Custom 3D Modeled Post-Operative Knee Brace Product Development
(Technical Paper)
The Equitable Design of Post-Operative Knee Rehabilitation Protocol
(STS Paper)

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Madeline Corona
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Technical Project Team Members
Sabrina Alessi, Tyler Burtner, Liam Kidd, and Kyleigh Talomie

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.

Signed: 

Technical Advisor: George Miroulis, ICARUS Medical Innovations

STS Advisor: MC Forelle, Department of Engineering and Society

Introduction

Total knee arthroplasty (TKA) and ACL reconstruction surgeries combined make up nearly one million surgeries performed annually in the United States alone (Hewett et al., 2010). After knee surgery, typical rehabilitation protocol works in stages, beginning with completely restricted movement, then progressing to movement with a limited range of motion, finally to a full range of motion with weight unloading on the joint. These post-operative rehabilitation plans are designed to ensure a full and proper recovery for the patient. Millions of individuals suffer from daily knee pain, and with the demand for total knee replacements being projected to grow by 673 percent to nearly 3.5 million procedures annually by the year 2030, the need for a proper rehabilitation protocol is more important than ever before (Kurtz et al., 2007). However, not all rehabilitation plans should look alike, depending on many factors related to the patient and their health. It is important to design a plan for each patient while keeping their age, physical ability, gender, and any other lifestyle or health factors in mind. A recovery plan tailored to the specific needs of the individual patient will make it easier on the physician to accurately monitor progress, while also making it easier on the patient both physically and mentally as they feel that they are making that progress. Another issue with the recovery process after TKA is that patients can lose up to 62% of their quadriceps strength due to atrophy of the muscle, and some patients can even have permanent physiological limitations on the knee's range of motion (Mizner et al., 2005). This condition is also known as knee flexion contracture, and is a result of the long-term immobilization of the joint (Anania et al., 2013).

Our technical project is centered around designing a custom 3D modeled post-operative knee brace with an adjustable range of motion to be used over the entirety of a patient's recovery process and rehabilitation. Each brace will be custom designed and 3D printed for the individual

patient and will include a BOA dial, a dial that can be turned to adjust the brace's range of motion. The custom 3D modeling will ensure that each patient will receive a brace best suited to their physiology, and the ability to continuously adjust the range of motion the brace permits ensures that this is the only brace that a patient will need to purchase over the duration of their recovery. This project is aimed at bringing the knee brace to market with final specifications designed for the best patient and physician experience. In order to design this knee brace with all potential users in mind, it is crucial to investigate the typical rehabilitation protocol (Alessi, S. F. et al., 2022). The STS portion of my project will hope to answer this question: How do the current standards of treatment and rehabilitation protocol for patients undergoing knee surgery contribute to an inequitable recovery process for patients of different ages, abilities, and genders, and why is this so when it produces undesirable outcomes for certain individuals? Investigating this question will be foundational to the equitable design of our technical product and the recommendations physicians and physical therapists provide to patients post-operatively.

Custom 3D Modeled Post-Operative Knee Brace Product Development

With the prevalence of TKA on the rise, the complications throughout its recovery process are rising too. One of the most common complications resulting from this procedure is a condition called flexion knee contracture, or flexion deformity. Knee flexion contracture is when the knee can no longer be straightened fully, either actively or passively, and it is estimated that up to 60% of patients undergoing TKA will experience knee flexion contracture throughout their recovery. Although some of these effects are reversible, some knee flexion contractures can be so severe that there is a permanent loss in range of motion, impeding a patient's full recovery (Su, 2012). Our technical project aims to reduce the prevalence of these post-operative

complications through the design and implementation of a novel knee brace (Alessi, S. F. et al., 2022).

We plan to create a 3D custom-modeled post-operative knee brace with an adjustable range of motion and an adaptable mechanism to redistribute the forces loaded on the tibia. With the help of Icarus Medical Innovations, we plan to complete three general aims over the course of the year. Our first general aim is to determine the specific market and biomechanical needs for a post-operative knee brace to be used after a variety of knee surgeries. This will include conducting preliminary research on the current market– including health and insurance codes, prior art, and projected trends for knee injuries and subsequent operations. We will also investigate the primary differences in functional and post-operative knee braces to determine the necessary mechanical features for our brace, as defined by current products and rehabilitation protocol (Alessi, S. F. et al., 2022).

Our second general aim is to design a new brace and its experimentation protocol to evaluate its efficacy according to established parameters in order to validate the product. Throughout the design process, we will need to remain cognizant of prior art to ensure we are not infringing upon currently patented designs. We will determine the key device characteristics that need to be validated and the consequent tests necessary to prove product effectiveness, and we will conduct testing on patient populations and collect data. Using this experimental data, we will assess the current brace design and iterate our product design until the product meets our set specifications. Our third general aim is to develop strategies for bringing the product and to determine the brace's projected growth. This will include developing a patent to protect our new technology, and addressing applicable insurance codes to make sure our brace is accessible to our target users. We will also use our experimental data with pertinent market research to

develop functional claims for the product, determine its viability, and create a launch strategy to bring it to market (Alessi, S. F. et al., 2022).

The Equitable Design of Post-Operative Knee Rehabilitation Protocol

After knee surgery, patients will undergo a post-operative rehabilitation plan to ensure a full and proper recovery. However, many factors such as age, gender, and physical ability influence an individual patient's response to such a protocol. This sheds light on the importance of designing proper protocol unique to each individual and developing a set of best practices for patients that fall into unique combinations of these groupings. A custom recovery plan that accounts for a patient's abilities and needs will help inform both physicians and patients of the progress they are making, while avoiding discouragement of the patient and the feeling that they are falling behind. For my STS topic, I wanted to dive deeper into the current inequities present in the standard rehabilitation protocol for total knee replacement in order to figure out why these inequities are still present.

The STS framework that I will be using to investigate my topic is outlined by Steve Woolgar in his 1990 article "Configuring the user: the case of usability trials". Woolgar proposes that the user and a machine or technology is analogous to a reader and a text. Woolgar states that just as different readers interpret the same text in different ways, users interpret and interact with technologies in different ways, due to their background. He mentions that in the design of the technology, machines inherently configure users in such a way that informs the way that they interpret the technology and interact with it (Woolgar, 1990).

I believe that this principle can be applied to investigating the post-operative rehabilitation protocol. I will connect this information to my prospectus by applying the concepts of user configuration to different patients' experiences with post-operative knee braces and

recovery programs. Woolgar writes, “users can’t help the way they behave; they just need to be educated to understand what we are trying to achieve here. Readers can’t help the way they interpret the text; they just need to be educated” (Woolgar, 1990, p. 89-90). This analogy can be further extended to the field of orthopedics and rehabilitation in that the design of protocol contains inherent bias and the way that patients react is dependent on the individual patient and their needs. There are a lot of factors that play into how any given person will interpret a text: do they have background knowledge on the subject, do they have a personal connection to the subject, what do they think other people’s perception of the subject is? Another factor comes from the author’s side; that is, who wrote the text? Who designed the rehabilitation plan? These same things, or analogies of them, could impact the way that a patient reacts to their rehabilitation plan both physiologically and psychologically. Viewing different patients’ experiences through this lens will help me to investigate why there are these discrepancies and inequities in rehabilitation programs.

Research Question and Methods

The goal of my research is to answer this question: How do the current standards of treatment and rehabilitation protocol for patients undergoing knee surgery contribute to an inequitable recovery process for patients of different ages, abilities, and genders, and why is this so when it produces undesirable outcomes for certain individuals? I plan to conduct my research by studying orthopedic journals to investigate the recovery processes for different types of knee surgeries (ACL reconstruction, full knee replacement, etc.) in order to understand the physical needs for patients in all different types of recoveries. Then, I plan to investigate the standards of rehabilitation programs (as set forth by the American Physical Therapy Association) to determine what type of patient the “typical” plan is designed for. Once I have an understanding

of that, I will marry the two together and uncover disparities in the standard of care provided to different types of patients with different needs. This question is critically important to investigate because a patient's recovery process not only has a large impact on their physical health, but it affects their mental health and self-image as well. The design of a tool to be used for something this vulnerable for such a broad pool of patients warrants extra consideration to ensure that everyone's needs are being met.

Conclusion

Our technical project research will improve the current post-operative knee brace by creating a custom 3D modeled brace with an adjustable range of motion and adaptable force unloading capabilities. This brace will help to minimize common complications found throughout the recovery process as well as fit the custom physiological needs of each user (Alessi, S. F. et al., 2022). My STS project will explore the inequities of post-operative knee rehabilitation protocol as a whole. Within the framework of user configuration, I will outline important considerations and detail an approach to ensure the equitable development and implementation of a post-operative knee protocol for all individuals.

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