Protocol Title: Body-Worn Sensors for Risk of Injury Prediction During Military Training

PI: Robert Gailey

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1) Protocol Title:

Body-Worn Sensors for Risk of Injury Prediction during Military Training

2) Study Objective and Aims:

Objective: The objective of this study is to externally validate a previously developed knee injury risk index (IRI), and to compare its performance with an updated, concurrently developed model of knee injury risk that uses the same inputs and metrics as the previously developed IRI – namely, the Region of Limb Stability (ROLS) and Transitional Angular Displacement of Segments (TADS). It has the potential to inform the clinical decision-making process related to Service Members entering the 82nd Airborne Division (82nd ABN DIV) Advanced Airborne School who present as healthy but may be at risk for lower limb injury after beginning school and undergoing strenuous training.

Aim 1: Validate the previously developed knee injury risk index (IRI)
Specific Aim 1a: Collect kinematic data related to knee stability

- **Hypothesis for Aim 1a**: We will be able to use the CaneSense™ system to capture kinematic data from Service Members entering the 82nd ABN DIV Advanced Airborne School, convert into measures of *Region Of Limb Stability* (ROLS) and the *Transitional Angular Displacement of Segments* (TADS) (details in Research Methods) and combine into a composite numerical value to represent Injury Risk Index (IRI) for military personnel.
- **Process for Aim 1a**: Use the CaneSense™ system to collect kinematic metrics – namely, ROLS and TADS – from the 82nd ABN DIV Service Members for inputs into the previously validated knee injury risk index (IRI). The ROLS quantifies joint excursion that translates to joint stability, including but not limited to the co-contraction strength and balance about the knee joint during standing expressed by the area of excursion within a joint segment to maintain static balance. TADS quantifies knee joint range of motion over time required to maintain dynamic balance during a change of direction. In short, ROLS is a measure of static postural stability and TADS is a measure of dynamic postural stability, where together or in isolation has the potential to predict if a Service Member from the 82nd ABN DIV has a functional impairment that would place them at risk for injury during strenuous activity.

Specific Aim 1b: Validate the previously developed knee injury risk index (IRI) in terms of its ability to predict knee injury and either dropout or physical profile assignment from the 82nd ABN DIV

- **Hypothesis for Aim 1b**: The previously developed knee injury risk index (IRI) will be able to prospectively discriminate between Service Members in the 82nd ABN DIV who dropout or receive a physical profile assignment due to knee injury and those who do not dropout and remain injury-free.
- **Process for Aim 1b**: Measure the area under the receiver operating characteristic curve (AUROC) of the students in the 82nd ABN DIV Service Members initial IRI and indicators of whether they dropped out or receive a physical profile due to knee injury. Moderate discriminatory ability will be indicated if AUROC > 0.7, good discriminatory ability if

AUROC > 0.8, and excellent if AUROC > 0.9. Calibration will be assessed using a natural spline of predicted vs mean observed values – that is, with a so-called calibration plot – with 95% confidence bands. Evidence of poor calibration will be indicated for non-overlapping regions.

Aim 2: Develop a knee-injury risk model for the 82nd ABN DIV Service Members

Specific Aim 2a: Generate a new, knee-injury risk model for Service Members from 82nd ABN DIV Advanced Airborne School.

- **Hypothesis for Aim 2a**: A new injury risk model will be able to categorize the Service Members into three injury risk categories (low, moderate, and high).
- **Process for Aim 2a**: At the end of study follow-up (18-months) knee-injury and drop out data along with their initially recorded ROLS and TADS values and brief past medical history gathered from self-report questionnaires will be used to generate candidate risk prediction models using machine learning. Specifically, we will employ extreme gradient boosting (XGBoost), support vector machines (SVM), and generalized additive models (GAM) in order to model knee injury dropout, 82nd ABN DIV physical profile assignment as a non-linear function of ROLS and TADS. The performance of competing machine learning models will be assessed and compared in terms of their cross-validated operating characteristics – namely, calibration and discrimination. The final selected model will be that which features the best performance.

Specific Aim 2b: Compare the performance of previously developed IRI with the concurrently developed machine learning model of knee-injury dropout or physical profile assignment and 82nd ABN DIV physical profile assignment.

- **Hypothesis for Aim 2b**: The concurrently developed machine learning model will outperform the previously developed IRI in terms of cross-validated operating characteristics.
- **Process for Aim 2b**: Use bootstrapped cross-validation (bootstrap validation) to assess and compare the operating characteristics (calibration and discrimination) of the concurrently developed machine learning model of knee injury with the operating characteristics of the previously developed IRI. Considering that the ultimate utility of these models will be within a clinical context, model parsimony will also be considered. For example, if the concurrently developed model only slightly outperforms the previously developed model but features a prediction surface with far greater complexity than that of the previously developed model, then we would prefer the latter to the former for the sake of parsimony.

3) Background:

More than 800,000 military service members are injured each year, leading to an estimated 25,000,000 days of limited duty annually.[1] Musculoskeletal injuries are the greatest threat to force readiness during both peacetime and combat operations.[2] Although the more severe injuries during combat can lead to a significant loss of military personnel, even seemingly mild injuries during sport and exercise could contribute to a lack of readiness and poorer overall fitness.[3] Furthermore, noncombat musculoskeletal injuries (MSI) (during physical training, tactical training, recreational activity, and sport) are endemic within the military population accounting for 85% of all MSI among United States (U.S.) military personnel.[4] Athletic injuries are also the leading cause of disability discharge among Service Members (SM) in the U.S. Army,

according to Physical Evaluation Board data. [5, 6] Thus, prevention and care of these sports and physical training injuries are top priorities for leaders in the Department of Defense (DoD).[6]

Most sports-related MSI affect the lower limb.[7, 8] Forty percent of these injuries occur at the knee, making it the most common site of musculoskeletal injury.[9] Specifically, soft tissue injuries are the most frequently encountered and represent 47% of all knee injuries.[10] For example, 100,000–175,000 anterior cruciate ligament (ACL) reconstructions are performed annually among civilians in the U.S.[11-15] Fibrocartilage, ligamentous, and tendinous integrity compromise about the knee can lead to joint instability. Knee joint instability can have short-term and/or long-term negative effects, affecting force readiness and return-to-duty/return-to-sport (RTD/RTS) decisions. Objective measures of knee stability could be used to determine those at risk for injury thus decreasing the rate of injury. In addition, objective measures of knee stability could be used throughout the rehabilitation process to determine healing and neuroadaptation of soft tissue and surrounding contractile musculature, respectively, enabling the SM to RTD/RTS without fear of re-injury and with a greater potential to achieve their pre-injury level of performance.[16]

Effective measures of injury risk and function are urgently needed in the military and athletic populations.[17] Traditional functional assessment tests such as the hop test and vertical drop jump tests are currently used to determine time of return to pre-operative physical activity level following knee injury [11, 18, 19] and used as a clinical screening tool for ACL injury, respectively.[20] However, the sensitivity for detecting functional weaknesses regarding, i.e. single-leg hop test for distance, is reported to be between 38-52%.[11,21,22] It was also recently reported that none of the vertical drop jump test variables were associated with increased ACL injury risk in a cohort study of 710 athletes.[23] None of these tests were found to be related to lower limb MSI risk in a cohort of 3,985 high school athletes. Age and injury history were the only factors significantly related to lower limb MSI risk.[24,25] To improve the accuracy of functional measurement, researchers have developed measures with force plates, pressure mats and other technologies for assessing standing balance to screen for lower limb injuries.[26-28] While sophisticated instrumented testing can provide greater measurement accuracy and analyze important kinematic and kinetic data, there are several limitations such as; highly trained staff is required, equipment is expensive, longer testing time, increased data analysis and interpretation time, constrained performance environment, and often the individual performs differently in the laboratory than on the field or court. Often by the time the test results are known the functional status of the healing individual has changed or the individual has made the decision to return to activity.

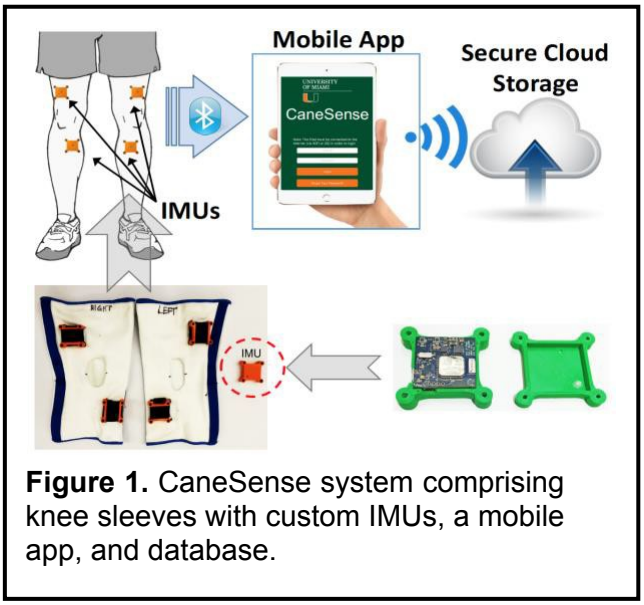


Figure 1. CaneSense system comprising knee sleeves with custom IMUs, a mobile app, and database.

To address these limitations in current functional testing, the use of inertial measurement unit (IMU) have been introduced in combination with functional testing. Minimal footprint IMUs are portable, easily placed on the body, and can be used in any environment making it a very attractive alternative to enhance traditional functional testing with accurate, real-time quantitative data. However, as IMU technology becomes more readily available. The validity of their application must be determined to ensure that they are being utilized and interpreted appropriately. For example, a recent study investigated the use of a single IMU placed on the sacrum during standing to measure gross body sway. [29] While the identification of gross movements is important; balance outcome measures lack the sensitivity to identify joint instability and/or range of motion impairment of the knee. Balance impairment may not be clinically observable at the time of RTD/RTS and often go undetected putting the individual at risk for re-injury.

Current priorities for military healthcare are focused on injury prevention and reduction strategies that are targeted, timely, and actionable for maximal efficacy. The use of mobile technologies and body-worn devices for point-of-care management prior to strenuous physical activity for the classification of at-risk Service members for MSI that can be performed in a matter of minutes and provide real-time analysis has significant benefits. The ability to predict which service members are at risk for injury prior to the adverse event and potentially preventing injury can have a major impact on the individual's health and career, as well as, the military unit's resources and overall healthcare costs.

To assess the risk for knee injury efficiently, we have previously developed a novel mobile lower limb motion capture system (known as CaneSense™, **Figure 1**) consisting of four small wireless IMUs secured in an elastic knee sleeve and one IMU on a waist belt, that communicates via Blue Tooth Low Energy to a custom mobile app on a mobile tablet that processes the kinematic data, displays the results in real-time, and transmits the results for storage on a secure cloud storage at the University of Miami (UM). [30-32]

4) Inclusion and Exclusion Criteria:

Subjects will be recruited from Fort Bragg, NC. They will include students entering the 82nd ABN DIV Service Members Advanced Airborne School. We will capture 82nd ABN DIV Service Members during the Airborne Integration Course (AIC) which occurs when they first report to Fort Bragg for duty. We anticipate capturing up to 7,500 82nd ABN DIV Service Members over the duration of the study.

Inclusion Criteria: Volunteers will be;

1. Between the ages of 18-55
2. Active duty Service Members in the 82nd ABN DIV

3. Fluent in English speak and reading

Exclusion Criteria:

1. Service members under the age of 18 or over the age of 55 will be excluded
2. Told by a doctor that they should not exercise.
3. Orthopedic injury/surgery of the lower limb or back within the last year and that limits study compliance
4. Regular use of medications that may alter balance, coordination or agility
5. Unwilling to comply with the study protocol

5) Procedures Involved

Testing protocol

For 82nd ABN DIV Service Members, testing will occur during the Airborne Integration Course (AIC) which takes place when they first report to Fort Bragg for duty. Research teams from UM will Fort Bragg, NC and work with research assistants from the military post during each data collection period. A University of Miami Institutional Review Board (IRB) and Womack Army Medical Center approved informed consent will be obtained from every subject after they undergo the informed consent process, have an opportunity to review the informed consent and study procedures with the study investigator, answer all questions, review potential risks involved and study rights. Any questions or concerns by potential subjects will be addressed prior to completion of the consenting process.

After signing the informed consent all subjects will be asked to complete a brief baseline questionnaire electronically on an iPad that will include: 1) Gender; 2) Age; 3) Current Assignment (82nd ABN DIV); 4) Rank; 5) Military Occupational Specialty; 6) Height; 7) Weight; 8) Lower Limb Injury Inventory (Do you have lower limb pain or a limitation today? Have you ever had an injury to either lower limb?); and 9) Past musculoskeletal history (additional information may be obtained from medical records by the research PT). Subjects who report current hip, knee or ankle pain or who report a previous musculoskeletal injury requiring medical attention, will be asked to complete a survey specific to the hip, knee, and/or ankle pain when performing functional activities specific to athletes. Each survey 20 questions long and should take less than 5 minutes to complete.

If for some reason the subject is unable to complete the lower limb joint-specific survey, subjects will be asked to complete the questionnaire at a later date. The imbedded physical therapist (PT) will be responsible for the follow-up administration of the questionnaire and will find a time that does not interfere with other duties and responsibilities of the subjects.

ROLS and TADS Testing

Subjects are to wear standard indoor physical training gear (T-shirt, shorts, socks, and sneakers). The following is the testing process that will be implemented for all subjects when performing ROLS and TADS:

1) The subject's shoes are removed and elastic knee sleeve with IMU sensors are slipped over both knees and shoes are re-donned.
2) The subjects are asked to perform a 13 second walking trial in order to align and calibrate the IMU sensors.

3) ROLS testing: The ROLS metric is calculated from the thigh and shank sensors on the stance limb when the subject performs the single limb stance test (SLS).
   a. ROLS is a measure of static knee joint stability, defined by thigh and shank movements on the horizontal plane in the anterior/posterior (AP) and medial/lateral (ML) directions during SLS (**Figure 2**). The ROLS Symmetry Index (SI) is a single metric generated to quantify differences within individuals by comparing the ROLS value between supporting lower limbs during left and right SLS where 100 percent suggests absolute symmetry and values less than 100 percent suggests an asymmetry and imbalance. Segmental excursions are computed using acceleration data from the two IMUs donned on the stance/supporting limb during SLS.

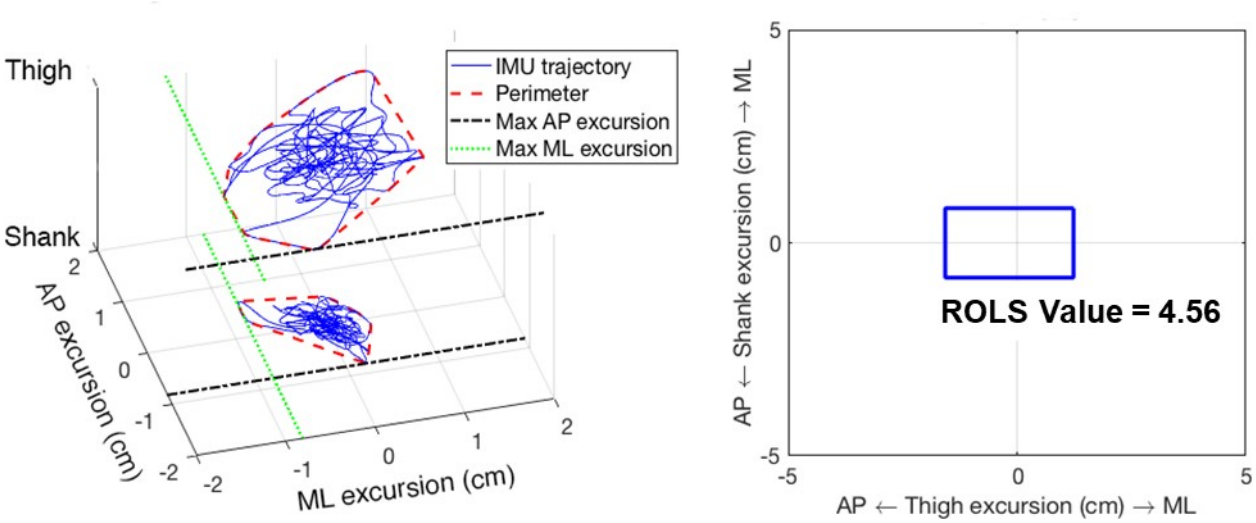


Figure 2. Description of ROLS excursion and ROLS calculation.

   b. The SLS is a standard measure of static balance and postural stability. The SLS records the time a subject could stand and balance on one lower limb while lifting and maintain the contralateral foot above a 15 cm cone while maintaining their arms crossed over their chest for 30 seconds. If the subject's contralateral foot falls below the 15 cm cone, they will be asked to raise it. Time will be stopped if the subject's: 1) foot touches the floor; 2) cannot maintain their foot above the 15 cm cone; 3) arms come un-crossed; 4) the stationary foot loses contact with the floor (i.e., hopping); or 5) achieve 30 seconds. The subjects will take a 30 second rest period after each trial. They will perform a minimum of 1 trial per lower limb and a maximum of two trials per lower limb.

4) TADS testing:
   a. TADS is derived from shank IMUs because measures of shank angular velocity can be reflective of knee moments. The Four-meter Side Step Test (FmSST) assesses uni-directional frontal plane agility and body control and the time to sidestep to the right four meters and then left a distance of four meters (total of eight meters) as quickly as possible a total of three times for a total distance of 24 meters. The FmSST is used to capture the shank segment movement with rapid side-step to the right and the left side, generating 5 transitions (two transitions captured with the right limb as the decelerating limb undergoing change of direction and three with the left limb as the decelerating limb undergoing change of direction) with 180° of change in direction illustrated in the wave diagram Figure 3.

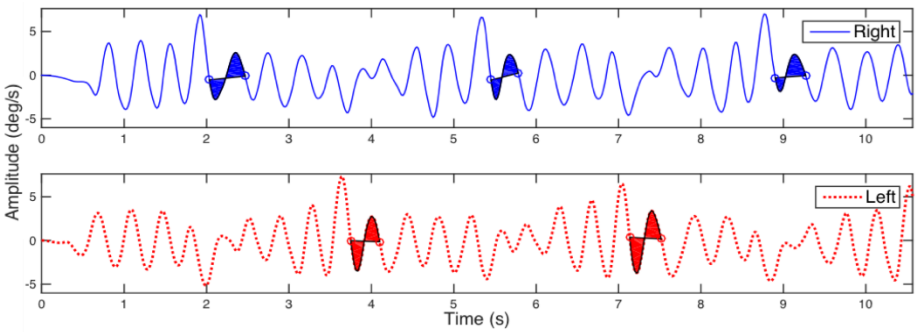


Figure 3. Description of TADS calculation when changing directions during FmSST.

b. The wave diagram for angular velocity, is the rate of change of angular displacement; thus, the TADS is based on a concept of the area under the wave (color filled area) during transition, resulting in relative displacement during this time period. The area under the wave during transition is illustrated with the blue and red waves represent the right and left shank, the blue graph represents the values of the right shank motion (top of Figure 3) and the red graph represents the values of the left shank motion (bottom of Figure 3).

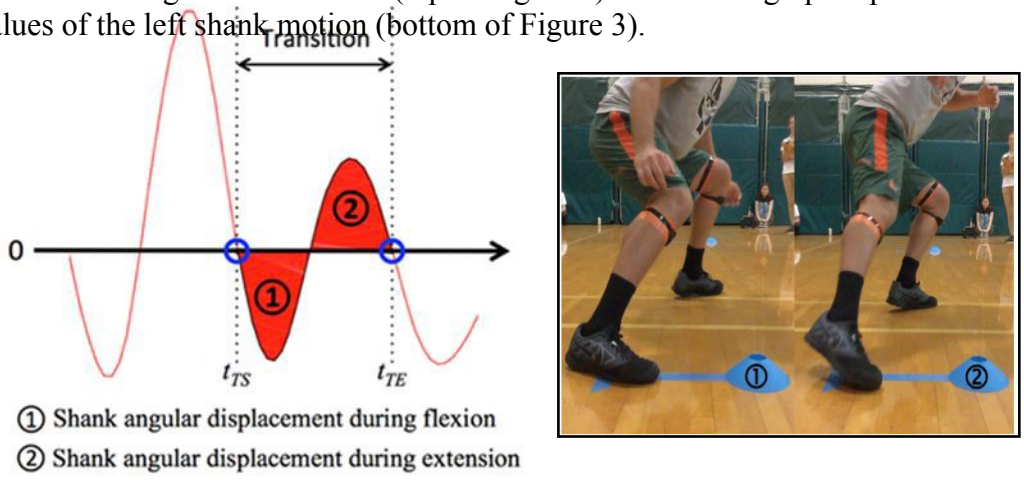


Figure 4. Shank angular displacement with knee flexion and extension during FmSST.

c. Knee flexion and extension are represented by negative displacement (1) and positive displacement (2), respectively (**Figure 4**). **Figure 4** illustrates the shank eccentrically flexing during the first phase of the transition (1) and then rapidly extending during the second phase (2) of the transion. These two phases (1) and (2) correspond with the displacement waves of Figure 4, which is derived by integrating angular velocity as a function of time, using the transition start point (tTS) and end point (tTE) as upper and lower bounds (Figure 4). Like ROLS SI, TADS SI is the percent difference calculated for TADS values between lower limb.

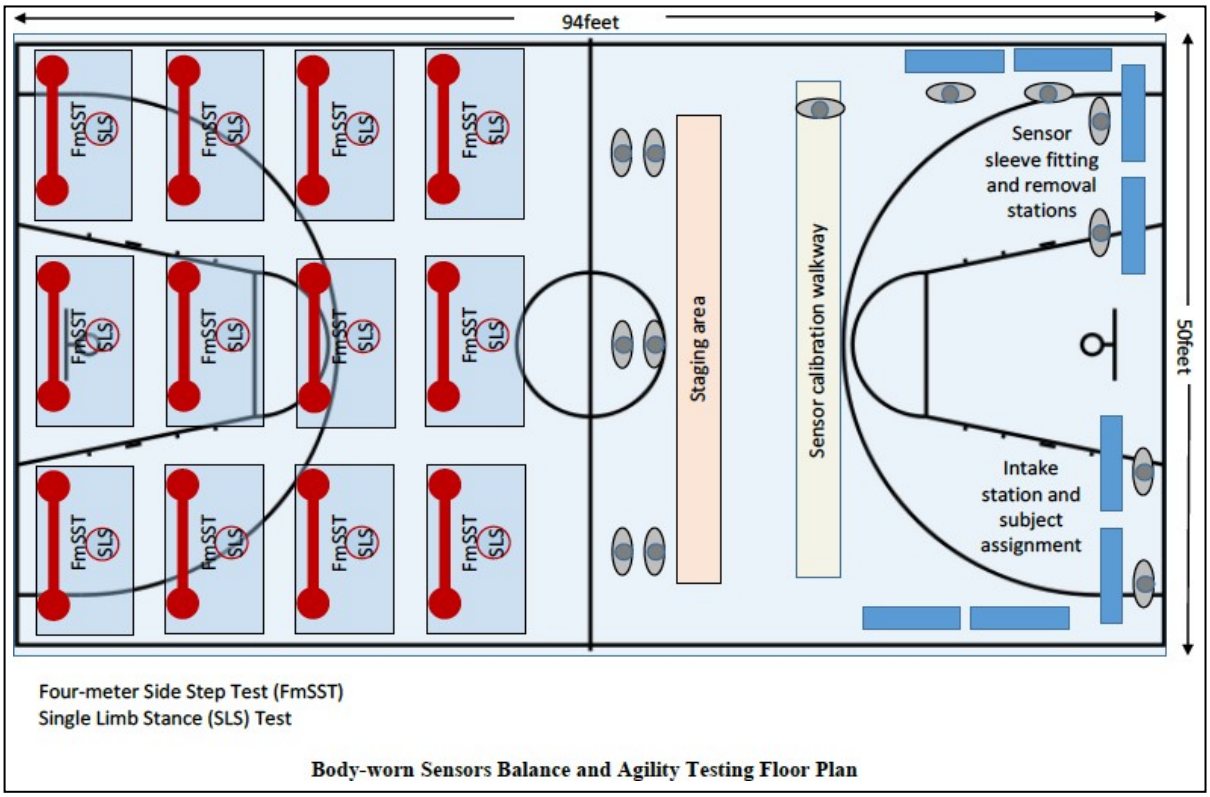
d. As stated above, the TADS metric is calculated when the subject performs the FmSST. The subject starts standing on the outside left tape mark. On “Go”, the subject sidesteps right until the right foot touches or crosses the right outside tape mark. The subject then sidesteps left until the left foot has touched or crossed the left outside tape mark. This is repeated a total of three times. The total time to complete the test is recorded. The subject will score a “0” and asked to repeat the test if: 1) they fail to touch or cross the outside tape marks; 2) fail to keep their trunk and feet pointing forward; and 3) cross their legs. They will be given a 60

second rest period after each trial. They will perform a minimum of two trials and a maximum of three trials.

5) At the completion of the TADS and FmSST, both shoes are removed, and the knee sleeves removed and shoes are re-donned.
6) The subject is thanked and dismissed.

As described above, the SLS and FmSST testing procedure is completed in about 4 minutes. From informed consent to removal of the wearable sensor sleeve the total time will take less than 15 minutes per Service Member.

The proposed diagram below outlines the data collection layout at one of the indoor gymnasiums at Fort Bragg, NC. The layout describes the testing day procedures (Figure 5). Multiple stations will be set up at the testing site to help facilitate task flow. After completion of informed consent process, the subjects will go to the intake and subject assignment area (bottom right corner), where they will complete demographic information, brief musculoskeletal injury history, and if necessary, the body part injury survey (see Appendix A). The subject's height and weight will also be recorded. All SMs will move to the next station (sensor sleeve fitting and removal station, top left corner) to don the wearable sensor system. They will be assigned a unique tester who will calibrate thesensor system and administer and record their ROLS and TADS at one of the SLS and FmSST stations.



They will then walk to the sensor calibration walkway where they will complete calibration process.

Figure 5. Diagram of the space and stations required for data collection.

They will then be assigned to SLS and FmSST station where they will perform both tests as described above. The sensor system is doffed after completion of the FmSST at the sensor sleeve

fitting and removing station. IMU sensor data will be recorded on an iPad using a custom mobile app.

With 12 stations and a team of 20 testers, a total of 120-150 subjects can be enrolled and tested per hour. An area with the dimensions of 100'x50'or the size of a basketball court would be requested for all testing procedures.

Physical therapists will be recruited as research assistants to track all injuries sustained during 82nd ABN DIV training. When a lower limb injury occurs, the following information will be documented:

1) Date and physical location of injury
2) Stage of training
3) Type of activity being performed when the injury occurred (i.e. contact vs. non-contact injury, jumping, running, maneuvers)
4) Body part(s) (hip, knee, ankle) injured
5) Injured structure (bone, ligament, cartilage, etc.)
6) Type of injury (fracture, dislocation, tear, etc.)
7) When possible physician orthopedic exam and imaging reports will also be documented
8) General classification of treatment (i.e. surgery, immobilization, PT, observation, none.)
9) The student will be asked to complete the appropriate Ankle, Knee or Hip Outcome Scale and Symptom Scale.
10) Post-injury activity and/or school status.

In addition, the Service Member may be given a physical activity restriction which is also known as a physical profile. A physical profile is defined as any condition associated with an illness, injury, or surgery which requires the Service Member to be restricted from returning to full functional duty. The restriction will be tracked as well until the physical profile is lifted and the Service Member returns to full functional duty.

The on-site research team would be blinded to all test results and be asked to obtain the aforementioned data. At the conclusion of data collection statistical analysis would determine: 1) IRI values, 2) the relationship between the Service Members who sustained injuries and the IRI, 3) determine if the ROLS and TADS metrics are capable of detecting other potential adverse events. Service Members will not be informed of any test results and all communications between the research team with Service Members will be directed through the assigned command.

The IRI will be developed specifically for military training and compared to the existing IRI used for collegiate athletes. Figure 6. Is an example of the Injury Risk Index.

SI%	Code	Injury Risk
80-100		Low Risk
60-79		Mod. Risk
< 59		High Risk

Figure 6. Example of the Injury Risk

6) Data and Specimen Banking

Data and specimen banking will not take place at the University of Miami for this study.

7) Data Management

To ensure that all of the information collected from the sensors, mobile application and iPad are private and secure, we partnered with the University of Miami Center for Computational Sciences. They helped us to facilitate that all information remains secure and is in compliance with DOD requirements for protecting personal information. All of the sensor and study related data and procedures are transmitted through our mobile application and stored on a central PostgreSQL database on a University of Miami supercomputer. In-flight transmission and database storage are encrypted and stored on an existing and active NIST SP 800-171 compliant data storage facility with standardized data security protocols that are in compliance with the Health Insurance Portability and Accountability Act (HIPAA). The database is housed in the NAP of the Americas' facility, which is located in downtown Miami at 50 Northeast 9th St. Miami, FL 33132. The database will be under a triple lock condition (Armed Guard, Locked Room, and Secured Cage) with 24/7 Electronic and Human surveillance.

Several layers of security are employed to protect program data from inadvertent modification or access by non-project personnel. Security measures are implemented on the operating system layer, at the file level, and even for specified data points (e.g. treatment assignment for intervention studies). Login procedures for data entry and access are restricted to the principal investigators and key staff of the project through database software protection. All data transfers are conducted using Secure File Transfer Protocols (SFTP). Electronically, the system is completely protected by multiple firewalls and IPS/IDS (Intrusion/Protection/Detection) and sits directly on the UM optical network for optimal performance and security. Additionally, the database is backed up onto separate distinct physical media allowing individual tracking of HIPAA information when required or requested by eligible representatives of Department of Defense.

Multifactorial authorization is used to login into the mobile application and database.
Study participant identifiers including name, date of birth, telephone number, email, military rank, height, weight, and past musculoskeletal history will be collected through the mobile application and transmitted securely to the database. Additional data collected on the mobile application includes injury surveys and performance measures such as SLS, FmSST, ROLS and TADS. Lastly, after completion of baseline measurement, assigned research physical therapist will use the secure mobile application to enter data related to musculoskeletal injuries sustained by the participant during the respective specialty training school. Each study participant will be assigned a unique study identification number which will be used for communicating study participant events between study PI and site PI via encrypted email.

Photos and Videos may be taken of the study participants for study purposes when disseminating study results in scientific conferences and government meetings. Patient identifiers will be recorded and stored in a separate database and access will be given to security managers and specific research personnel. Hard copies of the informed consent (if necessary) will be stored in the study master log and kept in a locked file cabinet separate within the PI’s office at the University of Miami. The PI’s office at the University of Miami is within the Department of Physical Therapy in the Plummer building. The address is 5915 Ponce De Leon Blvd, 5th floor,

room 50P. Patient unique study identification number will be shared between the University of Miami and DOD study site. Secure web-based program on the University of Miami Supercomputer will generate weekly tracking logs and shared between the study sites. Only unique participant study identification numbers will be on tracking logs. De-identified data will be available for analysis by study investigators.

The Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR) which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University (USU) is serving as a data coordinating center. Staff from the MIRROR/USU will not have access to the Master List or any other participant PHI/PII.

The coded electronic research data will be securely transmitted from the local study team to the MIRROR/USU via the DOD SAFE application (or other comparable safe data sharing system implemented by the local site and or the US Army/DHA). SAFE uses a TLS (Transport Layer Security) protocol when files are uploaded and downloaded.

There will be a data sharing agreement in place between the performance sites and the Uniformed Services University (USU).

8) Risks to subjects

Subjects may find that survey questions are personal and request information that they do not want to disclose (injury history). The risks associated with this study are the same as those normally incurred by these tactical athletes during participation in unit drills and activities. Subjects may become fatigued while performing the testing. We will take multiple steps to reduce the risks of fatigue. As stated above, they will be given standard rest periods between each trial. We will encourage subjects to rest whenever they feel tired. Subjects will be constantly monitored by investigators to detect signs of fatigue.

9) Potential Benefits to Subjects

Noncombat and nonfatal injuries during military operations and training affect short- and long-term health problems and reduce military readiness. Hence, prevention efforts should focus on not only external causes of injury that are fatal, but also those noncombat and nonfatal injuries associated with particularly high medical readiness and healthcare costs. The expected outcome of the proposed work is to provide a measure of soft tissue impairment at the knee and to quantify the relative risk of injury or re-injury. The study findings will lay the foundation for the development of more effective musculoskeletal screening, injury prevention and rehabilitation programs that will impact unit readiness and RTD rates in military training programs and active duty Service members across all branches of the armed services. If adopted as a training camp standard, this mobile application could become a critical metric for the proactive care of service members by providing real-time data about the risk of injury (especially women who are at greater risk for ACL injuries) with relatively little cost or assessment time. Knowing who is at risk for MSI to the lower limb would enable decision makers the option to protect a SM from risky maneuvers until rehabilitative care could be implemented or reassign Service members to more appropriate duty. Furthermore, the reduction of injuries in military situations could reduce

the psychological impact experienced by fellow Service members who must care for an injured solider.

10) Vulnerable Populations

No vulnerable individuals (e.g., pregnant women, prisoners, children, or cognitively impaired adults) will be recruited to participate in this study.

11) Setting

Data collection sessions will be held in Fort Bragg within an indoor gymnasium similar to what was described above in the testing procedures. An area with the dimensions of 100'x50'or the size of a basketball court would be requested for all testing procedures.

Study development will be performed at the University of Miami will take place at FORE Center. The FORE Center (1550 Brescia Ave Suite 140 Coral Gables, FL 33146) is jointly operated by the Departments of Physical Therapy and Music Engineering and is supported by industrial, foundational, as well as governmental funding. The FORE Center has been a leader in translational research, building on the expertise of the diverse group of engineers and clinicians. The FORE center offers opportunities for Dr. Gailey and the research team to pursue research collaborations across engineering, science and clinical disciplines. The laboratory is comprised of approximately 1,670 square feet that and includes open space for performance-based task testing and conference table for completion of online survey. It contains a 45-foot elevated instrumented walkway and 24 ft. long wooden inclined ramp, and collapsible stair system.

12) Resources Available

See attached

13) Prior approval

UM has not received prior approval. UM will request to act as the IRB of record on behalf of the Department of Research at Womack Army Medical Center, 2817 Reilly Road, Fort Bragg, NC 28310.

14) Recruitment Methods

For this study, the UM research team will work with 82nd ABN DIV to coordinate the recruitment of Service Members. The UM study team will enroll all subjects, obtain informed consent, and maintain all data (identifiable contact information and survey and performance data).

15) Local Number of Subjects

We will not be enrolling subjects at the University of Miami.

16) Confidentiality

Subjects will be assigned a personal identifiable number which will be used to track their study progress. Study PII will be stored separate from study PHI in the database. Only the security manager and select research staff will have access to PII.

17) Provisions to Protect the Privacy Interests of Subjects

All of the sensor and study related data and procedures are transmitted through our mobile application and stored on a central PostgreSQL database on a University of Miami supercomputer. In-flight transmission and database storage are encrypted and stored on an existing and active NIST SP 800-171 compliant data storage facility with standardized data security protocols that are in compliance with the Health Insurance Portability and Accountability Act (HIPAA).

Several layers of security are employed to protect program data from inadvertent modification or access by non-project personnel. Security measures are implemented on the operating system layer, at the file level, and even for specified data points (e.g. treatment assignment for intervention studies). Login procedures for data entry and access are restricted to the principal investigators and key staff of the project through database software protection. All data transfers are conducted using Secure File Transfer Protocols (SFTP). Electronically, the system is completely protected by multiple firewalls and IPS/IDS (Intrusion/Protection/Detection) and sits directly on the UM optical network for optimal performance and security. Additionally, the database is backed up onto separate distinct physical media allowing individual tracking of HIPAA information when required or requested by eligible representatives of Department of Defense.

18) Consent Process

The study participants will be given an informed consent to complete. This will be performed by the UM research staff.

19) The Process to Document Consent in Writing

UM research staff will be performing this task.

20) References

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Appendix A. iPad page by page of data collection

Current assignment

☐ Special Warfare Center and School

☐ 82nd Airborne Division

Subject

last name

first name

middle initial

Birth date

☐ New Subject

☐ Testing

☐ Injury Report

Balance and Agility Testing Pre-testing information

Rank		**Testing date**
☐ Private	☐ Sargent	Date Wheel
☐ Specialist	☐ Lieutenant	
☐ Corporal	☐ Captain	
	☐ Major	

Gender	**Weight**	**Height**
☐ Male	weight wheel	height heel
☐ Female		

Do you have pain or a limitation TODAY?

☐ No ☐ Yes If yes which joint: ☐Hip ☐Knee ☐Ankle ☐Foot ☐ Right ☐ Left

Have you ever had an injury to either lower limb?

☐ No ☐ Yes

If you responded "Yes" to having a past injury(ies) please answer the following.

Lower limb injury 1

Limb side: ☐ Right ☐ Left

Joint: ☐Hip ☐Knee ☐Ankle ☐Foot

Date: (date wheel)

Treatment: ☐surgery ☐physical therapy ☐other ☐none

Injured structure: ☐bone ☐muscle/tendon ☐ligament ☐cartilage ☐other

Type of injury: ☐ fracture ☐dislocation ☐tear ☐partial tear ☐sprain ☐contusion ☐avulsion

Does this injury still bother or limit you? ☐yes ☐no

Lower limb injury 2

Limb side: ☐ Right ☐ Left

Joint: ☐Hip ☐Knee ☐Ankle ☐Foot

Date: (date wheel)

Treatment: ☐surgery ☐physical therapy ☐other ☐none

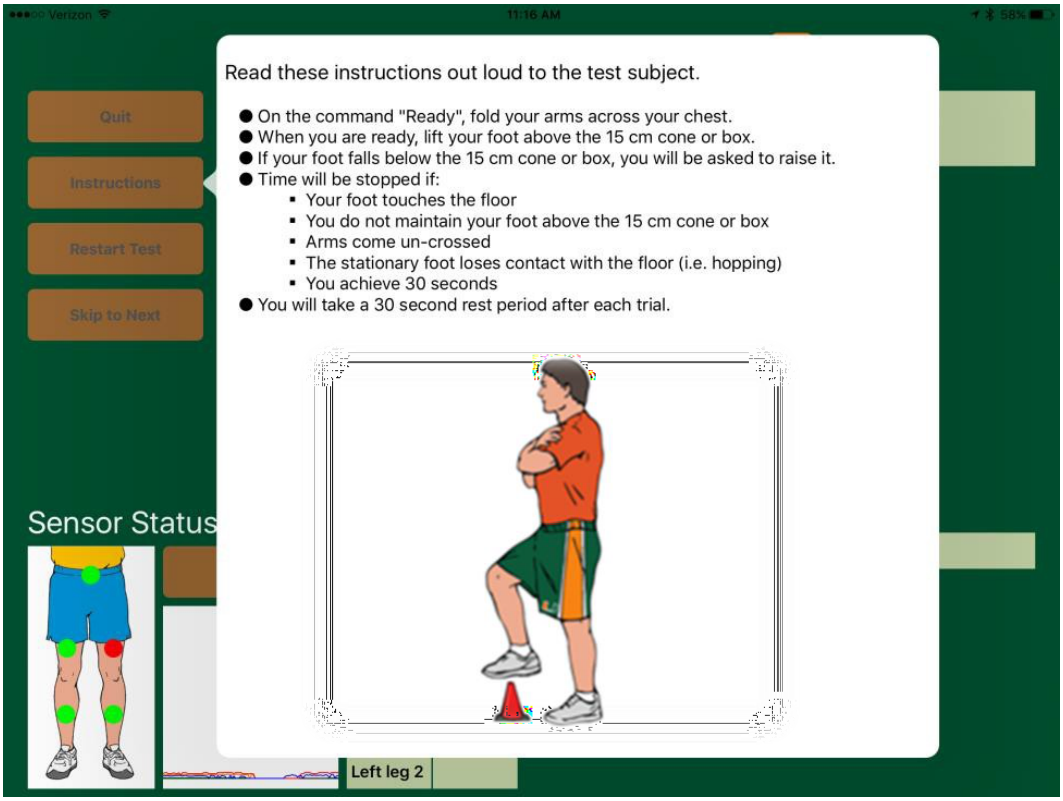
Injured structure: ☐bone ☐muscle/tendon ☐ligament ☐cartilage ☐other

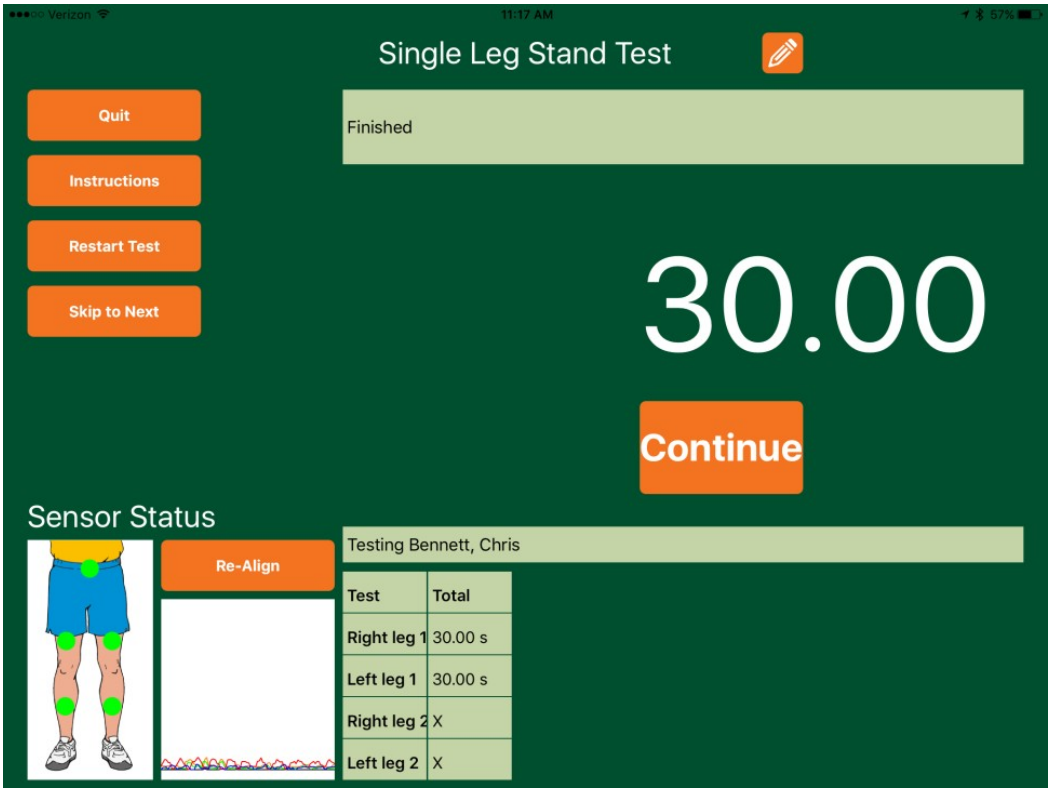
Type of injury: ☐ fracture ☐dislocation ☐tear ☐partial tear ☐sprain ☐contusion ☐avulsion

Does this injury still bother or limit you? ☐yes ☐no

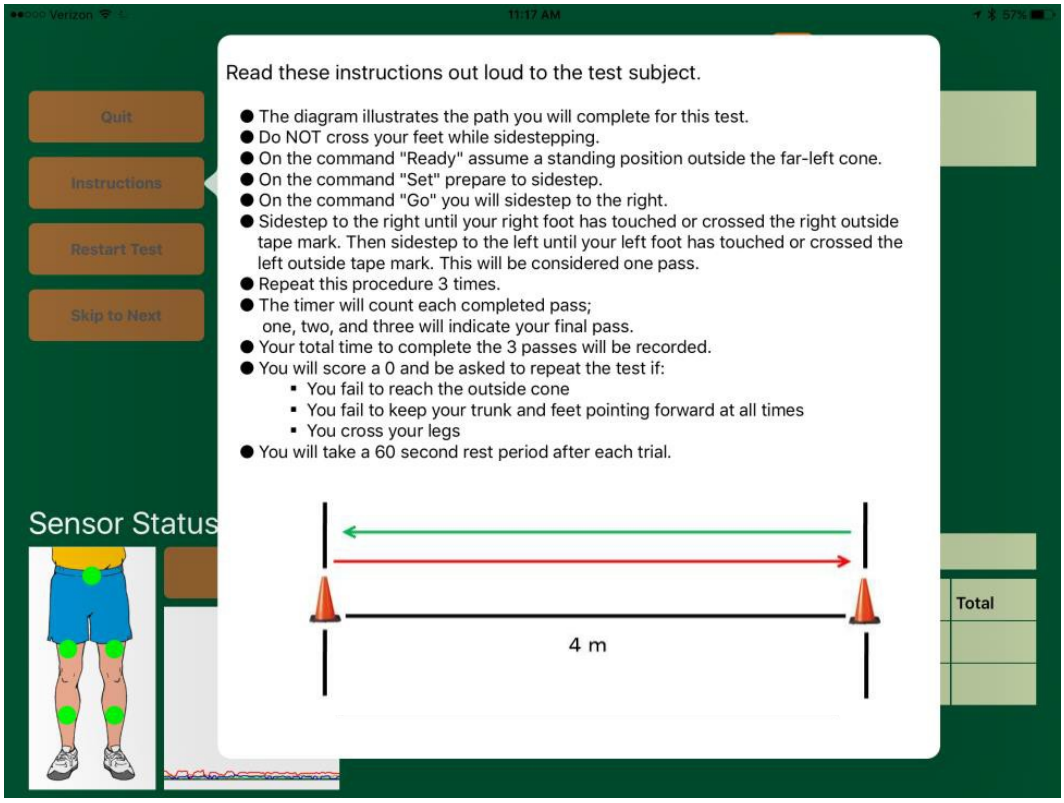
If you answered "Yes" to pain or a limitation Today or a past injury, please complete the following? (The ankle, knee or hip injury for will populate the screen)

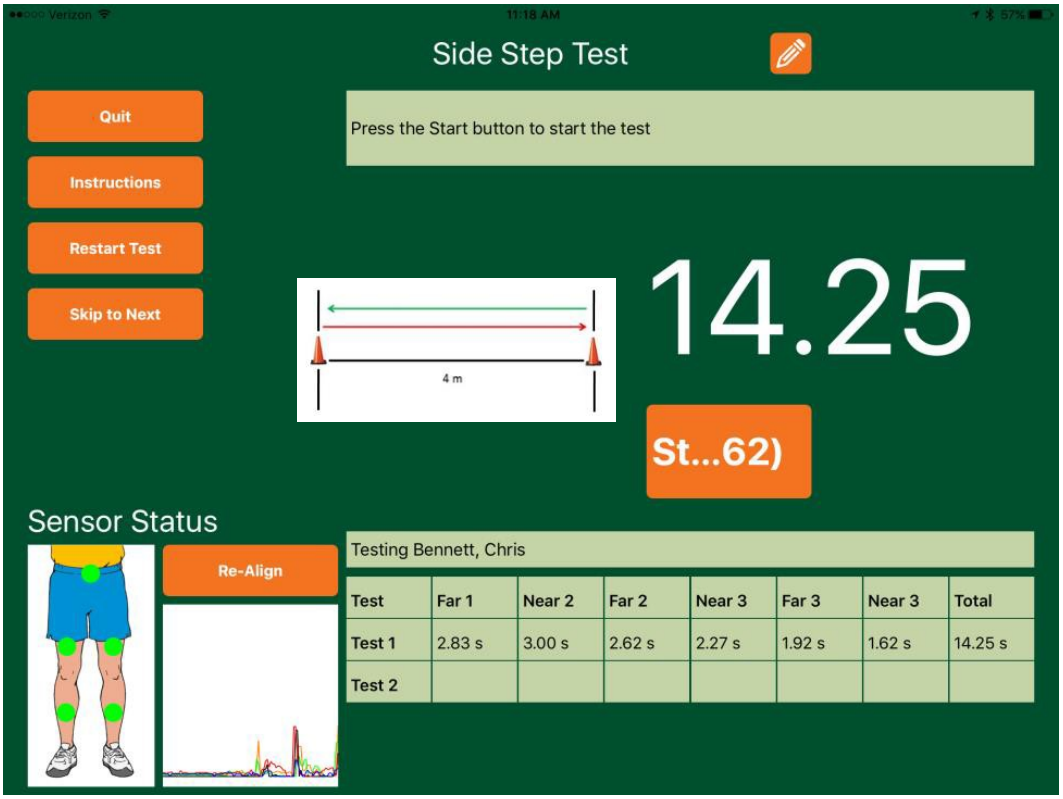
ROLS Testing Instructions and Results pages on the app





TADS Testing Instructions and Results pages on the app





Injury Report

Date: Date Wheel **Date of injury:** Date Wheel

Location: ☐ Ft. Bragg

☐ Other please describe

Curriculum: ☐ Other please describe

Injury activity: ☐hiking ☐running ☐agility maneuvers ☐jumping ☐tower jump
☐obstacle course ☐climbing ☐mobility training ☐parachuting
☐other tactical activities (describe):
☐non-training activities (describe):
☐unknown (describe):

Was there a previous injury to this joint? ☐yes ☐no

If yes, how long ago? ☐during current training ☐< 1 year ☐1-2 years ☐> 2 years

Did physical contact with another student or instructor occur at the time of injury?
☐ yes ☐ no ☐ unknown

Body part injured: (more than one maybe selected) **Limb side:** ☐ Right ☐ Left

☐ hip ☐ thigh ☐ knee ☐ leg ☐ ankle ☐ foot
☐ other please describe

Injured structure: (more than one maybe selected)
☐ bone ☐ muscle/tendon ☐ ligament ☐ cartilage ☐ other

Type of injury: (more than one maybe selected)
☐ fracture ☐ dislocation ☐ tear ☐ partial tear ☐ sprain ☐ contusion ☐ avulsion

Diagnosis (please describe):

Treatment: (more than one maybe selected)
☐ surgery ☐ immobilization ☐ physical therapy ☐ observation ☐ none

☐ other (please describe)

Activity status: ☐ no restriction ☐ limited activity ☐ no activity permitted

Relieved from school: ☐no ☐RAP week ☐academic ☐medical ☐Admin ☐LOM ☐SOR ☐other

If medical, please describe:

(LOM lack of motivation, SOR serious observation report)

If you answered "Yes" to pain or a limitation Today or a past injury, please complete the following? (The ankle, knee or hip injury for will populate the screen)

Foot & Ankle Disability Index (FADI) Score – Sports Module (modified)

Please answer every question with one response that most closely describes your condition within the past week.
If the activity in question is limited by something other than your foot or ankle, mark N/A

		No difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do	N/A
1	Squatting	0	1	2	3	4	
2	Running one mile	0	1	2	3	4	
3	Jumping	0	1	2	3	4	
4	Landing	0	1	2	3	4	
5	Twisting motions swinging objects like a golf club or baseball bat	0	1	2	3	4	
6	Starting and stopping quickly	0	1	2	3	4	
7	Cutting, lateral movements	0	1	2	3	4	
8	Low-impact activities like fast walking	0	1	2	3	4	
9	Ability to perform activity with your normal technique	0	1	2	3	4	
10	Ability to participate in your desired sport as long as you would like	0	1	2	3	4	
						Total Score	

During the past week, or since your injury did you experience:

		None	Mild	Moderate	Severe	Very severe
1	Pain during activity	0	1	2	3	4
2	Pain after activity	0	1	2	3	4
3	Pain at night	0	1	2	3	4
4	Swelling	0	1	2	3	4
5	Stiffness morning	0	1	2	3	4
6	Stiffness all day	0	1	2	3	4
7	Decreased joint motion	0	1	2	3	4
8	Feeling of instability or giving way	0	1	2	3	4
9	Catching or locking at the joint	0	1	2	3	4
10	Bruising or discoloration	0	1	2	3	4
					Total Score	

Knee Outcome Score (KOS) – Sports

Because of your knee how much difficulty do you have with:

If the activity in question is limited by something other than your knee, mark N/A

		No difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do	N/A
1	Squatting	0	1	2	3	4	
2	Running one mile	0	1	2	3	4	
3	Jumping	0	1	2	3	4	
4	Landing	0	1	2	3	4	
5	Twisting motions swinging objects like a golf club or baseball bat	0	1	2	3	4	
6	Starting and stopping quickly	0	1	2	3	4	
7	Cutting, lateral movements	0	1	2	3	4	
8	Low-impact activities like fast walking	0	1	2	3	4	
9	Ability to perform activity with your normal technique	0	1	2	3	4	
10	Ability to participate in your desired sport as long as you would like	0	1	2	3	4	
						Total Score	

During the past week, or since your injury did you experience:

		None	Mild	Moderate	Severe	Very severe
1	Pain during activity	0	1	2	3	4
2	Pain after activity	0	1	2	3	4
3	Pain at night	0	1	2	3	4
4	Swelling	0	1	2	3	4
5	Stiffness morning	0	1	2	3	4
6	Stiffness all day	0	1	2	3	4
7	Decreased joint motion	0	1	2	3	4
8	Feeling of instability or giving way	0	1	2	3	4
9	Catching or locking at the joint	0	1	2	3	4
10	Bruising or discoloration	0	1	2	3	4
					Total Score	

Hip Outcome Score (HOS) – Sports

Because of your hip how much difficulty do you have with:

If the activity in question is limited by something other than your hip, mark N/A

		No difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do	N/A
1	Squatting	0	1	2	3	4	
2	Running one mile	0	1	2	3	4	
3	Jumping	0	1	2	3	4	
4	Landing	0	1	2	3	4	
5	Twisting motions swinging objects like a golf club or baseball bat	0	1	2	3	4	
6	Starting and stopping quickly	0	1	2	3	4	
7	Cutting, lateral movements	0	1	2	3	4	
8	Low-impact activities like fast walking	0	1	2	3	4	
9	Ability to perform activity with your normal technique	0	1	2	3	4	
10	Ability to participate in your desired sport as long as you would like	0	1	2	3	4	
						Total Score	

During the past week, or since your injury did you experience:

		None	Mild	Moderate	Severe	Very severe
1	Pain during activity	0	1	2	3	4
2	Pain after activity	0	1	2	3	4
3	Pain at night	0	1	2	3	4
4	Swelling	0	1	2	3	4
5	Stiffness morning	0	1	2	3	4
6	Stiffness all day	0	1	2	3	4
7	Decreased joint motion	0	1	2	3	4
8	Feeling of instability or giving way	0	1	2	3	4
9	Catching or locking at the joint	0	1	2	3	4
10	Bruising or discoloration	0	1	2	3	4
					Total Score	