

STUDY OF OSTEOPOROTIC FRACTURES (V4)

Data Management Protocol for Osteon Data

1. Introduction

We are measuring heel densitometry again at visit 4 so that we can evaluate changes in bone density over the past 5 years. Heel BMD is more highly correlated with hip BMD than spine or forearm BMD. Heel 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 Osteon.

Side to measure: Refer to protocol sheet for determining which side to measure. On the densitometry data form, record the side measured at baseline, the side measured at visit 4, and the reason why they are different if applicable. 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 in to 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) BMC in grams: from the first page of the "Patient Clinical Report"
- 3) Area in cm²: 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. If the values continue to decrease all the way down the column, then use the values from the last line.

Please copy the reports of the first 20 participants and send them to Dana Seeley with appropriate result fields highlighted.

Radius BMD for bone loss cohort: We will be using 5 variables from the detailed report (Alt F7). These data values should be highlighted and then written in the

appropriate spaces on the examination densitometry sheet and entered into the V4 dataset. The 5 variables include:

1) Side of arm measured: Refer to protocol sheet for determination.

2-5) and for both DISTAL and PROXIMAL RADIUS:
gm/cm and width in cm from the average of rows 2-4

On the third page of the detailed report of the arm, you should find distal radius data. About two-thirds of the way down the page, you will find row information averaged for rows 2-4 for total bone (not the central 50% bone mineral data). The data will be taken from this row for all participants. The two values we need are the radius gm/cm value and the radius width (in cm) value.

It is very important to notice which side of the page is labeled "radius ". For left arm scans, the radius will be on the left hand side of the page (with the ulna information on the right). For right arm scans, the radius will be on the right hand side of the page (with the ulna information on the left). **WE DO NOT WANT INFORMATION ON THE ULNA.** As you can imagine, the fact that the report layout is reversed for right and left sides provides ample opportunity for data entry errors. Hence, we are asking that you take an extra minute or two to verify that you are indeed highlighting and abstracting the correct radius data from the printed report.

Distal and proximal: In addition, it is important to notice from the top of the page whether you are looking at data for the distal arm or the proximal arm. Usually the distal data is printed out first, however sometimes the sheets get switched around. Again, please take an extra minute to make sure that you are highlighting the correct values and entering the data in the correct spaces.

Attached are copies of the reports with the appropriate fields for entry are highlighted.

Please print out in duplicate or copy the reports of the first 20 participants and send them to Dana Seeley with appropriate result fields highlighted.

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 that can be generated by the program.

You will not be loading any old scans on to the computer so the change in disk size does not matter.

5) Quality control

Until and including November 30, 1992, every Monday gather and 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 MCA bell shaped spectrum and calibration information

After Nov. 30, send the above on the first day of every month. 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.

