Development of a Custom 3D Printed Plantarflexion Stop for Foot Drop

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Abstract

Foot drop, characterized by the inability to dorsiflex the ankle during gait, can stem from neurologic, traumatic, or compressive etiologies. Management often focuses on mitigating fall risk and restoring functional mobility, especially in progressive cases like Charcot-Marie-Tooth disease where reversal is unlikely. Ankle-Foot Orthoses (AFOs) are commonly prescribed to support dorsiflexion and prevent plantarflexion-related gait deviations. The Hermes brace by Icarus Medical Innovations offers a unique solution through its adjustable dorsiflexion tension system, customizable via a user-operated dial. Despite its innovations, the Hermes lacks a plantarflexion stop, limiting its efficacy for patients who exhibit excessive or uncontrolled plantarflexion. This study aimed to address this limitation by designing a modular plantarflexion stop compatible with the Hermes brace. Design criteria were established based on anatomical torque data, user comfort, brace weight constraints, and spatial compatibility with the existing frame. An iterative prototyping process was employed, culminating in a fixed mechanical stop consisting of top and bottom components that collide to limit ankle rotation. Finite Element Analysis (FEA) and material testing demonstrated that a Nylon 6/6 prototype met the required strength-to-weight ratio, yielding a safety factor of 2.2 while adding only 0.11 oz to the device. The proposed design provides sufficient plantarflexion restriction without compromising the lightweight, low-profile nature of the Hermes brace. While effective, the prototype requires further refinement to minimize potential pinch points and improve user safety. Compared to existing AFOs, functional electrical stimulation, and surgical interventions, the Hermes, with its now expandable modular features, offers a mechanically simple, scalable, and non-invasive solution suitable for a wide range of foot drop etiologies. Future development will focus on making the plantarflexion stop adjustable for customizable gait control and validating performance through torque testing and Failure Mode and Effects Analysis (FMEA).

Keywords: Assistive Technology, Orthotic Design, User-Centered Engineering, Foot Drop

Introduction

Foot drop is a disorder characterized by the inability to lift the forefoot due to weakness or paralysis of the dorsiflexors, primarily the tibialis anterior. This condition leads to the affected foot dragging during the swing phase of the gait cycle, causing the patient to lift their knee higher to compensate for the dropped foot. The condition may stem from a multitude of disorders or injuries. These include compressive disorders, such as peroneal nerve entrapment, traumatic injuries, neurologic disorders, such as stroke or multiple sclerosis, compartment syndrome, or other iatrogenic causes like surgical damage to nerves. In foot drop related to nerve compression or trauma, recovery may be possible with proper rehabilitation. However, for those suffering from progressive neurological disorders such as Charcot-Marie Tooth (CMT), the condition will typically worsen over time due to the disease's ongoing degeneration of the nerves responsible for muscle control (*Charcot-Marie-Tooth Disease | National Institute of Neurological Disorders and Stroke*, n.d.)

This poses a challenge in the management of foot drop, particularly in incurable diseases. While the condition is not treatable, it is important to manage the symptoms, focusing on preventing complications presented by falls and immobility. The risks of falls due to irregular gait pattern is a major concern, as patients are at an increased risk of tripping because of their inability to properly lift the forefoot while walking. This highlights the necessity of timely intervention to reduce the risk of falls and maintain patient mobility. Therefore, it is essential to explore possible solutions for managing foot drop in progressive and nonprogressive cases.

Clinicians evaluate foot drop through a range of gait testing protocols, assessing dorsiflexion weakness, muscle atrophy, and compensatory gait mechanisms. Gait testing is a critical component in determining the level of impairment and in guiding the decision-making process on appropriate intervention. These may include surgery, assistive devices, or therapeutic approaches. A physician will begin the diagnostic process by performing a comprehensive physical, which begins with musculoskeletal testing to pinpoint weakness in any of the muscle groups in the lower extremities.

Beyond observational assessment through the physical exam, standardized protocols to assess irregular gait associated with foot drop often incorporate biomedical analysis tools such as, 3D motion capture, force plates, and electromyography (EMG). These tools provide quantitative data on gait parameters, including stride length, walking velocity, ground reaction forces, knee flexion, and ankle dorsiflexion angle. For example, EMG can be targeted to track the tibialis anterior muscle, providing insight into the muscle's activity by analyzing the motor unit potential for amplitude, firing rates, and recruitment patterns (Nori & Stretanski, 2024). However, the use of these precise technologies is limited to specialized settings and require significant time commitments, cost, and expertise to operate.

In addition to these methods specific to specialized gait labs, clinicians and researchers also rely on non-instrumental assessments, such as the timed up and go (TUG) or 10 meter walk test (de Wit et al., 2004). These tests and others offer insight into a patient's functional mobility and are reliable measures in settings where advanced gait analysis equipment is unavailable.

Foot drop is typically treated using a combination of therapeutic and assistive solutions aimed at restoring a normal gait pattern. Depending on the cause and severity, treatment options vary from therapeutic approaches, electrical stimulation, to AFOs. Traditionally, AFOs have been prescribed to offer ankle support and facilitate foot clearance during the swing phase of the gait cycle. These devices are effective at stabilizing the ankle and preventing excessive plantarflexion, combatting foot dragging while walking. AFOs come in a variety of designs from rigid polypropylene braces to more advanced carbon fiber and 3D printed models, all offering different degrees of support and mobility

These devices are often evaluated using gait testing protocols to assess their impact on walking mechanics. The efficacy of an AFO in improving a patient's gait depends on its ability to restore the ankle's range of motion and improve irregular gait to a more normal cycle. AFOs accomplish this by reducing the need for compensatory motions, such as raising the knee higher to avoid foot dragging, which leads to fatigue and unnecessary strain on the joints and muscles. The incorporation of new materials, production methods, and dynamic features, have improved comfort, energy efficiency, and walking kinematics, making AFOs a key component in managing chronic foot drop.

This report focuses on the Hermes brace by Icarus Medical Innovations. The AFO is designed to assist individuals with dorsiflexor weakness. Unlike traditional AFOs, the Hermes features an adjustable tensioning system that allows users to tune dorsiflexion support up to 100 in-lb. of torque with a dial, providing tailored assistance depending on activity. The orthotic weighs under 12 ounces, its 3D-printed, low-profile frame is custom fitted using Icarus' scan-to-print technology, ensuring patient comfort and compatibility with standard footwear (*Hermes*, n.d.).

While the Hermes effectively supports dorsiflexion, it does not currently include a strict plantarflexion stop to limit excessive downward movement of the foot. The absence of this component may reduce the brace's effectiveness for users who exhibit uncontrolled plantarflexion. A plantarflexion stop is critical for preventing hyperflexion and improving knee stability during early stance by controlling the extent of foot lowering. Without it, users may be more prone to compensatory gait patterns, such as knee hyperextension or circumduction, which can lead to joint pain, fatigue, or long-term musculoskeletal issues. The goal of this research was to incorporate an adjustable plantarflexion stop to enhance functional alignment and improve overall gait biomechanics for users needing more rigid sagittal plane control, especially in less uniform walking environments.

Results

Design Specifications

To begin, specifications had to be set to guide the design process. Based on discussions with Icarus engineers and the existing Hermes brace. A list of guidelines to base our specifications on was created. The addition must maintain the low profile of the existing design, withstand a maximal plantarflexion moment, not add significant weight, and not impede patient comfort. Each of these were then quantified to better restrict the potential prototypes. To avoid disrupting the low profile of the brace, the decision was made to remain within the existing length of the brace while extending a maximum of 0.5 inches outside the original width to either side of the shank.

About the ankle joint, the average plantarflexion moment is approximately 169.4 Nm (Baxter & Piazza, 2014). Thus, to create a physical stop which could withstand this moment, required dimensions of a Nylon beam to prevent bending were calculated using the following equations:

$$\sigma_{max} = \frac{-y \cdot M_z}{I_z} \qquad [\#1]$$

$$I_z = \frac{bh^3}{12} \qquad [\#2]$$

Equation (1) of (*Bending Stress - an Overview | ScienceDirect Topics*, n.d.) source calculates the maximum yield stress (σ_{max}), which depends on the plantarflexion moment (M_z), the distance from the neutral axis (y), and moment of inertia (I_z) about the rotation of the footplate. Equation (2) of (*Engineering at Alberta Courses» Rectangular Moment of Inertia*, n.d.) calculates I_z, which depends on the width of the beam (b) and the height of the beam (h).
Based on Equation 2, height was deemed the most important dimension to calculate as moment of inertia (I_z) ~ 1/h^3, and therefore the most important dimension to determine. For this calculation, the width of the beam is assumed to be a minimum of 0.19 inches, the distance between the two interior faces of the hinge, measured across the foot plate. Additionally, assuming the brace and the stop are made of the same material, maximum yield strength was set to the lowest yield strength of Nylon found, 25 MPa. Finally, distance y for a rectangular beam is ½ h. With these values, a minimum beam height of 3.61 inches was determined.

To avoid any significant increase in weight no additions were to exceed 20% of the existing brace weight of 9 ounces or 1.8 ounces. Finally, maintaining patient comfort while not quantifiable during prototyping was considered when drawing each of the possible solutions and played into the goal of remaining within the original low profile of the brace which has already been proven to be comfortable for patients.

Prototyping

To address the Hermes brace's lack of plantarflexion restriction, an iterative prototyping process was undertaken to design and integrate a modular plantarflexion stop based on the design specifications outlined above. Initial concepts explored multiple locking mechanisms and adjustability strategies (Appendix A), including adjustable tensioning systems, rotational locks, and hydraulic rods. These early design sketches prioritized mechanical feasibility but required refinement for size, comfort, and strength compatibility with the existing brace.

The initial prototype (Figure 1) incorporated a dial locking mechanism inspired by the existing dial lock used in the Hermes' existing tensioning mechanism. These dial locks were to be placed on each hinge of the brace to provide even restriction across the affected ankle. Due to the 3D-printed nature of the brace, bending in the plastic necessitated all prototype mechanisms are present on both sides of the shank and footplate.

However, this design demonstrated limited structural integrity under loads when simulated in Nylon 6/6 or Nylon 12, as it did not meet the height requirement established in the design specification.

Through redesigning and testing, a final prototype (Figure 2) was produced featuring a compact form factor compatible with the Hermes frame. The bottom support, posterior to the hinge has a height of 1.5 inches. However, connected to the foot plate, its overall height is 3.8 inches, exceeding the height requirement. Additionally, this version emphasized simplicity with no moving parts, making it easily manufacturable and clear for patient use. The final prototype can be characterized by the top and bottom supports that collide to stop ankle rotation.

Finite Element Analysis (FEA) and material testing guided material selection for the final design based on a list of readily available materials from Icarus. Based on these tests, Nylon 6/6 was chosen over steel and Nylon 12 due to its balance between weight and strength. As shown in Table 1, Nylon 6/6 yielded a safety factor of 2.2 in the final design with only 0.11 oz of added weight (~1% of total brace weight), compared to the steel prototype's 0.806 oz. Although steel offered a higher safety factor, its increased weight posed a trade-off in user comfort and assumed compliance. The Nylon 12 design, while slightly lighter, did not meet minimum durability thresholds with a safety factor of 1.3.

The final prototype demonstrated superior performance, offering sufficient plantarflexion restriction at the specified torque with minimal additional weight and a safety factor above 2. The integration of this hard stop addresses a limitation of the Hermes brace, reducing the risk of hyperflexion and enhancing stability.

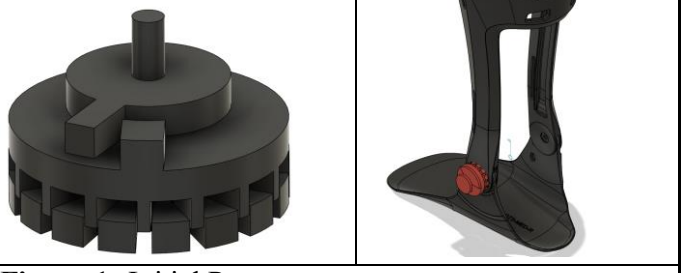

Figure 1: Initial Prototype

Figure 2: Final Prototype

Table 1: Calculated Safety Factors and Weights

Original Hermes Weight (oz): 9				
	Minimum Safety Factor		Added Weight (oz)	
Material	*Initial*	*Final*	*Initial*	*Final*
Steel	2.4	6.4	4.9	0.80
Nylon 6/6	0.80	2.2	0.70	0.11
Nylon 12	0.70	1.3	0.63	0.10

Discussion

Key Findings

An iterative prototyping process was implemented to design an effective plantarflexion stop that integrates with the Hermes design and meets all design specifications. Experimentation with multiple prototypes led to the development of a final design featuring top and bottom supports integrated into the orthotic's shank and footplate, respectively, allowing the two supports to connect and restrict rotation at a desired angle. FEA analysis and material testing proved the prototype would withstand deformation under normal walking torque and that Nylon 6/6 would be the ideal material for production.

Nylon 6/6 was found to be the most suitable material due to its safety factor (2.2) and light weight (0.11 oz). The Nylon is also a well-priced, easily accessible, and 3D printable material that is already in use within Icarus manufacturing, making it an ideal source. The simple design means it can be easily integrated into the preexisting Hermes orthotic.

Limitations

While the project focused on design functionality, further modifications will need to be made to the prototype before manufacturing and market circulation. The current design has a higher than acceptable chance of pinching the wearer. The collision of the top and bottom supports can cause the potential pinching of a user's pants or even skin. Modifications such as rounding edges or enclosing the supports can be made to reduce pinching, but these changes will require additional design prototyping.

Comparison of Existing Solutions

The approach to treatment of foot drop depends on patient etiology. Based on evaluation and diagnostic findings, there are many ways to treat or manage the condition.

Surgical

A surgical approach is often taken instead of more conservative management in trauma and nerve compression cases. In trauma cases foot drop usually stems from nerve damage or transection. In these situations, nerve reconstruction must take place promptly to ensure complete repair. In nerve compression cases the treatment may include necrolysis and nerve decompression. In some severe cases a nerve transfer may also be performed depending on the extent of injury to the compressed nerve (Nori & Stretanski, 2024).

Bracing

AFOs are prescribed to prevent excessive plantar flexion due to the weakness of the dorsiflexors in foot drop. Patient education is important to ensure the user applies the brace properly during their everyday activities to avoid injury and offer the best results. AFOs

Plastic AFOS are made of thermoplastics like polypropylene to allow for custom casting of the patient's lower extremities. They are the most widely used AFOs due to their low cost and comfort. Three main types of PAFOs to be discussed are solid AFOs, posterior leaf spring orthosis, and hinged AFOs

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The purpose of a solid AFO (SAFO) is to completely limit the ankle joint movement in foot drop patients. A posterior leaf spring orthosis (PLSO) is similar to a SAFO with the addition of leaf shaped corrugation near the ankle (Choo & Chang, 2021). These corrugations strengthen the most mobile part of the ankle that receives repeated loading. These creases act as a spring that allows for slight dorsiflexion during the gait cycle and may have a marginal effect on the toe-off. This type of PAFO is suited to more active patients with better balance than those who use SAFOs. Hinged AFOs (HAFOs) allow greater ankle mobility than SAFOs and PLSOs but still enact movement restrictions to a certain degree. These braces, rather than being one continuous shell, are created from two pieces, the shank and foot shell (Choo & Chang, 2021). These braces allow a degree of dorsiflexion due to their hinged construction which helps patients to navigate uneven or inclined terrain. In clinical studies it has been shown that SAFOs have a significant negative effect on stride length and speed when compared to PLSOs and HAFOs (Lewallen et al., 2010).

Carbon Fiber

Carbon Fiber AFOs (CFAFOs) are the most recent update to the standard of care in foot drop orthotics. Their carbon fiber construction makes them lighter, stiffer, and increases tensile strength when compared to traditional plastic or metal braces. These properties make CFAFOs more comfortable for long-term wear than other bracing options. Their composite material holds spring-like properties, which take over ankle work to help reduce energy cost. They can also improve walking speed by assisting with forward propulsion as the energy stored during the stance phase is released at toe-off (Bregman et al., 2012). Clinical studies have also shown significant improvements in ankle range of motion and other key parameters when using CFAFOs compared to walking barefoot. These improvements include better ankle angle at contact, range of motion during push-off, timing of maximum dorsiflexion, and velocity at toe-off (Desloovere et al., 2006). Despite these improvements, CFAFOs are not prevalent due to their high cost. This limits their accessibility, especially in healthcare systems where insurance may not cover them.

Functional Electrical Stimulation (FES)

FES is a valid approach for patients experiencing foot drop who have intact peripheral nerve pathways. This means it is not a valid solution for individuals with nerve damage. The device functions through surface electrodes over the patient's paralyzed tibialis anterior muscle, stimulating it to induce dorsiflexion during the swing phase of gait. This ensures that the foot is lifted and clears the ground, reducing the risk of falling and improving gait (Melo et al., 2015). Studies have also suggested that consistent, long-term use of FES can promote neuroplasticity, leading to lasting improvement in voluntary muscle control in affected areas (Stein et al., 2010).

The Hermes brace

The Hermes brace is unique with its incorporated adjustable tensioning mechanism that allows users to dial in dorsiflexion support based on their individual gait needs and daily activity level. Unlike static designs such as solid AFOs (SAFOs) that completely restrict ankle motion, or posterior leaf spring and hinged AFOs that offer fixed degrees of flexibility, the Hermes provides dynamic, user-controlled adjustability. While the carbon fiber AFOs offer some pliability in the stored and released energy, the brace cannot be tuned in real life and thus cannot be easily altered for change in activity or terrain. Furthermore, while Functional Electrical Stimulation (FES) systems provide neuromuscular activation for those with intact peripheral nerves, the solution is not applicable to those without, and the brace is known for its discomfort, high price, and heavy maintenance. Similarly, a surgical approach can only be used in limited cases and is a risky, invasive operation. The Hermes offers a mechanical solution that is suitable for a

broad patient population, including those with irreversible nerve damage. Its modular design and low-profile, customizable frame make it a versatile and scalable option in managing foot drop across a spectrum of etiologies.

Future Work

The current novelty of the Hermes device lies in its adjustability, allowing patients to set the desired tension to support their foot. The torque dial allows patients to modify the hinge angle depending on activity. The Icarus team wanted to maintain the tunability of the device and further stipulated that the plantarflexion stop be adjustable as well. During the design process the final protype was intended to allow patients to select the plantarflexion stop angle. This would be achieved by adding or subtracting height to the bottom support bar and thus affecting when the two supports hit, restricting motion. To change the height of the bottom support, stackable clips would need to be prototyped that allow angle adjustments at increments of five degrees.

While FEA analysis has been conducted to understand material selection, Failure Mode and Effects Analysis (FMEA) needs to be completed to identify design failure points and assess the risks of each possible failure. Pending FMEA, torque testing would need to be conducted on the final protype to ensure the device can withstand the simulated forces. Several methods can be used to test this, including the usage of a lower limb orthotic within standard test fixtures such as the RUCE, KST, SMApp, and EMPIRE or the use of a traditional weight hanging method (Shuman et al., 2023). Results would presumably match FMEA predicted safety factors and max load samples.

Once device testing is finished, the next step would be to conduct a pilot study with the final prototype to assess patient wearability and comfort. Assuming positive feedback, testing of the modified Hermes design would be completed under the larger scale Hermes clinical trial. The Hermes brace is currently pending IRB approval for a patient reported outcome study (PROMS) and gait metric study. The clinical trial will evaluate the orthotics comfortability and feasibility through industry standard PROMS like, EQ5D5L, OPRO-M20 and OPUS surveys. Quantitative data will also be collected through gait testing, including biomechanical analysis, kinetic data, and electromyography (EMG) results to validate the braces' effectiveness.

Materials and Methods

The iterative design process began in the brainstorming phase to understand our design specifications and sketch potential solutions. To adequately integrate the design with the Hermes device, a detailed CAD file was studied to understand the mechanics and operation of the brace. Yield stress calculations were performed to ensure that the design could withstand a maximal plantar flexion moment. Specifically, it was determined that the stop has minimum height of 3.61 inches, eliminating many early phase prototypes. The final prototype features all design specifications, both exceeding the minimum height specification and adding less than 20% of the original brace weight to the overall design. CAD design was conducted in Autodesk Fusion 360 as was the corresponding FEA and material analysis. Final printing was done in-house at Icarus on a Hewlett-Packard 3D Jet Fusion 4200 printer.

End Matter

Author Contributions and Notes

All authors contributed to initial prototyping and formation of the design specification. Cooper Wyatt and Miranda Sedehi were responsible for CAD Design, FEA, and material analysis in Fusion 360. The Icarus team printed the final prototype. All listed authors contributed to the writing of the paper.

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