Prosthetic Aid for Lifting (PAL)

Sponsored by Cal Poly TECHE

& Madeline Everson

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Statement of Disclaimer

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Chapter 1: Introduction

Approximately 1.7 million people in the United States use a limb prosthetic [1]. For these individuals, their prosthetic often enables them to engage in their choice of physical activities. Many prosthetic companies design prosthetic limbs for use in specific athletic activities such as weightlifting. These devices are not designed for everyday wear or a large variety of tasks but enable the person to interact with free weights and workout machines.

According to an email conversation between the team and Bob Radocy, Founder of Therapeutic Recreational Services (TRS Inc.) and upper limb amputee, while he could not reveal how many people purchased these attachments, he could say that three of their weightlifting attachments are the most popular attachments with the Black Iron Trainer being the most popular. And writing, “For myself, and I'm in the gym at least three times a week I combine a modified GRIP 2SS and my Black Iron Trainer and essentially access any type of exercise and weightlifting equipment designed for two-handed individuals.” TRS Inc. was founded in 1979 to address Bob Radocy’s frustration at the limited nature of commercially available prosthetics [2]. This all indicates that being able to interact with weightlifting equipment is popular among people who use prosthetics to aid in their exercise regimes. So much so that an amputee founded a lasting company primarily dedicated to the creation of these devices.

This project is being done as part of California Polytechnic San Luis Obispo’s (Cal Poly SLO) Interdisciplinary Senior Engineering Project. Madeline Everson is a senior at Cal Poly SLO majoring in Materials Engineering who has a left hand that developed abnormally. Madeline enjoys lifting weights in the gym but is unable to do so in a safe and comfortable way with her current prosthetic. The objective of this project is to design and develop a new lower arm prosthetic specific to Madeline’s personal needs and weightlifting goals to allow her to exercise safely and effectively, but not necessarily serve as something she would wear every day.

Madeline was previously fitted for a TRS prosthetic, but it has since deteriorated and now she wants to get a new prosthetic that solves the specific issues she had while using the TRS prosthetic. Even though the prosthetic was initially molded to fit her arm, a combination of her limb growth, deformation due to use, and her unique needs, has resulted in it no longer being able to assist her in the exercises she wants to engage in. By bringing this problem to a Senior Project team, a unique prosthetic specific to her needs may be created.

Chapter 2: Background

The prosthetics and orthotics industry is a robust field that continues to expand to meet specific patient needs. However, no two individuals with limb differences are the same. The design process of patient-specific prostheses and orthotics is ongoing, not only as new cases emerge, but as each patient ages.

According to the Merck Manual, "A limb prosthesis has 4 main parts: interface, suspension, structural components, and appearance components" [3]. Interface refers to the barrier that exists between the skin and the main components of the prosthetic device [3]. This barrier is not always used, but helps to even out pressure, protect the skin, and fine tune the fit of the prosthetic socket [3]. One's limbs change size from day to day, but this is especially frustrating for those who wear a prosthesis as liners may need to be added and removed frequently [4].

Suspension refers to the method used to maintain the prosthetic lower arm in the correct location and allow it to bear weight [3]. Vacuum, passive suction, locking pin, anatomical, and belts or straps are common suspension methods with various advantages and complexities [3]. Vacuum suspension uses a pump to continually draw a vacuum in the socket, which keeps the prosthesis in place [3]. Passive suction uses the residual limb itself to force air through a valve that doesn't allow air to reenter [3]. Locking pin retention includes a sleeve with a locking pin attached at the end in the axial orientation. When inserted into the device, the pin engages with a catch and locks the prosthetic lower arm in place [3]. Anatomical retention uses the geometry of the patient's body to help hold the prosthesis in place [3]. Lastly, belts and straps can be used [3]. Retention is especially critical when dealing with large axial forces such as in weightlifting.

The structural component of a prosthetic limb consists of the socket and the terminal device or appendage that allows the user to gain function [3]. Comfort is of paramount importance and socket design is both a science and art – often requiring a skilled physician to properly fit the socket to avoid pain and irritation [5]. The socket must also be strong enough to withstand forces and impacts. A myriad of materials is used to accomplish these strength requirements (plastics, silicone, carbon, fabrics, and metals) [5]. The first step, however, is often a thermoplastic socket that is clear to allow for observation of the skin and overall prosthetic fit [5]. The fit is then refined and replicated with the materials of choice. The terminal device is the part of the prosthesis that allows the user to interact with the outside world. For Madeline, this will be a device that allows her to interact with free-weights and cable workout machines. The terminal device must be able to interface with her socket while bearing weight, withstanding impact, and gripping weights securely.

Lastly, the visual component of a prosthetic limb can be important depending on the needs of the patient. Madeline would like her prosthetic lower limb to blend in better than her current solution (Figure 1). This may mean matching the color of the prosthesis to her skin or shaping it to appear like a hand.

Madeline was fitted for an upper limb prosthetic in 2017 and now experiences failure of the device as it is both deteriorating and no longer fits her arm to the point that it shifts forward and backwards on her arm throughout her exercises. This prosthetic is the Pro Cuff Distal Mount created by Fillauer TRS Inc. which is compatible with various TRS weightlifting attachments that she uses in the gym (Figure 1). In the initial meetings with Madeline, she expressed how her current prosthetic slides off her arm because she has outgrown it, demonstrated that the screw connecting her prosthetic to the TRS attachment has been stripped so it constantly rotates, showed that the support bars were bending and ultimately dislocated from the rivets holding them in place, and showed that the TRS attachment ends up holding weights approximately six inches beyond where she would naturally hold weight with her right hand. She owns two TRS weightlifting attachments, Black Iron Lite and Black Iron Trainer. The Black Iron Lite (Figure 1) grips weights and machines using a ratchet lock down strap that is designed for light-weight aerobic style dumbbell exercises and is intended for teenage and female beginner lifters [6]. It is composed of high strength polyurethane and nylon and has a maximum recommended load of 10 pounds [6]. The Black Iron Trainer uses a wingnut and screw mechanism to clamp down on weights and is designed for general everyday weightlifting. It is slightly heavier than the Black Iron Lite, composed of forged aluminum, steel hardware, and thick polymer rubber pads. The Black Iron Trainer is rated for 440 pounds [7] Madeline explained that she prefers the ratchet strap mechanism to the wingnut and screw mechanism for ease of use, but she lifts more than 10 pounds on each arm, so she primarily uses the Black Iron Trainer [6]. She also said that even while the prosthetic was functional, it was frequently pulled uncomfortable ways during certain exercises, or caused the threaded attachment port at the end of the prosthetic (Figure 1) to be pressed against her hand in a painful fashion. Despite this, she regularly went to the gym to maintain her personal health, fitness, and strength, but does not anticipate wanting to become a power lifter.

Figure 1. (Left) Madeline's current prosthetic, the Pro Cuff Distal Mount by Fillauer TRS Inc. (Right) Madeline's preferred TRS attachment for weightlifting, Black Iron Lite [6].

Most existing prosthetic attachments designed for weightlifting use the TRS attachments such as the Black Iron Lite in Figure 1. Other attachments can be seen with the Jaws Voluntary Opening Prehensor by Fillauer TRC Inc. as shown in Figure 2 [8]. This prehensor has the advantage of being able to open and close quickly through cable actuation and can be locked using a pin [8]. It is advertised for use in extreme motorsports and has a grip strength of 45lb. In addition, it has a replaceable flexible wrist section [8].

Figure 2. Jaws Voluntary Opening Prehensor [8]

Madeline's left radius and ulna are fused together and has a partially developed hand as shown in Figure 3. She demonstrated to the team that this limits her forearm rotation. She also specified that the nerves in her left arm are highly sensitive, and contact can easily cause her pain. As is shown in Figure 3, the residual hand extends much further forward than would be the case for an amputee. This added length causes the attachment to be much further out than might be expected if she were an amputee in need of a prosthetic to attach at their forearm, thus many prosthetics do not accommodate her specific needs. She does have the use of her thumb which she uses to hold things and complete certain tasks, and some ability to flex her wrist.

Figure 3. Madeline wearing her previous prosthetic, showing how the prosthetic collides with her hand.

The most prevalent users of lower arm weightlifting prosthetics are people with complete amputations, and typically use fully enclosed sockets [9], but there also examples of prostheses that use straps to simultaneously attach multiple pieces to the limb and allow for a secure connection to a weightlifting terminal device, such as Madeline's previous prosthetic as pictured in Figure 1 and Figure 3 [6]. In the design of Madeline's lower arm prosthesis, an important decision will be made as to whether the design will accommodate multiple attachments like the TRS system, or whether the prosthetic will have a single unique attachment. If only a single attachment is created, it may reduce the amount of space required to secure attaching parts. However, multiple attachments would allow more versatility or even potential compatibility with the TRS attachments she already has. Similarly, the socket may fully enclose Madeline's hand, or it could allow her hand to remain exposed to retain function. By encapsulating the entirety of Madeline's lower arm, it could allow the design to rely on forming a vacuum to suspend the prosthetic more effectively, but restricting her ability to move may make the prosthetic feel uncomfortable and restricting.

Chapter 3: Objectives

Upon listening to the limitations of Madeline’s current prosthetic and hearing her weightlifting goals, the team narrowed down the scope of the project to best meet Madeline’s needs. The team will focus on creating a lower arm prosthetic for Madeline to safely and comfortably complete specific strength training exercises. The methods of testing and recording measures of safety and comfort will be described in a later section. This prosthetic will not be intended to be an everyday wear prosthetic but an accessory to enable Madeline to achieve her weight-lifting goals during her time in the gym.

The team will focus on the biomechanics of the four main exercises in the gym that Madeline wants to be able to do. For each exercise Madeline has a different target weight that she wants to achieve. These exercises are listed below in no particular order:

1. Bicep curl with dumbbells
2. Cable triceps pushdowns
3. Lat pulldowns
4. Bent over rows (with barbell or dumbbells) / Romanian deadlifts (RDLs)

Illustrations of these exercises can be found in Appendix B. Madeline identified that aside from being able to do each specific exercise, Madeline stated that her prosthetic needs to be comfortable and feel stable when she is using it. With these three specifications in mind (ability to do each workout, comfort, and sense of stability) the initial engineering requirements were formed. Creating a House of Quality (see Appendix A) revealed that the weight of the prosthetic has a strong correlation to comfort level, sense of stability, and the ability to do each workout. The device needs to be as lightweight as possible to hit these marks. Her current prosthetic is just under two pounds, which was set as the maximum target weight for the new design.

Some additional insights were also obtained during the creation of the House of Quality. The three most impactful engineering requirements are overall weight, ensuring that Madeline’s arms are of equal length during exercises, and ensuring grasped weights cannot spin. Because Madeline’s workouts will include any added weight of the prosthetic, weight factors into most categories of Madeline’s requirements.

Ensuring Madeline’s left arm while wearing the prosthetic be of equal length to her right arm and gripping weight without spinning have strong correlations to the ability to perform each workout and the creation of a sense of stability while doing so. For the engineering requirements regarding ability to do each workout, measurements were divided based on different loading axes. The ability for the prosthetic to hold a certain amount of weight (in pounds) in the axial and transverse directions as well as during torsion were specified. The target weights for these specifications were derived from Madeline’s weightlifting goals for the exercises listed above.

The team spoke with Madeline about other attributes that she wants to see in her ideal weightlifting prosthetic. She explained that she does not like to have people looking at her differently while she works out – something that she feels occurs because her current prosthetic is metallic, bulky, and does not match her skin tone. While this will not prevent her from using the prosthetic, there are aspects that can be measured to ensure the “intense” look of the prosthetic, such as bulkiness, is mitigated.

Table 1 includes the chosen engineering specifications that were derived from customer requirements. Due to the focused and bespoke nature of this project, a list of specific engineering requirements was made based on the information that was gathered from the team’s initial meetings with Madeline. It is important to note that because the focus is being placed on improving Madeline’s ability to complete certain exercises in the gym, the engineering requirements have been specified to adhere to the maximums of the largest forces involved with each exercise. Madeline expressed that she would like to be able to perform balanced workouts. For example, her maximum bicep curl with her right arm of 15lbs, which would indicate that the prosthetic should be able to withstand holding 15lbs in the transverse direction, such as when the dumbbell is held straight out from the body and the weight pulls perpendicular to the arm. Madeline also expressed that she would like to perform bent over rows of 15 lbs, which would indicate that the prosthetic should be able to support a 15lb axial load and should not shift along her arm under the same loading conditions. In addition, because user safety is of high importance, weights held by the prosthetic should not be allowed to spin or rotate while held. To this end, a worst-case scenario of a 15 lb. dumbbell being grasped as far off center as possible so that half the weight is being supported by a lever arm of approximately 6 inches, resulting in a torque of approximately 7.5 ft lbs. This will ensure Madeline is able to engage with her workouts without fear of damaging the prosthetic by grasping things off center temporarily. In order to ensure that Madeline is not injured by the use of the prosthetic, Hanger Clinic recommended the team check to ensure that redness and skin indentations do not last longer than 30 minutes as that is an indication of too much pressure being delivered to an area of the body.

Table 1. Lower Arm Prosthetic Formal Engineering Requirements

Specification	Parameter Description	Requirement or Target (units)	Tolerance	Risk	Compliance
1	Smoothness of prosthetic material	Depends upon Madeline's discretion	N/A	M	I
2	Duration of Indentation/Redness	30 min	Max	M	T, I
3	Prosthetic fit	Depends upon Madeline's discretion	N/A	H	A, T, I
4	Bulkiness	Does not extend more than 3/4" farther than arm surface	Max	M	I
5	Weight of prosthetic	2lb	Max	H	T, I
6	Time to don/doff prosthetic	30 secs	Max	L	I
7	Overall cost	$500	Max	L	A, S
8	Total left arm length equal to right arm	Matches 6in length difference	±0.25 in	H	A, I
9	Grips weights without rotating	Rigid connection to the socket preventing relative rotation.	±5°	M	T, I
10	Withstands weight without slipping	15 lb	Min	M	T, I
11	Holds weight in axial direction	15 lb	Min	M	A, T
12	Holds weight in transverse direction	15 lb	Min	M	A, T
13	Withstands weight during torsion	7.5 ft-lb	Min	M	A, T
Key					
Risk	L: Low expected difficulty to accomplish M: Medium expected difficulty to accomplish H: High expected difficulty to accomplish				
Compliance	A: Analysis & Simulation T: Testing I: Inspection S: Similarity to Existing Designs				

The chart in Table 1 depicts three engineering requirements that will be high-risk and thus more challenging to accomplish. The prosthetic fit specification will likely be the most challenging to meet because the team is not trained in prosthetic fitting. However, resources from the TECHE Lab will be used as well as input from Hangar Clinic to create a prosthetic that fits Madeline as best as possible. Hangar Clinic in SLO has graciously agreed to support the team, such as using their technology to scan Madeline's left arm and render a 3D image and model. In addition to help from Dr. Black, they will be a sounding board for prosthetic fitting techniques. Similarly, ensuring that the total length of Madeline's left and right arms are nearly equal may be a challenge due to the space requirement of attaching the method of interfacing with the weights and equipment. The weight of the prosthetic will also pose a challenge as most weightlifting prosthetic on the market are around two pounds and decreasing the overall weight may compromise the prosthetic's strength. However, two members of the team have taken classes involving stress analysis in designs, so removing excess weight while maintaining structural integrity should not be overly challenging.

Chapter 4: Design Development

Members of the group decided to divide the conceptual design into two components: a base and a gripper. The base of the prosthetic is the “sleeve” that attaches to Madeline’s arm, and the gripper is the mechanism by which Madeline will grasp weights for exercising. The group decided that this system of two parts made the most sense for concept development, as bases and grippers could theoretically be interchanged with one another during idea generation. The group brainstormed conceptual designs individually before coming together to share ideas. Each group member selected between three and six designs (either of the base, the gripper, or a combination of both) to include in a collaborative Pugh Matrix (See Appendix C). The matrix consisted of sixteen designs that the group deemed to fit the customer requirements and be feasible in terms of manufacturing. Each conceptual design was compared with Madeline’s previous prosthetic (Pro Cuff Distal Mount with TRS attachment) in its fully functional state. Certain designs proved to score equally well, but upon closer inspection did not vary notably in design, so some promising designs were close enough to be considered duplicates so other concepts were prioritized to get a better variety of options. In addition to the Pugh Matrix, a graph of how well each of the most promising designs satisfies the customer requirements relative to the datum of the Pro Cuff Distal Mount was included with Figures 4-9.

Based on the customer requirements previously denoted by the group, three designs for each component (base and gripper) were selected for further consideration. The designs were selected based on the high ratings they received when compared to the datum, as well as their variability, meaning each concept used different mechanisms of fastening and gripping. Sketches of the top three concept selections (base and gripper) are included below, along with descriptions of why they were chosen.

Base – Top Three:

One of the most promising ideas created by the team included a neoprene sleeve that encapsulated the entire arm with a pin at the end to clip into a rigid shell as shown in Figure 4. This shell would allow the attachment to distribute held loads over more of the surface area of the arm in what would most likely be a very secure way. However, because it consists of multiple parts, that is more parts for Madeline to carry with her as she will not be wearing the prosthetic all the time.

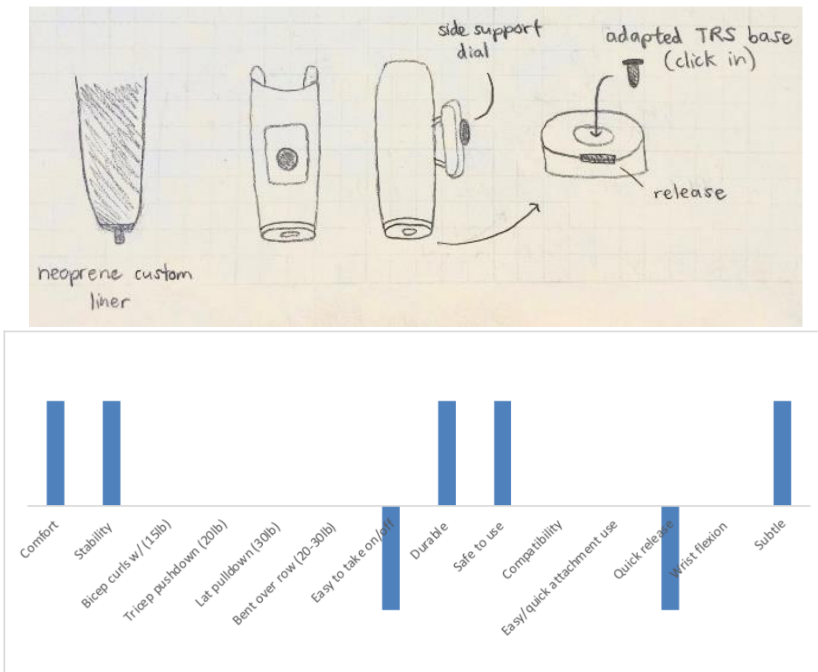


Figure 4. Prosthesis with neoprene sleeve, BOA lacing system, and adapted TRS base.

Another concept the team considered consisted of a rigid shell with a split down the middle to allow for tightening. The design includes the use of an attached neoprene sleeve that can be pulled above the elbow to add additional security without impeding movement by adding rigid components around the elbow joint. This design is shown in Figure 5.

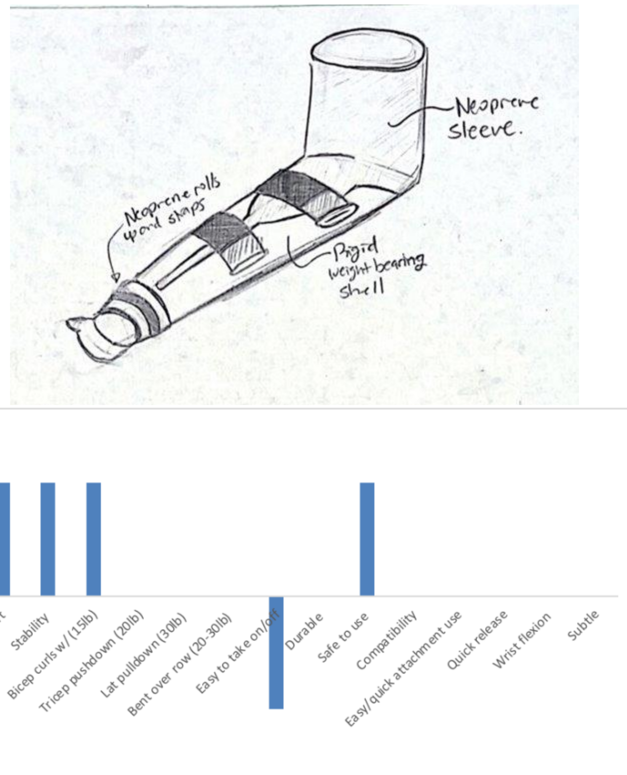


Figure 5. Prosthesis with above-elbow neoprene sleeve, rigid shell with split and Velcro adjustments

The third option the team considered involves a rigid structure inside a fabric case that attempts to distribute load to locations that may give mechanical advantage during exercises without fully encasing the arm and allowing it to remain breathable. However, making it adjustable so that it always stays on without sacrificing those benefits proved to be highly complex and impractical.

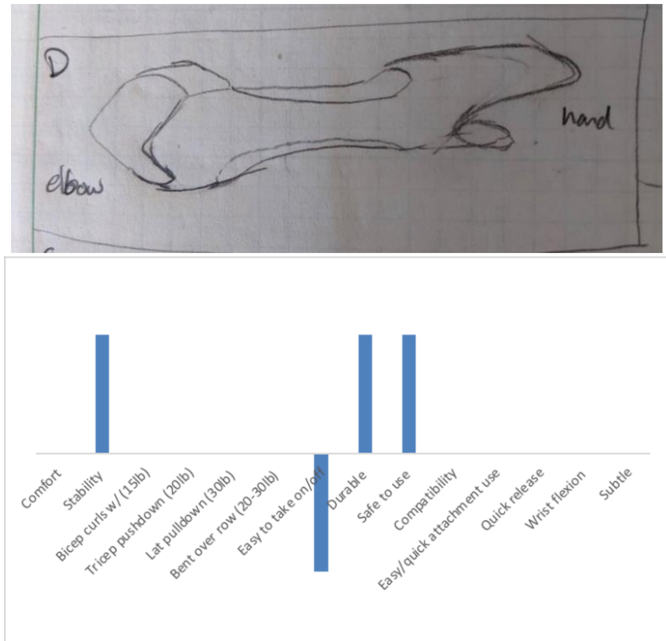


Figure 6. Prosthesis with single component rigid shell and soft inner lining

Gripper – Top Three:

When designing a gripper that Madeline can use to interact with weights, a hook design quickly emerged as an intuitive and versatile option. The first design that the team considered was a simple hook with considerable width. While this would allow Madeline to use barbells, it would be difficult or impossible for her to use free weights or grip onto the flexible yoke during the triceps pulldown exercise. Although flawed, this design functioned as inspiration for the following two designs.

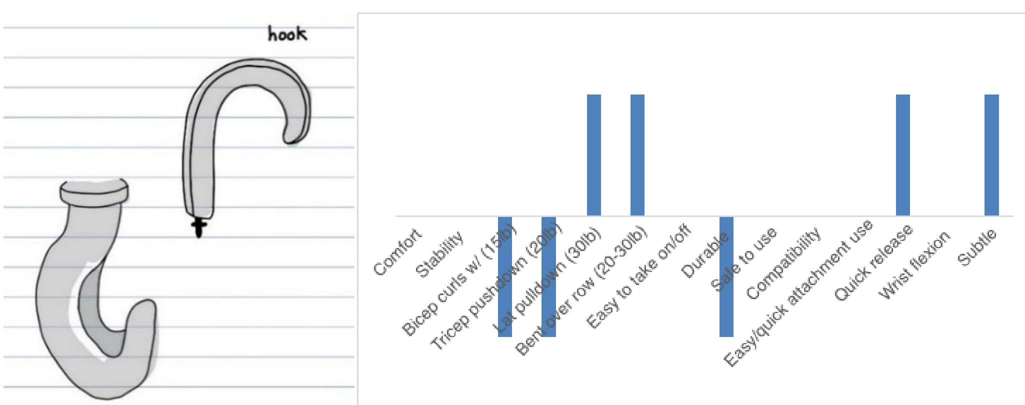


Figure 7. Wide, fixed hook.

The second design that was considered as an option was a hook, similar in dimension to that seen in Figure 7, but articulating. This design used a set of gears at each finger joint that connected to a worm gear near the base as shown in Figure 8. By rotating the worm gear, the finger joints would articulate and grip weights or ropes of various sizes with a significant amount of force. This demonstrates an interesting concept that would allow for the use of the gripper as a hook or as something that grasps the weight or rope. This design is complicated and would be difficult to manufacture using standard techniques. It would also likely be heavy.

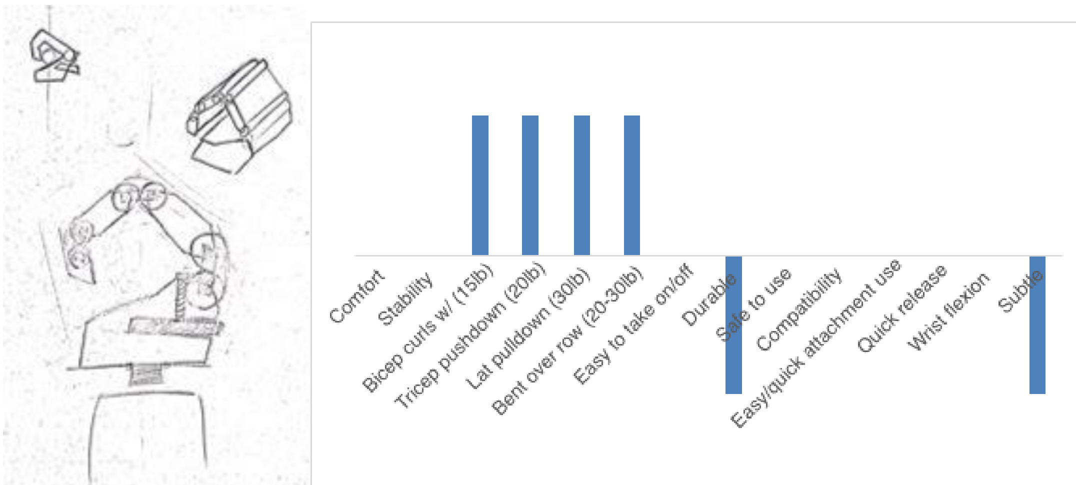


Figure 8. Wide, gear articulating hook

The third design considered for use by the team was a form of articulating hook that used cables instead of gears to actuate the joints as shown in Figure 9. This is a common, proven technique in the world of prosthetics. As with the gear system, a cable system would allow for the gripper to interact with free weights as well as dumbbells in an efficient manner. One additional benefit of this system is that it is less complex than a geared system. It is also likely less heavy and more durable as the joints can be made more robust.

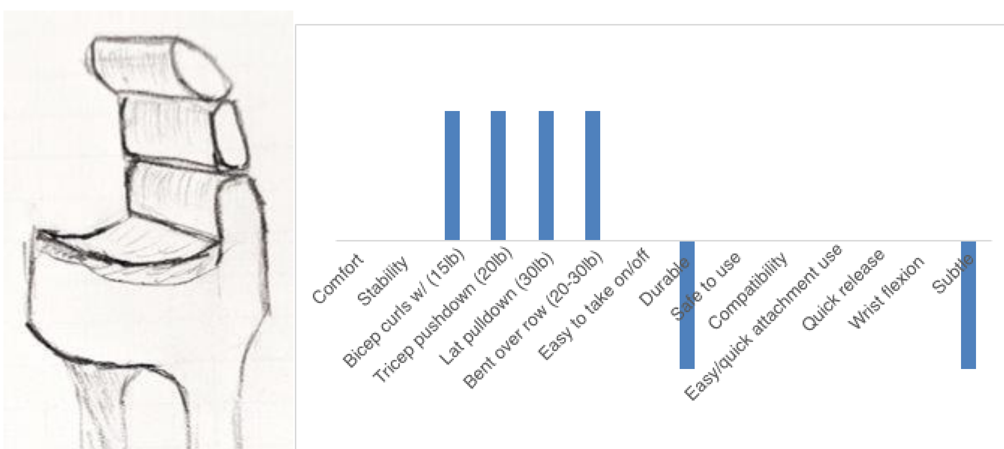


Figure 9. Wide, cable articulating hook

In Figures 10 and 11, CAD models of the rigid components of the designs from Figure 5 and Figure 9 were created to demonstrate the final candidates for the initial prototyping. These two designs were chosen because they had the best chance of satisfying customer requirements while also remaining simple enough to avoid unnecessary expense. The articulating cable gripper will have multiple joints to allow the panel to curl over multiple diameters with a slightly curved lip to mimic the curvature of a thumb in a power grip to prevent equipment from freely sliding out of its grasp beneath the opening between the articulating portion and the static portion of the gripper. This gripper then needs to be connected to the base of the prosthetic in a way where Madeline can comfortably adjust the angle of the gripper relative to the base, but not spin. For this purpose, a connection similar to a bike seat post collar may allow Madeline to loosen or lock the rotation of the gripper with her right hand. This would then be attached to parallel bars that extend past her wrist and socket into slots manufactured into the rigid shell of the base. The base could then be tightened around the arm using a BOA system —not pictured in Figure 11— that tightens a cord along the length of the opening to evenly distribute how tight the base feels on the arm. Figure 11 also does not depict the sleeve that would have been more comfortable for skin to contact and allows the prosthetic to benefit from static friction on the skin above the elbow.

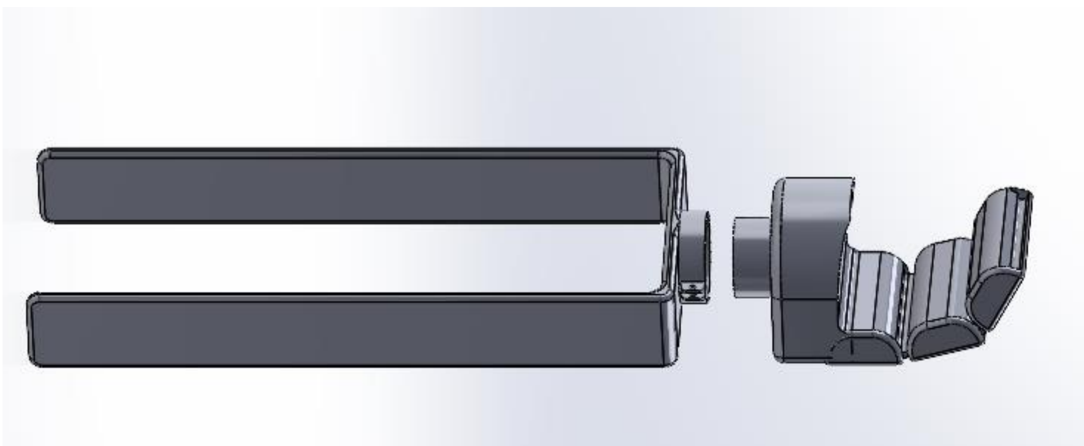


Figure 10. CAD model of the initial articulating gripper with metal struts to attach to base of prosthetic.

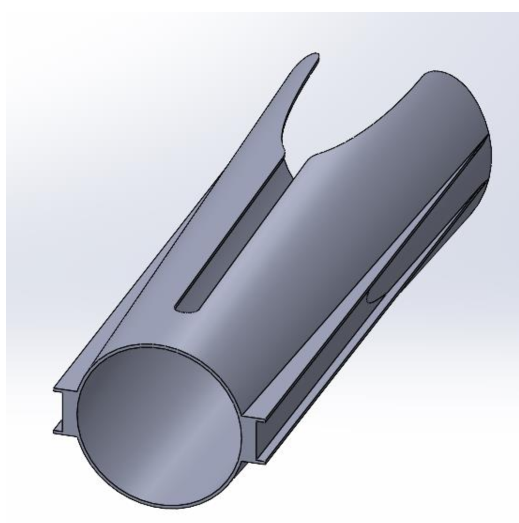


Figure 11. CAD model of the initial semi-rigid base without internal fabric lining.

This was an ideal concept as it meets the design requirements as outlined in Table 1. The use of a neoprene sleeve would ensure that the base is comfortable and that the material is smooth where it contacts her skin. This will solve the problem of the material feeling “scratchy” that Madeline has dealt with in her previous prosthetic. The use of neoprene as a sleeve material would also improve friction between her skin and the device by increasing the surface area that the load is bearing against. This would allow Madeline to lift more weight in the axial direction where slippage frequently occurs with the current solution. A neoprene sleeve is a commonly used component in the prosthetics industry because it generally improves patient comfort. As such, the team expected that the silicone sleeve would provide comfort for Madeline and reduce the risk of a capillary refill time longer than 30 minutes. By using a thin, semi-rigid shell as the main structural component of the base, the design fits the bulkiness criteria.

In order to understand how a thin rigid shell would feel when flexed, the team built a rapid prototype by first taking an impression of Madeline’s arm and creating a plaster casting. The team then wrapped the plaster cast with cotton fabric and orthopedic fiberglass casting tape. In a few minutes, the tape hardened and was able to be cut with a Dremel before being removed. Aluminum bars were added with more orthopedic tape to further replicate the design concept. This process is demonstrated in Figure 12 below.

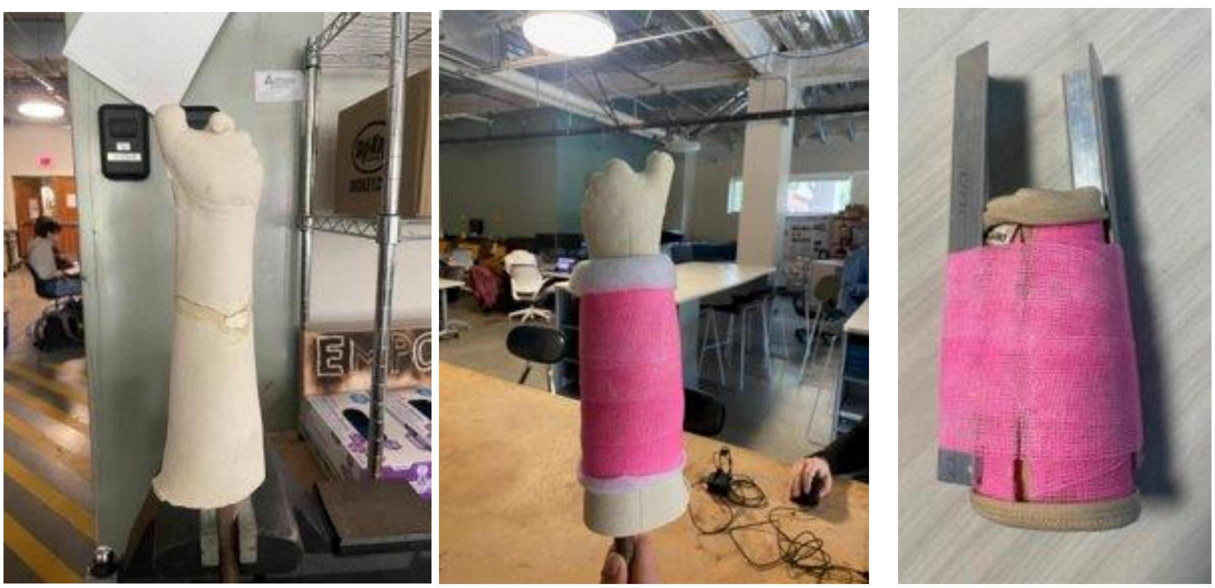


Figure 12. (Left) Plaster positive of Madeline’s arm. (Middle) Fiberglass wrapping of the plaster positive. (Right) Initial proof of concept using scrap aluminum bars bound to the fiberglass wrap.

This prototype demonstrated that it is feasible for a stiff, but lightweight material to make the final prototype weigh less than the 2lb limit. It also gave the team confidence in the weight bearing abilities of such a concept.

Now having a physical prototype, the team moved into methodically modeling Madeline’s arm in SolidWorks based on measurements taken from the plaster casting previously constructed. This would enable the use of 3D printing as a means of quickly iterating the fit of the prosthetic to make it comfortable. A 3D printed shell was created from this model, which was presented to Madeline in order to collect verbal feedback and her thoughts on a rigid shell around her arm. The feedback was positive, although there were notable fitment issues. Namely, the shell was too long, had sharp edges, and too tight. This progression is shown in Figure 13. A cost breakdown of purchased materials for prototyping is included in Appendix E.

Figure 13. (Left) taking measurements of the plaster casting. (Center) SolidWorks surface model. (Right) 3D printed shell being tested by Madeline

The team used the positive feedback and the notes about fitment to develop a revised prototype that addressed the pertinent issues and allowed for the testing of Velcro as a tightening method. This prototype was 3D printed and presented to Madeline as shown in Figure 14. It proved difficult for Madeline to put on the prototype without the flexible neoprene sleeve, so the team agreed to change the design to replace the flexible sleeve with a comfortable layer of fabric restricted to the dimensions of the rigid portion. It was also determined that while Velcro was a convenient material, the final design should not rely on this mechanism as it ended up being challenging to tighten using only one hand.

Figure 14. (Left) Conceptual Model of the prototype. (Right) 3D printed prototype being tested by Madeline with Velcro tightening straps.

Simultaneously, the team iterated on the gripper design. While continuing the design of the articulation mechanism for the gripper design shown in Figure 15, the team decided there was a simpler solution for an adjustable graph that did not have the extra difficulty in designing and manufacturing the multiple parts for an articulating system able to adjust to varied diameters of exercise equipment. This resulted in something closer to the fixed hook design shown in Figure 7, but with a simple height adjusting base as shown in Figure 13.

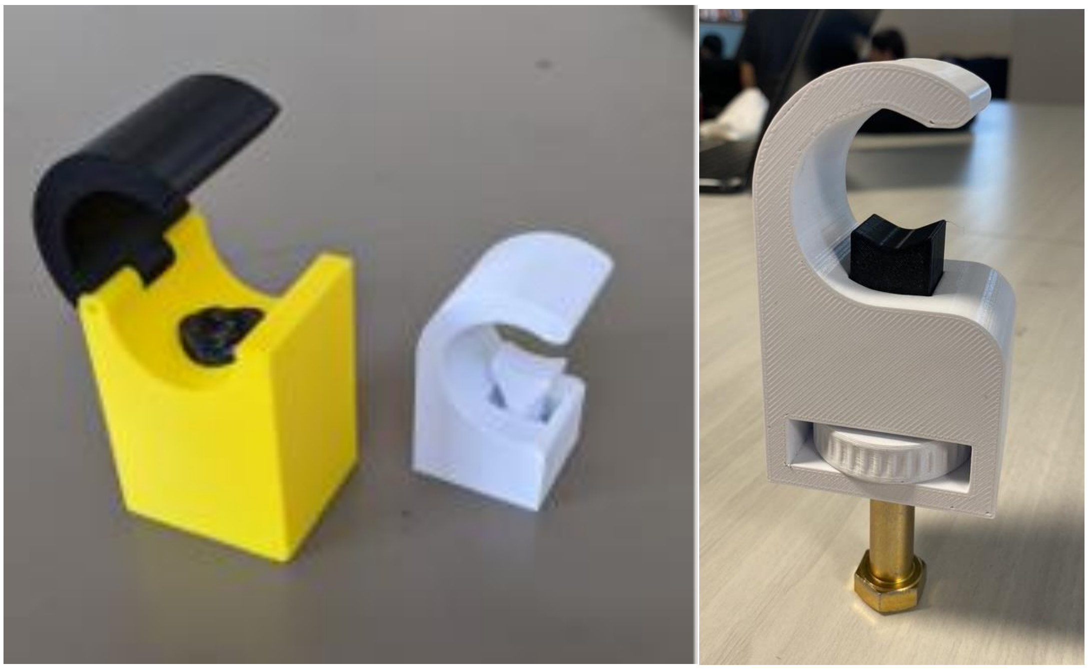


Figure 15. (Left) Latching gripper with adjustable diameter.

(Right) Fixed diameter hook design with adjusting base.

The group has primarily tested 3D printed versions of the base and gripper to check the fit and design functionality. However, the team is pursuing the use of more structural materials for use in the final prototype.

Chapter 5: Final Design Concept

The final design concept is pictured in Figure 16. The base will be constructed from carbon fiber and will feature a thermoplastic foam laminate liner, which will be permanently attached to the base with a waterproof adhesive (see Appendix F). A BOA tightening system will be used to tension the shell around her arm. Stainless steel bars extend from the base to a bicycle seat lock, which allows for the gripper to be angled as desired and fixed in place. The gripper is constructed of aluminum with stainless steel hardware and 3D printed components.

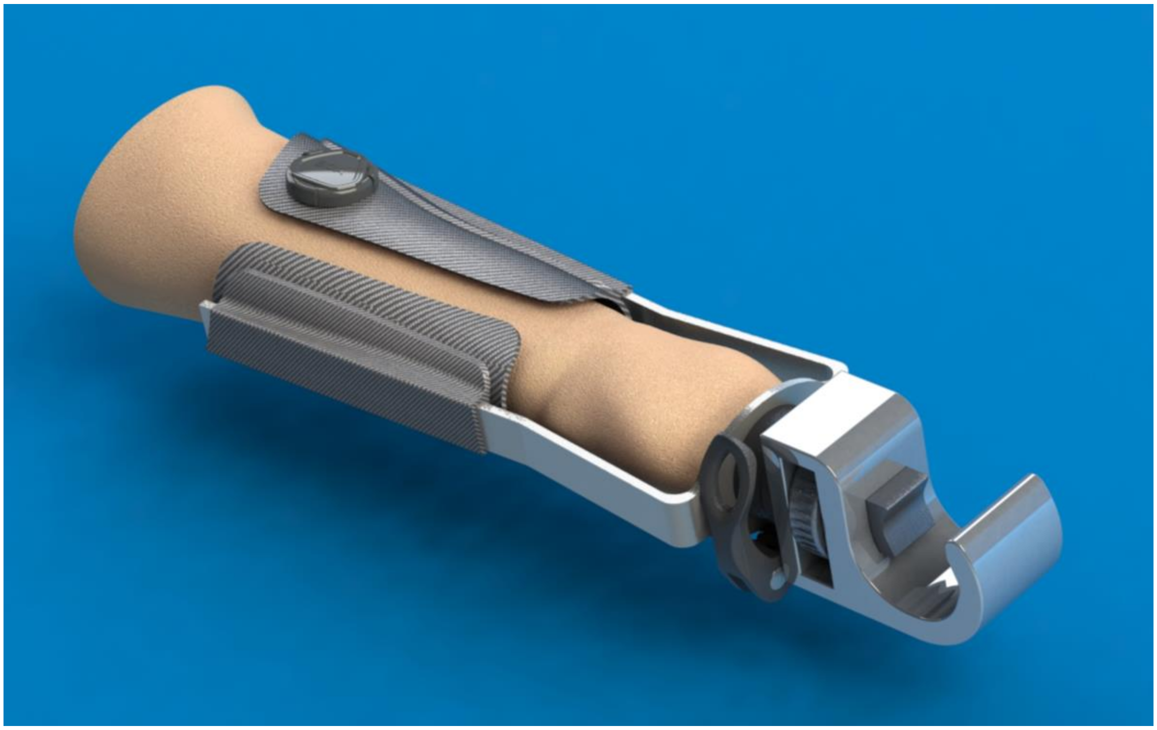


Figure 16. Render of the complete assembly of base and gripper, connected by rotational locking adjustment, sitting on a virtual mock-up of Madeline's Arm.

Fitment Improvements:

Since the previous prototype, notable changes have been made to improve the fit of the base onto Madeline's arm. Wrist range of motion and forearm length measurements were taken to develop a more accurate fit of the device. Using a goniometer, Madeline's wrist range of motion was taken in three degrees of freedom (flexion/extension, radial/ulnar deviation, pronation/supination). Madeline's left wrist range of motion was used as a clearance guide for the bars that run along the medial and lateral sides of her arm (Figure 17). Table 2 lists each wrist movement and their respective range of motion. Notability, due to the fusion of the radius and ulna in Madeline's forearm, she has significantly decreased supination/pronation ability (less than half the capability of an anatomically standard arm). The implication of this limitation was also evident while testing the fit of the 3D printed prototype. During testing, it was discovered that the straight slot opening did not properly align with the motion of Madeline's arm and the end of the base ended up pinching skin upon bending the elbow. The base was redesigned, as shown in Figure 18, in a way that allows for a more natural fit and gives more clearance on the inside of her elbow.

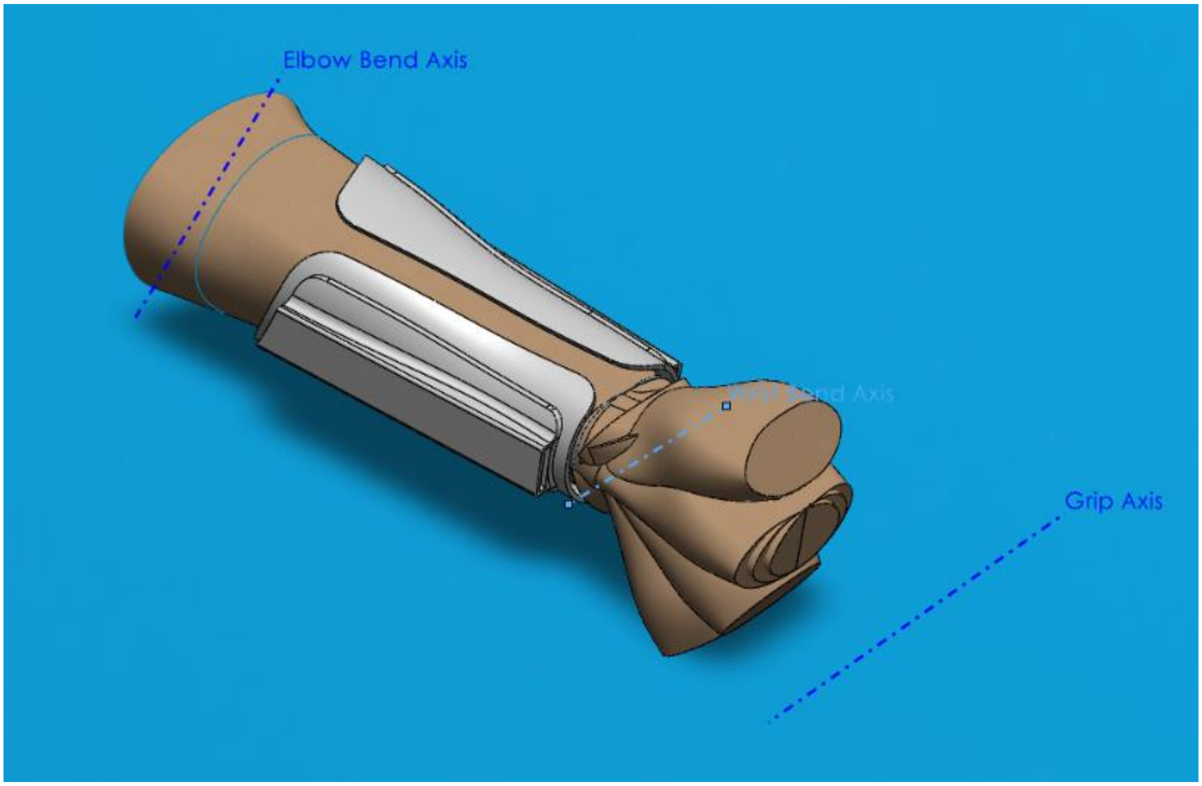


Figure 17. Visual representation of Madeline's left wrist range of motion

Additionally, forearm length measurements were taken from various points to ensure the prosthesis extends to the same length as her right hand. All forearm measurements were taken from both the medial and lateral epicondyles (bony protrusions at the elbow) to their respective medial/lateral distal locations. The PAL team found that while there is an obvious discrepancy between the length of Madeline's hands, there is also a significant difference in length of her forearms. The measurements in Table 3 were used to redesign the prosthesis in SolidWorks to account for the discrepancy in limb lengths.

Table 2: Wrist Range of Motion Measurements

Motion	Measurement (degrees)
Flexion	55°
Extension	30°
Radial deviation	5°
Ulnar deviation	5°
Pronation	13.5°
Supination	24°

Table 3: Wrist Length Measurements

Segment	Length (in.)	
	L	R
Medial epicondyle to center of bar/weight	9.5 in	12 in
Lateral epicondyle to center of bar/weight	9.75 in	13 in
Anterior wrist to fingertips	2.5 in	7 in
Top of prosthesis to anterior wrist	0.5 in	N/A

The measurements above were used to inform an improved base design in Figure 18 below. The design has been updated to ensure the length of the prosthesis matches the length of Madeline's right arm. Tolerancing at the elbow to avoid pinching has also been incorporated. A cable will be installed within the BOA system to allow Madeline to easily tighten/loosen the device with a simple twisting motion.

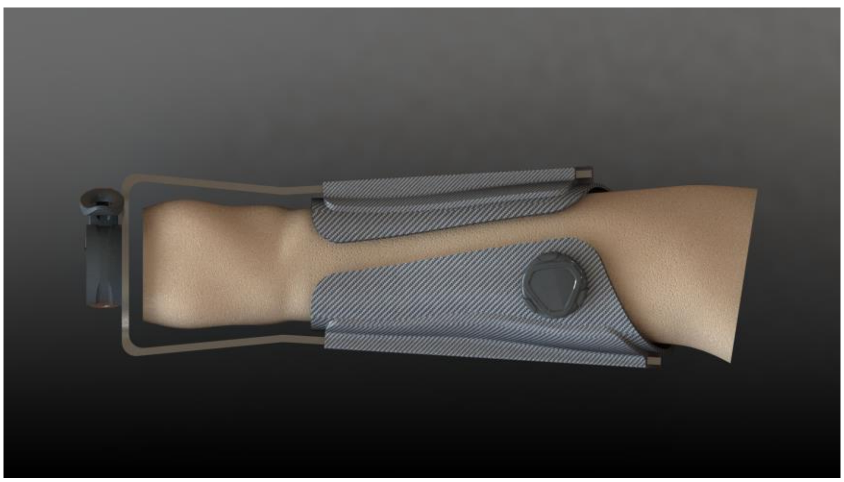


Figure 1817. Render of proposed final design concept for the base showing the BOA placement, angled slit, and rotational lock.

Material Selection:

Multiple factors went into deciding what materials to use for the final concept. Carbon fiber was chosen as the material of choice for the base due to its strength, stiffness, and light weight. It is also a net shape process, which works as a clear next step from the current 3D printed prototypes. Once a 3D printed design is achieved that is comfortable, a form can be 3D printed that will allow for a carbon fiber version to be constructed.

Stainless steel was chosen for the bars due to its high strength and corrosion resistance. As this will be used in an athletic environment, the prosthetic will be frequently exposed to sweat and water. The bars also must be strong enough to bear the forces of whatever workout Madeline is doing.

Aluminum was chosen as the primary material for the gripper as it is corrosion resistant and has a high specific strength. As the gripper is far from Madeline's elbow, it has a large impact on the perceived weight of the device. As such, it is critical that this component is utilizing good design practice and lightweight materials to minimize unnecessary discomfort.

Design for Strength and Stiffness:

As mentioned previously, loading cases were derived from the four exercises that Madeline would like to do as shown in Appendix B. These loading cases were used to perform the following analysis, which demonstrates the sufficient strength of the designs with their respective materials.

Hand calculations were first completed to validate future FEA analysis. Formulas were derived to describe the relationship between force, geometry, and stress in an assumed rigid, isotropic, material. These calculations indicated that the proposed designs will be able to carry loads in all directions.

The team then completed FEA analysis using the chosen materials to observe the maximum Von Mises stress, and deformation. This analysis shown in Appendix K demonstrates that with twice the expected load, the factor of safety is nearly 10 in the gripper. This does indicate that the main portion of the gripper is overdesigned and has material that could be removed to remove weight without sacrificing strength. Furthermore, with 2.5x the expected load, the factor of safety on the base is ~100. This indicates that significant reductions in weight are possible by using less material. The design for this sub assembly is included in Appendix G.

Maintenance and Repair Considerations:

An important feature of the prosthesis is its longevity. The device needs to sustain Madeline’s weightlifting needs for as long as possible while remaining comfortable for her to wear, sturdy, and clean. The soft thermoplastic laminate material lining the inside of the base will likely get dirty and deteriorate over time due to friction and sweat. To maintain good care of the device, Madeline will be able to scrub the inside of the base clean after each use (or as frequently as desired). To compensate for possible deterioration, the soft inner layer can be removed as needed and replaced using a strong waterproof adhesive.

Additionally, the metal bars that extend from the base of the prosthesis to the gripper will be removeable. In keeping these components detachable from one another, Madeline can potentially use the device with other terminal attachments. Detachability of the two main subassemblies also simplifies the cleaning process of the device. Negating the soft inner layer, the entire device is waterproof and should be wiped down frequently to maintain its longevity.

Chapter 6: Manufacturing Development Plan

Testing:

Due to the nature of prosthetic devices and the weightlifting goals for this project, most testing will take place after the device is manufactured. The 3D printed subassemblies are made of PLA which does not have the adequate strength properties needed for holding and lifting weights. Appendix H details a Design Verification Plan and Report. To obtain quantifiable testing information during the prototyping stage, the team developed a feedback form (see Appendix I) for Madeline to complete after each iteration. The questions on the form are based on the engineering requirements listed in Chapter 3, Table 1. The goal of the feedback form is to obtain measurable feedback from Madeline to influence and improve future iterations of the device.

Sustainability:

The PAL device best fits into Design for the Environment 6: Design for Recycling and use of Recycled Materials. The prosthesis will be made using carbon fiber, moldable thermoplastic laminate, and various metals. While some of these materials, such as carbon fiber, need to be newly purchased, other parts of the device can be constructed from recycled parts. The machine shops on campus as well as some of the members of the PAL team have scrap materials that have already been implemented into some prototyping of the prosthesis. The PAL team intends to first utilize scrap materials so the manufacturing process can be as sustainable as possible. It is important to note that this device is bespoke and is not designed for mass production. It is intended to serve Madeline's needs for as long as possible, ideally lasting several years before adjustments need to be made. With that, the project is sustainable and prioritizes the efficient use of materials.

Safety Considerations:

Each group member has completed Cal Poly mandated safety training modules as required to access the TECHE Lab. Safety considerations will be considered when the PAL team is manufacturing the device. The group has obtained certifications to operate machinery in machine shops such as the mill and lathe. Proper PPE will be worn when dealing with these machines, carbon fiber, and other potentially hazardous materials. Safety while testing is also a top priority. Testing for the prosthesis will involve human subjects research, including the lifting of heavy weights which could potentially cause harm if dropped or handled improperly. At the start of Spring quarter, the group will consult with the Cal Poly Institutional Review Board (IRB) to identify if the proposed testing plan renders approval by the Cal Poly IRB. If approval is necessary, the group will immediately complete all steps needed to be cleared for testing, including any Cal Poly mandated safety training and the submission of documentation related to testing.

Special fabrication and assembly instructions:

All custom components will be manufactured within Cal Poly's Mustang '60, Hangar, or the TECHE lab. The gripper and bars will be manufactured using standard metalworking equipment (waterjet, knee mill, engine lathe, drill press, press brake, etc…). Careful use of these machines is necessary for the safety of the team, Madeline, and the success of the project. The base, being constructed from carbon fiber, will be manufactured within the new composites area of the Hangar. The team will use vacuum resin infusion in order to achieve thorough infiltration of the carbon fiber weave. Extra care is necessary in the handling of raw carbon fiber and the post processing of carbon fiber parts due to the risk of skin/eye irritation and the carcinogenic effects of inhaled carbon fibers.

Chapter 7: Management Plan

To accomplish the goal of producing a satisfactory prosthetic for Madeline's needs, the group will organize itself in a few ways.

Emma Caringella will be the primary contact with Madeline so that she does not receive too many communications that may distract her from her classes, but enough so that the group is able to work with her. This will also limit the possibility that the group neglects communication with Madeline thinking it was being handled by other group members. Emma will also use her experience in biomedical engineering to develop prototype interfaces for Madline's arm and its biomechanics. Madeline has decreased supination range in her forearm due to the fusion of her radius and ulna, so the focus on biomechanics will be understanding the mechanisms during each of the four exercises and ensuring the device allows for those motions. For example, cable triceps pushdowns require minor wrist flexion/extension that the team will accommodate for in their design.

Dawn Veditz will be the primary scribe to record ideas, brainstorming sessions, meeting minutes, etc. She will also leverage her mechanical engineering knowledge and experience using CAD and stress analysis software. She will also provide machining support and will serve as the lead for any programming that is required.

Cameron Yartz will be the primary contact with Hanger Clinic and will serve as the primary machinist on the project. This means he will be responsible for setting up meetings with Hanger Clinic, performing machining tasks, and assigning machining tasks to the rest of the team as he deems appropriate. He will also leverage his mechanical engineering experience in CAD and stress analysis software.

The team will meet 3 hours twice per week during regular weekly lab times, organize and attend team meetings when tasks are to be completed, and attend any meetings that are organized with third parties such as Hanger Clinic, unless reasonable explanation is provided to the group beforehand for the absence. As such, the group members are expected to put in an average of at least 10 hours of work each week until the end of the Spring 2024 quarter, when the project will end. The group will make important decisions via consensus reached through discussion of ideas, or by simple majority in case swift decision making is required.

The deliverables for Madeline are expected to follow the schedule laid out in Table 3. The most notable feature of this schedule is the development of functional prototypes every two weeks beginning on Thursday February 13th. This should allow Madeline an opportunity to test the prototype for a week and deliver feedback so the group may constantly improve the comfort and functionality of the prosthesis as described in the Method of Approach section.

A Gantt chart was chosen as the most effective way to manage timelines and key milestones. A Gantt chart was created using Project Gantt and can be found in Appendix D. Dependencies were kept in mind when scheduling tasks. In Winter quarter, the team will go through three prototyping/revision cycles while incorporating feedback from Madeline.

Table 4. 4 Project Timetable

Deliverable	**Date**
Intro Letter	09/29/2023
Team Contract	10/05/2023
Project Requirements Document	10/23/2023
Conceptual Model	11/07/2023
Decision Matrix	11/16/2023
Project Schedule	11/28/2023
Conceptual Design Review Slides	12/05/2023
Conceptual Prototype	12/05/2023
Conceptual Design Report	12/08/2023
Presentation to Sponsor	12/08/2023
Critical Design Review Presentation	02/13/2024
Functional Prototype	02/13/2024
Presentation to Sponsor	02/22/2024
Functional Prototype	02/27/2024
Critical Design Review Report	02/27/2024
Functional Prototype	03/12/2024
Project Update Memo to Sponsor	03/15/2024
Functional Prototype	04/09/2024
Hardware & Software Demo	04/23/2024
Functional Prototype	04/23/2024
Functional Prototype	05/07/2024
Functional Prototype	05/21/2024
Final Project Report	06/04/2024
Presentation to Sponsor	06/04/2024

Chapter 8: Updated Final Design Concept

The final design concept (see Chapter 6) endured several changes prior to manufacturing.

Base Design:

The team developed a model similar to the previous final design, but with the addition of a "door" panel rather than a slit and a Click®Reel system rather than BOA (Fig. 19). In this updated final design, a mounting plate sits at the top of the base, acting as an interface between the base and the gripper components. A bike seat lock is placed inside the open part of the base (just distal to Madeline's hand) to allow for full rotation of the gripper only when desired. Note that during manufacturing, the door was moved to the medial side of the forearm and the Click®Reel collar was moved to sit just below the wrist.

Figure 19. (Left) Render of the complete assembly of the base, including mounting plate, sitting on a 3D scan of Madeline's arm. (Right) Frontal view of base with mounting plate.

Additionally, rather than adhere a thermoplastic foam laminate liner to the carbon fiber base, the team ordered a "soft sleeve" from Silipos, a polymer gel manufacturing company for foot care products (Fig. 20). A silicon ankle sleeve matched the dimensions of Madeline's arm and was ideal for wicking sweat. The 1/8-inch thickness of the sleeve was taken into account in the offset of the 3D print for manufacturing the base.

Figure 20. (Left) Silipos silicon sleeve. (Right) Sleeve on Madeline's arm under 3D printed base prototype.

Gripper Design:

The final gripper assembly utilizes a stainless-steel left-hand threaded 3/8" diameter, 2 start, 0.167" lead, lead screw to adjust the height of the platform. Unlike the prototype for the final concept, the lead screw does not move axially, but instead drives the platform along the lead screw mounted in the back of the grip. This modification reduces the overall height of the grip since there is now no need to have a receiving space for the retracting lead screw. The multiple starts allow the travel of the platform to be higher than a single start lead screw, but still maintains a pitch angle low enough to remain self-locking so the platform cannot be moved down without user intent.

The final assembly also uses a custom internally toothed gear with ridges along the outside. This can be seen in Figures 21 and 22 in blue. This, in combination with the left-hand threaded lead screw allows Madeline to turn the wheel clockwise to tighten the grip, and counterclockwise to loosen the grip. The gears are both 20-degree pressure angle, 0.5 module gears with 50 teeth on the pinion and 100 teeth on the adjustment wheel. This means that for every clockwise turn of the wheel, the internal gear will turn twice, and because the leadscrew is mounted into the smaller gear, the grip will reduce in size by a total of 0.33 inches. In order to adjust from a 1.5-inch diameter grip size to a 1-inch diameter grip, this means that Madeline needs to rotate the adjustment wheel less than 2 full turns, which is much less tightening motion than the previous prosthetic attachment. Additionally, because the front of the grip is otherwise an open hook design, only a portion of a turn is required to remove the grip from the exercise equipment and can alternatively be used without tightening if the exercise allows.

The topmost 3D printed part depicted in Figures 21 and 22 is mostly cosmetic, hiding the two small aluminum spacing rods, but the rectangular cut out assists in locating the parts during assembly. The largest 3D printed part that is wrapped around the back of the grip is entirely for aesthetic purposes as Madeline stated she was concerned about the overall look being too mechanical. This cover hides the lead screw and several bolts from view but is otherwise open to customization.

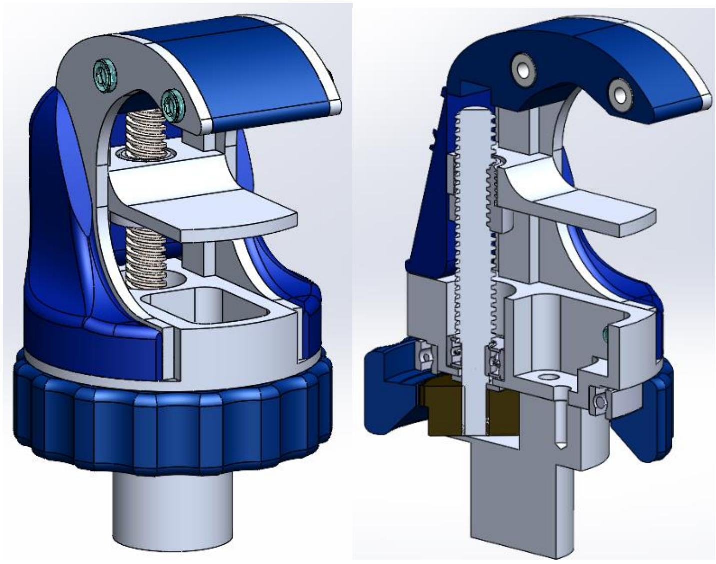


Figure 21. (Left) Render of the complete assembly of the gripper, including 3D printed parts marked in blue. (Right) Sectional view of the complete assembly demonstrating the function of the gears and leadscrew interaction.

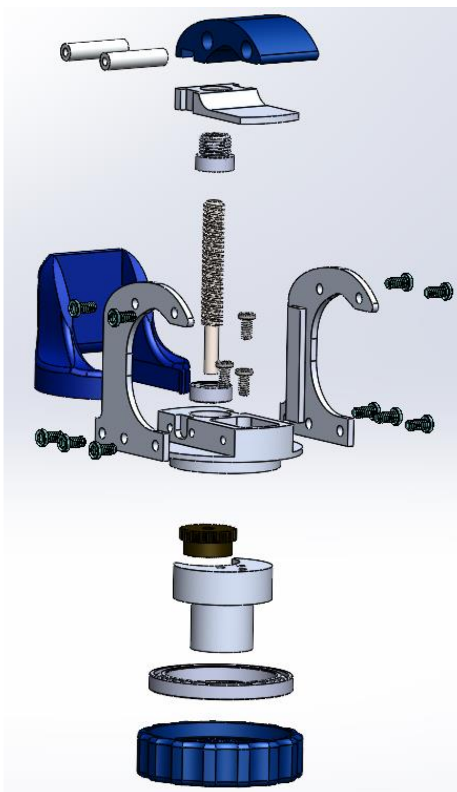


Figure 22. Exploded view of the gripper assembly

The total cost for the prosthetic came out to $640.53. See Appendix M for a cost breakdown of the final product.

Chapter 9: Product Realization

Base Manufacturing:

To create the carbon fiber base, a 3D-printed model of Madeline's arm was constructed in SolidWorks and printed at Mustang 60, as shown in Figure 23. The model accounted for Madeline's range of motion in her wrist and included an offset to match the geometry of her forearm.

Figure 23. PLA 3D print of Madeline's left forearm

The carbon fiber layup involved two layers of vacuum infused resin separated by a lamination layer for the Click®Reel system. First, a 4-inch diameter PVA bag was pulled over the print and tied at the top. Then a carbon fiber fabric sleeve was laid over the 3D print, tied at the top with twine, and folded back down to create a second layer (Fig. 24, Left). A nylon stocking was then slipped over the carbon fiber to support the dispersion of resin to all parts of the base (Fig. 24, Center). A 6-inch diameter PVA bag was added as an additional layer to allow for vacuum suctioning (Fig. 24, Right). A vacuum pump was sealed to the bottom of the base and turned on (Fig. 25). Next, a resin mixture (West System 105 Resin with 206 Hardener) was poured into the opening of the PVA bag at the top of the base to be gradually sucked down both by gravity and the pressure from the vacuum. String was used to support the movement of resin down the base until the entire component was fully covered in a thin layer of resin. The base was left to dry for 24 hours with the vacuum pump remaining on to mitigate resin displacement or clumping.

Figure 24. (Left) Carbon fiber fabric sleeve. (Center) Nylon sleeve overlay. (Right) PVA bag with resin infusion.

Figure 25. Vacuum pump setup for vacuum resin infusion.

Between resin infusions, a Click®Reel lamination collar and lamination tube were embedded in the base, as shown in Figure 26. This system would allow for Madeline to loosen/tighten the base on her forearm. Using chalk, a door was drawn on the medial side of her forearm which would later be cut out. The medial side of the arm has the most compressive surface area and thus is the most ideal spot for compression. Abiding by the Click®Reel Lamination Guide, the lamination collar and tubing system were mapped out and glued to the base. Additionally, an aluminum mounting plate was adhered to the top of the base which would later act as the connecting piece between the base and the gripper (Fig. 27). A lathe was used to center the mounting plate on the base. The lathe held the mounting plate securely to the base overnight while the adhesive cured.

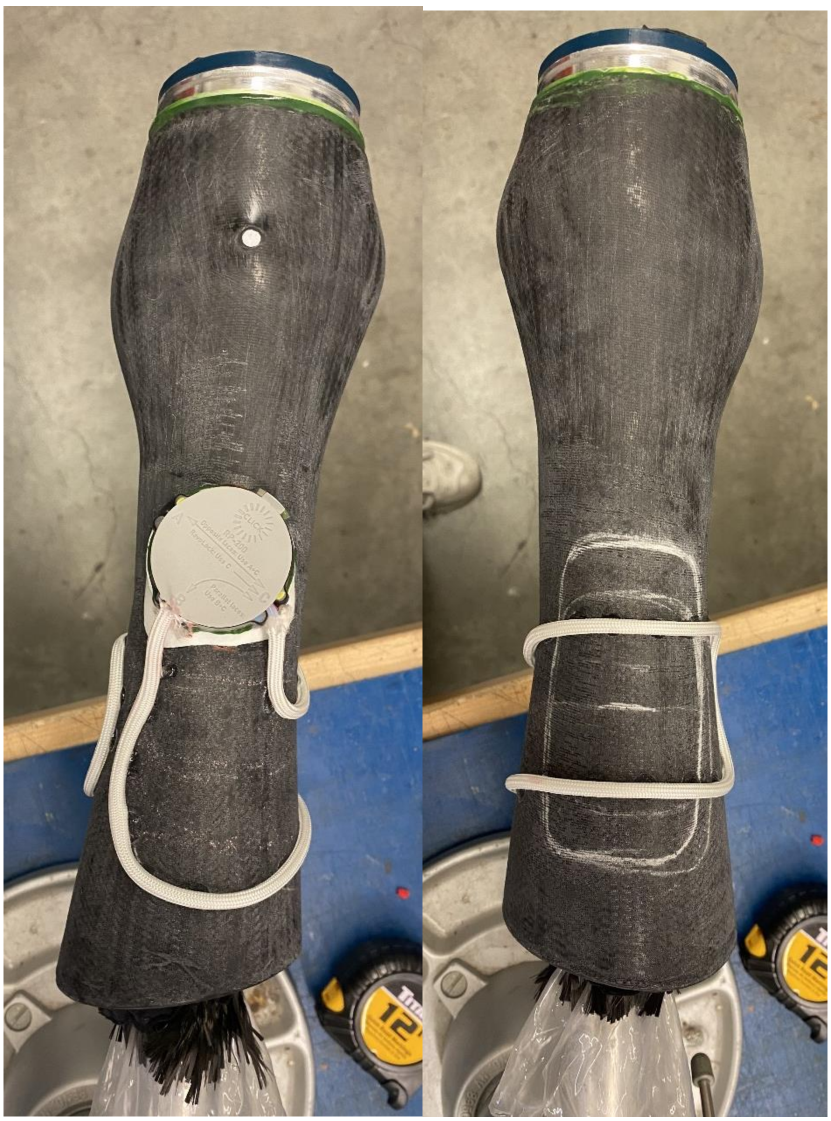


Figure 26. (Left) Click®Reel lamination collar and lamination tube adhered to base. (Right) Chalk layout for embedding lamination collar and lamination tube.

Figure 27. Adhering the aluminum mounting plate to the top of the base.

Following the adhesion of the Click®Reel components and mounting plate to the base, the second and final layer of the carbon fiber layup was completed. Similar to the first layer, the second layer involved a carbon fiber sleeve (tied at the top and folded back down), a nylon stocking, and PVA bag. The vacuum pump was again sealed to the end of the base and resin was poured into the opening of the PVA bag at the top of the base. This second infusion required a significant amount of support to ensure resin was evenly distributed to all parts of the base in a timely manner. The resin tended to "pool up" around the lamination collar and tubing, so the team worked against the clock to pull resin out of these pockets and into other areas. See Figure 28 for images of the resin infusion process.

Figure 28. (Top and Bottom) Second layer of vacuum resin infusion for carbon fiber base.

24 hours after the resin infusion, the carbon fiber base was dry and ready for further manufacturing. Upon attempting to melt the PLA print (now sitting underneath the carbon fiber) with a heat gun, the team realized that resin had seeped into the 3D print, rendering the “melting” method insufficient. Ultimately, a small saw was used to repeatedly and meticulously chip away at pieces of the PLA/resin composite until the print could be wiggled out of the proximal end of the base (Fig. 29).

Figure 29. Removing the 3D-printed base from underneath the carbon fiber base.

Using a Dremel with a cutoff wheel, the top and bottom faces of the base were cut off to expose the side bars. In this open section, Madeline’s hand will be able to sit comfortably with space to have full range of motion of her wrist.

The “door” panel was cut out on the medial side of the base using the Dremel with a cutoff wheel (Fig. 30). A Dremel with a sanding drum was then used to round out rough edges and shape the base to the desired dimensions.

Figure 30. Carbon fiber base with cut out door and exposed side bars, before installing Click®Reel lacing system.

Finally, the Click®Reel was laced up, and a small piece of foam was adhered to the inside of the door for additional compression (Fig. 31).

Figure 31. (Left) Front of base. (Right) Back of base.

Gripper Manufacturing:

The gripper was primarily made of machined aluminum and purchased components from McMaster-Carr. Below are images and descriptions of each gripper component including their material composition and how they were manufactured.

The core of the gripper was created using aluminum stock on a manual lathe (Fig. 32). Additional geometries of core were later machined using a CNC Mill under the supervision and assistance of Mike Hillman.

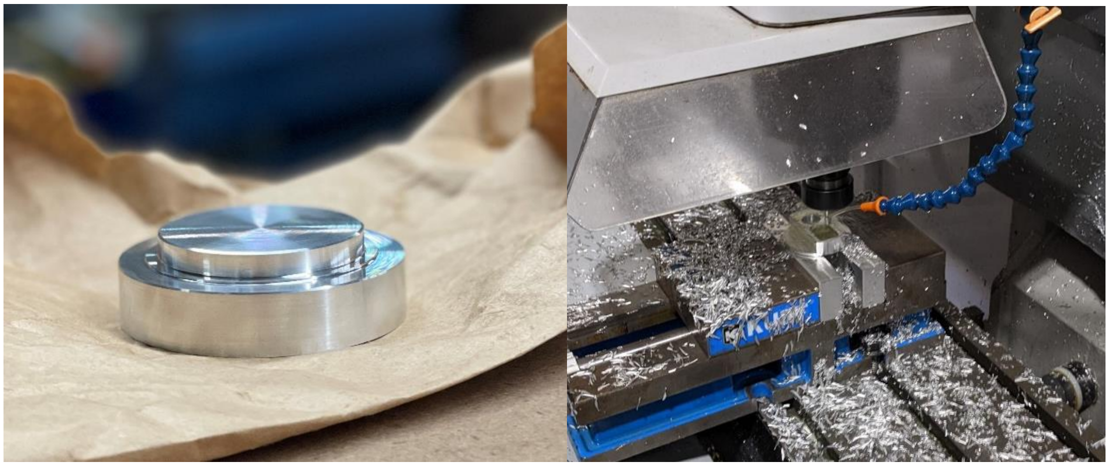


Figure 32. (Left) Gripper core after lathing. (Right) Gripper core on CNC Mill.

The sidebars of the gripper had some of the most critical dimensions of the entire part. However, due to their unique shape, manufacturing the sidebars out of aluminum proved to be a challenge. After about four failed attempts on the mill, the team pivoted to using stainless steel, sacrificing a heavier material for a slightly easier manufacturing plan. An angle grinder was used to cut out the general shape of the side bars from the stainless steel stock, and a Dremel with a cutoff wheel was used for obtaining exact dimensions (Fig. 33).

Figure 33. Sidebars made of machined stainless steel.

The platform (blue arrow, Fig. 34) is made of machined aluminum and was constructed on a lathe and mill. The external gear, which Madeline turns to raise/lower the platform on the lead screw, went through several 3D print iterations. The team later adhered rubber to the top and bottom of the platform to mitigate wear on the aluminum and soften the interface between the gripper and weights. After several attempts with PLA and resin printing, the team chose to print the gear using a carbon fiber filament (orange arrow, Fig. 34). The carbon fiber print produced the strongest and most developed gear teeth and was the most compatible option to interact with the internal gear. A bearing was press fit onto the core of the gripper and the external gear was press fit onto the outer diameter of the gear, allowing the gear to rotate smoothly in relation to the gripper core. The purchased lead screw was machined down to size using a lathe (yellow arrow, Fig. 34).

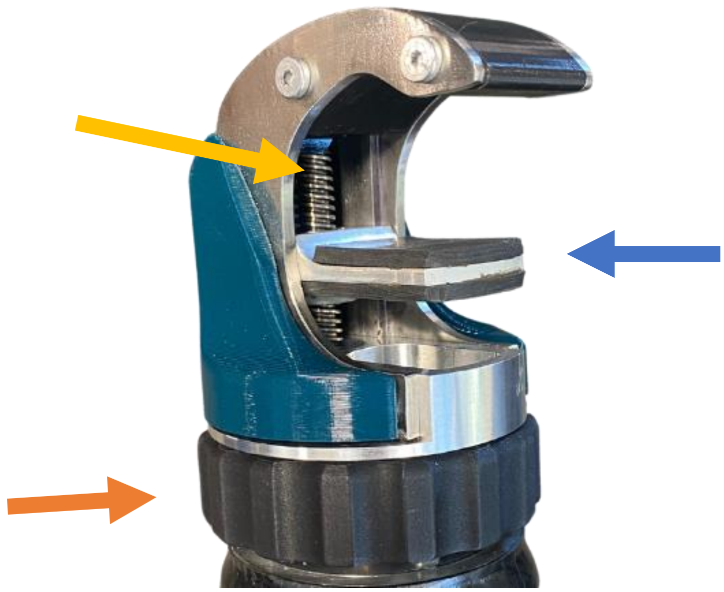


Figure 34. Final gripper design with blue arrow indicating platform, orange arrow indicating external gear, and yellow arrow indicating lead screw.

Within the PLA arch at the top of the gripper, there are two aluminum cylinders that were machined on the lathe and tapped with a #10-25 hand tap. The core and sidebars were also drilled with a mill and tapped using a #10-25 hand tap. Bolts ordered from McMaster-Carr were screwed into place to fasten the sidebars to the cylinders and the core, and to fasten the core to the internal parts of the gripper.

Figure 35. (Left) Bike seat lock in open position (Right) bike seat lock in closed position

To allow the bike seat lock to remain in a fixed position relative to the rest of the base, a small slot or keyway was milled into the bike seat lock and underlying fixture plate, as shown in Figure 35. A small aluminum disk was lathed to be a larger diameter than the opening of the bike seat clamp, and then a raised tooth or key was milled to match the keyways. This prevents the fixture plate, bike seat lock, and aluminum disk from rotating relative to each other. The aluminum disk is bolted to the gripper using a shoulder screw to prevent the gripper from moving axially but allowing the gripper to rotate freely.

Chapter 10: Design Verification (Testing)

Madeline and the PAL team completed all tests in the DVP&R (see Appendix H) to ensure the prosthetic met all engineering requirements. Below are notable specifications that were tested and their corresponding results. All test results are included in an updated DVP&R in Appendix L.

Prosthetic fit:

Madeline rated the prosthetic fit an 8/10, explaining that the device felt secure on her arm and was comfortable, but would need several weeks for her arm to acclimate to the feeling of the device. The group considers this a “pass” of the prosthetic specification, as the device stayed on her arm while holding weights and felt comfortable and secure.

Capillary refill time:

To complete the capillary refill test, Madeline secured the device to her arm and completed a series of upper body workouts for 10 minutes (limiting her workouts to the four previously defined). Upon completion of the workouts, the prosthetic was removed and a timer was set to assess capillary refill in the absence of the prosthetic. Madeline and the PAL team looked for signs of indentation or redness on her left arm where the prosthetic sat. There was obvious irritation from the swelling of Madeline’s arm in the soft sleeve, but the redness cleared up in under 5 minutes. There was also a small indentation on the posterior wrist from constant extension of the joint, but this also cleared up within 10 minutes. Since both indications of pressure and irritation disappeared within 30 minutes, this specification was considered passed.

Bulkiness:

To improve upon Madeline’s previous prosthetic aid for lifting, which was rather bulky, the team designed the base to be less than ¾ inch past the surface of her arm. The final carbon fiber base measured to around 1/20 inch and was form fit to her arm, resulting in a major decrease in bulkiness from her last device. The soft silicon sleeve added 1/8 inch thickness around her arm, which is still within the passing range for this specification.

Weight of prosthetic:

Madeline’s previous prosthetic device weighed 2 lbs, so the PAL team aimed to keep the overall weight of this device at 2 lbs or less. The final product weighed 1 lb 15 oz, resulting in a “pass” (Fig. 36).

Figure 36. Weighing the prosthetic on a scale after final assembly.

Time to don/doff prosthetic:

Starting with the silicon sleeve on her arm, it took Madeline 25 seconds to don the prosthetic, including turning the Click®Reel dial to her desired level of compression. The specification was passed, as the time was under 30 seconds. It took Madeline under 25 seconds to doff the prosthetic.

Total left arm equal to right arm:

To measure the potential discrepancy between the length of Madeline's arms while wearing the prosthetic, Madeline held a long PVC pipe (mimicking a bent over row) and measurements were taken from the medial and lateral epicondyles to the center of the bar on both arms. When Madeline was mimicking a bent over row, the left side (with the prosthetic) measured 13 inches in length and the right side measured 15.25 inches. This difference in length resulted in a 6° tilt on the PVC pipe measured from the contact point on the prosthetic. While this 2.25-inch discrepancy is not ideal, Madeline was able to comfortably accommodate by scooting her right hand down the bar toward her left hand. Nonetheless, a difference in length could lead to future injuries in the proximal parts of the arm, such as the shoulder joints. This specification was not passed.

Grips weight without spinning:

Madeline was able to complete each of the four designated workouts with the weights (barbells, dumbbells) remaining firmly gripped and not spinning. The bike seat lock mechanism ensured the gripper did not spin on its axis unless the lock was opened. This specification was passed.

Withstands weight without slipping:

Similar to the test above, Madeline completed each of the four designated workouts with the weights (barbells, dumbbells) remaining firmly gripped in the prosthetic. This specification was passed.

Holds weight in axial direction:

Madeline completed lat pulldowns and bent over rows holding 15 lbs for each exercise. She reached 17.5 lb before deciding to stop the test and her and the PAL team did not intend to test the device to failure.

Holds weight in transverse direction:

Madeline completed tricep pushdowns and bicep curls holding 15 lbs for each exercise. She reached 17.5 lb before deciding to stop the test and her and the PAL team did not intend to test the device to failure.

Withstands weight during torsion:

Madeline held the end of a barbell with her left hand (using the prosthetic) and completed quasi-bicep curls. She was able to comfortably lift 7.5 ft-lb in torsion (calculated from the length of the barbell from the gripper as well as weight of the barbell) and did not increase the weight as she did not feel comfortable doing so in the prosthetic. This specification was passed, as the goal was to withstand at least 7.5 ft-lb in torsion.

Chapter 11: Conclusions and Recommendations

The team learned early on that advice from experts in the prosthetics industry was crucial to their success. Namely, prosthetists Matt and Will from Hanger Clinic provided advice on what would and wouldn't work to create this device. They advised the team that a carbon fiber base would be challenging to manufacture but would best serve Madeline's needs of a form-fitting, lightweight prosthetic that could support heavy loads. The team also learned the importance of iteration. They utilized the Prusa 3D printers in Mustang 60 to print each iteration and subsequently met with Madeline to analyze the fit and obtain feedback. These "fitment" tests were pivotal in the team's design process, as each led to a slightly more improved design. In the end, the PAL team was able to create a functional Prosthetic Aid for Lifting that Madeline feels is comfortable and secure. (Fig. 37). She looks forward to using it in the gym to accomplish her weightlifting goals. See Figures 37 and 38 for images of Madeline wearing the PAL.

Figure 37. Madeline wearing the PAL while gripping a small metal bar to simulate a dumbbell.

Figure 38. Closeup of Madeline wearing the PAL while gripping a small metal bar to simulate a dumbbell.

Chapter 12: Acknowledgments

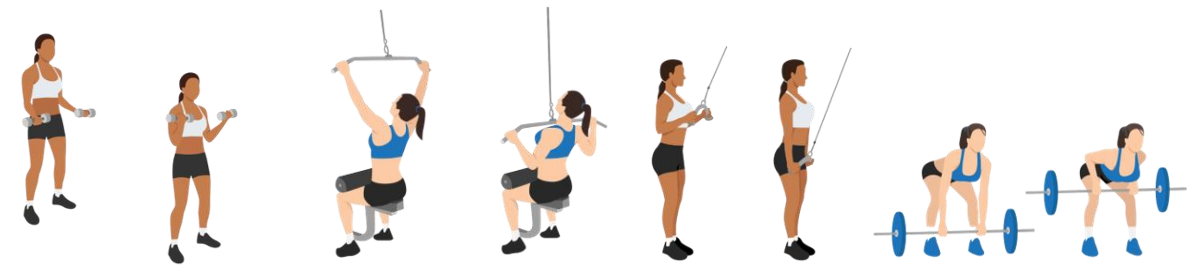
The PAL team is extremely grateful for the support and advice they received throughout their design and development process. They would like to thank Dr. iian Black for his guidance as a project advisor and for sharing his prosthetic expertise. His support and encouragement were instrumental to their success. Prosthetists Matt and Will from Hanger Clinic in San Luis Obispo supported the PAL team by providing access to a 3D scanner, sharing their advice from the industry, and supplying the team with PVA bags for the base manufacturing. Learning from prosthetists about the behavior of residual/anatomically unique limbs was extremely helpful during the team’s design stage. Their suggestions influenced many of the team’s design decisions, ultimately leading to a fully functioning product that fit Madeline well. Mike Hillman at the Cal Poly Hangar spent many hours helping the team use the CNC Mill, a machine that was vital in the manufacturing process of the gripper. The team would like to thank Mike for his generosity and time.

Finally, the team would like to thank Madeline for her unwavering willingness to meet with them, test numerous prototypes, and share her thoughts. Her encouragement throughout this process was pivotal to their success. Thank you for trusting the team to take on this challenge!

Appendix A—House of Quality

Customer Requirements	Weighting (1 to 5)	Smoothness of prosthetic material	Prosthetic fit	Bulkiness	Weight of prosthetic	Overall cost	Equal length to right arm	Grips weights without spinning	Withstands 30 pounds before slipping	Holds weight in axial direction	Holds weight in transverse direction	Withstands weight during torsion	Benchmarks: Pro Cuff Distal Mount (Current Prosethetic)		
Comfortable*	4	●	●	○	●	Δ	○	○	●				4		
Easy to take on/off prosthetic	1	Δ	●	Δ	○								7		
Safe to use	2		●	Δ	●		●	○	●	○	○	○	2		
Durable	3				Δ	○				●	●	●	6		
Wrist flexion	1			Δ	Δ	Δ	Δ	Δ			Δ		0		
Sense of Stability*	4		●	Δ	●	Δ	○	●	○	Δ	Δ	Δ	2		
Ability to do bicep curls w/ 15lb dumbells*	5		○	○	●	Δ	●	●	○	Δ	●	Δ	5		
Ability to do tricep pushdown 20lb*	5		○	○	●	Δ	●	●	○		●	Δ	5		
Ability to do lat pulldown 30lb*	5		○	○	●	Δ	●	●	●	●		Δ	3		
Ability to do bent over row 20-30lb*	5		○	○	●	Δ	●	●	●	●		Δ	5		
Quick release/connect of attatchments	1			Δ	○	Δ	Δ			Δ	Δ	Δ	0		
Easy/quick attachment use	1			Δ		Δ		○		Δ	Δ	Δ	3		
Compatibility with current attachments	1					○	○	●					10		
Subtle visual design	2		Δ	●		○	●						5		
Units		N/A	N/A	inches	lbs	$	inches	N/A	lbs	lbs	lbs	ft-lbs			
Target Values		Maddie Approved	Maddie Approved	Does not extend more than 3/4" farther than arm	2lbs or less	$500.00	Matches 6in length difference	Weightlifting attachment does not move	30lb	30lb	20lb	15ft-lb			
Pro Cuff Distal Mount (Current Prosethetic)															
Benchmark #2															
Importance Scoring		37	161	100	280	49	245	247	186	134	130	59			
Importance Rating (%)		13	58	36	100	18	88	88	66	48	46	21			

Appendix B—Exercise Diagrams



(From left to right) Bicep curl with dumbbells, lat pulldowns, cable triceps pushdowns, bent over rows.

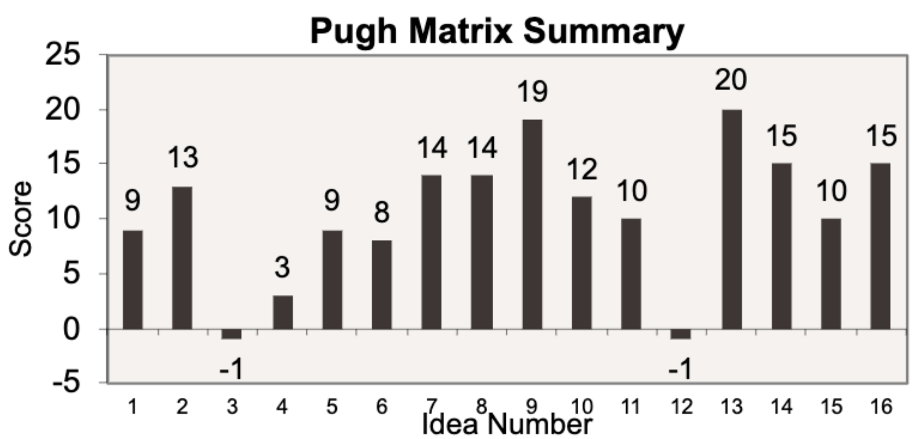
Appendix C—Pugh Matrix

Lower Arm Prosthetic Pugh Matrix

Concept Selection Legend: Better +; Same S; Worse -

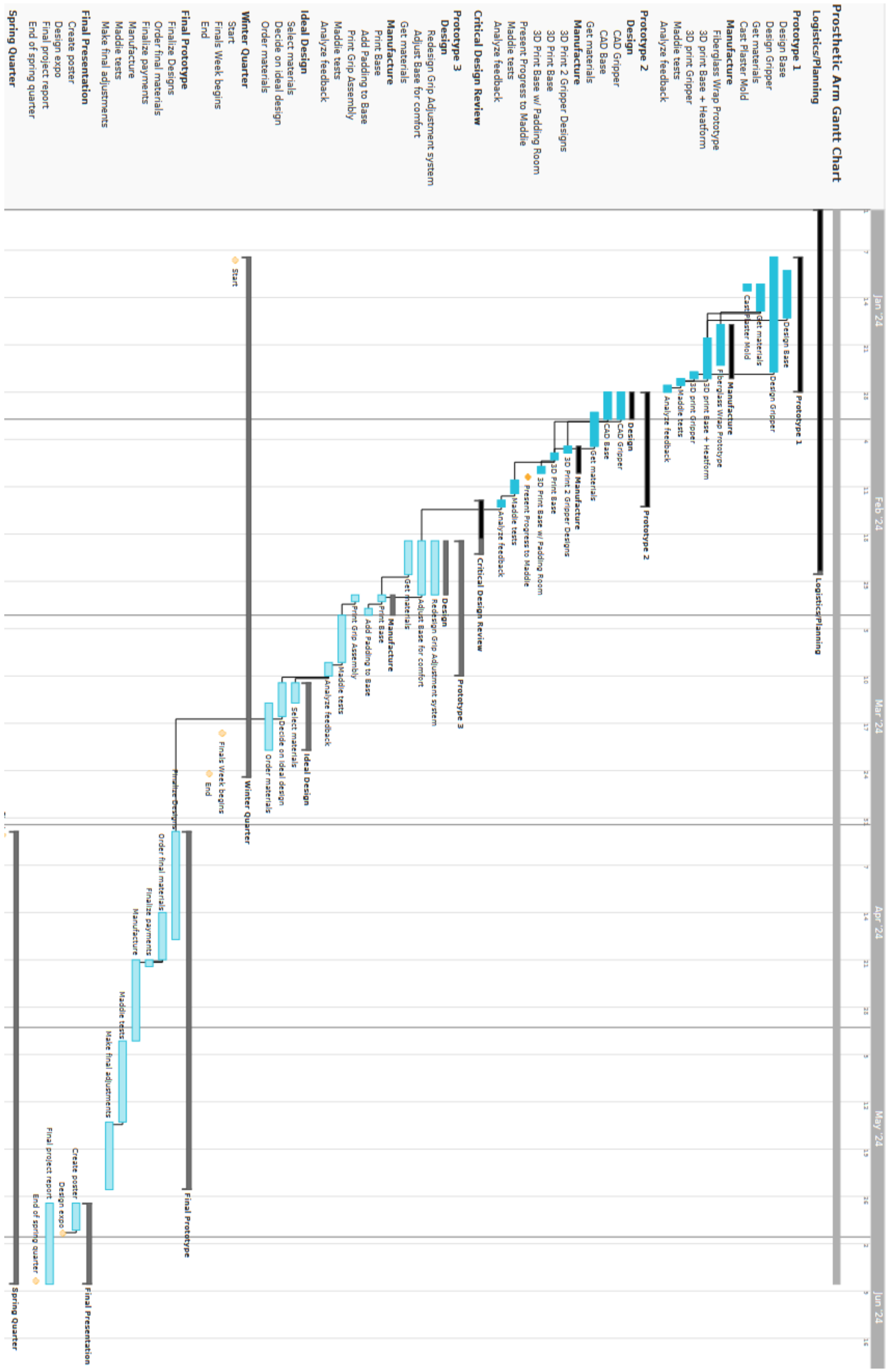
Key Criteria	Importance Rating	Benchmark Option: Pro Cuff Distal Mount (w/ TRS attachment)	1	2	3	4	5	6	7
			Alternative Concepts						
Comfortable	4		+	+	-	-	+	S	+
Sense of Stability	4		S	+	S	+	S	+	+
Ability to do bicep curls w/ 15lb dumbells	5		S	S	S	S	S	S	S
Ability to do tricep pushdown 20lb	5		S	S	S	S	S	S	S
Ability to do lat pulldown 30lb	5		S	S	S	S	S	S	S
Ability to do bent over row 20-30lb	5		S	S	S	S	S	S	S
Easy to take on/off prosthetic	1		+	-	-	+	+	-	+
Durable	3		S	+	S	S	S	+	+
Safe to use	2		+	+	+	+	+	+	+
Compatibility with current attachments	1		S	S	S	S	S	S	S
Easy/quick attachment use	1		+	S	+	S	+	S	S
Quick release/connect of attachments	1		-	-	+	S	-	S	S
Wrist flexion	1		S	S	S	S	S	S	S
Subtle visual design	2		+	+	S	S	+	S	S
Sum of Positives			5	5	3	3	5	3	5
Sum of Negatives			1	2	2	1	1	1	0
Sum of Sames			8	7	9	10	8	10	9
Weighted Sum of Positives			10	15	4	7	10	9	14
Weighted Sum of Negatives			1	2	5	4	1	1	0
TOTALS			9	13	-1	3	9	8	14

Key Criteria	8	9	10	11	12	13	14	15	16
Comfortable	-	+	+	-	-	S	S	S	S
Sense of Stability	+	+	+	S	S	S	S	S	S
Ability to do bicep curls w/ 15lb dumbells	S	+	S	S	S	+	+	+	+
Ability to do tricep pushdown 20lb	+	S	S	S	S	+	+	+	+
Ability to do lat pulldown 30lb	+	S	S	+	S	+	+	+	+
Ability to do bent over row 20-30lb	S	+	S	+	S	+	+	+	+
Easy to take on/off prosthetic	-	-	-	-	-	S	S	S	S
Durable	+	S	+	+	S	S	-	-	-
Safe to use	+	+	+	+	+	S	S	S	S
Compatibility with current attachments	S	S	S	S	S	S	S	S	S
Easy/quick attachment use	S	S	S	S	+	S	S	S	S
Quick release/connect of attachments	S	S	S	S	+	S	S	S	S
Wrist flexion	S	S	S	S	S	S	S	S	S
Subtle visual design	S	S	S	S	S	S	-	-	-
Sum of Positives	5	5	4	4	3	4	4	4	4
Sum of Negatives	2	1	1	2	2	0	2	2	2
Sum of Sames	7	8	9	8	9	10	8	8	8
Weighted Sum of Positives	19	20	13	15	4	20	20	15	20
Weighted Sum of Negatives	5	1	1	5	5	0	5	5	5
TOTALS	14	19	12	10	-1	20	15	10	15



Bar graph with scoring of each design compared to datum

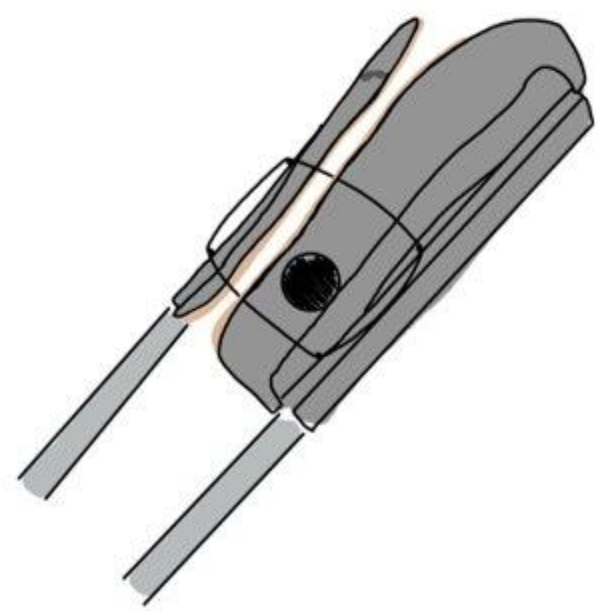
Appendix D—Gantt Chart



Appendix E— Prototype Materials Cost Breakdown

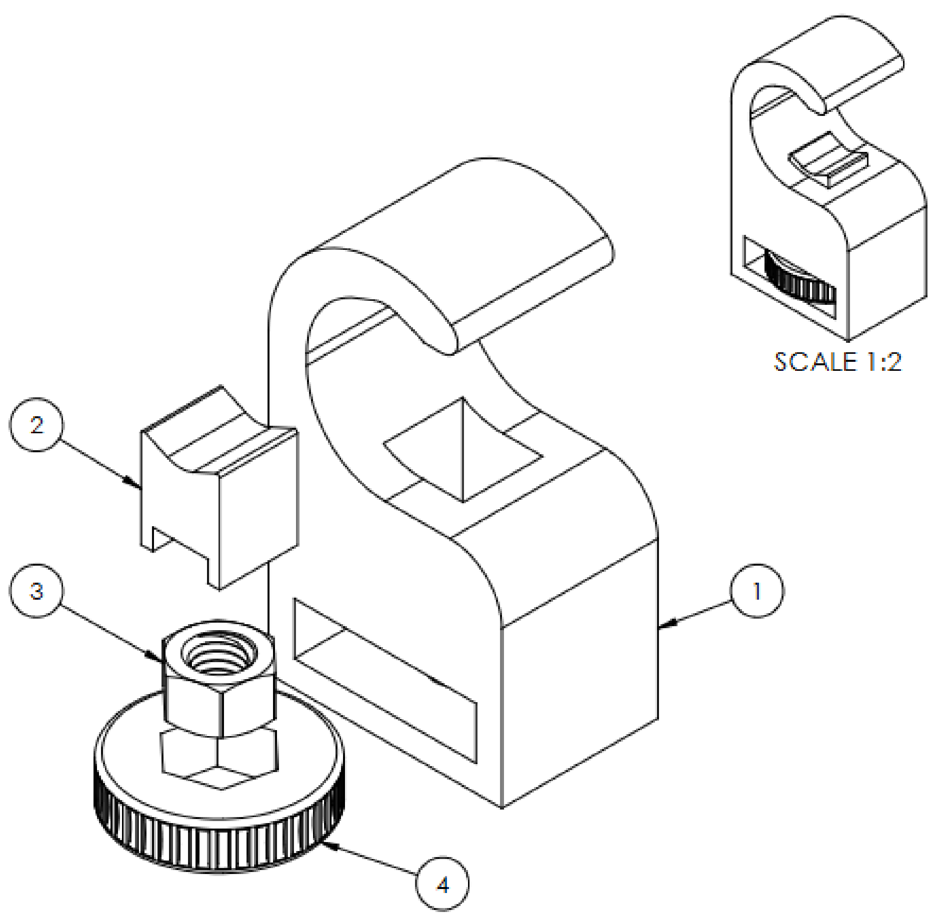
Item	Source	Cost
Pack of Velcro straps	TECHE Lab	$0
Fabric sleeve (above elbow)	Dick's Sporting Goods	$15
Long running socks	Dick's Sporting Goods	$15
Fiberglass casting tape	OrthoTape.com	$20
Orthopedic gauze	Amazon.com	$12
Total:		**$62**

Appendix F—Inner Sleeve Visual



Appendix G—Prototype Gripper Assembly Drawings

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Hook Base	Main Body of the Gripper	1
2	Platform	Platform Rising to Close Grip	1
3	95462A033	Medium-Strength Steel Hex Nut	1
4	Adjustment Wheel	User Interface to Adjust Grip	1



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NEXT ASSY | USED ON

APPLICATION

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

MATERIAL

FINISH

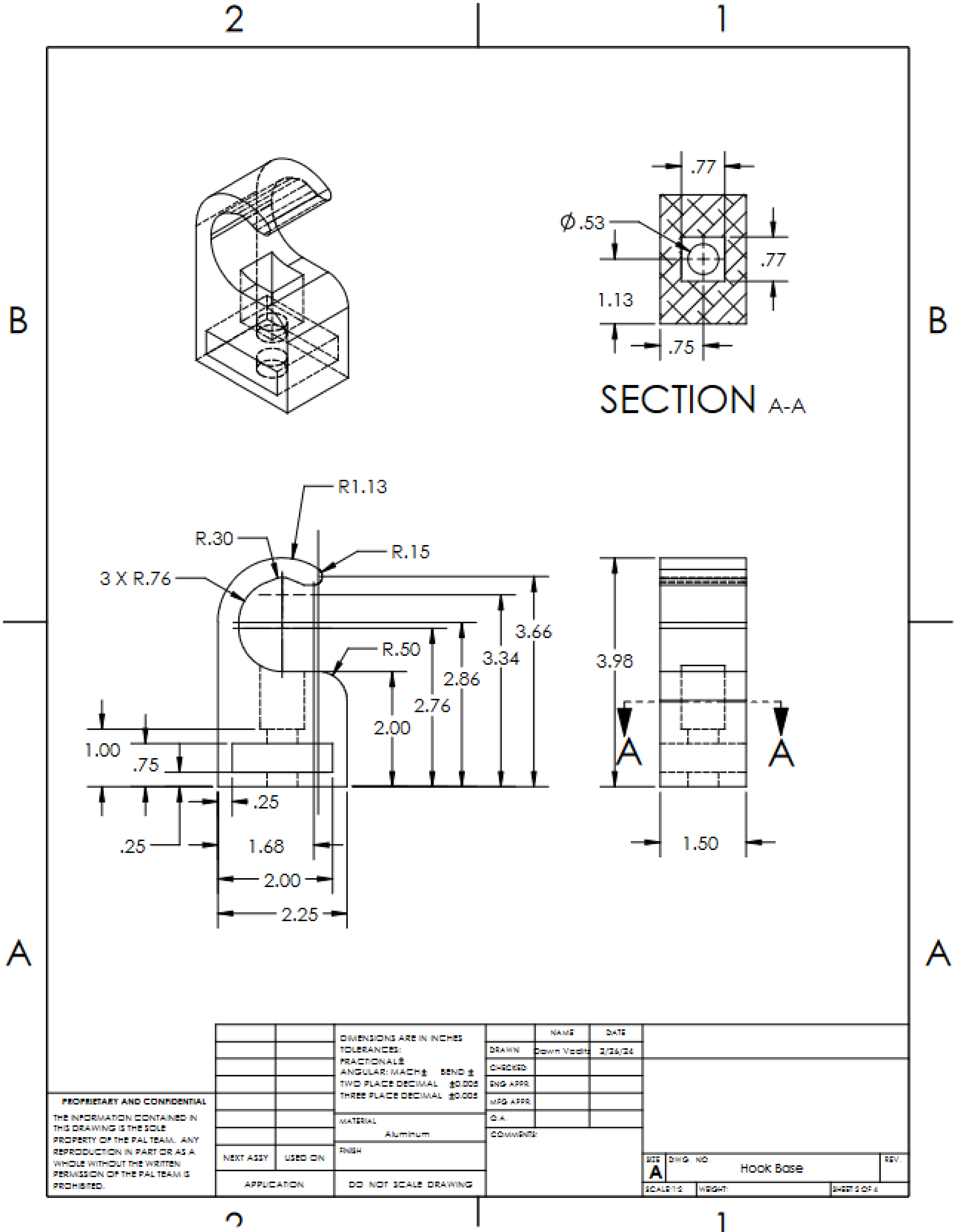
DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	Dawn Vadis	2/26/24
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SIZE A | DWG. NO. PAL Gripper Hook | REV.

SCALE: 1:1 | WEIGHT: | SHEET 1 OF 4



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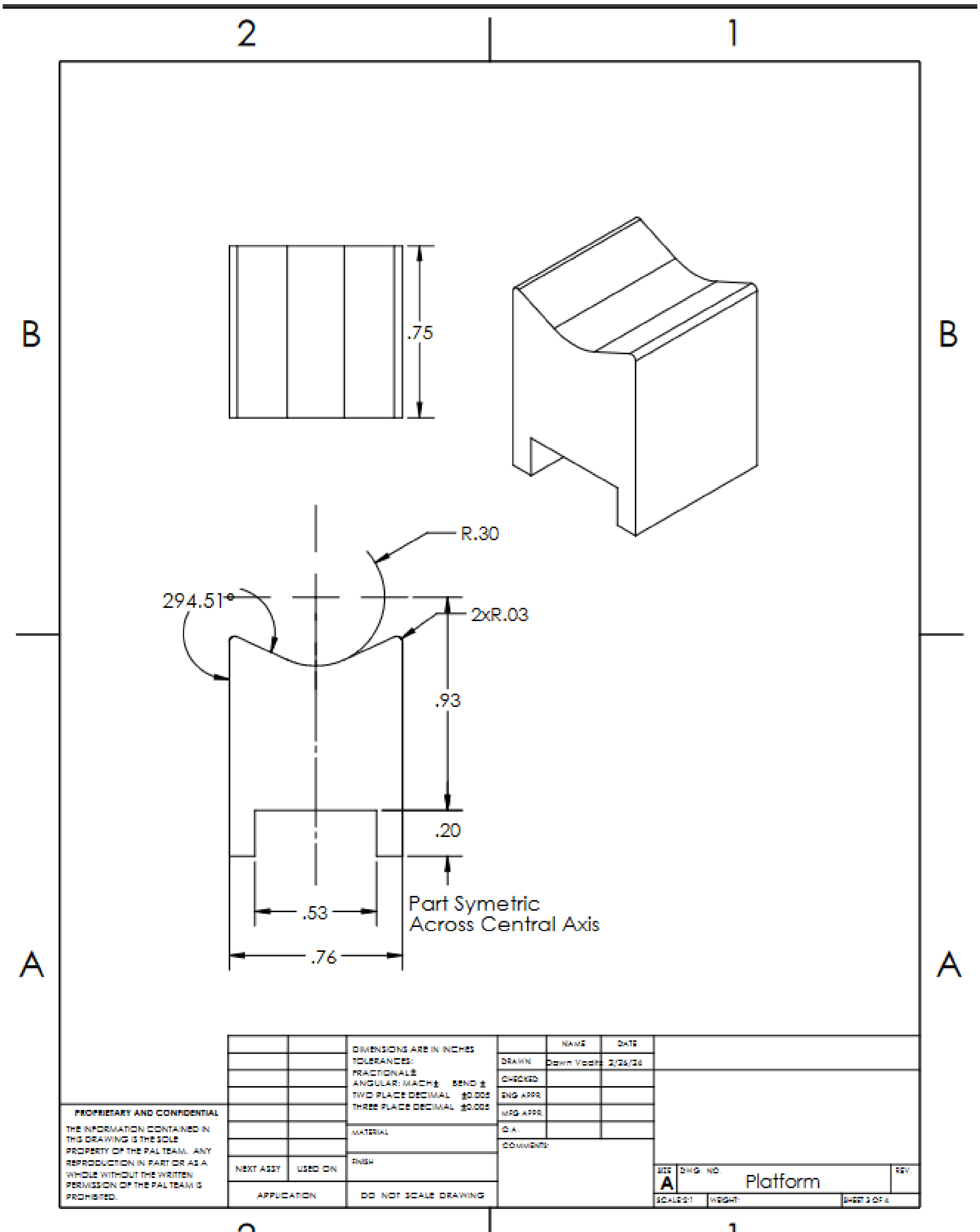
2
1
B
B
.75
R.30
294.51°
2xR.03
.93
.20
.53
.76
Part Symetric
Across Central Axis
A
A
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL±
ANGULAR: MACH± BEND ±
TWO PLACE DECIMAL ±0.005
THREE PLACE DECIMAL ±0.005
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
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APPLICATION
MATERIAL
FINISH
DO NOT SCALE DRAWING
SIZE
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DWG. NO.
Platform
REV
2
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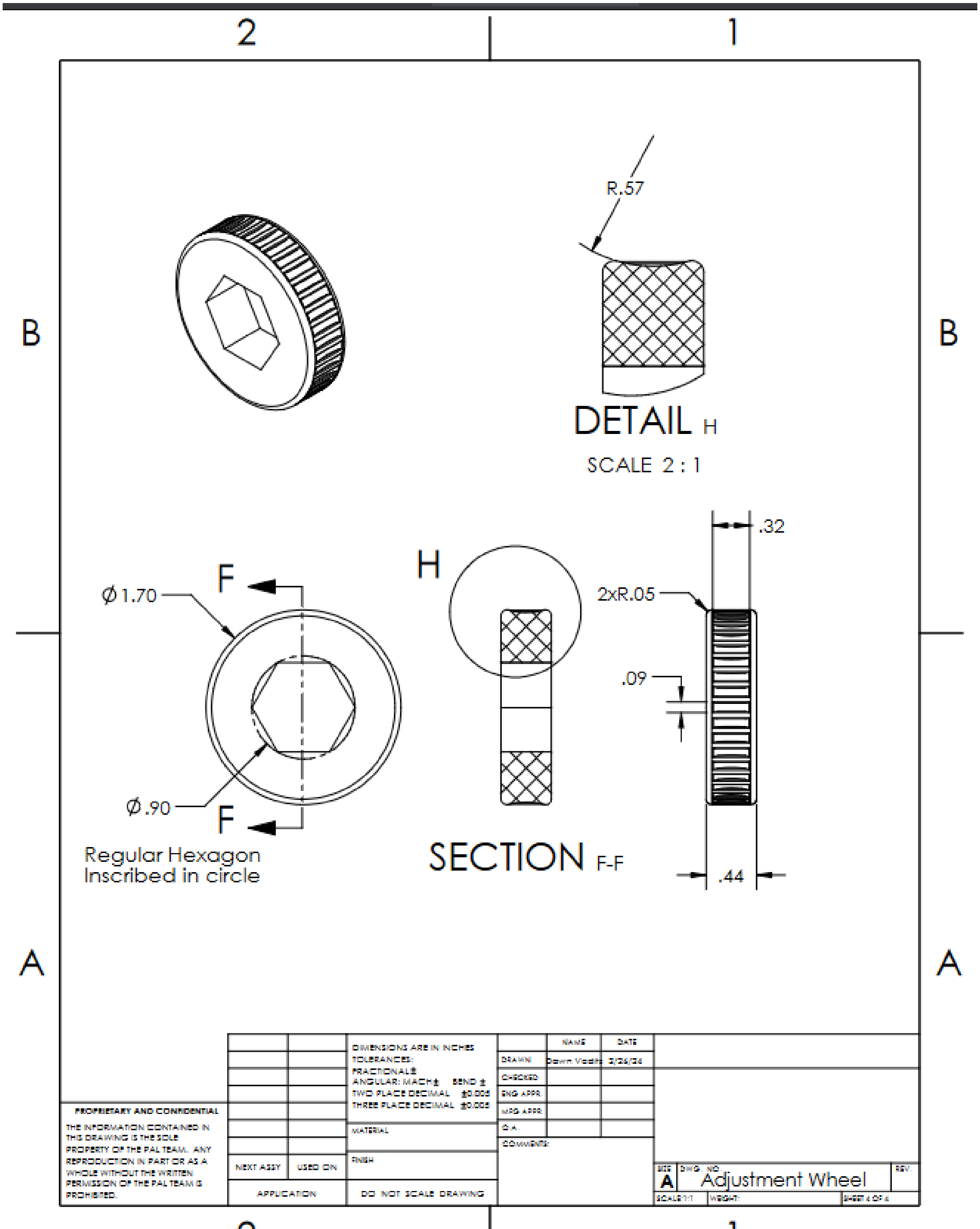

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Appendix H—Design Verification Plan and Report

			DVP&R						
Report Date: February 12, 2024			Sponsor: Madeline Everson						
		TEST PLAN							
Item No	Specification or Clause Reference	Test Description	Acceptance Criteria	Test Responsibility	Test Stage	SAMPLES		TIMING	
						Quantity	Type	Start date	Finish date
1	Smoothness of prosthetic material	Comfort Test - Maddie wears prosthetic with inner lining and rates her comfort level on a scale of 1 to 10	Maddie's discretion	Emma	DV	1	B	4/26/2024	4/26/2024
2	Capillary refill time	Capillary Refill Test - Prosthetic is secured to arm and a series of workouts are conducted for 10 mins. Prosthetic is removed and a timer is started to assess capillary refill in the absence of the prosthetic	30 min (max)	Dawn	DV	3	B	4/26/2024	4/26/2024
3	Prosthetic fit	Comfort Test - Maddie wears prosthetic with inner lining and rates her comfort level on a scale of 1 to 10	Maddie's discretion	Cameron	DV	1	B	4/26/2024	4/26/2024
4	Bulkiness	Measurement	3/4 in. past arm surface (max)	Emma	DV	1	B	4/18/2024	4/18/2024
5	Weight of prosthetic	Weight Test - Prosthetic device is measured on a scale inlcluding base, gripper, and soft sleeve	2 lb (max)	Dawn	DV	1	B	4/18/2024	4/18/2024
6	Time to don/doff prosthetic	Time Rate Test - Timer is started once prosthetic is picked up, stopwatch goes until prosthetic is securely fastened	30 secs (max)	Cameron	DV	5	B	4/20/2024	4/20/2024
8	Total left arm length equal to right a	Measurement Test - Maddie's forearms are measured (medial and lateral epicodyle to middle of bar) on both the right and left sides. She completes each of the 4 designated workouts. The same measurements are repeated to test for any discrepancies or changes in length.	Matches length difference	Emma	DV	1	B	4/18/2024	4/18/2024
9	Grips weights without spinning	Grip Test - Maddie completes each of the 4 designated workouts, Emma and Maddie watch to ensure that the weights do not spin.	No spinning	Dawn	DV	1	B	4/29/2024	5/3/2024
10	Withstands weight without slipping	Slip Test - Maddie completes each of the 4 designated workouts, Emma and Maddie watch to ensure that the weights remain in the gripper.	15 lb (min)	Cameron	DV	5	B	4/29/2024	5/3/2024
11	Holds weight in axial direction	Axial Strength Test - Maddie completes lat pulldown and bent over row holding 30 lbs for each exercise. If this test is passed, weight is increased for both exercises by increments of 5 lbs with a maximum of 45 lb for each exercise.	15 lb (min)	Emma	DV	5	B	4/29/2024	5/3/2024
12	Holds weight in transverse direction	Transverse Strength Test - Maddie completes tricep pushdowns and bicep curls holding 20 lbs for each exercise. If this test is passed, weight is increased for both exercises by increments of 5 lbs with a maximum of 35 lb for each exercise.	15 lb (min)	Dawn	DV	5	B	4/29/2024	5/3/2024
13	Withstands weight during torsion	Torsion Strength Test - Maddie grips dumbell with outstretched arm and slowly rotates the weight to both sides, stopping before she feels any pain or discomfort. Test is started with 5lb and increases by increments of 5 lb.	7.5 ft-lb (min)	Cameron	DV	5	B	4/29/2024	5/3/2024

Appendix I—Feedback Form

Prosthetic Aid for Lifting (PAL) Feedback

Winter 2024

1. How comfortable is the arm section? (Relative Importance: 4/5)

0 1 2 3 4 5 6 7 8 9 10

Comments:

---

2. How much pain does the prosthetic cause w/ and w/o weights? (Relative Importance: 4/5)

0 1 2 3 4 5 6 7 8 9 10

Comments:

---

3. How easy is it to take on and off? (Relative Importance: 1/5)

0 1 2 3 4 5 6 7 8 9 10

Comments:

---

4. Does it feel like things are grasped securely without moving unexpectedly?

(Relative Importance: 4/5)

0 1 2 3 4 5 6 7 8 9 10

Comments:

---

5. Does it feel safe overall? (Relative Importance: 2/5)

0 1 2 3 4 5 6 7 8 9 10

Comments:

---

6. How comfortable would you feel being seen wearing this? (Relative Importance: 2/5)

0 1 2 3 4 5 6 7 8 9 10

Comments:

---

7. Can you complete these exercises? (Relative Importance: 2/5)

Please list the weight you were comfortable completing them with.

Bicep Curl	**Tricep Pushdown**	**Lat Pulldown**	**Bent Over Row**
Yes No	Yes No	Yes No	Yes No
Weight: __________	Weight: __________	Weight: __________	Weight: __________

Comments:

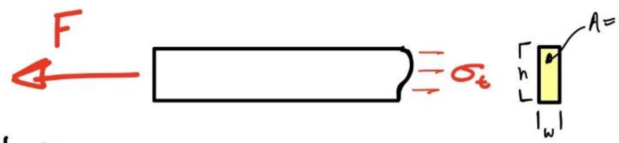
---

8. Any additional comments, notes, needs, wants, preferences, adjustments, or feedback about the prototype or this form? (Or anything else that did not fit in the lines above)

Comments:

Appendix J—Hand Calculations

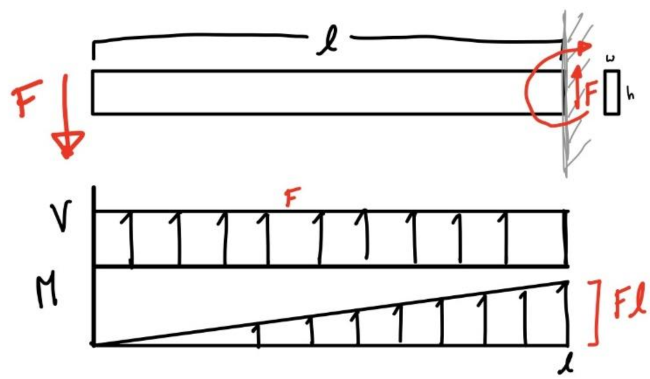
Case #4: Tension in bars.



Analysis

$$\boxed{\sigma_t = F/h \cdot w}$$

Case #5: bending in bars.



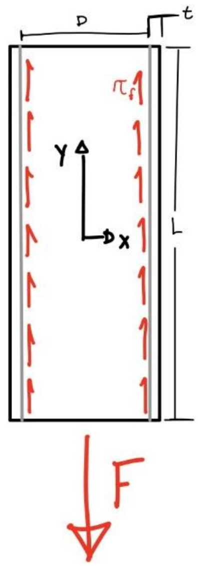
$$\sigma_b = \frac{My}{I}$$

$$= \frac{F\ell(h/2)}{\frac{1}{12}wh^3}$$

$$\boxed{\sigma_b = \frac{6F\ell}{wh^2}}$$

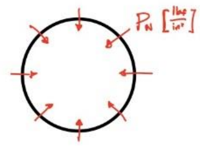
s

Case #1: longitudinal load friction.



Assumptions:
- even shear across surface
- even compression
- Assume static

Analysis:



$$\sum F_y = 0$$

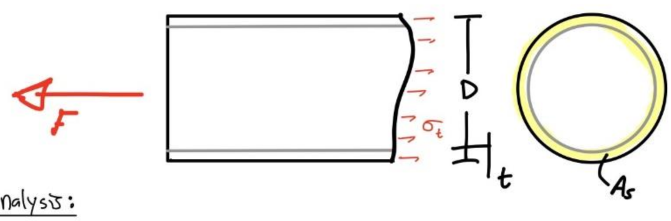
$$-F + \tau_f A_s = 0$$

$$F = -\tau_f \pi D L$$

$$F = -[P_N \mu_k](\pi D)L$$

$$\boxed{P_N = \frac{F}{\mu_k \pi D L}}$$

Case #2: longitudinal tension in base.



Analysis:

$$F = \sigma_t A_s$$

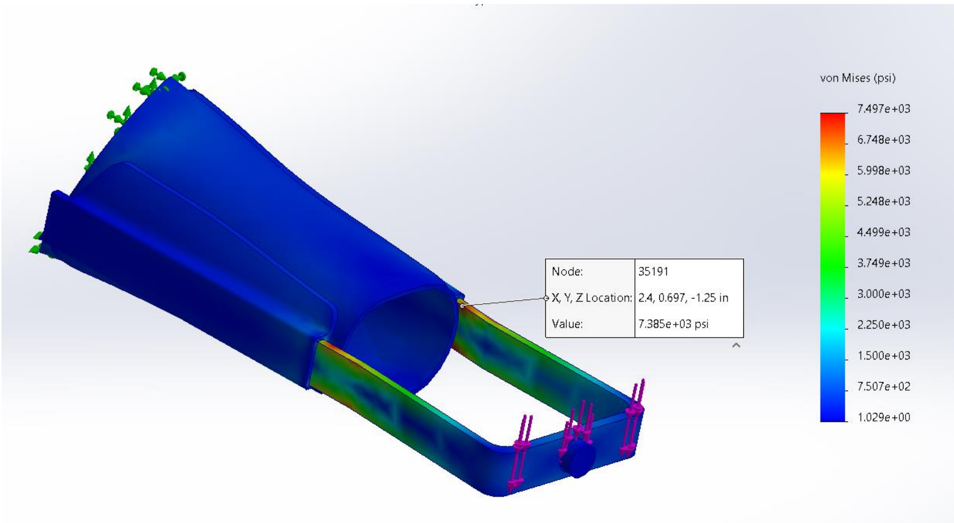
$$F = \sigma_t \left[\frac{\pi D^2}{4} - \frac{\pi (D-2t)^2}{4}\right]$$

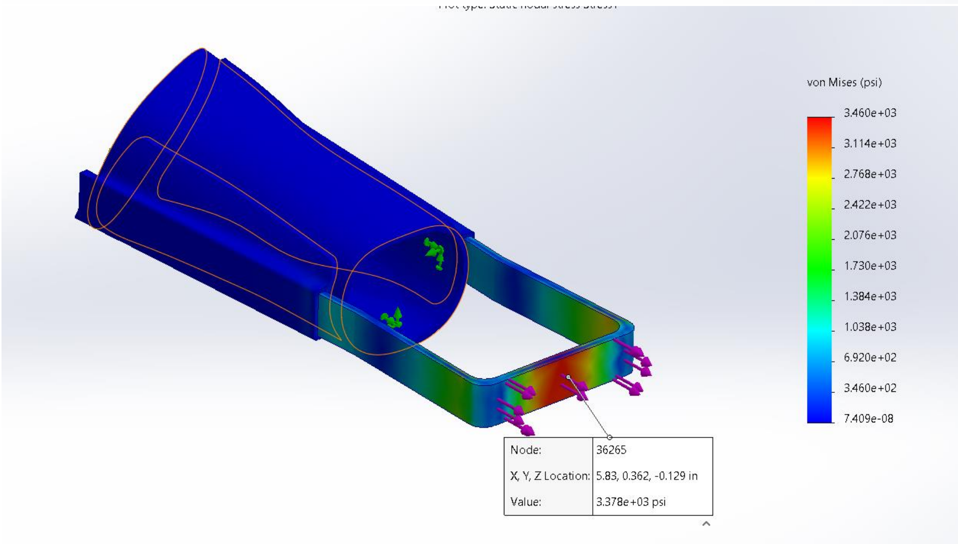
$$F = \sigma_t \frac{\pi}{4}\left[D^2 - (D-2t)^2\right]$$

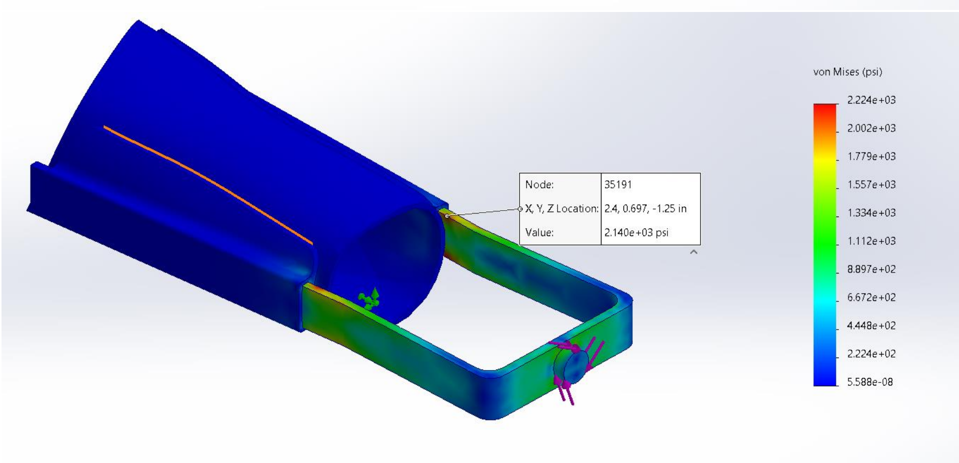
$$\boxed{\sigma_t = \frac{4F}{\pi\left[D^2 - (D-2t)^2\right]}}$$

Appendix K—Finite Element Analysis

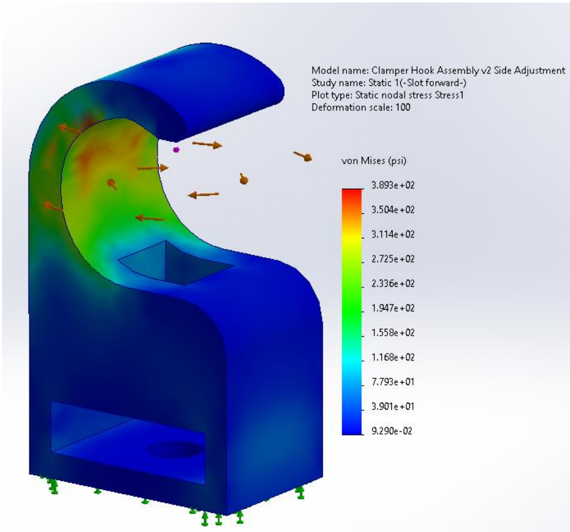
FEA for Base Subassembly

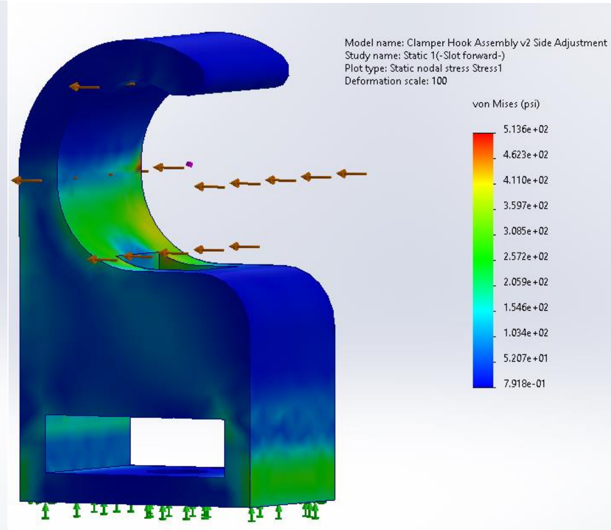


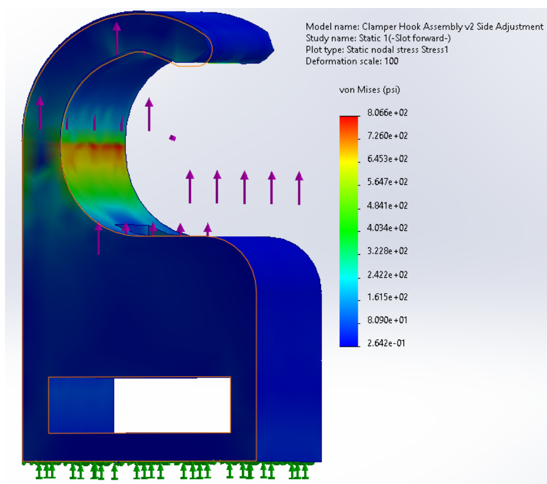




FEA for Gripper Subassembly







Appendix L—Test Results

DVP&R

Report 5-Jun-24 | Sponsor: Madeline Everson | REPORTING E

		TEST PLAN								TEST REP		
						SAMPLES		TIMING		TEST RESULTS		
Item No	Specification or Clause Reference	Test Description	Acceptance Criteria	Test Responsibility	Test Stage	Quantity	Type	Start date	Finish date	Test Result	Quantity Pass	Quantity Fail
1	Smoothness of prosthetic material	Comfort Test - Maddie wears prosthetic with inner lining and rates her comfort level on a scale of 1 to 10	Maddie's discretion	Emma	DV	1	B	4/26/2024	4/26/2024	8	Pass	
2	Capillary refill time	Capillary Refill Test - Prosthetic is secured to arm and a series of workouts are conducted for 10 mins. Prosthetic is removed and a timer is started to assess capillary refill in the absence of the prosthetic	30 min (max)	Dawn	DV	3	B	4/26/2024	4/26/2024	15 mins	Pass	
3	Prosthetic fit	Comfort Test - Maddie wears prosthetic with inner lining and rates her comfort level on a scale of 1 to 10	Maddie's discretion	Cameron	DV	1	B	4/26/2024	4/26/2024	8 (hard with liner)	Pass	
4	Bulkiness	Measurement	3/4 in. past arm surface (max)	Emma	DV	1	B	4/18/2024	4/18/2024	1/20 in past arm surface	Pass	
5	Weight of prosthetic	Weight Test - Prosthetic device is measured on a scale inlcluding base, gripper, and soft sleeve	2 lb (max)	Dawn	DV	1	B	4/18/2024	4/18/2024	1 lb 15 oz	Pass	
6	Time to don/doff prosthetic	Time Rate Test - Timer is started once prosthetic is picked up, stopwatch goes until prosthetic is securely fastened	30 secs (max)	Cameron	DV	5	B	4/20/2024	4/20/2024	24 secs	Pass	
8	Total left arm length equal to right a	Measurement Test - Maddie's forearms are measured (medial and lateral epicodyle to middle of bar) on both the right and left sides. She completes each of the 4 designated workouts. The same measurements are repeated to test for any discrepancies or changes in length.	Matches length difference	Emma	DV	1	B	4/18/2024	4/18/2024	2.25 in discrepancy (measured from elbow to palm). 6 degree tilt of barbell		Fail
9	Grips weights without spinning	Grip Test - Maddie completes each of the 4 designated workouts, Emma and Maddie watch to ensure that the weights do not spin.	No spinning	Dawn	DV	1	B	4/29/2024	5/3/2024	No spinning	Pass	
10	Withstands weight without slipping	Slip Test - Maddie completes each of the 4 designated workouts, Emma and Maddie watch to ensure that the weights remain in the gripper.	15 lb (min)	Cameron	DV	5	B	4/29/2024	5/3/2024	17.5 lbs	Pass	
11	Holds weight in axial direction	Axial Strength Test - Maddie completes lat pulldown and bent over row holding 30 lbs for each exercise. If this test is passed, weight is increased for both exercises by increments of 5 lbs with a maximum of 45 lb for each exercise.	15 lb (min)	Emma	DV	5	B	4/29/2024	5/3/2024	17.5 lbs	Pass	
12	Holds weight in transverse direction	Transverse Strength Test - Maddie completes tricep pushdowns and bicep curls holding 20 lbs for each exercise. If this test is passed, weight is increased for both exercises by increments of 5 lbs with a maximum of 35 lb for each exercise.	15 lb (min)	Dawn	DV	5	B	4/29/2024	5/3/2024	17.5 lbs	Pass	
13	Withstands weight during torsion	Torsion Strength Test - Maddie grips dumbell with outstretched arm and slowly rotates the weight to both sides, stopping before she feels any pain or discomfort. Test is started with 5lb and increases by increments of 5 lb.	7.5 ft-lb (min)	Cameron	DV	5	B	4/29/2024	5/3/2024	7.5 ft-lb	Pass	

Appendix M— Final Design Materials Cost Breakdown

Item	Source	Cost
50x65x7 Bearing	Amazon	$9.59
Lead screw (priced per ft)	Roton	$34.39
Bronze lead threaded mount nut	Roton	$41.34
Silipos Ankle Brace	Amazon	$19.56
Bike seat clamp (pack of 2)	Amazon	$5.43
Rubber	Amazon	$12.16
Bronze 0.5 mod gear + bearing for leadscrew	McMaster-Carr	$44.74
4 yards 3" bi-direction carbon sleeve	Composite Envisions	$52.40
for 50/50 ratio, need 107g resin/run	Fibreglast	$115.95
Click Medical lamination kit	Click Medical	$298.50
Total		**$640.53**

Appendix N—References

[1] T. L. M., & F. L. G. (n.d.). “29 Limb Loss Statistics, Facts & Demographics”. Pro Medical East. https://promedeast.com/limb-loss-statistics/

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