Value Sensitive Design in Medicine

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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 Thesis-Related Assignments

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Brace Design and VSD in the Technical Project as a Conclusion

The knee brace 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. 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) it is important to improve the technology to care for an expanding population of patients.

Current knee-brace manufacturers produce multiple devices that are suited specifically for different needs throughout the recovery process. The market is lacking a standalone brace that helps facilitate the recovery process in a dynamic way, rather than static current brace options. The inadequate support and versatility from current braces often result in prolonged immobilization of the knee. This can lead to knee stiffness or the loss of muscle function, which can develop into knee flexion contracture or arthritis in the joint(*5 Possible Problems With Knee Replacement*, n.d.). Movement in the knee shortly after surgery is crucial for reducing chances of post-operative complications, and our brace aims to reduce pain in the anterior knee directly after surgery to increase early mobility and use.

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.

At Icarus Medical Innovations in Charlottesville, Virginia a team including myself and 4 other undergraduate students at the University of Virginia biomedical engineering department created a novel knee brace that was meant to improve positive patient outcomes. The brace was designed to be custom fit to the patient and will have an adjustable range of motion throughout recovery and adaptable force redistribution intensity at the joint to unload forces on the tibia. Patients who have undergone TKA can lose up to 62% of their quadriceps strength due to the atrophy, and some patients have permanent physiological limitations to their knee's range of motion, a condition known as knee flexion contracture (KFC), as a result of the long-term immobilization of the joint(Mizner et al., 2005; Tanzer & Miller, 1989). Our brace hopes to address the shortcomings of current technology by allowing the patient to exercise their mobility

at all stages with assistance from the brace and foster better recovery of the knee joint following operation.

The design and metrics of success were completely informed by the group's application of value sensitive design. Before design began a long process of interviewing knee replacement patients, reconstructive surgery patients, and doctors to ascertain some preconceived and expected values of some of the most important stakeholders of the system. This conceptual investigation revealed many important values in the stakeholder, principally doctors needed to be able to trust that the brace would not lead to reinjury, patients needed to trust that the product would keep them safe, and they also wanted the brace to return them to their previous levels of ability. Many users thought that other products simply sought to get them to stand on their own rather than return their full quality of life. Many patients revealed that although they could walk around on their own, they could not get back into the gym or play as they would wish to because they had lost so much strength from the sedentary life they had had to adapt to during their recovery. The lack of trust that users and doctors had in competitors' braces was palpable and the team believed that there was an incredible opportunity to improve the user-device relationship through their own design.

With one conceptual investigation of value completed the team moved forward with a technical investigation that sought to create a tangible product to meet, uphold, and bolster the values of the users. Again, the problem with other braces is that the immobility of the user during recovery led to massive losses in strength. This massive loss of strength led to reinjury, loss of quality of life, and prolonged recovery. Our patients and their doctors needed to be able to trust that this brace would return them to a previous quality of life. To do this we decided to incorporate a design feature that would allow for an adjustable range of motion of the brace that

could be modified to accommodate the patient throughout the recovery process. This novel access to movement in recovery is linked to increased positive patient outcomes(Gans et al., 2018; Hewett et al., 2010). In this way the brace also acted as a one stop shop for recovery instead of switching to a new more accommodating device for each stage of recovery, which can be a costly barrier to healing.

The value of trust was approached through aesthetic and mechanical aspects of the design. The brace is sleek, yet the user can observe elements of steel and other strong materials. The lines are soft and fit each user's body type so that it might feel more like a part of their body. The look and feel of the brace were meant to inspire trust. When the user was ready to put weight on the knee the brace featured an unloading mechanism that took weight off of the knee and spread it to the femur and tibia with the sensation of taking 50 lbs. off of a person's body. This feeling allowed for the patient to not only trust the device, but to trust their own movements so that recovery might be expedited.

The empirical investigation was centered around patient feedback after surgery and brace fitting had been concluded. There were a series of tests that were meant to gauge the braces ability to uphold the values that were identified in the conceptual investigation and designed for in the technical. We used a host of industry standard tests to evaluate efficacy of rehabilitative competencies (Dávila Castrodad et al., 2019; Negrete et al., n.d.; Roos & Lohmander, 2003; *Tegner Score - Google Search*, n.d.), but we also asked users about their daily interactions with the brace.

The Device is currently in human trials and there is still much data to be gathered. The team believes that the incorporation of VSD into the project design was an important part of the initial success of the brace. First reports and metrics from users and doctors saw a comfort with

the brace and an effectiveness in returning people to play in a similar amount of time to our competitors. VSD allowed us to integrate our patients into the design process so that the final product might better align with their own value system. The medical field at large might benefit from a similar utilization of VSD to better serve their patients.

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