Design of a New Prosthetic Alignment Adaptor with Quantitative Alignment and Height Adjustment

A Major Qualifying Project Report:

Submitted to the Faculty

of the

WORCESTER POLYTECHNIC INSTITUTE

in partial fulfillment of the requirements for the

Degree of Bachelor of Science

by

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May, 2010

1. Prosthetics
2. Alignment
3. Adaptor

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Authorship Page

This report represents a group effort with equal distribution of writing between the team members. Each section was edited and revised by all members of the team so individual authorship would be misrepresentative of the team's work.

Acknowledgments

The team would like to thank Professor Gielo-Perczak and Professor Hoffman for taking on this design project and providing extremely useful advice throughout the year. Additionally, the team is grateful to Professor Higgins, Art Shea Lisa Wall, Tim Curran, Neil Whitehouse, and Adam Sears for their help with the project.

Abstract

After an amputation, a patient's prosthesis must be aligned with their body using an alignment adaptor. Current adaptors have two primary limitations: 1) the inability to adjust the vertical height during alignment, and 2) the inability to quantify the adjustments. Therefore, a new prototype adaptor was designed and manufactured that allows for adjustments in all six degrees of freedom, including height. In addition, a novel pin design allows for quantification of the alignment. The prototype was validated with prosthetist feedback and finite element analysis. A protocol for patient testing received IRB approval and is scheduled for the near future. Through a general cost analysis, it was estimated that the benefits of the device would save $25,000 in its ten-year lifetime.

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1.   Introduction

The number of amputations conducted annually in the United States is growing rapidly and is estimated to double by 2050 (Ziegler-Graham, 2008). While the number of patients requiring prosthetic care is increasing, there is a substantial lack of prosthetists to cater to the need (Nielsen, 2002). Due to such a lack of trained and certified prosthetists, it is extremely important for the prosthetist to be efficient with the prosthetic therapy and to maximize the number of patients they see. However, there are many parts of the prosthetic fitting procedure that are still time-consuming and crude, one of which is the alignment process.

Aligning the transtibial prosthesis is one of the most important parts of the fitting process in order to avoid injury or discomfort to the patient. Misalignment can result in asymmetric gait, causing the patient to place more load on one leg than the other (Blumentritt, 1999). Over time, this leads to damage in the healthy leg. Other complications of improper alignment include pain, slow movement, instability, incorrect posture, and high-risk stresses on hips, knees and ankles (Xiaohong, 2008).

The current standard alignment adaptor, the Fillauer Slide Unit allows for translation adjustments in the mediolateral and anteroposterior axes, and angular adjustment about all three axes, the third axis being the proximal-distal axis. However, the only way to adjust the proximal-distal distance, or height, of the prosthesis is to cut the pylon with pipe cutters or to acquire a longer pylon. This is a relatively time-consuming process that reduces the face-time between the prosthetist and patient.

During the actual fitting process, the prosthetist determines the proper alignment based on a patient's height, the structure of the sound limb, and his/her gait by subjectively observing how the patient stands and walks. Once the alignment is made, however, there is no way of quantifying the setting. Therefore, making precise adjustments or resetting the adaptor to a specific position is very difficult and time-consuming.

Thus, there is a great need to improve the alignment adaptor in order to increase precision and maximize efficiency. This need was addressed by designing a more efficient and quantitative prosthetic alignment adaptor, which possesses better functionality, increased adjustability, and allows the prosthetist to spend more time with their patients.

2.   Literature Review

Before delving into the design of the transtibial prosthetic alignment adaptor, it is important to build a solid foundation of background knowledge upon which the project can be framed. A literature review was conducted within the field of prostheses in order to fully understand the depths of the project, and to frame the goals and objectives of the design. The following sections provide a detailed documentation of the literature review conducted. Presented is information about transtibial amputations and prostheses, the importance of aligning such prostheses, an historical overview of alignments adaptors including the current state-of-the-art design, and the limitations of these devices.

2.1.   Transtibial Amputations

In order to accurately discuss limitations of certain transtibial prosthetic designs, one must have a solid understanding of what a transtibial amputation is, and how such amputations affect the anatomy of the lower leg. This section provides a brief overview of transtibial amputations, and changes to the anatomy of the limb due to such procedures.

A transtibial amputation is a type of lower-limb amputation that occurs below the knee joint. Such amputations account for approximately 70 percent of all lower-limb amputations conducted in the United States each year (Ertl, 2008). They are usually the last treatment option as a result of chronic vascular disease, trauma or tumors, and typically affect individuals older than 60 years of age with complications of diabetes and Peripheral Vascular Disease (PVD) (Kelly, 2009). Surgeons often make every effort to avoid such procedures. However, since it preserves much of the tissues and joints, a lower-limb amputation is conducted frequently (Muilenburg, 1996).

While the exact process of the transtibial amputation may vary from patient to patient, the general surgical procedure is the same. An amputation involves much more than cutting the leg off and allowing it to heal. The surgeons use their knowledge of anatomy to amputate and reconstruct the remaining limb. As shown in Figure 1, the healthy lower leg anatomy consists of two long bones, namely the tibia and fibula, and several muscles as labeled. During a transtibial amputation, surgeons first determine which muscles they would like to use for reconstruction of the limb. In general, they try to use the larger muscles of the leg, such as the gastrocnemius and soleus muscles. Depending on the nature of the

disease or extent of trauma to the tissues, the surgeons will separate and incise these muscles in such a way as to provide adequate padding after the limb has been cut (ASEC, 2005).
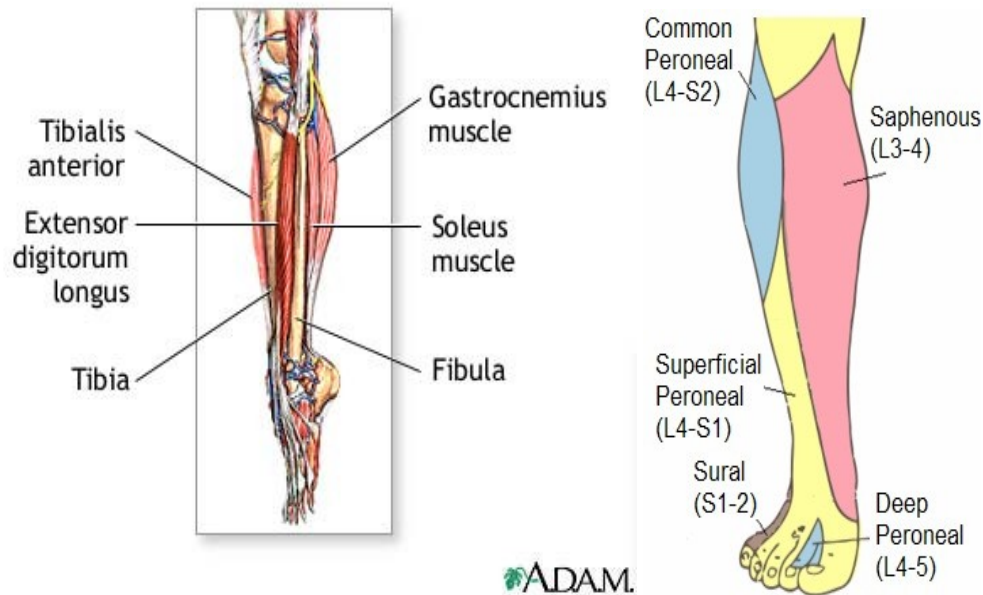
Figure 1: Muscles and Nerves of the Lower Leg (MedlinePlus)

Before the tibia and fibula are amputated, surgeons pay very close attention to the five nerves within the leg as shown in Figure 1(ASEC, 2005). During surgery, it is extremely important that these nerves are gently pulled down and retracted deep into the healthy soft tissue, away from the amputation and wound site. Such precautions are meant to minimize pain during healing and prosthesis use, and maximize function in the remaining limb (Haimovici, 2004). Once the muscles and nerves have been located and treated appropriately, doctors then amputate the tibia and fibula below the knee. To restore some function of the bones, some surgeons use a bone graft to bridge the two bones at the amputated site (shown in Figure 2) Regardless of whether the bones are bridged or not, the separated muscles are used to cover the amputation site and sutured together to form adequate padding, which promotes healing. The skin is then placed over the underlying tissue as carefully as possible, in order to simulate the layer of skin before the amputation (shown in Figure 2).

Figure 2: Image of an Amputated Leg (Haimovici, 2004)

While such amputations are quite life-changing, most patients are able to adjust and live fully productive lives. Once the amputation itself has been completed, sterile dressings are then applied and the residual limb is placed in a temporary splint. Sometimes, a transitory prosthesis, known as the immediate postoperative prosthesis (IPOP), can even be fitted in surgery. This temporary appendage allows the limb to be visualized in its correct place (Ertl, 2008). Such prostheses begin the stages of prosthetic treatment meant to restore a patient back to a pre-amputation lifestyle. These stages are detailed in the following section.

2.1.1. Treatment Timeline

The time immediately following an amputation involves extensive physical therapy and psychological support. This is a difficult period during which the patient learns to use the prosthesis and attempts to restore their pre-amputation way of life. The specific stages are shown in Figure 3, with more detailed descriptions of each phase following. However, this may not always be the order of recovery due to the cost of the prosthesis or other factors such as infection and re-amputation. (Van Dorsten, 2004)
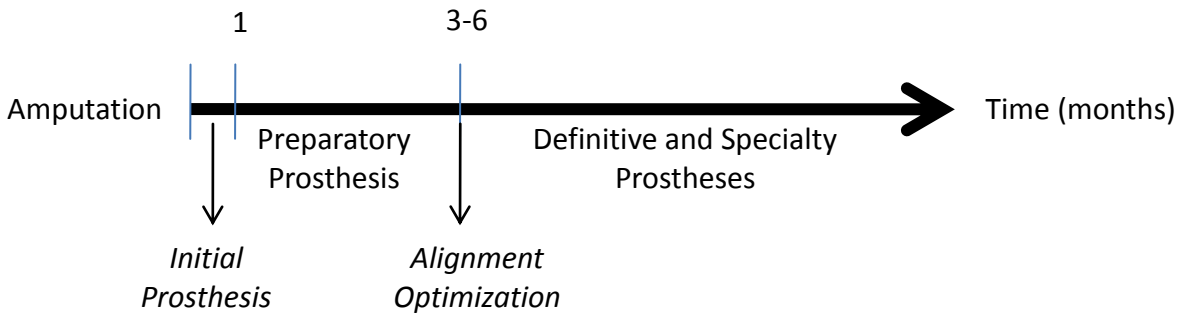
Figure 3: Timeline of Prosthesis Treatment

Initial Prosthesis

Once the wound healing process is almost complete and the sutures are removed, an initial "early postsurgical fitting (EPSF)" may be placed on the residual limb. Typically used during the first 1-4 weeks following the amputation, EPSF sockets are molded using plaster of Paris in order to cater to the rapid changes in physiology that the limb goes through during such time (Ertl, 2008). Such prostheses are utilized until the wound healing process is thoroughly complete and the skin is healed enough to endure more demanding prosthetic devices.

Preparatory Prosthesis

These prostheses are used after the initial prostheses phase, during the first 3-6 months of rehabilitation when the limb is still undergoing some physiological changes and has not yet fully matured (Kelly, 2009). These prostheses, although lacking in aesthetics, are used so that the patient can adjust to wearing a prosthesis before trying on a permanent prosthetic limb. After 3-6 months, it is changed to a more definitive prosthesis as the residual limb matures.

Definitive Prosthesis

Once the limb has matured sufficiently and the final, optimal alignment has been attained, definitive transtibial prosthesis is used. It is usually lightweight and more aesthetic than the preparatory prosthesis. The definitive prosthesis is typically used for 3-5 years before requiring replacement, although this time period could be shortened if there is a substantial change in the patient's weight or lifestyle (Kelly, 2009).

Specialty Prosthesis

Once the patient has had sufficient time to become comfortable with their prosthetic limb, some have the option to obtain special-purpose prostheses designed for activities such as running, swimming or skiing. Such prosthetic designs depend on the individual patient need and activity level (Ertl, 2008).

2.2.   **The Transtibial Prosthesis**

As mentioned previously, the primary prosthesis used following an amputation is the definitive prosthesis, which is also synonymously referred to as the transtibial prosthesis, (shown in Figure 4). From this point on, we will refer to the definitive prosthesis as the transtibial prosthesis, which is perhaps the most important type of prosthesis when discussing below-knee amputations. To gain a fuller understanding of how such a prosthetic device is incorporated into the patient's lifestyle, one must first have a working knowledge of the design and terminologies associated with such a device. This section provides a brief overview of the transtibial prosthesis, focusing particularly on the various aspects of the prosthetic design and vocabulary.

Figure 4: An example of a transtibial prosthesis (Delatorre Orthotics and Prosthetics)

The transtibial prosthesis is composed of many components that can be configured together based on the nature of a patient's amputation, including parameters such as the length and diameter of the

residual limb. Figure 5 illustrates how all these components assemble into a prosthetic leg for a patient with a transtibial amputation.
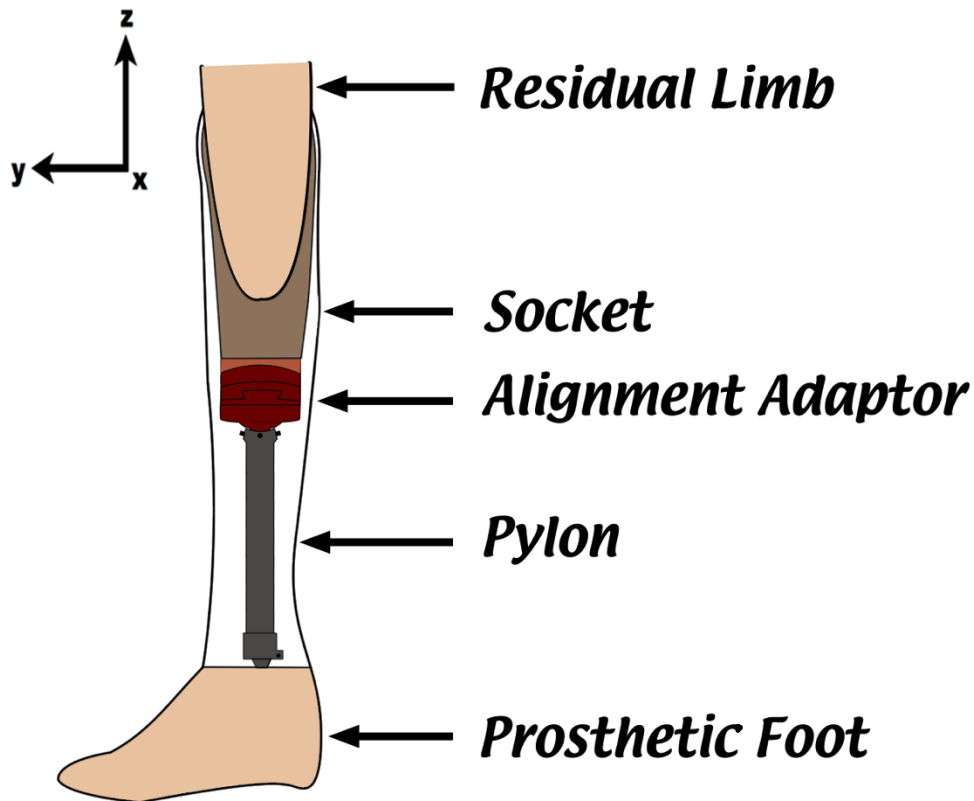
Figure 5: Components of a Transtibial Prosthesis

2.2.1. Socket

The first of these modules is the socket, which is the interface between the residual limb and the prosthesis. The socket may or may not utilize negative pressure to maintain attachment to the residual limb during standing and walking. It also allows for the transmission of forces and range of motion from the prosthesis to the residual limb during standing and ambulation, and is involved in the distribution of the patient's weight onto the prosthesis.

2.2.2. Alignment Adaptor

The next component, located below the socket, is the alignment adaptor that connects the socket to the rest of the prosthesis. The primary function of this component is to allow the foot to be properly

positioned beneath the leg. By observing the patient's gait and stance, particularly at how the foot strikes the ground, the length of the sound limb, and balance as the patient walks, the prosthetist can make adjustments to this device that will enable the patient to walk more comfortably and naturally. It is only a component in the preparatory prosthesis, as no adjustments are needed by the time the transtibial prosthesis is made. The lower portion of the adaptor, opposite of the socket, connects to the pylon.

2.2.3. **Pylon**

The pylon is a simple tube, typically made out of stainless steel or titanium that attaches the socket (or alignment adaptor) to the prosthetic foot. It can vary in length depending on the site of the amputation and height of the patient. The design of such pylons has progressed from simple, static shells to dynamic devices that allow axial rotation and absorb, store, and release energy (Kelly, 2009). However, the basic role of the pylon remains the same – to act as the replacement for some of the length of the fibula and tibia that were amputated.

2.2.4. **Prosthetic Foot**

The final part of the prosthesis is the prosthetic foot. The five basic functions of prosthetic feet are to provide a weight-bearing surface, absorb shock, replace lost muscle function, replicate the anatomical joint, and restore cosmetic appearance (Kelly, 2009).

2.3. **Using the Transtibial Prosthesis**

Learning to use a prosthetic leg can be very difficult and time consuming. The dynamics of standing, walking, and running are obviously altered by having a prosthesis. Not only are the mechanics of the prosthesis different than a human leg, but the muscles and nerves in the residual limb have been relocated. Before the effect of these changes can be examined, it is important to understand what a healthy gait pattern looks like.

2.3.1. **Normal Gait Analysis**

During a healthy gait cycle, there are two main phases, as shown in Figure 6 below, namely, the stance phase and the swing phase. A gait cycle begins with an initial foot contacting the ground (in this case the left foot), which begins the stance phase. Both feet are on the ground at this point, which is known as

double limb support. The other leg (in this case the right leg) is then lifted (called a toe off) and swung, which is called single limb support. The lifted leg reaches the ground (called a foot contact), ending the stance phase and starting the swing phase. The initial leg (in this case the left leg) continues normal gait with a toe-off. This limb then swings and lands, and the entire cycle repeat [4].
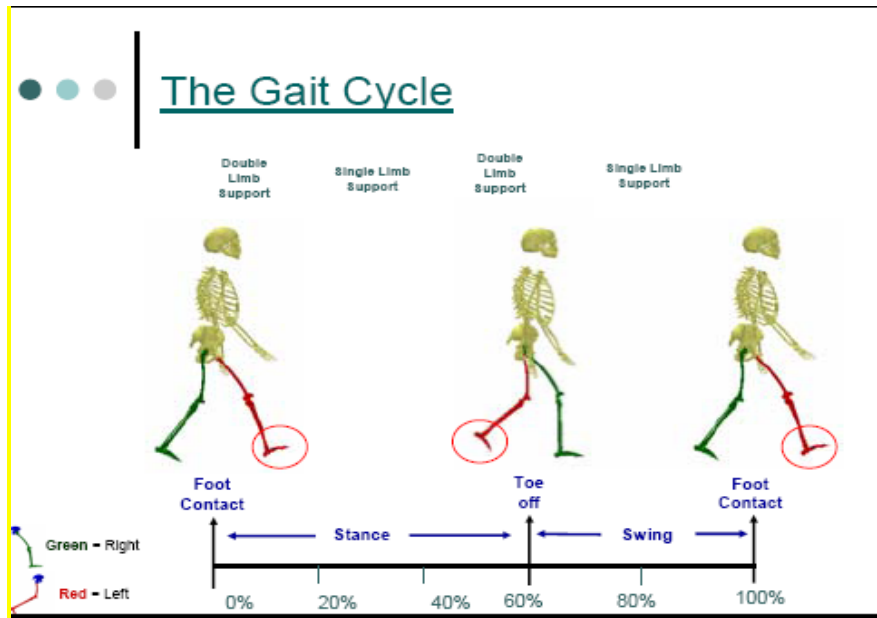
Figure 6: The Gait Cycle (Muybridge)

It is important to note, that while Figure 6 illustrates such a phenomenon by showing only bones, this is just for simplicity purposes. In reality, many muscles and nervous surrounding these bones initiate and aid in the process of walking. In fact, many of the joints and muscles within the leg allow many degrees of freedom essential during the foot contact and toe-off stages of gait. For example, the ankle joint and its surrounding muscles are necessary for toe-off and foot contact, because it allows the foot to dorsiflex and plantar flex, as illustrated in Figure 7. Furthermore, a related joint, the subtalar joint allows for motion in the inversive or eversive (side to side) directions (Peterson, 2006). Table 1 below provides a summary of all the muscles and joints that play a role during normal walking.

Triceps surae

Fibula

Fibularis muscles

Posterior compartment of leg (plantar flexes foot, flexes toes)

Tibialis anterior

Tibia

Lateral compartment of leg (plantar flexes and everts foot)

Key:

= Posterior compartment muscles

= Anterior compartment muscles

= Medial compartment muscles of thigh and lateral compartment muscles of leg

Anterior compartment of leg (dorsiflexes foot, extends toes)

Figure 7: Summary of the actions of the various leg muscles (Marieb and Hoehn 2007).

Table 1: Muscles acting on the ankle joint and toes (Marieb and Hoehn 2007).

(PM = prime mover)	ACTIONS AT THE ANKLE JOINT				ACTIONS AT THE TOES	
	Plantar Flexion	Dorsiflexion	Inversion	Eversion	Flexion	Extension
Anterior Compartment						
Tibialis anterior		X (PM)	X			
Extensor digitorum longus		X				X (PM)
Fibularis tertius		X		X		
Extensor hallucis longus		X	X (weak)			X (great toe)
Lateral Compartment						
Fibularis longus and brevis	X			X		
Posterior Compartment						
Gastrocnemius	X (PM)					
Soleus	X (PM)					
Plantaris	X					
Flexor digitorum longus	X		X		X (PM)	
Flexor hallucis longus	X		X		X (great toe)	
Tibialis posterior	X		X (PM)			

2.3.2. **Biomechanics of Walking with a Prosthetic Limb**

As evidenced by Table 1, it is obvious that the process of walking is an intricate and complicated phenomenon, dependent on many muscles and joints in the lower leg. Yet as mentioned earlier, many of these joints and muscles are either removed entirely or separated during the amputation surgery. Although the transtibial prosthesis attempts to replace these joints and muscles to restore some function back to the limb, the reality is that such prostheses are too simple to mimic the intricate design of the human leg., which has multiple degrees of freedom.

Mechanically, a transtibial prosthesis essentially replaces the foot, ankle and amputated portion of the fibula and tibia with a rigid body. It simplifies the complex articulations of the ankle and toes with a simple pylon attached to a foot, which has very minimal degrees of freedom (Postema, 1997). The only articulation points present across the entire prosthetic leg is the knee and hip joints. Thus, the ankle joint and foot, as well as the muscles within the lower leg, are not mimicked in the prosthetic limb. Such differences lead to a dramatic change in normal gait. In fact, several studies have been conducted to examine the differences in gait between normal walking and walking with a transtibial prosthesis. The results of these studies are presented in the following section.

2.3.3. **Changes in Gait during Prosthetic Use**

Due to the fact that the normal anatomy of the lower limb has been replaced with a rigid body during prosthetic use, the human body attempts to adapt its gait in order to maximize function and minimize energy use. In fact, many studies have shown that there are differences not only in the gait of non-amputated walking, but that there are differences in muscle use between the residual and sound limb. For example, studies by Czerniecki *et al* (1996) and *Yang et al (1991)* found that patients wearing a transtibial prosthesis experienced lower muscle use in the residual limb than in the sound leg. These studies suggest that the patient gait while using a prosthesis is asymmetrical, contrary to non-amputee gait. Particularly, these researchers found that there was a correlated decrease in the force measured during the toe-off phase of both limbs as compared to normal walking. This decrease in force is thus compensated by an increase in work done by the hip extensors and knee muscles of the amputated leg (Czearniecki*et al.,* 1991).

During the swing phase of the gait, there is increased muscle use in the hip and knee of the non-amputated limb, as it is compensating for the lack of symmetry while walking with a prosthesis (Buckley, 1991 & Seroussi*et al.,* 1996). Thus, the hip and knees of both legs are subjected to additional pressure

due to overcompensation for the lack of muscle use in the lower amputated limb. While there are changes in the forces and muscles during gait with a prosthesis, many biomechanics researchers have found that such changes can be affected and minimized by the various components of the prosthesis (Buckley, 1991). Most importantly, studies have shown that proper prosthetic alignment is extremely significant in minimizing these changes in gait, as it can minimize the asymmetry that occurs during prosthesis use.

2.4.   **Prosthetic Alignment**

The studies above have shown that appropriate and proper alignment need to be established early on in the post-operative stage and are extremely important to re-establishing a healthy gait (Schmalz, 2002). While it is very important that the patient walk with a healthy gait, studies have found that the prosthetic alignment also affects patient comfort, posture and wound healing. Therefore, prosthetists spend much of their time during a patient visit attempting to make sure that the alignment is as correct as possible.

2.4.1.   **Importance of Achieving Correct Alignment**

Table 2 illustrates the immediate effects of misalignment and their long-term consequences. Although misalignment of the prosthesis does the most damage during walking or running, it can also cause trouble while standing. The weight of the upper body during such a position can place unbalanced stress on the healthy hips, knees and ankle, causing pain to the individual. Furthermore, when an individual's prosthesis is misaligned, his or her posture is considerably affected, with ill effects on the back, neck, shoulders and even the toes. Too short of a prosthetic limb, for instance, can cause inward movement of the knees and altered hip alignment, leading ultimately to an altered alignment of the spine.

Table 2: Immediate effects of misalignment and their corresponding long-term consequences.

Immediate Effect of Misalignment	Long-term Consequences
Asymmetric gait	Additional amputations Reduced stability Slowed movement
Uneven weight distribution	Stress on hips Stress on knees Stress on ankles Pain during gait Pain during stance
Altered alignment of spine	Bent posture Pain in back Pain in neck Pain in shoulders Pain in toes
Unnatural forces on residual limb	Obstruction of venous outflow Development of distal limb edema Erythema Induration Skin breakdown
Uneven distribution of skin pressure over bony prominences	Pain at specific locations

Another consequence of a misaligned prosthesis is Choke Syndrome, which occurs when the socket becomes too tight due to unnatural forces on the residual limb. If the prosthetic socket fits tightly around the proximal residual limb, but the distal residual limb is not in good socket contact, there will be obstruction of venous outflow, and distal limb edema will develop. If unchecked, erythema, induration, and eventual skin breakdown ensues. The effect of Choke Syndrome on a residual limb is shown in Figure 8.

Figure 8: Effects of Choke Syndrome (Kelly, 2009)

As suggested in the previous section, misalignment can result in asymmetric gait, forcing the patient to overcompensate with the muscles in the sound limb. This situation can eventually damage the sound leg and lead to further complications such as additional amputations. Asymmetric gait can also reduce the individual's stability during ambulation. Tripping and falling become imminent in such conditions. Additionally, locomotion is significantly slower in uneven gait than in even gait (Blumentritt, 1999).

Aligning the prosthesis is not only important to gait but to several other factors as well, including patient comfort and posture. Consequently, prosthetists spend a significant amount of time ensuring that transtibial prosthesis is aligned properly to avoid such complications. The following section describes the methods through which prosthetists ensure proper alignment for a patient.

2.4.2. Methods of Achieving Correct Alignment

When a prosthetist meets with a patient, there are three stages of alignment: bench alignment, static alignment, and dynamic alignment, the most important being the dynamic alignment stage.

Bench Alignment

Bench alignment is conducted according to information from the patient's previous prosthesis alignment as well as a prosthetist's general knowledge about prostheses. As seen in Figure 9, a single-line plumb line can be used to visually match two identified points, one point on the socket and another on the ankle bolt when viewed from the patient's lateral side and on the center of the heel when viewed from the patient's dorsal side (Otto Bock HealthCare LP). This single-line plumb line approach allows the prosthetist to view the alignment from slightly varied angles. Figure 9 depicts the process and some measurements (not specific to any particular individual) that a prosthetist could use during the bench alignment phase.
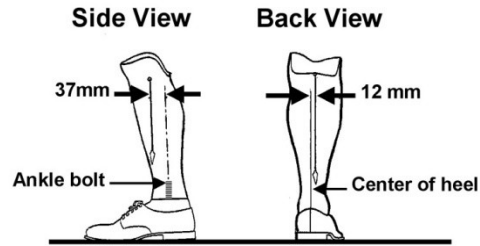
Figure 9: Traditional Bench Alignment of Transtibial Prosthesis (Wu)

Static Alignment

Static alignment is conducted while the patient wears the prosthesis. The prosthetist aligns the prosthesis based on subjective feedback and on observation of the patient's static posture. Sometimes, the LASAR Posture method can be used to optimize the static alignment of modular limb prosthesis during trial fitting. With this method, a laser projects the measured ground reaction force as a line, called the load line, onto the body's center of gravity. Correct alignment is visualized by comparing the distances between the ground reaction force and joint points or body points. The alignment of the prosthesis can then be optimized based on this load line, as shown in Figure 10.

Figure 10: A prosthetist aligning a prosthesis using the LASAR Posture (Otto Bock HealthCare LP)

Dynamic Alignment

Dynamic alignment is achieved through examination of the patient's walking pattern. The patient begins to use the prosthesis in a controlled manner by walking inside parallel bars. The prosthetist again relies on patient feedback and also on his clinical experience with gait analysis (Kelly, 2009).

The phases of the normal gait cycle include initial contact, loading response, midstance, terminal stance, preswing, swing, initial swing, midswing, and terminal swing. Table 3 shows common gait deviations in patients with a transtibial or transfemoral amputation during midstance of the gait cycle and circumstances when realignment is necessary for proper gait. Prosthetists follow similar tables for all stages of gait during the dynamic alignment stage.

<div align="center">

Table 3: Dynamic Alignment Process during Midstance (Kelly, 2009)

</div>

Gait Cycle Phase	Observed Gait Abnormality	Suggested Modifications	Desired Outcome
Midstance	1. Medial or lateral socket thrust. 2. Lateral trunk shift over prosthesis. 3. Pelvis drops or elevates.	1. Realign prosthesis. 2. Replace socket. 3. Adjust socks. 4. Adjust length of prosthesis.	1. Limited recurvatum forces. 2. Normal genu-varum moment. 3. Optimum loading of the medial tibial flare.

By adjusting the alignment with an alignment adaptor, the prosthetist can attempt to replicate normal gait patterns. The typical alignment unit allows for five degrees of freedom: anteroposterior translation and rotation of the pylon and foot, mediolateral translation and rotation of the pylon and foot, as well as rotation of the prosthetic foot about the longitudinal axis of the limb.

The prosthetist relies on experience, an understanding of the causes of gait deviations, knowledge of the loadings applied at the stump/socket interface, and feedback received from the patient to adjust the prosthesis. Alterations to the geometric configuration of the prosthesis lead to an acceptable configuration for both the patient and prosthetist. Therefore, the "correct" alignment is specific to each patient and is achieved subjectively with no quantifiable measurement of alignment.

2.5. Alignment Devices

As this project is concerned with the redesigning of alignment adaptors, it is first necessary to have an in-depth understanding of current adaptors. This section will first examine the requirements of an alignment adaptor, including a look at what past devices have done to meet these needs. This provides an important historical overview as well as exposure to different design solutions. Following that, the current state of the art device will be described, so that the most technologically advanced and most modern device is understood. However, the state of the art is not the most popular device used today, so this section will conclude by taking a look at this current standard adaptor.

2.5.1. Design Requirements

The four primary design requirements are mechanical design, comfort of the patient, ease of use for the prosthetist, and usability for a variety of patients. Over the past three decades, there have been many advances to each of these four areas. This section examines the importance of each design requirement and provides examples from patented devices.

2.5.1.1. *Mechanical Design*

For this section, mechanical design is defined as the physical means by which a specific function is accomplished. More specifically, it is the method in which the adaptor provides the needed motion along the six degrees of freedom. In the engineering field, this is a fairly simple, yet common, problem. There are countless solutions, but not all are appropriate for use in an alignment adaptor. In 1972, Patent 3659294 was issued to Richard Glabiszewski for an invention that is present on almost all modern day prostheses. Until this time, it was very difficult to adjust the angle between various members of the prostheses. Traditional ball and socket joints were used, but they had several disadvantages. They rotated about the axis of the limb when they were not supposed to and were hard to set back to a given position once moved. Glabiszewski solved these problems by implementing a frustopyramidal shape, shown below in Figure 11.
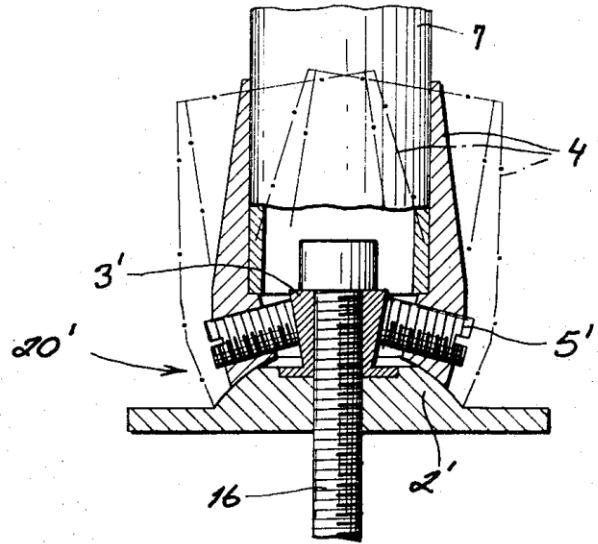
Figure 11: Frustopyramid shape allowing angular alignment of two prosthetic components (Glabisqewski 1972)

With this design, one angular degree of freedom can be controlled with two setscrews. The setscrews are located on the female component, and the frustopyramid is on the male component. As one screw is backed out, the other is screwed in, which changes the angle between the male and female components. The interface between the two components is slightly spherical, which allows for the proper abutment of the two pieces as the angle is changed. Although the details of its implementation has changed throughout the years, the same basic shape and operating principle as presented in this patent is still in use today(Glabisqewski 1972).

Until 1991, the major drawback to these adaptors was that they only allowed adjustment of the relative angle between two components. However, to properly align the center of gravity of the wearer to the prosthetic, it is beneficial to also adjust the lateral positioning. Patent 5047063 addressed this problem. In order to adjust the lateral positioning, four setscrews (piece 401) were used to position a disc (piece 2) within a slightly larger circular plate (piece 1), as shown in Figure 12.
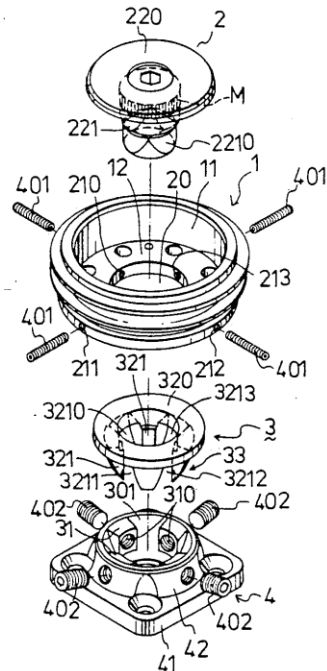
Figure 12: Adaptor allowing lateral and angular adjustment between two prosthetic components (Chen 1991)**.**

Depending on the positions of the four screws, piece 2 could be aligned laterally relative to piece 1. Notice the frustopyramid still being implemented to adjust the angle relative to the bottom component (piece 3). Although this exact device is rather outdated, the idea of allowing adjustment in the lateral directions and fixing it with setscrews is the same premise for state of the art adaptors today. (Chen 1991).

2.5.1.2. *Comfort for Patient*

Along with the importance of an effective mechanical design, it is necessary to take into consideration the comfort of the patient during the alignment procedure. As stated earlier, alignment is extremely important in a patient's gait and comfort while walking and standing. This means that the adaptor must be designed in such a way that adjusting it does not cause the patient any direct pain. In addition, comfort also implies that the alignment should not require the removal of the prosthetic socket from the residual limb. Since many sockets are friction or suction fits, repeatedly putting the socket on and off can irritate the skin and be a physical burden for older patients. Therefore, in 1995, Patent 5425782 was issued for the invention of a prosthesis that could be adjusted while the user was wearing it. The inventor states that "because any repeated adjustments can be made without removing the socket from the wearer, the invention provides substantial savings in time and energy necessary to properly adjust the prosthesis, as well as substantially reducing the discomfort and inconvenience to the wearer"

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(Phillips 1995). As is the case with many of the patents on alignment adaptors, the inventor did not substantially change the overall mechanics of the device. In the prior designs, the two pieces that moved relative to each other to provide the translational motion were constrained using a bolt and nut assembly. However, this bolt was only accessible when the patient was not wearing the prosthesis. The design described in this patent included openings in the two pieces, which allow access to this bolt while the patient is still wearing the prosthesis. Although a relatively simple change, it is nonetheless a critical consideration in the design process (Phillips 1995).

2.5.1.3. *Ease of Use for Prosthetist*

Since the prosthetist is the one that must actually adjust the adaptor, it is critical to consider how easy it is for them to work with the adaptor. It needs to provide enough range of motion to enable the prosthetist to properly align the limb to the patient's gait. It must also have a high enough resolution of adjustment to allow the prosthetist to obtain a precise alignment. A third consideration is that the degrees of freedom need to be independent of each other. When the prosthetist needs to adjust one degree of freedom, it should not simultaneously change the adjustment of a different degree of freedom. These adjustments should be mechanically simple to make; they should not require a high degree of dexterity or strength. Although modern adaptors often satisfy these three criteria, the majority of them do not provide quantitative measurements for a specific alignment. This means that if an alignment is lost or the adaptor must be exchanged, the alignment process must be redone. In 1990, Patent 4969911 attempted to solve this problem. The inventor designed markings that could be put on the side of the device to indicate the angular position in both the mediolateral and anteroposterior directions. Figure 13 shows a picture of the male and female components of the frustopyramid design. The markings can be seen right below the frustopyramid, with a close-up of the markings shown in Figure 14. Note that the indexing lines are in orthogonal planes, corresponding to the two degrees of freedom generated by the frustopyramid design. This serves as an example of how considering the ease of use for the prosthetist is a patentable idea. (Greene 1990).
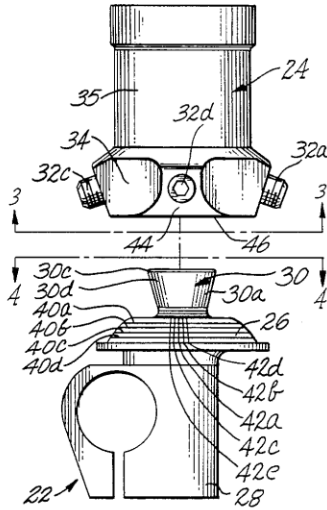
Figure 13: Alignment device for two prosthetic components with indexing lines (Greene 1990)**.**
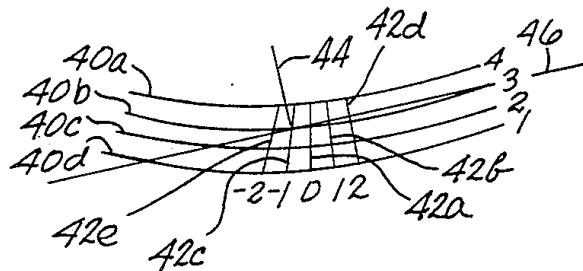
Figure 14: Close-up of orthogonal indexing lines (Greene 1990)**.**

2.5.1.4. *Usability for a Variety of Patients*

One of the more important measures of the success of an adaptor design is how many different types of patients can use it. For example, there are male, female, old, young, short, tall, heavy, light, bow-legged, athletic, sedentary, etc. patients, each of which has a slightly different design need. For example, a light person does not need to have the same amount of mechanical strength as a heavy patient, but it might need to weigh less. Often, a compromise can be made in which the adaptor will be strong enough and light enough for both patients. However, for different amputation types, this kind of compromise is more difficult to make. For example, when the amputation is made very close to the ankle (Symes amputation), the amputees have such a long residual limb that adaptors often do not even fit in the

prosthesis. This means that the adaptor has to be designed for specific amputation types, or take all types into account, in addition to optimizing it for the physical traits of the patient.

An example of a design that takes different patient types into account is Patent 6458163 from 2002. Many prior adaptors rely on the adjustment of the pylon to allow for rotation of the foot. However, in Symes patients, there often is an insufficient amount of clearance for a pylon as described above. Therefore, this patent describes a device (Figure 15) that allows rotation within the adaptor itself, without the need for a pylon.
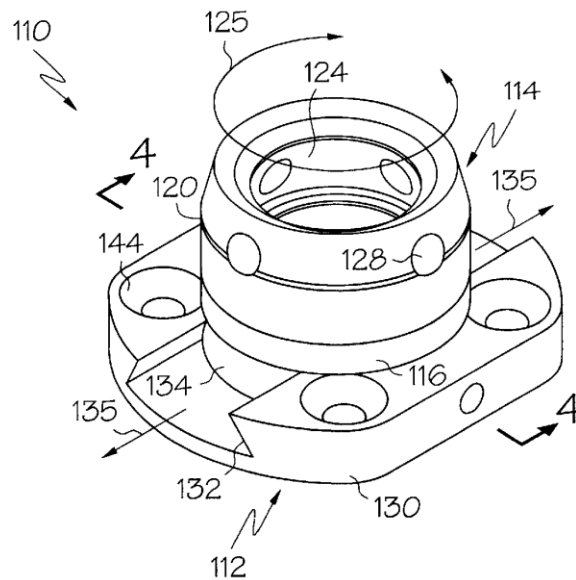
Figure 15: Adaptor allowing rotational motion and a small profile (Slemker, Wiggins, and Schall 2002)

The top piece with the four holes is actually a female component of the frustopyramid design, so it can easily interface with preexisting technology. The dovetail design allows for translational movement only along one axis. When compared with a prosthetic fitting that includes a pylon, this design has a much smaller profile and can be used in much tighter spaces where the residual limb does not allow for a pylon. This ultimately means that the device can be used for a wider variety of people, which is important when considering all the different patient types (Slemker, Wiggins, and Schall 2002).

2.5.2. State of the Art

As shown throughout this section, there are many factors that must be considered in the design of an alignment adaptor. Many of the aforementioned designs selected a small number of these factors to optimize. A table of other patented designs is provided in Appendix A as a reference. From the examples described above and the information from this table, it is apparent that many designs are effective only for one specific design consideration. Therefore, to describe the current state of the art, a design was chosen that does the most comprehensive job of meeting the four design requirements.

The current state of the art device as defined by the team is described in US Patent 7338532 from 2008. It is called the Haberman Alignment Device (HAD) after the inventor Louis Haberman. It allows for translational adjustment along both the mediolateral and anteroposterior axes. It also allows for rotation about the limb axis, and can be fitted with a male or female pyramidal component. One of the unique features of the HAD is that it interfaces with numerous and different modules. For example, if only one axis of translation adjustment is needed, the module that adjusts the other axis can be removed, saving weight. The prosthetist has the ability to adjust five degrees of freedom with the HAD, but does not have to use all the components. In terms of usability for a variety of patients, the HAD comes in three different weight classes to accommodate for different sized patients (Haberman and Dallos 2008). One configuration of the device is shown below in Figure 16.
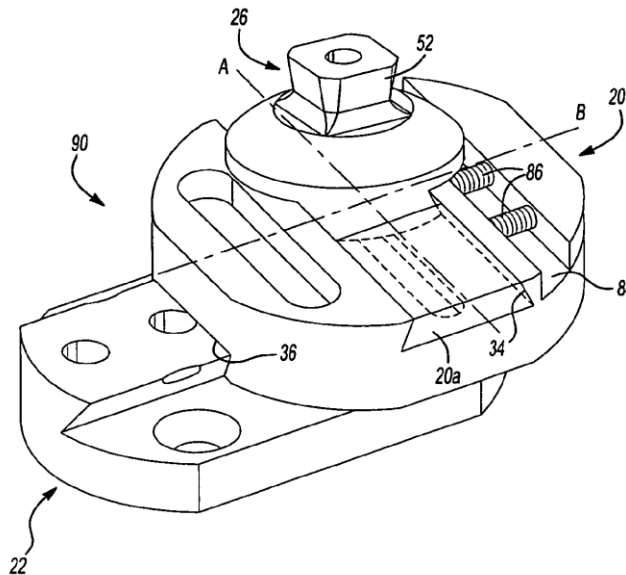
Figure 16: Haberman Alignment Device (Haberman and Dallos 2008)

Since this device is so adjustable, it is able to align a wide variety of patient types. By combining many different design features from other adaptors, it is a strong representation of the current state of the art. Despite arguably being the most technologically advanced, the HAD is not the most popularly used alignment device. The device that is the most popular, and against which all other devices are judged, is the Fillauer Slide Unit, described in the next section.

2.5.3. **Current Standard**

The Fillauer Slide Unit, more commonly referred to as the Red Unit, is the most commonly used alignment device to date (Figure 17 & Figure 18). It is comprised of four individual parts that allow for rotation about the axis of the limb (z axis), translation in the lateral-medial axis (x axis), translation in the frontal-distal axis (y axis), and rotation about the x and y axes. Figure 19 below shows the translation of the bottom link in the x axis.
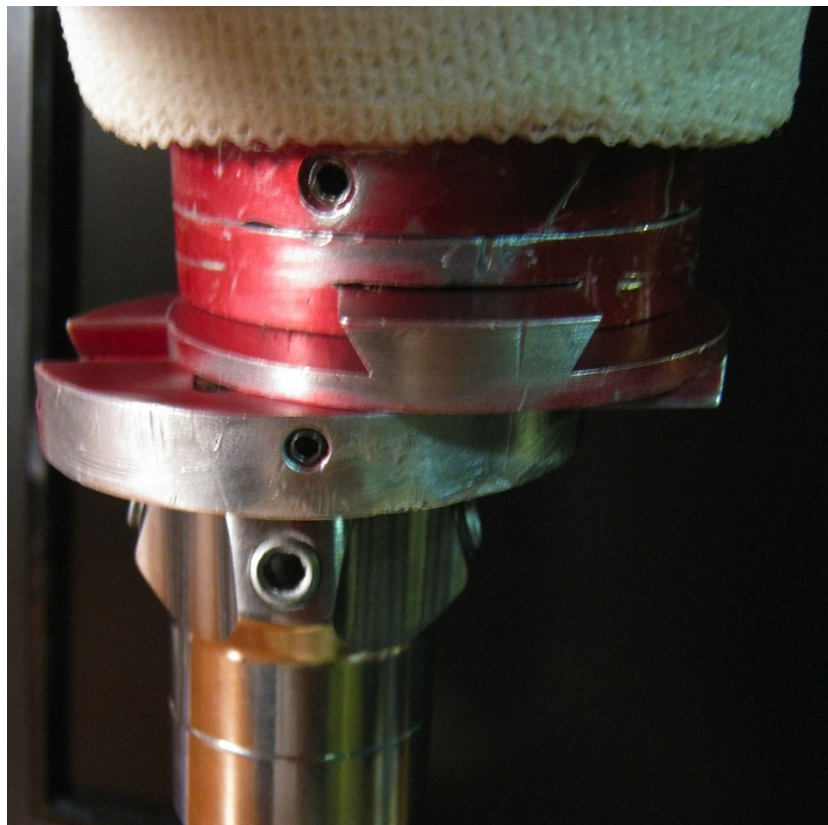
Figure 17: Fillauer Slide Unit attached to wooden socket (top) and tube clamp (bottom).
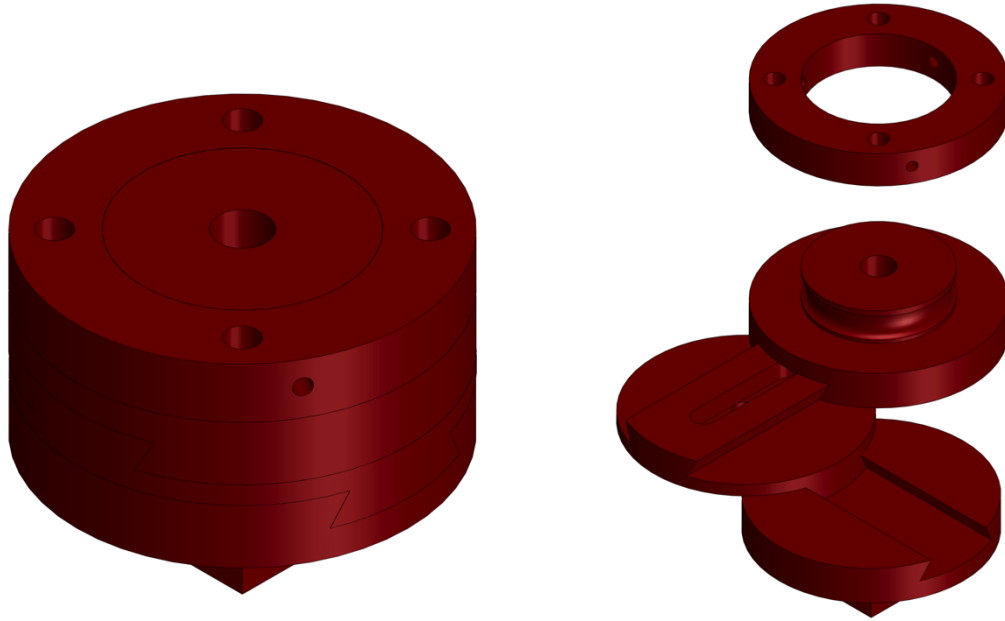
Figure 18: CAD model of the Fillauer Slide Unit, more commonly referred to as the Red Unit.
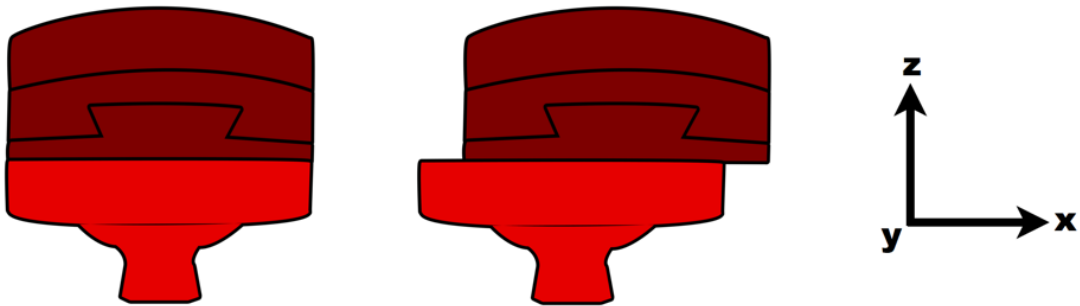
Figure 19: Red unit lateromedial translation (along the x-axis). This is also referred to as linear adjustment.

The two central pieces form another sliding joint, but rather than translation along the x-axis, this pair allows for anteroposterior translation, that is, translation along the y-axis (Figure 20).
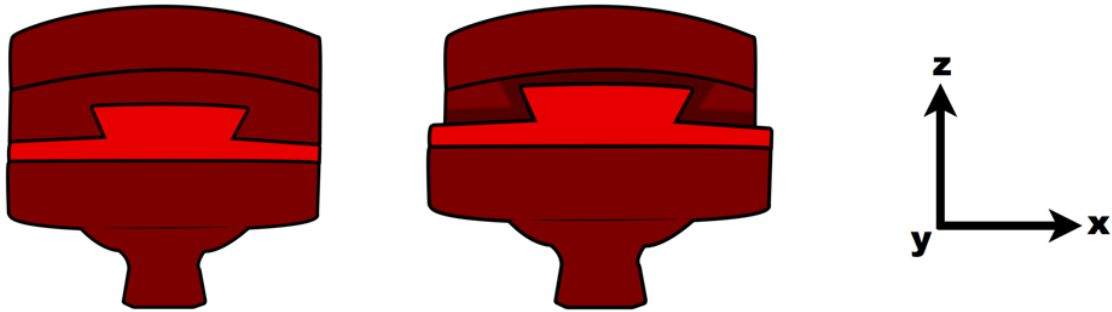
Figure 20: Red unit anteroposterior translation (along the y-axis). This is also referred to as linear adjustment.

There is a revolute joint between the top two parts, which allows for full rotation about the z-axis (Figure 21).
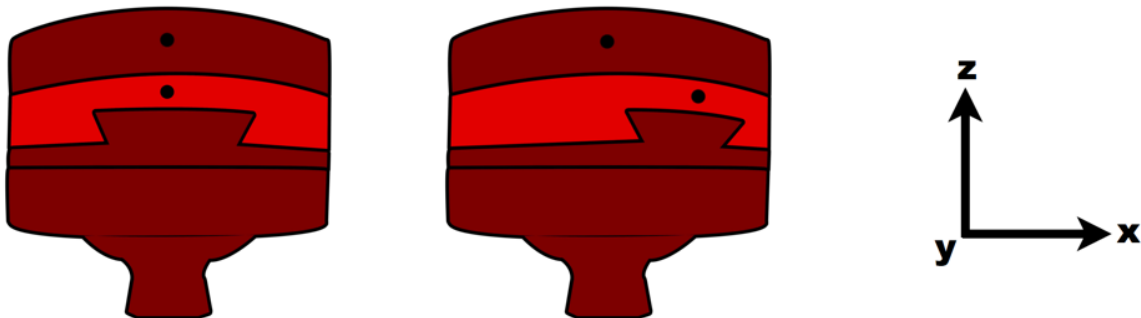
Figure 21: Red unit rotation about the longitudinal limb (z-axis). The black dots only serve as reference points in this image to show relative rotation about the z-axis.

The most distal link of the adaptor has a frustopyramid end that can interface with a pylon adaptor. The joint between the red unit and the pylon is technically a spherical joint (with limited z-axis rotation), but four individually adjusted set screws are used so that it becomes a double revolute pair. The double revolute allows for rotation about the x- and y-axes. There are two setscrews along the x-axis. When one screw is loosened, the other can be tightened, allowing for rotation about the y-axis (Figure 22). Similarly, there are two setscrews along the y-axis that allow for rotation about the x-axis. These adjustments are both referred to as angular adjustment.

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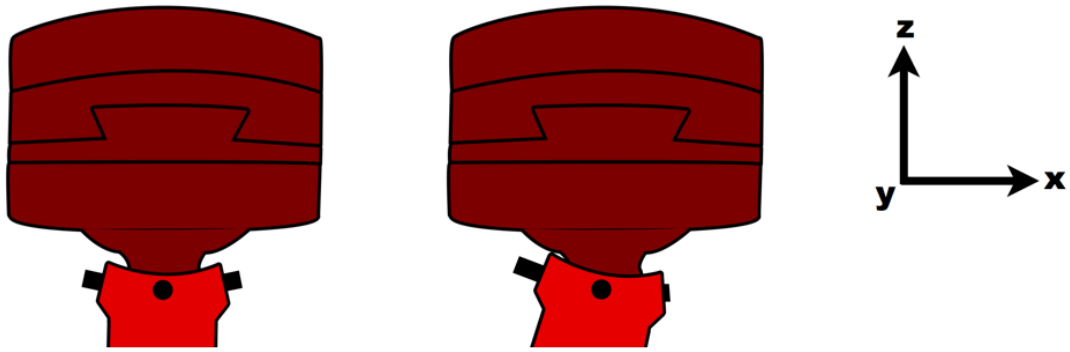
Figure 22: Pylon rotation about the y-axis. This adjustment, as well as the rotation adjustment about the x-axis, are also referred to as "angular adjustment."

In the red unit-pylon configuration, there is no reversible means of adjusting translation along the z-axis, or proximally-distally. The current practice of allowing for z-axial translation is to physically shorten the pylon. If the pylon is cut too short, a new pylon must be acquired (Hangar, Inc.). This is referred to as height adjustment.
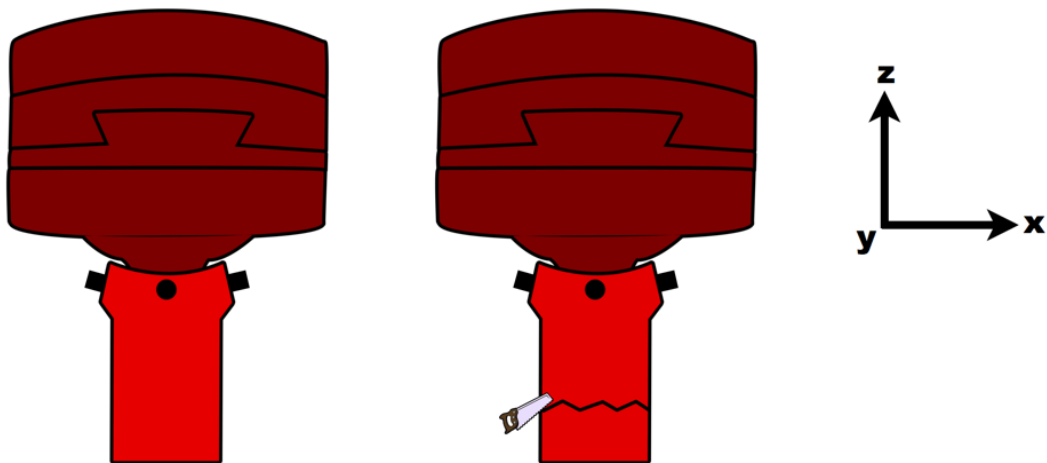
Figure 23: Pylon permanent-translation along the z-axis (proximal-distal). This is also referred to as height adjustment.

Setscrews and metal plates are used in these adaptors to provide a means of releasing and fixing the pairs. Sufficient static friction is achieved when these fasteners are tightened so that the links will not move.

One of the advantages to the red unit and pylon adaptors is in the ease of use for the prosthetist. The setscrews are a fairly simple way of controlling motion and that motion is confined to only one degree of freedom. This is beneficial because if a link in the device allows for adjustment of more than one degree

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of freedom at one time, the prosthetist's adjustment of one degree of freedom could cause unintentional adjustment to a different degree of freedom.

2.6. Need for Improvement

As suggested by this literature review, alignment is essential for the improved patient's gait and balance, muscle use, and overall comfort when using a prosthesis. However, none of the described adaptors meet the need of all four aforementioned major design requirements. Below is an analysis on where most adaptors fall short.

2.6.1. Height Adjustment

One of the largest drawbacks with all of the previously described designs is that they do not easily allow for height adjustment of the prosthesis. This is a problem with ease of use for the prosthetist. Since a prosthetist often has to fit a patient before they are able to stand up, it can be difficult to obtain the correct height of the pylon on the first attempt. Furthermore, since the pylon is built into the rest of the prosthesis and is not adjustable, this correction involves disassembling the prosthesis. The pylon must then be cut or a larger pylon must be obtained, and then reinserted into the prosthesis. This adjustment process is crude, time-consuming and difficult for the patient, and prevents the prosthetist from spending more time with the patient. Furthermore, occasionally, for Symes patients, there may not be enough clearance to place a shortened pylon in between the adaptor and foot. When this occurs, the pylon must be completely removed. Since the pylon is absent, a different kind of adaptor must be used to connect to the foot. Without a means of indexing to describe what the original adaptor adjustment settings were, the entire alignment procedure must be repeated. This leads into the second major problem, which is a lack of quantitative measurements.

2.6.2. Lack of Indexing

The idea of having indexing on the alignment adaptor allows the same exact alignment to be performed on two different prostheses. It would also standardize the language used by prosthetists in describing the amount of adjustment that must be made. Rather than subjective terms like "a little bit" or "about a quarter inch," exact measurements could be recorded. Since the overall field of prostheses is fairly subjective and imprecise, there is a need to provide more scientific measurements and methods to the alignment process.

2.6.3. **Mechanical Design**

Finally, there is a lot of room for improvement with regards to the mechanical design. An effective design would minimize the amount of materials used, be easy to use, and effectively perform the desired function. For example, the red unit is fairly crude in the sense that it performs the intended function, but is not particularly well suited or optimized for it. The setscrews used to lock onto the frustopyramid shape are not flush with the pyramidal surface. This increases the stress on the material and can cause gouges and wear on the parts.

A similar effect occurs when setscrews are used to lock the translational range of motion. Since the motion is stopped purely by friction, the setscrews must be tightened quite a bit. This can cause stripping and unnecessary wear on the modules, which increases the difficulty of their use (prosthetist must take care when adjusting them). With some of the more advanced designs like the HAD, it is difficult for the prosthetist because there is too much functionality. Since there are multiple modules that can be combined and recombined for different cases, the prosthetist has to have a whole set of parts and know how they all interface with each other for various situations. Ultimately, the alignment adaptor is a fairly simple mechanical device that can be greatly improved if consideration of these factors is carefully factored into their design.

The goal of this project is to therefore address the aforementioned limitations of the current adaptor designs and to design and prototype a new alignment adaptor to resolve such limitations. The process of approaching this design project is described in detail in the following chapters.

3. **Goals**

Based on the information obtained from the literature review, goals and design objectives were determined for the project. Additionally, a set of specifications was created in order to justify and measure the success of our prototype.

3.1. **Goal Statement**

The goal of this Major Qualifying Project is to prototype a transtibial alignment adaptor that provides refined and objective adjustments in all spatial directions, including the height, in order to maximize the time efficiency of the appointment and allow for a standardized alignment procedure. The device must improve upon the current state-of-the-art design, which (as previously mentioned) is unrefined, subjective, time-consuming, lacks height adjustments, and often reduces interaction time between the prosthetist and the patient. Such a prototype, in order to be considered successful, will meet the design specifications as stated in the following section.

3.2. **Design Specifications**

Before initiating the design process, a set of design specifications were created. They were placed in five general categories: performance, safety, ease of use, reliability and cost, as described in further detail below. Each of these specifications was created to be specific and measureable so as to provide a means to validate our prototypes throughout the design and testing process.

3.2.1. **Performance**

How well the device performs its intended task is perhaps the most important way of determining the success of a given design. It is generally the primary factor considered during the brainstorming process. The performance for this device can be categorized into its range of motion, resolution of motion, prosthesis interface, and physical limits. These specifications were created based on feedback from a prosthetist as well as a comparison to the features of the current state-of-the-art unit (as described in Chapter 2).

Range of motion:

-   Device must provide at least 2.0 inches of translational motion in the lateral-medial direction (X-axis).
-   Device must provide at least 2.0 inches of translational motion in the frontal-dorsal direction (Y-axis).
-   Device must provide at least 0.75 inches of translational motion in the proximal-distal direction (Z-axis).
-   Device must provide at least +/- 10° rotation about the X-axis
-   Device must provide at least +/- 10° rotation about the Y-axis
-   Device must provide at least 90° rotation about the Z-axis.

Resolution of motion:

-   Device must be adjustable to within 1/8 inch in all three translational directions.

Prosthesis Interface:

-   Device must interface with standard transtibial prosthesis modules.
-   Device must provide quantitative measurement of current alignment fitting.

Physical Limits:

-   Device must be able to sustain patients that weigh up to 250 lbs. (approximately 95th percentile).
-   Device must be usable on patients that have a 5 inch minimum distance from the bottom of their residual limb to their ankle joint.
-   Device weight must be less than 6 pounds

3.2.2. **Safety**

Like any medical device, safety is extremely important when designing an alignment adaptor. The device must not physically harm the patient or the prosthetist at any point throughout the fitting procedure.

Edges:

-   Device must not contain any sharp edges.

Pinch points:

-   The device should not have joints that result in a high risk of pinching during normal use.

3.2.3. **Ease of Use**

If a design were built that did not accommodate for the ease of use for the users (patients and prosthetists), it would not succeed in the medical market. The following list includes the specifications created to test for ease of use of the device.

Adjustability:
- Device adjustability will require no more than human hands, screwdrivers, hex keys or similar tools.
- Adjustment for each degree of freedom must be independent of other degrees of freedom (strictly orthogonal motion).
- All adjustments must be made without requiring the prosthetist to remove the socket.

Learning curve:
- A certified prosthetist must be able to independently align the patient after a 30-minute maximum training session on how the device works.

3.2.4. **Reliability**

Although the alignment adaptor will be used by any given patient for a maximum of two days, it will be reused for years during many fitting processes. It is thus important that the adaptor be reliable, which includes considering parameters such as fatigue and shock resistance.

Fatigue resistance

- Device must have a lifetime of at least 2 years.

Shock resistance

- Device must withstand a drop test from 5 feet from the ground.

3.2.5. **Cost**

In order for the prototype to be successful in the market of medical devices, its material and manufacturing costs must be comparable to the current state-of-the-art device. Thus, one must consider the following parameters.

Materials:

- The cost of materials should not exceed $290.00, the current cost of the current standard device.

Manufacturing:

- The device must be easily manufactured, and thus must be able to be manufactured in the WPI Machine Shops.

Total Cost:

- The raw cost of the device (materials and manufacturing, no sales mark-up) should not exceed $300.

4.   Design Process

Once the goals of the project were determined, the design process continued with conceptual designs in SolidWorks as well as prototyping. The following chapter provides a detailed description of the design process that was followed, including the approach taken to eliminate conceptual designs, and justification for the final design.

4.1.   Conceptual Designs

For ease of design and brainstorming, the adaptor was broken down into four major functions: height adjustment, linear adjustment, angular adjustment, and rotational adjustment. These four functions affect the gait and balance parameters such as asymmetric gait and uneven weight distribution. Several conceptual designs were created for each adjustment type; however, each of these conceptual designs was considered with the understanding that they would ultimately be combined to form a comprehensive adaptor able to perform all the functions of its individual modules.

4.1.1.   Height Adjustment

The height module was meant to adjust the height of the prosthesis. Based on the performance specifications, this particular module needed to not only have a range and resolution, but also discrete, quantitative measurements through which a prosthetist can accurately record the height adjustment. In order to fulfill these requirements, notched pipes, threaded pipes, and the use of pneumatics were analyzed as potential ideas.

4.1.1.1. *Notched Pipes*

Notched pipes were understood simply to be a series of holes drilled into two partner pipes along their lengths. Essentially, if a prosthetist wanted to change the height of the adaptor, they would simply have to align the holes in the counterpart pipes, thus increasing/decreasing the height to the appropriate setting. This is quite similar to the pipes used in track and field hurdles. An example of such a design is shown in Figure 24. The darker gray piece can be moved up and down and aligned with the holes in the light gray piece, thus changing the height of the module.
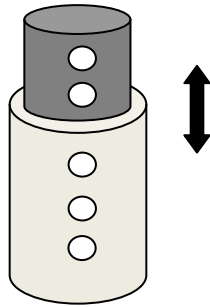
Figure 24: Notched pipes to align height

4.1.1.2. *Threaded Pipes*

The threaded pipe concept, as shown in Figure 25, was also analyzed as a potential design for the height adjustment. Essentially, one pipe would be threaded into its counterpart to increase or decrease the height accordingly.

Figure 25: Threaded pipes to align height

4.1.1.3. *Pneumatics*

A pneumatic device uses pressurized air to result in mechanical motion. Such means for mechanical motion is typically used in computer chairs and many power tools. Focusing particularly on its use within the computer chair, pneumatics function through a cylindrical air spring. Essentially, a cylinder is located at the base of the chair that stores compressed air. The air is contained by a plunger, which is also connected to a hand lever. By activating the hand lever, the plunger can move up or down depending on if the person is sitting in the chair pushing down, or trying to raise it up. Thus, compressed air is used as a spring to aid in the relative positioning between a cylinder and plunger.

4.1.2. **Linear Adjustment**

The linear module must allow for translation in the anteroposterior and mediolateral directions. This translational motion must be constrained to only one degree of freedom at a time and have the appropriate range and resolution based on the performance specifications. The primary concepts were a rack and pinion, shims, an internal screw, cords, and dovetails.

4.1.2.1. *Rack and Pinion*

The rack and pinion, or a similar gear concept, is a very popular mechanical way of controlling translational motion. The rack is a straight bar with teeth cut out of it and the pinion is a gear that rides along the rack (Figure 26). The teeth ensure that the motion is controlled and confined to the desired direction of motion. The primary advantage of gears is that they have continuous adjustability, so the resolution is extremely small. To be used on an adaptor, the pinion would most likely be fixed to one part with the rack on the other. By turning a knob attached to the pinion, the two parts could be moved relative to each other quite easily. The downside is that a rack and pinion would be difficult to fit inside the adaptor and would add quite a bit of complexity to the design.

Figure 26: Rack (bottom) and pinion (top) for linear adjustment (JS Auto Tech).

4.1.2.2. *Internal Screw*

The internal screw concept is quite similar to the rack and pinion. The idea would be for an internally threaded piece, such as a nut, to be fixed to one part of the module. An externally threaded rod would be screwed into this piece, but fixed to the other half of the module. One end of the rod might stick out from the part, so that the prosthetist could rotate it. The relative rotation of two threaded pieces causes them to have a translational motion along the axis of the rod. Similar to the rack and pinion, this setup

would have a continuous resolution and be fairly accurate. There are, however, some difficulties in getting this configuration to run smoothly. An internal screw would be exposed to reaction torques acting on the two parts, which may cause them to bind together and impede motion. Despite these setbacks, many XY tables such as those on CNC machines use this type of arrangement to get precise translational movement.

4.1.2.3. *Dovetail*

This idea is adopted from the Red Unit and takes a slightly different approach than the previous two. Both the rack and pinion as well as the internal screw require an input force to move, but are primarily fixed once the force is taken away. A dovetail allows free motion until an external force is applied. For the Red Unit, this external force took the form of friction by using a set screw to push against a steel plate, which would then hold the dovetail in position (Figure 27). There are many other variations and methods of restricting the motion between the two pieces, such as with pins or magnets. The primary advantages to using a dovetail are that it very effectively constrains the motion to a single axis, and also has very cheap methods of being constrained once in position. The disadvantage is that once the constraints are removed, the device can slide around easily and potentially alter the desired adjustment.

Figure 27: Hex Key on right tightens a set screw that presses the steel plate against the dovetail after it is inserted.

4.1.3. **Angular Adjustment**

The angular module needs to adjust the rotational alignment about the anterior-posterior and medial-lateral axes. This section describes a few of the major conceptual designs, including the use of a frustopyramid, ball and socket, and hinge.

4.1.3.4. *Frustopyramid*

This idea is copied directly from the Red Unit, so Chapter 2 can be referenced for a more complete description. Since it has been used for several years, it is the most proven method and probably the cheapest. A four-sided frustum is used in conjunction with four set screws on each side (Figure 28). Set screws on opposite faces work together to position the pyramid in a particular angular orientation. By backing out one screw and tightening the opposite screw, the frustum must sit skewed in the tube clamp. The problem with this design is that the screws do not always sit flush against the face of the frustopyramid, which causes gouging and wear over time. The alignment is also time-consuming and imprecise, as the amount of change depends on the thread pitch of the screw and how many times they are turned.

Figure 28: The adaptor's frustopyramid (top) is used in conjunction with a pyramid receiver that has 4 set screws.

4.1.3.5. *Ball and Socket*

The ball and socket (Figure 29) is a fairly well known universal joint, having three degrees of freedom. It can rotate about all three axes and is analogous to the human shoulder joint. Due to the fact that this kind of joint allows for rotation in three directions, it would be ideal for this kind of application. The main problem, however, comes with trying to constrain the rotation. A set screw or some kind of clamping mechanism is generally used to fix the ball in place. This does not work so well for an adaptor application, since the three angular directions need to be adjusted independently. Thus, there would need to be some means of fixing two directions at one time, while the third is adjusted. The mechanics of this problem are rather complex.
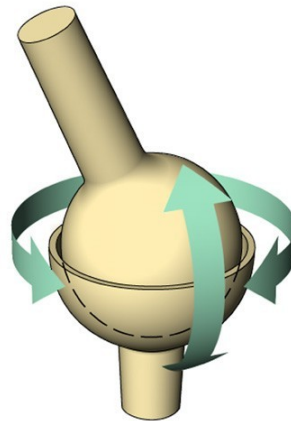
Figure 29: Ball and socket joint (Ball and Socket)

4.1.3.6. *Hinge*

A hinge, or simple pin joint, is another way of attaining rotational motion (Figure 30). Similar to a door hinge, the device would have one part of the module fixed while the other part would be allowed to rotate about the pin. The rotation could be constrained in a number of ways, such as by set screws or pins. The actual pin used to allow rotation could even be an expanding-diameter pin, so that it could be expanded when the desired orientation was reached and friction would hold it in place. The major issue with this idea is that it involves several components, some of which have to slide across one another. This increases wear, decreases lifetime, and adds to the complexity of its use and manufacturing.
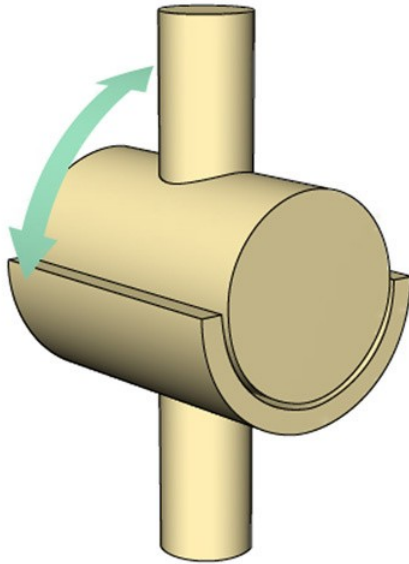
Figure 30: Hinge Joint (Hinge Joint)

4.1.4. Rotational Adjustment

The angular module was designed to adjust the rotational alignment about the proximal-distal axis. In order to meet the aforementioned specifications, the following conceptual designs were examined for this particular module.

4.1.4.1. *Rotational Stage*

This is a very general concept that encompasses a lot of different possibilities. The main inspiration came from an optical rotation stage (Figure 31), which allows for very precise rotational alignment. Essentially, it is just two pieces that can rotate with respect to each other. This motion is stopped with a set screw or similar mechanism. The Red Unit makes use of a similar design, although it is less accurate. Tick marks can be placed on the surface to allow for greater precision in either case, and this is a fairly cheap design that is effective. The major drawback is that the rotation must be set by hand, so there is no mechanical resolution in the device that ensures a precise alignment; there are only tick marks for reference.

Figure 31: Rotational stage with tick marks (Direct Industry).

4.1.4.2. *Ball and Socket Joint*

As mentioned above, using a ball and socket joint would come with built in rotation along the z-axis. However, it has the same drawback of allowing three degrees of freedom when only one is desired.

4.1.5. **Securing the Alignment**

The conceptual ideas described above are fairly general and tend to focus more on getting the desired motion rather than the specifics of its use. Although the specific manifestations will be examined later in the Preliminary Design sections, one of the important aspects to mention now is how the motion is to be constrained once the desired alignment is achieved. The most practical solutions for most of these designs were determined to be either a set screw or pin.

4.1.5.1. *Set Screw*

Set screws (Figure 32) are one of the cheapest and easiest ways of constraining motion between two parts. Essentially, one of the two pieces has a threaded hole through which the screw is inserted. As it is screwed in further, it applies pressure to one of the faces on the second part. By using multiple set screws that are evenly distributed, the second part can be squeezed in place by the pressure of the screws. The ultimate holding force in this case is friction, which varies with how tightly the screw is inserted.

Figure 32: Set screws with flat ends to apply holding pressure (DIY Mobile Audio).

4.1.5.2. *Pin*

The use of standard dowel pins (Figure 33) is also a simple, yet effective way of securing two components. By inserting a pin all the way through two different parts, the only way that relative motion can occur is by breaking the pin. With a strong enough pin, this would not be an issue.

Figure 33: Standard dowel pin with rounded ends for smoother insertion (McMaster-Carr)

4.2.   Means Selection

In order to quantitatively analyze and compare the use of each of these conceptual designs, a means comparison chart was used. Each of the five main categories of specifications described in Chapter 3 (performance, safety, ease of use, reliability, and cost) was weighted as described in the following section. Each mean was rated by giving it a score under a specification, and multiplying such score with the weight of that specification. This analysis provided information about which means would be more appropriate for the design based on which received the highest score within each alignment module.

4.2.1.   Determining Specification Weight

As the five key categories of specifications were performance, safety, ease of use, reliability and cost, it was important to carefully compare them to each other, and weight them accordingly. Each category of specification was given a number from 1 – 10, with 1 being unimportant to the overall success of the prototype, and 10 being extremely crucial to the function of the device. As performance was directly related to the function of the device, it was given a weight of 10. Because the device could potentially cause harm if not designed properly, safety was given a weight of 8. Ease of use was given a weight of 6, because while it is important that the prosthetist is able to use the device easily, it is not crucial to the overall functioning of the device. Since the device is to be used repeatedly for many years on a variety of patients, reliability was deemed a very important specification, and thus given a weight of 8. Lastly, since the device only needs to be purchased once and is long lasting, cost was determined to be less important to the overall success of the device and weighted with a score of 4.

4.2.2.   Design Selection

Each of the design means were placed into the means comparison chart (Appendix B) and scored by each team member from 0 – 10, 0 meaning that the means does not fully meet the requirements of the particular specification and 10 being that it is the best means for that specification. After discussion and comparison, a team consensus was reached based on the means, which received the highest score. Once this consensus was determined, the means was chosen as a part of the preliminary design. The means were initially analyzed separately for the individual modules, and then the preliminary design was analyzed as an assembly to ensure that the modules interfaced well together.

For the height module, notched pipes were given a score of 292 for many reasons. Such a design would allow for discrete and independent adjustments within the range and resolution needed, while

providing the prosthetist a means to quantify the height adjustments. In addition, they are fairly safe, as they have been used in such devices as track and field hurdles, and other piping. Furthermore, the design is easy to use, repeatable and intuitive to learn, without much use of sophisticated tools. It is also relatively simple to manufacture in terms of cost. On the other hand, the threaded pipes means was given a score of 172. While such a design provides adjustments within the necessary range, and an infinitesimally small resolution, it does not enable discrete height adjustments. Thus no particular height adjustment is repeatable, and so it received a 0 for the performance specification. In addition, an adjustment in the height using this design would require a change in rotational position, requiring dependent alignment adjustments. For the pneumatics means, a weighted score of 222 was given. While such means of height adjustments is reliable and safe, it does not lend itself well to ease of manufacturing. It also does not provide a discrete and quantitative means of alignment.

For the linear adjustment, the use of a rack and pinion, dovetails, and internal screws were compared using the specifications listed in Chapter 3. The dovetail was given the highest score of 294. This means could be designed to enable discrete and independent adjustments within the range and resolution needed, while providing the prosthetist a means to quantify the linear adjustments. In addition, they are fairly safe, and have been used in the current standard – the red unit. As a result of such uses, it is known that the design will be easy to learn, since the prosthetist already knows how to use it. The dovetail can be used without much use of sophisticated tools. It is also relatively simple to manufacture in terms of cost. On the contrary however, the rack and pinion and internal screws each received a score of 246 and 256, respectively. For example, the rack and pinion scored low on the performance category, as it does not provide discrete adjustments. Although it provides continuous resolution, the adjustments are not discrete and thus cannot be quantified. In addition, it scored low on the cost, as such a design would be expensive to manufacture in the shop. While the internal screw scored high for ease of use, it did not receive a very high score for performance, due to the fact that such rotation may impede motion of pieces, and it also would not provide discrete measurements of alignment. Such scores showed that the dovetail was indeed the best choice, and thus it was chosen.

For the angular adjustment, the hinge was given the highest score of 272. It would perform very well, allowing for a fine resolution of adjustments, and an appropriate range. In addition, it is safe and relatively easy to use and manufacture. The frustopyramid was given a score of 250. While it did not score extremely high on the performance category, it scored higher on the ease of use category due to the fact that such a system is already in place in the red unit, and prosthetist would have an easy time

using it. Based on the red unit, it is clear to see that although the use of set screws as the securing mechanism wears the material over time, the frustopyramid itself is reliable. On the other hand, the ball and socket means scored worst (218). One of its major problems was with the performance specification, in which it scored 5. Such design would not allow for independent or discrete adjustments of alignment, and thus would be ineffective at quantifying such alignment. Although the hinge received the highest score for this particular function, the frustopyramid was chosen for the preliminary design because of its compatibility with the existing components of the prosthesis.

For the rotational adjustment, we examined the rotational stage and the ball and socket. The rotational stage received the higher score of 280. As described earlier, the ball and socket does not provide an independent and discrete means of alignment and so scored low on the performance category. Although it may be difficult to design the rotation stage to be quantitative, it can be done, and thus this means was given a higher score. Furthermore, in terms of ease of use, the rotational stage has been used in the red unit, and thus would be ease for the prosthetists to learn and use.

For the securing mechanism, the two means (pin and screws) were virtually the same. The only difference was that the screw was given a lesser score in reliability, as it would tend to cause wear and tear of the device. Thus, pins were chosen as the best mechanism for securing alignment in the adaptor. In combining all the chosen means, the first preliminary design was created as described in the following sections.

4.3. Preliminary Design Iteration 1

The most appropriate design from each type of alignment was combined to form the first conceptual design. The model went through various testing procedures in order to ensure that it was the optimal design. It was first modeled in SolidWorks and then rapid-prototyped out of ABS plastic. Based on observations, the design went through further iterations to reach a final design that met the design specifications.

4.3.1. Overall Design

The parts of the design were chosen based on the ranking system described in Chapter 4.2.

Height Adjustment Module Shape

The height adjustment module involved two concentric cylinders that contained 18 circular holes for pins around all faces. These holes were offset by a sixteenth of an inch in order to provide different levels of height when the pin was inserted through both cylinders. To change the height of the adaptor, a prosthetist would simply have to align the holes in the counterpart cylinders, thus increasing/decreasing the height to the appropriate setting.

Linear Adjustment Module

For the linear motion, the design included a dovetail concept combined with a pin fastener to restrict motion to one axis. The inner dovetail consisted of 12 holes placed ¼ inch beside each other. The outer dovetail comprised 1 hole in the center. A prosthetist would insert a pin through the hole in the outer dovetail and into the appropriate hole on the inner dovetail. The various choices for the second hole allow for 12 different settings. Two of these linear adjustment modules would provide adjustment in both the x and the y directions. Figure 34 through Figure 37 show the rapid prototyped linear adjustment components from different views.
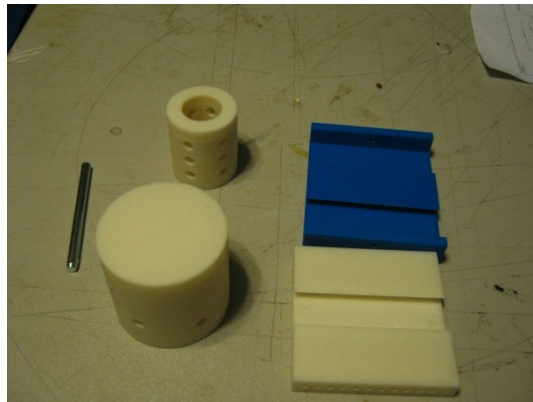
Figure 34: Rapid Prototyped Height (left) and Linear (right) Adjustment as separate components
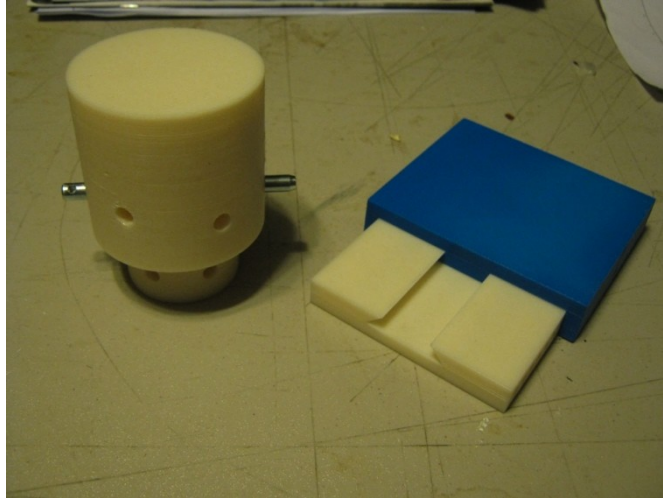
Figure 35: Rapid Prototyped Height (left) and Linear (right) Adjustment with components in place
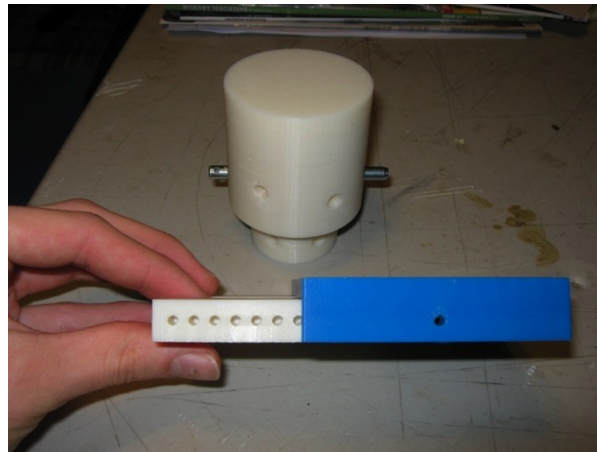
Figure 36: Rapid Prototyped Height (back) and Linear (front) Adjustment from a side view
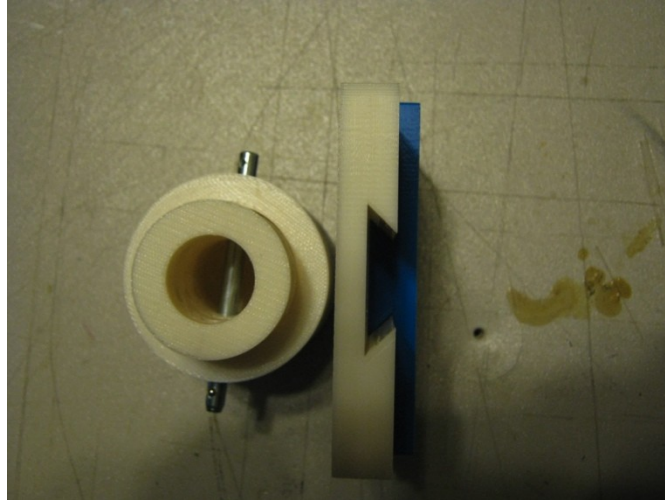
Figure 37: Rapid Prototyped Height (left) and Linear (right) Adjustment from a top view

Angular Adjustment Module

The angulation module of the conceptual design was adapted from the red unit, which utilizes a frustopyramid. This component allows for rotation about the x- and y-axes with screws that secure the device in place. A prosthetist would align the prosthesis to the proper setting and then insert screws from four different sides until the device is firmly locked into place. The similarity between the red unit and this design allows for effective interfacing with the pylon of standard transtibial prostheses.

Rotational Adjustment Module

The need for a separate rotational adjustment module was eliminated due to the fact that the specific design for height adjustment provided rotation in addition to height. A prosthetist would rotate the outer cylinder to the desired location and then proceed to adjust the height. This conceptual design is therefore flawed since it does not allow for independent adjustment of two degrees of freedom, a functional requirement for the new adaptor. Problems could arise when height needs to be compensated for a specific rotational adjustment.

4.3.2. **Need for Improvement**

The team analyzed the design and presented it to a prosthetist and a prosthetic technician. The feedback was then taken into consideration and incorporated into the second round of design.

Observation of the height adjustment module showed that there was tipping of the inner cylinder within the outer cylinder. This could affect the overall alignment since there is now a moving component in the device and it will constantly change the other modifications. Additionally, it was noticed that some holes gave a snug fit for the pin while others were too tight or too loose. The occasional movement of the pin would be inconvenient for the patient since his alignment would be varying. Therefore, tolerancing of the holes was a necessary consideration in the machining of the device. Also, the device overall was larger than the red unit. A more compact design would decrease the discomfort of the patient in switching adaptors.

Finally, the primary concerns identified in the first prototype were:

1. A need for precise tolerancing

2. A redesign of the height adjustment to eliminate redundant degrees of freedom

3. A decrease in the overall bulkiness of the model

These problems would be addressed in the subsequent iterations.

4.4. **Preliminary Design Iteration 2**

For this iteration of our design, we focused on two major design decisions:

1. The best shape to make the height adjustment module.
2. How to best combine all the different modules into one adaptor.

The progression of each of these design decisions led to improvements over the previous iteration and will be discussed in detail in this section.

4.4.1. **Areas That Were Improved**
The main improvements over the previous iteration were the following:

1. Using a square-shaped height adjustment module instead of a cylindrical height adjustment module.

2. Combining all the different adjustment modules, from proximal to distal, as follows: rotation adjustment, height adjustment, linear adjustment and angular adjustment.

It will now be discussed why the team reached each of these design decisions, beginning with the shape of the height adjustment module. Each individual module will also be discussed, followed by how the team decided to combine all the adjustment modules.

Height Adjustment Module Shape

To summarize from the previous iteration, the primary issue with the cylindrical height adjustment was the fact that there were a total of two degrees of freedom that could be adjusted. One was obviously the height, or z-axial translation, but the other, unintended adjustment was z-axial rotation. A cylindrical-shaped height adjustment allowed for free rotation about the z-axis since there was no means of fixing the rotation in our previous iteration. The team brainstormed three new solutions to address this issue:

1. Cylindrical Shape with Notch
2. Hexagonal Shape
3. Square Shape

All of these solutions will solve the issue of restricting the height adjustment to one degree of freedom, that is, z-axial translation. Additionally, they each could achieve at least a 12/16 inch range, the minimum required per our design specifications. They will each be discussed in detail.

Cylindrical Shape with Notch

The cylindrical shape with a notch addressed the fact that the cylindrical shape seemed to work with the exception of the additional degree of freedom (z-axial rotation). Upon further design within the nominal diameter of 2.5 inches, it was determined that this shape with a notch was possible but it lacked all of the possible adjustments. With a constrained diameter cylinder and the design consideration to have a pin pass through the entire module, it was geometrically determined that this design wouldn't allow for a symmetric arrangement in which a 1/16 inch resolution could be completely achieved for a full range of 15/16 inch. Specifically, the sizing of the cylinders and the spacing of the holes wouldn't allow for a symmetric positioning of the 1/2 inch position height adjustment. It's important to have a consistent

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resolution from 1/16 inch to 15/16 inch. This design was thus rejected since other designs could achieve the full range and resolution.
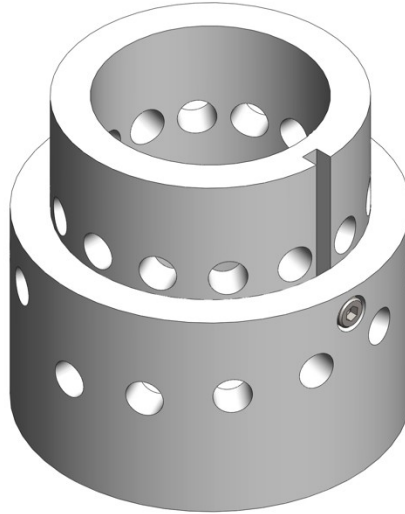
Figure 38: Cylindrical shape with a notch prevented z-axial rotation, an improvement over the previous iteration, but the full resolution within the desired range wasn't possible.

Hexagonal Shape

A hexagonal shape (Figure 39) was considered because of its symmetry, thus allowing the pin full clearance through the module, and the fact that it would prevent z-axial rotation. It also allowed for a 1/16 inch resolution across a 12/16 inch range. The main issue with this design was manufacturability. There are very few options, at least in terms of sizing and thicknesses, when considering hexagonal shaped metal tubing. While the full range and resolution could be achieved, it's of utmost importance to be able to acquire the necessary parts to actually manufacture the part.
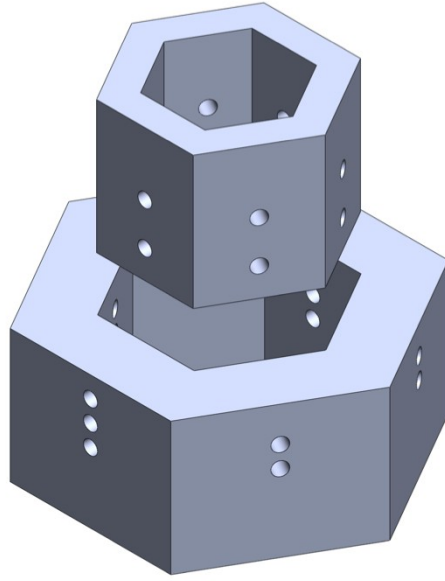
Figure 39: Hexagonal version of the height adjustment module. The exterior component is on the bottom while the interior component is on the top and fits inside the exterior component.

Square Shape

A square shape was then considered to address the issue of not being able to manufacture the hexagonal-shaped height adjustment.   A square shape would still preserve restriction to z-axial translation. Additionally, square shaped tubing is readily available from many different metal distributors. Through design in SolidWorks, it was determined that a square shape could achieve at least a 3/4 inch range with 1/16 inch resolution. It was therefore concluded that a square-shape would be the best choice for height adjustment (Figure 40).
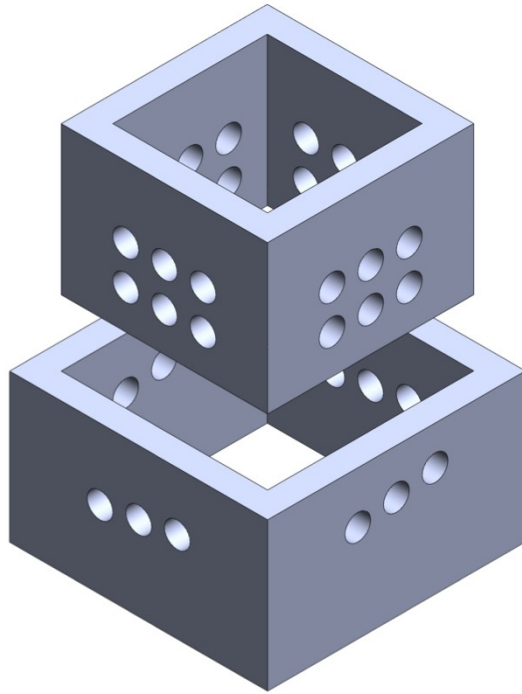
Figure 40: Square version of the height adjustment module. The exterior component is on the bottom while the interior component is on the top and fits inside the exterior component.

Linear Adjustment Module

Although the red unit also utilizes a dovetail for anteroposterior and mediolateral translation, our preliminary design incorporates a dovetail with quantitative adjustment, utilizing pinhole clearance through the entire module (Figure 41). All the holes are spaced ¼" apart and the holes of the opposite end are offset by 1/8 inch, allowing for a total resolution of 1/8 inch and a range of 2 inches, which is the desired goal of our design.
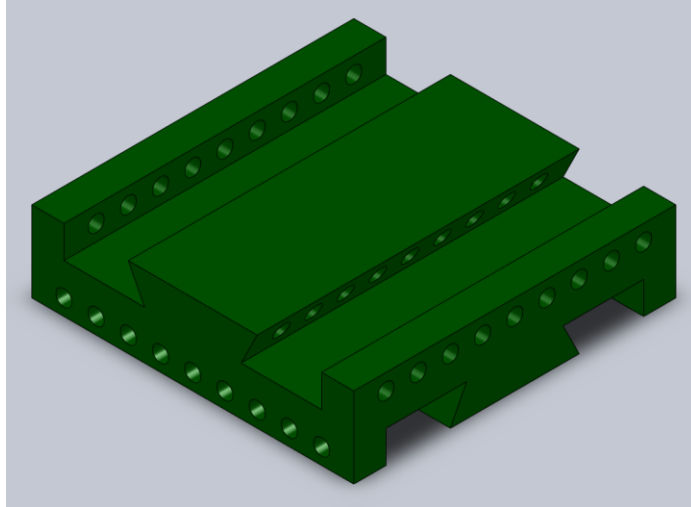
Figure 41: Anteroposterior/Mediolateral Translation (double dovetail) module.

Angular Adjustment Module

The angulation module of the preliminary design is the frustopyramid (Figure 42), which provides rotation about the x- and y-axes. Such a design is identical to that of the red unit; however holes have been placed on the receiving end of the frustopyramid in order to integrate it with the team's dovetail design for linear adjustment. Such similarity allows this module to interface effectively with the pylon of standard transtibial prostheses.
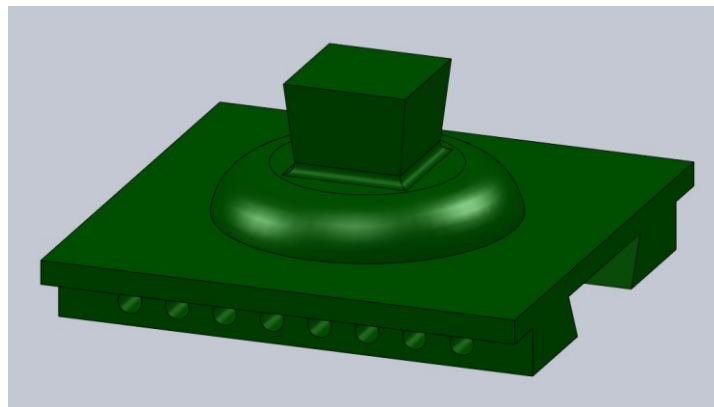
Figure 42: Angulation adjustment module (frustopyramid).

Rotation Adjustment Module

The rotation adjustment module was modeled after the red unit's rotation adjustment, which is the interface of its socket attachment plate and top plate assembly. The team considered adding pin clearance holes for quantization, but discarded this idea after determining the lack of necessary resolution. The conceptual idea is presented in Figure 43, but it was determined that using the same module as the red unit would be the most compatible and conventional.
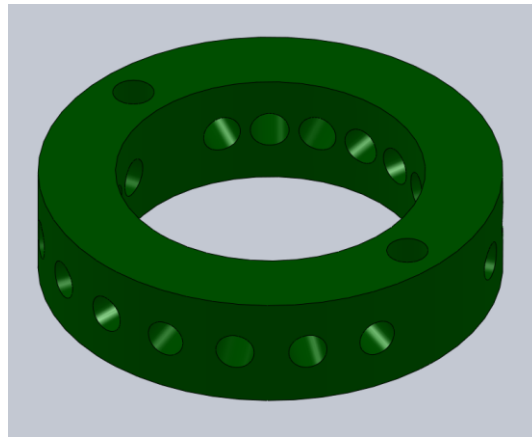
Figure 43: Rotation Adjustment Module with a conceptual idea of quantizing the amount of adjustment. The quantization was later discarded to comply with the standard means of rotational adjustment.

Combining the Modules into One Shape

In deciding how to combine the different modules into one adaptor, it was of extreme importance to consider how the current standard currently interfaces and attaches to the residual limb. While we are improving upon certain aspects of the alignment adaptor, we are also maintaining the function of certain modules of the red unit. Functions we are not changing include the interface of the alignment adaptor with both the prosthesis and the residual limb. The current standard device, from proximal end to distal end, begins with rotational adjustment, continues with linear adjustment, and ends with angular adjustment. Since we are adding in the option of adjustable height, we determined that it would be best to incorporate it between the rotational and linear adjustments, since the current standard already incorporates the interface of linear adjustment and angular adjustment into one module.

It was then decided that the ideal order of combining the modules while best preserving the configuration of the current standard would be: rotational adjustment, height adjustment, linear adjustment and then angular adjustment.

4.4.2. Areas That Need Improvement

While this iteration provides for two main improvements from the first conceptual design, there are still some key areas of improvement to attain the optimal design:

1. The design is yet not optimized for manufacturing.
2. Hole spacing and sizing is not yet optimized based on finite element analysis.

The goal of the next iteration is to directly address these issues to lead toward our final design.

4.5. Preliminary Design Iteration 3

Once all the modules were designed and in a form that could potentially be a real solution, it was much easier to improve each of the features. It is often necessary to see how the device will function as a whole before all the problems can be truly worked out.

4.5.1. Areas That Were Improved

This design iteration focused on improving the design in terms of strength, hole layout, and manufacturability.

4.5.1.1. *Strength: Finite Element Analysis*

Using ANSYS Workbench 12, it is possible to analyze the mechanical response of the device to the load it is likely to experience. This provides useful information, such as if the device is likely to break in a certain area, or if it is over engineered and material can be removed. Since the analyses can be time consuming and difficult to validate, the first stage is to look qualitatively at areas of high stress concentration. This means that the actual stress values are not very important, as they may not be entirely accurate or converged for all locations. The important information from these tests is whether or not the geometry of the device can be easily changed to reduce an area of high stress.

Throughout all the finite element analysis (FEA), certain parameters were left the same. First, the model of the preliminary design was imported into ANSYS as a parasolid from SolidWorks. All parts were assigned Aluminum Alloy as a material, except for the pins, which were modeled as stainless steel. The connections between the pieces were left as the default values, since they were previously defined within SolidWorks. The mesh was changed to have a medium relevance center to increase the accuracy

of the analysis. In other words, the number of nodes and elements was increased to provide a higher resolution mesh, which is important for geometries with sharp edges. The loading was applied to the bottom of the linear slide adaptor, and the fixed support was applied to the top of the device (see Figure 44). The load was applied to the bottom of the adaptor instead of the frustopyramid to simplify the modeling. The results consisted of Von-mises stress and deformation values.
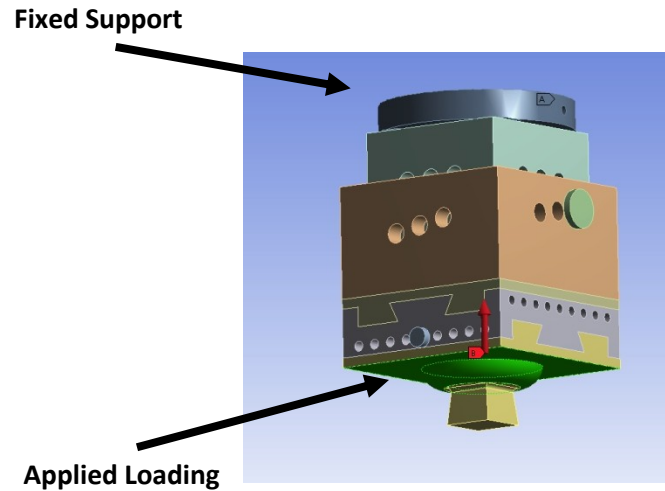
Figure 44: FEA support and loading of device

To ensure the modeling was being done correctly, it was advantageous to begin the analysis with a simple scenario. The first test conducted was with an applied vertical force of 1600 N. This number came from some basic force platform tests that identified the loading during a light jog. The lateral adaptors were both in their neutral position, but the vertical adaptor was extended to its maximum range. This allowed the problem to be fairly symmetric, while still including the primary force exerted on the device. The stress distribution that resulted is shown below in Figure 45:

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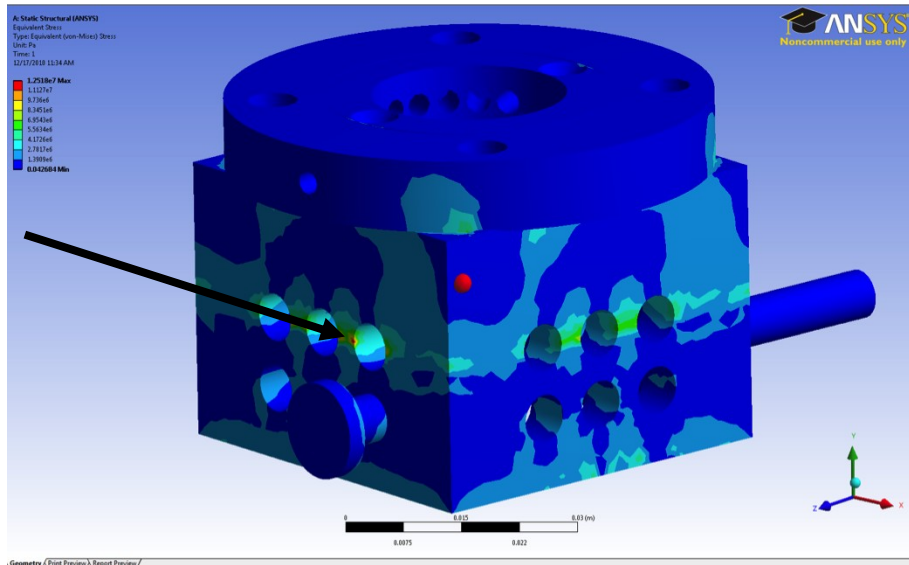
Figure 45: Stress distribution on device with vertical force only and no lateral adjustments

The other parts to the device have been removed from the picture in order to show the area of highest stress concentration, occurring at one of the holes on the device (as indicated by the arrow). Since this area results from close horizontal spacing of the holes, the holes can be spaced further apart. This would minimize the effect of the stress concentration from one hole adding onto that of its neighbor.

The next step was to analyze the device in a position it was likely to be used in, meaning both vertical and lateral alignments. Positions were chosen for the adaptor that were about half of the maximum extension in X and Y. The height was left at the maximum. To make the simulation even more realistic, forces and moments in all three dimensions were added, instead of just a vertical force. The values for these numbers were approximated from force platform tests conducted on a team member. The subject jogged across the force platform while the forces and moments at the foot were recorded. These numbers from the foot were then converted to numbers at the adaptor assuming a simple, rigid-body, and statics situation. The accuracy of these calculations is not critical at this point, since it is still the relative distribution that this analysis is concerned with, not the actual numeric values. The loading is summarized below in Table 4, and the resulting stress distribution is shown in Figure 46:

Table 4: Loading used for qualitative finite element analysis

	X	Y	Z
Force [N]	200	1600	350
Moment [Nm]	200	10	40

Thin walls that can be removed based on FEA results
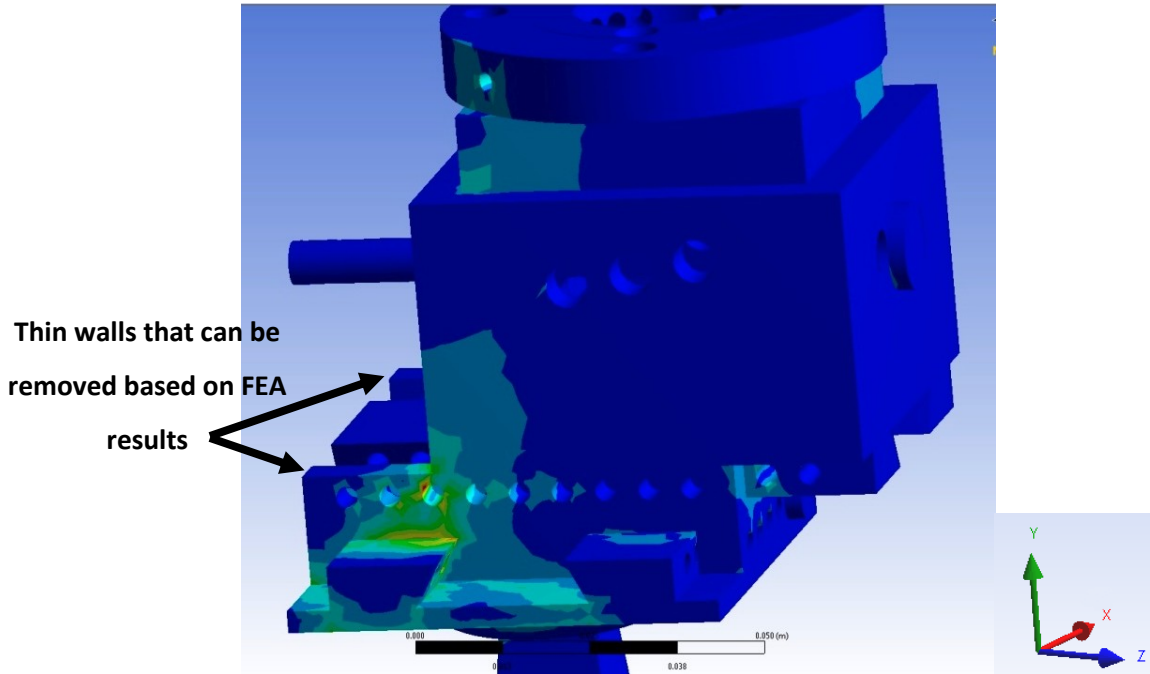
Figure 46: Stress distribution on device with full loading, and lateral and vertical alignment

As Figure 46 shows, the maximum stress again occurs on the edge of one of the holes, but this time it is on one of the linear modules. This suggests that either the 1/8 inch holes are spaced too close together or the wall is too thin for the load it will be subjected to. At this point it was decided that this wall could be removed and the pins would still have enough support. Getting rid of these walls eliminates an area of high stress, decreases the weight of the device, and makes the part easier to be manufactured.

4.5.1.2. *Hole Layout*

After these changes were made based on the FEA models, more attention was put on the particular arrangement of the holes. After spacing out the holes on the height module to reduce the stress concentration, it was observed that they looked too far apart to be efficient. The idea was then brought up as to whether or not four holes could be fit across each face. This would allow for an additional 1/16

inch per side on the larger square, per row on the smaller square. Thus, by simply adding a fourth hole, the range of the height module could be extended by ¼ inch. This increased the overall range to 15/16 inch, which was above our design specification of 12/16 inch.

The next major problem with the hole layout occurred in the translational modules. Since the different sides had holes that were offset from each other, it would be impossible to push a pin through the entire unit. This meant that the pin would stop about halfway through. Not only is this an unorthodox use of pins, but it also presents a problem with fixing the pin in place. If only one end of the pin is accessible, it makes fixing the other end a major challenge. To avoid this, it was decided that the pins really had to go all the way through the part. However, this would ruin the idea of offsetting the holes on opposite sides. The only way to get the needed resolution, therefore, was to create two rows of holes that were offset from each other. Each row could go all the way through without interfering with the other, so the same amount of resolution could be obtained. This came at the price of increasing the overall height of the unit. Although regrettable, this was a necessary design change.

With the change to two rows of holes through the dovetail, the concern came up as to whether or not the dovetail would be strong enough if it had lots of holes through it. It was also observed that there was a lot of redundancy in the hole placement. In other words, the same translational offset could be obtained with different pin configurations. This was the result of having a full set of holes on both moving components. The solution to both problems was to eliminate the full set of holes on the dovetail. In reality, only one hole was needed on the dovetail for each row.

4.5.1.3. *Manufacturability*

The final round of improvements for the adaptor pertained to making the device manufacturable. This proved an interesting challenge, since what looks like a good design in CAD is not always practical. The major limitation encountered was with regard to the pin sizes. With the pins now going all the way through the model, the easiest means of securing them would be to use the aforementioned detent pin. Once through the hole, the ball on the end of the pin would pop out and prevent the pin from working its way out. However, there were no commercially available detent pins that were 1/8 inch in diameter. The smallest size was 3/16 inch, since any smaller than that and it is too difficult to accommodate the spring-loaded detent ball. After modeling the 1/8 inch holes as 3/16 inch holes, it was clear that the part would have to be made even taller to accommodate them. This would then increase the cost of materials and require a larger, more expensive dovetail cutter. Rather than all of that, the decision was

made to go ahead with the 1/8 inch pins, but these would have to be secured by a different means. Attaching oversized magnets to each end would work, as would cutting a groove in each end of the pin and using a retaining ring. Until the part was complete and the exact tolerancing on the hole determined, this design decision was left unmade.

The next challenge was in selecting a dovetail cutter. The previous iterations were based on the dimensions of the dovetail from the Red Unit, but these would no longer work with the new spacing of the 1/8 inch holes. After researching the standard sizes of dovetails commercially available and considering the necessary space to fit two rows of 1/8 inch holes, the model was modified slightly to accommodate a standard dovetail size.

The last stage of this iteration was to ensure that all parts had the necessary fillets on them. Since cutting tools can't make an internal edge perfectly square, the parts had to be modified to account for the tool radius.

4.5.2. **Rapid Prototype**

Once these changes were made, the model was sent in to the WPI Mechanical Engineering Department to be rapid prototyped out of ABS. Figure 47 below shows the result of this iteration with all the changes made.
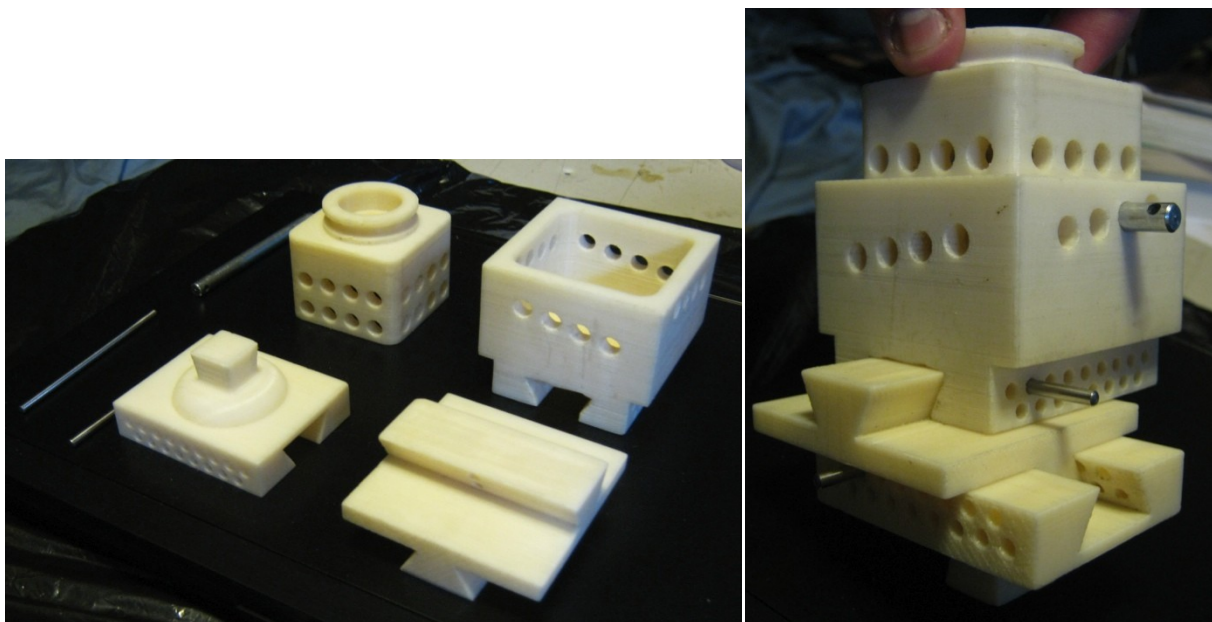
Figure 47: Pictures of the final design rapid prototype.

5.   Final Design

Once the final iterations were made to the preliminary prototypes, the final prototype, shown in Figure 49, was manufactured and analyzed. The following sections provide a detailed description of the prototype, how it can be used, and the process through which it was manufactured. Detailed drawings of each part with labeled dimensions can be found in Appendix C: Technical Drawings of Final Design. Note that the parts are colorized in several of these figures for visual clarity.
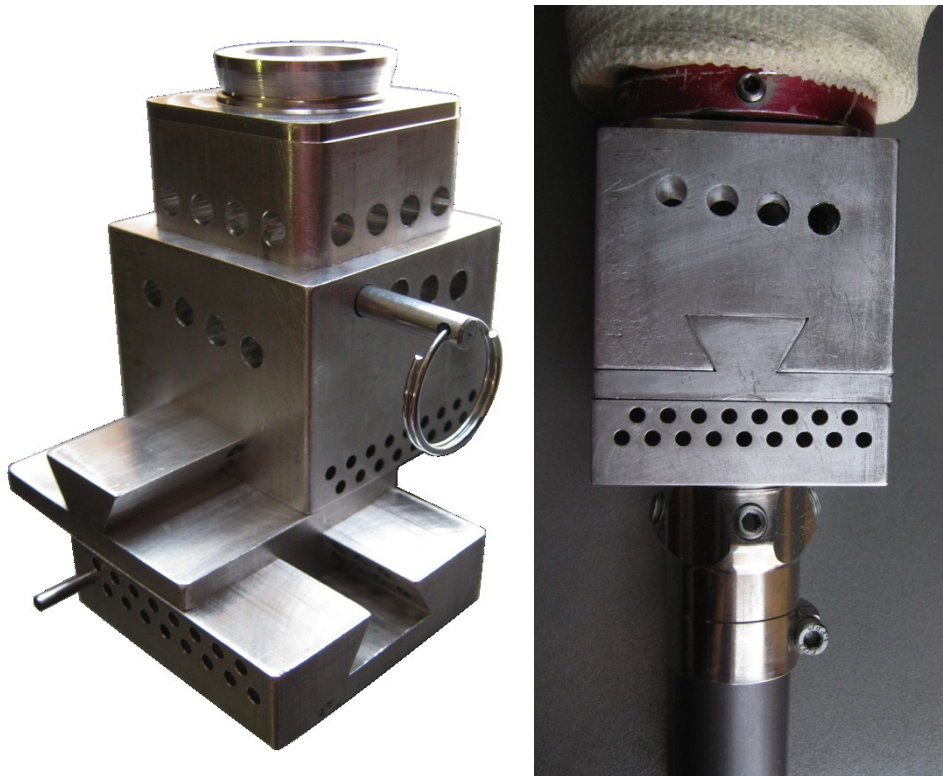
Figure 48: Manufactured prototype of the final design in an adjusted position (left) and in a neutral position (right).
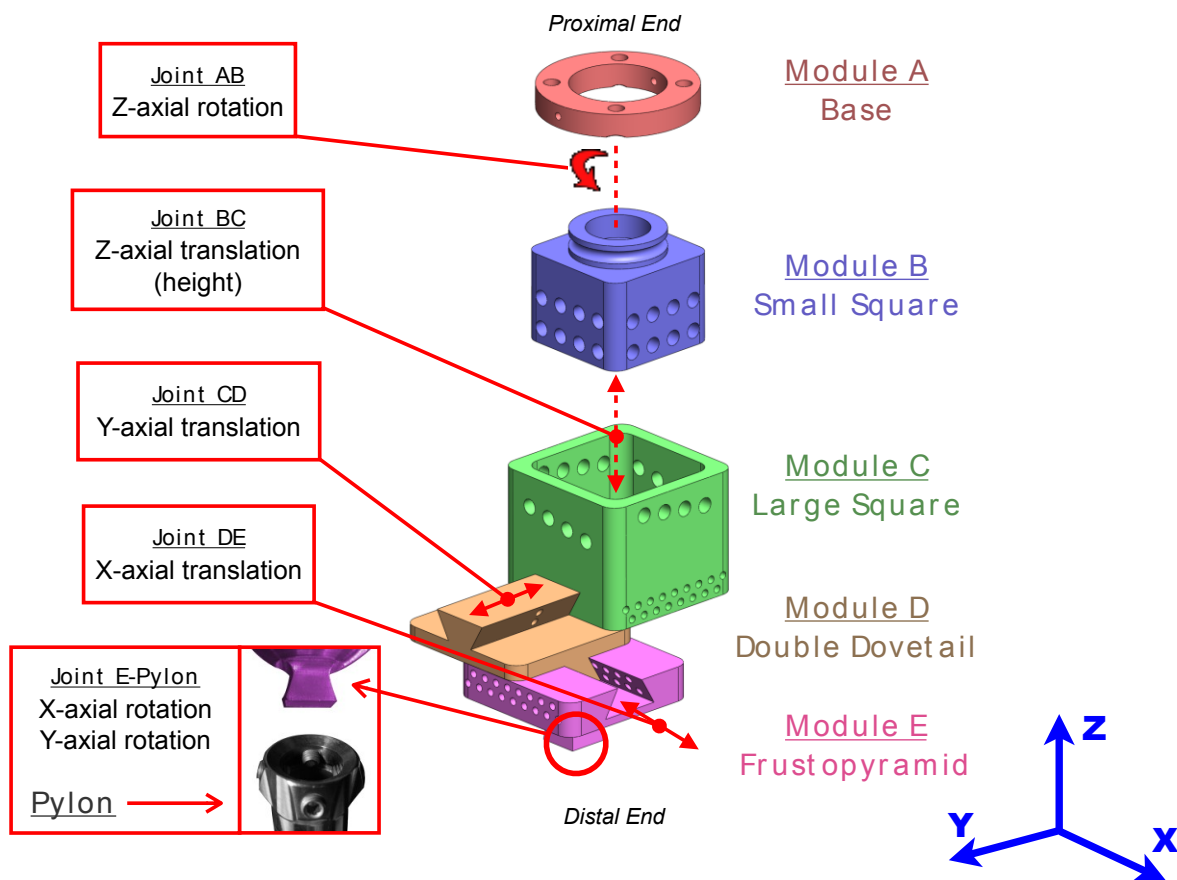
Figure 49: The final design of the new prototype (digitally colored for visual clarity), showing the 5 modules as well as the 4 inter-modular joints and the distal joint made with the pylon.

5.1. Attachment to Prosthesis

It was important to determine how the final design would attach to both the residual limb socket and the prosthetic leg pylon. While an innovative design can be more productive than prior art, it's also important to consider the apprenticeship approach of prosthetic fitting. It was therefore decided that the attachment to the socket and prosthesis would be best kept the same as the popular red unit.

5.1.1. **Module A: Base**

A large component of the adaptor's usability is how it interfaces with current modules. In a field that is dominated by an "apprenticeship" mentality, it is critical that any changes to the process are intuitive and easy to adapt to. For this reason, the final design uses a shared component with the red unit adaptor: the Socket Attachment Plate, which is the same as Module A (Base) shown below in Figure 50.

Screw attachment to wooden block

Set screw attachment to Module B
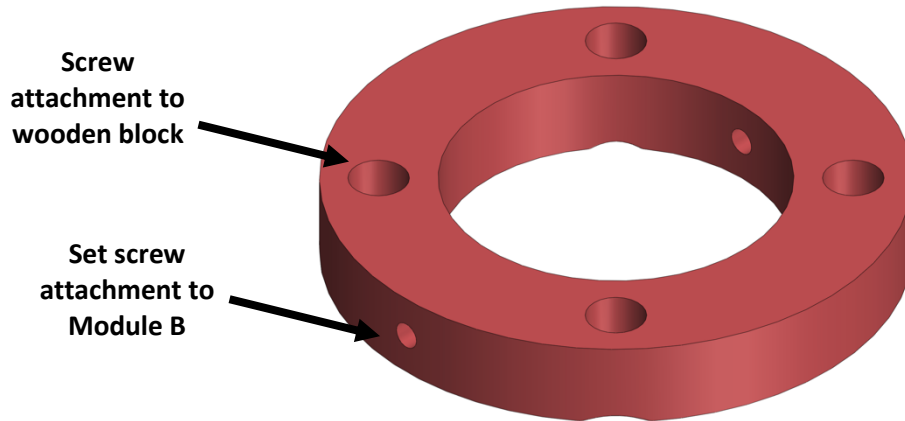
Figure 50: Bottom view of Module A (Base) of final design.

At the distal end of a patient's initial socket is a block of wood that allows the adaptor to be attached. The four countersunk holes in the socket attachment plate allow four screws to be inserted through the plate and into the wooden block. This secures the plate to the bottom of the socket, and provides an attachment point for the rest of the adaptor.

The rest of the adaptor can be attached to Module A by set screws. There are three set screws evenly spaced around the socket attachment plate that protrude into the open circular center when fully inserted. The next component of the adaptor, Module B, has a complementary circular boss that fits concentrically into this open region and is rigidly fixed by the set screws. Whereas Module A allows the top of the adaptor to attach to the residual limb, Module E attaches the adaptor to the lower region of the prosthesis.

5.1.2. **Module E: Frustopyramid**

At the most distal end of the adaptor is the classic frustopyramid feature (Figure 51). Although the functional use of this feature is to allow for angular adjustment, it is also the interfacing point between the bottom of the adaptor and the top of the tube clamp, at the proximal end of the pylon.
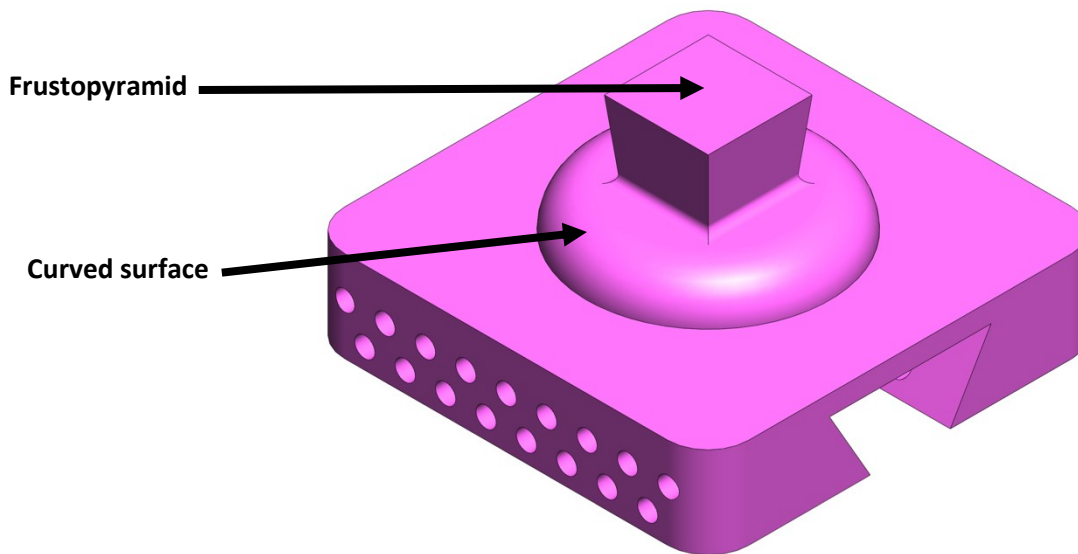
Figure 51: Bottom view of Module E (Frustopyramid) of final design.

The connection to the tube clamp has two major components: the curved surface and the actual frustopyramid. When it sits on the tube clamp, the curved surface is what bears all the weight. It needs to be curved so that various angular alignments can be made while maintaining contact with the clamp. The tapered sides of the frustopyramid are clamped by four set screws located on the tube clamp (Figure 52). The set screws on opposite sides of each other work together to define a specific angular orientation on one plane. For example, the set screws on the left and right define the angular position along the lateromedial plane. To change an alignment, one set screw is backed out and the other screwed in further. This forces the whole frustopyramid to be angled to one side while maintaining a rigid position. The tapered walls on the frustopyramid prevent the set screws from sliding down the walls and causing detachment. At the bottom of the tube clamp is an additional set screw that clamps down on the pylon once it is in place.

Figure 52: Interface of Module E (Frustopyramid, top) and the tube clamp of the pylon (bottom). The four set screws cause a fixed angle lateromedially and/or anteroposteriorly.

The socket attachment plate and frustopyramid are both standard ways of attaching an adaptor to a lower limb prosthesis. These parts were selected to increase usability for prosthetists and provide them with a familiar means of attaching a new device. It also reduces the complexity of the design, since no new pieces or attachment methods are necessary.

5.2. **Height Adjustment**

The red unit does not have a means for adjusting the height, so this was the most innovative aspect of the final design. The primary goal was to provide a quick and easy means of adjusting the height within a large enough range so that the prosthetist would not need to physically cut any pylons. Tube clamps come in a variety of standard heights, so the range of our device also covers the difference between these standard heights. Mechanically, the height adjustment module consists of a sliding joint between Modules B (Small Square) and C (Large Square) that is constrained with a pin.

5.2.1. Module B: Small Square

The top part of the sliding joint is Module B (Figure 53). It is 2 inches long, 2 inches wide, and roughly 1.8 inches tall. The inside is hollowed out so that the walls are ¼ inch thick. Each vertical side has two rows of four holes, with the holes maximally spaced across the length of the face. This was a design decision that was made after the finite element analysis showed areas of high stress concentration in the region between the holes when they were closer together. The holes are ¼ inch in diameter and pass completely through the part. The distance between the two rows of holes is ½ inch, the reasoning for which is explained in Section 5.2.3. Finally, there is a ¼ inch fillet on the vertical, outside edges that provides for a smooth sliding fit within Module C and allows the part to be machined easily.
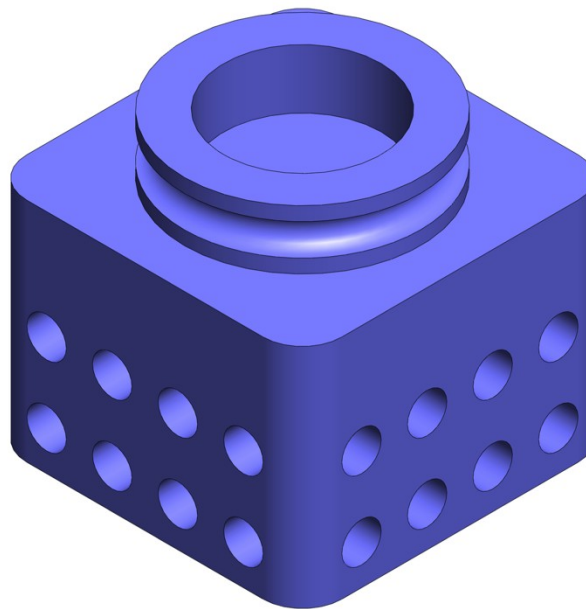
Figure 53: Module B (Small Square) of final design.

5.2.2. Module C: Large Square

The other half of the sliding joint is Module C (Figure 54). This piece is 2.5 inches long, 2.5 inches wide and 2 inches tall. There is a 2 inch square pocket on the top face of the part that allows for Module B to slide in and out. The walls of this pocket are ¼ inch thick, and the pocket is deep enough to allow Module B to fit fully inside, minus the circular boss (Figure 55). The floor of the pocket is 1/8 inch thick at its thinnest point (in the middle of the dovetail). There are four ¼ inch holes on each vertical face of

the part. The spacing of these holes horizontally matches that of Module B. The vertical spacing of the holes will be described in Section 5.2.3, but is in 1/16 inch increments.
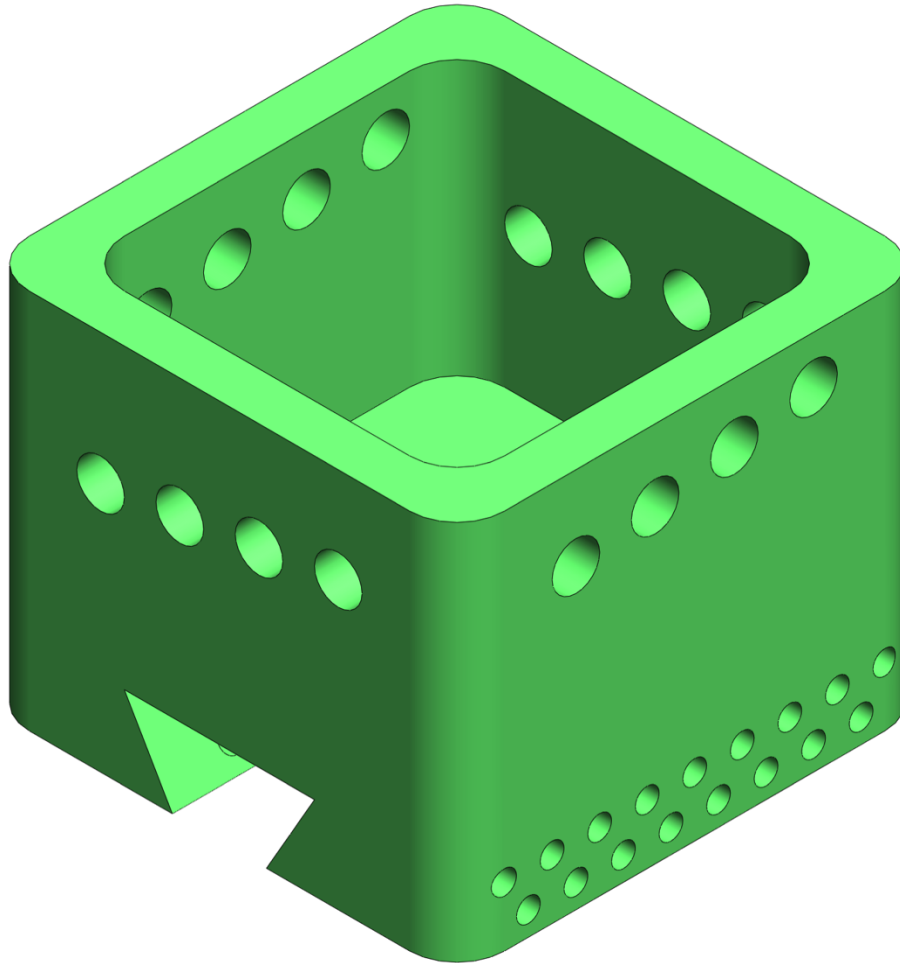
Figure 54: Module C (Large Square) of final design.
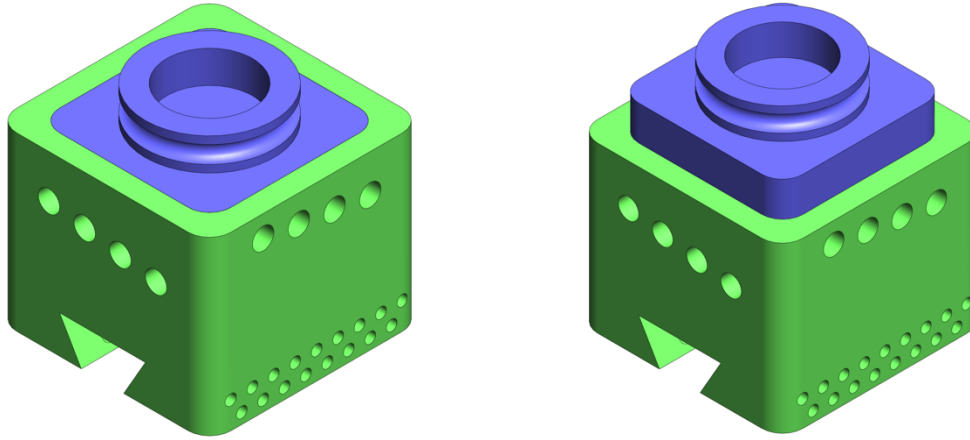
Figure 55: Interface of Modules B (purple) and C (green). Module B is lying fully in the pocket of Module C (left), and the height is partially adjusted (right).

5.2.3. Method of Changing the Height

In order to change the overall height of the adaptor, a ¼ inch pin is inserted through one of the ¼ inch holes of both Module B and C, and passes through the holes on the opposite end. Since the geometry of these parts forms a one degree of freedom sliding joint, and the pin removes that degree of freedom, the resulting structure will be fixed at a given height. The pin may be secured in a variety of ways. The easiest, and the one intended in this design, is to use a ¼ inch detent pin. This kind of pin has a spring loaded ball at one end and a key ring on the other. Once the pin passes through both parts, the ball pops out of its hole, increasing the effective diameter of the pin and ensuring it does not idly fall out. With enough force, the ball will retract and the pin can be removed.

Understanding how the height can be changed incrementally is a fairly simple concept, but can be difficult to visualize. For explanation purposes, a system of numbers and letters has been overlaid on Modules B and C in Figure 56 below.
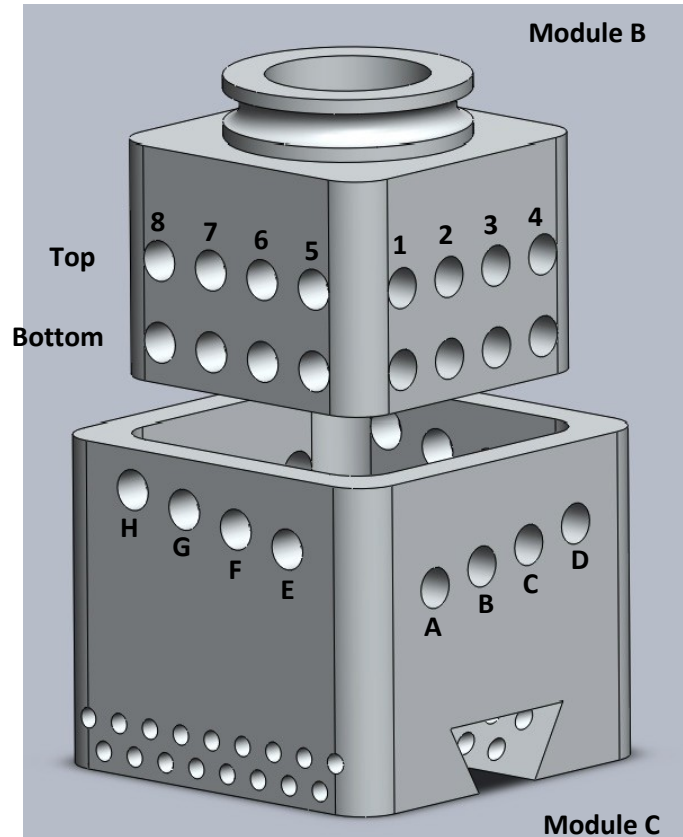
Figure 56: Schematic of height adjustment modules (B & C) with alphanumeric system.

The basic principle for height adjustment is that all of the holes on a given side of Module B are aligned into two rows and four columns, while the holes of Module C are offset vertically by 1/16 inch. In the shortest position, Hole T1 (Top row, 1st column) of Module B would line up with Hole A of Module C. To increase the height by 1/16 inch, the pin would be removed and the modules separated until Hole T2 lines up with Hole B. The next increment would be Hole T3 with Hole C and so on up to Hole T8 with Hole H. After this position, the modules could again be separated by 1/16 inch, but now the bottom row of holes on Module B must be used. Therefore, after Hole T8 and Hole H are aligned, the next increment would be Hole B1 (bottom row, 1st column) and Hole A. This would proceed with Hole B2 and Hole B all the way up to the maximum height of Hole B8 with Hole H. All in all, there are fifteen increments of 1/16 inch, so the range is 15/16 inch at 1/16 inch resolution.

5.3. **Linear Adjustment**

The red unit's dovetail design for linear adjustment was adapted for use in our adaptor, but with a key improvement. In addressing the issue of subjectivity in the alignment process, it was a heavily weighted goal to incorporate a means of quantifying the adjustment. Similar to using pins in the height adjustment module to provide a means of fixing the adjustment to a specific position, we have also incorporated a pin design to the linear adjustment for the exact same purpose.

Linear adjustment, that is, translational adjustment along the x- and y-axes, involves the interface of three of the modules: C, D, and E. The distal end of Module C and the proximal end of Module E both have female dovetails, or dovetail receivers, which interface with the male dovetails of the symmetric Module D, shown in Figure 57. There is a dovetail for each directional axis, allowing for x-y planar translation adjustment.
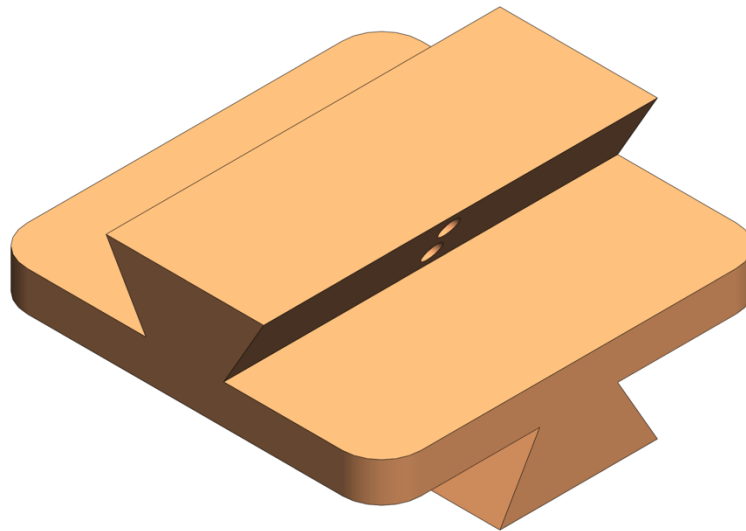
Figure 57: Module D (Double Dovetail) of final design.

Module D is 2.5 inches long, 2.5 inches wide and 1.125 inches tall. It is equipped with two 60 degree angle male dovetails, each with two 1/8 inch clearance holes through the center of them. The holes are vertically aligned and are both required in the design in order to achieve the proper adjustment resolution, which will be described next.

The magnitude of linear adjustment was designed to match that of the red unit, which was determined to be 2.0 inches along each axis. The female dovetails of Module C and E each have seventeen 1/8 inch holes that pass through the entire receiver. Nine holes are in one row and 8 are in the other. For a given adjustment, a 1/8 inch pin will pass through one of the 17 holes of the female dovetail and into one of the two (top or bottom) holes of the male dovetail. Any given hole of the female dovetail is 1/8 inch from the holes to either diagonal side of it, and ¼ inch from the holes to either horizontal side of it. All of these dimensions are outlined in Figure 58. This ensures a proper resolution and the 2.0 inches of translation adjustment range (17 holes that are 1/8 inch apart, so a 2 inch range). The center hole, in the row with 9 holes, is the zeroed location hole, at which there is no adjustment.
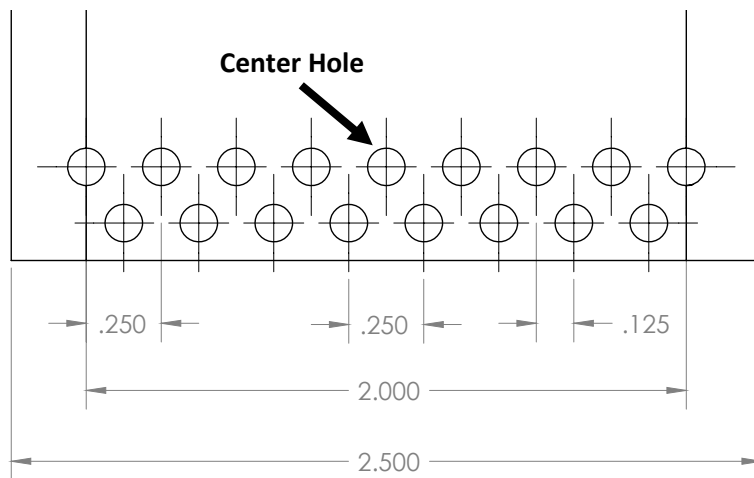
Figure 58: Hole dimensioning of the dovetail receivers for linear adjustment.

5.4.   **Manufacturing**

The team manufactured all the modules of the adaptor in the WPI Machine Shops using a horizontal band saw, a manual mill, a lathe, and a CNC (computer numerical control) machine with ESPRIT programs. An overview of the general process is provided in Figure 59 below for reference, with more detailed descriptions following.

Prepare material for machining	
Cut square stock material into smaller blocks	Use manual face mill to square up the block sides

↓

Drill out necessary holes
By drilling first, it ensures all the holes line up and are straight

↓

Machine out pockets and major contours on the CNC machines
Using the CNC machines ensures the pockets are accurately located on the part and is quicker than manual milling

↓

Use the lathe and manual ball mill to create curved profiles on Module B and E
Doing these parts manually is easier and faster than trying to set them up on a CNC

↓

Machine out dovetails on the CNC machines

↓

Verify all pieces fit together
Use files, deburring tools, hand drills/chamfers, and sand paper to ensure a proper fit.

↓

Sand and polish all pieces if desired (aesthetic only)

Figure 59: Flow chart of manufacturing process

5.4.1. Tolerancing

Before the specific operations are mentioned, it is important to address the level of precision needed in those operations. The tolerances of certain features and the clearances of the interfacing regions of the adaptor were critical to ensure the proper class fit, given the application of the adaptor. It was with great attention to detail in the machining process that we ensured a sliding class fit that balanced a tight enough fit without being too difficult to move. For each interface of the adaptor, the process began with

machining an exact, nominal fit. We then cut off fractional thicknesses, usually in the realm of 0.0005 inches, which allowed a progression up to each running class (RC) class fit per ANSI B4.1-1967(R1999) until a desired fit was established. Based on the descriptions of each RC fit, where RC 1 is the tightest fit and RC 9 is the loosest fit, the team determined that RC 1 or RC 2 would be best for a prosthetic alignment adaptor:

"RC 1 *Close sliding fits* are intended for the accurate location of parts that must assemble without perceptible play" (Machinery's Handbook, 27th Ed.)

"RC 2 *Sliding fits* are intended for accurate location, but with greater maximum clearance than class RC 1. Parts made to this fit move and turn easily small temperature changes" (Machinery's Handbook, 27th Ed.)

5.4.2. **Stock Material**

The team acquired four feet of 2.5 inch square stock aircraft aluminum grade 7075. The part was placed into a horizontal band saw, in which four smaller blocks could be cut, one for each individual module. Each block was cut slightly larger than needed to have extra material for the next step.

5.4.3. **Manual Face Mill**

After the team created four smaller blocks, these blocks needed to be formed into exact square shapes. We used a manual mill equipped with a face mill and made 0.005 inch passes until both the uneven cut surfaces from the horizontal band saw were perpendicular to the sides, forming an exact cube. The face mill passes were also made until the proper external height of that module was reached.

5.4.4. **Drilling**

Drilling for this project presented a major challenge. Drilling 2.5 inch deep holes with a ¼ inch and 1/8 inch diameter presents a high risk of breaking the drill bit. Such a long, thin drill bit that is spinning through metal can be subjected to high loads and quickly break apart if done incorrectly. To help compensate for this high risk, drill bits were bought that were just barely longer than 2.5 inches so that they would be as short as possible. It was also found through the procedure that using a parabolic drill bit instead of a standard shape bit was much more effective at cutting the 1/8 inch holes.

The general procedure for drilling was to drill through the holes with a slightly undersized drill bit first, then go back and re-drill with a slightly oversized reamer. By finishing with a reamer, the desired

tolerances could be achieved more easily. Although time-consuming, this method resulted in ideal hole tolerancing.

5.4.5. CNC Machine Milling

The CNC Machine was used to create all the pockets, holes, contours and dovetails of the adaptor. The machine was programmed using the computer-aided manufacturing (CAM) software Esprit. The SolidWorks models were imported into Esprit, where the various tooling and cutting operations could be defined. This program was then downloaded onto the CNC machine. After loading the machine with the appropriate tools, fixturing the part, and probing the tools and the part, this program could be run. Assuming the input parameters were correct, the CNC machine would do all the work and the part would be ready shortly thereafter.

5.4.6. Lathe and Manual Ball Mill

In order to produce the curved geometry of Modules B and E, it was necessary to use a lathe and a ball mill. Since these were short, simple operations, they were done manually instead of with a CNC machine. Module B simply needed the circular boss to have a groove in it so that the set screw would sit properly and not allow it to slip off of Module A. It was determined after looking at the Red Unit that a groove was not necessary, but simply slanting the circular face inwards would prevent the set screw from slipping. Module E's curved surface was designed off of the Red Unit's curved surface since they both need to interface with the same tube clamp. Thus, the proper lathe tools were chosen based on the red unit and applied to the stock material of Module E. Finally, the drafted walls of the frustopyramid on Module E were created using a ball mill and a two-angle vice. By measuring the angle of the draft of the frustopyramid on the red unit, the two-angle vice could be set up on the manual mill to replicate this draft angle. A ball mill was then used to cut vertically down so that the finished surface would have the appropriate draft angle and geometry.

5.4.7. Dovetails

The dovetails were created using the CNC machines, as mentioned above. By purchasing the desired dovetail cutter with the appropriate dimensions, these slightly exotic operations were made quite easy. The most difficult part was achieving the correct tolerance. However, by manufacturing the male dovetails first, the female dovetails could slowly be expanded until the male dovetails fit appropriately.

5.4.8. **Enhancing the Fit**

The final step in the manufacturing process was to ensure all the modules fit together. The sliding fits were easy to adjust because a little bit of sanding and filing could be performed to allow for the appropriate tolerancing. One method that worked very well at achieving the appropriate fit was to put hand soap in between the sliding joints and working them back and forth. The hand soap had gritty pellets in it, so there was enough abrasion to wear away the material where the pieces fit too tightly. To ensure the holes lined up, it was necessary to line up the holes on two different pieces and re-drill or re-ream through both parts. This ensures that the pin will fit through properly and that the holes are aligned.

5.4.9. **Cost**

The overall cost of the device is critical in determining how successful and marketable the device will be. Since the device was built at WPI where the machine shop services are free of charge, it was not obvious what an accurate price would be. Some of the non-labor costs such as materials and tools were purchased, but they were rather insignificant compared to the projected labor costs. The two methods used to estimate the labor costs of this device were looking at how long it took to build it at WPI and obtaining a quote from a local manufacturer.

5.4.9.1. *Non-Labor Costs*

The approximate material costs associated with building the actual device at WPI are shown below in Table 5. Note that although the largest expense was the aluminum stock material, only about a fourth of it was actually used and probably only a fifth would be needed to build a second device (assuming fewer mistakes). Considering this, the highest budget item is the dovetail cutter, followed by the drill bits. Since these cutting tools can be used to make many devices, their cost can be divided over the number of devices they each can build. A large machine shop might even have these tools already as part of their standard set. Indeed, the cost of some of the cutters was not included here because it is expected that a large machine shop would have the standard size end mills and reamers. Overall, once these one-time purchases are made and all the tools are in the shop, the non-labor cost of the device would only be about one fifth of the cost of the aluminum plus the price of the pins, or approximately $30.

Table 5: Non-labor costs of manufacturing

Item	Cost
4 Feet, 2.5 inch Square, Al 7075 Stock	$113
Dovetail Cutter	$43
Drill Bits	$30
Pins	$8
Total	$194

5.4.9.2. *Projected Labor Costs: WPI Method*

In order to estimate the labor costs of building the device, a record was kept of all the time actually spent in the shop using the machines. These times are broken down into various subcategories and presented in Table 6 below. These times include a very steep learning curve due to the unfamiliarity with machining practices. A lot of this time was spent learning how to machine and making small errors that would not need to be repeated for subsequent devices.

Table 6: Actual time of manufacturing

Type of Manufacturing	Time [hours]
Modeling in CAM software (Esprit)	25
Machining	91
Total	116

In order to get a more accurate prediction of the labor costs, some calculations were done to project the amount of time it would take to build the device a second time or to have an experienced lab technician build the device. These numbers are provided in Table 7. It is important to realize that the fixturing time is highly variable depending on the shop setup and experience of the user, so these are estimates. The CNC time is fairly constant and was calculated from the CAM software (Esprit). The manual time is extra time that needs to be spent on a manual mill or lathe to finish the parts, and is probably an over-estimate for an experienced user.

Table 7: Projected time of manufacturing

Item	Fixturing Time [Hours]	CNC Time [Hours]	Manual Time [Hours]	Total Time [Hours]
Module B	2.25	1.00	0.5	3.75
Module C	2	1.50	0	3.5
Module D	2	0.55	0	2.55
Module E	2.25	2.88	1.5	6.63
Total	8.5	5.93	2	16.43

The total predicted time that would incur labor costs is in between 16 and 17 hours. According to an experienced lab technician at WPI, an inexpensive shop would charge approximately $60 per hour. This could, however, reach up to $90 per hour. Therefore, the estimated price range of the device is between $960 and $1530, depending on the particular shop used.

5.4.9.3. *Projected Labor Costs: Quote Method*

The most accurate way to determine the price is to get a quote for the device by an actual machine shop. Therefore, drawings of Modules B, C, D, and E were sent to Saeilo Manufacturing Industries. The costs associated with building one of each part, including the materials, machining, and finishing operations is shown below in Table 8.

Table 8: Quoted prices of manufacturing

Part	Cost
Module B	$330
Module C	$365
Module D	$365
Module E	$405
Total	$1465

This total cost falls on the higher end of the price range calculated in Section 5.4.9.2, but is still within that range. This suggests that the predictions were fairly accurate and the price quoted by Saeilo is probably close to what other machine shops would charge.

6.   Validation Testing

In order to determine the success of the prototype, it was put through a series of validation tests. In particular, there were three phases of analysis: general characteristics analysis, finite element analysis, and patient testing. Such tests provided information about the weight, durability, and various functional characteristics of the device, and its ability to adequately meet all the specifications described in Chapter 3. The following sections provide a detailed description of the procedure and tests that were conducted on the device after it was completely manufactured. Results from these tests will be presented in Chapter 7.

6.1.   General Characteristics Analysis

The general characteristics analysis of the device was conducted in multiple small steps. The device was extended to its furthermost position from neutral; its range of translational adjustment was adjusted in the lateromedial, anteroposterior and proximal-distal directions.

In addition, the distance from the center of one pin hole to the adjacent pin hole was measured to validate the translational resolution in the lateromedial, anteroposterior, and proximal-distal axes. The angle of rotation about the lateromedial, anteroposterior and proximal-distal axes were also measured to determine the rotational ranges in these directions. After such characteristics were measured, the device was weighed on a digital scale. Furthermore, the device was fitted into a standard transtibial socket and pylon to determine the interface with standard transtibial prosthesis modules. It was then examined for any sharp or pinching edges which may pose a safety hazard for the patient or user. The device was also generally inspected for other physical characteristics, such as whether it provided a quantitative indexing scale, or if each degree of adjustment was independent from all others.

To test whether the device would be durable enough, it was placed in a backpack which was used for 24 hours to determine its durability during transport from one location to another.

6.2.   **Finite Element Analysis**

The setup for this round of analysis was very similar to the setup of the prior FEA, but there were several key differences. Once again, Ansys Workbench 12 was used for the analysis on a parasolid model imported from SolidWorks. Once imported, the material of all the modules was changed to aluminum 7075, which has a tensile yield strength of 505 MPa. This and other material properties were copied in from SolidWorks. All of the pins were modeled as structural steel, with a tensile yield strength of 250 MPa. The connections between the parts were left at their default value, which was a "bonded" connection type. Although different connection types were tried that allowed movement between surfaces, the bonded connection was determined to be the simplest and most appropriate for the purpose of these tests.

Once the model was successfully loaded in, the mesh was applied. Many different mesh sizes and types were tried throughout the course of the analyses. A discussion of the effect of the mesh size is provided in Section 7.1. The final mesh that was chosen had a "course" relevance center, which was the default value. This corresponded to a minimum edge length of each element being about 1.6 mm. Despite this being a relatively large mesh, it does not mean that the results are less accurate. To ensure the accuracy of the results, a convergence study was included in the solver. This is an automatic function that refines the size of the mesh at areas of high stress concentration. Together, the large mesh size allows for a quick, yet accurate calculation on the majority of the surfaces, while the convergence study creates a finer, more accurate mesh on the complex geometries.

The last stage of setup is applying the supports and loads. Identical to the first FEA setup, a fixed support was applied to the top surface of Module B and the loads were applied to the bottom surface of Module E (see Figure 60).
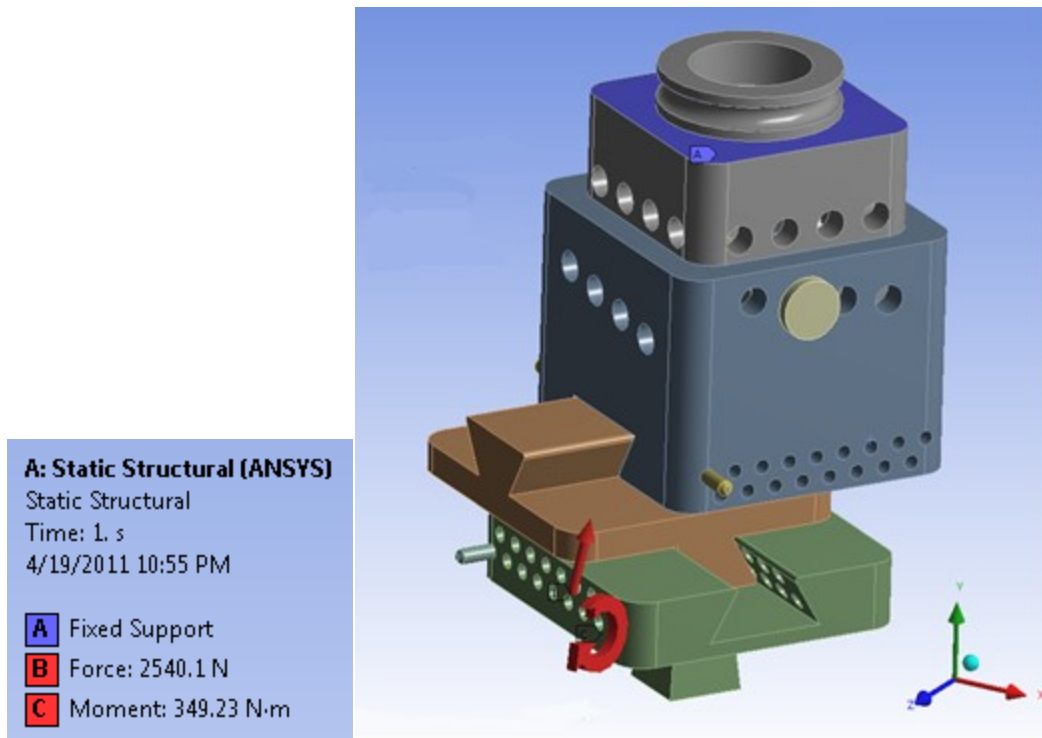
Figure 60: Supports and applied loads for the final FEA test.

The loading consisted of forces and moments in all three dimensions. To determine what the values for the loading should be, the team conducted some basic force platform tests and did some mechanics calculations. A more detailed description of this procedure was given in Section 4.5. Since this analysis required more careful attention to the actual numerical values and extreme conditions, the loading is different from the first analysis. The numerical values of these loads are provided in Table 9, with the coordinate axis defined as in Figure 60. These numbers were linearly extrapolated from the force platform tests to represent a 250-pound person jogging on the device, a situation that is unlikely to occur but is representative of the most extreme case anticipated. With this setup it was possible to determine the factor of safety for the new prototype.

Table 9: Loading for the final FEA test

	X Axis	Y Axis	Z Axis
Force [N]	291.7	2462.9	-548.8
Moment [Nm]	-342.9	-12.5	-65

6.3. **Patient Testing**

Patient testing, which has been approved by the WPI Institutional Review Board, will be conducted using the protocol in Appendix D: Protocol for Patient Testing. Not only will such testing provide feedback as to the performance, ease of use, and reliability of the device, but it would also allow for a comparison between the new prototype and the red unit. Various studies have shown that proper gait and balance is extremely important for patients with below-knee amputations. With such knowledge in mind, it was determined beneficial to examine how the gait and balance of such patients changed with the two different alignment adaptors.

For this testing, the prosthetist will be trained on how to use the device for 30 minutes. Once the prosthetist is fully trained, a patient will be asked to stand on the center of two ATMI AccuSway force platforms with their permanent prosthesis for 20 seconds as shown in Figure 61.
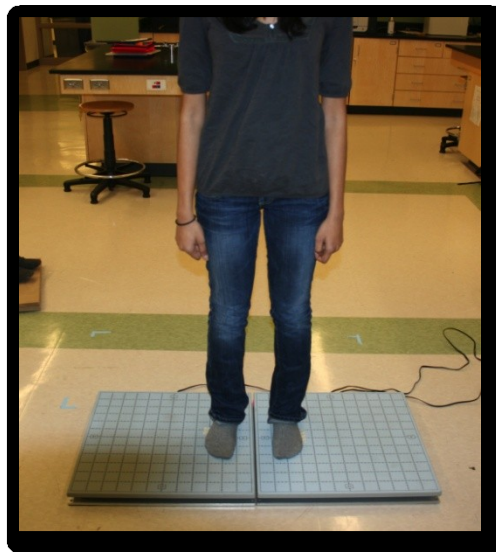
Figure 61: Configuration for standing on the force plate.

The patient will then be asked to walk across the plates, which will be arranged so that patient strikes each plate at its center (shown in Figure 62).
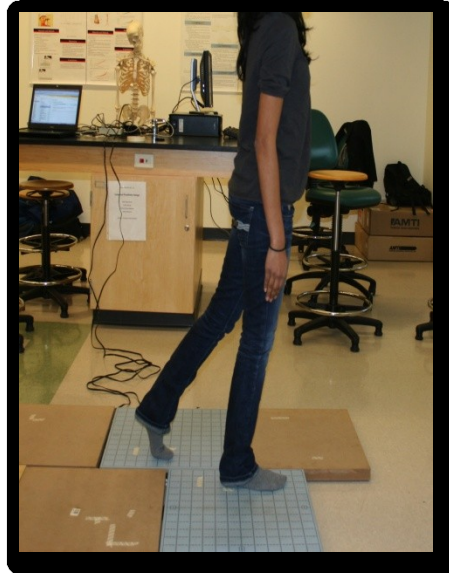
Figure 62: Configuration for walking on the force plates.

The same process will be repeated for each alignment adaptor. During each step, the impulse and ground reaction forces (Figure 63) of the patient will be measured, to see if there is a difference when using different alignment adaptors or none at all. Ideally, they should be the same if they both provide an adequate means for attaining proper alignment, but such a test will be for confirmation. The setup of the two force platforms will be such that the patient strikes each platform at its center during the initial contact phase of gait, as illustrated in Figure 62.
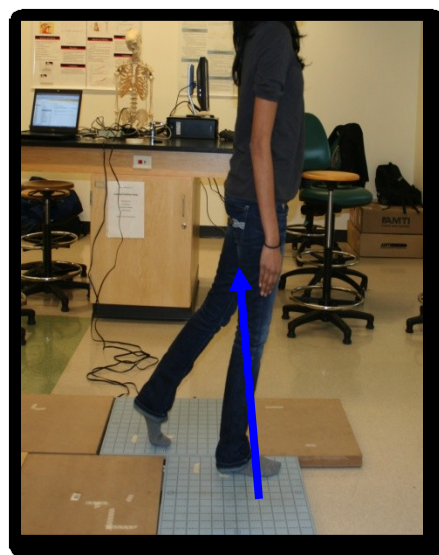
Figure 63: Ground reaction forces during gait analysis.

Any differences in gait or pressure analysis will indicate how the red unit compares to the new prototype in functionality. If one has a smaller center of pressure than the other, for example, then it is assumed that that particular adaptor is more effective at establishing an appropriate alignment adjustment. Similarly, a smaller impact force may indicate a more effective alignment adaptor.

6.4. Qualitative Analysis

Qualitative analysis will also be conducted to test the device during patient testing. The patients and the prosthetist will be given surveys to determine the comfort level and ease of use when using the device compared to the red unit. Such surveys will provide details on what patients and the prosthetist truly thought of the device, and potentially the results could be used to validate our design.

After all analyses are completed, Table 10 will be completed to determine whether the adaptor met all the aforementioned specifications. It is important to note that cost analysis was done during the manufacturing process and thus was not part of any testing procedure after the prototype was completed. The following table was completed first by the students and then verified by a certified prosthetist.

Table 10: Metrics Table

Performance Specifications	Met or Not Met	Details of the Feature
Device must provide at least 2.0 inches of translational motion in the lateromedial direction		
Device must provide at least 2.0 inches of translational motion in the frontal-dorsal direction		
Device must provide at least 0.75 inches of translational motion in the proximal-distal direction		
Device must provide at least +/- 10° rotation about the X-axis		

Table 10 Continued

Performance Specifications	Met or Not Met	Details of the Feature
Device must provide at least +/- 10° rotation about the Y-axis		
Device must provide at least 90° rotation about the Z-axis		
Device must be adjustable to within 1/8 inch in all three translational directions		
Device must interface with standard transtibial prosthesis modules		
Device must provide quantitative measurement of current alignment fitting		
Device must be able to sustain patients that weigh up to 250 lbs. (approximately 95th percentile)		
Device must be usable on patients that have a 5 inch minimum distance from the bottom of their residual limb to their ankle joint		
Device weight must be less than 6 pounds		
Safety Specifications	**Met or Not Met**	**Details of the Feature**
Device must not contain any sharp edges		
The device should not have joints that result in a high risk of pinching during normal use		

Table 10 Continued

Ease of Use Specifications	Met or Not Met	Details of the Feature
Device adjustability will require no more than human hands, screwdrivers, hex keys or similar tools		
Adjustment for each degree of freedom must be independent of other degrees of freedom (strictly orthogonal motion)		
All adjustments must be made without requiring the prosthetist to remove the socket		
A certified prosthetist must be able to independently align the patient after a 30-minute maximum training session on how the device works		
Reliability Specifications	**Met or Not Met**	**Details of the Feature**
Device must have a lifetime of at least 2 years		
Device must withstand a drop test from 5 feet from the ground		
Cost Specifications	**Met or Not Met**	**Details of the Feature**
The cost of materials should not exceed $290.00, the current cost of the current standard device		
The device must be easily manufacturable, and thus must be able to be manufactured in the WPI Machine Shops		

Table 10 Continued

Cost Specifications	Met or Not Met	Details of the Feature
The raw cost of the device (materials and manufacturing, no sales mark-up) should not exceed $300		

7.   Design Validation

Using the testing procedures described in Chapter 6, it was possible to validate the new prototype as a successful design. The general characteristics of the device were measured using the testing described in Chapter 6. The final weight of the device without pins is 1.66 lbs. To test the durability of the device, it was placed in a college student's backpack for a period of several days. This was a general testing that mimicked the prosthetist carrying the device around to clinics with them. No visible damage or detrimental effects were noted throughout this time period. Additionally, finite element analysis mathematically determined if our device was strong enough for its application in the alignment process.

7.1.   Quantitative Finite Element Analysis

A final round of FEA was performed to ensure the device would be safe to use in the most extreme adjustment position. Whereas previous FEA was done to qualitatively assess the distribution of stress, this analysis was done to quantitatively determine the strength of the device.

The maximum Von-mises stress encountered was 296 MPa (Figure 64), which results in a safety factor of 1.7 (Figure 65). The maximum displacement of any point was 0.26 mm (Figure 66). The original analysis without the convergence study involved 71,986 nodes and 33,604 elements, which resulted in a maximum stress of 301 MPa. After the mesh was refined, there were 189,969 nodes and 114,805 elements, for the aforementioned stress of 296 MPa. This represents a decrease of 1.69%. Considering the default convergence study stops when the values match up within 20%, the results from this test are quite accurate even without a refinement.
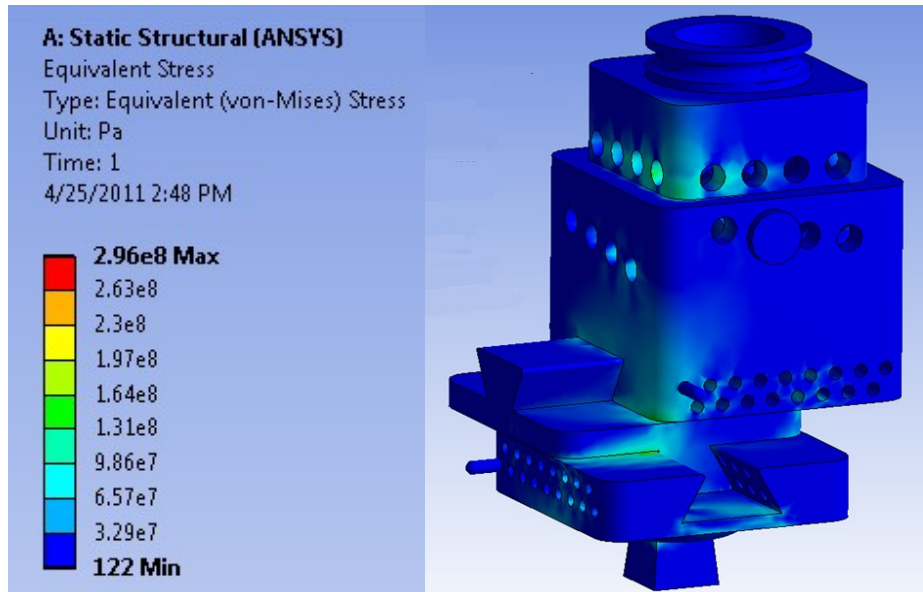
Figure 64: Von-mises stresses of final design
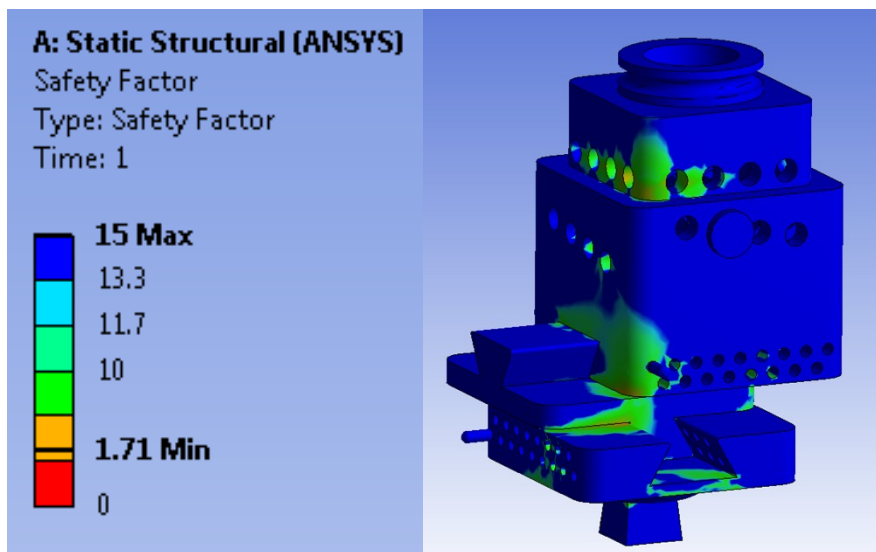
Figure 65: Safety factor of final design
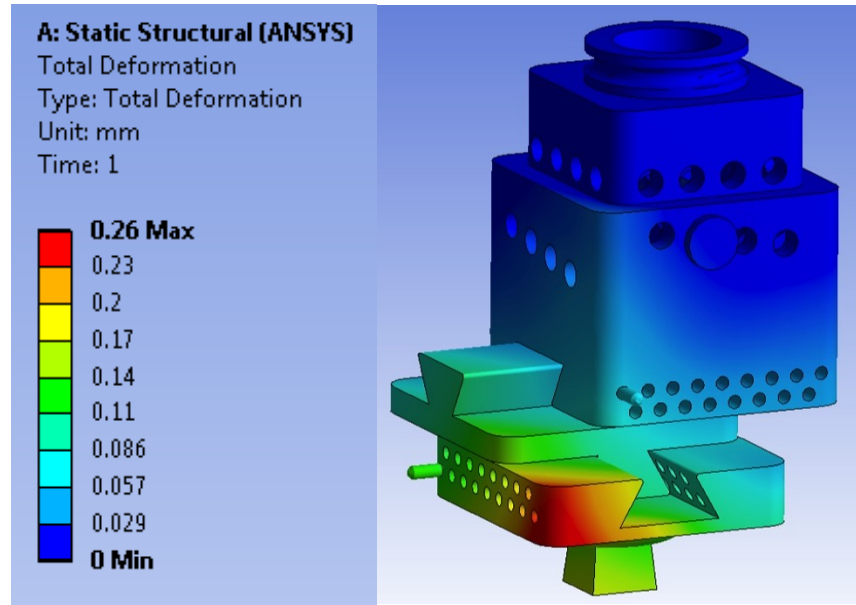
Figure 66: Total deformation of final design

Validating these results is a complicated process. When there is complicated geometry involved it is

difficult to simplify the problem to the point where it can be solved by hand, even for a small region.

Since this device was custom-made for a specific application, there are no prior studies that could be

used for comparison. Therefore, validation of the results depended on running multiple analyses with

slightly different settings to gain information on what the expected range was. For all the analyses, the

stresses were extremely low over most regions. It was only in areas that had sharp geometry that the

stress was near the tensile yield limit. Sharp geometry, or geometry that changes shape or direction

quickly, can cause problems for the solver because results may not converge. This is because the

computer model can have instantaneous changes in shape, whereas in the real device, the edges would

have a slight radius or would deform slightly to have a larger radius. For this reason, the original

SolidWorks model was changed several times so that sharp edges had fillets and the computer model

was closer to the actual manufactured device. Despite these changes, there were still convergence

problems for several of the studies. Even in the final study, it was only a specific region that was very

small that had the maximum stress. Because it was only a very small number of elements over an

extremely small area that had the high stress levels, it seems unlikely that actual stress levels would

reach the values given above. Finer meshes resulted in higher stresses, but only at an isolated point. It is

therefore most likely that these high stress values were a result of the computer modeling and not an

actual simulation of the real device. Given that the safety factor was above 1, the modeling was done for

an unusually extreme situation, and the calculated values are likely higher than real values, the device was determined to be safe for patient use.

7.2. **Meeting with a Prosthetist**

The original intent of this meeting was to test the device out on a patient. This is what the IRB procedure was for and what all the preparation anticipated. However, do to scheduling issues, the patient testing could not be completed before the submission of this report. In order to garner some general, informal feedback, however, the device was shown to a local prosthetist. The device design and functionality were explained, after which a prosthesis was assembled that included the new prototype. Through the discussion with the prosthetist and the assembly process, several advantages and problems were identified with the prototype.

7.2.1. **Advantages of New Prototype**

The first positive outcome of the meeting was the ease with which the prosthetist was able to learn how to make the new adjustments. Within approximately two minutes, the user interface was explained and well understood. This was an important outcome because of the apprenticeship nature of the prosthetist occupation. The device had to be intuitive and easy to use for it to be accepted, and this was found to be the case.

The second advantage that became obvious was the smooth interfacing with existing prosthetic components. The new prototype could seamlessly be integrated into a full functioning prosthesis. This was possible because of the standard methods of attaching it to the base piece and pylon.

The primary advantage of the new prototype, as identified by the prosthetist, was the unique height adjustment feature. Both the range and resolution of the adjustment were found to be adequate. In addition, the uniqueness of the device was commended as no other device makes use of the pin adjustments to allow for height changes. The advantage with this design comes with not having to make measurements with regard to the height. Because current methods rely on non-quantized adjustments, the new prototype is faster and more accurate to adjust. For example, a brief test was done to determine how long it took to adjust both the new prototype and the old pylon height. Whereas it took about 9 minutes to cut the pylon, it only took 9 seconds to adjust the new prototype.

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Finally, one new advantage that was unintended was that it could be used for above-knee patients as well. They must be aligned similar to below-knee patients, so the device could just be used higher up on the prosthesis. It was previously unknown whether or not there would be enough room to fit the device in this amount of space. Not all above knee patients could use the device due to this space constraint.

Overall, the interfacing with standard components and unique, quantized, height adjustment help make the design something that "may have a place in industry." The amount of time saved by not having to cut the pylons, smooth the edges, and reassemble the prosthesis was significant. The major problems identified were mostly with the other adjustments, primarily the x and y translation adjustment.

7.2.2. **Problems Identified**

The most prevalent problem the prosthetist identified was with the pin method of fixing the dovetails. The red unit uses a set screw and plate configuration to lock the device. Since the tightening of this set screw can be regulated to a certain torque, patients are allowed to wear the unit home on the prosthesis (only until their next prosthesis is ready). Although this is not common, it is an added benefit of the red unit. The pins are more of a hazard, however, since they could fall out more easily or stick out and harm the patient. This kind of design and safety risk would prevent the prototype from being allowed to go home with the patients that require it. With use restricted to the prosthetist's office, the value of the device would go down. The other problem that the prosthetist identified with the pins is that "when we have patients going home with things, any kind of rattle they'll hear it in their walk, so it has to be real close tolerances…we have a lot of slide adaptors that don't make the grade." Although the pins on the new prototype could be made so that they don't rattle or click, the tolerancing on these holes would have to be extremely precise and costly. It would likely be difficult to get the pins in at such a close tolerance. To solve all these problems, the prosthetist recommended preserving the set screw method of fixing the dovetails. Although it does not allow for quantification, by placing marks on the device it could be measured easily enough in his opinion.

The only other major problem with the device was in its size and weight. The prosthetist felt that if the device were taken home with the patient, they would complain about the size and weight. Although the device was not designed to be worn home by the patient, it would obviously increase its usefulness if it were able to be worn home. How often the patient wears a device home seems to depend on the specific patient and prosthetist, but to make the device appeal to the largest population it would be better to have a lighter device that could be worn all the time.

7.3.   Cost Effectiveness Analysis

In order to put the price of this device in perspective, it was necessary to consider how it compares to other adaptors and what benefits it offers that other adaptors do not. This helped to determine how marketable the device is.

7.3.1.   Determining the Retail Price

For the purposes of this analysis, the average of the two values calculated in Section 5.4.9 will be used as an estimate for the manufacturing cost. This manufacturing cost is likely to be lower if the device is manufactured in bulk. The retail price, however, would have to be much higher than this in order to make a profit. The difference between this retail price and the price of the red unit represents the cost of the added height adjustment and quantification. The calculations are provided below in Equations 1-5.

$$Projected\ Price = \ Stock + Pins + Machining = \$15 + \$8 + 16\ hours * \frac{\$80}{hour} = \qquad \$1303 \qquad (1)$$

$$Quoted\ Price\ = \qquad\qquad\qquad\qquad\qquad\qquad\qquad\qquad\qquad\qquad\qquad \$1465 \qquad (2)$$

$$Manufacturing\ Cost = \frac{\$1303 + \$1465}{2} * 25\%\ volume\ discount\ for\ 1000 = \qquad \$1038 \qquad (3)$$

$$Retail\ Price = Manufacturing\ Cost * 2 = \qquad\qquad\qquad\qquad\qquad \$2076 \qquad (4)$$

$$Total\ Savings = \ Retail\ Price - Red\ Unit\ [\$287] = \qquad\qquad\qquad \$1789 \qquad (5)$$

The numbers used above are just rough estimates to get an idea of the associated costs. Actually determining the retail price of a new product is an extremely complicated and difficult process. It depends a lot on the specific manufacturer and market research, as well as discussions with numerous prosthetists. Since this information was outside the scope of this project to obtain, estimates had to be made. The first major estimate was that 1000 units would be made in the first batch. This was based on the fact that there are over 3400 prosthetists in the US (OPCareers.org, 2008). Assuming about one third of the prosthetists would be interested in the new device, and that they could be sold over a period of several years, making 1000 units is a reasonable estimate. For this volume of units, and anticipating a steep price decline for any units made after the first one, it was estimated that the manufacturing cost

could be reduced by about 25%. To make a profit, the retail price would likely be at least double this manufacturing cost. With this rationale, the features of the new prototype must be worth about $1800 to make it marketable. The next stage of the analysis is to determine just how much the new features are worth.

7.3.2. **Determining the Savings**

Although the device offers many advantages over the red unit and other adaptors, the most objective way of determining its value is to look at how much time it would save the prosthetist. After meeting with the prosthetist and having him use both devices to make a height adjustment, it appears that the new device would save about 9 minutes for every height adjustment made. He also estimated that between 2 and 3 adjustments were made each week. By looking at the average salary of an experienced prosthetist (OPCareers.org, 2008) and considering the overhead charges, it is possible to estimate how much money the new device will save just by allowing for quicker alignments. These calculations are provided below in Equations 6-8.

$$Time\ Saved = \frac{3\ Adjustments}{1\ week} * \frac{50\ weeks}{1\ year} * \frac{9\ minutes}{1\ alignment} * \frac{1\ hour}{60\ minutes} = \qquad 22.5\ hours \quad (6)$$

$$Hourly\ Wage = \frac{\$95,667}{1\ year} * \frac{1\ year}{2000\ hours} = \qquad \frac{\$47.83}{1\ hour} \quad (7)$$

$$Total\ Savings = 22.5\ hours * \frac{\$47.83}{1\ hour} * overhead\ [2.5] = \qquad \frac{\$2690}{1\ year} \quad (8)$$

Thus, the device is likely to cost an additional $1800, but save $2700 over the course of a year. This means that the device will pay for itself in about 8 months, and over a lifetime of 10 years, save about $25,000.

8.   Future Recommendations

Due to time and budget constraints, there are some limitations to the new prototype, which will be discussed in this chapter. These weaknesses can be addressed such that improvements to the device could potentially be made in the future, leading to a device that would be more prepared for mass production.

8.1.   Device Dimensioning and Sizing

Due to the novel addition of an adjustable means of height adjustment, the new prototype has an inevitably larger overall length along the z-axis (height) than the red unit. Adding to this is the fact that the dovetails of the new prototype are taller to be able to accommodate both rows of eighth-inch holes through each dovetail. The z-axial length of the red unit is 2.00 inches. The z-axial lengths of the new prototype at its minimum and maximum adjustments are 3.92 inches and 4.85 inches, respectively, with the difference (of 4.85 and 3.92) matching the 0.9375 inch, or 15/16 inch, range of height adjustment. If a reduced overall length is needed, design revisions could make the device walls thinner (though that reduces the overall strength) or the adjustable height range could be reduced (as the prosthetists we consulted with determined that 12/16 inch is sufficient). It's also important to note that, while the new prototype has an increased overall height, it is directly displacing the height of the pylon.

The external dimensions of the new prototype are, overall, geometrically larger than the cylindrically shaped red unit. The new prototype took on a square shape to match the shape of the height adjustment modules. To match the linear adjustment range of the red unit, the side length of the square-shaped new prototype is equal to the diameter of the cylindrical-shaped red unit (Figure 67). This causes the length of the new prototype to be larger than the red unit along the diagonal of the square. Future designs could attempt to reduce this diagonal length with a smaller square shape or a different shape altogether.
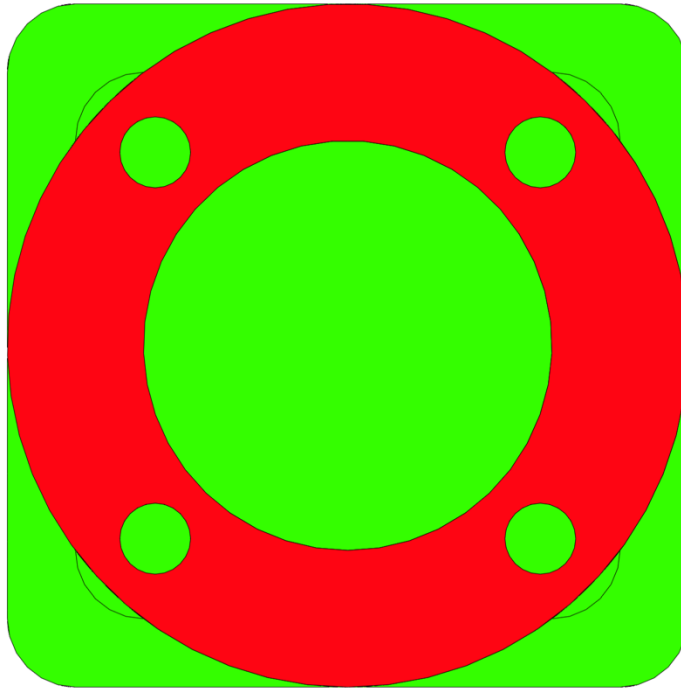
Although the weight of the device will not have a significant effect on the gait of the individual since the weight of the device relative to body weight is fractional, reduction of the amount of material used would be beneficial when considering manufacturing costs and time as well as material costs and waste. The weight of the red unit is approximately 350 grams, or 0.77 pounds. The weight of the new prototype is 753.34 grams, or 1.66 pounds, which is approximately double the weight of the red unit. As stated before, this relatively marginal increase will not have any detrimental effect on the accuracy of the fitting process.

The current device also contains several sharp edges, particularly around the dovetail. Incorporating rounds on these edges in the design as well as in the manufacturing process would prevent any unnecessary cuts on the patient or the user of the device. In the case of the manufactured prototype, the rough edges and sharp corners were manually smoothed and deburred, but for mass production this would be an undesirable approach.

8.2.   **Future Patient Testing**

The validation of the new prototype can be further enhanced beyond this project by testing it on patients who have had prior fittings. This is what the IRB-approved protocol was designed for, but testing could not be conducted before the report submission. These tests can assess the reliability and accuracy of the device to attain a proper alignment. Comparisons to previous fittings can show whether the new prototype is able to achieve the same or better alignment than the red unit. Depending on the number of available patients, statistical analysis can also be conducted comparing multiple fitting procedures across several patients.

Once testing is complete on patients who have had prior fittings and once the safety of the device is ensured, testing on new amputees who haven't had prior fittings could be arranged. This procedure will provide analysis on whether the device is able to achieve correct alignment without any prior knowledge of the patient's alignment.

The device can also be taken to prosthetists who are not familiar with the red unit in order to determine whether the device is easy to understand and adaptable. Since the new prototype adopts many design features from the red unit, a prosthetist that is not familiar with that device will be the only objective way to measure the ease of use of the new prototype.

8.3.   **Further Mechanical Testing**

Additional mechanical testing can be performed on the device to test its strength and durability. Since the device will be exposed to frequent adjustment and manipulation, high strength and durability would increase its longevity. One method to perform this test would be to put the device under the maximum loads that it must be able to withstand. As described in Section 6.2, the maximum loads were determined using force platforms and shown in Table 9. An Instron Uniaxial Testing device would be capable of inducing these loads onto the device. The damage transferred to the device will indicate its ability to resist high stresses and loads. While these types of tests have been conducted digitally using FEA analysis, a true mechanical test will yield physical results and definite failure points. Similarly, many adaptors are currently tested according to ISO standard 10328. The test comprises principal static and cyclic tests for all components and a separate static test in torsion for all components. The compound

loads in the test sample relate to the peak values of the components of loading which normally occur at different instants during the stance phase of walking. Compound loadings are produced by the application of a single test force. In the future, this test can be performed on the new prototype in order to assess the structure of the lower-limb prosthesis with an alignment adaptor.

8.4.   **Manufacturing**

Several issues were encountered during the actual manufacturing of the device. Although overall it was fairly simple and straightforward to build, any improvements in either the design or manufacturing techniques that make it easier to build can greatly reduce the cost of the device.

The most obvious issue with manufacturing is the creation of the 1/8 inch holes. Because they are 2.5 inches deep, they are a fairly risky operation. Such a deep, thin hole poses the risk of breaking the drill bit. The solution for this project was to use a parabolic bit that was just over 2.5 inches to minimize the risk of breaking, and indeed none of these bits did. However, the small pecking distance during the drilling operation and the deep hole combined for a very long procedure. It took about four times longer to drill these holes than any other operation. The best fix for the future, therefore, would be to have shallower holes. By decreasing the overall width of the modules with holes, the total depth would not have to be 2.5 inches. This improvement would have to be coupled with the dimensioning and sizing improvements to ensure it was still strong enough. Another way to address this problem is to not have the holes go all the way through the part. As long as the pin prevents the dovetail from sliding, there is no reason it has to pass all the way through. However, this would introduce the problem of keeping the pin from falling out, and the pin would most likely be in single shear instead of double shear. This design decision was looked at before manufacturing and it was determined that the holes going all the way through the part would be a better choice. However, given the difficulty of manufacturing and the anticipated added cost, this would be worth reexamining. Finally, as suggested by the prosthetist, the pin and hole method of fixing the dovetails could be replaced by a set screw. This would be similar to the red unit and prevent the manufacturing issues with holes, but would prevent the discrete quantification of alignment. Additional markings or indexing would need to be added.

The other major improvement that could be made with manufacturing is using a five-axis CNC machine. Unlike typical milling machines, a five-axis machine enables the part to be rotated as well as translated

during the operation. For example, instead of just drilling the holes on one face of the part, the part could be rotated after one face is done so that all the holes on all the faces could be drilled with one operation. This would most likely reduce the cost of machining quite a bit. The major cost associated with manufacturing this kind of device is in the labor time, most of which goes to fixturing the part in the machine. The number of fixtures involved with five-axis machining is much less than that with typical mills. The fifth axis would also increase the accuracy and placement of the holes. For example, instead of drilling through the 2.5 inches with a 1/8 inch drill bit as described above, each hole could be drilled 1.25 inches from each side. In a typical mill, this would be risky since it's unlikely the holes would exactly meet. With a fifth axis, the part could very accurately be rotated and they would be much more likely to line up.

Glossary

Ankle (talocrural) Joint – hinge joint where the foot and the leg meet

Anteroposterior – relating to, extending along, or being a direction or axis from front to back or from anterior to posterior

Calcaneus – heel bone of the foot

Condyles - a rounded prominence at the end of a bone, most often for articulation with another bone

Dorsiflexion – movement when the toes are brought closer to the shin

Edema – swelling caused by accumulation of fluid in the body's tissues

Erythema – skin condition characterized by redness or a rash

Eversion – the movement of the sole of the foot away from the median plane

Fibula – outer of the two bones of the lower leg

Genu-varum – a leg bowed outward at the knee (or below the knee)

Induration –hardening of a normally soft tissue or organ because of inflammation or an accumulation of blood

Inversion – the movement of the sole of the foot toward the median plane

Mediolateral – relating to, extending along, or being a direction or axis from side to side or from median to lateral

Patella – kneecap or a small flat triangular bone in front of the knee that protects the knee joint

Plantar Flexion – movement when the toes are going away from the shin

Proximal-distal – along the axis of the length of the leg

Recurvatum – the backward curvature of the knee; hyperextension of the knee

Subtalar (talocacaneal) Joint – joint of the foot where the talus and the calcaneus meet

Talus – anklebone or the bone of the ankle that articulates with the tibia and fibula to form the ankle joint

Tibia – inner of the two bones of the lower leg

Tibial Tuberosity – a large oblong elevation at the proximal end of the tibia

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Appendix A: Relevant Patents and Their Claims

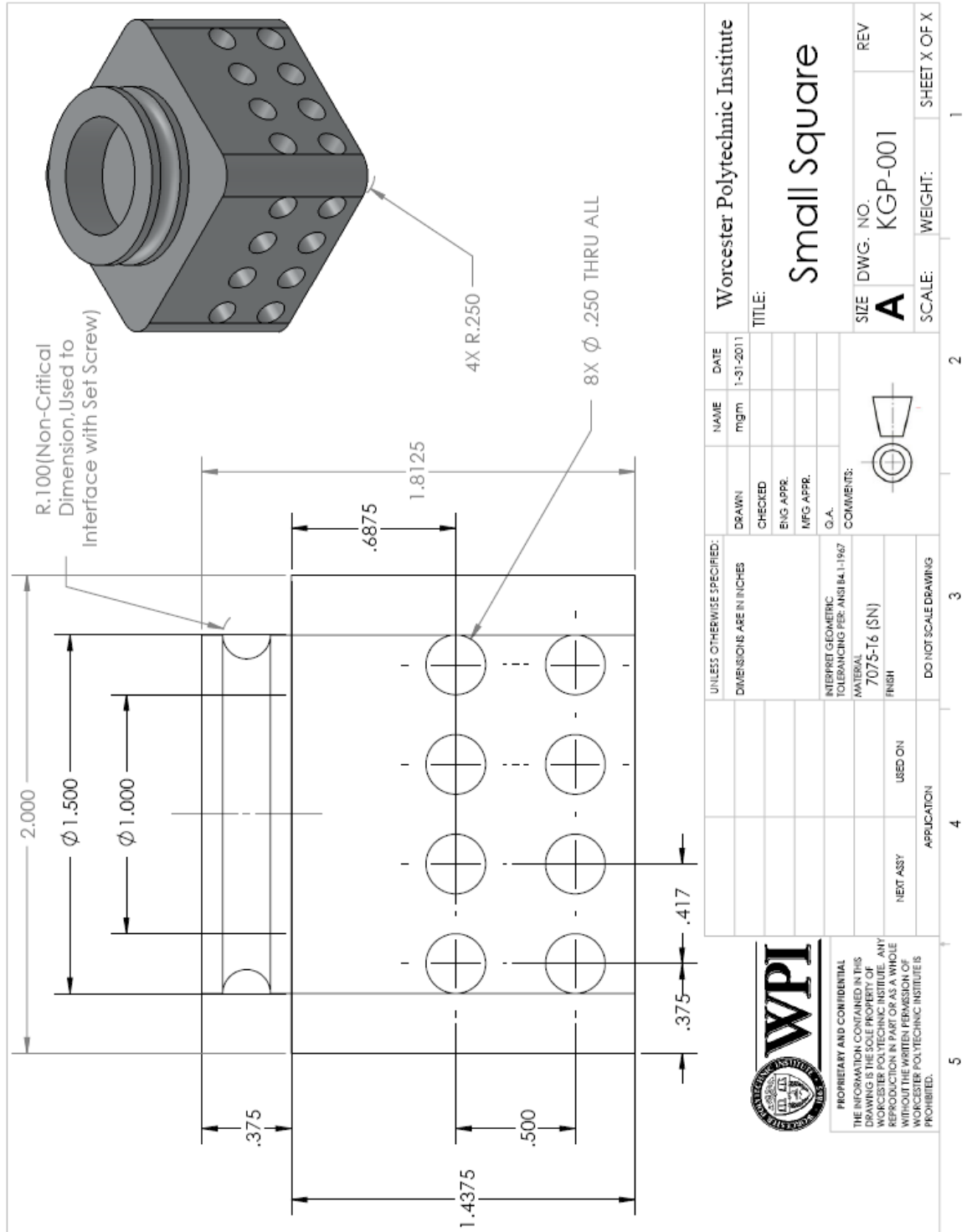The table below summarizes some of the important patents that involve alignment adaptors:

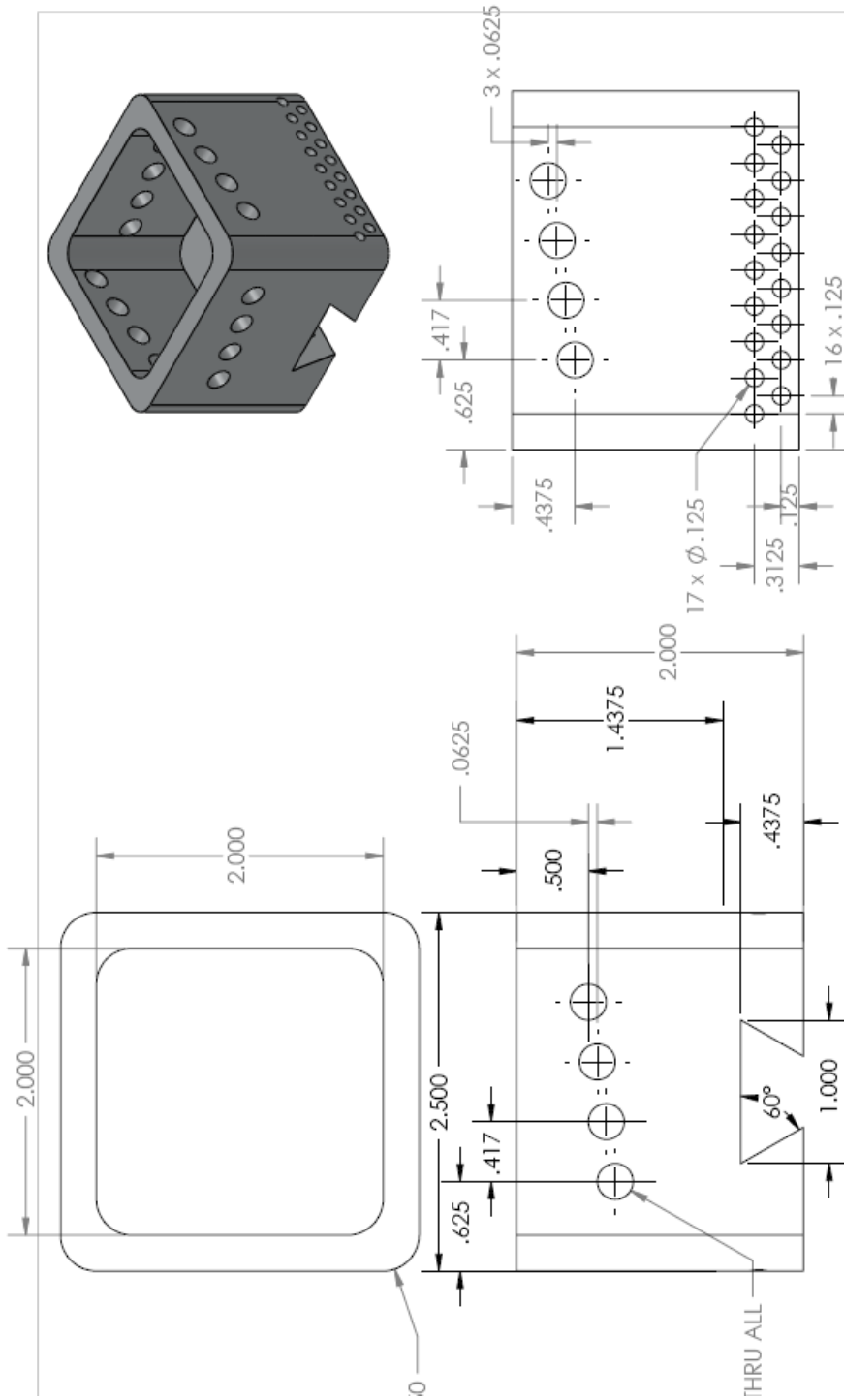| Date	Name	Patent Number	Primary Claims
1972	Adjustable Link for Prosthetic Limb	3659294	Pyramid design for adjusting angle
1990	Adjustable Prosthetic Joint with Alignment Means	4969911	Indexing angular adjustments
1996	Prosthetic Limb and Alignment Adaptor	5529576	Describes interfacing between all members of prosthesis, including alignment
2002	Coupling-socket Adaptor Assembly for a Prosthetic Limb	6458163	Shorter profile adaptors that provide continuous adjustment
1969	Prosthetic Leg Having Adjustable Alignment Means	3422462	Describes entire prosthesis, including lateral alignment
1996	Prosthesis mounting adaptor and method	5545230	Adjustment means for Symes patients
1996	Prosthetic locking device with integral pyramid	5507837	Lighter, less expensive, shorter device for locking prosthesis to socket
1995	Endoskeletal prosthesis having adjustable coupling	5458657	Ball and post method of adjusting angle
1995	Adjustable prosthetic connector assembly	5443526	Extend range of lateral adjustment
1995	Alignment fixture for prosthetic device	5425782	Extended lateral range, removing socket not required
1992	Prosthetic attachment device and method	5163965	Improved interface between socket and prosthesis
1991	Adjustment device for artificial limbs	5047063	Allow angular and linear adjustment with extended range
1986	Adjustable connection for connecting adjoining parts of an artificial limb	4608054	Allow angular adjustment similar to pyramid
1985	Device for the alignment research, alignment and orientation of prosthesis of the lower limbs	4536898	Allow angular and linear adjustment (no pyramid)
2006	Offset Alignment Device	11/504906	Combine multiple degrees of freedom in one device
2006	Three Prong Adaptor	6981992	Improved 3-prong device for socket-prosthesis interface

Date	Name	Patent Number	Primary Claims
2006	Device for Angularly Coupling Prosthetic Components	7097666	Extend range of angular adjustment without pyramid
2007	Limb with Modular Prosthetic Components	7189264	Adjust length of prosthesis
2007	Four Hole Offset Alignment Device	7267695	Allow prosthesis to be offset from central axis of leg
2008	Alignment Assembly for a Prosthesis	7338532	Combine multiple degrees of motion in one device
2000	Connecting Part Between Leg Prosthesis Components	Re. 36521	Extend range of angular adjustment

Appendix B: Means Comparison Chart

		Height Adjustment		
Weight	Parameter	Notched Pipes	Threaded pipes	Pneumatics
10	Performance	8	0	7
8	Safety	8	8	7
6	Ease of Use	8	4	6
8	Reliability	9	7	5
4	Cost	7	7	5
	Total	292	172	222

		Linear Adjustment		
Weight	Parameter	Rack and Pinion	Dovetail	Internal Screw
10	Performance	6	8	6
8	Safety	8	8	8
6	Ease of Use	7	9	8
8	Reliability	7	8	7
4	Cost	6	8	7
	Total	246	294	256

		Angular Adjustment		
Weight	Parameter	Frustopyramid	Ball and Socket	Hinge
10	Performance	7	5	8
8	Safety	8	8	7
6	Ease of Use	8	6	8
8	Reliability	5	6	7
4	Cost	7	5	8
	Total	250	218	272

		Rotational Adjustment		
Weight	Parameter	Rotation Stage	Ball and Socket	
10	Performance	9	9	
8	Safety	8	8	
6	Ease of Use	7	7	
8	Reliability	8	5	
4	Cost	5	7	
	Total	280	264	

		Securing Mechanism		
Weight	Parameter	Internal Screw	Pin	
10	Performance	8	8	
8	Safety	8	8	
6	Ease of Use	7	8	
8	Reliability	5	8	
4	Cost	10	10	
	Total	266	296	

Appendix C: Technical Drawings of Final Design

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Small Square

SIZE **A** DWG. NO. KGP-001 REV

MATERIAL 7075-T6 (SN)

8X Ø .250 THRU ALL

4X R.250

R.100(Non-Critical Dimension, Used to Interface with Set Screw)

2.000

Ø 1.500

Ø 1.000

.375

.500

1.4375

.375

.417

.6875

1.8125

3 x .0625

.417

.625

16 x .125

.250

17 x Ø.125

.4375

.3125

.125

2.000

1.4375

.0625

.500

.4375

2.500

.417

.625

60°

1.000

THRU ALL

2.000

2.000

Worcester Polytechnic Institute

Large Square

2.500

2.500

4X R.250

1.000

.250

.4375

.4375

1.125

.4375

.125

.125

60°

.125

60°

1.000

.125

Worcester Polytechnic Institute

TITLE:

Double Dovetail

SIZE DWG. NO.   REV
A   KGP-003

SCALE: WEIGHT: SHEET X OF X

WPI

Frustopyramid

2.500

.643

.643

.250

Ø 1.500

Ø 1.000

4X R.250

2.500

R.050

84°

60°

1.000

.4375

.3125

.475

.125

.750

.375

.250

.5625

1.2875

.250

17X Ø .125 THRU ALL

Worcester Polytechnic Institute

TITLE:

Frustopyramid

SIZE DWG. NO.   REV
A   KGP-004

SCALE: WEIGHT: SHEET X OF X

111

Appendix D: Protocol for Patient Testing

Materials

1. 2 ATMI AccuSway Force Platforms
2. 2 laptops with AccuSway software
3. 1 software key
4. 1 stop watch
5. The red unit
6. The new prototype
7. Tape
8. Tape measure

Procedure

Pre-testing

1. Explain purpose and procedure of study (detailed below) to the prosthetist and patient in a private setting.
2. Have the prosthetist and patient sign their respective Informed Consent Agreement form.
3. The prosthetist, having prior knowledge of the patient, will cut two pylons to appropriate lengths to accommodate the testing of both adaptors.

Part 1

4. 2 ATMI AccuSway platforms will be initially set up as shown below.
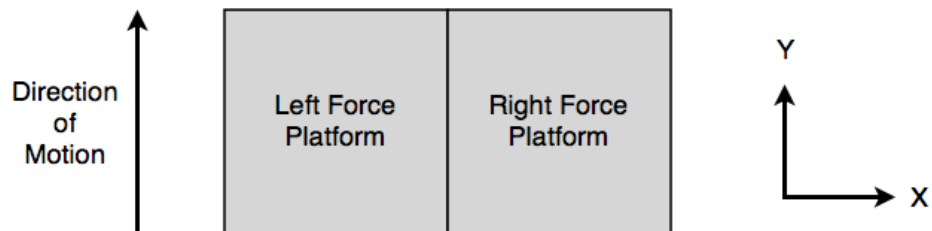
5. Zero the software, and make the necessary adjustments to the units and precision in order to measure the center of pressure.

<u>Balance Procedure</u>

6. The patient (with his permanent prosthesis) will be asked to stand with one foot on each platform. With feet at a comfortable position (approximately 75% shoulder width apart) for 20 seconds (shown below), the patient will be asked to stare at a specific spot directly in front of them for the 20 second period. This position will be marked clearly with tape.
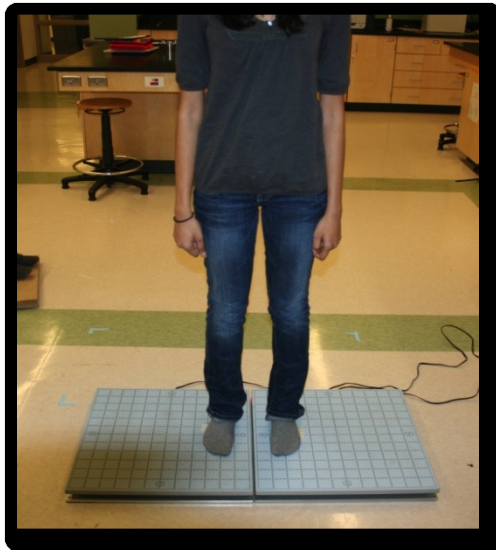

7. The patient will then be asked to stand on one leg (the prosthetic limb), as long as they feel comfortable doing so, for 20 seconds while staring at the same specific spot.

<u>Gait Procedure</u>

8. The patient will be asked to walk normally (with his permanent prosthesis) along a marked length of 10 ft. with their permanent prosthesis while the team measures the time it takes the patient to complete the task and calculates the number of steps/min (cadence) and speed.
9. Using the data collected, the team will calculate the stride length with the following equation:

$$stride\ length = \frac{120 * speed}{cadence}$$

10. Based on the calculated stride length, the team will place the left force platform in such a manner that the starting point of the patient is 3 stride lengths away from point A (as shown below), which is the center of the left force platform. This will cause the patient to strike the left force platform at point A after 3 strides.
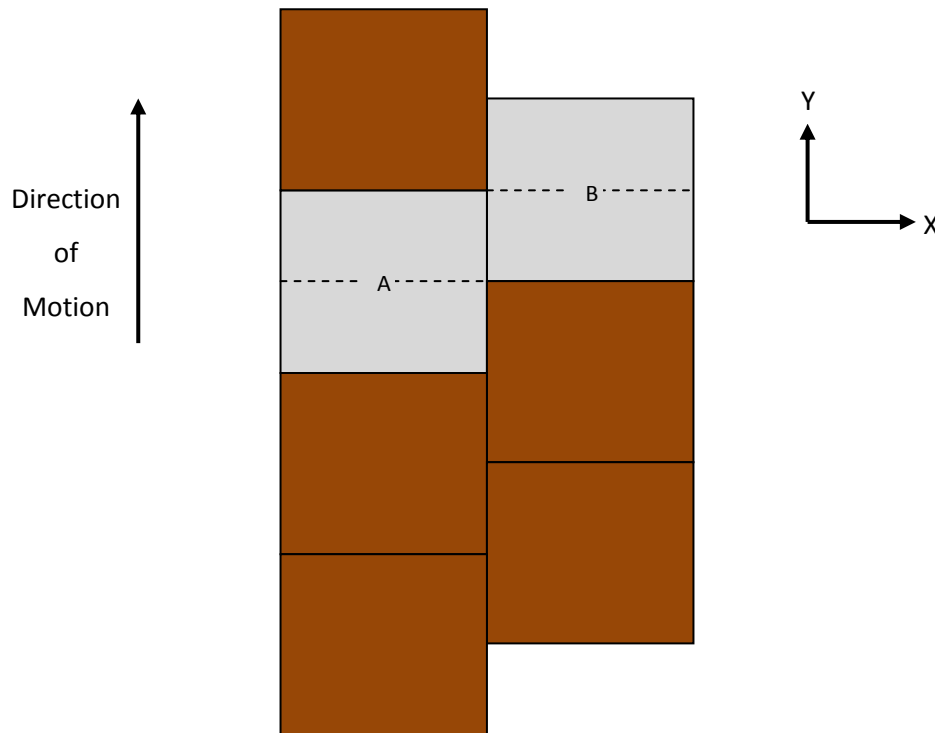
11. Point B on the right force platform will be at its center. The right force platform will be positioned such that points A and B are 1 stride length apart. This will cause the patient to strike the right force platform at point B immediately after striking the left force platform at point A.

12. The patient will walk along the prescribed path a few times until all the boards and plates have been placed in an appropriate position, and the patient is comfortable with the course. The boards are used to create an even level walking surface.

13. A piece of tape will be placed on the floor to denote the patient's starting point. The patient will then walk across the platforms, beginning at the marked starting point.
    a. The patient will be asked to minimize movement of their upper body.
   b. The patient will be asked to look forward while walking.

14. From this exercise, the team will determine the center of pressure during standing, as well as the impulse, impact forces and moments in the x-, y- and z- directions during ambulation.

Part 2

15. The student investigators will observe and silently record observations in a corner of the room, while the prosthetist then begins the fitting process, outlined below.
16. The student investigators will also be timing each fitting process beginning when the patient removes the prosthesis and ending when proper alignment is achieved as determined by the prosthetist.

Fitting Process A (Red Unit):

17. Patient will remove their prosthesis while seated, and will be given a prosthesis with the red unit purposefully offset to a pre-determined misalignment.
18. The patient will repeat the same process as Part 1 (refer to balance and gait procedures)
19. Prosthetist fits patient with the prosthesis as he usually does with the red unit.
    a. Prosthetist adjusts height to match the patient's gait and stance.
    b. Prosthetist adjusts linear alignment to match the patient's gait and stance.
    c. Prosthetist adjusts rotational alignment to match the patient's gait and stance.
20. Patient will walk up and down the ramp with the prosthesis.
    a. Patient may hold on to guardrails if he or she feels unbalanced or about to fall.
21. Modifications to the adjustment will be conducted as needed until the prosthetist feels the alignment is complete.
22. Once the prosthetist feels the alignment is complete, the patient will be asked to stand comfortably on the two force platforms for 20 seconds (as conducted in Part 1).
23. The patient will then be asked to walk across the platforms (again, as conducted in Part 1).
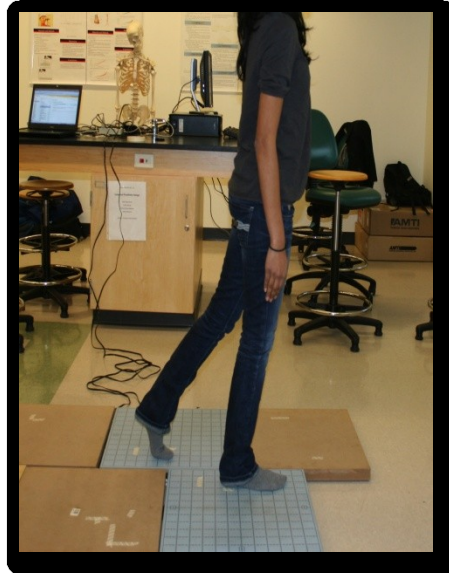
24. Patient will then remove the prosthesis while seated.

Fitting Process B (New Prototype):

25. Patient will remove their red unit prosthesis while seated, and will be given a prosthesis with the new prototype purposefully offset to a pre-determined misalignment.

26. Prosthetist fits patient with the prosthesis as he usually does with the new prototype.
    a. Prosthetist adjusts height to match the patient's gait and stance.
    b. Prosthetist adjusts linear alignment to match the patient's gait and stance.
    c. Prosthetist adjusts rotational alignment to match the patient's gait and stance.

27. Patient will walk up and down the ramp with the prosthesis.
    a. Patient may hold on to guardrails if he or she feels unbalanced or about to fall.

28. Modifications to the adjustment will be done as needed until the prosthetist feels the alignment is complete.

29. Once the prosthetist feels the alignment is complete, the patient will be asked to stand comfortably on the two force platforms for 20 seconds (as conducted in Part 1).

30. The patient will then be asked to walk across the platforms (again, as conducted in Part 1).

31. Patient will then remove the prosthesis while seated.

Post-testing

32. After all fittings have been completed, the prosthetist will be interviewed about the fitting process (questions detailed below).

33. Each patient will be given a brief survey to complete (as shown below).

Interview Questions for Prosthetist

1. What are the best features of the red unit?

2. What aspects of the red unit would you like to see improved?

3. What are the best features of the new prototype?

4. What aspects of the new prototype would you like to see improved?

5. Do you prefer the method of pins or the method of screws to secure the alignment adaptor?

6. Did you notice a difference between the two devices in terms of the patient's gait? If so, what?

7. Was there a difference in the precision of alignment you achieved with the two devices? Explain

8. Which device would you prefer to use? Why?

9. What are the advantages and disadvantages of the height adjustment feature in the new prototype?

Questionnaire for Patient

1. On a scale of 1 to 5, (1 – not important, 5 –very important), how important is your relationship with the prosthetist for a successful treatment?

<div align="center">

1   2   3   4   5

</div>

2. On a scale of 1 to 5 (1 – not important, 5 – very important), how important is it to have a short appointment time?

<div align="center">

1   2   3   4   5

</div>

3. Did you feel a difference between the first adaptor you used and the second? Explain.

4. Do you have a preference in the adaptor that you wear? If so, which one and why?