

Racial Disparities in Access to Effective Insoles

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

Anna Dugan

Spring 2025

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

Kent Wayland, Department of Engineering and Society

Introduction

Insoles are a form of orthotic device that are used as treatment and prevention aids for foot disorders and injuries, offering up to 75% success rates as a non-invasive intervention for a wide range of lower extremity problems (Zifchock et al., 2008; Stark et al., 2023). There are two main kinds of insoles: off-the-shelf and custom. Off-the-shelf insoles can be bought cheaply and readily, while custom insoles are more expensive and take longer to arrive after being prescribed (Cameron-Fiddes et al., 2013). Unfortunately, racial minorities in the United States of America face a higher likelihood of incompatibility with off-the-shelf insoles and also experience worse clinical encounters than the white majority, indicating there is a multifaceted racial disparity in access to effective insoles. This paper will examine the extent of the financial, temporal, and health disparity in access to effective insoles across race.

As the United States aims to create a society free from racial biases, access to effective insoles remains a healthcare disparity that must be fully understood and addressed (Williams et al., 2000). This research may inform medical advising (such as increased prescription of custom insoles for minorities), trigger studies to gather statistical proof of this disparity, open investigations into the causes of this disparity, and increase patients' demand for faster, easier, and cheaper access to custom insoles.

Background and Context

Orthotics are an appealing therapeutic aid because they are a non-invasive method to improve the alignment of musculoskeletal systems, which can address a wide variety of conditions (Redmond et al., 2009). In some cases, foot orthotics such as orthopedic shoes and insoles can obviate surgery (including amputation) and stop conditions from deteriorating, maintaining patient mobility and warding off disability (Robinson et al., 2015). While insoles

offer lofty medical benefits, there are still barriers to their adoption. These barriers motivate around 39% of patients against receiving their prescribed orthotic (Stevens et al., 2020). One barrier to insole adoption is insufficient understanding of why the orthotic was prescribed (Rambo et al., 2022). This barrier can be removed by enhancing the level of communication and understanding between clinicians and patients during the prescription encounter. Another difficulty in insole adoption is device cost. In some cases, insoles are still prohibitively expensive, especially when custom-made (Stevens et al., 2021). While insoles have many potential benefits, their adoption is currently hindered due to insufficient clinical encounters and prohibitive costs.

In the medical device industry, companies typically market products that are applicable to the broadest potential client base while keeping costs low. In the insole industry, this tenet has led companies to market off-the-shelf insoles, which are manufactured for generic, normal foot types in a range of typical foot sizes (Cameron-Fiddes et al., 2013). Off-the-shelf insoles are typically made cheaply and uniformly, on the business model that they will suit most people decently well but fit no one person perfectly (Zifchock et al., 2008). Indeed, a large subset of orthopedic patients find off-the-shelf insoles comfortable and effective. However, the other subset of patients cannot comfortably and effectively use off-the-shelf insoles and thus must seek other options, like custom insoles, to acquire effective bracing.

Patients can be unsuited to off-the-shelf insoles for two main reasons: foot sizes and shapes that are not catered to by off-the-shelf insoles. If patients do not find off-the-shelf insoles effective, custom insoles are their other main option for achieving the same level of care. Custom insole makers charge patients more money to make unique, personalized insoles, requiring a complex system of either scanning or molding, custom manufacturing, and delivery, which can

take months. Whereas off-the-shelf insoles are often soft and pliable to fit the wide range of potential users, custom insoles are made of semi-rigid or rigid construction so they better hold their unique shape (Zifchock et al., 2008). The basis of the racial disparity in access to effective insoles lies in the fact that minority patients are more likely to have foot disorders, which can preclude them from reaping the benefits of off-the-shelf insoles (Golightly et al., 2012; Brisbane et al, 2023).

In the search for a cost-sensitive alternative to custom insoles, two potential solutions have been offered. The first potential solution is semi-custom insoles. Insole laboratories have developed semi-custom insoles in an attempt to achieve a comparable level of personalization to custom insoles while lowering production costs. The process of making a semi-custom insole involves taking molds of a patient's feet, measuring certain dimensions, and making insoles based off of previously existing molds that best correspond to the patient's measurements. The semi-custom process cuts out molding steps, accruing money and time savings that are passed on to the patient. These benefits come at the cost of the insoles not being perfectly molded to the patient's foot. Semi-custom and custom insoles efficacy was compared in a pilot biomechanics study of 37 patients with abnormally high and low arches; the researchers found that both forms of insoles were biomechanically comparable and of similar comfort levels (Zifchock et al., 2008). Whereas semi-custom insoles are a step down from custom insoles, the other burgeoning solution is a step up from off-the-shelf insoles: chairside modification of off-the-shelf insoles. In chairside modification practices, the patient undergoes a biomechanical assessment, and podiatrists modify off-the-shelf insoles as they see fit, be that with a plantar metatarsal pad, valgus dome pad, rearfoot wedge, forefoot wedge, or other modification (Cameron-Fiddes et al., 2013). As the name suggests, these modifications can be performed on the day of the clinical

visit, which allows patients to instantly start reaping the therapeutic effects of orthotic wear. Despite the emergence of these solutions, off-the-shelf insoles are still the cheapest and most readily available insoles.

Despite the commonly-held belief that custom insoles are superior to off-the-shelf insoles, some research has indicated that they may actually be equally effective. In 2019, Tran et al. reported that custom and off-the-shelf insoles were equally effective in reducing pain or improving function in patients with plantar heel pain. Corroborating this finding, one biomechanics study on 15 patients with low arches found no significant differences in force distribution between semi-rigid off-the-shelf and semi-rigid custom insoles (Redmond et al., 2009). However, it is important to note that research has returned mixed results on the matter of custom vs. off-the-shelf insoles. For example, Stark et al. noted in 2023 that custom insoles offered an advantage over off-the-shelf insoles in function, but no differences in pain or mobility between insole types. Many factors influence the output of scientific studies of insoles, from the particular disease or disorder in question to the brand of insoles used to the comparative rigidity of the insoles to the variables tested. Due to the breadth of the insole research field, there has yet to be a scientific consensus on the comparative efficacy of off-the-shelf and custom insoles.

The quality of care a patient can achieve is directly impacted by their own unique foot shape, social and clinical pressures, costs, and insurance coverage. Insurance companies encourage patients to seek off-the-shelf insoles that can be bought cheaply in stores, although they may cover insoles if medically necessary (Stevens et al., 2021). Clinicians seek the dissolution of racial disparities in healthcare and attempt to provide patients with a standard of care that is balanced by cost feasibility and intervention effectiveness.

There is a lack of direct research studying racial disparities in musculoskeletal care. This has previously been noted as a knowledge gap, even among the medical practitioners in the field, which suggests a need to raise more awareness of such disparities to improve the quality of care for every patient (Stevens et al., 2021). Despite this knowledge gap, previous research in this field can be used to demonstrate that racial disparities exist in access to effective insoles. First, minorities experience worse clinical encounters than white people, across such metrics as orthotic acquisition failure rate (Rambo et al., 2022); insurance authorization; orthotic failure rate; time for evaluation, imaging, and treatment; follow-up visits; physical therapy; and outcomes (Sborov et al., 2023). Additionally, those seeking custom orthotics suffer extended wait times (Cameron-Fiddes et al., 2013). Second, minorities are more likely to have foot disorders (Golightly et al, 2012; Brisbane et al, 2023), making off-the-shelf insoles less likely to be effective for them. Off-the-shelf devices do not work well with those who have certain foot disorders (Zifchock et al., 2008). Compounding this, those who can wear off-the-shelf insoles experience equal efficacy for both custom insoles and off-the-shelf insoles; however, those with foot disorders that preclude off-the-shelf insole use stand to gain much more (Redmond, 2009). In summation, prior research in this area has asserted that minorities are disadvantaged in orthopedic care, more likely to have foot disorders, less catered to by off-the-shelf insoles, and subject to worse clinical encounters than their white peers.

To frame the argument that minorities face a disparity in access to effective insoles, a framework for analyzing healthcare disparities will be utilized. 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.” There are not direct statistics on the efficacy of off-the-shelf insoles across races, but other factors can be used to determine the likely

presence of bias: “(1) device factors, such as the design of the implant and its suitability for treating the patient's condition; and (2) features of the clinical encounter, such as the timeliness of the diagnosis and referral, and quality of communication between treating clinician and patient” (p. 572). By using the framework of device factors and clinical encounters, a racial disparity in access to effective insoles can be identified.

Methods

The research used to support this paper came from scholarly articles discussing the differences in likelihood of foot disorders across race; the ability of people with certain foot disorders to fit in off-the-shelf insoles; the efficacy, cost, and time of receipt of off-the-shelf vs. custom insoles; the differences in orthopedic clinical encounters across races; and a framework for studying bias in medical devices. This evidence was acquired from widely-cited papers, including some intensive review articles, via a rigorous literature search. Foot orthotics other than insoles, such as orthopedic shoes, were excluded from the device factors aim of the paper to narrow the research direction. The main exclusion criterion for the studies was having a sample size less than 100. However, some pilot studies and biomechanics studies with smaller sample sizes were included to supplement the breadth of burgeoning areas of foot orthotics study; where used in this paper, the sample size of these studies was noted.

In addition to device factors, direct clinical encounter evidence will establish that minority patients face higher wait times, worse orthotic receipt and follow-up rates, and worse overall outcomes than their white counterparts.

Results, Discussion, and Analysis

There are disparities in the prevalence of foot disorders across race. Black Americans are more likely than white Americans to have pes planus (low arches), hallux valgus, hammer toes,

and overlapping toes (Golightly et al., 2012; Brisbane et al, 2023). The etiology of these differences is not fully known, although shoe wear history, osteoarthritis, and occupation are suggested as possible factors. As a self-fulfilling prophecy, foot disorders themselves put people at greater risk of disability and falls, which is itself another source of disparity (Golightly et al., 2012).

As off-the-shelf devices do not work well for everyone and minorities are more likely to have foot disorders and conditions that preclude the wearing of off-the-shelf insoles, minorities are less likely to be able to benefit from off-the-shelf insoles. This incompatibility of off-the-shelf insoles with people of certain foot types details a device factor failing that requires some patients to seek personalized insoles to achieve the same level of care (Zifchock, 2008). In other words, off-the-shelf insoles as a technology offer a lower benefit for minorities than their white peers on the whole. Other reasons beyond foot disorders that require patients to seek custom insoles include excessive callusing and ulceration, which are symptoms of diabetes, which disproportionately affects minorities (Robinson et al., 2015). So, even those minority subjects without foot disorders have a higher need for custom insoles due to their higher likelihood of diabetes. The uneven outcomes of off-the-shelf insoles at treating people of different races highlights a disparity in device factors.

Similarly, custom insoles have a disparate potential benefit for people of different races. The white majority, less likely to have foot disorders, seems to extract no special benefit of custom insoles over off-the-shelf insoles (Redmond, 2009). On the other hand, minorities could reap enormous health benefits from custom insoles when compared to off-the-shelf insoles. One facet of this benefit is the case of black Americans and diabetes. On average, black Americans have a lower arch height than white Americans, rendering them more susceptible to diabetic foot

ulcers that can result in amputation and disability. Already at higher risk for foot ulcers, amputation, and death from diabetes than white Americans, black Americans have much to gain from effective insoles, but they are disadvantaged in acquiring them (Brisbane et al., 2023).

Despite the potential benefits of custom insoles, minorities are less likely to be able to afford custom insoles (Cameron-Fiddes et al., 2013). To acquire a pair of custom insoles, people must pay an average of 3.5 times more than off-the-shelf insoles, between \$100 and \$400, which is a prohibitively high cost for lower-income Americans, especially considering insurance plans often do not cover the cost of custom insoles (Zifchock et al., 2008). According to a 2021 study of orthopedic insole patients, race, form of insurance, and orthotic cost are major predictors of whether or not patients received their prescribed orthoses, and financial concerns were the main reason why people did not acquire prescribed orthoses (Stevens et al.). Interestingly, the same study found that even after accounting for insurance status, white patients were still three times more likely to receive their insoles than black patients. This finding suggests a financial and perhaps cultural barrier in minorities' utilization of medical care. The failure of insurance companies, orthotics companies, hospital administrators, and clinicians to adequately support those who need custom insoles is a major underlying factor in minorities' inability to access their required care.

Beyond the financial strain, custom insoles also take much longer from prescription to receipt; while off-the-shelf insoles can be acquired the same day as prescription, it can take weeks and months to get custom insoles (Cameron-Fiddes et al., 2013). Due to their increased likelihood of foot disorders and subsequent need to seek custom insoles, minorities bear a heavier financial and temporal burden of achieving effective bracing and treatment.

Beyond the financial and time issues, this issue also becomes a health burden. For some conditions, including rheumatoid arthritis and diabetes, the timeliness of insole use is tied closely to patient outcomes. For example, rheumatoid arthritis patients must be treated as early as possible to improve short-term pain and curb long-term deformity (Cameron-Fiddes et al., 2013). Further, in the case of diabetes, an estimated 50% to 75% of amputations can be prevented by early diagnosis, intervention, and treatment, which may include orthotics (Robinson et al., 2015). This means that patients who can use off-the-shelf insoles can start treatment immediately, but those who require custom insoles (disproportionately minorities) have to wait weeks or months for effective bracing, allowing ample time for their condition to deteriorate. Thus, the disparity facing minorities is not only financial and temporal, but is also a health burden.

In addition, minorities experience worse clinical encounters, which contributes to the disparity. Notable parameters of the clinical encounter include wait time, quality of the interactions between the clinician and the patient, and treatment outcomes (Hutchison, 2019).

Wait times for patients seeking orthotic care are often longer for minority patients. Minorities wait on average four times longer than their white peers for insurance to authorize lower limb orthotics. In addition, minority pediatric patients face longer wait times for both imaging and treatment (Sborov et al., 2023). Wait time is just one clinical encounter aspect that highlights disparities in orthopedic care for minority patients.

Minorities experience worse clinician-patient interactions and treatment outcomes in orthopedic care. Minorities have a lower rate of acquiring prescribed orthotics, which is indicative of some failing in the clinical encounter in expressing the importance of orthotic care (Stevens et al., 2021). Further, the failure rate in acquiring prescribed lower extremity orthotics is 1.64 times higher for black pediatric patients and 2.71 higher for Hispanic pediatric patients than

for their white counterparts (Rambo et al., 2022). Minority pediatric patients also face a higher orthotics failure rate; fewer follow-up visits; less physical therapy; and worse outcomes (Sborov et al., 2023). There are known racial disparities in clinical encounters for patients seeking orthotics across wait time, receipt and acquisition rates, follow-ups, and outcomes.

In summation, device factors in off-the-shelf insoles and clinical encounters highlight a racial disparity in insole access. The failings of off-the-shelf insole device factors to adequately support people of different foot types and racial groups was established to suggest that minorities are more likely to need expensive, hard-to-access custom insoles, resulting in financial, time, and health burdens. Clinical data demonstrated that minorities face longer wait times, lower orthotic receipt rates, and worse outcomes. A racial disparity in access to effective insoles was investigated through the scaffolds of device factors and clinical encounter data.

Conclusion

Despite sparingly little research into racial disparities in orthopedic care, concrete evidence of a racial disparity in access to effective insoles has been collected through the lenses of device factors and clinical encounters. The next step in research should be gathering quantitative data comparing the efficacy of off-the-shelf insoles for different racial groups. This paper demonstrates the failure of off-the-shelf insole device factors to equally accommodate all racial groups and collates clinical encounter failings. By elucidating the extent of this racial disparity, this paper will inform clinicians on the aspects of clinical encounters that need improvement and may lead to increased prescription of custom insoles for minorities, or perhaps increased adoption of chairside modification methods to improve the fit of off-the-shelf insoles. These findings may encourage insole laboratories to improve the pricing, availability, and accessibility of semi-custom insoles. Moreover, findings about inequalities in clinical

interactions and device factors will empower minority patients, clinicians, and orthotic companies to seek an equal standard of care for all patients.

References

- Brisbane, J. M., McCullough, M. B. A., Baker, C., London, J. S., & Queen, R. M. (2023). Impact of Race, gait speed and arch height on plantar loading. *Journal of Biomechanics*, 155, 111648. <https://doi.org/10.1016/j.jbiomech.2023.111648>
- Cameron-Fiddes, V., & Santos, D. (2013). The use of ‘off-the-shelf’ foot orthoses in the reduction of foot symptoms in patients with early rheumatoid arthritis. *The Foot*, 23, 4, 123-129. 10.1016/j.foot.2013.09.001
- Golightly, Y. M., Hannan, M. T., Dufour, A. B., & Jordan, J. M. (2012). Racial differences in foot disorders and foot type. *Arthritis Care & Research*, 64(11), 1756–1759. <https://doi.org/10.1002/acr.21752>
- Hutchison, K. (2019). Gender Bias in Medical Implant Design and Use: A Type of Moral Aggregation Problem? *Hypatia*, 34(3), 570–591. <https://doi.org/10.1111/hypa.12483>
- Rambo, A., Rhodes, L., Lomax, J., Cao, X., Steele, J., Romer, K., Spence, D., Sheffer, B. W., Warner, W. C., Sawyer, J. R., & Kelly, D. M. (2022). Factors that Influence Acquisition of Lower Extremity Braces in the Pediatric Orthopaedic Population. *Journal of Pediatric Orthopaedics*, 42(1), 40. <https://doi.org/10.1097/BPO.0000000000001998>
- Redmond, A. C., Landorf, K. B., & Keenan, A.-M. (2009). Contoured, prefabricated foot orthoses demonstrate comparable mechanical properties to contoured, customised foot orthoses: A plantar pressure study. *Journal of Foot and Ankle Research*, 2, 20. <https://doi.org/10.1186/1757-1146-2-20>
- Sborov, K. D., Haruno, L. S., Raszka, S., & Poon, S. C. (2023). Racial and Ethnic Disparities in Pediatric Musculoskeletal Care. *Current Reviews in Musculoskeletal Medicine*, 16(10), 488–492. <https://doi.org/10.1007/s12178-023-09860-0>

- Stevens, T. T., Bettin, C. C., Murphy, G. A., Richardson, D. R., Gear, B. J., & Hartline, J. T. (2020). Predictive Variables for Patient Compliance with Physician Prescribed Orthotics. *Foot & Ankle Orthopaedics*, 5(4), 2473011420S00460. <https://doi.org/10.1177/2473011420S00460>
- Stevens, T. T., Hartline, J. T., Ojo, O., Gear, B. J., Richardson, D. R., Murphy, G. A., & Bettin, C. C. (2021). Race and Insurance Status Association With Receiving Orthopedic Surgeon-Prescribed Foot Orthoses. *Foot & Ankle International*, 42(7), 894–901. 10.1177/1071100721990343
- Williams, D. R., & Rucker, T. D. (2000). Understanding and Addressing Racial Disparities in Health Care. *Health Care Financing Review*, 21(4), 75–90.
- Zifchock, R. A., & Davis, I. (2008). A comparison of semi-custom and custom foot orthotic devices in high- and low-arched individuals during walking. *Clinical Biomechanics*, 23(10), 1287–1293. <https://doi.org/10.1016/j.clinbiomech.2008.07.008>