Original article

Fixed-flexion knee radiography using a new positioning device produced highly repeatable measurements of joint space width: ELSA-Brasil Musculoskeletal Study (ELSA-Brasil MSK)

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ARTICLE INFO

Article history:
Received 18 November 2015
Accepted 21 October 2016
Available online 22 December 2016

Keywords:
Fixed-flexion radiography
Joint space width
Repeatability
Knee
Osteoarthritis

ABSTRACT

Objective: To describe the performance of a non-fluoroscopic fixed-flexion PA radiographic protocol with a new positioning device, developed for the assessment of knee osteoarthritis (OA) in Brazilian Longitudinal Study of Adult Health Musculoskeletal Study (ELSA-Brasil MSK).

Material and methods: A test-retest design including 19 adults (38 knee images) was conducted. Feasibility of the radiographic protocol was assessed by image quality parameters and presence of radioanatomic alignment according to intermargin distance (IMD) values. Repetability was assessed for IMD and joint space width (JSW) measured at three different locations.

Results: Approximately 90% of knee images presented excellent quality. Frequencies of nearly perfect radioanatomic alignment (IMD ≤1 mm) ranged from 29% to 50%, and satisfactory alignment was found in up to 71% and 76% of the images (IMD ≤1.5 mm and ≤1.7 mm, respectively). Repetability analyses yielded the following results: IMD (SD of mean difference = 1.08; coefficient of variation (%CV) = 54.68%; intraclass correlation coefficient (ICC) (95%CI) = 0.59 (0.34-0.77)); JSW [SD of mean difference = 0.34-0.61; %CV = 4.48%-9.80%; ICC (95%CI) = 0.74 (0.55-0.85)-0.94 (0.87-0.97)]. Adequately reproducible measurements of IMD and JSW were found in 68% and 87% of the images, respectively.

Conclusions: Despite the difficulty in achieving consistent radioanatomic alignment between subsequent radiographs in terms of IMD, the protocol produced highly repeatable JSW measurements when these were taken at midpoint and 10 mm from the medial extremity of the medial tibial plateau. Therefore, measurements of JSW at these locations can be considered adequate for the assessment of knee OA in ELSA-Brasil MSK.

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http://dx.doi.org/10.1016/j.rbre.2016.11.010
2255-5021/© 2016 Published by Elsevier Editora Ltda. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).
A radiografia do joelho em flexão fixa utilizando um novo posicionador produziu medidas da largura do espaço articular com alta repetibilidade: estudo Elsa-Brasil Musculosquelético (ELSA-Brasil ME)

RESUMO

Objetivo: Descrever o desempenho de um protocolo radiográfico em flexão fixa sem fluoroscopia em incidência PA com um novo posicionador, desenvolvido para a avaliação da osteoartrite do joelho (OA) no estudo ELSA-Brasil ME.

Material e métodos: Fez-se um estudo de teste e reteste que incluiu 19 adultos (38 imagens de joelho). A viabilidade do protocolo radiográfico foi avaliada por meio de parâmetros de qualidade da imagem e presença de alinhamento radioanatômico de acordo com as medidas da distância intermarginal (DIM). Avaliaram-se a repetibilidade dos valores de DIM e a espessura do espaço articular (EA) em três locais diferentes.

Resultados: Aproximadamente 90% das imagens de joelho apresentaram uma qualidade excelente. As frequências de imagens com alinhamento radioanatômico quase perfeito (DIM<1mm) variaram de 29% a 50%, e de alinhamento satisfatório (DIM<1,5mm e <1,7mm) de 71% a 76%, respectivamente. As análises de repetibilidade produziram os seguintes resultados: DIM [DP da média das diferenças = 1,08; coeficiente de variação (% CV) = 54,68%; coeficiente de correlação intraclasse (CCI) (IC 95%) = 0,59 (0,34 a 0,77)]; EA [DP da média das diferenças = 0,34 a 0,61; % CV = 4,48% a 9,80%; CCI (IC 95%) = 0,74 (0,55 a 0,85) a 0,94 (0,87 a 0,97)]. Encontraram-se medidas adequadamente reprodutíveis de DIM e EA em 68% e 87% das imagens, respectivamente.

Conclusões: Apesar da dificuldade de obter um alinhamento radioanatômico consistente entre radiografias repetidas em termos de DIM, o protocolo produziu medições de LEA altamente repetíveis quando essas foram tomadas no ponto médio e a 10mm da extremidade medial do plató tibial medial. Portanto, as medidas de LEA nesses locais podem ser consideradas adequadas para a avaliação da OA do joelho no estudo ELSA-Brasil ME.

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Palavras-chave:
Radiografia em flexão fixa
Largura do espaço articular
Repetibilidade
Joelho
Osteoartrite

Introduction

Conventional knee radiography is the most widely accessible and least expensive imaging technique for the evaluation of osteoarthritic alterations in epidemiological studies with long-term follow-up.\(^1\)\(^,\)\(^2\) Knee joint space narrowing (JSN), identified by reductions in joint space width (JSW) on serial knee radiographs, is considered an adequate proxy of cartilage damage and is frequently used as a marker for the progression of knee osteoarthritis (OA).\(^3\)\(^,\)\(^4\)

The validity of inferences on the progression of knee OA based on JSN requires precise and reproducible measurements of JSW. This is generally achieved by specific radiographic techniques designed to facilitate optimal radioanatomic alignment between the medial tibial plateau (MTP) and the X-ray beam, and to expose the region where the cartilage damage is most noticeable (i.e., the posterior aspect of tibia and femoral condyle).\(^5\)

The distance between the anterior and posterior margins of the MTP, known as intermarginal distance (IMD), is often used to quantify radioanatomic alignment. Perfect alignment would be present when the MTP and the X-ray beam are parallel, what produces a superimposition of MTP margins on the radiographic image. Protocols that include fluoroscopic guidance are able to achieve a nearly perfect radioanatomic alignment, with IMD values ≤1 mm.\(^6\) However, the implementation of fluoroscopic procedures is not straightforward in epidemiological studies because of the limited availability of fluoroscopy in non-specialized radiology services, higher costs, longer examination time, and a higher dose of ionizing radiation exposure.\(^7\) On the other hand, the non-fluoroscopic fixed-flexion PA protocol is easier to implement and can produce acceptable radioanatomic alignment, with IMD values of up to 1.7 mm.\(^8\) This protocol has also proved capable of providing reproducible JSW and IMD measurements.\(^9\)\(^,\)\(^10\) Thus, it is not surprising that the non-fluoroscopic fixed-flexion PA protocol has been the radiographic method of choice in large cohorts investigating risk factors for the progression of knee OA, including the Multicenter Osteoarthritis Study – MOST (http://most.ucsf.edu/studyoverview.asp) and the Osteoarthritis Initiative – OAI (https://oai.epi-ucsf.org/datarase). More recently, it was also chosen for the assessment of knee OA in the ELSA-Brasil Musculoskeletal Study (ELSA-Brasil MSK), which is an ancillary study of the Brazilian Longitudinal Study of Adult Health (ELSA-Brasil) aiming to investigate risk factors for the development and progression of multiple musculoskeletal disorders.\(^11\)\(^,\)\(^12\) Since 2012, ELSA-Brasil MSK has been monitoring a subcohort of approximately 2,900 public civil servants, aged between 38 and 79 years old [mean (SD) 56.0 (8.9)] at inception.\(^13\)

ELSA-Brasil and its ancillary studies follow rigorous methodological procedures to ensure the quality of the
cohort data. This includes testing the psychometric properties (feasibility, repeatability, validity and so on) of instruments and examination procedures for the target population.\textsuperscript{14–20} Here we describe the performance of the non-fluoroscopic fixed-flexion PA protocol developed for use in ELSA-Brasil MSK, with respect to feasibility and repeatability of IMD and JSW measurements. This protocol included the use of a novel positioning device, and was tested before the start of baseline data collection in ELSA-Brasil MSK.

\section*{Material and methods}

\subsection*{Study design and participants}

The performance of the non-fluoroscopic fixed-flexion PA protocol was evaluated in a test–retest design. The interval between repeated radiographic knee examinations was 7–9 days. Examinations were performed by radiology technicians, who underwent rigorous training and certification in image acquisition according to study procedures, under the supervision of an experienced radiologist. A trained radiologist performed radiographic readings and measurements of IMD and JSW on a different occasion.

We recruited a convenience sample of adult men and women. Individuals between the ages of 39 and 78 years were considered eligible for inclusion. This age range was selected to reflect the characteristics of participants included in ELSA-Brasil MSK at cohort inception.\textsuperscript{15} Exclusion criteria were occupational exposure to radiation (i.e., report of wearing a personal dosimeter at work), confirmed or suspected pregnancy, and participation in ELSA-Brasil as a study subject. The study was approved by the Ethics Committee of the Universidade Federal de Minas Gerais (Approval number CEP #1.160.939/CAAE 0186.1.203.000-06). Written informed consent was obtained from all of those willing to participate in the study.

\subsection*{Radiographic protocol}

Digital bilateral knee radiographs were acquired using computed radiology (ADC-70; Agfa Gevaert NV, Mortsel, Belgium). Focus-film distance was fixed at 72 in., and mAs and kVp ranges were 20–50 and 65–72, respectively. The X-ray beam was angled 10° caudal and centered between the knees, at the level of articular knee spaces (defined by the popliteal skin crease).\textsuperscript{21} The angle displayed on the X-ray tube dial was confirmed by a magnetic inclinometer placed on top of the X-ray tube (Lee Tools, model 610056, Houston, US). Participants stood on a novel device made of plexiglas and designed to standardize knee positioning in approximately 20° of flexion, while the angle subtended between the inside of the feet was fixed at 10° by a V-shaped wedge tipped vertically.\textsuperscript{22} The device was placed on top of a wood platform to allow the knees to be centered on the bucky. Fig. 1 provides a schematic illustration of participant positioning using the device.

This novel device has advantages over positioning frames used in previous studies (e.g., Synaflexer\textsuperscript{TM} frame), such as a moveable component that offers comfortable positioning for adults of short stature, and two sets of radiopaque markers innovatively distributed for easier real-time visual confirmation (without the need of software or other accessories) of a 10° caudal X-ray beam angulation tangential with the knee articular surface. For instance, the coincidence of a pair of radiopaque markers at the articular knee space level is indicative of proper angulation and centralization of the X-ray beam. Fig. 2 shows the distribution pattern of radiopaque markers during adequate (A) and inadequate (B–D) X-ray beam angulation and/or centralization.

\subsection*{Assessment of feasibility}

Feasibility was assessed by two different methods. First, each knee image had its quality rated according to four parameters: (1) amount of radiation exposure, (2) visualization of the
side marker and anatomically relevant structures, (3) knee rotation, and (4) proper angulation and centralization of the X-ray beam. The latter was considered adequate if device’s radiopaque markers coincided up to one level above or below the articular knee space. Images were rated as excellent (all parameters were adequate), satisfactory (≥1 parameter was inadequate, but image could still be analyzed), or poor (≥1 parameter was inadequate and it was impossible to analyze the image). Second, the capability of achieving proper radioanatomic alignment (i.e., superimposition between the anterior and posterior margins of the MTP) was evaluated according to the following cut-offs for IMD: 1.0 mm (nearly perfect or parallel alignment); 1.5 mm and 1.7 mm (acceptable alignment).

**Measurement of IMD and JSW**

IMD and JSW of images from test and retest were manually measured by a single experienced radiologist using image-processing software (OsiriX v.3.9.1, Pixmeo SARL, Geneva, Switzerland). All measurements were performed twice, 4-week apart, with the radiologist blind to participants’ characteristics and image chronology. Digital calipers were placed on selected landmarks and the computer calculated the distance in mm. IMD was defined as the distance between MTP margins, measured at midpoint of the medial compartment (which was identified by the midpoint between two vertical lines: one drawn at the extremity of the MTP and another between the two tibial spines). JSW was defined as the interbone distance between the distal convex margin of the medial femoral condyle and the MTP floor, at three sites along the articular margin of the medial compartment; perceived narrowest point, midpoint, and 10 mm from medial extremity of MTP (Fig. 3). Intra-rater repeatability of IMD measurements was assessed and found to be excellent (Table 1).

**Statistical analysis**

Descriptive statistics were used to characterize study participants and for feasibility analyses. Test–retest repeatability of IMD and JSW measurements was analyzed according to the Bland and Altman method, by calculating the standard deviation (SD) of the mean difference between readings of each pair of knee images. The coefficient of variation (\%CV = 100 × (SD/mean)), intraclass correlation coefficient (ICC) with 95% confidence interval (CI), and frequencies of adequately reproducible IMD (test–retest variation ≤1.0 mm) and JSW (test–retest variation ≤0.5 mm) were also
calculated. Assuming that an ICC of 0.50 indicates moderate reliability, and expecting a substantial to nearly perfect reliability (ICC ≥0.80) of IMD and JSW measurements in the current study, a sample size of 18 participants (36 knee images) was required to provide a statistical power of 90%, with a 5% significance level. Considering a possible loss of 5%, a sample of 19 participants (38 knee images) was recruited.

Results

Study participants

Four men and 15 women were included. The characteristics of the study sample were as follows: mean age 52.1 (SD 10.1) years, mean height 164.8 (SD 7.9) cm, and mean body mass index (BMI) 26.3 (SD 4.3) kg/m².

Feasibility analyses

The vast majority of knee images were rated as excellent by the radiologist at either the test (89.5%) or the retest (84.2%). All the remaining images were rated as satisfactory due to excessive knee rotation. The mean IMD was 1.33 (SD 1.13) mm and 1.38 (SD 1.14) mm at test and retest, respectively. Frequencies of nearly perfect radioanatomic alignment (IMD ≤1.0 mm) were 19 (50.0%) at test, 18 (47.4%) at retest, and 11 (28.9%) at both time-points. Frequencies of acceptable radioanatomic alignment according to less conservative cut-offs for IMD were as follows: 1.5 mm cut-off: 24 (63.2%) at test, 27 (71.1%) at retest, and 21 (55.3%) at both time-points; 1.7 mm cut-off: 29 (76.3%) at either test or retest, and 26 (68.4%) at both time-points.

Test–retest repeatability of IMD and JSW measurements

Overall, test–retest repeatability parameters for IMD measurement were fair. For example, the SD of mean difference and %CV were 1.08 and 54.68%, respectively (Table 1). An adequately repeatable IMD (i.e., test–retest variation ≤1 mm) was observed in 68.4% of the knees.

JSW repeatability parameters were good to excellent. JSW measurements taken at midpoint of the medial compartment were consistently more repeatable than those taken at other sites. For example, the SD of mean difference of JSW measurements between test and retest was 0.08 mm (23.5%) and 0.27 mm (79.4%) higher for JSW measured 10 mm from the medial extremity of the MTP and at the narrowest point of the medial compartment, respectively, when compared to JSW measured at midpoint (Table 1). Additionally, adequately repeatable JSW measurements were also more frequent when they were taken at midpoint: i.e., test–retest variations ≤0.5 mm were observed in 86.9% of knees when JSW was measured at midpoint, 84.2% of knees when it was measured at 10 mm, and 78.9% of knees when measures were taken at the narrowest point.

Discussion

This paper is part of a series of publications addressing methodological and operational aspects of the ELSA-Brasil cohort study, which is currently considered the largest

| Table 1 – Repeatability of intermargin distance (IMD) and joint space width (JSW) measurements. |
|----------------------------------|-------------------|-------------------|
|                                  | Intra-observer     | Test–retest       |
|                                  | SD of mean difference | %CV | ICC (95%CI) | SD of mean difference | %CV | ICC (95%CI) |
| IMD (mm)                         | 0.16              | 8.58%            | 0.99 (0.98–1.00) | 1.08          | 54.68% | 0.59 (0.34–0.77) |
| JSW (mm)                         |                   |                  |                  |               |        |                |
| Midpoint                        | 0.30              | 3.86%            | 0.95 (0.90–0.97) | 0.34          | 4.48%  | 0.94 (0.87–0.97) |
| 10 mm                            | 0.43              | 6.27%            | 0.86 (0.74–0.92) | 0.42          | 6.29%  | 0.86 (0.75–0.92) |
| Narrowest point                 | 0.57              | 9.00%            | 0.77 (0.60–0.87) | 0.61          | 9.80%  | 0.74 (0.55–0.85) |

SD, standard deviation; CV, coefficient of variation; ICC, intraclass correlation coefficient; CI, confidence interval.
epidemiologic study on chronic non-communicable diseases (NCDs) conducted in a Latin American country. We described the performance the non-fluoroscopic fixed-flexion PA protocol selected for the assessment of knee OA in the ancillary study ELSA-Brasil MSK.

Feasibility of the radiographic protocol using the new positioning device was found to be adequate, with approximately 90% of knee images being rated as excellent at any time-point. On the other hand, the protocol was able to produce a parallel alignment between MTP margins (i.e., IMD ≤ 1 mm) in only half of the knee images from either the test or the retest. Although disappointing at first glance, this result is in accordance with prior observations from Botha-Scheepers and colleagues, who found parallel radioanatomic alignment in up to 51% of images acquired by a similar radiographic protocol. Additionally, the frequency of a nearly perfect alignment at both time-points (test and retest) in our study was within the range described in the literature for radiographic protocols of the knee without fluoroscopy: 11%-42%. We consider this a very important finding given that the quality of MTP alignment on serial radiographs is known to influence the capability of identifying risk factors for the progression of JSN in longitudinal studies investigating knee OA.

The difficulty in achieving parallel radioanatomic alignment is inherent to non-fluoroscopic protocols. For example, prior studies have found IMD values twice as large in the non-fluoroscopic fixed-flexion PA protocol when compared to the Lyon Schuss view. For this reason, less conservative cut-offs for IMD are considered acceptable in the absence of fluoroscopy. We found 55% of acceptable radioanatomic alignment at both test and retest when the cut-off was set at 1.5 mm, a result superior to that reported in previous studies: for example, an IMD lower than 1.5 mm at both time-points was observed in only 12% of the images in the study of Nevitt and colleagues and in 34% of the images in the study of Le Graverand and colleagues. Finally, when considering the 1.7 mm cut-off for acceptable alignment, achieving this goal at both time-points was almost 40% more frequent in our study than in the study of Vignon and colleagues.

Although our protocol was somewhat superior in producing knee images with acceptable radioanatomic alignment when compared to non-fluoroscopic protocols used in previous studies, repeatability parameters for our IMD measurements were found to be fair. Nevertheless, IMD values classified as adequately repeated (test-retest variation ≤1 mm) were still more frequent in our study than in another high-quality cohort study investigating risk factors for the progression of knee OA: ELSA-Brasil MSK 68.4% versus Osteoarthritis Initiative 57.6%. It is possible that variations of up to 1 mm in IMD between consecutive knee radiographs comprise an excessively conservative target for non-fluoroscopic protocols, which would not always produce a relevant impact on the reproducibility of JSW measurements. This is supported by our findings of trivial test-retest variations (≤0.5 mm) for the vast majority (approximately 80%) of knee images. Although uncommon, a poor association between proper MTP alignment and reproducibility of JSW measurements has been reported by a few studies investigating similar radiographic protocols.

Interestingly, JSW repeatability differed considerably according to the site of measurement. JSW measured at midpoint and at 10 mm from the medial extremity of MTP were more repeatable than JSW measured at the narrowest point. Repeatability was particularly increased for JSW measures at midpoint, and this may be explained by a more accurate identification of relevant landmarks during the manual measurement of JSW at this site. Additionally, precision limitations of the digital calipers from the image-processing software may also predispose to greater variability when JSW is measured at the narrowest point. Taken together, these findings are of great importance for future studies considering manual measurement of JSW to infer about the progression of knee OA.

Our study has strengths and limitations that need to be acknowledged. First, the non-fluoroscopic fixed-flexion PA knee radiographs followed rigorous quality procedures, including the use of pre-defined protocols for image acquisition and reading, and a highly trained staff. Second, our results provided support for the use of a novel device that standardizes knee positioning during the examination, while allowing a real-time evaluation of key radiographic parameters. The incorporation of this relatively low-cost device in studies of osteoarthritic alterations conducted in Brazil could increase their scientific potential, given that the access to the imported technologies already available is not straightforward and can be extremely costly. The main limitation of our study is the lack of information on the performance of the radiographic protocol over longer periods of time. For instance, it is possible that factors related to the examiners or participants (e.g., changes in knee anatomy, worsening of symptoms) may impact the performance of the protocol in epidemiological studies with a long-term follow-up.

In conclusion, the performance of a non-fluoroscopic fixed-flexion PA protocol with a new positioning device was found to be satisfactory for measurements of JSW taken at midpoint and 10 mm from the medial extremity of the MTP. This provides support for the incorporation of these measurements during the assessment of knee OA in the ELSA-Brasil MSK cohort. Further investigations within the cohort will be able to test the precision and accuracy of the radiographic protocol over the long term in a larger and more heterogeneous sample.

Funding

The ELSA-Brasil baseline study was supported by the Brazilian Ministry of Health (Science and Technology Department) and the Brazilian Ministry of Science and Technology (Foncaldora de Estudos e Projetos and CNPq National Research Council), grants 01 06 0010.00 RS, 01 06 0212.00B, 01 06 0300.00 ES, 01 06 0278.00 MG, 01 06 0115.00SP, 01 06 0071.00 RJ. ELSA-Brasil MSK has been supported by the Coordination for the Improvement of Higher Education Personnel (CAPES) and Secretaria de Estado de Ciência, Tecnologia e Ensino Superior de Minas Gerais (SECTES), Serviço de Apoio às Micro e Pequenas Empresas (SEBRAE-MG), and Universidade Federal de Minas Gerais (UFMG). LAM and RCR are postdoctoral fellows of CAPES. SMB is a research fellow of CNPq and State of Minas Gerais Agency for Research and Technology (FAPEMIG).
Conflicts of interest

The authors declare no conflicts of interest.

Acknowledgements

The authors would like to thank the management and staff of the radiology service Clinica Radiológica Juvent Barros for their valuable assistance in this study, in special to Dr. Evandro Barros Naves.

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