August 28, 1986

# STUDY OF OSTEOPOROSIS AND FRACTURES

## Protocol for Radiographic Studies

Hip/Pelvic Film:

1) Position patient supine with feet taped at a 15°-30° internal rotation.
2) AP Pelvis.
3) Medium film/screen speed, 14" x 17". (200 speed prefered; 400 acceptable)
4) 70-80 kVp; mAs dependent on film screen system.
5) 40" focal fiml distance, with beam centered on the symphysis pubis.
6) Large focal spot.
7) Bucky screen technique.

Hand Film: The SAME hand as used for densitometry--generally the **right** hand.

1) Industrial grade films, non-screen system (Recommendation: Kodak XTL film, 8" x 10").
2) PA hand and wrist.
3) 50 kVp; 600 mAs.
4) 40" focal film distance.
5) Large focal spot.

Spine Films:

Lateral Thoracic

1) 14" x 17" cassette; medium (200) screen film speed.
2) Breathing technique; 2 second exposure.
3) 65-70 kVp; mAs dependent on film screen system.
4) 40" focal film distance.
5) Bucky screen technique.

Lateral Lumbar

1) 11" x 14" cassette; medium (200) screen film speed.
2) Held expiration technique.
3) 80 kVp; mAs dependent on film screen system.
4) 40" focal film distance.
5) Bucky screen technique.

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# MEMORANDUM # 25

## Osteoanalyzes and Radiological Techniques: Suggestions and Points to Remember

**TO:** **All Clinics**
**FROM:** **Peter Steiger**
**DATE:** **9/12/86**

In the following, we are trying to summerize some of the hints and suggestions we picked up during our site visits last week. We were impressed with the enthusiasm and imagination we encountered and would like to thank everybody for their active engagement. We are going to split our comments into 6 sections.

1. **OsteoAnlyzer:**
   - General Remarks
   - Accessories
   - Initialization and Calibration
   - Heel Measurements
   - Forearm measurements
2. **Radiological Techniques**

### 1. OsteoAnalyzer

#### General Remarks

-The items you need to enter for patient identification are: Last name, first name, middle initial, ancestry, age, ID number, side measured. All other items in the ID window are not required and are monitored by the questionnaire.

-Make sure the participant sits comfortably. Point out to her it is important that she is relaxed and does not move during the entire scan, (including the scout scan).

-Observe the bone edges during the scan - remember to correct the edges if necessary BEFORE you print any .

-Do not forget to press "F7" to obtain a clinical report after all three sites have been measured and all detail reports have been printed.

-Determine the side which should be used for the bone densitometry and the hand film by asking the following questions:

1) "Have you ever broken your right wrist or forearm?"
2) "Have you ever had an injury or a stroke that left your right arm weaker?"

If the answer to any one of the above questions is "yes", the OsteoAnalyzer measurements and the hand film must be performed on the left side, otherwise on the right side. If you have not done so

already, mark the side used on the X-ray requisition form.

-You will receive shortly an addition to your manual with instructions for the Bone Densitometry measurements and the radiographs.

-As long as it will not make the patient move you may use some of the scanning time for your interview work or other activities, (eye test, blood draw).

-We observed that the entire OsteoAnalyzer procedure takes about 35 minutes, as the source decays, this time may increase to 60-65 minutes.

-Please print out in duplicate or copy the copy the reports of the first 20 patients and send them to Peter Steiger with appropriate result fields highlighted.

Accessories

-Make sure you have all the accessories mentioned in Memo #19 available: a radiology foot stool, a pitcher with spout or watering can, a rubber spatula, sandbags and a bound log book with numbered pages. The foot stool and sandbags ought not to be shared with other experiements.

-Additional accessories have been suggested: a flash light (to check for air bubbles and correct position once the patient has been positioned and water has been filled into the tube) and cushions for the foot stool, (back and bottom).

-A chair with a hydraulic lift is essential for comfortable heel measurements. A chair without wheels may help avoiding problems with the scanner slipping away.

Initialization and Calibration

-Allow at least 30 minutes for the OsteoAnalyzer to warm up. Report to Peter Steiger if the calibration procedure fails more than twice (I.E. the standard values are not accepted after the first scan of the second "F9").

-Until September 30, gather daily and mail weekly to Peter Steiger the following information:
A "print screen" of the source activity messages and the MCA bell shaped spectrum that appears on the screen after initialization.
A print screen of the STDCHECK utility (called from the batch menu).
A detail report (ALT-F7) of the calibration.

After September 30, please mail out the above every first working day of the month.

Heel Measurement

-Lean the OstoAnalyzer against a wall if you have problems with the stability of the scanner due to uneven or slippery floor.

-Scan 15 rows , if possible. That way you will more likely reach a minimum on the 9 row averages. This will only add about 1.5 minutes to your heel scanning time.

-Start printing the detail report ("Alt F7") as soon as the heel scan is completed and start setting up the scanner for the arm measurements while you are waiting.

-Highlight the results that will be entered into the data base. Look for the line that yields the lowest "MG/SQCM WEDGE" value. Highlight values in the "AREA SQCM" and "BMC GRAMS"columns on that line.

-Normally, the values in the "MG/SGCM WEDGE"column will first decrease and then increase, so the lowest 9 row average is expected to be found starting between rows 2 and 5.

Highlight the results from the last line when you find the decreasing values only.

Forearm Measurements

Before you insert the arm tube into the scanner demonstrate to the participant how to position the arm in the tube and let her practice once. (Tell her to hold onto the rod loosely.)

-Fix some temporary "donuts" to immobilize the forearm until you receive the definite ones from Siemens. You may use some of the blue foam rubber that was used for shipping the OsteoAnalyzer.

-Insert the tube carefully and avoid bumping structures inside the source unit as this may result in damage of both the yoke inside the scanner and the arm tube.

-Do not forget to measure the ulnar length! Measure by having the participant resting her elbow on a flat surface in an "arm-wrestling" position and measure the ulnar length from the surface to the center of the ulnar styloid. Convert the measured length by means of the "Ulnar Length Conversion Table" and enter the converted value into the computer.

-Scan 4 rows for both the distal and the proximal sites.

-The participant should sit as closely to the scanner as possible to avoid the need of leaning over sideways .

-Print the detail report after the proximal scan has been completed ("ALT F7"). Select the distal scan with "F5" and print the detail report for the distal scan.

-Highlight the results that will be entered into the data base (the same for both forearm scans): Locate the 3-row average of total bone (NOT the central 50%) starting at row 2. Highlight the values in the column's "CM-RADIUS" and "RADIUS-GM/CM".

## 2. Radiographic Techniques

-Remember that we are evaluating vertebral deformaties (wedging and compression fractures) on the vertebrae from approximately T4 (depending on the size of the lung field ) through L5. Collimate such that no vertebrae are lost between the thoraces and lumbar film.

-Phototiming does not work well for lateral thoracic spines. Use a manual technique and set the MA such that you can get an adequate exposure at 2 seconds to make the breathing techniques work.

-The reason we want hand film over-rather than under-exposed is that we need good contrast between the cortex and medullary canal of the metacarpals to evaluate combined cortical thickness. Position the hand in the middle of the film with the wrist straight, this avoids rotation of the fingers.

-The internal rotation of the feet for the pelvic film is very important in our study, because we need optimal imagery of the femoral neck for the assessment of different groups of trabeculae (the Singh Index).

-Rebecca Smith will supply you with convenient mailing boxes with a capacity of 50 envelopes of 4 films each at a later date. Meanwhile, you can use regular x-ray mailing envelopes and mail fewer films at a time. More frequent delivery will also allow us better quality control during the initial period of the study.

# SOF Memorandum #55

Date: January 23, 1987

To: All Clinics

From: Peter Steiger and Michael Nevitt

Subject: Osteon

A few remarks concerning Osteon scans:

1. If a minimum of 10 rows cannot be scanned for the heel the scan is not valid. If the participant cannot insert her heel far enough to allow for 10 rows try the other side. This procedure may override the sides to be scanned determined according to the rules mentioned in point 2.

2. An additional screening questions needs to be asked to determine the side of the heel scan. Remember that we always want to scan heel and forearm on the same side, if possible. The first preference is to scan both forearm and heel on the right side. Only in some special cases, outlined below, do we want to perform the scans on opposing sides. The following screening questions and decision rules are designed to replace the ones of memo 25:

   1R) "Have you ever broken your right wrist or forearm?"
   2R) "Have you ever had an injury or a stroke that has made your right arm weaker than your left?"
   3R) "Over the past year, have you broken your right leg, ankle or foot?"
   4R) "Have you ever had an injury or a stroke that has made your right leg weaker than your left?"

   If the answer to all of the above questions is no, scan the right arm and leg. If not, repeat the above questions for the left arm and leg:

   1L) "Have you ever broken your left wrist or forearm?"
   2L) "Have you ever had an injury or a stroke that has made your left arm weaker than your right?"
   3L) "Over the past year, have you broken your left leg, ankle or foot?"
   4L) "Have you ever had an injury or a stroke that has made your left leg weaker than your right?"

   Then, use the following procedure to determine which arm and heel should be scanned:

   1. Determine side for arm scan:

      side scanned

| | |
|---|---|
| No right-sided fracture or weakness | Right |
| Fracture or weakness of: | |
| a) Right arm, not left | Left |
| b) Right and left arm | Right |

2. Scan heel on same side as arm, unless you determined a fracture or weakness of the leg on the same side as the arm scan and there is no fracture or weakness of the opposite leg.

Examples:
- A participant has problems with both arms and her right leg, but her left leg is ok: scan the right arm and the left heel.
- A participant has problems with her right arm only: scan the left arm and the left heel.
- A participant has problems with her right leg only: scan the left arm and the left heel.
- A participant has problems with both her arms and legs: scan the right arm and the right heel.

3. Based on the results for the first 480 participants entered into the data base we expect values within the following ranges:

| | minimum | maximum | units |
|---|---|---|---|
| Heel area | 9.0 | 13.1 | $cm^2$ |
| Heel bone mineral content | 1.0 | 8.0 | grams |
| Proximal forearm mineral density | 0.3 | 1.5 | grams/cm |
| Proximal forearm bone width | 0.7 | 1.9 | cm |
| Distal forearm mineral density | 0.1 | 1.9 | grams/cm |
| Distal forearm bone width | 1.0 | 3.1 | cm |

If you encounter values that lie outside these ranges, double-check the scan to ensure nothing went wrong with the scan, highlighting of values or data entry.

4. Portland has had problems with their disk. This suggests that it may be time to begin archiving if you have not already done so. I suggest the following archiving/backup scheme: At the end of each month, archive all data (including raw data files) up to the end of the previous month. That way you will always have the data of at least one month on the hard disk for easy retrieval. If you need to access data that has already been archived (i.e. for edge detection), all you need to do is insert the disk containing that scan (identified by the date it was taken, so make sure that you mark the dates of the backup period on the floppies) into drive A and proceed as if the data were contained on hard disk.
The archiving procedure of the OsteoAnalyzer does not allow to select the data you want to archive; it simply starts archiving with the

oldest data it can find and proceeds until the floppy is full or all data is archived. Therefore, you will need to interrupt the archiving process with the ESC key when it reaches a date close to the one you want to archive up to.
Once the data is archived it needs to be backed up. To do this you need to exit to DOS by selecting option 8 on the batch menu. Then proceed as follows (printed in bold is what you enter):

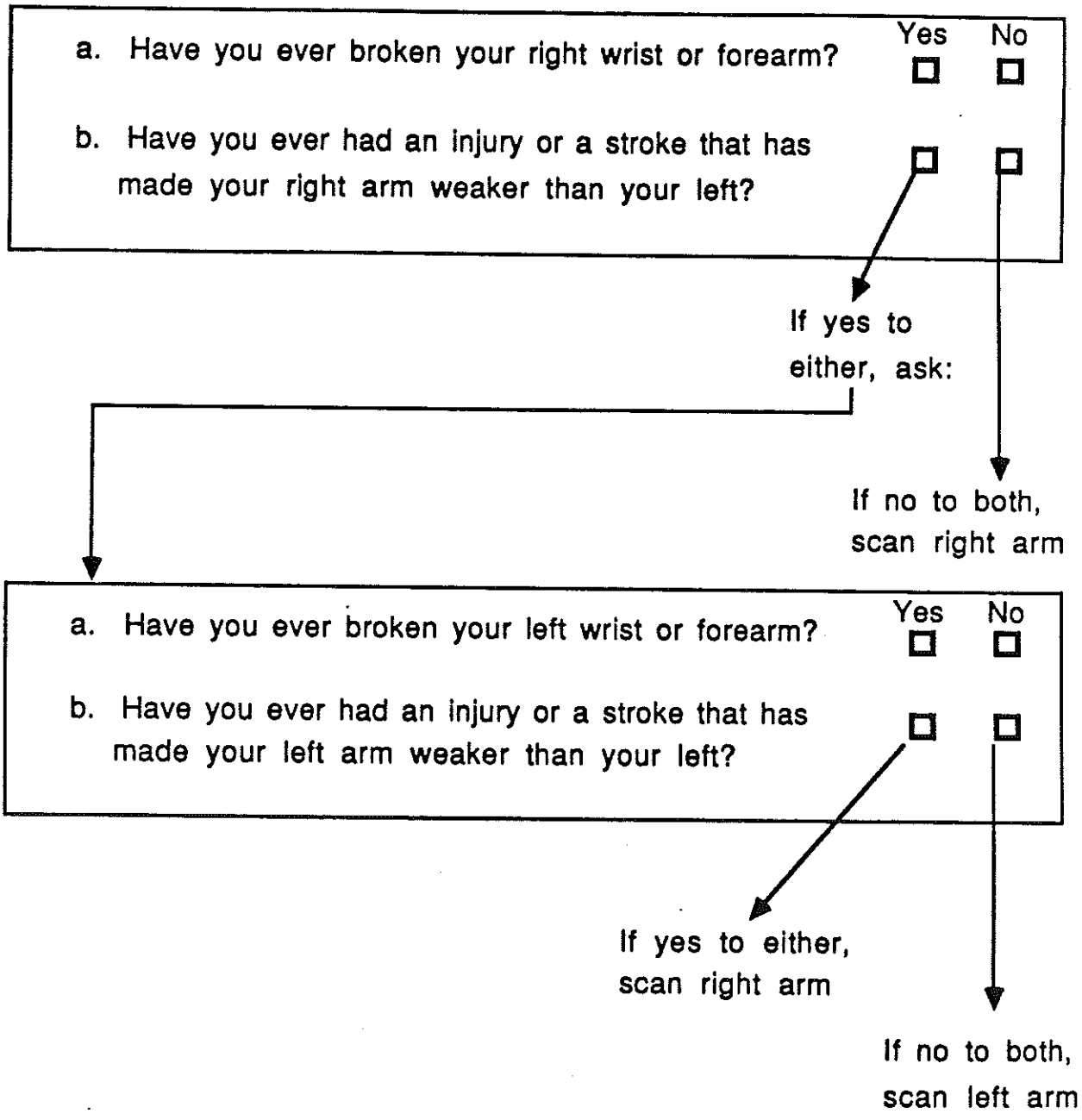
**C> CD DOS <RETURN>**
**C> DISKCOPY A: A: <RETURN>**
.... then follow the instructions given by the computer to back up the archive floppy
**C> <CTRL> <ALT> <DEL>** simultanously to reboot the system

After performing these steps you will have two identical copies of the archive disk. Mark one as backup and store seperately from the other.

5. Pittsburgh has been having lots of problems that Siemens field service engineers attribute to static electricity. We therefore recommend that you buy antistatic mats that may be obtained through stores such as Computerland at prices ranging from $100-150. The mats are to be placed on the floor under the scanner unit and the operator's chair.

## Algorithm for determining side of bone scans

1. Determine the side for arm scan by asking:



2. Determine the side for the heel scan:

Arm scan was performed on the _____ side.

Ask the following questions for the same side as the arm scan.

| | Yes | No |
|---|---|---|
| a. During the past 12 months, have your broken your _____ leg, ankle or foot? | ☐ | ☐ |
| b. Have you had an injury or stroke that has made your _____ leg weaker than the other side? | ☐ | ☐ |

If yes to either, ask:

If no to both, scan leg on same side as arm scan.

Ask the following questions for the opposite side as the arm scan.

| | Yes | No |
|---|---|---|
| a. During the past 12 months, have your broken your _____ leg, ankle or foot? | ☐ | ☐ |
| b. Have you had an injury or stroke that has made your _____ leg weaker than the other side? | ☐ | ☐ |

If yes to either, scan same side as arm.

If no to both, scan opposite side as arm.

September 30, 1986

# SOF Densitometry Procedures

## Addenda

1. What to tell participants about their densitometry measurements

When participants ask about their bone measurements, tell them that we are not yet certain of their meaning. The first participants are our "pioneers" helping us determine what is normal. After the first 100 measurements are collected from the clinics, a table will be produced showing the normal range for those participants. Participants can then be told where their measurements fall in relation to this normal range.

It is important to remember that no one knows what the measurments mean about a person's risk of fracture. That is what the study is trying to find out.

If a participant asks if she has osteoporosis, tell her that osteoporosis is not a disease and that the word "osteoporosis" means different things to different doctors. If her doctor has informed her that she has a crush fracture in her spine, then she does have osteoporosis. Some doctors use the word "osteoporosis" to mean that a person's bone density, as measured by machines such as the Osteon, is much lower than normal for someone her or his age.

After the first 100 or so participants, we will be able to tell the SOF subject whether her bone density is in the normal range for her age. If her density is much lower than normal, that does not mean that she is destined to have a fracture or a dowager's hump. Tell her that we do not yet know the chance of fractures for a person with her bone density measurements (that is the purpose of this study) and that there are many other factors involved in addition to the density of a person's bones.

**Refer all questions about treatment to the participant's physician.**

## ULNAR LENGTH CONVERSIONS TABLE

| When you measure this(cm). | Enter this (cm) | When you measure this (cm) | Enter this (cm) |
|---|---|---|---|
| 18 | 13.5 | 25 | 18.8 |
| 1/4 | 13.7 | 1/4 | 18.9 |
| 1/2 | 13.9 | 1/2 | 19.1 |
| 3/4 | 14.1 | 3/4 | 19.3 |
| 19 | 14.3 | 26 | 19.5 |
| 1/4 | 14.4 | 1/4 | 19.7 |
| 1/2 | 14.6 | 1/2 | 19.9 |
| 3/4 | 14.8 | 3/4 | 20.1 |
| 20 | 15.0 | 27 | 20.3 |
| 1/4 | 15.2 | 1/4 | 20.4 |
| 1/2 | 15.4 | 1/2 | 20.6 |
| 3/4 | 15.6 | 3/4 | 20.8 |
| 21 | 15.8 | 28 | 21.0 |
| 1/4 | 15.9 | 1/4 | 21.2 |
| 1/2 | 16.1 | 1/2 | 21.4 |
| 3/4 | 16.3 | 3/4 | 21.6 |
| 22 | 16.5 | 29 | 21.8 |
| 1/4 | 16.7 | 1/4 | 21.9 |
| 1/2 | 16.9 | 1/2 | 22.1 |
| 3/4 | 17.1 | 3/4 | 22.3 |
| 23 | 17.3 | 30 | 22.5 |
| 1/4 | 17.4 | 1/4 | 22.7 |
| 1/2 | 17.6 | 1/2 | 22.9 |
| 3/4 | 17.8 | 3/4 | 23.1 |
| 24 | 18.0 | 31 | 23.3 |
| 1/4 | 18.2 | 1/4 | 23.4 |
| 1/2 | 18.4 | 1/2 | 23.6 |
| 3/4 | 18.6 | 3/4 | 23.8 |