Custom 3D Modeled Post-Operative Knee Brace Product Development
(Technical Topic)

Analysis on the Network of Influences Embedded in Surgical Decision Making
(STS Topic)

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By
Sabrina Alessi

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Technical Team Members: Tyler Burtner, Maddie Corona, 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.

ADVISORS

Rider Foley, Department of Engineering and Society

Dr. Timothy Allen, Department of Biomedical Engineering

Introduction

Combined, total knee arthroplasty (TKA) and anterior cruciate ligament (ACL) reconstruction surgeries constitute nearly one million surgeries performed annually in the U.S. alone (Hewett, Ford, Hoogenboom, & Myer, 2010). Of the million procedures, 100,000 are attributed to an ACL tear and around 800,000 are knee replacements (Staff., 2021). Post-operative rehabilitation requires immobilization of the joint immediately following procedure. Such prolonged joint-rigidity can lead to knee stiffness or the loss of muscle function, which can develop into knee flexion contracture or arthritis in the joint (Anania, Abdel, Lee, Lyman, & Gonzalez Della Valle, 2013). As the knee surgery industry is projected to grow by 673% in the next ten years, there is value in developing a solution to address drawbacks current products possess (Kurtz, Ong, Lau, Mowat, & Halpern, 2007).

ICARUS Medical, located in Charlottesville, is a company specializing in custom 3D knee braces capable of multi-compartment unloading, improved stabilization, and fully-adjustable range of motion (Franklin, 2020). Members of their company have joined my capstone group as advisors in our technical project: the development of a novel post-operative knee brace that is both custom fit and patient-operated to adjust for each stage of the recovery protocol. This custom fitted design utilizes 3D scanning and printing technology to develop a personalized, multi-functional knee brace. The project involves product ideation, design and testing, as well as research on current patents, performing market-gap analysis, patient testing, and an Institutional Review Board (IRB) application. Once complete, this product stands to shift the knee brace market by combining features of immobilizer, rehabilitative, unloader, and patellofemoral braces with adjustable range of motion technology. The impact of providing patients with a single multi-functional rehabilitation solution will not only eliminate current

products on the market, subsequently changing the recovery protocol, but also facilitate a smoother and personal recovery following surgery.

The surgical industry is growing rapidly due to innovative technologies, and patient needs. Choosing to undergo surgery can be a difficult decision. For some, extenuating social, financial, or personal circumstances related to the operation or post-operative necessities may impact the decision. In the process of understanding market trends and practices for knee rehabilitation, I discovered that some individuals chose to postpone surgery and instead seek alternate solutions to their ailment (Mattingly et al., 2021). I wondered if this decision stemmed from personal motives, alternative medical advice, or external circumstances that rendered surgery inaccessible.

This prompted me to question the current standards and factors that contribute to surgical diagnosis. Based on previous experience with both elective and emergency operations, I am grateful for the support and surgical access I was afforded and understand this is not a universal experience. I am aware of the inequalities in the U.S. healthcare system, but unsure about their presence within surgical procedures, nor how they may influence the decision for a doctor to recommend a procedure to their patient. Does the doctor consider their ethnicity or financial background, or are there standards in place which force him to advise an operation? These considerations may contribute to the variability in medical diagnosis and common treatment methods apparent within the U.S. healthcare system. Utilizing Cresswell's Actor-Network Theory, I plan to explore the variability in treatment and influential factors a doctor considers when recommending surgery to their patient. Through my analysis of surgical decision making (SDM), I hope to uncover the key players involved in surgical treatment and technologies by addressing the influential factors apparent in the network of internal and external stakeholders.

Technical Topic

Background

Millions of individuals suffer from knee pain, and with the demand for total knee replacement surgeries projected to grow to nearly 3.5 million operations by 2030, the need to properly rehabilitate patients after their operation is of high importance (Kurtz et al., 2007). As discussed, rehabilitation protocol requires multiple brace types to properly heal a knee post-operation. Initial immobilization, achieved using a rehabilitative brace, may lead to a decrease in quadricep strength as knee stiffness can manifest after extensive use of an immobilizer (Mizner, Petterson, Stevens, Vandenborne, & Snyder-Mackler, 2005). Doctors will shift the patient into a functional brace increasing range of motion (ROM) while reducing translation and rotation in their joints following immobilization. The different levels of functionality between braces inflict drastic changes in joint-stiffness and muscular support. This in turn leads to future ailments like muscle atrophy or knee flexion contracture (KFC) which manifests in 17% of patients (Anania et al., 2013). The market is lacking a standalone knee brace addressing all post-operative concerns and capable of adjusting for each phase of recovery. (Paluska & Mckeag, 2000).

Project Objectives

ICARUS Medical partnered with my capstone team to design and develop a custom 3D modeled post-operative knee brace with an adjustable range of motion. This novel product is intended to be used over the entirety of a patient's recovery process, ultimately shifting the rehabilitation and knee brace industry. This design builds on a current Icarus device– the Ascender– to develop a knee brace with the ability to adjust to meet the patient's needs at each stage of recovery.

In order to develop a product, initial investigation and research on current product capabilities is conducted. Post-operative braces have a mechanism for immobilization of the joint, however, functional braces enable joint movement to a certain degree (Butler, Dai, Garrett, & Queen, 2014). To function as both, our device will incorporate a BOA dial to adequately adjust flexion and extension angles. To minimize the harmful forces on the knee, we plan to implement ICARUS's system for dynamic tensioning (Admin, 2022). This novel technology redistributes force intensity to unload the load at the joint. Despite its effectiveness in knee recovery, this technology has never been utilized in a post-operative brace (Hart, Crossley, Ackland, Cowan, & Collins, 2016).

Based on fundamental brace capabilities and conversations with knee surgeons and physical therapists, we will outline all brace parameters required by post-operative braces that promote a successful recovery (Melegati et al., 2003). The product will be developed via CAD systems and 3D printed with nylon plastic to ensure a lightweight product with minimal components. Because of the resources provided by ICARUS, their custom 3D modeling software will be leveraged to develop a custom-fitted model for each customer. This technology uses an iPhone app which scans the patient's knee to provide 3D images of leg and muscle orientations to our manufacturing and design team. This capability ensures each patient will receive a brace best suited to their physiology. Material and functional testing will be conducted to determine feasibility of the design. In accordance with regulatory requirements, mechanical and patient testing will subsequently define the level of support, ROM, and ease of use of the product. We intend to iterate our design until our product meets all necessary requirements.

This project also requires extensive market research. A main role of mine is to investigate the insurance claims, and health codes characteristic of knee braces. This requires research into

current products to ensure we do not infringe on valid patents, development of an IRB, and further understanding of market needs. Coupled with the data and findings from patient and product testing, final steps include development of a go-to-market strategy to address our target clientele. Our goal is to be a cost-effective option which warrants market analysis on comparable products (Tran & Spry, 2019).

This solution makes rehabilitation more convenient as adjustments can be made by the patient, lowering the frequency of hospital visits and the purchase of new braces. It also incorporates dynamic tensioning, unloading, and gradual flexion perpetuating a better recovery. By partnering with ICARUS and utilizing their technology and materials, we hope to be the first product on the market that can support the patient throughout the entire recovery process with a singular brace.

Role of Inequity in Surgical Decisions

Background

Surgery is an indispensable part of healthcare as there are numerous reasons an individual requires surgery (Meara et al., 2015). As I educated myself on knee operations, I came across a story documenting two boys with ACL injuries (Blundin, 2020). One had opted for surgery while the other focused on physical therapy first despite having similar symptoms and diagnosis. I questioned what each group considered before making a final decision. I reflected back on my experience with elective surgery: I fractured my nose at age fifteen and opted not to have immediate surgery as it was a minor injury and did not impact my way of life. Unfortunately, I found out I was breathing with 20% capacity two years later requiring immediate attention. I consulted multiple surgeons before opting for a dual-surgeon procedure to address my multiple

nose issues. This experience opened my eyes to the complex influential factors relevant to deciding whether or not to undergo surgery.

The main sources of healthcare inequality in the U.S. stem from race, ethnicity, and location. Heart disease and cancer are leading causes of death across race, ethnicity, and gender as African American men are 30% more likely to die prematurely from heart disease in comparison to white men (National Academies of Sciences et al., 2017). Geographical placement of both people and medical care centers perpetuates the unequal access to healthcare in the US. Access to specialists is more difficult for those in rural areas, and while urban locations have a higher concentration of resources, stigma and bias characteristic of different neighborhoods impact level of care (National Academies of Sciences et al., 2017). There is much variability in surgery, as indicated by the varying treatments for ACL recovery, and much conversation between different surgeons, but minimal discussion on their relationship to the inequalities embedded within healthcare.

Framework

Utilizing Cresswell's Actor-Network Theory (ANT), I plan to address the current standards of surgical diagnosis and investigate the influences acting within the network as it pertains to surgical decision making (Cresswell, Worth, & Sheikh, 2010). This framework provides a methodological approach to investigating how technologies, in this case surgical procedures, manifest themselves into a system. The healthcare system of surgery in specific involves multiple human characters: patients, treating physicians, surgeons, nurses etc. But with Cresswell's theory, I am able to address the non-human actors present: patient demographics, geographical placements, socioeconomic status, and financial factors. Because the surgical decision making process involves consideration of multiple factors, a framework that recognizes

the presence of both human and non-human influences and defines them all as actors, allows for equal analysis of all relevant components. Cresswell refers back to Callon's comment that everything can be considered both an actor and a network as it is only a matter of perspective (Bilodeau & Potvin, 2018). Such clarification reminds me that while economic characteristics may be considered an influential actor for the doctor, it is also a defining network for the patient as it redefines their role within the system at large. Analysis under the ANT framework provides a method for assessing what influences doctors as they determine the proper solution for their patient. Evaluating patient qualities or inequalities, accessibility or geographic considerations, as well as the doctors internalized bias or external incentives, I may piece together a network of influences relevant to surgical decision making.

The impact of SDM has been previously investigated by Shinkunas et al., and Gunaratnm et al., and uncovers clear factors that impact a doctor when he selects surgery as an option for patients (Shinkunas, Klipowicz, & Carlisle, 2020). It is apparent that a patient's age, physician's experience, geographic location of both the physician and doctor, as well as ulterior financial incentives play a role in SDM (Gunaratnam & Bernstein, 2018). Both authors claim more research into SDM is warranted, further validating this proposed investigation into the human and non-human factors manifested within surgical variation and the network of influences created. By focusing specifically on the surgical sector, and utilizing this method of analysis, I believe I can properly investigate the level of influence each key stakeholder possesses within the surgical decision making process.

Research Question and Methods

To understand the potential rationale behind surgical decision variability, I plan to investigate the network of actors involved with surgery and define the influential factors that play a role in their decisions. The main method of analysis I intend to use is interviews with surgeons, physical therapists, and patients. I believe that by targeting patient-doctor pairings, in which the patient has opted for an elective surgery, I can best distinguish what factors were considered by each party before making a decision while simultaneously removing any bias associated with emergency procedures.

Hosting separate interviews, I will first inquire about baseline content – race/ethnicity, geographical location, and financial status – from both parties. The patient will be asked about their condition when seeking the doctor, personal beliefs and feelings about surgery/hospitals, their relationship to the doctor/surgeon, if they sought advice from other medical professionals, and if true, at what stage. The doctor will be questioned regarding his/her academic background and medical experiences, if and who he/she spoke to regarding the patient, external partnerships with medical companies/corporations, experience with the specific injury and procedure, as well as probed for any internal bias potentially relevant to the patient (Gunaratnam & Bernstein, 2018).

I plan to supplement these interviews with literature reviews provided from existing studies on SDM, the relevant inequalities present, and background information on interviewee's (Bilodeau & Potvin, 2018). As I understand acquiring interviews may be difficult, I have acquired many references in the surgical and therapeutic field that I plan to leverage for content. These conversations, coupled with published literature, provide a window into the inner workings of medical decisions. Assuming feasible, I plan to conduct ten interviews or

conversations to acquire answers regarding surgical influences. If necessary, follow-up research regarding medical facilities, larger industry players, or geographical disparities may be conducted to provide another source of insight. In casting a large net, I intend to uncover a plethora of influential players relevant to the surgical network. I predict these methods of research and analysis will provide enough content to make conclusions on the influential factors driving treatment variability as well as explain the network of relationships relevant to surgery and ethics.

Conclusion

Following validation provided by product and patient testing, we will have successfully created a post-operative brace functioning for all recovery stages. Development of an IRB and marketing strategy will provide ICARUS with the next steps for both viability assessment and product launch. Because of its novel technology and adjustable characteristics, if accepted by insurance companies and physicians, this product has the capability to alter the recovery protocol typical following knee operations and effectively minimize spending typical of current rehab tactics. Additionally, because our project requires patient testing and insight from knee surgeons, these relationships provide valuable sources for my STS topic.

Whether or not the inequalities are prevalent in the decision, interview content uncovering the hierarchical relationships and influential factors considered will provide evidence necessary to answer my question of surgical variability. Conclusions from my research may persuade medical professionals to think differently when discussing treatment options with their patients. Because the majority of hospital costs stem from the surgeon's technology needs, my research may persuade surgeons to make more cost-effective decisions for treatments while

continuing to provide the necessary level of care (Kadakia, Perrier, & II, 2021). It is in this way that I can portray the broad and eternal network of influence apparent in our medical system.

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