KNEE AND FULL LIMB RADIOGRAPHY

TABLE OF CONTENTS

1.	Introduction	. 3
2.	Background and rationale	. 4
3.	Equipment and supplies	. 4
4.	Inclusion/exclusion criteria and safety	
4.1	Which participants get radiographs	
4.2	Required x-rays	
4.3	Radiation dose	. 5
5.	Training and certification	
5.1	Training	
5.2	Site and technologist certification.	
6.	Ongoing quality review at x-ray facility and BU Radiography Center	
6.1	Facility	
6.2	BU Radiography Center	
7.	Detailed knee imaging technique and examination procedure	
7.1	Single PA, standing, fixed flexion view of both knees	
7.1.1a	Imaging techniques: Iowa	
7.1.1b	Imaging techniques: UAB	
7.1.2	Imaging plate	
7.1.3	Preparation	
7.1.4	Participant position	
7.1.5	Knee position	
7.1.6	Central ray	
7.1.7	Participant instruction	
7.1.8	Criteria for assessing image quality	
7.1.0	Weight-bearing, lateral, semi-flexed view of each knee	
7.2.1	Imaging techniques: Iowa	
7.2.2	Imaging techniques: UAB	
7.2.2	Film/cassette size:	
7.2.3	Preparation	
7.2.4	Participant position	
7.2.5	Knee position	
7.2.6	Central ray	
7.2.7	Participant instruction	
7.2.7	Criteria for assessing image quality	
7.2.6 7.3	Single AP, full limb view of both lower extremities	
7.3 7.3.1a	Imaging techniques: Iowa	
7.3.1b 7.3.3	Imaging techniques: UAB	
	Tibial tuberosity	
7.3.4	Participant position	
7.3.5	Limb imaging	
7.3.6	Wedge filter and beam orientation	
7.3.7	Participant instruction	
7.3.8	Electronic stitching	
7.3.8a	Electronic stitching: Iowa	
7.3.8b	Electronic stitching: UAB	
8.	Radiograph labeling	. 31

Knee and Full Limb Radiography Operations Manual Vol. V

		Kilee aliu Fuli Liliib Kaulogi
MOST Operations Manual Vol.	MOST	Operations Manual Vol. V

8.1.1 DICOM header: Iowa	31
8.1.2 DICOM header: UAB	31
9. Completing X-ray data collection forms	32
10. Transmitting radiographs	32
10.1 Transmission of radiographs to the MOST Coordinating Center	
11. Readings, results, and incidental findings	
Appendix 1 MOST X-ray Facility Certification Form	34
Appendix 2 MOST X-ray Technologist Identification Form	
Appendix 3 Knee Radiograph Participant Report (New Cohort Screening Visit)	
Appendix 4 Beam Angle Calibration Form	
Appendix 5 Medial Tibial Plateau Images	
Appendix 6 Anatomical Location for Beekley Spot Placement	
Appendix 7 Instructions for using abdominal binder and wedge filter	
Appendix 8 Quality categories for knee x-rays	
Appendix 9 Repair/Service Log	

1. Introduction

Quality control: The purpose of this manual is to standardize the examination procedures among the MOST joint radiography centers. 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. These procedures should be carefully reviewed by the technologists at each facility assigned to the MOST study.

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 participating centers consistent and comparable.

During the study, questions regarding x-ray procedures should be directed to the <u>MOST</u> Radiography Center at Boston University. Centers that cannot meet the requirements detailed in the imaging technique sections will need to contact BU to discuss whether alterations to the specified parameters are acceptable.

The MOST Radiography Center will review the quality of the radiographs 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.

2. Background and rationale

MOST is a multicenter, longitudinal, prospective observational cohort study of risk factors for the development and progression of knee osteoarthritis (OA) and knee pain. This is a nationwide research study sponsored by the National Institute on Aging and coordinated by the San Francisco Coordinating Center. An existing cohort of 1500 men and women now aged 60+ have now been followed for 10 years. These participants along with a new cohort of 1500 younger men and women are currently being followed to help investigators better understand how to prevent and treat knee osteoarthritis, one of the most common causes of disability in adults.

Knee and full limb radiographs are being taken in MOST to obtain a radiological assessment of structural abnormality of joints is the current standard for classifying OA for epidemiological research and a key component of clinical diagnosis. Numerous studies have demonstrated a strong relationship between radiographic findings, symptoms, and outcome for knee OA.

To assess OA of the knee joints, the MOST study will include:

- a. a bilateral, standing semiflexed PA view of the tibiofemoral (TF) compartments of the knee joint,
- b. a unilateral weight-bearing, semiflexed lateral view of the knees that will provide information on the patellafemoral joint as well as the tibiofemoral joint space,
- c. an x-ray of the full lower limb incorporating the anterior superior iliac crest, hip joint, knee joint, and the tibio-talar joint for assessment of knee alignment (done only in newly recruited participants).

3. Equipment and supplies

For knee radiographs

- a. Plexiglass frame to control knee flexion and foot position in standing PA and to standardize position in lateral view.
- b. Johnson Level & Tool 750 Contractor Pitch and Slope Locator usually purchased at a hardware store (can be purchased from Amazon.com).
- c. Felt-tip pen
- d. 'Right' and 'Left' image markers
- e. Supplies necessary for image transmission

For full limb radiographs

- a. Abdominal binder (DAL 810) 12" wide, 30-45" long
- b. Compensating filter, e.g. a wedge filter to increase the gradient of radiation from the feet to the hips
- c. IV pole not on wheels
- d. Radiopaque ruler
- e. Beekley X-spot sticker

f. Supplies necessary for image transmission

4. Inclusion/exclusion criteria and safety

4.1 Which participants get radiographs

All participants in MOST from the new cohort, and all participants from the old cohort who had KLG<=2 in either knee at the 84-month visit will get knee x-rays (PA view and lateral). If they had a knee replacement on one side they will not need to get the lateral x-ray of the knee on that side. A full limb radiograph will be acquired only for newly recruited participants.

4.2 Required x-rays

Standing, fixed-flexion bilateral PA and weight-bearing, semiflexed lateral view(s) of the knees are required. Participants not able to have both of these views were excluded from MOST. Bilateral knee replacement was an enrollment exclusion for MOST. However, unilateral knee replacement is acceptable, and the lateral view of the replaced knee is not required.

The single AP "full limb" view of both lower extremities should be obtained in all newly recruited participants, including those with unilateral or bilateral hip replacements and/or unilateral knee replacement.

4.3 Radiation dose

Measurement PA and lateral knee x-rays	<u>Dose</u> For each x-ray, skin* dose is approximately 1,200 microSieverts (three x-rays taken, one PA for both knees and one lateral for each knee).
Full limb x-ray	The effective dose equivalent is 4.5 milliSieverts reflecting the large area of anatomy exposed.

*Only skin dose is available for the knee radiographs. Effective dose equivalent, not skin dose, is the appropriate quantity for the assessment of the risk of radiation injury. The effective/whole body equivalent dose from the extremity radiographs is very small with proper beam coning, as will be done in this study, and only a small portion of the total body bone marrow is exposed. For example, exposure to the testes or ovaries from a bilateral AP knee radiograph is less than 0.1 microSieverts (Handbook of Radiation Doses in Nuclear Medicine and Diagnostic X-ray, CRC Press, 1980), and overall effective dose to the participant is less than 0.005 milliSeiverts. (https://rpop.iaea.org/RPOP/RPoP/Content/Documents/Whitepapers/leaflet-x-rays.pdf)

5. Training and certification

5.1 Training

Separate on-site training of radiology technologists will take place before the start-up of a MOST visit, and to ensure prompt certification of x-ray technologists, all x-rays should be promptly transferred to the MOST Coordinating so that image quality can be checked. See section 5.2 below regarding continuing certification of x-ray technologists.

5.2 Site and technologist certification

- a. Each x-ray facility should designate a <u>primary contact/supervisor</u> for this study. Generally, this person should be the x-ray technologist's supervisor, with responsibility for seeing that the MOST x-ray procedures are carried out correctly.
- b. The primary contact should have a detailed knowledge of the MOST x-ray protocols. This person is responsible for assuring that:
 - 1) All x-ray technologists taking films in the study are certified on the MOST x-ray protocol and are assigned a MOST staff ID number.
 - 2) All MOST x-rays are taken according to the MOST protocol.
 - 3) Copies of the x-ray protocol are available to MOST x-ray technologists at all times.
- c. The primary contact should complete the MOST X-ray Facility Certification Form (Appendix 1) and send a copy of this form to the MOST Coordinating Center.
- d. The primary contact/supervisor should <u>assign specific technologists to this study</u>. Each technologist is given a MOST Staff ID number by clinical center.
 - 1) Two or three technologists are recommended.
 - 2) Technologists assigned to MOST should be experienced in bone and joint radiography.
- e. All assigned MOST technologists should <u>read</u> and have a thorough knowledge of the procedures outlined in <u>the MOST protocol</u> and review any questions with the primary contact. A MOST X-ray Technologist Identification Form, signed by each x-ray technologist and the primary contact/supervisor should be sent in to the Boston University Radiography Center (see Appendix 2).
- f. Individual technologists will be certified based on review of their first 10 sets of radiographs. Note that each set of radiographs is one participant's radiographs.
- g. Individual technologists will be recertified after an absence of no more than 3 months by the BU Radiography Center based on review of 5 sets of radiographs. If the absence is

more than 3 months, recertification will be based on review of 10 sets of radiographs. Again, note that each set of radiographs is one participant's radiographs.

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

6.1 Facility

- a. The technologist must carefully review all films, using the QA checklist, while the participant is still in the x-ray room so that, if necessary, a repeat radiograph may be obtained without additional burden on the participant.
- b. The primary contact at each facility should review all knee radiographs for protocol adherence and quality before they are sent electronically. If the primary contact plans an absence or vacation, then they should work with the replacement for at least one full day in clinic to review and refamiliarize the replacement with the protocol.
- c. In addition, "problem cases" where the technologist or supervisor is unsure of the quality of the image should be identified for review at the Radiology Coordinating Center. This is recorded in the "comment" section on the Knee X-ray Tracking Form.

6.2 BU Radiography Center

- a. The MOST Radiography Center at Boston University will review the quality of all radiographs during the study, and will assess the performance of each technologist.
- b. The technologist, supervisor, and the clinic coordinator will be notified of departures from optimal imaging and examination technique so that corrections can be made.
- c. Repeat radiographs will be requested for films that do not provide valid information.

7. Detailed knee imaging technique and examination procedure

Participant preparation: All participants need to have knees visible for these x-rays. They can either wear shorts or sweat pants that can be pulled above the knees. X-rays will be done with shoes off.

7.1 Single PA, standing, fixed flexion view of both knees

7.1.1a Imaging techniques: Iowa

a. imaging system: Quantum Medical Imaging Equipment, Fuji FCR Carbon

X, v8.0 *

b. imaging plate speed: Multispeed

c. film/focus distance: 72 inches (invariable)d. imaging voltage: 70 kVp (invariable)

e. mA/s: 9-24 mA/s (variable)

7.1.1b Imaging techniques: UAB

a. imaging system: Konica Image Pilot CR, Quantum Q-Rad X-ray

b. film/screen speed: 200-400

c. film/focus distance: 72 inches (invariable)
d. imaging voltage: 70 kVp (invariable)

e. mA/s: 5-12 mA/s (variable)

7.1.2 Imaging plate

Size: 14" x 17" (Crosswise in Bucky)

7.1.3 Preparation

- a. **Beam angle calibration**. At the beginning of the study and at the beginning of each subsequent month, the x-ray tube will be calibrated to ensure that a 5, 10 or 15 degree caudal (toward the feet) angle as indicated by the tube angle indicator is actually 5, 10 or 15 degrees. Use the inclinometer which is magnetically attached to the x-ray tube. First, angle the tube so that it is at 10 degrees caudal according to the dial. On the inclinometer, read off the actual degrees of this beam angle. If not 10 degrees caudal, adjust the beam angle so that the inclinometer reads 10 degrees. Mark where this is on the x-ray tube. This will be the '10 degree' beam angle that is used in the study. Next angle the tube to 15 degrees caudal, and use the inclinometer to check the actual angle. If not 15 degrees caudal, adjust the beam angle so that the inclinometer reads 15 degrees. Mark where this is on the x-ray tube angle indicator. Do the same procedure for a 5 degree beam angle. Record results on the beam angle calibration logs (Appendix 4).
- b. The x-ray tube is positioned so that the central ray of the x-ray beam is angled at 10 degrees toward the feet (caudal).
- c. You will also be occasionally repeating these x-rays at 5 degrees and 15 degrees.

d. **Beam angle check**. When angling the x-ray tube, confirm that the angle of the beam on the inclinometer is correct before taking each film.

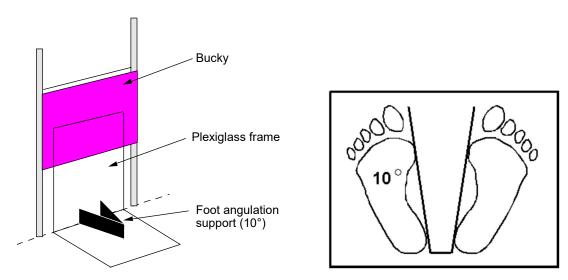


Figure 1. Plexiglass frame for reproducible knee flexion, foot fixation and external rotation. The frame is positioned with its anterior wall in contact with the Bucky such that the midpoint between the knees will be centered on the film.

- e. The anterior wall of the plexiglass frame is in contact with the Bucky tray (Figure 1). The plexiglass frame is positioned on the floor with the foot angulation support centered to the middle (left/right) of the Bucky tray. This will center the midpoint of the x-ray beam between the knees over the Bucky and the CR plate for most participants. Lower the Bucky so that the center of the plate is at the level of the tibiofemoral joint line. Do not affix quarters or other coins to the plexiglass frame.
- f. Identify the position of the tibiofemoral joint space by locating the inferior border of the patella and the superior margin of the tibial tuberosity; trace this line around to the side of the knee and mark the skin with a felt tip pen. This mark will be used to help align the center of the x-ray beam with the joint space (see Section 7.1.6b below).

7.1.4 Participant position

Both knees are x-rayed together

- a. The participant should be without shoes.
- b. The participant stands participawith both knees facing the CR plate in an erect Bucky or holder, with a film to focus distance (FFD) of 72 in.
- c. Body weight is distributed equally between the two legs, and the great toes of both feet are placed in contact with the front plate of the plexiglass frame. **IMPORTANT: The**

inner aspects and heels of both feet should be in contact with foot angulation support so that the foot position can be reproduced exactly on follow-up films.

d. The knees and thighs are pressed directly against the front plate of the frame and Bucky to fix the degree of knee flexion. **IMPORTANT: the knees and front of the thighs must be in contact with the front plate of the frame so that knee flexion can be reproduced exactly on the follow-up film.** First ask participant to touch knees to the frame; then ask them to lean forward so that the front of their thighs also touch the frame. (In this position the tibial plateau will be at, or near, a 10 degree angle (caudal) to the film.) The participant should hold onto the Bucky tray frame for support.

<u>Script</u>: "Touch your toes to the front plate of the plexiglass frame. Now press your knees into the front of the frame and then lean forward so that the front of your thighs are pressing firmly into the frame. Great. Now, make sure the insides of your feet and heel are snug up against the foot plates."

e. The external rotation of the feet is fixed at about 10 degrees by the frame. (Figure 2).

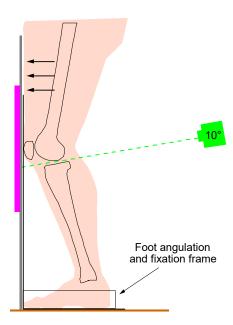


Figure 2. Proper patient positioning and beam angulation for radiography of the knee. Pressing the thigh against the Bucky fixes the degree of flexion of the femur. Reproducible positioning of the foot in 10 degree angulation is accomplished using a V-shaped support on a plexiglass frame.

7.1.5 Knee position

a. Both knees are imaged at the same time in a posteroanterior (PA) view. **Important: For** participants with asymmetric "bow legs," it may be necessary to position the frame slightly to one side so that the midpoint between the knees is centered on the film.

b. Place a **right** marker on the right edge of the cassette.

7.1.6 Central ray

- a. The tube is positioned so that the x-ray beam is directed at the midpoint between the back of the knees.
- b. The tube's positioning light is used to align the center of the x-ray beam midway between the knees and in the same horizontal plane as the center of the joints, defined by the marking of the joint space (see Section 7.1.3.e above), and which lies above the horizontal skin crease of the popliteal fossa.
- c. For participants already in MOST, the tube is positioned so that the x-ray beam angle is the same as the best beam angle(s) used in the past. See Data from Prior Visits report for beam angle(s).
- d. For screening visit x-rays for new participants, the initial beam angle will be 10 degrees, with the possibility that 5 and/or 15 degrees will also be used (see Section 7.1.8).
- e. The radiograph is taken immediately once this position is obtained.
- f. The beam angle(s) should be marked on the radiograph.

7.1.7 Participant instruction

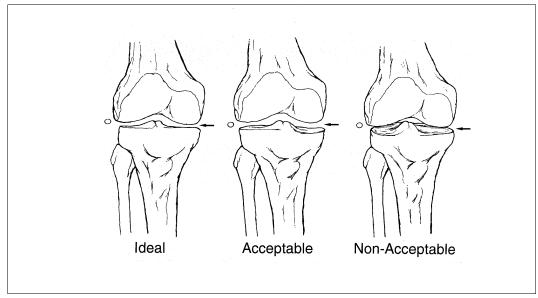
Have the participant understand the importance of holding still.

Script: "Please stand still so that the image will be clear."

7.1.8 Criteria for assessing image quality

See Figure 3 for anatomic drawing of acceptable and unacceptable films. Superposition of the posterior and anterior edges of the tibial plateau is required to accurately demonstrate the joint space (see Appendix 5 for examples of good and bad alignment of the tibial plateau).

- a. If the edge of the tibial plateau nearly touches or overlaps the distal femoral condyle on either knee (see Figure 3 below for unacceptable), repeat the x-ray at a beam angled at 5 degrees and then at 15 degrees, and record this on the form.
- b. Correct contrast/exposure: be able to see soft tissue; and medial and lateral sides of the knee joint including all bones without use of a bright light. See Figure 3b and Appendix 6.
- c. Exposure settings should be set to provide optimal visualization of the articular surfaces. The floor of the medial tibial plateau should be clearly delineated.
- d. The knees should be centered on the film.







Good Unacceptable

Figure 3b

Note: Figure 3a and Figure 3b should be used together to decide whether to repeat the PA view at different angles. These decisions are based on imaging of the joint space in the medial tibiofemoral compartment, specifically whether the tibial plateau's anterior and posterior margins overlap. When they overlap perfectly and the joint is seen straight through (Figure 3a "ideal"), they should not be repeated. Even if the anterior and posterior lips of the medial tibia are a short distance from one another and there is considerable space between the femur and the tibia (Figure 3a "acceptable"), the films do NOT need to be repeated. When the tibial plateaus don't

overlap completely and the tibia is either very close to (figure 3b "unacceptable") or overlapping with (Figure 3a "non-acceptable") the femur, these films need to be repeated.

7.2 Weight-bearing, lateral, semi-flexed view of each knee

For existing cohort participants, please use the relevant Data from Prior Visits report to determine which knee(s) a lateral view knee x-ray should be acquired for, but never take a lateral view x-ray of a knee for which a knee replacement was visible on the PA view x-ray.

For new cohort participants <u>at the screening visit</u>, both knees will usually require a lateral view knee x-ray, but if there is a <u>knee replacement visible in either knee on the PA view x-ray</u>, do not <u>acquire any</u> lateral view x-rays in that new cohort participant. This is because the knee replacement makes them automatically ineligible for the study and no lateral view x-rays are required. Please note this in the comments field on the data collection form.

7.2.1 Imaging techniques: Iowa

a. imaging system: Quantum Medical Imaging Equipment, Fuji FCR Carbon

X, v8.0*

b. imaging plate speed: Multispeed

c. film/focus distance: 72 inches (invariable)

d. imaging voltage: 65-70 kVp (invariable)

e. mA/s: 9-19 mA/s (variable)

7.2.2 Imaging techniques: UAB

a. imaging system: Konica Image Pilot CR, Quantum Q-Rad X-ray

b. film/screen speed: 400

c. film/focus distance: 72 inches (invariable)
 d. imaging voltage: 65-70 kVp (invariable)

e. mA/s: 7 - 13 mA/s (variable)

7.2.2 Film/cassette size:

14" x 17" cassette

7.2.3 Preparation

a. Participant should not be wearing shoes.

- b. For the right lateral knee x-ray, the plexiglass frame is positioned so that the large vertical front plate of plexiglass is perpendicular to the Bucky. This vertical front plate should meet the Bucky approximately 2 inches to the left of the middle of the Bucky. (If using the PA plexiglass frame, the foot plate and foot fixation device should be positioned so they are on the opposite side of the front plate from where the participant will stand.) Do not affix quarters or other coins to the plexiglass frame.
- c. For the second lateral radiograph, which will be of the left knee, turn the plexiglass frame 180 degrees from its position for the right knee. The vertical plate should meet the Bucky approximately 2 inches to the right of the middle of the Bucky. (If using the PA plexiglass frame, the foot plate and foot fixation device should be positioned so they are on the opposite side of the front plate from where the participant will stand.)

7.2.4 Participant position

Each knee is x-rayed separately.

RIGHT KNEE.

- a. The participant should turn so that their right side is parallel to the Bucky with their right leg against the Bucky. The tip of the right foot should contact the vertical plexiglass sheet.
- b. Participant should bend their right knee so that it also contacts the vertical plexiglass sheet.
- c. The left foot is positioned such that the toes of this foot is level with the back of the right heel. For the participant to be comfortable, the left foot does not have to be directly behind the right foot, but can be over to the side. This should produce 40-50 degrees of flexion of the RIGHT knee.
- d. Once the left foot is placed, the participant should have the left knee slightly flexed.

LEFT KNEE

- d. The participant should turn so that their left side is parallel to the Bucky with their left leg against the Bucky. The tip of the left foot should contact the vertical plexiglass sheet. The left foot should be pointed so that it is parallel to the Bucky and should be positioned so that the left leg and knee are contacting the Bucky.
- e. Participant should bend their left knee so that it also contacts the vertical plexiglass sheet.
- f. The right foot is positioned such that the toes of this foot is level with the back of the left heel. For the participant to be comfortable, the right foot does not have to be directly behind the left foot, but can be over to the side. Once the foot is placed, the participant should have the right knee slightly flexed.

Both left and right knee lateral films are weight bearing films, with <u>weight distributed evenly</u> <u>between both limbs</u>. Provide an object (such as an IV pole without wheels) for the participant to hold onto for support, if necessary, to ensure that both limbs bear weight and the participant feels comfortable holding the position.

Figure 4 on the next pages shows the positioning for taking a left knee lateral view.





Figure 4. Showing the correct position for taking a lateral view x-ray of the left knee.

7.2.5 Knee position

- a. Center the knee to the film.
- b. Place a right or left marker on each film.

7.2.6 Central ray

- a. Direct the central ray perpendicular to the knee. Tube is at 0 degrees, DO NOT ANGLE THE TUBE.
- b. Center the beam to the flexed (forward) knee joint at the joint line, as indicated in Section 7.1.3.e, above.
- c. Use collimation to reduce scatter radiation. Collimate only the horizontal dimension leave vertical open at maximum.

7.2.7 Participant instruction

a. Weight should be distributed evenly between limbs. Have the participant understand the importance of holding still.

7.2.8 Criteria for assessing image quality

- a. For these x-rays to be acceptable, all of the following structures need to be fully visualized. Figure 5 below is acceptable:
 - 1) tibial tubercle (where patellar tendon inserts)
 - 2) upper border of patella
 - 3) front of patella
 - 4) upper end of fibula
- b. If positioning is correct, (see Figure 5) the contours of the front edge of the medial and lateral femoral condyles should nearly overlie one another or be superimposed.
- c. Knee should not be excessively rotated. Figure 6 shows an excessively rotated lateral view, in which the contours of the front edges of the femoral condyles do not overlie one another and are instead separated by 1 cm or more.



Figure 5

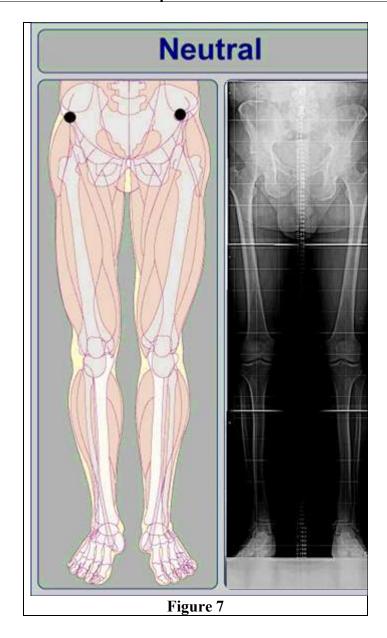


Figure 6

7.3 Single AP, full limb view of both lower extremities

With this view, we will image both entire lower extremities (including a full view of the anterior superior iliac crest and the ankle talus) at the same time, in a weight-bearing position. The goal of this is to measure knee alignment, defined here as the angle made by lines drawn from the femoral head to the knee and from the knee to the ankle surface, using specific femoral head, knee, and ankle landmarks. Alignment can be characterized as neutral (hip/knee/ankle angle is 0 degrees or a straight line), varus (alignment is < 0 degrees in the direction of a bow-legged appearance), or valgus (alignment is > 0 degrees in the direction of a knock-knee appearance). (Please see Figures 7-8).

Additional goals at this visit are to use this radiograph to get a measurement of the Q angle, an angle formed by the line of the quads muscles in the thigh and the patellar tendon from the patella to the tibial tuberosity. To assess Q angle, the anterior superior iliac crest (the front brim of the pelvis), the patella and the tibial tuberosity needs to be imaged. Participants should have a Beekley X-spot placed on their tibial tuberosity on both sides below the knees. The tibial tuberosity is the boney prominence that juts anteriorly from the tibia just below the knee.



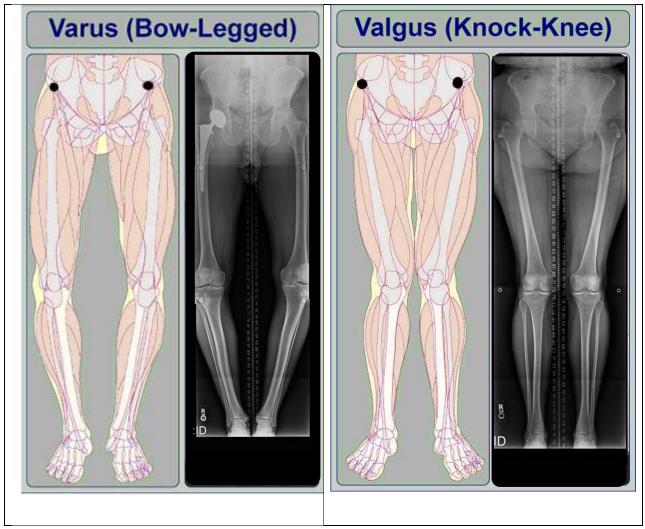


Figure 8

7.3.1a Imaging techniques: Iowa

a. Imaging system: Quantum Medical Imaging Equipment, Fuji FCR Carbon

X, v8.0 *

b. Film/screen speed: CR Imaging is a multispeed system

c. Film/focus distance: 80 inches. If the anterior superior iliac crest is not

visualized at 80 (unlikely but possible in long-legged individuals), increase the film/focus distance to include the

anterior superior iliac crest.

d. Imaging voltage 80-90 kVp

e. mA/s: 160-400 (default is 250)

7.3.1b Imaging techniques: UAB

a. Imaging system: Konica Image Pilot CR, Quantum Q-Rad X-ray.*

b. Film/screen speed: 400 speed (upper section)

200 speed (lower two sections)

c. Film/focus distance: 80 inches. If the anterior superior iliac crest is not

visualized at 80 (unlikely but possible in long-legged individuals), increase the film/focus distance to include the

anterior superior iliac crest.

d. Imaging voltage 80-90 kVp

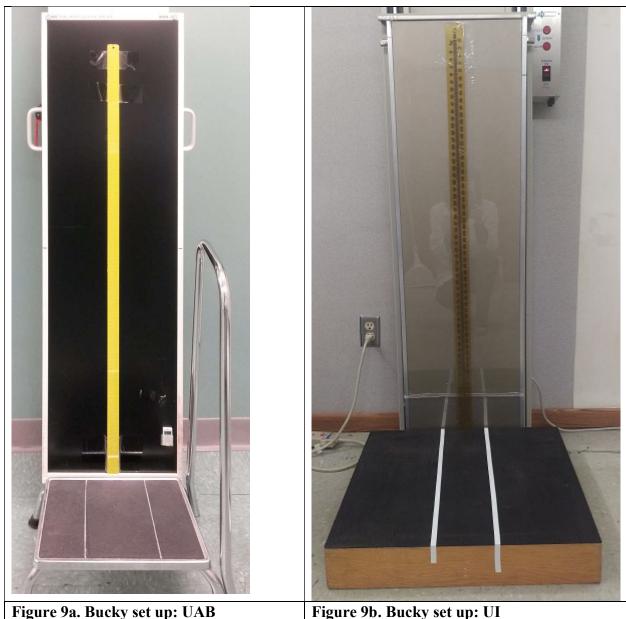
e. mA/s: 100-300

^{*} With the Fuji CR system for full-limb imaging there is a triple cassette used. There is a vertical wall Bucky with a grid attached to the front. The triple cassette is slid in the Bucky behind the grid. Once the triple cassette is exposed, it is separated into two cassettes and processed in the Carbon X. We then do the stitching process and send the images.

^{*} The Konica Image Pilot CR approach for full-limb includes a stack of cassettes, each holding an imaging plate. A standard wall Bucky is equipped with a rigid support, mounted in the vertical position to the Bucky. For the full-limb x-ray, there are three cassettes inserted in the support, such that each cassette overlaps with its preceding and succeeding cassettes. The front panel at the tube side of the support holds the rectangular grid that is utilized in the stitching process.

7.3.2 Bucky set-up: Cassette, Ruler and Step Stool/Platform

- a. Slide the cassette into the Bucky so it centered with the Bucky.
- b. Position the radiopaque ruler vertically to the center of the cassette with the numbers increasing downwards toward the feet (zero at the top). The bottom of the ruler should be level with the step stool or platform.
- c. Measure 3 inches from the center of the stool or platform, then line the stool or platform center up with the center of the cassette and the Bucky. Place two permanent lines on the step stool running parallel to each other, front to back 6 inches apart. These are used to position the feet.



7.3.3 Tibial tuberosity

A Beekley X-spot radio-opaque marker should be placed on the right and left tibial tuberosity. The marking for the tibial tuberosities can be done at any time during the visit prior to radiography, but the placement of the Beekley spot should be done just prior to taking the full limb radiograph.

The following procedure can be used to find the correct location of each tibial tuberosity:

a. Have the participant sitting or lying down with their knees flexed.

- b. Feel for and locate the patella tendon (firm vertical strap like band in the interval just below the patella and the tibial tuberosity).
- c. Manually define the medial and lateral margins of the tendon and mark each with a sharpie. Pick and mark a spot midway between these lines at the distal end of the tendon. Pick another point in line with the first point and midway between the tendon lines, one inch distally on the tibial tuberosity (see picture below). Mark this point with an X.
- d. Place the Beekley spot at the center of the X just prior to taking the radiograph. This is the mark that will be used to define the tibial tuberosity.
- e. Try to place the Beekley spot at the top of the tibial tuberosity right where it attaches to the patellar tendon (Appendix 6 shows the anatomical location on the tibial tuberosity).

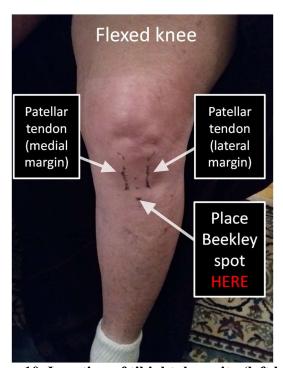


Figure 10. Location of tibial tuberosity (left knee)

f. Do this first for one leg and then for the other leg. In both legs, the tibial tuberosity should roughly be in the same place.

7.3.4 Participant position

a. Participant will stand on the step-stool or platform (necessary to ensure that the ankle is included).

- b. Participant should be standing without shoes facing ahead, with their buttocks against the cassettes and Bucky. Position the participant so the ruler is midway between the limbs and both limbs are centered on the radiograph.
- c. The technician begins by locating each foot with each heel centered on its respective permanent line on the step stool or platform.
- d. Each leg is then positioned so that the plane of knee flexion is straight ahead. To do this, have the participant bend the knee forwards and back then rotate that leg (inwards or outwards) so that the flexion plane is straight ahead.
- e. Then position the other knee the same way.
- f. Participant should be instructed to stand with knees fully extended and to bear weight equally on both limbs.
 - Script: "Please stand so that your weight is the same on your right leg and left leg."
- g. Participant may hold onto a hand rail for support, but not use the support to unload one or other leg.
- h. The participant's body should be against the grid to minimize participant-grid distance.

7.3.5 Limb imaging

- a. Both lower limbs are imaged at the same time in an AP view.
- b. The tube should be raised and lowered so it is at the level of the inferior border of the patella and the beam angle should be horizontal so the image will include the ankle and the pelvic brim.
- c. Check that the plane of knee flexion is towards you. Have the participant bend their knees to make sure the knees are aimed at you. (NOTE: that this does NOT necessarily mean that the feet are aimed towards you). If either knee is not aimed at you, have the participant rotate their feet to correct this (i.e. repeat 7.3.4 c and d above).
- d. The anterior superior iliac crest, the hip joint, the knee joint, the tibial tuberosity, and the tibio-talar (ankle) joint must be included in the image. NOTE: The tibial spines of both knees must be fully visible on the image. If this seems unlikely due to varus deformity, do a separate full limb of each leg, following the same protocol but repeating it for each limb separately. If the participant is too tall for the ankle joint and the anterior superior iliac crest to fit on the long limb image, first, try to make it fit. If it can't, the priority is to get hip, knee and ankle on the film. You can avoid the anterior superior iliac crest in that circumstance. If participant has a large abdominal pannus (fat) that obstructs the view of

the hip and pelvis, use abdominal binder (Appendix 7) to pull this pannus up out of the way.

- e. Place a right or left marker on each film
- f. A radiopaque ruler will also be imaged to provide a method to check the electronic stitching of the images.

7.3.6 Wedge filter and beam orientation

- a. If using a filter where the thickness varies, e.g. a wedge filter, the thickest end of the filter needs to be towards the feet of the participant when placing the filter on the tube head. If the filter is of uniform thickness, either end can be towards the head of the participant Position the participant for the film, look at their legs and place the upper end (the side towards the head of the participant) of the filter so that the edge of the shadow cast by the filter will be at the distal third of the femur.
- b. Direct the central ray perpendicular to the knee. Tube is at 0 degrees. DO NOT ANGLE THE TUBE.
- c. Center of the x-ray beam should be directed midway between the two knees at the level of the joint spaces. Locate the inferior border of the patella. This will be used to help align the center of the x-ray beam with the joint space (see Section 7.1.3.e above).

7.3.7 Participant instruction

Have the participant understand the importance of holding still.

Script: "Please do not move at all so that the image will be clear."

7.3.8 Electronic stitching

The following two sections describe how each clinic should stitch together a fill limb radiograph and once this has been done, the stitched image is ready to be transferred to the MOST Coordinating Center. The images that are transferred include the stitched image along with the three separate images (pelvis, knee and ankle). These should also be archived at the site.

7.3.8a Electronic stitching: Iowa

- a. Cassettes are exposed and placed into the image reader. While in the image reader, the image plate is read, erased, and then restored in the cassette for re-use. The image that is read is now on the work station and can be manipulated.
- b. CR technology creates one combined image from a series of overlapping sub images (which have been exposed simultaneously). A digital image-processing algorithm assembles the stitched image.

Creating the stitched image:

- 1) Once you have achieved optimal density and contrast on the image, you want to exit the QA screen by selecting the terminate QA icon.
- 2) Select one of the images to be stitched (where the words are and not the picture).
- 3) Select the image stitching icon.
- 4) The preview dialog box is displayed. As long as the image is correct, select OK. The stitched image is displayed.

7.3.8b Electronic stitching: UAB

- a. Cassettes are removed and placed into the digitizer. While in the digitizer, the laser plate is read, erased, and then restored to the cassette for re-use. The digitized image is now on the work station and can be manipulated.
- b. CR technology forms a total body part image from a series of overlapping subimages (which have been exposed simultaneously). During exposure, a rectangular grid of lines is present in the x-ray path to aid in the stitching process. A digital image-processing algorithm assembles a composite or "stitched" image.

Creating the stitched image:

- 1) On the browser screen, user selects all subimages that will make up the composite image, starting with the bottom-most image.
- 2) Highlight selected images.
- 3) Select "full-leg/full-spine" option which causes a screen to appear to display the subimages.
- 4) Rotate the subimages to bring them into the upright position.
- 5) Press "stitch" to created composite image.

7.3.8 On-site quality assurance

At the work station, after stitching and while the participant is still present in the x-ray suite, the following should be checked by the technician. If the image does not demonstrate good quality in the following points, it should be repeated. Important points to watch out for include hips and pelvis that are underpenetrated (too light and washed out) and limbs that are so varus (bowlegged) that one or both knees are left off the image.

- a. Anatomical coverage (see figure 11)
 - 1) The anterior superior iliac crest, hip joint, knee joint, and tibio-talar joint must be included and clearly visible in the image.
 - 2) The patella and tibial spines must be completely visualized. If not, repeat, doing a separate full limb radiograph of each leg.
 - 3) The tibial tuberosities of both sides must be seen as marked by the Beekley X-spot.
- b. Proper centering on the imaging plates.
- c. Delineation of anterior superior iliac crest, hip, knee, and ankle joint spaces. The hip joint and pelvis should be clearly visible (not washed out or underpenetrated), from the superior edge of the acetabulum the image to include the anterior superior iliac crest. Use the abdominal binder (Appendix 7), if necessary, in participants with sagging abdominal fat, to improve penetration at the hips and to better visualize the hip joints (see Appendix 8).
- d. Clear delineation of planned measurement landmarks (anterior superior iliac crest, center of femoral head, patella, tibial spines, tibial tuberosities and center of talar surface). The stitching should not cover any of these essential landmarks. If the stitch line obscures any of these landmarks, reposition the cassette(s) and/or participant and repeat the exam.
- e. Tibial spines of both knees must be fully visible on the image.
- f. Adequate exposure at proximal and distal extremes of the image to permit good images.
- g. No evidence of patient motion.
- h. Check for accurate alignment of radiopaque ruler on the image, especially at the stitching line, i.e. numbers on the ruler should be sequential. This should be right after the image is "stitched," i.e., on the workstation image.

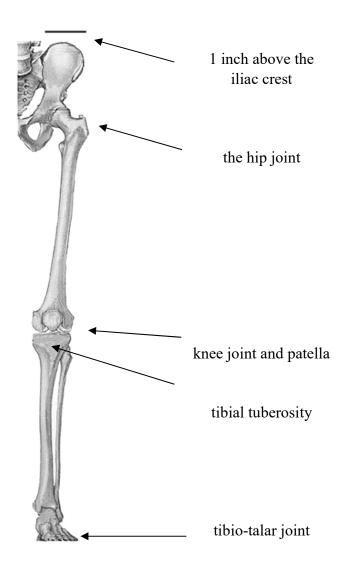


Figure 11. Essential landmarks to be included & clearly visible on the Full Limb radiograph

8. Radiograph labeling

- a. The x-ray images should include the following information on the ID stamp/DICOM header:
 - 1) Clinic site (Iowa, UAB) and/or x-ray facility name
 - 2) MOST ID and acrostic
 - 3) Date of x-ray
 - 4) X-ray tech ID or instead may be stamped on the x-ray with a lead marker
 - 5) X-ray view, e.g. Bilateral PA knees, Right Lateral knee, etc.
 - 6) Beam angle for PA films (can be combined with x-ray view, e.g. 10 degree Bilateral PA knees
- b. Be sure that each radiograph has a left/right marker that is clearly visible.
- c. The x-ray image, ID stamp or header cannot contain any of the following:
 - 1) Name or abbreviation based on the name
 - 2) Birthdate (if system requires entry of a date, use 01/01/1950)
 - 3) Medicare or SS#
 - 4) Medical record number

8.1.1 DICOM header: Iowa

Imaging system: Quantum Medical Imaging Equipment, Fuji FCR Carbon X, v8.0

Patient's Name: ACROSTIC Patient ID: MOSTID

Series Description: Name of X-ray, e.g., 10 degree PA, Left Lateral, Right Lateral, etc.

8.1.2 DICOM header: UAB

Imaging system: Konica Image Pilot CR, Quantum Q-Rad X-ray

Last name: ACROSTIC Patient Identification: MOSTID

Series Description: Name of X-ray, e.g., 10 degree PA, Left Lateral, Right Lateral, etc.

IMPORTANT: It is the responsibility of the clinical center to verify the legibility, completeness and accuracy of all identifying information on image before the x-ray is transmitted to the Radiology Coordinating Center.

9. Completing X-ray data collection forms

Fill out the relevant knee or full Limb radiograph X-ray data collection form for each MOST participant. First confirm that this is the correct participant. Ask their name, confirm in the chart that the name matches the MOST ID# and acrostic at the top of the form. Indicate on the form whether or not the x-rays were taken, the date of the x-rays, the staff ID# of the x-ray technician.

For knee radiography indicate each view taken (bilateral PA semiflexed view at 5, 10, and/or 15 degrees beam angle, lateral view of right knee, lateral view of left knee) and what the mAs setting was.

For full limb radiography, record whether a complete stitched image was acquired, the mAs setting and in the comments section, fill in when the abdominal binder and / or filter was used and also if you judge that the participants was obese plus any other relevant comments. This helps when images are borderline or unacceptable and the reading center has to decide to ask for a participant to be called back for a repeat x-ray.

10. Transmitting radiographs

10.1 Transmission of radiographs to the MOST Coordinating Center

Send the radiographs to the computer that is set-up to transfer the images to the MOST Coordinating Center electronically. Upon receiving the images, the UCSF Coordinating Center will check the images to confirm that all PHI/PII has been removed. This includes reviewing the DICOM header

10.2 Storage and archival of radiographs

Archive the radiographs for storage according to the local clinic site protocols. The radiographs should remain on the computer as long as reasonably possible. Do not manually delete radiographs from the computer unless instructed to by either the local clinic site protocols or the MOST Coordinating Center.

11. Readings, results, and incidental findings

The radiographs will be checked for quality at the MOST reading center, and the data will be reported back to the MOST Coordinating Center. If repeat radiographs need to be taken, an automated e-mail will be sent to the relevant staff at the clinical sites. Staff will be able to check the website (http://keeptrack.ucsf.edu) for reports on which participants require repeat radiographs and the reasons for the repeat, and automatically generated QC reports will also be available on that website

Incidental findings:

Note that if the sites identify images where there are 'spots' or other incidental findings on a participant's x-ray that they should enter a comment on the X-ray Data Collection Form. These 'spots' or incidental findings may also be noticed by the Reading Center. At the Reading Center these findings will be viewed by a rheumatologist and feedback from them will be e-mailed to the Coordinator at the site, or, if it is decided that the finding needs to be checked by a radiologist or the participant's primary care provider, then a letter regarding that finding will be sent to the PI at the site with copies to the Coordinating Center and the site coordinator.

Appendix 1 MOST X-ray Facility Certification Form

☐ Technicians have received comprehensive training in MOST x-ray imaging protocols				
☐ Only certified technicians do imaging				
☐ Imaging parameters specified in protocol are used exclusively				
☐ Films are repeated if they do not meet specified QA cr	riteria			
Technologist Supervisors statement: Only identified teastudy. If personnel need to be added, they should be identified. Center.	=			
Clinical center	X-ray facility location			
Last name, first name	Position			
Address	Phone number			
Signature	Date			

Knee and Full Limb Radiography Operations Manual Vol. V

Chapter 3J, page 35

Appendix 2 MOST X-ray Technologist Identification Form

I have carefully read the MOST Knee and Full Limb Radiography manual. I will adhere to the protocol as stated in the manual as closely as possible.

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

Technologist Supervisors statement:			
The above-listed individuals are qualified to per	form the required x-ray examinations.		
Clinical center	X-ray facility location		
Last name, first name	Position		
Address	Phone number		
Signature	Date		

Appendix 3 Knee Radiograph Participant Report (New Cohort Screening Visit)

	1	
4		
M	OS	T

MOST Knee X-ray Participant Results Report

OST	(Screen Visit Resul	ts for New Cohort Baseline Clinic Visit)		
Participant Name:				
	(Please print.)			
Date of knee x-ray:	Month Day Year			
Thank you for partic	ipating in the MOST Study!			
Osteoarthritis (OA) people. As part of Magnetic Resonanc usually get an x-ray can cause pain and you need treatment. The x-rays from this and lateral view film tiny or possible oste there was a larger, costeoarthritis' is presented.	a, also called degenerative arthring ACST (Multicenter Bone and Joi e Imaging (MRI) to study the cast to see if it is osteoarthritis. X-ray often x-rays show changes of odepends on whether you are has study were read by a trained rast both weight-bearing (or standing ophyte, an outgrowth of bone nedefinite osteophyte usually without the sent when there is an osteophyte sent when osteophytes are prescartilage loss.	age and often causes pain and disability. tis, is the most common type of arthritis in older nt Study), we are using x-rays. CT scans, and auses of knee pain. In people with knee pain, doctors as do not show all of the problems in the knee that steoarthritis that do not need to be treated. Whether a tring knee pain or other knee symptoms. Idiologist. These include a PA (posterior to anterior) ag). "Possible osteoarthritis" is present when there is a gear the joint. "Mild osteoarthritis" is present when the pout narrowing of the joint space. "Moderate and definite joint space narrowing and "Severe seent and the joint space is very narrowed or is gone		
	-rays of your RIGHT knee	The standing x-rays of your LEFT knee showed:		
☐ No osteoart ☐ Possible ost ☐ Mild osteoat ☐ Moderate ost ☐ Severe oste	teoarthritis rthritis steoarthritis	 □ No osteoarthritis □ Possible osteoarthritis □ Mild osteoarthritis □ Moderate osteoarthritis □ Severe osteoarthritis 		
being used for reseathat you got an MRI you. It is very important	arch, they are being looked at ve to help with the study, unfortuna	research. Because the knee MRIs in MOST are ery carefully and in great detail. While we are grateful ately, it will not be possible to share these results with are research findings and your usual doctor visit is pain.		

Thank you!

Appendix 4 Beam Angle Calibration Form

MOST MONTHLY BEAM ANGLE CALIBRATION LOG 5 DEGREES

Clinical Center:	□ Alabama □ Iowa		
X-ray tube number:			
_	tube so that it is at a	5 degrees caudal according to the dial	•
Task 3: On the inc	linometer, read off	-ray tube. the actual degrees of this beam angle. s caudal, adjust the beam angle so tha	
	0 0	k this on the x-ray tube.	t tille
(check boxes 1-4 if	tasks are completed)		

DATE	Staff ID #	

1	Z	3	4

MOST MONTHLY BEAM ANGLE CALIBRATION LOG 10 DEGREES

Clinical Center:	□ Alabama □ Iowa	
X-ray tube number:		
Task 2: Place inclir Task 3: On the incl Task 4: If above re	nometer on top of a inometer, read off ading not 10 degro 10 degrees and m	the actual degrees of this beam angle. ees caudal, adjust the beam angle so that the ark this on the x-ray tube.

DATE	Staff ID #

l	2	3	4

MOST MONTHLY BEAM ANGLE CALIBRATION LOG 15 DEGREES

Clinical Center:	□ Alabama □ Iowa			
X-ray tube number: _				
Task 1: Angle the to Task 2: Place inclin Task 3: On the incli Task 4: If above rea inclinometer reads (check boxes 1-4 if ta	ometer on top of x inometer, read off ading not 15 degre 15 degrees and ma	tray tube. the actual degr es caudal, adju ork this on the x	ees of this beam st the beam ang	angle.

DATE	Staff ID #	

1

Appendix 5 Medial Tibial Plateau Images



Figure 1. Example of a knee radiograph where the medial tibial plateau is acceptable

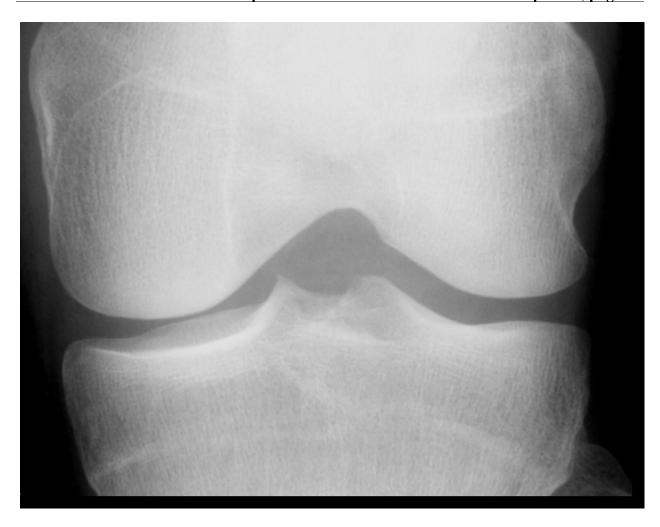


Figure 2. Example of a knee radiograph where the medial tibial plateau is unacceptable

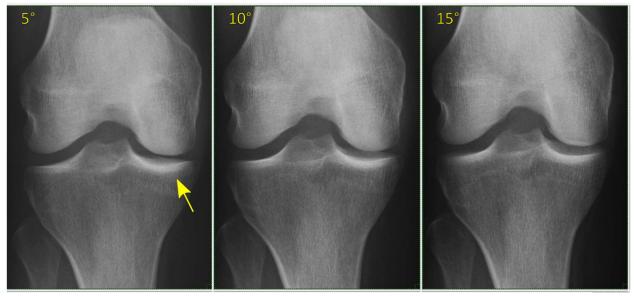


Figure 3. Example of knee radiographs at 5, 10, & 15 degree beam angles, where the 5 degree beam angle radiograph is acceptable.

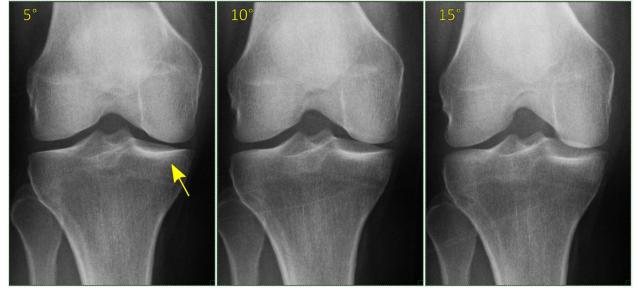


Figure 4. Example of knee radiographs at 5, 10, & 15 degree beam angles, where the 5 degree beam angle radiograph is acceptable.



Figure 5. Example of knee radiographs at 5, 10, & 15 degree beam angles, where the 10 degree beam angle radiograph is acceptable.



Figure 6. Example of knee radiographs at 5, 10, & 15 degree beam angles, where the 10 degree beam angle radiograph is acceptable.



Figure 7. Example of knee radiographs at 5, 10, & 15 degree beam angles, where the 15 degree beam angle radiograph is acceptable.

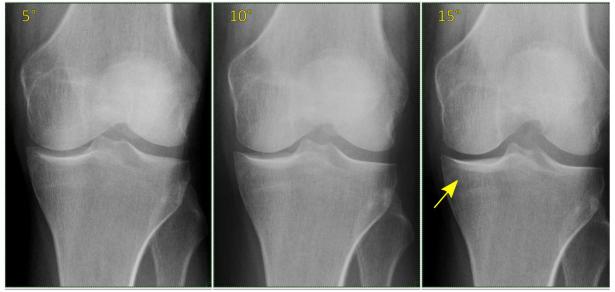
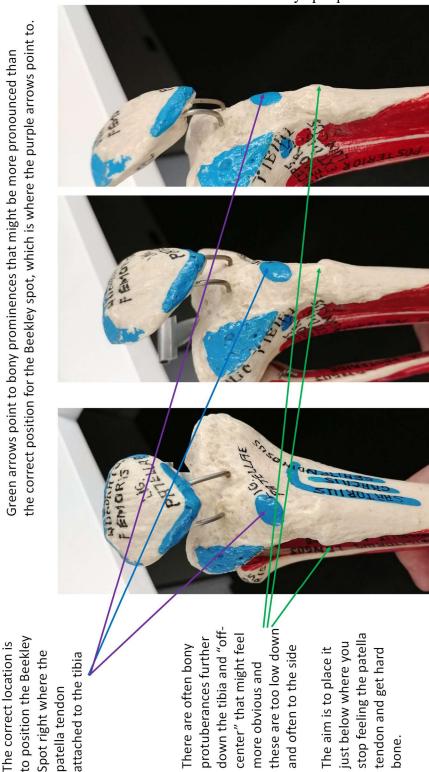


Figure 8. Example of knee radiographs at 5, 10, & 15 degree beam angles, where the 15 degree beam angle radiograph is acceptable.

Appendix 6 Anatomical Location for Beekley Spot Placement

The picture below shows some anatomical hints about Beekley spot placement.



Appendix 7 Instructions for using abdominal binder and wedge filter

Abdominal binder and wedge filter: use these together

Goal: To penetrate the hips but not burn out the knee and ankle joints

When to use:

- If available, check the participant's recorded height and weight can generally get a good idea if the weight seems extreme for the height
- Look at the participant is a large part of the lower abdomen hanging over the hips? If yes, then use the binder.
- Measure the hip area after the binder is placed on the participant. This will help in ascertaining the technique (i.e. kV/mAs) to penetrate the hips but not burn out the knee and ankle joints. Generally, the larger the hip area the more mAs needed but too much will result in a grayer film.
- Place the filter on the tube head. Use the filter when you use the binder

How to use the binder:

- Lay the binder across the table
- Ask the participant to lay on the binder supine with their lower back at the center of the binder
- Have the participant use their hands to pull their lower abdomen up towards their head
- Put the binder across the participant's abdomen as they slip their hand out & velcro the binder so that it is tight enough to hold up the abdomen but not so tight as to be uncomfortable
- Have the participant stand up and set them up for the film

Placement of filter:

- If using a filter where the thickness varies, e.g. a wedge filter, the thickest end of the filter needs to be towards the feet of the participant when placing the filter on the tube head. If the filter is of uniform thickness, either end can be towards the head of the participant
- Position the participant for the film, look at their legs and place the upper end (the side towards the head of the participant) of the filter so that the edge of the shadow cast by the filter will be at the distal third of the femur

Appendix 8 Quality categories for knee x-rays

C category	Sites	Coordinating Center
Acceptable		1=Acceptable
Unacceptable – call back participant	Unacceptable – call back participant	2=Unacceptable, call back
Unacceptable – don't call back participant (protocol completed)		3=Unacceptable, no call back
Unacceptable – don't call back participant (protocol not completed)	Borderline acceptable	3=Unacceptable, no call back
Unacceptable don't call back participant (protocol not completed)		4=>3 months since baseline visit
Unacceptable (protocol not completed)		5=Site decided not to call back participant
Unacceptable (protocol not completed)		6=Participant refused to come back
Bilateral TKR		7= Bilateral TKR

Appendix 9 Repair/Service Log



Equipment Repair / Service Log

O lowa

O Alabama

Month Day Year 4. Were you able to obtain partial or complete data using the equipment during this of Yes a. Did the problem affect the measurement? O Yes O No O Don't know b. Please describe: Day Year	
4. Were you able to obtain partial or complete data using the equipment during this of Yes a. Did the problem affect the measurement? O Yes O No O Don't know b. Please describe: Describe the participants missed having a complete measurement? O Yes O No O No O No O No O No Describe the action taken to solve the problem: A. Date problem was resolved: Month Day Year	
a. Did the problem affect the measurement? O Yes O No O Don't know b. Please describe: Describe Describe	
a. Did the problem affect the measurement? O Yes O No O Don't know b. Please describe: Describe Describe	
b. Please describe: Describe	this problem?
6. Will the participants be asked to return to clinic for this measurement? O Yes O No 7. Describe the action taken to solve the problem: B. Was the problem resolved? O No A- Date problem was resolved: Month Day Year	uipment out of days
O Yes O No Describe the action taken to solve the problem: B. Was the problem resolved? O No A. Date problem was resolved: Month Day Year	participants
O Yes O No Describe the action taken to solve the problem: B. Was the problem resolved? O No A. Date problem was resolved: Month Day Year	
B. Was the problem resolved? O No a. Date problem was resolved: Month Day Year	
a. Date problem was resolved: Month Day Year	
a. Date problem was resolved: Month Day Year	
a. Date problem was resolved: Month Day Year	
Month Day Year	
b. Please describe how the problem was resolved:	

Version 1.0, 2/24/09