Parametric Modeling and Rapid Prototyping of a Low-Cost Hinged Ankle-Foot Orthosis

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Abstract—**Hinged Ankle–Foot Orthoses (AFOs) are commonly prescribed to manage conditions such as drop foot and hypertonicity by allowing controlled ankle motion that facilitates dorsiflexion during gait. However, obtaining a custom AFO through an orthotic clinic is costly, creating a financial barrier for many patients. There is a clear need for a more affordable and accessible device. This work focuses on the development of a fully parameterized AFO design that can be 3D printed and customized using a small set of easily measured lower-limb parameters, enabling people to access this device at low cost. The initial model was developed in Fusion 360 using leg circumference and foot measurements collected from a potential user. The structural components of the model, shell thickness, and alignment can be adjusted to accommodate variations in anatomy without requiring manual 3D design modifications. In addition, hinge components from an off-the-shelf knee brace were repurposed to function as the AFO's ankle joint. An initial prototype has been fabricated using PLA, with planned fabrication in PETG and polypropylene to evaluate material-dependent performance. The iterative testing conducted thus far demonstrates that a 3D printed hinged AFO can improve gait patterns. Future improvements on the calf shell is necessary to optimize the AFO. Ultimately, this design will be released through an open-source product database to promote widespread adoption and allow others to refine the design.**

Keywords—Personalized medicine, hinged AFO, assistive devices, gait analysis, hypertonicity, 3D printing

I. INTRODUCTION

In 2016 a study from the Global Burden of Disease estimated that approximately 0.78-1.16 million people got a spinal cord injury (SCI) in that year alone, and that has only increased over the past decade [1]. This is a serious issue because the spinal cord is the main segway between the brain and the body for sensory and motor information. In many cases, body parts below a spinal cord lesion are also affected [2]. To address these challenges, physical therapists recommend an appropriate orthosis, "an individually designed or customized device, which is applied to the external part of the body to provide support and protection for that particular area of the body" [3]. An ankle-foot orthosis (AFO) is an example of one which is often used to support the weak muscles around the ankle joint and improve gait patterns [1].

The challenge with receiving an orthosis is that accessing a clinic is often not feasible for individuals who are uninsured or underinsured, as these devices typically cost thousands of dollars. In addition, expenses such as transportation and the potential loss of income when a family member must take time off work to attend evaluation appointments. An alternative option is to purchase an off-the-shelf device; however, these are typically available only in general sizes such as small, medium, and large, which may not fit the user well or support their needs.

The EGR 2210 Engineering Design for Service course presents opportunities for students to utilize their skills to address the need of an actual person in the community, which is where this project began. The Health Outreach Program of Elon (H.O.P.E. Clinic), a pro bono clinic managed and operated by Elon Doctor of Physical Therapy (PT) students, presented the case of a Spanish-speaking male whose life was altered completely in 2019. He was diagnosed with transverse myelitis, which led to a total loss of sensation from the waist down and limited motor control of his lower extremities that prevented him from walking without assistance. While he was still at the hospital, he was terminated by his employer, which left him uninsured. Given that he also comes from a low income background, he was unable to receive the care he requires. In 2023, he was referred to the H.O.P.E. clinic to receive physical therapy services at the Dream Center under the supervision of Dr. Crystal Ramsey, Director of the H.O.P.E. Clinic and Associate Professor of PT. During the PT sessions, it was recognized by Dr. Ramsey that his elevated and fluctuating muscle tone (hypertonicity) in his feet contributed to the rigid plantarflexed ankle positioning that affected his gait cycle. Additionally, it was observed that from an anterior view his right leg was slightly weaker than his left. The prescribed solution was an AFO, but since the client was unable to move his feet into a neutral position and has fluctuating tone, a hinged AFO seemed appropriate given that it allows controlled ankle motion and support at various angles.

In the field of orthotics, the standard process to create an AFO begins with taking a cast of the patient's lower limbs. Once it is ready, the cast is removed from the patient's leg and filled with liquid plaster to form a positive model. The Orthotist then modifies the positive model by adding or removing plaster as needed. Next, thermoplastic vacuum forming is conducted over the positive model with polypropylene [4].

However, within the last decade orthotic production has moved towards 3D printing orthotics to decrease labor intensity, costs, and waiting times [4]. Several studies examine the geometric characteristics of the AFO; for example, one investigation analyzed the trimline cuts along the dorsal and medial sides of the AFO [5]. Additionally, stress concentrations and load responses have also been researched. One study investigated the effect of outer shell thickness on AFO structural integrity, determining the failure load and identifying the corresponding fracture location [6]. Furthermore, several studies investigate material properties, such as polylactic acid (PLA) filament, to determine its suitability as a material choice for AFO fabrication [7]. As a final performance evaluation, one study conducted a durability test in which the AFO was subjected to a high number of cyclic loading trials to assess its reliability over time [8].

There is a gap in knowledge and research on the design process and performance outcomes of a 3D printed hinged AFO. Most research studies focus on a solid AFO, and the few research studies evaluating hinged AFOs, design them using traditional methods. The primary research question addressed in this work is: *What is an effective approach for designing and fabricating a 3D printed hinged AFO based on patient measurements rather than casting?* This research aims to generate a fully parameterized 3D printed hinged AFO integrated with parts from an off-the-shelf device. Some issues from AFOs that will be considered for this design include [9]:

- 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 the AFO

The final design will serve as a model for future replication for other patients with similar conditions. The 3D printed CAD components will be open-sourced, along with a bill of materials and a detailed instruction guide for others to follow.

II. PROCEDUCRE

A. *Off-The-Shelf Purchases*

Design work began with preliminary tests of off-the-shelf products to deepen understanding of the client's needs. Two Dorsiflexion Assist Drop Foot Braces (Fit Geno, Shenzhen, China) were selected to test on the client given that drop foot is a similar condition to the client's hypertonicity. A promising feature of the braces was an adjustable dial meant to change the angle of dorsiflexion to achieve the support needed, as shown in Fig. 1a. When the client tried it on, it was observed that it helped to limit his plantarflexion, but it lacked the structural rigidity necessary to control his ankle throughout his gait. Another issue was that the strap going around the ankle region would loosen and slip over time. Dr. Ramsey's observations demonstrated that there is a need for a more robust device that similarly has the ability to limit plantarflexion.

The more robust device would be a hinged AFO that would require a hinge joint. Through further off-the-shelf exploration, it was determined that an ACL brace like the one showed in Fig. 1b, could be sourced for locking hinges. The brace was purchased for $98 and modified by cutting it with a bandsaw to isolate the hinge while preserving two attached links that would be attached to the remaining components of the hinged AFO (calf shell and footplate).


(a) (b)

Fig. 1. (a) Drop Foot Brace, (b) ACL Brace

B. *Designing*

The designed parts of the hinged AFO consist of the calf shell and the footplate. The calf shell was designed by making ellipse cross-sections to approximate the major regions along the calf. Table 1 below details the measurements taken for the design. The footplate was made by splitting into three different sections which includes the heel, the arch of the feet, and the forefoot that extends to the ball of the foot. The measurements taken for each section are shown in Table 2. As the parameter measurements from both the calf shell and footplate are changed, the design will adjust accordingly.

TABLE I. Calf Shell Parameters

Parameter Name	Anatomical Feature	Measurement (cm)
CP1	Circumference below knee	33.0
CP2	Circumference of bulkiest part of gastrocnemius muscle	34.3
CP3	Circumference of beginning of Achilles tendon	30.5
CP4	Circumference of middle of Achilles tendon	26.7
DCP2	Vertical distance from CP1 to CP2	5.10
DCP3	Vertical distance from CP1 to CP3	12.7
DCP4	Vertical distance from CP1 to CP4	21.6

TABLE II. Footplate Parameters

Parameter Name	Anatomical Feature	Measurement (cm)
Heel Width	Medial to Lateral (width) heel distance	7.60
Bottom Heel Depth	Anterior to Posterior (end to end) distance of plantar heel	8.90
Protrusion Depth	Anterior to Posterior (end to end) distance of heel to calcaneus tuberosity	10.2
Top Heel Depth	Anterior to Posterior (end to end) distance of superior heel	9.50
BTP	Vertical distance of plantar heel to calcaneus tuberosity	2.50
PTT	Vertical distance of calcaneus tuberosity to superior heel	2.50
Arch Span	Horizontal distance across Medial arch of foot	11.4
Arch Height	Vertical distance of highest point of Medial arch of foot	1.00
BallofFoot Width	Medial to Lateral (width) distance across metatarsals	10.2
BallofFoot Length	Anterior to posterior (end to end) distance across metatarsals	3.80

Aside from the parameters, there are additional features included in both the calf shell and footplate to increase functionality. Slots were added on both ends of the heel section of the footplate to allow the links from the hinge joint to pass through and be firmly secured, as shown in Fig. 2a. Using the research conducted from the literature, a vertical ellipse trimline was incorporated into the posterior section of the calf shell design, shown in Fig. 2b. This was done to distribute the stress concentrations more uniformly across the calf shell and create more flexibility.

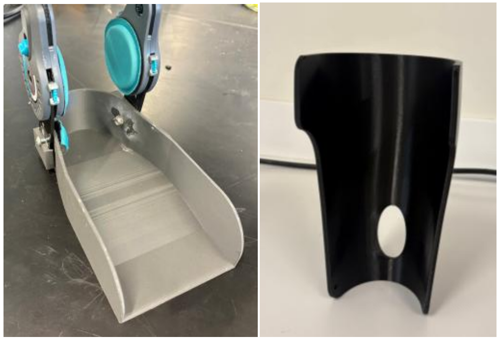
(a) (b)

Fig. 2. (a) Footplate (b) Calf shell

C. Rapid Prototyping

Both the calf shell and footplate were printed on the Prusa CORE One 3D printer (Prusa Research, Prague, Czech Republic). The parts were sliced and prepared for printing using the integrated slicing tools in 3DPrinterOS (3D Control Systems, New York, NY), with the main printing parameters shown in Table 3. The total printing time was 36 hours with 663.33 grams of generic PLA filament used, costing about $10 to print.

TABLE III. 3D Printer settings

Setting Type	Setting specification
Layer Height	0.2 mm
Perimeters	3
Infill Density	35%
Infill Pattern	Gyroid
Support Pattern	Tree

D. Final Design Assembly

Once all the parts had been printed everything began to be assembled. The links were attached to the calf shell and footplate using a 3/16-inch by 24 bolt, two washers in between the materials, and a nylon hex nut at the end. Padding that were on the ACL braces were repurposed to cover the hex nuts. A strap was then attached around the calf shell to keep it secure. For the footplate there were no straps used since the hinged AFO is meant to be used inside a shoe. The final design is shown in Fig. 3a along with it being put on the client in Fig. 3b.


(a) (b)

Fig. 3. (a) Final Design (b) Final Design on Client

E. Testing

The testing with the client was conducted at the Francis Center at Elon University, which involved using gait analysis. In a controlled environment, the client began walking slowly and over a short distance with the hinged AFO to begin getting comfortable. After that short session, the client was provided time to rest before conducting the 10-meter walk test. The 10-meter walk test consists of a 2-meter warmup phase, followed by 6 meters of measured walking, and a final 2-meter cooldown phase. The 10-meter walk test was conducted twice to compare the client’s performance with and without the hinged AFO.

III. RESULTS AND DISCUSSION

A. Design Evaluation

The measurement parameters that were selected for the construction of the AFO have proven to be effective in fitting smoothly to the anatomy of the client. Some measurements were changed between the first and final test of the device, such as the heel width from the footplate and one of the circumferences of the lower calf. Because the CAD models were parameterized, the overall design accurately adjusted automatically when these changes were made. This successful demonstration of the CAD parameterization supports that a simpler method for achieving anatomical accuracy is possible, especially compared to casting, which may not be accessible to many individuals and can be challenging to perform accurately.

Several common concerns in AFOs were addressed in this design. It included proper arch support, padding in the main areas of concern, was an appropriate overall size, includes user-friendly straps that secure the device and heel placement. The main issue this research was able to address was the cost of a hinged AFO. Compared to the thousands of dollars that an AFO can cost, both hinged AFOs were made for approximately $230. Although the cost could be further reduced by manufacturing the hinge joint instead of purchasing it, the hinged AFO developed is still significantly less expensive than obtaining one through a clinic. These results demonstrate that it is possible to obtain a more cost-effective hinged AFO.

PLA was the material choice for 3D printing the calf shell and the footplate, as it has been proven reliable for solid AFOs [6]. However, in this hinged AFO design, additional forces are introduced by the hinge links, which apply localized loads to the calf shell at the jointed section. After initial testing on the client, signs of cracking began to appear, as the straps further constrained the calf shell, increasing stress concentrations and ultimately leading to failure. The root cause of this issue is that the distal end of the calf shell needs to bend slightly, which cannot be avoided. Therefore, a reasonable solution is to transition to a different material, such as PETG, given that it has similar properties to PLA but it is a more ductile material. Another option is using TPU 95A, due to its increased flexibility and resistance to cyclic bending which could allow the AFO to be subjected to various loads and not fail. The use of PLA was not an issue for the footplate because it experiences similar loading to that of a solid AFO, and the hinge forces are transferred through the slotted links without introducing significant bending or additional stress concentrations.

B. Gait Analysis

By measuring the time it took the client to walk the 6 meters section from the 10-meter walk test, gait speed was determined for the trials performed with and without the hinged AFOs. The gait speed with and without the AFOs was 0.177 m/s and 0.170 m/s respectively. Although the gait speed of the client with the AFO was faster than without the AFO, this was not a significant difference. However, there were some noticeable improvements made that were observed by Dr. Ramsey. When the client used the AFOs, there was no toe drag throughout his gait which helped prolong the distance he could walk. This contributed to his step through movement, meaning that the foot steps past the other foot which looks like a more normal walking pattern. On the other hand, without the AFOs there was noticeable toe drag on his left foot, which is weaker. It takes more energy for the client to overcome lifting his foot up when it drags which renders him unable to walk as far. Finally, based on the gait speed measured he is very close to being able to walk normally in his home, which would be a significant achievement.

IV. Conclusion

This work addressed a critical gap in the design and of a hinged AFO by developing a parametric modeling approach that simplifies customization. The final prototype fit the client, addressed common design concerns, and demonstrated functional improvements in gait. The test highlighted the strength of the footplate and weakness of the calf shell, while providing insight into the improvements that could be made. Overall, this represents a meaningful step toward increasing accessibility for individuals who may not have access to traditional orthotic services so the progress that has been made will be uploaded to an open-source technology website.

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