Spring 2019

Project "Auxilia" - Jaiden's Prosthetic Arm

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Prosthetic Arm for Jaiden Foden

AUXILIA
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BME Design I 4800:491
Date Prepared: 04/26/2019

Table of Contents

Abstract
The main objective of this project was to create a prosthetic arm for a 15 year old boy named Jaiden Foden. Jaiden was born with only one fully developed limb as a result of a genetic disorder, Hanhart Syndrome II. His right arm becomes a residual limb below the elbow, but has two fingers which act in a "claw-like" movement. Jaiden's left arm becomes a residual limb above the elbow, and his left leg becomes a residual limb above the knee. The goal of the arm was to increase Jaiden's overall independence and to help in completing daily tasks, such as brushing his teeth. Additional objectives were to design the prosthetic to be adjustable, such that he could continue to use it as he grows; design the prosthetic to be relatively inexpensive to offset the overall costs of amputations and limb loss; and design it to be light and portable in order to be easily carried around and potentially applied to additional tasks. Requirements of the device included that it must be easily attachable/detachable to the user, be lightweight/portable, be relatively inexpensive, be comfortable, be resistant to skin damage, be durable, reduce overall fatigue in the user's current right hand, and resemble a hand aesthetically. If successful, hospital charges may decrease as replacement prosthetics will be cheaper, individuals who cannot afford proper treatment or accommodations can be considered to receive this device, children will be able to use their prosthetic for an extended period of time as they grow, and children with above the elbow residual limbs (like Jaiden) will be able to have more independence.

Description of the project problem
Jaiden Foden, a 15 year-old boy from East Liverpool, OH, was born with Hanhart Syndrome II. As a result of Hanhart Syndrome II, Jaiden was born with only one fully developed limb, his right leg. His left arm stopped growing mid-bicep, his right arm did not fully develop an elbow and only has two fingers which work in a "claw-like" movement, his left leg stopped growing mid-thigh, and his hips were not developed perfectly aligned. Jaiden's family had been able to afford a prosthetic leg for him, but not a prosthetic arm which would be helpful in his everyday life in order to be a more independent individual.

Background
According to the amputee coalition, "there are nearly 2 million people living with limb loss in the United States" [1]. An "amputation is the surgical removal of all or part of a limb or extremity such as an arm, leg, foot, hand, toe, or finger" [2]. After amputation, the resulting/remaining body part is known as a "residual limb". There are many reasons why an individual may require an amputation: poor circulation, severe injury, cancerous tumors, serious infections, thickening of nerve tissue, frostbite, and many others. This wide range of amputation determinants results in a population that can range anywhere from war veterans to children with birth defects. "Hospital charges for patients who underwent an amputation totaled $8.7 billion in 2013" [3], and according to the Journal of the American Podiatric Medical Association states that initial hospital costs for the amputation of a foot or leg costs between $30,000 and $60,000 [4]. These costs do not include any follow-up care or additional expenses such as wheelchairs, crutches, prosthetics, etc.

Among these 2 million individuals, in the U.S. alone, a portion of them are children; still growing and learning how to interact with the world around them. As they grow up and begin to integrate into society, one common struggle is independence in their everyday lives. One of

these children is Jaiden Foden. Jaiden's dream and goal is to become more independent in his life with simple daily tasks such as drinking from a water bottle, lifting textbooks, and soon driving a car, just like all other children. The team became aware of Jaiden and his condition after being approached by Michael Livingston, a co-founder of the group Donovan's Kids. Jaiden attended Donovan's Kids Camp where he met Michael.

The organization Donovan's Kids is a nonprofit that operates out of Akron, Ohio [5]. The group was founded by Michael Livingston, an Air Force veteran who served during the Vietnam conflict. Michael was inspired by a YouTube video of veteran amputees playing softball. After watching the softball video, Michael was driven to invite those individuals to Akron, Ohio to play a game, which was a three year process. During these years, Michael traveled to meet the team's owners and watched the team play. After the three years, the first Wounded Warriors softball game was brought to Akron. The team also had a kid's camp, which Michael was invited to attend. The team's camp was the inspiration for Donovan's Kids, which hosts a camp for kids who are amputees, suffer from spina bifida, or are a child of a veteran. The organization began in 2016 and has grown quickly through donations and a driven leadership team. Donovan's Kids is looking to expand to do more for the pediatric amputee community such as providing medical devices that would allow the kids to partake in fun activities they may have struggled to do before.

The current direction of prosthetic devices focuses on two innovative technologies: 3D-printing and myoelectric interfacing. 3D-printing has a promising future as it can produce many functional and relatively cheap components in a short amount of time. However, due to the decrease in density and structural integrity that is associated with 3D-printed plastics, there needs to be increased time and dedication to the design of each component. For example, if one is trying to 3D-print a sphere, the top half may be smooth while the bottom half may be rough due to all the supports required to print the shape above the workspace. With increased time to the design, a smooth shape could be printed to serve the same function, but be a different shape that requires fewer supports. Supports are only one manufacturing parameter that need to be kept in mind when designing for 3D-printing; the parameters could also include body and surface tolerances, overhanging surfaces, component integration, reduction and accommodation of range of motion, cross-sectional structure and density, and device use in relation to the printing plane [6].

Meanwhile, the scientific achievements in myoelectric interfacing have been expanding as well. Surface electromyographic (sEMG) signal recognition has been improving, resulting in enhancements in rate of grip and sense of operation increase [7]. There have also been improvements in instantaneous adjustments of components due to myoelectric interfacing, allowing for multiple consecutive trials to be performed. These consecutive, fast-paced trials present the opportunity for pattern recognition and development of pre-trained hand systems [8]. These trained hand systems are especially beneficial for children who typically do not have the patience or extended periods of time to train and practice with their prosthetics before use.

Design Requirements

This project revolved around the customer requirements as dictated by the clients: Jaiden, his mother, and Donovan's Kids president, Michael Livingston. Jaiden's requirements were prioritized, since he was intended to be the end-user of the prototype. The customer requirements are listed below.

- The device must allow the user to lift a bottle of water
- The device must be usable for daily functionality
- The device must function sufficiently to reduce fatigue in the client's right hand
- The device must attach and detach easily
- The device must be comfortable to wear
- The device must look like a hand
- The device must avoid damage to skin
- The device must be durable
- The device must be low cost
- The device must be lightweight

From these customer requirements, the design team decided that the significant components of the device are as follows:

Socket

- Interfaces with user's residual limb
- Supports device
- Houses all mechanical and electrical components

Elbow

- 1 Degree of Freedom (DOF) elbow
    - The elbow allows flexion and extension of the arm. The elbow should have a range of motion of at least 145 degrees of flexion and -5 degrees extension, to replicate typical anatomic capability [10]
    - The elbow shall be modular and optional to insert into the design
    - The elbow may be actuated mechanically or electrically

Hand- fingers with thumb

- The fingers will be capable of a barrel grasp
- Movement of all four fingers is grouped with one actuator for 1 DOF
- The thumb will have 0 DOF
- The grasp will accommodate a minimum diameter of 2.0 inches.
- The grasp will be modulated in two ways:
    - Avoid damaging delicate objects
    - Have sufficient strength for more rigorous tasks

DOF for each joint was selected based on the complexity of the movement, the functionality of the overall limb, and the desired tasks to be completed by the arm.

Reference Figures 1 and 2 in the Appendix for block diagrams of the prosthetic arm activation. The figures detail the electrical and mechanical activation, respectively.

The operation of each joint was assumed to have independent actuation, whether mechanical or electrical. Independence ensured modularity of the device. A failure of one joint should not greatly affect the function of other joints, outside of the natural effect of the resulting arm position. The function of each joint depended on the method of actuation, but was assumed to have the same characteristics regardless. That is, the same range of motion, strength, and position was expected to be the same for both mechanical and electric manifestations of the design. Dependencies also include the ability of the user (Jaiden) to operate the functional portions of the device. Coordinating movements of the device depended on Jaiden's ability to actuate the motion of the device. His general functional capabilities were analyzed during meetings and considered during the design process.

The prosthetic arm for Jaiden was a stand-alone product that does not use any other accessories. The socket of the device interfaces directly with the skin of the left residual limb. The hand component of the arm utilizes a power component (battery system) to control the movement of the hand. The elbow component of the arm is manually activated. The user interfaces at the electrical and mechanical controls of the device to activate or alter its functions.

Constraints had a significant impact on the design of the product. The following are general project constraints, followed by more specific constraints.

- Cost was a significant constraint for this project. A goal of the project was to minimize cost for affordable prosthetic options. Myoelectric arms have an average cost range of $20-30k [11]. Body-powered prosthetic arms range from 5-10k. The project goal was to develop a prototype within the given $1500 budget.
- Development & testing time was another significant constraint. All aspects of the project were constrained by semester end dates. Concept development, prototyping, and testing were all governed by a schedule. Any testing or validation requiring the user was constrained by time, since Jaiden lives in East Liverpool and transportation must be coordinated through Donovan's Kids. Thus, all user testing needed to be planned well in advance and completed within a limited number of time-restricted sessions.
- The end-user needed to use the device in a home and school setting. Additionally, Jaiden wanted to use the device outdoors in good weather. He also dictated the comfort and final approval of the prototype.

Requirements

- Standards compliance: The device should comply with ISO standards and other guidance documents provided for upper limb prostheses.
- Interoperability requirements: Interoperability is the design of things to work together. The term implies compatibility and integration without any special customization effort. Each functional joint operated independently to mimic natural movement. Operation should avoid the user maintaining awkward postures. A modular design ensured that the device can operate with as many or as few operational components as needed.
- Interface requirements: Interface occurred at the device socket. The user has specified that the socket must be comfortable, and his experience had shown that a suction style socket is preferred. The electrical interface for the first iteration of the design was to push

buttons for activation. Future iterations of the design may have a more sophisticated means of electrical activation. The interface between the electronic and mechanical components was also a constraint, since careful selection to ensure functionality and compatibility was a concern.

- Hazardous materials: No hazardous materials were involved in the fabrication process or in the device.
- Performance requirements: Refer to Table 1: Traceability Matrix for a full list of design requirements.
- Hardware and software integration requirements: The arm must operate as expected using the electronic controls. In this initial expression of the design, no software was used. Thus, no hardware-software integration was anticipated. Should future iterations of the design require software, a thorough integration test plan will be developed; however, software development was beyond the scope of this design.
- Size and space requirements: All components must fit within the envelope of the device. The device should be stand-alone and require no accessories to operate. This constraint included the limited space within the device considering that the device should be a similar length to Jaiden's other arm.

Maintenance, Supportability, Adaptability Requirements

Minimum maintenance was required. An easily obtained battery was needed to operate the device. Finger and housing components were easily replaceable with 3D printed parts. The CAD files were supplied to the end user to facilitate easy replacement in the event of damage. Other components were made to be durable and readily available for replacement, if required. The device had minimum support required. All documentation was turned over to the client. Training for device operation and maintenance was provided at device delivery. The systems were modular, and thus only included features/parts needed by the user. Components had the option to be operated mechanically or electrically, depending on user preference and power source availability. The device was designed to be adaptable between mechanical and electrical activation so that the device would have easy access to switch actuation type.

Based on these design requirements, the prototype that was created consisted of three main components: socket, elbow, and hand. Solidworks models and drawings of the design can be found in Figure 3, Figure 4 and Figure 5 in the Appendix.

Final Implementation

The final expression of the project was a modular design consisting of a framed ventilated socket, a manually activated elbow, and an actuator driven hand. All external components were 3D printed from PLA or PETG. The Traceability Matrix (Table 1 in the Appendix) provides a link between user needs and final implementation design. Reference the Alpha Model Assembly in the Design History File (DHF) for more detail of the components of the alpha prototype.

The socket was developed in response to the user requirement of comfort and avoiding damage to skin. A "nice-to-have" request from the end user was that the socket minimize sweating. As part of Jaiden's condition, his sweat glands are overactive, so the framed ventilated socket was chosen from the decision matrix and Pugh analysis (See Figure 6 and Figure 7 in the Appendix)

to best meet these user needs. The socket had a Hosmer Northwest harness system, a specific type of ring-harness from SPS (a manufacturer) commonly used with above-elbow amputations. This harness was intended to keep the socket in place, since pressure and a friction fit of the ventilated socket were insufficient for lifting heavier loads. Reference Figure 4 in the Appendix for a Solidworks model of the socket.

The elbow consisted of a ratchet to maximize the amount of available rotation while avoiding flexion of greater than 180 degrees. The elbow could lock at any applied degree of rotation, and direction change was operated manually through a finger lever located on the ratchet. The elbow provided an interface for connection to the socket and the hand through roller latches. This allowed for modularization of the arm: another requirement of the design. Individual latches could support seven pounds, the elbow-to-socket interface had six latches while the elbow-to-hand interface had four latches to ensure the arm would not pull apart under heavier loads. Individual customization for future arms should not require the use of the latch interface, and instead the components can be printed together to reduce the number of components required. Reference Figure 5 in the Appendix for a 3D-printed model of the elbow.

The hand was 3D printed from PLA. The CAD model was developed from a scan of a human hand to meet the user requirements. Each joint of the finger was modeled separately to maximize movement in the "D" configuration per the Pugh matrix (Figure 8). To minimize the inevitable axial rotation of the joints, they were secured using elastic in a similar manner to finger tendons. See Figure 3 in the Appendix for an illustration of the "tendon" location. PVDE fishing line was used to generate the curl needed in the fingers for a barrel grasp. The grasp type was determined through the decision matrix to meet the user requirement for lifting a weight (see Figure 9 in the Appendix for a free-body diagram of hand lifting objects) and to meet the budget and development time frame for design. An actuator contracted the fingers as the shaft retracts, and the fingers passively opened as the actuator shaft extends. The current iteration of the design operates through a DPDT on-off-on switch, with plans for future refinement of user operation.

Validation Test Results

Initial verification and validation testing was completed on the fully assembled prototype. A large majority of the specifications for this project stemmed from specific user needs. Therefore, many product requirements fall under validation testing. A portion of the validation testing included Jaiden filling out a survey indicating his satisfaction with certain areas of the device. Areas such as comfort, appearance, and ease of socket placement were examined during the validation portion of the test plan.

Initial validation of both the hand and the socket design was completed with the end user on March 9, 2019. Please see the initial validation notes from the meeting with the end user in the Appendix. The feedback from this meeting with him was very valuable and the end user's comments and concerns about the alpha prototype were incorporated into the beta model of the socket. The alpha prototype of the hand only received minor adjustments, but was not reprinted prior to testing of the fully assembled prototype.

The second round of validation testing was conducted on April 13, 2019 with the end user. This validation testing was conducted on the fully assembled prototype, which consisted of the alpha hand, alpha elbow and beta socket. Please reference second validation notes in the Appendix for feedback from the second validation meeting with the end user. The feedback from this meeting was mostly positive. The end user was able to don and doff the arm by himself and in a short amount of time. The end user was also very pleased with the aesthetics of the arm, specifically the shape and color of the hand. There were a few downfalls of the initial prototype design. The elbow component of the arm made the device bottom-heavy. The end user is not custom to wearing a prosthetic arm which may influence his views on the overall weight and feel of the device. Once the end user becomes custom to wearing the device, his standpoint on the weight and feel of the device should change in a positive direction. A second downfall of the device was in the form of activating the different components of the device. The hand is activated with a push switch and the elbow is a ratchet system which must be turned in order to activate it. The end user was not able to activate either of these components by himself. A more conducive mode of activation for the end user should be considered in future designs iterations.

For more test results stemming from end user validation, reference Table 2: Compact Test Results in the Appendix, specifically Test #5, Test #6 and Test #16. For objective scoring for the validation testing of the device, see Test Report #16 which contains the survey the end user completed during the second validation meeting. For more detail about individual tests (such as objective, background, protocol, results and conclusions), see the Test Plan or the individual test reports in the DHF.

Business Aspects

The Auxilia Project was funded by the nonprofit organization, and client, Donovan's Kids Inc. Since this project was designed for one specific user, this specific design cannot be marketed or commercialized. However, if Donovan's Kids Inc. plans to advertise these prosthetic arms to their other children in need, they could be in a good position to do so. At the inception of the project, the client requested a unique design rather than directly using an open-source printable prosthetic. This decision was made to preserve any potential intellectual property for the client to build a business upon. Although the designs for a final product/device will not be ready at the conclusion of this project, with a few more months or years of work, they could have a legitimized product that is easily manufactured, relatively cheap, and adjustable for children of all sizes.

The global robotics prosthetics market size was estimated at USD 790.8 Million in 2016. Key factors that are currently driving this market are the growing number of amputation and injury cases, technological advancements, and the holistic growth of the population as a whole. In terms of expected growth within this segment, it is expected to see a growth of 16.4% in the global prosthetics market, by 2022 [1]. In terms of current design patents, of the 335 patents reviewed, only 25 total design patents were applicable and taken into account throughout the design of the device.

The current 3D printing market revenue is expected to exceed 3.89 billion by 2022, and since rapid 3D printing allows customization for complex shapes, it could be possible to design arms

for a large variety of shapes, sizes, and tasks [12]. With 700,000 people in the US having an upper-limb amputation, and 6.8 million people in the US having fine motor and arm dexterity limitations, it can be well assured that there will always be customers in need [12].

Deliverables

The alpha prototype for the socket was initially validated by Jaiden at a meeting held on March 9, 2019, and the beta prototype for the socket was validated by Jaiden at a meeting held on April 13, 2019. The subsystems of the alpha prototype were tested individually. The alpha prototype was a proof of concept prototype. The materials for the alpha were analyzed, tested, and/or justified for their specific system purpose to ensure that the component would meet the design requirements. A fully assembled alpha prototype was tested during the week of April 8th, 2019. The socket component of the device was revised since the first meeting with Jaiden and was the only fully revised and reprinted component of the prototype. During capstone day, this same alpha prototype was seen and functioned as it did during testing and during the latest meeting with Jaiden. After the capstone day presentation, the prototype was delivered to Donovan's Kids Inc. in order to continue the project to a fully functional device in the future. A final DHF and report was compiled and delivered to both the College of Engineering at the University of Akron and to Donovan's Kids Inc. Capstone day marked the end of the project for the Senior Design Students.

The ultimate deliverables of the final project, in April 2019, included the following: prototype prosthetic arm assembly, maintenance manual, and documentation of development method (CAD drawings, specifications, final report, and DHF). With the exception of the prototype, these items were delivered to the professor and to the client, Donovan's Kids. The prototype was delivered to Jaiden Foden via Donovan's Kids.

Scope of the Work Excluded

The scope of the project changed slightly during the second semester of this project. Initially, the goal of the project was to provide an arm for Jaiden so that he would be able to ride a hand cycle. As initial testing was completed, it was realized that the force needed to propel a hand cycle was not feasible for the 3D printed prosthetic arm. The actuator that would be needed for the force requirement did not fit the size requirement specified. The actuator needed to fit in a space the size of a forearm, and the more force the actuator provides, the larger it is. Also, a second design team was working on updating the hand cycle. Since this team was working on the bike for Jaiden, an actual force reading could not be measured to dictate how much force was needed to propel the hand cycle. Therefore, the requirement that the arm would allow Jaiden to ride a hand cycle was modified to increase his overall independence instead so a smaller actuator could be used.

A second component that was modified included the wrist/forearm portion of the device. It was originally decided that a wrist rotation would be included in the design to aid in functionality of the device. This wrist rotation was excluded due to the complexity of the system and the time constraint of the project.

Performance Test Results

Testing was conducted on the fully assembled prototype during the week of April 8th, 2019. The fully assembled prototype consisted of the beta socket, alpha elbow, and alpha hand. Once all testing had been performed, data and results were analyzed and evaluated. Both verification and validation testing were performed prior to the conclusion of the project. Finite element analysis, as well as material testing, were also performed during the course of this project.

The verification portion of the test plan included examining the performance requirements of the device. See Table 1 in the Appendix for a list of tests that were performed during the project, including beyond the alpha prototype. Table 2: Compact Test Results in the Appendix displays a compact summary of the test results for all tests that were completed (both verification and validation). For more detail about individual tests (such as objective, background, protocol, results and conclusions), see the Test Plan or the individual test reports in the DHF.

A majority of the testing that was conducted indicated very positive results. For example, the hand component of the device was able to pick up an egg without crushing it and close into a barrel grasp position that was less than 2 inches in diameter. A few more passing test results included the overall weight of the device which was less than 6 pounds and the total cost of the device was under budget. There were also a few tests that showed poor test results. A few areas of the design that showed the greatest points of concern were identified in Test #2, #16, and #17. These tests had results that failed (fell outside of the specification range) or showed areas that could be greatly improved. For Test #2, the results concluded that the current prototype cannot currently lift a full bottle of water. For Test #16, the results indicated that the socket did not fit as intended, as it was slightly uncomfortable and rubbed against Jaiden's 'palm'. For Test #17, the results conclude that the range of motion of the elbow fell outside the anatomical range set in the design requirements. See the Future Work section for future design changes that should be implemented to improve these areas of the device.

Different types of analyses were also conducted throughout the course of the project. Finite element modeling and analysis (FEA) was performed on the socket and hand component of the device. The results from these analyses indicated that the weight of the socket should not induce major stresses or strains on the geometry of the socket, and that a force of 200N can be applied by the actuator to the fingers without major stresses or strains affecting the chosen NinjaFlex material. Specific results from the FEA socket analysis can be found in Figure 10, Figure 11, and Figure 12. Specific results from the FEA finger analysis can be found in Figures 13, 14, 15, 16, 17, and 18 in the Appendix. Refer to additional reports in the DHF for further details of these analyses.

A battery and power use analysis was also conducted on the actuator in the hand component of the device. The results from this analysis indicated that the battery system selected should have a lifetime of 6.3 hours at a 12 Volt power usage, which is more than the minimum specification of 2 hours. Results of this test can be found in Actuation and Battery Analysis and Figure 19 in the Appendix. For more detail of the actuation and battery analysis, reference Test Report #12 in the DHF.

Lastly, material testing was conducted on NinjaFlex, which is a material that can be used in 3D printing. The NinjaFlex material is a material option for the beta model of the hand. A uniaxial tensile test was conducted on this material to determine material properties. Two different strain rates were evaluated. The results indicated that NinjaFlex is a hyperelastic material and that the material constants are dependent on the strain rate that is utilized during testing. According to the plot of the data and the model (Figure 20 in the Appendix), the material was stiffer at the slower strain rate between 1.1 and 1.55 λ. The amount of stress per the amount of strain was greater in the slow strain rate model. No further conclusions can be drawn since the samples were not tested to failure.

Progress

In the beginning, the primary requirement had been to let Jaiden ride a handcycle that had been purchased for him by Donovan's kids. However, after analysis of the handcycle design, it was determined that it needed modifications, which would be handled by a separate team. Since it had been difficult maintaining contact with the handcycle team, it was agreed to change the primary requirements to focus on independent use instead. As the project progressed, it became more and more evident that the proposed timeline was too optimistic for the scope of this project. As a result, the team decided not to over-stress our resources in order to make a functional beta prototype, and instead the resources were put towards verification, validation, analysis, and thorough testing of the alpha prototype subsystems. Some of the requirements are only required/can be tested with the beta prototype, however. These requirements include prevention of blisters after 18 hours of daily use, mechanical stability after 6 months of use, and IEC 60601-1 and -2 compliance for electrical safety and IP ratings. Due to the limited time constraints, these specifications were unable to be tested, but plan to be as the project continues with the next group to work with Donovan's Kids.

Individual Contributions

At the beginning of the Fall 2018 semester, all team members were assigned the following roles:

- Nicholas Duliba - Primary Role: Systems, Secondary Role: Project Coordination
- Christopher Halley - Primary Role: Hardware, Secondary Role: Purchasing
- Lindsay Jaros - Primary Role: Electrical, Secondary Role: Documentation Manager
- Sara Toich - Primary Role: Mechanical Design, Secondary Role: Analysis
- Autumn Young - Primary Role: Report Coordinator, Secondary Role: Intellectual Property

For the most part, each individual team member had been able to handle their workload, but when challenges arose the other group members stepped up and were able to help with whatever parts were in their areas of expertise.

The following were the main contributions from each team member:

- Nicholas - Market and business analysis
- Christopher - Socket design, meeting minutes, and budget analysis.
- Lindsay - Test plan, status updates, and documentation
- Sara - Hand design, traceability matrix, and client communication
- Autumn - Elbow design

Table 3 in the Appendix shows the Work Distribution Form 007 that was used to track hours throughout the project. The hours recorded reflect the main contributions previously listed.

Financial Consideration and Benefits

Overall, the only financial consideration was the design requirement provided, to reduce cost as much as possible. Throughout the project, a component analysis and budget analysis have been completed in order to ensure that all parts meet the required specifications without stressing the available budget. Every time a part was determined necessary for the design, several vendors and sources were considered in order to determine a rough price for what the market cost is. A number of factors then contributed to the actual purchase including quality, previous experience, special deals/discounts, and shipping time. As the target goal has changed from riding a handcycle to generic daily independence, so has the focus of the components and their required limitations. Examples include actuator force, socket pressure, and elbow adjustability.

There are many benefits to be experienced from the use of the device. The main benefit experienced from the use of the device is an increased independence in daily life. By using our device, individuals will be able to function more independently and require less outside assistance in completing daily tasks such as brushing teeth and using the restroom. A second benefit experienced by using the device is a sense of normalcy. Having a prosthetic limb that resembles a normal human hand provokes less attention from strangers and provides a sense of normalcy to the individual.

Summary Feasibility Discussion

At the end of this project, the device was categorized as a prototype by the team, specifically an alpha prototype. In order to fully and thoroughly design with intent, some components initially considered in the project proposal had to be edited, reorganized, or pushed back. With the same time requirement, this left the team with only being able to test all subsystems of the alpha prototype and begin design modifications for the beta prototype. While a fully assembled and functional beta prototype was not able to be achieved, the alpha prototype was able to successfully pass a majority of the tests that were conducted based on the design requirements proposed near the beginning of the engineering design process. The tests that the fully assembled prototype successfully passed include:

- Test #1: Barrel Grasp Dimension
- Test #4: Adjustable Grip Strength
- Test #5: Donning and Doffing the Arm
- Test #6: People Required to Don or Doff Arm
- Test #7: Socket/Arm Length
- Test #11: Power Use
- Test #12: Cost Analysis
- Test #13: Device Weight
- Test #16: Customer Validated Specifications

The prototype failed two of the tests that were conducted. The two tests that did not have a passing result include:

- Test #2: Lifting Weights
- Test #17: Elbow Range of Motion

Although not all tests provided a passing result, the current design as well as future revisions of the design will be able to successfully provide Jaiden with greater independence while still meeting all physical requirements such as weight limit, cost effectiveness, and comfort.

Future Work

At this point in time, future work on the project is still being considered. Most of the future work includes the completion of additional testing of the device and design. Destructive testing was not performed due to the limited resources and time constraint of the project. Also, tests that required the end user to wear the device for extended periods of time and tests that required extensive time to conduct were excluded due to the time constraint of the project. For example, durability testing and stress testing of the entire assembly were not performed since these tests require large amounts of time and are expensive to conduct. These tests, and others like them, should be considered in the future.

A Failure Modes and Effects Analysis (FMEA) was created to identify potential failure modes for both the product and the program/overall development and delivery of the device. The FMEA was also used to suggest mitigations or controls to address each failure mode. The Product FMEA and the Program FMEA can be found in Table 4 and Table 5, respectively.

Based on both the verification and validation test results, multiple improvements should be incorporated into the design. The main areas of the device that should be focused on include socket comfort, elbow range of motion, elbow and hand activation, and hand grip strength.
The following lists the possible design considerations and areas of improvement that could be implemented in order to improve the design.

- Replace the actuator with one that provides more force/more strength
- Increase finger stability (possibly by utilizing NinjaFlex material) to grasp heavier objects
- Decrease overall weight of the arm or distribute the weight of the arm more evenly (arm is currently bottom heavy due to the elbow and hand components)
- Improve suspension of the socket so that the weight of the arm does not pull device out of fixation over time
- Redesign socket to provide a more snug fit without causing areas of excessive rubbing and irritation
- Redesign socket to allow end user to fully lower his arm
- Improve elbow design so range of motion falls within the anatomical range of motion for the human elbow
    - Add stopping mechanism to current elbow design to prevent rotation past 180 degrees
- Add lever to elbow ratchet to aid in activation of this component by the end user
- Move switch that activates hand to the socket so it can be activated by the end user or replace switch with one that can be activated by user if placed on forearm component of the device

It was also noted that one-on-one meetings with Jaiden were extremely productive, and produced the greatest amount of constructive feedback for the project. It is highly suggested that more frequent meetings with Jaiden be scheduled.

Discussion, Conclusions, Lessons Learned and Recommendations

Overall, the design team was able to work together to produce a functioning prototype for Jaiden. Team meetings were held on a weekly basis, with most weeks containing at least two team meetings. The tasks of the project were evenly divided among the members, with each member taking tasks that were in their field of expertise. Some team members were more familiar with Solidworks and therefore focused on part design and drawings. Other members had more experience in the business and quality aspect of engineering design and took tasks more focused on these areas.

The hardest portion of the project was determining specifications from the requirement forming stage. It was difficult for the team to formulate specifications from user needs. Another portion of the project that was difficult to manage was the client's expectations for the device. Due to the varying voices of the customers, the project did experience some scope creep. To determine the path moving forward, the initial MOU was referenced to keep things on track.

The team utilized decision matrices during the brainstorming process to aid in the design of the device. When issues arose around the design of the device, the team referenced the decision matrices to reinforce decisions that were made. Research was also conducted to aid in making decisions concerning the project.

Additional items to consider include purchasing and reimbursement issues, testing, report writing, outsourcing issues, mentorship guidance and course length. The senior design project is intended to be an inclusive learning experience overall, but the largest lessons learned in this project include the following:

1. Capitalize on previous designs. Non-technical clients should have less influence on dictating design origin.
2. Planning ahead despite unknowns when budgeting a project.
3. Implementing a ground-up design process, from ideation to implementation and testing.
4. Be more aggressive in finding a technical advisor. Most prosthetists do not work on above-elbow (AE) prostheses because of their complexity.
5. Setting up a weekly deliverable schedule rather than a Gantt chart.
6. Have more working meetings than high-level decision-making meetings.
7. Have design reviews with experienced engineers/technical advisors to review design to make adjustments earlier.
8. Build things earlier than planned to work out design flaws.

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Appendix

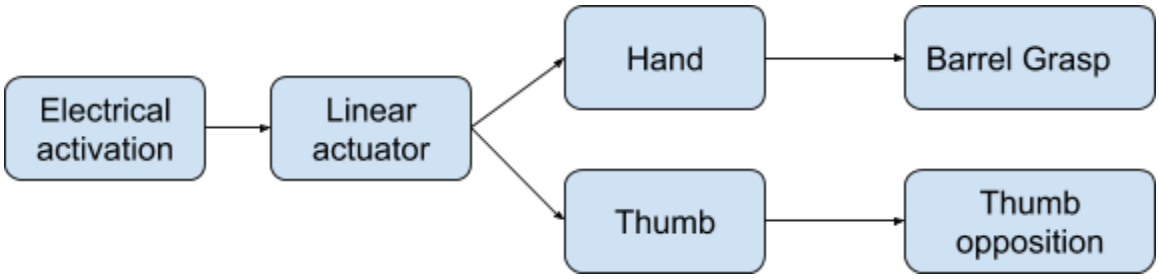

Figure 1: Electrical Activation Block Diagram

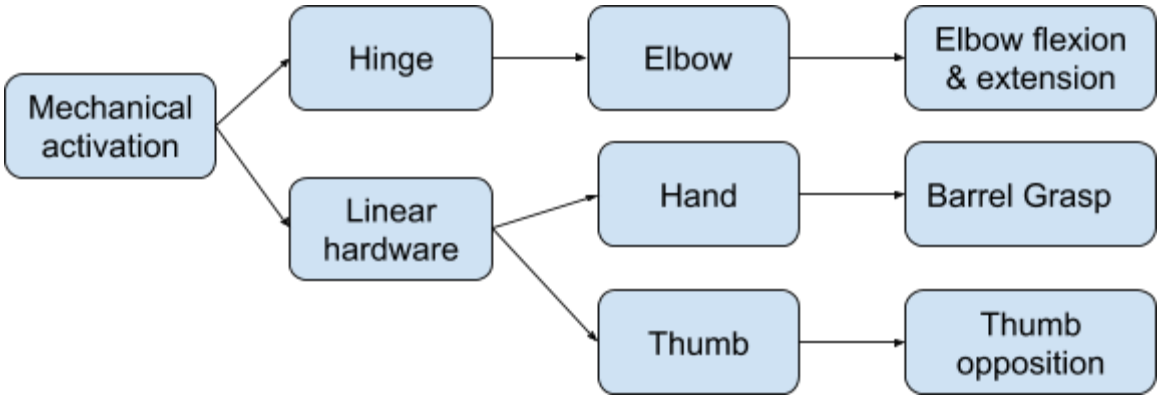

Figure 2: Mechanical activation. The same output is expected as the Electrical Activation method. Mechanical hardware and electrical hardware should be compatible.

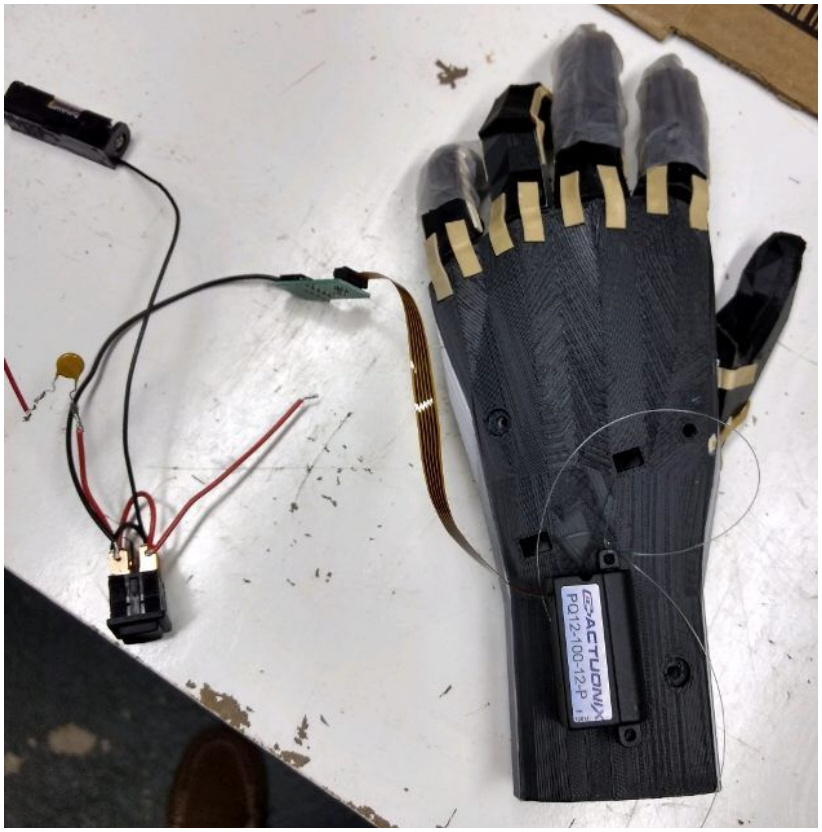

Figure 3: Alpha Prototype for Hand Subsystem

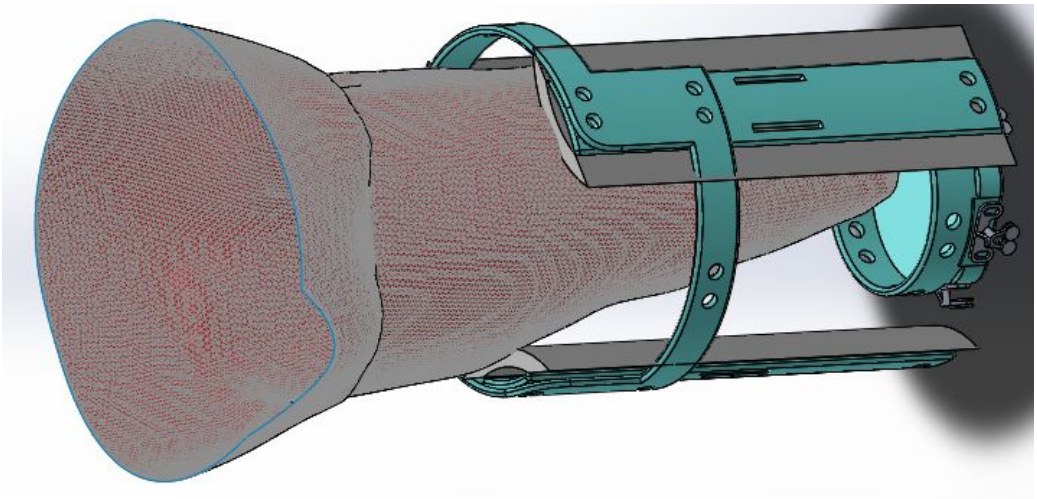

Figure 4: Solidworks Model of Socket Subsystem with 3D Scan of Jaiden Foden's Residual Limb

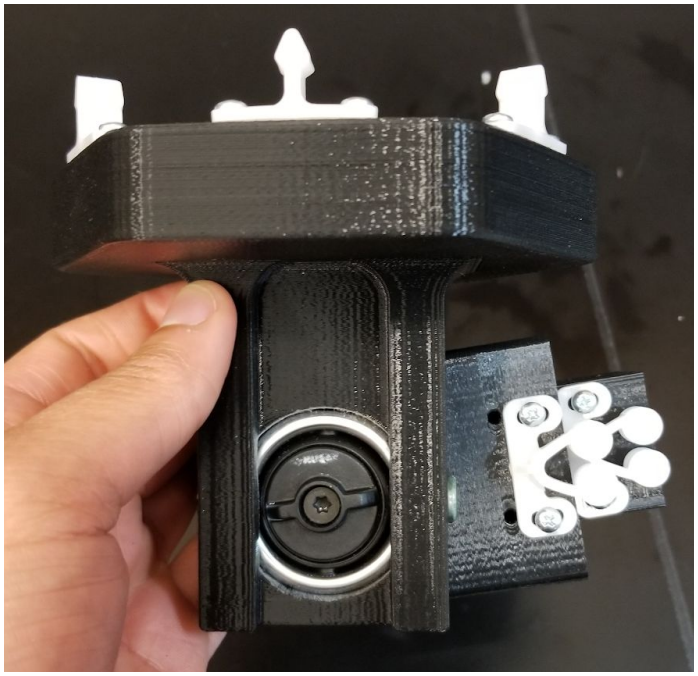

Figure 5: Alpha Elbow

Socket Types						
	4	5	3	4	5	21
	19%	24%	14%	19%	24%	100%
Option	One-handed don/doff	Comfortable	Ventilated	Complexity	Minimizes Cost	Score
Suction	75	100	0	35	50	260
Harness	10	25	35	75	75	220
Ventilated Shell	75	75	85	35	25	295
Sleeve	10	65	35	65	30	205

Figure 6: Socket Design Decision Matrix

Criteria	(Datum) Suction Socket	Flexible Socket-Vaccuum	Framed/Ventilated Socket	Harness
Comfort	0	+	0	-
Easy attachment/detachment	0	0	+	-
Cost	0	0	0	0
Complexity	0	+	+	+
Attachment Durability	0	0	+	+
Functionality	0	0	+	-
Lifting Capability	0	0	+	0
Weight	0	0	-	0
Customizability	0	0	0	-
3D-printability	0	0	0	0
Breathability	0	0	+	0
+	0	2	6	2
0	11	9	4	5
-	0	0	1	4

Figure 7: Pugh Analysis for Socket Design

Criteria	"D- Hand"	Importance Factor (1-5, 5 most important)	UNLV Hand	Ada Hand	Unlimited Tomorrow
Cost	0	5	0	-	0
Complexity	0	5	0	+	0
Power Usage	0	3	0	0	0
Durability	0	4	0	+	-
Movement	0	3	0	0	0
Functionality	0	4	0	0	0
Weight	0	4	-	-	0
Lifting Capability	0	4	0	0	0
Aesthetics	0	4	+	+	0
IP	0	5	-	-	-
3D - printability	0	3	0	0	0
+			1	3	0
0			8	5	9
-			2	3	2

Figure 8: Pugh matrix for Hand Configuration

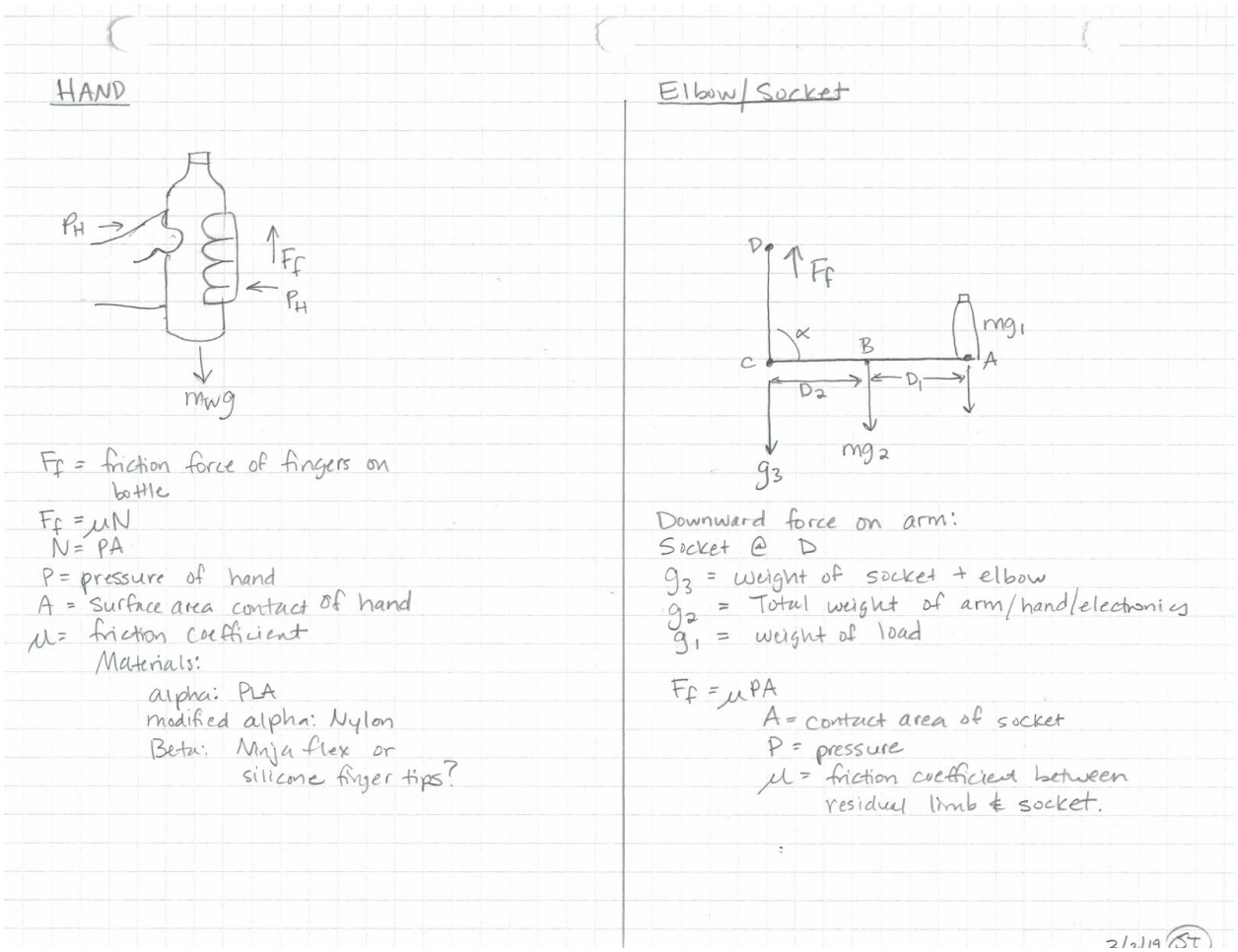

Figure 9: Hand and Elbow System Free Body Diagram

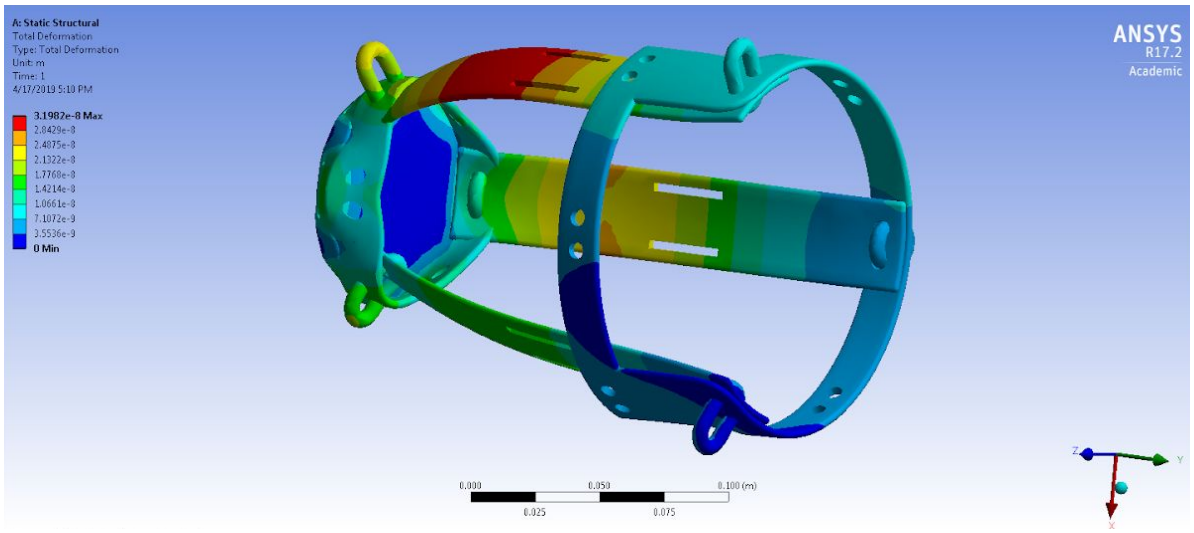

Figure 10: Finite Element Analysis of Socket Design in PLA- Total Deformation

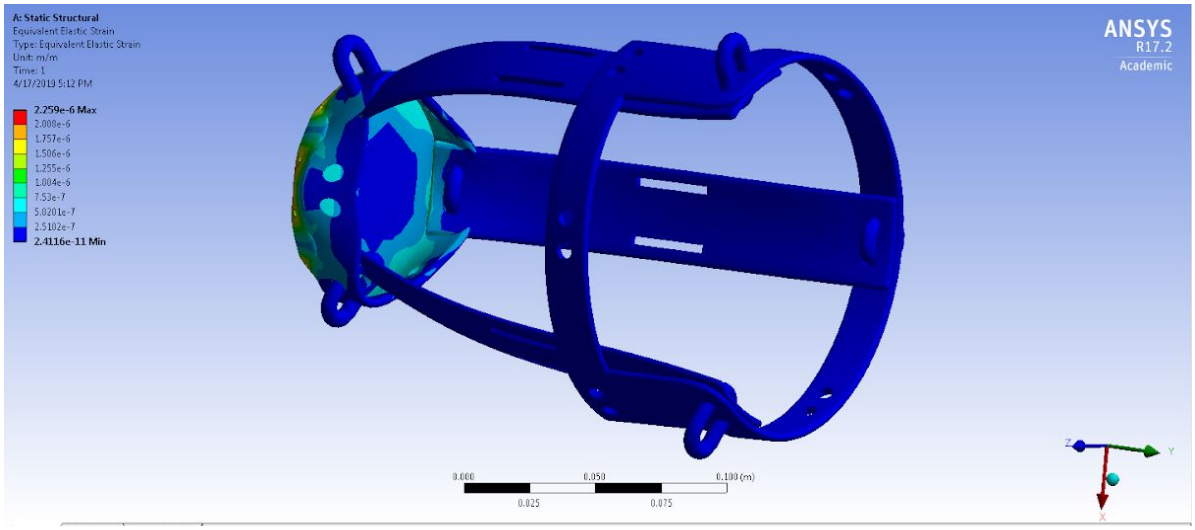

Figure 11: Finite Element Analysis of Socket Design in PLA- Equivalent Strain

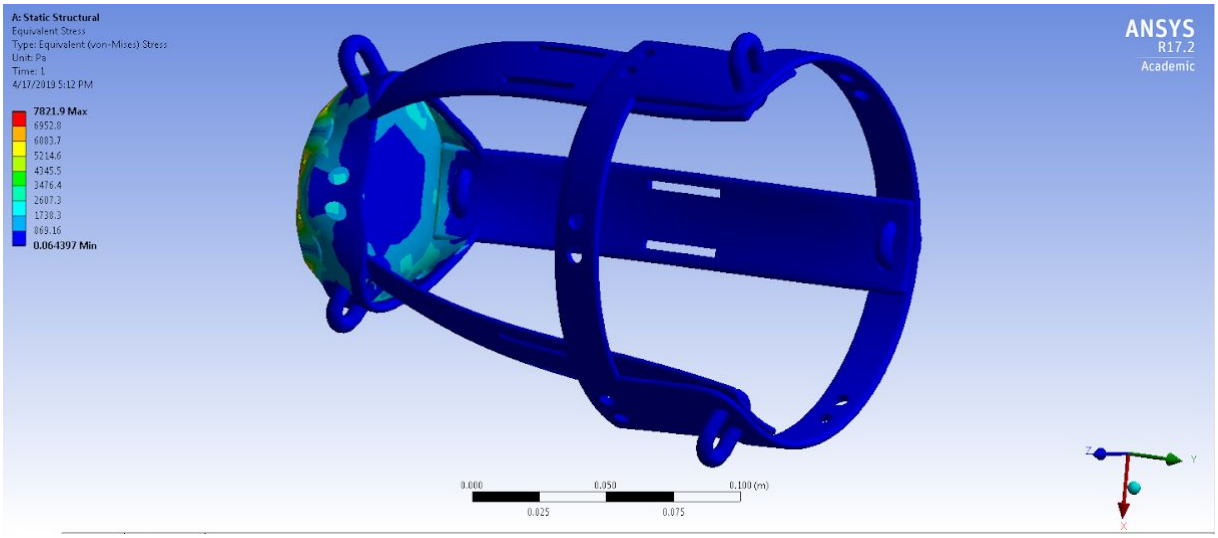

Figure 12: Finite Element Analysis of Socket Design in PLA- Equivalent Stress

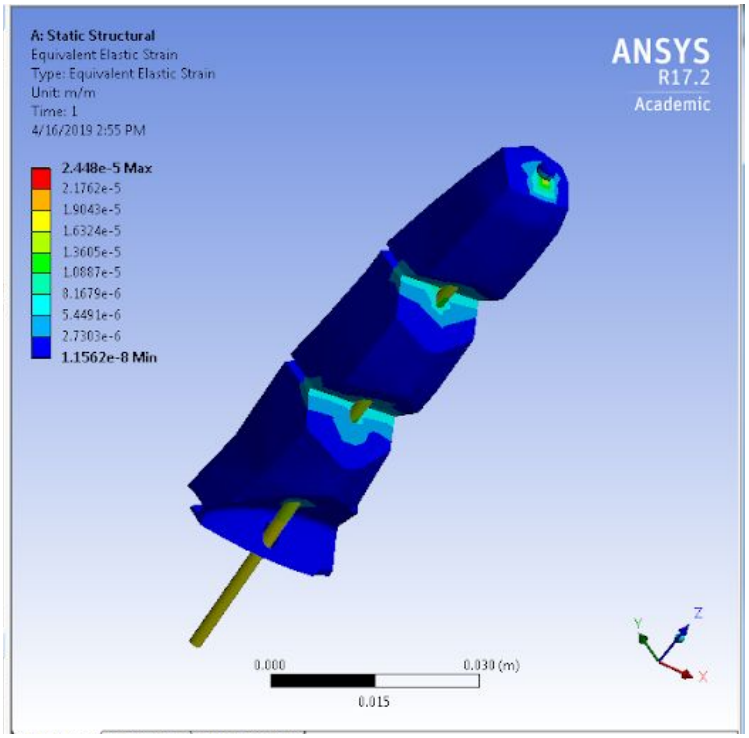

Figure 13: Finite Element Analysis of Finger Design in NinjaFlex - Equivalent Elastic Strain for 50 N actuation force

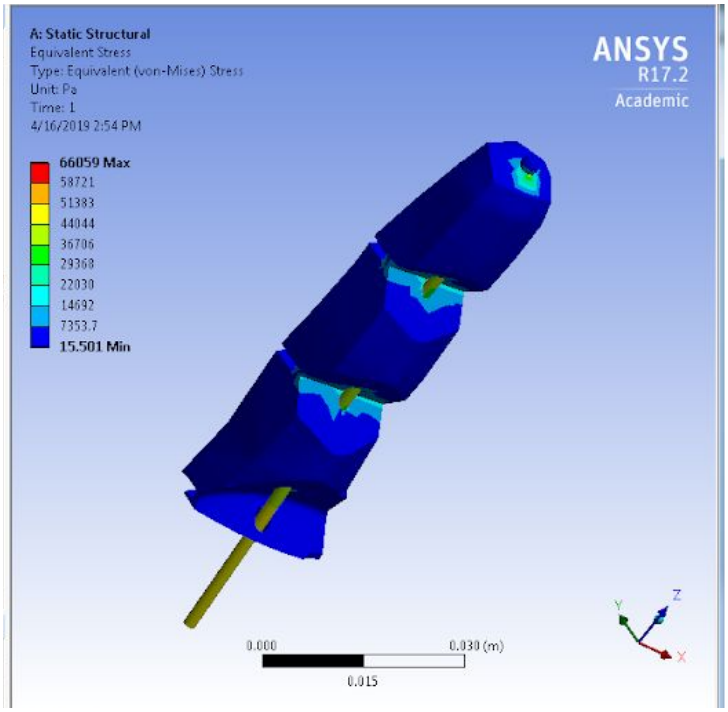

Figure 14: Finite Element Analysis of Finger Design in NinjaFlex - Equivalent Stress for 50 N actuation force

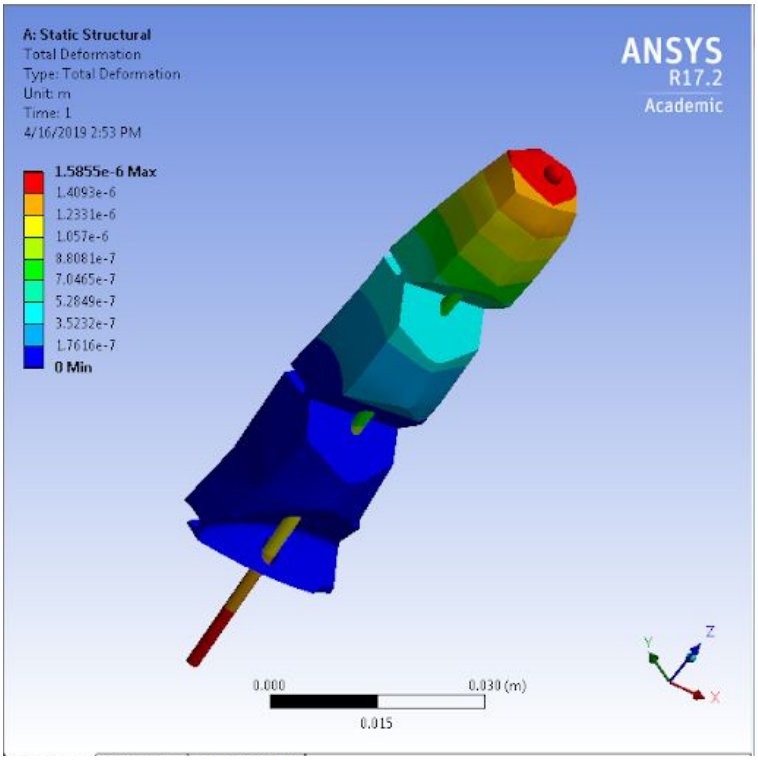

Figure 15: Finite Element Analysis of Finger Design in NinjaFlex - Total Deformation for 50 N actuation force

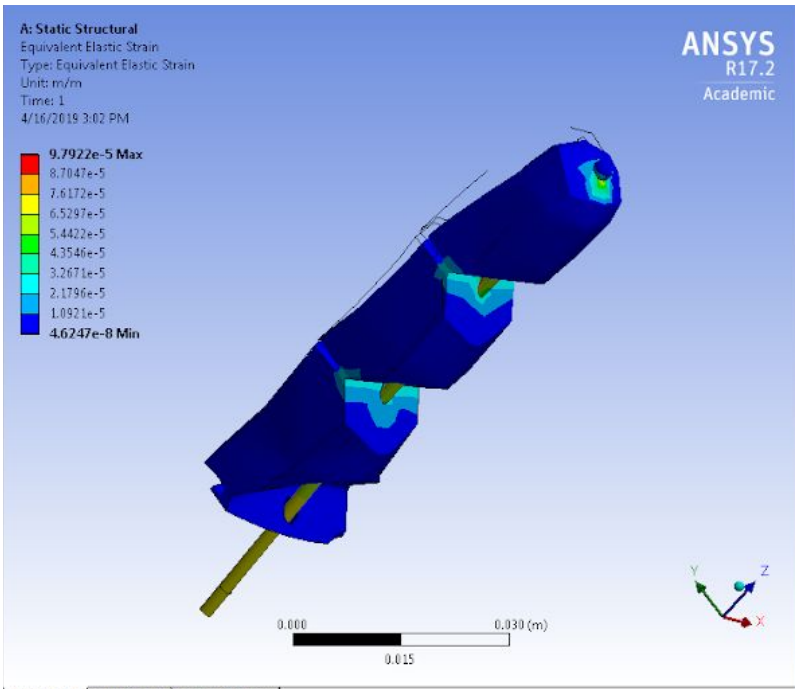

Figure 16: Finite Element Analysis of Finger Design in NinjaFlex - Equivalent Elastic Strain for 200 N actuation force

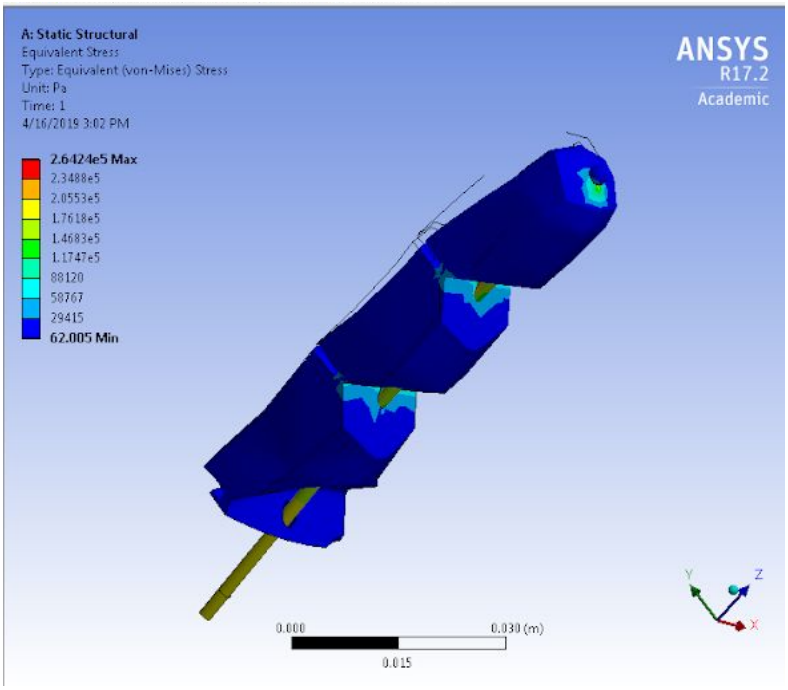

Figure 17: Finite Element Analysis of Finger Design in NinjaFlex - Equivalent Stress for 200 N actuation force

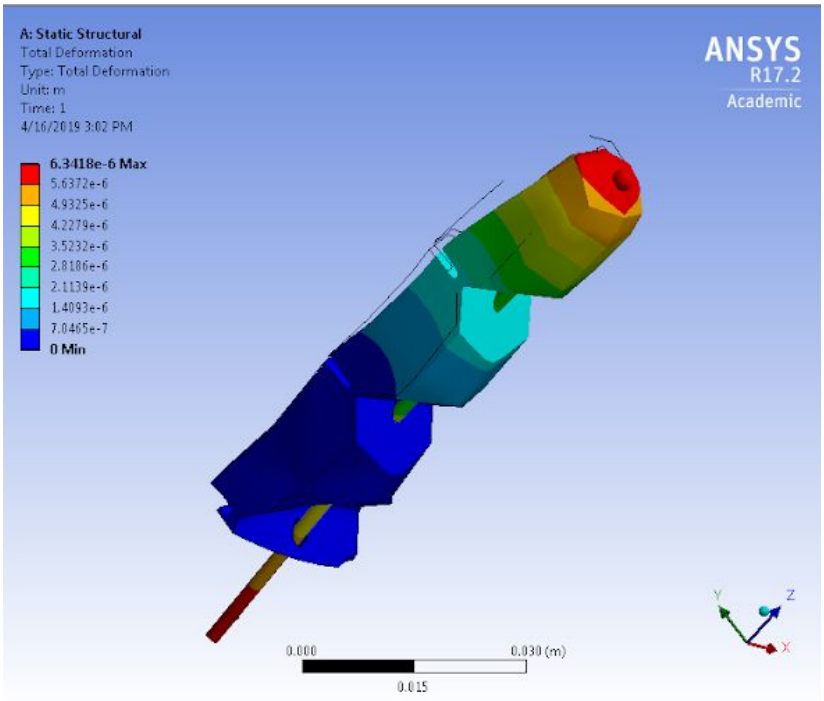

Figure 18: Finite Element Analysis of Finger Design in NinjaFlex - Total deformation for 200 N actuation force

Actuation and Battery Analysis

In terms of electrical power options that would help our prosthetic device carry out user desired functions, analysis was done to prove the power needs, battery lifetime, and actuation feasibility. Tests that were used to help aid the argumentation for why specific parts where desired over others were due to: Circuit analysis, power output needs, Lifecycle testing, and device constraints. Circuit analysis was done with both battery options (Energizer A23 Battery & Energizer E92 Batteries). The outputs of these tests yielded an expected battery lifetime of 6.3 hours, and 3 hours respectively. While these calculations were performed a couple of major variables were taken into account to ensure the feasibility of implementation. These variables included battery capacity, discharge, voltage, and overall cycles. To calculate the expected lifetime of our battery options within the circuit, we understood our maximum power needs (dictated by our desired actuators), and referenced various technical specifications to ensure expected lifetime. It was with the understanding of these constraints that allowed for the proper selection of Energizer E92 coupled with our Accutronix L16 actuators.

Expected Lifetime Testing: Energizer A23 = 6.3 Hours / 378 Minutes ; Energizer E92 = 3 Hours / @ 6 volt actuator.

Expected Lifetime of 12 Volt Actuator: Energizer A23 = 2 Hours / 90 Minutes; Energizer E92 (4 Pack Connection) x 2 = 6 hours (Recommended).

Cycles Testing (Via Technical Analysis Reporting): Actuonix - 300,000 Cycles w/ linear switch modification vs 210,000 Cycles of Smaller series.

Device Constraints: Actuation being to large, not enough space within housing.

Recommended Set Up (For Beta Prototype) - Two Energizer A23 @ a Actuator of 12V (Accutronix L16) (Essentially, doubling up on our current design with a higher voltage actuator.)

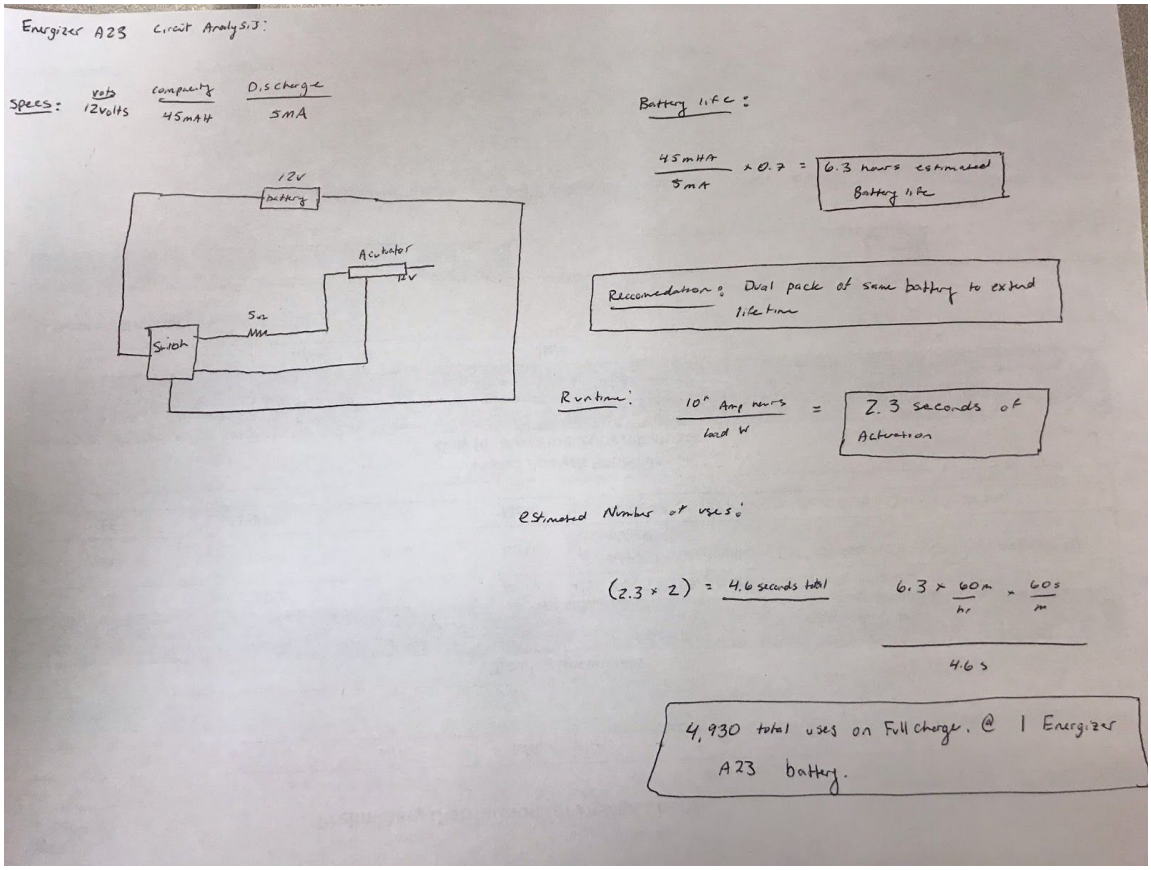

Figure 19: Circuit Analysis for Battery and Power Use

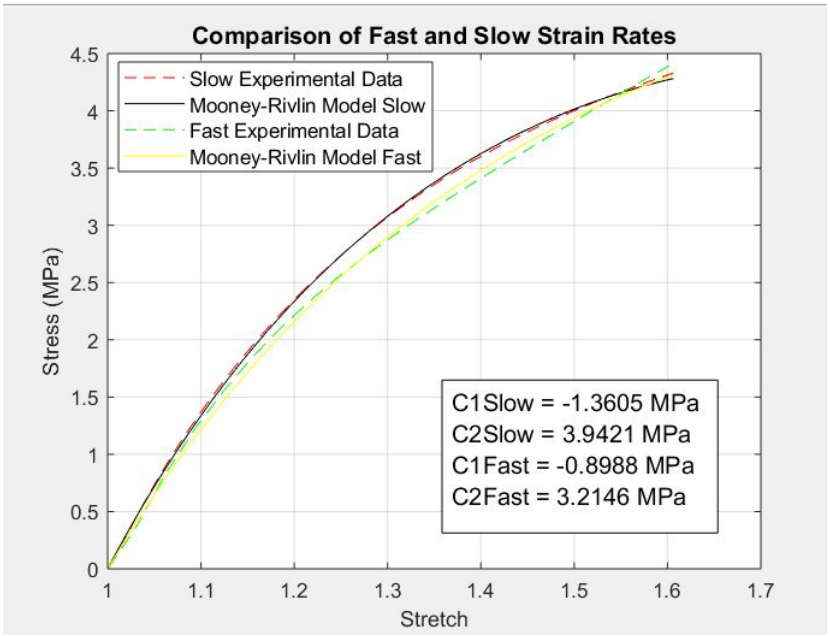

Figure 20: Material Testing Results

Table 1: Traceability Matrix

	Customer Need	Product Requirement/Design Input	Metric	Design Specification/Design Output	Verification Requirement	Test Methodology	Acceptance Criteria	Test Result
1.1	Daily use/Independence	Hand must grasp different size objects	Minimum grip size must be at most 1.5"	Angle between finger joints 90 degrees	Verification: Stackup Analysis	See Test #1 in the Test Plan	Grip size less than 1.5"	Pass
1.2		Lift at least 5 lbs	Will have to measure	Actuator	Verification: Test Plan	See Test #2 in the Test Plan	Must lift a minimum weight of 5 lbs without failure	Fail
1.3		Finger Grip	4.7 N contact force barrel grasp	Actuator	Verification: Test Plan	See Test #3 in the Test Plan	4.7 N contact force barrel grasp	Test was not conducted. No Result Available.
1.4		Adjustable grip strength	Able to pick up an egg without crushing it?	Actuator control board: PCB	Verification: Test Plan	See Test #4 in the Test Plan	Egg remains intact when picked up - no breaking of egg upon grasp	Pass
2	Reduce fatigue in right hand	Reduce fatigue - approval from Jaiden	Survey score of 5 or more (10 is reduced all fatigue, 1 is reduced no fatigue)	Sufficient device function	User Validation	See Test #16 in the Test Plan	User is satisfied with arm's ability to reduce fatigue - Answer of 5 or higher on survey	Test was not conducted. No Result Available.
3.1	Easily attachable/detachable	Must take a short amount of time to put on	less than 5 minutes	Socket Diameter, harness size	User Validation	See Test #5 in the Test Plan	Time to don arm is less than 5 minutes	Pass
3.2		Must take a short amount of time to take off	less than 1 minute	Socket Diameter, harness size	User Validation	See Test #5 in the Test Plan	Time to doff arm is less than 1 minute	Pass
3.3		Cannot drop to floor suddenly upon release	Pass/fail	Harness system with socket prevent unintended detachment	User Validation	See Test #16 in the Test Plan	Harness System prevents device from unintended detachment - removal of residual limb from socket does not result in arm falling to ground suddenly	Pass
3.4		Number of people required to don or doff	1 person/1 hand	Backpack style harness	User Validation	See Test #6 in the Test Plan	User is able to don/doff arm by himself without aid from others	Pass
4.1	Comfortable	Should decrease amount of care required for day (powder/gel/lubricant)	Customer validated	Ventilated shell socket	User Validation	See Test #16 in the Test Plan	User is satisfied with care needed for arm - answer of 5 or higher on survey	Initial validation passes
4.2		Socket size	Max socket length 8.75" (Axilla to distal end of residual limb)	Socket length	Verification Analysis: Dimensional Inspection	See Test #7 in the Test Plan	Socket length less than 8.75"	Pass

4.3		Quiet operation	Less than 35 dBA	User validation or <35 dBA	User Validation	See Test #16 in the Test Plan	User is satisfied with noise produced by arm - answer of 5 or higher on survey	Pass
6.1	Looks like a hand	Must resemble general anatomic shape of human hand	5 Fingers	Five finger design; 1 DoF for fingers, 1 DoF for thumb for a barrel grasp	User Validation	See Test #16 in the Test Plan	User is satisfied with aesthetics of the arm - answer of 5 or higher on survey	Pass
6.2		Must acquire aesthetic approval from Jaiden pre-building	Pass	Color, shape, surface, material	User Validation	See Test #16 in the Test Plan	User is satisfied with aesthetics of the arm - answer of 5 or higher on survey	Pass
6.3		Must acquire aesthetic approval from Jaiden post-building	Pass	Color, shape, surface, material	User Validation	See Test #16 in the Test Plan	User is satisfied with aesthetics of the arm - answer of 5 or higher on survey	Pass
6.4		Should be close to same length as his other arm or slightly shorter	Equal or shorter than other arm: Floor to thumb length 32"	Overall length of arm assembly	Verification Analysis: Dimensional stackup	See Test #7 in the Test Plan	Floor to thumb length of 32" +/-1"	Pass
7.1	Avoid damage to skin	Should not cause blisters	0 blisters present after 18 hours of daily use	Socket material contacting user	User Validation	See Test #16 in the Test Plan	No blisters form on user after device is worn for 18 hours	Test was not conducted. No Result Available.
7.2		Should be smooth skin-to-socket interface	Customer validated	Ventilated shell socket, smooth and comfortable finish	User Validation	See Test #16 in the Test Plan	User is satisfied with the smoothness of the socket and smoothness finish spec of material contacting user is	Pass
7.3		Biocompatibility - ISO 10993 for cytotoxicity & sensitization	Pass (or pass particular section)	Socket: Cytotoxicity & Sensitization for Surface device, permanent contact. remainder: surface device, moderate contact	Verification: Testing	See Test #8 in the Test Plan	Materials that contact residual limb pass biocompatibility testing	Test was not conducted. No Result Available.
8.1	Durable	ISO 22523:2006	Environmentally stable 6 months use	UV light exposure	Verification: Testing	See Test #9 in the Test Plan	Device does not show breakdown or failure after UV light exposure	Test was not conducted. No Result Available.
8.2				Exposure to body oil & lotions	Verication: Analysis	See Test #9 in the Test Plan	Device does not show breakdown or failure after being exposed to body oil and lotion	Test was not conducted. No Result Available.
8.3				Water Ingress (ie, rain): Water resistant IP 54	Verification Testing	See Test #9 in the Test Plan	Device does not show breakdown or failure after	Test was not conducted. No

							water ingress	Result Available.
8.4				High temp/high humidity stress testing	Verification testing	See Test #9 in the Test Plan	Device does not show breakdown or failure after being exposed to high stress/high temp environment	Test was not conducted. No Result Available.
8.5			Mechanically stable: Cycle tested for 6 months of use	Hand can open & close for 20,000 cycles	Verification Testing	See Test #10 in the Test Plan	Device failure does not occur prior to 20,000 cycles	Test was not conducted. No Result Available.
8.6			Power use: replaceable or rechargeable batteries	4 AAA batteries for electrical operation	Validation: Analysis	See Test #11 in the Test Plan	See battery analysis - how often will batteries need to be replaced? could put that spec here	Pass
9	Low cost	Reduce Cost of Materials & Manufacturing	Myoelectric: $20-30k, Standard: $5-10k	Device costs under $1500	Validation: Analysis	See Test #12 in the Test Plan	See budget analysis or BOM	Pass
10	Lightweight	Minimize overall weight	Less than 6 pounds	Device overall weight:	Verification: test or analysis	See Test #13 in the Test Plan	Overall weight of arm less than 6 pounds	Pass
11.1	Safe	Overall system must be safe to use in a variety of circumstances	Electrical safety	IEC 60601-1 and -2 compliant	Verification: test or analysis	See Test #14 in the Test Plan	Device is IEC 60601 Compliant	Test was not conducted. No Result Available.
11.2			Water Ingress: IP 54 rated	IEC 60601-1 and -2 compliant	Verification: test or analysis	See Test #14 in the Test Plan	Device is IEC 60601 Compliant	Test was not conducted. No Result Available.
11.3			No Pinch points	Customer is satisfied with comfort of the arm - no pinch points of socket identified by end user	Verification: test or analysis	See Test #16 in the Test Plan	Customer Validated - Survey answer of 5 or higher	Pass
11.4			EMC Compatible	IEC 60601-1 and -2 compliant	Verification: test or analysis	See Test #14 in the Test Plan	All device components are EMC compatible - look at material spec sheets	Test was not conducted. No Result Available.
11.5			Thermal Safety: surface components do not exceed 40 degrees C	IEC 60601-1 and -2 compliant	Verification: test or analysis	See Test #15 in the Test Plan	Device temperature is less than 40 degrees C after 18 hours of continuous use	Test was not conducted. No Result Available.

Table 2 : Compact Test Results

Test #	Test Name	Result	Conclusions
1	Barrel Grasp Dimension	Pass	All measurements were below the specification of 2 inches. Therefore the hand passes the barrel grasp dimension test. For future design improvements, the grip size should be minimize as much as possible in order to pick up a larger variety of objects. To shrink the grip size, the "tendons" at the base of the fingers must either be more flexible to provide less resistance against the actuation, or be moved closer to the point of rotation.
2	Lifting Weights	Empty Water Bottle = Pass Half Filled Water Bottle = Pass Full Water Bottle = Fail	The hand was able to successfully pick up both the empty water bottle and the half-full water bottle. The hand was not able to pick up the full water bottle. For the full water bottle, the hand was not able to fully grip the bottle and pick it up. The bottle would slip through the fingers prior to being lifted. Decreasing the grip size would aid in success of picking up the full water bottle. Future design improvements should also focus on adding traction to the fingers themselves to aid in picking up objects. This could involve changing to a different material with a higher coefficient of friction or adding a grip material to the surface of the fingers.
3	Force of Grip Strength	Test was not conducted due to budget and time constraints	Test was not conducted due to budget and time constraints
4	Adjustable Grip Strength	Pass	The egg was able to be picked up by the hand with no damage. Therefore, the hand passes the adjustable grip strength evaluation. For future design improvements, the control of the hand should be consolidated into a PCB board for further refinement of the adjustable grip actuation. The test conducted for this project passed only because the size of the barrel grasp was large enough to not cause any damage to the egg. If the grip size were to be minimized, the edd would most likely be crushed if the hand were to fully close. Implementing the control of grip size to a PCB board would allow finer control of the hand, instead of just a switch which does not control the grip size (only two options, open or closed). In conclusion, the hand passes the adjustable grip strength evaluation but future design improvements can refine this area of the project.
5	Donning and Doffing the Arm	Pass	The end user was able to successfully don and doff the system within the required time limit. Therefore, the prosthetic arm passes the donning and doffing evaluation. Additional comments: The time the user requires to don and doff the arm should both decrease as the user becomes more familiar with the system. Color coding the harness straps with make the donning process more efficient and will also decrease the time required to put on the prosthetic arm.
6	People Required to Don or Doff Arm	Pass	The end user was able to successfully don and doff the arm by himself alone. To put on the socket, the end user has to find a stationary object (such as a wall or table) in order to push the socket onto his arm. Therefore, the prosthetic arm passes the people required to don or doff the arm evaluation.

7	Socket/Arm Length (Dimensional Inspection)	Pass	All samples evaluated were within the provided specification. Therefore, the prosthetic arm has passed the socket/arm length evaluation. Additional Comments: Although the arm passed this test, the meeting with Jaiden showcased additional insights into this evaluation. Even though the dimensions were within the spec provided, the arm still seemed to be too long for Jaiden. Also, the prosthetic elbow could affect the floor to thumb length dimension based on the angle of the elbow when the measurement was taken. Jaiden's right arm is deformed, with a fixed elbow and a short upper arm and a short forearm, which makes the design of the arm a little more complicated and complex. Although the socket length was in spec and seemed to fit Jaiden well, the extra length of the elbow itself was not considered in the overall length of the arm, which affects the appearance of the prosthetic arm and makes it seem to long for the end user. Future design considerations should include making a low profile elbow or modifying the attachment between the end of the socket and the elbow to aid in the overall length of the arm.
8	Biocompatibility	Test was not conducted due to budget and time constraints	Test was not conducted due to budget and time constraints
9	Environmental Testing	Test was not conducted due to budget and time constraints	Test was not conducted due to budget and time constraints
10	Cycle Testing for Durability	Test was not conducted due to budget and time constraints	Test was not conducted due to budget and time constraints
11	Power Use	Pass	Conclusions of circuit analysis testing, and expected life cycles testing helped to yield data that would better explain reasoning for preferred battery usage. Through our analysis we were able to conclude the feasibility of our current battery use cases, and understand the expected life cycle of the battery & actuator connection. Two different setups were tested and modified to conclude the feasibility between the two batteries and methods of actuation. They are the following: Energizer A23 & an Actuator of 12V (Actruonix L16), Energizer E92 & an Actuator of 12v (Actruonix PQ12). The results yield that the battery setups had an expected lifetime of 6.3 hours and 3 hours respectively, at a 12 volt power usage. This will serve as justification for our current battery and actuator setup (Energizer A23 & an Actuator of 12V (Actruonix L16), as it meets both user and technical specifications for estimated lifetime for the user, and allows our user to be more independent in his everyday life. However, the conclusion of this reporting allowed us to understand that there is room for improvement when talking about future prototypes. Based on this analysis we have come to the conclusion that the addition of another Energizer A23 battery will increase the lifetime between battery charging/replacement. Moving forward, we will design housing of our beta prototype with these power needs in mind.
12	Cost Analysis	Pass	The overall cost of the prototype is less than the budget of $1500. Therefore, the

			initial prototype passes the cast evaluation.
13	Device Weight	Pass	The total weight of the prosthetic arm is 2.05 lbs, which is within the specification for device weight. Therefore, the prosthetic arm passes the device weight evaluation.
			Additional comments: Although the weight of the arm is less than the required amount, the end user still seems to struggle with the weight of the device. This could be due to the fact that the device is bottom heavy because of the elbow and that the end user is not custom to wearing a prosthetic arm. It is reasonable to assume that as the end user becomes more familiar with the device, the low weight of the prosthetic arm will feel normal to him.
14	Electrical Safety	Test was not conducted due to budget and time constraints	Test was not conducted due to budget and time constraints
15	Thermal Safety	Test was not conducted due to budget and time constraints	Test was not conducted due to budget and time constraints
16	Customer Validated Specifications	Pass	Overall, the end user seemed extremely satisfied with the alpha prototype of the prosthetic arm. The user was very pleased with the physical appearance of the hand component of the device. The end user's mother was very pleased by the minimal care that is required to clean the device.
			The socket component of the device had some drawbacks. The middle strap of the socket rubbed the end user's "palm" and was uncomfortable for him. Future design iterations should focus more extensively on the socket portion of the device to further customize it to the end user.
			The initial validation of the alpha prototype passes.
17	Elbow Flexion/Extension	Fail	The elbow fails the elbow flexion/extension test. The movement of the elbow does not reflect that of the human elbow. The minimum angle of the elbow falls within normal limits, but the maximum angle is much larger than it should be. Future considerations include adding some sort of stopping mechanism that does not allow the arm to rotate past 180 degrees. A lever should also be added to the elbow design to allow the user to activate the elbow by himself.
			This area of the design can benefit greatly from design improvements.
			Additional Comments: The elbow makes the arm bottom heavy according to the end user. This could be due to the end user not being familiar with wearing/using a prosthetic device, but the weight of the elbow should be minimized in future design revisions.

Table 3: Work Distribution

	TEAM #	Nicholas Duliba	Christopher Halley	Lindsay Jaros	Sara Toich	Autumn Young	TASK TOTALS
Prototyping	CAD Drawings	2	10.83	0	20	10	42.83
	Purchasing Parts	0	2.5	0	2	0	4.5
	Prototype Fab	0	6	0	5	7	18
	Analysis	7	3	1.5	5	4	20.5
Testing	Test Plan	0	0	10	0	0	10
	Test Results	2	0	8	1	0	11
Business Validation	Market Research	6	0	0	0	0	6
	Executive Summary	6	0	0	0	0	6
Miscellaneous Documentation and Reporting	Bill of Materials	1	0.5	0	1	0	2.5
	Project Budget	0	7.66	0	0	0	7.66
	Correspondence	0	0	0	5	0	5
	Meeting Minutes	0	5	0	0	0	5
	Status Reports and Presentations	1	0.5	1.5	0.5	1	4.5
	Mentor Status Slides	0	0	0	0	0	0
	eBinder Organization	0	0	0.5	0	0	0.5
CDR	CDR Report	1	7.25	6	1	4	19.75
Capstone Day	Capstone Poster and Setup	1	0.25	3	1	1	6.25
Video Demo	Video Demo	0	0	0.5	2	0	2.5
	TOTAL HOURS	27	43.5	31	43.5	27	172

Table 4: Product FMEA

Product Failure Modes and Effects Analysis (FMEA)					
Product Name:		Jaiden's Prosthetic Arm			
No	Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) Mechanism(s) of Failure	Suggested Mitigations
1	Arm attachment	Socket failure	Arm detaches during use	Poor socket design	User validation
2	Material Durability	Material failure	Unable to use arm	Material insufficient for repeated cycling/loading	Load test material
3	Comfortable socket	Skin breakdown	Blisters or sores	Socket causes friction	User validation
		Discomfort to user	User does not want to wear arm	Socket, weight, or clumsy design causes fatigue	User validation
4	Electric operation	no power	arm does not function	battery power runs out	Back up method mechanical operation
5	Grasp	Grasp too strong	Damage to object in grasp	actuator failure	Emergency release
6	Electric operation	incomplete development	Arm does not have intended electric actuation	Inexperience of development team	Open source myoelectric arms as a source
7	Interface compatibility	mechanical and electrical components fail to interface correctly	incorrect operation of device	Incorrect component selection based on inexperience	Use material specs to determine compatibility, research part materials

Table 5. Program FMEA

Program Failure Modes and Effects Analysis (FMEA)					
Product Name:		Jaiden's Prosthetic Arm			
No	Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) Mechanism(s) of Failure	Suggested Mitigations
1	Prototype Delivery	Late/Incomplete	Client does not receive arm	Timing problems, unforeseen complications	Accelerate project schedule and insert flex time, regular status meetings to check progress against Gantt chart
2	Product Training	No training given	Client unable to effectively use arm	Unqualified to give physical therapy	Make design intuitive
			Client fatigues due to improper use of arm		
3	Electric operation	unable to deliver	hand missing optimum features	Limited knowledge & experience with required elements	Mechanical operation back-up
4	Identifying client/end user	incorrectly identify the end user of the devce	End product dissatisfaction because correct user needs not met	Multiple stakeholders with different requirements	Regular communication with all stakeholders; MOU; Focus on end-user of device
5	Scope creep	Stakeholder expectations exceed capability of project	End product dissatisfaction because correct user needs not met	Broad potential scope for project	MOU, regular communication with funder to manage expectations
6	Prototype Efficacy	Ineffective design	Client does not receive arm	Increased development time	Strongly recommend to client to use open-source hand

Initial Validation Notes from Meeting with Jaiden
Actual Questions to ask Jaiden on Saturday March 9th, 2019

1. How do you like the overall appearance of the arm?
    a. Thinks overall design of arm is “pretty cool”
2. Do you like the color of the hand?
    a. Doesn’t seem to care about the color - may change this later
    b. blue/green - change color often - put some sort of logo on
3. Do you like the physical appearance of the hand?
4. What do you like most about the hand?
    a. Looks cool, likes that the fingers move
5. What do you like least about the hand?

6. What would you change about the hand?
    a. Doesn't seem to want to change anything other than what we have mentioned
        i. Different material to make it more flexible

I know the first model of the hand is a little rough and that we will explain this to Jaiden, but I think it would still be a good idea to ask him questions about things he would change/improve upon about the hand.

7. What do you think about the design of the socket?
8. Do you like the color of the socket?
9. Is the socket comfortable?
10. What would you change about the socket?
11. Do you like the backpack straps?
    a. Try shoulder holster
12. What do you like most about it?
13. What do you like least about it?
14. Do you sense any pressure points in the socket?
15. What do you think about having an elbow in the design?
16. What would you change about the overall design of the arm?

Jaiden's comments about the socket
Little pressure from the padding.
Furniture padding foam - look into this
Also some sort of medical foam - Mike is looking into this
Little heavy - maybe a little fatiguing
Thinner rings, thinner padding
Under armpit is a little sensitive - try to modify this area of the socket
Socket is too long - shorten it
When he puts his arm down, the socket shifts.
Modify top ring to be high on outside and low on inside to allow for him to place his arm to the side
Thinner strap - little bit too wide on the straps - smashes when he moves his arm inward

Second design will have a more durable finger/hand design.
Fingers will be held together with TPU (a more flexible material that will allow the fingers to move more like an actual hand). It will not be taped together.
Elbow will actually be attached and will be functional in the final prototype we design.

Notes from Second Validation Meeting with Jaiden

- Socket seems to be slipping off arm
- The whole thing needs to be tighter
- Weight of the elbow and hand is causing socket to slip

- All rings of socket need to be tighten or more padding needs to be added
- May be rubbing near his ‘palm’
- Tightening of the harness seems to hold socket in place
- Problem area around the palm - future work in this area
- No pinching under armpit - still not able to lower arm all the way
- Elbow is not conducive to being operated by Jaiden
- Will need to make a lever for him to be able to activate it
- Seems to really enjoy the elbow aspect of the arm
- Not able to activate switch for the hand
- Either need to make it larger or move it to the socket
- Weight still seems to be an issue
- Work on ways to reduce weight even further - elbow causes arm to be bottom heavy which seems to be causing issues
- Can not cause switch to go backwards
- In future have more design meetings with Jaiden himself throughout design process
- Foam is rubbing arm from socket
- Socket is easy to remove
- May be hard for him to put on socket by himself - may need assistance with this until he gets used to the process - same with the harness
- Rotate buckle on socket to make donning and doffing easier
- Taking off whole system - able to do it by himself in under 10 seconds
- Great for this test
- Putting on by himself - able to do it by himself in under 20 seconds
- Great for this test - 40 seconds for the second time
- Will be some trial and error until he gets the hang of putting it on and taking it off
- Consider color coding straps to help with distinguishing between them