Thesis Project Portfolio

Novel Distraction-Unloader Knee Braces for Medial Compartment Knee Osteoarthritis

Racial Disparities in Access to Effective Insoles

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Executive Summary

Orthotics offer therapeutic benefits to a wide variety of conditions by aligning musculoskeletal systems in a non-invasive manner. The technical side of this project involves the Adonis, a new orthotic introduced by Icarus Medical. The Adonis aims to treat medial compartment osteoarthritis by utilizing unloader and joint distraction technology. While the Adonis has many potential benefits, it suffers from a complex strapping system. In addition, it lacks clinical and modeled evidence proving its effectiveness. The sociotechnical side of this thesis involves identifying a racial disparity in access to effective foot orthotics, or insoles. While a racial disparity in clinical encounter quality has been previously established, there is another aspect of the disparity that has not been explored: device factors leading to unequal efficacy of off-the-shelf insoles, leading certain racial groups to require more costly custom insoles at higher rates. Both parts of this thesis identify current failings in the field of orthotics and propose solutions for improving orthotics technology and accessibility.

The Adonis brace uses a combination of technologies to alleviate medial compartment pain, but design improvements must still be made and effectiveness of the device must be established. To assist the production and validation of the Adonis brace, a three-pronged project was undertaken: improving the strapping system, submitting a project for institutional review board (IRB) approval to start a clinical trial, and making a knee model to measure the forces on the medial compartment. To improve the strap system, we simplified our four-clip system to a two-clip system. To submit the project for IRB approval, we conducted an extensive literature review and coordinated with clinicians, engineers, and statisticians to write a protocol for three of Icarus' novel orthotic devices. To construct a force-measuring knee model, we utilized computer-aided design (CAD), three-dimensional (3D) printing, and force-sensitive resistors in

an Arduino circuit. We found that strap simplification improved ease of donning and doffing, but worsened comfort and flexibility. The clinical trial has not been approved yet, but we succeeded in our goal of submitting the project to the IRB. The force-measuring circuit was successfully used to measure the force in the medial compartment, but requires further work to output the desired metrics.

The research question guiding my sociotechnical project was: what is the extent of the racial disparity in access to effective foot orthotics in the United States? The paper used an ethical framework that defined bias in medical devices as stemming from two sources: clinical encounter quality and device factors. I collated previous research identifying that minorities face worse clinical encounters than the white majority. Further, I incorporated research that showed differences in foot disorder likelihood across races to claim that minorities are less suited to cheap off-the-shelf orthotics. This inequality in device factors leads to minorities needing custom braces at a higher rate, which are more costly and take longer to make. I identify how device factors failings in off-the-shelf braces result in a financial, temporal, and (subsequently) medical disparity. I also identify that minorities have more to gain from effective insoles than the white majority, but they are less likely to be able to access them. In conclusion, I found that the racial disparity in access to effective insoles stems from both clinical encounters and device factors, and results in financial, temporal, and medical burdens felt heavier by minorities.

My research into orthotics this year has been fruitful. I achieved most of what I set out to do and achieved some things I did not anticipate at the start of the projects. In terms of the technical project, we tested a potential way to make the strapping system less complex. While our design was not chosen, it did inform the final device design. We were unable to get clinical trial data or establish how effective the Adonis is at unloading the medial compartment, but we

made considerable progress in these areas that will be a benefit to Icarus in the future. To get the desired metrics (extent of unloading of the medial compartment when wearing the brace vs. not), the model must be extended to incorporate physiological leg lengths, encased in silicone, and rated for a higher weight by changing the force-sensitive resistor. On the sociotechnical side, the most surprising finding was that minorities are the ones who have the highest potential benefit from insoles, but are less likely to be able to access them. This finding shows the vast promise of making effective insoles more accessible, perhaps raising the profile of semi-custom and benchside-modified insoles as cheaper but more customized options than off-the-shelf insoles. Both projects enhanced my understanding of orthotics access and design improvements.