Development of a Dynamic Tensioning Ankle Brace for Chronic Ankle Instability
(Technical Paper)

Impact of Additive Manufacturing Techniques on Underrepresented Patient Demographics in the Bracing Industry
(STS Paper)

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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 STS Thesis-Related Assignments

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Introduction

Bracing technology in the medical field has focused primarily on mass production of standardized joint braces. This results in a bracing device tailored to the general population of the 50th percentile male body (*Anthropometry and Biomechanics,* n.d.). Even for the general population, these braces provide an inadequate fit and thus imperfect unloading and support for the targeted joint. Icarus Medical Innovations, a company out of Charlottesville VA, has seemingly solved this problem. Through the use of scanning technology and 3D printing, Icarus has developed a custom fit, unloader knee brace (*Brace yourself; cutting edge medical device startup launches breakthrough mobility technology,* 2020). The custom fit and technology of production is truly innovative in the field of orthopedic braces and has the ability to significantly improve the quality of life for many people suffering from degenerative joint conditions such as osteoarthritis.

The capstone portion of my project will be focused on developing a brace to treat chronic ankle instability (CAI) and ankle osteoarthritis (OA) which utilizes the technology that Icarus has implemented into their knee brace. CAI is caused by the weakening of the lateral tendons in the ankle from high or recurring ankle sprains or a structural abnormality at birth (*Journal of the American Academy of Orthopaedic Surgeons,* 2008). On the other hand, ankle OA is caused by the deterioration of soft tissue in the ankle joint resulting in bone on bone contact which causes significant pain, inflammation, and bone osteophytes (*Clinical Orthopaedics & Related Research,* 2009). Current ankle bracing technologies ineffectively address inversion and eversion of the ankle. Additionally, these braces fail to allow sufficient dorsiflexion and plantarflexion of the foot, due to unnecessary rigidity and stiffness of the brace. This leaves a large market gap for an effective and flexible ankle brace.

The STS research portion of this proposal will look at the rapid production of a custom knee brace and its effect on the rapidly developing field of personalized medicine. The novelty of being able to tailor a medical solution to the individual patient seems extremely desirable for both effectiveness and risk mitigation. The improvement in patient outcome has been widely studied and proven in scenarios such as drug specification and device customization. In the specific case that will be explored in this article, custom fitted braces provide a solution to living an active lifestyle and successfully postponing surgery or avoiding surgery entirely (*BMJ Open Sport & Exercise Medicine,* 2017). This prospectus will explore the impact effective bracing technologies can have on a society that is constantly looking to develop new ways to prolong a functioning and mobile life. Additionally, the problem of mass production and distribution of custom patient matched braces will be explored. From this exploration, a comprehensive look at improving quality of life through effective bracing technologies will be provided.

Capstone Project

My capstone project will be focused on the production of a custom fit bracing technology for the ankle joint. My group and I will be working with the small startup company Icarus to expand their product line. Icarus has developed a process for rapid customization of joint braces to the patient anatomy using scanning technology and 3D printing. Currently, this technology has been applied to the knee joint in the form of the Ascender, a knee brace that unloads roughly 40% of the average force applied to the patellofemoral compartment (Icarus Medical, 2021). While the knee brace itself is innovative in its biomechanical properties, the process that Icarus has developed to produce the knee brace may be even more innovative. The customization of the brace to the patient's lower thigh, knee, and upper shin regions provides a perfect fit to the patient's anatomy. Additionally, the rapid process in which the braces are 3D printed enables the

brace to be available to the patient in 24-48 hours. The novelty of this product provides avenues for bracing solutions outside of the knee joint.

In order to provide a wider array of products available to patients in need of various bracing technologies, my group will aim to adapt Icarus' process of rapid customization to a specific need in a different joint. Through product research and customer discovery, we decided to target the ankle joint. Chronic ankle instability (CAI) is an extremely prevalent condition characterized by weakened tendons in the lateral side of the ankle due to recurring injuries such as sprains or an underlying condition (*Journal of the American Academy of Orthopaedic Surgeons,* 2008). Ankle braces range from gauntlet ankle braces made from cheap, flexible fabric to carbon-fiber spiral braces with semi-rigid footplates. These types of braces address one of two domains for aids to chronic ankle instability: stability or unloading. Off the shelf, gauntlet braces address stability while carbon-fiber spiral braces unload the ankle joint.

The first of these domains is stabilizing the ankle joint. This is done primarily through the use of gauntlet braces that wrap tightly around the ankle joint with loose fabric and prevent movement in the medial and lateral directions (Ankle Foot Orthoses for the Athlete, 2017). In addition to stabilization, large spiral braces clasp tightly around the anterior and posterior tibial sections and, through a connection to a semi-rigid footplate, provide superior unloading of the ankle joint (*Plastic spiral ankle-foot orthoses, 1974*). This unloading is necessary in the case of ankle osteoarthritis and can prolong the necessity for implant surgery and reduce pain in the joint. The purpose of my capstone project will be to implement the unloading technology developed by Icarus into an ankle brace that addresses both unloading and stability of the ankle joint. This brace will be produced using the scan to 3D printing process that is utilized by the

knee brace in order to provide a perfectly custom fit in a short amount of time. The novelty of this knee brace would provide much needed comfort and longevity for patients with CAI.

STS Thesis

Research Question: To what extent does the process for rapid production of a customized unloading knee brace impact the emerging field of personalized medicine and medical solutions?

Personalized medicine is a growing field with widespread application in medical solutions. From drug delivery to external technologies, personalization and customization of these devices both improve effectiveness and reduce risk. In the case of bracing technologies, the ability to scan patient anatomy and construct a brace that perfectly fits the body part and is able to address specific patient needs is extremely beneficial. However, this is not often explored due to the inability for mass production. For this reason, general technologies such as external braces are still tailored to the average male body. This results in discomfort and overall ineffectiveness when these technologies are applied to demographics that are not the average male such as females or disabled individuals. Therefore, there is a pressing need in the medical device industry to explore the extent to which personalization of devices to the specific patient provides improved care and treatment.

I will explore this question through multiple STS lenses in order to provide a comprehensive look at personalized medicine. The first of these lenses will be Actor Network Theory (ANT). There is a plethora of actors that are applicable to the network of braces. To explore how the patients, braces, bracing companies, insurance agencies, and doctors all work together to create the network of artificially alleviating pain in joints for people with severe osteoarthritis (Oxford Research Encyclopedia of Literature, 2020). Specifically, I will be focusing on the role of the underrepresented patient and the company producing the medical

devices for these patients. These actors play a significant role in the network of medical devices and the potential for personalized solutions. The second of these lenses will be exploring the politics that personalized bracing technologies inherently hold and are given by the distributors and users. In the context of bracing technologies, this analysis will look at how mass produced braces undervalue disabled people and people who belong to demographics not encompassed by the 50th percentile male (*Anthropometry and Biomechanics,* n.d.). This will be done by exploring the insurance coverage provided for customized bracing technologies as well as the companies that produce the braces themselves (Centers for Medicare & Medicaid Services, 2021). Using these STS theories, it will be possible to determine why current medical device technologies are tailored to the average male population and how personalized solutions can reduce marginalization of individuals with disabilities and individuals with a range of body types.

Key Texts

First, my thesis will analyze literature that supports the production of technologies that are tailored to the individual. *Brilliant Imperfections,* by Eli Claire, explores how underrepresented demographics are discriminated against in the medical device industry. Mass produced bracing technologies are designed for the average 50th percentile male. This devalues societal differences such as body type, gender, and disabilities. Claire argues that this treatment of individuals as a common, homogenized mass produces a bias within society towards deeming people who don't fit the 50th percentile male description as problematic. Through this lens, I will determine the extent that personalized solutions can promote equality amongst different demographics in society. This exploration will include the use of Langston Winner's text, *Do Artifacts Have Politics?.* This will provide context into why technologies are designed in a way that excludes specific demographics. In addition, my analysis will look at the possibilities of

establishing care webs. Leah Lakshmi Peipzna-Samarasinha's book *Care Work: Dreaming Disability Justice,* looks into the creation of care webs for underrepresented populations in the medical devices field. My analysis will determine the effectiveness of care webs in the context of creating medical technologies such as bracing devices that are designed for these minorities.

In addition, my thesis will incorporate research into the challenges that personalized medical devices face in production. Using the theory of economies of scale I will look into the problem of inefficiency in producing personalized braces (Economies of scale in theory and Practice, 1972). Without the ability to mass produce the product, the braces must be covered by an insurance code that reimburses a substantial amount of money for the patient (Centers for Medicare & Medicaid Services, 2021). This is a necessity if the company that produces the braces is to make a profit. In addition to an economic lens, I will analyze the process by which personalized technologies are produced through the lens of Carl Marx and his piece *Capital*. I will use this text to analyze the negative effects of the novel process for production of personalized bracing solutions on human labor and work. Using these texts, I will weigh the cost benefit of the production of custom bracing devices. Ideally, this exploration will prove the necessity of personalized medical technologies.

Conclusion

In summary, this prospectus will cover bracing technologies and the effect of customization of these braces on society and the network of healthcare providers. The capstone portion of this report will attempt to develop a novel ankle brace that addresses the problems with CAI and ankle OA. Through full product development, the result of this project will be a marketable brace that incorporates adjustable tensioning and customization via a scan and 3D print. This brace will improve patient quality of life and provide the possibility of postponing or

even avoiding surgery entirely. Furthermore, the effects of improved care through customization on the network of industries that benefit from the problems such as OA will be explored. This will involve a dive into the problem of mass production and the results that come from introducing a technology that has the potential to eliminate an industry. This will all be accomplished by analyzing personalized medicine in the form of customizable bracing technology.

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