PROTOCOL TITLE:

Accuracy of Lachman Test Performance in a Pre-Participation Physical Examination Environment

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REVISION HISTORY:

Revision #	Version Date	Summary of Changes	Consent Change?
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1.0 Study Summary

Study Title	Accuracy of Lachman Test Performance in a Pre-Participation Physical Examination Environment
Study Design	Prospective study
Primary Objective	To determine the accuracy of Lachman Test performance by healthcare providers performing pre-participation physical examinations (PPEs) at a large mass PPE event.
Secondary Objective(s)	Comparing Lachman Test accuracy among orthopaedic sports medicine surgeons, primary care sports medicine physicians, physical therapists, and certified athletic trainers.
Research Intervention(s)/ Investigational Agent(s)	Video tape of clinicians performing the Lachman Test scored according to the accepted Lachman Test performance metrics by trained evaluator.
IND/IDE #	N/A
Study Population	Clinicians (orthopaedic sports medicine surgeons, primary care sports medicine physicians, physical therapists, and certified athletic trainers) providing athlete care at mass PPE event (Baltimore City Pre-Participation Physical Event/ PROJECT RAMPART).
Sample Size	Approximately 50 participants or more
Study Duration for individual participants	For participants (referred to as Clinician-Subjects moving forward): Approximately 5 minute to complete a brief 7 question survey and an additional 10 minutes to perform the Lachman Test on a standardized knee 5 times while being videotaped.
Study Specific Abbreviations/ Definitions	N/A

2.0 Objectives*

2.1 Purpose

The purpose of this study is to prospectively determine the accuracy of Lachman Test performance by healthcare providers performing pre-participation physical examinations (PPEs) at a large mass PPE event. Secondarily, the study will compare Lachman Test performance accuracy among orthopaedic sports medicine surgeons, primary care sports medicine physicians, physical therapists, and certified athletic trainers.

2.2 Hypotheses

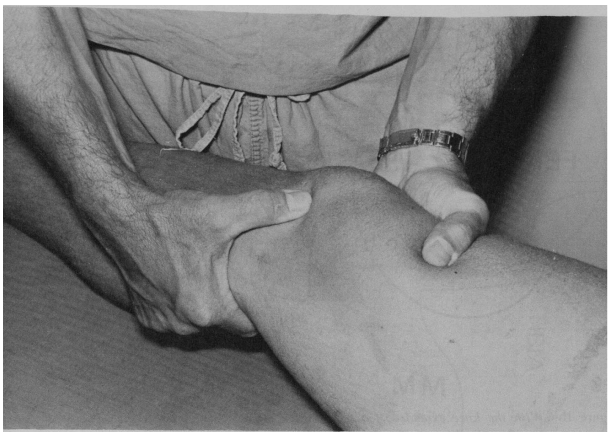
We hypothesize that clinicians at a mass PPE event will perform the Lachman Test accurately with no technique errors from the original description.

3.0 Background*

Physical examination is a critical component of injury evaluation. Despite advancements in medical technology, the importance and relevance of physical evaluation endures as a cost-effective diagnostic tool that strengthens patient-provider relationships[1-2].

In order for unambiguous clinical and scientific communication, the physical examination must be standardized. [3] A myriad of such tests has been described for specific clinical injuries. One of the most common injuries to an athletic population is the anterior cruciate ligament (ACL) tear of the knee. As the primary stabilizer to knee rotation and anterior translation of the tibia on the femur, the ACL is critical to athletes and individuals needing to perform cutting and pivoting activities. Many physical exam tests exist for various injuries to ligaments, meniscus cartilage and tendons about the knee. For the ACL alone, there are many examination maneuvers developed that are meant to clearly establish injury to this ligament. These tests include the anterior drawer test, the Lachman test, the pivot shift and several others. The Lachman is one of the most commonly performed.

The sensitivity of the Lachman test has been reported to range from 80% to 99%, with a specificity of 95% . [3]



The Lachman Test was originally described by Torg et al [4] and included both an explicit written description with a photograph of the positions of the examiner and the subject to be examined. The explicit elements of the examination are as follows:

1. The examination is performed with the patient lying supine on the table with the involved extremity on the side of the examiner.
2. The patient's knee is held between full extension and 15 degrees of flexion.
3. The femur is stabilized with one hand.
4. Firm pressure is applied to the posterior aspect of the proximal tibia in an attempt to translate it anteriorly.
5. The other (distal) hand grips the proximal tibia in such a manner that the thumb lies on the anteromedial joint margin.
6. When an anteriorly directed lifting force is applied by the palm and four fingers, anterior translation of the tibia in relationship to the femur can be palpated by the thumb.

A positive test indicating disruption of the anterior of cruciate ligament is one in which there is proprioceptive and/or visual anterior translation of the tibia in relation to the femur with a characteristic "mushy" or "soft" end point. This is in contrast to a definite "hard" end point elicited when the anterior cruciate ligament is intact.[4]

Despite the evidence supporting the continued use of physical examination and published standardized methods for the administration of these exams, physical examination errors still occur and can result in significant consequences. A study by Verghese et al. in which 208 providers self-reported physical examination errors, the consequences included missed or delayed diagnosis in 76% of cases, incorrect diagnosis in 27%, unnecessary treatment in 18%, no or delayed treatment in 42%, unnecessary diagnostic cost in 25%, unnecessary exposure to radiation or contrast in 17%, and complications caused by treatments in 4% .[5] It is important that we evaluate the accuracy of physical examination performance among providers to limit errors and patient harm.

References

1. Elder AT, McManus IC, Patrick A, Nair K, Vaughan L, Dacre J. The value of the physical examination in clinical practice: an international survey. *Clin Med (Lond)*. 2017;17(6):490-498.
2. Zaman J, Verghese A, Elder A. The Value of Physical Examination: A New Conceptual Framework. Southern Medical Journal. 2016 Dec;109(12):754-757. DOI: 10.14423/smj.0000000000000573. PMID: 27911967.
3. Malanga GA, Andrus S, Nadler SF, McLean J. Physical Examination of the Knee: A Review of the Original Test Description and Scientific Validity of Common Orthopedic Tests. *Arch Phys Med Rehabil*. 2003;84(4):592-603.
4. Torg JS, Conrad W, Kalen V. Clinical Diagnosis of Anterior Cruciate Ligament Instability in the Athlete. *Am J Sports Med.* 1976;4(2):84-93.

5. Verghese A, Charlton B, Kassirer JP, Ramsey M, Ioannidis JP. Inadequacies of Physical Examination as a Cause of Medical Errors and Adverse Events: A Collection of Vignettes. *Am J Med*. 2015;128(12):1322-4.e3.

4.0 Study Endpoints*

4.1 Primary endpoints

a) Clinician-Subject performs 5 iterations of the Lachman examination appropriately captured on video.

b) Clinician-Subject completes the background questionnaire.

4.2 Secondary endpoints

a) Videos scored by trained evaluators.

5.0 Study Intervention/Investigational Agent

Not applicable.

6.0 Procedures Involved*

This is a prospective study determining the accuracy of the Lachman test technique performed by clinicians. We will solicit the participation of physicians (in particular, orthopaedic surgeons and primary care sports medicine physicians), physical therapists, and certified athletic trainers who are providing clinical support at the Baltimore City Pre-Participation Physical Event/ PROJECT RAMPART on 3 August 2024.

Potential Clinician-Subjects will be invited to participate by the research team at the Baltimore Preparticipation Physical Examination event through verbal discussion. Clinician-subjects will be informed about the study using an informed consent script; however a written informed consent will not be obtained. We are requesting a waiver of documentation of written informed consent from the Clinician-Subjects, details of which are provided in Section 23.0.--

Clinician-Subjects will be brought to an examination table by a study team member. There will be another individual of the study team dressed in shorts on the table supine as if being examined. For standardization purposes, the simulated patient's **RIGHT** knee will be examined in all cases. The study staff member will read the instructions to the participant as follows:

> "Before you is a simulated patient. Your task is to perform a Lachman Test on their right knee. You will perform this examination 5 separate times. You will be recorded by a video camera. Between each of the 5 examinations, place the knee back onto the table, remove your hands from the simulated patient, and begin the process of the Lachman Test from the beginning for each of the next 4 test sequences. When finished with the fifth test sequence, place the knee back to the exam table, remove your hands, and step back from the table."

Once the instructions are provided, the clinician-subject will perform the Lachman test on the simulated patient. The test will be performed five times. The performance of all five tests will be videotaped. The video recording will only capture the clinician-subject's hands and arms. The clinician-subject's face will never be captured on video.

For the purpose of this study, the following data elements will be recorded and stored on a MedStar network drive/MedStar OneDrive: name, age, gender, dominant hand, profession (ATC, PT, Primary Care Physician, Orthopaedic Surgeon),Years Since Completing Training, and preferred examination to assess for ACL tear. Additionally, two fellowship-trained orthopaedic sports medicine surgeons ("evaluators") will review and score the Lachman Test videos for each of the participants. To score the Lachman Test video, guidelines will be provided to the evaluators according to the original description (Torg et al, 1976). Evaluators will interpret all Lachman Test videos without being provided the details of the clinician-subjects' demographics or questionnaire.

Scoring of the Lachman Test Videos will use the following criteria. Each criterion will be scored a value of 1 if present/performed and a value of 0 if not present/performed in the video. Each of the 5 Lachman Tests will be scored individually and a final score of 0-6 will be calculated. The average of the 5 tests will be calculated and this will be reported as the Lachman Test Accuracy Score (LTAS). LTAS will be rounded to one decimal place. The scored criteria are as follows:

Lachman Test Accuracy Score (LTAS) Criteria	1	2	3	4	5
1. Clinician-Subject stands on the **RIGHT** side of patient.					
2. Patient knee held between full extension and 15 degrees of flexion					
3. Femur stabilized with **LEFT** hand					
4. Tibia stabilized with **RIGHT** hand					
5. Anterior lifting force applied by palm and four fingers of **RIGHT** hand					
6. The **RIGHT** thumb lies on the anteromedial joint margin.					
Score					

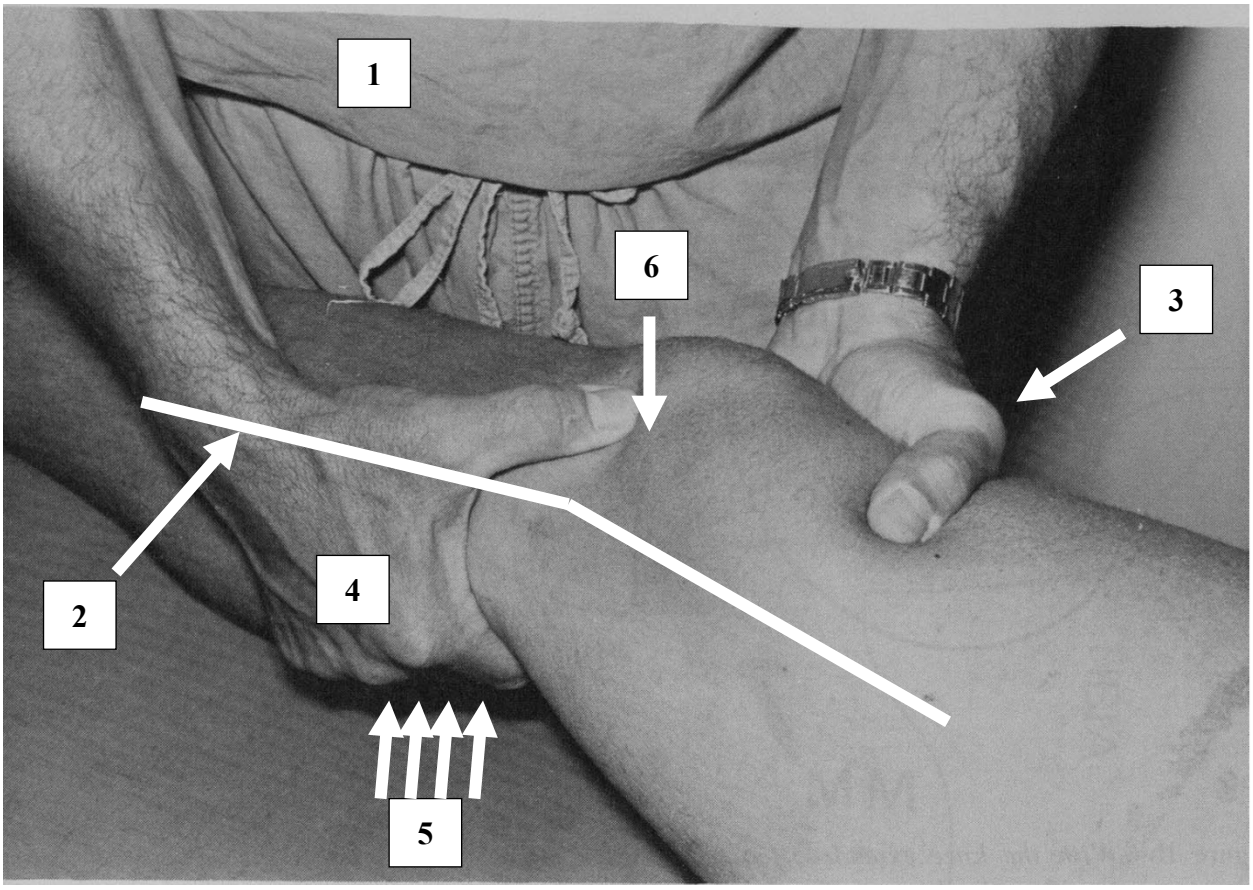


Figure 1. Elements of the LTAS

Examiner stands to the RIGHT of the supine patient to examine the RIGHT knee (Box 1). Examiner flexes the knee up to 15 degrees from extension (BOX 2). The examiner stabilizes the femur with their LEFT hand (BOX 3). Examiner stabilizes right tibia with their right hand (BOX4). With four fingers and the palm of the RIGHT hand, an anterior lifting force is applied (BOX 5). The RIGHT thumb is placed on the anteromedial joint line to determine the displacement between the femur and tibia (BOX 6). (Figure from Torg et al, 1976)

Figure 1 shows the original photograph illustrating the correct performance of the Lachman Test. An overlay of figures and numbered boxes representing the specific score criteria is present on the figure. This figure will be provided to the scoring evaluators to reference while completing the LTAS scoring sheet. Specific errors that would render the individual element score a zero are as follows:

Criterion 1	• Clinician-Subject stands on incorrect side of patient or faces the wrong direction
Criterion 2	• Clinician-Subject holds knee in hyperextension or more than 15 degrees of flexion.
Criterion 3	• Clinician-Subject uses RIGHT hand to stabilize femur • Clinician-Subject fails to adequately stabilize femur

Criterion 4	• Clinician-Subject uses LEFT hand to stabilize tibia • Clinician-Subject fails to adequately stabilize the tibia
Criterion 5	• Clinician-Subject does not use palm AND four fingers to apply force • Clinician-Subject does not apply an appropriate anterior directed force
Criterion 6	• Clinician-Subject does not place RIGHT thumb on the anteromedial joint line

7.0 Data and Specimen Banking*

Videos of the five Lachman tests and the data from the questionnaires will be stored on MedStar network drive/MedStar OneDrive or MedConnect. Only the IRB approved research staff will have access to the research data. The only identifiable information that will be collected for this study are the participants' names.

8.0 Sharing of Results with Subjects*

Individual or collective data will not be shared with the study subjects. Study data will be shared with the scientific community-at-large in the form of presentations and/or publication at the end of the study. All research data will be released in aggregate. All subject identifiers including any dates will be removed prior to release of research data.

9.0 Study Timelines*

- Study will start after the IRB approval has been obtained (by August 3, 2024).
- The duration of an individual clinician-subject's participation in the study will be from the time of enrollment until they complete 5 Lachman tests performed on video and the questionnaire. There are no research procedures that the clinician-subjects will need to complete after the mass PPE day.
- We anticipate requiring an additional year for completion of the study, including data reconciliation, data analysis, and presentation(s)/publication (Approximately August 2025).

10.0 Inclusion and Exclusion Criteria*

Inclusion criteria for participants

- Physicians, physical therapists, and athletic trainers present at the Baltimore City Pre-Participation Physical Event/ PROJECT RAMPART.
- Greater than 18 years of age

Exclusion criteria for participants

- Unable to use both upper extremities as described by the Lachman Test (Torg et al, 1976)
- Vulnerable populations:
  - Adults unable to consent
  - Non-English speaking
  - Prisoners
  - Minors

11.0 Vulnerable Populations*

We will include pregnant women as clinician-subjects who are able to perform their regular work tasks as ATCs, PTs, or physicians as the ability to perform a Lachman test is part of activities performed regularly by these professions.

As listed above in our exclusion criteria, the following vulnerable populations will be excluded:

- Adults unable to consent
- Non-English speaking
- Pregnant women
- Prisoners
- Minors

12.0 Local Number of Subjects

We plan to enroll approximately 50 participants as a convenience sample; however, we will attempt to enroll as many as possible into the study.

13.0 Recruitment Methods

All individuals invited to participate in the Baltimore City Pre-Participation Physical Event/ PROJECT RAMPART will be sent an orientation email which will include a section advertising the study and soliciting their participation. Those who meet all inclusion criteria and no exclusion criteria will be invited to participate in the study during the orientation period just prior to the beginning of the Baltimore City Pre-Participation Physical Event/PROJECT RAMPART.

Subjects will not be paid for their participation.

14.0 Withdrawal of Subjects*

At the discretion of the principal investigator or the sub-investigators, a subject might be withdrawn from the study without their consent if:

- A subject has the physical inability to perform the Lachman test
- Is unwilling to complete the study questionnaire

15.0 Risks to Subjects*

Risks of the study are:

- Possible breach of confidentiality which will be minimized by utilizing password protected files on the MedStar network for study data and having a closed loop communication with the research staff.

16.0 Potential Benefits to Subjects*

The study might not benefit the study participants directly, but we anticipate gaining knowledge that will benefit the orthopaedic community and might affect future patient care.

17.0 Data Management* and Confidentiality

Statistical analysis

For statistical analysis, the team plans to perform an ANOVA of interrater reliability of each profession within themselves and then compared against interrater reliability between professions. Descriptive statistics will be calculated for demographic and Likert scale questions on the Knee Physical Exam Test Questionnaire.

A convenience sample will be utilized; however we anticipate enrolling ~50 participants.

Data Management

Research data will be collected and stored on secure servers operated behind the MedStar firewall. Research data will be collected and stored on secure MedStar network drive/MedStar OneDrive and MedStar EMR (MedConnect) applications requiring user ID and password authentication for login. Research data will be accessible to the IRB-approved research staff only. Any paper records will be stored in locked cabinets/offices. The research staff will be responsible for collecting the study-related information.

Data will be reviewed periodically to ensure that it is being collected and handled per the protocol. Data will also be reviewed periodically for integrity and completion.

Research records will be maintained the longer of Federal regulation, state statute, sponsored contract terms, or institutional policy. There are no plans to retain the research data indefinitely. Records will be destroyed as per MedStar Health Corporate Policy "Record Retention and Destruction Policy".

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

The principal investigator and research staff will monitor the data periodically to ensure integrity and completion. In order to ensure individual confidentiality, all paper records will be stored in locked cabinets/offices and all electronic records will be stored in password protected MedStar EMR and on MedStar network drive/MedStar OneDrive. Any adverse events, serious adverse events, and/or protocol deviations will be reported to the IRB as per the “Adverse Event Evaluation and Reporting” policy.

19.0 Provisions to Protect the Privacy Interests of Subjects

Research data will be stored on a MedStar network drive/MedStar OneDrive or in secure password protected MedStar EMR (MedConnect). The research staff will collect the study data.

All study team members working with the study data have completed appropriate CITI training. Research staff is obligated to comply with MedStar’s policy on breach of data security notification and mitigation and will utilize only MedStar assigned user ID and password protocols to access study data.

Any paper records will be stored in locked cabinets/offices. Electronic medical records will be maintained on password protected MedStar EMR (MedConnect). Other research data will be maintained on an encrypted MedStar network drive/MedStar OneDrive.

20.0 Compensation for Research-Related Injury

Subjects will not be compensated for their participation. There is no available compensation in the event of study related injury. Any routine procedures/testing done would be paid for by the subject or their insurance company.

21.0 Economic Burden to Subjects

No economic burden on the research subjects.

22.0 Consent Process

All individuals invited to participate in the Baltimore City Pre-Participation Physical Event/ PROJECT RAMPART will be sent an orientation email which will include a section advertising the study and soliciting their participation. Those who meet all inclusion criteria and no exclusion criteria will be invited to participate in the study during the orientation period just prior to the beginning of the Baltimore City Pre-Participation Physical Event/PROJECT RAMPART. Clinician-Subjects will be informed of the study using an Informed Consent Script; however, a written informed consent will not be obtained. We are requesting waiver of documentation of consent as the research presents no more than minimal risk of harm to the Clinician-Subjects. Additionally, due to the nature of the event, it would not be feasible to consent participants within the time and environmental constraints of the event. We intend to recruit, enroll, and perform all data collection during the one-day event on August 3rd. Potential participants will be approached during the event and given a brief overview of the study. If they are interested in participating, an informed consent script will be presented verbally. Verbal agreement will be obtained before any study procedures are performed.

23.0 Process to Document Consent in Writing

We request a waiver of written documentation of consent. We ask that the subject's participation in the knee examination and participation in completing the knee exam questionnaire would suffice.

24.0 Resources Available

We anticipate 50 subjects will be enrolled in the convenience sample. Potential subjects will be identified and recruited from the pool of physicians, physical therapists, and athletic trainers in the Baltimore-Washington Region who work with MedStar Sports Medicine and the Baltimore City Pre-Participation Physical Event/ PROJECT RAMPART. We plan to devote approximately one year to completing the study. All study members will help recruit subjects. The research team will be fully briefed on the study protocols and procedures. IRB approved research staff will be provided with the IRB approved study materials for review. Weekly and monthly sports medicine research meetings will be used as a platform to discuss the study and challenges. We do not anticipate any significant medical or psychological risks to the individuals as a result of participation.

25.0 Multi-Site Research*

Not applicable.

Supplement: Participant Survey

Knee Physical Exam Test Participant Questionnaire

1. What is your dominant hand?
    a. Right
    b. Left
    c. Ambidextrous

2. What is your medical specialty?
    a. Physical Therapist
    b. Certified Athletic Trainer
    c. Orthopaedic surgeon
    d. Primary Care Sports Medicine Physician
    e. Physical Medicine and Rehab Sports Medicine Physician
    f. Emergency Medicine Sports Medicine Physician
    g. Other_____

3. How many years of experience do you have in your specialty?
    a. 0-2
    b. 3-5
    c. 6-10
    d. 11-15
    e. 16-20
    f. >21

4. What is your preferred examination to assess for ACL Tear?
    a. Anterior Drawer
    b. Lachman Test
    c. Prone Lachman
    d. Pivot Shift
    e. Other: _____

5. How familiar are you with the Lachman test?
    a. Not at all familiar
    b. Slightly familiar
    c. Somewhat familiar
    d. Moderately familiar
    e. Extremely familiar

6. How often do you perform the Lachman test when you have a patient with knee issues?
    a. Never
    b. Rarely
    c. Sometimes
    d. Often
    e. Always
7. How confident are you that you performed the Lachman test correctly today?
    a. Not at all confident

b. Slightly confident
c. Somewhat confident
d. Moderately confident
e. Extremely confident