

Rachel Lenhart

Nataly Sumarriva

Senior Design Project
Design of Improved Ankle-Foot Orthosis

J. Brooks, R. Lenhart, L. Morales, and N. Sumarriva

The University of Tennessee, Department of Mechanical, Aerospace, and Biomedical Engineering
Knoxville, TN 37996 USA

Table of Contents

Abstract	3
I. Introduction	3
II. Materials and Methods	3
III. Results	4
IV. Discussion	5
V. Pilot Testing	10
VI. Conclusions	11
VII. Acknowledgements	11
VIII. References	11

Design of Improved Ankle-Foot Orthosis

J. Brooks, R. Lenhart, L. Morales, and N. Sumarriva

The University of Tennessee, Department of Mechanical, Aerospace, and Biomedical Engineering
Knoxville, TN 37996 USA

Abstract

Many people with disabilities require positioning of the feet and stability at the ankles, which is achieved through the use of an ankle-foot orthosis (AFO). Models currently in use are bulky, uncomfortable, and hard to put on, especially for pediatric patients. These patients visibly have trouble walking as their oversized shoes, necessary for the insertion of the AFO, get in the way. The goal of this research is to design a pediatric AFO with modifications to solve the current issues. The design is constructed with many considerations taken into account. Input from patients and parents, as well as from doctors and manufacturers, tells current problems. Current designs provide modes for comparison. Finally, structure is kept paramount with research into ankle biomechanics. Foot pressure testing ensures proper alignment. The result is an AFO in which function is married with comfort and quality. A shoe has been attached to the detachable struts of the AFO in order to reduce bulk and size, as well as provide a medium for natural gait.

Keywords: Cerebral Palsy, brace, gait, hemiplegia, AFO

I. Introduction

Many medical conditions lead to foot and ankle instability. Cerebral palsy and hemiplegia are just a few of the conditions in which sufferers often benefit from the force provided by an ankle-foot orthosis (AFO) (1). Despite the benefits, many problems are present in current AFO designs. Though patients are able to walk with the aid of these devices, the gait is labored and very unnatural. Therefore, this project was undertaken in order to ease gait, making it more natural, sturdy, and sound.

The following will elucidate the process that was followed in the design of this new AFO, then discuss the findings from research and contacts. Finally, the proposed design will be discussed, along with reasonings for each decision.

II. Materials and Methods

A. Initial Ideas

Brainstorming ideas was step one in determining a feasible student project. Several ideas were mentioned in this initial

session; everything from creating a "Segway"-like wheelchair, to conducting studies on and redesigning "knee-savers" used by baseball catchers. From this long list, the top three ideas were unanimously agreed upon. One was to try to create a surgical sight infection detector of some sort. The thought was that hospital induced sickness and infection could be reduced by applying a simple patch around IV or surgical entrance sights. Perhaps the patch could change colors when levels of infection were increasing, to set precautionary measures into action before things became out of hand. The second idea was a sort of knee brace that could be remotely unlocked. Many knee braces are currently on the market, but most, if they unlock at all, unlock at the knee by pressing a large button. This can be awkward and cumbersome. The hope was to have a remote control unlocking system that would allow simple release of the knee. The third and final idea was to create a new ankle-foot orthosis (AFO). Many children wear these devices, but they are very bulky and seem to almost create more walking problems than they help. The shoes that the children are required to wear to get into their AFOs are huge and therefore do not fit properly. The goal was to create an AFO incorporated with a shoe to reduce an element in the equation.

B. Final Decision

Ultimately, the AFO was decided upon. It seemed most feasible, while still maintaining some degree of innovation. The surgical sight infection detector seemed to be out of league, as many unknown physiological and material properties would have to be researched and selected. The knee brace project seemed a little too simple in that simply adding a remote unlocking device would not alter the design or manufacturing of the knee brace very much.

C. Process

Many aspects of the AFO were explored in order to achieve the best design possible. Used and old models were researched in order to obtain a knowledge base. The biomechanics of the ankle were elucidated in order to ensure functionality and bone structure were carefully maintained. To begin grasping current problems and solutions, doctors, patients, and parents were contacted. After potential materials were researched, final decisions for the design were made.

D. Materials

Six pairs of children's tennis shoes were purchased of varying styles and sizes. Several of these pairs contained light sensors and these were taken apart and studied. Two right-foot AFOs were purchased (Sammons Preston, . In addition, two Jump Start Cricket insoles (Cascade, Washington) and two Hot Dog insoles (Cascade, Washington) were purchased.

To produce a pressure-sensing light-up system, a push button was purchased (Heath-Zenith Corporation, Kentucky).

A lever switch, LED light, watch battery, and electrical wires (RadioShack Corporation, Texas) were also purchased.

E. Prototype

The plantar section and some of the bottom portions of the AFO were cut off. This left only the back part of the AFO intact. The lighting system was wired by connecting the LED to the watch battery and push button, using electrical wiring. The tennis shoes were taken apart, separating the soles from the back of the shoes. Once the soles and padding were removed from the shoe, the cut AFO was inserted and the insoles and Hot Dog were added in place. A small hole was made in the back of the shoe where the light could be inserted and shown.

D. Pilot Testing

Pilot subjects are to be tested and surveyed for comfort and satisfaction. These subjects will also be subjected to an FSCAN foot pressure test. This will quantify the structural considerations taken into the design. Foot pressures with the AFO will be compared to baseline shoe pressures. Ideally, the AFO will be improved, due to the biomechanical considerations of foot structure taken into the design.

III. Results

A. Initial Design

The design aimed to solve many problems with current AFO designs. The main feature that was decided upon was the integration of a shoe with the AFO. This design solved many problems seen with current designs. First, this design allowed for better interaction of the AFO and the shoe. Currently, the AFO does not always fit in the shoe, causing the AFO to come out of the shoe or a blister to form. The integration of the shoe also makes the design more aesthetically pleasing for children, meaning the child will be more likely to wear the AFO.

The shoe provides for better support as well. With a shoe, arch supports can be used to give the child more support where needed. Also, metatarsal pads can be added to provide more support. Less slippage will also occur since there will not be friction between the AFO and the shoe.

Another idea explored was a detachable brace from the shoe. This would allow the child to take off the shoe quickly and replace the brace quickly. The child could also put it on by himself, allowing the child more independence. However, the downside to this feature is that the attachment to the shoe creates a weak point. At this point, the brace could become detached accidentally or it could break there. However, the final design chosen will try to minimize the risk of these problems occurring.

Straps are another important component of an AFO. Velcro is used fairly commonly for straps. Velcro allows for easy donning of the AFO. Current issues with the Velcro include

rubbing of the Velcro on the skin. Elastic straps are also used on AFOs. These have an advantage over Velcro since they do not have a rough side like Velcro. However, the elastic can cause pressure and blisters on the skin. Our design will look to make the straps easy to put on and take off without causing skin irritation or blisters.

Padding is another component of the AFO. Padding will be used in high pressure points to prevent sores from developing. Various types of foam and cloth can be used for padding, and the exact type used in this design will be determined.

Another consideration is fastening of the shoe. A lace-up shoe might allow more support, but a Velcro shoe would allow a younger child to put on the AFO by himself. Both options will be explored to see which provides a greater advantage.

The shoe design is yet another consideration. A high top shoe will provide more support for the ankle. A lower top shoe will be less obtrusive but will not provide as much support.

A sensor in the shoe that would go off when the foot is fully in the shoe is another feature that will be considered. From feedback from users, it has been seen that getting the foot all the way in the shoe can be a problem. Hopefully, a sensor will help fix this problem.

Finally, aesthetics of the shoe will also be considered. A light up shoe would make the shoe appealing to kids. Also, cartoon character designs, such as Hello Kitty and Spiderman, might make the shoe more child friendly, making the AFO look less like a medical device.

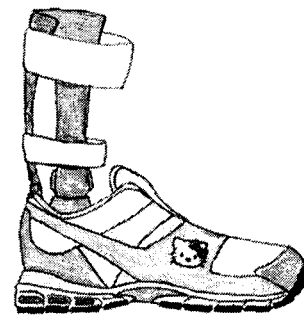


Figure 1: Initial AFO Design, Exterior Side View: This image demonstrates the design decided upon, including the decisions made on features, included straight struts, low top shoe, Velcro straps, and aesthetic designs.

This design encompasses many improvements from the traditional AFO. The improvements include:

- Shoe with detachable AFO struts
- Arch and metatarsal supports
- Velcro straps
- Padding for improved comfort
- Sensor to detect proper heel engagement
- Lights in shoes
- Kid-friendly designs

A. Final Design

Fig. 2 demonstrates the final AFO design. This design encompasses many improvements from the traditional AFO, including detachable AFO struts, supportive insoles, metatarsal supports, Velcro straps, padding, a sensor to detect proper heel engagement, lights, and child-friendly designs.

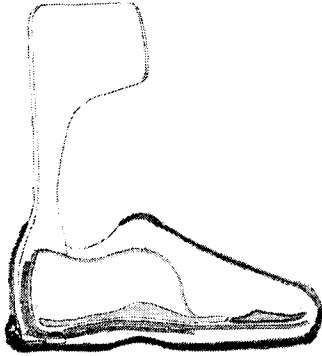


Figure 2: Final AFO Design: This image demonstrates the final design of the AFO, including the interior insole, metatarsal supports, and pressure sensor.

IV. Discussion

A. Indications for Use

The AFO is meant to help patients with drop foot, in which the foot drags along the ground, holding the foot and ankle in the correct position. The purpose of an AFO is to support weak or wasted limbs or to position a limb with tight and contracted muscles into a more natural position. It is especially used in disorders that affect muscle function such as stroke, spinal cord injury, muscular dystrophy, cerebral palsy, polio, and multiple sclerosis. Other disorders include cerebral vascular accident (CVA), or stroke, Charcot-Marie-Tooth syndrome, cerebral palsy, and other neurological conditions which result in contracted musculature. The AFO generally keeps the angle between the ankle and the leg in a perpendicular state, preventing the ankle and foot from fracture. Also, the AFO may be used in conditions in which the patient has ulcers on his heel and/or toes, for the AFO can prevent their contact with bed sheets or other items that may rub against the ulcers and aggravate them.

With each disease, there are certain types of AFOs that are designed to treat a condition in particular. For example, energy return, the angle between the ankle and leg, and range of motion of dorsiflexion and plantarflexion are factors which vary and which one should keep in mind when considering which AFO suits a patient's needs. Furthermore, it is possible for the AFO to be either hinged or fixed depending on the patient's needs. To obtain a good fit for a patient, an AFO can either be pre-fabricated and can be ordered in certain sizes, or it can be custom-manufactured by using a negative cast or computer-assisted imaging, design, and milling.

B. How the AFO Corrects Disorders

An AFO can help with static foot alignment, such as in patients with cerebral palsy. They are used to redistribute stresses on the foot as they make contact with the ground and to accommodate for abnormal function of defective muscles or ligaments. This is achieved by controlling the posture of the foot and by padding certain areas to relieve pressure and increase comfort. (2)

In patients with cerebral palsy, AFOs are often used to correct equines or pes planovalgus deformities. This results in enhanced gait function in diplegic subjects. There is an elimination of premature plantarflexion and improved progression of foot contact during stance.

C. Patents

The following patents are among the inventions relevant to AFO design and manufacture: (2,3)

Table 1: Current Patents Related to AFOs: These patents are relevant to the development of the AFO technology.

Patent Number	Description
US Patent D542920 (2005)	Ornamental design for AFO foot cover
US Patent 6827696 (2002)	AFO consisting of L-shaped member for lower leg support and a U-shaped cross section, a U-shaped heel support and a foot support portion
US Patent 6945946 (2005)	AFO with structural frame formed from at least one layer of fabric impregnated with a hardened structural resin
US Patent 6827696 (2004)	AFO provides a pivotal ankle support which is movable between open and closed positions
WO/1999.018896 (1996)	AFO design for resisting plantarflexion of the patient's foot, with the orthosis comprising a flexible yet resilient socklike structure enveloping a portion of the patient's ankle and a portion of the foot (multipodous splint)
US Patent 5853380 (1998)	New AFO design that both positions the ankle and foot at correct angles, yet also protects patients with ulcers, in the form of a multipodous splint

D. Types of Ankle-Foot Orthoses

There are several types of orthotic devices for the ankle. Most are specially designed for specific uses and conditions. The conventional types of AFOs described in this section are: solid AFO, posterior leaf spring, hinged AFO, and hybrid AFO.

Solid AFOs position the ankle in a fixed proper position and are shaped to fit the foot and may or may not come with padding to relieve pressure at key pressure points. This type of AFO is the simplest design usually consisting of one solid piece of plastic shaped to fit around the heel, and straps to hold it in place. Solid AFOs offer maximal stability by placing joints in a fixed position. Solid AFOs aid dorsiflexion and

plantar flexion of the ankle. Solid AFOs are used most commonly to treat foot drop associated with cerebral vascular accidents, and other diseases like cerebral palsy and Charcot-Marie-Tooth disease.

Posterior leaf spring AFOs are fairly similar to solid AFOs. The difference between these two kinds of AFOs is the thickness of the plastic as well as the trim lines, which determine the width and shape of the posterior shell. A posterior leaf spring AFO allows for controlled plantar flexion at loading response. The main function is to limit plantar flexion of motion during swing phase when an individual has weakness of the ankle dorsiflexors (4). An inherent flexibility of the design will not control excessive eversion, pronation, and abduction. The advantage of the posterior leaf spring is a smoother gait pattern compared with the solid AFO.

Hinged AFOs are widely used because they easily provide a system with sagittal plane plantar flexion stop and control in the coronal and transverse planes. Hinged AFOs have limitations in drop foot applications. This type of AFO can only be used on patients who have relatively stable knees. The joints that the AFO incorporates can provide free movement, limited movement, or assisted movement. Since the joints will be used frequently and heavily, they are susceptible to wear and play a big factor in hinged AFOs' durability.

Hybrid AFOs are the most complex type of ankle foot orthosis. This type of AFO incorporates a combination of plastic shells, metal, and carbon fiber. The plastic AFO is usually supported by lateral struts of metal for adjustability and/or impregnated with carbon fiber strut for high-energy return. Hybrid AFOs enable the patient to use a variety of shoes, and the ankle joints allow biomechanical options for adjustability of the ankle. The incorporation of the metal stirrup and the ankle joint provides an effective dorsiflexion stop that cannot be achieved by any of the other AFOs (2).

E. Competing Ankle-Foot Orthoses Manufacturers

There are several companies that manufacture orthotic devices and braces. As a brief overview, only a few companies that were proficient and prevalent in the making of ankle foot orthoses were examined. Ossur, Otto Bock, Sky Medical Incorporated, and Restorative Care of America Incorporated were the companies chosen. The company and its relative products were researched.

Ossur

Ossur is a global company with its headquarters in Iceland and offices in America, Europe, Asia, and Australia. Ossur has the most advanced and diverse selection of all the company. The AFO models offered are the AFO Dynamic, AFO Light, AFO Leaf Spring, and Foot Up. All of the models are lightweight and have slim designs. The different AFOs come in different materials from plastic to carbon fiber. Each AFO has its own purpose and indications for use.

Otto Bock

Otto Bock is another global company with subsidiaries in Europe, America, Asia, Australia, and Africa. Otto Bock offers custom orthotic devices. The AFO models offered

include the WalkOn Carbon Fiber AFO, Rigid Thermoplastic AFO, Articulating AFO, and Snap Stop. There are five different styles of their thermoplastic AFO varying from rigid designs to open heel posterior leaf spring AFO. Several of the AFOs have as a feature the Snap Stop system, which allows for ultimate customization by allowing the user to switch out pads and bumpers for the right fit and comfort.

Sky Medical Incorporated

When compared to the gigantic companies like Ossur and Otto Bock, Sky Medical is much smaller. Because of their small size, they only offer only a few AFO. Of all the companies, Sky Medical offers the least number of orthotic braces. The AFOs include AFO Posterior Leaf Spring (PLS), Semi Solid PLS, and various braces. These AFO are fairly standard with not many innovative features implemented in them. Sky Medical offers more braces than orthoses. In regard to braces, they have a plethora braces with variations.

Restorative Care of America Incorporated

Restorative Care of America is an old company with its name deeply imbedded in the orthotic market. RCAI provides a wide variety of orthotic braces. The AFO models offered are the Semi Rigid AFO, Leaf Spring AFO, Rigid AFO, and Swedish AFO.

Prices were explored for the main competitors in the AFO and shoe markets. The results appear in Table 2: Pricing for AFOs and Shoes

Table 2: Pricing for AFOs and Shoes: This table serves as comparison for current AFO and shoe prices.

Pricing AFO		
Trulife Lite AFO / Drop Foot Orthosis	\$43	www.allegromedical.com
AFO (Ankle Foot Orthosis) - Rigid - Large - Left	\$50	www.amazon.com
Sammons Preston Pediatric AFO	\$44	www.allegromedical.com
Sammons Preston Ultra-Light Foot Orthosis	\$57	www.allegromedical.com
Pricing Shoes		
Pedors 600-H Black High Top Shoes for Children	\$89.50	http://www.phc-online.com/Pediatric_Shoes_s/2264.htm
FreeStyle Hatchback Shoes	\$54.95	www.hatchbacksfootwear.com
Keeping Pace	\$99.87	www.healthyfeetstore.com

F. Other Competing Products

When searching literature, a company called Shoby Shoes was found. This company makes what looks like commander boots which incorporate AFO function into a large boot design. The boot laces all the way up the front and attempts to stabilize the ankle by this modality. (5)

G. Ankle Axis of Rotation and Foot Alignment

From contact with Dr. Kaufman at Mayo Clinic it was learned that the ankle axis of rotation was not maintained when wearing an AFO. Therefore, one element that should be taken into account when making our AFO is the alignment of

the foot and ankle. This is paramount to ensure the preserving of the mechanical stability and integrity of the limb as well as the whole body. Michelle Andrews comments on the importance of foot alignment in maintaining the body and gait functions in her analysis of reliability of gait analysis data. (6).

The literature confirms that most AFOs do not take into account the alignment of the foot. Westberry et al. concludes that even though many studies previously have shown kinetic benefits in children with cerebral palsy, ankle-foot orthoses do not improve static alignment. (7).

The model of the foot and leg presented in Human Factors Engineering (8) (Figure) has some notable characteristics. First of all, the medial foot lies directly inferior to the midline of the body. Yet the knee is located .05*height away from the midline. This creates an angle in the tibia which must be taken into account when forming the AFO. Also, in the model of the foot (Figure), the sole of the foot is .10 cm, meaning that the axes should not be considered to be directly on the ground when calculated. Finally, the distance between the axis of rotation and the posterior heel is .03*height. The axis of rotation is not the most posterior element in the foot. The length of the foot anterior to the axis is approximately .12 * height. This picture is important to note because the placement and alignment will also affect orthotic performance (9).

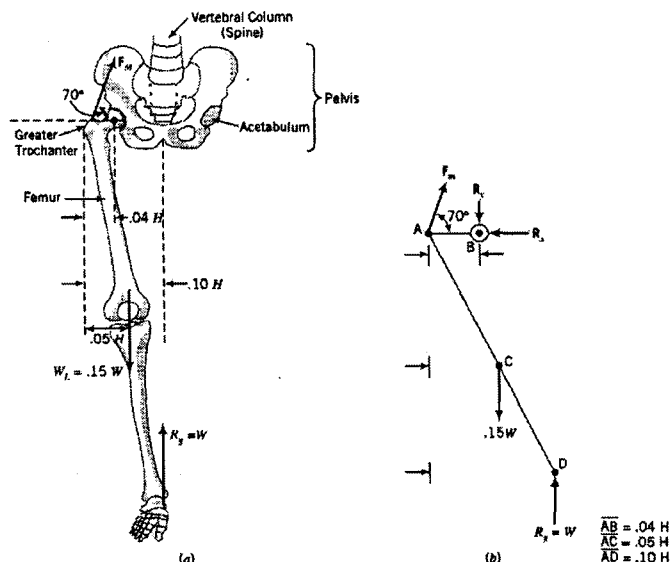


Figure 3: Structure and Geometry of Leg: This figure was used for reference in determination of brace orientation.

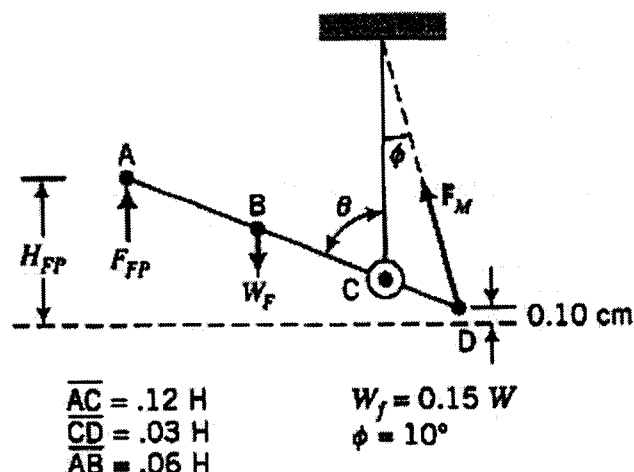


Figure 4: Structural Model and Geometry of Ankle and Foot: This figure was used for reference in determination of foot

Biomechanics of the Musculo-skeletal System (10) also elucidates some elements of the important ankle axes. Though no exact numbers are given for the engineering design, (Figure) shows some important lines of rotation for plantarflexion/dorsiflexion and for supination/pronation. Each of these axes are not in line with what one might think are the foot's x and y axes. Each is slightly off. The ankle axis appears to go through the anterior portion of the medial and lateral malleoli, and the subtalar axis runs from lateral heel to anterior

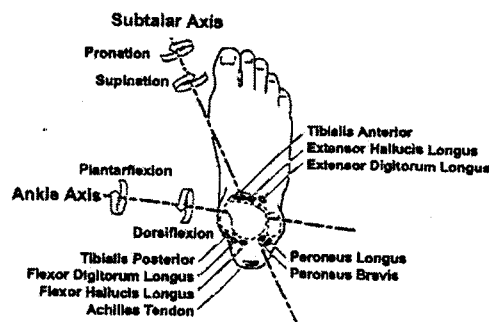


Figure 5: Rotation Axes for Foot and Ankle: This figure was used for reference in determination of brace orientation.

As far as how the tibia lies anterior to posterior not much data was found. It is suspected that the tibia should be at nearly 90 degrees, aligned over the angle center. Woodhull (11) does note though in the 1985 experiment, that the knee is usually 3.8 cm in front of the ankle center. Of course, little indication was given in the article as to the height of the subjects.

H. Contacts

In an attempt to define the project, outside resources were tapped. Doctors, patients, as well as those in design and

industry were all contacted for their input on the improvements that could be made to the pediatric AFO to make it more friendly to the child patient.

One contact that was made was with Dr. Kenton Kaufman, a biomedical engineer in the Motion Analysis Laboratory at the Mayo Clinic in Rochester, MN. His lab constantly has pediatric patients with AFOs in the office going through gait analysis. When asked about the problem with current AFOs, his response was: "AFOs don't fit properly because the axis of rotation of the AFO does not correspond with the ankle axis of rotation. Plenty of room for a good engineering design."

Orthopedic Surgeons were also a group that was contacted to try to find out about the AFOs. Dr. Jacks of Louisville, Kentucky let us know that the best AFOs on the market right now are those made of carbon graphite, but that these can be really expensive. This is not good for children because as they grow their AFOs need to be replaced fairly frequently. Therefore children's AFOs are often made out of plastic which tends to break. The trick would be to use a material that is thin and lightweight, but durable, somewhat flexible, but strong, and inexpensive. Dr. William Shaughnessy, a pediatric orthopedic surgeon at Mayo Clinic, made a comment on the frequency of outgrowth and wearing out as well. He also mentioned that AFOs tend to get hot, and they are not a pleasant experience for kids to wear. The children do not find them "cool" so dread wearing them. On more of the design side, Dave Madden, a certified orthotist at Gillette Children's in St. Paul, Minnesota said that the biggest problem he has is quantifying the amount of flexure that the AFO will have for the patient and correlating that with his/her need.

Finally, and probably most importantly, patients and their parents were contacted to see what they had to say about their experiences with AFOs. This first hand perspective was vital to the determination of specifications for the final design. A team member joined the Cerebral Palsy Network, an online support group for families of those with cerebral palsy. (Many cerebral palsy patients are forced to wear AFOs). Response was also obtained through the Children's Hemiplegia and Stroke Association. The following are some of the more frequent and relevant responses.

- Frequent Blisters and Skin Breakdown
- No arch or metatarsal support
- Slippery when not on carpet
- Attractiveness
- Adjustability
- Bulky
- Poor padding, causing bruising
- Not easy to put on
- Hard to get heel into the bottom of AFO

Dr. Jack Wasserman of the University of Tennessee has a daughter who wears AFOs. He commented how tough they were on her feet and that they broke every 6 to 9 months. On top of that, they do not account for the lean in the leg that she experiences.

Each of these contacts were taken seriously and incorporated as best as possible into the final design of the AFO.

I. Materials

Many materials were explored for use in the ankle-foot orthoses. The material needed for the AFO must fulfill many requirements. First, the material must be strong and able to provide support. However, the material also needs to be flexible to enhance comfort. Another important material property needed is breathability. Most plastics and materials feel hot against the skin and cause excessive sweating. A lightweight material would be ideal to once again enhance comfort. Also, the thinner the AFO can be, the more aesthetically pleasing the device will be. The material of choice also needs to be easily moldable. This is important since a lot of AFOs need to be custom made.

Polypropylene is a thermoplastic polymer, used widely for many applications. One main advantage of polypropylene is that flexibility can be varied greatly. The material can be made very flexible or very rigid, depending on the need. However, polypropylene tends to creep, making it not suitable for long-term use. Also, polypropylene is not very breathable, causing it to not be very comfortable. Polypropylene is very cost effective.

Another material used for current AFOs, such as the Ossur Dynamic, is carbon fiber. Carbon fiber is very strong and durable. Carbon fiber also offers high energy return, making it a good material for use with some patients who need AFOs. However, carbon fiber is much more expensive than polypropylene. A more expensive material, even though it might last longer, is not ideal for use in pediatrics who tend to quickly outgrow the orthotic.

Graphite is another possible material. Graphite can be very strong, even in a very thin layer. This would be ideal to make the AFO thinner and more aesthetically appealing. However, graphite is not breathable and is also quite expensive.

Plastazote is another material used in orthotics. This material is not ideal for this application since it tends to wear out in a short period of time, usually within a month.

More important than the actual material is how the material is formed for the orthotic. Even the best material will not be good if it is molded improperly. Milling the material allows the material to be stronger but thinner, making the orthotic more comfortable and aesthetically pleasing.

For the AFO, a polymer such as polypropylene, or carbon fiber will likely be used. The final decision will be based on availability of the material, ability to mold the material, as well as cost.

J. Final Decisions

Straight vs. Twisted

The decision was made to make an orthosis with straight rather than twisted struts. An illustration of the straight and twisted AFO can be seen in Figure 5. The straight struts will allow the patient to use them for a much longer period of time,

as growing legs will not be as big of an issue. As soon as the leg became a little bigger or fatter, a twisted version would need to be replaced. The straight version will also be much easier to don when the AFO is connected to the shoe. Placing a shoe on the foot is difficult enough for a child, without having to deal with a twisting AFO in the way.

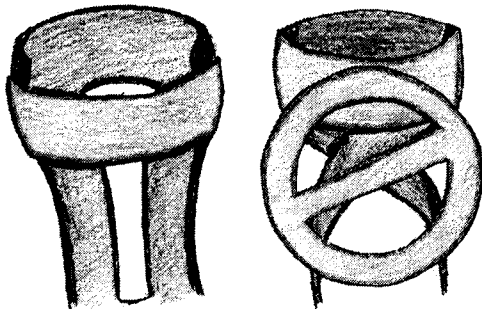


Figure 6: Straight vs. Twisted Designs: Straight struts were decided upon over a twisted version.

Detachable vs. Non-detachable

It was concluded that detachable struts for the AFO would be best. This will allow our design to be more cost effective, because the struts will not have to be replaced as often as the shoes. It will also allow multiple types of shoes to be worn with the AFO; children will not be confined to one type of athletic shoe. A drawing of the idea can be seen in Figure .

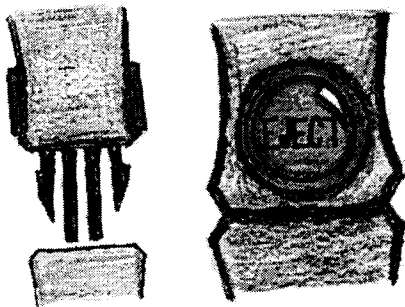


Figure 7: Detachable design: The AFO was designed to be detachable . These represent the desired design for detachment.

Lace-up vs. Velcro

Lace-up vs. Velcro could not be well quantified. Further study through prototyping will be necessary to make a final decision.

Velcro vs. Elastic Straps

Velcro was chosen for use on the straps. Elastic seemed to be too flexible and not provide enough support. Also, elastic is too constrictive and would easily stretch out over time. Velcro is highly adjustable, while providing good support. Also, Velcro maintains its integrity over time better than elastic.

Material

Various plastics and other composite materials were explored. Composite materials, such as carbon fiber, were ruled out due to cost. Various polymers will continue to be explored to determine the best option.

Aesthetics

An important component of this AFO design is the satisfaction of the patient. To obtain this objective, the design is aesthetically-pleasing to children. The design contains designs of popular children's characters on the sides of the shoes. Furthermore, the design contains lights in the outer heels of the shoes.

Pressure Sensor

Considering that the patient population of the AFO consists mostly of children, one prevalent concern is whether or not the child has the entire foot in the shoe. Since the child often will not elucidate whether or not the heel is touching the shoe, having a pressure sensor in the bottom of the heel portion of the AFO or shoe would be of great benefit. After observing this benefit, the current design includes a pressure sensor with a light activator on the outside of the shoe.

High Top vs. Low Top

In order to make the shoe more aesthetically pleasing to better suit the younger patients, the product will contain a shoe that has a low top. This allows the product to be worn with various types of shoes that are easily accessible in the market, such as tennis shoes, running shoes, or even comfortable casual shoes.

The picture below show the actual finished product. Some changes were made to the proposed design in the creation of this prototype. The attachment was created using a wing screw going through the insole, the brace and the shoe. The pressure sensor was created by adding a push button to the circuit of the light up shoes. This way, the only way that the shoes will light up when walking is if there is pressure on the heel.

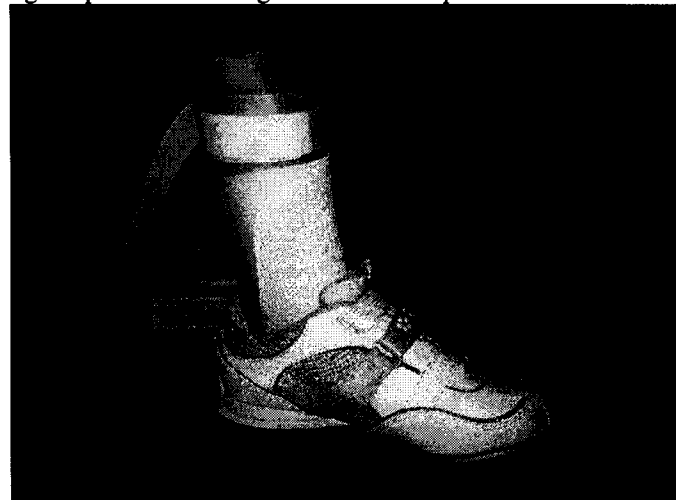


Figure 8: Final Product: This picture shows the final AFO product in use by the test subject.

V. Pilot Testing

The prototype was taken to the Sports Biomechanics Lab at the University of Tennessee and subjected to F-SCAN testing. The Tekscan F-Scan VersaTek System (12) is a foot pressure testing system that uses a sensor to determine regional distribution of pressure on the foot. The pictorial print out is used to determine “hot spots” of pressure. This is recorded during standing and gait.

A test subject was tested in a shoe without our brace to collect nominal values. This data was compared to data collected wearing the AFO.

Results

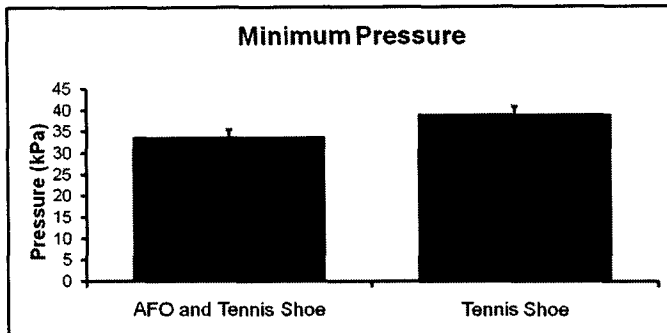


Figure 9. The minimum pressure experienced throughout the gait cycles was less when the patient was wearing the AFO and the tennis shoe than when wearing only the tennis shoe. Although not statistically significant, it is likely that a greater number of trials would have made the difference significant. (ANOVA: $F=3.53$, $df=1,17$, $P=.077$)

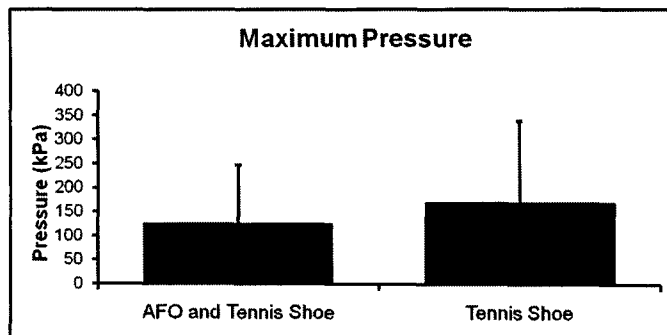


Figure 10. The maximum pressure experienced throughout the gait cycles was significantly less when the patient was wearing the AFO and the tennis shoe than when wearing only the tennis shoe. (ANOVA: $F=10.50$, $df=1,17$, $P=.0048$)

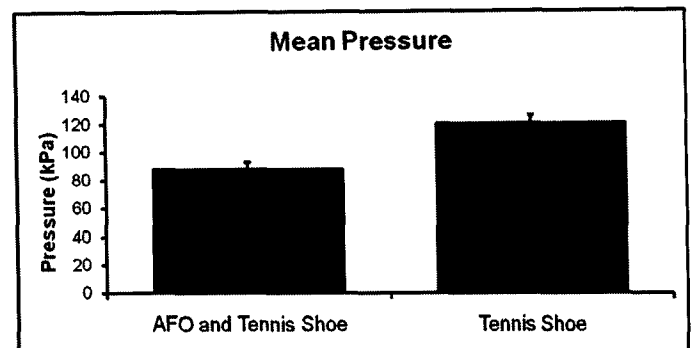


Figure 11. The mean pressure experienced throughout the gait cycles was significantly less when the patient was wearing the AFO and the tennis shoe than when she was wearing only the tennis shoe. (ANOVA: $F=15.58$, $df=1,17$, $P=.0010$)

As can be seen in Figure 9, the minimum pressure on the foot throughout the gait cycle was less when the patient was wearing the AFO combined with the tennis shoe than when the patient wore the tennis shoe alone. Likewise, Fig. 10 shows that the maximum pressure experienced was lower for the AFO and tennis shoe combined. Figure 11 also shows that the mean pressure experienced throughout the gait cycle was least for the AFO and tennis shoe combined. This data is statistically significant for the maximum force and mean force.



Figure 12. Pressure on foot when patient is wearing the AFO and the tennis shoe versus wearing the tennis shoe only. The foot with the AFO has no points of very high

pressure, which are seen in the other foot as bright red and yellow spots.

Discussion

Figures 9 through 11 demonstrate that the AFO helps decrease the pressure felt by the foot when the subject is walking. The statistically significant data for the maximum and mean pressure throughout the gait cycles imply that there is a tangible benefit when wearing the AFO. If a patient wears the AFO over a considerable period of time, this will likely result in reduced risks of injury to the foot and related muscles. More tests would likely have resulted in a statistically significant difference for the minimum pressure experienced, as well.

Furthermore, Fig. 12 demonstrates that the AFO better distributes the force load throughout the foot. The presence of hot spots, or bright red and yellow marks, on the image on the right shows that there are points of very high pressure when the patient wears a tennis shoe alone. The AFO eliminates these points of high pressure, which may again lead to decreased likelihood of injury to the foot and leg muscles. Figure 4 also demonstrates a better distribution of pressure throughout the foot when the patient wears the AFO and tennis shoe versus the tennis shoe alone.

The sources of error which may be present include the fact that the subject was tested with the AFO and tennis shoe on the left foot and with the tennis shoe alone on the right foot. This discrepancy may have thus been partly responsible for the statistical differences which were observed between the AFO and tennis shoe versus the tennis shoe alone. However, the same sensor and equipment was used for both sets of trials, eliminating some of the systematic error which may otherwise have been present.

VII. Conclusion

With the consideration that there are currently many available AFO designs on the market, a project was undertaken to design an AFO which is more amiable towards appeasing patient comfort. Through the use of patient contacts, background research, and actual product design and development, the design aspires to be an AFO which satisfies both the comfort and the product quality which patients need. A shoe incorporated with the AFO struts will allow for decrease in size and detachability will create a longer lasting product. Testing has quantified the biomechanical integrity of foot structure lost in current models. Pressure sensor will ensure proper usage.

VI. Acknowledgements

Grant support from the University of Tennessee Chancellor's Honors Program is gratefully acknowledged.

Thank you to Ossur as well for a donation of an AFO.

Thank you to the Machine Shop at the University of Tennessee in the Mechanical, Aerospace, and Biomedical Engineering Department.

Thank you to Ellie Jackson for her participation in testing of our device, and to the Sports Biomechanics Lab at the University of Tennessee, specifically Michael Wortley, for equipment and advice in the testing process.

REFERENCES

- 1 - Cincinnati Children's Hospital. "How to Care for Your AFO" <http://www.cincinnatichildrens.org/health/info/orthopaedics/home/ankle-foot-orthosis.htm>. Oct. 2007.
- 2 - Free Patents Online. www.freepatentsonline.com. Sept. 2007
- 3 - Patent Storm. www.patentstorm.us/patents. Sept. 2007
- 4 - AccessMedicine. "Current Diagnosis and Treatment in Orthopedics." www.accessmedicine.com. October 2007.
- 5 - Shoby Shoes. "Orthopedic Shoes for Special Needs Children." 2005. <http://www.shobyshoes.com/>
- 6 - Andrews, Michelle. "Lower limb and foot angle are related to stance phase knee adduction in normal subjects: A critical analysis of the reliability of gait analysis data." *Journal of Orthopaedic Research* Volume 14, Issue 2, Pages 289 – 295
- 7 - Westberry, David E. et al. "Impact of Ankle-Foot Orthoses on Static Foot Alignment in Children with Cerebral Palsy." *The Journal of Bone and Joint Surgery*. 2007;89:806-813.
- 8 - Phillips, Chandler Allen MD et al. *Human Factors Engineering*. John Wiley and Sons, Inc. New York. 2000. Pages 53-68.
- 9 - W. Vernon MD, *Spinal Cord Medicine: Principles and Practice*. 2003. Demos Publishing Inc.
- 10 - Nigg, Benno M. and Walter Herzog. *Biomechanics of the Musculoskeletal System*. 2nd ed. John Wiley and Sons.
- 11 - Woodhull, A.M. et al. "Alignment of the human body in standing." *European Journal of Applied Physiology*. 1985. York. 1999. Pages 208-209.
- 12 - Tekscan, Inc. "F-Scan VersaTek System." Boston, 2007. <http://www.tekscan.com/medical/system-fscan1.html>