved slots of the rotary disk does not coincide with the ones of the transfer disk. Third, the latching extrusion on the transfer disk is so thin that the printing quality was variable each time a prototype was printed. Also, for future machining procedures, creating such a thin latching mechanism between plates could become compromised due to the high precision needed.

Therefore, various iterations were designed and prototyped. The first set of prototypes consisted of three versions (see Figure 26), the first version was aimed to include the new calculations on the head screw radius, and it was prototyped to demonstrate the translation of the guide screw over the transfer disk while rotating the rotary disk. The second set of disks included a new latching method between plates (Figure 26 – 2) to avoid lateral slipping while rotating the mechanism. Due to the defects found and described previously in this second set of disks, a third latching version was designed and prototyped (Figure 26 – 3). This third version of disks showed a more feasible and simple solution to maintain the disks in place during any play between them due to the increased contact area and because of the higher tolerance rate in manufacturing the pieces.

Figure 26. First 3 set of adjustment mechanism prototypes (1- Conceptual design prototype, 2- Adjustment Disks with latching grip, 3- Adjustment Disks with latching surface area).
Demonstration as a verification method

After demonstrating a better performance on the third set of disks, it was then proceeded to validate its functionality on a socket. The first manufactured socket was based on the Aperture Socket manufacturing procedures. This first socket was then mounted onto the adjustment mechanism and presented during the LIMBS International Summit 2016 that took place at The University of Texas at El Paso (UTEP). The preliminary socket design was manufactured using a flexible Orfitrans™ medium soft plastic material for demonstration purposes.

From the six verification methods described by the Systems Engineering Handbook of the International Council on Systems Engineering (INCOSE; Inspection, analysis, analogy or similarity, demonstration, test, and sampling) [50], demonstration was chosen as the method to verify the improved functionality and performance of the adjustment mechanism. The first demonstration was made on a manufactured check socket. A modified version of the check socket was developed to adapt the sections of the socket to the new redesign adjustment mechanism. The modified version consisted of embedding one t-nut on each socket part to screw the M6x12 mm guide screw. Figure 27 depicts the first full system prototype.
Figure 27. Adjustable check socket with a mounted prototype of the adjustment mechanism (Top left, section socket with T-nut embedded; Top right, inside view of the check socket; Bottom left, side view of the adjustable check socket; Bottom right, Bottom view of the adjustable mechanism/adjustable socket).

Results from demonstrating the functionality of the full assembly and feedback during the LIMBS Summit 2016 was obtained. Different design opportunities emerged including:

- The adjustment mechanism should be capable of attaching a pyramid adapter, which is not currently capable of.
- There is high difficulty on rotating the rotary disk due to its thin design.
- There is confusion on what disk to rotate when adjusting the mechanism due to the design similarities
- There is no locking feature when adjusting the socket to keep it in a particular position.

These new design opportunities were then addressed in a new version of the adjustment mechanism (version 3). Therefore, a new gripping method was designed, and embedded hex nuts were added in the rotary disk to allow attachment of the pyramid adapter. At the same time, this new gripping method was designed to make socket adjustment easier and reduce confusion when adjusting the socket by providing a more ergonomic grip that simultaneously differentiates the disks. Figure 28 depicts a set of new designs that integrate a pyramid attachment point and ergonomic grip for the fourth version of the adjustment mechanism.

![Figure 28. Adjustment mechanism Version 4](image)

To develop the fourth version of the adjustment mechanism, various combinations of the gear-like gripping design were prototyped using 3D printing to improve the ergonomics of each disk. The combination prototyped for testing consisted of:
1. Rounded rotary disk mounted on a gear-like transfer disk
2. Gear-like rotary disk mounted on a rounded transfer disk
3. Gear like rotary disk mounted on a gear-like transfer disk

The demonstration results showed that the highest ergonomic combination for the gear-like design disks was the combination consisting of a gear-like rotary disk mounted on a rounded transfer disk. The addition of the hex nuts embedded in the transfer disk provided an attachment point for the pyramid adapter, which follows the same attachment procedures of a pin-lock adapter. The size of the hex nut corresponds to an M6X8.0 screw conventionally used in the prosthetics industry to attach pyramid adapters. The embedding of these nuts consists of mounting the hex nut on the top of the transfer disk by press-fitting it into a corresponding hex nut slot (shown in Figure 29).

![Embedded hex nuts in transfer disk - Version 3](image)

**Window latches**

To comply with the fourth specification (Mechanism should be able to remain still at the desired adjustment) of the design criteria from Table 2, a locking feature for the set of disks was developed. This locking feature allows users to maintain the desired volume adjustment at a particular position. The first design iteration consisted of the addition of two “window latches” on the rotary disk as shown in Figure 30. The objective of the window latches is to lock the disks to each other through the use of a screw to limit
rotational and translational movement. This window latch feature addresses the final improvement opportunities found while verifying the first prototype of the full system:

- The adjustment mechanism should be capable of attaching a pyramid adapter, which is not currently capable of.
- High difficulty in rotating the rotary disk due to its thin design.
- It results confusing to grab the rotating disk with the transfer disk.
- There is no locking feature when adjusting the socket to keep it in a particular position.

Figure 30. Locking mechanism – window latches - attached on the rotary disk

To incorporate the window latches onto the rotary disk, a modification of the transfer disk was then needed. This need lies on allowing a flat-head screw to tighten the window latches on the transfer disk, as seen in Figure 31. To keep consistency in the design, a millimetric screw and the correspondent millimetric nut was sought. Different options were evaluated based on the ease of use and the total area of tightening support. Table 4 shows the different screw options that were evaluated.
Table 4. Window Latch Screw Evaluation

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
<th>Dimensions</th>
<th>Adjustment tool</th>
<th>Figure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Metric Stainless Steel</td>
<td>Head: 12mm</td>
<td>Hex key</td>
<td><img src="image1.png" alt="Image" /></td>
</tr>
<tr>
<td></td>
<td>Hex Drive Flat Head Screws</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Union Toe Strap Adjustment Screws</td>
<td>Head: 20mm</td>
<td>Hands/Fingers (use of a lever)</td>
<td><img src="image2.png" alt="Image" /></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Burton Binding Strap Adjustment screw</td>
<td>Head: 18mm</td>
<td>Phillips screwdriver</td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

From the options given in Table 4, the Union toe strap adjustment screw was chosen to be the adjustment screw for the window latches due to its wider contact area with the window latches and because of the tool-free adjustment. The easiness of adjusting the screw will allow users to manually adjust the plates without the need for any additional tools. Also, the larger contact area decreases the likelihood that the discs will unlock between them due to the constant movement produced when an amputee is in motion.

To attach the window latch screw, a modification on the transfer disk was made. This modification included an embedded square nut in the transfer disk as shown in Figure 41.
The assembly of this full redesign is shown in Figure 32.
After fully assembling the disks and the window latches in CAD, the design simulation assembly was then prototyped to demonstrate strength capabilities and adjustment performance.

**Demonstration of the window latches**

Demonstration of the adjustment performance was satisfactory. However, the strength capabilities of the design did not pass the demonstration test.

Results showed that the window latch screw produces a high amount of stress on the bottom part of the window latches. The window latches are then bent, and the screw produces fatigue that consequently exceeds the elastic zone of the material to lead it to failure finally. The failure of the window latches is shown in Figure 33.

![Figure 33. Broken window latches on the first prototype](image)

After analyzing the results, it was determined that the design of the window latches needed to be treated as a separate element and made out of a robust material, such as aluminum. To do so, an Aluminum 6061 T6 tube was sought with similar dimensions (diameter and thickness) as the original window latch design.

Furthermore, the window latches were manufactured in aluminum using basic machining procedures at the Machine Shop at UTEP (See Appendix III for more details).

The addition of the window latches, as a separate element from the system, required another modification on the disk where they are to be assembled, i.e. the rotary disk.
This change consisted of embedding two square nuts per window latch in the rotary disk, giving a total of four embedded square nuts as shown in Figure 34.

Figure 34. Adjustment mechanism with aluminum window latches

3.1.2.3 Conclusion

The demonstration technique used during the verification process helped in detecting many defects injected during the design process. At the same time, many improvement opportunities emerged to provide a stronger, more stable, and user-friendly adjustment system for the transtibial socket. A modification of the Aperture Socket is now presented, including its adaptation to the new adjustment mechanism and subsequent testing, are presented in the next section.

3.2 Redesign of the Socket

As the design process of the adjustment mechanism was evolving, so was the redesign of the socket.

The first socket redesign was manufactured in the early stages of the system design, depicted in Figure 27. Its first redesign iteration included the addition of a T-nut on the distal end of each socket section to connect the socket to the guide screw attached to the adjustment mechanism. Also, Chicago screws were replaced by the Union Toe Strap Adjustment Screws (described in Table 4) on both adjustment straps. This was with the
purpose of complying with the user requirement #5 of Table 1- “The adjustment system should be user-friendly.”

The second design iteration of the socket was the result of analyzing some of the requirements gathered during the early stages of the system lifecycle and the participation of the I-CORPS™ program.

This new second design iteration was aimed at complying with the fourth elicited system requirement: *the socket should not increase pressure on bony prominences at any time*. This requirement needed a modification of the full system of the transtibial prosthesis. Since the design of the Aperture Socket is intended to provide a uniform radial volume change, it results in reducing volume on bony prominences areas that consequently increases pressure on these areas. Therefore, a modification on the adjustability performance of the adjustment mechanism and the socket design is then needed.

To protect the bony prominences of an amputee’s residual limb, a change in the volume compensation method should be made. This change consists of avoiding global volume changes and allowing volume compensations in particular areas on the residual limb that can be modified and does not affect bony areas.

Therefore, a modification of the adjustment mechanism was designed to hold in place the anterior socket section that covers the primary the bony areas (tibia and fibula head). This allows the socket to focus the volume adjustment over the posterior areas of the residual limb where the majority of the volume fluctuating soft-tissue is located. As a result, the anterior section of the prosthetic socket that protects the tibia remains steady while the areas over the calf muscles (including the gastrocnemius and soleus) can be modified to adjust available volume (Figure 36) [43].

Figure 35 shows a comparison of preliminary adjustment mechanism design versus the design that protects the bony areas of the residual limb.
However, in this stage, it was noted that maintaining the position of one section of the socket would affect the alignment and structure support of the socket to the residual limb. Therefore a change from overlapping **socket sections** to **socket struts** with a flexible socket insert was made (See Figure 37).

The purpose of the addition of the socket struts was aimed at providing a more secure structural support that can compensate volume loss in common areas by pressuring a flexible socket. Also this design changed was motivated by reducing the manufacturing
complexity of overlapping surfaces (socket sections). This new idea is also intended to reduce future socket replacements to only the flexible socket.

Figure 37. Comparison of the Aperture Socket with overlapping socket sections (Left) vs. the Redesign Aperture Socket with struts and flexible socket insert (Right)

A preliminary embodiment of the full Aperture Socket, including the new strut system and adjustment mechanism, is shown in Figure 38.
Prior beginning with the implementation design phase, it is needed to summarize the detailed design of the entire system and to verify and validate each element [44]. The detailed design phase of a system is still an abstraction, but it should have enough details and information to verify the system requirements that were allocated to each component summarized in Chapter 2 [42].

To do so, the first detailed design of the redesign adjustable socket has been manufactured using conventional prosthetic manufacturing procedures. This full prototype was manufactured in collaboration with local prosthetic clinicians and technicians from Hanger Clinic, El Paso, Texas who have over 30 years of experience in the field. The
manufacturing process to be followed is based on the process used for the original Aperture Socket with appropriate modifications to adapt it to the new redesign adjustable socket (see Appendix V). The following procedures depict the different changes that have been implemented during the manufacturing of the redesign

**Adjustment mechanism**

After successfully verifying the preliminary designs for the adjustment mechanism above, both disks were manufactured (rotary and transfer disk) on what would be the final detailed design for further verification and validation tests (see Chapter 4). As defined previously, the final device is to be manufactured using Delrin® (see Table 3 for Delrin property values). The device is machined out of Delrin® using the CNC machines located in the Machine Shop at the University of Texas at El Paso. Figure 39 depicts the Final detailed design of the adjustment mechanism assembly. Also, final detailed design specs can be found in Appendix IV.

![Figure 39. Detailed adjustment mechanism assembly](image)

**Adjustment straps**

As in the original version, the use of adjustment straps in the redesign socket is needed to keep in place the four different struts. The application of straps is aimed at improving ease of use by providing a faster and more efficient method of adjustment while also increasing stability and socket strength.
Therefore, two different sets of adjustment straps were tested. First, a similar approach of the adjustment straps on the Aperture Socket was used on the redesign to verify the usability and strength performance (Figure 40). Second, off-the-shelf ratchet straps were acquired and tested to check the same parameters as the original straps approach.

Figure 40. Aperture Socket adjustment straps

Figure 41. Redesign m2® adjustment straps with adjustment ratchet

The m2® ratchet straps were selected due to its high-end design and performance. These straps were designed for skiers and athletes of all ability. Some of its features include simple tightening and loosening, and fine tuning of belt tension to provide a more comfortable and performance use. Its application includes sports, prosthetics, and military.
Table 5. m2® Adjustment Strap Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>1</td>
<td>Inch</td>
</tr>
<tr>
<td>Length</td>
<td>26.5</td>
<td>Inch</td>
</tr>
<tr>
<td>Width</td>
<td>1.5</td>
<td>Inch</td>
</tr>
<tr>
<td>Weight</td>
<td>2.6</td>
<td>Oz</td>
</tr>
<tr>
<td>Max Load</td>
<td>300</td>
<td>Pounds</td>
</tr>
</tbody>
</table>

Manufacturing Socket Wall Segments with Embedded Nuts

The first challenge in manufacturing a definitive laminated socket was to insert a nut able to be connected with the guide screw. The previous version detailed in the preliminary stage of the system lifecycle (Figure 27) allowed the connection of the guide screw through the use of a T-nut. However, definitive versions of a socket require the use of more durable, stiffer, and stronger materials to provide a longer lifespan and enough support to amputees for daily life challenges. Embedding a T-nut in a check socket (made out of polypropylene or polyethylene) is easy, its process only requires the nut be pressed into the desired area with basic hand tools. Unfortunately, due to the use of carbon fiber and fiberglass materials, embedding a T-nut becomes a more challenging task.

Therefore it was defined that for definitive versions of the redesign socket, hex nuts will be used, rather than T-nuts, to keep consistency in the inventory system tools since hex nuts are also used in the adjustment mechanism.

Therefore, a dummy mold (Figure 42) was designed, and 3D printed to allow embedding of the hex nuts into the distal end of each socket section. Also, this dummy mold was aimed to provide symmetry on the distal end of each of the sections.
After 3D printing the dummy mold, the definitive socket was manufactured. Manufacturing procedures and details are described below.

**Manufacturing the definitive redesign socket**

The materials used in the final version of the redesign socket consist of materials similar to those used to manufacture a traditional, non-adjusting, carbon-fiber definitive socket. These same materials were also used in the original Aperture Socket. Prior to manufacturing the definitive socket, a list of materials was defined and are listed in Table 6. While a brief version is shared here, a more detailed explanation of the manufacturing process is defined in the Appendix V.

The first attempt at manufacturing the detailed product, however, resulted in a failure. After laminating the socket, it was noted that the dummy mold (Figure 43) melted into the distal end of the socket. The exothermic reaction of curing the epoxy used in laminating the socket (Epoxy Acrylic Resin EAR1) resulted in such high temperatures (294F, 146C) [56] that the PLA material used in the 3D printed dummy, which has a melting point of ~174C [45], deformed (Figure 43).
Figure 43. Dummy mold melted on distal end of definitive redesign socket

Table 6. Material Specifications Used for Definitive Socket Manufacturing

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Picture</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PVA Bags</td>
<td><img src="image" alt="PVA Bags" /></td>
</tr>
<tr>
<td>2</td>
<td>Cotton Stockinette</td>
<td><img src="image" alt="Cotton Stockinette" /></td>
</tr>
<tr>
<td>3</td>
<td>Fiber glass</td>
<td><img src="image" alt="Fiber glass" /></td>
</tr>
</tbody>
</table>
Therefore, a different manufacturing material was sought. The new material selected for the new dummy mold was Delrin®. However, the machining techniques needed to manufacture the dummy out of Delrin® requires the use of CNC or also known as subtractive manufacturing machine.

To manufacture the new dummy, a black Delrin® acetal resin rod, 4” diameter, 1 ft length was ordered and sent to the University’s machine shop to further machine the piece using CNC (see Figure 44).
After successfully manufacturing the dummy mold, it was then used during the lamination of the second detailed, definitive adjustable socket. This time, after the lamination occurred, the model was easily removed from the device without any issues detected as seen in Figure 45. Also, the dummy came out from the socket intact without any dents or wear.

Following lamination, the socket then goes through the following shaping and assembly steps:

1. Shaping socket struts
2. Grinding and sanding
3. Adding hex nuts
4. Riveting socket ratchet m2® straps
5. Assembling adjustment mechanism

For more details on each building step, see Appendix V.
Final Assembly

After successfully manufacturing the components of the final redesigned Aperture Socket, the socket was assembled and prepared for verification and validation of the design (described in Chapter 4). To assemble the socket, the socket wall struts were mounted onto the adjustment mechanism before riveting the socket m2® straps (Figure 46).

Figure 46. Assembly of second detailed manufactured socket without m2® straps
Chapter 4. Verification and Validation of Detailed Design

4.1 Demonstration as a Verification Method

The demonstration of the assembly only consists of rotating the rotary disk to verify the translation of the socket struts along the radial direction given by the transfer disk. After successfully testing the translation of the socket struts, the m2® socket straps were riveted to complete the final detailed adjustable device design assembly for further mechanical tests.

Figure 47. Assembly of second detailed manufactured socket with m2® straps

4.2 Mechanical Test as a Verification Method

Two different static tests were performed on three different socket specimens following guidelines determined by the ISO 10328:2006 Prosthetics – Structural testing of lower-limb prostheses – Requirements and test methods.
**Static test set-up**

The first set of trials were executed on two sockets. The methodology used during these trials consisted of designing a set of jigs that are to mimic the propulsive phase (heel lift until toe off) of the gait cycle (Figure 48). This is with the purpose of reproducing the stage in which the maximum forefoot load takes place [8]. Similar to the setup used by Vaughan [8] to test the Aperture Socket, a third socket was tested in axial orientation.

![Figure 48. Normal biomechanics in the gait cycle](image)

**Testing equipment**

One of the challenges in testing prosthetics is the limited information available and existing guidelines, especially for transtibial prostheses. It is important to mention that there are no specific ISO standards for socket testing. Instead, a modified version of the testing apparatus for prosthetic knees was used to be adapted to the redesigned Aperture Socket.

Testing of the specimens was completed under compressive loads applied by an ISO 10328 Static Test Machine, a custom-made testing machine for prosthetic devices
developed by LIMBS International, Inc. This machine’s maximum load capacity of 6800 N exceeds the minimum load capacity of 4025 N required to complete the static test.

The equipment used to test the socket includes a pair of jigs attached to the compression machine and a dummy limb (see Figure 49), all designed and developed in collaboration with Pablo Servin, an undergraduate research assistant working at the Empathic Design Studio at the University of Texas at El Paso.

Figure 49. Static test setup (Left, Side view of the load orientation of the modified ISO standard test setup; Right, Socket testing components installed on a calibration non-adjustable check socket).
Elements of the Testing System

The testing system correspondent to the condition II requires the development of various elements. A better understanding of the system development is depicted in Figure 50, as well as a description of each element from such system.

Figure 50. Test loading applied to a socket unit with attachments, aligned to simulate a left-sided test sample.

1. Load cell – Serves as an input/output mechanism that reads force from the cylinder and sends out the results to a software.
2. Top jig – Connects the prosthetic system to the load cell.
3. Four-hole adapter – Assist as a connector of the dummy limb pylon. Also, it allows connecting at a specific position, which will count as the offset. The main objective of this element is to keep all offsets aligned.
4. Dummy limb – Transmits an even load towards the walls of the socket.
5. Socket – The specimen to be tested.
6. Adjustment mechanism – A subsystem of the adjustment system of the Aperture Socket.

7. Four-hole adapter.

8. Adjustable pylon – This piece of pylon is meant to be of different sizes, the length of the pylon depends mostly on the dummy size. This element is used to connect the distal end of the socket to the bottom jig, and its size can vary to compensate the length of the system.


10. Bottom jig – Connects the prosthetic system to the pneumatic cylinder.

11. Jig/Cylinder connector – Aids in connecting the Jig to the Cylinder.

12. Pneumatic Cylinder – It applies the upward force that will test the system.

**Dummy limb**

To complete the test, one element of the testing system consists of manufacturing a “dummy limb.” This dummy was designed and built to simulate as close as possible the real-life anatomical aspects of a human leg, such as the skin, muscles, and fat. It has been hypothesized, that by doing so, forces will be equally distributed along the inner walls of the socket, and therefore, the system will be able to simulate a more realistic gait activity to finally provide accurate results that can mimic the use of a prosthesis.

To address this need, a dummy was built out of ballistics gel (Figure 51-A), a material commonly used to simulate human-like limbs due to the similar material properties as the human soft tissue. Its manufacturing procedures include the need for a prosthetic socket (check or definitive) to pour the molten gel into it to finally let it dry until cure. Also, before pouring the gel, a structurally rigged rod is used which provides stability to the limb in simulation of a bone (Figure 51-B). This last “bone” rigid rod is used as an interface between the dummy limb and the compression machine connector (Figure 51-C).
Testing jigs

The second element of the testing system is the testing jigs. A set of two machined jigs were built; they were designed to properly fit the entire prosthetic system (Socket, dummy, distal end attachments, and connectors) inside the compression testing machine. The jigs used during the verification phase were designed specifically to meet the offsets stated by the ISO 10328:2006. The mentioned offsets state the level of force to be applied in the system which ranges from 1 to 5, known as P levels (P1 to P5), where P1 is the testing condition with the least force applied, and P5 being the level on which the load applied is the highest or also known as the ultimate static level condition.
Testing Procedure

To comply with the normative dictated by the ISO: 10328 Static test procedure, an ultimate strength test was performed on each specimen, along with a modified proof test procedure (See ISO 10328, section 16.2 for more details). The maximum load level P4/P5 was applied to ensure that the socket was loaded at the standard maximum condition based on average ground reaction force data for amputees, including those exceeding 100kg (220 lb, Table 7). For each test loading level, condition I and II represent the maximum load occurring early and late in the stance phase of walking. (See ISO 10328, Annex B for more details). Testing a socket at this level and conditions ensures that the socket is mechanically capable to be worn by any amputee.

Every condition, however, requires to develop particular equipment and procedures due to the nature of the load applied during its gait cycle phase. Therefore, the procedures and equipment developed for the further socket tests correspond to the condition II for the
test loading levels P3, P4 and P5, where the maximum load is applied late in the stance phase of walking.

Table 7. Test Forces for Test Loading Levels P5, P4 and P3 [64].

<table>
<thead>
<tr>
<th>Test procedure and test load</th>
<th>Unit</th>
<th>Test loading level (P_i) and test loading condition (I; II)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>P5</td>
</tr>
<tr>
<td>Stabilizing test force</td>
<td>(F_{\text{stab}})</td>
<td>N</td>
</tr>
<tr>
<td>Settling test force</td>
<td>(F_{\text{set}})</td>
<td>N</td>
</tr>
<tr>
<td>Proof test force</td>
<td>(F_{\text{ap}})</td>
<td>N</td>
</tr>
<tr>
<td>Ultimate static test force</td>
<td>(F_{\text{su, lower level}})</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td>(F_{\text{su, upper level}})</td>
<td>N</td>
</tr>
</tbody>
</table>

**Modified Proof Test Procedure**

1. Align socket in jig for axial loading
2. Apply \(F_{\text{set}}\) (settling force, 1024N \(\sim\)230.2 lb) for 30 seconds and record time.
3. Allow sample to rest at zero for 5 min and record time.
4. Record permanent deformation

**Static Ultimate Strength Test Procedure**

1. If the sample has completed proof test without breakage, repeat initial set-up and alignment.
2. Record loading condition and level.
3. Apply \(F_{\text{set}}\) (settling force) for 10-30 seconds and record time.
4. Increase test force at rate 100-250N/s to \(F_{\text{su}}\) (ultimate test force, 4025N–904.856).
5. Record highest test force and if failure occurred. (Failure is defined by breakage rendering the specimen unable to continue testing or inability to reach \(F_{\text{su, lower level}}\))
4.3 **Volumetric Analysis.**

The procedure for assessing volume adjustability consisted of comparing the volume of the socket in fully expanded versus a fully contracted mode. Thus, the procedure is followed by measuring the volume contained inside the socket by a liner full of water in both configurations (Figure 53). The water displaced by the second mode (fully contracted) was measured and compared with the water contained in the first mode by taking the weight of the water in both scenarios. For results see Chapter 5 Section 5.1

![Figure 53. Volumetric Liner Assessment](image)

4.4 **Weight Analysis**

One of the prosthesis-related issues of importance that has been identified by diverse people living with a transtibial prosthesis is the weight of their artificial limb. Marcia W. Legro et al. had identified and ranked the weight as one of the top 8 utility issues of moderate importance to consider when amputees wear a prosthesis [47]. Lower weight sockets are preferred. Therefore, the final volume adjustable redesign has been weighed to compare improvements dictated by the user requirements and POC to the original Aperture Socket. For results see Chapter 5 Section 5.2
4.5 VALIDATION OF THE SYSTEM DESIGN: HUMAN INTERFACE TESTING

4.5.1 Purpose

As stated in ISO/IEC/IEEE 15288,

[6.4.11.1] The purpose of the Validation process is to provide objective evidence that the system, when in use, fulfills its business of mission objectives and stakeholder requirements, achieving its intended use in its intended operational environment [48].

After verifying the strength, volume adjustability, and weight of the redesign, validation of the redesign will be carried out with one subject trial. The objective of the experiment tests is to validate adjustability performance, ease of adjustability, comfort, and pressure distribution inside the system. Results will be compared with the subject’s current prosthesis and analyzed against the design criteria and user requirements.

4.5.1 Testing Protocol

The subject for the validation trial was found through a local prosthetist in El Paso, Texas who identified and active and experienced amputee. The amputee was not experiencing any medical complications and was rated at an activity level of K3 by the prosthetist. The recommender, a licensed prosthetist, will help in building a definitive prosthetic socket for the amputee based on the redesign of the Aperture Socket. This includes casting and molding the residual limb of the patient. These trials were previously approved by the Institutional Review Board (IRB) at the University of Texas at El Paso and will be conducted according to the following procedures

User Mobility. The L-Test of Functional Mobility is used to assess user mobility. The L Test of Functional Mobility incorporates 2 transfers and 4 turns, of which at least 1 would be to the opposite side [7]. The total distance covered is less than 20m. Standardized instructions are given to the subjects to ensure successful completion of the test. The participants are evaluated and timed from the moment the command to begin is given, until
they return to a seated position [51]. Also, photos and video of the participant’s residuum while walking are taken during the trial to analyze the performance of the participant. Participants are asked to perform this activity several times, once with their current prosthetic socket and twice with the study prosthetic socket. Instructions are given to the subjects along with a demonstration to ensure successful completion of the test.

Socket Comfort. Prior to starting and after finishing performing the L-Test of Functional Mobility, the participant is asked to rate their socket comfort using the Socket Comfort Score and their ease of breathing and level of fatigue using the Borg Scale (Appendix VI). The SCS asks the patient the following question: “If 0 represents the most uncomfortable socket fit you can imagine and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb at the moment?” [50].

Static Pressure Distribution Test. In-socket pressure data will be collected during this procedure. Tekscan® sensors are placed inside the flexible socket. The participant is then asked to stand still for 10 seconds (see Figure 54) while pressure data is obtained, recorded, and stored in a computer. This is done for both the participant’s original and Aperture Socket.

The sensors are calibrated using a custom calibration system that pressurizes a gel liner in a closed system environment as shown in Figure 55. A two-point calibration method is used.
Figure 54. Mounted Tekscan™ Pressure Sensors on the Flexible Study Socket

Figure 55. Custom Calibration System of the Tekscan™ Sensors
Chapter 5: Results

5.1 Volumetric Analysis

A volumetric assessment was completed to determine the ability of the socket design to achieve the desired volume change of 15%. The assessment procedure consisted of comparing the volume change of the socket in full expanded vs. a full contracted mode. Thus, the procedure is followed by measuring the volume contained inside the socket by a liner full of water in both configuration modes (Figure 53). The water displaced by the second mode (fully contracted) was measured and compared with the water contained in the first mode by taking the weight of both scenarios. Results are shown in Table 8.

Table 8. Percentage of Volumetric Change on a Non-User Socket Assessment

<table>
<thead>
<tr>
<th>Configuration Mode</th>
<th>Weight (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – Expanded</td>
<td>2174</td>
</tr>
<tr>
<td>2 - Contracted</td>
<td>1850</td>
</tr>
<tr>
<td>Resultant</td>
<td>324</td>
</tr>
<tr>
<td>% Change Goal</td>
<td>+/-15%</td>
</tr>
<tr>
<td>Actual</td>
<td>Total of 14.90% (+/- 7.5%)</td>
</tr>
</tbody>
</table>

5.2 Weight Analysis

One of the prosthesis-related issues of importance that has been identified by diverse people living with a transtibial prosthesis is the weight of their artificial limb. Marcia W. Legro et al. had identified and ranked the weight as one of the top 8 utility issues of moderate importance to consider when amputees wear a prosthesis [47]. Lower weight sockets are preferred. Therefore, the final volume adjustable redesign has been weighed to compare improvements dictated by the user requirements and POC to the original Aperture Socket.
A list of each element of the system weighed is presented in Table 9, followed by a weight comparison graph of the Aperture Socket vs. the Redesign.

Table 9. Weight Analysis of the Redesign Aperture Socket

<table>
<thead>
<tr>
<th>Element</th>
<th>Subsystem</th>
<th>Weight (g) per element</th>
<th>Total Weight (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socket Struts (4)</td>
<td>Socket</td>
<td>~80</td>
<td>320</td>
</tr>
<tr>
<td>M2® Straps (2)</td>
<td>Socket</td>
<td>76</td>
<td>152</td>
</tr>
<tr>
<td>Rotary Disk</td>
<td></td>
<td>84</td>
<td>84</td>
</tr>
<tr>
<td>Transfer Disk</td>
<td></td>
<td>79</td>
<td>79</td>
</tr>
<tr>
<td>Window latch (2)</td>
<td></td>
<td>17</td>
<td>34</td>
</tr>
<tr>
<td>Window latches locks (2)</td>
<td>Adjustment</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Window latches screws (4)</td>
<td>Mechanism</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>M5 Square nut (6)</td>
<td></td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Screw M6 X 35 (4)</td>
<td></td>
<td>7</td>
<td>28</td>
</tr>
<tr>
<td>M6 Hex nut (4)</td>
<td></td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total Weight</strong></td>
<td></td>
<td></td>
<td><strong>723</strong></td>
</tr>
</tbody>
</table>
5.3 Strength Analysis

The first modified ISO 10328 test was completed (Figure 57) on two definitive Redesigned Aperture Sockets following the offset ultimate strength test procedure described in Chapter 4 Section 4.2. A third socket test, also with the same limb mold, was completed using an axial orientation to compare against results obtained from the axial load testing of the original Aperture Socket. All specimens were manufactured in partnership with a local Hanger Clinic. A dummy limb was built based on the limb mold used to manufacture the test sockets (Figure 51).
First Mechanical Strength Analysis Definitive Socket Results: Ultimate Strength Test

Using the method described in the Static Ultimate Strength Test Procedure, the first definitive socket was tested using the offset orientation described in the ISO standard. Loaded at a rate of 100N/s, the definitive socket was not able to withstand the minimum force to pass the settling force, $F_{set}=1024N$ (230.2lb), for the prescribed 10-30 seconds (Figure 58).
The maximum load had reached before failure was 810.28N (182.15 lb). No significant fractures were found on the specimen, and no deformation or fracture occurred in the adjustment mechanism. However, it was found that the distal end connectors of the socket broke by following a similar pattern on each socket section. The analysis of the fracture concluded that due to poor elastic properties of the acrylic contained on the distal end connectors, the high stress concentrated on such connectors lead to failure when the specimen was subjected to deflection (see Figure 59).
Second Mechanical Strength Analysis Definitive Socket Results: Ultimate Strength Test

The analysis of the first socket test failure saw the opportunity of design improvements. It was found that within socket walls, tension exerts stress on the outer surfaces, while in the inner surfaces a compressive stress is exerted. The space in between these two surfaces is called the “Null Zone,” which is where tension and compression forces are transitioning (Figure 60). This space produces an “I-Beam” effect. Therefore, the distance in between these surfaces (inner and outer wall) is directly proportional to increased resistance to fracture [50].
The second socket manufactured then saw the opportunity to create an “I-Beam” effect to have a better response to the concentrated high stresses on the distal end connectors. Within the socket, a new layup was considered. This layup consists on rearranging the fiberglass (Nyglass) to be sandwiched between the Coyote Composite (Carbon Fiber replacement) and by adding an extra layer of Coyote Composite. More specifically, the layup is as follows:

1. Add one layer of Coyote Composite
2. Add two layers of Fiberglass
3. Add one layer of Coyote Composite
4. Add two layers of Fiberglass

For more details on manufacturing procedures see Appendix V.

In addition to the new layup, two Carbon Fiber strips were mounted onto the socket dummy mold in order to increase strength on the distal end connectors, see Appendix V step 6.

After successfully manufacturing the second specimen, it was then tested using the same procedures as the first specimen. Again, similar results were obtained where the second definitive socket was not able to withstand the minimum force to pass the settling force, $F_{set}=1024$N (230.2lb), for the prescribed 10-30 seconds (Figure 61).
The maximum load had reached before failure was 736.18N (165.5lb). Similar fractures as the first test were found in the second specimen. This time, the test kept running until almost reaching the Ultimate Test Force of 4025N. Although the output readings showed a less load withstand before failure than the first test, the second specimen was able to stand a test in which a force of ~4000N was applied without showing any deformations or fractures on another element of the system, other than the distal end socket connectors. Figure 62 shows the fractures found after testing the second volume adjustable socket specimen.
Third Mechanical Strength Analysis Definitive Socket Results: Axial Load Test

A final test took place with a third manufactured specimen. This time, an axial load test was performed (Figure 63). The building process of the third definitive socket followed the same I-Beam manufacture procedures as the second definitive specimen. Also, a different testing setup equipment was prepared for the test.
Since the axial test mode does not fall within the guidelines specified by the ISO 10328 standard, the specific Load Conditions are irrelevant. The principal objective in testing the third specimen in an axial orientation is to comply with the same testing procedures followed in the Aperture Socket.

To complete a similar approach as the Ultimate Strength Test, the third socket specimen was loaded to the ultimate strength load, $F_{su}$ (4025N ~ 904.85lb) at a rate of 100 N/s. The socket successfully withstood the load for the prescribed 10-30 seconds without failure (Figure 64).
5.4 HUMAN INTERFACE TESTING

One participant was selected to validate the redesign Aperture Socket based on the initial criteria stated in Chapter 4, section 4.5. The demographics of the participant include a weight of 273lb and height of 5’8”. After performing the L-Test, the participant was asked to answer the Socket Comfort Score and the Borg Scale questionnaire as stated in Chapter 4, section 4.5. Results from the tests are shown in Table 10. The speed of the participant was recorded with a chronometer using his current socket and the redesigned Aperture Socket while doing the L-Test. A negative speed difference of 2.35 was obtained, i.e. the participant lasted longer to complete the L-Test while using the socket specimen than using his current socket (Table 10).
Results from the Socket Comfort Score show a little variance in the Pre and Post L-Test using the socket specimen shown in Table 10; the comfort score decreased from 10 to 9 after completing the test. The participant commented that even though the comfort was very good, he felt the socket struts moving side to side while he was walking.

Table 10. L-Test, SCS, and Borg Scale Results

<table>
<thead>
<tr>
<th>L-Test</th>
<th>Time (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current non-adjustable Socket</td>
<td>24.95</td>
</tr>
<tr>
<td>Redesign Aperture Socket</td>
<td>27.30</td>
</tr>
<tr>
<td><strong>Speed Difference</strong></td>
<td><strong>-2.35</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Socket Comfort Score</th>
<th>Current Socket (0-10)</th>
<th>Aperture Socket (0-10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre L-Test</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Post L-Test</td>
<td>10</td>
<td>9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Borg Scale</th>
<th>Current Socket (0-10)</th>
<th>Aperture Socket (0-10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breath Pre L-Test</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Breath Post L-Test</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Fatigue Pre L-Test</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Fatigue Post L-Test</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Pressure Distribution**

Data from only one sensor strip was recorded during the static pressure test. The computer was not able to read more than one pressure handle. Therefore, the sensor strip was allocated on the patella area for both sockets (the study socket and the current socket of the participant). The greatest peak pressure occurred in the participant’s original socket (63.99 KPa) while the peak pressure in the redesign Aperture Socket was 46.63 KPa. These peak pressures were found located in pressure sensitive areas, between the tibial tuberosity and the tibial crest [53]. High pressure concentrations in sensitive areas can compromise the quality of the socket design and therefore reduce comfort of use. Figure 65 shows the results of the pressure distribution of the redesigned Aperture Socket (Left) and the participant’s original socket (Right).
Figure 65. Pressure Distribution inside the Socket (Left, Redesign Adjustable Socket; Right, Current Socket of the Participant).
Chapter 6: Discussion and Future Work

6.1 Discussion

Results

The final manufactured adjustment mechanism met most of the design specifications established in Table 2. The mechanism was not able to produce a volume change range of +/- 15% but it achieved a total volume change of 15% with a more user-friendly interface. The addition of the m2® straps has the capability of producing an additional adjustment on volume in an ease manner in the non-bony areas of the residual limb. However, the redesign allows the mechanism to protect the bony prominences by remaining fixed the anterior socket strut when an adjustment in volume is performed. While the ISO 10328 Ultimate Strength Test for Condition II was not successfully passed, the system is able to withstand the maximum load of 4025 N in the axial orientation of the ultimate strength force for a constant time of 30 seconds.

Though the use of a dummy to embed hex nuts helps in maintaining a consistent distal end design and allow the guide screws to be aligned, it increases the risk of failure. Results from the Ultimate Strength Test showed a weak point and a high-stress concentration around the edges of the hex nuts embedded on the struts connectors when subjecting the specimens to extreme bending pressure. The brittleness of the acrylic resin and the stress concentrated on the embedded hex nuts created a fracture pattern on each socket strut. Future designs should consider alternative methods for securing the hex nuts that does not impact the strength of the distal end of the socket.

While not a significant improvement, the weight analysis saw a reduction for the redesign. Based on previously manufactured sockets of the original design, an average was obtained and compared against the new redesign Aperture Socket. The result showed a 95g weight reduction (~11%) of the previous adjustable socket design.

The results from the L-Test of the subject trials showed a reduction in speed of 2.35 seconds when using the redesign socket compared with the subject’s current socket. This
negative speed variance was due to complications that the participant had at the moment of standing up from the chair to begin with the test activity. The participant commented that it took more time for him to stand up with the socket redesign because it was the first time he was wearing it and he needed to make sure his stability was enough to rely on prior to taking the first step. Once the patient started walking, his gait was as natural as walking with his current socket, according to video records and comments from the participant.

The results from the Socket Comfort Score saw a little variance on the Post L-Test interview. The patient rated his current socket at a 10 on both L-Test scenarios, i.e. prior performing the L-Test (Pre L-Test) and after performing the L-Test (Post L-Test). On the other hand, the patient rated the study socket at a 10 during the Pre L-Test, and 9 after completing the L-Test. The patient commented after performing the L-Test with the study socket that, even though the socket has a comfortable fit, the struts feel a little bit loose, which could cause discomfort after extended periods of time.

The Tekscan™ sensors placed on both sockets (redesign Aperture Socket and the participant’s current socket) indicated a pressure concentration reduction of 17.36 KPa on the sensitive pressure areas in the redesign Aperture Socket. The results of the socket pressure reduction indicated a positive asset in the redesign since the concentrated peak pressures should be avoided in the aforementioned pressure sensitive areas (tibial tuberosity and tibial crest). It was then concluded that the flexible socket provided a higher probability of producing a more comfort use due to the reduced load applied on the pressure sensitive areas [53].

Manufacturing of System Components

There were some struggles during manufacturing of the adjustment disks due to the high precision needed. One of the advantages in using rapid prototyping is to be able to see the interaction of the components once they become real prior manufacturing the final prototype. However, machining the detailed designs of the prototypes in CNC was not as precise as using 3D Printing. Much of the defects found in the rotary and adjustment
disks of the mechanism were due to the unadjusted precision tolerance of the machines and due to the lack of detail finish given in the process. This lack of accuracy jeopardized the adjustment performance of the mechanism leading to sending for machining to a professional third party manufacturer.

The newly manufactured pieces by the third party company provided a better quality performance by fulfilling the demands of the adjustment design. Therefore, the high manufacturing precision of the parts produced a more efficient adjustment performance as the 3D printed prototypes did.

The manufacture of the window latches did not represent an issue during the process. The simplicity of the design allows for a fast and straightforward process that took around 1 hour per component pair. Minimum waste is produced from the building process, allowing future manufacturers to save material and cost.

The manufacture of the socket struts follows a simple conventional socket manufacturing process. No significant problems were found during its production. However, detail attention should be put when releasing the distal end dummy used to build the strut connectors. From the different socket manufactured, from which three were presented in this thesis, only the last specimen saw problems when releasing the dummy. After laminating the socket, the distal end was sand down to find the pins of the dummy. Once the pins were found, they were hammered using a chisel to release the dummy, as conventionally made with the previous specimens. This time it was noted that the dummy was stuck and due to the several hammer hits, the dummy came out broken.

**System Performance**

The volume adjustment works well with the mechanism. However, much torque is needed to collapse the struts if the limb is inserted into the inner flexible socket (artificial dummy limb used to simulate limb). Instead, it was noted that the best way to achieve adjustment of the struts is to do it before introducing the residual limb, i.e. insert the flexible plastic socket and adjust the struts by rotating the mechanism until the struts meet the inner
socket. Further improvements are needed to achieve easier adjustment with less torque required.

The **locking mechanism** was able to maintain a set adjustment amount. The lever of the Union Toe Strap Adjustment Screws allows the system to tighten and released in a very simple form. The window latches can be easily attached to the rotary disk, and the Adjustment Screws also can be screw easily.

A summary of the achieved design specifications is presented in Table 11.

Table 11. Summary of Achieved Design Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Pass/Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Adjustment Mechanism must be able to adapt to the adjustable socket</td>
<td>✓</td>
</tr>
<tr>
<td>2. Socket System should be able to provide a +/-15% of volume change</td>
<td>?</td>
</tr>
<tr>
<td>3. Adjustment Mechanism must be able to provide stability on the socket sections</td>
<td>✓</td>
</tr>
<tr>
<td>4. Mechanism should be able to remain still at a desired adjustment</td>
<td>✓</td>
</tr>
<tr>
<td>5. Socket System weight should be less than 300g</td>
<td>✓</td>
</tr>
<tr>
<td>6. Should be able to manufacture using basic machinery</td>
<td>❌</td>
</tr>
<tr>
<td>7. Must be able to withstand the ultimate strength test from ISO 10328</td>
<td>?</td>
</tr>
</tbody>
</table>

**Original Design vs. Redesign**

A comparison of the two Aperture Socket versions is presented in Figure 66. Improvements on the distal end connectors are also shown in Figure 67. Finally, a comparison between the adjustment mechanisms is depicted in Figure 68.

The redesign of the socket shown in Figure 66 shows a change in the adjustment method of the socket walls/struts. The custom made Velcro straps were replaced by an off-the-shelf prosthetic ratchet strap, allowing users to provide support and adjustment of the socket sections/struts on the go. Furthermore, the use of the distal end dummy allows the manufacturing of the distal end slots (shown in Figure 67) to be more precise and provided
a more concise design between sections, providing a more stable form to anchor onto the adjustment mechanism. Finally, the redesign adjustment mechanism eliminated the use of bolts and nuts to keep in place both plates/disks. Also, a locking mechanism was introduced to allow users are maintaining the desired adjustment.

Figure 66. Aperture Socket. Original Version (Left) and Redesign Version (Right)

Figure 67. Distal End Socket Connectors. Original Version (Left) and Redesign Version (Right)
6.2 **Future Work**

Further development of the redesign socket should include:

1. The transition of the process of manufacturing the adjustment disks from CNC to a more basic method. This improvement will allow manufacturers to create in-house components without depending on lengthy and expensive manufacturing processes.

2. Expand to the pin-lock system. A redesign improvement should be adaptable to the pin-lock system since it is commonly used in the developing world.

3. Replace m2® ratcheting straps for a similar off-the-shelf product. Although the m2® straps can withstand mechanical tests and to adjust the socket struts actually, the big and wide strap design may compromise their use if the user wears pants or wants to cover over the prosthesis.
4. Improve the strength of the distal end struts. Future work on creating stronger strut connectors is crucial. Current distal end struts are made out of acrylic resin that, due to its brittle material, do not withstand the force applied during the Ultimate Strength Test under Condition II of the ISO 10328 standard.

5. Fix the ratcheting straps. During the validation stage, the participant complained about the constant movement of the adjustment straps. A need to fix the ratcheting straps to the definitive socket walls has been identified to also provide a more snug fit of the socket by providing a more tighten system.
Chapter 7: Conclusion

There is a need for a prosthesis that can accommodate the constant volume changes that are present in the residual limb of lower-limb amputees. The presence of such need is becoming stronger due to the steady growth of the amputee population. Therefore, the aim of this research was to improve socket comfort, adjustability and manufacturing features of the Aperture Socket, a low-cost volume adjustable socket, patented and licensed to LIMB International, Inc. The design criteria for this redesign were derived from research via a literature review, benchmark analysis, user feedback, and requirements elicitation process from stakeholders. Based on the design criteria, and strength tests results, the redesign of the Aperture Socket was found to be an improved and feasible solution.

The verification phase of the product development was performed by acquiring quantitative data from strength tests while the validation of the socket design methods included weight and volumetric analysis. Two specimens were mechanically verified following the Ultimate Strength Test procedures dictated by the ISO 10328 for late stages of the gait cycle (P5 level, Condition II). Results showed a deficiency on the distal end connectors fracturing at ~810N (182.15lb) and ~736N (165.5N), respectively. A third experiment was conducted in an axial orientation by subjecting it to the ultimate strength force of 4025N (P5 level, Condition II). While no fracture nor appreciable deformation occurred, the socket demonstrated the ability to withstand the maximum load of the ultimate strength test in an axial orientation (4025N ~904.85lb). Volumetric and weight analysis validated the design criteria set in the early stages of the lifecycle. Results from the volumetric analysis showed that the adjustment of the redesign can accommodate a total of 15% of volume change while the weight analysis showed a ~11% (95g) of weight reduction from the original design. Finally, the in-socket pressure test saw a more distributed force over the patella area on the redesign adjustable socket compared with the current socket of the patient. The addition of a flexible socket help reducing the maximum
pressure peaks concentrated on the patella area from 63.99KPa to 46.63Kpa (total reduction of 17.36Kpa) that consequently produced a more comfortable fit.

The ease of adjusting volume mechanism will provide amputees with a greater quality of life by compensating volume changes on a daily basis and throughout time. At the same time, by replacing the soft plastic socket, prosthetist will manage easier replacements without the need of a new laminated definitive socket. Finally, the improvement asset on distributing pressure over the residual limb of the flexible plastic socket will continue providing a higher comfort and fit that will consequently aid amputees to have better control over the appliance.
References


Appendix I: Stakeholder Interview

Interview #1
Age: ~58
Nationality: Mexican
Occupation: Orthopedic, Surgeon

Q: What was/is your motivation for working in the prosthetics field?
A: Actually in orthopedics. Since I was studying medicine, I always wanted to see patients of all ages; from new born to elder people. I have attended people from 2 months old to 110 years old. With latter I performed a hip surgery to further install a prosthesis. They always give me positive energies to continue doing my work. I consider my patients my biggest motivation.

Q: What was/is your motivation for working in the prosthetics field?
A: I have different roles since I attend multiple clinics.

Q: Which of those roles/activities you enjoy the most?
A: All of them, specially working with athletes.

Q: Which role/activity you enjoy the least?
A: Working with patients with cancer. Cancer is one of the main reasons why my patients have amputations. Other diseases also are the cause of amputations such as diabetes, but these are performed different, they go on a ladder scale. This means that you start performing an amputation from fingers until you end up amputating the leg from above the knee. This happens because the blood vessels get clogged.

Q: What does it take to properly prescribe and fit a prosthesis?
A: This is not part of my business. We only perform surgeries, we amputate limbs, and then we send the patient with the prosthetist.

Q: When the patient complains about their prosthesis, do they come with you?
A: Yes. Nowadays there are a lot of features in prosthetics that allow them to have a better performance. Suction methods, for example, help the residual limb in adjust itself to the socket. Some days ago a patient brought a prosthesis made out of aluminum that was able to adjust.

Q: When you say “was able to adjust” what part of the prosthesis was the one in being able to adjust? In what manner?
A: It was the socket the one that could be adjusted. It was able to get bigger and shorter.

Q: Can you explain how it was adjusted?
A: The prosthetist was the one who was adjusting it with some methods that I have no knowledge of.

Q: Who is harder to fit, kids or adults? Why?
A: The problem with children is that they continue growing. Even if you amputate them a limb, their bone continues growing. Then the patient comes complaining because their bone, tibia or femur, is hitting the edge of the skin. The muscle does not adapt because it does not grow anymore, but the bone.

Q: Is it possible to fit children with a prosthesis?
A: Sure it is! But we need to replace it regularly because of their growth.

Q: How often?
A: Very often, a couple of times or more every year.
Q: What are the most common issues you patients complain about?
A: When they have ulcers on their residual limb. With the suction system, this problem has reduced a lot.

Q: How do you know if an amputee is having problems?
A: When the patient comes to his/her appointment they usually tell me. But the number of patients complaining about that has reduced a lot thanks to those suction systems I’m telling you about.

Q: What do you usually recommend to them when they come to you with these type of problems?
A: Either patients with above/below knee amputations, the major problem besides the residual limb is their spinal column; they have uneven gait due to an increased wear in their hip. Therefore the prosthesis needs to be well made. Unfortunately, in Mexico, we do not have good resources. Many people don't have insurance and others that do; their insurance doesn't cover prosthesis. To sum up, I would say the biggest issues are the spinal column and money.

Q: When you perform amputations, do you take into account the patient’s insurance?
A: No. I only perform the amputation and is up to the patient if they acquired a prosthesis or not.

Q: When you were mentioning those problems in the spinal column. How is that related with the prosthesis?
A: Since there is not enough muscle in the amputated limb, there is certain unbalance in the posture. That consequently causes wear in the spinal column and the hip.

Q: How do you think the prosthesis can help in reducing these problems in the spinal column and the hip?
A: The residual limb is in about a third distal of the femur. Therefore it doesn’t give much support. Even if the prosthesis is good or bad, there will be muscle deficiency.

Q: What do you think can be a more comfortable prosthesis that can solve this spinal column and hip issues?
A: No. The problem is on the muscle since there is not enough stability, there will not be good stance.

Q: Is there something you would like to improve in the prostheses?
A: The socket because is the one that supports everything. Sockets nowadays are like a cane, they don’t provide a good point of support that could allow the patient in doing their daily activities in a better manner.

Q: Are there any volume issues during the process of amputation?
A: Yes, a lot! The healing process starts right away after performing the amputation. The residual limb is first super swollen because of the trauma, and then it starts healing, and with this I mean it shrinks.

Q: Is there a typical pattern in which the residual limb is modified?
A: No, the surgical techniques we use are the same. What we do is to cover the bone with muscle.

Q: About those techniques, you use to cover the bone, does that affect the final shape of the residual limb?
A: The residual limb has to be well covered by the muscle.
Q: Does that affect the final shape of the residual limb?
A: No, the technique is the same. We just give some time to the residual limb so it can be healed up. At the beginning, the residual limb looks very awful.
Q: How much time does a patient need to wait to get fitted with a prosthesis after amputation?
A: There are some people that go and get a prosthesis right after four days, some a week after the amputation. Although they are not going to use it much, they do it, so the residual limb gets the shape of the prosthetic socket.
Q: Is that socket the final and definitive one?
A: No, the first one is only a test socket. Then they need to get a new definitive one.
Q: How long does it take to get a definitive one?
A: They are usually made in 6 weeks.
Q: How much does the residual limb shrinks after the healing process?
A: About a 20% of the volume
Q: Why do these volume reductions happen?
A: Because of the trauma. The residual limb reacts by getting swollen and then it goes back to a normal shape.
Q: What should we have asked you that we did not?
A: I think everything is fine.
Q: Do you know anyone else that we could talk to?
A: Yes, a technician here in Juarez. His name is …., you can find him by the 16 de Septiembre Street, in front of the house of the singer Juan Gabriel.
Appendix II: Design Parameters of the Adjustment Mechanism

Design of the adjustment disks was based on the modular shuttle lock dummy shown in Figure below.
Appendix III: Window Latches Manufacturing Process

Draft Design

Manufacturing Process
1. First, a negative mold was 3D printed. The mold serves as a guide to draw the cut lines on the Aluminum tube (89 mm OD, 81 mm ID). See figure below
2. After delimiting the cut lines, it is then proceeded to cut the window latches by following the delimited lines using a saw machine as seen in the figure below.

3. Then, after cutting a couple of pieces, the next step is to thinning the rail slot as shown in the following figures; this is made by using a 7 mm diameter thinning bore.
4. Finally, both holes are drilled with a 6 mm diameter drilling bore.
Appendix IV: Detailed Design Specs of the Adjustment Mechanism

CAD Draft Design

A. Rotary Disk
B. Transfer Disk
C. M5 Square nuts for top rotary disk (4) and top transfer disk (2)
D. M5 x 12mm Screw for tightening window latches to rotary disk (4)
E. M5 Burton Screw

Note: For Window Latches specifications see Appendix III
Appendix V: Definitive Manufacturing of Redesign Adjustable Socket

1. After making the limb mold using plaster-casting material, sand down the cast to create smooth surfaces

2. Place bubble formed flexible socket on the mold. Add a piece of PVA bag on the distal end of the socket, stretch it and tape it applying pressure to prevent from contracting. The piece of PVA bag is added to facilitate removing the flexible socket after being laminated.
3. Remove tape and excess of PVA bag by cutting it with a knife

4. Moisten two PVA bags for 20 minutes using a wet towel. Then, put on the first PVA bag.
5. Using clay, roll a strip around the socket-base dummy and attach it to the distal end of the socket. Align the dummy as shown in figure below

6. Add one carbon fiber strip on each socket section on the dummy mold. Make sure the strips are covering most of the section mold on the dummy as shown in the figures below.
7. Put on the cotton sock and cover the whole mold. Tie it with a thin ribbon to the tube of the mold
8. Add first layer of Coyote Composite (replacement of Carbon Fiber)

9. Add the first layer of fiber glass (Nyglass)
10. Add the second layer of Coyote Composite, and tight it to the fiberglass using a thin ribbon.

11. Add the second layer of fiberglass
12. Add second moistened PVA bag

13. Add Epoxy Acrylic, mixed with a tinted color if desired.
14. After the lamination sets down, sand down the distal end until one of the dummy pins are visible. Then, grab a sharp tool (screwdriver or chisel) and hammer down the pin until the dummy gets off the socket. Then, sand down the distal end to create a smooth flat surface.

15. Identify the socket sections and cut the socket sections following the trim lines, given by the dummy.
16. Cut the four socket sections. When sectioning the socket, keep in mind: avoid using trim lines that would run over bony prominences (Distal end of the tibia).

17. Draw a ¼ inch reduction lines over each section of the socket and sand down by following the reduction line. Sand down the excess of the socket base material.
18. After the pieces are sand down to the desired shape, wash the sections. Use a smooth sand paper to sand the sharp edges to give a smooth finish.

19. Place the M5 square nuts on each section socket. If needed, add epoxy glue on the edges of the square nuts after placing them in each slot to prevent them from falling off.
Appendix VI: Socket Comfort Scores and Borg Scales

**Interviewee may opt to not answer questions if desired.**

Date: ___________________ Location:

________________________________________________________________________

Interviewer:

________________________________________________________________________

Interview Identifier: ________________________________________________

Socket: __________________________

**Socket Comfort Score**

On a 0 – 10 scale, if 0 represents the most uncomfortable socket fit you can imagine, and 10 represents the most comfortable socket fit you can imagine, how would you score the comfort of the socket fit of your artificial limb at the moment?¹

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**Borg Scale**

“Please grade your level of shortness of breath using this scale.” Then ask this: “Please grade your level of fatigue using this scale.”

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Socket: _____________________

Socket Comfort Score
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Pre 6MWT & Gait Analysis
Breath  0   1   2   3   4   5   6   7   8   9   10
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Fatigue  0   1   2   3   4   5   6   7   8   9   10
Nothing at all

Post 6MWT & Gait Analysis
Breath  0   1   2   3   4   5   6   7   8   9   10
Nothing at all
Fatigue  0   1   2   3   4   5   6   7   8   9   10
Nothing at all
Vita

Samuel Terrazas was born in Delicias, Chihuahua, Mexico. Samuel obtained his Bachelor of Science in Aerospace Engineering from New Mexico State University in December 2013. He became interested in developing projects in the biomechanical field after having the opportunity to participate in a research project to improve insulin control for people with diabetes when he started pursuing his M.S. in Systems Engineering. He is currently working for Cardinal Health as a Leader of the logistics department.

Contact Information: sammtq@gmail.com

This thesis was typed by Samuel Terrazas Quezada