Orthopedic Device for Forefoot Offloading

Final Report

ME 450: Design & Manufacturing III F21

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ABSTRACT

Our project objective is to design an orthopedic device that will assist a user with a traumatic foot injury to walk with minimal pain. Our sponsor, Steve Schrader, suffers from a severe case of pes cavus and experiences pain when walking, especially during the toe-off phase. His current solution, the Rocker Shoe, helps to alleviate the pressure on the forefoot, but it does not allow forefoot flexion. Therefore, this new device must be able to reduce pressure on the metatarsal region while still allowing forefoot flexion. Some additional requirements include height constraints and 3D printability for reproducibility.

EXECUTIVE SUMMARY

Our project objective is to design an orthopedic device that will assist a user with a traumatic foot injury to walk with minimal pain. Our sponsor and co-researcher, Steve Schrader, suffers from severe pes cavus, which causes pain when walking, especially during the toe-off phase.

A loss of push during the toe-off phase in walking can greatly alter one's gait. Not only does this affect the movement of ambulation, but further complicates joint and circulation problems. There are limited remedies, all with impressive faults. One option is a transtibial amputation; a transtibial amputation is just below the knee. The receiver of this operation is then fitted with many options for prosthetics. If trying to avoid amputation the alternative solution is to wear a "Rocker Shoe." The Rocker Shoe is a 4" tall trapezoidal wedge with a pivot under the midfoot.

Other college research teams offered designs, but Schrader still faced certain difficulties and problems with the developed products. Therefore, our project's objective is to alleviate the pressure on the metatarsal region of the foot while still allowing for toe flexion and normal gait.

Reducing pressure on the metatarsal region is the primary user requirement; the derived engineering specification is defined as a 30% reduction in pressure under the metatarsal region compared to the Rocker Shoe. To help improve blood flow and prevent the onset of arthritis, toe flexion is necessary. A flexion of 15° between the toes and sole of the foot is the representative engineering specification. Schrader's access to a 3D printer dictated an engineering specification of needing to be manufacturable by 3D printing. A height user requirement set an engineering specification of a maximum of 2" tall unloaded and 1" tall loaded with 200 pounds of force. The new design is to have a larger base of support than the Rocker Shoe's 100 square centimeters. The respective engineering specification is 5" width and 12" length.

Our team generated and sketched 20 design possibilities. Our alpha design chosen using a Pugh chart is like the rocker design, but with an auxetic pattern to help redistribute pressure and support called the "Auxetic Rocker." However, the Auxetic Rocker design quickly exceeded the scope of this project and a different design, the Moon Shoe, was pursued as our final design. The design is inspired by a prosthetic foot and consists of various splines for support. In addition, the front of the shoe behaves as a springboard to allow for toe flexion.

Verification of the Moon Shoe has been carried out with FEA using Altair HyperWorks. All the engineering specifications were met except for the height requirement. The shoe is 2" tall unloaded and loaded, but in the next iteration it can be fixed so it is only 1" when loaded. To further complete verification, the most recent Moon Shoe design was printed in Nylon PA12 for $280.66. The prototype was tested by several of the team members. Although the team members found that the shoe allows for forefoot flexion and reduced pressure in the metatarsal, there is no way of knowing if the results give Schrader relief without him testing himself. For final validation, the prototype was sent to Schrader for qualitative testing and approval. Our final designs are to be taken as prototypes for Schrader to continue with. We recommend that Schrader adjusts the dimensions and scaling of the shoe to maximize his comfort and ensure he can achieve the pressure reduction and forefoot flexion he needs.

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PROBLEM DESCRIPTION

Our team is working closely with our sponsor, Steve Schrader, who suffers from a severe case of pes cavus. Throughout the semester we have met with him over Zoom to discuss the project and learn more about the necessary user requirements. This project has been attempted by the previous Michigan and Georgia Tech teams, so we will be leveraging what they have completed or attempted to help us approach our project. In addition, we have also conducted our own research to better understand the problem and the design requirements.

Physics of Walking

To understand Schrader's difficulties while walking, it is important to understand the physics of walking. The normal walking gait cycle consists of two parts: the stance phase and the swing phase. During the stance phase, the foot is in contact with the ground and during the swing phase the foot is in the air [1]. Within the two phases there are six different modes: heel strike, foot flat, midstance, heel-off, toe-off, and mid swing. In our project we will only focus on the heel strike, midstance, and toe-off, which can be seen in Figure 1. One full gait cycle begins at the heel strike of one foot and continues until the heel strike of the same foot begins the next step.

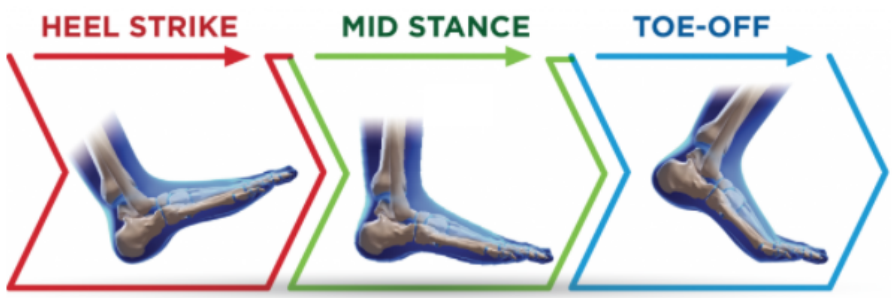

Figure 1. The three stages of the normal walking gait cycle our project will be focusing on, the heel strike, midstance, and the toe-off. https://www.chiroeco.com/gait-cycle/

The heel strike is the start of the stance phase, and it occurs when the heel contacts the ground and ends when the opposite foot reaches its toe-off phase [2]. Throughout this period, the vertical ground reaction force increases steadily until it peaks at slightly greater than body weight at the end of the period [3], as seen in Figure 2.

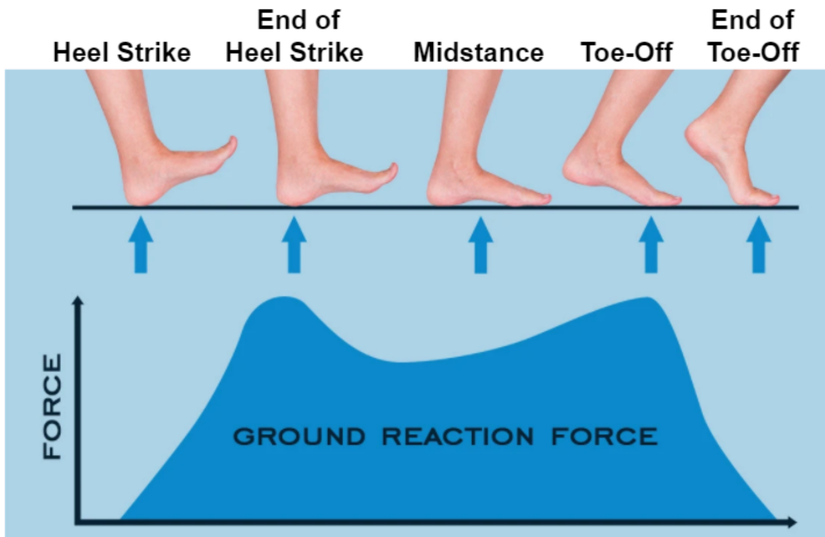

Figure 2. Graph that represents the ground reaction force at the different phases - heel strike, midstance, and toe-off - in the gait cycle. https://mass4d.com/blogs/clinicians-blog/the-effect-of-ground-reaction-forces-on-gait

A breakdown of the forces into the x, y, and z components during each of the three phases, heel strike, midstance, and toe-off, can be seen in Figure 3 below and Table 1 [4]. For a right foot, the x-direction is measured from the inside of the foot to the outside, the y-direction is measured from the heel to the toes, and the z-direction is from the bottom to the top of the foot (Figure 3). The forces are also determined by the percentage body weight of the user walking.

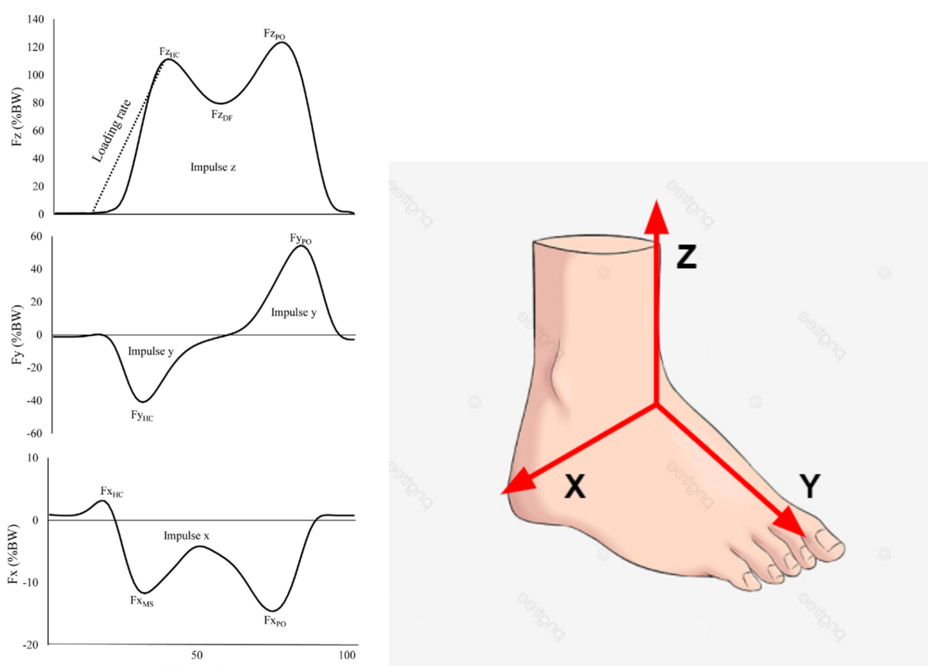

Figure 3. Graph of the forces by percentage of body weight, split during the different phases in the different directions (left). Coordinate system of the forces on a right foot (right). https://www.sciencedirect.com/science/article/pii/S0021929016304237 (left) and https://pngtree.com/freepng/foot-clipart-cartoon-painted-soles-of-feet_6124389.html (right)

Table of the forces broken down as the percentage of body weight in the three different directions during the three phases of the walking gait.

Table 1. Percentage of body weight for each of the gait cycle phases

Phase	Fx (% BW)	Fy (% BW)	Fz (% BW)
Heel Strike	9.91%	27.57%	106.12%
Midstance	7.33%	0%	82.68%
Toe-off	5.52%	34.11%	111.97%

The midstance is when the leg in the swing phase passes the leg in the stance phase. During this phase, the vertical ground reaction force decreases, and reaches approximately 75% of the body weight midway through the midstance before it rises again to slightly greater than the body weight at the end of the phase [3]. The toe-off is the period when the stance phase ends, the swing phase begins, and the foot pushes off the ground. During the toe-off phase, the vertical ground reaction forces on the foot increase until it peaks again, as seen in Figure 2, and reaches approximately 125% of the body weight about one-third of the way through the toe-off period. However, once the heel of the opposite foot contacts the ground, the vertical reaction force will steadily decrease until it reaches zero at the end of the toe-off phase [3].

During the swing phase, potential energy is stored when the foot is raised. This is turned into kinetic energy as the foot swings forward. At the heel strike phase, the energy is dissipated from the contact with the ground. During the midstance mode, the legs create an inverted pendulum with the pivot point at the ground, illustrated in Figure 4 below. At the toe-off phase the foot is pushed off the ground and is propelled into the next swing cycle. Our primary focus will be on the toe-off phase since the metatarsals experience high pressure when the forefoot pushes off the ground.

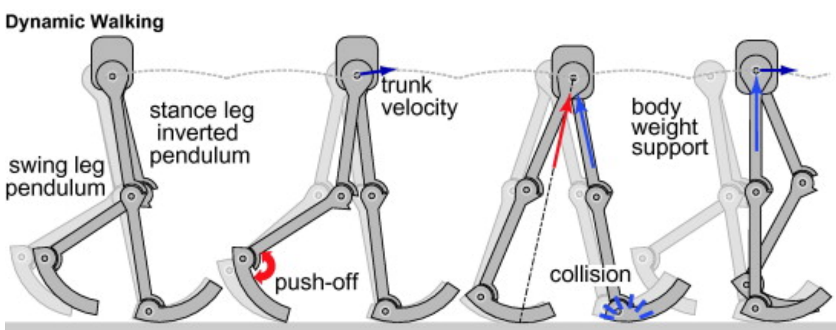

Figure 4. When walking, the legs become an inverted pendulum with the pivot point at the ground. https://www.semanticscholar.org/paper/The-six-determinants-of-gait-and-the-inverted-A-Kuo/4e29328d7c13cbb4c921be860bfe1892995fca76/figure/1

Sponsor's Background

Our sponsor suffers from pes cavus, which is a medical condition that is characterized by high arches in the foot. Figure 5, shown below, highlights the differences in a foot with pes cavus and a normal foot.

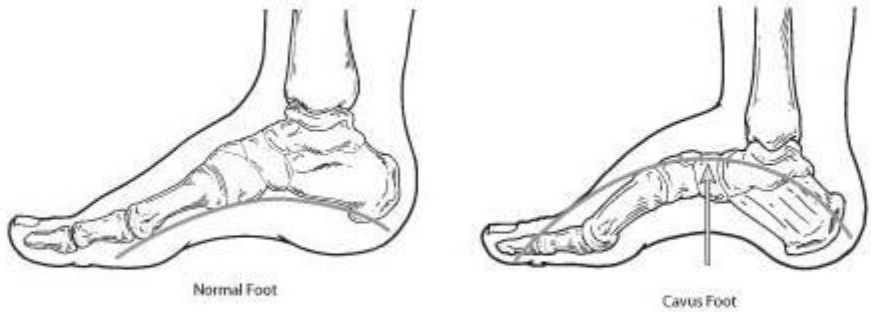

Figure 5. Diagram showing the difference in structure between a normal foot (left) and a foot with pes cavus (right).

As a result of the high arches, the load from walking then ends up being distributed over a smaller surface area of the foot, which in this case is primarily the metatarsal bones (the forefoot), which can lead to pain, contusions, and osteophyte formation. Thus, to treat this condition, the main treatment options consist of arch support, pressure redistribution, structural alignment, and shock absorption [5].

Schrader has had six surgeries to try to fix his foot injury, but they have been unsuccessful and have only caused his situation to become worse. The first surgery Schrader had involved adding screws to alleviate the cavus deformity, but it ended up making his right foot stiffer (Figure 6).

Figure 6. X-ray showing the two screws for the primary surgery to fix Schrader’s cavus deformity. The two screws are located approximately in the middle of the foot under the big toe.

During one of Schrader's surgeries to attempt to reduce the foot’s stiffness, a tendon was rerouted from his big toe, which caused him to lose his foot’s natural spring and his ability to curl his big toe. As a result, Schrader has lost most of the function in his forefoot, and he is no longer able to complete a normal gait cycle which has caused significant compromises in his mobility. Figure 7 illustrates the pressure map of his right and left foot and shows that his healthy foot (left) is forced to compensate for the load that his right foot is unable to bear. Another important takeaway from Figure 7 is the amount of pressure located on his right metatarsals compared to his left foot; this is pain inducing.

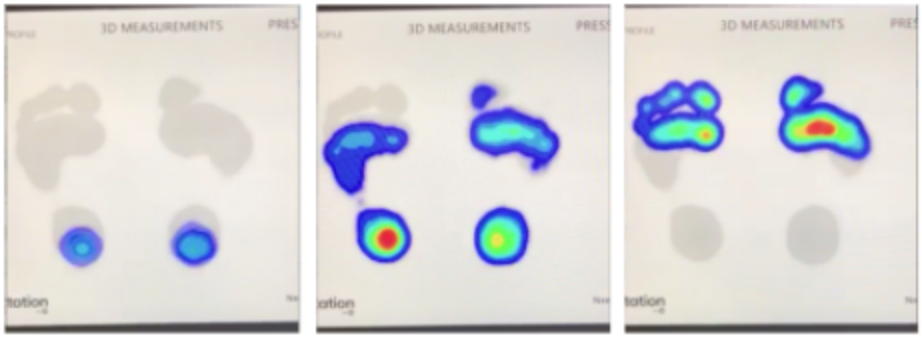

Figure 7. Pressure map of Schrader's feet that highlights the difference between Schrader's left and right feet during the heel strike (right), midstance (middle), and toe-off (left). The red indicates areas of high pressure.

His forefoot is unable to bear his body weight during the toe-off phase without an immense amount of pain. During the toe-off phase the metatarsals experience high pressure when the forefoot pushes off the ground, as can be seen in Figure 8, since it is the foot's only point of contact with the ground.

Figure 8. During the toe-off phase the metatarsal region experiences high pressure when the forefoot pushes off the ground.

However, the toe-off phase is essential to allow forefoot flexion which helps distribute blood to the toes and exercises his joints, reducing the risk of arthritis. If Schrader is not able to flex his forefoot, there is reduced blood flow to the toes, which causes issues with blood circulation in the entire foot. This, in turn, can lead to other health problems, including complete loss of function in the toe region, and our sponsor would like us to be able to preserve the function that he has remaining. Schrader's current solution, the Rocker Shoe (Figure 9), helps to reduce the pressure on his metatarsal region by redirecting the GRD to his midfoot, however his design keeps his foot stiff and does not allow any forefoot flexion. The lack of forefoot flexion and toe movement causes venous insufficiencies and ossification. Additionally, the Rocker Shoe is cumbersome and tall; Schrader has difficulties with doorways and maneuvering. The shoe's minimal contact area and pivot point strikes a bargain between midstance and toe-off. Schrader's current design currently is sacrificing midstance balance.

Figure 9. Schrader's current solution, the Rocker Shoe, helps to alleviate pressure on the metatarsals but does not allow forefoot flexion.

There are currently limited solutions to users who suffer from similar injuries and elective trans-tibial amputation is sometimes the only resort. Therefore, due to the nature of our sponsor's current condition, we will be focusing on shock absorption and pressure redistribution to alleviate the pain in the metatarsal region while still allowing forefoot flexion during the toe-off phase of the gait cycle.

Georgia Tech Design Team

A previous Georgia Tech senior design team has worked on this project and had a final design solution called the "Roman Sandal", which can be seen in Figure 10. Although this team was able to meet most of the given design requirements, there were some limitations to this design. The manufacturing of the Roman Sandal required manufacturing beyond 3D printing, and their recommended material was Carbon Fiber which is commonly used in orthopedic devices and very expensive. Our sponsor wants our team to focus on a design that is entirely 3D-printable and is compatible with the foot sole that he is currently developing.

Figure 10. Georgia Tech's Roman Sandal with human foot for reference.

Michigan Design Team
A previous University of Michigan senior design team has also worked on this project, and had a final design called the Springblade design, shown in Figure 11 below.

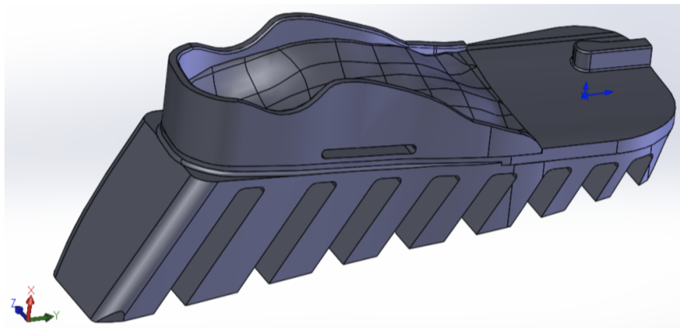

Figure 11. CAD rendering of the Springblade design.

However, this design did not meet the design requirements, as the spring blades were too flexible, which meant the design did not work as intended. This was since the Finite Element Analysis (FEA) was conducted improperly, with the incorrect material, so the design was not optimized for the final material. Therefore, we will avoid this error from occurring again by making sure that we invest time into the FEA process and make sure that we follow the process closely. In addition, we will do some rapid prototyping to make sure that our design decisions work as intended.

Design Process
We will be following the prescribed ME 450 design process for our project. A solution-oriented model for our design process is best, since we have an initial solution already proposed and will be focused on analysis and modification of that design. The need identification phase had already been completed by our sponsor. The next phase, Problem Definition, was then started by our team. This included literature review using library resources to understand the problem as well as frame out our specific problem statement. This literature review included studying the motion of walking, specifically the gait cycle and the phases that take place. This helps us understand the forces that are applied throughout the feet during these phases and how they can be reduced and shifted. Another resource that was provided to us was efforts by two previous university teams that Schrader worked with to generate designs. We also utilized interviews to elicit as much information on the stakeholders' needs. The primary stakeholder for this project is Schrader since the design we arrive at will directly impact his lifestyle and well-being. Other stakeholders that have been identified include other people who are impacted by situations like Schrader's and would like some form of orthotic option before they undergo an elective trans-tibial amputation. Employing both Schrader's input and our initial research has helped us create a solid foundation of understanding for where the project currently stands and what work we need to do to meet the goals of the sponsor. Following this, we then enter the Concept Exploration phase. Here we plan on utilizing the research we have conducted, past designs provided to us by the sponsor, and our experience in previous classes to generate new design ideas. Since the sponsor is providing us with a design, we will be using this phase to create different iterations on what he has. These will be sketched out first, then modeled as a CAD, simulated in FEA, and initial prototypes will be 3D printed as soon as possible. Finally, we enter the Solution Development and Verification phase. For this phase, we will take all our CAD

designs created and use FEA to simulate and compare our designs. Once we have agreed on a final design to proceed with, we can continue to use FEA to finalize a CAD design to send to the sponsor. As we progress through this process, it will be stage/activity repetitive as we expect to find ourselves moving between concept exploration and solution development often, especially as we create our initial prototype designs. Our current progress is the completion of the Problem Definition Stage. The next step of the process as we move towards Design Report 2 is Concept Generation. The final deliverable for this project will be an orthotic device that can help alleviate the pain caused to Schrader while he walks by redistributing the pressure in his foot.

Intellectual Property

There are no Intellectual Property Agreements or Non-Disclosure Agreements pertaining to this project. The project is considered "open source" where we will be combining the progress of previous projects that Schrader found most useful with our own findings to help improve upon his current designs.

Social Context Assessment

Our project has many different stakeholders, which are outlined in the next section. Most of these stakeholders are positively impacted by this, as it provides a possible solution to a medical issue without requiring extreme measures, such as an amputation. As a result, prosthetic manufacturers are the primary stakeholders that are negatively impacted since less people would be needing prosthetics because of successful completion of this project. However, these supporters of the status quo could transition into producers of this solution. Due to the nature of this problem, there is not any intentional opposition to this project.

Stakeholder Analysis & Ecosystem Map

Table 2 shows the combined Ecosystem and Stakeholder map. The ecosystem map includes six categories: Resource Providers, Supporters/Beneficiaries of the Status Quo, Complementary Organizations/Allies, Beneficiaries/Customers, Opponents/Problem Makers, and Affected/Influential Bystanders. Stakeholder analysis breaks down all stakeholders into three groups based on their impact or involvement with the problem or solution: primary, secondary, and tertiary.

Table 2. Combined Ecosystem and Stakeholder Mapping

	Primary	Secondary	Tertiary
Resource Providers	Steve Schrader Team 17	Professor Hulbert ME 450 Peers ME 450 GSI's Previous Student Project Teams	University of Michigan College of Engineering
Supporters/Beneficiaries of the Status Quo	Prosthetic Manufacturers	Bespoke Cobblers	
Complementary Organizations/Allies	Footwear Companies Orthotic Manufacturers Corporate Footwear Research Teams	Previous Student Project Teams Academic Footwear Research Teams	
Beneficiaries/Customers	Steve Schrader Anyone that suffers from a severe foot injury (injured veterans, athletes, etc) Footwear Companies	Family/Friends	
Opponents/Problem Makers	Medical Malpractice		
Affected/Influential Bystanders		Family/Friends	Media 3D Printing Companies Material Development Companies

Public Health, Safety and Welfare

Our project, although intended specifically for Schrader, can positively impact many people. The current solution for Schrader's problem is a trans-tibial amputation. Living with an amputation results in many lifestyle changes. However, the orthotic device that our team is working on along with Schrader is meant to provide another possible solution that prevents an amputation. Thus, creating an orthotic that prevents amputation will result in an improvement of the welfare of those living with traumatic foot injuries. It also reduces the risks associated with amputations, such as phantom limb syndrome. Thus, by creating a solution for Schrader, we would be able to adapt the solution for others with similar conditions, including by adjusting the size and scaling of our design.

Global Context

Our orthotic will be 3D-printable, meaning that it is very easily reproducible. Thus, this project can be beneficial for lower income countries, as those countries sometimes must resort to amputations due to a lack of medical care. However, for some of these injuries, which can consist of foot injuries like Schrader, if they are able to be fitted for this orthotic, the amputation can be avoided. In addition, this device will have a much lower cost than an actual prosthetic. So, this device has the potential to be very beneficial for lower income countries. For those who would like to spend more money, but want a similar device, future iterations of this design can investigate other methods of manufacturing that can result in an even more precise fit for the user with increased durability.

Social and Economic Impact

Because our design is 3D printed, there is a positive impact on both economic and social aspects. It allows the design to be accessible to everyone that is detailed in our stakeholder analysis and ecosystem map, due to its ease of manufacturing as well as low material costs. The adaptability of the design allows it to be tailored to a wide variety of people as well, to match each individual case. In addition, none of the work we are doing is protected by Intellectual Property rights, so it is open source and can be used by anyone, which has a positive social and economic impact for anyone pursuing this problem. For the disposal of this product, there are no specific requirements for this design since it cannot be recycled and is not made of any materials that require extra attention.

Library

Because our team's project is more reliant on Schrader's experiences than prior research, we did not interact with the librarian much. However, we made great use of the MLibrary online resources to clarify any concepts that we were unfamiliar with, as there was quite a bit of medical jargon we needed to learn and become familiar with. This also allowed us to better understand Schrader's requirements and initial problem.

Inclusion and Equity

Our team did our best to consistently practice inclusive design throughout the semester. We went about this by establishing a close relationship with our sponsor, who is our main stakeholder and the main user of the product. This close relationship allowed us to fully capture all his needs and wants in the product and translate them into our requirements and specifications, as only he truly understands the issues that needed to be solved. Throughout the concept generation and selection processes, we maintained this relationship, due to that firsthand experience he has with the problem and previously attempted solutions. He is also an engineer himself, lending our team to value his insights and ideas throughout this process. In general, if any viewpoints differed between our team and our sponsor, we leaned towards our sponsor's point of view, as he has years of firsthand experience with the issues he is going through, as well as different attempted solutions.

When dealing with the power structure, most of it fell under visible power that we had as a part of class. Our sponsor originally wanted to move into analysis and prototyping work immediately, however once we shared with him the structure of the class, he was comfortable with us following that. As a team, we believe that we did the best we possibly were able to when it comes to inclusive design work by not including any hidden power and establishing a close, working relationship with our sponsor.

In terms of cultural similarities and differences among our team affecting our approaches to the design problem, it is our belief that they did not. While each of us may have different backgrounds, all of us have experienced real engineering work and education, which is what we relied upon throughout the process of our class. With our sponsor, it was much the same. While we may all come from different locales, our engineering experiences, sponsor included, all went through University of Michigan, and are therefore similar. The only difference that presented some issues for us was the professional culture that he experiences everyday versus the academic culture that our team is living in. As mentioned previously, our sponsor had a desire to focus more on the analysis and prototyping work, whereas we had reports and presentations that fell more on the academic side that we also had to incorporate into our schedule. These differences were remedied easily with just a quick discussion about the timeline and expectations of the class.

Ethics

An ethical concern of our project was the physical handicap of our sponsor. It was a subject that we took great care in being sensitive with when discussing, as the multitude of failed surgeries have left Schrader with an abnormal gait and in pain. This is something that no one in our group has experience in dealing with. It has been a great experience working with a sponsor that chose to be as involved in the process as Schrader was, and our constant contact allowed us to keep an open and honest dialogue about any ethical issues that could arise from Schrader's handicap.

Otherwise, the project has typical applications of ethics for engineering projects with some added importance. Since this project is related to the well-being and health of people, there needs to be an added focus on the affordability, ease of access, and comfort of the design. The alternatives to finding a solution are to follow current medical practices and go through with an amputation or keep the status quo of using the Rocker Shoe. Amputations can have possible side effects that might be more devastating than the prior condition. The Rocker Shoe has important side effects of its own which can affect many aspects of health: blood circulation, ossification, arthritis, difficulty exercising, and more. There are other side effects of the current Rocker Shoe including: struggles maneuvering with increased height, difficulties walking with others, frustrations walking off-road. Therefore, our project has no intention of securing intellectual ownership of any ideas or designs. Our research and ideas will remain open sourced and focused on accessibility. 3D-printable designs will hopefully mitigate and minimize costs while allowing ease of access. Even though our final deliverable will be specifically tailored to Schrader, it can act as a proof of concept to help develop future orthotics for other beneficiaries that have similar conditions.

In addition, because this solution needs to be 3D-printable, it is very likely that it would have to be manufactured out of a plastic-based material. Therefore, it is also very likely that the solution would be difficult to recycle at the end of its life cycle. This would impact the prototyping stages, as the prototyping stage is meant to be disposable. We need to make sure that we mitigate the negative implications of using plastic. The material that we have chosen to manufacture the prototype with is Nylon PA12; our sponsor has access to this material and its material properties meet our design needs. Nylon PA12 currently is not easily recycled, as it requires a very intense cleaning process to be able to reshape and reuse it [8][9], but there is research into recycling processes for Nylon PA12 [10]. We have mutually agreed with Schrader to print out small portions of the design to gain a better understanding of the implications of the design while minimizing the plastic usage and manufacturing time and energy. However, once Schrader prints a final model, it is very durable, flexible, and can sustain “repeated and sudden loading” [11]. This means that while it is not easily recyclable, it should have a long enough lifespan to make the material choice worth it.

Despite the environmental consequences of creating our solution, the aspect of improving the well-being and health of people with a medical condition is a very important benefit of our project. There are aspects to the ease of mobility that many people take for granted. Our design aims to help alleviate these possibly alienating side effects. A successful design following our engineering specifications will help to socially integrate benefactors of the device and aid inclusivity. As Schrader once said, “[he] would like to walk on the beach with [his] daughter.” Therefore, it is ethically important of us to keep this an easily accessible and manufacturable open-source project.

The team’s personal ethics found no clashes with professional expectations. Both the university, sponsor, and team were aligned on this project in objectives and behavioral expectancies.

ENGINEERING SPECIFICATIONS

The primary user requirement is that the product should reduce pressure on the metatarsals and allow forefoot flexion while walking with a normal gait. This can be quantified by setting an engineering specification of reducing the force on the metatarsal region by 30% compared to our baseline design, the Rocker Shoe. Any reduction of the pressure will be effective because the force on this region causes pain, but our stretch goal is to reach at least 30%. Our goal for the forefoot flexure is to have at least an angle of 15°, measured from the angle between the ground and the bottom of the heel (Figure 12). 15° was chosen due to working up from the previous toe flexion of zero degrees while using the Rocker Shoe. The maximum amount of flexion bearable by Schrader while walking is unknown and not evaluable.

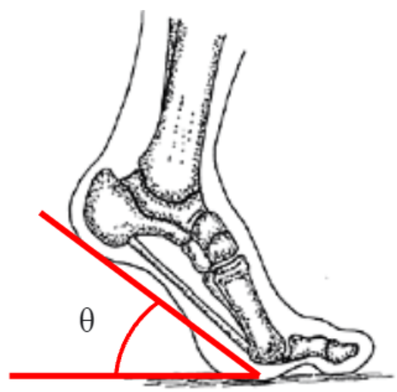

Figure 12. Angle between the ground and heel to measure the forefoot flexion.

One of the secondary priorities is to have a more manageable height than the Rocker Shoe. This is important to our stakeholder because he is already 6’4”, and the Rocker Shoe adds an additional 4”. Our engineering specifications, given to us by our sponsor, is to create a product that does not exceed 2” when unloaded, and 1” when loaded with a weight of 200 lb., which is the estimated weight of Schrader. Another important requirement to our design is to be 3D-printable. Creating a design that can be fabricated via 3D printing allows us an accessible and affordable way to rapidly prototype and would allow our sponsor to continue work on this project since he has easy access to a printer. Previous teams before us have been unsuccessful due to not prototyping early in the design process, so our team wants to try to produce at least one prototype before our final design. An additional secondary priority requirement is stability. This is necessary to ensure that the risk of falling when using the device is minimized as much as possible. The requirement is quantified as having a base of support that is greater than 100 cm^2. This value was determined based on an increase of the current support base of the Rocker Shoe, as that design has some stability issues, specifically because it moves the pivot point closer to the middle of the foot, and while that makes it easier to walk, it decreases the base of support during midstance. Some additional requirements on the area include having the base of the design have a max length of 12” and max width of 5”. The area requirement of the design is for the product to fit under the foot, not protrude from the sides, and not extend past. A unique aspect of this project is that the device needs to be compatible with the provided sole that Schrader is currently developing. Fitting onto the provided sole will allow both Schrader and our team to work parallel and let us focus on the goal of reducing the pressure on the metatarsals. Therefore, it is important that our design is durable and can stay attached to the provided sole that Schrader is developing for a lifetime of at least 10,000 steps. A lightweight product is important to not impede a user's ability to walk and less material will be more affordable when 3D printing, and the engineering specification of 1 lb. was given to us by our sponsor. Two tertiary requirements given to us by our sponsor are durability and cleanability from daily use with a garden hose. We did not include the durability requirement in our table because it is not a high priority of our sponsor currently. Our sponsor is more focused on the proof of concept of a design he can iterate upon and not a final design. Cleanability was also not included in our table because how clean a product is is a subjective measurement. Reducing the pressure on the metatarsal is the highest priority, and the rest of our user requirements are important but are not necessary. If we can achieve our first priority, we would most likely be able to iterate upon the design and reach the other requirements. Our user requirements can be seen below in Table 3, from our highest priority to the lowest.

Table 3. User requirements and engineering specifications

User Requirement	Engineering Specifications	Justification
Reduce pressure on metatarsals (primarily 2nd and 3rd) while walking with normal gait	Reduce pressure in right forefoot by 30% compared to the Rocker Shoe during step off phase of gait	Reducing pressure from the forefoot is the top priority of our design, any reduction is effective, but we will strive for 30%
Aid toe flexion or upwards bending of the toes	Bend the toes upwards 15° relative to the sole of the foot	Toe flexion pumps blood out of the foot and prevents ossification
Lower height than the Rocker Shoe	Product height must not exceed 2” when unloaded, and 1” when loaded with a weight of 200 lb. during midstance	Schrader requested that the prosthetic does not add onto his height too much because he is already 6’4”
Reproducibility	Mechanism to be 3D-printable	This is an accessible and affordable way for Schrader to get the design in hand and for us to test it
Stability	Base of support must be larger than 100 cm^2	Minimize the risk of falls and ensure that balancing is not too difficult despite the raise in height
Fit within base area constraints	Max length of 12” and max of width 5”	Dimensions provided by Schrader to make sure the prosthetic is not obtrusive
Lightweight	Product weighs less than 1 lb.	Product should not impede a user's ability to walk, and less material will be more affordable

In terms of competitive products or processes, there are few, considering the device we are looking to build is specifically for our sponsor and his impediment. In Schrader’s situation, the competitive process is a trans-tibial amputation. This is an amputation of the leg just below the knee. This process would “solve” the main requirement of reducing pressure in the metatarsal region of the foot but would do that by simply removing the problem area, not attempting to fix it. The accompanying trans-tibial prosthetic is difficult and costly to manufacture; they are not easily reproducible or 3D-printable. Along with that, the removal of such a large part of the leg is quite a drastic and severe solution for an issue in the forefoot. Therefore, our sponsor is seeking alternative solutions.

CONCEPT GENERATION PROCESS

To begin the concept generation process we have broken it down into four different phases (Figure 13), Brainstorming, Grouping of Diverse Ideas, Initial Selection, and the Alpha Design. In this section, the brainstorming and grouping of diverse ideas sections will be covered.

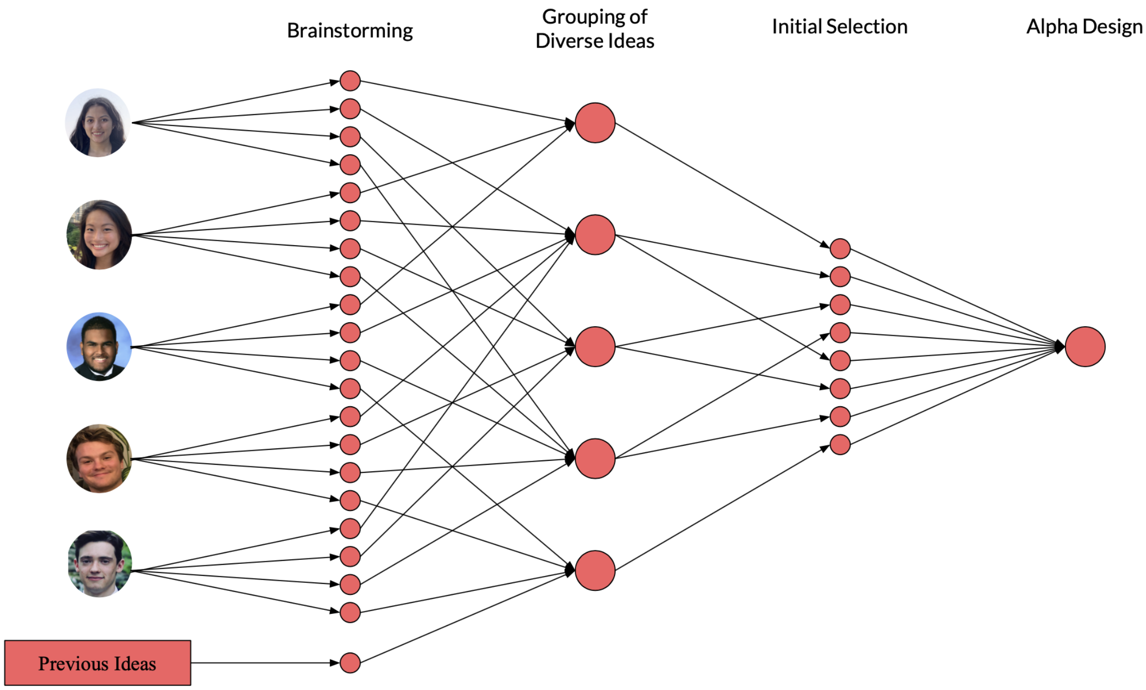

Figure 13. Flow chart of the concept generation process, incorporating four different phases: Brainstorming, Grouping of Diverse Ideas, Initial Selection, and the Alpha Design.

Brainstorming

Brainstorming is an essential step to pushing the innovation process forward. The focus during the brainstorming was to achieve the user requirements given by Schrader. The most important requirement was to alleviate the pressure on the metatarsals. Some additional requirements that were put into consideration were toe flexion, stability, and manufacturability. To successfully collect ideas, the following brainstorming rules from Tom Kelly were taken in consideration: defer judgement, encourage wild ideas, build on other's ideas, go for quantity, one conversation at a time, stay focused on the topic, and be visual [12]. To encourage the difference of judgement and to encourage wild ideas, each member of the team individually brainstormed at least four ideas for 60 to 90 minutes by sketching out a design. Afterwards, the team came together, and each member individually shared and explained their ideas. Since we had individually brainstormed, there were a few designs that were repeated. By discussing one design at a time, our team was able to stay focused on the topic and iterate upon each other's ideas. In addition, the final designs from the Michigan and Georgia Tech design teams were added to the brainstorm collection in case they could inspire future ideas. Several concepts from Schrader, the sponsor of the project, were also included since he has been working on this project for years and is now working in parallel with this project. A total of 24 ideas were generated by our team in our brainstorming session.

Grouping of Diverse Ideas

The next phase of the concept generation process is to sort and evaluate diverse ideas into similar groups. Our team sorted the 24 ideas generated in the brainstorming phase into seven different categories: Prosthetic Foot Inspired, Auxetic Material, Bistable Switch, Layers, Hinge, Hoop, and Childhood Toy Inspired. In this section, only concepts from Prosthetic Foot Inspired, Auxetic Material, Bistable Mechanism, and Hoop will be included, and the rest of the ideas can be found in Appendix B.

Prosthetic Foot Inspired

There are several different types of prosthetic feet, but one of the newest models is called dynamic response feet, shown in Figure 14.

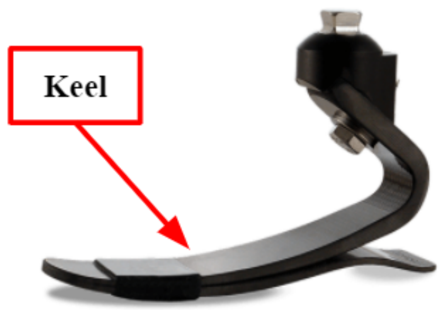

Figure 14. Below-knee dynamic response foot.

These prosthetic feet can store and release energy during the walking cycle by absorbing energy in the flexible keel during the "roll-over" phase of the stance phase (Figure 15, left) and release energy during the push-off of the toe-off phase (Figure 15, right) [13]. Oftentimes the materials used to make energy storage and return (ESAR) prosthetic feet have a high strength and the geometry of the design allows the foot to act like a spring during the toe-off phase. The materials used are usually either carbon fiber or Kevlar [13].

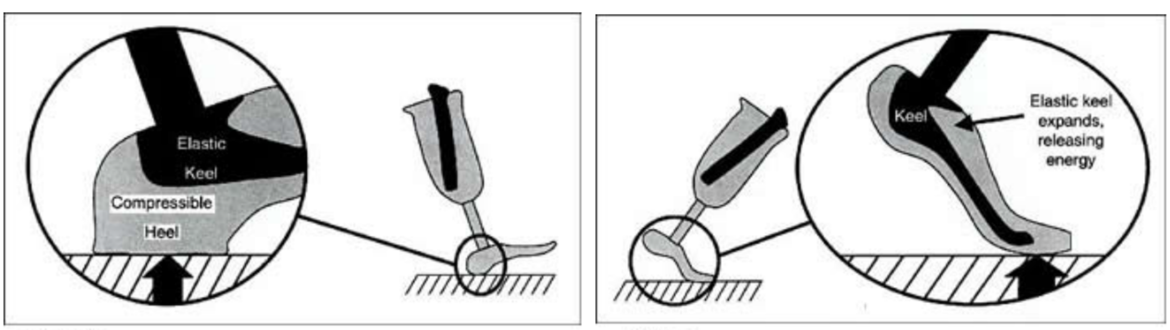

Figure 15. During the roll-over of the stance phase, the prosthetic foot absorbs energy in the keel of the prosthetic (left). During the push-off of the toe-off phase, the elastic keel releases the energy stored (right).

From the brainstorming session there were many sketches that were grouped under the Prosthetic Foot Inspired category and can be seen in Appendix A. One of the ideas that really stood out was the Ice Skate design, shown in Figure 16.

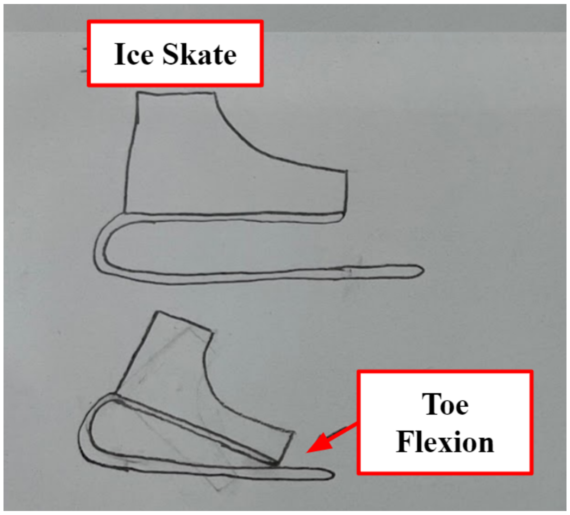

Figure 16. The Ice Skate design would help alleviate the pressure on the metatarsals by attaching at the ankle and during toe-off, there would be toe flexion.

In the Ice Skate design, the platform would attach to the user's ankle which would help reduce the pressure at the metatarsals. The platform is shaped like an ESAR prosthetic foot and would be able to store and release energy during the walking cycle. Since this design does not have direct contact with the metatarsal regions and the ground, the platform could have a larger base of support than the Rocker Shoe, which would help with stability. In addition, this design would allow toe flexion during the toe-off phase by allowing for the overhanging toe to meet the level blade as the foot is angled down.

Auxetic Material

Auxetic materials, also known as metamaterials, are unique materials that have a negative Poisson's ratio due to its geometry. Most materials have a positive Poisson's ratio, and when they are compressed (Figure 17, left), the material orthogonal to the load expands. However, since auxetic materials have a negative Poisson's ratio, when the auxetic material is compressed (Figure 17, right) the material orthogonal to the load will contract [14].

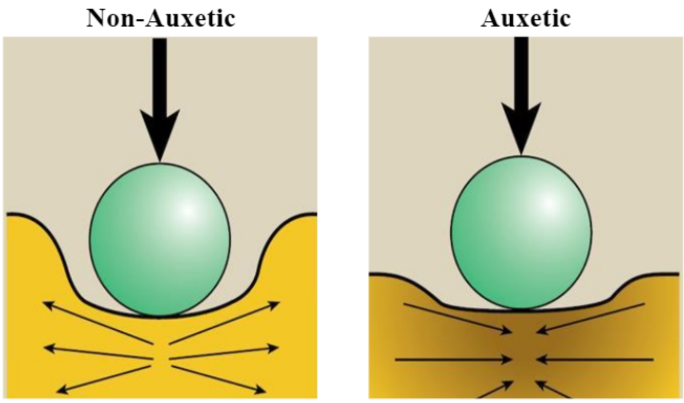

Figure 17. The non-auxetic material (left) expands orthogonal to the load. The auxetic material (right) contracts orthogonal to the load.

The Auxetic Rocker is shown below in Figure 18.

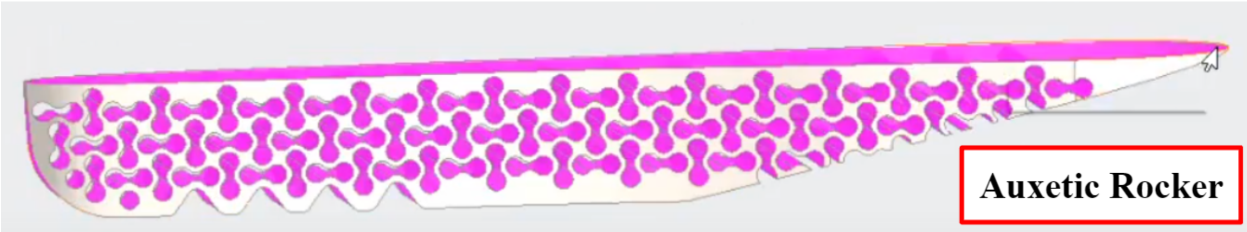

Figure 18. The Auxetic Rocker helps to distribute the load felt at the metatarsals to the rest of the foot and allows toe flexion during toe-off.

The Auxetic Rocker is shaped like the Rocker Shoe, except it has some extra tread toward the heel to help with gripping the ground. The auxetic material in this design will help to distribute the load felt at the metatarsals while still being flexible enough to allow toe flexion during the toe-off phase. If the auxetic material can significantly decrease the pressure at the metatarsals, the pivot point of the shoe could be extended out towards the toes which would increase the base of support and help with stability.

Like the Auxetic Rocker is the Dual Auxetic Rocker and is shown below in Figure 19.

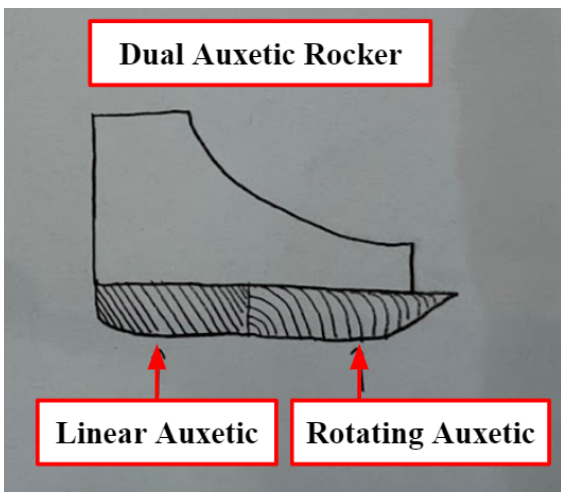

Figure 19. The Dual Auxetic Rocker combines linear and rotating auxetic material. The linear material helps to absorb energy and the rotating auxetic helps with toe flexion.

The Dual Auxetic Rocker combines linear and rotating auxetic material to create a Rocker Shoe that has a moving pivot point. The overall auxetic design will help alleviate pressure on the metatarsals and the stiffer, linear auxetic material will help with absorbing energy. The more flexible rotating auxetic material will shift the pivot point as the foot begins the toe-off phase which will allow more toe flexion. This shift in the pivot point could also help increase the stability by increasing the area of base support.

Bistable Mechanism

A bistable mechanism has two stable equilibrium positions and will rest in either of the positions until an external force is applied (Figure 20). A common example of a bistable mechanism is a light switch, and its equilibrium positions are either "on" or "off". The advantage of compliant bistable mechanisms is that they can incorporate motion and energy storage with minimum power input [15].

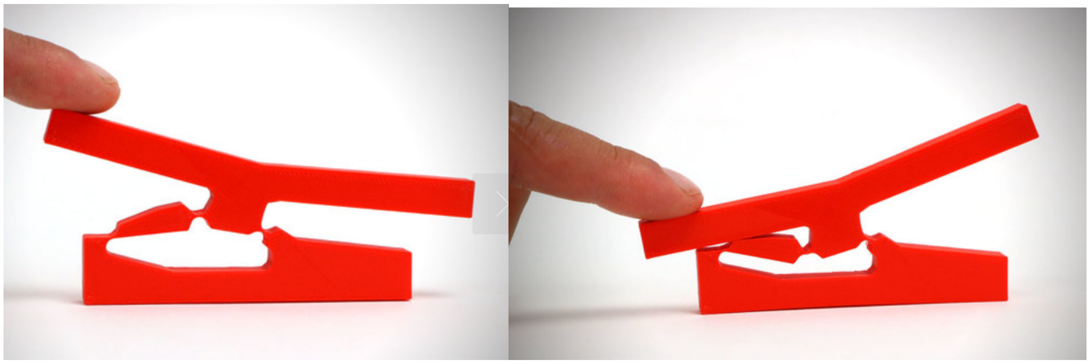

Figure 20. A bistable mechanism has two stable equilibrium positions, and the stable positions can be seen in the right and left image.

Below is the Bistable Hoop (Figure 21), which is a bistable mechanism.

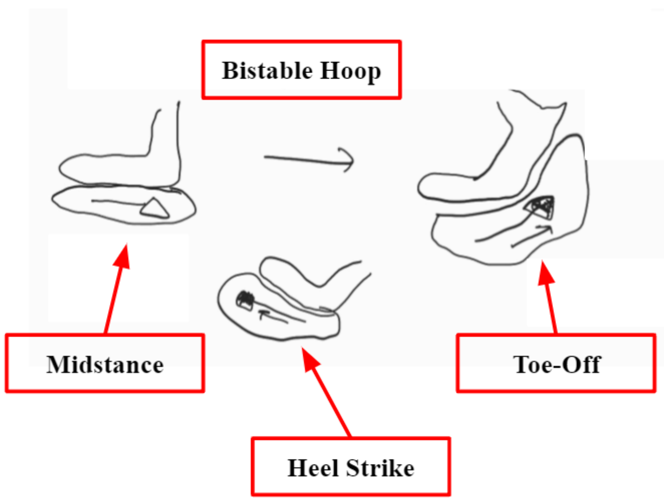

Figure 21. The Bistable Hoop has two equilibrium positions, one at the heel strike and one at the toe-off. Due to the bistable mechanism, the mass inside the hoop can move from one equilibrium position to the other.

The Bistable Hoop has two equilibrium positions, heel strike and toe-off, and the bistable mechanism moves the mass from one position to the other. Having the mass moves helps to distribute the pressure at the metatarsals during toe-off and increase stability during the midstance because there is constant contact between the ground and the entire foot. In addition, the Bistable Hoop can form an incline which helps to allow toe flexion during toe-off.

Hoop

The Hoop Shoe, shown in Figure 22, is one of the more unique concepts generated and it is very similar to the Bistable Hoop except it does not have a bistable switch.

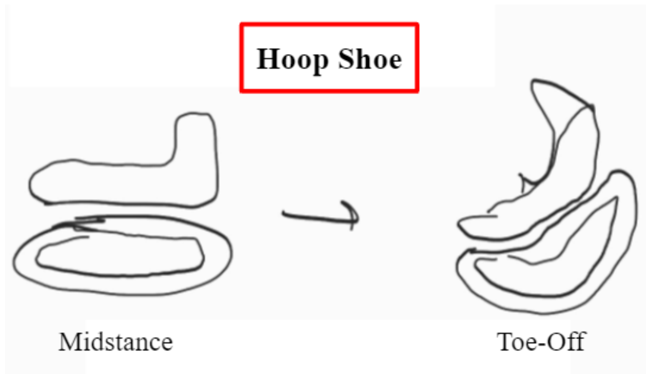

Figure 22. The Hoop Shoe helps to alleviate pressure by maintaining constant contact with the ground. It is made from a rigid but flexible material that can compress during toe-off and allow toe-flexion.

The Hoop Shoe can help distribute the load felt at the metatarsals by maintaining constant contact with the ground but without having the forefoot region directly touching the ground. The Hoop Shoe must be made out a strong but flexible material so that it will be able to deform and allow toe flexion during the toe-off phase but also spring bake into the hoop shape during the midstance phase.

CONCEPT SELECTION PROCESS

Once all our initial designs were sorted into groups, we then began our selection process. For this we selected our top eight designs. To select the top eight designs, we looked at the groupings that were created. We decided to choose designs from the Prosthetic Foot Inspired, Auxetic, Hinge, and Hoop categories. After discussing the groupings, we felt these categories contained designs that would be able to produce the best results for our sponsor. Another team discussion took place, this time selecting the top designs based on how we thought they would help meet our design requirements. This was a more subjective discussion with the team to help select from the diverse ideas that were generated. We looked at how feasible the designs were and how they fit into our design requirements. The top designs that were chosen were the Ice Skate, Auxetic Rocker, Dual Auxetic Shoe, Hoop Shoe, Banana, Auxetic Banana, Hinge Shoe, and Roman Sandal.

Pugh Chart

Next, we chose the criteria for the Pugh Chart (Table 4). Our criteria were based on our design requirements. The weights that were assigned were based on how critical each requirement was. Our first criterion, alleviate pressure, was given a weight of 5 points. This was based on our design requirement to reduce pressure off the right fore foot by 30%. This is the most critical requirement for our group and any design that does not meet this criterion cannot be considered for our alpha design. The next criterion, Toe Flexion, was given a weight of 4 points, as this is the next critical requirement for us. Based on our requirement for an upward bend of 15° at the toes, it is important for Schrader to help with blood flow in his foot. Our next 3 criteria were all given a weight of 3 points. These are the Manufacturability, Stability, and Height criteria. All of these are interconnected requirements that relate to the dimensions of our design, so they were given the same weight. These are important for Schrader's comfort when using the design, but they are not as important as the function of the design itself, as they can be improved upon with smaller changes in the design. As for our other requirements, base area and weight, we did not include these as criteria for the Pugh Chart. These requirements would not have helped with selecting the alpha design because all the designs would have scored the same. Below is the Pugh Chart with the weightings, assigned points, and final values.

Table 4. Pugh Chart comparing generated ideas to Rocker Shoe

Criteria	**Weight**	Rocker Shoe	Ice Skate	**Auxetic Rocker**	Duo Auxetic Shoe	Hoop Shoe	Bana na	Auxetic Banana	Hinge Shoe	Roman Sandal
Alleviate Pressure	5	0	1	**1**	1	0	0	1	0	1
Toe Flexion	4	0	1	**1**	1	1	0	1	1	0
Manufact urability	3	0	0	**0**	0	0	0	0	-1	-1
Stability	3	0	1	**1**	1	-1	1	1	0	1
Height	3	0	0	**1**	1	0	0	1	0	0
Total	18	0	12	**15**	15	1	3	15	1	5

The Rocker Shoe was given weights of zero points for everything. Since it is Schrader's current solution to mitigate pressure, we are using it as our baseline design to compare the other designs to. From here, the other designs were given points according to how they compared to the Rocker Shoe. The Auxetic Rocker was found as our Alpha Design. Even though this scored the same as the Auxetic Banana and the Dual Auxetic Shoe, we decided to move forward with this design because it is the simplest change from the Rocker Shoe and allows us to get a better understanding of how the auxetic material will benefit Schrader.

Top 5 Ideas

The Alpha Design that was chosen was the Auxetic Rocker (Figure 23). This design scored a 1 in each category except for Manufacturability, where it scored a 0. By looking at the functions required by our design, which include alleviating pressure, toe flexion, and stability, this design can incorporate all of those together, meeting all of our critical requirements. This design scored the same as the other auxetic designs, but it is the simplest version for our team to move forward with.

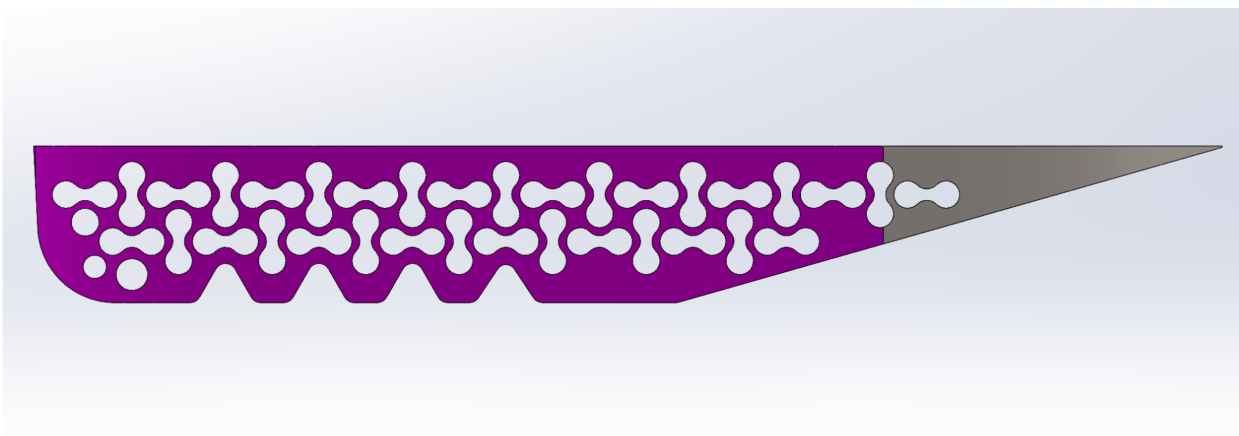

Figure 23. A side view of the Auxetic Rocker. The holes that go through the design are what give the design auxetic properties. Those thin walls that are created will act as the auxetic material shown in Figure 17.

One of the top designs found from the Pugh Chart was the Dual Auxetic Shoe. Shown in Figure 24, it has 2 different auxetic materials that each cover about half of the design. The idea behind this design is that the material towards the heel is a regular auxetic material but towards the forefoot it has rotational auxetic material to help aid with toe flexion. This scored similarly with the other auxetic designs, with the only 0 scoring for Manufacturability. Because of its slightly more complicated design when compared to the Auxetic Rocker, it was not chosen as the alpha design.

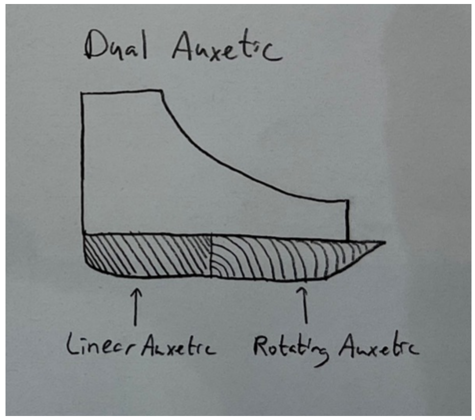

Figure 24. The Dual Auxetic Rocker, with the Linear Auxetic and Rotating Auxetic Regions labeled. The Rotating Auxetic material would help with flexing the toes.

The next top design was the Auxetic Banana. Another one of the auxetic designs that scored high, and only lost points on Manufacturability. As seen in Figure 25, it has a "banana" shaped rigid part that dissipates most of the pressure towards the rear of the foot. The addition of the auxetic material is to help alleviate more of the pressure during the heel strike and toe-off phases of gait. As stated before, while this design meets all our critical requirements, the Auxetic Rocker was chosen over it because it has a simpler design that can better let us understand how the auxetic material benefits Schrader.

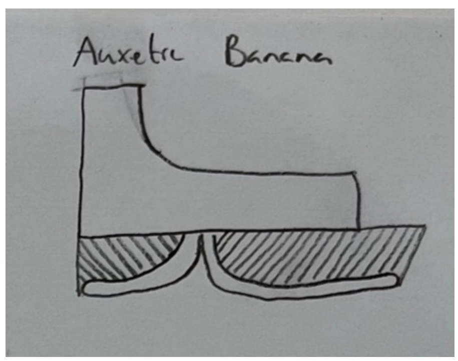

Figure 25. The Auxetic Banana combines both a banana design that helps dissipate pressure during heel strike and toe-off with auxetic material that will ideally help dissipate more pressure.

Following the 3 highest scoring designs was the Ice Skate, which scored 12 points. This design is one of the blade designs, inspired by the Georgia Tech Roman Sandal. It consists of a rigid body that bends at the heel to help drive the pressure away from the metatarsal region of the foot. At toe-off, seen in Figure 26, the toes would have just enough contact with the bottom part of the blade that they would be allowed to flex. However, this design will lead to a concentration of stress in the rear. On top of that, this design is the same height as the Rocker Shoe roughly, giving it a 0 for Height. Manufacturability was given a 0 as well because of the specific material choices this design would need as well as the fact that it would need to be 3d Printed.

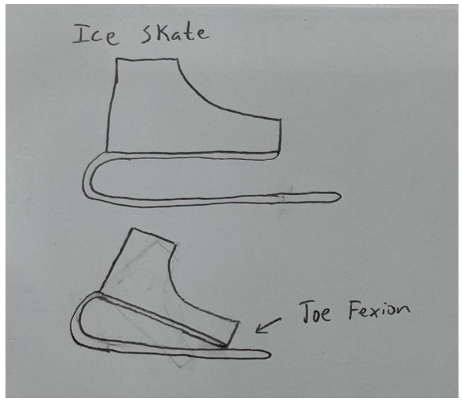

Figure 26. The Ice Skate is a blade design. As shown, there is toe flexion allowed by this design. However, the region towards the heel where there is most of the bending would need a lot of design attention to make it as robust as possible.

The design with the fifth highest score was the Roman Sandal. Another one of the Blade designs, this was the design created by the Georgia Tech team. We wanted to compare it to the designs we came up with so that we can make sure that we did not fall into any of the issues with their design. With a total of 6 points, it scored a 1 in Alleviate Pressure and Stability. Looking at the design (Figure 27), it would solve the issue of pain in the metatarsal region. It is also very well engineered and robust, just like other medical grade orthopedic devices. However, because of specific materials needed for the design, such as carbon fiber, and is made of many parts that would need to be assembled, it scored a -1 for Manufacturability. It was a good design, but Schrader found it to be too expensive and too complex, hence the push for 3D printing. For Height and Toe Flexion, it scored a 0 since it was roughly the same height as the rocker shoe and did not allow for toe flexion.

Figure 27. The Roman Sandal design from the Georgia Tech team. It has a blade like the Ice Skate and attaches at the ankle and below the knee for added support.

ALPHA DESIGN

The Auxetic Rocker (Figure 28) was chosen as our final design based on our Pugh Chart selection. Even though it scored the same as the Auxetic Banana and the Dual Auxetic Shoe, it is the simplest auxetic design and is also very similar to Schrader's current solution. This design meets or exceeds the Pugh Chart criteria when compared to the Rocker Shoe.

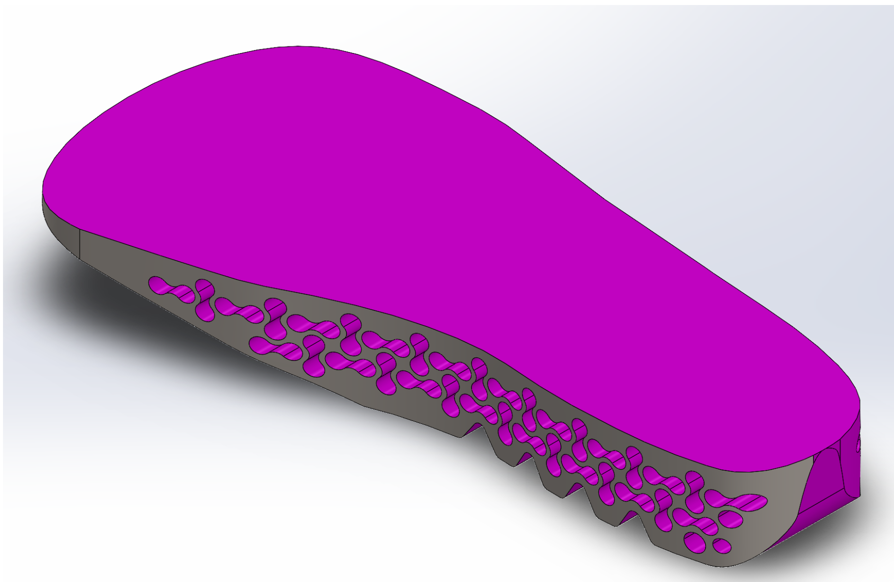

Figure 28. Isometric View of the Auxetic Rocker. Compared to the Rocker Shoe, this design has the added tread at the back, an auxetic pattern throughout the body, and an inclined forefoot with a pivot closer to the toes.

For the Alleviate Pressure criteria, the Auxetic Rocker was scored as a 1 because the auxetic material will help redistribute the pressure throughout Schrader's foot. This will help reduce the amount of pressure felt in the metatarsal region of his foot. The Toe Flexion criteria was also scored as a 1 because the auxetic material can be tuned to flex his toes during the toe-off phase, helping with blood flow in his foot (Figure 29). Manufacturability was given a 0 since this design would be 3D printed. Compared to the Rocker Shoe, which was made by modifying an old sneaker, 3D printing would not be easier or harder. Stability was given a 1. Our stability requirement is made from the Rocker Shoe's current base of support, and the Auxetic Rocker will have more ground contact than the Rocker Shoe. Currently, the Rocker Shoe has a pivot point around the midpoint to reduce pressure in the metatarsal region. Since the Auxetic Rocker will help alleviate the pressure in the metatarsal region of the foot, the pivot point will be able to be moved closer to the toes. This will allow the Auxetic Rocker to have a larger surface area where it contacts the ground, increasing the base of support (Figure 30). Also, because the Auxetic Rocker is shorter than the Rocker Shoe, Height was given a 1. This is because the Auxetic Rocker will be able to alleviate pressure with much less material. The Auxetic Rocker has a lot of areas with higher internal stresses (Figure 31) versus the solid block of the Rocker Shoe, and the Auxetic Rocker would have to be 3D printed, which can have its own faults coming from supports or infill settings.

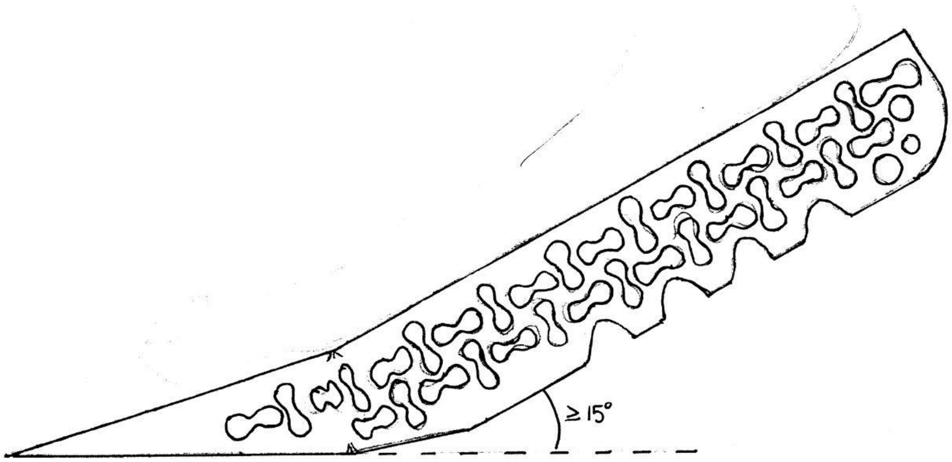

Figure 29. A side view of the Auxetic Rocker showing off the flexibility of the design. The auxetic material helps it meet our toe flexion requirement, allowing the toes to bend while having auxetic material under the forefoot to alleviate pressure.

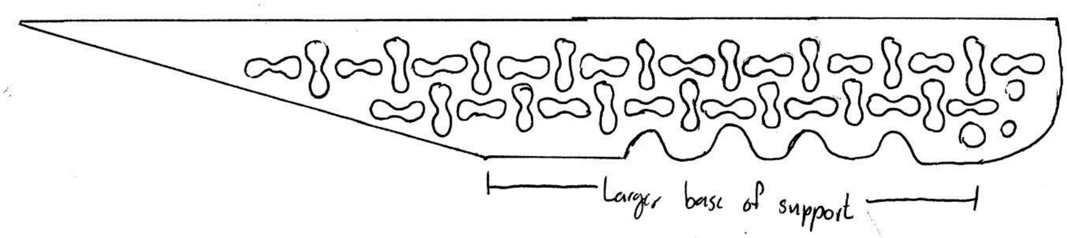

Figure 30. A side view sketch of the Auxetic Rocker. Highlighted is the larger base of support contributing to the stability criteria.

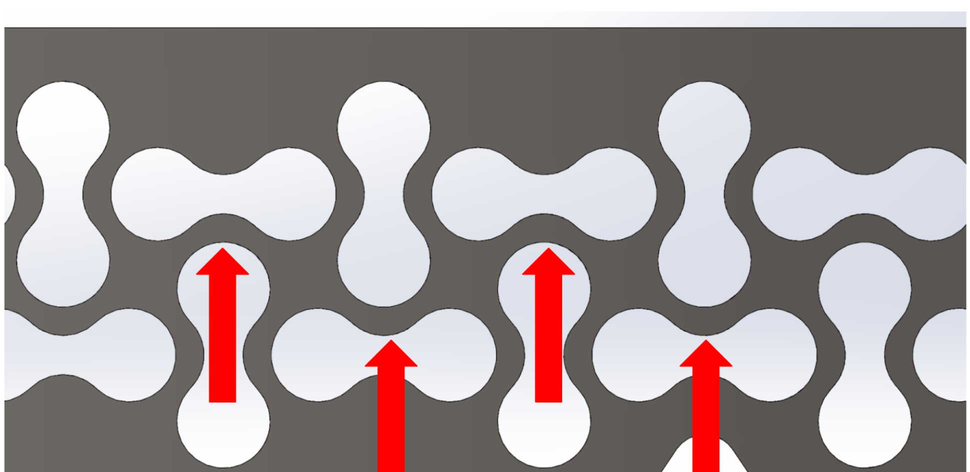

Figure 31. A closer look at the auxetic material of the Auxetic Rocker allows us to see where the areas of higher stress concentration are located. These are what allow the design to be flexible and absorb pressure. The red arrows indicate the thin wall regions mentioned where higher internal stresses are expected.

ENGINEERING ANALYSIS

The main engineering specifications that need to be tested relate to pressure and deformation. Finite element analysis is a great resource for simulating the stresses and deformation of materials under load. Each model to be tested was loaded with the appropriate forces incurred during each gait cycle phase. Figure 3 and Table 1 have the cartesian breakdowns of the ground forces applied while walking. To calculate the stresses of a design during walking, to be used as an approximator for pressure, the top surface of the model was constrained, and the ground forces applied for each stage. Figure 32 is an image of the FEA software showing the constraints and forces on the model.

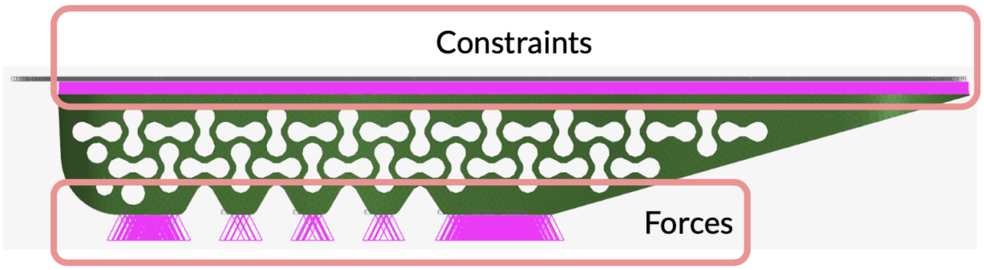

Figure 32. Labeled FEA model of forces and constraints on the CAD used for calculating metatarsal pressure.

The maximum stress in the metatarsal region, measured as 174 mm to 215 mm from the heel is used as a relative pressure that would be applied during walking. The method of overlaying an x-ray of Schrader's foot on top of a Rocker Shoe (Figure 33) allows for visual examination of the location of the metatarsals, which can be tricky to measure externally.

Figure 33. Rocker Shoe with an overlay of an X-ray of Schrader's foot. The Rocker Shoe is 274.57 mm (10.81") long, and the metatarsal regions are estimated to be between 174 mm and 215 mm from the heel.

The stress can be used as an estimator for pressure because for the material to deform and react as we constrain it to, there needs to be forces on the high stress regions. This would equate as the more stress a surface has the more force the foot would need to exert on it. There is similarly a positive relation between stress and pressure as an increase in pressure will increase stress. This experiment verified that the way we were using FEA to identify pressure was appropriate, thus allowing us to continue with the analysis.

To calculate the angle of toe flexion during walking the bottom surface of the model was constrained and the forces of walking applied from the heel to 215 mm from the heel. Only using this region is designed to emulate the inability of the sponsor to apply force through their toes; this is one of the consequences of a surgery. This most accurately simulates any deformations of the material while walking. Using the deformations of the toe and metatarsal region calculated by the FEA allows for an angle to be calculated of what the toes would be at relative to the sole of the foot.

FEA can produce misleading results if used incorrectly (Appendix E). The procedure and model that we create in FEA should be tested and compared to a real model. This will allow the accuracy of the model to be tested and verify the FEA engineering analysis strategy. Testing our engineering analysis approach helps us to verify the material properties that we are using are accurate. 3D printing materials are not as rigorously tested as other manufacturing materials. Not all 3D printing material data sheets include the Young's Modulus and Poisson's ratio. Often third-party testing is the only information that is available, which sometimes is prone to variance due to differences in 3D printers. A test of the Kevlar reinforced Nylon (sometimes referred to simply as Kevlar) was carried out; both FEA and the experiment show very minimal deformation even with loads of 200 pounds. Figure 34 illustrates the physical test of a TPU 88A auxetic section. The section was loaded with a 30-pound weight. This force and distribution were comparatively modeled in FEA. The two tests agree well enough: confirming our FEA modeling practices to be appropriately accurate.

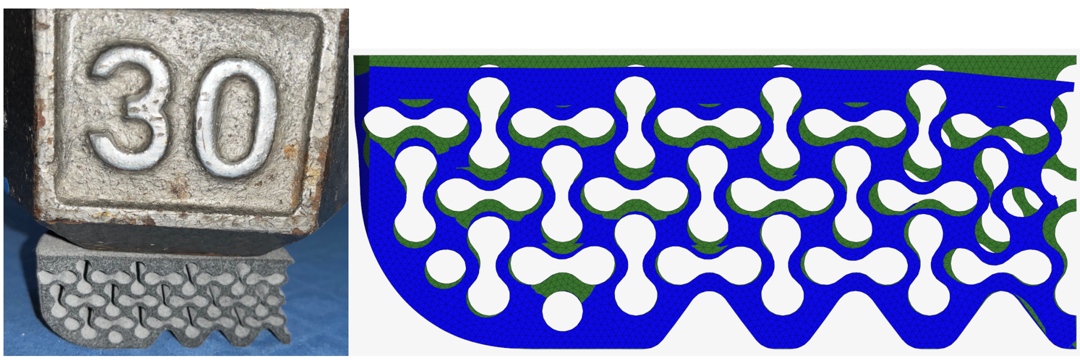

Figure 34. Left: auxetic section that was printed from TPU 88A and tested by loading it with 30 pounds. Right: FEA deformation result of simulated TPU 88A with 30 pounds of force. Both show very similar results that are within an acceptable margin of error.

Altair's HyperWorks is an easily accessible FEA application for University of Michigan students, as it is available for student use on CAEN computers. This reduces prototyping and iteration costs. Printing a design that is not a material Schrader has access to exceeds $300. With a budget of $400, physical prototypes of materials the sponsor does not have will be limited to one final print. There is a timing concern with relying on physical models for testing. Any design that we wish to print heavily relies on material properties and that limits us to only certain materials. Any print using these materials will need to be shipped to us. Upon that, 3D prints of this size take upwards of 10 hours. FEA allows for iterations and prototypes to be tested for our most important specifications in minutes or a couple hours. FEA is a great resource to help mitigate engineering analysis costs and times.

FINAL DESIGN JUSTIFICATION

The alpha design from the concept generation was the Auxetic Rocker, however due to resource limitations our team was not able to pursue it as the final design. Since the issues would persist for all our auxetic designs, the Ice Skate was the next best design from the concept generation. However, due to time constraints, the Ice Skate was evolved into our final design, the Moon Shoe, which is a design that our sponsor had been developing. The following sections detail the development and results of the Auxetic Rocker and Ice Skate and the final sketches and CAD renderings of the modified Moon Shoe.

Auxetic Rocker

From our alpha design, chosen as the Auxetic Rocker, we then went through our engineering analysis. During this process, we iterated through the material properties of the auxetic rocker to find different materials that would give us the best stress values as well as deformation to satisfy our engineering requirements. This was important because when part of the design was printed using Kevlar, it did not deform at all (Figure 35).

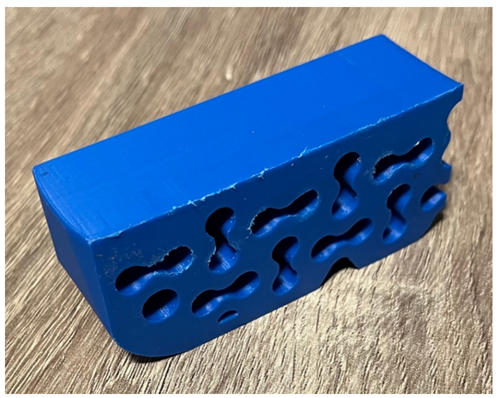

Figure 35. This is the test print of the Auxetic Section out of Kevlar Reinforced Nylon that Schrader provided us with.

We realized that using FEA, we can continue to iterate through different material properties until we found the best one for our design. The next material we used for the Auxetic Rocker was TPU since it is flexible, commonly used in footwear, and accessible for our group to print. Schrader would also have access to printing with TPU 95A, but the machine that prints with this material is currently out of order. This means that TPU 95A is out of scope for us currently, but for a future team they may be able to investigate auxetic designs using this material. Schrader's TPU 95A material is a filament for FDM type 3D printing; TPU 88A is the same polymer but a powder used for SLS 3D printing. Even though the 3D printing technique and material form vary, the material properties of both methods are comparable [16] [17].

Using FEA, the maximum pressure in the metatarsal region for the Auxetic Rocker during toe-off was about 0.70 MPa (Figure 36), which is higher than the pressure from the Rocker Shoe (0.17 MPa). This FEA was conducted using TPU 88A, and an alternative to lower the pressure would be to use a different material that could absorb more energy.

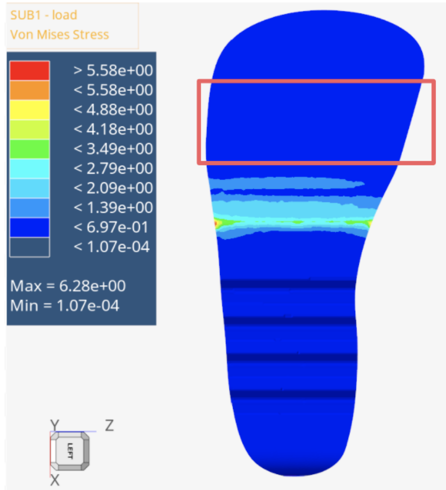

Figure 36. Top view of the Auxetic Rocker. The stress on the metatarsal region (shown in the red box) is 0.71 MPa

For the Auxetic Rocker, the deformation during toe-off can be seen in Figure 37. There is minimal to none deformation, which is not ideal since we want to have forefoot flexion. The biggest change that could be made would be to use a material that is more flexible and less stiff.

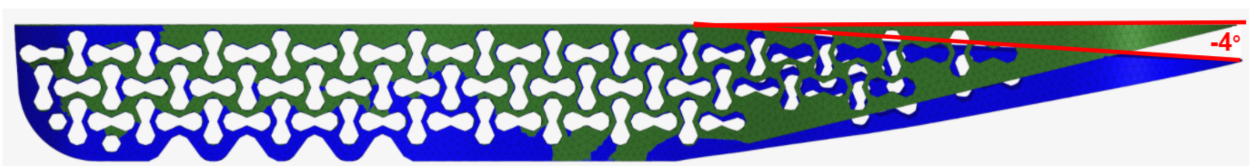

Figure 37. Auxetic Rocker in the toe-off phase. The deformation (shown in blue) is -4° from the unloaded phase (shown in green) when using TPU 88A.

Although our engineering specifications were not met, we still found the results promising and our sponsor was interested in a physical model. We printed one of our Auxetic Sections out of TPU 88A to understand the deformation for this material as well as confirm that our FEA was being done correctly (Figure 38).

Figure 38. The TPU 88A print that we ordered (left). As seen in the deformation, it behaves as we expected and compresses when loaded (right).

After seeing the results from this, we think that TPU 88A or TPU 95A may be a good material to study for future work, but it is not the end solution. If we continued with this material selection process, we found that it was out of scope for our project because it would incur many costs for both our team as well as Schrader. This is because the 3D printing would have to be outsourced by both parties to test different materials, even after the materials are found using FEA.

Ice Skate

The Ice Skate is one of our prosthetic foot inspired designs, which in its simplest form is just a u-shaped blade that goes under the foot (Figure 39).

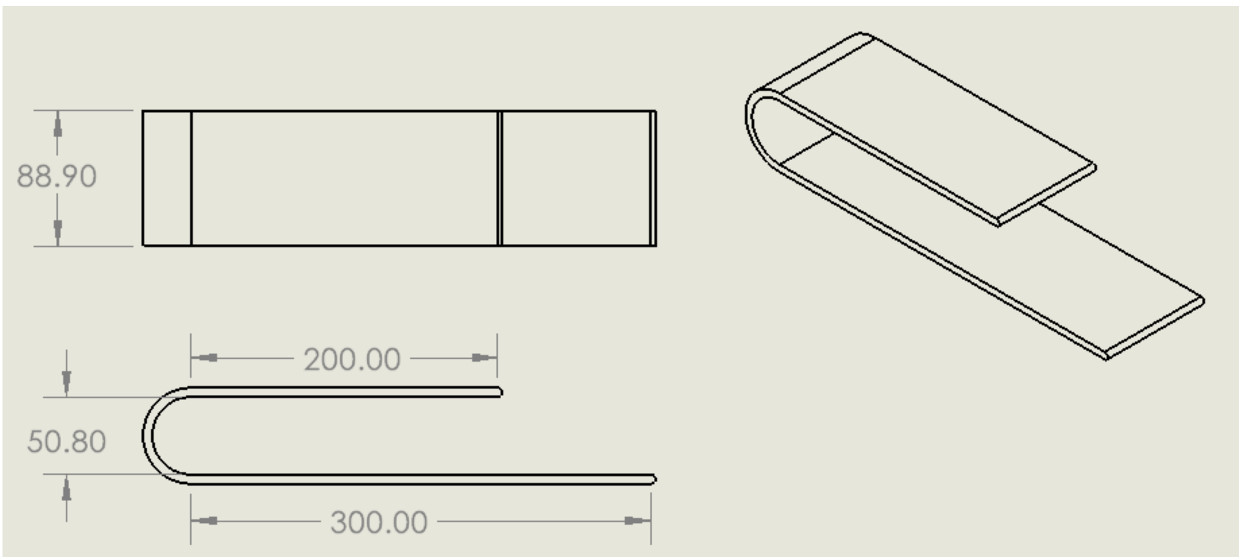

Figure 39. This is the prosthetically inspired Ice Skate Design. It uses the natural spring force in the curve to help absorb energy and alleviate pressure.

As an initial test, we applied forces during midstance to the Ice Skate in HyperWorks to understand how the stress values and deformation were influenced by the design when using Kevlar. Kevlar is a very strong and stiff material that is optimal for products that experience repeated and sudden loading [11]. Although Kevlar has a very high tensile strength of 610 MPa, it has a lower compressive strength of only 97 MPa and our product is more likely to fail in compression in the heel region. As shown in Figure 40, the stress values for the initial FEA are way too high for Kevlar, and the deformation is also too drastic for midstance.

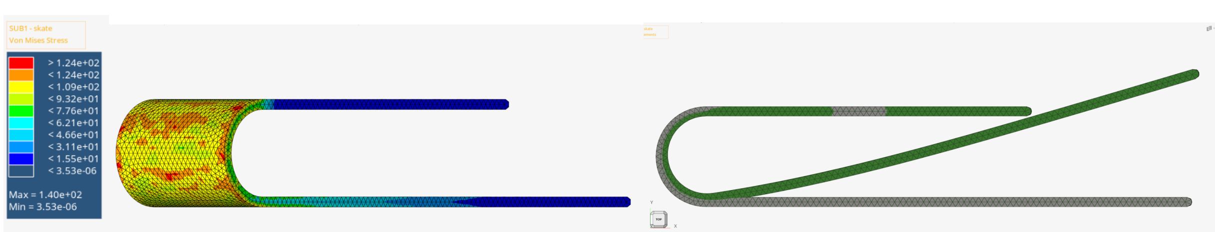

Figure 40. The FEA results of the initial Ice Skate loading in midstance. As we can see there is a stress value of 140 MPa (left), which exceeds the maximum compressive stress, and a deformation of 81 mm (right), which is also too high.

Because of this, we began iterating the design so that we could find a balance between stress values and deformation. To begin this process, we started by adding ribs to the Ice Skate to help alleviate stress and reduce deformation. Figure 41 shows how the addition of a rib helps to change the stress values as well as reducing the deformation.

Figure 41. Here we can see how just adding one rib helps increase stress to 184 MPa (left) and decreases deformation to 45 mm (right). We can also see that the location of the major stresses shifts. Although this is an improvement, the design would still fail stresses and deformation.

We continued this process with more iterations, trying different design additions such as more ribs, rib location, rounding off rib attachments, etc. However, we found that this process would take a lot more time than we had, between making new geometries, running FEA on them, and then figuring out how to make the next one more effective. This optimization approach, while it would probably yield our best design, was not something we could accomplish with our schedule. Finally, after meeting with Schrader and bringing this issue up to him, we arrived at the Moon Shoe.

Final Design: Moon Shoe

Our final design, dubbed the Moon Shoe, was created by Schrader after being influenced by some of the designs we presented. It had many similarities to the way that we iterated through the Ice Skate, and due to our sponsor's extended interest in this design, we decided to pursue it as a final design. From here, we will be iterating the design so that we can make sure that it meets the engineering specifications that we have detailed. As shown in Figure 40, the Moon Shoe design is like an Ice Skate with multiple splines that run from the top surface to the bottom surface.

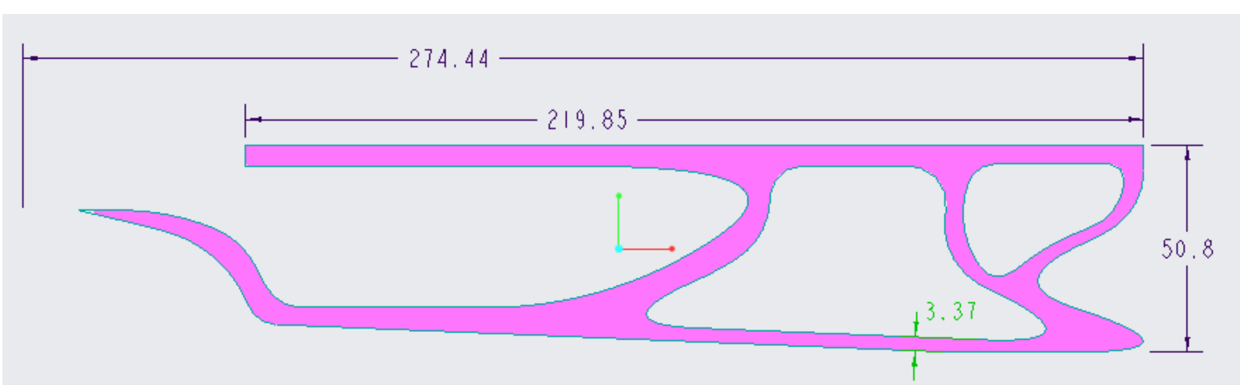

Figure 40. This is a side view of the Moon Shoe. It has splines that help it deform different amounts in different places which will help with the pressure in Schrader's foot. The major dimensions and thinnest splines are labeled. All dimensions are in millimeters.

This causes the design to deform more in certain areas than in others. By controlling the amount of deformation that the design undergoes, we will be able to help ensure that Schrader will be comfortable while using it. Our future design iterations will follow this, and we will work to balance the deformation with the stress values throughout the design, the same approach we took with the Ice Skate.

Figure 41. This is how the Moon Shoe deforms. As seen in the image, there is 30° of forefoot flexure, which is more than the required 15°.

To justify this as our final design, we reiterate that the Moon Shoe, given to us by Schrader, was a natural point for how we planned to iterate the Ice Skate. The Moon Shoe, also like the Ice Skate, was inspired by prosthetic designs. This is seen in the curvature of some of the splines that connect the top and bottom surfaces. Using HyperWorks FEA, we will finalize this design by iterating through it and make sure we have the optimal balance of deformation with stress values for the Kevlar material that Schrader will print. Even though the Kevlar material was previously reported as being very stiff, the design choices for the Moon Shoe will hopefully still allow it to deform as needed while preserving rigidity. Schrader sent us a test print of the original Moon Shoe out of Nylon, without the Kevlar inlay, and so far, it performs as expected (Figure 42).

Figure 42. A sample print of the Moon Shoe. This was printed out of Nylon without the Kevlar reinforcement.

Unsuccessful prints have shown us that the Kevlar material can be very stiff if printed too thick and that proper analysis is important for this material. As an example, Schrader printed out a section of the auxetic design out of Kevlar. When he went to test this, he said that there was no deformation when he applied pressure. A recommendation we have if this is pushed to a future design team is to explore using TPU 95A more for an auxetic design. As of right now, Schrader does not have access to this material because the machine that prints it is out of order, but for the future if he has access to this material for printing, then it seems to be a promising step forward for his goals. For the Moon Shoe, we decided to try Nylon PA12, as this material is more flexible than Kevlar, and is a material that Schrader would have access to in the future. Thus, we have a better chance of achieving the deformation necessary with this new material.

Build Description

Our final design (Appendix F) prototype was manufactured using selective laser sintering (SLS) 3D printing process from Craftcloud® using Nylon PA12 (polyamide). This company and process was chosen due to its material properties, cost, and manufacturing time. Schrader has access to Markforged's Nylon material. Even though the Markforged printer is a fused deposition modeling (FDM) process; it can model SLS by increasing the infill percentage close to 100%. Due to the design of the product and how it is a two-dimensional design extruded along the width of the foot, the layered method of FDM will not noticeably impact the product's strength. The important material properties (Young's modulus and Poisson's ratio) of Nylon PA12 and Schrader's Nylon material are similar enough that our model should behave close to if Schrader printed it on the Markforged [17]. Due to our budget constraint and previous budget expenditures, our prototype had to be printed and shipped for under $340. Craftcloud® could produce a full-size prototype and shipping it to us for $280.66. This was well below our budget. Craftcloud® also was able to ship us the prototype in under 5 days -- took 3 days.

VERIFICATION AND VALIDATION

Verification and validation are both critical aspects of the design process, as they provide a method to help ensure that the solution is the best solution possible. Verification confirms whether quantitative specifications are met and can start as soon as a design solution is developed far enough (likely before a near-final prototype is ready and) to allow for reasonable verification tests. Validation typically confirms whether a near final prototype addresses the original problem statement and creates a satisfactory value for the user. Thus, because these are two different philosophies regarding creating the best possible solution, we will have two different processes to test our design - one using verification techniques and another using validation techniques.

Verification

For the verification of the project, we will be evaluating the Moon Shoe in comparison to the seven engineering specifications using CAD and FEA.

Engineering Specification #1

The most important engineering specification is to reduce pressure in the right forefoot by 30% compared to the Rocker Shoe during the toe-off phase of the gait cycle. To find this value, the region of the metatarsals must be defined. By overlaying an image of the Rocker Shoe to an x-ray of our Sponsor's injured foot, a rough approximation of the metatarsal region was estimated to be between 174 mm to 215 mm measuring from the heel.

The pressure on the metatarsals for the Rocker Shoe during toe-off was calculated to be 0.17 MPa and an image of the FEA can be seen in Figure 43.

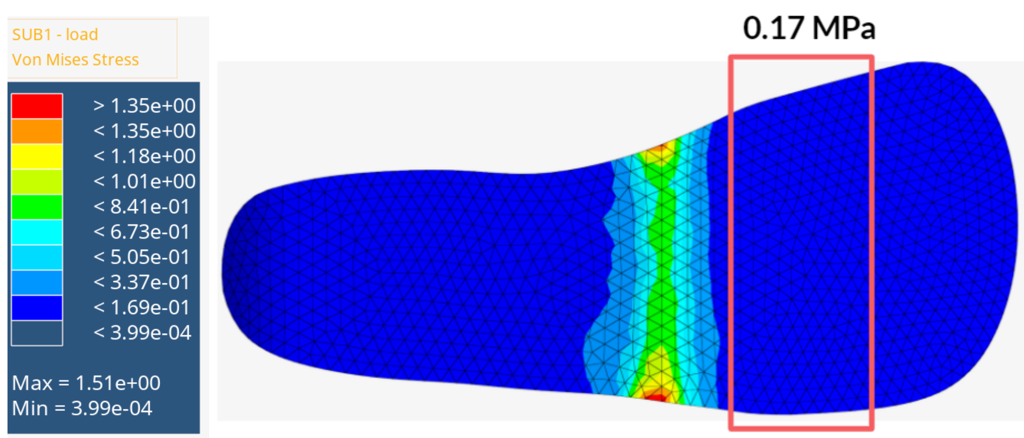

Figure 43. Bottom view of the FEA of Rocker Shoe during toe-off. The maximum pressure in the metatarsal region is 0.17 MPa.

Therefore, to meet the specifications of reducing the pressure by 30% compared to the Rocker Shoe during toe-off, the pressure of the final design must have a pressure equal or less than 0.12 MPa in the metatarsal regions.

An FEA of the Moon Shoe (Figure 45) was conducted in toe-off and the stress in the metatarsal region was found to be 0.02 MPa, which is significantly less than the engineering specification of pressure equal or less than 0.12 MPa.

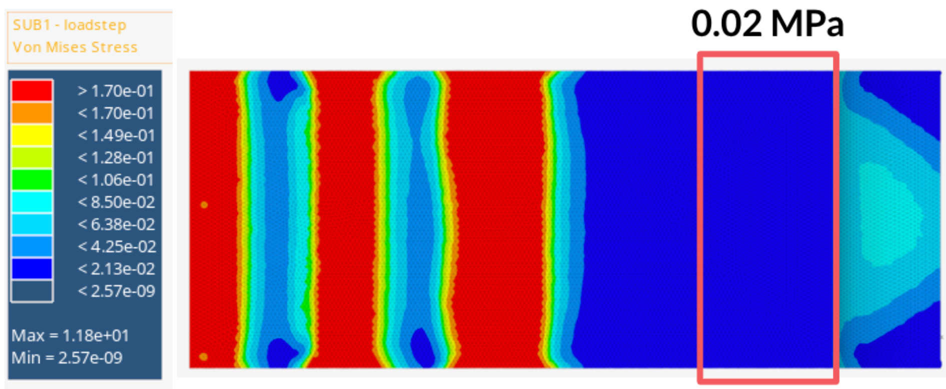

Figure 45. FEA of the Moon Shoe. In the metatarsal region (shown in the red box) the maximum stress was 0.02 MPa, which is significantly lower than the goal of 0.12 MPa.

Engineering Specification #2

Another important engineering specification is for the forefoot flexion to have at least an angle of 15°, measured from the angle between the bottom of the foot (green) and the toes (red), which can be seen in Figure 46.

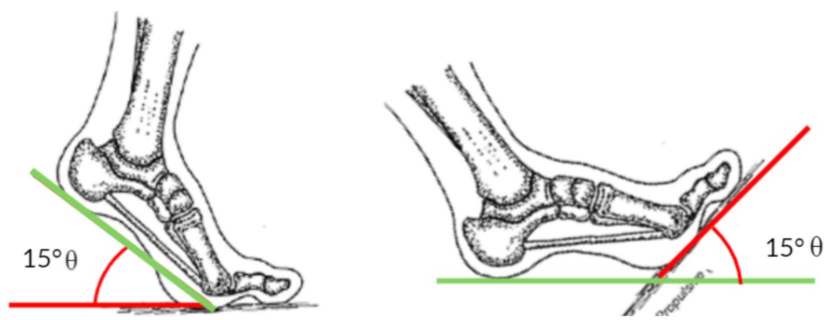

Figure 46. The left image is a foot during toe-off with the angle formed between the bottom of the foot (green) and the toes (red). The right image is a rotated view of the toe-off phase to show the adjacent angle of the forefoot flexion.

The right image is how a step may look during toe-off and the left image is a rotated view of the toe-off phase to show that toe flexion does not always require the heel lifting completely off the ground. During the push-off phase of the gait cycle, there is an intense amount of pressure on the metatarsal regions since it is the only contact with the ground, so to reduce the pressure on the metatarsals, the design cannot have the metatarsals be the only contact with the ground during toe-off.

In the Moon Shoe there is an anticipated beam deflection during the toe-off phase that will cause the forefoot to lower and lift the toes upward (Figure 48). With the upward motion, there could be an angle formed between the bottom of the foot and the bottom of the toes. By determining this angle, the toe flexion angle could be measured and compared to the engineering specification of 15°. If the pedestal did not lift the toes, a rough estimation of the beam deflection was 16°. This would mean that the forefoot flexion would be at least 16°.

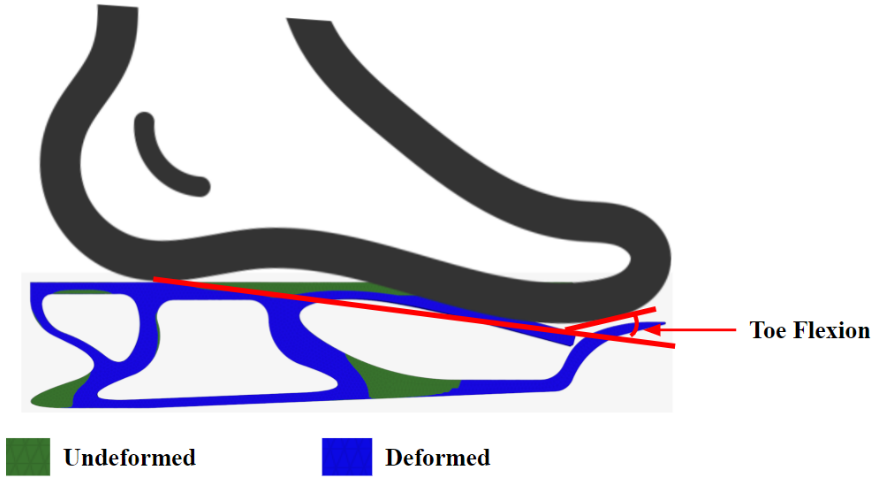

Figure 48. Deformation (shown in green) of the Moon Shoe when made from Nylon. There is significant deformation in the forefoot region.

However, to find the actual angle of toe flexion, the prototype was printed and tested during the toe-off phase (Figure 49). For the actual testing, the toe flexion was measured to be 30°, which surpasses the engineering specification of 15°. During the testing, the user noted that there was an additional pressure felt at the foot pedestal underneath the toes during the toe-off phase. However, the beam could be modified so that it would flex less and alleviate the pressure felt at the toes.

Figure 49. Moon Shoe prototype at toe-off. The angle flexion is 30° which surpasses the engineering specification.

Engineering Specification #3

Product height must not exceed 2” when unloaded, and 1” when loaded with a weight of 200 lb during midstance. For the unloaded condition, the CAD of the product can be measured using

CREO’s measuring tools. The Moon Shoe was measured to be 2” which meets the unloaded height specifications. For the loaded condition, the Moon Shoe was loaded with a weight of 200 lb evenly distributed in the Midstance; the FEA deformation results showed that the heel and midstance region did not compress, which meant that the loaded height specifications were not met. The unloaded and loaded conditions of the Moon Shoe can be seen in Figure 50.

Figure 50. Deformation of the Moon Shoe during midstance. The height is 2” unloaded (grey) and is 2” when loaded (green) with 200 lb. since there is minimal deformation in the heel region.

To test the height specifications on the real prototype, the team member that was the closest to weight to our sponsor’s, stood on the Moon Shoe in midstance (Figure 51). Like the FEA results, the Moon Shoe did not compress in the heel or midfoot region, and the height requirement was not met. To achieve the height requirement, there are several modifications that could be made; the design could have less structure in the middle and at the heel, the material could be less rigid, or the overall height of the Moon Shoe could be only one inch. However, changing any of those three parameters could affect the other specifications such as the pressure felt at the metatarsals and the forefoot flexion, so there might need to be some compromise.

Figure 51. Deformation of the Moon Shoe prototype during midstance, there is minimal to no deformation at the heel and midfoot. The Moon Shoe is 2” loaded and unloaded.

Engineering Specification #4

A unique requirement for our project is that our design needs to be 3D-printable. For the Moon Shoe we will be using a Markforged printer because our sponsor has easy and free access to it. This helps relieve some challenges with the budget constraints since we will be able to iterate and print designs as needed. We will print our design in Nylon PA12. More details about the print can be found in the Manufacturing Plan.

Originally our team had planned to use Kevlar reinforced Nylon because it is a strong and stiff material. However, through our FEA analysis, we found that it was going to be too stiff for toe flexion and we needed some flexibility. The properties of Selective Laser Sintering (SLS) Nylon PA12 can be seen in Table 5. Nylon (polyamide PA) is a very versatile material. When it is printed thin enough it can be used for springs and when it is thicker, it is strong enough for functional parts [18]. Currently it is not easy to recycle SLS, but there is research that is being conducted to figure out how to recycle SLS Nylon PA12 [10]. If Nylon PA12 can be recycled, it would be more beneficial to the environment and could also help reduce the cost.

Table 5. SLS Nylon PA12 Properties [19]

Property	Value
Young's Modulus (GPa)	1.7
Tensile Strength (MPa)	45
Poisson's Ratio	0.39

Engineering Specification #5
The fifth engineering specification is focused on stability, and it requires the base of support to have an area equal or greater than 100 cm^2 which is the current area of the Rocker Shoe. Using CREO's measuring tool the bottom area of the Moon Shoe was found to be 259 cm^2, shown in Figure 52.

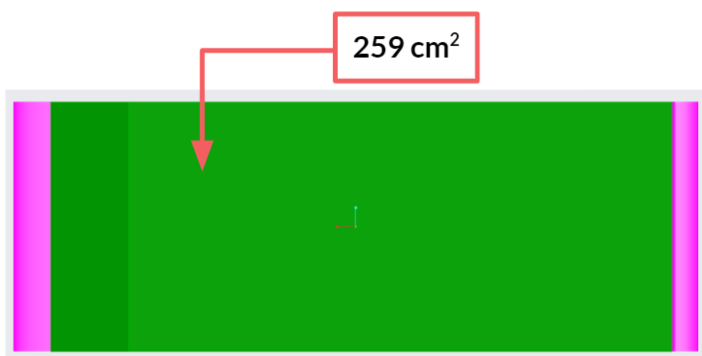

Figure 52. Bottom of the Moon Shoe, showing the base of support to have an area of 259 cm^2 which is significantly higher than the Rocker Shoe.

Engineering Specification #6
The next engineering specification also involves the product's geometry, and it requires a length maximum of 12" and width maximum of 5". The CREO's measuring tool was used to determine that the Moon Shoe length is 10" and the width is 4" (Figure 53), which are both well within the given engineering specification.

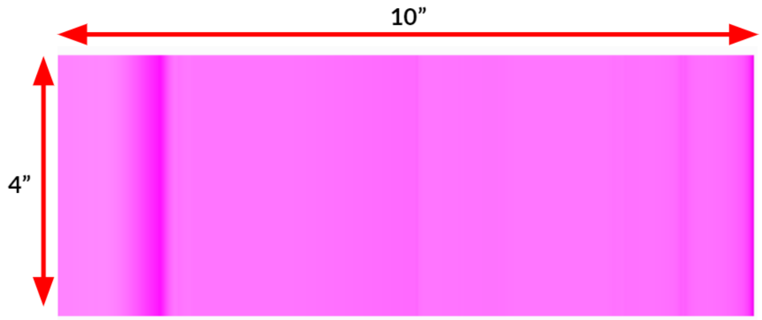

Figure 53. Top view of the Moon Shoe. The max length of the Moon Shoe is 10 inches, and the max width is 4 inches, which are both within the maximum length specifications of 12 inches and 5 inches.

Engineering Specification #7

Product weighs less than 1 lb. The Moon Shoe’s mass (0.85 lb.) was measured using its volume found on CAD and Nylon PA12 known density. This value meets the engineering specification of less than 1 lb.

Verification Summary

All the engineering specifications were met, except for the loaded height requirement. For the most important user requirement, reducing pressure on the metatarsals, the FEA verification exceeded this requirement. However, on the actual printed prototype the pressure was not tested quantitatively, and it will be best tested during validation since it is subjective to our sponsor’s comfort level. Similarly, the toe flexion engineering specification was met in the FEA and the printed prototype, but the requirement still needs to be validated by our sponsor to ensure it satisfied his needs. The loaded height requirement that was not met was a stretch goal rather than a hard requirement, and it is something that can be improved in a future iteration. Overall, we have successfully created a design that meets most of the engineering specifications and the next step is for our sponsor to validate our design to see if the user is satisfied with the results.

Validation

Because the product we are creating is specifically designed for Steve Schrader, the best way to validate that Schrader is satisfied with the outcome of our design is to have him try it out himself. Along with having Schrader try out the final printed prototype, we decided to also have him test throughout our intermediate steps as well. The original Moon Shoe design had been handed off to us from our sponsor and did not meet all our engineering specifications. More specifically, engineering specifications 1 (reducing pressure in the metatarsal region), 2 (forefoot flexion), 3 (height), and 7 (weight) have not been met. For the original Moon Shoe, we printed out a thinner version of the design using Nylon, shown in Figure 54 below.

Figure 54. Partial print of Moon Shoe iteration.

The results from the prototype were promising, but not perfect. This prototype drove the design changes to the modified Moon Shoe that we used as the final design. These design changes included the decrease of height to 2 inches, the beam at the forefoot, and the material change to Nylon PA12. For the final design, the prototype was able to meet all the engineering specifications except for the loaded height requirement. The final Moon Shoe printed out as a prototype can be seen in Figure 55, and we will be sending this print to our sponsor so he can validate the design. Because our project is dynamic, after Schrader validates our final prototype, he will continue to iterate upon it to create the ideal solution for himself.

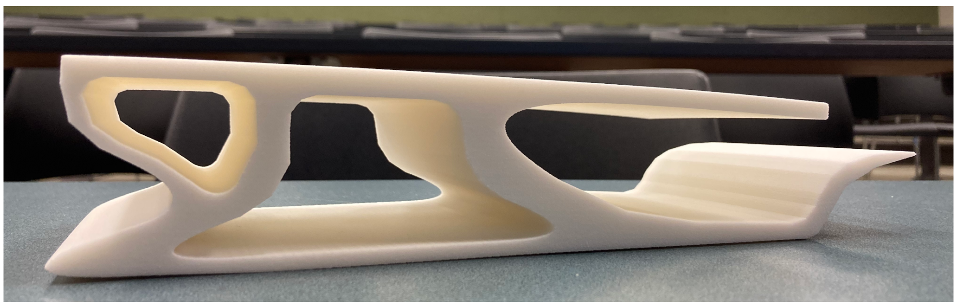

Figure 55. Final print of moon shoe design.

DISCUSSION

Problem Definition

Our main objective for this project was to create a 3D-printable orthotic that alleviates pressure on the metatarsal region during the toe-off phase of the gait cycle while still allowing forefoot flexure. If we had more time and resources, it could have been beneficial to know what our sponsor's maximum limit for the pressure felt at the metatarsals. The benefits of this value would be to verify the accuracy of our values found via FEA and to have a methodology to test our prototype. To find the real pressure felt by our sponsor, our team would have to use pressure sensors or some sort of equipment to test our sponsor's comfort levels. Similar to the pressure specification, it would have been helpful to have known the exact angle needed for toe-flexion. It was estimated that 15° would be a reasonable goal for the team to strive for, but it was not actually tested before the engineering specification was created. If we were to have found this value, we would have had to conduct tests on our sponsor to figure out what the minimal toe flexion that allows blood flow but also is not painful. However, besides time and resources, there are other factors preventing both tests from happening such as distance (our sponsor lives in Florida) and safety concerns for our sponsor.

Design Critique

If we were able to redo this project, we would have started with the Moon Shoe design as a "final" design because there would have been more time to create multiple prints and iterations. If we had the resources, we would have also printed a prototype that fit one of us to test the verification. It was difficult for our team to properly assess the prototype because none of our feet fit the dimensions of the shoe correctly. The Moon Shoe design was built to fit our sponsor's foot since we would be sending it to him for validation at the end of the project.

The customization of the design is one of the strengths of the Moon Shoe design because it could be easily tuned to fit the user. One of the Moon Shoe's other strengths included its ability to be quickly iterated via CAD and simulated in HyperWorks. The Moon Shoe has a lot of areas that could be easily adjusted that would affect the pressure felt on the metatarsals and the forefoot flexion. Some of these parts include the beam, foot pedestal, and midfoot structures, and each part could be thickened or thinned depending on the need.

In our final design, we were able to achieve the pressure reduction and forefoot flexion we wanted, but we still need to have our design validated by our sponsor. If our sponsor is satisfied by the pressure reduction and forefoot flexion, some improvements that could be made is a reduction of the thicker sections to make all sections thinner and uniform to save time and money when 3D printing. The thinner design would need to be verified and validated to ensure that it is still able to meet the engineering specifications and satisfy our sponsor. Below is Figure 56 that shows the thicker areas (blue) that could be reduced.

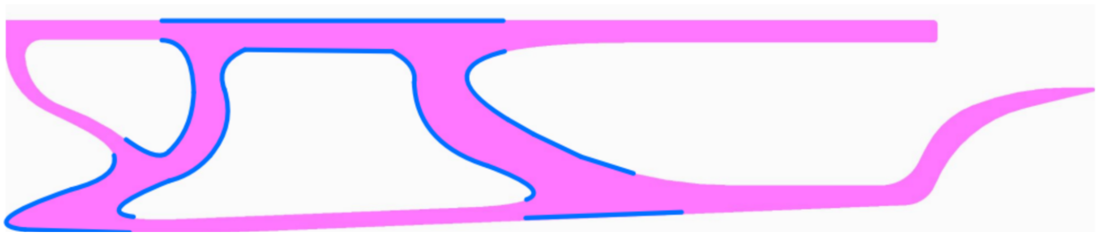

Figure 56. The blue lines show the thicker areas that could be reduced to save money and time.

A major weakness to the current Moon Shoe design is its rigidity in the heel and midfoot region. Ideally, the prototype would be able to compress from 2” to 1” and decrease the height of the shoe. There are several options to solve this problem; lower the overall height of the prototype to a maximum of 1” or change the material and design so it is able to compress when loaded. If the overall height of the Moon Shoe is decreased, it could affect the toe flexion. Currently, the beam deflects downward more than one inch, so it would touch the bottom if the prototype were only 1” tall, which could also affect the pressure felt on the metatarsals. However, the Moon Shoe design exceeded the forefoot flexion of 15°, so the beam may not need to bend as much as it does in the current design. The minimum amount the beam needs to deflect is dependent on our sponsor’s need that he will be able to determine during validation. Figure 57 shows an example of what a shorter version of the Moon Shoe could look like.

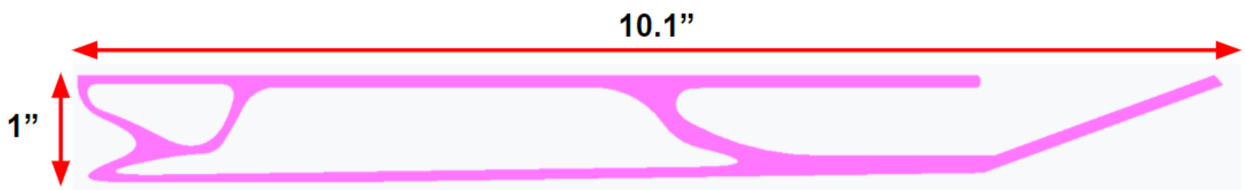

Figure 57. 1” version of the Moon Shoe.

For the second option, if the material and design is changed, there could be compression to 1” when loaded during midstance and not during toe-off, which could allow the beam to deflect as normal. During our project, we saw that TPU 88A in an auxetic pattern, compressed significantly when loaded. Using a similar material, we could redesign the heel region to compress when loaded but still allow for the beam in the forefoot region to deflect for toe flexion.

RECOMMENDATIONS

There were several design approaches to this project; several had to be cut short due to the nature of the project and class. We would like to make sure that our sponsor has full access to the intentions of our project and its future. The sponsor and team had a mutual understanding of the project being continued beyond our efforts and time. Even though we will not directly work on the project after this semester, we have ideas that could shape and inform this project's trajectory.

Auxetic Material

During this semester, we spent plenty of time researching auxetic materials. Several other footwear manufacturers have been researching auxetic materials due to possible proclivities for reducing pressure while walking. In our FEA simulation setup we did not find a reduction in pressure in the metatarsal region, and production of an entire Auxetic Rocker Shoe was too expensive for this project. This led to us abandoning the design and focusing on the Moon Shoe design. However, our FEA setup might possibly not yield what would truly happen. We did print a section of an auxetic design. The design behaved exactly as expected in how it deformed. One member when stepping on it thought it felt comfortable and soft. We are not certain how the Auxetic Rocker Shoe design would hold up for toe deformation, but a slipper or flip-flop type shoe with an auxetic design might possibly help to reduce pressure on the metatarsal region. Once Schrader receives our printed sample, we recommend that he tests standing on it. Due to its slim nature, it might be hard to test what it could provide. If the sponsor, Schrader, is interested in this design then we would recommend that a full-sized flip-flop be printed so as to test its capability to reduce pressure in the metatarsal region.

Moon Shoe

The team has so far been satisfied with the Moon Shoe results; the Moon Shoe meets most of the design specifications. However, there are still certain design elements that can be iterated upon to improve its performance and comfort. There are several elements of the pedestal that need to be altered to the sponsor's needs. Figure 58 shows the final design and labels the important regions and design features.

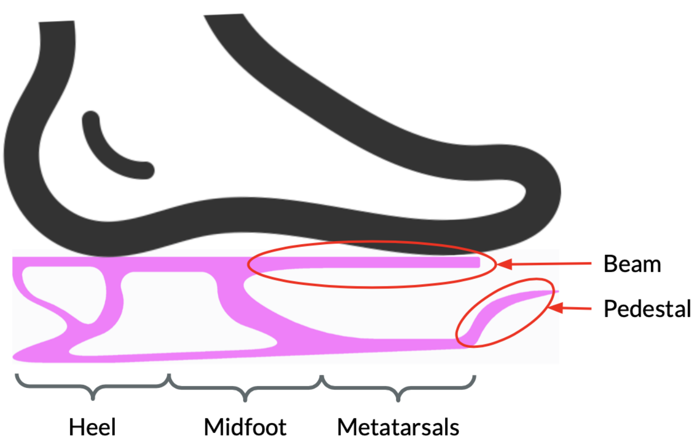

Figure 58. Illustration of labeled final design interfacing with the foot.

Currently our toe flexion is measured at 30° and is exceeding our design specifications. This means that if Schrader finds the current toe flexion to be too great and uncomfortable the pedestal could be lowered and still meet the design specifications. If the toe flexion is found to be too small for Schrader's liking, then the pedestal could be raised to increase the toe flexion. The pedestal also has an angle to. The angle of the pedestal could be changed to provide the support that Schrader finds most desirable. Another characteristic of the pedestal that should be altered to how Schrader wants it is the length of the pedestal. It was found that the pedestal was too small even for the team, so it is likely that Schrader will want to lengthen it to his feet on the next iteration.

The overall length of the beam and Moon Shoe design can be altered to best fit Schrader's foot size, but we think the length should be close.

During testing of the Moon Shoe prototype, the stiffness of the heel was a noticeable region for improvement. There is no energy absorption currently during heel strike due to the stiffness and structural design of the heel region. The heel region could be iterated by either thinning the support structures so that they elastically deform under less pressure, or the design of the heel supports are altered to more resemble the beam under the toes. The heel region is very much available to plenty of design changes. However, making the heel region too elastic will most likely affect the deformation of the toe beam. This might mean that the heel and toe regions will need to be altered together to balance each other correctly and improve both.

One design specification that the Moon Shoe does not currently meet is its vertical height when under load. The design exceeds one inch in height. There is room for this to be fixed. Plenty of material in the middle is stationary and not necessarily important. The one design concern for shortening the overall height of the design is its impact on available toe flexion. If the height of the design is shortened, then the toe beam has less available height to deform down to affecting the possible toe flexion. Since the current toe flexion is measured at 30°, there is room for the shoe to be shortened and still meet the toe flexion criterion.

During testing, the team found that the beam deformed more during toe-off than expected. The beam does have a limit on its maximum degree of flexure due to the bottom of the shoe, but since the beam deflects more than expected it meets the pedestal and pushes it forward. Schrader will need to watch this during testing. If it becomes a disagreeable side effect of over flexure, then the beam could be thickened to decrease its flexibility. Alternatively, the location of the start of the pedestal could be moved away from the heel so that the beam does not interact with it.

Something that was not taken into consideration during the design phases was the grip of the shoe. During testing, the bottom of the Moon Shoe was found to be slippery on most surfaces. We increased the friction of the bottom of the shoe by applying duct tape to the bottom of the shoe, but for future iterations a real solution will need to be explored. We recommend that a thin, rough rubber sheet be glued to the bottom of the shoe. This is like the current design solution of most shoes. What type of adhesive to use will need to be researched. If typical adhesives do not provide a strong enough adhesion between the two materials, then fasteners could be explored. The bottom of the Moon Shoe could afford to have holes or pegs added to it without impacting the functionality of the rest of the shoe.

Human feet are not perfectly squared off (Figure 59). The metatarsals all vary in length; typically, with the fifth metatarsal being the shortest and generally increasing as you move towards the first metatarsal. Our current design does not reflect this. During testing an increase of pressure could be felt on the shorter metatarsals because the midfoot support of the Moon Shoe does not reflect these differing lengths. An important design iteration that Schrader could make would be to arch the midfoot support to the lengths of his metatarsals.

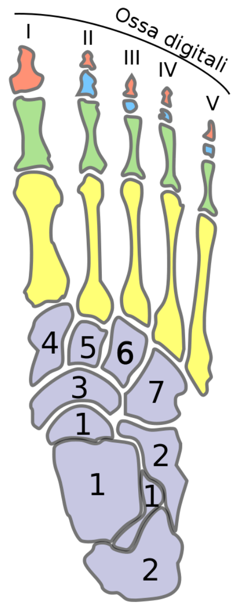

Figure 59. Image showing the differences in lengths of the metatarsals.
https://commons.wikimedia.org/wiki/File:Ospied-it.svg

Since the team does not know how Schrader will react to wearing the device, we cannot conceive all the possible recommendations and design choices that will best satisfy his needs. We hope that the work achieved and completed during this project and semester will help Schrader find pain relief. The recommendations above should cover all our thoughts about the continuation of the project.

CONCLUSION

Our sponsor, Steve Schrader, suffers from a severe case of pes cavus, a condition that is characterized by high arches in the foot, ultimately providing a smaller surface area for the load from walking to be distributed over, causing pain and discomfort. Through a series of six unsuccessful surgeries the condition has deteriorated, resulting in Schrader losing his foot's natural spring. Due to this, Schrader's right forefoot can no longer handle his body weight during the toe-off phase of the gait cycle, because there is an immense amount of pressure on the metatarsals. Due to the importance of the toe-off phase in the gait cycle, we will be focusing on shock absorption and pressure redistribution to alleviate the pain in the metatarsal region while still allowing forefoot flexion during the toe-off phase of the gait cycle.

Using ME 450's design process for our project, we started from the problem definition phase, as our sponsor had already completed the need identification phase himself. We used both research and interviews with our main stakeholder, Schrader, to fully define the problem, as well as flesh out our requirements and specifications. We have split up these requirements between our primary and secondary priorities. Our primary priority is simple, and that is to decrease the pressure on the metatarsals (primarily the 2nd and 3rd) while walking with a normal gait. Our selected specification for this is to reduce the pressure on the metatarsal by 30% from the current Rocker Shoe that Schrader is using, which we consider a stretch goal, as any decrease will be seen as valuable. Beyond this, there are several secondary priorities, including ensuring the height is lower than the current Rocker Shoe, area constraints, and a few others. These are considered secondary priorities as Schrader's condition is painful and reduces his mobility, so we want to ensure our focus is to decrease the pressure in his metatarsals, alleviating pain and allowing better movement. Once that is successful, iterations can be made to conquer some of the other requirements, but first and foremost needs to be about dealing with the force on the forefoot.

For the design process each team member independently sketched and proposed four design ideas. All twenty of these plus several ideas from Schrader and the previous design teams were then grouped together by similar design characteristics. The team collectively discussed and voted on what we perceived to be the top eight designs. These eight designs were scored using a Pugh Chart with categories representing engineering specifications and reflecting their importance with a point weight. The most important, and highest valued, being the design's capability to alleviate pressure on the metatarsals. Toe flexion was the penultimate design characteristic each design was evaluated on. Each design and category were scored against the baseline Rocker Shoe design. An alpha design was chosen from the Pugh Chart which is called the "Auxetic Rocker." The Auxetic Rocker is a Rocker Shoe with an auxetic geometry that will allow for improved pressure distribution and toe flexion.

Our designs and alpha design pull heavily from several engineering fields of study: design for manufacturing, solid mechanics, and dynamics. To help us apply these fields of knowledge to design iterations we used Finite Element Analysis (FEA). FEA allowed us to model the forces of walking through the phases -- heel strike, midstance, and toe-off -- on the proposed design. FEA computing time replaced and reduced manufacturing costs and times for prototyping.

Through this FEA we found promising results for the Auxetic Rocker Shoe, however, concerns with determining a proper material, and the need to outsource the printing, put this design out of the time and budgetary scope of the class. This caused us to move towards focusing on our runner up from the concept selection phase, the Ice Skate. Through engineering analysis and discussions with our sponsor, we saw the evolution of the Ice Skate to one of Schrader's designs, the Moon Shoe, which we then adopted.

After conducting verification on the first iteration of the Moon Shoe, we learned that it failed several of our specifications. Adjusting our design, we continued to verify that it met our specifications using FEA. The Moon Shoe was able to meet all the engineering specifications except for the loaded height requirement. To further verify the design, we had it 3D printed in SLS Nylon PA12 for $280. Our team qualitatively tested the pressure reduction and measured the actual degree of toe flexion. For validation we have sent the prototype to our sponsor to see if it meets his user requirements. One of our critiques for the final design is that the heel does not compress, failing our height requirement. This was not a hard requirement however so we did not put too much emphasis on it, and it is something that can be changed in the next iteration to be shorter. Another critique is that the design is just a two-dimensional drawing that is extruded in a third direction, giving it thickness. To improve the design in this way, we recommend that the design is unique in all three dimensions. This would allow for the design to be better fit to his foot. We also recommend that some form of cushioning is placed where Schrader's toes will be in contact with the Moon Shoe, since our team found a lot of pressure on the toes. Although this is still a prototype for him to continue working with, our hope is that this design will be able to help him greatly in his process.

ACKNOWLEDGEMENTS

We wanted to take a moment to extend our thanks to Steve, for all the guidance and wisdom he provided to us throughout the semester. It was a pleasure working with him, and we are glad he trusted us to work with him to help alleviate his walking impediment. We would also like to extend a special thank you to Professor Hulbert, for being there to give advice and encouragement whenever we felt stuck and providing key advice for our FEA analysis. Our ME 450 section also deserves to be thanked for all the positive and constructive feedback they gave to us throughout the semester. Finally, we would like to acknowledge all the work put in by previous design teams, as some of the information they gathered proved vital to our own work.

INFORMATION SOURCES

In our initial literature search, we focused on finding materials on the physics of walking and prosthetics to gain a better understanding of the task at hand. After some discussion with our sponsor, we learned that we will be working in parallel with him and learned about his medical condition (pes cavus) and the work he has done so far. Thus, our sponsor is a good resource for a lot of the background knowledge that we lacked. After initial discussions, we gathered more information on his condition. In addition, because our sponsor is working in parallel with us, he had an initial design, so we investigated potential materials we could use for that design. However, we realized that we want to use a material that works with an auxetic design for the Auxetic Rocker. Because we need to be able to 3D print our design, finding a 3D-printable material that fits our needs is a challenge that we must solve. One way of doing this is talking to people in the Materials Science department. The Moon Shoe design was created by Schrader, who was inspired by our concept generation process. Thus, our sponsor would also be a very good resource in helping us refine the design, as we would be able to discuss any design decisions with him. In addition, one of our tasks is to be able to do an FEA. Our team and our sponsor have very limited knowledge about FEA, but it is an important task, since the previous University of Michigan team was not able to produce a product that fit their design requirements due to an unsuccessful FEA. Therefore, to help fill in the knowledge gaps, we have guidance from Professor Hulbert, who teaches the FEA course at the University, watched tutorials on Altair, the FEA software's website, and reached out to the ambassador to Altair that has been assigned to the University of Michigan. We believe that with these resources, we will be able to fill in the gaps in knowledge that our team does not have and be able to have a successful FEA.

Outside of technical information, because the situation we are designing our product for is so unique, there are not many already existing solutions. As mentioned earlier, the most common solution for this issue is a trans-tibial amputation, which is exactly what we are trying to avoid. Therefore, we have compiled resources on trans-tibial amputations and the associated prosthetics. These resources help justify why we want an alternative solution to amputation, and we can use the properties of prosthetics to aid in our design decisions. However, the concept of orthotics as a solution for this problem is relatively novel, and we have been able to compile minimal information on this. Because we are working so closely with the end user, the end user is aware of the lack of information, and we will be able to get any necessary information from the user himself about his condition and experiences with orthotics.

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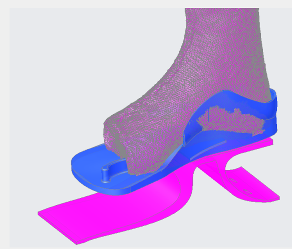
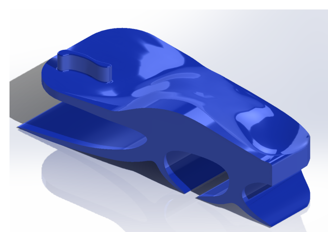
APPENDICES

Appendix A - Concept Generation

The additional brainstormed ideas are sorted into seven different categories: Prosthetic Foot Inspired, Auxetic Materials, Bistable Mechanisms, Layers, Hinge, Hoop, and Childhood Toy Inspired.

Prosthetic Foot Inspired
Prosthetic dynamic response feet can store and release energy during the walking cycle by absorbing energy in the flexible keel during the "roll-over" phase of the stance phase and release energy during the push-off of the toe-off phase. Table 6 includes the sketches that were inspired by the prosthetic dynamic response foot.

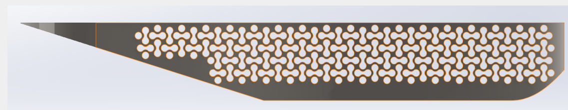
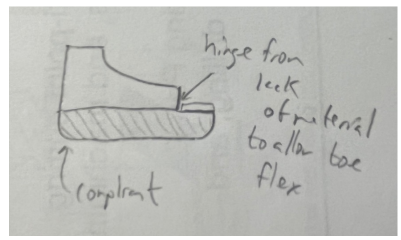
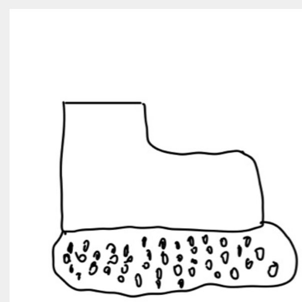
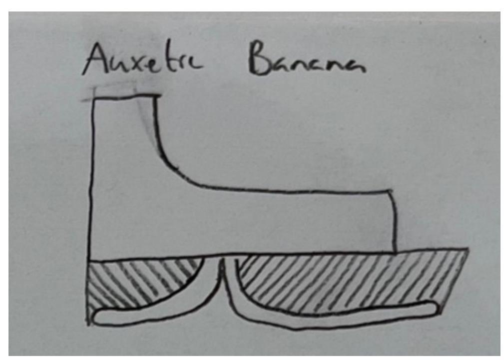
Table 6. Prosthetic Foot Inspired sketches

#	Name	Picture
1	Banana	
2	Double Banana	
3	Roman Sandal	
4	Sled Shoe	

Auxetic Material

Most materials have a positive Poisson's ratio, and when they are compressed, the material orthogonal to the load expands. However, since auxetic materials have a negative Poisson's ratio, when the auxetic material is compressed the material orthogonal to the load will contract. Table 7 shows the sketches that incorporate auxetic material.

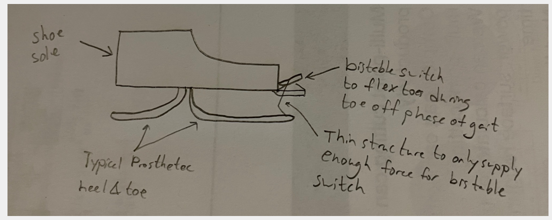
Table 7. Auxetic Material sketches

#	Name	Picture
1	Flat Auxetic Rocker	
2	Hinge Auxetic Rocker	
3	Sponge Shoe	
4	Auxetic Banana	

Bistable Mechanism

Bistable mechanisms have two stable equilibrium positions and will rest in either of the positions until an external force is applied. The advantage of compliant bistable mechanisms is that they can incorporate motion and energy storage with minimum power input. Another example of a bistable mechanism can be seen in Table 8.

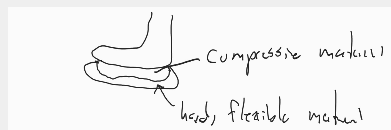
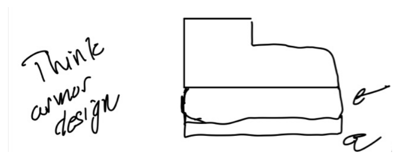
Table 8. Bistable Mechanism sketches

#	Name	Picture
1	Bistable Banana	

Layers

The layer designs incorporated compressive and flexible materials in separate layers. Table 9 shows several designs that have layered components.

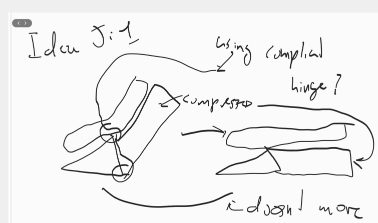
Table 9. Layers sketches

#	Name	Picture
1	Moon Shoe	
2	Layered Shoe	

Hinge

Table 10 displays the Hinge Shoe, which includes a hinge at the pivot point to allow toe flexion.

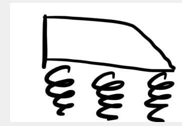
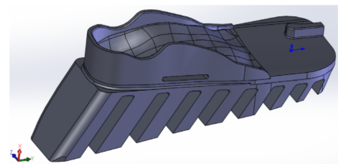
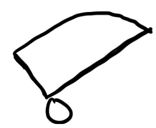
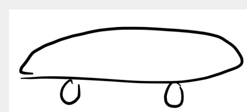
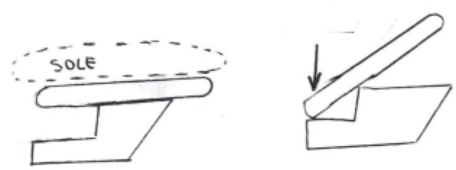
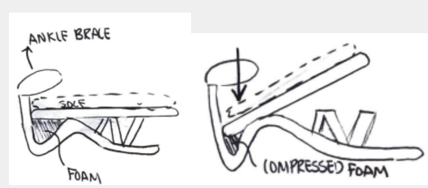
Table 10. Hinge sketches

#	Name	Picture
1	Hinge Shoe	

Childhood Toy Inspired

The final group the brainstormed ideas were sorted into were the Childhood Toy Inspired category (Table 11). These ideas are a bit wilder idea and less feasible, but they were still part of the concept generation process.

Table 11. Childhood Toy Inspired sketches

#	Name	Picture
1	Spring Moon Shoe	
2	Springblade	
3	Spring Shoe	
4	Heelys	
5	Skateboard	
6	Seesaw	
7	High Heel Shoe	

Appendix B - Pugh Chart Decisions

The sixth highest scoring design in the Pugh Chart was the Banana (Figure 60). One of the prosthetic foot inspired designs, it features two “tongues” that help redistribute the pressure during heel strike and toe-off. However, we were concerned that this would not be enough to alleviate pressure from the metatarsal region, so we scored it a 0. It also scored a 0 for Toe Flexion, Manufacturability, and Height. It scored a 1 for stability giving it a total score of 2 points. Most of the concerns with this design was that the force in the metatarsal region would just continue to be prevalent while making walking more difficult for Schrader.

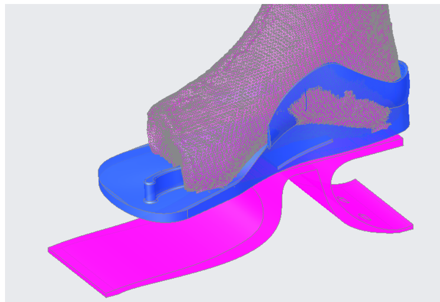


Figure 60. The Banana design. Based on how it attaches to the sole that Schrader is designing, concerns arose about it still affecting the metatarsal region of the foot.

The seventh highest scoring design was the Hinge Shoe (Figure 61). This design had a total score of 0. It did not meet the criteria for Alleviate Pressure, Stability, and Height, scoring these as 0 points each. It met the Toe Flexion criteria with a score of 1 since it is focused on toe flexion for its design. However due to the moving parts and assembly needed it scored a -1 for Manufacturability. While the design was a good idea for concept generation, specifically with functional breakdown having it focus on the toe flexion, it did not meet our overall needs.

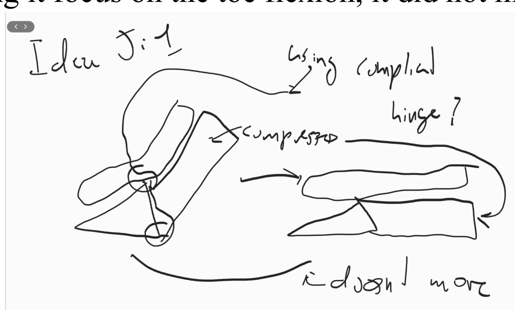


Figure 61. The Hinge Shoe idea. It includes a hinge mechanism towards the toes that allows for bending during the toe-off phase.

Finally, the lowest scoring design was the Hoop Shoe. Sharing a score with the Hinge Shoe, the Hoop Shoe scored a 0 for Alleviate Pressure, Manufacturability, and Height. It scored a 1 for Toe Flexion and a -1 for Stability. The idea behind this design was to have something like a rigid tank tread that would help form around the foot and bend where it needed to to reduce pressure as much as possible (Figure 62). However, the team agreed that trying to make this design work would have been a much more difficult task than anticipated. Through our discussion we found that when comparing it to the Rocker Shoe it did not score well at all.

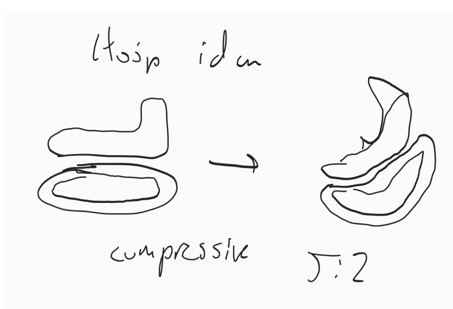
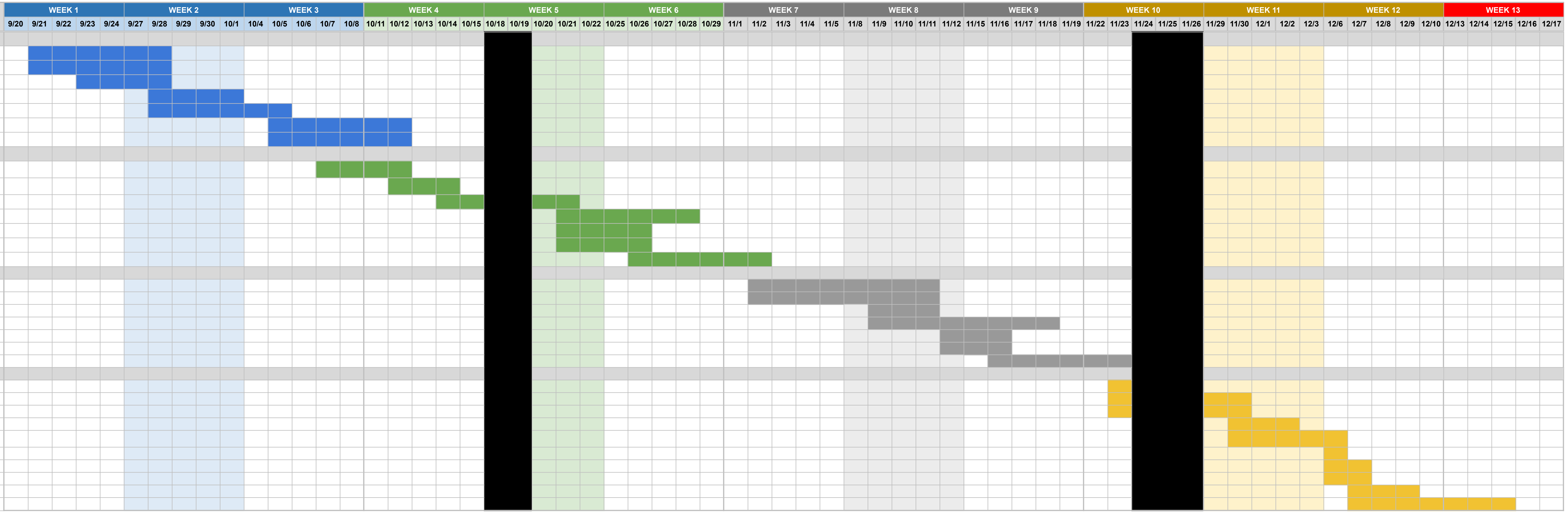


Figure 62. The Hoop Shoe is made of a flexible hoop that would form around the foot to help reduce pressure and allow for toe flexion.

APPENDIX C - Gantt Chart

TASK TITLE	START DATE	DUE DATE	DURATION	STATUS
Design Review #1				
Problem Definition	9/21/2021	9/28/2021	6	**Complete**
Engineering Specifications	9/21/2021	9/28/2021	6	**Complete**
Project Plan	9/23/2021	9/28/2021	4	**Complete**
Practice Presentation	9/28/2021	10/2/2021	4	**Complete**
Design Review #1 Presentation	9/28/2021	10/5/2021	6	**Complete**
Executive Summary	10/5/2021	10/12/2021	6	**Complete**
Design Review #1 Report	10/5/2021	10/12/2021	6	**Complete**
Design Review #2				
Initial Analysis via FEA of Steve's Design	10/7/2021	10/12/2021	4	**Complete**
Concept Generation & Evaluation of Variations on Steve's Design	10/12/2021	10/14/2021	3	**Complete**
CAD Model of our alpha design	10/14/2021	10/21/2021	4	**Complete**
FEA of our alpha design	10/21/2021	10/28/2021	6	**Complete**
Practice Presentation	10/21/2021	10/26/2021	4	**Complete**
Design Review #2 Presentation	10/21/2021	10/26/2021	4	**Complete**
Design Review #2 Report	10/26/2021	11/2/2021	6	**Complete**
Design Review #3				
CAD Ice Skate Design	11/2/2021	11/11/2021	8	**Complete**
FEA of Auxetic Design	11/2/2021	11/11/2021	8	**Complete**
Complete FEA of all designs	11/9/2021	11/11/2021	3	**Complete**
FEA on Design Iterations	11/9/2021	11/18/2021	8	**Complete**
Practice Presentation	11/12/2021	11/16/2021	3	**Complete**
Design Review #3 Presentation	11/12/2021	11/16/2021	3	**Complete**
Design Review #3 Report	11/16/2021	11/23/2021	6	**Complete**
Final Presentation				
Recieved Print of Auxetic Design	11/23/2021	11/23/2021	1	**Complete**
Update CAD of Final Design	11/23/2021	11/30/2021	3	**Complete**
Begin FEA of Final Design	11/23/2021	11/30/2021	3	**Complete**
Complete FEA of Final Design	11/30/2021	12/2/2021	3	**Complete**
Compete Testing Plan for Print of Final Design	11/30/2021	12/6/2021	5	**Complete**
Recieved Print of Final Design	12/6/2021	12/6/2021	1	**Complete**
Prepare Sideshow for Final VIdeo	12/6/2021	12/7/2021	2	**Complete**
Record Video	12/6/2021	12/7/2021	2	**Complete**
Design Expo Preparations	12/7/2021	12/9/2021	3	**Complete**
Final Report	12/7/2021	12/15/2021	7	**Complete**



Appendix D - FEA Parameters

Altair's HyperWorks modeling can be approached in multiple ways. Our team has developed certain guidelines and parameters to have a structured testing methodology. The dimensions of the CAD are to always be in millimeters. The forces applied are in Newtons. The CAD is meshed using HyperWorks' Tetramesh feature with a value between 0.1 and 2. Any stress measurements are made by constraining the top -- from heel to end of metatarsals (Figure 33) -- of the design and applying the appropriate ground forces for each phase of the gait cycle to the plane that meets the ground (Table 1). Any deformation measurements are made by constraining the bottom plane of the design that encounters the ground and applying the appropriate reaction forces for each phase of the gait cycle to the top of the design from heel to end of metatarsals.

Appendix E - Design Sketch

Creo sketch of the final Moon Shoe design with the driving dimensions (Figure 63).

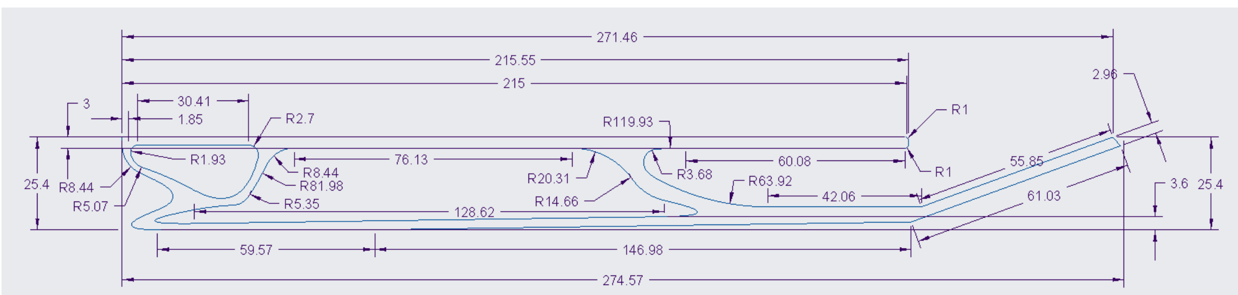


Figure 63. Creo sketch of final design with important dimensions.

The Bill of Materials for the final prototype of the design in Figure 63 can be found below (Table 12).

Table 12. Bill of Materials

Item	Material	Supplier	Cost ($)
Moon Shoe	Nylon PA12	Craftcloud ®	280.66

AUTHOR BIOGRAPHIES

Eric Lastfogel hails from just outside of Grand Rapids from Rockford, Michigan. Always interested in cars and always worked on my own car. Mechanical Engineering seemed like a good path to follow. Similarly, not interested in sitting in front of a computer every day for a career and mechanical engineering appears to offer some escape from that. Currently a researcher for the University of Michigan's Naval Engineering Education Consortium; along with a fall internship for the Naval Research Laboratory. The plan is to get a job back in Grand Rapids after graduation. Had two bulls while growing up with chickens, ducks, cats, hamsters, rabbits, turtles, and a bearded dragon.

Katie Martin is from Grand Rapids, Michigan. She is majoring in Mechanical Engineering and minoring in Material Science and Engineering. After graduation, Katie will be joining Stryker's Advanced Operations Global Engineering and Development Program (AOGEDP) in Memphis, Tennessee. Outside of classes, she is heavily involved in the U of M chapter of the Society of Women in Engineering (SWE) as the College Relations Co-Officer, the Michigan Materials Society (MMS) as Treasurer, and an Instructional Aide for Design for Manufacturing II (ME 350). When Kaite is not in class or in a club meeting, she enjoys playing tennis, reading, running, and trying new arts and crafts.

Justin Ramlall is from Levittown, New York, and was born in Georgetown, Guyana. He is studying Mechanical Engineering with a Minor in Electrical Engineering. He has always had an interest in taking things apart and putting them back together when he was very young. Since elementary school he always wanted to study mechanical engineering. He is currently applying to graduate schools to study a Master's Degree in Robotics or Systems Engineering. He is an Eagle Scout and currently is part of the board for the Umich Powerlifting Club. He also enjoys facilitating discussion sessions for the College of Engineering's Common Reading Experience and volunteering wherever else he can.

Shriya Shah is from Troy, Michigan. She is double majoring in Mechanical Engineering and Computer Science. She has always been a very hands-on person and likes to work on physical things. After graduation, she will be working at Microsoft as a Software Engineer in Redmond, Washington. Outside of classes, she is involved with the University of Michigan chapter of the Society of Women Engineers (SWE) as the Team Tech Co-Director and as an Instructional Aide for the Introduction to Programming course (ENGR 101). Shriya also loves playing sports, especially basketball, and reading in her free time.

Aaron Youmans is from Northville, Michigan and is majoring in Mechanical Engineering. He has lots of experience in the automotive industry, both in research and development and manufacturing, and plans on continuing that path after graduation, at Toyota North America. Outside of schoolwork, Aaron is the president of the Club Golf team at the University of Michigan and was involved in research at the Vibrations and Acoustics Laboratory. When not involved with class and club golf functions, Aaron is an avid outdoor enthusiast, involved in camping, hiking, climbing, and skiing.