STAND UP WORLDWIDE

Prosthetic Leg Kit for Deployment in Developing Countries

California Polytechnic State University, San Luis Obispo
ENGR 461: Multidisciplinary Senior Design Project
In association with Help One Walk International

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Executive Summary

The World Health Organization estimates that over 30 million people require some sort of prosthetic technology. However, traditional prosthetic fitting practices take a lot of time and cost a lot of money, making them inaccessible to millions of people around the world. StandUP Worldwide is an interdisciplinary project team devoted to creating low-cost prosthetic technologies for use around the world, especially in resource poor areas. They are currently developing a low cost, below-the-knee prosthetic kit that can be easily deployed in a resource-poor area. The following presents their solution for a below-the-knee prosthetic socket, foot, and leg.

1. Chapter 1: Introduction

1.1 Sponsor Background

Team StandUP is an interdisciplinary senior project group working under the guidance of Help One Walk International (HOW) to develop a highly functional and robust prosthetic leg. HOW is a non-profit organization dedicated to helping landmine victims in Mozambique. The centerpiece of HOW's mission is helping a young woman named Florencia and her community who otherwise would be the other forgotten landmine victims. Florencia is an 18 year old mother of two who has an amputation below her right knee. She and approximately 12,000 other amputees in Mozambique need a prosthesis for a chance to live a life undeterred by amputation. It is this story of Florencia and the mission of HOW that inspired our sponsors to advocate this project.

HOW has partnered with Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS), the leading provider of prosthetic services in the developing world. BMVSS has provided various prosthetic technologies to over a million patients worldwide, all free of charge and regardless of the patient's ability to pay. Their most renowned product, the Jaipur Foot, costs approximately $50, a mere fraction of the cost of a prosthesis found in America, which typically cost anywhere from $5,000 - $50,000 and lasts only between three to five years.

BMVSS's success with the Jaipur Foot revolves around the low cost, incredible durability, high performance, and culturally sensitive design. Additionally, BMVSS's success also revolves around the availability of clinics all around India, with over 23 clinics and prosthetic facilities in India alone. The majority of the products used by BMVSS are sourced locally and manufactured in-house – all of the tooling and manufacturing equipment lie on the same grounds as the clinic, which dramatically reduce the cost of providing prosthetic services.

While BMVSS is a leader in providing services in India, there are millions of amputees all around the world that need prostheses, many of whom live in areas without the infrastructure, facilities, and manufacturing capabilities found in India and at BMVSS. Drawing upon the best aspects of the Jaipur Foot, the focus of this project is to create a transtibial prosthetic system, which includes a socket, pylon, and foot, designed for deployment in the most resource-poor areas around the world. The intention is to create a prosthetic kit requiring minimal tooling – the majority of the parts will be premanufactured and then will be applied to patients using only a handful of tools. The design will also focus on creating a culturally sensitive product at the lowest cost for the highest possible performance. It is our hope that the design we bring forward can be used to restore functionality and create a new life for patients like Florencia around the world.

1.2 Objectives and Project Definition

StandUP's goal is to create a below-the-knee prosthetic leg kit for deployment in low resource areas. This kit includes a socket, a pylon, and a foot. The intention is to create a prosthetic kit requiring minimal tooling – the majority of the parts will be premanufactured and then will be applied to patients using only a handful of tools. The design will also focus on creating a product at the lowest cost for the highest possible quality. It is our hope that the design we bring forward can be used to restore functionality and create a new life for patients like Florencia around the world.

2. Chapter 2: Background

2.1 Scientific Background

The background knowledge needed to design a prosthesis is extensive. This section introduces amputation physiology and biomechanics.

2.1.1 Amputation and Discomfort

The project's area of focus is on below-the-knee (transtibial) amputees. Although transtibial amputees have a gait more similar to non-amputees than above-the-knee (transfemoral) amputees, below-the-knee amputees face a unique set of complications when it comes to amputation. As seen in Figure 1, below-the-knee amputations necessitate cutting through both the tibia and fibula, where below-the-knee amputations only require cutting through the femur. If performed improperly, below-the knee amputations can result in complications where the tibia and fibula merge and promote the growth of painful bone spurs (citation).

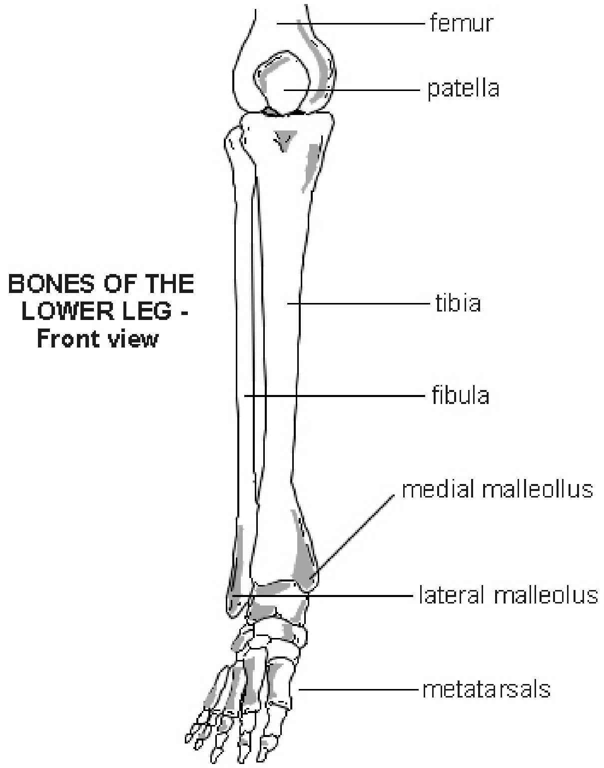


Figure 1: Bones of the lower leg

In addition to the promotion of bone spurs, below-the-knee amputees can also suffer from the following:

- Heart complications – such as heart attack blood clots (venous thrombosis)
- Slow wound healing and wound infection
- Pneumonia (infection of the lungs)
- Residual limb and "phantom limb" pain
- Psychological problems
- Swelling

2.1.2 Biomechanics and Physiology

When discussing how to emulate biological structures, it is important to use the same clinical language that is found in medical papers. As an overview, a structure (bone, muscle, tendon, etc.) that is further away from the body's center than another structure is referred to as 'distal', where the opposite is called 'proximal'. See Figure 2 for an illustration of these terms.

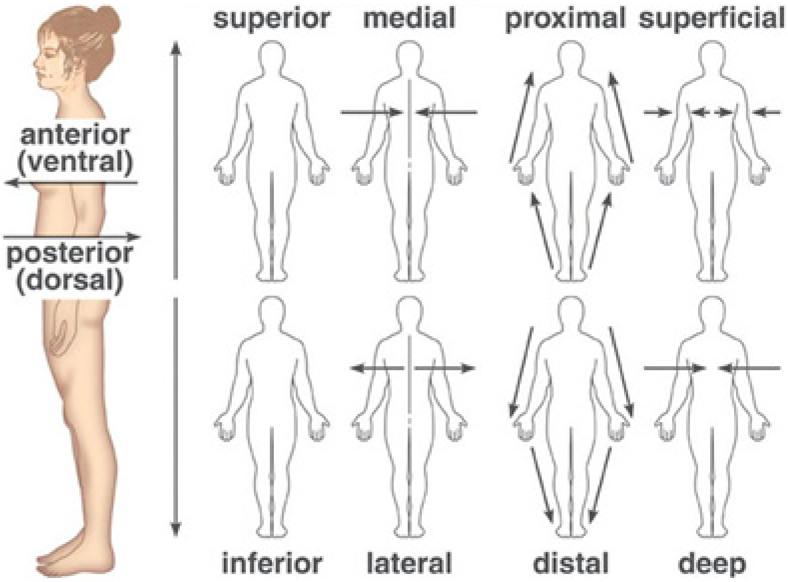


Figure 2: Anatomical location terms related to prosthetic biomechanics

When speaking specifically about the ankle, there are terms that define position relative to a resting position. Raising the toes above the resting position of the ankle is called 'dorsiflexion,' while lowering them is called 'plantar flexion'. When the bottom of the foot is turned medially, the position is defined as 'inversion', where it is called 'eversion' when it is turned laterally. See Figure 3 for ankle anatomical positions.

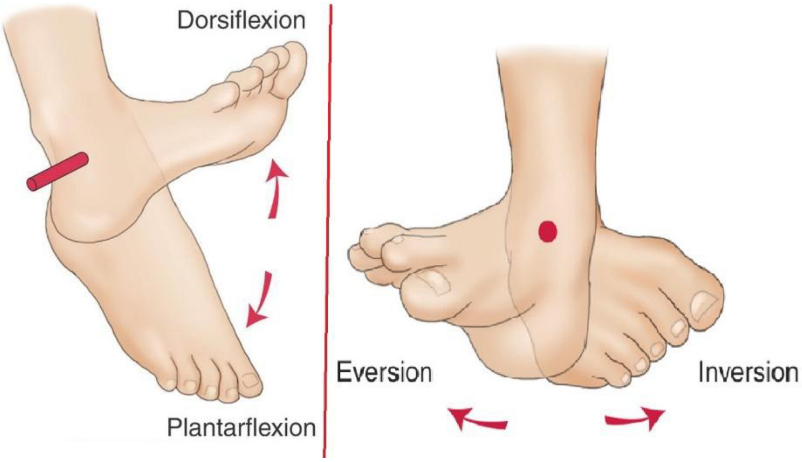


Figure 3: Anatomical positions and movements of the ankle

Human gait analysis is the study of bipedal locomotion to measure body movements, body mechanics, and muscle activity. It is crucial to understand the behavior of the body under typical, uninhibited conditions so that prosthetic limbs can be designed that properly emulate natural limbs. The most important phases for study are the heel strike and push off phase of the gait cycle. The heel strike creates a large force that could conceivably be converted into energy and be used during the push off phase. See Figure 4 for a clear illustration of the various stances of the human gait cycle.

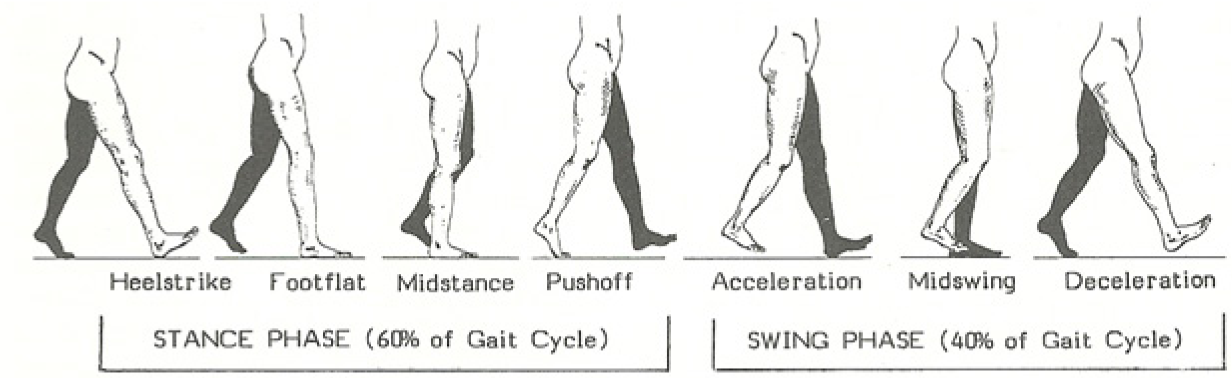


Figure 4: The complete gait cycle from heel strike to deceleration

2.2 Existing Designs and Considerations

As the intent of this project is to improve on the best aspects of the Jaipur Foot, it is helpful to define and explain the existing design. As seen below in Figure 5, the Jaipur Foot is comprised of a variety of different parts, each with a very specific and well-intended purpose. The most significant design aspect of the Jaipur Foot relates to the usage of three different high-density foam rubbers. The densest part of the three foams is located in the heel region, where the high density is used to withstand heel striking. The middle section of rubber is less dense than the heel section and accounts for the rolling of the foot throughout the gait cycle. The toe section of rubber is the least dense, and provides the springiness needed for push off in the gait cycle. Another great design feature is the flesh colored rubber, which has a long life span and is waterproof.

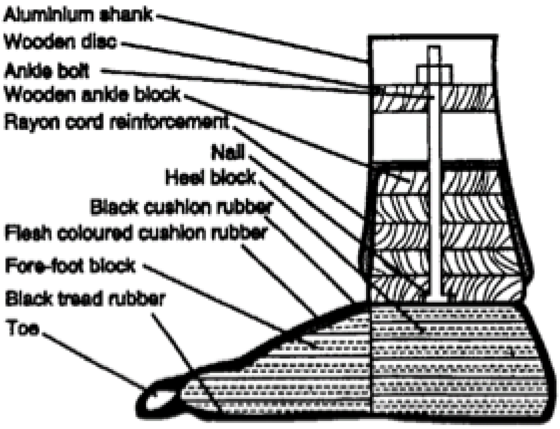


Figure 5: A sagittal cross section of the Jaipur Foot

Another example of a successful, low-cost prosthesis that our group looked at was the development of the LC Knee, an above-the-knee limb designed by Dr. Jan Andrysek, professor of Biomedical Engineering at the Institute of Biomaterials and Biomedical Engineering in Toronto, Canada. Andrysek has created a knee joint mechanism that locks when the patient puts weight on it and unlocks with forward movement, acting much like a biological knee. While more expensive technology can cost well over $3,000, Andrysek predicts the LC Knee will cost less than $100 when put into production. The leg can be seen below in Figure 6.

Figure 6: Dr. Jan Andrysek displaying the LC Knee in action

Another interesting design which we hope to draw off of is the prosthetic socket design done by LIM Innovations in San Francisco, California. Their flagship product, the Infinite Socket (shown below), allows increased an easy don/doff process in addition to increased cooling with the semi-open design and increased weight dispersal due to the longitudinal support straps. The Infinite Socket also accounts for a variety of different activity levels, ranging from K1 (household ambulation) all the way up to K4 (athletic performance). The outer frame of the socket can be seen below in Figure 7.

Figure 7: LIM Innovations Infinite Socket

While an incredibly well thought out design, the Infinite Socket is prohibitively expensive – between $7,000 and $30,000.

The Niagara Foot, which is pictured in Figure 8, was also examined because of its use of relatively inexpensive and durable materials. This design had a unique yet simple geometry that eliminates stress concentrations and might allow for fabrication amongst a wide selection of materials.

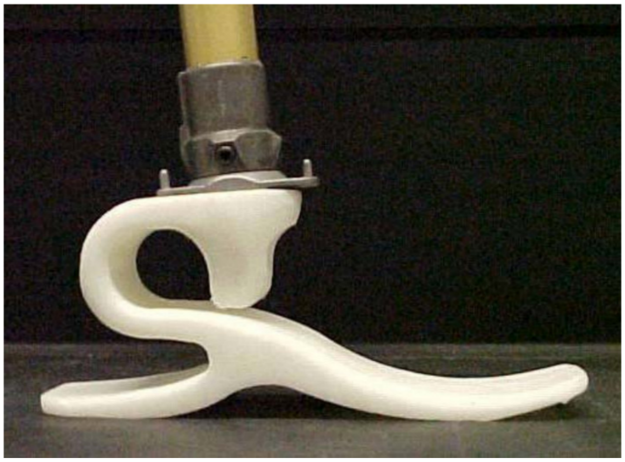


Figure 8: Niagara Foot being tested

A material would need to be selected that is resilient, durable and has a relatively high strength. Sizing and dimensioning of a one-piece foot like this would also require finite element analysis in order to certify that the design would not fail under certain loading conditions. Nevertheless the Niagara Foot reaffirmed that with the right material selection and geometry, a similar design could meet and exceed our engineering requirements for this project.

2.3 Referenced Standards

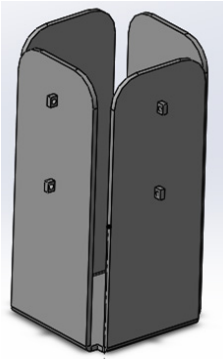
ISO standard 22675-Prosthetics was taken into consideration to determine the load cases. It specifies the cyclic test procedure for ankle-foot device of lower limb prostheses, to simulate the loading conditions of the complete stance phase of walking from heel strike to toe-off for the verification of performance requirements such as strength and durability. For our analysis we used at the highest values for ultimate strength to ensure the design satisfy that requirement.

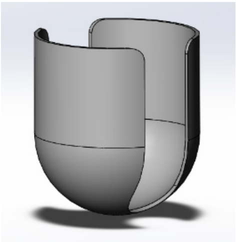
3. Chapter 3: Design Development

3.1 Conceptual Socket Designs

Our design history includes designs currently in production that serve as an inspiration to our own design. We analyzed and decided on properties from each product that that we would also want to include in our design, as well as aspects that we could improve upon. The following charts, Table 1 and Table 2 in combination with our Pugh chart led us to which potential design considerations may be more important than others.

Table 1: Socket Design Iterations and Considerations

<u>JAIPUR SOCKET</u> Desirable Features ● Simple Design ● Full Contact Areas of Improvement: ● Inner-socket shrinks and separates from the outer part which expands ● Cannot adjust	 *Figure 9: Jaipur Socket*
<u>LIM SOCKET DESIGN</u> Desirable Features ● Open air ● Ratchet system to tighten Areas of Improvement: ● Not full contact ● Isolated Pressure ● Need a stiff inner sock ● Takes a long time to custom mold	 *Figure 10: LIM Socket*
<u>STARFISH THERMOFORM SHELL</u> Desirable Features ● Open air ● Ratchet system to tighten ● Less Tooling ● Thermoformed Areas of Improvement: ● Not full contact ● Need robust inside liner	 *Figure 11: Starfish Thermoformed Shell*

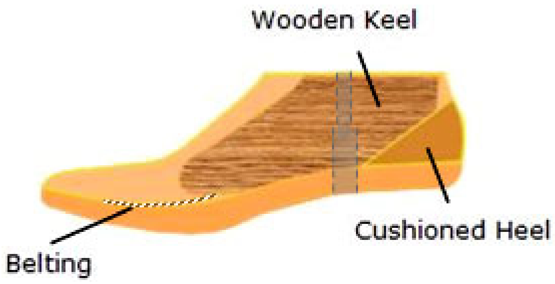
BOWTIE THERMOFORMED SHELL Desirable Features ● Partially full contact ● Ratchet system to tighten ● Minimal tooling ● Form directly to inner liner Areas of Improvement ● Thermoformed design needs to consider pylon attachment mechanism	 *Figure 12: Bowtie Thermoformed Shell*

3.2 Socket Design Selection

The next part of the design involves the inner liner of the socket. This unique design is based off of a design in a manual written in 1986 by Wieland Kaphingst and Sepp Heim titled "On Stump Socket Lamination", where a prosthetic socket liner is created by wrapping the limb in a nylon stockinette; then covered the limb with two plastic bags, one of which is sealed; pouring a resin mixture into the space between the sealed plastic bag and the unsealed bag; sealing the unsealed bag; and finally, allowing the resin to cure, creating a soft, inner liner that can be placed in between the bowtie socket and residual limb for comfort. This method creates geometric integrity of the patient's residual limb without the use a plaster cast, saving time and money in addition to not needing a specialized skillset to do so. This method can also be applied in a similar manner to create a hard outer shell using the inner liner as the geometric support.

3.3 Conceptual Foot Designs

Table 2: Foot Design Considerations and Iterations

<u>SACH (Solid-Ankle Cushioned-Heel) FOOT</u> Useful Design Considerations: ● Cushioned heel dampens forces from heel strike ● Mimics normal plantar flexion ● Easy to produce Areas of Improvement: ● Intended for low activity patients ● Solid ankle, minimal flex and multiaxial rotation ● Minimal energy return	 *Figure 13: SACH Foot*

JAIPUR FOOT

Useful Design Considerations

- Rubber in the heel is less dense to soften the force of the heel strike and more dense through the rest of the foot to provide energy return
- Tire tread strands used to hold sponge rubber blocks together and mimic tendons
- Rubber foot body permits for multiaxial rotation allowing the patient to sit as well as handle uneven terrain.

Areas of Improvement:

- Best suited for low to medium activity levels
- Better energy return than SACH foot, but is still inefficient

Figure 14: Cross-section of Jaipur

C-WALK® ENERGY AND COMFORT

Useful Design Considerations

- Large plantar flexion
- Multi-axis rotation
- Ring acts like a spring to mimic typical foot motion and efficiently store and release energy. Thus, smooth transitions between gait phases
- Can be used for patients with high activity levels

Areas of Improvement:

- Have to buy footsheel separately
- Expensive
- Not easily manufacturable in large quantities, and by minimally trained workers
- Made of carbon fiber reinforced plastic, which is too expensive

Figure 15: C-Walk Energy and Comfort Foot

NIAGARA FOOT

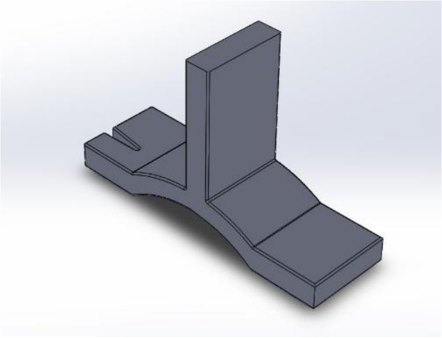
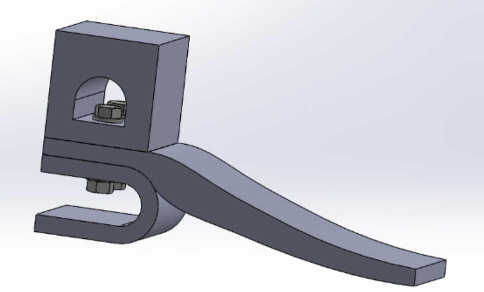
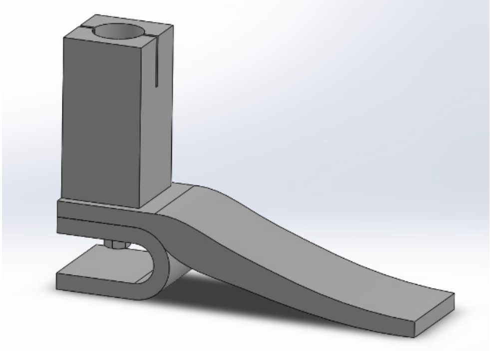
Useful Design Considerations:

- Formed as one complete part
- Dynamic C section at heel acts as a spring for energy return
- Made from a thermoplastic elastomer
- Can stand more cyclic loading than rubber
- Resilient yet still maintains strength and durability

Areas of Improvement:

- Better energy return
- More stability
- Expensive outer cover

Figure 16: Niagara Foot

Single Piece CNC Foot Useful Design Considerations: ● Cut from single piece of material ● Mimics normal plantar flexion ● Easy to produce Areas of Improvement: ● Toe geometry leads to extra machining operation for not that much benefit ● Stress concentration at T	 *Figure 17: Single Piece StandUP CNC Foot*
3 Piece CNC Foot Useful Design Considerations: ● Energy conserving ● Modular ● Easy to replace components Areas of Improvement: ● Assembly of components might be challenging ● Fracture potential in heel and bending failure at C-block ● Unsure of how to attach pylon	 *Figure 18: 3 Piece StandUP CNC Foot*
Improved 3 Piece CNC Foot Useful Design Considerations: ● Attachment to pylon realized ● Same other benefits as above Areas of Improvement: ● Same disadvantages as above except for method of pylon attachment	 *Figure 19: Improved 3 Piece StandUP CNC Foot*

3.4 Prosthetic Foot Design Selection

Careful consideration went into a foot and ankle design that would be strong, durable, inexpensive, easily reproducible, and modular for easy repairs. We wanted to blend the reliability and consumer value of the Jaipur Foot with a design that offered greater ease in manufacturing and assembly. This became even more evident when the team toured the facility in India where the Jaipur Foot is produced. The current manufacturing processes would not be possible in a country with strict health and safety regulations without a major overhaul to these manufacturing steps. It is because of this that we set out to design a manufacturing process and assembly procedure that would be acceptable in virtually any country, regardless of how strict health and safety regulations might be.

We first decided to select a geometric design that would lend itself to ease of manufacturing, and have a very simple momentum conserving dynamic to it. In attempting to make the design as simple as possible, the team came up with the design shown in Figure 18. Though this successfully accomplished our goal of a geometrically simple design, it became evident that momentum conservation would be very minimal, and fatigue and cyclic loading would most likely cause it to fail.

A substantially more modular design loosely based on the Niagara Foot was conceptualized, and is shown in Figure 19 It was estimated that this design would this design would greatly improve the patient’s gait, and would be made up of components that would be relatively easy to manufacture. This would also mean that parts could also be replaced, meaning that the whole foot would not have to be thrown away due to failure of a particular piece. We noted that special consideration would have to be given to the heel, as failure here was most likely if any part was to fail. An attachment interface to the pylon had yet to be designed as well, so we set out to design a sensible way to incorporate that into the prosthetic.

This brings us to the most second to last design iteration before the most recent, which is pictured in Figure 20. There are a few slight modifications that were made to the previous design, most notably the method in which the pylon would be attached to the ankle section. Also the two bolt design that fastened the heel and keel to the ankle was changed to a single bolt design. The diameter of that single bolt was increased to ensure that all three components would be fastened securely. Initial stress calculations were performed to ensure that the design was feasible based on our possible material candidates. Our design, having met the initial design criteria set forth, was selected for further evaluation and eventual prototyping.

3.5 Preliminary Analysis

A primary area of concern for the design of a prosthetic leg is how much loading it will encounter. In order to get a general understanding of how much human mass to factor into calculations, it was assumed that the average patient in Mozambique is 70 kg (150 lbs). Since the intended application of this leg is not to merely stand in place, one leg would not merely take half of the person’s weight. Imagining a person running, they will have a period of time where only one foot is in contact with the ground, taking on the full weight of the body. However, again the person is not standing with one foot on the ground, they are running. As such, the dynamic loading of the activity must be factored in with an assumed operating loading of double the weight: 140 kg (300 lbs). Since any number of scenarios could play out where the leg would endure more than that amount of weight, a factor of safety of 2 was included in the analysis. As such, all calculations performed relied on the assumption that the leg would be loaded with 280 kg (600 lbs). The calculations in Appendix F evaluate the ability of the foot to withstand the selected load with varying dimensions of the heel, the primary loading point of the design. These calculations determined a baseline off which multiple FEA models were developed for several iterations of the foot design using the Solidworks Simulation toolbox. It was found that using the early design of the foot as seen in Figure 20 that significant deformation would occur under the worst case loading conditions of 350 pounds and cyclic loading conditions of the same weight. As such, the design was bolstered as seen in Figure 21 to resist this deformation. A secondary FEA study using the same boundary conditions was run and a visual representation of the results can be seen in Figure 24. As the results of this FEA analysis seemed conclusive, it was determined that the foot should be manufactured to these specifications.

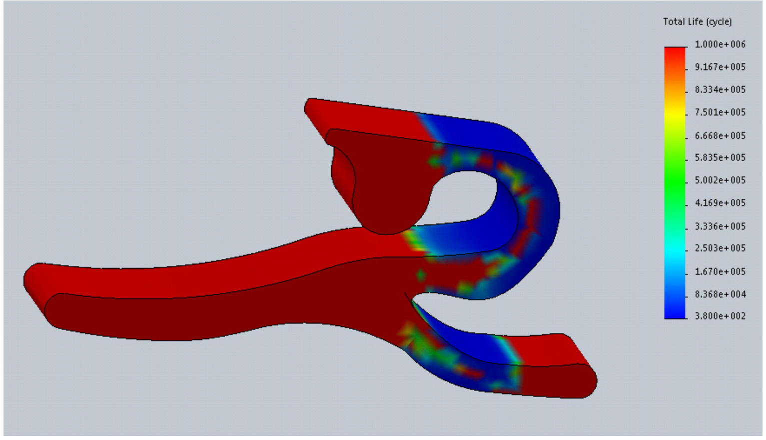


Figure 20: FEA deformation of early foot design

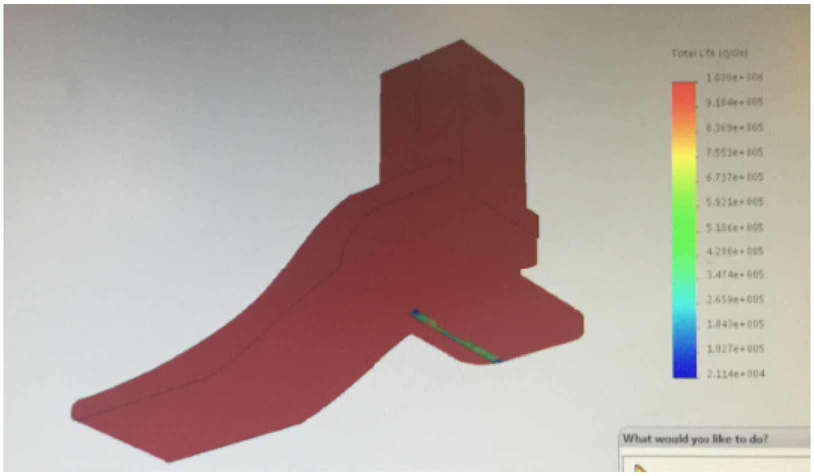


Figure 21: FEA deformation of current foot design

Other structurally necessary components of the design were determined to not be as highly at risk for fracture. The socket relies on the large surface-area-to-body ratio and adherence to residual limb geometry so that any loading is evenly distributed across the residual limb. The angular adjuster primarily relies on the integrity of the M10 bolt to withstand the loading, which an experienced prosthetist that has worked in developing countries said would be a conservative measure to prevent fracture. The Delrin ankle block and keel are thicker and less eccentrically loaded than the heel. This concept and the fact that the Niagara Foot uses the same material and similar geometries as the StandUP design, these components will not be at risk of fracture [Ziolo].

In regards to the socket, numerical analysis is difficult because of the highly variable nature of each residual limb. As such, most of the criteria for the socket design have a largely qualitative aspect to the analysis. The analysis and design based around the socket accounted for the load transfer between the residual limb and the socket, the ability to adjust the tension/tightness of the socket, and the ease of interfacing between the socket and pylon.

The inner socket liner, which will be a resin impregnated fabric liner, will sit inside the frame. This method of socket creation allows virtually total contact between the residual limb and the liner. Total contact will allow good load transfer between the residual limb and socket system. Combined with the outer socket, the entire socket forming process will not need a plaster cast in order to create the socket.

4. Chapter 4: Description of the Final Design

After careful consideration of the pros and cons of the above concepts, the team zeroed in on the fundamental design requirements that were deemed paramount above all others. What we strived to create was an inexpensive, user-friendly, and robust leg kit that can be scaled up and rapidly deployed to virtually any region in the world. Pictured below in Figure 22 is the image of the final design. The final design of the prosthetic leg kit is shown below. Additional drawings are included in Appendix C.

Figure 22: System Level View of the StandUP Leg

The socket consists of a multi-layer epoxy composite. The inner liner is formed using two layers of cotton stockinette and a non-exothermic, two-part, and fast-hardening epoxy which cures directly on the patient for perfect fitting. On the outside of this, a more rigid, two-part epoxy is used in conjunction with two more layers of stockinette to achieve the structural support required of a prosthetic socket. At the distal tip, a bolt secured in a metal plate is embedded into the harder of the two epoxies in order to create an interface by which to attach the pylon, as discussed above. Additionally, during use a sock is to be used over the patient's residual limb possibly along with pelite (a thermoplastic polyethylene with expanded cross linked closed-cell foam material) in order to create a comfortable experience for the user.

The pylon consists of a single cylinder stock of aluminum whose length is dependent on the intended patient. A cavity is drilled on one side of the stock so that the bolt from the foot can extend up through and not obstruct the ability of the pylon to rest in the ankle block. A hole is also drilled in the transverse direction, all the way through the cavity, to allow a bolt to secure the pylon to the ankle block. On the opposite end of the pylon, a tapped hole allows it to be secured to a bolt extending from the socket. In this way, the pylon is firmly attached to both the foot and the socket. The pylon can be seen in Figure 23.

Figure 23: View of Prosthetic Pylon

The foot is composed of three different components: the ankle block, the C-heel, and the S-keel. They are all composed of Delrin and secured to various other components by M10 bolts, washers, and nuts. The ankle block is attached to the pylon by a single bolt that runs through and secures it from any motion relative to the foot. The cut spaces on the side of the ankle block allow for flexion during the clamping process which will enable a tighter fight with no wiggling. The ankle block is also connected to the rest of the foot by a bolt that runs through the center of all the other pieces. The shape of the S-keel is such that while running forward, it will flex and act as a spring to store energy that will be released when moving forward. The shape of the C-heel serves a similar purpose as it absorbs energy during the heel strike phase of gait and propels that patient forward as they rock forward. The bottoms of the heel and keel that contact the ground will be textured to allow the user to grip the ground if there is no cosmetic cover in place. See Figure 24 for an image of the foot, both assemble and exploded.

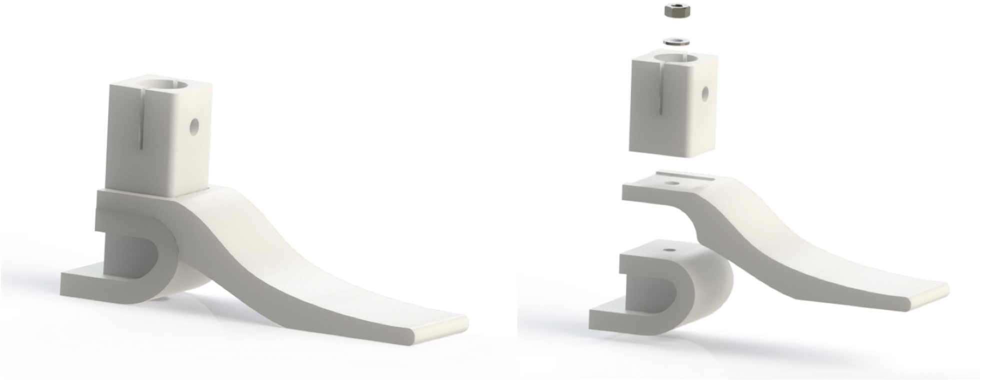


Figure 24: View of StandUP Prosthetic Foot

A cosmetic cover for the foot is still being considered, but not detailed in this report as it will require precise fitting to the selected foot design.

4.1 Cost Breakdown

The cost breakdown for the concept development of the socket can be seen in Appendix D. A summary of the costs for the full prototype and the estimated costs of a scaled model can be seen in Table 3.

Table 3: Prototype and Estimated Scale Costs

Material	Quantity	Prototype Cost (Including Labor)	Est. Scaled Cost (Including Labor)
Soft Epoxy	8oz	\$16.00	\$6.00
Hard Epoxy	8oz	\$12.00	\$6.00
Metal Disk (20mm)	1	\$1.00	\$0.50
Shin Post (150mm)	1	\$2.00	\$1.50
Long M10 Bolt	1	\$1.00	\$0.50
M10 Washer	2	\$1.00	\$0.50
M10 Nut	3	\$1.00	\$0.50
Short M10 Bolt	1	\$1.00	\$0.50
Delrin Foot	1	\$135.62 (CNC)	~\$27 (Injection Mold)
Est. Total Costs		~\$150	~\$50

Despite the relatively high cost of \$150 for a prototype, scaling up the production of the device will dramatically reduce the cost of production, primarily due to the suggested method of foot manufacture: approximately \$27. This figure is based on estimations made by initial research on the subject, but is not a solidified figure.

4.2 Material Selection

Material selection is an important part of our design. We evaluated and analyzed several materials to determine the most appropriate material that can support the desired expectations for quality. During analysis to determine which materials would be most appropriate for the foot several materials were considered, but in the end Delrin (Dupont branded polyoxymethylene) was selected. It has a high tensile strength and is easily machined, which makes it the most attractive material for the foot design. When compared to polypropylene (PP) and polyethylene (PE), Delrin is more expensive, however when compared by their tensile strength and elastic modulus, Delrin is the best choice. See Appendix F for graphical representations of why these materials were selected.

As mentioned previously, the socket system includes two components – an inner liner for comfort and an outer shell for durability and connection to the pylon. The material selection will be broken into sections by component. Types of materials were chosen guided by the “Direct Socket Lamination” manual. Nylon stockinettes were chosen because they are relatively inexpensive, are readily available, and provide higher strength than cotton as fiber reinforcement for the laminate. Polyester resin is typically used for boat hull applications but works well for filling the matrix of nylon fibers. The resin has a low viscosity and will begin setting within 25 minutes after pouring though different amounts of resin catalyst can speed up the process. For example, most resins can be sanded at 6 hours and are fully set at 24 hours. This information was taken from the product data sheet. Additionally, the relevant material properties can be seen below in Table 4.

Table 4: Summary of the properties of selected materials

Material	Relevant Properties	Reason for Selection
Fiberglass Coatings Inc. Crystal Clear Table Top System	Hardness: 70-75 shore D Elongation: >15% Gel-time: 25 mins Non-exothermic	The lower hardness and higher elongation values result in a less rigid laminate, able to act as a liner. Non-exothermic prevents discomfort of the patient. The quick gel-time allows for a shorter overall fitting time of the socket.
TotalBoat 5:1 Epoxy Fast Hardener	Tensile Strength: 8,000 psi Tensile Modulus: 4.1x10^5 psi Compressive Strength: 11.5x10^3 psi Elongation: 3.5% Set time: 60 mins Cure time: 6 hrs	The desirable properties include high tensile strength and modulus, as well as modulus. These properties combined with minimal elongation make it the ideal resin to provide the structure of the socket. It is strong enough to support the weight of an adult male. The resin also adheres to the cotton stockinette.
Cotton Stockinette	Low cost Conforms to shape of body	Can be used for heat protection as well as reinforcement for the epoxy resin in both the inner and outer laminate. Resin is able to adhere to the cotton fibers.
PVA Bag	Heat Resistant Water Soluble Resistant to Solvents	Resin does not adhere to the bag. In lack of a vacuum system the sandwiching of PVA bags makes it possible to manually spread the resin evenly around the mold.
Pe-Lite Foam	Thermoplastic moldability Good energy absorption Impermeable to liquids Isotropic	Pe-lite foam was selected as a liner material because its thermoplastic property allows for it to be molded to take the shape of the limb and is able to provide sufficient padding between the laminate and the limb.

4.3 Safety Considerations

According to the MSDS data sheet of the materials used during the manufacturing process are not known to contain any toxic chemicals and do not present a respiration hazard. However they might cause burn to the skin and/or irritating fumes may be produced. To reduce the risks we plan to have enough ventilation, and to follow the first aid measure on the MSDS datasheet. The final product will be subjected to extreme environment conditions such as humidity, cold, high temperatures, etc. this can create an unsafe condition for the user, however we have reduced the risk by choosing the best materials that can withstand these conditions as previously discussed.

4.4 Maintenance Considerations

To maintain a low-cost we have designed the prosthetic in various components. This will reduce the manufacturing time and the cost. It will make easier and faster to replace a component if needed and it will allow anyone without any complex training to do it. We plan to use a cosmetic cover to give it a more life-like appearance. This cover will also protect it from the environment (dust, water, etc). In case a cover is not used it is important to try to reduce exposure to wet environments.

5. Chapter 5: Product Realization

5.1 Manufacturing Process

5.1.1 Overview

The prosthetic leg is designed in such a way that several, various size components will be able to taken to a rural location and with minimal tooling, assemble a perfectly fit leg. The foot and pylon will potentially only require a small amount of grinding to ensure proper dimensional fit to the patient, while the liner and socket will require much more assembly.

Fasteners were purchased from McMaster-Carr, and consist of stainless M10 bolts, washers, and nuts where needed. All pieces will be assembled and tightened as specified in drawings in Appendix C.

5.1.2 Foot

The ankle, keel and heel pieces will be made of Delrin and will be CNC machined according to dimensions calculated and specified in SolidWorks. Special considerations will be made when machining this material in regards to cutting speed and using the correct cutting bit for the job.

5.1.3 Pylon

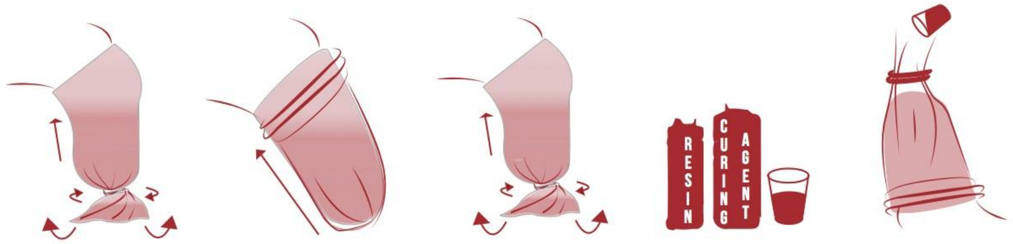
The prosthetic pylon or shin piece of the design will be made of stainless steel. They are a common over-the-counter part that can be cut to the specific size required for our needs. A washer will be sized to the correct inner diameter of the pylon and will be welded in place. The washer will also have a M10 threads tapped in the center so that the heel and keel can be fastened to the pylon.

5.1.4 Socket

The manufacture of the socket includes an inner liner in combination with an outer laminate. Both are applied directly to the limb, beginning with the inner liner, then the outer laminate is applied directly on top of it. The socket itself will be manufactured in Mozambique directly to the patient. This will eliminate the need for the plaster molds, which would require significantly more material and energy, and produce more waste. The materials that would be manufactured outside and brought into Mozambique the include; two part epoxy with curing agent (Table Top), two part epoxy with hardener (Total Boat resin), cotton stockinette, PVA bags, cups, tape, bolts, aluminum disks, and PE-lite. This process was adapted from the manual entitled “On Stump Lamination” written by Wieland Kaphingst and Sepp Heim, and is outlined below.

5.1.5 Inner Liner

The purpose of the inner liner is to act as a soft layer in between the residual limb and the hard outer shell. This will make using the prosthetic more comfortable. The fabrication process starts with the patient sitting on the edge of a chair or table with the residual limb dangling downward. The first step is to wrap the residual limb in two layers of cotton stockinette, the purpose of which is to provide a medium that conforms to the residual limb geometry. This is achieved by pulling half of the stockinette sleeve over the residual limb, twisting the sleeve in the middle, and pulling the remaining half of the sleeve back over itself, effectively creating a double layer. A polyvinyl acetate (PVA) sleeve is then pulled over the end of the limb and taped shut at the distal end of the limb. Another stockinette sleeve is pulled over the sleeve to create a double layer like before, and then another PVA sleeve is pulled over the residual limb, though this time the proximal end is sealed, not the distal end. At this point, there is a layer of stockinette sandwiched between two layers of PVA. Now, an epoxy resin and curing agent are mixed and poured through the opening of the proximal end of the unsealed PVA bag. At this point, the patient should be on his or her back with the limb flat to the table. The end of the bag is sealed and the resin is then pushed from the end of the bag into the cotton stockinette, impregnating it and creating a resin-nylon composite that conforms to residual limb geometry. Resin will be pushed onto the stockinette as much as possible. The liner is left to cure on the patient until partially set and slightly firm, at which it can then be removed. The process is illustrated in Figure 25..



Double layer of cotton stockinette

PVA bag over stockinette and tape distal end

Double layer cotton stockinette

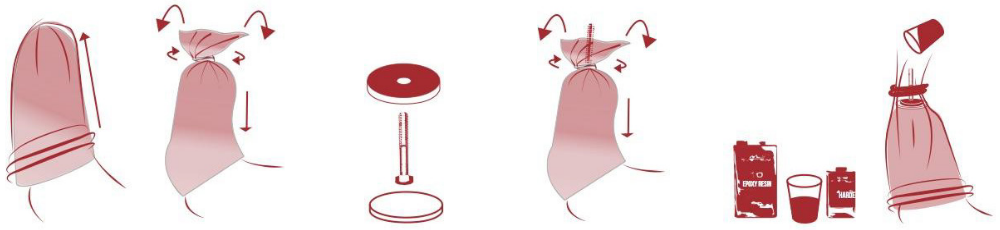
Mix two part soft epoxy resin

Apply outer PVA bag, pour in resin mixture, and let cure about one hour

Figure 25: Production process of the inner liner

5.1.6 Outer Shell

The process for creating the hard outer shell is similar to the inner liner. However, instead of applying the stockinette and PVA bags over the patient's limb, they can be formed over the firm inner liner. At this point the outer PVA bag is removed. Two layers of cotton stockinette are then pulled over the cured liner, as before. A PElite circle (slightly larger than two inches in diameter) will be heated with a heat gun and formed over the end of the residual limb. Next, a pre-machined, two inch aluminum disk with a center hole big enough for an M10 screw will be placed on top of the PElite circle. Another stockinette will be applied in the double layer fashion and the placed over the aluminum disk and screw (the screw will have to puncture the stockinette). The stock Part of a PVA bag should be wrapped and taped around the bolt to prevent the resin from sticking to it. Next an outer PVA bag will be put on just as in the process for the inner liner. The epoxy resin used for this part should be strong and hard, we used boat resin. Highly exothermic resins should be avoided because of discomfort and melting of the PVA bags. The resin and hardener are mixed according to proportions on the bottles, poured into the bag and evenly spread, just as before. Curing time was about an hour, but ideally a resin with a faster curing time would be used. An abbreviated process is shown in Figure 26.



Remove outer PVA bag	**Apply two layers of cotton stockinette**	**Aluminum disk, bolt and PE-lite pad (cut circle from PE-lite sheet) combination**	**Place bolt combination on distal end, then double layer cotton stockinette**	**Mix resin and hardener**	**Apply outer PVA bag, pour in resin mixture and let cure**

Figure 26: Production process of the outer laminate

Once hardened, the PVA bag can be removed, and the socket should be pulled off the patient's stump after which the remaining PVA bag and stockinettes can be removed. Once removed the socket should be left alone for around 12 hours to be be sure that it cures completely before use.

5.1.7 Manufacturing

The prosthetic leg is designed in such a way that several, various size components will be able to taken to a rural location and with minimal tooling, assemble a perfectly fit leg. The foot and pylon will potentially only require a small amount of grinding to ensure proper dimensional fit to the patient, while the liner and socket will require much more assembly.

The angular adjuster will have its initial shape cut out of wax using a CNC machine. This wax positive mold will be used to create a ceramic negative mold, which will subsequently be filled with stainless steel to produce the desired shape. It will be post-treated to eliminate undesirable geometries.

The prosthetic pylon or shin piece of the design will be made of stainless steel. They are a common over-the-counter part that can be cut to the specific size required for our needs. A washer will be sized to the correct inner diameter of the pylon and will be welded in place. The washer will also have a M10 threads tapped in the center so that the heel and keel can be fastened to the pylon.

The ankle, keel and heel pieces will be made of Delrin and will be CNC machined according to dimensions calculated and specified in SolidWorks. Special considerations will be made when machining this material in regards to cutting speed and using the correct cutting bit for the job.

Fasteners will be purchased from McMaster-Carr, and will consist of stainless M10 bolts, washers, and nuts where needed. M4 bolts for affixing the angular adjuster to the socket will also be purchased from McMaster-Carr. All pieces will be assembled and tightened as specified in drawings in Appendix C.

6. Chapter 6: Testing

Seven requirements were set about halfway through the quarter which established the metrics for success of this project. These requirements are listed below and then summarized in a table at the end of this section.

6.1 Longevity

In this test, a mean load based on ISO 22675 in Appendix J is applied to the specimen and the number of cycles (2000, ISO 22675) to produce failure. The force was to be applied in axially, in torsion, or in flexure. Unfortunately Cal Poly does not have the equipment necessary to perform this test. As such, the FEA analysis was performed to evaluate how the foot would survive extended cyclic testing. Instead of stopping at 2000 cycles, the foot was pushed to 10 million cycles. This number is more realistic as it assumes a person would walk an average of 5 miles a day for 5 years. The FEA analysis proved successful as discussed previously in the preliminary analysis section.

6.2 Weight Bearing Capacity

The weight bearing capacity of the prosthetic system with a factor of safety is determined to be 150kg, or about 350lb. The entire prosthetic system should be able to support this load safely. One method of testing the weight bearing capacity is to perform a weight test, where a 350lb load was applied to the prosthetic system. While only a one time load, the test gave an initial look at how the system performs under high loads. A fully assembled prosthetic system was used, with a plaster cast placed inside the residual limb to simulate human contact. As there were not many models to test, it was not made a destructive test. The socket was able to support 350lbs – while being supported from the sides to maintain a vertical orientation.

6.3 Light Weight

This was a simple test that consisted of weighing the final prototype. The specification was set to be less than 5kg so that it would be lighter than the limb that was missing. For the adult male size that was developed for the report, it weighed in at 4.47kg. Thus, it met the requirement.

6.4 Cost

As discussed in section 4.1, the leg should be able to be manufactured for around $50. This fell within the specification of $70 which was set as a conservative price tag to avoid setting ambitions too high.

6.5 Time to Fit Mold to Leg

The goal of this project was to create an entire below-the-knee prosthetic leg system in under 24 hours. This involved two timed tests: one to measure how long it took to mold the inner liner to the test residual limb, and the second to measure the length of time to mold the outer liner on the outside of the first. The test concluded that it would take a total of 6 hours for both epoxy levels to cure.

6.6 Fully Mechanical

Due to technological requirements and the need for a robust design, the leg was made to be fully mechanical. Thus, satisfying this requirement by design.

6.7 Modular

Like the last requirement, this was more of an attribute than variable test (i.e. self-evident and incorporated into the design. The design is modular on two scales. First, there are three components of the main design which can be interchanged: socket, pylon, and foot. Second, the foot has three parts as well: the c-heel, s-keel, and the ankle block. With these features included into the design, the requirement was satisfied.

Table 5: Test Method Summary

Attribute	Specification	Test Method	Result
Longevity	5 years	FEA Evaluation	10,000,000 cycles
Weight Bearing	150 kg	Static Testing	> 150 kg
Light Weight	< 5 kg	Scale	4.5 kg
Cost	< $100	Bill of Materials	$50 (at scale)
Fitting Time	< 24 hours	Timer/Practice	Pass
Fully Mechanical	Limited Access to Technology	Self-evident	Pass
Modular	Facilitate replacement & Manufacturing	Self-evident	Pass

7. Chapter 7: Project Management Plan

After the initial expectations were established, the project followed a relatively predictable timeline for the development of several iterations of the design. This project has followed the Gantt chart established in Appendix G.

8. Chapter 8: Conclusions and Recommendations

The StandUP Worldwide team has created a design of a prosthetic leg kit that can be deployed in resource-poor areas. The components consist of a modular Delrin foot, an aluminum alloy pylon, a soft inner liner, and a hard outer socket. Together, these four items form a kit where the contents of one kit equal on prosthetic leg. Preliminary costs are also under $40.00, potentially allowing the mass production of these products to patients in need around the world.

Further steps for this project include the full prototyping of this system. Full prototyping will allow inspection into each individual component as well as into process optimization.

9. Appendices

See attached.

CAL POLY
SAN LUIS OBISPO

Appendix A: References

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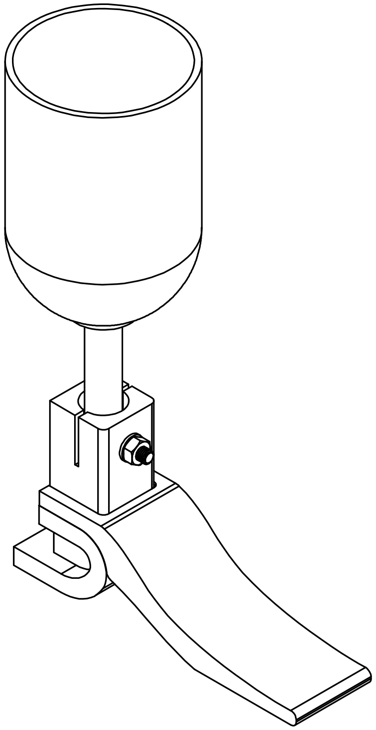
Appendix B: QFD and Decision Matrices

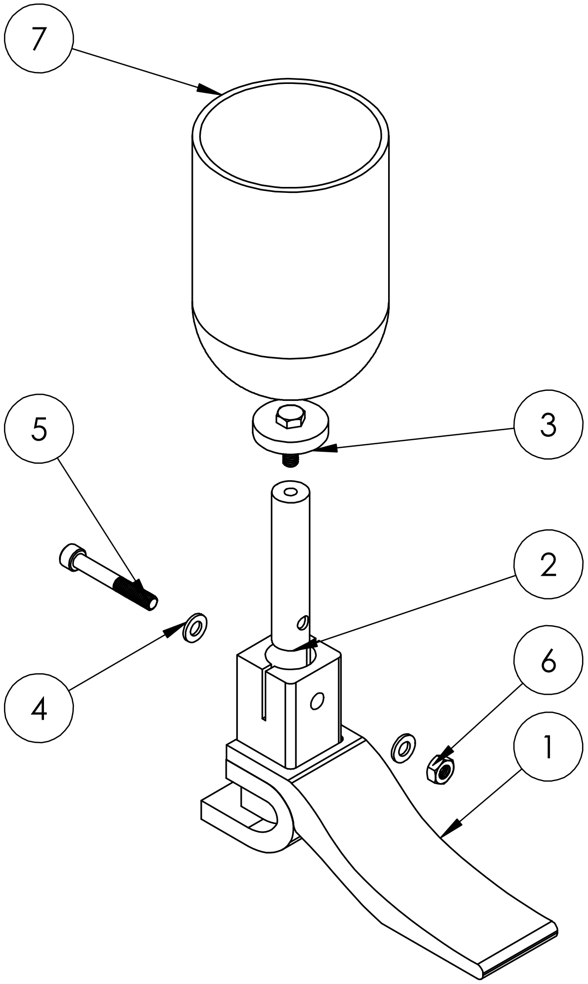
Engineering Requirements (HOWS)

StandUp Leg Customer (Step #1) Requirements (Whats)	Weighting (1 to 5)	Vibration Dampening	Support >150lbs/Area	Weight < 9lbs	strength to weight ratio high	Inversion Angle	Eversion Angle	Angle of Toe Deflection	Force Dampening	Torsionsal Limit	Shear Limit	2.25:1 Design Factor	High Volume to Tooling Ratio	Socket Pullout Force	Correct Socket Pressure	Local Availability of Materials	High Heat Trasnfer Rate	Range in height	Range in diameter of socket	Time study for Fitting	Energy output better or equal to Jaipur	Benchmarks	
Stability	5	9	9	3		3	3	3		1	1	9		9				3	1		3	285	91.35%
Fully Mechanical	5	9			3				9	1	1	3	3			9		3			9	250	80.13%
Low Cost	5	3	1	9	3				3				9			9	3	3	3	3	9	290	92.95%
Good Socket	4	9	9	3					9			3	9		9	3	9	3	9	3		312	100.00%
Modular	4	3	9	9	3				3	9	9	9	3			3		3	3			264	84.62%
Adjustable	4		9	3								3	9	9	9	3		3	9	9		264	84.62%
Longevity	3	3			3				9	3	3	9	3			9		3	3		3	153	49.04%
Momentum Conserving	2	3		9	3	1	1	9	3						3	1		3			9	90	28.85%
Near-human Aesthetic	2	3		9	9	3	3	3	3			3				9					3	96	30.77%
Less Practitioner Interacti	1															9		9	9	9		36	11.54%
Perform Common Activiti	1	3	9	9	3	9	9	9	9			9		3	3		9		3	3	9	99	31.73%
Less Time for Fitting	1			3										9	9		3		9	9		42	13.46%
Units																							
Targets																							
Benchmark #1																							
Benchmark #2																							
Importance Scoring		**177**	**167**	**168**	78	32	32	48	**156**	55	55	**162**	**153**	93	90	**182**	63	105	134	84	**147**		
Importance Rating (%)		97	92	92	43	18	18	26	86	30	30	89	84	51	49	100	35	58	74	46	81		

● = 9	Srong Correlation
○ = 3	Medium Correlation
∆ = 1	Small Correlation
Blank	No Correlation

Appendix C: CAD Drawings

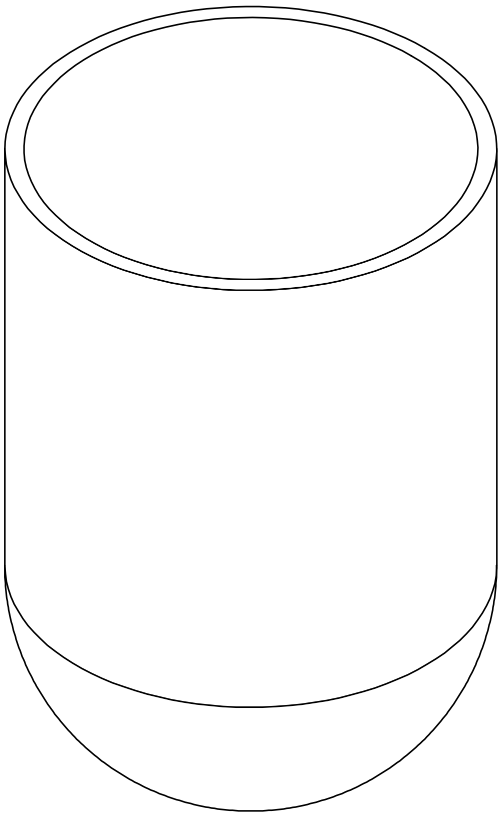




ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	1000-300	FOOT SUBASSEMBLY	1
2	1000-201	PYLON, 6061 AL	1
3	1000-100	SOCKET BOLT INTERFACE SUBASSEMBLY	1
4	90965A200	M10 WASHER, SS	2
5	92290A548	M10 BOLT, SS	1
6	94150A358	SS M10 NUT	1
7	1000-102	EPOXY COMPOSITE SOCKET, ASSEMBLY INSTRUCTIONS SEPARATE	1

Cal Poly Engineering	TEAM StandUP	FINAL	Title: StandUP Leg		Drwn. By: BRIAN MURPHY
	#: 1000	ENGR 460	Date:05 JUNE 16	Scale: 1:1	Chkd. By:

NOTE: 1000-100 WILL BE FORMED ON SITE



Cal Poly Engineering	TEAM StandUP	FINAL	Title: StandUP Leg		Drwn. By: BRIAN MURPHY
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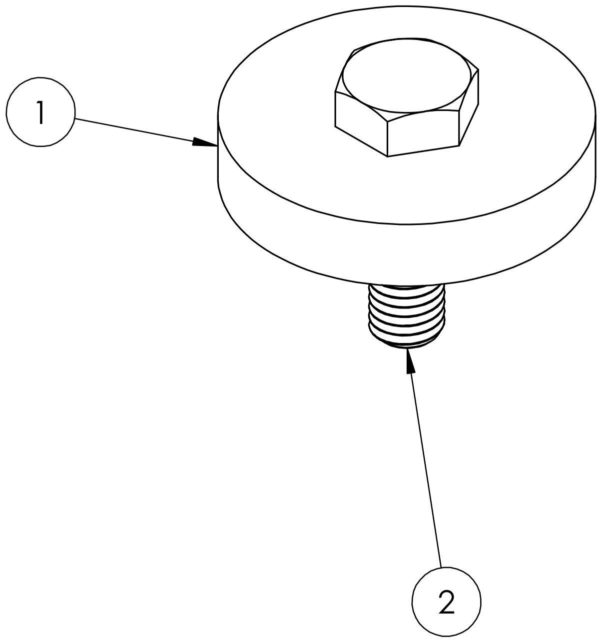

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	1000-101	STABILIZING DISK, 6061 AL	1
2	93635A428	M10 x 1.5 MM THREAD, SS	1

Cal Poly Engineering	TEAM StandUP	FINAL	Title: StandUP Leg		Drwn. By: BRIAN MURPHY
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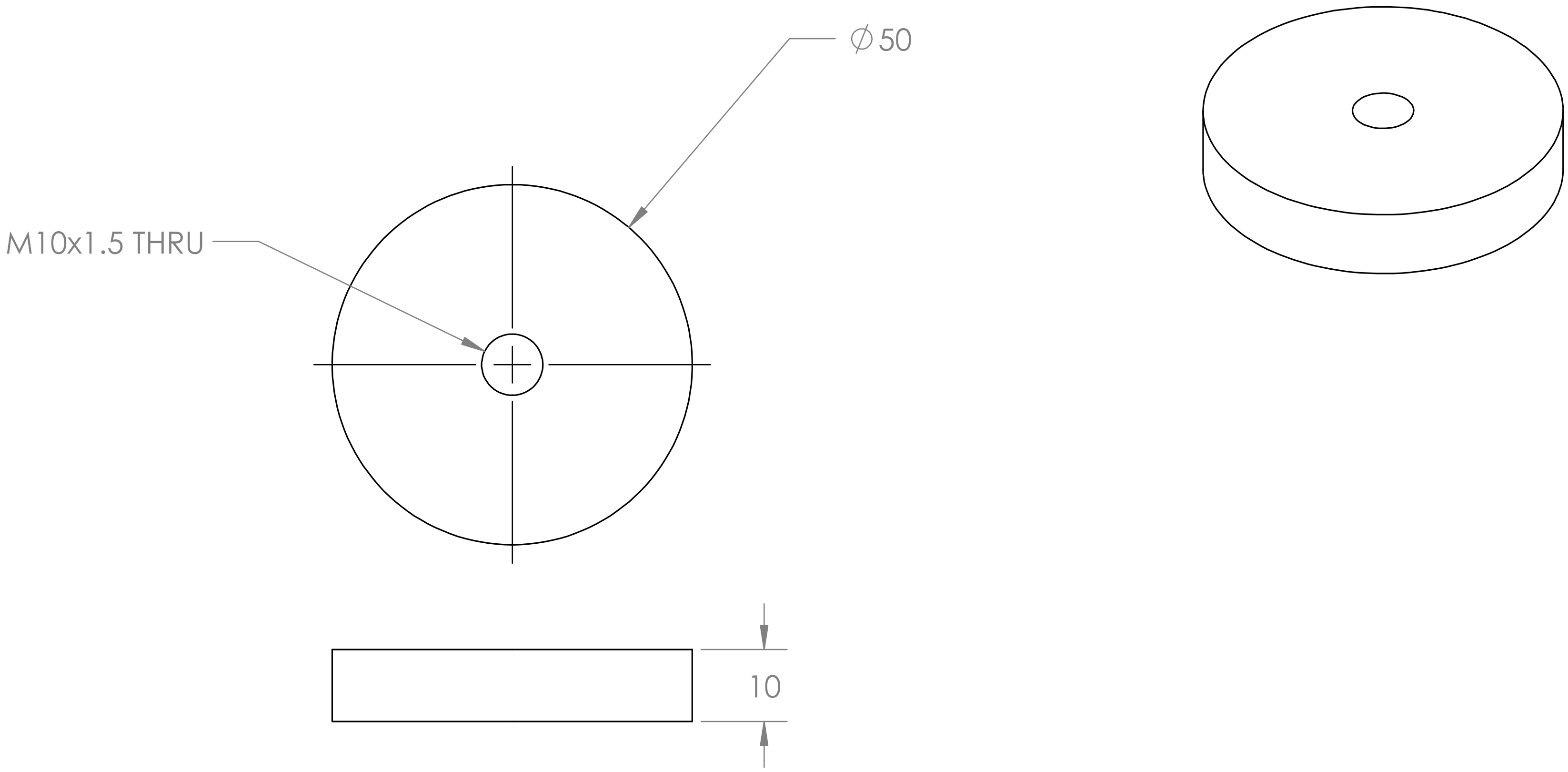

Cal Poly Engineering	TEAM StandUP	FINAL	Title: StandUP Leg		Drwn. By: BRIAN MURPHY
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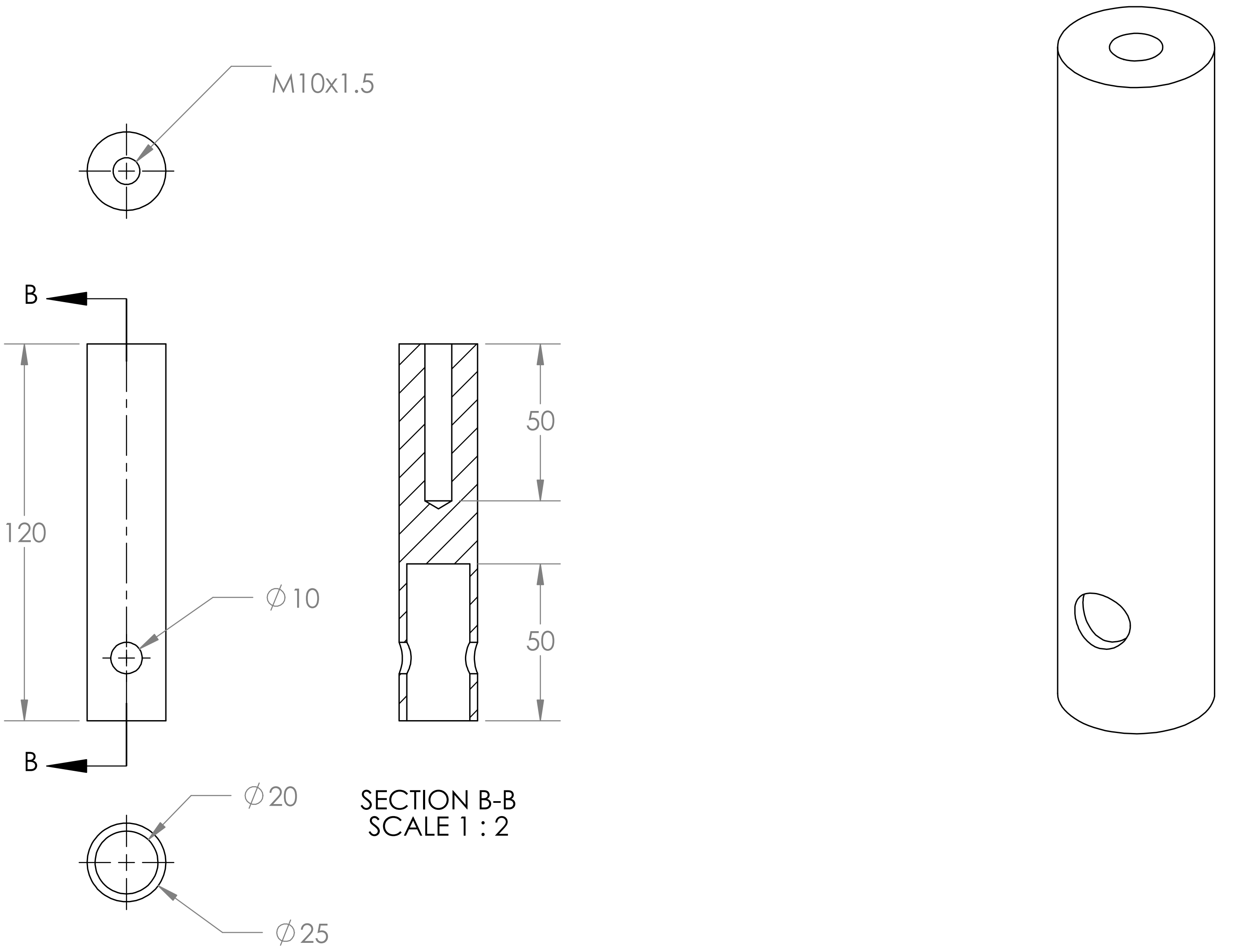

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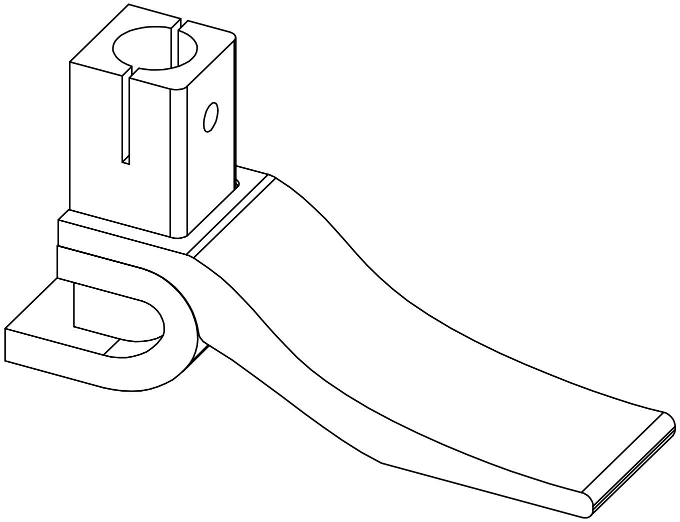

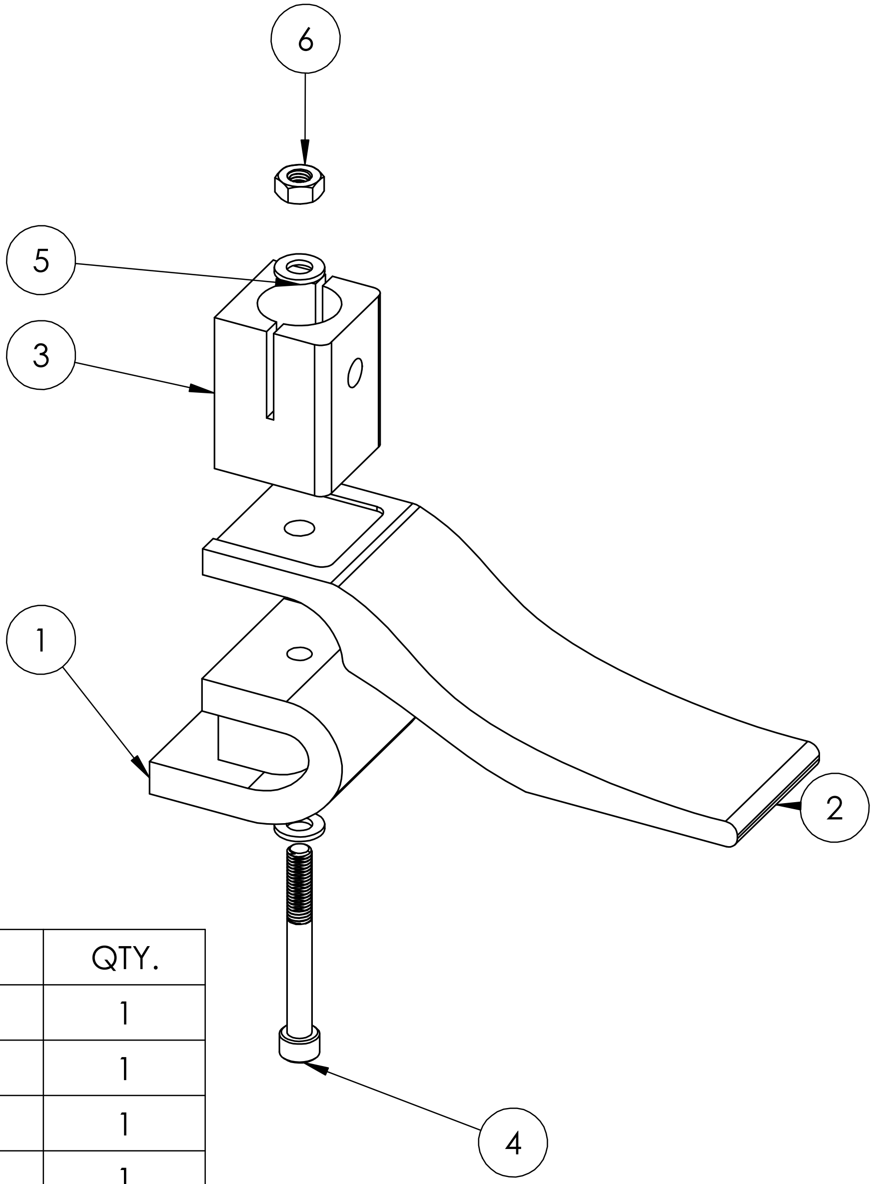

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	1000-302	C-BLOCK, DELRIN	1
2	1000-301	S-KEEL, DELRIN	1
3	1000-303	ANKLE BLOCK, DELRIN	1
4	91292A826	M10 BOLT, SS	1
5	90965A200	M10 WASHER, SS	2
6	94150A358	SS M10 NUT	1

Cal Poly Engineering	TEAM StandUP	FINAL	Title: StandUP Leg		Drwn. By: BRIAN MURPHY
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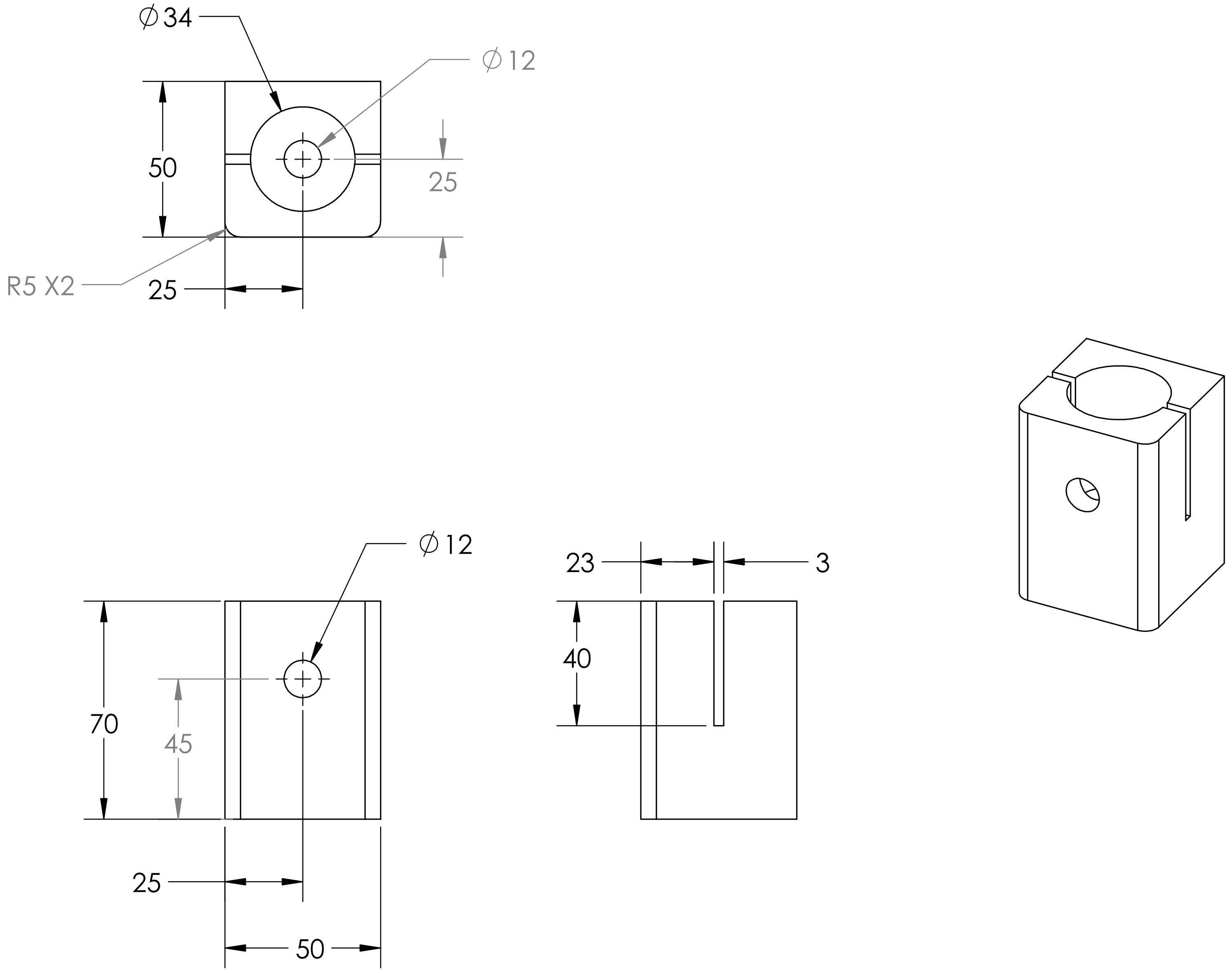
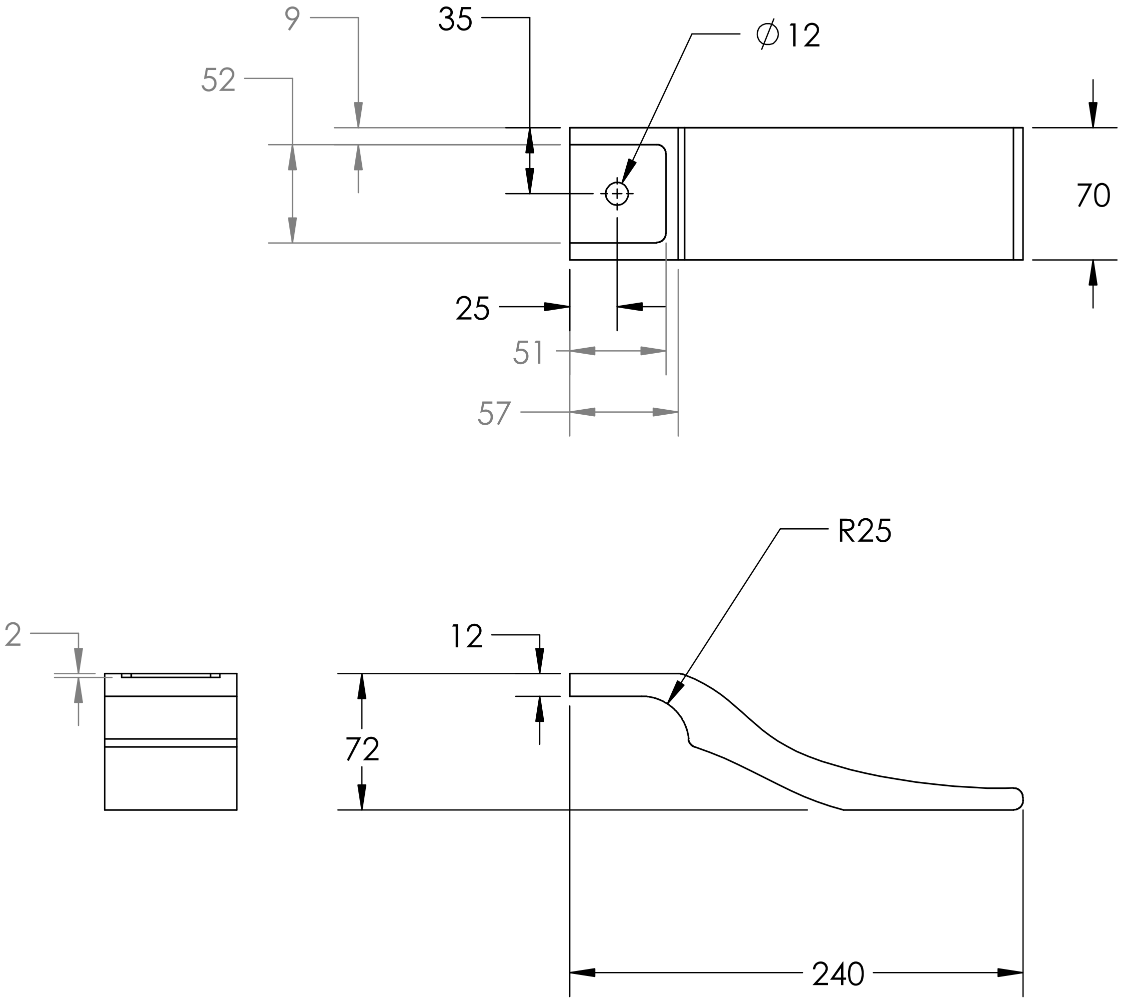
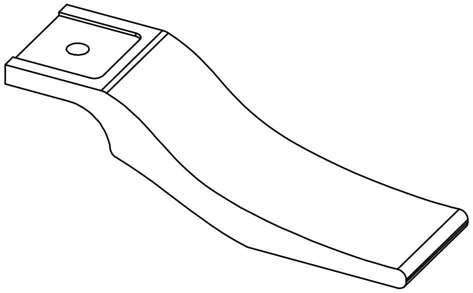
NOTE: COMPONENT WILL BE CNC MANUFACTURED



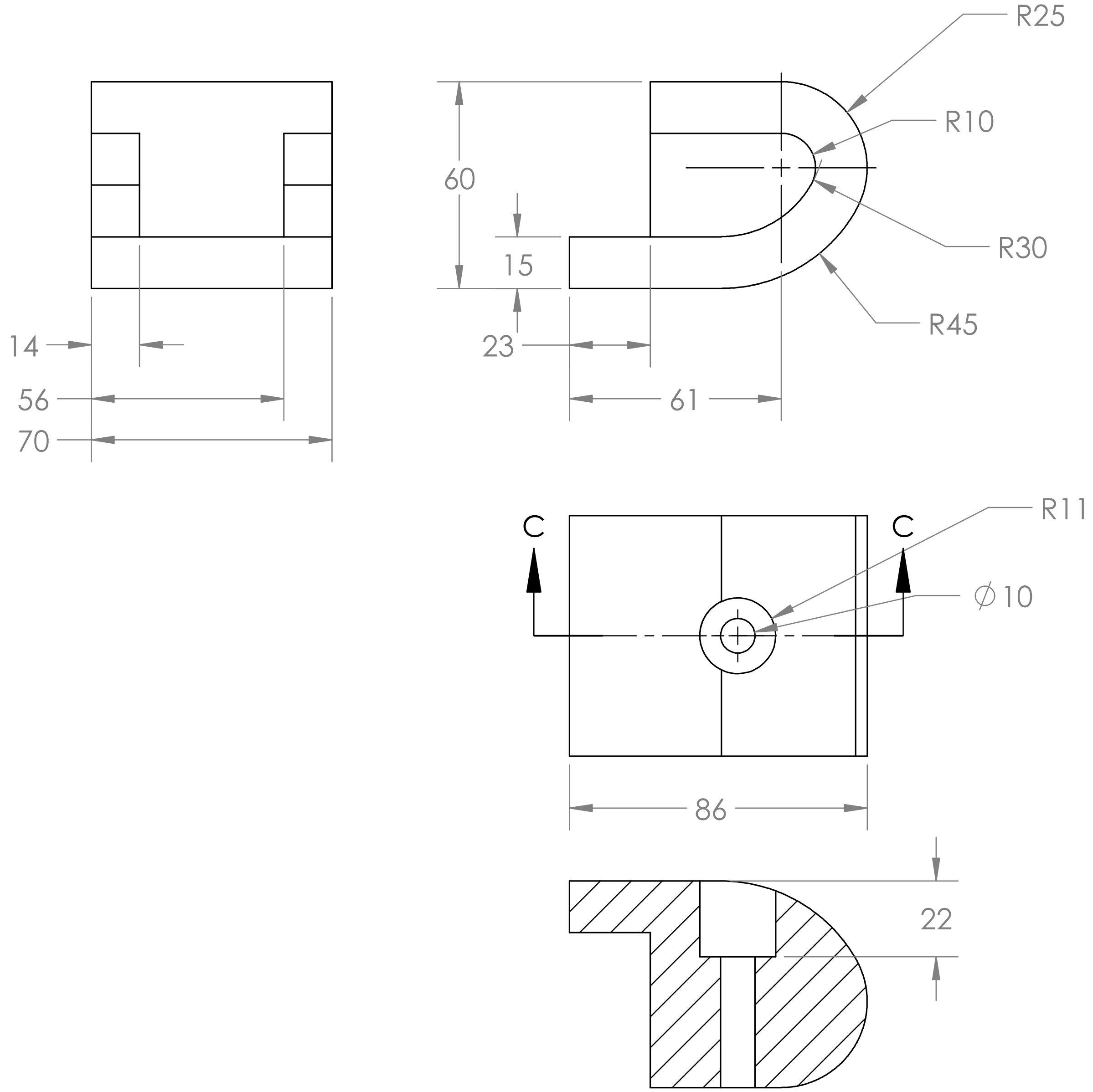
Cal Poly Engineering	TEAM StandUP	FINAL	Title: StandUP Leg		Drwn. By: BRIAN MURPHY
	#: 1000-303	ENGR 460	Date: 05 JUNE 16	Scale: 1:1	Chkd. By:

NOTE: ONLY DIMENSIONS LISTED SHOULD BE HELD FIRMLY. OTHER FEATURES SHOULD BE TAKEN DIRECTLY FROM CAD FILE WHEN BEING CNC MANUFACTURED



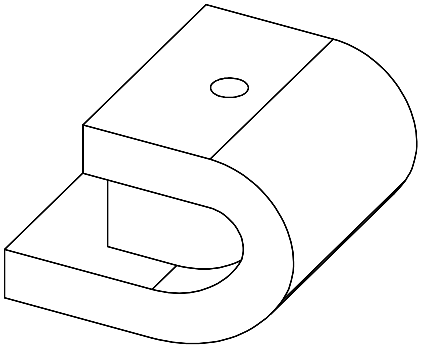


Cal Poly Engineering	TEAM StandUP	FINAL	Title: StandUP Leg		Drwn. By: BRIAN MURPHY
	#: 1000-301	ENGR 460	Date:05 JUNE 16	Scale: 1:1	Chkd. By:



SECTION C-C
SCALE 1 : 2

NOTE: ONLY DIMENSIONS LISTED SHOULD BE HELD FIRMLY. OTHER FEATURES SHOULD BE TAKEN DIRECTLY FROM CAD FILE WHEN BEING CNC MANUFACTURED



1000-302

Cal Poly Engineering	TEAM StandUP	FINAL	Title: StandUP Leg		Drwn. By: BRIAN MURPHY
	#: 1000-302	ENGR 460	Date: 05 JUNE 16	Scale: 1:1	Chkd. By:

Appendix D: Vendor Information and Pricing

Table D1: Socket Material Vendor and Pricing Breakdown

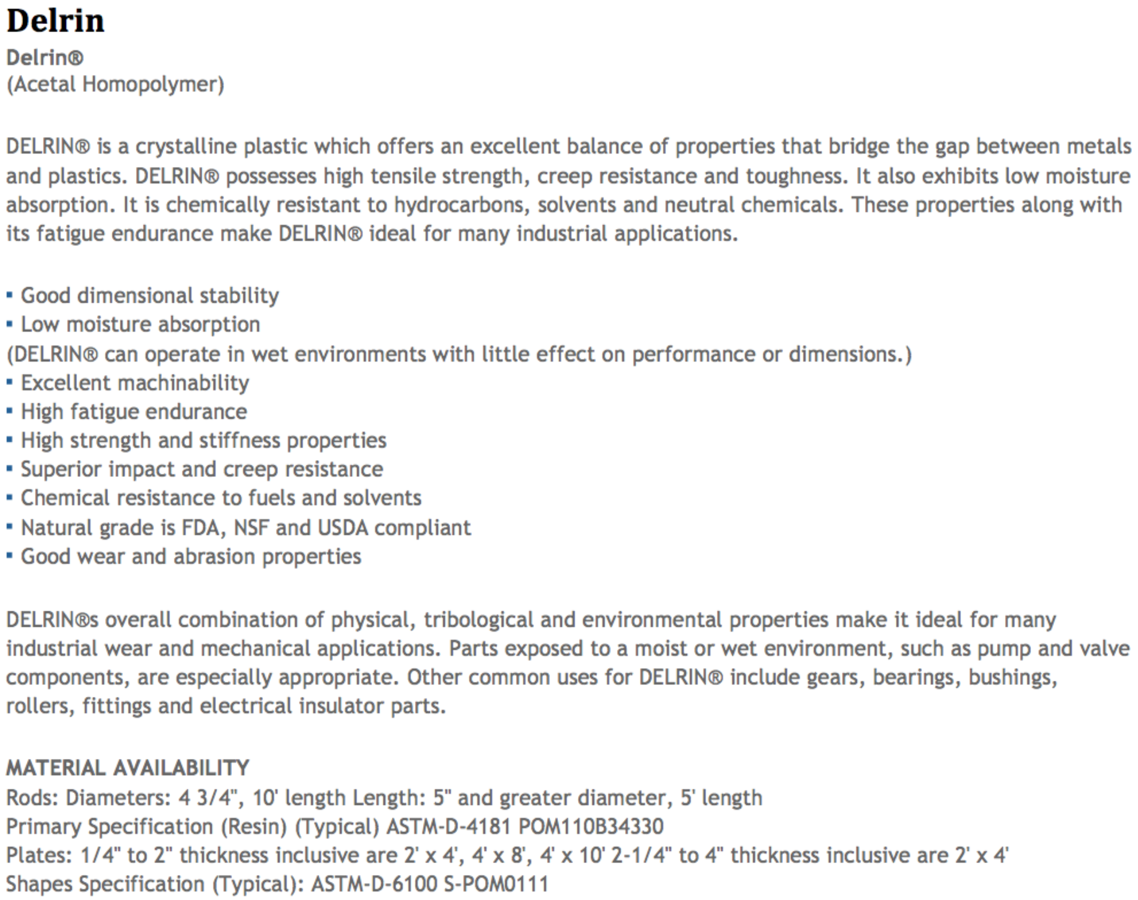
Component	**Material**	**Company**	**Cost**	**Estimate material per person**	**Cost per person**
Socket Laminate	Polyester Resin w/ hardener	Fibre Glast	$36.95/quart	1/8 quart or about 1/4 lb	$4.62
Socket Laminate	Nylon Stockinette	Paceline	$27/ 25-Yd roll (900”)	64”	$1.92
Liner	PE-lite foam	Friddles	$43/(3/16"X39"X39")	Varies w/ person - avg 16” by 16” per person, about 6 per sheet	$7.20
Liner	Glue	Pattax	$10.50/40g	about ¼ gram	$0.07
Laminate process	PVA bags	Paceline	$30/20 bags	2 bags	$3.00
Heat Protection	Cotton Stockinette	AliMed	$25.75/(3" X 25 yd)	66”	$1.88
Sliding off	Talcum Powder	AliMed	$5/5oz	1/8oz	$0.13
Heat Protection	Medical Adhesive tape	3M	$66.30/ Case -24 Rolls(1”by 10yds)	40” (2 loops around large distal area)	$0.31
Shaping	Plaster of Paris	AliMed	$30/12(2”x3 yds)	2 feet (b/c multiple layers in bony areas for relief)	$1.67
Outer layer to fit shell	Polyurethane Shore A40	Smooth On	$105.43/gallon	1/16 gallon	$6.56
Shell	HDPE	Interstate plastics	$15.98/1/8”x24”x48”	⅓ of sheet (30” by 10”)	$5.33
Tooling	HDPE	TBD	TBD	TBD	TBD
Shell	Ratchet System	m2inc	$3.75/unit	$3.75	$3.75
Average Total Cost Per Socket					$36.44 + tooling

Table D2: Prosthetic Foot and Pylon Vendor and Pricing Breakdown

Component	**Material**	**Company**	**Cost**	**Estimate material per person**	**Cost per person**
Modular foot	Delrin	McMaster-Carr	$70	1 block (4”x4”x12”)	$35
Pylon	Aluminum	McMaster-Carr	$17.08	1 rod	$17.08
Ankle block	Delrin	McMaster-Carr	$150	1/16 (4”x4”x12”)	$10
Angular adjuster	Stainless steel	McMaster-Carr	$41.40	½ (2”x2”)	$20.70
M10 hex nut	stainless steel	McMaster-Carr	$12.66	2 (pack of 10)	$2.52
M10 25MM bolt	Stainless steel	McMaster-Carr	$8.03	1 (pack of 5)	$1.60
Interface (angular & pylon)	1095 steel	McMaster-Carr	$21.25	1/40 (8”x12”)	$0.54
M10 70MM bolt	Stainless steel	McMaster-Carr	$2.58	1	$2.58
M10 washer	Stainless steel	McMaster-Carr	$11.17	1 (pack of 50)	$0.22
Average Total Cost Per Pylon & Foot Assembly					$90.00

Appendix E: Vendor Specifications

Specifications of materials from CES:



Delrin

Delrin®
(Acetal Homopolymer)

DELRIN® is a crystalline plastic which offers an excellent balance of properties that bridge the gap between metals and plastics. DELRIN® possesses high tensile strength, creep resistance and toughness. It also exhibits low moisture absorption. It is chemically resistant to hydrocarbons, solvents and neutral chemicals. These properties along with its fatigue endurance make DELRIN® ideal for many industrial applications.

- Good dimensional stability
- Low moisture absorption

(DELRIN® can operate in wet environments with little effect on performance or dimensions.)

- Excellent machinability
- High fatigue endurance
- High strength and stiffness properties
- Superior impact and creep resistance
- Chemical resistance to fuels and solvents
- Natural grade is FDA, NSF and USDA compliant
- Good wear and abrasion properties

DELRIN®s overall combination of physical, tribological and environmental properties make it ideal for many industrial wear and mechanical applications. Parts exposed to a moist or wet environment, such as pump and valve components, are especially appropriate. Other common uses for DELRIN® include gears, bearings, bushings, rollers, fittings and electrical insulator parts.

MATERIAL AVAILABILITY
Rods: Diameters: 4 3/4", 10' length Length: 5" and greater diameter, 5' length
Primary Specification (Resin) (Typical) ASTM-D-4181 POM110B34330
Plates: 1/4" to 2" thickness inclusive are 2' x 4', 4' x 8', 4' x 10' 2-1/4" to 4" thickness inclusive are 2' x 4'
Shapes Specification (Typical): ASTM-D-6100 S-POM0111

Caption

Zips.

The material

POM was first marketed by DuPont in 1959 as Delrin. It is similar to nylon but is stiffer, and has better fatigue and water resistance - nylons, however, have better impact and abrasion resistance. It is rarely used without modifications: most often filled with glass fiber, flame retardant additives or blended with PTFE or PU. The last, POM/PU blend, has good toughness. POM is used where requirements for good moldability, fatigue resistance and stiffness justify its high price relative to mass polymers, like polyethylene, which are polymerized from cheaper raw materials using lower energy input.

Composition (summary)

(CH2-O)n

General properties

Density	1.41e3	kg/m^3
Price	* 3.1	USD/kg

Mechanical properties

Young's modulus	3.54	GPa
Yield strength (elastic limit)	59.3	MPa
Tensile strength	73.3	MPa
Elongation	27.4	% strain
Hardness - Vickers	19	HV
Fatigue strength at 10^7 cycles	* 27.4	MPa
Fracture toughness	2.68	MPa.m^0.5

Thermal properties

Melting point	445	K
Maximum service temperature	360	K
Thermal conductor or insulator?	Good insulator	
Thermal conductivity	0.278	W/m.°C
Specific heat capacity	1.4e3	J/kg.°C
Thermal expansion coefficient	124	µstrain/°C

Electrical properties

Electrical conductor or insulator?	Good insulator

Optical properties

Transparency	Opaque

Eco properties

Embodied energy, primary production	* 89.8	MJ/kg
CO2 footprint, primary production	* 4.05	kg/kg
Recycle	✓	

Recycle mark

Polymers >

Organisation Details

Company name

DuPont Engineering Polymers

Website http://www.plastics.dupont.com

Materials and tradenames

Crastin® PBT polyester resin
Sorona® EP thermoplastic polymer
Delrin® acetal resin
Vespel® polyimide parts and shapes
Elvamide® nylon multipolymer resin
Zytel® HTN high performance polyamide
DuPont™ ETPV engineering thermoplastic vulcanizate
Zytel® PA nylon resin
Hytrel® TPC-ET thermoplastic polyester elastomer
Zytel® PLUS nylon resin
Minlon® mineral reinforced nylon resin
Zytel® RS renewably sourced nylon resin
Rynite® PET polyester resin

Other notes

Operating in more approximately 80 countries, DuPont offers a wide range of innovative products and services for markets including agriculture, nutrition, electronics, communications, safety and protection, home and construction, transportation and apparel.

Producer status	Active
Information confirmation date	3/23/2012

Links

MaterialUniverse ...

No warranty is given for the accuracy of this data

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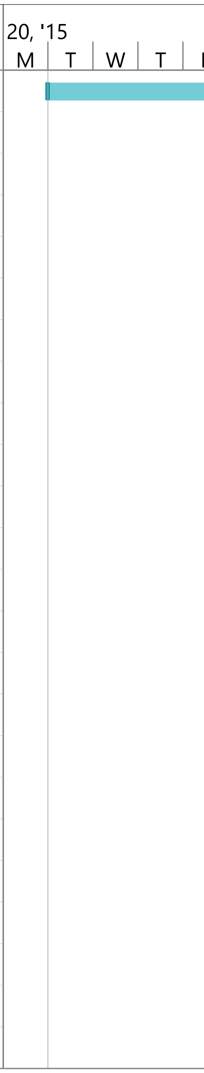
Appendix F: Supporting Analysis

Buckling evaluation of stainless steel pylon.

Parameter	Meaning	Value	Units	Justification
	Universal Constants			
pi	Pi	3.14	[N/A]	N/A
g	Gravitational Constant	9.81	[m^2/s]	N/A
	Material Selection			
rho	Density of Material	7700	[kg/m^3]	Aluminum
m	Mass of Shaft	2.050441312	[kg]	Aluminum
E	Young's Modulus	190000000	[Pa]	Aluminum
	Geometry			
d_out	Outer Diameter of Shaft	0.033	[m]	http://www.mcmaster.com/#4561t311/=10ww5r7
d_in	Inner Diameter of Shaft	0.028	[m]	
A	Cross-sectional Area	2.66E-04	[m]	N/A
l	Length	0.08	[m]	
I	Moment of Inertia	1.74E-04	[kg*m^2]	Cylinder
C	End-Condition Constants for Euler Columns	1.2	[N/A]	Table 4-2; Recommended; Fixed-Fixed
	Patient Population			
m_max	Maximum Mass of Patient	70	[kg]	
w_max	Maximum Weight of Patient	686.7	[N]	N/A
P_max	Body Force Under Dynamic Loading	1373.4	[N]	
	Evaluation Parameters			
P_cr	Critical Load	6.11E+07	[N]	
P_load		1373.4		
n	Engineering Safety Factor	44472.49	[N/N]	

Appendix G: Gantt Chart

ID	Task Name	Duration	Start	Finish	Predecessors
1	Project Preference	4 days	Tue 9/22/15	Fri 9/25/15	
2	Meet Team	2 days	Mon 9/28/15	Tue 9/29/15	1
3	Team Intro Letter to Sponsor	4 days	Mon 9/28/15	Thu 10/1/15	1
4	Team Contract	12 days	Mon 9/28/15	Tue 10/13/15	1
5	Define User Needs	7 days	Wed 9/30/15	Thu 10/8/15	2
6	Develop Performance Requirements	5 days	Fri 10/9/15	Thu 10/15/15	5
7	Brainstorm	2 days	Fri 10/16/15	Mon 10/19/15	6
8	Decision Matrix	1 day	Tue 10/20/15	Tue 10/20/15	7
9	Project Requirements Document	3 days	Wed 10/21/15	Fri 10/23/15	8
10	CP Connect	17 days	Mon 10/26/15	Tue 11/17/15	3,4,9
11	Travel Documents	17 days	Fri 10/2/15	Mon 10/26/15	3
12	List of Technical Functional Requirements	7 days	Wed 10/21/15	Thu 10/29/15	8
13	Conceptual Prototyping Supplies	3 days	Fri 10/30/15	Tue 11/3/15	12
14	Initial Solidworks model	3 days	Wed 11/4/15	Fri 11/6/15	13
15	Conceptual Model	7 days	Wed 11/4/15	Thu 11/12/15	13
16	Pugh Matrix	3 days	Fri 11/13/15	Tue 11/17/15	15
17	Project Schedule	1 day?	Tue 11/24/15	Tue 11/24/15	
18	Heat Transfer Calculations	14 days	Wed 11/18/15	Sat 12/5/15	
19	Basic Heat Transfer FEA	7 days	Mon 12/7/15	Tue 12/15/15	18
20	Conceptual Design Review Slides	12 days	Wed 11/18/15	Thu 12/3/15	16
21	Conceptual Design Report	2 days	Fri 12/4/15	Mon 12/7/15	20
22	Reflection Memo on Team Dynamic	25 days	Fri 12/11/15	Thu 1/14/16	21
23	Critical Design Review Presentation	42 days	Mon 12/7/15	Tue 2/2/16	21
24	Critical Design Review Report	5 days	Wed 2/3/16	Tue 2/9/16	23



Project: Gantt Chart
Date: Mon 11/23/15

Task	▬	Inactive Summary	┌─┐	External Tasks
Split	┈	Manual Task	▬	External Milestone
Milestone	◆	Duration-only	▬	Deadline
Summary	┌─┐	Manual Summary Rollup	▬	Progress
Project Summary	┌─┐	Manual Summary	┌─┐	Manual Progress
Inactive Task	▭	Start-only	[	
Inactive Milestone	◇	Finish-only	]	

ID	Task Name	Duration	Start	Finish	Predecessors	20, '15 M T W T
25	Initial Prototype	4 days	Wed 2/10/16	Mon 2/15/16	24	
26	Redesign	1 day	Tue 2/16/16	Tue 2/16/16	25	
27	Evaluation of Socket	3 days	Wed 2/17/16	Fri 2/19/16	26	
28	Evaluation of Foot	3 days	Mon 2/22/16	Wed 2/24/16	27	
29	Modification of Redesign Based on Redesign	3 days	Thu 2/25/16	Mon 2/29/16	28	
30	Ethics Case Studies Presentations	2 days	Mon 2/29/16	Tue 3/1/16		
31	Purchase New Supplies	3 days	Tue 3/1/16	Thu 3/3/16	29	
32	Build Second Prototype	4 days	Fri 3/4/16	Wed 3/9/16	31	
33	Evaluation of Redesign	1 day	Thu 3/10/16	Thu 3/10/16	32	
34	Project Update Memo to Sponsor	1 day	Fri 3/11/16	Fri 3/11/16	33	
35	Manufacutring Process Definition	2 days	Fri 3/11/16	Mon 3/14/16	33	
36	Drawing with Tolerances	3 days	Tue 3/15/16	Thu 3/17/16	35	
37	BOM Redevelopment	3 days	Tue 3/15/16	Thu 3/17/16	35	
38	Final Redesign	3 days	Fri 3/18/16	Tue 3/22/16	37	
39	Patent Disclosure	8 days	Wed 3/23/16	Fri 4/1/16	38	
40	Client Reflection	8 days	Wed 3/23/16	Fri 4/1/16	38	
41	Hardware and Software Review	4 days	Mon 4/4/16	Thu 4/7/16	39	
42	Purchase Final Materials	10 days	Fri 4/8/16	Thu 4/21/16	41	
43	Report to Sponsors	1 day	Fri 4/22/16	Fri 4/22/16	42	
44	Self-Directed Reflection	2 days	Mon 4/25/16	Tue 4/26/16	43	
45	Complete Fabrication Process	10 days	Wed 4/27/16	Tue 5/10/16	44	
46	Assembly of Complete System	5 days	Wed 5/11/16	Tue 5/17/16	45	
47	Test System Against Functional Requirements	5 days	Wed 5/18/16	Tue 5/24/16	46	
48	Evaluate Results	1 day	Wed 5/25/16	Wed 5/25/16	47	

Project: Gantt Chart
Date: Mon 11/23/15

Task	▬	Inactive Summary	┌─┐	External Tasks
Split	┈	Manual Task	▬	External Milestone
Milestone	◆	Duration-only	▬	Deadline
Summary	┌─┐	Manual Summary Rollup	▬	Progress
Project Summary	┌─┐	Manual Summary	┌─┐	Manual Progress
Inactive Task	▭	Start-only	[	
Inactive Milestone	◇	Finish-only	]	

ID	Task Name	Duration	Start	Finish	Predecessors	20, '15 M T W T
49	Report to DR Metta	1 day	Thu 5/26/16	Thu 5/26/16	48	
50	Senior Design Expo	2 days	Thu 5/26/16	Fri 5/27/16	48	
51	Final Project Report	6 days	Thu 5/26/16	Thu 6/2/16	48	
52	Design Log Submission	6 days	Fri 5/27/16	Fri 6/3/16	49	

Project: Gantt Chart
Date: Mon 11/23/15

Task	▬	Inactive Summary	┌─┐	External Tasks
Split	┈	Manual Task	▬	External Milestone
Milestone	◆	Duration-only	▬	Deadline
Summary	┌─┐	Manual Summary Rollup	▬	Progress
Project Summary	┌─┐	Manual Summary	┌─┐	Manual Progress
Inactive Task	▭	Start-only	[	
Inactive Milestone	◇	Finish-only	]	

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Appendix H: Safety Checklist

SENIOR PROJECT CRITICAL DESIGN REVIEW HAZARD IDENTIFICATION CHECKLIST

Y	N	
☐	☒	Do any parts of the design create hazardous revolving, reciprocating, running, shearing, punching, pressing, squeezing, drawing, cutting, rolling, mixing or similar action, including pinch points and sheer points adequately guarded?
☐	☒	Does any part of the design undergo high accelerations/decelerations that are exposed to the user?
☐	☒	Does the system have any large moving masses or large forces that can contact the user?
☐	☒	Does the system produce a projectile?
☒	☐	Can the system to fall under gravity creating injury?
☐	☒	Is the user exposed to overhanging weights as part of the design?
☐	☒	Does the system have any sharp edges exposed?
☐	☒	Are there an ungrounded electrical systems in the design?
☐	☒	Are there any large capacity batteries or electrical voltage in the system above 40 V either AC or DC?
☐	☒	Is there be any stored energy in the system such as batteries, flywheels, hanging weights or pressurized fluids when the system is either on or off?
☐	☒	Is there any explosive or flammable liquids, gases, dust, or fuel part of the system?
☐	☒	Is the user of the design required to exert any abnormal effort and/or assume an abnormal physical posture during the use of the design?
☒	☐	Is there be any materials known to be hazardous to humans involved in either the design or the manufacturing of the design?
☐	☒	Will the system generate high levels of noise?
☒	☐	Will the product be subjected to extreme environmental conditions such as fog, humidity, cold, high temperatures, etc. that could create an unsafe condition?
☒	☐	Is it easy to use the system unsafely?
☐	☒	Is there be any other potential hazards not listed above? If yes, please explain on the back of this checklist?

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Appendix I: Engineering Specifications and Testing Verification

Spec. #	Parameter Description	Requirement	Risk	Compliance	Justification	Testing Method
1	Strength (ability to support body weight)	280 kg	L	T	The weight selected is based off of the average weight of adults in Mozambique.	Tensile tester
2	Weight	< 5 kg	L	T	The weight selected is based off of the typical below-the-knee prosthesis on the market. This small of a weight should not be negatively impactful to proper gait.	Scale
3	Eversion Inversion	5° 5°	H	A,T,I,S	The article by Neumann outlines the typical abilities of the human ankle. As this team intends to restore function as closely as possible to the patient, creating components that are as close as possible to the original leg is desired.	Protractor
4	Dorsiflexion Plantarflexion	10° 0°	H	A,T,I,S	The article by Neumann outlines the typical abilities of the human ankle. As this team intends to restore nearly full function to the patient, creating components that are as close as possible to the original leg is desired.	Protractor
5	**High Safety Factor**	2:1 Design Factor	M	A	The data collected in the Kahtan article use the assumption of western norms for bipedal locomotion (i.e. flat and hard surfaces, ambient temperatures, low moisture exposure, etc...). The designed leg will be used is much more rugged applications and thus will require an integrated factor of safety.	Self-evident
6	**Low Prototype Cost**	< $100	H	A,S	As desired by our sponsors, the device is required to be low-cost. The baseline price of $50 is taken from the industry standard, the Jaipur foot.	Self-evident
7	Force Necessary to Remove Limb From Socket	>600N	M	A,T,I	The prosthesis needs to securely be attached to the residual limb. The Kahtan article describes forces experienced in the z-direction. The requirement is set with a factor of safety of 2.25 while looking at the force the leg experiences if it gets stuck to the ground during the Gait cycle.	Tensile Tester
8	Socket Pressure	Evenly Distributed	H	S,I,A	Forces from the socket should be evenly distributed along the residual limb. Lack of pressure in one area may cause pistoning or disassociation.	Force Transducers
9	Heat Transfer Rate Socket Materials	<49 °C	H	A,I,S	Heat conductivity should remain as constant as possible to prevent large changes in temperature	Thermocouple Map
10	Extendable Pylon	Between .5in to 6in	M	I,T	The requirement was found using the typical lengths of the shin, the possible lengths of the residual limb, and how tall the Jaipur Foot design's foot is.	Ruler
11	Adjustable Socket (Increase/Decrease Socket)	Between -11% and 7%	H	T,I,A	While socket should maintain equal pressure while in contact with residual limb, there should exist a mechanism that allows minor adjustments of the limb while donning to allow for maximum comfort.	Balloon inflation
12	Time To Fit the Leg	<24 hours	H	T,A	Time to fit and manufacture should be short so as to allow as many patients to be treated per day	Timer
13	Angular Adjustment	+/- 30° in sagittal and frontal planes	H	T		

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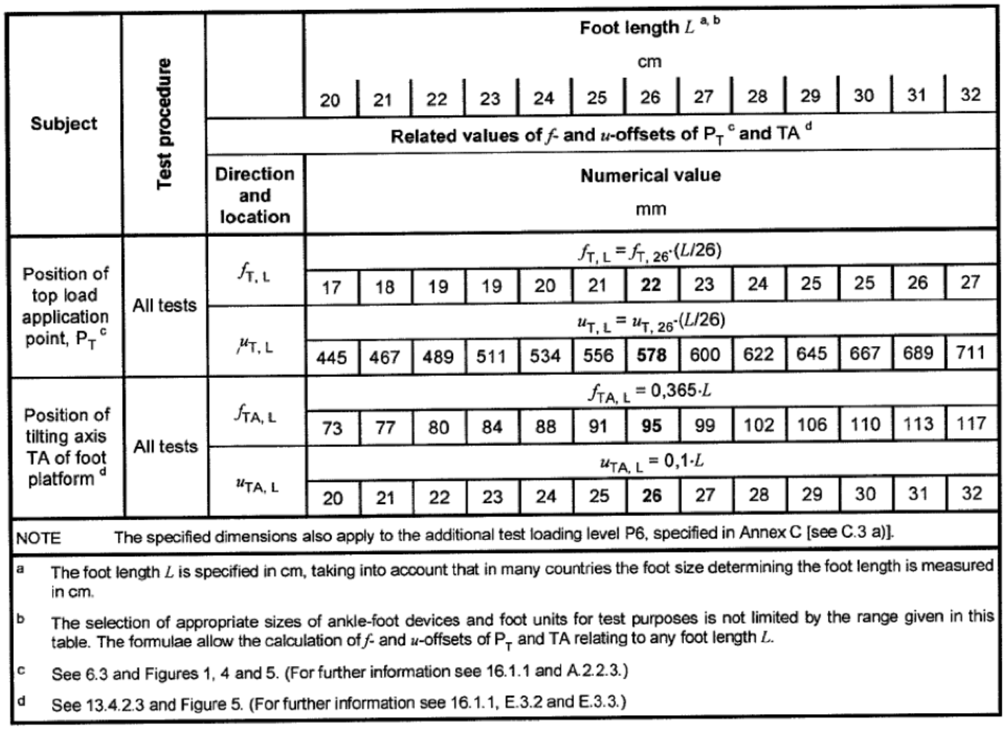
Appendix J: Applicable Standards for Evaluation



Subject	Test procedure		Foot length L [a, b] cm												
			20	21	22	23	24	25	26	27	28	29	30	31	32
			Related values of f- and u-offsets of P_T [c] and TA [d]												
		Direction and location	Numerical value mm												
Position of top load application point, P_T [c]	All tests	$f_{T,\,L}$	$f_{T,\,L} = f_{T,\,26} \cdot (L/26)$												
			17	18	19	19	20	21	**22**	23	24	25	25	26	27
		$u_{T,\,L}$	$u_{T,\,L} = u_{T,\,26} \cdot (L/26)$												
			445	467	489	511	534	556	**578**	600	622	645	667	689	711
Position of tilting axis TA of foot platform [d]	All tests	$f_{TA,\,L}$	$f_{TA,\,L} = 0{,}365 \cdot L$												
			73	77	80	84	88	91	**95**	99	102	106	110	113	117
		$u_{TA,\,L}$	$u_{TA,\,L} = 0{,}1 \cdot L$												
			20	21	22	23	24	25	**26**	27	28	29	30	31	32

NOTE The specified dimensions also apply to the additional test loading level P6, specified in Annex C [see C.3 a)].

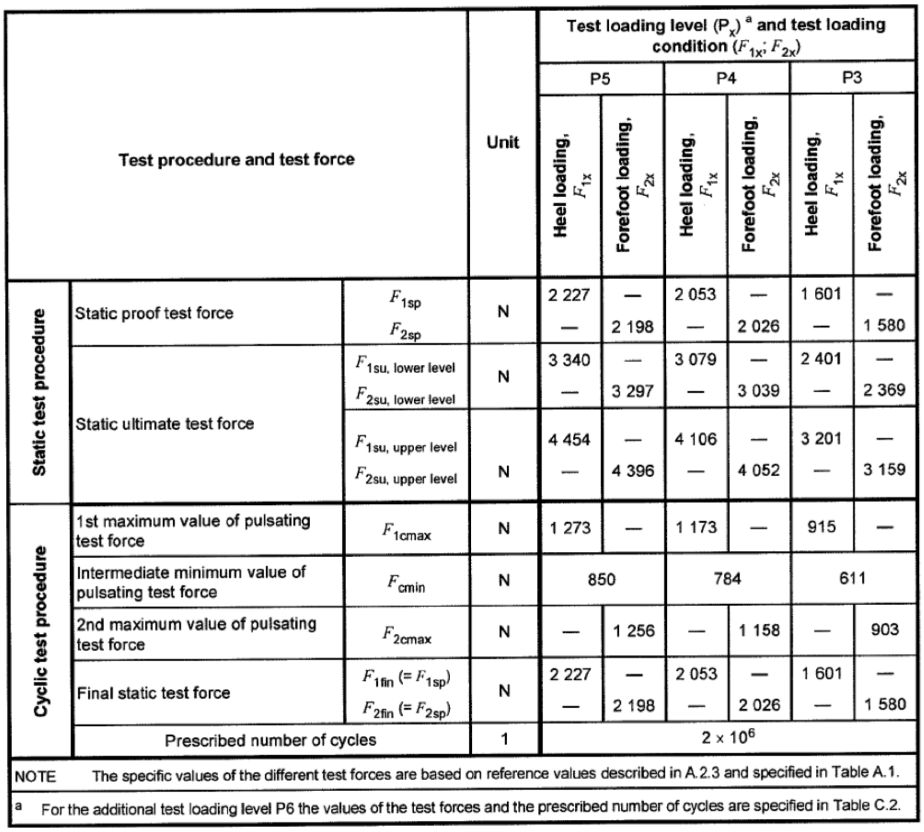
[a] The foot length L is specified in cm, taking into account that in many countries the foot size determining the foot length is measured in cm.

[b] The selection of appropriate sizes of ankle-foot devices and foot units for test purposes is not limited by the range given in this table. The formulae allow the calculation of f- and u-offsets of P_T and TA relating to any foot length L.

[c] See 6.3 and Figures 1, 4 and 5. (For further information see 16.1.1 and A.2.2.3.)

[d] See 13.4.2.3 and Figure 5. (For further information see 16.1.1, E.3.2 and E.3.3.)

Table J1: ISO 22675 table showing the position of load on the foot



Test procedure and test force			Unit	Test loading level (P_x) [a] and test loading condition (F_{1x}; F_{2x})					
				P5		P4		P3	
				Heel loading, F_{1x}	Forefoot loading, F_{2x}	Heel loading, F_{1x}	Forefoot loading, F_{2x}	Heel loading, F_{1x}	Forefoot loading, F_{2x}
Static test procedure	Static proof test force	F_{1sp}	N	2 227	—	2 053	—	1 601	—
		F_{2sp}		—	2 198	—	2 026	—	1 580
	Static ultimate test force	$F_{1su,\ lower\ level}$	N	3 340	—	3 079	—	2 401	—
		$F_{2su,\ lower\ level}$		—	3 297	—	3 039	—	2 369
		$F_{1su,\ upper\ level}$		4 454	—	4 106	—	3 201	—
		$F_{2su,\ upper\ level}$	N	—	4 396	—	4 052	—	3 159
Cyclic test procedure	1st maximum value of pulsating test force	F_{1cmax}	N	1 273	—	1 173	—	915	—
	Intermediate minimum value of pulsating test force	F_{cmin}	N	850		784		611	
	2nd maximum value of pulsating test force	F_{2cmax}	N	—	1 256	—	1 158	—	903
	Final static test force	F_{1fin} (= F_{1sp})	N	2 227	—	2 053	—	1 601	—
		F_{2fin} (= F_{2sp})		—	2 198	—	2 026	—	1 580
	Prescribed number of cycles		1	2×10^6					

NOTE The specific values of the different test forces are based on reference values described in A.2.3 and specified in Table A.1.

[a] For the additional test loading level P6 the values of the test forces and the prescribed number of cycles are specified in Table C.2.

Table J2: ISO 22675 table showing the required test force