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Reproducible Assessment of Radiolucent Lines in Total Knee Arthroplasty

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The Knee Society Total Knee Arthroplasty Radiographic Evaluation and Scoring System was introduced to encourage uniform reporting of radiographic outcome. However, the method for evaluation of radiolucent lines has been shown to be unreliable. Because it has been shown that reducing the complexity of classification systems increases reliability and reproducibility, we questioned whether a simplification of the Radiographic Evaluation and Scoring System would improve reliability and reproducibility. A new system for assessment of radiolucent lines was introduced, and the interobserver reliability and intraobserver reproducibility were studied in 100 patients with 120 total knee replacements. For the new system the mean kappa intraobserver reproducibility coefficient was 0.71 (range, 0.62–0.85) for the femoral component, 0.86 (range, 0.80–0.96) for the tibial component, and 0.58 (range, 0.46–0.75) for the patella prosthesis. The mean interobserver reliability coefficient among three observers was 0.61 (range, 0.45–0.72) for the femoral component, 0.82 (range, 0.73–0.88) for the tibial component, and 0.58 (range, 0.43–0.72) for the patella prosthesis. The new system for assessment of radiolucent lines increased reliability and reproducibility and should supplement the Knee Society's Radiographic Evaluation and Scoring System.

Level of Evidence: Diagnostic study, Level II-1 (development of diagnostic criteria on basis of consecutive patients—with universally applied reference gold standard). See the Guidelines for Authors for a complete description of levels of evidence.

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Evaluation of radiolucent lines frequently is done in the radiographic assessment of total knee arthroplasties.[1,13,19–21,24,27,29–31] In 1989 the Knee Society Total Knee Arthroplasty Radiographic Evaluation and Scoring System was introduced. The score was developed by consensus to encourage uniform reporting of the results of total knee arthroplasties so comparisons could be made between different institutions and between different implants.[8] Furthermore, such a system was intended to detect radiographic changes with time, which may indicate implant failure. Since its introduction the system has been used in various studies.[5,12,15,21,27]

The Radiographic Evaluation System provides reliable methods for assessment of component positioning.[3] However, the method for evaluation of radiolucent lines has been shown to be unreliable. Correlation coefficients for the radiolucent lines were low (Pearson correlation coefficient range, –0.17–0.34) except for measurements at the tibial side in the AP view. Calculation of the mean differences indicated significant differences for all components ($p < 0.05$ each).[3] The absence of reproducibility clouds the comprehension and comparison of studies that are based on such a classification system.[25]

Because it was shown that reducing the complexity of classification systems increases reliability and reproducibility, we questioned whether simplifying the Radiographic Evaluation System would improve its reliability and reproducibility.

MATERIALS AND METHODS

One hundred twenty total knee arthroplasties (Kinemax and Kinemax Plus, Howmedica, Rutherford, NJ) in 100 patients—59 women and 41 men—were assessed consecutively at our clinic. The average age of the patients was 73.6 years (range, 46–89 years). The average followup was 7.2 years (range, 3–16 years).

At followup, standardized radiographs were made with the patient supine, the knee extended, and the xray beam directed perpendicular to the joint line at the level of the middle of the

shaft in the AP plane, with the foot pointing directly to the ceiling to control rotation. The lateral radiograph was made with the knee in the same position but with the xray beam directed at an angle of 90° to the AP plane and pointing to the lateral part of the joint line at the level of the middle of the shaft. The joint line location was estimated by palpation. The tibial component was evaluated in the AP and lateral view, the femoral component in the lateral view, and the patella on 30° axial and lateral views. The views were taken without changing the patient's position. A goniometer was used for obtaining 30° axial radiographs. Measurement of radiolucent lines at the cement-bone interface was done for all three prosthetic components. Radiolucent lines were measured in millimeters.

For assessment of reliability and reproducibility of the evaluation systems, the series of 120 knee replacements (360 radiographs) was measured independently on three occasions. Three observers who were blinded to the outcome made the measurements using the current Knee Society Radiographic Evaluation system for assessment of radiolucent lines and with a new, modified scoring system for assessing radiolucent lines.

The current Knee Society system suggests seven zones for the tibial component (AP), seven zones for the femoral component (lateral view), three zones for tibial component (lateral view), and three to five zones for the patella, depending on the type of knee prosthesis used. The total widths of radiolucent lines of a prosthetic component were determined by adding the widths of radiolucent lines as measured at the specific component zones defined by Ewald.[8] Therefore, the total widths of radiolucent lines is a calculated value and not actually a single measurement. The total widths were recorded independently for the tibial component in the AP and lateral views, for the femoral component in the lateral view, and for the patellar prosthesis in the axial view.

For the new evaluation system for assessment of radiolucent lines, the current Knee Society system was modified in two ways. First, the zone classification system described by Ewald[8] was not used. For the tibial component a radiolucent line was recorded if it was located medial, lateral, anterior, or posterior. For the femoral component a radiolucent line was recorded if it was located anterior or posterior. Radiolucent lines were measured for the femoral component in the lateral view; for the tibial component, the measurements of the AP and lateral view were combined; and for the patella component, the measurements of the AP and lateral view were combined (Table 1).

Second, the radiolucent lines were not measured as a continuous value (in millimeters). The sum of widths of radiolucent lines was categorized as no, narrow, or wide radiolucent lines. If the total sum of widths of radiolucent lines for a prosthetic component was 4mm or less the category narrow was used, and if the total sum of widths was greater than 4 mm the category wide was used.

Figure 1 shows how the system facilitates measurement of radiolucent lines. There is no need to allocate the radiolucent lines to a predefined zone, and there is no need to give a continuous value for the total sum of widths of radiolucent lines of a prosthetic component. A decision must be made if the total sum of widths of radiolucent lines of a prosthetic component is greater or less than 4 mm.

Each radiograph was classified by three observers on three occasions. As it has been suggested that that the expertise of the raters can effect interobserver agreement,[16,18] only observers who had similar training and clinical experience were asked to participate in the study. All observers were orthopaedic surgeons with at least 5 years (range, 5–12 years) experience in clinical and radiographic assessments of total joint replacements. The guidelines of the current and the modified version of the Knee Society Radiographic Evaluation and Scoring System for assessment of radiolucent lines were available to all of the blinded raters, and all observers were given similar instructions. Before the first review of the radiographs, the observers were trained. After the first review had started no questions or discussions were allowed during or after testing. The observers were given as much time as they needed to review each radiograph. The radiographs were classified by each observer on three separate occasions, 2 months apart. In the interim, the radiographs were not available to any of the observers, and no feedback was provided. All identifying data on the radiographs were obscured, and the radiographs were numbered randomly.

For the modified Knee Society system, kappa values were generated by setting the observed agreement in relation to the proportion of agreement expected by chance. The kappa coefficients ranged from 1 (complete agreement) to 0 (chance agreement) to less than 0 (less agreement than expected by chance).

TABLE 1. Modified Version of the Knee Society Total Knee Arthroplasty Radiographic Scoring System for Assessment of Radiolucent Lines

Component	View	Radiolucent Lines	Localization
Femoral component	Sagittal	none narrow (≤4 mm) wide (>4 mm)	anterior posterior
Tibial component	AP and sagittal	none narrow (≤4 mm) wide (>4 mm)	anterior posterior medial lateral
Patellar component	Sagittal and axial	none narrow (≤4 mm) wide (>4 mm)	

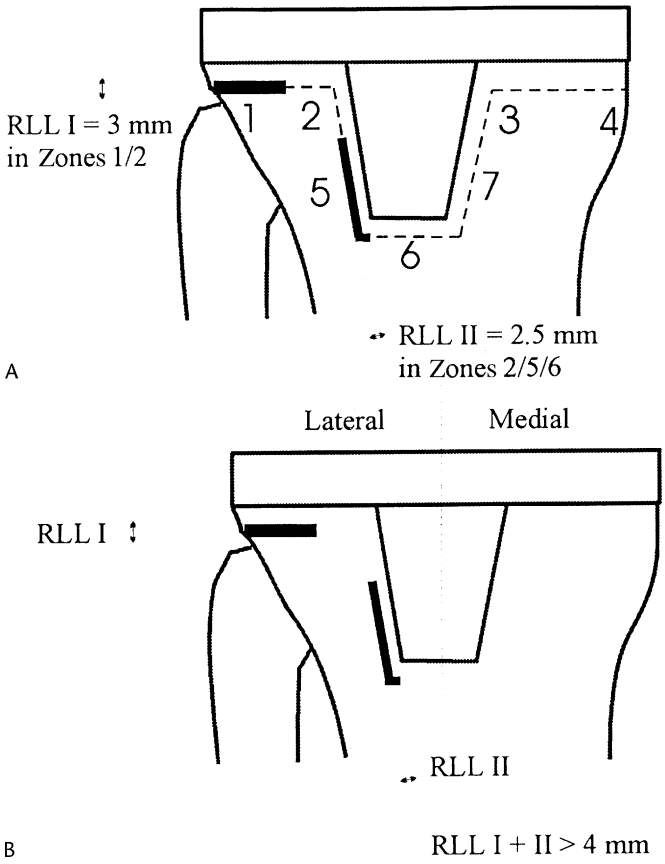

Fig 1A–B. This (A) AP drawing of a tibial component is shown using the current Knee Society system for measurement of radiolucent lines. There is one 3-mm radiolucent line in Zone 1, probably in Zone 2; and there is a second 2.5-mm radiolucent line in Zone 5, probably in Zones 2 and 6. The radiolucent lines are measured in millimeters and are summed to a total score. (B) The modified system assesses two radiolucent lines of the lateral tibial component. The total sum of radiolucent lines is greater than 4 mm (wide radiolucent lines).

The guidelines of Svanholm et al[26] were used for interpretation of kappa values. Values less than 0.5 indicated poor agreement and those greater than 0.75 indicated excellent agreement. According to Smith et al,[25] kappa values between 0.5–0.75 were interpreted as fair. The levels of agreement between paired observers (interobserver reliability) and between the reviews of the same observer (intraobserver reproducibility) were calculated. To account for interobserver variability of the current Knee Society score for assessment of radiolucent lines, the pairwise Pearson's correlation coefficient was calculated. The SPSS software package was used for all analyses (SPSS Inc., Chicago, IL).

RESULTS

The mean total number of radiolucent lines measured is shown in Table 2.

For the original Radiographic Evaluation System of The Knee Society, fair to poor intraobserver and interobserver correlations were found. The mean intraobserver correlation was 0.42 (range, 0.26–0.55) for the femoral component, 0.46 (range, 0.32–0.62) for the AP view of the tibial component, 0.47 (range, 0.29–0.69) for the lateral view of the tibial component, and 0.05 (range, –0.07–0.23) for the patella prosthesis. The mean interobserver correlation was 0.26 (range, 0.20–0.36) for the femoral component, 0.69 (range, 0.52–0.73) for the AP view of the tibial component, 0.26 (range, 0.15–0.40) for the lateral view of the tibial component, and 0.13 (range, –0.03–0.24) for the patella prosthesis.

For the new, modified radiographic evaluation system, fair to excellent intraobserver and interobserver correlations were found. The intraobserver correlation was 0.71 (range, 0.62–0.85) for the femoral component, 0.86 (range, 0.80–0.96) for tibial component, and 0.58 (range, 0.4–0.75) for the patella prosthesis. The mean interobserver correlation was 0.61 (range, 0.45–0.72) for the femoral component, 0.82 (range, 0.73–0.88) for the tibial component, and 0.58 (range, 0.43–0.72) for the patella prosthesis (Table 3).

DISCUSSION

The Knee Society Total Knee Arthroplasty Radiographic Evaluation and Scoring System provides reliable methods

TABLE 2. Mean Total Number of Radiolucent Lines for the Three Prosthetic Components among the Three Observers and the Three Reviews

	Femoral Component		Tibial Component		Patella Component	
Radiolucent Lines	*Total*	*Range*	*Total*	*Range*	*Total*	*Range*
None	72	64–78	43	37–47	94	82–104
Narrow (≤4 mm)	46	39–54	68	62–74	26	16–38
Wide (>4 mm)	2.3	2–3	9.4	5–13	0	0

TABLE 3. Interobserver Reliability among the Three Observers for Each Review Using the Modified Radiographic Evaluation System

Review	Kappa Values		
	Observer 1 versus Observer 2	*Observer 1 versus Observer 3*	*Observer 2 versus Observer 3*
First			
Femoral component	0.71	0.71	0.72
Tibial component	0.85	0.88	0.85
Patella component	0.45	0.60	0.43
Second			
Femoral component	0.45	0.53	0.49
Tibial component	0.74	0.84	0.81
Patella component	0.63	0.72	0.66
Third			
Femoral component	0.66	0.64	0.59
Tibial component	0.73	0.82	0.87
Patella component	0.55	0.66	0.52
Total			
Femoral component	0.61	0.63	0.60
Tibial component	0.77	0.85	0.84
Patella component	0.54	0.66	0.52

for assessment of component positioning. However, the method for evaluation of radiolucent lines is unreliable.[3] A classification should be reproducible among observers and by one observer on separate occasions. Reliability is essential for any classification system.[10] Without these qualities, a precise language on which scientific studies and comparisons can be based is impossible.[25] In the absence of interobserver reliability, it is not sound to compare studies of similarly classified patients from different centers.[26] Also, in the absence of intraobserver reproducibility, it is not sound to rely on outcome studies that were assessed during time, in the same center, or by the same observer or group of observers.[25] Reported evaluations of orthopaedic classification systems have yielded disappointing results for interobserver reliability and intraobserver reproducibility[2,4,10,11,17,22,23,25,28] (Table 4). Because it was shown that reducing the complexity of classification systems increases reliability and reproducibility, we thought that simplifying the Knee Society's Radiographic Evaluation System might improve reliability and reproducibility.

We found fair to poor interobserver correlation with the original Radiographic Evaluation System. These findings were consistent with the results of a previous study showing poor interobserver correlation (femoral component,

TABLE 4. Intraobserver and Interobserver Reliabilities of Other Classification Systems (Review of the Literature)

Classification System	Number of Radiographs	Intraobserver Reliability	Interobserver Reliability	Authors
		Kappa Values		
AO Classification of fractures of the distal radius	30			Flikkila et al[10]
14 categories			0.18	
5 categories			0.23	
2 categories			0.48	
Neer classification system for proximal humeral fractures	50	0.55–0.83	0.48–0.52	Sidor et al[22]
Classification of fractures of the proximal end of the humerus	95			Siebenrock and Gerber[23]
Neer system		0.60	0.40	
AO/ASIF system		0.58	0.53	
Modified version of the Knee Society Total Knee Arthroplasty Radiograpic Evaluation and Scoring System	120	Femoral 0.71 Tibial 0.86 Patella 0.58	Femoral 0.61 Tibial 0.82 Patella 0.58	Current study
		Pearson Correlation Coefficient		
Knee Society Total Knee Arthroplasty Radiographic Evaluation and Scoring System	65		Femoral 0.20 Tibial (AP) 0.47 Tibial (sagittal) 0.22 Patella –0.02	Bach et al[3]

0.20; tibial component (AP), 0.47; tibial component (sagittal), 0.22; patella component, −0.02).[3] Therefore, we developed a modified version of the Knee Society's Radiographic Evaluation and Scoring System. Our intent was to eliminate two sources of error. The first error may arise from the zone definition procedure. A radiolucent line is not always located exactly in a predefined zone as defined by the scoring system. In addition, the zones are not precisely defined, as for some zones, the definition of where one radiolucent line and the next begins is lacking. Therefore, it is not always possible to exactly allocate a radiolucent line to a zone, and therefore, different observers may have different opinions as to which zone(s) a radiolucent line should be allocated. This may reduce the reliability of the system. The second error may arise from measurement of radiolucent lines using continuous values (millimeters and half-millimeters). This methodology may seem more precise but is also a source of error. Categorization of measurements (0 mm or < 4 mm or > 4 mm) avoids intraobserver and interobserver variations in the chosen category. The source of error in such a categorized system is reduced to errors between the categories. Using the modified system, the only decision that must be made is if a radiolucent line is absent or if a radiolucent line is greater or less than 4 mm. For assessment of the tibial component, the AP and sagittal views were combined because we think this practice is clinically more useful. It may be of limited value if a component appears loose on one view but stable on the other.

A limitation of the current study is the radiographic technique. The method of taking the radiographs may introduce a systematic error because of limited control for beam direction and limb rotation. This may influence the extent and the overall frequency of radiolucent lines. However, this error was the same for all observers, and therefore it does not influence the results of intraobserver and interobserver variabilities in the current study. If repeated radiographs were taken from the same patient (eg, longitudinal control radiography) differences in the radiographic technique may bias the results of radiolucent line measurement.

A radiographic evaluation system should detect radiographic changes with time, which may indicate implant failure.[9] Such a time-based analysis was not done in the current study. The modified classification system might prove useful in future studies if applied to a longitudinal study of a series of implants to correlate the radiographic and the clinical outcomes of a patient with a total knee replacement.

The proposed scoring system attempts to improve reliability by simplifying the scoring system. However, no clinical or functional data were correlated with the modified radiographic score. We cannot say if the modified system adequately reflects the clinical status of a patient in the long term. It is possible that the original score better captures the longer-term clinical implications than the modified score.

It has been shown that reducing the complexity of classification systems increases reliability and reproducibility. Flikkila et al[10] tested the interobserver reliability of the AO system of classification of fractures of the distal radius. Interobserver reliability was poor when detailed classification (14 categories) was used. By reducing the categories to five, interobserver reliability was improved but still poor. When only two AO types were used, the reliability was moderate using plain radiographs and good to excellent with the addition of computed tomography.

On the other hand, Sidor et al[22] reported that reducing the number of categories did not significantly improve intraobserver reproducibility and interobserver reliability. This may indicate that disagreement is at a very basic level and that poor reproducibility is a problem of the radiographic imaging rather than of the classification system.[23]

In the current study, the three-point classification system achieved excellent intraobserver reproducibility and fair to excellent interobserver reliability for the femoral and tibial components, respectively. However, for the patella component, poor intraobserver agreement and interobserver agreement were achieved when only axial view radiographs were used. When the axial and the sagittal views were combined, the reliability and the reproducibility improved to a fair level of agreement.

Radiolucent lines are observed much more frequently about the tibial component than about the femoral component.[7,14,19] In the current series, radiolucent lines about the tibial component were seen in 64% of the patients, about the femoral component in 40% of the patients, and about the patella component in 22% of the patients. This may be related more to the difficulty in observing the radiolucent lines under the femoral component, rather than to their true occurrence.[6,29] Ecker et al[6] stated that rotation or flexion of the prosthesis greater than 5° caused the radiolucent lines to be hidden. The lines also could not be seen if the central beam was angulated either cephalad or caudad greater than 6°. Fluoroscopically assisted radiography may have advantages for focusing the xray beam. Vyskocil et al[30] assessed observer agreement for evaluation of radiolucent lines using conventional and fluoroscopically assisted radiography. They found that the agreement was better for the fluoroscopically assisted radiographs. For conventional radiography, intraobserver agreement was moderate and interobserver agreement was fair for the femoral and poor for the tibial component. The patella component was not mentioned. Our results do not support their findings. For the current classification system, intraobserver reproducibility was excellent and in-

terobserver reliability was fair for the femoral component and excellent for the tibial component. These differences of intraobserver agreement and interobserver agreement may be explained by the method of assessment used in the two studies. Vyskocil et al[30] assessed seven different zones for the tibial component and six zones for the femoral component. The complexity of assessment might have contributed to low observer agreement.

Simplification of the Radiographic Evaluation System of The Knee Society improved reliability and reproducibility. The new system for assessment of radiolucent lines should be used to supplement the Knee Society Radiographic Evaluation and Scoring System.

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