Prosthetic Hand

Final Report

BME 400

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Abstract

A low income, uninsured individual suffered from a severe infection in their dominant hand, which resulted in the amputation of the thumb, index finger, middle finger, and the medial side of the palm. The ring finger lost all function, and the pinky finger has only 10 degrees of flexion. The individual can not complete simple tasks such as picking up or holding everyday items. The individual lacks dexterity and strength in their dominant hand, which has caused difficulty in finding a job. Prosthetic devices that are currently on the market are too expensive for this individual to buy. In response to this problem, a low-cost, operational prosthetic controlled by wrist flexion was designed, developed, and built. It works to oppose the currently functioning pinky finger to increase hand function for this individual. The prosthetic has proven success in picking up and holding small objects such as holding a phone. Creating a low-cost, functional prosthetic device was a challenge. Various design approaches were considered and evaluated before choosing a bionic prosthetic thumb option. This option was best suited for the specifications the patient requested.

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Introduction

Motivation

The motivation behind this project is to help improve the life of an uninsured individual who lost part of his dominant hand from an infection. Building a functional prosthetic for him will allow him to return to work and regain hand functionality in his life. Additionally, there is a gap in the market for affordable and functional prosthetics. A customizable, functional prosthetic controlled by wrist flexion fits that need. To provide a prosthetic for a man who lost part of his dominant hand is enough motivation, however to create an inexpensive option for many people in this situation offers even more motivation.

Current Methods

Currently, the patient is using a simple, custom fitted, thermoplastic piece attached with elastic around his hand. Its primary function is to oppose his functional pinky, giving him some rudimentary ability to pick up very light objects. This design is very limited by the ability of the elastic to grip the hand and the strength of the thermoplastic. It is not a very robust or viable long-term solution. A pen can be attached to it with rubber bands, but that doesn't allow for a lot of strength or control when writing.

Figure 1: Current prosthetic designed by OT. The device provides a minimal opposing force for the patient to use when gripping things.

Figure 2: Prosthetic currently used for writing.

Problem Statement

The patient is a low-income individual who has suffered a severe infection, resulting in the loss of his thumb, index finger, and middle finger, the medial part of his palm in his right (dominant) hand. The ring finger is immobile, while the pinky can bend up to an angle of 10 degrees. His wrist can bend 20 to 30 degrees from the neutral position. The skin spanning from his palm to ⅔ way up his forearm received an allograft. Superficial nerve function in this area is lost, resulting in hypoesthesia. There is sensitivity and pain at the locations of the lost digits, so contact should be avoided at these points. The patient is unable to complete simple tasks that require substantial weight bearing or dexterity, resulting in an inability to perform required tasks at a job or even daily living. To help the patient, a functional, long-term thumb prosthetic is designed, allowing a counter force for the pinky of up to 17N [2]. It must also provide a way to hold smaller items, such as a writing utensil, and assist in writing among other fine motor functions.

Background

Prosthetics Considerations

Amputations are a common occurrence in the United States with between 500,000 and 100,000 limb amputations (including trans-carpal amputations) occurring per year [12]. As of 2008 approximately 1.7 million people in the United States are amputees and of those people an estimated 500,000 have minor upper limb amputation, defined as amputation at the fingers, the hand, or the forearm distal to the elbow [13].

The US census reports that in 2019 8.0% of people were uninsured for the entire year, however this does not give an accurate understanding of how many people are uninsured at any given point in time [14]. The CDC reported that at the time of an interview in 2019 14.7% of people aged 18-64 were uninsured [15]. The percentage of uninsured 18-64 age people has been increasing again since 2016, showing a peak in 2019 [16].

A body-powered hand prosthetic costs from $4,000 to $20,000, and a myoelectric prosthetic can cost between $25,000 and $75,000 which also does not account for the medical bills that come with some of the most common ways someone becomes an amputee: trauma, vascular disease, infection, etc. [17][18][12]. With the population of amputees in the United states rising, and the percentage of insured people declining, a more affordable prosthetic option is needed [13].

Biology and Physiology

The hand and wrist work in tandem to complete an astounding array of functions in daily life. They are a very complex system of bones, muscles, tendons, and skin. The bones are the underlying structure of the hand, wrist, and forearm. Through a series of insertion points, muscles and tendons attach to different bones to cause coordinated movements. The wrist generally rotates in an ellipse, but there are many small movements between the numerous wrist bones that also aid in movement [19]. The flexor carpi ulnaris inserts at the 5th metacarpal, and the flexor carpi radialis inserts at the base of the second and third metacarpals. Both originate from the humorous, and act to flex the wrist [20] The pads of the fingers are exceptional at gripping and holding onto objects. There is a layer of fat underneath the sensitive skin of the fingers. This provides padding and small deformations of the skin that aid in holding or gripping. The skin cannot be loose, or objects would slip out of a grasp. To counter this, there is connective tissue that keeps the skin in place [21].

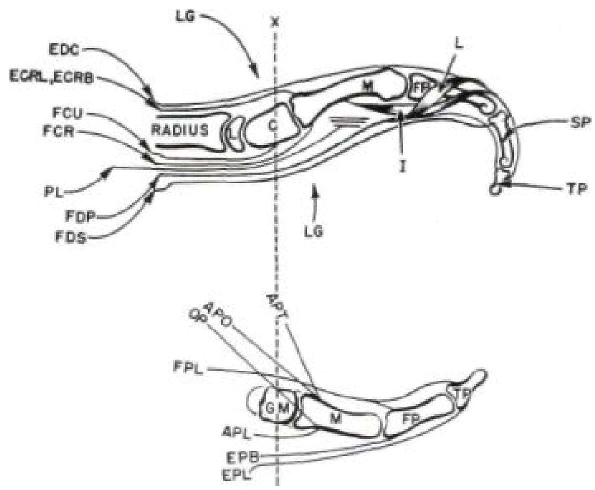


Figure 3: A cross section of the hand shows how various muscles are inserted and connected [24].

The innervation of the integument allows fine touch reception, pain and temperature reception, as well as deep touch sensation. This allows humans to sense their surroundings and respond to them.For this humans have many kinds of reception including: tactile receptors (fine touch and low frequency vibrations), Bulbous corpuscles (continuous deep pressure), lamellated corpuscles (deep pressure and high frequency vibrations), and free nerve endings (pain and temperature). These are all located in different layers of the integument. The most superficial layer is the epidermis, which itself is subdivided into 4 layers on an area like the arm, but 5 for thick, glabrous skin on areas such as on the palms of the hands. The deepest layer of the epidermis, and the layer in which innervation begins is the stratum basale. After the epidermis is the dermis, containing the papillary layer (more superficial), and the reticular layer. The last layer of the integument is the hypodermis or subcutaneous layer. Which mostly functions to connect the skin, bones, and muscles. This layer also functions to store fat and acts as cushioning.

Tactile cells are found in the stratum basale, tactile discs in the epidermal-dermal junction, and tactile corpuscles in the papillary dermis. Free nerve endings are scattered throughout the stratum basale and papillary dermis. Bulbous corpuscles are found throughout the dermis, and Ruffini corpuscles are in the reticular layer of the dermis and in the hypodermis. Keeping the light touch receptors and the free nerve endings more superficial is important because the body can respond more quickly to changes in temperature, and it allows better sensation of fine touch. However, the more superficial layers are less vascularized, thus if being in a superficial layer is less important to function, the receptors will be in deeper layers.

Since the patient has experienced damage to the integument, specifically the epidermis, minding the friction caused by and load distribution of the device is very important. In order to prevent rubbing and unintentional blistering of skin that has diminished tactile sensation the design incorporates a sleeve to go underneath the cuff. This design was to keep the cuff from rubbing against the patient's skin and causing abrasion. Additionally with reduced sensation load distribution was considered it influenced the use of a linear motor, the motor design coupled with the angle used allowed for a natural distributed load. To add to the even load distribution it was ensured that the cuff itself was modeled to the dimensions of the patient’s wrist, and a thermomold of the forearm was done to allow for an even distribution.

Safety

Safety concerns for this project need to be addressed for general prosthetic use, and also considered for the patient's individual needs. The final design needs to incorporate considerations that minimize safety risks. The first general prosthetic consideration is avoiding socket discomfort, and this can be achieved by creating a device that uses padding for comfort and a tight mechanism of attachment for proper fitting. Another important consideration is reducing sharp corners or areas of high pressure from the weight of the prosthetic. Distributing the weight of the prosthetic device over an area of the hand and forearm is necessary as a function and comfort consideration, but most importantly the design needs to avoid cutting off circulation to the hand. A well fitted prosthetic designed to distribute the load of the device evenly will achieve this.

The patient also has safety considerations associated with his specific injury. There is pain to the touch at the location of his finger amputation, so the final device must avoid any touching or rubbing onto this area. Further, the patient has a skin graft as a result of his injury. The skin graft is located at the wrist up the forearm, leaving him with almost no sensation with touch in this area. The loss of feeling at his forearm has potentially dangerous consequences; if a prosthetic causes irritation to this area he would not be able to feel it. Thus safety has been kept as a top priority throughout fabrication and testing of the prototype.

Other Concerns

Because the patient speaks Spanish and is not able to communicate in English, issues may occur when ensuring the client gets his desired features out of the design. Looking forward, this language barrier will make patient meetings and prototype testing more difficult. Communication with the patient is of utmost importance so being mindful of a language barrier will improve the communication that occurs.

Competing Designs

There are devices on the market that would work for the patient, but they are expensive or ineffective due to his remaining anatomy. In terms of finances, the patient is unable to afford more technologically advanced solutions from bigger companies. One cheaper solution for the patient would be a prosthetic from the company, e-NABLE, shown in Figure 4 [27]. This prosthetic is intended for users who have lost all digits on their hand. Due to the patient's remaining two fingers, it makes this solution much more complex. In addition, the patient has only 20 to 30 degrees of flexion at the wrist, making this design impractical because it requires strong flexion at the wrist to bend the fingers and grasp objects using a pulling mechanism with cords. The cords that run from the tips of the prosthetic fingers and are attached at the wrist of the prosthetic. Strong force must be applied to flex the wrist, which increases the distance the cords travel from wrist to fingertip. The cords are inextensible, so prosthetic fingers must bend to accommodate the increased distance the cords need to span. The further the wrist is flexed and the more force used to do so causes a stronger and more complete flexion of the prosthetic fingers. The patient also has sensitivity at the area where the amputations occurred that results in pain whenever the area is touched. This adds an additional layer of complexity when considering the generic budget options currently on the market. Another option available to the patient are simple 3D printed cosmetic designs, shown in Figure 5. This design provides no functionality, making this an impractical solution for the patient.

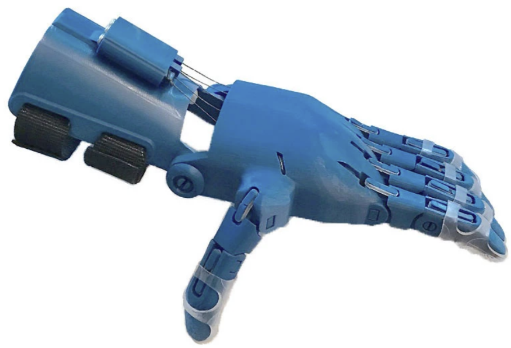


Figure 4: e-NABLE mechanical prosthetic [27].

Figure 5: Cosmetic design.

Client Information

The patient had an amputation of necrotic thumb, index, and middle fingers, and a portion of the palm resulting from a severe infection. Twelve surgeries were needed to preserve what is left at the hand. The ring finger is non-functional and acts only as an appendage. The pinky finger has approximately ten degrees of flexion at the metacarpophalangeal joint and is able to hold 2.5 kg. This number was found by the patient's occupational therapist loading the patient's pinky finger to its max force. The prosthetic works in opposition to the pinky, so it would not be beneficial if the thumb applied more force than the pinky can hold. The patient has a range of motion at the wrist limited to 10-15° of flexion and 10-15° of extension. The patient experiences pain at the location where the index and middle fingers were removed. A skin graft extends proximally from the palm to ⅔ of the way up the forearm (see: Fig. 6). The patient has lost most superficial sensation on the areas covered by graft.

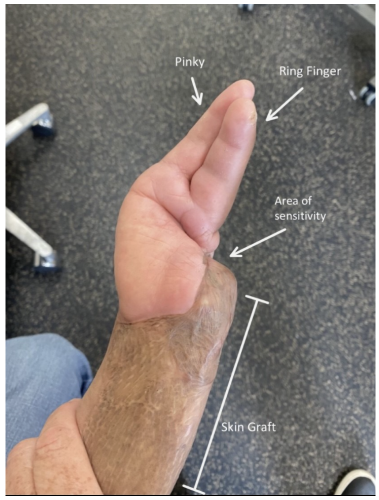


Figure 6: supine view of the affected right (dominant) hand.

<u>Design Specifications</u>

According to the client and patient, the prosthetic must provide the patient with basic functionality to help him regain some independence in his daily life. This means the device must include a thumb that will work in opposition to the existing pinky finger. The device must be able to stabilize and hold objects that range in size from 1-10 cm. The user must be able to lift and hold objects up to 1.8 kg [2]. This should be consistent in both a pincer grasp and loaded normal to the line of the forearm. The prosthetic device needs to be stable enough for the opposing force of the functioning pinky to push against without moving, allowing the user to perform fine motor skills, such as writing and drawing. Due to the residual tissue damage at the patient's hand and lower forearm, the device must allow for comfortable extended daily wear. To ensure the patient is able to get back into the workforce, the device must allow him to perform skills necessary for employment on an assembly line, such as picking up and relocating objects within the design parameters of 1-10 cm and 1.8 kg. The design will also have to allow for future modifications based on specific work tasks desired. Finally, due to the patient's low income and unemployed status, the device must have minimal cost in order to be accessible to him and other low income or uninsured amputees.

Figure 7: Supine view of 3D scan of the affected right (dominant) hand.

Preliminary Designs

Design 1 - Cosmetic

Figure 8: Example of a cosmetic silicone hand mold (on the right) intended to blend seamlessly with the natural hand (on the left) [25].

The cosmetic design was created with cosmesis at the forefront of importance. This design would focus on materials and details that blended in seamlessly with the user's natural hand. Therefore silicone would be used for the majority of the device and details would be added with paint or artificial hair. In addition to cosmetics, this design would be extremely comfortable for the user, as their natural hand is only in contact with the flexible silicone material. With the specific patient's specific injury and needs in mind, the design would have to consist of the thumb, index, and middle finger. Considering the sensitivity the patient has where the original fingers were removed, the design would have to avoid contact with this area, and add padding around the area. This would mean forcing the resting points to be elsewhere on the patient's hand and create a gap to avoid contact at this point.

Design 2 - Mechanical

Figure 9: CAD model of the mechanical design intended to provide more functionality.

The mechanical design takes a similar approach as the competing design from e-NABLE. However, this design is more effective for the patient because it allows for the user to have pre-existing digits. The competing e-NABLE design requires the user to have no fingers, so this is not a feasible option for the patient. This design functions when the user bends their wrist. Wrist flexion causes the finger(s) to close by pulling on a chord that is attached at the wrist on one end and the finger on the other (see Figure 10). This design would be easily fabricated through 3D printing. The device would be attached at the wrist with a sturdy cuff to counteract the force when bending the wrist. Which will be padded with a sleeve to go underneath the cuff and prevent abrasion.

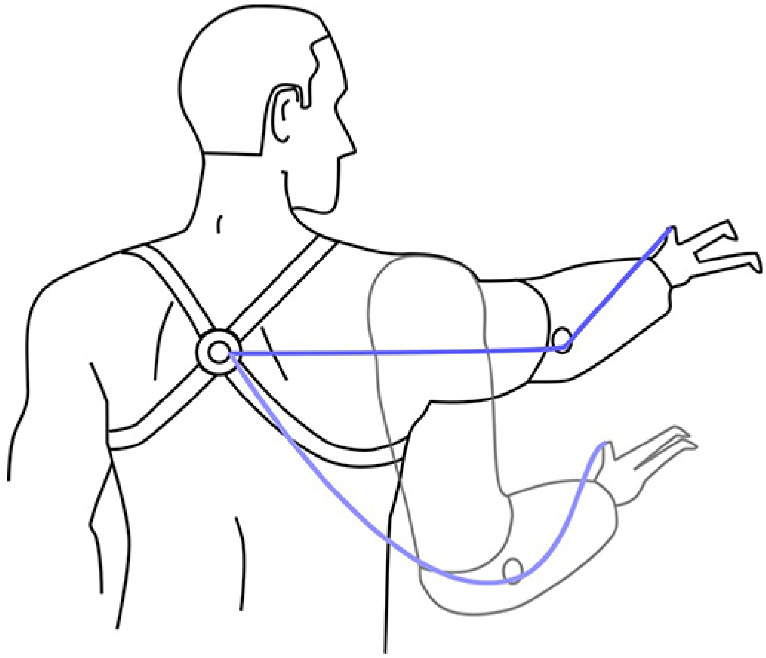


Figure 10: Example of a body-powered upper limb prosthesis. In this instance when the elbow is in extension a tension force is produced on the cord causing the device to extend [26].

Design 3 - Bionic

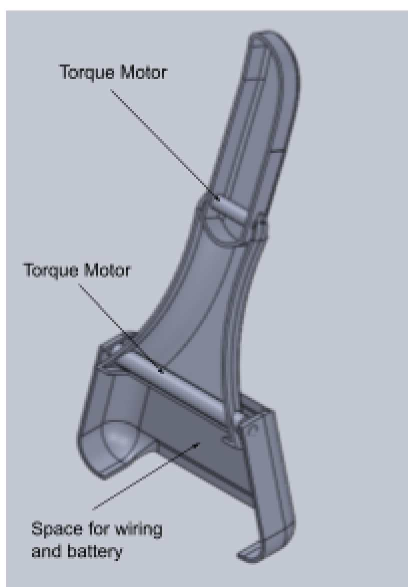


Figure 11: Example of a bionic addition to provide better functionality.

The bionic design utilizes EMG sensor electrodes attached on the skin of the forearm. These sensors read electrical signals emitted by the muscles in the user's forearm. These signals are then read by a microcontroller and translated into movement of the fingers. Because the patient experienced an infection that went up part of his forearm, the EMG signals will likely have to be rectified, amplified, and conditioned (filtered) satisfactory output to drive the torque motors if they are to generate sufficient grip.

Three EMG sensors will be used to sense the muscle activity in the patient's arm. One negative, one positive, and one grounded. The positive and negative electrodes will be placed in the middle and at the insertion of the flexor carpi ulnaris. For consistency of electrode placement, the same forearm will be used; the middle will be measured as exactly halfway between the origin and insertion of the muscle. The ground electrode will be placed on an adjacent bony prominence to ground the signal. The signal will then be passed through a differential amplifier. This is what will allow the signal to be amplified. Then the signal will pass through a band pass filter. These are simple filters that use resistors in order to only use signals within a specified range. This will lessen the noise of the signal. Expected signal range from the muscle is between 50 and 150 Hertz [22]. Anything out of this range will be filtered out [22]. The mechanical element would be a deconstructed robotic claw design with the thumb acting as one half of a claw for the user to push against with their existing pinky finger. This would provide much more force for the user to be able to grasp and hold different items because it is not dependent on the amount of wrist flexion they have.

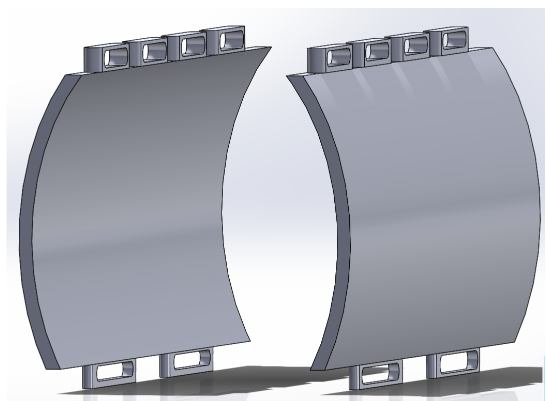


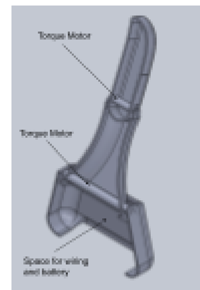
Figure 12: The patient has sensitivity on the hand at the amputation points, so the thumb will be anchored to this custom cuff that will fit on the forearm. Velcro straps will join the halves. The two straps on the bottom are to reduce the time it takes to secure and remove the device.

The prosthetic thumb must be anchored securely in order to support any weight being lifted. It cannot slip, so it needs to have a tight, secure fit without being too tight. One major challenge is that the patient's hand has sensitivity at the points of amputation. It was suggested by the client to stay away from those areas. This can be especially difficult with a moving part, as the additional weight of the motor and motion of the device provides different loading compared to both other designs. For this reason, the thumb was anchored onto a cuff that is supported by the forearm, and the motor will be contained within the cuff. This way, the patient's hand will not be bothered by coming into contact with any solid materials. In this design, Velcro straps will connect each pair of slots. The side with 4 slots will be adjusted to the patient, then can stay at this adjustment. The side with two slots will be the side the patient uses to put on and take off the prosthetic. The client will need to put the prosthetic on with one hand, so the simple velcro straps will allow him to do so. To maximize the comfort and safety of the patient, a silicone sleeve will be fitted to the patient's arm, and rest in between the prosthetic and the skin. To provide additional padding, closed-cell foam will be attached to the inside of the cuff [23]. Finally, any sharp edges or corners on the cuff will be removed to ensure it does not catch on anything or cause discomfort.

Preliminary Design Evaluation

Design Matrix

Table 1: Design matrix demonstrating how the bionic design is chosen

Name		Cosmetic		Mechanical		Bionic	
Criteria:	Weight:						
Comfort	20%	5/5	20	(1/5)	4	(3/5)	
Ease of use	15%	1/5	3	(3/5)	9	(5/5)	
Cost	15%	4/5	12	(4/5)	12	(1/5)	
Cosmesis	5%	5/5	5	(1/5)	1	(2/5)	
Functionality	15%	1/5	3	(2/5)	6	(5/5)	
Ease of Fabrication	10%	4/5	8	(5/5)	10	(1/5)	
Strength	15%	1/5	3	(2/5)	2	(5/5)	
Response Time	5%	1/5	1	(5/5)	5	(3/5)	
Total	100%	55		49		57	

Design Matrix Summary

Design 1: Cosmetic

This purely cosmetic design would be made with materials that best resemble the touch and feel of skin, however would not provide much additional functionality past a backbone for the patient to pinch against with his pinky finger. This design would be easier to fabricate as it would have less moving pieces, but creating a realistic looking finger could be challenging. Additionally without any moving pieces this design would have less potential pinch points, or electrical issues making it comfortable and more easily worn in the rain/water. However, this design does provide much functionality or strength to the patient as some of the other designs and therefore it was not selected.

Design 2: Mechanical

The fully mechanical design is the most simple design. The string is shortened by flexion of the wrist, allowing the user to grasp items. The major shortcoming in this design with regards to the patient, is that they are unable to move their wrist more than 20-30 degrees. This would severely limit either the range of motion of the thumb or grip strength of the prosthetic, as with increased range of motion the force provided would decrease. It is a straight forward design, so it scored well in the ease of use, cost, and ease of fabrication. One of the major benefits of this design is the low cost. However, since the client did not provide a budget, it is crucial to keep the cost relatively low so that it can be funded from outside sources. The response time in the mechanical design would also be the best because there will be no lag time that some of the electronic components in other designs may have.

Design 3: Bionic

The bionic design meets some of the client's most important requirements, which are strength and functionality. These criteria would allow the patient to go back to work. The design would be far more complex and therefore expensive than the other designs. However, based on the criteria of making an inexpensive model, this is a trade-off for making a prosthetic that works for the user. There would also be a larger learning curve for the user, resulting in a lower score in the ease-of-use category. Finally, when considering the difficulty of designing a base mechanical support, the electronics required, and the timeframe available, it was concluded that the bionic design is too difficult to fabricate in the given amount of time, resulting in a low ease of fabrication score. However, it came to light that the patient experiences sensitivity and pain during palpation of the amputation site. Due to this, the prosthetic design was limited to the thumb, and thus the decision was reversed and the bionic model became feasible.

Proposed Final Design

The overall winner of the design matrix was the bionic design. This design won because it scored the highest in the most valued categories. The bionic design provides the user with the greatest amount of force and strength when grasping and holding objects. This was the most important quality to consider for the patient because he is looking for a solution to help him get back into the workforce. In addition to strength, the bionic design is also easier to use for the patient because of the limited flexion in his wrist. The use of a microcontroller allows for the patient to be able to grasp many objects of different sizes and weights. The microcontroller is able to amplify any signal read from the forearm into any movement response necessary. This is valuable to the patient because he will be able to hold larger and heavier objects as well as utilize smaller movements for tasks such as writing. This solution will take some adjustment initially, but it will ultimately be a better solution for the patient.

Final Design

For the final design, the bionic design was used, but the sensors were changed from myoelectric sensors to a flex sensor. Myoelectric electrodes were attached to the left forearm of a test subject and connected to an electrical circuit in order to read the signals. Clear signals could not be obtained from myoelectric sensors. For this reason, the myoelectric sensor was replaced with a flex sensor for the final bionic design. This was chosen because it is a simpler mechanism that will give clear changes in resistances based on flexion. The flex sensor will be placed on the wrist and be attuned to the patient's wrist flexion, which will determine the degree of flexion of the thumb. The flex sensor was also a better option because the myoelectric electrodes were not reusable.

Fabrication/Development Evaluation

Materials:

Electronics

The main electronic elements of the design include an arduino uno, motor driver, linear actuator, and flex sensor. The linear actuator is attached directly to the 3D printed thumb using a nut and bolt. When the linear actuator is commanded to extend through the circuitry, the portion attached to the thumb will push upward, resulting in the flexion of the thumb, allowing the user to grasp. When the linear actuator is commanded to retract, the thumb will extend, allowing the user to release their grip. The linear actuator moves when the flex sensor is manipulated. When the flex sensor is bent greater than 30 degrees, shown in the figure below, the linear actuator extends. When the flex sensor is flattened, the linear actuator retracts.

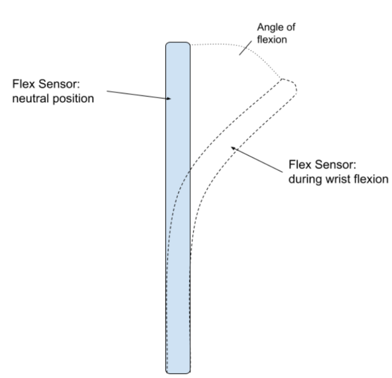


Figure 13: Diagram of the flex sensor bent from neutral

Mechanical Thumb

The mechanical thumb was 3D printed using PLA with 60% infill. The pieces of the thumb were joined by stainless steel clevis pins. The tip of the thumb was dipped in flex seal and texturized to reduce slippage. The base of the thumb was attached to the linear motor using a nut and bolt.

Forearm Cuff

The forearm cuff is strapped tightly to the patient's forearm. It is the basis of how the prosthetic thumb can support 4.45 N of force. It provides a surface to attach the thumb mechanism, motor and flex sensor. The fit needed to be secure and sturdy on the patient. A mold of the patient's forearm was made out of a plywood core and non-drying clay. Two plywood pieces were glued together with gorilla glue. The cuff was made from ⅛ inch polystyrene plastic. Velcro straps cinched around the outside of the cuff to secure it in place. One side of the cuff was held together by a flexible joint made of nylon fabric glued to the cuff. Additionally, there was a fabric sleeve from a sweatshirt that was sewn to fit underneath the cuff to provide housing for the flex sensor along with padding for the forearm.

Methods:

Solidworks and 3D Printed Thumb

The Solidworks model was constructed with the aim of mimicking the natural motion of a thumb joint. Splitting the device into sections, each of which with their own motion, helped to create a function similar to that of a natural thumb. A piston piece is attached by a screw to the linear motor, and moves in line with the motor. The linear movement of the piston piece then causes movement of the other pieces that when in conjunction mimic the flexion of a thumb.

The pieces included in the solidworks design were designed and evaluated multiple times throughout the semester. The final design optimizes range of motion, length of the pieces, efficiency of movement, and stabilization. All pieces were designed with tolerances(+ 0.02in) that created easy assembly once printed. CAD of the purchased stainless steel clevis pins were input into the Solidworks assembly and tested with the design.

Pieces were then 3D printed in PLA with 20% infill on prototypes and 60% on the final design before being assembled, with sanding as needed.

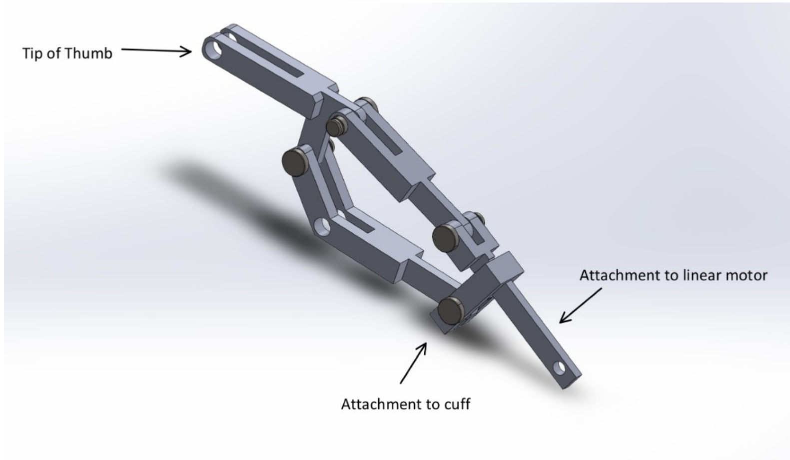


Figure 14: Final design of mechanical thumb.

<u>Circuitry and Code</u>

The electronic elements of the prosthetic device are connected and controlled through the circuitry and code. The code utilizes the decision tree method, shown in figure 15, to determine when the linear actuator needs to be extended, retracted, or remain in place. The code takes input from the flex sensor, sends the angle of flexion through the decision tree, and then outputs a command to the linear actuator based on the resulting decision. If the angle is greater than 30 degrees and the thumb is not flexed, the linear actuator is commanded to extend. If it is already flexed, the code continues to loop until the angle is changed. If the angle is less than 30 degrees and the thumb is flexed, the linear actuator is commanded to retract. If it is not flexed, the code again continues to loop until the angle is changed. The function of this code is only possible through the circuitry that connects the main electronic components: linear actuator, motor driver, arduino uno, and flex sensor. This circuitry design can be seen in Appendix D.

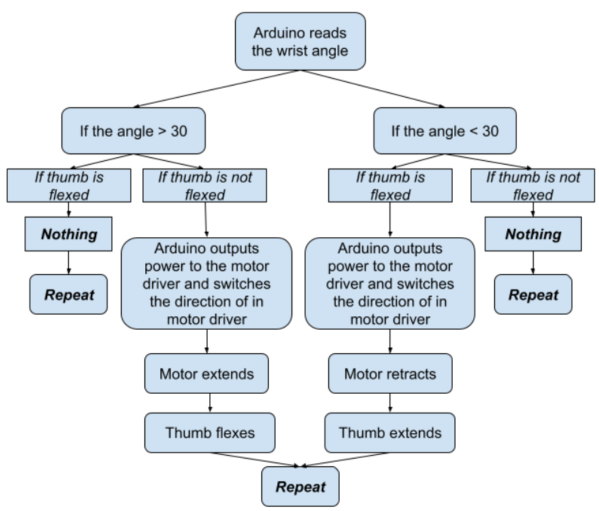


Figure 15: Flow chart depicting the decision tree of the Arduino code shown in Appendix C

Forearm Cuff

A mold of the patient's forearm was created (see Appendix H). First, two ½" x 1" x 10" pieces of plywood were glued together to act as the core material for the arm. This was to ensure the mold was strong and would hold its shape under the pressure applied in the thermoforming process.

Figure 16: Two pieces of plywood being glued together to act as the core material for the model forearm. The strong core provided a backbone for the clay to be molded onto.

Then, non-drying clay was stuck to the plywood in the shape of the patient's forearm. Circumference measurements and pictures with scale were provided to make the model as accurate as possible to the patient's forearm.

Figure 17: The completed forearm model with a 3D model of the patient's hand set on top. Measurements depict the cross sectional circumference at various points along the arm

After the forearm model was created, the thermoforming machine was turned on and preheated. After 15 minutes, the model was set into the thermoforming machine so that the posterior side of the forearm was facing up to get molded. The ⅛" polystyrene was then set above the model on top of the foam seal of the machine so that it could create a vacuum seal. The heating hood of the thermoforming machine was pulled forward, and the plastic was heated. After about 3 minutes, parts of the plastic began to droop, signalling that it was pliable. The heating hood was pushed back, and a lever that raised the model into the plastic was pulled.

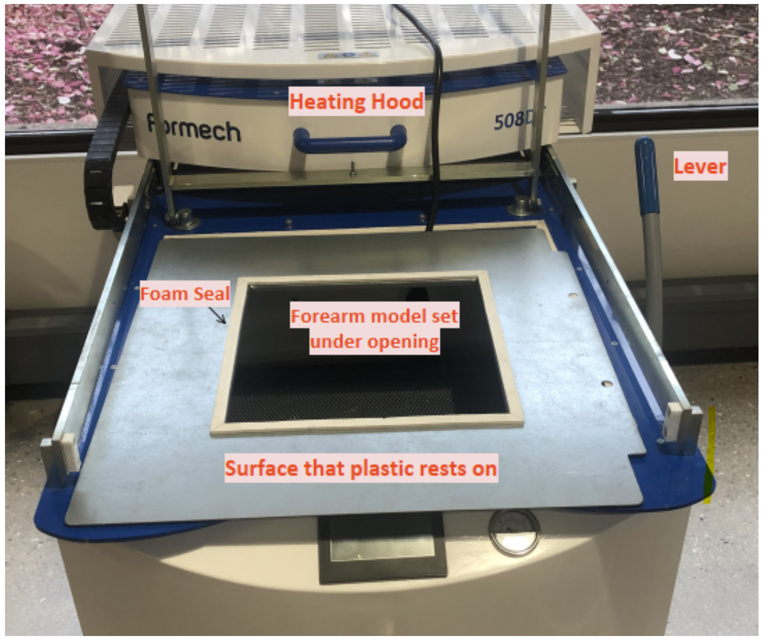


Figure 18: Thermoformer machine with various parts labeled.

A button was then pressed to activate the vacuum function of the thermoformer. It was pushed on and off for about 8 seconds in order to reach a balance between following the contours of the model and not stretching the plastic to the point of tearing. If the vacuum is left on too long, the plastic may be suctioned too strongly, and the plastic may stretch too far and become too thin with the possibility of tearing. If the vacuum is not left on long enough, the contours of the forearm model would have been lost. The plastic was allowed to cool for 1 minute before being removed from the thermoformer. The forearm model was stuck to the inside of the thermoformed plastic mold, so it needed to be scraped out, then reformed. The forearm model was remeasured to ensure the same size for the plastic mold of the anterior side of the forearm. The same thermoforming process was followed for the second mold.

Figure 19: Forearm mold to be cut out of the excess polystyrene.

After both sides of the molds were cooled, they were cut out of the surrounding plastic with a bandsaw, and sanded down using sandpaper. A nylon fabric was then glued to one side of the cuffs in order to form a flexible hinge. Velcro straps were then wrapped around the forearm cuff in order to hold it securely onto an arm.

A cuff sleeve was sewn from a sweatshirt sleeve. The sleeve was measured off of the mold of the patient's forearm. A small pocket 3" long and .25" wide was sewn onto the inside of the cuff to house the flex sensor. The cuff sleeve provides cushion and protection to the forearm as well as securing the flex sensor in the correct position.

Final Prototype

The final prototype consisted of a forearm cuff, a mechanical thumb, a linear actuator, cuff sleeve, motor driver, arduino microcontroller, two 9V batteries and a flex sensor. The forearm cuff was customized to fit the patient's arm. It was attached with a nylon hinge on one side and velcro straps to hold it closed. The mechanical thumb turns linear motion from the linear actuator into a gripping motion. The linear actuator is controlled by the flex sensor at the wrist. When the flex sensor is bent from the patient bending his wrist, the linear actuator will activate and the gripping function and the prosthetic thumb will move toward the pinky. The design works in opposition to the existing pinky finger. The client wanted a device that worked in opposition to the pinky because the pinky is still functional.

Figure 20: Picture of the final design.

Testing

The device was evaluated with a series of tests, each of which analyzed various aspects of the prototype. Initially, a general test of motion was performed (n=10) to determine if prototype motion was replicable. To perform this test, the flex sensor is deployed at full flexion amount to input highest resistance. Following, the device performs mechanical movement of the linear actuator and prosthetic thumb to full flexion. The movement of each trial is noted, specifying if any abnormal movement is detected. The general motion test is evaluated on a pass fail basis, and no further testing is performed until a pass is achieved.

Second, a range of motion test is performed (n=10) on the thumb by deploying the device to full flexion repeatedly to see if a consistent range of motion is achieved. Prototype was imaged at each position for each trial and images were analyzed in ImageJ. Angles in imageJ were measured from the axis determined by the linear cuff.

Third, a force test was performed to determine the average peak force the thumb could produce at the distal ½" portion of the second phalanx of the thumb. This was done by fixing the cuff attachment to a rigid surface and attaching a crane scale to the second phalanx (see Figure 21). From here the thumb was set in motion and the peak force exerted by the thumb over the whole range of motion was recorded for a set of n = 10 trials. The aim of this trial is to determine whether the thumb could produce an adequate counter for the pinky finger of the patient. The patient's pinky finger can hold 17N, meaning the thumb needs to be able to counter that amount of force [2].

Lastly, a reaction time test was performed. The aim of this test was to determine if the time from sensor bending to full flexion of the thumb could be done in under 2.75s. This time is to account for 2.5s of flexion and 0.25s of run time on the code. This test is performed by timing the action from bending of the sensor to full flexion, and repeated for a total of 10 trials. To determine if the thumb could fully flex in that time a one-sided z-test is performed on the thumb to ensure it is within that range.

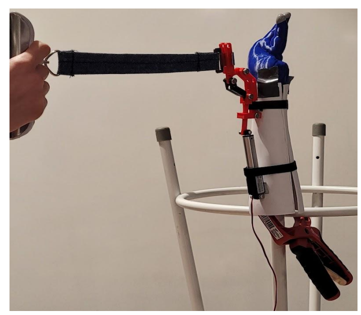


Figure 21: Example of Force Testing with a Crane Scale. The handheld force sensor was held still while the prosthetic thumb flexed.

Figure 22: Example measurement of ImageJ analysis. Pictured is angle of full flexion, not example calculation. ImageJ measures an angle of 18.35 degrees.

Figure 23: The prosthetic thumb

successfully holding a small container.

Results

The results of motion testing proved that the thumb works, with every movement trial, a pass was recorded. The force test produced an average maximum force of 4.45N with a variance of 0.214. This was lower than the desired 17N counter for the patient's pinky finger [2]. The design of the thumb has a flaw in which it can flex backwards which needs to be corrected, after which more force testing will be done to determine the force is significantly above 17N. See Appendix F for full data.

The range of motion tests produced a range of 7-13cm of motion with an average of 20 degrees of flexion. A range of motion 7-13cm signifies the variable lengths of objects that can be held by the design, with 13cm being the largest possible and 7cm being the smallest object length. As the range of motion and the degree of flexion are directly related, increasing the degrees of flexion capable of being produced by the prototype will directly increase the range of motion possible. See appendix G for full data.

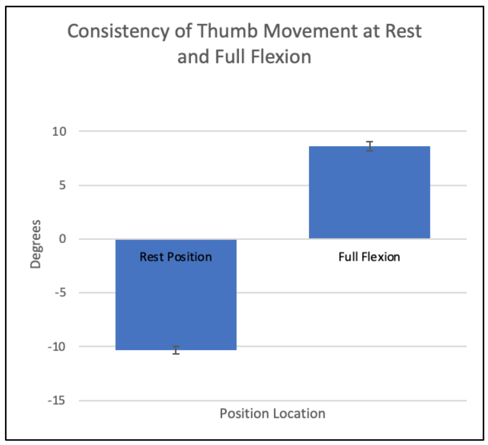


Figure 24: Plot of thumb motion testing displaying the relationship between the position of the thumb and angle of flexion (angle of the thumb relative to the neutral axis).

The reaction time test produced an average of 2.44s reaction time between the sensor being bent and full flexion of the thumb. This was significantly less than 2.75s with an alpha of 0.05 given the results had a p-value of 0.0018, the value 2.75s was chosen to account for 2.5s for full flexion and 0.25s of run time for the code. Results of the reaction time test allow confidence that the full flexion mechanism can reliably deploy in less than 2.75s. See Appendix E for full data.

Discussion

The design works to effectively hold small objects with a linear motor. The function of the device starts with a flex sensor, which detects changes in angle.This is measured against the neutral axis, once the sensor is bent (occurring during wrist flexion), that change is detected by the arduino. Once an adequate amount of flexion has been detected, the arduino sends power to the motor driver allowing it to supply power to the linear motor extending it. This motion needs improvement in future. The code needs reworking in order to be less sensitive to small changes. The current design when worn in the sleeve continuously moves in and out as the sensor reads. Once the motor is extended the sensor continues to read the angle from the sensor. If the sensor has returned to the neutral position the motor will retract and the thumb will extend with it. It is ideal if the reaction time (averaging 2.4s) can be reduced. It may be beneficial if the motor can be smaller in size with a smaller reaction time, as the full extension of the current motor is not being utilized.

During thumb flexion (when the thumb is at the position closest to the pinky finger), the thumb can provide a stable force on the pinky and can provide a force through the range of motion as well. The object is stabilized by friction on the thumb provided by a texturized flex seal coating on the second phalanx. The thumb moves backwards about 2cm which can be an issue during testing. This motion prevents the thumb from holding heavier objects as the joint with that motion can move and the object may fall. The Solidworks design of the thumb will need adjusting in the future semester. During force testing the thumb displayed a backwards movement that is not ideal. To fix this issue, incorporating a piece that reinforces the position may be necessary. This can likely be accomplished adding a design element that attaches the existing pieces in another area.

Conclusion

A functioning bionic thumb was successfully created that has the ability to pick up and hold objects of about 0.5kg (see Appendix F). The overall price point of the thumb remains under $200 which is significantly reduced from the thousands of dollars a bionic upper limb prosthesis costs on the market. The thumb reacts in under 2.75s and has a range of motion of 7cm-13cm. However, the thumb can still be improved.

Further modeling and testing of the thumb needs to be done. The mechanical design of the thumb can be improved upon by remodeling to reduce extension between the first and second phalanx of the thumb before a kinematic analysis can be run in solidworks for proof of concept. After it is determined the mechanical model can support 17N of force in computational analysis. A physical model will be tested as outlined previously. Other improvements to the Solidworks model can be made to increase the length of the thumb. An increase of the currently existing model by approximately 120% length will provide a better match in opposition to the pinky. A final objective in the thumb revision is to increase the efficiency of movement. Adding more tolerance in areas of the design, or removing aspects of pieces that hinder further motion will be considered and addressed.

The electronics are also to be improved upon. The circuitry will need to incorporate an Arduino Nano Every and must be soldered to eliminate the use of a breadboard and reduce the size drastically. Once this portion has decreased in size, a location for these components will be determined. It is likely to be attached to the wrist or worn on a pack at the hip. This will also need to be contained within a water resistant container, which will allow the client to use the arm in all weather conditions. The circuit will also need to be calibrated to the patient's needs, the patient will help determine what a comfortable level of wrist flexion is for the maximum thumb flexion, and how many levels of flexion is appropriate can be determined based on fine motor control and degrees of comfortable wrist flexion available. After the above revisions are addressed, testing with the patient will be the next step. Any issues arising from this testing will be noted and further adjustments will be made.

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Appendix

Appendix A: PDS

Prosthetic Hand

PDS | Sept. 24, 2021

Client: Ms. Shirley Katz

Advisor: Mitchell Tyler

Team: Emmalina Groves - Team Leader

Karen Scharlau - BWIG

Danielle Lefko - BSAC

Stephanie Silin - Communicator and BPAG

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Function

Losing part of a hand is an incredibly difficult obstacle to overcome considering how much a person uses their hands throughout any given day. Not only does it affect many physical aspects in a person's life, but it can cause mental hardships as well. Unfortunately, state of the art prosthetics can cost a fortune, which is not an option for many people. In this case, the patient has lost their thumb, pointer, middle finger, and much of their palm to a serious infection. They retain their ring finger and pinky finger, however movement is severely restricted. The ring finger is immobile, and the pinky finger can bend at the metacarpophalangeal joint a maximum of 10 degrees. Our team will work to help this patient restore functionality to his hand while making it look as real as possible. The goal is to create an affordable solution so that more people like our patient can regain use of their hands.

Client requirements:

- Prosthetic must be able to stabilize and hold objects.
- Cosmetic appearance of prosthetic is more important than the function.
- Prosthetic needs to be comfortable for extended, daily wear.
- Prosthetic should include at least a thumb, preferably 2-3 additional digits.
- Prosthetic needs to be water-resistant or water-proof.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*:

The prosthetic must provide the user with the ability to stabilize and hold objects that are light to moderate in weight. The prosthetic hand should give a gripping force of 2.5kg. It should be able to manipulate any utensils, i.e. pencil, fork, etc. Additionally, the attachment to the body should not put the user in danger, or be too costly as this is intended to be a cost-efficient device.

b. *Safety*:

The prosthetic must be safe for continuous wear for 3 to 5 years[1]. All materials used must be safe for extended contact with skin, and sharp edges or pinch points must be covered.

c. *Accuracy and Reliability*:

The prosthetic hand must move in a controlled manner so the patient is able to benefit from understanding the consistent movements. Hand must be able to continuously function for 8 hours of use so the user is able to work without changes in function.

d. *Life in Service*:

The prosthetic must be functional for constant wear by the user for 3 to 5 years, and be durable enough to withstand common daily tasks [1].

e. *Shelf Life*:

The prosthetic should not have any problems being stored for several years.

f. *Operating Environment*:

The prosthetic must be functional in all environments the user encounters in daily life. This includes rain and very cold weather. It would be ideal for it to function fully submerged in water, but not necessary. The device should be able to be cleaned with soap and water.

g. *Ergonomics*:

The prosthetic should be comfortable for writing, picking items up, and holding items. It should act as an extension of the body, and prolonged use should not cause any discomfort.

h. *Size*:

The prosthetic must blend in with the size of the user's natural hand. A 3D scan of the user's affected hand was obtained and can be used to reference specific measurements.

i. *Weight*:

According to the prosthetic development community, there is no specific maximum weight of prosthetic hands. However, the general consensus is that the prosthetic hand should remain below 400 grams, which is the average weight of an adult human hand. Many current users indicated that when wearing a prosthetic hand that weighed the same as a natural hand, it felt too heavy. This is a direct result of the attachment. [2] A smaller weight would be ideal as it would be easier to stabilize and reduce wrist torque. The goal is to produce a device that is around 300 grams.

j. *Materials*:

The materials used should not cause any adverse effects to the user after prolonged use. They should provide both structural support and grip in order to pick up and hold various objects. A 3D printing material such as PLA or ABS, a prosthetic structural material, cushioning, and electronic components will make up the bulk of the design.

k. *Aesthetics, Appearance, and Finish*:

The user desires a more cosmetic approach to this device. This means that the prosthetic hand must maintain cosmesis and blend appropriately with the rest of the body. The device should achieve the closest to a natural look as possible, and if possible include natural features such as fingernails.

2. Production Characteristics

a. Quantity:

The device is being made for a specific patient, so only one device is necessary to manufacture. However, the prosthetic device will be made so that others who have lost some or all digits can use the same design principles with aspects of the design tailored to the limb of the patient.

b. Target Product Cost:

The prosthetic device must be as economical as possible because the client did not provide a budget. All funding will be coming from an outside source.

3. Miscellaneous

a. *Standards and Specifications*:

1. Grip light-medium objects with 2.5 kg of force . This max force should be for steady grip of smaller rectangular objects such as a phone.
2. Remain around 300 grams [3]
3. Match size of the client's hand provided by .stl file
4. Must be reproducible in multiple skin tones.
5. Velcro adjustable brace will attach to lower forearm above the wrist. This will be accompanied by a 'sweatband'/sock type material to go underneath and prevent frictional irritation and distribute uneven stresses on the wrist.
6. Strings pulled by motors will close the fingers into a grip. The motors will engage when an electrode, attached to the skin of the forearm, registers muscular movement.
7. The user should be able to pick up a cup and small items off of a flat surface.

b. *Customer*:

The customer for this project is the client's patient. However, this project will be applicable for other users down the line. These users will be individuals who have had one or more compromised digits on their hand that has limited functionality.

c. *Competition*:

The client has reached out to other organizations for additional assistance. One company includes Enabling the Future. E-nable is a company that produces 3D printed mechanical prosthetic hands for individuals who have at least some movement of the wrist.

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Appendix B: Material Cost Spreadsheet

Table 2: Summary of project Costs

Item	Manufacturer	Quantity	Price	Total
Glue	Buy On Purpose	1	$10.13	$10.13
Velcro Ties	Buy On Purpose	1	$5.79	$5.79
Clevis pins	Grainger	10	$1.66	$16.60
Arduino Nano Every	Arduino	1	$12.90	$12.90
9 V Rechargeable Batteries	EBL	1	$26.99	$26.99
Arm Sleeve	IovyoCoCo	1	$13.24	$13.24
Flex Seal	Flex Seal	1	$14.99	$14.99
Motor Driver	HiLetgo	1	$10.99	$10.99
3D Printing	N/A	N/A	N/A	$20.00

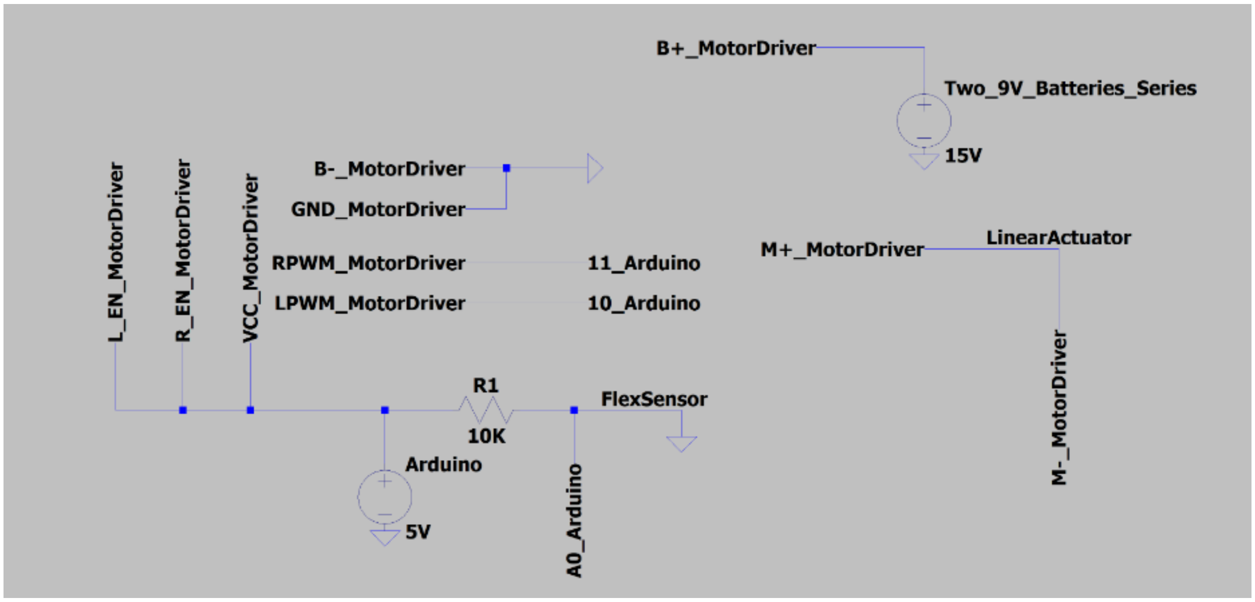
Flex Sensor	Adafruit	1	$12.00	$12.00
Polystyrene	Makerspace	2	$15.00	$30.00
			Total:	$173.63

Appendix C: Arduino Code

```
//Constants:
const int ledPin = 3;   //pin 3 has PWM function
const int flexPin = A0; //pin A0 to read analog input

//Variables:
int value; // convert analog value to scale of 0-5
int flexValue; //save analog value
int oldValue; // marker to stop movement of motor when necessary

byte Speed = 255; // Initialize Variable for the speed of the motor (0-255);
int RPWM = 10;  //connect Arduino pin 10 to IBT-2 pin RPWM
int LPWM = 11;  //connect Arduino pin 11 to IBT-2 pin LPWM
bool caught = false; // ensures that after the loop goes around once it doesn't continue to extend after it has already
extended

void setup(){

pinMode(ledPin, OUTPUT);  //Set pin 3 as 'output'
Serial.begin(74880);   //Begin serial communication
pinMode(10, OUTPUT); // Configure pin 10 as an Output
pinMode(11, OUTPUT); // Configure pin 11 as an Output

// start at full retraction of motor for baseline
//Speed = 255;
analogWrite(RPWM, Speed);
analogWrite(LPWM, 0);

delay (7500); // max length = 7.5 seconds

oldValue = 0; // initialize value for comparison
}
void loop(){

flexValue = analogRead(flexPin);        //Read and save analog value from potentiometer
value = flexValue * (5.0 / 1023.0);  // convert to a scale of 0-5
Serial.println(value);              //Print value

if(value != oldValue) {    // if value does equal old value, this means no change has been made by user
                            // and desire is to maintain that amount of flexion
if(value <= 2 && !caught) { // full flexion of wrist = full bend in thumb desired
// Extend Actuator at Full Speed
analogWrite(RPWM, 0);
analogWrite(LPWM, Speed);

delay(2000); // 2 Seconds
```

```
caught = true; // establishes that it has already gone through and extended once
}
else {
// Retract Actuator fully
analogWrite(RPWM, Speed);
analogWrite(LPWM, 0);
caught = false;

delay(2000); // 2 Seconds

}

// Stop Actuator
analogWrite(RPWM, 0);
analogWrite(LPWM, 0);

}
oldValue = value;
}
```

Appendix D: Device Circuitry



Appendix E: Reaction Time Trials

Trial #	Time
1	2.21
2	2.22
3	2.17
4	2.47
5	2.07
6	2.57
7	2.48
8	2.95
9	3.05
10	2.24
avg	2.443
st dev	0.3337680499
variance	0.1114011111
t >= 2.75s	
p-value	0.00181

Appendix F: Force Reaction Data

Trial	kg		N
1	0.45		4.4145
2	0.5		4.905
3	0.4		3.924
4	0.4		3.924
5	0.45		4.4145
6	0.5		4.905
7	0.45		4.4145
8	0.5		4.905
9	0.35		3.4335
10	0.45		4.4145
Avg	0.445		4.36545
Variance	0.002472222222		0.2141253225

Appendix G: Range of Motion Data

Rest Position	Full Flexion	
-10.76	9.88	1
-9.56	9.02	2
-10.22	9.44	3
-10.7	8.93	4
-9.98	8.88	5
-10.5	9.45	6
-10.42	9.6	7
-10.11	9.37	8
-10.59	8.52	9
-10.39	9.56	10
-10.323	8.62	
0.3659705513	0.4366983565	
Rest Position	Full Flexion	
-10.323	8.62	

Appendix H: Client Arm Measurements

Length Proximal to the Wrist	Circumference (cm)
At elbow	25.0
+7.5	23.6
+6	22.0
+4.5	20.0
+3	17.4
+1.5	16.0
+0	15.7
-1.5	17.4