HIP X-RAY

1. Introduction

<u>Quality control:</u> The purpose of this manual is to standardize the examination procedures among the centers performing hip radiography in MrOS. It is intended to support both technologists and radiologists in their respective responsibilities by spelling out technical details and radiological aspects that may otherwise be left vague or inconsistent. The technologists at each facility assigned to the MrOS study should carefully review these procedures.

It is expected that all technologists participating in this study already have an in-depth knowledge and extensive experience in their field. This manual can by no means be regarded as a training course. This manual simply points out details pertaining to this specific study that otherwise are likely to differ between centers. There is no claim that the proposed techniques are the only ones to yield acceptable results. Rather, this manual provides guidelines to make the results of all participating centers consistent and comparable.

Centers that cannot meet the requirements detailed in the imaging technique sections will need to contact Nancy Lane at the MrOS Coordinating Center to discuss whether alterations to the specified parameters are acceptable.

The Radiology Coordinating Center will review the quality of the hip images during the study, and will notify the centers if problems with image quality are found. Possible sources of error, and possible solutions, will be suggested, but responsibility for the resolution of technical problems rests with the radiology facility and the clinical center.

During the study, questions regarding x-ray procedures should be directed to the MrOS Coordinating Center or Radiology Technician Consultant.

MrOS Radiography

Nancy Lane, MD San Francisco Coordinating Center 185 Berry St., Lobby 4, Suite 5700 San Francisco, CA 94107 Phone: (415) 514-8000

Phone: (415) 514-8000 Fax: (415) 514-8150

E-mail: nancy.lane@ucdmc.ucdavis.edu

2. Background and rationale

Hip x-rays are being obtained as a portion of a study to better understand the reasons behind variations in the utilization of lower extremity total joint arthroplasty, that is, total hip arthroplasty. We will be examining how men with OA may differ with regard to patient-specific factors such as perceptions and preferences that may in turn influence consideration of total joint replacement as a treatment option. The hip x-rays are being obtained to determine the degree of hip OA for participants.

Anterior/posterior (A/P) radiographs of the hip will be obtained on MrOS participants who complete Visit 2. For all radiographs, please concentrate on image quality and optimum positioning of the participant.

3. Equipment and supplies

- · screen/x-ray film combination: as specified in detailed protocol
- · right/left lead markers
- positioning paper to ensure 5 degree internal rotation

4. Inclusion/exclusion criteria and safety

4.1 Which participants get hip x-rays

All participants who complete Visit 2 will receive a hip x-ray.

4.2 Inclusions

- · participants who have had only one hip replacement
- participants who have had one or two knee replacements

4.3 Exclusions

Participants who have had bilateral hip replacements are excluded from having a hip x-ray.

5. Training and certification

5.1 Training

The Coordinating Center/Hip X-ray Reading Center will train the participating radiology facilities. Film quality will continue to be reviewed throughout the study.

5.2 Site and technologist certification

- a. Each x-ray facility should designate a <u>primary contact/supervisor</u> for this study. This person should generally be a chief technologist, technologist supervisor, or supervising radiologist at the facility, with responsibility for seeing that the MrOS x-ray procedures are carried out correctly.
- b. The primary contact should have a detailed knowledge of the MrOS x-ray protocols. This person is responsible for assuring that:
 - all x-ray technicians involved in the study are certified on the MrOS x-ray protocol and are assigned a MrOS staff ID number.
 - all MrOS hip x-rays are taken according to the MrOS protocol
 - copies of the x-ray protocol are available to MrOS x-ray technologists at all times.

- c. The primary contact should complete the MrOS X-ray Facility Certification Form (Appendix 1). The clinical center should send a copy of this form to the MrOS Coordinating Center.
- d. The primary contact should <u>assign specific technologists to this study</u>. Each technologist is given a MrOS Staff ID number by the clinical center.
 - Two to four technologists are recommended
 - · Technologists assigned to MrOS should be experienced in bone and joint radiography.
- e. All assigned MrOS technologists should <u>read</u> and have a thorough knowledge of the procedures outlined in <u>the MrOS protocol</u> and review any questions with the primary contact. A MrOS X-ray Technologist Identification Form, signed by each x-ray technician and the technologist supervisor should be sent in to the Coordinating Center (see Appendix 2).
- f. Individual technologists are certified by Coordinating Center review of the first 10 sets of radiographs (see Appendix 3 for Technician Certification Form).

6. Ongoing quality review at x-ray facility and Coordinating Center

6.1 Facility

- a. The technologist or the primary contact should review films while the participant is still at the facility so that if necessary a repeat film may be obtained without additional burden on the participant.
- The primary contact at each facility should review all hip films for protocol adherence and quality before they are shipped.
- c. In addition, "problem cases" where the technologist or chief technician is unsure of the quality of the image should be identified for review at the Coordinating Center. This is recorded in the "comment" section on the Hip X-ray Shipment Log (See Appendix 4).

6.2 Coordinating Center

- The MrOS Coordinating Center will review the quality of all films during the study, and will assess the performance of each technologist.
- Clinic project directors and primary contact will be notified of persistent departures from optimal imaging and examination technique so that corrections can be made.
- c. Repeat films will be requested for films that do not provide valid information on hip OA.

7. Hip radiograph

Anterior/posterior (A/P) radiographs of the hip will be obtained on all MrOS participants. For all radiographs, please concentrate on image quality and optimum positioning of the participant.

7.1 Hip radiographic technique

The film should be exposed to provide optimal visualization of the articular surfaces of the hip.

Exposure Technique

Imaging System	Bucky	Required
FFD	44"	Required
kVp Range	70-80 kVp	Recommended
mAs	Dependent on Film/Screen System	
Focal Point	Large	Required
Collimation	Full Size of the Film	Required
Cassette	14"x 17"	Recommended
Film/Screen Combination	Standard/regular film	Recommended
Lead Markers	Use Right/Left Lead Markers	Required

Examination Procedure

- Explain the procedure to the participant.
- Ensure foreign objects (i.e., zippers) are removed from participant's pelvic region as necessary.
- Ensure the participant's clothing is removed as required.
- Use a drape sheet or a patient gown to cover the participant's pelvic region. Note that participants should not wear pants of any type when they have their hip x-ray. It is OK for participants to wear shorts with an elastic waistband, as long as the shorts have no zippers, belts, rivets, etc., and there should be nothing in the participant's pockets.

Positioning the Participant

- Participant is standing upright on the positioning paper, facing the X-ray tube with the back against the Bucky.
- The heels of both feet are placed in contact with the anterior wall, below the film (Fig. 1).
- Both feet are fixed in internal rotation, aligned according to the positioning paper, which the
 participant stands atop.
- Body weight is distributed equally between the two legs.
- The participant is not moving
- The exposure is made appropriately

Please include a note in the Comments section of the Hip X-ray Tracking form if the optimal positioning was not achieved, if the participant could not stop moving, if the body weight could not be distributed equally, or any other diversion from the protocol.

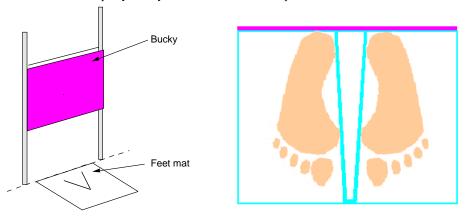


Figure 1— Foot mat. With the heels touching the anterior wall, both feet (in diagram above right) are fixed in 5° internal rotation by placing them against the V-shaped support on the base of the frame. Body weight is distributed equally between the two legs.

Positioning the x-ray Tube and Film Comments

- Position the tube so that the X-ray beam is perpendicular to the plane of the film and centered two inches above the symphisis pubis (at the level of the great trochanters). The symphisis pubis is identified by manual palpation.
- Collimate to the size of the film and include iliac bones entirely.

Side markers

• Use small lead right/left side markers and place them on the film where they will not be obscured by the study label, preferably on the lateral side. Place the markers right side up, so they can be read without reorientation of the radiograph.

Special Remarks

To assist with participant confidentiality, the biographical information flashed onto the films should include participant study information, **not the participant's name**. The flash region may be covered with the self-adhesive study label, but do not apply multiple layers of labels.

7.2 Assessing quality of hip radiographs

Common Mistakes

- Incorrect beam centering, superimposition and unsharp contours of the joints.
- Overexposure (radiographs too dark) or underexposure (radiographs too light).
- Motion during image acquisition identified by blurring of bone edges and poor resolution of anatomical structures.

Criteria of good quality hip radiographs

- Central ray is properly centered two inches above symphisis pubis.
- The entire hip is depicted, including both hip joints and iliac bones (see example on page 9).
- Joint space margins of both hips are clearly delineated.
- · Left/Right markers are on the film.
- The film is not underexposed or overexposed.

7.3 Examples of hip projection

See examples of acceptable and unacceptable quality hip radiographs below.

Unacceptable



The radiograph is underexposed.

Acceptable



Example of good radiograph.

8. Radiograph labeling

- a. The x-ray films should include the following information on the ID stamp:
- · clinic site and x-ray facility name
- MrOS ID (and four-letter namecode [acrostic])
- · date of x-ray
- x-ray tech ID (may be on a stick-on label)
- b. Be sure the ID stamp is on the right side and that each film has a left/right marker that is clearly visible.
- c. To ensure legibility, all label information should be typed whenever possible.

IMPORTANT: It is the responsibility of the clinical center to verify the legibility, completeness and accuracy of all identifying information on the x-ray label before the x-ray is shipped to the Coordinating Center. Missing or illegible information should be typed on a separate stick-on label, and placed next to (NOT OVER) the ID stamp. The x-ray tech ID may also be recorded on a stick on label.

In general, additional stick-on labels with redundant information (e.g., film date) are unnecessary and are discouraged. Any stick-on labels used should be placed next to (but not over) the imaged ID plate.

9. Hip X-ray Tracking Form and X-ray Shipment Log

Each MrOS participant who will be having a hip x-ray will have a Hip X-ray Tracking Form (see Appendix 6) which is partly filled out before the participant goes to the x-ray facility and completed when they go for their x-ray.

Section of Hip X-ray Tracking form that is filled out in clinic:

- · the participant's name
- the participant's enrollment ID# and acrostic

Section of the Hip X-ray Tracking form that is filled out at the x-ray facility:

- whether x-ray was obtained
- X-ray tech study ID number
- comments

As each participant's hip film is completed, fill in the information requested on the Hip X-ray Shipment Log (Appendix 4). The original of this log should be kept at the X-ray facility.

Two xerox copies of the current log should be provided with the x-rays to the MrOS clinical center at the end of each two-week accumulation period.

10. Packaging and shipping films

- Before leaving the facility, each participant's set of hip films should be placed in a paper jacket labeled with:
 - clinic site and x-ray facility name
 - MrOS ID and four-letter namecode (acrostic)
 - date of x-ray
- b. Films will be inventoried, boxed and shipped by staff at the MrOS clinical center.
- c. A <u>sturdy shipping container or other packaging should be used for each batch of x-rays shipped (i.e., x-rays should be double wrapped).</u>
- d. Package a copy of the MrOS Hip X-ray Shipment Log with the shipment. The Log will be checked against the films contained in the shipment at the Coordinating Center. Keep a copy of the X-ray Shipment Log at the MrOS clinical center.
- e. Fax a copy of the X-ray Shipment Notification Form to the Coordinating Center when the shipment is sent (Appendix 5).

Fax to: Clara Yeung, MrOS Hip X-Rays: (415) 514-8150.

f. Send all films to:

Clara Yeung MrOS Hip X-Rays MrOS Coordinating Center 185 Berry St., Lobby 4, Suite 5700 San Francisco, CA 94107

> Phone: (415) 514-8174 Fax: (415) 514-8150

- g. For security and speed of delivery, use of second day courier service (e.g., UPS second day air) is recommended.
- h. Include a copy of the X-ray Tracking Form with the x-ray sent to the Coordinating Center.
- h-i. Accumulated films should be shipped every two weeks (except for the first few weeks that the x-rays are obtained when they should be shipped every week).

Formatted: Bullets and Numbering

11. Hip x-ray reading

a. The hip x-ray will be read at the Reading Center (Appendix 7). The reader will look for osteophytes, joint space narrowing, sclerosis, cysts, deformity, and buttress.

11.1 Incidental suspicious findings seen on x-ray

Conditions that affect film quality should be noted in the comments section of the x-ray from. If a participant has a condition that might cause a problem with the quality of the film, the technician should note this in the comments section of the tracking form. This will avoid unnecessary requests for repeat images. The x-ray technician does not have to diagnose the condition that may be causing a decrease in film quality.

Occasionally, an x-ray technician will see a finding on the x-ray that should be further investigated. At the discretion of the field center, the x-ray technician may flag the image. To flag the image, the technician should write their impression in the Comments section of the tracking form. Ultimately, the Reading Center will look at the images regardless of whether the film was flagged by the Reading Center, decide if there are suspicious findings, and write a letter to the PI that describes the problem found on the x-ray. It will be up to the clinical sites to decide what to do with this information. Usually a call is made to the participant to ask them to see their primary care physician. Keep in mind that these films are collected for research purposes only. The participants are told that no diagnoses will be made from the materials collected in MrOS and that the information they provide is not for diagnostic purposes.

Formatted: Bullets and Numbering

7. /	C
IVI	1111

page 12

Appendix 1 Mr.OS X-ray Facility Certification Form

A. Imaging Technique - Facility	
Our facility can meet the following protocol specifications:	
Imaging system: Erect Bucky tray for 14" x 17" film	
Screen/Film combination is standard regular film	
Focal point is large	
Plexiglass positioning frame	

B. Imaging Technique - Technologists

The *film/focus distance* will be as specified for each image. It is critical to maintain this distance carefully.

44 inches

Exposure level: 70 to 80 kVp

Hip Radiography
Visit 2

page 13

C. Positioning

MrOS

Protocols will be followed with respect to specified:

- positioning paper used properly
- participant's back against Bucky
- both feet fixed in internal rotation
- body weight distributed equally between the two legs
- exposure made appropriately
- review for acceptable image quality and repeat x-ray if necessary

Technologist Supervisors statement: Or study. If personnel need to be added, they Center.	, ,	
Clinical center	X-ray faci	dity location
Last name, first name	Position	Phone number
	Date	Signature
Address	_	

1/4	[r(S

page 14

Appendix 2 MrOS X-ray Technologist Identification Form

I have carefully read the MrOS x-ray manual. I will adhere to the protocol as stated in the manual as closely as possible.

Last name	First name	MrOS Staff ID #	Date	Signature of X-ray Technologist

The above-listed individuals are qualified	ed to perform the required x-ra	y examinations.
Clinical center	X-ray faci	lity location
Last name, first name	Position	Phone number
	Date	Signature

page 15

Appendix 3 Technician Certification Form MrOS Hip X-ray Technician Certification Form

This form is to be used to request x-ray technician certification. Each technician will receive a technician ID for the MrOS study. Be certain that each hip x-ray is obtained according to the protocol. Hip x-rays should be sent in the regular shipments to:

ipments to:
Clara Yeung
MrOS Hip X-Rays
MrOS Coordinating Center
185 Berry St., Lobby 4, Suite 5700
San Francisco, CA 94105
Phone: (415) 514-8174
Fax: (415) 514-8150

	a hip x-ray technician is requ		-
			24
		Mr.OS Staff II	
	1 2	itted to the Hip X-ray Coordinatir	C
Participant ID	Hip x-ray Date	Participant ID	Hip x-ray Date
		6.	
		/.	
		8.	
		10.	
	ief contact signature:		Date
6. X-ray facility ch This section to be 1. Date Request Re	completed by the Reading ecceived: ended: Pass without Pa	Center: comment: ss with comment:	Date
6. X-ray facility ch This section to be 1. Date Request Re	completed by the Reading ecceived: ended: Pass without Pa	Center: comment: ss with comment:	Date

Appendix 4 MrOS Hip X-ray Shipment Log

MrOS Hip X-ray Shipment Log Attention Clara Yeung (Fax: 415-514-8150)

Clinical Center: Birmingham	□ Minneapol	is □ Palo Alto	□ Pittsburgh	□ Portland □ San Dieg	o
Date of Shipmer	nt:	/	/		
ID#	Acrostic	Date of Film	Tech ID	Comments	

110	_
Wirt E	۰

page 17

Appendix 5 MrOS Hip X-ray Shipment Notification

TO: FAX:	Clara Yeung (415) 514-8150
FROM: SITE:	
FAX:	
RE:	X-ray Shipment of MrOS Participant Data
	Message
The following	g data is being sent to you today(today's date)
For delivery	On (date)
VIA: Mail	Delivery service: Airbill #(airbill number)
Exam Date R Month	Lange of Participants Included: Day Year Month Day Year
Please call	atif you have any questions.
Response fro Shipment rec	m Coordinating Center eived on: Month Day Year
Not receive	ed as of: Month Day Year
Comments: _	

Appendix 6 Foot Positioning Paper

 $(This \ is \ only \ a \ copy; \ please \ use \ the \ full \ page \ version \ available \ on \ the \ study \ website)$

