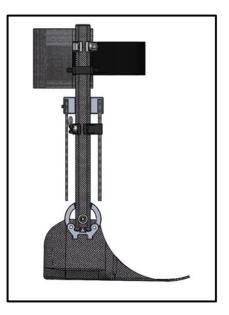
Dynamic Leaf-Spring AFO

Preliminary Proposal

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DISCLAIMER

This report was prepared by students as part of a university course requirement. While considerable effort has been put into the project, it is not the work of licensed engineers and has not undergone the extensive verification that is common in the profession. The information, data, conclusions, and content of this report should not be relied on or utilized without thorough, independent testing and verification. University faculty members may have been associated with this project as advisors, sponsors, or course instructors, but as such they are not responsible for the accuracy of results or conclusions.

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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 and soleus muscles located around the tibia in the human body. 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

As discussed in the introduction the current state of technology available for people diagnosed with cerebral palsy is lacking in innovation compared to other industries. The Biomechatronics 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. This device should also have integrated sensors for data collection in experimental validation and possible uses in tracking progress for patients undergoing therapy.

1.3 Original System

1.3.1 Original System Structure

The original system consists of 2 Leaf-Springs used to store gravitational potential energy that is created when the user lifts their foot above the ground and places it back during a normal gait cycle during plantarflexion and dorsiflexion. The system also features an adjustable slider block used to change the spring stiffness making it adaptable for users of all sizes and levels of impairment. This is a staple feature of this device because it can be used in parallel with resistance training and progress can be seen as opposed to a device where there is only one level of assistance. This adjustment is also continuous giving the user the ability to fine tune it to their preferences and needs.

1.3.2 Original System Operation

The system stores energy through the plantarflexion leaf-spring, located furthest from the heel of the foot, during the stance phase and it is applied back at the beginning of the swing phase of the gait cycle. The dorsiflexion spring, located closest to the heel of the foot, stores energy at the

beginning of the swing phase and is applied to the ankle in the middle of the swing phase to prevent the foot from dropping. This torque is applied through a pulley and a cable that acts as a transmission system to the foot which sits in the foot plate. As the leaf spring is loaded it applies a reaction torque to the pulley in the opposite direction.

1.3.3 Original System Performance

The original system weight is 1.5 kg for each leg of the device. The maximum torque application is 50 Nm. The real measures of system performance such as metabolic cost savings, muscle activity, and gait patterns have yet to be evaluated for this device. The current device contains 2 leaf springs for both plantar and dorsiflexion. The refined device will only include a plantarflexion spring and will be a good platform to test whether providing assistance in both directions is significant in the functionality of the device. There will be tests conducted on both devices to evaluate the effectiveness of the single leaf-spring design over the double leaf-spring design which involve the biometric data mentioned above as it is the best way to test system performance for our device and the current prototype.

1.3.4 Original System Deficiencies

The current device has yet to be tested for its main performance defining parameters as mentioned above so it is not known what deficiencies it will have in these categories. The device needs to be made lighter and more user friendly. The durability can also be improved to suit a wide range of users.

2 **REQUIREMENTS**

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. Cost within budget

Our budget for this was initially \$500; however, if the team proves that they require more funding that that the work can verify the need. The budget can be increased.

2. Durable and Robust design

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.

3. Reliable design

The design has to accommodate a range of users. So the design has to be adjustable and the adjustments have to be reliable to provide an accurate output for a particular user.

4. Safe to operate

The design must be free from causing harm to the user or people around the user during proper use. If any part were to malfunction or fail, the system should not lead to the complete unit falling apart and should not cause direct harm.

5. Data Output

The design would be able to output both angle and torque data. This would allow the team and the client to evaluate the design and make improvements.

6. Professional Appearance

The design should look complete and professional. It should be ready to present to users.

7. Comfortable

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

2.2 Engineering Requirements (ERs)

Below are the engineering requirements that the team has developed using the customer requirements alongside the comments from Dr. Lerner.

- 1. The design should last at least 10,000 running steps.
- 2. The torque should be adjustable to accommodate a range of users.
- 3. The design should include a continuous adjustment for the neutral angle.
- 4. It should have at a maximum, 1 moving part to maintain a professional appearance.
- 5. It should include an angle sensor and output data.
- 6. It should include a torque sensor and output data.
- 7. It should be lightweight, with a maximum of 6lbs.

2.3 House of Quality (HoQ)

Our House of Quality included our 5 customer requirements and 7 engineering requirements. Each customer requirement had at least one associated engineering requirement. The customer requirements had assigned weights from 1-5. The team had discussed to assign the weights for the CRs and ERs. Each engineering requirement had a measurable target value and tolerance.

The engineering requirements for our project each had specific target values and tolerances on those values. For the first engineering requirement the device had to last 10,000 running steps at a minimum. Minimum being our tolerance and 10,000 being our target. The other engineering requirements had similar measurable tolerance targets. The HoQ is included in the appendix.

3 DESIGN SPACE RESEARCH

[Use this chapter to describe alternative approaches to designing your new or re-engineered system. Sources for this information include existing product descriptions, catalogs, engineering textbooks, the engineering literature, and the internet. Another very important source for some projects, especially (but not exclusively) for process re-engineering projects, is benchmarking.]

This chapter will cover what technical aspect each team member has been focusing on, including the sources they have been using and any design tools, textbooks, or other information. Included in this chapter are the benchmarking alternatives that the team has considered.

[Put introduction to Ch. 3 here detailing what the chapter contains before leading into Section 3.1.] **3.1** Literature Review

[Use this section to describe what sources were used for benchmarking and design research. This could have been done by examining similar systems, literature review, or web searches. Each student should have at least five relevant sources (academic and professional journals, books, websites, catalogs, interviews with sponsor, advisor, design tools etc.), given in the following subsections. For each source, include a summary and discuss how it specifically applies to your project design space.

3.1.1 Sensor Implementation and System Modeling (Samuel Maxwell)

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

Table 1: T	Table of Sources	used by Samuel	Maxwell
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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.

3.1.2 Customizability (Jacob Lee)

Jacob Lee has focused on finding ways to give the device customizability to help fit to people of all shapes, ages, and sizes. Cerebral Palsy is a condition that begins in people's adolescence and lasts a person's entire life. By creating a device that can grow with the user as they do and as their abilities change through life will create a better sense of comfortability and trust with the product.

Source	Description
Improving Hand Function in Children With Cerebral Palsy: Theory, evidence and intervention.	Motor Learning principles for children with Cerebral Palsy

The effect of a knee brace in dynamic motion	How the fitting of knee braces affects overall health and healing
The comparison of the effect of innovative designed storing-restoring hybrid passive AFO versus posterior leaf spring AFO on ankle joint kinematic in drop foot patients: A case series using a single subject design	How AFOs effect a patients gait and how it helps with drop foot
Effects of solid ankle-foot orthoses with individualized ankle angles on gait for children with cerebral palsy and equinus.	The range of motion and positive effects given to children through AFOs
The impact of ankle-foot-orthosis (AFO) use on the compensatory stepping response required to avoid a fall during trip-like perturbations in young adults: Implications for AFO prescription and design	How AFOs help those with cerebral palsy avoid tripping or falling like motions

"Improving Hand Function in Children With Cerebral Palsy: Theory, evidence and intervention" discussed the process that it is taken that children take to learn to develop their motor skills living with cerebral palsy. Not all children are able to develop in the same way as they all have different strengths and weaknesses. A big factor for some can be cognitive ability, which can increase, decrease, or stay stagnant as time passes. With this it is important to implement functions that are simple to use for those who may not have the ability for complicated mechanics in the adjustment process as well as being able to be done by an outside user for those unable to do these tasks alone.

"The effect of a knee brace in dynamic motion" discusses how the fitting of a knee brace can affect the rehabilitation of the user. With knee braces being too tight, it may not leave the body room to heal, or it may make the pain worse. Being too loose however can also lead to an improper healing of the knee. These al depend on size, shape and position of the injury and having high flexibility to adjust the points of contraction can help pinpoint proper healing.

"The comparison of the effect of innovative designed storing-restoring hybrid passive AFO versus posterior leaf spring AFO on ankle joint kinematic in drop foot patients: A case series using a single subject design" focuses on using different types of AFOs on a single subject to see the results. This article shows the leaf springs provide a great decrease in drop foot incidents for this patient and are a good functioning model.

"Effects of solid ankle-foot orthoses with individualized ankle angles on gait for children with cerebral palsy and equinus." Is an article that goes into how individual neutral angle adjustments helps different children benefit form AFOs. Each child has a different gait, thus have this adjustment is imperative to allow for proper movement.

"The impact of ankle-foot-orthosis (AFO) use on the compensatory stepping response required to avoid a fall during trip-like perturbations in young adults: Implications for AFO prescription and design" revolves around tripping motions. With each body type comes a different center of gravity. Being able to make adjustments based on this can help gradually decrease the number of incidents that occur with patients

falling.

These source help show us some ways to increase comfort in the product and reliability from the user. Small changes such as angle adjust was shown to create a great effect in the users ability to walk comfortably.

3.1.3 Mechanical Concept Evaluation (Adrian Tran)

[Explain what technical aspect of the project this student focused on and then list the 5+ relevant sources with summaries and discussions. Cite all textual information and figures.]

Adrian has been focusing on the evaluation/verification of the mechanical designs. This includes using ANSYS and MATLAB as design tools to evaluate and develop designs. The design is currently made of carbon fiber and aluminum parts. The aluminum parts are expensive to manufacture and have long lead times. So, to cut down on costs and to evaluate designs early Adrian has been using design tools to help in this step of the process.

Adrian has been using ANSYS to evaluate the designs in a static structural simulation. The concern is that the new design won't be able to handle for forces of the original design. A previous pully design from the prototype had bending issues, so the team wants to avoid machining an aluminum pulley only to find that it experiences plastic deformation under the expected loads. In the future Adrian would like to preform dynamic simulations and calculate fatigue estimates from those for the pulley. This would allow the team to estimate how many cycles the pulley design would last.

MATLAB was used to write a small code that would determine the feasibility of the spring concept. Using the following equation from Shigley's Mechanical Engineering Design.

$$k \approx \frac{d^4G}{8D^3N}$$

The code would calculate the spring stiffness. Knowing the stiffness would need to be 700 lbf/in to match the previous prototype. Matlab was used to determine a range of coil diameters and wire diameters that would fit in a compact volume.

Shigley's Mechanical Engineering Design was used for the spring concept and for the failure theory of ductile materials. While ANSYS does do the calculations, Adrian needed to know what to make of the data. For example implementing factors of safety for the static loading simulations and for the future fatigue loading.

Introduction to Finite Element Analysis and Design was used to reference problem setup for dynamic problems. While static simulation is fairly straightforward, Adrian needed references for dynamic problems. The book does not cover ANSYS specifically but the book has topics that are still applicable to the use of ANSYS in this case.

Source	Description
ANSYS	Static structural simulations and fatigue estimates
MATLAB	Feasibility verification for the spring design
Shigley's Mechanical Engineering Design 11th Ed.	Used for: Failure theory for ductile materials (aluminum) and compression springs
Introduction to Finite Element Analysis and Design	Referencing Ch. 8 for FEA for dynamic problems

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

3.2.1.1 Composite AFO Brace



Figure 1: 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.

3.2.1.2 Resistive Therapy Device (Jacob)



Figure 2: 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.





Figure 3: Walking Cane

Figure 4: 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

3.2.2.1 Torque Sensing

3.2.2.1.1 Load Cell



Figure 5: 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.

3.2.2.1.2 Reaction Sensor



Figure 6: 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 +/- 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.

3.2.2.1.3 Rotary Optical Encoder



Figure 7: 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.

3.2.2.2 Neutral Angle Adjustment

3.2.2.2.1 Snowboard Angle Adjustment



Figure 8: 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.

3.3 Functional Decomposition

[Use this section to describe a functional decomposition or system/process hierarchy of your system. Use this space to describe the main functions of the projects and elaborate on your functional decomposition process. Describe your functional decomposition in this section, including (at minimum): a Black Box Model and a Functional Model, Work-Process Diagram, or Hierarchical Task Analysis. Each subsystem listed in the previous section should be included in the functional decomposition (NOTE: Although this section shows up after subsystem benchmarking in this report, you SHOULD perform this activity before and/or concurrently with your subsystem benchmarking.) Your functional decomposition must contain at least three subsystems. For example, if you were designing a race car, your functional decomposition would include braking, steering, and suspension subsystems (among others). The content of Section 3.2.2 would then include a discussion of existing designs for (i) braking, (ii) steering, (iii) suspension, etc.]

3.3.1 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. It helped 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. Nothing else comes in or out of the system. 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 systema and that energy would come out as a signal. The mechanical energy would be both an input and an output. The input would be provided by the users 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 and 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 wasn't specified.

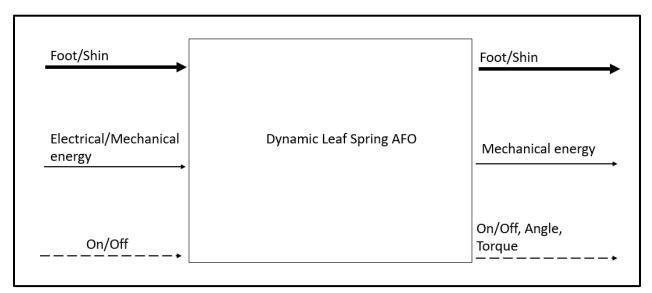


Figure 9: Black Box Model for the Dynamic Leaf Spring AFO

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

4 CONCEPT GENERATION

4.1 Full System Concepts

4.1.1 Single Enclosed Leaf Spring



Figure 102: 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.

4.1.2 Full System Design #2: Descriptive Title

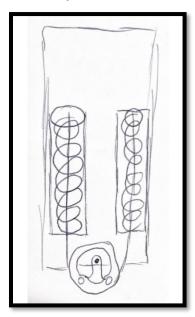


Figure 11: Spring Canister Design

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

4.2.1 Torque Sensing Concepts

4.2.1.1 Hall Sensor Concept

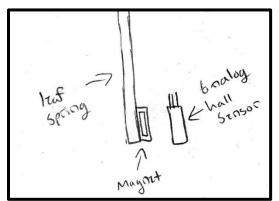


Figure 3: Analog Hall Torque Sensor

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.

4.2.2 Angle Adjustment Concepts

4.2.2.1 Snowboard Inspired Adjustment

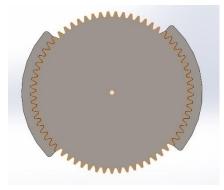


Figure 4: Snowboard Inspired Angle Adjustment

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.

4.2.2.2 Bike inspired adjustment: 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.



Figure 5: Inline Barrel Adjuster

5 DESIGNS SELECTED – First Semester

6.1 Rationale for Design Selection

[Use this section to explain / justify the TOP TWO design solutions selected. Your selections must be two of the possible solutions described in the previous chapter or a combination of several, and you should discuss why, given the various advantages and disadvantages of all of the options given, the selected two solutions are most appealing. All teams must include a Pugh Chart and Decision Matrix to justify their findings in at least one part of their selection process. Typically, the Pugh Chart is used to qualitatively narrow down the designs to the top few, and then the Decision Matrix is used to quantitatively choose the top design. You should provide justifications (back-of-the-envelope calculations or existing data) for why each design scored the way it did, relative to the other designs. Use an Appendix for any lengthy engineering calculations or large figures/tables.]

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8 **APPENDICES**

8.1 Appendix A: HoQ

8.2 Appendix B: Descriptive Title