Course: ME428/429/430 – Section #3

Design and Testing of a Low Cost Prosthetic Foot

Final Design Report

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Nomenclature

Ankle adapter: a component that allows a prosthesis to be attached to the pylon.

Anterior/posterior: Towards the front / rear of the body.

Crepe: See Vulcrepe

Delrin: A durable and easily-machined thermoplastic.

Engineering World Health: An organization that promotes international humanitarian projects.

Gait: A manner of walking. Includes rhythm , body position, and weight transfer.

ICRC: International Committee of the Red Cross

ISO: International Organization for Standardization (acronym based in French)

Modular: Prosthesis attachment system that uses an inverted pyramid ankle adapter. Very strong and common design.

Otto Bock: Prosthetics company.

Pe-lite: a lightweight and durable foam compound.

Physiological: of or relating to living systems.

Poly Stack Foot: the prosthetic foot developed in this senior project.

Prosthetic: Relating to artificial body parts.

Prosthesis: An artificial body part.

Pylon: Prosthetic component whose biological parallel is the tibia.

Quasi-static: Describes a system that does not move freely, but rather in defined intervals.

Roll-over test: A test performed on a prosthetic foot to characterize its resemblance to biological feet.

Roll-over shape: The quantitative product of a roll-over test. Indicates the location of the center of pressure on the foot relative to a fixed point on the ankle.

Shank: the lower part of the leg.

Stance: the phase of a step in which the mass of the body is over the foot and the leg is more or less vertical.

Trias: A prosthetic foot produced by the Otto Bock company.

Vida Nueva: A prosthetics clinic in Choluteca, Honduras.

Vulcrepe: A vulcanized rubber compound.

Abstract

This report, prepared for Dr. Mohammad Noori, describes the concept design of a low-cost prosthetic foot intended for distribution in developing nations. Working from literature on the subject, we describe the need for this product in the third world. We then discuss the specifications and requirements of the prosthesis, and the proposed design in its current form. The prototype will be implemented in a rural Latin American clinic, at which time we will be able to better assess its applicability to wide-scale use in underdeveloped countries.

Chapter 1: Introduction

1.1 Sponsor Background

The Vida Nueva prosthetic clinic in Choluteca, Honduras, services patients who have lost limbs as a result of war, natural disasters, poor health, diabetes, and accidents. According to Program Director Reina Estrada, Vida Nueva is the sole service provider for the entire southern region of Honduras. Land mine accidents are rare, though they continue to be discovered sporadically. More typical for Vida Nueva are patients who have lost a limb from an accident incurred while attempting to jump aboard a moving train.[2]

1.2 Problem Definition

Because of its location, the Vida Nueva clinic has limited access to quality prostheses for its patients. This clinic, whose patients need durable and effective prostheses to be able to remain employed and support their families, would benefit greatly from the implementation of a low-cost foot prosthesis which can be manufactured on-site within a matter of hours. Because aesthetics are culturally important to the clinic's patients, this prosthesis should also fit within a locally available cosmetic shell with the appearance of a human foot. Our senior project seeks to fill this need by providing Vida Nueva with the design of a new prosthetic foot which meets both the professional requirements of the clinic and the individual requirements of each patient.

1.3 Objective/Specification Development

Data on prosthetics patients in underdeveloped countries can be difficult to obtain, especially when the patients live largely in rural environments. Studies show that there can be large discrepancies in patient care, even between nearby regions of the same country. Even in countries where government health care does exist, the government will frequently choose to provide more support to citizens in economically vital regions, and less to citizens in more rural or less crucial regions[3]. Programs such as ours have the capability to fit in where the government does not operate, and improve patient care at local clinics.

The objective of the Piernas de Vida project is to develop and implement a low-cost, easily-manufactured prosthetic foot for distribution by facilities like the Vida Nueva clinic in Choluteca, Honduras. The project was initiated in the fall of 2010 and is currently undergoing its second iteration, with the ultimate goal of having a working prototype ready for extended patient testing by the end of May 2012. Several organizations have made great headway in reducing the production cost of foot prostheses, as well as effectively simulating physiological function. The shortcoming that permeates even the most successful of these projects, however, is the complex geometry of their products. As a result of their complicated forms, many prostheses require advanced manufacturing processes. Because of this, production is often highly centralized, dramatically limiting access to these devices. With limited means of acquiring prostheses, clinics located in rural areas find themselves in need of a product with which to support local amputee populations.

In order to accommodate the financial and physical limitations of the Vida Nueva clinic, it is essential that the clinic be able to independently acquire the materials for the prosthesis, manufacture it, fit it to the patient, and adjust it throughout its life. Everything from the design of the foot to the materials used to fabricate it will be geared to achieve this end. Ideally, the project will be completed when any clinic with basic manufacturing capabilities can create our prosthesis on-site while the patient waits. Furthermore, we hope to keep the production process simple enough to allow the patient to take part, further reducing labor cost and familiarizing the user with the device.

With the intention of meeting the spring deadline for implementation, three milestones must be realized. The first is the adaptation of the current Layer Foot to fit the cosmetic cover available to the Vida Nueva clinic. This will lower the foot's profile and allow it to function inside a shoe, reducing wear and material deterioration. The second milestone is a series of tests on the prosthesis, both with and without the cover, in order to further characterize its performance. Fatigue testing and rollover testing will be chief among these. The Piernas de Vida team will be working in cooperation with the Engineering World Health club to construct a test rig in order to perform a roll over test without the assistance of human subjects. The third milestone is the development of a business strategy, in conjunction with the prosthesis, with the aim of distributing the foot to a broader and more disparate patient base. It is expected that, through the feedback and insight provided by Vida Nueva personnel, the team will construct a business model that is widely applicable and can be utilized by clinics all over the world.

Specifications

- Fits snugly and securely inside both the Otto Bock cosmetic cover and the Pelite cover manufactured on-site.
- Made of Delrin plastic (aka: polyoxymethylene)
- Design only utilizes shapes easily made with only a jig saw, drill press, grinder, and basic hand-held tools
- Foot design lasts for 3 years, by analysis
- Works with the prosthetic leg components currently used by Vida Nueva, ICRC and modular adapter.

- Materials cost less than $30
- Manufacturing time less than 3 hours

1.4 Project Management

The Piernas de Vida team consisted of two mechanical engineering students, John and Shalan, and one biomedical engineering student, Seija. To ensure project success, tasks were assigned and a schedule was made, the Gantt chart can be found in Appendix F. Research, brainstorming, concept selection, and manufacturing were areas that each member contributed to equally. The rest of the tasks were divided as follows:

Shalan: team coordinator, external communication, material procurement, manufacturing lead

John: analysis, technical writing, CAD modeling, ISO testing

Seija: quasi-static rig testing, Spanish communication, biomedical reference

Chapter 2: Background

2.1 Existing Products

There is an incredible amount of technological variety in the modern field of prosthetics. This variety stems from the many different goals which prostheses are designed to accomplish. Some prostheses are created to give the best appearance of physiological limbs; others are created to provide the best functionality at day-to-day tasks. Because of the high dependence of form on the specificity and type of design goals, each prosthesis design on the market occupies a different niche. In our study, we will focus on foot prostheses which are designed with cost, performance, and durability as the three most important factors.

Successful prostheses which aim to reduce production cost while maximizing performance generally rely on the elasticity of their component materials to provide a “spring,” which approximates the stride of a physiological foot. One effective way to characterize a synthetic foot’s similarity to a real foot is the roll-over shape test, which locates the center of pressure relative to the ankle throughout a stride. Plotting the location throughout a step shows a multiple-order curve, and the best prosthetic feet are the ones have curves with shapes similar to the physiological case. The roll-over shape test process is discussed in depth in the Procedure section.

Examples of prostheses which deform to simulate a true foot include the Niagara Foot, the Shape & Roll Foot, and, to some extent, the Jaipur Foot.[10] Although not as spring-like as the others, the Jaipur Foot has achieved great success in India because it is manufactured with a compression mold that encases the mechanical foot in vulcanized rubber, shaped like a human foot. This high-durability cosmetic foot allows the user to wear sandals and kneel to pray – important cultural activities in many regions.

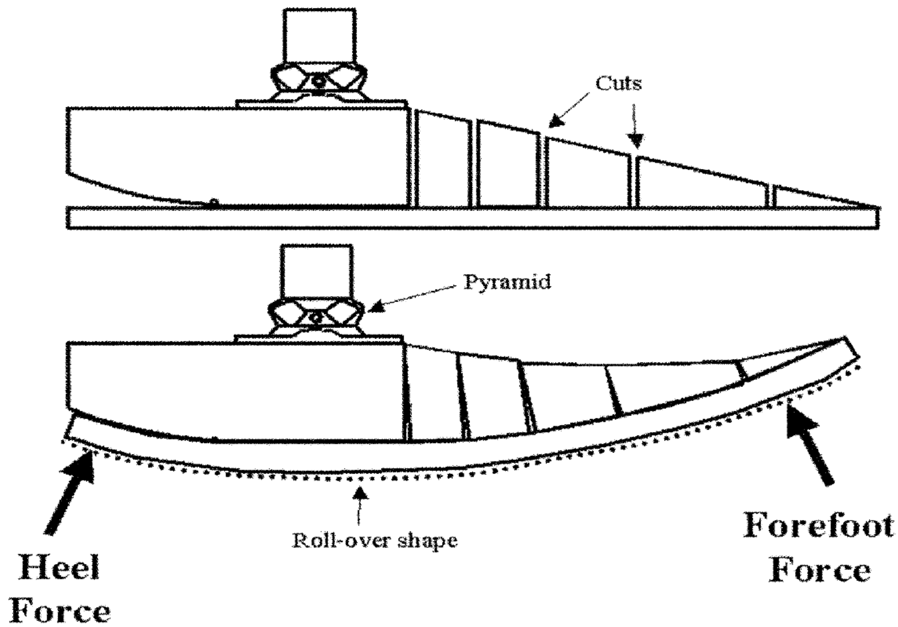
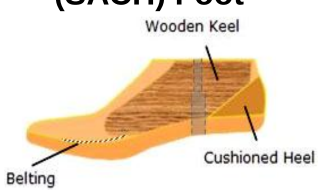
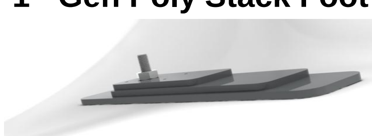


Figure 1. The Shape and Roll Foot, which produces a good approximation of the step of a physiological foot.[8]

The Solid Ankle, Cushion Heel Foot, or SACH Foot, is a very common prosthesis model in the developing world. It consists of a shaped wooden core, surrounded by cosmetic foam. Although it is rigid and does not provide the elastic gait of other prostheses, it has become popular because it is cheap, durable, lightweight, and provides a supple platform during the “heel-strike” phase of a patient’s gait. Currently, the Vida Nueva clinic implements the SACH foot, but it is seeking for a better design. The primary drawbacks of the SACH Foot for the Vida Nueva clinic are that its outer polyurethane coating has been observed to deteriorate rapidly in the humid Honduran climate, and the foot cannot be produced on-site in the Vida Nueva clinic.

Last year, the students of the Piernas de Vida project set out to design a foot that could provide elastic support to simulate the natural gait of the patient, withstand the natural conditions of Choluteca, Honduras, be produced on-site with as little manufacturing equipment and expertise as possible, and which minimized material and production costs. They created the Poly Stack Layer Foot, which utilizes layers of Delrin plastic to simulate the feel of walking naturally. It can be manufactured easily, the material is resistant to wear and humid climates, and the production cost is estimated at just under US $20.[2]

Table 1. Survey of competing prosthetic feet along with estimated costs.

Prosthesis	Approximate Cost	Functionality
Niagara Foot[11] 	$35	• Flexes to simulate human foot. • Requires advanced shaping and molding techniques to produce. • Cosmetic cover available (extra cost).
Jaipur Foot[4] 	$35	• Rigid foot with flexible ankle that allows squatting, walking on uneven ground, sitting cross-legged, and kneeling. • Kneeling function allows patient to pray and participate in other culturally important activities. • 3 year lifespan. • Uses vulcanized rubber mold – requires complex manufacturing processes. Cannot be produced on-site.
Solid Ankle, Cushioned Heel (SACH) Foot[11] 	$5	• Rigid aside from heel area. • Red Cross standard prosthesis. • Cover deteriorates in humid climate. • Requires frequent replacement.
Flex-Foot 	Wide range. Dependent on patient location, type of foot, and provider.	• Flexes to simulate human foot. • Uses advanced composite materials such as carbon fiber to achieve high performance. • Requires expensive manufacturing processes. • Cosmetic cover available (extra cost).
1st Gen Poly Stack Foot 	$17.70	• Flexes to simulate human foot. • No cosmetic cover. • The only foot which can be produced on-site, minimizing wait time and transportation cost and guaranteeing availability.

Chapter 3: Design Development

3.1 Conceptual Designs

The starting point of this design development was the first generation of the Poly Stack Foot, seen in Figure 2. This foot consists of pyramidal layers of Delrin plastic, stacked upon each other, which allow material deflection and a comfortable feel at the heel and toe while providing stability when the foot rests flat on the ground. Most of our designs vary this concept to meet the project requirements and provide added comfort to the patient.

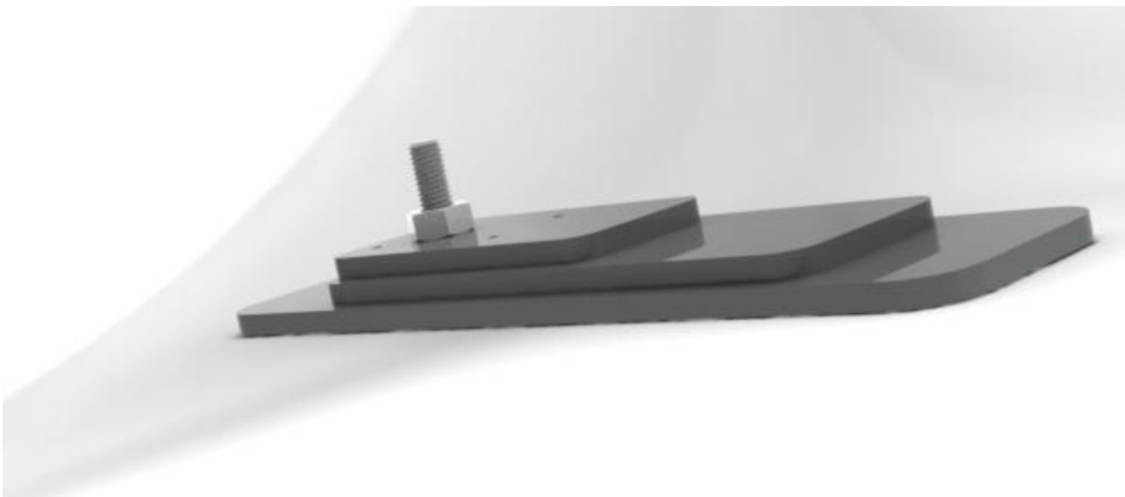


Figure 2. The first generation of the Poly Stack Foot.

During the first few months of the current school year, our project's objective was to create a prosthesis that could fit and operate within a shoe. We developed several designs with this objective in mind. Later, however, a conversation with the Vida Nueva clinic brought us to the realization that the clients put high value on the aesthetics of their prostheses, and would desire a prosthesis that fit one of several available rubber shells shaped like a human foot. Despite the obsolescence of these first design concepts, we include them because they shaped the evolution of our final design.

3.1.1 Designs to Fit a Shoe

When approaching the task of developing a design that fits in a shoe, three concepts were developed during brainstorming sessions.

The first idea was to create a mold of a foot and use that to reproduce covers. Only one mold would be needed to produce a standard cover, which could be easily filed down to whatever size was needed. It would be an easy repeatable process. However, this concept quickly became a manufacturing problem for a clinic with limited resources. Finding a material that is easy to mold and has good properties for a hot, humid climate is difficult enough. Creating a mold and process to shape this material is an even greater challenge. The next idea sought to fill that empty space, not with a solid but with air. If an air bladder were inserted into the shoe, along with the foot, then it could be inflated to eliminate any wiggle room, see Figure 2. This concept encountered manufacturing and durability issues as well. Making a durable, custom balloon would not be easy and recycling bicycle tires is impractical.

Finally, the third idea used no additional materials but simply altered the geometry of the foot. This concept attempts to address the shortcomings of the original Poly Stack by refining its shape to better fit a shoe while retaining its structural strengths. This concept required no additional materials, but did require more intricate machining work on the Delrin plastic. The intermediate horizontal plate was replaced by two vertical plates. This raised the top of the foot considerably and provides a contact surface against the area at the top of the shoe. Also, the profile of the bottom plate was modified to better fit a shoe.

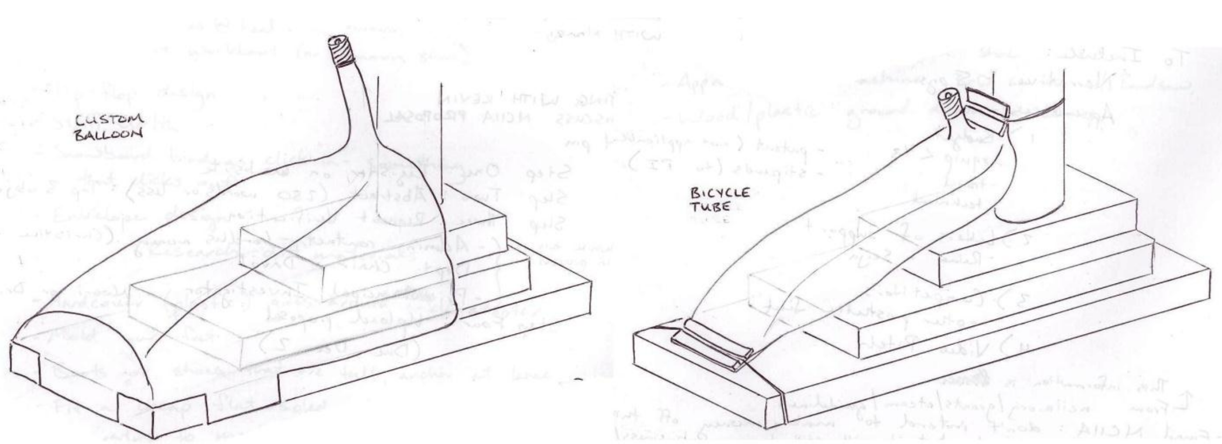


Figure 3. A schematic sketch of the air balloon concept.

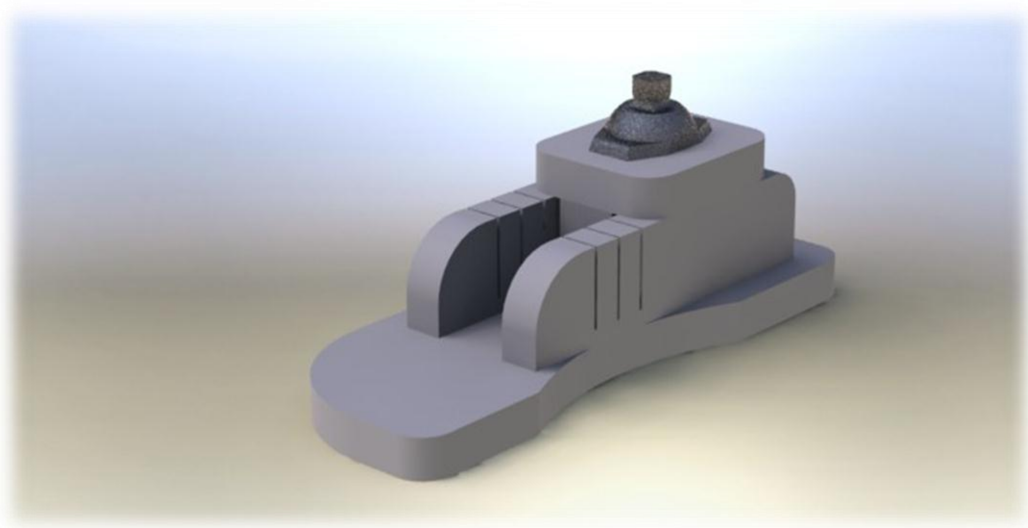


Figure 4. Isometric view of slotted intermediate layer concept.

3.1.2 Designs to Fit a Cosmetic Shell

There is considerably less room inside a cosmetic cover than inside a shoe. This limited the dimensions of foot as well as the shape. The contours of the design seen in Figure 4 would have prevented the Poly Stack from neatly fitting into a shell. The following concepts were developed to design a compact foot that would better suit Vida Nueva's needs.

One of the more important changes that were made to fit the cosmetic shell was the altered profile of the Delrin layers. The shell has a strictly defined interior space, and the Delrin layers took on much more complicated geometries in order to fit snugly and securely. The primary focus of the next round of conceptualization was to create designs which had the overall physical properties desired and could be inserted and fit snugly into the Otto Bock Trias shell. The Trias shell was selected because the Vida Nueva Clinic is capable of obtaining it more easily than other similar models, and because Vida Nueva clientele like its close resemblance to a real foot.

Soft Middle

In this design, the Poly Stack Foot is modified by the addition of several more complicated intermediate layers. These layers are made of the same Delrin, except in the posterior section, close to the heel of the prosthesis. There, the Delrin is replaced by Vulcrepe, a softer rubber material, which allows a smooth transition from heel impact to normal stance.

Hinge Design

This design is a drastic departure from the geometry of the Poly Stack foot. In it, a hinge attaches the horizontal lower Delrin layer to a slanted intermediate layer, propped up by a wedge of softer Vulcrepe. Screws hold the Vulcrepe wedge to the Delrin above and below it. The hinge allows the Vulcrepe to compress when a load is applied at the heel, softening the impact of the heel on the ground and providing a more comfortable transition into vertical stance for the patient.

Separated Lower

The “Separated Lower” design addresses a specific concern with the cosmetic shells: the interior surface of the cosmetic shell does not have a perfectly flat plane for the prosthesis to rest on. Instead, the toe and heel surface are parallel but distinct planes, and the toe surface is several millimeters lower than the heel surface. The Separated Layer design attempts to fit the shell better by dividing the Poly Stack Foot’s single lower Delrin layer into an anterior and a posterior section, with a gap between where the shell’s lower surface rises at the “arch” of the foot.

Wedge Platform

This is another modification to the original Poly Stack foot. In it, the entire Delrin foot rests at an angle, held up by a wedge of Vulcrepe at the heel of the shell. The horizontal layers, which rest at an angle, compress the Vulcrepe when the heel touches the ground.

3.2 Concept Selection

To select a best design, we generated a Pugh Matrix that evaluated the four designs based on their ability to fit the cosmetic shell, their durability, their ability to provide a natural heel strike feel to the patient, their ease of manufacture, and the simplicity of their interface with a standard ankle adapter. The Pugh Matrix is given in Appendix A.

Based on the results of the Pugh Matrix, we selected the Hinge and Soft Middle designs as the two with which we wanted to proceed forward. The Soft Middle design boasts significant advantages in that it is much simpler to manufacture and characterize. The Hinge design, while much more complicated from a manufacturing standpoint, has the greatest potential to soften the heel while keeping the stance and toe relatively stiff. The stiffness and abruptness of the heel was one of the greatest weaknesses of the first generation of the Poly Stack Foot, so these advantages are particularly interesting.

After manufacturing had begun, the Hinge design proved to have too many production problems. Securely attaching the wedge of Vulcrepe required a mechanism more complicated than could easily be replicated using the limited manufacturing capabilities of the Vida Nueva clinic. Furthermore, several hinges were tested, but all of them were too loose and allowed some unwanted lateral rotation in directions other than the hinge's primary axis. As a result, the layers which rested on the Vulcrepe wedge were unstable. Despite its potential, these flaws led to the dismissal of the Hinge design as a potential direction for the Poly Stack Foot.

3.3 Preliminary Analysis

The Matlab code produced in conjunction with the top concept (given in full in Appendix E) assumes that the intermediate layer of the foot, which is thick and has a large area moment of inertia, has negligible deformation. It models the toe and heel of the foot as cantilevered beams with a point load at the toe. These are very conservative assumptions – the intermediate layer will deform, distributing the load more evenly, and the center of pressure on the foot will not be at the furthest possible toe region. Because of this, the program underestimates the strength of the prosthesis, and provides results which are very capable of withstanding the stresses applied.

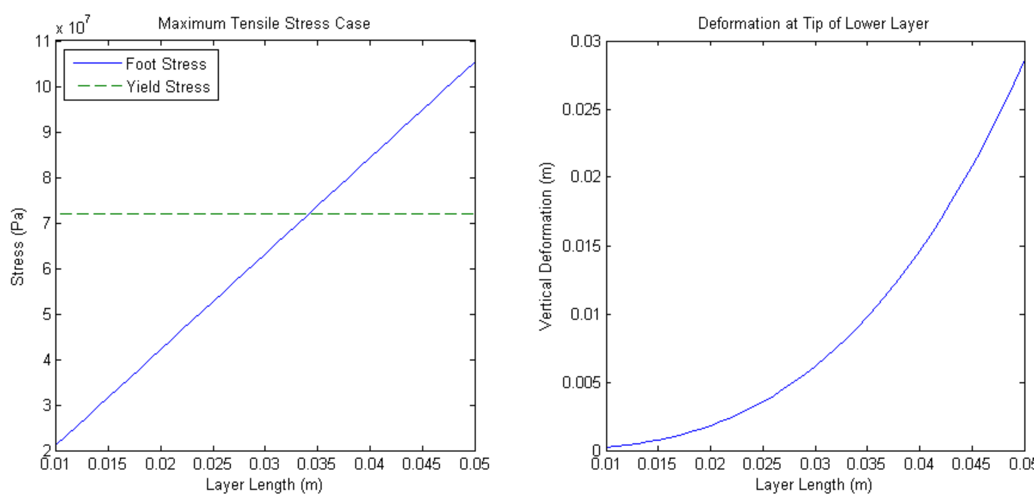


Figure 5. Maximum tensile stress and maximum toe deformation in the Poly Stack Foot for varying toe lengths.

Figure 6 gives the results of the Matlab code. The geometry of the lower layer has been simplified to a uniform width of 6 cm. The analysis suggests, as expected, that a very conservative layer length be used – the lower layer should stick out no more than

3.5 cm. This is problematic because the overall foot length is approximately 22 cm long, and the first generation of the Poly Stack Foot, created last year, has a lower layer which projects much longer than 3.5 cm in the front. Further calculations, provided in Appendix E, also demonstrate that the desired deformation requires a length of approximately 9 cm beyond the middle layers.

Because the geometry of the Poly Stack Foot is complicated, the layers deform to a great extent under everyday use, and their interaction is mathematically difficult to predict, this numerical analysis is of limited use. In particular, the deformation of the plastic is great enough that the assumption necessary to make the calculations – that of a cantilevered beam with small deformations and a point load at the end of the toe – is not valid. For this reason, it was a great deal more useful to ascertain the effectiveness of the design with testing than preliminary numerical analysis. For more information, see Chapter 5: Design Verification.

The Poly Stack Foot's fatigue life is difficult to predict because most fatigue analyses assume a fully reversed load is applied to the material. Over the course of a step, however, the critical region experiences only a tensile loading. This dramatically increases the fatigue life.

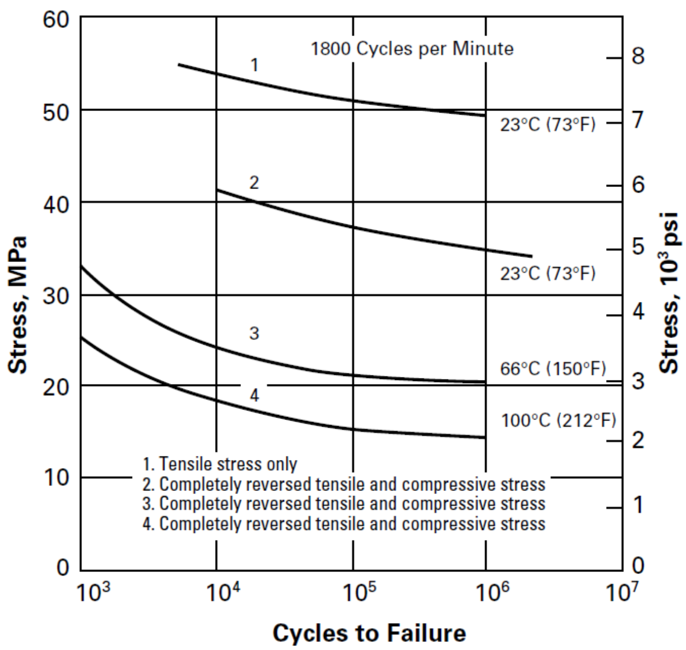


Figure 6. Delrin fatigue characteristics, published by DuPont.

Figure 9 illustrates the effects of solely tensile loading. The Poly Stack Foot should follow the behavior indicated by the first curve. This suggests that a maximum stress of 50 MPa will cause fatigue failure at around $2x10^5$ cycles, while a stress reduced to around 45 MPa can last up to 10^7 cycles. Estimates of the average person's habits suggest that most people take around 5,000 steps per day, while active people take up to 10,000 steps per day. A foot with a maximum tensile stress of 50 MPa, then, might last between 20 and 40 days, while a foot with a maximum tensile stress of 45 MPa could last between 3 and 6 years.

Chapter 4: Final Design

The final design fits in the Otto Bock Trias shell and has a performance comparable to existing prosthetic feet. Its prototype models have all passed the strongest standard level of ISO proof strength testing for ankle-foot devices, and it has been successfully used by two patients in a trial. It requires only a jigsaw, a drill press, and a small set of hand tools to produce. Its material cost is $15.68, and including labor its manufacturing cost is $45.68.

4.1 Overall Design Description

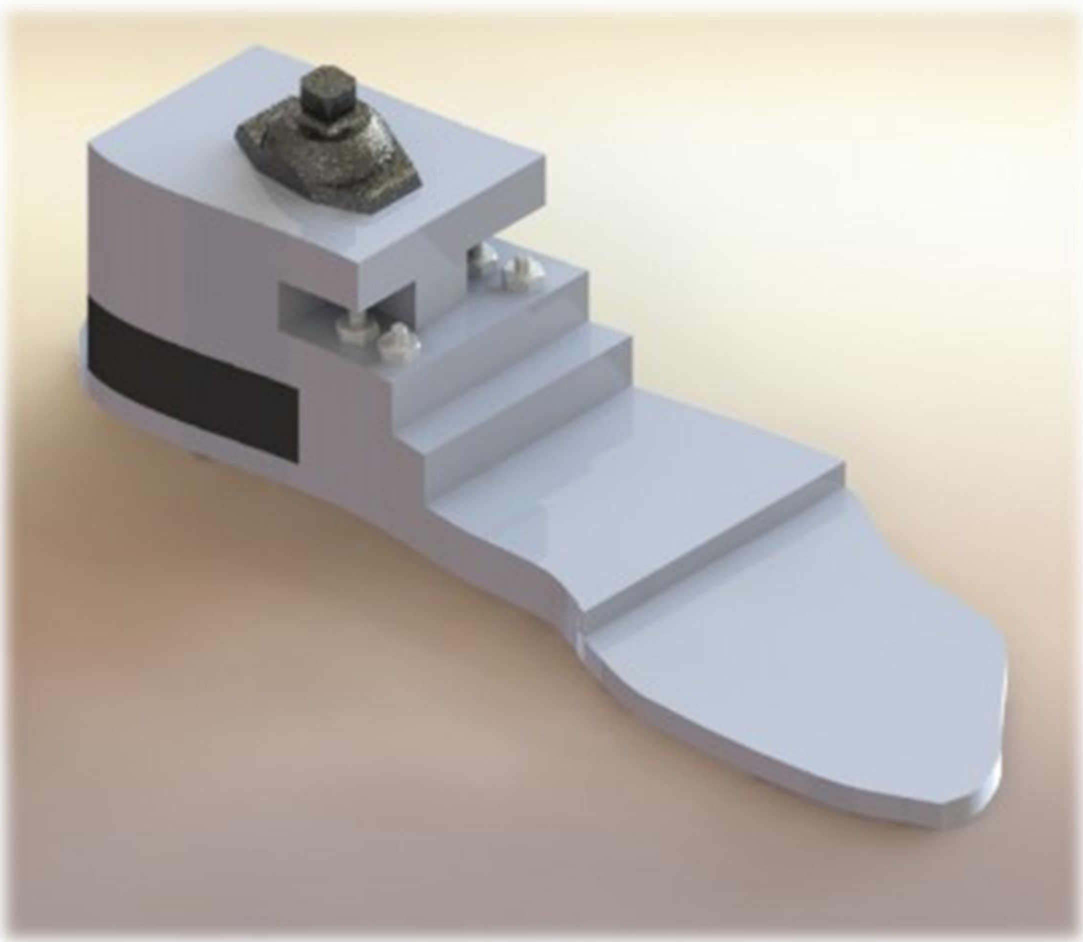


Figure 7. CAD-based model of the Soft Middle design concept. The gray color represents the layers of delrin sheet, while the black shape represents the softer Vulcrepe layer that allows the heel to deform upon contact with the ground.

The second generation of the Poly Stack Foot differs from its predecessor in several important aspects. It incorporates:

- A block of vulcanized rubber below the ankle adapter which softens the heel and creates a smoother transition from heel strike to stance during gait.

- More and thicker intermediate layers which raise the ankle adapter to the top of the cosmetic shell and allow the heel to deform more upon contact with the ground. This also gives the foot a comparable height to existing prostheses, eliminating the need for a longer pylon.

- Altered layer profiles which fit the interior cavity of the Otto Bock Trias cosmetic shell.

- A tailored heel shape in the lower layer of Delrin which fits snugly and securely into a heel pocket in the shell, locking the prosthesis into the shell for superior performance.

4.3 Material and Components

The primary material used in the Poly Stack foot is Delrin®, which is a self-lubricating thermoplastic made by DuPont™. It is durable and strong, but flexible enough to deform under the loads experienced by the Poly Stack Foot. Delrin® is relatively inexpensive and is available to the Vida Nueva clinic in Honduras.

The secondary material is Vulcrepe. This is a vulcanized rubber material often found in the midsoles of shoes. It is durable, relatively compressible, and cheap. The Delrin® provides the structure and support for the Poly Stack Foot, and the Vulcrepe provides a cushion for the heel-strike phase of gait.

The rest of the components consist of the fasteners used to hold the foot together. Four #6 X 2” bolts connect the Delrin® layers anterior to the ankle adapter. The Vulcrepe block is held in place by two slotted pins that pass through the rubber vertically and into the plastic above and below. Finally, an M10 socket-head bolt is used to attach the foot to a standard pyramid ankle adapter. This interface with the adapter is common among foot prostheses, and makes our foot compatible with most prosthetic legs in the world. For an assembly drawing of the Poly Stack Foot, see Appendix B.

4.4 Cost Analysis

Table 2. Cost Breakdown of Poly Stack Foot Materials. Manufacturing time is an estimate of the Vida Nueva technician's wage.

Material / Component	Quantity	Cost/ Quantity	Total Cost
0.25"-Thick Delrin® Sheet	0.25 ft^2	\$19.25 / ft^2	\$4.91
0.5"-Thick Delrin® Sheet	0.17 ft^2	\$38.5 / ft^2	\$6.40
0.25"-Thick Vulcrepe	0.047 ft^2	\$2.88 / ft^2	\$0.13
0.5"-Thick Vulcrepe	0.047 ft^2	\$4.88 / ft^2	\$0.23
#6 Bolt	4	\$0.09 /pc.	\$0.37
#10 Bolt	1	\$3.80 / pc.	\$3.80
Slotted Pin	2	\$0.10 / pc.	\$0.21
		TOTAL W/O LABOR	**\$15.68**
Manufacturing Time	2.5 hours	\$15/hr	\$37.50
		TOTAL W/ Labor	**\$53.18**

4.5 Manufacturing Process

The Poly Stack Foot is specifically designed with ease of manufacture in mind. To that end, it requires only the equipment which can be found at Vida Nueva. Machining the Delrin and Vulcrepe layers requires only a jig or band saw, and the layers are held together by pins and standard sizes of bolts. The holes for all of these can be drilled with a basic drill press and a small variety of bits. Based on our experiences, the time required for an experienced technician to manufacture a complete Poly Stack Foot is around three hours. The manufacturing process is given below. For technical drawings of each piece, see Appendix B.

1. First, the individual layers are created. The pattern of the lower layer is traced on a ¼" thick sheet of Delrin®. This pattern is then cut out of the sheet using a jigsaw.
2. The two middle layers up are cut in a similar fashion. The lower of the two is cut from ¼" sheet, while the upper is cut from ½" sheet. Each layer follows the contour of the lower layer on the medial and lateral edge, but is shortened at the anterior and posterior edge according to its own specification. A 1.5cm x 1.5cm square notch is made in the center of the posterior edge of each to house the tab protrusion of the Vulcrepe layer. This helps to hold the Vulcrepe in place without preventing it from deforming when necessary.
3. The heel block is made by cementing two ¼" thick Vulcrepe sheets together, and then cutting out their shape according to Appendix B. The tab that protrudes from

the anterior face should be cut such that it must be pressed into the corresponding slot in the two middle layers, after which it fits snugly in the space.

4. The fourth layer from the bottom has a simple shape. It is made from ½" Delrin®. Again, it should be cut such that its medial and lateral faces follow the contour of the lower layer, while its posterior and anterior end are cut short according to the alignment of layers given in Appendix E.
5. The four layers and the heel block are aligned and clamped together so that the interference holes for the slotted pins can be drilled with the drill press. A 3mm bit gives the interference necessary.
6. Once both pin holes have been drilled, the pins are driven into the holes with a hammer to secure the Vulcrepe.
7. While the layers are still clamped, the four bolt clearance holes are drilled with the drill press. Care should be taken to ensure that the Vulcrepe is not being deformed by the clamp's compression during any of these steps.
8. At the bottom of the foot, the bolt clearance holes should be countersunk so that the bolt heads do not protrude from the surface.
9. The bolts and nuts are attached to hold the layers together for the following operations.
10. The M10 bolt hole is drilled through the entire heel.
11. The clearance for the M10 bolt head is counterbored through the bottom layer and the Vulcrepe, but not the top layer. A 21/32" bit or similar size is suitable, but the bolt size can vary, so the hole should be the smallest size that allows the bolt head to pass through unrestricted.
12. The two half-inch thick layers which form a platform for the ankle adapter are manufactured in the same way as the others. They are cut out using the pattern given in Appendix E, and the M10 hole is drilled.
13. For final assembly, the M10 bolt is inserted through the bottom of the foot and the ankle adapter is attached at the top.

4.6 Safety Considerations

Although the Poly Stack Foot has consistently passed the ISO proof strength test, its fatigue life is unascertained. Fatigue life is a concern because prosthetic feet should be built to last. A low-cost foot becomes a high-cost foot if it requires frequent replacement, and if it fails too often it becomes a safety concern for the patient. Fatigue testing for prosthetics is common, but requires expensive equipment. The best way to test the Poly Stack Foot's fatigue life would be to contact a large company with the capability and machinery to perform the test accurately. Quantitative data is required before the Poly Stack Foot can be certified for patient use.

Some rubbers and plastics do not survive long in the warm and humid Honduran environment. The Trias shell used by the Vida Nueva clinic, for example, lasts only 6-8 months, according to Vida Nueva technicians. To fully understand how the Poly Stack Foot meets the clinic's requirements, it is necessary not only to perform a fatigue test, but also to perform a long-term on-site material test. Before the Poly Stack Foot is ready for implementation, it must be shown that the Delrin® and the Vulcrepe are suitable material choices for a prosthetic that must perform in a humid climate. To do this, a long-term patient trial should be organized with the clinic in Choluteca, during which willing patients would use the Poly Stack Foot on a regular basis. Vida Nueva is excited about the possibility of using the Poly Stack Foot; however, it must undergo standardized fatigue testing before it can ethically be used in a long-term trial.

4.8 Maintenance Considerations

As mentioned above, the Otto Bock Trias shell deteriorates relatively quickly in the humid Honduran climate. The Vida Nueva clinic has expressed dissatisfaction with this, but many shells use a similar rubber which does not stand up well to the local conditions. As a result, one technician has built an alternative using a more durable rubber compound called Pe-Lite for a fraction of the cost of the Trias shell. As it is now, this alternative shell fits the same feet as the Trias shell, but can last up to three years. However, the vast majority of Vida Nueva's clientele prefers the more expensive, less durable Trias shell because its color and molded features give it a much closer resemblance to a biological foot.

If this alternative shell could be improved on, perhaps in a future senior project, the overall prosthesis cost and quality could be dramatically improved. Until a better option exists, Vida Nueva will continue to use the Trias shell, which requires frequent replacement.

Chapter 5: Design Verification

To understand the performance of the Poly Stack Foot, several tests were implemented. The Roll-Over Shape test was used to quantitatively compare the foot's behavior in a normal step to that of other prostheses and biological feet; both human patients and a quasi-static test rig were used in conjunction with the Roll-Over Shape method to characterize the Poly Stack Foot. In order to ensure that the Poly Stack Foot preliminary models could safely support human patients, each individual prosthesis was subjected to a static proof test designed by the International Organization for Standardization (ISO). Finally, to assess how the Poly Stack Foot felt to human patients, qualitative descriptions of the foot's performance was collected after the Roll-Over Shape test had been conducted.

5.1 ISO Strength Testing

In order to certify that the Poly Stack Foot could be used in conjunction with human patients, it was subjected to the static proof test for ankle-foot devices described in *ISO 10328: Prosthetics – Structural testing of lower-limb prostheses – Requirements and test methods*. This ISO specification details the appropriate procedure necessary to determine that a prosthesis is capable of safely withstanding the loads experienced during normal use.

Three test levels are defined in the ISO specification: P3, P4, and P5. P3 testing corresponds to a foot appropriate for a patient with mass of up to 60 kg, and P4 to a patient with mass of up to 80 kg. P5, the strongest of the standard strength levels, corresponds to most other patient sizes, including a mass exceeding 100 kg. To meet the needs of all of Vida Nueva's patients, the P5 strength level was selected.

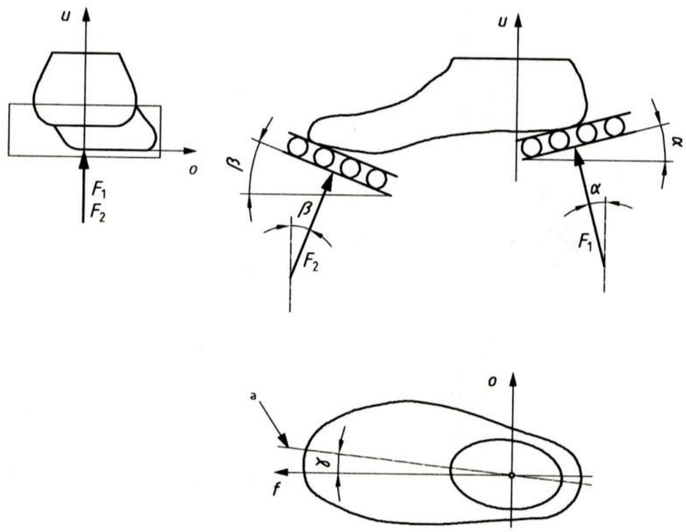


Figure 8. Diagram of ISO ankle-foot device proof strength test.

Table 3. Angles of positions of ISO proof strength test. Symbols correspond to those in Figure 8.

Angles	Degrees
α	15
β	20
γ	7
NOTE The specified directions of loading also apply to the additional test loading level P6 specified in Annex D.	

In the proof test, the heel and toe are loaded separately according to the geometry prescribed in the specification and given in Figure 8 and Table 4. Initially, a load is applied to the prosthesis' bottom surface which increases by 100 to 250 Newtons per second until it reaches a predetermined maximum value. The magnitude of the maximum load experienced depends on the degree of severity of the test. At the P5 level, the normal force that the slanted surface applies to the prosthesis should be 2,240 Newtons. Once this threshold has been reached, the force is sustained for 30 seconds while any signs of material failure are recorded. At the end of the 30 seconds, the load is released. If the prosthesis sustains both heel and toe testing without failure or visible alteration during or subsequent to loading, it passes the test and is ready for use by human patients in the roll-over test.

Six variations of the Poly Stack Foot were developed for human trial. All six passed the static proof test with no failure or visible alteration. After the test, the bolts that hold the layers together were all replaced. During subsequent patient testing, all six performed as expected, with no failures. Although six is a small sample size, the data thus far support the conclusion that the Poly Stack Foot design is strong enough for use on human patients.

5.2 Roll-Over Testing

The primary test used to quantitatively characterize the Poly Stack Foot is the roll-over shape test. The roll-over shape of a foot gives the location of the center of pressure on the foot relative to a fixed point on the ankle throughout a step. A biological foot has curves and multiple degrees of freedom to smooth the transition from heel to toe. Prostheses seek to imitate this smooth curve by deforming gradually throughout a step. A successful prosthesis has a continuous, gentle roll-over shape with that appears similar to that of a physiological foot.

Roll-over shape of a prosthetic is used to several different ends, but the primary application in this case will be to compare the prototype to a biological foot. Roll-over shape will also provide information about the compliance of the heel and toe – two very important factors when designing a prosthetic foot, as they contribute greatly to replicating the 'feel' of a natural limb.

5.2.1 Quasi-Static Roll-Over Testing

Though patient trials provide the most valuable insight into a prosthesis' performance, the timetable of the project required rapid turnaround between the development and the testing of a design iteration. Because patients were only seldom available for testing, and extra precautions must be taken to use a prosthesis in conjunction with human use, it was necessary to build a mechanism that could simulate a human step. Led by team member Seija Maniskas, an Engineering World Health club team designed and built a test rig that allowed multiple design iterations in a short time period.

The design of the rig utilized an inverted pendulum model to simulate the motion of a leg during a natural gait. A vertical pylon and weight system was employed to represent the leg and center of mass of an individual. To assemble the system, one end of an Olympic sized barbell as removed with a chop saw while the other was left intact. The barbell was cut to a length that put the weight at .98 meters, the typical leg length for a person of 1.80 m body height. The bar was oriented vertically with the remaining weight collar pointing up. The lower end of the bar interfaced with an ankle adaptor (just as a patient's pylon would), which was then attached to whichever prototype was undergoing testing. Plates were placed on top of the weight collar to simulate a body mass of 70kg and create a constant vertical force of 690N as the foot was loaded at various shank angles.

The motion and positioning of the barbell were supported by a custom-made wood frame, which was built to a height of 0.8 m. The main portion of the frame was composed of two 0.8m I-beams connected at each end by a cross bar, which was such a length as to create a narrow space between to two connected beams. The body of the frame was supported by four legs, which were attached at an angle to provide stability and help prevent sliding.

The most important piece of equipment in the test is the force plate, a flat plate built into the floor which detects forces applied to the surface. In conjunction with specialized software, the force plate is capable of resolving these forces into their directional magnitudes and the center of pressure at which they are acting.

To conduct the quasi-static testing, the cut end of the barbell was fed through the space in the frame and the adaptor/foot complex was attached to the end so that the foot rested on the force plate with the shank at one of several pre-specified angles. As the angle of the shank varied, the weight attached to the barbell was altered to keep the vertical force acting on the plate at 690 N, the weight of a typical patient.

To begin taking data, the barbell was placed at each specified angle and loaded with the appropriate weight. The center of pressure on the plate was recorded, along with the location of a set point on the ankle area of the pylon. Data was taken with shank angles of -15°, -7°, 0°, 7°, 15°, and 23°. By comparing the coordinates of the center of pressure with the location of the ankle, the roll-over shape was developed.

After being loaded approximately 70 times, the rig failed due to fatigue in one of the legs, which resulting in it shearing off of the bolts holding it to the main body of the frame. Subsequently, the contralateral leg also failed. Fortunately, all of the data that was needed had been collected for the existing prototypes. It was determined that it would not be necessary to rebuild the rig as, due to time restrictions, no more feet would be subjected to quasi-static roll over shape testing. In addition, due to the mode of failure it was decided that this type of testing had some substantial safety concerns that need to be addressed before any further testing could be done.

5.2.2 Patient Roll-Over Testing

During human patient roll-over testing, the prosthesis was attached to a human patient, who walked over the force plate. Again, the force plate recorded the load applied to it and resolved that into the location of the center of pressure on the surface. This time, reflectors were attached to the knee, ankle, and at either corner of the force plate. A camera set perpendicular to the patient’s path filmed the foot’s travel.

Software analysis of the video footage yielded spatial coordinates of the reflectors on the leg relative to the force plate. These coordinates were synthesized with the coordinates of the center of pressure on the force plate, which yielded the roll-over shape of the prosthesis.

5.2.3 Patient Qualitative Feedback

While the roll-over shape test is a good method for quantitatively characterizing the differences between feet, the performance of a prosthetic foot must ultimately be rated by the patient. A roll-over shape can suggest that one foot is more comfortable than another, or allows the wearer to walk more efficiently. However, these analyses mean nothing if they are not supported by the testimony of the patient. For this reason, the qualitative feedback we received from the two patients had the most value to the project, despite being subjective and somewhat general.

After each separate trial of a prosthesis model, the two patients were invited to share how the foot felt to them as they walked. Often, their observations were given in the form of comparisons to their own prostheses or the others they had recently tried. For this reason, it became even more appropriate to also do a roll-over shape test of their personal prostheses. All results are documented in the next section.

5.3 Results

Three design iterations took place over the course of the project. In the first iteration, four feet were built to test the effect of changing two variables: the thickness of the Vulcrepe layer and the anterior length of the middle plastic layers. These feet were named Low Short, Low Long, High Short, and High Long. Each of these underwent quasi-static testing, and the results were compared to known physiological data. The parameters of each foot are given in Table 4, and the results are given in Figures 9-12. It is important to note that, because the reference point is placed arbitrarily on the ankle pylon, the roll-over shapes may be moved along the vertical axes freely – they are represented separately to allow comparisons to be drawn by the observer. However, the roll-over shapes are not free to move along the horizontal axis.

Table 4. First design iteration characteristics. The heel indentation is the distance from the tip of the heel to the beginning of the intermediate layers. Vulcrepe thickness is given in inches because the sheets are available in inch sizes.

Foot Name	Second layer length (cm)	Heel Indentation (cm)	Vulcrepe thickness (in)
Low Short	9.0	3.0	0.75
Low Long	140	1.5	0.75
High Short	9.5	3.0	1.0
High Long	14.0	1.5	1.0

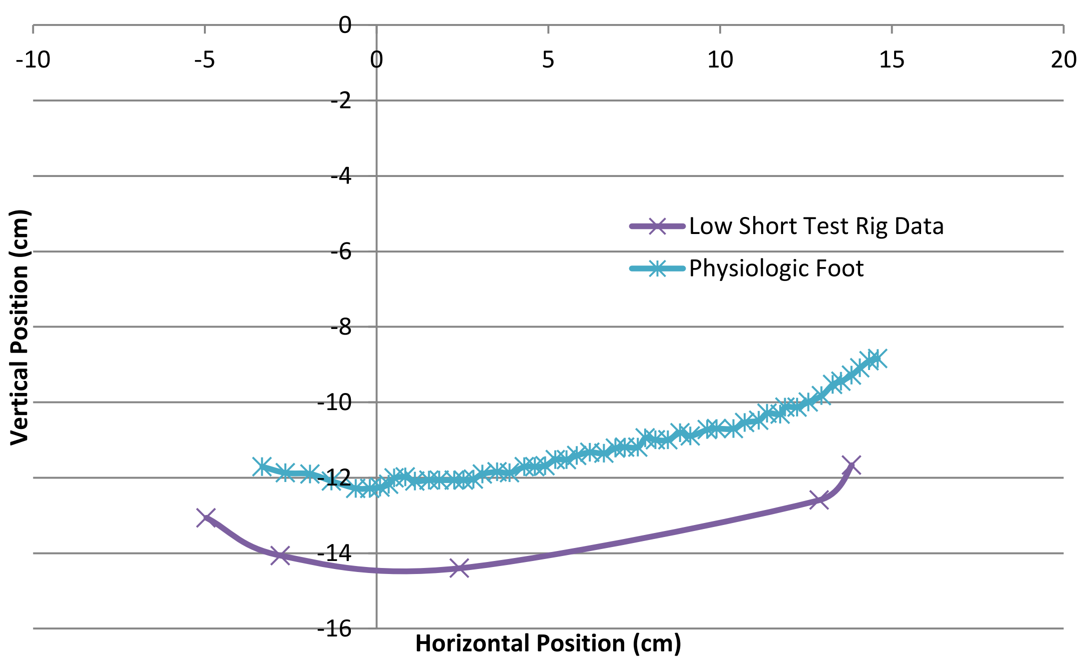


Figure 9. Quasi-static roll-over shape comparison of Low Short foot and physiological data.

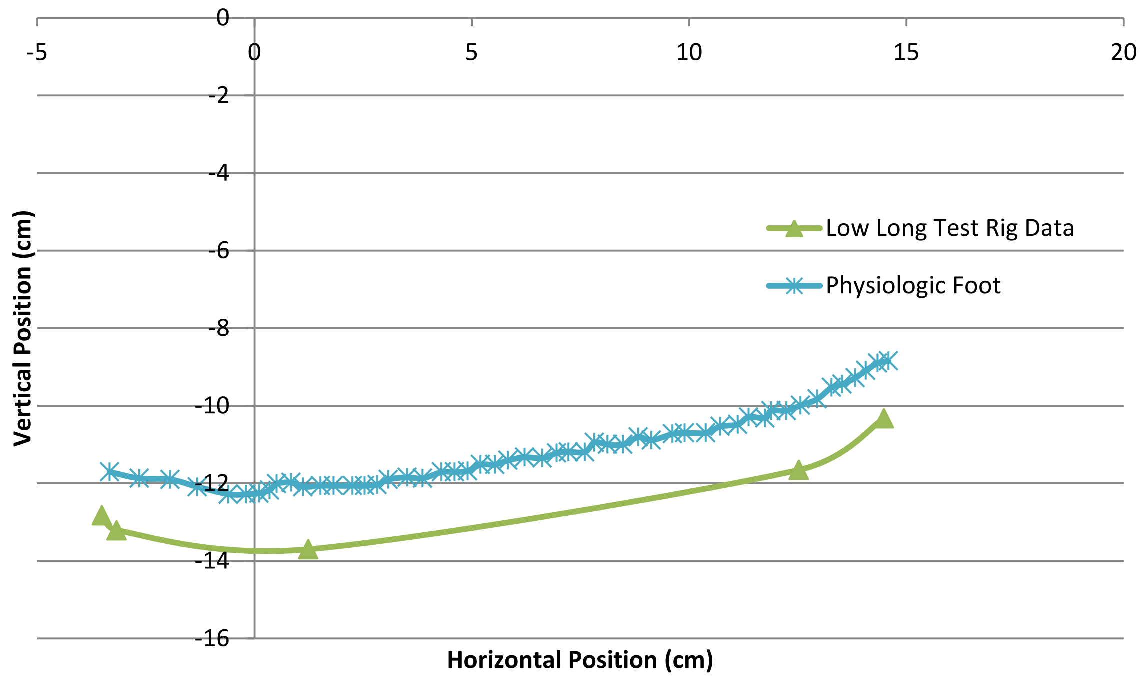


Figure 10. Quasi-static roll-over shape comparison of Low Long foot and physiological data.

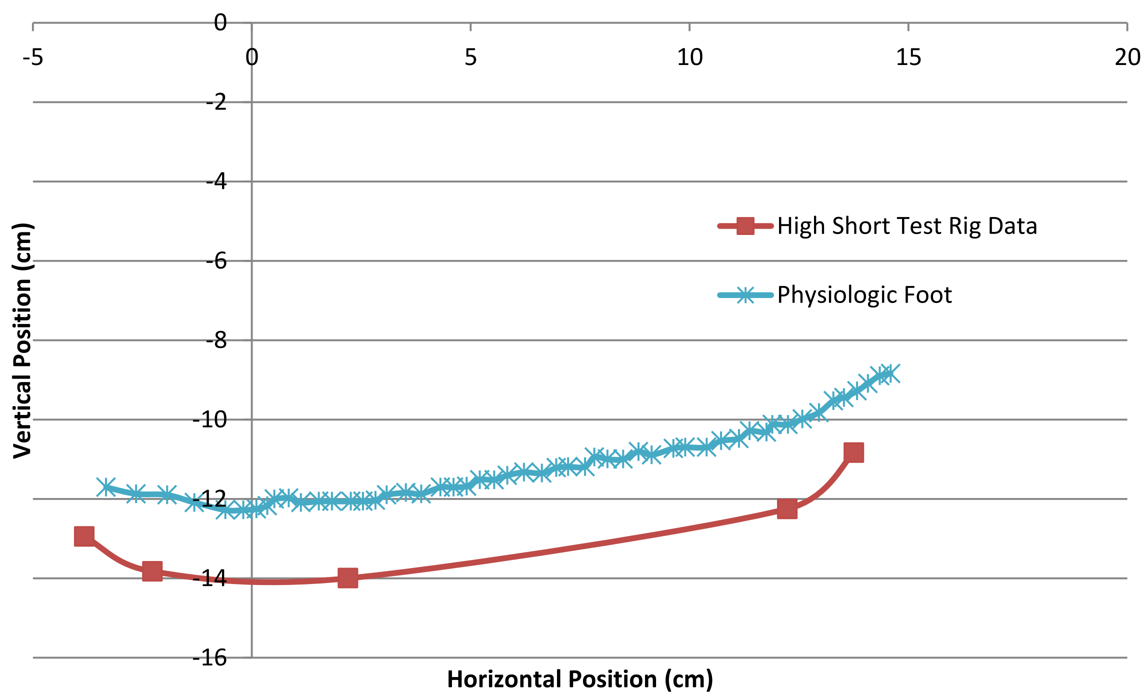


Figure 11. Quasi-static roll-over comparison of High Long foot and physiological data.

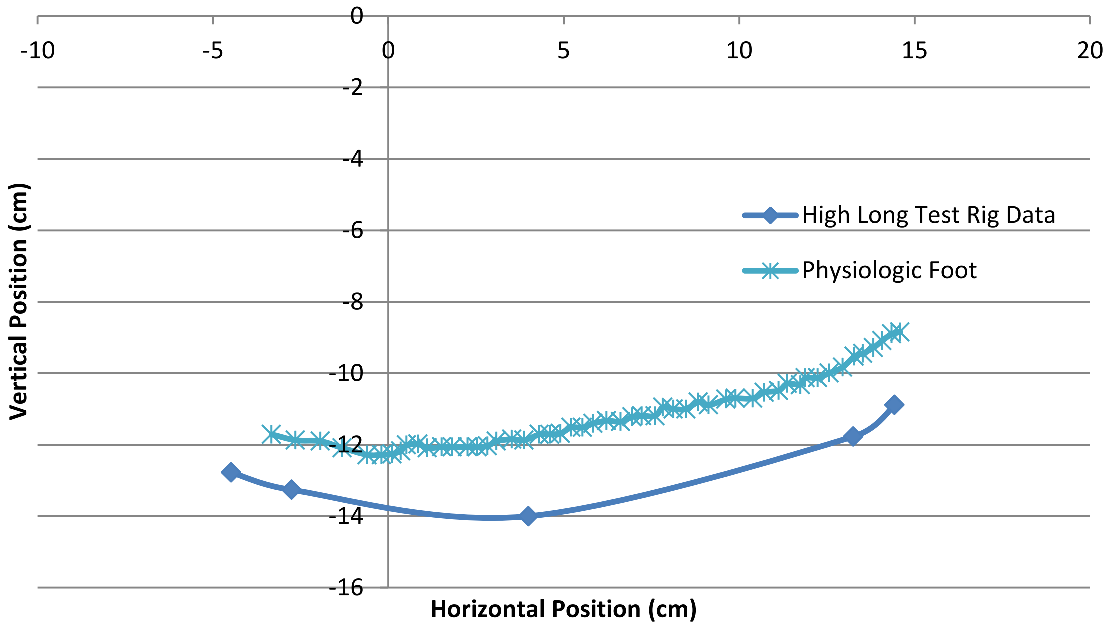


Figure 12. Quasi-static roll-over shape comparison of High Long foot and physiological data.

The roll-over shapes we received from the first iteration of testing indicated that the feet did a good job of imitating the physiological condition, but there was plenty of room for improvement. Specifically, the toe (the region furthest along the positive x-axis) curves up sharply at the end in each of the roll-over shapes, indicating that it is too soft. Based on these results, four new design iterations were developed and again tested using the quasi-static method.

In the second round, the variables changed slightly. To harden the heel, the second layer from the bottom was extended and given a shape that paralleled the curve of the lowest layer. In the case of 2L-D and 2L-C, the third layer up was also extended to provide an even stiffer toe. In the case of feet 1L-D and 2L-D, the thickness of the Vulcrepe block was reduced, and the second layer became solid Delrin® throughout. These new iterations are given in Table 5, and the roll-over shape test results are given in Figures 13-16.

Table 5. Second design iteration characteristics.

Foot Name	Long Third Layer	Solid Second Layer
1L-D	No	Yes
1L-C	No	No
2L-D	Yes	Yes
2L-C	Yes	No

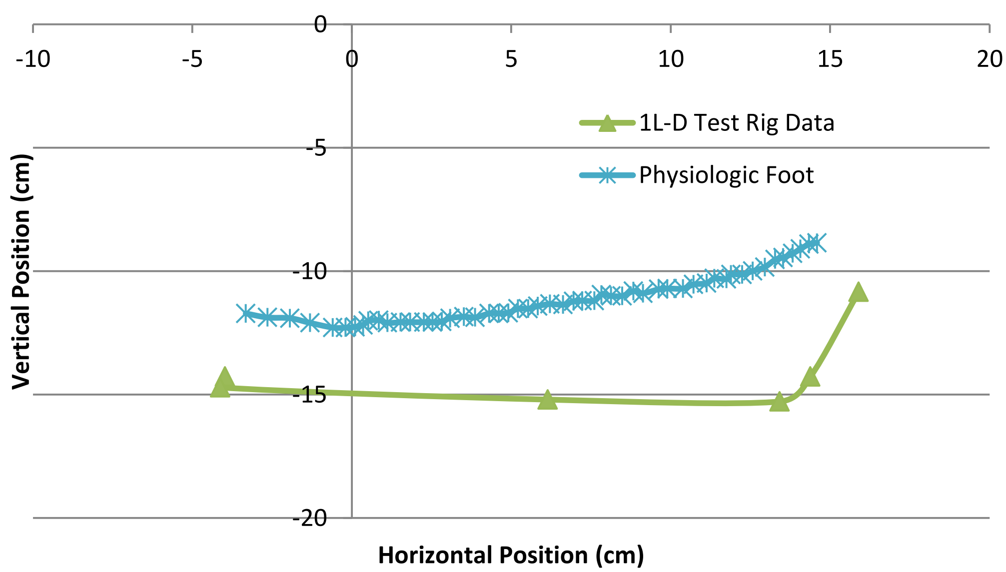


Figure 13. Quasi-static roll-over shape comparison between 1L-D foot and physiological data.

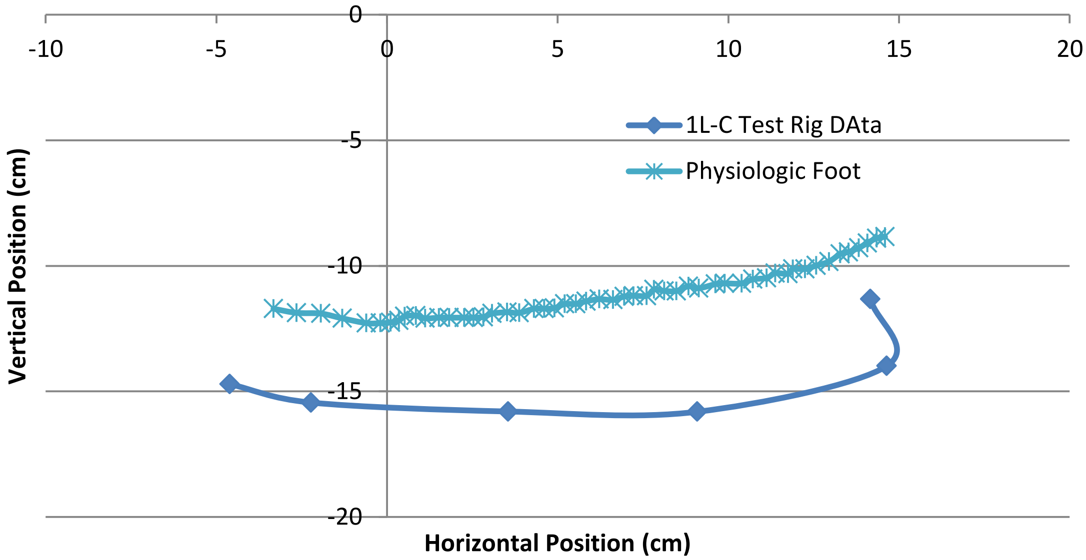


Figure 14. Quasi-static roll-over shape comparison between 1L-C foot and physiological data.

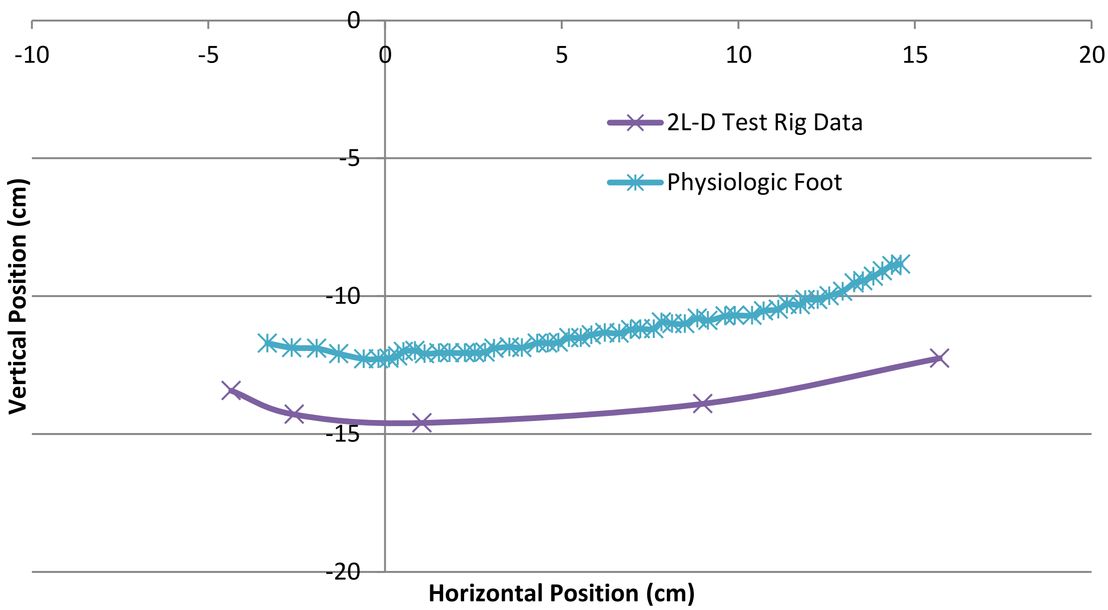


Figure 15. Quasi-static roll-over shape comparison between 2L-D foot and physiological data.

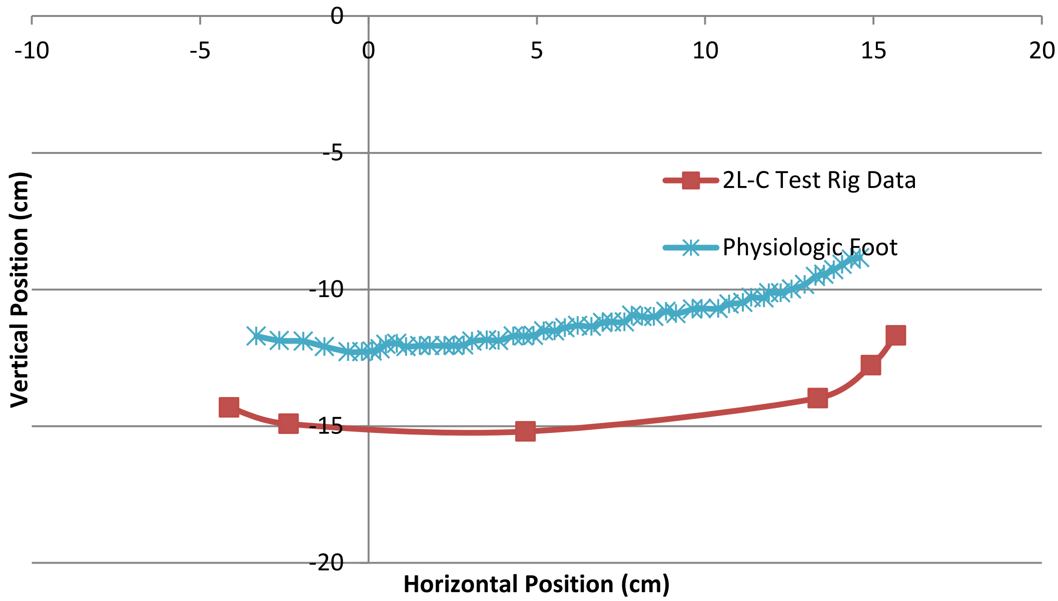


Figure 16. Quasi-static roll-over shape comparison between 2L-C foot and physiological data.

The results of the second iteration were mixed. The longer toe layers stiffen the feet slightly during stance, as can be seen by the relatively flat areas in the middle of the curves. However, the toe shape of every foot but the 2L-D, at the right end of each curve, swerves sharply up. This indicates that where the second layer ends, the foot becomes suddenly too soft, and bends exaggeratedly.

In the toe, a prosthesis works almost like a spring, deforming to absorb energy and then releasing that energy when the foot is lifted. When the toe of a prosthesis is too soft, the foot does not return to its unstressed position with enough force, and the patient must work hard to transition from the prosthesis onto the opposite foot. This often causes symptoms such as muscle aches in the healthy foot.

Of these eight shapes, three were selected for patient testing: the High Short, Low Long, and 2L-D feet. These three were selected based on the similarities their rollover shapes bear to the physiological data. In fact, the curves of all three imitate a real foot closely. The foot developed last year by the previous Piernas de Vida team was also tested by patients to understand how the design has changed. This represents the new physiological data curve given in Figures 17 and 18.

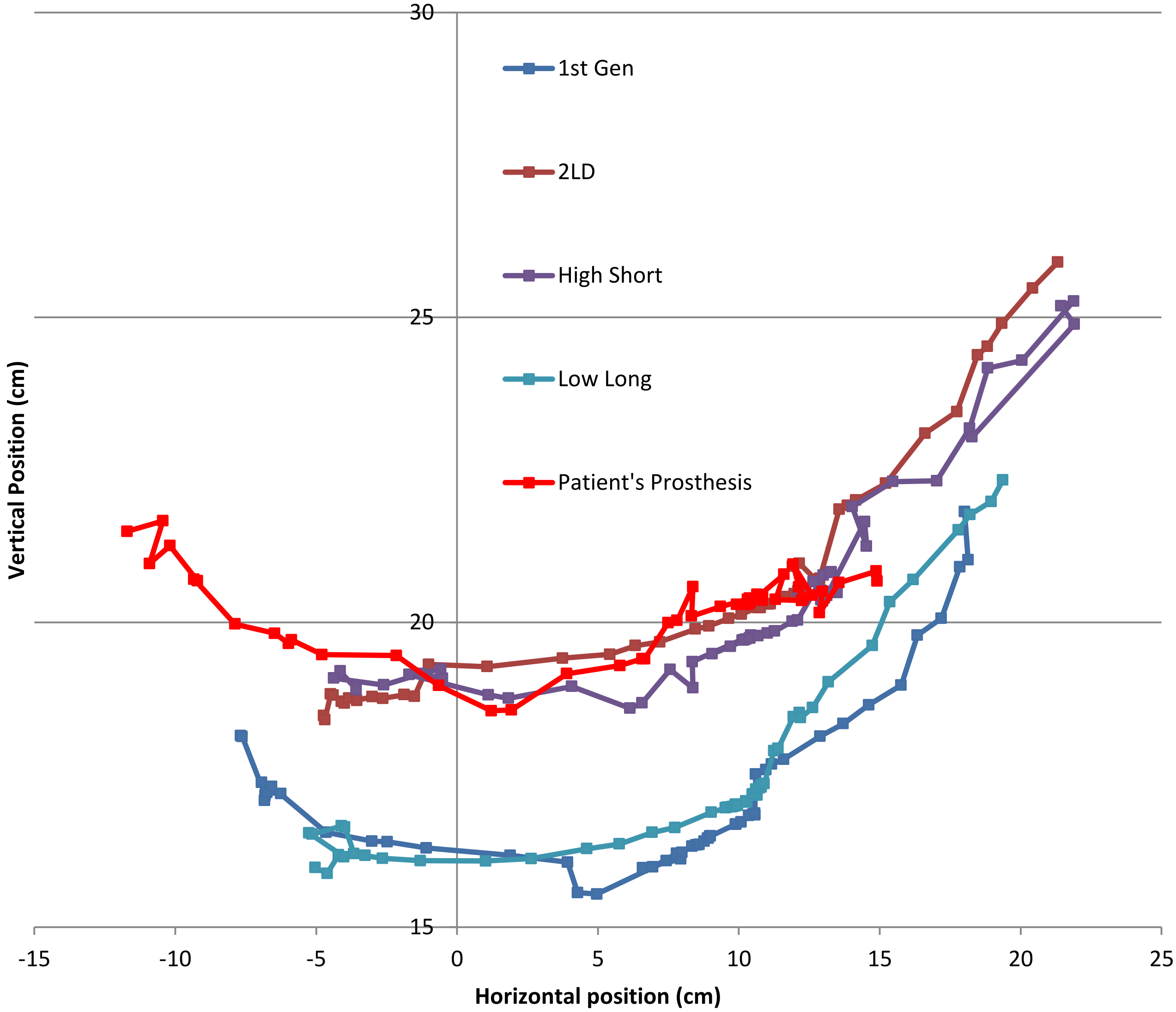


Figure 17. Patient 1 roll-over shape results.

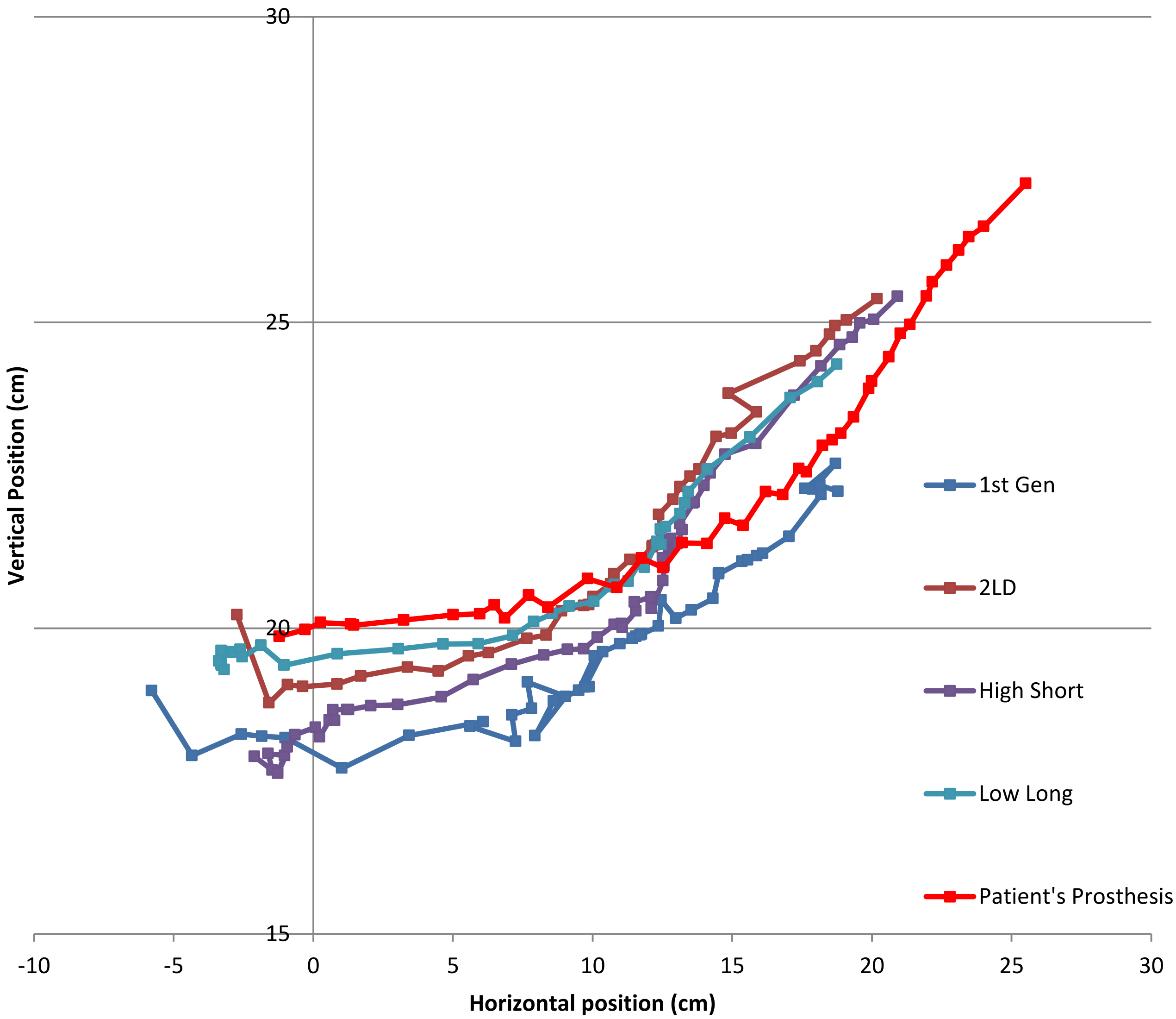


Figure 18. Patient 2 roll-over shape results.

Three trials were done of each foot by each patient. Despite the high variation and noise present in each roll-over shape in Figures 17 and 18, there was very little variation between trials of the same foot. This high degree of precision is promising, because it indicates that results are highly repeatable using the equipment and method available at Cal Poly.

Patient 1 was a middle-aged left transtibial amputee weighing 224 lb. His walking gait and his personal prosthesis were somewhat abnormal, as can be seen in Figure 17.

Because he had unique requirements of a prosthesis, the Poly Stack Feet presented some challenges for him. However, he still found it relatively easy to differentiate between the different models.

Patient 1 found that each Poly Stack Foot was too stiff for his comfort in both the heel and toe. The 1st Generation foot and the 2L-D foot were the least comfortable for him, while the High Short and Low Long models both felt comparably better. Most notably, Patient 1 reported that the heel of every foot transitioned too quickly to stance, causing him to feel like he was being rocked forward too early in his step.

The rollover shapes of the Poly Stack Feet are all similar in Figure 17. The 1st Generation foot has the most variation. It consistently showed a downward spike near the x=5cm mark, as well as steep heel and toe curves. This indicates that, as weight is distributed over the course of the step, each layer is activated suddenly, causing a rapid shift in the foot's behavior. The other feet have somewhat steep toe regions. This would normally indicate that the toe is too soft – something that both Patient 2 and prosthetist Matt Robinson noticed. However, Patient 1 maintained that the feel of each foot was stiff throughout.

Patient 2 was a much steadier walker. Aged 27, he was a right transtibial amputee weighing 170 lb. Because he had been an amputee since very close to birth, his gait was comfortable, and the roll-over shapes for each foot were much closer together in Patient 2's trials.

In the 1st Generation foot, Patient 2 also noted a distinctly sharp transition from heel to stance. He found the heel to be somewhat stiff and the toe to be too soft, forcing him to work more than normal to take each step.

The 2L-D foot felt better to Patient 2. The toe was stiffer, and as a result he didn't have to make as noticeable an effort during the step. The heel transition felt smoother to him, and he said it felt similar to his normal prosthesis.

The High Short foot again had too soft a toe. This makes sense, since the High Short's middle layers do not extend far, and the single lower layer provides the only stiffness in the toe.

The Low Long foot felt the best to Patient 2. He found the transitions smoother, the toe firmer, and the heel transition smoother than previous feet. However, he preferred his normal prosthesis for its longer heel platform, smoother transitions, and stiffer toe. Patient 2 said that the Poly Stack Feet "definitely feel usable."

Much of what Patient 2 had to say is supported by the roll-over shapes of Figure 18. The Poly Stack Feet follow Patient 2's prosthesis curve closely, but stray in particular areas. Most noticeable is the softer toe shape that the Poly Stack Feet exhibit around the x=12cm point. At this point, their roll-over shapes begin to slope upwards more steeply, indicating that the toe has become more compliant and less comfortable. The stance phases of each foot are all comparable, while the heel varies from foot to foot.

One of the most significant complaints from both patients was the heel transition. All Poly Stack Feet felt as if they had a very short heel which forced a transition into stance rapidly. In other words, the foot began to rock forward before the patient was ready, coming to rest on level ground before the leg was prepared. This complaint was prominent during the testing of the 1st Generation foot as well, and was one of the areas targeted by the second Piernas de Vida team. Although both patients reported that the problem had been improved by the 2nd Generation Poly Stack Feet, this area still requires more improvement in the future.

Furthermore, a stiffer toe is required to support the patient throughout the entire course of the step. As stated above, when the toe is too compliant, the foot flexes in the toe during push-off, but it does not return much energy as it returns to its original shape. As a result, the patient feels like he must try harder to take a step. Because the rest of the body must work harder to make up for this flaw, symptoms of this often include sore muscles in the legs and opposite foot.

After data analysis was complete, it was decided that the Low Long foot presented the best overall characteristics. It was selected as the final design for the Poly Stack Foot.

Chapter 6: Conclusion and Recommendations

The Low Long design is a clear improvement over the first generation Poly Stack. It produced one of the better roll-over curves from the quasi-static test, but the results from the the roll-over tests were similar enough that it is hard to make a judgment based on that alone. When test results are spaced so closely, qualitative feedback from users or patients is the most valuable data. This is especially the case with a device such as a prosthesis, whose performance and comfort are hard to determine based on analysis and testing. Our test results were confirmed by the feedback given by the patients.

6.1 Conclusions

The Low Long was more stable, yet had a comfortable softness in the heel strike. The biggest difference between the Low Long and Patient 2's normal prosthesis was that the heel strike was shorter. This indicates that the transition from heel strike to stance is too fast. The short heel is probably the result of an error due to inconsistent manufacturing techniques. Even though the process was proved reliable by the consistent roll-over shapes produced by the testing, when the different prototypes are compared, the ankle adapter in the later ones is positioned closer to the posterior end of the foot than in the early prototypes. This means the adapter was located closer to the heel than it was designed to be. However, simply moving the ankle adapter farther forward is probably not enough to cure the "short heel".

It is important to note that the roll-over shape test compared the Poly Stack Foot to a much more costly prosthesis that uses much more expensive materials and is on the commercial market in the United States. While the Poly Stack Foot cannot offer the same comfort level as such a product, it can at least offer the same mobility and utility. Because the Poly Stack Foot has been engineered to deform smoothly and return energy to the patient's step, there is little doubt that it holds significant advantages over the SACH foot currently carried by the Vida Nueva clinic. Last year, patients at Vida Nueva reviewed the 1st Generation foot positively. As a noticeable upgrade over the first Piernas de Vida prosthetic, the Poly Stack Foot has the very real potential to improve the lives of every patient at the Vida Nueva clinic.

6.2 Recommendations

There are several more steps that must be taken before the foot can be implemented at Vida Nueva.

First the design must be fine tuned and scaled. The comfort and performance of the foot is still not comparable to current prostheses. Action steps must be taken to extend the heel yet keep the stance and toe stable. Next, not everyone has a foot that is 26 mm long, therefore a procedure must be developed on how to properly resize the foot but keep the important characteristics. Unfortunately, this is probably not as simple as changing each layer by a respective amount. So the foot must be resized following different strategies and then tested to see which method keeps the roll-over shape consistent.

Secondly, Vida Nueva expressed interest in having an inexpensive cosmetic shell. The Pelite cover that the technician there currently makes does not resemble a foot closely enough for most patients to want to use it. Instead, they order expensive covers that must be replaced often.

For the project to continue, it is recommended that the fine tuning and cosmetic shell are picked up by multi-disciplinary teams next year. The scope of these projects may not be enough to fulfill the design requirements of the mechanical engineering department. However, the project has proved not only to be a challenging design problem, but also a greatly beneficial humanitarian effort. The potential real-world benefit from continuing this project is enormous, and the opportunity to work on the international scale and even travel to Honduras is an experience that also offers considerable personal enrichment to the open-minded engineer. From the personal to the international scale, there is every reason to support the Piernas de Vida project's continued progress into future years of Cal Poly seniors.

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Appendix A: Decision Matrices

Table 6. Pugh Matrix comparing four possible prosthetic foot designs.

		Hinge	Soft Middle	Separated Lower	Wedge Platform
Requirement	Baseline	1	2	3	4
Snugly Fits Shell	-	S	S	+	-
Lasts 6-8 Months	SACH Foot	+	+	S	+
Natural Heel Strike Feeling	Poly Stack Gen. 1	+	+	S	+
Easy to Manufacture	Poly Stack Gen. 1	-	S	S	-
Interfaces w/ Ankle Adapter	Poly Stack Gen. 1	+	S	S	+
	Σ+	3	2	1	3
	Σ-	1	0	0	2
	ΣS	1	3	3	0
	Total	2	2	1	1

A + indicates that the design performs significantly better than the baseline prosthetic with which the design is being compared. A – indicates that there are noticeable drawbacks to the design in a particular area. An S indicates that the design performs comparably to the baseline design in a particular area. The Hinge and Soft Middle designs, which have more comparative advantages than disadvantages, are selected.

Table 7. Subsystem Matrix comparing various potential Poly Stack Foot designs.

Poly Stack Foot				
Ankle	Heel	Stance	Toe	Shell Interface
Low-Rise	Delrin Layer (unmodified)	Delrin Layer (unmodified)	Delrin Layer (unmodified)	Lower Layer Fits in Heel Pocket
Slanted w/ Spherical Washer	Delrin, Modified Cross-Section	Separated Lower Layer	Separated Lower Layer	Material Removed at Foot Arch Curve
	Delrin, Rounded Middle Layer	Compression of Rubber Core		Separated Lower Layer at Foot Arch Curve
	Rubber Platform/Base			
	Rubber Interior/Core			
	Separated Lower Layer			

Appendix B: List of Vendors

Piper Plastics
www.piperplastics.com

257 E. Alamo Drive
Chandler, AZ 85225
(480) 926-8100 (phone)
(480) 497-1530 (fax)
AZSales@piperplastics.com

Delrin:

2' x 2' sheet, ½ inch thick	$154
2' x 4' sheet, ¼ inch thick	$154

J Weiner & Co., Inc.
www.jweiner.com

Roanoke, VA 24027
1-800-444-6979 (phone)
1-800-999-3883 (fax)

Crepe:

18" x36" sheet, ½ inch thick (24 iron)	$12.95
18" x36" sheet, ½ inch thick (12 iron)	$21.95

McMaster-Carr
www.mcmaster.com

600 N County Line Rd.
Elmhurst, IL 60126-2081
(630) 833-0300 (phone)
(630) 834-9427 (fax)
chi.sales@mcmaster.com

Slotted Spring Pins:

1/8"diameter, 1 1/2" long	$10.36/100
1/8" diameter, 1 ¾" long	$7.40/50

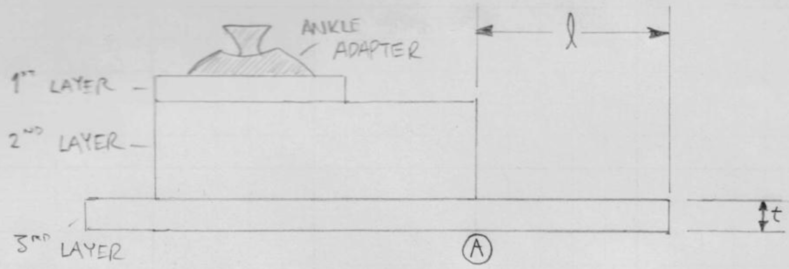
Flat Head Phillips Machine Screws:

#6, 2 inches long	$9.26/100

Appendix C: Detailed Analysis

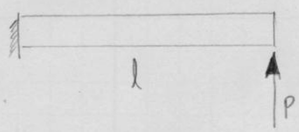
C.1 Beam Theory Hand Calculations

THE OBJECTIVE OF THESE CALCULATIONS IS TO DETERMINE THE APPROPRIATE LENGTH, l, BY WHICH THE BOTTOM LAYER OF THE POLY STACK EXTENDS FROM THE MIDDLE LAYER.



I. BECAUSE THE INTERMEDIATE HAS A SIGNIFICANTLY GREATER 2ND MOMENT OF AREA, I ASSUME THE BOTTOM LAYER ACTS AS A CANTILEVER BEAM EXTENDING FROM POINT A. DISREGARDING DEFORMATION OF INTERMEDIATE LAYER:

BOTTOM LAYER: FIND DEFORMATION WHEN FORCE IS ACTING AT TOE.



$$y_{max} = \frac{Pl^3}{3EI}$$ (Snigley, Table A-9)

$I = \frac{1}{12} w t^3$ WHERE w = CROSS-SECTIONAL WIDTH

$$l^3 = \frac{y_{max} E w t^3}{4P} \qquad \boxed{l = \sqrt[3]{\frac{y_{max} \cdot E w t^3}{4P}}} \qquad (1)$$

II. INCORPORATE ROLLOVER TEST DATA OF A PHYSIOLOGICAL FOOT. A TYPICAL ROLLOVER DEFLECTION AT THE END OF THE FOOT, WHEN ALL FORCE ACTS AT THE TOE, IS 2.5 cm.

OTHER GIVENS:

$E_{DELRIN} = 3.175$ GPa

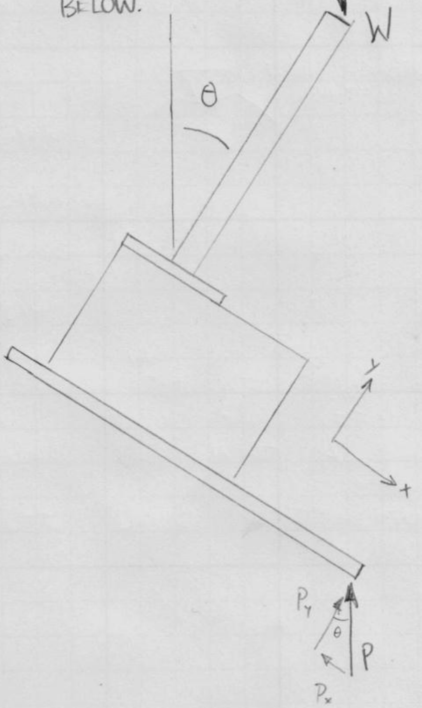
GEOMETRY (TENTATIVE):

$t = 0.25$ in

$w = 90$ mm

PROBLEM: DETERMINE P FROM GEOMETRY OF FOOT & WEIGHT OF HUMAN, THEN APPLY TO EQUATION TO DETERMINE l.

III. SOLUTION A SAMPLE STEP, USING GEOMETRIES ESTIMATED FROM FILMED TEST RUNS OF THE POLY STACK FOOT, IS ILLUSTRATED BELOW.



- W IS THE PATIENT WEIGHT. USE A MASS OF 80 kg.
- $\theta = 30°$
- DISREGARD P_x - USE P_y AS DEFLECTION FORCE

$$P_y = W \cos\theta$$

EQUATION (1):

$$l = \sqrt[3]{\frac{y_{max} \cdot Ewt^3}{4P_y}}$$

$y_{max} = 0.025\ m$ $E = 3.175 \cdot 10^9\ Pa$ $w = 0.09\ m$ $t = 0.25\ in = 0.00635\ m$

$$P_y = (80\ kg)(9.81\ m/s^2)\cos(30°) = 680\ N$$

$$l = \sqrt[3]{\frac{(0.025\ m)(3.175 \cdot 10^9\ N/m^2)(0.00635\ m)^3(0.09\ m)}{4\ (680\ N)}} = 0.088\ m = \boxed{8.8\ cm}$$

- SINCE THERE IS KNOWN SMALL DEFLECTION IN THE INTERMEDIATE LAYER, THE BOTTOM LAYER SHOULD EXTEND NO MORE THAN, AND LIKELY SOMEWHAT LESS THAN, 8.8 CM.

- FEET SHOULD BE SIZED DIFFERENTLY ACCORDING TO PATIENT WEIGHTS.

C.2: Numerical Analysis

The following is the code from the Matlab analysis program.

```
% Piernas de Vida project
% Shalan Ertis, John Kearns, Seija Maniskas
% March 11, 2012

% This program shows how varying the dimensions of the lowest layer of the
% Poly Stack foot alter the foot's performance. It uses simple beam theory
% and assumes small deformations. It also assumes little deformation at the
% interface with the intermediate foot.

% Changes to make:
% -Iterate based on C.O.P. results from tests.

clc;
clear all;

% Delrin properties, according to DuPont
E = 3100 * 10^6;     % MPa
E_b = 2900 * 10^6;   % MPa
S_y = 72 * 10^6;     % MPa

% Human body properties
m = 100;             % kg
theta = 30; % Highest angle of foot from horizontal.

W = m * 9.81;        % Vertical force from body on foot.
P = 0;               % Horizontal force to move forward.
F = W*cosd(theta) + P*sind(theta); % Shear force on foot.

% Foot dimensions & properties
t = 0.25 * 25.4/1000;    % m, thickness of layer
w = 0.06;                % m, width of layer
lstep = 0.001;
lmin = 0.01;
lmax = 0.05;
l = [lmin:lstep:lmax];    % m, length of extension of lower layer

I = 1/12 * w * t^3;
c = t/2;

% Stress case
M = F * l;
sigma = M*c/I;

lsteps=(lmax-lmin)/lstep +1;
for n=[1:lsteps]
    yields(n)=S_y;
end

% Deformation
y = F .* l.^3 / (E_b*I);
```

```
subplot(1,2,1);
plot(l, sigma, l, yields,'--');
xlabel('Layer Length (m)');ylabel('Stress (Pa)');
legend('Foot Stress','Yield Stress','Location','NorthWest');
title('Maximum Tensile Stress Case');

subplot(1,2,2);
plot(l, y);xlabel('Layer Length (m)');ylabel('Vertical Deformation (m)');
title('Deformation at Tip of Lower Layer');



% Fatigue calculations are difficult, since they are based on figures
% supplied by DuPont. However, examination of Figure 20 in DuPont's
% "Design and Processing" .pdf allows estimation of cycle life based on
% tensile stress applied.

% cycles_50 = 2*10^5;     % At sigma = 50 MPa
```

Appendix D: Gantt Chart

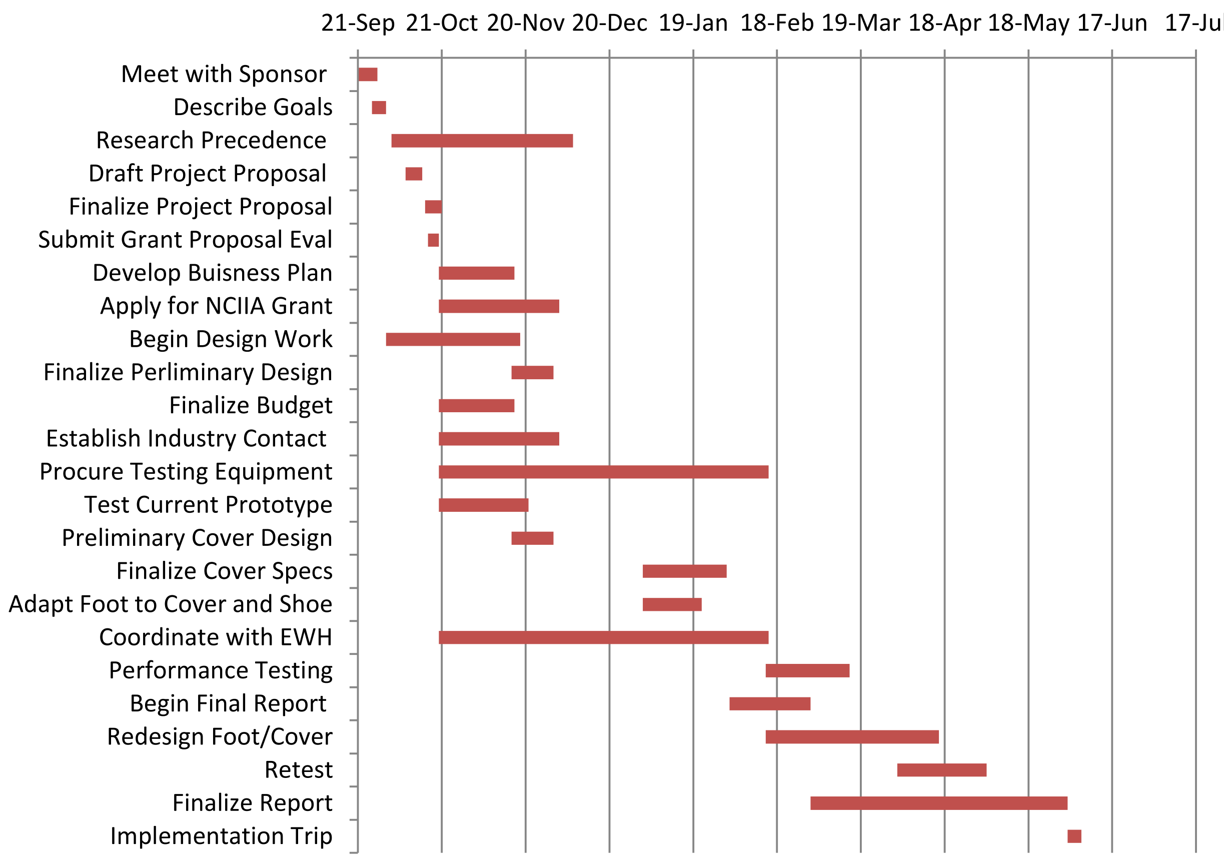
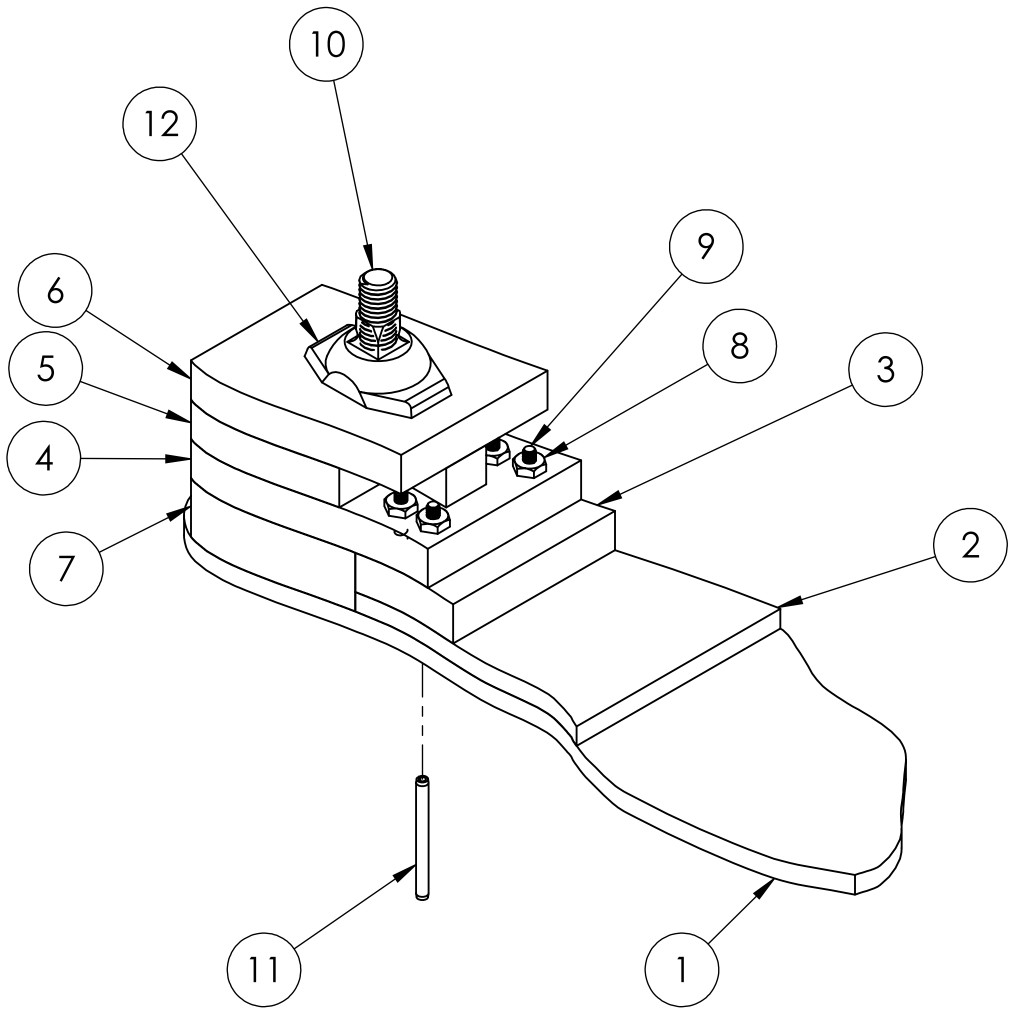


Figure 19. Schedule for fall 2011 through spring 2012.

Appendix E: Part and Assembly Drawings



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	1	Base Layer	1
2	2	Layer 2	1
3	3	Layer 3	1
4	4	Layer 4	1
5	5	Layer 5	1
6	6	Top Layer	1
7	7	Vulcrepe Block	1
8	-	#6-32 Nut	4
9	-	#6-32 X 2.0 Screw	4
10	-	M10 X 70 Bolt	1
11	-	1/8" X 1.5" Slotted Pin	2
12	-	Ankle Adapter	1

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL

FINISH

NEXT ASSY | USED ON

APPLICATION

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	JK	5/25/12
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

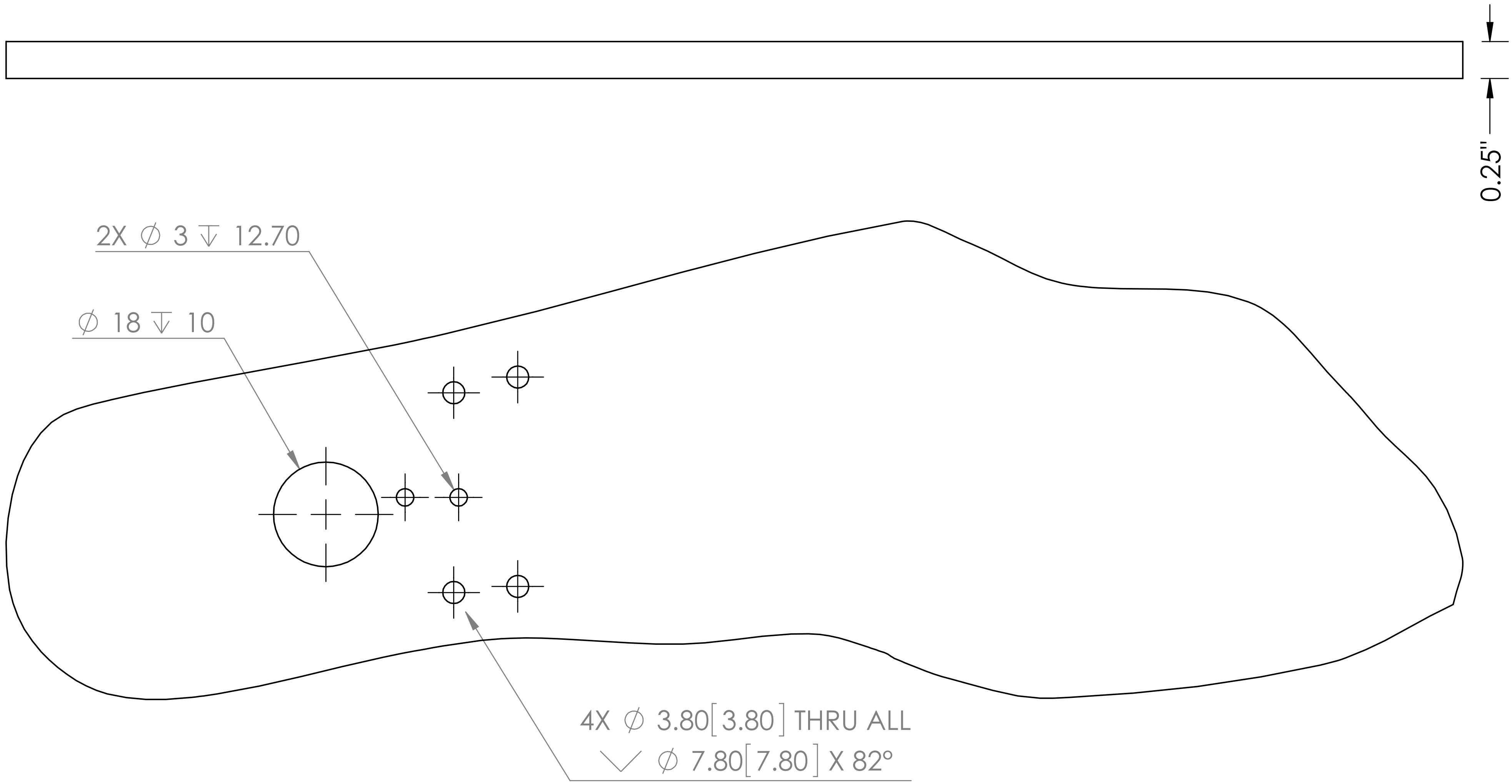
TITLE:

Poly Stack Foot

SIZE	DWG. NO.	REV
A	-	

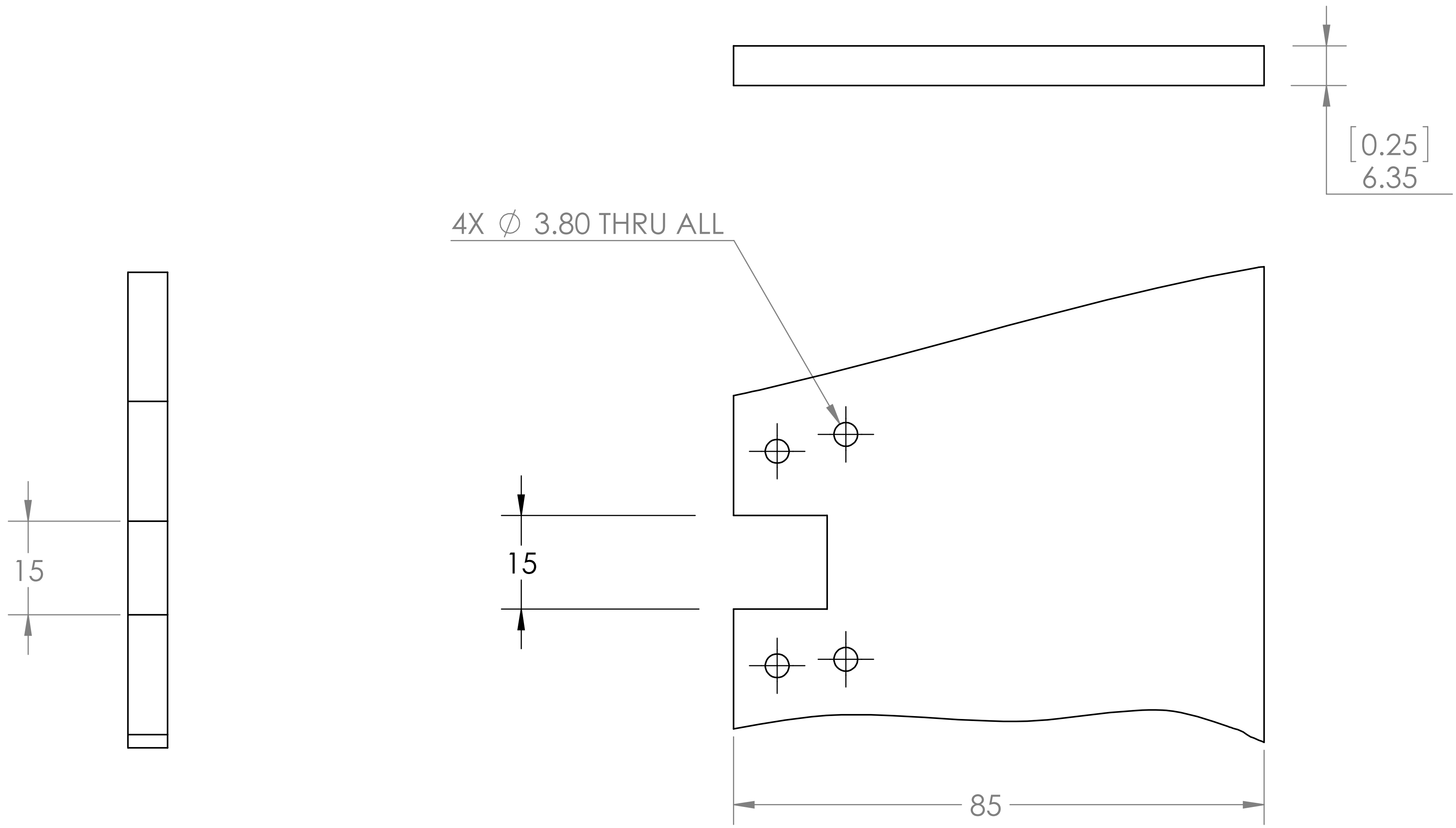
SCALE: 1:4 WEIGHT: SHEET 1 OF 1

5 4 3 2 1



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN MM [IN] TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN	JK	5/25/12	
			CHECKED			TITLE:
			ENG APPR.			Bottom Layer
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL DELRIN (R)	COMMENTS:			SIZE A / DWG. NO. 1 / REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 1:1 / WEIGHT: / SHEET 1 OF 1

5 4 3 2 1



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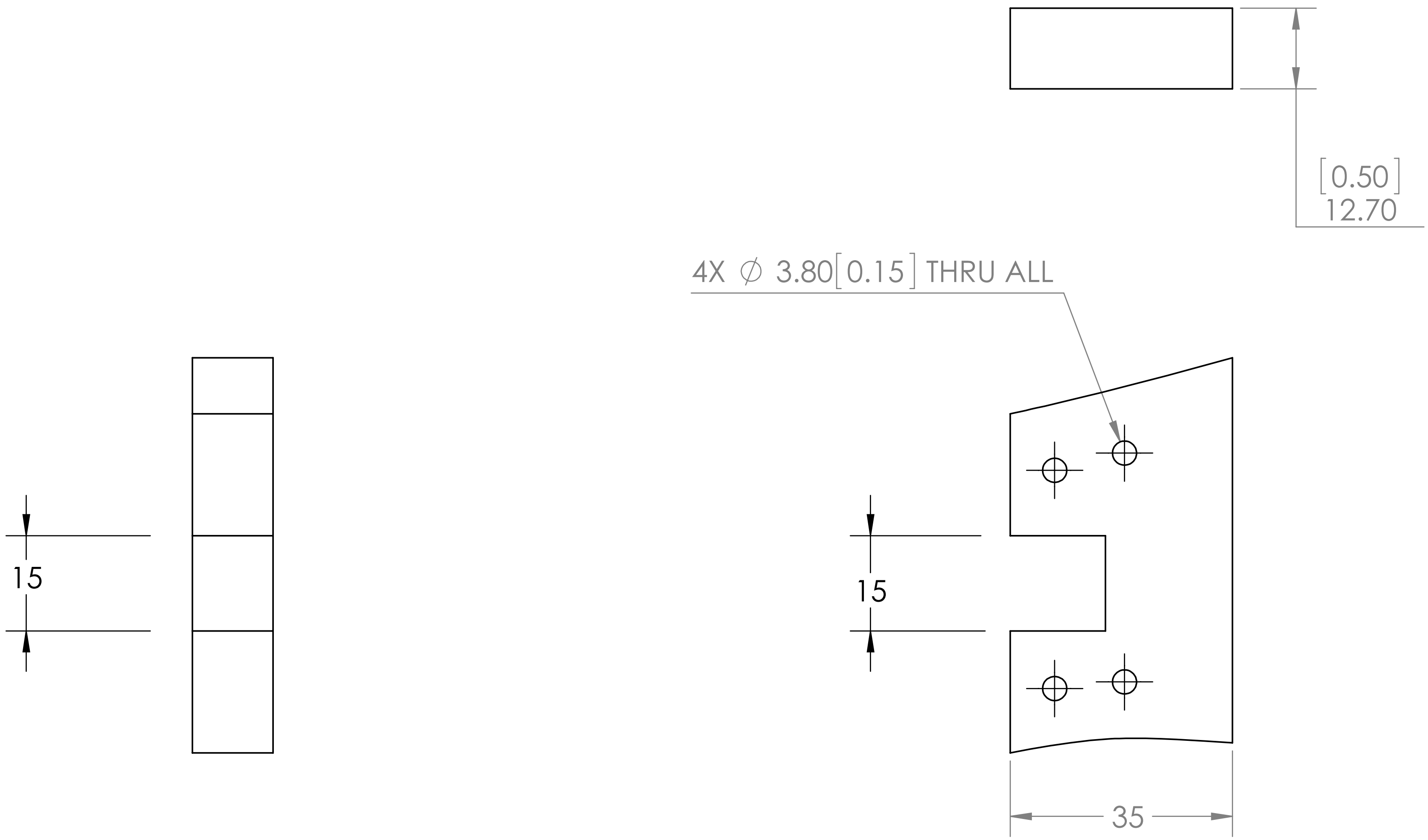
			CHECKED			TITLE:
			ENG APPR.			Layer 2
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL DELRIN (R)	COMMENTS:			SIZE A DWG. NO. 2 REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 1:1 WEIGHT: SHEET 1 OF 1

5 4 3 2 1



		UNLESS OTHERWISE SPECIFIED:
		DIMENSIONS ARE IN MM [IN] TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±
		INTERPRET GEOMETRIC TOLERANCING PER:
		MATERIAL DELRIN (R)
NEXT ASSY	USED ON	FINISH
APPLICATION		DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	JK	5/25/12
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		
COMMENTS:		

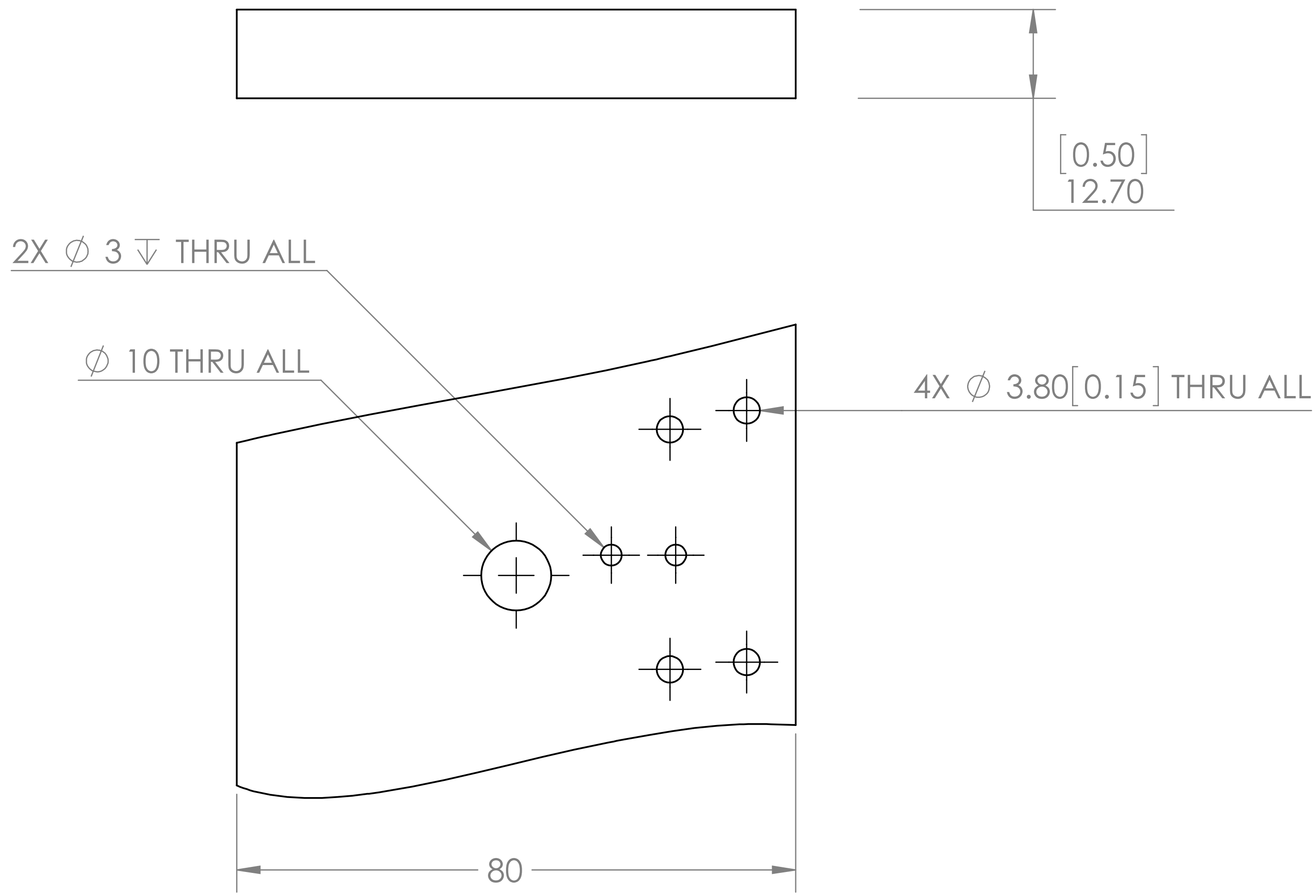
TITLE:

Layer 3

SIZE	DWG. NO.	REV
A	3	

SCALE: 1:1	WEIGHT:	SHEET 1 OF 1

5 4 3 2 1



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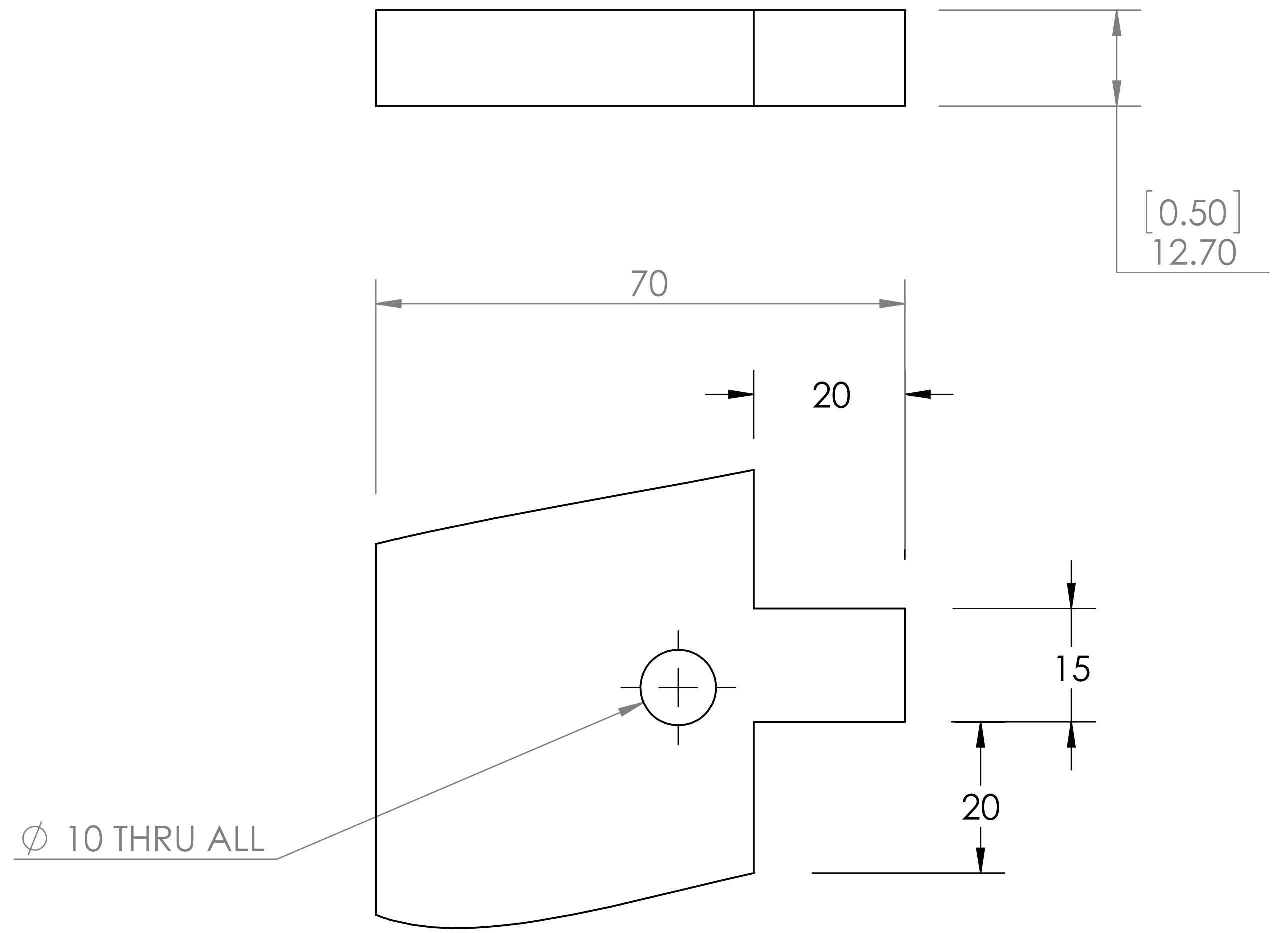
			CHECKED			
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL DELRIN (R)	COMMENTS:			SIZE A · DWG. NO. 4 · REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 1:1 · WEIGHT: · SHEET 1 OF 1

5 4 3 2 1



UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM [IN]
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
DELRIN (R)

FINISH

NEXT ASSY | USED ON

APPLICATION

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	JK	5/25/12
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

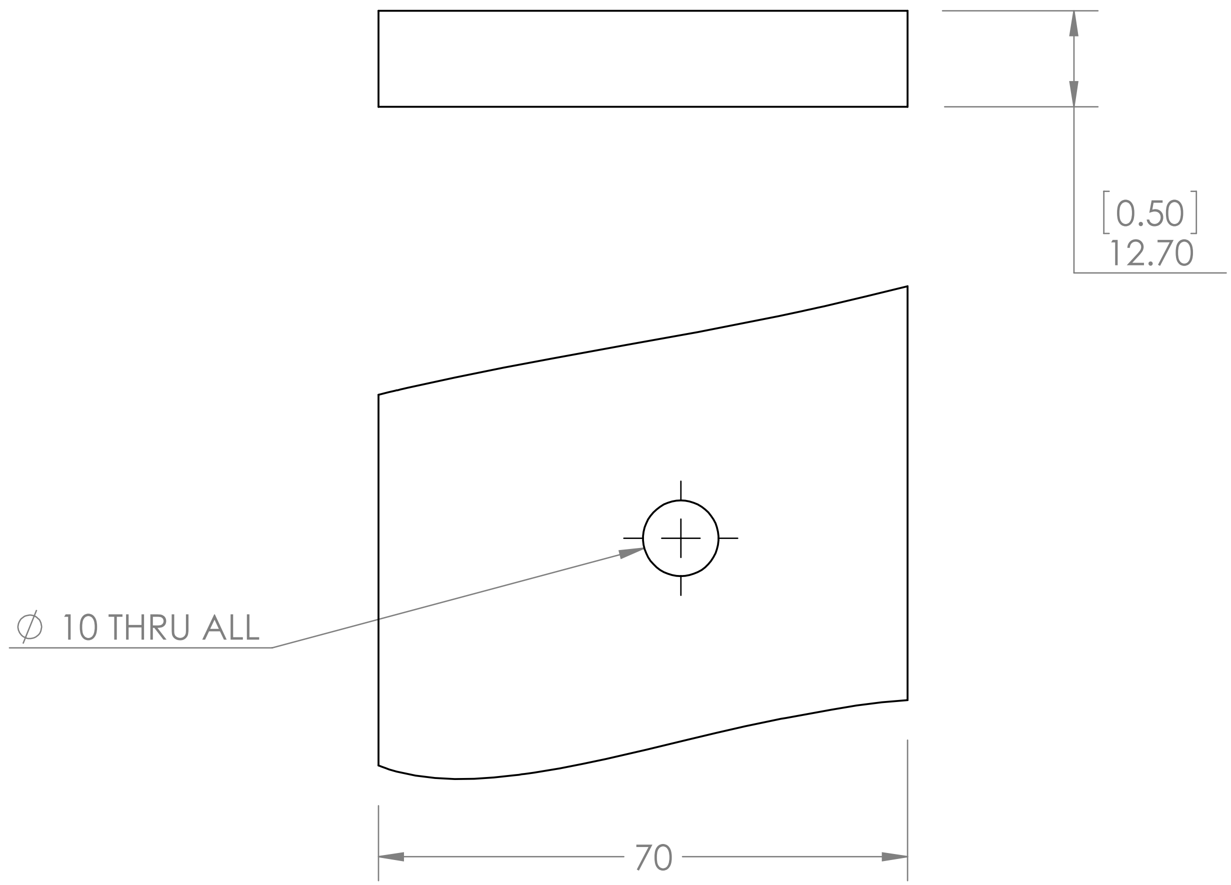
TITLE:

Layer 5

SIZE **A** DWG. NO. 5 REV

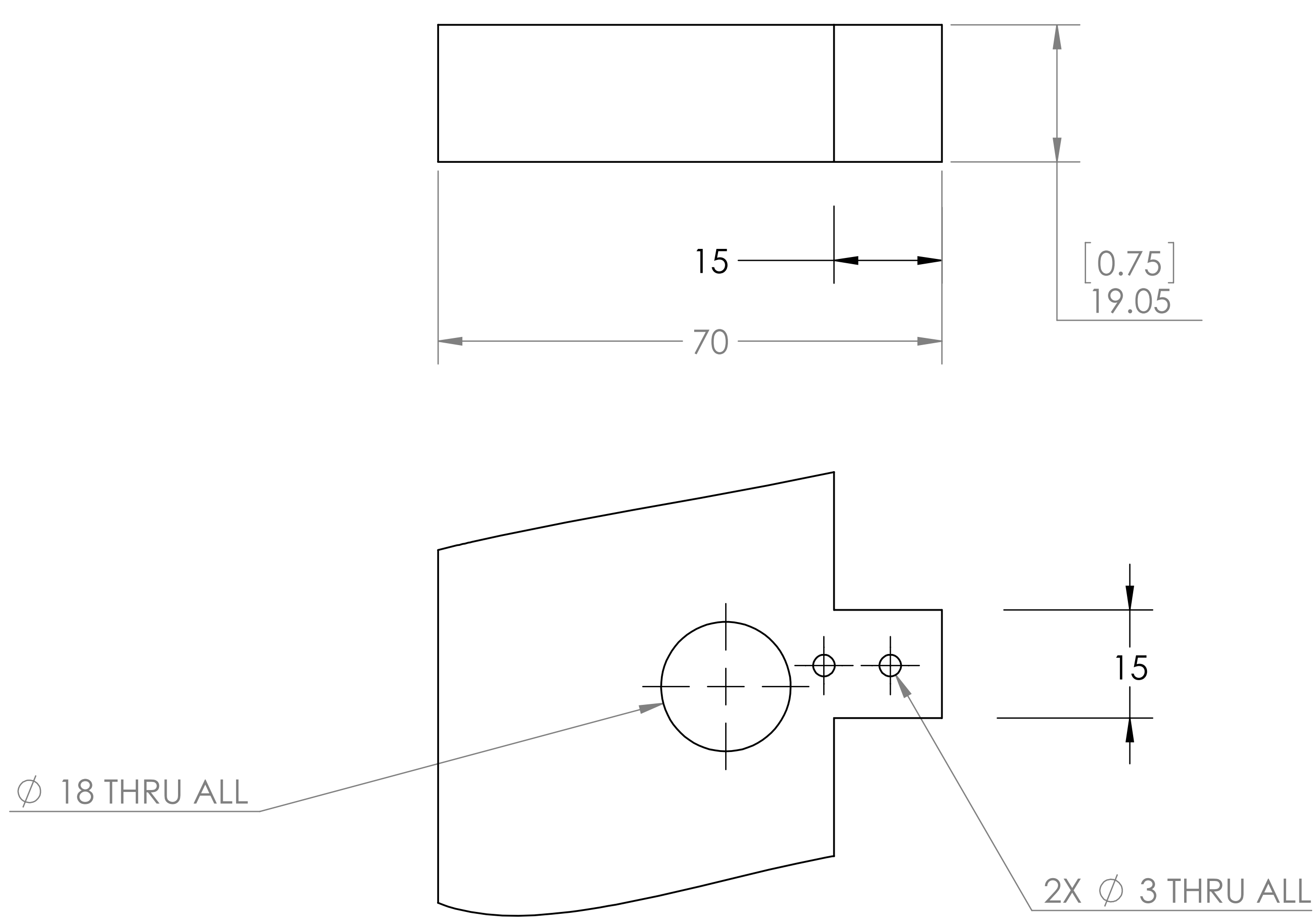
SCALE: 1:1 WEIGHT: SHEET 1 OF 1

5 4 3 2 1



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN MM [IN] TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN	JK	5/25/12	
			CHECKED			TITLE:
			ENG APPR.			Top Layer
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL DELRIN (R)	COMMENTS:			SIZE A — DWG. NO. 6 — REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 1:1 — WEIGHT: — SHEET 1 OF 1

5 4 3 2 1



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN MM [IN] TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN	JK	5/25/12	TITLE:
			CHECKED			Vulcrepe Block
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL VULCREPE	COMMENTS:			SIZE A · DWG. NO. 7 · REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 1:1 · WEIGHT: · SHEET 1 OF 1

5 4 3 2 1