Diagnostic Accuracy of the Anterior Drawer Test and Internal Rotation Test on Isolated Anterior Talofibular Ligament Injuries using Wearable Inertial Measurement Unit (IMU) Sensors

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Technical Project Team Members

Haley Frye

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

Ankle instability is a pervasive issue, particularly among active individuals (Wilkstrom et al., 2013). In an effort to measure such instability, a series of manual stress tests, each indicating laxity of specific ligaments, are performed by an orthopedic clinician. Currently, these tests are subjectively evaluated by the clinician, and the degree of mechanical laxity detected is entirely dependent upon their personal discretion and expertise. This lack of standardization may lead to problems in diagnostic accuracy and consistency. Additionally, little comprehensive research on the diagnostic accuracy of these tests currently exists (Croy et al., 2013; Netterström-Wedin et al., 2021). Diagnostic accuracy of ankle instability is critical to effective patient treatment and positive clinical outcomes, as test judgements help determine and guide clinical decisions. Injury to the anterior talofibular ligament (ATFL), which connects the fibula to the talus, accounts for up to 73% of the underestimated two million acute ankle injuries that occur each year (Herzog et al., 2019). By clinical standards, testing of this ligament is performed through the anterior drawer test (ADT) and the talar tilt test (TTT). However, concerns regarding the diagnostic accuracy of these tests have been raised. In an attempt to address these concerns and improve the accuracy and precision of these tests, the objective of the present study is twofold: 1) to conduct research which discerns the diagnostic accuracy of these manual tests and 2) to establish and develop an objective measurement tool to achieve standardization and quantifiable assessment of instability. We propose that utilizing the internal rotation test (IRT), rather than the ADT, will provide earlier and more precise indication of an isolated ATFL injury, and that drawer is not changed with such an injury. We believe a positive, abnormal ADT results from more extensive ligamentous damage to the ankle, specifically conjunctive trauma to the deltoid ligament, ATFL, and other ligaments such as the CFL, rather than isolated injury to the ATFL. In alignment with our hypothesis, we expect to observe less ankle displacement from the ADT and increased ankle yaw, or inversion, angle change from the IRT in our isolated ATFL patients, and increased ankle displacement from the ADT in our more extensive ligamentous damage group.

Keywords: Ankle Instability, Anterior Talofibular Ligament Injuries, Manual Stress Tests, Anterior Drawer Test, Talar Tilt Test, Internal Rotation Test, IMU Sensors

Introduction

Significance

Ankle instability results from recurrent ankle sprains and trauma to the ankle. Diagnostic accuracy of ankle instability is crucial to patient treatment and clinical outcomes, as judgement of these tests help govern clinical decisions. Most ankle treatment options are purely elective and physician-guided, highlighting the importance of accurate diagnoses and appropriate proposed treatment strategies. Frequently utilized treatments include ankle bracing, physical therapy, activity restrictions, ankle immobilization devices (a protective walking boot with or without crutches), or a combination of these. When these conservative measures fail, surgical treatment may include ankle reconstructive surgery of ligaments, cartilage, and/or bone. Return to activity and future capacity for activity largely depends on the treatment plans prescribed by orthopedic doctors. Up to 40% of ankle sprains are misdiagnosed or inadequately treated, resulting in chronic ankle pain and disability (Cavazos & Harkless, 2021). If ankle instability is untreated or mistreated, frequency of reinjury increases, leading to chronic ankle instability (CAI) which may result in post-traumatic osteoarthritis (PTOA) (Herzog et al., 2019).

CAI develops in 70% of individuals who sustain an acute lateral ankle sprain with a higher incidence among active populations such as athletes (Herzog et al., 2019). CAI presents either as mechanical or functional ankle instability (Al-Mohrej & Al-Kenani, 2016). Mechanical instability is characterized by ligamentous laxity and is diagnosed by mechanical stress tests. Functional ankle instability is largely evaluated through patient-reported complaints of general instability during daily or athletic activities and can be accompanied with clinical laxity. The aforementioned early- to mid-treatment options are consistently prescribed and performed by individuals with CAI in an attempt to reduce the likelihood of recurrent injury and sprains. Exhaustion and failure of these early treatments are likely for these individuals, often resulting in their pursuit of elective surgical procedures such as arthroscopic ankle debridement and the Broström-Gould repair (Camacho et al., 2019). 78% of individuals with chronic ankle instability are likely to develop early posttraumatic osteoarthritis in the ankle (Camacho et al., 2019). Surgical repair may help to slow or prevent this progression (Camacho et al., 2019).

PTOA, a subtype of osteoarthritis, is characterized by a painful and disabling degeneration of cartilage and bone following recurrent injury (Thomas et al., 2017). It has been estimated that 80-90% of arthritic change in the ankle is post-traumatic (Delco et al., 2017; Song et al., 2019). Patients with this chronic disease experience ankle joint pain, swelling, stiffness, and tenderness to touch (Cleveland Clinic, n.d.). One retrospective analysis showed that patients with a history of recurrent ankle sprains comprise 70–85% of end-stage ankle PTOA surgical candidates (Delco et al., 2017). Lateral ankle ligamentous damage due to lateral sprains are the main cause for developing ligamentous PTOA (Valderrabano et al., 2006).

Of particular importance, injuries to the ATFL, the lateral ligament connecting the fibula to the talus **(Figure 1),** account for up to 73% of the two million acute ankle injuries that occur each year (Herzog et al., 2019), with incidence very likely underestimated. This is the most commonly injured ligament in lateral ankle sprains due to its low strength and low ultimate load threshold, which is the force or load required for complete breakage (Fong et al., 2009; Dubin et al., 2011; Camacho et al., 2019). The mechanism of injury to this ligament typically consists of a combination of plantar flexion and inversion (Melanson et al., 2022). By clinical standards, testing of this ligament is done through the anterior drawer test (ADT), a forward translational ankle movement exam **(Figure 2A)**. Testing of generalized lateral ligament damage is typically done through the talar tilt test (TTT), an inversional roll of the ankle similar to the mechanism of injury **(Figure 2B)**. Concerns regarding the ADT test have been raised by researchers due to its “limited ability to detect excessive anterior talocrural joint laxity” (Croy et al., 2013) and high specificity but low sensitivity (Li et al., 2020; Netterström-Wedin et al., 2021). This finding is in part, alike to all ankle instability mechanical stress tests, due to it being subjectively deemed “normal” or “abnormal” by a clinician – a determination that is predicated on their personal experience and expertise. The degree of abnormality is estimated on a scale of pluses (+) or a 0-to-4 scale with no specific guidelines or easily measurable demarcations. In fact, one study noted when examining test sensitivity,

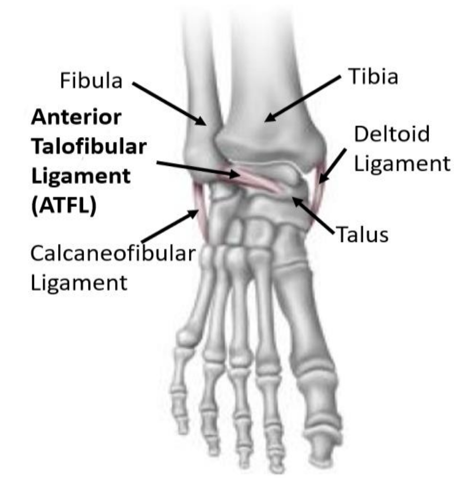

Figure 1. Anatomy of Ankle. ATFL bolded. Image from J. Bernstein.

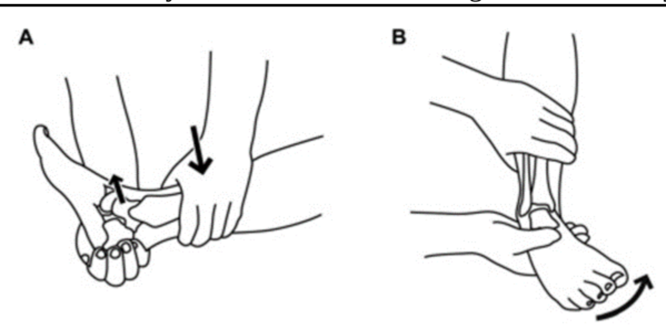

Figure 2. Standardized Lateral Ankle Instability Tests. A) Anterior Drawer Test, B) Talar Tilt Test. Arrows indicate change in direction. ADT measured by forward displacement in mm. TTT measured by degree roll. Image from Clinical tests of the lateral ligament complex.

judgements for physical examinations varied significantly from person to person as it is precepted by the examiner and noted low sensitivity in less experienced hands (Li et al., 2020).

Magnetic resonance imaging (MRI) scans are used to visualize the structural integrity of the ankle joint and its ligaments, while ankle stress radiographs (ASR) can be opted for to capture the mechanical functionality of the ankle (Choi et al., 2021). An ankle stress radiograph is an x-ray of the ankle during mechanical stress, such as stresses alike to those exerted during the TTT and ADT. This type of scan is typically applied only to patients with severe instability. Using this methodology, the tilt angle and anterior translation can be measured from the x-ray scans (Choi et al., 2021). However, replicability and consistency within scans within one patient have been found to be low and not acceptable (Choi et al., 2021). Researchers have concluded that a reliable and accurate decision regarding patient ankle instability treatments should not be gathered from one ankle stress radiograph scan (Choi et al., 2021). Another study concluded this imaging alone cannot be utilized to determine pathology associated with ankle instability (Sy et al., 2021). In addition to this, in order to take the scan, a prolonged period of stress exertion must be maintained by a healthcare provider to take the x-ray. This sustained force and stress on the ankle joint causes pain and significant discomfort to the patient. It also includes radiation exposure to all involved, namely the patient and the provider performing the radiograph. Devices to maintain the applied stress and eliminate the provider during the scan have been created and tested in studies; however, researchers have noted that it is difficult and may be painful to be performed in acute cases, is not a validated method to apply stress force, may result in rotation of the limbs image alteration, and the device can increase the stress strength of the patient (Aguiar et al., 2017).

Questionnaires are also regularly employed to measure subjective ankle instability, such as the Ankle Instability Instrument (AII), Ankle Joint Functional Assessment Tool (AJFAT), Chronic Ankle Instability Scale (CAIS), Cumberland Ankle Instability Tool (CAIT), Foot and Ankle Ability Measure (FAAM), Foot and Ankle Instability Questionnaire (FAIQ), Foot and Ankle Outcome Score (FAOS) (Donahue et. al, 2011), and the American Orthopedic Foot and Ankle Score (AOFAS). “While these questionnaires are widely used, it is unclear how accurately each measure predicts a participant’s ankle stability or instability status” (Donahue et al., 2011, p. 1141). The AOFAS for hindfoot, FAAM, CAIT, and the CAIS were utilized in a study to compare chronic lateral ankle instability pre- and post-Broström-Gould procedure, and researchers concluded, “the disparity of the results obtained with the different scores shows the necessity to establish a common evaluation system in the literature to assess ankle instability and its treatment options” (Buerer et al., 2013).

As stated previously, misdiagnosis of ankle instability is frequent and can be connected to the lack of a universal standard among testing and scoring of ankle instability. The problem associated with ankle instability testing is its subjective, qualitative, and inconsistent nature. This is largely due to the inability to quantitatively and objectively measure ankle instability and the research deficit on the diagnostic accuracy of the standardized mechanical tests. Due to the current lack of objective measurement in this field, quantifiable standards have not been placed around the degree of ankle laxity appropriate for differing medical treatments, procedures, or surgeries. In order to combat this subjectiveness and inconsistency, research must be conducted on the diagnostic accuracy of these tests. To do this, a tool must be created to objectively measure the displacement and degree changes in movements within these tests to allow for successful comparison and conclusion.

The field of orthopedic medicine would greatly benefit and undergo a transformative era if a universal, consistent, objective, easily performed, and financially low-cost product was created to identify and classify the degree of ankle instability and laxity. This product would facilitate standardized and comparable research within acute and chronic ankle instability, diagnostic ranges of such, and treatment efficacy. With this surge of objective data, a better understanding of the progression of ankle instability from ankle injuries would ensue. From this, numerical ranges could be instituted for ankle instability severity classifications, aiding in consistency of diagnosis and clinical treatment decisions. This, too, would allow tracking of patient instability development over subsequent sprains and rehabilitation over treatment. Such a device would also decrease the incidence of unindicated surgery that is performed to treat MRI findings, rather than actual mechanical instability. It would help instill surgeon confidence and allow for quantification of a problem that is currently dependent solely on personal expertise and skill of the clinician.

Innovation

In this project and study, an early phase of this product was created and utilized to evaluate the diagnostic accuracy of the ADT in diagnosing isolated ATFL injury using MTw Awinda Sensors, MT Manager Software, and MATLAB Software. MTw Awinda Sensors collect IMU data and interact with the MT Manager Software to export the data in a MATLAB readable text file. MATLAB Software used to create algorithms to extract manual stress test data in order to calculate test parameters and to process signals of such data.

No technology to date has been proposed precisely alike to our sensor ankle instability mechanical test measurement tool. Other technologies utilized to measure movement in other joints such as the knee have been proposed through patents (Meere & Verstraete, 2018; Howard et al., 2019; Mirza et al., 2022). Many of these patents briefly mention their technology may be configured for other joints such as the ankle, but that is the extent of their comment on the topic. A patent for knee sensors with the purpose of being worn during a study to investigate the diagnostic accuracy of the Lachmann test for anterior cruciate ligament integrity is the closest patent related to our product (Boos et al., 2011). Additionally, a patent from the University of Pittsburgh for a motion-based marker system to monitor instability in the anterior cruciate ligament (ACL) during the pivot shift test is similar to the aforementioned patent as both patents monitor the knee and are utilized in studies to evaluate instability during knee stress tests (MUSAHL et al., 2013). Sensor ankle patents regarding gait analysis are numerous, with extensive prior art (Wiggin et al., 2013; 横 et al., 2020). However, no singular living patent has been filed directly equivalent to our product. Of course, many motion and kinematic sensors have been patented (Ely et al., 2016) and are commercially available, such as the Xsens and Notch sensors, on the market, but none have been created or marketed for our specific application and intended purpose.

Our product differs from relevant prior art due to its intended purpose and structural framework. The intended purpose is to objectively quantify, either in degrees or mm, ankle instability during mechanical tests through use of a wearable sensor and MATLAB program. A single sensor connected to an adjustable strap will be secured to the dorsal midfoot of the ankle undergoing the mechanical exam to measure the spatial change **(Figure 3).** The early product utilized for this capstone project will have the algorithm for two standardized tests, the ADT and the TTT, and one novel test, the internal rotation test (IRT).

Other devices and technologies have been utilized to characterize movement in the ankle such as physical and digital app arthrometers and advanced research tools; however, these tools have been criticized for a lack of practicality necessary for in-clinic use (Wenning et al., 2021). Common ankle arthrometer tools used in research include the Hollis and the LigMaster. It was an important design goal to be able to measure ankle movement during normal conduction of manual stress tests that mimic those used in-clinic as closely as possible. This way, the adoption of this technology would be easier among ankle orthopedists without much adaptation or deviation from the typical conduction of these tests.

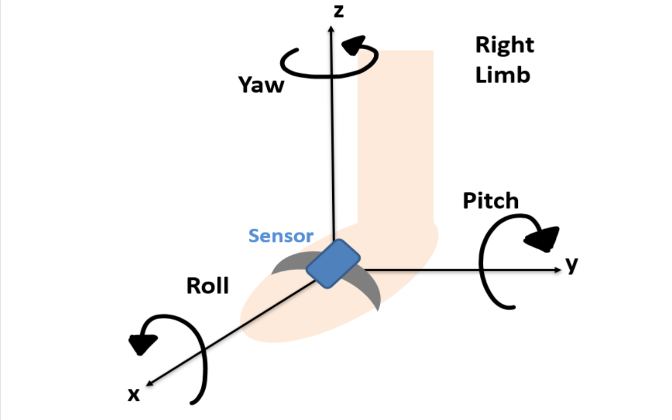

Figure 3. Sensor Placement and Gyroscope Measurements. Sensor placement on dorsal midfoot. Roll, pitch, yaw measurements (as well as other IMU sensor parameters) collected for test data and algorithm.

Previous studies investigating the diagnostic accuracy of ankle instability measures such as questionnaires and some mechanical stress tests have been completed, as denoted previously. Studies have been deemed inadequate due to methods of measurement and/or utilization of frozen specimens (Vaseenon et al., 2012). Some have concluded with similar statements suggesting the need for more research, use of alternative or a combination of exams (Croy et al., 2013; Donahue et al., 2011), and/or standardized, precise diagnostic tools (Buerer et al., 2013; Wenning et al., 2021).

Characterization of ligamentous integrity is critical in diagnosis and treatment of ankle sprains and ankle instability development, for which diagnosis via the ADT requires more research. This study is one of the first to quantify ankle instability utilizing a test- specialized objective tool and will result in conclusions surrounding the diagnostic accuracy of the ADT. Other instrumented tests, the IRT and TTT, will be utilized in the study to conclude diagnostic involvement and accuracy of these tests in diagnosing isolated ATFL injury. Results will add to the current educational climate surrounding diagnostic accuracy of ankle instability exams and mechanical tests for ATFL injuries.

Project Aims

To address the aforementioned concerns, we propose the development of an objective and quantitative tool to measure ankle instability utilizing a wearable sensor aided with a computational program in order to evaluate the diagnostic accuracy of the clinical standard anterior drawer (ADT) and an internal rotation (IRT) test **(Figure 4)**. We hypothesize that the IRT will provide earlier and more precise indication of an isolated ATFL injury and that the ADT is not changed with this injury. We believe a positive, abnormal ADT results from more extensive ligamentous damage to the ankle, specifically a more generalized pattern of injury including that to the deltoid ligament, ATFL, and calcaneofibular ligament (CFL). In contrast, we hypothesize that isolated injury to the ATFL will result in an increase in internal rotation instability, while the ADT will remain unchanged. We will also perform and document the talar tilt test (TTT), as this standardized mechanical test is utilized to demonstrate varus instability arising from injury to the ATFL and CFL.

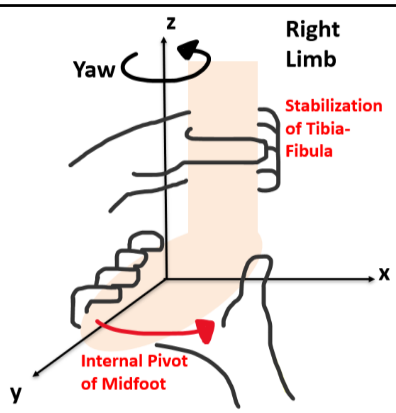

Figure 4. Internal Rotation Test. Stabilization of tibia-fibula and internal pivot of the midfoot. Red arrow indicates movement of the foot. IRT measured by degree yaw.

The objective of the study is twofold with two main project aims. Aim 1: Develop a novel ankle multi-instability-testing computational program to calculate the angle change and displacement of the ankle. The MATLAB computational program, consisting of the three tests' (ADT, IRT, TTT) algorithms, will receive raw kinematic data from a lower-extremity-adjustable-strap Xsens MTw Awinda Sensor and compute the appropriate parameter; either degree or displacement change, depending on the test selected and performed. Aim 2: Utilize the computational program and sensor to test the hypothesis that an isolated ATFL injury can be indicated earlier and more precisely through an IRT and that drawer is not changed with this injury. MRI studies of the ankle will be reviewed by UVA radiologists and orthopedic foot and ankle surgeons. Patients will be classified as either isolated ATFL injuries or extensive ligamentous injuries including the ATFL. One wearable sensor will be placed on the dorsal midfoot of both patient ankles of both groups. All three tests will be performed three times each on each ankle. In alignment with our hypothesis, we expect less ankle displacement from the ADT and increased ankle yaw angle change from the IRT in our isolated ATFL patients. In contrast, we anticipate that increased ankle displacement from the ADT will be present in our more extensive ligamentous damage group. These findings will also be compared to the ankle roll angle change from the TTT in order to evaluate the role of ATFL injury. Additionally, pre- and post-op ankle instability will be measured among qualifying participants and compared using the same methods to further investigate how this quantifiable instability changes with surgical intervention.

Materials and Methods

Materials

MTw Awinda Sensors & MT Manager Software

Xsens MTw Awinda Sensors and associated MT Manager Software was bought from Movella. These sensors capture IMU data including gyroscope, accelerometer, and magnetometer data. Roll, yaw, free acceleration, and packet counts were utilized for our study's purposes. MT Manager Software wirelessly connects to the sensors in order to control the sensors, settings, to collect data, to display data, and to export the data. Update rate of wirelessly connected MTw Awinda Sensors is 100 hertz and internal sampling frequency is 1000 hertz

Immobilization Device

This device was created to immobilize the lower limb, reducing noise and providing standardization/consistency within the testing procedures. This is a two-part device consisting of the sitting board and motion reduction structure **(Figure 5).** The motion reduction structure is composed of three separate pieces of

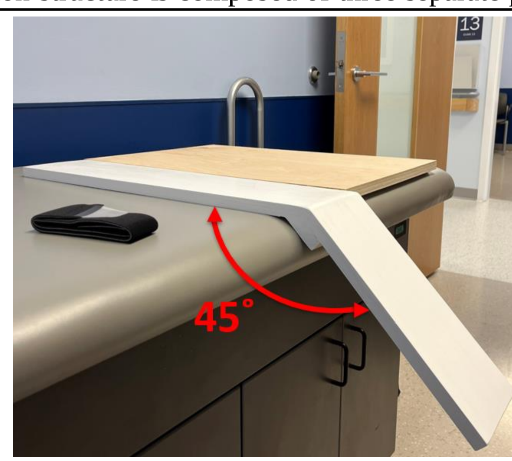

Figure 5. Immobilization Device. Motion reduction structure (left) and sitting board (right). 45-degree rigid angle between the top and bottom pieces. Xsens Velcro Strap (all the way to the left) secures tibia-fibula to the bottom piece.

wood. The top piece serves to support the thigh, the bottom piece supports the lower portion of the leg, and the middle piece supports the 45-degree junction between the top and bottom pieces. This structure is held together by screws and was painted white. The individual's leg is immobilized through securement to the bottom piece utilizing Xsens Velcro Straps. This structure was optimized to fit the length of the lower limb of most individuals, allowing their heel to extend and hang off the end of the bottom piece. The sitting board serves to equalize the hips of the individual being that it is the same height as the motion reduction structure, ensuring comfort, reducing unnecessary movement, and supporting correct anatomical positioning. The immobilization device was optimized to fit design criteria such as: allowing movement of the structure to either leg, allowing proper movement of tester's hand during testing alike to in-clinic procedures, allowing resting of the leg in the proper position for testing, and reducing motion in the leg during testing.

The first iteration of this device had the same dimensions and features, but allowed manual selection of the angle between the top and bottom pieces of the motion reduction structure using a door hinge, two washers, a hex bolt, and a tightening knob **(Figure S1A).** This adjustment capability was proposed to provide best selection of leg angle for the test performer to best maneuver during the tests. This initial iteration proved to be successful in accomplishing this and other desired criteria and constraints; however, after multiple uses, the angle adjustment mechanism failed to hold the angle stationary upon weight placement of the lower limb. Due to this failure, a rigid connection between the top and bottom pieces was opted for. Despite the departure from its use, the design of the first iteration allowed for experimentation of leg placement and helped guide the decision that placement at 45-degrees was the best angle for test conduction. The second iteration of this device with the applied changes was utilized for testing and was described above **(Figure S1B).**

Methods

Inclusion and Exclusion Criteria

All participants were surgical candidates placed into two groups within this study: A) patients with isolated ATFL injury and B) patients with ATFL and additional ligamentous injury. Inclusion criteria for Group A included: chronic isolated ATFL injury with history of ankle sprain greater than three months, MRI images obtained and read by radiologist at the University of Virginia, radiologist confirmation of isolated ATFL injury, patient aged 18 years or older and skeletally mature, and no major or minor history of contralateral ankle injury. Group B inclusion criteria is identical to Group A, but with additional extensive, chronic ligamentous damage including the ATFL as confirmed by a UVA radiologist. Extraneous joint laxity was controlled for using Beighton's Criteria for Global Laxity. Exclusion criteria included: lower limb fractures, previous ATFL or ankle surgeries, Achilles tendon injuries, severe open wounds, neuropathy, or a Beighton's score of 8 or 9.

General Test Steps

After a patient was identified and radiographic/clinical confirmation of inclusion criteria was obtained, subjects provided written consent prior to any study procedures. Three mechanical tests (ADT, IRT, TTT) were performed on the patient. A sensor was placed on the patient's left ankle's dorsal midfoot to track and collect movement of the ankle during the tests. Data collection from the sensor was initiated, the clinician performed the test, and then data collection ceased. Sensor data was exported from MT Manager, imported into MATLAB, received by the appropriate MATLAB algorithm, and then the appropriate measurement was calculated. The test was repeated three times with clear periods of rest in between and the averages were taken from the data set. This procedure was replicated on the patient's right ankle, namely three repetitions of each of the three mechanical stress tests (ADT, IRT, TTT).

Anterior Drawer Test Conduction

To conduct the anterior drawer test, the patient's left distal tibia fibula is stabilized with physician's left hand. The physician's right hand holds the posterior plantar portion of the patient's foot. The physician applies anterior force using their right hand. Patient's ankle should shift or translate forward due to this force. Physician continues application of force till ankle mechanical rigor is felt.

Talar Tilt Test Conduction

To conduct the talar tilt test, the patient's left distal tibia and fibula is stabilized with physician's left hand. The physician's right hand holds the posterior plantar portion of the patient's foot. The physician applies inversional rotational force using their right hand. Patient's ankle should rotationally invert. Physician continues application of force till ankle mechanical rigor is felt.

Internal Rotation Test Conduction

To conduct the internal rotation test, the patient's left distal tibia-fibula is stabilized with physician's left hand. The physician's right hand holds the posterior plantar portion of the patient's foot. The physician applies internal force towards the midline using their right hand. Patient's ankle should pivot towards midline. Physician continues application of force until ankle mechanical rigor is felt

Lower Limb Immobilization Device Setup

Sitting board and motion reduction structure placed next to each other on the examining table. Motion reduction structure first placed on the left side to conduct left ankle testing. Patient sits on sitting board and rested left leg on the motion reduction structure. Patient's left limb is secured at the mid tibia-fibula to the downward board of the motion reduction structure using Xsens Velcro straps. This process is repeated on the right limb of the patient by switching the placements of the sitting board and motion reduction structure.

Zeroing of Initial Ankle Placement

Test positioning for a particular test was set up prior to zeroing of initial ankle placement. This positioning included the full resting of the patient's ankle and the test performer's hand placement on the patient's ankle for the particular stress test. Additionally, patient was reminded to relax and be still during the tests and the examiner was reminded to limit jostling and movement during the zeroing. MT Manager Orientation Reset Method of Alignment Reset was used to zero the initial ankle placement. This method combines two methods: heading reset, correcting the direction of the x-axis, and inclination reset, aligning the coordinate frame of the sensor to the object which it rests on.

Anterior Drawer Displacement and Signal Processing

Free acceleration in the x-plane was collected for one data capture, consisting of three cycles of the anterior drawer test. Single cycle linearization method utilized to remove acceleratory drift and to calculate average net displacement. Acceleratory drift is a well-known phenomenon to occur with IMU sensors upon double integration of acceleration **(Figure 6).** This results in a drifting signal due to the integration of noise present within the signal. Due to this, processing of the signal prior to integration is necessary. Increased signal drifting occurred when attempting to apply such methods to the three-cycle, continuous signals. It was found that better processing with less drifting occurs when truncating the three cycles within the signal into separate, single cycles.

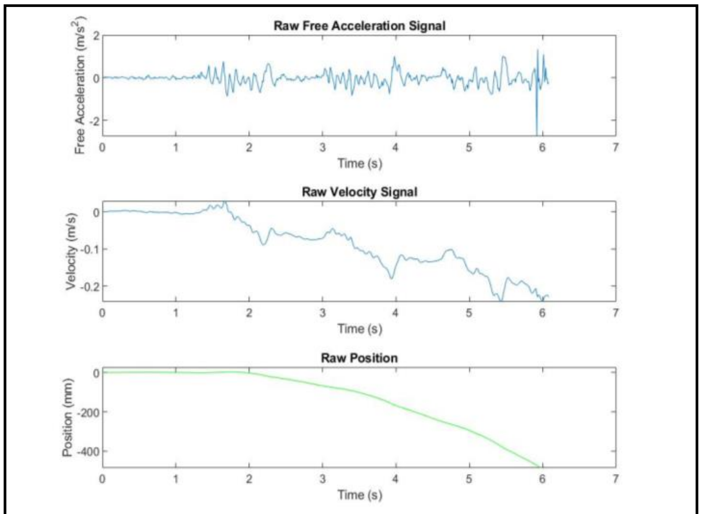

Figure 6. Acceleratory Drift in Raw Position Signal. Raw free acceleration signal (top) integrated to raw velocity signal (middle) integrated to raw position signal (bottom). Downward drifting of raw position signal due to acceleratory drift. Position signal should return to zero after each cycle repetition.

A MATLAB preprocess function was created using Wavelet Signal Denoiser App with selection options 'Wavelet: sym4, Level: 8, Denoising Methods: Bayes, Threshold Rule: Median, Noise: Level Independent.' This preprocess function was created with the help of the UVA Research Computing Department.

To conduct the single cycle linearization method, the free acceleration is first preprocessed with this preprocess function, then linearized with the MATLAB linear detrend function. The acceleration signal was subsequently plotted and cycle demarcations noted. Data was analyzed in three separate portions according to cycle demarcations. Data was zeroed before and after each cycle demarcation. Then, this demarcated data section was integrated twice using the MATLAB cumtrapz function to get positional data. The initial value and maximum displacement were noted and the net displacement was calculated by taking the difference between these two values. This was repeated for each demarcated data section. The average of the net displacement from each demarcated data section was taken to compute the average displacement during the anterior drawer test.

This method was tested for validity in ideal conditions in which the sensor was translated forward 1.65 inches and back to zero three times on a flat surface **(Figure S2)**. The same data collection procedure was conducted. This was conducted five times. Error of measurement ~1.42mm with no individual error greater than 3mm. Error associated with actual experimental data estimated to be higher than this value due to the greater presence of noise within the signal.

Talar Tilt Degree Roll

Roll degree data was collected for one data capture, consisting of three cycles of the talar tilt test **(Figure 7)**. This data was plotted and the three local maxes were collected. The average of these three maxes were taken to compute the average tilt/roll. This method was tested for validity in ideal conditions in which the sensor was tilted or

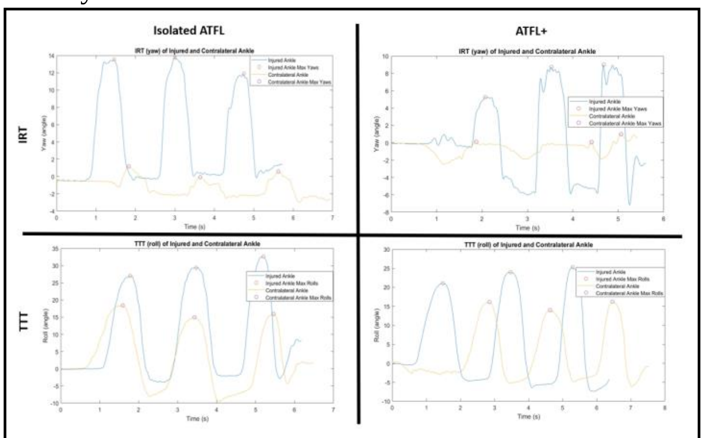

Figure 7. Internal Rotation Test and Talar Tilt Test Data Collection. IRT (top row) and TTT (bottom row) for single data capture of an Isolated ATFL participant (right column) and ATFL+ participant (left column). Injured ankle (blue) and contralateral ankle (orange) with maxes of each labeled by markers. Three cycles or repetitions of each test within each data capture. Average taken of the three maxes labeled as markers.

rolled three times on a flat surface to 90 degrees using a glass box. The same data collection procedure was conducted. Error of measurement less than one degree.

Internal Rotation Degree Yaw

Yaw degree data was collected for one data capture, consisting of three cycles of the internal rotation test **(Figure 7)**. This data was plotted and the three local maxes were collected. The average of these three maxes were taken to compute the average internal rotation/yaw. This method was tested for validity in ideal conditions in which the sensor was rotated or yawed three times on a flat surface to 90 degrees using a carpenter square tool. The same data collection procedure was conducted. Error of measurement less than one degree.

Relative Laxity Index

Each of the manual stress tests have their own respective parameter, either millimeters (ADT) or degrees (IRT, TTT). In order to compare the sensitivity of the three manual stress tests, a unitless index, the relative laxity index (RLI), was created **(Eq. 1).** A higher RLI indicates a more laxity detected in the injured ankle compared to the contralateral ankle, indicating a more sensitive test in detecting the injury within the injured ankle.

$$(RLI)\ Relative\ Laxity\ Index = \frac{Laxity\ of\ Injured\ Ankle - Laxity\ of\ Contralateral\ Ankle}{Laxity\ of\ Contralateral\ Ankle} \quad [1]$$

Results

Aim 1: MATLAB Manual Stress Test Algorithms

As discussed in the methods section, fully automated algorithms exist for the IRT and TTT and semi-automated algorithms exist for the ADT. IRT and TTT algorithms were quite simple and quick to produce and validate. The ADT algorithm was much more challenging to produce given the phenomenon of acceleratory drift as discussed previously in the methods section. The current algorithm for the ADT parameter calculation requires more intervention than that of the IRT and TTT. Currently, manual selection of demarcation points and truncation of the signal is required. This is unique to the ADT as more noise is present within the signal and more processing is required to compute an accurate displacement. Improvement of the ADT algorithm to automate the demarcation and truncation will result in full automation of the algorithm. While this is in progress, it has been suggested to proceed with ADT collection in single cycle data captures rather than three cycle data captures. This will allow more automation of the ADT algorithm.

Aim 2: Research Study

The study protocol, manual stress test conduction, and data analysis was conducted as such as outlined in the materials and methods section. Only three subjects thus far have participated in the study. The data from these three subjects including their group, identification, injured ankle, test parameters, and test RLIs are summarized in **Table 1.** Primary differences in IRT and ADT RLIs can be noted among the subjects. TTT RLIs among all subjects are very low. Subject three (isolated ATFL) has an IRT RLI 6.1 times higher than its ADT RLI, indicating greater relative laxity of the patient's isolated ATFL injured left ankle in response to the IRT compared to the ADT. Subject two (ATFL + mild deltoid sprain) has a high RLI and a negligible (< 2mm) ADT, indicating greater relative laxity within the patient's ATFL+ injured left ankle in response to the IRT compared to the ADT. Subject three (ATFL+++) has an IRT RLI estimated to be at most 6.3 times higher than its ADT RLI being that its ADT RLI is estimated to be greater than 2.85. This indicates greater relative laxity

Subject	Group	Identification	Injured Ankle	IRT L, R (deg)	IRT RLI	TTT L, R (deg)	TTT RLI	ADT L, R (mm)	ADT RLI
1	ATFL+	ATFL+++	L	7.67	17.89	23.44	0.52	7.69	N/A, estimated >2.85
				0.41		15.45		Negligible, < 2	
2	ATFL+	ATFL+ (mild deltoid sprain)	L	15.89	10.63	30.61	0.02	Negligible, < 2	N/A, estimated to be low
				1.37		29.91		Negligible, < 2	
3	Isolated ATFL	ATFL	L	13.07	22.37	29.67	0.80	10.42	3.65
				0.56		16.44		2.24	

Table 1. Summary of Subject Data. Three subject's group, identification, injured ankle, and test (IRT, TTT, and ADT) averaged data for each ankle and relative laxity index (RLI).

within the patient's ATFL+++ injured left ankle in response to the IRT compared to the ADT. It is important to note that the magnitude between subject one and two is fairly similar with three being slightly greater. This is expected as subject three has an ATFL injury plus more ligamentous damage. Being that the sample size is currently only three subjects, more subjects are needed to confirm the sensitivity and diagnostic accuracy of the IRT, TTT, and ADT. However, preliminary findings suggest IRT sensitivity in diagnosing isolated ATFL injuries.

Discussion

Challenges

The primary challenge of this project was the removal of the acceleratory drift upon the double integration of the ADT acceleration signal. Most of time spent on the project was allocated to this issue. Numerous processing methods such as signal filtering (high-pass, low-pass, band-pass), data interpolation, detrending, and a combination of such methods were explored to remove the drift. Each of the methods had varying successes and downfalls. Many of the methods responded differently to ideal data and actual experimental data. This can be largely attributed to the greater amount of noise present in the actual experimental data. Many methods had downfalls as they required great intervention in order to be successful and would be extremely challenging to automate and streamline. The secondary challenge of this project was limiting, identifying, and removing the noise present within the ADT acceleration signal. The previously discussed processing methods were used to explore identification and reduction of the noise. Additionally, creation of the immobilization structure helped to reduce this noise. Due to these two challenges, the single cycle linearization method outlined in the methods section was decided upon.

Project & Study Future Direction

Much improvement upon both aims exists to be completed in the future. Improvement within aim one would align with signal processing, algorithm automation, and the user interface. Improvement within aim two would include further development of variables being monitored or tested.

Aim 1

The greatest room for improvement is upon the data processing algorithm to remove the acceleratory drift and noise present within the ADT signals, specifically reducing error in computation and automation of the algorithm. As noted in the methods section, the single cycle linearization method has an error of ~1.42mm when computing position displacement within an ideal dataset. The true error within actual experimental data is unknown, but is expected to be greater than this due to the presence of noise. Reduction of error by more precisely identifying the noise present in the ADT signal and attuning data processing to such noise is an area of improvement within this project. As previously discussed, automation of the ADT algorithm is an area of improvement of top priority. With automation, it will allow more consistent data processing being that steps are removed from human intervention and error. Additionally, it will enable translation of such technology beyond technical use in research to practical and easy use in in-clinic settings. In order to do this, many improvements are needed upon the project/device, leading to the next area of improvement. Creation of a more user-friendly interface for data upload, processing, and test parameter output is an area of improvement that would allow advancement of the device to be used by larger populations and does not require great technical background to operate. Such interface would allow test selection, provide instructional videos how to utilize the device and conduct the tests, carry out recording and data collection during test conduction, and then output the appropriate parameters. MTw Awinda sensors are compatible with MATLAB code and can control sensor recording and data collection. Improvement to such an interface is possible given the infrastructure of the sensors, namely if MATLAB code was paired with another language for user interface aesthetics.

Aim 2

Improvement within the research study and its processes would include the reduction of noise, inclusion of more test performers, and the investigation of inter- and intra-rater reliability of test performers. To reduce noise within this aim, improvement upon the immobilization structure, specifically better securing of the lower limb, a mechanism to which the foot can slide on during the ADT to reduce other directional movement, and a mechanism to reduce external pivot during the IRT. Additionally, including more test performers will add depth to the study by providing the ability to investigate inter- and intra-rater reliability of the manual tests.

Future Research Avenues

If this tool were to be validated, multiple research opportunities would benefit from the objective and quantitative measurements that this device offers. Research investigating the progression of ankle instability following recurring sprains would aid in better understanding of instability severity and characterizing instability ranges (i.e., stable, moderately unstable, severely unstable). This research would easily translate into research surrounding ankle instability and patient outcomes following different rehabilitation and treatment options such as operative versus non-operative (conservative) measures. From here, research into optimal instability ranges for specific treatment options could ensue, paving the way for the formation of suggested instability guidelines for specific procedures. All of these research opportunities would greatly benefit the orthopedic field by providing more insightful and quantitative information to the physician, leading to better and more measurable patient outcomes.

End Matter

Author Contributions and Notes

H.V.F designed research, J.S.P and A.E.S and H.V.F performed research, H.V.F wrote software, H.V.F analyzed data, and H.V.F wrote the paper, and A.E.S. and J.S.P edited the paper.
The authors declare three conflicts of interest.
J.S.P funded the cost of the Xsens MTw Awinda Sensors.
Participants were sourced from J.S.P's surgical candidate patients.
J.S.P was the test performer.
This article contains supporting information at the end.

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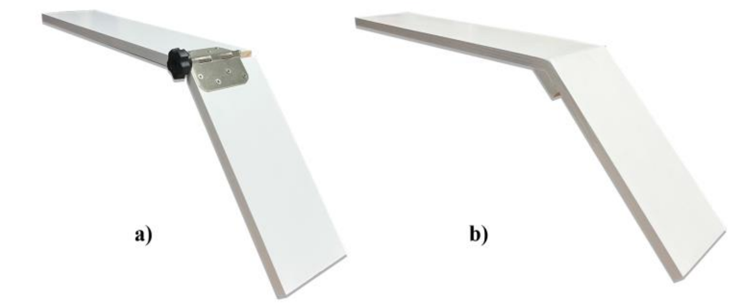
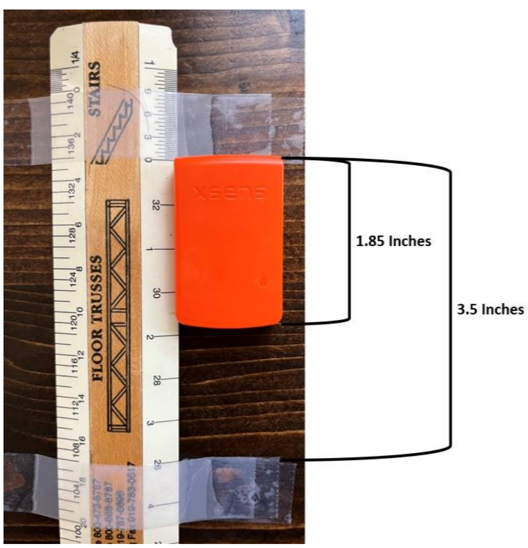
Supplementary



Supplementary Figure 1. Motion Reduction Structure Iterations. First iteration (a) allows manual selection of angle between top and bottom pieces and second iteration (b) is rigid at 45 degrees between top and bottom piece. First iteration utilizes a door hinge, two washers, a hex bolt, and a tightening knob.



Supplementary Figure 2. ADT Validity Test Set-Up. Sensor placed on flat table and moved back and forth 1.65 inches (3.5 inches – 1.85 inches) between the two demarcations. This is considered "ideal" testing conditions.