Design, Iteration, and Testing of a Novel Class of Ankle-Foot Orthotics

A Patient Centered Approach to Orthotic Design: An Actor-Network Theory Perspective

A Thesis Prospectus
In STS 4500
Presented to
The Faculty of the
School of Engineering and Applied Science
University of Virginia
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Biomedical Engineering

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November 8, 2024

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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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Introduction

Foot drop, a condition characterized by difficulty lifting the forefoot due to muscle weakness or paralysis, presents a significant challenge for individuals across the US. Current orthotic devices, like traditional ankle foot orthoses (AFOs), often address this condition with a rigid structure that stabilizes the ankle without allowing for movement. However, these designs limit the ankle's range of motion and hinder natural gait patterns, reducing patient mobility and quality of life (Lewallen et al., 2010). As such, there is a critical need for AFO solutions that balance structural support with improved dynamic function and adaptability to ensure patients regain a more natural gait and maintain independence.

My group's Capstone project plans to address this problem by evaluating an innovative, 3D-printed AFO equipped with a quick release mechanism and dorsiflexion assist to enhance its dynamic functionality and usability. These features distinguish the design from traditional plastic and carbon fiber AFOs and allow for greater mobility while maintaining the necessary support for walking, standing, and exercising. The primary focus of my team's research is to evaluate how this novel brace will influence the gait patterns and overall mobility of patients with foot drop. Utilizing gait testing and patient feedback, the design will be continuously refined to meet user needs. With this technology, we aim to improve therapeutic outcomes and quality of life for individuals suffering from foot drop.

We will approach AFO design through Actor-Network Theory (ANT), which views the AFO as an active participant within a broader sociotechnical network that includes healthcare providers, insurance companies, cultural attitudes, and patients. Each actor in this network influences the device's design, acceptance, and effectiveness, making it essential to consider both technical and human factors. By treating the AFO as an interconnected actor, this project aims to design a device that is biomechanically effective and socially acceptable. This approach acknowledges that a successful AFO must meet both mechanical and social needs, enhancing patient compliance, comfort, and dignity while reducing stigma and financial barriers to use. Through this ANT lens, the design process becomes an iterative, patient-centered effort, integrating feedback from all actors to ensure the device supports each user holistically.

By addressing the broader network, we can encourage consistent use of the device. Typical AFOs do not address actors such as cultural attitudes which lead to many patients opting out of treatment due to the device's negative perception. Our project emphasizes a patient-centered approach, involving direct feedback from study participants through standardized surveys to ensure the AFO design is socially acceptable and economically viable. By creating an AFO that fulfills its mechanical functions and addresses humanistic concerns, we aim to enhance user compliance and satisfaction.

The core connection between the technical and sociotechnical facets of this project lies in the recognition that engineering innovation alone cannot solve the problems associated with foot drop. The success of the AFO depends on its ability to integrate into the lives of its users. Through this iterative, patient-focused design process, we aim to develop a solution that is technically sound and discreet.

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Foot drop, characterized by weakness or paralysis of the dorsiflexors, causes the affected foot to drag during the swing phase of the gait cycle, leading patients to lift their knee to avoid tripping. Foot drop can result from various disorders or injuries, including compressive disorders, injuries, or iatrogenic causes like surgical nerve damage (Nori & Stretanski, 2024). For patients with nerve compression or trauma-related foot drop, recovery may be possible with proper rehabilitation, but progressive neurological disorders, such as Charcot-Marie Tooth (CMT), often lead to worsening symptoms as motor nerves degenerate over time (*Charcot-Marie-Tooth Disease | National Institute of Neurological Disorders and Stroke*, n.d.).

For those with incurable conditions, managing symptoms and preventing complications presented by falls and immobility is crucial, highlighting the need for effective foot drop solutions. AFOs support individuals with foot drop by stabilizing the ankle and preventing excessive plantarflexion, facilitating foot clearance, and restoring natural gait patterns. Traditional AFOs use rigid materials such as thermoplastics, though recent innovations incorporate carbon fiber or 3D printing to enhance comfort, mobility, and customization (Nori & Stretanski, 2024). Despite these advancements, many designs remain rigid due to the high cost associated with carbon fiber braces, limiting walking speed (Lewallen et al., 2010).

Our Capstone project involves testing and iteratively designing an innovative AFO featuring assistive technology and a quick release mechanism to improve usability. The quick-release button allows for easy tension release in the AFO, enabling greater range of motion during daily activities. This design seeks to address limitations of traditional AFOs by enhancing patient usability and mobility while maintaining a similar level of structural support.

AFO effectiveness is often evaluated through gait testing that assesses walking kinematics such as stride length, walking velocity, and joint angles (Gök et al., 2003). More precise gait testing uses technologies like 3D motion capture, force plates, or EMG to analyze muscle activity and gait patterns in detail (Nori & Stretanski, 2024). Simpler, non-instrumental assessments, such as the timed up and go (TUG) test or the 10-meter walk test are frequently used to measure functional mobility and assess a patient's gait at a lower cost and time commitment (de Wit et al., 2004).

The project combines advanced gait analysis with patient feedback to ensure the novel AFO design improves mobility and user satisfaction. By creating a technically advanced and user friendly AFO, we aim to address the unmet needs of individuals with foot drop, improving compliance and long-term mobility for better rehabilitation outcomes.

A Patient Centered Approach to Orthotic Design: An Actor-Network Theory Perspective

Foot drop is not only a biomechanical problem, but a condition that impacts an individual's social identity and psychological well-being. In this project, we approach AFO design through the lens of Actor-Network Theory (ANT) (Latour, 2005), which views the AFO not as a standalone tool but an actor within a complex sociotechnical network that includes healthcare providers, insurance companies, cultural attitudes toward disability, and patients. By understanding each actor's influence within this network, we can design an AFO that effectively meets patients' mechanical, social, and emotional needs.

In the ANT framework, the AFO is an active participant, shaping patient experience. Current AFOs are typically designed with a technical focus, often failing to address the discomfort, social stigma, and financial barriers patients encounter (Christ et al., 2012). The technical design of AFOs impacts patient compliance and satisfaction by hindering or facilitating the wearer's social integration. For instance, a highly visible AFO can unintentionally signal disability. By treating the AFO as an actor within the foot drop network, we can reframe the design process to address the device's broader influences including social acceptance, adherence, and efficacy (Deshpande et al., 2011).

Each actor within this network exerts influence on the design and adoption of the AFO. Patients are a critical component as their feedback directly impacts device modifications to enhance comfort, mobility, and social usability. Healthcare providers act as intermediaries, assessing patient needs and providing them with the appropriate solutions, while insurance companies shape access and affordability through coverage decisions. These financial actors can be restrictive, limiting AFO options for patients from economically disadvantaged backgrounds, impacting device adoption and long-term outcomes (Miller et al., 2020).

Cultural attitudes toward disability further affect the perception and acceptability of AFOs. These social actors contribute to patients' self-perception. When AFOs are associated with visible disability, cultural stigma can discourage consistent use, compromising the device's efficacy. By recognizing these actors, our design will aim to reduce the social visibility of the device while improving user comfort, ensuring the AFO aligns with mechanical function and user dignity.

ANT emphasizes the constant influence actors within the network exert on each other, creating a feedback loop that will inform our design process. By collecting patient reported outcomes (PROs) over a 6-month period, we will gain insight into how patients interact with the AFO in daily life, capturing data on psychological impact, cost-effectiveness, mobility and balance confidence, and comfort. This feedback loop will allow the device design to evolve iteratively, with user experiences guiding design changes (Schmidt & Hoffman, 2018).

Our analysis will focus on the interaction between technological and human factors. These will include societal aspects, cultural context, healthcare systems, and human interaction with the device. Societal aspects will include economic constraints and feelings of social stigma (Renfrew et al., 2019). In examining the cultural context around AFOs, the project aims to understand the attitudes that may influence the acceptance of AFOs into existing sociotechnical structures. Research into healthcare systems will focus on how insurance coverage, healthcare access, and rehabilitation practices shape the availability, cost, and use of AFOs (Miller et al., 2020). Finally, the interaction between patients and the device will be studied in detail to create a feedback loop that will inform the iterative design of a more user-friendly, affordable, comfortable, and socially viable orthotic device (Schmidt & Hoffman, 2018).

In ANT, non-human elements, like insurance policies and economic structures, are seen as actors that also influence the AFO's design and use. Insurance coverage directly impacts device affordability, which in turn influences patient access. The lack of coverage for advanced dynamic AFOs limits patients' options, disproportionately affecting economically disadvantaged users. By examining these factors, we can design a technically sound AFO that is also financially viable within common insurance frameworks. We aim to create a device that maintains accessibility without compromising quality, recognizing the powerful role financial barriers play in our sociotechnical network (Renfrew et al., 2019).

Our analysis will integrate technical performance measures with PROs, viewing gait lab testing and user feedback as complementary data sources. Objective metrics, such as stride length, will be balanced with subjective outcomes, such as comfort. If gait improvements occur alongside reported discomfort, the design will be adjusted to prioritize these human factors. This feedback loop becomes a dynamic actor that will continually refine the AFO based on patient interactions and sociocultural considerations, ensuring that all actors contribute to the design.

ANT enables us to see the AFO as part of a sociotechnical ecosystem in which each actor shapes its success. By examining these interactions, we can design an AFO that corrects gait while respecting patient identity, economic situations, and social belonging. This approach prioritizes a design process that responds to its environment, where every actor's influence is acknowledged, resulting in an AFO that holistically addresses foot drop.

Conclusion

In conclusion, our technical deliverable is a paper outlining the quantitative testing and development of a novel AFO for foot drop management. This design will prioritize patient mobility, comfort, and ease of use, addressing both biomechanical and real-world user needs.

From an STS perspective, this research addresses the societal challenges of accessibility, affordability, and stigma associated with current orthotic devices. Using ANT, we view the AFO as an active participant in a sociotechnical network involving patients, healthcare providers, insurance companies, and cultural attitudes toward disability. By considering these diverse influences, we aim to create a socially and economically viable solution that meets both technical and human needs. This approach emphasizes patient feedback to enhance comfort, discretion, and usability, while engaging with non-human actors, like insurance policies, to make the AFO accessible for a broader population. By setting a new standard for inclusivity in medical device design, this project underscores that advancing orthotic solutions requires biomechanical innovation and a commitment to social responsibility and patient-centered care.

The expected outcome is a device that not only improves gait mechanics but also reduces barriers to consistent use, leading to better long-term patient outcomes. This project demonstrates how integrating technical innovation with a holistic design process can address the medical and societal aspects of foot drop.

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