

Prosthetic Thumb Design

A Senior Project
presented to
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Biomedical Engineering

By

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1.0 Executive Summary -

The Prosthetic Thumb Project is a senior design project completed by Biomedical Engineering Undergraduate students at California Polytechnic State University. This senior design project is aimed at designing a prosthetic thumb for a Cal Poly Pomona student who lost their thumb in an accident last year. The patient has ultimately lost between 30-40% of functionality of his left hand, and so we would like to give him that mobility back. Originally, the patient was worried about having a prosthesis, and wanted something more stagnant that would resemble the look of the thumb he lost. However, after working with him, we determined that in order to regain functionality of the left hand, he would need a body-powered prosthesis that will move with his thumb residual in order to mimic the natural motion of a hand. Since we are designing a product for our customer, we still wanted to make a design that does not entirely look mechanical.

The patient expressed a few specific needs and expectations for his new prosthesis. The patient ideally wanted to be able to perform everyday tasks that he used to, but now is unable to do. These included the ability to fit his hand, with the prosthetic thumb attached, into his pocket and have the ability to grasp items in the pocket. Other specified expectations include a low cost, lightweight-slim design, high durability, and an ability to still weight-lift. However, we do not believe we will be able to produce a prosthetic for weight lifting because of time constraints but instead we will provide suggestions for alternative devices to aid in weightlifting, but the main focus of this design should be for a day to day functional prosthetic.

After brainstorming and weighing all of our original design ideas, we decided to move forward with a prosthetic design that used hinges in order to drive the motion of the thumb. The hinge uses four points and four linkages in order to do so. The distal points are anchored distal of the IP joint while the proximal two points are anchored proximal to the IP joint. Depending on how much movement the patient has of the residual thumb distal to the MCP joint, the proximal anchor points of the prosthetic can be shifted back to sit over the MCP joint. However, upon meeting with our project sponsor, he informed us that there was most likely not enough residual left to drive that motion, and so our project decided to change to a mechanical wire driven prosthetic. A wire will connect to a wrist strap, and sit atop the proximal piece. The wire will be inserted inside the prosthetic, and wrap around an internal cam that will thus drive the forward and backwards motion of the prosthetic. As the proximal piece is moved forward by the motion of the residual, the cable will get shorter pulling the lever down, and pushing the distal piece down. This wire was incorporated into a design that resembled the human thumb by taking a 3D scan of the patients non-injured hand, mirroring it, and then cutting away the excess pieces to create a prosthetic that will match patients form. By doing so, we were able to have a body-powered prosthesis that does not have a mechanical appearance and roughly resembles the patients normal thumb.

The prototype of our design was generated using the 3D printers at innovation sandbox. Our parts were printed using PLA in order to utilize the free resources to students and keep the cost of the prosthetic low. When undergoing compression testing, the parts were tested using the instron in the Biomedical Engineering lab. The proximal and distal pieces were secured, and tested up to a force of 500 N. The proximal pieces experienced minor cracks, but still withstood the overall force without any internal support. The distal pieces withstood the force of 500 N with no cracks when the force came from the side. We also tested using a “hyper-extension” method, meaning we secured the prosthetic to a model of the hand, and hung weights off of the distal piece. This test did fail due to a crack in the material. However, the Prosthetic Thumb Group will be working on the final product that is being delivered to the patient next quarter as well. We plan on changing the material of the 3D printed parts to give the prosthetic thumb more strength.

2.0 Statement of Work -

Attached below is the Statement of Work for the Prosthetic Thumb Project. It outlines our project problem, deliverables and timeline for completing the design and product of a custom fit prosthetic thumb.

2.1 Introduction:

The Prosthetic Thumb Project is a six month long senior design project being completed by three California Polytechnic State University, San Luis Obispo students, and one California Polytechnic State University, Pomona student. The project is aimed to design a custom fit mechanical prosthetic thumb for a student with an amputee just above the metacarpal (MCP) joint.

2.2 Background:

Andrew Emmert, our Cal Poly Pomona counterpart, met with the patient to discuss the initial design ideas and figure out exactly what the patient wants out of the prosthetic design. The patient would like to retrieve objects out of his pocket easily, and misses the ease of texting and gaming with both hands. The prosthetic should be easily removable for washing hands and showering. The patient also was curious about if a prosthetic could be made that would help him lift weights again. However, the patient seems to struggle with the look of prosthetic and is having a difficult time with the concept of having to wear a prosthetic. A body-powered prosthesis would give the patient the mobility he desires, however the mechanical design is harder for the patient to grasp. After the San Luis Obispo students met with Emmert, we decided that the challenge would be designing a functional prosthetic that does not look entirely mechanical. Current partial hand prosthesis designs were researched, and the pros and cons were determined to help us gain a better understanding of what we want to incorporate into our design. These notes can be found in Table 1. Approved and currently pending patents were also researched, to determine what will constrain our design. Those notes can be found below in Table 2.

Table 1: Partial Hand Prosthesis Currently on the Market.

Product Name	Description	Pros	Cons
Thumb Driver (Naked Prosthetics) Body-Powered Prosthesis	Tracking natural CMC motion allows for the majority of motion, rigid structure that allows the hand to grasp objects	Interchangeable suspension rings allow patients to have an ideal fit. Cage-like structure of the linkages provide increased protection for the residuum/distal end of the amputation (can be hypersensitive). Tracks the natural multi-axial motion of the thumb complex	Must have enough residuum to engage the ring. Minimum 6 week lead time.
PIP Driver (Naked Prosthetics) Body-Powered Prosthesis	For partial finger amputees (through the middle or distal phalanx), rigid linkage that is self-suspended on the base of the finger residuum. The prosthetic joints line up with anatomic ones to provide natural motion/form	Lightweight, custom designed, strong. Can be connected with other Naked Prosthetic devices. Silicone rubber tip pads resemble natural fingertips (and come in a variety of colors).	Must have enough residuum to engage the ring. Minimum 4-6 week lead time. Not used for thumb amputations.
MCP Driver (Naked Prosthetics) Body-Powered Prosthesis	Designed for amputations through the proximal phalanx (restores middle and distal phalanges), designed to restore power grasps and grip stability	Abduction/adduction washers allow the user to adjust mechanical fingers, and the patient can gain optimal grip. Strength and functional force (1-9 lb force at each fingertip). Lift substantial weight, and transfer load to suspension on wrist.	Must have enough residuum to engage the ring. Minimum 6-8 week lead time. Not used for thumb amputations.
Living Skin (Ossur) Passive Partial	Designed to be unnoticed. Designed for patients with finger, hand, arm, toe, and foot deficiencies.	Cosmetic. Hand-painted and hand-crafted to match patients anatomy and skin tone. Functional capabilities: pushing, pulling, stabilizing, supporting, light grasping, typing.	No movement capabilities. Very limited functionality. Subject to Uncanny Valley Effect.
Silicone Finger and Partial Hand Prosthetics (Ottobock) Passive Partial	Natural, custom prosthetic system. Each product is tailored to the specific shape and skin color of the patient. This low profile option can be customized to include freckles, veins, and hair making it look as realistic as possible.	Cosmetic. Wires in the fingers allow for manual positioning of the fingers. Very customizable.	No active movement capabilities. Very Limited functionality. Subject to Uncanny Valley Effect.
Titan Series (Partial Hand Solutions) Passive Partial	Designed to meet the needs of the heavy duty user. Machined out of titanium, with a ratchet design that allows the user to manually position the joints in the most function position and provide a secure grasp.	Very Durable. High functionality for a passive prosthesis. Can be used for partial digit amputations and in complete absence of a finger or thumb. Titan Thumb features full rotation of the base.	No active motion

Table 2: Prosthetic Patents

Patent	Product Name	Claim Issue	Avoiding Problem
US Patent 9375319 (Granted June 28, 2016)	Bio-Mechanical Prosthetic Thumb	“...a thumb strap ring having a direct pivoting connection with the proximal end of the proximal phalanges; ... and an anchoring portion having an operable connection with the thumb strap ring...”	This claim mentions how their prosthetic thumb uses a thumb strap to anchor the prosthetic to the hand. We would continue using a thumb strap in our design because the strap is too common of an anchoring method and the patent claims more about the design of the proximal and distal phalanges, specifically.
US Patent 7361197 (Granted April 22, 2008)	Prosthetic Hand Having a Conformal, Complaint Grip and Opposable, Functional Thumb	“The hand of claim 1 in which an activation system comprises a highly flexible flexion cable, one end of which being attached within the distal end of said thumb...”	This claim refers to the use of flexible flexion cables on the palmar side of the thumb. We were considering the use of cables to actuate our thumb. We could change our design to use rigid linkages instead.
US Patent 10016289 (Granted July 10, 2018)	Bio-Mechanical Prosthetic Thumb	“... the ring comprises a select one of a number of interchangeable rings, each of the interchangeable rings having a diameter that is sized to receive a different sized residual thumb.”	Instead of using a ring that fits over the residual thumb, we could use a wrist strap as the primary anchoring method.
US Patent Application 20190183661 (Applied June 20, 2019)	Powered Prosthetic Thumb	“... comprising a first worm wheel and a first worm gear in mechanical communication with the first worm wheel, wherein the actuator is configured to cause rotation of the digit about the first axis by causing rotation of the first worm gear.”	We may use gears, if cables do not work. We could utilize different types of gears or use linkages to transmit force across the digits, therefore avoiding the use of worm gears.
US Patent Application 20190290454 (Applied June 11, 2019)	Bio-Mechanical Prosthetic Finger with Y-Shaped Rocker	“... A method of fitting a customized <i>prosthetic</i> finger having a proximal ring configured to anchor to a patient's residual finger...”	This design uses a proximal ring used to anchor the prosthesis to the residual thumb. Since the patient's residual thumb is not very large, we may include a wrist strap, or another securing method wrapping around the base of the hand.
US Patent Application 20170296360 (Applied October 19, 2017)	Bio-Mechanical Prosthetic Thumb	“The bidirectional prosthetic thumb device of claim 14, wherein the hand strap is configured for attachment about a hand of the user.”	This claim discusses using a strap wrapped around the hand to attach the prosthetic to the thumb, which could infringe on our design ideas. We could work around this by anchoring a strap lower down, on the wrist instead, which could potentially work better for transferring the load.

The largest make up of amputees are partial hand amputees, accounting for nearly 75% (National Academies of Sciences). There is a difficulty in standardizing prosthetics, due to the nature of amputations. Each amputation can occur in a different location, severing different nerves, etc. which makes designing prosthetics as a mass product difficult to do. As 3D printed devices are becoming more popular due to lower cost and decreased production time, a few people have attempted to create body powered hand prosthetics. This could be used to customize each prosthetic to the user. A highly advanced 3D printed hand was printed using a MakerBot Replicator. The device is called the Raptor Reloaded 3D printed body powered prosthesis (Case Comparison of Electric...). While this device did not perform as well as an electric prosthetic hand device, it was still able to grasp objects due to movement of the wrist. If we had access to a prestigious 3D printer, the option of designing and printing a prosthetic thumb would be a cheaper and faster option to produce for our patient.

For some individuals, the robotic look of body powered prosthetics is frightening. Therefore, for some patients with “limb loss, cosmetic restoration is highly valued or even preferred over functional restoration because of its mitigating effect on the disruption to body image” (National Academies of Sciences). However, a majority of these prosthetics are passive, meaning they do not serve a real function. Passive prosthetics are designed to look as if they naturally replace the missing limb. They are generally made out of silicone, and must be positioned how the user wants it (Rotter). For our device, our patient is self-conscious about the looks of a prosthetic, but wants the utility factor of a body powered prosthetic, and so we are tasked with finding a happy medium between the two.

The Food and Drug Administration (FDA) considers most upper limb prosthetics to be a Class I device. Class I devices have “minimal potential for harm and are specifically defined by the FDA as not intended to be for use in supporting or sustaining life, of importance in preventing impairment to human life, and may not present a potential unreasonable risk of illness or injury” (Resnik). The majority of marketed prosthetics in the past few decades have not had to go through FDA regulation requirements of “PMA and premarket notification [510(k)]” (Resnik). PMA is a FDA regulated premarket approval process, and premarket notification [510(k)] is a document proving that the device is safe to use and similar to a previously marketed device. Prosthetics however must undergo clinical trials (with humans). The FDA does not provide specific guidelines to the prosthetic industry, but companies must do human trials and “comply with Federal regulations through FDA/CDRH processes before they can be marketed within the United States as required by 21 CFR Parts 800-1299” (Resnik). The 21 CFR Parts 800-1299 contains the product regulations for medical devices and radiation emitting devices. A new prosthetic design must comply with these regulations as stated by the FDA (Center for Devices and Radiological Health).

2.3 Objectives:

The patient expressed a few specific needs and expectations for his new prosthesis. These included the ability to fit his hand, with the prosthetic thumb attached, into his pocket and have the ability to grasp items in the pocket. Additionally, the patient prefers to have a body powered prosthetic rather than a passive-partial prosthetic with no active movement. Other specified expectations include a lightweight-slim design, high durability, and an ability to still weight-lift. The problem is that the patient has had an amputation of the proximal phalanges of his left thumb. This has made grasping and holding items difficult and reduced the effectiveness of his left hand. Daily tasks such as fishing items out of pockets and getting dressed have become difficult without

the patient's left thumb. This project will tackle this problem by developing a prosthetic thumb capable of restoring the functionality of the patient's left hand.

The scope of this project includes developing a body powered prosthetic thumb that is capable of movement similar to that of the human thumb. This prosthetic will need to be securely attached to the patient's hand and residual digit with a minimal amount of movement where the harness meets the hand. This harness will most likely include a strap that wraps around the base of the hand or wrist. The interface of the harness will need to be biocompatible with human skin to minimize irritation. Lastly, we will explore ideas of how to make this prosthetic capable of weightlifting applications, or design an attachment to accompany the existing harness. However, we will not explore any electrical options for the prosthetic due to the time frame and financial restrictions of the project. Also, we will not pursue making the prosthetic resemble the human anatomy cosmetically with the use of silicone and painting.

Seen below in Figure 1 and Table 3 are the House of Quality (HOQ) and Engineering Specifications, respectively. The customer requirements generated in the HOQ were used to determine the engineering specifications required for our product to function as desired. The customer requirements were as follows: easy to take on and off, appearance, lightweight, durable, slim, body-powered, attached to wrist and ability to weightlift. The customer requirements of lightweight, slim and easy to take on and off helped drive the engineering specifications of weight and length. We want the design to be no bigger or heavier than that of a normal human thumb. The customer requirement of body powered drove the engineer specification for the degree of flexion at the IP and MP joints. The body powered prosthesis needs to act and bend as a normal human thumb, meaning that the joints will flex at least 90 degrees. After talking with the patient, we have determined that weightlifting is not feasible for this design, and he will need to use a separate prosthetic or attachment for those needs. However, we do still want to give the patient a strong enough grip strength for his daily needs, and so we would like to match that of his non-injured hand. Because he is a weightlifter, he is strong and so while we are aiming to match that grip strength, we are unsure if we will be able to in our design.

Prosthetic Thumb		Load Applied to Prosthetic	
Design		Grip Strength	
●=9	○=3	-	
△=1	-	Weight of Device	
WHO		Cost to Manufacture	
Patient		Engineering Requirements	
Doctor/Engineer		Load Applied to Prosthetic	
Patient		1 (Worst)	
Doctor/Engineer		2	
Patient		3	
Doctor/Engineer		4	
Patient		5 (Best)	
Doctor/Engineer		6	
Patient		7	
Doctor/Engineer		8	
Patient		9	
Doctor/Engineer		10	
Patient		11	
Doctor/Engineer		12	
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Patient		195	
Doctor/Engineer			

2.4 Engineering Specifications

Table 3: Engineering Specifications

Spec. #	Parameter Description	Requirement or Target	Tolerance	Risk	Compliance
1	Production Cost	\$400	+\$100	H	A
2	Weight	65 g	+/- 10 g	L	A, T, S
3	Grip Force	125 lbs	+/- 10 lbs	H	T
4	Length	7cm	+/- 0.2 cm	L	I, A
5	Degree of flexion at MP Joint	90°	+/- 5°	H	A, T, I
6	Degree of flexion at IP Joint	90°	+/- 5°	H	A, T, I

Production Cost: Ultimately, the functionality of the prosthetic thumb is of the utmost importance. If the prosthetic is not functional, nothing else matters. However, minimizing cost, while maximizing functionality is an important balance to find. Attempting to stay close to, or within, our proposed budget will be the best way for analyzing our spending. Production cost is currently rated as “High Risk” for a few reasons. First, we are still in the early stages of the design phase and do not have a solid idea of what materials will be necessary. Once we have a better idea of what our final design will look like, we will know specifically what materials and how much we will need.

Weight: The weight of the prosthetic thumb will be measured using a scale. We want the thumb to have a weight similar to that of the patient's actual thumb for ease of use and comfort.

Grip Force: Grip force will be measured using a hand grip dynamometer. This parameter is labeled as ‘High Risk’ because not only is it crucial to the degree of functionality of the prosthetic, but it may also be our hardest parameter to achieve our target value. Applying excessive force to the prosthetic may cause it to articulate on the residual thumb, or even crack and compromise the integrity of the prosthetic.

Length: The length of the prosthetic will simply be measured using a ruler or small tape measurer. The only importance of this parameter is that it is similar to the thumb of the patient's right hand for consistency, aesthetics, and ease of use.

Degree of Flexion at MP Joint: The degree of flexion at the MP Joint will be measured using a protractor. The reason that the degree of flexion is labeled as “High Risk” is because it is essential to functionality. Additionally, an anatomically correct degree of flexion may prove difficult to achieve due to movement and the prosthetic-residual thumb interface.

Degree of Flexion at IP Joint: The degree of flexion at the MP Joint will be measured using a protractor. The reason that the degree of flexion is labeled as “High Risk” is because it is essential to functionality. Additionally, an anatomically correct degree of flexion may prove difficult to achieve due to movement and the prosthetic-residual thumb interface.

2.5 Project Management:

We plan to follow the overall design process shown below in Table 4. In order to build, fit and test our prosthetic thumb by March, 17 2019 we will need to stick to this strict timeline.

We have gained access to a broken Naked Prosthetic (PIP Driver), and we are using that to brainstorm ideas on how we want to design our thumb prosthetic. As shown above in the House of Quality, Naked Prosthetics perform well in the categories that our patient requires, and so we will use their design as inspiration when coming up with our own design. We have gotten scans of both the patient's hand (injured hand and non-injured hand), converted them to .stl files and have sent them to the innovation sandbox to be 3D printed. This will help us visualize and start to prototype directly on the hand. Finally, we have finished the necessary documentation (pro/con chart, budget sheet, etc.) to move forward with our project.

The next step in the process is to obtain the 3D printed hands, and begin building a prototype that can fit directly on the 3D models. We will also need to meet with the patient to discuss his desire for a prosthesis that he can weight lift with. After researching the topic more, we believe that our main focus should be on creating a day to day functional body powered prosthesis, as most amputees weight lift with hooks or loops they can attach to their wrist. We can discuss with him that if we have time at the end of the project, we could maybe create a new design, but that is not the main priority currently.

As seen in Table 4 below, there are a lot of different tasks that need to be completed in order to finish this project on time. The highlighted tasks are ones that are on our critical path. Microsoft Outlook generated this critical path for us, highlighting the most important things that we as a group need to get done. The first step is to complete all of Phase 1. The next important step is to order the necessary materials and design a functional prototype. After that, the test plan and functional prototype video are necessary to complete for the Phase 3 Review. After that, completing Phase 4 is important, and delivering a functional prosthetic thumb to our patient is critical. If we stick to the project timeline and emphasize the importance of the objectives on our critical path, the project should be able to be completed in time.

Table 4: Key Deliverable and Project Timeline

Network Diagram Step	Task Name	Duration	Start Date	Finish Date
1	Phase 1	13 days	10/1	10/17
2	Skype Meeting with Andrew	1 day	10/3	10/3
3	Generation of Potential Designs	5 days	10/4	10/10
4	Create Budget Rough Draft	3 days	10/10	10/14
5	Draft Pro/Con Chart	2 days	10/14	10/15
6	Get Scans of Patients Hands in .stl Files	6 days	10/1	10/8
7	Get Hands Printed in Innovation Sandbox	5 days	10/9	10/15
8	Project Requirements Document + Powerpoint	3 days	10/13	10/15
9	<i>Phase 1 Review</i> (Meeting with Whitt and Heylman)	3 days	10/15	10/17
10	Apply for Hannah-Forbes Fund	1 day	10/17	10/17
11	Phase 2	36 days	10/17	12/5
12	Create CAD designs for prototypes	6 days	10/17	10/24
13	Review and Update Contract and Budget	1 day	10/21	10/21
14	Assign Kinematics to CAD Models	7 days	10/28	11/5
15	Conceptual Design Report	5 days	10/25	10/31
16	Prototyping Ideas	18 days	11/1	11/26
17	<i>Phase 2 Review</i> (Critical Design Review Presentation)	3 days	12/3	12/5
18	Phase 3	19 days	1/6	1/30
19	Order Necessary Materials	6 days	1/6	1/13
20	Finish SolidWorks Design	6 days	1/6	1/13
21	Print Design w/ Innovation Sandbox	3 days	1/14	1/16
22	Manufacture Glove to Prosthetic	2 days	1/17	1/20
23	Attach Internal Cam and Wire System	3 days	1/17	1/21
24	Design a Test Plan	6 days	1/7	1/14
25	Perform Tensile and 3 Point Test	7 days	1/19	1/25
26	Record Functional Prototype Video	2 days	1/22	1/23
27	<i>Phase 3 Review</i> (Functional Prototype Demo/Test Plan Presentation)	4 days	1/27	1/30
28	Phase 4	35 days	2/1	3/17
29	Continue Testing	22 days	1/22	2/20
30	Meet with Patient to Properly Fit Prototype	11 days	1/31	2/6
31	Redesign Prosthetic if it Does Not Fit Customer Needs	11 days	2/7	2/21
32	Hazard and Risk Assessment	1 day	2/4	2/4
33	Finalize Product	6 days	2/24	3/2
34	Senior Project Design Report	6 days	3/3	3/10
35	Expo Poster	6 days	3/3	3/10
36	<i>Phase 4 Review</i> (Final Presentation and Expo Poster)	5 days	3/11	3/17

2.6 Conclusion:

This document serves as an outline for the scope of the project, and outlines the work that needs to be done. By the end of this project, we will have developed a lightweight but functional, body powered prosthetic thumb that is capable of movement similar to that of the human thumb. This prosthetic will be securely attached to the patients hand and residual digit with a minimal amount of movement where the harness meets the hand. The next project deliverable is to begin building a prototype for a body powered prosthetic thumb on the 3D printed hands that we will receive from the innovation sandbox in a few days. We are aiming for the prototype to be completed by January 31, 2020. As of January 37, 2020, a prototype has been completed and printed using the Innovation Sandbox. We have very minor changes to make from this prototype to our final design, and that is slightly increasing the tolerances on holes, but otherwise the SolidWorks design is finalized.

3.0 Network Diagram

In Microsoft Project, we input the tasks and deadlines that all components of the project need to be completed by. It outlined a network diagram that our team should follow in order to finish the prosthetic thumb design on time. Seen below in red is the critical path - the most important tasks that need to be completed that will result in the project being completed in minimum time. The specific steps are outlined above in Table 4 of the Statement of Work section.

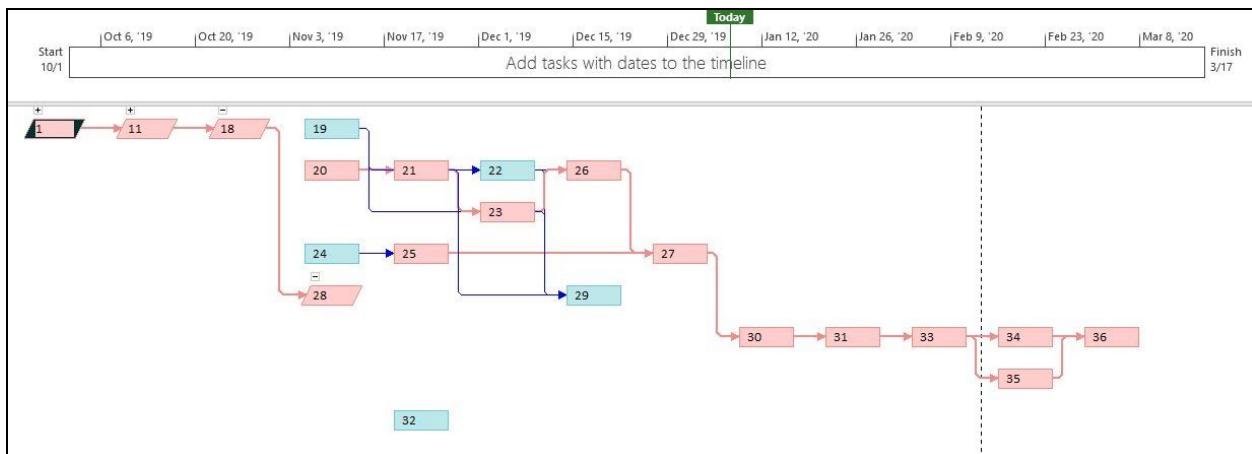


Figure 2. Network Diagram.

4.0 Indications for Use

The Cal Poly Prosthetic Thumb Team has come up with the following indications for use for FDA approval of our device: This device will be used by an individual who has recently undergone a thumb amputation distal of the Metacarpal-Phalangeal (MCP) joint, in order to improve the overall functionality of the left hand. The degree to which functionality may be improved is largely dependent upon the length of residual thumb. Our team will design a lightweight prosthetic that the user can actively move and engage to mimic natural thumb movement, function, and strength.

5.0 Budget

The Cal Poly Prosthetic Thumb Team has come up with the following budget for the prosthetic thumb design. The project is planned to be low cost. To keep the costs to a minimum for the patient, we plan on utilizing free 3D printers and materials from the Cal Poly SLO and Pomona campuses. The budget is subjected to change, in the event that a major change in design occurs. All Purchase Requisition Forms and stores in which each part was purchased can be found in Figures 66-68 of the Appendix.

Table 5. Proposed Budget.

Item Description	Product Number	Associated Task	Planned			
			Unit	Quantity	Cost/Unit	Total Cost
Shipping prototype		32	2-lb Box	2	\$20	\$40.00
3D Printed Shell (PLA)		19		10	\$0.00	\$0.00
PowerPro Hollow Ace		19	1 Yard	15	\$0.75	\$0.00
Button Head Torx Screws 18-8 Stainless Steel, M2 x 0.4mm Thread, 5mm Long	90910A921	19		100	1	\$11.60
316 Stainless Steel Ring Shim 0.001" Thick, 1/8" ID	97022A864	19		5	2	\$9.09
18-8 Stainless Steel Dowel Pin Stock 1/8" Diameter	95609A310	19		1	1	\$12.31
TiN Coated High-Speed Steel Tap Set, M2 x 0.4 mm Thread	26475A11	19		1	1	\$57.81
Screwdriver T6 Torx	5756A32	19		1	1	\$6.25
302 Stainless Steel Torsion Spring 180 Degree Right-Hand Wound, 0.216" OD	9287K21	19		1	5	\$3.83
Narrow Fillister Head Slotted Screw 18-8 Stainless Steel, High-Profile, 2-56 Thread, 1/2" Long	91794A081	19		100	1	\$5.31
Short-Length Drill Bit 1.6mm Size, 33mm Overall Length	2979N13	19		1	2	\$3.81
Tap Wrench with Fixed Straight Handle, 5" Long	2546A12	19		1	1	\$46.24
Plastic Box with 12 Compartments, 10-3/4" x 6-1/2" x 1-7/8", Clear		19		1	1	\$8.84
Delrin® Acetal Resin Balls 1/16" Diameter	9614K5	19		25	1	\$4.97
18-8 Stainless Steel Screw-to-Expand Insert for Plastic 2-56 Thread Size	92394A111	19		10	2	\$10.14
High-Performance Fabric 0.75" Elastic Spool	621596	19	2 Yards	1	\$13.75/ yard	\$27.50
Ball Point Hand Needles	B005573G3Q	19	11 Yards	1	\$7.99	\$7.99
Stretch Thread	B074N5CMP G	19	48 Needles	1	\$6.38	\$6.38
Futuro Deluxe Thumb Stabilizer		19	225 Yards	1	\$5.11	\$5.11
Instron Tester (Tensile Testing)		21		1	\$21.00	\$21.00
Materials Tester (Flexural Testing)		21		1	\$0.00	\$0.00
					Total:	\$326.54

Shipping/Travel
 Prosthetic Design
 Attachment Design
 Testing

6.0 Customer Requirements

The patient expressed a few specific needs and expectations for his new prosthesis. These included the ability to fit his hand, with the prosthetic thumb attached, into his pocket and have the ability to grasp items in the pocket. Additionally, the patient prefers to have a body powered prosthetic rather than a passive-partial prosthetic with no active movement. Other specified expectations include a lightweight-slim design, high durability, and an ability to still weight-lift. Finally, we would like to create a low cost design, to keep the prosthetic at no cost to him. However, as of November 2nd, we do not believe we will be able to produce a prosthetic for weight lifting because of time constraints. We can provide suggestions for alternative devices to aid in weightlifting, but the main focus of this design should be for a day to day functional prosthetic.

7.0 Specification Development

The engineering specifications can be seen above in Table 3 of the Statement of Work section. Minimizing cost, while maximizing functionality is an important balance to find for our design. Attempting to stay close to, or within, our proposed budget will be the best way for analyzing our spending. Production cost is a “High Risk” specification because we are still in the early stages of the design phase and do not have a solid idea of what materials will be necessary. Once we have a better idea of what our final design will look like, we will know specifically what materials and how much we will need. The second most important specification is the weight of the device. This will be measured using a scale. We want the thumb to have a weight similar to that of the patient's actual thumb for ease of use and comfort.

8.0 TAM and Competitive Advantage

TAM: Individuals of any age and gender requiring enhanced functionality from their fingers.

Around 30,000 people a year in the United States undergo a finger amputation (“How to Avoid...”). Most amputations are generally due to accidents with doors and power tools. If we are estimating the cost of our product to be \$200, it is estimated that we could make \$6,000,000/year from our product.

SAM: Individuals who have some sort of amputation of any of their fingers in the California area.

Around 12% of U.S. citizens live in California, so 12% of the 30,000 finger amputations a year should occur in California. This results in 3,600 people a year in California have an amputation of their fingers. Therefore it is estimated that we could make \$720,000/year from our product.

SOM: Individuals who have a thumb amputation distal to the MCP Joint and Proximal to the Interphalangeal joints.

Around 20% of finger amputations are of the thumb, and so 20% of 3,600 people is 720 people a year. This is the market that we are aiming to serve. We estimate that we would make \$144,000/year on our prosthetic thumb product.

For the current stage of this project, we are designing for the custom fit of one patient. This can later be expanded for more patients on a wider scale.

Table 6 below shows the comparison between the Thumb Driver and Living Skin prosthetics, and our design. Our design is much more cost effective than our competition due to the fact that we are using 3D printed materials, however the material then is not as strong as our competitors. However, It will still perform well and therefore is a competitive option when comparing to other prosthetic companies.

Table 6. Competitive Advantage.

Specification	Naked Prosthetic (Thumb Driver)	Ossur (Living Skin)	CP Prosthetic Thumb Design
Cost	Bad	Ok	Good
Weight	Good	Ok	Good
Appearance	Ok	Ok	Ok
Prosthetic Type	Good	Bad	Good
Material	Good	Ok	Ok
Mounting	Ok	Ok	Good
Grip Force	Good	Bad	Good

9.0 Intellectual Property Assessment

Current products and pending patents were assessed to verify where intellectual property currently exists, and what design choices we may have to make when designing the prosthetic, so that we can be sure to avoid infringement. These assessments can be seen above, in the Statement of Work section, in Table 2 (patents and patent applications).

10.0 Conjoint Analysis

We completed a conjoint analysis to determine which attributes of the prosthetic thumb were most desirable. Seen below in Table 7, are the factors we weighed with the different levels. The level 0 factors are more desirable than the level 1 factors. We then made eight different design options, using each of the factors from the level 0 design and the level 1 design. Those options were turned into eight different conjoint cards, which can be seen below in Table 8.

Table 7: Factors and Levels of Prosthetic Thumb Design

Factor	Level 0	Level 1
Cost	\$200-\$500	\$500-\$1000
Weight	40-90 g	>90 g
Appearance	Mechanical	Natural
Type	Body	Passive
Material	Carbon Fiber	Stainless Steel
Mounting	Glove	Thumb Strap
Grip Force	Full	Half

Table 8: Listing of Conjoint Cards

Card #	Cost	Weight	Appearance	Type	Material	Mounting	Grip Force
1	0	0	0	1	1	1	1
2	0	0	0	1	1	1	1
3	0	1	1	0	0	1	1
4	0	1	1	1	1	0	0
5	1	0	1	0	1	0	1
6	1	0	1	1	0	1	0
7	1	1	0	0	1	1	0
8	1	1	0	1	0	0	1

Thirty-nine of our classmates were surveyed and they ranked the conjoint card options from one to eight (one being the best option and eight being the worst option). That data was input into excel, and a multivariate regression was run in excel. The excel statistical output can be seen below in Figure 3. Based on the information from the multivariate regression, cost, appearance, type of prosthetic, material, mounting and grip force are all important to the success of the product because their p-values are less than 0.05%. The coefficients add up to a total of 200 points, and to determine the most important factors we look only at the statistically significant factors. Type of prosthetic and mounting have the highest importance, at 17%. Since the coefficients are positive, this means that our peers believe that the level zero factor is most important, so in this case, carbon fiber material and a glove mounting type should be used in order to create a successful product. The only non-significant factor is the weight of the prosthetic, however this is important to us as designers and to the patient. We will not throw out that factor, and will still design the product with the intention of keeping the weight of the device as low as possible.

SUMMARY OUTPUT								
Regression Statistics								
Multiple R	0.261305317							
R Square	0.068280469							
Adjusted R Square	0.046826401							
Standard Error	88.07341682							
Observations	312							
ANOVA								
	df	SS	MS	F	Significance F			
Regression	7	172812.2679	24687.46684	3.182635035	0.002889281			
Residual	304	2358105.732	7756.92675					
Total	311	2530918						
	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	42.45454545	26.55513433	1.598732092	0.110918935	-9.8005985	94.70968941	-9.8005985	94.7096894
Cost	23.81582551	11.20324386	2.125797297	0.03432599	1.77010308	45.86154794	1.77010308	45.8615479
Weight	20.86940176	11.20324386	1.86279992	0.063454799	-1.176320671	42.91512419	-1.176320671	42.9151242
Appearance	24.32896654	11.20324386	2.171600194	0.030658864	2.283244106	46.37468897	2.283244106	46.374689
Type	34.31678705	11.20324386	3.063111674	0.002386513	12.27106462	56.36250948	12.27106462	56.3625095
Material	32.4302992	11.20324386	2.894724029	0.004069663	10.38457676	54.47602163	10.38457676	54.4760216
Mounting	34.50492808	11.20324386	3.079905116	0.002259844	12.45920564	56.55065051	12.45920564	56.5506505
Grip Force	33.89344022	11.20324386	3.025323795	0.002695771	11.84771779	55.93916265	11.84771779	55.9391627

Figure 3: Multivariate Regression Output from Excel

11.0 Morphology

Functional decomposition was used to generate a morphology for a prosthetic thumb design. The main functions of our thumb consist of how the prosthetic moves, how the prosthetic attaches to the thumb, and how the entire product will attach to the wrist. We are also worried about the cosmetic appearance of our device, because the patient has said that he is self conscious about the look of the industrial/robotic looking prosthetics. For active movement, the device needs to be able to move at the joints through the body powered movement when the patient moves the thumb residual. Three ways that we believe we can do this is through hinges, cables or a single joint. Another function that is essential to the product is how the prosthetic will attach to the thumb residue. Ideas we came up with include attaching it to a glove that the patient can wear, attaching it to a ring that sits on the residue, a plastic brace that can attach over the thumb and down the side of the hand, or with a single pin that locks and can be quick released. For attachment to the wrist, we want the patient to be able to do so with ease (he should be able to do it quickly with one hand). Velcro or d-ring loops seem to be the best options for that. Finally, for a cosmetic look, we are considering having no cover (the device would have exposed metal), a silicone sleeve or cover that has the appearance of a realistic thumb, or using paint to mask the metal. These concept ideas can be seen below in Table 9. After creating the morphology table, each team member was tasked with generating a design using the concept ideas from the table. The three designs we came up with can be seen below in Figures 4-6.

Table 9: Morphology Assessment

Morphology				
Product: Prosthetic Thumb		Organization Name: California Polytechnic State University		
Function	Concept 1	Concept 2	Concept 3	Concept 4
Active Movement (Body Powered)	Hinge Design	Cable Design	Single Joint Design	Linkage Design
Attachment to Thumb	Sewing/Gluing into Glove	Oval Ring	Plastic Brace	Locking Pin with quick release
Attachment/ Detachment to Wrist	Velcro	Velcro + Loops	Loops (D Ring)	
Cosmetic	No covers	Silicone sleeve/cover	Skin Colored Paint	
Team member: Sahil Sharma	Team member: Allison Sigdestad			Prepared by: Sahil Sharma, Allison Sigdestad, Cale Foreman
Team member: Cale Foreman				

11.1 Concept Design I

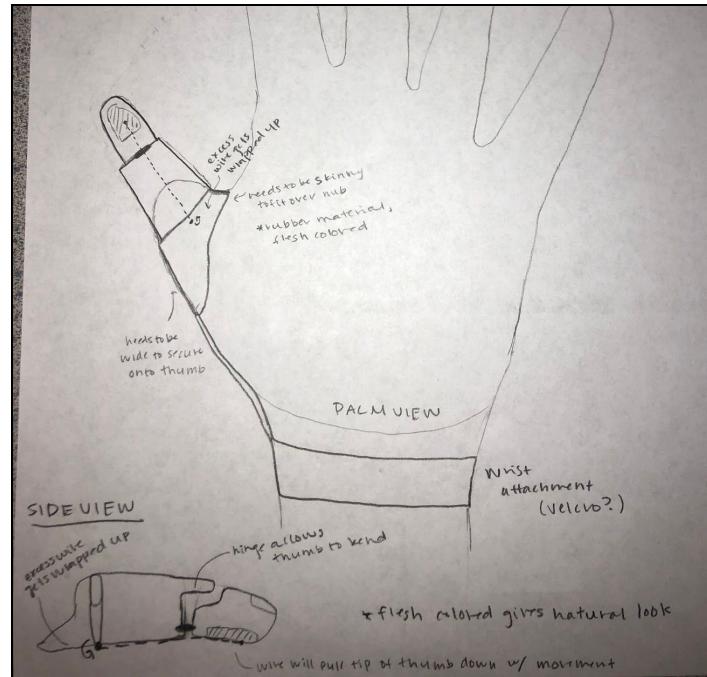


Figure 4. Concept Design I.

Concept one utilizes a wire mechanism to drive the body powered prosthetic. It has two main components - the larger part represents the proximal phalanx while the smaller part represents the distal phalanx. The proximal piece will be larger in radius and jet out over the distal piece. The tip of the thumb will be connected to the locking mechanism by wire, and have some sort of mechanism that will either wrap up the wire or move the wire to a different location when the thumb is bending. The attachment to the thumb is a silicone “ring” which will sit over the residue. It will be much wider on the outside of the hand to help secure it into place. This concept was thought of to be a more realistic thumb, but still body powered. The silicone and plastic can be chosen to be any color, even flesh colored if the patient desires that.

11.2 Concept Design II

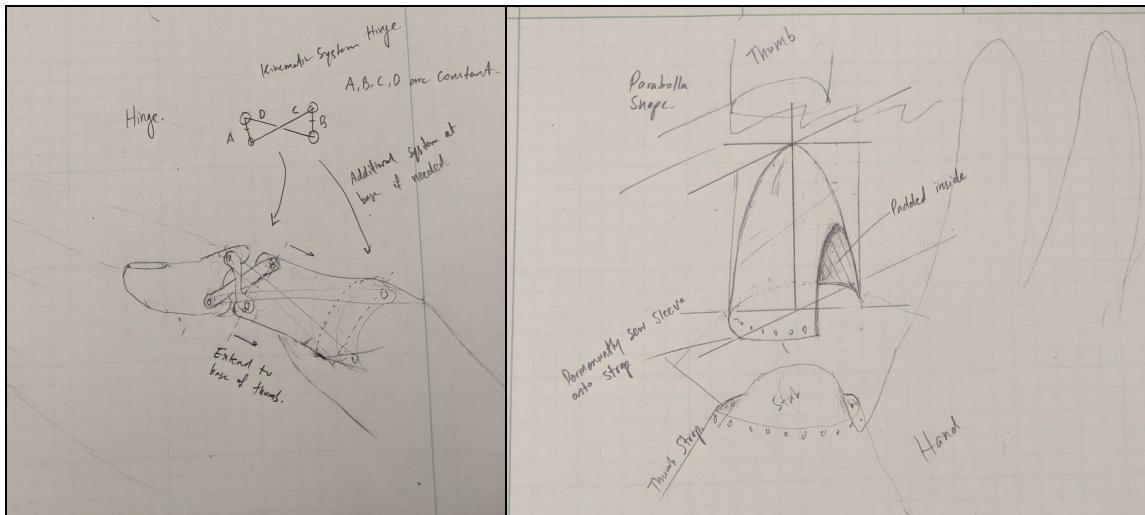


Figure 5. Concept Design II.

Concept two uses a hinge design to provide active movement of the prosthetic thumb. The hinge uses four points and four linkages configured in the A, B, C, D system seen in the drawing. The distal points are anchored distal of the IP joint while the proximal two points are anchored proximal to the IP joint. Depending on how much movement the patient has of the residual thumb distal to the MCP joint, the proximal anchor points of the prosthetic can be shifted back to sit over the MCP joint. The prosthetic would be glued/epoxied to a sleeve that sits over and cushions the residual thumb. The sleeve can be made of a flexible fabric/gel. It has a cutout on one side to fit snugly around the residual thumb without interfering with the webbing between the thumb and index finger. The sleeve is permanently sewn onto the thumb strap/glove. The strap/glove is secured to the hand using a velcro strap around the wrist.

11.3 Concept Design III

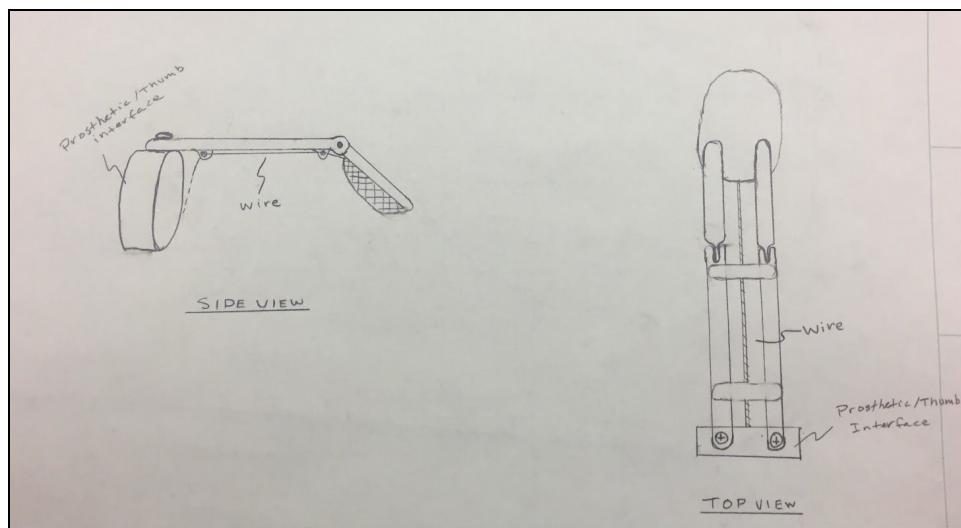


Figure 6. Concept Design III.

Concept three is very similar to Concept one in how it functions, but with a more mechanical look. The main components include the prosthetic/thumb interface (silicone ring) where the device is actually in contact with the residual thumb, 4 stainless steel rods, thumb pad, and wire. The stainless steel rods will be connected via hinges, while the wire runs through the middle of the rods and connects to the thumb pad. As tension in the wire increases, the thumb pad will bend inward. At the moment, we are unsure of how exactly the user will increase wire tension to cause the bend at the joint.

12.0 Concept Evaluation

To evaluate the three concept designs generated, we used a pugh matrix. The pugh matrix compares each of the concepts against each other to determine a frontrunner. We used criteria from our QFD (House of Quality) to evaluate each of the concepts. An example of the empty pugh matrix can be seen below in Figure 7, however each of the team members filled out the pugh matrix and the results can be seen in the Appendix in Figure 65. Each team member filled out the matrixes individually, using one matrix as the baseline and comparing the other two concepts to that one. A score of -1 means that the evaluated concept performs worse than the baseline concept, a score of 0 means the two concepts perform the same, and a score of 1 means the evaluated concept performs better than the baseline concept. 100 points distributed to the five factors. Grip strength and load applied were weighted the highest, and each given 25 points because those are detrimental to the function of the prosthetic. Grip strength is the primary function of this prosthetic thumb. It also needs to be structurally sufficient to maintain the desired grip strength. If the prosthetic cannot withstand a load or apply strong grip strength the device is useless to the patient. Cost to manufacture was given 20 points, because we are looking to keep the device at a low cost. Finally weight and reliability were weighted the lowest, with 15 points each. While we want a low weight device that will last a long time, they are the least concern at the moment for creating a functional device for the patient.

Choose a Prosthetic Thumb Configuration		BASELINE	Concept 1	Concept 2	Concept 3
Cost to Manufacture	20				
Weight of Device	15				
Reliability/Lifetime	15				
Grip Strength	25				
Load Applied	25				
		Total	0	0	
		Weighted Total	0	0	

Figure 7. Pugh Matrix.

After each team member filled out the pugh matrixes, each concept's weighted total was added together. Concept 1 scored significantly lower than the other two, at -140. In order to make a more realistic looking prosthetic, reliability, grip strength and load applied are lost. Concept 3 scored a score of 215. This concept scored very well, however the cost to manufacture did not compare to the other concepts and may be less reliable than Concept 2. Concept 2 scored the highest with a score of 250. Concept 2 scored consistently higher than the baseline in the grip strength and load applied, which were the two most

important criteria for the prosthetic design. Because of this, we have decided that Concept 2 is our front runner, and we will continue forward with a design for this concept.

13.0 Conceptual Model

To better understand the movement that the prosthetic needs to match, a solidworks ball and model representation of the distal and proximal phalanges was generated by our Cal Poly Pomona counterpart. The model has been overlaid onto a 2D photo of the injured hand and angle constraints were inserted to mimic the motion of the patient's hand. Degrees of motion were taken from the patients physical therapist to ensure that the exact motion of the right thumb can be given to the left thumb prosthetic.

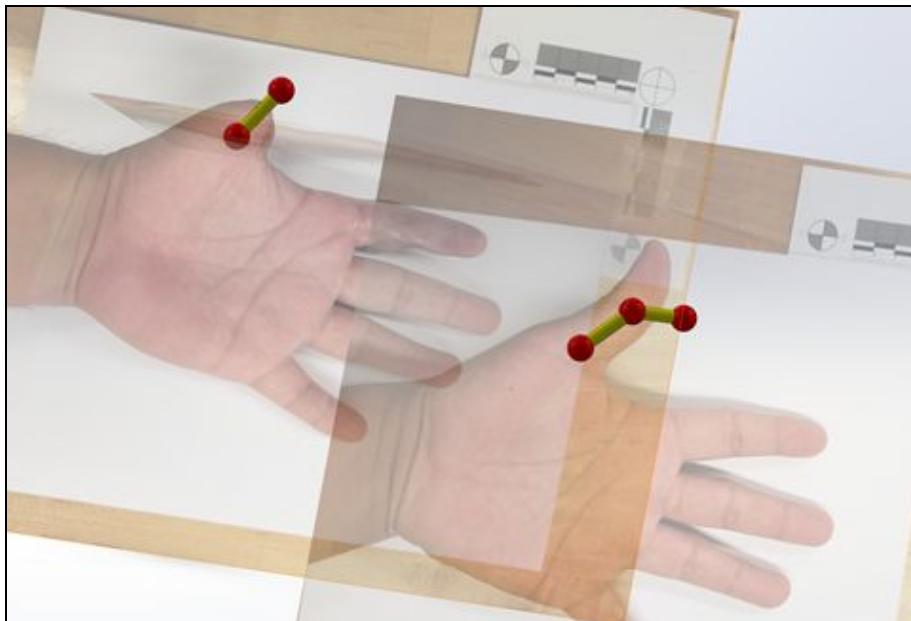


Figure 8. Ball and Stick 2D Model

The 2D model shows the patient's injured hand, and non-injured hand but flipped so that it also appears as the left hand. The joints and bones are modeled as a ball and stick model. As seen in the full hand, there are two bones and three joints. The degrees of motion of those balls were constrained using the values received from the patients physical therapist: Right thumb 1st joint can move from 0 degrees to 50 degrees (0 is upright position), and 2nd joint can move from 0 degrees to 70 degrees. The injured left hand 1st joint can move between 0 degrees and 35 degrees. We compared how this basic thumb model moves compared to our thumbs, and the movement was very accurate. We now have a SolidWorks model that accurately depicts the motion we would like the prosthetic to be able to do. Using this information, we can further our design by building a 3D model of the prosthetic design that we want to create directly on top of this current model. That way we can verify that the movement of the prosthetic design will match the movement needed by the thumb.

In short, this model is an interactive representation of the kinematic system governing our prosthetic design. We can use this skeleton to position and align the joints, pins, and force applications of the full prosthetic.

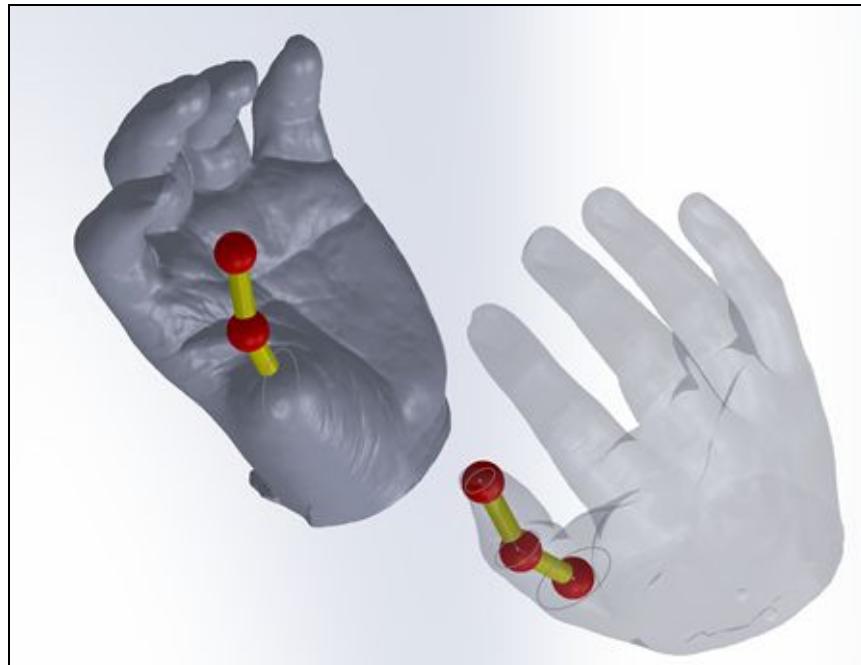


Figure 9. Ball and Stick 3D Model.

This model has the same idea as the previous model - it shows the movement of the bones and joints in the patient's full finger. In this case, the full model was inserted into the scan of the patient's injured hand. The patient still has the MCP joint, and so the bottom joint (ball) was inserted directly on top of it. This model shows how the prosthetic joints should line up with the amputated thumb, and also give us measurements on how long the distal and proximal sections should be given the residual length of thumb. As with the other model shown above, this will aid us when we build our prosthetic model on top of this current model, and verify that the segments are the correct length and the joints move as they should.

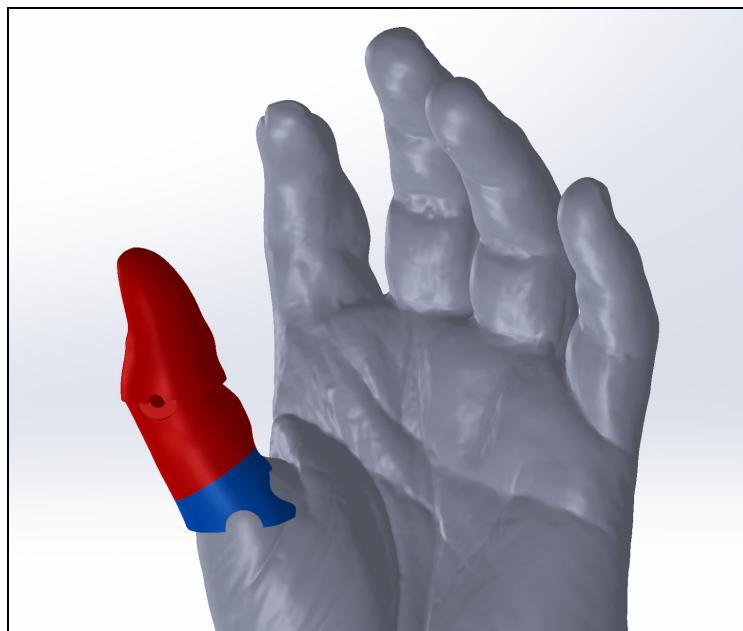


Figure 10. Prosthetic Thumb Model.

For this model, the mirrored 3D body of the right thumb was superimposed on the left hand. The thumb was converted into a proximal and distal phalanx, connected with a singular joint. The purpose of this Solidworks model is to show how much of the proximal phalanx clips/collides with the residual thumb. We can also determine the contours of the socket that will seat the prosthetic against the hand. This is the model that we will change and build upon to create the realistic looking prosthetic device that can be 3D printed.

14.0 Detailed Design

14.1 Detailed Design I

After meeting with our sponsor and Cal Poly Pomona counterpart, it was established that our concept design we wanted to move forward with would not be feasible for the active movement our patient desires. We believe that there is not enough residual of the thumb there to create a big enough moment to drive the motion of the prosthetic thumb using the hinge design, as we had previously believed. After receiving videos showing the patients range of motion, and discussing with Dr. Haghi, we decided to change the design of our prosthetic to using a wire based mechanism to drive the motion of the thumb. A cable system will allow the patient to generate and amplify larger motions of the prosthetic from the little residual that is left. Seen in Figure 11 is the outer shell of the prosthetic thumb. This will encase the wire and the internal cam mechanism that will drive the motion of the thumb.

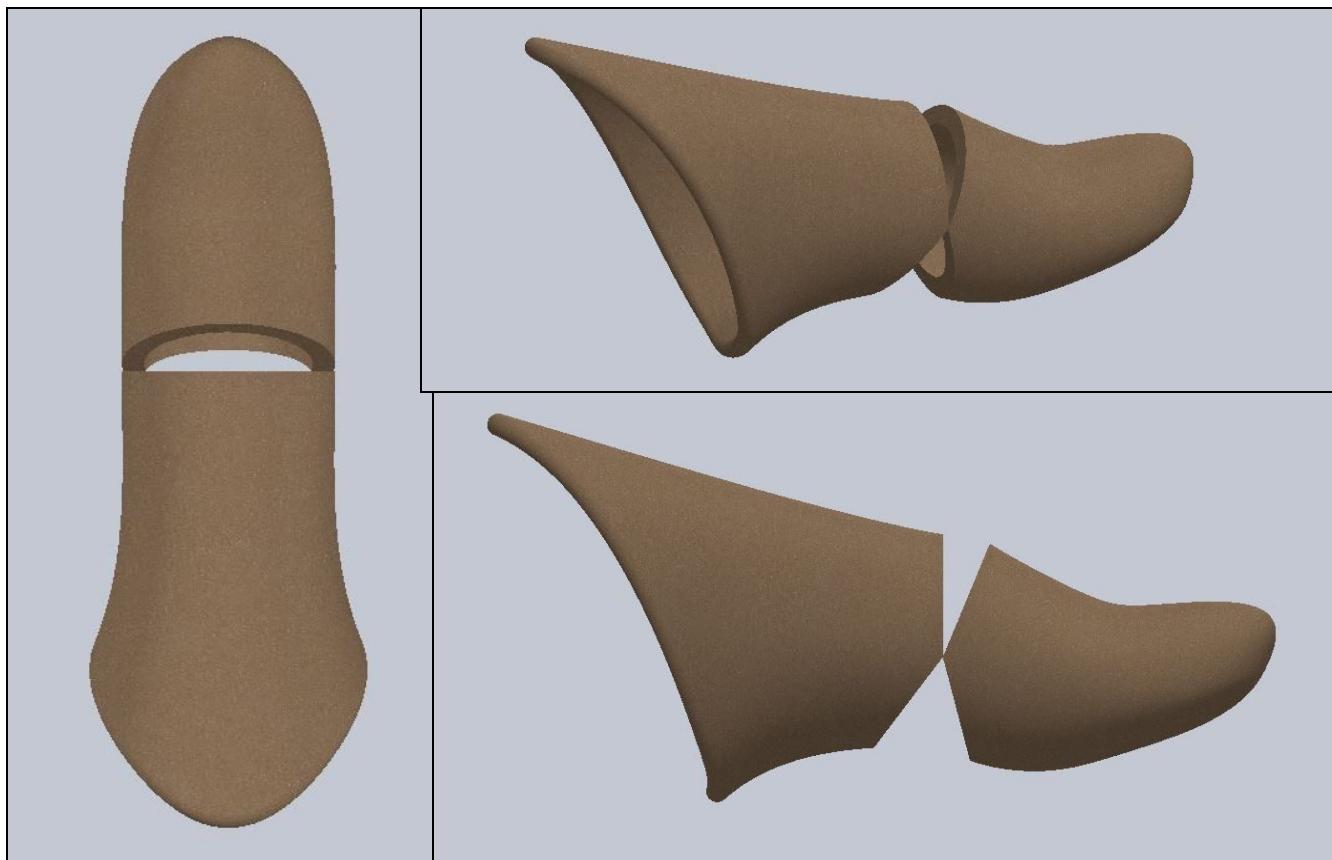


Figure 11. Detailed Design I of Prosthetic Thumb Shell.

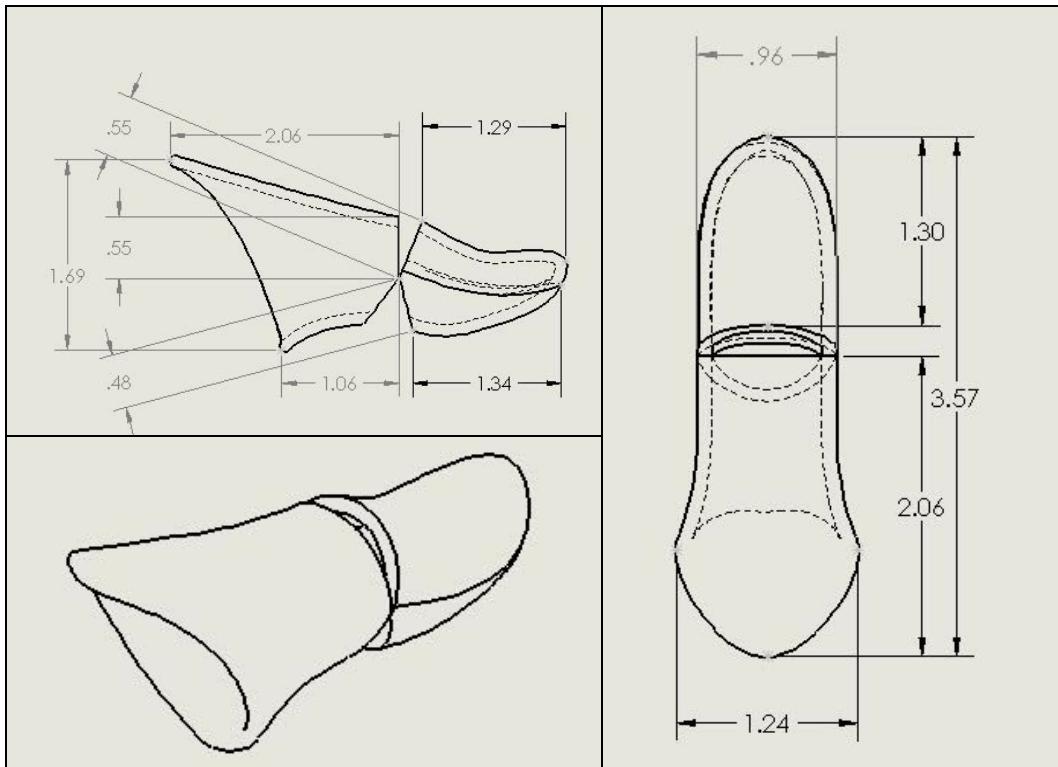


Figure 12. Outer Shell Dimensions.

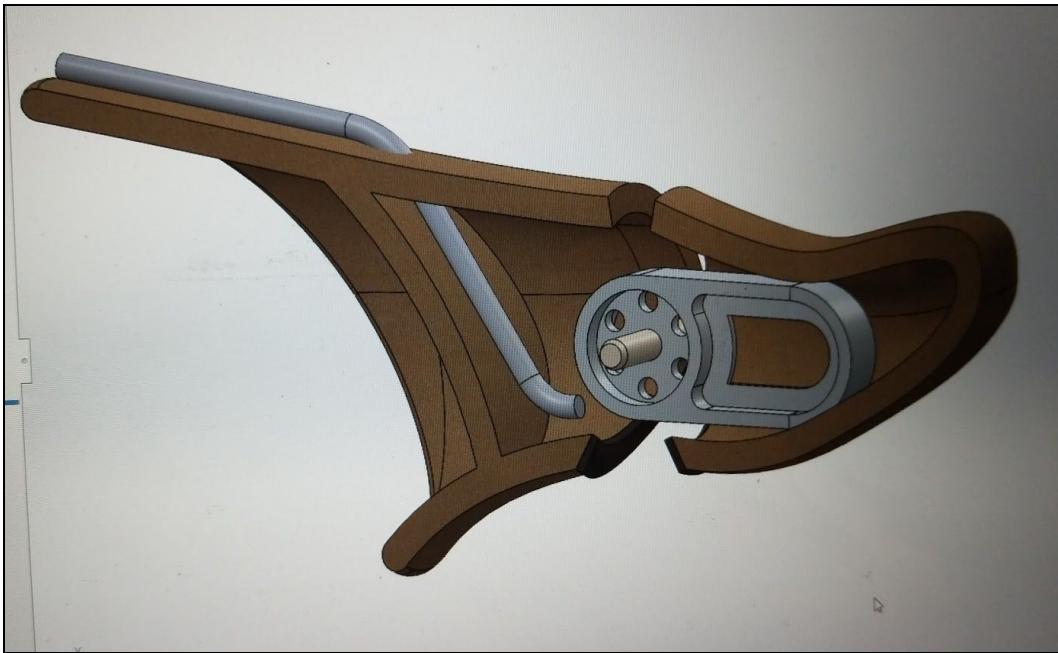


Figure 13. Detailed Design I of Prosthetic Thumb.

The prosthetic thumb will sit atop the residual and attach to a glove. We have a store bought thumb stabilizing brace that we can cut down and use, and we also have purchased materials to design and sew together our own glove. The cable needs to have a fixed anchor point, and that

will be to the wrist strap because the wrist strap will not be moving depending on the residual. The wire will connect to the wrist strap, sit atop the proximal piece, go inside and wrap around an internal cam that will thus drive the forward and backwards motion of the prosthetic. As the proximal piece is moved forward by the motion of the residual, the cable will get shorter pulling the lever down, and pushing the distal piece down. A torsion spring will be between the proximal and distal pieces. The spring will save space to mount the cable inside the tip of the thumb. The proximal and distal pieces will overlap with one another, and be held together with a washer, dowel pin and screw. The model will be split in half so that the wire and cam can be placed inside, and so that the patient can easily access the components if anything breaks or needs to be repaired.

Dimensions shown in Figure 12 above are not driving the design of the thumb. The dimensions were taken from the exact hand scan of the patient and converted into a .stl file. The right thumb was translated into a design for the left thumb so that the measurements exactly matched the patients biology. Pieces of the thumb were then cut away at the joint where the proximal and distal components meet so that the two parts do not interfere. The overall length of the thumb is 3.57 inches while the width is 0.96 inches, which fall within the normal range of thumb measurements.

For materials, we have decided to use PLA from the Innovation Sandbox for the outer housing of the prosthetic thumb. The lifetime for the product is only 1-2 years, and so we do not feel that it is necessary to proceed with carbon fiber and instead save costs. It held up to preliminary tests and seems strong enough and so we would like to use PLA. We may look into a primer to add a more sophisticated surface finish on the pieces, and also we have considered adding a rubber overmold or piece on the end of the thumb for gripping purposes. We will be using blind rivets to hold the proximal and distal pieces together. We intend on adding these pieces later on after the design has been proven to work. We have decided to use PowerPro Hollow Ace fishing line for the wire that will drive the motion of the thumb. This fishing line is much less expensive than the nylon wire we were considering and is already weighted to very high strengths. It is a braided line, and so it has little to no stretch which is ideal for our design. This particular fishing line is also meant to be run between your fingers, and therefore it is safe to handle and will not cause any damage or injury to our patient. For the internal cam, we will also be 3D printing using the PLA from innovation sandbox. Andrew will be continuing the project until May (after the SLO students are done with the project) and he has discussed maybe using CNC to manufacture an internal cam out of stainless steel. His reasoning is because it is a small enough piece where steel would not add too much weight to the device. Stainless steel would add an extra corrosion resistance, which is ideal to protect against any damp conditions such as water, rain or sweat. For our time purposes however, our BMED 456 final design will have a PLA internal cam.

14.2 Detailed Design II

As of January 25th, 2020, the detailed design was updated to include hardware such as screws and shims. The added features include screws and shims on the axle, press-in nuts and screws to fasten the two halves of the distal housing together, a resized linkage, a torsion spring on the axle, cable routing integrated into the housing itself, a longer shroud around the proximal housing with holes to fit a sewing needle, and ribs along the proximal housing for added strength. The proximal housing was designed to be 50 thousandths of an inch thick with the ribbing being 80 thousandths. The geometry of the proximal housing is molded around the left thenar.

Design II also changes from using the PowerPro Ace Hollow fishing line to a medical grade wire provided by Loos and Company. They gave us around 3 feet of free samples.

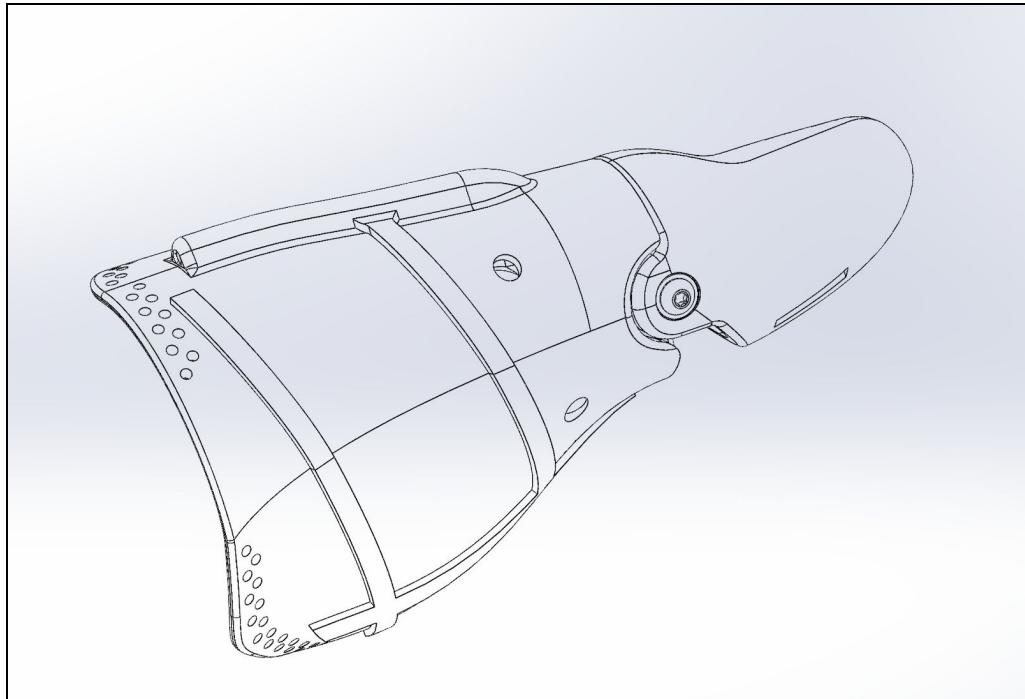


Figure 14. Detailed Design II of Prosthetic Thumb.

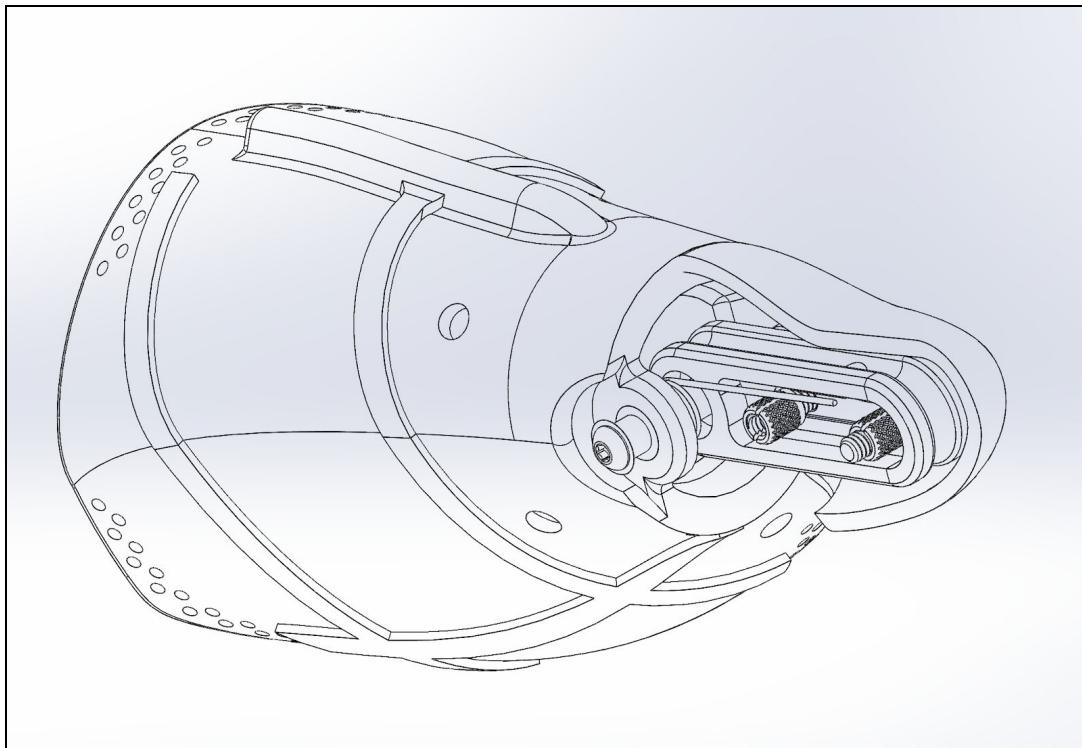


Figure 15. Detailed Design II of Prosthetic Thumb with Cutaway.

15.0 Prototype Manufacturing Plans

Seen below in Tables 9-10 is our Detailed Manufacturing Process Instructions (MPI). Table 10 includes documentation for manufacturing the proximal and distal phalanges, the glove and the cam. Table 11 includes documentation for assembling the prototype. All prototype manufacturing will take place at both the Pomona and San Luis Obispo campuses.

The facilities to be used for prototype manufacturing include Cal Poly Pomona campus and Cal Poly San Luis Obispo Campus. 3D printing will be carried out in the Innovation Sandbox located on the Cal Poly San Luis Obispo campus, using their 3D printers. The Innovation Sandbox is located in 197-205 (Bonderson Projects Center). The axle will be manufactured in the San Luis Obispo machine shops. The final prototype/product will be assembled on the San Luis Obispo campus. The San Luis Obispo students require yellow tag certification to use the machine shops.



Figure 16. Ultimaker 3+ Extended 3D Printer.

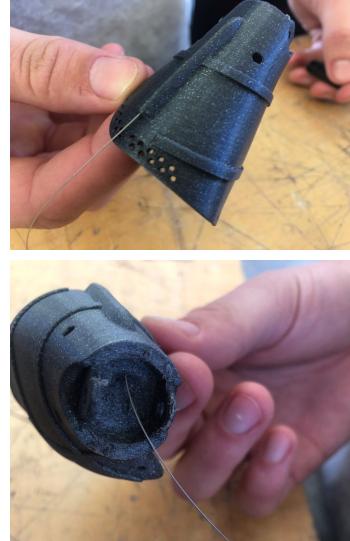
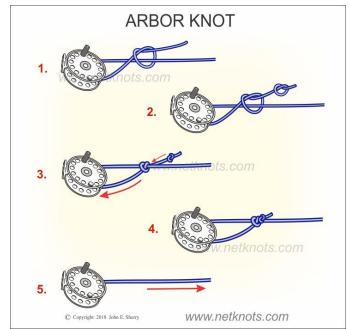
Table 10: MPI Manufacturing

1. Proximal and Distal Phalanges, and Cam			
Step	Parts/Tools Used	Description	Picture
1.1	<ul style="list-style-type: none"> • Ultimaker 3+ 3D Printer • PLA filament 	<ul style="list-style-type: none"> • Load the 3D printer with PLA filament. • Upload the “.stl” files of the proximal and distal phalanges to Cura. • Orient both parts upright with the most proximal sides laying on the bed of the printer. • Begin print. 	
1.2	<ul style="list-style-type: none"> • Files, exacto knife, sandpaper, pliers 	<ul style="list-style-type: none"> • Use files, knives, and sandpaper as necessary to remove 3D printing scaffolding and deburr edges 	
1.3	<ul style="list-style-type: none"> • 1.5mm drill bit • Hand drill 	<ul style="list-style-type: none"> • Using a 1.5mm drill bit, enlarge and clean the holes around the base of the proximal phalanx 	
2. Glove			
Step	Parts Used	Description	Picture
2.1	<ul style="list-style-type: none"> • 3M Thumb Stabilizer • Exacto knife 	<ul style="list-style-type: none"> • Use an exacto knife to cut off approximately one inch of the upper thumb strap and remove the stitches around the steel plates in the glove. • Remove the steel plates from the glove 	
2.2	<ul style="list-style-type: none"> • Scissors 	<ul style="list-style-type: none"> • Place the printed proximal phalanx over the glove at the thumb. • Measure 1 inch of fabric from the base of the proximal phalanx and cut the excess material from the glove 	

3. Axe			
3.1	<ul style="list-style-type: none"> • Lathe • Dowel Pin • 1.6mm Drill bit • Chamfer bit 	<ul style="list-style-type: none"> • Note: Follow all shop safety protocols • Install the dowel pin on the lathe. • Cut the dowel pin to length. • Use the tailstock and a 1.6mm drill bit to drill a blind hole 8 mm deep into the dowel pin. • Use a chamfer bit to lightly deburr the hole. • Repeat on the opposite side of the dowel pin. 	 
3.2	<ul style="list-style-type: none"> • M2x0.4 Tap Set 	<ul style="list-style-type: none"> • Using a set of M2x0.4 taps, tap both holes 6mm deep 	
3.3		<ul style="list-style-type: none"> • Clean tapped holes of the dowel pin with compressed air and shop towels. • Degrease with warm soap and water. Dry thoroughly. 	
4. BOA Fixture			
4.1	<ul style="list-style-type: none"> • Boa S2-S Dial Closure System 	<ul style="list-style-type: none"> • Unscrew the top screw using a T-6 Torx Screwdriver. • Remove the top piece. • Remove the outer white locking dial. • Remove the opaque circular piece that houses the wire by pushing through from the bottom of the device. • Cut or untie the knot securing the existing wire and remove wire. • Resecure the new wire in the 	

		<p>same orientation as the original wire.</p>	    
4.2		<ul style="list-style-type: none"> Repeat the previous steps in reverse order to reassemble the Boa S2-S Dial closure system. 	

Table 11: MPI Assembly

Step	Parts Used	Description	Picture
1.	<ul style="list-style-type: none"> • Wire • Proximal phalanx 	<ul style="list-style-type: none"> • Thread the loose end of the wire through the hole on the dorsal side of the proximal phalanx 	
2.	<ul style="list-style-type: none"> • Wire • Cam 	<ul style="list-style-type: none"> • Take the wire and tie an “Arbor knot” around the cam as shown. Tighten the knot so that the knot rests where the line meets the cam. Center the wire along the groove of the cam 	<div style="display: flex; align-items: center;"> <div style="flex: 1;">  </div> <div style="flex: 1; text-align: right;">  </div> </div>

3.	<ul style="list-style-type: none"> • Distal Phalanx (Left Side) • Cam 	<ul style="list-style-type: none"> • Install the cam with the wire to the left half of the distal phalanx 	
4.	<ul style="list-style-type: none"> • Distal Phalanx (right side) • Torsion spring • Axle • Shims 	<ul style="list-style-type: none"> • Place the right side of the distal phalanx on the left side of the distal phalanx • Place the torsion spring on the axle and seat on each leg to their respective anchoring points on the inside of the proximal and distal phalanges • Align the distal phalanx with the proximal phalanx • Line up the shims along the proximal anchoring holes • Insert the axle 	  
5.	<ul style="list-style-type: none"> • Screws 	<ul style="list-style-type: none"> • Use a T6 Torx screwdriver to install one screw on each end of the axle 	

6.	<ul style="list-style-type: none"> • Glove • Proximal phalanx 	<ul style="list-style-type: none"> • Place the proximal phalanx over the remaining thumb portion of the glove cut from Manufacturing step 2.2 	 
7.	<ul style="list-style-type: none"> • Size 5 ball-point sewing needle • Stretch thread 	<ul style="list-style-type: none"> • Using the sewing needle and thread, sew the proximal phalanx to the glove using a cross-stitch pattern as shown 	
8.		<ul style="list-style-type: none"> • Sew the BOA fixture to the base of the glove 	
9.		<ul style="list-style-type: none"> • Confirm that the thumb is under tension by flexing the IP joint. Confirm the return action by releasing the distal phalanx 	

Table 12. Bill of Materials

Part Number	Product Number	Part Name	Task	Quantity	Vendor
1.		PLA 3D Printing Filament	Prosthetic Thumb	1.0 in ³	Innovation Sandbox
2.		Loo's and Company Medical Grade Wire	Wire-Driven Mechanism	3 Ft	Donation from Loo's and Co.
3.	B074N5CMGP	Stretch Thread	Thumb Attachment	10 Yd	Amazon
4.	6620K221	Stainless Steel Stock	Internal Cam	1	McMaster-Carr
5.	90145A475	Dowel Pin	Joint/Axle	1	McMaster-Carr
6.	9287K271	Torsion Spring	Joint/Axle	1	McMaster-Carr
7.	90910A921	Screw	Joint/Axle	2	McMaster-Carr
8.	98126A011	Shim	Joint/Axle	2	McMaster-Carr
9.		Futuro Deluxe Thumb Stabilizer	Wrist Attachment	1	Target

16.0 Test Protocols

Figure 17 below shows the network diagram for all testing activities.

Also seen below in Table 13 is the pert chart for all testing. The pert chart numbers relate directly to the steps taken in the network diagram. Testing will be performed on Cal Poly San Luis Obispo's campus. Testing preparation locations include the biomedical engineering senior design class room (192-329). Testing locations include the biomedical engineering lab (192-328) and the Cal Poly Machine Shop (aero hangar). Allison, Cale and Sahil can perform the testing preparation and hyper-extension testing on their own. Supervision from personnel is required in order to use the Instron Tester, and thus the Instron T.A. (Eric Dubofsky) will be supervising the compressive and tensile testing.

Compressive and tensile testing will be of the proximal and distal pieces on their own (not attached as they would be in full assembly). The distal piece will however be completed with all internal parts (such as cam, screws, shims, spring, etc.). The hyper-extension test will consist of the full prototype, with proximal and distal pieces fully attached to one another, connected by sewing mechanisms to the thumb stabilizer and with wire running through the assembly.

The testing criteria for the tensile test is 100 lbs +/- 5 lbs. If the test fails, we will either use a higher rated fishing line or look into using a stronger wire.

The testing criteria for the compression test is 100 lbs +/- 10 lbs. If the test fails, we will look into using a resin printer with Dr. Laiho.

The testing criteria for the hyper-extension test is 25 lbs. If the test fails, we will need to determine which part of the design failed first. If it is the hinges, then we will need to print them with a thicker outer diameter. If it is the threading attachment of the prosthetic to the thumb stabilizer, then we will look into using stronger thread, or add more holes so that there is more stitching.

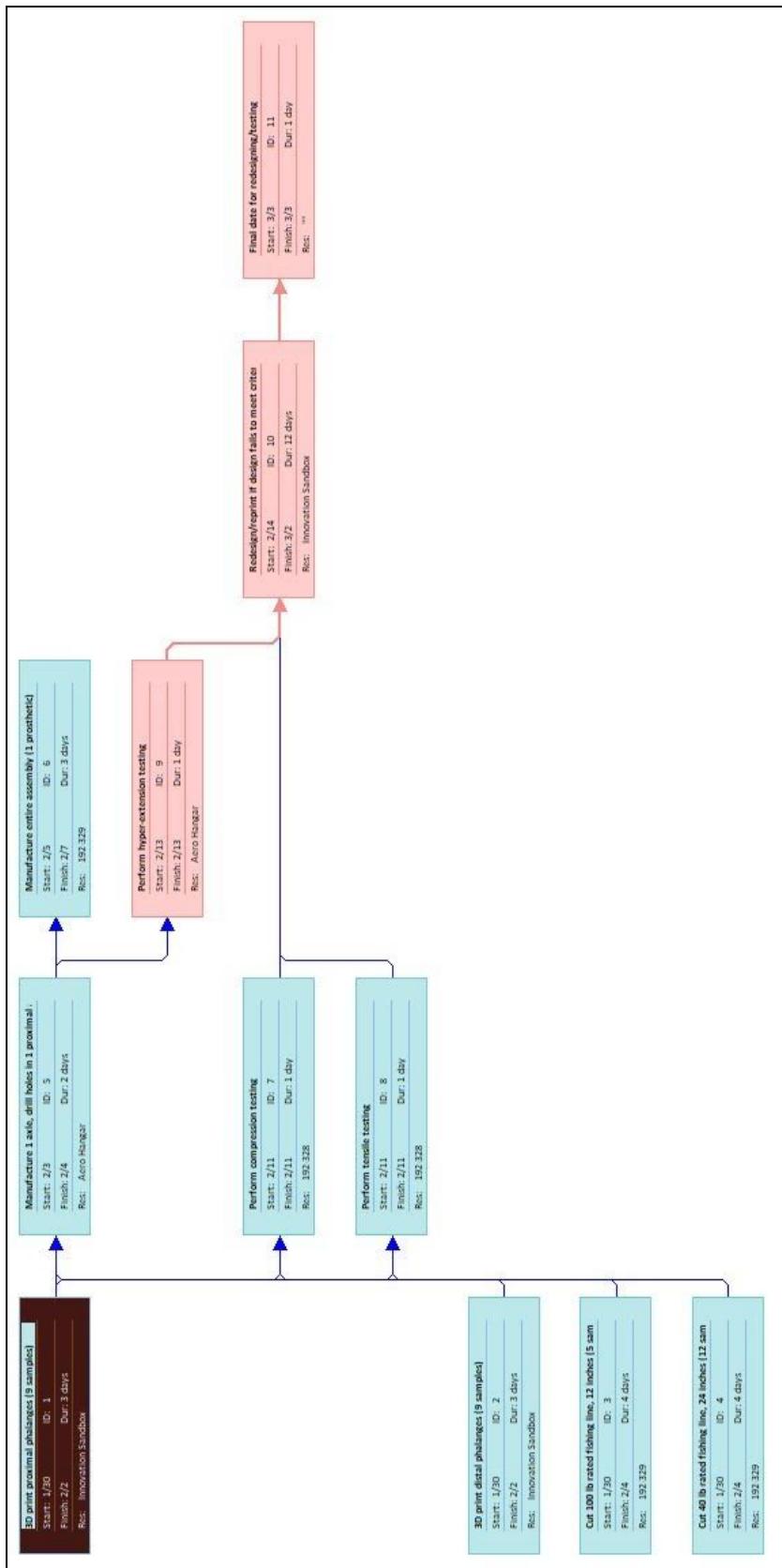


Figure 17. Network Diagram for Testing Activities.

Table 13. Pert Chart for Testing Activities.

Network Diagram Step	Task Name	Date	Time	Lab Space	Personnel	Equipment	Materials
1	3D print proximal phalanges - 9 samples	02/02/20	By 12 P.M.	Innovation Sandbox	Innovation Sandbox employees	Ultimaker 3+ Extended 3D Printer	PLA
2	3D print distal phalanges - 9 samples	02/02/20	By 12 P.M.	Innovation Sandbox	Innovation Sandbox employees	Ultimaker 3+ Extended 3D Printer	PLA
3	Cut 100 lb rated fishing line (12 inches) - 5 samples	02/04/20	By 4 P.M.	192-329	N/A	Scissors	PowerPro fishing line (100 lb)
4	Cut 40 lb rated fishing line (24 inches) - 12 samples	02/04/20	By 4 P.M.	192-329	N/A	Scissors	PowerPro fishing line (40 lb)
5	Manufacture 1 axle, drill holes in 1 distal and 1 proximal piece for torsion spring, and cut the 100 lb rated fishing line	02/04/20	By 4 P.M.	Aero Hangar	N/A	Hand drill, lathe, tap set, scissors	PLA, PowerPro fishing line (100 lb), stainless steel stock
6	Manufacture entire assembly - 1 prosthetic	02/07/20	By 4 P.M.	192-329	N/A	screwdriver , needle	Proximal and distal phalange, internal cam, torsion spring, shams, screws, thread, thumb stabilizer, 100 lb PowerPro
7	Perform compression testing	02/11/20	12 P.M.	192-328	Eric Dubofsky (Instron TA)	Instron Tester - compressive plates	6 PLA proximal phalanges, 6 PLA distal phalanges, 12 40 lb rated fishing line
8	Perform tensile testing	02/11/20	12 P.M.	192-328	Eric Dubofsky (Instron TA)	Instron Tester - tensile grips	5 100 lb rated fishing line samples
9	Perform hyper-extension testing	02/13/20	12 P.M.	Aero Hangar	N/A	Vice - soft jaws, 5 lb weights	Completed prosthetic design
10	Redesign/reprint design if fails to meet criteria	02/20/20	12 P.M.	Innovation Sandbox	N/A	Ultimater 3+ Extended 3D Printer	PLA, or change of material?
11	Final date for testing/redesigning	03/03/20	12 P.M.	“ ”	“ ”	“ ”	“ ”

16.1 Tensile Testing

Tensile testing will be performed in the Biomedical Engineering Materials Lab located in the Engineering IV building (192-328). In order to perform the tests, we will need to undergo training by the lab instructor as well as be supervised by him for the entire duration of using the Instron Tester. We do predict the wire during tensile testing to withstand 100 pounds of force, because that is what the fishing line has been rated by the manufacturer.

The Instron will be tested using a load 5 cm/s and the failure condition is until failure. The Instron only goes to a force of 500 N (112.4 lbs), and so if the wire does not fail before then, the test will stop at 500 N to prevent damage to the Instron tester. The test will succeed if the fishing wire can withstand the force of the rated pound test (100 lbs). Testing Criteria: All five individual trials need to pass in order for tensile testing to be considered as passing.

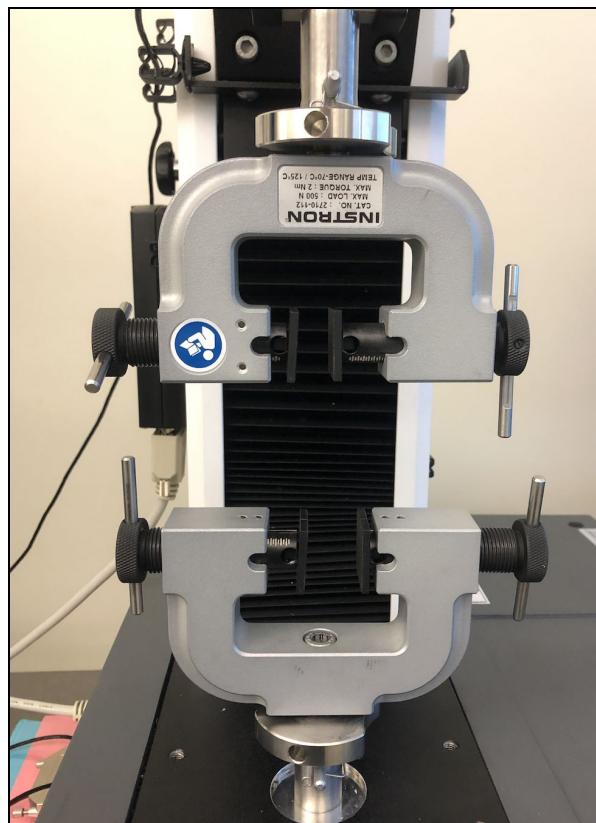


Figure 18. Instron Tester for Tensile Testing.

Power Pro Braid Fishing Line

1. Turn on and calibrate Instron Tester
2. Measure and record line dimensions
3. Load test samples and measure length between grips
4. Zero gauge length, balance the load, and run the tensile test
5. Repeat for 5 samples
6. Ensure the average is within +/- 5 lbs of rated pound test (100lbs)



Figure 19. Power Pro Braid Fishing Line.

16.2 Compression Testing

Compression testing will be performed in the Biomedical Engineering Materials Lab located in the Engineering IV building (192-328). In order to perform the test, we will need to undergo training by the lab instructor as well as be supervised by him for the entire duration of using the Instron Tester. In order to secure the proximal piece, we will be using the fishing wire to secure the piece to the bottom compressive plate. The fishing wire will be wrapped through the piece (using the holes cut out of the piece for the threading for the attachment to the wrist strap), then tied around the bottom of the bottom compressive plate. This will ensure that the proximal piece will not slide off the plate once contact has been made.

We will be testing until failure or up to 500 N (maximum load rate for the Instron tester). We expect the proximal piece to not fail, but we do expect the proximal piece to fail. Human bone of the femur can withstand forces up to 4,000 N before breaking. This is approximately 900 lbs of force. No material we choose will have the strength to match human bone, and so therefore we are only going to test up to a fraction of that. We want to test the proximal and distal pieces up to 100 lbs of force on the Instron compression test. If it can withstand that force, it should be good for our purposes. Testing Criteria: All three individual trials of the specific test run need to pass in order for compression testing to be considered as passing for that particular test.

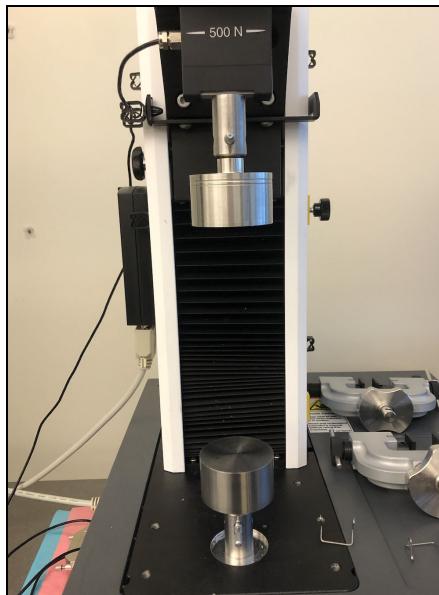


Figure 20. Instron Tester for Compression Testing.

Proximal and Distal PLA Phalanges

1. Exchange tensile Grips for compressive plates
2. Turn on and calibrate Instron Tester
3. Turn on materials tester and computer
4. Load necessary software
5. Measure all samples
6. Load proximal phalanx
 - a. Use fishing line to attach to bottom compressive plate
 - b. Measure support span length
7. Calibrate and start the experiment
8. Repeat test 3 times per phalange
 - a. 2 orientations: horizontal along both axes
 - i. See Figures 27, 29 & 31 below for orientation 1 of the proximal piece
 - ii. See Figures 33, 35 & 37 below for orientation 2 of the proximal piece
 - b. 6 total tests
9. Repeat step 6 through 8 with distal phalange
 - a. 6 total tests
 - i. See Figure 39 below for orientation 1 of the distal piece
 - ii. See Figure 43 below for orientation 2 of the distal piece

16.3 Attached Segments in Hyper-Extension

The hyperextension test will be done in the Cal Poly Machine Shop - Aero Hangar. There is not any special requirements needed to perform this test, other than obtain a red/yellow tag to have access to the hanger (which all team members have completed as of December 2, 2019).

Testing will be completed until failure, or until 15 lbs, whichever comes first. Testing Criteria: The individual trial needs to pass in order for hyper-extension testing to be considered as passing.

Hyper-extension

1. Secure the prosthetic to the 3D printed hand model
2. Secure hand model with prosthetic in vice with soft jaws in pronated orientation
 - a. See Figures 56 & 57 below for orientation
3. Hang weights off of the distal phalanx of the prosthetic in one pound increments, until failure
 - a. To complete our testing, we used a bucket, and filled it in increments of 15 oz of water (15.34 oz = 1 lb)

16.4 Water Testing

Water testing will be done in the Biomedical Engineering Materials Lab located in the Engineering IV building (192-328). Due to PLA's tendency to absorb water, and thus break down and lose rigidity, we want to make sure that our product will not be compromised due to sweat, water or rain.

In order to complete this testing, we will be 3D printing two prosthetic thumbs, and coating one prosthetic with XTC-3D, a high performance 3D print coating. Both parts will be soaked in a water bath for 30 minutes, and the structural integrity will be compared between the two parts.

17.0 Testing Data and Analysis

17.1 Tensile Testing

Initial tensile testing was conducted on February 6, 2020 in 192-328 at 12:00 P.M.. Three testing attempts were conducted, and all three tests failed.

We measured and cut the 100 lb rated fishing line to be 6 inches, and made 5 samples. For the first round of testing, we secured the fishing line between the tensile grips, and ran the first test. However, as seen in Figure 23, the stress concentration was too high and the fishing line snapped just below the tensile grips. We then attempted to secure the fishing line by taking off the tensile grips, and tying the line around the pins that secure the grips into place, as seen in Figure 25. However, this test also failed due to the fact that the knot slipped. We tied it with a fisherman's knot, and the double uni knot (which is the best knot for our specific fishing line), and both tests failed at around 20 lbs due to the knot slipping. Finally, we removed the pins and tied the wire around the holes in the instron, however this test also failed. The internal edges were too sharp and cut the wire during the test, and so we need a new method in order to proceed with tensile testing.

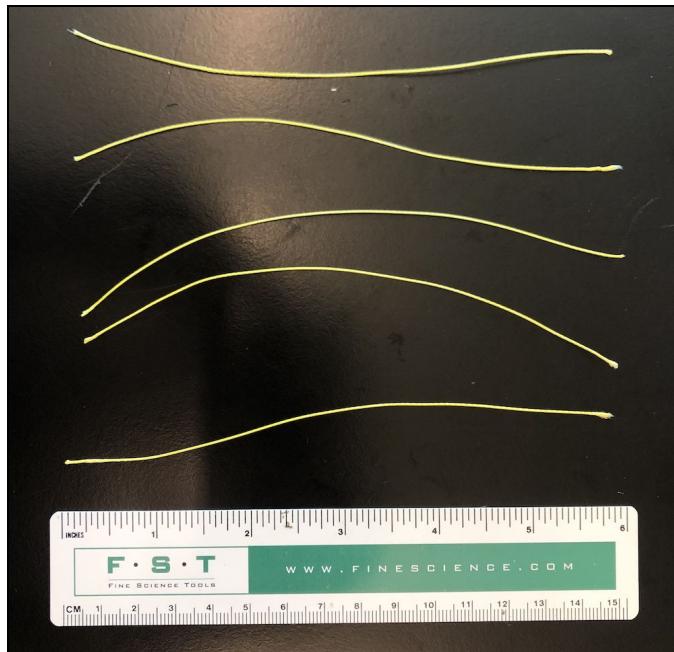


Figure 21. Fishing line samples 02/06/20.

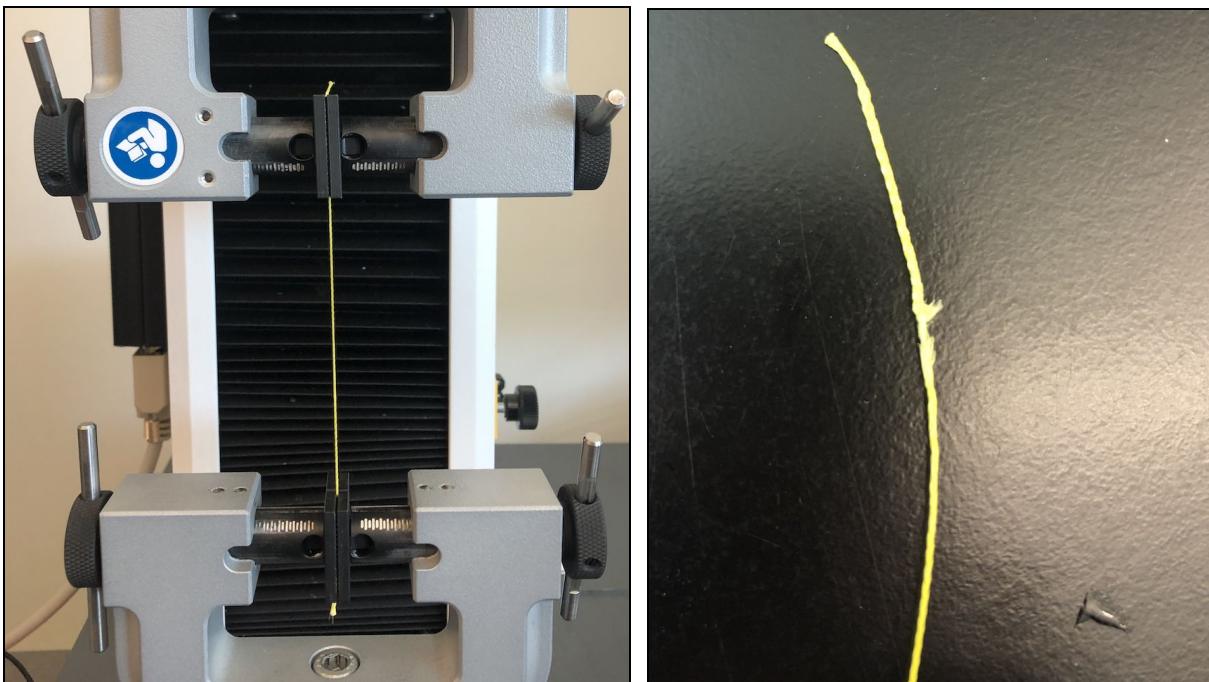


Figure 22 & 23. Tensile testing 02/06/20, attempt 1.

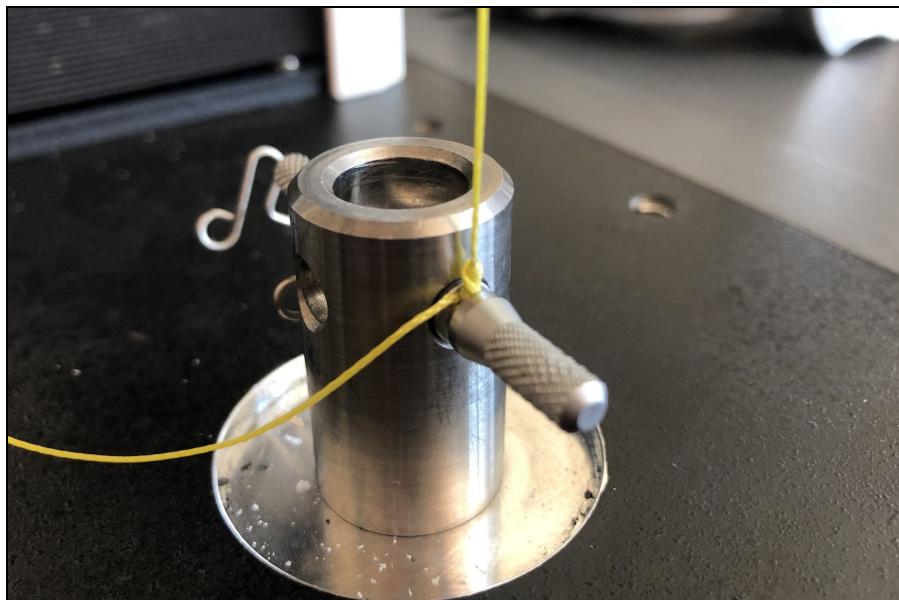


Figure 24. Fisherman's knot.

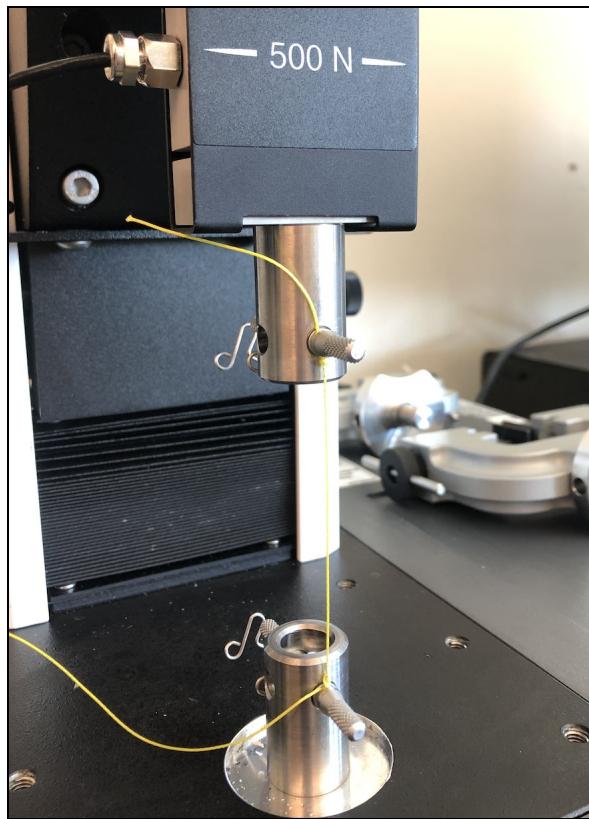


Figure 25. Tensile testing 02/06/20, attempt 2.

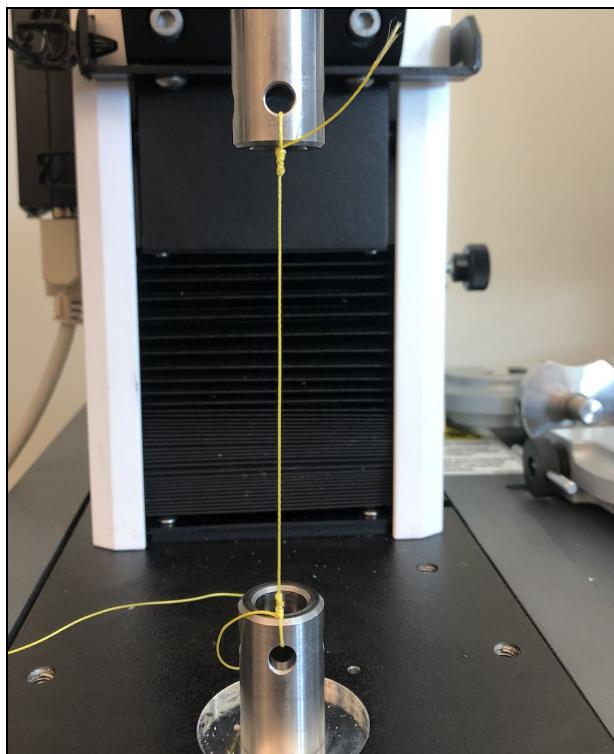


Figure 26. Tensile testing 02/06/20, attempt 3.

17.11 Conclusion:

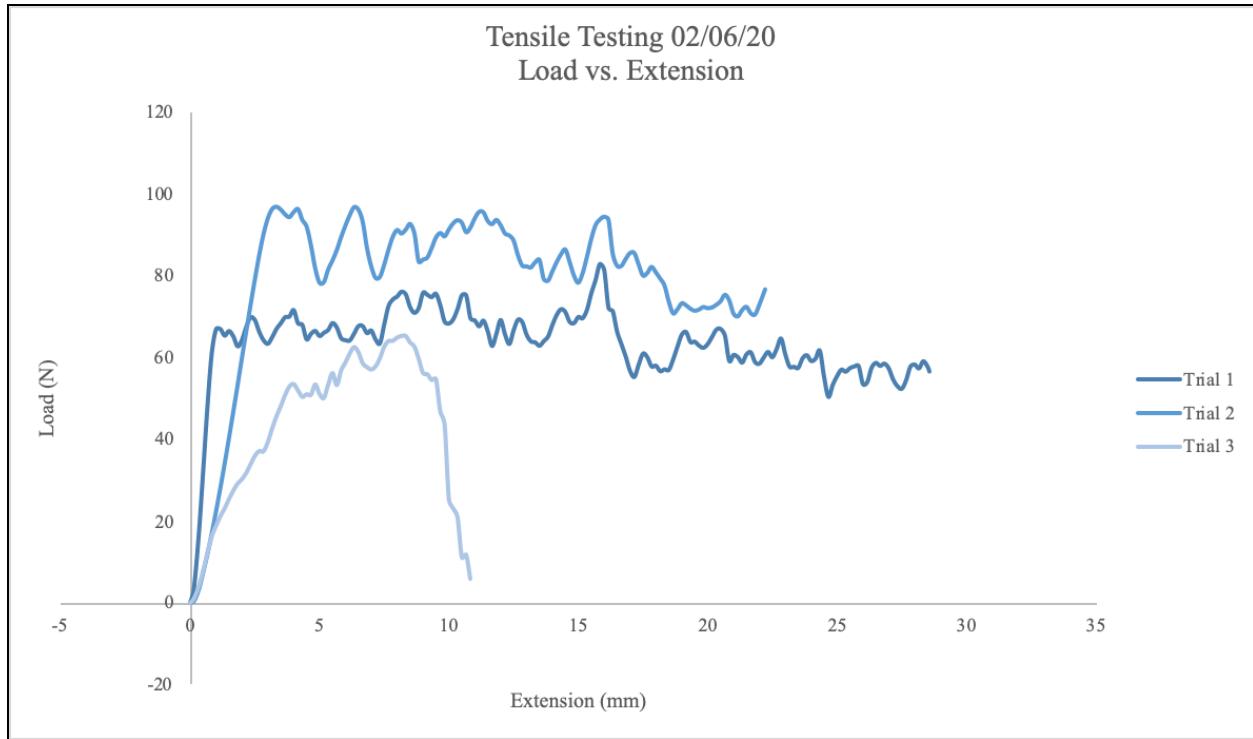


Figure 27. Tensile Testing, 02/06/20

All tensile testing failed.

The knot in the wire could not withstand a great force, as seen in Figure 27. The loads varied greatly as the knots slipped, and therefore all testing was inaccurate and therefore failed. Because of this, we are going to change materials to Loo's and Company medical grade wire, as noted in our detailed design II section. This wire was given to Andrew as a free sample at a medical device convention in Pomona. We have also received the testing documents for the wire, and have decided to move forward with it. If we have time next quarter and the resources to purchase more wire, we will perform our own tests, however we will not be able to do so before March 17.

17.2 Compression Testing

Initial compression testing was conducted on February 20, 2020 in 192-328 at 12:30 P.M.

Proximal pieces were tested first. We tested three parts in two different directions. The pieces were secured by using extra fishing line to tie the piece around the bottom compression plate. In the first orientation, the proximal piece failed at 38 N, due to a crack along the holes, seen in Figure 29. During the second test, the proximal piece slipped at initial contact with the top compressive plate because the wire was not tight enough, so the test was stopped at around 4 N, the part was resecured and the test was run again. The piece minorly cracked at 45 N, but the test was run until the maximum load was applied (500 N). The part had a crack seen in Figure 31, but the structural integrity of the part was not completely compromised, as it was still able to withstand 500 N. The third test was run, and there was a minor crack at 50 N (seen in Figure 33), but the test was run until the maximum load was achieved. This test also showed that the part

could still withstand a load of 500 N.



Figure 28 & 29. Proximal compression testing 02/20/20, orientation 1, attempt 1.

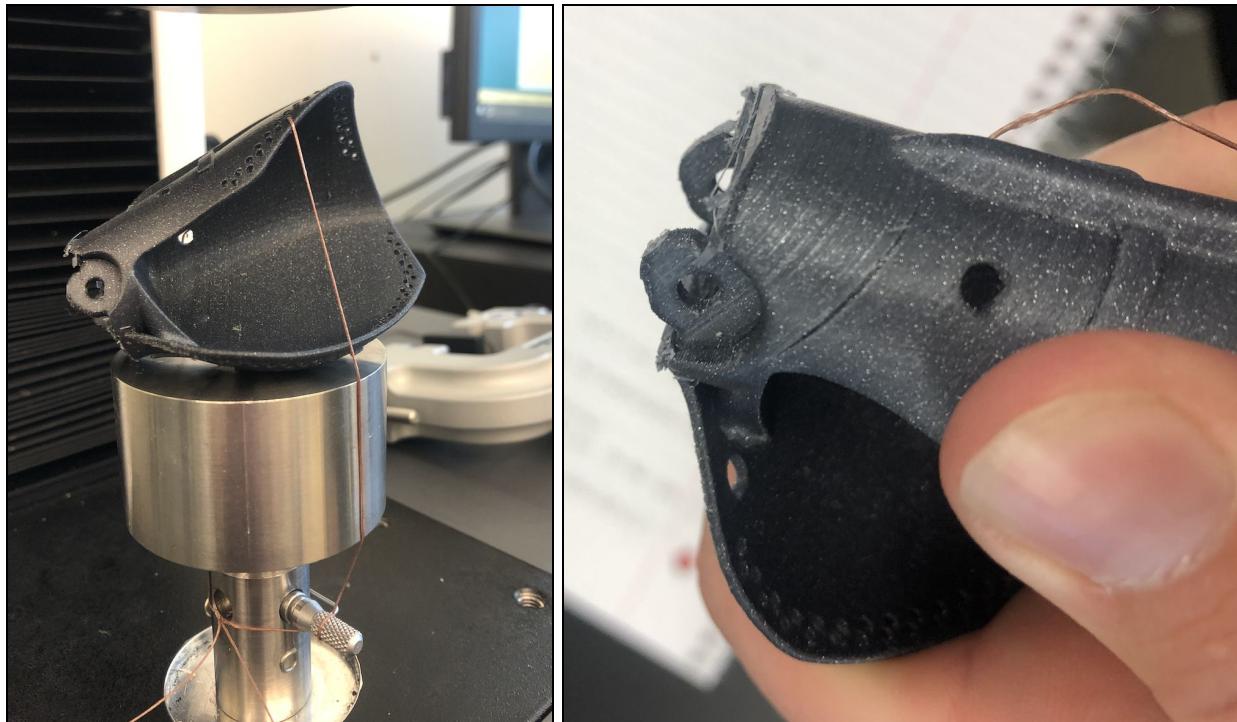


Figure 30 & 31. Proximal compression testing 02/20/20, orientation 1, attempt 2.

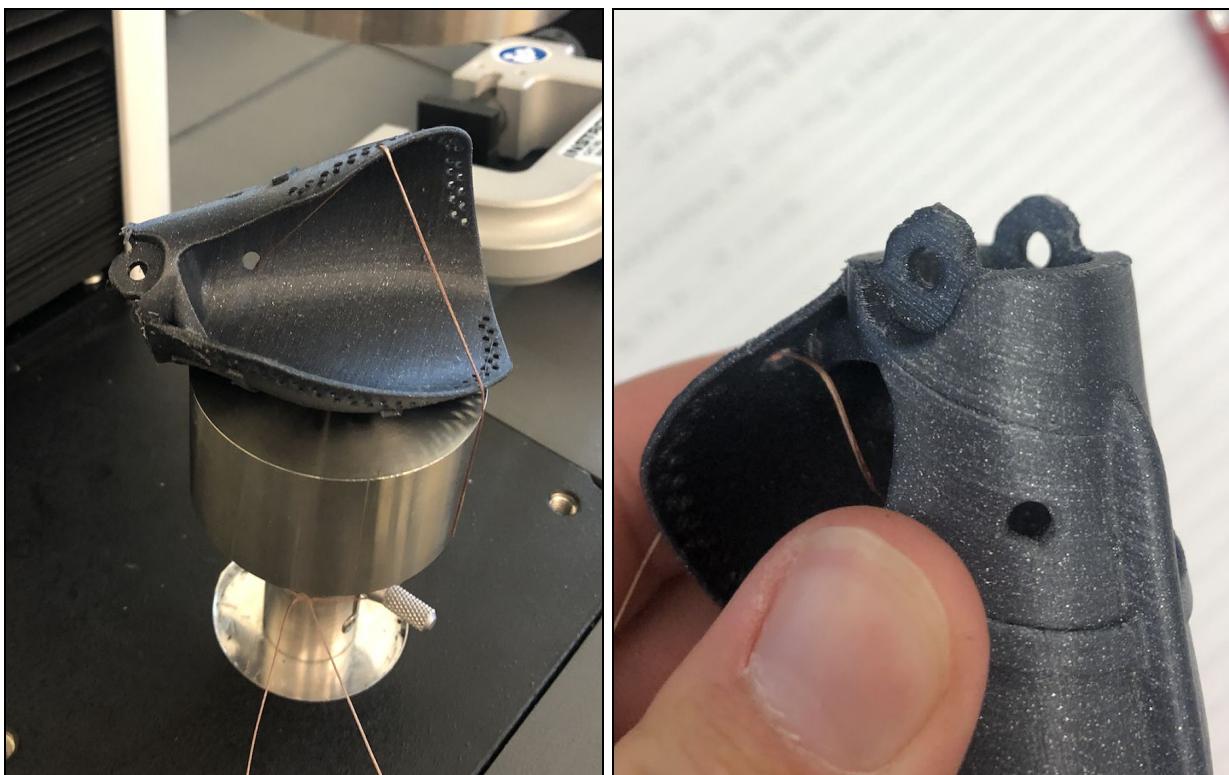


Figure 32 & 33. Proximal compression testing 02/20/20, orientation 1, attempt 3.

The proximal pieces were then tested in another direction; pressure from the upper compressive plate was applied to the outer portion of the proximal piece. They were also secured using extra fishing line, and tied securely to the bottom compressive plate. The first test was run, and the part failed at 70 N along the support material, as seen in Figure 35. The second test was run and the part failed at 170 N. As seen in Figure 37, the inner portion of part shattered. Finally, the third test was run, and the part had a minor crack at 47 N, another crack at 100 N, but still withstood compression until the load maxed out at 500 N.

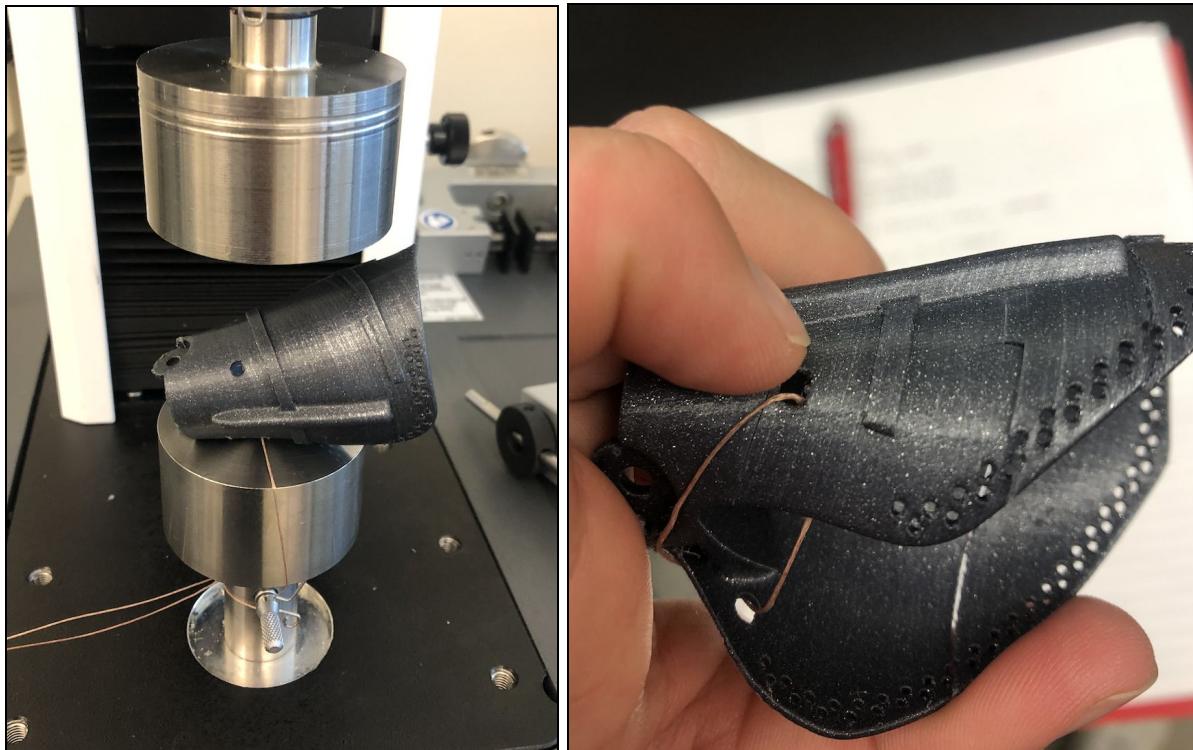


Figure 34 & 35. Proximal compression testing 02/20/20, orientation 2, attempt 1.



Figure 36 & 37. Proximal compression testing 02/20/20, orientation 2, attempt 2.



Figure 38 & 39. Proximal compression testing 02/20/20, orientation 2, attempt 3.

The next testing was conducted on the distal pieces. The distal pieces were connected with the internal cam inside. We wanted to test the distal pieces in two directions. The first compressive test was run with the distal piece laying on its side, and the load was set to 2 N in order to hold the part in place and prevent slipping. There were three trials of this test run, and all three tests passed. They withstood the maximum load the instron could give, of 500 N. All three parts can be

seen in Figure 41, and none had any defects. When we attempted to run the test in the second orientation (with the compressive plate putting pressure on the top of the distal piece), the parts slipped. We will need to retest the pieces once the set screws are able to hold the parts together.

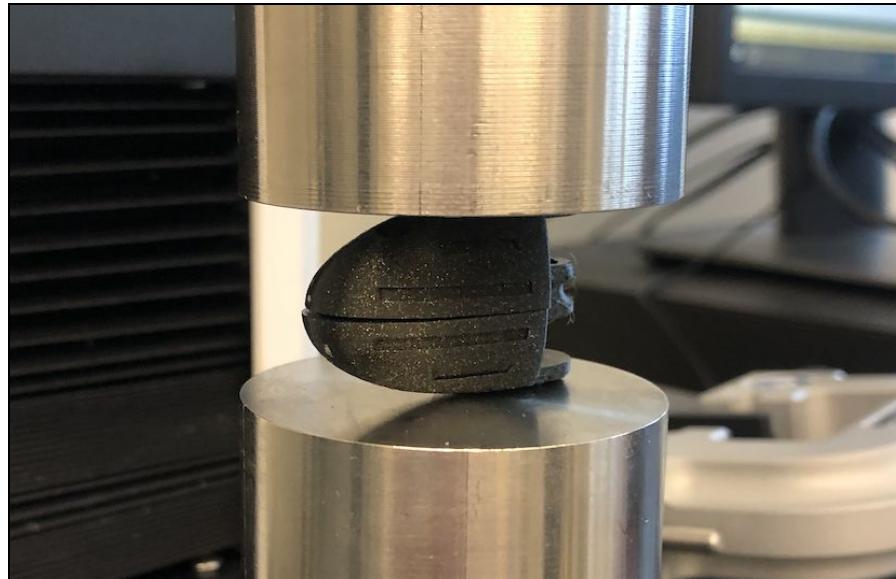


Figure 40. Distal compression testing 02/20/20, orientation 1.



Figure 41. Distal compression testing 02/20/20.

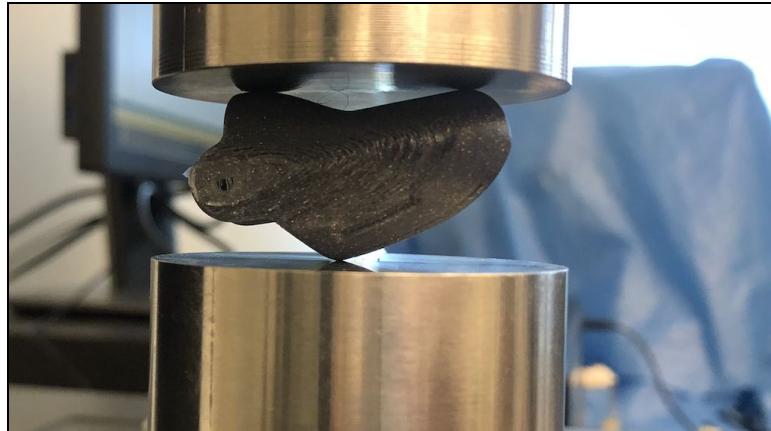


Figure 42. Distal compression testing 02/20/20, orientation 2, attempt 1.

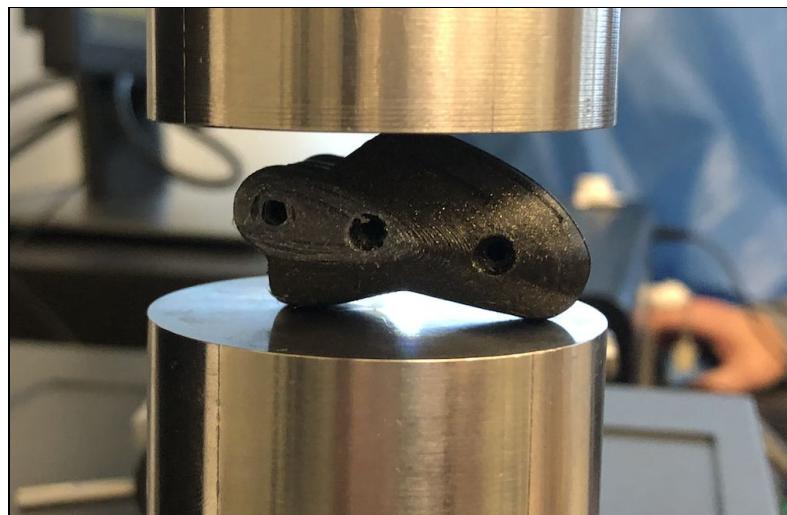


Figure 43. Distal compression testing 02/20/20, orientation 2, attempt 1.

The second round of distal compression testing was conducted on February 26, 2020 in 192-328 at 12:00 P.M.

The distal pieces were connected with two set screws and two screws with the internal cam inside. The orientation of the test can be seen below in Figure 44. The first test conducted failed, because the set screws came out of their internal holes. The test failed due to the internal components; the two distal parts were unharmed as seen in Figure 45. The second test made it to 500 N, but the part is deformed as seen in Figure 46 and 47. The set screws and screws stayed in tact. For the third test, the distal piece also withstood 500 N of force, but the part deformed and there were lots of cracks in the material, as seen in Figure 48 and 49. The set screws and screws stayed in tact; the part failed because of the material.



Figure 44 & 45. Distal compression testing 02/26/20, orientation 2, attempt 1.



Figure 46 & 47. Distal compression testing 02/26/20, orientation 2, attempt 2.



Figure 48 & 49. Distal compression testing 02/26/20, orientation 2, attempt 3.

17.21 Conclusion:

Proximal Pieces:

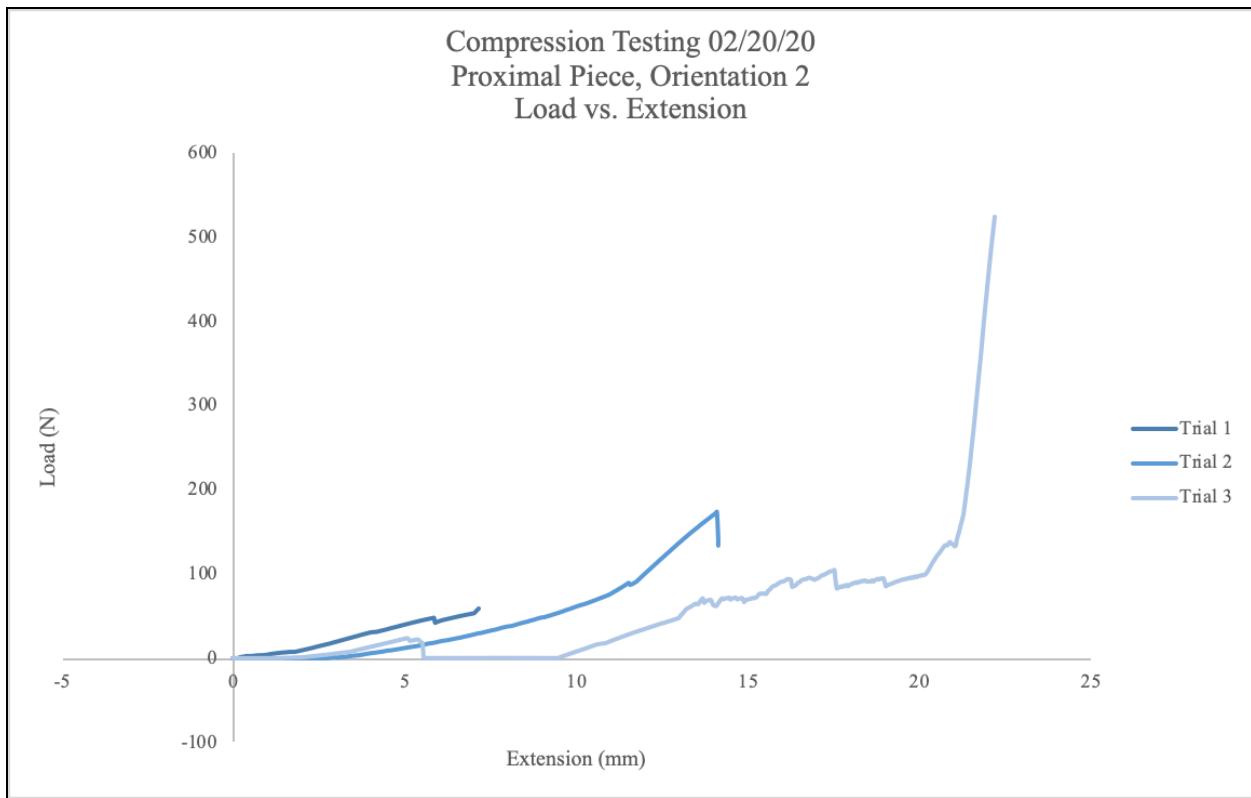


Figure 50. Proximal Compression Testing for Orientation 1, 02/20/20.

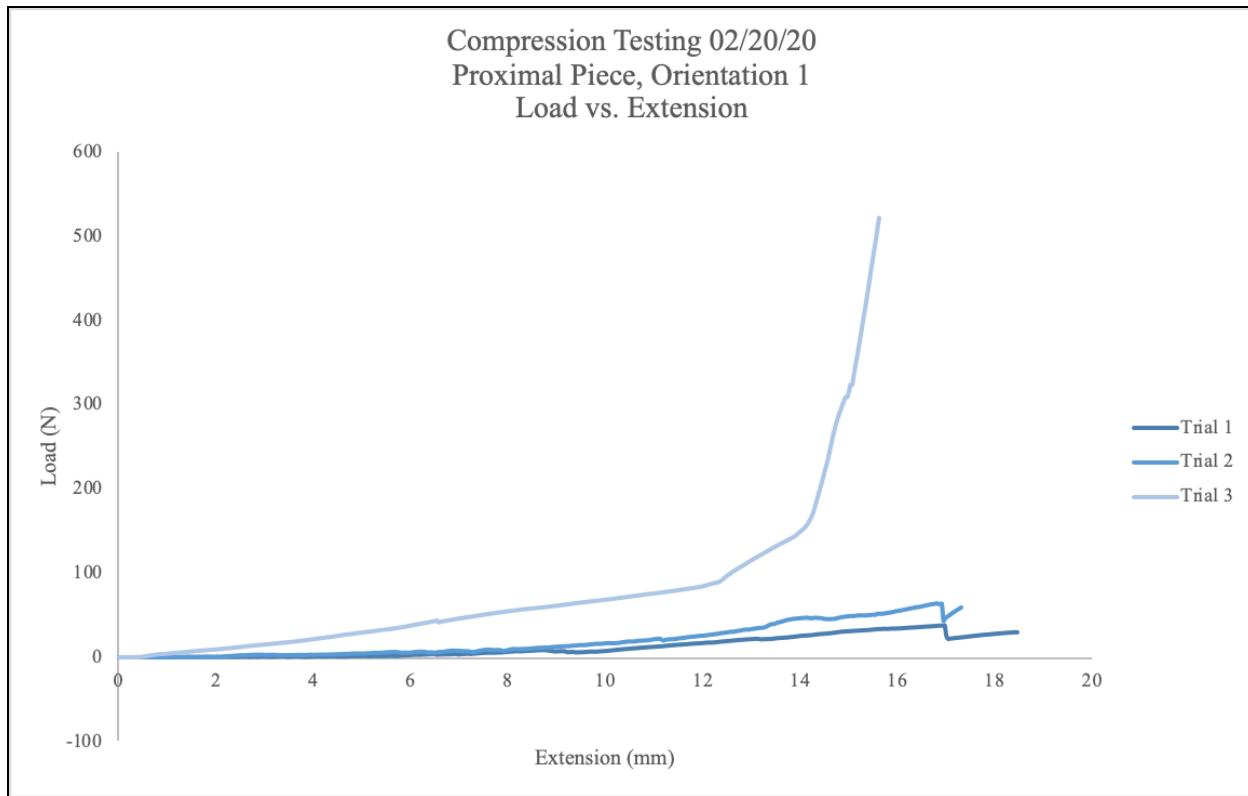


Figure 51. Proximal Compression Testing for Orientation 2, 02/20/20.

Proximal testing in orientation 1 and orientation 2 failed.

Each test had cracks either along the holes, or where the part internally loses thickness. The tests still were able to withstand a force of 500 N, so we are feeling confident that if we change materials so something slightly stronger, it would be able to still withstand that force, and possibly not crack. We also tested the pieces without anything supporting the inside of the prosthetic, which is unrealistic for when the patient is wearing it. In reality, the residual of the thumb will be supporting the prosthetic where the material gets thinner and cracked, so we do believe that the prosthetic when he is wearing it will be able to support a greater force without failing.

Distal Pieces:

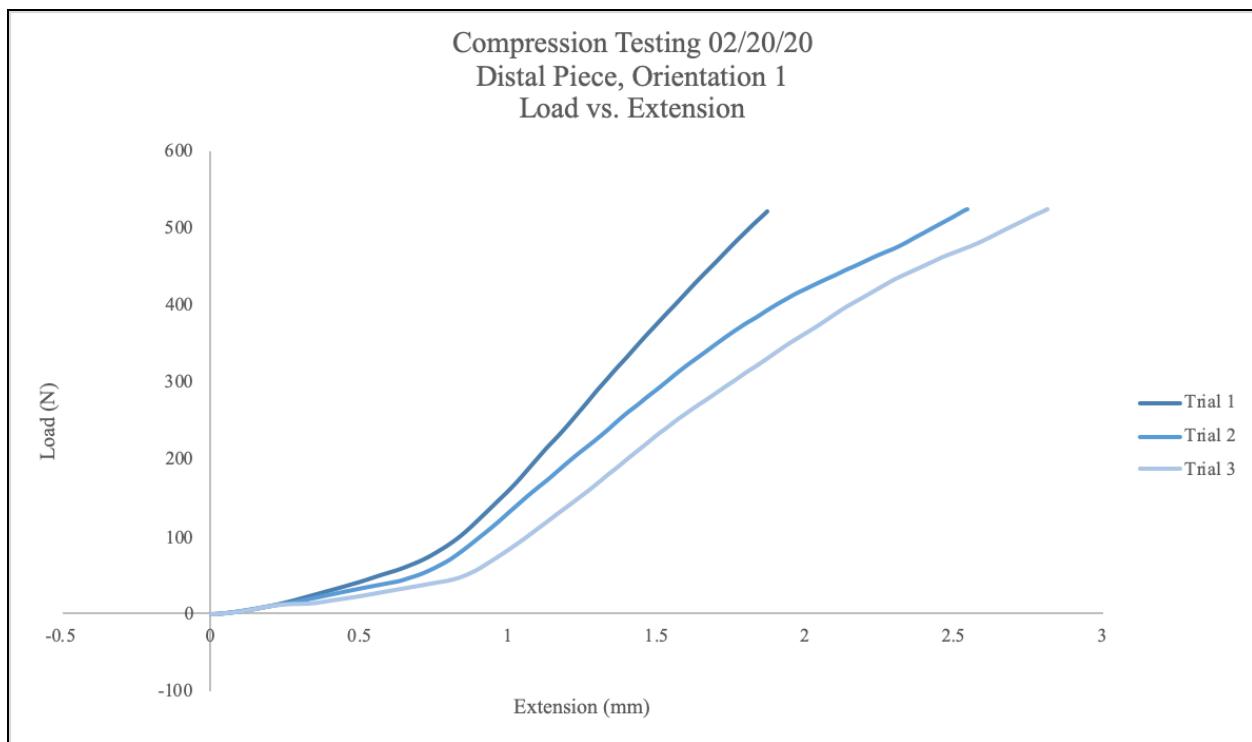


Figure 52. Distal Compression Testing for Orientation 1, 02/20/20.

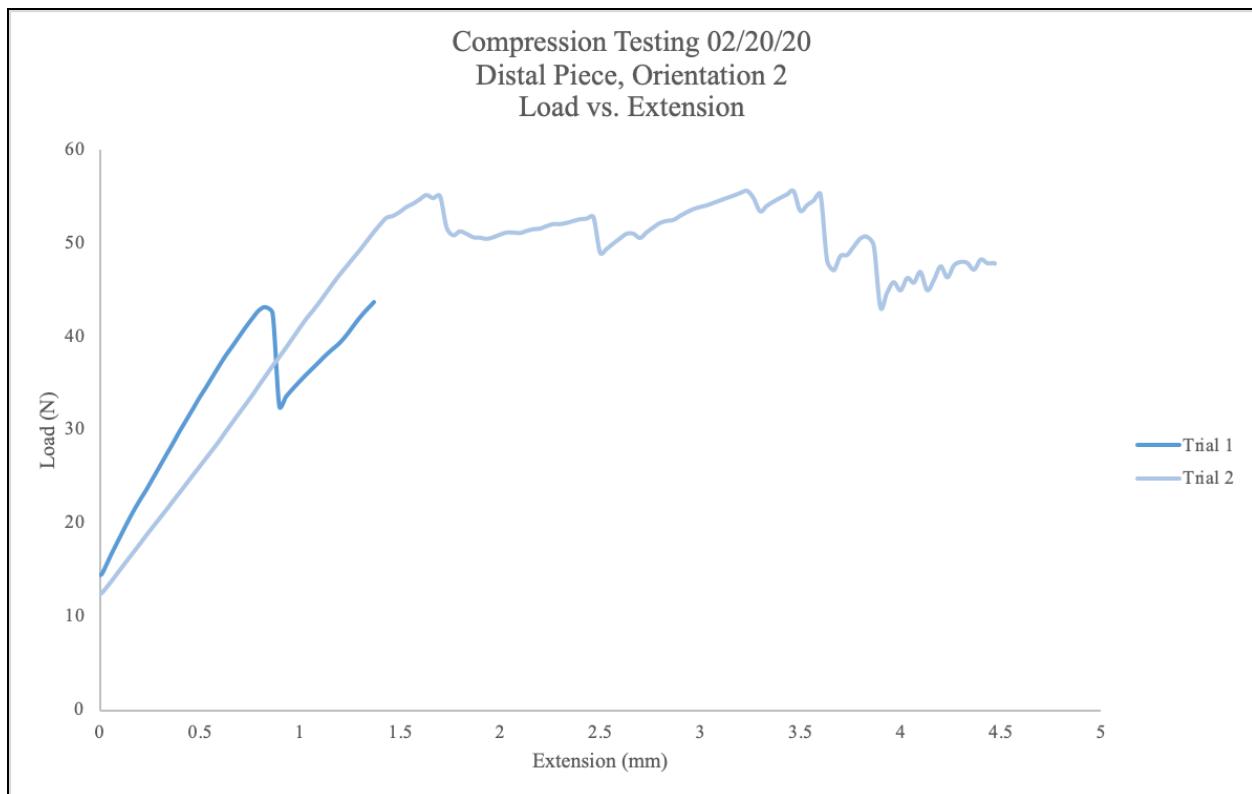


Figure 53. Distal Compression Testing for Orientation 2, 02/20/20.

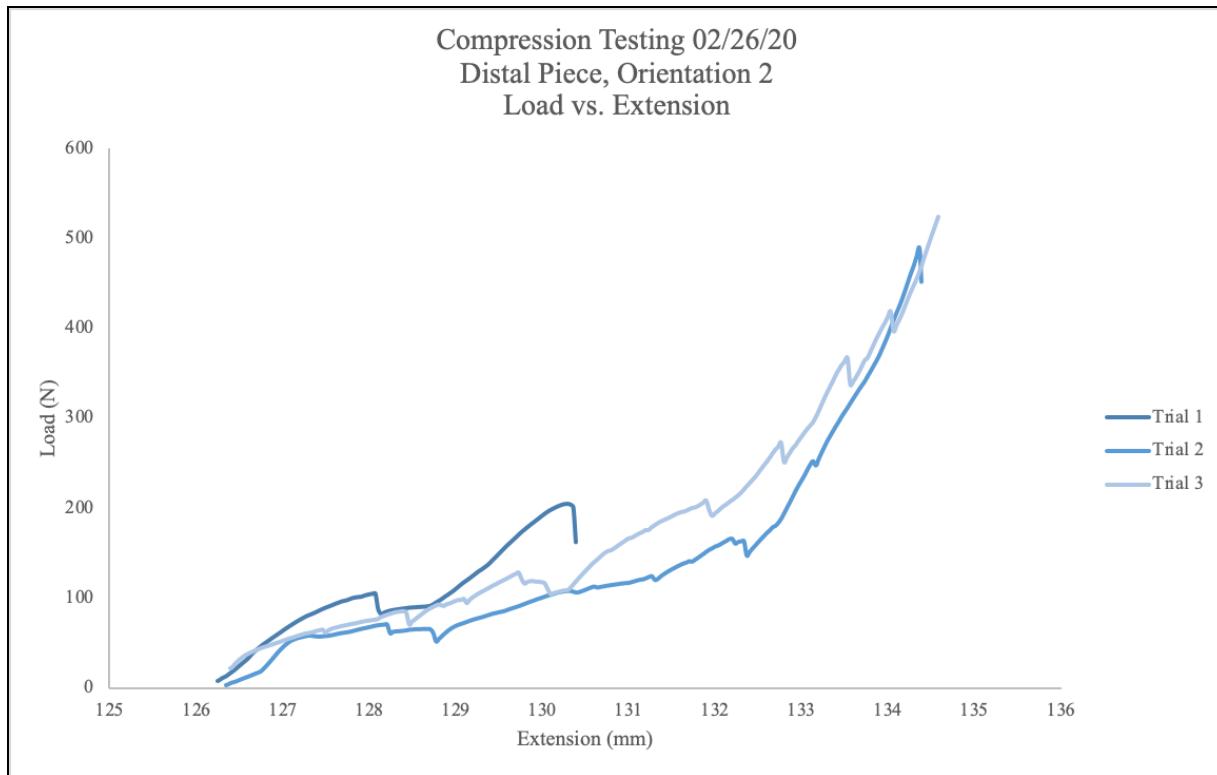


Figure 54. Distal Compression Testing for Orientation 2, 02/26/20

Distal testing in orientation 1 was a success and distal testing in orientation 2 failed.

Orientation 1 (force from the side) succeeded. The parts were able to withstand a force of 500 N without failing. There were no cracks noticeable, and the parts retained their structure as seen in Figure 41 above. Figure 52 represents the Load Vs. Extension for the distal pieces in orientation 1. It is seen that as the instron compression plates extended and the piece was compressed, there were no dips indicating any cracks in the material, and all three tests passed the test as they made it to 500 N.

Orientation 2 (force from the top) failed. In the first test, it was the internal components such as the set screw that caused the part to fail. The internal parts came out and so the distal piece was not intact and able to withstand 500 N. In the second and third test, the two halves of the distal piece and internal parts stayed intact, but the PLA material was cracked. Figure 54 shows numerous cracks that the second and third test experiences. There were numerous cracks (which are shown as dips in the graph), which can be seen in Figures 46 and 48.

The patient will most likely not experience a force of 500 N directly on the top of the distal piece, and so we were expecting the test to fail. We are planning on changing materials, and so we are hoping that next quarter the stronger 3D printed material will be able to withstand a higher force, without cracking.

17.3 Hyper-Extension Testing

Hyperextension testing was conducted on March 5, 2020 in the Aero Hangar at 12:30 P.M.

The test was conducted by attaching the 3D printed hand model to a block of wood, and securing the prosthetic assembly over top of the hand/wood. The hand was secured horizontally in soft jaws of a vice, as seen in Figure 55 and 56. A bucket (measured at 14.6 g) was secured to the prosthetic using extra of the fishing line, as seen in Figure 58. The bucket was secured along the axis of rotation between the proximal and distal pieces, and 16 oz of water were slowly poured into the bucket.

The part failed at 13 lbs (1 lb of the bucket, and 12 additions of 16 oz of water). The part failed due to a crack in the material. We were expecting the stitching holding the proximal piece to the glove, or the hinge to fail. However, we are reprinting our final product that we will deliver to our patient in a stronger material.



Figure 55. Prosthetic Secured to Hand Model.



Figure 56 & 57. Compression Testing Orientation.



Figure 58 & 59. Bucket Secured to Prosthetic.

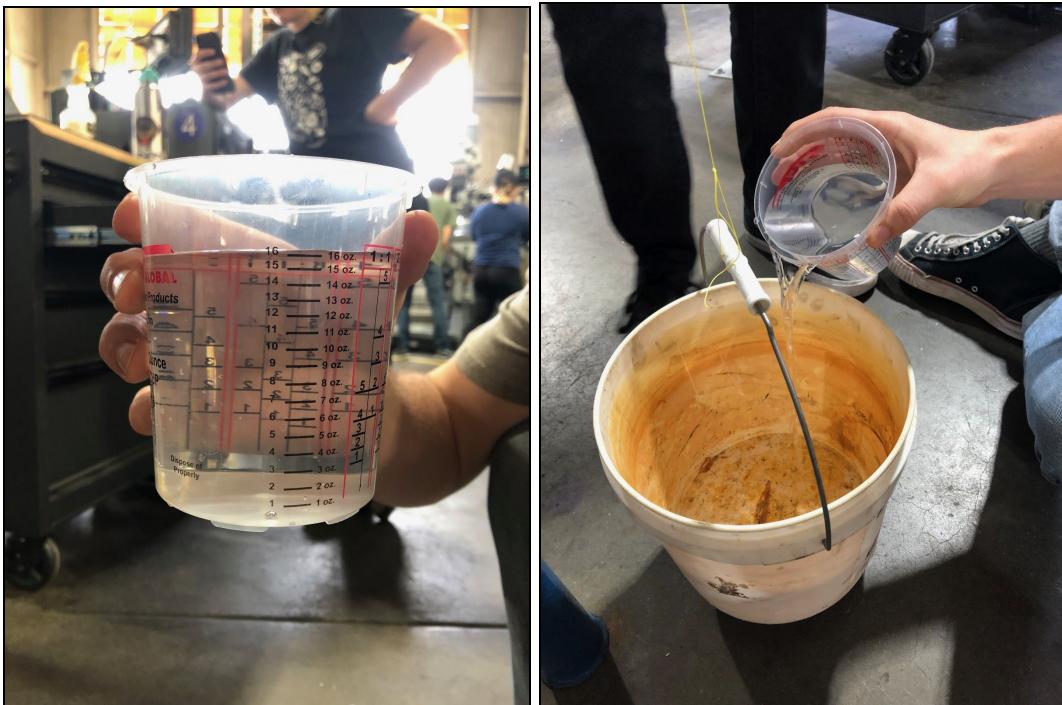


Figure 60 & 61. Tools for Testing.



Figure 62. Hyperextension Testing, 03/05/20.

17.31 Conclusion:

Hyper-extension testing failed. The proximal piece cracked due to the weight of the bucket and

water, as seen above in Figure 62. Due to the failure of the other tests, we anticipated that the material would also fail during the hyper-extension test. We are changing the material of our final product to carbon fiber, and therefore believe that the stronger 3D printed material will be able to withstand a greater force without cracking.

17.4 Water Testing

We have decided not to conduct the water testing. We are switching to the 3D printers at Cal Poly Pomona that can print with carbon fiber impregnated nylon. Therefore, there is no need to conduct a test to determine if PLA will withstand 30 minutes of a water bath.

18.0 Patient Fitting

On March 10, 2020, the Cal Poly SLO team met with Andrew and the patient in Oxnard, CA.

We performed an initial fitting of the prosthetic with the patient. He told us that the brace is comfortable, however when he attempted to lift items too heavy the entire brace would slip over the residual of the thumb and fall off. We determined the cause of this to be that the brace was too loose along the palm of the hand. After quickly sewing the top of the glove to make the fit tighter, the patient was able to grasp and lift items.

The distal phalanx bent forward as intended. When he propelled the residual of his thumb, the wire shortened, causing the distal phalanx to bend inwards, allowing him to grasp items. However, we noticed that the spring was too weak to propel the distal component back to the starting position after grasping the items. We will be implementing a design change to add another spring on the inside of the prosthetic to allow for that to happen.

Figures 63 and 64 below show how the prosthetic fits on the patient.



Figure 63. Initial Fitting, 03/10/20.



Figure 64. Initial Fitting, 03/10/20.

19.0 Conclusions

At the end of two quarters, we have successfully 3D printed and built a functional prosthetic thumb prototype for a Cal Poly Pomona student who lost his thumb in an industrial accident. The prosthetic meets the specifications he requested: it was cost effective, lightweight, body-powered and attached to the wrist comfortably. The patient had originally requested that we incorporate a way for him to continue weight lifting into the design. However, after discussing with the patient, we decided to first focus on a design that allowed him to regain basic functionality of his left.

After attempting to perform tensile testing, we had to determine that the test failed. We were unable to secure the fishing line to the Instron without the wire cutting on sharp edges, slipping from the tensile grips or having the knots come undone at a lower force than the wire was supposed to withstand. Because of that, we decided to replace the fishing line in our design with a sample of medical grade wire that Loo's and Company has donated to our group. They have also offered to provide us with their testing data, and upon receiving that information we will cross reference it to ensure that it can withstand the tensile force that we would like it to. We did not attempt to perform testing on the medical grade wire because we have only received a small sample of around three feet, and we did not have enough of the sample to both use for our prototype and use for tensile testing.

Compression testing also failed for the proximal pieces. They were unable to withstand a force of 500 N without cracking or severe deformation. Compression testing failed in vertical orientation for the distal piece, and passed for horizontal orientation. The hyper-extension test also failed. After the other two failed tests, this was expected and used as an opportunity to solidify a workable protocol for testing of future materials. Since all of these failures came from cracking of the PLA 3D printed material, we have decided to make a design change from the prototype to our final product of changing the print material to

carbon fiber impregnated nylon. This material is a much stronger material than PLA, and thus we are expecting after the design change that when we rerun testing in the spring quarter, the tests would all pass.

Due to the fact that Pomona is on a semester system, we will be continuing to work with Andrew on this final design next quarter, up until May. We will be completing user testing in April, and making any comfort changes for the patient (such as adding foam to the inside of the prosthetic where it rests upon the thumb residual if he experiences discomfort). All the design changes we stated above are going to be implemented after this quarter ends, and the final product will be given to the patient at the end of May.

20.0 Discussion

While five of our six testing methods did fail, we are taking those tests into account as we finalize our prototype into our final product that we will be presenting to our patient in May. Our prototypes main use was to test the feasibility of our design, and to determine whether or not the wire driven prosthetic option would work for our patient. The design did end up articulating as intended, as the wire shortens the proximal phalanx closes allowing the patient to grasp items.

The compression testing we performed on the proximal piece was tested without any internal support. In reality, when our patient is wearing the thumb and undergoing a compressive force in either direction, the residual of his thumb will be providing a counterforce. We do believe that in that instance, the PLA material would be able to withstand the force of 500 N without cracking. However, since our test failed for that part, and Cal Poly Pomona has access to a carbon fiber impregnated nylon 3D printer, we will be printing our final product with that. Carbon fiber is a much stronger material than PLA, and so we do expect it to be able to pass the tests that PLA failed.

By the end of May, we will have a completed product for our patient to receive and use until he decides to move forward with a real prosthetic company.

21.0 Appendix

Ally		Sahil		Cale	
Choose a Prosthetic Thumb Configuration		Concept 1		Concept 2	
Cost to Manufacture	20	1	0	20	1
Weight of Device	15	1	1	15	0
Reliability/Lifetime	15	0	1	15	1
Grip Strength	25	1	1	25	-1
Load Applied	25	1	0	25	1
Total	75	4	2	Total	2
Weighted Total	85	40	Weighted Total	85	25
Choose a Prosthetic Thumb Configuration		Concept 3		Concept 3	
Cost to Manufacture	20	1	1	20	0
Weight of Device	15	0	1	15	-1
Reliability/Lifetime	15	1	1	15	1
Grip Strength	25	1	1	25	0
Load Applied	25	1	0	25	1
Total	75	4	4	Total	2
Weighted Total	85	75	Weighted Total	30	25
Ally		Sahil		Cale	
Choose a Prosthetic Thumb Configuration		Concept 1		Concept 3	
Cost to Manufacture	20	1	1	20	-1
Weight of Device	15	0	1	15	1
Reliability/Lifetime	15	-1	0	15	-1
Grip Strength	25	1	1	25	1
Load Applied	25	1	0	25	-1
Total	75	0	1	Total	0
Weighted Total	15	20	Weighted Total	5	50
Ally		Sahil		Cale	
Choose a Prosthetic Thumb Configuration		Concept 1		Concept 3	
Cost to Manufacture	20	1	1	20	0
Weight of Device	15	0	1	15	-1
Reliability/Lifetime	15	-1	0	15	-1
Grip Strength	25	1	1	25	1
Load Applied	25	1	0	25	-1
Total	75	0	1	Total	0
Weighted Total	15	20	Weighted Total	5	50
Ally		Sahil		Cale	
Choose a Prosthetic Thumb Configuration		Concept 1		Concept 3	
Cost to Manufacture	20	0	1	20	1
Weight of Device	15	-1	0	15	-1
Reliability/Lifetime	15	-1	0	15	-1
Grip Strength	25	0	1	25	0
Load Applied	25	0	1	25	-1
Total	75	-2	2	Total	-1
Weighted Total	15	20	Weighted Total	-55	45
Ally		Sahil		Cale	
Choose a Prosthetic Thumb Configuration		Concept 2		Concept 1	
Cost to Manufacture	20	0	1	20	0
Weight of Device	15	-1	0	15	1
Reliability/Lifetime	15	-1	0	15	-1
Grip Strength	25	0	1	25	0
Load Applied	25	0	1	25	-1
Total	75	-2	2	Total	-1
Weighted Total	15	20	Weighted Total	-55	45

Figure 65. Completed Pugh Matrixes.

PURCHASE REQUEST

Department: BMED

Date: 11/17/2019

Name of Requestor Sahil Sharma

Cal Poly Email: ssharm11@calpoly.edu

Class & Project Title BMED 455 Prosthetic Thumb

Must be under \$2,500 / Submit electronically / Order will be placed by BMED office / All information is needed or order will not be placed / Double check your information for accuracy / All orders will be delivered to 13-260

Vendor (website, phone, or fax)	Product & Part Number (copy & paste the exact product title, include all text, and product or ASIN #)	Product Hyper Link	Qty	Price/Ea	Total
fabric.com	Perfo-Tek High-Performance Moisture Management Jersey Knit White Fabric; 0621596	https://www.fabric.com/buy/0621596	2 Yards	\$13.75 /yard	\$27.50
Amazon	eBoot Black Elastic Spool (1.5 Inch x 11 Yard); B01DXRG7JO	https://www.amazon.com/eBoot-Bl	1	\$7.99	\$7.99
Amazon	eBoot Black Elastic Spool (1 Inch x 11 Yard); B07CQNXH54	https://www.amazon.com/eBoot-Bl	1	\$7.99	\$7.99
Amazon	eBoot Black Elastic Spool (0.75 Inch x 11 Yard); B07G86CFJX	https://www.amazon.com/eBoot-Bl	1	\$7.99	\$7.99
Amazon	Dritz 48 Ball Point Hand Needles, Size 5/10 (10-Count); B005573G3Q	https://www.amazon.com/Hand%20	1	\$6.38	\$6.38
Amazon	Coats Eloflex Stretch Thread 225Yd-Black; B074N5CMPG	https://www.amazon.com/Coats-S9	1	\$5.11	\$5.11

TOTAL **\$62.96**

Special Instructions:	N/A
Deliver to:	(BMED office will make every effort to deliver to your lab)

Figure 66. Purchase Requisition Form (11/17/2019).

PURCHASE REQUEST

Department: BMED Date: 1/9/2020

Name of Requestor Sahil Sharma Cal Poly Email: ssharm11@calpoly.edu

Class & Project Title BMED 455 Prosthetic Thumb

Must be under \$2,500 / Submit electronically / Order will be placed by BMED office / All information is needed or order will not be placed / Double check your information for accuracy / All orders will be delivered to 13-260

Vendor (website, phone, or fax)	Product & Part Number (copy & paste the exact product title, include all text, and product or ASIN #)	Product Hyper Link	Qty	Price/Ea	Total
McMaster-Carr	Button Head Torx Screws 18-8 Stainless Steel, M2 x 0.4mm Thread, 5mm Long Part number: 90910A921	https://www.mcmaster.com/90910a921	1	\$11.60	\$11.60
McMaster-Carr	316 Stainless Steel Ring Shim 0.001" Thick, 1/8" ID Part number: 97022A864	https://www.mcmaster.com/97022a864	2	\$9.09	\$18.18
McMaster-Carr	18-8 Stainless Steel Dowel Pin Stock 1/8" Diameter Part number: 95609A310	https://www.mcmaster.com/95609a310	1	\$12.31	\$12.31
McMaster-Carr	TIN Coated High-Speed Steel Tap Set, M2 x 0.4 mm Thread Part number: 26475A11	https://www.mcmaster.com/26475a11	1	\$57.81	\$57.81
McMaster-Carr	Screwdriver T6 Torx Part number: 5756A32	https://www.mcmaster.com/5756a32	1	\$6.25	\$6.25
McMaster-Carr	302 Stainless Steel Torsion Spring 180 Degree Right-Hand Wound, 0.249" OD, for 0.14" Maximum Shaft Diameter Part number: 9287K22	https://www.mcmaster.com/9287k22	5	\$3.71	\$18.55
McMaster-Carr	Narrow Fillister Head Slotted Screw 18-8 Stainless Steel, High-Profile, 2-56 Thread, 1/2" Long Part number: 91794A081	https://www.mcmaster.com/91794a081	1	\$5.31	\$5.31
McMaster-Carr	Short-Length Drill Bit 1.6mm Size, 33mm Overall Length Part number: 2979N13	https://www.mcmaster.com/2979n13	2	\$3.81	\$7.62
McMaster-Carr	Tap Wrench with Fixed Straight Handle, 5" Long Part number: 2546A12	https://www.mcmaster.com/2546a12	1	\$46.24	\$46.24
McMaster-Carr	Plastic Box with 12 Compartments, 10-3/4" x 6-1/2" x 1-7/8", Clear Part number:	https://www.mcmaster.com/catalog/125/1817	1	\$8.84	\$8.84
McMaster-Carr	Delrin® Acetal Resin Balls 5/8" Diameter	https://www.mcmaster.com/9614k6	1	\$11.00	\$11.00
McMaster-Carr	18-8 Stainless Steel Screw-to-Expand Insert for Plastic 2-56 Thread Size Part number: 92394A111	https://www.mcmaster.com/92394a111	2	\$10.14	\$20.28

TOTAL \$223.99

Special Instructions:	N/A
Deliver to:	(BMED office will make every effort to deliver to your lab)

Figure 67. Purchase Requisition Form (01/09/2020).

PURCHASE REQUEST

Department: BMED Date: 1/21/2020

Date: 1/21/2020

Name of Requestor: Sahil Sharma Cal Poly Email: ssharm11@calpoly.edu

Cal Poly Email: ssharm11@calpoly.edu

Class & Project Title BMED 456 Prosthetic Thumb

Must be under \$2,500 / Submit electronically / Order will be placed by BMED office / All information is needed or order will not be placed / Double check your information for accuracy / All orders will be delivered to 13-260

TOTAL \$24.12

Special Instructions:	N/A
Deliver to:	(BMED office will make every effort to deliver to your lab)

Figure 68. Purchase Requisition Form (01/21/2020).

Table 13. Design Hazard Checklist

Team: Prosthetic Thumb	Sponsor: Dr. Mehrdad Haghi
Y/N	
Y	1. Will any part of the design create hazardous revolving, reciprocating, running, shearing, punching, pressing, squeezing, drawing, cutting, rolling, mixing or similar action, including pinch points and sheer points?
N	2. Can any part of the design undergo high accelerations/decelerations?
N	3. Will the system have any large moving masses or large forces?
N	4. Will the system produce a projectile?
N	5. Would it be possible for the system to fall under gravity creating injury?
N	6. Will a user be exposed to overhanging weights as part of the design?
N	7. Will the system have any sharp edges?
N	8. Will any part of the electrical systems not be grounded?
N	9. Will there be any large batteries or electrical voltage in the system above 40 V?
N	10. Will there be any stored energy in the system such as batteries, flywheels, hanging weights or pressurized fluids?
N	11. Will there be any explosive or flammable liquids, gases, or dust fuel as part of the system?
Y	12. Will the user of the design be required to exert any abnormal effort or physical posture during the use of the design?
N	13. Will there be any materials known to be hazardous to humans involved in either the design or the manufacturing of the design?
N	14. Can the system generate high levels of noise?
Y	15. Will the device/system be exposed to extreme environmental conditions such as fog, humidity, cold, high temperatures, etc?
Y	16. Is it possible for the system to be used in an unsafe manner?
N	17. Will there be any other potential hazards not listed above? If yes, please explain in Table 14.

Table 14. Design Hazard Corrective Actions.

For any "Y" responses, add (1) a complete description, (2) a list of corrective actions to be taken, and (3) date to be completed on the reverse side.		
Description of Hazard	Planned Corrective Action	Planned Date
1. The user will experience pinch points and/or irritation of the skin where the prosthetic meets the residual of the thumb.	We are researching medical grade foam that we plan on lining the distal piece with to provide comfort for the user when he starts to experience pain from the contact points of the prosthetic.	02/20/20
12. The user will be required to exert more effort to use the device than he is normally doing.	We will have to teach the user how to use the device, and make sure he understands that this is a learning process and he will have to continue to practice using the prosthetic until it becomes a natural movement.	03/06/20
15. The user will most likely be wearing the device in all weather conditions. It is possible that extreme weather conditions could diminish the strength or tarnish the appearance of the product.	PLA is a material that absorbs water, and thus can start to break down. We will be coating the prosthetic in a high performance coating to protect the PLA from undergoing damage with water absorption. We will be testing whether the coating works by placing the prosthetic in a bowl of water for 10 minutes, taking it out and letting it dry, then testing the strength.	Coating: 02/20/20 Testing: 02/26/20
16. It is possible for the prosthetic to be used in an unsafe manner. If the user uses it to lift extremely heavy objects (or weighlift) using the prosthetic, there is a strong possibility that the linkages or wire will not be able to withstand the force and fail, causing a minor or severe injury to the patient.	We will test the chosen material to determine the maximum weight the user can use before the prosthetic will fail. We will test this using the material of the prosthetic, the linkages between the proximal and distal pieces, and finally the strength of the wire. We will incorporate a high factor of safety. Once this value is determined, we will inform the user not to go over this value due to the possibility of failure and injury.	02/30/20

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