Ankle Foot Orthotic

Midsemester Report

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Abstract

In the beginning of the semester, our client, Dr. Robert Przybelski, was urged to propose the active ankle/foot orthotic project at the request of one of his patients. His patient, suffering from a medical condition known as foot drop, was very dissatisfied with the orthotic she was currently using and was hopeful that our design team could improve upon it. The orthotic she used only addressed the basic problems associated with foot drop, such as supporting ankle weakness and holding the foot at a fixed position of 90 degrees to the ankle. It was also very bulky and did not easily fit in a shoe. This design only stopped the foot from "dropping" and made walking very uncomfortable and awkward. In fact, the device was so cumbersome, the patient preferred to walk without it. Leading a very active lifestyle and very interested in being able to hike, the patient was seeking an orthotic that more closely simulated a normal human gait pattern and actively enhanced the walking motion. With this is mind, it was our team's goal to design an orthotic that not only supported ankle weakness and held the foot in a fixed position, but also actively enhanced walking and improved balance and proprioception.

Background

Thousands of people worldwide are afflicted by diseases that affect their normal gait pattern. Several neuropathies that commonly cause walking abnormalities are stroke, Charcot-Marie-Tooth Disease (CMT) and multiple sclerosis (MS). Each of these diseases afflicts the patient in a different manner; stroke affects the patient by depriving the brain of essential nutrients while CMT and MS affect the peripheral nervous system.

Stroke is an illness that strikes a person when part of the brain is prevented from receiving oxygen and other essential nutrients from the bloodstream. The two primary types of stroke are ischemic and hemorrhagic stroke. Ischemic stroke occurs when a blood vessel supplying blood to the brain is blocked, suddenly disrupting the blood flow to the brain. As a result, the part of the brain being supplied by this blood vessel dies. On the other hand, hemorrhagic stroke occurs when the brain itself bleeds and blood spills into the spaces surrounding the brain cells and suffocates parts of the brain. Although the types vary in their origin, they both prevent the brain from receiving nutrients and cause part of the brain to die. Once a region of the brain dies, the body loses all functions that were controlled by that area of the brain. The severity of a stroke depends on the region of the brain that was affected as well as the size of the region that was affected. While they can range from mild to severe, the symptoms that primarily affect a normal walking pattern are partial or complete paralysis as well as problems with vision.

While stroke affects a person's ability to walk through brain death, Charcot-Marie-Tooth affects normal gait because it afflicts the peripheral nervous system. The main components of the peripheral nervous system are the nerve cells, axons, myelin sheath and muscle fibers (Appendix A, Figure 1). Normally, the nervous system relays messages between the brain and muscle fibers via electrical signals through the axons. The axon is surrounded by myelin, which is responsible for insulating the axons from the surrounding cells. By acting as an insulator, the myelin protects the structure of the axon and prevents the electrical signal from dissipating as it travels further distances.

Damaging the myelin causes the electric impulses to be conducted more slowly than normal; and harm to the axon itself causes the strength of the signal to be reduced.

Charot-Marie-Tooth (CMT) is a disease that causes mutations in genes responsible for the structure and function of both myelin and axons. CMT1 and CMT2 are the most common variations of the disease; CMT1 causes mutations in the myelin and CMT2 causes mutations in the axons. Other variations of the disease result in a more severe affliction or a combination of the mutations. Because the myelin and axons are mutated in Charcot-Marie-Tooth, the nerves slowly begin to degenerate and lose the ability to transmit signals from the brain to the limbs and vice-versa. As the ability to communicate fades, the motor nerves at the end of the axons function to a lesser extent and as a result, the person afflicted with the disorder experiences increased muscle weakness and atrophy. Because the patient has increased muscle weakness, he/she often has an increased difficulty in walking because of the lack of ability to balance, propel oneself forward and support his/her weight.

Although multiple sclerosis is a disease that also affects the peripheral nervous system (Appendix A, Figure 1), it does so in a different manner than Charcot-Marie-Tooth. MS is an autoimmune disease in which the body's immune system attacks the nervous system, especially the myelin and axons. As the body attacks these cells, it produces numerous regions of scar tissue (sclerosis) that disrupt the signaling between the brain and motor nerves similar to the disruption caused by CMT. Because MS affects the body in a very similar fashion to CMT, it has many of the same symptoms including the inability to balance and lack of propulsion. In addition to the shared symptoms, MS also causes patients to lose feeling in their lower extremities, making it almost impossible to walk because of lack of proprioception.

Because these diseases are so common, many people are often afflicted with abnormal gait patterns and therefore experts have studied normal gait in order to develop ways to cure these abnormalities. The main task of the gait cycle is to translate the individual's center of gravity through space with the least energy possible. In order to do so, the entire lower half of the body must act as a closed kinetic chain in which the action of one muscle or joint supports the action of another. In other words, the hip, knee, tibia, ankle, foot, and muscles and tendons in the leg must all act in conjunction to transfer the body's center of gravity in the most efficient manner possible. When one of the above components is prevented from executing its normal function (such as the increased muscle weakness caused by CMT and MS), a variety of the other joints, bones, and muscles will work harder to allow the body to translate the center of gravity, albeit with a greater energy expenditure. The gait cycle can also be broken down into different phases (Appendix A, Figure 2) in which each phase has a primary task (Appendix A, Figure 3). In addition to the different phases and tasks that correspond to each phase, specialists have also determined the biomechanics occurring at the hip, knee, tibia, ankle, foot and the muscles and tendons in the leg during each part of the cycle. Once these requirements were determined for a normal gait cycle, experts had the ability to compare abnormal walking patterns to the normal gait cycle and determine the cause of the irregularities.

One of the most common irregularities to the gait pattern is know as foot drop. Foot drop refers the inability of the patient to dorsiflex, or raise his/her toes above the horizontal toward the tibia (Appendix A, Figure 4). The lack of ability to dorsiflex causes the patient to be unable to lift his/her foot properly as he/she is walking and subsequently causing the foot to drag along the ground as the leg swings forward. The inability to plantarflex is the opposite of dorsiflexion, in which the patient cannot push their toes downward and away from their tibia (Appendix A, Figure 5). Normally, the ability to plantarflex provides the necessary propulsion for a person to maintain forward momentum. Limited ability to plantarflex makes it hard for a patient to create the force necessary to propel his/her center of mass forward and often an assistive device is used for walking. Both limited dorsiflexion and plantarflexion are a result of increased muscle weakness due to the aforementioned diseases of CMT, MS and stroke.

Specifications

A common treatment for people suffering from gait abnormalities due to increased muscle weakness and other symptoms resulting from neuropathies is to fit the patient with an orthotic. Often, the orthotic is specially molded out of thermoplastic to fit a specific patient. There are many different kinds available but many are often very bulky, uncomfortable and can cause complications arising from increased temperature along the leg within the orthotic. In order to better suit the patient, the orthotic must follow several specifications. First of all, it must provide the necessary added stabilization to assist the patient in balancing because he/she will have trouble doing so on his/her own due to the increased muscle weakness. Furthermore, it must assist dorsiflexion as well as plantarflexion in order to correct foot drop as well as help propel the patient forward. In addition, the orthotic must be light enough so that a person suffering from severe muscle weakness will be able to use it without difficulty; however, it also must be strong enough that it can support the weight of the patient without breaking. Additionally, it will be created out of thermoplastic, biopolymers, carbon fibers, neoprene or a combination of the materials because these are materials commonly used today. While the orthotic will be made from these materials, they are often very expensive and due to a limited budget the orthotic must incorporate a mixture of the materials that minimizes the price around $300. Finally, the orthotic must have a component that makes it available for universal distribution but also have the ability to be customized to fit a specific patient.

Previous Work

As a secondary part of brainstorming, current orthotic designs were examined to better understand what styles are commercially available and how our design would uniquely meet the needs of our patient.

The primary function of most current designs is to maintain a 90 degree angle at the ankle to support and control weakness at the joint and passively correct foot drop. The majority of such designs are universally molded thermoplastic that tend to be uncomfortable and prove irritating in their generic cut. Additionally, they are often bulky, cumbersome, and rarely fit in the shoe, making this design impractical for active patients. Some of these designs even contain unnecessary surface area covering the lower extremities, which has proven extremely irritating to multiple sclerosis patients with sensitivities to heat.

Other designs employ a hinge or joint at the ankle to offer a more extensive range of motion. These designs aim to assist plantar or dorsiflexion for patients who require assistance due to weak muscle control and accomplish this task by using a unidirectional hinge, an “assist” or “tamarack” joint. While this concept provides more active assistance, it is often paired with standard thermoplastic molds and shares their disadvantages.

Designed solely to provide structural support, very few existing designs consider propulsion or energy return necessary for patients with neuropathies that limit control of the lower limbs. Basic coil springs have been incorporated into athletic shoes for additional push-off, but such shoes lack ankle support critical for stabilization and fail to provide correct structure for the prevention of foot-drop. Other designs utilize the high energy return of carbon fiber or other polymers to transfer downward kinetic energy into energy used to maintain a normal stride by pushing off the ball of the foot. The application of carbon fiber or materials with similar energy return properties may be useful in optimizing energy invested by the patient.

The integration of a combination of propulsion concepts is vital for active patients to return to a normal gait pattern and distinguishes our design ideas from existing designs. Although several orthotics and athletic shoes address single criteria necessary for meeting the unique needs of our patient, none incorporate all of our three primary criteria: ankle support, propulsion, and foot-drop correction.

Design Ideas

Spring Design

The first of our three design alternatives integrates a leaf spring into the sole of a thermoplastic orthotic to aid in propulsion. The universal solid insole would consist of a full thermoplastic frame, which extends upward to the middle of the calf muscle and from the medial to the lateral side to maintain a supportive 90 degree angle at the ankle. Custom-fit foot orthotics could be inserted to correct foot anatomy based on the individual needs of the patient. An angled leaf spring in the heel of the orthotic provides propulsion that patients lack and a rounded surface under the toe would aid forward momentum, allowing the patient to effectively roll off the ball of the foot with each step (Appendix A, Figure 6)

The raw cost of the thermoplastic along with the machining and expertise necessary to create a functional mold, plus the cost of a custom leaf spring are the primary expenses of this design. While this design promises to be cost effective and provide sufficient ankle support for the patient, unnecessary surface area covering the calf muscle can be an adverse annoyance to patients with multiple sclerosis. Difficulties with this design may include variance in spring assistance on irregular terrain and varying degrees of inclination. Additionally, the limited range of motion of the full frame mold may prove insufficient for active patients who wish to return to a normal gait pattern.

Joint Design

For our second design alternative we decided to pursue a design, similar to the spring design in that it is also made out of thermoplastic, but that would allow for greater mobility of the ankle joint. This thermoplastic design would be in three pieces. One piece would be comprised of the sole and heel portion. The other two pieces would be strips of plastic that would run up either side of the calf above the ankle joint. The rods would be held in place by two velcro straps that extend around the calf (Appendix A, Figure 7). The pieces would be connected by means of a joint called a tamarack joint (Appendix A, Figure 8).

The sole of the AFO would only extend ¾ of the way down the bottom of the foot. This would allow the patient to push of their toes while walking. The thermoplastic would also form a cup around the heel of the foot. This would ensure that the base of the foot has adequate stability. It would prevent the foot from turning outward when raised off the ground. On the bottom of the device where it would touch the foot, a customized orthotic would be made. This would prevent any irritation that could possibly occur if the thermoplastic were in direct contact with the skin. The thermoplastic used in this portion would also be of varying width. The portion by the heel would be stiffer and have a greater thickness than the part that extended down the bottom of the foot. As the plastic ran down the bottom of the foot it would gradually decrease in width. By having varying thickness of plastic it would allow the patient greater flexibility of their foot while wearing the device.

The bars on either side of the calf would be made of much thicker thermoplastic then the plastic used in the sole area. This increased thickness would be needed in order to provide the necessary support. By only having two rods running up the leg you would eliminate any concern that would arise regarding the patients ability to tolerate heat. Midway up the calf a fabric strap that fastened with velcro would surround the calf and hold the rods in place. Another strap would be at the top of the rods for the same reason (Appendix A, Figure 7).

The joints connecting the two pieces would be tamarack joint. There are a variety of tamarack joints that are available to use on AFO's, however, in our case we will be using a dorsiflexion assist flexure joint (Appendix A, Figure 8). This type of joint is specifically designed to assist with dorsiflexion. It helps to maintain a 90 degree angle when the foot is lifted off the ground during walking. These polyurethane joints are pre-flexed and are available in a variety of strengths. By varying the strengths on either side of the ankle, the moment about the ankle joint observed during movement can be adjusted to fit the patient's needs. The area where the joint attaches to the thermoplastic will be covered with cosmetic patches. These patches will be placed between the skin and the joint. It will prevent any irritation that could be caused by the joint itself, as well as serve a cosmetic purpose.

This device will provide adequate ankle support through the heal cup and the rods on either side of the calf. However, this device can be bulky because of the tamarack joints on either side of the ankle joint. Because of this, it could be difficult to fit this device in a shoe. Also, although the sole will be adjusted and made as comfortable as possible, thermoplastic is a hard material and may not be as comfortable as the patient would like.

Material Design

Our last design alternative is a material design that allows for a less bulky structure because most of the support and stability is provided by the material itself. The AFO is made out of carbon fiber. This device would be similar to our first design alternative in that I would be molded in one piece at a 90 degree angle. However, this design would be very light weight and would not encompass the whole leg like our fist design.

Carbon fiber is a very light weight material. The material has a high energy return that would assist in both plantar and dorsiflexion. When the patient’s heel would strike the ground energy would be stored. It would be released as the patient rolled their foot forward and pushed off their toes and ball of their foot. This would help to create a normal gait pattern, through the use of the heel to toe motion.

The sole of this device would cover the entire bottom of the patient’s foot. To avoid discomfort that could be caused by the carbon fiber rubbing on the bottom of the foot, an orthotic will be placed between the foot and the sole of the AFO. The sole will also contain varying strengths of the material. The anterior part and the heel would be more flexible. This would allow for the heel to toe motion and give the patient the ability to push off their toes.

In order to provide stability a bar, also made of carbon fiber, would extend from the sole of the foot to midway up the calf. This bar would prevent pronation of the foot that is often a symptom that occurs along with foot drop. The bar would have a bend in it so that it would not go directly over the ankle. The bend could guide the bar directly behind the ankle bone towards the heel of the foot. The bar would then run up the back of the calf, as opposed to the side. The carbon fiber in the bar would be stronger then that used in the sole. This would be necessary in order to provide the necessary ankle support. The top of the bar is held in place with a velcro strap that be strapped around the top of the calf.

This AFO would be extremely light weight which would avoid any strain that could be placed on the remainder of the leg by a heavy AFO. By having the device molded completely out of one material you avoid the bulkiness that could be associated with having a joint connecting around the ankle. However, this device does have limited ankle support. It prevents pronation of the foot, but does not provide complete stability through the use of bars on either side. This device is also very costly because of the materials that would need to be used.

Design Matrix

In order to evaluate our three main designs, we constructed a matrix in which we established five main design components under which we could judge them. The five components our team felt were the most important in our final design were cost, balance, stability, propulsion, material, and foot clearance. We weighted each design component by assigning them a percent value that we felt reflected how much we wanted it to influence our final design. We gave cost the largest amount of weight (.3) due to our fairly limited budget and stability the least amount of weight (.05) simply due to the fact that this was something our client wasn't specifically looking for. Next, we ranked each of our designs on a scale from 1-7 based on how well they fit with our previously established design components; 7 being the best and 1 being the worst. We then multiplied the weight of each design component with its respective ranking and added all five products together to achieve a total design score for each design. (Appendix B, Table 1) Upon doing so, we found our material design came up with the highest score of the three designs and thus, was the one we chose to pursue for our final design.

Final Design

After completing our design matrix for our three preliminary designs: joint, spring, and material, it was clear that the material design ranked highest. Based on this, our group decided that it would be best to proceed with the material design for the remainder of the semester. We chose this design for the simple reason that the pros of the design outweighed the cons. Creating an orthotic from a material such as carbon fiber will truly provide the best structure. Carbon fiber is lightweight, flexible, and durable. It also yields a high energy return which is crucial for forward propulsion from step to step. However, it is important to note that due to the estimated cost of the material design, it is well out of our limited budget range, possibly making the design not feasible unless we can procure some free or below cost high energy return material such as carbon fiber. If our team is unable to come up with the necessary materials, our final design will be either the spring or joint design. However, it is more likely that the final design will consist of a combination of certain aspects from both spring and joint designs. In past design courses, we have found that a combination of ideas from all or most of the preliminary designs leads to the best overall product.

Potential Problems

Although our team is confident in our choice to pursue the material design, there will likely be several obstacles during its fabrication. First, as previously mentioned, we are working with a fairly limited budget and due to the fact that the materials for this design are relatively expensive, we may run into a fair amount of problems when attempting to buy parts. As a result, we may end up employing some of the ideas incorporated in the spring and joint designs in order to keep our expenses within our allotted budget. In addition, our design will need to be fit to the needs of our specific patient as well as made available to the general public. As a result, we will need to find a way to fabricate our design in a simple, cost-effective way that can easily be duplicated from one client to the next. Due to the fact that our team has a limited amount of experience fabricating this kind of a product, this task may pose as fairly difficult when we are attempting to finalize our design.

Future Work

In order to continue our design process in the future and finalize our material design, we will continue our research on the biomechanics of gait as well as the anatomy of the foot until we have a solid understanding of the body's natural walking pattern. In addition, we will perform a gait analysis on our patient in order to evaluate her specific gait patterns so that we may appropriately fit our design to her specific needs. From there, we will complete our solid, finalized design incorporating our most fitting design ideas and begin fabrication based on the information gathered and the brainstorming ideas we have come up with. We will order the necessary parts, build our design and test it as necessary on our patient until we, and more importantly our client, are satisfied with its performance.

Appendix A (Figures)

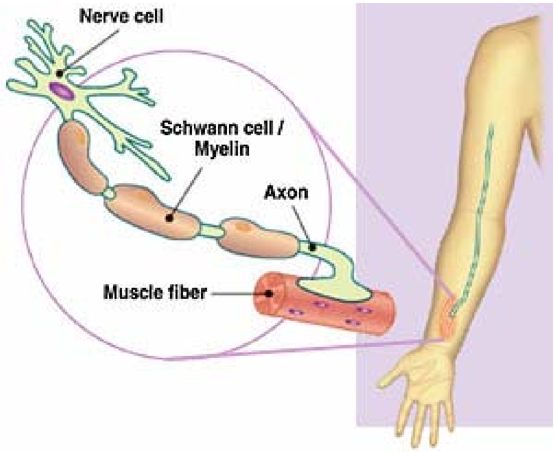

__Figure 1:__ Depiction of the nerve cells, axons, myelin sheath and muscle fibers

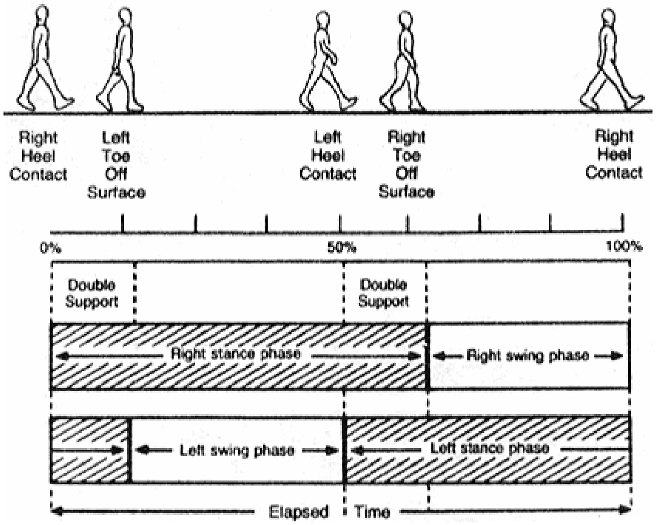

__Figure 2:__ The phases of the gait cycle in normal gait pattern

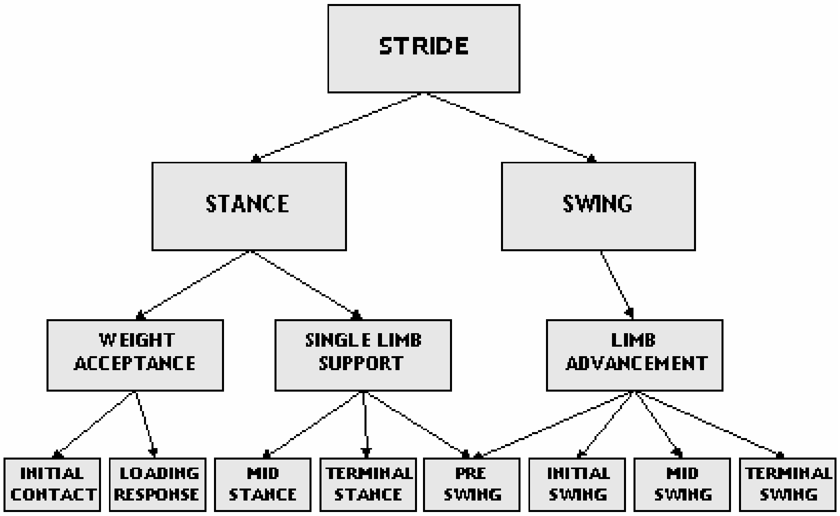

__Figure 3:__ The phases of the gait cycle broken down into their primary tasks.

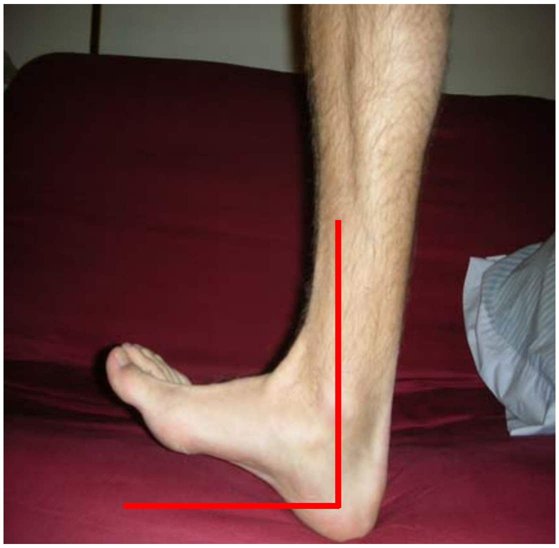

Figure 4: *A foot exhibiting normal dorsiflxion (raising the toes above the horizontal toward the tibia)*

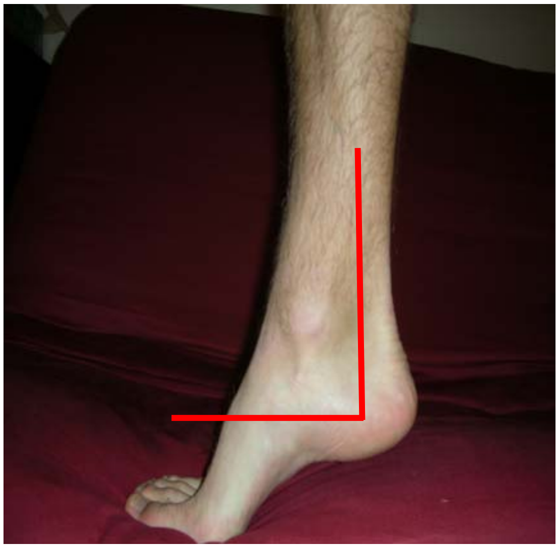

Figure 5: *A foot exhibiting normal plantarflexion (pushing the toes downward and away from the tibia)*

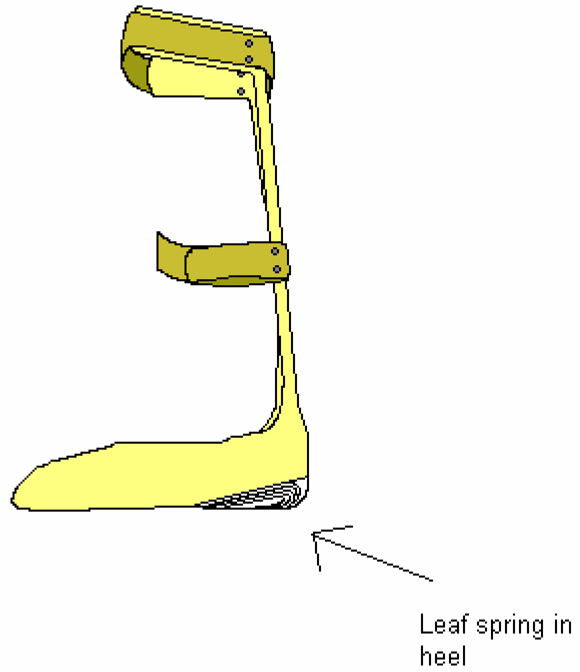

Figure 6: *Spring design with a leaf spring in the heel, thermoplastic that wraps around the calf, and Velcro straps.*

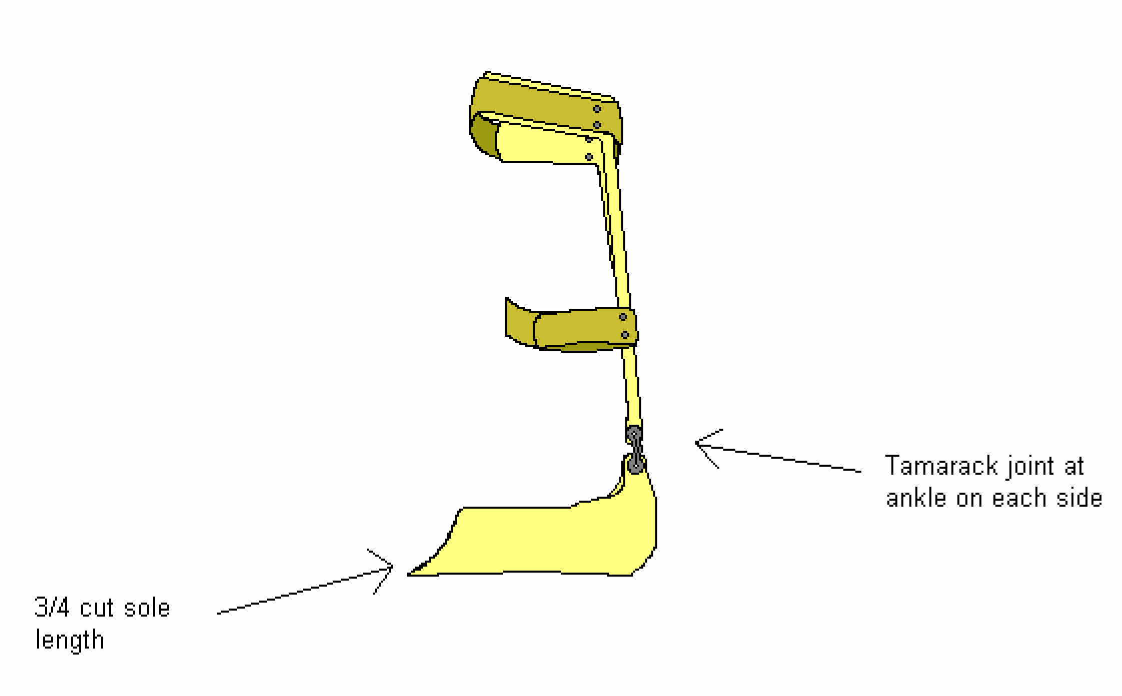

Figure 7: *Joint design with two thermoplastic rods running up the calf, a ¾ cut sole, Velcro straps and a tamararack joints at both sides of the ankle*

Figure 8: *Tamarack joints designed to assist with dorsiflexion through a loaded spring action*

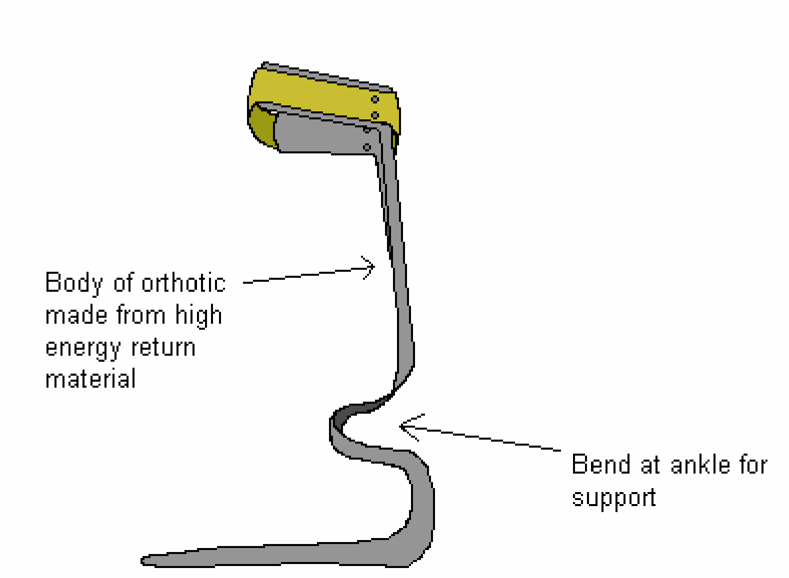

Figure 9: *Material design made of strong, but light-weight nano-fiber with high energy return, a bend at the ankle for support, and a Velcro strap.*

Appendix B (Tables)

	Cost (0.3)	Balance/ Stability (0.05)	Propulsion/ Push-off (0.25)	Material (0.25)	Foot Clearance (0.15)	Total
Spring	**$500 (0.6)**	**Ankle Brace (0.3)**	**Spring with rounded toe (0.75)**	**Thermoplastic with lining (0.75)**	**Molded at 90 degrees (0.45)**	**2.85**
Joint	**$400 (0.9)**	**Stirrup (0.25)**	**3/4 cut, Tamarack joint (1.25)**	**Thermoplastic with lining (1)**	**Joint assists with dorsiflexion (0.75)**	**4.15**
Material	**$700 (0.3)**	**Stirrup (one-sided) (0.2)**	**Energy return material (1.5)**	**Carbon nanofiber (1.75)**	**Memory material (0.9)**	**4.65**

Table 1: Design Matrix *Designs were evaluated based on the 5 main design components weighted to reflect their influence on the final design. They were then ranked 1-7 based on these components and the product of these two values summed to give their total evaluation score.*

Appendix C (References)

American Stroke Association

http://www.strokeassociation.org/presenter.jhtml?identifier=1200037

Charcot-Marie-Tooth Association

http://www.charcot-marie-tooth.org

Dr. Stephen M. Pribut

http://www.drpribut.com/sports/spgait.html

LaTrobe University

http://www.latrobe.edu.au/podiatry/thegaitcycle.html

Molson Medical Informatics Project

http://sprojects.mmip.mcgill.ca/gait/normal/intro.asp

Muscular Dystrophy Association

http://www.mda.org/publications/fa-cmt.html

National Institute of Neurological Disorders and Stroke

- http://www.ninds.nih.gov/disorders/charcot_marie_tooth/charcot_marie_tooth.htm
- http://www.ninds.nih.gov/disorders/stroke/stroke.htm
- http://www.ninds.nih.gov/disorders/multiple_sclerosis/multiple_sclerosis.htm

National Multiple Sclerosis Society

http://www.nationalmssociety.org

Appendix D (PDS)

Product Design Specification (PDS)

Project: Active ankle/foot orthotic (AFO) to enhance walking and balance

Team Members:
Jessica Hause
Erin Main
Josh White
Emily Andrews
Tony Schuler

Function: Create a device that actively enhances forefoot step-off and increases proprioception to improve balance for people experiencing ankle weakness, foot-drop and the inability to walk and balance safely as a result of various neurological diseases such as Charcot-Marie-Tooth disease, multiple sclerosis and stroke. The device should be non-obtrusive, fit in a shoe, comfortably attach to the leg, and be economical.

Client requirements:

- Ability to push of the ball of the foot
- Prevents foot drop
- Ankle stability

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements: The patient would like to use the device on a daily basis with activities ranging from walking around the house to hiking. The load that will be exerted on the device will be based on the patient's weight and load distribution throughout their foot and ankle.

b. Safety: The device cannot exert any pressures on the skin that could cause irritation. It must be breathable and very durable.

c. Accuracy and Reliability: The basic structure will be designed as a standard that can be used on a variety of patients. Parts of the structure will be custom fit and will have to be adapted to each individual patient.

d. Life in Service: The device will be worn on a daily basis while the person is mobile. Ideally it will be able to be worn at night so that in the event that a person needs to get out of bed they will be able to walk around with ease.

e. Shelf Life: The shelf life for this product is unlimited due to the use of plastics and other materials that do not have a limited shelf life.

f. Operating Environment: The operating environment for this device is somewhat unlimited and is only restricted to what the person wearing the device can withstand. The device will most likely be exposed to water, heat, sand, dirt, cold, etc.

g. Ergonomics: The device will be designed to withstand the forces exerted on it by the person wearing the device during their normal day to day activities. Height restrictions and shoe size can be adapted so that the device will be able to fit a variety of people. Forces that are out of the norm of forces exerted by a patient on the device will not necessarily be able to be withstood by the AFO.

h. Size: The size of the AFO will depend on the weight and height of the person wearing the device.

i. Weight: The weight of the device should be as light as possible so as not to impede the ability of the patient to lift their foot while walking.

j. Materials: Plastics, biopolymers, and carbon nano fibers.

k. Aesthetics, Appearance, and Finish: It will have a molded plastic or carbon nano fiber exterior. The majority of the device will be hidden within the shoe so aesthetics will not be that large of a concern. The part that will be visible will have two support bars on either side of the leg and a velcro strap around the top.

2. Production Characteristics

a. Quantity: For our client we will need one AFO for each ankle.

b. Target Product Cost: Our target cost is $300.00.

3. Miscellaneous

a. Standards and Specifications: Currently there are no set specifications for this product.

b. Customer: The costumer would like to see “new” materials being used. Currently a lot of plastics are being used on the product, so he would like to see a new material that is lightweight and that has more spring.

c. Patient-related concerns: The patient’s main concern is that she wants to be able to push off the toe/ball of her foot.

d. Competition: There are currently a variety of products on the market. The majority are made from plastic.