Development of a Custom 3D-Printed Ankle Brace for Chronic Ankle Instability

(Technical Paper)

Creating Equitable Access to Orthopedic Devices & Treatment for Low-Income Populations

(STS Paper)

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
William P. Zimmerman

October 27, 2022

Technical Team Members:
Emma Donatelli
Ashar Kamal
Erin McIlhinney

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. MC Forelle, Department of Engineering and Society

Dr. Timothy Allen, Department of Biomedical Engineering

Introduction

Musculoskeletal disorders hinder the mobility and dexterity of the human body, and they plague the daily lives of an estimated 1.71 billion people worldwide (World Health Organization, 2022). Chronic ankle instability, or CAI, is a type of musculoskeletal disorder that affects the strength and stability of the ankle joint. CAI encompasses a variety of prevalent ankle injuries from acute ankle sprains to drop foot (Al-Mohrej et al., 2016). Generally speaking, ankle injuries are difficult to treat due to the complexity of the joint and the many surrounding ligaments. For some ankle issues like severe fractures, surgical procedures are needed to structurally repair the joint and enable full recovery (Cleveland Clinic, 2020). However, orthopedic surgery is typically very expensive and not always necessary to prompt the healing process. Physicians often recommend assistive technology, such as bracing, to aid in a patient's recovery.

The market for orthopedic devices has steadily grown over the past decade and is expected to continue on its current trajectory to reach $68.5 billion by 2027 (Orthopedic Devices Market Size, 2020). Despite this growth, access to orthopedic bracing and treatment remains limited, specifically for low-income populations. It is glaringly evident that the existing healthcare system does not adequately serve every community it reaches. Healthcare disparities related to funding, resources, and regulations lead to lower-level care and decreased accessibility across the board for marginalized socioeconomic groups (Centers for Disease Control and Prevention, 2020). Further, structural racism – rooted in America's history with slavery – plays a role in perpetuating these inequalities and preventing African Americans from receiving the proper treatment for musculoskeletal injuries. On top of this, the incidence of musculoskeletal disorders such as arthritis was actually found to be higher in those who have retired from blue-collar jobs when compared to their more affluent white-collar counterparts (Caban-Martinez

et al., 2011). It is clear that systemic change is needed to tackle the ongoing problems that low-income communities experience in orthopedic care. The advancement of 3D-printed ankle bracing may be a potential first step.

The technical portion of my prospectus seeks to combat CAI through the design and fabrication of a novel ankle brace that will mitigate ankle pain instability. The goal of creating a custom 3D modeled brace is to provide targeted care to each individual based on their specific ankle pathology. The STS portion of my prospectus will delve into the realm of orthopedic care more broadly and identify limitations in accessibility for low-income individuals. My research will ultimately provide an engineering solution addressing CAI, as well as a plan of action to address systemic issues, both of which will contribute to increasing accessibility of the brace to target patients.

Technical Project: Development of a Custom 3D-Printed Ankle Brace for Chronic Ankle Instability

Epidemiology studies show that up to 40% of ankle sprains can result in CAI (Hershkovich et al., 2015). A majority of these sprains occur laterally – on the outside of the foot – resulting in ankle inversion (Herzog et al., 2019). Another CAI pathology is drop foot, which is typically the result of a neurological disorder called Charcot-Marie-Tooth (CMT) that reduces control in the muscles that support dorsiflexion, or flexing the ankle upwards (MedlinePlus, 2018). Certain groups such as athletes and military service members are at a higher risk of acute ankle sprain, so they are more prone to developing CAI throughout their lives. CAI can be a massive roadblock, not only in these professions, but for anyone who enjoys being physically active. Thus, I aim to engineer solutions that will mitigate its negative impact.

Despite the persistent need for CAI solutions, there is a surprising design gap in the current ankle brace market. Current technologies are limited to either rigid Ankle-Foot Orthoses (AFOs) such as the Alimed Freedom® Swedish AFO (AliMed, 2022), or compressive support braces such as the Bauerfeind® Sports Ankle Support brace (Bauerfeind, 2022). These braces provide assistance to drop foot and lateral ankle sprain, respectively, but they each have significant limitations in their design that leave room for technological innovation. Neither of these braces are tailored to the individual, so issues with comfort and ankle security may arise. Additionally, like most AFOs, the Alimed almost completely restricts the ankle's range of motion, which is normally undesirable. The Bauerfeind® compression brace, on the other hand, only provides a marginal amount of support that cannot be adjusted. With this many design problems yet to be solved, I have chosen to work on product development of a custom 3D printed ankle brace with adjustable tensioning and multi-axial control, in conjunction with a local biotech startup – Icarus Medical.

My technical project will leverage existing Icarus technologies in the process of developing an ankle brace targeted at three main forms of CAI: acute ankle sprain (both lateral & medial) and drop toe. Since its inception in 2020, Icarus has sold 3D printed knee braces to patients with osteoarthritis. Icarus' patented LIDAR technology allows patients to scan their own leg using a smartphone app, and this is how braces are customized to the individual (Icarus Medical, 2022). Braces are then modeled using Fusion360 – a CAD software – and 3D printed in-house. The goal of my technical research and development is to finalize a functional ankle brace design using these existing tools and techniques, ultimately to create a product that is scalable and marketable. Since the majority of Icarus' current knee brace revenue comes from orthopedic clinics, the advancement of this project is extremely relevant to my STS topic as well.

STS Project: Creating Equitable Access to Orthopedic Devices & Treatment for Low-Income Populations

Just as important as developing technically viable products is ensuring that these products will effectively reach their intended users. In orthopedic device design specifically, the user is centric to all aspects of design and innovation. Engineers often get carried away by trying to create the most creative, efficient, and profit-generating technology possible while failing to understand how this may induce social ramifications such as restricted accessibility for marginalized populations. I will first apply the Social Construction of Technology (SCOT) framework when analyzing these limitations. SCOT suggests that a product or machine is defined by how relevant social groups use and interpret it (Pinch & Bijker, 1984, p.414). "Relevant social groups" refer to a group of individuals "who share the same set of meanings attached to an artifact," or piece of technology. In the orthopedic space this is typically more affluent people, thus these groups often have a stronger influence on the way devices are adopted and integrated into society. According to a cross-sectional study conducted in 2010, the median treatment cost for lateral ankle sprains was $1008 (Shah et al., 2016). This data helps to express that, for low-income individuals, it is often more feasible to leave injuries untreated in order to reduce excess costs. However, this perspective is clearly unequitable and needs to be systemically addressed through healthcare policy and administration.

In addition, the reach of orthopedic care is dampened by the current system which limits high-end procedural options and bracing availability to those with prescriptions from a physician. This brings another STS perspective to light: the Ethnography of Infrastructure. One of the properties of infrastructure, as described by Susan Leigh Star, is the extent of its reach or

scope (Star, 1999). Essentially, in the realm of orthopedic treatment this calls upon the affordability of doctor's appointments along with the scope of insurance coverage. A 2016 study by the CDC showed that 25% of the population classified as "low-income" indicated troubles paying their medical bills, with another 23% of that population having no usual source of care (Cunningham, 2018). Combined with the fact that this same group exhibited greater health risk factors across the board (eg. obesity), it is clear how the current infrastructure alienates less affluent groups and elicits systematic healthcare restrictions based on socioeconomic status. Further, significant orthopedic treatment disparities exist due to varying insurance types. While over 80% of private insurance and Medicare holders were given orthopedic appointments without a referral (according to a 2018 study), only 55% of Medicaid holders were able to get one even *with* a referral, and the other 45% were denied entirely (Segal et al., 2018). Insurance is another factor that greatly diminishes the scope of orthopedic treatment, and thus it is important to critique and push for changes in the infrastructure to broaden its social reach.

Although it is imperative to consider the pipelines that allow for brace accessibility, the sociopolitical nature of the technology itself is another barrier to consider and overcome. The design of ankle braces as artifacts can be seen as inherently discriminatory, especially to lower-income communities which generally experience higher obesity rates – making it harder to fit into standard brace sizes (Cunningham, 2018). This ties back into the aforementioned SCOT framework that establishes how technological artifacts evolve due to sociopolitical influence. The fact that we see explicit biases towards obese individuals in brace design epitomizes SCOT as it truly does shape how their technology will become integrated into society.

Research Question & Methods

The research question that will be explored in my thesis is: *In what ways are lower-income communities restricted access to orthopedic treatment?* This question is important for a number of reasons. First, as a society we must work toward eliminating structural biases, and this includes seeking equitable healthcare solutions. Second, it is important to understand the profound socioeconomic impact of orthopedic injury and trauma (O'Hara et al. 2020). Lastly, identifying ways to increase accessibility to orthopedic treatment will, by and large, improve the viability of our ankle brace in the market.

One of the main objectives of my thesis will be to identify historical events and policy changes that have contributed to the system of inequity currently seen in orthopedic care. To do this, I will collect healthcare and public policy data from relevant time frames – such as the Jim Crow era – in order to analyze trends on racial and socioeconomic discrimination (Yearby, 2018). Using this data, I aim to provide suggestions on how to counteract structural inequities in the orthopedic space. Another objective of my report will be to address equitable market entry strategies with the goal of increasing the accessibility of our brace, particularly in low-income areas. This objective will incorporate research on different clinics, health insurance plans, and physician implicit biases to help model a comprehensive strategy on allocating resources to marginalized communities.

Conclusion

The prevalence of musculoskeletal disorders, particularly CAI, has introduced a need for novel, personalized ankle bracing technology. However, current limitations in brace accessibility make it equally important to identify the roots of socioeconomic disparities in orthopedic treatment. It is imperative that, as a society, we work to combat these disparities so that *all*

individuals can receive proper medical care. Through the described methods above, I will seek to promote greater accessibility of our ankle brace and other orthopedic products alike.

References

Al-Mohrej, O., & Al-Kenani, N. (2016). *Chronic Ankle Instability: Current Perspectives*. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5054646/

Ankle and Foot Orthoses (AFOs). (2022). AliMed. https://www.alimed.com/afo/?gclid=CjwKCAjw2OiaBhBSEiwAh2ZSP8O4hVFiBr_SS9vNRZUpAbV-rDYQR3dvgSK4H4YUCMC8F_xWOVbyEBoCveIQAvD_BwE

Ankle Braces. (2022). Bauerfeind. https://www.bauerfeind.com/b2c/Products/Ankle-Braces/c/ankle-braces?gclid=CjwKCAjw2OiaBhBSEiwAh2ZSP91r-kNgsqM-WCNBOgTOBeKD2IBtnrwZSRjJiDRHYYalgBW8zTPxixoCNrsQAvD_BwE

Ankle Surgery. (2020, February 11). Cleveland Clinic. https://my.clevelandclinic.org/health/treatments/21047-ankle-surgery

Caban-Martinez, A., Lee, D., Fleming, L., Tancredi, D., Arheart, K., LeBlanc, W., McCollister, K., Christ, S., Louie, G., & Muennig, P. (2011). *Arthritis, Occupational Class, and the Aging US Workforce*. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3154222/

Charcot-Marie-Tooth Disease. (2018, October 1). MedlinePlus. https://medlineplus.gov/genetics/condition/charcot-marie-tooth-disease/#frequency

Choonara, Y., du Toit, L., Kumar, P., Kondiah, P., & Pillay, V. (2016). *3D-Printing and the Effect on Medical Costs: A New Era?* Expert Review of Pharmacoeconomics & Outcomes Research.

https://www.researchgate.net/publication/289570223_3D-printing_and_the_effect_on_medical_costs_A_new_era

Cost of Osteoarthritis. (n.d.). Osteoarthritis Action Alliance. https://oaaction.unc.edu/policy/cost-of-osteoarthritis/

Cunningham, P. (2018, September 27). *Why Even Healthy Low-Income People Have Greater Health Risks Than Higher-Income People*. The Commonwealth Fund. https://www.commonwealthfund.org/blog/2018/healthy-low-income-people-greater-health-risks#:~:text=Although%20research%20has%20shown%20that,%2Dincome%20people%20(4%25).

Health Disparities. (2020, November 24). Centers for Disease Control and Prevention. https://www.cdc.gov/healthyyouth/disparities/index.htm

Hershkovich, O., Tenenbaum, S., Gordon, B., Bruck, N., Thein, R., Derazne, E., Tzur, D., Shamiss, A., & Afek, A. (2015). *A Large-Scale Study on Epidemiology and Risk Factors for Chronic Ankle Instability in Young Adults*. The Journal of Foot and Ankle Surgery. https://journals.scholarsportal.info/details/10672516/v54i0002/183_alsoeacaiiya.xml

Herzog, M., Kerr, Z., Marshall, S., & Wikstrom, E. (2019). *Epidemiology of Ankle Sprains and Chronic Ankle Instability*. Journal of Athletic Training. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6602402/#:~:text=A%20sprain%20of%20the%20lateral,in%201%20competition%20or%20practice

Improving Data Collection Across the Healthcare System. (n.d.). Agency for Healthcare Research and Quality. https://www.ahrq.gov/research/findings/final-reports/iomracereport/reldata5.html

Musculoskeletal Health. (2022, July 14). World Health Organization. https://www.who.int/news-room/fact-sheets/detail/musculoskeletal-conditions

O'Hara, N., Isaac, M., Slobogean, G., & Klazinga, N. (2020). *The Socioeconomic Impact of Orthopaedic Trauma: A Systematic Review and Meta-Analysis*. Plos One. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0227907

Orthopedic Devices Market Size, Share & COVID-19 Impact Analysis, By Type (Joint Reconstruction Devices, Spinal Devices, Trauma Devices, Orthobiologic Devices, Arthroscopy Devices, and Others), By End User (Hospitals, Orthopedic Clinic, Ambulatory Surgical Centers, and Others), and Regional Forecast, 2020-2027. (2020). https://www.fortunebusinessinsights.com/orthopedic-devices-market-102586

Pinch, T. & Bijker, W. (1984). *The Social Construction of Facts and Artefacts: Or How the Sociology of Science and the Sociology of Technology Might Benefit Each Other.* 399-441.

Segal, D., Grabel, Z., Shi, W., Gottschalk, M., & Boden, S. (2018). *The Impact of Insurance Coverage on Access to Orthopedic Spine Care*. Journal of Spine Surgery. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6046315/

Shah, S., Thomas, A., Noone, J., Blanchette, C., & Wikstrom, E. (2016). *Incidence and Cost of Ankle Sprains in United States Emergency Departments*. Sports Health. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089353/

Sismondo, S. (2008). *Science and Technology Studies and an Engaged Program*. 13–26.

Star, S. L. (1999). *The Ethnography of Infrastructure*. 377–390.

The Icarus Ascender. (2022). Icarus Medical. https://icarusmedical.com/

Yearby, R. (2018). *Racial Disparities in Health Status and Access to Healthcare: The Continuation of Inequality in the United States Due to Structural Racism*. The American Jounal of Economics and Sociology. https://onlinelibrary.wiley.com/doi/full/10.1111/ajes.12230?casa_token=n8-sqX0GTHUAAAA%3A8tWCdCeXcGnCuCFlb9E3pJFWpHNkDOLkukRUNVJED1QIbh_I9HcAQWjK-YCebpEwfLg25dr313UQnxY