DESIGNING AND TESTING KNEE DISTRACTION UNLOADER BRACES FOR MEDIAL COMPARTMENT OSTEOARTHRITIS (OA)

RACE-BASED DISPARITIES IN ACCESS TO EFFECTIVE FOOT ORTHOTICS

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

By
Anna Dugan
December 15, 2024

Technical Project Team Member
Mira Zineddin

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.

ADVISORS
Dr. Kent Wayland, Department of Engineering and Society
Dr. Timothy Allen, Department of Biomedical Engineering

How can orthotics be made more accessible and effective?

Orthotics are external devices used to improve the alignment of musculoskeletal systems to address a wide variety of conditions (Redmond et al., 2009). Both off-the-shelf and prefabricated orthotics are used to provide pain relief and treatment, offering up to 75% success rates as a conservative intervention for lower extremity problems (Zifchock et al., 2008; Stark et al., 2023). Orthotics companies are constantly striving to produce cheap, easy-to-use, and effective braces for the treatment of many conditions.

The Adonis is an orthotic in development by Icarus Medical that targets medial compartment knee osteoarthritis (OA). OA is a chronic disorder characterized by cartilage degeneration, joint pain, and immobility. The Adonis' novel design alleviates OA symptoms via two techniques: joint distraction and unloading. Joint distraction is the physical separation of the impacted bones (in this case, the patella and the femur). Unloading is the redistribution of load from the joint onto the rigid structure of the brace. Due to these advancements, the Adonis is expected to be a prime option to postpone or obviate costly knee surgery, but this must be proven through clinical trials. Additionally, the Adonis must undergo redesigns to improve its ease of use.

Despite the potential that orthotics have in improving patient outcomes, access to these orthotics varies. Focusing on the microcosm of foot orthotics, the availability of orthotic treatment is tied to the dimensions of a patient's foot. People with foot types not catered to by off-the-shelf orthotics face major accessibility challenges in acquiring functional orthotics due to the prohibitively high cost of custom orthotics (Stark et al., 2023). In addition, these patients face a higher physical burden due to having to wait extended periods of time to receive custom orthotics (Cameron-Fiddes et al., 2013). In turn, the likelihood of foot disorders is tied to race

(Hoey et al., 2023). Moreover, people of certain races and insurance statuses face disparities in receiving prescribed orthotics (Stevens et al., 2021). Thus, people of certain races may shoulder a higher cost—both financial and physical—in receiving the same level of treatment as groups catered to by off-the-shelf orthotics.

Even as the field of orthotics strives for improved efficacy and ease of use, it may disadvantage certain groups.

Designing and Testing Knee Distraction Unloader Braces for Medial Compartment OA

How can the efficacy of the Adonis brace be established, and how can its ease of use be improved?

OA is a disabling condition that affects over 365 million people worldwide, and that number is expected to increase alongside rising obesity and injury rates and an aging population (Long et al., 2022). The knee is the joint most prone to OA, with the knee's medial compartment most frequently affected (Segal, 2012). Knees with OA are often varus, or inward-bowing, introducing further loads to the medial compartment that accelerate cartilage breakdown and disease progression (Petersen et al., 2019).

Due to long surgical wait times and high costs, there is an increasing demand for non-surgical treatments for patients with medial compartment OA. Current non-surgical options like intra-articular injections are limited to short-term symptom relief (Ciapini et al., 2023). Distraction unloader knee braces such as Icarus Medical's Adonis brace, which apply a distraction force to manually separate and offload the knee joint space to correct varus

deformities, offer a promising, noninvasive alternative with rehabilitation outcomes that may rival or surpass surgery. Before being brought to market, the Adonis' efficacy must be established through clinical trials and design improvements must be made.

Efficacy of the Adonis must be established through clinical trials. Though the Adonis boasts positive anecdotal feedback, there remains insufficient clinical research showing significant benefits over existing market options. We aim to collaborate with the UVA Prosthetics department to secure institutional review board (IRB) approval and perform clinical trials on patients with medial compartment OA. We will conduct a randomized controlled study with two groups: patients using the Adonis knee brace and a control group with a standard knee brace. The study will include 50 patients, with assessments at baseline and at 4 weeks, 8 weeks, and 3 months post-fitting. Patient-reported outcome measures (PROMs) will be measured using the Knee Osteoarthritis and Outcome Score (KOOS) and the Visual Analogue Scale (VAS). Subgroup analyses will evaluate knee joint-space width and cartilage repair via fluoroscopy, as well as gait analysis. The ideal outcome from the clinical trial will be evidence that the Adonis provides superior improvements in PROMs, joint-space width, and gait than competitors.

We will improve the ease of use of the Adonis brace by identifying problems with the current design via personally donning and doffing the brace, brainstorming solutions, and making prototypes in computer-aided design (CAD) software. Currently, the strap system of the brace is complex, consisting of four straps with four identical clips. The donning and doffing system must be simplified to facilitate ease of use. The system will be simplified by merging the four clips into two clips in CAD software while maintaining the original angles and device functionality. The new Adonis brace will be judged based on a variety of Icarus' established device scores, including durability, manufacturability, strength, ease of use, and more. The ideal

result of this research project will be a finalized, simplified clip-and-brace Adonis design in a CAD file, to be used by the company. Then, the file can be further edited for custom brace orders, 3D printed, and distributed to medial compartment OA patients. By improving the device's ease of use, the Adonis will be brought one step closer to the market.

Race-based Disparities in Access to Effective Foot Orthotics

How is access to effective foot orthotics affected by race?

Off-the-shelf foot orthotics may be biased against certain people of certain races, meaning that those groups must pay more and wait longer to acquire costly custom orthotics to achieve the same standard of care. Previous research showed that people of certain races are more likely to have foot disorders (Golightly et al., 2012). One paper showed that people with foot disorders are not catered to by off-the-shelf orthotics and thus must seek custom orthotics (Zifchock et al., 2008). Another study found that custom foot orthotics are more expensive than off-the-shelf orthotics and take longer to arrive after being prescribed (Cameron-Fiddes et al., 2013). A gap in current research exists because these findings have not yet been synthesized to assert that racial bias in orthotics access is a problem.

The context of this problem can be explained by defining its actor-network, which involves four stakeholders: orthotics companies, insurance companies, medical practitioners, and patients. Off-the-shelf orthotics companies seek to cut costs by making devices as universally applicable as possible (Cameron-Fiddes et al., 2013). Custom orthotics companies charge patients more for scans and custom orthotics, which are considered superior but may actually

hold equal efficacy to off-the-shelf orthotics for people of normal foot types (Redmond et al., 2009). Insurance companies seek to turn a profit; thus, they encourage patients to buy off-the-shelf orthotics, although they may cover orthotics if medically necessary (Stevens et al., 2021). Medical practitioners and patients alike pursue the highest standard of care. Patients are confronted with device comfort or lack thereof, social pressures, device cost, insurance coverage, and device efficacy. A subsection of patients are well suited to off-the-shelf orthotics, but the other subsection do not comfortably fit into off-the-shelf orthotics. The makeup of these subsections of patients is influenced by race.

Patients shape the orthotics industry by demanding better and cheaper orthotics. In turn, the orthotics industry caters its off-the-shelf orthotics for the standard foot size of the general public. In this way, orthotics companies instill politics into an object by pressuring people to conform to a standard foot shape. Here is the point where society may inspire pushback on orthotics companies: if there is a disparity in orthotics access, disadvantaged patients may pressure orthotics companies, medical practitioners, and insurance companies for faster, easier, and cheaper access to custom orthotics.

There is a lack of society, technology, and society (STS) research about this topic. I will use race and foot disorder associations within the framework of previous medical device bias studies to investigate possible disparities in access to effective orthotics.

Identifying Race-based Disparities in Access to Foot Orthotics

There may be disparities in access to effective foot orthotics depending on foot shape. Compounding this, there are differences in foot shape across race (Hoey et al., 2023). Taking

these ideas together, there is the basis for an argument that there are race-based disparities in access to effective foot orthotics.

According to Hutchison (2020), the existence of bias in medical devices can be demonstrated by "[s]tatistics showing that one group has worse outcomes than another from a device" (p. 572). Thus, I must prove that some groups are unequally served by off-the-shelf orthotics. To understand the sources of these biases, two further factors must be scrutinized: device factors and clinical encounter quality. Device factors encompass the device's design and efficacy, and clinical encounter parameters include diagnosis time and levels of communication between medical practitioner and patient (Hutchison, 2020). To examine whether there is bias in access to effective orthotics, I will study device factors, clinical encounter parameters, and statistics showing access to off-the-shelf orthotics.

Existing literature will be used to prove that device factors, clinical encounter parameters, and statistics point to inequitable access to off-the-shelf orthotics. First, not all foot types are amenable to off-the-shelf orthotics, lending support for how device factors differ based on foot types (Zifchock et al., 2008). Second, previous studies have shown that clinical encounter parameters, such as likelihood of receiving prescribed foot orthoses, differ based on race and insurance status (Stevens et al., 2021). Third, statistics have shown that some groups are more likely to suffer from foot abnormalities and disorders. Particularly, black Americans are more likely than white Americans to have pes planus (low arches), pes cavus (high arches), Tailor's bunions, hallux valgus, hammer toes, and overlapping toes (Golightly et al., 2012). Further, black Americans have a lower arch height on average than white Americans, rendering them more susceptible to diabetic foot ulcers that can result in amputation and disability; already twice as likely to die from diabetes than white Americans, black Americans perhaps have the most to

gain from orthotics, but they are still disadvantaged in acquiring orthotics (Brisbane et al., 2023). Since certain races have a higher proclivity for foot disorders, are not catered to by off-the-shelf foot orthotics, and are less likely to receive prescribed orthotics, there is a strong basis for an argument that certain groups experience bias in acquiring off-the-shelf orthotics.

If I discover that there is bias in access to off-the-shelf orthotics, I will investigate whether there are financial and health costs to disadvantaged groups due to their need to acquire custom orthotics. Whereas people with typical foot types receive effective bracing from off-the-shelf orthotics, those with foot disorders have to pay an average of 3.5x more for custom orthotics (Cameron-Fiddes et al., 2013). This inequality is exacerbated by the fact that it takes longer for custom orthotics than off-the-shelf orthotics to be used once prescribed by a medical professional (Cameron-Fiddes et al., 2013). Thus, people with atypical foot types not only have to pay more for their orthotics, but they also have to wait longer, which allows more time for their condition to deteriorate. I will show that patients that are ill-suited for off-the-shelf orthotics and thus must seek custom orthotics face both financial and health detriments.

Two key findings from literature will provide the basis for my argument: first, race and foot type are connected; second, certain foot types are ill-suited to off-the-shelf orthotics, necessitating custom orthotics for effective treatment. Together, these findings indicate that people of certain races may shoulder an exacerbated financial and health burden to acquire effective foot orthotics. Next semester, I will conduct further research on device factors, clinical encounter parameters, and orthotics access statistics to look for evidence of race-based biases. I will analyze the costs of these possible biases by factoring in prevalence of foot disorders, prescription receipt rates, orthotics costs, and orthotics time scales to quantify the burden of

unequal access to effective orthotics. The consequences of not pursuing this research are that groups may continue to unknowingly bear a heavier burden to receive the same standard of care.

Conclusion

The STS research is expected to reveal whether there are race-based disparities in access to effective orthotics, using foot disorder prevalence and clinical orthotics studies. The technical research is expected to result in confirmation of the clinical efficacy of the Adonis brace and an easier-to-use strap system design. Both these projects examine current gaps in orthotic treatments that must be bridged to further optimize the potential of orthotics as a therapeutic aid. These research projects will elucidate factors impacting efficacy and accessibility of orthotics to enhance patient outcomes. Efficacy and equitable accessibility of orthotic devices must be improved to provide greater relief to people with a wide variety of backgrounds and musculoskeletal disorders.

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