VARUS-VALGUS LAXITY

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1. Background and rationale

Knee laxity may be defined as any abnormal displacement or rotation of the tibia with respect to the femur. In clinical settings, laxity is typically assessed in one of two planes: the sagittal (anteroposterior laxity, or front-to-back motion at the knee); and the frontal (varus-valgus or medial-lateral laxity, or side-to-side motion at the knee). The focus of this protocol is frontal plane (varus-valgus or medial-lateral) laxity, which may play a role in both the initial development and progression of knee osteoarthritis (OA). (Anteroposterior laxity is not being measured in this study.)

Devices to measure knee laxity in the frontal plane are not commercially available. The device described in this protocol is similar to that being used in an ongoing study at Northwestern University on participants who all have knee OA. This device and protocol address the major sources of variation that occur during the physical exam assessment of frontal plane laxity: inadequate immobilization of the distal thigh and ankle; incomplete muscle relaxation; variation of the knee flexion angle; variation of load applied during the test; and crude means of measuring varus-valgus rotation with load application.

This protocol is intended for individuals who have been trained in the performance of this measurement of varus-valgus laxity. The protocol by itself, i.e. without training, is not sufficient to perform this measurement. This protocol is for use in the Multicenter Osteoarthritis Study (MOST) only.

From this point on in this protocol, “laxity” will mean frontal plane (varus-valgus or medial-lateral) laxity.

2. Equipment and supplies

- Laxity measurement device
- Hand-held dynamometer with force transducer

The device will be provided to the clinical centers by Dr. Sharma.
Nothing needs to be done to maintain the device.
There are no additional supplies required for this laxity measurement.

2.1 Description of equipment

The device consists of a bench on which the participant sits and an attached arc-shaped, low-friction track, which serves as a foot rest and serves to standardize aspects of the participant's positioning. The ankle rests on a sled that travels within the track. A hand-held dynamometer is fitted via a force transducer into either side of the sled and is used to apply a fixed load. Motion at the thigh and at the ankle is limited by adjustable, cushioned restraints

The device is about 2 feet in height and 3 to 4 feet in other dimensions. It can be carried by two people but is best stored near the examination site. It should not be left out in an examination area but be kept in a locked room, i.e., storage room or closet near the exam site, or the examination room itself. Other material should not be stored or stacked on top of the device.

3. Safety issues and exclusions

This exam is safe for all participants and is not painful, even if the participant has arthritis or other conditions. There are no exclusions. The device is designed to accommodate a variety of limb lengths and thigh sizes. All MOST participants will undergo assessment of laxity at their baseline evaluation. Laxity should be measured in both limbs of all participants, including limbs that have undergone total knee replacement.

4. Participant and exam room preparation, examiner and assistant

4.1 Device position

For the laxity measurement, the device must be placed against a wall. The size of the bench allows the participant to lean their back against the wall during the test. The wall should be free of any hanging material (i.e., that would prevent the participant from leaning against the wall, or hanging material above the participant's head that might distract the participant. The participant's concern that something might fall on them may lead to involuntary muscle contraction).

4.2 Examination room

The room should be warm, quiet, and away from external noises and distractions. The room requirements are the same as those for the proprioception test; these two assessments could occur in the same room.

4.3 Dress

Acceptable attire includes shorts and socks. Pants, stockings or pantyhose, long-underwear, and shoes should not be worn during testing.

4.4 Examiner and Assistant

One examiner (who performs the measurement) and one assistant (who confirms starting position of the limb and records the results) are needed for this procedure.

5. Examination procedures

5.1 Dynamometer

Check that the dynamometer is turned on and connected to the force transducer.

5.2 Introduce the test

Script: "This is a test to see how much side to side motion you have at each of your knees. You will be sitting on this bench and I will be moving your knee gently side to side *(demonstrate the movement with your hands as you say this*). Only a small amount of movement occurs in this direction at the knee. This bench allows us to measure this small movement carefully. This test is not painful"

5.3 Participant positioning

The participant sits on the left side of the bench (i.e. the participant's left when the participant has their back to the wall) and is asked to turn to face forward and bring the right leg into the thigh and ankle cushioned restraints. To position the test limb in the device, first, the test limb between the groin and the top of the patella should be in a straight line and perpendicular to the wall.

Second, the superior (upper) pole of the patella (i.e. the most superior part of the patella palpable when you push your finger over the superior edge of the patellar surface) should be level with the inferior (bottom) edge of the thigh restraint. When the patella is in the correct position, the visible superior pole of the patella (which falls below the palpable superior pole) looks as if its about a fingers breadth below the inferior edge of the thigh restraint.

Third, the tibial tubercle should be pointing directly superior (i.e., straight up) and not be pointing in an angled direction (see Figure 1 below).

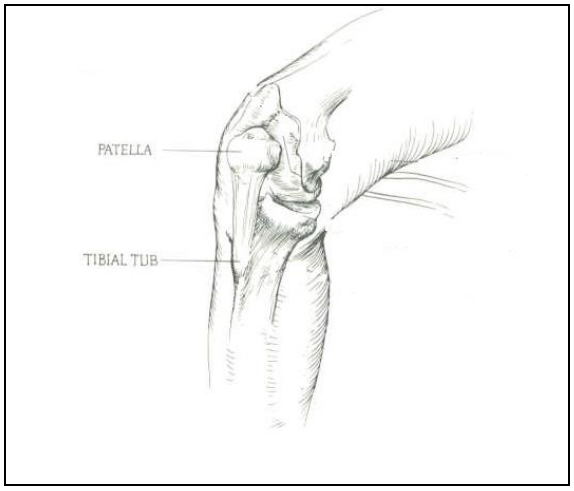

Figure 1

Once the positions of the patella and the tibial tubercle are confirmed, tighten the cushioned restraints so that the thigh is immobilized, but the restraints are not so tight as to cause discomfort. The thigh restraint should be tight enough to keep the tibial tubercle pointing straight up. (If the thigh restraint is too loose, the knee will rotate during the test and the tibial tubercle will no longer be pointing straight up.)

The ankle should be placed centrally in the sled. Then tighten the cushioned restraints at the ankle, so that the ankle is immobilized but the restraints are not so tight as to cause discomfort. The left limb (i.e., the limb that is not being studied) should be flexed at the knee and hip and rest on the floor. Hands may rest on the bench at the participant's sides. The participant should be instructed to lean back against the wall. Four measurements of medial and four of lateral laxity will be completed on each knee.

Script: "Are you comfortable?"

5.4 Examiner positioning

The steps the examiner should take to get into standard position:

- Kneel on the right side of the participant (i.e., the participant's right).
- Fit the transducer into the sled. The rectangular part of the transducer should be parallel to the tray on which the ankle sled sits.
- Oscillate (massage using rapid small movements of fingertips) the participant's calf with your left hand and verbally encourage participant to relax muscle.

Script: "Your only job for this test is to keep your muscles relaxed and loose."

- Cup the popliteal fossa (the undersurface of the knee) in your left hand.
- Curve your fingers under the side of the fossa away from you, and thumb on the side of the fossa close to you. Fingers on the opposite side of the fossa act as a pivot point for the motion that will occur. At least a moderate amount of tension will develop in the fingers in this position when the test is done correctly. These fingers are preventing the whole limb from moving as a unit (i.e. preventing motion of the limb at the hip joint). The fingers on the opposite side of the fossa help to ensure that the motion being assessed is at the knee only, andthat the laxity being measured is how much the compartment on the examiners side can be "opened". . The hand under the popliteal fossa also serves to assess sudden participant movement or involuntary contraction. If the girth of the fossa is too large for examiners thumb and fingers to assume these positions, the priority is for the fingers on the opposite side of the fossa to be in position.
- Brace your left elbow on the plexiglass tray on which the track sits.
- Place right hand on the grip of the force transducer.

5.5 Assistant positioning

The assistant should sit or kneel so that their line of vision is directly above the grid mark where the center of the sled falls. The assistant will need to move (a small amount) with the sled during the test to maintain this position.

5.6 Performance of the test

Right knee measurements
Lateral measurements

- The assistant should record the neutral position (i.e., the position of the sled, after the participant's limb is immobilized and with muscles relaxed).
- Immediately before the test is performed, after the examiner is in position, examiner should pause and be sure that their full attention is on the next maneuver
    - Examiner should apply forward motion with the right hand at a moderate constant speed, in a direction that is perpendicular to the ankle rest. Do not rotate the tibia during the test; check during the test that the tibial tubercle is pointing straight up.
    - Do not change hand position during the test.
- Stop moving the right hand as soon as the dynamometer beeps (indicating pre-set load reached). At this point, the assistant, who has maintained a position directly above the sled, records the position of the sled. This is the measurement of right knee lateral laxity (i.e., the movement that leads to opening of the lateral joint line).
- As soon as the assistant records the position of the sled, assistant states “ok” and the examiner allows the sled to return to the neutral position.
- After a pause, the examiner asks the assistant “ready?” and then performs the second trial.
- Perform a total of four trials while the assistant records the measurements. Prior to each trial, examiner should confirm that muscle is relaxed (visually and by palpating to gauge muscle tone).

Medial measurements

Script: "I’m now going to check the movement for this knee in the other direction."

- The participant’s position remains the same (and should not be altered in any way).
- The examiner should then walk around to the participant’s left side and repeat all steps above for the right knee ***medial*** laxity measurement, i.e., the same measurement on the opposite side of the right knee. For this measurement, the examiner's right hand is placed under the popliteal fossa and the left hand on the force transducer.

Left knee measurements

Script: "I'm now going to check the movement in the same two directions in the left knee. Remember, your job is to keep your knee as relaxed as you can."

- The participant's right limb is removed and the left limb placed in the thigh and ankle restraints according to the steps described above. The examiner remains on the participant's left side and completes the measurement of left lateral laxity (i.e., the movement that results in opening of the lateral compartment of the left knee). Lastly the examiner moves to the participant's right side and performs the measurement of left medial laxity.

Full assessment of both knees including positioning time will take about 5 minutes in the initial period of data collection, and about 3 minutes after the examiner has gained some experience.

6. Alert values/follow-up/reporting to participants

There are no alert values. This is a research measurement and what is normal or abnormal is not known.

7. Quality assurance

7.1 Training and certification

This measurement should only be performed by staff directly trained by Dr. Sharma. Special qualifications or experience are not essential to perform this assessment. However, some experience with the physical exam of the knee may be helpful. The examiner who will be performing the musculoskeletal physical exam would be the ideal person to perform the laxity exam.

Dr. Sharma will visit each center 2 weeks (or less) before the initiation of the laxity measurement in MOST to further train the examiners. At that time, Dr. Sharma's laxity measurement on five volunteers (with healthy knees; clinic staff or investigators) per clinic site will be recorded. These measurements will serve as a standard for re-certification of the examiners by the QC officer that will occur every 4 months. To be certified, the examiners need to get within 1 degree of Dr. Sharma's result on all five volunteers. Six weeks after the data collection has begun at each site, Dr. Sharma will visit each site and evaluate examiners and QC officer. Dr. Sharma will re-visit a site if there is a personnel change in examiners. If there are no personnel changes, a follow-up

visit to each site will occur between 4 and 6 months after initiation of the laxity measurement in MOST.

Trainees will

- Read and study manual
- Attend MOST training session on techniques: a didactic presentation, a review of the protocol, and demonstration and practice using the device on volunteers
- Further practice on volunteers until the required accuracy of measurements is achieved.
- Discuss problems and questions with Leena Sharma

7.2 Certification and recertification requirements

- Complete training and certification requirements above
- Every 4 months: conduct exam on five "gold standard" volunteers while being observed by QC officer:
  - According to protocol, as demonstrated by completed QC checklist
  - Achieving accuracy of measurement within ± 1 degree of Dr. Sharma's laxity results (Note that the neutral, i.e. starting, point may change. The goal is to get the same total (medial + laxity). Results may differ for medial or for lateral, but the average of the totals should fall within 1 degree of the average of Dr. Sharma's totals.)
- Every 1 month, each examiner will be observed by the QC officer during a MOST participant laxity exam and the QC checklist completed

7.3 Quality assurance checklist

Preparation

- ☐ Device against a bare wall without hanging material
- ☐ Participant's knees bare of clothing

Right knee

Check just prior to test performance:

- ☐ Superior pole of the patella level with the inferior edge of the thigh restraint
- ☐ Tibial tubercle pointing directly superior
- ☐ Participant resting their back comfortably against the wall
- ☐ Left limb resting comfortably on the floor
- ☐ Calf muscles and the quad muscles relaxed
- ☐ The test limb between the groin and the top of the patella should be in a straight line and perpendicular to the wall

Test performance

- ☐ Examiner's hand that cups the popliteal fossa creating a firm pivot point with the fingers on the side of the knee opposite to the examiner
- ☐ Assistant's line of vision directly above the center of the sled
- ☐ Tibial tubercle position (pointing superior) maintained during each test
- ☐ Muscle relaxation confirmed prior to the performance of each trial
- ☐ Test limb between knee and groin should remain perpendicular to the wall and should not move. All side-to-side motion should occur below the knee and below the examiner's hand

Left knee

Check just prior to test performance:

- ☐ Superior pole of the patella level with the inferior edge of the thigh restraint
- ☐ Tibial tubercle pointing directly superior
- ☐ Participant resting their back comfortably against the wall
- ☐ Right limb resting comfortably on the floor
- ☐ Calf muscles and the quad muscle relaxed
- ☐ The test limb between the groin and the top of the patella should be in a straight line and perpendicular to the wall

Test performance

- ☐ Examiner's hand that cups the popliteal fossa creating a pivot point with the fingers, but not stabilizing the joint
- ☐ Assistant's line of vision directly above the center of the sled
- ☐ Tibial tubercle position (pointing superior) maintained during each test
- ☐ Muscle relaxation confirmed prior to the performance of each trial
- ☐ Test limb between knee and groin should remain perpendicular to the wall and should not move. All side-to-side motion should occur below the knee and below the examiner's hand

Data collection

- ☐ Reviews form for completeness
- ☐ Correctly completes form

8. Laxity data collection

Laxity

Draft

MOST ID #	Acrostic	Date Form Completed	Staff ID#
Office Use Only		Month / Day / Year	

Script: "This is a test to see how much side to side motion you have at each of your knees. You will be sitting on this bench and I will be moving your knee gently side to side ***(demonstrate the movement with your hands as you say this)***. Only a small amount of movement occurs in this direction at the knee. This bench allows us to measure it carefully."

Participant sits on their left side of the bench with their back leaning against the wall. Ask participant to bring their right leg into the thigh and ankle cushioned restraints. The superior pole of the patella should be level with the bottom edge of the thigh restraint. The tibial tubercle should be pointing straight up.

After the Participant is positioned ask: "Are you comfortable?"
If Participant responds "yes", then say, "Your only job for this test is to keep your muscles relaxed and loose."

① Right knee:

Starting position: °	***Script: "I'm now going to check the movement for this knee in the other direction."***
	Lateral / Medial
Trial 1 °	Trial 1 °
Trial 2 °	Trial 2 °
Trial 3 °	Trial 3 °
Trial 4 °	Trial 4 °

Script: "I'm now going to check the movement in the same two directions in the left knee. Remember, your job is to keep your knee as relaxed as you can."

② Left knee:

Starting position: °	***Script: "I'm now going to check the movement for this knee in the other direction."***
	Lateral / Medial
Trial 1 °	Trial 1 °
Trial 2 °	Trial 2 °
Trial 3 °	Trial 3 °
Trial 4 °	Trial 4 °

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