

Procedure Manual for Radiographic Examinations of the Knee, Hand, Pelvis and Lower Limbs

Osteoarthritis Initiative: A Knee Health Study



OAI

RADIOGRAPHIC PROTOCOL MANUAL:

Osteoarthritis Initiative: A Knee Health Study

***Baseline, 12-, 24-, 36-, 48-, 72- and 96-month visits
(18- or 30-month visits)***

14 June 2013

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1.0 INTRODUCTION

The purpose of this manual is to standardize the radiograph acquisition and assessment procedures among the centers participating in the OAI study.

1.1 Participant Subcohorts and Schedule of Radiographic Examinations

The OAI participants are split into three cohorts. The progression cohort consists of participants with symptomatic knee OA at the beginning of the study. The incidence cohort consists of participants who do not have symptomatic knee OA at the beginning of the study, but who have a high risk of developing knee OA. The control cohort consists of participants who do not have knee symptoms or radiographic evidence of tibiofemoral knee OA at the beginning of the study.

The radiographs acquired for a participant will differ depending in their subcohort assignment and visit.

1.2 Procedure for Repeat Exams

Repeat exams should be performed as quickly as possible. **Ideally, radiographs of insufficient quality should be identified by the radiology technologist at the time of acquisition and repeated immediately.**

Repeat exams should be taken within 2 weeks of the original radiograph.

2.0 TECHNIQUE AND EXAMINATION PROCEDURES FOR RADIOGRAPH ACQUISITIONS

Because of the need to assess small changes over time, the quality criteria for radiographs in a study are stricter than in standard clinical practice. The most reliable evaluations of the radiographs require adherence to uniform acquisition and quality standards by all study sites involved.

2.1 Bilateral PA Fixed Flexion Knee Radiograph

Radiographs of both the right and left knees will be acquired using this protocol in all participants at screening, 12 months, 24 months, 36 months, and 48 months. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate progression of the disease.

2.1.1 Bilateral PA Fixed Flexion Knee Radiographic Technique

Exposure Technique

Imaging System	Bucky	Recommended
Focus-Film Distance (FFD)	72"	Required
Film Size	14" x 17"	Required
mAs	Dependent on Film/Screen system	
KVp Range	65-72 kVp	Recommended
Focal Spot	Small	Required
Other	Use Right/Left Lead Markers	Required

Examination Procedure

At the beginning of each week the x-ray tube should be calibrated to ensure that a 10 degree caudal (toward the feet) angle as indicated by the tube angle indicator is actually 10 degrees. Angle the tube so that it is at 10 degrees caudal according to the dial. Place the inclinometer on the top of the x-ray tube so that its base is aligned with the long axis of the tube. Read off the actual degrees of the beam angle. If not 10 degrees caudal, adjust the beam angle so that the inclinometer reads 10 degrees. Mark this spot on the x-ray tube. This will be the “10 degree” beam angle that is used in the study. Record results on the inclinometer calibration form.

Positioning the Participant

- The anterior wall of the SynaFlexer positioning frame must be in direct contact with the bucky, cassette holder or reclining table top of the radiographic unit such that there is no angle or gap between them. Lower the bucky or cassette holder so that the center of the film will be at the level of the participant’s tibiofemoral joint line. Position the center line of the positioning frame to the center of the bucky or cassette holder.
- Position the participant in a standing upright position on the frame facing the bucky, cassette holder or reclining table top.
- The great toes of both feet are placed in contact with the anterior wall of the frame (Fig. 1).
- Both feet are fixed in external rotation by pressing the inner aspects of the foot and heel against the V-shaped support on the base of the frame (Fig. 1).
- Both knees are flexed until they touch the anterior wall of the frame. This fixes the angulation of the tibias.
- With the great toes and knees still touching the anterior wall, both thighs are also pressed directly against the wall to fix the angulation of the femurs (Fig. 1).
- Gently push the participant forward with your hand in the small of the back to ensure firm contact of both thighs with the wall of the frame. **IMPORTANT:** the toes, knees and thighs must all be in firm contact with the wall of the frame in order for knee flexion to be reproduced exactly on follow-up radiographs.
- Body weight is distributed equally between the two legs.
- Shield the participant’s gonads with a half apron.

Positioning the X-ray Tube and Film Comments

- Angle the x-ray tube to 10° caudal (Fig. 2).
- Without altering the beam angle or the vertical position of the beam, reposition the beam so that it is centered midway between the two knees at the level of the joint line, defined by the horizontal skin crease of the popliteal fossa.

- If it is difficult to identify the knee crease in obese subjects, ask them to increase the flexion of the knees determine the knee crease and then return them to the proper flexion for imaging (pressing the thighs against the anterior wall of the frame). If this maneuver does not help, try to feel the tibial tuberosity and inferior rim of patella, and center the beam between these two anatomical structures. Mark the skin with a felt pen if necessary. Remember that beam centering above or below the knee crease will alter the projection of the tibial rims and the joint space on the radiograph and deteriorate the reproducibility of serial measurements. Accordingly, precise beam centering and angulation is critical to the success of the study.
- Collimate to the size of the film.
- Use small lead Right/Left markers and place them on the cassette close to the knees but where they will not obscure the knees or the location for study label. Properly collimated images will include the entire femoral and tibial metaphyses, the head of the fibula, at least 5 metal beads of the SynaFlexer, and the Right/Left markers.
- Expose both knees on one film and approximately equidistant from the center of the film. See special remarks for participants with varus deformity (“bow legs”).

Special Remarks

- 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. Both knees should be completely visible on the image, with the lateral femoral and tibial bone margins visible without the use of a high intensity light. In extreme cases, it will be necessary to image each knee separately in order to get an adequate coverage of each knee. When imaging an individual knee, center the knee on the film and center the beam on the knee (**not** on the column of beads). Be sure the beads are visible on the film (See the first example in section 2.1.3).

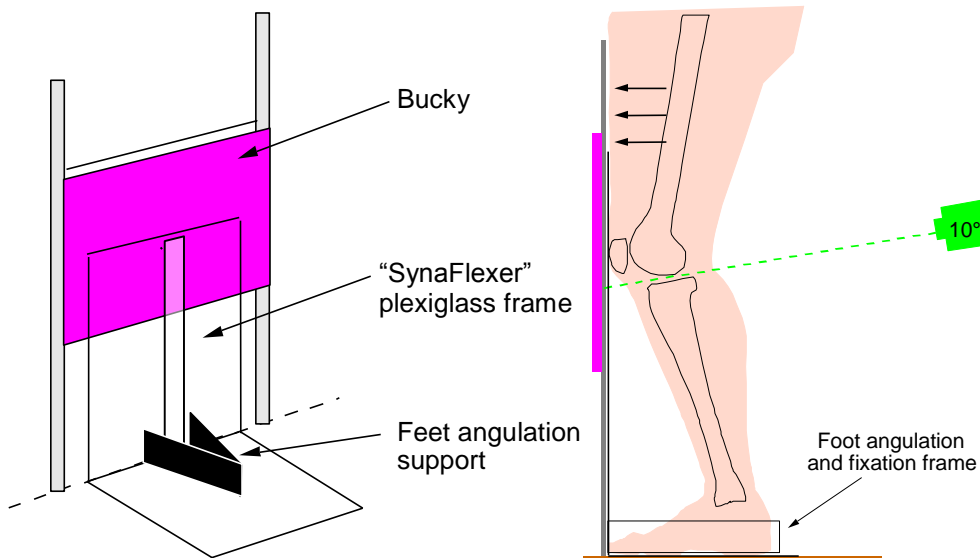


Figure 1— SynaFlexer for reproducible feet fixation and knees flexion. The frame is positioned with its anterior wall in direct contact with the bucky, cassette holder or reclining table top such that both knees are centered on the film. With the great toes touching the anterior wall of the frame, both feet are fixed in external rotation by pressing them against the V-shaped support on the base of the frame. Body weight is distributed equally between the two legs. Both knees and thighs are pressed against the anterior wall of the frame in order to fix flexion of the knees. The x-ray beam is angled 10° caudal and centered at the level of the joint line midway between the two knees.



Figure 2— Proper participant positioning and beam angulation for radiography of the knees. The left panel shows proper positioning against a bucky. The right panel shows proper positioning with a reclining table unit.

2.1.2 Criteria for Assessing Quality of Bilateral PA Fixed Flexion Knee Radiographs

Common Mistakes

- Incorrect beam angle determined by the position of the SynaFlexer beads.
- Incorrect exposure technique used causing over or underexposure of the image
- Side marker not visualized on the film.

Criteria of good quality bilateral knee radiographs

- Both knees are exposed on one film.
- Both knees should be completely visible on the film. This includes the femoral and tibial metaphyses as well as the proximal fibula. If either knee is partly cut off, repeat with better centering of the knees relative to the film. In the case of severe varus deformity, image each knee separately.
- Optimum exposure to visualize the medial and lateral sides of the knee joint, including bone margins, and soft tissue should be clearly visible without the use of a high intensity light.
- The cortex of the tibial plateau floor should be clearly delineated.
- The articular surface of the medial femoral condyle must be sharply delineated.
- Medial tibia plateau should be flat; ideally with the anterior and posterior tibial margins superimposed.
 - There are some cases where the tibial margins may not be aligned even on a properly acquired image, however if the x-ray beam has not been correctly angled and/or the beam not correctly centered at the joint line, this may cause poor alignment of the tibial plateau rims and should be corrected.
- Beam angle is 10 degrees and centered at the level of the knee joint line as indicated by the position of the SynaFlexer beads.
- At least 5 beads from each column of the SynaFlexer frame should be clearly visible on the film.
- Right/Left side markers are present on film.

2.1.3 Examples of Bilateral PA Fixed Flexion Knee Projection

Bilateral PA Fixed Flexion Knee – Acceptable



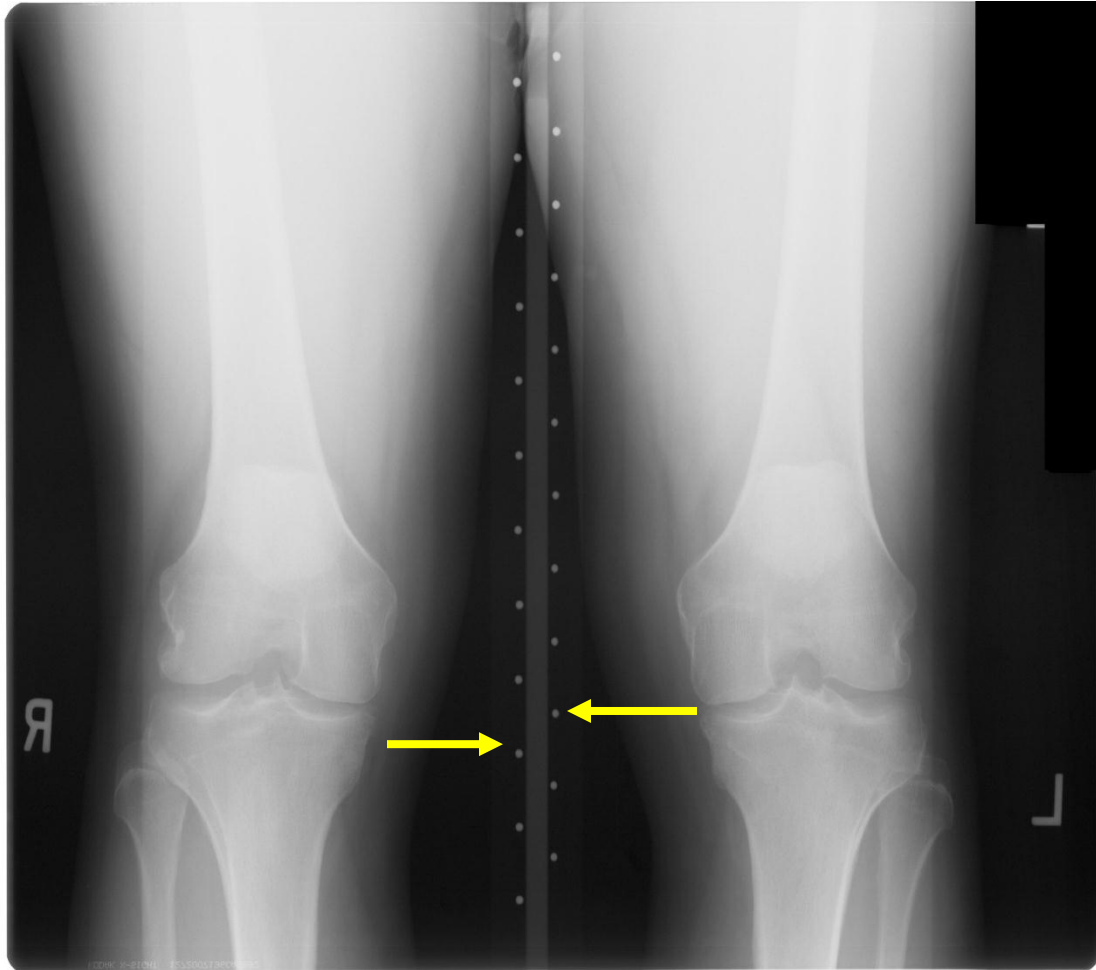
An image with good contrast. The cortical rims of the tibial plateaus are clearly delineated and at least 5 beads from each row of the SynaFlexer frame are visualized.

Bilateral PA Fixed Flexion Knee – Acceptable



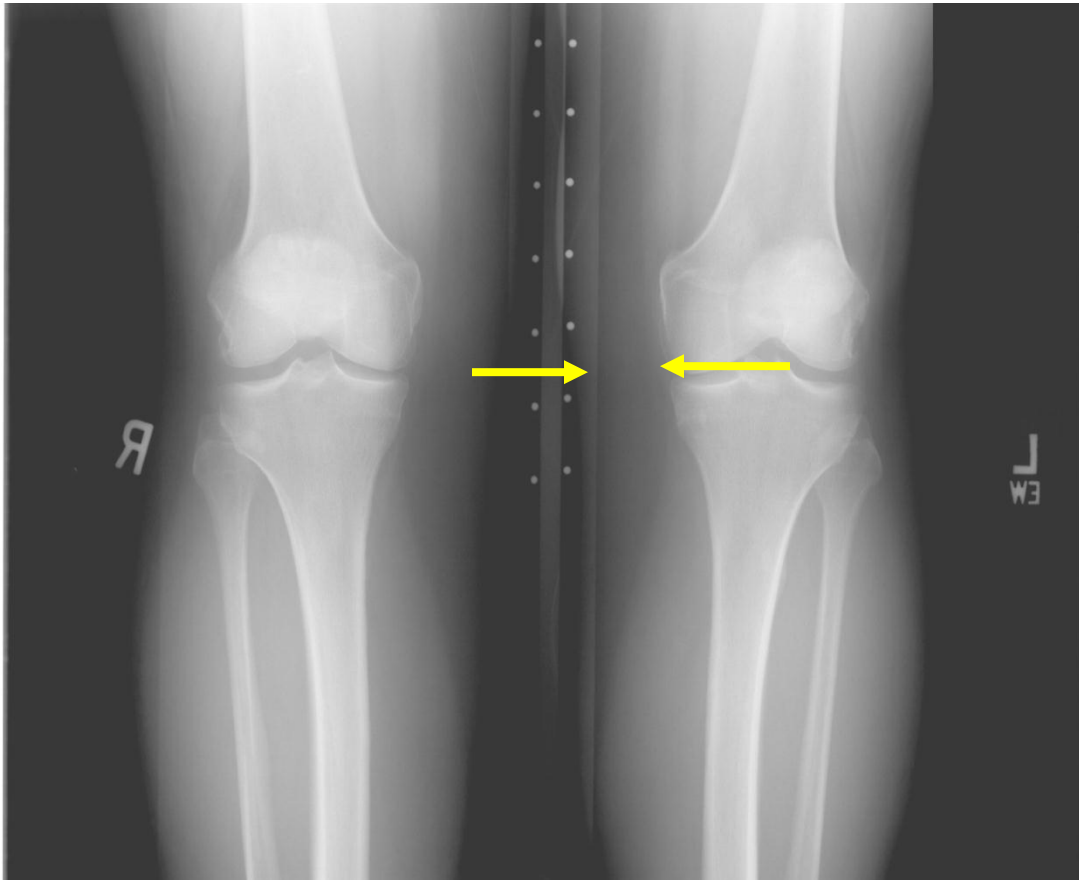
The cortical rims can be poorly aligned even when the participant has been positioned in the SynaFlexer correctly and the x-ray beam has been angled and centered properly. However, if the tibial rims are poorly aligned due to incorrect beam angulation (determined by the position of the double row of beads on the SynaFlexer at the level of the joint space) or the knees are incorrectly centered on the film, then a repeat may be requested.

Bilateral PA Fixed Flexion Knee – Unacceptable



This is a poor quality bilateral knee image due to incorrect beam angulation (> 10 degrees, determined by the position of the SynaFlexer beads at the level of the joint space) and incorrect centering of the knees.

Bilateral PA Fixed Flexion Knee – Unacceptable



The tube angle is too shallow as indicated by the parallel position of the SynaFlexer beads in the two columns at the level of the joint space. When the tube is angled 10° caudal per the study protocol, the columns of beads near the right knee will appear lower than the column of beads near the left knee producing a “staggered” appearance (as above; see example of the impact of different beam angles on page 34). The central ray should always be set to 10° caudal, and then centered on the popliteal fossa. Check the x-ray tube weekly with the inclinometer to determine the accuracy of the tube head reading. Record the results in the log book.

2.2 Hand Radiograph

For the OAI study, postero-anterior (PA) radiographs will be taken for the dominant hand (or both hands at selected sites) at Enrollment and 36 Months or 48 Months. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate progression of the disease.

2.2.1 Hand Radiographic Technique

Exposure Technique

The film should be exposed to optimally depict trabeculae and joint spaces.

Radiographic Table	Central ray perpendicular to point midway between the head of the 2nd and 3rd MCP joint.	Required
FFD	40"	Required
kVp	50-55 kVp	Required
mAs	Dependent on Film/Screen system 7-13 mAs	Recommended
Focal Spot	Small	Required
Collimation	Full size of the film	Required
Cassette	10" x 12" (single hand); 11" x 14" (bilateral)	Recommended
Film	Single emulsion film. Please make sure the film is loaded with the emulsion side (dull) to the screen.	Recommended
Lead Markers	Use Right/Left lead markers	Required

Examination Procedure for Single Hand

Positioning the Participant

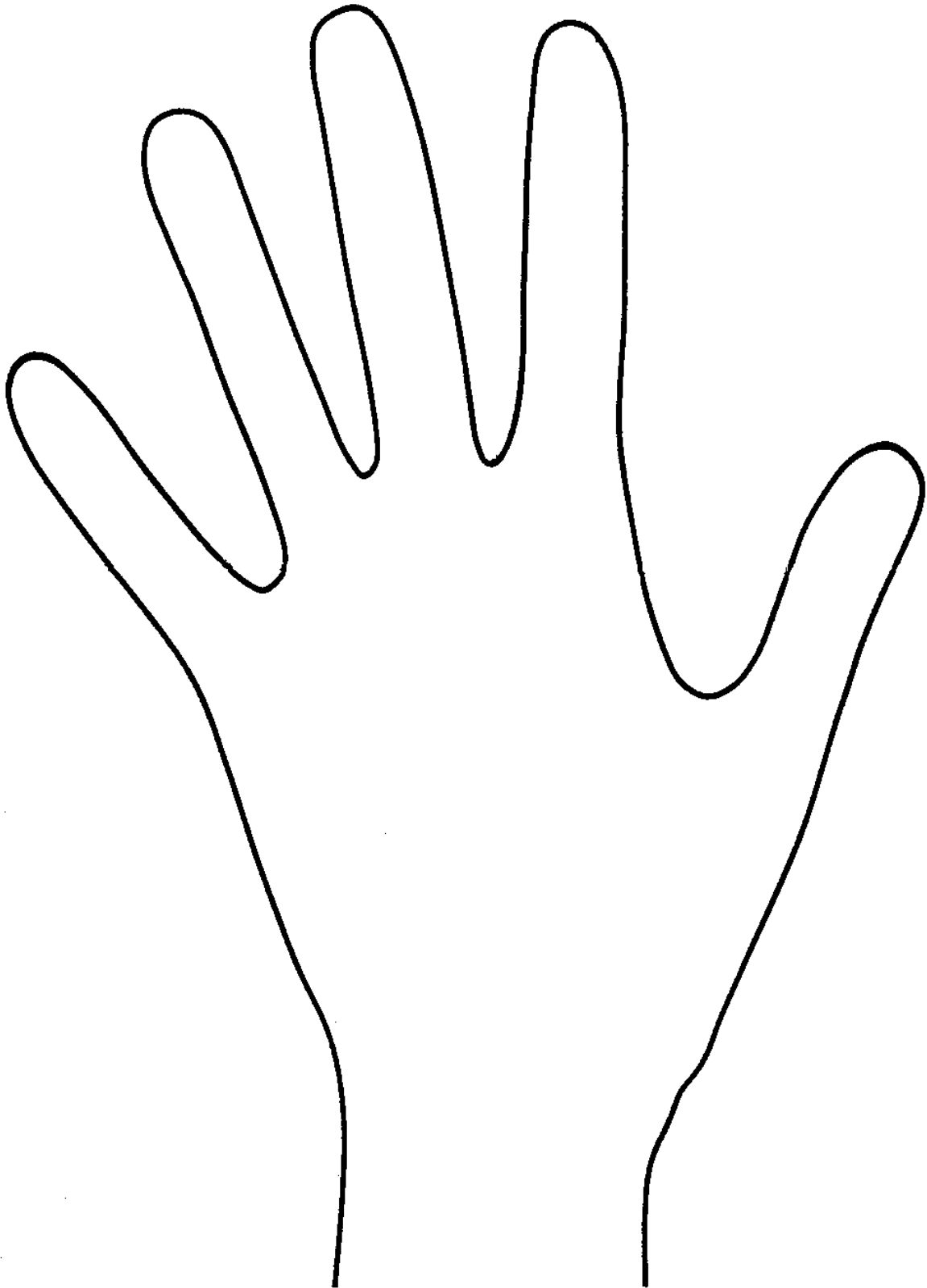
- Explain the procedure to the participant.
- Ask participant to remove all rings and jewelry from hand and wrist.
- Place the participant comfortably in a chair next to the table. The surface of the table should be slightly lower than the participant's shoulder: approximately the level of the axilla (Fig. 3).
- Flex the elbow approximately 90° (Fig. 3).
- Place the palm, wrist and entire forearm flat against the cassette. A sandbag may be placed across the forearm to help stabilize it.
- Center the transparent "Hand Positioning Aid," (see example found in this section) on the cassette and place the participant's dominant hand and wrist on it.

- Position the hand in slight ulnar deviation so that the index finger falls along a straight line through the radius (Fig. 4).
- Spread the fingers slightly apart, as on “Hand Positioning Aid.”
- The palm and wrist should be kept firmly in contact with the cassette. This usually requires conscious effort on the part of the participant as there is a natural tendency to supinate the forearm and flex the knuckles lifting the radial side of the hand and wrist off the cassette. **Therefore, please tell the participant to make an effort to keep the hand flat. A sandbag across the forearm helps to stabilize the arm.**

Examination Procedure for Bilateral Hands

Positioning the Participant

- Ask participant to remove all rings and jewelry from hand and wrist.
- Place the participant comfortably in a chair next to the table. The surface of the table should be slightly lower than the participant’s shoulder: approximately the level of the axilla (Fig. 3).
- The elbow should be flexed approximately 90° (Fig. 3).
- The entire forearm should be flat against the x-ray table (i.e., the wrist should not be extended). A sandbag may be placed across the forearm to help stabilize it
- Center the transparent Hand Positioning Aid, (next page) on the half side of the cassette to be exposed and rest the participant’s hand on it.
- Position the cassette in a landscape position and mask the side that will not be exposed with lead. The right hand should be exposed on the right side of the film and the left hand should be exposed on the left side of the film so that when the film is entirely exposed, both hands will be displayed with the fingers pointing in the same direction. **IMPORTANT:** The cassette will need to be turned around after the right hand exposure when the participant turns to place their left hand on the table. If the cassette is not turned around, the hands will be displayed pointing in opposite directions (see the last example in section 2.2.3).
- Center each hand on the half side of the film with the metacarpo-phalangeal joints mid-line and the forearm parallel to the short axis of the cassette. Make sure the entire wrist is included.
- Use the Hand Positioning Aid to place the hand in slight ulnar deviation so that the index finger falls along a straight line through the radius (Fig. 4.) and spread fingers slightly.
- Keep the palm and wrist in firm contact with the cassette. This usually requires conscious effort on the part of the participant as there is a natural tendency to supinate the forearm and flex the knuckles lifting the radial side of the hand and wrist off the cassette. **Therefore, please tell the participant to make an effort to keep the hand flat. A sandbag across the forearm helps to stabilize the arm.**



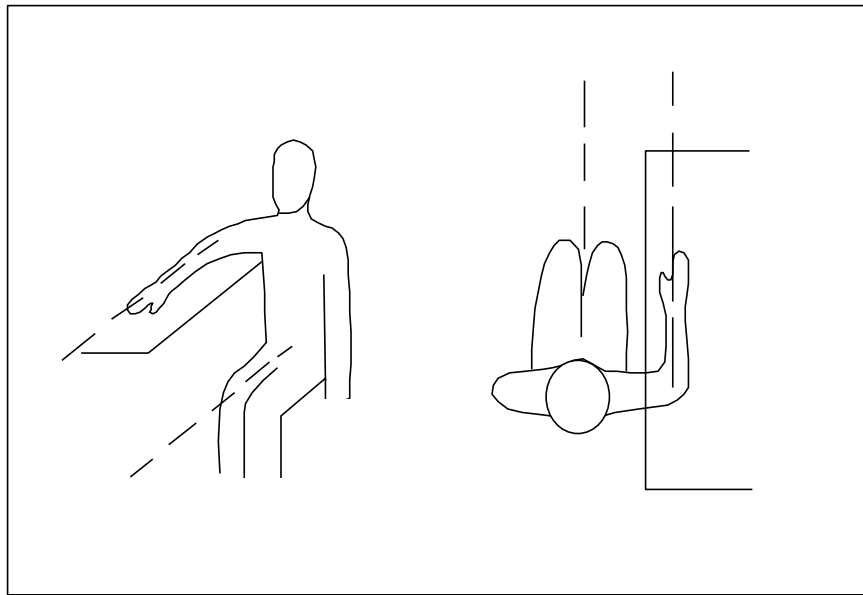


Figure 3— Proper Participant Positioning (right hand radiograph). The participant is seated beside a table at the level of the axilla with the arm resting on the table, the elbow bent 90°, and the forearm parallel to the thigh.

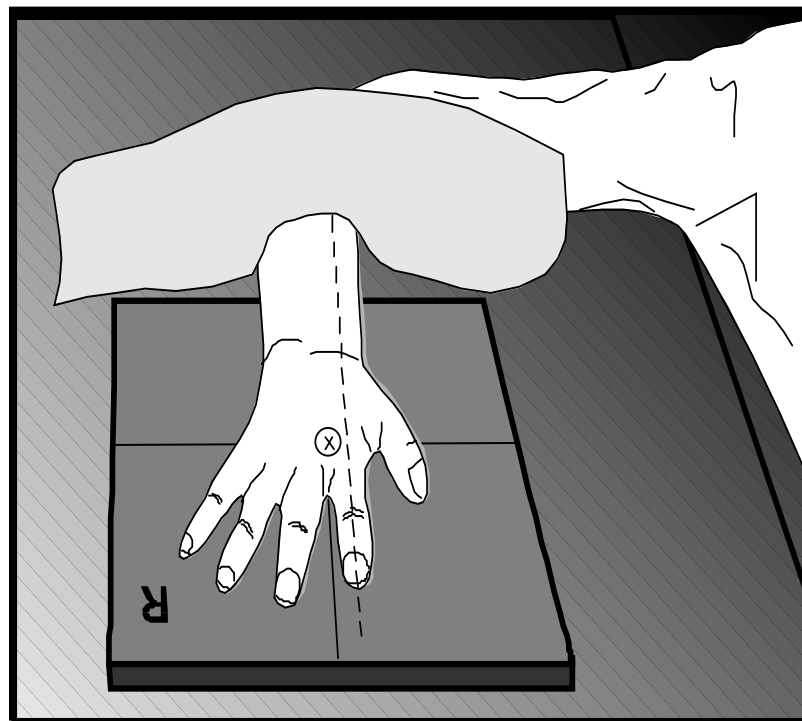


Figure 4— Proper Positioning of the Hand Unilateral: The hand is centered on the film with the palm and forearm pressed firmly against the cassette, the index finger aligned with the radius along the long axis of the cassette, and the fingers spread slightly. The x-ray beam should be centered between the 2nd and 3rd knuckles (⊗). A sandbag across the forearm helps stabilize the arm. Unilateral hand exposed on One Film: In the case of both hands

acquired separately on the same film, the cassette (11" x 14") should be positioned in a landscape position with the side that is not exposed being masked with lead. The right hand should be exposed on the right half side of the film and the left hand should be exposed on the left half side of the film so that when the film is entirely exposed, both hands will be displayed with the fingers pointing in the same direction.

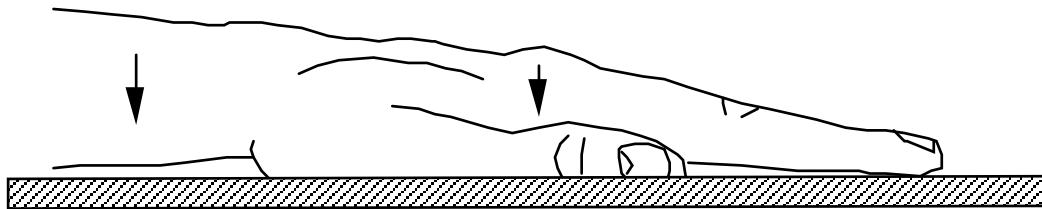


Figure 5— Proper Positioning. Ensure firm contact between the film cassette and the participant's hand. This requires mild effort by the participant; however, the participant should not press so hard as to cause trembling.

If the participant has difficulty maintaining this position, you can place a sandbag across the forearm to help prevent movement. Make sure the sandbag is not on the film. If you use tape to immobilize the hand or straighten arthritic fingers, please use paper tape as other tapes may show up on the film.

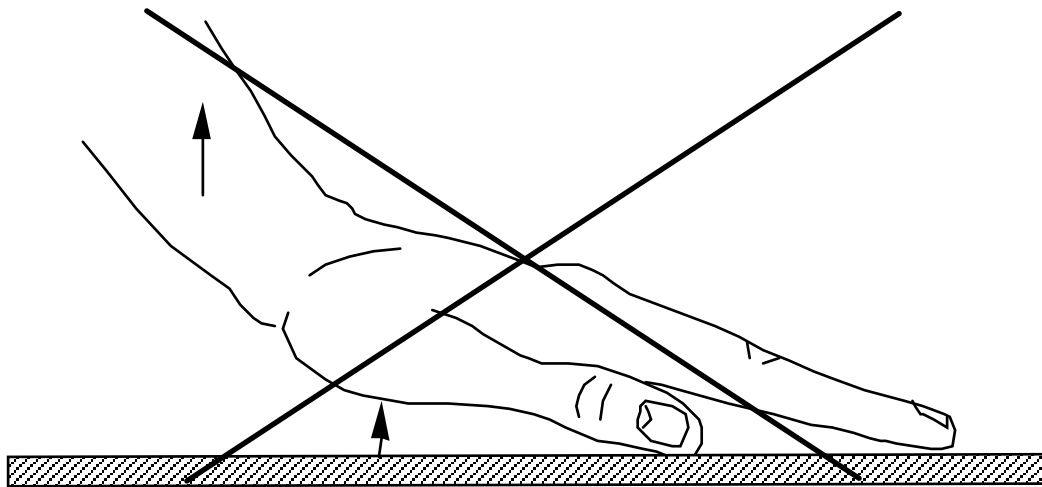


Figure 6— Improper Positioning. If the table level is not high enough (arm is insufficiently abducted) or if the participant does not consciously press hand and wrist against the cassette, the wrist will tend to rise off the film. This leads to image blurring, geometric magnification and superimposition of anatomy.

Positioning the X-ray Tube and Film Comments (Single and Bilateral Hand)

- Center the beam between the 2nd and 3rd metacarpo-phalangeal joints (knuckles) (Fig. 4). The central ray should be at 90 degrees to the plane of the film (Fig. 7).
- Collimate to the size of the film (single hand radiograph) or to the half size of the film (in the case of bilateral hands radiographs). In order to optimize the radiologist's ability to identify subtle pathological changes, the entire film must be exposed to produce a black background against which to view the anatomy. There should be no white margins on the films.
- Use small lead right/left markers and place them on the film where they will not be obscured by the study label, preferably on the lateral side of the hand. Place the markers right side up, so they can be read without reorientation of the radiograph.

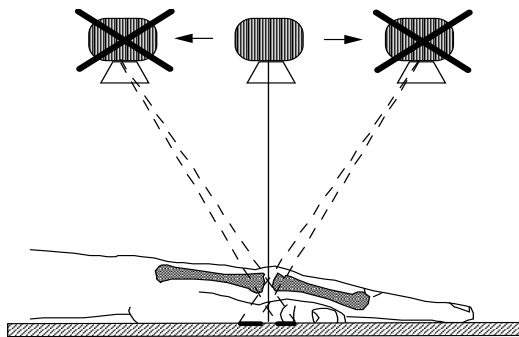


Figure 7— Beam Centering. The x-ray beam should be centered between the 2nd and 3rd metacarpo-phalangeal joints and perpendicular to the film surface. This will image the joints tangentially. Improper beam centering will result in overlapping joint margins.

2.2.2 Criteria for Assessing Quality of Hand Radiographs

Common Mistakes

- Both hands acquired with a single exposure produce incorrect alignment of the forearm, incorrect beam centering, superimposition and blurred contours of the joints.
- Hands incorrectly positioned for the bilateral film. Fingers **should** be pointing in the same direction.
- Poor positioning of the participant :
 - Supination of the forearm (the forearm and the palmar surface of the hand should be pressed flat against the cassette, see Fig. 5 and Fig. 6).
 - Not using the “Hand Positioning Aid” leading to:
 - Incorrect alignment (the index finger should fall along a straight line passing through the radius and parallel to the long edge of the cassette).
 - Fingers and thumb too close together.
- Improper beam centering will result in overlapping joint margins in a hand otherwise properly positioned.
- Incorrect exposure technique used causing over or underexposure of the image.

Criteria of Good Quality Hand Radiographs

- All jewelry (rings, watches, bracelets, etc.) should be removed if possible.
- **The hand should be centered on the film with the index finger aligned with the radius along the long axis of the cassette.** The fingers should be slightly spread apart and the thumb slightly extended. Proper projection of the ulnar styloid (without superimposition) will indicate the wrist was kept flat against the cassette.
- Complete anatomical coverage of the entire hand is required, including the distal radius, ulna and the radiocarpal joint.
- Optimum exposure to visualize and evaluate of all joints of interest, including bone margins, and the trabeculae and joints should be clearly visible without the use of a high intensity light.
- The x-ray beam should be centered exactly between the 2nd and the 3rd metacarpophalangeal joints (knuckles) with no angulation. Improper beam centering will result in overlapping joint margins in a hand otherwise properly positioned.
- Each hand is exposed separately.
- Proper collimation to the size of the film.
- Left/Right side marker should be present on the film.

2.2.3 Examples of Hand Projection

Hand – Acceptable



Good exposure technique used. Hand and wrist visualized. Fingers and thumb are well separated. The index finger is aligned with the radius. No overlapping of contours of the MCP's (indicating proper beam centering). Correct orientation of the ulnar styloid (indicates that the wrist is flat).

Hand – Acceptable



Good bilateral hand film (both hands acquired separately on the same film). Both hands and wrists are completely depicted. Both hands are displayed with the fingers pointing in the same direction.

Hand – Difficult cases



Finger deformities: For mild cases, try to improve alignment by taping the fingers with paper tape. In severe cases where positioning is impossible to correct (as the example above) please do the best that you can.

Hand – Unacceptable



This hand is incorrectly positioned because the fingers and thumb are not well separated. The index finger is not aligned with the radius. The side marker is not visualized on the film. This situation can be avoided by using the hand positioning aid consistently.

Hand – Unacceptable



This hand was incorrectly positioned diagonally across film and the light field was collimated. Failure to expose the entire film resulted in white borders, which transmits excessive light and impairs the radiologist's ability to analyze the image accurately.

Hand – Unacceptable



Both hands on one film acquired with a single exposure leads to incorrect alignment of the index finger to the radius of the hand and wrist and supination of the forearm. The fingers are not separated and the beam has been incorrectly centered in the middle of the film. This causes distortion of the joint spaces which can lead to inaccurate image analyses.

2.3 Pelvic Radiograph

For the OAI study, anteroposterior (AP) radiographs will be taken of the pelvis at Enrollment and 36 Months or 48 Months. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate progression of the disease.

2.3.1 Pelvic Radiographic Technique

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

Exposure Technique

Imaging System	Bucky	Required
FFD	40"	Required
kVp Range	70-80 kVp	Recommended
mAs	Dependent on Film/Screen System	
Focal Spot	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

Positioning the Participant

- Explain the procedure to the participant.
- Ensure clothing and foreign objects (i.e. zippers) are removed from participant's pelvic region as necessary. Use a drape sheet or a patient gown to cover the participant's pelvic region.
- Instruct the participant to remove their shoes.
- Place the anterior wall of the SynaFlexer in direct contact with the bucky, cassette holder or reclining table top of the radiographic unit.(Fig. 8).
- Participant is standing upright on the frame, facing the X-ray tube with the back against the bucky.
- The heels of both feet are placed in contact with the anterior wall of the frame (Fig. 8).
- Both feet are fixed in internal rotation against the V-shaped support on the base of the frame.
- Heels and medial aspects of the feet are in close contact with the frame.

- Body weight is distributed equally between the two legs.
- Ask the participant to hold still during exposure.
- Place a side marker on the film.

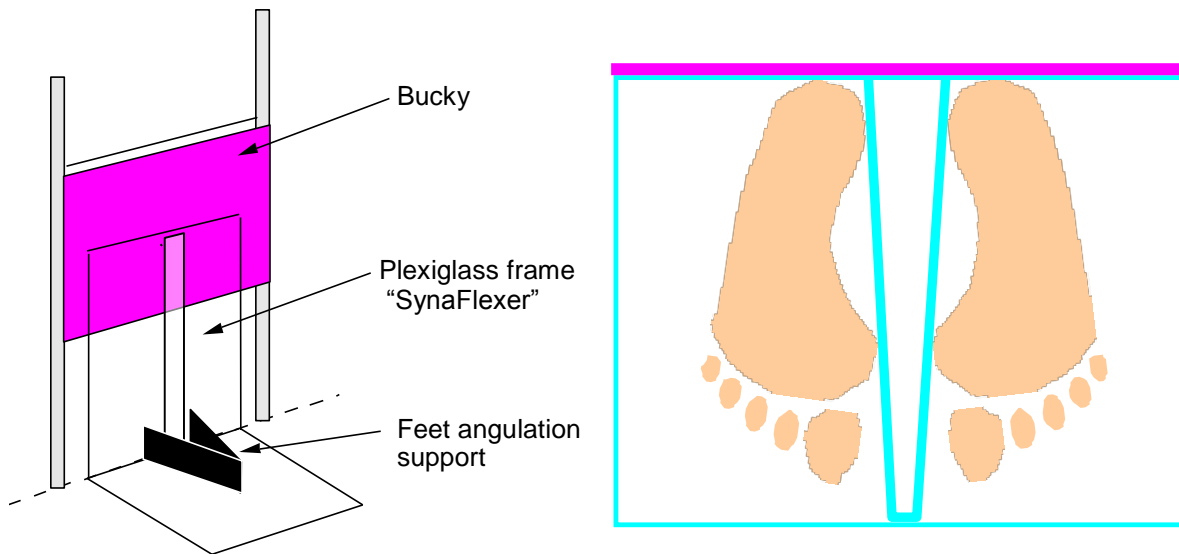


Figure 8— SynaFlexer for reproducible feet fixation. The frame is positioned with its anterior wall in contact with the bucky (or cassette holder or reclining table top). With the heels touching the anterior wall of the frame, both feet (in diagram above right) are fixed in 5° internal rotation by placing the medial side of the heel and forefoot directly 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

- Center the x-ray beam perpendicular to the plane of the film two inches above the symphysis pubis (at the level of the greater trochanter). The symphysis pubis is identified by manual palpation.
- Collimate to the size of the film and include iliac bones entirely.
- 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.

2.3.2 Criteria for Assessing Quality of Pelvic Radiographs

Common Mistakes

- Incorrect beam centering causing superimposition of the joints.
- Incorrect exposure technique used causing over or underexposure of the image
- No markers are visualized on the film.

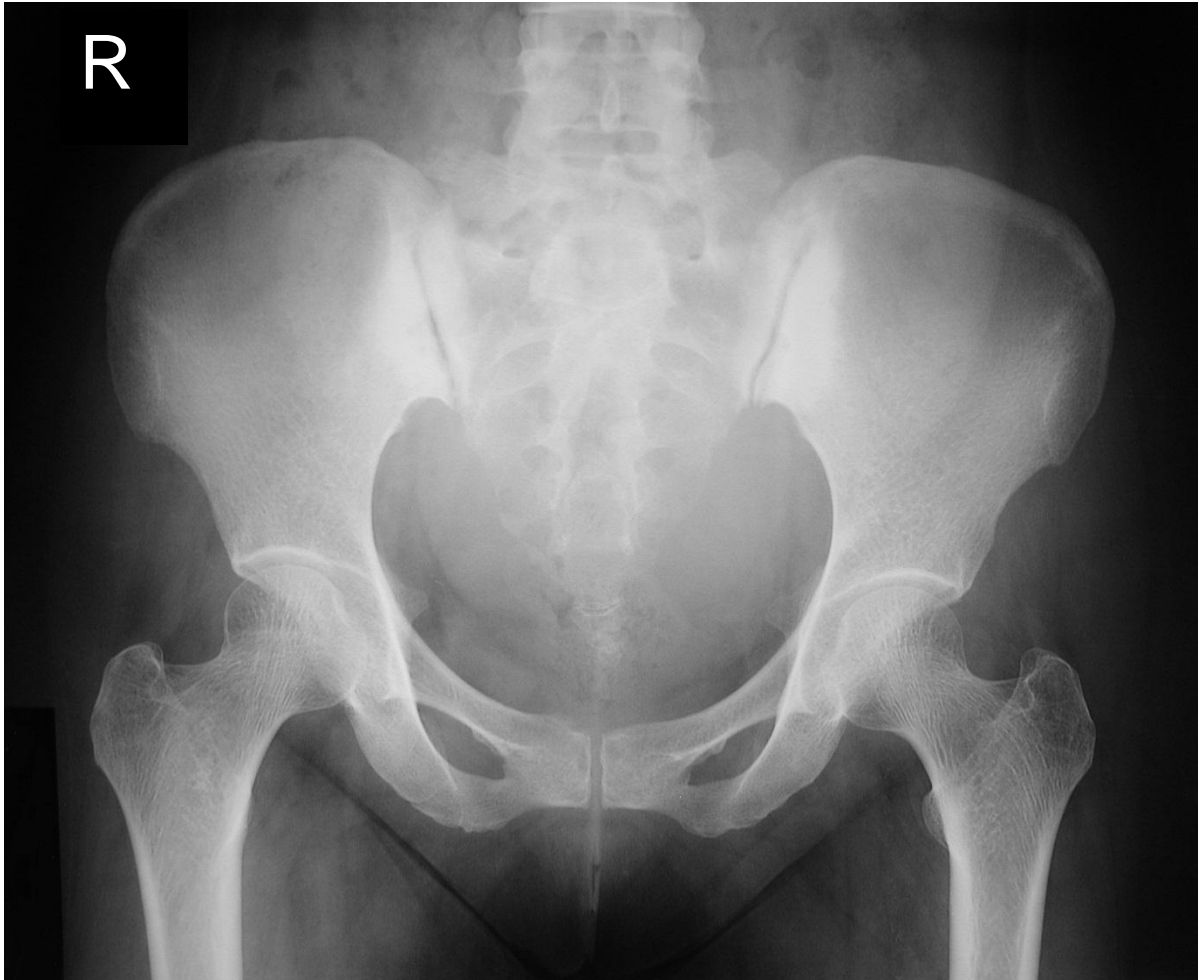
Criteria of good quality pelvic radiographs

- Central ray is centered two inches above symphysis pubis.
- The entire pelvis is depicted, including both hip joints and iliac bones (see the first example in [section 2.3.3](#)).
- Optimum exposure to visualize clear delineation of the hip joints of interest, including the trabeculae, and soft tissue should be clearly visible without the use of a high intensity light.
- Right/Left side markers are on the film.
- Correct exposure of the film.

2.3.3 Examples of Pelvic Projection

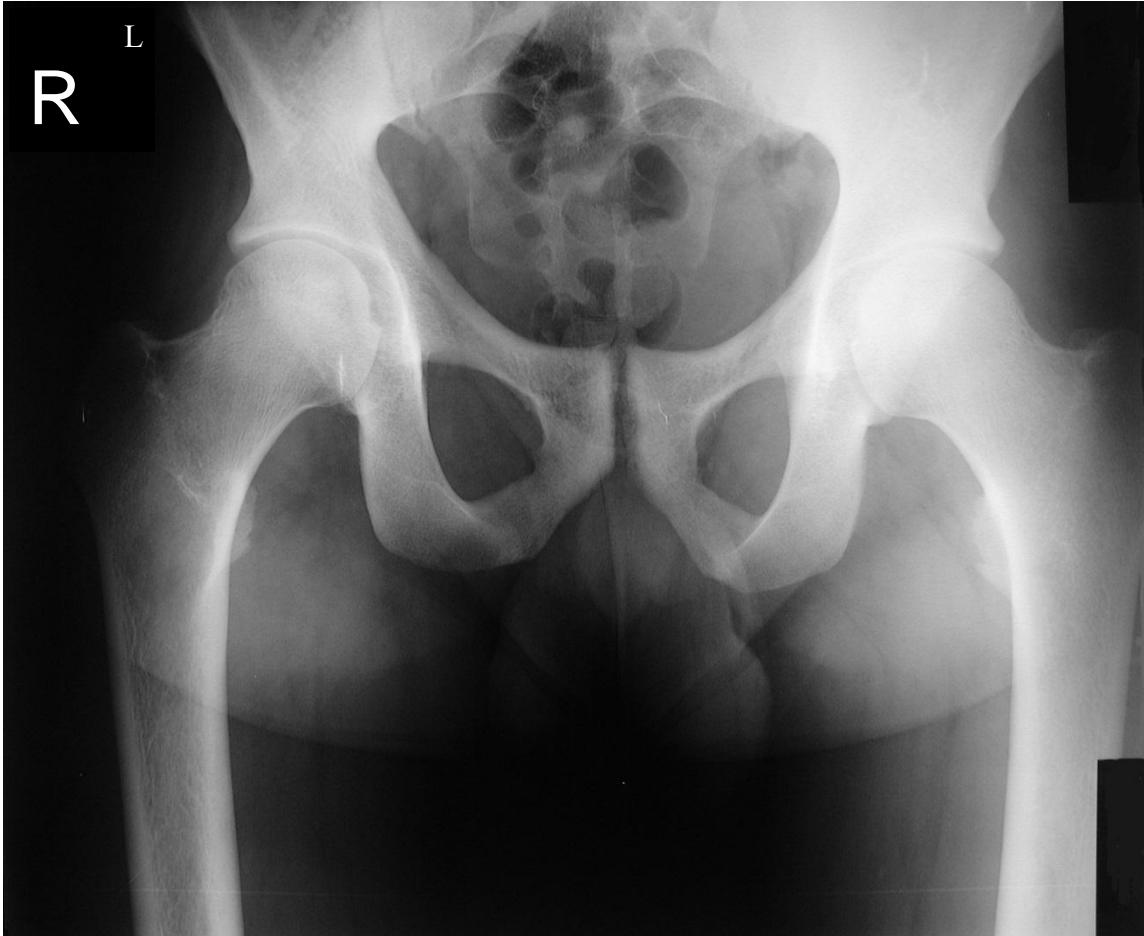
For examples of acceptable and unacceptable quality pelvic radiographs, see the following pages.

Pelvis – Acceptable



This is an acceptable pelvis radiograph because it is properly exposed and centered.

Pelvis – Unacceptable



The iliac bones and right greater trochanter are clipped due to incorrect centering of the pelvis to the film.

Pelvis – Unacceptable



The radiograph is underexposed causing inadequate visualization of the hip joints. Furthermore, the side marker is not present on the image.

2.4 Unilateral PA Fixed Flexion Knee Radiograph with Fluoroscopy

Radiographs of the right and left knees will be acquired separately using the fluoroscopy-guided technique. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate progression of the disease.

Please note: if a participant has a total knee replacement in one knee, do not acquire a fluoro-guided x-ray for that knee.

2.4.1 Fixed Flexion Fluoro Guided Knee Radiographic Technique

Exposure Technique

Imaging System	Bucky	Recommended
Focus-Film Distance (FFD)	47"	Required
Film Size	10" x 12"	Required
Film/Screen Speed	400	Required
KVp Range	65-70 kVp	Recommended
mAs	7-13 mAs (variable)	Recommended
Focal Spot	Small	Required
Densitometer	1 to 1.2	Recommended
Beam Centering	Joint line	Required
Beam Angulation	Aligned with medial tibial plateau	Required
Other	Use Right/Left Lead Markers	Required
Other	Fluoroscopic equipment with variable x-ray beam angulation	Required

Examination Procedure

Positioning the Participant

- Participant positioning is exactly the same as for bilateral PA fixed-flexion knee radiographic technique. (Section 2.1.1).
- Place the anterior wall of the SynaFlexer direct contact with the upright table top of the fluoroscopy unit. Lower the cassette holder so that the center of the film will be at the level of the participant's tibiofemoral joint line.
- Participant is standing upright on the frame facing the anterior wall.
- Center the knee of interest to the cassette.
- The great toes of both feet are placed in contact with the anterior wall of the frame (Fig. 1).

- Both feet are fixed in external rotation by pressing the inner aspects of the foot and heel against the V-shaped support on the base of the frame (Fig. 1).
- Body weight is distributed equally between the two legs.
- Both knees are flexed until they touch the anterior wall of the frame. This fixes the angulation of the tibias.
- With the great toes and knees still touching the anterior wall, both thighs are also pressed directly against the wall to fix the angulation of the femurs (Fig. 1).
- Gently push the participant forward with your hand in the small of the back to ensure firm contact of both thighs with the wall of the frame. **IMPORTANT:** the toes, knees and thighs must all be in firm contact with the wall of the frame in order for knee flexion to be reproduced exactly on follow-up radiographs.
- The participant's gonads are shielded with a half apron.

Positioning the X-ray Tube and Film Comments

- Center the beam to the back of the knee at the level of the joint line, defined by the horizontal skin crease of the popliteal fossa.
- Starting with a horizontal beam at zero degrees, increase the angle caudally under fluoroscopy to achieve superimposition of the midpoint of anterior and posterior rims of the medial tibial plateau (see Fig. 9 below).



Figure 9—In the example shown above, the beam was angled at 5° (left panel), 10° (middle panel), and 15° (right panel): for this knee, the 10° angulation is optimal for clear delineation of the medial joint space, and shows superimposition of the medial tibial rims.

- Expose the knee when the anterior and posterior rims are optimally aligned. The medial tibia plateau should be flat and the vertical distance between the anterior and posterior tibial margins at the center of the medial tibial plateau should not be greater than approximately 1 mm (see Fig. 1 and Fig. 9).
- Fluoroscopic exposure per knee should be in the 5-10 second range.
- At least 5 of the metal beads in the positioning frame must be visible on the radiograph.
- Collimate to the size of the film.

- Use small lead Right/Left markers and place them on the cassette close to the knee but where they will not obscure the knees or the location for the study label.
- In contrast to the non-fluoro technique, each knee is imaged separately with the fluoro technique.
- Repeat the process for the other knee.

2.4.2 Criteria for Assessing Quality of Fixed Flexion Fluoroscopy Guided Knee Radiographs

- Each knee is exposed on a separate film.
- Each knee must be centered on the film.
- The medial tibia plateau should be flat; the vertical distance between the anterior and posterior tibial margins at the center of the medial tibial plateau should not be greater than about 1 mm (see Fig. 10).
- Optimum exposure to visualize the delineation of the articular cortex of the medial femoral condyles, tibial plateaus and the soft tissue should be clearly visible without the use of a high intensity light.
- The entire joint, including the femoral and tibial metaphyses and the head of the fibula, must appear on the film.
- Each image is collimated to the size of the film
- At least 5 metal beads of both columns of beads in the positioning frame must be visible.
- Right or left side markers are present on both films.

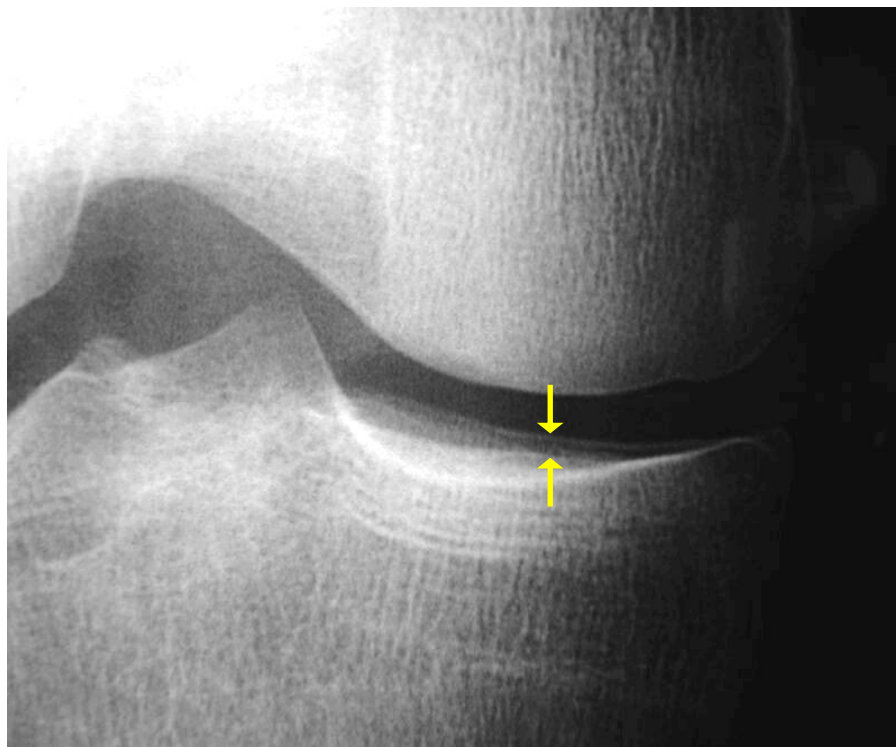


Figure 10—A closer look at the medial joint space: The distance between the anterior and posterior tibial margins at the center of the medial tibial plateau (distance between arrows) should be less than about 1 mm and the cortex of the tibial plateau floor should be sharply delineated.

2.4.3 Examples of Fixed Flexion Fluoroscopy Guided Knee Projection

For examples of acceptable and unacceptable quality fixed flexion fluoro-guided knee radiographs, see the following pages.

Fixed Flexion Fluoro Guided Knee – Acceptable



Good quality posterior-anterior knee radiograph. The knee is well depicted with the anterior and posterior rims of the medial tibial plateau. The image is marked. There is at least 5 beads of both columns of beads of the SynaFlexer frame are visible.

Fixed Flexion Fluoro Guided Knee – Unacceptable



Although this is a good quality posterior-anterior knee radiograph (the medial tibial plateau is flat), this image is unacceptable because the beads of the SynaFlexer are not visible.

Fixed Flexion Fluoro Guided Knee – Unacceptable



Poor positioning and incorrect tibial alignment. The anterior and posterior rims of the medial tibial plateau are not superimposed and are more than 1 mm apart.

Fixed Flexion Fluoro Guided Knee

Unacceptable



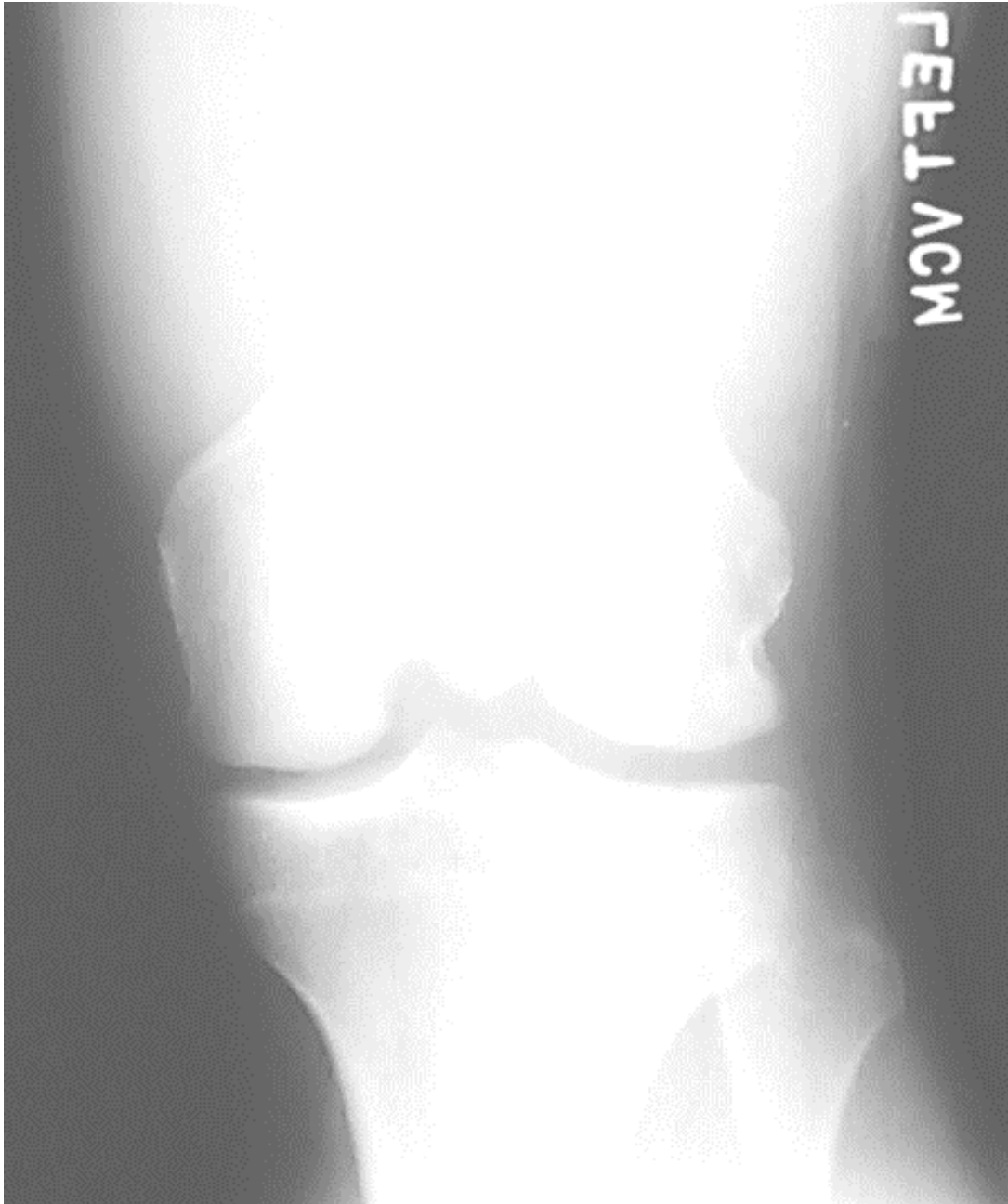
The anterior and posterior rims of the medial tibial plateaus are not superimposed. Furthermore, the side marker and SynaFlexer beads are not visible on the image.

Acceptable



Good quality repeat

Fixed Flexion Fluoro Guided Knee – Unacceptable



Poor Quality: image is underexposed, beads are not visible on radiograph.

2.5 PA Semi-flexed Knee Radiograph with Fluoroscopy

Radiographs of the right and left knee will be acquired separately using the fluoroscopy-guided technique. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate progression of the disease.

If a participant has a total knee replacement in one knee, do not acquire a fluoro-guided x-ray for that knee.

2.5.1 Semi-Flexed Fluoro-Guided Knee Radiographic Technique

Exposure Technique

Imaging System	Bucky	Required
Focus-Film Distance (FFD)	47"	Required
Film Size	10" x 12"	Required
Film/Screen Speed	400	Required
kVp Range	65-70 kVp	Recommended
mAs	7-13 mAs (variable)	Recommended
Focal Spot	Small	Required
Densitometer	1 to 1.2	Recommended
Beam Centering	Joint line	Required
Beam Angulation	Horizontal	Required
Other	Use Right/Left Lead Markers	Required

Examination Procedure

Positioning the Participant

- The single-ball spherical phantom is secured laterally to the knee of interest lateral to the knee at the level of the head of the fibula (secured with gauze, paper tape, or Velcro straps).
- The double-ball rectangular phantom is taped to the cassette in a vertical orientation lateral to the knee in a location where it will not obscure the anatomy.
- Ask the participant to stand upright facing the table on the footboard with the medial border of the foot and heel of the knee of interest parallel to the tape marker on the footboard that indicates 10° of external rotation. Lower the cassette holder so that the center of the film/receptor is at the level of the participant's tibiofemoral joint line.
- Ask the participant to slowly flex both knees until they touch the anterior wall. Then press both thighs against the table.

- Body weight is distributed equally between the two legs.
- The participant's gonads are shielded with a half apron.

Positioning the X-ray Tube and Film Comments

- The horizontal x-ray beam is centered on the back of the knee at the level of the joint line, defined by the horizontal skin crease of the popliteal fossa.
- Starting with the knees extended, the participant slowly flexes both knees during fluoroscopy until the midpoint of anterior and posterior rims of the medial tibial plateau are superimposed (see Fig. 11 below). Participant holds this position without further movement.
- Radiograph the knee when the anterior and posterior rims are superimposed. In contrast to the non-fluoro technique, each knee is imaged separately with the fluoro technique.
- Fluoroscopic exposure per knee should be in the 5-10 second range.
- Collimate to the size of the film.
- Use small lead Right/Left markers and place them on the cassette close to the knee but where they will not obscure the knees or the location for study label.
- Repeat process for the other knee.

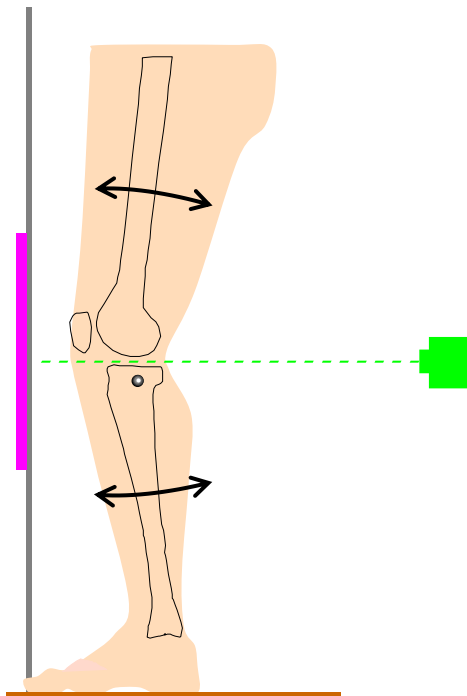


Figure 11— The single-ball metal-ball spherical phantom is strapped to the knee of interest over the head of the fibula. The double-ball rectangular phantom is taped to the cassette in a vertical orientation lateral to the knee in a location where it will not obscure the anatomy. The feet are fixed in external rotation by aligning them with the tape on the footplate. Body weight is distributed equally between the two legs. The horizontal x-ray beam is centered on the femorotibial joint line of the knee of interest. Both knees are flexed during fluoroscopy until the anterior and posterior rims of the medial tibial plateau superimpose. The radiograph is acquired with this knee flexion.

2.5.2 Criteria for Assessing Quality of Semi-Flexed Fluoro Guided Knee Radiographs

- Each knee is exposed on a separate film.
- Each knee must be centered on the film.
- The medial tibia plateau should be flat; the vertical distance between the anterior and posterior tibial margins at the center of the medial tibial plateau should not be greater than approximately 1 mm (see Fig. 12).
- Optimum exposure to visualize the delineation of the articular cortex of the medial femoral condyles, tibial plateaus and the soft tissue should be clearly visible without the use of a high intensity light.

- The entire joint, including the femoral and tibial metaphyses and the head of the fibula, must appear on the film.
- The single-ball phantom over the head of the fibula must be visible on the film.
- The double-ball phantom should be visible on the film superior to the single-ball phantom.
- Right or left side markers are present on both films.

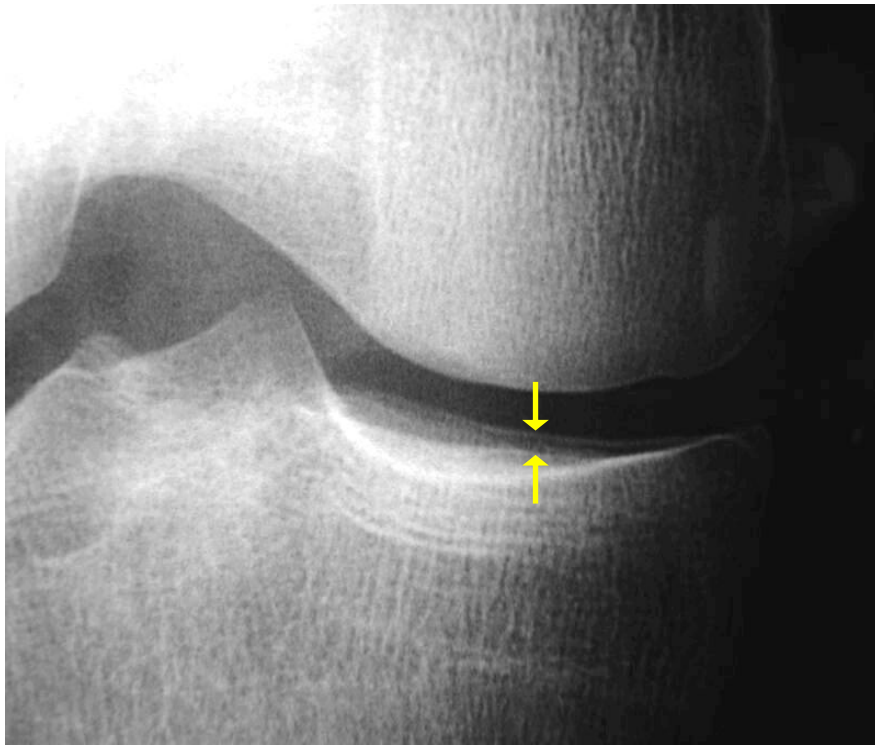
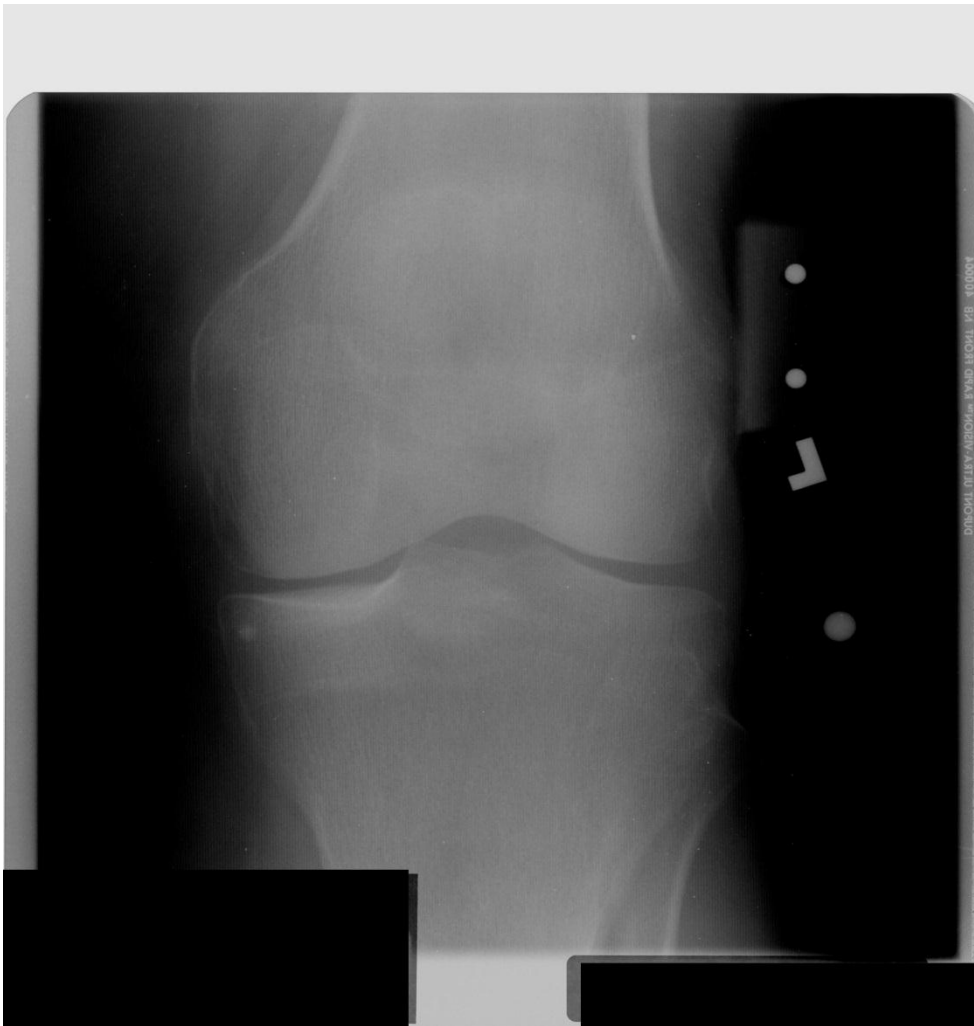


Figure 12— a closer look at a good quality depiction of the medial joint space: The distance between the anterior and posterior tibial margins at the center of the medial tibial plateau (distance between arrows) should be less than 1 mm, and the cortex of the tibial plateau floor should be sharply delineated.

2.5.3 Examples of Semi-Flexed Fluoro-Guided Knee Radiographs

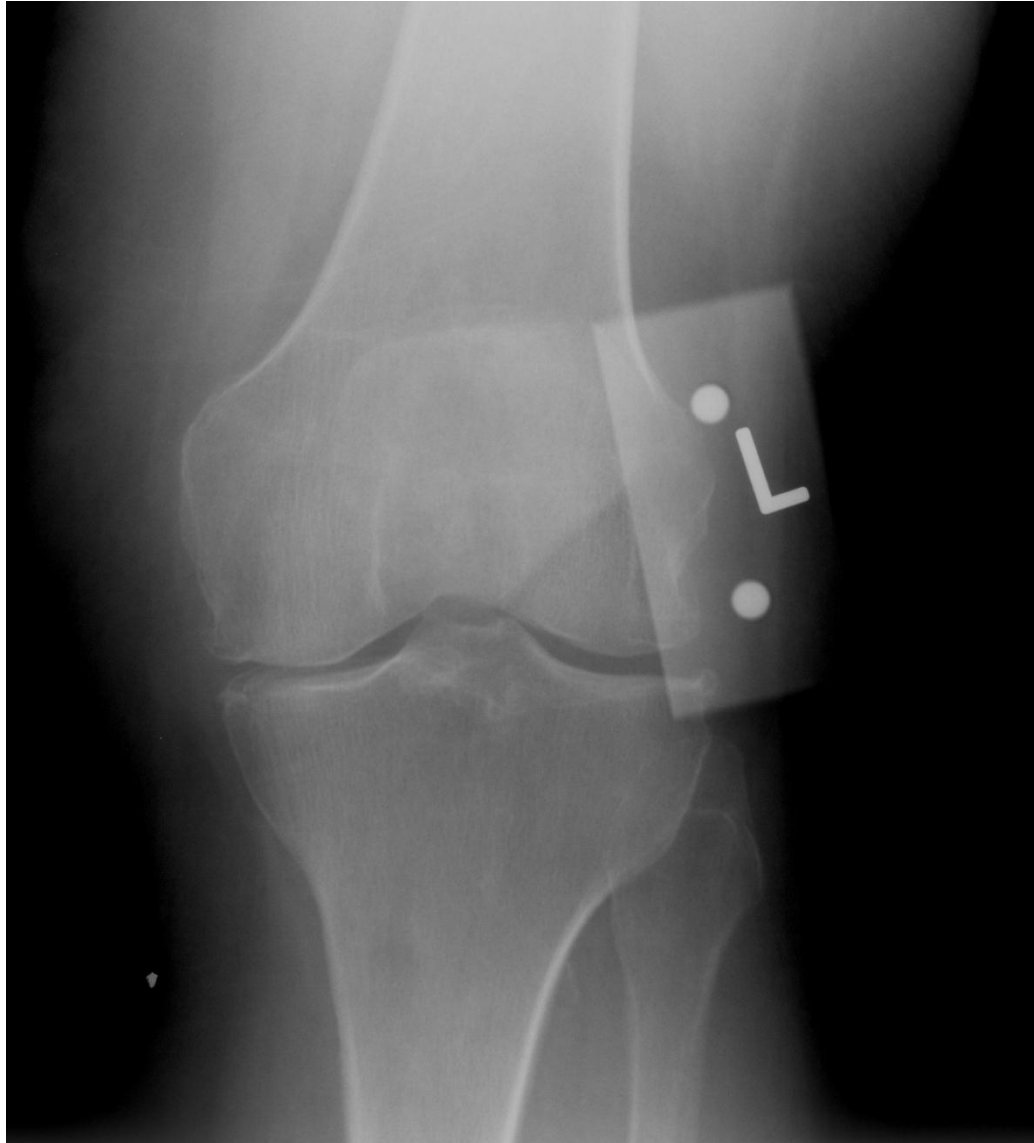
For examples of acceptable and unacceptable quality semi-flexed fluoro guided knee radiographs, see the following pages.

Semi-Flexed Fluoro Guided Knee – Acceptable



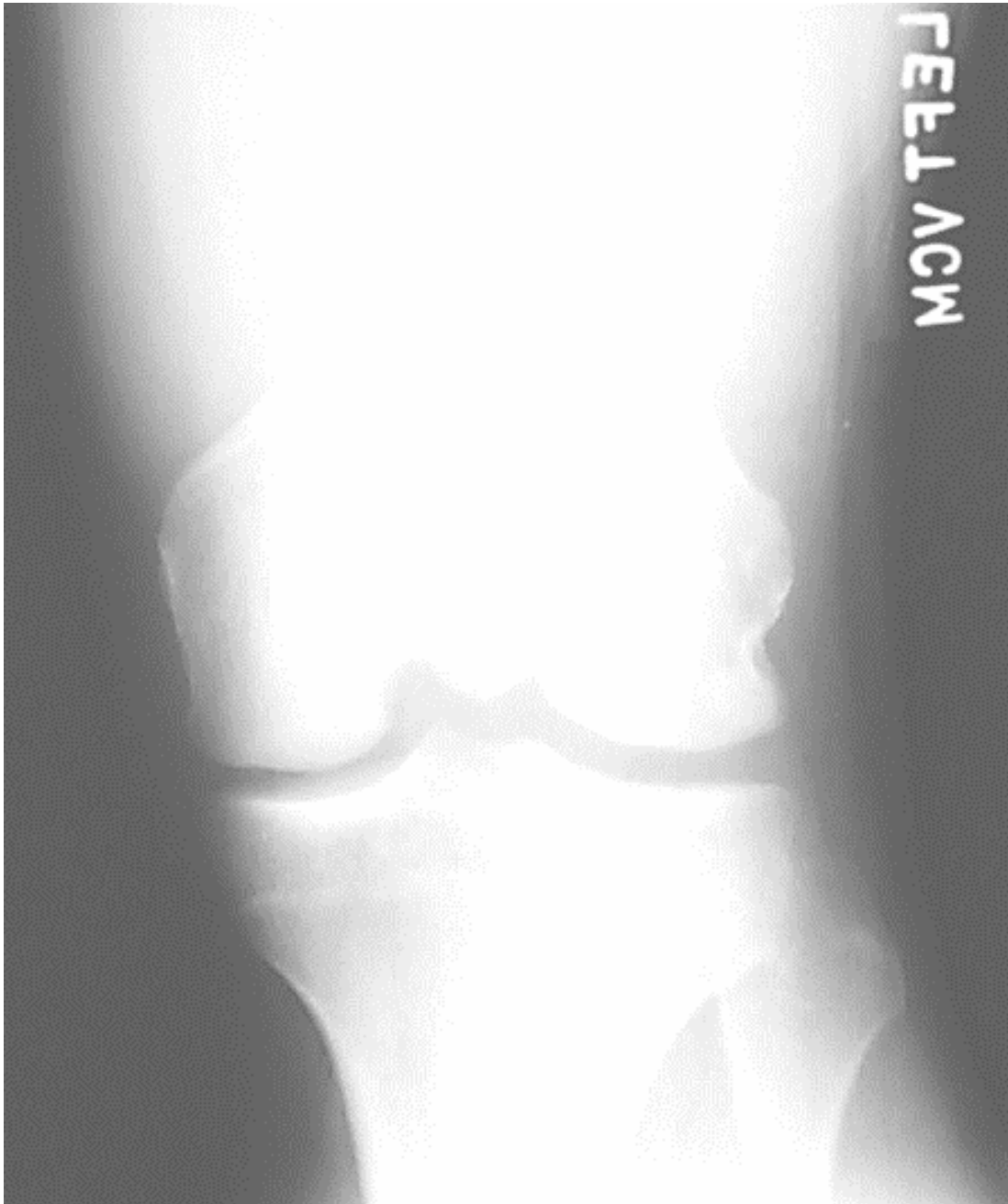
This is a good quality image because the anterior and posterior rims of the medial tibial plateaus are superimposed. The single ball phantom has been attached to the knee (can determine this by its magnification and blurred contours) and the double ball phantom has been secured to cassette in correct orientation.

Semi-Flexed Fluoro Guided Knee – Unacceptable



The anterior and posterior rims of the medial tibial plateau are not superimposed. There is no delineation of the tibial floor. The double ball phantom should not obscure the anatomy and the single ball phantom should be visualized at the level of the head of the fibula.

Semi-Flexed Fluoro Guided Knee – Unacceptable



This image is underexposed and the single and double ball phantoms are not present.

2.6 Lateral Knee Radiograph for Normal Controls

For the OAI study, separate radiographs of the right and left knees will be acquired in the normal control subcohort at Enrollment, 24 Months and 48 Months. For all radiographs, please concentrate on image quality and optimum positioning of the participant since follow-up radiographs will be compared to baseline radiographs to evaluate development of new disease.

2.6.1 Lateral Knee Radiographic Technique

This protocol requires a weight-bearing, semi-flexed position.

Exposure Technique

Imaging System	Bucky	Required
FFD	72"	Required
Film Size	10" x 12"	Required
mAs	Dependent on Film/Screen System	
kVp Range	65-72 kVp	Recommended
Beam Centering	Knee joint	Required
Beam Angulation	0	Required
Focal Spot	Small	Required
Lead Markers	Use Right/Left Lead Markers	Required

Examination Procedure

Positioning the Participant

- Instruct the participant to remove their shoes.
- The participant is standing upright lateral position to the plane of the bucky with the leg and knee to be x-rayed nearer and parallel to the bucky, positioned as close as possible.
- Place the ball of the foot (first MTP joint) on the same side as the knee to be x-rayed in the middle of the horizontal dimensions of the cassette. This will be helpful in centering of the knee to the cassette.
- The foot of the leg not being x-rayed should be in normal stance and just posterior to the foot of the leg being x-rayed (see Fig. 13). Weight is distributed evenly between the feet.
- Have the participant flex the knee to be x-rayed to about 30 degrees by aligning the front of the patella vertically with the tip of the great toe.
- Adjust the participant's hips and/or the forefoot until the knee is in a true lateral position where the anterior rims of the femoral condyles are superimposed and the plane of the patella is perpendicular to the cassette. This will ensure that the x-ray beam will pass

through joint space opening beneath the patella and the anterior femoral condyles will appear superimposed on the film.

- Shield the participant's gonads.

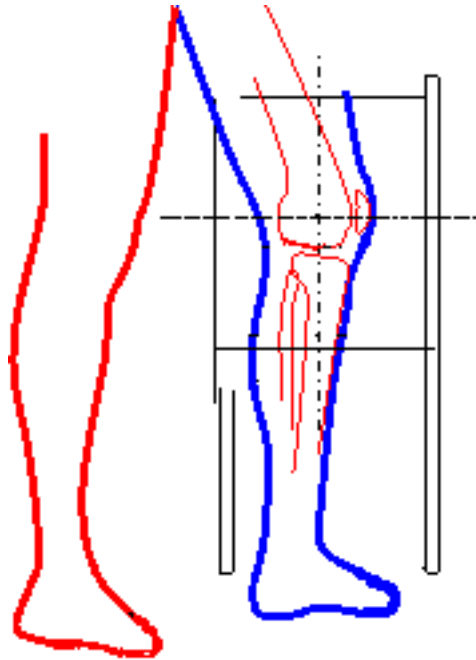


Figure 13— Positioning the participant for the lateral knee x-ray.

Positioning the X-ray Tube and Film

- Place a small ink mark on the surface of the skin of each knee over the bony projections of the medial and lateral epicondyles. These points should be approximately on the same level anterior in the middle of the patellofemoral joint. These landmarks will be used to center the x-ray beam.
- The angle of the x-ray tube is 0°, with the central ray perpendicular to the cassette.
- Center the x-ray beam over the medial epicondyle.
- Collimate to the size of the film.
- Use small lead Right/Left markers and place them on the cassette where they will not obscure the knees or the location for the study label.
- Each knee is x-rayed separately.

2.6.2 Criteria for Assessing Quality of Lateral Knee Radiographs

The primary quality goals for this view are superimposition of the anterior margins of the femoral condyles and a clear and open projection of the joint space between the femur and patella (see examples on following pages).

Criteria of good quality lateral knee radiographs

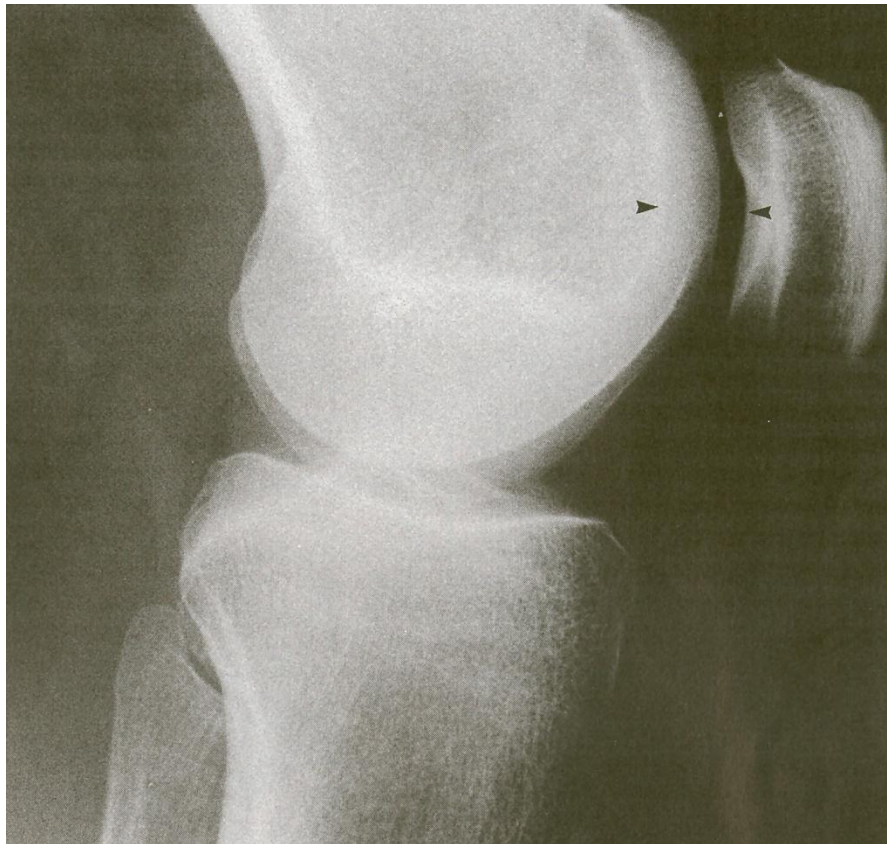
The following quality criteria should be evaluated for each examination:

- Both knees are exposed on a separate film.
- Each knee must appear in the center of the film.
- Optimum exposure to visualize the delineation of the articular cortex of the medial femoral condyles and the patella, and the soft tissue should be clearly visible without the use of a high intensity light.
- Complete depiction of the knee joint including the fibular head, tibial tubercle, and patella.
- **Knee in true lateral position:** The anterior rims of the femoral condyles should be superimposed and their anterior articular surfaces sharply delineated. The patellofemoral joint space should be open.
- Complete depiction of the knee joint including the fibular head, tibial tubercle, and patella.
- Right or left side markers are present on both films.

2.6.3 Examples of Lateral Knee Projection

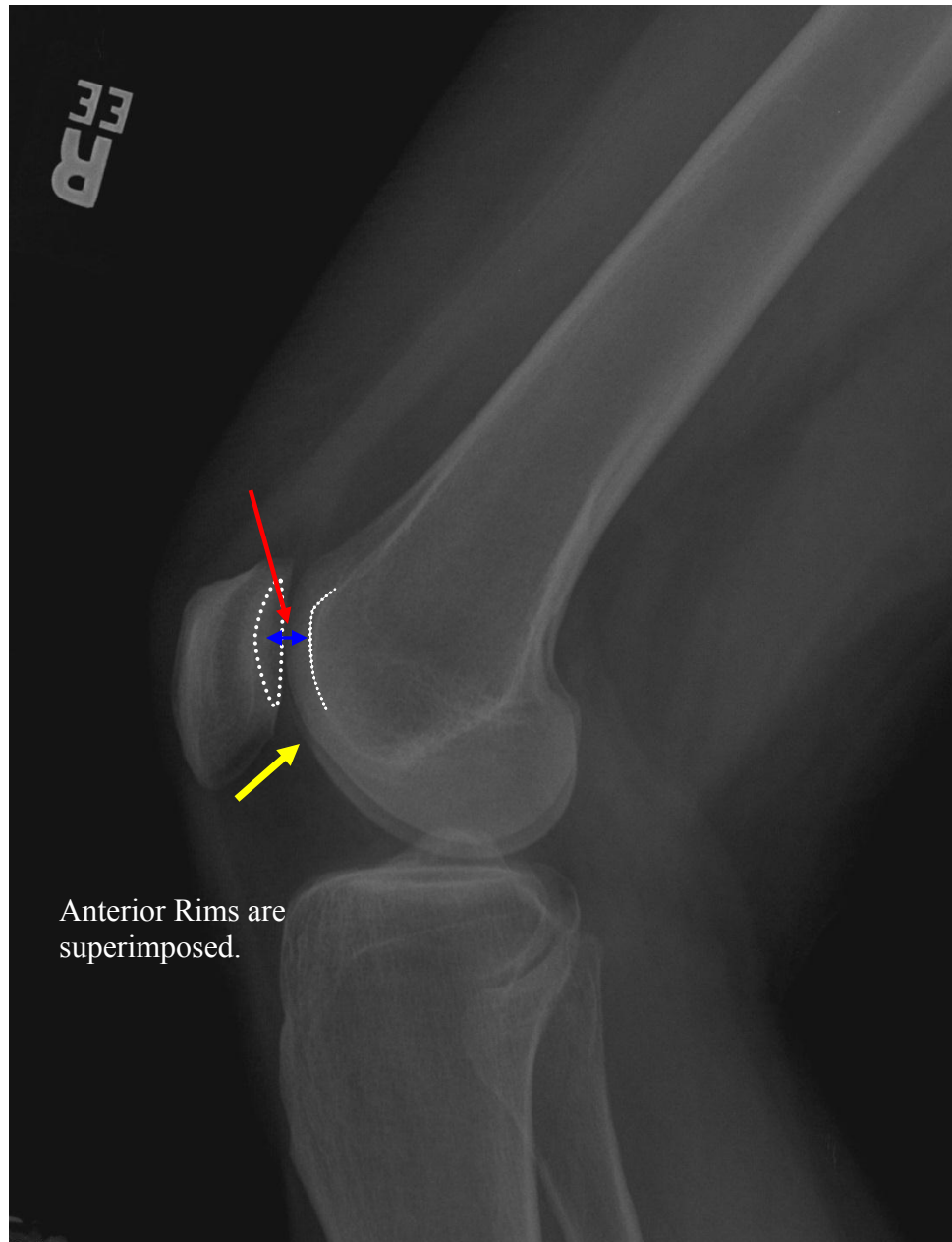
For examples of acceptable and unacceptable quality lateral knee radiographs, see the following pages.

Lateral Knee – Acceptable



A closer look at the patellofemoral compartment. This is a good quality mediolateral radiograph because the anterior surfaces of the femoral condyles are superimposed and the patellofemoral joint space is open (identified by arrows).

Lateral Knee – Acceptable



This is an acceptable lateral knee radiograph of a participant because the anterior rims of the femoral condyles have been superimposed. An accurate measurement can be made of the patellofemoral joint space from the posterior elements of the patella to the intercondylar fossa because the knee was positioned in a true lateral position.

Lateral Knee – Unacceptable



Poor positioning of the knee leading to an oblique view. Femoral condyles not superimposed, and patellofemoral joint space is not clearly delineated.

2.7 Full Limb Radiograph for Progression Subcohort.

Radiographs of both entire lower extremities will be acquired using this protocol in all participants in the Progression Cohort at 12 months. For all radiographs, optimal image quality and positioning is critical because precise measurement will be made from these images.

2.7.1 AP Full Limb Radiographic Technique

Exposure Technique

Site	Imaging System	Focus-Film Distance (FFD)	Film Size	mAs	KVp Range
Pittsburgh	GE Compax 40E	80"	14" x 51"	100-300	80-90 kVp
Ohio State	Continental TM 80-2	84"	3 14" x 17" cassettes	100-300	80-90 kVp
Univ of Maryland	GE MVP 60	80"	3 14" x 17" cassettes	100-300	80-90 kVp
Johns Hopkins	Siemens Multix	80"	14" x 51"	100-300	80-90 kVp
Rhode Island	GE	120"	3 14" x 17" cassettes	100-300	80-90 kVp

Examination Objective

Radiographs of the entire lower extremities are taken together in an upright weight-bearing position. This image (Fig. 14 and Fig. 15) includes complete visualization of the femoral head and the talus of the foot. The objective of this examination is to measure knee alignment. The measurement is made by drawing a line from the femoral head to the knee and from the knee to the ankle surface using specific landmarks. Alignment is characterized as neutral (hip/ knee/ankle angle is 0 degrees), varus (alignment is > 0 degrees contributing to a bow-legged appearance) and valgus (alignment is < 0 degrees contributing to a knock-knee appearance).

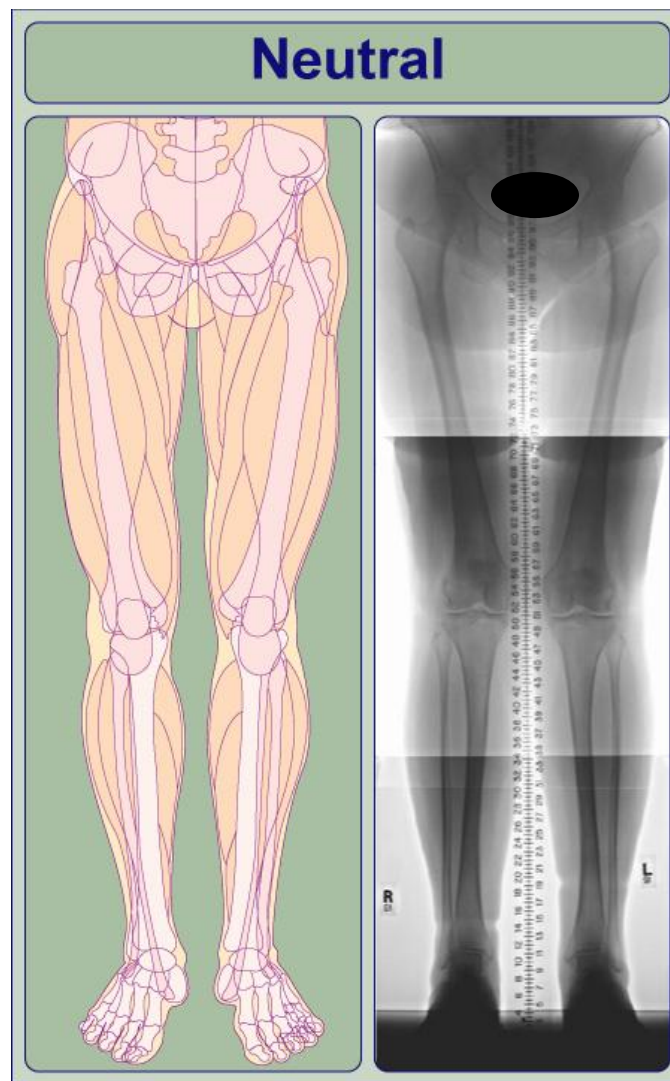


Figure 14-Full limb image of neutral alignment.

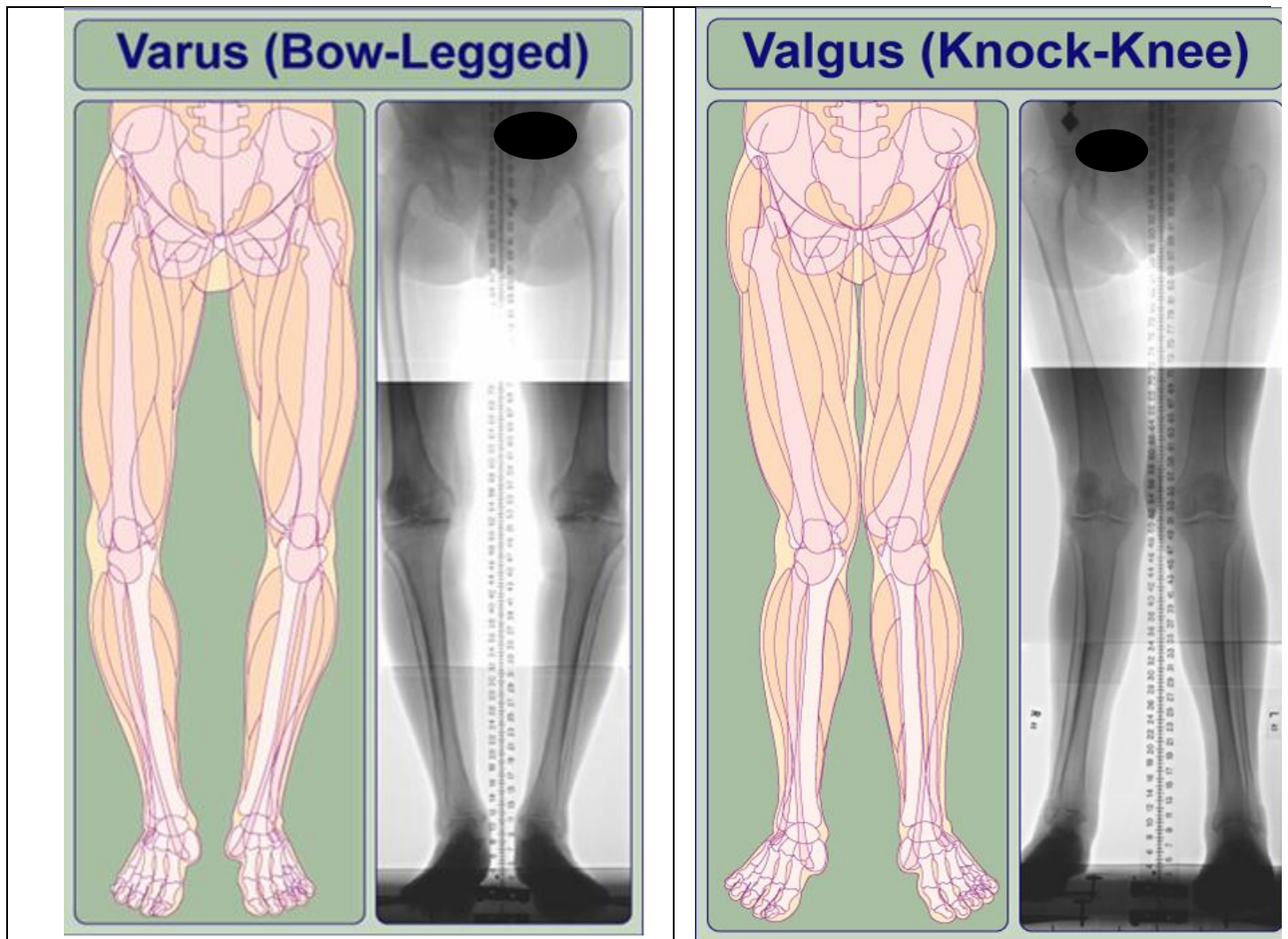


Figure 15-Full limb image of varus and valgus alignment.

Positioning the Participant

- Remove clothing, shoes, and metal material from lower limb area.
- Position the radiopaque ruler vertically to the center of the cassette with the numbers increasing upwards toward the pelvis.
- Place the participant in an upright AP position with their back toward the bucky. Center both lower limbs to the film.
- Position the participant's feet 6 inches apart. Permanent markings can be made on the step stool 6 inches apart. Position the great toes on these markings for consistency.
- Ask the participant to place the toes perpendicular to the film and help adjust the leg to position the femoral epicondyles parallel to the cassette.
- Instruct the participant to stand straight with knees fully extended and distribute weight evenly.
- Shield the participant's gonads without obscuring the hip joint.

Positioning the X-ray Tube and Central Ray

- Secure the wedge filter on the collimator. For wedge shaped filters place the thicker end inferior to the thinner end. The thicker end will attenuate the x-ray beam nearer the ankle joint to avoid overexposure from the higher technique needed to expose the hips. Ensure that the filter covers the entire light field for uniform exposure of the lower limbs.
- Direct the central ray horizontal and center it midway between the knees at the level of the knee joint. (If the participant is over 6 feet, center at a point midway between the knees at the level of the top of the patella).
- Angle the tube at zero degrees perpendicular to the film
- Place a right and left marker on the film
- Instruct the participant to hold still.
- Image both lower extremities on one film.

Special Remarks

- For participants with extreme cases of "bowed legs", it will be necessary to image each lower limb separately in order to get adequate coverage.
 - When imaging each lower limb separately, center the limb on the film and center the beam on the knee joint space.
 - Position the radiopaque ruler on the lateral side of each limb and include on the image.

- The use of a grid is advised to reduce secondary and scatter radiation to increase the quality of these images. This will require an increase of the exposure technique.

Electronic Stitching for Digital Images

After the image has been acquired and processed, stitch the images together using the procedure steps in your software operating manual. Make certain that these steps are accurately repeated with each full limb image acquired.

2.7.2 Criteria for Assessing Quality of Full Limb Radiographs

Common Mistakes

- Incomplete visualization of the femoral heads or the ankle joints due:
 - Underexposure of the hips due to insufficient exposure techniques and/or exposing the image without a grid.
 - The stitch line covering the anatomical landmarks for measurement. If the stitch line obscures any of these landmarks, reposition the cassette(s) and/or participant and repeat the exam.
 - Not covering the entire light field with the filter.
- No markers are present on the film.

Criteria of good quality full limb radiographs

Ideally, radiographs of insufficient quality should be identified by the radiology technologist at the time of acquisition and repeated immediately. If the film does not demonstrate good quality in the following criteria, please repeat the exam:

- The lower limbs are centered on the film.
- Optimum exposure to visualize the articular cortex of the measurement landmarks (center of the femoral head, tibial spines, center of talar surface) without the use of a high intensity light.
- Accurate alignment of the radiopaque ruler on the stitched image.
- Right or left side markers are present on both films.

2.7.3 Examples of Full Limb view

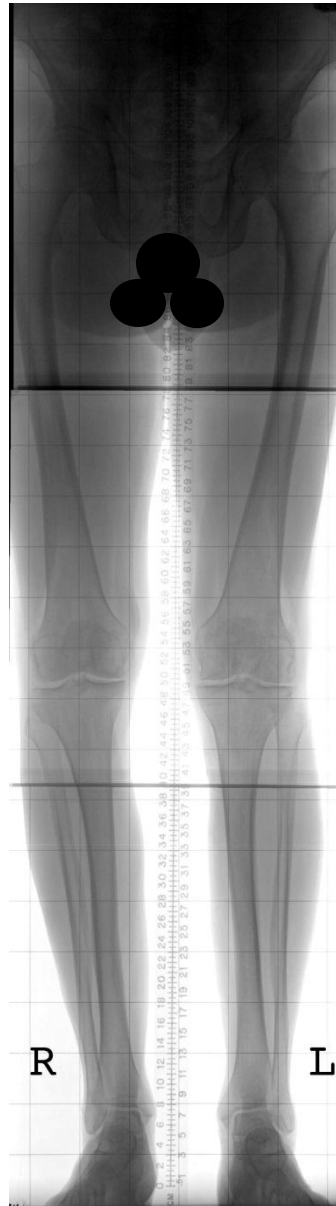
For examples of acceptable and unacceptable quality full limb radiographs, see the following pages.

Full Limb – Acceptable



This is an example of an acceptable full limb image. The participant has been centered and all three joints (hip, knee, and ankle) are visualized.

Full Limb – Acceptable



This is an example of an acceptable full limb exam performed on a larger participant. Although the participant is centered, his uneven stance causes the right trochanter to be clipped. This is acceptable as long as the proximal femoral shaft is visualized on the image.

Full Limb – Unacceptable



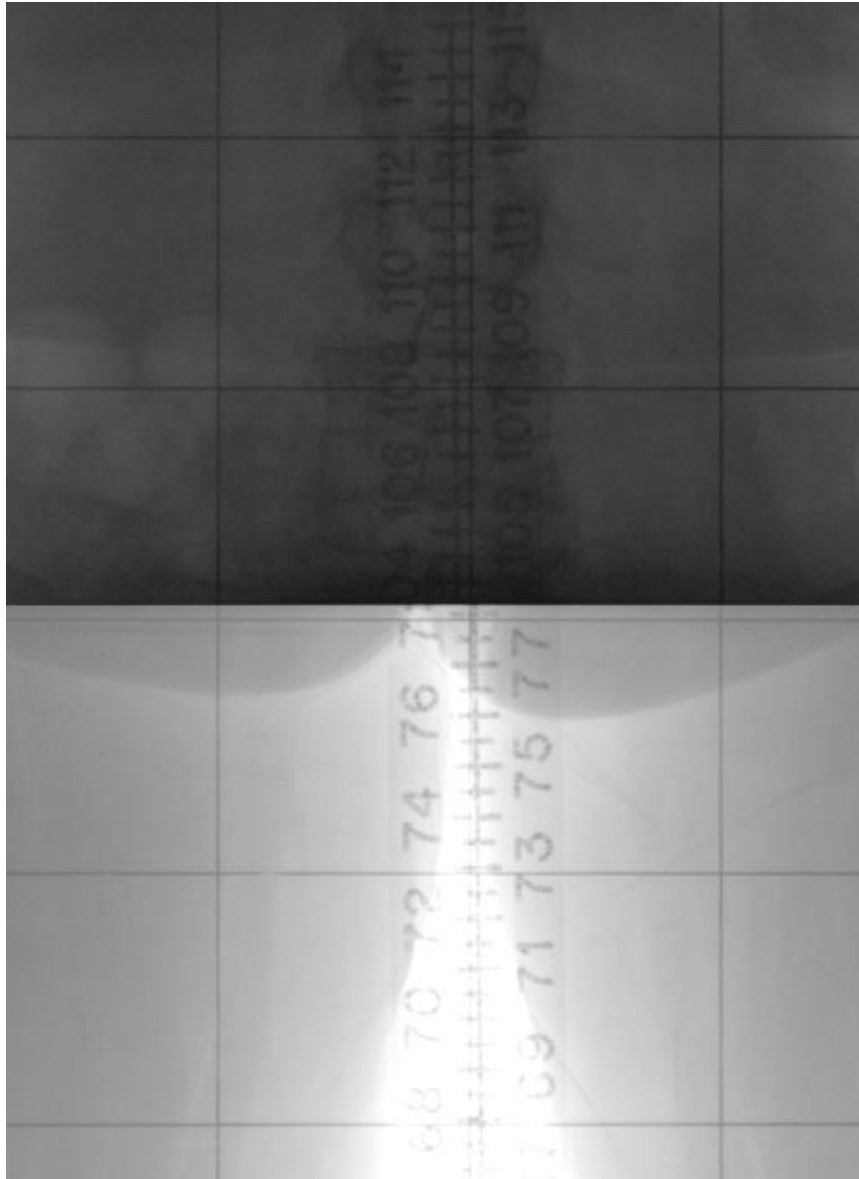
This image is unacceptable due to underexposure of the hip joints and the lead markers are not visualized. Always remember to shield the participant's gonads.

Full Limb – Unacceptable



This image is unacceptable because it has been digitally “stitched” incorrectly causing the pelvis to be missing from the image. Furthermore, the feet are positioned too close together.

Full Limb – Unacceptable



A closer look at the previous unacceptable image that has been digitally “stitched” incorrectly. Note that the numbers on the ruler “jump” from 77 to 105.

Grid Use with Full Limb Exams



UNACCEPTABLE

This image was taken without the grid and an insufficient exposure technique leading to loss of contrast and overall underexposure of the image.



ACCEPTABLE

This image was taken with the grid and optimum exposure was achieved allowing visualization of the measurement landmarks.