WORCESTER POLYTECHNIC INSTITUTE

Passive, Variable-flex Prosthetic Ankle

Major Qualifying Project

Patent Pending

Team Members:
Sarah Basehore, Tyler Bouchard, John Foy, Jerrod Heiser, Alexander Verrelli, Chadwick Whitcher

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Project Advisor:
Professor Christopher Brown

Abstract:
In the US alone, there are approximately 1.7 million individuals currently living with limb loss. This number is only growing, with 120,000 below-knee amputations performed annually. Most current prosthetics on the market have problems that stem from either a lack of performance or high cost. There is a growing need to provide an affordable lower limb prosthetic device that provides functionality for everyday activities. The objective of this project was to design and prototype a successful load-limiting below knee K3 prosthetic ankle and foot. A CAD model was first created in SolidWorks and then fabricated using CNC machining. The prototype was then tested on a human subject amputee using force plates and analyzed using Netforce software for data acquisition.

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1.0: Introduction

1.1: Objective

The objective of this Major Qualifying Project (MQP) was to use axiomatic design processes to design and prototype a successful load-limiting below knee prosthetic. The success of the prototype was determined by its ability to perform as a K3 prosthetic. A K3 prosthetic is one that is capable of accomplishing everyday mechanical movements such as walking, stepping up stairs and going up inclines and down declines. Please reference Section 1.3.1 for additional descriptions of the mechanical requirements for a K3 prosthetic.

Part of the objective is to test the prosthetic device using standard force plate and human gait analysis methods. The ability of the prototype to serve as load limiting to the residual limb was determined through specific questions to our experimental subject and through an analysis of the duration of time the prosthetic spent in contact with the ground.

The main constraint for the design and production of the prototype was to keep the overall cost within $5,000. This amount was chosen in order to keep the prosthetic within the price range of most medical coverage plans. The significance here is that currently, many prosthetics fall outside of coverage plans and therefore put a heavy financial burden on the amputee.

1.2: Rationale

There is a growing need for prosthetic devices around the world, especially in the United States. In the U.S. alone, there are approximately 1.7 million people living with limb loss ("Amputation Statistics of Cause, Limb Loss", 2008), and 1 out of every 200 people has had an amputation ("Amputation", 2011). In lower limb amputations specifically, the affected area of the leg is removed and the residual limb is formed to fit into a pylon cup. The most difficult and dangerous part of these amputations is avoiding infection to the residual limb and reducing pain and pressure on the limb while walking. If the amputation is successful, the patient must learn to walk again, and simple everyday tasks suddenly become extremely difficult and time consuming. Below knee amputations are most common; in the U.S alone there are over 120,000 below knee amputations performed annually ("Current Estimates from the National Health Interview Survey", 10). More than 50% of these amputations are caused by diabetes. The remaining amputations are caused by peripheral arterial disease and traumatic events ("Current Estimates from the National Health Interview Survey", 10).

With the aid of prostheses and other adaptive devices, it is often possible to make a near perfect return to everyday life (Garrity & Coulter, 2010). The ultimate goal of a prosthetic device is to restore the body part to its former, or normal, condition. When activity is averaged over a number of steps, each of twenty-five lower limb and trunk muscles involved with the walking process has a characteristic average activity pattern over the "step cycle" and retains a similar pattern within most people ("Amputation", 2011). Therefore, the activity of walking or running can be broken down by the step cycle and recreated in a prosthetic device in order to restore the normal function of the leg.

The natural human leg has more flexibility, dexterity, and adaptability than any current, state-of-the-art, artificial replacement available today, commercially or otherwise. The materials used to make prosthetic limbs are barely adequate, constraining many design considerations ("Limb Loss in the United States", 2010). The conventional prosthetic limb has a lifespan of approximately three years, as compared to a normal leg, which is limited only by the lifespan of the person to whom it is attached and said individual's propensity for losing or retaining limbs (Garrity & Coulter, 2010). High-end models include hydraulic systems with a motor to provide power to the device, while low-end models depend on the user to provide all movements and rely on the properties of the materials for energy return. Prices for these models range drastically depending on the level of technology used in the device.

The disadvantages of the prosthetics on the market stem from a lack of performance or a cost that places them outside the price range for the majority of the market. Most medical insurance companies will either cover up to $5,000 dollars for a prosthetic, or up to a max of 80% of the cost. However, the most functional devices cost much more than $5,000. This gap in price places a financial burden on the amputees who also have to pay for additional medical bills and physical therapy bills because of the incident. Also, as mentioned earlier, cheaper devices that would be covered do not transfer energy at the same efficiency of the higher end models. This gap in performance leads to a higher risk for the amputee via fatigue and damage to the residual limb due to higher load concentrations.

1.3 State-of-the-Art

There currently are many prosthetic devices available for below knee amputees. Many of these are excellent designs and can accurately imitate a normal human foot and ankle. All designs on the market are rated with a K-Level classification. This rating depends on the prosthetic’s ability to simulate the motions and capabilities of a normal ankle. By studying the designs currently on the market, two major problems were identified. Those designs that were rated as K4 devices had a high ability to perform, but cost more than the average amputee can spend. On the other end of the spectrum, there are K0 and K1 devices that are affordable, but cannot perform up to the standards of a human ankle. This gap in the market creates a great demand for a low-cost, high-performance ankle that this design covers. Additional market products besides those mentioned in this section can be seen in Appendix A: Additional Existing Prosthetic Models.

1.3.1 K-Level Classifications

There is a large variety of prosthetic devices currently on the market that vary greatly in functional ability as well as cost. A common measurement to help differentiate between lower-leg prosthetic devices is referred to as K-Levels. Each prosthetic device can be separate into one of five K-Levels based on its functional ability and intended market. ("K Levels," 2013) The K-Level classification allows doctors to recommend a specific kind of prosthetic device based on the functional needs dictated by each individual patient's lifestyle. (Nelson, 2010)

The K-level classification for a prosthetic device is based on the functional ability that the device offers to the user. This functional ability is measured by the mobility that it offers the user in terms of their ability to navigate their environment. ("Outcome Measures in Lower Limb Prosthetics," 2012) The breakdown of these requirements is defined in Figure 1 below:

K-Classification	Functional Requirements
K0	Does not have the ability to safely move around an environment without assistance
K1	Has the ability to walk across level surfaces at normal speeds ("K Levels," 2013)
K2	Has the ability to travers low-level environmental barriers such as curbs, stairs, or uneven surfaces ("Function Levels for Prosthetic Limbs," 2013)
K3	Has the ability to move at a variable cadence, as well as most environmental barriers ("Outcome Measures in Lower Limb Prosthetics," 2012)
K4	Exceeds basic ambulation skills in high impact and high stress situations. Typically built for athletes ("Prosthetics and Orthotics Modifiers K0, K1, K2, K3, K4 and KF," 2014)

Figure 1: Prosthetic Ankle Classification Table

1.3.2 High-End Prosthetic Device

Many of the devices that exist on the market today are geared towards creating the best motion and function possible through the use of advanced technology. However, most of these devices cost more than the average user is able to pay, and therefore fall to a luxury market. One such example, as can be seen in Figure 2 below, is the BIOM Ankle System with Bionic Propulsion.

Figure 2: BioM Prosthetic Ankle

This ankle features a unique method to actively supply power to the ankle's motion. This net power inwardly simulates the lost calf muscle of the patient which allows for normal ankle function during movement. This ankle also has Bluetooth implemented technology to adjust systems electronically. (Herr et al., 2013)
The main components of the system are dampers and springs which cannot release more energy than is stored within them which provides no positive net power.

However, this power comes at a cost which is mainly attached to the cost of the device. This model is currently sold in the British market for £30,000 which equates to around $50,000. There are reimbursement options but with the different health care systems we have in the United States, these options fade somewhat as there is not a universal system of healthcare that can accommodate for this level of purchase. (Herr et al., 2013)

Overall, this ankle provides multiple angles of rotation, flexion control, and adjustment for weight difference which provide the patient the ability to walk seamlessly again. However, at such a high cost, the ankle is rendered useless to a vast majority of patients. (Herr et al., 2013)

1.3.3 Low-End Prosthetic Devices

On the other end of the spectrum, there is also a variety of low-cost devices that the average patient will have no problem affording or having covered by insurance. Unfortunately, these devices tend to sacrifice substantial amounts of functionality in order to cut costs. One such model, which can be seen in Figure 3 below, is the Fitbionic Foot.

Figure 3: Fitbionic Prosthetic Foot

This foot accomplishes walking motion through a unique foot material which stores energy in the heel contact phase and releases this energy in the toe off phase. This design is very simple and has no electric components. This makes for a much easier manufacturing process and a low cost of approximately $2,000.

The downside to this ankle as compared to higher end ankles and devices is that it does not provide for x-axis rotation. The compliance of the material allows for slight deflections in terrain but has no option for compensating larger variations such as curbs. Although the cost is much lower than higher-end devices, it compromises by offering fewer functions.

1.4 Approach

As the number of amputations increases in the United States, the need for an affordable, functional prosthetic device increases as well. For this design, there were three main goals created in order to separate the device from those that already exist on the market. First, the device needed to perform close to the normal human gait in multi-axial directions without the need for generators, hydraulic systems, or batteries. The second goal was that the device needed to meet the criteria to be classified as a K3 prosthetic. As mentioned above, this entails the device allowing the user to complete locomotive requirements such as walking, bending, going up stairs, slight lateral movements, and a variable cadence. Finally, the third goal was to make the device affordable by having a cost constraint of $5,000. This goal was accomplished by choosing materials that were affordable, but performed up to expectations.

Overall, this design has the potential to affect the entire market for below knee amputees. The design for a K3 prosthetic contains many innovative aspects that give the device distinct advantages over the competition, while simultaneously serving as a low cost option to both patients and insurance companies. This design has the potential to affect all sectors of the market, including amputees, manufacturers, and insurance companies. This affordable, functional design would benefit amputees because they will save money that they will be able to put towards proper therapy and assistance so that they can get the best performance possible out of their prosthetic. Manufacturers would benefit from using more affordable materials and having a simple but effective design that does not need motors or generators. Insurance companies would benefit because they would be able to keep coverage costs in check and not be forced to increase their coverage of prosthetics. The market is in need of a high performance prosthetic that is affordable and within medical coverage price ranges and our design can fit that niche.

2.0 Design Decomposition

For designing our device and how it would accomplish our main objective, we decided to apply axiomatic design concepts. Axiomatic design was used to streamline the design process by achieving a design that abides by the Axiomatic design rules, being collectively exhaustive and mutually exclusive with minimal information. Axiomatic design helps decouple the design making sure there is no interference of functions.

Axiomatic design uses two major concepts to drive product design, functional requirements (FR's) and design parameters (DP's). Functional Requirements (FR) are created through the customer needs and research. FR's are broken down by level with all of the children summing to the parent. They are broken down by complexity with each child describing in more detail until the function is completely exhausted. Each functional requirement is achieved through a Design Parameter (DP). DP's are part of the physical domain, they are how the function will look and act. The top level FR, classified as FR-0, is the goal of the project, to limit loads on the residual limb of a below knee amputee. FR-0 is accomplished with DP-0, a K3 prosthetic ankle device.

2.1 Developing Functional Requirements

The first step in the axiomatic design process is to develop Functional Requirements (FR's). As stated above, these FR's need to be independent from each other but cover all of the functions the device needs to perform. In order to determine our FR's we first developed several constraints for our design. These are listed below:

- Weight less than 3.5 lbs
- Cost less than $5,000
- Device must be purely mechanical (no electronics, hydraulics, etc.)
- Size of device must be small enough to fit in standard foot cover
- Functionality must match K3 classification level

Once constraints were developed, we began the process of breaking down the basic functions of our device into FR's. The team's first attempt at doing so can be shown below in Figure 4.

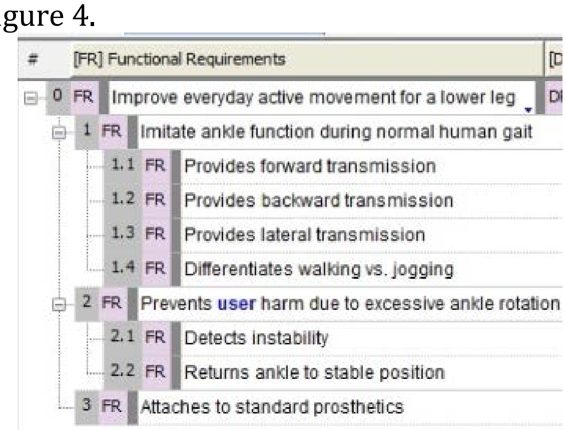

Figure 4: First Decomposition Iteration

This first attempt at developing FR's had a serious flaw. As can be seen, the FR's are based on actions performed by the user, rather than by the device. In addition to not focusing on the device, the FR's are not independent. For example, FR-1.1 and FR-1.2 would be accomplished by the same mechanisms simply working in reverse. Based on this, we developed a second decomposition focused specifically on the device, rather than the user, which can be seen in Figure 5 below.

Figure 5: Second Decomposition Iteration

As can be seen, this decomposition was much more specific and broken into the different functions of the device, rather than the user. Although this decomposition was more thought out and detailed, the FRs were overly complicated, which did not comply with the second axiom. The FR's were very independent since they were divided into axes, which led to a final design that had too many parts. Additionally, the FRs were not broken down into specific systems, rather, they were broken down by rotation, force, and power transmission. This type of breakdown did not show a clear path to the best design and instead added more variability in design alternatives. After our second decomposition, we had several more revisions that can be seen in Appendix B: Additional Decompositions. Through these revisions, we were able to reach our final decomposition of FR's, which can be seen in Figure 6 below.

#		[FR] Functional Requirements
0	FR	Provide for everyday active movement for a lower leg amputee while limiting the load on the residual limb
1	FR	Connect to existing prosthetic pylons
2	FR	Provide controllable rotation in the ankle joint
2.1	FR	Allow controllable rotation around x-axis
2.1.1	FR	Set minimum torque required for rotation at non-zero number
2.1.2	FR	Provide increasing resistance through +/- 5 degrees to fit a cubic curve
2.1.3	FR	Apply logarithmic torque resistance at and beyond maximum rotation
2.2	FR	Allow controllable rotation around y-axis
2.2.1	FR	Set minimum torque required for rotation at non-zero number
2.2.2	FR	Provide increasing resistance through +12.5/-17.5 degrees to fit a cubic curve
2.2.3	FR	Apply logarithmic torque resistance at and beyond maximum rotation
2.3	FR	Allow controllable rotation around z-axis
2.3.1	FR	Set minimum torque required for rotation at non-zero number
2.3.2	FR	Provide increasing resistance through +/- 5 degrees to fit a cubic curve
2.3.3	FR	Apply logarithmic torque resistance at and beyond maximum rotation
2.4	FR	Control the movement of the joint when no moment is applied
2.4.1	FR	Control X-Axis motion with no applied moment
2.4.2	FR	Control Y-Axis motion with no applied moment
2.4.3	FR	Control Z-Axis motion with no applied moment
3	FR	Reduce impulse of ground on the ankle joint
3.1	FR	Distribute weight of user over a foot-sized base
3.2	FR	Absorb force from residual limb to ground
4	FR	Provide controllable toe rotation during gait
4.1	FR	Provide a stable toe base on which to toe off
4.2	FR	Allow controllable toe rotation around y-axis

Figure 6: Final Decomposition of FR's

This decomposition represents the top level of our final FR's, which are described below. For a full breakdown of all FR's, please see Appendix C: Full Breakdown of FR's:

- **FR-0:** Our overall FR was to match the requirements of a K3 prosthetic in terms of everyday movement for the amputee. This is very similar to our overall objective described in Section 1.1: Objective.
    - **FR-1:** The purpose of this requirement was to design a device that was modular with most existing prosthetics on the market. We wanted to make the design universal as well as make the ankle and foot independent. The user could install the entire device to a prosthetic pylon or install the ankle or foot autonomously to existing prosthetic hardware.
    - **FR-2:** In order to provide the amputee with a realistic rotation of the ankle joint, we had to mimic the ankle rotation of an actual ankle as much as possible. This rotation also had to be controllable by the user.
    - **FR-3:** We intended for the design to dissipate a load over a greater length of time. The prosthetic device should be able to distribute the load to areas other than the residual limb or knee.
    - **FR-4:** The design needs to mimic human toe off. Many prosthetics do not grant realistic toe off and energy return is generally low

2.2 Developing Design Parameters

Once we finalized the FR's, we then went into the process of selecting our design parameters (DP's), which represent the physical components that will achieve our FR's. Due to the independence of the FR's, we treated the DP's for each of the four major FR's as separate systems.

2.2.1 DP-1

We decided that for DP-1, we would use a male pyramid mounting system. A male pyramid mounting system consists of an inverted tetrahedral mount that is attached to the top of the prosthetic ankle. This is then placed into a socket in the pylon, which is supplied by the patient's doctor and is held in place using four set screws. Through our research, we determined that this kind of system is an industry standard for any prosthetic device, and in order to make our device modular, we chose to include it at the top of our ankle device.

2.2.2 DP-2

When exploring potential designs for constructing the ankle joint, the group examined multiple iterations and eventually narrowed the selections to two similar designs. The first was a ball and socket joint, shown below in Figure 7, which connected the ball to the socket using eight conventional springs that expand when a tensile force is applied and would compress when the force is removed. This method would allow the springs to be interchangeable and would provide increasing resistance as the springs were expanded.

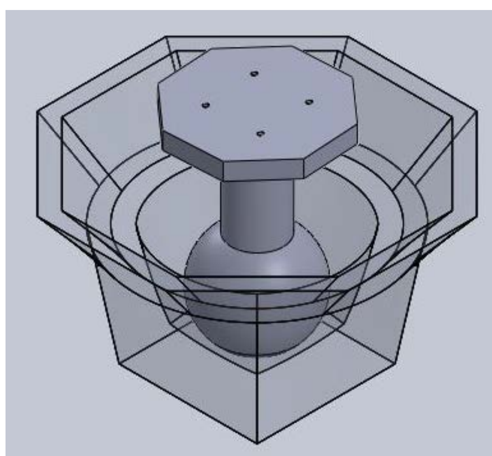

Figure 7: Conventional Spring Ankle Design

This would be a useful design to fit the decomposition because the resistance in each axis of rotation is independent. The springs along each axis could be adjusted to provide the necessary resistance for the particular user.

Another design iteration that the group considered was using cantilever springs instead of conventional springs. Cantilever springs work by bending when a force is applied to one end of a beam while the other end of the beam is fixed. With this design, the octagon at the top of the rod applies pressure to deflect the cantilevers, which store the applied energy until the foot is in swing phase, when the cantilevers return back to their normal positioning. This design, like the conventional spring design, accomplishes the functional requirements for the ankle joint by providing controlled rotation about all axes. Each of the cantilevers can be adjusted individually to match the needs of the user without affecting the function of any other cantilevers in the ankle.

Also, vertical cantilevers would allow the prosthetic to be more compact and would not appear as bulky as other designs might. Cantilevers also offer a unique ability to provide variable resistance by changing where the pressure is applied, the width of the beam, the thickness, or any combination of the three. This is another way that cantilevers could be tailored to whatever the user may need.

Ultimately, considering the two design iterations, the cantilever springs or the conventional springs, the group decided to continue with the cantilever spring design. This was deemed the more useful design because it would be more robust in a physical model and would also not be as large as the conventional spring design. Both were able to accomplish each of the functional requirements detailed in the decomposition, but the use of cantilever springs would accomplish every necessary functional requirement in a more compact model, thus reducing the weight and cost of the design.

2.2.3 DP-3

In order to achieve FR3, we developed a foot system designed to absorb the loads transmitted from the ground to the residual limb through the ankle joint.

One of the most important parts of the foot design was that the prosthetic mimicked the dimensions of a real foot. In order to facilitate this, we investigated what dimensions a standard foot size was for the shoe size of the test subject we were using. By making the foot mimic the dimensions of a biological foot, we accomplished FR 3.1.

In order to achieve FR 3.2, to absorb the forces on the residual limb from the ground, we designed part of the foot to act as a leaf spring. This leaf spring was placed directly under the center of the ankle device so that it would absorb the most force possible. By creating a leaf spring made out of fiberglass, we were able to create a foot that absorbed force from the ground. By absorbing force, the foot reduces the impulse by extending the time that the foot is in contact with the ground. This reduces the maximum force, thus limiting the load on the residual limb.

2.2.4 DP-4

Our first design was to have a rubber piece which would be attached to the foot and act as a toe system. This piece would flex as one rubber piece and would allow for a toe like function. This design came about after analyzing how toes operated. This toe piece would connect to the foot by means of two screws which would be placed to hold the toe piece in place.

This design came about from a problem the group realized with the split rubber design. The split rubber design had no means of applying a variable force based upon the users' varying weight. A new system was developed to allow for varying weight while keeping the split toe system. The split however was modified to act as the toes do. The split consisted of a “big toe” piece which provided the majority of the support during forward gait and a “little toe” piece which simulated the other four toes which provided the majority of the balance. This design allocated for all the functions the toes have. As for the varying rigidity of the toes, a system of planks was created. This system of three planks, one for the big toe and two for the little toes, could be changed out for each specific patient. They would then connect to a toe piece which would provide an area for the toes to safely contact the ground.

We ultimately went with our Off Split Toe design. It had elements for different patients, allowed for controllable toe rotation, and also had a means for dealing with varying terrain through the split.

3.0 Physical Integration

Once all of the final designs had been determined in the Design Parameters of the Decomposition, the group began assigning materials and dimensions to each of the designs. By completing the specifics of how each design parameter was going to be built, the group was able to construct a 3D CAD model of the full prototype.

3.1 Ankle Physical Integration

3.1.1 Physical Integration of Top Octagon and Rod

An octagon made of Aluminum 6061 with dimensions of 2.4 inches across with each side being approximately 1 inch long. On top of the octagon would be a male pyramid that would fulfill functional requirement 1; enable existing prosthetic pylon's to be attached. The octagon screws into the rod through a tapped hole on the bottom of the octagon. Each side of the octagon would engage the cantilever beams when the prosthetic pylon changed direction.

Additionally, a rod made of Aluminum 6061 threaded on both ends with a length of 5 inches. The rod would screw into both the octagon and the ball.

3.1.2 Physical Integration of Ball and Socket

A ball made of Aluminum 6061 with a diameter of 1.3 inches is screwed into the rod. The socket well is made out of Aluminum 6061 and has similar dimension to the ball to ensure a tight fit. The socket well is coated with an epoxy that will eliminate most friction. The ball itself would fulfill functional requirements 2.1, 2.2, and 2.3 by allowing rotation in the x, y and z-axis.

A top socket piece, threaded on the inside will screw over the ball and rod into the top half of the socket. As this piece is tightened, more friction will be created between the ball and the top socket piece. The friction will give a required force to rotate the ball, which will fulfil function requirements 2.1.1, 2.2.1, 2.3.1 setting a non-zero minimum torque to generate rotation within the ball and socket.

The outside of the socket has an octagon shape. On each side of the octagon, two tapped holes were drilled so the cantilever beams can be screwed into the socket.

The bottom of the socket has a rounded extension with four tapped holes 90 degrees apart from each other. The rounded extension comes out 0.5" from the bottom of the socket. A male pyramid attached to the top of the foot connects into the rounded extension, and four screws when tightened will secure the ankle socket to the foot.

3.1.3 Physical Integration of Cantilever Beams

To accomplish our functional requirement of 2.1.2, 2.2.2, 2.3.2 and 2.4 we decided to integrate cantilever beams similar to a diving board. We wanted to mimic ankle rotation in humans, so we set the ankle rotation around the y-axis to be between 12.5 and 17.5 degrees and rotation around the x-axis to be between 4 and 6 degrees. We added eight cantilever beams to each octagon face.

In order to find the dimensions of the cantilevers, we used the equation: $\Phi = FL^2/2EI$, where:

- Φ=the deflection angle of the cantilever
- F=the applied load
- L=length
- E=Elastic Modulus
- I=Moment of Inertia ($\frac{1}{12} * width * thickness^2$)

Using this equation, we were able to find suitable dimensions for the cantilever beams that incorporated variable width and constant length and thickness. All of the beams were made of Aluminum-Bronze, an aluminum alloy that has high fatigue strength. The front and back cantilever beams were expected to experience a load between 100 and 1500 lb/in during a normal gait cycle. They were 5 in long and 0.25 in thick. They had a variable width of 0.6 inch to 1 in from the top of the cantilever to0 .16 in down the cantilever. The rest of the cantilever has a width of 1 in.

A constant width cantilever creates a linear function when plotting load over angle of deflection, which can be seen in Figure 8, below. To ensure a safer device we determined it would be more beneficial to change the function of the plot to fit a more cubic curve, which can be seen in Figure 9. To achieve this we applied a variable width to the cantilever beams. We also took into account the sliding of the octagon down the cantilever beam as the cantilever bent from a specific load.

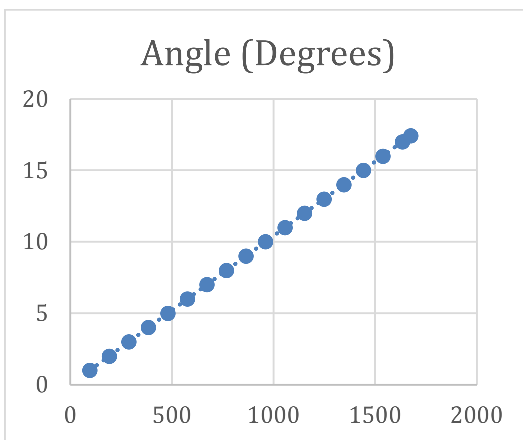

Figure 8: Constant-Width Cantilever Function

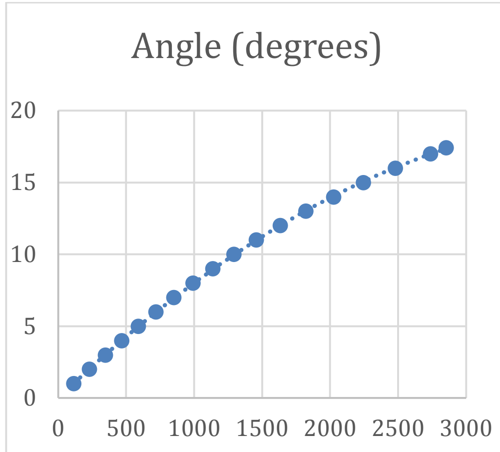

Figure 9: Variable-Width Cantilever Function

The side cantilever beams were expected to experience a load between 100 and 1500 lb/in during a normal gait cycle. They were 5 in long and .375 in thick. They had a variable width of .6 inch to 1 in from the top of the cantilever to .02 in down the cantilever. The rest of the cantilever has a width of 1 in.

The diagonal cantilever beams were expected to experience a load between 100 and 1500 lb/in during a normal gait cycle. They were 5 in long and .25 in thick. They had a variable width of .6 inch to 1 in from the top of the cantilever to .06 in down the cantilever. The rest of the cantilever has a width of 1 in.

We also calculated a maximum bending angle before the cantilever would plastically deform. In order to calculate the maximum bending angle, we used the equation: $\Phi_{max} = \left(\frac{2L^2}{3Et}\right)\sigma_{yield}$ where:

- L = length,
- E = Elastic Modulus,
- t = thickness, and
- σ_{yield} = yield strength

We determined the maximum bending angle for each cantilever before plastic deformation would be:

- 18.5 degrees at a load of 3100 lb/in. – Front
- 18.5 degrees at a load of 16000 lb/in. – Side
- 18.5 degrees at a load of 6500 lb/in. – Diagonal

The cantilever beams also accomplished functional requirement 2.3, controllable rotation around the z-axis allowing 4 to 6 degrees and functional requirement 2.4 return to a neutral stance. The cantilever beams act as a spring, so when a force is applied to them they bend, but when no force is applied they return to an upright position.

3.2 Foot Physical Integration

The main purpose of the foot assembly is to serve as the primary load-limiting element of the device. This part is designed to increase the time that the foot is in contact with the ground during the gait cycle, thus decreasing the impulse on the residual limb. The foot assembly is comprised of two parts that combine to accomplish FR 3: Reduce impulse of ground on the ankle joint. The first of these parts is the connector, which connects the bottom of the ankle socket to the foot assembly and the foot piece itself, which absorbs the force the ground imparts during impact.

3.2.1 Physical Integration of Connector

The first piece that makes up the foot assembly is the connector. The primary purpose of this piece is to connect the bottom of the ankle socket to the foot piece while maintaining the leaf spring curve in the foot. Therefore, this piece helps to accomplish FR 3.1: Distribute weight over a foot-sized base. In order to connect the ankle socket to the connector, we installed a male pyramid mounting system on the top flat face of the connector.

3.2.2 Physical Integration of Foot

The second piece that comprises the foot assembly is the connector. Overall, the goal of this piece is to absorb the force that the ground imparts on the residual limb. There are a plethora of features on this part that allow it to accomplish goal. The first feature is the material of the piece. The second feature is the curve in the back of the piece that represents the "heel" of the foot which allows the user to roll into each gait cycle through the heel contact with the ground. The final feature that accomplishes this task is the leaf spring curve. When the user enters the mid-stance phase of the gait cycle, this leaf spring engages and absorbs part of the load from the user's weight. By combining all of these features, the foot piece is able to accomplish FR 3.2.

3.3 Toe Physical Integration

The third part of our prosthetic design is our Split toe and plank design. The Toe section of our design is a Split toe arrangement. This plank and split toe system separate our prosthetic design from others on the market. Our plank system allows for greater bend than most prosthetics on the market, which will help to better simulate the normal human gait and fluid motion. The split toe design satisfies FR 4.1 and will allow for a stable region for "toe-off". Toe-off is the third operation in taking a step and is the moment when the toe region is bending and force is being applied downwards to propel the toe up and forwards. This is important as the energy transfer here dictates how well the prosthetic performs in energy return and propelling the prosthetic forward.

Our toe region is designed as a Split toe system instead of one solid piece because by having it split it allows for greater balance and mobility. Our theory is that when the toe is one solid piece any misstep or rock can cause an imbalance and problem to the user. By having a split toe system if there is a disturbance the other toe section can compensate and help maintain balance. Our material selection for this part of our prototype is Aluminum. We chose aluminum because it is affordable, has good mechanical properties, and is reasonably light when compared to other metals such as steel.

3.3.1 Physical Integration of Planks

The toe part of our prosthetic is attached to the foot via three planks. These planks accomplish of FR 4.2 by allowing for the mechanical bending which is desired for optimal toe-off. There are three planks, two of identical sizes and one which is slightly larger. The larger plank is connected to the “big-toe” area of our toe design and the other two planks connect to the remaining region of our toe design. The planks are meant to serve as a clean connector and interface between our foot and toe design and will need to handle high loads, and frequent cycles. The planks will be bending every time the subject walks. Therefore, the team had to look into very specific types of materials that both are durable and tough, but also have an elastic modulus that will allow for the bending and defection we desire.

The team conducted a material selection process that took into account the properties desired, cost of the material, and the ease of manufacturing the prototype piece. Ideally, carbon fiber would be the material of choice for our plank design; however, due to the budget of our project and the manufacturing tools at our disposal we selected a different material with similar mechanical characteristics to carbon fiber. We selected a material composite called E-glass 7781. The properties of E-glass 7781 make it a suitable material selection and a good choice for our prototype.

3.4 Final Design CAD Models

Our final design assembled in SolidWorks can be seen below in Figure 10. Additional screenshots can be seen in Appendix D: Additional SolidWorks Screenshots.

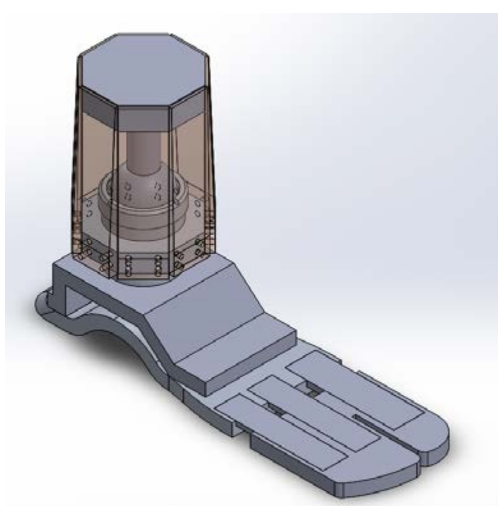

Figure 10: Isometric View of Final Design

4.0 Manufacturing Prototype

Production of the prototype included six major manufacturing processes: aluminum milling, aluminum turning, ball joint production, cantilever beam production, composite curing, and assembly. The following outlines these processes.

4.1 Aluminum Milling

4.1.1 Connector

The connector for the prosthetic was designed to provide a stable base that would attach the mechanism for the ankle to the prosthetic foot. By making a connector piece, the foot and ankle could become completely modular, allowing for the ankle to be used with existing prosthetic feet or for the foot to be used with existing ankle devices. Making the prosthetic completely modular was a goal of the group as it allowed for more possibilities if the project were to be expanded.

To make the connector, the group weighed two primary options for how it could be milled. The first option that was considered was a Contouring operation designed to cut the side profile of the connector to its desired width. This method would allow the angled faces of the part to be milled smoothly and the excess stock could be easily cut off either with a Facing operation on the mill or by using a band saw. The primary flaw with this method was the amount of stock that would need to be exposed was large and the length of the end mill that was being used was also quite long. This combination would cause a great deal of chatter, or vibration of the end mill and stock, which made the operation rather risky as it would likely damage either the stock or the mill in some way.

The second method that was considered was two Freeform Contouring operations, one to cut the top half of the connector and one for the bottom half. This method would be much safer for both the part and the tool, but the angled faces would have steps as the tool made passes. The part was simulated using an end mill and a ball mill, both were available in the shop and the group determined that using the end mill would be most effective and the steps could be reduced using finishing tools.

After weighing both options, the group determined that the second method would be most effective as it was safer for both the part and the tool being used to cut it and the shape of the part would still be close to what was desired. Once the connector was milled, members of the group drilled and tapped holes that would later be used to mount the connector to the foot and to mount a male pyramid to the connector that would allow it to attach to the ankle piece.

4.1.2 Collar

The collar was manufactured simply to correct an error with the dimensions of the socket. When the socket was manufactured, the large diameter that was to be used to make the octagonal surface was too small, so to correct the error, the group designed a collar that would press fit onto the socket and have the originally desired octagonal surface.

The collar was manufactured using Contouring and Pocketing operations on the mill. To begin the process, the stock was leveled using a Facing operation across the entire top side. The program then ran the Contouring operation first to cut the outside profile of the octagon, and then used the Pocketing operation to bore out the inside of the collar. With the profile of the collar successfully milled, most of the excess stock was removed using the band saw. For the extra stock that could not be removed with the saw, the group ran a second Facing operation to remove the last of the stock and leave nothing but the finished part.

With the part successfully milled and faced, the group pressed it onto the socket to the point where it would be resting. Once the collar was pressed on, the group then drilled and tapped holes through the collar and into the socket such that bolts could be used to attach the cantilevers to the socket.

4.1.3 Top Octagon

The top octagon is the part of the ankle that rests at the top of the rod, providing points of contact to all of the cantilevers and thus acting as the part that the cantilevers resist when force is being applied.

The manufacturing process of this part was quite similar to the process behind manufacturing the collar. To make the top octagon, Contouring, Pocketing, and Facing operations were used. The Contouring operation cut the profile of the octagon and the Pocketing operation cut a circular hole in the center of the octagon for the rod to fit into. Finally, a Facing operation removed excess material and the rest of the excess stock was taken off with the band saw.

With the finished octagon fully milled, the group drilled and tapped a hole through the center of the top face of the part such that a screw could butt the rod into the top octagon and provide a sturdy connection.

4.1.4 Socket

The socket is the part that is the base for the ball to move inside of. The socket is the part that attaches the ankle to the connector. It was primarily manufactured on the lathe, with some other features of it being outsourced for manufacturing, but in order for the socket to be able to hold the cantilevers, an octagonal surface needed to be milled.

Once the socket was turned on the lathe and the ball joint was coated with epoxy, it was brought to the mill to cut an octagonal surface that would fit inside the collar. This operation was accomplished using a single Contouring feature that turned the circular face into an octagonal one that would press fit into the collar.

4.1.5 Toes

The toes were another vital part for the prosthetic. They make the prosthetic foot flexible where toes would normally be and it is cut to allow stable walking on uneven terrain.

The toes were manufactured using multiple Contouring operations. The first Contour milled the outline of the toes into the stock. Once the first Contouring operation was completed, the next ones began, milling out cavities for the flexible planks to rest inside of. Upon completion of the milling operations for the toes, the group cut off all of the excess material using the band saw and then separated the “big toe” portion of the toes from the rest of the part. This separation allows for the toes to flex in multiple directions, which allowed the user to walk on non-uniform terrain.

4.2 Aluminum Turning

4.2.1 Socket

The socket was our most geometrically complex shape and required the most operations to complete the part. We started from the aluminum stock which was a 3 inch diameter and 33 inch long cylinder. This was then cut down with the horizontal band saw to a piece which was reasonable to work with.

The machining motions of this part consisted of drilling into the middle of the stock, boring the inner socket shape, contouring the outside, and a threading operation which would create a thread on the outside surface. In order for the part to be coated in the frictionless surface, the threads would have to be added in at a later date. We moved forward with the machining motions as planned but without the threading option.

What we received was a part which had the general contours but due to an error had a slightly smaller outside diameter than intended. We unfortunately had to move forward with the coating process. We devised a plan to create a collar which would allow for the octagonal shape to be achieved.

When we received the socket back from coating, we began the threading. The threads had to have a flat surface at the tip to ensure a good fit so we took that into account when creating our thread depths. Through ESPRIT's thread data base, we selected the 12 UNC threading. This gave it a standard thread lead which was then applied to our diameter.

Using a V-Notch tool, we began to carve the outside diameter threads. The threads were created and the extra material from machining was removed to give a clean thread. Later we reduced the thread lengths by manual turning to make a proper fit with the top socket.

4.2.2 Rod

The rod is essentially an aluminum rod which has threading on one end and a tapped hole on the other. We found a piece of aluminum in the machine shop scrap pile which was our dimensions exactly so we took it and cut out the machining for the part.

We created the threads on the outside diameter with a 5/8" threading die and a hole was drilled and tapped manually on the opposite end of the rod.

4.2.3 Top Socket

The top socket consisted of four machining operations. These were a drilling operation, an inside boring operation, an outside contouring, and threading the inside diameter. These operations were executed a first time and upon fitting the socket pieces together we realized that they did not fit properly. We manually turned the thread lengths on both pieces down and when that did not solve to issue, we realized our thread depth on the top socket needed to be deeper. We also had to slightly change the inside diameter to comply with our threading tool.

We created the top socket another time and this time the threads matched up. A hand tool was used to clean out the threads after and a file was used to create a fillet on the opposite end of the piece.

4.3 Composite Curing

Our foot piece was a simple design to create with no exuberant geometry but the main issue was how to create it. The material was the key determinate of how the foot was to be made. If we decided aluminum we would have to mill the part which would not be that hard. In the end we decided to go with composite material and to mold the part.

We found the material we would use which was E-Glass 7781 which is a fiberglass cloth which is pre-impregnated with resin. The way in which it is manufactured is through an oven or autoclave. The cloth comes in layers 0.008" thick so the part must be made up of many layers. Since the cloth is unidirectional fiber, meaning the fiber has strength along one axis, orientation of layer to layer will vary. This particular cloth uses a 45/45 layup meaning that each layer is cut 45 degrees to the fiber line. These layers are then laid in an alternating fashion until you get your desired part thickness.

Our method for curing these molds will be to use an oven to allocate for our temperatures. The cycle we must obtain is one hour at 310 F, two hours at 290 F, and four hours at 270 F. This cure cycle is given through the material datasheet and should allow for proper curing of the part.

The part itself once laid up must be placed properly in the oven. First an aluminum plate must be coated with a mold release wax. This wax allows for the part to be lifted off the plate once the curing cycle is done. After the molding wax is placed down and dried, the fiberglass layups are then placed on. After the layup a layer of release film is laid adjacent to the part upon curing. This release film retains resin emitted from the fiberglass. Then next layer is then a peel ply which provides a further barrier between the part and the breather. The breather allows for all the excess resin to be absorbed. The last layer is the vacuum bag which keeps all of the airspace in the part contained. This vacuum bag is sealed with sealant tape around the edges of the aluminum plate and then the air is drawn out through a vacuum pump by means of a special fitting and a hose.

4.3.1 Foot 1 – 48 layer

Our first model of the foot was to be 48 layers thick. The individual ply thickness of the foot over 48 layers gave us on overall part thickness of 0.384". There is a required vacuuming to be done on the part to ensure a proper fit. The vacuum for this trial did not work as planned so the part came out thicker and crooked then we had intended.

4.3.2 Foot 2 – 40 layer

We realized that our 48 layer foot was entirely too stiff so we reduced the overall thickness by cutting out plies. We reduced the number to 40 to give it more flexibility. We also bought a stop valve to ensure the vacuum would hold suction and create a good part. We created the part using the same curing cycle and it came out looking clean. The improved vacuum method worked perfectly. We fitted the foot to the connector and toes by drilling holes, counter-bores, and other features to ensure a good mesh of the two parts.

4.3.3 Foot 3 – 8 layer

Upon further examination of our 40 layer part, we still felt it was stiff. We decided to go to the opposite end of the spectrum and create a part which was 8 plies thick. We intended this foot to be more flexible and easily manipulated. This last manufacturing used the last of our material and the foot came out in exactly how we predicted. The foot was flexible and allowed bending upon stressing.

4.3.4 Toe Planks

Our first toes were manufactured alongside our first foot model. They were 0.33" and 0.18" thick for the large and smaller toes. They came out the same dimensions we intended unlike the foot, however they felt brittle. Further stress testing would show that they did not handle the calculated loads correctly.

Moving on, we explored two other options, spring steel and aluminum bronze. The group purchased spring steel cabinet scrapers and cut them into our shape and cut enough layers to achieve the necessary levels of stiffness. However these layers did not hold up well together so the group ran numbers for aluminum bronze and cut the toes out from our pieces of aluminum bronze.

4.4 Ball Joint Production

In order to create the ball joint and socket for our prototype, we worked with Mikrolar in Hampton, NH. Mikrolar specializes in creating robots that utilize multiple ball joints during their operation and they have all of the technology on site to create such a joint.

Upon multiple visits to their facility, we were able to utilize their equipment and expertise in order to create our ball joint. The most involved part of this process was the coating of the socket with epoxy. In order to perform this process, we first had to calculate approximately how much epoxy would be required to coat the surface of our socket. After calculating this amount, we clamped the socket into a Bridgeport machine and clamped the ball itself in where one would usually use a drill bit. After coating the ball in a non-stick coating in order to prevent the epoxy from hardening to the ball joint, we carefully drew out the amount of epoxy using a syringe and inserted it into the socket. We then slowly lowered the ball into the socket using the Bridgeport machine in order to create the correct contour so that the epoxy coating was perfectly contoured to the ball. After leaving the assembly clamped for 24 hours, we were able to detach the ball from the socket and insert an O-ring into the bottom of the socket in order to provide a smooth motion for the ball joint.

4.5 Cantilever Beam Production

For the cantilever beams, it was initially decided to construct them out of phosphor bronze, a bronze alloy that had a Young's Modulus that was ideal for our specific application. However, after much research, it was determined that acquiring such a material would not be possible. It is for this reason that we decided to use aluminum bronze, which was recommended as an acceptable substitute for phosphor bronze.

Upon acquiring the sheets of aluminum bronze, we had to cut out the specific shapes we wanted to achieve for our cantilevers. Each beam was cut to be approximately 1" long and 5" long using a band saw. Based on the calculations described earlier, we then cut the variable width at the top of each beam to match the beam's design. This process was also done using a band saw. Holes were then drilled in each beam such that they would fit a #8-32 screw.

4.6 Assembly of Prototype

The majority of our assembly work took place in Washburn Shops with the hand tools. Nearly every part needed to be drilled and holes needed to be tapped and this was all done using the machines in Washburn Shops. There were also stock screws in the lab which the group utilized along with other specific parts which were purchased elsewhere.

As for the specific connections:

- The toe planks fit to the toes by means of screw and nut
- The toe planks connected to the foot by screw and nut
- The foot connected to the connector by screw and nut and also by three tapped screw holes in the connector
- The connector had holes drilled for attaching the male pyramid mounting system by screw and nut
- The male pyramid mounting system allowed for the socket to be attached
- The socket had tapped holes which allowed the cantilevers to be screwed in place
- The ball joint was threaded to fit with the rod
- The rod was screwed into the top octagon
- The top octagon had threaded holes for another male pyramid mounting system

5.0 Testing Prototype

5.1 Part Testing: Toes

To individually test the planks, we fixated them to a rigid surface in the lab. They were fixated with C-Grips and were tightened till a secure lock was made. We then measured off five inches and made sure that the planks extended 5 inches off the table to provide us with a consistent lever arm for which we would then apply weight. We then acquired different size weights in the lab and tied them together with a rope. We then looped the roped around the cantilever beams at the measured off 5 inch mark. We then applied a weight of 5lbs and 10lbs. At each weight we took a picture of the defection and then of the weights themselves to ensure correct data filing. One of these pictures can be seen below in Figure 11. We then used ImageJ software to measure the angles of deflection at each weight increment.

Figure 11: Cabinet Scraper Plank with 5lb weight

The team originally had plans to use carbon fiber as the material for this component but due to manufacturing and budget constraints for the MQP we decided to try spring steel. Below is a picture showing the bending of the planks when a 5-pound weight was added to it. Unfortunately, the planks bent too much and fell outside of the elastic modulus and strength range that we were looking for. The thin plank bent 12.56 degrees when the 5lb weight was added and the thick plank bent 11.23 degrees when the 5 lb weight was added.

Therefore, the planks made from spring steel filed to meet our needs and for the first prototype we added cantilever planks cut to the same dimensions as those used for the ankle to serve as our plank components. These will serve to be stronger than the idea material for a final prototype, however for a first prototype they will be acceptable.

5.2 Part Testing: Foot

In order to test the mechanical properties of the fiberglass foot prototype the team subjected the foot to a compressive strength test. The team tested both the 40 layer and the 8 layer foot. Ideally the foot will flex a good amount but still be able to maintain structural integrity and properties. The team tested each foot in the WPI Rec Center as this was the only place that was capable of having enough weight to apply to the feet. Weight was added in 45 lb increments and was measured at each added weight via pictures. Figure 12 below shows the 40-layer foot with over 450 lbs of pressure. The results indicated that this model was indeed much too stiff and strong. Even at the applied weight of over 450 lbs, the foot failed to visibly flex.

Figure 12: 40 Layer Foot with over 450lb. Applied

In testing the 8 layer foot, a much different result occurred. The 8 layer foot began to flex heavily at 90 lbs. We applied a max weight of 225 lbs to the 8 layer foot at which the foot was nearly entirely flexed and flat. However, once removed the foot came back into original position and no plastic deformation was detected. Figure 13 below shows 90 lbs of load while Figure 14 shows 225 lbs of load.

Figure 13: 8 Layer Foot with 90lb. Applied

Figure 14: 8 Layer Foot with 225lb. Applied

Therefore, it can be estimated that the optimum number of layers needed for a fiberglass foot that meets our requirements is around 12-14 layers. This layer amount will allow for there to still be a good amount of flexion in the foot while remaining better structural integrity during gait. The foot needs to flex because that will reduce load sent vertically to the residual limb, while also allowing for some energy return. The foot also needs to have a degree of stiffness and allow for good structural integrity because the amputee needs to have a stable base in order to keep his or her balance.

5.3 Part Testing: Ankle

To individually test the cantilevers, we fixated them to a rigid surface in the lab. They were fixated with C-Clamps and were tightened until a secure lock was made. We then measured off five inches and made sure that the cantilevers extended 5 inches off the table to provide us with a consistent lever arm for which we would then apply weight. We then acquired different size weights in the lab and tied them together with a rope. We then looped the roped around the cantilever beams at the measured off 5 inch mark. We then applied weight in increments of 30 lbs, 60 lbs and 90 lbs. At each weight we took a picture of the deflection and then of the weights themselves to ensure correct data filing. We then used ImageJ software to measure the angles of deflection at each weight increment.

Figure 15, below, represents the data we calculated from the weight added and the angle of deflection discovered via our pictures and ImageJ software. In addition, Figure 16 shows the linear function that we derived from the data we acquired up to 1500 lbs of load.

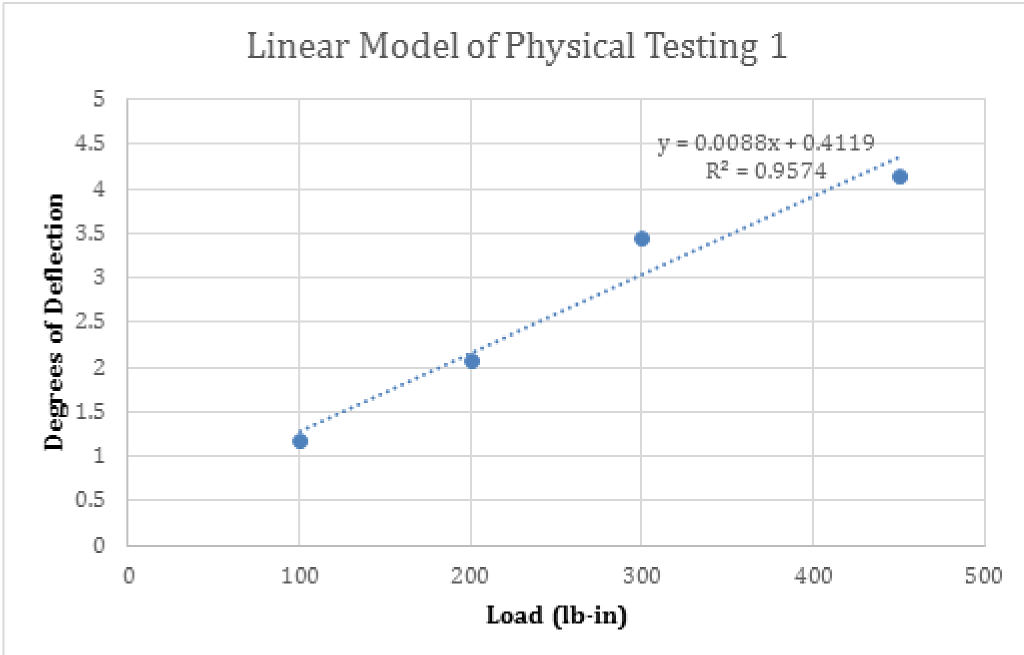

Figure 15: Data Acquired from Cantilever Testing

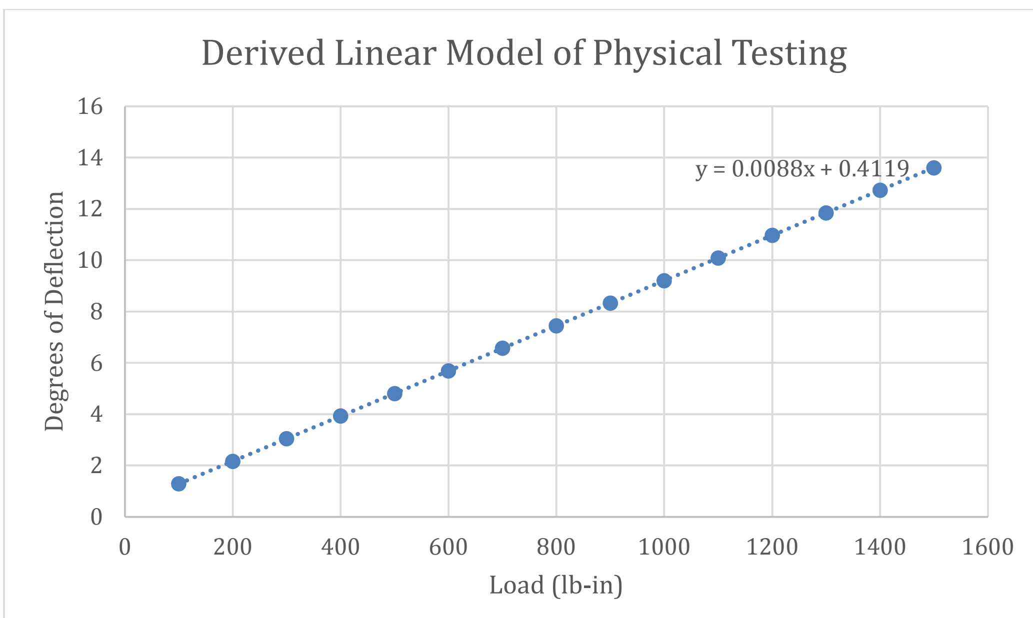

Figure 16: Linear Relationship Derived from Cantilever Testing

The R squared value from the physical testing was .9574, which indicates that the data fits closely to a linear model and 95.74% of the variance can be explained. The bending of aluminum bronze is a linear model so from data we can deduce our physical testing nearly matches a theoretical graph of a metal bending under increasing loads.

The testing procedure and the angles observed between the thick and thin planks can be seen in Figure 17 and Figure 18, respectively.

Figure 17: Thin Cantilever with 90lb. Applied

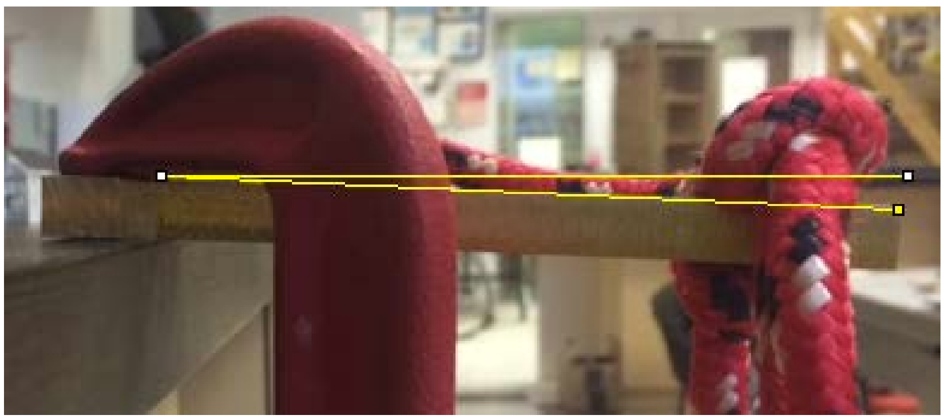

Figure 18: Thick Cantilever with 90lb. Applied

5.4 Assembly Testing

To test the success of the variable-flex ankle, the team brought in a human subject amputee. The human subject has had a left below knee prosthetic since 1995. He is highly active, regularly doing activities such as hiking, skiing, etc.; therefore, his personal prosthetic device is categorized as a K4. K4 devices, as described in previous sections, are the highest performing devices on the market. The subject's K4 device costs around $23,000. His K4 prosthetic device was tested against the team's prosthetic device as a way to benchmark the success of the new design. The type of testing completed was gait analysis and motion capture. Motion capture was utilized to assess symmetry of stride length and gait speed. Gait analysis was completed using AMTI software (50 Hz for 6 seconds).

5.4.1 Gait Analysis

Gait analysis was completed by setting up two force plates in line with each other so the human subject could naturally walk, completing a full gait cycle, while striking the two force plates with the same foot, twice. A full human gait cycle can be seen below. There are two phases during a natural gait: stance and swing. As seen in the picture, the stance phase consists of heel strike, mid-stance, and toe off. Heel strike is also called the braking phase because a ground reaction force is causing friction in the opposite direction of motion to eliminate slipping. Likewise, toe-off is also called the propulsive phase because a ground reaction force is causing momentum in the same direction of motion to allow energy return. This toe-off energy return is used to complete the swing phase which completes the full gait cycle. As seen below in Figure 19, the complete gait cycle can be summarized as heel strike of one foot to heel strike again of the same foot. The set-up of the subject testing can be seen in Appendix E: Subject Testing Set-Up.

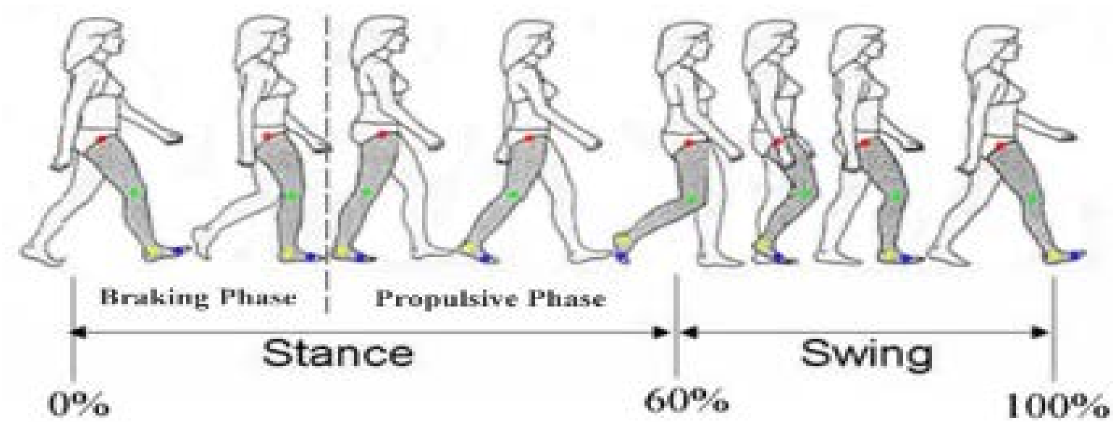

Figure 19: Schematic of the Gait Cycle

The force plate data was imported into Microsoft Excel, plotted (Fz vs Time), and then analyzed to find cadence, time from heel strike to toe off, percentage of time foot is on the group during entire gait cycle, and rate of rise. The Fy-Time data was also graphed and analyzed for average braking and propulsion forces.

5.4.1.1 K4 Prosthetic

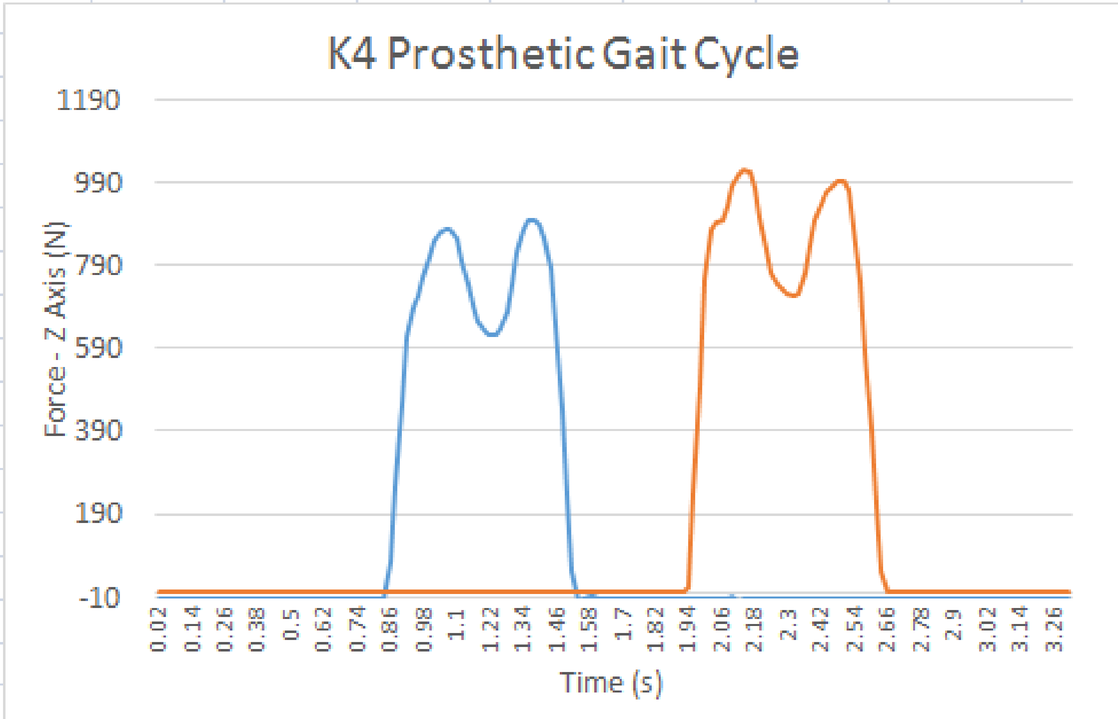

Figure 20: Force Plate Data for K4 Prosthetic

The blue line in Figure 20, above, indicates force plate 1 and the orange line indicates force plate 2. For both curves, the first hump demonstrates the maximum force from heel strike, the dip demonstrates the shift to mid-stance, and the second hump demonstrates the maximum force from toe-off. From this graph, four types of analysis can be assessed. The first is cadence. Cadence is the time from heel strike to heel strike, or time of complete gait cycle. This is measured by finding the time interval from maximum heel strike peak of force plate 1 to maximum heel strike peak of force plate 2. The second analysis is average time from heel strike to toe off. This is measured by finding the time interval from the peak of heel strike to the peak of toe-off for both force plates and taking the average. The third analysis is the percentage of time the foot is on the ground during gait cycle. This is completed by measuring the time interval the force plate 1 is reading a force above zero (foot on ground) and dividing that time by the measured total gait time interval. The final analysis for this graph is the average rate of rise. Rate of rise is the amount of time elapsed from the moment the foot hits the force plate to the moment maximum heel strike force is reached. This calculation was found for both force plates and averaged. The values for each analysis for this graph are shown below in Figure 21.

Analysis	Value
Cadence (Time From Heel Strike to Heel Strike)	**1.08 s**
Heel Strike to Toe Strike	
FP1	0.36 s
FP2	0.36 s
Average Time Heel Strike to Toe Strike	**0.36 s**
% of Foot on Ground during Gait Cycle	**64.80%**
0.7 s/1.08 s	
FP1 Rate of Rise	0.20 s
FP2 Rate of Rise	0.24 s
Average Rate of Rise	**0.22 s**

Figure 21: Summary of Force Plate Data for K4 Prosthetic

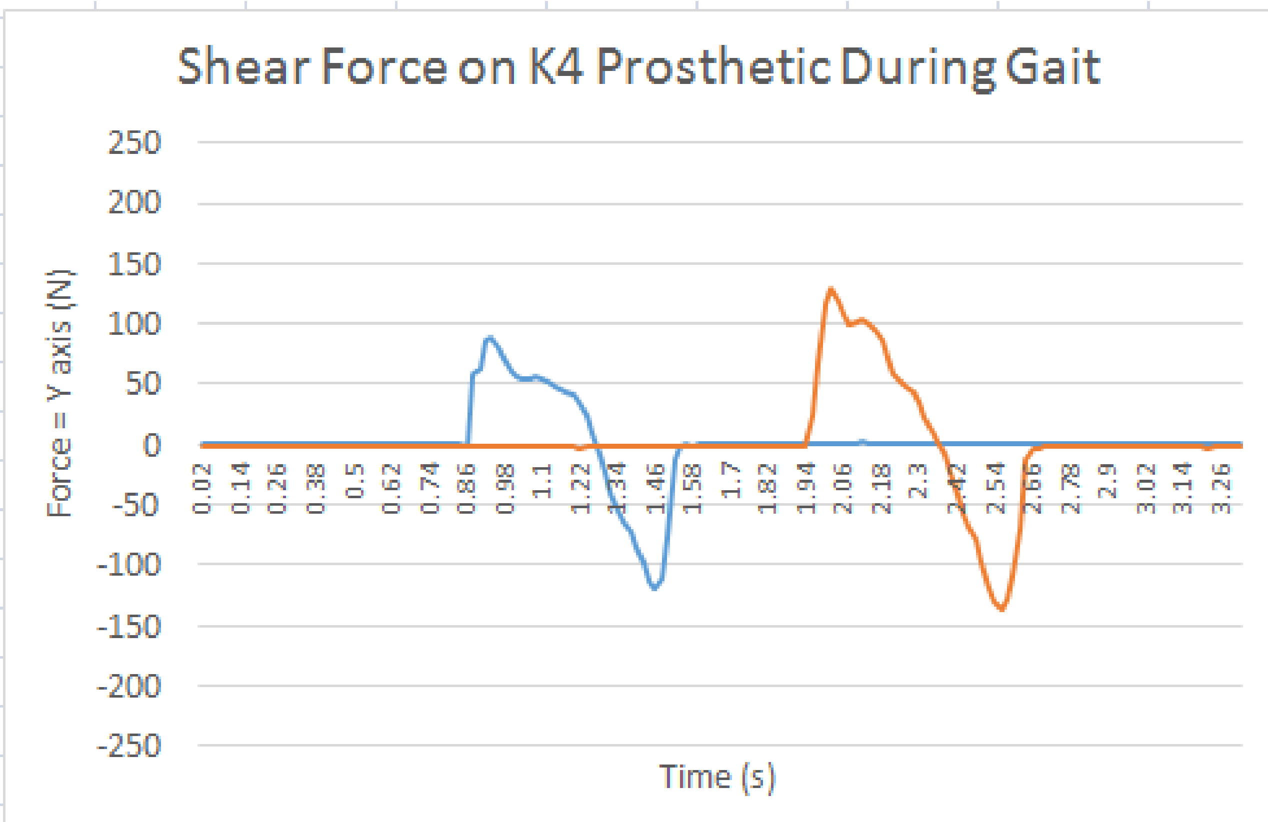

Figure 22: Shear Force Data for K4 Prosthetic

The graph in Figure 22, above shows the shear force (Fy) experienced by the foot while walking. The human subject was walking in the negative y direction; therefore, the positive values on this graph actually indicate a negative Y force value.

As discussed before, the stance phase is broken into two sub-phases: braking and propulsion. The first hump on the graph indicates the braking force during heel strike (negative ground reaction force) and the second hump indicates the propulsion force during toe-off (positive reaction force). Again, the blue is the first force plate and the orange is the second force plate. To find the average braking force overtime and the average propulsion force over time, the integral of each curve must be found. The area under the force-time curve is the impulse (F*s). Therefore, by taking the integral in excel for each time point on the graph; the impulses for each hump were determined.

$$Impulse = \Delta Momentum \text{ can also be written as } \int F_{net}\, dt = \Delta(m \times v)$$

The equation in excel used to take the integral was: (1/50)*(F-$F_{initial}$). By summing each impulse at the time intervals during which the individual humps occur, the total braking and propulsion impulses for each force plate are determined. Once the total impulses were determined, they were divided by the time interval they occurred to find the average braking and propulsion forces. The derivation is shown below.

$$Impulse = Force * Time$$
$$Force = Impulse/Time$$

Once the average braking and propulsion forces were found for each individual force plate, the two were averaged together to find an overall average braking and propulsion forces (ground reaction forces) experienced on the foot during gait. The values for this analysis are summarized in Figure 23 below.

Force Plate 1	
Braking Impulse (N*s)	21.33 N*s
Time	0.42 s
Propulsion Impulse (N*s)	17.88 N*s
Time	0.32 s
Average Braking Force	50.78 N
Average Propulsion Force	55.90 N
Force Plate 2	
Braking Impulse (N*s)	30.57 N*s
Time	0.40 s
Propulsion Impulse (N*s)	21.31 N*s
Time	0.32 s
Average Braking Force	76.43 N
Average Propulsion Force	66.61 N
Average Braking Force	**63.61 N**
Average Propulsion Force	**61.26 N**

Figure 23: Summary of Shear Force Data for K4 Prosthetic

The Fz-Time graph analysis as well as the Fy-Time graph analysis was completed for each of the four tested scenarios. The next section details the data for the prototype ankle as described above. The data for the normal foot gait for both the K4 Prosthetic and prototype can be found in Appendix F: Normal Foot Data.

5.4.1.2 Variable-Flex Ankle

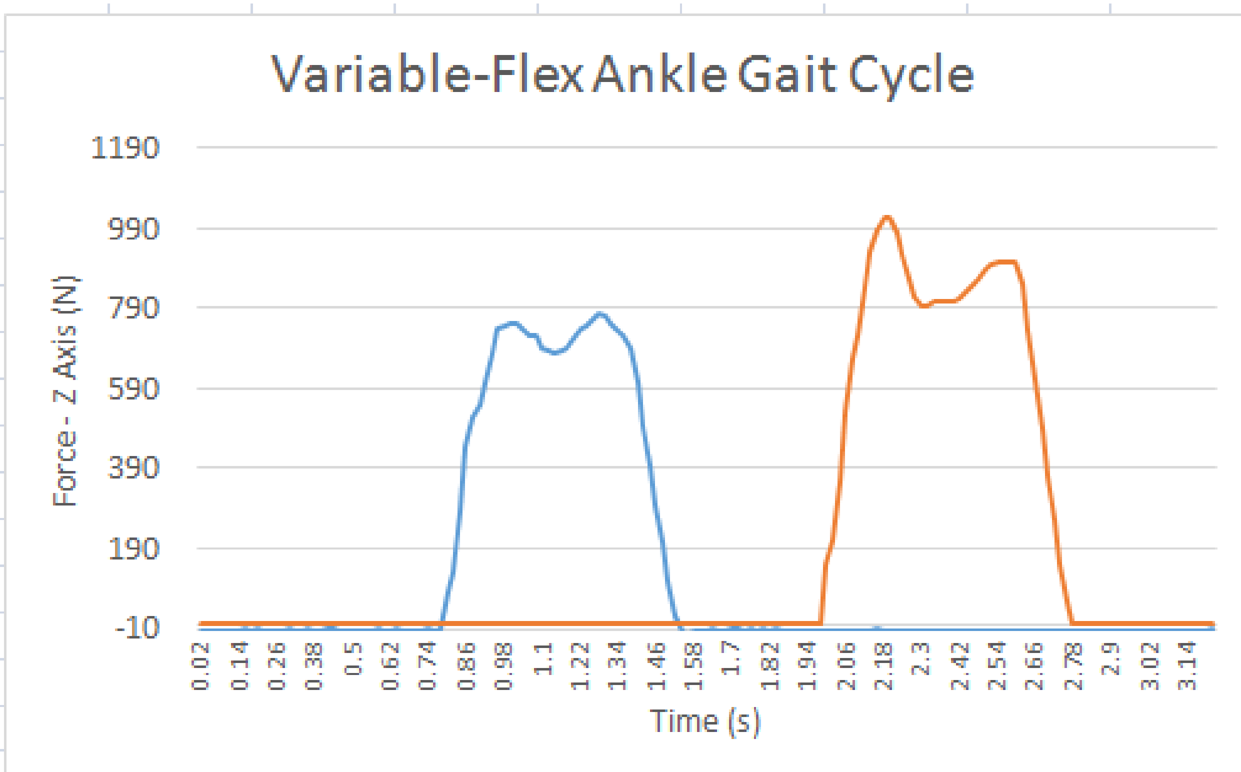

Figure 24: Force Plate Data for Prototype Ankle

Analysis	**Value**
Cadence (Time from Heel Strike to Heel Strike)	**1.16 s**
Heel Strike to Toe Strike	
FP1	0.32 s
FP2	0.42s
Average Time Heel Strike to Toe Strike	**0.37 s**
% of Foot on Ground during Gait Cycle	**62.07%**
0.72 s/1.16 s	
FP1 Rate of Rise	0.23 s
FP2 Rate of Rise	0.21 s
Average Rate of Rise	**0.22 s**

Figure 25: Summary of Force Plate Data for Prototype Ankle

Figure 24 and Figure 25, above, show the Fz Force Plate data for our prototype ankle design. As discussed above, these data can lead to the calculations for the time the foot spends in contact with the ground, as well as the rate of rise. The comparison between these data and the data collected on the K4 Prosthetic will be discussed in more detail in Section 5.4.3 Gait Analysis Discussion.

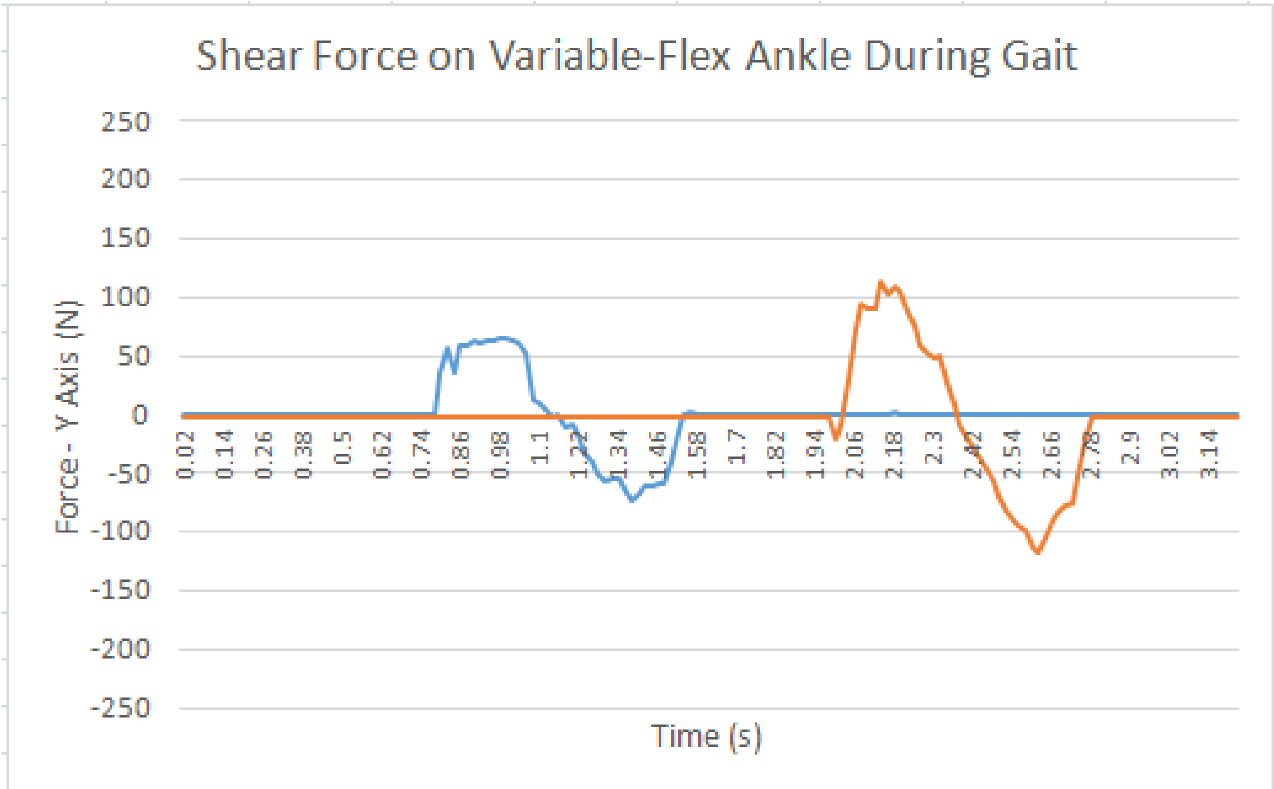

Figure 26: Shear Force Data for Prototype Ankle

Force Plate 1	
Braking Impulse (N*s)	16.46 N*s
Time	0.32 s
Propulsion Impulse (N*s)	16.70 N*s
Time	0.38 s
Average Braking Force	51.45 N
Average Propulsion Force	43.94 N
Force Plate 2	
Braking Impulse (N*s)	27.21 N*s
Time	0.32 s
Propulsion Impulse (N*s)	23.85 N*s
Time	0.40 s
Average Braking Force	85.04 N
Average Propulsion Force	59.72 N
Average Braking Force	**68.25 N**
Average Propulsion Force	**51.83 N**

Figure 27: Summary of Shear Force Data for Prototype Ankle

Figure 26 and Figure 27 show the Fy, or shear force data for the tests involving our prototype ankle. As described above, these data can lead to a calculation of the braking and propulsion force provided by the ankle. The comparison between these data and the data collected for the K4 prosthetic will be discussed in Section 5.4.3 Gait Analysis Discussion.

5.4.2 Motion Capture Testing

To test the variable-flex of the designed ankle, motion capture was used to video the movement of the ankle while completing several tasks. Aside from normal walking, gait initiation, side step, and incline walking was also completed. The main objective of the ankle is to provide controllable rotation to assist in every day movements such as walking. The team wanted to capture the ankle in use completing various every day activities. The two pictures below, Figure 28 and Figure 29 show a snapshot of a side step and gait initiation, respectively. Here, the pictures of these tasks can demonstrate the success of the ankle flexion.

Figure 28: Lateral Movement with Prototype Ankle

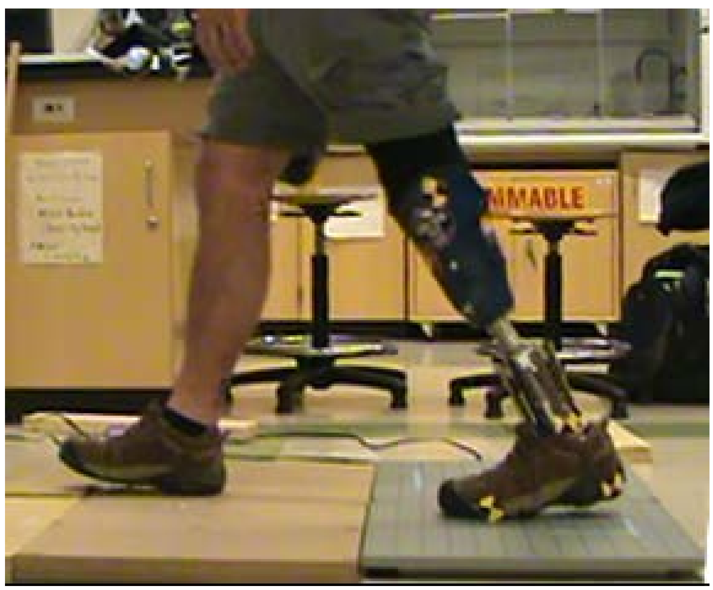

Figure 29: Gait Initiation with Prototype Ankle

The next motion capture test completed was walking up and down on an incline. The human subject completed this task with the variable –flex ankle as well as his K4 prosthetic. The one side of the incline was raised approximately 6 inches off the ground. The following pictures, Figure 30 and Figure 31, demonstrate the incline test done with the K4 Prosthetic and the prototype ankle. The incline analysis was based on video capture as well as human subject personal opinion from 21 years of experience of walking with prosthetic devices.

Figure 30: Incline Movement with K4 Prosthetic

Figure 31: Incline Movement with Prototype Ankle

Snapshots of the task show ankle flexion, whereas video capture demonstrates the difference in walking speed and ease of walking. The differences in results between the K4 and variable-flex ankle will be discussed in the next section.

5.4.3 Gait Analysis Discussion

To aid in data analysis discussion, the results from each of the four different feet are summarized below in Figure 32.

	Normal Foot with K4	Normal Foot with Variable-Flex	K4	Variable-Flex
Cadence (Time From Heel Strike to Heel Strike)	1.10 s	1.28 s	1.08 s	1.16 s
Average Time Heel Strike to Toe Off	0.40 s	0.54 s	0.36 s	0.37 s
% of Time Foot is on Ground during Gait Cycle	70.90%	65.60%	64.80%	62.07%
Average Rate of Rise	0.24 s	0.15 s	0.22 s	0.22 s
Average Braking Force	69.84 N	102.05 N	63.61 N	68.25 N
Average Propulsion Force	101.87 N	76.49 N	61.26 N	51.83 N

Figure 32: Summary of Gait Analysis Data

Looking at the table in Figure 32 above, there is definite symmetry between the results from the K4 and variable-flex devices. The normal foot data was analyzed only as a control. However, the success of the variable-flex ankle is best seen when compared to the K4 prosthetic device. It is difficult to design and create a device that perfectly mimics the human foot and ankle. This is because an amputee does not have the muscles and tendons which greatly aid in a person walking. Therefore, it is the duty of the new device to mimic the work that muscle and tendons naturally do. The goal of this prosthetic ankle was to show K3 capabilities. By comparing the gait analysis of this ankle to a K4, the team can determine if the new ankle was successful. Although the K4 prosthetic has running and jumping capabilities, only walking on flat terrain as well as incline was assessed.

To start, the variable-flex cadence was 1.16 seconds as compared to 1.08 seconds for the K4. This difference could be attributed to the unfamiliarity of walking with the variable-flex device. The human subject was more comfortable walking with his K4 because he is familiar with it and can easily walk with the normal gait. The 0.16 seconds showed the human subject was walking a little slower with the new ankle; however, the difference is only 0.08 seconds which is not significant. For average heel strike to toe off, the K4 averages 0.36 seconds and the variable-flex averaged 0.37 seconds. Again, the time is 0.01 second longer for the variable-flex ankle, and can be attributed to a different walking speed as well.

The percentage of time the foot is on the ground during the gait cycle is comparable. The K4 prosthetic was on the ground for 64.8% of the total gait cycle whereas the variable-flex prosthetic was only on the ground for 62.07% of the gait cycle. This means the human subject felt more stability and comfort with his K4 device. When walking with the variable-flex device, the human subject switched back to his normal foot sooner. This data can be attributed to two different situations: the variable-flex ankle did not provide adequate support or the human subject was nervous and did not trust the device as much as he trusts his K4.

The average rate of rise is the time from the foot hitting the force plate to the time the heel strike reaches maximum force. A load limiting device that absorbs force upon impact will have a slower rate to rise than one which does not limit the load at all. The K4 and variable-flex ankle averaged the exact same rate to rise (0.22 seconds). This proves both devices limit loads similarly and show equal compliance.

The last analysis completed was the average braking and propulsion force. As mentioned before, the integral under the shear force curve was taken, also known as the impulse, and then divided by the time interval. The braking force is the ground reaction force causing friction during heel strike and the propulsion force is the ground reaction force propelling the foot off the ground during toe-off. The variable-flex had a higher braking force (68.25 N) in relation to the K4 (63.61 N). Because the cantilevers bend and allow maximum controlled rotation, the human subject applied more ground force during heel strike to add more friction. He mentioned the feeling of looseness during gait, showing his hesitancy in believing the ankle could control his movements in a safe manner. Therefore, the 5 N different demonstrates that uncertainty and need for a higher braking force to control his forward movement. That braking ground force hinders the chance of slipping.

The opposite is true for the propulsive force. The K4 showed a propulsive force of 61.26 N as compared to 51.83 N for variable-flex. This shows the K4 device had a higher energy return to help propel the foot forward during toe-off. The variable-flex ankle was not designed to help propel the foot forward during toe-off, instead it was designed to allow maximum controlled rotation to help mimic the natural human gait. The designed foot and toe system was not tested on the subject. The foot and toe had not been effectively tested separately; therefore, the team did not feel confident testing the foot and toe on the human subject. If the variable-flex ankle was attached to a properly manufactured foot and toe system designed and described earlier, a better propulsive force most likely would have been reached. However, the variable-flex ankle was connected to a dummy prosthetic foot which gives zero energy return so the propulsive force during testing was lower.

5.4.4 Motion Capture Test Discussion

From the motion capture of side step and gait initiation, it is clear the variable-flex ankle does provide adequate arterial and lateral motion. The human subject did not have difficult initiating gait pushing off with both the normal foot and prosthetic foot. Additionally, the subject did not have difficult side stepping to the left or the right as well. This proves the cantilever springs provide substantial flexion required for every day walking activities. During the gait tests as well as these small tests, he mentioned feeling like the prosthetic was loose. This was due to the cantilevers providing too much flexion. From this feedback, the team discussed adding a new part to the device that will allow the person to manually be able to adjust the stiffness and flexibility of the cantilevers depending on the activity they are performing. For normal walking, the cantilever springs could have been stiffer and not as flexible; whereas, during the incline test, the cantilever springs needed to be more flexible to allow for natural heel-toe walking up and down an incline.

For the incline test, the human subject preferred to walk with the variable-flex ankle. He described it as a potential specialty hiking prosthetic. When walking with his K4 prosthetic device, he only uses his toes to propel himself up the hill because it takes too much energy to try to make the K4 device walk heel-toe up the incline. He said, “It feels like I’m walking up double the incline in this.” When walking up and down the incline with the variable-flex ankle, he said, “This is the best I’ve felt since ’05.” and “This walks phenomenal [sic] up and down the incline.”

This positive feedback encouraged the success of this device for a potential specialty ankle for active amputees. Because the cantilevers allowed for maximum flexion, while maintaining overall stability in the ankle joint, a person can walk up and down inclines with ease. The human subject tests proved that this novel prosthetic design has demonstrated the potential to change the market for low cost, passive prosthetic ankles that provide for an active lifestyle.

6.0 Discussion and Conclusion

6.1 Issues with Material Selection

We experienced a number of complications with material selection for manufacturing our prototype. First, we did not order appropriate stock. Our stock was a thick rectangular prism of aluminum which proved difficult to cut properly and was always a hassle to machine. Aluminum proved easy to machine despite the stock and we had a surplus which gave us room for errors. Moving forward to improve our design we would look into Titanium to reduce the overall weight while still maintaining strength.

With regards to the Aluminum-Bronze, it proved the concept and operated exactly how we calculated it to. It was difficult to track down a manufacturer to give us our specific part dimensions. It was also heavy for our specific parts. Moving forward we would experiment with carbon fiber planks and different dimensions for our planks to maintain the same stiffness.

For the foot material, we would not use the same E-Glass 7781. It proved to have a low yield strength which would make it more susceptible to catastrophic failure. We would recommend carbon fiber since it is stronger and lighter than fiberglass and it can also bend more.

6.2 Issues with Manufacturing

There were multiple hindrances that slowed the manufacturing process of the first generation prototype. First and most prevalent was the human error in machining. A majority of the parts were machined on a CNC machine using the machining program Esprit. With these programs, users are able to specify offsets that will slightly alter the orientation of the cutting tool to a certain side of the exact cutting line. Some of these offsets were specified incorrectly and resulted in some parts being machined too small and having to be remade and others being machined too large and having to be adjusted. This slowed the overall machining process slightly and some of the finished parts were rougher than anticipated, so they needed to be adjusted slightly in order to fit. Through the duration of this project however, the prolonged exposure to these tools and programs made constructing some of the later parts significantly easier and realizing the initial errors allowed the group to keep them from repeating.

Another problem that we ran into was limited access to the machines in the school's manufacturing labs. Because of machining classes at various times throughout the week, it was difficult to find times where the team could reserve a CNC machine when a member was available. This restricted access reduced the team's available time to reserve a machine to approximately two hours per day, which was not always sufficient time to manufacture a part.

The third and final significant issue with the manufacturing process was the limitations of the tools and the machines in the shop. Because of the machining classes, the available tools were limited, so the team was not able to use the exact sizes that we had been planning to use. There were also parts that needed angled faces to be machined, which required the use of rounded nose mills, which were unavailable until after the part had been manufactured using a standard end mill which left steps in the angled face that needed to be sanded down. The limitations of the machines were not a significant issue, as the parts being machined were all small and fairly simple. The only problems arose on the parts that did not have all straight faces. Orienting the part in the machine was difficult and in order to safely operate the machine, the orientation needed to be altered, which resulted in a less precise final part after the machining was completed.

Despite the setbacks of scheduling and tooling, we received fantastic support from our staff contact, Mike Poon, throughout the manufacturing process. Mike provided us with many resources such as tutorials and assisted us when we did not know how to operate a machine effectively. He also assisted us in getting access to lab equipment in order to meet our testing deadlines

6.3 Design Advancements

The team gathered useful data from the original prototype design and manufacturing. Moving forward, the material selection for the next prototype would involve higher end materials such as titanium and carbon fiber. These materials would replace the aluminum and aluminum bronze components in our first prototype. By changing out the materials the next prototype will be significantly lighter, and also perform better. While the cost will certainly increase, it will remain below our constraint of $5000 dollars. The team will also look into a way to preload the ball joint socket of our design. Doing so will increase the stability and performance of the ankle prosthetic.

6.4 Conclusions

- Fulfilled the objective of being a load limiting K3 prosthetic
- Prototype cost below $5000
- Filed for a provisional patent on April 17th, 2014 patenting the IP of the MQP design
- Device fits into a niche as both an affordable K3 prosthetic, and also as a high end customizable component for amputees who enjoy hiking, climbing, and other outdoors activities
- Low-quality materials hinder performance and increase weight

7.0 Acknowledgments

Our team would like to acknowledge Christopher Brown, Steve Thibeau, Jason Rizzo, Todd Keiller, Mikrolar, and Michael Poon. Thank you for everything.

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Appendix A: Additional Existing Prosthetic Models

Most prosthetic ankles that have K3 classification today are powered by means of motors, actuators, or hydraulics. All of these technologies are used because humans raise their center of mass by approximately 5cm during toe off of every stride. Because of this need to generate a lifting force, prosthetic ankles resort to these active technologies instead of attempting to find solutions using less expensive, passive technology like springs.

As an example of the technologies noted above, patent number US8574312 details a prosthetic ankle that is powered both by means of motors and hydraulic pistons. (Moser, 2013) According to the patent, the ankle is classified as self-stabilizing, meaning that the hydraulic system acts as a damper for the ankle such that it comes to rest in a neutral position. Because of the added resistance from the hydraulic system, the prosthetic is advertised as a product that can assist with stability in walking on stairs and ramped surfaces.

Patent number US8512415 describes another prosthetic ankle. This particular product uses two uniaxial springs to provide stability to the ankle joint and one of the springs is force controlled by an actuator that allows the prosthetic to provide the necessary force to allow the user to walk with a normal gait (Herr, 2013). Additionally, the prosthetic has a motor that controls the flexion of the ankle. The actuator actively controls the ankle's push off and applies its peak torque to the ankle.

The iWalk PowerFoot BiOM generates power during plantar flexion, propelling the prosthesis forward. It is comprised of a shank member, a foot member that is operatively configured with respect to the shank member, a motor configured to plantar flex the foot member with respect to the shank member; a series elastic element connected between at least one of the motor and the shank member and the motor and the foot member; at least one first sensor having an output from which a walking speed of an upcoming step can be predicted; at least one second sensor having an output from which ankle torque can be determined; and a controller configured to control the motor's torque. The prosthetic device predicts the walking speed of the upcoming step using its sensors (H. Herr, 2012a). The predictions then modify the net work performed during the step by altering the ankle torque. The torque is lower for slow walking speeds and higher for fast walking speeds. This reduces the work performed by the actuator over a gait cycle. The iWalk PowerFoot BiOM users indicate less pain, more energy, and the feeling of having their leg back. They report less fatigue, an increase in daily activities, fewer pressures inside of the socket, and more stability on uneven terrain (H. Herr, 2012b). The result of this prosthetic device is a healthier patient with a more active lifestyle.

The C-Leg prosthetic is a microprocessor-controlled knee that the user can speed up, slow down, use to take on hills, and go down stairs with a secure, more natural gait. The microprocessor that controls the prosthetic receives feedback from multiple sensors 50 times a second, allowing the knee to anticipate your next move and make adjustments in real time ("The C-Leg", 2014). This actively keeps the knee stable upon weight and free swinging during a step. Another aspect of the C-leg is its ability of stumble recovery. Whenever the C-Leg senses that the user is in an insecure position, it will stiffen to provide the support needed to recover. When it senses that the user is secure again, it returns to its normal support. The C-leg prosthetic has multiple modes for various types of activities. There is a mode for activities like walking, riding a bike, and driving. There is also a standing mode that locks the leg at certain flexion angles to help use less energy. The user can manually change modes by a wireless remote control. Overall, the C-leg is durable and user friendly. It has a tough exterior shell that protects it from the environment. It also includes an anti-slip feature to make the knee more stable during a gait cycle ("The C-Leg", 2014).

Appendix B: Additional Decompositions

Decomposition 3

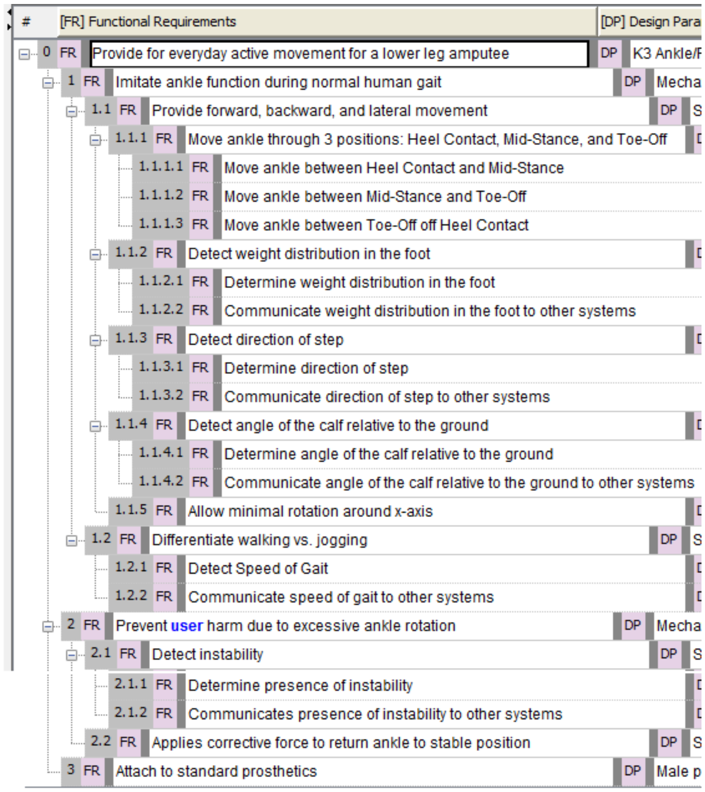

Figure 33: Third Decomposition of FR's

Our third attempt at decomposing the FR's began with a major change in top level FRs, as can be seen in Figure 33, above. The team simplified the previous iterations into three top level FR's. The top level FRs at this point included:

- Imitate ankle function during normal human gait
- Prevent user harm due to excessive ankle rotation
- Attach to standard prosthetics

The biggest fault with this design iteration was that it did not lead to a design that would fit under the constraints of the device. Under the Top FR1: Imitate ankle function during normal human gait were lower level FRs which included:

- Provide forward, backward, and lateral movement
- Differentiate walking and jogging

These lower level FRs broke down into systems which were based on sensors. The design parameters included force plate sensors, accelerometer sensors, angle sensors, and gyroscope sensors. Because the design would include four different types of sensors and response devices, the device would end up being too expensive, and would be too bulky to fit into a foot cover. The design was not simple, failing to abide by axiom 2. The entire decomposition was goal oriented rather than function oriented. The FR's were broken down in terms of gait cycle. The mechatronics added to much complexity, without enough improved benefit. Therefore, this decomposition did not lead to a device that was simple, met the design constraints, and proved to be a viable design option.

Decomposition 4

#		[FR] Functional Requirements
0	FR	Provide for everyday active movement for a lower leg amputee while limiting the load on the residual limb
1	FR	Connect to existing prosthetic pylons
2	FR	Provide controllable rotation in the ankle joint
2.1	FR	Allow controllable rotation around x-axis
2.1.1	FR	Set minimum torque required for rotation at non-zero number
2.1.2	FR	Provide increasing resistance through +/- 5 degrees to fit a cubic curve
2.1.3	FR	Apply logarithmic torque resistance at and beyond maximum rotation
2.2	FR	Allow controllable rotation around y-axis
2.2.1	FR	Set minimum torque required for rotation at non-zero number
2.2.2	FR	Provide increasing resistance through +12.5/-17.5 degrees to fit a cubic curve
2.2.3	FR	Apply logarithmic torque resistance at and beyond maximum rotation
2.3	FR	Allow controllable rotation around z-axis
2.3.1	FR	Set minimum torque required for rotation at non-zero number
2.3.2	FR	Provide increasing resistance through +/- 5 degrees to fit a cubic curve
2.3.3	FR	Apply logarithmic torque resistance at and beyond maximum rotation
2.4	FR	Return to neutral stance when no moment is applied
2.4.1	FR	Return to neutral x-axis position
2.4.2	FR	Return to neutral y-axis position
2.4.3	FR	Return to neutral z-axis position
3	FR	Reduce impulse of ground on the ankle joint
3.1	FR	Distribute weight of user over a foot-sized base
3.2	FR	Absorb force from residual limb to ground
4	FR	Provide controllable toe rotation during gait
4.1	FR	Provide a stable toe base on which to toe off
4.2	FR	Allow controllable toe rotation around y-axis
4.2.1	FR	Provide increasing resistance through +20/-5 degrees to fit a cubic curve
4.2.2	FR	Apply logarithmic torque resistance at an beyond maximum rotation

Figure 34: Fourth Decomposition of FR's

Our fourth decomposition, as seen above in Figure 34 is close to the final decomposition. There are two major problems with this iteration. The design parameters are not specific enough and not accurate to the final design alternative. For example, the design parameters had pre-loaded springs as part of the design, but the team decided not to incorporate pre-loaded springs into the final design. Additionally, the decomposition does not include specific tolerances and numbers. Each spring force should include the value of spring constant. The carbon fiber planks should include a thickness value of each plank. There should also be a numerical value for the exact amount of logarithmic torque resistance that should be applied after a specified maximum rotation for the toe rotation around the y-axis. Because this decomposition only failed to be specific, this overall design proved to be a viable design alternative. To complete this decomposition, the team needs to measure and calculate tolerances and specific design parameter values. Once that is complete, the axiomatic decomposition will be final.

Appendix C: Full Breakdown of FR's

- FR-0: Our overall FR was to match the requirements of a K3 prosthetic in terms of everyday movement for the amputee. This is similar to our overall objective described in Section 1.1: Objective
- FR-1: The purpose of this requirement was to design a device that was modular with most existing prosthetics on the market. We wanted to make the design universal as well as make the ankle and foot independent. The user could install the entire device to a prosthetic pylon or install the ankle or foot autonomously to existing prosthetic hardware.
- FR-2: In order to provide the amputee with a realistic rotation of the ankle joint, we had to mimic the ankle rotation of an actual ankle as much as possible. This rotation also had to be controllable by the user.
    - FR-2.1: The purpose of this requirement was to enable a user to feel rotation similar to an ankle during normal gait. From our Cartesian coordinate system, rotation around the x-axis was equivalent to the ankle rolling from side to side. To avoid coupling rotation in other directions we assured the ankle would only rotate around the x-axis when the user engaged a torque in the y direction.
        - FR-2.1.1: Bio-mechanically an ankle does not rotate freely due to the attachment of muscles, ligaments and tendons. It requires an adequate torque generated from the user's dynamic motion to rotate the ankle. The device was designed to require a set torque value that initiated rotation around the x-axis to simulate the muscles, ligaments and tendons.
        - FR-2.1.2: We wanted to create resistance as torque increased in magnitude. The human ankle only rotates side to side only +/- 5 degrees. Our device needed to be able to continually resist side to side torque while also preventing the ankle from rotating past +/- 5 degrees.
        - FR-2.1.3: Upon reaching the maximum allowable rotation, we want the mechanism to apply additional resistance to any further movement in the x-direction. This will help to prevent injury of the user and damaging of the prosthetic.
    - FR-2.2: The purpose of this requirement was to enable a user to feel rotation similar to an ankle during normal gait. From our Cartesian coordinate system, rotation around the y-axis was equivalent to the ankle in dorsal flexion and plantar flexion. To avoid coupling rotation in other directions we assured the ankle would only rotate around the y-axis when the user engaged a torque in the x direction.
        - FR-2.2.1: Bio-mechanically an ankle does not rotate freely due to the attachment of muscles, ligaments and tendons. It requires an adequate torque generated from the user's dynamic motion to rotate the ankle. The device was designed to require a set torque value that initiated rotation around the y-axis to simulate the muscles, ligaments and tendons.

        - FR-2.2.2: We wanted to create resistance as torque increased in magnitude. The human ankle only rotates in dorsal and plantar flexion only +/- 12.5-17.5 degrees. Our device needed to be able to continually resist dorsal and plantar torque while also preventing the ankle from rotating past +/- 12.5-17.5 degrees.
        - FR-2.2.3: Upon reaching the maximum allowable rotation, we want the mechanism to apply additional resistance to any further movement in the y-direction. This will help to prevent injury of the user and damaging of the prosthetic.
    - FR-2.3: The purpose of this requirement was to enable a user to feel rotation similar to an ankle during normal gait. From our Cartesian coordinate system, rotation around the z-axis was equivalent to the foot abducting and adducting. A foot abducting and adducting is more complicated to control since it does not encompass ground reaction forces. From this we decided a design that limited rotation around the x and y-axis would also limit rotation around the z-axis.
        - FR-2.3.1: Bio-mechanically an ankle does not rotate freely due to the attachment of muscles, ligaments and tendons. It requires an adequate torque generated from the user's dynamic motion to rotate the ankle. The device was designed to require a set torque value that initiated rotation around the z-axis to simulate the muscles, ligaments and tendons.
        - FR-2.3.2: We wanted to create resistance as torque increased in magnitude. The human foot on abducts and adducts only +/- 5 degrees. Our device needed to be able to continually resist abducting and adducting torque while also preventing the ankle from rotating past +/- 5 degrees.
        - FR-2.3.3: Upon reaching the maximum allowable rotation, we want the mechanism to apply additional resistance to any further movement in the z-direction. This will help to prevent injury of the user and damaging of the prosthetic.
    - FR-2.4: The human ankle returns itself to a neutral stance automatically through muscles, ligaments and tendons. The learned technique of walking in a human's developmental stage helps an ankle return to a neutral stance during swing phase. Our design needed to return to neutral stance without any interference from the user.
        - FR-2.4.1: The ankle must return to a neutral x-axis position after rotation around the y-axis or z-axis
        - FR-2.4.2: The ankle must return to a neutral y-axis position after rotation around the x-axis or z-axis
        - FR-2.4.3: The ankle must return to a neutral z-axis position after rotation around the x-axis or y-axis
- FR-3: We intended for the design to dissipate a load over a greater length of time. The prosthetic device should be able to distribute the load to areas other than the residual limb or knee.

- FR-3.1: The design should mimic the size of an actual foot as to fit in a standard prosthetic foot cover, and cover the maximum surface area.
- FR-3.2: The design needs redirect the load normally experienced from the residual limb to a mechanical system capable of withstanding the load.

- FR-4: The design needs to mimic human toe off. Many prosthetics do not grant realistic toe off and energy return is generally low
    - FR-4.1: The design needs to enable enhanced balanced when providing energy return during the toe off phase of gait. The foot will see considerable cycles and terrains, so the design needs to be durable enough to withstand those forces.
    - FR-4.2: The design must provide sufficient user control when operating rotation around the y-axis.
        - FR-4.2.1: The design must provide rotation at +20/-5 degrees to mimic human toe rotation.

Appendix D: Additional SolidWorks Screenshots

Top View

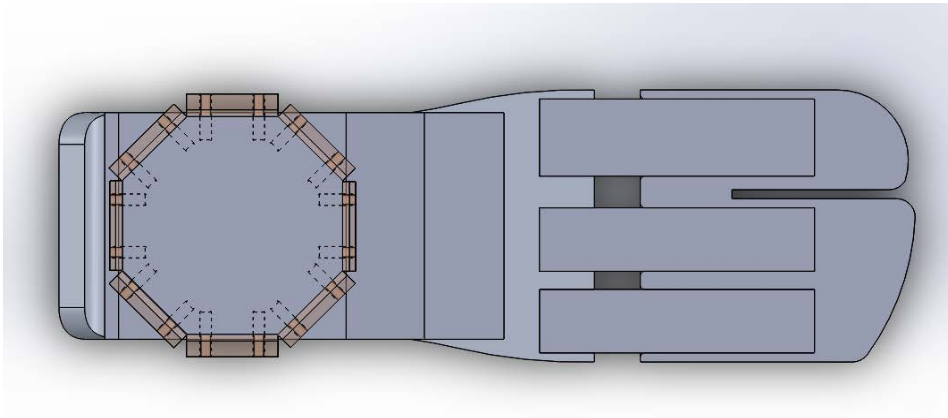

Figure 35: Top View of Final Design

Front View

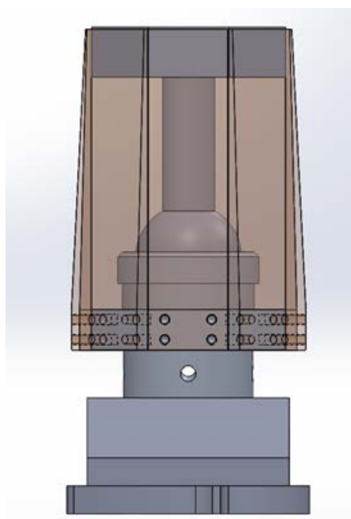

Figure 36: Front View of Final Design

Side View

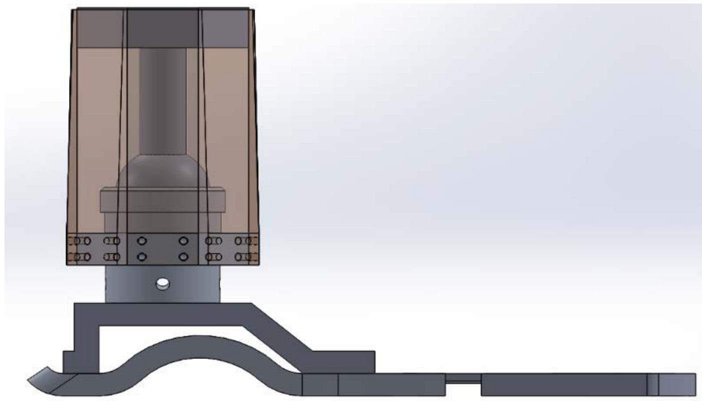

Figure 37: Side View of Final Design

Appendix E: Subject Testing Set-Up

To mimic the natural gait cycle, two force plates are placed on the floor with wooden boards as shown in Figure 38 below. The distance from the center of force plate 1 to the center of force plate 2 was 109 cm.

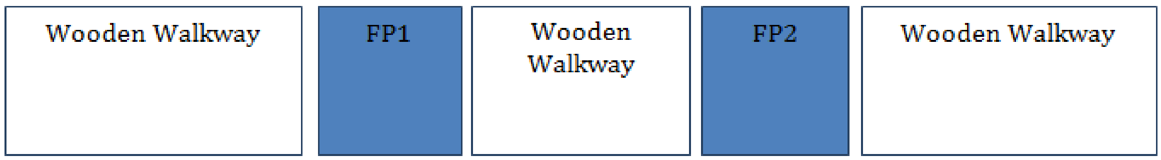

Figure 38: Subject Testing Set-Up

The subject information and trial information are shown in Figure 39 and Figure 40 below.

Category	Value
Subject Height	182.9 cm
Subject Weight	220 lbs
Sex	Male
Amputated Leg	Left

Figure 39: Test Subject Information

Trial #	Foot Hitting Force Plates
Trial 1	Normal Foot with K4
Trial 2	Normal Foot with K4
Trial 3	Normal Foot with K4
Trial 4	K4 Prosthetic
Trial 5	K4 Prosthetic
Trial 6	K4 Prosthetic
Trial 7	Variable-Flex Ankle
Trial 8	Variable-Flex Ankle
Trial 9	Variable-Flex Ankle
Trial 10	Normal Foot with Variable-Flex
Trial 11	Normal Foot with Variable-Flex
Trial 12	Normal Foot with Variable-Flex

Figure 40: Subject Testing Trial Information

Motion Capture Video Snapshots of testing are shown below in Figure 41 and Figure 42 .

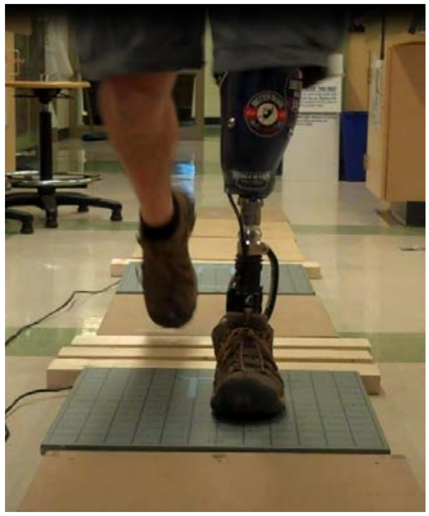

Figure 41: Subject Testing of K4 Prosthetic

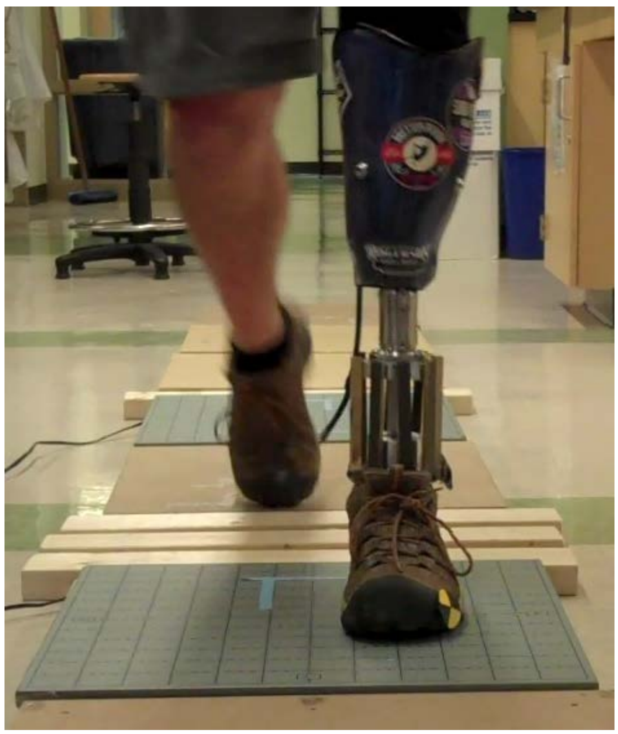

Figure 42: Subject Testing of Prototype Ankle

Appendix F: Normal Foot Data

Normal Foot with K4 Prosthetic

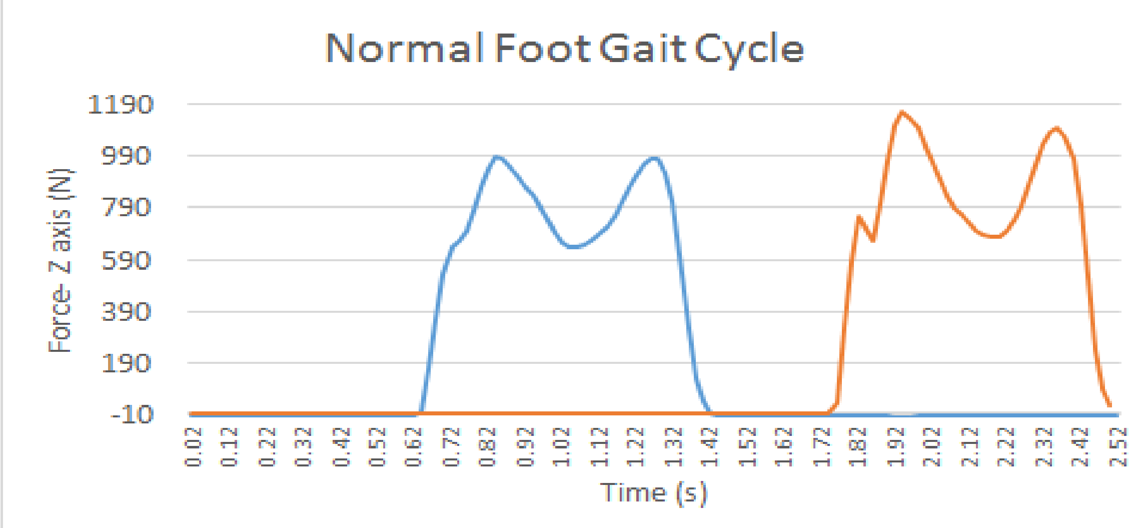

Figure 43: Force Plate Data from Normal Foot with K4 Prosthetic

The blue line in Figure 43, above, indicates force plate 1 and the orange line indicates force plate 2. For both curves, the first hump demonstrates the maximum force from heel strike, the dip demonstrates the shift to mid-stance, and the second hump demonstrates the maximum force from toe-off. From this graph, four types of analysis can be assessed. The first is cadence. Cadence is the time from heel strike to heel strike, or time of complete gait cycle. This is measured by finding the time interval from maximum heel strike peak of force plate 1 to maximum heel strike peak of force plate 2. The second analysis is average time from heel strike to toe off. This is measured by finding the time interval from the peak of heel strike to the peak of toe-off for both force plates and taking the average. The third analysis is the percentage of time the foot is on the ground during gait cycle. This is completed by measuring the time interval the force plate 1 is reading a force above zero (foot on ground) and dividing that time by the measured total gait time interval. The final analysis for this graph is the average rate of rise. Rate of rise is the amount of time elapsed from the moment the foot hits the force plate to the moment maximum heel strike force is reached. This calculation was found for both force plates and averaged. The values for each analysis for this graph are shown below in Figure 44.

Analysis	Value
Cadence (Time from Heel Strike to Heel Strike)	**1.1 s**
Heel Strike to Toe Strike	
FP1	0.44 s
FP2	0.36 s
Average Time Heel Strike to Toe Off	**0.4 s**
% of Foot on Ground during Gait Cycle	**70.90%**
0.78 s/1.1 s	
FP1 Rate of Rise	0.22 s
FP2 Rate of Rise	0.26 s
Average Rate of Rise	**0.24 s**

Figure 44: Summary of Force Plate Data for Normal Foot with K4 Prosthetic

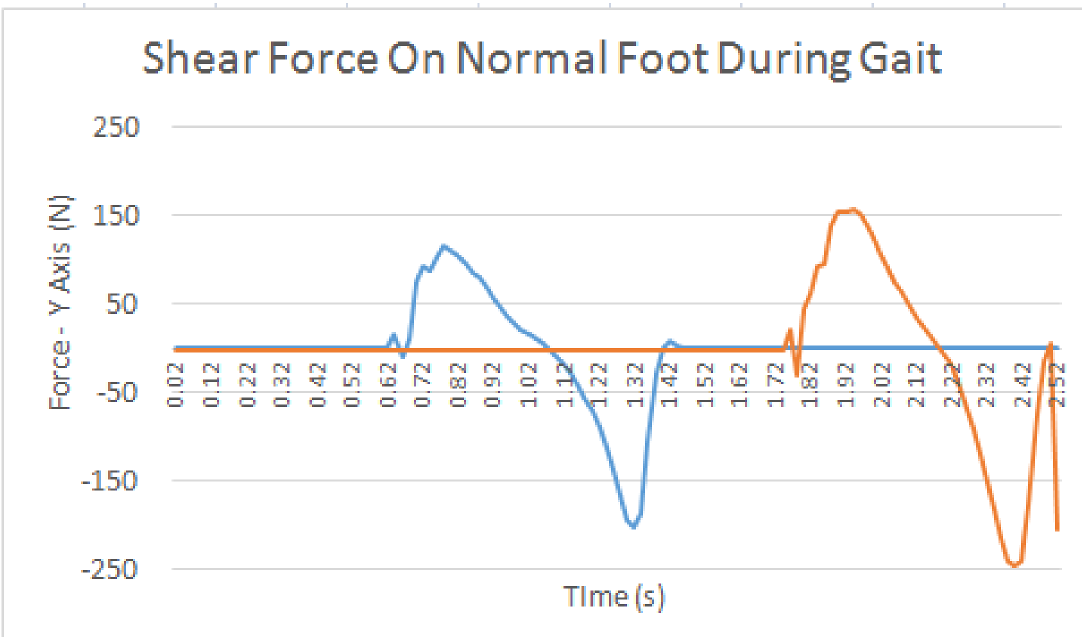

Figure 45: Shear Data for Normal Foot with K4 Prosthetic

This graph in Figure 45, above, shows the shear force (Fy) experienced by the foot while walking. The human subject was walking in the negative y direction; therefore, the positive values on this graph actually indicate a negative Y force value. As discussed before, the stance phase is broken into two sub-phases: braking and propulsion. The first hump on the graph indicates the braking force during heel strike (negative ground reaction force) and the second hump indicates the propulsion force during toe-off (positive reaction force). Again, the blue is the first force plate and the orange is the second force plate. To find the average braking force overtime and the average propulsion force over time, the integral of each curve must be found. The area under the force-time curve is the impulse (F*s). Therefore, by taking the integral in excel for each time point on the graph; the impulses for each hump were determined.

$$Impulse = \Delta Momentum \ can \ also \ be \ written \ as \int F_{net} \, dt = \Delta(m \times v)$$

The equation in excel used to take the integral was: (1/50)*(F-$F_{initial}$). By summing each impulse at the time intervals during which the individual humps occur, the total braking and propulsion impulses for each force plate are determined. Once the total impulses were determined, they were divided by the time interval they occurred to find the average braking the propulsion forces. The derivation is shown below.

$$Impulse = Force * Time$$
$$Force = Impulse/Time$$

Once the average braking and propulsion forces were found for each individual force plate, the two were averaged together to find an overall average braking and propulsion forces (ground reaction forces) experienced on the foot during gait. The values for this analysis are summarized in Figure 46 below.

Force Plate 1	
Braking Impulse (N*s)	28.63 N*s
Time	0.38 s
Propulsion Impulse (N*s)	24.92 N*s
Time	0.38 s
Average Braking Force	75.34 N
Average Propulsion Force	65.60 N
Force Plate 2	
Braking Impulse (N*s)	36.08 N*s
Time	0.48 s
Propulsion Impulse (N*s)	40.75 N*s
Time	0.32 s
Average Braking Force	75.17 N
Average Propulsion Force	127.34 N
Average Braking Force	**69.84 N**
Average Propulsion Force	**101.87 N**

Figure 46: Summary of Shear Data for Normal Foot with K4 Prosthetic

Normal Foot with Variable-Flex Ankle

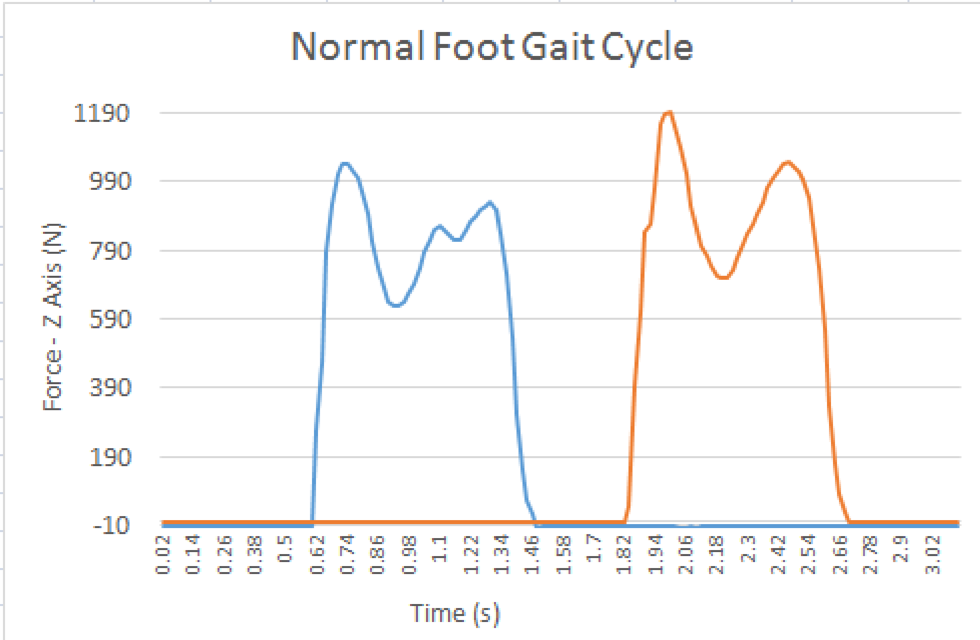

Figure 47: Force Plate Data for Normal Foot with Prototype Ankle

Analysis	**Value**
Cadence (Time from Heel Strike to Heel Strike)	**1.28 s**
Heel Strike to Toe Strike	
FP1	0.58 s
FP2	0.50s
Average Time Heel Strike to Toe Strike	**0.54 s**
% of Foot on Ground during Gait Cycle	**65.60%**
0.84 s/1.28 s	
FP1 Rate of Rise	0.14 s
FP2 Rate of Rise	0.16 s
Average Rate of Rise	**0.15 s**

Figure 48: Summary of Force Plate Data for Normal Foot with Prototype Ankle

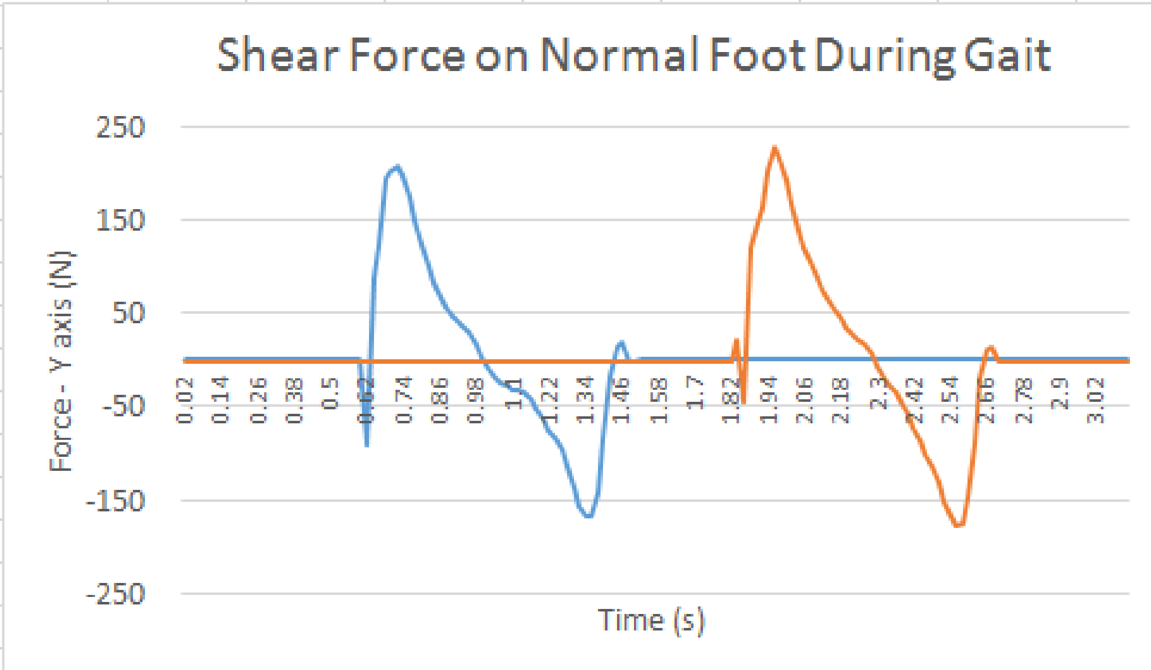

Figure 49: Shear Force on Normal Foot with Prototype Ankle