An Improved Tibial Guide to Increase Clinical Stability Outcomes of ACL Reconstruction Surgeries
(Technical Topic)

The Factors Influencing Physician's Decisions on Adopting New Medical Technology
(STS Topic)

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By
Aaron Lin

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Technical Project Team Members: Na Hyun Bae, Jasmine Cao, Tzuyu Cheng

On my honor as a University student, I have neither given or received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

ADVISORS

Dr. MC Forelle, Department of Engineering and Society

Dr. Timothy Allen, Department of Biomedical Engineering

Introduction

The field of healthcare is rapidly changing through technological development, from new drugs and treatments to new devices (Thimbleby, 2013). These innovations have lessened some of the burdens on physicians as well as allowed the automation of certain procedures which grants other healthcare workers the opportunity to perform more meaningful tasks. Additionally, medical technology has greatly increased life expectancy and saved many lives through new therapies. According to the National Bureau of Economic Research (NBER), therapies accounted for 45 percent of the increase in life expectancy in the late 1990s and 73 percent in the early 2000s. (*The Value of Medical Innovation*, n.d.). The adoption of more technology in healthcare will improve the quality of treatment and help address more serious conditions.

Even with all the benefits of incorporating technological development in medical practice, there are situations where practitioners are still reluctant to utilize it. Not all physicians will agree on the use of every innovation and the adoption of new technology can come down to individual preferences. Many factors may influence this decision but there is no clear indication or measurement scale to determine the likelihood a medical technology will be adopted by hospital-based physicians. There was a study that created the physician-motivation-adoption (PMA) scale to create a reliable way to validate and identify the adoption motivations of the physician, but more research needs to be done to generate more information on this decision-making process of physicians (Hatz et al., 2017). It is important for the engineers that are developing the technology to understand the perspectives of the physicians in order to create a product that they are willing to use, which will help to improve medical treatment. There is a disconnect between how engineers and physicians view the same technology.

In order to help advance medical technology and have them be utilized in a hospital, there needs to be an increase in communication and understanding between the physician and the engineers, or developers. The challenge lies in creating interdisciplinary collaboration when the two professions come from different areas of science and have different approaches and viewpoints (Hassani, 2019, p. 3). To address this problem, for my STS project, I will be researching the psychological and social factors that influence physicians' motivations when deciding whether they will adopt a medical technology. In addition to this research, for my technical project, I will be working in a team, under the supervision of a surgeon, to design and improve on the current tibial guide utilized by surgeons in anterior cruciate ligament (ACL) reconstruction surgeries. The improved device will help with the variability that results from the current method and improve the clinical outcomes for patients who require surgery. This technical project will help me understand the relationship between engineers and physicians throughout the life cycle of medical device development, which I can use to help improve the gap between the two disciplines. Moreover, the results of the research study will also improve my ability to better work with physicians as a biomedical engineer.

An Improved Tibial Guide to Increase Clinical Stability Outcomes of ACL Reconstruction Surgeries

There are between 100,000 and 200,00 ACL tears per year in the United States, where females and athletes are at greater risk (*ACL Tear*, 2020; Friedberg, 2022). Surgery most commonly occurs in adolescence, specifically in males from age 19 to 25 years old and females from 14 to 18 years old (Sanders et al., 2016). Although some ACL tears can be treated with rehabilitative therapy, the ligament will not heal or reattach itself without surgery. Thus, the

patient can only reduce the swelling and pain; however, the patient will have a drop in performance level when returning to their sport or other activities in comparison to before the injury (*ACL Rehabilitation Without Surgery*, n.d.). Additionally, without surgery, long-term effects include an increase in instability and an increase in the risk of other injuries. Of the athletes that had ACL reconstruction, only 65% can return to their original performance (Gokeler et al., 2022). This is often due to failed surgeries which may cause knee discomfort or pain.

ACL reconstruction surgery replaces the damaged ligament with a graft, normally made from a piece of the patient's tendon, by drilling tunnels in the femur and tibia. These tunnels are used to position the graft, which is secured to the bones with screws or staples (*Knee Ligament Surgery - How It Is Performed*, 2017). The location of these tunnels is determined with a tibial guide that utilizes anatomical landmarks, arthroscopy, and the surgeon's discretion for placement. A common landmark is the border of the meniscus' front horn, but it yields inaccurate and inconsistent tunnel location. This location has an average anteroposterior (AP) placement distance of 37.0% ± 5.2% and a range of 26.4% to 49.2% (Werner et al., 2016). The surgery results are negatively impacted by the large variation in AP distance because the tunnel placement directly affects clinical outcomes. Improper placement of the tunnel often causes failures. Studies show that an AP distance of less than 40% of the total distance yields improved clinical stability. Our surgical advisor, Dr. Mark Miller, patented "an adjustable device for identifying the target location for, and placement of, a bone tunnel" to improve the clinical outcome of ACL reconstruction surgery (Miller, 2020). The patent outlines the novel components and contains engineering sketches of the proposed guide (see Figure 1).

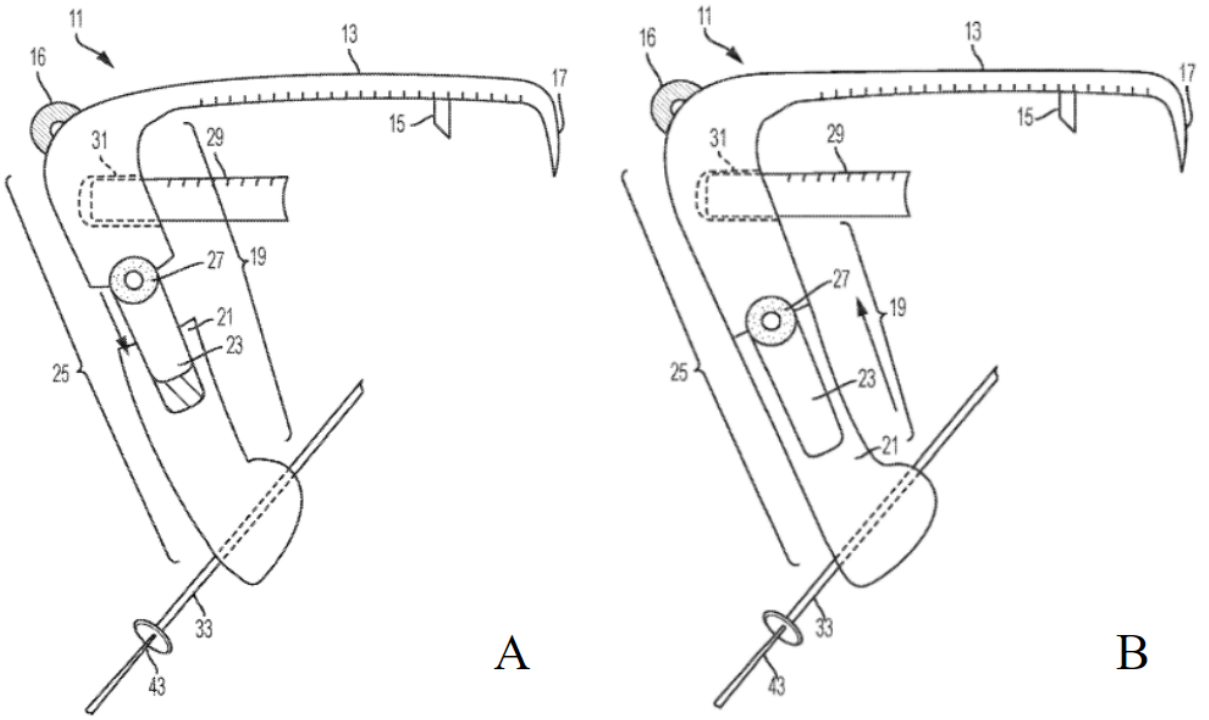

Figure 1: Technical drawing of patented tibial guide design. A and B demonstrate the hinge mechanics. From *Assignee: University of Virginia Patent*, by M. D. Miller, 2020.

For the technical project, we are redesigning the ACL tibial guide according to the restraints outlined in the patent and by our advisor. The new design should measure the total distance across the tibial plateau and engage the tibial plateau at a precise location based on the optimal AP distance without the use of imaging techniques. This will be done by designing a retractable ruler mechanism using a knob to determine the total AP distance of the tibial plateau, designing a track for the guide's upper arm to set the drilling distance, incorporating a hinge to set the drill in a specific angle for drilling the bone tunnel, and then using computer-aided design (CAD) to model and print prototypes for iterative testing. The goal is to design a tibial guide with these components and to test the accuracy and consistency of the bone tunnels to optimize ACL reconstruction surgeries.

By creating a tibial guide with an adjustable targeting mechanism, we expect to improve clinical outcomes and increase the success of ACL reconstruction surgery by increasing knee

stability. The issues with inconsistent and inaccurate tunnel positions are expected to be reduced as a result of implementing this device, therefore, creating a more dependable surgical treatment that will have fewer surgical failures. This project will be completed in a team of four students over two academic semesters through the courses BME 4063: Capstone Design I and BME 4064: Capstone Design II. Designing the differing tibial guide components, modeling and printing the guide, and testing the guide will be split equally amongst the team.

By playing the part of the engineer, I am embedding myself into half of the equation for producing medical technology that will be easily adopted. From my experience through iterative prototyping and conversing with doctors, I will identify key factors that physicians look for in their technology. I will incorporate these factors into development strategies and find ways for all engineers to better invent technology that will be utilized in hospitals.

The Factors Influencing Physician's Decisions on Adopting New Medical Technology

The market for medical technology is ever-growing, with an annual revenue growth rate of 5.95%, and the market is projected to reach $575.80 billion in 2022 (*Medical Technology - Worldwide*, n.d.). However, not all new medical technology is adopted by all physicians as "the rate of adoption of new technologies into healthcare systems is considered to be slower than in other settings" (Williams & Dickinson, 2010, p. 309). This causes an issue for patients as they are the ones suffering from not being able to receive the best advancements that have been produced. Although there are sometimes multiple methods to address a medical condition, it is important that the best choice is utilized by the physicians. There may be inherent factors of the technology or how it was produced that make the physician more reluctant to adopt it.

The connection between the technical, social, and human elements revolves around the values that the physicians hold compared to those of the engineers producing the technology. The social and human values the two groups hold will determine how they view the technical product. Medical practitioners often rely on older technology as it has proven its reliability, such as with the use of pagers instead of switching to the use of smartphones (Fisher, 2018). They see the use of the old, proven technology and are not ready for the risks that come with using something new. Additionally, the way physicians think and make decisions on how to treat a given patient is dependent on more than just what they have learned in their profession. They are affected by their specific backgrounds, which can also be altered as they gain new experiences, since "the role of the environment on physician behavior is twice as important as physician-specific factors" (Molitor, 2012, p. 3). Some other factors include looking at gender differences as well as influence from ethical perspectives, also known as the Doctor's Dilemma (Méndez et al., 2021; Sackett, 1996). The engineers need to understand all these possible factors that influence the physician in order to make a product that the user can apply in their work. Without an understanding of the user, the medical technology becomes useless as the engineers are not designing a device for themselves, they are for the physicians to use on patients.

To better understand this gap between the user's and non-user's way of thinking, I will rely on the framework of "configuring the user" as explained by Steve Woolgar (Woolgar, 1991). In this chapter, Woolgar explains how there is a distribution of knowledge and expertise between the users and the developers. By conducting a case study on users trying a new device, he was able to identify assumptions that engineers make about the users as they are developing the technology. He discovered that the various developers involved in the device's creation had different ideas about the user's way of thinking, which affected the way they viewed how the

product should be made. As seen from the study, this results in a disconnect as the user is unable to utilize the tool at all. Woolgar argues that user configuration is necessary by looking at the user's character, capacity, and possible future actions with the device. In the context of medical technology, physicians are the users that the engineers need to configure. By making assumptions instead of trying to understand the practitioners, the engineers are creating devices that the user is unable to utilize. The engineer must not only focus on a singular aspect of improvement, even if it is supported by research. They must also incorporate the physicians' viewpoints. For example, the improved tibial guide might incorporate all the requirements described by the studies to improve consistency and clinical outcome but if it is not made in a certain shape that allows the surgeon to comfortably hold it for long periods, then the device will not be used by the practitioners. Therefore, engineers, managers, and those involved in marketing the device need to understand how to configure the physician in order to create medical technology that will be easily adopted and utilized to improve healthcare. Moreover, an engineering team consists of individuals with different backgrounds and disciplines, each with their version of who the users are, that need to gain a common and proper understanding of the users in order to not restrict their actions in meaningful ways. This is especially important in the medical field as the engineers do not want to create a device that sets strict parameters for the physicians' actions. The device should predict the future actions of the physician and complement these actions.

Research Question and Methods

What are the main factors that influence physicians' decision to adopt new medical technology and how can these factors help engineers better develop their devices?

To identify these factors, I plan to utilize literature and discourse analysis to better understand the perspectives of the engineer and the physician around medical technology. Instead of utilizing a case study such as Woolgar, I will be looking through the literature to understand the research already done on physician decision-making. The literature analysis will allow me to take apart a text and understand what the author is trying to argue (*Literature Analysis | Writing Center*, n.d.). By compiling existing research on social and psychological motivations for physician decision-making, I will be able to examine the overlaps and identify the key factors that influence their choice in adopting medical technology. Additionally, I will conduct a discourse analysis on user manuals of medical devices and how they are presented to the world. The discourse analysis will help me find patterns in the way engineers expect their work to be used. By looking more at the way they are presenting their technology, not the actual information itself (Tannen, n.d.), I can determine if these manuals address the concerns and factors most important to the physicians. The literature analysis on physicians' way of thinking will help inform engineers on how they can effectively configure the user in the technology they are making. Instead of relying on assumptions made by the engineer, the analysis will identify the factors that will help predict the future actions of the physicians with the technology. Moreover, the discourse analysis will inform engineers on how they should present their discoveries to address physicians' concerns.

Conclusion

Medical technology is a rapidly growing industry, and its developments are crucial in the improvement of healthcare. However, physicians' reluctance to adopt new technology causes a limitation on the actual use of these devices. This slows the process of improving medical care

and prevents patients from receiving the highest level of care technology can provide. Additionally, newer technology is important and necessary to address new conditions and diseases that are being discovered. The issue of lack of adoption stems from the disconnect between the two disciplines of engineering and physician. The results of this research will address this problem by identifying key factors that influence physicians' likelihood to adopt technology and incorporating that into the engineering design process. Furthermore, this research will inform engineers how to present their technology in a way that persuades the physicians of the device's reliability and targets the factors most important to the physicians. This will be considered in the development of the redesigned tibial guide to promote better usability by the physicians and increase stability in patients that require ACL reconstruction surgery.

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