Passive Pressure Modulation Mechanism for Improved Locomotion

Final Report

ME450 - Design and Manufacturing III (W21)

Team 24

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EXECUTIVE SUMMARY

Our team was tasked with designing and fabricating a passive mechanism to assist with walking. Our sponsor, Steve Schrader, suffers from pes cavus, and experiences severe pain when walking. His current solution, the Disco Shoe, adds too much height and constrains blood flow in his foot, adding to his pain. The mechanism must reduce pressure in his metatarsal region and not impede his motion/allow for normative gait. It also must be affordable, durable, easy to clean, and be 3D printable. These requirements came from the sponsor and our own research into gait and similar products.

To accomplish the requirements and their associated specifications, our team, with advice from Mr. Schrader came up with the Springblade design. This design aimed to absorb energy during heel strike and release it later to assist with push off, reducing pressure on the metatarsal region. The blades of the design also collapsed into a curved shape, mimicking rocker sole footwear, which is shown to reduce pressure on the foot. This design was analyzed using FEA (Hypermesh-Optistruct), in order to determine stress distributions and deformation. This allowed us to make predictions and some design changes prior to fabricating a physical prototype. We also performed multiple kinematic analyses of regular shoes vs. the Disco Shoe, the sponsor's current solution. Using this analysis, we were able to create a standard for normative gait that the Springblade could be compared to.

Following these analyses, the Springblade prototype was made using rubber. It was then tested in the Neurobionics lab alongside regular shoes and the Disco Shoe for comparison. After analyzing the data, we found that there was a slight reduction in the push off ground reaction force. Our analysis also showed a return to normative gait relative to the regular shoes. However, the overall length of the Springblade prototype made it difficult to push off, so that could have contributed to the data we obtained. The rubber was less stiff than the material we modeled with, so the blades collapsed more than anticipated, leading to less assistance during push off. After testing, several design changes were made, including reducing the length and number of blades. Blades were also thickened to increase stiffness. The sponsor's orthotic was also integrated into the design.

Moving forward, we recommend more iteration and prototyping. This will allow for more testing on the part of the sponsor, and he can continue to iterate on the design. Investigation into other methods of manufacturing will be beneficial since 3D printing will soon become expensive if used for every iteration. Testing with force or pressure plates might also improve feedback and design refinement.

TABLE OF CONTENTS

PROBLEM DEFINITION

We met with our sponsor as a team many times throughout the semester, and from these meetings we were able to learn more about his problem and were given requirements for the design. We also conducted our own research, from which we were able to come up with our own additional requirements and specifications.

Problem Description and Background

Our sponsor suffers from pes cavus, a physical condition in which his right foot is unable to flatten and distribute the pressure caused by his body weight evenly throughout his foot. In an attempt to fix his pes cavus foot and normalize his gait, he went through multiple surgeries. Unfortunately, these surgeries failed and have left him with a permanent functional deficit.

Figure 1. This x-ray shows the screw in our sponsor's first metatarsal. The multiple surgeries attempted to fix his pes cavus foot and normalize the arch in his midfoot.

Before describing his functional deficit in detail, we need to explain the gait cycle and create a common understanding to pinpoint which phases our sponsor is experiencing discomfort. The gait cycle splits up one's gait into two major phases, the stance and swing phases, and we will label the right leg as the plant leg in the stance phase. At heel strike, energy from the previous gait cycle is dissipated from contact with the ground. During loading response and midstance, the plant leg acts as an inverted pendulum to efficiently transfer the remaining energy from the previous gait cycle. Our primary focus of the gait cycle is the push off stage, in which the metatarsals experience high pressure and push on the ground to propel its respective leg to the swing phase. Figure 2 below helps visualize the gait cycle in its respective stages. It also shows the ground reaction force (GRF) vector as it acts on the body during the gait cycle. The GRF is at a maximum during the push off phase, which is when the sponsor experiences pain due to pressure on the metatarsals [1].

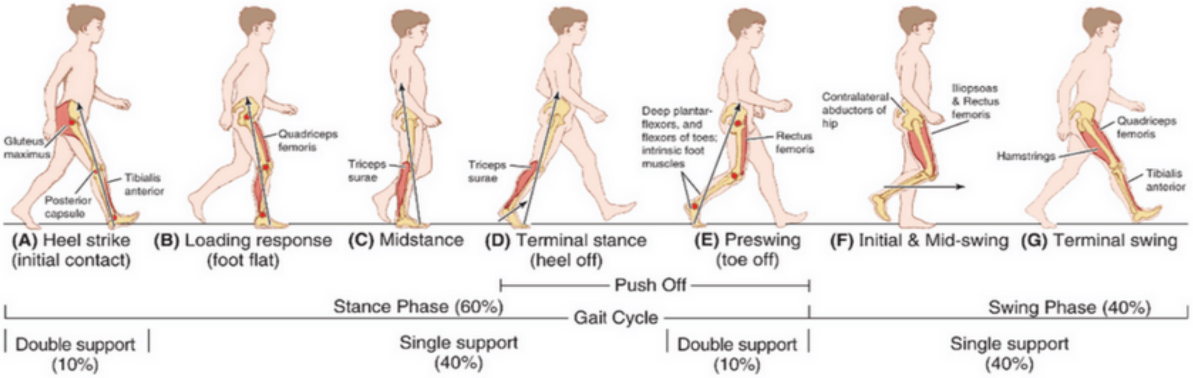


Figure 2. This diagram shows the gait cycle, including the GRF vector at the various stages. The right leg is on the ground in the stance phase and airborne in the swing phase. Our main focus is the push off phase, which occurs at the end of the stance phase. During push off, the GRF vector points up from the metatarsals, where our sponsor experiences his pain.

His permanent functional deficit has severely impaired his gait due to the high-pressure concentration in his metatarsals during push off. This can be seen from the pressure gradient in Fig. 3 and from the difference in stride length in Fig. 4.

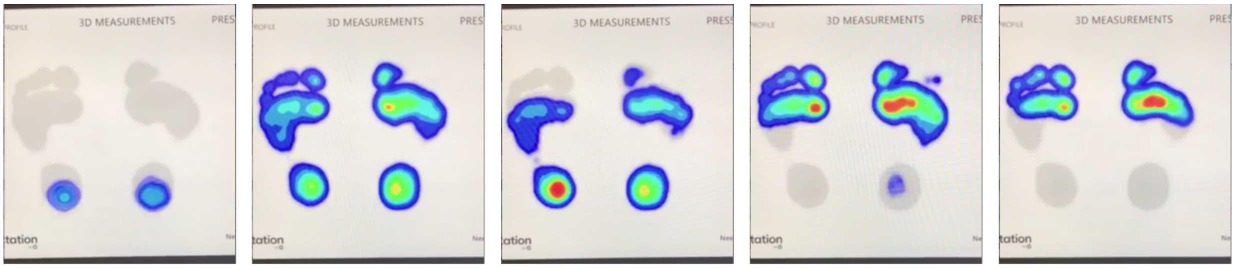


Figure 3. During the push off phase (far right), there is more pressure on the left foot (reversed in the picture) due to the sponsor's attempt to not load his right (injured) foot. Present in his right foot is a smaller area of distributed pressure and a high concentration directly on his first metatarsal.

Figure 4. This figure shows a difference in the range of motion during push off phase with and without his current solution. The left shows the sponsor's unaided walking, and his stride is significantly shorter than in the right image, when he wears the Disco Shoe, his current solution.

The current solution our sponsor uses helps to normalize his gait and increase his range of motion when transferring from stance to swing phase. It works by redirecting the GRF towards his midfoot during the push off phase, reducing pressure on his metatarsals. However, his current solution had drawbacks that our sponsor wanted us to improve. There was a lot of excess material underneath his foot that he wanted to remove. Due to the height of the Disco Shoe, he was forced to add material underneath his left (uninjured) leg to compensate for the change in height. Furthermore, he lacked circulation in his right forefoot due to the stiffness of his solution, and this created another source of discomfort when walking. With our background and research, we were able to create a comprehensive problem definition:

Our primary objective is to design, prototype, and finalize a passive mechanism to decrease the pressure in the sponsor's forefoot, improve his gait, and provide overall comfort when walking. Beyond the scope of this project, the goal is to make the end product accessible and reproducible.

Requirements and Specifications

Through continued meetings with our sponsor, we were able to refine our requirements and specifications. This means that some of our original requirements were changed or simply discarded as we gathered data and made design alterations. Our final requirements and specifications can be seen in Table 1.

Table 1: Set of sponsor and research driven requirements and specifications listed from highest to lowest priority. Priority comes from the sponsor's preferences and our own goals for the project.

Requirements	Specifications	Justification
Reduce Pressure on Metatarsals	Reduces pressure by at least 50% compared to normative	Due to our sponsor's functional deficit, he experiences pain in the metatarsals. Based on existing pressure modulation products [2]
Limited hindrance on mobility	Device cannot exceed 2'' in height	Maintain walking efficiency [3] and allow for maneuverability, given by sponsor
Allows for more normative gait	Kinematic diagrams generated by analysis are closer to normal gait than Disco Shoe diagrams	A non-normative gait could lead to other problems
Durable	At least 10,000 steps before failure	Sponsor given, justified by research [4]
Affordability	Cost less than $200 to 3D print	Accessible to may people
Easy to Clean	No specification	Cleanable with hose water
Mechanism to be 3D printable	No specification	Sponsor has access to 3D printer and would like the ability to iterate

Some of the specifications, such as “Limited Hindrance on Mobility,” came directly from the sponsor. Others came from research and existing solutions, like “Reduces pressure by at least 50%.” Most of the specifications are quantifiable and were tested throughout the semester. Others, like “Mechanism to be 3D printable” did not require quantification and were considered to be parameters of the design itself. Many specifications are goals to improve upon the sponsor’s current solution, the Disco Shoe.

Relieves Pressure on Metatarsal Heads

In order to relieve the pain our sponsor experiences while walking, the pressure on his metatarsals must be reduced as much as possible. A study by Kavros, et al shows that a foot rocking sole with a typical insole can reduce pressure on metatarsal heads up to 39%. This increases to 50% when a thicker insole is added [2]. Based on this, our team hopes to reach a 50% reduction in pressure.

Limited Hinderance on Mobility

In order to improve the mobility of our sponsor, the solution must not exceed 0.6 lbs. For context, we measured a few of our own shoes and they weighed on average around 0.75 lbs. Adding weight to lower limbs decreases the metabolic efficiency of walking [3]. Oxygen consumption roughly increases linearly at 5% ml/(kg*min) per additional kilogram of mass added to the foot, so a 0.6 lb increase corresponds to less than a 2% increase in oxygen usage [3]. In addition, the final solution must not exceed 2” while unloaded. This is to make sure our sponsor, who is 6’4”, does not have any interference with doorways which are usually 6’8” high.

Allows for More Normative Gait

To ensure that the sponsor’s gait is not altered more than it already is, the solution must at least meet or exceed the Disco Shoe in terms of normative gait. This can be measured by comparing kinematic analyses of normal shoes, the Disco Shoe, and the solution we develop. This method is explained in detail in the *Engineering Analysis* section of the report.

Durable

The finished product should be able to go 10,000 steps without failing. This is roughly 4.7 miles. While this does not seem very far, our sponsor does not walk very much, and this device is to assist him with what little he does, like going to the beach. Because of this, it should also be resistant to water and able to go outdoors. This specification is reasonable, as shown in a study that demonstrated that Nylon 6.6 underwent 13,000+ cycles of 26MPa loading before failing [4]. It is also worth noting that as the cost of the device changes, the relative importance of durability could change as well.

Affordable

Our sponsor wants to be able to produce the solution at a low cost, specifically less than $200 in materials and printing fees. He realizes that there is only so much we can accomplish in a shortened semester and wants the ability to iterate on the design further after the semester is over. He also wants the solution to be affordable to produce for others who might have a similar foot deficit - an affordable solution will be accessible to people of all socioeconomic backgrounds. The factors with the largest impact on the price of our solution are material type and the 3D printing technology selected.

CONCEPT EXPLORATION

For such a specific and unique problem, we knew we would need a very thorough design process. We met several times as a group to brainstorm to ensure we completely explored the design space. We took inspiration from our sponsor's input, existing footwear, and even prosthetics.

Concept Generation and Development

Our specific concept generation portion of the design cycle was somewhat unique. Our sponsor was heavily invested in our project and already had a solution space in mind that he wanted us to pursue. We respected the amount of experience and personal intuition that our sponsor had regarding his functional deficit, and appreciated the amount of designs/ideas he had given us. In addition to these, our research led us to complimentary designs ideas that could address this problem from a different perspective. Therefore, we split the concept generation step into two simultaneous parts. In addition, our sponsor had a workaround solution that he employed to manage his pain, so we created a model of that to help with our design process.

Concept One: Disco Shoe Prototype

In order to better understand the current solution from our sponsor, we approximated the "Disco Shoe" as he called it, by cutting foam and attaching it to an old pair of shoes. The original Disco Shoe can be seen alongside our model in Fig. 5. Recreating the Disco Shoe improved our understanding of the sponsor's functional deficit. Having our own approximate version of the solution allowed us to compare other designs to the Disco Shoe in addition to getting our sponsor's pain reduction input when we sent him prototypes.

Figure 5. The black foam block in the left picture is our first Disco Shoe approximation. The right photo is the sponsor's own Disco Shoe.

Concept Two: Sponsor Driven

In addition to the Disco Shoe that our sponsor created, we were provided many sources of inspiration to guide our design process in a specific direction. These concepts focused on compliant mechanisms located at and around the heel of the foot. The aim of this type of solution is to store energy during the heel strike phase of the gait cycle. This energy would be returned as the shank rotates around during midstance and push off and would help propel the foot off the ground before too much pressure is applied to the metatarsals. A lessened load on the metatarsals means our sponsor would feel less pain. In addition, this solution set was lightweight and doesn't have a large width of material at the toe which allowed our sponsor to still move his toes and increase circulation to decrease swelling. This subset of the design space was inspired by existing footwear, such as the *Adidas Springblade.* Some of the concepts sent by the sponsor can be seen in Fig. 6.

Figure 6. These pictures are various concepts or sources of inspiration sent by the sponsor. The SOLIDWORKS model in the upper left was the most developed of our sponsor's concepts and the three images on the bottom are some initial prototypes and designs that our sponsor is working on. The top center image is the *Adidas Springblade.*

Concept Three: Team Design

In order to come up with a robust design based on both our research and our sponsor's experience, we held a brainstorming session to generate a wide range of initial ideas. We took different aspects from these ideas and separated them into categories. These categories were organized into a morphology chart which helped us ideate more concepts. The main design categories that we explored were "Spring Design," "Shoe Geometry," and "Miscellaneous." The resulting morphology chart is shown in Fig. 7.

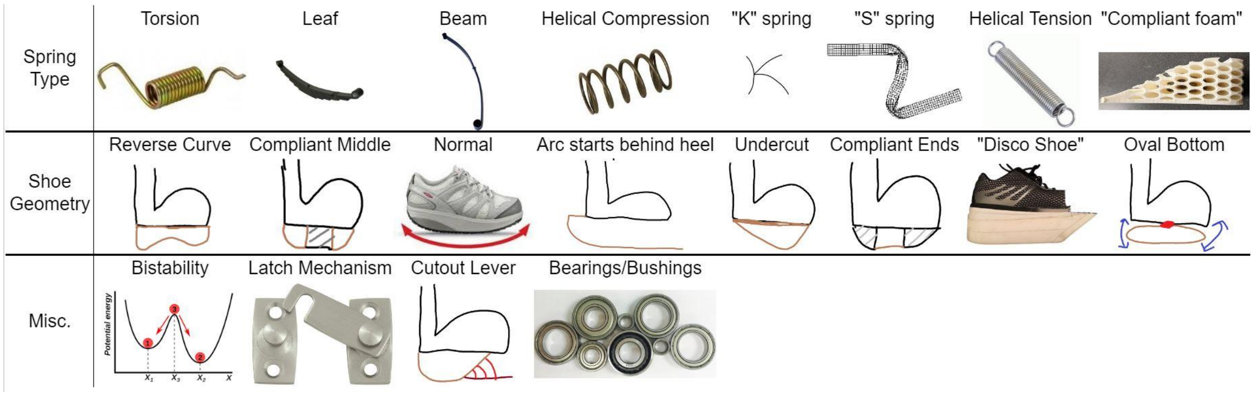


Figure 7. This is the morphology chart we used to help generate new design concepts from the individual design ideas from the brainstorming session. The morphologies are based on ideas from the sponsor, Prof. Shorter, and our individual research.

Concept Evaluation and Selection

The concept selection process for the sponsor driven and team designs involved a variety of methods such as interviewing the sponsor in depth and conducting a thorough examination of the sponsor's requirements. We then applied Prof. Shorter's input and experience on the sponsor's requirements. Because this was a personal project, there was not much precedent to follow. This meant a lot of research came from other fields and applications. Therefore, the sponsor's input and personal preference on our design was critical in ensuring an effective outcome to the project.

Concept One: Disco Shoe Prototype

The Disco Shoe, seen in Fig. 5 above, was used to gain a better understanding of the sponsor's current solution and give us a base on which to compare the other designs. This design helped our sponsor to walk with reduced pain and a more normal gait. However, the Disco Shoe didn't meet all of our design requirements and specifications. The design was quite thick and cumbersome which was a problem for our sponsor who is 6'4" tall. Also, this design didn't allow our sponsor to move his toes at all which restricted blood flow and caused swelling and discomfort. In order to understand the sponsor's functional deficit, we performed a gait analysis on a team member while wearing the shoes. The knowledge this analysis provided was useful in refining the other two design concepts. Because this solution already existed, we did not need to employ a concept selection method, we simply recreated it so we can perform our own testing.

Concept Two: Sponsor Driven

Our sponsor driven designs focused on compliant mechanisms located at the heel. A lot of concepts and ideas came from already existing footwear, and from solutions that the sponsor had already attempted. We took these designs and iterated on them to be more refined. We focused on trying to incorporate a more rounded figure than our sponsor's designs to more closely resemble rocker-sole footwear; our research indicated that this should provide some additional pain management benefit to our sponsor, so we wanted to incorporate it.

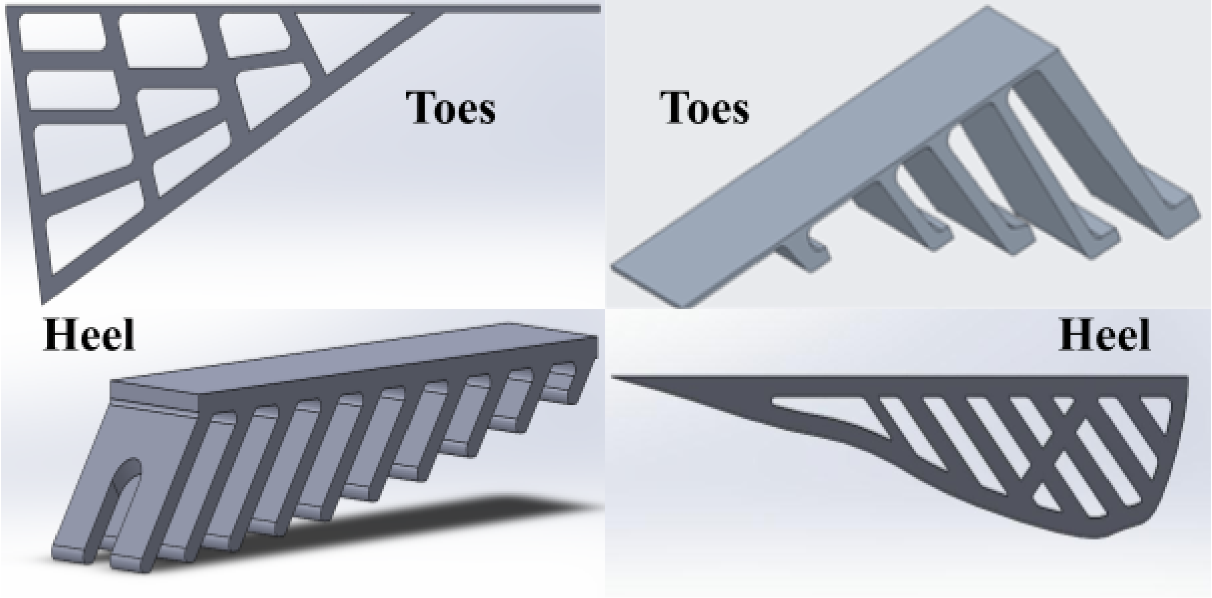


Figure 8. The top two SOLIDWORKS images were the most recent concepts given to us by the sponsor. The bottom two images are the team's iteration on the upper two. They both go the full length of the foot, rather than just the heel region. The one on the left also incorporates footrocker elements while being compliant. Upon conversation with the sponsor, we analyzed these further using FEA.

We chose this design over others because we believed it accomplished our design requirements and specifications better than other design concepts. In conjunction with our research, our interactions with our sponsor, and Prof. Shorter this was our final design concept. In addition to being the superior design concept in terms of sponsor feedback, the final design concept also had a relatively simple cross sectional shape. This meant we could more easily iterate on the geometries of the orthotic and or change the number of supports.

Concept Three: Team Design

During the initial research phase of the design cycle, we found that rocker-sole footwear can reduce pressure on the metatarsal region of the foot during the push off phase of the gait cycle and increase walking efficiency [3]. This research was reinforced by our sponsor's current Disco Shoe solution, which is essentially a large rocker sole. This type of footwear works because it shifts pressure back from the metatarsal region towards the midfoot as the shank rotates over the foot. We believed we could improve upon this simple rocker design feature by adding some compliant material under the metatarsals. This compliant material would store energy during the transition between midstance and push off phases of our sponsors gait cycle. This stored energy should be returned at the end of the push off phase and would help our sponsor walk more easily. In addition, having compliant material at the front of the orthotic near the toes would allow our sponsor to flex his toes more than he can in his current Disco Shoe which would help with the circulation issues mentioned in the *Team Design* section above. These design considerations led us towards the design in Fig. 9.

Figure 9. Sketch of the final design concept we came up with based on the research we conducted regarding rocker-sole footwear and compliant design.

SOLUTION DEVELOPMENT AND VERIFICATION

In order to make sure our design met specifications, we performed different analyses on it, namely FEA and kinematic. These analyses helped us make changes to our design and provided a benchmark against his existing solution, the Disco Shoe.

Engineering Analysis

Our engineering analysis consisted of two approaches: a computational approach and an experimental approach. The computational analysis used Finite Element Analysis to model the deformations and stress distributions on our prototypes. The software used was Altair Hyperworks. The experimental approach used video footage of a team member walking in our prototypes to measure joint angles. These two forms of analysis were essential in improving our design and quantifying our prototype's ability to improve gait.

Finite Element Analysis

After coming up with the initial Springblade design idea, we had to ensure that it would experience the desired deformations and stress distributions at the three stages of gait that we are focused on: heel strike, midstance, and push off. The purpose of performing FEA on the first model was to analytically determine if there would be any fracture due to a design, forcing condition, or material issue. After making significant changes to the design in order to remove any potential fractures or unwanted deformations, we could then make minimal adjustments to the design to achieve the desired deformation, von Mises stress distribution, and vertical normal stress distribution.

Key Assumptions

We assumed a Nylon-6 material in the FEA software, which has a Tensile Modulus of 420,000 psi and a Poisson's Ratio of 0.40 [Goodfellow]. When brainstorming different materials for our design, we wanted a material that was compliant enough to provide the desired deformation and energy storage in the Springblade design. The material also needed the strength to withstand the total ground reaction force throughout the gait cycle, especially at the push off phase when this force is at a maximum.

In addition to the material properties, we needed consistent forcing conditions for each of the three stages. There was no perfect solution to this, and much was based on our intuition and that of our stakeholder. Additionally, we were able to reference results from previous studies shown in Figure 10 below [1]. The magnitudes of the ground reaction forces worked with the assumption of a 200-pound individual. In each phase, the extruded top portion of the design was constrained while the forces were applied upwards on the blades. After much consideration, Table 2 below describes the forcing conditions at each stage of the gait cycle.

Table 2: A table showing the forcing conditions at heel strike, midstance, and push off. The negative %BW force in the horizontal direction at heel strike indicates that the direction of the force from the ground on the individual is backwards. The Springblade design has 10 total blades, so the active blades in the heel strike and push off stages were with respect to the half of the design that would be in contact with the ground.

Stage of the Gait Cycle	Active Blades	% BW in Vertical	% BW in Horizontal
Heel Strike	5 blades at heel	120	-40
Midstance	All blades	100	0
Push off	5 blades at forefoot	125	50

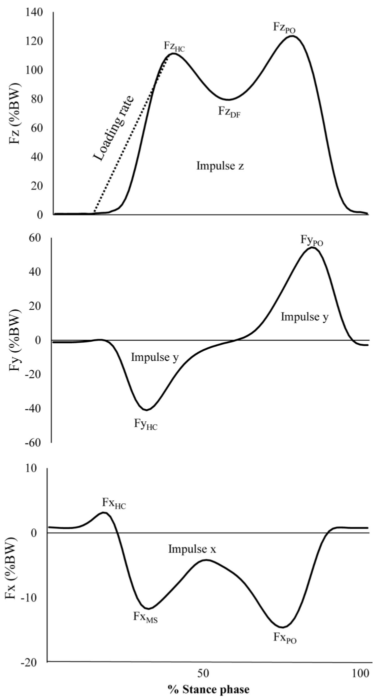


Figure 10: This figure depicts the magnitudes of the ground reaction force in the x, y, and z-directions throughout the stance phase. To simplify the forcing conditions, we ignored any bodyweight component in the x-direction (lateral direction), as the impact on the overall forcing condition in this direction is minimal. The two peaks in the z-direction can be seen as the heel strike and push off phases, and the point of zero force in the y-direction can be interpreted as midstance [1].

Deformation Analysis

Intuitively, the deformation analysis was the easiest of the three analyses to draw information from. It shows visually how the Springblade design would react during the three phases based on the forcing conditions applied. The initial design had shown severe deformations during the heel strike and push off phases, so changes were made in further iterations of the Springblade design to remove the unwanted deformation, such as increasing the thickness of the individual blades. The final iteration of the design, pictured below in Figure 11, removed all potential fractures and significant unwanted deformations.

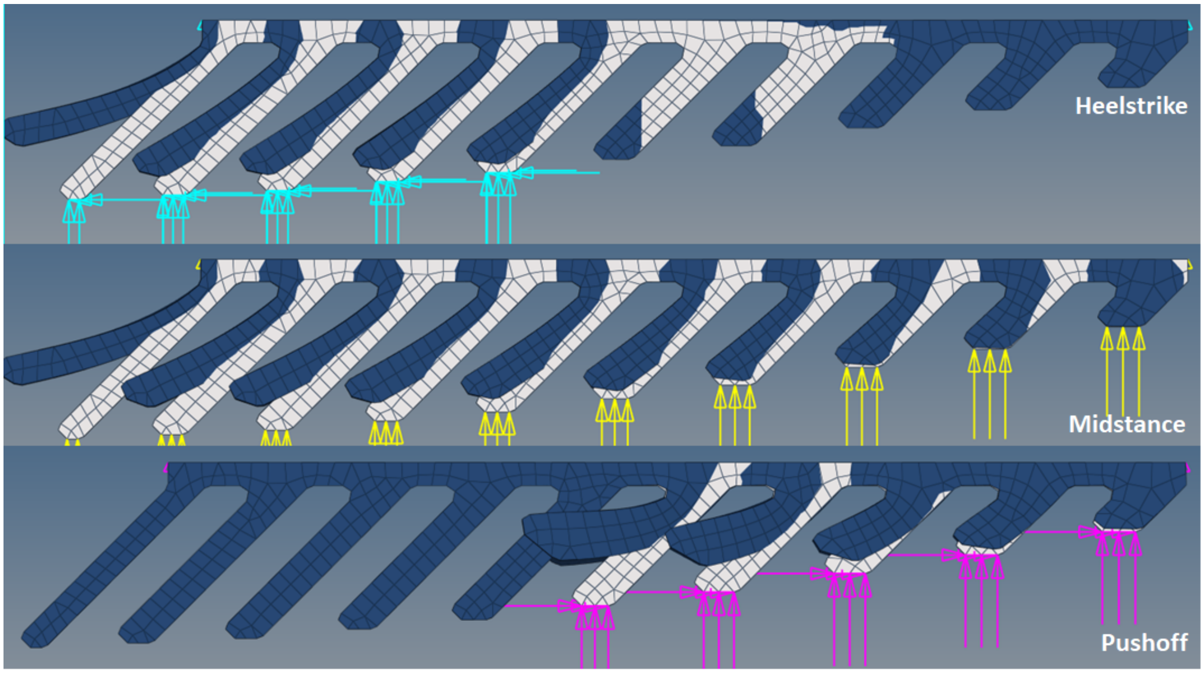


Figure 11: This figure shows the deformation of the Springblade design with the aforementioned forcing conditions at the heel strike, midstance, and push off phases of the gait cycle. The forcing conditions can be seen from the vertical and horizontal force vectors on the blades. The portion of the design highlighted in white represents the initial position of the design while the colored portion represents the deformation. Although one of the blades seems to interfere with its adjacent inactive blade, the forcing conditions are idealized and this will likely not occur.

Von Mises Stress Distribution

The von Mises stress distribution was important for two reasons. The first is analogous with the deformation analysis in which we can see where the critical points are in the design that might result in fracture. If the maximum stress at some point in the design is larger than the ultimate tensile strength of the material, fracture will occur. The forcing conditions at heel strike and push off represent critical points in the gait cycle. Therefore, it can be safely assumed that if the design can withstand the forces at those points, it can withstand the forces at any other point in the gait cycle. Secondly, the von Mises stress distribution shows where the active energy storage is taking place throughout the gait cycle. In the heel strike and midstance phases, we would like to see a stress distribution dispersed among the blades in the heel and midfoot. This stress will be recovered later in the gait cycle during push off when the design will provide extra force to aid in the lack of force generated from the metatarsal region. The von Mises stress distributions can be seen in Figure 12 below.

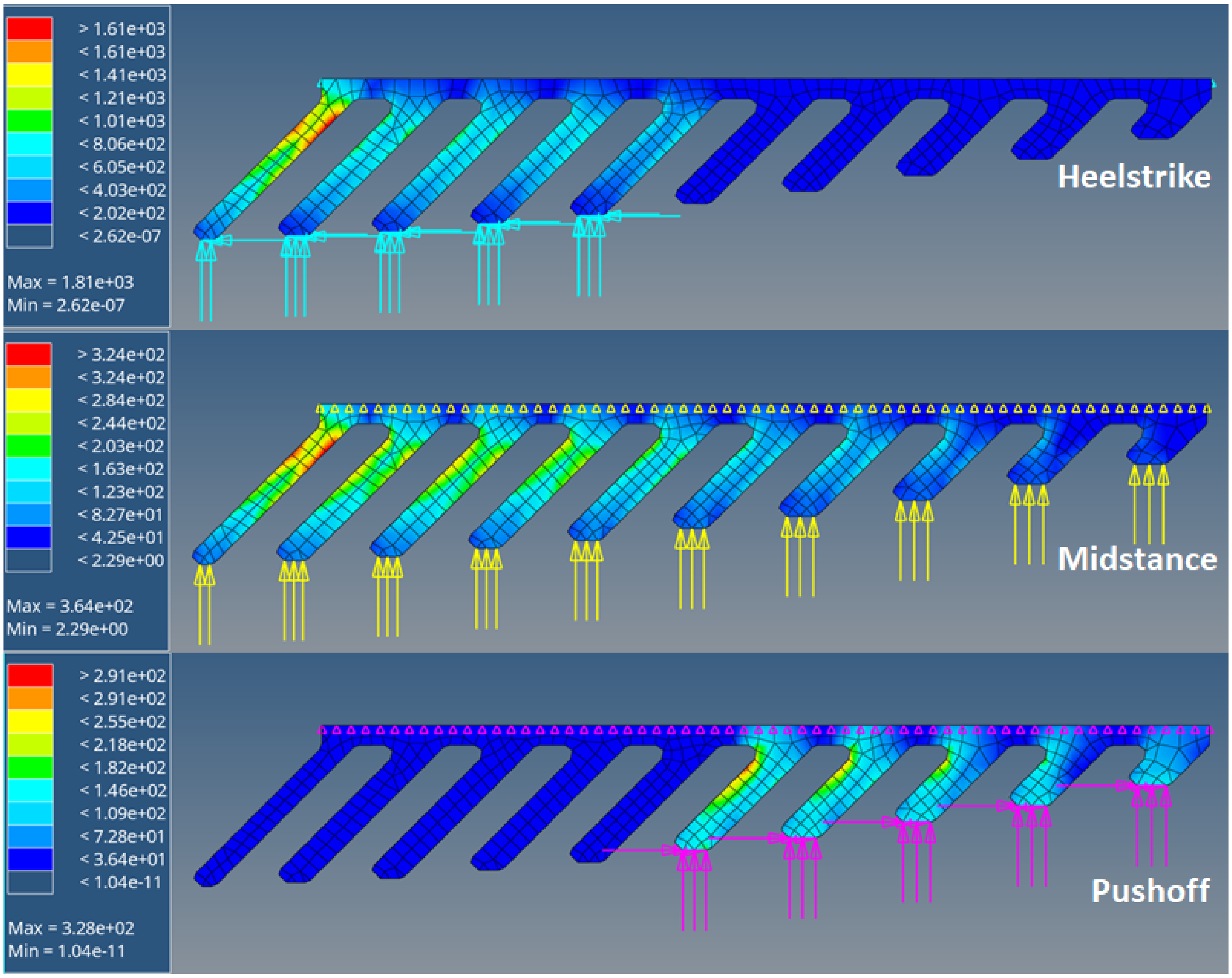


Figure 12. This figure shows the von Mises stress distributions at the heel strike, midstance, and push off phases of the gait cycle. In all cases, the maximum stress at any point in the design is less than the tensile strength of Nylon-6, which is 11,300 psi, by a safety factor greater than 6. The coloration in the model shows where the stress distribution is taking place in the design, which also indicates active energy storage.

Vertical Normal Stress Distribution

The last analysis we performed on the design using FEA was the vertical normal stress distribution. This was the closest our team could get to determining the forces acting on the foot from the Springblade design at the three stages of the gait cycle. In theory, the vertical stress distribution shows the vertical force interaction within the material over the area of the top rectangular portion shown below in Figure 13. The resulting stress distribution along the top of the design serves as a forcing boundary condition which would show how the forces act along the bottom of the foot. Our team was careful about the information we took away from the vertical normal stress distribution, as the alleviation of the pressure in the metatarsal region would ultimately be determined subjectively by walking with the design.

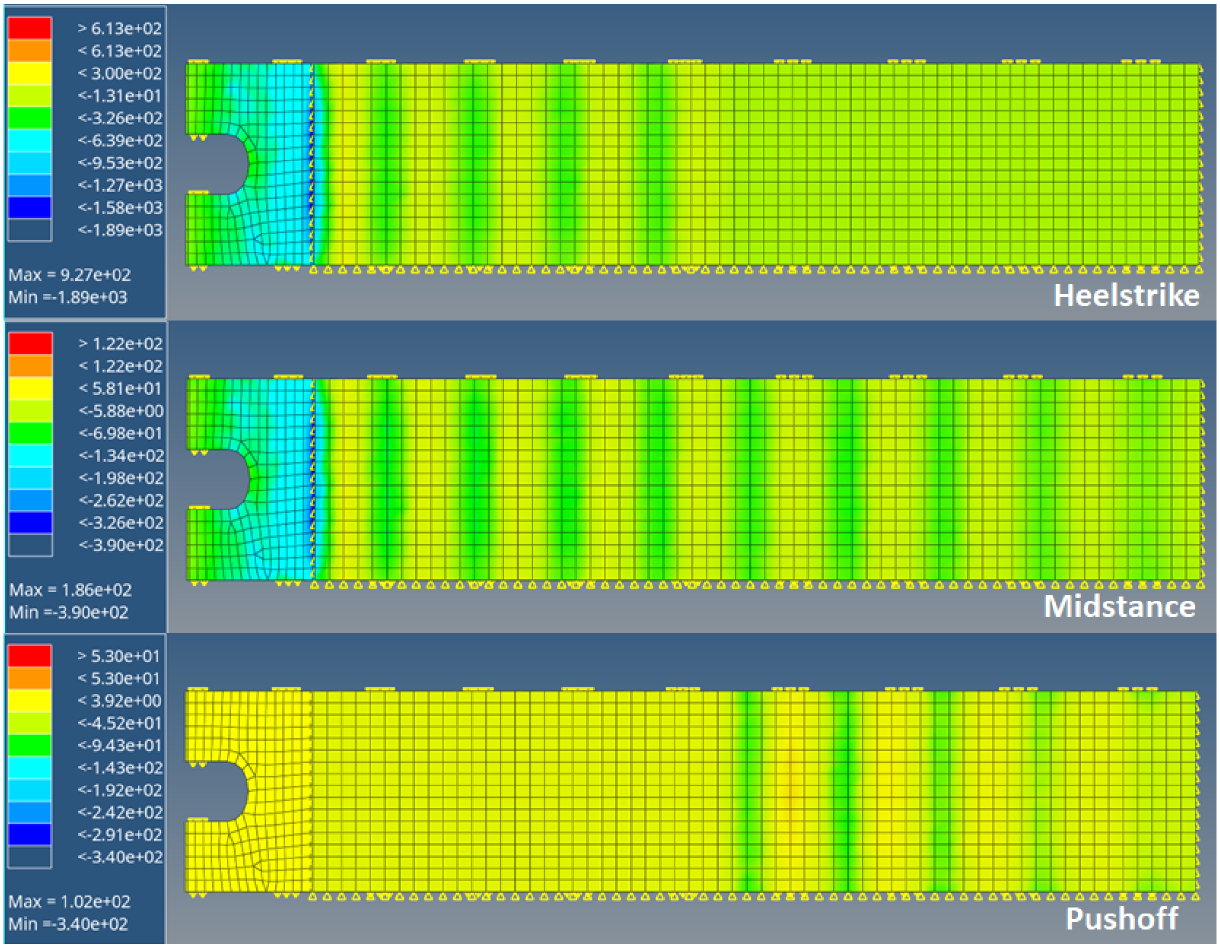


Figure 13. This figure shows the vertical normal stress distribution at the three stages of the gait cycle. We were able to determine that there were no vertical stress concentrations from the Springblade design that would impact the pressure on the bottom of the foot. The areas in green tend to be spots directly over the blades, and these areas seem to alleviate some pressure. This is distributed throughout portions of the design in which the force is applied.

Kinematic Analysis

The purpose of the kinematic analysis was to gain more insight into how our sponsor's current solution, the Disco Shoe, alters his walking and also test if our solution leads to more "normative" gait. In our analyses, we define normative gait as the joint angles obtained when Aidan, the team member walking during testing, walks with regular shoes, so without either prototype. Additionally, according to our specifications, we wanted the joint angles measured with the Springblade prototype to be more similar to normative gait than the Disco Shoe are.

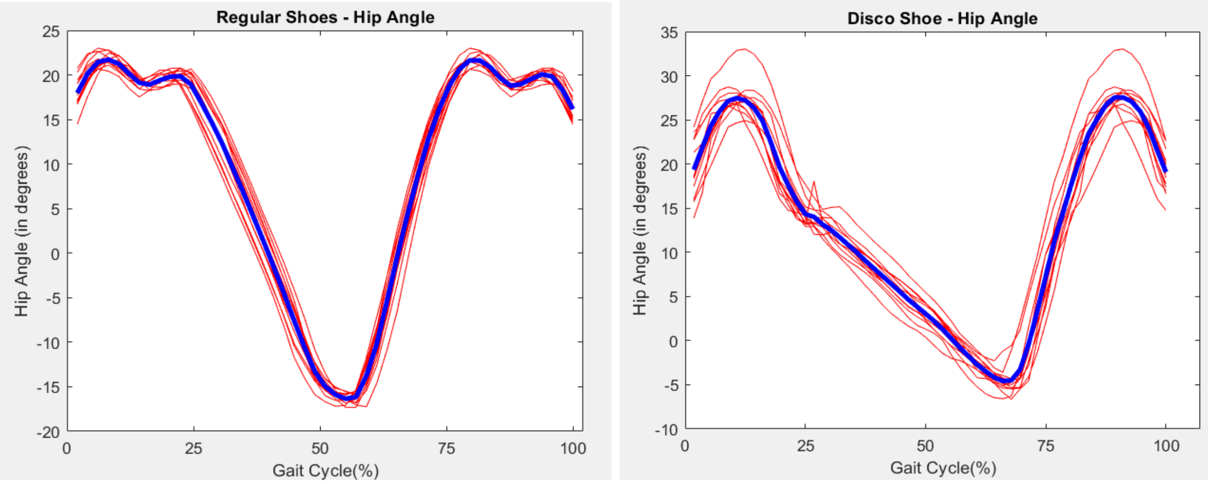
Testing Set-Up

In conducting our kinematic analysis, we had to make various assumptions. Since our sponsor lived in another state, we were not able to meet him or perform analysis while he walks in our prototypes. Due to this, we performed our kinematic analysis on a team member, and assumed that the effects of the prototypes on the gait cycle would be the same for our team member and the sponsor. To do the analysis we set up a tripod and recorded a team member walking on a treadmill with normal shoes, the Disco Shoe, and the Springblade design. Figure 14 below shows the footage collected.

Figure 14. The tripod set-up to collect video footage of normal gait (left) and gait with the prototype Disco Shoe (right). The white squares are placed along the legs for tracking purposes during analyses.

Hip Angle

We inputted the video footage into MATLAB and used the *DLTdv8a* video digitization tool to track certain points marked with white squares in Figure 14. After multiple trials in the CCRB as well as the Biomechanics Lab, we obtained data for hip angle, knee angle, and ankle angle for all prototypes. Figure 15 shows the hip angle throughout the gait cycle. To ensure we were obtaining accurate results, we compared our data to data found in studies calculating the joint angle throughout the duration of the gait cycle. The graphs can be found in Appendix B.



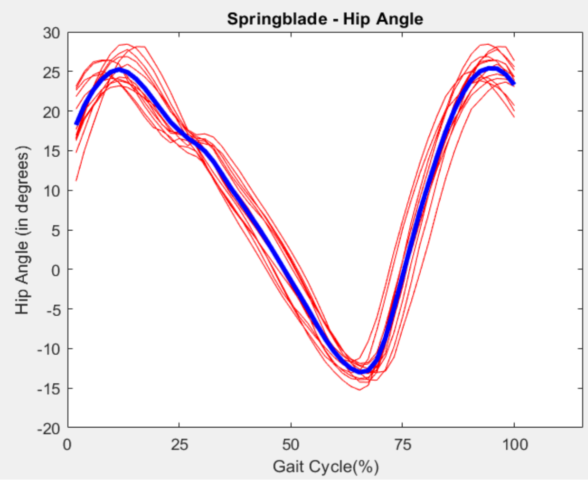


Figure 15. Using the extracted points from the digitization software, we plotted the Hip Angle in degrees at each point of the gait cycle. The x-axis is presented as a percentage of the gait cycle where 0% is standing mostly straight up and beginning to walk. The blue line is the mean of the curve. The upper left graph plots the hip angle with regular shoes, the upper right graph plots the hip angle with the Disco Shoe and the bottom middle graph plots the hip angle with the Springblade design.

The key takeaways from the hip angle data are changes in the shape of the curve and the maximum and minimum values. The hip angle curve with the Disco Shoe shows a dip in angle at around 20% of the gait cycle (Figure 15). This dip is not evident in normative gait and not prominent with the Springblade design. We concluded that the design of the Disco Shoe causes this abrupt dip in hip angle and thus the Springblade design leads to more normative and smoother gait. Furthermore, the maximum angle and minimum angles also show that the Springblade design leads to more normative gait. Table 3 lists the maximum and minimum angle values of the hip angle curves.

Table 3. The maximum and minimum knee angles in regular shoes, the Disco Shoe, and the Springblade design.

Prototype	Maximums (° degrees)	Minimum (° degrees)
None (Regular shoe)	21.7	-16.3
Disco Shoe	27.5	-4.5
Springblade Design	25.4	-13.0

As seen in Table 3, the Disco Shoe has significant changes to maximum and minimum angles when compared to normative gait. The Springblade design does not exactly match the angles during normative gait, but as according to our specifications, the angle values are closer to normative gait than the Disco Shoe. With this data, we concluded that the Springblade design makes gait more normative than the Disco Shoe.

Knee Angle

We completed the same process to obtain the knee angles. Figure 16 shows the graphs of our results and Table 4 directly below them show the angle values of the two peaks and the valley.

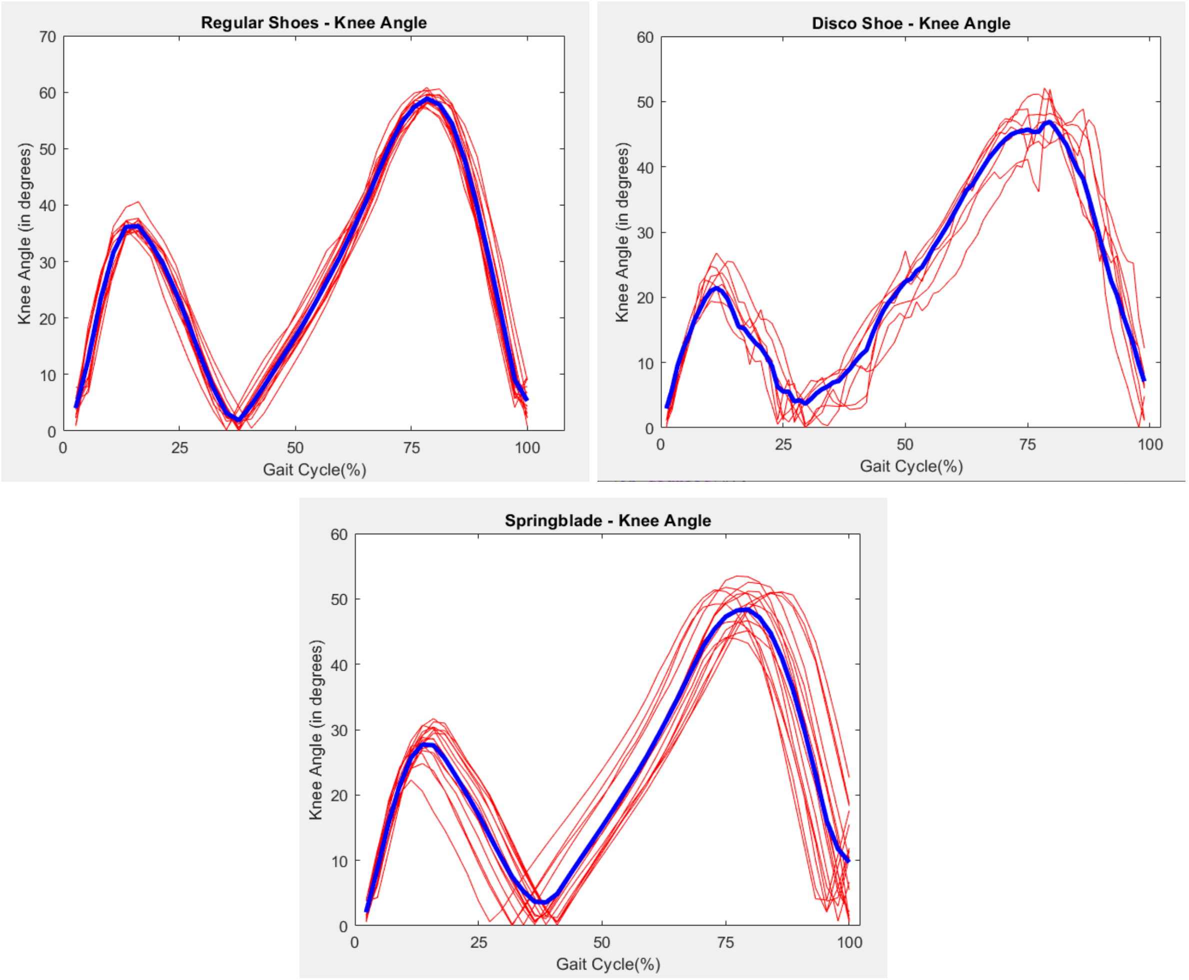


Figure 16. Using the extracted points from the digitization software, we plotted the Knee Angle in degrees at each point of the gait cycle. The x-axis is presented as a percentage of the gait cycle where 0% is standing mostly straight up and beginning to walk. The blue line is the mean of the curve. The upper left graph plots the knee angle with regular shoes, the upper right graph plots the knee angle with the Disco Shoe and the bottom middle graph plots the knee angle with the Springblade design.

Table 4. The maximum and minimum knee angles in regular shoes, the Disco Shoe, and the Springblade design. Peak 1 corresponds to the first peak and peak 2 corresponds to the second peak.

Prototype	Peak 1 (° degrees)	Peak 2 (° degrees)	Valley (° degrees)
None (Regular shoe)	36.2	58.8	1.8
Disco Shoe	21.4	46.9	3.67
Springblade Design	27.7	48.2	3.5

The shape of the knee angle curve does not have any significant differences between shoe type. The differences between the curves are quantified by the peak and valley values in Table 4. The Disco Shoe significantly decreased the peak knee angle values by upwards of 10°. The improvement made by the Springblade is not as evident with the knee angle, but the knee angles do increase with the Springblade design. The first peak increases by 6.3° from Disco Shoe to Springblade design and the second peak increases by 1.3°. Even though the measurements are not as significant as the hip angle, we still met our specification as we improved upon the Disco Shoe.

Ankle Angle

The ankle angle graphs from our analysis had significant differences to the ankle angles found in the studies we reference in Appendix B as well as additional sources we compared them to. This was not an effect of the porotypes as the data similarly did not match with regular shoes. We concluded that our test subject, Aidan, might simply have a different gait than others and chose to move forward with analyses on the hip and knee angles. The way we attached the prototypes to the foot and the way we placed the markers also could have affected our results. Overall, the data did not make sense for this analysis and we believe that data we collected was enough to yield significant results.

Risk Assessment

The risk assessment we decided to perform for the Springblade design was a simplified version of a Design Failure Modes and Effects Analysis. Aimed more towards assessing the risks of the design itself as opposed to the detection ratings, we removed this aspect from the Risk Priority Number calculation. Therefore, the RPN is equal to the product of the Severity rating and the Occurrence rating. We targeted four primary functions of our design listed in the abbreviated DFMEA below in Figure 17. As seen from the final RPN ratings, the design changes we made sufficiently decrease the likelihood and severity of failures with regards to the functions of the Springblade design.

DFMEA

Design Failure Mode and Effects Analysis

Item: Springblade Final Design

Team: 24

Function	Potential Failure	Potential effect(s) of failure	Severity	Potential cause(s) of failure	Occurrence	RPN	Action taken	Severity	Occurrence	RPN
Withstand required loading conditions	Fractured in blades	Loss of function	9	Force exceeds material specifications	5	45	Increase thickness of blades and radius of curvature with upper surface	9	1	(9)
Remain intact over 10,000 steps	Overall wear and eventual fracture	Loss of function	5	Repeated force exceeds material durability	2	10	None -- material was sufficient	5	2	(10)
Compliance in metatarsal region to allow for flexion in toes	End user to walk due to extreme discomfort	Discomfort in end user for extended use	8	Not enough compliance at forefoot	6	48	Decrease thickness in blades at forefoot and include orthotic upper mesh	5	3	(15)
Withstand climate conditions	Degradation of blades or attachment method	Loss of function	5	Moisture from rain or heat alters material properties	2	10	None -- material was sufficient	5	2	(10)

Figure 17. The abbreviated DFMEA highlights four key functions and their potential failure modes, causes and effects of each failure mode, the actions our team took to reduce each respective risk, and ratings prior to and after including the changes. The adjusted RPN scale would indicate that all changes we made to the design sufficiently reduced the risks that were initially present.

Verification

The most important specification for our sponsor was reducing the pressure on the metatarsals. In order to verify that our solution met this requirement we got access to a treadmill with force plates to measure the ground reaction forces at each phase of the gait cycle. The treadmill is in the biomechanics lab and Figure 18 shows our team member, Aidan, walking with the Springblade design on the treadmill.

Figure 18. Team member, Aidan, walking on the treadmill with embedded force plates in the biomechanics lab. He is wearing the Springblade design with sandals supplied by the sponsor.

This piece of technology specifically gave us data on the forces acting on the treadmill over time. Unfortunately, the raw data could ot directly be translated into a pressure distribution across the bottom of the foot. A pressure distribution would have been the most useful way to see how effective our design is because it is pressure on the metatarsals which causes our sponsor pain. The data we were able to collect was the X, Y, and Z-axis ground reaction forces acting on the foot over time. This information, combined with our knowledge of the gait cycle, gave us a way to compare different walking trials. We tested the regular shoes, Disco Shoe, and the Springblade design in order to compare the forces. We had Aidan walk at a comfortable walking pace for each shoe trial. Although the actual walking speed varied slightly between trials (± 0.3 m/s), we wanted to compare based on comfortable walking pace rather than a specific speed, The data from these trials was inputted into MATLAB and we created the graphs below seen in Figure 19.

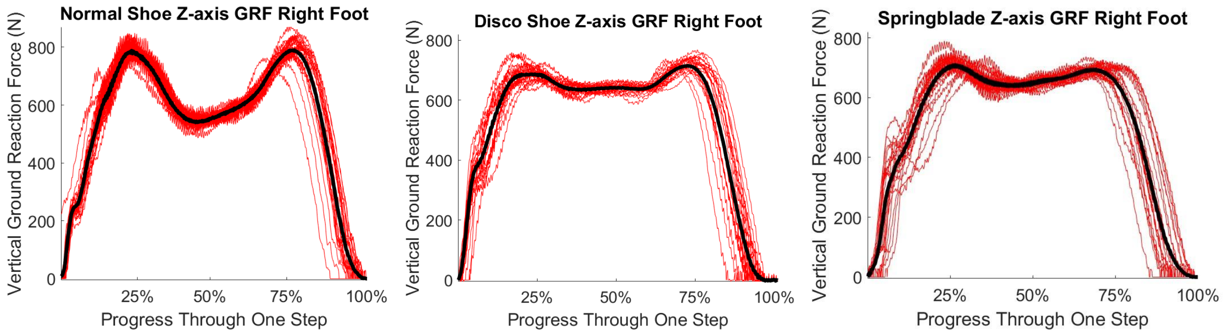


Figure 19. The leftmost graph shows the Z-axis ground reaction forces through one step wearing normal shoes. The middle graph shows the same data with the Disco Shoe, and the graph on the right shows the ground reaction forces with the Springblade design.

These three graphs show the Z-axis ground reaction forces from the three different trials as the right foot progresses through one step. The many red lines are the individual force readings from the approximately 20 steps that Aidan's right foot made under each walking condition. The black line is the averaged ground reaction force curve.

The most striking result from this test is large curve shape discrepancy between walking in normal shoes and the Disco Shoe/Springblade trials. The normal walking condition has two much more pronounced peaks near the beginning and end of each step. These correspond to the heel strike (~20% through one step) and push off (~75% through one step) portions of the gait cycle. The Springblade and Disco Shoe designs have much lower peaks.

The lower peak during push off was especially encouraging to us from a design verification perspective. Our sponsor experiences the most pain during push off, so a lower Z-axis ground reaction force should lessen his pain. With normal shoes the average ground reaction force peak during push off was 790 ± 28 N, with the Disco Shoe it was 715 ± 16 N, and with the Springblade design it was 710 ± 15 N (mean ± one standard deviation). This result demonstrates that the Springblade design statistically improved upon normal walking Z-axis ground reaction forces during push off. However, due to somewhat high uncertainty values, we are unable to definitively say if the Springblade design improved upon the Disco Shoe design, but even matching the disco shoe performance points to a successful design.

DETAILED DESIGN SOLUTION

After the positive results from our analysis and testing, and in agreement with our sponsor, we iterated upon the Springblade design. This final design has multiple changes due to our subjective and objective results in testing. The design is intended to be 3D printed, but due to the timing of printing and final report due date, the results from testing the final 3D printed prototype will not be in this report. Figure 20 shows the CAD model of the design to be printed.

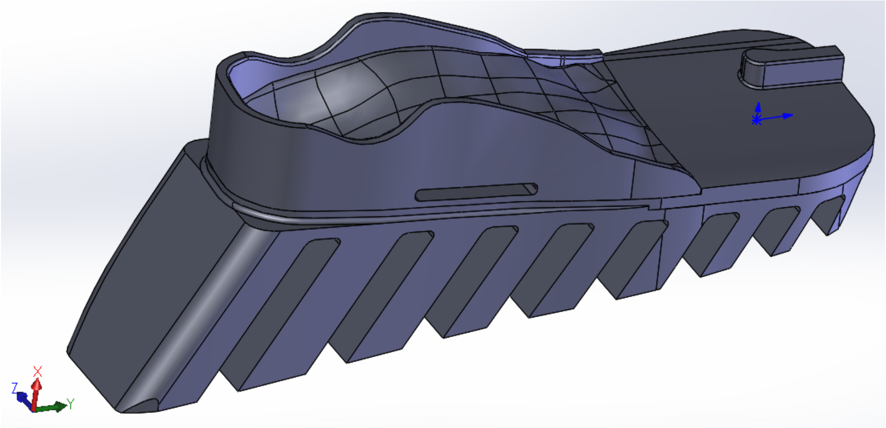


Figure 20. This figure shows the final design to be 3D printed. In addition to the Springblade design is the orthotic and attachment method that is specific to the shape of our stakeholder's foot. An advantage that 3D printing allows for is the specificity and uniqueness in design.

Most notably, this design incorporated our sponsor's orthotic as seen by the extra material on top of the individual spring blades. A 3D scan of his orthotic allowed us to integrate the Springblade design. This is important to our sponsor as it removes the need to find a means of attaching the orthotic to our design solution. In addition, it adds stiffness at the arch which is beneficial because the main fault of our design was flexibility. After walking on the treadmill with the Springblade design, Aidan had a lot of subjective feedback. He noted that the design felt too flexible and did not give as much spring in the heel as we intended. He also felt the design was too long which altered his gait. Other team members observing in the lab noticed that the last blade never made contact with the ground because the blades before it collapsed and merged with each other. While our results confirm a decrease in force at push off, we did not decrease the pressure as much as we defined in our specifications. We mailed the prototype to our sponsor and he agreed the material was not as stiff as it needs to be. He also noted that the design felt too stiff in the forefoot.

Due to our own experience testing our design and our sponsor's feedback we made several design changes. First, we reversed the trend of increasing stiffness towards the forefoot to have increasing stiffness towards the heel. This means the blades at the heel are thicker than the blades in the forefoot. We also made the blades thicker overall. To ensure the blades do not merge into one another, we increased the radius of curvature where the blades interface with the upper material. We also removed 1 blade from the design, which decreased the overall length of the protype.

DISCUSSION AND RECOMMENDATIONS

From the results obtained during testing, it is clear in Fig. 19 that although there was a reduction in GRF while using the Springblade design as compared to the Disco Shoe, it was not 50%, which was the goal of specification 1. Part of the reduction could be due to length of the mechanism. The design is long enough that push off is almost impossible, which would reduce the force on the foot during push off phase. However, gait analysis shows that there was a return to more normative gait with the Springblade*,* fulfilling one of our specifications. Because the prototype was made of rubber, it did not have the stiffness that was modeled in FEA. This means that it did not assist with push off nearly as well as hoped. However, this failing can be mostly attributed to material differences, rather than design.

Another failing of our design was the cost of 3D printing. The only printer available to us that was large enough to accommodate our design was the J750 Polyjet printer in the University of Michigan Fabrication Studio, located in the Duderstadt Center. With a sponsor-designed orthotic incorporated into the Springblade*,* this drove the cost of printing to $470, well above our budget for the project. After checking a few outside companies for quotes, $470 appeared to be around the standard. This cost is likely due to the size of the design since it spans the length of the foot. The desired material properties could also factor in because a fairly high material stiffness was used during modeling.

Moving forward, it might be helpful to look at other methods of manufacturing or find a material that is cheaper to 3D print, since the custom polyjet material is a driving factor of the cost. Other manufacturing methods could also allow for cheaper iterations of the design. For future testing, access to a facility that allows for pressure or force measurement while walking could also be incredibly helpful for determining the efficacy of the design.

CONCLUSION

Overall, we were tasked with finding a passive device to reduce a specific cause of foot pain during locomotion. Our sponsor, Steve Schrader, initially suffered from extreme pes cavus which was worsened over time due to several failed surgeries. The result of his condition and surgeries is that he experiences pain in the metatarsal region of his foot (the area between the toes and the middle of the arch). To mitigate this pain, our sponsor developed his own make-shift solution that he dubbed the Disco Shoe.

This Disco Shoe is essentially a normal upper shoe attached to a sole several inches thick and with a slanted cutout in the front. This slanted cutout shifted the location of the ground reaction forces from his foot pushing off the ground and propelling him forward. Instead of the force acting on the metatarsals like normal walking form, the Disco Shoe moves the forces back towards our sponsor's heel and away from his pain area.

Although the Disco Shoe does a serviceable job reducing our sponsor's pain, it has several limitations that we were tasked with improving upon. The Disco Shoe is too tall for our sponsor, and it does not allow his toes to spread properly which constricts blood flow and causes additional soreness. Our improved design had to address these concerns as well as reducing the pressure acting on his metatarsal region while not impeding his normal gait cycle. Additional requirements were for our device to be affordable, easy to clean, and 3D printable.

To address these requirements our team, with input and guidance from our sponsor, came up with a final solution that we called the Springblade design. This design has several spring blades attached at a backwards sweeping acute angle. They attach to the bottom of a sole that is specifically modelled after the form of the bottom of our sponsor's foot. The purpose of these blades is to absorb some of the energy imparted into the ground during the heel strike portion of a step, and use that energy to propel our sponsor forward during his step while he is in the push off phase of the gait cycle. This energy storage and return mechanism was designed to help reduce pressure on the metatarsal region which causes our sponsor pain. In addition, the individual blades were designed to collapse into a general curved shape while being walked on. Our research showed that this curved shape, also known as a foot rocker, helps to reduce the pressure on the metatarsals. Therefore, our Springblade shape was designed to combat metatarsal pressure in two ways.

We tested our solution in two different ways in order to compare it to normative gait and our sponsor's Disco Shoe design. We did a kinematic analysis by recording one of our team members walking in both the Disco Shoe and the Springblade designs. We tracked both knee and hip joint angles over several steps for both designs and compared them to normal gait curves. This analysis demonstrated that walking in the Springblade design more closely resembled normative gait than walking in the Disco Shoe.

In addition to kinematic analysis, we compared normative gait to the Disco Shoe and Springblade designs by using a force plate and treadmill setup. Again, one of our team members walked in both prototype designs, and we used the force plate to track the ground reaction forces over time. We graphed these forces in a similar way to in our kinematic analysis and looked at the peak Z-axis ground reaction forces during the push off phase of gait. This experimental setup showed that the Springblade design significantly reduced the forces acting on the foot during push off, and roughly matched the force levels that occurred while using the Disco Shoe.

Our subjective analysis showed that our Springblade design was as good if not better than the Disco Shoe while being shorter and easier to construct. However, subjective analysis while walking on the Springblade design during testing was not as positive. The first prototype iteration we made was heavier than anticipated and the blades near the back of the design were long which made walking somewhat cumbersome and made push off a little difficult. An improved design was modelled based off of this feedback, although we ran out of time before being able to 3D print and test it.

AUTHORS

Aidan Vander Tuin - Aidan is a senior studying mechanical engineering; in his free time he likes to workout, cook with his girlfriend, and obsess about *Lord of the Rings*. He will graduate after this Spring term, ideally with a job.

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Benjamin Kaufman - Ben is a senior studying mechanical engineering with a specialized study in sustainable engineering. Outside of class, he loves running and was on the board of the Michigan Running Club. He also helps out with the Michigan Concrete Canoe Team, and is part of Pi Tau Sigma, the mechanical engineering honors society. Ben is also a huge baseball fan and loves watching Michigan compete in a variety of sports. He will graduate this May.

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APPENDICES

Appendix A - Manufacturing Drawings and Plans

The prototype was made by water jetting a large sheet of rubber. Because of this, no manufacturing plans were necessary, only drawings and DXF files.

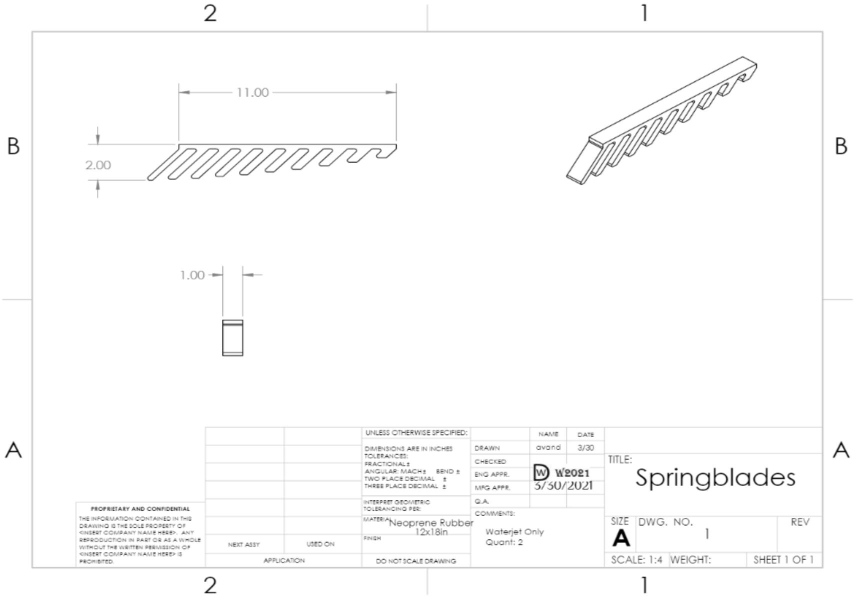

Figure 21. This is the manufacturing drawing for the Springblade prototype. Because the rubber was only 1in thick, two were cut using the waterjet and then glued together using E6000. The rubber had a Shore hardness value of 70A.

As a team we also had a secondary design, known as Team Dezign2. Although it was never properly analyzed and fabricated, a drawing was made for it.

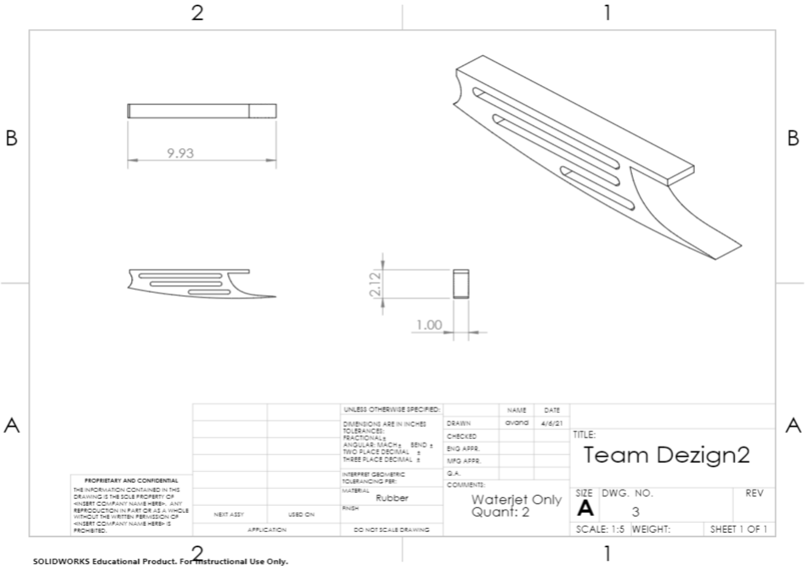

Figure 22. The manufacturing drawing for the *Team Dezign2* prototype. Like the Springblade, it would have been made from two identical rubber pieces that were glued together. This drawing was never approved.

Appendix B - Joint Angle Comparison Graphs

We compared our data with data from the same experiments we did. Figure 21a shows the hip angle throughout the gait cycle and Figure 21b shows the knee angle throughout the gait cycle.

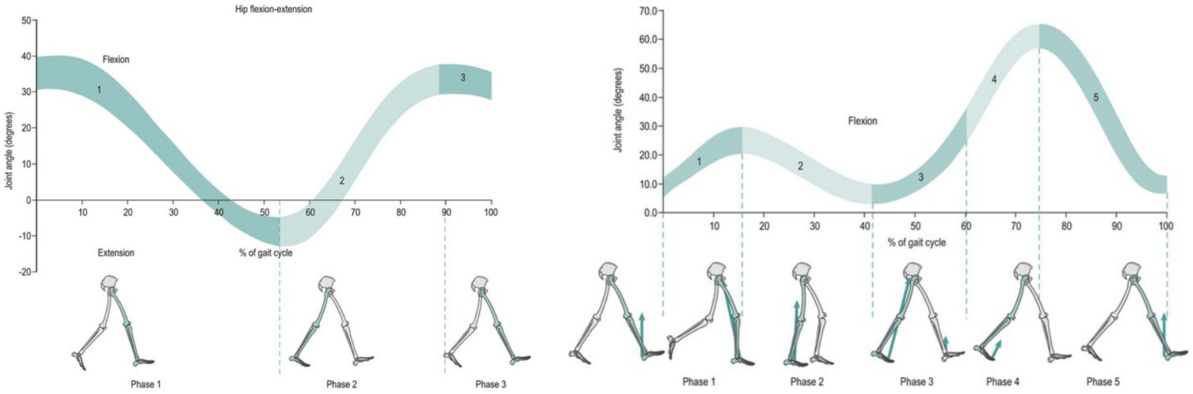

Figure 23a and 23b. The graph on the left (23a) shows the hip angle through one full gait cycle. The y-axis is degrees and the x-axis is the percentage of the gait cycle. On the right is the same type of graph, but for knee angle [6].

Although we noticed significant differences in the peak values between our normative data and this data, we are more concerned with comparing our data with both prototypes. The differences in peak values could simply be due to our teammates specific gait patterns.

Appendix C - Engineering Standards

Our project centered around the design and production of an application to the bottom of a shoe in order to lessen the pressure applied from push-off during that phase of the gait cycle. In researching the background necessary to go forward with this project we realized that with inventing something new like this there weren't any appropriate standards for our project. This included voluntary, mandatory, performance specification, criteria, or superseded standards. If this type of assisted locomotion is advanced in the future then maybe there will be standards developed for it later on but as of now there are none in existence.

Appendix D - Engineering Inclusivity

Our team did an excellent job at practicing inclusive design throughout the entire process. In regards to defining the problem we made sure to address exactly what our sponsor wanted out of the project. We explicitly asked our sponsor to provide us with his requirements for the solution and then using our engineering background added some requirements to ensure the product would be safe and effective. In making design decisions, we talked over changes in design with our sponsor before moving forward. With the design it was really important to be aware of the different social identities between our team in general and the sponsor. Our sponsor is a mechanical engineer as well with many years of experience in industry. Moreover, he is the person dealing with the physical disability and therefore we highly valued his intuition and suggestions when making design choices.

In regards to the power framework, there was visible power due to the structure of ME450. While our sponsor wanted to jump right into prototyping very early on in the project, we told him we had to follow the framework of the class as it was laid out to us. This ultimately was not an issue once we addressed our concerns with the stakeholder. The only hidden power we exhibited in this project was that we are all mechanical engineers without education in biomechanics. To ensure we were not making incorrect assumptions or obtaining inaccurate data we asked for constant feedback and direction from our professor who has extensive knowledge in the field. To avoid practicing invisible power and trying to influence the sponsor in an unethical manner, we made sure our meetings were an invite space. This meant the meetings themselves involved constant back and forth in terms of ideas we had and feedback from the sponsor and vice versa. We had meetings every Monday as well as constant email communication.

I believe that our team could not have done a better job at practicing inclusive design. Not only did we understand differences in social identities and use them to guide defining the problem and designing our prototype, we also made sure we were not using hidden or invisible power to influence our design.

Appendix E - Environmental Context Assessment

The mechanism attempted to meet a largely unmet social challenge: helping those with severe pes cavus. There was no immediate environmental need met by the design; however, if the mechanism is successful in improving the locomotion of people suffering from severe foot pain, it could lead to less reliance on active devices that require an outside power source. This could extend to cars, scooters, and even public transportation. With that in mind, the mechanism could have a positive environmental impact.

The most obvious environmental consequence of the 3D printed mechanism is at the end of its useful life, when it would be thrown away. This would introduce plastic waste into the environment, unless there were some way to recycle the material. Most 3D printed material cannot be recycled curbside, and must be recycled at a specialized facility, so most discarded mechanisms would end up in landfills [7]. Another potential consequence is the emissions due to the energy consumed by 3D printers. The main source of energy consumption is heating and maintaining the temperature of the nozzle [8]. The average 3D printer draws 70W, but since our mechanism is on the larger end in terms of 3D printed objects, a printer with a larger bed could be necessary, leading to more energy use [9]. For example, the printer in the Fabrication Studio is a J750 3D Polyjet printer, with between 220-240 V and 7A of electrical consumption [10]. This means it could draw a maximum power of 1680W (1.68kW). This is far above the average, smaller, 3D printer. For a J750 printer, assuming the print lasted about 5 hours, and the electricity were coming from a natural gas power plant, this would result in roughly 1kg of CO_2 emissions

[11]. This also assumes that the printer runs at full power the entire print, which is not the case in reality. However, this value provides a useful upper bound of emissions. For context, this is roughly equivalent to driving 2.5 miles in an average passenger vehicle [12]. So the 3D printing element of our mechanism has relatively low emissions compared to other industries, like transportation.

The material waste and emissions need to be balanced against the benefits, which in this case is improved locomotion and less pain for people suffering from pes cavus. There is also the potential for less reliance on other modes of transportation, like cars or buses, which could reduce emissions. Overall, the environmental impact of our solution would likely be fairly low in terms of either positive and negative impacts.

Appendix F - Ethical Decision Making

The primary ethical factor that we encountered and considered in the design process and final design solution is the functional deficit that our stakeholder has. It is a subject that we should be very sensitive when discussing with our stakeholder since this is something that he has dealt with for years. Over the process of multiple failed surgeries, he is unable to walk with a normal gait, something that most all of us take for granted. He is unable to walk without a sharp pain in his right foot and his range of motion is severely limited, so it takes much longer for him to travel on foot. We were very lucky to have a stakeholder and end user that was very involved with the design process. All things considered, we don't know how he feels in his shoes, and meeting with our stakeholder regularly was our method of facing this ethical factor head on. We used his expertise and experience and the knowledge that he has built up since the start of his functional deficit.

The main decision process that we used was the reversibility test. Every decision we made during the design process we asked ourselves if we would make the same decision if we were in our stakeholder's shoes. We made sure that he was involved with every decision in the design process and got his approval before we moved forward with choosing a design or printing a prototype. In addition to the reversibility test, we also referenced the ASME Code of Ethics of Engineers and used our engineering knowledge to aid in normalizing the gait of our stakeholder [13]. We made sure that any decision we made was to benefit our stakeholder. In a non-covid environment, we would have liked to meet our stakeholder in person and receive advice from him and his expert opinions of our designs first hand. In place of this, we held weekly meetings and sent PowerPoint updates when necessary to keep our stakeholder updated as regularly as possible.

Appendix G - Social Context Assessment

While assessing the overall sustainability of our solution we realized that we should go beyond simply evaluating the environmental sustainability. We also wanted to evaluate the social context and social sustainability of our final design. By definition, socially sustainable designs must follow three general criteria. The solution must be likely to be adopted and self-sustaining in the market, it must not be so likely to succeed that other environmental or social systems will be worse off, and it must be resilient to disruptions in “business as usual.”

We believe our solution narrowly fulfills the first criteria. Without doing an in depth market analysis, it is impossible to say how many people would be willing to either buy our solution directly from a supplier, or buy access to the rights to 3D print the design on their own. These would be the two potential ways to turn our solution into a profitable product that could help people with this functional deficit. Although we don’t know how common the problem is, we do understand that people who suffer from extreme pes cavus experience pain while walking. Our solution offers some reprieve from this pain, which should be highly motivating to our potential target customers. We wouldn’t want to exploit people who suffer from pes cavus, so finding a price that allows as many people as possible to benefit while a profit could still be turned would be important. Overall, there might not be a large volume demand for our product, but the potential customer base would probably be quite dependable which we believe would make the product self-sustaining.

We also believe that our solution achieves the second criteria for social sustainability as well. As outlined above, we do not think that the market for our solution is very large. This means that even if our product reaches its peak market saturation, not many units would be produced. Also, one of our main design specifications is durability. Hopefully our solution would last a customer years before needing to be reprinted. This reduces the amount of waste being generated over time. As we laid out in the environmental context section, there are some carbon costs to printing this device, and the end of life location is most likely going to be a landfill. However, we believe that greatly reducing walking pains for many people outweighs the small environmental tradeoffs, especially as we transition to a more green electricity grid over the coming years. This belief, combined with the fact that our market is overall pretty narrow, means we are confident that our solution could not become so successful that other global systems are harmfully disrupted.

The final criterion of social sustainability is related to resilience against market disruption. We believe our solution meets this criterion very well. Our sponsor came to us with this project specifically because nothing currently exists to solve his painful functional deficit. If nobody had put the effort into creating a product that helps people with similar foot problems up unto this point, it is unlikely that someone will design a solution so much better than ours that our product becomes obsolete. It is impossible to predict the future, or what kinds of medical advancements will be made in the future, but overall we feel it is unlikely that a large disruption in the foot orthotic industry would happen in the near future. And if a large disruption were to happen soon, we would view that as a positive because it would mean more people could be helped so as to not feel pain while walking.