

**Operations Manual for CT Scanning: Osteoporotic Fractures in Men (MrOS)  
MrOS Study Visit 3: (2007-2009)**

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## 1. Introduction

Overview: A consortium of seven universities, sponsored by the National Institutes of Health, is undertaking a study of osteoporosis in elderly men. This study, referred to as “Mr Os”, has enrolled 6,000 men aged 65 years and older. 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. As part of the MrOS study, participants from the Birmingham, Alabama and Portland, Oregon cohorts will be asked to receive repeat QCT scans at the third study visit (Visit 3). The visit period will be approximately March 2007-September 2009.

Study Visit 3: At the scheduled visit, QCT scan will be repeated in order to update information about bone geometry and volumetric bone density measures. The QCT scans will be performed at facilities local to the study site. These are Highland Diagnostics in Birmingham AL and the OHSU Department of Radiology facilities.

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. Please direct questions pertaining to these protocols may be directed to the local contacts, Philip Johnson at UAB; or Janet Blank, Noal Clemons or Lynn Marshall at OHSU.

## 2. Participant Setup and Positioning.

MrOS Study staff will bring the necessary forms for each scheduled exam. The participant form is labeled, “**QCT—Visit 3**” at the top. Please complete the remainder of the form for the specific details of the QCT scans to be performed. MrOS Study staff will retrieve the form when they return to pick-up the participant.

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 study 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 artifact.

Verify that the table is set to the correct height as documented in the sections below.

Verify that the two calibration reference phantoms are placed on the table, corresponding roughly to the location of the patient’s lumbar spine and 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. If a sponge or bolster is placed under the participant’s knees for comfort during the lumbar scan, please remove it before taking the hip scan and ensure that the hip bones are level.

**Bolus Bag Placement:** Place one bolus bag at the patient’s lower lumbar spine under the small of the back to minimize the air gap. Place the second bolus bag underneath the patient’s legs so that it extends from the coccyx to the mid-thigh. It is important to minimize all air gaps under the patient’s back and legs.

**Participant Position in the Scanner:** The patient should be 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 patient’s legs should be straight and held in place with velcro straps or other positioning aids used at the technologist’s discretion if it makes the patient more comfortable.

**Check Placement of the Reference Phantoms:** When the patient is in the final position, the spinal phantom should be centered under the small of the patient’s back. Its inferior aspect should align with the top endplate of the sacrum and cover all of L5.

The second reference phantom should be located beneath the patient’s left hip. Its superior aspect should coincide with the patient’s iliac crest and its inferior aspect should include the superior half of the femoral shaft. The phantoms should be aligned as straight as possible with the axis of the patient table.

Use the laser lights on each iliac crest to ensure that the patient is as level as realistically possible. Set the exam table height to the QCT Table Height Value that was defined during the training session.

### 3. Lumbar Spine Series Acquisition

3.1. Lumbar Scout View: Acquire a lateral scout (Figure 1): 120 kVp, 70 mA “fast” mode, direction “out.” Use the xyphoid as the landmark for the superior limit of the scout scan. The scout view should extend to the tip of the sacrum. If applicable to your scanner, the scout views can be performed using the dual view facility. On the scout view, check that the first reference phantom is covering the whole range from the bottom of T12 to the bottom of L5. Ensure that there aren’t any large air gaps between the phantom, the bolus bags and the patient’s back. If you discover any problem, reposition the phantom and/or the patient and re-acquire the scout view. On this scout view, two scan series--the L1/L2 series and the L4/L5 series--will be defined. These are shown in Figure 1 and described below.



3.2. L1/L2 series: If metallic hardware such as for spinal fusion are visible on the L1 or L2 vertebrae or both, do not continue with the L1/L2 series. Note the reason that the L1/L2 series was not obtained on the QCT Visit 3 form. The superior limit should be set 5 mm above the L1 superior endplate and the inferior limit should be 5 mm below the L2 inferior endplate. Use the scan parameters specified in Table 1.

3.3. L4/L5 series: The superior limit is the mid-L3 vertebra. The inferior limit is the mid-L5 vertebra. Scan parameters are denoted in Table 2. If metal devices such as for spinal fusion are visible on either the L4 or L5 vertebrae or both, do not continue with the L4/L5 series. Note the reason that the L4/L5 series was not obtained on the QCT Visit 3 form.

Parameter	Setting
Acquisition mode	Spiral, with images reconstructed at 1-mm intervals
kVp	120
mA	150
Matrix size	512 <sup>2</sup>
Collimation	Philips: 16x0.75 High-Resolution GE: 16x0.625
Resolution	High
Reconstruction	Standard contiguous
Field of view	48 cm
Slice thickness	Philips: 1 mm ; GE: 1.25 mm
Increment	Philips: 1 mm ; GE: 1.25 mm
Pitch	Philips: 0.567; GE: 0.562
Filter	Philips: D; GE: “bone”

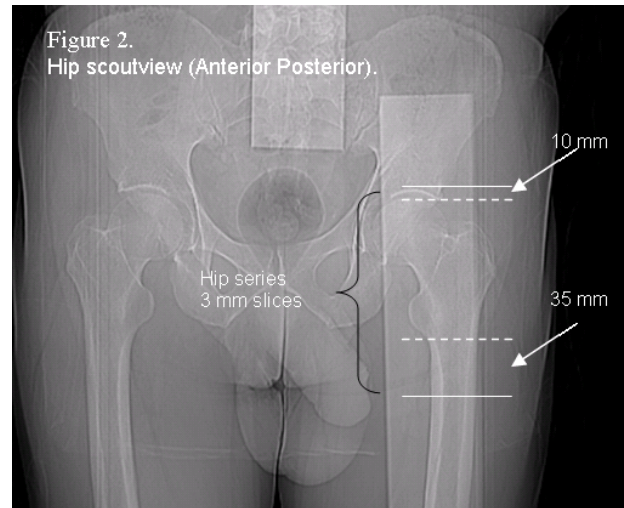
Parameter	Setting
Acquisition mode	Spiral, with images reconstructed at 5-mm intervals
kVp	Philips: 90 ; GE: 80
mA	140
Matrix size	512 <sup>2</sup>
Collimation	8x1.5 Standard resolution
Resolution	Standard
Reconstruction	Standard contiguous
Field of view	48 cm
Slice thickness	5-mm
Increment	5 mm
Pitch	Philips: 1.0 ; GE: 0.938
Filter	Philips: C; GE: “standard”

#### 4. Hip series Acquisition

4.1. Scout view: 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. An AP scout view should be acquired at 120 kVp, 70 mA in fast mode. The scout view should range from the superior aspect of the iliac crest through the superior 2/3 of the femoral shaft, shown in Figure 2. If the patient has had a hip replacement or has other metallic hardware in the hip scan range, do not continue with the hip series. Note the reason that the hip series was not obtained on the QCT Visit 3 form.

4.2. Helical Acquisition: The limits of the hip series are defined from the scout view. The superior limit should be 10 mm 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 a helical CT scan with the settings in Table 3, which prescribes two reconstructions of the same single acquisition.

Table 3. Scan Parameters for Hip Series	
Parameter	Setting
Acquisition mode	Spiral with images reconstructed at: 1 <sup>st</sup> reconstruction at 1-mm intervals, 2 <sup>nd</sup> reconstruction at 3-mm intervals 3 <sup>rd</sup> reconstruction left hip at 1-mm intervals at FOV of 200mm 4 <sup>th</sup> reconstruction right hip at 1-mm intervals at FOV of 200mm
kVp	Philips: 90 ; GE: 80
mA	280
Matrix size	512 <sup>2</sup>
Collimation	Philips: 16x0.75 High-Resolution GE: 16x0.625
Resolution	High
Reconstruction	Standard contiguous
Field of view	48 cm
Slice thickness	Philips: 1 mm ; GE: 1.25 mm
Increment	Philips: 1 mm ; GE: 1.25 mm
Pitch	Philips: 0.558 ; GE: 0.525
Filter	bone filter (Philips: D ; GE "bone")



4.3. The 3<sup>rd</sup> and 4<sup>th</sup> reconstructions shown in Table 3 should be in a field of view (FOV) of 200mm over the entire length of the scan and centered at the left hip bone and right hip bone, respectively. Make sure that the reference phantom remains in the field of view in the left hip.

## 5. Longitudinal Calibration and Quality Control

In order to detect any drift in the CT scanners' bone mineral response which could affect the study data, the Quality Control Torso phantom by Image Analysis, Inc. (the "QC" phantom) should be imaged every 3 weeks during the MrOS participant visit period. The first measurements will be performed during the training sessions in early 2007 (before study visits begin). They are to be performed every 3 weeks after that until the end of the study visits.

**QC Scan Setup:** Always use the QC phantom that was provided by Image Analysis. Place one of the reference phantoms that are normally used underneath the patient on the exam table exactly as you would position it for a lumbar scan of a patient. Then place the QC phantom squarely on top of the reference phantom. Using the laser light, position the QC phantom for an axial scan acquisition parallel to the QC phantom's endplates and centered at the center of the phantom. Adjust the table height so that the center of the insert hole is at the center of the scanner field. The table height should be set to the following:

- at UAB on the GE Brightspeed, 170 mm
- at OHSU on the Philips MX-8000, 156mm

(as determined during training session). **Use this table height for all subsequent longitudinal QC scans and for all patient studies.** If the patient is so large or obese that his torso cross-would extend beyond the scan field, it is OK to lower the exam table just enough to enable a correct acquisition. Please remember to record the table height used for each study participant in the appropriate box on the form labeled 'QCT'.

**QC Scan Acquisition:** Perform three sets of single axial scans (no table movement)—one set using the settings in Table 1, a second set using the settings in Table 2, and a third set using the settings in Table 3. For the first set of scans, set the scan parameters to the values in Table 1 (L1/L2 series). Perform one axial scan and verify that the center of the insert is at the center of the field of view. If it is not, reposition it and rescan. Scan a total of five times using the parameters specified in Table 1. For the second set of scans, set the scan parameters to the values in Table 2 (L4/L5 series). Perform one axial scan and verify that the center of the insert is at the center of the field of view. If it is not, reposition and rescan. Scan a total of five times using parameters in Table 2. For the third set of scans, set the scan parameters to the values in Table 3 (Hip Series). Perform one axial scan and verify that the center of the insert is at the center the field of view. If it is not, reposition it and rescan. Scan a total of five times using the parameters in Table 3. For these QC scans, please enter the following information into the Patient Name field in the header file enter: "MROS-QC-DDMOYR" (eg MROS-QC-01FEB07). In the Study ID field please enter: MROS-QC.

## 6. 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:

- Each series includes the minimum scan limits.
- Both reference phantoms are parallel to the long axis of the patient.

- Both reference phantoms are horizontal, not rotated in the axial field of view.
- There is no air gap between the phantom and the patient.

## **7. Data Transmission**

Along with the QCT Forms, the CD-ROM copy will be collected by the MrOS Study Coordinator at the end of each day. The pickup location is to be designated by the Radiology staff at each study site.

## **8. Site Training, Study Setup and CT Scanner Calibration**

In early 2007, prior to the beginning of patient visits, Dr. Sven Prevrhal will visit the Birmingham and Portland study sites 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 the QC torso 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.

Feedback during the study: The MrOS Study staff will be in regular contact with the radiology staff at each site to determine if any adjustments are necessary to maintain high quality scans. It is important that each set of patient scans be obtained according to standards and settings shown in this protocol. Scans not taken according to this protocol cannot be used and we are unable to ask study patients to return to be rescanned.

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 during the training session. This measurement should take 10 minutes. Please note that the table heights determined during the site visit have been recorded above in Section 5. in the paragraph labeled “QCT Scan Setup”.

Spine and hip phantoms: 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 used for each skeletal site on every patient. The head and foot ends of each phantom are clearly labelled. The phantoms must be oriented consistently for each scan in order for the data to be evaluable.

## **9. 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, the same technologist will perform all of the scans, but this may not be practical. Therefore, if a new technologist (who was not present at the initial training) is to start performing scans for this study, it is important that he/she be given the chance to review this manual. Should questions arise during the study period, please contact the Birmingham or Portland MrOS Study staff and we can arrange for a telephone consultation with Dr. Prevrhal at UCSF if necessary.

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 a scanner must be changed out over the course of the study, please notify the Portland MrOS Study staff 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.

## **10. Patient questions**

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 local MrOS Study staff. The study staff will take charge of explaining the purpose of the scans to the participant.