Quantitative Ultrasound of Bone

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1. Introduction/Overview of Ultrasound Measurements in MrOS

Bone mass explains 30-90% of the variance in bone strength determined in vitro. However, bone mass is not the only determinant of bone strength: the geometry and quality of bone play vital roles. Current methods of assessing bone health are inadequate. Parfitt postulated that bones are weakened by accumulation of fatigue damage as bone ages, including microscopic fractures. In support of this hypothesis, Parfitt observed that women with vertebral fractures had greater bone age than women without fractures who had similar degrees of osteopenia.

The strength of trabecular bone also depends on the number and integrity of connections between trabecular rods and plates. Loss of these connections (decreased "connectivity") accounts for about 40% of the decrease in trabecular bone mass with aging in women. For the same bone mass, the strength of trabecular bone will vary inversely with its connectivity.

Quantitative ultrasound (QUS) may be a useful measure of both the quality and quantity of bone. Two ultrasonic measurements in particular, sound velocity and broadband ultrasonic attenuation (BUA), may correlate with bone fragility. Ultrasonic transmission velocity, or speed of sound (SOS), is related to both the mass density and modulus of elasticity of a substance. The elastic modulus of a material depends upon a number of physical properties, and is believed to reflect fatigue damage and the size and spatial orientation of bone microstructure. BUA is thought to measure the attenuation of sound energy from scattering and absorption for a spectrum of frequencies (typically 0.2-0.6 MHz), but the exact correlates of BUA in bone remain unclear. Both SOS and BUA measurements correlate with bone strength in vitro, but in vivo the two measurements are not highly correlated with BMD at other sites (r=0.4-0.6), nor are they highly correlated to each other.

Although QUS is not a good surrogate measurement for bone density, it does have clinical utility because is appears to assess bone strength. In SOF we have demonstrated that low calcaneal QUS is associated with a variety of fractures, and more importantly, QUS is strongly associated with the risk of future hip fractures. The relationship between QUS and hip fractures is similar to that observed with hip BMD. Other large prospective studies have found similar relationships. There are few data on QUS in men or the relationship between QUS and weight loss, inactivity or major medical illness.

Besides it's potential for assessing bone strength, QUS has several practical advantages over densitometry: it is quicker, less expensive, portable, and entails no radiation exposure. Both ultrasonic velocity and BUA measurement are sufficiently reproducible, generally 0.5-1.0% and 2-4%, respectively, for clinical applications. If ultrasound predicts hip and other types of fractures as well as measurements of bone mass, it would be the best approach to screening individuals to assess their risk of fracture.

In MrOS we will be measuring QUS with the Hologic Sahara Clinical Bone Sonometer. Compared to other available devices, the advantages of the Sahara include reduced scan time, improved precision, dry coupling to the heel (no water bath), and importantly, an established and reliable service network.

Calcaneal Ultrasound

2. Equipment

QUS measurements will be carried out using a Hologic Sahara Clinical Bone Sonometer. A matrix of 3x3 locations is measured and the final results are obtained by averaging these 9 measurements which in turn are averages of signals obtained in the left-right and right-left ultrasound propagation directions.

The scanner allows for assessment of BUA as well as velocity parameters. BUA reflects the frequency dependence of ultrasound attenuation. SOS measurements are also obtained with the Sahara. Lastly, the Sahara combines both BUA and SOS measurements into a single parameter called the Quantitative Ultrasound Index (QUI).

Details regarding the initial set up, including room requirements, unpacking, set up, and system calibration are in the Sahara Advanced Clinical User's Guide, Chapter 2, "Initial Set Up".

For equipment or repair problems related to the Sahara system, please contact Hologic directly at 800-321-4659.

Equipment list
Sahara Clinical Bone Sonometer
PC with Sahara Advanced Clinical Software
Sahara Advanced Clinical User's Guide
Sahara ultrasound coupling gel. Do not use other brands of coupling gel.
Baby wipes and dry, lintless wipes (ie. Kim Wipes)
Sahara QC phantom
Positioning aid
Power module
Optional: foot papers are available from Hologic when you order coupling gel

3. Subject preparation

MrOS participants should be informed that a painless, radiation-free measure of heel bone integrity will be done during their first (baseline) and followup visit. The test will require removing the shoe and sock or stocking, placing the heel into the ultrasound device (no water) and then sitting quietly for approximately 5-10 minutes.

Each participant should be told not to use lotions, creams, powders or ointments on the lower extremities the day of his visit. The foot must be completely clean and dry before the measurement is made!

4. Computer Screen BIOGRAPHY Entry

See the Sahara Advanced Clinical User's Guide, Chapter 5, "Patient Measurement", for information on selecting a new or existing Biography screen. Be sure to use the existing Biography at Followup visit. Entering the participant data correctly on the Biography screen is of utmost importance for retrieval of the electronic data at the Quality Assurance (QA) Center.

Enter the participant's information on the Biography screen according to these instructions:

Last Name, First Name, and Middle fields: Enter the participant's full name with middle initial in capital letters. This information will be held in strict confidence at the QA Center.

Patient ID field: Enter the MrOS clinic code and participant number. **This field MUST be entered correctly.** The following are the clinic letter codes and participant numbers that will be used for the MrOS study:

Birmingham	BI0001 – BI1500
Minneapolis	MN1501 – MN3000
Palo Alto	PA3001 – PA4500
Pittsburgh	PI4501 – PI6500
Portland	PO6501 – PO8000
San Diego	SD8001 – SD9500

Study ID field: Enter MROS

Sex field: Choose correct gender

DOB field: Enter the date of birth that is in the official study records (check with your study coordinator)

Ethnic field: Choose the most appropriate ethnicity from the choices provided.

The rest of the Biography fields can be filled in or left blank at the operator's discretion.

5. Measurement Procedure

The protocol for obtaining Sahara measurements is detailed in the Sahara Advanced Clinical User's Guide, Chapter 5, "Patient Measurement". Be sure that the device is kept at room temperature for at least 1-2 hours prior to use.

Deciding which side to scan

In general, scan the right heel unless the participant has recently injured that extremity, has a deformity on that side, has permanent right sided weakness (usually from a stoke), or has an open wound in the right heel/ankle area.

Follow these guidelines while referring to the Ultrasound Data Collection Form (Teleform). Ask each participant the following:

1) "Have you ever broken either heel or have hardware in either heel?"

2) "Do you have an open sore on either ankle or heel?"

3) "Have you broken any bones in either leg? (Do not include isolated toe fractures.)

4) "Do you have any permanent weakness in your legs, ankles, or feet from an old injury or stroke?"

Document side selection by using the flow chart on the Ultrasound Data Collection Form.

Number of scans to obtain

Each participant will have at least two measurements of the same heel. The foot should be removed from the scanner and repositioned between measurements. If the second BUA measurement differs by more than ten units, obtain a third measurement. It is not necessary to obtain more than three measurements on a participant, even if they all differ by more than 10 BUA measurements.

Asterisk results

Asterisk results for Estimated BMD indicate a non-linear BUA result which may be inaccurate. They may occur with unusual sized or shaped heels.

If asterisks are obtained on the first scan, pay special attention to positioning of the heel and use plenty of gel when repeating the measurement. If asterisks are obtained on one or both scans, obtain a third measurement.

Interpretation of results

Some participants will want to know the results of their test and its interpretation. Indicate that low ultrasound measurements may be an indication of poor bone quality, but the exact meaning is unclear. It is important to emphasize that ultrasound measures of bone are less well established than bone densitometry and that we hope to further study the relationship between ultrasound measures and skeletal health in this study. Refrain from discussing the exact meaning of specific ultrasound values. Keep in mind that the vast majority of physicians, even those who are knowledgeable about osteoporosis, will not be able to interpret the meaning of a specific BUA, SOS, or QUI level.

Special problems

a. Bunions. The centering device for the Sahara assumes normal foot anatomy. Some participants will have significant bunions (outward deviation of the toes) which complicates positioning of the foot. If a bunion is present, do not use the centering line (normally placed between the participants second and third toes), simply position the foot as best as possible so that the long axis of the proximal foot is perpendicular to an imaginary line drawn between the two heel transducers.

b. Swollen/big feet. A small proportion of participants will have very large heels because of foot edema or other problems. If the heel does not fit easily into the Sahara, do not attempt to scan the participant.

6. Data Collection

All data collected for the Sahara measurements are stored electronically and on paper. Data are transmitted to the coordinating center electronically and by FAX.

a. Electronic Participant Identification

See Section 3 for instructions on filling in the computer Biography screen.

b. MrOS Ultrasound Data Collection Form (teleform)

Record the Staff ID and participant's MrOS acrostic and ID number on the top of the form. Fill in the flow chart to determine which heel to scan. For each Sahara measurement, record the BUA, SOS, and QUI values as they appear on the Sahara screen. Record any asterisk results for Estimated BMD.

If Sahara measurements are not obtained for any reason, note the reason in the space provided.

c. Sahara Printed Results

Although the Sahara computer is capable of printing results, this will not be done in MrOS because the data will be captured electronically and on the Ultrasound Data Collection Form. If the computer is not working, keep the data tape from the scanner with the participant's records.

d. Data Backup and Transfer

Weekly data backup

Each week copy the Sahara database onto a floppy diskette(s). Follow the instructions detailed in the Sahara Advanced Clinical User's Guide, Chapter 7, "Archiving the Database". These procedures copy the entire database, so each week after you successfully archive the database you may erase or reuse the diskette(s) from previous weeks. For added security, keep the archive from the two previous weeks and use a new diskette(s) periodically.

Monthly data transfer

On or about the 15th of every month, send your Sahara data diskette(s) using the instructions listed below. Include a copy of the Monthly Ultrasound (Sahara) Data Transfer Form. Send the Sahara Repair/Service/Upgrade Log and a copy of the Hologic service report, if repairs were done during the month. If we have not received your monthly data transfer by the end of the month we will send you a reminder.

Instructions for Sahara data diskette(s) transfer to UCSF:

1) Open the Sahara program.

2) Go to the <Utilities> menu and click on <set program defaults>. Check that the archive/ restore directory is set for <a:\arch_dat>. This can be changed following the directions in the Sahara Advanced Clinical User's Guide, Chapter 8, "System Customization" if <a:\arch_dat> is not the default.

3) At the main Sahara screen, pull down the <Database> menu and choose <Archive Database>. The program will prompt for the insertion of diskettes. Be sure to have a 3.5 floppy diskette in the a: drive.

4) Label each diskette with: Sahara Data, study name, clinic name, and date.

5) Fed Ex Monthly Ultrasound (Sahara) Data Transfer form, labeled floppy diskette(s), and Sahara Repair/Service/Upgrade Log and service report (if needed) to:

Bonnie Blunt
MrOS QUS QA Center
UCSF Prevention Sciences Group
74 New Montgomery St., Suite 600
San Francisco, CA 94105

Phone: 415-597-9287

6) Please call with any questions or problems with the backup or transfer procedures.

7. Quality Control

a. Training and Certification of Operators

Although QUS measurements are relatively simple, to obtain reproducible results considerable attention must be paid to preparing the participant and positioning the foot. All trained staff who wish to be certified to perform QUS measurements on MrOS participants must complete the following:

- Carefully read this manual and the Sahara Advanced Clinical User's Guide
- Receive training from the MrOS QC Officer or the designated staff member who attended the central training session
- Practice scanning with the acoustic phantom and then on other staff or volunteers

b. Phantom Scans

Each site will receive an acoustic phantom from Hologic. Phantom scans should be performed daily, but at least on each day that a participant is scanned. As phantom results are very temperature dependent, we recommend that the phantom be kept at room temperature (to the extent possible), and that daily phantom scans be performed after the ambient temperature of the room and machine have been stable for several hours (for example, during the noon hour or early afternoon). Participants may be scanned before the phantom scan is performed.

A single phantom scan should be performed each day the machine is used. Be sure the QC passes. See the Sahara Advanced Clinical User's Guide, Chapter 4, "Quality Control" for scanning instructions and if the QC does not pass.

c. Cross Calibration

A study wide ("gold standard") phantom will be circulated to each site with instructions on its use. The phantom will be circulated periodically during the course of the study.

d. Reproducibility

We plan to assess the reproducibility of the Sahara units in the near future. Detailed description of these in vitro (phantom) and in vivo (staff or participants) studies will be distributed.

8. Equipment maintenance and repair

Routine maintenance of the Sahara is discussed in detail in the Sahara Advanced Clinical User's Guide, Chapter 9, "System Care and Maintenance". Do not use other brands of coupling gel.

Sahara Maintenance Logs

The QA Center would like to keep track of repairs, upgrades and equipment replacement. Please use the Sahara Repair/Service/Upgrade Log to record any problems and their resolution. Include a copy of the Hologic service report. The forms should be sent with the monthly data transfer to the QA Center. Be sure to record (with dates) all scheduled and unscheduled maintenance performed on your device, as well as any changes in hardware or software.

9. General remarks

Unlike bone densitometry, ultrasound scanners are fairly new devices and there is not much knowledge about what kind of problems will be encountered. Therefore, we encourage you to call not only Hologic, but also the QA Center when problems arise. Bonnie Blunt at 415-597-9287 will be available to help you.

10. <u>Quality control checklist</u> (Keep a copy of this checklist with your Sahara scanner)

☐ QC scans

- ☐ • Phantom maintained at room temperature
- ☐ • Proper placement of phantom
- ☐ • Results indicate "QC Passed". If not, follow instructions in Sahara Advanced Clinical User's Guide, Chapter 4, "Quality Control".

☐ Participant preparation

- ☐ • Foot clean and dry
- ☐ • Shoe and stockings removed
- ☐ • Chair and leg positioned properly

☐ Foot positioning

- ☐ • Correct side scanned (use flow chart on Ultrasound Data Collection Form)
- ☐ • Gel applied correctly
- ☐ • Positioning/restraint applied correctly

☐ Scanning of participant

- ☐ • Duplicate scans performed
- ☐ • Third scan performed if indicated

☐ Results transcribed to Ultrasound Data Collection Form

☐ Weekly archive of Sahara database to diskette(s)

☐ Monthly shipment of Monthly Ultrasound (Sahara) Data Transfer form, labeled Sahara data diskette(s), and Sahara Repair/Service/Upgrade Log and service report (if needed) to:

Bonnie Blunt
MrOS QUS QA Center
UCSF Prevention Sciences Group
74 New Montgomery St., Suite 600
San Francisco, CA 94105

Phone: 415-597-9287

11. MrOS Study Forms

Ultrasound Data Collection Form (teleform)

Monthly Ultrasound (Sahara) Data Transfer

Ultrasound Sahara Repair/Service/Upgrade Log

Master copies of the forms will be mailed directly to your clinical center. The coordinating center will provide multiple copies of the **TELEFORM ONLY** (see your study coordinator). Other forms must be photocopied at the clinical center as needed. Always keep a copy of any form you send to the QA Center.