ME 450 – Fall 06

Novel Foot Orthosis

Project 22

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Final Report

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EXECUTIVE SUMMARY

Design Problem

The posterior tibial tendon initiates heel inversion in the heel rise phase of the gait cycle. The heel inversion locks the transverse tarsal joints into a rigid lever during the weight bearing phases of the gait cycle. When this tendon weakens or ruptures, the foot remains un-inverted resulting in a state where mid-foot is abnormally loaded with the body weight and causes pain and flat-feet.

Customer Requirements and Engineering Specifications

To fully assist the tendon, the design must support a heel inversion ranging from 5 – 25° and arch heights of 0.25 – 2 inches. The design should weigh less than 0.5 lbs, last for at least 2 years, have a bottom thickness less than 7/16 inches and support the forces created by a 300 lb person jumping 2 feet onto concrete. Specifications were incorporated for foot motion and user comfort.

Concepts Generation and Selection Methodology

11 concepts were generated and rated based on how well they meet engineering specifications. These ratings were weighted based on importance (As per QFD). The top five concepts selected are High Heel Pull Concept, Heel Slot Concept, Cable and Ankle Concept, Wheel Concept. All these concepts are based on using simple mechanisms that will assist the foot motion.

Final Design

When the foot bed is on the ground in contact with the stirrup, there is slack in the cable connecting the foot bed to the lever. The spring connected to the leg cuff is stretched to its maximum length. When the heel begins to rise, the force in the spring rotates the lever. The rotating lever pulls up on the cable, which pulls up the side foot bed. There is enough tension in spring to maintain heel inversion. When the shoe makes contact with the ground, the leg moves downward closing the gap between the foot bed and stirrup. The body weight is translated to the stirrup slat, applying an upward force on the lever, rotating the lever clockwise. This extends the spring and releases tension in the cable everting the foot.

Manufacturing Plan, Cost Analysis and Test Results

The PTTO used simple manufacturing techniques of casting the foot model and then molding the polypropylene onto the foot model with necessary hardware embedded in it. Other components are manufactured using simple processes and equipment. The final steps of assembly include finish processes such as buffing metallic components, adjusting hardware and applying low-density EVA and Velcro straps. The total cost of PTTO is $ 214 which includes material, labor and equipment cost. This cost excludes cost for foot model and medical appointments. The PTTO satisfies 14 of the 17 engineering specifications. Heel inversion which is the most important specification can be achieved by preventing the repositioning of the leg cuff.

Design Critique and Conclusions

The PTTO is light-weight, fits in a shoe and is durable. The PTTO also assisted in heel inversion upto 8 °. However, the force required for this heel inversion is not reliable or consistent because of repositioning of the leg cuff. This design can be improved by securing the leg cuff, using stronger and non-metallic components and minimizing protrusions on the medial side of the ankle. With these improvements the PTTO can be used as a beneficial device that can be patentable, marketable and produced in all orthotic

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INTRODUCTION

The objective of this design project is to implement a device capable of resting the posterior The tibialis tendon (for less advanced stages of PTT), or (for more advanced cases) to perform the functions of the tendon by initiating heel inversion, while allowing full range of foot motion. We will be working with the University of Michigan's Orthotics and Prosthetics Center. Our sponsor is Chuck Greene. Currently, there are no pro-active dynamic foot orthotics for the treatment of PTT. The advantage of a pro-active dynamic system is that it would allow patients to be fully active during the rehabilitation process.

Description of Medical Condition

The posterior tibialis tendon is essential for walking. It initiates heel inversion during the heel-rise phase of the gait cycle. This inversion shifts the axes of the talonavicular and calcaneocuboid (transverse tarsal) joints into a non-parallel position locking the foot into a rigid lever during the weight bearing heel-rise and toe-off phases, with the help of the Achilles tendon.

When the posterior tibialis tendon weakens, it no longer has enough power to invert the foot in heel-rise, so the peroneus brevis muscle keeps the foot everted. Thus, the transverse tarsal joints of the midfoot remain unlocked, abnormally loading the midfoot with the body weight, causing pain. With continued loading, the midfoot ligaments weaken from the unrestricted eversion force of the peroneus brevis muscle and permanent shift in Achilles tendon insertion position. Thus the longitudinal arch falls and results in fixed hindfoot deformity and contraction of the Achilles tendon. If the condition is not treated, further deformity and eventually arthritis develop.[1]

Figure 1: Locations of tendons for the inside of the right foot[2]

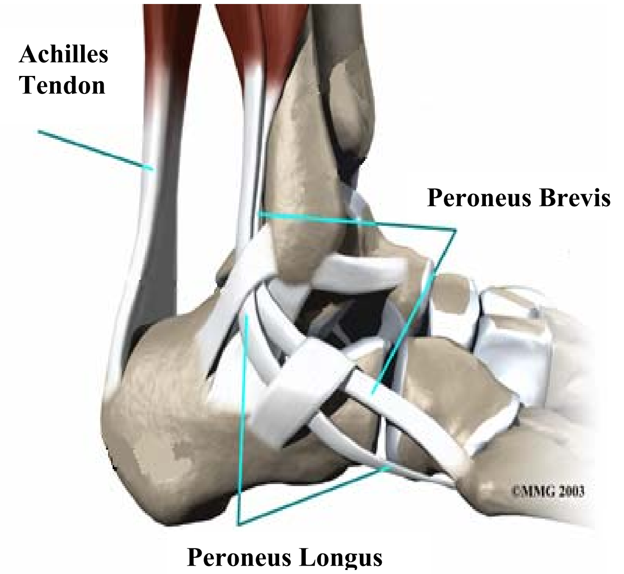

Figure 2: Locations of tendons for the outside of the right foot[3]

CUSTOMER REQUIREMENTS

Requirements Development

Customer requirements were initially established by meeting with our sponsor Chuck Greene and using his explanation of what a successful product would include. The main focus was on a dynamic orthotic function that would both support the arch and simulate heel inversion for people with posterior tibialis tendonitis. After our discussion with Mr. Greene, each team member developed their own list of requirements. We then combined these requirements and compared them to the ones defined by the previous design group and had similar results. The other requirements were based on what is necessary for a shoe orthotic, such as lightweight, custom fit, comfortable, fits in athletic shoe. All the customer requirements are listed in the Table 1.

Relative Importance

Each customer requirement was individually compared to all other requirements. For each pair, a value of one was given to the one that was relatively more important, with a zero value applied to the other one. The values for each customer requirement were summed after all had been individually compared. These values allowed us to rank the requirements in order of importance from 1-12 with the highest value given the greatest weight (12). Refer to QFD matrix on page. 9

ENGINEERING SPECIFICATIONS

Specifications Development

Engineering specifications were developed from the customer requirements, by first developing general design specifications. Then these specifications were quantified where necessary. Values for the specifications were obtained by consulting the engineering requirements from the previous design team and modifying them in concordance with team discussion, a literature search of existing orthotics and gait cycle, and feedback from Mr. Greene regarding the shortfalls of the previous prototype. While developing this list, we made sure that the requirements were feasible so that concept generation would not be restricted by prohibitive guidelines. The complete list of engineering specifications in included in the table 1.

Table 1: Costumers Requirements and Engineering Specifications

Costumer Requirements	Engineering Specs
Does not restrict normal foot motion	Protrusions less than 1/8" on bottom
Fits in athletic shoe	Protrusions less than ½" on sides
Recreates heel inversion	No exposed edges with R less than 1/16"
Restores arch of foot	Zero water absorption
Durable	Toes can dorsi-flect up to 90 degrees
Easy to put on	Ankle can dorsi-flect up to 20 degrees
Flexible	0 degrees of heel inversion at pronation
Lightweight	Accommodate arch sizes ¼ - 2"
Comfortable	Customizable to shoes sizes 6-15
Custom fit	Weighs less than ½ pound
Adjustable once constructed	Constructed from laminates, thermoplastics, and metal hardware
Easy to manufacture	Life-cycle of atleast 2 years
	Able to withstand a force generated from a 300 lb person jumping 2' onto concrete
	Gaps or spaces less than 10mm
	Temperature stability upto 150 °F
	Bottom thickness less than 7/16''
	Forced heel inversion adjustable to 5 - 25° at supination

According to the Richie Brace website[4] the toes can dorsi-flect up to 90 degrees, and the ankle up to 20 degrees. At pronation, the heel has 0 degrees of inversion, and at supination the heel can invert up to 25 degrees. A foot orthotic device should not restrict these normal foot motions.

Using information provided by our sponsor Mr. Charl Greene[5] combined with our engineering knowledge we were able to come up with some approximate engineering specs for a shape, size and materials for our device.

In order for our orthotic to be durable it should be able to support forces incurred by a 300lb person jumping from 2ft down to concrete. According to the BMI [6](body mass index) the upper weight for a tall obese person is less than 300lbs. The hardest surface that patients will likely be on is concrete. 2ft is about twice the height of a large step. This should give us a comfortable safety factor and should allow our design to last for a competitive 2+ years.[7]

The average Nike shoe weighs around 20 ounces[8] which is approximately 1.25 lbs. In order to keep the orthotic comfortable, it must weigh no more than ½ lb. The orthotic must have no sharp corners and thus the mechanism cannot have any exposed edge blends with an R greater than 1/16 inches. In order to make the orthotic flexible and stiff, a common thermoplastic will be chosen. Most thermoplastics do not have melting point less than 150 ºC [9] which is higher than the max temperature in a shoe. Thermoplastics are resistant to heat distortion and have excellent fatigue strength. They are chemically inert, resist water absorption and show poor resistance to weathering. This will ensure that orthotic geometry is maintained and it will be durable for at least 2 years.

Since a foot orthotic is used by a diverse population, it is essential that our design can be custom built for a range of shoe sizes 6 – 15. The bottom thickness of the orthotic should be less than 7/16" in order to fit in a normal athletic shoe.

Application of Engineering Specifications

The engineering specifications were correlated with customer specifications based on a numerical system for defining the relationship. Some specifications were applicable to more than one customer requirement. Ultimately we ensured that each customer requirement corresponded with at least one specification, to insure that the final engineered prototype is both functional and desired by the customer.

Cross-Correlation

The triangle at the top of the QFD is a visual representation of the correlation of engineering specifications. Two specifications that are highly correlated are represented with a '++' in this matrix and indicate that if one is satisfied then the other is most likely also fulfilled. Specifications that are positively related but not collectively satisfied are represented with a '+' in the matrix. Unfortunately, some specifications are in competition, and thus if one is satisfied, it makes it harder to also complete the other. This relationship is represented with a '-' in the matrix.

Engineering Specifications Ranking

The engineering specifications were ranked in order of importance by multiplying each relationship number with its corresponding customer weight, and summing these values at the bottom of the QFD matrix. The highest total corresponds to the most important specification. This system allowed us to determine the order of importance of the engineering specifications, which will be very useful during concept generation.

Engineering Targets

At the bottom of the QFD matrix, we evaluated the engineering specifications of our competitors. This information helped us with a realistic approach to creating our engineering targets. UBCL, Richie Brace and the 450 design had some engineering requirements which we would like to match, such as support in the arc of the foot, minimal restricted toe and angle motion, etc. The ME 450 design has a unique forced horizontal heel inversion which is key engineering requirement which we would like to match and expand with an additional vertical heel motion. We have completed a patent search and there are no existing products with a heel inversion like the ME 450 design.

On the right side of the QFD matrix, we evaluated the customer requirement of our competitors. This information will help us with an approach to creating a product with practical use. Unlike the ME 450 design we would like to match some of the customer requirements with UBCL and Richie Brace, such as durable, easy to put on, comfortable, fits in a shoe, etc.

PATENT AND BENCHMARK RESEARCH

Products on the market today for PTT are designed to statically support the arch of the foot. The UCBL shoe insert (figure 3) and Richie Brace (figure. 4) are two common foot orthotics used. A third design (figure 5), created by a ME 450 group in Winter 2006, used a dynamic system with a horizontal motion of the heel in an attempt to recreate heel inversion. The performance of these three designs was evaluated based on a ranking system between 1-10, with 10 being the highest and 1 being the lowest. The rankings were applied to each customer requirement, with judgment based on our engineering knowledge of the devices as seen in the QFD matrix.

A patent search[12] was conducted to investigate current designs for foot orthotics. Currently there are no dynamic shoe inserts that are able to effectively support the foot motion. The UCBL and the Richie brace support the arch but do not assist in heel inversion.

Figure 3: Typical UCBL[10]

Figure 4: Richie Brace[11]

Figure 5: ME 450 Design Prototype

CONCEPT GENERATION

Concept generation began with a group session of deconstructing the problem. Our three most important considerations were: heel inversion, arch support and power generation. The power can be generated from three sources: toe actuation, ankle actuation and body weight. We then decided to spilt-up and try to come up with unique ideas on our own. Brainstorming was conducted again as a team using a chalk board and evaluated each others' perception on how to incorporate ideas. This enabled us to fine-tune and create more complete concept designs. From this analysis, five concepts were generated: High Heel Pull, Heel Slot, Cable and Ankle, The Wheel, and Alpha Prototype – PTTO. All other individual designs are in Appendix A on page. 42.

High Heel Pull Concept

One of our concepts had the approach of integrating an ideal heel motion during the gait cycle. This concept uses our idea for following the normal actions of the tendon by pulling from the calf to invert the heel. This device will be a series of pulleys and springs to translate the power from the toe to a pulling motion from the calf.

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 is greater than the original length of the straight wire. Thus increase in wire tension can be used to invert the heel.

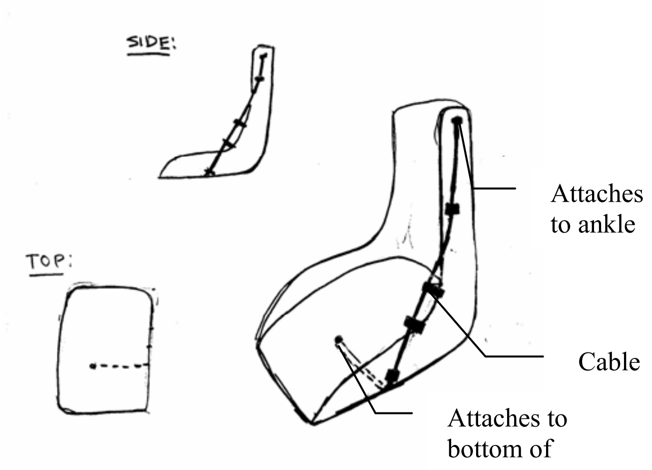

Figure 7: High Heel Pull concept - A cable/spring pull from the calf and inverts the heel

Heel Slot Concept

This is another one of our concepts that had the approach of integrating an ideal heel motion during the gait cycle. This concept uses the idea of slots to guide the motion of the heel inversion. Two slots will push and pull the heel using power from the toe and a pulley system similar to the *high heel pull concept*.

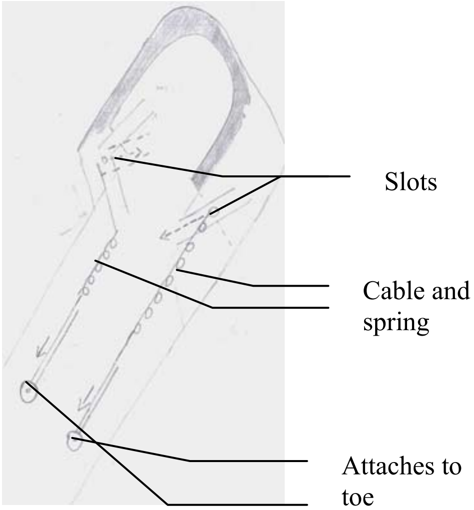

Figure 8: Heel Slot concept – Heel is guided by a slot to get desired motion

Cable and Ankle Concept

Another concept had the approach for using the ankle for a power supply. Like the toes the ankle will dorsi-flect creating an arc during the gait cycle, which creates our power source. Using a pulley system we can translate this power from the ankle and force the heel to invert.

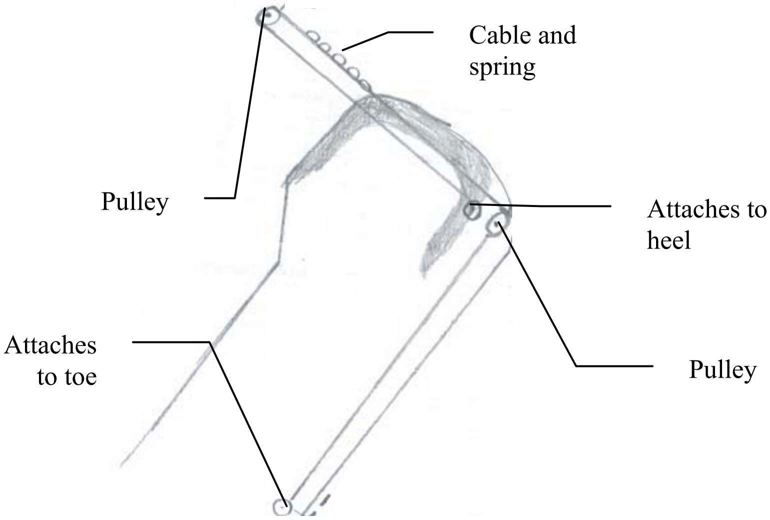

Figure 9: Cable and Ankle concept – Powe+r is derived from the ankle to force the heel to invert

Wheel Concept

Another concept of ours involves the force of a person stepping down to create the power we need. This concept uses an upper spring that will store power when a person steps down. To control this power we used the fact that the foot flattens out when pressure is put on it. The force we get from the foot flattening out will turn a wheel which will control the upper spring from forcing the heel to invert at pronation. The power will be released when the foot lifts off the ground, turning the wheel which allows the upper spring to invert the heel.

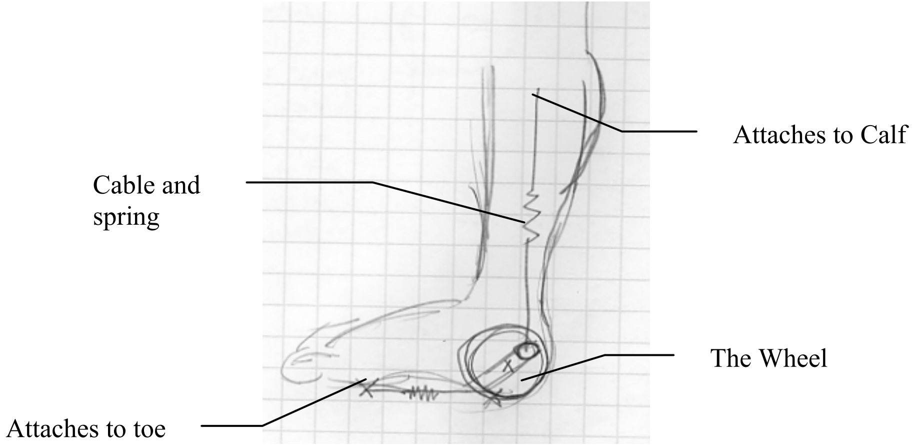

Figure 10: Wheel concept – Power is derived from the person's weight to invert the heel

Alpha Prototype – Posterior Tibialis Tendonitis Orthotic (PTTO)

This concept is much like the wheel concept; it uses the power of the body weight to invert the heel. A detailed description is in the final design description section

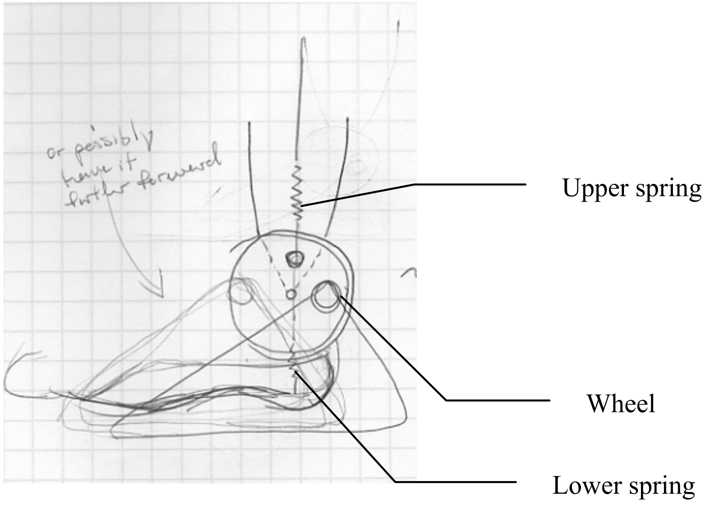

Figure 11: PTTO

CONCEPT SELECTION PROCESS

Our team generated 11 concepts over the past few weeks. After the infeasible concepts were filtered out, our team evaluated the top five. The top five concepts where then scored using our QDF (Appendix B, page 46) and a scoring matrix. A list of advantages and disadvantages were also created for each concept. Using this information we were able to choose a concept most likely to succeed.

We began by comparing our concepts with the customer requirements in the QFD on page 9. A scoring matrix to compare our concepts with the engineering specifications in the QFD was developed. The scoring matrix uses a ranking system from 0-2: 0 it does not accomplish the engineering specifications, 1 somewhat accomplishes or unsure and 2 accomplishes engineering specifications. Since some specifications are more important then others we used the results in our QFD and multiplied the 0, 1, or 2, by the importance and summed up each concept to get a final score. The results are shown in table 2.

Table 2: Scoring Matrix for top five concepts

	Cable and Ankle	Heel Slot	High Heel Pull	Wheel	PTTO (Alpha Design)
No protrusions greater than 1/8" on bottom	2	2	2	2	2
No protrusions greater then ½" on sides	1	1	1	1	1
No points with R less then 1/16"	1	1	1	1	1
Zero water absorption	2	2	2	2	2
Toes can dorsi-flect up to 90 degrees	2	2	2	2	2
Ankle can dorsi-flect up to 20 degrees	1	2	1	1	1
0 degrees of heel inversion at pronation	2	2	2	2	2
Accommodate arch sizes of 1/4 - 2 "	2	2	2	2	2
Customizable to shoes sizes of Womens 6 to Men's 15	2	2	2	2	2
Weighs less than ½ pound	1	1	1	1	1
Constructed from laminates, thermoplastics, and metal hardware	2	2	2	2	2
Must last 2 years	2	2	2	2	2
Able to withstand force of 300 pound person jumping 2' onto concrete	1	1	1	1	1
No spaces less then 10mm	2	0	1	2	2
Maintains geometry at 150 degrees Fahrenheit	2	2	2	2	2
Bottom thickness no greater than 7/16''	1	1	1	1	1
Forced heel inversion adjustable to 5- 25 degrees at supination	1	1	1	2	2
Total	**2693**	**2744**	**2651**	**2955**	**2955**

Having determined the top five concepts, we could focus on each concept individually. Advantages and disadvantages were listed for each concept, which allowed us to see any potential problem in each design.

We began with the *heel slot concept* shown in figure 8 on page. 11. The key design features were the slots that control the motion of the ankle inversion and the simple design in translating the power from the toe to the heel. A concern we have is the size of the mechanism since it will have to fit into the shoe. This may result in user not being comfortable and put undesirable pressure on other parts of the foot. Another concern we have is with the power source. It is difficult for the toes to dorsi-flect, and thus make it harder for the person to bend the toes, which may cause additional problems.

Next, we looked at the *high heel pull concept* shown in figure 7 on page.10. This concept is similar to the heel slot concept in using the toes as power, so it will have the same advantages and disadvantages with the power source. The design feature we liked was that the device was mostly out of the shoe, which could be more comfortable for the user. Another advantage with this concept is that tension will be applied from a higher point on the calf and thus allow to get an ideal heel inversion.

The *cable and ankle concept* was the next concept we considered, shown in figure 9 on page. 11. The power source for this concept seems ideal in location since it is right above the heel, which will allow for a simple design. We dismissed this concept due to lack of power that the ankle can supply. This design will also face a problem of unstable power source due to the ankle being able to move in more then one plane.

Moving on to the *wheel concept* shown in figure 10 on page. 12, we found this to be the best power source. Using the power from the weight of the body and translating that to a forced heel inversion doesn't add any additional forces on the foot. A concern with using this power source is how to store power and further use it. The power needed to turn the wheel which causes the foot to come out of the inverted state at pronation may not be reached by the foot flattening out. Another concern we had was the size of the device, the wheel would have to fit into the shoe which could cause user problems.

Lastly, we analyzed the highest scored concept, *the PTTO*, shown in figure 11 on page. 12. It is similar to the wheel concept, and uses the weight of the body as the power source. This device will be out of the shoe around the calf, which allows more room in the shoe. We can pull the heel from a higher point, for a more ideal heel inversion. A concern we had was the durability of the device, it is a complicated device with more parts which could break down easier. Another concern was restricting ankle motion thus making it uncomfortable to walk.

After careful consideration of the scoring, advantages and disadvantages, we determined that *the PTTO concept* would best satisfy the customer and engineering requirements. To correct future design problems, we will utilize our resources to satisfy the requirements of supporting foot motion, durability and simplicity.

SELECTED CONCEPT DESCRIPTION - PTTO

Engineering Design Parameter (Initial Analysis)

Using design parameter analysis we were able to calculate specifications for our mechanism. These specifications involve dimensions for each component, material selection and other parameters for springs and cable.

Wheel (Lever) Design

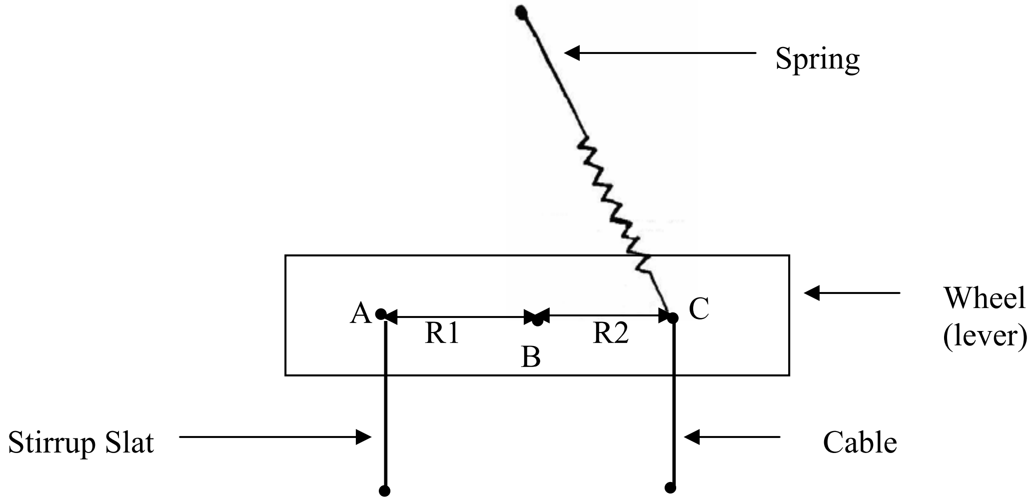

Figure 12: Wheel (lever) schematic

The lever contains three points attached to other components of the assembly. Refer to Figure 12 above for described connecting points and variables. Point A corresponds to the position of the lever connected to the stirrup slat, point B is the pin joint to the ankle brace, and point C is the attachment point of the upper spring and the cable leading to the heel.

Three-dimensional simulation in Unigraphics showed that the lever rotated about point A during heel inversion cycle. There is some horizontal and vertical displacement of point A when the heel is inverted, but is negligible compared with the displacement of points B and C. Thus, it is appropriate to approximate this displacement as zero, since it has the same impact on points B and C, and thus will not significantly affect displacement ratio of these points. To figure out the required distances R_1 and R_2 between these points, we had to find the vertical displacement of points B and C. These vertical displacements were determined for our prototype using two-dimensional positional analysis in Unigraphics.

Our prototype is custom-designed for a team member's foot. Thus, the height (5 cm) and width (7 cm) dimensions for his foot were used for the simulation. The axis of foot rotation is at the center, making the fulcrum of rotation half the width of the foot. The maximum rotation needed by the design specifications is 5 -25 degrees. Thus we rotated the foot upward 25 degrees by pulling up on the cable of length 13 cm. The vertical distance traveled by the top edge of the foot (1.5cm) determines the required gap height between the foot bed and stirrup in the shoe. This distance must be the same as the vertical displacement of point B in the lever. For this same rotation, cable point C was displaced 2 cm. The positions used in the positional analysis were redrawn for clarity, as seen in Figure 13 below.

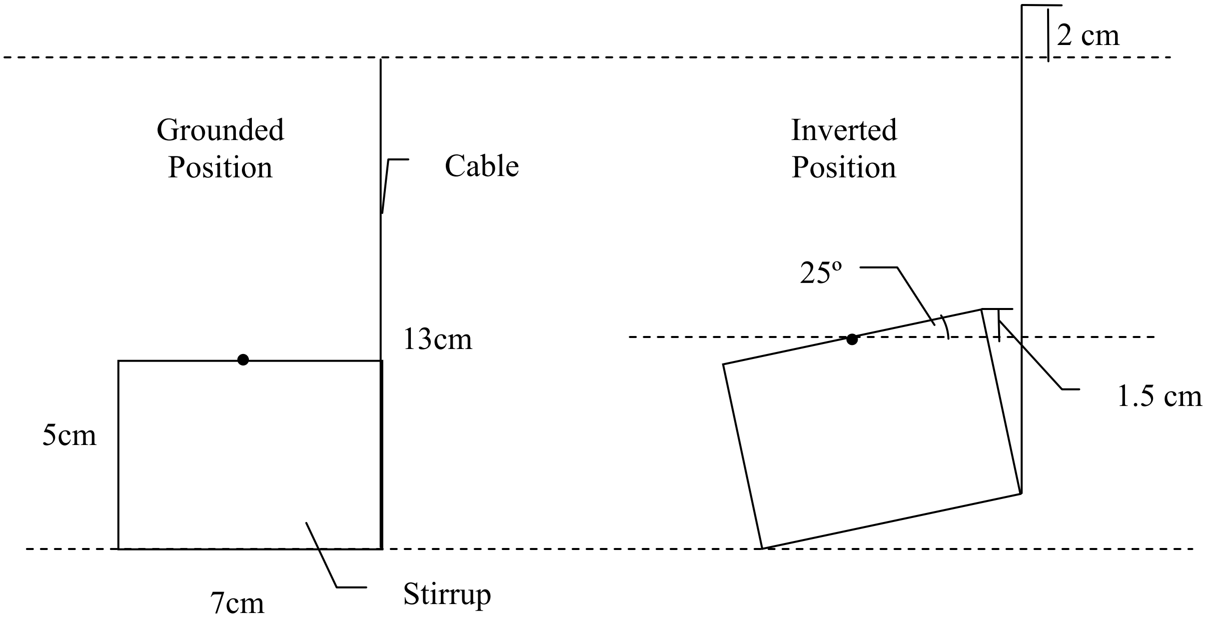

Figure 13: Vertical displacement schematic

The ratio of displacements ($\Delta B_y/\Delta C_y = 1.5/2$) is equal to ¾. This ratio must be equal to the ratio of point B and C distances from point A ($\Delta B_x/\Delta C_x = R_1/(R_1+R_2) = 0.75$), because of similar triangles as seen in Figure 14 below, since point A is the axis of rotation.

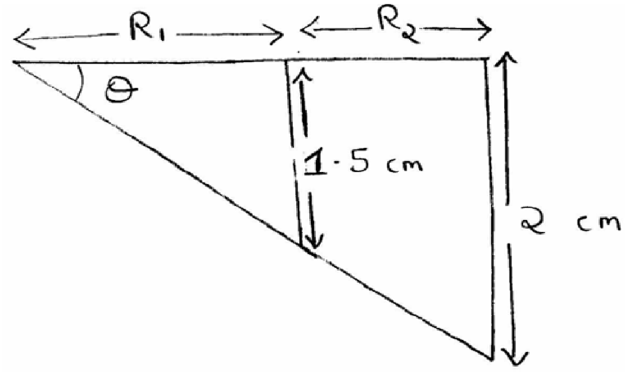

Figure 14: Wheel (lever) displacement ratio

Once the ratio is known, we came up with the distances by figuring an overall length of the lever to be less than the length of the ankle. Thus 4.5 cm was chosen and the two outside points (Points A, C) were set ½ cm from the edge. Thus the distance between the points (R_1+R_2) was 3.5 cm, and using the calculated ratio, the distance between A and B was 2.625 cm. This gives us the lengths for R_1 and R_2 (R_1 = 2.625 cm, R_2 = 0.875 cm). The initial lever design was a circular well, but to allow for a more compact design, this component became a rectangular lever with a length of 2 cm chosen, which is small enough not to interfere with other components.

We did not have time to perform stress analysis or failure criteria on the wheel/lever. Thus aluminum was chosen as the material for this component

Spring Design

Free body diagrams of the lever at the inverted (Figure 15) and grounded (Figure 16) positions were evaluated to develop equations for determining an appropriate spring constant and other pertinent forces. It was difficult to establish an accurate value for the force required to raise and invert the heel. This upper limit for this force (F_w) was assumed to be 10% of a person's body weight. For our prototype, this force is 20 lbf or approximately 90 N.

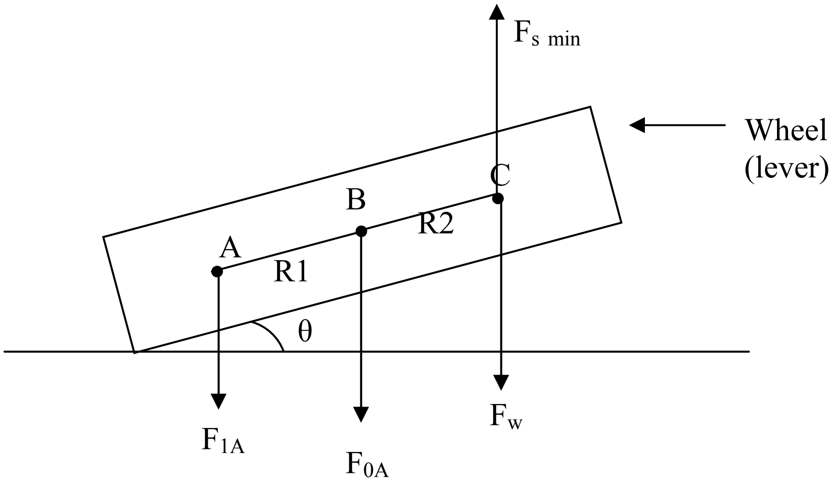

Figure 15: Inverted wheel (lever) FBD

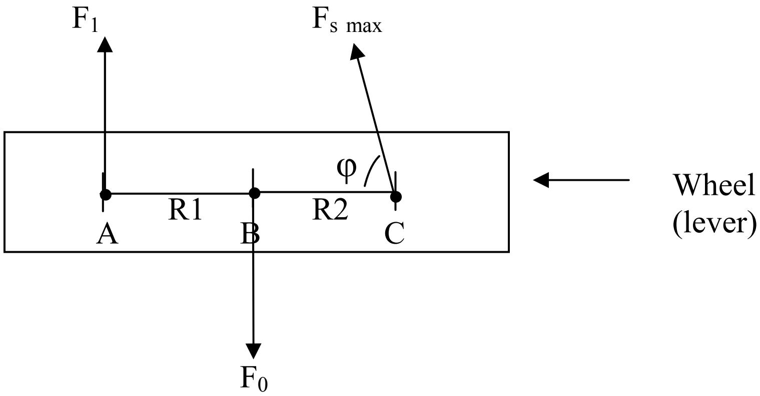

Figure 16: Grounded wheel (lever) FBD

The sum of vertical moments was taken about points A and B along with the sum of vertical forces on the lever in both orientations. Since the lever is at rest at both positions, the sum of all forces and moments is equal to zero. Additionally, in the inverted position, forces F_0 and F_1 are negligible since the force of the spring (F_s) and force of inverting the heel (F_w) are in the same one-dimensional plane. Thus, for our calculations they are assumed to be zero. Figure 17 below shows the orientation of the spring in the inverted (1) and grounded (2) positions.

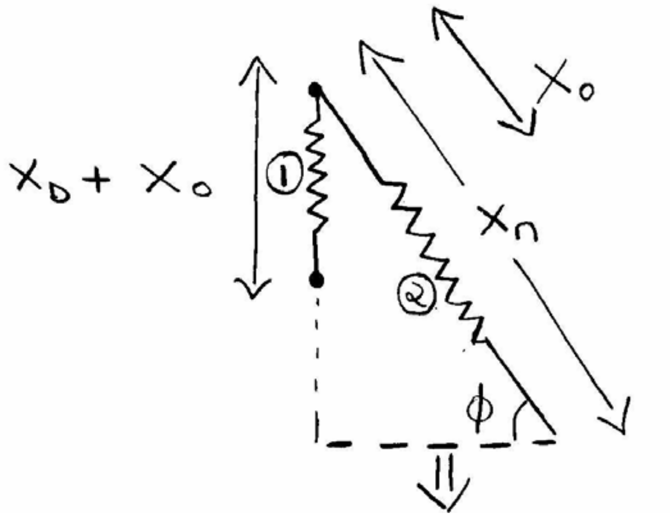

Figure 17: Spring positional analysis

These dimensions were used in combination with the equations for the free body diagrams to find equations for the spring constant. The two equations derived for the spring constant at the inverted (Eq.1) and grounded (Eq.2) positions are shown below.

$$k = \frac{F_{s\min}}{X_D} = \frac{F_w}{X_D} \qquad \text{(Eq.1)}$$

$$k = \frac{F_{s\max}}{\frac{\left[(R_1 + R_2)(1 - \cos\theta)\right]}{\cos\phi} - X_0} \qquad \text{(Eq.2)}$$

In the equations, X_0 is the resting/equilibrium length of the spring, X_D is the initial displacement and X_n is the overall length of the spring at the grounded position. Refer to Appendix C for a detailed overview of equations used in these calculations. We initially used Eq.1 to find a spring constant corresponding to an appropriate spring since the only unknown variable was the displacement of the spring in the inverted position. Different values of this displacement were used to find several springs available for order. Then the specifications on these springs (spring length = X_0 and spring constant = k) were used to find angle φ and then applied to Eq.2 to make sure F_{smax} was not too large at the grounded position. Finally a spring was chosen which minimized the space needed for the spring and the maximum force (approximately 150 N) required at the grounded position. The specifications of this spring are listed in Table 3 below.

Table 3: Spring design specifications

Specifications	Dimension
Spring Constant (k)	25.5 N/cm
Resting Length (X_0)	5.08 cm
Inverted Displacement (X_D)	3.50 cm
Grounded Displacement (X_S)	5.80 cm
Grounded Overall Length (X_n)	11.4 cm
Outside Diameter	1.27 cm

Leg cuff Design

The bottom of the leg cuff starts right above the rotating point in the ankle (malleolus), because the radius of the ankle is larger there. This larger radius is what the leg cuff rests on and will prevent the leg cuff from sliding downward when spring and foot forces are applied.

The leg cuff height was determined by the overall length of the spring when fully extended. Once the spring was determined, the vertical component of the length was calculated by knowing the hypotenuse (length of spring X_n) and the horizontal component (displacement of spring from inverted to grounded positions). The vertical length of the spring at maximum displacement was 11.4 cm. Thus the leg cuff must extend a minimum of 11.4 cm above the wheel. We increased this required dimension to 12 cm to allow space to connect the spring to the cuff. The lever is connected to the leg cuff 4 cm above the bottom edge, to allow space for lever rotation. Thus, the total height of the cuff is 16 cm. The width of the leg cuff is variable and customized for each individual and dependent on calf size. Refer to Appendix C for force calculations.

Stirrup Slat Design

The force from the lever applied to the slats should be analyzed with the parameters of the chosen material, to find the required cross-sectional area needed to withstand that force with repeated loading. The result would then be multiplied by a safety factor. Thus we chose aluminum as the material for this component because it will be more then strong enough to handle the applied loads over repeated cycles.

Stirrup

The stirrup was designed to connect to the stirrup slats at the rotating point of the ankle. For our prototype, this distance was about 7.5 cm. The required gap between the foot bed and stirrup is 1.5 cm. Thus, the overall height of the stirrup, accounting for thermoplastic material thickness of 0.48 cm, was 10.48 cm. A width of 2.5 cm was chosen to match the diameter of the rotating point in the ankle.

Foot Bed

The foot bed is a standard orthotic currently molded out of polypropylene in the prosthetics lab. Thus the inside dimensions correspond to the dimensions of the foot. The standard material has a thickness 0.48 cm.

Stress Analysis

We conducted a basic and approximate stress analysis of our components. Analysis shows that we have a large order of magnitude of safety for all of our critical joints. The largest stress in the aluminum is present in the center rivet of the wheel (lever). This rivet has the largest force in the system (173N). The largest force applied to the polypropylene is due to the spring which attaches to the leg cuff (148N). For a list of all forces in the mechanism see Table C1 in Appendix C. Location of forces can be found in Figure 16, page 18.

Table 4: Material Specifications

Material (thickness 4.76mm)	Max local stress (Mpa)	Yield Stress (Mpa)	Safety factor (to nearest order of magnitude)
Polypropylene	2.0	34	10
Aluminum	2.3	235	100

The equation used for local stress is shown below

$$\sigma = \frac{F}{A} \qquad \text{(Eq.3)}$$

F is the force acting on a rivet
A is the area in the rivet that the force is acting over.

Area that the force would be acting on in a rivet would be equal to the surface area of one half of the rivet. Each rivet has a 0.005 m radius, and the thinnest material used was 4.76 mm. This would give us our thinnest cross sectional area and the greatest chance for failure (Eq.4):

$$A = \pi * 5 * 4.76 \text{ mm}^2 \qquad \text{(Eq.4)}$$

Design for Manufacturability

The PTTO will be designed for a large number of patients, but each product must be customized for each patients/costumer. To simplify manufacturing for each customized orthotic, the number of components that are varied between designs had to be minimized. Thus the product is divided into components that are adjusted for each customer and the components that remain constant.

Constant Components
- Stirrup
- Lever
- Adjustable spring joint
- All connecting joints
- Gummy joint

Adjustable Components
- Foot bed and Leg cuff
- Spring
- Lower Cable
- Straps
- Stirrup slat

The constant components will be combined into a kit, which will be sold together to orthotics laboratories. These kits will also include a spring. There will be multiple kits with the only difference being varying spring constant. The appropriate kit will be ordered once the initial diagnosis and calculation of appropriate spring constant is complete. Availability of these kits will reduce the manufacturing time and labor cost in the laboratory.

The adjustable components are constructed by technicians in orthotics laboratories. The foot bed and leg cuff are manufactured using standard molding procedures. The standard adjustable spring joint allows variation of initial spring displacement. The spring constant is determined based on force required to initiate and maintain heel inversion. This force is estimated as a fraction of the patient's overall body weight. The lower cable length is determined by the designed angle of heel inversion and foot geometry. The stirrup slat and straps will be manufactured based on the foot geometry of the patient.

Failure/Safety Analysis

For the PTTO, we identified the first source of failure as the joint with the largest applied force. Based on force analysis, this is the joint that attaches the lever to the leg cuff (refer to Point B, Figure 12, page 15). To calculate failure criteria at this point we used behavior of material equations. The initial design used aluminum metals at these joints, but due to the high stresses we will recommend stainless steel for the joints (calculations are done with the properties of stainless steel). We began analysis by applying Eq. 5 shown below, where N_f is the number of cycles until failure, C_1 and a are empirical constants for stainless steel, and σ_a is the amplitude of stress during a cycle. Refer to Appendix F for calculation of these variables.

$$N_f = (C_1 / \sigma_a)^{1/a} \qquad \text{(Eq.5)}$$

To find the number of cycles until failure, Eq. 5 was applied using the empirical constants for steel (*C_1=927 MPa*[16], *a=0.138*[16]), and yield stress amplitude (σ_a = 39.4 MPa, calculations shown in Appendix D, page. 53-54). The yield stress value incorporates a safety factor of 10 to account for unnatural loading or flaws. The number of cycles to failure was calculated to be 8.69×10^9 cycles. The loading cycles in gait ranges from 0.5 to 3 million cycles per year depending on age and activity level.[17] Taking the upper limit (3×10^6 cycles), we can see that ideally the joint will last for much more than 2 years.

With a more secure leg cuff, a smaller force from the spring will be adequate to achieve the same motion from the heel, because the mechanism will be less inefficient. Thus the force from the spring will be more concentrated on the heel and less will be lost to friction or other areas. This will also distribute the stress more evenly across all the joints and minimize high local stress buildup at the joints. Another possible point of failure is the cable. One issue is that the cable rubs on the leg cuff. Repeated cycles could cause the cable to fray, weaken and eventually fail.

PFMEA (Process Failure Mode and Effects Analysis)

Since the lever and leg cuff joint of the PTTO failed during design EXPO, we conducted a PFMEA. It is essentially a tool used to evaluate potential failure modes and their causes. It prioritizes potential failures according to their risk and drives actions to eliminate or reduce their occurrence. By conducting this, it will provide a good documentation for future analysis or for design improvement.

A detailed PFMEA is attached on page 23. It consists of a description of parts, their potential causes of failure and effects. It also contains a few corrective actions based on our engineering judgement and analysis. The RPN is a value calculated based on severity (SEV), occurrence (OCC) and detection (DET)

Thus RPN = SEV x OCC x DET

The lever and leg cuff joint and the stirrup received the highest RPN which indicates the highest potential for failure. Corrective action for the stirrup includes securing stirrup to shoe and designing a guided path for its motion. This will ensure that stirrup is always in the right location and also ensure that prototype is not incorrectly put on leg. Corrective action for the wheel lever joint includes using a stainless steel fastener and also using longer post screws. Analysis of the fastener after failure indicated that the fastener had snapped out of the threads without breaking the screw. Since a aluminum post screw was used, it was unable to carry sufficient load.

FINAL DESIGN DESCRIPTION

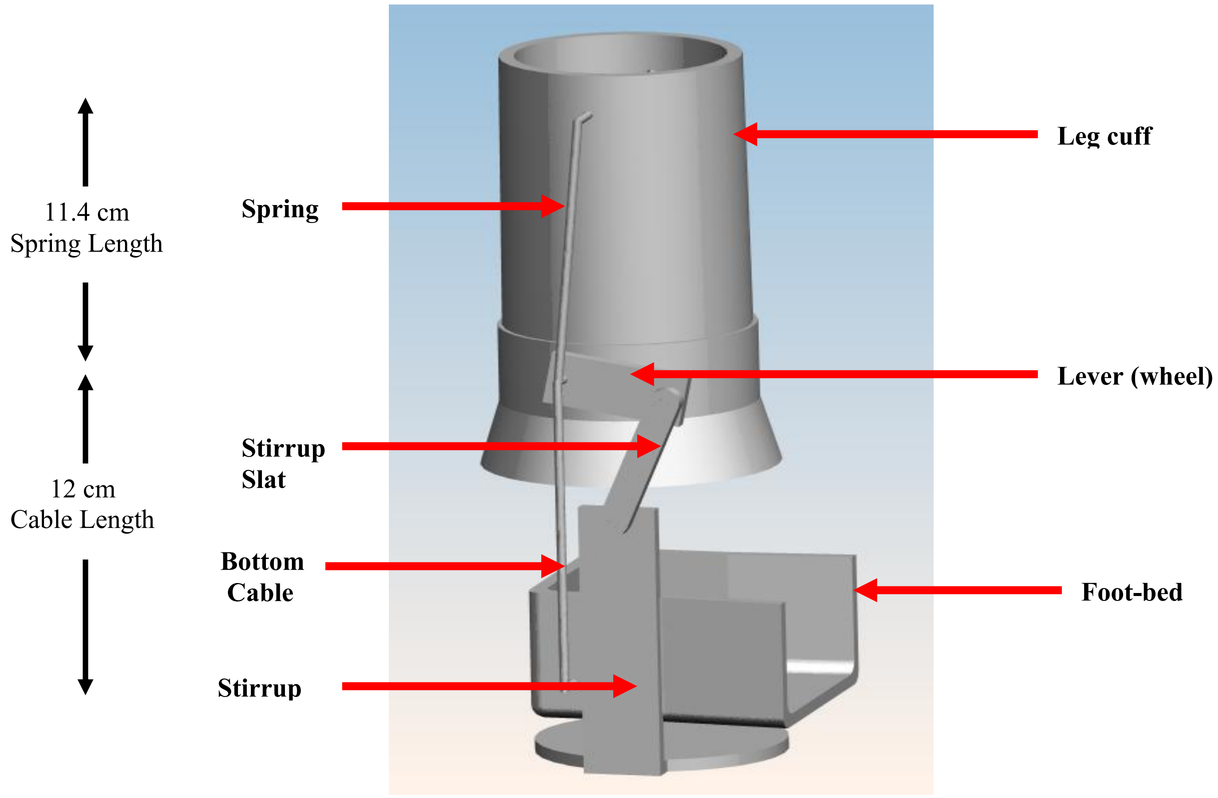

Figure 19: Schematic view of PTTO

Motion Description

Our design motion is simple in concept. During heel inversion in the gait cycle, the tibial muscle attached to the posterior tibialis tendon contracts effectively turning the tibial system into a spring. When the tendon becomes weakened, it stretches and in effect, the overall spring constant decreases. Thus it no longer has enough force to invert the heel.

Orthotic System Dynamics

Our orthotic uses a physical spring to assist the tibial muscle and tendon in inverting the heel. We have oriented the spring so that it can closely emulate the function and motion of the tendon. The other dynamic portion of the design allows the heel to evert during foot fall. Heel eversion is important because it allows the foot to be loose during impact with the ground, which disperses the impact force throughout the foot and up into the leg. This prevents regions of high stress from forming in the foot. Figure 20 on page. 25 represents a functional decomposition for the PTTO. Layout drawings for each component are included in Appendix E

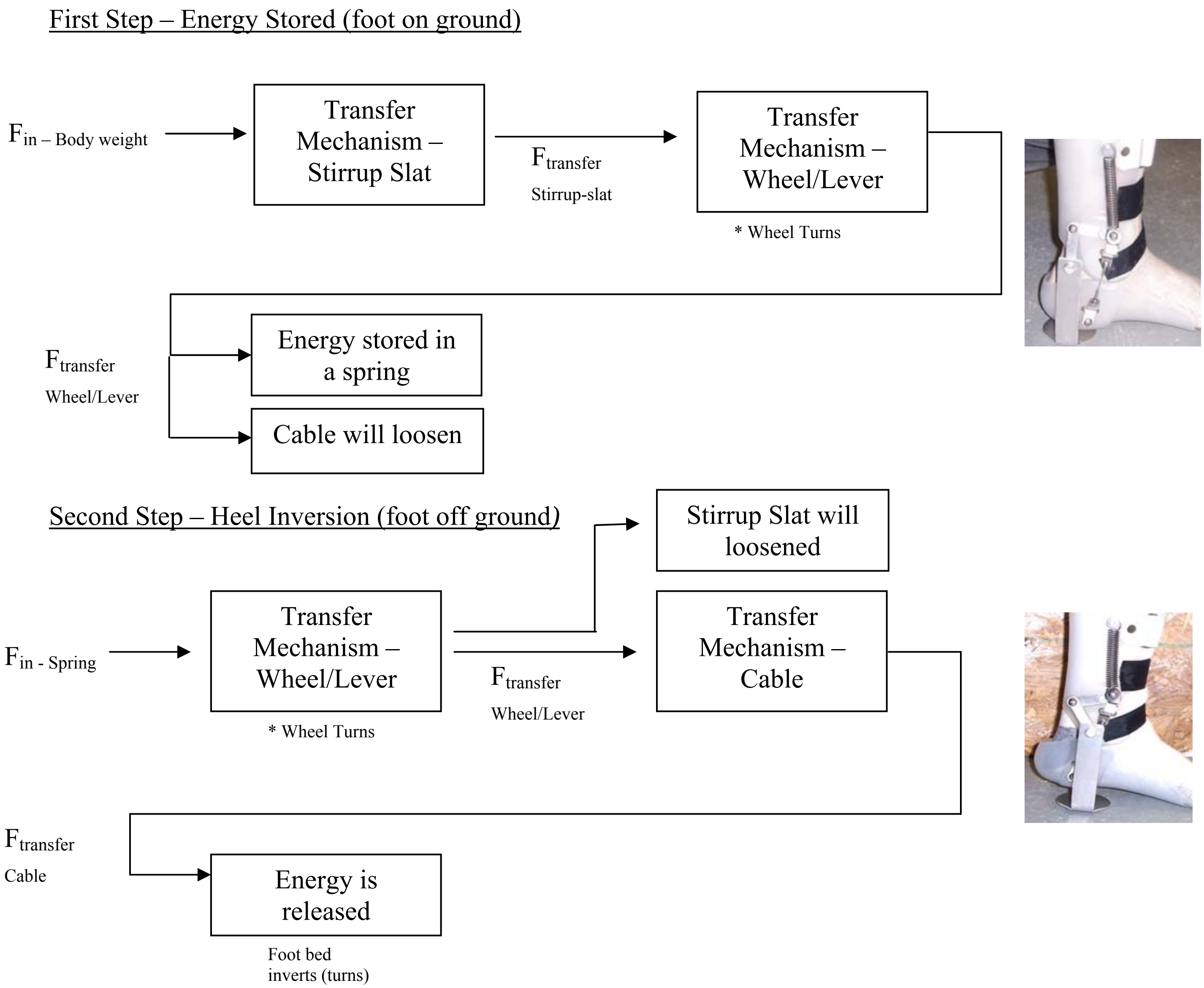

Figure 20: PTTO functional decomposition

Heel Inversion

When the foot is on the ground, the foot bed is in contact with the stirrup. There is slack in the cable connecting the foot bed to the lever and the lever is oriented horizontally. The spring connected to the leg cuff is stretched to its maximum length. When the heel begins to rise, the force in the spring rotates the lever. The rotating lever pulls up/tightens the cable, which pulls up the side foot bed. At this point the spring is at its shortest length with enough tension to keep the heel inverted during push-off.

Heel Eversion

When the shoe makes contact with the ground, the leg moves downward closing the gap between the foot bed and stirrup. The body weight is translated to the stirrup slat, applying an upward force on the lever. Thus, the lever rotates clockwise extending the spring and letting down the cable. Letting down the cable allows the heel to evert.

Component Motion and Description

There are two categories of components in our foot orthotic. The first are molded pieces custom-made to fit individual feet. These pieces are the foot bed and leg cuff and they are fabricated from thermoplastics. These components have some regions lined with foam padding for comfort and to help distribute pressure. The other components, which carry the majority of the load, made from aluminum and steel. Aluminum was chosen for the larger metallic components because it is a light-metal, but strong enough to ensure there will not be plastic deformation with many loading cycles.

Each component has a specific role in assisting in heel inversion or allowing heel eversion. The role of each component is described below. Refer to appendix D for drawings of each component. All dimensions included in these drawings are for one customized foot orthotic.

Overall Description of Mechanism

There is a cable connected to the side of the footbed which is displaced upward (inverting the heel) and downward (everting the heel). The cable is displaced by the lever rotating clockwise (everting the heel) and counter-clockwise (inverting the heel). The lever is rotated by the spring (inverting the heel) and the stirrup/stirrup slat (everting the heel).

Lever (Wheel)

When the foot is completely everted, the lever is horizontal and the force in the spring is balanced by the body weight. When the body weight is removed as the heel lifts off the ground, the force in the spring causes the lever to rotate and move upward. This applies a downward force in the lever from the tension in the cable. The main function of this component is to translate applied forces into lever rotation and motion.

The lever parameters will remain consistent in all PTTO mechanisms. The 0.72 ratio of lengths [$R_1/(R_1+R_2)$] between the joint connections (see Figure 12, page 15) was slightly modified, due to geometrical constraints of the joints, but the change was not significant. Thus, this constant ratio should function for all mechanisms, and the lever will be available with the joint holes already manufactured.

Stirrup Slat

The main function of the stirrup slat is to cause the lever to rotate and move downward when the leg moves downward, allowing heel inversion and increasing the force in the spring. The stirrup slat is mostly stationary and is the point of rotation for the lever. The stirrup slat is customized for each patient and will be manufactured to the appropriate length once all others parameters for the mechanism have been defined and the components assembled.

Leg cuff

The leg cuff is the base to which the lever and spring can attach. For the orthotic to function properly, this component must not move relative to the ankle during any phase of the gait cycle. Thus the bottom is in contact with the rotating point of the ankle, which will prevent it from moving downward with the force from the spring.

Spring

The spring is pre-loaded so that there is enough tension to hold the foot inverted when the heel is on the ground. It then stretches, storing energy when the heel contacts the ground. This energy storage causes forced heel inversion when the heel lifts off the ground.

The point at which the spring is anchored on the leg cuff can be changed by inserting a post screw into one of the vertically aligned holes in the spring connecting joint. (Refer to figure 21 on page 31).

The spring chosen for the PTTO will have varying spring constants and lengths depending on the overall weight of the patient. The spring chosen for our prototype was customized for our team member. The spring initially chosen for the design was not adequate because it was based on a upper estimate for heel inversion force required.
The final prototype was designed for a heel inversion of 8° and springs of varying spring constants and lengths were tested on the PTTO until the design heel inversion goal was achieved. The spring constant, original length and stretched lengths at the inverted (minimum) and grounded (maximum) positions are listed below.

Table 5: Spring Parameters

Specification	**Dimension**
Spring Constant (k)	17.4 N/cm
Spring Length (L_s)	7.0 cm
Spring Minimum Length (L_I)	9.0 cm
Spring Maximum Length (L_G)	10.8 cm
Spring Minimum Displacement (X_I)	2.0 cm
Spring Maximum Displacement (X_G)	3.8 cm

Since the spring constant and displacement parameters are known, as listed above, the force in the spring at the inverted and grounded positions can be calculated using:

$$F_S = -k \cdot x \qquad \text{(Eq.6)}$$

where x is spring displacement. The force at the inverted position corresponds to the force required to maintain the foot inversion. Since we know the overall body weight (F_w=910 N), we can find the inversion force as a fraction percent of overall body weight.

$$\%Fw = F_1 = \frac{F_1}{Fw} \cdot 100 = \frac{k \cdot X_1}{Fw} \cdot 100 \qquad \text{(Eq.7)}$$

Thus the inversion force (F_I) can be calculated for patients of varying weights. This inversion force was about 4% of the body weight. This force can be used to find the appropriate spring and displacement at the inverted position for patients of varying body weights. Thus the design driver for choosing the appropriate spring is:

$$k = \frac{0.04 \cdot Fw}{X_1} \qquad \text{(Eq.8)}$$

The two variables to be determined are the spring constant and displacement at the inverted position. An additional constraint on spring selection is that the maximum force in the spring should not exceed 10% of the body weight. This can be checked by using Eq XX once the spring constant has been determined, and comparing that force to the overall body weight (F_w).

The maximum displacement of the spring is a function of the gap between the foot bed and the bottom of the shoe (X_F) and the designed heel inversion (X_A). For the prototype, this gap was set at 2cm to insure adequate space for the heel to maneuver. However, the recommendation is a spacing of 1.5cm since this will leave enough space for the heel to invert up to 25°, which is the upper limit of our inversion range. The spring extension from the required heel inversion can be calculated by the geometry of the lever, which will be unchanged for all PTTOs. This displacement (X_A) is calculated from:

$$X_A = (4.5\text{ cm})\cdot\sin(\beta) \qquad \text{(Eq.9)}$$

Now the maximum spring length at the grounded position can be calculated:

$$X_G = X_I + X_F + X_A \qquad \text{(Eq.10)}$$

Applying this displacement to the spring force equation in Eq XX, page XX will give the maximum spring force in the mechanism (F_G), and it should satisfy:

$$F_G < 0.10\cdot F_w \qquad \text{(Eq.11)}$$

The final consideration is that the maximum spring length (L_G) is small enough to allow the spring to fit on the orthotic.

Cable

The main function of the cable is to connect the lever and spring system to the foot bed. When the spring compresses rotating the lever upward, it creates tension in this cable which forces the foot bed and consequently the heel upward. Conversely, when the potential energy in the spring is increased as it is stretched; the cable becomes slack, allowing the heel to evert.

Stirrup

The stirrup remains in contact with the bottom of the shoe for all phases of the gait cycle. It prevents the stirrup slat from moving downward when the ankle moves down and the body weight is applied, because that force is opposed by the bottom of the shoe. This is critical for causing lever rotation and heel eversion during pronation.

Foot bed

The foot bed is a static support for the arch and is molded around the foot. It is connected to the lever by the cable. The foot bed moves up with respect to the shoe during heel rise, and then back downward during landing. The forced motion of the foot bed is critical for both heel inversion and eversion.

Adjustable Spring Joint

The adjustable spring joint has holes aligned vertically to allow for varying connection points for the upper spring. This adjustable facet serves two purposes. The first is that since there will be some variability among patients, the spring can simply be initially stretched to a different length. This allows for some flexibility with the chosen spring and eliminates the hassle and expense of ordering another spring if the parameters do not function exactly as intended. Second, if the heel inversion design goal is changed for the same patient, the spring could possibly be adjusted to a different position without having to modify other parts of the mechanism. Refer to figure 21 on page 31.

Gummy Joint

To give the orthotic additional stability, a gummy joint is used. It is placed between the two pieces of the orthotic on the lateral side of the ankle. It also makes the orthotic easier to put on, by keeping the leg cuff and foot bed separated. Refer to figure 20 on page 31.

MANUFACTURING PLAN

The prototype was manufactured by molding polypropylene (PP) onto a team member's foot model cast. The orthotic was articulated to define the necessary shape. Components such as the lever, stirrup, stirrup slat were machined using the bandsaw, drill and a grinding machine. Components were attached to the prototype using binding posts, a special spring joint and a customized cable joint. Finally, the spring and cable were attached to the orthotic.

The following procedure was used to fabricate the prototype. A bill materials outlining different components and materials used is in Appendix F on page 59.

Plaster Model

- A team member's foot was placed in nylon sock and covered with plastic sheet. The foot was wrapped with thin epoxy/plaster material. Once dry the epoxy was cut off and cast prepared.
- A metallic tube was inserted into cast to provide a rigid gripping mechanism.
- Cast was filled with plaster and vermiculite additive. Cast was allowed to dry for 3 hours to ensure good adhesion.
- The solidified plaster was removed from cast and extra material was sanded down.
- Additional plaster was applied to sections of the model to provide space in the plastic mold for comfort and protective padding.

Adjustable Spring Joint

- Aluminum stock was machined using bandsaw to appropriate dimensions. The piece was then smoothened with a grinder. The holes, for adjustable spring connections, were formed by center punching and then were drilled into the component.

Stirrup Slat, Stirrup, and Lever

- The stirrup slat, stirrup and the lever were machined using a simple bandsaw. Rough edges were smoothened out using grinding wheels. The components were buffed to provide a cleaner surface finish.
- Holes were drilled into stirrup slat and lever where required.

Plastic Mold

- Plaster model was placed in oven to bring it to room temperature. This allowed a better cooling and adhesion of plastic mold to foot model.

- A gummy joint and an adjustable spring joint (Refer to Figure. 20&21, page 29) was fixed using a simple fastener to the foot model. This will ensure that the components fit into the plastic mold once formed.
- Polypropylene (1/8") was placed in oven at 395°F
- Multipurpose adhesive was applied at locations of where reinforcing PP sections will be applied.
- Glassy PP was applied onto the plaster model, with reinforcing PP sections added to force bearing areas of the mold (footbed, spring connection, lever location)
- After cooling to room temperature, required PTTO shape cut from mold.
- The PTTO was cut into two components, the foot bed and the upper leg cuff portion
- Orthotic was articulated to required shape by grinding and smoothening out rough edges.
- A thinner was applied onto orthotic. Butane torch was used to flash plastic and smooth out any abrasions or rough edges.

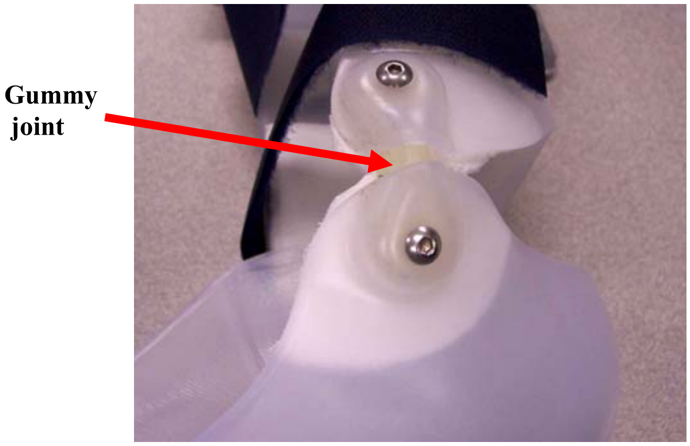

Figure 20: Gummy joint

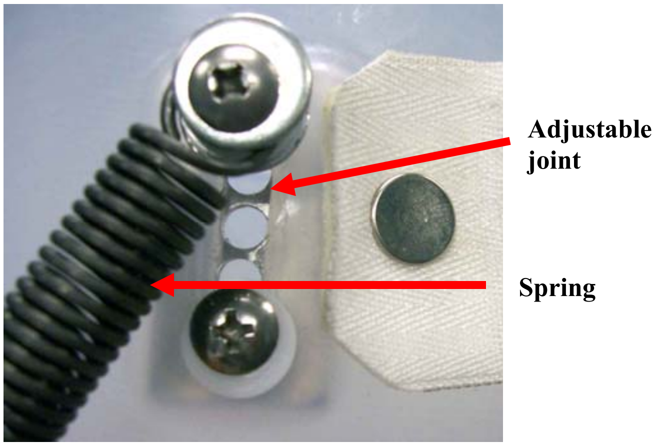

Figure 21: Adjustable spring joint

Orthotic

- First step was the install spring connecting joint into orthotic. This was done using a post screw. Holes were drilled in the orthotic in alignment with the holes in the spring connecting joint component.
- Gummy joint used to connect foot bed and leg cuff
- Hole drilled in orthotic to attach lever. Lever was attached via post screws.
- Stirrup was attached to stirrup slate via post screws and washers. Finally the stirrup slate was attached to the lever via post screws.
- Lower and upper ends of spring attached via post screws and Teflon washers.

Front Straps

- Fabric (Dacron) was glued onto attachment bracket (Refer to Figure 22). Hole was drilled into Dacron fabric and attached to right side of orthotic via post screws.
- Front opening of orthotic was measured to cut sufficient length of Velcro strip. The Velcro strip is glued onto the front side Dacron fabric strip. Hole drilled into Velcro strip and attached to left side of orthotic via post screws.
- The other straps were installed by gluing Velcro strips to the orthotic.

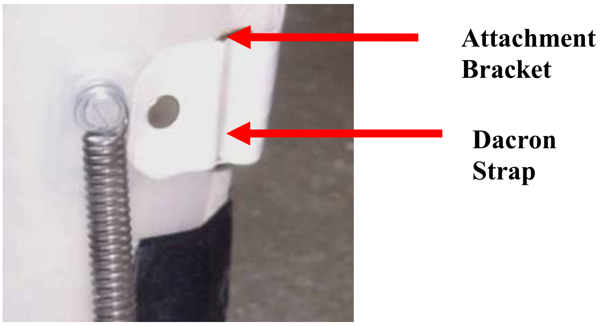

Figure 22: Front strap schematic

Other components

- *EVA Padding*: To provide padding sufficient comfort to user and reduce pain while walking, a low-density EVA was cut to shape and glued to inside of orthotic where necessary.
- *Stirrup Padding*: Shoe sole lining was glued to bottom of stirrup.

Prototype Cost

During this project we had very few budge considerations since majority of the material was provided by the University of Michigan Orthotics and Prosthetics Center. However based on material used for the mechanism, we were able to estimate total cost for the prototype mechanism

∴ Total cost of prototype = Cost of Material + Cost of labor + Cost of equipment

= \$ 49.22 + \$ 125 + \$ 40
= \$ *214.22*

This cost is based on 4 hours of technician time and average equipment cost. (*Per information provided by University of Michigan Orthotics and Prosthetics Center).* Appendix G on page 60 contains a detailed breakdown of material cost used for prototype. This cost does not include fabrication of foot model which is unique to every patient. Also the cost excludes clinical fees and any adjustments conducted by technicians to prototype.

Every patient has a different foot structure. Adjustments will be made to design specifications based on severity of posterior tibialis tendonitis problem and foot design. Thus we cannot conduct cost analysis for mass production of prototype. However average orthotic cost for a foot is approximately $ 650 which includes clinical visits, material, labor and orthotic adjustments.

TESTING

The testing of the prototype was conducted to validate if prototype was able to satisfy engineering specifications. Table 6 contains a list of various tests conducted and the corresponding results.

Table 6: Validation tests and results

Engineering Specifications	Test	Result	
Protrusions less than 1/8” on bottom	Visual Inspection	0"	🟢
Protrusions less than ½” on sides	Measured	7/8"	🔴
No exposed edges with R less than 1/16”	Visual Inspection	Yes	🟢
Zero water absorption	Satisfied by material selection of thermoplastics	Zero	🟢
Toes can dorsi-flect up to 90 degrees	Visual Inspection	90°	🟢
Ankle can dorsi-flect up to 20 degrees	Goniometer analysis	20°	🟢
0 degrees of heel inversion at pronation	Evaluate heel is flat on ground when standing and not inverted	0°	🟢
Accommodate arch sizes ¼ - 2”	N/A (customized)	N/A	🟢
Customizable to shoes sizes 6-15	N/A (customized)	N/A	🟢
Weighs less than ½ pound	Measure using normal scale	0.9 lb	🔴
Constructed from laminates, thermoplastics, and metal hardware	Visual Inspection	Yes	🟢
Life-cycle of at least 2 years	Life-cycle analysis	Yes	🟢
Able to withstand a force generated from a 300 lb person jumping 2' onto concrete	Subject jumps off 2 ft chair, walks around with orthotic in shoe	Yes	🟡
Gaps or spaces not less than 10mm	Visual Inspection	2mm	🔴
Temperature stability upto 150 °F	Test durability in high-temperature furnace	Yes	🟢
Bottom thickness less than 7/16’’	Measure using calipers	3/8"	🟢
Forced heel inversion adjustable to 5-25 ° at supination	Goniometer analysis (customized)	8°	🟡
KEY	**Passed**	🟢	
	Suspect or variable	🟡	
	Failed	🔴	

Geometry

The orthotic was tested in its current form to validate if it can assist in heel inversion at supination and pronation, maximum ankle and toe dorsi-flection and whether it can accommodate different foot geometries. Heel inversion of 5 - 25° was initially specified for the orthotic. However, we measured heel inversion of a team member's foot without the orthotic. Since actual heel inversion was siginificantly lower than upper limit of the specification, the design parameter was set to 8 ° which is within the adjustable range of 5 - 25°.

Heel inversion with the orthotic was 8°. This was measured using a goniometer. A goniometer is an instrument that either measures angles or allows an object to be rotated to a precise angular position. However, it would be difficult to determine if this orthotic would have the same inversion for a patient with posterior tibialis tendonitis. This is due to a poor distribution of the force required for heel inversion. Similarly heel inversion of 0° at pronation and ankle dorsi-flection upto 20° was confirmed using a goniometer. Dorsi-flection of the toes was confirmed using visual analysis. In this analysis, images were captured with the foot and toes flat on the ground. Next set of images were captured with toes at dorsi-flection. The angle at dorsi-flection was thus measured by measuring change in angle.

Two other key specifications of arch size and shoe size were not directly satisfied since the PTTO was customized to a team-members foot. The orthotic fit extremely well on the team-member's foot and thus the specifications of arch size and shoe size were met specifically for his foot. We are confident that our design can meet the specification range for arch size and shoe sizes since the orthotic can be custom-built for each patient's foot.

Strength and Durability

A normal prototype has a life-cycle of 2 years, which was our target in engineering specifications. We calculated life-cycle of PTTO by estimating number of cycles that key components can undergo without failure. This is included on page 22. Thus our prototype is able to meet the specification of 2 years.

To measure if PTTO can withstand impact forces, a team member jumped onto ground from a height of 3 feet. No catastrophic failure was observed. This experiment was repeated 10 times with similar results. The PTTO should also withstand high temperature if used in hot climates and should have zero water absorption. No physical experiments were conducted since all materials had a stable operating temperature of at least 150° F. Also no porous or water absorbable materials were used. These are based on material properties. Thus our prototype meets the engineering specifications of temperature stability at high temperatures and zero water absorption.

Finish and User Comfort

There were no protrusions on the bottom part of the orthotic. It also had no exposed sharp edges. This was verified by visual analysis. There is a 2 mm gap between lower and upper orthotic, which can serve as a pinch point. This can be eliminated by removing more material, increase overall gap space and solve the problem of pinch points. There are protrusions present on the side of the foot. This may hinder normal motion of opposite leg. By using a casing of soft foam material for the protruding components, one can eliminate this problem.

User comfort was evaluated by measuring weight, thickness of lower orthotic, and if user had discomfort while walking. The weight of the PTTO was 0.4 lbs higher than our specified weight limit of 0.5 lbs. This is not a significant weight increase for the patient and will not cause additional pain or discomfort. Weight can be further reduced by trimming off extra material from PTTO and using plastic springs and joints. The thickness of the lower orthotic was 3/8” which meets our specifications. The PTTO fits in the same shoe size of team member and has a good snug fit. It has a soft EVA padding for additional comfort. However the upper part of the PTTO tends to push on the malleolus of the foot which can cause pain and discomfort. This can be fixed by firmly securing the leg cuff portion of the foot to the orthotic. Overall, team member had very little discomfort while wearing the orthotic.

ENGINEERING CHANGES

Inversion angle reduced

The heel inversion design goal for the PTTO prototype was reduced from a maximum of 25° to 8°. This change was made because the unassisted heel inversion of the team member, whose foot the PTTO was designed for, was 6°. Thus, a 25° inversion is not appropriate. The new design inversion goal is slightly above the unassisted inversion so that an increase in heel inversion can be verified.

Different spring constant

The initial spring and corresponding constant was chosen based on the following three factors: (1) estimated force required to maintain heel inversion, (2) minimizing maximum space required for the spring on the leg cuff and (3) minimizing the maximum force stored in the spring. The actual force required to maintain heel inversion and the heel inversion angle are different than the initial, thus a new spring had to be chosen to match these new values.

Modified stirrup

The original stirrup was designed to go around the foot to stabilize the mechanism. A gummy joint was added to the design on the lateral side of the ankle. Due to space constraints, we redesigned the stirrup so it only extended up the medial side of the ankle.

For the same reason, the height of the stirrup was increased so that it connected to the stirrup slat above the malleolus and not directly over it as originally designed. A layout drawing of the stirrup is included in Appendix E

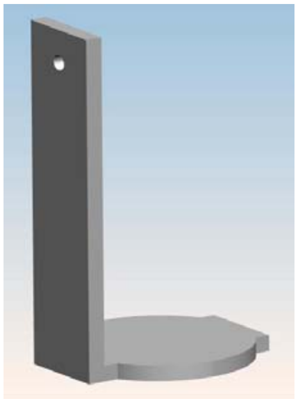

Figure 23: Redesigned Stirrup Slat

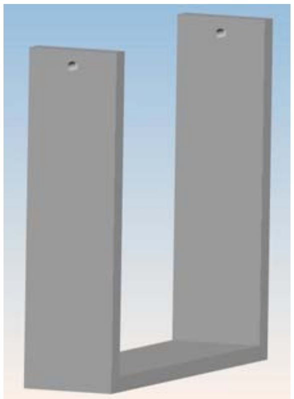

Figure 24: Original Stirrup Slat

Different Lever ratio

The original lever ratio [$R_1/(R_1+R_2)$] was reduced from 0.75 to 0.72. This slight decrease in ratio was necessary to allow for placement of washer at the connecting joints without overlapping. The lever length was slightly increased and the spacing between points B and C (Figure 12, page 15) was constrained by the diameter of the washers. These two points were placed as close together as possible, and the resulting lever ratio was not significantly less than the original design. This slight decrease does not have a significant impact.

DISCUSSION

Advantages

The PTTO is a simple mechanism which is light-weight, fits in a shoe, provides arch support, and will not be damaged due to harsh environments. Our prototype used common material and manufacturing processes for orthotics. All of its components can be found in, or ordered by, an orthotic center. These components can also be customized to each patients needs. The orthotic fits snuggly in a shoe and provides a good cushion due to low density EVA present on the inside. Most importantly the orthotic is capable of heel inversion, which was the key goal for this project. It provides the necessary force as long as it is kept in the desired location. This however, is very difficult.

Disadvantages

The issue of stability around the ankle is not an easy one to address. It is a fundamental problem for all orthotics used around the ankle, including ours. The basic problem is that it is very difficult to make something that stabilizes on soft muscle. The only feasible way to address this problem would be to design an orthotic that is self- supportive. I.e. an orthotic that does not rely on the leg to hold it up, but is designed to hold itself in position. Since the orthotic slips down the ankle, it does not provide the force necessary to effectively invert the heel. It also makes the device quite painful to wear. Instead of the orthotic hugging the malleolus, distributing the downward force, it rests on a very small area on the malleolus.

The motion of mechanism was designed to perform in two dimensions. In practice it has to be compliant with the curvature of the ankle. (Needs to work in three dimensions) To cope with this problem, the joints were left somewhat loose then desirable, so that different parts of the mechanism could extend at the angle necessary to circumnavigate the ankle. This reduces the mechanism's structural stability and also puts unnecessary stress and friction into the joints.

Another problem with our mechanism is that the stirrup and stirrup slat, do not necessarily have defined positions. That is to say, they don't automatically go where they are supposed to. There needs to be some hardware put onto place that keeps these parts from moving out of their desired locations.

Given the chance to do the project again, it would better to address the design project not from how to get the heel to invert, but rather where to put the force. It would be beneficial to investigate a solid location that can be used to pull or push from, while remaining true to the other design requirements. A rigorous analysis and modeling of the foot movements would also benefit.

RECOMMENDATIONS

There are several things that could be done to improve the performance and appearance of the prototype orthotic.

Stabilization

The most important element about the PTTO is that it works. However, it will not work properly until the two pieces (leg cuff and foot bed) of the orthotic are stabilized. Stabilizing the leg cuff will be extremely difficult and is already a bane for the people who currently design them. The orthotic works by bringing the leg cuff and foot bed together, which occurs for the PTTO. Since the leg cuff and the foot bed are not secured to respective locations, the heel does not necessarily invert when they approach each other. We recommend that the structure be made self supportive, so that it does not rely so much on adhering to the patient. To a lesser extent this is also true for the lower piece of the orthotic. Currently this is not as issue for the lower orthotic.

One piece of hardware used on the prototype to help stability is the gummy joint, which is placed on the side of the orthotic opposite to the mechanism. The gummy joint contributes to the stability of the orthotic; however it does inhibit the inversion of the heel to some degree. It is recommended that another sort of joint be custom made for this location. One that would help with stability just as much as the gummy joint, but not inhibit the inversion of the heel.

Mechanism

All of the post screws should be stainless steel and ordered to be the exact size needed in each location. There is significant shear stress on them to be made from aluminum. They could also be replaced with rotational joints. All joints consist of components that rotate and thus have potential to loosen up while the orthotic is in use.

The exposed mechanism should be given a casing. Uncovered, the mechanism has the potential to become entangled in clothing or harm the leg opposite to it by rubbing. Any sort of wear and tear of this nature would reduce the PTTO's life time, effectiveness, and be irritating to the user.

To overcome the circumnavigation around the ankle, a joint that moves with and around the ankle would benefit. It would be a far more stable device and potentially a much smaller device. This could be an entire new project.

It would be a good idea to look into alternative springs. The benefits of using metal springs are that they provide a lot of force in a small package, different spring designs, and they are relatively cheap. The down side is that they are ugly, bulky, can pinch, and are hard to put on the orthotic.

Another important requirement for the design is that orthotic centers can manufacture the orthotic. Therefore the mechanism needs to be standardized to fit broad ranges of individuals. It would help to make some general guidelines for the building of this mechanism. A kit that could be used with the custom made orthotic would complete our design.

Fool Proof

The patient should not have to understand the mechanism to use the orthotic. The main part of the orthotic can be put on without difficulty. The problem comes with the stirrup and stirrup slat. These two pieces do not have a fixed location. The design should be set up in such a way, such that there is only one correct orientation. It is possible that the stirrup slat could be eliminated without causing too many problems. Its purpose is to allow the ankle to move freely, but it makes the orthotic very unstable.

New Designs

An entire project could be devoted to the development of a design to enable the orthotic to stay on the ankle. Another project could be making a supportive ankle joint that allows full range of motion while remaining compliant with the round nature of the ankle. A device than can determine forces within the ankle or the force necessary for heel inversion in different patients would be effective. This project is not one solitary design problem, but several, each more challenging than the next.

PROJECT PLAN

It is necessary to plan in advance and assign major responsibilities in a project. One can thus hold team-members accountable for their responsibilities and prevent major delays. Thus a project timeline is critical. It helps in keeping the project on schedule and helps in implementing a recovery plan if required.

A detailed project timeline is attached in Appendix H on page 61

The important steps to ensure a solid outcome of this project are as follows

- Form team and assign roles
- Ensure project problem definition and background has been well understood.
- Stress the importance of organizing and planning activities.
- Brainstorm and plan to get it right the first time
- Prepare for all design reviews

CONCLUSIONS

The objective of this design project was to implement a device capable of resting the posterior tibialis tendon (for less advanced stages of PTT), or (for more advanced cases) to perform the functions of the tendon by initiating heel inversion, while allowing full range of foot motion. Our key engineering specifications were adjustable heel inversion between 5-25° and an arch support that can accommodate arch heights ranging from 1/4 – 2”. The PTTO used a simple mechanism of spring, levers and cable and assists in heel inversion. This mechanism is powered by the force generated from the foot hitting the ground. Parameters for the design were developed using force analysis and simple engineering judgment. The design parameters can be adjusted to accommodate different foot geometries and varying degrees of heel inversion. The prototype was manufactured from aluminum and thermoplastics such as polypropylene and EVA. Although the inversion force is unreliable and inconsistent, it can be corrected by securing the leg cuff. The prototype is light-weight, durable and fits in a shoe. The PTTO can be improved by securing the leg cuff, using stronger and non-metallic components and minimizing protrusions on the medial side of the ankle. With these improvements the PTTO will be able to meet all engineering specifications. Thus the PTTO will be marketable, patentable and beneficial to patients with posterior tibilias tendonitis.

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Printed Resources

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- Professor Albert Shih, Head Lecturer, ME 450, Fall 2006
- Adrian Vine, GSI, ME 450, Fall 2006

Appendix A – Other Concepts

These are some other concepts that were considered by the previous design team. We rejected the designs were rejected based on the reasons listed for each concept below. Ultimately, all these designs did not have a good power source and did not guide the heel through the required plane of motion.

Four Bar Linkage

A four bar linkage system would not be a reasonable design solution because it takes up a lot of space, which is not available within the constraints of a shoe. Moreover, especially considering the geometry issue, it would be difficult to apply a strong and stable enough force to guide the heel through its 3-dimensional motion.

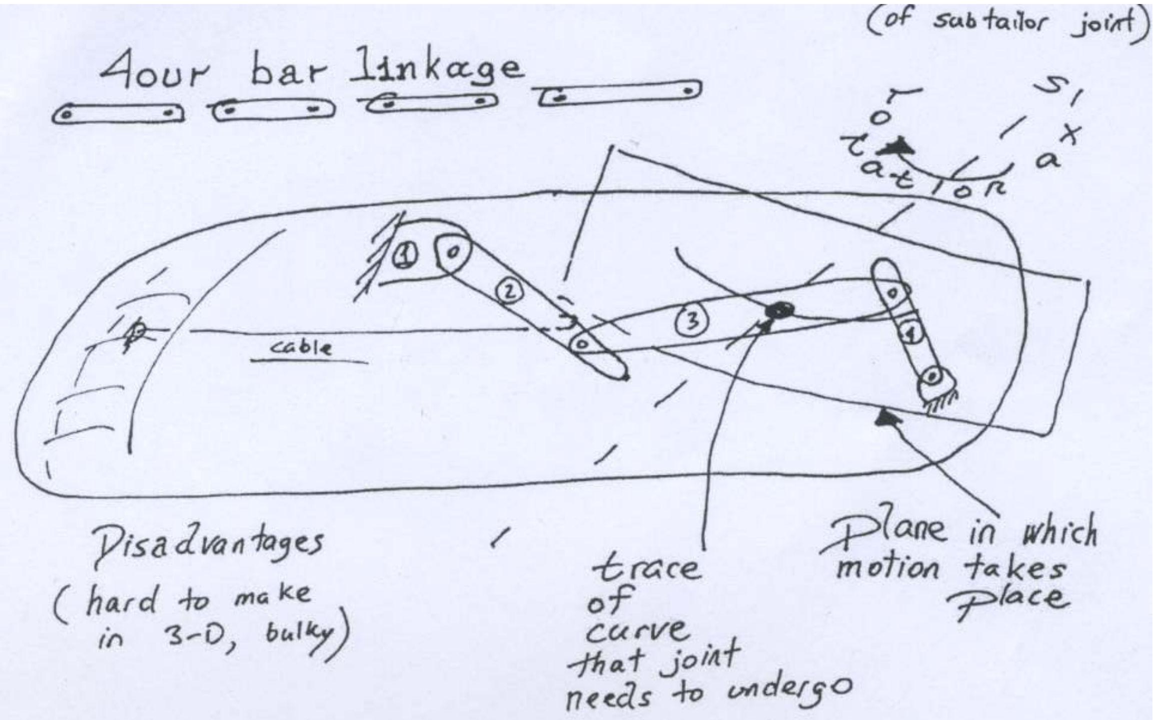

Figure A1: Four Bar Linkage – Toe driven four bar linkage

Cable and Piston

This design seems to produce the opposite motion from that which is desired. When the heel leaves the ground, the rod attached to the heel would press into the piston. However, rather than applying a force in the desired direction of rotation, the piston resists the motion of the rod in this direction.

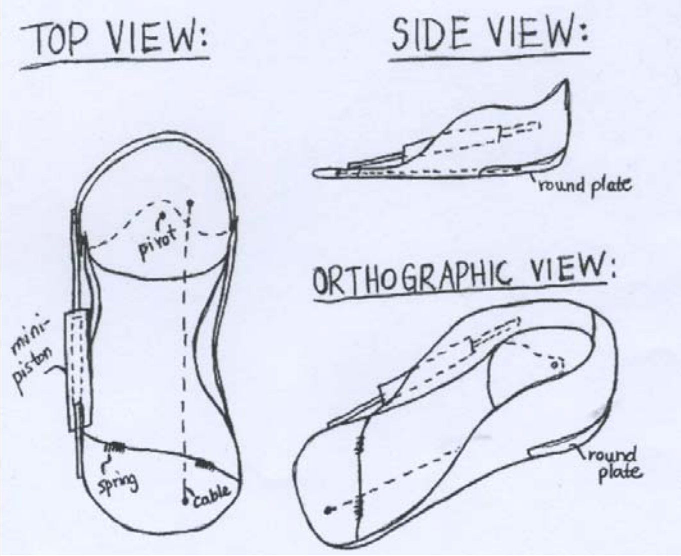

Figure A2: Cable and Piston – Piston used to drive heel inversion

Slotted Heel Plate

This design is only capable of rotating the heel in a horizontal plane, which is not the correct plane of rotation. Also with the cable, there is not enough power and not enough displacement when the orthotic rotates about the toes.

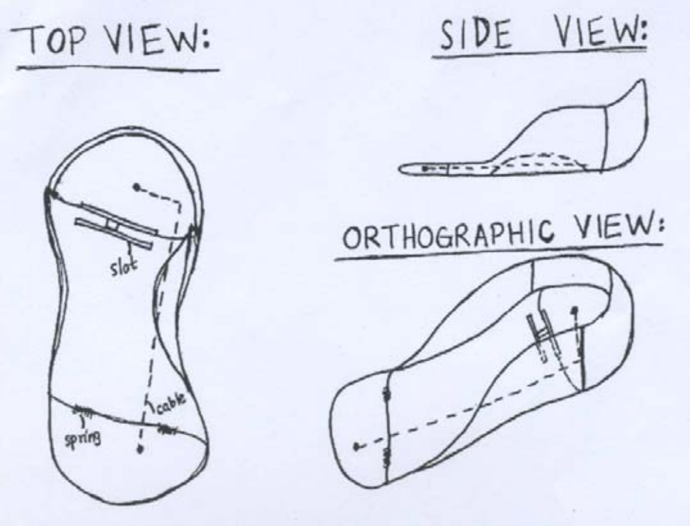

Figure A3: Slotted Heel Plate – Entire heel inverts using a slot

Arch adjustment

This design does not rotate the heel in the correct plane and is too complex

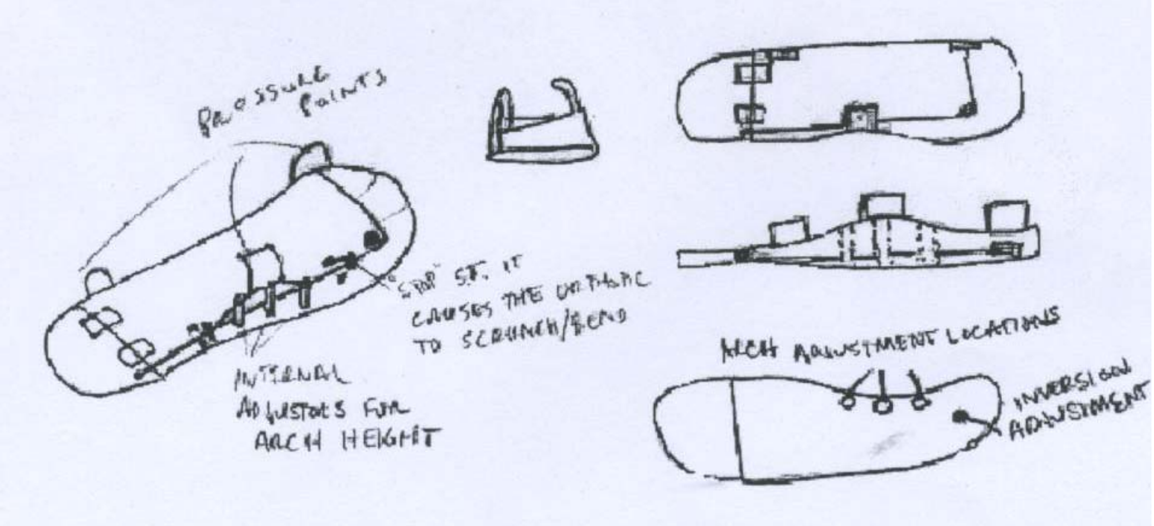

Figure A4: Arch adjustment – Too complex for use

Heel Pivot

The power source is not strong or stable enough to rotate the heel, and the heel inversion is only in the horizontal plane.

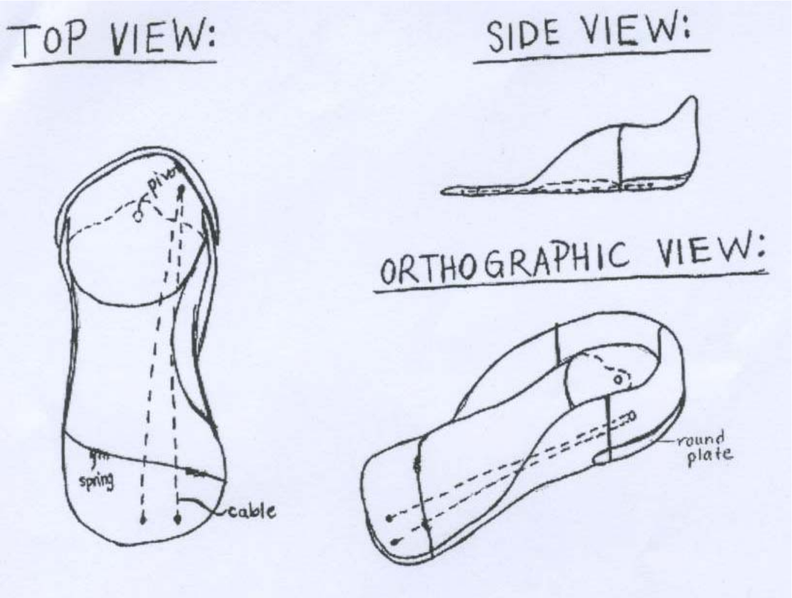

Figure A5: Heel Pivot – Entire heel inverts using a cable

Ankle Support

Toe powered heel inversion while keeping the ankle and foot stabilized. Too much restriction may inhabit heel inversion.

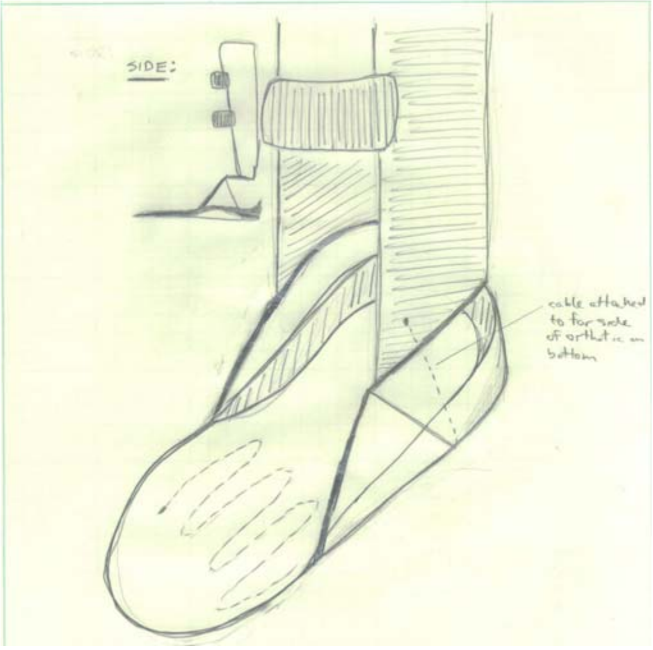

Figure A6: Ankle support – Added ankle support

Appendix C – Force Analysis

This appendix includes detailed calculations on how spring and lever dimensions and specifications were defined.

Ratio of Lever Distances

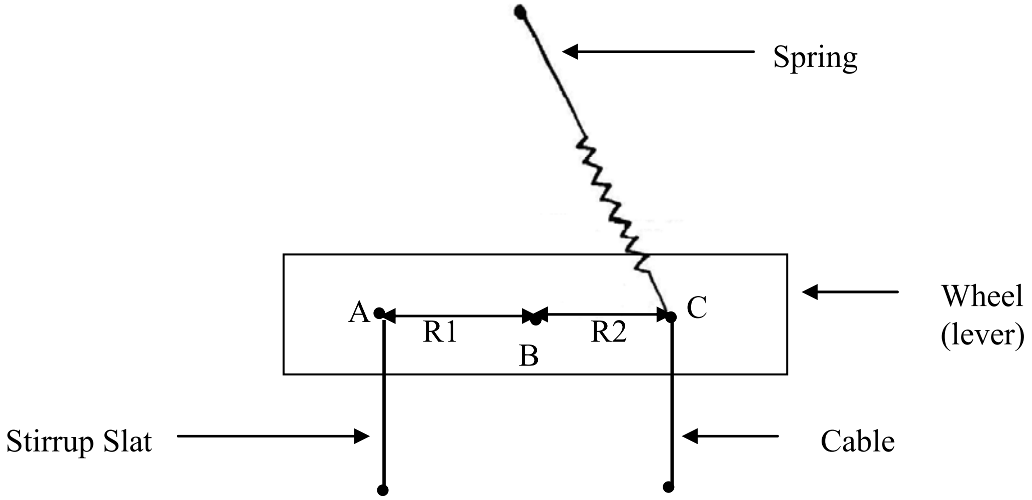

Figure C1: Wheel (lever) schematic

The lever contains three points and rotates about point A. Thus we need to find the ratio of distances AB and AC so that points B and C move down the correct distance. Two-dimensional simulation in Unigraphics showed for 25 degree rotation of our foot, point C must move up by 2 cm and point B by 1.5 cm. Refer to Figure C2 below for visualization of this rotation.

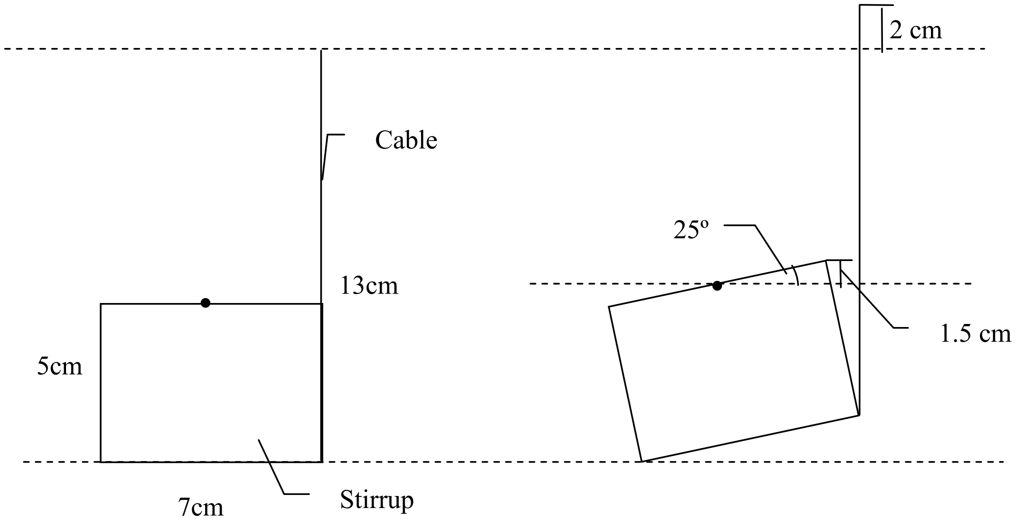

Figure C2: Vertical displacement schematic

Using this information, we were able to use similar triangles analysis, since both points B and C rotate about the same point, but with different lever arms as seen in Figure C3 below.

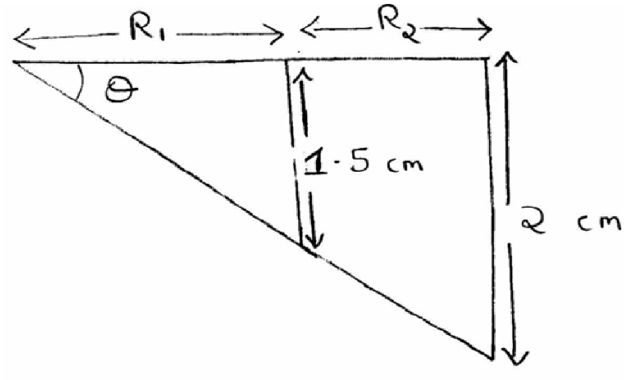

Figure C3: Wheel (lever) displacement ratio

Using the triangles, we came up with a ratio for the lengths, based on the ratio of the vertical distance traveled as seen below.

$$\frac{\Delta \mathrm{By}}{\Delta \mathrm{Cy}} = \frac{1.5}{2} = \frac{3}{4} = \frac{R_1}{R_1 + R_2} \qquad \text{(Eq.C1)}$$

A overall lever length was set to 4.5 cm, with points A and C set ½ cm from the edges. The resulting distance AC is 3.5 cm giving the equation below.

$$R_1 + R_2 = 3.5 \text{ cm} \qquad \text{(Eq.C2)}$$

Using Eq.C1 to get the ratio, we find that the distance AB has to be 2.625 cm.

Inverted FBD and Equations

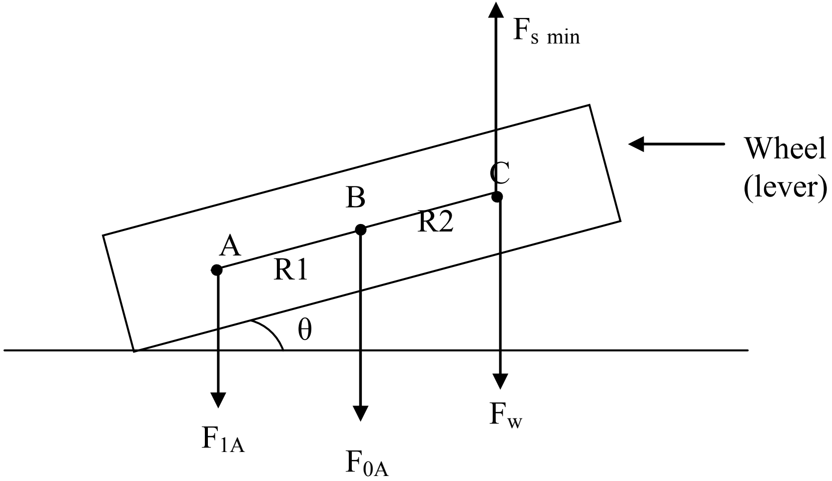

Figure C4: Inverted wheel (lever) FBD

Sum of forces was taken in the vertical direction

$\sum F_y$: $F_{s\ min} + F_{oA} - F_{1A} - F_w = 0$ (Eq.C3)

The forces at A and B are negligible as compared with the forces at C, and thus are approximated to zero. Thus, we do not have to use sum of moment equations.

$F_{oA} = 0$ (Approximated to zero) (Eq.C4)

$F_{1A} = 0$ (Approximated to zero) (Eq.C5)

Since the other forces are approximated to zero, the force in the spring equals the force in the weight or tension on the lower cable.

$\therefore\ F_{s\ min} = F_w$ (Eq.C6)

The spring constant is defined below, where the F_{smin} is the force in the spring and X_D is the displacement of the spring from equilibrium, at the inverted position.

$F_{s\ min} = k\ X_D$ (Eq.C7)

It was very difficult to get an accurate force required to invert the heel, so we approximated the upper bound of the force at 10% of the body weight. For our prototype this was 20 lbf or about 90 N, giving the equation for spring constant below.

$$k = \frac{F_{s\min}}{X_D} = \frac{90N}{X_D} \qquad \text{(Eq.C8)}$$

The angle at the inverted position can be calculated because we know the distance AC (3.5 cm) and the vertical distance traveled by point C (2 cm). Thus we have a right triangle with the hypotenuse of length 3.5 cm and vertical component of length 2 cm. Using the relationship in the equation below, we can find the angle θ referenced in Figure C4, page 40.

$$\sin(\theta) = \frac{2}{R_1 + R_2} = \frac{2}{3.5} \Rightarrow \theta = \sin^{-1}(\tfrac{2}{3.5}) = 29.75^\circ \qquad \text{(Eq.C9)}$$

The dimension 29.75 degrees indicates that the wheel (lever) must rotate upward by that amount, to get the required vertical displacement of points B (1.5 cm) and C (2 cm).

Grounded FBD and Equations

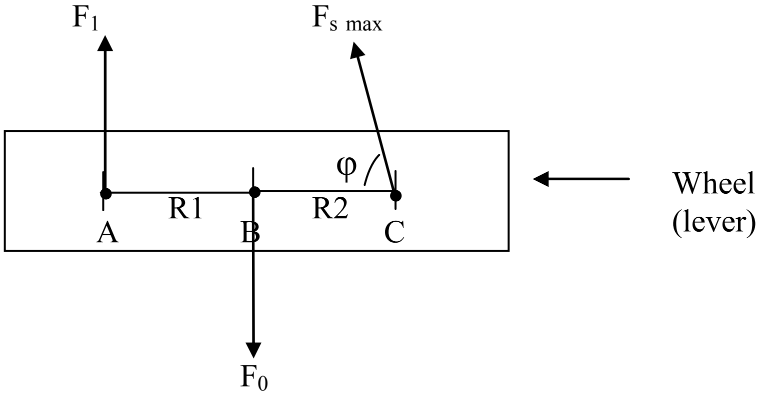

Figure C5: Grounded wheel (lever) FBD

Sum of forces in the vertical direction were taken as shown below

$\sum F_y : F_{1B} + F_{s\ max} \sin\phi - F_{0B} = 0$ (Eq.C10)

Then the sum of vertical moments about points A and B were taken.

$\sum M_{0_y} :\ F_{s\ max} \sin\phi\ R_2 - F_{1B}\,R_1 = 0$ (Eq.C11)

$\sum M_{1_y} :\ F_{s\ max} \sin\phi\ (R_1 + R_2) - F_{0B}\,R_1 = 0$ (Eq.C12)

This gives us three equations and three unknowns. However, the unknown angle φ can be calculated once the spring has been chosen since it depends on the attachment point of the spring. This leaves us with only three unknown variables. Before we can solve for the unknown forces, we must find the displacement of the spring at the new position, and apply this to the definition of spring forces. The displacement of the spring in the grounded position in reference to the inverted displacement is illustrated in Figure C6,

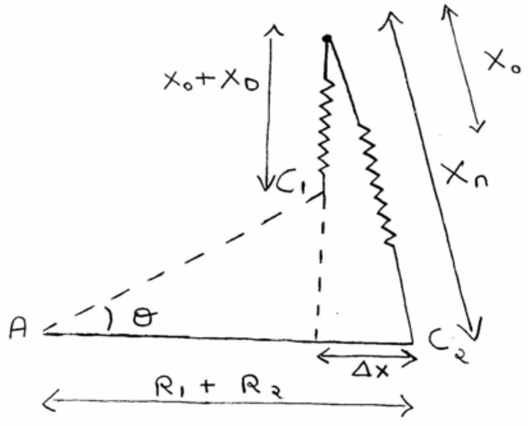

Figure C6: Spring Positional Analysis

The horizontal arm on the spring triangle (Δx) shown above is the horizontal distance traveled by point C when it rotates 29.75 degrees to the grounded position. At the inverted position, the horizontal component of the length AC is $(R_1+R_2)\cos(\theta)$. In the grounded position the entire length is in the horizontal place so the length AC is R_1+R_2. Thus the equation for this displacement is the difference of these lengths and is shown in the equation below.

$$\Delta X = (R_1 + R_2) - (R_1 + R_2)\cos(\theta) = (R_1 + R_2)[1 - \cos(\theta)] \qquad \text{(Eq.C13)}$$

Now to find the overall length of the spring in the grounded position (X_n), we use right triangle properties to get the equation for X_n below.

$$X_n = \frac{\Delta X}{\cos(\phi)} = \frac{(R_1 + R_2)[1 - \cos(\theta)]}{\cos(\phi)} \qquad \text{(Eq.C14)}$$

The new spring displacement (X_s) is the overall spring length (X_n) subtracted by the spring length at equilibrium (X_0) as seen in the equation below.

$$X_s = X_n - X_0 = \frac{(R_1 + R_2)[1 - \cos(\theta)]}{\cos(\phi)} - X_0 \qquad \text{(Eq.C15)}$$

Now we can solve the force and moment equations above for the unknown forces in terms of known variables, giving us the equations below.

$$F_{s\max} = kX_s = k \cdot \left(\frac{(R_1 + R_2)[1 - \cos(\theta)]}{\cos(\phi)} - X_0 \right) \qquad \text{(Eq.C16)}$$

$$F_{1B} = k \cdot \left(\frac{R_2}{R_1} \right) \cdot \left(\frac{(R_1 + R_2)[1 - \cos(\theta)]}{\cos(\phi)} - X_0 \right) \cdot \sin(\phi) \qquad \text{(Eq.C17)}$$

$$F_{0B} = k \cdot \left(\frac{R_1 + R_2}{R_1} \right) \cdot \left(\frac{(R_1 + R_2)[1 - \cos(\theta)]}{\cos(\phi)} - X_0 \right) \cdot \sin(\phi) \qquad \text{(Eq.C18)}$$

We used the equation for the spring constant from the inverted position because the only unknown component is the initial displacement of the spring. The orthotic was designed so that the spring is directly above the cable in the inverted position, simplifying calculations. Once the spring had been found, we were able to find numerical values for all forces, displacements and angles. We first found the angle φ knowing the spring length, which is shown below.

$$\phi = \cos^{-1}\left(\frac{\Delta X}{X_n}\right) = \cos^{-1}\left(\frac{3.5 \cdot (1 - \cos(29.75))}{10.3}\right) = 87.4^\circ \qquad \text{(Eq.C19)}$$

Then all the remaining variables are known allowing us to solve for the unknown forces, which are listed below.

Inverted Forces:

$F_{s\ min} = k\ X_D = 89.2N$ (Eq.C20)

Grounded Forces:

$$F_{s\max} = kX_s = k \cdot \left(\frac{(R_1 + R_2)[1 - \cos(\theta)]}{\cos(\phi)} - X_0 \right) = 148N \quad \text{(Eq.C21)}$$

$$F_{1B} = k \cdot \left(\frac{R_2}{R_1} \right) \cdot \left(\frac{(R_1 + R_2)[1 - \cos(\theta)]}{\cos(\phi)} - X_0 \right) \cdot \sin(\phi) = 43.2N \quad \text{(Eq.C22)}$$

$$F_{0B} = k \cdot \left(\frac{R_1 + R_2}{R_1} \right) \cdot \left(\frac{(R_1 + R_2)[1 - \cos(\theta)]}{\cos(\phi)} - X_0 \right) \cdot \sin(\phi) = 173N \quad \text{(Eq.C23)}$$

All the pertinent forces, displacements and spring specifications are listed in Table C1.

Table C1: List of forces and spring displacements and specifications

Description	Numerical Values
Spring constant (k)	25.5 N/cm
Point C horizontal displacement (ΔX)	0.46 cm
Resting length (X_0)	5.08 cm
Force to invert heel (F_w)	89.2 N
Inverted spring displacement (X_D)	3.15 cm
Inverted spring force (F_{smin})	89.2 N
Inverted stirrup slat force (F_{1A})	0 N
Inverted leg cuff force (F_{0A})	0 N
Grounded spring displacement (X_s)	5.8 cm
Grounded overall length (X_n)	11.4 cm
Grounded spring force (F_{smax})	148 N
Grounded stirrup slat force (F_{1B})	43.2 N
Grounded leg cuff force (F_{0B})	173 N

Appendix D – Failure/Safety Analysis

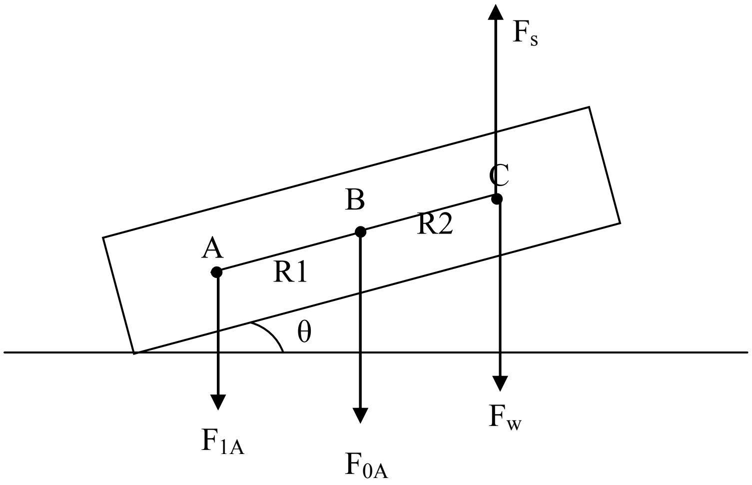

Figure D1: Inverted Lever Schematic

To find F_{0A} we took the sum of the moments at point A. From the pervious force analysis the variables F_s and F_w are known. We assumed $F_w = 0$ because this would give a larger F_{0A}, increasing the safety factor.

$$\sum M_A = 0$$

$$\sum M_A = R1 \cdot F_{0A} - (R1 + R2) \cdot F_S = 0$$

$$F_{0A} = \frac{(R1 + R2)}{R1} \cdot F_S$$

$$\frac{R_1 + R_2}{R_1} = 1.39$$

With the F_{0A} and area we are able to calculate the stress at the joint. The cross-sectional area is calculated by assuming that the joint is a solid cylinder. This assumption is valid if the set screw goes all the way through the entire diameter of the joint.

$$A_{0A} = \frac{\pi}{4} \cdot d^2 \text{, d = 4.76E-3 m}$$

A_{0A} = 1.78E-5 m^2

The stress $\sigma_{0A} = F_{0A}/A_{0A}$,

Table D1 below, shows the maximum and minimum values for the force and stress at point B.

Table D1: Minimum and Maximum Stresses at Point B

$F_{s\ min} = 48$ N	$F_{0A\ min} = 48.61$ N	$\sigma_{0A\ min} = 2.73$ MPa
$F_{s\ max} = 66$ N	$F_{0A\ max} = 91.67$ N	$\sigma_{0A\ max} = 5.14$ MPa

The amplitude of stress during a cycle σ_a is found using:

$\sigma_a = (\sigma_{0A\ max} + \sigma_{0A\ min})/2$

This gives us a yield stress amplitude of $\sigma_a = 3.94$ MPa. A safety factor of 10 was applied to account for stress concentration at this joint giving a new yield stress amplitude of $\sigma_a = 39.4$ MPa.