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# 3D Printed Below-the-Knee Prosthetic Leg

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**Executive Summary**

There are over 2 million amputees in the United States and more than 90 percent of amputations done today are for lower limbs. While there are highly advanced options on the market today, there are still several areas of improvement. For instance, there are not many options that are completely waterproof, and the more advanced ones are extremely expensive and heavy. Our project idea is to create a below-the-knee prosthetic leg that is water resistant, affordable, and promotes comfort. The leg will be designed to disperse the loads and stresses over the whole structure using 3D printing and supporting metal rods. The model will be analyzed in Solidworks Motion in order to see how the forces under an applied load are acting.


# MEMS 411: Senior Design Project

## 3D Printed Below-the-Knee Prosthetic Leg


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# 1 Introduction and Background Information

## 1.1 Initial Project Description

Our project idea is to design a prosthetic leg for adult that can be 3D printed. The prosthetic need to be able to support the weight of a large man and affordable to all. This is because for many veterans and others prosthetics can be very expensive and 3D printing is an alternative cheaper way to make them. The problem is that it is hard to design legs that can support and an adults weight.

## 1.2 Existing Products

Robohand is working on a 3D printed prosthetic leg design, but as of the time of this writing, it is not currently available for the public. The plastic parts of it are 3D printed while the metal elements still need to be bought from other retailers. They make the designs for their prosthetics available online for people to print themselves. Currently their Robohand can be made for $500 (Sevenson).

Figure 1: Model of Robohand's Prosthetic (Sevenson).

Protosthetics prints prosthetics using both polymers and metals. They can print them based off 3-D scans customers send them. They also make legs that can be used for swimming and other outdoor activities (Peels).

Figure 2: Model of Protosthetic's Prosthetic (Peels).

Standard Cyborg creates 3D printed waterproof legs for under $500. However, they aren't meant to be a person's main prosthetic but rather are supposed to be used when in water or to shower. A main selling point is that it only takes 10 seconds to put it on ("3D Design").

Figure 3: Model of Standard Cyborg's Two Prosthetic Models ("3D Design")

## 1.3 Relevant Patents

US 20140188260 A1: A prosthetic limb and process to digitally construct a prosthetic limb which includes first, digitally producing a modified mold of a residual limb via 3-D scanners and software; constructing a test socket from the digitally modified mold and be equipped with an alignable system; accurately scanning the test socket, along with finalized alignment that has been recorded and adjusted by a certified practitioner to provide a 3D Image of the finalized prosthetic alignment; transferring the finalized digital alignment of the test socket to the finalized digitally modified mold; once the modified model has received the transferred alignment, fabricating the type of hookup in the socket; i.e., plug fit, four hole, support drop lock, or any other type of industry standard connection or accommodation via basic 3-D software; and once the desired prosthetic attachment is finalized, sending finished file to a 3D printer to produce the definitive prosthetic device.

US 8366789 B2: A prosthetic limb has an outer surface that is a mirror image of an intact limb or a generic limb design. The intact limb is scanned and the surface data is manipulated to create a virtual mirror image. If generic data is used, the intact leg can be measured and the generic surface can be adjusted so the prosthetic limb appears similar to the intact limb. The end of the amputated limb is also measured to obtain socket data. A knee and foot are incorporated to form a virtual prosthetic limb represented by design data. The design data for the virtual prosthetic limb is forwarded to a rapid prototyping machine that fabricates the entire leg simultaneously. Once completed, the prosthetic limb is shipped to the patient.

## 1.4 Codes & Standards

One standard was found that pertained prosthetic for the lower leg, which was US8366789 B2. However it does not go through much that can be implemented during the design phase. It covers the testing of lower limb prosthetics to make sure they adhere to safety requirements. These tests are done through static and cyclic load testing to determine if it can withstand harshest conditions it may have to experience ("Prosthetics").

## 1.5 Project Scope

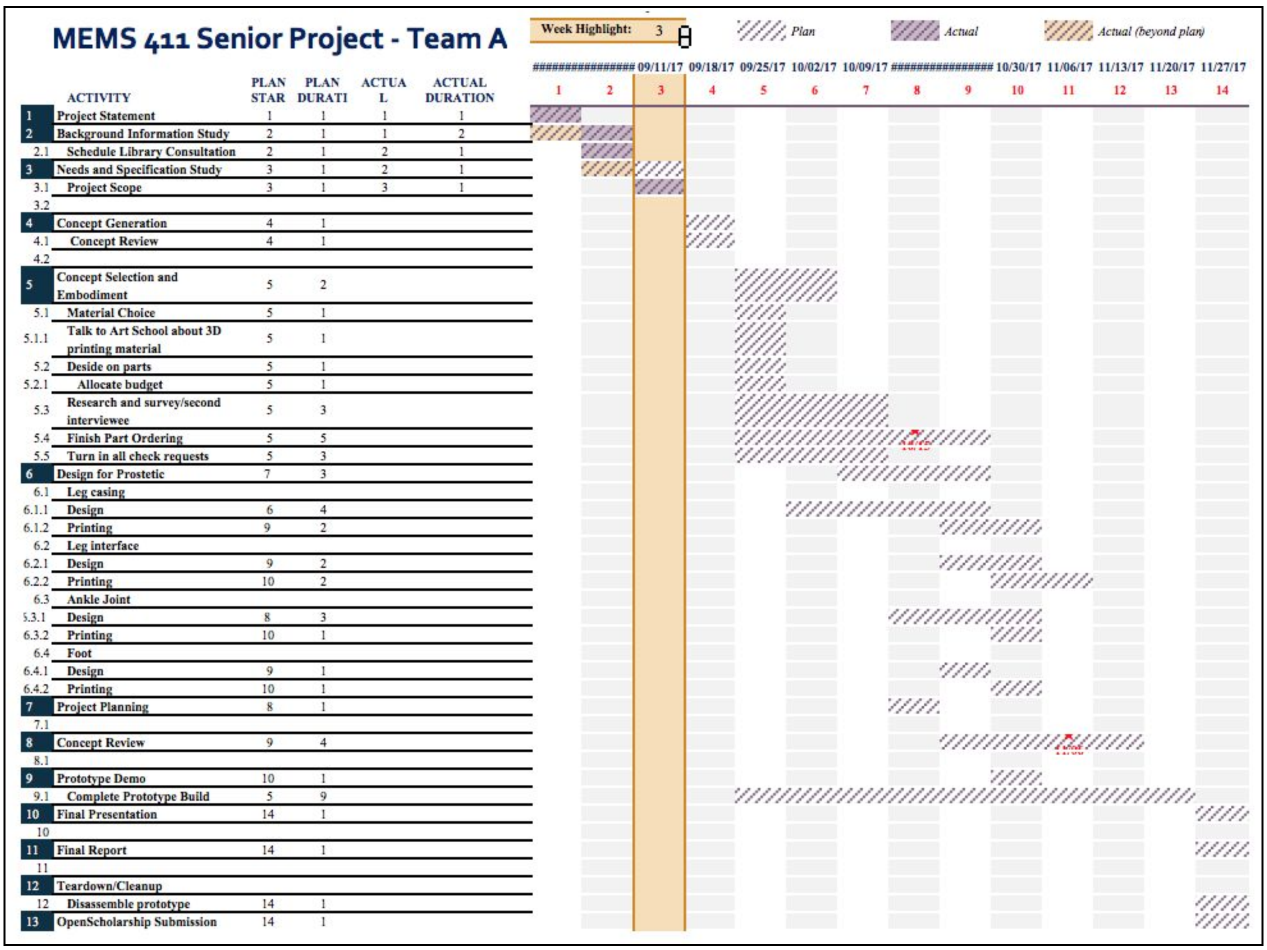
In Scope:

- Coming up with a few designs and analysing the top ones using CAD program / stress analysis
- Creating a prototype
- Creating a design that is attractive to a wide range of people
- The cost of making it is under $500

Out of Scope:

- Including a knee joint
- Manufacturing in larger scale
- Designing different foot attachments
- Can not perform long term test
- No stress cycle performance tests

## 1.6 Project Planning




| | ACTIVITY | PLAN STAR | PLAN DURATI | ACTUAL | ACTUAL DURATION |
|---|---|---|---|---|---|
| 1 | Project Statement | 1 | 1 | 1 | 1 |
| 2 | Background Information Study | 2 | 1 | 1 | 2 |
| 2.1 | Schedule Library Consultation | 2 | 1 | 2 | 1 |
| 3 | Needs and Specification Study | 3 | 1 | 2 | 1 |
| 3.1 | Project Scope | 3 | 1 | 3 | 1 |
| 3.2 | | | | | |
| 4 | Concept Generation | 4 | 1 | | |
| 4.1 | Concept Review | 4 | 1 | | |
| 4.2 | | | | | |
| 5 | Concept Selection and Embodiment | 5 | 2 | | |
| 5.1 | Material Choice | 5 | 1 | | |
| 5.1.1 | Talk to Art School about 3D printing material | 5 | 1 | | |
| 5.2 | Deside on parts | 5 | 1 | | |
| 5.2.1 | Allocate budget | 5 | 1 | | |
| 5.3 | Research and survey/second interviewee | 5 | 3 | | |
| 5.4 | Finish Part Ordering | 5 | 5 | | |
| 5.5 | Turn in all check requests | 5 | 3 | | |
| 6 | Design for Prostetic | 7 | 3 | | |
| 6.1 | Leg casing | | | | |
| 6.1.1 | Design | 6 | 4 | | |
| 6.1.2 | Printing | 9 | 2 | | |
| 6.2 | Leg interface | | | | |
| 6.2.1 | Design | 9 | 2 | | |
| 6.2.2 | Printing | 10 | 2 | | |
| 6.3 | Ankle Joint | | | | |
| 5.3.1 | Design | 8 | 3 | | |
| 6.3.2 | Printing | 10 | 1 | | |
| 6.4 | Foot | | | | |
| 6.4.1 | Design | 9 | 1 | | |
| 6.4.2 | Printing | 10 | 1 | | |
| 7 | Project Planning | 8 | 1 | | |
| 7.1 | | | | | |
| 8 | Concept Review | 9 | 4 | | |
| 8.1 | | | | | |
| 9 | Prototype Demo | 10 | 1 | | |
| 9.1 | Complete Prototype Build | 5 | 9 | | |
| 10 | Final Presentation | 14 | 1 | | |
| 10 | | | | | |
| 11 | Final Report | 14 | 1 | | |
| 11 | | | | | |
| 12 | Teardown/Cleanup | | | | |
| 12 | Disassemble prototype | 14 | 1 | | |
| 13 | OpenScholarship Submission | 14 | 1 | | |

Figure 4: Gantt Chart Created to Plan the Weekly Project Development

## 1.7 Realistic Constraints

- Every amputation is different and one prosthetic may not be comfortable or fit all
- Can only 3D print in a small range of materials
- Discovering the impact of long term water contact will be difficult given the time left to create a product

### 1.7.1 Functional

Given the limited time of the project, it's not guaranteed that the prosthetic will have the same range of motion as competitors.

### 1.7.2 Safety

While stress and impact testing will be done on the model, it's not guaranteed that the prosthetic will hold up to a person's day to day movements.

### 1.7.3 Quality

Without a high end printed, some details of the design may get lost in the process.

### 1.7.4 Manufacturing

Without precise machining and printing tools, some parts may look clunky or not have an ideal range of motion.

### 1.7.5 Timing

Making a unique design for a specific user will be impossible given the timing of the project.

### 1.7.6 Economic

None.

### 1.7.7 Ergonomic

Without an actual test subject to model the leg after, it will be difficult to efficiently design the leg ergonomically.

### 1.7.8 Ecological

None.

### 1.7.9 Aesthetic

The design is meant to be cheap, and its aesthetics will reflect that. None of us claim to be artists, so minimal work will be done to enhance the prosthetic's aesthetic appeal.

### 1.7.10 Life Cycle

There is no way of determining the design's true life cycle without a human model wearing it consistently until it breaks, which can't happen given both the timing and resources at our disposal.

#### 1.7.11 Legal

None.

## 1.8 Revised Project Description

Our project is to design a prosthetic leg for below the knee to be used by adults. It needs to be able to be 3D printed to make it as affordable as possible. The prosthetic needs to be appealing so that the user feels comfortable wearing it for any occasion. It also need to be waterproof, so that it can be used for more outdoor activities as well as in the shower. This device has to also be comfortable and fairly easy to put on and remove

# 2 Customer Needs & Product Specifications

## 2.1 Customer Interviews

**Customer Data:** Below-the-knee Prosthetic (BP)
Customer: Bradie Corcoran
Address: Over messenger
Date: 9/16/2017

| Question | Customer Statement | Interpreted Need | Importance |
|---|---|---|---|
| What is the model of your current Prosthetic? What are your favorite features of it? What could be improved? Is it waterproof? | I currently have three different prostheses; one for working out (1), one for wearing heels (2), and one for the water (3) | BP can be used for all occasions | 3 |
| | 1) The ankle component underneath the skin cover gives me the ability to bounce on it and not feel like I am walking on a 2 X 4 (not waterproof) | BP has a bounce to it when walked on | 2 |
| | 2) This leg is like walking on a board of wood and truly doesn't give me a good range of motion when walking (not waterproof) | BP is waterproof and flexible | 5 |
| | 3) I have a third leg that I use specifically for beach activities, showering, etc. This leg is by far the most uncomfortable. It is heavy and bulky and looks mostly like a "prosthetic leg" | BP is lightweight and aesthetically pleasing | 5 |
| What's the most difficult to do with your prosthetic? Specific activities? | The liner that connects my limb to my prosthesis fills with sweat and I have to empty it out before continuing my workout | BP and liner is breathable | 1 |
| | Another difficult task is taking off pants/jeans. The pants often times get stuck on the heel of the prosthetic and it is a | BP can have clothing easily put over it | 4 |

| | | | |
|---|---|---|---|
| | difficult journey getting them off. | | |
| How many different prosthetics have you used? What was the price range of these and were there any issues with the ones of lower cost? | I have used over 6 different prosthetics ranging from no cost to several thousands of dollars. | BP is affordable | 5 |
| Were any of your prosthetics painful or uncomfortable for a longer period of time? In what way were they painful/uncomfortable? | After being "fit" several times, I found out from a new doctor that my hip was out of place because of the alignment of my old one. | BP is properly aligned for each customer | 5 |
| What was your favorite way of having your leg placed in the prosthetic? Pin/suction etc? | Customer has only used pin/lock system as it was suggested by the healthcare specialists she has worked with due to the rather bony end of her leg. | BP has a fixture method that is adapted to the type of leg stump for optimal fitting | 2 |
| What is the most important features of a prosthetic to you? | Getting the best fit for a patient is ideal for eliminating any other pain they have.<br><br>Another important factor is durability, making sure the leg can last in harsh conditions as well as lasting you more than a couple years or so. | BP can be custom fitted<br><br>BP is durable | 3<br><br>4 |
| If you have any other comments or suggestions of what would make your "dream prosthetic" | Shoes are the biggest inconvenience I would say. So making something that can fit into a variety of shoes and getting out of those shoes EASILY would be ideal. | BP can be worn with a variety of shoes | 2 |

Table 1: Interview Data from Below-the-Knee Amputee

## 2.2 Interpreted Customer Needs

| Need Number | Need | Importance |
|---|---|---|
| 1 | BP can be used for all occasions | 3 |
| 2 | BP has a bounce to it when walked on | 2 |
| 3 | BP is waterproof and flexible | 5 |
| 4 | BP is lightweight and aesthetically pleasing | 5 |
| 5 | BP and liner is breathable | 1 |
| 6 | BP can have clothing easily put over it | 4 |
| 7 | BP is affordable | 5 |
| 8 | BP is properly aligned for each customer | 5 |
| 9 | BP has a fixture method that is adapted to the type of leg stump for optimal fitting | 2 |
| 10 | BP can be custom fitted | 3 |
| 11 | BP is durable | 4 |
| 12 | BP can be worn with a variety of shoes | 2 |

Table 2: Interpreted Customer Needs from Interview Data

### 2.3 Target Specifications

| Metric Number | Associated Needs | Metric | Units | Acceptable | Ideal |
|---|---|---|---|---|---|
| 1 | 7 | Cost | $ | <500 | <300 |
| 2 | 4,11 | Weight of Leg | lbs | <8 | <2 |
| 3 | 11 | Weight of Person | lbs | 100 to 150 | 100 to 200 |
| 4 | 1,3,5,11 | Time Able to be Submerged in Water | hours | 250 | 1000 |
| 5 | 8,10 | Length of Leg | in | >12,<24 | >10,<30 |

Table 3: Target Product Specifications for Prosthetic Leg

## 3 Concept Generation

### 3.1 Functional Decomposition

Functional Decomposition is the process of taking a complex process and breaking it down into its smaller, simpler parts. Below is a diagram detailing the major components of our design and its importance to the overall design.

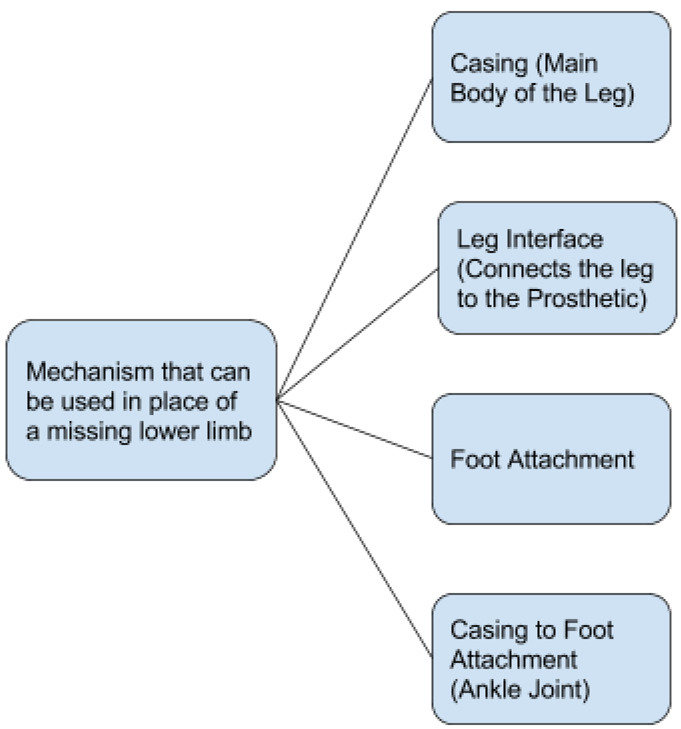



Figure 5: Function Tree for Prosthetic Leg

## 3.2 Morphological Chart

Below is our morphological chart for the proposed prosthetic leg. Each row signifies one branch of our function tree, and is filled with 3-4 designs for that specific component. Using these proposed designs, 6 overall concepts were generated.

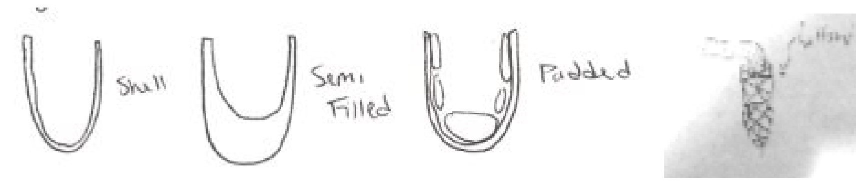
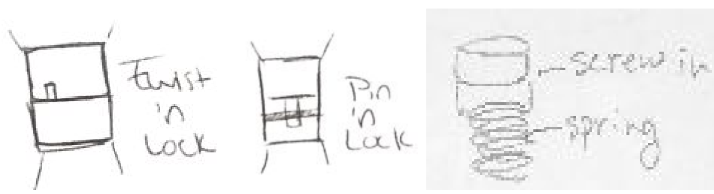
<table>
<tr><td>Casing (Main Body of the Leg)</td><td>
</td></tr>
<tr><td>Leg Interface (Connects the leg to the Prosthetic)</td><td>
</td></tr>
<tr><td>Casing to Foot Attachment (Ankle Joint)</td><td>
</td></tr>
<tr><td>Type of Foot</td><td>
</td></tr>
</table>

Figure 6: Morphological Chart for Prosthetic Leg

### 3.3 Concept #1 – "The Padded Leg with a Posable Foot (PPTL)"

Using a pin to secure the Interface with the Casing, the PPTL offers the most secure connections of the 6 designs. Padding within the Casing can be increased or decreased to fit the user's needs and comfort level.

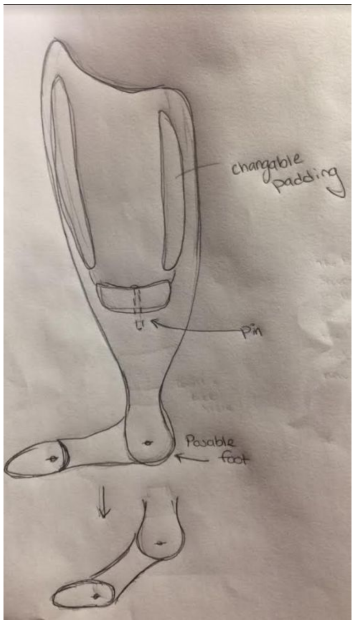



Figure 7: Concept Design #1

### 3.4 Concept #2 – "Leg with Ankle Attachment and Gel Filled Foot (SFPPL)"

Utilizing a semi-filled shell, the SFPPL gives the user the weight typically associated with a lower leg without becoming a burden with every step. The more solid structure also leads to a more secure design, lowering the chance of fracture within the leg's structure. A gel-filled foot adds flexibility in a somewhat rigid design.

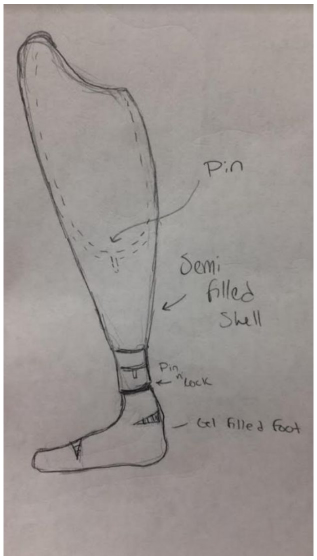


Figure 8: Concept Design #2

### 3.5 Concept #3 – "Leg with Silicone Insert and Posable Foot (SFSMTL)"

Bringing the nostalgia, the SFSMTL utilizes air bubble technology to pump up user's games. The silicon mold gives the support needed, while the air pocket elevates them to the next level. Incorporating the classic air bubble with cutting edge prosthetic technology, people will be dunking like Mike in no time (results not guaranteed).

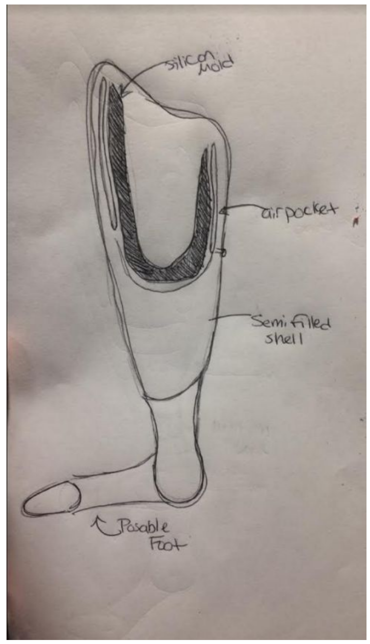



Figure 9: Concept Design #3

### 3.6 Concept #4 – "Leg with Metal Frame and Spring Ankle (HSMS)"

For users needing a bit more bounce, the HSMS includes a spring attachment in the ankle joint, giving users a fluidity in their movement not seen in other designs. Additionally, the hollow casing minimizes printing time and cost, making the HSMS quite affordable. Spring not included.

Figure 10: Concept Design #4

### 3.7 Concept #5 – "Leg with Metal Frame and Ankle Attachment (MFTL)"

The MFTL is by far the most durable and secure of the six designs, sporting a multi-spoked interior metal skeleton built to disperse even the heaviest of loads away from pressure points in the leg. The skeleton will be able to withstand nearly any punishment the user can give it and still come back for more. With the MFTL, people can take on any challenge with the ease of mind that they won't be leaving a part of themselves behind.

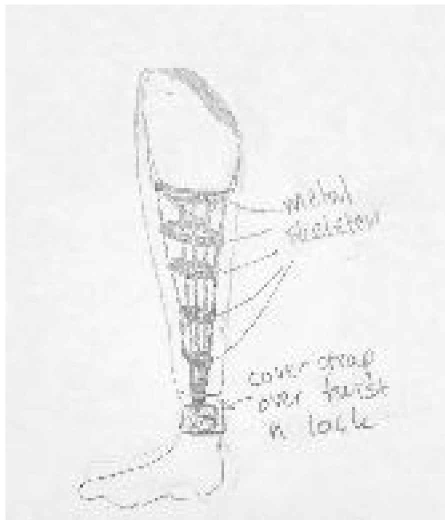



Figure 11: Concept Design #5

### 3.8 Concept #6 – "Leg with Silicon Insert and Latch on and Ankle Attachment (HSMTL)"

The addition of a hinge and latch to the leg casing maximizes the user's ability to put on and take off their prosthetic at any time and in any weather. The silicon mold and twist 'n lock add the comfort and security needed in a quality product, making the HSMTL a great all-around prosthetic.

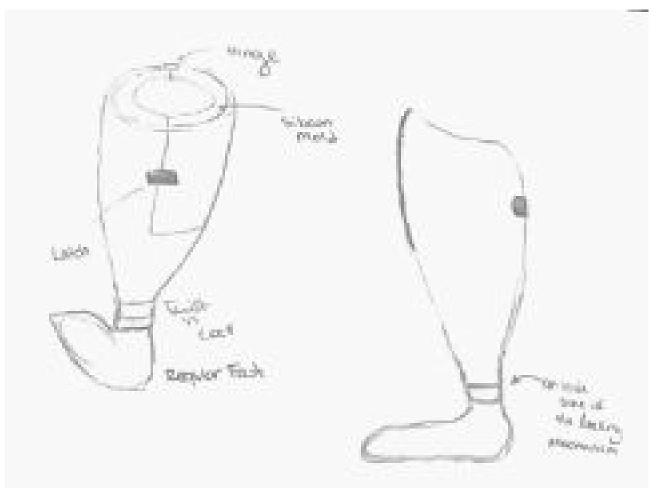


Figure 12: Concept Design #6

# 4 Concept Selection

## 4.1 Concept Scoring Matrix

Below is the Concept Scoring Matrix for our prosthetic leg. The six designs outlined above were scored against each other, with Design 2 serving as the most average design. Every other concept was scored against Design 2, and those results were multiplied by the weighted sums found in earlier sections to find a cumulative total score for each one.

| | | Alternative Deisgn Concepts | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | |  | |  | |  | |  | |  | |  | |
| **Selection Criterion** | **Weight (%)** | **Rating** | **Weighted** | **Rating** | **Weighted** | **Rating** | **Weighted** | **Rating** | **Weighted** | **Rating** | **Weighted** | **Rating** | **Weighted** |
| Mechanical safety | 32.67 | 3 | 0.98 | 2 | 0.65 | 2 | 0.65 | 2 | 0.65 | 2 | 0.65 | 5 | 1.63 |
| Cost of components | 18.89 | 2 | 0.38 | 4 | 0.76 | 3 | 0.57 | 4 | 0.76 | 2 | 0.38 | 1 | 0.19 |
| Availibity of part | 17.01 | 2 | 0.34 | 4 | 0.68 | 3 | 0.51 | 4 | 0.68 | 3 | 0.51 | 3 | 0.51 |
| Ease of Construction | 9.39 | 2 | 0.19 | 3 | 0.28 | 3 | 0.28 | 4 | 0.38 | 2 | 0.19 | 1 | 0.09 |
| Ability to be Refitted | 4.06 | 3 | 0.12 | 3 | 0.12 | 4 | 0.16 | 4 | 0.16 | 4 | 0.16 | 4 | 0.16 |
| Durability | 5.63 | 4 | 0.23 | 2 | 0.11 | 3 | 0.17 | 3 | 0.17 | 4 | 0.23 | 5 | 0.28 |
| Can be Worn in Different Footwear | 4.14 | 4 | 0.17 | 5 | 0.21 | 1 | 0.04 | 5 | 0.21 | 1 | 0.04 | 1 | 0.04 |
| Waterproof | 4.39 | 3 | 0.13 | 3 | 0.13 | 3 | 0.13 | 4 | 0.18 | 3 | 0.13 | 3 | 0.13 |
| Appealing | 2.12 | 4 | 0.08 | 5 | 0.11 | 3 | 0.06 | 5 | 0.11 | 4 | 0.08 | 4 | 0.08 |
| | Total score | 2.615 | | 3.050 | | 2.580 | | 3.285 | | 2.375 | | 3.128 | |
| | **Rank** | **4** | | **3** | | **5** | | **1** | | **6** | | **2** | |

Table 4. Concept Scoring Matrix

## 4.2 Explanation of Winning Concept Scores

Concept #3 had the highest score making it the winning design. It had the highest scores in through all of the criteria except in *mechanical safety* and *durability*. Even though those 2 categories could be of concern extra support could be added to the design and most of the parts in this design are replaceable if broken or damaged. Compared to the reference design is it is much easier to assemble due to the removable parts and allows it to be better fitted for the user. The reference allows for some flexibility in the foot but not enough to be with a variety of shoes like concept #3. Overall this is a much better concept that can allow the user to only have one leg that can be used during a large range of activities.

## 4.3 Explanation of Second-Place Concept Scores

This design got a really good score for *mechanical safety* as it includes a larger metallic 'skeleton'. This would make it easier to hold up the weight of a person, which is one of our main objectives. However, it did not score as well on *cost of components* as we would not be able to 3D print as much of the design, and we would have to order more metal parts. In addition, the *ease of construction* was low for this design as we would have to find a way to incorporate the metal parts within the 3D printed structure, which would be extremely difficult. This design was somewhat of a hit or miss type of design as it hit really high on some of our selection criterion and really low on some. Ultimately what made it #2 was that it had such a high rating in mechanical safety, and in our analytical hierarchy process we put a lot of weight on this criterion. At the end this design most likely would not have worked well at all after considering some components of the design as a whole, which is why it could never have made #1.

### 4.4 Explanation of Third-Place Concept Scores

Design 2 shared a lot of similarities with the winning design, yet crucially failed to provide the same amount of comfort, durability, and ability to be refitted. Constructing the interface out of separate pads is a much poorer design choice than the silicon mold because the padding material simply can't compete with regard to the design goals. The pads can't easily adhere to the leg casing, they won't stand up to consistent usage in water, and they can't easily react if a leg starts to atrophy or gain new muscle. Since this design only varies from the winning design by a change in leg interface, it would be expected that this model comes in second instead of third. However, since so much of the overall design's goals center around the interface, having even the second best interface concept greatly affects its final tally.

### 4.5 Summary of Evaluation Results

In deciding how to weight each of the given criteria, the user's ability to operate the leg in water while making it comfortable and affordable became readily apparent. Each design centered on fulfilling each of these goals, but had varied results. Some designs, like Concepts 1 and 2, scored well in one or two categories, but couldn't capture all three needs while others, like Concepts 4 and 6, couldn't quite achieve desired results across the board. The "Cost of Components", "Availability of Parts", and "Ease of Construction" criterion all focus around the prosthetic's ability to be used by a wide variety of people across different income levels and machining ability, and in all three categories, Concept 3 outstripped the competition. For this reason, along with its solid performance in nearly every other category, it became the clear winner. With these results, we will proceed to further flesh out and construct this design alone.

# 5 Embodiment & Fabrication plan

## 5.1 Isometric Drawing with Bill of Materials

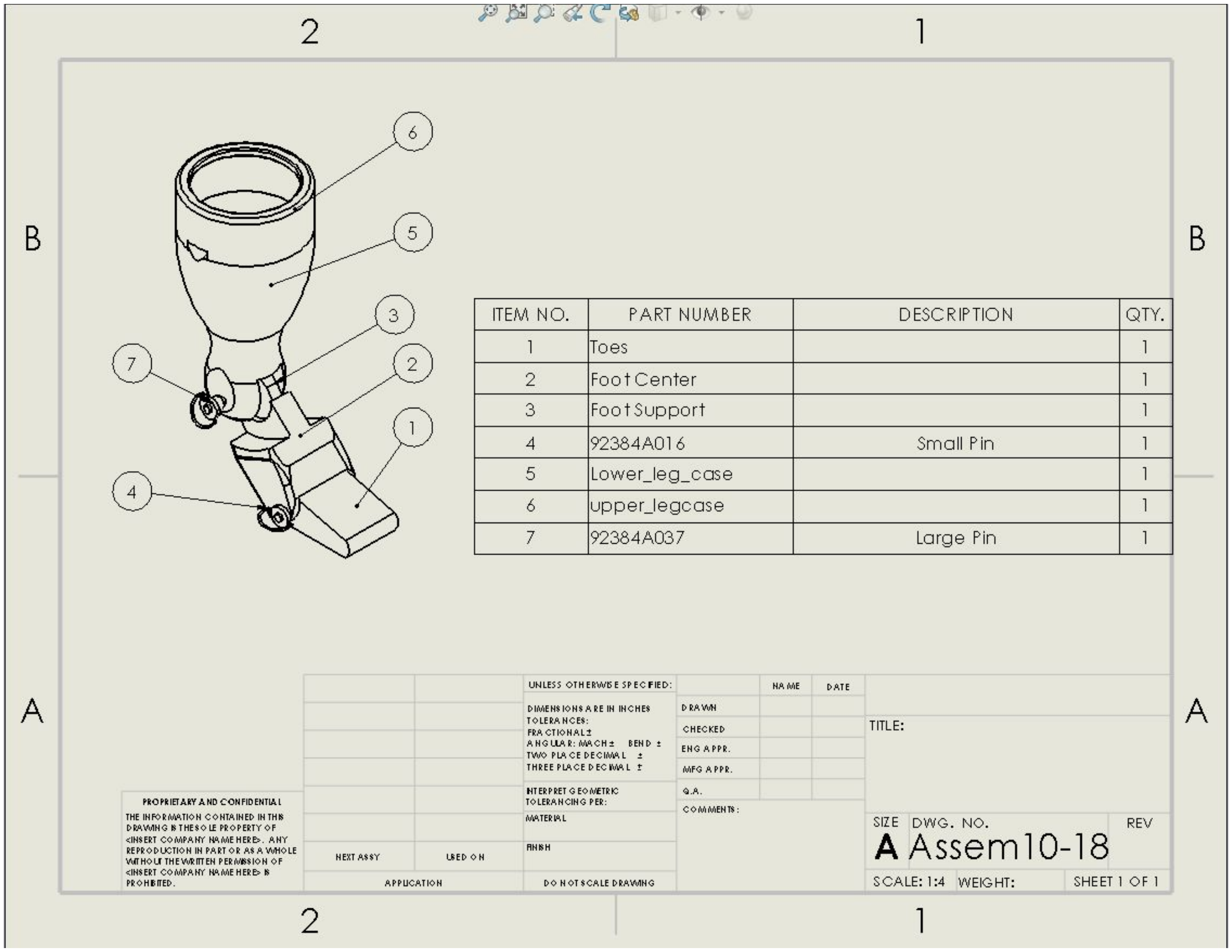



Figure 13: Isometric Drawing with Bill of Materials

| | Part | Source Link | Supplier Part Number | Color, TPI, other part IDs | Unit price | Tax ($0.00 if tax exemption applied) | Shipping | Quantity | Total price |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Magikmold GT-6142 28A Tin Cure RTV Silicone 2.2 lb Kit Lavender | Amazon | GT-6142 | Purple | $46.00 | - | $0.00 | 1 | $46.00 |
| 2 | Micro Essential Labs Water Finder Detection paper | Amazon | B005FYH586 | - | $16.99 | - | $0.00 | 1 | $16.99 |
| 3 | 2 Free Standing Mannequin Leg Sock and Hosiery Display Foot. | Amazon | B004JPWFRS | - | $29.99 | - | $14.99 | 1 | $29.99 |
| 4 | Knob-Grip Push-Button Quick-Release Pin | McMaster | 90985A129 | Steel | $19.97 | $0.00 | - | 1 | $19.97 |
| 5 | Densite Plaster | Blick | 33537-1008 | - | $6.38 | $0.96 | $4.95 | 1 | $6.38 |
| 6 | STEEL BAR | McMaster | 8910K949 | Steel | $7.41 | $0.00 | - | 1 | $7.41 |
| 7 | Ring-Grip Push-Button Quick-Release Pin | McMaster | 92384A016 | Steel | $23.50 | $0.00 | - | 1 | $23.50 |
| 8 | | | | | | | | | $0.00 |
| 9 | | | | | | | | | $0.00 |
| 10 | | | | | | | | | $0.00 |
| 12 | | | | | | | | | $0.00 |
| 13 | | | | | | | | | $0.00 |
| 14 | | | | | | | | | $0.00 |
| 16 | | | | | | | | | $0.00 |
| Total: | | | | | | | | | $150.24 |

Table 5. Bill of Materials

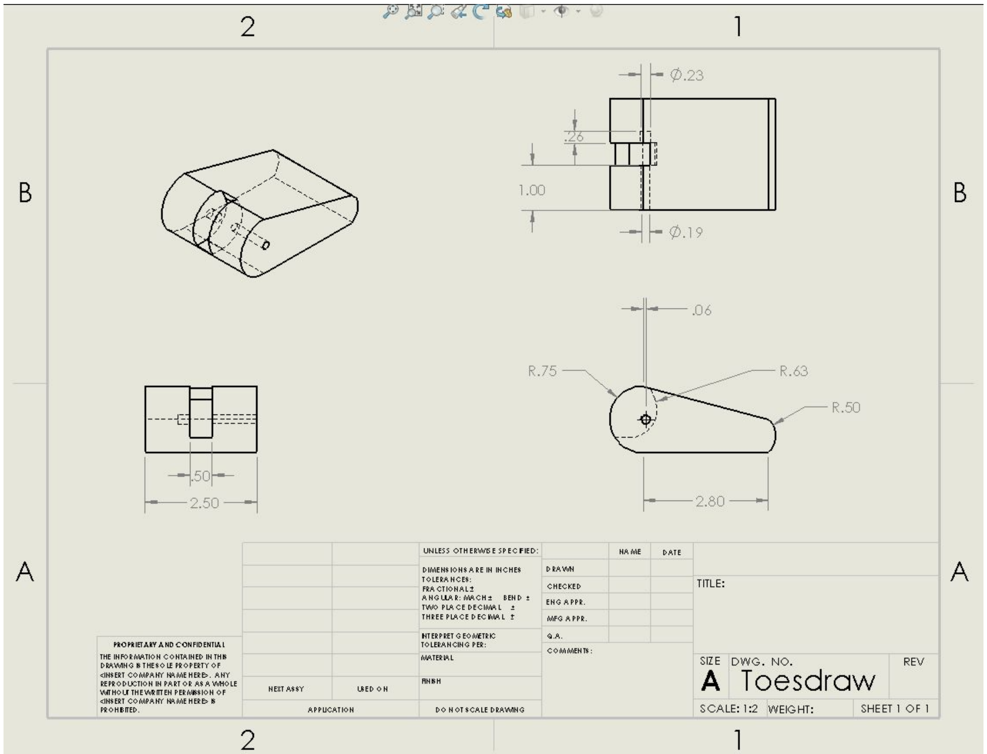



Figure 14: Drawing of Toe Section

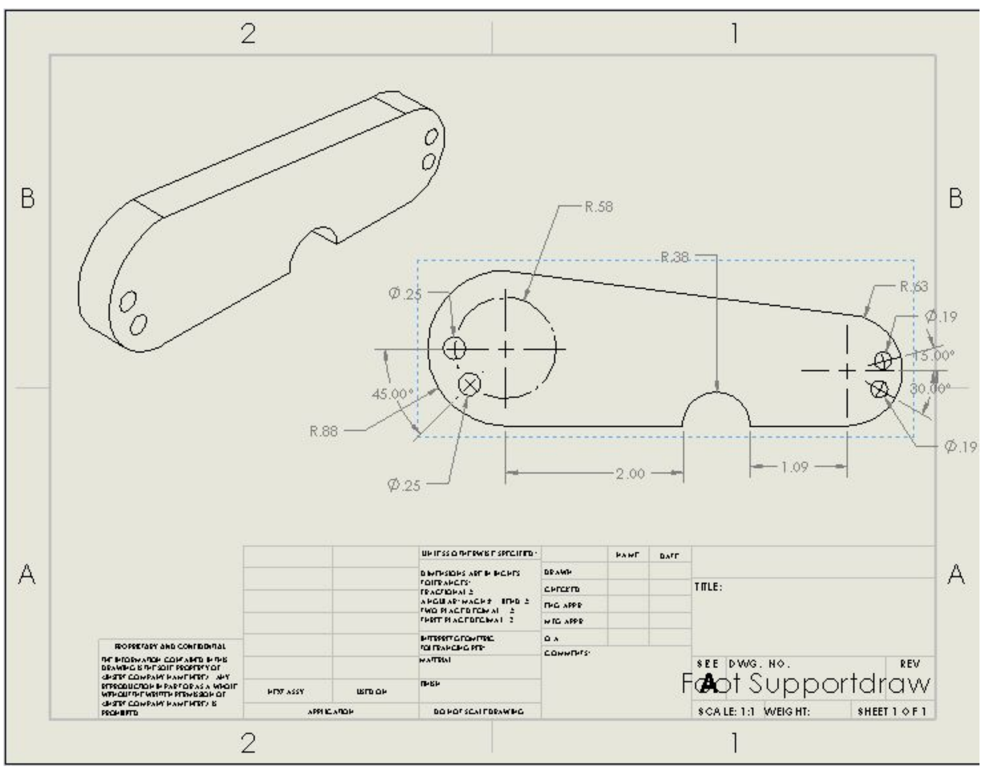



Figure 15: Drawing of Steel Mid Foot Support

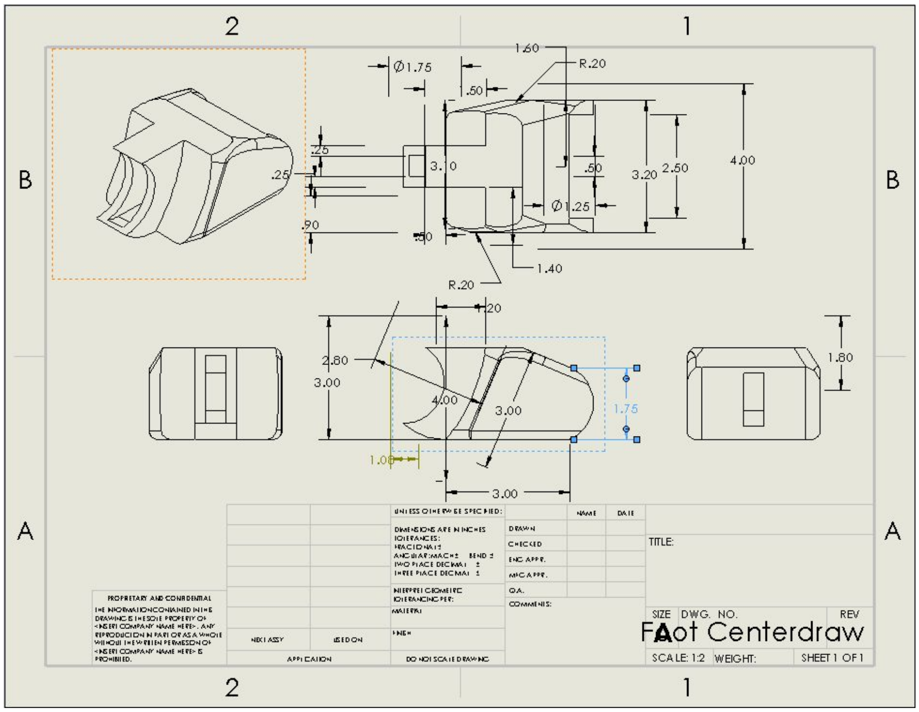


Figure 16: Drawing of 3D Printed Foot Center

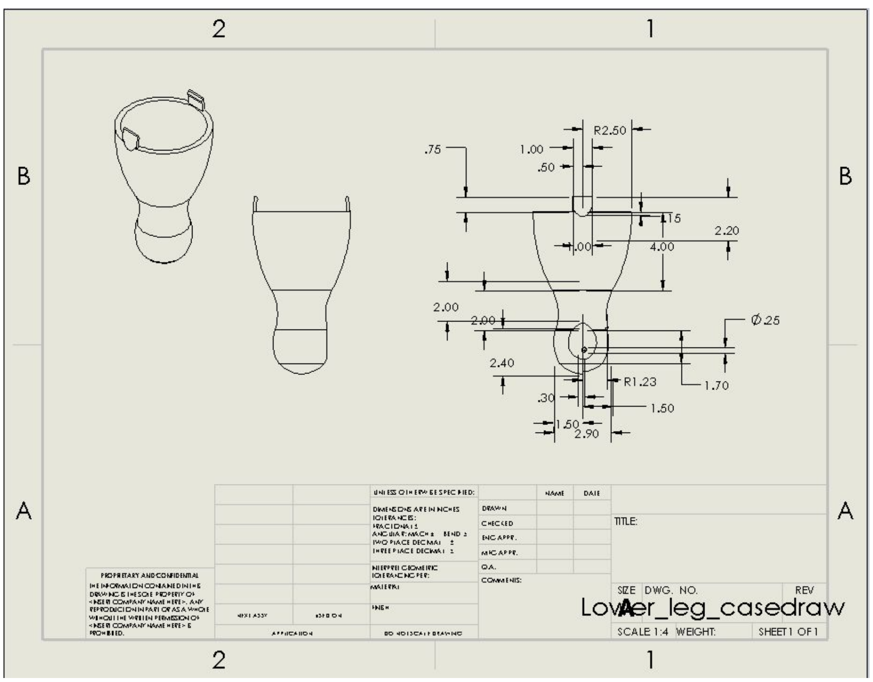


Figure 17: Drawing of Lower Leg Casing

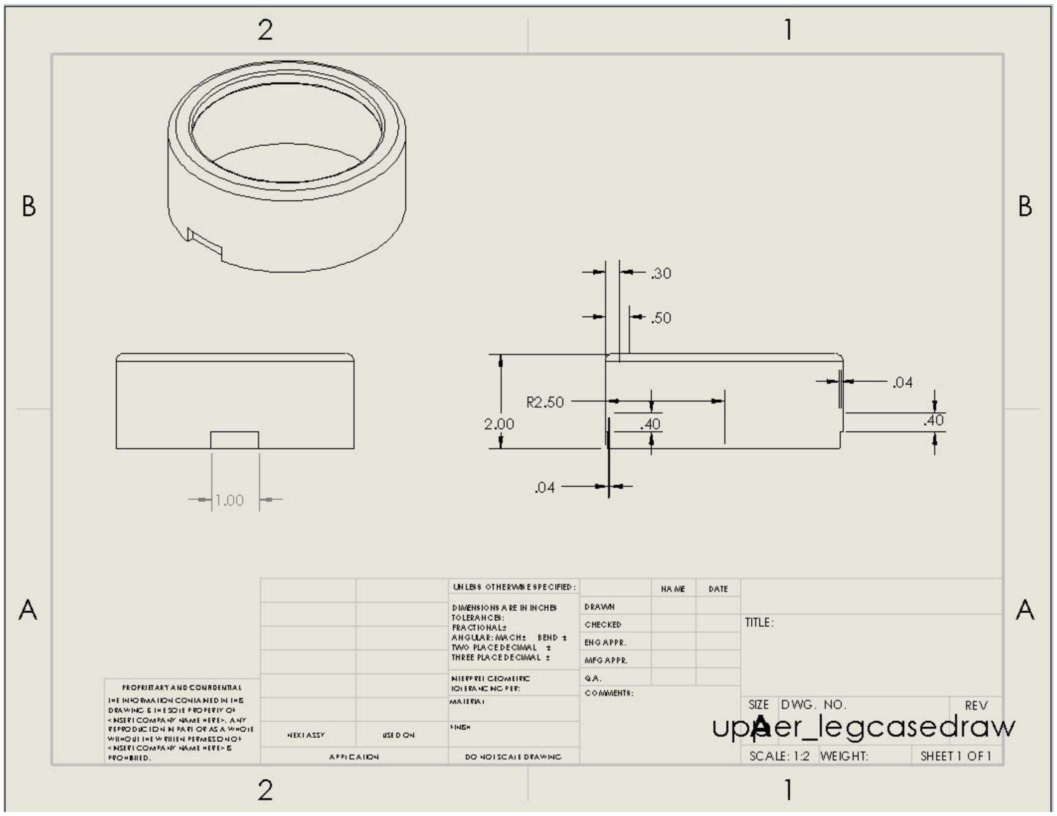



Figure 18: Drawing of Upper Leg Casing

## 5.2 Exploded View

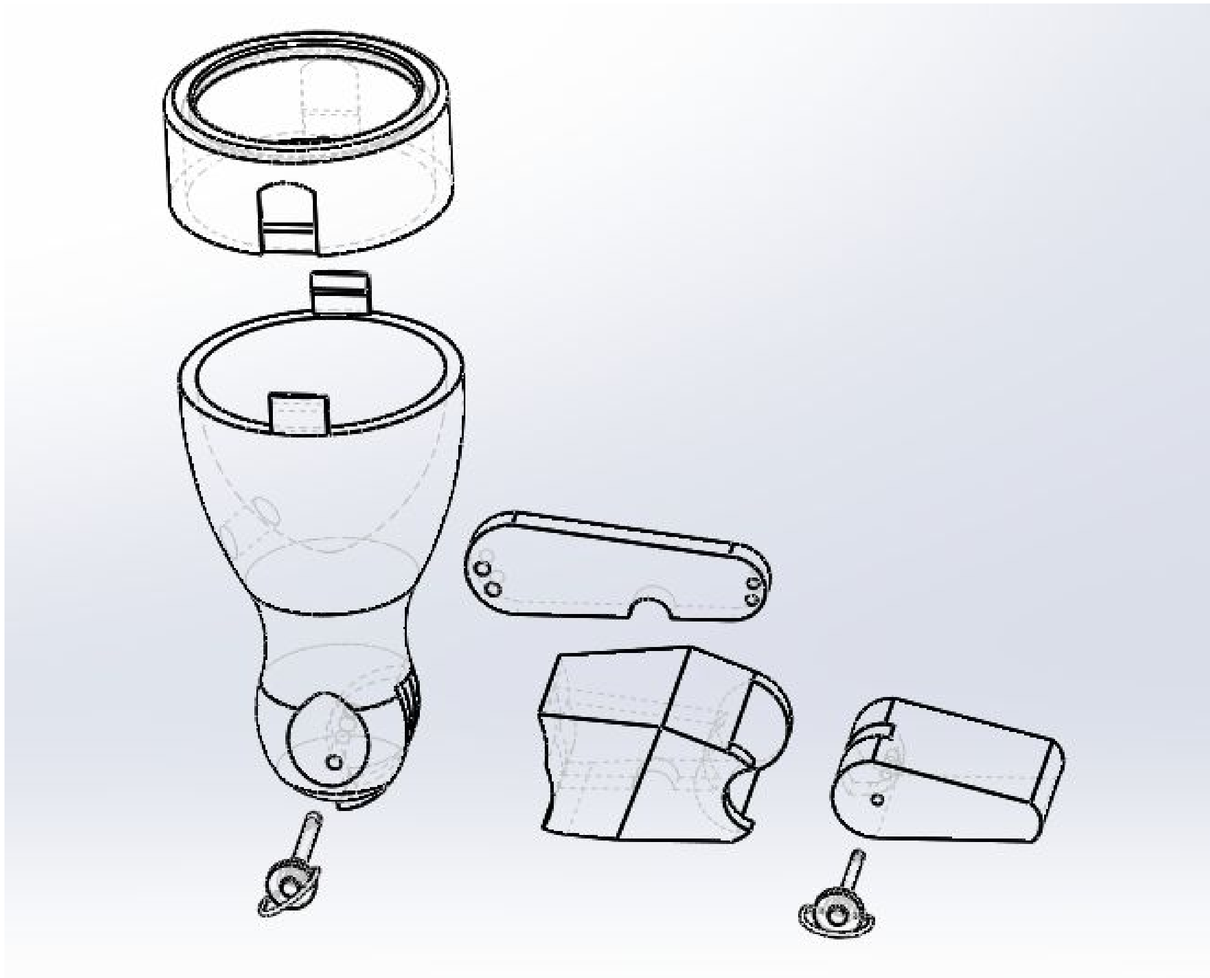


Figure 19: Exploded View of Design in SolidWorks

### 5.3 Additional Views

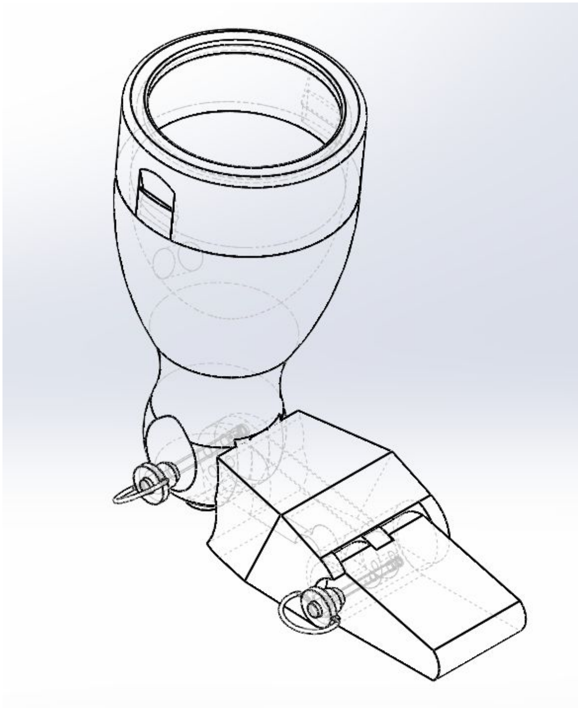


Figure 20: Isometric View of Design

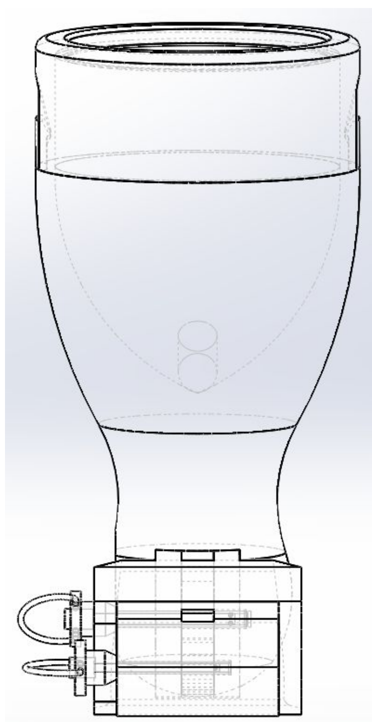


Figure 21: Front View of Design

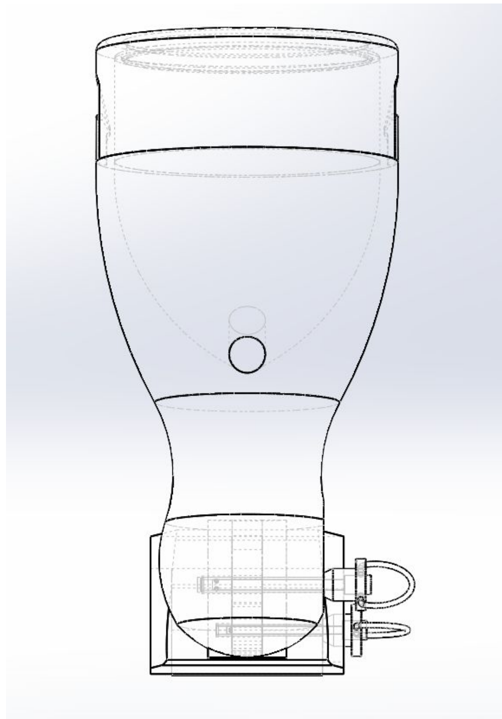


Figure 22: Rear View of Design

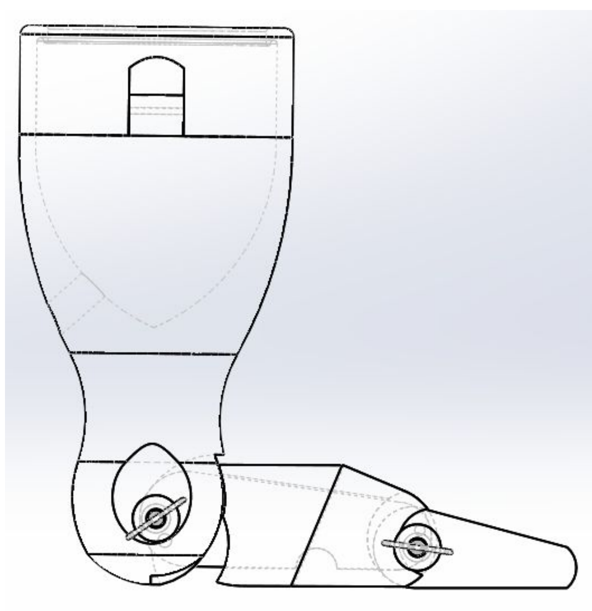


Figure 23: Side View of Design

# 6 Engineering Analysis

## 6.1 Engineering Analysis Results

### 6.1.1 Motivation

As there are no codes or standards directly relating to 3D printed prosthetics yet, our group mainly focused on designing a leg that could stand up to the forces a user would typically apply to it. By using SolidWorks Motion, our CAD model did not have to be exported or tweaked at all from the design to analysis phase, which minimized the risk for error creeping in. We focused on running static load tests on the leg, as that was deemed the most likely cause for failure of the leg of all the design goals we settled on. From these tests and the design goals themselves, we expect to have a rough idea of how the actual load test will run once the leg has been fully completed. Additionally, we can see where the stresses are concentrating and whether any changes to the model need to be made before printing.

### 6.1.2 Summary Statement of the Analysis

A Solidworks simulation was performed to the model where the maximum stresses would occur on the prosthetic when a load is applied. For this simulation the load used was 200 lbs from our performance goals and Von Mises stress around the device can be seen in Figure 24. Hand calculations were also done to determine the maximum load the ankle of the lower casing could withstand if the user were to trip. This was done by modeling the leg as a rod under bending. A simplified model of the bending test can be seen in Figure 25. Equation 1 was used to find the maximum force (F) and a length (L) of 5 m was assumed due to the irregular shape of the casing and PLA has a flexural strength (σ) of 48-110 MPA.

$$\sigma = \frac{FL}{\pi R^3} \qquad \text{EQUATION 1}$$

| Name | Type | Min | Max |
|---|---|---|---|
| Stress1 | VON: von Mises Stress | 0.000e+000N/m^2<br>Node: 18706 | 2.606e+006N/m^2<br>Node: 6434 |

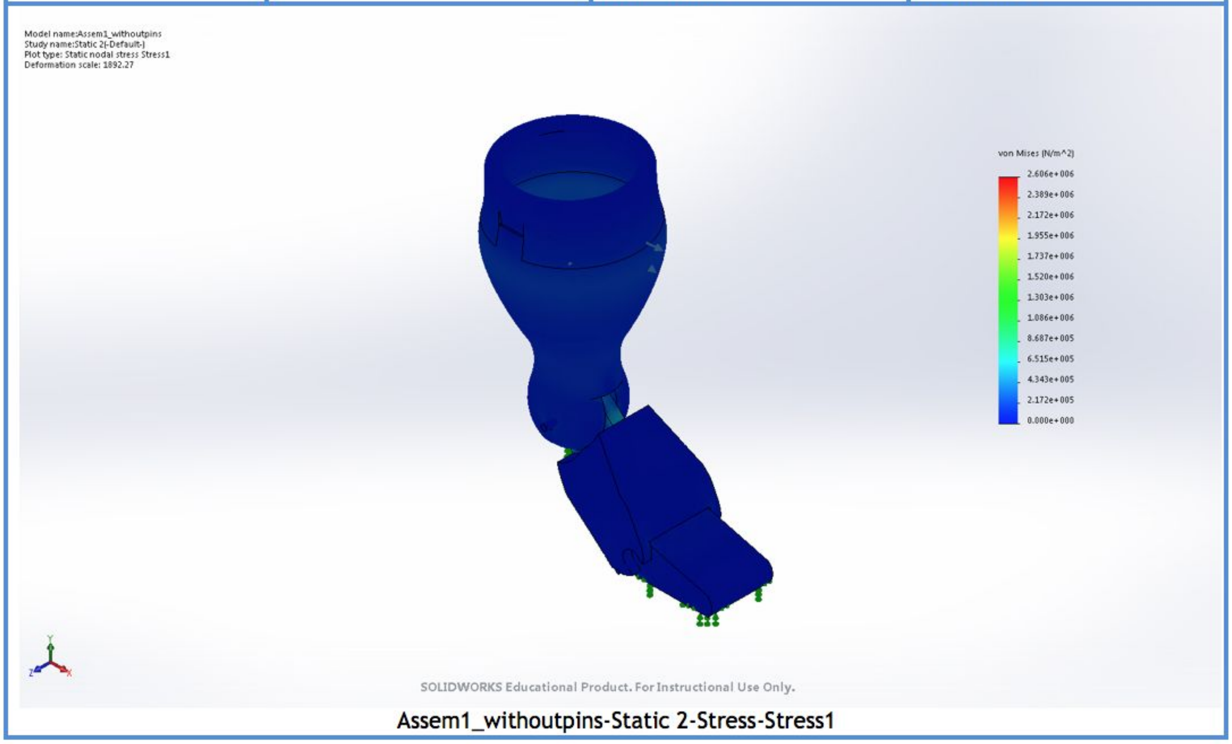



Figure 24: Von Mises Stresses on Prosthetic with 200 lb Load Applied

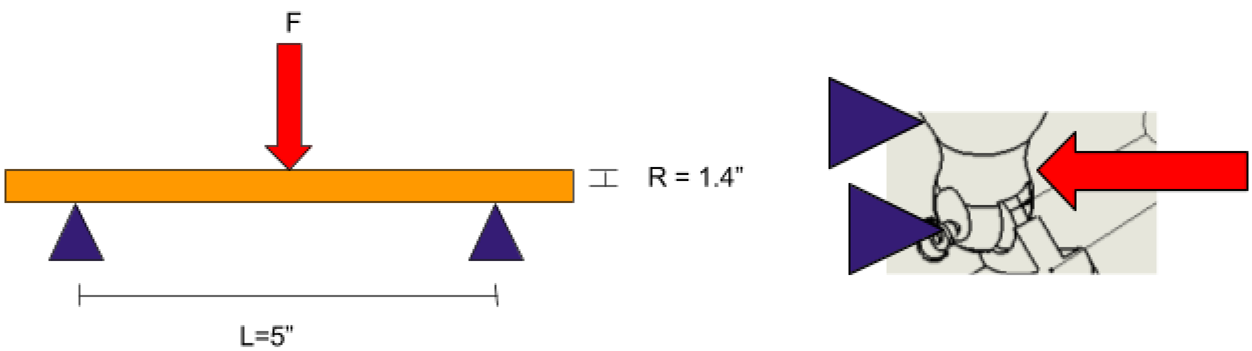



Figure 25: Simplified Model to Represent Force on Ankle during a Fall

### 6.1.3 Methodology

The analysis was performed in SolidWorks Motion without any real world experimentation. The model was imported into the motion software without any conversion or modification from the original, and a 200 pound load was applied to the interior of the prosthetic. Some difficulties arose from the type of load which SolidWorks could apply however, as simulating a leg as a point load or distributed load both fall short of reality. The 200 pounds we were testing for should have been applied across a certain area along the bottom portion of the interface, but SolidWorks limited us to either applying the load to all points of the interior interface wall or upon a certain point in the interface. In the first case, finding an equivalent load for that area was difficult and ultimately inaccurate because of the increased area when compared to the real world. When a leg is inserted into the real prosthetic, hardly any load will be distributed across the side walls, yet SolidWorks deemed those as having equal force to the bottom portion. Applying the load as a point would have resulted in an even worse simulation though, since a leg is closer to a distributed load than a point load. In the end, we went with applying a distributed 200 pound load across the interface knowing the results would not be a perfect reflection of how the leg will actually perform.

### 6.1.4 Results

From the load simulation it is found that the maximum stress in on the metal plate in the center of the foot and the pins attached to it. Although the Solidworks models of the pins would not work in the simulation so they were modeled at rods and may have not properly displayed deformation since the pins are hollow. Figure 24 shows an exaggerated view of the model's deformation, and actual variances in the structure under a 200 lbs. load are miniscule.

The hand calculations determined that the ankle in 3 point bending should be able to support a maximum force between 9565 and 24663 lbs. This result seems extremely high and is probably due to the assumption that the part will have a 100% infill, maximizing the part's density and weight. While 100% infill was used for this first prototype, future versions would more than likely have closer to 50% infill, making it structurally weaker but still more than capable of supporting 200 lbs. Additional error comes from the simplifications needed to do such quick calculations. This model will not experience a perfect 3-point bend, and the more complicated geometry will serve to alter expected loads even more so. This is why the results from a computer simulation like SolidWorks is more trusted than back of the envelope calculations.

### 6.1.5 Significance

The results of this analysis confirmed to us that our prototype is suitable and will surpass our design goals easily. While bowing in the lower leg casing did occur, the amount and associated load led us to believe that with 100% infill, the casing should maintain its integrity. There were ideas of reducing the infill before this analysis, but with these results showing that the lower leg is the most at risk of failure, minimizing that possibility with (arguably) excessive infill became an obvious solution. The stress concentrations in the metal bar within the midfoot suggest that a strong material be used, so the decision between aluminum and steel became an obvious choice for steel, at least for the final prototype. As the group would rather have an intact, over engineered final product than something that is at risk of breaking with the slightest over loading, steel will be used. It is both readily available and the toughest material we have on hand for the prototype.

## 6.2 Product Risk Assessment

### 6.2.1 Risk Identification

1) Risk Name: Prosthetic Leg Breaks

   Description: A large load is applied due to heavier person. The PL needs to stand several cycles, as the person is going to be walking on it and with each step the load is applied.

   Impact: 4 - If the prosthetic leg were to break while walking on it, the amputee might fall and get injured. Most likely the PL would start to crack before completely breaking however.

   Likelihood: 2 - After doing the load testing during the Prototype Demo, we can confidently say that our design can withstand a force much greater than necessary.

2) Risk Name: Leg Detaches from PL

   Description: Leg stump comes out of the silicon due to the vacuum not being sealed well enough

   Impact: 3 - It would not be fun if the leg detaches, however, it could be reattached quite easily. If it keeps coming off the silicon mold might be adjusted.

   Likelihood: 3 - If the PL is subject to a larger tensile force, then there is a possibility the leg would detach. However, it is assumed that this would only be an issue during specific weather and environmental conditions such as excessive mud or heavy rain. Further field testing of the leg would need to be done to verify these assumptions. In addition, if the PL would be redesigned to be less dense, making it lighter overall, then the likelihood of it slipping off of its own accord becomes even less likely.

3) Risk Name: Slipping

   Description: Bottom of Prosthetic Leg might slide against certain surfaces that have low friction and wet.

   Impact: 3 - Slipping is always a concern for people on certain surfaces. The fact the bottom is made of plastic and is so stiff might increase the risk of slipping however.

   Likelihood: 3 - Slipping on surfaces like ice, leaves on a sidewalk, and other low-friction surfaces is certainly within the realm of possibility. It happens to people with two legs all the time, and replacing one with a prosthetic only makes staying upright even harder.

4) Risk Name: Pins Getting Stuck

   Description: Pins on side of foot could get stuck on something external to the PL such as shoe laces, edges or pieces of clothing.

Impact: 2 - You can always get stuck in something, however the pins might get stuck which could result in falling.

Likelihood: 2 - This is not very likely since the foot is designed to have the pins sticking out the least amount possible, thus resulting in a lower risk of this happening.

5) Risk Name: Watering Entering Joints

Description: On rainy days or if submerged in water, liquid could enter joints and make the metal parts deteriorate faster.

Impact: 2 - The water might get into the PL which would result in it getting slightly heavier, which would not have that big of an impact due to the already quite sturdy structure. The parts would deteriorate faster, however no sudden failure would occur without ample warning and time to replace the rusting part.

Likelihood: 4 - It is very likely that water would enter the joints if submerged in water, as seen in the prototype demo however, this would only be due to certain weather conditions and environments such as rainy days, pools, showers etc.

6) Risk Name: Deformation

Description: There is risk for deformation of the PLA, as the heat capacity is rather low. For example if exposed to sunlight through a window or in a car on a really hot day for a significant duration of time, the leg may begin to warp.

Impact: 3 - Having the leg deform would significantly impact the usability and longevity of the leg. While it may still work in the short term, a new leg will have to be made relatively soon afterwards in order to not warp it any further and risk it breaking while in use.

Likelihood: 1 - Unless the leg is stored in a significantly hot area (a black car on a hot sunny day), it will not have a chance to get hot enough to deform in daily use.

### 6.2.2 Risk Heat Map

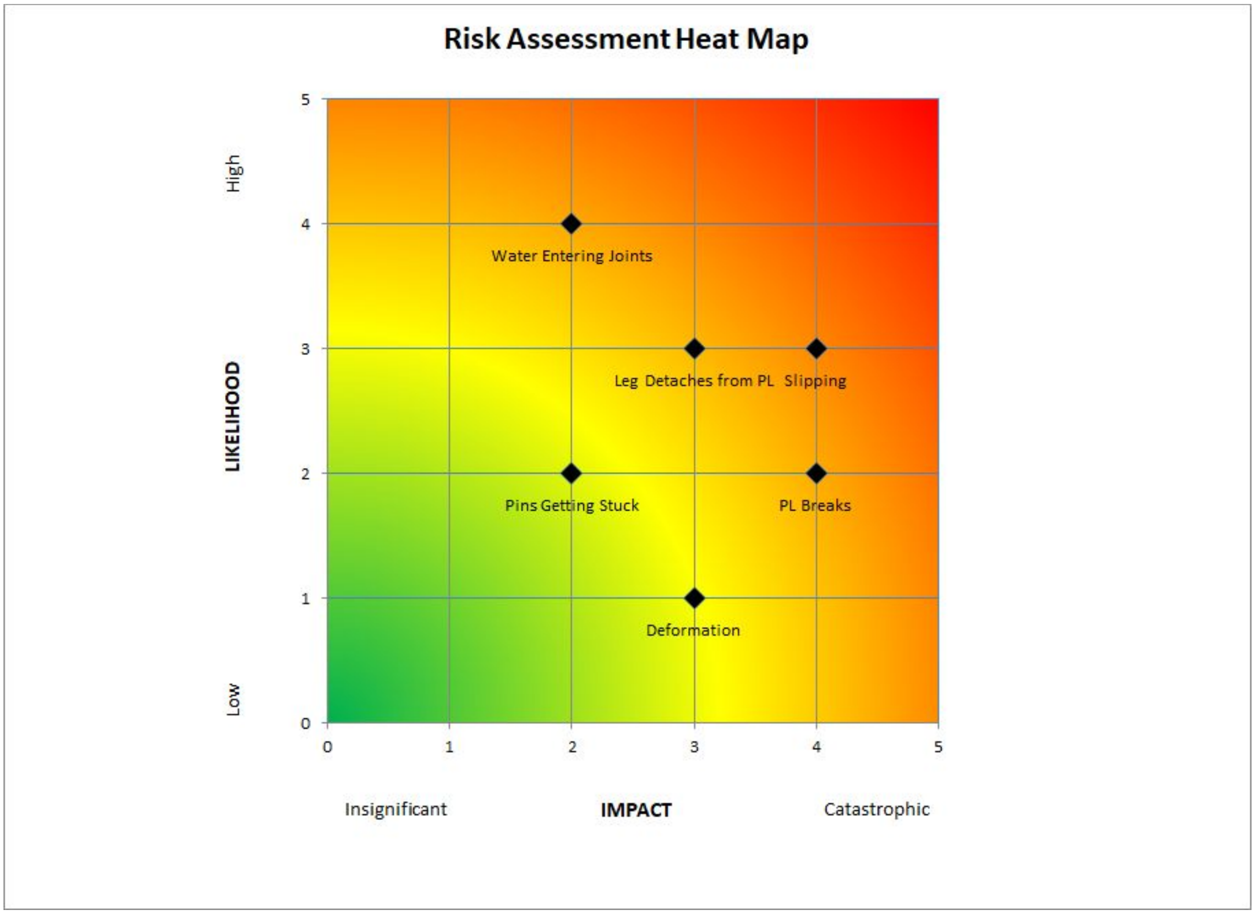



Figure 26: Risk Assessment Heat Map

### 6.2.3 Risk Prioritization

Based on the Risk Assessment, it's clear that the highest risk of this design is slipping. Since it is such a sudden and relatively harder to prevent accident, when it occurs, it is the most impactful overall. Without field testing however, it is hard to determine whether concern for slipping for this design is justified or not. The design process to alleviate this risk would be fairly straightforward (adding some non-stick material to the bottom of the toes should help immensely), but it cannot at this time be determined if those steps are needed.

Further risks to be wary of are water entering the joints, the leg detaching, and the leg breaking entirely. Steps to resolve the water issue have already been outlined, though as previously stated, the current lower leg design would need to be changed in order to most effectively make the prosthetic water resistant. While leg detachment will always be a problem, improving the vacuum seal would most directly counteract that issue. As for breaking, the leg has proven to be quite durable, so while it would be quite impactful were it to ever happen, it has been decided that no major redesigns need to be done with preventing breaking in mind.

# 7 Design Documentation

## 7.1 Performance Goals

1) Prosthetic Leg needs to be able to carry 200 lbs
2) Prosthetic Leg has adjustable foot settings
3) Prosthetic Leg can be submerged 1 foot in water
4) Prosthetic Leg will hold when jumping from a height of 1 foot
5) Prosthetic Leg can withstand a tensile stress of 25 lbs

## 7.2 Working Prototype Demonstration

### 7.2.1 Performance Evaluation

From the Prototype Demo the calculations from the stress analysis were confirmed as the Prosthetic Leg seemed to withstand the applied load of 200 lbs with grace. Additionally, when pulled on with a tensile force of 25 lbs, the leg stuck to the prosthetic. The Prosthetic Leg ended up having two settings in which the foot can be placed in, one having it be flat and the other in a position allowing high heeled shoes to be worn. The leg failed to remain dry after 3 minutes submerged in 8 inches of water, which while unfortunate, is not the largest concern, as water resistance was the part on which the team focused the least on. Water resistance is something that can easily be improved with more time and materials, making it a superfluous aspect to the overall design. Unfortunately, the team failed to come up with a way to safely and securely evaluate performance goal number 4. It is with great confidence however, it can be assumed that the prosthetic would be able to withstand this load after seeing it withstand the other load evaluations as well as it did.

### 7.2.2 Working Prototype – Video Link

Video detailing the leg and the design goals chosen:
https://www.youtube.com/watch?v=0ELoelXDRwY&feature=youtu.be

Video showing testing of the Prosthetic:
https://www.youtube.com/watch?v=RO02nJ9JiIg

### 7.2.3 Working Prototype – Additional Photos

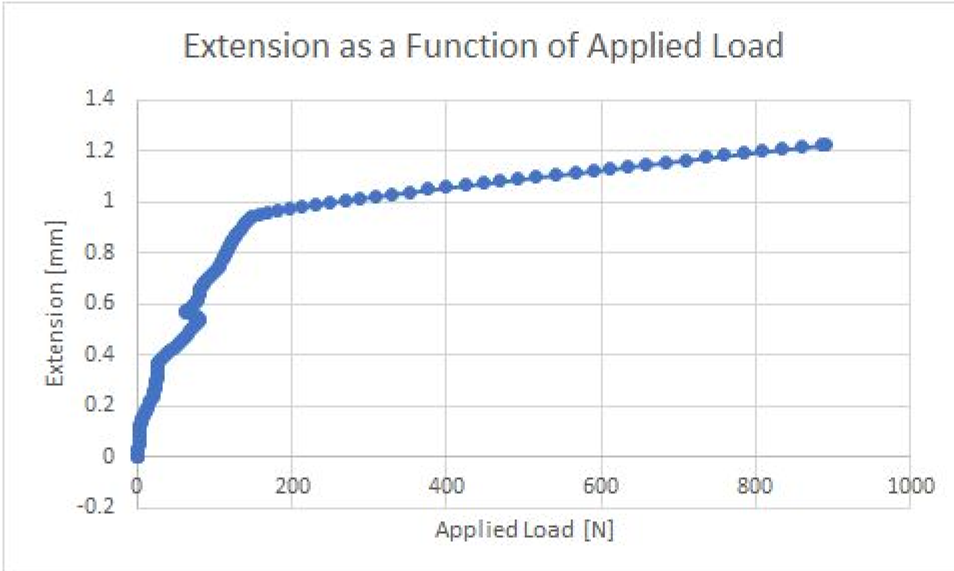



Figure 27: Results from applying 200 lbs to the top of the Prosthetic Leg

Figure 28: Isometric View of Prototype

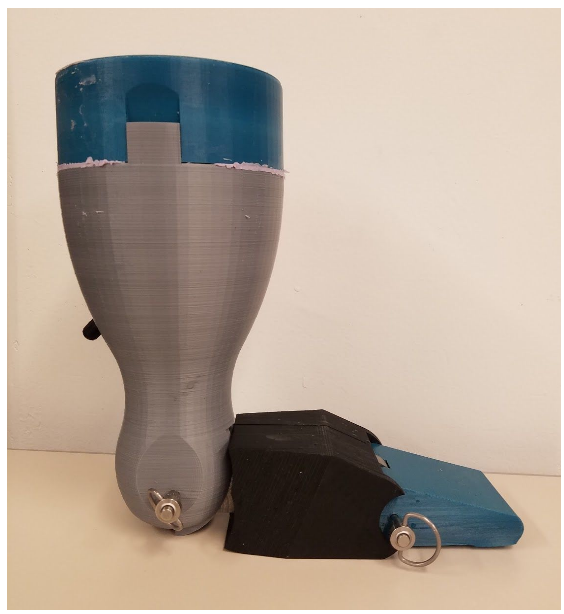


Figure 29: Side View of Prototype

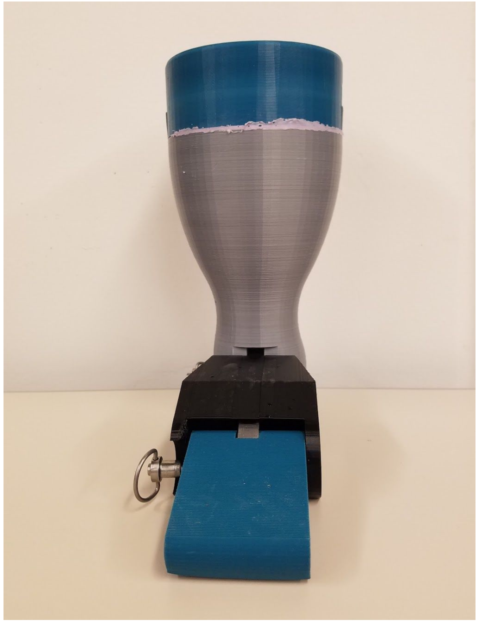


Figure 30: Front View of Prototype

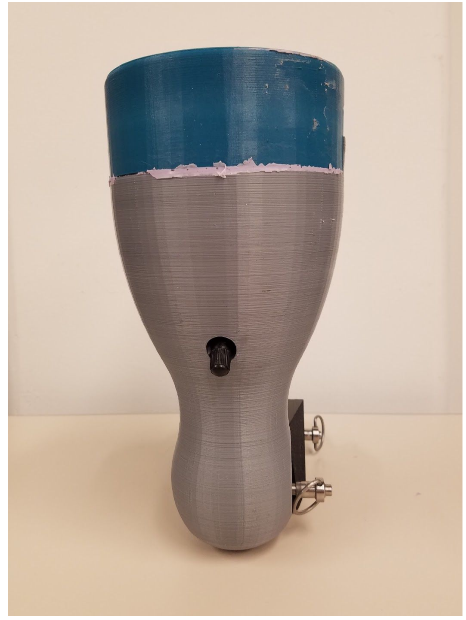
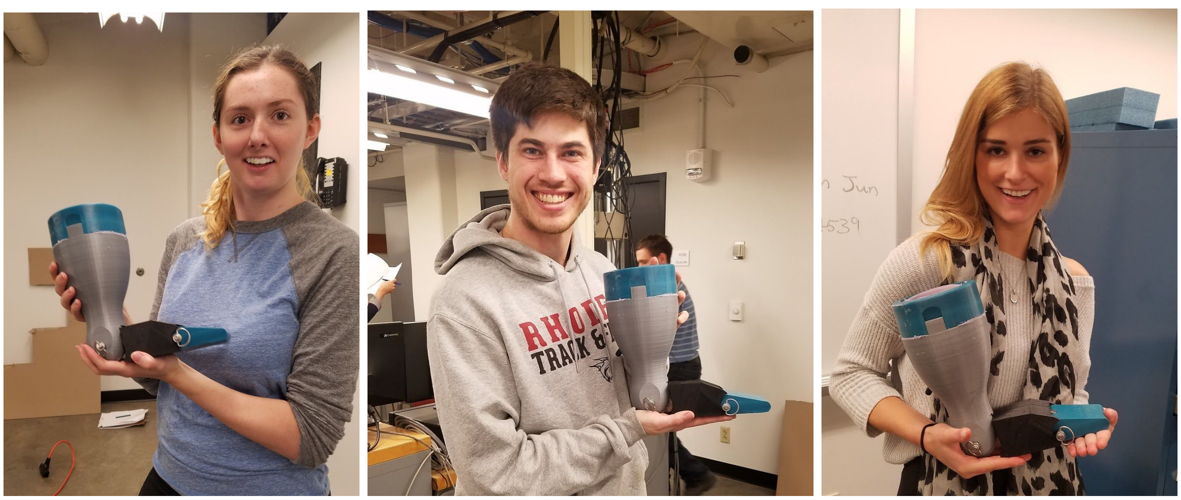


Figure 31: Rear View of Prototype

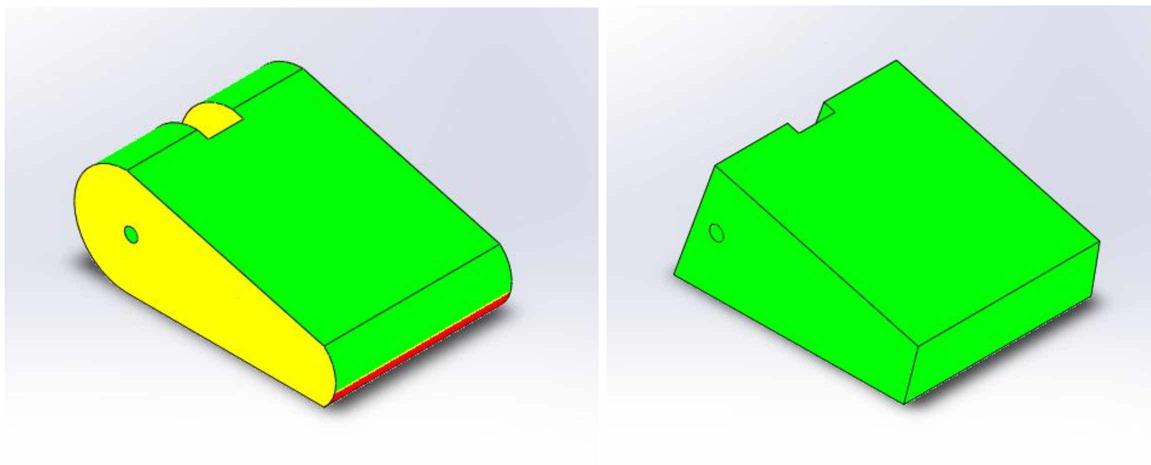


Figures 32, 33 & 34. All Team Members Posing with the Prosthetic Leg

# 8 Discussion

## 8.1 Design for Manufacturing – Part Redesign for Injection Molding

### 8.1.1 Draft Analysis Results



**BEFORE** **AFTER**


Figure 35: Results of Draft Analysis of Prosthetic Toe Block in SolidWorks

To simulate the steps needed to prepare our design for mass production, we analyzed our toes to see what modifications would be needed to make it easier to produce. Using the top face as the draft direction, the two side faces and curved sides lit up as places which needed drafting. Additionally, the two small faces in the slot connecting to the midfoot would have to have sloped sides as well. A 3 degree drafting was added, and the After picture shows the results. While easier to produce and circulate, the drafted toes lose a significant portion of its aesthetic design and ergonomics. It would be significantly harder for a user to walk around with the new toes, which is a big factor in whether the prosthetic is a success or not. In the end, no drafting was done as it was determined that no mass production of the prosthetic leg would ever happen.

### 8.1.2 Explanation of Design Changes

Our device could not realistic be mass produced and there is not a need for it to be. Although the foot pieces are removable and only have to follow standard foot sizes many of the same could be made. It is possible to make a few standard casing sizes since the silicone mold inside allows for the length of the leg to be adjust, but by doing this the prosthetic would not be as fitted and making it less appealing. Another reason this could not be done is that the weight of the leg would need to be lightened and by 3D printing it allows for the fill of the print to be adjusted, so to get it any lighter a new material other than PLA would have to be used for injection molding.

## 8.2 Design for Usability – Effect of Impairments on Usability

### 8.2.1 Vision

If a user has vision impairment it may make changing the position of the foot harder. On the foot there are markers on the heel of the lower casting and back of the center of the foot that when aligned allow the pin to be pushed through locking the position of the foot. These markers are also on the front of the center of the foot and toes as well. This could potentially be solved in further designs by having the edge of the movable parts be closer and on the same plane, that way if the alignment markers are small ridges it can be felt when the 2 markers match up.

### 8.2.2 Hearing

If the prosthetic was to start experiencing fatigue or wear, it may be expected to hear some cracking of plastic as the layers of the 3D print start to pull away from each other. Without this early warning, users are at more risk of experience a total leg failure during day to day use. However, with the prosthetic being as mobile as it is, coupled with the fact that users will use the leg hundreds if not thousands of times a day as they walk around, it is reasonable to assume that the tactile response of that early onset fatigue would be equally noticeable. So long as users are cognizant of how their leg is working from step to step, it should be

### 8.2.3 Physical

The device is specifically created for people with partial leg loss, however is the customer has other impairments that limit the use of their hands then the device would be much harder to use. Currently the use of 2 hands is required to change the position of the foot and open the air valve, although not much force should be needed to do either.

### 8.2.4 Language

There is nothing written on our device, so language should not have an effect on the use of the prosthetic. Also how to use it can be quickly demonstrated to the consumer, a lengthy manual is not required.

## 8.3 Overall Experience

### 8.3.1 Does your final project result align with the initial project description?

The final project did align with our initial project description of our 3D printed prosthetic leg. We were able to create a posable leg from materials under $500 that could be set in different positions.

### 8.3.2 Was the project more or less difficult than you had expected?

This project was less difficult than anticipated. Once the CAD model was finished we were able to get the parts printed relatively quickly. The most difficult was trying to figure out how to make a cover for the prosthetic so that the metal parts would not get wet.

#### 8.3.3 In what ways do you wish your final prototype would have performed better?

We wish it could have repeatedly been able to attach and hold onto the leg, but the leg was damaged when it was first removed. Also it would have been nice to have had a waterproof sock because the support in the center foot piece can rust. However due to the value on the back of the prosthetic and the hook and loops strap on the sock being too short the sock filled with water.

#### 8.3.4 Was your group missing any critical information when you evaluated concepts?

One piece of critical information was missing, which was the maximum weight a prosthetic of this size should weigh. This caused our prototype to be very heavy.

#### 8.3.5 Were there additional engineering analyses that could have helped guide your design?

Knowing the weight of each part, as well as the exact properties of the PLA used could have resulted in a more accurate analysis. For instance, knowing the strength of the PLA with different printing densities, in order to minimize weight while still withstanding the applied load. In addition the quite substantial weight could have been reduced by keeping this in mind. Making a more lightweight prosthetic could be part of our future goals.

In order to create a prosthetic that will last long, cycling of the load could have been included. This analysis could have been done theoretically, however trying to test it in order to cover a lot of cycles would have taken longer than what was within the scope of our project.

#### 8.3.6 How did you identify your most relevant codes and standards and how they influence revision of the design?

Multiple meetings were had with Lauren Todd and other librarians at Washington University and during this process, few codes and standards were identified that were directly relevant to this project. Identifying the codes we did find however was made relatively easy due to the abundance of resources available to us. Thankfully, the codes didn't limit the designs we had already made, but served as boundaries for ideas we had later on in the design process.

#### 8.3.7 What ethical considerations (from the Engineering Ethics and Design for Environment seminar) are relevant to your device? How could these considerations be addressed?

One of the reasons PLA was used for the majority of the design is that it is a biodegradable thermoplastic, making manufacturing of the product have less of an effect on the environment. Other ethical considerations would have to do with making sure the device is safe before being put on the market. For example, if it were to be found out that the Prosthetic Leg would fail after a certain amount of cycles under an applied load, this would have to be dealt with before moving along in the manufacturing process.

### 8.3.8 On which part(s) of the design process should your group have spent more time? Which parts required less time?

More time should have been spent on the concept designs because there were some concepts that were not thought out enough and required more time later on to get them to work. This is especially true for the prosthetic waterproof covering.

### 8.3.9 Was there a task on your Gantt chart that was much harder than expected? Were there any that were much easier?

Creating the final 3D model for the prosthetic was much more arduous than initially expected, mostly due to the fact that it was the main crux of the project. While it did get done with plenty of time, it still took longer than expected. Everything after printing was easier than expected due to the work put in before printing to make sure the initial model would stand up to the design requirements and no modifications would be necessary.

### 8.3.10 Was there a component of your prototype that was significantly easier or harder to make/assemble than you expected?

Making the silicone insert mold was a little bit harder than anticipated because we had to create a support system to hold the leg and prosthetic upright while the mold was setting.

### 8.3.11 If your budget were increased to 10x its original amount, would your approach have changed? If so, in what specific ways?

By increasing the budget it would only allow for use to make more prototypes and test different valves for the leg interface. We would not need it to buy more expensive material since it was desired to keep the cost as low as possible.

### 8.3.12 If you were able to take the course again with the same project and group, what would you have done differently the second time around?

Reducing the infills of the printed parts to at least 75% if not down to 50% would have saved material, cut costs, and streamlined the printing process drastically. The model was well designed, it was just over-engineered.

### 8.3.13 Were your team member's skills complementary?

Our skills worked quite well with each other. We all brought different skill sets which meshed well and allowed us to work at our fullest potential.

### 8.3.14 Was any needed skill missing from the group?

The machining that was done on the steel part was outside of what any group members had the skills or knowledge to do. The machine shop manager helped out with the programming and machining that was done in creating the steel part.

#### 8.3.15 Has the project enhanced your design skills?

All team members got more familiarized with the CAD software Solidworks, as small issues were run into during the initial design decisions of the parts. Being able to assemble the parts without interferences was harder than either of us had expected, however the team worked long and hard together to figure it out as best possible.

#### 8.3.16 Would you now feel more comfortable accepting a design project assignment at a job?

We all feel much more capable of taking on design projects in the future and are confident that any design job given to us can be done easily and efficiently.

#### 8.3.17 Are there projects you would attempt now that you would not have attempted before?

None of us had experience 3D printing before this project, but now we have a working knowledge of the process and can look to create more advanced designs in the future.

# 9 Appendix A - Parts List

| Part | Dimensions (Diameter x Length) | Supplier | Supplier Part Number |
|---|---|---|---|
| Knob-Grip Push-Button Quick-Release Pin | .25” x 1.75” | McMaster Carr | 90985A129 |
| Ring-Grip Push-Button Quick-Release Pin | .1875” x 1.5” | McMaster Carr | 92384A016 |

# 10 Appendix C - CAD Models

See Figures 19-23

# 11 Annotated Bibliography

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