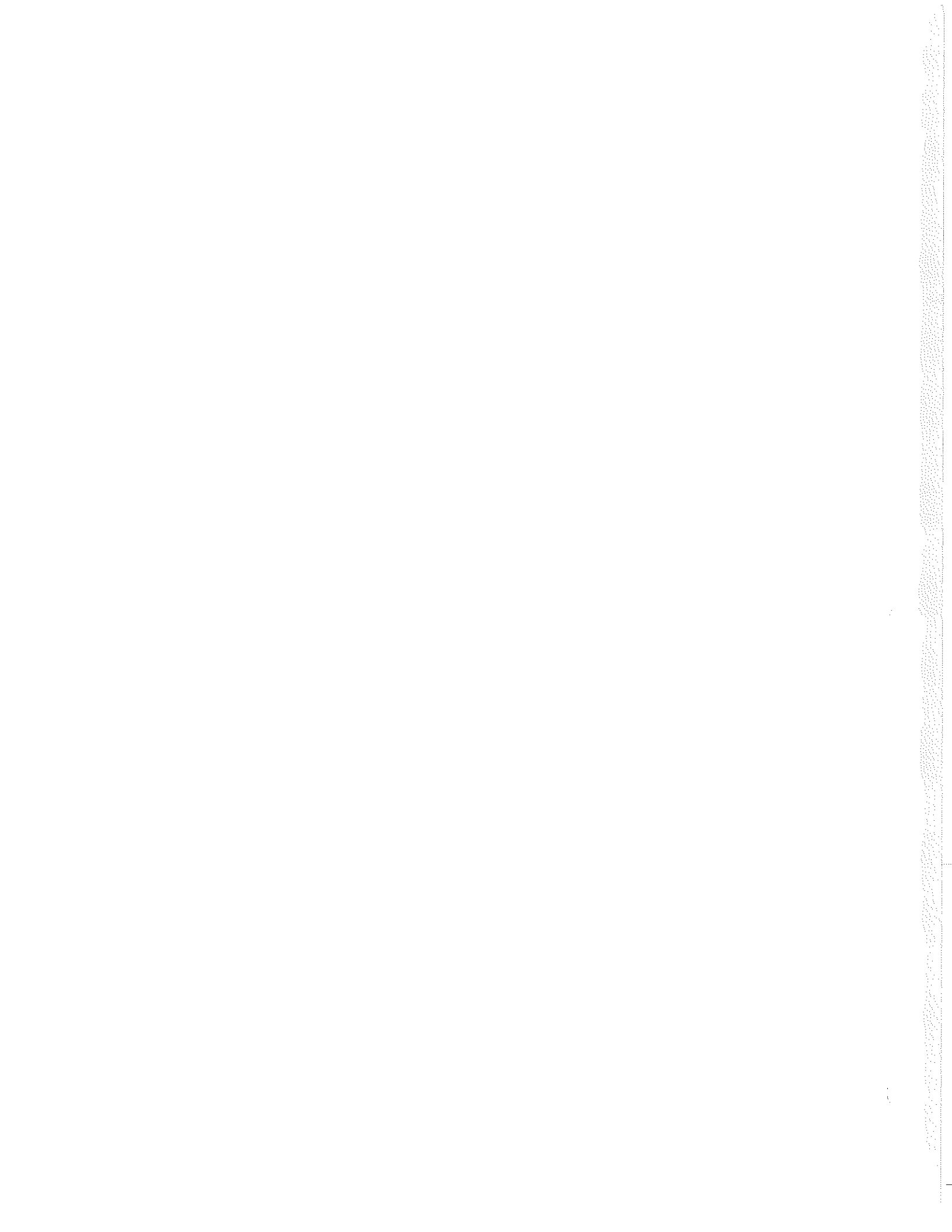


Osteon: SXA



STUDY OF OSTEOPOROTIC FRACTURES (V5)

Protocol for Osteon Measurement

1. Introduction

Calcaneal density measured by SXA will be assessed at visit 5 so that we can evaluate changes in calcaneal bone density over an 8 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.

Side to measure: Refer to protocol sheet for determining which side to measure. On the densitometry data form, record the side measured at baseline and the side measured at visit 5. 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

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 three variables. They are:

- 1) Side: the side the heel measure was taken on.
- 2) Area in cm²: from the first page of the "Patient Clinical Report"
- 3) BMC in grams: from the first page of the "Patient Clinical Report"

The 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 BMC and area values. Mark this row by underlining or highlighting the 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.

Once a month, send the coordinating center a disk copy of the data for that month. Send the disk, labeled "V4 Osteon data, month, clinic" to Lisa Palermo at 74 New Montgomery. Please include a report of what participants are on the disk.

5) Quality control

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

2. Every two weeks (instead of every week as in visit 4), send to Dana Seeley 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.