Active Ankle Foot Orthotic

Department of Biomedical Engineering
BME 201

Final 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 patient, Stefani Morgan. 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 prevented 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 with a passion for hiking, the patient was seeking an orthotic that more closely simulated a normal human gait pattern and actively enhanced the walking motion, helping the user by increasing push-off from step to step. 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 a 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 and proprioception.

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 (Figure 1). Normally, the nervous system relays messages

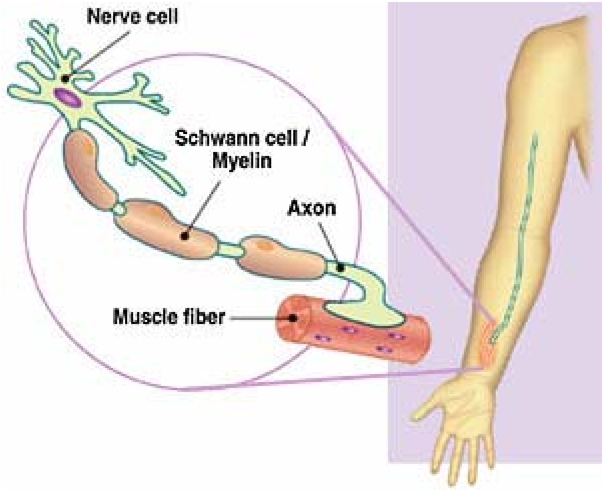


Figure 1: *Depiction of the nerve cells, axons, myelin sheath and muscle fibers of the arm.*

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.

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, 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 the swing and stance phase (Figure 2) in which

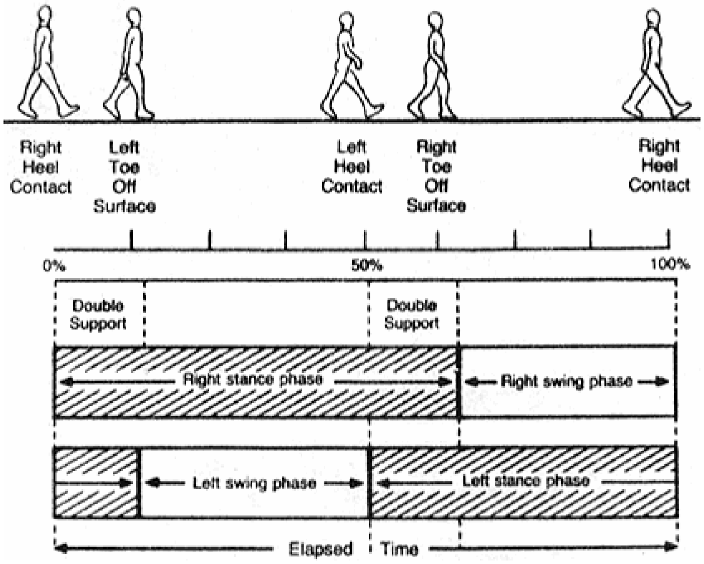


Figure 2: *The phases of the gait cycle in normal gait pattern.*

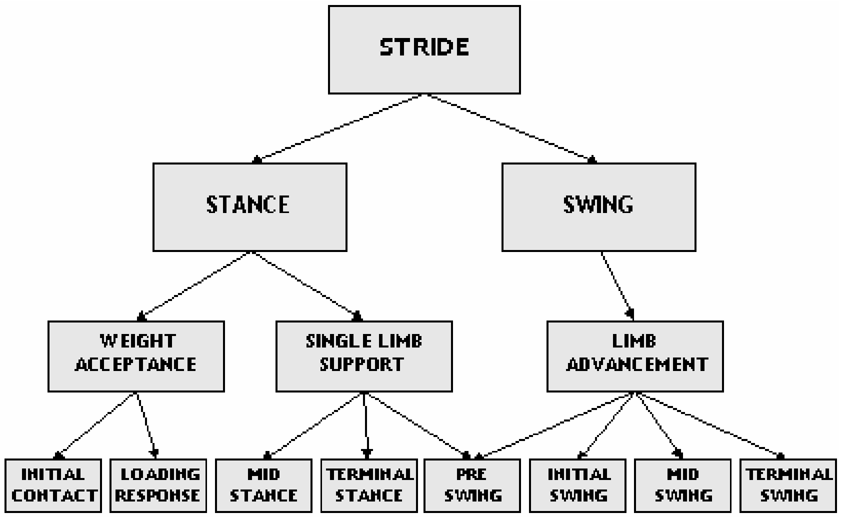


Figure 3: *The phases of the gait cycle broken down into their specific tasks.*

each phase has a primary task (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.

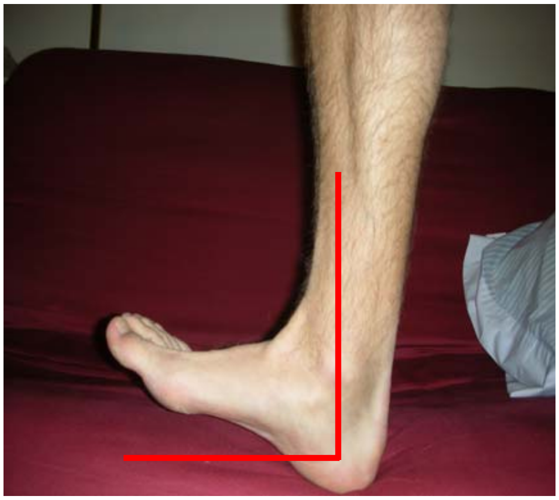


Figure 4: *A foot exhibiting normal dorsiflexion (pulling the toes above the horizontal toward the tibia)*

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 (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 (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.

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

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 but other materials including carbon fiber are also used. Two of the most commonly used thermoplastics are polyethylene and polypropylene; both are commonly used because they are lightweight, strong, and easily molded by applying heat. On the other hand, carbon fiber is much more difficult to mold because it is more brittle, however, it is extremely lightweight and durable and provides the best energy return out of the materials currently available on the market. Although these materials are exceptionally effective, an orthotic made from these materials ranges in price from $300-$700 for and therefore they are often only available to higher economic classes. Therefore, the first goal for the prototype was to mold it out of a durable thermoplastic for as low a price as possible so as to make marketable to a wider range of people.

In addition to the materials used for creating the orthotic, many other aspects of the design are carefully considered to create the best product possible. First of all, because a patient has limited ability to plantarflex and dorsiflex, orthotics are commonly molded so as to help the patient effectively propel him/herself forward and lift his/her foot off the ground. This is accomplished in several manners: by employing energy-return materials, by permanently molding the orthotic at a right angle, and through the use of tamarack joints. By using high energy return materials, the patient is able to maintain a more normal gait pattern because the orthotic provides extra force to propel the person forward. As the patient steps onto the foot wearing the orthotic, it will bend slightly and become tense. At the end of the stance phase, the patient will begin stepping with the foot wearing the orthotic, and as he/she does so it will spring back to its original form and provide more energy to propel the foot forward through the swing phase. In addition to using effective materials, orthotics are also commonly molded at a

Figure 6: *An orthotic molded at a ninety degree angle to prevent foot drop*

right angle to ensure the patient achieves proper dorsiflexion so his/her foot clears the ground as he/she walks (Figure 6). By maintaining this orientation, the patient's foot will have a constantly dorsiflexed orientation and therefore the foot cannot drag as it goes through the swing phase of the gait cycle. This is the least expensive method to aid the patient in dorsiflexion; however, it can also cause discomfort because the patient is unable to plantarflex properly. Finally, tamarack joints (by Tamarack inc.) are also used to help the patient dorsiflex properly (Figure 7). Tamarack joints are made of a thermoplastic shell with an elastic twine wrapped around the holes in a figure-eight pattern. Because the twine is wrapped in such a manner, the joint creates a moment about the center of the joint, and when employed in an orthotic assists the patient in dorsiflexing. As the patient first plantarflexes, the insole rotates around the joint away from leg piece; the moment provided by the tamarack joint rotates the insole back toward a right angle and allows the patient to dorsiflex so his/her foot clears the ground. Regardless of the design, all orthotics are equipped with the ability to help the patient plantarflex and dorsiflex and therefore the prototype must do the same.

Figure 7: *An orthotic equipped with Tamarack joints designed to assist dorsiflexion through a loaded spring action.*

In addition to the aforementioned necessities for building a viable orthotic, other aspects of the design were considered including the amount of material needed, the strength and weight of the product, the ability to fit the orthotic in a shoe, the ability to make the orthotic of two detachable pieces and the possibility of making a universal product. First of all, the orthotic must be made out of as little material as possible. Patients suffering from multiple sclerosis often experience complications when they are exposed to increased temperatures, and therefore minimal material must be used so the patient does not experience these problems. Furthermore, the product must be lightweight; it must be light enough so the patient (with decreased muscle strength) will be able to pick their leg up easily. At the same time, the product must be strong enough so it can support the weight of the person without breaking or deforming. Therefore, the most likely material for the prototype will be a thermoplastic because it has the strength and weight requirements necessary. Furthermore, the prototype must be easy to fit in a shoe so the patient has the ability to wear the orthotic at all times. Additionally, all existing orthotics are currently made out of one solid piece of material or two pieces that are permanently attached. Therefore, in order to differentiate the prototype from existing products, a quick-release system is desired. By allowing the patient to detach the two pieces, he/she will have the option of wearing only the insole for short-term use or the entire orthotic for longer and more durable use. Finally, it would be beneficial to create an orthotic with a universal mold that could be customized to fit a specific patient with customized insoles and an adjustable leg-piece. By creating a universal mold, the price of production would drastically be reduced and make the orthotic more available to people with lower socioeconomic backgrounds.

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

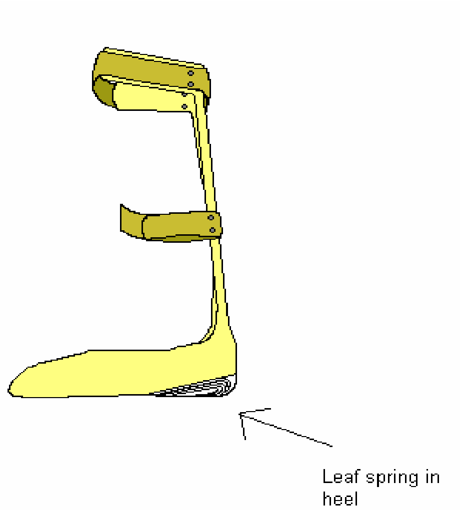


Figure 8: *Spring design with a leaf spring in the heel, thermoplastic that wraps around the calf, and Velcro*

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 (Figure 8).

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. The pieces would be connected by means of a joint called a tamarack joint (Figure 7).

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 (Figure 9).

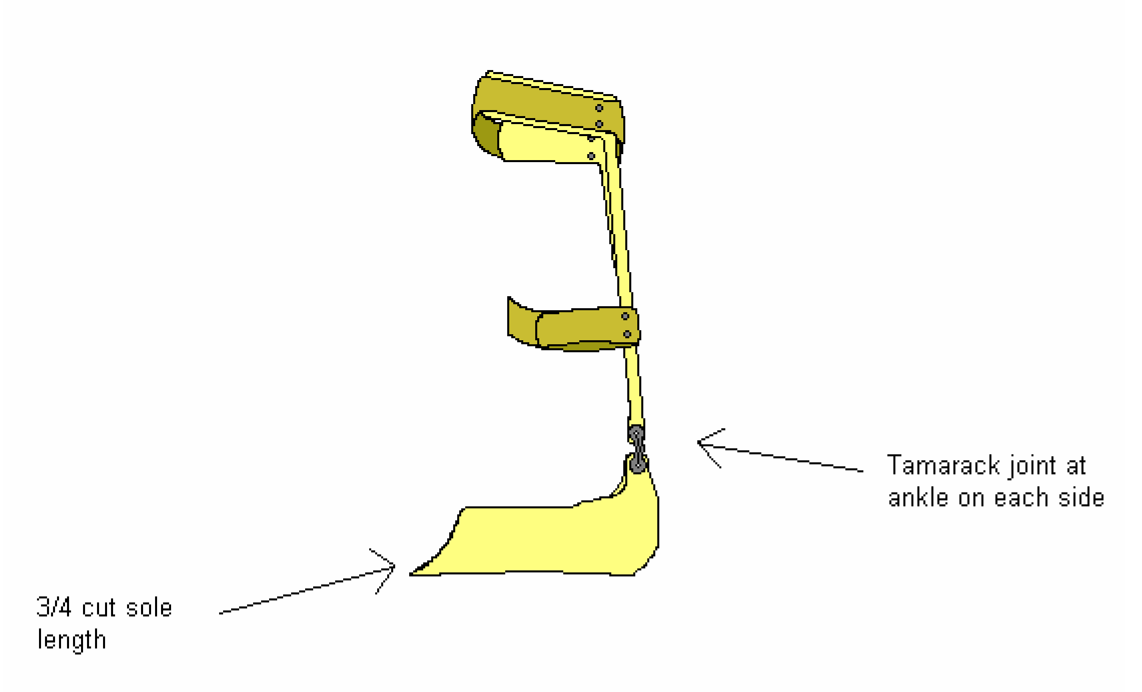


Figure 9: *Joint design with two thermoplastic rods running up the calf, a ¾ cut sole, Velcro straps and tamararack joints*

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.

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 (Figure 10). 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.

Figure 10: *Tamarack joints designed to assist with dorsiflexion through a loaded spring action*

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

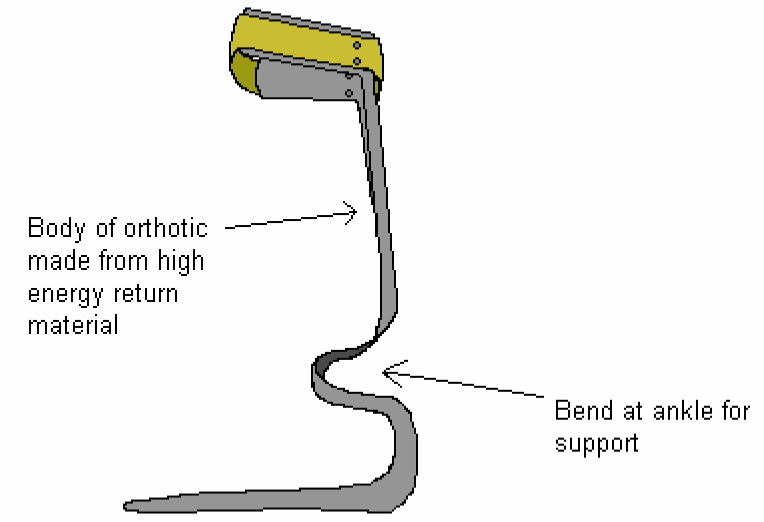


Figure 11: *Material design made of strong, but light-weight nano-fiber with high energy return, a bend at the ankle for support, and a Velcro strap*

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 (Figure 11).

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. 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 (Table 1).

	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*

Methods and Materials

Based on the background information that we collected and the design constraints that were developed, we were able to create our final design. This process began by creating a mold of our patient's foot. An elastic stocking was placed over the patient's leg that covered from directly below the knee to the toes. A rubber tube, approximately ½'' in diameter, was run along the shin and down through the center of the foot. After these two pieces were in place, a casting material was moistened and wrapped around the leg of the patient. During this process the patient's leg was placed in dorsiflexion, allowing our orthotic to provide maximum assistance. After this was allowed to dry, a Dremel was used to cut along the rubber tubing. The cast was pealed off and the leg was removed. Staples were used to reattach the cast allowing it to regain its original form. An additional strip of casting material was placed over the stapled area and over the toes to ensure that the cast was completely sealed (Figure 12).

Figure 12: *Cast of patient's foot*

The next step in creating or final design was to fill the cast we created with plaster. In doing this it allowed us to create and actual mold of our patient's foot. We began this process by measuring the depth that we would need to place our metal rod into the mold. The metal rod will be used during the thermoplastic stage of the process. A small plastic clamp was used to measure the appropriate distance that the metal rod would need to be placed at once the plaster is poured (Figure 13). A soapy water solution was used to coat the inside of the cast to prevent the plaster from sticking. The plaster was mixed to the correct consistency and then was poured into the cast. The metal rod was then placed back into the cast at the distance already measured. The plaster was allowed to harden for about two days, then the casting material on the exterior was removed. We first removed the strip that ran down the shin. After this was taken off the staples were taken out allowing the cast to be separated with ease. This left us with our plaster mold. We sanded down the mold with both a Dremel and wet sand paper, allowing us to create the plaster mold (Figure 14).

***Figure 13:** Metal rod and plastic clamp*

***Figure 14:** Plaster mold of the patient's foot*

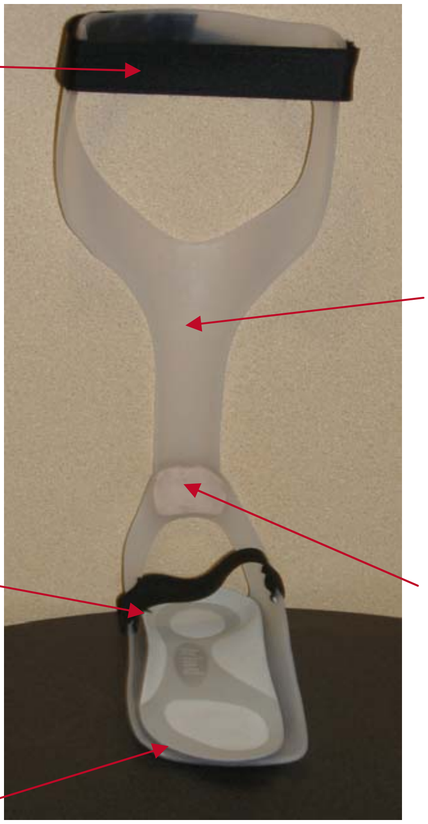
The plaster mold was then taken to a lab where we could mold the thermoplastic. To begin this process we added an additional layer of plaster to the bottom of the foot in order to create a level surface and maintain a 90 degree angle. This was allowed to dry and then proceeded to be sanded down again to ensure a smooth surface. The plaster mold was then attached to a vacuum device through the metal rod. We decided upon a thermoplastic based upon the different properties that each thermoplastic offered. We chose a 1/8th inch thick Polypropylene thermoplastic that would offer the most spring back. This was then heated in a specialized oven until it turned clear, which coincided with it being pliable enough to be molded. At this pint the thermoplastic was removed from the oven and laid over the back of our plaster mold. It was pinched together on the top of the foot and in the shin area. The vacuum was then turned on and all the excess air was removed allowing the thermoplastic to follow the contours of our mold. The thermoplastic was allowed to cool for several hours and was cut into two pieces based upon our final design (Figure 15).

Figure 15: *Thermoplastic pieces after being cut*

The last step in creating our final design was attaching all of our different components. We attached the two pieces of thermoplastic together using two Chicago screws. Two were used to prevent any rotation of the two pieces while our patient was wearing then, as well as to distribute the stress placed on the thermoplastic in the areas where the screws were attached. An additional Chicago screw was at the top to attach one side of the velcro. The other side was attached using its own adhesive backing. Once the velcro was in place we proceeded to attach our elastic strap that would run over the top of the foot. To do this we used a circular rotating Dremel to cut two small slits on either side of the bottom piece of thermoplastic. We threaded our elastic through on both sides and sewed the pieces together creating a loop of velcro. We used a square stitching pattern in order to provide the maximum strength. These steps allowed us to create our final design.

Final Design

After considering various design alternatives, our final prototype design best met the primary design constraints determined by the client. (Diagram 1)



Velcro incorporates size adjustability.

Polypropylene thermoplastic frame provides support and energy return with each step.

Insole can be used independently or with ankle support. Two pieces detach for compact storage.

Elastic strap maintains alignment and minimizes foot drop.

Custom orthotic insole provides comfort, support, and promotes normal gait.

Diagram 1: *Final design prototype*

The first goal in correcting the patient's foot drop is to create a permanent 90 degree angle at the ankle so that an over exaggerated stride no longer necessary to avoid dragging the feet on the ground. Along with supplying the appropriate ankle support, this fundamental mechanism will promote a more natural gait pattern in the patient, which will reduce stress on the hip and knee joints as well as the back.

The thermoplastic frame is made of custom molded polypropylene, which is both supportive and flexible. The elasticity dynamically aids in propulsion by providing significant energy return centered at the hour glass-shaped hinge, which functions much like a leaf spring system.

Push-off is also aided by the three-quarter cut thermoplastic sole that extends the ball of the foot and is cut off just before the metatarsals. Such a cut maximizes natural plantar and dorsiflexion and permits increased proprioception and balance executed by contact between the toes and the ground.

A custom fit orthotic insole increases comfort and support and corrects for any structural abnormalities of the foot, thus promoting a normal gait pattern.

The sole and ankle support pieces are detachable. The more basic insole comfortably fits into the shoe and is appropriate for independent use during light walking. It can also be used in conjunction with the full ankle support for more durable, long-term use. Currently, these two pieces are connected with Chicago screws and are covered in moleskin to prevent skin irritation. When disconnected, the prototype is compact for easy storage.

The simple elastic strap across the top of the foot allows the patient to easily slip their foot into place and maintains constant alignment in the orthotic, while reducing the patient's foot drop.

Finally, the orthotic can easily be adjusted to fit different patients using the Velcro cuff that spans the shin.

When compared to the top-of-the line Otto Bock Walk-on, our final prototype replicates successful performance and incorporates several unique convenience and comfort features (Figure 16).

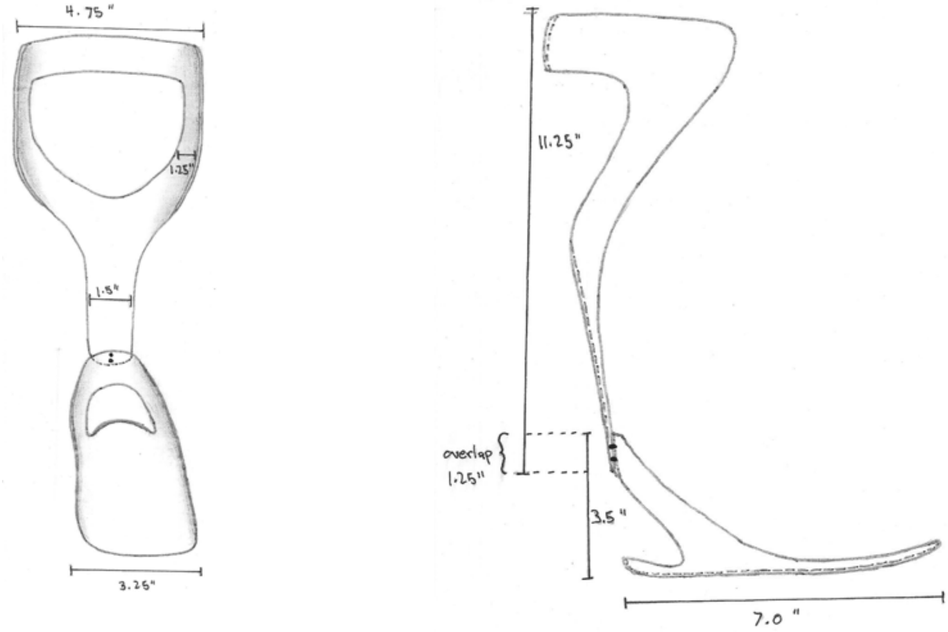


Figure 16: *Final design prototype, front and side view with dimensions*

Testing

In order to evaluate our design, we asked our patient to do a comparison test using the top of the line orthotic available on the market now (Otto Bock's Walk-On) as well as the product we designed (Figure 17). The Walk-On employs a material known as carbon-fiber that provides the best energy return for its weight and durability in order to propel a patient forward. On the other hand, our product makes use of a ¾ polypropylene sole that

Figure 17: *The top of the line orthotic available on the market now, Otto Bock's Walk-On*

propels a patient's foot forward without the use of extra materials. It stops just before the ball of the foot to keep a patient's toes free for push-off and proprioception. In this way, our orthotic provides increased support and propulsion while still allowing patients to use their own plantarflexion to push themselves forward. Our product provided slightly less propulsion than the Walk-On but the material we employed was more usable during fabrication and significantly less expensive.

A major drawback to the Walk-On is the fact that is made up of one solid piece, making it slightly less easy to transport and cumbersome when the orthotic only needs to be strapped on for a short distance. As a result, our device is designed so that the top and bottom pieces can easily be detached from one another making the product easy to transport and much more usable for short-term and long-term use.

Another major drawback of the Walk-On design is its inability to be customized for specific patients. As a result, our device is designed so that the top piece can easily be adjusted from one patient to the next using the Velcro strap located at the top while the bottom piece can be designed for specific patients during the molding process, making it much more comfortable to use.

Finally, our device is superior to the Walk-On due to our use of a slightly simpler material and design, making it significantly less expensive than the Walk-On and thus, much more appealing to customers.

Cost Analysis

Due to a fairly limited budget, a major challenge of this particular project was to keep costs as low as possible (under $300). As a result, we employed a simple material and design that would accomplish the same means as other orthotics, while keeping costs limited.

Our device is comprised mainly of thermoplastic which is formed around the plaster mold of the patient’s foot. Thermoplastic is a fairly inexpensive material (approximately $56.43 for the entire orthotic) and the plaster used to create a mold of the patient’s foot cost a mere $7.99. After the thermoplastic had set and the two pieces cut apart, the two Chicago screws used to attach the two pieces together were also very inexpensive at $.98 a screw. Upon connecting the orthotic, it was equipped with the orthotic insert that cost approximately $9.99 as well as the Velcro strap around the calf at $4.49 and the elastic band that went around the top of the foot at $1.09. The device was then completed with the moleskin at $3.49 to prevent rubbing.

All of our materials cost a grand total of $86.42 for the entire orthotic. Our group was fortunate enough to find a specialist willing to provide the labor during the thermoplastic molding which was a major factor in helping us to keep costs down

(Table 2)

Plaster	$7.99
1/8" Thermoplastic	$56.43
Chicago Screws	2 @ $.98
Orthotic Insert	$9.99
Velcro	$4.49
Elastic	$1.09
Moleskin	$3.49
Total	**$86.42**

Table 2: *Cost Analysis*

Future Work

If we were to continue this project next semester, there are a few things we would like to improve upon. Due to limited budget and resources we constructed our orthotic out of thermoplastic as opposed to other materials, such as carbon fiber. In the future we would like to explore using carbon fiber to construct either the entire orthotic or just the sole due to its high energy return, which would give the user more push-off from step to step. Additionally, we feel a modification to the 2-part system allowing for faster disassembly would be beneficial to the user. Finally, we would like to produce 3 standard sizes of the orthotic, small, medium, and large to fit the general population and then allow for customized orthotic insoles to be worn along with the device to maximize functionality and comfort. All improvements aside, we are very confident in our prototype and pleased with the overall results.

Appendix A: 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
Dr. Scott Amyx, University Health Services: Orthotics.
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Dr. Darryl Thelen, University of Wisconsin Mechanical Engineering Department
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LaTrobe University
http://www.latrobe.edu.au/podiatry/thegaitcycle.html
Molson Medical Informatics Project
http://sprojects.mmip.mcgill.ca/gait/normal/intro.asp
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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
Otto Bock
www.ottobock.com/

Appendix B: PDS

Product Design Specification (PDS)

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

Team Members: Jessica Hause
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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.