Ideal ACL Treatment According to Post-Treatment Activities and Financial Capability

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Tzuyu Cheng

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Advisor

Richard D. Jacques, Ph.D., Department of Engineering and Society

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Introduction

If you are a Golden State Warriors fan, you probably remember when Klay Thompson got injured during the NBA playoff finals in 2019 and the Warriors eventually lost to the Raptors. It was later reported that Klay Thompson tore his anterior cruciate ligament (ACL) during the game. The knee is a complex joint that connects bones, cartilage, ligaments, and tendons. One of the most important ligaments in the knee is the ACL. The ACL connects the thigh bone (femur) to the shinbone (tibia) and provides rotational stability for the knee. ACL injuries are one of the most common knee injuries and are typically caused by sudden changes in ligament direction. This often occurs during sports such as soccer, basketball, and football, where sudden stops or changes in direction, jumping and landing causes strain and injures the ACL. There are between 100,000 and 200,000 ACL tears per year in the United States[1], and they can happen to anyone at any age but athletes are at a greater risk. (*ACL Tear*, n.d.; Friedberg, n.d.) These injuries tend to be complete or almost complete tears of the ligament. One common treatment mostly used on athletes is ACL reconstruction surgery, which is the focus of our technical topic. During the surgery, an ACL tibial guide will be used to drill a bone tunnel across the tibia. Doctors will be able to replace the torn ACL with the graft tendon, which is usually taken from another part of the patient's knee or a human donor, through the bone tunnel. There are several other ACL treatments such as rehabilitation. My STS topic is to find an ideal ACL treatment for each patient according to their planned post-injury activities and economic considerations.

The goal of this project is to redesign the tibial guide for ACL reconstruction surgery to reduce variability in the location of the drilled bone tunnels and improve post-operative knee stability. The current guides on the market utilize anatomical landmarks identified through arthroscopy to locate the tunnel placement; however, this yields inconsistent tunnel locations (Werner et al., 2016). Our advisor Dr. Mark Miller has patented a design that utilizes measuring components to bring a quantitative element to the surgical procedure (Miller, 2020) – specifically utilizing the anteroposterior (AP) distance of the tibial plateau. We will identify mechanisms to incorporate the patented features while maintaining the clinical usability of the device by comparison to current models, namely the Arthrex AR-1510T ("Transtibial ACL Reconstruction for BTB Grafts Surgical Technique," n.d.). In this paper, I argue that my approach to this problem will draw attention to increase the success rate of the ACL surgery and improve patient's post-operative conditions.

Methodology

By creating a tibial guide with an adjustable targeting mechanism, we expect to improve clinical outcomes and increase the success of ACL reconstruction surgery. The issues with inconsistent and inaccurate tunnel positions are expected to be reduced as a result of implementing this device. We implemented three specific aims to accomplish these goals. Measuring the entire AP distance across the tibial plateau for each reconstruction surgery will allow us to better understand the surgical site and define the best tunnel location for each patient (Aim 1). The adjustable target arm will allow the surgeon to accurately position the tunnel location to the predetermined percentage of the AP distance without the variability of reliance on a landmark and surgical experience (Aim 2). Through iterative designs and testing, we expect to assemble a device that will produce consistent measurements and tunnel placements (Aim 3). The outcome of this project will increase knee stability and create a more dependable surgical treatment for those who suffer ACL tears. An increasing trend towards physical activity results in an increase in injuries in the knee, such as ACL tears (Kaplan & Witvrouw, 2019). 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.

For Aim 1, the measuring component will be designed using the CAD software Autodesk Fusion. The drawn prototype will then be 3D printed utilizing the Qidi I-Fast 3D printer with PLA filament for the prototypes (*Qidi I-Fast, a Pioneer in Solving Complex Printing*, n.d.). The final product will be made of stainless steel. This component will be evaluated on the rest of the components of the ACL guide. The length of the measuring arm would be adjusted using a screw-lock mechanism, which can be manually changed by the doctor according to each patient's tibial plateau length.

For Aim 2, the targeting arm will also be drawn using Autodesk Fusion and 3D printed utilizing the same 3D printer and materials as previously stated. The targeting component needs to be able to move independently of the measuring arm. Therefore, a hinge with a lever lock mechanism is adopted to set the rotated arm in place while the surgery proceeds. The angle component will still utilize the screw-lock mechanism.

For Aim 3, we would complete the entire model on the CAD software once we have our improved prototype of the tibial guide. This would lead us to be able to 3D print it and evaluate it on simulated knee joints and styrofoam bones. The CAD software would be continuously used to implement the specific changes that we would like to add to the current tibial guide. Through this, we would be able to have a more accurate design. We would modify depending on the results to create the most accurate tibial guide. After finalizing the design, we would have access to cadavers to evaluate the prototype.

The preliminary measurements will be qualitative since we need numerical data to decide the length of the top arm of the tibial guide. These data sets will be primary as we will be collecting the data firsthand, and they will be used to determine the dimensions of the tibial guide and the accuracy of the bone tunnel placement through experiments on Styrofoam bone models. Once the preliminary data is obtained, the finalized prototype will be evaluated by surgeons for qualitative assessments for further refinements of our redesigned device. The redesigned tibial guide will be evaluated based mostly on ergonomics and the efficacy of usage.

To evaluate the ACL treatment for patients of different social and economic backgrounds, several qualities of different treatments and patient demographics will be quantified. The most common ACL treatments will be evaluated based on post-treatment knee stability, trauma after treatment, target patients and affordability. Each patient will be classified according to whether they are an athlete, their age, future activity plans, and financial capability. Characteristics of each treatment as well as each patient will be quantified into numerical measurements. The measurements of the treatment will be compared to the values of the patient. A goodness-of-fit model could be used to evaluate the statistical compatibility between the patient data and different treatment methods to determine the most ideal treatment for each patient.

ACL Tibial Guide for Improved ACL Reconstruction

ACL reconstruction surgery replaces the damaged ligament with a graft, 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., n.d.). The surgery results are negatively impacted by the large variation in AP distance because the tunnel placement directly affects clinical outcomes and 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 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, n.d.). The patent outlines the novel components and engineering sketches of the guide (see Figure 1).

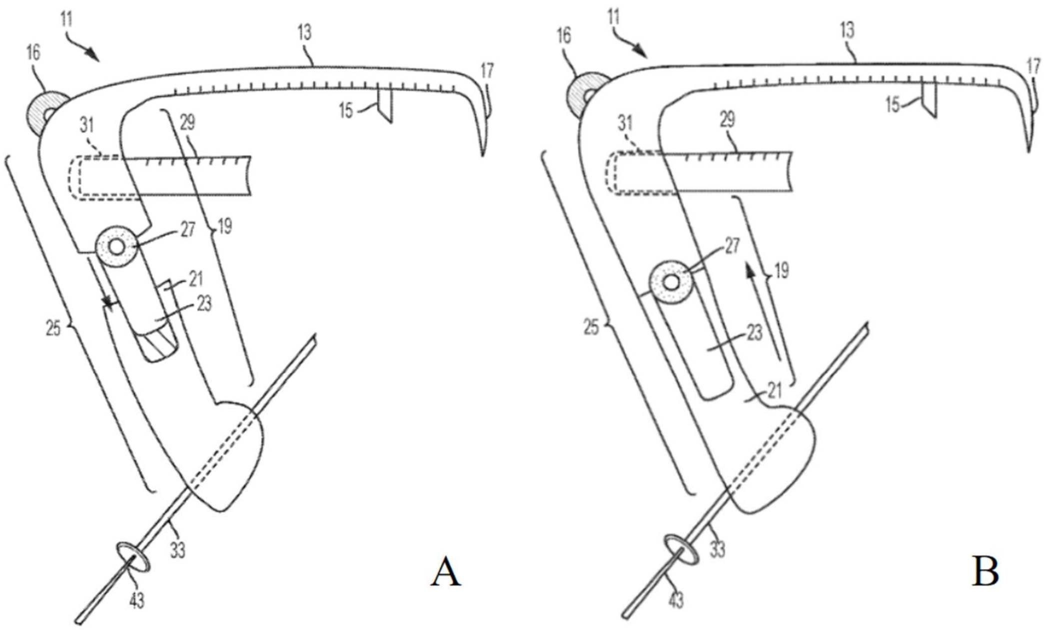

Figure 1: Technical drawing of patented tibial guide design. A and B demonstrates the hinge mechanics.

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 was initially done in the first prototype by designing a retractable ruler mechanism using a knob to determine the total AP distance of the tibial plateau, implementing a track for the guide’s upper arm to set that distance, creating a retractable 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 evaluate the accuracy and consistency of the bone tunnels to optimize ACL reconstruction surgeries.

However, after further evaluation, several parts of the first prototype were revised to simplify the mechanisms of the tibial guide while remaining intact functionally. As a result, instead of the sliding measuring arm, the handle is now a rigid attachment. The new movable part is the shin stopper, which was originally rigid in the first prototype. This was due to needing the measuring arm to not move because it is the only portion that goes inside the knee of the patient. The top measuring arm still maintains its function but changes how the measuring is done. Now, the point of the measuring arm is positioned statically in the knee while the shin stopper moves and hits the front, exterior part of the knee. The distance between these two points is measured.

Furthermore, the handle and curved portion of the targeting component are now statically combined instead of with a hinge. This works in conjunction with the upper half of the handle, which allows the targeting arm to extend up and down. This is necesssary because at various measured distances, the targeting arm needs to be aimed at the point of the measuring arm. The angle adjustment piece remained the same shape but a side holder for the drill guide was implemented, along with a bottom stopper. This bottom stopper allows the device to sit against the leg to offer more stability. The holder is necessary because where the AP distance is clinically measured from is a few centimeters to the side of where the drilling normally occurs. Thus, the creation of the targeting component is preserved but Aim 2 was altered to have the extendable handle instead of the rotating hinge.

New discoveries and revisions ideas were found from weekly team meetings and bi-weekly advisor meetings to better understand how the surgeons perform the procedure. These helped us produce preliminary sketches to talk through possible designs before doing CAD. The most important design criteria are the need to incorporate these functions with the most simplistic mechanisms so that the device can be most efficient in a clinical setting.

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 courses BME 4063: Capstone Design I and BME 4064: Capstone Design II. Designing the differing tibial guide components, modeling, and printing the guide, and evaluating the guide will be split equally amongst the team.

Ideal ACL Treatment According to Post-treatment Activities and Financial Capability

ACL reconstructions are mostly done on athletes since they require high functional stability of the knee to perform high level sports. However, even with surgery, only 65% of the athletes return to their sports at the same level preinjury (Gokeler et al., 2022). There are also alternative treatments such as rehabilitation therapy for non-athletes that allows them to perform daily tasks and their regular activities, which is why surgery is not always required. When encountering ACL tears, it is important to find the most suitable option for everyone from the various ACL treatments.

The topic of my project is in the field of orthopedic surgery clinical research, specifically in the sports medicine division since most patients receiving the ACL reconstruction treatment are athletes. With the high incidence rate of 100,000 to 200,000 ACL tears per year as mentioned earlier, there is significance in finding the best treatment that allows the patient to return to their preinjury activities, whether they are athletes or not. There are controversies related to ACL reconstruction as well, including the surgical technique and ligament graft used in the process being impossible to recreate the same rotational stability of the native ligament (Hospodar & Miller, 2009). Research also showed that ACL reconstruction causes larger trauma than the initial injury and that there is no difference in patients' pain level or knee functional stability between conservative rehabilitation and ACL reconstruction surgery (BMJ, 2020).

The unreliability of current surgery methods is one main contribution to the low surgery success rate. Our newly designed ACL tibial guide mentioned in the technical discussion aims to increase the success rate for ACL surgeries so that more athletes can return to their preinjury level of sports. For non-athletes, their age and post-treatment activities are the major factors contributing to choosing their treatment method. Another consideration factor is the cost of the treatment. Research showed that ACL reconstruction is more cost-effective than non-operative treatments with merely rehabilitation. The cost of graft materials also varies, which leads to variability in the total cost of ACL reconstruction surgery (Saltzman et al., 2015). The improved surgery method from my technical discussion will be evaluated along with the existing treatments to search for the ideal ACL tear treatment method that provides strengthened knee stability and reduced trauma for each patient according to the patient's post-surgery activities and financial capability.

My STS topic is tightly coupled with my technical topic since the technical topic aims to improve the current ACL surgery process with a newly designed ACL tibial guide and my STS topic aims to find the best ACL treatment for individual patients by evaluating social and economic considerations.

Conclusion

ACL injuries are a common knee injury, especially within athletes that participate in sports such as soccer, basketball, and football. Current reconstruction methods rely on arthroscopic landmarks and could not achieve accurate tibial tunnel placement. My technical project focuses on designing an ACL tibial guide that allows for consistent and accurate tibial tunnel placement that ensures functional stability of the knee after surgery. Results showed that our newly designed tibial guide has more accurate tibial plateau length measurements compared to the current tibial guide on the market, namely the Arthrex AR-1510T model, and that the values are more aligned with MRI scans. This as a result leads to more accurate calculation of the ideal location of the bone tunnel. In terms of bone tunnel placement, our new design also has increased bone tunnel placement accuracy and better consistency compared to Arthrex AR-1510T. These results confirm that our aims were achieved and could be better understood from the visualization of data. These results are crucial because they show that our new design can decrease post-surgical complications associated with unsuccessful surgical procedures and would significantly eliminate the need of additional post-surgical modifications to the site of injury. This will greatly benefit the patient's clinical stability of the knee and life quality after the operation.

My STS project focuses on finding an ideal ACL treatment method that best improves the clinical stability of the knee and minimizes trauma post treatment according to the patient's post-treatment plans and financial capability. Considering multiple aspects regarding the treatment cost and the patient's socioeconomic status, ACL reconstruction surgery is predominantly the best option for most of the patients. This result is especially true if the patient is an athlete who wishes to return to their professional level of sport. With our newly designed tibial guide, patient can expect to significantly reduce unwanted post-surgical procedures for injury modifications since the accuracy of the bone tunnel placement is expected to greatly increase, and the patient would less likely need to undergo additional treatments to compensate for undesirable surgical outcomes. The modifications on the surgical tool are expected to make the ACL reconstruction surgery a more financially affordable option for patients with ACL injuries and to improve their treatment outcomes.

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