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

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William Wyatt

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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

Advisor

Bryn E. Seabrook, Department of Engineering and Society

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Introduction

Foot drop affects approximately 19 out of every 100,000 individuals (Nori & Stretanski, 2025). Ankle-foot orthoses (AFOs) have long been the standard solution for individuals suffering from foot drop, a condition that severely impairs mobility and independence. However, despite their biomechanical effectiveness, studies reveal that over half of the patients prescribed AFOs discontinue their use (İsmail Safaz, 2015). This disconnect raises a crucial question: Why do devices designed to restore movement often end up sidelined? This research investigates how sociotechnical factors influence the design, acceptance, and effectiveness of AFOs, aiming to bridge the gap between mechanical functionality and user-centered needs. By applying Actor-Network Theory (ANT), this paper examines the AFO as an active participant within the medical network of healthcare providers, insurance companies, cultural attitudes, patients, and medical device manufacturers. Through this lens, the research seeks to uncover how social and technical elements combine to shape the success or failure of AFOs, ultimately guiding the design of more effective orthotics.

Methods:

This research uses documentary research and discourse analysis to explore the design of orthotic devices, specifically AFOs, through the lens of Actor-Network Theory. The analysis draws on peer-reviewed literature, engineering design documents, insurance policy, and patient testimonials. Discourse analysis of patient feedback and lived experiences from medical case reports reveals dominant narratives and assumptions in orthotic design. Sources are organized thematically: beginning with historical and clinical context, then identifying patterns in user experience, followed by a breakdown of engineering and design innovations. ANT is applied throughout to trace relationships between human actors (patients, clinicians, designers) and non-human actors (AFO devices, clinical environments, insurance policies).

Keywords: assistive technology, orthotic design, Actor-Network Theory, user-centered engineering, foot drop

Considerations in Foot Drop Management

Foot drop, a condition characterized by the inability to lift the front part of the foot, significantly impairs mobility and quality of life (Tracy M. Christianson & Kimberley Morris, 2023), affecting individuals with neurological disorders such as stroke, multiple sclerosis, and cerebral palsy (Gil-Castillo et al., 2020). Traditional ankle-foot orthoses are commonly prescribed to assist in foot clearance during walking, enhance stability, and prevent falls. However, despite their biomechanical effectiveness, many patients discontinue use due to discomfort during daily activity, poor fit, social stigma, and inconvenience. Current AFO designs, including rigid braces, carbon fiber models, and functional electrical stimulation (FES) devices, focus primarily on mechanical correction, often neglecting the social and emotional needs of users (Bregman et al., 2012).

Cultural attitudes also play into this disconnect, as visible medical devices are often stigmatized, leading to diminished user confidence and social exclusion. To further exacerbate the issue, medical device manufacturing companies prioritize functionality and cost-effectiveness over social acceptance and patient comfort, resulting in designs that fail to address the emotional and cultural dimensions of disability. Financial constraints due to a lack of insurance coverage or more technologically advanced devices are another dimension that limits access, highlighting the need for economically viable solutions (Ho & Adcock, 2018). As a result, user compliance remains low, limiting the overall effectiveness of these interventions. This disconnect between technical functionality and user experience highlights the necessity for a more holistic approach to AFO design, one that puts humanistic needs at the forefront of development. This research examines how sociotechnical factors influence AFO design, acceptance, and effectiveness, emphasizing the importance of patient-centered solutions that enhance comfort, dignity, and social acceptance.

Actor-Network Theory and Orthotic Accessibility

This research employs Actor-Network Theory (ANT) to analyze the sociotechnical dynamics influencing AFO design and acceptance. ANT, developed by Bruno Latour, Michel Callon, and John Law, views technology and society as interconnected entities, suggesting that devices like AFOs are active participants within complex networks (Latour, 2005). In contrast to traditional technological determinism, which views technology as an independent force shaping society, ANT posits that social and technical elements are co-constructed, influencing and reshaping each other. This perspective makes ANT particularly valuable for examining medical device design, where user experience and social acceptance are tightly intertwined with technical functionality.

In this study, the AFO is conceptualized as an active participant within a network involving healthcare providers, insurance companies, cultural attitudes, users, and medical device companies. Each actor influences the device's design, acceptance, and effectiveness, necessitating an iterative, feedback-driven approach (Prout, 1996). For example, cultural perceptions of disability can affect user compliance, while insurance policies dictate financial accessibility. By treating the AFO as an actor within this network, ANT allows for a comprehensive analysis of the social, cultural, and technical factors that influence user experience.

While ANT is sometimes criticized for its perceived subjectivity and complexity in mapping sociotechnical networks, it provides a fluid analytical framework capable of revealing the interactions between technical design and social acceptance (Law, 1999). Critics argue that ANT's avoidance of hierarchical structures can lead to ambiguous interpretations. However, its focus on relational dynamics and distributed agency is particularly useful for medical device analysis, as it captures the interconnectedness of user needs, cultural perceptions, and design decisions.

Previous research demonstrates ANT's effectiveness in analyzing medical devices and assistive technologies. For instance, Oudshoorn used ANT to explore how pacemakers were co-shaped by engineers, clinicians, and patients, revealing the importance of patient feedback in design iterations (*Sustaining Cyborgs*, n.d.). Similarly, Moser applied ANT to prosthetic limb development, showing how social norms and cultural values influenced user satisfaction and dignity (Moser, 2000). These studies highlight ANT's utility in bridging technical and social considerations, validating its application to AFO design.

This approach provides insights into the challenges faced by traditional AFOs, guiding the development of more effective, patient-centered solutions that enhance mobility, independence, and quality of life. By considering the influence of all actors, this research aims to design an AFO that fulfills both biomechanical and humanistic needs, reducing stigma and financial barriers while promoting consistent use and satisfaction. In doing so, ANT contextualizes the technical aspects of AFO design and addresses the social dynamics that impact device adoption and sustained use.

Research Question:

What sociotechnical relationships shape the design and development of ankle foot orthoses (AFOs) for foot drop, and how can Actor-Network Theory (ANT) be used to identify and reconfigure these networks to better integrate patient feedback, reduce stigma, and improve accessibility?

Results and Discussion

This paper explores the application of Actor-Network Theory to the design of ankle-foot orthoses for foot drop, revealing critical tensions between clinical functionality, user experience, and social perception that are often overlooked by traditional engineering approaches. ANT illustrates the network of interactions between patients, clinicians, devices, policy, and everyday environments, showing how each contributes to mobility, autonomy, and dignity. Through analysis of current AFO technologies, patient narratives, and clinical design practices, four key themes emerge: (1) the stigma associated with visible and bulky orthotic devices, (2) barriers related to affordability and accessibility, (3) the disconnect between clinical functionality and real-world use, and (4) the underutilization of patient feedback in the design process. Each theme highlights how AFOs are more than mechanical supports but socially embedded artifacts shaped by the actors around them. Integrating ANT into AFO development provides a framework for more inclusive, adaptive, and user-centered design solutions.

Orthotic Stigma and Visibility

One of the most persistent challenges faced by individuals with foot drop is the social stigma attached to wearing visible orthotic devices. Traditional AFOs are often bulky, rigid, and visually distinct from standard footwear, which can mark the wearer as disabled and attract unwanted attention or pity. This issue extends beyond aesthetics, it influences whether individuals choose to wear their devices at all, especially in social or professional settings

(Turner et al., 2022). ANT reveals how stigma is not a social issue external to the device but is constructed by the interactions between human and non-human actors.

The orthotic device becomes an actor in a larger network that includes cultural narratives about disability and visibility. For example, interviews and forum posts from patients often mention feelings of embarrassment, self-consciousness, or helplessness while wearing standard AFOs, particularly during early stages of rehabilitation. Some even report choosing to walk unsafely or avoid going out rather than wear a brace they find stigmatizing (Ramstrand et al., 2021). These individual choices reshape the network: if patients resist the device due to its visibility, the intended clinical outcomes, improved gait and reduced fall risk, may not materialize, weakening the link between prescription and practice.

Manufacturers and clinicians, trained in technical optimization rather than social dynamics, may overlook these lived experiences. In some cases, they prioritize durability and biomechanical performance over appearance, inadvertently reinforcing the stigma. However, newer models such as low-profile carbon fiber braces or customizable 3D-printed designs show how attention to form can alter the device's position in the network (*Hermes*, n.d.). These alternative devices, when co-designed with users, shift the orthosis from a symbol of impairment to a tool of empowerment, something chosen rather than reluctantly worn.

Cultural and policy actors (e.g., insurance coverage) often fail to support these more discreet orthoses due to policies that require prefabricated braces to be the first option, categorizing custom orthotics as “non-essential” (*CG-DME-22 Ankle-Foot & Knee-Ankle-Foot Orthoses*, n.d.). ANT helps highlight how these regulatory bodies act as gatekeepers, shaping what types of devices are accessible and socially acceptable. As a result, stigma persists not just in the visible artifact, but in the broader sociotechnical system that prevents certain design choices from reaching users.

By tracing these actor-networks, it becomes clear that stigma is a product of misaligned priorities within the design process, and that reducing it requires more than aesthetic redesign. It requires reconfiguring the relationships between all actors involved, from users and engineers to clinicians, insurers, and even fashion norms, to elevate patient preferences as central, not peripheral, to the design and implementation of AFOs.

Affordability and Accessibility Gaps

Affordability remains a major barrier to the widespread adoption and sustained use of ankle-foot orthoses (AFOs). While newer, more discreet, and ergonomic designs are emerging—such as carbon fiber braces, 3D-printed customizable models, and devices with integrated smart components—their cost often renders them inaccessible to the majority of patients. In the United States, a standard off-the-shelf plastic AFO may cost \$500–\$1,000, while custom or advanced models can exceed \$2,000, not including the cost of consultations, fittings, physical therapy, and potential replacements (*How Much Do Custom Orthotics Cost? - GoodRx*, n.d.). Using ANT, we can trace how affordability is not only a financial issue but relational, emerging from the broader network of interacting actors including insurance providers, orthotists, designers, patients, and federal regulators. The value of an AFO is not just determined by its material cost but by the collective decisions of non-human actors such as insurance codes, FDA classifications, and reimbursement systems. For example, Medicare's Durable Medical Equipment (DME) reimbursement guidelines frequently categorize advanced or aesthetically enhanced AFOs as "deluxe," meaning they are not covered despite their potential to improve adherence and long-term outcomes (*Ankle Orthoses, Ankle-Foot Orthoses (AFOs), and*

Knee-Ankle-Foot Orthoses (KAFOs) - Medical Clinical Policy Bulletins | Aetna, n.d.). This institutional categorization acts as a non-human actor that shapes which devices are produced, recommended, and used.

These limitations disproportionately affect underinsured populations, veterans, and individuals with limited mobility, the very populations who would benefit most from innovative orthoses. Veterans, for instance, may receive care at VA hospitals, where innovation in orthotic design is often slowed by procurement challenges, centralized contracts, and inflexible formularies (Seck, 2024). Even within these systems, the actors determining what devices are "available" remain largely invisible to the patient but deeply influential within the network. Geographic location and access to certified orthotists further complicate accessibility. In rural areas or low-resource clinics, patients may not be offered the proper materials to maintain their brace or in the case of amputees, prosthetic socks (Ennion & Manig, 2019). ANT helps us see how local clinicians, transportation infrastructure, clinic funding, and regional economic conditions all become part of the socio-technical network that affects whether a patient actually receives an effective device.

By tracing the actors involved in cost, reimbursement, and distribution, we begin to understand affordability and accessibility not as individual challenges but as outcomes of system-level configurations. Reconfiguring these networks—by designing devices that meet biomechanical and economic needs, by lobbying for updated insurance standards, or by including patients in device evaluation processes—could begin to close the gap between what exists and what's accessible.

Clinical vs. Everyday Functionality

A persistent disconnect exists between how AFOs perform in clinical evaluations and how they function in the everyday experiences of users. In clinical environments, AFOs are assessed based on controlled gait analysis, biomechanical efficiency, and short-term improvement metrics. However, these assessments often fail to account for the realities of daily life: uneven terrain, shifting weather conditions, varying levels of fatigue, social interaction, and the user's emotional response to the device. ANT helps illuminate how these competing environments host different configurations of actors, each shaping what "success" means for an orthotic device.

Within the clinical actor-network, key human actors include physicians, physical therapists, and orthotists, while non-human actors include force plates, motion capture systems, and standardized gait tests. This network privileges technical outcomes such as stride length, dorsiflexion angles, or reduction in toe drag (Dobler et al., 2024) over the user's social, emotional, or environmental context. Devices are often prescribed based on performance in this network, yet the very metrics used may not reflect how the brace performs during a 12-hour work shift, a walk through a crowded store, or while navigating a gravel driveway. ANT helps show how these clinical tools shape the device's identity as "successful," even when it may fail in real-world conditions.

On the other hand, the user's actor-network in daily life is vastly different. Non-human actors include shoes, stairs, carpet, and weather. Human actors, such as coworkers, family members, and strangers, also play a role in shaping how the user perceives and engages with the AFO. Emotional actors like embarrassment, frustration, or confidence also have an influence. In this complex network, the brace must adapt to physical, social, and personal demands and expectations. Yet this network is largely invisible to designers and clinicians unless patients actively communicate their struggles, feedback that may be de-emphasized if it doesn't map onto clinical metrics.

For example, an AFO may pass clinical muster by correcting foot clearance during walking trials, but a patient might abandon it due to discomfort when driving, poor fit with their preferred shoes, or difficulty donning the device independently. These real-world challenges are often reported anecdotally but dismissed as secondary in the clinical decision-making process. ANT helps center these overlooked actors in the design and evaluation process, arguing for a reconfiguration of priorities that places everyday functionality on par with biomechanical optimization.

Some newer designs attempt to bridge this gap, offering adjustable components, modular footplates, or braces compatible with multiple footwear types (Alam et al., 2014). However, these designs are still exceptions, not norms, often driven by individual designers rather than systemic shifts. An ANT-informed design process would bring everyday actors like users' transportation needs or housing layout into the early stages of orthotic development and evaluation. It would treat patient testimonials as data, recognizing that functionality is a product of sociotechnical interactions rather than laboratory-defined outcomes.

This disconnect is more than a design flaw, it is a misalignment in how success is defined and by whom. Reconfiguring this actor-network means embedding patients' lived environments and functional goals directly into the evaluation criteria. ANT enables a deeper understanding of the asymmetries between clinical and everyday networks and offers a framework to integrate them, rather than letting one dominate the other.

Patient Feedback and Actor-Network Reconfiguration

AFO users are often treated as passive recipients of medical technology rather than active participants in its design and refinement. Traditional development networks prioritize clinical expertise, biomechanical optimization, and cost efficiency, while patient feedback remains secondary or is incorporated only after a device has already been designed and distributed. ANT highlights how this exclusion of patient voices is not merely a failure of individual practitioners or companies but a structural issue embedded in the sociotechnical network surrounding orthotic development. By reconfiguring this network, elevating the role of patients from test subjects to co-designers, AFOs can better meet real-world needs, reducing stigma, improving adherence, and fostering greater independence.

The Current Role of Patient Feedback in the AFO Network

Within the current AFO design and prescription system, patient feedback enters the network at limited and often ineffective points. Users may provide input during clinical assessments, but this feedback is typically constrained to comfort adjustments rather than structural modifications. Some manufacturers conduct post-market surveys, but these tend to focus on broad satisfaction metrics rather than identifying specific usability concerns. Moreover, insurance policies and clinical guidelines dictate which devices are available, further restricting patient agency. The result is an asymmetrical network where healthcare providers exert greater influence over design choices than the users themselves.

This imbalance is evident in the persistence of common patient complaints: difficulty donning and doffing AFOs, discomfort when worn for extended periods, interference with preferred footwear, and the social stigma of visible orthotic devices (Bashir et al., 2022). These concerns, while widely reported, are often dismissed as secondary to clinical gait improvements. As a result, many users either abandon their devices or modify them independently.

Reconfiguring the Actor-Network: A Patient-Centered Approach

To create a more responsive and effective orthotic design network, the role of the patient must be redefined from passive end-user to active co-designer. ANT provides a framework for mapping the relationships between key actors and identifying where new connections can be forged. Three critical shifts in the network can facilitate this reconfiguration:

1. Embedding Patient Feedback in Early-Stage Development

   Rather than incorporating user input only after a device has been manufactured, developers should engage patients in early prototyping. Patient advisory panels, design workshops, and real-world wear testing should be integrated into the R&D cycle. This would allow manufacturers to address issues of comfort, ease of use, and aesthetics before mass production, rather than reacting to negative feedback post-market.

2. Expanding the Definition of "Successful" AFO Design

   Current clinical assessment methods focus on biomechanical metrics while largely ignoring factors like social acceptability, ease of integration into daily routines, and psychological comfort. By redefining success to include qualitative patient reported outcomes the network can shift toward more holistic designs.

3. Leveraging Digital Platforms for Direct Patient Engagement

   The rise of online disability communities, telemedicine, and crowdsourced assistive technology has created alternative spaces where patients exchange knowledge, rate orthotic devices, and even design their own modifications. Integrating these digital platforms such as patient-led design forums, open-source modification platforms, or clinician-moderated feedback portals into the formal orthotic development can create more opportunity for responsive design processes.

The Role of Non-Human Actors in Reconfiguration

Reconfiguring the network requires addressing non-human actors as well. Insurance codes and regulatory classifications must evolve to support innovative and user-centered orthoses rather than limiting coverage to outdated models. Emerging technologies such as 3D printing could also serve as key non-human actors that reshape patient-clinician interactions, allowing for more personalized solutions.

Conclusion

By mapping the limitations of the current AFO development network and identifying key points for reconfiguration, Actor-Network Theory provides a framework for centering orthotic design around the patient. Integrating patient feedback earlier in the design process, redefining clinical success to include everyday functionality, and leveraging emerging technologies can shift the actor-network toward greater accessibility, usability, and social acceptance. Rather than rigid, standardized medical devices, AFOs can become adaptable, empowering tools that enhance mobility, independence, and quality of life for users.

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