Dynamic Leaf Spring AFO

Final Report

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DISCLAIMER

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EXECUTIVE SUMMARY

The Dynamic Leaf Spring ankle foot orthotic (AFO) is a concept developed in the Biomechatronic's Lab at NAU by Dr. Zachary Lerner and Leah Liebelt. The design takes inspiration from a standard commercial AFO used by people diagnosed with cerebral palsy as a brace to improve walking and mobility. A typical AFO will act as a brace to keep the foot in line with the rest of the leg and will store some energy acting like a spring when the foot compresses against the ground. This spring effect is important to people with impairments that affect the muscles acting around the ankle because, during a healthy gait the muscles and tendons can store energy that can be used later in the gait cycle. Impaired individuals with Cerebral Palsy are not able to store this energy making walking strenuous and inefficient. The Dynamic Leaf Spring AFO utilizes two composite leaf springs that attach to a pulley that provide a resorting torque around the ankle when the pulley is rotated from its initial position. There was a second version of the Dynamic AFO that utilized a cam system to actuate the springs that was encased in a carbon fiber tube. This prototype had inherent flaws in because the cam would allow the toque to drop off as the pulley reached high angles. After this it was decided that the cable transmission system provided a more favorable torque curve that better represents normal walking. The desire for this sleek design and the torque transmission of the cable system led to our project, which involves encasing the cable transmission system in a carbon fiber tube like the cam version.

Our current design attempts to merge the two prototypes with some additional functionality such as a two leaf springs and a neutral angle adjustment. Neutral angle adjustment is accomplished by using a friction pad material on the interface between the neutral angle adjustment and foot plate. This subsystem took inspiration from the splined angle adjustment used in a snowboard to provide different stances but the adjustment in our design allows for continuous adjustment. To meet the size constraint on our device the pulley needed to be adapted and made to fit within the carbon fiber tube while maintaining a similar torque output. There were concerns that came up with the amount of force it would undergo so a FEA was performed to estimate the load capabilities of the design.

The design outputs a maximum of 20 Nm, and it has a cycle durability of at least 10,000 steps. The final design is encased in a carbon fiber tube that hides the internals and protects the parts from the environment to some extent.

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1 BACKGROUND

1.1 Introduction

The biomedical engineering field is challenged with assisting in the rehabilitation and aid of people with a wide variety of physical disabilities. This team's purpose starts with rehabilitation. There are over 760,000 people in the us alone that suffer from cerebral palsy. One of the main effects of cerebral palsy that is quite common in patients that are diagnosed are movement disorders. These disorders manifest in the tibialis anterior which is responsible for dorsiflexion and in the soleus muscles which in part control plantarflexion [1].



Figure 1: Dorsiflexion and plantar flexion

These muscles have a large effect on how we walk and the patterns we develop during walking from an early age. Generally measured and referred to as the gait cycle. During a normal gait cycle of a person not diagnosed with movement disorders, these muscles are able to contract independently of each other. People with cerebral palsy lack development somewhere in the neural pathway that allows for reciprocal inhibition. A lack of development in this neural pathway can lead to co-contraction at the ankle. People that are born with these impairments often use braces to augment mobility. These braces are often inexpensive and are often only affective for low to moderate levels of impairment. With the current technology available in other industries, it is a wonder why these devices have not been improved to better augment impaired individuals.

1.2 Project Description

The current state of technology available for people diagnosed with cerebral palsy is lacking in innovation compared to other industries. The Biomechatronic Lab and team at NAU is developing this technology to hopefully one day have more advanced options that will better aid in mobility and therapy training for people who are dealing with this uncurable diagnoses. Due to the nature of rehabilitation, it is not easy to make a device that is effective in augmenting mobility and providing effective therapy. Our team is tasked with improving a current prototype device that assists in mobility that utilizes the framework and interfacing of a widely available ankle foot orthotic (AFO) and adds a spring actuation mechanism to provide higher levels and more adaptive assistance.

2 **REQUIREMENTS**

Our client Dr. Zachary Lerner had a wide range of requirements that were envisioned for this project. Because this device is to be worn by people with movement disorders it needed to be able to accommodate a wide variety of gait/walking patterns. Some of the suggestions for this provided by our client to achieve this were an adjustable zero engagement point for the spring, adjustable torque mechanism, adjustable attachment/ interfacing points. Some of these were already included in the previous prototype but this new design hinged on an enclosed version of the device with some additional functionality.

2.1 Customer Requirements (CRs)

For the customer requirements, we consulted with the project sponsor, Dr. Lerner. With a previous working prototype being supplied with the project, the goal was to build off, and improve on the ideas and structures. The main priorities and reasons for improving the prototype given by Dr. Lerner are listed below.

1. Durable

The design must last for at least 10,000 running steps. Meaning a user would wear the design and test it to 10,000 steps without the design failing.

2. Adjustable Torque

The design must accommodate a range of users. So, the design must be adjustable, and the adjustments must be reliable to provide an accurate output for a given user.

3. Adjustable Neutral Angle

The design musting include a clutch-able power train that allows the user to adjust the engagement point of the spring

4. Hight Torque The torque should be substantial to assisting the ankle.

5. Comfortable:

The device should be comfortable to wear and use for at least short periods of time.

2.2 Engineering Requirements (ERs)

- 1. Minimum durability of 10,000 running steps
- 2. Adjustable torque (5 Nm -30 Nm)
- 3. Adjustable neutral angle +/- 20 degrees
- 4. Maximum output torque of 30 Nm
- 5. Range of motion of +/-30 degrees

2.3 Functional Decomposition

2.3.1 Black Box Model

The black box model the team used included inputs and outputs in the form of materials, energies, and signals. The black box model was used to facilitate the concept generation

discussions by helping the team visualize how broad the solutions were for storing the mechanical energy and outputting it for our system. The same could be said for the signal system, there are a lot of ways to measure torque and angle. This black box model helped the team visualize what the AFO needs to do and how different our solutions could be. Below is the black box model, where the material inputs and output are the foot. For energy inputs and outputs, the team listed mechanical and electrical energies as inputs and mechanical as an output. The team had reasoned that electrical energy would go in to power the angle and torque sensing system and that energy would come out as a signal. The input would be provided by the user's movement, so in the form of mechanical energy, and it would be stored in some way by the AFO and output later as mechanical energy still. For the signal chain the input would simply be an on/off command to start recording data and the output would be an on/off command and an angle and torque reading. This signal transfer could be done via a hard cable connection or through wireless communication, but the black box made it so that when we were generating concepts that it was not specified.



Figure 2: AFO Black Box Model

When applying to the black box model in the brainstorming process, the team was able to decide if an idea was reasonable to be done

2.3.2 Functional Model/Work-Process Diagram/Hierarchical Task Analysis

Figure 3: Functional Model

In figure 2, a functional model can be seen. The team used this to determine the steps that the model would take in the process of use. This helped us determine what subjects needed extra



steps to improve the model. In the design process, the team walked the ideas through this chart to ensure that the device had all the capabilities needed for the device to function at the capacity wanted.

2.4 House of Quality (HoQ)

House of Quality (HoQ)						
			E	Ingineering	Requirements	
Customer Requirement	Weight	Lasts 10,000 running steps →	Adjustable Neutral Angle	Range of Motion of +/- 30 degrees	Maximum output torque of 30 Nm	Adjustable torque
1. Adjustable Torque	5					9
2. Durable	5	9			3	
3. Adjustable Zero Angle	4		9	3		
4. Comfortable	3	3	3	9	3	9
5. High Torque	3				9	9
Engineering Requirement	Units	#	N/A	N/A	ft-lb	ft-lb
Absolute Technical Import	ance (ATI)	54	45	39	42	54
Relative Technical Importa	ance (RTI)	2	3	4	6	1
Target ER values		10,000	+/-10° adjustment	-/- 30 degrees	30 Nm	5 - 30 Nm
Tolerances of ERs		10,000 Minimum	+/-10% min	+/- 5 degrees	+ /- 10 Nm	+/- 10 Nm
Testing Procedure (TP#)		2	3	1	1	1

Table 1: HoQ

2.5 Standards, Codes, and Regulations

The Human Factors Design Process for Medical Devices standard will be used as a guideline to ensure that our design will be effective, safe, and efficient. Errors can arise when a client interfaces with the device due to poor engineering or design interpretation. Following the guidelines will help the team improve the usability of the device and reduce user errors.

The ASME Y14.5 standard will guide the team when we are making the CAD drawings. This will help the team make clear drawings for the parts and it will help the team communicate with other parties during the manufacturing phase. Following the standard will ensure that the drawing will be understood by manufacturers. This standard will also apply more specifically to the geometric dimensioning and tolerancing that will be used to ensure that the pulley will be machined properly.

<u>Standard</u> <u>Number or</u> <u>Code</u>	<u>Title of Standard</u>	How it applies to Project
ASNI/AAMI HE 74:2001	Human Factors Design Process for Medical Devices	Helps in the design of how the device with interface with the user in a safe manner.
ASME Y14.5	Dimensioning and Tolerancing	Standard applies to CAD drawings and GD&T principles.

Table 2: Standards of Practice as Applied to this Project

3 DESIGN SPACE RESEARCH

3.1 Literature Review

Samuel Maxwell will be focusing on the sensor implementation into the design. This will include torque sensing and angle sensing. There are many options available for sensing torque and joint angles. Some of these include rotary encoders, hall sensors, potentiometers, and strain gauges. It is important to understand the system behavior when taking measurements like this because the output will likely be produced through some model of the system. The literature will cover the options on implementation of these different sensor-types. Table 1 discusses the sources related to this topic and a short description of what they will be used for.

Source	Description		
Theory and design for mechanical	Implementation of wheat-stone bridge		
measurements by R. S. Figliola and D. E.			
Beasley			
INNOVATION IN AUGMENTING HIP AND	System modeling and general information on		
ANKLE PERFORMANCE DURING	the system		
WALKING by Leah Liebelt			
The Complete Guide to Building a	Data acquisition and software requirements		
Measurement System NI			
Arduino Cookbook by M. Margolis	Software and Bluetooth interface		
Mechanics of Materials by R.C. Hibler	Beam deflection and spring equations		

Table 3: Table of Sources used by Samuel Maxwell

Theory and design for mechanical measurements by R. S. Figliola and D. E. Beasley will be used as a reference to determine and design the required circuitry to interface with strain gauge sensors. The most common circuit used to interface with these types of sensors is a wheatstone bridge. This is preferred because it can be set up in such a way to reduce noise from temperature variation. In section 6.4, page 222 the wheat-stone bridge is discussed in context with the deflection method which is commonly used to measure strain. These circuits use four sensors that vary in resistance when it is activated and outputs the difference between the 2 sides of the bridge. This allows for train due to temperature differences to be ignored. The bridge consists of few components and is relatively small when implemented correctly. The system is also useful in taking measurements that vary in time and need a continuous stream of measurements.

INNOVATION IN AUGMENTING HIP AND ANKLE PERFORMANCE DURING WALKING is a thesis paper written by NAU alumni Leah Liebelt and describes the design process and testing that went into developing the initial protype. The document contains information relevant to the system model and determining spring stiffness and how different sizes effect the applied torque.

The Complete Guide to Building a Measurement System NI will be used to determine the type of signal post processing that will be applied after it leaves the circuit. It also discusses sampling rate and how to determine the best rate for the system. Digital sensor resolution is also discussed and will be useful in determining how much amplification of the signal is required. Strain gauge orientation and placement is also discussed based on the measurement that is needed. Measuring displacement is also discussed and the various methods used commercially to implement them. All these types of sensors are being considered in the Leaf Spring AFO design so it will be a good reference to have when making decisions related to sensing.

The Arduino Cookbook is a book design to provide documentation for Arduino related projects. The Leaf Spring AFO will need to communicate sensor data to a phone or a computer to work effectively and the current plan is to use Bluetooth to allow for an untethered device. The Arduino Nano BLE Sense has a Bluetooth low energy communication protocol which requires different code to work with than previous Bluetooth releases. BLE is discussed and how to interface with it from a computer or phone. Sensor interfacing is also discussed which will be useful when trying to obtain signals from a custom sensor.

Mechanics of Materials discusses material properties and the behavior of these materials in certain configurations. The Leaf Spring in the Leaf Spring AFO design can be thought of as a beam and will be evaluated as such. Beam deflection of a simple cantilevered beam is discussed, and the basic equations are provided to find the applied force per unit of measured deflection. This will be useful when modeling the system and analyzing the voltage response of the sensor.

3.2 Benchmarking

There are not a lot of assistive devices available for people diagnosed with Cerebral Palsy. The system level benchmarking will be filled with the most suitable designs that are currently available on the market even though they may not be direct competitors to our design. The subsystems currently available on the market will be more direct competitors and have the possibility of being implemented into our design.

3.2.1 System Level Benchmarking *Composite AFO Brace*



Figure 4:Composite AFO

The composite AFO is commonly used to aid mobility in people diagnosed with cerebral palsy. The system works by providing support to the muscles around the ankle and keeping them controlled during walking. The composite AFO is very light due to its carbon fiber body and will be difficult to match in weight. Most composite AFOs feature a rocker shape near the toe to provide a spring effect on toe off during the gait cycle. This is where the Leaf Spring AFO is hoped to surpass this device.

Resistive Therapy Device



Figure 5: Resistive Therapy Device

Resistive therapy devices such as the one shown in Figure 2, the focus is not an immediate solution, but a gradual one as the device helps the muscles regain some function through resistive training. While this works well to return those who are injured back to full health quickly, it is not an ideal solution for those who have degenerative muscle diseases as it will not work nearly as well. The goal product to create a device that is an option as both a

temporary assistant or a permanent assistant for those who have short term injuries and long-term disabilities.

Cane or Walker



Figure 5: Walking Cane Figure 6: Walker The cane and walker are very simple solutions, and don't offer much ankle or leg support to the user. These just offer a solution that will down the line create other body issues including back pain. It is important to look at these solutions to see that just because a solution works, does not mean it will be healthy or a good long-term solution.

3.2.2 Subsystem Level Benchmarking

Torque Sensing

Load Cell



Figure 7: Load Cell Torque Sensor

The load cell torque sensor is a common choice for sensing torque at a joint. This sensor is small and durable, so it is a great choice when space is a constraint and the. The downside to using an off the shelf sensor like this is it will never integrate as well as a custom sensor. The sensor has a metal body which makes it heavy and undesirable to place at the ankle. The accuracy is not listed but is expected to be well within the engineering requirement of +/-1 Nm. Cost is the factor that will not allow this to be a viable option in our design because these types of sensors can cost well over \$500.

Reaction Sensor



Figure 8: Reaction Sensor

Reaction sensors are mainly used for inline torque measurements which is perfect for this project. The sensor is low profile and has a large inner diameter. The accuracy is within the engineering requirement of \pm 1 Nm. These sensors are somewhat big for where they would be needed for this project so it would make the system look a little bulky which goes against another engineering requirement.

Rotary Optical Encoder



Figure 9: Rotary Optical Encoder

The rotary optical encoder is a device commonly used to measure joint angles on robotic devices. Optical encoders tend to be bulky and are not preferable for a device that has a

constraint on space. The rotary optical encoder is very accurate and is good for high precision applications but is not compact enough to work with our project.

Neutral Angle Adjustment



Snowboard Angle Adjustment

Figure 10: Snowboard binding Adjustment

A snowboard uses a gear mechanism to adjust the angle of its bindings and does well at dealing with torsional forces. There are currently not a lot of angle adjustment solutions being applied in the physical therapy industry so this is the closest design that could be compared to our device. Some variation of this could be applied to our design to get the correct angular resolution to satisfy our client.

4 CONCEPT GENERATION

4.1 Full Concepts

1. Single Enclosed Leaf Spring



Figure 1: Single Enclosed Leaf Spring

The single enclosed leaf spring design is a similar design to the original prototype except it only consists of a singular leaf spring enclosed in a carbon fiber case. This design is lightweight and would reduce the weight of the prototype system. The low-profile shape also allows it to be worn more comfortably around clothing and tight spaces. This design also allows for easier torque sensing because there is a linear relationship between the angle of the pulley and the applied torque. It is not able to apply assistance to the dorsiflexor muscles, but this is something that was discussed with our client Dr. Zachary Lerner and is not sure to be an inherent disadvantage.

2. Full System Design #2: Descriptive Title



Figure 12: Spring Canister Design

The spring canister design is a drastic overhaul from the current prototype as instead of leaf springs, this model contains standard helical compression springs. The springs will act as resistive for to the motions of the leg and propel the user when releasing the tension. In the drawing, two springs are in place but in practice only one would be used to focus on the plantarflexion. This design can be compact at the springs can be placed closer to the pully as there is no concern of scraping with the casing like the leaf spring has. This model may also be more durable than those with leaf springs as the deflection is in a more durable direction. One downsides of this model is that the springs may become costly as they would likely be metal and custom ordered. This takes out the advantage of having leaf springs made already.

4.2 Subsystem Concepts

Torque Sensing Concepts

Hall Sensor Concept



Figure 13: Analog Hall Torque Sensor

The analog hall sensor can be used to measure torque by measure the displacement of the leaf spring. If the system can be model to a high enough accuracy this design can be used to estimate the torque at the ankle. If this design is used it will be cheap relative to other designs and off the shelf parts. One of the disadvantages of using this design is the model would have to be updated based on the position of the slider used to adjust spring stiffness.

Angle Adjustment Concepts

Snowboard Inspired Adjustment



Figure 14: Snowboard Inspired Angle Adjustment

The snowboard inspired angle adjustment device uses gear slots like a snowboard and can be optimized to have a high enough angular resolution to be considered continuous for the purposes of this design. It would most likely need to be machined from aluminum which makes it expensive and possibly heavy. It has a familiar user interface making it friendly towards new users. This is currently the most reasonable and easiest design to implement into any of our full system design concepts. Bike inspired adjustment: Barrel Adjuster



Figure 15: Inline Barrel Adjuster

An inline barrel adjuster was another one of our concept variants for the neutral angle adjuster. It would be placed at the end of the wire just past the leaf spring shown below circled in red. The pros are that it is an off the shelf solution. The cons being that we would only get a few degrees of adjustment and that the adjustment would be along the y-axis. So, this would make the overall enclosure wider.

5 DESIGN SELECTED – First Semester

This section will cover the selected design from the first semester. For the first semester the team has selected the neutral angle adjustment method and the overall spring layout and design. The team prototyped some of the components and the results of these prototypes are reflected on at the end of this section.

5.1 Design Description

5.1.1 Single Leaf Spring Design

For the first semester the team decided to continue the project with the single leaf spring design. This decision was made due to the client wanting the entirety of the final product to be lighter, more compact, and to look less like a research prototype. After discussing the ways to implement this, the team and client decided to remove the dorsiflexion spring and focus on the plantarflexion aspect of the design. This design is the same as the design presented in the preliminary report. The figure below shows the single leaf spring design and some other hardware.



Figure 16: First semester carbon fiber enclosure and leaf spring design

5.1.2 Pulley Design

Since the pulley will be experiencing less wear due only using one spring, the pulley was redesigned to be smaller, lighter, and cheaper than the previous iteration. This new part looks very different from the previous iteration because the new pulley has to fit within a new volume and still output the same torque. The pulley has also been designed to be made of aluminum instead of steel as the aluminum will still be able to withstand the desired 1200 N that would be placed on it from the cable pulling the spring. This model has been slightly altered since the preliminary report but is the same overall concept. The angle of the pulley was slightly changed to help apply a slightly greater force when rotating.



Figure 17: First semester pulley design

5.1.3 Neutral Angle Design

The design for the neutral angle adjustment is a toothed disk. This will be bolted onto the foot plate along with the pulley system and it is adjustable. The neutral angle can be changed but it also applies enough pressure to keep the adjuster in place. This model was thought to be the most feasible design, which is why the team chose this design for the first semester. It was also small enough to fit in the desired location and strong enough to withstand the forces applied to it during normal use.



Figure 18: First semester neutral angle adjuster

5.2 First Semester Design Conclusions

Between semesters the team changed the selected design dramatically, with some parts being redesigned completely. After prototyping the neutral angle adjuster and pulley, the team realized that it would be too costly and difficult to manufacture the parts. So, Sam redesigned both parts

and talked with the client to reimplement both leaf springs. The concepts of each component were preserved from the first semester but now it was accomplished differently by the start of the second semester. These redesigns improved the manufacturability of the parts and the functionality as well. The neutral angle which previously has discrete adjustment points was now continuously adjustable like the client had requested. Also, the pulley was now in theory, much easier to manufacture and it had a different power transmission method which allowed for the new neutral angle adjustment. The pulley redesign also allowed for both springs to be reimplemented into the design so the design could assist both dorsiflexion and plantar flexion.

6 Project Management – Second Semester

6.1 Gantt Chart

The Gantt Chart is included in the Appendix and the team roughly followed the chart. If done differently the team would have divided up the work in the Gantt chart to reflect more accurately what was done. The team also could have improved how well we followed the start dates for the Gantt chart as the team didn't really start deliverables when the Gantt chart has originally stated.

6.2 Purchasing Plan

The purchasing plan is shown below and the major differences from this plan to reality are the lead times. From the top down the part descriptions are below.

- Neutral angle pulley Machined part purchased form GoProto
- D-profile shaft Off the shelf part from McMaster
- Bearings Off the shelf part from McMaster
- Neutral angle plate Machined part purchased form GoProto
- Thumb screw Off the shelf part from McMaster
- D-profile collar Off the shelf part from McMaster

Item					Primary		Lead	Part
No.	ltem	Count	Make/Buy	Cost	, Vendor	Manufacturer	Time	Status
	Neutral Angle						2	In
3	Pulley	1	Buy	\$174.96	GoProto	GoProto	weeks	inventory
	8017T2 D-Profile						1	In
9	Shaft	1	Buy/make	\$18.62	McMaster	-	week	Inventory
	4390N111						1	In
10	Bearing	2	Buy	\$16.61	McMaster	-	week	Inventory
	Neutral Angle						2	In
12	Plate	1	Buy	\$146.16	GoProto	GoProto	weeks	Inventory
	9687T441 D-						1	In
13	Profile Collar	1	Buy	\$24.57	McMaster	-	week	Inventory
	92552A426						1	In
18	Thumb Screw	1	Buy	\$3.06	McMaster	-	week	Inventory

Table 3: Purchasing Plan

There are some key differences between the current purchasing plan and the original plan from the beginning of the semester. Some parts were changed out in favor of better parts and some of the lead times were inaccurate. If the team were to purchase everything over again, they would first order the parts with the longest lead times. While the team expected the machined parts from GoProto to have a lead time of 2 weeks they had a much longer lead time closer to a month. Aside from that the team followed the purchasing plan.

6.3 Manufacturing Plan

The manufacturing plan that was followed is shown below. The team used a few different manufacturing techniques in this project. The team used a manual lathe, 3d printing, and a StepCraft CNC. The StepCraft was used to manufacture the neutral angle tube. The lathe was used for the shaft and the rest of the parts were 3d printed. Opposite to the purchasing plan the team overestimated the lead times for the manufactured parts. The team could have improved the quality of the neutral angle tube because there were some mishaps with the StepCraft but otherwise the team is happy with the manufacturing plan and the results of following the plan.

Item No.	Item	Count	Make/Buy	Cost	Lead Time	Part Status
2	Neutral Angle Tube	1	Make	Donated	1 week	In inventory
4	Tube Cap	2	Make	Donated	2 days	In inventory
5	Leaf spring	2	Make	Donated	None	In Inventory
6	Leaf spring mount	1	Make	Donated	2 days	In inventory
7	Neutral angle slider	1	Make	Donated	2 days	In inventory
9	8017T2 D-Profile Shaft	1	Buy/make	\$18.6 <mark>2</mark>	1 week	In Inventory
11	Friction Pad	1	Make	Donated	1 week	In Inventory
21	NA Slider A	1	Make	Donated	2 days	In inventory
22	NA Slider B	1	Make	Donated	3 days	In inventory

Table	4:	Manuj	facturing	Plan
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7 Final Hardware

7.1 Final Hardware Images and Descriptions

Table 5: Outsourced Components

Pulley	
The pulley is responsible for taking the linear force produced by the leaf spring and translating it to a torque that can be used by the ankle.	
	Figure 1: Neutral Angle Pulley
D-Shaft	
The shaft is responsible for transmitting the torque from the pulley to the neutral angle adjustment.	
	Figure 2: D-Profile Shaft
Ball Bearings	
The ball bearings hold the shaft in place relative to the case while allowing it to move freely in the rotational axis.	
	Figure 3: Ball Bearing
The neutral angle plate is used to allow the user to adjust the zero-engagement angle of the leaf springs.	
	Figure 4: Neutral Angle Plate
D-Profile Collar The D-Profile collar is used to prevent the device from sliding along the D-shaft, while also allowing for some lateral adjustment.	
	Figure 5: D-Profile Collar



Table 6: Manufactured Components



7.2 Design Changes in Second Semester



Figure 6: Semester 1 Design



Figure 7: Semester 2 Design

7.2.1 Design Iteration 1: Change in pulley design

In the first semester, to create a system that was lower profile and could fit within the smaller case a new version of the pulley was though of to reduce the overall size and weight. This involved optimizing the pulley to only using sections that were critical to functionality to a single plantarflexion spring. This design was lower profile, but it lacked the ability to provide dorsiflexion assistance and with the complex geometries brought into question the structural integrity of this new component.



Figure 98: Semester 1 Pulley Design

In the second semester we reverted to a design that was like the original design but reduced in size to allow it to fit within the carbon fiber casing. This included a cable routing that allowed the cables to wrap around and transmit torque to the pulley from the springs and a d-shaft interface to make mounting more centralized and modular.



Figure 9: Semester 2 Pulley Design

7.2.2 Design Iteration 1: Change in neutral angle design

The neutral angle was another critical component of the design that needed to be refined. The semester 1 design took inspiration from a snowboard binding clip that locks on by a gear-like mesh that could be adjusted discretely by lifting it out of the current slot and re locking it in the gear mesh to a new location. Due to its extremely complex geometries and tight tolerances, this part would have been extremely expensive to manufacture as well as not satisfactory to our clients request to make this adjustment continuous.



Figure 10: Semester 1 Neutral Angle Design

The semester 2 version of the neutral angle design was a much simpler design that feature slots that would allow the user to rotate it about the center axis. This design was had a much more reasonable manufacturing cost and more intuitive user interface while also allowing it to adjust continuously making it an improvement upon our previous design.



Figure 11: Semester 2 Neutral Angle Design

7.3 Challenges Bested

One of the main challenges was our timeline for the acquisition of the machined parts, specifically the pulley and neutral angle plate. Because the design for both components went under such drastic changes late in the design process, they were ordered very late with respect to the relatively long 1-month lead time. The parts also came from the factory with tolerances that were larger than expected for the reported machining process. The manufacturer claimed to use EDM which reports a standard tolerance of ± 0.001 however when the parts were received, they were smaller than expected which required our team to remove extra material to create the desired fit.

8 Testing

8.1 Testing Plan

The team has a total of 10 design requirements, 5 engineering requirements and 5 customer requirements. Two of the customer requirements are about adjustability. The design should allow for adjustable torque and zero angle. The torque adjustment will allow a wider range of users to comfortably use the design. In this design "zero angle" or "neutral angle" refers to the angle that is formed between the flat of your foot and your shin. For zero angle adjustment the client wants the design to be able to adjust where the springs apply no force to the ankle. The other three customer requirements include durability, comfort, and high torque output. The 5 engineering requirements are directly related to the customer requirements. The engineering requirements include two adjustability requirements that directly reflect the customer requirements and one requirement related to the range of motion. There is also a minimum durability requirement of 10,000 running steps and a torque requirement of 30 Nm. Each design requirement is shown in the table below.

Customer Requirements	Engineering Requirements
CR 1 – Adjustable Torque	ER 1 – Adjustable torque TBD
CR 2 – Durable	ER 2 – Minimum durability of 10,000 running steps
CR 3 – Adjustable Zero Angle	ER 3 – Adjustable neutral angle +/- 20 degrees
CR 4 – Comfortable	ER 4 – Range of motion of +/- 30 degrees
CR 5 – High Torque	ER 5 – Maximum output torque of 30 Nm

Table	2:	Design	Reauir	ements
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The team will be performing two experiments. The first experiment is the leaf spring test and using a load cell the team determine the minimum and maximum force outputs from the springs. Using the force data, the team will then calculate the torque output at different settings. Experiment 2 is the cycle test experiment. The team will take turns wearing the design and cycle it for 10,000 running steps total. This test will measure the steps taken and it will document any wear that occurs throughout the test. During this test the team will also document what leaf spring lengths are used and so if any catastrophic failure occurs the team can estimate at what torque the design failed at. By catastrophic failure the team has defined it as a failure that would prevent normal operation of the design. The main goal of experiment 2 is to fulfill engineering requirement 1.

Table 2: Test Summary Table				
Experiment/Test Relevant Drs				
Exp1	ER1, ER4, ER5, CR1, CR4, CR5			
Exp2	ER1, ER2, CR1, CR2, CR3, CR4			

8.2 Testing Results

The figure below shows the results of the force test (exp 1) showed a max output of 20 Nm. This was just within the bounds of our engineering requirements. This mechanical loss in torque can be attributed a few design decisions. To support the large loads of the deflecting springs, the mounting hardware needed to be heavily reinforced. Our team added carbon fiber infill to mitigate these losses however, to achieve any higher torques these mounting pieces would need to be machined from a stronger material like aluminum. This force test was also responsible for determining whether our other components like the neutral angle adjustment, pulley components, and crimping hardware could withstand the expected forces.



Figure 12: Max Force Test

The figures below show the main components of the 10,000-step fatigue test (exp 2). The neutral angle adjustment was a critical component of this test due to the high stress concentrations around the mounting points of the D-shaft. This test showed no significant amounts of wear around these stress concentrations. The aluminum-steel interface between the D-shaft and the D-shaft interface caused concern for wear on these high stress concentration spots. The results of this test can be seen in figures 9 and 10 below.



Figure 13: 10,000 Steps Testing Results



Figure 14: 10,000 Steps Testing Results

9 RISK ANALYSIS AND MITIGATION

This section will cover the top potential critical failures that were determined from the FMEA for each semester. The team will describe these potential failures and discuss how the team is currently working to prevent them. After the critical failure discussion, the team will then discuss the risk trade-off analysis that was performed that weighed the benefits, drawbacks, and potential conflicts that some solutions might have with one another. With the limited budget of \$500 in mind the team did their best to verify critical parts before they were manufactured or purchased. To verify the parts the team looked at the dimensions and loads. By looking closer at the part and assembly dimensions the team could apply GD&T principles to validate the part fitment. The expected loads were used to estimate the stresses within the parts for each semester as the parts changed. Both techniques were used to mitigate the risk of component failure or component interference.

9.1 Potential Failures Identified First Semester

In the Spring semester the team had identified 9 potential failures from the design then. The table below shows the highest scoring items from the FMEA, where RPN represents the risk priority number, and a higher number equals a greater risk. From the table below it can be seen that the highest risk item was the pulley and all the components in the power train.

Item Name	Description	RPN
Pulley v2	Aluminum pulley	256
Neutral angle adjustment	Spline adjustment	96
Spring	Carbon fiber spring	72
Cable swages	Aluminum cable crimps	64
Cuffslider_top_rectangle	Calf cuff mount	64
7804k143	Flanged bearings	40
Slider v3	Onyx slider	32
Mounting plate	Onyx block	28
Upright machined pattern	Carbon fiber upright	24

Table 3: Shortened FMEA from Spring 2022

9.1.1 Potential Critical Failure 1: Leaf Spring Due to Adjustment Block Interface

Through previous testing in the Biomechatronic's lab, it is known that the leaf springs will succumb to the shear stress applied to them by the aluminum slider block that allows them to deflect at different effective lengths. This failure is catastrophic to the functionality of the device and could result in injury to the user. This failure is being mitigated by allowing provided some curvature to the mounting and slider blocks to avoid in the stress concentrations that will likely cause the spring to crack and eventually shear off entirely.

9.1.2 Potential Critical Failure 2: Leaf Spring Due to Mounting Block Interface

The mounting block where the leaf spring attaches to the device suffers similar issues to the adjustment block where the spring is known to shear due to the stress concentration at the edge of the block. This risk will be mitigated in a similar fashion where a curved surface will be provided to allow the stress to be distributed.

9.1.3 Potential Critical Failure 3: Cable Swage Fitting Due to Leaf Spring

The Swage fitting where the cable interfaces with the leaf spring is known to deform and fail causing catastrophic failure in the transmission system. This risk is being mitigated by using stronger swages and looping the wire back into the swage to provide more surface area for the swage to attach to.

9.1.4 Potential Critical Failure 4: Neutral Angle Adjustment

The teeth on the neutral angle adjustment will be subjected to forces up to 1.2 kN. The current plan is to 3D print this part out of carbon fiber reinforced onyx filament. This material is known to have strength comparable to lower grade aluminum making it one of the weakest links in our transmission system. This failure risk is being mitigated by attaching it directly to the foot plate and providing multiple mounting points and surfaces to distribute the load over the surface of the aluminum pulley and carbon fiber foot plate.

9.1.5 Potential Critical Failure 5: Pulley Due to Yielding

The pulley will be subjected to approximately 1200 N. The pulley can yield under the load and cause catastrophic failure and potentially harm the user. The potential failure is currently being mitigated by running static simulations to determine if the current design would fail in a static simulation.

9.1.6 Potential Critical Failure 6: Pulley Due to Fatigue

The pulley will be made of 7075-T6 aluminum. The concern is that if the pulley does not yield it will instead fail before the current design goal of 10,000 steps due to fatigue failure. To determine if the pulley would fail the team is using FEA data combined with the appropriate S-N curve to determine the cycle life of the design.

9.1.7 Potential Critical Failure 7: Upright Due to Yielding at the Bearing

The upright could fail due to bearing pressure. It is possible that the carbon fiber upright would fail before the bearings, bolt, and pulley. This failure is highly dependent on three factors, the forces the upright is subjected to, the size of the bearing which acts as a stress riser, and the thickness of the upright. The thickness is fixed due to the confined space the team is working with and the availability of the carbon fiber tube sizes. So, the only thing the team could potentially change is the size of the bearing which changes the stress riser.

9.1.8 Potential Critical Failure 8: Footplate Mount Due to Bearing Stress

The footplate could fail due to bearing stress from the two bolted connections. It is likely that the carbon fiber footplate would fail before the bolts or aluminum connections. The failure is again dependent on the thickness of the footplate, the forces the part is subjected to and the diameter of the bolts. Like the previous failure mode, the team can only change the diameter of the bearings.

9.1.9 Potential Critical Failure 9: Bearing Failure Due to Wear or Corrosion

The bearings on either side of the pulley could fail due to wear or corrosion. The failure would not be critical but over time it would be noticeable to the average client. The bearings are not likely to fail from the load because the interface is an aluminum pulley and carbon fiber upright. However, the bearings would still be subject to environmental factors, compared to the carbon fiber parts which are not vulnerable to the environment. While the chosen aluminum alloy is less resistant to corrosion than other aluminum alloys, it would still not fail before the bearings if corrosion were the leading cause.

9.2 Potential Failures Identified This Semester

From the beginning of the Fall semester the team started to identify new failure points in the new design. While many of the failure points remained, the same there were new failure points with the new parts. Below is an updated FMEA table with the new design and parts taken into consideration. As in the previous table, a higher risk priority number (RPN) means the part is more likely to fail and requires attention. Using the table below the team identified some new potential failures. Because there is some design overlap between the Spring and Fall semesters this section will only include failure point that are new to the design.

Item Name	RPN
Neutral angle pulley	256
Neutral angle adjustment 2	128
Friction pad	96
Spring	72
Cuffslider_top_rectangle	64
Cable swages	64
Flanged bearings	40
D-profile shaft	32
Slider v3	32
Mounting block	32

Table 4: Shortened FMEA from Fall 2022

9.2.1 Potential Critical Failure 1: Pulley due to yielding

The number one identified risk with the redesign is still the pulley. It is the most critical component in the design, and it has a high risk for failure. The new design interfaces with a steel D-profile shaft. If failure does occur due to the high loads it is expected that the pulley will fail before the shaft.

9.2.2 Potential Critical Failure 2: Pulley due to tolerance

The pulley now interfaces with a shaft and a tight fit is required. The pulley could be sized so that the shaft doesn't fit into the cutout and the team would have an interference problem. On the

other hand, if the pulley is oversized there will be too much clearance between the two. If this happens then the steel shaft will wear down the pulley as it moves around in the pulley. As a result, the pulley needs to have a tight tolerance now so that it can interface with the shaft.

9.2.3 Potential Critical Failure 3: Neutral angle adjustment, friction pad due to slipping

The neutral angle adjustment has been changed compared to the last design and it now has new failure potentials. With this design the concern is that there will be slipping between the neutral angle adjustment plate and the friction pad. The design relies on compression from three fasteners that will hold the foot plate assembly together. If the coefficient of friction is not high enough or if there is not enough compression from the fasteners, then there is potential for the adjustment angle to slip.

9.2.4 Potential Critical Failure 4: Neutral angle adjustment due to yielding

The neutral angle adjustment plate is made from the same material as the pulley, 7075-T6 aluminum. So, there is also concern for this part to yield under high loads at the interface with the shaft. If this part experiences failure the entire design would not work properly.

9.2.5 Potential Critical Failure 5: Neutral angle adjustment due to tolerance

The neutral angle adjustment also interfaces with the D-profile shaft and as a result it has the same tolerance concerns as the pulley. The team expects the same failure modes to occur if this part is oversize or undersized. If the tolerance is off with this part, it will either result in interference or too much clearance and wear.

9.2.6 Potential Critical Failure 6: D-profile shaft due to yielding

The main concern with the shaft is that it will yield to the expected forces. The torsion could twist and permanently damage the shaft. There is no tolerance concern with the shaft because it comes from the manufacturer with a tolerance of -0.002".

9.3 Risk Mitigation

Most of the new potential failures were either contributed to tolerancing or yielding. To mitigate the new risks mentioned above the team relied heavily on geometric dimensioning and tolerancing (GD&T) principles and finite element analysis (FEA). Using these two techniques the team could proactively reduce the risk of critical failure.

To mitigate the tolerance concerns of failures 2 and 5 the team applied GD&T principles to both the pulley and neutral angle adjustment. The tolerance of the shaft is given by the manufacturer as 0.375-0.002". The team then took the manufacturers tolerance for the machined parts. At first the team was going to purchase the machined parts from Protolabs, a rapid manufacturing company. Protolabs has a stated CNC machining tolerance of ± 0.005 ". However, there were issues with material removal and the current design. So, after a recommendation from our advisor Dr. Lerner the team used GoProto as the vendor for the machined parts. Using the tolerances from the shaft manufacturer and the parts vendor, the team sized the pulley and neutral angle adjustment to account for the minimum and maximum dimensions of each part so that the parts should fit with minimal clearance and interference.

FEA was used for the parts that the team was concerned about yielding. These parts included the pulley, neutral angle adjustment, and the shaft. An assembly was made from these parts and the

assembly was tested in Solidworks Simulation in a static analysis. The figures below show the assembly and the load conditions for the study. The load is applied to the face of the pulley, and it is assumed that the back of the neutral angle plate is fixed. A load of 2,500 newtons was applied and the material selected was 7075-T6 aluminum for the pulley and plate. The team found that while there are expected to be high contact stresses between the parts, much of the volume of the parts have a factor of safety higher than 1.





Figure 15: FEA load and fixed conditions.

Figure 16: FEA Assembly

Figures 13 and 14 show the results of the FEA study. Figure 13 highlights where the FOS is between .87 and 1. The lowest FOS in the assembly is 0.87. Figure 14 highlights where the FOS is between 1 and 2. All other areas not highlighted in either figure have a FOS higher than 2.



Figure 17: FEA study, FOS less than 1.



Figure 18: FEA study, FOS between 1 and 2.

Through the risk mitigation the team used FEA and GD&T to reduce the risk of tolerance issues or parts yielding. The tighter tolerances helped mitigate the risk of failure and the FEA study that was done for the material selection did not hurt any of the other potential failure points. So, the team's efforts to mitigate risks in one area either has no effect on other areas or it helped another area.

10 LOOKING FORWARD

10.1 Future Testing Procedures

The future testing of the dynamic leaf spring AFO will be left to researchers that can evaluate its performance on patients with cerebral palsy. This will include a waking efficiency test with metabolic rate to determine if the device will save the user energy. There is a standard procedure that is used on all research devices that uses a K2 metabolic rate tracker, emg sensors to analyze muscle activity, and a motion capture camera that monitors joint angles and walking kinematics. All of these can be used to validate the device and determine if it is worth pursuing.

10.2 Future Iterations

Future iterations of this device might include a different method if deflecting the leaf springs. Our project mentor Leah Liebelt is working on a paddle system that use 2 arm-like paddles to deflect the springs instead of the cable driven design that is dominant in the lab. This would be easy to prototype with the D-shaft interface as a lot of the dimensions can be kept the same. The next suggestion for a future iteration is replacing the D-shaft with a spline interface to reduce the stress concentrations and need for high precision tolerancing, making the device more manufacturable. This custom spline would be the next step to create a more durable and higher performance device. In future iterations that use a small lever arm the focus should be on reducing any mechanical play in the system. This was an issue that came up with our device. Any mechanical play felt on the connecting pieces is amplified at a smaller radius because of the relationship between arc length, diameter, and angle. Another consideration is expanding the case at the joint to make more room for a larger lever arm and completely removing this issue. This mechanical advantage would also reduce stress on critical components and reduce the required spring size needed to apply the same amount of torque. The neutral angle piece was a good development from our project and should be considered in future designs. This neutral angle piece would be better if the adjustment was quicker. This could entail attaching a quick release mechanism that would allow the user to quickly move the adjustment angle without the need for tools.

11 CONCLUSIONS

With the goal to create a sleek, comfortable, and durable leaf spring AFO, the team brainstormed ideas after meeting with the client to bring it to life. Through several iterations and research, the team was able to make a final product that we believed would meet these requirements. We developed a two-leafspring ankle AFO that incorporated a d shaft and pulley power train as the main piece to provide the ankle plate movement. The device is strong, and adjustable to provide support for many different body types and ability levels. At first, the testing results met all requirements except the torque output was lower than desired. After some adjustments and retesting, we had a product that was able to output the amount of power that was requested. In the end, resulting in a product that has made the client happy and met their requirements

11.1 Reflection

With Cerebral Palsy, as well as several other muscular disorders being uncurable and taking lifelong treatment to better, our leafspring AFO allows for people with these disabilities to be able to live in more comfort in their day to day lives. Economically, the device was not too far Especially with the developments that were made off the previous prototype, the design is sleeker, lighter weight, and all the moving parts are internal making the device less noticeable. team tested it's safety by wear it and using it for multiple days of walking, running, and jumping to see how long it will last and what uses it can withstand. The results were promising, as with little wear, we feel the device will be a benefit to the disabled community.

11.2 Resource Wishlist

If we were to do this project over again, some resources that would have been helpful include team keys to the biomechatronic lab to allow for the team for access to the resources in there whenever possible for each member. A larger budget would also allow for the team to have made more of the parts out of metal instead of being 3D printed which would have given us less loses on the springs. Lastly, specialized training for the materials we used and a walkthrough on how the previous prototype was developed would have provided a good starting point for the team.

11.3 Project Applicability

This project has given the team a good sense of what being an engineer in the real world would look like. From talking to a client, doing independent research, machining, prototyping, testing a product, and analysis on materials, the team has learned a lot of what the process of designing a new product for a client looks like. While we may not be doing all these steps when we go into the field, at least we learned a little bit of each piece that goes into the process. The team had many speedbumps, redesigns, and challenges throughout the project timeline. However, we have pushed through to achieve the final product that we believe is well suited to hand off to the client.

12 REFERENCES

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13 APPENDICES

13.1 Appendix A: Complete FMEA Table

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13.2 Appendix B: Complete BOM

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13.3 Appendix C: Gantt Chart