

MOST Reading of Baseline and 60-Month Full Limb X-rays for Individual Radiographic Features of Hip OA Dataset Description

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1. Overview

The V03HIPOA dataset contains Baseline (V0) and 60-month (V3) paired longitudinal readings of full limb x-rays for radiographic hip osteoarthritis (OA). Readings were performed by Dr. Kim Chen, under the direction of Drs. Ali Guermazi and David Felson at Boston University.

In addition to individual radiographic features (IRF) from Baseline and 60-month, the dataset contains information about prevalence and incidence of radiographic hip osteoarthritis (V0/3HIP_STATUS) for each participant and side (right and left).

Details of the reading protocol and methods are published here: https://doi.org/10.1002/art.40537 (Kim, 2018, *Arthritis and Rheumatology* (4))

1.1 Variables and reading methods

Variables include:

- Individual radiographic features (IRFs) such as osteophytes and joint space narrowing in specific anatomic locations, based on a published atlas⁽¹⁾.
 - Radiographic hip OA (RHOA) status calculated from the IRFs (see section 2.3.2).
 - Additional feature: Kellgren-Lawrence grade is provided
 - Meta-data related to reading procedures, exclusions (see section 2.3.3).

2. Methods

2.1 Image type

Full limb radiographs obtained at baseline and 60-month. The acquisition protocol is available in Appendix A (MOST Knee and Full-Limb Radiography Operations Manual Chapter).

2.2 Time points

Baseline and 60-month visits.

- Most participants have their first full limb x-ray at the Enrollment visit (V0 Baseline).
- If the 60-month (V3) follow-up full limb x-rays were acquired and paired baseline image existed, the pair is eligible to be read.
- If the quality of images at both visits was not sufficient for readings to be completed at either timepoint, this was indicated on the score sheet and no data for those hips is in the final dataset.
- If only one image was readable, the readings are included for that visit, and for the other visit, missing values (see section 2.3.3) are indicated in the dataset, and user can make decision in terms of missing hip ROA status based on additional review.

2.3 Measurement methods

Radiographs were assessed for individual radiographic features (IRF) of hip OA using the OARSI atlas⁽¹⁾. A list of the IRFs assessed are in Table 1. The readings consisted of a screening phase and, for participants selected during the screening, a complete assessment of IRFs on the available radiographs, and details are published⁽⁴⁾

Table 1. Individual Radiographic Features (IRFs).

Individual Radiographic Feature	Variable name in dataset	Grading*
Supero-lateral joint space narrowing (JSN)	VxHJSNSL	0, 0.5, 1, 1.5, 2, 2.5, or 3
Supero-medial joint space narrowing (JSN)	VxHJSNSM	0, 0.5, 1, 1.5, 2, 2.5, or 3
Superior acetabular osteophytes	VxHAOSS	0, 0.5, 1, 1.5, 2, 2.5 or 3
Inferior acetabular osteophytes	VxHAOSI	0, 0.5, 1, 1.5, 2, 2.5, or 3
Superior femoral osteophytes	VxHFOSS	0, 0.5, 1, 1.5, 2, 2.5, or 3
Inferior femoral osteophytes	VxHFOSI	0, 0.5, 1, 1.5, 2, 2.5, or 3
Acetabular subchondral cysts	VxHCYA	absence or presence
Femoral subchondral cysts	VxHCYF	absence or presence
Acetabular subchondral sclerosis	VxHSCA	absence or presence
Femoral subchondral sclerosis	VxHSCF	absence or presence
Femoral head flattening/deformity	VxHFLAT	absence or presence
Kellgren-Lawrence grade	VxHKL	0, 1, 1.5, 1.9**, 2, 2.5, 3, 3.5, 4

^{*}The non-integer grades of x.5 are not described in the referenced atlas, but it was allowed to be scored for some IRF in order to capture possible (but not definite) osteophytes, JSN or change between baseline and follow up.

All readings were performed with the baseline and 60-month radiographs viewed together and in known chronological order. Readers were not provided any clinical information.

All participants with acceptable quality radiographs at the baseline and/or 60-month time-point were included in the reading. When only a baseline or only a 60-month radiograph was available, the single time-point was not read. A small number of participants and/or hips with available radiographs are excluded due to the presence of conditions or artifacts that interfere with the reading and/or the interpretation of the findings.

2.3.1 Non-integer grades for osteophytes and JSN

Non-integer grades are not described in the referenced atlas for scoring IRFs but were allowed in some circumstances. Superior and inferior femoral osteophytes could be scored as 0.5 to record the presence of very small or questionable possible osteophytes. Within-grade changes in supero-lateral or supero-medial JSN were also scored at follow up visit when the JSN had worsened since the prior visit, but not enough to warrant a whole OARSI grade change.

2.3.2 Definitions of RHOA

Femoral and acetabular osteophytes and supero-lateral and supero-medial JSN with grade >=2 were considered "definite" IRFs. Hips were classified as "definite RHOA" when:

- (1) the modified Croft grade⁽²⁾ was 2 or greater (presence of two or more of definite osteophytes, definite JSN, sclerosis, cvsts or deformity); or
- (2) there was definite JSN plus grade >=1 femoral osteophytes or grade >=2 acetabular osteophytes; or
- (3) there was grade >=2 femoral osteophytes regardless of other features; or
- (4) there was supero-lateral JSN >=2 or supero-medial JSN>=3 regardless of other features.

^{**}Kellgren-Lawrence grade 1.9 represents "2N" to mark osteophytes without JSN.

Hips were classified as "possible RHOA" when other individual or combinations of, indefinite IRFs were present (e.g., grade 1 osteophytes or grade 1 JSN). All other hips were classified as radiographically "normal"^(2,3).

Variables used to define RHOA status are:

```
V0HIP_STATUS: baseline RHOA status (0: No OA, 1: Possible OA, 2: Definite OA) V3HIP_STATUS: 60-month RHOA status (0: No OA, 1: Possible OA, 2: Definite OA)
```

If images were of poor quality, a special missing value .M was used to indicate that situation. The following SAS code will apply the correct format to these variables:

```
proc format library=work; value hipoaiff
0="0: Hip No OA"
1="1: Hip Possible OA"
2="2: Hip Definite OA"
.E=".E:excluded for medical reason"
.P=".P:HR"
.M=".M:missing";
run:
```

2.3.3 Missing Data

Missing data can occur for a variety of reasons. In the individual datasets, SAS special missing values are used to indicate the following:

- .P if data is missing due to a prosthesis/hip replacement.
- .M if data is missing due to technical reasons (e.g., poor image quality).
- .E for exclusion due to medical conditions (e.g., Paget's disease, hip fracture, rheumatoid arthritis)

2.4 Sample

Dataset V03HIPOA contains data for 2030 MOST participants with paired x-rays acquired at baseline and 60-month visits and readable hip OA parameters from at least one image. The following table gives some demographic information about the participants with data currently released:

Table 2a. Hip OA sample: Distribution of Race by Sex, for participants with defined RHOA status

	White or Caucasian	Non-White	Total
Female	1026	193	1219
Male	703	108	811
Total	1729	301	2030

Table 2b. Hip OA sample: Distribution of Age by Sex, for participants with defined RHOA status

	Age (years)			
	50 to 59	60 to 69	70 to 79	Total
Female	486	498	235	1219
Male	340	308	163	811
Total	826	806	398	2030

3. References

- Altman RD, Gold GE. Atlas of individual radiographic features in osteoarthritis, revised. Osteoarthritis Cartilage 2007;15 Suppl A: A1-56. PMID: 17320422 http://dx.doi.org/10.1016/j.joca.2006.11.009.
- 2. Croft P, Cooper C, Coggon D. Case definition of hip osteoarthritis in epidemiologic studies. J Rheumatol, 1994, 21(4), 591-592. PMID: 8035380.
- Arden NK, Lane NE, Parimi N, Javaid KM, Lui LY, Hochberg MC, Nevitt M. Defining incident radiographic hip osteoarthritis for epidemiologic studies in women. Arth Rheum 2009, 60(4) 1052-1059. PMID: 19333950 https://doi.org/10.1002/art.24382.

4.	Kim C, Nevitt M, Guermazi A, Niu J, Clancy M, Tolstykh I, Jungmann PM, Lane NE, Segal NA, Harvey WF, Lewis CE, Felson DT. Brief report: Leg length inequality and hip osteoarthritis in the Multicenter Osteoarthritis Study and the Osteoarthritis Initiative. Arthritis Rheumatol 2018 Oct;70(10):1572-1576. PMID: 29700988. https://doi.org/10.1002/art.40537 .

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IMPORTANT: It is the responsibility of the clinical center to verify the legibility, completeness and accuracy of all identifying information on the x-ray label before the x-ray is transmitted to the Radiology Coordinating Center. [Baseline through 30-month: Missing or illegible information should be typed on a separate stick-on label, and placed next to (NOT OVER) the ID stamp. The x-ray tech ID may also be recorded on a stick-on label.]

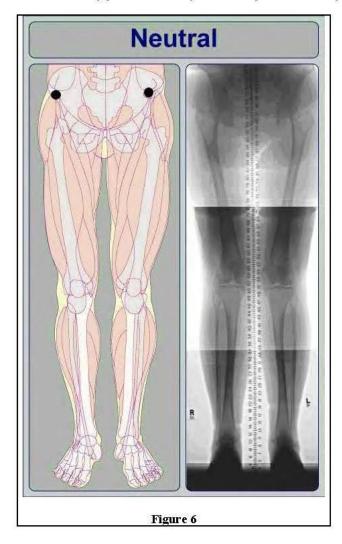
7.3 Single AP, full limb view of both lower extremities - after 30-month follow up

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 6-7.).

Additional goals at this visit are to use this film 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 tubercle. To assess the Q angle, we will need to make sure we know on the image where the anterior superior iliac crest is (the front brim of the pelvis), the patella and the tibial tubercle.

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Participants should have a Beekly x-spot on their tibial tubercles on both sides below the knees. The tibial tubercle is the boney prominence that juts anteriorly from the tibia just below the knee.



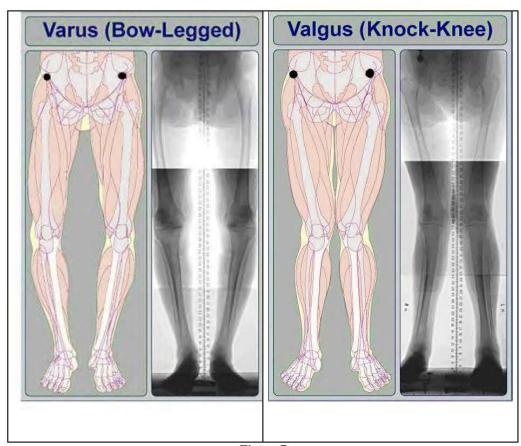


Figure 7

7.3.1.1 Imaging techniques: IOWA

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

X, v6.0 *

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: 50-300

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* 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.

7.3.1.2 Imaging techniques: UAB

a. Imaging system: Agfa ADC System, Quantum Q-Rad CR-based imaging

technique.*

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

* The Agfa 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 Participant position

- a. Participant will stand on the step-stool (necessary to ensure that the ankle is included).
- b. Participant should be standing without shoes, with their back to the wall Bucky that holds the three cassettes. <u>Both tibial tubercles should be facing directly forward.</u> (the x-spots should be placed on these tubercles). Feet should be 6 inches apart. Two permanent marks will be made on the step stool that are 6 inches apart. The tips of the big toes should be positioned at these marks.
- c. Participant should be instructed to bear weight equally on both limbs.

Suggested script: Please stand so that your weight is the same on your right leg and left leg."

d. Participant's gonads should be shielded with a gonad shield that will be folded (folding held by velcro) differently for men and women to shield gonads without obscuring hip joint.

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- e. Participant will hold onto hand rails for support, if necessary.
- f. The participant's body should be parallel to the grid plane. The participant-grid plane distance should be kept as small as possible.

7.3.3 Limb position

- a. Both lower limbs are imaged at the same time in an AP view.
- Center the knees to the film (in participants above 6 feet in height, center at the top of the patella).
- c. The anterior superior iliac crest, the hip joint, the knee joint, the tibial tubercle, 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.

- Place a right or left marker on each film
- e. The film marker block (ID stamp) must be in same place each time
- f. A radiopaque ruler will also be imaged to provide a method to check the electronic stitching of the images.

7.3.4 Central ray

- Direct the central ray perpendicular to the knee. Tube is at 0 degrees. DO NOT ANGLE THE TUBE.
- b. Center of the x-ray beam should be directed midway between the two knees at the level of the joint spaces. 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 7.1.3.e above).

7.3.5 Participant instruction

Have the participant understand the importance of holding still.

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

7.3.6.1 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.
- c. The stitched image is ready to be transferred to BU. The images that are transferred include the stitched image along with the three separate images (pelvis, knee and ankle).

7.3.6.2 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.
- Rotate the subimages to bring them into the upright position.
- 5. Press "stitch" to created composite image.
- c. The stitched image should be:
 - 1) archived at the site and
 - 2) sent to reading center at BU

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7.3.7 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 film 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
 - The anterior superior iliac crest, hip joint, knee joint, and tibio-talar joint must be included and clearly visible in the image. The image should extend far enough superiorly to capture the anterior superior iliac crest
 - The patella and tibial spines must be completely visualized. If not, repeat, doing a separate full limb film of each leg.
 - 3) The tibial tubercles of both sides must be seen as marked by the x-spot.
- b. proper centering on the film
- 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 lateral edge of the acetabulum the film should go high enough to see the anterior superior iliac crest. Use the abdominal binder, if necessary in participants with sagging abdominal fat, to improve penetration at the hips, to better visualize the hip joint space (see Appendix 7).
- d. clear delineation of planned measurement landmarks (anterior superior iliac crest, center of femoral head, patella, tibial spines, tibial tubercles and center of talar surface). The stitching should not cover any of these essential landmarks.
- e. proper exposure at proximal and distal extremes of the image
- f. no evidence of patient motion
- g. check for line-up of radiopaque ruler. This should be right after the image is "stitched," i.e., on the workstation image.

7.3.8 Record the mA/s used on the tracking form

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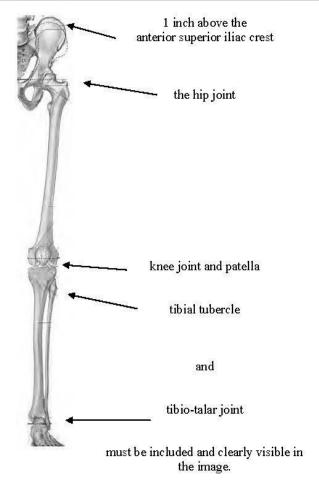


Figure 8

8. Radiograph labeling

- a. The x-ray films 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

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