Redesigning the Tibial Guide for ACL Reconstruction Surgery

Disparities in Service and Accessibility for ACL Reconstruction between Medicaid Adolescent Patients and Privately Insured Adolescent Patients

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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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Introduction

Anterior cruciate ligament (ACL) injuries are one of the most common knee injuries, typically caused by sudden changes in ligament direction. Patients would have to get ACL reconstruction surgery, but it is not cheap. If not covered by health insurance, it can easily reach $20,000 to $50,000, but with health insurance, there would be an out-of-pocket price between $800 - $3000 (*Cost of ACL Reconstruction - 2022 Healthcare Costs*, n.d.). Even so, this does not include postoperative measures such as physical therapy (PT), potentially an additional $1000, and graft failure.

With every ACL reconstruction surgery, there is a chance of graft and reconstruction failure, which is when the tendon used to replace the ACL fails to heal properly, and the knee's motion is restricted. The most common reason for ACL reconstruction failure is due to surgical technical errors, specifically the malposition (incorrect positioning) of the tibial and femoral bone tunneling (Ho et al., 2018). These errors result in reduced functionality of the placed graft, leading to failure and costly second reconstruction surgery. To reduce technical errors in the surgery, I propose a design for an ACL tibial guide that will reduce the occurrence of graft failures, therefore reducing the chance of a second surgery.

When looking at the technical perspective too closely, the economic and political factors can be missed. Surgery is costly. Public and private health insurance usually covers the costs, but there are differences such as disparity in diagnostic rate, delay in appointment times, and low accessibility for postoperative PT (Patel et al., 2019). Those under public insurance may receive the surgery, but publicly-insured patient restrictions could potentially render the surgery useless.

It is important to acknowledge that both technical and social factors have an impact on reducing the graft failure rate. By focusing on reducing the rate through only technical means

and neglecting the social factors, the whole sociotechnical challenge is not fully addressed. Through designing and modeling, I will create a more efficient ACL tibial guide. In addition, I will use technological politics to analyze how adolescence with Medicaid are marginalized from accessing ACL services when comparing them to those under private insurance.

Technical Research Project

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*, n.d.; Friedberg, n.d.). 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 (Pignolet, n.d.). Additionally, without surgery, long-term effects on the knee can increase its instability, and the risks of other injuries increase. Of the patient 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, 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 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).

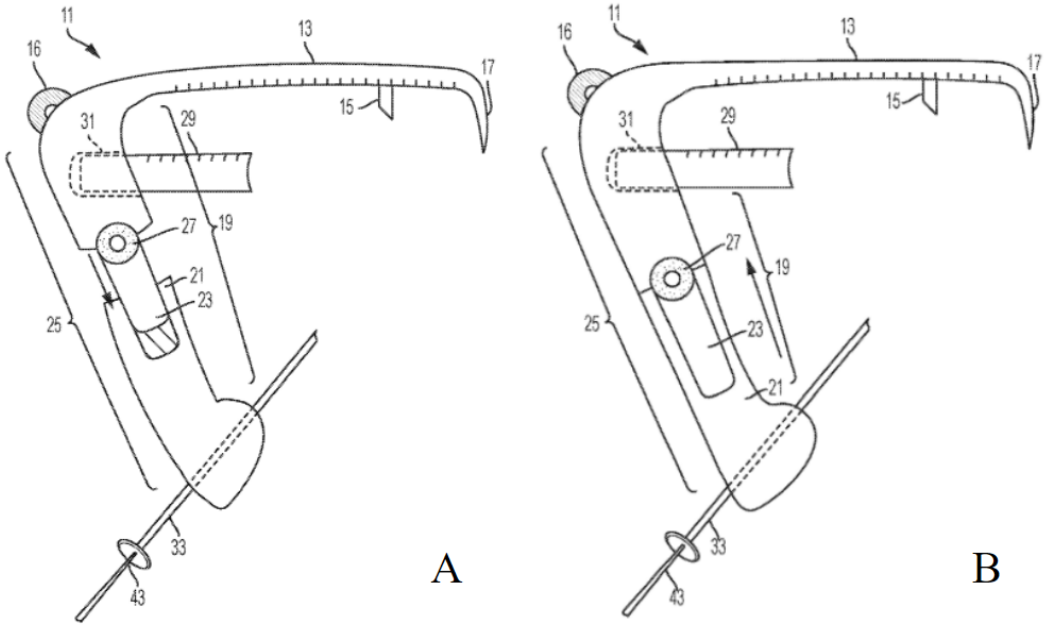

Figure 1: Technical drawing of patented tibial guide design. A and B demonstrates the hinge mechanics.

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 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 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 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.

STS Research Project

In 1965, Lyndon B. Johnson enacted the first public insurance programs in the United States which would cover over 20% of Americans: Medicare and Medicaid (Tikkanen et al., 2020). For this analysis, I will be mainly focused on the Medicaid program from the perspective of ACL reconstruction surgery and adolescent patients. Medicaid is a state program that follows federal requirements where 63% of its funds come from federal taxes and the rest from state taxes (Tikkanen et al., 2020). The program funds many health services including inpatient and outpatient care, long-term care, diagnostics services, etc. with possible additional services such

as PT for those qualified (i.e. low-income families and young children). Later in 2010, Barack Obama further expanded the Medicaid program through the Affordable Care Act (ACA) which expands coverage to adults under 65 years old, addresses affordability, improves quality and efficiency, etc (Canonico, n.d.). However, many ACL reconstruction Medicaid patients still struggle to receive the necessary care and treatment in comparison to privately insured patients. For instance, in the Cincinnati area, including Ohio, Indiana, and Kentucky, 38 of 42 orthopedic services offered privately insured adolescent patients an appointment within 2 weeks, while 6 of 42 Medicaid adolescent patients were offered an appointment also within those 2 weeks (Pierce et al., 2012). This means the privately insured is 57 times more likely to get an appointment than a Medicaid patient.

Medicaid and the addition of ACA increased the number of insured Americans, but there is still a disparity in health services and accessibility between those under Medicaid and those under private insurance. Medicaid successfully covers the cost of ACL surgery and allows the surgery to occur, but Medicaid adolescent patients are still marginalized. An example is with diagnosis, in Florida, privately insured patients were diagnosed 14 days after the injury while Medicaid patients were diagnosed after 56 days (Baraga et al., 2012). Another example is in Massachusetts, privately insured patients had access to 96.4% of PT services while publicly insured patients only had access to 51.8% with the main reason being low reimbursement rates or no existing contract (Rogers et al., 2018). While Medicaid does not intentionally specify these outcomes, Medicaid unintentionally overlooks the inequality in accessibility from differing providers and services, allowing privately insured patients to be more privileged. Because of this, lower economic standing patients that undergo the surgery have an unstable post-treatment, increasing the likelihood of graft failure and resulting in the need for a second operation.

I argue that ACL reconstruction failure is not due to only inaccurate tunneling for graft placement but also due to the inequality in service between differing insured patients which ultimately excludes Medicaid adolescent patients from a stable recovery. Such services include receiving early appointment times, the possibility of earlier ACL injury diagnosis, and more accessibility to postoperative PTs. Technological politics aims to address concerns of power and justice in technological design (Winner, 1980). It does this by questioning the intentions of a design, whether it implicitly or explicitly biases or excludes affected groups because of the technology's design. By applying technological politics, I will analyze and uncover, for ACL reconstruction patients, how Medicaid adolescent patients are unintentionally marginalized by services and providers and certain components of the Medicaid program. By fully understanding the political and economic components of the situation, it will help in furthering the context in redesigning the ACL tibial guide. I will use evidence from various primary research articles and journals that focus on comparing Medicaid and privately insured adolescent patients that underwent ACL reconstruction in addition to government documents about the program.

Conclusion

The deliverable for the technical project discussed above will be an iterated 3D printed prototype ACL tibial guide designed with the necessary components and features to achieve accurate measurement of the AP distance and tunneling position. The STS research project will look further into how the political and economic factors create differences in treatment between Medicaid and privately insured adolescent patients and how this marginalizes Medicaid patients and favors privately insured patients. Technological politics will be applied to analyze the biases against ACL-injured Medicaid patients through the STS project, and then that analysis will be

used to provide another perspective on the increasing ACL surgical failure rate from the technical portion. Using the deliverable from the technical project and the analysis from the STS portion, the issue of graft and reconstruction failure can be addressed from a sociotechnical perspective by addressing the technical cause of graft failure and by understanding how marginalizing and excluding specific patient groups can be a factor in that failure.

Word count: 1,775

References

ACL tear: Symptoms, recovery & treatment. (n.d.). Cleveland Clinic. Retrieved October 25, 2022, from https://my.clevelandclinic.org/health/diseases/16576-acl-anterior-cruciate-ligament-tears

Baraga, M. G., Smith, M. K., Tanner, J. P., Kaplan, L. D., & Lesniak, B. P. (2012). Anterior cruciate ligament injury and access to care in south Florida: Does insurance status play a role? *The Journal of Bone & Joint Surgery*, *94*(24), e183. https://doi.org/10.2106/JBJS.K.00852

Canonico, M. (n.d.). *Medicaid: A brief history of publicly financed health care in the United States*. 5. Retrieved October 25, 2022, from https://www.chcs.org/media/Medicaid-Timeline-Fact-Sheet_01.14.20v2.pdf

Cost of ACL reconstruction—2022 Healthcare costs. (n.d.). Retrieved October 25, 2022, from https://health.costhelper.com/acl-reconstruction.html

Friedberg, R. P. (n.d.). *Patient education: Anterior cruciate ligament injury (Beyond the Basics)*. Retrieved October 25, 2022, from https://www.uptodate.com/contents/anterior-cruciate-ligament-injury-beyond-the-basics

Gokeler, A., Dingenen, B., & Hewett, T. E. (2022). Rehabilitation and return to sport testing after anterior cruciate ligament reconstruction: Where are we in 2022? *Arthroscopy, Sports Medicine, and Rehabilitation*, *4*(1), e77–e82. https://doi.org/10.1016/j.asmr.2021.10.025

Ho, B., Edmonds, E. W., Chambers, H. G., Bastrom, T. P., & Pennock, A. T. (2018). Risk factors for early ACL reconstruction failure in pediatric and adolescent patients: A review of 561 cases. *Journal of Pediatric Orthopaedics*, *38*(7), 388–392. https://doi.org/10.1097/BPO.0000000000000831

Knee ligament surgery—How it is performed. (2017, October 23). Nhs.Uk. https://www.nhs.uk/conditions/knee-ligament-surgery/what-happens/

Miller, M. D. (n.d.). *Adjustable device for identifying a target location for a tibial tunnel and related method thereof.* (Patent No. US 10,758251 B2).

Patel, A. R., Sarkisova, N., Smith, R., Gupta, K., & VandenBerg, C. D. (2019). Socioeconomic status impacts outcomes following pediatric anterior cruciate ligament reconstruction. *Medicine*, *98*(17), e15361. https://doi.org/10.1097/MD.0000000000015361

Pierce, T. R., Mehlman, C. T., Tamai, J., & Skaggs, D. L. (2012). Access to care for the adolescent anterior cruciate ligament patient with Medicaid versus private insurance. *Journal of Pediatric Orthopaedics*, *32*(3), 245–248. https://doi.org/10.1097/BPO.0b013e31824abf20

Pignolet, J. (n.d.). *Rehabbing your torn ACL without surgery*. Retrieved October 25, 2022, from https://acltear.info/anterior-cruciate-ligament-rehabilitation/acl-rehabilitation-without-surgery/

Rogers, M. J., Penvose, I., Curry, E. J., DeGiacomo, A., & Li, X. (2018). Medicaid health insurance status limits patient accessibility to rehabilitation services following ACL reconstruction surgery. *Orthopaedic Journal of Sports Medicine*, *6*(4), 2325967118763353. https://doi.org/10.1177/2325967118763353

Sanders, T. L., Maradit Kremers, H., Bryan, A. J., Larson, D. R., Dahm, D. L., Levy, B. A., Stuart, M. J., & Krych, A. J. (2016). Incidence of anterior cruciate ligament tears and reconstruction: A 21-year population-based study. *The American Journal of Sports Medicine*, *44*(6), 1502–1507. https://doi.org/10.1177/0363546516629944

Tikkanen, R., Osborn, R., Mossialos, E., Djordjevic, A., & Wharton, G. A. (2020, June 5).

International health care system profiles United States. https://www.commonwealthfund.org/international-health-policy-center/countries/united-states

Werner, B. C., Burrus, M. T., Gwathmey, F. W., & Miller, M. D. (2016). A prospective evaluation of the anterior horn of the lateral meniscus as a landmark for tibial tunnel placement in anterior cruciate ligament (ACL) reconstruction. *The Knee*, *23*(3), 478–481. https://doi.org/10.1016/j.knee.2015.10.009

Winner, L. (1980). Do artifacts have politics? *Daedalus*, *109*(1,), 121–136. http://www.jstor.org/stable/20024652