Kronos Knee Brace

STS 4500 Prospectus

Icarus Medical

Biomedical Engineering

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Projected Graduation Date: Fall 2023

Submission Date: Spring 2023

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Overview:

The prevalence of knee surgery continues to rise, and current post-operative knee braces fail to adequately prevent complications such as atrophy, loss of quality of life, and knee flexion contracture. These complications serve to prolong an individual's journey to a full recovery. We designed a brace that addressed current complications including range of motion and joint stability to provide an industry-leading option for post-operative knee joint rehabilitation. The brace is custom fit to each patient and designed with their needs in mind by allowing for modification throughout the recovery process.

Positionality:

The project creator identifies as white bisexual man who was raised by his single mother. The difficulties his family faced during his childhood in an impoverished community shaped his experience as an adult. Many in his community had diabetes and access to care, and medication was limited. These experiences ignited a passion for fighting for equity in medical care and devices for those in similar communities. Through multiple life-changing injuries, the author has gained an even deeper appreciation for his ability to provide medical care to underprivileged communities.

The project's goal was to create a brace that was cheaper, lighter, and more effective in creating positive patient outcomes after a full knee replacement. Typically, the patients that undergo these operations are elderly, predominantly black women, and overweight. Osteoarthritis is a violent disease that targets these groups and makes them much more needy of a total knee replacement(Zhang & Jordan, 2010). Secondary goals included providing an alternative to other braces on the market used to treat ACL and MCL reconstructive surgeries in mostly younger (18-30 years of age(Gans et al., 2018)) patients. The author (myself) used his experiences and passions to shape the design specifications that are deemed important. Success in this project was defined as the brace's ability to achieve better patient outcomes.

Problematization:

Combined, total knee arthroplasty (TKA) and ACL reconstruction surgeries constitute nearly one million surgeries performed annually in the U.S. alone(Moses et al., 2012; Sanders et al., 2016). Millions of individuals suffer from knee pain, and the demand for total knee replacement surgeries is projected to grow by 673 percent to nearly 3.5 million operations by 2030(Kurtz et al., 2007) and the need to properly rehabilitate patients after their operation is of high importance. Typical rehabilitation protocol works in stages, beginning with completely restricted movement, then progressing to movement limited to a minimal range of motion, to full movement with weight unloading on the joint. Along with physical therapy, rehabilitation efforts involve multiple knee braces, which often perpetuates the occurrence of post-operative complications(Kahn et al., 2013). Current products only act as a range of motion delimiter, and subsequent braces need to be purchased during recovery because of limited capabilities each brace has. Patients are rarely involved in the design process, and this has created problems within

their own experiences including discomfort and a loss of quality of life and dignity. Patients should be involved in their medical care, and exercising this autonomy could help to improve the design process by weaving their needs and values throughout the project. Annemarie Mol says that historically, care has failed to account for the complexity of day to living(Kelly, 2009). The brace industry has often considered only pain levels and a return to some degree of normal activity levels as adequate markers of successful care; this attitude fails to account for the broader level of user experiences that affect their care. Throughout the design we sought to understand more about user experiences so that we could integrate those encounters into the design.

Main Argument:

How did we incorporate value-based design into this capstone project, and where did we fall short?

Projected Outcomes:

Patients who have undergone TKA and ACL reconstructions can lose up to 62% of their quadriceps strength due to the atrophy during their recovery(Mizner et al., 2005), which can even result in a condition known as knee flexion contracture (KFC), a permanent deformity of the knee joint(Healy et al., 2013). We hoped to challenge this status quo by incorporating current and past user input into our design process to reimagine the relationship between user and engineer. This methodology of value-sensitive design was aimed at improving patient outcomes and returning them to the quality of life they desired.

Technical Project Description:

Our solution was to create 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. This design built on a current Icarus device, the Ascender("Products," n.d.), to develop a knee brace that can meet patient needs at each stage of recovery. The custom 3D modeling ensured that patients would receive a brace suited to their body type, and the ability to continuously adjust the range of motion the brace ensured that this is the only brace that patients will need to purchase over the duration of their recovery. Our design is aimed at achieving full joint-immobilization in the first weeks of the healing process using a mechanism that locks the brace out completely; this mechanism can be adjusted to allow for assisted flexion and extension using the unloading technology when the case doctor deemed it appropriate.

We embraced current and future patient feedback during the design process and sourced information from multiple patient based studies that covered values and preventative care(Hewett et al., 2010),(Dávila Castrodad et al., 2019). Information directly from current users of the Icarus Ascender and patients electing for TKA allowed the team to place the needs and values of the patients at the forefront of the design process. Their concerns were many: swelling, lack of mobility, appearance, longevity, weight, ease of use, dignity, reinjury, return to normal life, loss of quality of life, and a multitude of others. These guiding concerns were important to the team so that the standard of care for each patient could be met and exceeded.

Preliminary Literature Review & Findings:

The field at large has not made significant innovation on the current design for nearly a decade(Mistry et al., 2018), nor have they incorporated value based design in substantial ways. Bracing design has not been able to face problems of reinjury, poor patient experience, and adaptability for some time. With the number of elective and reactive surgeries set to increase substantially in the next two decades, it is important to improve the technology to care for an expanding population of patients. To improve upon anything, one must first fully understand the problem of their predecessor. Biostatisticians from universities around the country have started to implement a broader data collection that captures more nuanced aspects of their patients' needs and values so that they can try to incorporate specific patient feedback on their personal experience into their interpretation of data(Maio, 2018; Petersen et al., 2020). What they believe is that this resource of patient values must be given weight as an important variable in the equation of patient outcomes. Though it was difficult to establish what was most important and impactful for patient recovery, the research elucidated many concerns that users felt were never addressed at all. Failure to account for the actual feedback on need and value from the patient could have a large impact on the physical and mental health of the patients. Authors like Smits, Friedman, and Backonja outline the key features of value sensitive design and how they employed these methodologies within their own projects(Backonja et al., 2018; Friedman et al., n.d.; Smits et al., 2022). Each sought to use the tripartite structure of the theory to look at the whole of the values they were defining. All of them dealt with subtle nuances that made final distinctions difficult, but this struggle served to create a hierarchy of needs within their respective projects. We hoped to incorporate this methodology of investigation into our project.

STS Project Proposal:

Patients could be vulnerable both physically and emotionally while recovering, and we wanted to ensure that we are putting ourselves in their shoes when designing a product for them and having them test it. The aim of the brace was to guarantee patients their dignity, comfort, and efficacy throughout the recovery process. We believed that the standard of care was not meeting this responsibility to current patients. The problem was based in systemic problems that were prevalent in healthcare including a separation of patient and care provider and a failure to integrate them into the design process. Within this paper, I will present the ideals of Value Sensitive Design, how we used them to try and solve the problem, and how we fell short.

Value sensitive design (VSD) is a user driven methodology(Smits et al., 2022), which gives users the power of defining the values that are most important to the project. Value in this sense is defined as what our users saw as an important part of their life while in the brace. VSD consists of three methods that build upon each other yet are distinct like paint on a canvas. Conceptual, empirical, and technical investigations are the colors used to paint the picture. You may use the same color twice at completely different times in the process, in this way VSD is an iterative methodology. Conceptual investigations helped to identify the fundamentals of the

problem at hand and to whom were our efforts directed. Empirical investigations allow for quantitative and qualitative analysis of user experience. This is where we identified values most important to our users. Technical investigations evaluated how to best meet the values established in the conceptual and empirical frameworks. All these methods come together to form the picture of VSD.

This project had so much potential for VSD to make meaningful changes in users lives. Empowering our end users to shape their own experience through incorporating them fully into each stage of the project could reshape how we as a team define, design for, and eventually meet their own standards of care. Other braces are designed for their consumers, we want to design with our users. A redefining of the designer-user relationship that emphasizes autonomy could increase better patients' outcome by assuring that their needs and values are woven directly into the foundation of the project. The application of VSD could potentially shake up the stagnation of the brace industry that has poorly affected patients for so long. Any methodology that could potentially impact our user's quality of life in a positive way is a worthwhile endeavor.

There were many limitations and mistakes made throughout these investigations. The iterative aspect of VSD was never successfully implemented. As a team we were not at all intentional about going back and reappraising values or questioning what we thought to be true about our users. Friedman often employs a second technical investigation that develops new answers to the same set of values. The conceptual investigation was informed entirely by literature and our leadership's previous experiences addressing similar problems. Typically, users are brought into this process to understand who stands to be affected the most by the technology. Doing so might have changed the scope of our project by illuminating certain stakeholders we had not considered. A major limitation was the timeline. In the world of medical devices, internal review boards (IRBs) and the FDA dictate what and how you can test a device's efficacy. The regulations that protect patients are stringent and approval of projects takes months. Because of this we did not obtain permission to ever test the efficacy of our designs and therefore could not iterate parts of our process. The rush on the timeline also caused distortion of values. Quality of life was crowned even though the original aim was to level it with the other values, but the timeline needed to obtain IRB approval forced us to pick one only we thought was critical. In the future much greater care should be taken in reiterating parts of the process to ensure truths are tested and values are confirmed.

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