Foot Orthosis Device: Final Report

ME 450 Winter 2006

Team FOD (#23):
Michelle Albright
Dmitry Beletsky
Bob Halgren
Dan Hilgart

Section Instructor: Dr. M. Koç
April 18, 2006

Sponsors: Mr. C. Greene and Mr. M. Taylor
University of Michigan Orthotics and Prosthetics Center

EXECUTIVE SUMMARY

Design Problem

When the posterior tibial tendon in the lower leg and foot is injured or ruptured, the patient's arch tends to flatten out, and the normal heel inversion does not occur while stepping forward during the walking cycle. Eventually, this can lead to arthritis, and generally makes walking labored and difficult.

Customer Requirements

The top customer requirement is to re-create the function of the posterior tibial tendon. This means that the heel inversion needs to be recreated, as well as the arch support (meaning the device will have both active and passive assist functions). Secondary concerns are patient comfort, durability, fitting into a normal tennis shoe, and a general adjustability and customizability for the individual patient.

Engineering Specifications

Converting the customer requirements into engineering specifications can be seen directly in the QFD chart included in this report. Some highlights are: 15° of heel inversion (with +/- 10° adjustability); accommodates arch sizes from ¼" to 2" (in height); it must last 5 years; etc. The Engineering Specifications were generated in the attempt to include all possible foot motions so that it is comfortable for any user.

Concepts Considered, Selection Methodology

Fourteen concepts were generated and rated based on how well they met engineering specifications. These scores were then weighted based on importance (as specified by the QFD). The top five concepts were: A cable-driven device with an adjustable arch; pneumatic cylinders coupled with air bladders; an electric motor driven device; a fixed pivot heel joint; and finally, a compliant materials joint.

Manufacturing Plan, Cost Analysis, and Test Results

The device is manufactured in several steps: First, molding the foot, and vacuum forming ThermoPlastic Elastomer over the mold, with hardware embedded in it. Second, finishing the device, and adjusting the hardware. Finally, the foam liner is installed. The total cost for the prototype was $279.11, not including labor, equipment time, or costs for TPE and foam liner. Test results on the prototype device show that it meets 13 of 15 design specifications, failing on total inversion desired, and durability. However, the prototype does prove that the concept works, and can be modified to achieve the necessary heel inversion. Verifying durability will require a repetitive motion study, which we were unable to perform.

Design Critique and Conclusions

Positive aspects of the final design include its simplicity, specifically the SLFP, and the ease of adjustability. Furthermore, the TPE construction allows for the device to be extremely customizable, easy to construct, as well as durable. Qualities of the device to be improved upon include meeting the heel inversion requirement, as well as some changes to make the manufacturing process faster, easier, and of higher quality.

Overall, we met 13 of 15 engineering specifications, and believe that the device produced is patentable, marketable, and able to be produced and sold after further refinements.

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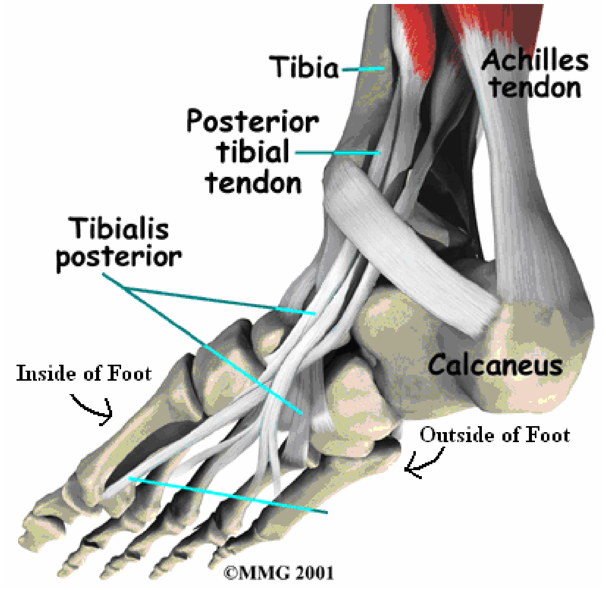
INTRODUCTION

The University of Michigan Orthotics and Prosthetics Center has teamed up with ME 450 to design and fabricate and in-shoe dynamic foot orthosis device. The O&P Center currently manufactures devices for patients and also studies new ways to improve current devices. One such device in need of improvement is the static foot orthosis device. It is used when patients have injured a muscle or tendon in the foot or ankle area. Our team is specifically targeting an orthotic device to treat posterior tibialis tendonitis.

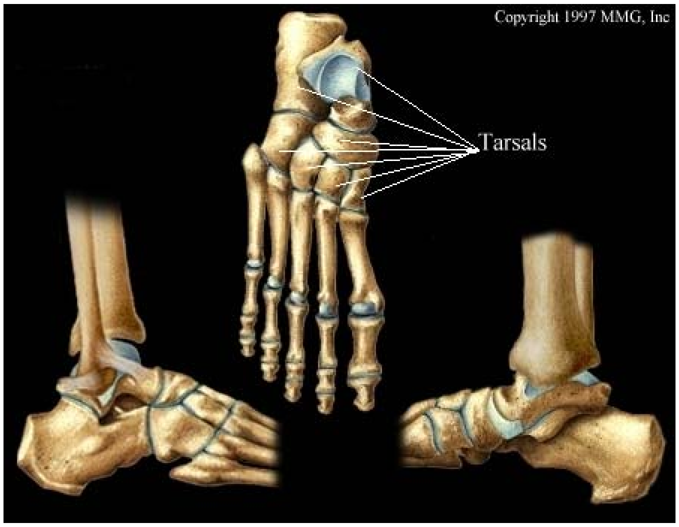
The posterior tibial muscle and tendon are integral to a gait cycle. The tendon runs behind and below the inside ankle bone and under the arch of the foot, as shown in Fig. 1 below:

Figure 1: Posterior tibial tendon runs behind and below the inside ankle bone and under the arch of the foot [4]



As the foot pushes off the ground, the tendon tightens. This allows the heel to slightly invert such that the mid-tarsal joints in the foot align to create a rigid structure. The rigid structure is key at this point in the gait cycle, and helps propel the foot forward. Mid-tarsal joints are shown in detail in Fig. 2 on pg. 4. If the posterior tibial tendon is damaged or ruptured, the foot joints will not align, and therefore, the foot will not propel itself forward well. Overtime, due to misaligned joints, arthritis will form, leading to a flat and rigid foot.

Figure 2: The mid-tarsal joints align to create a rigid foot structure. This helps propel the foot forward during the gait cycle [5]



To heal the posterior tibial tendon, it needs to rest. Thus far, treatment has been passive, and has included different forms of removable casts, ankle braces, and UCBL foot orthotics. Although the tendon is able to rest because of the rigid structure, walking becomes uncomfortable and difficult, making day-to-day life complicated. Thus, the University of Michigan Hospital Orthotics and Prosthetics Center would like to fabricate an in-shoe dynamic device that not only replaces the tendon function, but also restores the arch of the foot. If this device is successful, it will be the most significant advance in orthotics technology in over the past fifty years.

CUSTOMER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

Process of Defining Customer Requirements

Results of sponsor meeting. Customer requirements were developed by a very straight forward discussion with the project sponsor, Mr. Charl Greene. These were developed after first defining the major two functions of the device: to support the arch of the foot, and to recreate heel inversion. After these had been defined, the rest of the requirements came out as basic definitions or requirements of all shoe inserts or orthotics: comfort, customization, minimum restriction on all movement, easy to construct, etc. Effectively, this can be summarized as foot and ankle device being a dynamic assist mechanism with the same general properties of a regular shoe orthotic insert. The full list of customer requirements is shown in Table on pg. 5.

Table 1: Customer requirements

- Recreates heel inversion
- Restores arch of foot
- Fits in an athletic shoe
- Allows pronation
- Allows vertical toe motion
- Custom fit
- Adjustable once constructed
- Easy to construct
- Does not damage shoe
- Durable
- Comfortable
- Lightweight
- Easy to put in shoe
- Easy to put on foot

Relative importance values. Once the customer requirements had been defined, we ranked each requirement by importance. This was done by generating all combinations of two requirements and then assigning a value of zero to the less important requirement of each pair and a value of one to the other. When all the ones were summed together, each requirement had a unique importance value. The importance values are listed in the QFD diagram in App.1.A on pg. 38.

Process of Defining Engineering Specifications

Engineering specifications descended from customer requirements. Engineering specifications were developed by discussing each customer requirement as a team. Some customer requirements, such as “The device must allow vertical toe motion,” had one directly related engineering specification. Others, such as “The device must be comfortable,” had many different associated engineering specifications.

Engineering specifications not too restrictive. We tried to quantify each engineering specification such that they would not limit the possibilities of concepts and designs. For example, if we were to state that there must be 3 reconfigurable pressure applicators in the device, then a more simplistic, elegant design with only one or two applicators would not meet our requirements. Thus, each engineering specification was scrutinized to try to minimize the possibility of restricting design and conceptual options, while still establishing a good target window. A list of engineering specifications can be found in Table 2 below:

Table 2: Engineering specifications

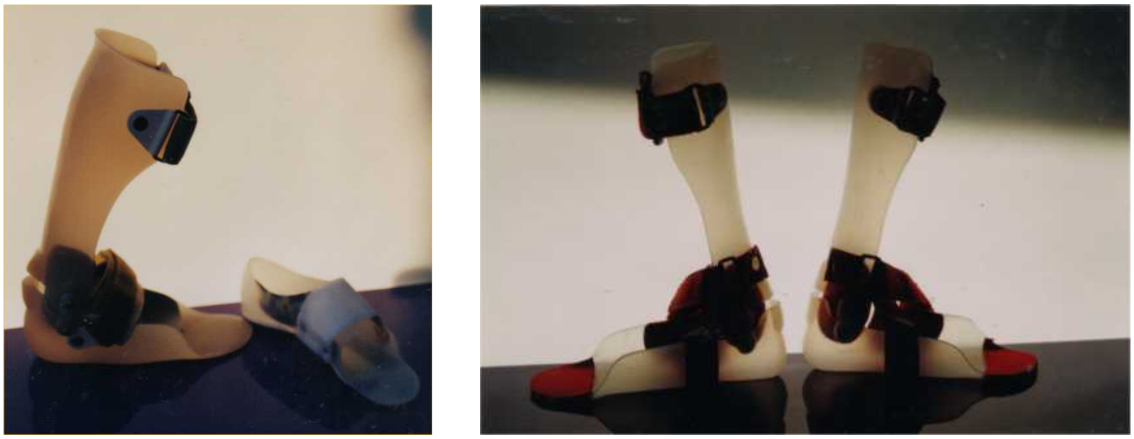
- Must last 5 years
- Constructed from laminates, thermoplastics, and metal hardware
- Weighs less than 1 lb.
- Customizable to shoe sizes of Women’s 6 to Men’s 15
- Device opening must be greater than 100% of shoe opening
- Accommodate arch sizes of 1/4” to 2”
- Forced heel inversion adjustable to 5° - 25° at supination
- 0° of forced heel inversion at pronation
- Ankle can dorsi-flect up to 20°
- Toes can dorsi-flect up to 90°
- Exterior surface roughness less than 0.01’
- No protrusions greater than 1/2” on side
- No points with Radius of curvature less than 1/64”
- No protrusions greater than 1/8” on bottom
- Able to withstand force of 400 lb person jumping 2 feet onto concrete

Cross correlation matrix. All engineering specifications were compared to each other to determine how they were related. The cross correlation matrix is the triangular section at the top of the QFD diagram which can be found in App. 1.A on pg. 38. Some specifications have a negative relationship in that satisfying one will make it more difficult to satisfy the other; these are marked with a '-' in the cross correlation matrix. Others showed a positive correlation in that satisfying one specification would make satisfying the other easier; these are marked by a '+' in the correlation matrix. Still others have a very strong relationship and are marked with a '++'; a design that satisfied one would likely satisfy the other. This cross correlation matrix will give us some guidance in the convergence portion of our design process.

Benchmark Competition. Effectively all competitive products on the market today are static (passive assist) devices, whether they are shoe inserts (shown in Fig. 3 below), or a more elaborate restrictive device that attach as high as the calf muscle area, such as the Richie Brace shown in Fig. 4 below. The performance of the Richie Brace and the UCBL were evaluated based on a ranking system form 1 to 5, with 1 being the lowest and 5 being the highest level. The rankings were applied to each customer requirement, with judgment based on our engineering knowledge of the two devices.

Figure 3: Typical UCBL [7].

Figure 4: Richie Braces [8]. Static devices used to let the posterior tibial tendon rest.



Target specifications. After the Customer Weights were assigned and their relation to the engineering specifications determined, each relation was multiplied by the customer weight. The total sum was then calculated at the bottom of each column. This information was used to help rank the engineering specifications in order of relative importance, as listed in the last line of the QFD diagram in App. 1.A on pg. 38.

Engineering targets. The value of each engineering specification was estimated for the UCBL and the Richie brace, at the bottom of the main QFD matrix. The target value of each specification for our device was listed in the next row. Our engineering targets are based largely upon matching or exceeding the performance of competing products, when the requirements match. For example, we aim to match the UCBL and Richie Brace in their having no protrusions, points, etc. We aim to match the toe movement (which is unlimited in the competitors). In unique requirements, such as forced heel inversion, the target is derived from the customer requirement, with adjustment ability added. A certain amount of realism was also applied – clearly a shoe insert weighing an ounce would be great, but it is not realistic.

CONCEPT GENERATION

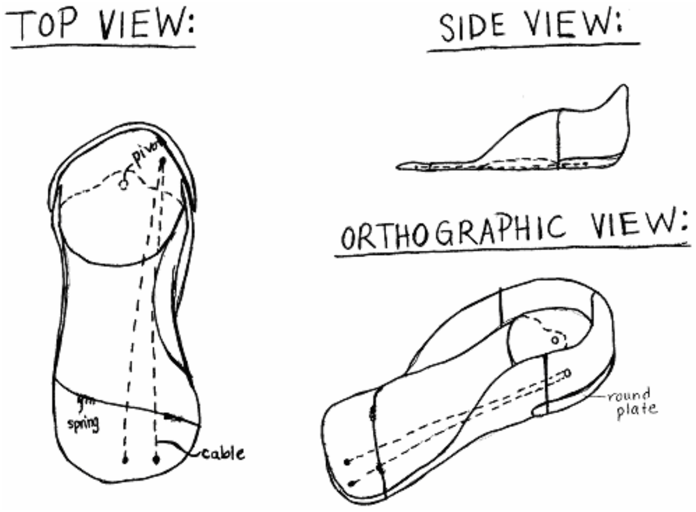
Brainstorming and Concept Categories

Concept generation began with a group session of brainstorming. By using a concept map, we first deconstructed our problem into the three most important aspects: heel inversion, toe actuation, and arch support. An example of this concept map is shown in App. 1.B on pg. 39. At first, any idea was written on the board regardless of absurdity. Once the board was nearly filled, we began to eliminate some of the most unfeasible ideas, such as magnetic levitation shoes. Next, our group split up and took time to think each idea through individually. We came back together and listened to each others' perception on how to incorporate each idea. This enabled us to bounce ideas off of each other and create more complete concept designs. From this analysis, five categories of concepts were generated: cable and pulley systems, areas of customizability, pneumatics, outside power sources, and compliant mechanisms.

Cable and pulley system. This concept category was the most simple of the five. Utilizing the natural motion of the toes, we could create pulley systems using cables embedded in the structure to cause motions necessary for heel inversion and arch support. From meeting with our sponsor, Mr. Greene, we have seen that hollowed out areas in orthotics and prosthetics are quite common and simple to manufacture. Thus, a cable system would be ideal for design.

The general idea of the pulley system is to utilize the displacement of the toe bending motion to create heel inversion. During supination, the toes dorsi-flect creating an arc where the toes meet the foot. Using basic geometry, we can see that the length of the wire around the arc ($r\theta$) is greater than the original length of straight wire. Therefore, as the toes dorsi-flect, tension in the cable increases, and the wire pulls forward the amount of $r\theta$ from the natural arc. A concept example is shown in Fig. 5 on pg. 8. Variations of the cable and pulley system are included in App 1.C on pg. 38.

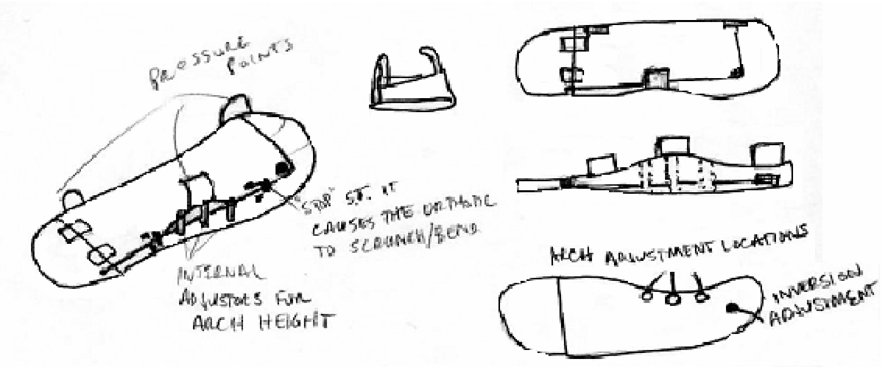
Figure 5: Heel pivot concept. As the cables pull the inner back of the heel plate, the plate turns inward, inverting the heel.



Areas of customizability. One of our concepts had the approach of integrating the most customizability possible into the various mechanisms and systems involved. Specifically, an arch height adjustment was installed so that the device could be further customized after it was constructed. This concept led directly to a method to adjust the amount of heel inversion. The arch adjustment would be a simple screw adjustment, while the heel inversion adjustment would be accomplished by utilizing the simple idea of a lever arm and adjusting the length of the arm.

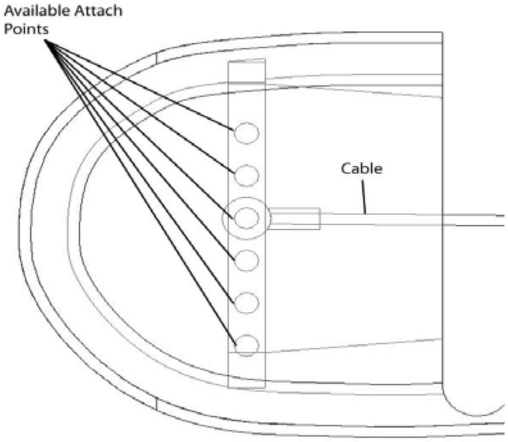
The arch adjustment in this concept was accomplished by having three separate screw adjustments that could be used to vary the height of the arch from approximately ¼" tall up to 2", depending on the total height of the orthotic. This idea is shown in Fig. 6 below. This concept is also detailed further in the Alpha Design concept section.

Figure 6: Arch adjustment concept. Used to customize for each patient based on the severity of flattened arch.



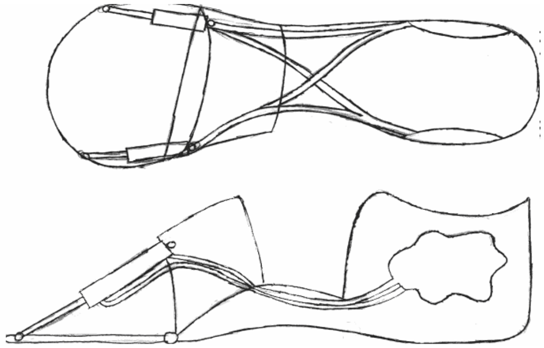
Another concept that dealt with adjustment was the idea of using multiple pull points on the heel plate for the cable. It is assumed that the wire displacement will be relatively constant, no matter the attach point. Therefore, if we attach the cable very close to the pivot point, then there will be a resulting heel plate rotation that is relatively large, whereas if we attach it farther away, the rotation will be much smaller. See Fig. 7 below.

Figure 7: Heel plate attachment points used to customize the amount of heel inversion.



Pneumatics. Another concept of ours involved the use of air bladders with pneumatic pistons to move the air from one bladder to the other, thus resulting in a heel inversion. These pistons would be actuated by the toe dorsiflection, and would result in a relatively smooth heel inversion. See Fig. 8 below.

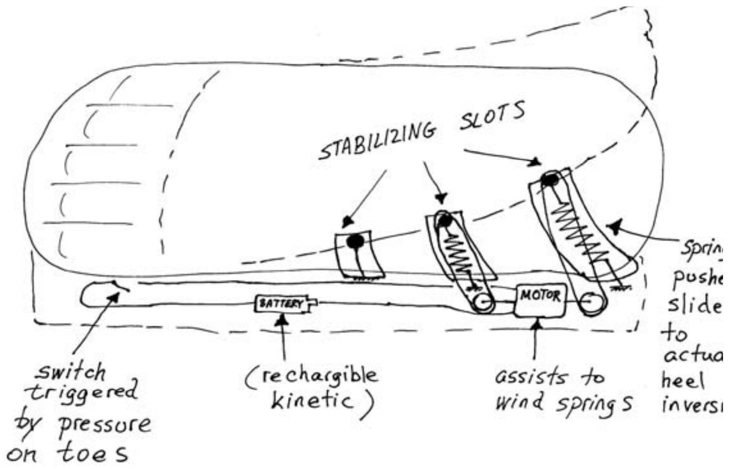
Figure 8: Pneumatic concept. As the toes dorsi-flect, the piston is compressed and air is pushed in the outside air bladder, inverting the heel.



Outside power sources. The use of outside power sources to supply a small electric motor or linear actuator is also another possibility. Instead of using a cable or piston, the heel inversion can be directly and precisely controlled with a motor of some sort. This provides the option of utilizing a micro controller, level sensors, pressure sensors, and other various electronic components to provide a very high quality, controlled mechanism.

Unfortunately, battery technology is not quite small enough to be able to integrate this nicely into the size of a shoe orthotic. Instead, the batteries would likely be along the lines of a car battery size, and would need to be carried in a backpack at all times, with power wires running down the person's legs into their shoes. For most all people, this is not an acceptable solution, despite its obvious potential to deliver a precise foot motion. Fig. 9 below details this concept further.

Figure 9: Electric motor. A kinetic battery powers an electric motor to wind up springs. Springs push heel up and inwards to achieve inversion.



Compliant mechanisms. After a discussion with Mike Cherry, and Christine Vehar from the Compliant Mechanisms Laboratory, the idea of using a Small Length Flexural Pivot (SLFP) came into play as a way to replace a pin joint for the heel plate. This SLFP is detailed further in the Alpha Design concept section; however, the idea is that the material thins down to a small cross section so that it is able to bend repeatedly without breaking or fatiguing.

CONCEPT SELECTION PROCESS

Our team generated fourteen total concepts over the past month. In order to find the best concept with regards to the engineering specifications, we designed a straightforward systematic method of scoring. The concepts with the highest scores would be most compatible with the specifications outlined in Engineering Specifications on pg. 5.

We began by comparing a concept to each specification and rating it: 0 (does not accomplish), 1 (somewhat accomplishes or unknown), or 2 (completely accomplishes or will accomplish with fine tuning). Since some specifications were more essential than others in the final design, we wanted to incorporate the importance rating of each specification into the score. This would ensure that the scoring was accurate and consistent. Using the results from our QFD in App. 1.A on pg. 38, we multiplied the 0, 1, or 2, by the importance and summed up each concept to get a final score. The scoring results for the top five concepts are shown below in Table 3 on pg. 11, while the bottom nine concepts' results are displayed in App. 1.D on pg. 47.

Table 3: Concept scoring matrix for top five concepts

Engineering Specifications (and Importance)	Arch Adjustment	Pneumatic	Motor Mechanism	Cable System	Compliant Joint
Protrusion < 1/8" on bottom (132)	2	2	1	2	2
Points with radius < 1/64" (20)	1	2	2	2	2
Protrusions < 1/2" on side (45)	2	0	1	2	2
Exterior surface roughness < 0.01' (145)	2	2	2	2	2
Toes can dorsi-flect up to 90° (135)	2	2	2	2	2
Ankle can dorsi-flect up to 20° (174)	2	2	2	2	2
0° forced heel inversion at pronation (226)	2	2	2	1	1
Forced heel inversion adjustable 5° to 25° (386)	1	2	2	2	2
Accommodates arch sizes of 1/4" to 2" (225)	2	2	2	1	2
Device opening > 100% of original shoe opening (162)	2	2	2	2	2
Customizable to shoe sizes of women's 6 to men's 15 (171)	2	2	2	1	2
Weighs < 1 lb (153)	1	1	2	2	2
Constructed from laminates, thermoplastics, and metal hardware (147)	2	0	0	2	2
Must last five years (49)	1	1	0	2	2
Able to withstand force of 400 lb. person jumping 2' onto concrete (45)	1	1	1	1	2
TOTAL	3777	3799	3816	3988	4204

Having determined our top five concepts, we could now focus more on each concept individually. Listing the advantages and disadvantages of each concept would not only allow us to see any potential problems, but would clearly show us which concept was best. In addition, the advantages would also allow us to focus on how to incorporate these advantages into our final design.

We began with the arch adjustment concept shown in App. 1.C.10 on pg. 44. Our first concern with this design was the pressure points along the sides of the device. Not only would these be uncomfortable as they dug into the side of the patient’s foot, but they would have large amounts of stress on them, making the device prone to failure. In addition, there were no moving plates to isolate the heel movement. Therefore, the entire foot would be rotating during each step, requiring much more force. The key design feature that we liked in this concept was the arch adjustment. It gave the design the customizability factor. The arch could be adjusted up or down depending on the severity of the condition and their point in the healing process. Second, there is no need for an outside power source. All of the motion would be caused by the natural movement of the toes.

Next, we analyzed the pneumatic (air bladder) concept shown in App. 1.C.11 on pg. 45. We suspected there would be a problem with the space constraints. We calculated that the pistons that were needed to provide the ankle inversion would be greater than ½” in diameter, which would not satisfy our side protrusion requirement and would not fit into a standard athletic shoe. Since the piston design would be so detailed, we felt that the device would be difficult to manufacture, unless the technician was proficient in customizing pistons and assembly. In addition, the piston assembly would be likely to become loose from repeated use and would therefore require in-depth maintenance on a regular basis. In other words, it would be an inconvenient device for the customer to personally maintain. There were few, but important benefits to the design. First, the device would be comfortable for the patient to wear everyday and would provide a nice fluid inversion motion (would not be jerky). Second, there is no need for an outside power source. All of the motion would be caused by the natural movement of the toes.

Moving on to the motor mechanism concept shown in App. 1.C.12 on pg. 45, we found immediate dissatisfaction with the need for an outside power source. This would create a need for additional motor and micro-controller knowledge in manufacturing, assembly, and customization. Also, since there was a battery involved, it would require more maintenance than a design without an outside power source. On the other hand, the device would be comfortable for the patient since the micro-controller would offer precise control over the motion that occurs.

Next, we looked at heel plate pivot concept shown in App. 1.C.13 on pg. 46. The most undesirable aspect of this design was the method of possible heel inversion. Since the heel plate is just rotating and not pushing the heel inward, we cannot confidently say that the heel will be inverted every time. Instead, the heel may just slide against the back of the device and not move at all. Also, after constructed, the device would not be customizable. All of the specific measurements would need to be incorporated into the construction. This leaves a lot of room for error. The key points that we liked about this concept were the simplicity of the design, durability, and the fact that it was lightweight. These factors would aid in ease of construction for technicians and ease of mind for the patients. In addition, there is no need for an outside power source. All of the motion would be caused by the natural movement of the toes.

Lastly, we analyzed the highest scored concept, the compliant joint, shown in App. 1.C.14 on pg. 46. Our only dislike on this concept was the compliant pivot joint we would need to design. We want the joint to provide the correct amount of ankle movement, but at the same time, not inhibit the motion at all either. There were many aspects of the concept that we liked. First, as with the previous concept, the design is simple, durable, and lightweight. In addition, it would be comfortable for the patient, and customizable after construction due to the arch adjustment. Also, as with most of our concepts, there is no need for an outside power source. All of the motion would be caused by the natural movement of the toes.

After careful consideration of the scoring, and advantages versus disadvantages, we believe that the compliant joint concept would best capture the customer and engineering requirements. To correct the one aspect that we are unhappy with, we will utilize our resources to better understand compliant joints, so that we may design a simple but long-lasting joint.

SELECTED CONCEPT DESCRIPTION: THE ALPHA DESIGN

Abstract

The Alpha Design will function based on the use of a cable attached to a toe plate that creates a force on a heel plate, which will then rotate to invert the heel. This heel plate will be pivoting by using a thinned cross section on one side that will connect the heel plate to the main body of the orthotic. This is called a Small Length Flexural Pivot (SLFP), and is analogous to the cap of a toothpaste tube that is attached, and allowed to bend, but is not significantly affected by fatigue, and lasts for many hundreds (if not thousands) of cycles. Additionally, this concept includes the arch height adjustment feature by using three screw adjustments. The Fig. 10 below and Fig. 11 on pg. 14 are designed to give an overview of the alpha concept.

Figure 10: An orthographic view of the orthotic device as modeled in Pro/Engineer.

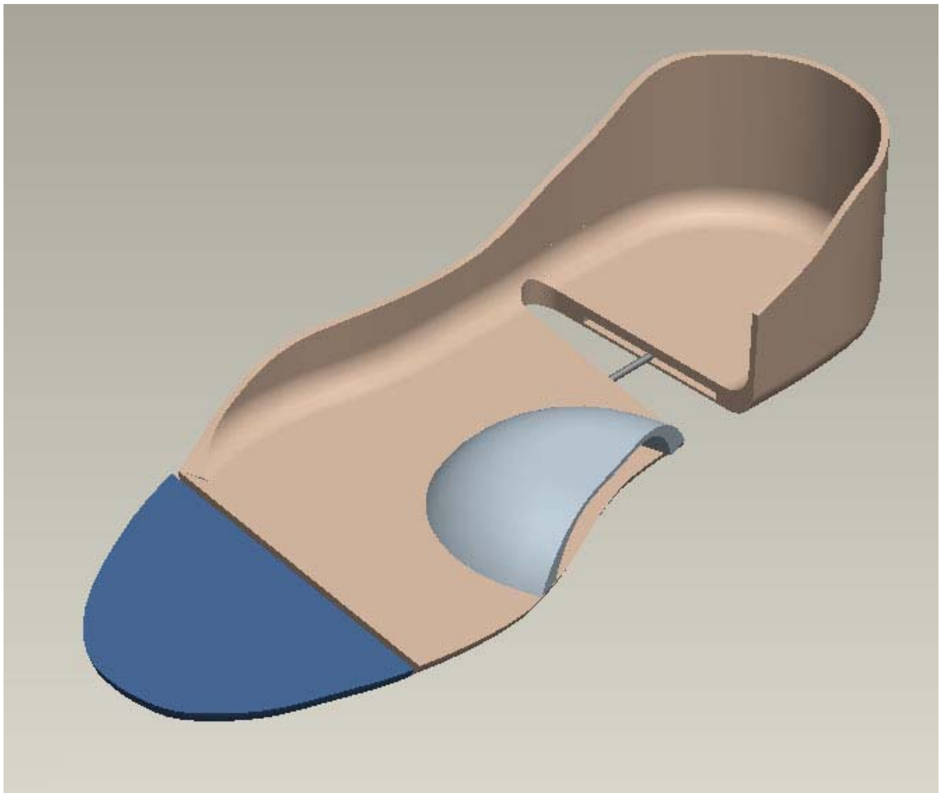
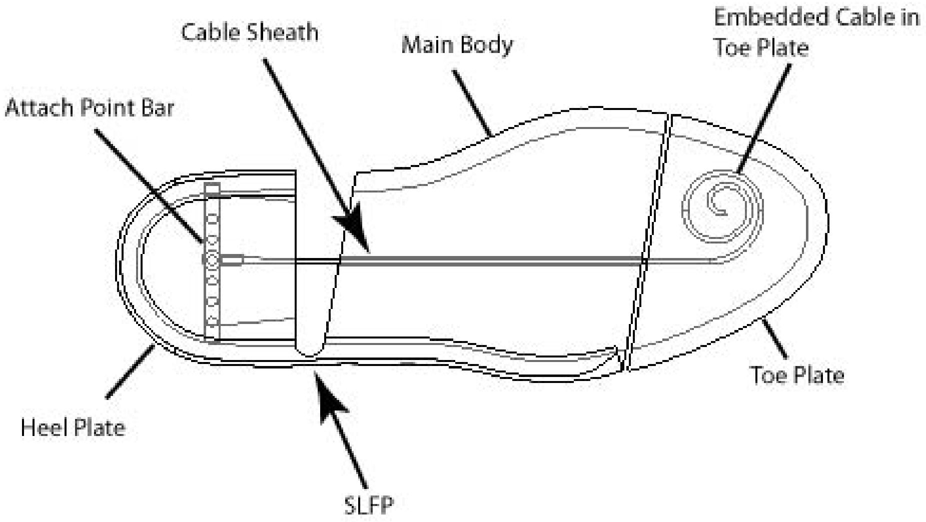


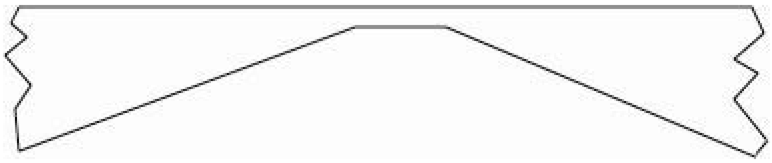
Figure 11: A detailed top view of the major features of the Alpha Concept. Note: arch support system has been hidden for clarity.



Specific Features

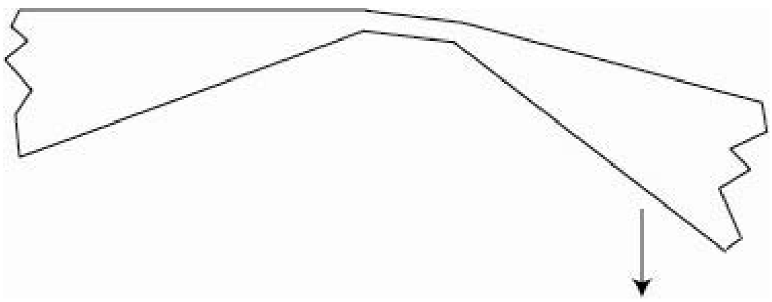
SLFP. The heel plate will be pivoting with respect to the rest of the device by way of a complaint joint mechanism called a Small Length Flexural Pivot. This mechanism is created simply by having the material neck down as shown below:

Figure 12: An example of the Small Length Flexural Pivot when unloaded.



Effectively, when a force is applied to one side of the mechanism, the thin portion of it is allowed to bend. The amount of bending can be easily controlled by the cross sectional thickness and material used for construction, with the application of solid mechanics principles. This bending is shown below:

Figure 13: An example of the SLFP when loaded.



Cable actuation. The mechanism will be actuated by the use of a cable which will be attached to a toe plate on one end, and then to the heel plate on the other end. The toe plate attachment location will be fixed and will be embedded into the material (between layers of carbon fiber, or something similar). Fig. 14 and Fig. 15 below show the source of cable displacement, and how we can predict the amount of displacement we will get for given dimensions chosen for our design.

Figure 14: A side view of the toe plate and main body when flat.

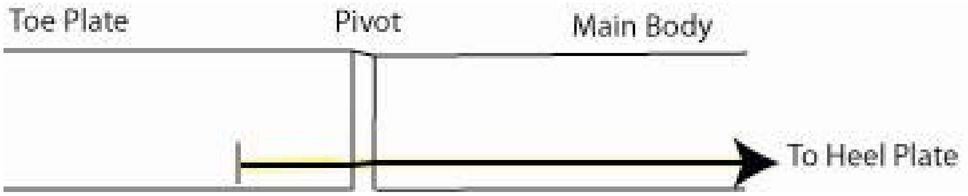
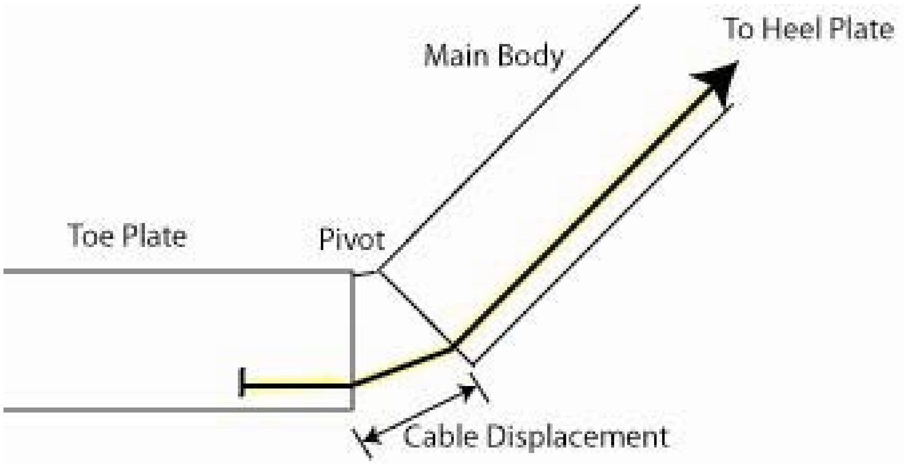
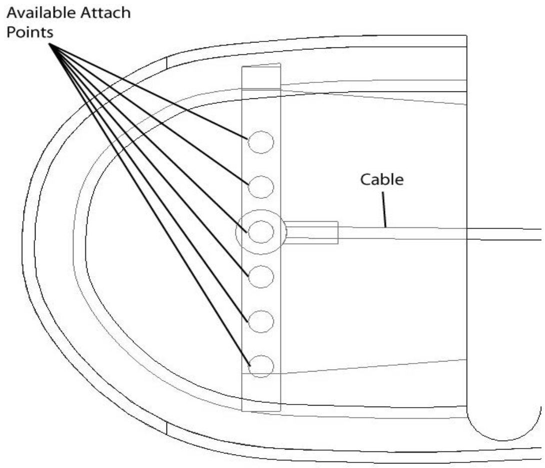


Figure 15: A side view of the toe plate and main body when in stride, and the toes are bent. The cable displacement is easily found by calculating the distance of the resulting (near) triangle that forms.



It will then run in a low-friction tube (Teflon) through the main body of the device, and will then attach to the heel plate. For adjustment purposes, there will be multiple locations that the cable can be attached to on the heel plate, which will act as a lever. Fig. 16 on pg. 16 shows the multiple attach points available.

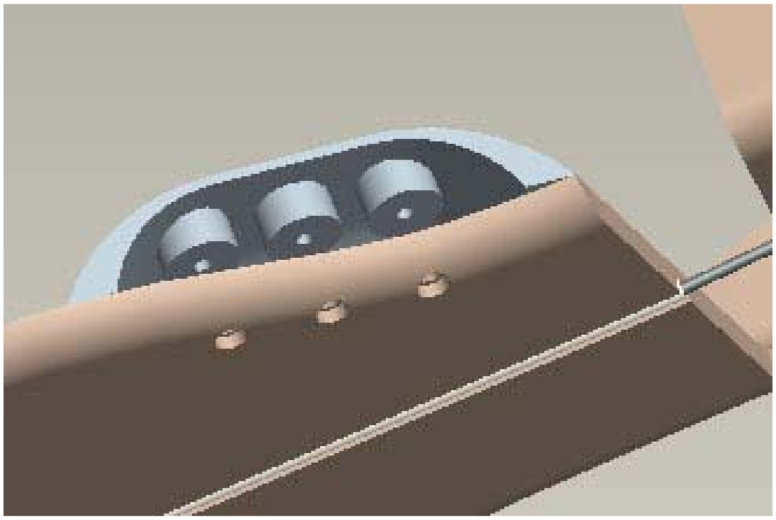
Figure 16: The multiple attach points for the cable, which will allow for total displacement adjustment.



The closer to the pivot side that the cable is attached, the greater the total displacement of the heel (however, this also requires a larger force). An attachment further away from the pivot side will result in lower forces and lower displacement. Analysis will need to be done to find the total forces that will be transmitted through the cable, however, it has been estimated that a quarter inch of lateral motion should be sufficient to create a heel inversion of 15°.

Arch Height Adjustment. The arch height device can be adjusted simply by one to three supporting screw adjustments, as shown below:

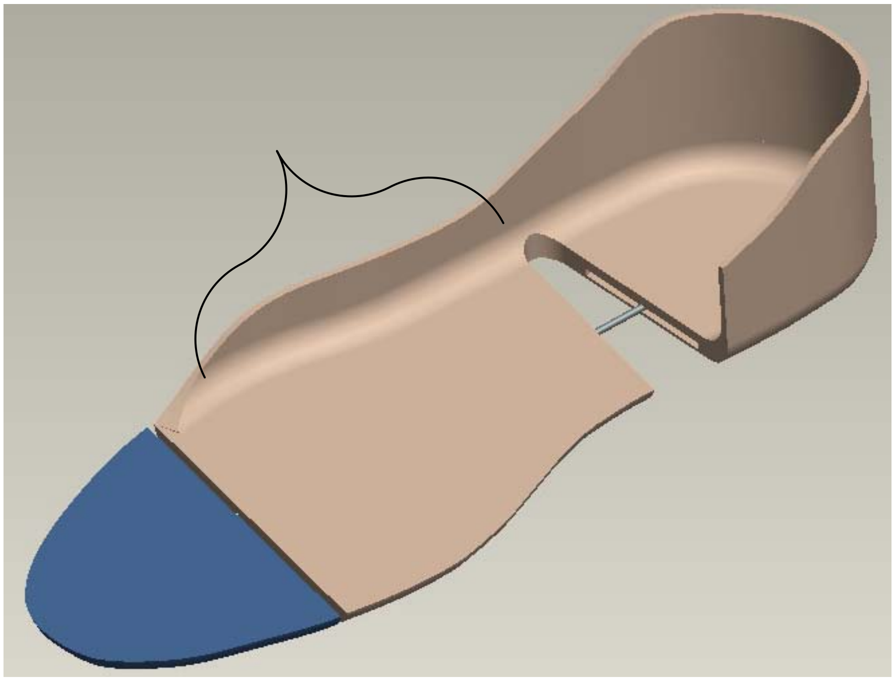
Figure 17: The underside of the arch adjustment. Note that screws are not shown.



These adjustments are very simple to install, however the main difficulty will be finding a material to attach these screws to that will be flexible enough to conform to the adjustments made, yet will be rigid enough to provide adequate support to the foot without yielding to its forces. Also, another design difficulty will be integrating this with the rotating heel plate without creating an area that will cause pinching of skin, sock, or creating any other discomforts.

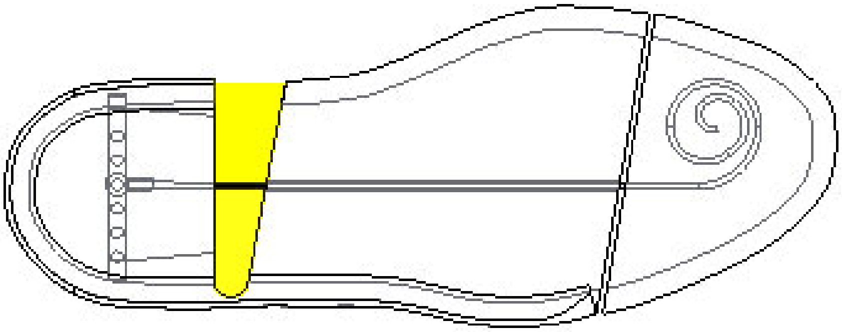
Sidewalls. The sidewalls of this device will be high enough to achieve the side forces necessary on the foot, and no higher. Ideally, this means that it will be no higher than the side of a standard tennis shoe, and this is a very reasonable target. The major design consideration is then how far to extend them forward; essentially whether or not a "reaction" surface will be necessary, or whether the shoe can perform this task alone. Initially, the device will be made with "full" sidewalls, and these can then be removed later if they are determined to be not needed. The sidewalls are shown below in Fig. 18, with the potentially unnecessary area noted. In addition, to ensure the strength of the sidewalls, the same rigid material used for the base of the device will be used for the sides. Thus, there will be no elastic deformation and it will be able to force the heel to invert.

Figure 18: The potentially unnecessary wall area of the device. Note: The Arch support device has been omitted for clarity.



Flexible Filler Material. In the void created by the compliant joint mechanism as described above, there will need to be some sort of supporting filler material so as to make the device comfortable for the user. This material must be flexible enough so as to provide the minimum amount of lateral resistance possible to the movement of the heel plate, while also still providing the maximum amount of vertical support to the user's foot. Fig. 19 on pg. 18 shows the rough shape that the opening will be.

Figure 19: The area where material choice will be crucial to allow the compliant joint to function correctly. Note: The arch support device has been omitted for clarity.



It is possible that this region will be covered by the arch adjustment feature, also previously described, and therefore, there will not be a large need for the area to be filled.

Additionally, it is also possible that this section will not even be large enough for the user to feel it. Further calculations must be conducted to determine the appropriate opening, which may actually be at a maximum of less than 3/8", meaning that no filler would be necessary.

ENGINEERING DESIGN PARAMETER ANALYSIS

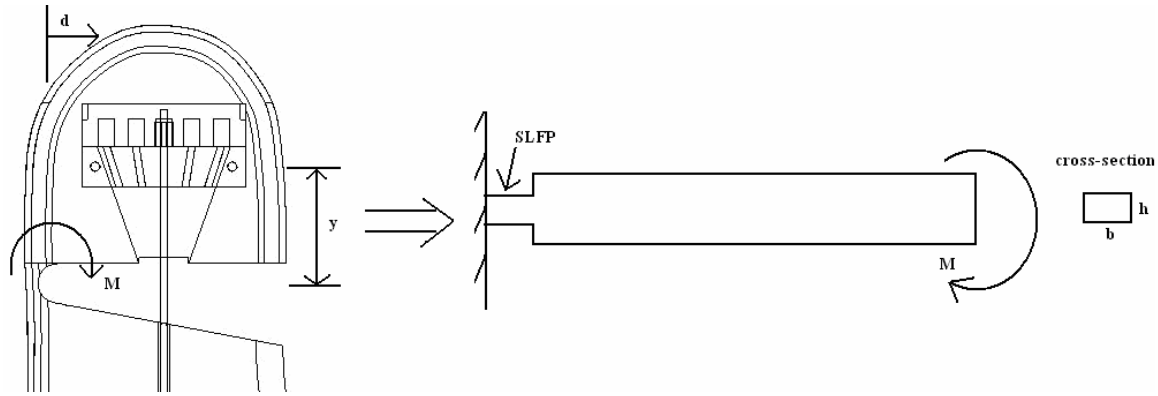
We performed detailed engineering analysis to determine forces, cable displacement, materials, dimensions, and shape for our foot orthotic device. We designed our orthotic with customizability and ease of manufacturing in mind. The fact that it is customizable allows it to work uniquely for each patient, based on their specific needs. For our Alpha prototype, we have chosen to model our orthotic with a subject foot (Men's Size 10). Therefore, all of the specific dimensions, such as height, widths, cable length, and arch height, are specific to this patient's foot.

Forces Necessary to Invert Heel

Heel inversion is able to occur due to the twisting of the SLFP joint. As shown in Fig. 20 on pg. 19, a moment is created from the tension force in the cable, thus turning the heel plate inwards. To determine the force in the cable, we need to analyze the SLFP joint. To simplify the analysis, we model the SLFP joint as a semi-rigid beam. Using basic cantilever beam theory, we can connect the force in the cable to the moment created: $M = dF$, where M is the moment, d is the distance from the SLFP to the cable, and F is the tension force in the cable. Next, using beam stress analysis with a moment at one end, we can apply $\sigma = Mc/I$, where σ is the maximum stress, M is the moment, $2c$ is the width of the joint, and $I = {}^{1}/_{12}\, bh^3$ (b is the joint thickness) is the second moment of inertia. Combining all variables, we determined the maximum stress in the SLFP in Eq. 1 below. This stress can be used in choosing a material with known yield stress properties.

$$\sigma_{\max} = \frac{6dF}{bh^2} \qquad \text{Eq. 1}$$

Figure 20: A moment is created at the SLFP joint when tension in the cable increases, thus inverting the heel plate and the heel. The SLFP can be modeled as a semi-rigid beam.



Cable Dimensions

The diameter of the cable was chosen based solely on the space constraint in the base of the orthotic. We chose to make our cable diameter about 0.0625" since the space constraints in the heel plate are 0.25". This extra space would allow us to make a channel within the base material to reduce friction with the wire. Length of the cable will be custom to each patient depending on foot size and attachment point on the heel plate. For our Alpha prototype, we are choosing to use an attachment point of d = 0.456" (dimension d is shown in Fig. 20 above), with a foot length of 9.9375". Thus, the cable length will be 11.375". This length includes 8.375" of cable from the toe plate to the attachment point with 3" of extra cable for embedding and crimping at the attachment point.

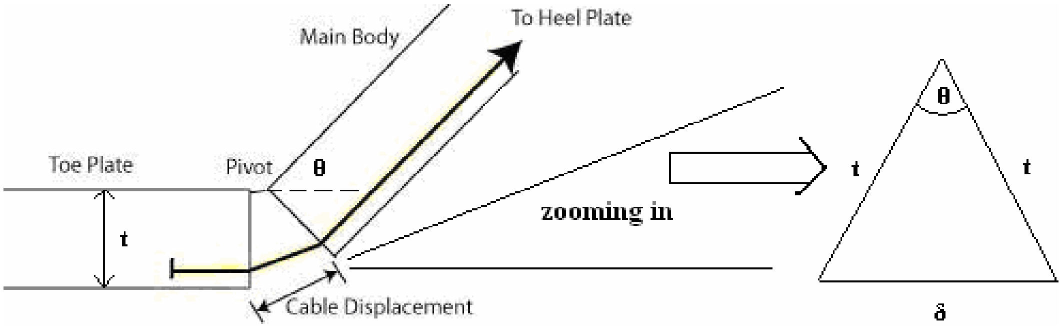
Cable Material

To determine the cable material, we had to consider the maximum amount of force it must withstand and its diameter. Considering the maximum amount of force, we can apply the determined dimensions of the SLFP to Eq. 1 on pg. 18 and find the resulting maximum force in the wire to be 91.94 lbs. (This force analysis for the cable is sufficient because the material will yield before the cable.) In addition, we chose a cable material that was within the diameter limits that we set earlier to allow for extra space in the base of the orthotic. Thus, we will be using PTFE-Coated Grade 18-8 Stainless Steel Wire Rope (7x19 strand core; coated diameter 0.0625"; breaking strength 270 lbs.)[18] for our cable.

Cable Displacement

To determine the amount of cable displacement during the walking cycle, we began by looking at the basic geometry set up of our system. As shown in Fig. 21 on pg. 20, as the toes bend, a triangle is created. The cable displacement, δ, can be found by applying simple geometry rules: $\delta = 2t\sin(^{\theta}/_{2})$, where t is the thickness and θ is the degree of toe bending. Furthermore, by increasing the number of times the cable passes over the pivot gap, we can yield more displacement out of just one cable. In other words, the total displacement is $\Delta = n\delta$, where n is the number of time the cables crosses the gap.

Figure 21: Zoom in of the toe plate as it attaches to the main body. When the toes bend, a triangle is created, yielding cable displacement, δ.



SLFP Dimensions and Material

To determine the dimensions for the SLFP joint, we first chose the material. Evoprene® 029 Thermoplastic Elastomer, Unreinforced, TPE, (0.0419 lb/in^3) was chosen based on its yield strength, flexibility, availability, and ease of manipulating during manufacturing. Other materials considered are displayed in Appendix 1.F on pg. 49 along with their respective yield strengths.

Knowing the limitations of the material, we were then able calculate our dimensions for the SLFP. To simplify the analysis, we modeled the SLFP joint as a semi-rigid beam with a moment at one end as shown in Fig. 20 on pg. 20. As described in Eq. 1 on pg. 18, the end analysis result is an equation for the maximum stress. Solving this equation, we were able to find the thickness, b = 1”, width, h = 0.25”, and perpendicular distance to the attachment point, d = 0.456”.

Height and Thickness of Orthotic Walls

To determine the height of the walls, we took the most reasonable height (so that it would not go over the ankle bone or protrude over the top of the sides of a shoe). This height will vary with each patient, but only slightly, since we are basing it off the location of the ankle bone.

To determine the thickness of the walls, we used the Mechanica package of Pro/Engineer to perform a finite element analysis of the model to verify that the standard 3/16” thick TPE (with a full wrap around the back) would be able to withstand the lateral forces without major deflection.

Arch Adjustment Dimensions and Materials

The arch filler is customizable during manufacturing from the foot mold. After manufacturing is complete, though, the only way to adjust the arch height would be with an arch adjustment feature. The arch adjustment is comprised of three screws that will be able to adjust the height of the arch filler in the orthotic. Ideally, this adjustment will range from ¼” tall up to 2”. For our Alpha prototype, we are not incorporating this feature since our main focus is for the dynamic portion of the device to work.

Length, Width, Thickness, and Shape of Orthotic

The length, width, thickness and shape of the orthotic will be customizable to each patient. Since a foot mold is used as a guide, the dimensions will always vary from person to person. For our

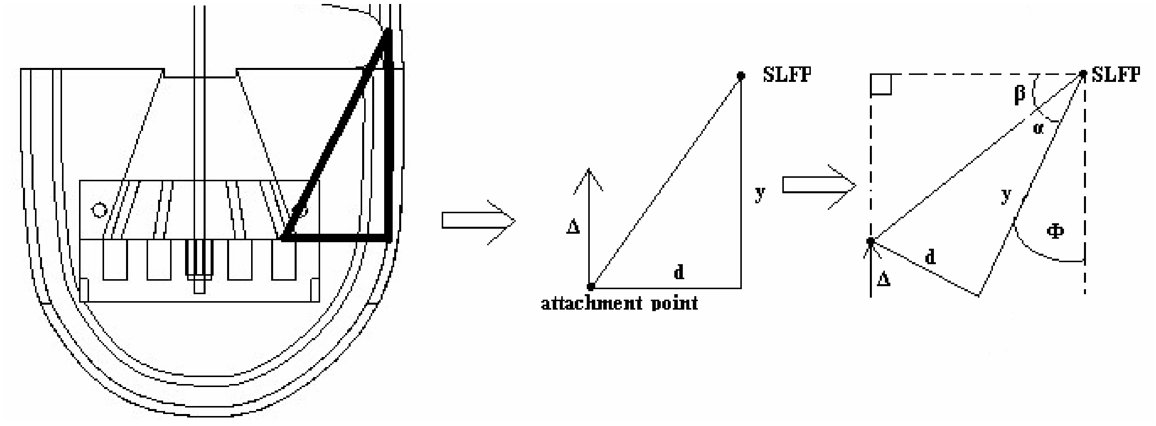
Alpha prototype, the dimensions of the foot are shown in Table 4 below. From here, we can directly find the length and different widths for our prototype. The shape of the orthotic will come directly from the foot mold. Thus, it will fit the person's foot very well. Furthermore, we are able to customize the orthotic based on the arch height and also determine the shape and length of the toe plate for easier walking.

Table 4: Dimensions of the Alpha prototype foot mold.

Description of Measurements	Dimension
Length from biggest toe to back of heel	9.9375"
Width at tarsal joints	3.75"
Width at mid-tarsal joints	3.5625"
Heel width	2.625"
Heel length	2.5625
Arch height	0.375"
Distance from end of big toe to tarsal joints	2.375"
Distance from end of small toe to tarsal joints	0.875"

To determine the thickness of the orthotic, we applied geometry principles. We began by focusing on the heel plate. We simplified the area between the SLFP and the cable attachment point to a right triangle, as shown below in Fig. 22, where y is the distance from the SLFP to the attachment point, d is the perpendicular distance from the SLFP to the attachment point, and Δ is the total displacement from the cable. Writing equations for angles β, and α (Eqs. 3 and 4 on pg. 22, respectively) and setting their sum equal to their combined (90° – Φ) angle, we can find Eq. 5 on pg. 22.

Figure 22: Zoom in of the heel plate as it attaches to the SLFP joint. Angle Φ is the degree of heel inversion obtained from the cable displacement Δ.



$$\beta = \sin^{-1} \frac{y - \Delta}{\sqrt{d^2 + y^2}} \qquad \text{Eq. 3}$$

$$\alpha = \tan^{-1} \frac{d}{y} \qquad \text{Eq. 4}$$

$$\Phi = 90 - \tan^{-1}\frac{d}{y} - \sin^{-1}\frac{y - 2nt\sin(\theta/2)}{\sqrt{d^2 + y^2}} \qquad \text{Eq. 5}$$

From here, the thickness of the toe plate can be chosen. Based on our engineering specifications, we need $5° < \Phi < 25°$. Thus, we can solve for where the attachment points will be placed on the heel plate. These final attachment point details are very critical to our design since customizability is our main goal. Thus, the results of Eq. 5 will be discussed in the Final Design Description section.

Flexible Filler Material

The flexible filler material will not only serve as padding for the patient, but will also serve to keep the foot from being pinched in the cut out area for the SLFP. In other words, it does not have any function other than comfort for the patient. Thus, we have chosen to use Pelite® as it is readily used and available at the University of Michigan's Orthotics and Prosthetics Center.

Design for Manufacturability and Assembly

Designing for manufacturability is key when putting a new device into production. With regards to our orthotic device, designing for manufacturability meant a simple design. Since the design relies on customizability and not mass production, we needed to ensure that the technician creating the orthotic was easily able to manipulate and assemble the device. To achieve this, we kept the amount of necessary hardware and materials to a minimum. As discussed above, we used only three types of materials: one for the body of the orthotic, one for the wire, and one for the padding in the orthotic. In addition, the hardware includes basic hardware such as screws and wire crimpers.

Failure

Failure of our orthotic device was estimated using basic behavior of materials equations. In order to meet our durability requirement set forth by our customer, we need the device to last approximately 5 years or 24 million steps. The main modes of failure include the SLFP joint and the wire. We begin analysis by applying Eq. 6 below, where N_f is the number of cycles until failure, C_1 and a are empirical constants for TPE, and σ_a is the amplitude of stress during a cycle. From FEA, we can see that the maximum stress in the SLFP joint is 17.32 psi. Using values of $C_1 = 61$ and $a = 0.10$, we estimate the number of cycles before failure to be 3.0×10^8. This is well above the required 24 million cycles; therefore, we believe that SLFP failure will not occur during usage.

$$N_f = \left(\frac{C_1}{\sigma_a}\right)^{1/a} \qquad \text{Eq. 6}$$

To estimate the number of cycles before wire failure, we can again use Eq. 6 above. Here, the force in the wire varies from 0 lbs to 91.94 lbs, thus, σ_a is 3.93 psi. Using values of $C_1 = 86$ and $a = 0.14$ for stainless steel, we estimate the number of cycles before failure to be 3.73×10^9. Again, this is well above the required 24 million cycles if the manufacturing of the wire channel is done properly.

Safety

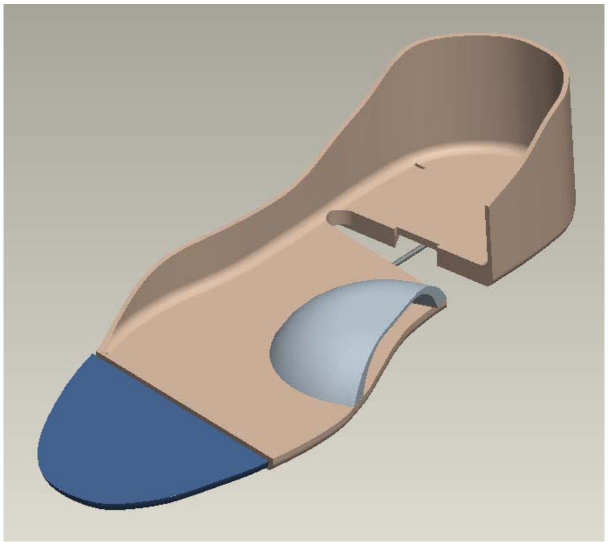
Using DesignSafe 3.0, we were able to analyze the safety issues and risks associated with our final design and testing. It reiterated what we needed to pay close attention to when designing and fabricating the device. Since our main goal is customizability for the patient, many of the hazards associated with patient discomfort would result from improper foot measurement, and thus improper design. We assume that the technician taking the measurements and the assemblers are experienced orthotists. They will therefore not need detailed instructions for measuring the foot and creating a custom device. A full DesignSafe Report is shown in Appendix 1.G on pg. 51.

FINAL DESIGN DESCRIPTION

Overview

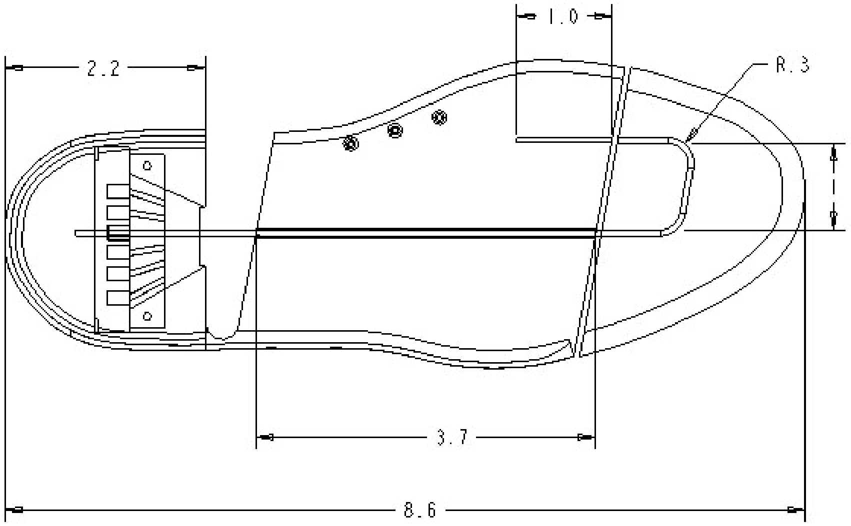
As previously discussed, the final design has multiple concepts integrated, including the adjustable arch, adjustable cable location & stop, etc. These sub-systems will be described in detail in this section. Below are figures of the orthotic, revealing several of its features:

Figure 23: Basic view of the orthotic device.



Next, Fig. 24 on pg. 23 shows a dimensioned top view to give an idea of scale and features.

Figure 24: Dimensioned top view of orthotic.



How it Works

When the user takes a step forward, pronating their foot, the toe plate is bent up. This causes the embedded cable to contract (as discussed previously in 'Cable Displacement'), which then pulls on the heel plate at its designated attachment point. Because the heel plate is attached using a Small Length Flexural Pivot (SLFP) Joint, it is allowed to flex and rotate relative to the rest of the orthotic. The sidewalls then apply pressure to the side of the heel, forcing it to invert. When the user lifts their entire foot off of the ground, the toe plate is released, and the SLFP causes the heel to return to its natural position.

Specific Features

For further specific details regarding any of the parts mentioned below, please reference the Bill of Materials included at the end of this section.

Adjustable cable attachment location in heel plate. As shown in the figures above, there will be a total of six locations where the cable may be attached in the heel plate. These specifically vary the amount of force and displacement that the heel plate will transmit to the foot. We know that the displacement of the cable will remain constant, but the length of the lever arm is changing, thus the total displacement and force must change as well. (See Fig. 25 on pg. 24.)

Figure 25: A close-up view of the bottom of the heel plate area.

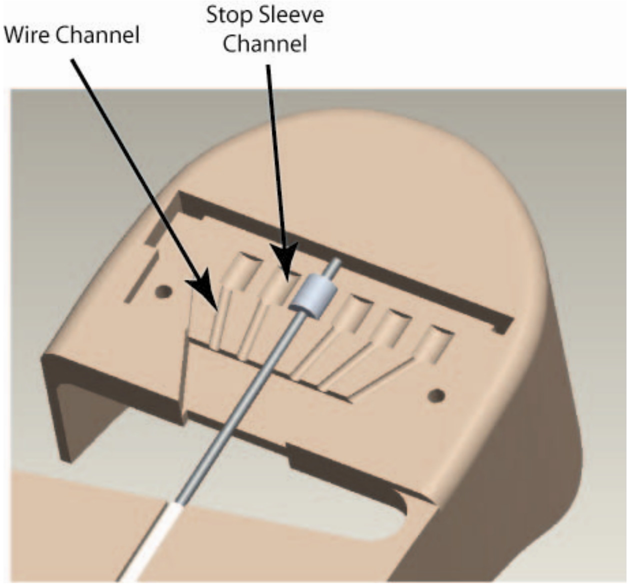
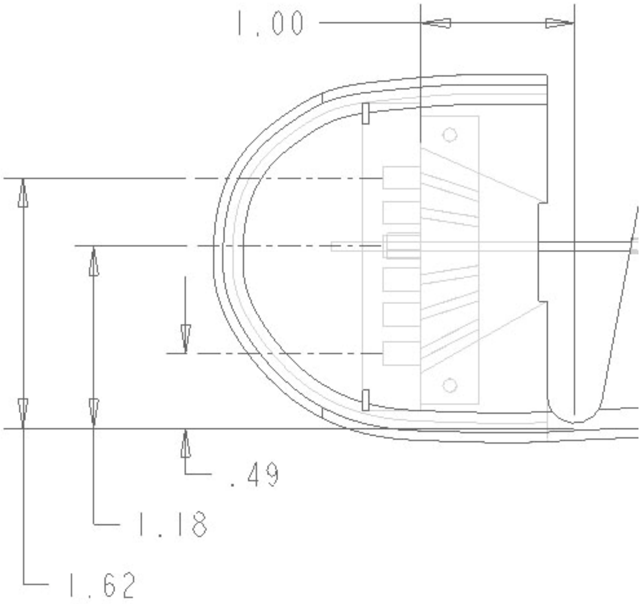
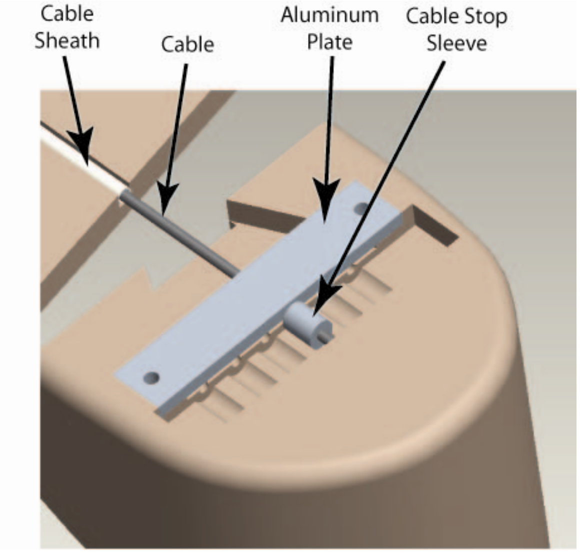


Figure 26: Dimensioned cable attach points.



Additionally, this cable will be held in place in its channel by a small aluminum (6061) bar that will be placed over the cable tray, and screwed into place with two very small machine screws. This feature has been omitted from the above figures for clarity. See Fig. 27 on pg. 25 for its actual placement.

Figure 27: A close up view of the bottom of the heel plate area. Specifically note the small aluminum bar that will hold the cable in place.



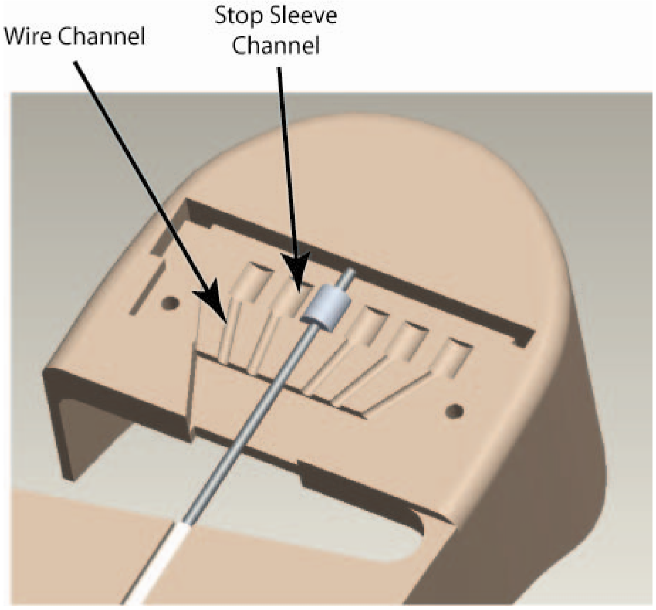
Cable and placement. A $^1/_{16}$" OD Teflon coated cable will be routed through a Teflon tube through the base of the orthotic.

The tubing will be embedded into the TPE, and will ensure that the wire is allowed to slide without resistance. Furthermore, it allows us to easily embed the wire system during the manufacturing process (a discussion on this will follow).

The cable will be secured into the main body of the orthotic by simply embedding it within the TPE. This will be accomplished by stripping away the Teflon coating from approximately 2 inches of the end of the wire, fraying the end, and then embedding this between two layers of TPE. Testing thus far has shown this approach to be effective up to at least 50 Lbs of applied force. Further testing should be conducted to determine what method of embedding is most effective.

Attachment at the heel plate will be accomplished by using a stop sleeve that will be crimped onto the wire. This sleeve will then serve as the means of transmitting the actual forces to the heel plate, against the TPE, as well as a small aluminum bar that will be keeping the wire in its channel. See Fig. 28 on pg. 26 for a detailed view.

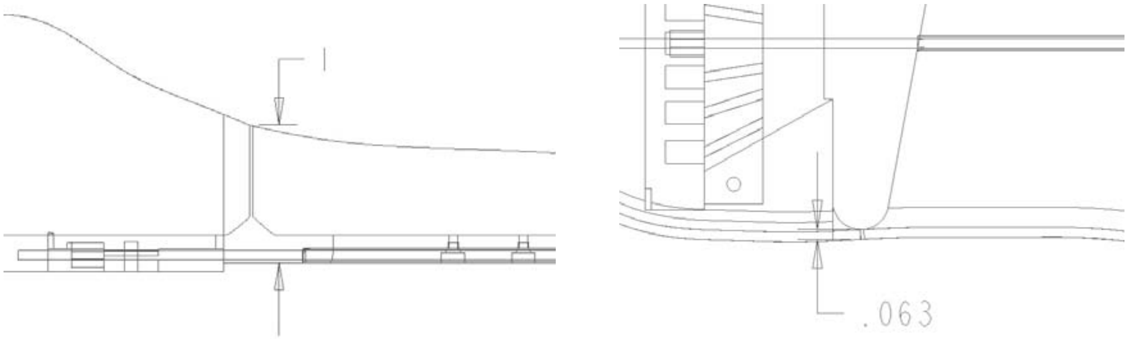
Figure 28: View of the bottom of the heel plate. Note the attachment point, wire channels and aluminum bar.



This stop sleeve approach provides an effective measure of customization as to the length of the wire that would not be accomplished through an eyelet or other swaged fitting. Furthermore, it is much easier for manufacturing, while still provides quality results.

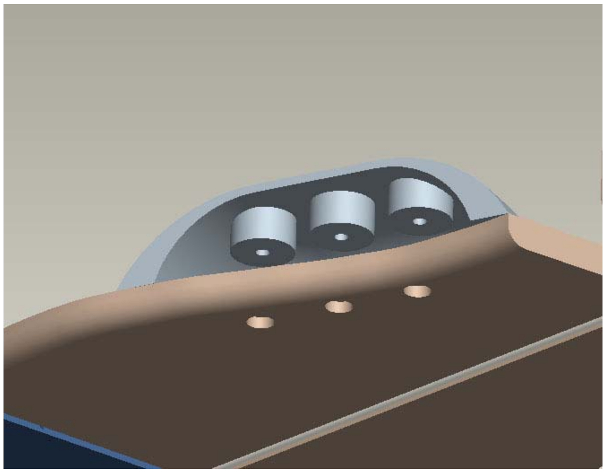
SLFP pivots & resists the wire force. The Small Length Flexural Pivot has been employed in order to provide a simple, yet elegant pivot point for the heel plate to rotate about. Essentially, the SLFP will act as a very small beam, bending with an applied moment force. This will not only allow the heel plate to rotate to induce the inversion, but it will also serve the purpose of a return spring, returning the heel plate to its natural position once the wire force has been removed (once the user picks their foot up from the ground). Details of the SLFP are shown below:

Figure 29: Views of the dimensioned SLFP joint.



Arch Adjustment. The arch will be adjustable through three screws that will run through the bottom of the orthotic, connecting to the top of the arch support. See Fig. 30 below.

Figure 30: Side view of the orthotic displaying the arch support in detail.



These three screws should serve as an easy way to vary the height of the support in those areas so as to achieve the desired results for the patient.

Padding on contact surfaces. Thin padding will be applied to all surfaces that contact the foot, including going over the toe joint, the arch support joint, and the open area for the SLFP. This will be done with standard padding available and used in all orthotic devices. The manufacturing plan goes into further detail about its application.

Bill of materials

A Table of the materials needed is shown on pg. 28, their source, part number, and cost. This information will be used during our manufacturing stage.

Table 5: Bill of Materials

Item	Source	Part #	Cost/Item	Quantity	Item Sub Total
PTFE Coated 18-8 SS Wire Rope; 7x19 strand core, 3/64" bare, 1/16" coated. 270Lb breaking strength; sold by the foot	MMC [19]	3423T29	$1.76	2.00	$3.52
Zinc-Plated Copper Stop Compression Sleeve for 3/64" Robe Diameter, 1/4" Sleeve Length; Pack of 50	MMC	3936T34	$7.42	1.00	$7.42
Single Groove Hand Tool for oval/stop sleeves for 3/64" copper, zinc-plated copper	MMC	3377T11	$136.46	1.00	$136.46
Machine Screws 18-8 SS Phillips, 4-40 threads 3/16" length, undercut head; sold in a pack of 100	MMC	91771A111	$3.17	1.00	$3.17
PTFE Tube 1/16" ID, 1/8" OD Semi-Clear; sold by the foot	MMC	5239K24	$0.73	2.00	$1.46
6061 Aluminum Block 1/4" x 1.5" x 1'	MMC	6023K231	$10.12	1.00	$10.12
6061 Aluminum Sheet .080" Thick, 12" x 12"	MMC	89015K16	$13.44	1.00	$13.44
TPE	UM O&P	n/a	$0.00	0.00	$0.00

PROTOTYPE DESCRIPTION

The prototype built will integrate all features listed above, with the exception of the arch adjustment. We feel that the dynamic functions of the orthotic are the main goals for this project, and should thus be the focus. Furthermore, the arch can be adjusted (once) by the technician when he/she makes the orthotic and casts it, the only exception being that this will not be adjustable after fabrication.

During fabrication of the prototype, we needed to make only one engineering change to our design: the type of stop sleeve used to hold the wire in place. More details of this change are shown and described in Appendix 1.H on pg. 52. The primary reason there were not many engineering changes was that our manufacturing process was flexible enough to allow for small changes within it. For example, the tolerances we used allowed the placement of the wire to be very flexible. More specifically, the final design is not one that relies on precision—the wire rope will displace whether it is in the middle of the TPE, or on the bottom of it, for example. Thus, the final design did not have to be perfect in order for the prototype to successfully prove that the concept works.

MANUFACTURING PLAN

Procedure

We first fabricated an aluminum slug to mold the attachment plate for the orthotic. The aluminum molding insert was constructed out of 6061-T651 anodized aluminum rectangular bar measuring .25” x 2” x 12”. Machining was done on a Proto-Trak CNC Mill using 0.25” and 0.125” end mill bits. The tool paths were input on the spot using coordinates to define pockets and paths to mill out. The entire process took approximately 4 hours to complete.

The following procedure was used to fabricate the remainder of the orthotic:

1) Make plaster casting
2) Cut & heat TPE for the toe plate and mid section
3) Tape parachute cord across toe joint
4) Apply toe plate TPE to casting, butted against parachute cord
5) Immediately press toe plate tubing into TPE
6) Apply mid section TPE to casting, butted against parachute cord
7) Immediately press mid section tubing into TPE
8) Allow to cool
9) Smooth out edges of mid section and toe plate section with grinder
10) Heat a 2” x 2” square of TPE and a piece large enough to cover entire foot
11) Replace tubing and cover with another nylon sleeve
12) Remove both pieces from oven and place square over heel then cover the rest with the sheet
13) Immediately push the attachment plate template into the hot TPE at the heel
14) Vacuum and allow to cool
15) Cut out TPE to approximate shape of finished device
16) Cut out SLFP with band saw
17) Cut toe joint in outer layer
18) Grind edges of toe plate and mid section to create a straight edge for the toe joint
19) Cut cable to appropriate length and strip and fray the end
20) Run cable through tubing and insert into grooves
21) Epoxy toe plate and mid section together
22) Grind out grooves in attachment plate with angle grinder
23) Attach cable stop to end of cable
24) Screw attachment plate cover on
25) Grind down excess material
26) Heat and form foam padding to inside of device
27) Cut off excess padding
28) Glue padding to device
29) Adjust attachment at heel plate as necessary

(1) The first step is to make a plaster casting of the subject's foot to which the device will be molded. (2) Once the casting is ready, we cut and heated the TPE for the toe plate and mid section. Then we covered the casting with a nylon sleeve. (3) We taped parachute cord across the toe joint and marked the points where cable would cross the joint. The next step was to cut and shape the Teflon tubing for the toe plate and mid section. (4) We could then remove the toe plate TPE from the oven and lay it over toe plate section, butted against the parachute cord. (5) Immediately, we pressed the toe plate tubing into the TPE before it hardened too much. (6) Next, we removed the mid section TPE from the oven and butted it against parachute cord. (7) We immediately pressed the mid section tubing into TPE like the toe plate portion. (8) We then allowed it to cool.

(9) Once the TPE had cooled, we removed the mid section and toe plate section and rounded the edges with a grinder. (10) We then heated an approximately 2" x 2" square of TPE along with a sheet large enough to cover the entire casting. (11) While those were in the oven, we removed the parachute cord and placed the mid section and toe plate section, along with their respective tubing back onto the casting. We then put a second nylon sleeve over the entire assembly. (12) Using three people, we removed both pieces from the oven. One person placed the square over the heel before the other two immediately covered the rest with the sheet. (13) A fourth person pushed the attachment plate template into the hot TPE at the heel as soon as the sheet was in place. (14) The TPE was then vaccuum formed while it cooled.

(15) Now that all of the TPE had been molded, we cut out the TPE to the approximate shape of finished device. (16) We then cut out the SLFP with a band saw. (17) We separated the toe plate and mid section pieces from the outer layer before cutting through the outer layer of TPE at the toe joint. We roughed up the contacting surfaces of the toe plate and the mid section with a grinder so that they would adhere better. (18) We also ground the edges of the toe plate and mid section to create a straight edge for the toe joint. (19) Next, we cut the cable to the appropriate length and stripped 1" of Teflon off before fraying the end. (20) We ran the cable through the Teflon tubing and inserted the tubing into its grooves in the toe plate and mid section, leaving the frayed end at the embedding spot. (21) We could then epoxy the toe plate and mid section together with the Teflon tube and cable sandwiched between. We clamped it while it set. (22) After it had set, we ground out the grooves in the attachment plate with an angle grinder and (23) attached the cable stop to the end of the cable. (24) We put the cable in the appropriate groove and screwed the attachment plate cover on.

(25) In order to make the device more comfortable, we ground down the excess material and sanded it smooth. (26) The padding was put in the oven to heat. Meanwhile, we put tape across the SLFP for support. We took the foam padding out of the oven and formed it to the inside of the device and allowed it to cool. (27) We then cut off the excess padding and removed the tape from the SLFP before (28) gluing the padding to the device. (29) Finally we adjusted the attachment at the heel plate as necessary to achieve our desired inversion.

Tolerances

The tolerances for the vacuum forming and embedding processes are very variable. The final contouring is mostly taken care of through sanding or grinding off the excess material after the mold is formed. The only area where we will require tight tolerance control will be in the machining of the fixture for the heel attachment area. There we will be able to obtain tolerances better than 0.020” by using CNC machining in the mechanical engineering machine shop.

TEST RESULTS

Several parameters of the device were subjected to physical tests to verify whether our initial performance metrics were reached. Among these, the most important criteria included the geometry of the actuated motion and the mechanical strength of the assembly. The fit and finish of the device were also reviewed, and certain other tests that were not feasible to conduct during development were considered for the future. Overall, we believe that our final design will meet all specifications, pending on the implementation of our recommendations.

Geometry

The orthotic device was tested in its current state to achieve a heel plate rotation of about 5.5 degrees. This was verified through digital imaging of the operation of the device.The orthotic was held firmly against the table, while lying on its side, with the digital camera pointed toward its bottom. The opening between the heel and the mid plate was photographed in the "neutral" position, with the toe plate in line with the rest of the orthotic, and in the maximum toe-bend position, with the toe plate fully bent and exerting the maximum amount of pull on the heel plate. The difference in the opening angles was then found by subtracting the minimum opening from the maximum opening. During this process, the toe plate was bent by hand to over 45˚ of rotation, which represents the sighted amount of rotation that the foot was found to typically undergo during normal, relaxed walking gait. Although the 5˚ of heel rotation achieved falls short of our goal, this is due mostly to errors in the manufacturing. These errors caused excessive slack in the hinge joint between the toe and the mid plate, which in turn caused a delay and limited the actuation of the heel rotation. The device did not interfere with the range of motion in the toe and ankle. We verified experimentally that the ankle was able to dorsi-flect by 20˚, and the toes were able to dorsi-flect by 90˚.

Strength

In order to measure the strength of the attachment of the wires to the plastic, a pull test was conducted. To make our results statistically significant, we collected data from 8 specimens that we made. All of the specimens were able to withstand a force of 50 lbs, which was measured with a simple fish-scale and vice grips in the mechanical engineering machine shop. The specimens were manufactured with the wire embedded between two pieces of TPE, which bonded to each other while heated. Although the final prototype used a different method of adhesion, (wire epoxied to TPE), this was done purely in the interest of saving time and producing a working model. As will be described further, the direct TPE-TPE bonding method is preferable to the use of epoxy, and will be recommended to be used in the final design. Thus, the strength testing that was undertaken for the prototype gives assurance that our device is capable of withstanding the load imposed upon it. To estimate the actual force occurring in the wires, we consulted with a medical journal, which measured the strength of muscles responsible for the inversion of the heel. We determined that the forces occurring under steady walking conditions were much lower than the absolute maximum imposed by the muscles. However, we advise that the actual forces occurring in the wires of our device when it is in operation need to be measured. Under these loads, we do not expect there to be significant fatigue occurring in the wires.

However, there should be further physical testing on the fatigue limits of our device, as well as tests for potential high disturbance forces that can occur during the life time of the device.

Fit, Finish and Weight

The size, fit, and comfort of the device was tested by placing the orthotic in an actual shoe. The test subject then reported a snug fit, since the inside of the orthotic was previously custom-contoured to the foot. The shoe size had to be 2 sizes greater that the normal shoe worn by the user, in order to accommodate the device. This is 1 size greater than what we anticipated, but still acceptable in the context of our design. The specifications on the comfort of the device such as surface roughness and exterior protrusions were experimentally verified by wearing the device, and noting the absence of any sharp points. Due to the low density of the plastic that was used in our design, the weight of our device was not significantly noticeable to the user, when the device was inserted into an actual shoe.

DISCUSSION

Advantages of the design

The design exhibits many good qualities. The dynamic assist in heel inversion helps relieve stress on the injured tibial tendon at the proper point in the gate cycle, which was the main objective of the project. Our design also exhibits good customizability and adjustability due to the custom molded nature of the device and the multiple attachment points in the heel. The design is also simple, using just a cable system powered by the patient's own walking motion. It does not add excess weight or bulk to the patient's foot either. It is comfortable, due to the custom molding and foam padding. Lastly, the design is constructed from materials that are easy to work with.

Drawbacks of the design

The prototype had a few problems. There was some slack in the toe joint and the inversion did not begin to actuate until the toe had already bent a significant amount. We also found that there was not enough heel inversion. Our prototype only gave 5.5 degrees of inversion instead of the desired 5 to 25. This is also likely caused by the slack in the toe joint. The slack should be eliminated if the toe joint were made straighter or if a rigid hinge were implemented. If the inversion were actuated at the proper point, we should see larger inversions as expected. However, if there is still not enough inversion, the design could be modified to loop the cable around one more time, increasing displacement by 50%.

A final drawback of our design was that the prototype will not last for 5 years. The cable running through the device began to get frayed at one point after we accidentally cut through a little bit of the Teflon coating. This fraying continued to get worse and will eventually cause the prototype to fail prematurely. However, this problem can be avoided if more care is taken in manufacturing.

Modifications to design process

Things to do differently in the future might include a more thorough engineering analysis of the project. While we did a decent analysis and prediction of the inversion, we obviously did not account for various imperfections, since our resulting heel inversion was less than half of what we predicted it to be. Therefore, it would have been better to apply a more rigorous analysis process.

RECOMMENDATIONS

There are a few recommendations that we believe need to be implemented in order to verify if our device is truly successful at achieving its purpose. They include changes to the manufacturing process, further testing, and an addition to the initial design.

The manufacturing process needs to be carried out with more precision (by a trained technician) as well as partially changed. First, we recommend that the device be created without the use of epoxy. The metal wire should be encapsulated by two layers of TPE, which will bond to each other, thus securing it to the orthotic. This was demonstrated in the initial test samples (as described in the *Test Results* section). However, the difficulty of this approach lies in the forming of the hinge for the toe plate. This may have to be done by cutting the plastic around the wire very carefully, which would result in increased manufacturing time. Alternatively, a jig could be used to carve out the necessary impression. With this design, we also recommend there be a "living hinge" (similar to the SLFP joint) that would ensure that the top of the toe joint is connected more securely to the mid-plate. It would eliminate the play and slack currently occurring in the wire, which prevents the orthotic from gaining full inversion. The alteration will also improve the response time of our device to the actuating signal which occurs in the wires as soon as the toes are bent.

More rigorous tests need to be performed to determine whether the device is successful at fulfilling its intended purpose of inverting the heel of the foot. Specifically, the amount of inversion could be imaged with the aid of X-rays, which would show the internal bone structure of the foot, as it undergoes the inversion motion. We would also need to test the device on a subject whose foot has an injured Posterior Tibial Tendon, thus determining the effects of our device in correcting this condition.

Lastly, we believe that we need to add an adjustable arch mechanism. In order to promote the formation of the arch throughout the walking cycle, we propose to add an adjustable arch height platform, whose size can be regulated by turning a series of set screws. This will enable the orthotist to vary the amount of static arch assist that the device will provide, as the foot heals. Details of this arch adjustment addition are described in the *Final Design Description* section.

CONCLUSIONS

Between Design Review One and Two, fourteen concepts were developed, all were ranked, and one was chosen as the initial Alpha Design. This concept was then further developed by generating a CAD model, as well as some very basic, preliminary calculations to ensure its feasibility. .After Design Review Two, we completed in-depth engineering analysis of the initial design concept which allowed us to determine the materials, dimensions, shape, and force details of our design. Our CAD models were updated with slight changes to make our calculations feasible. Finally, since Design Review Three, we successfully completed the fabrication of the working prototype, meeting all engineering requirements but two. In the future weeks, we hope to work with our sponsor to further refine the manufacturing methods and to implement our current recommendations. This will allow us to gain a final product that meets all of our engineering specifications. We foresee no problems with putting our final product design into the market sometime in the near future.

ACKNOWLEDGEMENTS

We would like to thank our sponsors, Mr. Mark Taylor, and Mr. Charl Greene, and technical advisers, Jake and Megan, from the University of Michigan Orthotics and Prosthetics Lab. From the University of Michigan, we thank our project adviser, Dr. Muammer Koc, Professors Shih, Saitou and Skerlos, as well as Mike Cherry, Christine Vehar, Dr. James Ashton Miller, and Tom Bress, for their invaluable input and contributions to helping generate ideas for the execution of our project.

INFORMATION SOURCES AND REFERENCES

We gathered information on our project from text books, on-line sources, and consultations with our project advisers and colleagues. Our main information sources include the University of Michigan Orthotics and Prosthetics Lab and the departments of Mechanical and Biomedical Engineering. Detailed reference for all of our sources are listed below:

Textbooks.

1 Sarrafian, Shahan K.,
Anatomy of the Foot and Ankle
Descriptive, Topographic, Functional
Second Edition
J. B. Lippincott Company, Copyright 1993

2 Robert M H McMinn, Ralph T Hutchings, Bari M Logan
Color Atlas of Foot & Ankle Anatomy, Second Edition
Mosby-Wolfe, Copyright 1996

3 *"When the feet hit the ground everything changes"*
A three-day practical seminar on the biomechanics of human gait
Presented by Practical Programs for applied Biomechanics
The American Physical Rehabilitation Network, Copyright 1984

Online sources.

4 Posterior Tibial Tendon Problems
http://www.eorthopod.com/eorthopodV2/index.php/fuseaction/topics.detail/ID/1e69153b4390c6eff3095daeefe6031a/TopicID/4e3db8ef62a567eae3b89f9bd29a745f/area/20

5 Tarsal Bones
http://osprey.sechrest.com/performancewest/reflib/foot/anatomy/tarsals.jpg

6 Digitized Foot Model

http://www.vard.org/jour/02/39/3/ledoux.htm

7 Posterior Tibial Tendonitis
http://orthopedics.about.com/??/footproblems/?/posteriortibial.htm

8 The Richie Soccer Brace
http://www.klm.lab.com/klm

9 Orthotic & Prosthetic Professional Care
http://www.opt-care.com/?i=y&t=PedLower&c=1&n=27

10 Orthotic Options
http://www.orthopedictecbreview.com/issues/maranr03/pg34.htm

11 American Journal of Roentgenology
http://www.aironline.org/cgi/content/full/175/3/627/FIG1

12 UCBL
(University of California Biomechanics Laboratory)
http://www.delatorre.biz/deviceDetail.asp?Section=Devices&DeviceID=220

13 Mayo Clinic
www.mayoclinic.com

14 US Patent Office → checked to verify no previous device existing
www.uspo.com

15 University of Michigan Biomechanics Laboratory
http://me.engin.umich.edu/brl/

16 Video: Anatomy of the foot
http://www.med.umich.edu/lrc/coursepages/M1/anatomy/html/musculoskeletal_system/leg_vid.html

17 The Pseudo-Rigid-Body Model
Based on “Compliant Mechanisms”
By Larry L. Howell (BYU)
Presented by Michael S. Cherry
http://www.engin.umich.edu/labs/csdl/ppslides/PseudoRigidBodyModel_files/frame.html

18 Material Property Data
http://matweb.com

19 McMaster-Carr
http://www.mcmaster.com

Advisors.

University of Michigan Orthotics and Prosthetics Center
- Mr. Charl Greene, University of Michigan Orthotics and Prosthetics Center
- Mr. Mark Taylor, Project manager

Mechanical Engineering Department, design process advisors
- Professor Steven Skerlos
- Professor Kazuhiro Saitou
- Professor Albert Shih
- Dr. Muammer Koc, project leader

Biomedical Engineering Department, Biomechanics Research Laboratory
- Dr. James Ashton-Miller

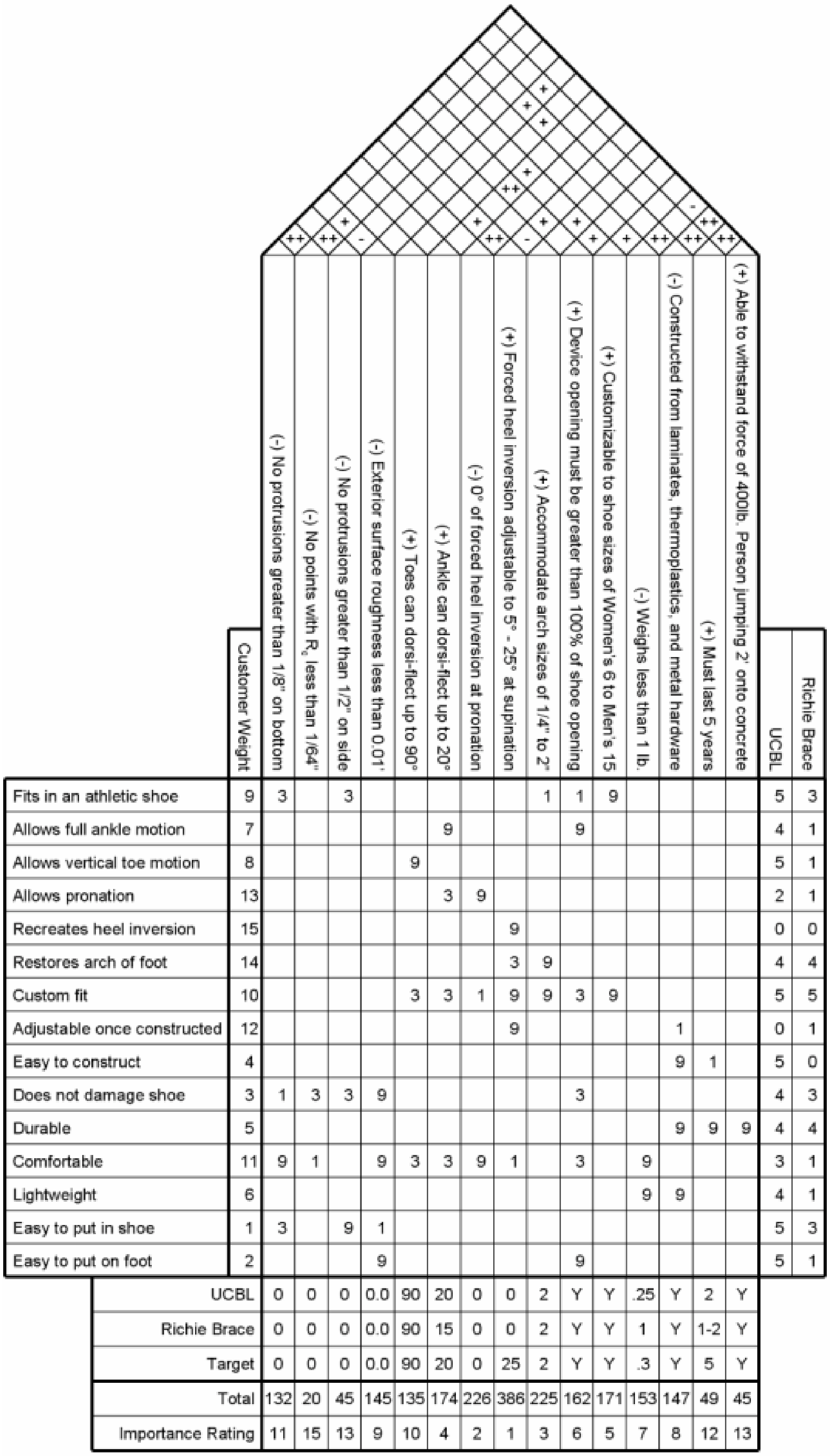
Department of Kinesiology, Pennsylvania State University
- Dr. Neil A. Sharkey. Professor of Kinesiology, Director of Research. Ph.D.,

Compliant Mechanisms Laboratory
- Michael Cherry, Graduate Student
- Christine Vehar, Graduate Student

University of Michigan, Testing Laboratory
- Tom Bress

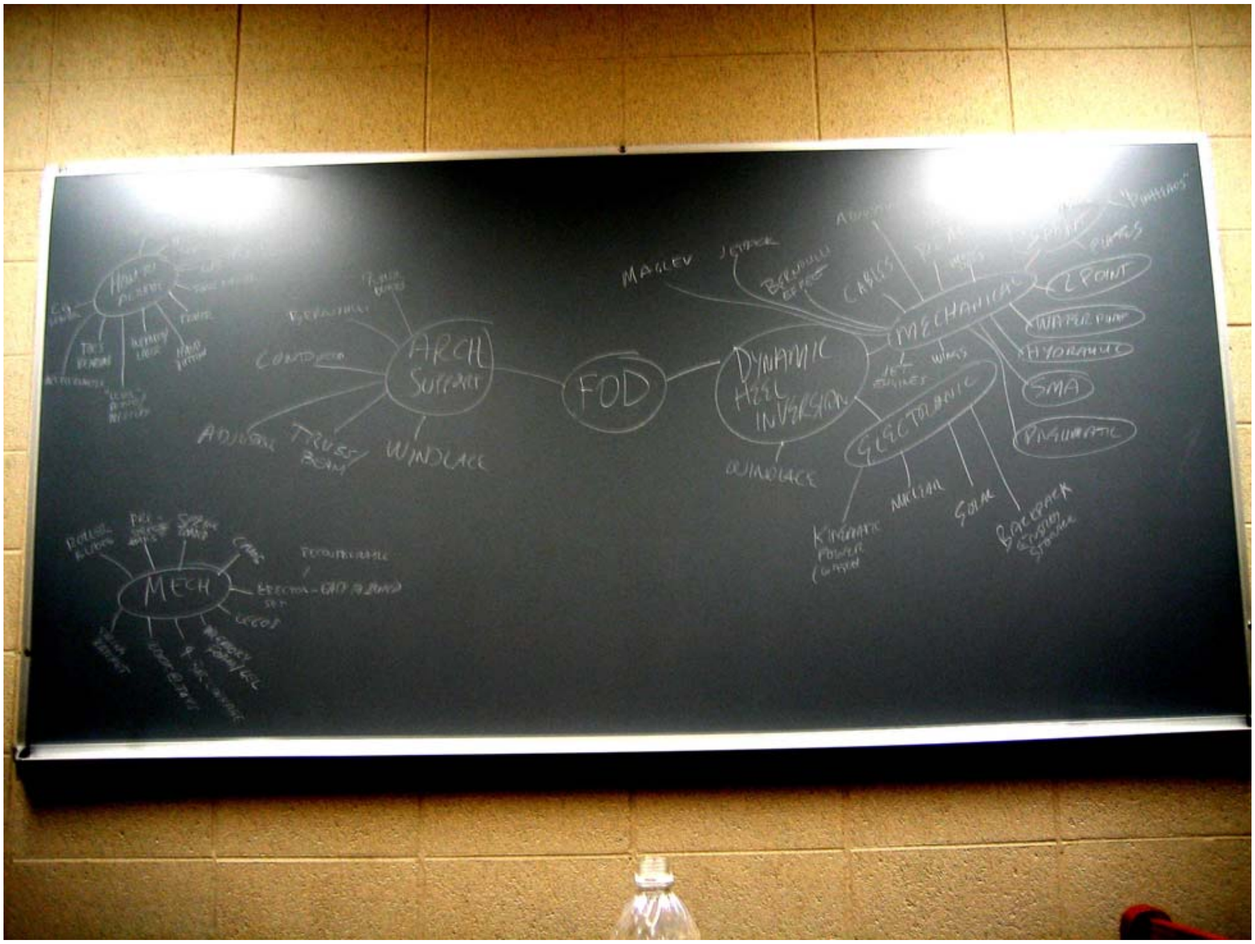
APPENDICES

1.A QFD Diagram



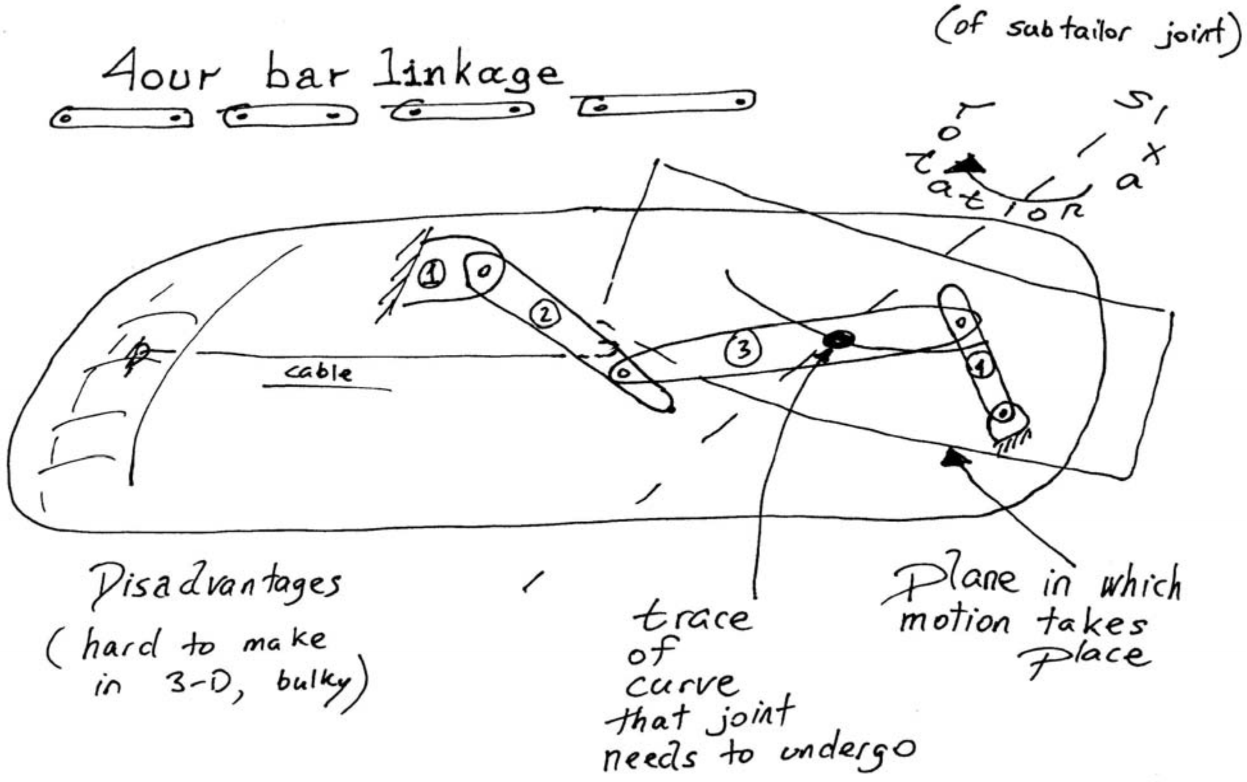
	Customer Weight	(-) No protrusions greater than 1/8" on bottom	(-) No points with R_c less than 1/64"	(-) No protrusions greater than 1/2" on side	(-) Exterior surface roughness less than 0.01'	(+) Toes can dorsi-flect up to 90°	(+) Ankle can dorsi-flect up to 20°	(-) 0° of forced heel inversion at pronation	(+) Forced heel inversion adjustable to 5° - 25° at supination	(+) Accommodate arch sizes of 1/4" to 2"	(+) Device opening must be greater than 100% of shoe opening	(+) Customizable to shoe sizes of Women's 6 to Men's 15	(-) Weighs less than 1 lb.	(-) Constructed from laminates, thermoplastics, and metal hardware	(+) Must last 5 years	(+) Able to withstand force of 400lb. Person jumping 2' onto concrete	UCBL	Richie Brace
Fits in an athletic shoe	9	3		3						1	1	9					5	3
Allows full ankle motion	7						9				9						4	1
Allows vertical toe motion	8					9											5	1
Allows pronation	13						3	9									2	1
Recreates heel inversion	15								9								0	0
Restores arch of foot	14								3	9							4	4
Custom fit	10					3	3	1	9	9	3	9					5	5
Adjustable once constructed	12								9					1			0	1
Easy to construct	4													9	1		5	0
Does not damage shoe	3	1	3	3	9						3						4	3
Durable	5													9	9	9	4	4
Comfortable	11	9	1		9	3	3	9	1		3		9				3	1
Lightweight	6												9	9			4	1
Easy to put in shoe	1	3		9	1												5	3
Easy to put on foot	2				9						9						5	1
UCBL		0	0	0	0.0	90	20	0	0	2	Y	Y	.25	Y	2	Y		
Richie Brace		0	0	0	0.0	90	15	0	0	2	Y	Y	1	Y	1-2	Y		
Target		0	0	0	0.0	90	20	0	25	2	Y	Y	.3	Y	5	Y		
Total		132	20	45	145	135	174	226	386	225	162	171	153	147	49	45		
Importance Rating		11	15	13	9	10	4	2	1	3	6	5	7	8	12	13		

1.B Brainstorming

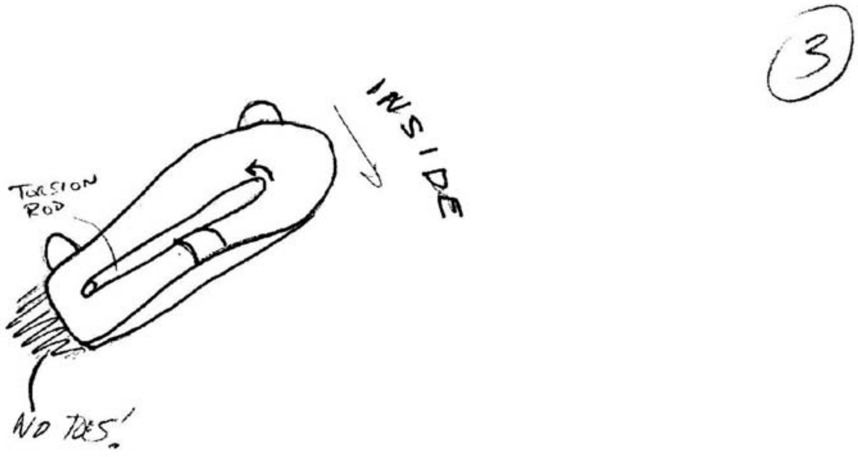


1.C Concepts

1.C.1 Four bar linkage:

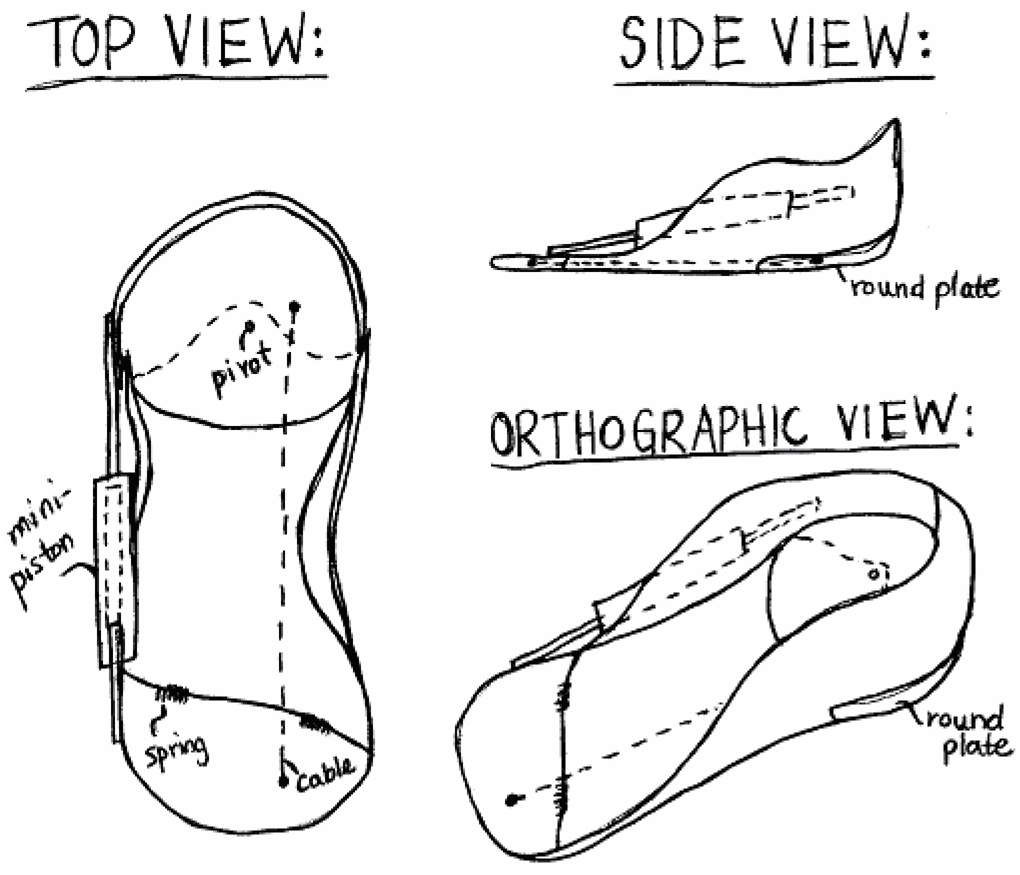


1.C.2 Longitudinal torsional rod:

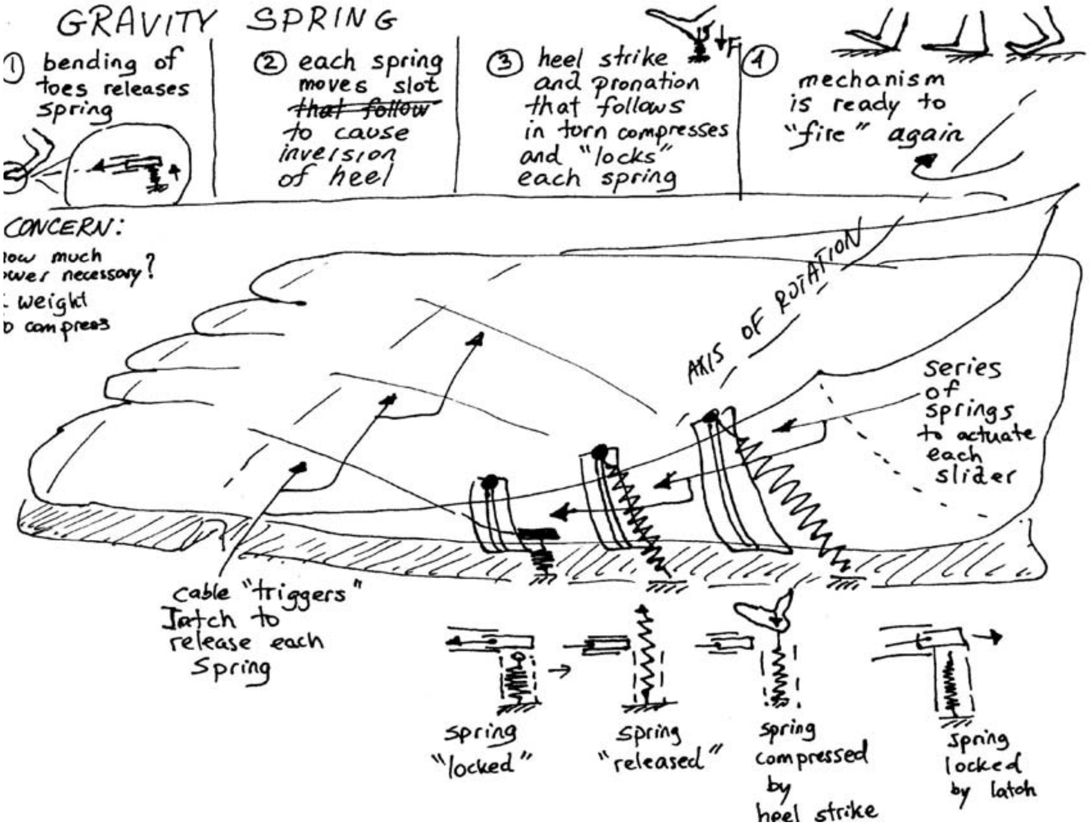


1.C.3 Horizontal torsional rod with cables:

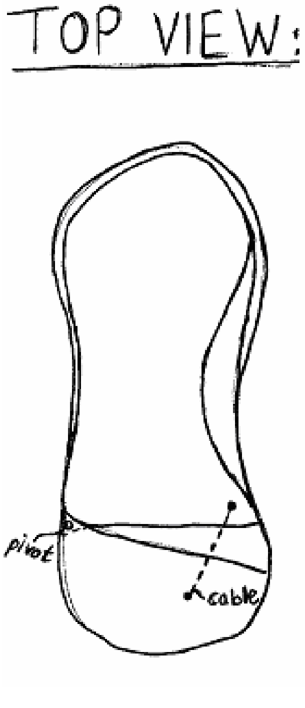
1.C.4 Cable and Piston:

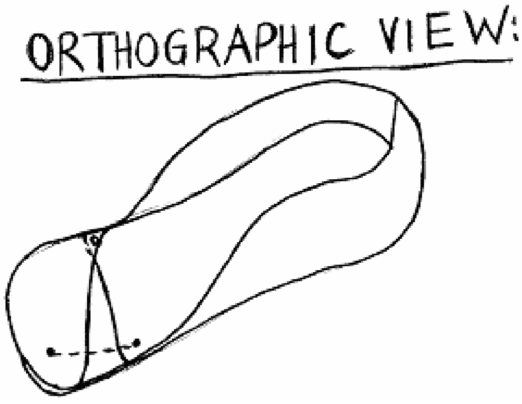


1.C.5 Multi-spring:

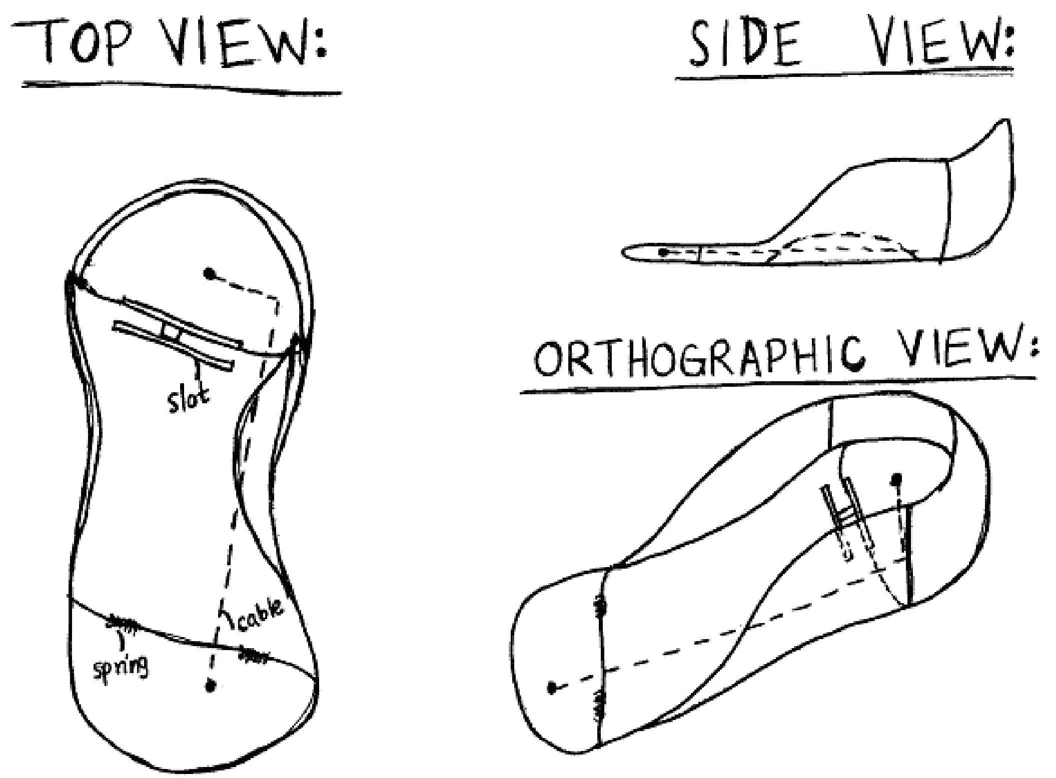


1.C.6 Single toe joint:

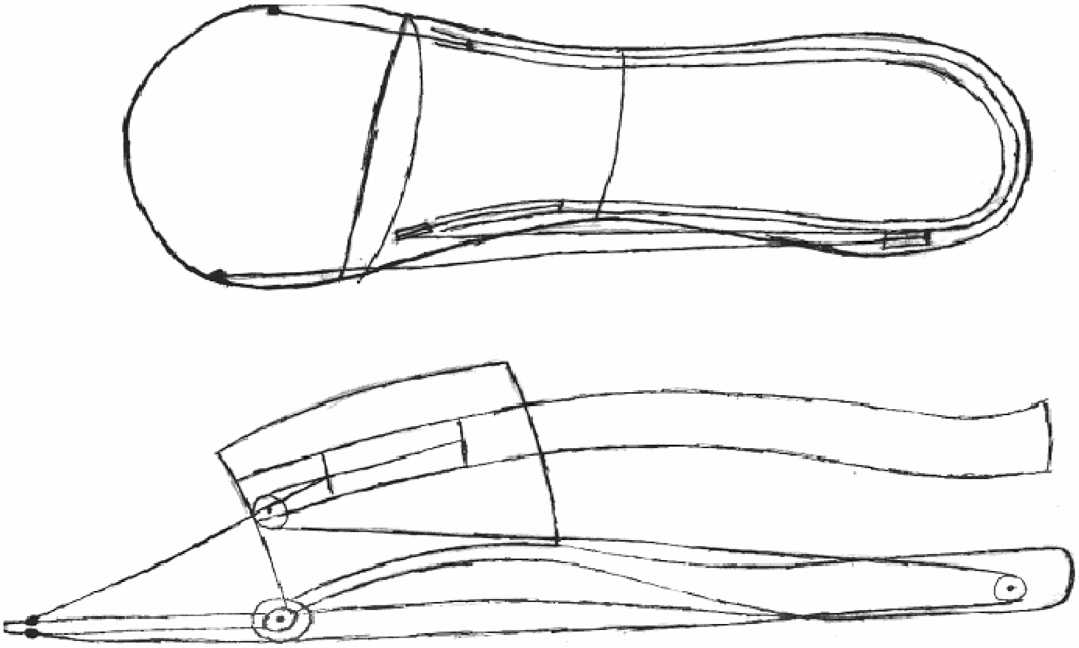




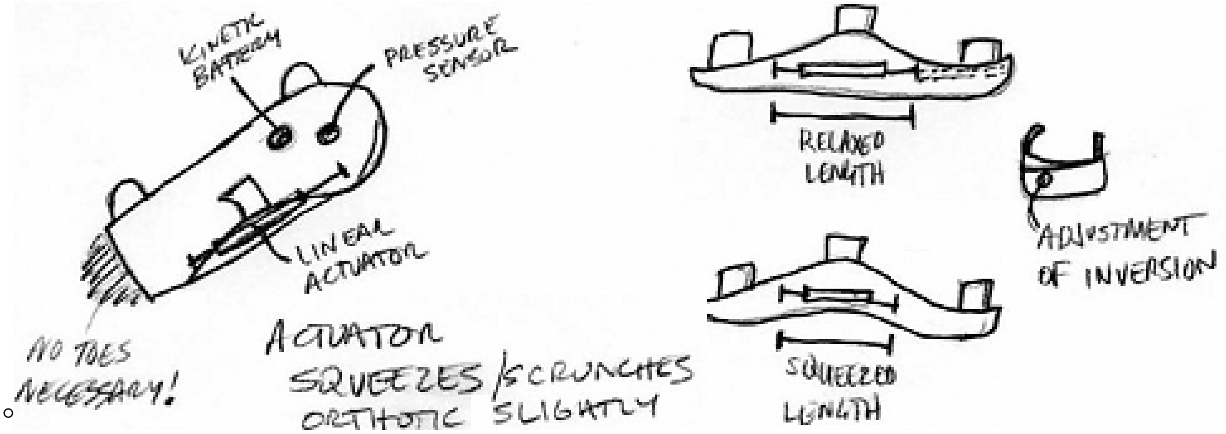
1.C.7 Slotted heel plate:



1.C.8 Cable and heel hoop:



1.C.9 Electrical linear actuator:



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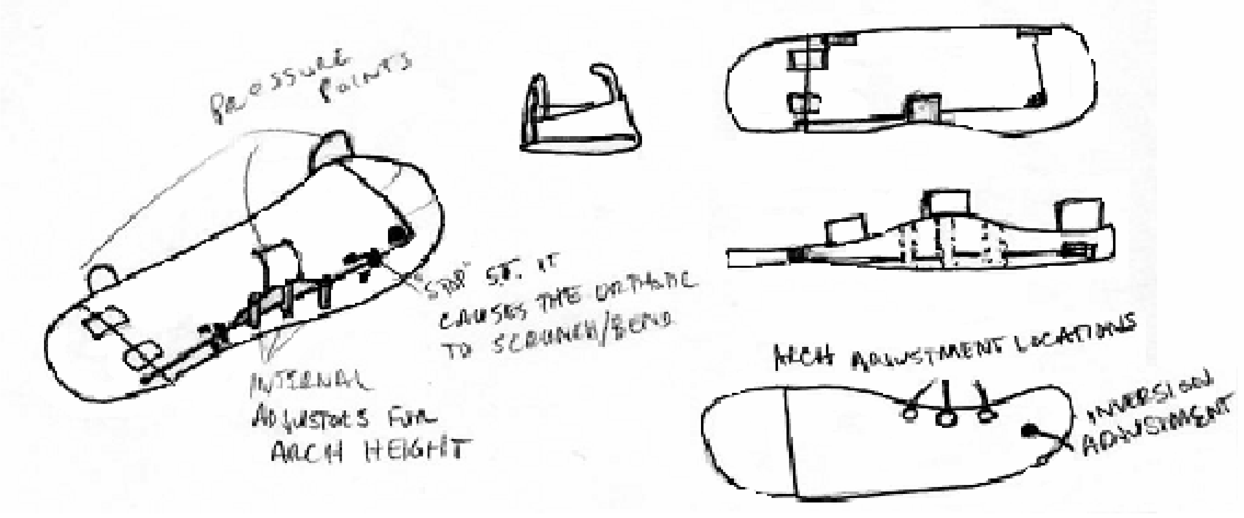
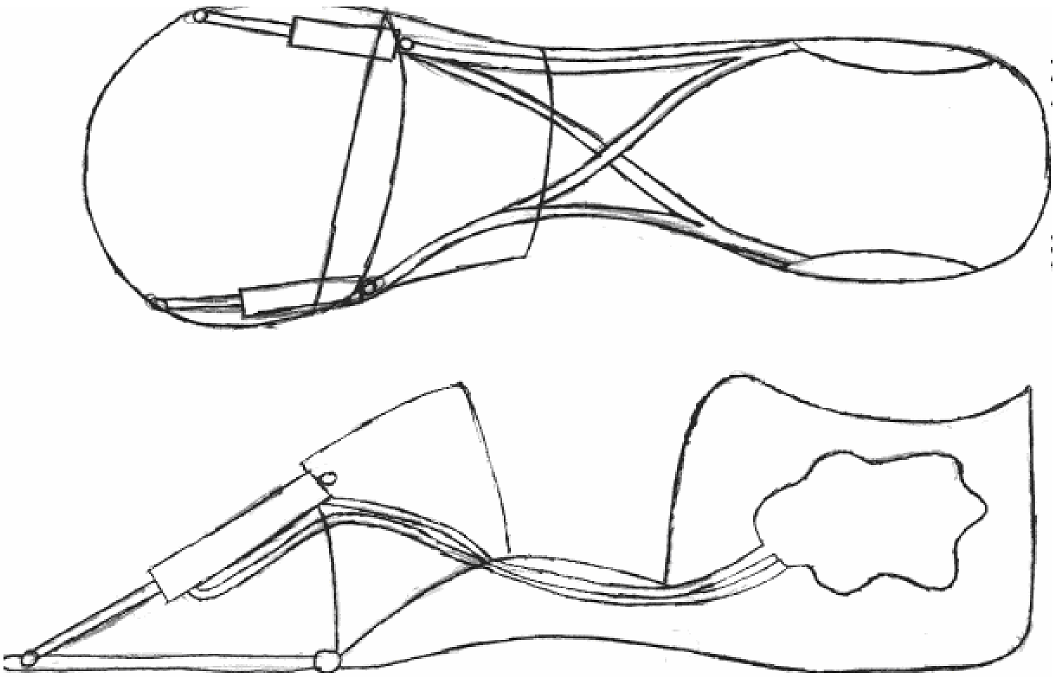
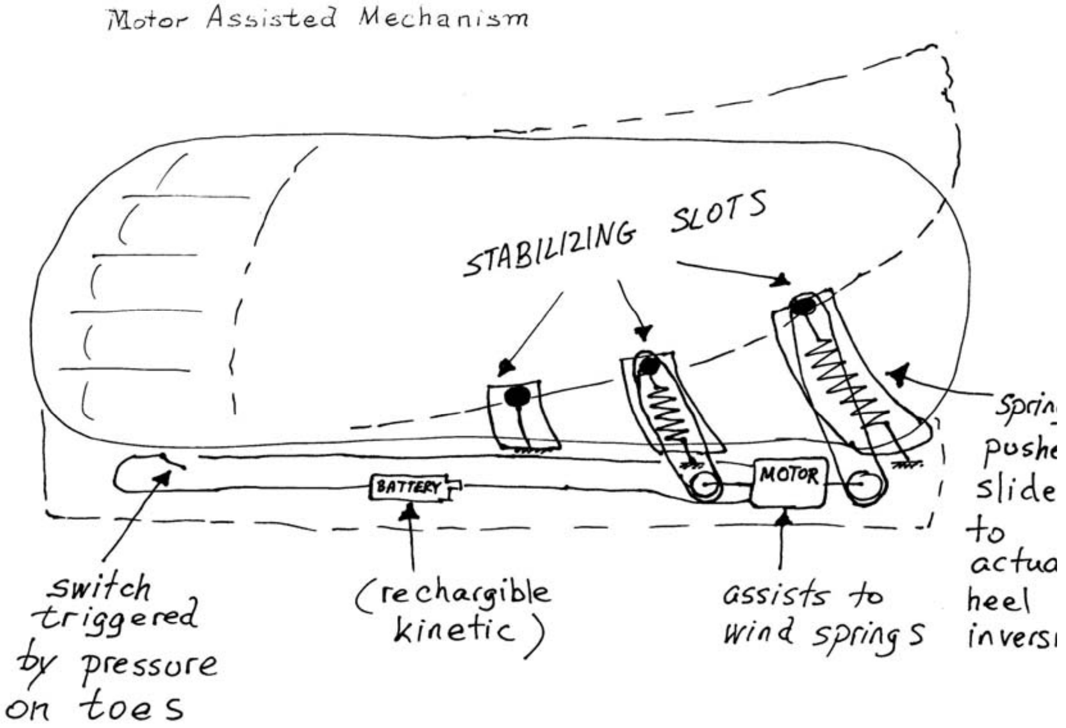
1.C.10 Arch adjustment:



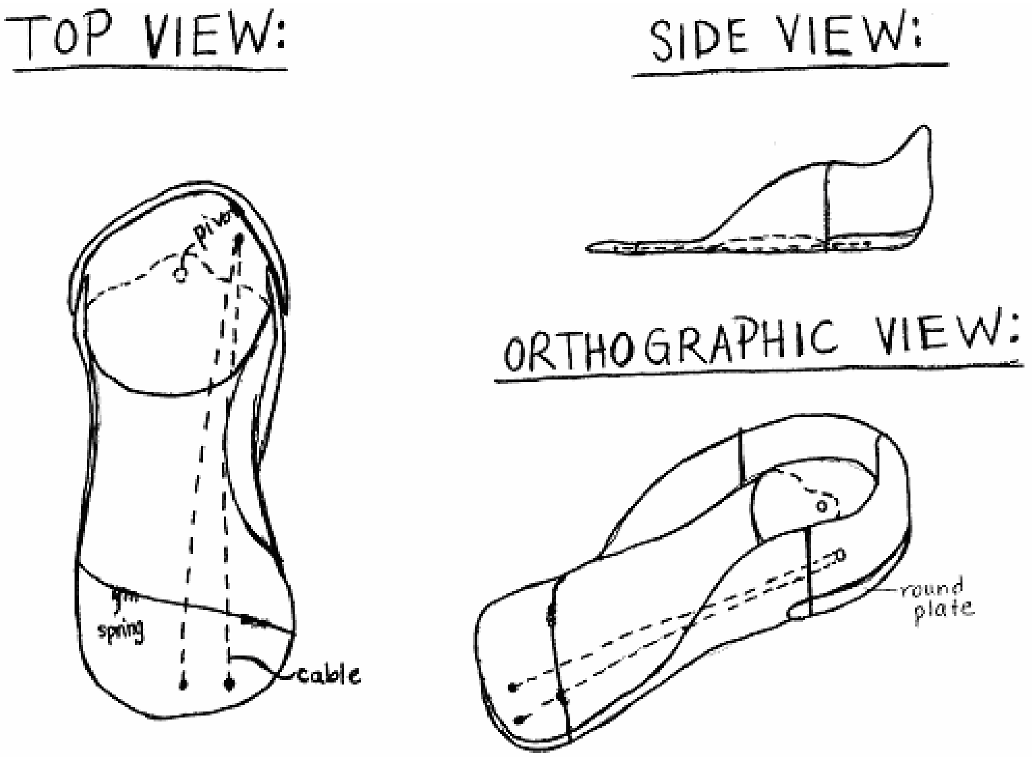
1.C.11 Pneumatic:



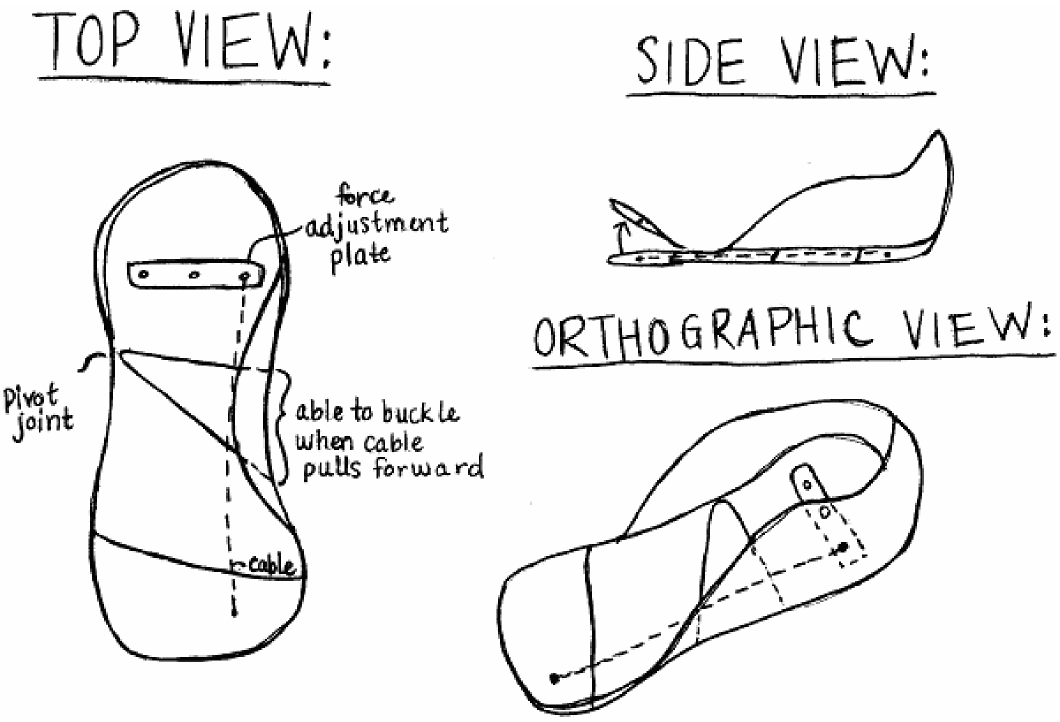
1.C.12 Electric motor:



1.C.13 Heel pivot:



1.C.14 Complaint joint:



1.D Concept Selection Matrix

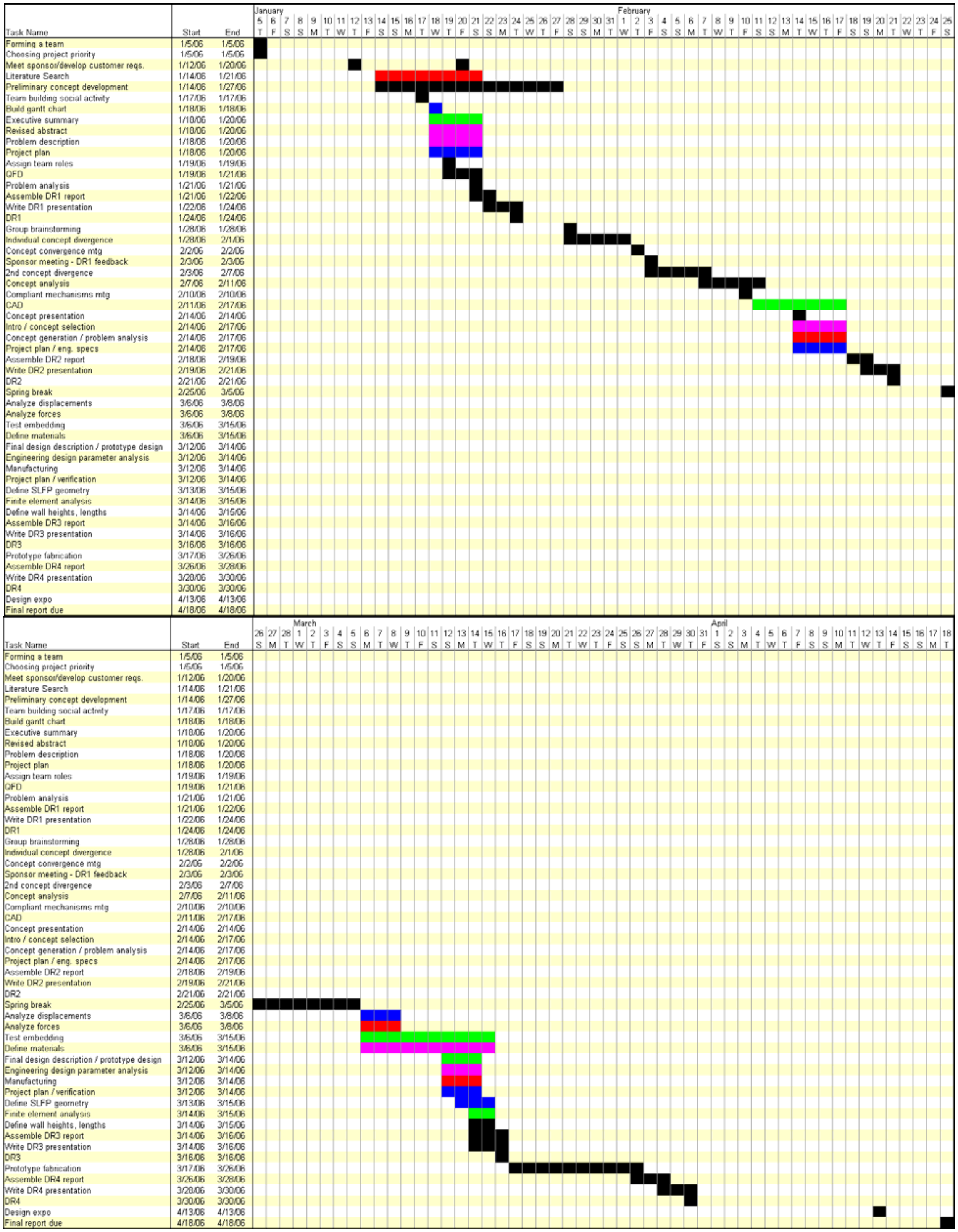
Engineering Specifications (and Importance)	Arch Adjustment	Pneumatic	Motor Mechanism	Heel Pivot	Compliant Joint
Protrusion < 1/8" on bottom (132)	2	2	1	2	2
Points with radius < 1/64" (20)	1	2	2	2	2
Protrusions < 1/2" on side (45)	2	0	1	2	2
Exterior surface roughness < 0.01' (145)	2	2	2	2	2
Toes can dorsi-flect up to 90° (135)	2	2	2	2	2
Ankle can dorsi-flect up to 20° (174)	2	2	2	2	2
0° forced heel inversion at pronation (226)	2	2	2	1	1
Forced heel inversion adjustable 5° to 25° (386)	1	2	2	2	2
Accommodates arch sizes of 1/4" to 2" (225)	2	2	2	1	2
Device opening > 100% of original shoe opening (162)	2	2	2	2	2
Customizable to shoe sizes of women's 6 to men's 15 (171)	2	2	2	1	2
Weighs < 1 lb (153)	1	1	2	2	2
Constructed from laminates, thermoplastics, and metal hardware (147)	2	0	0	2	2
Must last five years (49)	1	1	0	2	2
Able to withstand force of 400 lb. person jumping 2' onto concrete (45)	1	1	1	1	2
TOTAL	3777	3799	3816	3988	4204

Engineering Specifications (and Importance)	Slotted Heel Plate	Cable and Piston	Single Toe Joint	Multi Spring	Four Bar Linkage
Protrusion < 1/8" on bottom (132)	1	1	2	1	0
Points with radius < 1/64" (20)	2	2	2	2	2
Protrusions < 1/2" on side (45)	2	0	2	1	0
Exterior surface roughness < 0.01' (145)	2	2	2	2	2
Toes can dorsi-flect up to 90° (135)	2	2	2	2	1
Ankle can dorsi-flect up to 20° (174)	2	2	2	2	2
0° forced heel inversion at pronation (226)	1	1	1	2	1
Forced heel inversion adjustable 5° to 25° (386)	2	2	1	0	1
Accommodates arch sizes of 1/4" to 2" (225)	1	1	1	2	1
Device opening > 100% of original shoe opening (162)	2	2	2	2	2
Customizable to shoe sizes of women's 6 to men's 15 (171)	1	1	1	2	2
Weighs < 1 lb (153)	2	1	2	2	1
Constructed from laminates, thermoplastics, and metal hardware (147)	2	1	2	2	2
Must last five years (49)	1	1	2	1	2
Able to withstand force of 400 lb. person jumping 2' onto concrete (45)	1	1	2	1	2
TOTAL	3450	3192	3422	3387	2951

Engineering Specifications (and Importance)	Electrical Linear Actuator	Longitudinal Torsional Rod	Horizontal Torsional Rod with Cables	Heel Hoop and Cables
Protrusion < 1/8" on bottom (132)	0	1	2	0
Points with radius < 1/64" (20)	1	2	2	1
Protrusions < 1/2" on side (45)	2	2	2	1
Exterior surface roughness < 0.01' (145)	2	2	2	2
Toes can dorsi-flect up to 90° (135)	2	2	2	2
Ankle can dorsi-flect up to 20° (174)	2	2	2	2
0° forced heel inversion at pronation (226)	2	1	1	2
Forced heel inversion adjustable 5° to 25° (386)	2	0	0	1
Accommodates arch sizes of 1/4" to 2" (225)	2	2	2	2
Device opening > 100% of original shoe opening (162)	2	2	2	2
Customizable to shoe sizes of women's 6 to men's 15 (171)	2	2	2	2
Weighs < 1 lb (153)	1	1	1	1
Constructed from laminates, thermoplastics, and metal hardware (147)	0	2	2	2
Must last five years (49)	0	1	1	1
Able to withstand force of 400 lb. person jumping 2' onto concrete (45)	1	1	1	1
TOTAL	3556	3053	3185	3468

1.E Gantt Chart

🟪 Michelle 🟥 Dmitry 🟩 Bob 🟦 Dan ⬛ All



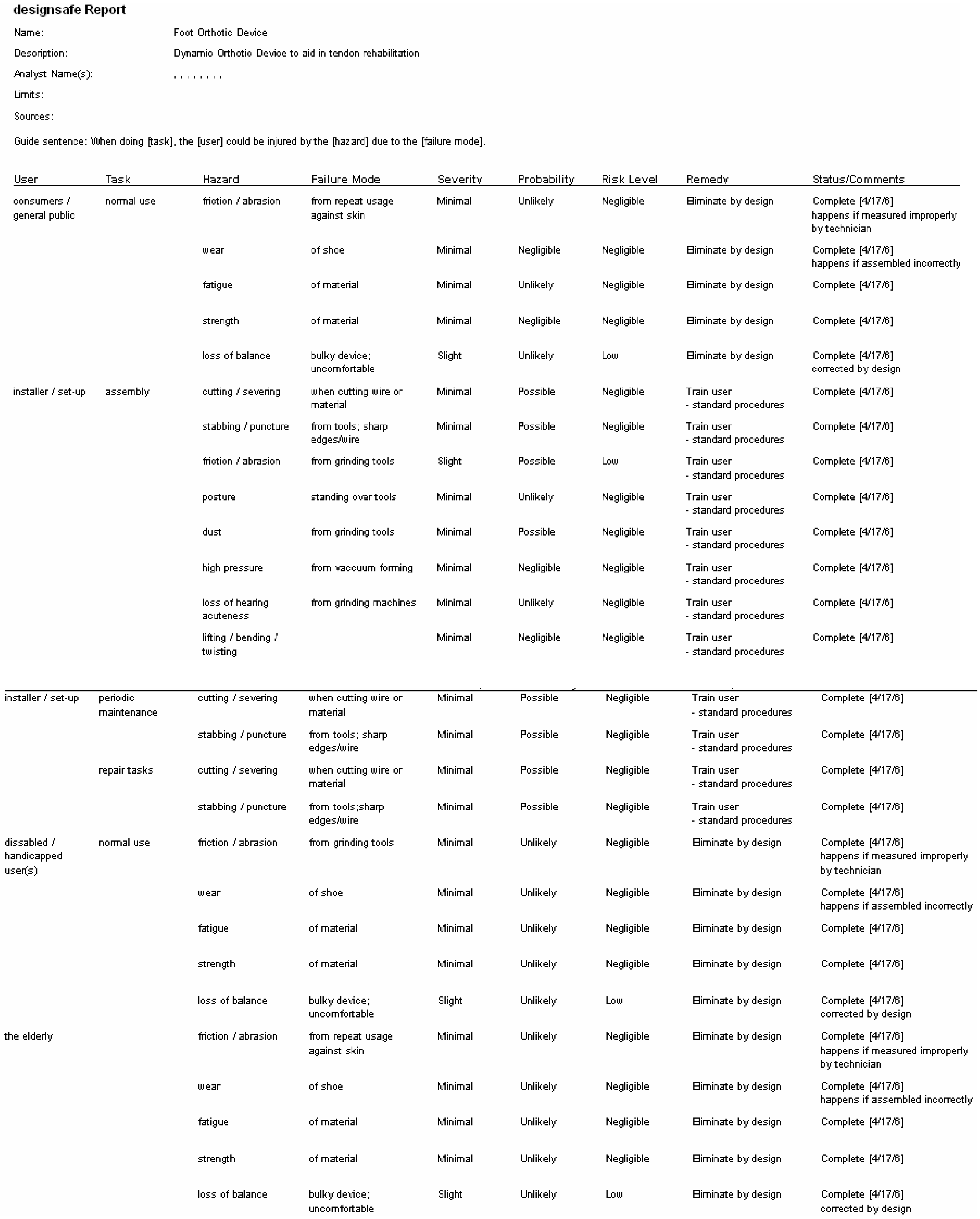
Task Name	Start	End
Forming a team	1/5/06	1/5/06
Choosing project priority	1/5/06	1/5/06
Meet sponsor/develop customer reqs.	1/12/06	1/20/06
Literature Search	1/14/06	1/21/06
Preliminary concept development	1/14/06	1/27/06
Team building social activity	1/17/06	1/17/06
Build gantt chart	1/18/06	1/18/06
Executive summary	1/10/06	1/20/06
Revised abstract	1/10/06	1/20/06
Problem description	1/18/06	1/20/06
Project plan	1/18/06	1/20/06
Assign team roles	1/19/06	1/19/06
QFD	1/19/06	1/21/06
Problem analysis	1/21/06	1/21/06
Assemble DR1 report	1/21/06	1/22/06
Write DR1 presentation	1/22/06	1/24/06
DR1	1/24/06	1/24/06
Group brainstorming	1/28/06	1/28/06
Individual concept divergence	1/28/06	2/1/06
Concept convergence mtg	2/2/06	2/2/06
Sponsor meeting - DR1 feedback	2/3/06	2/3/06
2nd concept divergence	2/3/06	2/7/06
Concept analysis	2/7/06	2/11/06
Compliant mechanisms mtg	2/10/06	2/10/06
CAD	2/11/06	2/17/06
Concept presentation	2/14/06	2/14/06
Intro / concept selection	2/14/06	2/17/06
Concept generation / problem analysis	2/14/06	2/17/06
Project plan / eng. specs	2/14/06	2/17/06
Assemble DR2 report	2/18/06	2/19/06
Write DR2 presentation	2/19/06	2/21/06
DR2	2/21/06	2/21/06
Spring break	2/25/06	3/5/06
Analyze displacements	3/6/06	3/8/06
Analyze forces	3/6/06	3/8/06
Test embedding	3/6/06	3/15/06
Define materials	3/6/06	3/15/06
Final design description / prototype design	3/12/06	3/14/06
Engineering design parameter analysis	3/12/06	3/14/06
Manufacturing	3/12/06	3/14/06
Project plan / verification	3/12/06	3/14/06
Define SLFP geometry	3/13/06	3/15/06
Finite element analysis	3/14/06	3/15/06
Define wall heights, lengths	3/14/06	3/15/06
Assemble DR3 report	3/14/06	3/16/06
Write DR3 presentation	3/14/06	3/16/06
DR3	3/16/06	3/16/06
Prototype fabrication	3/17/06	3/26/06
Assemble DR4 report	3/26/06	3/28/06
Write DR4 presentation	3/28/06	3/30/06
DR4	3/30/06	3/30/06
Design expo	4/13/06	4/13/06
Final report due	4/18/06	4/18/06

Task Name	Start	End
Forming a team	1/5/06	1/5/06
Choosing project priority	1/5/06	1/5/06
Meet sponsor/develop customer reqs.	1/12/06	1/20/06
Literature Search	1/14/06	1/21/06
Preliminary concept development	1/14/06	1/27/06
Team building social activity	1/17/06	1/17/06
Build gantt chart	1/18/06	1/18/06
Executive summary	1/10/06	1/20/06
Revised abstract	1/10/06	1/20/06
Problem description	1/18/06	1/20/06
Project plan	1/18/06	1/20/06
Assign team roles	1/19/06	1/19/06
QFD	1/19/06	1/21/06
Problem analysis	1/21/06	1/21/06
Assemble DR1 report	1/21/06	1/22/06
Write DR1 presentation	1/22/06	1/24/06
DR1	1/24/06	1/24/06
Group brainstorming	1/28/06	1/28/06
Individual concept divergence	1/28/06	2/1/06
Concept convergence mtg	2/2/06	2/2/06
Sponsor meeting - DR1 feedback	2/3/06	2/3/06
2nd concept divergence	2/3/06	2/7/06
Concept analysis	2/7/06	2/11/06
Compliant mechanisms mtg	2/10/06	2/10/06
CAD	2/11/06	2/17/06
Concept presentation	2/14/06	2/14/06
Intro / concept selection	2/14/06	2/17/06
Concept generation / problem analysis	2/14/06	2/17/06
Project plan / eng. specs	2/14/06	2/17/06
Assemble DR2 report	2/18/06	2/19/06
Write DR2 presentation	2/19/06	2/21/06
DR2	2/21/06	2/21/06
Spring break	2/25/06	3/5/06
Analyze displacements	3/6/06	3/8/06
Analyze forces	3/6/06	3/8/06
Test embedding	3/6/06	3/15/06
Define materials	3/6/06	3/15/06
Final design description / prototype design	3/12/06	3/14/06
Engineering design parameter analysis	3/12/06	3/14/06
Manufacturing	3/12/06	3/14/06
Project plan / verification	3/12/06	3/14/06
Define SLFP geometry	3/13/06	3/15/06
Finite element analysis	3/14/06	3/15/06
Define wall heights, lengths	3/14/06	3/15/06
Assemble DR3 report	3/14/06	3/16/06
Write DR3 presentation	3/14/06	3/16/06
DR3	3/16/06	3/16/06
Prototype fabrication	3/17/06	3/26/06
Assemble DR4 report	3/26/06	3/28/06
Write DR4 presentation	3/28/06	3/30/06
DR4	3/30/06	3/30/06
Design expo	4/13/06	4/13/06
Final report due	4/18/06	4/18/06

1.F Material Selection Sheet [19]

Material	**σ_y [MPa]**
Thermoplastic Polyurethane, Elastomer, Glass Filled	40
Evoprene® 029 Thermoplastic Elastomer, Unreinforced	11.1
Polyester Thermoplastic Elastomer (min)	2.1
Polyester Thermoplastic Elastomer (max)	30.3
Spartech Royalite S370 TPO Spectrum® Polyolefin Sheet	16.5
Spartech Royalite S630 MDPE Spectrum® Polyolefin Sheet	20.5
Spartech Royalite R561M Low Smoke Resin	39
Epoxy, Cast, Unreinforced	60
Epoxy, Cast, Silica Filled	70
Epoxy, Molded, Glass Fiber Filler	100
Epoxy, Cast, Flexible Grade	40
BP Amoco Thornel® Carbon Fiber P-55 Carbon Fiber/Epoxy	510
Fluorocarbon ETFE, with Glass or Carbon Fiber Filler	55
Nylon 66, 10% Carbon Fiber Filled	83
Polysulfone, 40% Carbon Fiber Reinforced	150
CYRO Acrylite® S-10 Acrylic Molding Compound	78

1.G DesignSafe Report



designsafe Report

Name:	Foot Orthotic Device
Description:	Dynamic Orthotic Device to aid in tendon rehabilitation
Analyst Name(s):	. . . .
Limits:	
Sources:	

Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

User	Task	Hazard	Failure Mode	Severity	Probability	Risk Level	Remedy	Status/Comments
consumers / general public	normal use	friction / abrasion	from repeat usage against skin	Minimal	Unlikely	Negligible	Eliminate by design	Complete [4/17/6] happens if measured improperly by technician
		wear	of shoe	Minimal	Negligible	Negligible	Eliminate by design	Complete [4/17/6] happens if assembled incorrectly
		fatigue	of material	Minimal	Unlikely	Negligible	Eliminate by design	Complete [4/17/6]
		strength	of material	Minimal	Negligible	Negligible	Eliminate by design	Complete [4/17/6]
		loss of balance	bulky device; uncomfortable	Slight	Unlikely	Low	Eliminate by design	Complete [4/17/6] corrected by design
installer / set-up	assembly	cutting / severing	when cutting wire or material	Minimal	Possible	Negligible	Train user - standard procedures	Complete [4/17/6]
		stabbing / puncture	from tools; sharp edges/wire	Minimal	Possible	Negligible	Train user - standard procedures	Complete [4/17/6]
		friction / abrasion	from grinding tools	Slight	Possible	Low	Train user - standard procedures	Complete [4/17/6]
		posture	standing over tools	Minimal	Unlikely	Negligible	Train user - standard procedures	Complete [4/17/6]
		dust	from grinding tools	Minimal	Possible	Negligible	Train user - standard procedures	Complete [4/17/6]
		high pressure	from vaccuum forming	Minimal	Negligible	Negligible	Train user - standard procedures	Complete [4/17/6]
		loss of hearing acuteness	from grinding machines	Minimal	Unlikely	Negligible	Train user - standard procedures	Complete [4/17/6]
		lifting / bending / twisting		Minimal	Negligible	Negligible	Train user - standard procedures	Complete [4/17/6]
installer / set-up	periodic maintenance	cutting / severing	when cutting wire or material	Minimal	Possible	Negligible	Train user - standard procedures	Complete [4/17/6]
		stabbing / puncture	from tools; sharp edges/wire	Minimal	Possible	Negligible	Train user - standard procedures	Complete [4/17/6]
	repair tasks	cutting / severing	when cutting wire or material	Minimal	Possible	Negligible	Train user - standard procedures	Complete [4/17/6]
		stabbing / puncture	from tools;sharp edges/wire	Minimal	Possible	Negligible	Train user - standard procedures	Complete [4/17/6]
dissabled / handicapped user(s)	normal use	friction / abrasion	from grinding tools	Minimal	Unlikely	Negligible	Eliminate by design	Complete [4/17/6] happens if measured improperly by technician
		wear	of shoe	Minimal	Unlikely	Negligible	Eliminate by design	Complete [4/17/6] happens if assembled incorrectly
		fatigue	of material	Minimal	Unlikely	Negligible	Eliminate by design	Complete [4/17/6]
		strength	of material	Minimal	Unlikely	Negligible	Eliminate by design	Complete [4/17/6]
		loss of balance	bulky device; uncomfortable	Slight	Unlikely	Low	Eliminate by design	Complete [4/17/6] corrected by design
the elderly		friction / abrasion	from repeat usage against skin	Minimal	Unlikely	Negligible	Eliminate by design	Complete [4/17/6] happens if measured improperly by technician
		wear	of shoe	Minimal	Unlikely	Negligible	Eliminate by design	Complete [4/17/6] happens if assembled incorrectly
		fatigue	of material	Minimal	Unlikely	Negligible	Eliminate by design	Complete [4/17/6]
		strength	of material	Minimal	Unlikely	Negligible	Eliminate by design	Complete [4/17/6]
		loss of balance	bulky device; uncomfortable	Slight	Unlikely	Low	Eliminate by design	Complete [4/17/6] corrected by design

1.H Engineering Changes Since Design Review Three

The only design change of significance was the use of an adjustable stop sleeve by an Alan wrench set screw. This was used in place of a crimping type stop sleeve for the reason that it makes adjusting the device much easier, since it avoids having to grind or cut off the old stop sleeve to re-crimp a new one on.

Figure 1.H.1: Old version of wire stop sleeve; crimper.

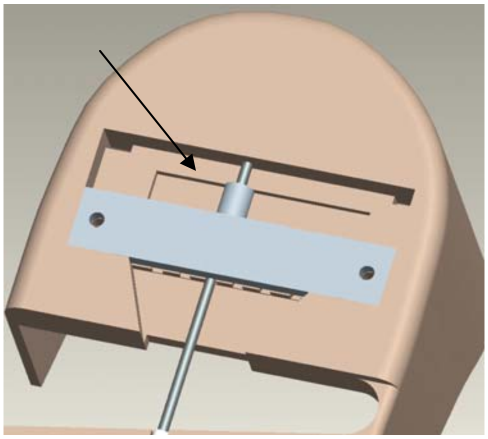
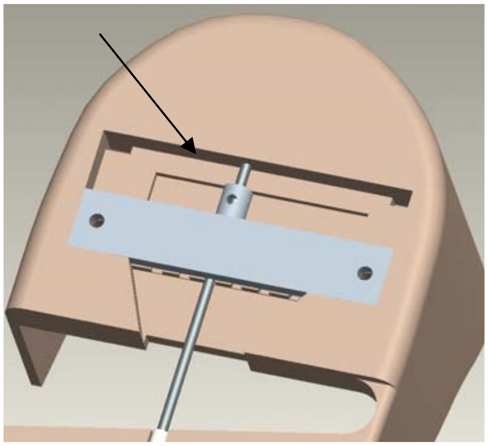


Figure 1.H.2: New version of wire stop sleeve; adjustable screw.



1.I Engineering Drawings used to Fabricate the Heel Plate Jig