SHOE HARDNESS

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1. Background and rationale

Hardness may be defined as a material's resistance to indentation. To quantify hardness, a durometer measures the depth of an indentation in the material created by a given force on a standardized presser foot. This depth is dependent on the hardness of the material, but also on the shape of the presser foot and the duration of the test. The basic test requires applying a constant force through a standardized instrument, without shock. A handheld device records a value from 0 to 100 based on the depth of the indentation.

Our interest is in acquiring a measurement of shoe hardness based on the depth of the indenter just after all of the "slack" is felt to have been taken up in the shoe material and no further penetration of the material by the indenter is immediately possible. If the indenter penetrates 2.54 mm (0.100 inch) or more into the material, the durometer will indicate a score of 0. If the indenter does not penetrate at all, then the durometer will indicate a score of 100.

In this exam of shoe hardness, we are expecting typical measured values to be in the range of 40 (a cushioning midsole that is about as soft as a pencil eraser) to 80 (the heel of a rigid men's dress shoe with no midsole). However, if the participant uses either a cushioning or supportive shoe insert inside of their shoes, then this insert must be identified since its presence may explain the rare occurrences when a minimal score of 0 or a maximal score of 100 is recorded.

2. Equipment and supplies

• Handheld Shore A durometer

3. Shoe hardness administration

The assessment of shoe hardness will take place when the participant has already removed their shoes for the purposes of measuring standing height on the stadiometer. The examiner will avail of the opportunity to measure the hardness of the participant's customary walking shoes using the handheld Shore A durometer.

When scheduling participants for their clinic visit, they should be instructed:

<u>Script</u>: "Bring with you the walking shoes or sneakers that you would typically wear if you knew that you were going to be on your feet for a long while, such as when shopping or taking a walk."

The Shoe Hardness data collection form asks which leg the participant uses to kick a ball. The foot that the participant uses to kick a ball is the preferred/dominant side. This will be the side that shoe hardness will be measured on. If the participant uses both legs to kick a ball or does not know, shoe hardness should be measured for the right shoe.

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The participant may use a cushioning or supportive shoe insert inside their customary walking shoes. If so, the presence and type of insert should be determined prior to the assessment of shoe hardness.

The Shoe Hardness data collection form asks the examiner to identify and *characterize the shoe insert in the following manner for the shoe being measured*:

- Supportive = a contoured or molded foot orthosis, arch support, or heel wedge is present in the shoe (see Figure 1A).
- Cushioning = a flat or non-contoured gel or foam insole, or a non-wedged heel cup or viscoelastic heel pad is present in the shoe (see Figure 1B).
- Both = both supportive and cushioning inserts are present in the same shoe
- Other = unable to characterize the insert that is present in the shoe

<u>Script</u>: "Next I am going to use a piece of equipment that will measure the hardness of your shoe sole."

Look at the participant's shoe to determine if an insert is present. Once the insert (if present) is characterized, the shoe insert should remain in the shoe during the assessment of shoe hardness using the Shore A durometer if the participant usually wears the insert in their shoe. Take 3 durometer readings (see Figure 2 below) and record the 3 readings on the data collection form.



Figures 1 (top row) and B (bottom row). **Shoe inserts.** Contoured or molded foot orthoses, arch supports, and inclined heel wedges ("Supportive" inserts, Figure 1A, top) are distinguished from flat or non-contoured gel or foam insoles, viscoelastic heel pads, and heel cups ("Cushioning" inserts, Figure 1B, bottom).



Figure 2. Shoe hardness assessment using Shore A durometer. Hold the Shore A durometer durometer as shown (left). With the indenter at the lateral heel-shoe interface as shown on the right, press on the indenter until all slack has been taken up. Record the reading from the position of the red needle.

4. Quality assurance

4.1 Training and certification

Dr. Gross will provide onsite training to the staff at each clinic.

The examiner requires no special qualifications or experience to perform this assessment.

Training should include:

- Observing execution of study protocol by an experienced examiner
- Reading MOST operations manual with goal of understanding:
 - the proper use of equipment
 - o exclusions and safety considerations
 - detailed testing procedures
- Practicing on colleagues and "naïve" volunteers
- Attending training session

4.2 Certification requirements

- Completion of training requirements
- Recitation of exclusion criteria and stopping rules
- Performance of exam on two volunteers under the observation of clinic QC officer, according to protocol, as demonstrated by completed QC checklist

4.3 Quality assurance checklist

- Dominant side determined and recorded on data collection form
- □ Shoe insert assessment properly performed and results recorded on data collection form
- □ Shoe insert kept in shoe for the measurement if participant usually wears the insert in their shoe
- □ Shoe hardness test properly performed on shoe belonging to dominant side (or right shoe if unable to determine dominant side) and results for 3 readings recorded on data collection form
- \Box If durometer readings were not done, reason why recorded on data collection form

5. Data collection form

Please see the Overview of the 144-month Follow-up Visit Operations Manual for an overview of the data collection forms, information on whether each form is in REDCap or TELEForm, and where the forms can be accessed on the study website.