Low-Cost Prosthetic Leg for the Vida Nueva Prosthesis Clinic

by

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Abstract

The Piernas de Vida team partnered with the Vida Nueva Clinic of Prostheses and Orthoses in Choluteca, Honduras to design, plan, and implement a prosthetic foot that could be manufactured entirely by the technicians at the clinic in order to reduce their costs and ultimately allow them to serve more patients each year. Currently, the clinic uses a prefabricated prosthetic lower limb provided by the International Committee of the Red Cross (ICRC) which can be adapted to both trans-femoral and trans-tibial patients. The team has successfully developed a foot, currently called the Layer Foot, which can be used by the clinic and reduces the expense to purchase a prosthetic foot by more than half. The foot has a simple geometry, which allows for ease of manufacturing, and is made of Delrin, a self-lubricating thermoplastic which is very easy to machine. Multiple iterations have been carried out based on results from both static testing and patient gait analysis, however further testing including cyclic fatigue testing will be necessary for the Layer Foot to compete as a viable product. Future Cal Poly design teams will be assigned the task of carrying out further iterations and developing more advanced testing methods in order to validate the durability and overall design of the product.

Table of Contents

List of Tables iii

List of Figures iv

Nomenclature vi

Chapter

1 Introduction 1

1.1 Project Description 1

1.2 Engineering Specifications 2

1.3 Project Management 4

2 Background 5

2.1 Existing Designs 5

2.2 Materials 8

3 Concept Selection 11

3.1 Ideation 11

3.2 Concepts 12

3.3 Down Select 17

4 Final Design 22

4.1 Layer Foot 22

4.2 Further Iterations of Layer Foot 28

4.3 Material Selection/Explanation 29

4.4 Cosmetic Covers… 30

4.5 PET Processing… 31

5 Product Realization 33

6 Design Verification 35

6.1 ISO Testing 33

6.2 Patient Testing- America 35

6.3 Patient Testing- Choluteca 38

6.4 PET Testing… 40

7 Conclusions and Recommendations 47

7.1 Conclusions 47

7.2 Recommendations 47

References ……………………………………………………………………………………………………..50

Appendix A HOQ, Pugh Matrix, Proof of Concept Analysis 51

Appendix B Final Drawings...65

Appendix C List of Vendors, Contact information, Pricing 73

Appendix D Vendor Supplied Data Sheets 74

Appendix E Detailed Supporting Analysis 78

Appendix F Gantt Chart...90

Appendix G Stakeholder Analysis..98

List of Tables

Table 1.1 Design Specifications 3
Table 1.2 Piernas de Vida Team Divisions. 4
Table 3.1 Subsystem Matrix 11
Table 3.2 Results of Rim Foot Analysis 18
Table 3.3 Results of Layer Foot Analysis 19
Table 3.4 Cost estimate of pylon cup adapter 20
Table 4.1 Final Dimensions of Layer Foot 25
Table 4.2 Bill of Materials for Layer Foot 28
Table 4.3 Bill of Materials for second generation Layer Foot 29
Table 6.1 Legend of Angles for ISO Test Set-up. 33
Table 6.2 Compression Molding Parameters Tested 45
Table A.1 HOQ for Foot 51
Table A.2 HOQ for Ankle Adapter 52
Table A.3 Pugh Matrix for Ankle Adapter 53
Table A.4 Pugh Matrix for Foot 54
Table A.5 Pugh Matrix for Knee 55
Table E.1 Coordinates of Top Load Application Point and Tilting Axis 79
Table E.2 Test Forces for all Tests 79
Table E.3 Excel Results for Roll-over Analysis 88

List of Figures

Figure 1.1 Reina Estrada, Director of Vida Nueva 1
Figure 2.1 Cross-Section of Jaipur Foot 5
Figure 2.2 Inverted Pyramid Adapter 6
Figure 2.3 Stability Diagram of Prosthetic Knee 7
Figure 2.4 Three Prosthetic Knees Designed for Developing Countries 8
Figure 2.5 CES Graph Comparing Tensile Strength and Young's Modulus 9
Figure 2.6 CES Graph Comparing Price and Density 10
Figure 3.1 Solid Model Rendering of Layer Foot 12
Figure 3.2 Solid Model Rendering of Rim Foot 12
Figure 3.3 Solid Model Rendering of Uni-axial Ankle 13
Figure 3.4 Side View of Ankle Bolt 13
Figure 3.5 Solid Model Rendering of Rail Adapter 14
Figure 3.6 Solid Model and Section View of Pylon Cup Adapter 14
Figure 3.7 Concentric Tube Adapter 15
Figure 3.8 Cradle Adapter 15
Figure 3.9 Two Plate Adapter 16
Figure 3.10 Cam Knee 16
Figure 3.11 Points of Interest for Layer Foot Stress Analysis 18
Figure 4.1 Solid Model Rendering of Layer Foot with Ankle Adapter 22
Figure 4.2 Isometric View of Layer Foot 22
Figure 4.3 Depiction of Roll-over Shape 23
Figure 4.4 Graph of Roll-over Shape 25
Figure 4.5 Comparison of Calculated Roll-over Shape with Natural Foot 26
Figure 4.6 Rendering of third generation Layer Foot 29
Figure 4.7 Cal Poly IT Lab Compression Molding Machine 31
Figure 5.1 Jen and Justin Cutting Prototype Material with the Table Saw 33
Figure 5.2 Six Prototypes for Use in Vida Nueva 34
Figure 6.1 Test Angles for ISO 22675 35
Figure 6.2 ISO Plate- Not Supporting Full Foot 35

Figure 6.3 Solid Model of ISO Test Fixtures 36
Figure 6.4 Broken Pyramid Adapter 36
Figure 6.5 Patient Testing on Force Plate with Reflectors 38
Figure 6.6 Reference Coordinate System for Force Plate Testing Setup....................37
Figure 6.7 Sample Roll-over Shape from Patient Testing 39
Figure 6.8 Original Layer Foot with 0.5 inch Layers 40
Figure 6.9 Modified Design with Middle Layer Shifted Forward....................40
Figure 6.10 Honduran Patients Testing Layer Foot 41
Figure 6.11 Modified Foot with EVA Foam 41
Figure 6.12 Sample of Vulcrepe Rubber....................41
Figure 6.13 Plastic Pieces in the Melting Pan....................43
Figure 6.14 Discolored and Brittle Plastic 43
Figure 6.15 Cal Poly IT Compression Molding Machines 44
Figure 6.16 Square Mold Filled with PET Pellets....................44
Figure 6.17 RPET Testing Results 46
Figure 7.1 Vida Nueva Staff and Patients 48
Figure B.1 Assembly Drawing and Bill of Materials for the Layer Foot 65
Figure B.2 Drawing of the Bottom Layer of the Layer Foot 66
Figure B.3 Drawing of the Middle Layer of the Layer Foot 67
Figure B.4 Drawing of the Top Layer of the Layer Foot 68
Figure B.5 Assembly Drawing of Revised Layer Foot 69
Figure B.6 Drawing of Top Layer of Revised Layer Foot 70
Figure B.7 Drawing of Middle Layer of Revised Layer Foot 71
Figure B.8 Drawing of Bottom Layer of Revised Layer Foot 72
Figure E.1 Test Set-up for Forefoot Ultimate Strength Testing 78
Figure E.2 Roll-over Shape Varying Length of Middle Layer 82
Figure E.3 Roll-over Shape Varying Length of Top Layer....................82

Nomenclature

- **Angulation:** Changing of an angle
- **Anterior/Posterior:** In front of/behind the body
- **Articulated:** Capable of pivoting
- **Center of Pressure:** The point where a distributed load can be resolved into a single load.
- **Chain Scission:** Breaking of the bonds in a polymer chain.
- **Compression Molding:** Shaping a material by applying heat and pressure in a mold.
- **Cyclic loading:** Loading that varies in a periodic manner.
- **Degrees of Freedom:** Numbers of directions a body is free to rotate and translate.
- **Delrin (Polyoxymethylene):** A self-lubricating thermoplastic.
- **Dorsiflexion/plantar flexion:** Rotating the ankle such that the toe points up/down.
- **EVA foam:** A foam used to make cosmetic covers for prostheses.
- **Eversion:** Rotation of the ankle such that the sole of the foot moves away from the centerline of the body.
- **Extrusion:** Shaping a material by heating it and forcing it through a die.
- **Flexion/extension:** Rotating about a joint that decreases/increases the angle.
- **Force plate:** A flat surface embedded in the ground capable of measuring forces imparted upon it.
- **Gait Cycle:** The periodic movement of the legs that leads to motion. Characterized by heel strike, midstance, and finally toe-off.
- **Hyper-stabilized polycentric four-bar mechanism:** Mechanism used in place of the knee for trans-femoral amputee. It provides stability and controlled motion because the instant center is posterior to the load line.
- **ICRC:** International Committee of the Red Cross. A non-government agency that provides worldwide aid.
- **Injection Molding:** Shaping a material by shooting molten material into a mold.
- **Inversion:** Rotation of the ankle such that the sole of the foot moves toward the centerline of the body.
- **ISO:** International Standards Organization.
- **Kinematic Data:** Information about an object's position in space and time.
- **Kinetic Data:** Information about the forces and moments acting upon an object.
- **Load control:** A material test where the amount of force applied is varied.
- **Medial/Lateral**: Toward/away from the centerline of the body.
- **Non-articulated:** Incapable of pivoting.
- **Proximal/Distal:** Closer to/farther from the center of the body, e.g. the foot is distal to the knee.
- **Roll-over Shape:** The position of the center of pressure relative to a coordinate system fixed to the shank during the gait cycle.
- **Static loading:** Loading in which the loads or displacements are constant.

- **Thermoplastic:** A plastic that returns to a liquid state when enough heat is applied.
- **Trans-tibial:** An amputation through the tibia.
- **Trans-femoral:** An amputation through the femur.
- **Polyethylene Terephthalate (PET/RPET):** A thermoplastic found in plastic soda bottles.
- **Polypropylene (PP):** A thermoplastic used in many ICRC prosthetic components.
- **Vulcrepe:** A vulcanized rubber used in shoe soles.
- **0.5" original:** This was our original design with three 0.5 inch thick layers. All three layers were staggered.
- **0.375" original:** Same design as 0.5" original but each layer was 0.375 inches thick.
- **0.25" original:** Same design as 0.5" original but each layer was 0.25 inches thick.
- **0.375" modified:** In this design the middle layer was shifted forward to be in line with the top layer. This was done to soften the heel and stiffen the toe. Each layer was 0.375 inches thick.
- **0.25" modified**: Same design as 0.375" modified but using 0.25 inch layers.
- **0.1875" modified:** Same design as 0.375" modified but using 0.1875 inch layers.

Chapter 1- Introduction

1.1 Project Description

1.1.1 Statement of Purpose

We are an interdisciplinary team of four engineers designing a low-cost prosthetic leg for the Vida Nueva Clinic in Choluteca, Honduras, and an adjustable ankle adapter for the Rotary Club of La Paz's prosthesis clinic in La Paz, Bolivia. Our product will provide a unique solution that meets the specific needs of our stakeholders. This project serves as the starting point for a long-term collaboration between the Cal Poly student chapter of Engineering World Health and clinics throughout Central and South America.

1.1.2 Customer Need

Walking is such an important part of everyday life in the developing world that it is frequently taken for granted. In Choluteca, Honduras, public transportation is sparse and the roads are often riddled with potholes and cracks. Many of the patients at Vida Nueva, and throughout Honduran clinics, have had a limb amputated due to injuries sustained while stowing away on trains bound for the United States. During a needs assessment trip we interviewed patients who described how they "had the American dream" and sought the opportunities available in America. Their stories illustrated the limited opportunities found in most parts of Honduras and the need for low-cost care solutions. Coupled with the injuries sustained through train accidents are those caused by land-mines, diabetes, or other health issues. To serve this large population of amputees, clinics like Vida Nueva need a low-cost option that will allow their patients to work and travel pain-free. Furthermore, just as the need for low-cost prostheses is great in Honduras, many countries in Central and South America have large amputee populations and can benefit from a low-cost prosthesis design.

Our second partner, the Rotary Club in La Paz, Bolivia has been providing local amputees with prosthetic devices for the past 15 years. They recently opened their own independent clinic in early 2011 and have begun fabricating their own prosthetic legs. The clinic has already picked out the knee and foot designs they are going to implement, but they have not developed an adjustable adapter to connect the foot to the pylon. In order to meet their goal of 100% in-house fabrication, they need a low-cost adjustable ankle adapter designed to be used with their foot and pylon.

1.1.3 Stakeholders

This project has potential to positively impact many people if it is implemented properly. The most obvious stakeholder is Vida Nueva Clinic in Choluteca, Honduras. Reina Estrada, director of Vida Nueva, seen at right in Figure 1.1, will gain access to high quality yet low-cost devices, allowing her to provide prostheses to more clients. The Vida Nueva technicians Roque and Walter will also benefit from the opportunity to provide their patients with higher quality components and will profit from improved

Figure 1.1: Reína Estrada, director of Vida Nueva

adjustability in the components and control over the manufacturing processes.

A second large category of stakeholders is the patients. Many of them had previously been concerned with how quickly the foot deteriorated and were especially concerned with alignment. Components that maintain alignment for at least six months will cut down the number of trips they have to take to the clinic each year. Furthermore, parts that both cost less and have a longer usable life will cut down on the overall cost to each patient. With lower costs more patients can afford the devices and any replacement parts.

The third stakeholder is Matt Pepe with Rotary Club in La Paz, Bolivia. He has designed components that work well with locally available materials, but would like to explore better ankle-adapter options. Our universal adapter will give him better adjustability than the washer design he is exploring and will likely maintain alignment longer. It will also cost less than the typical adapters found on the market so he can provide more patients with prostheses.

Matt Robinson, a prosthetist local to San Luis Obispo, holds some stake in the project because it is a place for him to explore a few designs and provide his experience as a prosthetist to help these developing clinics advance.

Lastly, Cal Poly students hold stake in the project. This project can continue over the next few years and provide several groups of students the opportunity to design and implement prostheses. We have seen a large interest amongst Cal Poly students in prosthesis design and many students can benefit from the experience of designing for a foreign developing country. The Cal Poly chapter of Engineering World Health has committed to participating in design projects as well as providing members for future senior project teams. These students will benefit from many learning opportunities, including cross-cultural engineering, low-cost design, and multidisciplinary team dynamics.

A more detailed table of stakeholder analysis can be found in Appendix G.

1.2 Engineering Specifications

The ultimate goal of the Piernas de Vida design team is to develop an affordable and easily manufacturable prosthetic leg that will serve both above-knee and below-knee amputees. Through a series of correspondences with Reína, Walter, and Roque from the Vida Nueva clinic as well as Matt Pepe in Bolivia, we discussed the needs of the patients and developed a set of qualitative requirements. To assign quantitative specifications we broke the design down into four subsystems: Knee/Articulator, Adapter, Ankle-Foot System, and Pylon. Then, through the design comparisons described below we determined that the Le Tourneau M1 knee fulfills our requirement and have chosen to implement it as the Knee/Articulator component of our final design. For each remaining subsystem, we developed a complete set of specific engineering specifications, seen here in Table 1.1.

Table 1.1: Design Specifications

Spec #	Parameter Description	Requirement or Target	Tolerance	Risk	Compliance
Adapter (Male and Female Ends)					
1	Degrees of Freedom	1	Min	M	A,T,S,I
2	Angular Adjustment	±8-10 degrees	Min	M	A,T,S,I
3	Range of Adjustment	± ¼ in	Min	M	A,T,S,I
4	Adapt with existing systems	Fits	Min	H	A,I,S
5	Weight Forbearance	380kg	Max	H	A,T
6	Manufacturing	Mill	-	L	T,I
7	Maintain Alignment	12 months	Min	H	A,T,I
Ankle-Foot System					
1	Heel Strike Force	2.5 N/kg body weight	Min	H	A,T
2	Ankle-Angle Response	Actual response	±50%	M	A,T,I
3	Manufacturing	Mill	-	L	T,I
4	Deterioration	<5% in 2 years On highly distressed roads	Min	H	A,T,I
5	Tibial advancement and ambulation	Normal	Min	M	T,S,I
6	Cost	<$30	Max	L	A,S
7	Weight	0.23-0.8 kg	Max	M	A,T,I
8	Shape and sizing	Fit shoe or external soling	-	L	A,T,I
9	Proof Load Bearing	ISO standard 22675 16.2	Min	H	A,T
10	Ultimate Strength	ISO standard 22675 16.3	Min	H	A,T
11	Fatigue Strength	ISO standard 22675 16.4	Min	H	A,T
Pylon					
1	Weight Forbearance	115 x s.f. 3.28	Max	H	A,T
2	Durability	No Fatigue Failure within 3 years	Min	H	A,T
3	Weight	200-280g	Max	M	A,T,I
4	Manufacturing	In Choluteca	-	L	I
5	Interfacing	With all pylon adapters	-	L	A,T,I,S

A=Analysis I= Inspection T=Test S= Similarity to existing designs

L= Low M= Medium H= High

Each specification was carefully selected based on comparisons with existing products, design standards, such as ISO 22675, and our project's unique goal of in-house manufacturability. The designation of high (H), medium (M) or low (L) risk given to each specification is an assessment of the risk associated with not meeting each requirement. Also we have specified how to gauge whether the specification has been met; these methods include analysis (A), testing (T), inspection (I), similarity to existing designs (S), or any combination of the four.

Matt Robinson was extremely instrumental in developing the engineering specs. He has many years of experience with prostheses and orthoses and is familiar with necessary measurements for properties such as angulation, translation, durability of components, and more. Matt was consulted during the development of the specifications in order to ensure that they are achievable and relevant. The specifications were also approved by Walter, Roque, and Reina.

1.3 Project Management

Throughout the year our project roles morphed into the following:

Table 1.2: Piernas de Vida Team Divisions

Team Member	Primary Task	Tasks
Sarah Baker	PET processing	• Materials and manufacturing specialist • Contact with materials professionals • Research Recycling processes
Justin Lekos	Testing and Design	• Assist with testing procedures • Partner with design analysis • Contact with Vida Nueva
Jen Van Donk	Writing and Networking	• Lead report writing and editing • Project sustainability- grant, conferences, EWH contacts, etc. • Lead Manufacturing
Kevin Yamauchi	Design and Solid Modeling	• Perform design analysis • Create solid models and design drawings • Lead patient testing analysis

A completed Gantt chart for our project can be found in Appendix F.

Chapter 2-Background

2.1 Existing Designs

Before we could begin a new design we had to investigate existing products in order to provide a baseline, as well as ensure we were not copying an existing design. We performed a search and literature review of existing components and compared their strengths and weaknesses. We intended to use this information to guide our modifications to ensure we came up with a product that was superior in some capacity. Our review of these products follows.

2.1.1 Foot Design

While there are many prosthesis designs, there are few success stories in developing a prosthetic foot for low-income patients. Some designs effectively address the issue of affordability in developing countries while sacrificing accessibility and performance. The three leading designs for affordability are the Solid Ankle Cushioned Heel (SACH) foot, Jaipur foot, and Niagara foot. Other high end feet, like the Flex foot, produce very natural gaits but are difficult to manufacture in the developing world.

Prosthetic feet can be categorized as either articulated or non-articulated. Non-articulated feet are popular in the developing world because they are simple and affordable. The Solid Ankle Cushioned Heel (SACH) foot, Jaipur foot, and Niagara foot are some of the most effective prosthetic feet designed for use in developing nations.

The SACH foot is one of the most widely used low-cost prosthetic feet, and is offered by organizations such as the International Committee of the Red Cross (ICRC), Veterans International in Cambodia, and Handicap International. The SACH foot is comprised of a solid keel that extends from the ankle to the toe and a cushioned heel made from a more compliant material. The keel is most often made of polypropylene, and serves as the ankle joint to which the pylon of the prosthesis connects via a rigid bolt attachment. The SACH foot does not produce a natural gait because the rigid keel does not allow the necessary dorsiflexion[1]. Deterioration of exterior materials is also a common problem experienced by SACH foot users. For example, the ICRC SACH foot has a polyurethane coating that breaks down in high temperature and humid environments[2]. Vida Nueva implements the ICRC SACH foot and has observed that the feet must be replaced within two years due to deterioration of the polyurethane coating. Also, the SACH foot requires expensive molding and equipment in the fabrication process, so a small clinic cannot manufacture their own. While Vida Nueva is currently implementing SACH-type feet, they would benefit from a design with improved durability at lower cost.

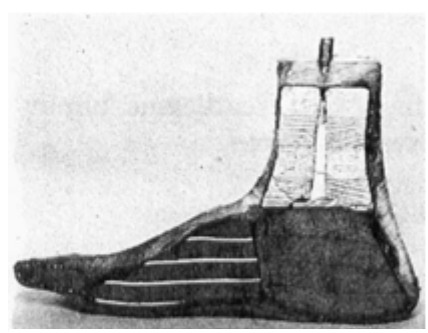

Figure 2.1: Cross-section of the Jaipur foot, demonstrating the compartmentalized design[3]

The Jaipur foot was developed in 1968 by Dr. P. K. Sethi, an Indian Orthopedic surgeon, and Masterji Ram Chander, a social worker, in Jaipur, India[3]. The foot was developed to replace imported feet that did not allow users to participate in important cultural norms, such as wearing sandals or kneeling for prayer. The Jaipur Foot consists

of a wood block, rigidly attached to the pylon via a carriage bolt, and a system of compliant materials, all encased in vulcanized rubber. The compliant interior materials function similarly to the bones of a normal human foot. The foot costs around $30US to manufacture[4]. While the Jaipur foot is affordable, its manufacturing process requires specialized equipment so they must be produced at a centralized location.

While two models described above have served as the standard for low-cost solutions for many years, more advanced designs have implemented composite structures or plastics to store energy from the loading response phase and release it during the push-off phase. Such designs decrease the metabolic energy expended by the user during gait and produce a more natural gait cycle. A very popular energy-return concept is the Niagara Foot, developed by a group of Canadian scientists for landmine victims. The foot, one of the least expensive of the energy return style, is made from Delrin, a flexible thermoplastic, and is designed to produce dorsiflexion and plantar flexion similar to that of a healthy foot. It is has a high fatigue life because it is designed for more active individuals. While the Niagra Foot is the most affordable energy-return foot available, the manufacturing process uses injection molding, a technique that Vida Nueva cannot easily perform on their premises[5].

The Flex Foot also provides energy return to the user; however it is made from carbon fiber composite material and thus can be extremely costly. This high cost prevents their use in a clinic such as Vida Nueva. These components are typically only used in developing countries if they are donated to a clinic. While these components are generally more comfortable for the patients, they are not a sustainable alternative for low-income patients.

These designs each offer a benefit, however the critical element missing in each of them is the ability to manufacture the foot in-house. While many are low cost, clinics must still purchase them and import them from another source. If we can use local materials and allow the clinics to manufacture the components they will be less dependent on foreign sources and be able to fit more patients with prostheses. Therefore our design will focus on the manufacturability and aim towards a product that requires only basic shop tools.

2.1.2 Ankle Adapter Designs

The ankle adapter performs the function of interfacing the foot with the pylon and simultaneously allows a clinician to make adjustments of the angulation and translation between components. During a clinic visit, the technicians make adjustments in the medial-lateral, anterior-posterior, and proximal-distal directions as well as rotation about each axis. Poor adjustment can lead to discomfort and an unhealthy gait cycle for the patient. While a standardized adapting device has not been implemented, there are a variety of designs that may accomplish this task.

Figure 2.2: Inverted pyramid with male (left) and female (right) ends[6]

Arguably the most widely used adjustment mechanism is a "male-female" type adapter with an inverted pyramid

and hemisphere as the male, seen on in Figure 2.2, and four independent set screws on the female end. Typically the female end attaches to the pylon while the male end attaches to the connecting component. This allows four degrees of freedom, as mentioned above, and is effective in adjusting to patients' needs. This geometry, however, is difficult to machine and requires more complex equipment than that which is available at Vida Nueva.

A different, more complex design uses adjustable helical gears to set the location of the knee. These types of complex systems are impractical in the conditions of Honduras, where most areas have dirt roads and a lot of dust particles in the air that can penetrate into the gears and increase the rate of wear within the components. Additionally, maintaining these parts requires that the clinic have a significant stock of replacement parts. Vida Nueva does not have the capacity to keep a large supply of materials so this is not a sustainable option.

2.1.3 Knee Designs

The overarching goal of all prosthetic knees is to replicate the kinematic and kinetic behavior of healthy knees, allowing the user to ambulate with stable, pain-free, gait[7]. There are many designs currently available but the following literature review focuses on the models currently deployed in developing nations.

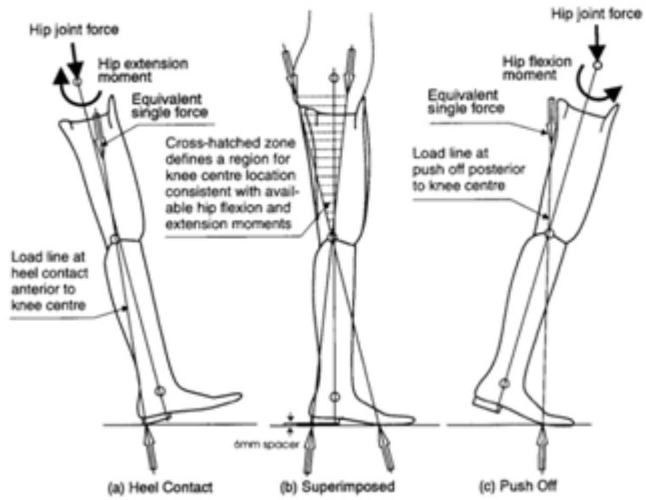

Figure 2.3: Example of a stability diagram of a prosthetic knee. Notice the location of the knee center relative to the load line[8]

Vida Nueva currently implements the ICRC Uniaxial knee, pictured below in Figure 2.4C, in their above knee prosthetic legs. Uniaxial knees are the simplest articulated prosthetic knees. They articulate about a single degree of freedom hinge and often implement a constant friction system to control the rate at which the knee rotates during the swing phase of gait. The ICRC uniaxial knee does utilize this constant friction system and has a manual lockout that locks the knee at full extension. A major drawback of uniaxial knees is that their stability is dependent on the location of the load line in relation to the center of rotation. Figure 2.3 above shows a stability diagram for a normal gait cycle. The schematic shows the location of the knee center and load line during various phases of the gait cycle. With this inherent instability the knee can easily buckle or become unstable under loading, especially on rough surfaces. Users have to continuously compensate for the variable loading experienced when walking on uneven surfaces[8]. As previously mentioned, many of the roads in Honduras are rough and uneven, exacerbating the inherent instability found in uniaxial knees. Furthermore, Vida Nueva purchases the ICRC Uniaxial knees from the Unites States and Switzerland, which incurs significant import costs, likely higher than if they were to simply import material and manufacture the components in-clinic. Vida Nueva can better meet their patients' needs if they implement a more stable knee that can be manufactured in-house.

The LeTourneau M1 knee, pictured below in Figure 2.4A, articulates with a hyper-stabilized polycentric four-bar mechanism and can be manufactured with tools commonly available to clinics in developing nations. Hyper-stabilized polycentric four-bar mechanisms provide stability during heel strike and remain stable during push off because the instant center is posterior to the load line[9]. This stability is ideal for the rough roads found in Honduras. The M1-knee is constructed of Delrin, a low-cost, self-lubricating plastic. Since the knee is built from low-cost materials and is manufacturable by the clinics, it only costs $20 to produce[10].

Figure 2.4: Three prosthetic knees designed for developing nations: the LeTourneau M1[11] (A) the Re:Motion Designs JaipurKnee[12] , and the International Committee of the Red Cross Uniaxial Knee

The Re: Motion Designs JaipurKnee, pictured above in Figure 2.4B, is a competitor to the LeTourneau M1. Like the M1, the JaipurKnee is a polycentric, four-bar mechanism. They differ in that the JaipurKnee bears the load on the blocks, rather than linkage at full extension. The JaipurKnee is constructed of an oil-impregnated nylon and is manufactured with Computer Numeric Control (CNC) machines. While the JaipurKnee is manufactured on expensive machinery, it only costs approximately $20 to produce[12]. Even though the JaipurKnee offers stability at a low cost, the requirement of CNC machines makes it difficult to produce in-house.

2.1.4 Pylon

Standard modular prostheses use a 30mm aluminum or carbon composite pylon. ICRC components use a variation of this design that has a polypropylene exoskeleton over an aluminum rod. Our design will adapt with modular prostheses as well as the ICRC components.

2.2 Material

An important part of the design is material selection. The team has evaluated several materials to determine the most cost-efficient material that can support our high expectations for quality.

2.2.1 Polypropylene

Polypropylene (PP) is currently used at Vida Nueva for the ankle adapter and cosmetic cover. Vida Nueva receives one shipment a year from the International Committee of the Red Cross of all their components, including Polypropylene. PP is a thermoplastic polymer, meaning it turns liquid when heated and freezes to a glassy state when cooled, and can be re-melted and molded into different shapes as many times as needed. Polypropylene is an ideal material for third world applications due to

its low cost. However, when compared to a Polyethylene Terephthalate and Polyoxymethylene, it significantly lacks in tensile strength and elastic modulus, as seen in Figure 2.5 below. Also, the staff at Vida Nueva has noticed that the PP cosmetic covers degrade quickly in the high heat and humidity that is common in Choluteca. This degradation is cause by chain scission, which occurs when oxide layers form on the surface layer of the PP. As a result, the molecular bonds of the side chain groups are lost, creating a shorter, degraded polymer chain.

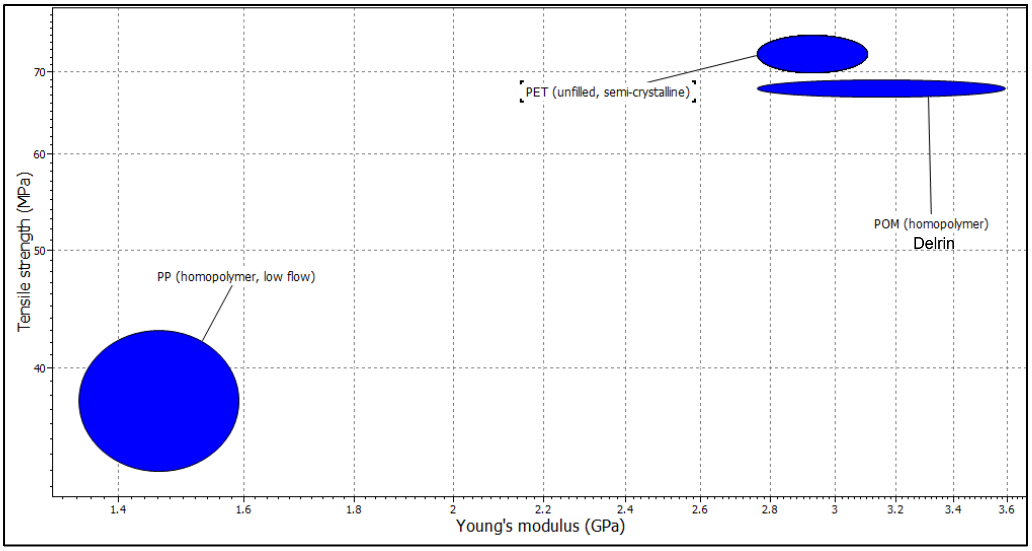

Figure 2.5: CES[15] graph comparing the tensile strength and Young's Modulus of PP, PET, and Delrin

2.2.2 Polyethylene Terephthalate

Polyethylene Terephthalate (PET) is a semi-crystalline thermoplastic polymer that plays a major role in the packaging of non-food and food related products. PET is sustainable, meaning it can be created out of 100 percent PET and does not need to be mixed with other types of plastic; therefore it maintains its original properties and energy. Through processing and re-manufacturing PET can be recycled back into society as packaging, fibers, and strapping. In order to implement PET into the clinic in Honduras we would need to develop a process for recycling the material on a small scale. If we can develop a sustainable small-scale process and equip Vida Nueva for PET recycling, then it would be a more viable choice than PP due to its high tensile strength and elastic modulus (Figure 2.5), as well as its higher durability against humidity and UV radiation.[15]

2.2.3 Polyoxymethylene

Polyoxymethylene, commonly known by its trade name Delrin, is another material option. The LeTourneau M1 knee is manufactured from Delrin because of its high tensile strength and because it can be machined easily. When compared with other medical grade plastics, Delrin (at $3.50 per kilogram) is fairly low cost, however it is more expensive than PP and PET (Figure 2.6). One advantage of Delrin over PET and PP is its ability to self-lubricate; this characteristic is particularly beneficial because it means the material has a low water absorption rate which is important in the humid climate of Honduras. This in turn leads to a lower wear rate. Furthermore, as mentioned above the M1 knee is manufactured from

Delrin, so the clinic must set up this supply chain if they begin to use that component. This makes Delrin a more attractive material option for the foot because they can simply purchase more from the same dealer.

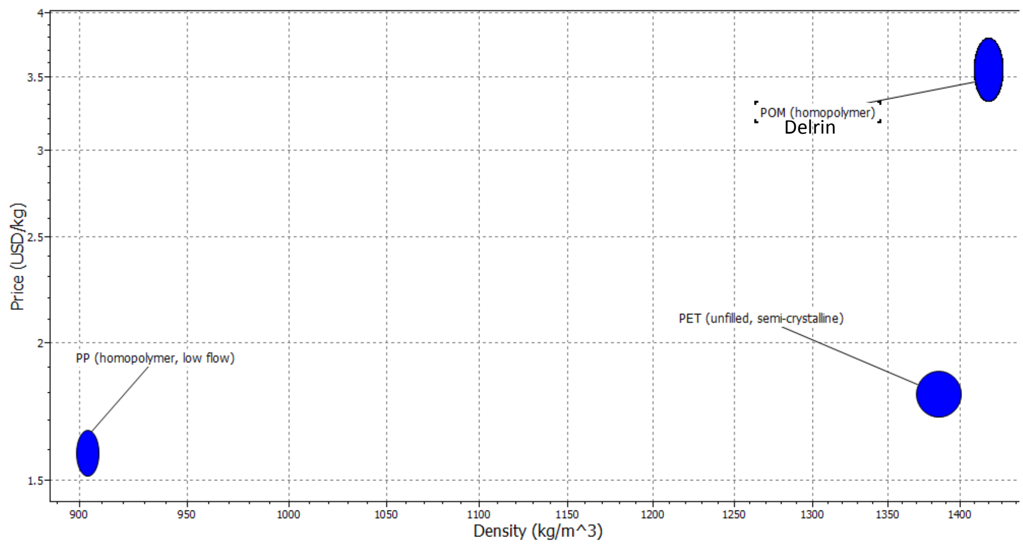

Figure 2.6: CES[15] graph comparing price and density of PP, PET, and Delrin

Chapter 3- Concept Selection

3.1 Ideation

We began the conceptualization phase by defining the problem and developing engineering specifications. After confirming our understanding of the customer needs and engineering specifications with Vida Nueva, we brainstormed and subsystem matrix to develop a selection of concepts. Using the subsystem matrix the prosthetic leg was divided into components and we brainstormed solutions for one component at a time. Several iterations of this process helped ensure we came up with as many concepts as possible. We then eliminated ideas that were deemed too far-fetched. The final subsystem matrix can be seen below in Table 3.1.

After the final subsystem matrix, we selected our top concepts with a decision matrix. The decision matrix compared each concept to our customer requirements in order to determine which concepts best met Vida Nueva's needs. Prototypes of the top concepts were constructed and each concept was analyzed to assess viability.

Table 3.1: Subsystem matrix used to develop concepts for each component of our prosthetic leg. Our top concepts are highlighted in yellow.

Prosthetic Leg				
Knee	**Foot**	**Pylon**	**Connector**	**Ankle**
4-bar linkage	flex foot	hollow circular tube	set screws	high friction bearing w/pin
uni-axial bolt	block	solid cylinder	notched pins	c-flex shape
2 hinged wooden blocks	horseshoe/rim foot		bolts	threaded rod (bolt up through the foot)
rigid connection	melt plastic and create molded foot		rails	ball and socket
guided cam and plateau	rubber tire strip with plastic bottle		threads	uni-axial with damper
	blade foot with multiple toes			
	shell foot			
	layered foot			

3.2 Concepts

3.2.1 Feet/Ankle

3.2.1.1 Layer Foot

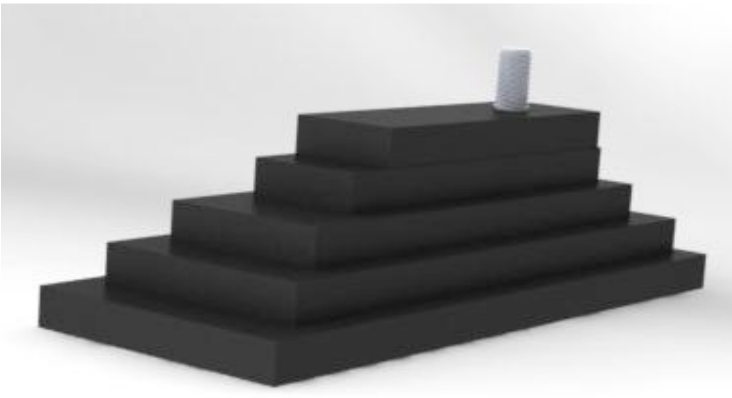

Figure 3.1: Solid model rendering of Layer Foot concept. This model incorporates layers of material that can move relative to one another providing the proper flexion.

The Layer Foot, seen in Figure 3.1, is composed of several layers of thin material of varying lengths and widths. Altering the layers' location and thickness modulates the stiffness of the foot. Potential materials to use with this design include PET, Delrin, or steel. It is also possible to layer multiple types of materials to vary the stiffness and flexion. This foot can be designed to be compatible with a cosmetic cover or shoe. A solid bolt ankle is ideal because the flexion will occur within the length of the foot. Furthermore, the bolt is necessary to securely hold all the layers together. It is possible to rivet the layers at different points to control stiffness and flexion with even greater accuracy.

3.2.1.2 Rim Foot

The rim foot, seen in Figure 3.2, is based on a bent tube or pipe secured between two plates. This foot provides flexion based on geometry and material selection. It is ideal because it is composed of less than ten components, nearly all of which can be readily found in Honduras including simple metal tubing and sheet metal. Depending on the stiffness of the rim, a rigid or articulating ankle may be appropriate. Another advantage to this design is that the plate provides a large platform to place the ankle on. It is also easier to manufacture because it requires few parts to assemble. The greatest downside to this concept is that it would not fit well into a shoe or cosmetic cover.

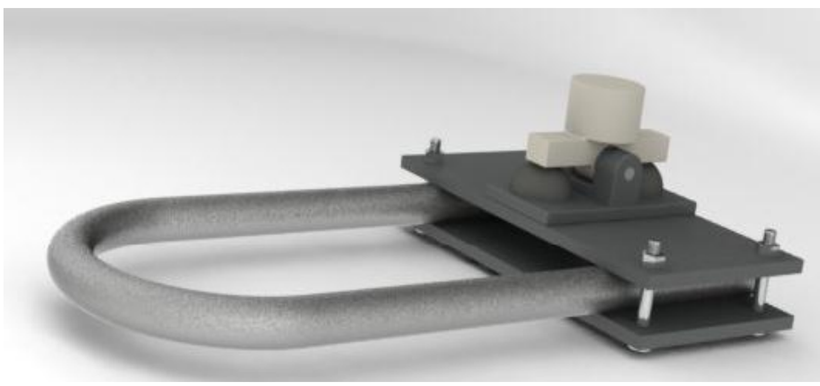

Figure 3.2: Solid model rendering of rim foot with uni-axial ankle. Rim foot is useful because it uses parts that would likely be readily available within Honduras.

3.2.1.3 Uni-Axial Ankle

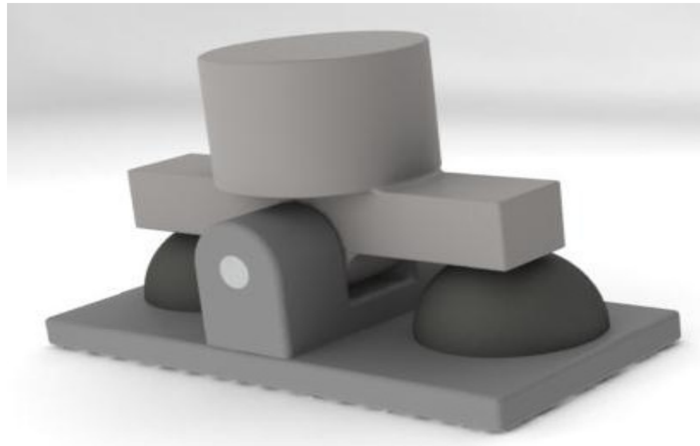

Figure 3.3: Solid model rendering of uniaxial ankle. Ankle is ideal for feet with limited flexion because it provides the necessary rotation.

The uni-axial ankle, seen in Figure 3.3, uses a simple hinged “tee” with rubber bumpers to control the flexion of the foot. The “tee” is supported on a shaft between two end-posts. This design supports smooth ankle flexion with a constant friction brake along the axle. The parts on this ankle are small and may be difficult to manufacture, however in spite of this difficulty the ankle could still be fully manufactured, a considerable advantage over the ICRC ankle Vida Nueva currently uses. This ankle is ideal for feet that are not designed to flex because it allows the foot to rotate.

3.2.1.4 Bolt Ankle

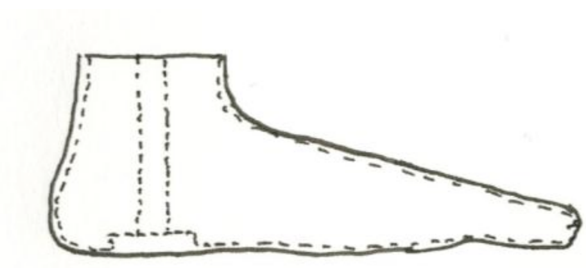

Figure 3.4: Side view of bolt ankle

The bolt ankle, seen in Figure 3.4, is a fixed ankle that has no ankle flexion control but is extremely simple to design, manufacture, and modify. This design uses a standard bolt that would be readily available in Honduras and is extremely low cost. Flexion control is required in the foot because it is not present in the ankle, so it is ideal for feet like the Layered Foot or SACH foot (where it is currently used). This ankle design would also provide the necessary compression to hold the pieces of the Layer Foot together.

3.2.2 Universal Adapter

After the first round of brainstorming we were still dissatisfied with the ankle adapter concepts we had developed. Therefore, we returned to the brainstorming phase but this time with slightly modified requirements. We spoke with Matt Robinson and he recommended we brainstorm ideas with fewer degrees of freedom and focus instead on ease of manufacturing and low part count. The ideas from our first round as well as our latest ideas are discussed below.

3.2.2.1 Rail Adapter

The rail adapter, seen in Figure 3.5, is similar to the inverted pyramid design that is commonly used in many prosthetic applications, but the configuration of the set screws differs slightly. Instead of the radial orientation of the screws, as seen on the inverted pyramid, the screws are oriented such that two screws are parallel on either side of the component. Due to this geometry, the male component is simplified to a rail, or protrusion that interfaces with the screws on either side.

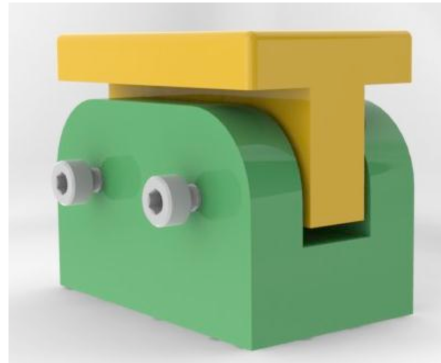

Figure 3.5: Solid model rendering of rail adapter.

This geometry, unlike the inverted pyramid, is feasible for the technicians at Vida Nueva to manufacture using the tools available. All cuts for this design are at right angles which would require a simple band saw or jig saw, and could possibly even be accomplished with a grinder.

The component allows for four degrees of freedom. Translation is provided in the anterior-posterior direction as well as a small amount in the medial-lateral direction, and rotation can be adjusted in both the sagittal and transverse planes. Both the medial-lateral translation and transverse rotation are dependent on the clearance within the slot, and would be considerably limited by this space. When adjusting this design to fit patients in the clinic, the technicians simply loosen the screws on one side. This allows the original alignment to be retained while translation in the anterior-posterior direction and rotation in the sagittal plane are adjusted. A disadvantage posed by this concept is the difficulty of retaining the rotational alignment in the transverse plane during adjustment, as well as the anterior-posterior translational positioning. A second disadvantage is that friction is the only element maintaining the alignment, and the positioning of the set screws is not ideal for maintaining large vertical forces. In order to attach to the pylon an additional cup fixture would be attached to the top of the adapter. To attach the adapter to the foot, the solid bolt from the foot would come up through the bottom of the adapter, similar to how the pyramid adapter functions. Due to its manufacturability and effective alignment capabilities, this concept is a viable option.

3.2.2.2 Pylon Cup Adapter

The pylon cup, seen in Figure 3.6, uses a cup that will slide around the pylon; this cup is attached to a small metal plate with a center hole cut out for the bolt, and four set screws at the corners of the plate

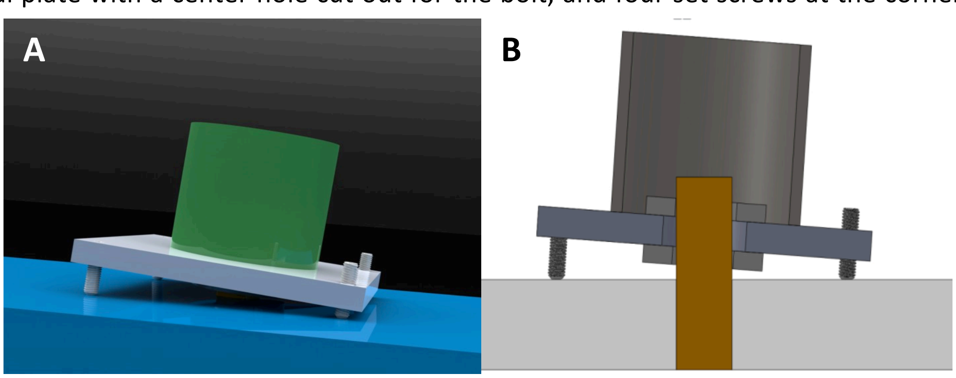

Figure 3.6: A solid model [A] and section view [B] of the pylon cup adapter. The pylon is inserted into the cup and the four set screws allow two axes of rotations (inversion/eversion and flexion/extension).

that allow the angle to be adjusted in both inversion/eversion and flexion/extension directions. The hole through the plate will be slightly larger than the diameter of the bolt to allow some rotations and translation. The bolt is fixed to the plate with a washer and nut above and below the plate. We like this design because it consists of only eight parts, is easy to manufacture, and will still allow at least three of the four degrees of freedom we were hoping for. A spherical washer will help maintain enough friction for the cup to remain aligned even if the pylon is at an angle. This spherical washer is placed below the adapter between the bottom plate and the foot. Four set screws will hold the cup adapter to the pylon to capture it in place.

3.2.2.3 Concentric Tube Adapter

The concentric tube concept, seen in Figure 3.7, strives for simplicity and versatility. The design is similar to the inverted pyramid adapter in that it uses four radially-oriented set screws to secure the male and female ends in a concentric or nearly concentric fashion. The design requires very minimal fabrication, which merely involves drilling and tapping the threaded holes for the screws.

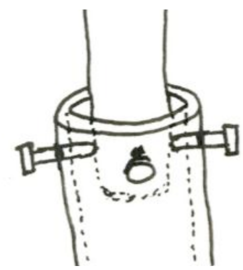

Figure 3.7: Concentric tube adapter- uses four set screws to hold alignment and provide simple adjustment.

The component can be translated in the anterior-posterior and medial-lateral directions, and rotated in the transverse axis. One large downfall to this simpler design is that rotational alignment is not provided in the sagittal plane, which may hinder proper alignment and lead to improper gait or the inability of the patient to use the prosthesis entirely.

3.2.2.4 Cradle Adapter

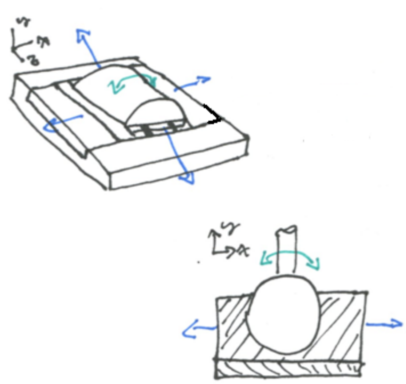

Figure 3.8: Cradle adapter allows translation in x and z directions with rotation about the z- axis.

The cradle adapter, seen in Figure 3.8, is a simple way of achieving translation and rotation. It is a very basic means of achieving only two degrees of freedom, but is easy to manufacture and has a low part count. The basic design is a cylinder cradled in a translating slider. There is a space in the cradle to allow movement in the z direction. The initial concept would use several set screws to fix the position in x and z directions. The greatest problem with this design is fixing the cylinder once the adjustment had been made.

3.2.2.5 Two Plate Adapter

The two-plate adapter, seen below in Figure 3.9, again uses set screws to provide adjustment between two plates, one attached to the pylon and the other fixed to the ankle bolt. The adjustment is held with c-clamps that slide over the set screws after adjustment. This design does provide the desired degrees of freedom but it has a high part count and many loose parts that could easily be lost.

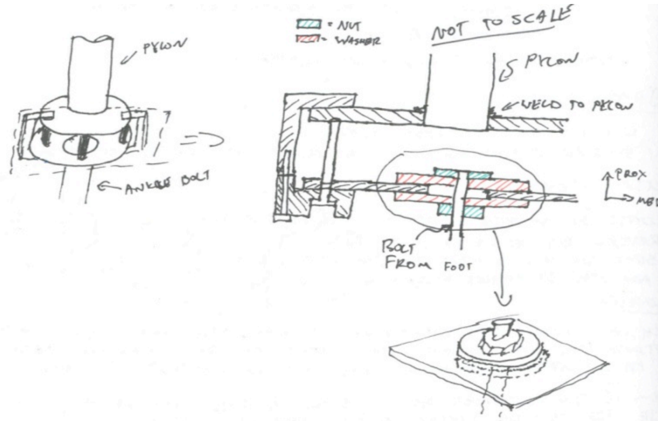

Figure 3.9: Two plate adapter offers incremental adjustment with four degrees of freedom

3.2.3 Knee

3.2.3.1 Cam Knee

The first concept idea that was selected to was the cam knee. The knee aims to mimic normal human anatomy by imitating the tibial plateau and femoral condyle with geometrically similar, yet much simpler, components. The plateau is formed into a cam shape that is specifically designed to provide the proper stability during the plant phase and to release easily during the swing phase of the gait cycle. The two components interface via elastic elements that act much in the same way as the ligaments in the human body, providing stability and assisting in the swing phase.

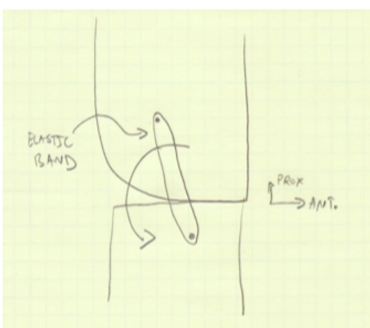

Figure 3.10: Cam knee provides similar movement to natural physiological knee. Elastic bands hold the two sides together as well as act as tendons to provide stability and assist swing phase

While this design is potentially less stable than other existing knee designs, many possible kinematic solutions are offered by varying the geometry of the plateau. This design is a strong candidate as it can be manufactured with the simple tools available in the clinic, and is relatively easy to assemble.

3.2.3.2 Four- Bar Linkage Knee

While there are many four-bar-mechanism-type solutions available for the knee, many variations can be explored during the detailed design phase. The four bar knee is effective in providing stability because of its symmetry and can be designed using geometries that are very easy to manufacture. Both LeTourneau and Stanford have developed four-bar linkage knees in their attempts to design low-cost prostheses for low-income nations.

3.2.4 Pylon

We did not brainstorm new ideas for pylons because we feel that the current design adequately fits our needs. Typical prostheses use 30mm aluminum tube pylons therefore we will incorporate this component into our design.

3.3 Down Select

In order to select our top concept from the brainstormed ideas we performed preliminary analysis to ensure that the idea was viable, looked at initial cost estimates, and created Pugh matrices to compare the design against other existing components.

3.3.1 Analysis

3.3.1.1 Uni-axial Ankle Analysis

The uni-axial ankle is a relatively simple design, utilizing a steel shaft that supports the pylon attachment component between the two supports. The loading of the shaft can be characterized by the schematic in Appendix E. The shaft was assumed to be 36mm in length, and 10mm in diameter.

The loading creates a large bending moment in the center of the shaft; this is where the critical failure point is. In order to ensure the viability of the design, we performed a stress analysis and compared the resulting maximum stress to the yield stress for steel. The magnitudes of the shear forces and moments seen throughout the shaft can be seen in Appendix A.

With the assumed geometry, the loads can be sustained without yield failure. The hand calculations found in Appendix A outline the method for analyzing the bending stress. The largest stress experienced by the shaft during testing is approximately 201.5MPa. This load is calculated using the peak ISO static loading case, which is about 3.28 times higher than average human weight. Therefore this load condition has a built-in safety factor of 3.28. When compared with the yield strength for steel, 250MPa, it is found that this stress state will not cause yielding and is therefore a viable design. Since the shaft is the most likely component to fail in the relatively simple design, we were able to retain the uni-axial ankle as a strong candidate.

3.3.1.2 Rim Foot Analysis

Per ISO Standard 22675 section 16.3, the foot must withstand the loading illustrated in Appendix E. In order to evaluate the feasibility of the rim foot design, we performed a stress analysis in the rim itself, which will experience the highest stresses and is most likely to fail due to yielding. First, a cut was made at the most posterior point of the rim that is in contact with the retaining plates. The rim experiences the largest bending stress here, and also sees a significant compressive load. A schematic and free-body diagram can be found in Appendix A.

We analyzed the bending moment caused by the vertical component of the loading on the toe, as well as the compressive load caused by the anterior-posterior component of the load.
The combination of these stresses gives the maximum compressive load experiences by the rim. Results for different schedule 40 pipe sizes, outlining the different stress components and eventually comparing the maximum stress to the yield stress, are tabulated in Table 3.2. We found that even the smallest of schedule 40 steel piping diameters could withstand the loading experienced by the foot. The handwritten calculations are in Appendix A. Since failure does not occur with this loading, the rim foot is still a viable option for the foot component.

Table 3.2: Results of rim foot analysis with the rim made of different schedule-40 pipes. Note that all cases pass the test case.

Nominal Size (in.)	Outer Diameter (in)	Inner Diameter (in)	Bending Stress (MPa)	Axial Stress (Mpa)	Total Compressive Stress (Mpa)	Yield Stress (Mpa)	Fail?
1/8	0.41	0.270	163.4	7.6	171.0	250	N
1/4	0.54	0.360	72.4	4.5	76.8	250	N
3/8	0.68	0.490	39.8	3.3	43.1	250	N

3.3.1.3 Layer Foot Analysis

We developed a Matlab script to analyze the stresses in the Layer Foot concept at points of interest, seen below in Figure 3.11. The program allows inputs of the Layer Foot's dimensions and the applied loads and then outputs the compressive and tensile stresses at each point of interest. We checked the stress at each layer and were especially interested in evaluating the stress at the bolt hole. Loading protocol was selected from ISO 22675 Section 16.3, which can be seen in Appendix E.

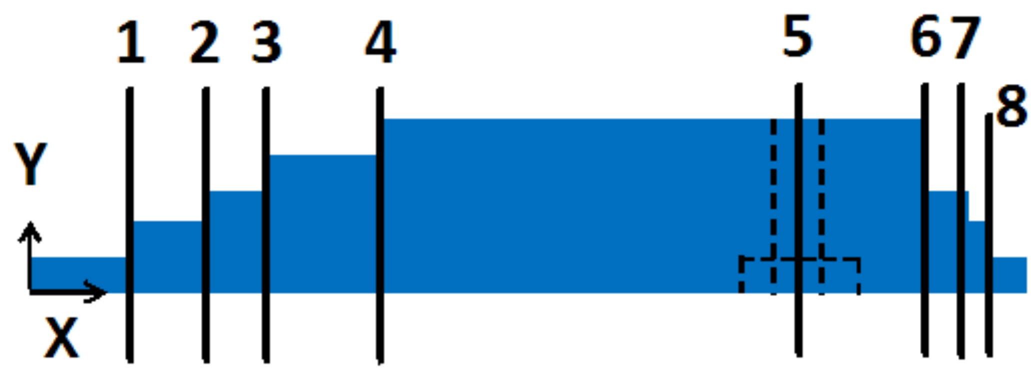

Figure 3.11: Points of interest for Layer Foot stress analysis

First, the script calculates the centroids at each point of interest using the centroid equations for a composite body. Next, the script calculates the area moment of inertia around the neutral axis at each point of interest using the parallel axis theorem. The equations of static equilibrium were applied to determine the moment and forces at each point of interest. Finally, the stresses were calculated at each point. The Matlab script and sample calculations can be seen in Appendix A.

The analysis indicated that the Layer Foot is a viable concept. The maximum compressive stress was 3.79MPa and the maximum tensile stress was 2.78MPa. The ultimate tensile strength of PET is approximately 50MPa, which means the Layer Foot has a factor of safety of 18 for the ISO test. The factor of safety of 18 on top of the test's built in factor of safety of 3.28 (the same factor as described above, resulting from the ISO test load cases) means the preliminary Layer Foot is overdesigned and has room for material reduction. The full results can be seen in Table 3.3.

Table 3.3: Results of Layer Foot analysis. Location of each position can be seen in Figure 3.10. Note that all stresses are less than the tensile strength of PET (50MPa).

Position	1	2	3	4	5	6	7	8
Tens [MPa]	0.587	1.216	1.650	1.589	2.782	0.794	0.808	0.048
Comp [MPa]	1.273	2.158	2.708	2.970	3.792	1.700	1.409	0.734

3.3.1.4 Pylon Cup Adapter Analysis

In order to verify that the pylon cup adapter would be a feasible option for the ankle component, it was important to evaluate the ability of the threaded members to hold the weight under maximum load. In the worst case, the entire ground reaction force would be directed through the ankle bolt, the brown member in Figure 3.6B, and would be set upon the threads between the bottom nut and the bolt.

The stress analysis that was performed used the geometry and the published material strength of the ankle bolt to determine whether the design was reasonable. An analysis of the compressive stress in the bolt as well as the shear stress present in the threads revealed that in order to sustain the maximum load as required by ISO 22675, the nut that supports the load of the plate (the nut on the distal side of the plate) would have to be at least 8.15mm thick. Supporting calculations can be found in Appendix A. Since nuts of 5mm thickness will be used in the foot design, we can place two of these adjacent to each other below the plate, which will also help minimize the possibility of the nut displacing along the bolt. Based on this rough analysis and its overall compliance to our requirement we will move forward with the pylon cup adapter.

3.3.2 Cost

We performed an initial cost analysis of the pylon cup adapter to determine how it would factor into our overall costs. As you can see in Table 3.4, the cost, even with the somewhat expensive spherical washer, is extremely low in comparison with the rest of the prosthetic limb.

Table 3.4: Cost estimate of pylon cup adapter

Item	Cost	Quantity	Total
8x40x40mm Plate	$0.10	1	$0.10
Pylon cup	$0.64	1	$0.64
Ankle washer	$0.39	2	$0.78
Ankle nut	$0.19	2	$0.38
Set screw	$0.04	4	$0.16
Spherical Washer	$6.00	1	$6.00
		Total:	$8.06

The prices listed in the Table 3.4 are approximations based on the materials we think we will need and prices found on McMaster Carr. These are not true costs because Vida Nueva will have different access to materials than we do here. Ideally we would use the same parts for the foot and ankle wherever possible, so a driving factor in our design for the ankle adapter will be materials we have chosen for the Layer Foot. While the $8.00 does seem fairly low, we do not anticipate the costs will be much higher than $10.00, which will still allow our prosthesis to be well within the budget.

3.3.3 Pugh Matrices

The foot design was chosen using a Pugh Matrix, which can be found in Appendix A. The concepts seen in Table 3.1 above were evaluated based on their ability to fulfill the requirements of the customer. For each requirement, an existing product was selected that effectively fulfilled that requirement, and our concepts were compared to that product. Our concepts were each given a score of + (better) - (worse) or S (same), compared to the existing design. Then the scores were summed and the best design was selected based on the scores. Based on the Pugh Matrix and our analysis, which proved the feasibility of the design, we ultimately decided to move forward with the Layer Foot. Since the Layer Foot allows flexion within the length of the foot, and provides control over heel strike force based on the material properties and geometry of the foot, it is unnecessary to include a complex ankle. Therefore, we will implement the bolt ankle with the Layer Foot, which is very simple to manufacture and configure.

A Pugh Matrix was also used to decide the most effective concept for the adapter component (see Appendix A). After our initial brainstorm, we went back to generate additional concepts and developed the cradle adapter, two plate adapter, and pylon cup adapter. From the new Pugh Matrix we

determined that the pylon cup adapter surpassed all other ideas and we have chosen to implement this design in the project.

To bring all the components together we need a pylon, and as mentioned above, have decided to use a standard prosthesis pylon of 30mm hollow aluminum tube. Our primary goal for the pylon is that it allows the components we design to interface with existing components. Therefore, we will keep the 30mm standard and design around this value for our other parts.

Chapter 4- Final Design

4 The Complete Prosthesis

As previously mentioned, Piernas de Vida plans to move forward with a prosthesis comprised of the Layer Foot with a bolt ankle, a LeTourneau M1 knee, a standard pylon, and the pylon cup adapter. The following section describes in detail the materials and dimensions of each component and our analysis for each component.

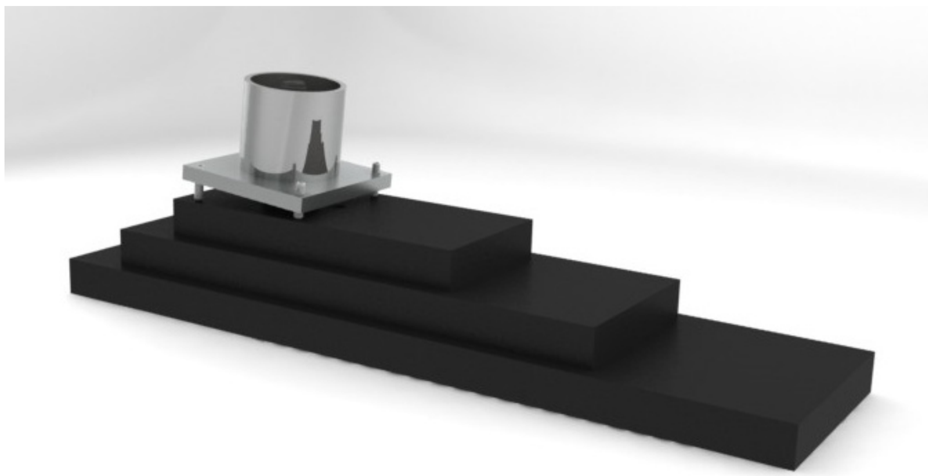

Figure 4.1: Solid model rendering of foot with ankle adapter

4.1 Layer Foot

4.1.1 Functional Description of Part

The Layer Foot was designed to be a simple product that addresses the issues of cost and manufacturability for the Vida Nueva Clinic. It is comprised of multiple layers that interact with each other to provide flexion at the heel and the toe. The properties of the layers can be altered to change the gait response of the foot to mimic that of a normal human foot.

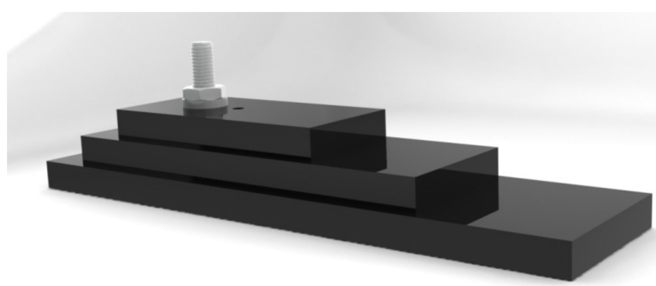

Figure 4.2: Isometric view of Layer Foot. 10 mm bolt holds layers together and pin 2cm anterior of bolt prevents rotation between layers

The layers of the foot will be manufactured out of Delrin. A metal pin inserted 2 cm anterior of the bolt will prevent rotation of the layers around the bolt and will add stiffness to the toe section of the foot. In the future, a cosmetic cover, or cosmesis, will be available to provide protection for the foot from normal wear and tear, as well as to add aesthetic appeal.

4.1.2 The Analysis

The analysis of the Layer Foot consisted of two parts: the deflection response analysis (DRA) and stress analysis. The DRA predicted the deflections during gait to determine how closely the Layer Foot matches physiological performance. The stress analysis predicted stresses at key points in the Layer Foot to ensure the foot met our strength requirements.

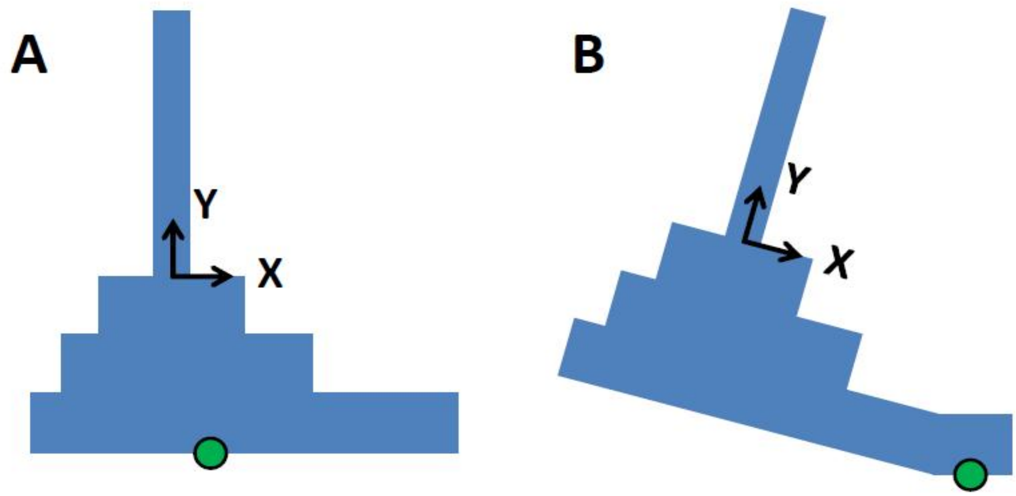

Figure 4.3: The roll-over shape is the profile of the center of pressure, relative to a coordinate fixed to the ankle, throughout the stance phase of gait. The center of pressure is represented by the green circle. Notice how the center of pressure shifts anterior as the foot transitions into push-off (A to B).

The DRA evaluated how the foot reacts to loading by predicting the roll-over shape. The roll-over shape is a measure of how the center of pressure moves relative to a coordinate system fixed to the ankle that rotates with the pylon[17]. The positions of the stance phase of gait are plotted together to create a profile that can be compared to other prosthetic feet and normal gait. See Figure 4.3, above, for a schematic explaining roll-over shape. Hansen et al developed a method to statically evaluate the roll-over shape of prostheses[17]. In this method, the toe or heel of the prosthetic foot is placed on a plate with a field of strain gauges and is deflected as seen during gait. The center of pressure is determined by finding the center of the strain field. A more detailed explanation of this test can be found in Chapter 6.

We used Engineering Equation Solver (EES) to create a model of the test developed by Hansen et al to predict the rollover shape of the Layer Foot. The foot was split in the Medial-Lateral direction at the bolt and modeled as stacked cantilevered beams. The toe and heel were analyzed separately because only the heel and toe are active in the heel strike and push-off phases of gait, respectively. Static analysis was used to determine the forces between the layers and the reaction forces and moments at the bolt. To make the analysis statically determinate, the deflection at the stabilization pin was set to be equal for all layers. This is reasonable because the pin will hold the layers together at that point. Once the forces on the layers were known, the toe deflection was calculated. All deflections were found using singularity equations. Once the toe deflection was found, the length of foot contacting the ground was found using trigonometry. Using the angle that the foot was offset, θ, the deflection, δ_{Toe}, and

trigonometry, the length of the foot contacting the ground was found. Since the loads were assumed to be uniformly distributed, the center of pressure is at the center of the contacting area. The center of pressure was then compared to the assumed center of pressure. The residual was minimized through iteration with the "min" function in EES to predict the center of pressure. The position of the center of pressure was then found relative to the coordinate system anchored to the ankle. The equations and EES code can be seen in Appendix E.

The stress analysis predicted the stresses at the ankle bolt. The stresses will be largest at the ankle bolt because the moment arm is largest and there is a stress concentration. The forces found in the deflection response analysis were used with the pure bending equation to determine stress.

Lastly, we performed a parametric analysis to determine the effect changing each layer dimension had on deflections and stress. To accomplish this we developed a model of the Layer Foot in EES so we could input different configurations and output a parametric table with the characterization of the foot. The study was conducted by changing the length of one layer while the other two were held constant. The data was then post-processed in a custom Excel spreadsheet and compared to physiological rollover shape. This method gave us a better understanding of the effect of varying each layer so that we could find the optimum geometries needed to produce a roll-over shape similar to that of a human foot.

4.1.3 Results

From the parametric study performed, we were able to determine that varying the length of the bottom layer produced the largest effect on the roll-over shape of the foot. Since the bolt that holds the layers together provides a rigid connection, the toe and heel sections can be treated separately in our model in order to find the optimal lengths of each. Reasonable lengths were approximated for the top and middle layers of the toe, and the roll-over shape was produced for bottom-layer lengths ranging from 14cm to 22cm. Deflection calculations determined that 0.5 inch layers would provide the desired response, so the parametric study was performed assuming 0.5 inch layers. A graph displaying the roll-over shapes of the toe section can be found in Figure 4.4.

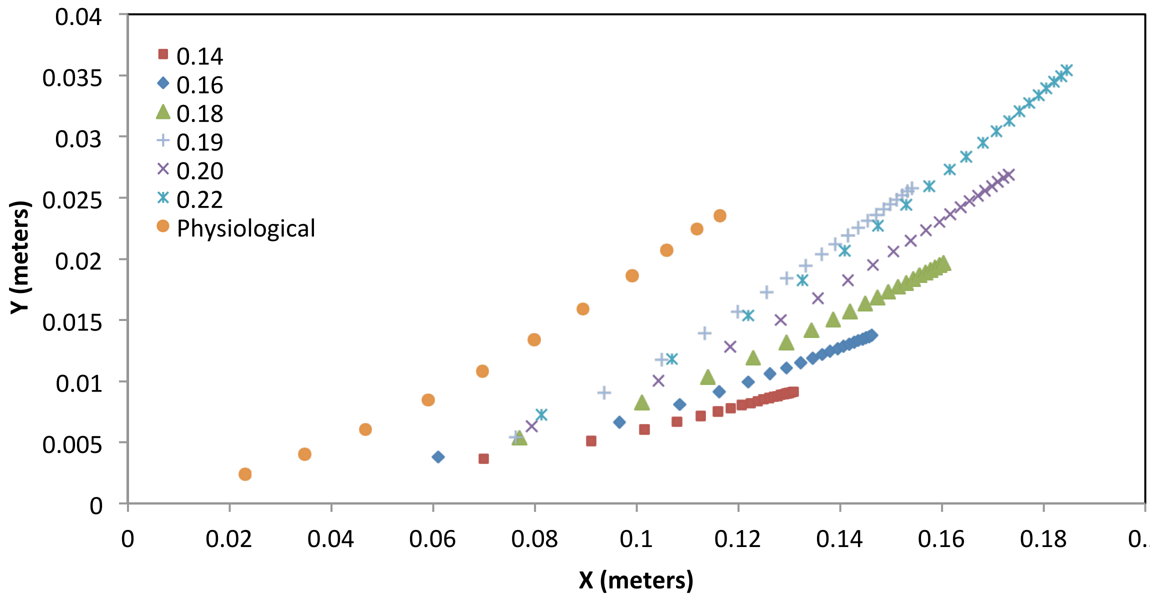

Figure 4.4: Sample graph of roll-over shape calculated with fixed top and middle layer lengths at 0.04m and 0.06m respectively. The bottom layer lengths are varied from 0.14m to 0.22m and compared with physiological data. Each layer in this solution is 0.5 inches thick.

The shapes at each length follow a very clear trend, and from these data it is clear that when the bottom layer of the toe section is 19cm, it produces a roll-over shape that is very similar to that of the physiological human foot. The data resulting from varying the middle and top layers did not display as significant of a trend, and none of the configurations tested yielded a roll-over shape as similar to the physiological data as the 19cm configuration above. Nonetheless, this data was useful in examining the effect that varying each layer had on the shape. Ultimately, though, we made the bottom layer the length of the average prosthetic foot, 26cm, and scaled the top and middle layers to correspond. Graphs of the data from varying the middle and top layers can be found in Appendix E. The same methodology was used to calculate the optimum lengths of the heel layers, and the following final dimensions were determined:

Table 4.1: Final Dimensions of Layer Foot

Dimension	Top	Middle	Bottom
Thickness	0.5in	0.5in	0.5in
Length	11cm	18cm	26cm
Width	5cm	6cm	7cm

The responses to the heel and toe sections of the chosen geometries were then superimposed onto the same graph, and it is clear from Figure 4.5 that the geometries produce a very accurate roll-over response when compared with the physiological data of a human foot.

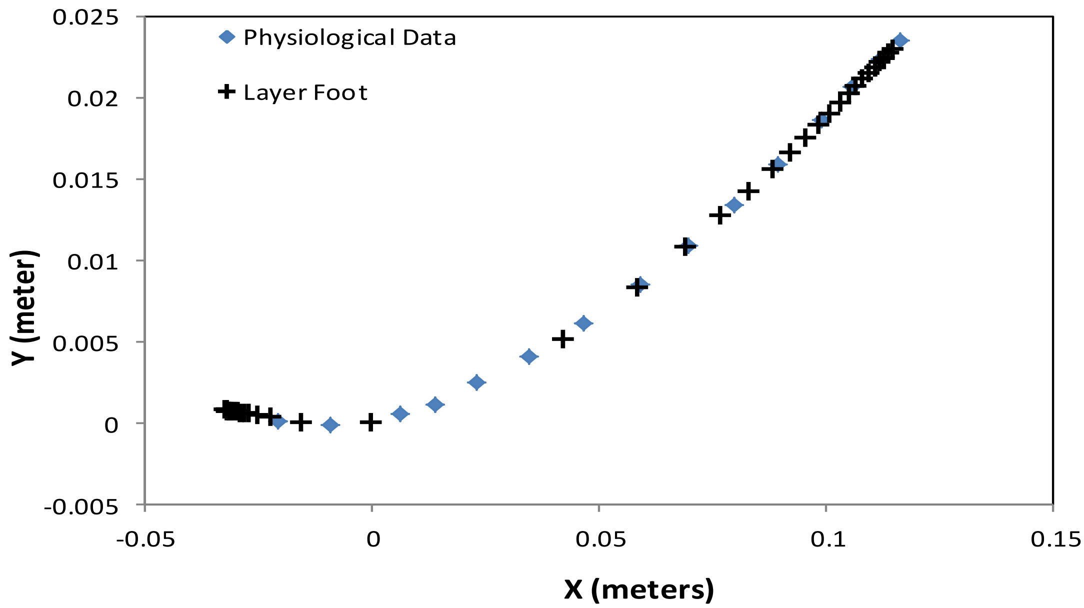

Figure 4.5: The roll-over shape produced from computer-simulated DRA compared with actual physiological data

There is very little error between the calculated roll-over shape and that of a human foot, and the results of our study seem promising. There are, however, many limitations on the design that must be considered.

4.1.4 Limitations of the analysis

Analyzing the response of a body composed of discrete layers is difficult because of the non-linear nature of contact forces and the large deflections seen by the Layer Foot. For our analysis, we had to assume infinitesimal strains, uniformly distributed contact loads, and beam members. In reality, the foot was tested at a maximum angle of 30^{o} relative to the ground plane, which does not yield infinitesimal strains. In addition, contact loads are generally non-linear, but we modeled them as uniformly distributed.

While the Layer Foot model required some assumptions that reduce its accuracy, we feel that the predictions provide a good starting point for the testing phase of our project. It would be possible to apply a more rigorous analysis, but our time is better spent testing the Layer Foot and using the test data to optimize the Layer Foot dimensions and geometry.

4.1.5 Safety Considerations

Since the technicians at Vida Nueva will be manufacturing the foot in the clinic, proper measures must be taken to ensure the safety of both the technicians themselves and the patients who will be using the product.

The manufacturing process will involve the use of power tools including a band saw, a drill press, and a grinder wheel. Severe injury could result if extreme care is not taken and proper use of the tools is not practiced. Each tool should be examined routinely for malfunction, and safety equipment including glasses, earplugs, and clothing and skin protection must be worn during operation.

There are inherent risks involved in the use of a lower-prosthetic limb that we have been conscious of during our design. Should the limb fail catastrophically, the patient may potentially sustain serious injuries including broken or sprained limbs, or collision with nearby objects. To prevent failure under normal usage, we will test all components to verify that the fatigue life of the product will be above two years. In addition, the limb is designed to be robust and to withstand the climate and terrain of Honduras and not lose adjustment or deteriorate before the patient's routine check-up occurs. Lastly, when working with plastic material yielding is a significant concern, therefore we must address the likelihood of this occurring under the rough conditions of Honduran terrain.

4.1.6 Cost

The target price for our entire prosthesis is $150. We are not considering labor costs at this time, though ultimately this will add to the overall costs. Therefore, the only costs we will consider at this time are material costs and shipping. Ideally, all of the components could be found within Honduras, but we will need to partner with the staff at Vida Nueva to find sources where they can purchase the appropriate parts. It is hard to make cost estimates without direct access to the sources.

One item that they will almost certainly have to import is Delrin. This plastic is used for both the knee and the Layer Foot, so if they purchase in bulk, they may be able to reduce costs. We have purchased a 2'x4'x ½" sheet of Delrin from Piper Plastics for $255 and calculated that this can make approximately 28 layers. With three layers per foot, one sheet of plastic will make 9 feet and therefore each Delrin for each foot will cost approximately $27.32. The hardware costs $2.59 from McMaster Carr. A detailed bill of materials can be found below.

Table 4.2: Bill of Materials for Layer Foot

Item	Cost	Quantity	Total
Delrin	$27.32	1	$27.32
Ankle bolt	$2.16	1	$2.16
Ankle washer	$0.09	1	$0.09
Ankle nut	$0.19	1	$0.19
Pin	$0.15	1	$0.15
		Total:	$29.91

While the prices in Honduras are unlikely to be the same, Vida Nueva will be ordering in bulk, so they will probably receive a price break. All of the hardware is standard and will be readily available. The Delrin is less common, but Vida Nueva may purchase it for use in the M1 knee so the supply chain should be established regardless.

4.2 Further iterations of Layer Foot

4.2.1 Second Generation

After constructing the first foot we realized that the material was much too stiff and we were not really seeing any deflection at all. We then milled down the sheets to create three other prototypes with sheets of thicknesses 0.375, 0.25, and 0.1875 inch. The rest of the design maintained the same geometry and alignment, but we had to create a different means to attach the layers together. In this design the bolt did not attach the bottom layer because we had to drill a through hole so the head of the bolt would not protrude from the bottom. Therefore, to attach the bottom layers we used four standard wood screws. All of these iterations were considerably more flexible than the original half inch prototype.

4.2.2 Third Generation

The feedback during the first patient testing, as described in Chapter 6, was mainly directed toward the stiffness of the heel and somewhat excessive flex in the toe. To address this we shifted the middle layer forward to be in line with the top layer. We could not lengthen the heel or we would lose the alignment corresponding to human physiological geometries. However, by shifting the middle layer forward we solved both problems at once. We manufactured this design in 0.375, 0.25, and 0.1875 inch thicknesses,

and, except for shifting the layer, maintained the same manufacturing procedure as in the second generation foot. A rendering of the third generation Layer Foot can be seen below in Figure 4.6.

The new cost for the second generation Layer Foot is seen below in Table 4.3. Note the Delrin cost assumes 0.25 inch sheets, which we determined were the most effective overall.

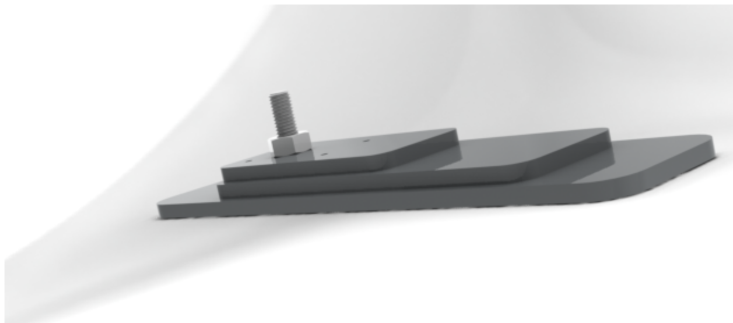

Figure 4.6 Rendering of third generation Layer Foot.

Table 4.3: Bill of Materials for second generation Layer Foot

Item	Cost	Quantity	Total
Delrin	$14.89	1	$14.89
Ankle bolt	$2.16	1	$2.16
Ankle washer	$0.09	1	$0.09
Ankle nut	$0.19	1	$0.19
Screws	$0.09	4	$0.37
		Total:	$17.70

4.3 Material Selection/Explanation

4.3.1 Delrin

Initially we had hoped to form the layers of the foot out of recycled PET, but we do not yet have a suitable process so we cannot use this material. Because we are using Delrin for the M1 knee and want

to minimize the number of materials used in the design we looked into the material properties and determined that they are very similar to PET. Delrin has slightly lower tensile strength (σ=67.95 MPa) than PET (σ=70 MPa), but a slightly higher elastic modulus, (E=3.175 GPa) than PET (E=2.90 GPa). Unfortunately Delrin is slightly more expensive and less available locally than PET, but even with these higher costs we can manufacture the feet within the desired price range. Also, Delrin is very easy to work with and it will be easy to manufacture the feet in-house.

4.3.2 EVA foam

Ethylene Vinyl Acetate is a thermoplastic elastomer that Vida Nueva purchases from the ICRC in Switzerland. The clinic uses it for the construction of their cosmetic covers. This material performs well as a cosmetic cover because it contains elastomeric properties such as softness and flexibility, but it can be manufactured similar to that of a thermoplastic. EVA is fairly UV resistant and is waterproof, which is a key requirement for Cholutecan patients as it rains often. However, the downside of EVA is that its glass transition temperature is quite low, -99.4 degrees Fahrenheit.[15] This means it begins to transition from a solid to a viscous material at this temperature. As a result the material will degrade over time especially in the Choluteca heat. EVA foam is typically used for shoe soles, flexible toys, and tubing.[15] As discussed in Chaper 6.3, the EVA foam was used to compensate for the height difference of our layer foot design because we could not adjust the pylon of the ICRC component. The EVA foam was attached to the layer foot design with zip ties, and patients tended to say that it felt softer. However, the foam was so soft that the Delrin hardly deflected, effectively negating the utility of the Delrin design.

4.3.3 Vulcrepe Rubber

Vulcrepe rubber is vulcanized crepe rubber, which is a typically soft soling material. Once vulcanized, the material becomes hard and stiff. Vulcanization is the process in which polymers, such as rubber, are transformed into a more durable, strong material through the addition of elements that are used to crosslink the polymer chains. Crepe rubber is quite sensitive to oils and UV radiation.[20] The Vulcrepe rubber was found and bought in Choluteca, so it is a local material that Vida Nueva could purchase. It was purchased to compensate for the height difference of the layer foot and the patients' ICRC foot. Compared to the EVA foam, patients claimed that the Vulcrepe rubber was more secure. This is due to the fact that the material was so stiff and the keel was doing more work. The thickness of the Vulcrepe was also great enough to cause the roll-over shape to not be as smooth. These two materials are preliminary candidates for future material uses for a cosmetic cover design.

4.4 Cosmetic Covers

Due to time constraints, the Piernas de Vida team will not design a cosmetic cover for the Layer Foot design this year. The Layer Foot will be designed so that Vida Nueva will not have to use a cover. The technicians expressed a concern, though, that if the foot is placed inside a shoe it will have a lot of room to shift side to side and will not provide the necessary stability, so they are interested in a cover that would fill the empty space. At this time the foot does not fit into standard cosmetic covers, however the technicians currently have a method of creating cosmetic covers from EVA foam that could serve well with this design. Unfortunately the EVA foam is purchased from Switzerland, so future teams should look for more locally available material to create this cover.

4.5 PET Processing

Polyethylene Terephthalate is a recyclable thermoplastic used all across the world. Due to its recyclability, PET can be reprocessed and used again for new consumer goods. Though we are moving forward with the Delrin design at this time, we are still exploring the possibility of using PET in the future. With the implementation of a recycling program and the right equipment, Vida Nueva may be able to use PET as the material for the Layer Foot.

Figure 4.7: Cal Poly IT Lab Compression Molding Machine

4.5.1 Types

PET can be processed in many different ways. These methods include:

- **Calendering:** Threads raw material through half a dozen heated controlled rollers to produce thin sheets of PET.
- **Compression Molding:** Similar to the casting of metals and is used mainly for thermosetting polymers. The pellets are placed into a pre-heated mold and the mold is then closed and placed in between two hot plates. Pressure is added to force the molten plastic into all portions of the mold. Compression molding of PET is increasing in manufacturing plants with the invention of the Preform Advanced Molding (PAM) process, but is still rarely used commercially.
- **Injection Blow Molding:** The main process technique for PET and is used to create the common thin shaped water bottles. The melted plastic is injected under high pressures into a mold where the plastic crystallizes under pressure and is then ejected from the mold. Production rate is high but the process also has high tooling costs.
- **Rotational Molding:** A very slow, precise process in which powdered plastic is placed into a mold within a rotational machining device. The machine rotates the mold as it heats up to the plastic's melting temperature. The rotation allows for the plastic to spread across the entire mold and is good for filled shell products; however this technique requires complex, expensive machinery.
- **Thermoforming:** Similar to compression molding but uses a vacuum to pull a plastic sheet against the mold.
- **Extrusion:** Another form of processing with precise, fast production. This is typically used to create pellets and thin sheets by heating the plastic as it moves through a chamber after which it is forced through a die of the proper dimensions. Most processing techniques extrude PET before molding it into the desired shape. Unfortunately the typical sheets created by extrusion are under 40 mils thick.

4.5.2 Vida Nueva Recycling

Of the processing methods listed above only a few are practical for implementation at Vida Nueva. Extrusion would be the ideal process because it leaves less room for user error and is a highly repeatable process. However, because the typical thickness is that of a plastic bag they would have to use injection

molding to achieve the final product. This additional step makes the process too expensive for use at the clinic. The next best option is compression molding. While this method is not yet popular commercially because pressure and heat must be strictly regulated, with appropriate training and proper design the process could be repeatable. Due to the cost constraints we face we will move forward with investigation into a compression molding process for Vida Nueva.

Chapter 5- Product Realization

As previously mentioned, manufacturability was a critical concern for our design. We were committed to manufacturing the full prosthetic foot with nothing more than a band saw and drill press. While we were in the shop building prototypes we only used tools the clinics would have easy access to. First, we used a jig saw to cut out the pieces from the big sheet of Delrin. Next, we measured out the locations for the holes using a square, center punched the hole, and then drilled out the holes with a drill press. Finally, we inserted the ankle bolt and installed the pin with a mallet. The prototypes took approximately 3 hours to build.

It would be possible to drill the holes with a hand drill, but easier to achieve the required accuracy with a drill press. Accuracy of the holes is important because the bolt and pin are inserted through a series of holes, so alignment is critical. To help improve accuracy we clamped the layers together and drilled the holes through all the layers simultaneously. Furthermore, clamping the layers reduced the time required by reducing the number of driller operations. Using this technique, we were able to successfully build each prototype in 2.5 hours.

We experimented with different techniques for cutting out the layers of Delrin. Initially, we used a table saw, which produced straight cuts, but Vida Nueva does not have a table saw. We then tried using a handsaw, which worked, but took an additional hour and a lot of additional effort. This is a viable technique but it is very time consuming and would limit the number of layers a technician is able to cut out in one session. Finally, we tried cutting out the sheets with a jigsaw. While extra care was required to ensure accurate cuts, cutting out the layers did not take more time than the table saw. In addition, jigsaws are fairly low cost and would be a worthwhile investment for Vida Nueva.

Figure 5.1: Jen and Justin cut out material for concept prototypes on the table saw

As we tested our foot we realized that our initial design of 0.5 inch thick sheets was too thick. Because we had purchased 0.5 inch thick sheets, we had to plane down the material to make thinner prototypes. Initially we used a wood planer, however this process was noisy, time consuming, and left us with a fairly inaccurate piece. We decided to then use the mill to reduce the material thickness. We used the mill to create 3/8, 1/4, 3/16, and 1/8 inch thick pieces. We recommend that Vida Nueva buy sheets in the thickness they need due to the time consuming nature and equipment cost of reducing the sheet thickness. Furthermore, we wasted about half of our material in this milling process, which Vida Nueva would certainly not want to do.

Figure 5.2: Collection of six prototypes of varying thickness of both first and second generation designs

Layers thinner than 3/8” are not thick enough to support a counterbore for the ankle bolt head. As a result, we drilled the ankle bolt hole in the bottom layer large enough to accommodate the bolt head and joined the layers together with screws. Countersunk screws were selected so the head would not extend past the bottom of the bottom layer. The screw holes were drilled on a drill press and the screws were driven in with a hand drill. The layers were clamped together when driving the screws to help minimize separation between layers.

Because we were manufacturing prototypes we did not create a useful system for maximizing the amount of material used, or plan out the steps to take. In the future teams should formulate a plan of how to cut the material to get the most layers from a single sheet. Also, future teams should write up a manufacturing procedure and follow it step by step; this procedure can later be adopted as a training guide for new clinics. Ultimately each technician will likely develop their own tricks to speed up the process; however we need a baseline procedure that can easily transfer the knowledge of the manufacturing process.

The Layer Foot can easily be manufactured at Vida Nueva. Vida Nueva currently has a drill press, belt sander, and hand tools. The only equipment they would be required to buy is a jigsaw, a hand drill, and a countersink bit. The technicians already have experience cutting out and shaping material with tools similar to those used to build the Layer Foot, so we are confident they will be able to fabricate it with little additional training.

Chapter 6- Design Verification

6.1 ISO Testing

In order to prove the strength of our design before patient testing, we planned to follow the ISO testing procedures as described in ISO standard 22675. These standards specified load control testing at a rate of about 175N/s up to 4454N on the forefoot and 4396N on the heel. We designed test fixtures to hold the foot at the prescribed angles. The test specified a 15 degree heel loading angle, 20 degree toe loading angle, and 7 degree toe-out angle, as picture in Figure 6.1.

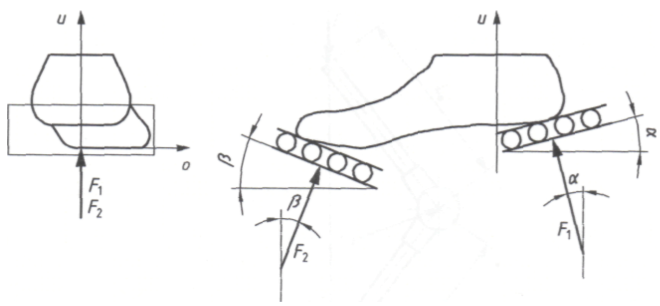

Figure 6.1: Test angles as described by ISO standard 22675

Table 6.1: Legend of angles for ISO test set-up described at right

Angles	Degrees
α	15
β	20
γ	7

To accomplish this testing we constructed fixtures to use in the Instron 8500 located in the composites lab. These fixtures, Figure 6.3, were composed of several flat plates welded to square tubing. We encountered several significant difficulties with these fixtures. In the first test the foot simply slipped off the fixture, so we added a rubber mat to the fixture to increase friction. Figure 6.2 shows the rubber held to the plate with c-clamps. This addition helped considerably, however when we loaded the foot up again we realized that the top plate was too short to support the foot and there was a load concentration where the plate ended, seen here in Figure 6.2. To remedy this we added an additional plate on top of the original that would support the full length of the foot. The next issue occurred when we attempted run the test using load control. The machine did not stop at the set limit and it continued loading until we hit the emergency stop. Unfortunately the test fixture broke before we were able to stop the test, however it revealed that the welds did not penetrate the lower plate and likely would not have held through all the tests. Before we could continue our tests we had to re-weld the bottom plates onto the square tubing. To remedy the issues we had, we should have done better geometry calculations to determine the exact sizing and positioning of the pieces of the test fixtures.

Figure 6.2: The plate does not support the full foot and creates a load concentration where the fixture ends

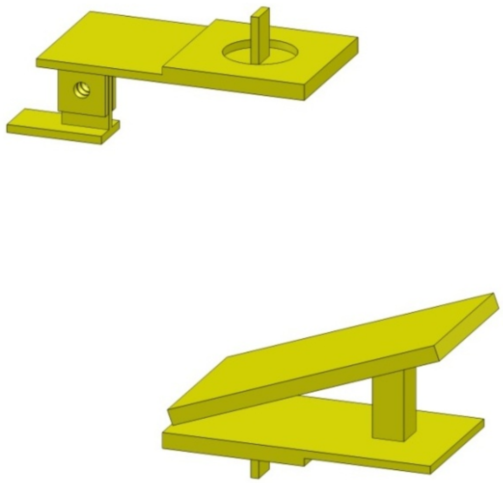

Figure 6.3. Solid Model of ISO Test Fixtures without prosthetic limb installed.

Load control testing was a critical element of following the ISO standards, so we performed several additional tests on sample pieces using load control to test the Instron's load control accuracy. Each time, though, the accuracy of the measurements was extremely poor, none of the trials stopped at the desired end value, and while most trials stopped at the max limit, the load overshot the max value first and then fluctuated around the max value prior to stopping. We were not satisfied with this result, so we chose to forgo ISO testing at this time. We instead simply loaded up each of the feet with position control and because we can measure the force output we manually stopped the tests at the desired peak load value.

One success from our attempt at load control testing is that we noticed the loading rate is fairly high. In our initial position control tests we set a deflection rate of only 0.005 in/sec. Later we increased this rate to four and eight times faster to reach loading rates closer to those seen in the load control trials. We tested each foot- the 0.5 in, 0.375 in, and 0.25in- up to the max load and then examined each for any signs of failure.

6.1.1 Results

Overall we did not see any damage to the feet after the Instron testing. The feet deformed considerably during the tests, however none of them remained deformed after the load was removed. We did, however, break the ankle adapter we had been using. This was a used pyramid adapter we received from Matt Robinson, and the proper screw was missing to clamp the pylon into the adapter. During one test the screw head snapped off so we replaced it with another new screw. During the next trial the screw started to strip and the bottom of the adapter began to crack, seen in Figure 6.4. This effectively ended our trial on the Instron, however we had already completed at least one trial on the heel and forefoot of each prototype.

Figure 6.4: Picture of pyramid adapter broken during ISO testing.

As we were expecting, we saw the feet start out relatively soft at the toe and stiffen considerably as the load shifted back toward the ankle. Also, the 0.25 inch foot showed considerable separation between the layers as the load increased to about 1800N. The foot did return back to its original state after the load was removed,

though, so it appeared that the layer separation did not have a negative effect, at least on the first cycle. Repeated separation could have less desirable effects.

We were unable to perform cyclic loading as we were hoping. This would be a good test to perform in the coming year to ensure that the foot does not deteriorate with repeated use. The current test set-up does not permit the cyclic testing as described in ISO because we cannot alternate heel and forefoot loading in rapid succession. Furthermore, standard tests release the load completely between each cycle to mimic the swing phase of gait. In our tests, though, the load cannot be completely released between each cycle because the foot would fall out of alignment. Regardless it would still provide useful information to cycle the foot between two compressive loads for several hundred rounds.

6.2 Patient Testing- America

On May 13, 2011, we performed tests with two trans-tibial patients. Patient 1 weighed about 300 pounds and his foot was amputated 18 years ago. Patient 2 weighed about 230 pounds and is a more recent amputee.

6.2.1 Procedure

6.2.1.1 Patient Trials

The patient testing was begun with a qualitative survey in order to collect information on how the patient felt when standing or walking, how comfortable the limb was, and what differences the patient felt between the Layer Foot and their standard prosthesis.

The team then attached the foot to the patient. Before each trial the patients were allowed to walk a few paces to become accustomed to the foot. They then walked across the force plate while both the force plate software and the video camera collected data. Each foot (0.5 inch, 0.375 inch, and 0.25 inch layer thickness) was tested with the force plate on either patient three times for a total of 18 runs. Two runs of data were also collected for each patient on their standard prosthesis for comparison.

The testing equipment included a force plate from the Cal Poly Kinesiology Department and a long-zoom digital video camera. The force plate records the location of the Center of Pressure (COP) of the foot during gait as well as the magnitude and direction of the ground reaction force on the foot. Simultaneously, the video camera captures kinematic data from markers placed on the shank and on the ankle of the patient during gait. These two sets of data are then matched to produce an accurate rollover shape, as discussed in Chapter 3.

After each prototype foot the patients were asked a series of qualitative questions about their experience. Both patients had similar responses and helpful feedback. The following were questions asked in the survey:

- Did you feel more or less balanced on this prosthesis when you were standing/walking?
- Did you feel the foot turn inward or outward at all?
- Was the foot heavier or lighter than your standard prosthesis?

During this testing phase, there were minor adjustment issues in the interface between the patient's standard prosthetic limb and the prototypes. The patients did note a slight height difference which could greatly skew their perception of how the foot actually performed. Therefore, while valuable, the data must be analyzed with that in mind.

6.2.1.2 Data Processing

The main objective of these patient testing rounds was to retrieve the rollover shape of each foot in order to compare the performance to a physiological foot as well as the patients' standard prosthetic feet. As mentioned above, the kinematic data gathered from the video camera and the COP data from the force plate was used simultaneously to produce this shape. Microsoft Excel and the Vicon Motus software were the primary tools used in the development of the rollover shape.

After the video data was recorded for each run, it was processed using the Vicon Motus software. This software uses a user-defined global coordinate system to track the movement of user-selected points throughout each frame during the trial. Figure 6.5 shows a frame capture from Patient 1's test.

Figure 6.5: Patient testing with reflectors giving coordinate axes

The user is required to define the origin of the global coordinate system along with a distance scale for each direction (X and Y, or horizontal and vertical respectively). Once the coordinate system was defined, the reflective markers were assigned coordinates throughout the gait and exported to spreadsheet format for post-processing.

Also, the kinetic data from the force plate was collected with a DAQ. The user could define the desired data to be collected and that data could then be exported in spreadsheet format. The data of interest from the force plate included the X position and the magnitude of the force (not essential to the rollover development but good reference data). The force plate coordinate system can be seen in Figure 6.6

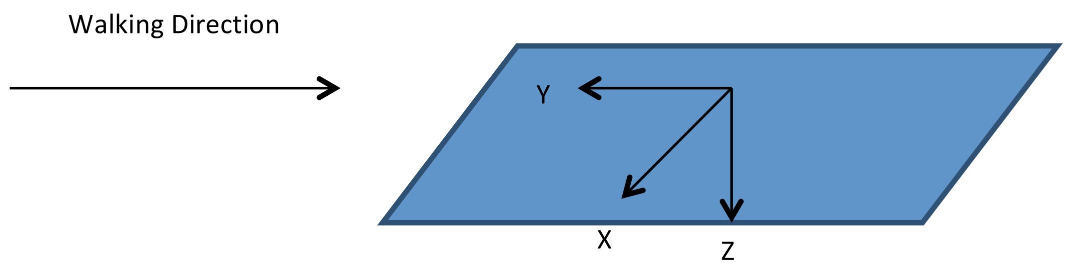

Figure 6.6: Reference Coordinate System for Force Plate Testing Setup

Both sets of data (kinematic and kinetic) were then imported into an Excel spreadsheet and used to develop the rollover shape. The equations used in the development of the rollover shape can be found in Appendix E for reference. An example roll-over shape is below in Figure 6.7.

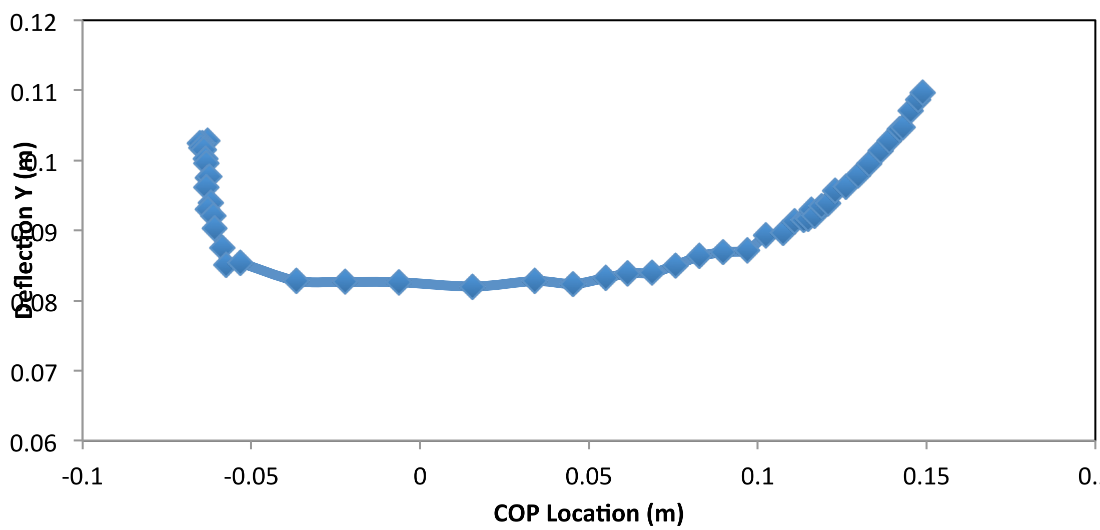

Figure 6.7: Sample rollover shape from patient testing.

The process was streamlined such that the rollover shape can now be produced quickly and efficiently for future testing. This method of prosthetic limb analysis can prove very useful in further iterations.

6.2.2 Results

Patient 1, because he was much heavier, felt most comfortable on the 0.5in foot. We saw considerable deflection in the toe from this foot under his weight, however little to no deflection in the heel. Patient 2 responded best to the 0.375in foot. Their comments alone made it clear that there was a correlation between weight and appropriate thickness. Further testing would be required to determine the exact correlation, however there was promising evidence to support that this relation exists.

Patient 1 frequently commented that the foot "felt out of whack." It was clear that he was not accustomed to the foot, and did not find it particularly comfortable. Both patients felt that they heel strike was significantly too hard and there was little to no give. We observed the toe was too compliant on the thinner feet, so the patients felt as though they were "falling forward", "going downhill," or being "thrown forward."

6.2.3 Recommendations for adjustments

We were pleasantly surprised at how much flexing we did see. We did not believe we would see as much deflection as we did, however all three feet showed considerable deflection, and some even showed too much deflection. Our primary suggestion is to shift the bottom layer back in order to improve deflection in the heel while reducing the deflection in the toe. The issue will be that you can only shift the bottom layer out a few centimeters. If the heel protrudes too far behind the ankle it will not induce natural walking motion. Furthermore, the sizing of the layers may need some adjustment. If we have longer top layers we can control the flex in the toe a bit more.

6.3 Patient Testing- Choluteca

Ultimately we created six prototypes which will hereafter be defined as follows:

1. 0.5" original: This was our original design with three 0.5 inch thick layers. All three layers were staggered as seen in Figure 6.8.
2. 0.375" original: Same design as above but each layer was 0.375 inches thick.
3. 0.25" original: Same design as above but each layer was 0.25 inches thick.
4. 0.375" modified: In this design the middle layer was shifted forward to be in line with the top layer. This was done to soften the heel and stiffen the toe. Each layer was 0.375 inches thick.
5. 0.25" modified: Same design as number four above but using 0.25 inch layers.
6. 0.1875" modified: Same design as number four above but using 0.1875 inch layers.

Figure 6.8: Original Layer Foot design with 0.5in layers

6.3.1 Modifications after Patient testing

After the feedback we received from the patients in San Luis Obispo we modified the foot by shifting the middle layer forward in order to soften the heel and stiffen the toe.

Figure 6.9: Modified design with middle layer shifted forward attached to an ICRC trans-tibial prosthesis

6.3.2 Patient Testing in Honduras

In May 2011 we traveled to Choluteca to test our prototypes on their patients. We brought along our original design in which the middle layer was still shifted

back (Figure 6.8) as well as the new design with the middle layer shifted forward in line with the top layer (Figure 6.9). For each patient we tested all the prototypes, starting with the thickest design and working our way down to thinner layers. We wanted them to compare the feeling of walking on a stiff block with the more flexible layers. The patients we tested in Honduras were a bit lighter than the patients we tested in the states so their response to the feet was a little different.

Figure 6.10: Vida Nueva patients Eugenio Paz [A] and Marvin Geobani Linares [B] test out the Layer Foot.

Our first patient, Eugenio Paz, seen in Figure 6.10A, was a trans-tibial patient weighing 215 lbs. He was using ICRC components with a Kingsley foot. We tested in succession the 0.5 original, 0.375 modified, 0.25 modified and 0.1875 modified. With his weight the 0.25 modified created the best roll-over. With the ICRC components it was not possible to lengthen the length of the tibia, so the thinner feet were 4cm too short. To compensate for this we first created a platform from layers of EVA foam. This is the same foam they typically use to create covers, liners and is a very soft, compliant material. It helped with the height difference, but because it was so soft that it reduced stability of the foot, so over time it could cause a lot of strain on the hip muscles. Furthermore, because the material is so compliant it would likely plastically deform over time and not provide the necessary height. However, the patients seemed how the soft material was absorbed the heel strike impact. One individual mentioned that he felt some energy return as he walked forward.


Figure 6.11: Modified foot with EVA foam platform attached to provide height

On the first afternoon we went to the local shoe store and purchased soling material. These sheets are sold for 350 Lempiras (a little over $15) for a 39” x 40” sheet. We purchased two different types of material, one was a thicker foam with a ridged surface, Vulcrepe, a common soling material (Figure 6.12) and the other a thinner but more dense Neolite rubber. On day two we formed a similar platform as we created with the EVA foam with Vulcrepe rubber. This material was considerably stiffer and we were concerned we would lose the flexion in the foot. However, when we tested this platform, several patients still commented that it felt similarly flexible, and visibly we still saw comparable movement. In reality, it is likely that we will not add quite as much material because we can extend the length of the pylon to compensate for

Figure 6.12: Sample of Vulcrepe rubber procured in Choluteca, Honduras for use as a platform.

the shorter foot. We did not make these adjustments during testing because they cannot change the pylon length, dorsi-flexion, and inversion/eversion on the on the ICRC systems,.

Several of the lighter patients commented that even on the 0.1875 modified the toe was a bit stiff. Walter, the Vida Nueva technician, made several suggestions, including cutting the toe a bit shorter or using an even thinner layer in the middle. Another concern was the overall length of the foot. Many of the patients were shorter and would not normally use a 26 cm foot. Their complaint was that they were unable to reach the toe flexion point in the foot in their natural gait because it was so far forward. We have not yet tested scaling the feet down, so it is unclear how the foot will perform if we shorten all of the layers.

The second patient, Marvin Geobani Linares (Figure 6.10B), was also had a trans-tibial amputation and uses ICRC components; however he was considerably smaller than the first subject and weighed only 138 lbs. We started with the 0.375 modified and worked our way down to the 0.1875 modified. With the 0.1875 modified he said it felt considerably smoother than the ICRC foot he had been using even though it was a bit too long for his height. We then added height with the EVA foam to compensate for the short foot. He felt very comfortable on this foot, and walked around with confidence, even testing out the hills and steps in the dirt area behind the clinic. He also brought in his bike and rode around a few laps with ease. This was very clearly still a prototype design, though, because the zipties we used to attached the sole and platform to the foot did not hold it in place well. After we removed the foot from Linares we saw that the sole had shifted quite a bit.

Walter (a Vida Nueva technician), who currently uses a Flex Foot, also tested out the foot. We only tested the 0.1875 foot, initially with no platform. He said he liked the feel of the foot, though the pylon was a little long so it was hard to get an accurate feel. When we added the platform, he mentioned that the heel felt a little stiff and commented that it would be a good idea to potentially use a different material for the heel than the rest of the foot. If we do not use the large platform, though, it may not be necessary to use different materials.

Patient testing at Vida Nueva yielded promising qualitative results. Further quantitative studies will need to be carried out to further evaluate the Layer Foot, but these pilot tests suggest that it is worth pursuing.

6.4 PET Testing

We have been working to develop a method to recycle the PET found in plastic soda bottles in order to form sheets that can be used for the layer foot. Since initial tests have not provided us with adequate results to begin designing with PET, we are currently assuming the use of Delrin, as a supply chain will already be open to provide the M1 knee. However, we are optimistic that being able to produce materials locally is still a feasible option, so we are continuing to research ways to recycle PET in the clinic.

6.4.1 Testing Procedure 1- Furnace Melting

In our first test study we simply melted several plastic bottles in the furnaces in the Cal Poly MATE lab. We collected plastic bottles and after cutting them down, separated them into the following groups: caps/rings, sides, and bottom. The first test batch was large pieces cut out of the sides of the bottle. These pieces were placed in a basic cooking pan and then put in a furnace at 75˚C (this is the glass temperature of PET, or the point at which secondary bonds between polymer chains begin to break, creating a more ductile, pliable plastic). The raw plastic can be seen in Figure 6.13. We then raised the temperature to 175˚C and held it there until the total furnace time was 50 minutes. We removed the sample from the furnace without cooling it first, thereby essentially just quenching the material causing it to be brittle. As seen in the image below, the sample did not melt fully, was extremely brittle, and was slightly discolored.

Figure 6.13: Plastic pieces in the melting pan

Figure 6.14: After melting the plastic was discolored and brittle

In the second test batch, we cut the samples down into small flakes to see if we could achieve more uniform melting. These samples were placed in the furnace at 220˚C and held there for 60 minutes. Instead of taking the sample straight out of the furnace we allowed the sample to cool slowly to room temperature in the furnace. However, the sample appeared to have the same properties as group one: brittle and opaque.

After investigation, we found that the problem with this test was due to chain scissioning (or cutting of the polymer chains) caused by oxygen in the furnace. Plastics each have their own degree of polymerization, or number of repeat units in an average polymer chain at a given time, typically ranging within the thousands for a given polymer. When air is added into the plastics, as occurred with the oxygen in our furnace, it causes chain scissioning and results in brittle, discolored material. In order to solve this problem you must add compression or vacuum to the process to ensure that no air is entering the material.

6.4.2 Testing Procedure 2- Compression Mold

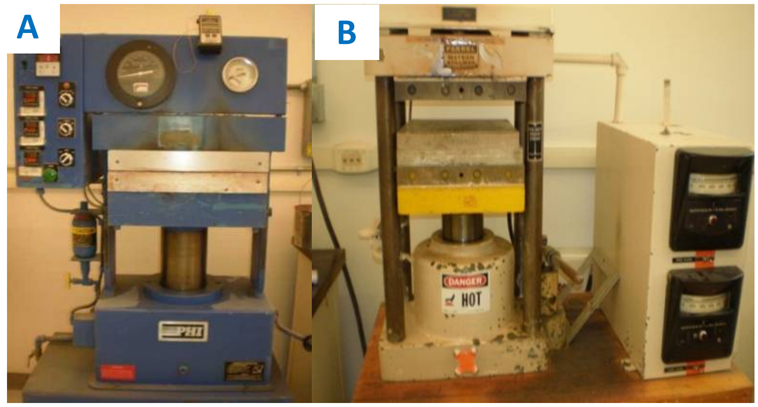

Figure 6.15: Cal Poly IT Lab Compression Molding Machines. (A) Compression molder with digital temperature gauge. (B) Compression molder with a dial temperature range.

For our next test we used the compression molder in the IT department. Our mold, donated from Kyle Bentz the IT technician, had the outer dimensions of 9x9x0.8 inches and inner dimensions 6.2x6.2x0.6 inches. The mold was filled to the top with virgin PET pellets (i.e., newly made, not recycled) and then placed in the compression molder at 425 degrees Fahrenheit under 4500 lbs. After three minutes the pressure was raised to 7500 lbs for another three minutes. We removed the mold from the machine but when we checked the material it was clear that it had not yet melted. We returned the mold to the machine and raised the temperature to 520 degrees Fahrenheit and held it there for ten minutes under 4500 lbs. We quenched the mold in cool water so we could open it and remove the melted plastic. Though the plastic was more ductile than the material produced in the furnace test described above, it still was not an ideal procedure because there were weak heterogeneous spots where the plastic did not melt evenly throughout. Also the plastic broke when we opened the mold and was difficult to. Two more trials were tested with measured amounts of resin. The first was 142.14 grams of resin and the second was 77.19 grams. They were both held at 520 degrees Fahrenheit at 4500 lbs for ten minutes. In the first test there was too much resin because it ended up coming out of the mold, and the second test was not enough due to too many amorphous regions.

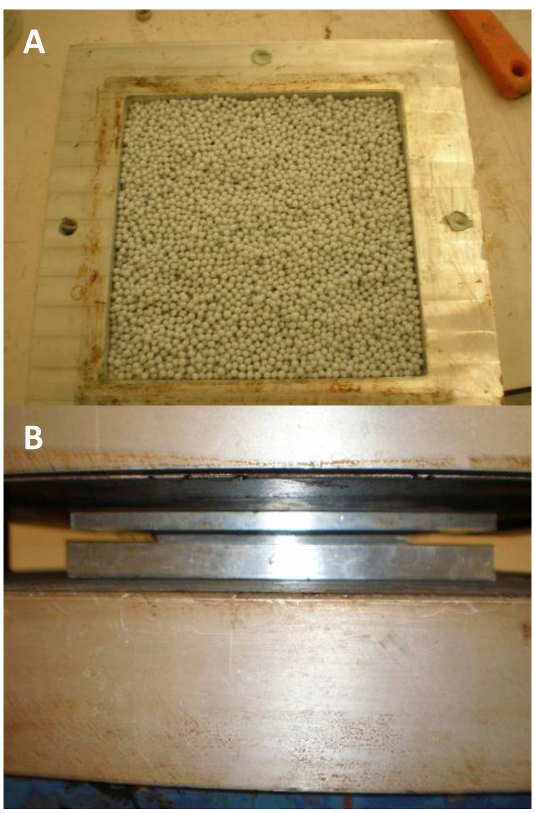

Figure 6.16: Square mold filled with PET pellets [A] and square mold compressed between the heated plates of the molder [B].

In order to successfully accomplish PET compression molding, we needed to have a better understanding of the molding techniques of different dies. We sought out the help of Martin Koch from the Industrial Manufacturing Engineering Department at Cal Poly. He suggested a bore and ram shape that we could punch out after compression. Typically circles are easier to work with than squares or rectangles when casting because there are fewer corners where material could get caught. A circular mold was created out of Aluminum with an outer diameter of 3.5 inches, inner diameter of 3.0 inches, and a height of 0.60 inches. The next ten compression molding tests were conducted with this

circular mold using Recycled PET, or RPET, which was donated by the IT Department. Due to failures of one of the compression molding machines in the IT lab, half of the tests were conducted using the compression molder with a dial temperature gauge and the other half were used with the digital temperature gauge (Figure 6.15).

After compression molding, the RPET was hammered out of the mold. This proved to be a challenge because the RPET leaked over the top of the mold because it became stuck to the top layer of the mold. However, this method was more effective than using the square mold. A silicone lubricant was used during one of the tests, but the resulting RPET was discolored. This may signify that the RPET and silicone acted as a mixture, which decreased the melting temperature of the RPET. As a result, the silicone was not used after that test. Table 6.2 represents the parametric study of compression molding that was conducted on PET.

Table 6.2: Compression molding parameters tested

Test No.	Mold	PET Type	Molder	Weight (grams)	Temperature Range (^{0}F)	Compression Force	Total Time (min)
1	Square	Virgin	(A)	not measured	425 - 520	4500 lbs	16
2	Square	Virgin	(A)	142.14	520	4500 lbs	10
3	Square	Virgin	(A)	77.19	520	4500 lbs	10
4	Circular	Virgin	(A)	67.27	520	4500 lbs	3
5	Circular	RPET	(B)	32.40	450-500	15 tons	25
6	Circular	RPET	(B)	36.90	510-520	3 tons	30
7	Circular	RPET	(B)	36.60	300-400	16 tons	15
8	Circular	RPET	(B)	41.27	400-450	16 tons	30
9	Circular	RPET	(B)	36.30	360-475	16 tons	50
10	Circular	RPET	(A)	36.39	505-510	16 tons	30
11	**Circular**	**RPET**	**(A)**	**35.68**	**510-525**	**15 tons**	**12**
12	Circular	RPET	(A)	36.61	510-525	15 tons	15
13	Circular	RPET	(A)	33.95	520-525	15 tons	15

The reason that there is a temperature range is because the temperature was set to around 525 degrees Fahrenheit and sometimes the compression molder reached this temperature and sometimes it did not. The ideal melting temperature range for PET is 518 degrees Fahrenheit according to CES.[15] This temperature can change when dealing with RPET due to contaminants. The molding pressure range is

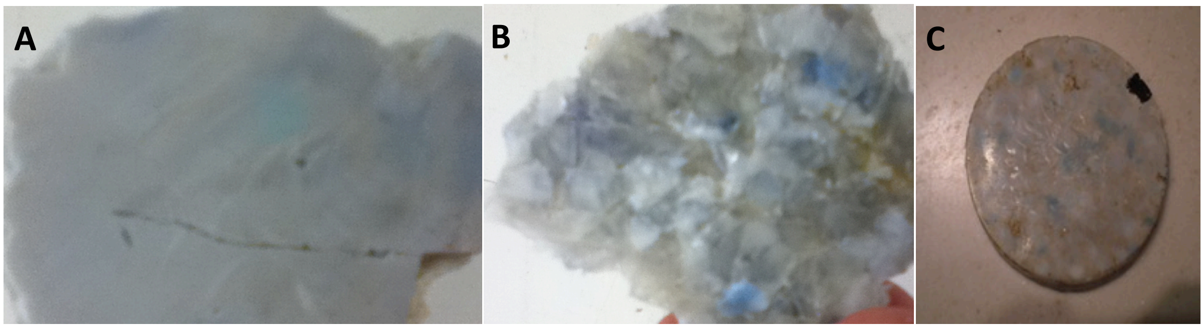

Figure 6.17: RPET result side closest to the mold lid (A). RPET result side farthest from the mold lid (B). RPET sample that turned out not fractured # 11 (C).

4.49 ksi, and with the area of the mold the force required turns out to be around 15.9 tons. The times were varied to ensure heat was distributed throughout the RPET. Heat transfer turned out to be the greatest problem. The thickness of the top and bottom lids of the mold only allowed the surfaces of the specimen to receive proper melting. The eleventh test was the only sample that did not fracture while getting out of the mold. Thus, these parameters were distinguished as the best throughout parametric testing of compression molding PET. However, there are still too many heterogeneous areas to be implemented as the material for the layer foot design. This technique is not yet a repeatable process that could be implemented in Vida Nueva. More design mold research is required to implement the greatest amount of heat transfer throughout the die. The current mold design results in a heterogeneous sample that does not meet the design specifications for the layer foot. Alternative processing methods should be investigated including extrusion or injection molding.

Chapter 7- Conclusion & Recommendations

7.1 Conclusions

Our team started out with high expectations. We had high hopes for completing several components of the prosthetic leg as well as utilizing an untested material, and throughout the year we slowly narrowed our focus to a single component. While we lost time exploring designs for many other components, we were able to lay a strong foundation for our design and have a comprehensive understanding of the full prosthetic system. The cost per unit remained under $30 and patient testing at Vida Nueva suggests the Layer Foot is an improvement over the ICRC foot they currently use, so it appears that the foot is a viable design. In addition to the Layer Foot, we have built ISO test fixtures and developed a protocol for testing the roll-over shape using a force plate and video camera. These tests will be useful in further optimizing the Layer Foot and designing other prosthetic components. Lastly, and perhaps most importantly, we have developed a strong working relationship with Vida Nueva. Continuing this relationship will ensure that we have a location to implement the design, and staff and clients from Vida Nueva can continue to provide useful feedback for future iterations of any component we design.

Throughout this year we also determined that compression molding PET is not yet a repeatable process that could be implemented in Vida Nueva. The use of recycled PET and virgin PET with our current design mold results in a heterogeneous sample that would not meet specifications for the Layer Foot. Even our “best” sample was only good because it was the only sample that did not break while getting out of the mold. Though we repeated two more trials with the same conditions to repeat the results, both samples fractured while trying to hammer them out of the mold. It is important for this process to be reproducible and repeatable for the Vida Nueva technicians because it is not efficient for them to be producing bad samples; with our current system this is clearly not yet a possibility. Finally, even the best sample does not have the necessary modulus and yield strength to work successfully in the Layer Foot design.

7.2 Recommendations

In the future, it would be wise to narrow the project focus to one component at a time. Teams larger than three students should be avoided where possible to maintain a narrowed focus. Furthermore, when designing for developing countries it is easy to want to solve all the problems they have simultaneously. However, the impact of one well developed item will be far more significant than several mediocre designs.

Future teams could benefit greatly by studying our methodology in developing the various testing setups and exploring further prosthesis testing. The ISO and roll-over shape tests were what we found to be the most crucial in prosthesis development, but the product may still require more accurate or entirely different methods. We are confident that the concept has a potential future, but the key to success will be proving its viability in the market. While we did receive very positive feedback after patient testing in Honduras, this qualitative feedback can only carry the design so far. However, if predictable and reproducible rollover shapes or other quantitative testing methods are developed, the

Layer Foot will be a much stronger product. Quantitative results can help us correlate the response of the foot to varying patient weight, height, and physique, and can help characterize how to size the foot for different patients. The team would also benefit by testing much more often with patients. The combination of good feedback and quantitative data will provide the team with valuable feedback, and the more often this feedback is received the more effective the team can be.

After our trip to Vida Nueva in the spring we developed a list of the steps we should take next to progress with the foot design. The primary concern for the technicians at Vida Nueva is that the foot is stable inside of a shoe. With our current design the foot could slide side to side within the shoe. To compensate for this, Walter in particular thought it would be helpful to have a cosmetic cover. Previously we had been concentrating on pre-made cosmetic covers, but their cost is prohibitively high to be very useful. Walter then mentioned that they make their own covers in the clinic and showed one to us. This is definitely a viable option and one that should be further explored in the coming year. The cosmetic cover does not need to aesthetically match a physiological foot, but it does need to make the Layer Foot stable in a shoe. Like the Layer Foot, the cosmetic cover materials should be locally sourced and should require minimal time to construct. Our second concern for the foot is durability. Future testing should involve considerable cyclic testing as well as a study of how the material breaks down under difficult conditions, including heat, humidity, rough terrain, etc.

In order to implement our design we must establish training modules for manufacturing and find a supplier for Delrin. We have received a list of Delrin contacts from Matt Pepe in Bolivia and intend to send this list to Reina so she can begin exploring the costs and availability of the material. Future teams should also continue to plan for expansion. In order to deploy the Layer Foot we must develop a manual to train the technicians to build and fit the feet as well as a means to spread this knowledge throughout the clinics. The next goal of the project should be to deploy the Layer Foot at Vida Nueva in limited quantities by/during Summer 2012.

Further work for compression molding PET includes researching and designing a better bore and ram shaped mold to punch out the sample more quickly and/or continuing research of other recycling devices. Currently, it takes anywhere from five to ten minutes to hammer out the sample from our existing mold, so it is not efficient by any means. This is likely caused by poor design, and could easily be improved upon if someone with even a little knowledge of material processing designed a more suitable mold. Future molds should more closely match the geometries of the actual layers to determine if those geometries are more feasible. If compression molding proves not to be viable it would be beneficial to investigate alternate processing methods, including extrusion and injection molding. Future senior design projects will likely include a low cost recycling method for third world applications.

We are extremely pleased with our success so far and Vida Nueva is also excited about our results. We look forward to the improvements we will make in the coming year and are eager to see the lives that our product can change. We have built a platform for future Cal Poly engineering students to continue developing prosthetic devices for the developing world. This program is starting out with a prosthetic foot for Vida Nueva but has the potential to expand to other devices at other clinics.

Figure 7.1: Vida Nueva staff and patients with our team on our May 2011 trip

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Appendix A

House of Quality

This house of quality was built from the design requirements laid out by the stakeholders in the project. Those can be seen on the left. On the top is the list of the engineering requirements we determined to be suitable for the project. In the center is a correlation of how each specification fills each requirement to ensure that all of them are fulfilled. Also included is a weighting of how important each design requirement is to the user to ensure that we understand which specifications are especially important to focus on. Lastly there is a brief analysis of how well the other designs fulfill the specifications. This gives makes us check that our design will ultimately perform better than the previous designs.

Table A.1: HOQ for Foot

Piernas de Vida FOOT																	Bench-marks		
Customer Requirements	Patient	Walter, Roque, and Matt P.	Manufacturer	Reina and Matt P.	0.23-0.8 kilograms	$30 max	Ankle- Angle Response	Lasts for 3 yrs min.	Heel Strike Force	Manufacture with mill	Deteriorate <5% in 2 years	Shape and Sizing	Proof Load Strength	Ultimate Strength	Fatigue Strength	VI-SACH	Jaipur	College Park
Natural Gait	14.0	16.0	0.0	2.0	○		●		●		Δ	Δ	Δ	Δ	Δ	4	4	8
Weight	16.0	11.0	0.0	4.0	●		Δ		○			○				7	7	8
Adjustability	9.0	18.0	0.0	7.0	Δ		○					Δ				2	0	6
Durability	11.0	13.0	17.0	13.0		Δ		●	Δ	Δ	●	Δ	Δ	Δ	Δ	2	9	9
Producible in house	5.0	7.0	22.0	16.0		○	○			●		Δ				0	0	0
Aesthetic	18.0	2.0	0.0	9.0						Δ	Δ	●				7	8	2
Easy to Manufacture	2.0	4.0	25.0	11.0						●	○	Δ				4	3	1
Cost	20.0	9.0	22.0	18.0	Δ	●	Δ	○		Δ	●	○	Δ	Δ	Δ	8	8	2
Safety	5.0	20.0	14.0	20.0	Δ	Δ	○	○	●	Δ	●	Δ	●	●	●	7	7	8

Table A.2: HOQ for Ankle Adapter

Piernas de Vida ADAPTER — Customer Requirements	Patient	Walter, Roque, and Matt P.	Manufacturer	Reina and Matt P.	1 degree of freedom	±8-10 degrees angluar adjustment	± ¼ in translation adjustment	Allen Wrench adjustment	115 x s.f 3.28 weight forebearance	Manufacture with mill	Cost < $5.00	Maintain Alignment for 12 months	Bench-marks: Inverted Pyramid	ICRC	Mighty Might
Manufacturable in house	0.0	12.6	45.0	17.6	∆			∆		●	○		1	1	1
Min one degree of freedom	11.9	7.9	0.0	0.0	●	○	○				○		5	4	4
Adjustable by hand tools	0.0	11.0	0.0	0.0	∆			●				∆	4	2	4
Maintains alignment	39.5	4.7	0.0	21.2				○	●			●	5	4	3
Easy to adjust	0.0	12.6	0.0	0.0	∆	○	○	●					5	3	4
Angular adjustment	0.0	9.4	0.0	0.0	○	●	∆	∆					5	5	2
Translation	0.0	9.4	0.0	0.0	○	∆	●	∆					2	5	5
Easy to manufacture	0.0	14.2	45.0	21.2	●					●	○		1	1	1
Cost	9.1	5.7	1.0	8.3				∆		∆	●		2	4	2
Safety	39.5	12.6	9.0	31.8					●			●	5	5	5

Legend

∆=Weak correlation

○= Medium correlation

●=Strong correlation

Pugh Matrices

Below are the Pugh Matrices we developed to compare our ideas against each other and against the current existing designs. We created a separate matrix for each component that we are designing and have moved forward with the designs for the idea with the highest total value.

Table A.3: Pugh Matrix for Ankle Adapter

	Concept:	Concentric Tube Adapter	Cradle Adapter	Two Plate Adapter	Pylon Cup Adapter
Requirement	**Baseline**	1	2	3	4
Manufacturable in house	ICRC	+	+	+	+
Min one degree of freedom	Inverted pyramid	+	-	+	-
Adjustable by hand tools	MightyMite™	+	+	-	+
Maintains alignment for 6 months	MightyMite™	S	+	S	+
Can adjust one degree of freedom at a time	Inverted Pyramid	S	-	-	S
Angular Adjustment ±8-10 degrees	Inverted pyramid	+	+	S	+
Translation ± ¼ inch	Inverted pyramid	+	+	S	-
Easy to manufacture	Inverted pyramid	+	+	-	+
	∑+	4	5	1	6
	∑-	1	3	4	1
	∑S	2	0	3	1
	Total	3	2	-3	4

The Pugh Matrices rates each concept based on the design requirements against an existing design that we think best meets the requirement. Each concept is scored with a +, -, or S depending on whether the design fulfills the requirement better, worse, or the same as the baseline concept. Then from the sum of the pluses, minuses, and sames we arrived at the design with the highest overall score.

Table A.4: Pugh Matrix for Foot

	Concept:	Rim foot	Layer Foot	Molded plastic foot
Requirement	Baseline	1	2	3
Manufacturable in house	Shape and Roll	+	S	-
Effective Gait Reproduction	Niagara Foot	-	S	-
Low Cost	ICRC SACH	+	+	-
Minimal Deterioration	Niagara Foot	-	S	S
Long Replacement Interval	Jaipur Foot	-	+	-
	∑+	2	2	0
	∑-	3	0	4
	∑S	0	3	1
	Total	-1	**2**	-4

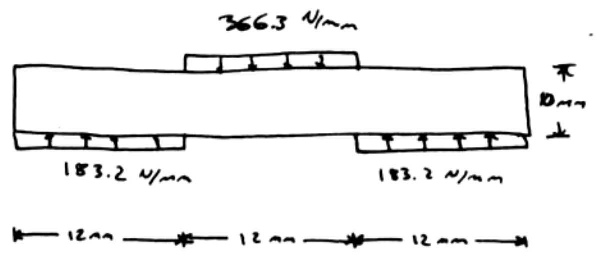
Table A.5: Pugh Matrix for Knee

	Concept:	Cam Knee	M1 Knee	Jaipur Knee
Requirement	Baseline	1	2	3
Manufacturable in house	ICRC	+	+	+
Effective Gait Reproduction	ICRC	-	+	S
Low Cost	ICRC	+	+	+
Minimal Deterioration	ICRC	-	S	S
Long Replacement Interval	ICRC	-	+	S
	∑+	2	4	2
	∑-	3	0	0
	∑S	0	1	3
Total		-1	**4**	2

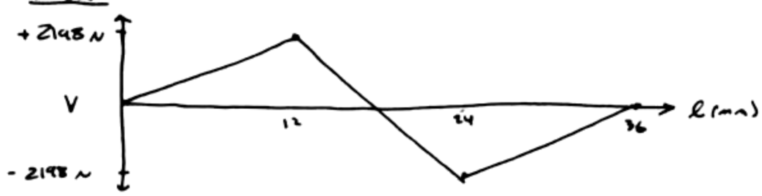
Analysis for Concept Proof

Uni-Axial Ankle

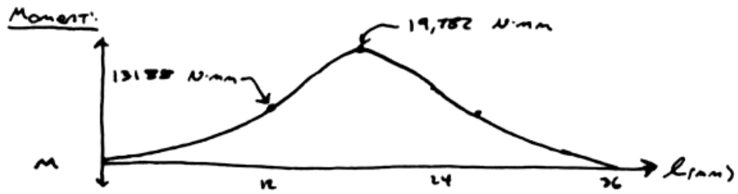
Shaft Analysis for uniaxial ankle:



Shear:



Moment:



Bending Stress @ maximum:

$$\sigma = \frac{Mc}{I} = \frac{Md}{2\left(\frac{\pi}{64}\right)d^4}$$

$$\sigma = \frac{(19{,}782 \text{ N·mm})(10\text{mm})}{2\left(\frac{\pi}{64}\right)(10\text{mm})^4}$$

$$\sigma = 201.5 \text{ MPa}$$

Yield stress of steel: $S_y = 250$ MPa

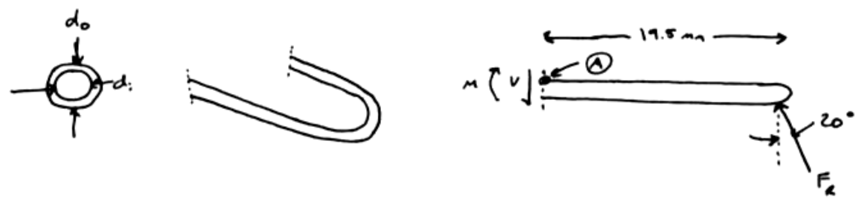
$$\sigma \overset{?}{\leq} S_y$$

$$201.5 \text{ MPa} \leq 250 \text{ MPa}$$

This shaft can support kinematic loading during gait.

Rim Foot

Stress analysis for Rim foot:



Maximum loading will occur at point A in compression

$$\sigma_{bending} = \frac{Mc}{I} = \frac{(F_R \cos 20°)(d_o/2)(19.5\,mm)}{(\pi/64)(d_o^4 - d_i^4)}$$

$$\sigma_{axial} = \frac{P}{A} = \frac{F_R \sin 20}{\frac{\pi}{4}(d_o^4 - d_i^4)}$$

$$\sigma_{max} = \sigma_{bending}$$

Check:

$$\sigma_{max} \overset{?}{\leq} S_y$$

Layer Foot Analysis Matlab Script

```
% LayerFootAnalysis_ToeLoadv01.m
% By: Kevin Yamauchi, 2010
%
% The script calculates the stresses in a given layer foot at points of
% interests.
%
% Coordiate system:
% Origin: anterior-distal most portion of foot
% x-direction: anterior-posterior direction
% y-direction: proximal-distal direction
% z-direction: medial-lateral direction
%
% Units:
% length: mm
% area: mm^2
% area MOI: mm^4
% force magnitude: newtons
% force direction: degrees (+ = CW From -y axis)
% stress: MPa
%
% Assumptions:
% 1) Layers stay joined and behave as continuous body
% 2) Infinitessimal strains (linear)
% 3) Homogeneous, isotropic material
% 4) Saint Venat's principle
%
% Input:  1) Foot dimensions in mm
%         2) Loading parameters
% Output: 1) Stresses at each step in sagital plane
%         2) Centroids in sagital plane
```

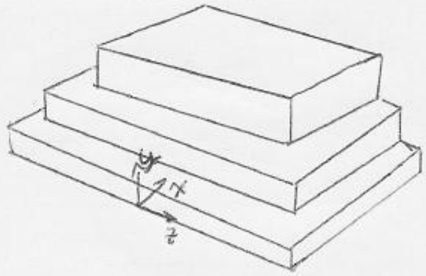
```
%         3) Area MOI about neutral axis normal to sagital plane

 %% Initialize workspace
clc; clear all; close all;

%% Define foot dimensions

% Number of layers
numLayers = 5;

% Height of layers (uniform thickness)
height = 15; % [mm]

% Lengths (anterior-posterior direction)
length = [20, 20, 30, 20 105]; % [mm]

% Widths (medial-lateral direction)
width = [104.1, 84.1, 64.1, 44.1, 44.1]; % [mm]

%% Define load
P = 4300;
theta = 20;

%% Define Material Properties

E = 3000E6; % [Pa]

%% Calculate centriods (sagittal plane)

% all centroids in mm from anterior-distal most point

% Preallocate arrays
area_s = zeros(1, numLayers); % array of areas in sagittal plane
c_x = zeros(1, numLayers); % array of centroids in a-p direction
c_y = zeros(1, numLayers); % array of centroids in prox-dist direction

% Find centroid for each layer cut
for layer = 1:numLayers

    % Calculate area
    area_s(layer) = length(layer) * (layer * height); % [mm^2]

    % Find centroid of first layer
    if layer == 1
        c_x(1) = length(1) / 2;
        c_y(1) = height / 2;

    else % for all other layers
        c_x(layer) = (c_x(layer - 1) * sum(area_s(1:layer-1))...
            + (sum(length(1:(layer-1))) + (length(layer) / 2))...
            * area_s(layer)) / sum(area_s(1:layer));

         c_y(layer) = (c_y(layer - 1) * sum(area_s(1:layer-1))...
            + (height * layer) / 2 * area_s(layer)) / sum(area_s(1:layer));
```

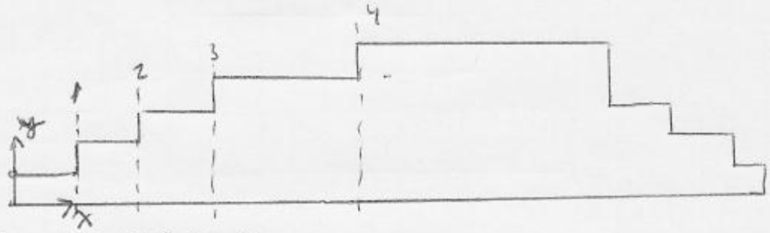
```
end

 end

%% Calculate moment of inertial (neutral axis normal to sagittal plane)

% Preallocate arrays
I = zeros(1, numLayers);
I_NA = zeros(1, numLayers);

% Find area MOI of each individual layer
for layer = 1:numLayers
    I(layer) = (1/3) * width(layer) * height ^ 3;
end

% Find MOI for each cut
for section = 1 : numLayers

    for layer = 1 : section
        I_NA(section) = I_NA(section) + I(layer) + width(layer) * height...
           * ((height * (layer - 1)) - c_y(section))^2;

    end


end

%% Calculate stresses at each step

% Preallocate arrays
F_norm = zeros(1, numLayers);
F_shear = zeros(1, numLayers);
M = zeros(1, numLayers);
S_bend_tens = zeros(1, numLayers);
S_bend_comp = zeros(1, numLayers);
S_norm = zeros(1, numLayers);
sigma_tens = zeros(1, numLayers);
sigma_comp = zeros(1, numLayers);

for section = 1:numLayers

% Find forces and moments at cut
F_norm(section) = P * sind(theta);
F_shear(section) = P * cosd(theta);

M(section)  = (F_shear(section) * sum(length(1:section)))...
    - (F_norm(section) * c_y(section)); % [N/mm]

% Find stress due to bending
S_bend_tens(section) = (M(section) * c_y(section)) / I_NA(section);
S_bend_comp(section) = (M(section) * (section * height - c_y(section)))...
   / I_NA(section);

% Find stress due to normal force
```

```
S_norm(section) = F_norm(section) / (height * sum(width(1:section)));

% Find stress due to shear

% Find total stress
sigma_tens(section) = S_bend_tens(section) - S_norm(section);
sigma_comp(section) = S_bend_comp(section) + S_norm(section);


end
```

Sample Calculations

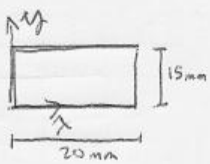
CENTROID SAMPLE CALCULATIONS





CENTROID SAMPLE CALCS

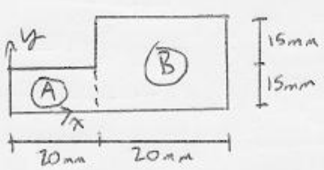
(1)



$C_{x_1} = \frac{20mm}{2}$ $\boxed{C_{x_1} = 10mm}$

$C_{y_1} = \frac{15mm}{2}$ $\boxed{C_{y_1} = 7.5mm}$

(2)



$$C_{x_2} = \frac{\Sigma C_{x_i} A_i}{\Sigma A_i}$$

$$= \frac{C_{x_A} A_A + C_{x_B} A_B}{A_A + A_B}$$

$$= \frac{(10mm)(20mm \cdot 15mm) + (30mm)(30mm \cdot 20mm)}{(20mm \cdot 15mm) + (30mm \cdot 20mm)}$$

$$\boxed{C_{x_2} = 23.33mm}$$

$$C_{y_2} = \frac{\Sigma C_{y_i} A_i}{\Sigma A_i}$$

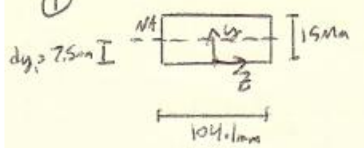
$$= \frac{C_{y_A} A_A + C_{y_B} A_B}{A_A + A_B}$$

$$= \frac{(7.5mm)(20mm \cdot 15mm) + (15mm)(30mm \cdot 20mm)}{(20mm \cdot 15mm) + (30mm \cdot 20mm)}$$

$$\boxed{C_{y_2} = 12.5mm}$$

MOI SAMPLE CALCULATIONS

1

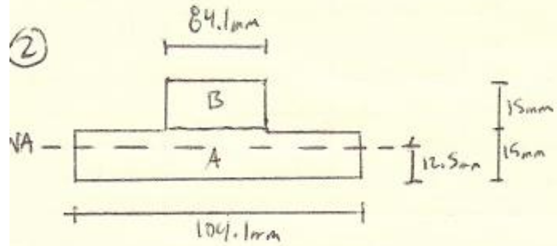


$$I_{NA_1} = I_z + A_1 dy_1^2$$

$$= \frac{1}{3}(104.1mm)(15mm)^3 + (104.1mm)(15mm)(7.5mm)^2$$

$$\boxed{I_{NA_1} = 204946.9 mm^4}$$

2



$$I_{NA_2} = I_{NA_A} + I_{NA_B}$$

$$= (I_A + A dy_A^2 + I_B) + (I_B + A_B dy_B^2)$$

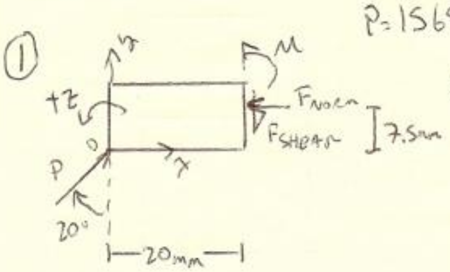
$$= \frac{1}{3}(104.1mm)(15mm)^3 + (104.1mm)(15mm)(12.5mm)^2 + \frac{1}{3}(84.1mm)(15mm)^3 + (84.1mm)(15mm)(15mm - 12.5mm)^2$$

$$\boxed{I_{NA_2} = 463590 mm^4}$$

FORCES/ MOMENTS

$P = 1565.37N$

(1)



$$\Sigma F_x = 0 = P\sin 20° - F_{NORM}$$

$$F_{NORM} = 1565.37N \sin 20°$$

$$\boxed{F_{NORM} = 535.4\,N}$$

$$\Sigma F_y = 0 = P\cos 20° - F_{SHEAR}$$

$$F_{SHEAR} = 1565.37 \cos 20°$$

$$\boxed{F_{SHEAR} = 1470.97N}$$

$$\Sigma M_0 = 0 = M - F_{SHEAR}(20mm) + F_{NORM}(7.5mm)$$

$$M = 1470.97N(20mm) - 535.4N(7.5mm)$$

$$\boxed{M = 29419.3N\,mm}$$

$$25403.8\,N\,mm$$

$$\sigma_{BEND,COMP} = \frac{Mc}{I} = \frac{(29419.3Nmm)(7.5mm)}{204946.9mm^4}$$

$$\boxed{\sigma_{BEND,COMP} = 0.9297\ MPa}$$

$$\sigma_{BEND,TENS} = \frac{Mc}{I} = \frac{(29419.3Nmm)(7.5mm)}{204946.9mm^4}$$

$$\boxed{\sigma_{BEND,TENS} = 0.9297\,MPa}$$

$$\sigma_{NORM} = \frac{F}{A} = \frac{535.4N}{(7.5mm)(104.1mm)}$$

$$\boxed{\sigma_{NORM} = 0.3429\ MPa}$$

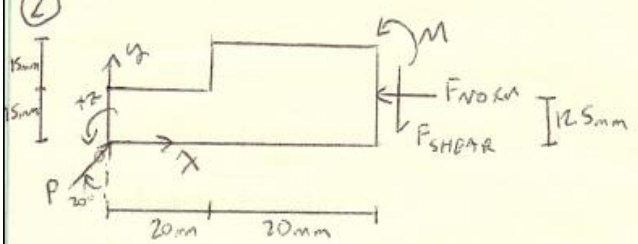
$$\sigma_{COMP,MAX} = \sigma_{BEND,COMP} + \sigma_{NORM} = 0.9297MPa + 0.3429\ MPa$$

$$\boxed{\sigma_{COMP,MAX} = 1.2725\,MPa}$$

$$\sigma_{TENS,MAX} = \sigma_{BEND,TENS} - \sigma_{NORM} = 0.9297MPa - 0.3429$$

$$\boxed{\sigma_{TENS,MAX} = 0.5868MPa}$$

(2)



$P = 1565.37N$

$\sum F_x = 0 = P\sin 20° - F_{NORM}$

$F_{NORM} = 1565.37N \sin 20°$

$\boxed{F_{NORM} = 535.4N}$

$\sum F_y = 0 = P\cos 20° - F_{SHEAR}$

$F_{SHEAR} = 1565.37N \cos 20°$

$\boxed{F_{SHEAR} = 1470.47N}$

$\sum M_0 = 0 = M - F_{SHEAR}(40mm) + F_{NORM}(12.5mm)$

$M = 1470.47N(40mm) - 535.4N(12.5mm)$

$\boxed{M = 521463\ Nmm}$

$\sigma_{BEND,comp} = \frac{Mc}{I}$

$= \frac{(52146.3Nmm)(30mm - 12.5mm)}{463590mm^4}$

$\boxed{\sigma_{BEND,comp} = 1.4684 MPa}$

$\sigma_{BEND,TENS} = \frac{Mc}{I}$

$= \frac{(52146.3Nmm)(12.5mm)}{463590mm^4}$

$\boxed{\sigma_{BEND,TENS} = 1.4060 MPa}$

$\sigma_{NORM} = \frac{F}{A}$

$= \frac{535.4N}{(84.1mm)(15mm) + (104.1mm)(15mm)}$

$\boxed{\sigma_{NORM} = 0.1897 MPa}$

$\sigma_{COMP,MAX} = \sigma_{BEND,comp} + \sigma_{NORM}$

$= 1.4684MPa + 0.1897MPa$

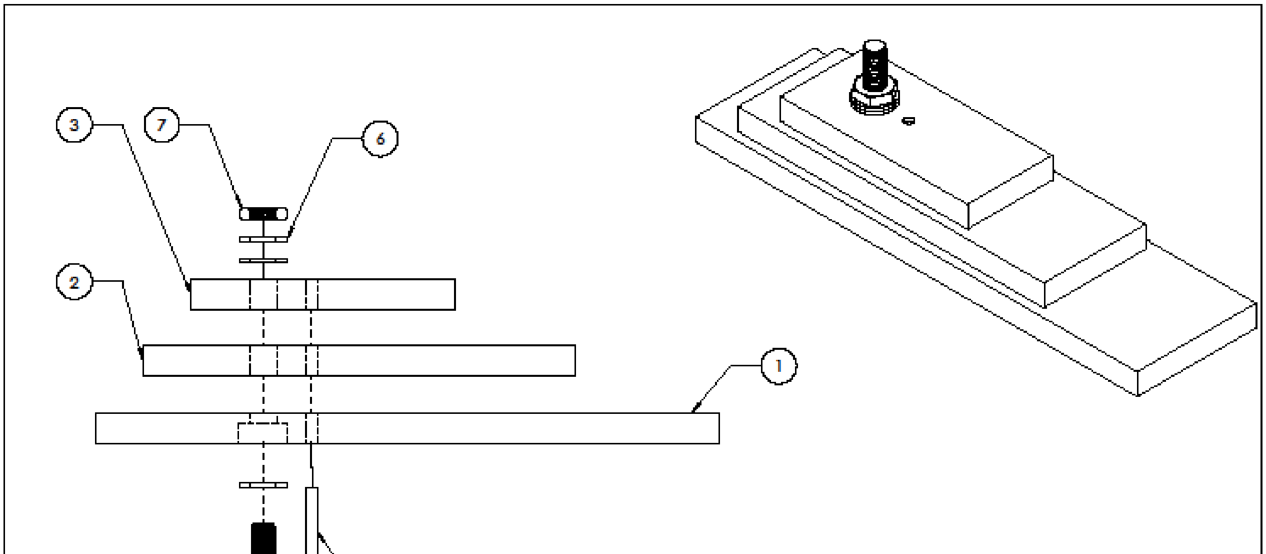
$\boxed{\sigma_{COMP,MAX} = 2.1581 MPa}$

$\sigma_{TENS,MAX} = \sigma_{BEND,TENS} + \sigma_{NORM}$

$= 1.4060MPa - 0.1897MPa$

$\boxed{\sigma_{TENS,MAX} = 1.2164 MPa}$

Appendix B- Detailed Design Drawings



ITEM NO.	PART NUMBER	QTY.
1	BottomLayer	1
2	Middle Layer	1
3	TopLayer	1
4	Spring Pin - 91610A613	1
5	M10x60 Bolt - 91610A613	1
6	M10 Washer - 93475A280	3
7	M10 Nut - 90710A125	1

Piernas de Vida Mechanical Engineering CAL POLY	DATE: 2/1/2011	UNITS: mm	TITLE: Layer Foot - Assembly
		SCALE: 1:2	
		NEXT ASSY: NA	NAME: KevinYamauchi
		DRAWING #: LF_ASSY	SIGNATURE:

Figure B.1: Assembly drawing and bill of materials for the Layer Foot.

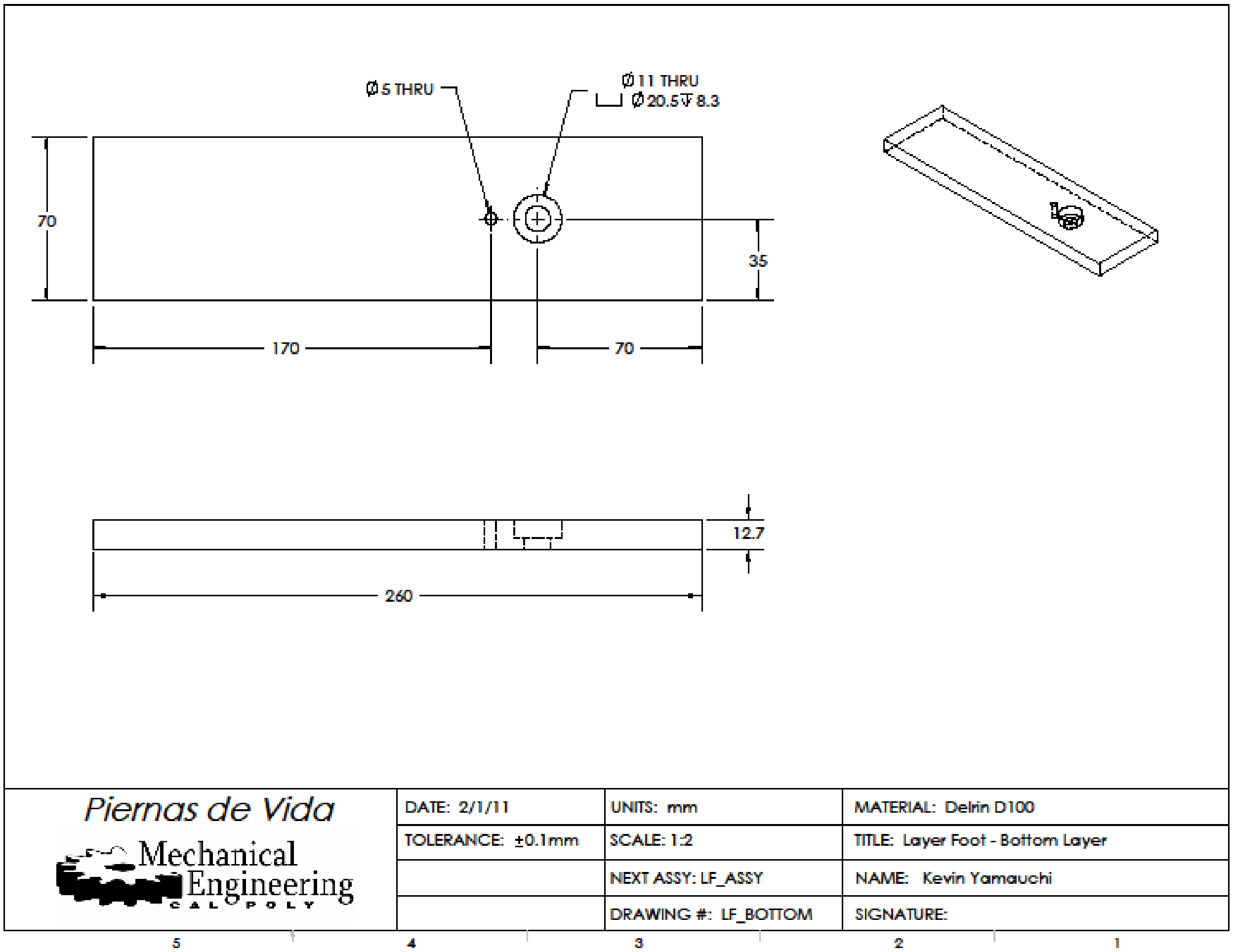


Figure B.2: Drawing of the bottom layer of the Layer Foot.

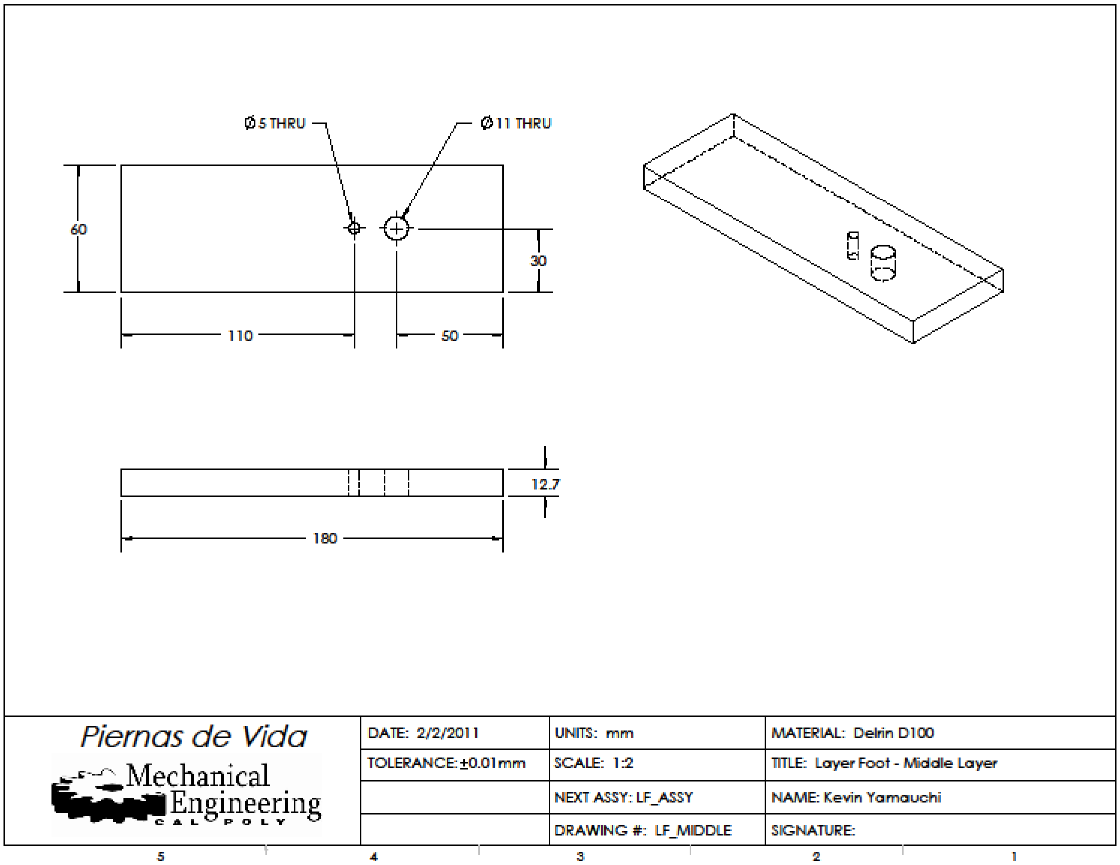


Figure B.3: Drawing of the middle layer of the Layer Foot.

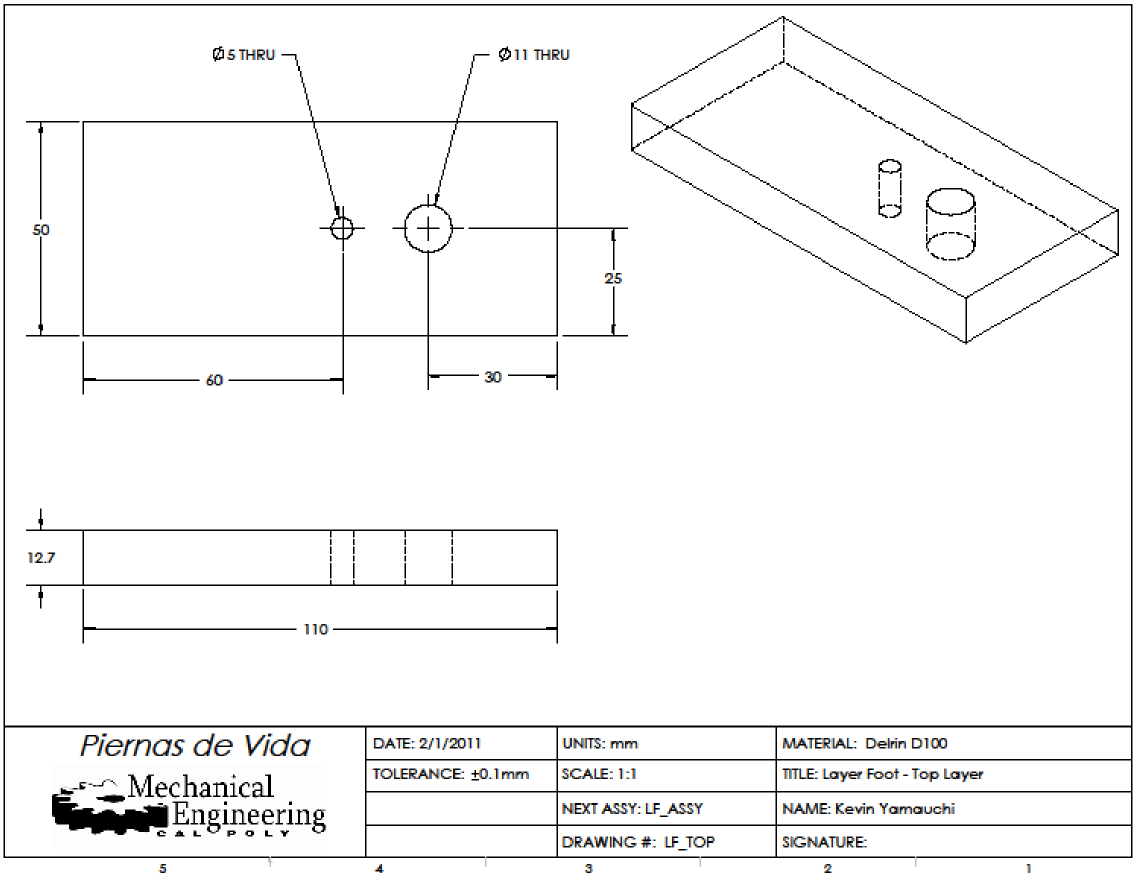
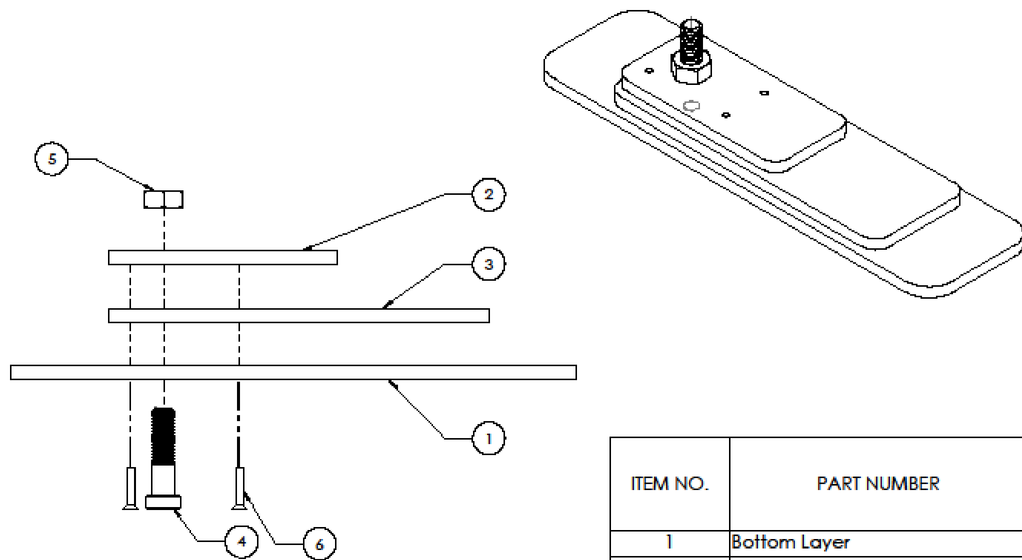


Figure B.4: Drawing of the top layer of the Layer Foot.



ITEM NO.	PART NUMBER	QTY.
1	Bottom Layer	1
2	Top Layer	1
3	Middle Layer	1
4	M10 Bolt - 93070A221	1
5	M10 Nut - 90591A171	1
6	#6 Screw - 90294A151	4

ME152 - FALL 2010	DATE: 5/19/2011	UNITS: mm	TITLE: Layer Foot - Assembly
		SCALE: 1:2	
		NEXT ASSY: NA	NAME: Kevin Yamauchi
		DRAWING #: LF_ASSY	SIGNATURE:

Figure B.5: Assembly drawing of the revised Layer Foot

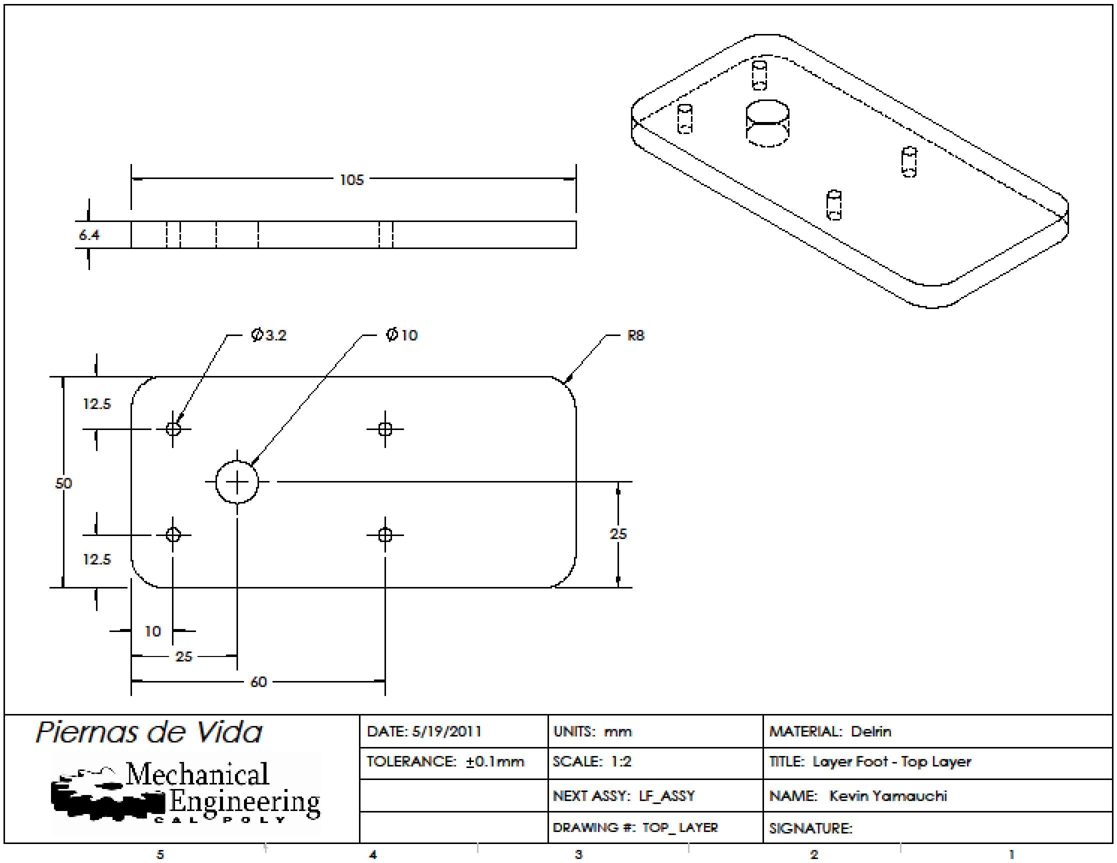


Figure B.6: Drawing of the top layer of the revised Layer Foot

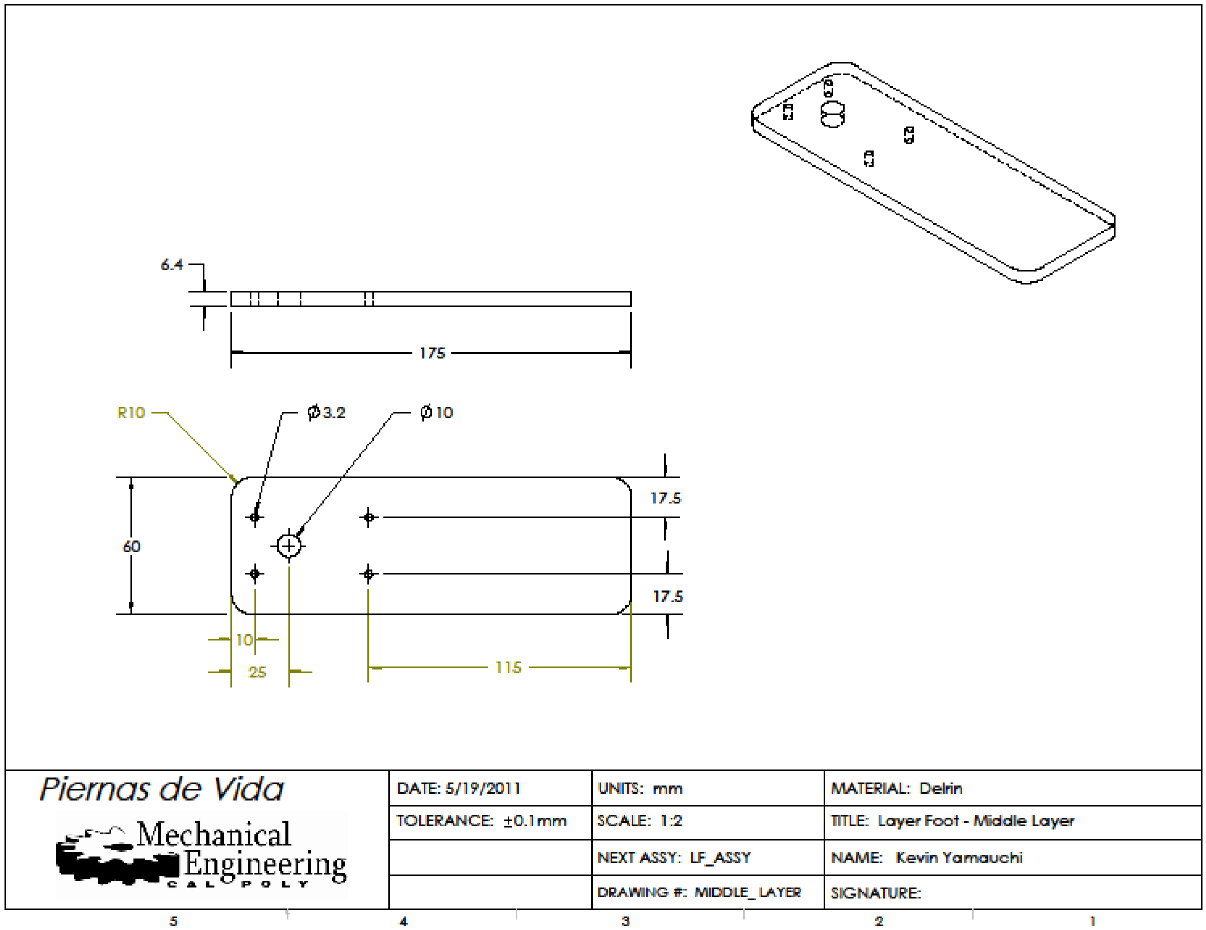


Figure B.7: Drawing of the middle layer of the revised Layer Foot.

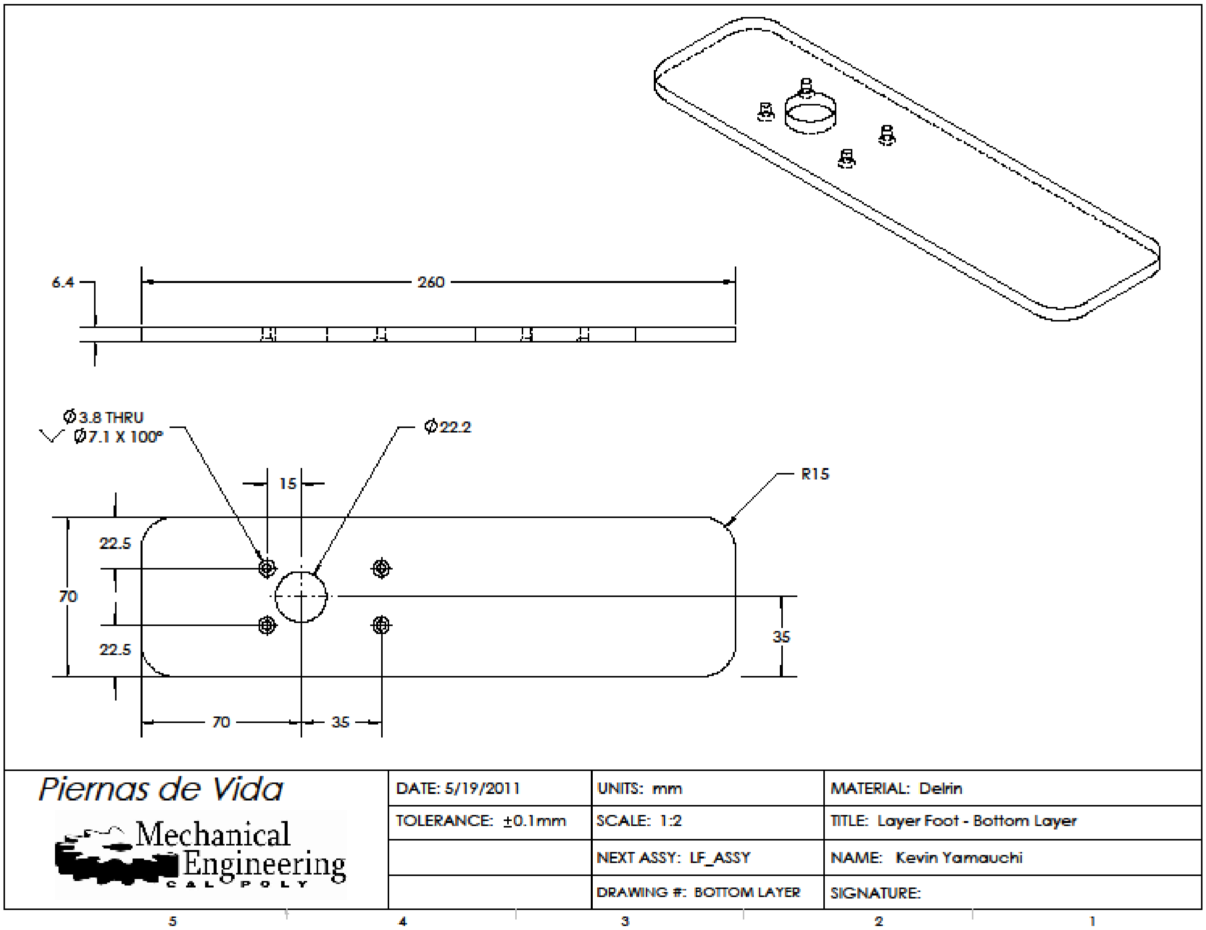


Figure B.8: Drawing of the bottom layer of the revised Layer Foot.

Appendix C-Material Purchasing and Contacts

Sponsor Contact Information

Contact	Position	Email / Phone Number
Reina Estrada	**Director** – Vida Nueva Clinic *½ cuadra al sur de la Iglesia la Merced Choluteca, Honduras CA*	Clinic Phone Number: 011-504-782-7296 Reina Cell Number: 011-504-95-74-47-44 Skype name: provinu20031 E-mail: provinu2003@yahoo.com.mx
Matt Robinson	**Orthotist/Prothetist** – Hanger Prosthetics *2400 Broad St* *San Luis Obispo, CA 93401-5702*	E-mail: amrobinson@hanger.com
Matt Pepe	**Director - La Paz Rotary Club Prosthesis Clinic** *La Paz, Bolivia*	**E-mail:** mattpepe@yahoo.com
Dr. Brian Self	**Advising Professor -** Mechanical Engineering *Cal Poly SLO*	**Office Number:** 805-756-7993 E-mail: bself@calpoly.edu

Company	Material	Contact Info
Piper Plastics, Inc.	Delrin 100 Series Natural ¼ " 2'*4' $134.00	257 E. Alamo Drive Chandler, AZ 85225 480-926-8100
McMaster-Carr	Socket Cap Screws $10.80 for pack of 5 Ankle Nut $4.78 for pack of 25 Screws $9.42 for pack of 100	600 N County Line Rd. Elmhusrt, IL 60126 630-833-0300

*Note, this information is useful for ordering for prototypes, however we still need to establish contacts to purchase supplies within Choluteca. This may be a task that Reina and the technicians should do because they are more familiar with what is locally available. We should likely send them a list of materials needed so they can begin establishing supply chains for each part.

Appendix D- Vendor Supplied Data Sheets

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

1 PET (unfilled, semi-crystalline)

General properties

Designation

Polyethylene Terephthalate (unfilled, semi-crystalline)

Density	1.37e3 - 1.4e3	kg/m^3
Price	* 1.72 - 1.89	USD/kg

Tradenames

Anjadur; Arnite; Aspect; Axpet; Azdel; Cleartuf; Cobiter; Cronar; Crystar; Dialamy; Eastabond; Eastapak; Ekolon; Ektar; Encore; Enpla; Ensitep; Ertalyte; Eslon; Esmo; HiPET; Hostaglas; Hylox; Hyperite; Impet; Kodapak; Kopel; Kopet; Lamapet; Laser+; Lupet; Maxnite; Melinar; Melinex; Murylat; Mylar; Nopla; Novapet; Permastat; Petra; Pibiter; Raditer; Relpet; Rynite; Sedapet; Selar; Serapet; Shinite; Shinlon; Shinpet; Skypet; Sustadur; Tairilin; Tarolox; Tarolux; Tecadur; Terphane; Tetron; Texpet; Thermx; Trelgum; Tripet; Tynep; Valox; Vivak; Vylopet

Composition overview

Composition (summary)

$(CO\text{-}(C_6H_4)\text{-}CO\text{-}O\text{-}(CH_2)_2\text{-}O)_n$

Base	Polymer	
Polymer class	Thermoplastic : semi-crystalline	
Polymer type	PET	
Polymer type full name	Polyethylene terephthalate	
% filler (by weight)	0	%
Filler type	Unfilled	

Composition detail

Polymer	100	%

Mechanical properties

Young's modulus	2.76 - 3.1	GPa
Compressive modulus	* 2.76 - 4.14	GPa
Flexural modulus	2.99 - 3.09	GPa
Shear modulus	* 0.994 - 1.49	GPa
Bulk modulus	* 4.94 - 5.19	GPa
Poisson's ratio	* 0.381 - 0.396	
Shape factor	5.7	
Yield strength (elastic limit)	* 65 - 70	MPa
Tensile strength	70 - 75	MPa
Compressive strength	75.8 - 103	MPa
Flexural strength (modulus of rupture)	* 70 - 75	MPa
Elongation	65 - 75	% strain
Hardness - Vickers	* 17 - 20	HV
Hardness - Rockwell M	82 - 87	
Hardness - Rockwell R	120 - 125	
Fatigue strength at 10^7 cycles	* 19.3 - 29	MPa
Fracture toughness	* 4.75 - 5.25	MPa.m^0.5
Mechanical loss coefficient (tan delta)	* 0.00966 - 0.0145	

Impact properties

Impact strength, notched 23 °C	2.86 - 3.15	kJ/m^2
Impact strength, unnotched 23 °C	190 - 200	kJ/m^2

Thermal properties

Melting point	255 - 265	°C

Glass temperature	68	-	80	°C
Heat deflection temperature 0.45MPa	105	-	115	°C
Heat deflection temperature 1.8MPa	70	-	80	°C
Maximum service temperature	115	-	120	°C
Minimum service temperature	* -58	-	-38	°C
Thermal conductivity	0.138	-	0.151	W/m.°C
Specific heat capacity	1.1e3	-	1.2e3	J/kg.°C
Thermal expansion coefficient	75	-	80	µstrain/°C

Processing properties

Linear mold shrinkage	1.5	-	1.7	%
Melt temperature	260	-	280	°C
Mold temperature	125	-	145	°C
Molding pressure range	13.8	-	48.1	MPa

Electrical properties

Electrical resistivity	3.3e20	-	3e21	µohm.cm
Dielectric constant (relative permittivity)	3.5	-	3.7	
Dissipation factor (dielectric loss tangent)	* 0.002	-	0.003	
Dielectric strength (dielectric breakdown)	16.5	-	18	MV/m
Comparative tracking index	200	-	325	V

Optical properties

Refractive index	1.57	-	1.58	
Transparency	Opaque			

Absorption, permeability

Water absorption @ 24 hrs	0.1	-	0.2	%
Water vapor transmission	0.464	-	0.707	g.mm/m².day
Permeability (O2)	1.2	-	2.77	cm³.mm/m².day.atm

Durability: flammability

Flammability	Highly flammable

Durability: fluids and sunlight

Water (fresh)	Excellent
Water (salt)	Excellent
Weak acids	Acceptable
Strong acids	Unacceptable
Weak alkalis	Acceptable
Strong alkalis	Limited use
Organic solvents	Limited use
UV radiation (sunlight)	Good
Oxidation at 500C	Unacceptable

Primary material production: energy, CO2 and water

Embodied energy, primary production	* 82.6	-	91.3	MJ/kg
CO2 footprint, primary production	* 2.59	-	2.86	kg/kg
Water usage	* 164	-	181	l/kg

Material processing: energy

Polymer molding energy	* 19.7	-	21.7	MJ/kg
Polymer extrusion energy	* 8.18	-	9.01	MJ/kg

Polymer machining energy (per unit wt removed)	* 2.04	-	2.25	MJ/kg

Material processing: CO2 footprint

Polymer molding CO2	* 1.58	-	1.74	kg/kg
Polymer extrusion CO2	0.654			kg/kg
Polymer machining CO2 (per unit wt removed)	* 0.163	-	0.18	kg/kg

Material recycling: energy, CO2 and recycle fraction

Recycle	True			
Embodied energy, recycling	49.9	-	51	MJ/kg
CO2 footprint, recycling	1.5	-	1.53	kg/kg
Recycle fraction in current supply	20	-	22.1	%
Downcycle	True			
Combust for energy recovery	True			
Heat of combustion (net)	* 23	-	24.2	MJ/kg
Combustion CO2	* 2.24	-	2.35	kg/kg
Landfill	True			
Biodegrade	False			
A renewable resource?	False			

Notes

Typical uses

Electrical fittings and connectors; audio/visual tapes; industrial strapping; capacitor film; fibers.

Other notes

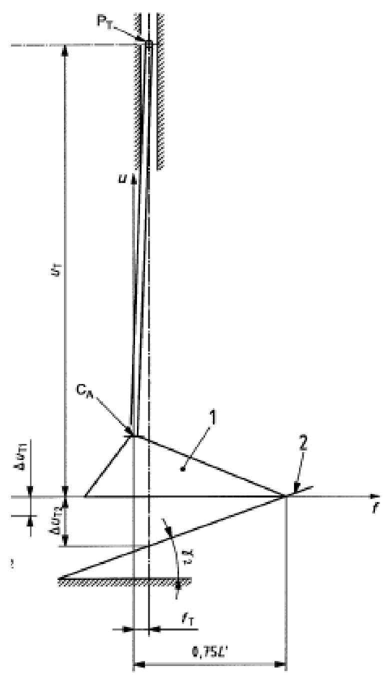
Crystalline (nucleated) PET is more heat resistant than the amorphous grades, but is not transparent.
Unfilled PET is problematic to injection mold, compared to unfilled PBT.

Appendix E- Supporting Analysis

Testing Protocols

ISO Protocol

To determine the load cases for our calculations we turned to the ISO standards. ISO standard 22675 lays out the requirements and test methods to test ankle-foot devices and foot units. We particularly looked at Section 16 which lays out the test procedures for proof, ultimate strength, and cyclic load tests including set-up, load forces, and all dimensions. For our initial analysis we simply looked at the highest value for the ultimate strength test because we want to ensure that our designs satisfy that before we move on to further analysis. This load case can be seen below in Figure __. We assumed an average foot length of 26cm.



- F = 4396N
- d_1 = 22mm
- d_2 = 578mm
- d_3 = 195mm

Figure E.1: Test set up for forefoot ultimate strength testing as described in ISO 22675 Section 16.3

Key

1	Symbolic view of foot
2	Foot Platform
P_T	Top load application point
C_A	Effective ankle-joint centre
γ_2	Platform angle: for forefoot loading =20°
f_T	Anterior offset of P_T from effective ankle
u_T	Proximal offset of P_T from effective ankle

Table E.1: Coordinates of top load application point P_T and tilting axis TA of foot platform based on given values of foot length L, for all test loading levels

Subject	Test procedure	Direction and location	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] — 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 E.2: Test forces for all tests and prescribed number of cycles for the cyclic test, for test loading levels P5, P4, and P4

Test procedure and test force			Unit	Test loading level (P_x) [a] and test loading condition (F_{1x}; F_{2x}): P5 Heel loading, F_{1x}	P5 Forefoot loading, F_{2x}	P4 Heel loading, F_{1x}	P4 Forefoot loading, F_{2x}	P3 Heel loading, F_{1x}	P3 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
		$F_{1su,\ upper\ level}$	N	4 454	—	4 106	—	3 201	—
		$F_{2su,\ upper\ level}$		—	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.

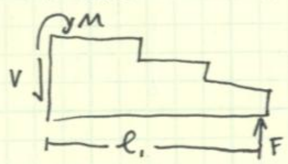
[a] For the additional test loading level P6 the values of the test forces and the prescribed number of cycles are specified in Table C.2.

Detailed Layer Foot Analysis

NEW LAYER FOOT DEFLECTION METHOD

JUSTIN AND I DECIDED THAT THE SHEAR ON THE FIXED ENDS ARE NOT EQUAL. WE FOUND TWO NEW EQUATIONS INSTEAD.

EQUILIBRIUM OF EXTERNAL FORCES & MOMENTS:



$\Rightarrow$ $\Sigma F = 0$

$V_1 + V_2 + V_3 = F$ ①

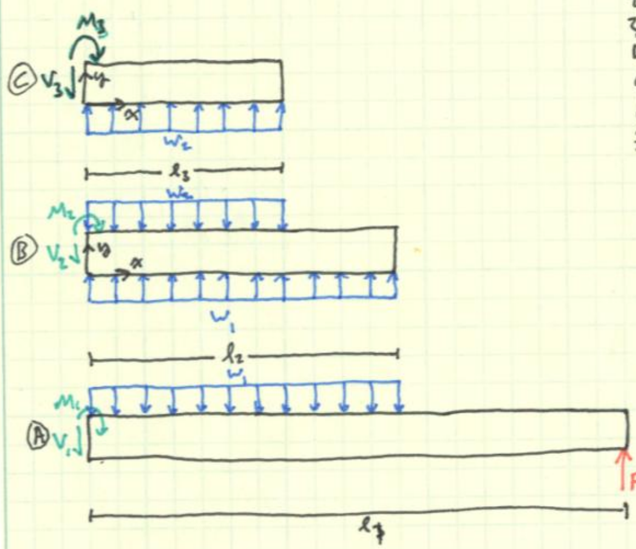
$\Sigma M = 0$

$M_1 + M_2 + M_3 = F l_1$ ②

ASSUMPTIONS

1) SMALL STRAINS
2) LINEAR ELASTIC ISOTROPIC MAT.
3) ST. VENANT
4) UNIFORM CONTACT LOADS
5) STATIC
6) RADIUS AT DEFLECTION APPROX. AS ANGLE
7) CENTER OF PRESSURE IN MIDDLE CONTACT

STACKED BEAM FBDs



CONS. LINEAR MOMENTUM

$\Sigma F_A = 0$

$w_1 l_2 + V_1 = F$ ③

$\Sigma F_B = 0$

$w_1 l_2 - V_2 - w_2 l_3 = 0$ ④

$\Sigma F_C = 0$

$w_2 l_3 - V_3 = 0$ ⑤

CONS. ANGULAR MOMENTUM

$\Sigma M_A = 0$

$F l_3 - w_1 \frac{l_2^2}{2} - M_1 = 0$ ⑥

$\Sigma M_B = 0$

$w_1 \frac{l_2^2}{2} - w_2 \frac{l_3^2}{2} - M_2 = 0$ ⑦

$\Sigma M_C = 0$

$w_2 \frac{l_3}{2} - M_3 = 0$ ⑧

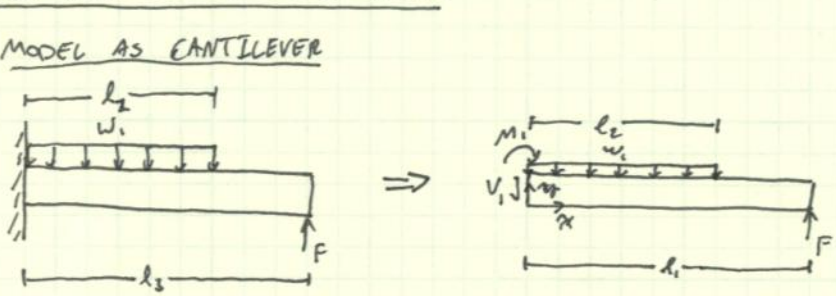
UNKNOWNS

M_1, M_2, M_3 $\quad w_1 \ w_2$ $\Big\}$ 8 EQNS, 8 UNKNOWNS ✓
V_1, V_2, V_3

14 1/17/11

ANALYZE DEFLECTION IN LOWER BEAM

MODEL AS CANTILEVER



USE SINGULARITIES TO FIND DEFLECTION

$$q = M_1\langle x\rangle^{-2} + V_1\langle x\rangle^{-1} - w_1\langle x\rangle^0 + w_1\langle x-l_2\rangle^0 + F\langle x-l_1\rangle^{-1}$$

$$V = M_1\langle x\rangle^{-1} - V_1\langle x\rangle^0 - w_1\langle x\rangle^1 + w_1\langle x-l_2\rangle^1 + F\langle x-l_1\rangle^0$$

$$M = M_1\langle x\rangle^0 - V_1\langle x\rangle^1 - \tfrac{1}{2}w_1\langle x\rangle^2 + \tfrac{1}{2}w_1\langle x-l_2\rangle^2 + F\langle x-l_1\rangle^1$$

$$EI\frac{dy}{dx} = M_1x - \tfrac{1}{2}V_1x^2 - \tfrac{1}{6}w_1x^3 + \tfrac{1}{6}w_1\langle x-l_2\rangle^3 + \tfrac{1}{2}F\langle x-l_1\rangle^2 + C_1$$

$$EI\,y = \tfrac{1}{2}M_1x^2 - \tfrac{1}{6}V_1x^3 - \tfrac{1}{24}w_1x^4 + \tfrac{1}{24}w_1\langle x-l_2\rangle^4 + \tfrac{1}{6}F\langle x-l_1\rangle^2 + C_1x + C_2$$

APPLY BOUNDARY CONDITIONS

1) @ $x=0,\ y=0$

$$EI(0) = \tfrac{1}{2}M_1(0) - \tfrac{1}{6}V_1(0) - \tfrac{1}{24}w_1(0) + \tfrac{1}{24}w_1(0) + \tfrac{1}{6}F(0) + C_1(0) + C_2$$

$\underline{C_2 = 0}$

2) @ $x=0,\ \frac{dy}{dx}=0$

$$EI(0) = M_1(0) - \tfrac{1}{2}V_1(0) - \tfrac{1}{6}w_1(0) + \tfrac{1}{6}w_1(0) + \tfrac{1}{2}F(0) + C_1$$

$\underline{C_1 = 0}$

QUESTIONS

1) THE DISTRIBUTED LOADS ARE NOT ACROSS THE ENTIRE WIDTH... DOES THIS AFFECT THE DEFLECTION?

NO... THEY ARE ACTUALLY LINE LOADS.

2) IS PUTTING THE POINT LOAD AT THE TIP APPROPRIATE.

YES, BUT SHOULD ITERATE BASED ON CENTER OF PRESSURE

1/17/14

Roll-Over Shape Results

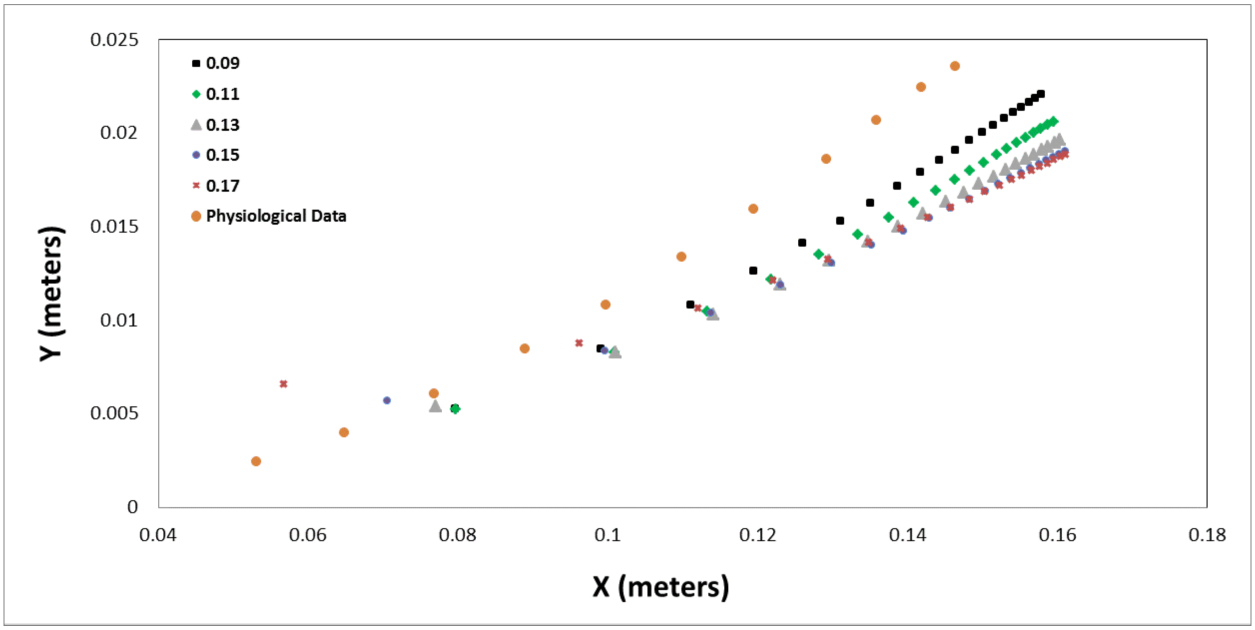


Figure E.2: Roll-over shape varying length of middle layer with top and bottom layers fixed

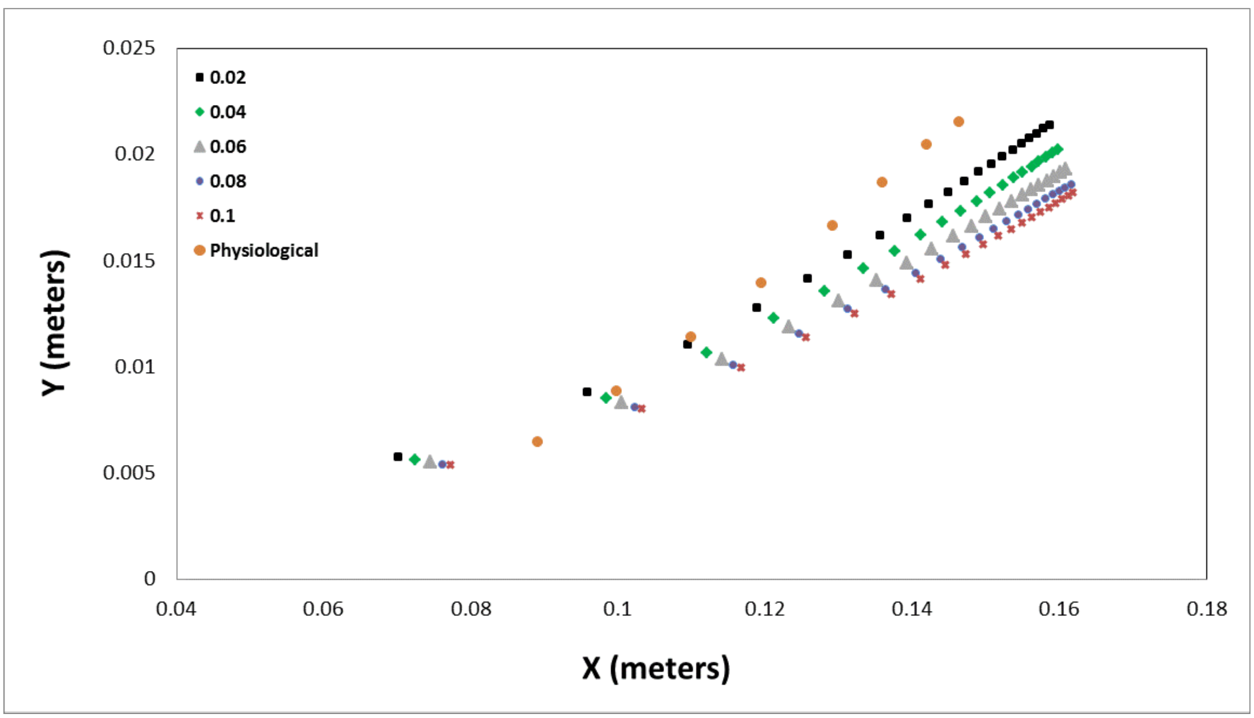


Figure E.3: Roll-over shape varying length of top layer with middle and bottom layers fixed

EES Code

```
"Piernas de Vida: Layer Foot Analysis
January 15, 2011

Kevin Yamauchi
Justin Lekos

This code utilizes static analysis and beam theory to
model the layer foot in order to produce the roll-over
shape for performance analysis."




"Change log"
"v1: Initial code. Calculates deflection assuming load at toe"
"v2: Iterates to find COP"
"v3 added bending stress at fixed end of beam and parametric table"


"TEST LOAD"
F=800 "N"



"LAYER MATERIALS AND GEOMETRY"
t=1/2*0.0254
E = 2.75*10^9 "Pa"
I1=1/12*0.05*t^3 "m^4"
I2=1/12*0.06*t^3 "m^4"
I3=1/12*0.07*t^3  "m^4"



"PIN PLACEMENT"
d_pin=0.005 "m"



"STATIC ANALYSIS
Conservation of linear and angular momentum is conserved"

"MOMENTS"
0=L1/2*(w1*L1)-M1
0=L2/2*(w2*L2)-M2-L1/2*(w1*L1)
0=F*COP-L2/2*(w2*L2)-M3

"FORCES IN Y-DIRECTION"
0=L1*w1-V1
0=L2*w2-L1*w1-V2
0=F-w2*L2-V3



"BEAM SINGULARITY EQUATIONS
```

A constraint is placed on the displacement at the placement of the pin (in the toe) or close to the bolt (in the heel)."

"Interface between layers 2 & 3:"
E*I3*y_23=M3/2*d_pin^2-V3/6*d_pin^3-w2/24*d_pin^4
E*I2*y_23=M2/2*d_pin^2-V2/6*d_pin^3+w2/24*d_pin^4-w1/24*d_pin^4

"Interface between layers 1 & 2:"
E*I1*y_12=M1/2*(d_pin)^2-V1/6*d_pin^3+w1/24*d_pin^4
E*I2*y_12=M2/2*d_pin^2-V2/6*d_pin^3+w2/24*d_pin^4-w1/24*d_pin^4

"Toe Deflection"
E*I3*y_toe=M3/2*L3^2-V3/6*L3^3-w2/24*L3^4+w2/24*(L3-L2)^4+F/6*(L3-COP)^3

"ITERATION TO FIND COP"

"Calc COP"
CS = y_toe / sin(theta)
COP_CALC =L3 - (CS/2)

"Compare COP"
Delta_COP = abs(COP_Calc - COP)

"Rollover Coordinate"
X = COP
Y = y_toe

"BENDING STRESS AT BOLT"
sigma_bend3 = ((F * COP) - (0.5*L2^2*w2))*(t/2) / I3
sigma_bend2 = ((0.5*L2^2*w2) - (0.5*L1^2*w1)) * (t/2) / I2
sigma_bend1 =(0.5*L1^2*w1) * (t/2) / I2

Rollover Shape Development:

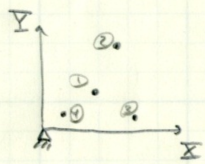
During Patient Testing, The team collected Data From Two Sources:

1) Vicon Video (Kinematic) Data
2) Force Plate (COP) Data

Via The following method, The two can be used to develop the rollover Shape.

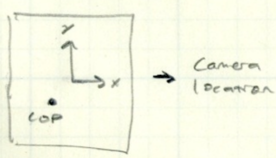
Data Collected:

1) Kinematic Data



- Global X + Y coordinates for (4) points over time
- Points include:
  - ankle
  - Shank
  - Force plate edge (Left + Right).

2) COP (kinetic) Data



- COP location over time for COP
- Necessary Data:
  - Y-coordinate of COP over time

Goal: Develop a plot of the COP over time in a relative coordinate system whose origin lies at point ① above and is anchored to the frame of reference of the shank.

①

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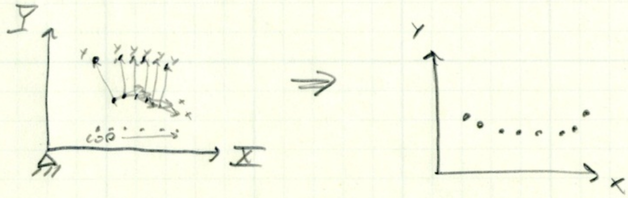
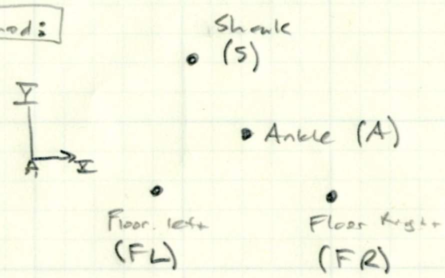
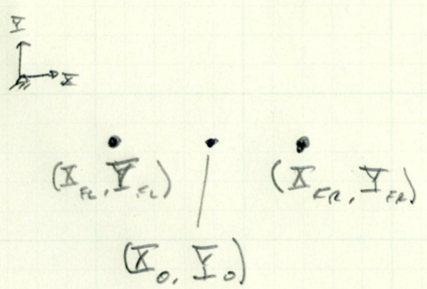
Approach: Superimpose COP and kinematic Data onto the same Global coordinate system. Then use the geometry to locate the COP in relation to the Shank coordinate System:



Method:



Since the COP is located on the floor, the Global Y coordinate will be that of FR and FL which, inherently, will be equal. In order to locate the global X of the COP, we set the origin to the center of FL and FR and then add the y-coordinate of the data set from the Force plate (2):



$$X_o = \frac{X_{FL} + X_{FR}}{2}$$

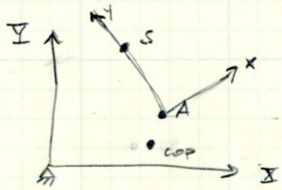
$$Y_o = \frac{Y_{FL} + Y_{FR}}{2}$$

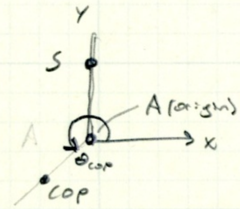
$$X_{COP} = X_o + y_{COP}$$

$$Y_{COP} = \frac{Y_{FL} + Y_{FR}}{2}$$

2

Now we have the global coordinates for the Ankle, shank, and COP:





In order to anchor the new coordinate system on the shank, the following must be true:

- $x_A = 0$ • $y_A = 0$
- $x_S = 0$ • $y_A = d_{S-A}$
- $x_{cop} = d_{A\text{-}cop} \cos(\theta_{cop})$ • $y_{cop} = d_{A\text{-}cop} \sin(\theta_{cop})$

Where:
- d_{S-A} is the distance from the ankle to the shank
- $d_{A\text{-}cop}$ is the distance from the ankle to the COP
- θ_{cop} is the angle made between the line drawn perpendicular to the Ankle Shank line, and the line drawn from the ankle to the COP.

$$d_{A\text{-}cop} = \sqrt{(X_A - X_{cop})^2 + (Y_A - Y_{cop})^2}$$

$$d_{S-A} = \sqrt{(X_S - X_A)^2 + (Y_S - Y_A)^2}$$

3

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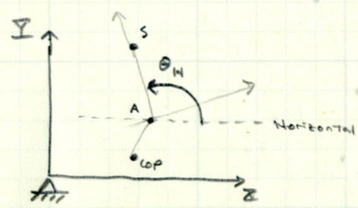
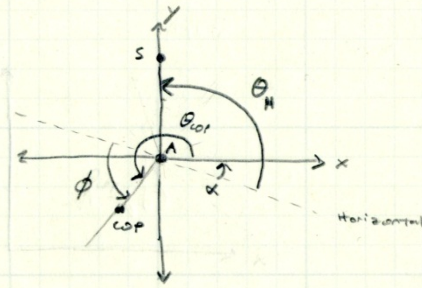
Find θ_{cop}:





From the diagrams:

$$\theta_H = \tan^{-1}\left[\frac{Y_S - Y_A}{X_S - X_A}\right]$$

$$\phi = \tan^{-1}\left[\frac{Y_A - Y_{cop}}{X_A - X_{cop}}\right]$$

$$\alpha = \theta_H - 90^\circ$$

So, to define θ_{cop} using these:

$$\theta_{cop} = -\alpha + 180^\circ + \phi$$

$$= -(\theta_H - 90^\circ) + 180 + \phi$$

$$\theta_{cop} = \phi - \theta_H + 270^\circ$$

Therefore, the coordinates of the cop in the new coordinate system must be:

$$X_{cop} = d_{cop} \cos\left[\phi - \theta_H + 270^\circ\right]$$

$$Y_{cop} = d_{cop} \sin\left[\phi - \theta_H + 270^\circ\right]$$

We can now use these formulas to plot the rollover shape using collected data.

4

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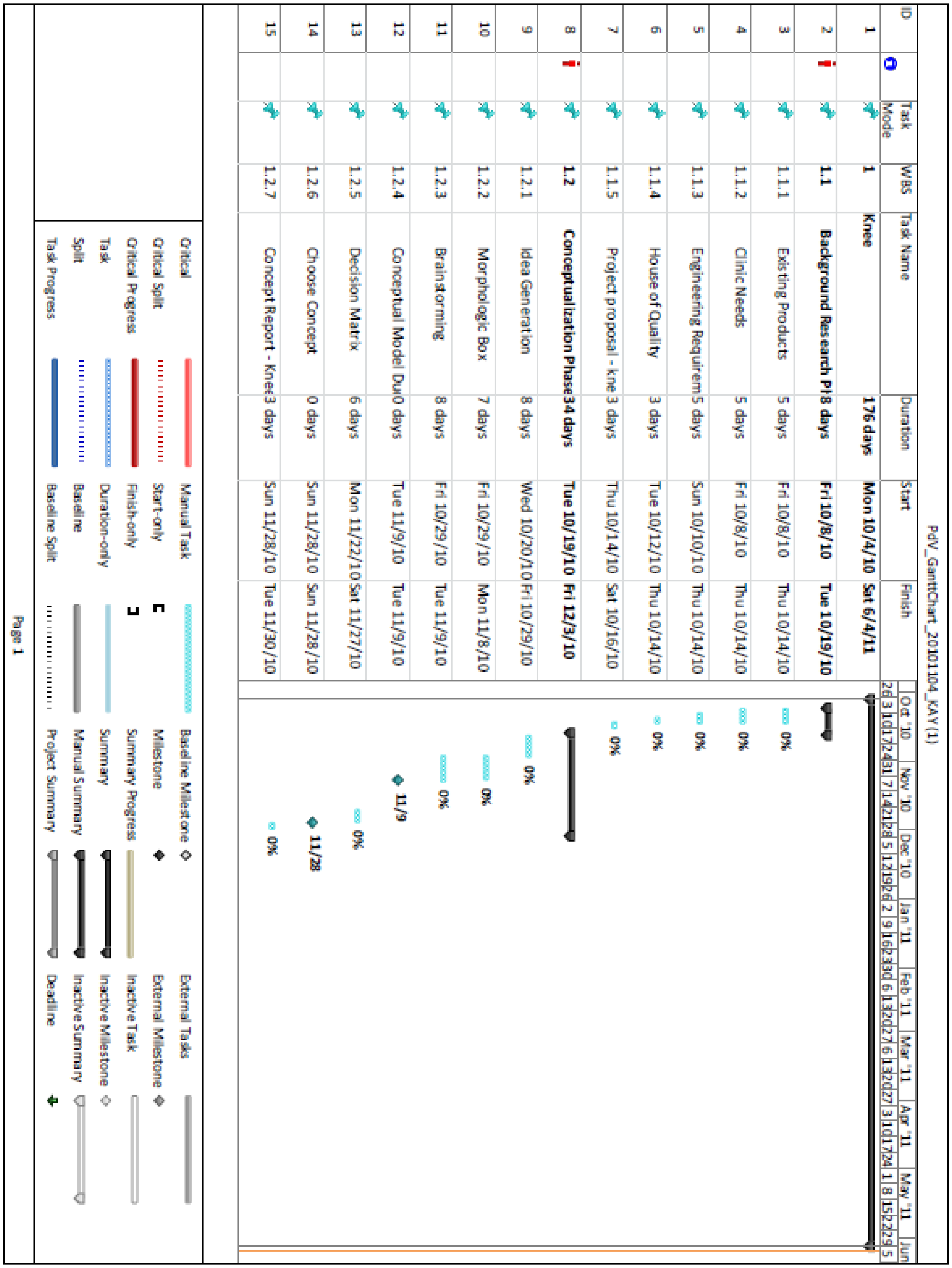
Table E.3: Excel results for roll-over analysis

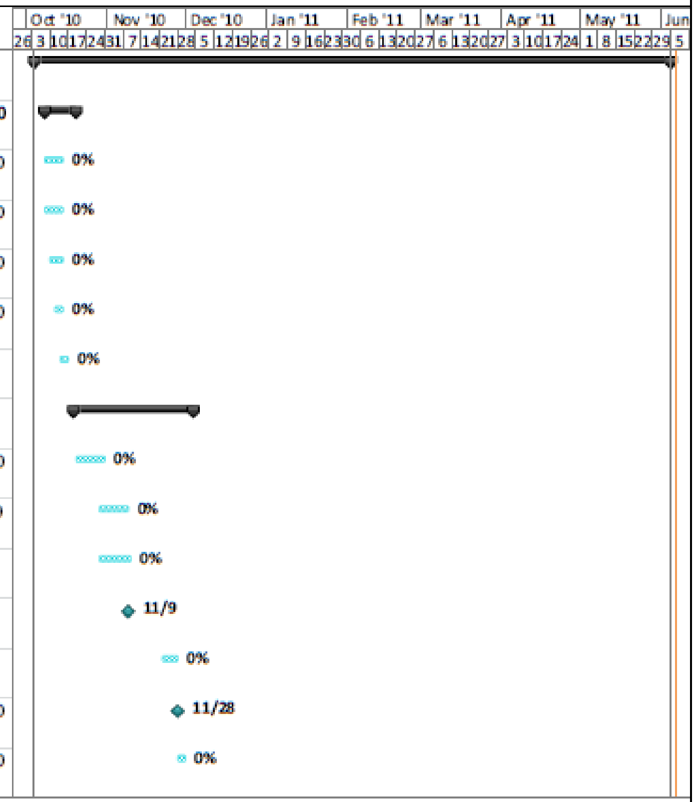
	Kinematic Data (via lookup)								Force Plate Data (via lookup)					Calculated Data								Rollover Shape	
Time (s)	X_knee	Y_knee	X_ankle	Y_ankl	X_Floor_L	Y_Floor_L	X_Floor_RI	Y_Floor_RI	X_cop	Y_cop	Force_	FP_O_	FP_O_	D_shank	Theta	Phi	D_n	x_ankle	y_ankle	x_knee	y_knee	x_cop	y_cop
0.017	-0.12638	0.3794	-0.0498	0.2073	-0.19104	-0.01826	0.42333	-0.02008	-0.05	-0.02	114.07	0.1161	-0.02	0.18828885	113.99	89.737	0.227	0	0	0	0.1883	-0.093	0.2078
0.033	-0.11658	0.3797	-0.0448	0.207	-0.19104	-0.01826	0.42333	-0.02008	-0.05	-0.02	158.96	0.1161	-0.02	0.18699701	112.57	88.309	0.2268	0	0	0	0.187	-0.093	0.2119
0.050	-0.10655	0.3793	-0.0382	0.2055	-0.19104	-0.01826	0.42333	-0.02008	-0.05	-0.02	219.92	0.1161	-0.02	0.18679388	111.48	86.996	0.2255	0	0	0	0.1868	-0.093	0.2138
0.067	-0.09641	0.3783	-0.0314	0.2023	-0.19104	-0.01826	0.42333	-0.02008	-0.05	-0.02	319.26	0.1161	-0.02	0.18761195	110.29	86.204	0.2225	0	0	0	0.1876	-0.091	0.2133
0.083	-0.08603	0.3775	-0.0255	0.2003	-0.19104	-0.01826	0.42333	-0.02008	-0.04	-0.02	418.77	0.1161	-0.02	0.1872247	108.86	86.037	0.2205	0	0	0	0.1872	-0.086	0.2131
0.100	-0.07678	0.3761	-0.0198	0.1974	-0.19104	-0.01826	0.42333	-0.02008	-0.04	-0.02	518.43	0.1161	-0.02	0.18757394	107.68	85.793	0.2177	0	0	0	0.1876	-0.081	0.2117
0.117	-0.06667	0.3758	-0.0143	0.1957	-0.19104	-0.01826	0.42333	-0.02008	-0.03	-0.02	631.91	0.1161	-0.02	0.18761326	106.22	86.089	0.2159	0	0	0	0.1876	-0.074	0.2109
0.133	-0.05738	0.3748	-0.009	0.1945	-0.19104	-0.01826	0.42333	-0.02008	-0.02	-0.02	732.22	0.1161	-0.02	0.1866317	105.01	86.306	0.2146	0	0	0	0.1866	-0.069	0.2105
0.150	-0.04815	0.375	-0.0041	0.1936	-0.19104	-0.01826	0.42333	-0.02008	-0.02	-0.02	806.43	0.1161	-0.02	0.18671303	103.65	86.249	0.2137	0	0	0	0.1867	-0.064	0.2105
0.167	-0.03966	0.3744	0.00102	0.1925	-0.19104	-0.01826	0.42333	-0.02008	-0.01	-0.02	861.36	0.1161	-0.02	0.18639333	102.61	85.841	0.2127	0	0	0	0.1864	-0.061	0.2104
0.183	-0.03123	0.3744	0.00552	0.1918	-0.19104	-0.01826	0.42333	-0.02008	-0.01	-0.02	944.8	0.1161	-0.02	0.18630065	101.38	87.016	0.2117	0	0	0	0.1863	-0.053	0.2095
0.200	-0.02328	0.374	0.00975	0.1908	-0.19104	-0.01826	0.42333	-0.02008	0.00	-0.02	1028.2	0.1161	-0.02	0.18614391	100.22	88.267	0.2105	0	0	0	0.1861	-0.044	0.2082
0.217	-0.01593	0.3744	0.01263	0.1907	-0.19104	-0.01826	0.42333	-0.02008	0.01	-0.02	1119.9	0.1161	-0.02	0.18593651	98.836	90.214	0.2104	0	0	0	0.1859	-0.032	0.2078
0.233	-0.01003	0.3748	0.01613	0.191	-0.19104	-0.01826	0.42333	-0.02008	0.02	-0.02	1206.1	0.1161	-0.02	0.18568203	98.099	91.961	0.2108	0	0	0	0.1857	-0.023	0.2076
0.250	-0.00357	0.375	0.01945	0.1907	-0.19104	-0.01826	0.42333	-0.02008	0.03	-0.02	1274	0.1161	-0.02	0.18571225	97.12	93.717	0.2108	0	0	0	0.1857	-0.013	0.207
0.267	0.00169	0.375	0.02223	0.1895	-0.19104	-0.01826	0.42333	-0.02008	0.04	-0.02	1320.1	0.1161	-0.02	0.18659395	96.32	95.357	0.2101	0	0	0	0.1866	-0.004	0.2057
0.283	0.00733	0.375	0.02439	0.1898	-0.19104	-0.01826	0.42333	-0.02008	0.05	-0.02	1356.3	0.1161	-0.02	0.18593431	95.264	97.115	0.2111	0	0	0	0.1859	0.0068	0.2062
0.300	0.01187	0.3753	0.02663	0.1903	-0.19104	-0.01826	0.42333	-0.02008	0.06	-0.02	1374.6	0.1161	-0.02	0.18562774	94.561	98.581	0.2123	0	0	0	0.1856	0.0149	0.2067
0.317	0.01676	0.3755	0.02875	0.1898	-0.19104	-0.01826	0.42333	-0.02008	0.07	-0.02	1374.9	0.1161	-0.02	0.18606672	93.695	99.943	0.2127	0	0	0	0.1861	0.0232	0.2067
0.333	0.02067	0.3751	0.03048	0.1904	-0.19104	-0.01826	0.42333	-0.02008	0.07	-0.02	1355.9	0.1161	-0.02	0.18494036	93.041	101.25	0.2142	0	0	0	0.1849	0.0306	0.2076
0.350	0.02448	0.376	0.03261	0.1903	-0.19104	-0.01826	0.42333	-0.02008	0.08	-0.02	1323.3	0.1161	-0.02	0.1858579	92.507	102.52	0.2151	0	0	0	0.1859	0.0374	0.2077
0.367	0.029	0.376	0.03451	0.1906	-0.19104	-0.01826	0.42333	-0.02008	0.09	-0.02	1280.3	0.1161	-0.02	0.18542189	91.703	104.06	0.2168	0	0	0	0.1854	0.0464	0.2086
0.383	0.03305	0.3763	0.03654	0.1914	-0.19104	-0.01826	0.42333	-0.02008	0.10	-0.02	1239	0.1161	-0.02	0.18493293	91.081	105.62	0.2192	0	0	0	0.1849	0.055	0.2099
0.400	0.03727	0.3768	0.03874	0.1915	-0.19104	-0.01826	0.42333	-0.02008	0.10	-0.02	1210	0.1161	-0.02	0.18526583	90.455	107.12	0.221	0	0	0	0.1853	0.0634	0.2107
0.417	0.04146	0.3771	0.04086	0.1919	-0.19104	-0.01826	0.42333	-0.02008	0.11	-0.02	1199	0.1161	-0.02	0.18525097	89.814	108.22	0.2227	0	0	0	0.1853	0.0703	0.2118
0.433	0.04572	0.3766	0.04275	0.1925	-0.19104	-0.01826	0.42333	-0.02008	0.12	-0.02	1201.4	0.1161	-0.02	0.18421394	89.076	109.12	0.2245	0	0	0	0.1842	0.077	0.2133
0.450	0.04943	0.3779	0.04469	0.1929	-0.19104	-0.01826	0.42333	-0.02008	0.12	-0.02	1210.5	0.1161	-0.02	0.18507071	88.532	109.74	0.2259	0	0	0	0.1851	0.0817	0.2145
0.467	0.05325	0.3774	0.04663	0.1929	-0.19104	-0.01826	0.42333	-0.02008	0.12	-0.02	1226.4	0.1161	-0.02	0.18455877	87.944	110.15	0.2264	0	0	0	0.1846	0.0856	0.2153
0.483	0.05671	0.3783	0.04809	0.1933	-0.19104	-0.01826	0.42333	-0.02008	0.13	-0.02	1242.8	0.1161	-0.02	0.18529062	87.334	110.5	0.2273	0	0	0	0.1853	0.0894	0.2164
0.500	0.0597	0.3772	0.0498	0.1936	-0.19104	-0.01826	0.42333	-0.02008	0.13	-0.02	1261.4	0.1161	-0.02	0.18389667	86.914	110.64	0.2279	0	0	0	0.1839	0.0917	0.2173
0.517	0.063	0.3788	0.05136	0.1938	-0.19104	-0.01826	0.42333	-0.02008	0.13	-0.02	1279.1	0.1161	-0.02	0.18537581	86.4	110.68	0.2282	0	0	0	0.1854	0.0938	0.2181
0.533	0.06543	0.3782	0.0521	0.1938	-0.19104	-0.01826	0.42333	-0.02008	0.13	-0.02	1299	0.1161	-0.02	0.18488118	85.865	110.8	0.2283	0	0	0	0.1849	0.0963	0.2187
0.550	0.06865	0.3788	0.05346	0.1943	-0.19104	-0.01826	0.42333	-0.02008	0.13	-0.02	1312.8	0.1161	-0.02	0.18511428	85.293	110.73	0.2288	0	0	0	0.1851	0.0983	0.2199
0.567	0.06865	0.3788	0.05346	0.1943	-0.19104	-0.01826	0.42333	-0.02008	0.14	-0.02	1319.8	0.1161	-0.02	0.18511428	85.293	111.06	0.2293	0	0	0	0.1851	0.0997	0.22
0.583	0.07087	0.3796	0.05498	0.1943	-0.19104	-0.01826	0.42333	-0.02008	0.14	-0.02	1324.4	0.1161	-0.02	0.18603984	85.1	111.06	0.2293	0	0	0	0.186	0.1004	0.2202
0.600	0.0739	0.3798	0.05649	0.1954	-0.19104	-0.01826	0.42333	-0.02008	0.14	-0.02	1325.1	0.1161	-0.02	0.18518023	84.605	111.01	0.2304	0	0	0	0.1852	0.1025	0.2219
0.617	0.07663	0.3805	0.05839	0.1954	-0.19104	-0.01826	0.42333	-0.02008	0.14	-0.02	1323.2	0.1161	-0.02	0.18602638	84.373	111.09	0.2305	0	0	0	0.186	0.1036	0.2221
0.633	0.08072	0.3814	0.05975	0.1965	-0.19104	-0.01826	0.42333	-0.02008	0.14	-0.02	1320.3	0.1161	-0.02	0.18604559	83.528	111.27	0.232	0	0	0	0.186	0.108	0.2243
0.650	0.08445	0.3809	0.06177	0.1969	-0.19104	-0.01826	0.42333	-0.02008	0.15	-0.02	1315.8	0.1161	-0.02	0.18537266	82.972	111.4	0.2326	0	0	0	0.1854	0.1107	0.2254
0.667	0.08892	0.3819	0.06433	0.1983	-0.19104	-0.01826	0.42333	-0.02008	0.15	-0.02	1310.4	0.1161	-0.02	0.18524929	82.372	111.25	0.2339	0	0	0	0.1852	0.113	0.2273
0.683	0.09309	0.3821	0.06617	0.1977	-0.19104	-0.01826	0.42333	-0.02008	0.15	-0.02	1308.9	0.1161	-0.02	0.18635463	81.694	111.5	0.2336	0	0	0	0.1864	0.1161	0.2274
0.700	0.09756	0.3828	0.06888	0.1992	-0.19104	-0.01826	0.42333	-0.02008	0.15	-0.02	1309.3	0.1161	-0.02	0.18587594	81.124	111.28	0.2348	0	0	0	0.1859	0.118	0.2294
0.717	0.10149	0.3832	0.07099	0.2	-0.19104	-0.01826	0.42333	-0.02008	0.16	-0.02	1308.8	0.1161	-0.02	0.18567222	80.545	111.22	0.2357	0	0	0	0.1857	0.1202	0.2307
0.733	0.10633	0.3829	0.07359	0.2005	-0.19104	-0.01826	0.42333	-0.02008	0.16	-0.02	1309.9	0.1161	-0.02	0.18522647	79.819	111.07	0.236	0	0	0	0.1852	0.1224	0.2317
0.750	0.11106	0.3837	0.07551	0.2007	-0.19104	-0.01826	0.42333	-0.02008	0.16	-0.02	1309.1	0.1161	-0.02	0.18649957	79.011	111.15	0.2362	0	0	0	0.1865	0.1257	0.2325
0.767	0.11674	0.3845	0.07872	0.2021	-0.19104	-0.01826	0.42333	-0.02008	0.16	-0.02	1310.3	0.1161	-0.02	0.18637911	78.229	110.81	0.2372	0	0	0	0.1864	0.1277	0.2343
0.783	0.12279	0.3837	0.08183	0.2026	-0.19104	-0.01826	0.42333	-0.02008	0.17	-0.02	1306.1	0.1161	-0.02	0.18569377	77.257	110.67	0.2375	0	0	0	0.1857	0.1308	0.2353

Appendix F - Project Gantt Chart



PdV_GanttChart_20101104_KAY (1)

ID		Task Mode	WBS	Task Name	Duration	Start	Finish
16			2	**Adapter**	**176 days**	**Mon 10/4/10**	**Sat 6/4/11**
17			2.1	**Background Research Ph**	**8 days**	**Fri 10/8/10**	**Tue 10/19/10**
18			2.1.1	Existing Products	5 days	Fri 10/8/10	Thu 10/14/10
19			2.1.2	Clinic Needs	5 days	Fri 10/8/10	Thu 10/14/10
20			2.1.3	Engineering Requirem	5 days	Sun 10/10/10	Thu 10/14/10
21			2.1.4	House of Quality	3 days	Tue 10/12/10	Thu 10/14/10
22			2.1.5	Project proposal - Ada	3 days	Thu 10/14/10	Sat 10/16/10
23			2.2	**Conceptualization Phase**	**34 days**	**Tue 10/19/10**	**Fri 12/3/10**
24			2.2.1	Idea Generation	8 days	Wed 10/20/10	Sun 10/31/10
25			2.2.2	Morphologic Box	7 days	Fri 10/29/10	Mon 11/8/10
26			2.2.3	Brainstorming	8 days	Fri 10/29/10	Tue 11/9/10
27			2.2.4	Conceptual Model Du	0 days	Tue 11/9/10	Tue 11/9/10
28			2.2.5	Decision Matrix	6 days	Mon 11/22/10	Sat 11/27/10
29			2.2.6	Choose Concept	0 days	Sun 11/28/10	Sun 11/28/10
30			2.2.7	Concept Report - Ada	3 days	Sun 11/28/10	Tue 11/30/10

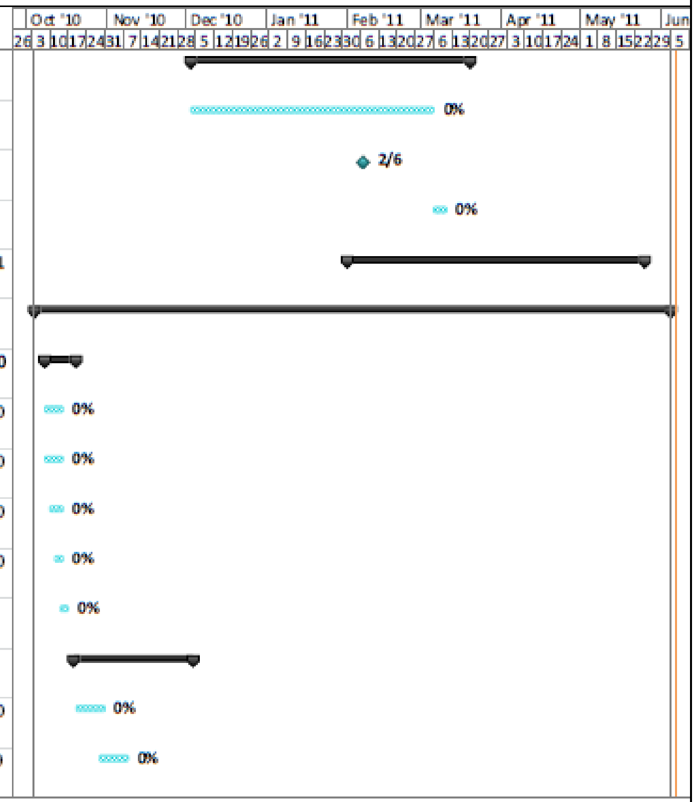


Critical
Critical Split
Critical Progress
Task
Split
Task Progress
Manual Task
Start-only
Finish-only
Duration-only
Baseline
Baseline Split
Baseline Milestone
Milestone
Summary Progress
Summary
Manual Summary
Project Summary
External Tasks
External Milestone
Inactive Task
Inactive Milestone
Inactive Summary
Deadline

Page 2

PdV_GanttChart_20101104_KAY (1)

ID		Task Mode	WBS	Task Name	Duration	Start	Finish
31			**2.3**	**Design Phase**	**76 days**	**Fri 12/3/10**	**Sun 3/20/11**
32			2.3.1	Initial Product Design	66 days	Fri 12/3/10	Sun 3/6/11
33			2.3.2	Design Iterations	0 days	Sun 2/6/11	Sun 2/6/11
34			2.3.3	Design Report - Knee s	5 days	Sun 3/6/11	Thu 3/10/11
35			**2.4**	**Build Phase**	**82 days**	**Tue 2/1/11**	**Wed 5/25/11**
41			**3**	**Foot**	**176 days**	**Mon 10/4/10**	**Sat 6/4/11**
42			**3.1**	**Idea Generation**	**8 days**	**Fri 10/8/10**	**Tue 10/19/10**
43			3.1.1	Existing Products	5 days	Fri 10/8/10	Thu 10/14/10
44			3.1.2	Clinic Needs	5 days	Fri 10/8/10	Thu 10/14/10
45			3.1.3	Engineering Requirem	5 days	Sun 10/10/10	Thu 10/14/10
46			3.1.4	House of Quality	3 days	Tue 10/12/10	Thu 10/14/10
47			3.1.5	Project proposal - Foo	3 days	Thu 10/14/10	Sat 10/16/10
48			**3.2**	**Conceptualization Phase**	**34 days**	**Tue 10/19/10**	**Fri 12/3/10**
49			3.2.1	Idea Generation	8 days	Wed 10/20/10	Sun 10/31/10
50			3.2.2	Morphologic Box	7 days	Fri 10/29/10	Mon 11/8/10

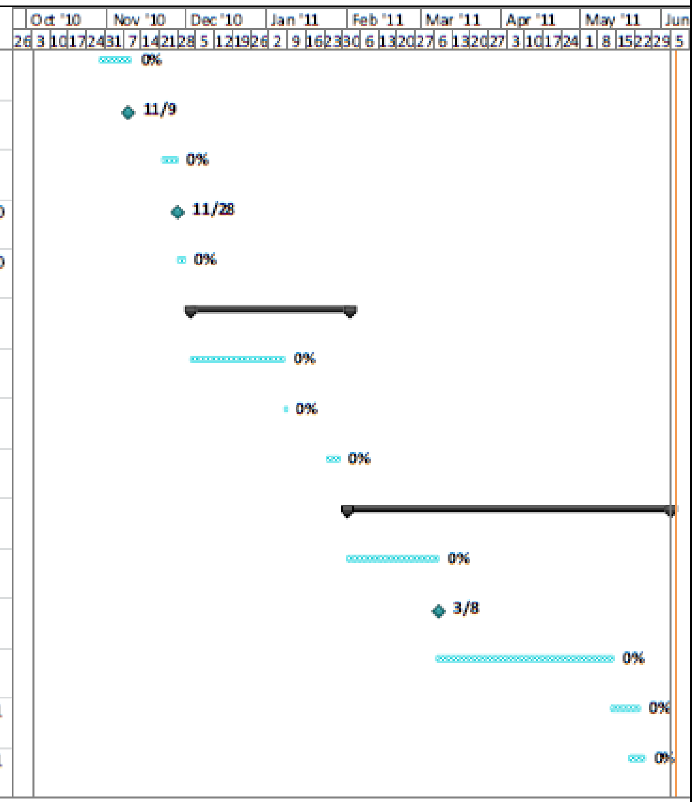


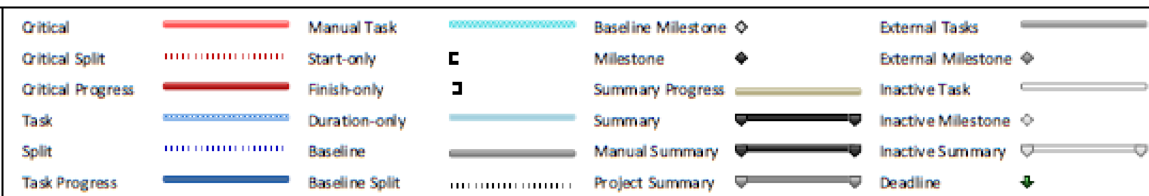
Critical	Manual Task	Baseline Milestone	External Tasks
Critical Split	Start-only	Milestone	External Milestone
Critical Progress	Finish-only	Summary Progress	Inactive Task
Task	Duration-only	Summary	Inactive Milestone
Split	Baseline	Manual Summary	Inactive Summary
Task Progress	Baseline Split	Project Summary	Deadline

Page 3

PdV_GanttChart_20101104_KAY (1)

ID		Task Mode	WBS	Task Name	Duration	Start	Finish
51			3.2.3	Brainstorming	8 days	Fri 10/29/10	Tue 11/9/10
52			3.2.4	Conceptual Model Du	0 days	Tue 11/9/10	Tue 11/9/10
53			3.2.5	Decision Matrix	6 days	Mon 11/22/10	Sat 11/27/10
54			3.2.6	Choose Concept	0 days	Sun 11/28/10	Sun 11/28/10
55			3.2.7	Concept Report - Foot	3 days	Sun 11/28/10	Tue 11/30/10
56			**3.3**	**Design Phase**	**43 days**	**Fri 12/3/10**	**Tue 2/1/11**
57			3.3.1	Initial Product Design	26 days	Fri 12/3/10	Sat 1/8/11
58			3.3.2	Design Iterations	1 day	Sat 1/8/11	Sat 1/8/11
59			3.3.3	Design Report - Foot s	5 days	Mon 1/24/11	Fri 1/28/11
60			**3.4**	**Build Phase**	**90 days**	**Tue 2/1/11**	**Sat 6/4/11**
61			3.4.1	Build Initial Prototype	25 days	Tue 2/1/11	Mon 3/7/11
62			3.4.2	Project Update Memo	0 days	Tue 3/8/11	Tue 3/8/11
63			3.4.3	Patient testing and ite	50 days	Mon 3/7/11	Fri 5/13/11
64			3.4.4	Finalize Design	7 days	Fri 5/13/11	Mon 5/23/11
65			3.4.5	Final Design Report - F	4 days	Fri 5/20/11	Wed 5/25/11

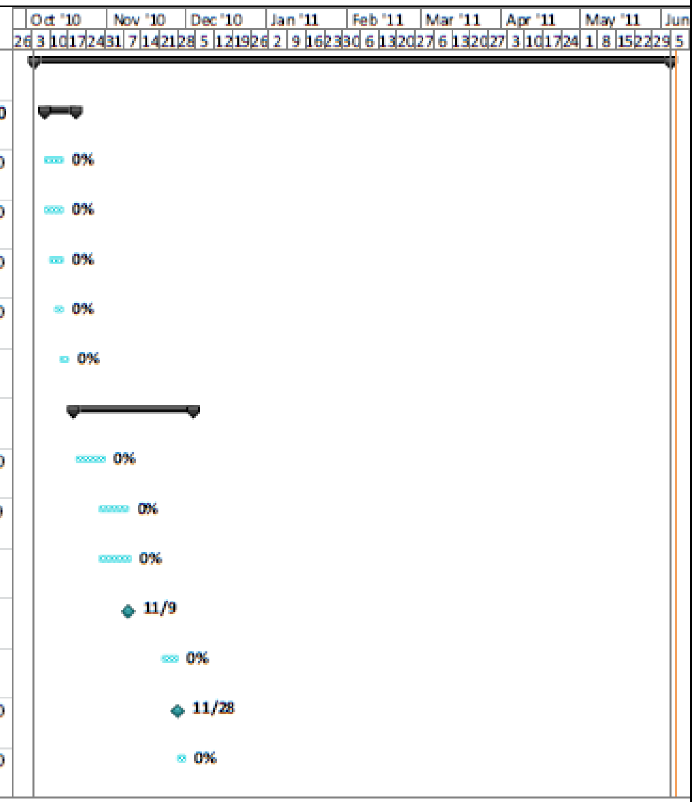




Page 4

PdV_GanttChart_20101104_KAY (1)

ID		Task Mode	WBS	Task Name	Duration	Start	Finish
66			**4**	**Ankle**	**176 days**	**Mon 10/4/10**	**Sat 6/4/11**
67			**4.1**	**Background Research Pl**	**8 days**	**Fri 10/8/10**	**Tue 10/19/10**
68			4.1.1	Existing Products	5 days	Fri 10/8/10	Thu 10/14/10
69			4.1.2	Clinic Needs	5 days	Fri 10/8/10	Thu 10/14/10
70			4.1.3	Engineering Requirem	5 days	Sun 10/10/10	Thu 10/14/10
71			4.1.4	House of Quality	3 days	Tue 10/12/10	Thu 10/14/10
72			4.1.5	Project proposal - Ank	3 days	Thu 10/14/10	Sat 10/16/10
73			**4.2**	**Conceptualization Phase**	**34 days**	**Tue 10/19/10**	**Fri 12/3/10**
74			4.2.1	Idea Generation	8 days	Wed 10/20/10	Sun 10/31/10
75			4.2.2	Morphologic Box	7 days	Fri 10/29/10	Mon 11/8/10
76			4.2.3	Brainstorming	8 days	Fri 10/29/10	Tue 11/9/10
77			4.2.4	Conceptual Model Du	0 days	Tue 11/9/10	Tue 11/9/10
78			4.2.5	Decision Matrix	6 days	Mon 11/22/10	Sat 11/27/10
79			4.2.6	Choose Concept	0 days	Sun 11/28/10	Sun 11/28/10
80			4.2.7	Concept Report - Ankl	3 days	Sun 11/28/10	Tue 11/30/10

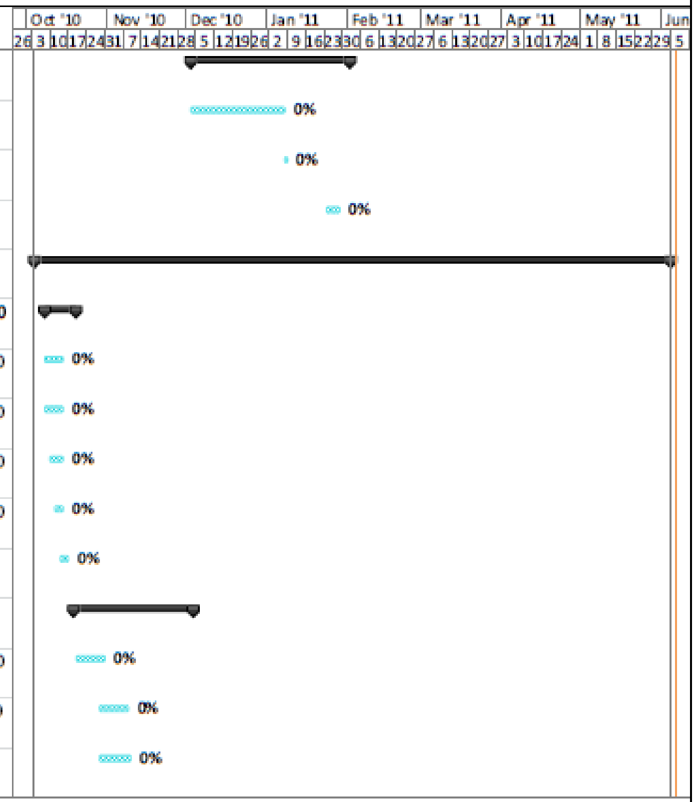


Critical		Manual Task		Baseline Milestone		External Tasks	
Critical Split		Start-only		Milestone		External Milestone	
Critical Progress		Finish-only		Summary Progress		Inactive Task	
Task		Duration-only		Summary		Inactive Milestone	
Split		Baseline		Manual Summary		Inactive Summary	
Task Progress		Baseline Split		Project Summary		Deadline	

Page 5

PdV_GanttChart_20101104_KAY (1)

ID		Task Mode	WBS	Task Name	Duration	Start	Finish
81			**4.3**	**Design Phase**	**43 days**	**Fri 12/3/10**	**Tue 2/1/11**
82			4.3.1	Initial Product Design	26 days	Fri 12/3/10	Sat 1/8/11
83			4.3.2	Design Iterations	1 day	Sat 1/8/11	Sat 1/8/11
84			4.3.3	Design Report - Ankle	5 days	Mon 1/24/11	Fri 1/28/11
85			**5**	**Pylon**	**176 days**	**Mon 10/4/10**	**Sat 6/4/11**
86			**5.1**	**Background Research Ph**	**8 days**	**Fri 10/8/10**	**Tue 10/19/10**
87			5.1.1	Existing Products	5 days	Fri 10/8/10	Thu 10/14/10
88			5.1.2	Clinic Needs	5 days	Fri 10/8/10	Thu 10/14/10
89			5.1.3	Engineering Requirem	5 days	Sun 10/10/10	Thu 10/14/10
90			5.1.4	House of Quality	3 days	Tue 10/12/10	Thu 10/14/10
91			5.1.5	Project proposal - Ank	3 days	Thu 10/14/10	Sat 10/16/10
92			**5.2**	**Conceptualization Phase**	**34 days**	**Tue 10/19/10**	**Fri 12/3/10**
93			5.2.1	Idea Generation	8 days	Wed 10/20/10	Sun 10/31/10
94			5.2.2	Morphologic Box	7 days	Fri 10/29/10	Mon 11/8/10
95			5.2.3	Brainstorming	8 days	Fri 10/29/10	Tue 11/9/10

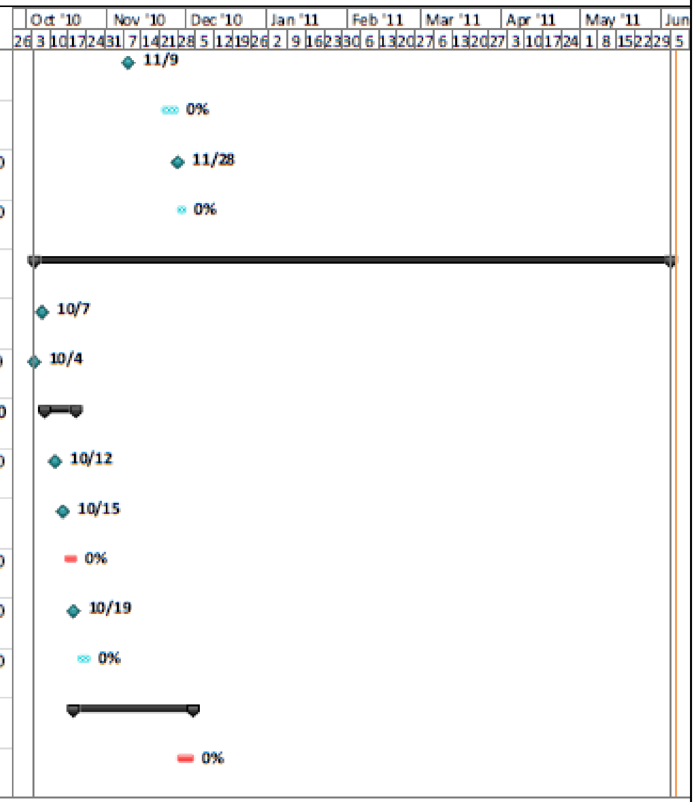


Critical		Manual Task		Baseline Milestone		External Tasks	
Critical Split		Start-only		Milestone		External Milestone	
Critical Progress		Finish-only		Summary Progress		Inactive Task	
Task		Duration-only		Summary		Inactive Milestone	
Split		Baseline		Manual Summary		Inactive Summary	
Task Progress		Baseline Split		Project Summary		Deadline	

Page 6

PdV_GanttChart_20101104_KAY (1)

ID		Task Mode	WBS	Task Name	Duration	Start	Finish
96			5.2.4	Conceptual Model Du	0 days	Tue 11/9/10	Tue 11/9/10
97			5.2.5	Decision Matrix	6 days	Mon 11/22/10	Sat 11/27/10
98			5.2.6	Choose Concept	0 days	Sun 11/28/10	Sun 11/28/10
99			5.2.7	Concept Report - Pylo	3 days	Sun 11/28/10	Tue 11/30/10
100			**6**	**Deliverables**	**176 days**	**Mon 10/4/10**	**Sat 6/4/11**
101			6.1	Team Contract Develope	0 days	Thu 10/7/10	Thu 10/7/10
102			6.2	Project Kickoff Meeting	0 days	Mon 10/4/10	Mon 10/4/10
103			**6.3**	**Background Research Pl**	**8 days**	**Fri 10/8/10**	**Tue 10/19/10**
104			6.3.1	Introduction: Telecon	0 days	Tue 10/12/10	Tue 10/12/10
105			6.3.2	Team Progress Reflect	0 days	Fri 10/15/10	Fri 10/15/10
106			6.3.3	Compile Project Propc	3 days	Sat 10/16/10	Tue 10/19/10
107			6.3.4	Project Proposal Deliv	0 days	Tue 10/19/10	Tue 10/19/10
108			6.4	Honduras: Fact-Finding T	3 days	Thu 10/21/10	Sun 10/24/10
109			**6.5**	**Conceptualization Phase**	**34 days**	**Tue 10/19/10**	**Fri 12/3/10**
110			6.5.1	Compile Concept Repc	6 days	Sun 11/28/10	Fri 12/3/10

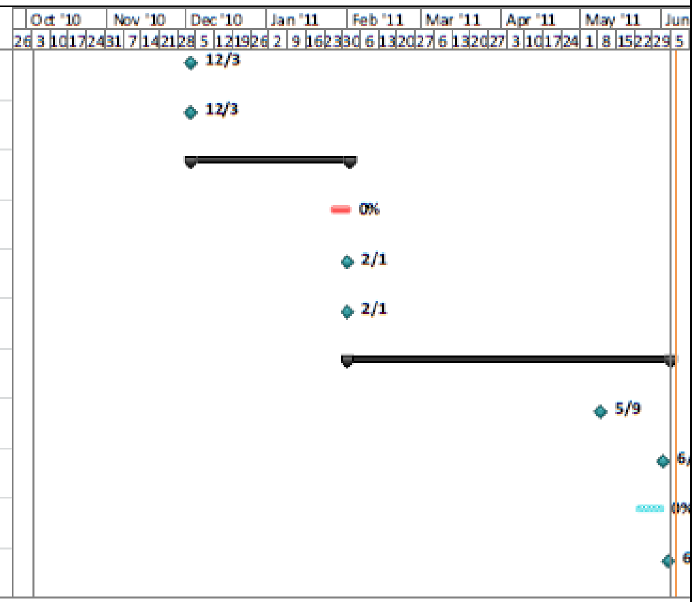


Critical		Manual Task		Baseline Milestone		External Tasks	
Critical Split		Start-only		Milestone		External Milestone	
Critical Progress		Finish-only		Summary Progress		Inactive Task	
Task		Duration-only		Summary		Inactive Milestone	
Split		Baseline		Manual Summary		Inactive Summary	
Task Progress		Baseline Split		Project Summary		Deadline	

Page 7

PdV_GanttChart_20101104_KAY (1)

ID		Task Mode	WBS	Task Name	Duration	Start	Finish
111			6.5.2	Conceptual Design Re	0 days	Fri 12/3/10	Fri 12/3/10
112			6.5.3	Conceptual Design Re	0 days	Fri 12/3/10	Fri 12/3/10
113			**6.6**	**Design Phase**	**43 days**	**Fri 12/3/10**	**Tue 2/1/11**
114			6.6.1	Compile Design Repor	5 days	Wed 1/26/11	Tue 2/1/11
115			6.6.2	Design Report Deliver	0 days	Tue 2/1/11	Tue 2/1/11
116			6.6.3	Status Meeting with V	0 days	Tue 2/1/11	Tue 2/1/11
117			**6.7**	**Build Phase**	**90 days**	**Tue 2/1/11**	**Sat 6/4/11**
118			6.7.1	Hardware Demonstra	0 days	Mon 5/9/11	Mon 5/9/11
119			6.7.2	On-Campus Senior De	0 days	Thu 6/2/11	Thu 6/2/11
120			6.7.3	Compile Design Repor	8 days	Mon 5/23/11	Wed 6/1/11
121			6.7.4	Final Design Report D	0 days	Sat 6/4/11	Sat 6/4/11



Critical		Manual Task		Baseline Milestone		External Tasks	
Critical Split		Start-only		Milestone		External Milestone	
Critical Progress		Finish-only		Summary Progress		Inactive Task	
Task		Duration-only		Summary		Inactive Milestone	
Split		Baseline		Manual Summary		Inactive Summary	
Task Progress		Baseline Split		Project Summary		Deadline	

Page 8

Appendix G – Miscellaneous Items

Stakeholder Analysis

The follow table describes the benefit to various groups involved if the project succeeds. The table describes how important the project is for each stakeholder as well as the impact each stakeholder may have on the success of the project. Each stakeholder receives a value from U to 5 (U for unimportant) for their degree of investment and degree of impact.

Stakeholder Analysis				
Stakeholder Groups	Interests at stake in relation to project	Effect of project on interests (- 0 +)	Stakeholder importance for project success: U,1,2,3,4,5	Degree of influence of stakeholder: U,1,2,3,4,5
Reina Estrada	Will get cheaper	+	5	4
	Able to help more	+		
	Publicity for her	+		
	Provide higher quality products	+		
Roque y Walter	Have easier means of	+	5	5
	Provide patients with high	+		
	Control over	+		
Vida Nueva Patients	Will receive feet that last	+	5	2
	Will not have to come in for adjustment	+		
	Receive prosthesis at lower	+		
Matt Robinson	Has an opportunity to try out new design ideas	+	2	3
Tomas	May have a business that he can start	+	3	U
	May provide Vida Nueva with a potential resource for materials	+		
Matt Pepe	More adjustable	+	4	2
	Longer maintained	+		
	Low cost products	+		