Design of a Software to Quantify Ligament Laxity in Patients with Chronic Ankle Instability (CAI)

Analysis of the History and Development of X-Ray Technology

A Thesis Prospectus In STS 4500 Presented to The Faculty of the School of Engineering and Applied Science University of Virginia In Partial Fulfillment of the Requirements for the Degree Bachelor of Science in Biomedical Engineering

> By Anna Workman

December 3, 2023

Technical Team Member: Maddie Krotine

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.

ADVISORS

Benjamin Laugelli, Department of Engineering and Society Joseph Park MD, Orthopaedic Surgery

Introduction

Americans spend more on healthcare than any other OECD country with expenditures accounting for 18.3% of Gross Domestic Product (GDP) in 2021 (Centers for Medicare & Medicaid Services, 2023). With the rapid momentum of medical technologies, especially in diagnostic tools, there are powerful opportunities for improving patient outcomes and reducing the economic burden of healthcare. One area of growth is in the diagnosis and treatment of Chronic Ankle Instability (CAI). Acute ankle sprains occur approximately 2 million times annually in the United States with CAI developing in approximately 40% of individuals who sustain a first time Lateral Ankle Sprain (LAS) (Miklovic et al., 2018; Waterman et al., 2010). Current diagnostic methods are based upon the surgeon's discretion and experience and fail to quantify the level of mechanical instability in the patient's ankle.

To address the absence of an accurate diagnostic method, I propose the development of software that calculates the relative laxity index (RLI) of a patient's ankle ligaments to help inform treatment decisions. This technical project leverages a previously existing technology, Inertial Measurement Unit (IMU) sensors, for the innovation of a novel diagnostic tool. When introduced to the healthcare landscape, this innovation has the potential to gain technological momentum and shape its environment. To examine the mechanisms in which diagnostic tools gain momentum, I will draw on the STS framework of Technological Momentum to analyze the development of X-ray technology in healthcare. Specifically, I will investigate the X-ray as it evolved from an accidental discovery into a technology with a powerful influence on the healthcare system.

Inequities and economic burdens existing in the US healthcare landscape are socio-technical in nature. Implementing a new medical diagnostic tool requires addressing the

project's technical and social aspects. In the subsequent section, I outline the technical project that aims to improve diagnosis and treatment of mechanical instability in ankles. I also describe the STS project that will examine the history of X-ray technology and its momentum in healthcare. As I develop the proposed software, I will apply insights from the analysis of X-ray technology's momentum to inform the potential social influences of the designed diagnostic tool in healthcare including improvement in patient outcomes and affordability.

Technical Project Proposal

The development of diagnostic tools is paramount to creating a more informed and equitable healthcare system. Currently, there is no standardized qualitative method for determining levels of ankle instability. CAI leads to recurrent LAS and decreased function of the ankle joint which can lead to swelling, pain, and risk of developing posttraumatic osteoarthritis (Herzog et al., 2019). Clinicians measure instability by performing a series of manual stress tests called the Anterior Drawer Test (ADT) and the Talar Tilt Test (TTT). During these tests, clinicians are subjectively evaluating the laxity of ankle ligaments. The lack of a quantitative method to evaluate mechanical instability means that diagnostic and treatment decisions are entirely dependent on the clinician's discretion and expertise (Nauck et al., 2010).

Clinicians may use surveys such as the Foot and Ankle Ability Measure (FAAM) and the Foot and Ankle Disability Index (FADI) to diagnose CAI. In addition to physically examining patients with manual stress tests, clinicians will order static testing to display the morphological situation of the ankle joint (Nauck et al., 2010). Ankle stress radiographic testing is a dynamic testing method that utilizes a stress testing apparatus and X-ray to measure displacement angles during TTT and ADT. A recent approach to measure ankle instability is through arthometer-assisted ankle joint stress testing. The most commonly used arthrometer devices for

objective evaluation of patients with CAI are the Telos ankle device, Blue-Bay device, LigMaster, Quasi-static anterior ankle tester, Dynamic anterior ankle tester, Ankle flexibility tester, and the Cheuba stress-producing device (Guerra-Pinto et al., 2021).

Ankle surveys, MRI, ultrasound, stress radiographs, and arthrometers all offer a more objective approach to evaluating ankle instability, yet each method has limitations. CAI encompasses both mechanical and functional instability and the FAAM and FADI surveys fail to identify whether ankle laxity is the underlying cause of the patient's history and symptoms. For static testing, MRI and ultrasound can detect ligament tears or ruptures but are unable to measure the laxity of the ligaments. Stress radiographs have reported low specificity which may be attributed to muscle guarding due to patient discomfort during these prolonged imaging tests (Choi et al., 2021). Scientific literature reports a high heterogeneity regarding the measurement methods and use of concomitant imaging with arthrometers which has led to a large variance in laxity outcomes in individuals with CAI (Guerra-Pinto et al., 2021). Both stress radiographs and arthrometers can prolong the pain and discomfort of patients, require additional infrastructure for in-clinic testing, and increase patient exposure to radiation.

There is a need for standardized testing and measuring methodologies of ankle laxity to achieve more objective and definitive conclusions on CAI diagnoses. Without a technical solution, patients will have to rely on the experience of their surgeon, make less informed decisions, and risk receiving inadequate treatment. This technical project aims to design software in MATLAB that will calculate the RLI of the ankle using IMU data. Previous work on this project has shown that IMU sensors can be used to track the ankle in 3D space and provide numerical values for diagnostic tests. Throughout this project, an algorithm using filters and

custom functions will be developed to process IMU data. A user-friendly application will be created to input patient data files and obtain RLI measurements.

A research study will be conducted to measure ankle ligament laxity over time and results will be compared between groups that choose operative (eg. Brostrom Procedure) and nonoperative (ie. physical therapy) treatment. RLI will be measured at the initial visit, and 6 weeks, and 3 months following the commencement of treatment. Ankle displacement and rotation will be measured by performing the ADT and TTT on the injured and contralateral healthy ankle. Additionally, the Internal Rotation Test (IRT) and External Rotation Tests (ERT) will be performed to increase the assessment of the mechanical stability of all ankle ligaments. IMU data will be collected using a lower-extremity-adjustable-strap Xsens MTw Awinda Sensor while the clinician performs the manual stress tests. After the project, a visual tool will be developed to categorize levels of ankle instability. This will be used to inform surgeons on treatment options and results.

STS Project Proposal

The X-ray was accidentally discovered on November 8th, 1895 by German physicist Wilhelm Conrad Röntgen (Panchbhai, 2015). News about his discovery spread quickly around the world. People were fascinated by the superhero-like capabilities of the X-ray and scientists immediately began exploring the possibilities it offered. Since 1895, the power of the X-ray has expanded from scientific research to medical applications, and airport security, and has even spotted many appearances in pop culture, art, and literature. In the world of healthcare, the X-ray has the distinguished title of the first medical imaging technique (Panchbhai, 2015). It has become a tool for the detection of fractures, heart and lung problems, locating foreign bodies, cancer screening, treatment, and much more. Its dangers and limitations inspired the

development of more medical imaging techniques such as Computed Tomography (CT) scans, contrast X-rays, fluoroscopy, and Medical Resonance Imaging (MRI) (Sansare et al., 2011). With such far-reaching applications, it is important to consider how the X-ray, an accidental discovery, evolved to become a medical tool with a powerful influence on the practices, regulations, ethics, and values present in healthcare.

Publications written about the impacts of X-rays talk widely about the medical applications of X-rays. Historians write about the key events that describe the use of X-rays in a variety of fields and scientific discoveries (Gunderman, 2012). Medical professionals sing praises about the technological innovation that stemmed from the X-ray while also citing the lessons learned from discovering the damaging effects of radiation (Behling, 2021). The current discourse about the X-ray fails to consider the increasing complexity of its relationship with the healthcare system and the societal impacts that have resulted from it. We must recognize that the X-ray was once an accidental discovery that society shaped to use as a scientific tool across a variety of disciplines. If we continue to commemorate the history of the X-ray without analyzing its evolution over time, we will fail to fully recognize its powerful influence on society.

I argue that Röntgen's discovery of the X-ray not only led to innovation across a variety of scientific applications. Instead, the X-ray gained technological momentum by establishing itself as a powerful tool while shaping the practices, regulations, economics, ethics, and values of the system around it. I will examine X-rays' role in shaping attitudes towards healthcare, the doctor-patient relationship, safety and quality standards, the rising costs of healthcare, and equitable access to healthcare.

To frame my analysis, I will draw upon the STS framework of Technological Momentum. Developed by historian Thomas Hughes, Technological Momentum is a theory that accounts for

the interconnected and evolving relationship between technology and society (Johnson & Wetmore, 2009). Interpreting the history of technology through the lens of Technological Momentum demonstrates the ability that society has in shaping a system before it has acquired political, economic, and value components. Hughes states that a technological system grows, it becomes more complex and thus has a greater shaping effect on society (Johnson & Wetmore, 2009, pp. 148-149). I will use this framework to describe how early in the history of the X-ray, society had more power to shape its design, purpose, meaning, and role. The system in which it operated gained momentum, complexity, and scale and thus the X-ray began to have more power to influence the people and groups invested in it. To perform this analysis, I will draw upon reports of historical events and discoveries, the applications of X-ray technology across various industries, and information from The U.S. Department of Health and Human Services (HHS), academic journals, and research institutions.

Conclusion

Upon completion of the technical project, the designed software will leverage IMU sensors to improve measurement and diagnosis of mechanical ankle instability. The technical design will improve the standardization of surgeon recommendations, better inform patient decisions, and offer an affordable solution for clinical testing of ankle stability. The STS research paper will provide readers with a better understanding of how technologies can be transformed into diagnostic tools and gain power in their influences on society. This will be illustrated through the analysis of the history of X-rays by drawing from the STS framework of Technological Momentum. This case will aid in understanding the power of diagnostic tools on the healthcare system. The joint efforts of the technical and STS projects will contribute to recognizing the possible socio-technical impacts associated with implementing diagnostic tools

such as the proposed software for quantification of ankle instability. This valuable insight will be applied to the design of the technical project in efforts to improve patient outcomes and decrease the inequities and economic burden in healthcare.

References

- Behling, R. (2021). *Modern diagnostic X-Ray sources: Technology, manufacturing, reliability.* CRC Press.
- Choi, J. H., Choi, K. J., Chung, C. Y., Park, M. S., Sung, K. H., & Lee, K. M. (2021).
 Consistency and Reliability of Ankle Stress Radiography in Patients With Chronic Lateral Ankle Instability. *Orthopaedic Journal of Sports Medicine*, 9(5), 23259671211004099. https://doi.org/10.1177/23259671211004099
- Guerra-Pinto, F., Andrade, R., Diniz, P., Luisa Neto, A., Espregueira-Mendes, J., & Guimarães Consciência, J. (2021). Lack of Definition of Chronic Ankle Instability With Arthrometer-Assisted Ankle Joint Stress Testing: A Systematic Review of In Vivo Studies. *The Journal of Foot and Ankle Surgery*, 60(6), 1241–1253. https://doi.org/10.1053/j.jfas.2020.04.026
- Gunderman, R. B. (2012). *X-Ray vision: The evolution of medical imaging and its human significance*. Oxford University Press.
- Herzog, M. M., Kerr, Z. Y., Marshall, S. W., & Wikstrom, E. A. (2019). Epidemiology of Ankle Sprains and Chronic Ankle Instability. *Journal of Athletic Training*, 54(6), 603–610. https://doi.org/10.4085/1062-6050-447-17
- Johnson, D. G., & Wetmore, J. M. (2009). *Technology and society: Building our sociotechnical future*. Massachusetts Institute of Technology.

- Miklovic, T. M., Donovan, L., Protzuk, O. A., Kang, M. S., & Feger, M. A. (2018). Acute lateral ankle sprain to chronic ankle instability: A pathway of dysfunction. *The Physician and Sportsmedicine*, 46(1), 116–122. https://doi.org/10.1080/00913847.2018.1409604
- Nauck, T., Lohrer, H., & Gollhofer, A. (2010). Evaluation of Arthrometer for Ankle Instability:
 A Cadaveric Study. *Foot & Ankle International*, *31*(7), 612–618.
 https://doi.org/10.3113/FAI.2010.0612
- Centers for Medicare & Medicaid Services. (2023, September 6). *NHE Fact Sheet*. https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expendit ure-data/nhe-fact-sheet
- Panchbhai, A. S. (2015, March). Wilhelm Conrad Röntgen and the discovery of X-rays: Revisited after centennial. https://journals.lww.com/aomr/Fulltext/2015/27010/Wilhelm_Conrad_R_ntgen_and_the_ discovery_of.20.aspx
- Sansare, K., Khanna, V., & Karjodkar, F. (2011). Early victims of X-rays: A tribute and current perception. *Dentomaxillofacial Radiology*, 40(2), 123–125. https://doi.org/10.1259/dmfr/73488299
- Waterman, B. R., Owens, B. D., Davey, S., Zacchilli, M. A., & Belmont, P. J. J. (2010). The Epidemiology of Ankle Sprains in the United States. *Journal of Bone and Joint Surgery*, 92(13), 2279. https://doi.org/10.2106/JBJS.I.01537