REMOTE MONITORING & WEARABLE SENSING POST ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

IMPACT ON REMOTE MEDICAL CARE

A Thesis Prospectus
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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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The anterior cruciate ligament, also known as the ACL, is the primary ligament responsible for stabilizing the knee. The ACL is essential for twisting, turning, and any sudden movements in the lower half of the body (Filbay & Grindem, 2019, para. 9). This makes the ligament crucial for any physical activity or sport that requires frequent lower half movements. There are many cases in professional and amateur sports where an athlete suffers a rapture to their ACL and is unable to compete for the rest of the season. In some rare cases, the athlete is able to play with the tear in their knee. Supportive braces are used to help them compete through their injury but these athletes suffer through restricted movements and extremely reduced lateral mobility (Blewett, 2011, para. 5). The anterior cruciate ligament is unlike many other ligaments in the body that can heal with time and therapy; it requires reconstructive surgery to return the knee to its original tensile strength and therefore its overall health.

ACL reconstructions (ACLR) are among the most common sports medicine procedures performed in the world (Csintalan, R. P. et al., 2008, pp. 17-21). Currently, there are approximately 100,000 to 200,000 ACL reconstructions per year in the United States alone and this number is increasing at a rate of 2.3% each year (Ganley, 2017, para. 1). Although this is such a common procedure, it shockingly only has a success rate of 80-90%. That leaves approximately 20,000 people per year that do not have satisfactory results and that number increases by 500 people per year on average. Failure of an ACLR is hard to describe by many patients. Many quote constant knee instability, pain, stiffness, or the inability to return to their desired activities (Blewett, 2011, para. 6). Fixing a previously failed surgery becomes even more complex in these situations and ultimately ends up hindering a major part of the patient’s everyday lifestyle (Csintalan, R. P. et al., 2008, pp. 17-21).

Less than 10% of the unsuccessful surgeries are due to weakness in the ACL graft and this raises question to how the other 90% do not recover correctly (Southern California Orthopedic Institute, para. 2) . There are many different recovery methods by physical therapists all over the country with different variations in the timing to return to specific exercises and activities. This time period is crucial in the healing and strengthening of the ligament. Even with the best medical treatment one can find, there is a possibility that the ligament never regains its original tensile strength. There is strong evidence that suggest rapidly reduced physical performance and deteriorating joint health in the years following surgery (Cavanaugh, J. T. & Powers, M., 2017, pp. 289-296). Following their ACL reconstruction, patients have stated that they suffer from persistent muscle weakness and altered movement patterns (Beaumont, para. 7). Many attempts have been made to diagnose and prevent the deterioration of the ligament but still 29.5% of athletes suffer a second ACL injury within 24 months of returning to activity ("Second ACL Injuries", 2013, para. 3).

The technical project and loosely coupled STS research project proposed in this prospectus examines this issue and provokes thought as to what could happen in the future. The technical project aims to leverage the use of wearable sensors to continuously monitor a patient recovering from an anterior cruciate ligament reconstruction. This idea follows a recent trend in the transition to telehealth methods following the Covid-19 pandemic. Providing medical services to patients outside of the office environment is becoming more capable as technology has improved. This will be the focus of the STS research and prove important in understanding the contribution and societal impact this technical research will have on the health environment today and in the near future.

The basis of this project will be built on current and past research reports on ACL recoveries—more particularly projects that use the capabilities of wearable technologies. Also, the team will be exposed to in person clinical research performed at UVA with current student athletes. This project will be implemented during the Fall 2021 and Spring 2022 semesters accounting to a total of 28 weeks, as depicted in Figure 1.

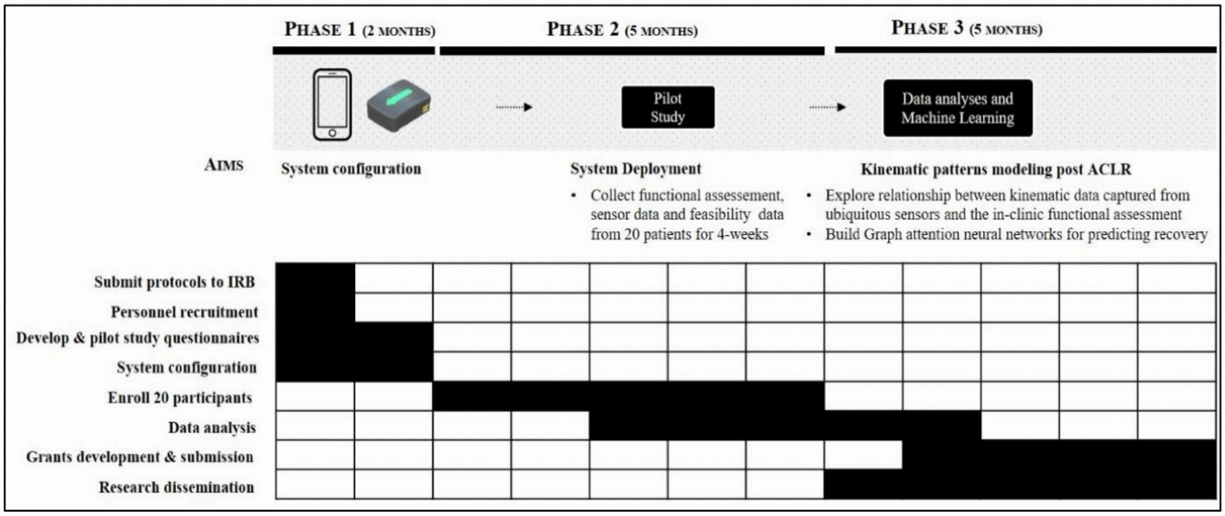

Figure 1: UVA ACL Monitoring Capstone Technical Project - Fall 2021 to Spring 2022. This figure displays the expected timeline for milestones achieved on the technical project (Hamrock, 2021).

REMOTE MONITORING & WEARABLE SENSING POST ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

Anterior Cruciate ligament (ACL) injuries are common, especially in young athletes with rates ranging from 6 to 32 injuries per 100,000 athlete exposures (Joseph et al., 2013, pp. 810-817; Mihata et al., 2006, pp. 899-904). Over 100,000 patients in the United States annually elect to have ACL reconstruction (ACLR) with the goal to return to pre-injury level of activity and to maintain a healthy and active lifestyle (Collins J.E. et al., 2013, pp. 544-549; Mall N.A. et al., 2014, pp. 2363-2370) . Within the first two years following an ACLR and return to sports, young active patients are at the highest risk for re-injury both to the ipsilateral/ACLR and contralateral knees (Grindem H. et al., 2016, pp. 804-808; Paterno M.V. et al., 2012, pp. 116-

121). These athletes are at six-times greater risk for subsequent knee injury compared to uninjured athletes ("Second ACL Injuries", 2013, para. 1). Prevention of secondary injury is paramount, especially in those who are young with continued risk exposure due to competitive sports.

The decision about when to return to unrestricted physical activity or competitive sports is a decision that has come under much scrutiny due to the lack of evidence-based criteria that have sufficient predictive value (DiFabio M. et al., 2018, pp. 144-150; Norte G.E. et al., 2018, pp. 1-9). Currently, the practice of collecting objective data to inform return to sports decisions is common in clinical settings (Manzer H. et al., 2017). Current return to sports tests are limited in that there is considerable redundancy, sensitivity to change after exercise and generalizability to demands of specific activities or sports (Bookbinder H. et al., 2019, pp. 1-7; Slater L.V. et al., 2018, pp. 35-40). The need for a precise, objective and whole-body approach to movement evaluation is essential for the health and safety of patients recovering from ACLR.

Early detection of functional deficits is vital to optimize post-operative rehabilitation and to restore normal movement patterns in patients. Current methods of detection require unconventional movements such as jumping which cannot be done in the early stages of recovery in fear of damaging the newly repaired ACL. Further, current evaluation methods are only administered in clinics and lacks a day to day picture on the patients' recovery progress. The ability to detect and track subtle movement asymmetries in a natural and unrestricted environment will assist clinicians to track progress in order to make informed decisions on rehabilitation.

The objective of the technical research is to leverage sensing technologies to monitor patients post ACLR. The broader aim is to enable clinicians and researchers to evaluate patients in representative environments and activities that are outside the clinic and lab and at early time points following surgery. This study takes an initial step in understanding how data from body sensors can be used to aid medical decision-making regarding rehabilitation progressions. The technical project's goals are to (1) investigate the correlation between sensing methods versus current in-clinic functional assessments in detecting functional abnormalities and (2) develop a predictive modeling method to forecast the rehabilitation trajectory of patients recovering from ACLR.

Phase one of the technical project is to leverage the Trigno Avanti, accelerometer, gyroscope, and EMG sensors to collect data in real time and transmit the data wirelessly for further storage and analysis. Phase two will begin with recruiting twenty participants from the UVA Exercise and Sport Injury Laboratory. These participants will then undergo traditional in-clinic functional assessments such as jumping and walking. When the in-clinic assessments are completed, participants will be instructed to place the devices on the quads and hamstrings of both legs and wear them for at least two hours a day for four weeks. An example of the sensors placed on a subject is further illustrated in Figure 2.

Figure 2: Sensor Example. An example of a set of Trigno sensors placed on a participants Vastus lateralis and Bicep femoris. Each device contains an accelerometer, gyroscope, and EMG sensors (Hamrock, 2021).

Phase three will include conducting multi-level analysis on the sensor data. The data will be preprocessed to remove noise, segmented into time windows, and used to extract features indicative of mobility and muscle activations. This data will then be used to achieve the two main goals of our technical project as presented earlier. The framework of this process is displayed in Figure 3. It is acknowledged that this analysis may not have significant results; however, given the exploratory nature of this pilot, we believe that exploring these results will help gain valuable insight to the feasibility of this novel

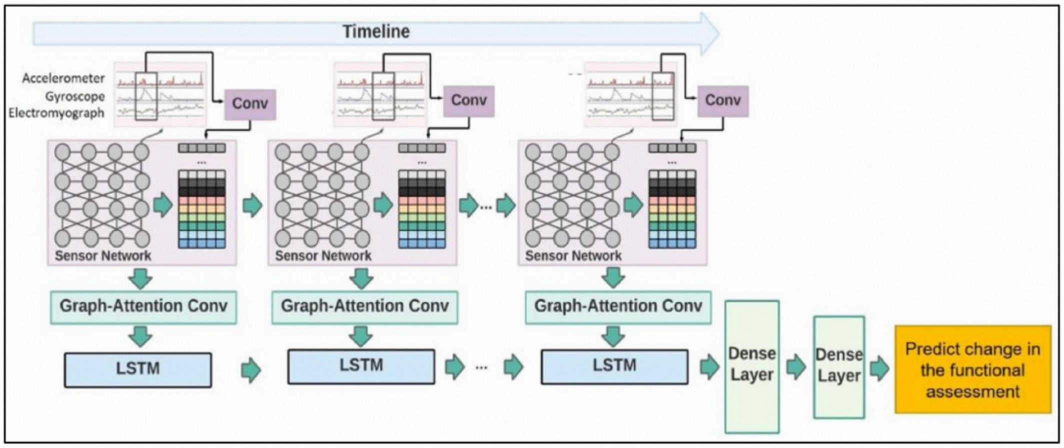

Figure 3: Modeling Framework. The proposed predictive modeling framework (Hamrock, 2021).

technology. This will provide valuable preliminary findings for a larger grant.

The development of this remote monitoring technology is sponsored by the University of Virginia. Resources dedicated to the study and implementation of this project will be from UVA Exercise and Sports Injury Laboratory. The operation of the technical project will be under the guidance of Mehdi Boukhechba, a faculty member in the Engineering Systems and Environment Department, and Dr. Joe Hart, a professor of orthopaedic research in the Department of Orthopaedic Surgery. The team members on this project include Kevin Cox, Sydney Lawrence, Sean Lynch, Jane Romness, Johnathan Saksvig, and Alice Warner. Each team member is an undergraduate student studying systems engineering in their fourth year at the University of Virginia School of Engineering and Applied Science. This project will be documented in a technical report.

IMPACT ON REMOTE MEDICAL CARE

The impact of Covid-19 in 2020 has left an immense impact on the healthcare industry and the process of safe, prompt medical visits. Since the pandemic, out-patient visits to healthcare providers have dropped as low as 67% and remains close to 8% lower today than seen in typical years (Mehrotra, 2019, para. 3; Mehrotra, 2021, para. 8). While the number of out-patient visits has declined, there has been a large increase in the amount of telehealth visits. During the peak of the pandemic, telehealth visits had approximately a 15% increase from its baseline. This concept of providing medical services outside of the office was extremely applicable during a situation like the pandemic where it allowed patients to receive the medical advice they needed without coming into physical contact with other potentially infected individuals. The scope of telehealth visits could prove to be effective in many situations where a patient requires advice from a medical professional. Patients who are old and struggle to get transportation to a clinic would be a great example of how telehealth could be applied and deliver the desired service to the user. This could extend to patients who are located too far away from their desired healthcare professional or are extremely busy and cannot make it into the office. This poses the question of if the healthcare industry has the capabilities of moving into a more remote, virtually connected environment.

As technology grows, telehealth can be used in a wide amount of applications such as this technical project that creates a new integrated system for in-home patient rehabilitation monitoring. Given success, this idea could ultimately branch into many different areas of the human body. Systems similar to the technical project could be applied in many different ways that could provide feedback to medical professionals. This could expand the reach of remote health sensing to a variety of applications and develop the health industry exponentially with regards to the number of patients they will be able to interact with. A large amount of the rehabilitation prescribed by medical professionals will occur outside of the office and most likely in the comfort of the patient's home (Hauser & Dolan, 2011, para. 15). Though surgeries and other medical practices will need to continue to take place in person, this could suggest the decline of out-patient visits overall in the coming future.

Telehealth has the potential of being a very large network in society. This can be illustrated using Pacey's Triangle of Technology Practice (Pacey, 1983, p.12) in Figure 4 on page 9. Culturally, telehealth would touch society in many different ways. This technology would offer users to communicate with their clinicians in an alternate way, therefore changing how often patients visit the hospital in person. The ease of access to advice would increase dramatically and could see patients consistently requesting feedback. Non-users would likely be motivated by the invasion of privacy that threatens the doctor-patient social relationship. The sensors that are placed on individuals would be seen by others and could represent a sign of wealth due to the cost of such technology, in result, creating a larger disparity between social classes. Also, as the telehealth technology grows and expands into new areas, society could develop an overreliance on technology to monitor their care instead of their natural body feedback. Organizationally, telehealth would leave less resources for patients due to the decreasing demand of in person visits. This would result in the health industry moving into a more technology-based approach which would involve increased cyber security and other organizational demands. The health industry would now be able to assist previously unreachable clients and would have an increased communication reliance with the interconnected health systems. When some groups have access to new knowledge and expertise and others do not, disparities grow. Advances in in telecommunication can help overcome some of these disparities by redistributing knowledge and expertise where it is needed (Nesbitt, 2012, para. 1). Technologically, the business of health would rely on an increase in knowledge of sensor technology and machine learning. As telehealth becomes more common, this will impact the cost and location of sensors as well as a need for larger data storage than with previous methods.

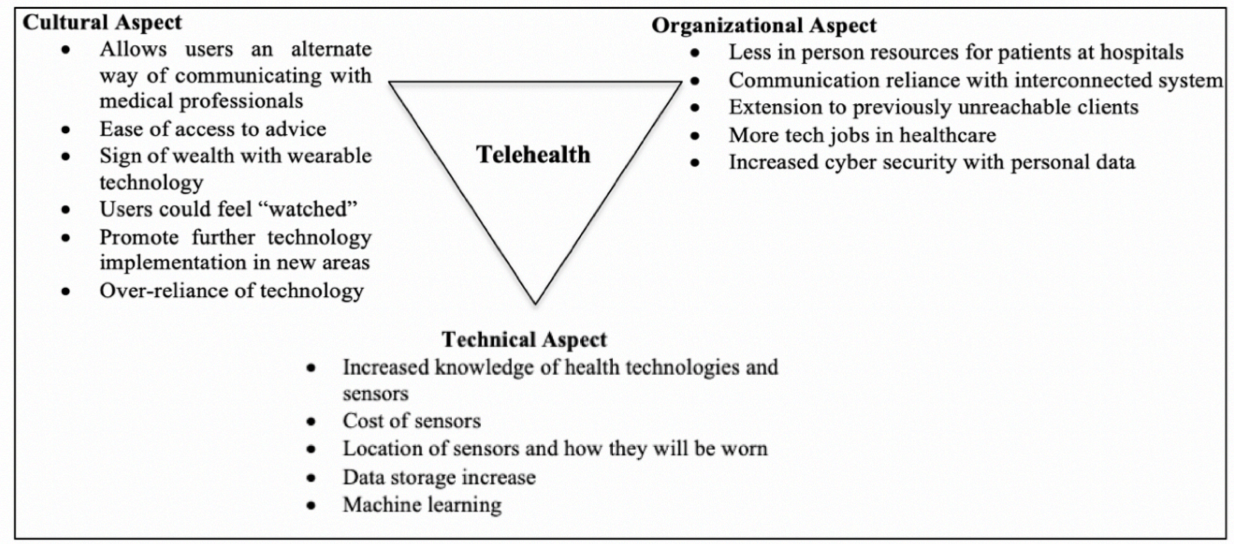

Figure 4: Telehealth Pacey's Triangle. Adapted by (Hamrock, 2021) from (Pacey, 1983, p. 12).

For telehealth to emerge its way into society there will many steps that will be crucial in its development. This process is further illustrated using a Handoff Model (Carlson, 2009) in Figure 5 on page 10. A new telehealth product would start its life with a researcher or designer that develops the original idea for the sensing technology. This would then be passed to a sponsor such as a university health department who could provide funding and resources. Approval would be needed from health organization such as the FDA who regulates medical devices sold in the United States to assure their safety and effectiveness (U.S. Food & Drug Administration, 2018, para. 2). The artefact would then be passed to engineers to develop a prototype for testing. Once given to a trial study, it would bounce back and forth between engineers and trials to achieve the desired functionality of the artefact. When the technology is satisfactory for implementation, it would be given to a smaller population to determine its effectiveness. Education and training would need to be provided to the subjects receiving the new telehealth device in order to properly use and be effective. Engineers would then patch any changes required based off customer feedback and then the artefact would gradually diffuse its way into all of society. Persuasion may be necessary at the final level to develop credibility with the technology as well as trust with the monitoring feature. Risks would be taken throughout the chain but largely in its initial development with the sponsor funding the research and ultimately beginning the artefacts life cycle.

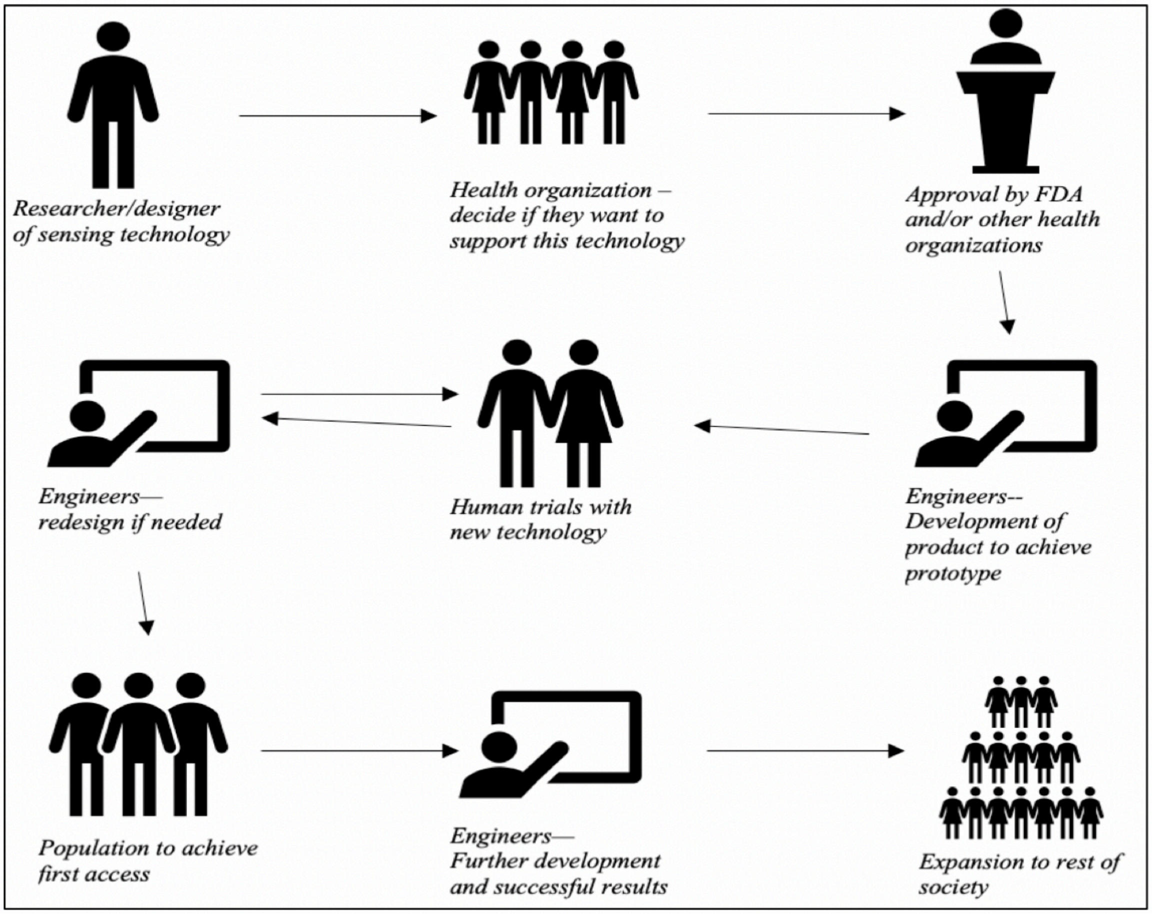

Figure 5: Telehealth Handoff Model. Adapted by (Hamrock, 2021) from (Carlson, 2009).

This research project will be in the form of a scholarly article outlining the potential and direction telehealth medicine could see in the future. It will further examine the movement of the healthcare industry into a more remote, virtually connected environment; furthermore, providing faster, more reliant, data driven care. Establishing whether issues could arise in the handoff process in Figure 5 and also examining any deeper issues in the larger network in which telehealth will contribute to in Figure 4 will drive this STS research.

FUTURE OF THE HEALTH INDUSTRY

The growth of sensor technology has opened up the opportunity to make an immense impact on the health industry. Real-time, continuous monitoring of patients has the potential to enhance health care well beyond its current state of in-clinic assessments. As more of these technologies make their way into industry, society could see shift on the cultural and technical views of telehealth. Both the technical and STS research presented will aim to provide answers on the outlook of the healthcare environment in years to come.

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