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OSTEON PROTOCOL
(SUBSET)

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1. Introduction

Calcaneal density measured by SXA will be assessed on a subset of participants at each clinic center at Visit 6 so that we can evaluate changes in calcaneal bone density over a 10 year period. Calcaneal BMD is more highly correlated with hip BMD than spine or forearm BMD. Calcaneal BMD provides a potentially easy and inexpensive measure of BMD.

2. Machine and Participant Preparation and Measurement

Follow guidelines spelled out in the Operations Manual provided by Dove Medical.

Determining side to scan:

- In general, scan on the same side as baseline (refer to lists from Visit 4 sent by CC). Baseline scan was usually on the right side.

- Reasons why visit 6 scan may need to be done on side opposite baseline scan:

  1. Heel (calcaneal) fracture on baseline side since baseline scan (refer to lists sent by CC). If baseline side fractured, then scan the other side. We are trying to identify women who've fractured their heel (calcaneus) since baseline and measure them on the other side. If the participant fractured her foot (not her toes) and it is unclear whether or not it was a calcaneal fracture, scan the other side.

     If both heels have been fractured, scan the baseline side.

  2. Possible hardware on baseline side. If hardware present, scan on side opposite baseline scan.

On the densitometry data form, record the side measured at baseline and the side measured at visit 6. If the sides are different, record the reason why they are different. Also record the bone density values from the printout as detailed below.

3. Data management and coding

Heel measurement: The numbers to be entered on the exam densitometry form and into the computer can be obtained from the normal printed report (F7). On the exam form you'll see that there are spaces to enter four variables. They are:

1) Side: the side the heel measure was taken on.

2) Area in cm^2: from the first page of the "Patient Clinical Report"

3) BMC in grams: from the first page of the "Patient Clinical Report"

4) BMD in gm/cm2: from the first page of the "Patient Clinical Report"

BMD, BMC, and area should be taken from the bottom of the page, under the 9-row average values section. To determine which row to read from, look down the fourth column, titled "mg/cm2 WEDGE". Locate the minimum value in this column; that is the row from which you should take the BMD, BMC and area values. Mark this row by underlining or highlighting the BMD, BMC and area values.

Normally, the values in the "mg/cm2 wedge" column will first decrease and then increase. The lowest 9 row average can usually be found between rows 2 and 5 and may be bolded on your printout. If the values continue to decrease all the way down the column, then use the values from the last line.

4) Data management

Data should be backed up to floppy weekly.

While you are conducting the osteon subset study, send the coordinating center a disk copy of the data once a month (provided you have new scans from that month). Send the disk, labeled "V6 Osteon data, month, clinic" to Gabrielle Milani at 74 New Montgomery. Please include a report of which participants (including IDs) are on the disk.

5) Quality control

1. Please copy the calcaneal reports for the first 20 participants and send them to Gabrielle Milani at the coordinating center with appropriate result fields highlighted.

2. Every two weeks, send to Gabrielle Milani the following:

   - a copy of the SUMSTATS utility check including the last 10 standard calibration values.
   - a copy of the report printed after initialization and calibration containing the MCA bell shaped spectrum and calibration information

   Record on the printouts how many times it took for the machine to calibrate if it was more than two and any other pertinent information.

   3. *Anti-virus checks:* At least monthly, an anti-virus software program should be run on the hard disk and any recycled floppy disks that are used with the osteon.

6) QC Checklists

☐ Machine calibrated daily
☐ Side measured at baseline determined
☐ Side to scan at V6 accurately determined and coded
☐ Correct values recorded from osteon printout
☐ Ensures adequate scan

Machine - QC

☐   Calibration performed daily?

☐   Other QC measures as outlined by Osteon?

☐   Calibration and initialization sent to CC (weekly or biweekly)?

☐   Data backed up weekly (or daily)?

☐   Monthly backup of data sent on disk to CC?