Operations Manual for CT Scanning: Osteoporotic Fractures in Men

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- **Introduction**

Overview: A consortium of seven universities, sponsored by the National Institutes of Health, is undertaking a study of Osteoporosis in elderly men. This 7-year study, referred to as "Mr Os", will enroll 5,700 men aged 65 years and older and follow them for an average of 4.5 years. The overall study goal is to determine the extent to which the risk of fracture in men is related to bone mass and structure, biochemistry, lifestyle, tendency to fall, and other factors. Other ancillary goals of the study are to better understand the relationship between osteoporosis and two other severe health problems in men, heart disease and prostate cancer.

Organization of the study: Patients will be recruited and followed at six Clinical Centers: University of Alabama at Birmingham (UAB), University of Minnesota (UMN), Oregon Health Sciences University (OHSU), University of Pittsburgh (PITT), Stanford University (STAN) and University of California at San Diego (UCSD). The Coordinating Center for Mr Os is at the Prevention Sciences Group at the University of California, San Francisco (UCSF) and is responsible for most aspects of study coordination, including data transfer and archival, quality assurance, development and distribution of manuals and other activities. Professor Eric Orwoll, residing at OHSU, is the principal investigator of the study and is responsible for its overall scientific and administrative direction.

QCT Measurements: An important feature of the study is the use of CT to perform sophisticated three-dimensional measurements of bone mineral density and geometry. This will allow us to better understand the relationship between skeletal mass, skeletal geometry and risk of fracture at the spine and other sites. CT measurements will be performed as part of the baseline visit. The CT part of the study will be coordinated by the CT Reading Center, directed by Thomas Lang. The CT Reading Center is responsible for development of the CT protocol, QC of the image data, and reading of the images. Thomas Lang will be the primary liaison with the CT technologists on any technical aspect of the study. Non-technical aspects of the study will be handled by the local study coordinators.

The QCT measurements are based on helical scanning protocols. There are two measurements: one in the lumbar spine and one in the hip. The lumbar spine measurement has two scan series. The first series encompasses the L1 and L2 vertebral bodies and will be used to measure the bone mineral density (BMD) and geometry of these vertebrae. The second series encompasses the L4 vertebral body and will be used to measure both the calcification in the abdominal aorta and the size and quality of the spinal musculature. The hip measurement will be used to measure the bone mineral density and geometry of the hip and the volume of the prostate.

The methodology for collecting and analyzing the QCT data are comprehensively described in this document. It is critical that the methods outlined herein are followed as specified; any variability in the process may severely impact the quality of the study data.

- **Key Personnel and Contact Numbers**

Below is a list of the sites and of some of the key personnel involved in the study. Again, all technical questions should be directed to Thomas Lang, and questions relating to study logistics should be directed to the local study coordinator.

SITE	PI	Study Coordinator
UCSF CT Reading Center	Thomas F. Lang, PhD Phone: (415) 502-4698 Fax: (415) 502-2663 Pager: (415)719-2363 E-mail: thomas.lang@oarg.ucsf.edu	
UCSF Coordinating Center	Steven Cummings, MD	Katie Stone, PhD (415) 597-9252
UAB	Cora E. Lewis, MD MSPH	Phil Johnson (205) 934-2602
UMN	Kristine Ensrud, MD, MPH	Eileen Mitson (612) 336-4892
PITT	Jane Cauley, DrPh	Loretta Harper (724) 684-7419
OHSU	Eric Orwoll, MD	Mike Wright (503) 494-2814
STAN	Robert Marcus, MD	Romelia Delay (650) 493-5000 x22030
UCSD	Elizabeth Barrett-Connor, MD	Mary Lou Carrion-Petersen (619) 642-0232

- **Patient Setup and Positioning.**

Enter the patient information for CT while the patient is undressing. This is a good opportunity to crosscheck the patient identification information (acrostic and patient ID) on the paperwork brought by the patient and to begin to fill out the CT Patient Logsheet. This form will be critical in helping us inventory what scans should be on the data tapes or MOD's.

Patients should dress down to their underclothes, wearing a hospital gown or pajamas fastened with ties rather than snaps. It is important that all metallic objects or jewelry be removed if these are in the field of view. **Ask the patient if he has had a hip replacement.** If this is the case, then the hip scan should not be done, due to the resulting metallic artifact.

Verify that the table is set to the correct height as documented in **Section 7**. Verify that the two calibration reference phantoms are placed on the table, corresponding roughly to the location of the patient's lumbar spine and non-dominant (usually left) hip. The head ends of the phantom (these will be marked in the training visit) should point to the head of the patient, who will be positioned feet first, supine in the scanner. In order to ensure that the patient is comfortable, place padding next to the hip phantom to level the patient.

The patient is positioned supine, feet first in the scanner. Ideally the patient should have their hands placed behind their head to keep the arms out of the field of view. This position may be difficult to hold for elderly patients, so they may rest with their arms bent, and hands resting on their foreheads. The patients legs should be straight, with velcro straps, or other positioning aids used at the technologist's discretion if it makes the patient more comfortable. When the patient is in the final position, the spinal phantom should be centered under the small of the patients back. Its inferior aspect should align with the superior aspect of the patient's iliac crest. The hip phantom should be located beneath the patient's hips. Its superior aspect should coincide with the patient's iliac crest. The phantoms should be aligned as straightly as possible with the axis of the patient table. Use the laser lights on each iliac crest, or a bubble level to ensure that the patient is as level as realistically possible.

- **Lumbar Spine Series**

4.1. Scoutview: . Lateral scout (Figure 1): 120 kVp, 70 mA "fast" mode. Use the xyphoid as the landmark for the superior limit of the scout scan. The length of the scoutview should be 40 cm or the scan length necessary to include the sacrum. Two scan series are defined from the scoutview. These are shown in Figure 1.

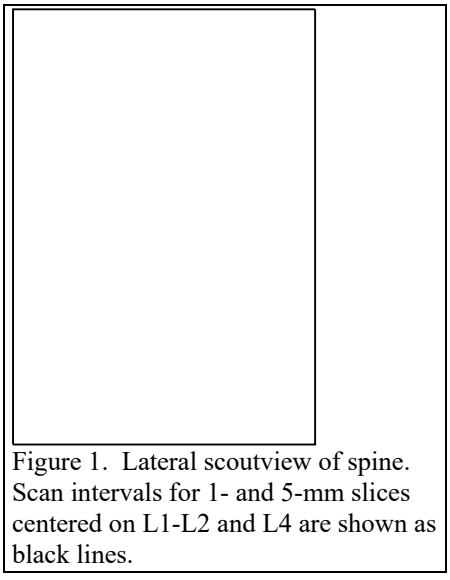

Figure 1. Lateral scoutview of spine. Scan intervals for 1- and 5-mm slices centered on L1-L2 and L4 are shown as black lines.

4.2. L1/L2 series: The superior limit is 5-mm above the L1 superior endplate and the inferior limit is 5-mm below the L2 inferior endplate. Use the scan parameters specified in Table 1. If L1 or L2 are fractured, scan T12 as an alternate. If both L1 and L2 are fractured, scan T12 and L3 as alternates.

4.3. L4 series: The superior limit is the mid-L3 vertebra. The inferior limit is the mid L5 vertebra. Scan parameters are denoted in Table 2.

Table 1	
parameter	setting
kVp	120
mA	150
matrix size	512^2
field of view	48 cm
reconstruction	standard
slice thickness	1-mm (pitch=1)
acquisition mode	spiral, with images reconstructed at 1-mm intervals

Table 2	
parameter	setting
kVp	80
mA	140
matrix size	512^2
field of view	48 cm
reconstruction	standard
slice thickness	5-mm (pitch=2)
acquisition mode	spiral, with images reconstructed at 5-mm intervals

- **Hip series**

5.1. Scoutview: The patient does not need to be repositioned for this study, but he may now rest his hands across his stomach, if that is more comfortable. The AP scoutview is performed at 120 kVp, 70 mA in the fast mode. The anatomy to be scanned is shown in Figure 2.

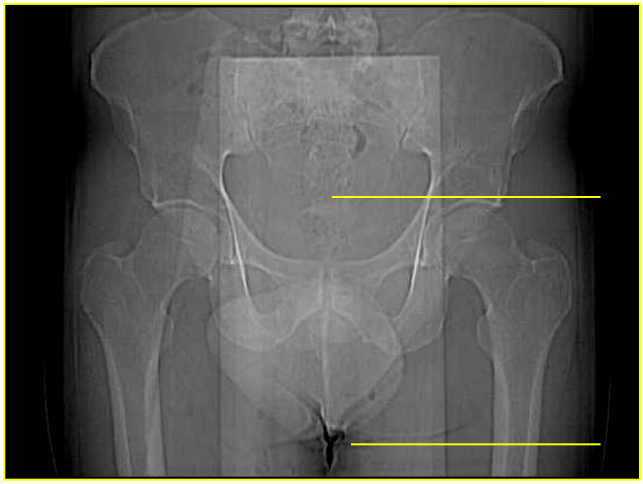

Figure 2: AP scoutview of hip. Lines depict the scan interval.

5.2. The limits of the hip series are defined from the scoutview. The superior limit should be 1 cm superior to the superior aspect of the left femoral head. The inferior scan limit should be 35 mm inferior to the inferior aspect of the lesser trochanter of the left hip. Acquire the CT scan data with the settings in Table 3.

Table 3

parameter	setting
kVp	80
mA	280
matrix size	512^2
field of view	48 cm
reconstruction	standard
slice thickness	3-mm (pitch=1)
acquisition mode	spiral, with images reconstructed at 3-mm intervals

- **Data Archival**

All image data must be at least double archived, one copy remaining at the local clinic per the local standard archival procedures. For example, if you archive your scans onto MOD at the end of the day, do the same with these scans. A second copy of the data must be archived onto DAT tape or MOD for transfer to the QCT Reading Center. Sites archiving onto MOD will use one of several "shuttle" MOD's which will be sent to the QCT Reading Center and then returned after the images have been offloaded. When you have completed the CT Patient Logsheet, keep one copy for yourself and make one for the Study Coordinator. Along with the Patient Logsheets,

the tapes and MODs will be collected by the Study Coordinator for transfer to the QCT Reading Center.

- **Site training, Study Setup and CT Scanner Calibration**

In January and February, prior to the beginning of patient recruitment, Thomas Lang will visit each site to practice the imaging protocol and to perform some important calibration measurements. You should have received this manual prior to the visit, along with the two bone mineral reference phantoms and torso QC phantom. The visit will be an opportunity to go over all aspects of the protocol and to answer any questions that arise. The visit will also be used to perform some important calibration measurements. The calibration measurements should require 30-40 minutes, but we can spend as much time as you require in order to clarify the protocol and address questions. Prior to this visit, please review this operations manual, and make sure that your system is properly calibrated at 80 kVp.

Feedback during the study: The CT reading center will provide feedback to the CT scanning centers. For each patient, we will provide a sheet notifying receipt of the scan, as well as comments about the acquisition. Hopefully, this feedback will be helpful in maintaining and continually improving the quality of the scans at each site. During the first year of the study, Thomas Lang will make a followup visit to each site. This will allow us to discuss our experience so far, and to consider possible ways of improving our process for acquiring and handling the CT scan data.

Determination of table height: Using the Image Analysis Torso Phantom which arrived along with the calibration phantom, we will perform a procedure to determine the correct table height to be used for CT scanning. This table height will be used for all measurements. This measurement should take 10 minutes.

Selection of spine and hip phantoms: We will also select and label the individual phantoms to be used for the spine and hip measurements. Because individual reference phantoms may show small differences in the densities of their bone mineral reference materials, it is critical that the same phantom be for each skeletal site on every patient. Finally, we will also label the head and foot ends of each phantom. The phantoms must be oriented consistently for each scan in order for the data to be evaluable.

Cross-calibration: We will perform a phantom study to measure calibration factors which will be employed to combine bone mineral density measurements from the 6 different CT systems in the study. Thomas Lang will bring this phantom with him to each site. This measurement should take 20 minutes.

Longitudinal calibration protocol: In order to detect any drift in the CT scanners bone mineral response which could affect the study data, we ask that the Image Analysis Calibration phantom be imaged on a bi-monthly basis. We will perform the first measurement, which should take about 10 minutes. The protocol is as follows:

Table 4: acquisition parameters for longitudinal QC scanning

Parameter	Setting
Technique	Single energy: *80kVp@280mAs*
FOV	40 cm
Matrix Size	512^2
Slice Thickness	5 mm
Enter table height for Long. QC $\Rightarrow$	

Use the Image Analysis QC Torso phantom as provided by Image Analysis

Place the torso phantom directly on top of the calibration phantom used for the spinal measurement.

Using the laser light, center the slice over the center of the torso phantom. Adjust the table height so that the center of the insert hole is at the center of the scanner field. Record this table height and use it for all subsequent longitudinal QC scans and for all patient studies.

Set the scan parameters to the values in Table 1. Do one axial scan and verify that the center of the insert is at the center of the field of view. Scan five times using the parameters specified in Table 1. Longitidunal QC scans will be repeated every two weeks for the duration of the study.

- **Changes in technical personnel and CT scanners**

Our goal in this study is to maintain the highest possible degree of consistency between scans. Thus, it is very important that all personnel performing these scans be trained in the protocol. Ideally, we would desire that the same technologist perform all of the scans, but this may not be practical over a three-year period. Therefore, if a new technologist (who was not present at the initial training) will be starting to perform scans for this study, it is important that he/she be given the chance to review this manual. Also, Thomas Lang should be notified so that he can go over the protocol with the technologist by phone at his/her convenience.

All CT scanners, even those of the same make and model, show some differences in bone mineral response. Therefore, it is imperative that all examinations for this study be scheduled for a single scanner. In case of a scanner breakdown, patients should not be sent to another available system. They must be rescheduled for the designated scanner. If, in the worst case, a scanner must be changed out over the course of the study, the CT Reading Center must be notified ahead of time, so that measures can be taken to cross-calibrate the new system and to adjust for potential changes in the image transfer procedure.

- **Patient questions and abnormalities evident from scans**

Patients almost always inquire about their results, i.e. “When do I get them”, or “How does my scan look?”. In response, please refer all such questions back to the study staff. The study staff will take charge of informing patients of their results.

Procedure for dealing with anomalous findings on the CT scan: will be determined prior to start of patient accrual.

- **Examples of acceptable and unacceptable scans**

We have included some examples of acceptable patient and phantom positioning for the CT scans on the following pages. You should always try to achieve the following conditions:

- The calibration phantoms are parallel to the long axis of the patient.

- The calibration phantom is horizontal, not rotated in the axial field of view.

- There is no air gap between the phantom and patient.

The goal of this section is not to set strict rules about what scan quality is “good enough”. Ultimately, this is decided by the technologist on a case by case basis. This section illustrates a range of acceptable scans, and should serve as a general outline as to what constitutes acceptable scan quality.