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# The Wrist Brace Project

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Senior Honors Project by Nathan Nicholas

April 26, 2019

PEMDAS

The Wrist Brace Project

Team 16

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# Abstract

## Project

Our design team was formed of Senior Biomedical Engineering students at The University of Akron, consisting of Michael Coon, Chris Courson, Robert Henry, Nathan Nicholas, and Samuel Wilson. The team formed and chose a name of PEMDAS, an acronym for the basic order of operations in mathematics. PEMDAS was tasked with creating a device that could be used to keep the hand of the client in a static position that assists in therapy. The client has been undergoing therapy to gain finger control on the right hand, and if the hand is stable the therapy is more effective.

The family of the client have been unable to find a device on the market that meet his unique needs. He is an active young child with a unique physical condition that prevents available solutions from working. The goal of this project is to design, manufacture, test, and deliver an inexpensive and effective device. The team was allowed the timeline of approximately one full school year or from September 2018 to mid-April 2019 for a total time of approximately 8.5 months.

## Client

The client for this project is an eight-year-old boy from the Akron-Cleveland area. This boy had a stroke during a medical operation at the age of 18 months that resulted in him developing Right Spastic Hemiplegic Cerebral Palsy. Due to his condition, he experienced paralysis on the right side of his body. Through therapy and time, the client has been able to regain control and mobility in the majority of his right side. However, he has not been able to develop control of the fingers on his right hand or his wrist. The parents of the client have been the main point of contact for this project and have been very helpful in this project.

## Problem Definition

The client does not have full control of the fingers on his right hand. Therapists that have worked with him informed his parents that if his hand is stabilized, then it is possible to undergo therapy to develop finger control effectively. To accomplish this, he needs a unique device that keeps his hand in a neutral position relative to his forearm. The neutral position is defined as a position where the hand is not flexed greater than 5 degrees from the axis of the forearm. The device needs to be useful for therapy but also be sturdy and low profile to allow for long-term and daily use.

The specific accommodations of the device are not to touch the palm of the right hand due to an involuntary response to stimulus, not interfering with the function of the fingers, and being simple enough that the a young child can put on without assistance. Additionally, the device should provide

variable stiffness. This stiffness variability allows the device to always be applicable to the needs of the client as his condition changes.

## Requirements

### Customer Requirements

The first step in creating a device for the client is to determine the requirements of the device. The creation of these customer requirements was accomplished through emails with the mother of the client and an interview. Through these interactions with the client, the team was developed a list of requirements that would be used to drive the design of the device. The team took these general needs and created a more detailed list of requirements to cover the initial needs communicated in the interview. The requirements derived can be found in Appendix 1.

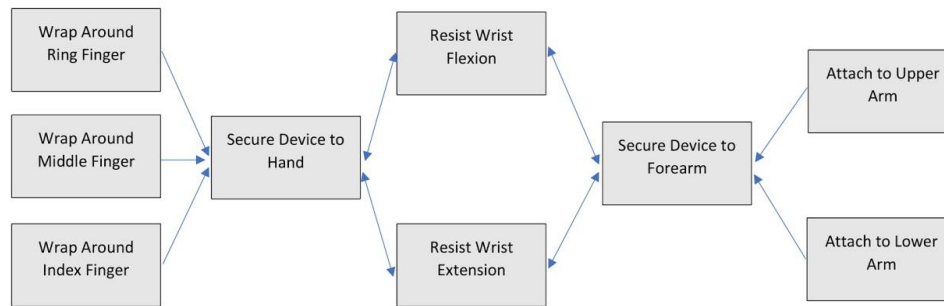
### Design Specifications

Once a detailed list of needs device was created, the team created a set of design specifications that were used to direct the design process and test the device to determine if the device meets the needs of the client as interpreted by the team. These specifications have numerical and objective requirements that can be tested against and during testing these specific values were used to verify the design of the device. The design specifications derived for this project are in Appendix 2.

## Design

### Design Concept and Generation

With design specifications and client needs determined, the team was able to begin design generation. The team began by holding a brainstorming session to generate ideas. At the beginning of the session, the team determined the general components that would be necessary for the device and created a general diagram of the components and the functions of each. This model is seen in Figure 1.



*Figure 1: Initial Functional Model of Device*

This model of the basic functions and parts of the device was critical for the initial brainstorming session and was the basis for the development of a variety of potential solutions that would fill each role. Drawings of this initial brainstorming session are in Appendix 3. The team developed various possible solutions and decided upon a modular design to the brace that can be easily adapted. The team also derived potential designs for the various device components from research into similar devices and methods that are relevant to the needs of the client.

### Design Decision Process

After generating ideas and design solutions for the project the team used a down-select analysis to compare the different designs with consideration for various parameters. The parameters and scores of this analysis are in Appendix 4. PEMDAS then determined the optimal solution from the brainstormed ideas and used these designs to create the initial prototype. This initial prototype consisted of simple forearm section made of polylactic acid (PLA) with Velcro® straps to attach to the forearm, a hand attachment part with a hard PLA plastic base and cloth rings that attach to the fingers of the hand, and finally torsion springs were used to counter disturbing forces and return the hand to a neutral position. The model of this initial prototype is in Appendix 5. The team created this initial prototype using common materials and made the housing and all custom parts with 3D printing. The team purchased necessary hardware from McMaster Carr. After the creation of the physical prototype, the team realized the device was too bulky. The client desired a low-profile device and the team created a design specification that accounted for this by limiting the dimensions of the device. In the process of sourcing the torsion springs, the team found a set of springs that met needed specifications. However, after creating the prototype, it was determined that the design specification needed to be changed as the device would not be considered low-profile. With a change in design specifications to more accurately represent the requirements a redesign was necessary.

The team considered new design solutions and replaced several components of the initial design. The torsion spring resistance component was replaced with a flexible metal plate made of spring steel that fit inside the body of the brace. To accommodate this new resistance component, a flexible plastic housing made of Ninja Flex, a thermoplastic polyurethane (TPU) from NinjaTek®, was designed to bend with the spring steel while still keeping the steel contained and prevent possible pinching. In addition, the cloth rings were replaced with a custom made palmless glove that would

secure the device to the client's hand using elastic bands on the fingers and the thumb with a wrap around the wrist without contacting the palm. This second iteration of design is in Appendix 6. Additionally, in this appendix are images of the original device purchased and the scaled down version.

After investigating the design and during the assembly process the team decided to make minor adjustments to allow for simpler and more durable assembly of the device, specifically the method used to attach the spring steel plate to the printed PLA modules. The team decided to pivot from using printed PLA plates adhered to metal to drilling holes directly into the spring steel and screwing the metal plate and into the PLA body. This adjustment makes the device easier to assemble and improves the longevity of the device. The palmless glove material was changed and extended to encompass the entire device. This design is in Appendix 7. This design is what was used for final verification testing and modeling.

## Testing

### Modeling

Before the creation of any physical prototype, a Solidworks model of the device was created to determine exact geometries and check for interferences. This basic modeling was required in order to create the 3D objects needed by the 3D printer, but these models also helped the team quickly find design flaws. These early models greatly improve design efficiency. In addition to the Solidworks modeling, the team also created a model of the final brace using the Finite Element Method (FEM). Using this method, the team worked to ensure that the materials used and the geometry of the device were sufficient to withstand the expected forces that the device would incur and to check for any unforeseen concentrations of force in the device that would potentially cause a potential weakness in the device, and evaluate the different behaviors of different metal plates. The results of this FEM modeling can be found in Appendix 8. The FEM model did not show any unexpected force concentrations that would be problematic in the design and cause a possible break in the device. Additionally, the team determined that if the client were to fall on the brace, the brace would be able to withstand the impact of the fall without deflecting past the bounds of the device.

### Prototyping

A significant concern of this project for the team was delivering a fully functional device for the client in the time allowed. Additionally, the team needed to make a highly customized and lightweight device. These two factors made 3D printing an excellent option for creating quick and highly customized prototypes of the devices. Our team focused on making designs that lend were highly compatible with 3D printing to make the prototyping and testing process as simple as possible. The first prototype was rapidly created using 3D printing, and after a total printing time of approximately 4 hours, the prototype was quickly assembled in under 30 minutes. This prototype consisted of 3D printed components made



of PLA including the forearm module, the hand module, and two torsion spring casings. In addition to these parts, the model also included four screws to hold the parts together and two torsion springs. The creation of this prototype was not carried further than this because after physically holding and examining the device the team decided that the torsion spring idea was not viable and quickly pivoted to the second design.

The second prototype was also made mainly using 3D printing, but it did include the creation of a prototype for the fabric and elastic palmless glove which was used to attach the device to the hand and wrist. Printing time required for the parts was similar to the first iteration, but the design changes slightly changed the parts that were made using PLA. These PLA printed parts included the forearm module, the hand module, and four metal plate inserts that were used to join the metal spring steel to the 3D printed hand and forearm module. Also, the team also printed a flexible wrist joint out of Ninja Flex. Due to the nature of printing, this flexible material required different settings, and these resulted in the print for this part adding in an additional printing time of 45 minutes for the creation of the second prototype. The team purchased a palmless glove to evaluate, and due to a lack in availability of sizes for the glove, the team was forced to modify or remake the glove to fit the client. The team used the purchased model as a guide to make a scaled down version that would fit. To attach the spring steel plates to the PLA the team decided to use small PLA printed inserts that the spring steel was adhered to. Then the PLA inserts were attached to the forearm and hand modules using screws. The team quickly realized during assembly that the adhesive and PLA inserts represented a potential weakness in the device. After consulting Steve Patterson at The University of Akron the team decided that the best method to attach these plates to the hand and forearm module was by drilling a through hole in the plates and using a screw to attach the spring steel plates to the modules directly. This change prompted a minimal redesign and change in process for the third prototype.

The third prototype is very similar to the second prototype in design with the change of the elimination of the printed PLA inserts for the spring steel. The elimination of these inserts also resulted in a change to the cavities inside the printed hand and forearm modules. The new cavity has a variable height which goes down as low as a height of 1 millimeter. With 3D printing it is not possible to print a geometry without support under the current print layer, so supports are needed under the top layer of the cavity. However, because the cavity goes down to a height of 1 millimeter removing these supports with conventional tools would be very difficult. To overcome this issue, the team decided to use a dual extruder printer with the main body of the part composed of PLA and all support composed of polyvinyl acetate (PVA). PVA is a water-soluble filament; this allows the removal of supports after printing using the method of submerging the entire part in water and dissolving the support structure. This change in production also allows the team to use a higher density of support structure so that the upper layer has minimal variation in thickness of the cavity.

Additionally, this prototype had a change in material for the fabric palmless glove. This new fabric was more breathable and had better water resistance properties to create a more comfortable fit. Also, the glove was extended to cover the entire brace with a single Velcro® closing at the proximal end of the forearm module of the device. The final prototype was used for verification testing before preparing the device for the client.

## Testing Process

The team performed both verification and validation testing to confirm that the device meets the needs of the client. The validation testing was done with the client in the form of usability testing. During these meetings, the team had him test the current idea and design of the brace to validate that the design would work and meet his needs.

The first usability test was done with a version of the device that was between the first and second prototype versions. The purpose of this test was to evaluate the effectiveness of the palmless glove in holding the device to the hand. During this meeting, the team evaluated the dimensions of the prototype and adjusted to ensure a proper fit. The meeting ended with the client and his mother being pleased with the attachment method. Based on this information the team went forward with the creation of the second prototype.

The second usability test was done with the second prototype including the modified palmless glove. This test was again to evaluate the attachment method, but with the addition of the use of the flexible plate method of resisting the forces. The team also re-evaluated the fit of the device. Another high priority for this meeting was to determine if the client could put the device on himself. After allowing the him and his mother to evaluate and use the device, they believed that the client could put the device on himself or with minimal assistance from either parent. The team used this meeting as the final validation of the dimensions by the client. With this completed the team went forward with the creation of the third prototype and a focus on the verification testing of the device.

From the design specifications developed, the team performed verification testing to ensure the device meets the needs that were interpreted from the interviews with the client. A list of all tests completed and the process of performing each test is in Appendix 9. In order to completely verify the device material and design evaluation was conducted to ensure that the device meets the needs of the client as defined in the customer requirements and the design specifications.

## Testing Results

Testing results can be split into verification testing and validation testing. Verification testing was done to ensure the device produced meets the needs of the design specifications and validation testing is done to ensure that the client is pleased with the device. The results of each verification and validation test is located in Appendix 10.

Unfortunately, in the time provided for the project the team could not complete all testing. This is especially true with the validation testing. In order to complete the majority of the validation testing the client would need to use the product in their daily life and then report to the team whether or not the device meets their needs. This is not possible due to the client undergoing surgery and the time restraints of this project.

In order to track the current overall testing results the team created a table that is found in Appendix 11. The team tracks the customer requirements derived, the design specifications, and the

appropriate testing used to ensure the need was met. For various design parameters testing was not required and the properties of purchased materials or the physical properties of the device itself were sufficient to verify the specification. All FDA and formal regulatory requirements were not tested because for the context of a single device created by students these were not applicable. If this device were to be brought to market these regulations would need considered, followed, and tested against.

## Final Implementation

The team will soon provide the device to the client. However, he recently had a surgery on the wrist which will cause him to be unable to wear the brace immediately. For this reason, the team will not receive immediate feedback but hope to hear from the client in the coming weeks about the use and functionality of the device. The team will consider this initial period of using the brace to be the user testing of the device and allow for final validation of the device. An image of the final device in use is located in Appendix 12.

## Business Aspects

### Competition

When researching, the team found that there is no device currently on the market that would fulfill all the needs of the client. However, some devices would provide partial solutions and could be seen as competitors to our product if it were brought to market. These devices are the DeRoyal DeROM Wrist Splint and the Rolyan Wrist Splint. A comparison of these products with the proposed brace developed by the team is in Table 1.

*Table 1: Comparison of competitor products*

Product Comparison			
Company	PEMDAS	DeRoyal	Sammons Preston
Product	Wrist Brace	DeRoyal DeROM® Wrist Splint	Rolyan Wrist Splint
Easy to Use	x	x	x
Good Quality	x	x	x
Meets Expectations	x	x	
User-Friendly	x	x	x
Wears Out Quickly			

Stable Support	x	x	x
Worn by children	x		x
Replaceable Parts	x	x	x
Adjustable tension	x	x	x
Inexpensive	x		
Easily for Patient	x		
Worn by Adults	x	x	x

As can be seen in this table the proposed brace by PEMDAS would meet the requirements of the client and provide additional functionality compared to the braces and splints of the competitors. The most significant benefit of the device offered by PEMDAS is the modular design that allows for brace that is high quality, easily repaired and inexpensive but provides functionality of a brace of \$150 or more.

## Market Analysis

The team performed an analysis of the current market in an attempt to determine the market potential of a device or company that could be created as a result of the project. The orthopedic braces and supports brought in \$3.29 billion in 2016 and this value is projected to increase by 5.6% through 2022 to reach \$4.93 billion (Market, O). This evaluation leads the team to believe that the creation of devices such as braces and supports are profitable and is a market that can support a business. Additionally, this market is growing indicating that a company in the market with a competitive product has the potential to grow.

In addition to the market analysis, the team analyzed the customer base that the team identifies as the intended customers for the device developed by PEMDAS. There are roughly 500,000 children under the age of 18 that currently have Cerebral Palsy, and about 10,000 babies born each year will develop Cerebral Palsy (cerebralspalsy.org). While not all children with Cerebral Palsy need a brace such as the one developed by the team, some potential customers would need a device similar to what PEMDAS can provide. As seen in the research into the competitive products there are no devices on the market that can fulfill the needs of customers with needs similar to the client. Therefore, the team can use this customer base to establish the company and then expand over time to gain an increased percentage of the market by creating superior devices for the customer.

## Financial Considerations

## Resources Used

The team was fortunate enough to have the help of many groups and people to complete this project. The team received the help of The University of Akron and the Biomedical Engineering department for assistance in numerous accommodations for this project such as providing software packages to assist in design and modeling such as Solidworks and Ansys. PEMDAS also used the resources of Matrix Tool and Machine Company in the assistance of creating and preparing the various spring steel plates.

## Purchases

For this project, the team made minimal purchases for the project. All purchases were made to assist in the creation of prototypes to test the designs created by the team. Purchases for this project included various parts from McMaster Carr. The parts used include a pack of stainless-steel screws with part number 90116A008 that cost \$8.63 for a pack. Additional parts from McMaster Carr include 2 sets of torsion springs with a different directional winding. These springs were parts 9271K708 and 927K674 each costing \$5.38 per pack. The other purchased made by the team was a reversible palmless glove from Sun Protection Clothing USA. These gloves were purchased as a possible item to attach the device to the hand of the client and then was repurposed as a guide to create custom versions of the product. This glove costs \$18.95 to purchase in addition to the shipping required for the item. These purchases by the team came to a total of \$38.34 of purchases made by the team.

## **Future Work**

The team was pleased with the progress that was made and the current state of the project. With additional time the team can complete testing including the user testing to validate the device. Additionally, more work is needed if the device were to go past a single brace made for a single client. This work would begin with the completion of the endurance testing that could not be completed in the allotted time for this project. The team would also like to explore additional options so that the device can provide more utility for the client past the stabilization of the wrist. Some functionality that would improve the device would be assisting in daily activities the client undergoes while the client is in the process of regaining muscular control.

## **Conclusions**

## Feasibility

The team was able to bring a finalized device to the client by the end of this project. If the team were to continue with this project past this point, it is believed that this is a device that could be brought to market as a low budget brace to assist in the stabilization of the hand. The device is currently made using 3D printing for the bulk of production, and this method is beneficial for making limited runs of a part such as a highly specified brace such as was done in this project. If the team were to move away from the unique product for each client business model and instead went for a mass production model of more generic models the team would have molds made to reduce the cost and time of production.

## Lessons Learned

Throughout this project, the team learned a variety of lessons. The team learned and experienced the design process by taking the needs of a client and translating them into a device. The team developed skills in patent research, client interview, the creation of customer and design requirements, part sourcing, and prototype creation. The team also learned a significant amount about the brace market and business through research into the industry. Additionally, all members of the team developed the skills necessary to complete a project with a minimal amount of time.

## Conclusions

The team was tasked with providing a device to fulfill the need of stabilizing the hand of the client relative to the forearm. This project had 8.5 months for the team to complete. The team followed the engineering design process to take the needs of the customer, derive design requirements, design a device, prototype and test the device, and finally deliver a device to meet the needs of the client. If the team were to continue this project past the current scope of the project the team would perform more tests of the device and make a more modular and customizable device that could easily adapt to other customers.

## **Team Roles**

The team for this project consisted of Five Biomedical Engineering Seniors at The University of Akron. The members of the team consisted of Michael Coon, Chris Courson, Robert Henry, Nathan Nicholas, and Sam Wilson. The primary roles of each member are listed below, but at various phases of the project, the responsibilities of the members shifted to assist the member responsible for that phase in completing the task. All decision making for the project was made as a team with the final say being decided by the member in charge of the phase or the team leader if necessary.

Michael Coon was designated as the leader of the team with this project. He was responsible for organizing the team and project to complete the task. He also was responsible for making team decisions that did not fall under the responsibilities of the other members of the team. In addition to

these tasks, Michael took the lead on contact with the client and his mother as well as contacts with other parties.

Chris Courson was responsible for a large amount of research and business aspects of the project as well as working on testing with Nathan Nicholas. He performed much of the research into the physiology and business aspects of the project with the assistance of Sam Wilson. Chris also assisted in the creation of appropriate tests to verify the design of the device.

Robert Henry was responsible for the maintenance of the documents of the team and ensuring that documents were made and submitted when needed. Rob also took responsibility for keeping meeting minutes of each meeting and keeping track of topics discussed in the meetings as well as the responsibilities of each member assigned in team meetings.

Nathan Nicholas was responsible for the CAD, 3D printing, and testing of the project. He took the lead on creating various designs that would meet the design requirements for the project. Additionally, Nathan owns a 3D printer and has experience with using the 3D printer, so he was responsible for the printing of various components necessary for the creation of prototypes and testing of the project. Nathan also created the testing procedure with Chris Courson.

Sam Wilson was responsible for much of the manufacturing and competitive product research. Sam researched and found the majority of the products on the market and patents that would be competitive to the device created by the team. He also took the lead in procurement and machining of the spring metal plates used to resist disturbing forces in the device.

## Acknowledgments

The team would like to thank The University of Akron and the Biomedical Engineering Department for providing space and tools to work on the project. The team would also like to thank Anna Henry for helping the team create the sewn cover for the device by providing her skill and expertise in sewing. The team thanks Matrix Tool and Machine Company for assisting the team with the creation of the machined spring steel plates. Finally, the team would like to thank our client and the parents of our client for meeting with the team and assisting the team during this project.

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## Appendices

### Appendix 1: Customer Requirements

Team 16: Wrist Brace Project

Authors: Nathan Nicholas, Chris Courson

Editors: Nathan Nicholas, Chris Courson

**Brief Description of project:** The client has no motor control of wrist, which has rendered it limp, and if the palm is stimulated it will cause the hand to clinch up. The team will design a brace that will hold the wrist in a neutral position that will not cause the palm to be stimulated. It must stand up to the daily use of a 7-year-old active child. The brace must be easy to put on and comfortable to use.

#### **Requirements:**

##### 1.0 User/patient/clinical performance characteristics

- 1.1\_Brace will align wrist with arm
- 1.2\_Brace will be used for physical therapy as a passive brace
- 1.3\_Brace will not stimulate hand causing reaction
- 1.4\_Client would like the ability to play on monkey bars

##### 2.0 Privacy and security

- 2.1\_Possible nondisclosure in the MOU
- 2.2\_Possible nondisclosure form with therapist

##### 3.0 Safety

###### 3.1 Mechanical

- 3.1.1\_Brace Material will cause no damage to child's skin
- 3.1.2\_Straps must resist usual wear and tear
- 3.1.3\_Material for brace and straps must be at least water resistant
- 3.1.4\_Brace should be resistant to impacts

###### 3.2 Biological

- 3.2.1\_Biocompatibility of materials has been proven
- 3.2.2\_Material can be easily cleaned to reduce bacterial growth

##### 4.0 Regulatory

- 4.1\_Regulations defined by governing entities (FDA, ISO, etc.) will be followed.
- 4.2\_Device will meet adequate testing standards defined by above stated entities

###### 4.3\_FDA

- 4.3.1\_21CFR890.3475

###### 4.4\_ISO

- 4.4.1\_Quality management: ISO 9001-13485
- 4.4.2\_ISO Management system standards: ISO 13485:2016

###### 4.5\_ANSI

- 4.5.1\_ANSI B46.1: Surface texture

##### 5.0 Quality

- 5.1\_All allergies will be taken into consideration

- 5.2\_Highest quality materials available within cost restraints will be utilized
- 5.3\_Device is not disposable, but material will be robust enough to withstand demands of daily use
- 6.0 Reliability
  - 6.1\_Able to be worn for long periods time and will repeatedly work as a therapy device
  - 6.2\_Straps and brace will fit consistently as well as adapted to size change
- 7.0 Compatibility with accessories/auxiliary devices or products
  - 7.1\_Compatible with clothing worn (sleeves, jackets, etc.)
  - 7.2\_Compatible with other therapy devices (digital game)
- 8.0 Compatibility with the intended environment
  - 8.1\_Resistent to damage from light (moderate outdoor activities)
  - 8.2\_Compatible with high range of temperatures (0 Fahrenheit in winter to near 100 Fahrenheit in Summer)
  - 8.3\_Resistance to corrosion from common liquids (water, beverages, soap, etc.)
- 9.0 Human factors
  - 9.1\_Easy to put on
  - 9.2\_Not exceedingly bulky
  - 9.3\_Visually pleasing design
  - 9.4\_Comfortable for extended use (~8-12 hours)
- 10.0 Physical characteristics
  - 10.1\_Brace will be compact and fit on the forearm and hand
  - 10.2\_Will have adjustable fittings
  - 10.3\_Non-leachable, non-toxic material
  - 10.4\_Lightweight
  - 10.5\_It will smooth edges
- 11.0 Sterility
  - 11.1\_Not applicable
- 12.0 Manufacturability
  - 12.1\_Non-Disposable, and low unit price
  - 12.2\_Material easily manufactured
- 13.0 Serviceability
  - 13.1\_Device will be easy to sanitize
  - 13.2\_Interchangeable parts in order to repair
- 14.0 Labeling, packaging, storage
  - 14.1\_Compatible storage without disassembly
  - 14.2\_Easily stored at room temperature
- 15.0 Requirements for intended markets (domestic or international)
  - 15.1\_Marketing specifically for domestic, academic purposes
  - 15.2\_Must validate claim for increasing wrist stability

## Appendix 2: Design Specifications

1. General Information:
  - a. Project Overview:
    - i. The client has little to no voluntary motor control of their fingers or wrist on their right side. In order to progress the therapy of improving finger control on the right hand the client needs a method to maintain his wrist in a neutral position. Traditional braces have not worked because the client also uncontrollably clenches his hand when the palm is stimulated.
  - b. Purpose:
    - i. The purpose of this project is to provide a specialized and unique brace for the client to hold his wrist in a neutral position.
  - c. Scope:
    - i. The current scope of the project is to create a single brace for a young boy who is the client. If it is determined that there is a larger need and market for such a device a more generalized model may be considered.
2. Standards and Regulations:
  - a. Regulations defined by governing entities (FDA, ISO, ANSI) will be followed.
  - b. Device will meet adequate testing standards defined by above stated entities:
    - i. FDA:
      1. 21CFR890.3475
    - ii. ISO:
      1. Quality management: ISO 9001-13485
      2. Management system standards: ISO 13485:2016
    - iii. ANSI:
      1. ANSI B46.1: Surface texture
3. Assumptions and Dependencies:
  - a. It is assumed that the torsion springs for the device will resist the movement of the child's wrist. The amount of resistance in the spring is dependent on the weight of the child's hand. We assume the brace will be used for about 6-8 hours per day over three years. The elastic straps that will go around the child's hand should not cause his hand to close. We assume the brace will be adjustable to how much the wrist is allowed to freely move.
4. General Constraints:
  - a. Hardware or software environment:
    - i. Hardware will mostly be exposed to the possibility of falls onto hard materials. Hardware will be placed on the forearm, back of the hand, and around the fingers
  - b. End-user environment:
    - i. Mostly used as a therapeutic device with the possibility of becoming a daily wear device in which new elements will be encountered
  - c. Standards compliance:
    - i. All FDA and ISO regulations/Standards will be followed
  - d. Interoperability requirements:
    - i. There are no interoperability constraints for this project.

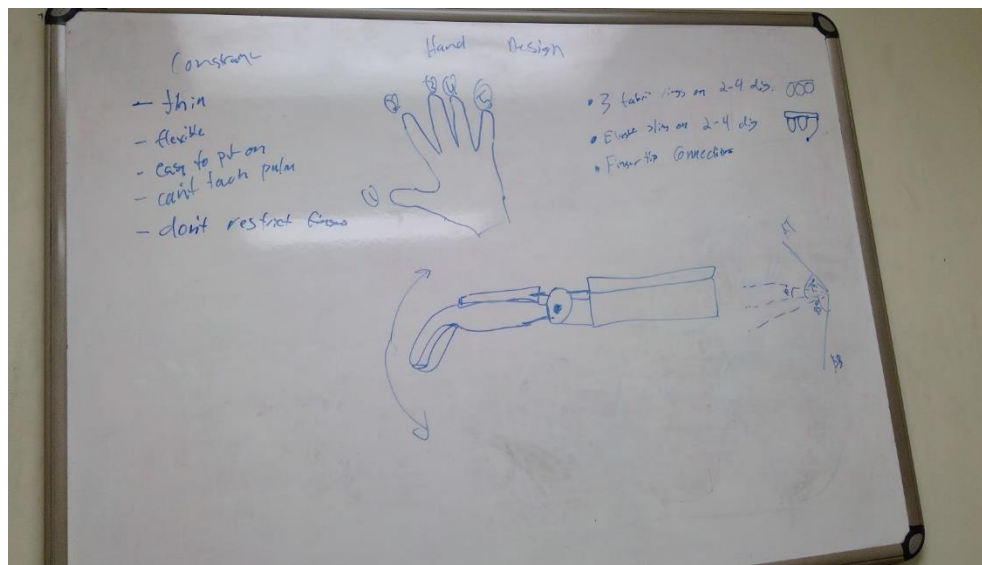
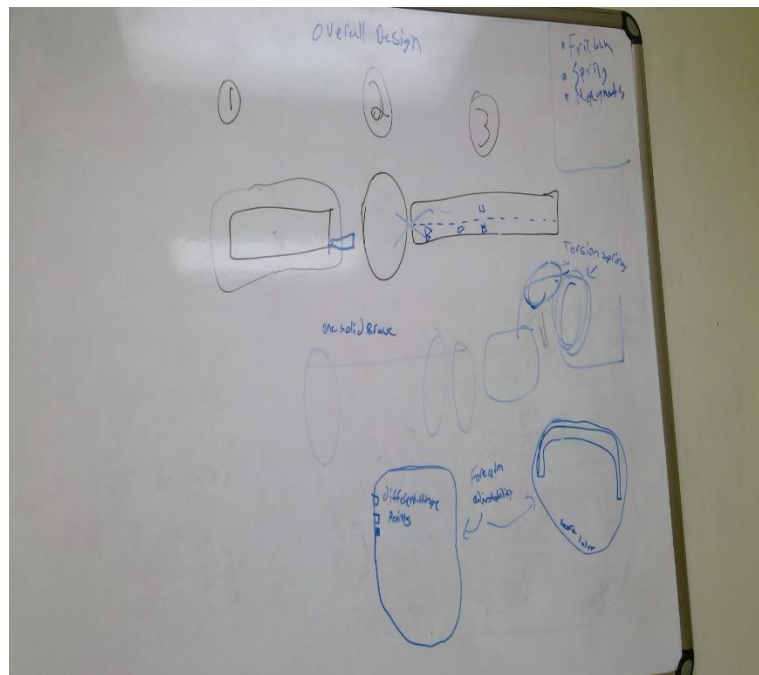
- e. Interface requirements:
    - i. There is no intended interface interaction required from the user, but for safety concern any area where the customer may interact with the device sharp edges and corners should be removed.
  - f. Security requirements:
    - i. No security requirements necessary as no personal information and/or data will be stored by device
  - g. Hazardous material issues:
    - i. No use of Hazardous material
  - h. Performance requirements:
    - i. Device will adjust the wrist into a neutral position without interfering with the palm of the client's hand. Allows for therapy of finger movement along with rehabilitation of gripping objects
  - i. Communications:
    - i. Device does not need the ability to communicate with user and/or doctor/therapist
  - j. Hardware and software integration issues:
    - i. Attaching finger securing hardware to the rest of the device. Finding correct and comfortable hardware for the client
  - k. Verification and validation requirements:
5. Project Description:
- a. Discuss any of the following topics that apply to the product, service, process, or System:
  - b. Capacity analysis:
    - i. Physical:
      - 1. Start-up company small space for storage. Mostly made to order device at current company life stage
    - ii. Production:
      - 1. Unsure as of now as the required data has not been obtained as PEMDAS is still in development phase
    - iii. Mechanical:
      - 1. The device will contain hardware readily available from other companies
      - 2. A 3D printer will have the capacity to print one brace every six hours
  - c. Data requirements:
    - i. To ensure a proper fit measurement of the patient may be needed for a custom fitting.
  - d. Hardware and software description:
    - i. There is no intended software needed for this device.
    - ii. Hardware will be limited to simple machines and custom fit parts.
  - e. Input and output requirements:
    - i. The user's fingers wrist and forearm will be placed in the brace. The device will receive the input of the user's wrist wanting to fall but will the output will be the user's wrist remains in a neutral position
    - ii. The elastic bands will be used as the contact point to allow the wrist

- f. Mechanical enclosure(s):
  - i. All parts that move shall be enclosed to prevent the possibility to pinch or inflict injury in any way to the user or those near the user of the device.
- g. Performance requirements:
  - i. The device must be able to bring the clients wrist back to neutral within 0.25 seconds of a single displacement from neutral. The device will also be able to withstand at least 1.5 million cycles.
  - ii. After discussion with the team, an approximate desired lifetime of the product was determined using the following estimations. To approximate about 3 years of use, assume 2 movements per minute during the active portion of the day (8 am to 8 pm). 720 minutes in a day during that time, so 1440 in a day. 365 days in a year so 525,600 movements in a year. In 3 years, that is 1,576,800 times. The device should remain viable for approximately 1.5 million cycles of use without critical failure.
- h. Support considerations:
  - i. The device should require no post sale support aside from part replacement or technical assistance. But even this should be minimal.
- 6. Attributes:
  - a. Low-Profile
    - i. The device should not have any piece that sticks away from the user further than 0.5 inches during use.
  - b. Lightweight
    - i. The device should way no more than 2 lbs.
- 7. Maintainability and Support Requirements:
  - a. Maintenance Requirements:
    - i. Easily cleaned
    - ii. Replacement parts inexpensive and readily available
  - b. Supportability Requirements:
    - i. Testing/calculations for correct torsion spring
    - ii. Testing for correct elastic band
  - c. Adaptability Requirements:
    - i. Adjust to different finger position/length
    - ii. Adjust to different forearm sizes/hand sizes
- 8. Timing:
  - a. Throughput time:
    - i. 6 hours for the braces to be 3D printed
  - b. Timing requirements:
    - i. 0.5 second reaction for wrist to go back to neutral
  - c. Sequencing or interaction of activities within a system:
    - i. torsion spring reacting to movement in the wrist
  - d. Input/output transfer time:
    - i. Brace should immediately put wrist into neutral position
- 9. Design Description:
  - a. The design for this product has not been finalized. As such this section will be updated in future versions of the document when the design is known sufficiently.
- 10. Interfaces:

- a. User Interfaces:
    - i. Placing the wrist brace on the child
    - ii. Adjusting spring accordingly
  - b. Hardware Interfaces:
    - i. Connecting forearm piece to wrist stabilizer piece
    - ii. Connecting hand piece to wrist stabilizer piece
    - iii. Connecting elastic bands to hand piece
  - c. Software Interfaces:
    - i. There are no intended software interfaces with this product.
  - d. Safety and regulatory compliance:
    - i. FDA and ISO regulation/Standards
11. Reliability:
- a. As indicated in a previous section, the estimated life cycle of the device is 1.5 million cycles. The team believes and acceptable number of non-critical failures during the lifetime of the device would be approximately 2 failures.
12. Security:
- a. Access Requirements:
    - i. N/A
  - b. Integrity Requirements:
  - c. Privacy Requirements:
    - i. N/A
  - d. Audit Requirements:
    - i. Not applicable at this time.
13. Safety and Hazardous material Issues:
- a. The device should not contain any part of component that is toxic to a person without sufficient covering to prevent accidental exposure such as a battery. All materials used to produce the device must be non-toxic.
14. Environment:
- a. Operation and storage conditions:
    - i. The device should be robust and be able to operate in conditions that range from 0 Fahrenheit to 100 Fahrenheit without performance loss. The device must also be able to function when held in any orientation. Additionally, the device shall be able to be stored in a range of temperatures from 40 Fahrenheit to 90 Fahrenheit for extended periods of time without degradation of the unit. Due to the nature of the device it should also be able to be stored in an environment where it will be exposed to numerous forces and varying conditions such as a school backpack without significant loss of functions.
  - b. Operating Noise level:
    - i. Due to the nature of the device it is desirable that the device not make a significant amount of noise to prevent the device from causing an annoyance any noise made by the device without external influence, for example motors, interference, frictional rubbing must not exceed 20 dB in volume.
  - c. Vibration levels:
    - i. The device made is intended to be used for a long amount of time, approximately 12 hours a day at maximum. To prevent adverse health effects that can result from large amounts of vibrations, the device must not have significant mechanical vibrations for extended periods of time.
  - d. Shock loading:

- i. The device must not impose any sudden loads on the user with forces in excess of 3 lbs. The device should be able to withstand sudden loading in excess of 100 lbs.
  - e. Exposure to dirt and other contaminants:
    - i. After complete exposure to fine granular media for at least 30 minutes the device should still be able to operate with no significant difference. The device should also be able to withstand being submerged in water for over 10 minutes without losing functionality.
    - ii. The device should not deteriorate in any appreciable way when exposed to direct sunlight
- 15. Quality:
  - a. We are going to approach the client with several different prototypes to determine what meets their expectations. We will use the highest quality components that fit into our budget once a final prototype is determined
- 16. Supporting Documentation:
  - a. Design History File
    - i. Testing/Validation documents
    - ii. Client interview
    - iii. Risk analysis
    - iv. Design verification
    - v. Predicate devices
    - vi. 510(k)
- 17. Testing
  - a. Plans for testing are in development
- 18. Definitions, Acronyms and Abbreviations

### Appendix 3: Initial Brainstorming Session





#### Appendix 4: Initial Down Select Analysis

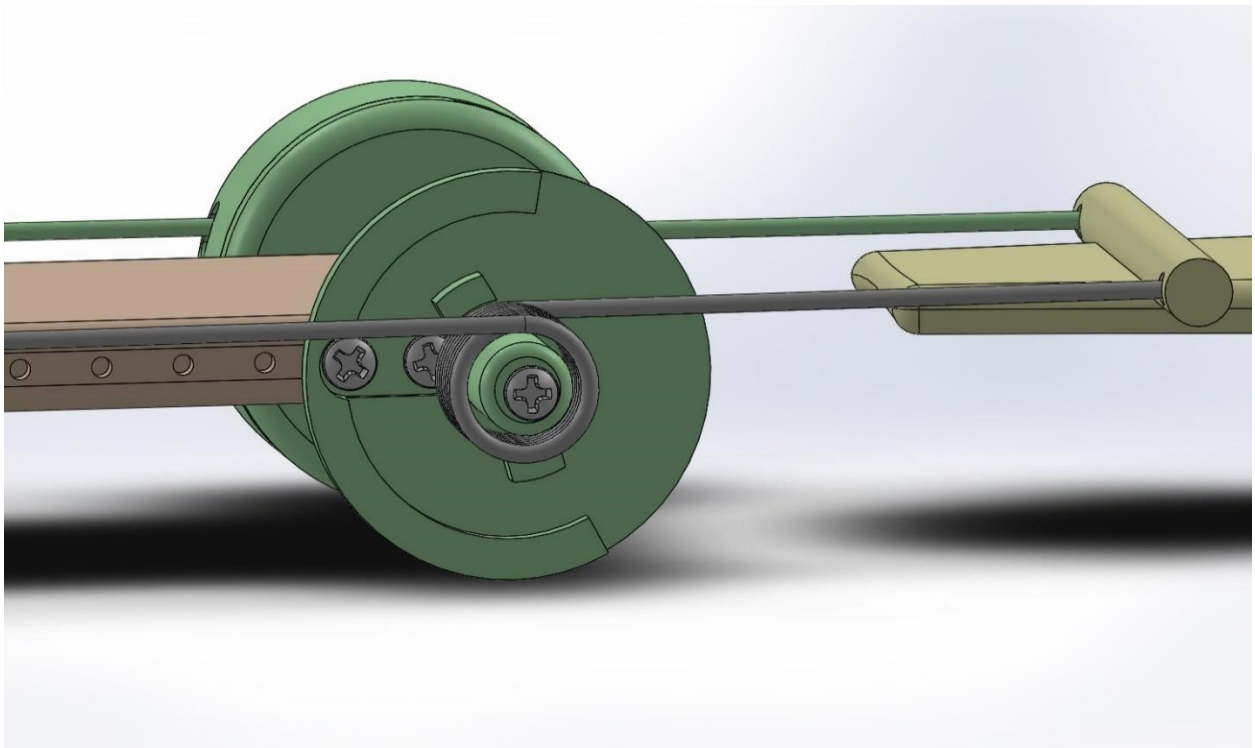
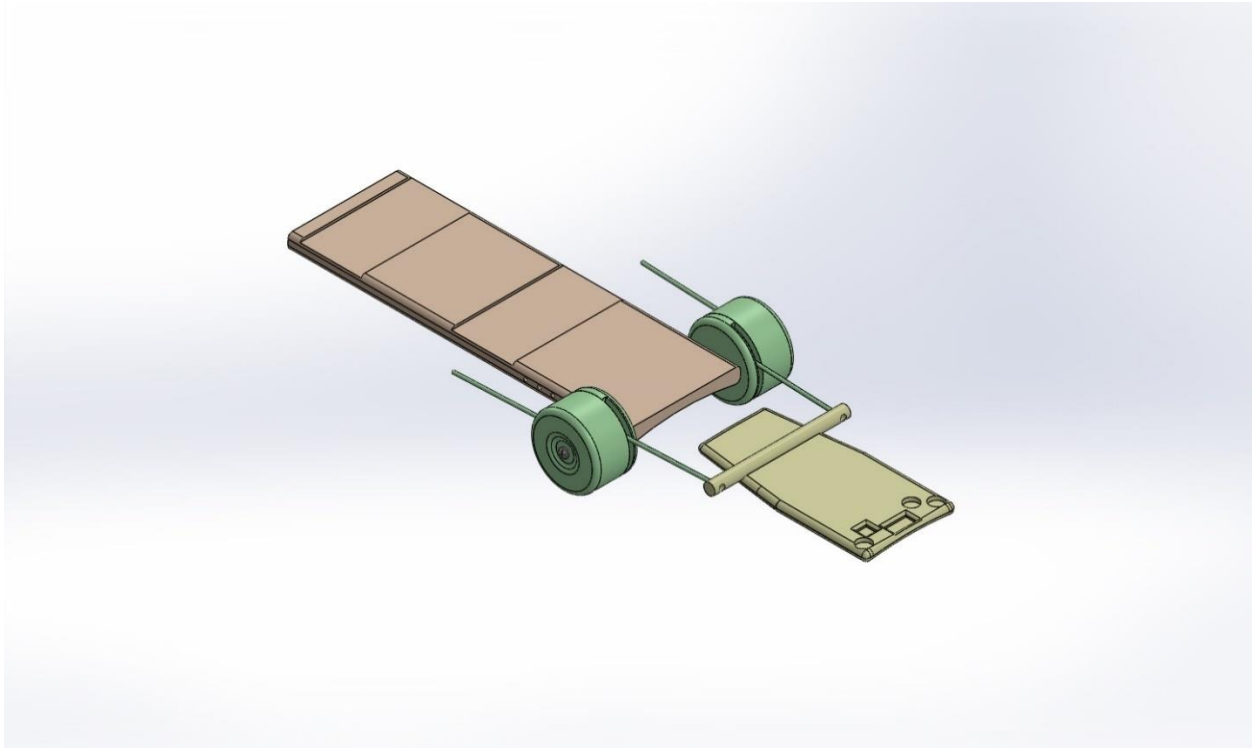
Rotational Component:

Design	Parameters				
	Ease of Manufacture	Longevity	Safety	Adjustability	Total
Magnetism	4	6	5	4	19
Friction	2	4	9	6	21
Linear Spring	6	5	6	5	22
Torsion Spring	7	5	7	5	24

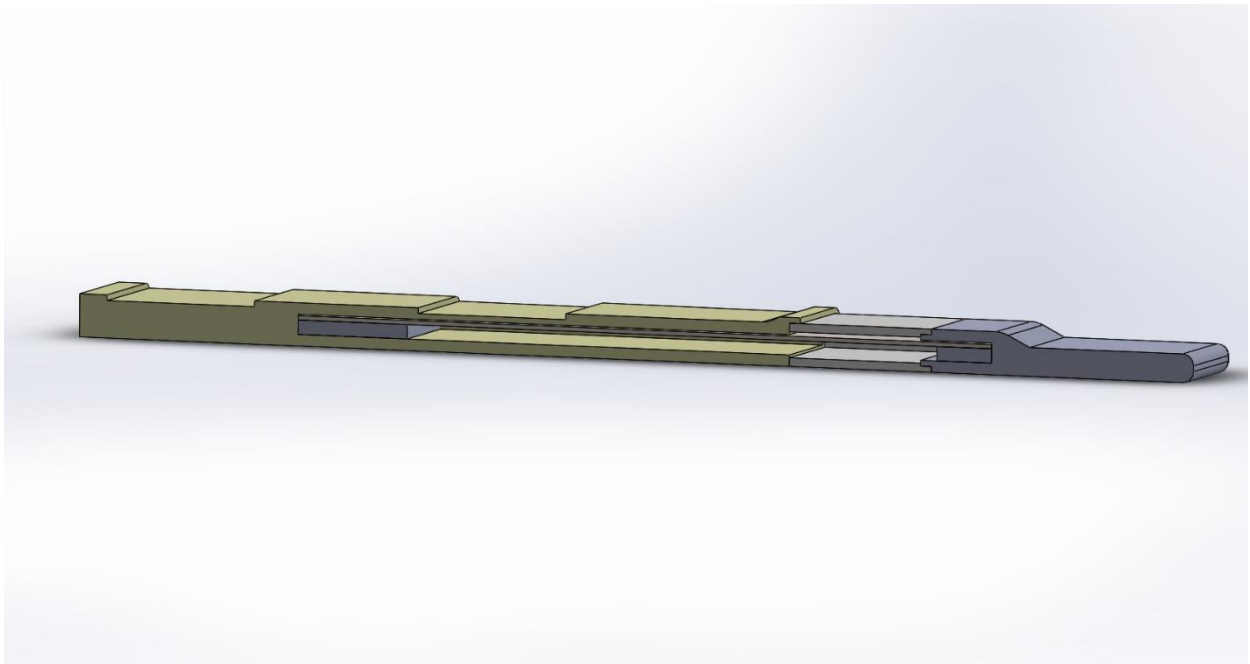
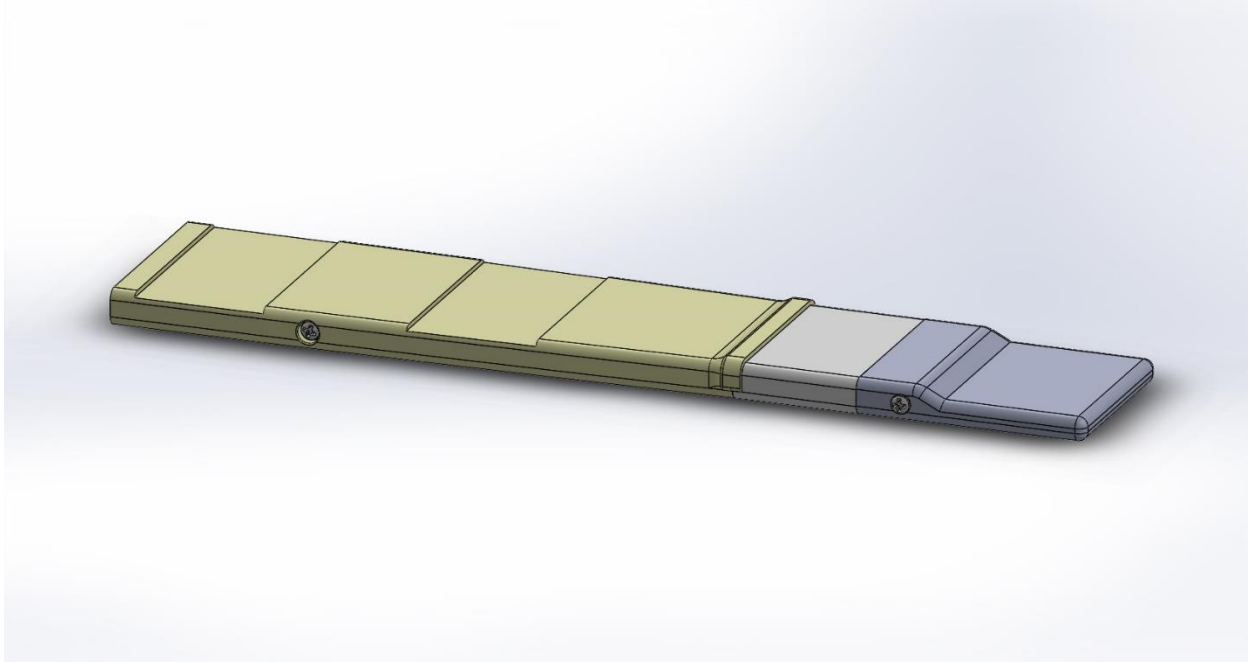
Hand Attachment:

Design	Parameters				
	Ease of Manufacture	Ease of Use	Stability	Non-Restrictive	Total
Cloth Rings	6	6	5	6	23
Wrapping Bands	5	8	5	6	24
Fingertip Connections	4	6	6	2	18

## Appendix 5: Initial Design Model

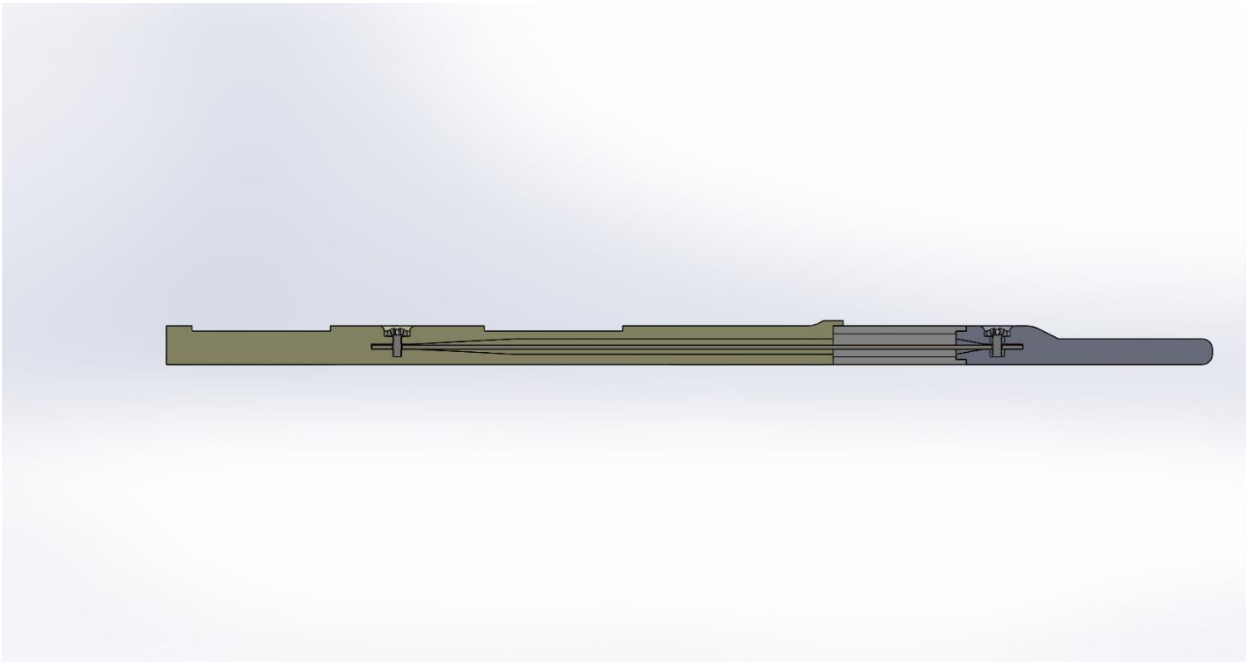
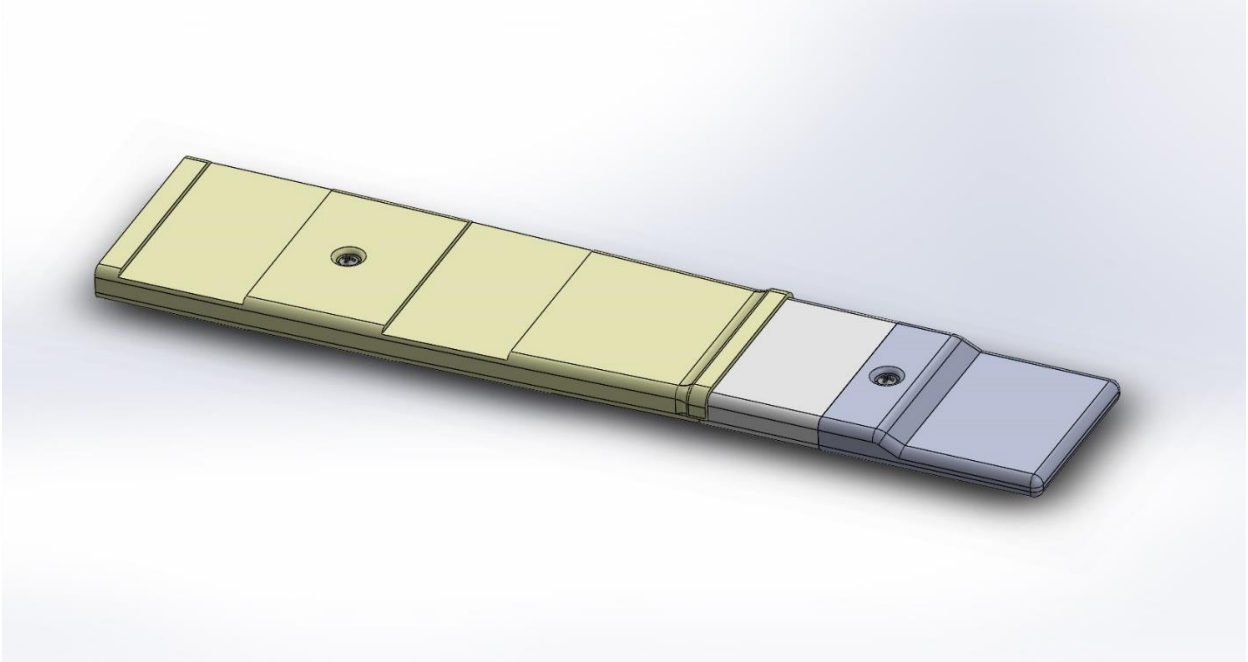


## Appendix 6: Second Design Model





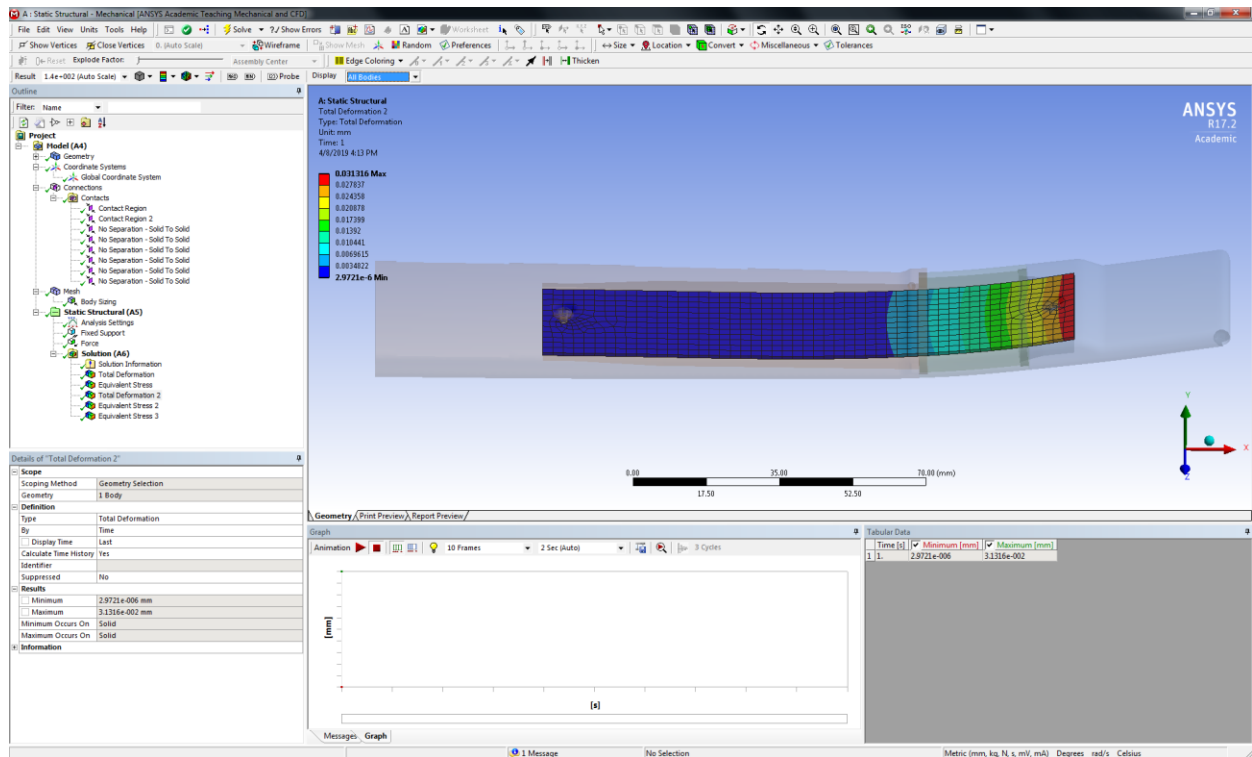
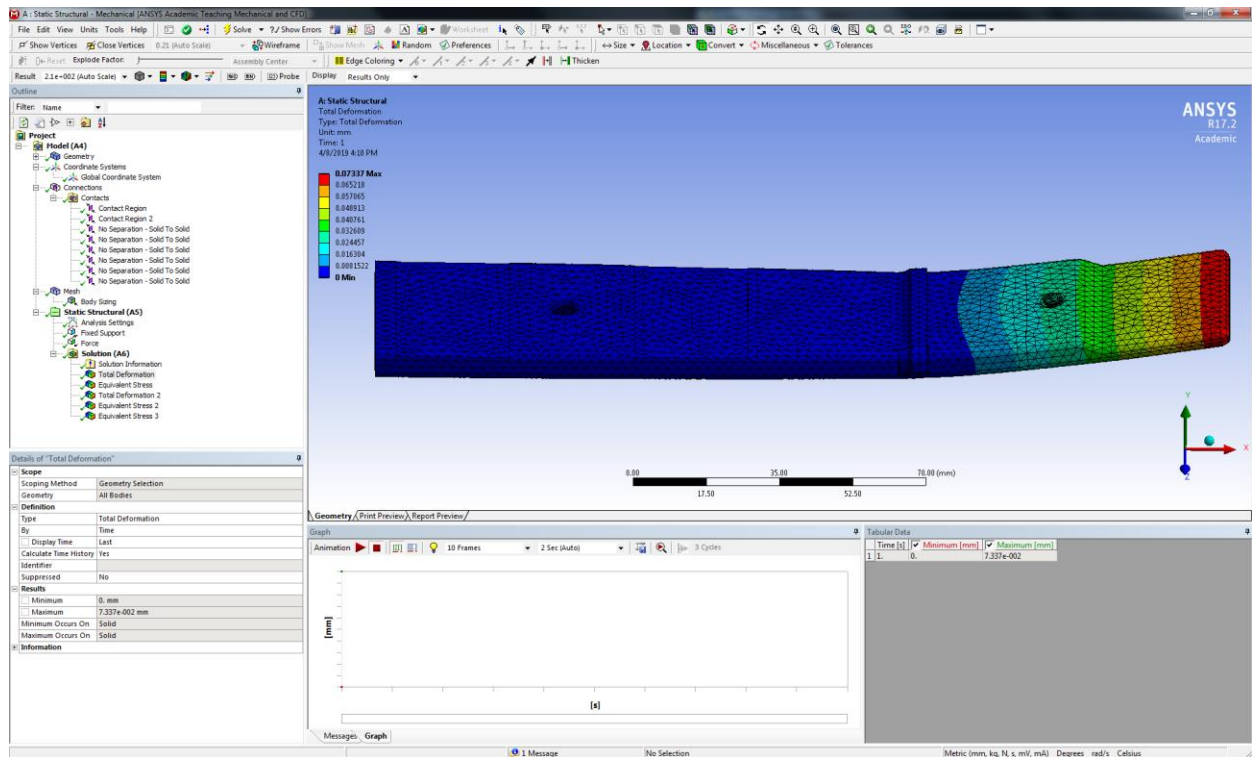
## Appendix 7: Third Design Model

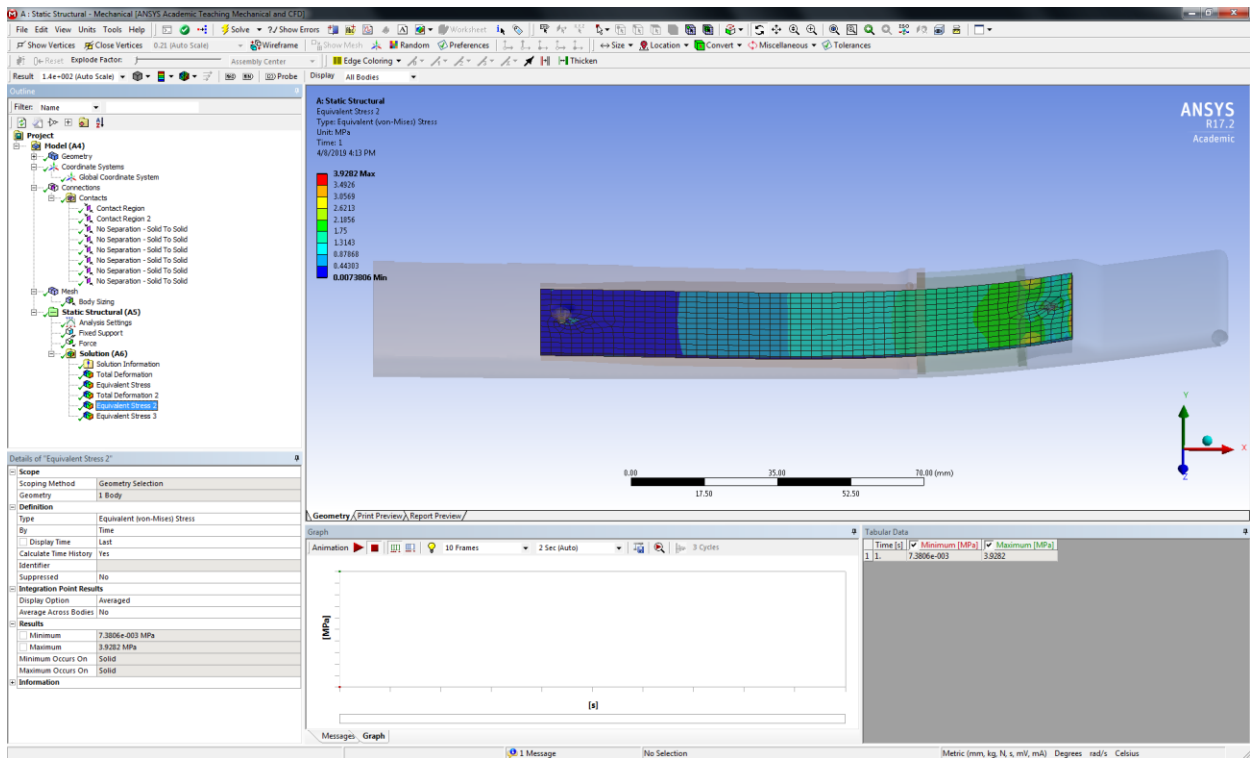
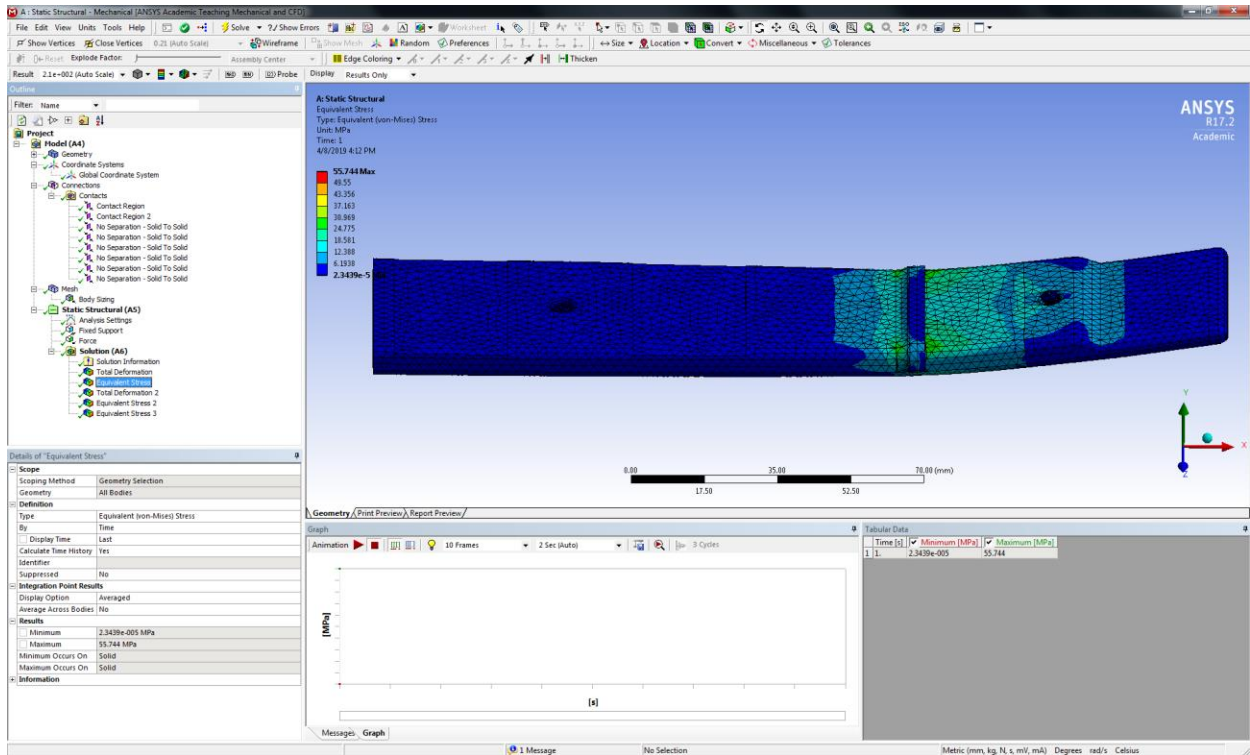




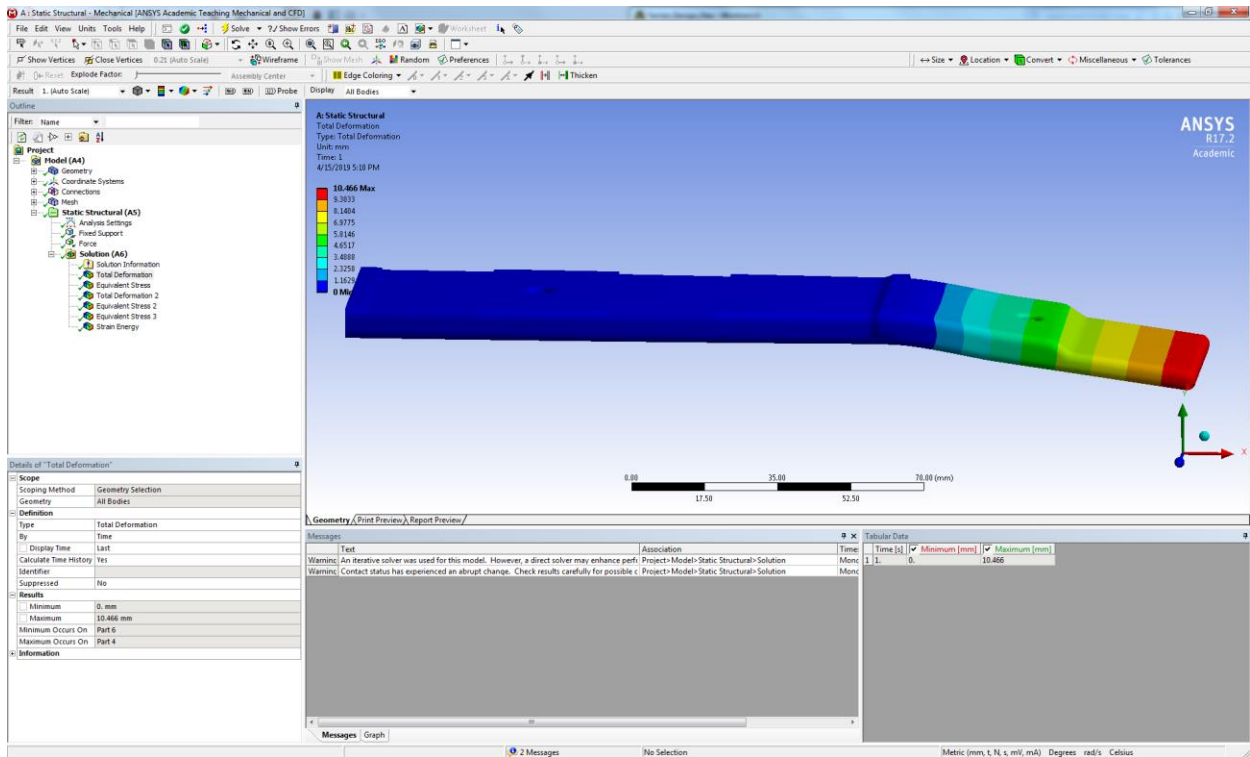
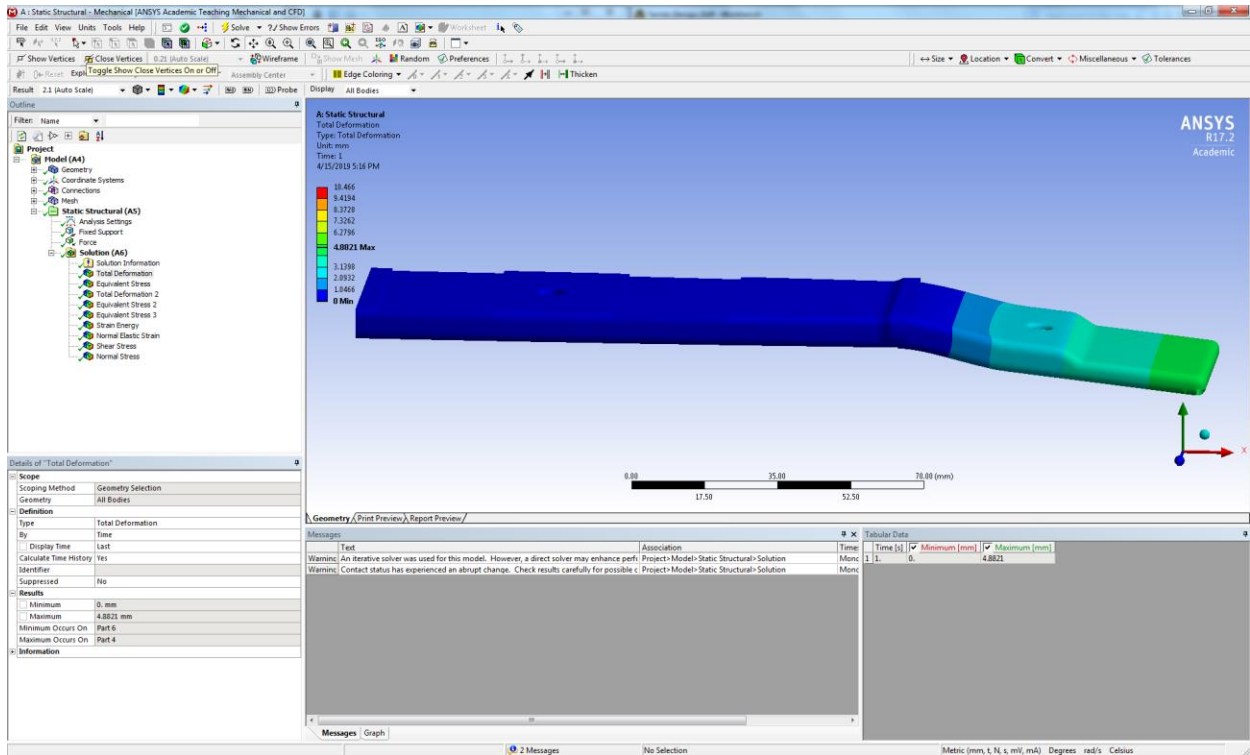


## Appendix 8: FEM Model









## Appendix 9: Testing Methodology

### **Performance Testing**

- Time for correction
  - Requirement
    - Return wrist to neutral position within 0.25 seconds from a perturbing force after force is removed
  - Method
    - Expected time for return is going to be very fast, so to measure the speed a camera will be used. Restrain the forearm of the brace to prevent it from moving. Move the hand part of the brace to a disturbed position ( $\pm 30^\circ$ ,  $\pm 60^\circ$ ). Setup the camera to record the brace. Release brace from disturbed position. Record video and analyze to count the frames beforehand is sufficiently at rest in the neutral position.
- Endurance Test
  - Requirement
    - The brace should remain functional for at least 1.5 million cycles based on the original design specifications.
  - Method
    - The only moving part of this brace is the metal flex plate, so endurance testing will focus on this component of the system. Using a cyclic motor and cam type system, bend the plate to at least  $\pm 30^\circ$ . In the time remaining with the current setup it is not feasible to validate the full 1.5 million cycles. For this reason, the goal will be to do at least 10,000 cycles and plan to do more in the future.

### **Bench Testing**

- Device Imposed Loads
  - Requirements
    - The device must not under its own power impart a force of more than 3 lbs. on the user at any time during operation
  - Method
    - Identify the ways the device can actively impart a force and determine the maximum force each method can impart.

### **Strength Testing**

- Repetitive fatigue loading on flex plate
  - Requirements
    - After the device has been fatigued it should still operate in an acceptable fashion without major decreases in performance.
  - Method

- This test relies on the metal plate being used in the endurance testing. Using this device that has been stressed evaluate the physical properties of the metal plate and determine whether or not the change in property values is acceptable or not. Additionally, place the plate in the device and evaluate functionality.
- Impact Testing
  - Requirements
    - The device will be able to maintain functionality and not break in a way that would produce sharp edges that could harm the client. The force imposed during impact will be representative of the forces experienced if the client were to fall and brace himself with the hand with the device.
  - Method
    - The team will drop an object of known mass from a determined height to impact the brace with a sufficient load at a sufficient loading rate to simulate an impact such as if the user fell while wearing the brace. Impacts will need to happen at various points along the brace, but must include the forearm component, flexible component, and hand component. Verify the component does not show sufficient damage or break in a way that is problematic.

## Environment Testing

- Device Degradation Test
  - Requirements
    - The device should not actively deteriorate in an appreciable way in the expected environment defined as an environment of common humidity with temperatures ranging from 40°F to 90°F
  - Method
    - This testing is very difficult/impossible to do with current available resources. In order to verify this, research needs done on the materials used to determine the degradation of the material.
  - Results
    - Test not completed yet (Include date/time when test is run and a location to found results along with pass/fail and short summary)
- Light impact testing
  - Requirements
    - The device needs to be able to survive in a variable environment that its user (student) will encounter. One aspect of this is the ability to store the brace in a backpack with other items without expected device breakdown
  - Method
    - Place the device in a soft bag such as a backpack. In the bag also place a variety of items that a student may have (pencils, books, ruler, notebook, etc.) Pick up the bag and shake lightly for at least 2

minutes. Evaluate the status of the brace. Perform this test at least 5 times.

- Using the same setup as before drop the bag in several orientations at least 6 times from a height of 3 feet. After all test evaluate the state of the brace and determine if significant damage has occurred.

- Water Exposure Testing

- Requirements

- The device should be able to be exposed completely to water without sufficient damage to the device

- Methods

- Completely submerge the device in room temperature water for at least 20 minutes. After this time, remove the device and evaluate functionality. Dry the device sufficiently and evaluate functionality and wear/damage of the device.

- Finite Granular Exposure Test (Dirt Test)

- Requirements

- The device should be able to continue operating after exposure to a fine granular media such as dirt.

- Methods

- Submerge the device in a granular media such as dirt or sand. While submerged flex the device as if in use multiple times to ensure full exposure. After the brace is well covered in the media, carefully remove the device and test operation. Attempt to quickly shake off media from the device and note how easy the device is to clean. Evaluate the device functionality and any wear/damage

- High Heat Test

- Requirements

- The device must be able to be exposed to significant temperature (100°F) and continue working as expected.

- Methods

- Expose the device to the required temperature for at least 5 minutes. After exposure allow the device to cool and determine wear/damage of the device.

- Results

- Test not completed yet (Include date/time when test is run and a location to found results along with pass/fail and short summary)

- Fire Test

- Requirements

- When exposed to a flame the material covering the device should not have an explosive reaction, quickly catch fire, or burn in a way that is unsafe.

- Methods

- Take a sample of the fabric being used. Light a match and place the match on the material. Determine the effect of the match on the material. Hold the material to a sustained flame, determine whether

or not the material catches fire and how long it will take to catch fire if this were to occur.

- User Safety Test
  - Requirements
    - The bands must be under  $\frac{3}{8}$  inch or over  $\frac{1}{2}$  inch to make sure that the user's fingers do not get stuck in the bands. There should be no sharp edges on the device.
  - Methods
    - Gauges would be used to run through the bands to see test if the sizing is correct. If the gauges can't go through, then the bands will have to be resized. Check for sharp edges on the device to make sure that the user can't be injured.

## Appendix 10: Testing Results

### **Performance Testing**

- Time for correction
  - Results
    - 0.1 sec from 30 degree offset and 0.17 sec from 60 degree offset.
    - These results indicate that the device passes the test
- Endurance Test
  - Results
    - Test not completed yet
    - The team was put the device through 5,000 cycles currently and the device shows no signs of degradation.

### **Bench Testing**

- Device Imposed Loads
  - Results
    - This test was Not Executed. The device cannot actively impart a force, therefore all imparted forces by the device are below the required threshold.

### **Strength Testing**

- Repetitive fatigue loading on flex plate
  - Results
    - Testing in progress
    - The device used in endurance tests is used for this testing, the device was checked to ensure the plate still was performing as expected.
- Impact Testing
  - Results
    -

### **Environment Testing**

- Device Degradation Test
  - Results
    - The device was exposed to at least the temperatures as described for sufficient time without any noticeable device degradation.
- Light impact testing
  - Results
    - No damage to the device was observed following the testing.
- Water Exposure Testing
  - Results

- The device showed no reduction in performance or degradation due to water.
- Finite Granular Exposure Test (Dirt Test)
  - Results
    - The device showed no reduction in performance or degradation due to exposure to the granular media.
- High Heat Test
  - Results
    - The device was exposed to high temperatures for sufficient time to ensure the entire device had reach a high temperature. The device showed no degradation due to the temperature.
- Fire Test
  - Results
    - The fabric covering does not show properties that would cause exposure to a flame to be an issue for the device.
- User Safety Test
  - Results
    - The device is deemed safe due to a lack of sharp corners, pinching, and choking hazards on the device.

#### Material Evaluation

- The materials used for the device are known to not cause rashes or reactions to the skin over long periods of time and is thus seen as biocompatible for this application.
- The material used is not toxic.
- The material used does not show damage due to light exposure.
- The material used for the covering is machine washable.

#### Design Evaluation

- The device is only attached to the user at the hand and forearm.
- The device is passive and does not actively move without outside force.
- The straps on the device are all either adjustable or elastic.
- There are no protruding parts of the device that would catch on clothes.
- The process of putting the device can be done with one hand and should be simple.
- No part of the device is farther than specified from the arm or hand of the user.
- The weight of the device was measured as approximately 4 oz. which is well below the specified weight limit.
- The device is very small and thin and can be stored without disassembly.

#### User Testing

- Meeting with the client it is believed that the device can be put on by the himself without assistance.
- By test fitting the early versions of the device the dimensions of the device are accurate.
- More testing is needed by the client to ensure the device meets all needs.

## Appendix 11: Design Verification and Validation Tracking

Customer Requirement	Design Spec	Test	Results
1.1 Fall	14.D.1, 4.A.1	Impact Testing, FEM	Pass
1.2 Passive	8.B.1,	Design Evaluation	Pass
1.3 No palm stimulation	4.H.1,	Design Evaluation, User Testing	Pass
1.4 Monkey bars	None	User Testing	Not Executed
3.1.1 Skin Damage	4.G.1, 13.A	Material Evaluation	Pass
3.1.2 Good wear and tear	11.A	Endurance Testing, Material Evaluation	In Progress
3.1.3 Water Resistant	14.E.1	Water Exposure Testing	Pass
3.1.4 Multiple impacts	4.B.1,	Light Impact Testing	Pass
3.2.1 Biocompatible	13.A	Material Evaluation	Pass
3.2.2 Easily cleaned	7.A.1	Material Evaluation	Pass
4 Regulatory	Section 2	None	Not Executed
5.1 Allergies	13.A	Material Evaluation, User Testing	Pass
5.2 High Quality materials	None	Material Evaluation, User Testing	Pass
5.3 Daily Use	11.A.1	Endurance Testing, User Testing	In Progress
6.1 Wear for long time	5.G.2	User Testing	Not Executed
6.2 Adjustable Straps	7.C.1, 7.C.2,	Design Evaluation	Pass
7.1 Does not interfere with clothes	4.E.1,	Design Evaluation, User Testing	Pass
7.2 Does not interfere with other therapy devices	4.E.1,	Design Evaluation, User Testing	Pass
8.1 Resistant to light damage	14.E.2	Material Evaluation	Pass
8.2 Compatible with common temperatures	14.A.1	Device Degradation Testing, High Heat Testing	Pass
8.3 Resistant to common liquids	7.A.1,	Water Exposure Testing, Material Evaluation	Pass
9.1 Easy to Put on	5.G.1	Design Evaluation, User Testing	Pass
9.2 Not bulky	6.A.1	Design Evaluation	Pass
9.3 Visually pleasing design	None	User Testing	Not Executed



9.4 Comfortable for extended use	5.G.2	User Testing	Not Executed
10.1 Fit on hand and forearm	4.H.1	Design Evaluation, User Testing	Pass
10.2 Adjustable Fittings	7.C.1, 7.C.2,	Design Evaluation	Pass
10.3 Non-Toxic material	4.G.1, 13.A	Material Evaluation	Pass
10.4 Lightweight	6.B.2	Design Evaluation	Pass
10.5 Safe for children	5.E.1	User Safety Testing	Pass
11.0 Sterility Considerations	None	None	Not Executed
12.1 Non-disposable, low cost	None	None	Not Executed
12.2 Easily obtained material	None	None	Pass
13.1 Easy to sanitize	None	None	Pass
13.2 Interchangeable parts	7.A.1	Design Evaluation	Pass
14.1 Stored without disassembly	6.A.1	Design Evaluation, Light Impact Testing	Pass
14.2 Easily stored at room temperature	14.A.1	Device Degradation Testing	Pass
15.0 Market	None	None	Not Executed

Appendix 12: Final Device in Use

