

Radiation Dose Reduction in Digital Plain Radiography of the Knee after Total Knee Arthroplasty

Dosisreduktion in der digitalen Radiografie des Kniegelenkes nach endoprothetischem Gelenkersatz

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Key words

- skeletal-appendicular
- digital radiography
- radiation safety

Abstract



Purpose: To reduce radiation exposure of frequently performed radiographs of the knee in follow-up of total-knee arthroplasty ensuring accurate assessment by using objective quality control criteria.

Materials and Methods: In this prospective randomized study 278 radiographs of the knee in follow-up of total-knee arthroplasty were performed with standard and 37% reduced radiation dose. The evaluation of the plain-radiographs was conducted using the following criteria: bone-implant interface, implant-surface character, implant-implant discrimination and periarticular heterotopic ossification. Two radiologists evaluated these criteria using a score ranging from 1 (definitely assessable) to 4 (not assessable). If a single criterion had been evaluated with a score ≥ 3 or more than 2 criteria with ≥ 2 points, the radiograph was score das „not assessable“. The study was designed as non-inferiority-trial.

Results: 100% of examined radiographs were scored as assessable, hence no statistical inferiority between the examinations with standard and reduced dose could be observed. Singular assessment of the defined criteria was likewise dose-independent.

Conclusion: Plain-radiography of the knee following total-knee arthroplasty can be performed with 63% of standard dose without loss of diagnostic validity.

Key points:

- ▶ Due to the non-inferiority of digital radiographs of the knee joint after total-knee arthroplasty done with 37% reduced image receiver dose we recommend the tested speed class of SC 800 as a new reference value for digital radiographs with this indication.

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Zusammenfassung



Ziel: Reduktion der Strahlenexposition bei häufig zu wiederholenden Projektionsradiografien des Kniegelenkes nach endoprothetischer Versorgung unter Einhaltung objektiver indikationsspezifischer Qualitätskriterien.

Material und Methoden: Prospektiv randomisiert wurden insgesamt 278 Projektionsradiografien des Kniegelenkes nach Prothesenimplantation mit Standarddosis und 37% reduzierter Dosis durchgeführt. Die Beurteilung der Aufnahmen erfolgte anhand folgender Kriterien: Metall-Zement-Knochen-Interface, Oberflächenbeschaffenheit, Diskriminierung der Implantatkomponenten und periartikuläre Ossifikationen. Diese wurden von 2 Radiologen mit einem Score von 1 (vollständig beurteilbar) bis 4 (nicht beurteilbar) bewertet. Die Einschätzung „nicht beurteilbar“ wurde bei Bewertung eines Einzelkriteriums ≥ 3 oder zweier Kriterien ≥ 2 vergeben. Die statistische Auswertung erfolgt als Nichtunterlegenheitsanalyse.

Ergebnisse: 100% der in die Studie eingeschlossenen Röntgenaufnahmen waren nach o.g. Score beurteilbar, somit konnte die Nichtunterlegenheit der Aufnahmen mit reduzierter Dosis bestätigt werden. Die Bewertung der Einzelkriterien war ebenfalls dosisunabhängig.

Schlussfolgerung: Röntgenuntersuchungen nach Knieendoprothese können ohne Verlust der diagnostischen Aussagekraft mit 63% der Standarddosis durchgeführt werden.

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Introduction

Plain radiography (PR) of the knee joint is regularly performed during routine follow-up examinations after total knee arthroplasty (TKA) [1]. Image acquisition is quick, cost-effective and readily accessible. It allows diagnosis of most postoperative complications: septic and aseptic loosening, periprosthetic fractures as well as material failure or wear. For the most part, assessment of these complications is based upon the evaluation of the metal-bone-cement interface when loosening is suspected, and on the position of the implant components with respect to one another, e. g. in cases of inlay wear. This poses particular challenges to plain radiography due to its limited ability to penetrate metallic components. Thus computed tomography (CT) is gaining importance in imaging; however this imaging method is linked to essentially higher radiation exposure [2]. This is significant, since for years younger patients have increasingly been candidates for a total joint replacement, for example in cases of post-traumatic osteoarthritis or juvenile rheumatoid arthritis, and thus must undergo repeated CT scans due to extended prosthetic joint service life [3, 4]. For this reason cumulative radiation exposure even in cases of endoprostheses has increased in importance. Although PR requires a significantly lower dose than a CT of the same region of the body, frequent repetition of this examination during follow-up requires a careful consideration of total radiation exposure.

In this context, reduction of exposure during follow-up examinations of the knee joint in digital PR is the primary outcome criterion of this study. Dose reduction is possible in this case, since the reference values of the German Federal Office for Radiation (BfS) are organ-specific and not specific to indications [5]. The radiation dose for a follow-up after TXA may have other requirements than for tumors screening, for example. In addition to the primary outcome criterion, quality measures developed by orthopedists and trauma surgeons are introduced which assess the quality of the radiograph in terms of orthopedic and surgical evaluation standards. Since conventional film-screen systems influence the BfS reference values, the recognized higher quantum efficiency of digital imaging systems should allow additional dose reduction [6, 7].

Materials and Methods

Study Population

Prior to its inauguration, the study was positively evaluated by the Ethics Committee of Heidelberg and the BfS. Between 06/2011 and 08/2014a total of 278 digital PR follow-up images of the knee joint after TKA were assessed (170 women, 108 men). The median age was 67 years (23.3 – 86.9 years). Both branches of the study were balanced with respect to sex and age (sex: $p=0.15$; age: $p=0.91$).

Radiographic images

The projection radiographic images were acquired using a flat detector system consisting of an X-ray tube (SRO 33 100) with generator (Optimus 50) and digital flat detector ("Digital Diagnost", all by Philips Healthcare, Best, Netherlands). The image receptor format was 43×35 cm, and the image voltage was 66 kV; a scattered radiation grid (r8 26/cm) was employed. The X-ray image was obtained in supine position with ovarian shield or testicle pouch used on the patient.

The guidelines of the German Medical Association indicate speed class SC 400 for PR of the knee joint. This concept, based on standard film-screen systems, corresponds to dosage indicator S in digital radiography. This is a device-specific value which, under identical imaging conditions, correlates with the image receptor dose. For images with reduced dose, the dosage indicator was doubled, relying on similar studies [8, 9], thus corresponding to an SC 800 sensitivity class.

Image Analysis and Quality Criteria

Four quality criteria for the radiographic images were developed jointly by orthopedists and traumatologists (Table 1, Fig. 1). They reflect the requirements for an X-ray image after TKA in the clinical practice and are especially important for the assessment of implant-associated complications.

1. Interface: metal-cement-bone interface for the evaluation of septic or aseptic loosening.
2. Surface quality: surface and shape of the implant.
3. Implant components: differentiation among implant components, especially polyethylene (PE) inlay.
4. Periarticular ossification: Delineation of periarticular heterotopic ossification (PHO).

no.	short form	parameters	assessed structures
1	interface	bone implant and bone-cement interface	femoral and tibial prosthetic interface – evaluation of loosening seams, stress shielding and fractures
2	surface	surface characteristics	assessment of the prosthesis structure and shape
3	components	differentiation of various implant components	differentiation of femoral shield, polyethylene inlay and tibial plateau – assessment of luxation, material fracture and wear.
4	PHO	periarticular heterotopic ossification	assessment of periarticular heterotopic ossification of adjoining musculature and soft tissue.
score			
1	fully assessable		
2	$\geq 50\%$ assessable		
3	$< 50\%$ assessable		
4	not assessable		

Table 1 Quality criteria for the assessment of radiographic images of the knee after metal implantation.



Fig. 1 Illustration of quality criteria Interface 1, Surface 2, Components 3 and Periarticular Heterotopic Ossification 4.

Two radiologists with respectively 14 and 8 years expertise in musculoskeletal radiology evaluated the images using a score ranging from 1 (fully assessable) to 4 (not assessable) without knowledge of the applied dosage indicator. A radiographic image was rated “not assessable” if at least one criterion was given a score of 3 or greater, or if more than two criteria were evaluated with a score of 2. The assessment was performed using the clinic’s PACS unit (Centricity PACS 3.2, GE Healthcare, Barrington, Illinois).

Study Design and Statistics

Using the rate of assessable images, this prospective, randomized, two-arm, monocentric blinded study reviewed the non-inferiority of digital PR of the knee joint with reduced dosage compared to the standard dosage. Block randomization with a 1:1 ratio was performed in both groups. Statistical design was performed as a non-inferiority study, i. e., the null hypothesis of the non-sufficient rate is formally tested unilaterally against the alternative of the sufficient

rate lying close to the standard [10, 11]. The primary measure of the outcome – rate of assessable images with a standard dose (R_S) or reduced dose (R_R) – was defined at 0.9 and is based on the drop-out rate in the so-called Paris scheme [12], as well as in previously published works regarding dose reduction with a similar study design [8, 9]. A difference of $\Delta = 0.1$ in the rate of assessable images is still considered acceptable. This means that when compared, R_R should be seen equivalent to R_S , if it can be statistically shown that R_R is less than Δ than under R_S .

The four quality criteria, interface, components, surface and PHO were described separately for both dosage groups and are based on the evaluations of the radiologist with the greater expertise. Exploratory statistical tests were performed to compare both arms of the study: χ^2 test or Fisher’s exact test, if the prerequisites for the χ^2 test had not been met. In addition, the concurrence of both radiologists was considered with respect to both the assessability of the images as well as the individual quality criteria. Dichotomous features were qualified using Cohen’s κ coefficient. The weighted κ coefficient was used to calculate features with more than two levels, and Bowker’s symmetry test was applied. The degree of agreement was defined based on the classification by Landis and Koch [13, 14].

Determining radiation exposure

In digital projection radiography, the effective dose as typical measure of radiation exposure to a patient is calculated by determining the dose area product (DAP) multiplied by a conversion factor that is dependent on the examined region of the body and the technical parameters of the radiographic image. Since such a conversion factor is known for the extremities, and despite thorough research, could not be reliably determined, the actual exposure in both groups was correlated based on the dose area product measured at the image receptor.

Results

Primary Outcome Criterion

All images, whether using standard or reduce dose, were assessable according to the applied criteria (● Fig. 2). Consequently no difference between the two radiation dosages can be observed in the rate of evaluable images; the unilateral 97.5 % confidence interval for the differential rate of assessable images between the reduced dose and standard dose is shown as $[-0.014, 1.00]$. The non-inferiority limit of -0.1 is not included in the 97.5 % confidence interval. It follows that the rate of evaluable images acquired with a reduced dose is not less than the rate of those acquired with a standard dose ($p < 0.001$).

Quality Criteria

With respect to the “surface” criterion, the proportion of fully assessable images was marginally greater in the standard dose group compared to those acquired with reduced dose, whereas comparable proportions were demonstrated in both groups for the “PHO” criterion. Regarding the “interface” and “components” criteria, the reduced dose group demonstrated a marginally higher proportion of fully assessable images (● Table 2, ● Fig. 3, 4). Fisher’s exact test is non-



Fig. 2 Images with normal dose **a** and reduced dose **b** compared: the named quality criteria are fully assessable for both 76-year-old female patients.

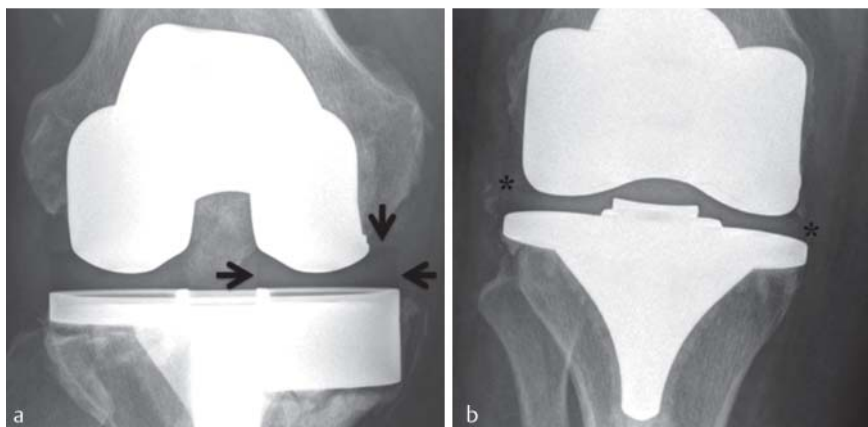


Fig. 3 Comparison of the delineation of non-radiopaque polyethylene inlays (Criterion no. 3: “Components”). In image **a**, the inlay of a 73-year-old male patient is well defined as an increasingly transparent structure (black arrows). In addition, loosening of the interface can be seen medially. In image **b** of a 75-year-old female patient, localization of the inlay is not possible (*). **a** was acquired with reduced dosage, **b** with standard dosage.

		standard dose (SC 400)	reduced dose (SC 800)	p-value ¹
interface	fully assessable	143 (97.3 %)	129 (98.5 %)	0.69
	≥ 50 % assessable	4 (2.7 %)	2 (1.5 %)	
components	fully assessable	141 (95.9 %)	127 (96.9 %)	0.75
	≥ 50 % assessable	6 (4.1 %)	4 (3.1 %)	
surface	fully assessable	146 (99.3 %)	129 (98.5 %)	0.6
	≥ 50 % assessable	1 (0.7 %)	2 (91.5 %)	
PHO	fully assessable	145 (98.6 %)	129 (98.5 %)	1.0
	≥ 50 % assessable	2 (1.4 %)	2 (91.5 %)	

¹ Fisher's exact test.

Table 2 Evaluation of individual quality criteria.

significant for all four criteria, i. e., the null hypothesis of the independence of judgement and group membership cannot be rejected at the 5 % level.

In all cases the assessability of each criterion was greater than 50 %, so that the evaluation scores “3” and “4” were not given.

Agreement of both Radiologists

All images were considered to be “assessable” by both radiologists (total agreement: 100 %). With respect to the individual quality criteria, there is substantial concurrence in the evaluation of interface (total agreement: 99.28 %; κ -

coefficient: 0.8, 95 % CI [0.52 – 1.00]), and weak moderate agreement regarding “components” and “surface” (total agreement: 96.6 % and 98.56 %; κ -coefficient 0.59, 95 % CI [0.23 – 0.95] and [0.35 – 0.83]). Since one radiologist used only the “completely assessable” rating for the “PHO” criterion, calculation of the kappa coefficient was omitted (total agreement: 98.56 %).

Radiation Exposure

Average DAP was 1.537 $\mu\text{Gy}\cdot\text{m}^2$ for reduced-dose images and 2.432 $\mu\text{Gy}\cdot\text{m}^2$ for images acquired with the standard dose. Presuming a comparable correlation of DAP and effec-



Fig. 4 Pronounced periarticular heterotopic ossification (white arrows) in a reduced-dose radiographic image of a 52-year-old male patient after post-traumatic osteoarthritis and several replacement operations due to loosening of the prostheses.

tive dose in both groups, a dosage reduction of 37% can be assumed, especially in the study population in which the same body region (knee joint) was investigated.

Discussion

In all areas of diagnostic application of radiation, radiologists are required to employ the lowest possible dosage for an examination that can obtain a suitably assessable image for the medical issue (ALARA principle: as low as reasonably achievable). This effort is supported and advanced by the recent European campaign “EuroSafe Imaging” (www.euro-safeimaging.org) of the European Society of Radiology (ESR) [15]. However, the lowest required dose is not a fixed value and is dependent upon the body region and examination indications as well as current technical advances. This is implemented in the guidelines of the German Medical Association so that new reference values obtained statistically from all medical users of radiation can be taken into consideration, particularly the dissemination of technical innovations [5]. Our work addresses the above-named influences

on the lowest required dosage using the experimental approach of a prospective randomized study design. The establishment of quality criteria targets an indication-specific evaluation; dose reduction in digital projection radiography should take into account these criteria compared to conventional film-screen systems.

Based on existing results, a 37% dose reduction in PR of the knee joint after TKA is possible without measurable loss of quality with respect to important indications. All radiographic images – with or without reduced dosage – were assessable with respect to the clinical issues.

The developed quality criteria are aimed specifically at the diagnosis of septic or aseptic loosening as well as material failure, e.g., abrasion of the PE inlay or inlay luxation. Both complications represent an absolute indication of surgery; therefore the quality of the radiographic examination is highly important in such cases [1]. PHO can be observed among approx. 25% of patients after prosthesis implantation, and can result in postoperative motion limitations [16]. Likewise, the statistical analysis of the individual criteria showed this to be independent of the dose. The important “interface” and “components” criteria were marginally better evaluated, underscoring the non-inferiority of this study arm.

Comparison with similar studies of PR of the full spine and full leg images further suggest another conclusion. In these studies, non-inferiority was statistically confirmed; however, unlike our work, there were also non-assessable examinations [8, 9]. The proportion of these was higher in the reduced-dosage groups compared to the standard groups. On the other hand, assessability of 100% in our current study makes the potential of an additional dose reduction of more than 37% likely.

Although there are no mandatory national or European guidelines regarding the frequency of PR follow-up examinations after TKA, the preferred standard is four follow-ups within the first two years after surgery and then at least a two-year checkup interval over the entire service life of the prosthesis. To our knowledge, there have been no comparable studies dedicated to consideration of dose reduction after TKA. Even though the examined area is distant from the body trunk, it should be noted that the stochastic radiation effect is independent of the total dosage in its magnitude. However, the likelihood of this occurrence is influenced by any dose reduction.

Our study statistically confirmed the non-inferiority of post-TKA digital radiographs with an image receptor dose reduced by 37% when compared to the standards of the German Federal Office for Radiation. In addition, with regard to further technical developments such as reduced-dose biplanar stereo radiography systems [17, 18], the possibility of prospectively guided, statistically grounded quality assurance is demonstrated.

Digital radiographic images of the knee joint after endoprosthesis implant with a 37% reduced image receptor dose are not inferior to those acquired with the standard dose.

All physical structures required to evaluate the clinical outcome can be sufficiently assessed with sensitivity class SC 800.

Conclusion

We recommend sensitivity class SC 800 as the new reference value for digital radiographic images of the knee joint with the above-mentioned indication.

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