QUANTIFYING ANKLE LIGAMENT RELATIVE LAXITY INDEX CHANGE WITH DIFFERENT TREATMENTS

INTRODUCTION AND USE OF NOVEL MEDICAL TECHNOLOGIES BY HEALTH CARE PROVIDERS TO IMPROVE DIAGNOSTIC AND TREATMENT METHODS

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
Madeleine Krotine

October 27, 2023

Technical Team Members: Anna Workman

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

Rider Foley, Department of Engineering and Society

Timothy Allen, Department of Biomedical Engineering
Joseph Park, Department of Orthopedic Surgery, Department of Mechanical and Aerospace Engineering

Introduction

Acute lateral ankle sprains are the most common injuries in both athletes and the general population. Around two million occur each year and they account for two billion dollars in healthcare spending (Waterman et al., 2010). Treatments for sprains are generally noninvasive and include rest, ice, non-steroidal anti-inflammatory drugs, followed by physical therapy and proprioceptive therapy (Hunt & Griffith, 2020; McCriskin et al., 2015). However, numerous studies have shown that 20-40% of these patients develop Chronic Ankle Instability (CAI) (Hunt & Griffith, 2020; Knupp et al., 2015; Ramírez, 2021). Chronic ankle instability negatively affects patients in numerous ways including recurrent sprains, pain, and tenderness, as well as feelings of insecurity, instability, and giving way in the ankle that can limit daily activities and participation in sports (Knupp et al., 2015).

Hunt and Griffith showed in their 2020 review that the modified Brostrom Procedure, the Brostrom-Gould Repair, remains that gold standard technique for treating CAI (Hunt & Griffith, 2020). This technique, which involves shortening the ankle ligaments to increase stability as shown in Figure 1, has proven to yield excellent outcomes (Hunt & Griffith, 2020). A study by Mafulli et al. demonstrated the long term success of the Brostrom repair in 38 patients, finding that at an average of 8.7 years post operation, ankle laxity scores remained higher than pre-operation and 58% of patients continued to play their sport at preinjury levels (Maffulli et al., 2013). The non-operative treatment for CAI is physical therapy and proprioceptive training to help strengthen the ankle, improve balance, and re-establish position control (McCriskin et al., 2015).

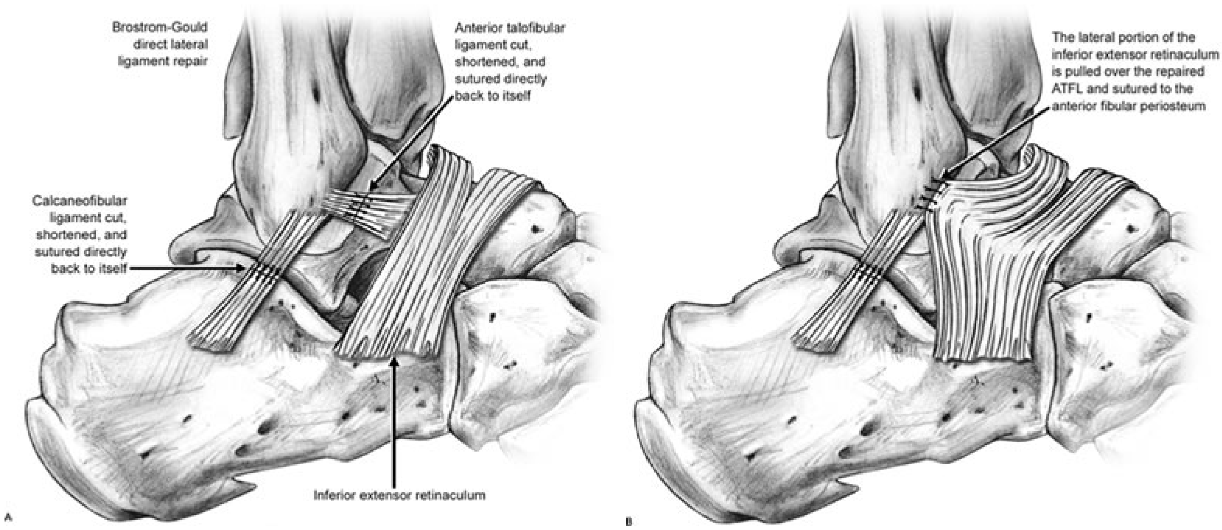

Figure 1. Demonstration of Brostrom Repair technique (Source: Rosenfeld, n.d.).

To determine whether a patient should undergo surgery, surgeons perform multiple diagnostic tests, including two manual stress tests: the Anterior Drawer Test, which tests the laxity of the anterior talofibular ligament, and the Talar Tilt Test, which tests the laxity of the calcaneofibular ligament, as shown in Figure 2 (Hunt & Griffith, 2020). In these tests, the physician judges the extent of instability based on the movement of the injured ankle compared to the contralateral ankle. However, a review done by Beynon et al. showed that because these tests are qualitative and depend on a physician's experience and subjectivity, none of them demonstrate robust reliability or validity scores (Beynon et al., 2022). This capstone project will develop and test a novel method of quantifying ankle ligament laxity, and the second portion of this paper will understand doctor's adoption of new medical technologies.

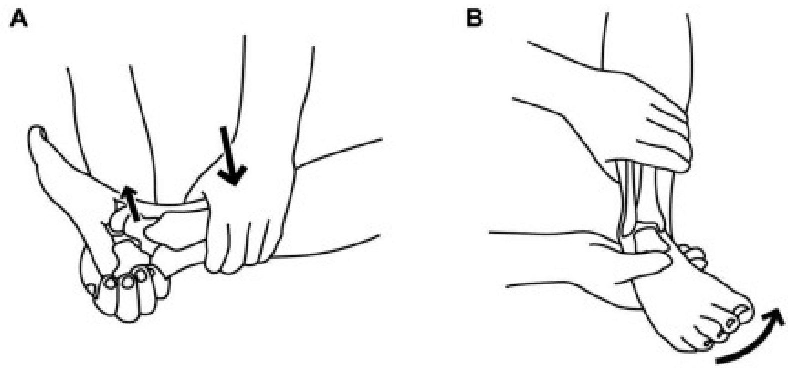

Figure 2. A: Anterior Drawer Test, B: Talar Tilt Test (Source: Epomedicine, 2017)

Quantifying Ankle Ligament Laxity Using an IMU Sensor

This technical project focuses on developing a new diagnostic tool to quantify ankle ligament laxity that will inform doctors decisions on treatment for patients with chronic ankle instability. To develop this tool we will conduct a research study measuring the change in ligament laxity before and after treatment in both surgical and non-surgical treatment methods. Currently, the only existing tool for quantifying ankle laxity is an arthrometer which can be used to perform the previously described ankle stress tests as shown in Figure 3 (Guerra-Pinto et al., 2021). However, Guerra-Pinto, et al. showed in a systematic review that there is a large variation in ligament laxity measurements and studies varied widely in their pathologic thresholds for both tests (Guerra-Pinto et al., 2021). The lack of reliability and consistency using this diagnostic tool shows that there is a need in the field for a better way to quantify and understand laxity measurements.

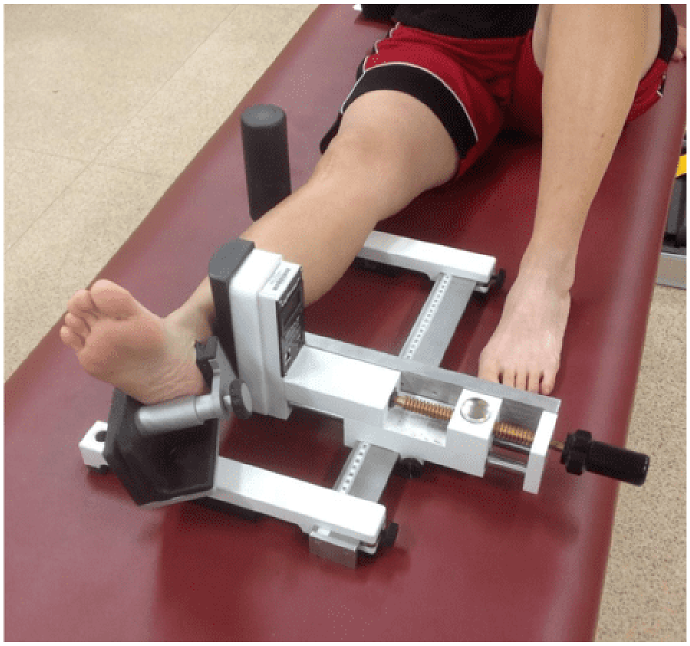

Figure 3. Talar Tilt Test performed using an ankle arthrometer (Source: Ng, 2015).

Novel Device For Quantifying Ligament Laxity

Our novel diagnostic tool will consist of an inertial measurement unit (IMU) sensor, a device that measures an object's 3-dimensional velocity and orientation using an internal accelerometer, gyroscope, and magnetometer, to collect kinematic data during testing (ScienceDirect, n.d.). We will use an MTw Awinda IMU sensor, which provides highly accurate orientation motion tracking and the data is easily exported into a text file for processing (Paulich et al., n.d.). These characteristics make it a good choice for this project since it is reliable, small, easy to use, and already exists. An application will be developed in MATLAB, a computer programming language with good data processing capabilities. The user will input the data files collected from a patient using the MTw Awinda IMU sensor into the MATLAB application which will process the data using algorithms to measure rotation angles, quantify translation of the ankle, and calculate the relative laxity index for each test. This technology will improve over existing technologies because the sensor is small and lightweight, it still allows the doctor to perform the stress tests, and it will output quantitative data.

Research Study Protocol

To measure the change in ligament laxity after treatment we will collect data using the novel device on both patients who undergo the Brostrom surgery as well as those who elect for non-invasive treatment. Four manual stress tests will be performed for three repetitions each: the anterior drawer test and talar tilt test, described above, as well as external rotation and internal rotation tests in which the patient's ankle is rotated inward or outward. While the last two tests are not always performed by physicians while evaluating CAI, Dr. Joseph Park, a foot and ankle surgeon (personal communication, September 13, 2023), has found that these tests can detect injuries and laxity to other ankle ligaments not tested in the talar tilt and anterior drawer tests such as the deltoid ligament (Physiopedia, n.d.). Testing will be performed at the beginning of treatment, after 6 weeks, and again after 3 months. The data will be used to:

1. Quantitatively measure relative laxity index in patients with CAI and validate our novel method of diagnostic testing
2. Determine if surgery quantitatively improves ligament laxity
3. Compare the changes in relative laxity index in surgical patients to the changes after non-operative treatment.

The development of a reliable diagnostic method that is supported by evidence, easy to use, and builds off of existing diagnostic methods will help the device become widely adopted by physicians.

Infrastructure and The Adoption of Medical Technologies

Every year, nearly 3000 new medical devices are approved by the FDA, however most of these don't become widely adopted in healthcare (Dubin et al., 2021). Varabyova, et al. (2017) found in a review that the three key forces at play in determining when to adopt new innovations are organization, individualistic, and innovation-related characteristics. Groups involved in the adoption of medical technologies include doctors, patients, physical therapists, insurers, and healthcare administrators. For doctors, factors such as how accurate they believe the device is, whether it is as good as or better than other methods, efficiency, and ease of use may affect their decision to adopt the technology (Danesi et al., 2020). While the Federal Drug Administration (FDA) decides whether the device is safe and effective (FDA, 2023), doctors may initially be wary of new devices until they have been proven. Additionally, patients trust their doctors to make the right decisions for them, and will often agree with the doctor's advice for treatment just because the doctor "is the expert". Better diagnostic technologies can help assure the patient that they are taking the correct actions. The field of medicine is full of policies, values, expectations, and institutions that are in place to protect patients while helping doctors exercise their abilities as trained medical professionals.

Using the properties of *infrastructure* as defined in Star's (1999) article *The Ethnography of Infrastructure*, we can explore the connection between technology and humans (Star, 1999). Star's framework describes the underlying concepts inherent in system design creation and how technological developments demonstrate these concepts (Star, 1999). One facet of infrastructure is *links with conventions of practice*, which describes how infrastructure is designed a certain way because that is how it has always been done. Another facet of infrastructure is that infrastructure is *built on an installed base*, which describes how infrastructure uses, expands or modifies existing infrastructure to improve it or fit a new need. The third facet I will be using is *embodiment of standards*, which describes how technology has qualities that allow it to fit into the existing system in a standardized fashion (Star, 1999).

Novel medical technologies tend to exhibit these properties of infrastructure. Danesi et. al (2020), argue that the introduction and use of medical technologies should be thought of as the adjustment and attachment needed to fit the new technology into the existing care infrastructure. They describe a new glucose monitoring system that will fit into the care infrastructure, thus linking with conventions of practice (Danesi et al., 2020). Additionally, they found that the device must fit ergonomically on the body and users must be able to trust the information received from the device (Danesi et al., 2020). These needs show how the technology must embody certain standards we have as a society, that the devices are comfortable and provide accurate information. In a case study on a cardiac telemonitoring technology by Nelly Oudshoorn (2008), we see how an existing technology, electrocardiograms, are used in combination with telemedicine technology as a new diagnostic tool (Oudshoorn, 2008), thus showing how medical technologies are built on an installed base.

Research Question and Methods

With the influx of new medical technologies, hospitals and doctors are constantly making choices about which new technologies they should buy and start integrating into their practice. With the many social groups involved and the importance of a correct diagnosis and treatment, there are many values at play. A logical question follows: How are novel technologies introduced and used by healthcare providers in medicine to improve diagnostic and treatment methods?

To investigate this question, I will conduct interviews with UVA Health personnel including doctors, nurses, and administration staff. I will begin with interviewing my capstone advisor, Dr. Park, a foot and ankle orthopedic surgeon, and I will ask him to refer me to some of his colleagues. I will ask the questions in Table 1 to analyze their decision process through the lens of Star's infrastructure framework (Star, 1999).

Table 1

Interview Questions

What are the new medical technologies that you have recently adopted? When and why did you start using them?
What are some of the ways you discover new technologies that you would like to use in your practice?
What are the most important considerations you take when deciding to adopt a new medical technology or method?
Are you more likely to adopt a new technology if it doesn't change your normal workflow?
What factors make you trust a new technology?
How important is it that a new technology allows you to maintain the same workflow that you currently have?

Through these questions, I will gather examples of technologies that hospitals have recently adopted, as well as the thought process that goes into different healthcare workers' decisions on adopting new medical technology. I will analyze the responses using the facets of the infrastructure framework including built on an installed base, links with conventions of practice, and embodiment of standards. I will evaluate how often the interviewees make mention of the different facets as well as how strongly they seem to feel about each. I will then draw a conclusion on how medical technologies' embodiment of infrastructure facets influences their adoption and use in a medical setting.

Conclusion

The lack of a reliable way to quantitatively measure ankle laxity leads to subjective decisions made by surgeons to determine the best course of treatment for a patient. The goal of this capstone project, to develop a quantitative way to measure and track ankle instability, will provide doctors with a better diagnostic method.

The STS portion of this prospectus outlines how medical technologies can be viewed as infrastructure. The research outlined will provide insights into how medical technologies' infrastructure characteristics aid them in being adopted by medical professionals. These insights will allow engineers to better design medical technologies that are more likely to be adopted.

.

References

Beynon, A., Le May, S., & Theroux, J. (2022). Reliability and validity of physical examination tests for the assessment of ankle instability. *Chiropractic & Manual Therapies*, *30*(1), 58. https://doi.org/10.1186/s12998-022-00470-0

Danesi, G., Pralong, M., Panese, F., Burnand, B., & Grossen, M. (2020). Techno-social reconfigurations in diabetes (self-) care. *Social Studies of Science*, *50*(2), 198–220. https://doi.org/10.1177/0306312720903493

Dubin, J. R., Simon, S. D., Norrell, K., Perera, J., Gowen, J., & Cil, A. (2021). Risk of Recall Among Medical Devices Undergoing US Food and Drug Administration 510(k) Clearance and Premarket Approval, 2008-2017. *JAMA Network Open*, *4*(5), e217274. https://doi.org/10.1001/jamanetworkopen.2021.7274

Epomedicine. (2017, October 29). *Ligament Tests for Ankle Injuries*. Epomedicine. https://epomedicine.com/emergency-medicine/stress-tests-ankle-ligaments/

FDA. (2023, August 15). *Device Approvals, Denials and Clearances*. FDA; FDA. https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances

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

Hunt, K. J., & Griffith, R. (2020). Open Brostrom for Lateral Ligament Stabilization. *Current Reviews in Musculoskeletal Medicine*, *13*(6), 788–796. https://doi.org/10.1007/s12178-020-09679-z

Knupp, M., Lang, T. H., Zwicky, L., Lötscher, P., & Hintermann, B. (2015). Chronic Ankle Instability (Medial and Lateral). *Clinics in Sports Medicine*, *34*(4), 679–688. https://doi.org/10.1016/j.csm.2015.06.004

Maffulli, N., Del Buono, A., Maffulli, G. D., Oliva, F., Testa, V., Capasso, G., & Denaro, V. (2013).

Isolated anterior talofibular ligament Broström repair for chronic lateral ankle instability: 9-year follow-up. *The American Journal of Sports Medicine*, *41*(4), 858–864. https://doi.org/10.1177/0363546512474967

McCriskin, B. J., Cameron, K. L., Orr, J. D., & Waterman, B. R. (2015). Management and prevention of acute and chronic lateral ankle instability in athletic patient populations. *World Journal of Orthopedics*, *6*(2), 161–171. https://doi.org/10.5312/wjo.v6.i2.161

Ng, J. (2015, November 19). *The Reliability of Instrumented Knee and Ankle Orthopedic Special Tests Performed with A LigMasterTM Multijoint Arthrometer*. https://www.semanticscholar.org/paper/The-Reliability-of-Instrumented-Knee-and-Ankle-with-Ng/63a9fc2edac6aa02a6362673d476c82fd499a88c

Oudshoorn, N. (2008). Diagnosis at a distance: The invisible work of patients and healthcare professionals in cardiac telemonitoring technology. *Sociology of Health & Illness*, *30*(2), 272–288. https://doi.org/10.1111/j.1467-9566.2007.01032.x

Paulich, M., Schepers, M., Rudigkeit, N., & Bellusci, G. (n.d.). *Xsens MTw Awinda: Miniature Wireless Inertial-Magnetic Motion Tracker for Highly Accurate 3D Kinematic Applications*.

Physiopedia. (n.d.). *Kleiger's Test*. Physiopedia. Retrieved October 27, 2023, from https://www.physio-pedia.com/Kleiger%27s_Test

Ramírez, J. C. (2021). Long-Term Outcomes in Athletes with Chronic Lateral Ankle Instability Treated Integrally With an Anatomic, Minimally Invasive Surgical Technique. *International Journal of Foot and Ankle*, *5*(2), 053. https://doi.org/10.23937/2643-3885/1710053

Rosenfeld, P. (n.d.). *Ankle Ligament Reconstruction (Brostrum repair)*. Retrieved September 13, 2023, from https://www.londonfootankle.co.uk/foot-ankle-surgeon/brostrom-repair/

ScienceDirect. (n.d.). *Inertial Measurement Unit*. ScienceDirect. Retrieved September 22, 2023, from https://www.sciencedirect.com/topics/engineering/inertial-measurement

Star, S. L. (1999). The Ethnography of Infrastructure. *Animal Behavioral Scientist*, *43*(3), 377–391.

Varabyova, Y., Blankart, C. R., Greer, A. L., & Schreyögg, J. (2017). The determinants of medical technology adoption in different decisional systems: A systematic literature review. *Health Policy*, *121*(3), 230–242. https://doi.org/10.1016/j.healthpol.2017.01.005

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. *JBJS*, *92*(13), 2279. https://doi.org/10.2106/JBJS.I.01537