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# Collapsible Prosthetic Shower Leg

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# Collapsible Prosthetic Shower Leg

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# Design Report

Capstone Project: Collapsible Prosthetic Shower Leg

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*Abstract:* The purpose of this capstone project is to build a collapsible prosthetic shower leg that can provide a transtibial amputee with reliable support while showering. Phil Tamoush, an 83-year old transtibial amputee, was the inspiration for this work. Phil's constant travel for his arbitration work leaves him without the option to bring along his usual shower leg due to the additional space it takes up in his travel bag. There are currently no commercially available prosthetic shower legs that can collapse into a condensed unit, so this capstone project explores an unexplored field for which there is a significant need. The current prosthesis prototype hosts the residual limb in a cone-shaped socket and straps to the thigh using a modified knee brace for primary support. The pylon utilizes a telescoping mechanism to adjust two rods which allow for customization based on the user's height. Ultimately, the universality incorporated into various aspects of the prosthesis shall allow for accommodation of various transtibial amputees.

Table of Contents

# 1. Design

a. <u>Objective</u>

The objective of this project is to create a collapsible prosthetic shower leg for use by transtibial amputees. Since traditional prostheses are bulky and usually not waterproof, they are not ideal for travel. A successful design will allow the user to easily transport their shower leg and remain stable in the shower while allowing for a free range of motion to clean the rest of the body. The goals for this project are to create a leg that can support 200 pounds and collapse to fit into a compact case that can be easily transported during travel. Secondary objectives are for the overall weight to be below five pounds, for assembly to take less than two minutes, for the foot to be non-slip, and for the construction to be primarily plastic to avoid rust or wear from prolonged exposure to humidity.

b. <u>Background</u>

Prosthetics are essential for humans with amputated or missing limbs to ensure a smooth integration or reintegration into normal life. Though archeologically proven to have existed as early as 700 BCE, hinged prosthetics are a relatively newer invention dating back to the 1600s.[1] Since then, the prosthetics industry has grown to be a 5.93 billion dollar industry. [1] This has made modern-day prosthetics boast a plethora of mechanical technology that can be very customizable to an individual. This also makes prosthetics and orthotics exceptionally expensive, which makes access to such prostheses difficult. Besides the cost alone of the prosthetics, the reliability of these parts can be seriously inhibited by unfavorable conditions; being especially sensitive to moisture. This has made showering difficult for leg amputees being that they would need to support themselves on something externally while washing the affected limb. The risk of injury from a fall in the shower is increased when one does not have support in the shower whether amputee or not, so it is the task of this project to design a portable and collapsible prosthetic leg for transtibial amputees to use in the shower which allows for hassle-free access to the body.

For reference purposes, articles were found who studied the interaction between the socket and amputee's affected limb [2]. These results will factor into the design process of the prosthetic with optimal comfort and breathability for the user as a design requirement. Being that one of the objectives of this project is optimal comfort, the team chose a stiff leg design for simplicity and the least amount of dynamic adverse reaction forces from an articulating joint. Considering the use of the prosthesis is exclusive to the shower, a fully articulating joint would lead to a higher degree of complexity in meeting a cost-effectiveness objective.

To successfully design the prosthetic and collapsible mechanisms an iterative process will be used in conjunction with 3D printing. When the leg's collapsibility dimensional requirements are met and the fea simulations run, the final materials will be chosen. Finally, a prototype will be fabricated with the final materials and the design will be tested in compressive strength tests to find the optimal performance loading and identify the range of loads the assembly is capable of holding. If further iterations are needed the process can be repeated or the final prototype can be modified.

c. Prior Work

This project has had no design, fabrication, or testing completed prior to the 2020-2021 academic year. There are, however, a few prosthetic options specifically for showering. One alternative prosthesis is the Lytra prosthetic shower leg. The Lytra leg is made from three molded acrylic pieces that fit together to make an adjustable prosthetic [4]. The Lytra leg is an aesthetically pleasing and cheap option for shower legs, but it does not collapse into a portable travel size. Another showering option for amputees is to sit down on a shower chair. While this alternative provides stability and comfort, it takes away from the individual's mobility. Finally, some amputees opt to use a shower sleeve, which uses a waterproof material that secures to the prosthesis and keeps it dry during the shower. These sleeves can use a hand pump that creates an airtight seal to lock out the water. However, in order to form this vacuum seal, the latex material must be in tight contact with the skin, which may not be an option for some users depending on their type of amputation [5]. To date, there have been no publicly released collapsible prosthetic shower legs, so this capstone design project will be venturing into an unexposed field.

d. Design Specifications

The following design specifications, listed in Table 1, originated from conversations with Philip Tamoush, the transtibial amputee who has inspired this collapsible prosthetic shower leg project. While the original prototype will go to Phil, the ultimate aim is to create the leg to accommodate use by amputees of different sizes. ISO 22523: 2006 was identified as an applicable international standard for this project. This standard was acquired through the LMU Library, and it mentioned the requirements should be specified on a case-by-case basis with references to relevant scientific literature where applicable. In the case of the first priority design specification, strength, prosthetic pylons are often made of metal tubing which will almost always have more than a sufficient amount of strength to support the human body. The strength of the other components such as the clamp, socket, and foot will be verified with a compressive load test.

Table 1- Design Specifications

| Priority | Parameter | Requirement | Capability | Margin | Basis |
|---|---|---|---|---|---|
| 1 | Strength | Can support 200 lbs. with a safety factor of 2.5 | 400 lbs | -20% | Analysis |
| 2 | Securement to user (Fig. 1) | Ability to remain secured to user for at least 100 steps | Comply | Comply | Testing |
| 3 | Slip resistance- sole (Fig. 5) | Ability to maintain grip during shower | Comply | Comply | Testing (team) |
| 4 | Stability | Feels sturdy while showering and moving | Comply | Comply | Testing, Analysis |
| 5 | Water-resistant | Can undergo showering without degradation | Comply | Comply | By design (material) |
| 6 | Socket comfort (Fig. 2) | Leg use does not cause limb irritation or discomfort | Comply | Comply | Testing (Phil) |
| 7 | Collapsible height (Fig. 5) | <= 3.5 inches | 3 inches | 14.3% | By design |
| 8 | Weight | <= 5 lbs | 4 lbs | 20% | By design |
| 9 | Adjustable height (Fig. 3) | 10 inches <= h <= 16 inches | Comply | Comply | By design |
| 10 | Universal socket (Fig. 2) | Ability to fit limbs of different sizes in socket | Comply | Comply | By design |

e. Concept Development and Selection

With the design specification from Phil in mind, the team began concept development on the prosthesis. Bearing in mind the most important aspect from Phil's perspective, collapsibility became the focal point of the first design iterations. The group presented independent solutions to one another which appear in Appendix D (Figs. D-1 to D-4). Once a rough collapsibility method was produced from these ideas, the focus of the group was shifted to the suspension system. The team decided to have three upright panels which would attach to the leg using a comfortable strap that would stabilize the prosthesis onto an amputee's residual limb. The team again independently designed solutions to this and reported back with the results. The designs are referenced in the Appendix D (Figs. D-5 to D-7). With all of the designs laid out, a design matrix was made for the collapsibility and for the suspension independently as shown in the tables below.

Table 2- Design Matrix for Collapsibility

| Collapsability method | | | | |
|---|---|---|---|---|
| Appendix No. | D-1 | D-2 | D-3 | D-4 |
| Ease of Handing | 0 | - | - | + |
| Ease of Collapsability | 0 | 0 | 0 | + |
| Size when Collapsed | 0 | 0 | 0 | 0 |
| Weight | + | - | - | + |
| Manufacturing Ease | + | - | - | + |
| Pluses | 2 | 0 | 0 | 4 |
| Sames | 3 | 2 | 2 | 1 |
| Minuses | 0 | 3 | 3 | 0 |
| Net | 2 | -1 | -1 | 4 |
| Rank | 2 | 3 | 3 | 1 |
| Contiune? | yes | no | no | yes |

Table 3- Design Matrix for Suspension Method

| Suspension Method | | | | |
|---|---|---|---|---|
| Appendix No. | D-5 | D-6 | D-7 | D-8 |
| Ease of Handing | - | + | - | + |
| Surface area of leg covered | 0 | 0 | 0 | + |
| Size when Collapsed | + | - | + | + |
| Weight | + | - | + | + |
| Manufacturing Ease | + | - | + | + |
| Pluses | 3 | 1 | 3 | 5 |
| Sames | 1 | 1 | 1 | 0 |
| Minuses | 1 | 3 | 1 | 0 |
| Net | 2 | -2 | 2 | 5 |
| Rank | 2 | 3 | 2 | 1 |
| Contiune? | no | no | no | yes |

As seen from Tables 2 & 3, the collapsibility design evolved as a combination between the sketches shown by Figure D-1 and D-4, in Appendix D. In terms of suspension, the design iterated from Figures D-5 to D-7. The overall conceptual product is a leg that includes a thin thigh strap attached to the prosthetic leg via a pair of appropriately/adjustable lengthened vertical supports running from the lower thigh down to the knee.

At this stage of the design iteration, the interfacing for the socket to pylon are based on a bike seat clamp where a larger diameter tube is placed over a smaller diameter tube and is circumferentially tightened as the clamp tightens. A threaded approach with the pylon to foot design was studied to find how the part may shear depending on angled and non-angled loading conditions. Upon further inspection and prototyping of this system, this friction based locking mechanism was not going to be sufficient to hold the pylon to the bottom of the socket, so the team decided to go with two thumb screws instead in the place where the clamp would have been which run through the diameter of the pylon to ensure the pylon does not protrude through the bottom hole of the socket unintentionally.

With further discussion with Phil, the team also determined that the target size for the leg needed to be reduced. The new target size for the overall prosthetic falls between 10 inches and 16 inches from the bottom of foot to residual limb. This reduction was necessary being that the team had originally underestimated the average residual limb length.

A preliminary foot design was run through an FEA analysis and found to not perform as well as the team would have hoped. The original design was a threaded peg protruding out of a flat bottom semi ellipse design lined with slip-resistant rubber/lining material. This concept was replaced with the existing crutched tip design, but this proved challenging to ensure slip proofing liner existed on the bottom of the crutch tip. So the team landed on the current iteration which is a robust teardrop shape to mitigate the opportunity for the foot to catch at an angle which could cause the full assembly to slip out from under the user. Designed into the foot was an inset region that could accept a custom laser cut non-slip shoe rubber underneath to provide traction for the foot.

A proof of concept was created using 1.5 inch telescoping aluminum piping with 0.110 in thickness to simulate the pylon with guide holes drilled in for testing the button clip. A pipe clamp similar to a bike seat clamp was designed and machined from aluminum for a custom fit onto the socket to pylon interfacing. A quick release bolt system was implemented for easy breakdown of parts for storage.  A 5 vertical support system was 3D printed and secured with nuts and bolts as shown in.


Figure 2: 4/5 Prongs on Previous Socket

This proof of concept was presented to Phil at this time. The feedback received included having a mesh-based material or matrix in the socket to disperse loads away from the end of the residual limb, adapting the design to be more ergonomic with both knee shapes, and utilizing potential weight-bearing bone regions. This will also lead to more design considerations such as including another ratcheting strap higher above the knee of the user.

This then led the team to search for a better solution to the ratchet strap to the vertical supports. The team chose to use a velcro fastened knee brace with articulating angle vertical supports built-in which would then all slot and slide into the socket itself. These articulating vertical supports would allow the team to find the optimal angle of the final single-piece supports. The bottom of the knee brace was cut to Phil's particular need and would sit at the top of the socket. Another change in design would be decreasing the diameter of the pylons to reduce weight as the previous pylons proved to overperform what was needed for this project. The vertical supports from the original knee brace were measured and new ones of the same size and optimal angle would be created to also fit the profile of the socket and the brace.

f. <u>Description</u>

After a few iterations and tests using the previously proposed design for the socket, some changes were made to improve the safety of the design and reliability. During the delta CDR stage of the design, the plan was to use a socket and five or more vertical supports to hold the leg. The pylon would be held in place by a clamp that contracted the socket to provide friction. Through testing, it was determined that even using shims and other types of inserts, the clamp mechanism would not provide sufficient vertical securement for the design. Other major changes that were made include the vertical support system. Rather than having multiple smaller supports, two large supports are being used on each side of the leg. The final production ready design of the leg now has four main component groups which include the suspension, socket, pylon, and foot.

Beginning with the suspension, this system comprises three components: two vertical supports and the knee brace. The vertical supports are machined from 6061-T6 aluminum and are connected to both the socket and the brace. To ensure a comfortable standing position a 2.5 degree bend was added to match the natural bend of Phil's leg. A CAD model of the supports can be seen in Figure 3. The supports are adjustable and can move up and down on the socket which allows for the residual limb to be raised or lowered. Adjusting the height of the residual limb independently of the socket height is part of what makes the design adaptable to different amputees. A taller person with a shorter residual limb could move the vertical supports down while simultaneously extending the pylon. The second part of the suspension system is the knee brace which can be seen in Figure 4. A consumer, off-the-shelf brace was chosen due to the difficulty of fabricating a custom brace. Additionally, since the brace is from an off-the-shelf brand, the size can be changed to accommodate smaller or larger residual limbs as well. The brace is attached to the vertical supports by two pockets on the brace. The brace slides over the supports and is primarily held on by the circumferential force of the straps on the brace. One concern of Phil and the team was that when walking the brace may slip off of the vertical supports when lifted off the ground. To ensure that the brace stays attached two nylon button snaps were added. These snaps loop through the slot near the middle of the vertical supports and through the brace. The snaps also allow the brace to quickly be removed for travel or to dry.

The next major component in the design is the socket, this is also where the majority of the design work has been focused since the delta CDR revision of the product. The updated socket can be seen in Figure 5 and is the final version that will be delivered to Phil. The main purpose of the socket is to use the suspension and supports to transfer the user's weight to the pylon. In order to produce the complex geometry of the socket, seen in Figure 6, without advanced machining, additive manufacturing was used. It was decided to make the socket out of carbon-reinforced nylon 12 filament. Nylon was chosen due to its durability, abrasion resistance, high operating temperature, and the carbon fiber was added to improve strength and help reduce weight.

Figure 3- Suspension Supports Figure 4- Suspension Brace

Using 3D printing also helped to iterate the design and provide the ideal size for Phil. To initially verify the material, a test was performed in which samples were submerged for 24 hours. The results of the test showed a 13.6% strength decrease which was better than expected and better than other 3D printable filaments such as PLA. Moving on to functionality, to hold the suspension, the socket uses countersunk screws and thumb nuts that hold each support. Countersunk screws were chosen so that no metal parts were protruding into the socket. The screws then go through the socket and supports and are tightened with knurled thumb nuts. It should be noted that all hardware used in the socket is 316 stainless steel and is expected to offer good corrosion resistance. The hardware should outlast the socket and can be reused if a geometry change is needed in the socket. The second main function of the socket is to support the pylon. Previously, the design used a clamp to secure the pylon with the intent of offering small adjustments to the height of the pylon if needed. Due to difficulties in machining and tolerancing machined components and 3D printed components together, this design had to be abandoned. Had there been more time to dial in the parameters, this design may have worked. In the current design, the pylon is held in place by two knurled head thumb screws that screw into heated inserts that press into the socket. This design is much more secure than the previous method because there are physical screws that are resisting vertical movement from the pylons. Another benefit to the new method is that the socket is not going to be clamped and compressed, so there is less fatigue in the thin features of the socket. Other design choices in the socket included modifying the full shell. One option that was being considered was to remove material from the socket walls to create a fork shape. After consulting with Phil, he decided he liked the full shell more due to feeling more secure.

Figure 5- Socket

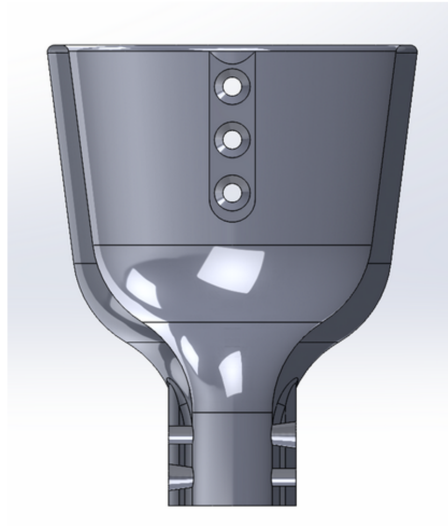


Figure 6- Socket Cross Section View

The third component of the design is the pylon assembly. The pylon assembly is relatively straightforward and consists of two concentric shafts that are held together by a button clip, which is seen in Figure 7. Both shafts are aluminum 6061 with 0.05" wall thickness and are again anodized to protect against oxidation and corrosion. The button clip is made from stainless steel. The combination of tubing and button clip was chosen to reduce weight from previous designs and was found to support more than a 1000 lbf compressive load which is more than sufficient for Phil and the design requirements. The button clip allows the pylon to be adjustable in its length. At the top of the assembly, the pylon is attached to the socket with two additional holes so that the thumb screws can pass through the side of the upper shaft.

The foot is the final main component of the leg. It is 3D printed from the same nylon carbon filament as the socket and can be seen below in Figure 8.

Figure 7- Pylon Subassembly

Figure 8- Foot

After many iterations of different foot geometry, a rounded off shape was chosen. The foot is much larger than a traditional crutch tip in order to provide more stability during walking and standing. Additionally, the rounded shape was chosen to reduce stress concentration during the gait cycle. To provide traction, the foot has an indentation on the bottom in which a rubber boot sole is secured to the foot using epoxy. A few different non-slip fabrics were tested but many were difficult to attach to the nylon foot. The rubber was chosen as the final option due to its superior grip, good bonding, and availability.

As for the fabrication, all the parts are made of anodized aluminum or carbon-reinforced nylon 3D printed parts. In addition to the manufactured parts, all hardware was purchased on McMaster Carr and only stainless steel was used to prevent corrosion and ensure high strength. The materials were chosen primarily because of their high strength to weight ratio. Because the leg is going to be used for travel, weight is a major concern in the design. The materials were also tested and verified using various tensile or compressive tests to ensure that they would meet the design requirements of the device. In addition to preliminary testing, the final design will be proof tested before being given to Phil. The proof testing will involve running the device through as many of the required loading scenarios as possible to see if the device fails. While the device is expected to survive given all previous testing, this last step ensures that the system as a whole can be used by Phil safely.

g. <u>Innovation</u>

For this project, the team avoided using surplus metal in the construction of the piece to avoid rusting, which could lead to part failure. However, where metals are used, coatings and other methods to prevent corrosion were implemented. From its conception, this prosthesis is pioneering into a niche field of prosthetics. While there are limited shower legs on the market, they are often cost-prohibitive for such a specific prosthetic and are not collapsible. Currently, only one affordable assistive shower prosthesis exists, the Lytra, but with no adjustability nor collapsibility, which makes the portability of the prosthesis low. The design created by the team directly addresses these issues in the existing prosthesis's portability by making the design as collapsible as possible while still maintaining a sturdy structure that can be trusted with the amputee's full weight if needed.

One area where the existing prosthesis (Lytra) falls short is also any attachment to the leg itself. The existing design serves as a leg rest where the user would simply rest their knee and residual limb on a horizontal member which was then attached to a pylon down to a peg-like foot. This design lacks the amputee being able to free stand without holding onto a handle at the helm piece. In the team's design, an upright suspension design was elected as the optimal solution for this problem.

## 2. Analysis

a. Failure Modes and Effects Analysis (FMEA)

The FMEA shown in Table 4 takes a systematic approach to proactively identifying potential failures of the prosthetic shower leg and following these identifications with approaches for mitigation. The analysis is organized into sections of failures that stem from the four different leg components: Pylon, foot, suspension, and socket. Each failure was classified by a probability from A to E, and a severity level from I-V. In Appendix B (Table B-1), the severity classification is shown to range from “no relevant effect” (I) to “catastrophic” (V). Appendix B (Table B-2) shows the probability rankings which range from “extremely unlikely” (A) to “frequent” (E). An FMEA risk assessment was performed to identify the risk levels based on a combination of the probabilities and severities for each potential failure. This risk assessment chart is shown in Appendix B (Table B-3).

After completing the risk assessment, the highest risk failures were identified in the pylon and foot components: Buckling and sole material degradation. The sole material will be finalized during a later prototype but is expected to be the aforementioned EPDM rubber. The buckling was addressed through additional buckling failure calculations which are shown in section 2-b (Project Specific Subsections). The clamp strength will be verified during the performance testing of the prosthesis.

Table 4- Failure Modes and Effects Analysis

| **Item** | **Failure Mode** | **Prob.** | **Sev.** | **Risk** | **Effects** | **Mitigation** |
|---|---|---|---|---|---|---|
| Pylon | Buckling | A | V | Moderate | Center of shaft breaks and user falls in shower | Sufficient pylon material strength |
| Pylon | Button clip misalignme nt | C | II | Low | User inconvenienced until clip is realigned | Addition of button clip slot inside shaft to ensure alignment |
| Foot | Sole material degradation | C | III | Moderate | Decreased grip and user stability during use | Appropriate material selection + Inclusion of foot replaceability option |
| Foot | Slippage on shower floor | B | III | Low | User instability while standing | Non-slip material on sole |
| Suspension | Binding strippage | B | II | Low | Prosthesis less secured to thigh | Reliable binding purchased |
| Suspension | Binding jammed | A | II | Low | Thigh attachment cannot be tightened to full extent → Prosthesis less secure | Reliable binding purchased |
| Socket | Liner material degradation | B | III | Low | Slight discomfort for user's residual limb | Waterproof liner material selection |
| Socket | Thigh attachment pivot point breaking | A | II | Low | Prosthesis less secured to thigh | Stress analysis completed on pivot point for suspension |

b. <u>Project Specific Subsections: Calculations</u>

The two calculations shown in this section, button clip and buckling, both analyze aspects of the prosthetic leg design where strength could have been a crucial factor. First, the maximum shear stresses for the button clip and foot threads were calculated.

The maximum button clip shear force was first calculated as follows:

$$\tau = \frac{3}{2}VA \tag{1}$$

Where:

- V = load ($lbf$)
- A = area where load is applied ($in^2$)

Then, the factor of safety (FOS) was determined as follows:

$$FOS = \frac{Material\ yield\ strength}{Max\ shear\ force} \tag{2}$$

By applying the parameters of the button clip into equations (1) and (2), the FOS was identified to be 4.28 for the maximum shear force experienced. This can be seen below in Table 5.

Table 5- Button Clip Calculations

| **Pin Max Shear** | | |
|---|---|---|
| **Variables** | | **Units** |
| D1 (pin) | 0.3 | inch |
| Load | 400 | lbf |
| Material yield strength | 36300 | psi |
| | | |
| Max Shear | 8488 | psi |
| **Observed FOS** | 4.28 | |

The second calculation shown in this section, buckling, addressed the potential for the prosthetic pylon to give way under a simplified central load of the amputee’s weight. The crippling load of a hollow cylinder was analyzed to approximate the buckling experienced by the pylon.

The equation used to calculate the crippling load was as follows:

$$P_E = \frac{\pi^2 EI}{L_e 2} \quad (3)$$

Where:

- $P_E$= Crippling Load ($lbf$)
- E = Young's Modulus for HDPE ($psi$)
- I = Moment of Inertia ($in^4$)
- $L_e$ =Length of Column ($in$)

In order to find the area moment of inertia for the cylindrical pylon, used in equation (3), the following equation was used:

$$I = \frac{\pi \ \ ({D_o}^4 - {D_i}^4)}{64} \quad (4)$$

Where:

- I = Area Moment of Inertia ($in^4$)
- $D_o$ = Outer Diameter ($in$)
- $D_i$ = Inner Diameter ($in$)

Then, the factor of safety (FOS) was determined as follows:

$$FOS = \frac{Crippling\ Load}{Required\ Strength} \quad (5)$$

Buckling calculations for the shaft that is more prone to failure, the lower shaft, are shown in Table 6 below. The resulting FOS identified is 4.15.

Table 6- Buckling Calculations

| **Buckling Load: Lower Shaft** | | |
|---|---|---|
| **Variables** | | **Units** |
| Outer Diameter, D2 | 1.25 | inch |
| Inner Diameter, D1 | 1.14 | inch |
| Length of Column, L | 6 | inch |
| | | |
| Moment of Inertia, I | 0.0369 | in^4 |
| Young's Modulus, E | 81900 | psi |
| | | |
| Crippling Load (P) | 829.3 | lb |
| Required Strength | 200 | lb |
| | | |
| **Observed FOS** | 4.15 | |
| | $P_E = \frac{\pi^2 EI}{L_e^2}$ | |

c. <u>Project Specific Subsections: Finite Element Analysis (FEA)</u>

FEA was performed on the prosthesis subassemblies that would undergo significant forces. This includes the vertical supports, top and bottom shafts, button clip, and the foot. The FEA results can be seen in Figures 9-14, below.

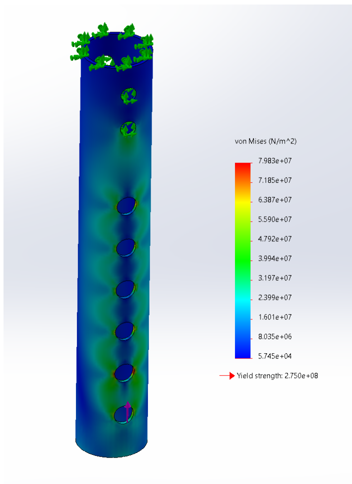



Figure 9: Top Shaft FEA

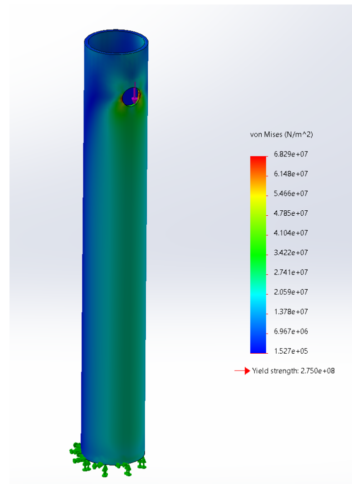



Figure 10: Bottom Shaft FEA

FEA analysis was performed on the Top and Bottom shafts that make up the pylon. A 200 lb force was applied to the top of a hole on the Top Shaft and the same amount of force was applied to the bottom of the hole on the Bottom Shaft. In both instances, the force was there to simulate the pin's pressure on the shafts.

It was found that the Top Shaft had max stress of 11578 psi and the Bottom Shaft had a max stress of 9905 psi. In order to estimate the factors of safety, aluminum with a yield stress of 35,000 psi was assumed. This resulted in a factor of safety of 3.02 for Top Shaft and 3.53 for the Bottom Shaft.

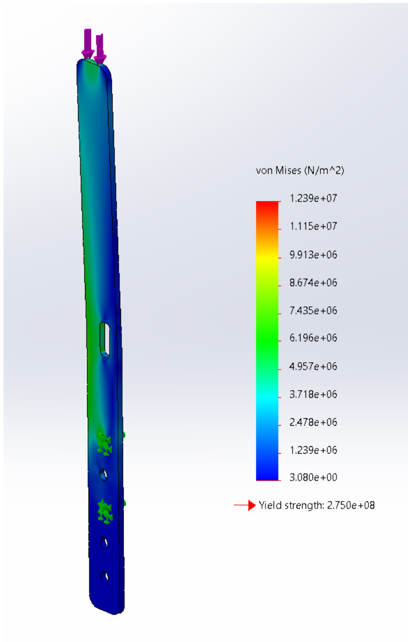



Figure 11: Vertical Support FEA- View 1

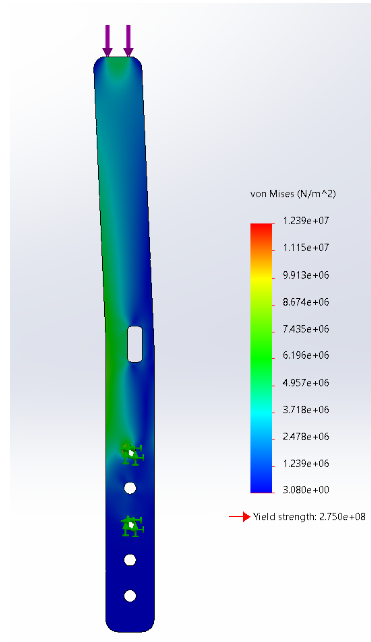



Figure 12: Vertical Support FEA- View 2

For the FEA shown above in Figure 11 and 12, a 100 pound force was applied at the top face of each support. This is where the load from the knee brace will push down, and evenly split the 200 pound load specified for the overall prosthesis. The FOS was determined using the following equation:

$$FOS = \frac{Al\ 6061\ avg.yield\ stress}{Max\ stress\ experienced} = \frac{35000\ psi}{1797\ psi} \quad (6)$$

$$FOS = 19.5$$

The FOS of 19.5 contributed to the decision to keep the updated design compared to previous iterations. While the factor of safety in compression is good, the material thickness still allows for the vertical supports to flex slightly to conform to the leg when strapped in using the brace.

The analysis performed on the button clip simulated the clip being inserted into both of the shafts with the full weight of the user on the single pin. This FEA is shown above in Figure 11. The pin surface was split into four sections using a split line perpendicular to the pin through the center, and vertically at the middle of the pin lengthwise. The bottom surface near the pin vertical was fixed as if being supported by the bottom shaft. The top outer half of the pin has a vertical load applied to its face. The results of the simulation were a max stress of 20,580 psi and a FOS of 4.38. The pin is stainless steel so it is a very robust part. From the simulation no failure is expected.

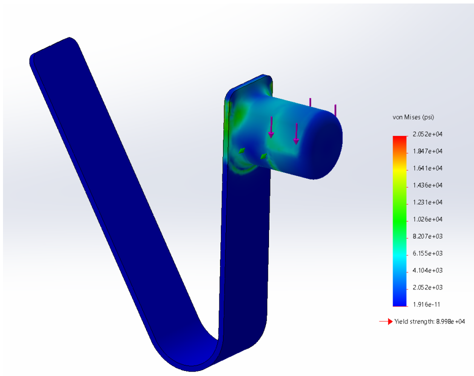
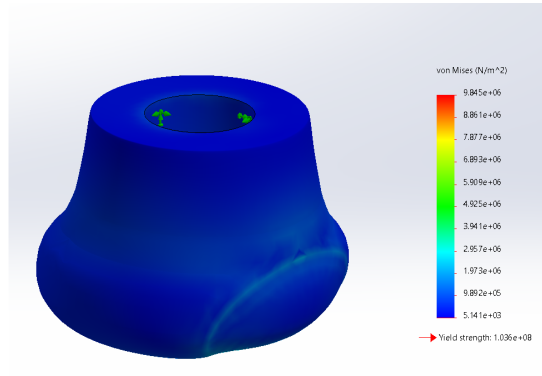



Figure 13: Button Clip FEA Figure




14: Initial Foot Design FEA

For the analysis of the foot (Figure 14), a section of the foot was split and a pressure load was applied to the section. The load applied was roughly three times the max body weight of the user. This represents the max impulse that is applied during a normal walking cycle. This simulation resulted in a max stress of 1428 psi which resulted in a FOS of 1.33 for nylon carbon fiber. After a redesign, this was the resulting foot shape. This had a greatly increased factor of safety and is no longer expected to fail.

d. Cost Analysis

Table 7: Bill of Materials for Prototype

| ***Item*** | ***Quantity*** | ***Cost*** | ***Total Cost*** | ***Description*** |
|---|---|---|---|---|
| PLA Filament | 2 | $64.31 | $128.62 | Prototyping filament |
| PVA Filament | 1 | $86.50 | $86.50 | Prototyping support material |
| Nylon 12 Carbon Filament | 1 | $83.85 | $83.85 | Socket and foot material |
| Miscellaneous hardware | 1 | $125.00 | $125.00 | Nuts, screws |
| Knee Brace 1 | 1 | $15.93 | $15.93 | Hold leg |
| Al Tube 1: 1.5" OD | 1 | $7.51 | $7.51 | Pylon material |
| Al Tube 2: 1.25" OD | 1 | $6.18 | $6.18 | Pylon material |
| Button Clip 1 | 2 | $5.16 | $10.32 | Adjust/hold pylons |
| Silicone Rubber | 1 | $23.74 | $23.74 | Foot material |
| Nylon Strap | 1 | $10.50 | $10.50 | Suspension material |
| Ratcheting Buckle | 2 | $7.65 | $15.30 | Suspension mechanism |
| Ladder Straps | 2 | $3.00 | $6.00 | Suspension mechanism |
| | | **Total Proto. Cost (post-tax/shipping):** | **$623.34** | |

Table 8: Bill of Materials for Final Product

| Item | Quantity | Cost | Total Cost | Description |
|---|---|---|---|---|
| Nylon 12 Carbon Filament | 1 | $83.85 | $83.85 | Socket and foot material |
| 1/8" Aluminum Sheet | 1 | $0.00 | EDC | Vertical support material |
| 1' 1.125" OD Al tubing | 1 | $7.39 | $7.39 | Pylon material |
| 1' 1" OD Al tubing | 1 | $5.04 | $5.04 | Pylon material |
| Button Clip | 1 | $4.54 | $4.54 | Adjust/hold pylons |
| Rubber Sole | 1 | $13.75 | $13.75 | Foot bottom |
| 1/4" 20 1" screws | 4 | $5.14 | $20.56 | Holding vertical supports |
| 1/4" 20 thumb nuts | 4 | $5.46 | $21.84 | Tighten vertical supports |
| 2" knurled thumb screw | 2 | $10.18 | $20.36 | Support pylon in socket |
| 1/4" 20 threaded insert | 4 | $6.63 | $26.52 | Add threading to socket |
| Knee brace | 1 | $66.81 | $66.81 | Attach to users thigh |
| Annodizing | 1 | $40.00 | $40.00 | Anodize shafts and vertical support |
| Epoxy | 1 | $5.70 | $5.70 | Attatch printed parts to aluminum |
| | | Final Cost (post-tax/shipping): | $372.79 | |

The cost analysis was divided into two portions. In Table 8, the final materials can be seen. In Table 7, the prototypes' bill of materials can be seen. The cost estimation for the various materials was achieved through research of different vendors. In the final bill of materials, the parts correlate directly with the anticipated final design. A summation of the materials in both bills of materials arrives at a total cost of $1,278.41.

The materials in Table 7 were chosen in order to complete multiple iterations of prototypes. It was anticipated that testing will be extremely important for the design process as non calculable parameters such as comfort and stability are present. Due to this, the materials chosen in Table 7 can be applied to multiple designs. The PLA and metal for various designs of the uprights were chosen as rolls and sheets respectively, as they can be printed and machined into a wide variety of shapes to fit requirements.

# 3. Testing

## a. Developmental Testing

For the early-stage developmental testing of the collapsible prosthetic shower leg, the team 3D printed a version of the leg to test its functionality. More specifically, the 3D-printed prototype allowed for demonstration and observation analysis of mechanisms such as the shaft collapsing, pylon attachment to the socket and foot, and the collapsibility of the socket. With a printed model, tolerances and clearance measurements could be taken and applied where moving parts exist on the assembly to ensure proper final fitment. After each print, adjustments were made to improve tolerances. Since the full-scale prototype was created, Phil has been able to try it on and comment on the design and comfort. His insight has shown that the prototype sockets needed to be redesigned in order to be more flexible and adjustable. Once the new prototype was completed, the fit and functionality were once again tested with him to ensure the design was headed in the correct direction. After the second major socket revision, Phil was happy with the overall form and fit of the socket/suspension system. Although not completed before the report deadline, Phil will do a final test of the whole system. Key factors in the functional testing realm would be the shaft's ability to handle the vertical loading along with smoothness and consistency of the collapsing mechanism. By having Phil test the full-scale prototype, he can also provide feedback on the comfort of the socket. He will also be able to see if the pressure coming through the shaft is being distributed properly to his residual limb. Additionally if the contact surface of the socket brings any discomfort. Finally, the team will perform a weight test to assess the strength of the pylon and the button clip.

b. Performance Testing

The performance testing for the prosthetic leg consisted of two different tests: the submersion test and the compression test.

The goal of the submersion test was to identify the decrease in ultimate strength in a Nylon 12 Carbon Fiber tensile bar sample after being submerged in room temperature water for 24 hours. Six tensile bars were printed in total, three of which were submerged, and three of which were kept dry. The tensile testing was performed using an Instron 5500R Machine. Figure 15, below, shows the raw data from the submersion test.

| | Yield Strength @ (Offset 0.2 %) [ksi] | Ultimate Strength [ksi] | Modulus (Automatic Young's) [Msi] | Initial Length [in] |
|---|---|---|---|---|
| 1 | 2.72 | 5.89 | 0.51 | 1.00000 |
| 2 | 2.70 | 5.68 | 0.46 | 1.00000 |
| 3 | 2.77 | 5.90 | 0.48 | 1.00000 |
| 4 | 2.09 | 5.13 | 0.34 | 1.00000 |
| 5 | 2.08 | 5.10 | 0.34 | 1.00000 |
| 6 | 2.00 | 4.86 | 0.32 | 1.00000 |
| Mean | 2.39 | 5.43 | 0.41 | 1.00000 |
| Standard deviation | 0.37 | 0.45321 | 0.08289 | 0.00000 |
| Coefficient of variation | 15.41 | 8.35289 | 20.31118 | 0.00000 |

Figure 15- Submersion Test Raw Data

After acquiring the ultimate strength data for the samples, averages were taken of both the dry and submerged samples. These average ultimate strengths came out to 5.82 ksi and 5.03 ksi, respectively. These values represent a 13.6% decrease in ultimate strength after a 24-hour submersion period. Since the showering process will not consist of complete submersion or extended periods of time in wet conditions, the 13.6% strength reduction was considered a highly conservative estimate. Therefore, the strength decrease observed was deemed adequate for the purpose of the prosthesis.

The second main performance test was the compression test. The goal of this test was to identify the maximum bearable load for the pylon and button clip subassembly. In order to test for failure without breaking the pylon need for the prosthesis, samples that were 3 inches in length were cut from the excess aluminum shafts and used for the testing. These shaft samples, connected with a button clip, were placed in an Instron 5500R with compression plates in place, and an increasing load was applied until failure. Figure 16, below, shows the load applied in relation to the strain observed in the sample.

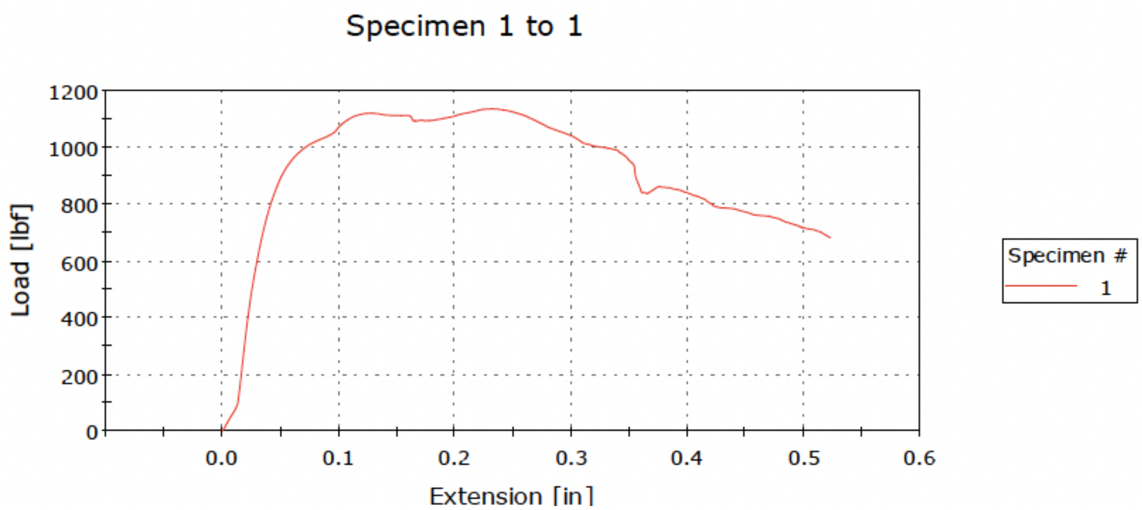



Figure 16- Compression Test Load Graph

The maximum load was observed to be 1133.98 lbf, and it occurred at an extension of 0.231 inches. This resulted in a factor of safety of 5.67 for the strength of the pylon and button clip. While the pylon subassembly was considered to have failed at this load, it is important to note that the button clip did not yield. Figure 17, below, shows that the steel button clip deflected vertically in the aluminum pylon's through hole, identifying the location of failure.

Figure 17- Compression Test: Aluminum Shaft Yielding

The final part of the performance testing was the qualitative comparison of various rubber sole materials and their slip resistance. While this test was not able to be quantified, comparative testing was performed to see which of four materials provided the most traction in an environment consisting of soap and water. The different materials tested were "Bumpy Slip-Not" rubber, silicone rubber, EPDM rubber, and a hiking boot sole. After comparing the slip performance of these four materials, the hiking boot sole was selected for its relatively stronger performance in wet conditions.

After completing the compression, submersion, and slip tests, the development of the leg was accompanied by quantitative and qualitative supporting data that verified the overall strength and water resistance abilities.

c. Project Specific Subsections

Testing for the final design will include the following. To test the weight bearing of the shaft with a user, Phil will place his entire weight upon the device and do light walking in it. The methods mentioned in Safety and Ethics will be employed to ensure he does not get hurt in case of failure. This will ensure the prosthesis can bear weight with natural movement. As the prosthesis will spend a lot of time wet, testing of the entire device will need to be made to understand how it performs when exposed to moisture for long periods. The prosthesis will be submerged in water to understand how its performance is affected from various periods of time. Additionally, a slip test will need to be performed to understand how the device performs when in wet, slippery conditions. The test will be performed by applying force in the gravitational direction and varying the angle of the device. Angles at which the device loses traction will give insight into the slippage performance. The same test will be performed with a wet floor to simulate showering conditions.

## 4. Safety and Ethics

Once a full-sized prototype has been created and will be tested with Phil, procedures will need to be in place to ensure a safe test can be performed. The prototype will likely be made out of materials not suited for full weight bearing. Due to this, Phil will need to be fully secured with other methods in the case that the prototype fails. This will be accomplished by having Phil standing with crutches. To test comfort, keeping Phil seated could still test pressure points without the added danger of standing on an unreliable prototype. To date, Phil has only tested the prototype for the fit of the socket. This has provided information on how to update the design before later testing the full functionality and weight bearing.

# 5. Conclusion

a. <u>Comparison</u>

The initial design specifications for the device are partly verifiable and are partly subjective according to Phil. Some of the quantifiable specifications were a weight capacity of 400 lbs, device weight of fewer than 5 lbs, adjustability range of 10-16", and a max collapsible height of 3.5". In terms of the completed device the total weight came out to be 2.42 lbs with a total adjustability range of 10-16". Both of these values meet or beat our design specifications. The specification of 3.5" was not met, the socket height ended up being around 6".

While the completed device was not able to be tested as a system before the report deadline, individual components were tested. The pylon was able to withstand a compressive load of around 1100 lbf leading to a FOS of 5.5 which exceeds our goal of 2.5 FOS. As a whole we do not expect the device to fail under Phil's weight, however, the socket may fail under the max compressive load of 400 lbs. From CAD simulations the FOS for the socket is expected to be 8.5 at 400 lbs but this value assumes solid material. Because the socket is printed it is expected that accurate failure modes cannot be modeled using FEA.

b. <u>Evaluation</u>

The objective of this project is to create a collapsible prosthetic shower leg for use by transtibial amputees. The shower leg must be able to pass several parameters to ensure safety, reliability, functionality, and comfort. The prosthesis needed to support 400 lbs yet weigh less than 5 lbs. It must also remain secured to the user for at least 100 steps while remaining stable to the user. Additionally, it needs to be slip-resistant and water-resistant when in use in the shower. Finally, it needs to be collapsible to less than 3 inches tall and have universal adjustability between 10 and 16 inches.

When testing the weight-bearing capacity of the prosthesis, both FEA and a compression test were performed. It was found that the prosthesis would exceed a standard weight-bearing of 400 lb in both cases. A final weight of 2.42 lb was well below the 5 lb objective. While the prosthesis is nearly complete, a test has not been performed with Phil to ensure it will stay attached for 100 feet nor that is comfortable enough for use. A slip-resistant rubber foot was tested in water and soap and found to slide out when subjected to a high slip angle and force. When used with low angles and on dry surfaces, the leg met objectives. More tests will need to be performed to understand the limitations of the prosthesis with regard to slippage. Submerged tests on the epoxy adhesives found that even when submerged for a prolonged time (24 hours), the adhesive maintained sufficient strength. The aluminum shafts will be anodized in order to resist oxidation. The collapsibility objective failed, with the final minimum length being 10 inches. Universality was mostly achieved with socket adjustability and with a maximum height and minimum height of 16 and 10 inches, respectively.

c. Recommendations

If future work on this project were to occur, a primary focus should be on improving the manufacturability of the prosthesis. With additional time, this product has potential for mass production, since there are no collapsible shower prostheses that are currently being sold. More specifically, one of the components that can be optimized for manufacturing is the socket. Since the current socket is additively manufactured, it takes over 24 hours for the print to complete in the MakerBot X. Creating a socket out of anodized aluminum would decrease the production time, increase the strength, and improve the water resistance of this component.

Another component that could be improved is the foot. The foot is also 3D-printed, and with more time, a more stable, slip-resistant, and manufacturable foot could be developed. The current foot has to be secured to the pylon with epoxy, and the sole is epoxied to the foot as well. The sole epoxy may be more difficult to avoid, but identifying a different fastening method between the foot and the pylon would be more ideal for manufacturing purposes.

Finally, a pylon-socket fastening method that utilizes the previously developed clamp could be more ideal for adjustability and ease-of-use. The clamp was removed from the design within the final week in order to implement the heated inserts with their accompanying screws. This new design was deemed much safer in terms of supporting the vertical load as it was distributed from the socket to the pylon. Unfortunately, the incorporation of these screws removes the added degree of adjustability that comes with the free movement of the pylon within the socket before clamping. With more time to work on the project, it would be ideal to incorporate the quick-release clamp while finding a method to protect the pylon from slipping and protruding through the socket.

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## Appendix A: Project timeline

| Task | Assigned To | Progress | | Start | Days | End |
|---|---|---|---|---|---|---|
| **PDR** | | | | **10/6/20** | | **10/26/20** |
| Initial Design Sketches | | 100% | | 10/6/20 | 2 | 10/7/20 |
| Initial CAD Designs | | 100% | | 10/8/20 | 5 | 10/12/20 |
| Plan PDR | | 100% | | 10/13/20 | 7 | 10/19/20 |
| PDR Presentation | | 100% | | 10/20/20 | 7 | 10/26/20 |
| **CDR** | | | | **10/27/20** | | **12/27/20** |
| Internal Design Revision | | 100% | | 10/27/20 | 21 | 11/16/20 |
| FMEA/Cost Estimation | | 100% | | 11/17/20 | 6 | 11/22/20 |
| Project Specific Subsections | | 100% | | 11/23/20 | 7 | 11/29/20 |
| Cost Analysis | | 100% | | 11/30/20 | 4 | 12/3/20 |
| Developmental Testing | | 100% | | 12/4/20 | 20 | 12/23/20 |
| Safety and Ethics | | 100% | | 12/24/20 | 4 | 12/27/20 |
| **ΔCDR** | | | | **12/28/20** | | **2/22/21** |
| Update: Cost Analysis | | 100% | | 12/28/20 | 7 | 1/3/21 |
| Update: Project Specific Subsections | | 100% | | 1/4/21 | 14 | 1/17/21 |
| Update: FMEA | | 100% | | 1/18/21 | 7 | 1/24/21 |
| Update: Developmental Testing | | 100% | | 1/25/21 | 23 | 2/16/21 |
| Update: Safety and Ethics | | 100% | | 2/17/21 | 6 | 2/22/21 |
| **2nd Semester: FDR** | | | | **2/17/21** | | **4/21/21** |
| Comparison | | 100% | | 2/17/21 | 14 | 3/2/21 |
| Evaluation | | 100% | | 3/3/21 | 30 | 4/1/21 |
| Recommendations | | 100% | | 4/2/21 | 14 | 4/15/21 |
| Sell to the masses | | 100% | | 4/16/21 | 6 | 4/21/21 |

# Appendix B: FMEA Parameter Definitions

Table B-1: FMEA Severity

| Rating | Meaning |
|---|---|
| I | No relevant effect on reliability or safety |
| II | Very minor, no damage, no injuries, only results in a maintenance action (only noticed by discriminating customers) |
| III | Minor, low damage, light injuries (affects very little of the system, noticed by average customer) |
| IV | Critical (causes a loss of primary function; Loss of all safety Margins, 1 failure away from a catastrophe, severe damage, severe injuries, max 1 possible death ) |
| V | Catastrophic (product becomes inoperative; the failure may result in complete unsafe operation and possible multiple deaths) |

Table B-2: FMEA Probability

| Rating | Meaning |
|---|---|
| A | Extremely Unlikely (Virtually impossible or No known occurrences on similar products or processes, with many running hours) |
| B | Remote (relatively few failures) |
| C | Occasional (occasional failures) |
| D | Reasonably Possible (repeated failures) |
| E | Frequent (failure is almost inevitable) |

Table B-3: FMEA Risk Assessment

| Severity / Probability | I | II | III | IV | V |
|---|---|---|---|---|---|
| A | Low | Low | Low | Low | Moderate |
| B | Low | Low | Low | Moderate | High |
| C | Low | Low | Moderate | Moderate | High |
| D | Low | Moderate | Moderate | High | Unacceptable |
| E | Moderate | Moderate | High | Unacceptable | Unacceptable |

# Appendix C: 2D CAD Drawings

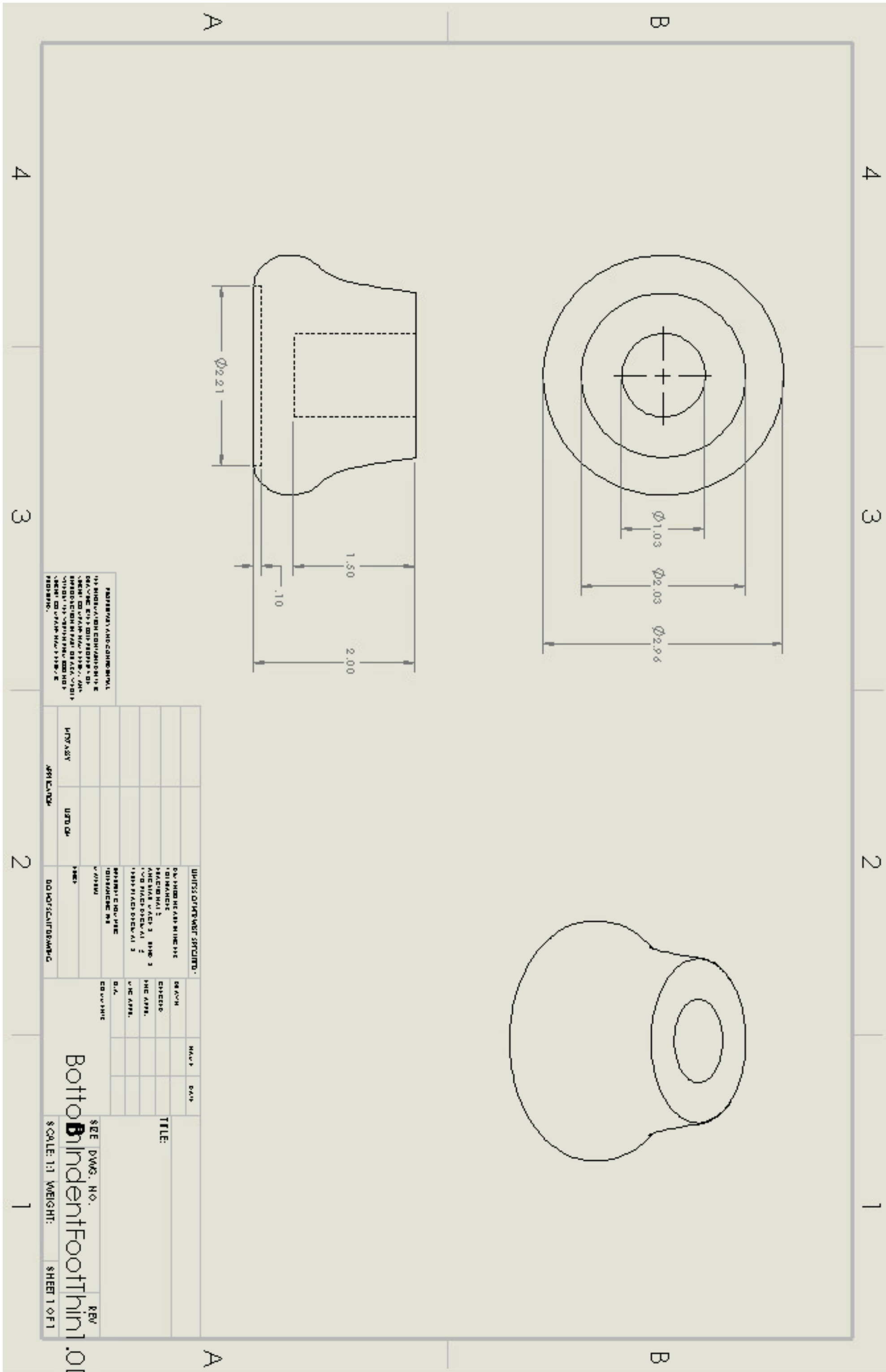


Figure C-1: Foot CAD Drawing

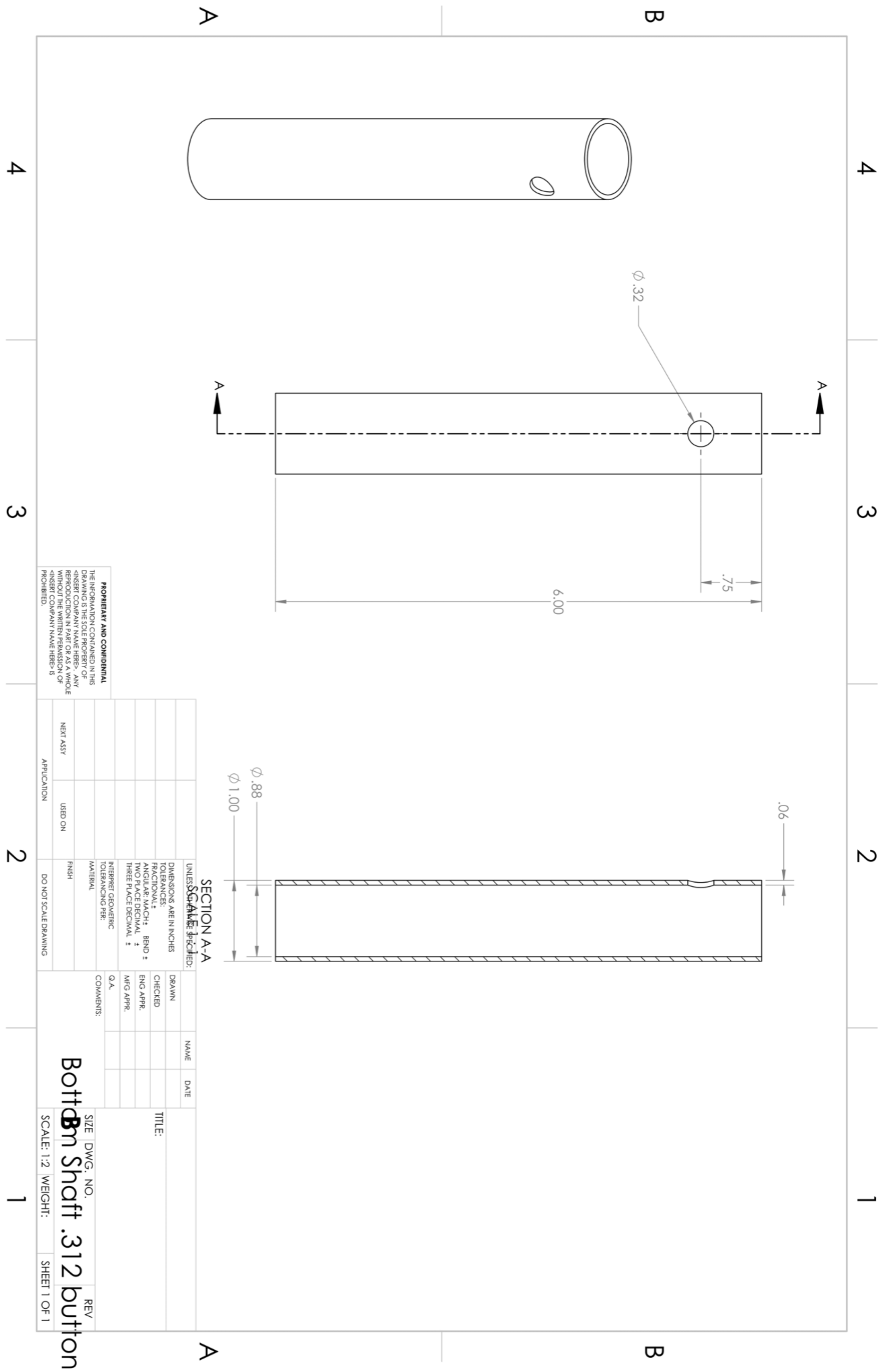


Figure C-2: Lower Shaft CAD Drawing

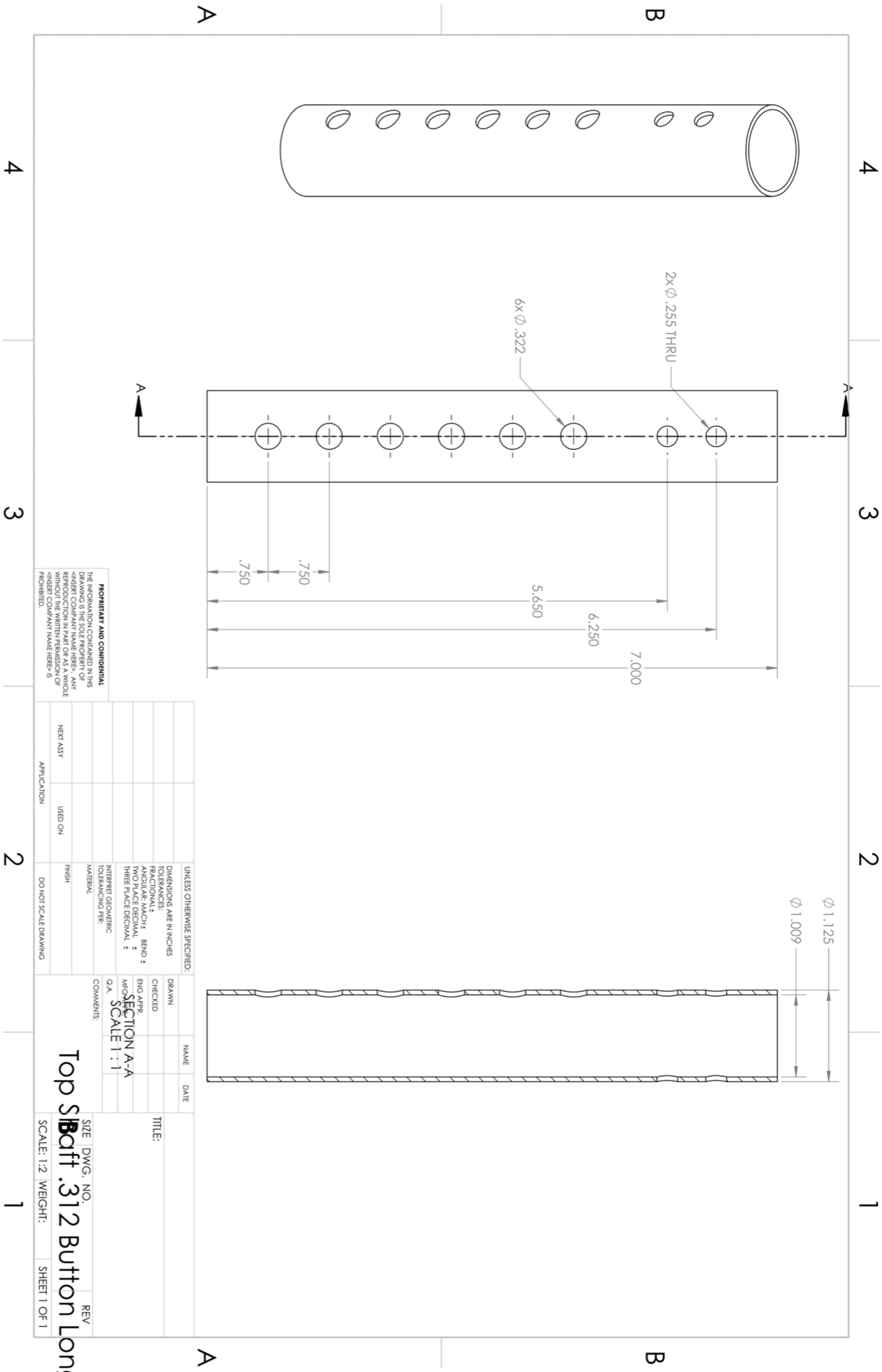


Figure C-3: Top Shaft CAD Drawing

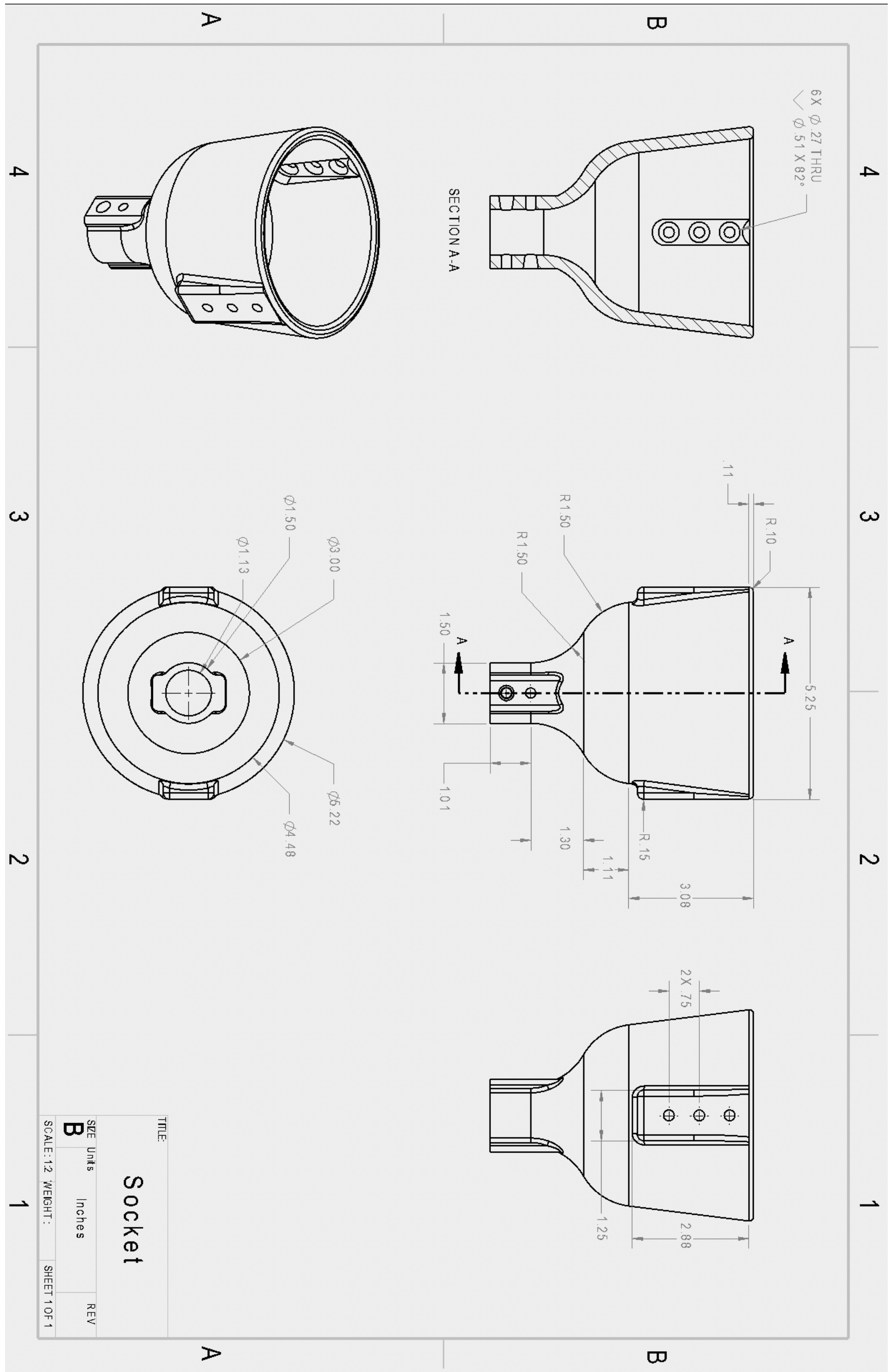


Figure C-4: Socket CAD Drawing

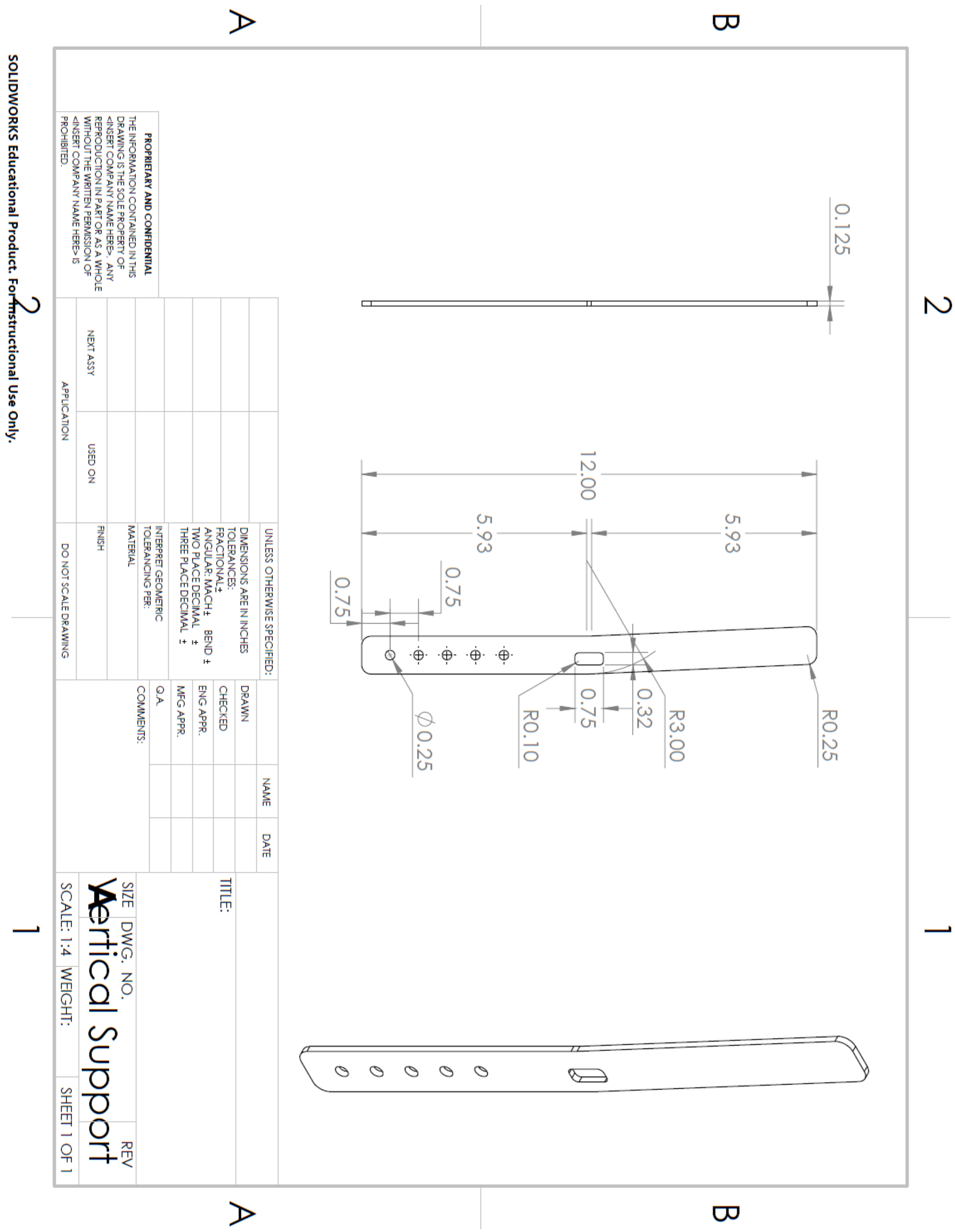


Figure C-5: Vertical Support CAD Drawing

# Appendix D: Concept development sketches

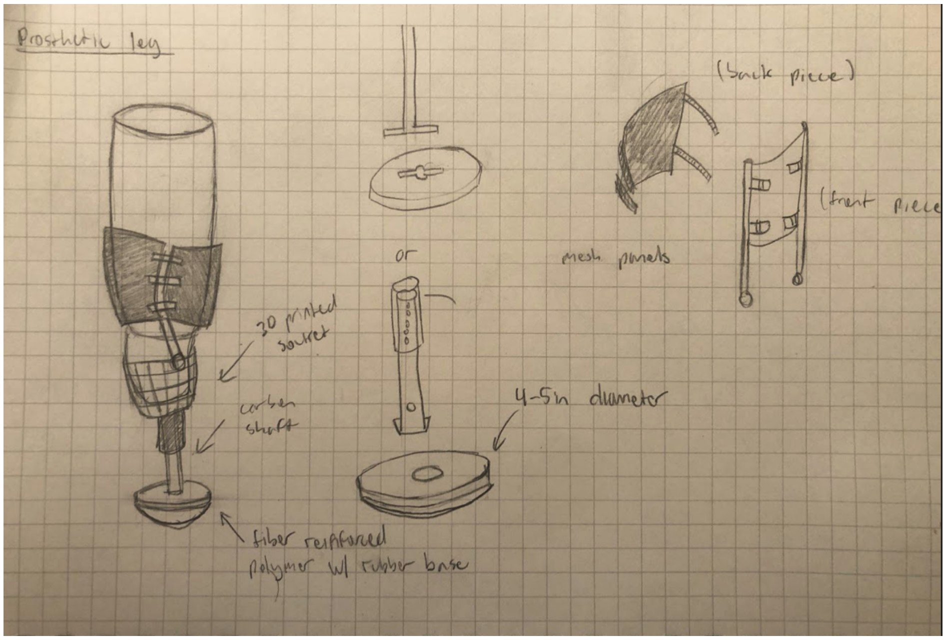


Figure D-1: Sketch [A][E] Design Schematics for Collapsibility Method and Suspension

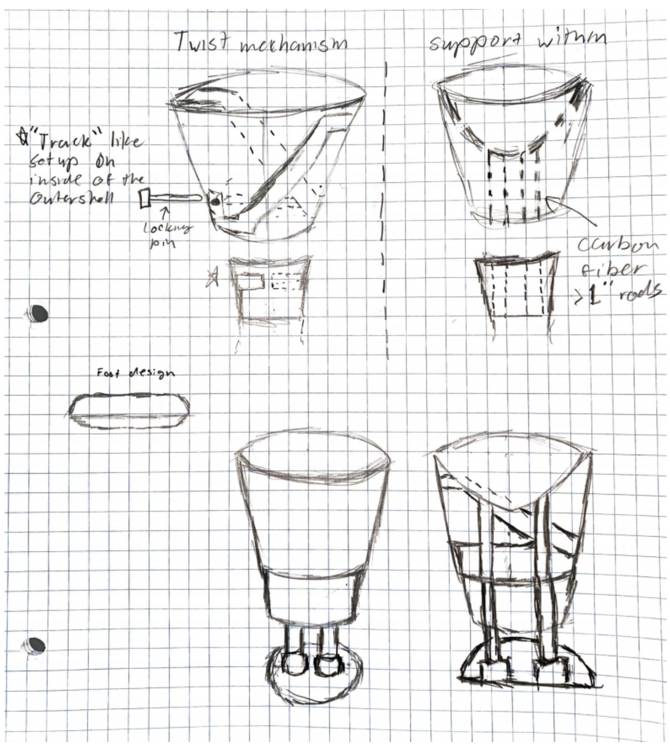


Figure D-2 [B]: Twist Collapsible design

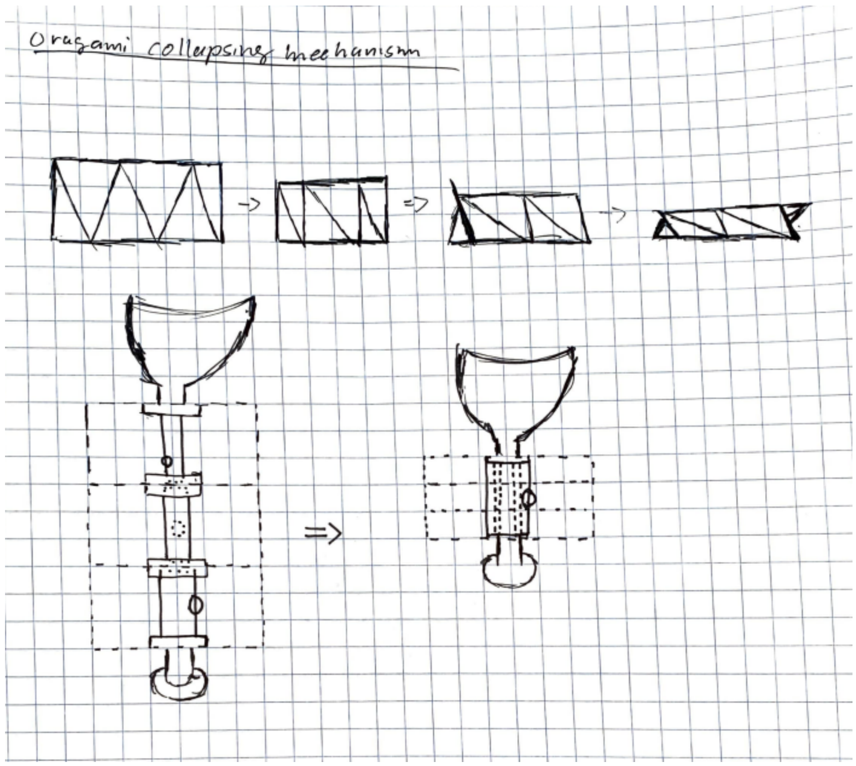


Figure D-3 [C]: Origami Collapsibility

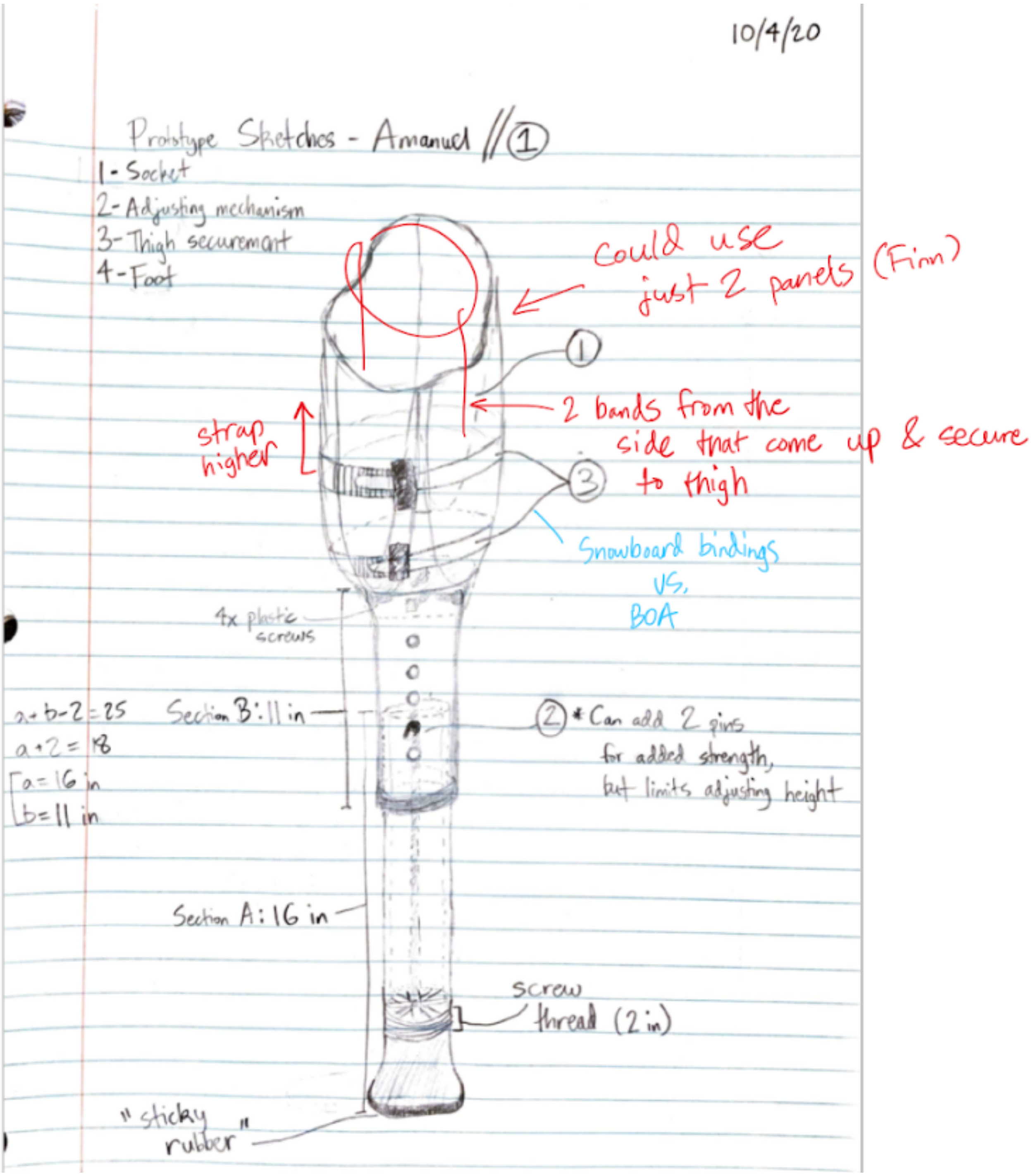


Figure D-4 [D]: Telescope/ Concentric Piping Collapsibility

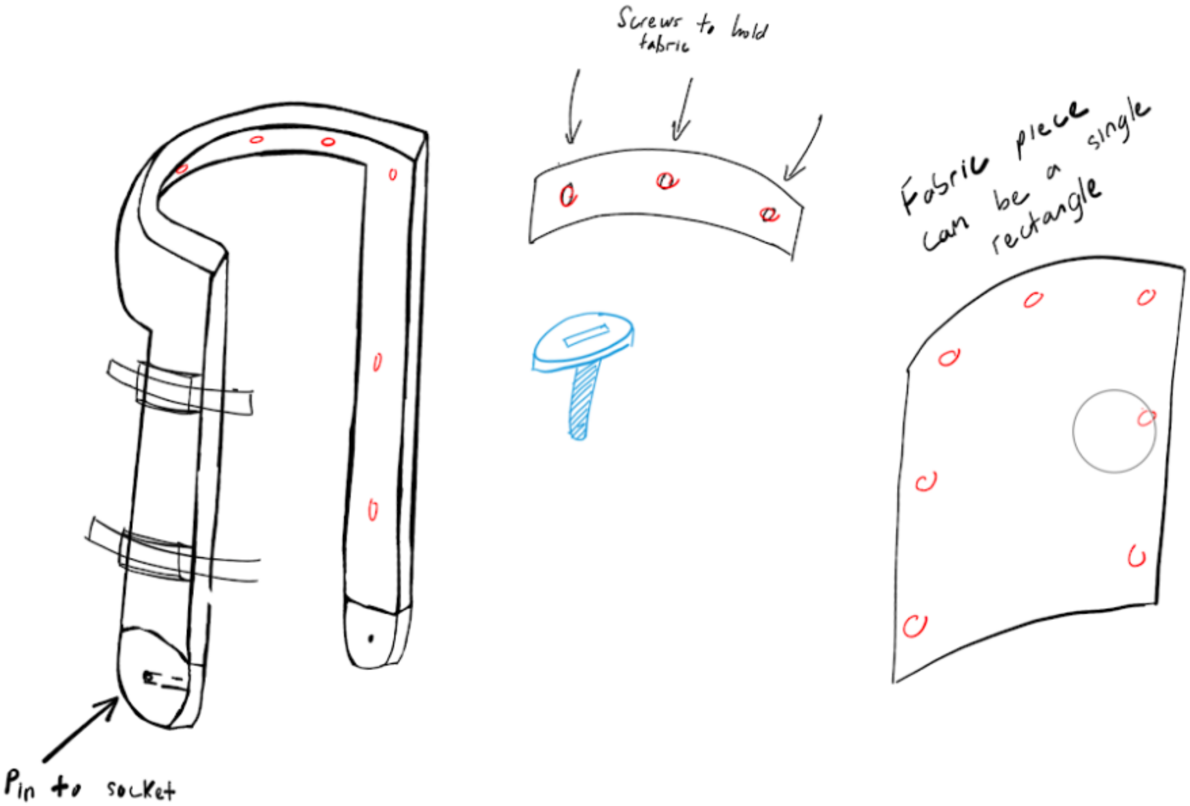


Figure D-5 [F]: Thick Foam Suspension System Design

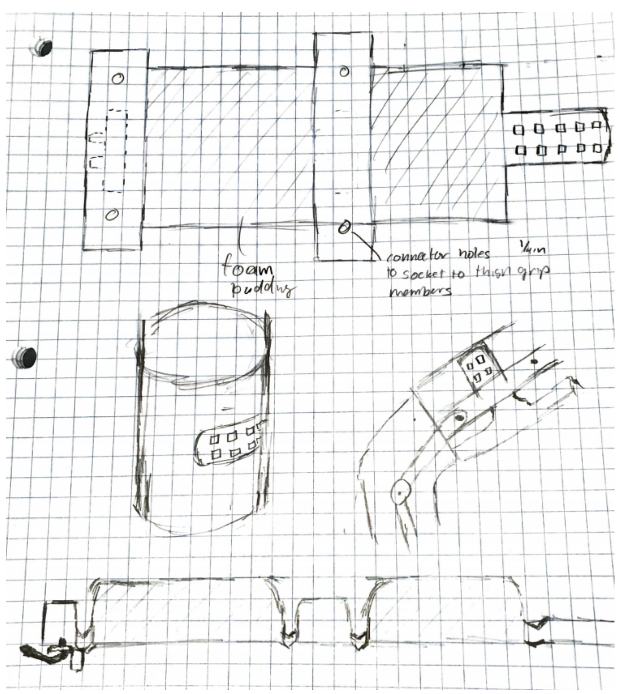

Figure D-6 [G]: Brace Mesh Design Suspension System Design

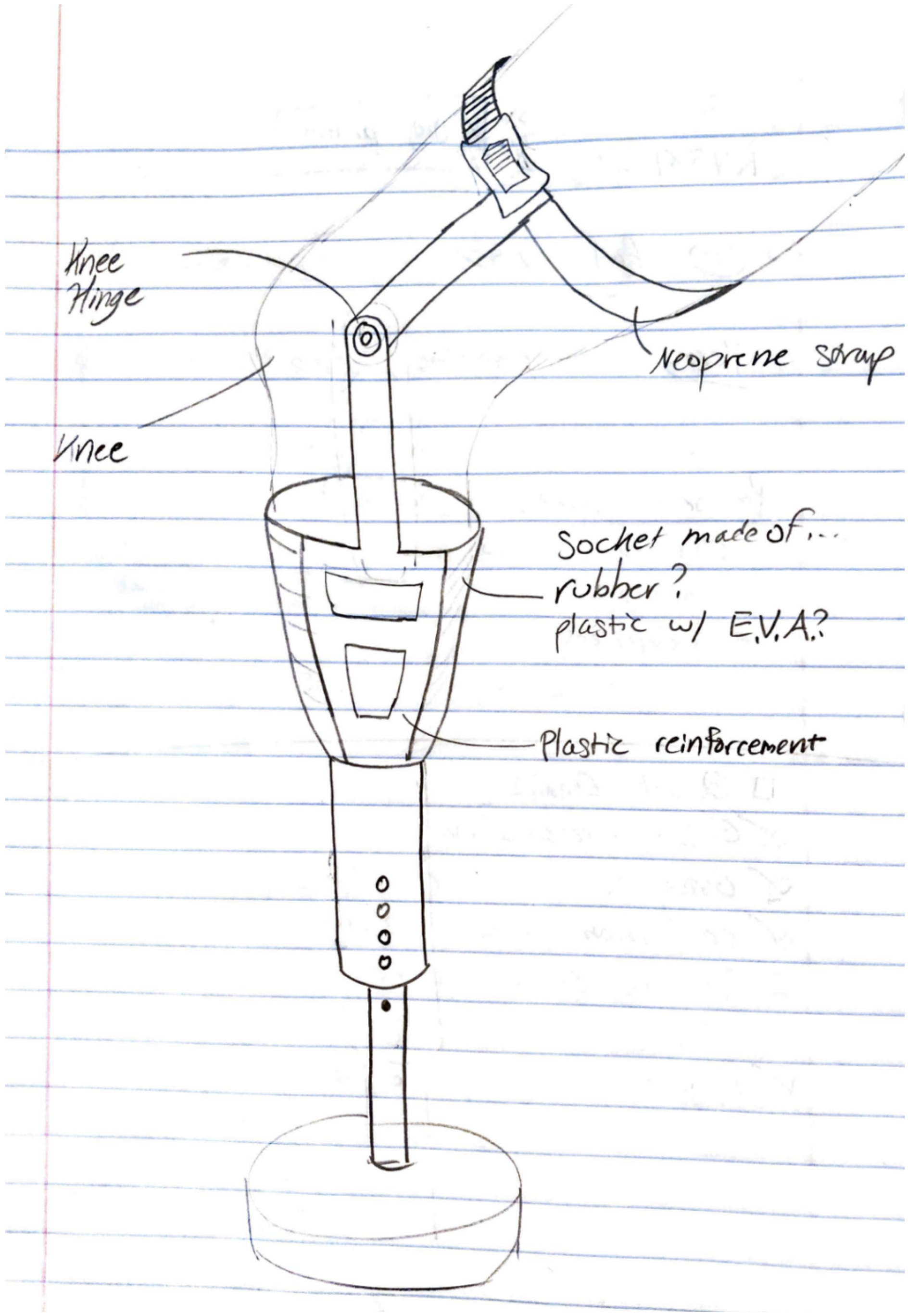


Figure D-7 [H]: Single Strap Suspension System