Design of Patient Specific Ankle-Foot Orthotic Devices

Design Team

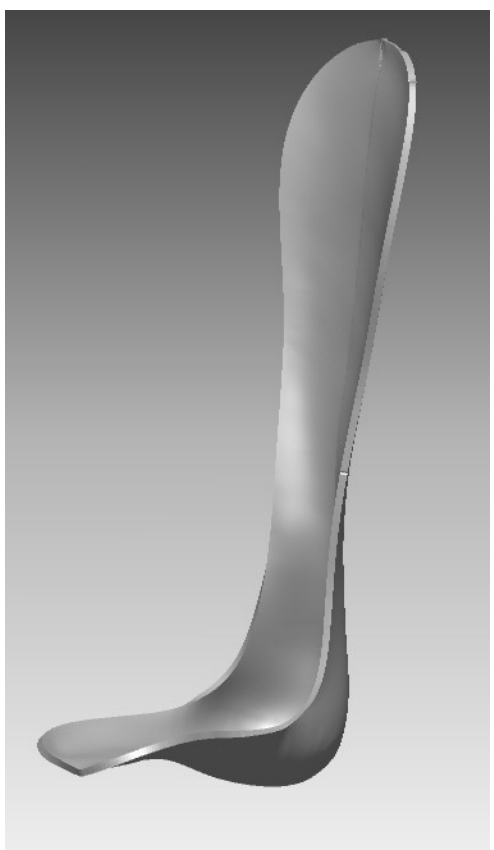
Alyssa Caddle, Kara Gilhooly, Lauren Govoni,
Mark Sivak, Seth Sivak

Design Advisor

Prof. Constantinos Mavroidis

Abstract

Developments in three-dimensional scanning have made it possible to get accurate 360º models of nearly anything with extreme accuracy. Manipulation of this data using computer aided design (CAD) software allows for input into rapid prototyping machines which quickly create a physical model. The non-invasive scanning technique makes this technology ideal for medical applications. Several different design concepts were considered as possible projects, however, the design of a patient specific ankle-foot orthotic (AFO) was chosen. This orthotic device will be used to help stabilize the ankle-foot region in patients with limited mobility, and more specifically drop foot. The purpose of this device is to match or exceed the comfort and effectiveness of a standard orthotic while being matched to the patient's specific needs and anatomy.



The Need for the Project

For a patient using an ankle-foot orthotic everyday, a proper fit is not only ideal; it is necessary.

Current ankle-foot orthotic devices are not created to fit specific patient anatomy. Most orthotics are built to fit a range of users, the wider the range the less likely it is to fit any patient well. The nature of this product means that comfort is a high priority. The patient will be using this orthotic every single day, so a proper fit is important; especially for children.

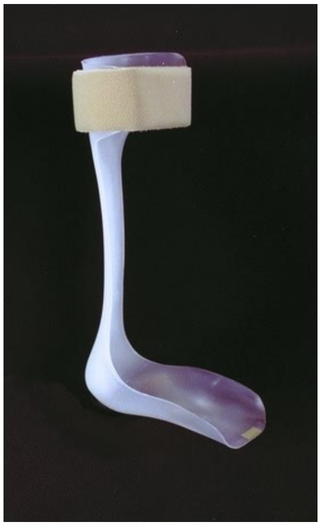
Ankle-foot orthotics are used as rehabilitation devices, so it is essential to be able to manipulate the stiffness and support based on the patient's needs. This is currently done in a very qualitative way: a licensed orthotist will shave or remove material until a satisfactory gait has been achieved. The unique ability of RP technology means that multiple iterations of an orthotic can be made with little turn around for the patient to test. Changes to physical dimensions are achievable using typical CAD software.

The Design Project Objectives and Requirements

The objectives of this project are to develop a process for utilizing 3D scanning and RP technology and then use the process to create a workable prototype AFO.

Design Objectives

This project has two main goals. The first is to design a process by which a three dimensional model can be developed and used to create a rapid prototyped part. The second is to develop a prototype ankle-foot orthotic that matches the support of a standard AFO but is designed for a specific patient to maximize comfort. (Rep. 5.1)



Standard AliMed AFO

Design Requirements

The prototype AFO will be compared to a standard posterior leaf spring AFO provided by AliMed. The prototype AFO should have comparable physical characteristics to the standard AFO; most importantly it should have a similar weight (117g). During normal gait the prototype should be able to flex up to 20° in dorsiflexion and 7° in plantarflexion. Gait analysis of the two AFOs should be comparable, specifically in postural-sway, and stride properties. The stride properties considered will be the walking velocity, length, width and acceleration. Finally and most importantly the prototype AFO should be more comfortable for the patient, based on a patient survey.

NO PAGINATE, Department will do it

Design Concepts Considered

Five concepts were developed and through analysis with experts the Patient Specific AFO was chosen.

The project initially started with a very broad topic. The idea was to research the use of rapid prototyping in the medical field and develop several concepts that would utilize the unique abilities of RP technology and three-dimensional scanning. The research was split into five main areas including: surgery, dentistry, rehabilitation and orthopedics, medical modeling and prosthetics. This research included general background research, patent searches and interviews with subject matter experts. From this research five concepts were developed. (Rep 2, Rep 4)

The first concept was the design of a custom fitting socket for amputees. This socket would be designed and built for the specific patient. By creating this socket the comfort of the prosthetic would be significantly increased and it would eliminate the need for additional padding. (Rep 4.2.1)

The second concept considered was the creation of a feedback surgical trainer. This device would be created based on the specific patient or specific surgery to be performed. Sensors would be imbedded at critical locations to judge the accuracy and optimal procedure for complex surgeries. This tool would be used for surgical planning and training. (Rep 4.2.2)

Another concept developed was a custom made outer covering for a prosthetic. The goal of this design would be to scan the patient's alternate limb and use software to mirror the data. A custom mold would be created using RP and then a latex like plastic covering would be created. (Rep 4.2.3)

The concept of a multilayer surgical planner was also considered. This tool would be created with patient x-ray and MRI data. The model would have multiple layers to show the anatomy of a certain body part in full. This device would be used to help teach procedures and for surgical planning. (Rep 4.2.4)

The final concept, which was later chosen through extensive interviews and in-depth analysis, is the patient specific orthotic. The initial concept was for any orthotic ranging from splints and casts to knee and ankle orthotics. The decision to create an ankle-foot orthotic was made with help from Dr. Paolo Bonato. (Rep 4.2.5)

Recommended Design Concept

The final concept design improves comfort over the standard AFO while giving comparable support. The process to create this AFO is improved over the current technique.

Design Description

The process involves many different steps to go from the collection of the patient's data to the actual manufacture of the AFO. The first step is to collect the 3D data for the foot. This was done by taking multiple shots of the sides and back of the leg in conjunction with information for the bottom of the foot. A model is created by meshing the different images together in the RapidForm software. This model is then built in the RP machine. The picture at the left shows the first prototype as it was built in the RP machine. (Rep. 5.2)

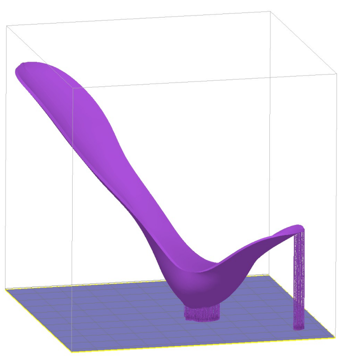
The initial prototype proved that the process was valid. The next goal was to create the prototype that could be usable as an AFO. This meant that a considerable amount of analytical and experimental analysis would be necessary to make key decisions about material and construction.

First Prototype on Build Platform

Analytical Investigations

Analysis of normal human gait was done to find ground reaction forces and angle of deflection during a typical male gait cycle. This data was then used to gather preliminary information for the specifications necessary for the prototype.

The standard prototype that is used as a benchmark for the project was analyzed to find the material properties. The material of the AFO is extremely important because of the stiffness characteristics and the active flexure required of this device. This analysis was done through the use of the Instron machine available at Northeastern and a detailed analysis using knowledge of mechanics of materials.



Final Prototype on Build Platform

Experimental Investigations

The biomechanical characteristics of the patient are very important to the design of the AFO. Thorough testing of stride and standing stability was completed. This testing was carried out in both the Physical Therapy Lab at Northeastern and at the Motion Analysis Lab at Spaulding Rehabilitation Hospital.

The data collected at these sites will be used to further the analysis of the design and will later be used to compare the prototype AFO to the standard AFO. The image at the left shows a patient during testing at Spaulding Rehabilitation Hospital.

Biomechanics Testing at Spaulding Rehabilitation Hospital

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Comfort Comparison Test showing the standard (left) and the final prototype (right)

Key Advantages of Recommended Concept

The advantages of the recommended concept are two-fold in that both the process of AFO personalization and the AFO itself will be improved (as compared to the standard). In regards to the process, it will no longer be necessary for a patient to make multiple appointments with an orthotist. Additionally, the orthotist should not have to significantly alter the orthotic once it is built.

With respect to the prototyped AFO, this concept will allow for similar mechanical properties while improving comfort. An added benefit to improving comfort is that the patient will be able to maintain the most normal gait pattern possible. Another benefit to this prototype is that the stiffness could be altered through a change in resin, should that capability be required.

Financial Issues

Initial costs would be significant due to capital equipment, however high volume use over time would drive down the cost of an individual AFO.

During development several prototypes were created using the RP machine available at Northeastern. However, for the final prototype it was necessary to have it made at an external facility. With commercialization, it would not be possible to outsource the fabrication.

The financial concern for this procedure would be absorbing the large initial cost. The RP machine and the vision system including the camera and software would be very expensive. Once the system is in place, the customized AFO's will become cost effective. The cost of resin required to build an individual prototype is very small, and a streamlined process would result in minimal necessary labor.

Recommended Improvements

To improve the current process, more research will be completed to refine the data collection process.

The collection of the three-dimensional data is the essential step in the process. Currently, the process is still being developed. It is clear that a custom apparatus for the 3D camera would facilitate higher quality data and improved patient comfort. With improvements to this step in the process it would make creation of the CAD model much more efficient.