Application for Quantifying Ankle Ligament Laxity Using an Inertial Measurement Unit (IMU) Sensor to Assess Rehabilitation Progress During and After Treatment for Chronic Ankle Instability

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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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Abstract
Acute ankle sprains are diagnosed approximately 2 million times per year in the United States [1]. Chronic ankle instability (CAI) develops in 20-40% of individuals who sustain acute lateral ankle sprains [2]. CAI can result in persistent discomfort, swelling, tenderness, tendon disorders, and posttraumatic osteoarthritis [3]. Orthopedic surgeons will recommend surgery based on the degree of instability in the ankle or the lack of response to nonsurgical approaches [4]. However, current diagnostic methods are based on the surgeon's discretion and experience and fail to quantify the level of instability in the patient's ankle. Surgeons will typically perform the Anterior Drawer Test (ADT) and Talar Tilt Test (TTT) to subjectively assess the mechanical stability of the ankle joint. Stress Radiographs and MRIs are used in conjunction with physical tests to diagnose ligament tears [5], [6]. The absence of a quantitative method for evaluating ankle instability leaves gaps and uncertainty for patients and doctors when determining the best course of treatment. Additionally, there is no existing way to quantify the benefits of undergoing surgery. Prior work done on this project has shown that IMU sensors can be used to track the ankle in 3D space and provide numerical values for the diagnostic tests. The goal of this project is to design a user-friendly method for quantitatively measuring CAI to improve current diagnostic methods and assess treatment outcomes. Using the IMU sensor method in conjunction with the manual stress tests, it was found that relative laxity decreases after surgical repair for all four tests. An intuitive application was developed to enable nearly instantaneous data processing and visualization of patient data and patient history.

Keywords: Chronic Ankle Instability (CAI), Anterior Talofibular Ligament Injuries, Manual Stress Tests, Ankle Ligament Laxity, Internal Rotation Test, Talar Tilt Test, Anterior Drawer Test, External Rotation Test, IMU Sensor, Novel Application

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Introduction

Significance

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 [1], and 20-40% of these patients develop Chronic Ankle Instability (CAI) [6], [8]. 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 [8]. Various issues fall under the name chronic ankle instability including mechanical insufficiencies, such as pathologic laxity, and functional insufficiencies, including impaired proprioception and strength deficits. While there are existing methods for diagnosing chronic ankle instability via stress tests that test ligament laxity, these tests are subjective when performed by physicians and methods of quantifying ligament laxity thus far have shown high variability [5], [9].

It is important to measure ankle laxity before a treatment decision is made because many factors contribute to the stability of the ankle joint. The three main contributors to ankle stability are the congruity of the articular surfaces when the joints are loaded, static ligamentous restraints, and musculotendinous units [10]. Deficiencies or injuries of the musculotendinous units can be remedied with rest and physiotherapy, however ligament damage may require surgical intervention. Ankle sprains can lead to increased ligament laxity due to changes in joint mechanics during the tissue-repair phase of the healing process which may cause the ligaments to heal in a lengthened state [11]. Tears to ligaments can heal without surgical intervention, however, Gould et al. determined that a "fore n' aft" stress measurement exceeding 4 mm, results in a positive anterior drawer test and indicates the need for surgical repair [12].

The modified Brostrom-Gould Repair, is the gold standard technique for treating CAI [6]. This technique, which involves shortening the ankle ligaments to increase stability as shown in Figure 1, has proven to yield excellent outcomes [6]. Studies have demonstrated the long-term success of the Brostrom repair with one 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 [13]. However, since there is no good way to quantitatively measure ligament laxity, the ability of the surgery to decrease ligament laxity has been measured via improved symptoms, the ability of patients to return to athletics, and cadaveric studies [14], [15]. While these can produce meaningful results, they fail to provide quantitative evidence that the surgery improves ligament laxity when compared to preoperative levels. Additionally, they are unable to quantitatively assess how the change in ligament laxity after surgical repair compares to changes when treated with physical therapy and other noninvasive methods. This project intends to fill these gaps in the literature by measuring the change in ligament laxity using the novel device before and after patients undergo their chosen course of treatment.

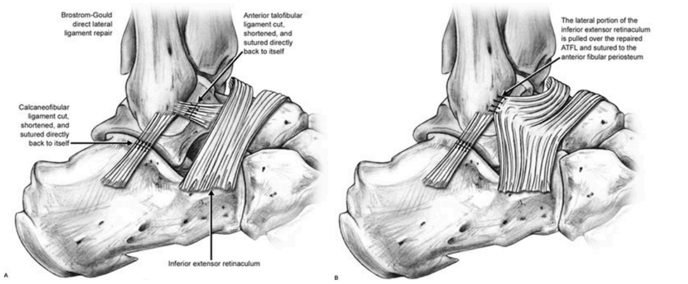

Figure 1. Demonstration of Brostrom Repair technique [16].

A quantitative way to measure chronic ankle instability will provide doctors and patients with numerical test results that can be compared to other patients with chronic ankle instability to help understand the patient's extent of instability and how that compares to patients who do well with the surgery. In addition, a study working to understand the change in ankle laxity with different treatment methods will show that the surgery makes a quantitative difference in ankle instability. It will also help patients and doctors compare the outcomes of surgical vs non-invasive treatments. Overall, the outcomes of this work will help both doctors and patients decide on the best individualized treatment method.

The outcomes of this work could also be applied to research working to understand the effect a woman's menstrual cycle and hormonal changes have on ligament laxity and injury likeliness. Generalized joint laxity (GJL) has been shown as a risk factor for anterior cruciate ligament (ACL) injury [17], and studies have found that ACL laxity increases with estrogen and progesterone levels when measuring laxity with a knee arthrometer [18]. Similar to the reported 4- to 6-fold increase in women's ACL injury rate vs men's injury rate in high-risk sports, another study found a higher incidence of ankle sprain in females compared to males (13.6 vs 6.94 per 1,000 exposures) [19], [20]. The IMU sensor and software developed by this capstone project would allow researchers to further investigate the variance in incidence by studying the variation in ankle ligament laxity throughout the menstrual cycle.

Innovation

The standard practice for evaluating ankle instability is by performing a physical examination [21]. In two manual stress tests that are most utilized, the Anterior Drawer Test (ADT) and the Talar Tilt Test (TTT), a clinician applies a load to the ankle and subjectively evaluates the degree of instability [22]. However, these tests do not provide quantitative measurements and have low sensitivity and specificity [5]. The ADT assesses the integrity of the ATFL while the TTT can assess the integrity of the lateral collateral ligaments (CFL, PTFL, and ATFL) or the deltoid ligament [23]. To provide a more comprehensive examination, we introduce the internal rotation test (IRT) and external rotation test (ERT) to test the laxity of other ligaments not tested by the anterior drawer and talar tilt tests such as the deltoid ligament. The IRT has been found to correlate with isolated injury to the ATFL in the setting of an intact deltoid ligament. Similarly, the ERT correlates with a deltoid injury with concomitant syndesmotic injury.

Clinicians may also order static testing to display the morphological situation in the ankle joint [22]. Magnetic Resonance Imaging (MRI) and ultrasound can be used to detect any tears or ruptures in the tendons and ligaments. Surveys such as the Foot and Ankle Ability Measure (FAAM) and Foot and Ankle Disability Index (FADI) are used to report symptoms and pain across daily living and sports [24]. These questionnaires provide clinicians with a subjective measure of ankle instability but fail to quantify mechanical instability.

Currently, the only existing tool for quantifying ankle laxity is to use an arthrometer to perform the previously described ankle stress tests [9]. However, a systematic review of 68 studies testing a total of 3,235 ankles showed that there is a large variation in ligament laxity measurements and studies varied widely in their pathologic thresholds for both tests [9]. The lack of reliability and consistency in using this diagnostic tool shows that there is a need in the field for a better way to quantify and understand laxity measurements. The device we are designing is different from an arthrometer because it will allow the physician to perform the tests as normal, uses IMU sensors, and will collect data using a computer that can then be analyzed to quantify ligament laxity.

Additionally, our device is an improvement over arthrometers because arthrometers are large, cumbersome, and can be difficult to perform the imaging evaluation in a normal clinic setting. Additionally, they involve putting the patient in an uncomfortable and painful position for a prolonged period to obtain imaging [25]. Our device is small and lightweight, does not cause the patient any more pain than the regular clinical examination, and the testing is very quick, taking less than 10 minutes from start to finish.

The gold standard for assessing human body joint kinematics is three-dimensional (3D) motion capture systems [26]. These marker-based approaches require the use of many cameras, are vulnerable to marker occlusion, have high costs, and are impractical to use in a variety of settings [26]. To address these limitations, IMU sensors have been proposed as an alternative measurement tool. Their wearable design allows for real-time 3D motion measurement data to be sent to a computer, providing users with immediate feedback. IMUs have not yet been used as a device to quantify ankle instability during manual stress tests. Previous work on this project has shown that IMU sensors can be used to track the ankle in 3D space and provide numerical RLI values for diagnostic tests. The use of IMU sensors will allow clinicians to increase the sensitivity and specificity of clinical tests. IMU sensors are compact, easy to use, and cheap. They have been proven to be a useful tool in the collection of human body kinematics [14]. In a comparison between optoelectronic motion capture (MOCAP) systems and IMUs, it was found that IMUs compared well to MOCAP in their ability to assess pelvic orientation angles [14].

IMU sensors have been incorporated into the design of a smart knee brace to obtain information about static and dynamic laxities [27]. The smart knee brace was designed to support the diagnosis of ACL tears in inpatient and outpatient settings by using IMU sensors to report rotational and translational information during three diagnostic tests [27].

Materials and Methods

Materials

MTw Awinda Sensors & MT Manager Software

Xsens MTw Awinda Sensors, Xsens velcro straps, and associated MT Manager Software were bought from Movella. The Inertial Measurement Unit (IMU) sensors are composed of accelerometers, gyroscopes and magnetometers and are used to measure acceleration, orientation, and angular rates. The sensors wirelessly connect to MT Manager Software. The update rate was set to 100 hertz and the internal sampling frequency to 1000 hertz. Export settings were set to include euler orientation angles (roll, pitch, and yaw), free acceleration, and packet counts.

Immobilization Device

The immobilization was created for last year's Capstone Project. It consists of a sitting board and a motion-reduction structure that places the patient's leg at a 45-degree angle. The immobilization device serves to immobilize the lower limb during data collection to reduce noise and provide consistency during testing procedures.

Methods

Inclusion and Exclusion Criteria

Study participants were identified from a group of patients who attended a clinical visit for ATFL injury and/or extensive ligamentous injury and who had already made a treatment decision. All participants were subsequently placed into two groups: O) Patients with Chronic Ankle Instability receiving surgical treatment and NO) Patients with Chronic Ankle Instability receiving non-surgical treatment. To be eligible for this study participants were required to meet the following inclusion criteria: 1) Age between 18 and 65 years, 2) Skeletally Mature, 3) Able to give written consent, and 4) Confirmed diagnosis of isolated ATFL or ATFL + Other Ligamentous Injury with history of ankle sprain > 3 months. Participants were excluded from the study if they met any of the following exclusion criteria: 1) Prior ipsilateral ankle surgery for instability, 2) Prior history of ankle injury/surgery on the contralateral ankle, 3) Beighton's criteria ≥ 8, and 4) Any current or history of lower limb fracture, Achilles tendon injury, severe open wounds, or neuropathy.

Data Collection

12 subjects were included in the research study; 10 surgical (group O) and 2 non-operative (group NO). Data collections were performed preoperatively for operative patients, and after the initial clinical visit for non-operative patients. For both groups, data was collected again at 6 weeks and 12 weeks following the initial collection (Figure 2).

First, the patient sat atop the sitting board, and their left lower leg was secured to the immobilization device by wrapping an Xsens velcro strap around the tibia-fibula and the structure. The Xsens Mtw Awinda Sensor was secured to the patient's mid-dorsal left foot using the Xsens velcro strap. The IMU sensor was connected to MT Manager Software. The clinician performed three repetitions of each of the following manual stress tests: internal rotation test (IRT), talar tilt test (TTT), anterior drawer test (ADT), and external rotation test (ERT). Each set of manual tests was recorded on MT Manager and saved as .MTB files. This procedure was then repeated on the patient's right foot. The files were then exported as .TXT files for use in MATLAB.

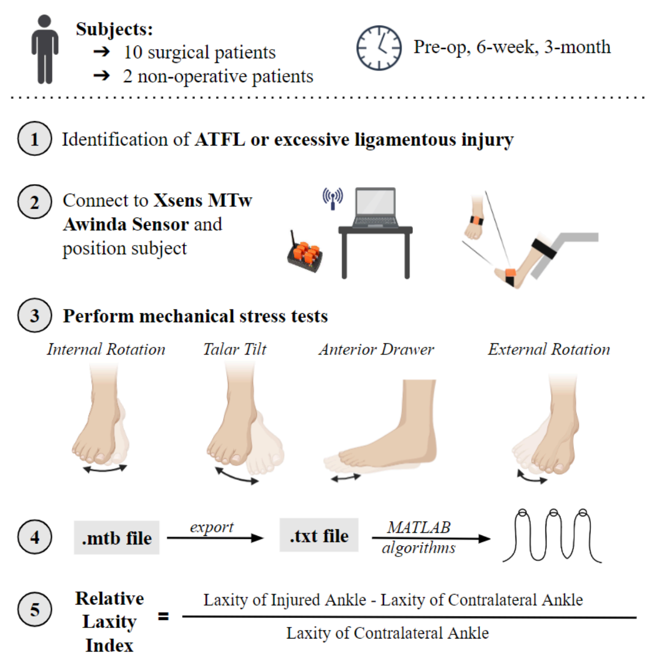

Figure 2. Data Collection Method.

Internal Rotation Test

The internal rotation test (IRT) is performed by stabilizing the distal tibia-fibula with one hand and holding the posterior plantar portion of the patient's foot with the other hand. An internal force on the foot is then applied towards the midline. The force should continue to be applied until mechanical rigor is felt as the foot pivots toward the midline.

Talar Tilt Test

The talar tilt test (TTT) is performed by stabilizing the distal tibia-fibula with one hand and holding the posterior plantar portion of the patient's foot with the other hand. An inversional rotation force is then applied to the foot. The force should continue to be applied until mechanical rigor is felt as the foot rotationally inverts.

Anterior Drawer Test

The anterior drawer test (ADT) is performed by stabilizing the distal tibia-fibula with one hand and holding the posterior plantar portion of the patient's foot with the other hand. An anterior force is then applied to the foot. The force should continue to be applied until mechanical rigor is felt as the foot translates forward.

External Rotation Test

The external rotation test (ERT) is performed by stabilizing the distal tibia-fibula with one hand and holding the posterior plantar portion of the patient's foot with the other hand. An external force on the foot is then applied away from the midline. The force should continue to be applied until mechanical rigor is felt as the foot pivots externally.

Signal Processing

Algorithms were developed to extract the maximum rotation or displacement in the direction of interest for each test. For each test, the three peak values were averaged.

For the internal rotation test, yaw data (degrees) is first centered around 0, and then filtered using a low-pass filter with a cutoff frequency of 1 Hz to remove high-frequency noise. The algorithm then finds the three highest yaw values.

For the talar tilt test, the roll data, in degrees, was centered around 0. Then the three highest roll values are identified. The process is the same for the external rotation test, using yaw instead of roll.

Signal processing for the anterior drawer test begins with filtering the acceleration data using a low-pass filter with a cutoff frequency of 5 Hz. The filtered acceleration data is then zero-centered. Next, the acceleration data is integrated twice to calculate the time-displacement curve. The MATLAB function 'trenddecomp' was used to remove any long-term linear trends from the displacement data. A third-degree polynomial is fit to the displacement data using 'polyfit' which is subsequently subtracted from the displacement data to remove non-linear drifts from the data. Peaks in the displacement data are sorted based on their prominence, and the three highest values are identified.

Relative Laxity Index

The RLI allows comparisons to be made between treatment groups, time points, and manual stress tests. ADT measures the displacement of the ankle in millimeters while the TTT, IRT, and ERT measure displacement in degrees. The RLI equation (**Eq. 1**) was used to convert results to a unitless index. Laxity refers to the average maximum rotation/displacement that occurred during each respective manual stress test. A high RLI indicates more laxity detected in the injured ankle compared to the contralateral ankle, while a lower RLI indicates greater stability.

$$RLI = \frac{Laxity\ of\ Injured\ Ankle - Laxity\ of\ Contralateral\ Ankle}{Laxity\ of\ Contralateral\ Ankle}$$

Equation 1. Relative Laxity Index equation.

RLI is also a useful metric because ligaments naturally vary in laxity depending on the person. By comparing the injured ankle to the healthy ankle, the RLI allows results to be interpreted according to the level of injury or defect in the ankle rather than the natural laxity of the individual's ligaments.

Statistical Analysis

To analyze the data, a one-way paired t-test was used to determine whether the relative laxity index statistically decreased following surgery.

App Development

The user interface was developed in MATLAB app designer. Open source code from the MT SDK in the MT Software Suite was used to connect the sensor, collect data, and export data to a .TXT file which can be read by MATLAB. The application was integrated with the developed algorithms to process the data.

Results

Aim 1: Research Study

Data collections were performed at all three time points on 6 of the participants (group O). Patient demographics, experimental group, affected laterality, and MRI reports can be found in Table I. Processed data for each test can be found in Tables II-V.

All tests showed a statistically significant decrease ($p<0.05$) using a one-way paired t-test between the initial and 6-week post-operative measurements (Figure 3), indicating that the surgery increases ligament stability. All tests except for ADT also showed a statistically significant decrease between the initial and 12-week measurements, demonstrating that the increased stability remains 3 months post-surgery. The anterior drawer test produced some unexpected results after processing due to the low signal-to-noise ratio, which may account for the lack of significant results at the 12-week time point. The talar tilt measurements also showed a statistically significant increase between the 6 and 12-week measurements, as the average became closer to 0, which may be indicative of decreased stiffness and swelling after healing from the surgery. We would expect all measurements to slightly increase over time, returning closer to 0, after the surgery as initial stiffness subsides, swelling decreases, and mobility is regained. Initial RLI measurements for the IRT were the highest for operative patients among the four tests and also had the largest standard deviation, 13.25 ± 10.42, but all were above 3, indicating 300% more laxity in the injured ankle vs the healthy ankle. After surgery, this test showed the biggest drop in RLI, decreasing to 1.34 ± 2.82 at 6 weeks and 0.23 ± 0.56 12 weeks postoperatively. The average maximum rotation of the injured ankle was 11.81 ± 0.9 degrees at the initial collection. This value decreased to 2.78 ± 1.2 degrees and 2.62 ± 1.59 degrees at 6 and 12 weeks respectively.

Table I. Subject information, experimental group, and injury information. L = Left, R = Right.

Subject	Group	Age	Sex	Affected Laterality	MRI Findings/ Impressions
5	O	32	F	L	ATFL tear
6	O	36	M	L	ATFL + CFL complete tears, partial thickness tear of deltoid
7	O	21	F	L	No tear, high grade lateral ankle sprain
8	NO	39	M	L	Thickening of ATFL + CFL, tear of PTFL
9	O	46	F	L	Normal ligaments
10	O	42	M	L	N/A
11	O	23	F	L	Complete ATFL tear, thickening of CFL, chronic injury of deep deltoid ligaments
12	O	19	M	L	Complete ATFL tear, high grade tear of PTFL
13	NO	65	F	R	Complete ATFL tear, partial CFL tear, partial deltoid tear
16	O	23	F	L	N/A

Table II. Internal Rotation Test data. C = Contralateral/healthy ankle, I = Injured ankle. * Significantly lower than initial, [+]significantly different than 6-week ($p<0.05$)

Subject	Group	Ankle	Initial		6 Week		12 Week	
			IRT (deg)	*IRT RLI*	*IRT (deg)*	*IRT RLI*	*IRT (deg)*	*IRT RLI*
5	O	C	1.39	7.15	3.47	-0.84	3.34	-0.06
		I	11.33		0.57		3.15	
6	O	C	0.70	18.06	2.11	0.38	2.95	0.05
		I	13.26		2.90		3.11	
7	O	C	2.11	4.63	9.29	-0.68	4.77	0.10
		I	11.89		2.94		5.25	
8	NO	C	3.29	2.11	3.07	2.22	-	-
		I	10.21		9.87		-	
9	O	C	0.55	19.87	0.83	4.38	1.36	-0.47
		I	11.41		4.47		0.72	
10	O	C	1.34	7.61	-	-	-	-
		I	11.50		-		-	
11	O	C	2.39	3.32	6.92	-0.62	0.91	1.12
		I	10.31		2.63		1.93	
12	O	C	0.36	34.38	0.49	5.44	0.98	0.62
		I	12.67		3.18		1.59	
13	NO	C	7.39	-0.87	-	-	-	-
		I	0.99		-		-	
16	O	C	1.02	10.95	-	-	-	-
		I	12.13		-		-	
Average ± Std Dev (Operative)		C	1.23 ± 0.73	13.25 ± 10.42	3.85 ± 3.54	1.34 ± 2.82*	2.38 ± 1.56	0.23 ± 0.56*
		I	11.81 ± 0.9		2.78 ± 1.26*		2.62 ± 1.59*	
Average ± Std Dev (Non-Operative)		C	5.34 ± 2.9	0.62 ± 2.11	-	-	-	-
		I	5.6 ± 6.52		-		-	
Average ± Std Dev (All)		C	2.05 ± 2.09	10.72 ± 10.65	3.74 ± 3.24	1.47 ± 2.59	2.38 ± 1.56	0.23 ± 0.56
		I	10.57 ± 3.49		3.79 ± 2.92		2.62 ± 1.59	

Table III. Talar Tilt Test data.

Subject	Group	Ankle	Initial		6 Week		12 Week	
			TTT (deg)	*TTT RLI*	*TTT (deg)*	*TTT RLI*	*TTT (deg)*	*TTT RLI*
5	O	C	26.39	0.03	22.85	-0.56	22.72	-0.16
		I	27.24		10.09		19.03	
6	O	C	21.10	-0.05	17.38	-0.47	13.10	-0.30
		I	20.05		9.29		9.12	
7	O	C	27.83	0.33	29.29	-0.72	26.58	-0.48
		I	37.09		8.06		13.89	
8	NO	C	22.37	0.33	18.85	0.43	-	-
		I	29.79		26.91		-	
9	O	C	17.44	0.30	17.44	-0.33	16.05	-0.14
		I	22.69		15.03		13.85	
10	O	C	23.03	0.28	-	-	-	-
		I	29.50		-		-	
11	O	C	17.84	0.91	13.57	-0.17	15.96	0.01
		I	34.06		11.22		16.11	
12	O	C	24.51	0.09	19.72	-0.44	19.77	-0.28
		I	26.62		11.11		14.33	
13	NO	C	28.44	-0.40	-	-	-	-
		I	17.06		-		-	
16	O	C	19.08	0.57	-	-	-	-
		I	29.94		-		-	
Average ± Std Dev (Operative)		C	22.15 ± 3.93	0.31 ± 0.31	20.04 ± 5.46	-0.45 ± 0.19*	19.03 ± 4.99*	-0.22 ± 0.17*,+
		I	28.4 ± 5.58		10.8 ± 2.39*		14.39 ± 3.25*	
Average ± Std Dev (Non-Operative)		C	25.41 ± 4.29	-0.03 ± 0.52	-	-	-	-
		I	23.43 ± 9		-		-	
Average ± Std Dev (All)		C	22.8 ± 3.99	0.24 ± 0.36	19.87 ± 5.01	-0.32 ± 0.37	19.03 ± 4.99	-0.22 ± 0.17
		I	27.4 ± 6.13		13.1 ± 6.47		14.39 ± 3.25	

Table IV. Anterior Drawer Test data.

Subject	Group	Ankle	Initial		6 Week		12 Week	
			ADT (mm)	*ADT RLI*	*ADT (mm)*	*ADT RLI*	*ADT (mm)*	*ADT RLI*
5	O	C	3.30	2.95	7.20	0.22	11.65	-0.90
		I	13.06		8.76		1.15	
6	O	C	8.32	-0.59	9.70	-0.80	2.24	-0.46
		I	3.43		1.92		1.21	
7	O	C	4.93	0.40	6.67	-0.53	2.04	6.79
		I	6.90		3.11		15.89	
8	NO	C	2.67	1.40	3.62	-0.13	-	-
		I	6.41		3.14		-	
9	O	C	5.30	0.11	3.48	-0.15	4.38	-0.54
		I	5.89		2.96		2.00	
10	O	C	3.18	1.06	-	-	-	-
		I	6.55		-		-	
11	O	C	4.28	3.31	1.99	-0.42	11.04	-0.90
		I	12.43		1.15		1.06	
12	O	C	7.33	-0.28	3.67	-0.22	8.54	-0.57
		I	5.24		2.88		3.70	
13	NO	C	6.05	-0.36	-	-	-	-
		I	3.89		-		-	
16	O	C	3.90	0.54	-	-	-	-
		I	6.02		-		-	
Average ± Std Dev (Operative)		C	5.07 ± 1.87	0.94 ± 1.45	5.45 ± 2.88	-0.32 ± 0.35*	6.65 ± 4.33	0.57 ± 3.05
		I	7.44 ± 3.44		3.46 ± 2.7*		4.17 ± 5.83	
Average ± Std Dev (Non-Operative)		C	4.36 ± 2.39	0.52 ± 1.24	-	-	-	-
		I	5.15 ± 1.78		-		-	
Average ± Std Dev (All)		C	4.93 ± 1.85	0.85 ± 1.35	5.19 ± 2.72	-0.29 ± 0.33	6.65 ± 4.33	0.57 ± 3.05
		I	6.98 ± 3.24		3.42 ± 2.47		4.17 ± 5.83	

Table V. External Rotation Test data.

Subject	Group	Ankle	Initial		6 Week		12 Week	
			ERT (deg)	*ERT RLI*	*ERT (deg)*	*ERT RLI*	*ERT (deg)*	*ERT RLI*
5	O	C	11.28	0.10	9.90	-0.49	14.86	-0.70
		I	12.42		5.05		4.40	
6	O	C	8.29	0.02	7.87	-0.56	6.46	-0.37
		I	8.41		3.50		4.09	
7	O	C	9.25	0.80	10.21	-0.59	10.25	-0.69
		I	16.63		4.16		3.14	
8	NO	C	6.92	-0.02	6.12	0.46	-	-
		I	6.78		8.94		-	
9	O	C	6.92	1.16	10.14	-0.33	11.85	-0.51
		I	14.94		6.82		5.84	
10	O	C	11.19	0.20	-	-	-	-
		I	13.37		-		-	
11	O	C	15.46	-0.19	11.42	-0.54	11.01	-0.69
		I	12.55		5.23		3.42	
12	O	C	7.09	1.03	8.27	-0.29	9.02	-0.49
		I	14.35		5.89		4.61	
13	NO	C	13.43	-0.39	-	-	-	-
		I	8.25		-		-	
16	O	C	9.77	-0.39	-	-	-	-
		I	6.00		-		-	
Average ± Std Dev (Operative)		C	9.91 ± 2.79	0.34 ± 0.58	9.63 ± 1.33	-0.47 ± 0.13*	10.58 ± 2.82	-0.58 ± 0.14*
		I	12.33 ± 3.5		5.11 ± 1.19*		4.25 ± 0.96*,+	
Average ± Std Dev (Non-Operative)		C	10.17 ± 4.61	-0.2 ± 0.26	-	-	-	-
		I	7.52 ± 1.04		-		-	
Average ± Std Dev (All)		C	9.96 ± 2.9	0.23 ± 0.57	9.13 ± 1.8	-0.33 ± 0.37	10.58 ± 2.82	-0.58 ± 0.14
		I	11.37 ± 3.71		5.66 ± 1.81		4.25 ± 0.96	

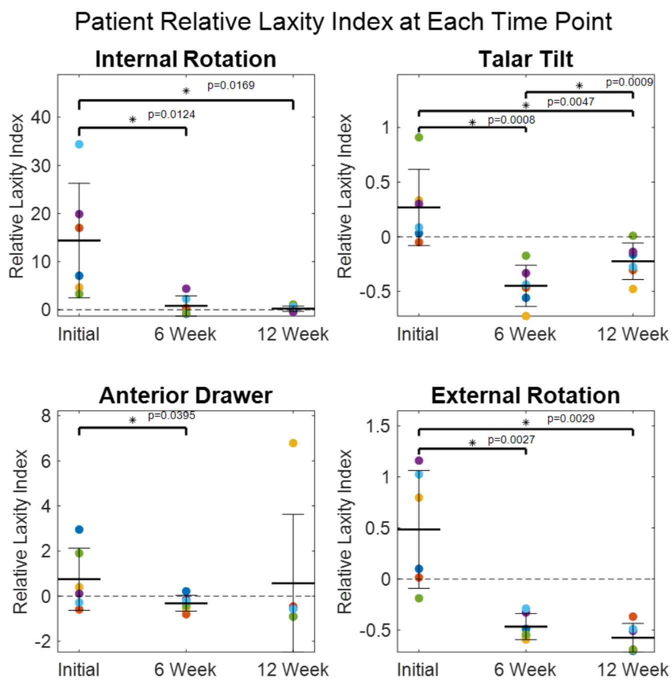

Figure 3. Patient relative laxity at each time point

Following surgery, the maximum ankle rotation or translation of the injured ankle significantly decreased ($p<0.05$) for all four tests (Figure 4).

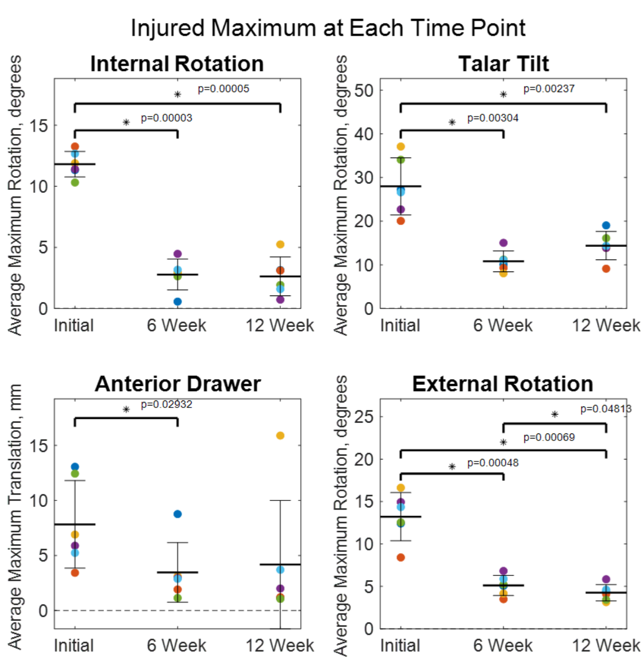

Figure 4. Injured ankle maximum rotation/ translation at each time point.

As expected, the maximum ankle rotation or translation of the healthy ankle showed no statistical difference between any of the time points for the IRT, ADT, and ERT (Figure 5).

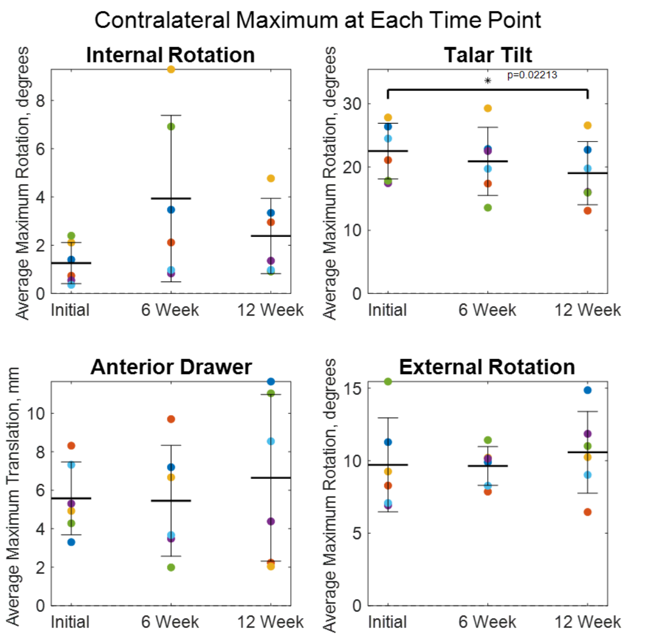

Figure 5. Contralateral ankle maximum rotation/ translation at each time point.

Aim 2: Software Design

An application was developed to provide a method of data collection with nearly instantaneous data processing to help ensure valid data. The application was also designed to quickly process and visualize patient data for a single visit as well as to view trends over time.

<u>Collect New Data</u>

Front End Software

On the first page of the application, Figure 6, the user can connect the sensor to their computer to collect, visualize, and save data with a few clicks. After plugging the MTw Awinda USB wireless connector into the laptop and removing the IMU sensor from the charging dock, the user can click “Connect MTw Awinda Sensor”. The feedback box shows the status of the sensor connection and provides instructions to the user if any issues are encountered. The user must also input the patient ID and select the current ankle and manual stress test that data is being collected for. Additionally, the user must select a location to save the .MTB and .TXT files. Drop-down menus were used for the ankle and test selections to provide the user with the given possibilities. When the buttons to save the .txt and .mtb files are pressed, the commonly used file explorer interface is launched to provide the user with a familiar interface. Once the sensor is properly connected and all necessary fields are populated, the “Collect Data” button becomes enabled to indicate that the user may begin collecting data. An optional time delay feature was added to enable clinicians to collect data independently. The user can also select if they want to play a sound when the measurement recording begins. This aids in their ability to collect data independently and to account for the slight delay that sometimes occurs as background processes happen after the “Collect Data” button is pressed.

Once “Collect Data” is pressed, the button will turn green and the clinician may begin the manual stress tests. After three consecutive tests, the user can press “Stop” and the .MTB and .TXT files will automatically be saved to the selected location. Files are named using the patient ID, date, test, and ankle. On the bottom right, a graph will appear showing the processed data of the test. A marker will indicate the peaks in the data where the algorithm detected the maximum rotation/displacement of the ankle during the test. If the graph appears to have correctly identified the three peaks of the manual stress test, the user can move on to the next test by selecting the next ankle and test. If the test was not done properly or the maximums are incorrectly selected, the test can be performed again and the new results will automatically be saved and overwrite the previous results.

Back End Software

When the user presses the connect button, the code runs to recognize the plugged in antenna and initiates the connection between the antenna and the IMU sensor. Once “Collect Data” is pressed, the software creates a new file under the naming convention: *PatientID_MM_DD_YYYY_Test_CurrentAnkle.mtb*, resets the axis orientation of the device, puts the IMU sensor in collection mode, and stores the data packets in that file. Once the stop button has been pressed, the collection mode is turned off, the file is exported to a .TXT file with the same naming convention in the previously indicated folder, and then the data is sent through the appropriate processing algorithm, depending on the test and side.

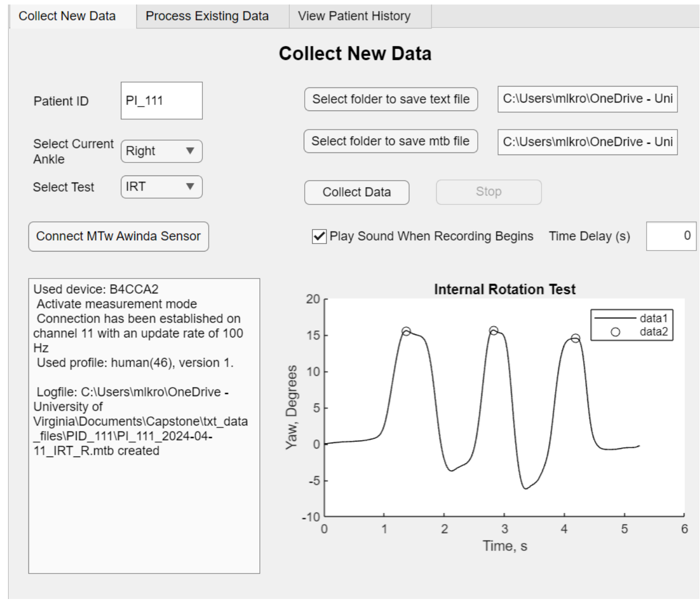

Figure 6. Tab 1 of the application; Collect New Data**.**

Process Existing Data

On the second page of the application, Figure 7, the user can process any pre-existing data. To do so, they must first select the patient’s injured ankle and click “Load Data". A window will open, prompting the user to select the location of the folder containing the .TXT files that they want to process. Once opening the folder, the app will automatically process the IMU data using developed algorithms. Due to noise and low peaks for some IRT tests, an option is provided for the user to process the IRT data using an alternate algorithm that selects the peaks that occur before minimums and are a certain distance apart. The graph will populate with the rotation (IRT, TTT, and ERT) and displacement (ADT) data for each test. Once again, a marker indicates the peaks in the data where mechanical rigor occurred during the test and maximum rotation/displacement was reached. The average +/- standard deviation of the peaks for each ankle and test is reported in the table. Additionally, the relative laxity index is reported in the table.

The second page of the application also gives users the ability to save the processed results to a MATLAB structure (.MAT file) to be used for future reference. It will automatically select the path that the .TXT files were taken from to save the file. The user can change this path by clicking the "Select New Location" button. To use the results structure in the patient history feature of the app, the filename must have the correct naming convention (PatientID_YYYY-MM-DD). Once ensuring that the desired path is chosen and the structure is properly named, the user can click "Save Struct to Results Folder". The application will also provide a warning in the event that a file already exists with the same name to prevent accidentally overwriting data.

Figure 7. Tab 2 of the application; Process Data.

View Patient History

The third and final page of the application, Figure 8, gives users the ability to visualize patient history if they have obtained results at more than one time point. After the user clicks "Load Patient Results", they will be prompted to select the .MAT files for each collection date they want to include. The first graph will populate with the relative laxity index plotted over time. The second graph allows users to look at the rotation/displacement of the injured ankle at each time point. Users can then toggle along the top of the graphs to select which test they want to look at the results history for.

The second feature of the Patient History tab, allows users to generate a PDF report that includes the patient's results from each data collection. After the user clicks "Generate Patient Report", they will once again be prompted to select the .MAT files for each collection date that they want to include. The report includes a summary of the collection dates, the patient's injured ankle, and patient-ID. Additionally, it includes graphs for visualizing the patient's history.

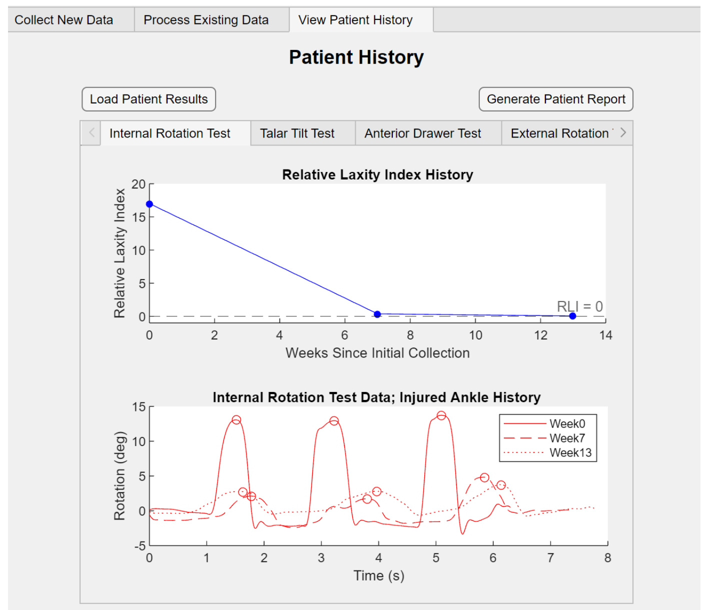

Figure 8. Tab 3 of the application; Patient History.

Reliability

A one-way random, average measure intraclass correlation coefficient (ICC) was calculated to measure the intra-rater reliability using the repeated measures of the contralateral ankle. The ICC values for the talar tilt test showed excellent agreement (0.8765) and fair to good agreement for the external rotation (0.7169) and internal rotation (0.5233) tests. No agreement was found for the anterior drawer test due to complications with signal processing.

Usability

To assess the usability of the application we invited athletic trainers and kinesiology academic faculty to attend a training session. After presenting the background for our project, we demonstrated how the application is used. We then showed videos of a clinician performing the four manual stress tests. Next, we had the athletic trainers perform the four tests, on both ankles, while using the application.

From the training session, we received positive feedback through a survey, where one participant noted that the application is “very intuitive” and another expressed that we “have built something practical and useful”. We conclude that with appropriate training, our application can be used to collect data for all four tests, on both ankles, in under five minutes.

Aim 3: Visual Tool to Inform Treatment Options

A visual tool to inform treatment options was not developed. To complete this aim, more data would need to be obtained for operative and non-operative patients, and at more time points. At this time, we do not have enough results to quantitatively define and categorize the extent of ankle instability to recommend specific treatment types. Additional information such as patient injury history, MRI results, pain levels, and ability to perform everyday activities would also contribute to the development of an effective visual tool for informing treatment options.

Discussion

This capstone project demonstrated a significant decrease in ankle ligament relative laxity index in patients with chronic ankle instability following surgical repair via the Brostrom Procedure. This study also demonstrated moderate reliability for this method of quantifying ligament laxity. Finally, this project succeeded in developing an application to make this method of quantifying CAI feasible in the clinic.

The significant decrease in ligament laxity following surgery provides quantitative results to support previously found evidence based on patient-reported outcomes that the Brostrom Repair has a high success rate. These results provide evidence that doctors can provide patients who are deciding whether or not to undergo surgery. Additionally, these results start to form a basis for the comparison of pathologic thresholds that require surgery versus can be treated using non-operative methods. The variation of MRI findings, and sometimes lack of any pathologic findings, indicate that chronic ankle instability requires further diagnostic testing.

The results of the IRT proved that it was a better mechanical test for identifying ATFL laxity than the ADT. This shows that the IRT may be a more effective clinical mechanical test for isolating the ATFL and evaluating the stability of the ankle. To further assess the effectiveness of isolating ligamentous damage using the ADT, TTT, and ERT, a study with patients having a broader range of ligamentous injuries would need to be performed.

The initial reliability testing shows promising results for three of the tests, and it is expected that the use of the newly developed application will increase the reliability for all of the tests, but especially the anterior drawer test by eliminating faulty data. It is important to do a more robust reliability study in the future collecting data on more subjects in a shorter period of time to reduce possible changes to the ankle ligaments. It is also important to do an inter-rater reliability study to determine whether or not others can use the device and get the same results.

The application that was developed works very well for the first version and can be used by someone not familiar with the project. This is important for the continued success of this research study as well as expanding the device to other uses and marketing it for sale. More training would be required for those who are not familiar with the manual stress tests, especially considering that the IRT and ERT are more novel. A larger training session with a more diverse range of professions would enable us to collect more feedback to implement into the application. The application provides a single piece of software in which data can be collected, processed, and visualized in a streamlined manner. By taking less than 10 seconds to perform and visualize the data per test, more people are likely to use the device and software. The ability to visualize the data over time and print out a PDF report for each patient also increases the possible applications of our software.

This project provides an excellent stepping stone for more research to be done on chronic ankle instability caused by ligament laxity while providing empirical support for a standard procedure that previously lacked quantitative support. This device and methodology can change the way doctors evaluate ankle injuries and instability. It will help standardize the physical exam, which is heavily depended on to make surgical decisions. It provides a quick and easy to use method that can be used by surgeons, athletic trainers, and physical therapists to measure ankle instability and track rehabilitation. This device also can be used extensively for research to better understand the outcomes of different surgeries, assess rehabilitation progress, and explore differences within the population in ligament laxity such as male vs female, as well as female-specific research.

In conclusion, this study succeeded in demonstrating the importance of including two additional mechanical stress tests, the internal and external rotation tests in clinical evaluations. It also demonstrated the increase in ankle stability via lower relative laxity index results following surgical repair. The methodology introduced as well as the application developed in this project will allow for future research to expand on this study. Using these tools to gather more data on ankle ligament laxity will help the field of orthopedic surgery in effectively diagnosing and treating chronic ankle instability.

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