Comparison between ACL Reconstruction Surgery and Rehabilitation

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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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STS Research Paper

Introduction

Imagine yourself getting injured in the knee from just a wrong foot landing. In other ways, leading to having to completely stop the sports activities that once brought joy to you. One of the most common knee injuries is the anterior cruciate ligament (ACL) injury, where there are between 100,000 and 200,000 ACL tears per year in the United States (Friedberg, Ryan, n.d.). The injuries usually occur in college and high school athletes and are a more common occurrence for females than males due to the difference in physical anatomy. The most common form of injury is non-contact injury and can happen from sudden deceleration or change in direction when moving, pivoting, or landing in a rotational or lateral bending (Friedberg, Ryan, n.d.).

ACL injury is where there is a slight or complete tear in the ligament within the knee, leading one to experience continuous pain and discomfort if left untreated (Trasolini & MD, n.d.). In most cases, ACL reconstruction surgery is recommended. During the surgery, a medical device called the tibial guide is used to replace the damaged ligament with a graft by drilling tunnels in the femur and tibia. The current tibial guide in the market uses the surgeon's discretion for the placement. This dependency can lead to inconsistencies and inaccuracies in the tunnel placement location and could lead to future consequences within the patient's knee, one being knee instability. Therefore, in this paper, I argue that my approach to this problem will be focus on improving and redesigning the current tibial guide to reduce variability in the drilling of the bone tunnel during ACL reconstruction surgery.

In addition to the reconstruction surgery, there are many other challenging factors that must be considered before the surgery occurs. The project will then dive deeper into the societal and economic impact of ACL tears. The focus would be comparing and contrasting the nonsurgical and surgical ACL injury treatments by taking into consideration the cost, recovery period, effectiveness, and more (Mather et al., 2013).

Literature Review

The focus of redesigning the tibial guide is to create a more accurate and safer device during the reconstruction surgery, and therefore looking at the current tibial guide in the market is important. The current tibial guide that the project would be redesigning is based on the Anthrex AR-1510T (*Transtibial ACL Reconstruction for BTB Grafts*, n.d.). This tibial guide provides specific functions of the tibial guide and how the device's mechanisms work. From this current tibial guide, it was noticeable that many steps require extreme precision but are currently insufficient, leading to possible ACL surgery complications. The Anthrex AR-1510T would provide the baseline of how the improvements of the device should be made.

The capstone team's advisor presented research papers to our team showing how the tunnel placement affects the knee stability and other clinical outcomes (Büyükdoğan et al., 2021). Through this research, my capstone team could identify some of the current tibial guide's challenges such as the arthroscopic landmark creating a wide range of tunnel location positions in the anteroposterior (AP) distance across the tibial plateau. These factors would be considered when redesigning the tibial guide to provide a higher accuracy in the device.

The paper focused on looking at the societal impacts of the ACL injury and evaluating the cost-effectiveness by comparing the ACL reconstruction surgery to the ACL rehabilitation

only (Mather et al., 2013). When deciding to do ACL reconstruction surgery, many societal, psychological, and social factors need to be considered, such as the patient's fear of reinjury, mood disturbance, cost, and recovery expectations (Vutescu et al., 2021). There were more cost-utility analysis of comparing early reconstruction (ER) and rehabilitation with an optional delayed reconstruction (DR)(Mather et al., 2014). This comparison also shows in which order the reconstruction and rehabilitation should be done to successfully help the patient recover from an ACL injury. Through these resources and guidance, this paper will elaborate more on the redesigning of the tibial guide and continue to look at how the tibial reconstruction surgery impacts an individual in separate ways.

Methodology

Starting in Fall 2022, my Capstone team focused on redesigning about three to four new prototypes of the tibial guide using computer-aided design (CAD) software and 3D print the prototypes. Most of this designing portion of the project would be focused on quantitative descriptive data rather than qualitative. Modifications of the tibial guide are done by having specific aims that work in designing the main components. To accomplish this goal, we have identified three (3) aims that work toward designing the main components and evaluating their functionality in clinical use. Aim one (1) is designing a measuring component for the tibial guide to determine the total AP distance of the tibial plateau. Aim two (2) is to design a targeting component to set the desired endpoint for drilling the bone tunnel. Aim three (3) is to iterate and evaluate the designed guide prototypes.

ACL reconstruction surgery's ethical considerations and comparing the surgery to ACL rehabilitation were done with both qualitative and quantitative descriptive analysis. Ethical considerations such as considering the patient's safety, confidentiality, and honesty are critical in

developing a safe and efficient medical device. Additionally, as an ACL injury is one of the most common injuries, ensuring that having the surgery is effective in distinct aspects is important. If looking at other societal and economic factors suggest that ACL rehabilitation leads to a better outcome, then those factors must be considered in deciding what kind of treatment the patient would want.

Our advisors, Dr. Mark Miller, and Dr. Ian Backlund, provided the Capstone team with secondary data such as their research papers, patented papers, and an actual current tibial guide. This information guided us in a way on what modifications and improvements of the tibial guide should be focused on. In addition to the secondary data provided to us by our advisors, this paper gathered more in-depth secondary information by researching more about the affects the ACL reconstruction surgery would have on individuals.

ACL Surgery and Rehabilitation Cost-Effectiveness

ACL is one of the most common injuries and is the ligament that connects the front top of the tibia, which is the lower leg bone, to the rear bottom of the femur, which is the thigh bone. ACL reconstruction surgery requires replacing the damaged ligament with a graft. The replacement is done 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 ACL tibial guide can use anatomical landmarks, arthroscopy, and the surgeon's discretion for the placement of the drills. The current problem is related to the landmark. The 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). Due to the

variation in the AP distance, the surgery results could lead to undesirable clinical outcomes, and improper placement of the tunnel could often lead to failed surgery.

There are societal factors that need to be considered within having the device. As most devices could be expensive, many patients might not be able to afford the cost of the surgery. Being able to receive this surgery for those in need is critical in going on with their daily lives but being able to afford it could be another concerning factor. The average cost would range from $800 to $3000 with health insurance. People without medical coverage would cost approximately $20,000 to $50,000. There will also be additional costs for medical equipment such as knee braces and crutches, which will add $500 more. In addition, the physical therapy would cost approximately $1,000 (*Evaluating Costs for Your ACL Surgery*, n.d.). The cost of the surgery could ultimately lead to doubt in the patient of whether they truly need the surgery and how efficient and effective the surgery truly is. Still, being able to get the treatment as quickly as possible could lead to a significant difference in short-term and long-term outcomes depending on how fast they are able to receive the treatment. Without the treatment, the ACL injury could turn into a chronic ACL deficiency and other negative outcomes leading to the knee becoming more and more unstable (*ACL Injury*, n.d.)

In the paper "Societal and Economic Impact of Anterior Cruciate Ligament Tears," there were two studied done with one being short to intermediate term (six years) and the other more on the lifetime (Mather et al., 2013). The societal perspective of the costs and benefits of the treatment has shown a distinct difference between getting the surgery and getting only the rehabilitation.

To look at the difference between rehabilitation and surgery, a cost-utility analysis should be undertaken. Then, the effectiveness should be measured based on the cost-effectiveness

comparison, expressed as quality-adjusted life years (QALYs) gain. QALY takes into consideration numerous societal factors that includes the patient's work status, earnings, and disability. Having these comparisons could provide the patient with a better understanding and hopefully not avoid the surgery and have a chance to look at the long-term outcomes too.

In the short to intermediate term, the ACL reconstruction was less costly and more effective. The cost reduction compared to the rehabilitation only was about $4503 and QALY gain of 0.18 (Mather et al., 2013). In the long term, the mean lifetime cost for patients having undergone ACL reconstruction and rehabilitation was approximately $38,121 and $88,538, respectively with QALY gain of 0.72. This showed that the ACL reconstruction was more cost-effective in the short and long term in addition to providing better quality-adjusted life years for the patient.

The data provided that ACL reconstruction surgery was a better treatment than just rehabilitation. However, there were more answers that needed to be done with the timing of the reconstruction surgery. Through another cost-utility economic analysis comparing ER and DR, the cost-effectiveness also provided significant data. The ER group had QALYs gain of 0.28 compared to the DR group. In addition, the ER group had an overall lower cost to society of $1572(Mather et al., 2014). The most sensitive variable that was gathered was when looking at the knee instability. When the rate of instability falls to 51.5%, the DR is less costly. In addition, if the rate falls below 18.0%, then the Dr is the more effective treatment. In all, the research, and data show that early reconstruction is more effective and less costly than rehabilitation with a delayed reconstruction surgery.

Ethical Considerations

The biomedical research for our project must present safety, confidentiality, and honesty. Some biomedical ethics issues that can arise are creating a representative sample of the patients, inaccurate representation of the surgeons using the device, and patient confidentiality. By understanding and discussing the ethical implications, any assumptions or harm that may come with our design can be alleviated before it ever goes on the market.

One ethical consideration is having an appropriate sample size to guarantee more precision in our data. As each patient would have variability in the anatomical structure, making sure the sample size represents the entire patient population is important. As our sample population focuses on young athletes, making sure to take into consideration the patient's different physical traits is quite difficult. Different races, weights, muscle masses, heights, and more could be varied among the patients. Current ACL tibial guides have used an average patient's knee structure to base on when designing the surgical device and could turn less fit for some patients with either shorter or longer anterior-posterior (AP) distance.

Confidentiality related to obtaining personal identifying information, in our case MRI scans, is another ethical issue to consider. Biases related to name, sex, and gender should be eliminated to promote healthcare equality. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule protects patients' privacy and controls the disclosure and usage of information by healthcare providers. A limitation associated with HIPAA, however, is that obtaining a patient's record for medical research may be more difficult.

One long-term biomedical issue that may arise is in case a surgeon seems to show signs of fatigue and is not able to efficiently perform the surgery. As this surgery requires an arthroscopic procedure and an elevated level of precision during the surgery, making sure the surgeon performs the procedure well is crucial for the patient's safety and comfort.

Societal Impact

Empathy and compassion are crucial factors in engineering because you are unable to properly solve problems without understanding the users of the device. Moreover, negative outcomes can arise when making assumptions. This is especially important in the field of surgical devices as the tool can directly impact surgical outcomes and the patient's quality of life. Additionally, by keeping empathy in mind, we are better able to meet the needs and expectations of the users, which are predominantly surgeons and their patients. These considerations are woven into the engineering design from the beginning by influencing the ideas, namely, health disparities compel engineers to create solutions and tools. Although this is a good start, empathy, and compassion still need to be included in other parts of the design. Engineers often focus on the direct problem, in this field, it is usually the surgical procedure. However, there is a serious need to also consider pre- and post-operational effects on the patient.

It is important to consider how the device will impact recovering times, physical therapy, and other follow-up needs. This is important as the patients are often athletes. Athletes need their knees for work and student-athletes might also need to recover quickly to meet the requirements for scholarships. Additionally, the longer the recovery time, the more it could hurt the patient's mental health. ACL reconstruction surgeries usually lead to repeat surgeries due to failures and needing to put more force on your uninjured leg. All these ethical and societal factors must be considered when providing the best treatment for patients through patient care and increase in accuracy level of the surgery.

Conclusion

As there has been an increase in the trend towards physical activities by society, there has also been an increase in injuries to the knee such as the ACL tearing (Kaplan & Witvrouw, 2019). ACL injuries are a common occurrence, particularly among active individuals, and finding and innovating the right treatment is crucial in helping them to restore their quality of life. For the technical project, my capstone group will be creating a more accurate tunnel placement of the tibial guide for those who need ACL reconstruction surgery. Developing a device with better accuracy when using the tibial guide could be extremely important in being able to successfully help those in need. For the STS aspect, I researched more into the difficulties and demand factors that are necessary for receiving the ACL reconstruction treatment required.

Consequently, the STS part of this paper is tightly coupled to my technical project. Both factors need to be considered when trying to determine the ultimate benefit of the device given that it is designed to help those people experiencing knee discomfort. The technical portion will focus on the design of the device while the STS will focus more on analyzing which societal factors need to be taken into consideration when doing the ACL surgery. The outcome of this project is expected to increase knee stability and create a more dependable surgical outcome for those who suffer ACL tears and reduce the chance of ACL reconstruction failure. Finding a more accurate and reliable design for the tibial guide could be a potential solution for patients and athletes to successfully return to their sports. In addition, learning more about the distinct differences and benefits of ACL surgery and rehabilitation would help determine what would be better for patients in a societal and economic aspect.

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