Bolin Symes Prosthetic

Sponsor: Anthony Bolin

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Executive Summary (Abstract)

This project's purpose is to design a comfortable prosthetic for an individual with a Syme's amputation, which is a below-knee amputation that removes the foot from the leg at the ankle joint. The goal is to minimize the discomfort that is associated with the current prosthetic leg options for the client, Mr. Bolin, who has the Syme's amputation. This project also seeks to improve mobility, quality of life, and activity levels of the client. The stakeholder for this project is Mr. Bolin. The final prototype performed successfully when worn by the client and passed comfort testing. Furthermore, COMSOL modeling of the device confirmed that it is strong enough to withstand maximum loading conditions with ease.

Introduction

The sponsor, Mr. Bolin, suffered a leg injury at a young age, resulting in his foot being amputated in the Syme's Amputation. A Syme's amputation is performed at the lower leg limb near the ankle, separating the foot from the leg, with the goal of retaining as much of the residual leg as possible. Syme's amputations were performed throughout the 20th century, as it allows the amputee to put weight on their residual limb without a prosthesis [1].

While there are not strong statistics regarding how many individuals have received the amputation, modern orthopedic surgeons do not generally perform it [1]. Today, it is an uncommon amputation compared to others, leading to an underdevelopment in prosthetics technology for Symes prosthetics. Prosthetics made for this amputation also must accommodate a larger residual limb compared to other leg amputations, making it hard for many traditional prostheses techniques to design a well-fitting and comfortable prosthetic. Mr. Bolin's prosthetics never fit correctly, and currently his limb socket is too large for his residual limb, causing painful chaffing and pain when the residual limb slams against the inner wall of the prosthetic. Therefore, the goal for this project is to make a more ergonomic limb that reduces the chaffing, pressure, and pain that Mr. Bolin feels on his residual limb.

This document will further discuss the scope of the project and relevant information. The background section outlines the current research, patents, and products used by Symes amputees. The objectives section will discuss the goals for this project in more detail and how specific requirements set forth by the customer will be measured in terms of engineering. The project management section outlines the critical path to project completion and specific challenges of the project. The stakeholder for this project is Mr. Bolin.

Background

Despite its low prevalence, the Syme's amputation is a highly successful procedure that often does not limit the quality of life of the amputee. Because of the nature of the operation, much of the patient's limb is preserved, allowing individuals with the amputation to be mobile on the limb without a prosthesis [1]. This alone shows the advantages of the Syme's amputation over other below-knee operations. Many individuals that have the amputation report much better mobility compared to individuals with other transtibial amputations. In fact, 72% of people who have had a Syme's amputation report unchanged employment status and 66% report unchanged social activity participation. [2]. The way the surgery is performed allows the heel pad to a) be preserved via the retention of the heel flap and skin, and b) be used as the bottom of the stump, cushioning the residual limb [3]. In the surgery, extensor tendons are stretched, transected, and allowed to retract into the proximal limb. The Achilles tendon is removed in the same manner, and extensor and flexor muscles are tied under tension [1].

Individuals with Symes amputations may encounter unique difficulties in relation to their prosthetic. The bulbous end of the leg stump limits prosthesis design due to its unusual shape; the stump typically has a larger circumference than the crural region (leg) of the residual limb [4]. This is due to muscular and bone degeneration of the residual limb. Another issue with Symes prosthetics is their bulky nature at the distal end. Due to the long residual limb and bulbous stump, there is little room for a standard prosthetic foot that features better ankle mobility, such as springs that dampen impact forces during gait. Symes prosthetic feet that do accomplish this usually increase the bulkiness and weight around the ankle, requiring users to exert more force than normal for gait [5].

There are significant changes to the biomechanical characteristics of individuals that use Symes protheses. For example, individuals may have reduced self-selected walking speeds (SSWS), increased variability in muscle excitation patterns, increased gait asymmetry, and increased metabolic costs [6]. Users also experience altered impact forces on the residual limb, which may cause pain. The energy generated by ankle movement during gait is also missing, and therefore must be generated elsewhere. The knee and hip joints of the residual limb compensate for this missing work, which lead to additional pathologies [6].

Due to the low prevalence of Syme's amputation, there are fewer options on the market compared to other transtibial procedures. This is due to the Syme's amputation operation not being performed as often as previously [1]. With less space to work with, designs for other types of amputation are not feasible for application to the Syme's amputation.

The main issue associated with the current option for prostheses communicated by the sponsor was comfort. Mr. Bolin explained that his discomfort is a result of two key issues with his current hardware. The first problem he identified is the incompatible fit. His prosthetic is too tight in some areas, and too loose in others, which causes uncomfortable pressure points in different areas of his socket. This issue can be attributed to the unusual geometry of the bulbous stump many Symes amputees have. The second problem he expressed was the rigidity of the foot component, which results in a high impact force transferred to the bottom of his stump every time he takes a step. Without cushioning to dampen the forces with the heel strike phase of the gait cycle, he experiences discomfort.

These issues are important to Mr. Bolin, as he desires to retain an active lifestyle as he ages. Mr. Bolin reports that he walks on his treadmill at least 45 minutes a day and frequents his local gym. He also wants a prosthetic that gives him confidence in his social life, which means a prosthetic that would not draw attention to his gait or his mobility.

Table 1 displays the patents that were researched during the initial stages of this project. *Table 2* displays a selection of products from the current market for Syme's prosthetic sockets and feet.

Table 1. Patent Table. Patents explored include socket designs, socket liners, and foot designs.

Patent	Summary	Figure
METHODS AND APPARATUS FOR IMPROVED INTERFACE BETWEEN THE HUMAN BODY AND PROSTHETIC OR SIMILAR DEVICES - 20210298927	This invention describes a cushion that interfaces between a prosthetic socket and an amputee's residual limb. A variety of methods of fabrication methods, fitting, and use of the interface are described within the patent. Some methods use patty-filled packets that are assembled into a liner, while others use fluid-filled bladders that may or may not be disconnected from each other, may or may not be adjustable, and/or may or may not be filled with a non-Newtonian fluid. This design will provide a cushion that absorbs impact during gait while retaining its shape, minimizing differential movement of the residual limb within the socket.	
PROSTHETIC FOOT WITH REMOVABLE FLEXIBLE MEMBERS - 20230064710	This patent describes a prosthetic foot that achieves stability throughout the gait cycle by absorbing and returning elastic energy and having enhanced energy conservation during ambulation. This patent describes methods to achieve this, such as an actuator at the heel that can compress or stretch to mimic dorsiflexion and plantar flexion of a real foot. This actuator	

	can be active, as with a motor, or passive, as with a spring. Another embodiment has an extended heel plate, which can elastically bend. This creates a moment about the ankle joint, mimicking dorsiflexion. A prosthetic foot with an actuating element, as described above, would address one of the customer requirements that are listed below, namely the heel-strike impact absorption mechanism.	
EXPANDABLE WALL PROSTHETIC SOCKET WITH RETENTION RING - 20220287858	This patent describes a prosthetic socket that is configured with at least one retention ring in the socket wall and a telescoping element that translates inwardly and outwardly through the socket wall, such that the telescoping element applies a force on the residual limb. The intent of this device is to reduce the volume of certain areas of the socket, effectively tightening the fit of the socket around the residual limb. This patent would allow Mr. Bolin to adjust the fit of his socket in a straightforward way, allowing him to tighten or loosen the fit of the socket depending on his needs.	
ADJUSTABLE PROSTHETIC LIMB SOCKET - 20150119997	This patent describes an adjustable prosthetic limb socket system that can be used for a variety of amputations. The main features of this socket are a rigid support system, a non-elastic flexible support "sail" secured to the rigid support, and an adjustable strap system that can shorten the circumference of the socket to maintain a volumetric fit of the residual limb. As mentioned before, an adjustable socket system would allow Mr. Bolin to adjust the fit of his socket quickly and easily, allowing him to get back to whatever activity he wants to participate in.	
SYMES ANKLE JOINT - US3874004A	This patent describes an artificial ankle joint comprising a metal sole plate that has pivot bearings for swinging the socket upwardly posteriorly and anteriorly. This allows the foot to mimic the plantar flexion and dorsiflexion of the ankle joint. An artificial ankle joint would provide "springiness" to each step that Mr. Bolin takes. This allows the foot to mimic plantar flexion	

	and dorsiflexion, provide energy absorption and moment resistance about the “ankle” joint.	

Table 2. Existing products. This table shows existing components of Syme's prosthetics.

Product	Description	Figure
Ottobock© 1e57 Lo Rider [7]	Carbon fiber foot component of Mr. Bolin's most recent prosthetic.	
Ottobock© 1c63 Triton LP [8]	Carbon fiber foot with low build height and high flexibility for impact reduction.	
Össur Flex-Symes™ [9]	Carbon prosthetic foot with low build height for Syme's amputations and an actively deflecting heel	
Ottobock© 6y95 Caleo 3D liner [10]	TPE liner designed for durability to improve function in more active patients	
Martin Bionics Socket-less Socket™ ICON™ Symes [11]	Adjustable lower leg socket that uses a patent pending hammock system to reduce impact on the stump.	

Some innovative designs for Symes prostheses have been made to address the issues Mr. Bolin described. Flexible heel components of the foot portion have been designed by Ottobock and Össur, shown in *Table 2*. These systems aim to dampen the impact force of the heel strike to alleviate the pain associated with the rigid transfer of energy Mr. Bolin described. Additionally, specified liners have been made to further reduce impact. Less progress has been made in shell design. Conventional rigid designs are made by creating a mold of the leg and a rigid shell around it. While these reliably function to attach the leg component to the foot, they are uncomfortable. Mr. Bolin explained that some prosthetic vendors will cut out a portion of these conventional sockets to make them adjustable, however, this comes at the expense of strength. The Socket-less Socket™ is a novel design that uses suspension of the residual limb as well as adjustability to provide a comfortable fit. This product aspires to solve the problem of impact in addition to comfort.

Objectives

Problem Statement:

Mr. Bolin suffers from a prosthetic that does not accommodate or fit his residual limb, especially when it comes to his walking gait. He experiences 1) poor socket fit which causes chaffing, 2) limited foot movement from a lack of springiness or elasticity of the prosthetic foot, and 3) no impact absorption measures in the socket. All three of these contribute to general pain/discomfort and his abnormal gait.

Boundary Definition:

To solve this problem, the project includes remaking his socket to fit him better, as well as making changes to the socket or foot to give him a more natural walking feel. Since the fit of his socket is his main problem, modifying the foot is secondary. The design group is not looking to revolutionize the production process of making his socket, but instead to refine already existing methods with the help of Mr. Bolin's input. The project is also not intended to act like an exoskeleton or be battery powered. It should only have passive components, such as springs, which will provide additional capabilities if the project group chooses to incorporate them.

Indications for Use

The Syme's prosthetic should be used by individuals who have had the Syme's amputation and are healthy post-operation and are cleared for use by their practicing clinician. The device should not be used by individuals who are currently healing from a recent amputation. This device is meant to alleviate discomfort in those who find their current prosthetic uncomfortable. The device is only intended for individuals with a Syme's amputation in either leg. Individuals of any gender can use it. The device is designed for and should be used by skeletally mature adults (at least 25 years of age). Daily activities, such as walking or climbing stairs, should be achievable by users of the prosthetic. The device should prevent leg instability while also appearing aesthetically pleasing.

Summary of Customer Requirements

The prosthetic must fulfill three main categories for the customer: form, function, and aesthetics. Ensuring the leg is ergonomic and comfortable will address the form aspect of the customer requirements. Function will be addressed via improvement of Mr. Bolin's walking cycle to provide him stability. Finally, aesthetic requirements will be considered as the leg must not stand out from the rest of his body and match the silhouette of his other leg.

Summary Engineering Requirements

The goal of the engineering requirements was improving the flexion of his foot component, reducing the impulse felt on his residual limb, and form fitting the prosthetic to his leg among other requirements. The flexion and impulse reduction will address the form and function customer requirements, while form fitting will more directly address the aesthetic requirement. The engineering requirements were then compiled into a table showing out target, tolerance, risk, and compliance for each parameter.

Table 3: Engineering Specifications table. Engineering specifications are shown with their corresponding target values.

Spec. #	Parameter Description	Required or Target (units)	Tolerance	Risk	Compliance
1	Stem Strength	Max: 190 GPa	Min	L	T, A
2	Fiberglass Strength	Max: 52 GPa	Max	H	A, T, I, S
3	Steel Epoxy Strength	Max: 2.10 GPa	Min	L	I, S
5	Weight	< 4 lbs.	Max	H	A, T, I, S

To meet the engineering requirements' targets, tests will be done to verify that the target values have been fulfilled. For the flexion of the foot, the plans are to measure plantarflexion and dorsiflexion with a goniometer. This will compute the angles for use via software. When the heel strikes the ground, the foot should create a bending moment like plantarflexion, absorbing some of its impact. When the foot prepares for toe-off, there should be dorsiflexion-like bending of the foot. This will cause a moment of the ankle, and as the foot returns to the neutral position, the foot will push off the ground, creating a bounce to each step. The impact impulse can be measured by having Mr. Bolin walk on force sensing pressure pads, like the ones in the HMB lab. Along with this, the max moment the ankle joint can withstand can be assessed by loading that joint with a moment via fixing the joint and applying a force to a bracket attached to the joint. The force can be applied using a compression tester. The stem strength can also be evaluated in the compression tester by taking a sample stem and subjecting it to a load until failure in a three-point bend test.

When it comes to making sure the prosthetic fits correctly, the uniform gap between the limb and the socket can by assessed by taking a spacer sized to the gap width, and making sure there is a snug fit in between the socket and limb. Similarly, the adjustment gap would be measured the same way, but with each tightening adjustment, a smaller spacer would be used in conjunction with that adjustment. The weight of the prosthetic would be measured using a scale. Finally, the silhouette of the leg will be measured by taking a picture of his leg, and a picture of the prosthetic at the same distance, and then overlaying those images in a photo editing software. The percentage of the silhouette of the prosthetic that does not match the leg could then be estimated.

Some of the engineering specifications are harder to meet, and its why Mr. Bolin has the problem he does in the first place. Making sure that there is a uniform gap between his leg and the prosthetic that is comfortable for him is going to be the biggest challenge, along with adjustability. **Figure 1** displays the illustration of a uniform gap engineering specification.

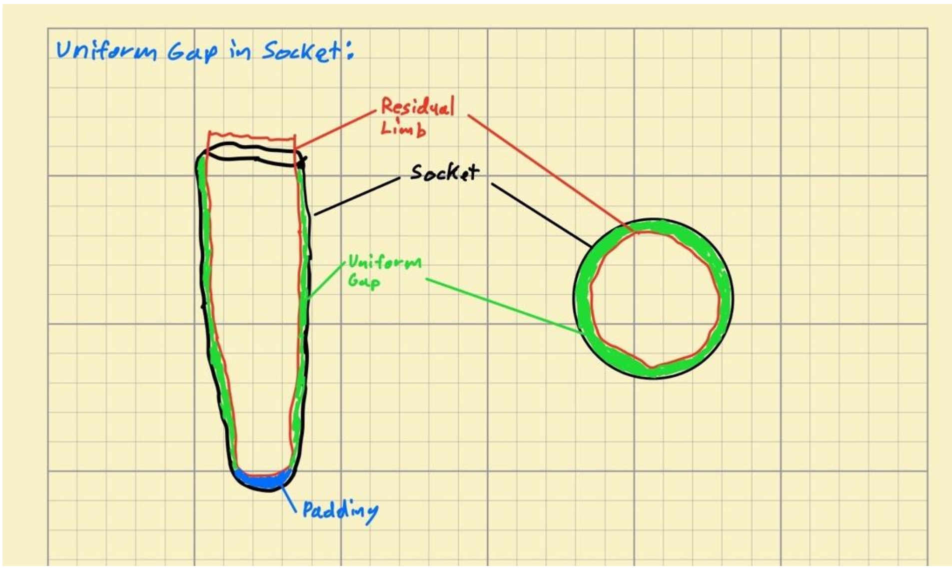


Figure 1. Illustration of the uniform gap engineering specification. The width of the gap is exaggerated to illustrate its significance.

This is because the initial gap is highly dependent on the casting process, meaning there is only one shot at making a good mold. If it does not come out the as intended, it is possible to file out parts that are too tight, or pad up parts that are too loose, but there is not much room for error. Mr. Bolin has shown that if it is not right the first time, there is not much padding or filing will do. Adjustability will be a challenge too since comfortable adjustability is also dependent on making a good cast. Along with this, the more adjustable the prosthetic is, the more unstable it becomes. Mr. Bolin has had prosthetics snap in the past, and although he has not personally had an adjustable leg, he has heard from others that they are more unstable than non-adjustable ones. The number one priority is to get more comfort out of these requirements, so a comfort survey will also be given to Mr. Bolin after a socket is made for him. The specifics of the survey can be found in the appendix. The weight of the prosthetic is also going to be hard to get right, as lightweight materials that are strong enough to withstand the forces of walking under full body weight are expensive. With a tight budget, it will be hard to meet this requirement.

House of Quality

Once the customer and engineering requirements were set, a house of quality was made to determine the relationships between each of the two categories. First, the customer requirements were ranked in terms of importance, and it was found that the order of importance for most important to least important was form, function, and then aesthetics. From this, it was determined which engineering requirements should be focused on. The results yielded that the foot flexion was most important, minimizing the impact impulse was next, then the stability of the foot, and finally how the leg fit and its aesthetic. The house of quality is shown in the appendix [A-1]

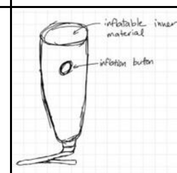
Project Management

Per Mr. Bolin, most prosthetics sell for anywhere between $8,000 and $10,000. With a limited budget of $200 (and $500 more pending the Hannah-Forbes fund), the design must be perfected before manufacturing of the prototype. Engineering and customer requirements were defined in quantifiable terms and plan to achieve these by following schedule and the stage-gate process. It is planned to use a prosthetics facility or hospital that will allow the group to plaster Mr. Bolin's leg to develop a prototype that fits him specifically. Prototyping will also require the group to make measurements such as the distance between the bottom of his stump and the ground. Another technical challenge is the engineering of the socket-foot interface in such a way that the weight of his body will be supported by the prosthetic when loaded. Specific loading testing will also need to be conducted to ensure safety before the prosthetic is worn by Mr. Bolin.

The Gantt chart summarizes future tasks and deadlines that must be completed. The critical path follows key deliverables from start to finish of the project. The critical path is as follows: Statement of Work, Conceptual Model, prototype, and Final Report. This critical path will be essential in completing the project by the desired date of June 4th and proceeding with this plan is paramount to success.

Morphology

Table 4. Morphology design. Functions are shown in the leftmost column with their corresponding design solutions to the right.

Morphology						
Product: Symes Prosthetic	Organization Name: UltraLeg					
Function	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6
Reduce Stump Force	Spring dampener	Hydraulic Stabilizers	Foam Cushions	Hammock design		
Allows for Walking	Jointed ankle	Elastic foot	Spring that mimics ankle flexion	Actuators		
Protect Stump	Thick bearing	Thick Shell	Multiple Layers	Rebar-like beams		
Provide Support	Strong plastic lining	Wide foot	[1] Suspension tied to upper leg			
Allows for Adjustability	Rigid Shell with elastic member w/straps	Can be lengthened or shortened	Folding socket W/straps	Ski bootstraps	 Inflatable Socket	Elastic Straps
Induces comfort	Cooling pads	Cushions	Can be customized	Inner liner		

Team member: Jake Hacker	Team member: Sam Collins	Prepared by:	
Team member: Rowan Sun	Team member:	Checked by:	Approved by:
The Mechanical Design Process		Designed by Professor David G. Ullman	
Copyright 2008, McGraw Hill		Form # 15.0	

Figure 2 displays concept sketch 1.

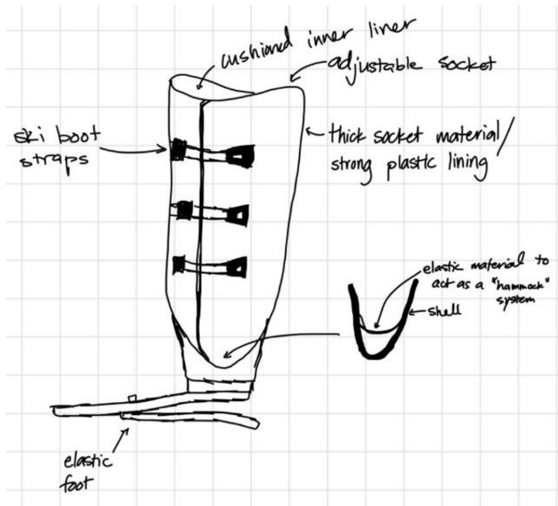
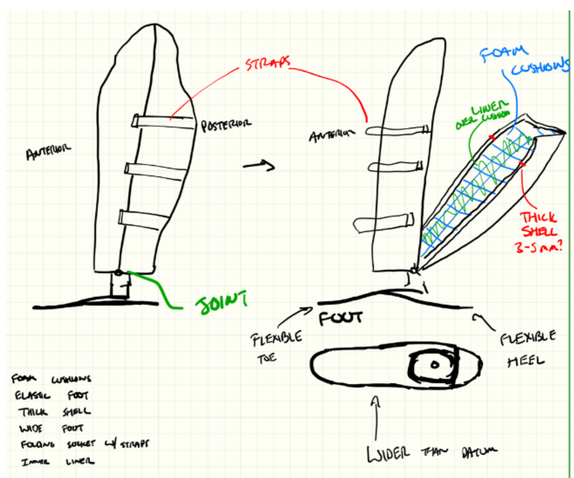


Figure 2. Concept sketch 1. Morphology elements: Hammock design, Elastic Foot, Thick Shell, Strong Plastic Lining, Ski-Bootstraps, Cushioned Inner liner.

The goal of this design is to use a ski-boot like design with ratchet straps to tighten the boot to the desired fit. The structural portion of the socket will be made of a strong plastic that supports user weight. The foot will have an elastic heel to dampen the impact force. The hammock like material in the bottom of the shell should suspend the limb in the boot and allow for small vertical movement of the limb up and down to further minimize the impact and increase the comfort of the fit. **Figure 3** displays concept sketch 2.



test

Figure 3. Concept sketch 2. Morphology elements: foam cushions, elastic foot, thick shell, wide foot, folding socket with straps, inner liner

The goal of this concept is to maximize comfort by using a thick rear or front shell, and a thinner more flexible shell that can be tightened against residual limb using straps. A wider foot will provide more stability, and a flexible heel/toe would provide springiness to the gait cycle. Foam cushions with an inner liner over them would provide additional comfort. A thick shell on the socket's anterior or posterior would retain a portion of the original prosthetic's strength. **Figure 4** displays concept sketch 3.

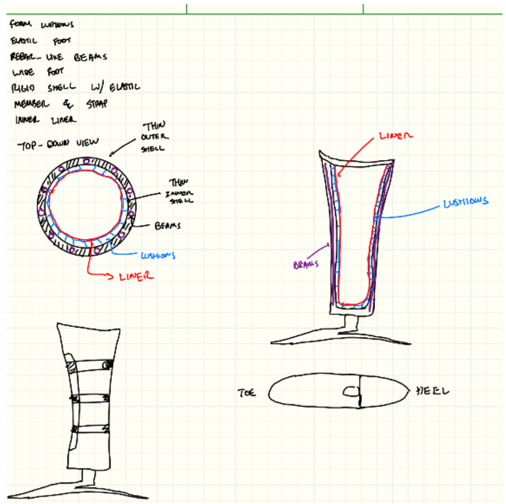


Figure 4. Concept sketch 3. Morphology elements: foam cushions, elastic foot, rebar-like beams, wide foot, rigid shell with elastic member and strap, inner liner

The goal of this concept is to provide strong material support while allowing for adjustability. Rebar-like beams go down a thin shell that is made of more flexible components. The stiffness of the beams provides support for the residual limb. An elastic strap on one side of the prosthetic allows for the tightening of the flexible components about the residual limb. An elastic foot provides more toe-off bounce and heel-impact absorption during gait. A wide foot furthers the stability of the residual limb. Foam cushions and a liner on the inside of the socket enhance comfort for the residual limb while reducing impulse experienced during gait. **Figure 5** displays concept sketch 4.

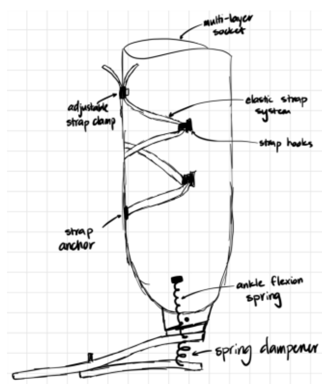


Figure 5. Concept Sketch 4. Morphology elements: multi-layer socket, elastic strap system, ankle flexion spring, spring dampener.

The goal of this concept is to create an easy-to-use adjustment system and maximize the use of elastic features to improve comfort and reduce impact. The spring system associated with the foot is aimed at reducing the force of heel strike. The elastic strap system allows the user to simply pull on the top end of the straps to adjust the socket tightness. Additionally, the multi-layer socket allows for more cushioning on the inner socket to further address comfortability concerns. **Figure 6** displays concept sketch 5.

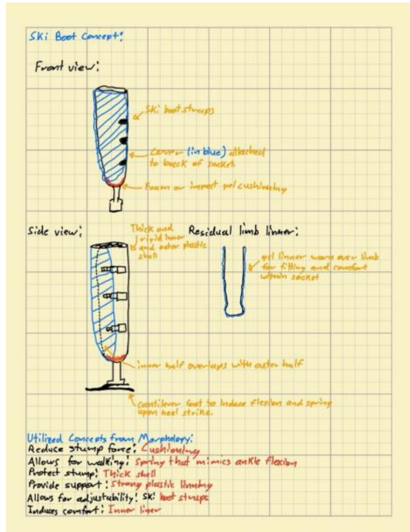
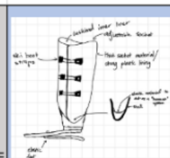
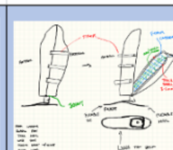
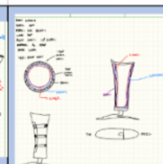
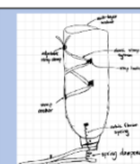


Figure 6. Concept Sketch 5. Morphology Elements – Cushioning, spring that mimics ankle flexion, thick shell, strong plastic lining, ski bootstraps, inner liner

For this design, the concept is to have a ski boot outer shell that can fit tightly around Mr. Bolin's residual limb. This would be accompanied by an outer liner that would be worn over the residual limb to help with adjusting fitment and comfort. The ratcheting ski boot adjustment system should provide him with an exceptionally snug fit around his limb, while also providing a good range of adjustability. Normally, the outer layer of the ski boot is flexible over some sections, like the ankle, to provide some deformation across moving parts. Since Mr. Bolin's limb is anatomically different, the sections where the outer layer is thinner and more flexible would have to be determined. More thin or flexible sections would be put in place to ensure that he has the range of motion he needs, along with making sure the socket is a snug fit for him. The adjustable straps would ideally go over these more flexible sections.

Table 5 displays the Pugh matrix for selecting the conceptual model to pursue.

Table 5. Pugh Matrix displaying the product specifications and how well each of the 5 design concepts satisfy them in comparison to the current solution. Concept 5 has the greatest weighted total. Note that Concept sketch 2 was the final prototype built in spring quarter,

Issue: Mr. Bolin's Symes prosthetic is uncomfortable and causes pain							
Criteria	Importance Rating (1-5)	Mr. Bolin's current prosthetic solution	 Concept 1	 Concept 2	 Concept 3	 Concept 4	 Concept 5
Toe-off bounce	3	Datum	1.0	1.0	0.7	0.7	0.7
Minimized heel impact	4		1.7	1.3	1.0	1.7	1.3
Acute/Fatigue durablity	5		0.7	0.3	1.0	0.5	0.8
Matches other leg dimensions	2		0.7	0.7	0.7	0.5	0.7
Adjustablity	3		1.3	1.7	1.0	1.3	1.0
Minimizes knee pain	4		1.0	1.0	1.0	1.0	1.0
Minimizes stump pain	5		1.0	1.3	1.3	1.3	1.7
Minimizes chaffing	5		0.3	0.3	0.7	0.3	0.3
Color matching other leg	1		0.0	0.0	0.0	0.0	0.0
Easy to put on	2		0.3	0.7	0.3	0.7	0.3
Sum of Positives			8.0	8.3	7.7	8.0	7.8
Sum of negatives			0.0	0.0	0.0	0.0	0.0
Sum of Sames			1.0	1.0	1.0	1.0	1.0
weighted sum of positives			29.7	30.0	30.0	29.8	30.3
weighted sum of negatives			0.0	0.0	0.0	0.0	0.0
Totals			29.7	30.0	30.0	29.8	30.3
Legend: scale of -2 to 2 with 0 indicating same as baseline							

It was decided to pursue the design used in Concept 5. The concept is to have a ski boot-like shell that could fit tightly around Mr. Bolin's residual limb, which would be accompanied by a liner that would be worn over the residual limb. The adjustability provided by the ratcheting ski-boot system would allow an exceptionally snug fit around Mr. Bolin's residual limb. Areas that need to be flexible can be thinner to allow a better sense of toe-off bounce or heel-strike absorption. A cushioning inner liner along the inside of the socket would also reduce the impact felt by Mr. Bolin's residual limb. This design was chosen over the other concepts because of its ability to provide strong support and durability while allowing Mr. Bolin to adjust the fit on the prosthetic. It also better fulfills the primary goals of minimizing knee, stump, and chaffing pain caused by the prosthetic.

Concepts 1, 3, and 5 are remarkably similar in terms of design and score from the Pugh matrix calculations. If a certain function within concept 5 is unexpectedly unfulfilled, certain design features from concept 1 or 3 can be used instead. In this way, the risk of making the wrong decision is mitigated with certain aspects of the design.

Conceptual Model

The conceptual model is based on concept 5 from the Pugh matrix because this design was awarded the highest rating. As shown in the sketches, the socket portion will be composed of an outer harder material, with an inner gel lining for comfort. It will be adjustable with a ski-boot-like ratcheting strap system. The foot portion will connect to the socket via a large screw that will be inserted into the cemented metal plate interface.

The conceptual model lacks dimensions intentionally. Rough measurements of Mr. Bolin's residual stump were collected, which varied from about 8 inches in diameter at its smallest, to about 15 inches in diameter near his knee. His stump length was also measured to be 15.5 inches. These measurements were intended to give the group a rough estimate of the size of his residual limb, because it is planned to make a negative and then positive mold of it to obtain more accurate geometric measurements. The positive mold will serve as a guide for when the socket is eventually shaped. An accurate measurement of the distance between his stump and the ground was also collected. Mr. Bolin stood on his left foot with his shoe off and blocks of varying height were placed under his residual limb until his hips were level with the ground. The height of the blocks was measured to determine the clearance between the stump and the ground as 3.094 in. **Figure 7** displays the conceptual sketch of an adjustable socket with concentric layers.

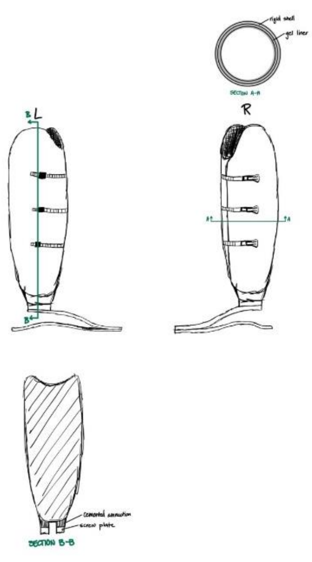


Figure 7. Conceptual design sketch. Views shown of both sides of the prosthetic as well as vertical and horizontal cross-sectional areas of the socket.

The socket is intended to be adjustable to provide Mr. Bolin to tighten or loosen it based on his needs. For example, the socket can be loosened if Mr. Bolin is experiencing inflammation in his residual limb, or tightened if he desires a snug fit during his exercise routine.

There are two designs related to adjustability that are being considered now: a socket with a posterior flexible component and an anterior flexible component. The socket with the anterior flexible component would be easier to adjust for any user, as the straps to adjust fit are located on the front of the prosthetic. There is a concern that there would not be enough stability on the anterior portion of the prosthetic when walking or during other activities due to the lack of a rigid structure in that area. The socket with the posterior flexible component would be more difficult to adjust but would be more stable. The reasoning behind this is that when the leg swings forward during the swing phase, the front of the socket would "catch" the residual limb as it moves. The posterior flexible socket would have more stability during most of the stance phase, between heel strike and toe off. **Figure 8**. shows the designs for an anterior flexible component and a posterior flexible component on the same socket.

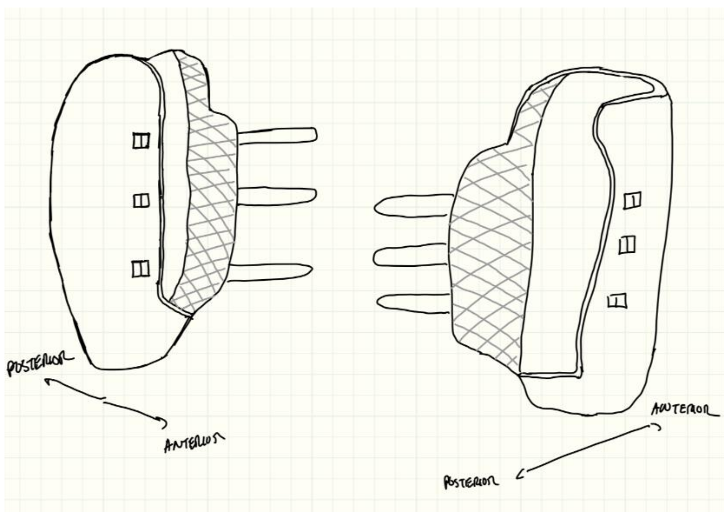


Figure 8. Flexible components of socket. The flexible fabric is shaded grey on the sketch. Left: Anterior-facing flexible component. Right: Posterior facing flexible component.

Mr. Bolin is also concerned about the impulse on his residual limb during heel strike. Therefore, it was desired to minimize this, not only with cushioning in the socket, but also with a foot that has spring to it. As a result, a foot was designed with the elasticity of the material in mind to provide the spring force necessary to reduce the impact impulse via a cantilever system. **Figure 9** displays the foot attachment mechanism and new foot for the prosthetic.

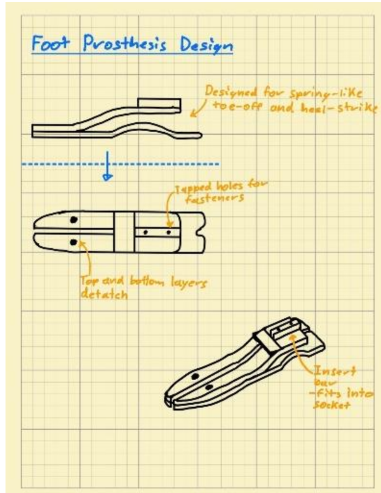


Figure 9. Foot attachment for Symes socket with cantilever heel design to reduce heel strike impulse. Side, top, and orthogonal views of the foot are shown.

Slow motion video was taken of Mr. Bolin’s walking cycle from the sides, front, and back. For these measurements, Mr. Bolin was instructed to walk as normal past a slow-motion camera at ground level. There are certain aspects of his walking, like how he swings his legs out and the way he presses on his heel to fully depress his foot prosthesis that gave insight on how to design the foot. For example, the project intends to give the foot two toes to be more flexible with his toe-off angle and to make the heel more flexible, so he does not have to press so hard when he steps. Once there is a finished foot, some simple testing will be done, replacing the foot on a prosthesis he does not use with the foot that was made for him. This way the project can receive input from him on how it feels, along with taking the same video measurements of his walking cycle to see how the new foot affected him.

FMEA

Table 6 shows the failure mode and effects analysis (FMEA) table.

Table 6. Failure Mode and Effects Analysis table. Severity ratings of each failure mode is shown in column RPN, with higher numbers corresponding to greater severity.

Function Affected	Potential Failure Mode	Potential Effect(s) of Failure	OCC	DET	SEV	RPN	Cause of Failure	Recommended Actions	Responsible Person	Taken Actions
Prosthetic stability	End of foot breaks	Foot is damaged, toe-off bounce is gone	3	1	6	18	Excessive amount of torque applied to the foot component	Ensure that yield strength of the toe is enough to withstand the applied force	Jake	3 point bend test of toe material to determine if yield strength is greater than the expected applied forces
	Foot stem breaks	Foot would detatch from socket, making walking impossible	3	1	9	27	Bending stress on stem is over the capacity of the stem material	Chosing a material that has a high yield strength, and looking at where a critial moment is most likely to occur.	Rowan	3 point bend test on the foot stem to confirm the results of our analysis on the moment.
Reduce Stump Force	Foot spring system breaks	Foot elasticity would be eliminated, increasing the stump force	3	1	8	24	Impact force on the heel is too great for the elasticity of the foot to handle	Ensure that the spring can withstand the force of a heel strike by the user	Jake	Cyclic loading test on the heel to determine how many times a load can be applied before it breaks
	Cushioning rips	Impact felt by residual limb is increased	2	5	4	40	Excessive shear applied to material caused by rubbing of the residual limb against the material	Ensure the fabric is durable enough to withstand the expected rubbing	Rowan	Shear force tests to gauge when product tears
Adjustability	Ratcheting Strap breaks	Customer is unable to tighten strap, socket will be too loose	3	1	8	24	Excessive tension on strap or ratcheting mechanism can cause system to tear or break	Select ratcheting straps from vendors that have yield strengths listed, perform tests on straps to test limit	Jake	Tensile test on strap to measure yield and ultimate tensile strengths
Prosthetic stability	Shell of socket cracks	A crack development could lead to a critial and sudden failure in the future.	3	5	5	75	The prosthetic falling and craking, something hitting the prosthetic, or a fatigue crack.	Select materials that have higher yield and ultimate strengths than expected stresses, minimize stress concentrations	Team	Perform solidworks FEA to identify key critical locations, perform compressive/tensile tests, perform fatigue experiments
	Shell-Foot interface failure	Screws or screw plate breaks	4	1	10	40	Excessive torque or force applied to the joint of the prosthetic	Select materials for plates that have higher yield and ultimate strengths than expected stresses	Team	Perform 3-point bending tests, cantilever beam moment tests, compressive load test
Provide Comfort	Inner Liner rips	More chaffing on residual limb	3	3	4	36	Excessive shear force applied to inner line resulting in surface tears, which may result in entire liner tearing at a location	Ensure that inner liner can withstand shear force during normal leg movement, minimize "shear" movement on inside of socket	Sam	Shear force tests that mimic similar shears during gait to gauge when tearing occurs

The FMEA table displays the possible modes of failure of the product and the corresponding severity rating. The possible cracking of the socket shell presents the greatest risk, with a severity rating of 75. Due to the importance of this criteria, the whole team has been assigned responsibility for minimizing this risk via various mechanical tests and computer simulation of expected loading.

Detailed Design

The conceptual model was refined and such that the final design has been slightly modified for practical purposes. The final design, including the materials and dimensions that will be used are discussed in this section.

Adjustability will be achieved via Velcro straps. It was decided to pivot from the ratcheting ski boot system to decrease cost and increase ease of manufacturability. It is also expect that the Velcro design will improve ease of use. The functionality and stability of the adjustment system will not be reduced by this change. Three Velcro straps will be attached to the back of the shell and go through both the inner and outer portion of the prosthetic. The first strap will be placed near the top of the shell. The second one will be placed 3 inches below and the third another 2 inches below that. These Velcro straps will allow the soft portion of the shell to flex to meet the desired fit.

Mr. Bolin has 78.5876 mm (3.094 inches) of space between his stump and the ground when standing on his left leg. The Flex Symes™ by Össur will be used for the foot portion of the design due to its low profile. The socket adapter has a height of 10mm, so when this is removed, the foot will have a total height of 60 mm. This leaves 18.5875 mm (about 0.73 in) of space for the design of the interface between the socket and the foot. Given that the thickness of the socket at the bottom is 4 mm, there is 14.5875 mm (about 0.57 in) of space for the interface of the foot and the socket.

The foot-socket interface will be composed of a rod that extends from the foot into a housing component, which is cemented to the bottom of the socket. The rod is a square shaped piece which is a universal modular attachment part made by Össur. A simplified version of this part of the device is shown in **Figure 11** for simplicity purposes. The actual part that will be used is shown in the next section which discusses how this system will fit together. This interface between the foot and socket will be secured by four screws. The screws will be inserted through holes drilled into the bottom of the socket. This design is shown in **Figure 14.** The threaded screws will be 1.8 inches in length and 0.4 inches in diameter.

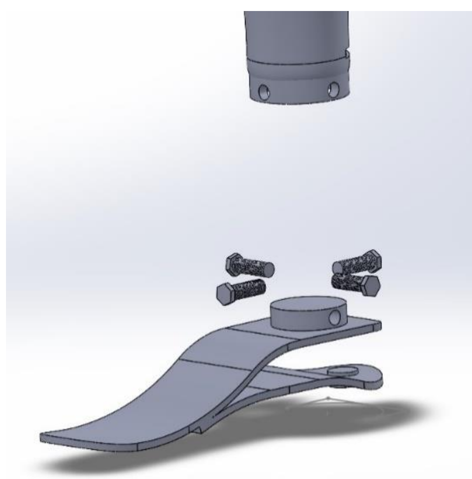


Figure 11. Exploded view of shell-foot interface. The interface between the shell and the foot will be held in place by 4 screws.

The shell portion of the prosthetic will consist of an inner fabric for comfort and an outer hard shell for structural stability. The soft fabric-gel lining will be purchased from a third party and will be worn like a sock covering Mr. Bolin's residual limb to provide comfort. The outer hard shell will be made from fiberglass. The shell will be molded as one piece and open in the back so it can be adjusted. The shell will be fabricated via molding to a positive mold of Mr. Bolin's leg; therefore, exact measurements of the shell are not necessary. The shell will extend up and around his knee on the sides, providing support and preventing unwanted lateral movement of the knee joint. Portions were cut out of the shell's side to decrease the amount of material needed, increase the aesthetic appearance of the shell, and increase ventilation of the shell. **Figure 12** shows the orthographic and rear view of the initial socket design in SolidWorks.

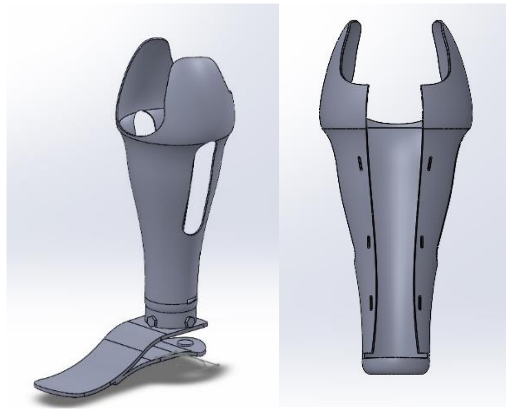


Figure 12. Orthographic (left) and rear view (right) of initial design socket shell. This initial design featured knee guards and windows to reduce weight and provide more flexibility. Note: these were removed to limit chaffing and retain structural stability.

Prototype Manufacturing Instructions:

Manufacturing of the prototype is a two-step process. First, a positive mold of Mr. Bolin's limb is created using ceramic. To do this, a negative mold is made of his leg by applying layers of alginate to the outside of his residual limb. The alginate is painted on until a sufficient layer is developed, fully engulfing his leg, and after a plaster-cast frame is wrapped around his limb and the alginate. This will give a negative mold, through which casting cement will be poured into. Once the positive mold is made, the socket itself is ready to be created. First, saran wrap is wrapped around the mold to prevent the socket from sticking when curing, and to give clearance for a comfortable gap for Mr. Bolin. Next, fiberglass is wrapped around the mold of his limb, and as the fiber glass is wrapped around, laminating resin is painted on, hardening the socket into shape. **Figure 13** shows the first layer of fiberglass that is wrapped around the positive mold and painted with resin.

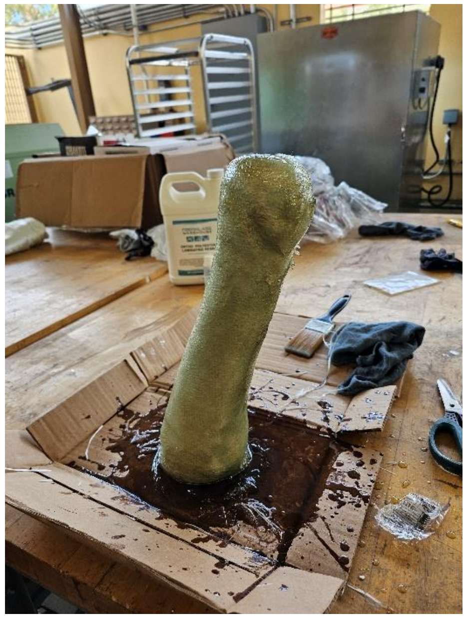


Figure 13. First fiberglass layer applied to positive mold. The positive mold was wrapped in several layers of saran wrap to mimic a Symes sock placed over the residual limb.

After the first layer is done, the socket should be separated from the mold using a dermal, cutting vertically along the back. This should be done on the first layer as the socket is still flexible enough to be maneuvered off the mold. Fiber glass should continue to be layered after the first layer is separated from the mold. Only 2 layers of fiberglass should be put on at a time, and at least 8 layers total should be applied to ensure sufficient strength and rigidity. Before putting on a subsequent layer, each layer should be set to dry for a minimum of 10 hours, or when the resin starts to solidify. If too many layers are put on at a time, this can affect how the resin dries throughout the socket. Finally, with the socket done, the foot stem can be attached. To do this, an outer reservoir will be used to hold the resin in place around the socket as shown in **Figure 14.**

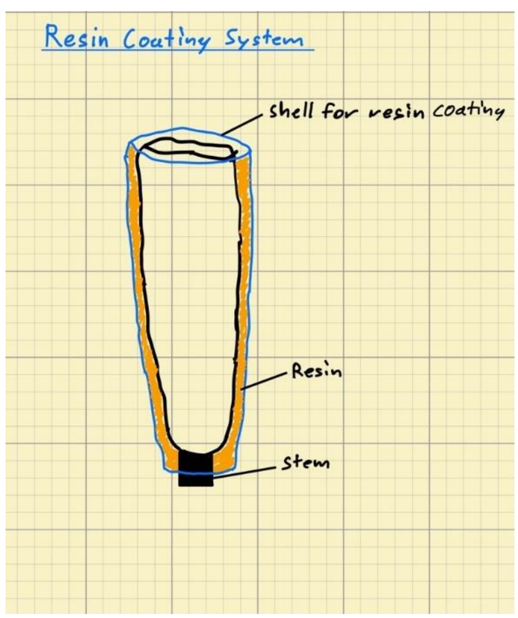


Figure 14. Resin coating system. The Resin Coating revisor for holding resin in place on the outside surface of the socket, and to aid in foot stem attachment. Note: this manufacturing process is not used for the final product and is included for posterity.

This will allow for the resin to flow around the socket, coating it, while also leaving space for the foot stem to be embedded in the resin, which will attach the foot to the socket. After the resin coating process, cuts can be made in the socket, both for socket flexibility and for threading the Velcro straps.

The second priority, after the socket, is manufacturing the foot and foot stem. The foot is not manufactured by the group, as stated before, and instead the Flex Symes™ by Össur was purchased. The stem also was not purchased, and instead it was salvaged from Mr. Bolin's most recent leg, which does not fit him. **Figure 15** displays the modular stem attachment point for the prosthetic foot from Mr. Bolins most recent prosthetic socket.

Figure 15: Modulor stem attachment point for a prosthetic foot from Mr. Bolin's most recent leg. Screws will be inserted into the 4 tapped holes as seen in the figure.

Since most prosthetic feet, including the Össur, have a modular attachment point, Mr. Bolin's old stem will fit directly onto this foot. **Figure 16** shows the standardized stem attachment points on the different prosthetic feet.

Figure 16: Standardized stem attachment points on the Össur (bottom) and the foot from Mr. Bolin's most recent leg (top).

From there, the stem will be placed over the attachment point, and can use the four included screws from the stem to attach the foot. Once the leg is fully manufactured, padding in the form of neoprene rubber will be placed inside the socket for cushioning. This padding will be placed on the particularly sensitive spots of Mr. Bolin's limb that he has pointed out to the group. **Figure 17** shows the sensitive spots on Mr. Bolin's residual limb.

Figure 17. Sensitive spots on Mr. Bolin's residual limb.

Once these spots are covered and cushioned, a gel inner liner will be worn by Mr. Bolin in conjunction with his prosthetic. This liner will be purchased.

Final Design

The final product included some manufacturing changes in material and design. The final product was made from Ossur Techform Premium Casting Tape. This casting material was soaked in water to be activated and then quickly wrapped around the positive mold. The layer was let to harden for about five minutes, after which another layer was added on. Several layers total were used. After, the positive mold was broken, leaving only the socket remaining. The foot housing component was fixed to the socket using steel reinforced epoxy and then wrapped with more layers of casting tape. Two slots were cut into the sides of the shell so it would be easier to slip the prosthetic onto the residual limb. To secure the prosthetic in place, external straps were added. The final prototype is shown in **Figure 18.**

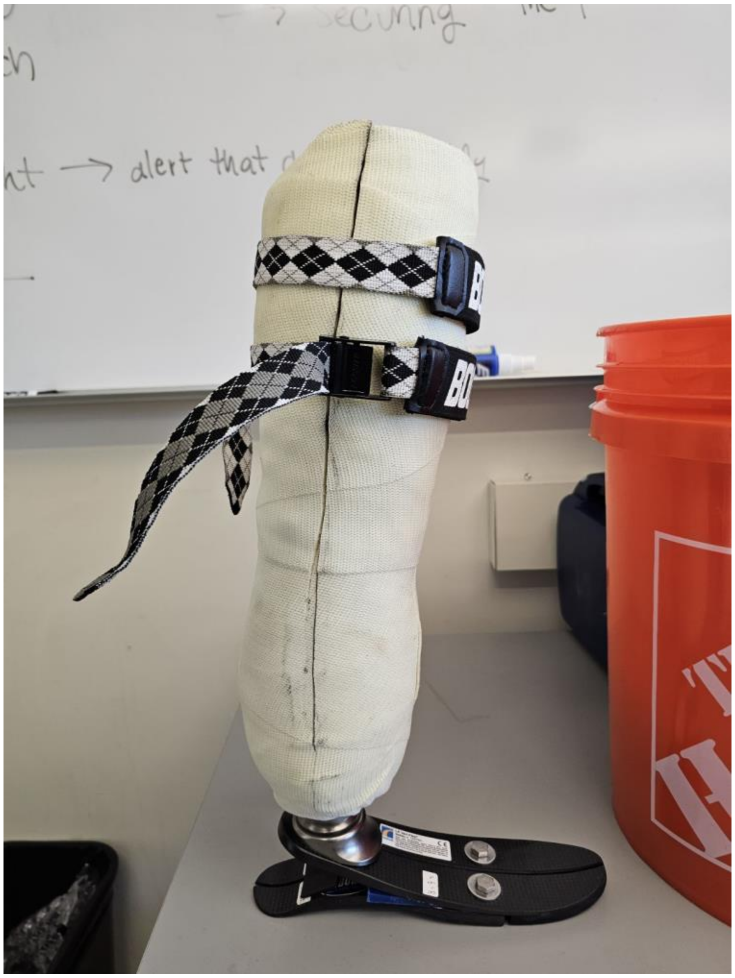


Figure 18. Final prototype.

Summary of Test Plans

Table 7 shows the test plans for each engineering specification listed in *Table 3*. Test type, sample size, and facility equipment for each test is described.

Table 7. Summary of Test Plans. Test type, sample size, and location/equipment used are described.

Spec. #	Parameter Description	Test-Type	Sample Size	Facility	Equipment
1	Stem Strength	COMSOL	1	General	Computer
2	Fiberglass Strength	COMSOL	1	General	Computer
3	Steel Epoxy Strength	COMSOL	1	General	Computer
4	Pain Mitigation	Comfort survey	1	General	Form that Mr. Bolin to answer
5	Weight	Comfort survey	1	General	Form that Mr. Bolin to answer
6	Comfort	Comfort survey	1	General	Form for Mr. Bolin to answer

Tests 1, 2, and 3 were accomplished via COMSOL using the CENG remote desktop services. The reasoning for computer simulations as opposed to physical stress tests were twofold: 1) There was only enough time to manufacture one prototype with the materials at hand, so the destruction of the prosthetic via testing would have halted the project, and 2) tensile tests or 3-point bending tests do not provide relevant data for the project. The simulation of deformation and stresses within the socket provides more than enough insight into the durability of the product.

Product satisfaction will be determined via a satisfaction and comfort survey as shown in tests 4, 5, and 6. The survey will ask him to answer various questions on a scale of 1 to 5, 1 being the most comfortable, and 5 being the least. A lower score will indicate a greater level of comfort. This will also allow the project to target weak points of the design. The goal is that the prosthetic will be light enough for Mr. Bolin to hold in hands comfortably and move when worn on his leg and the silhouette of prosthetic matches the other leg to satisfy Mr. Bolin's aesthetic requirements.

COMSOL Testing

Material Strength testing was done in COMSOL. First, a laminated cylinder with a spherical end was created. The three layers represent the layers of fiberglass on the inside, steel-reinforced epoxy between the layers, and an outer fiberglass layer. The steel connector was added to the end. The simulation assumed a 2D axisymmetric model, which rotated the model about the origin y-axis to create a 3D model. The young's modulus, density, and poisons ratio for all three materials were required for the simulation. The young's modulus for each material is featured in *Table 3.* A load of 1335 N was applied to the inside surface of the socket, which approximates the force of impact during walking gait (1.5x body weight). The young's modulus used for fiberglass was about 3500 MPa and 2500 MPa for steel reinforced epoxy [12]. The steel material was pulled from the COMSOL material library. **Figure 19** shows the 2D stress profile for a purely axial load.

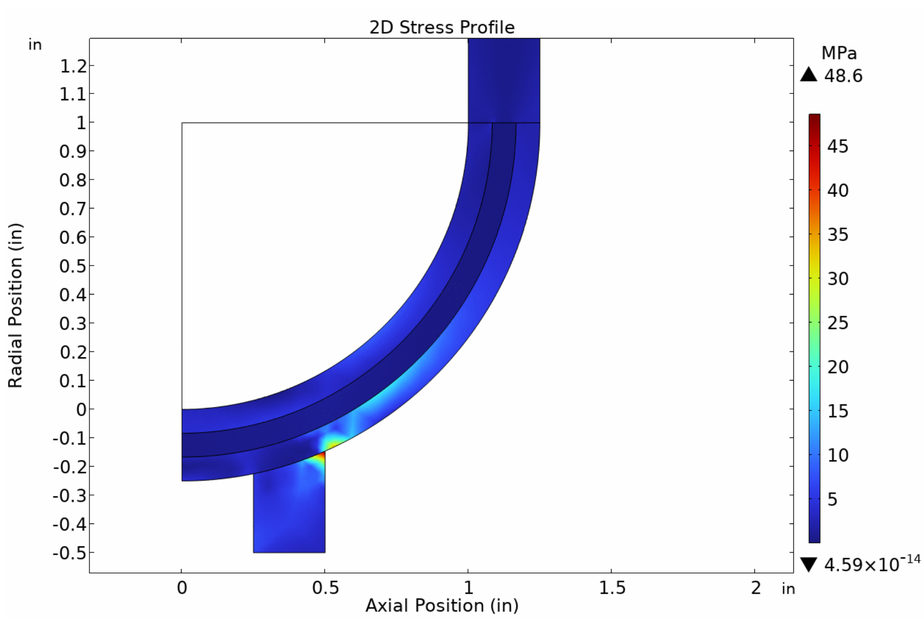


Figure 19. 2D Stress profile for purely axial load. Axial load z = 1335 N. Von-mises stress model used for simulation.

Note that the maximum stress experienced is 48.6 MPa at the steel connector, far below the yield of steel (190 GPa). **Figure 20** shows the 2D stress profile for a purely radial load.

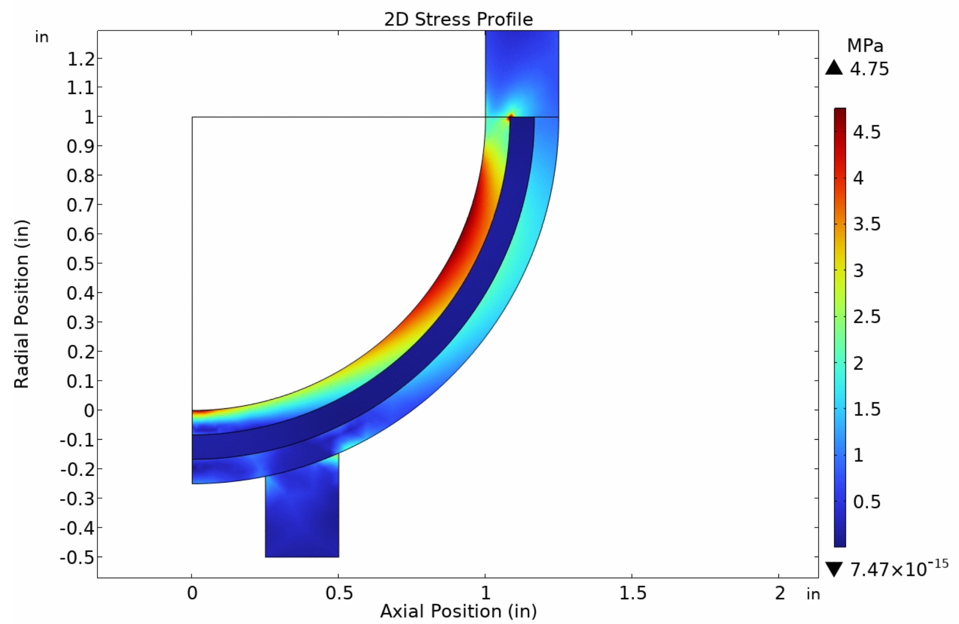


Figure 20. 2D Stress profile for purely radial load. Axial load r = 1335 N. Von-mises stress model used for simulation.

Again, the maximum stress within the socket (4.75 MPa) is far below the yield stress of fiberglass (52 GPa). **Figure 21** displays the 3D stress profile for a purely axial load.

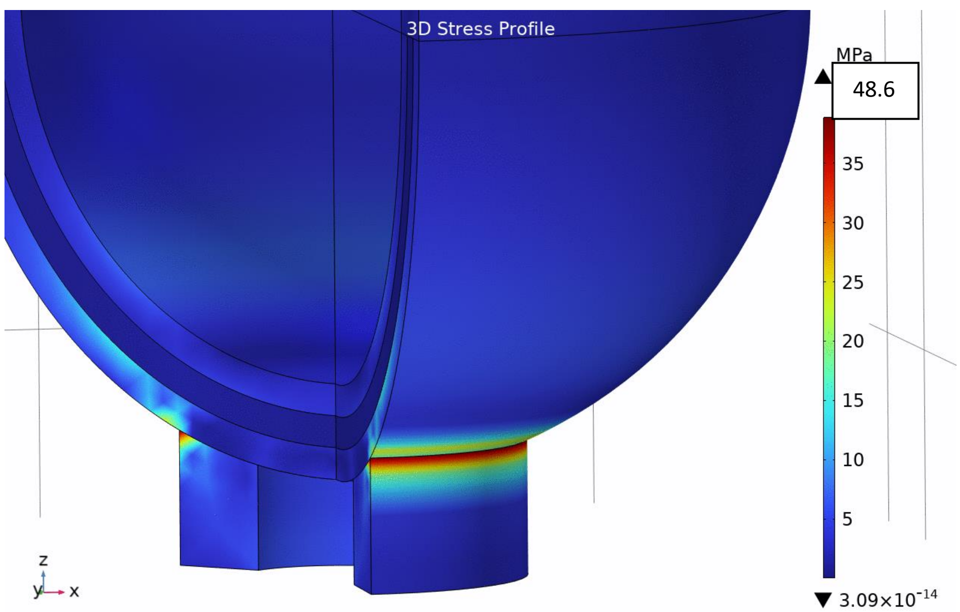


Figure 21. 3D Stress profile for purely axial load. Axial load z = 1335 N. Von-mises stress model used for simulation.

Figure 22. displays the 3D stress profile for a purely radial load.

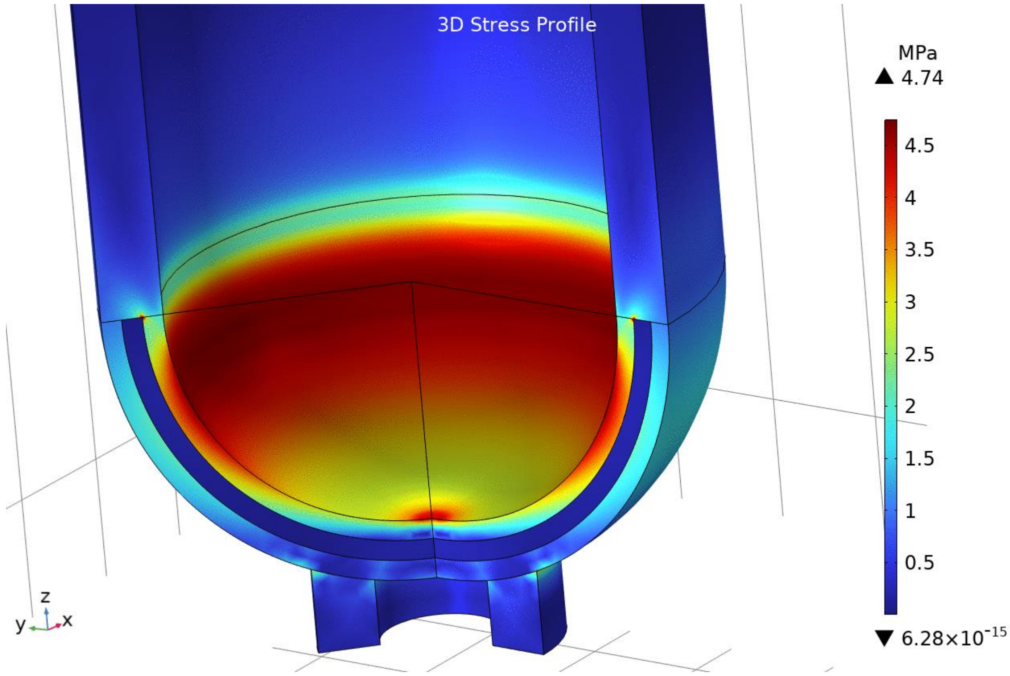


Figure 22. 3D radial load.

Based on the results of these simulations, it can be concluded that the socket will not break under static loading during walking-speed gait.

Comfort Survey Results

Mr. Bolin completed the survey used to assess the overall comfort of the prosthetic. Scores were given on a scale from 1 to 5 assessing the fit of the device on the residual limb, with lower scores indicating more comfort and higher scores indicating discomfort. Overall score results could range from 8 to 45. The final device achieved an overall score of 12, indicating that we successfully created a comfortable device.

Table 8. Results of the comfort survey. The overall comfort score was 12, which indicates that the device was comfortable.

Rate comfort 1-5	Score
Tightness around limb	2
Tightness around end of limb	1
Pressure on boney spot at end of limb	1
Pressure on boney spot right of knee	2
Pressure on boney spot left of knee	2
Chafing	1
Overall comfort	2
Overall pain	1
Overall Score	**12**
Score system	
1	Not impactfu at all
2	Slightly impactful
3	Moderately impactful
4	Heavily impactful
5	Extreemely impactful

Instructions for Use

1) Prepare residual limb for socket wear.
    a. Wear at least one sock.
2) Remove straps from socket if they are already attached.
3) Insert residual limb into opening of socket. Press down until the bulbous end of the residual limb is at the bottom of the socket.
4) Make sure that the residual limb is comfortable within the socket.
5) Fix the straps to the top of the socket. They should be placed 1 inch apart from each other.
    a. Tighten the straps as much as possible to ensure that the socket does not deform during use.
    b. If the limb experiences swelling or inflammation, loosen the straps as needed.
6) When done with the prosthetic, remove the straps and remove residual limb from socket. If needed, have another individual assist with the removal of the prosthetic.

Conclusion

This project's scope was to develop a working prosthetic prototype for Mr. Bolin addressing the issues associated with his current model. Those issues being mainly being associate with the comfort of his socket and foot stiffness. The goals were accomplished by making a proof-of-concept prototype that had a comfortable socket fit and a foot that had a more accommodating stiffness. In this way, the design was superior to what Mr. Bolin currently has. However, there are certain issues with the design, such as the material texture and orientation of the socket, that make it impractical for Mr. Bolin to use daily. Despite this, with the concept proven, it only takes working out these fixable issues to make something extremely versatile and comfortable for Mr. Bolin.

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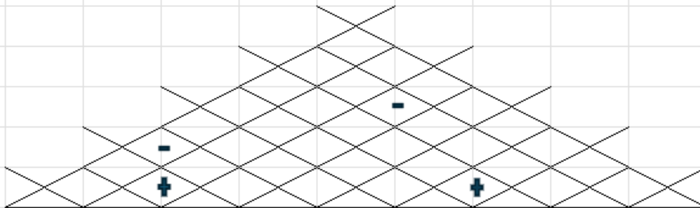
Appendices

[A-1] House of Quality

Customers:

- Anthony Bolin
- Prostheticians
- FDA
- Manufacturers
- Sales Team



Current Market: 1 = Very bad; 5= very good

Customer Requirements:		Engineer Requirements:	Range of Motion of Foot ~20° Toe off	Range of motion of Foot ~25°Heel Strike	Impact impulse	Withstand moment force at ankle joint (FS=1)	Stem Strength(FS =1)	Uniform gap between leg and prosthetic	Adjustability (Uniform gap adjustment)	Weight	Matches silhouette of other leg	Current Prosthetic	Martin Bionics (socket)	Flex Syme
Desired Change			^	^	^	\	^	\	^	v				
Units			°	°	Ns	Nm	Mpa	mm	mm	lbs	%			
		Weighting												
Form	East to Put on - Good Fit	15	0	0	0	0	0	3	9	1	0	2	5	\
	Minimizes pain	20	9	9	9	0	0	3	3	3	0	1	5	5
	Support/stability for whole leg	10	9	9	1	0	0	3	3	1	0	2	4	\
Function	Toe-off bounce	15	9	9	3	3	3	0	0	0	0	1	n/a	5
	Less impact through heel	10	1	3	9	9	9	0	0	1	0	2	n/a	5
	Durable - acute/chronic damage	7	0	0	1	9	9	1	1	3	0	3	3	4
Aesthetics	Color/Surface designs	7	0	0	0	0	0	0	0	0	3	1	1	3
	Dimensions match other leg	7	0	0	0	0	0	3	3	0	9	3	2	2
	Able to wear shoes	9	1	1	3	3	3	0	0	0	9	5	n/a	0
Totals			424	444	359	225	225	163	253	116	165			
Target value			~15-20°[1,	0-25° [2,3]	2x normal	977	7.57	1 to 2	4	< 4 lbs	>85			

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Comfort Survey

https://docs.google.com/spreadsheets/d/1E9nDW4Drok97E3mjAiYrR3KZe3yAkDFm2SVCA05ASj8/edit?usp=sharing