Assessment of radiolucent lines in cemented shoulder hemi-arthroplasties: study of concordance and reproducibility

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Abstract We report on the concordance and reproducibility of the evaluation of radiolucent lines in the humeral component of shoulder arthroplasty. Thirty-two shoulder prostheses were assessed independently, on two occasions, by five observers. The level of inter- and intra-observer agreement was calculated using the kappa statistic. Intra-observer agreement: the overall kappa values ranged from 0 to 0.6, meaning poor, fair and moderate agreement levels. Inter-observer agreement: when the anteroposterior (AP) views were analysed, the values obtained for the bone–cement interface ranged from 0.290 to 0.539, meaning a poor-to-moderate agreement. For the cement–implant interface, the values ranged from 0.064 to 0.684, meaning a poor-to-good agreement. When radiolucent lines of the humeral component were analysed, inter-observer agreement proved to be as low as that obtained when total hip or knee components were analysed. Intra-observer agreement showed better results.

Résumé Le but de cette étude est d'évaluer les liserés du composant huméral de la prothèse d'épaule. 32 prothèses d'épaules ont été suivies de façon indépendante à deux reprises par 5 observateurs. L'évaluation a été réalisée de façon statistique en intra et en inter observateurs. l'évaluation intra observateur est classée de 0 à 0.6 (mauvais, médiocre, moyen) et pour l'évaluation inter observateur, ces valeurs sont toujours basées sur l'analyse de la radio antéro postérieure et de 0.290 à 0.539. En ce qui concerne l'analyse de l'interface ciment - implant, ces valeurs variant de 0.064 à 0.684. l'évaluation inter observateur concernant

les liserés est identique à ce que l'on peut observer dans l'analyse des prothèses totales de hanche ou de genou. L'analyse intra observateur améliore encore les résultats de cette évaluation.

Introduction

Total shoulder arthroplasty has proven to be effective in the treatment of glenohumeral arthritis, and, although in some studies the results of total shoulder replacement are reported to be better than those of hemi-arthroplasty, glenoid component loosening remains the major concern when total shoulder replacement is analysed over time, and it has been subjected to widespread study [3, 4, 7, 17, 21, 23].

The presence of radiolucent lines around arthroplasty components has been attributed to several different factors, including poor cementing technique, component design, surgical technique, bone quality and component stability [2, 8, 10, 11, 16, 22]. While the significance and clinical correlation of size and location of radiolucent lines is still unknown, the progression of a radiolucent line over time has been commonly associated with component loosening [8]. The rate of radiolucent lines observed is extremely variable from one study to another, making the comparison of related factors more difficult [2, 4, 8, 16, 20, 22].

Although the humeral component does not appear to be a major cause of failure in shoulder replacement, [15, 18] Hasan et al. have pointed out that humeral loosening was present in 12 % of unsatisfactory shoulder replacements [7]. The purpose of our study was to determine the concordance and reproducibility of assessments of radiolucent lines in cemented humeral components as well as to analyse the accuracy of assessments of the progression of these lines over time. To our knowledge, the reliability of evaluation

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and evolution of humeral radiolucent lines has not been previously reported.

Materials and methods

Thirty-two shoulder prostheses in 31 patients were assessed independently, on two occasions, by five observers. Of the 32 shoulder prostheses, 12 corresponded to hemi-arthroplasties performed because of gleno-humeral arthritis and 20 to hemi-arthroplasties performed for proximal humeral fracture. Each hemi-arthroplasty was studied radiologically, with an anteroposterior (AP) view and an outlet view obtained postoperatively and after one year, i.e two pairs of X-ray examinations for each patient. All identifying data on the radiographs were obscured, and all the radiographs were numbered randomly.

Radiolucent lines were assessed on each radiological film with use of a shoulder adaptation [19] of the system described for hip assessment by Gruen et al. [5]. The stem of the humeral prosthesis was divided into seven zones: 1 and 7 corresponded to the lateral and medial aspects of the proximal third of the humeral stem, zones 2 and 6 corresponded to the lateral and medial aspects of the middle third, zones 3 and 5 corresponded to the lateral and medial aspects of the distal third, and zone 4 was the area at the tip of the stem (Fig. 1). Each zone was evaluated at the bone–cement interface and the cement–stem interface. If a specific zone was considered to have no radiolucent line, it was given a value of 1. If a radiolucent line between 0 mm and 1 mm was detected, the zone was given a value of 2; if a radiolucent line between 1 mm and 3 mm was detected, the value given was 3, and if the radiolucent line was considered to be greater than 3 mm, the given value was 4. Zones 1 and 7 were not included in the analysis if hemi-arthroplasty had been performed for proximal humeral fracture. The five observers were orthopaedic residents who had had similar training and

clinical experience, and they were instructed on how to complete the questionnaire for each X-ray, but no other special training was considered to be necessary because the nature of the study was purely observational and no clinical interpretation was requested. Observers were allowed to reject zones where they felt classification was not possible. The two observations were performed three weeks apart. Every observer analysed a total of 128 X-ray films, 896 zones and 1,792 interfaces.

The level of inter- and intra-observer agreement was calculated using the kappa statistic. The levels of agreement were classified as: less than 0 (no agreement), 0 to 0.2 (poor agreement), 0.21 to 0.4 (fair agreement), 0.41 to 0.6 (moderate agreement), 0.61 to 0.8 (good agreement) and 0.81 to 1 (very good agreement) [13].

As every patient included in the study underwent postoperative and one year follow-up X-ray examinations, the observers evaluated, in a blind fashion, the one year evolution of radiolucent lines. That permitted us to analyse the accuracy of their interpretations of the changes in the radiolucent lines from the immediate postoperative examination to the one year follow-up examination. We evaluated this by examining the percentage of “possible responses” registered. If the value obtained at the one year follow-up for each specific zone was equal or superior to that obtained at the immediate postoperative evaluation, that was called a “possible response”; otherwise, if the value obtained at the one year follow-up was inferior to that obtained at the immediate postoperative evaluation, that was called a “non-possible response”.

Results

Intra-observer agreement

The results of the kappa values obtained when we analysed the bone–cement interface and the cement–implant inter-

Fig. 1 Radiolucent zones in the humeral stem

Table 1 Intra-observer kappa values for the bone–cement interface in the AP and outlet X-ray views (*CI* confidence interval)

Zone	AP view	CI 95%	Outlet view	CI 95%
Zone 1	0.6531	0.52–0.72	0.6217	0.46–0.78
Zone 2	0.5151	0.21–0.64	0.5552	0.26–0.74
Zone 3	0.6016	0.30–0.74	0.6274	0.33–0.81
Zone 4	0.2068	0.11–0.66	0.0342	0.10–0.28
Zone 5	0.5972	0.25–0.82	0.5742	0.26–0.79
Zone 6	0.4897	0.18–0.69	0.5937	0.29–0.79
Zone 7	0.6249	0.48–0.70	0.6221	0.46–0.69

face are summarised in Tables 1 and 2, respectively. The overall kappa values ranged from 0 to 0.6, meaning poor, fair and moderate levels of agreement. Nevertheless, it is interesting to point out that, in both interfaces and in both radiological projections, the lowest agreement levels were obtained when zone 4 was analysed (0.2068 and 0.0342 for the bone–cement interface and 0.2855 and 0.2864 for the cement–implant interface), except for zone 5 in the AP view of the cement–implant interface (0.0174). Moderate-to-good agreement was found among zones 1,2,3,6 and 7, no matter which X-ray projection or interface was evaluated.

Inter-observer agreement

All possible combinations from the five observers were evaluated, and the results are listed in Table 3. When the AP views were analysed, the values obtained for the bone–cement interface ranged from 0.290 to 0.539, meaning a poor-to-moderate agreement. When the cement–implant interface was considered, the values obtained ranged from 0.064 to 0.684, meaning a poor-to-good agreement.

Interestingly, observer 1, when faced with any other observer, never reached agreement values higher than poor or fair, while all the other observer combinations reached fair-to-good agreement, pointing out an observer-dependent phenomenon. Accuracy of the follow-up examination values ranged from 69.7% to 97.5% of “possible responses” for the cement–implant interface and from 88.1% to 97.2% of “possible responses” for the cement–implant interface. The

Table 2 Intra-observer kappa values for the cement–implant interface in the AP and outlet X-ray views (*CI* confidence interval)

Zone	AP view	CI 95%	Outlet view	CI 95%
Zone 1	0.6221	0.46–0.69	0.6555	0.47–0.87
Zone 2	0.405	0.26–0.62	0.5041	0.15–0.73
Zone 3	0.5052	0.14–0.76	0.5277	0.12–0.81
Zone 4	0.2855	0.04–0.44	0.2864	0.01–0.41
Zone 5	0.0174	0.01–0.04	0.5791	0.14–0.84
Zone 6	0.2489	0.07–0.29	0.5215	0.15–0.79
Zone 7	0.5712	0.41–0.68	0.6607	0.45–0.89

Table 3 Inter-observer kappa values for the bone–cement interface in the AP and outlet X-ray views (*SE* standard error)

Observers	AP view	Outlet view
1–2	0.343 (SE 0.021)	0.304 (SE 0.022)
1–3	0.307 (SE 0.020)	0.149 (SE 0.020)
1–4	0.299 (SE 0.020)	0.261 (SE 0.022)
1–5	0.290 (SE 0.018)	0.204 (SE 0.017)
2–3	0.518 (SE 0.020)	0.149 (SE 0.020)
2–4	0.539 (SE 0.020)	0.261 (SE 0.022)
2–5	0.448 (SE 0.019)	0.204 (SE 0.017)
3–4	0.529 (SE 0.020)	0.455 (SE 0.022)
3–5	0.519 (SE 0.020)	0.387 (SE 0.020)
4–5	0.499 (SE 0.020)	0.438 (SE 0.020)

worst results were obtained in zone 2 of the bone–cement interface, and the best ones were in zone 4 of both cement–bone and cement–implant interfaces.

Discussion

Radiolucent lines in hip replacements have been analysed over the past 30 years so that we can better understand prosthesis survival and septic as well as aseptic loosening of the components [9, 20]. Several concordance and reproducibility studies have been performed, either for the femoral component [6] or for the acetabular component [12]. The results obtained varied from poor to moderate or good agreement but were considered to be insufficient to allow comparison of the results in different series in the studies [6, 12].

Total knee replacement has also been the subject of studies of radiolucent lines. Correlation between surgical technique and implant survival rate by the presence of implant radiolucent lines has been sought, with no consistent results. Studies on the reproducibility and concordance of radiolucent lines in knee arthroplasty have also failed to reach reliable agreement rates, although, with the simplified radiographic evaluation system proposed by the Knee Society’s total knee arthroplasty radiographic evaluation and scoring system, better agreement has been obtained [1].

The presence of radiolucent lines around prosthetic components of any joint arthroplasty has been attributed to poor cement technique, component design, surgical technique, bone quality, component stability or prosthesis mismatch [6, 9, 12, 20]. Nevertheless, progressive increase in the width of a radiolucent line has commonly been correlated with component loosening.

As the glenoid component remains the major concern of loosening in total shoulder replacement, several studies have been conducted to better understand the presence and

progression of glenoid radiolucent lines [8, 10, 14, 16, 24]. Studies differ widely when considering the rate of glenoid radiolucent lines, probably because many different circumstances can produce them, such as component mismatch, cemented or metal-backed, pegged or keeled components, position of the scapula on the radiograph, and cement techniques [2, 8, 10, 16, 19, 22]. However, a direct correlation of radiolucent lines with component loosening, as well as the significance of their size and location, is still unproven [10].

The humeral component in total shoulder arthroplasty is commonly considered to have a low risk of loosening; nevertheless, Sanchez-Sotelo et al. reported the presence of radiolucent lines in the humeral component in 16 of 43 shoulder arthroplasties studied, and 2% of the implants were considered to be at risk of loosening [18]. Furthermore, Hasan et al. found that, among the different causes of unsatisfactory shoulder arthroplasties, humeral loosening was present in 12% [7]. In total shoulder replacements, wear debris associated with the glenoid component can lead to aseptic loosening of the humeral component similar to the experience in total hip and knee arthroplasty [11]. As longer follow-up studies for patients undergoing total shoulder arthroplasty are available, the more aseptic loosening may play a part in components failure.

Evaluation of concordance and reproducibility of radiolucent lines in humeral components of shoulder arthroplasty have provided no better results than those obtained when either total hip or knee arthroplasty are analysed.

The worst results are obtained when inter-observer agreement is analysed, meaning that when one is considering the evaluation of radiolucent lines in different studies, no consistent conclusions can be drawn. Furthermore, inter-observer agreement seems to have an observer-dependent effect, since, in our study, when we compared observer 1 with the other observers, the agreement obtained was far lower than with the other observers' pairings.

Intra-observer agreement reached better results for both interfaces than did inter-observer agreement. Zone 4 is a common site for bone cysts as well as cement or bone reactions, and, interestingly, it obtained the lowest agreement for both interfaces, meaning that, for a location where component loosening is most likely to start, radiolucent line analysis is not as reliable as it is for other zones.

To analyse the accuracy of the evaluations of radiolucent line progression through time, the observers examined, in a blind fashion, two pairs of X-rays taken one year apart. Commonly, accuracy is obtained by the comparison of observer evaluation with what is considered to be the "gold standard", meaning that an independent observer has to assign, arbitrarily, a radiolucent line score for each zone and X-ray to be considered the "gold standard". To avoid this arbitrary evaluation, the possible and non-possible response

system was defined. This system allows one to know how many times the evaluation of radiolucent lines through time, for a specific zone and interface, is clinically possible. The overall results obtained ranged from 69.7% to 97.5%, meaning that, in the vast majority of cases, the same observer could consistently evaluate the progression of the radiolucent lines.

The limitations of this study included the inclusion of non-consecutive cases, although we had not pre-selected the cases, and the use of non-standardised X-ray projections, although we believe that the use of non-standardised X-ray projections better reflects the usual clinical scenario.

Thus, in conclusion, inter-observer agreement when the radiolucent lines in the humeral component were examined proved to be as low as the agreement obtained when total hip or knee components were analysed. Intra-observer agreement reached better results but was proven to be observer dependent. The evaluation of progression of radiolucent lines through time by the same observer gave a high percentage of possible responses.

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