Radiographic comparison of pegged and keeled glenoid components

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Glenoid loosening is one reason for failure of total shoulder arthroplasty. Several factors, including radiographic lucency, have been shown to be associated with glenoid loosening. The purpose of this study was to assess the correlation between glenoid design and immediate radiographic lucency in a prospective randomized clinical trial. Total shoulder arthroplasty was performed in 43 patients over a 2-year period. Twenty-three patients were randomized into the keel group and twenty patients into the pegged group. Postoperative radiographs obtained within 6 weeks of surgery were evaluated by 3 raters to determine glenoid lucency. On a scale from 0 (no lucency) to 5 (gross lucency and component loosening), the rate of lucency was 39% (9/23) in the keeled components, which was significantly higher than the rate of 5% (1/20) observed in the pegged components ($P = .026$). Patient age, gender, and glenoid size did not significantly affect glenoid component lucency ($P > .05$). The consistency reliability among raters (Cronbach α) was 0.87, and the intertester reliability was 0.87. Pegged glenoid components have less radiographic lucency when compared with keeled glenoid components in the immediate postoperative period. (J Shoulder Elbow Surg 2005;14:252-257.)

Glenoid component loosening is one of the primary reasons for failure of total shoulder arthroplasty.[9,10,12,21,32,33] Component loosening has been associated with several patient and technical factors. These include preoperative diagnosis (osteoarthrosis vs rheumatoid arthritis or fracture),[11,17] use of cement,[4,13,18,23] prosthesis component mismatch,[20,21,29] mechanical wear of polyethylene components,[5,8,24] osteolysis (stress shielding) with metal components,[5,16,17,23] component malpositioning,[9,21] poor bone stock,[10,22] and deficiency of the rotator cuff.[7,10,19,21,28]

Periprosthetic radiographic lucency after arthroplasty of other joints such as total hip arthroplasty has also been shown to be associated with component loosening.[1,25,26] Extrapolating from the studies of hip arthroplasty, it is reasonable to assume that component loosening in total shoulder arthroplasty may result from periprosthetic radiolucency. Limited evidence of this association has been reported. Torchia et al[27] reported that early radiolucent lines were present in 37 of 40 glenoid components (93%) that eventually developed radiographic loosening, whereas early radiolucent lines were present in only 18 of 41 components (44%) that did not eventually develop radiographic loosening. Furthermore, they reported that 12 of 15 patients (80%) who reported moderate to severe pain also had radiographic loosening.

Recent biomechanical, animal, and retrospective studies have implicated glenoid design in the development of glenoid lucency.[12,14,28,31] These studies indicate that cemented pegged glenoid components appear to have better fixation, better bony ingrowth, and a lower rate of radiographic lucency over time when compared with keeled components.[12,14,28,31] The retrospective human studies may have the disadvantage of incorporating a selection bias in which many surgeons will implant a keeled glenoid if exposure is difficult. This implies that pegged components are placed under more optimal conditions, which may result in a lower incidence of glenoid component lucency. No prospective randomized trial in human beings has been published, to our knowledge, that specifically examined the relationship between glenoid design and glenoid lucency.

The purpose of this study was to perform a prospective randomized trial among patients with primary osteoarthritis of the glenohumeral joint to compare radiolucency between pegged and keeled glenoid components in the immediate postoperative period. Because there would be no selection bias favoring pegged components, our hypothesis was

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that there would be no difference in glenoid lucency between the 2 glenoid designs.[2,3,6,15,30]

MATERIALS AND METHODS

Subjects

This study was a prospective randomized trial. The patients were not told which glenoid component design they had received.

All patients had the diagnosis of primary osteoarthritis of the glenohumeral joint. Patients were excluded from participation in this study if they had radiographic evidence of osteopenia or other metabolic bone disease. There were no other inclusion or exclusion criteria. Two patients in the keeled group and two patients in the pegged group were excluded from the study because the raters were unable to grade the postoperative radiographs because of poor image quality.

A power analysis conducted before the study determined that at least 18 patients per group would be required to identify a mean difference of 1 category (see below) in the rating of glenoid component lucency with a power of 90%. Patients were recruited to participate by the surgeon (G.M.G.) and indicated their willingness to participate by signing an informed consent form.

Surgical procedure

All procedures were performed by the same surgeon (G.M.G.) over a 2-year period from September 2000 through October 2002. The Cofield 2 Modular Arthroplasty (Smith and Nephew, Memphis, TN) system was used. A standard deltopectoral approach was used. The subscapularis was incised at its insertion on the lesser tuberosity. The capsule was separated from the subscapularis and excised. Humeral neck cuts were made at a 45° angle with the humeral shaft and in approximately 30° of retroversion by use of a cutting guide. The humerus was reamed to accept a press-fit prosthesis. The trial stem was placed to protect the humeral cut while preparing the glenoid.

The glenoid was prepared by releasing the capsule and labrum to allow for exposure. The glenoid face was prepared by creating a centering hole. The glenoid reamer was used to remove the articular cartilage and create a congruent base for the final prosthesis. At this point, the random selection of a pegged or keeled glenoid component was made. The circulating nurse consulted a random number list to select the implant.

The appropriate sizing and targeting guides were then used to create either a trough for the keel or holes for the pegs. The cancellous surfaces were then irrigated and soaked with Gelfoam (Pfizer, Peapak, NJ) and Surgicel (Ethicon, Somerville, NJ) before the final polyethylene component was cemented in place. The cement was placed with a syringe, and digital pressure was used to impact the cement and seat the component.

Drill holes were placed in the lesser tuberosity before press-fitting of the final humeral stem. The final head was impacted on the stem. The subscapularis was repaired through the lesser tuberosity drill holes. The wound was then irrigated and closed in standard fashion.

Postoperative care consisted of sling wear for 2 weeks. We instructed the patients in active range-of-motion exercises 2 weeks after surgery and began passive range-of-motion stretching exercises 6 weeks after surgery. At 12 weeks after surgery, patients were advised to resume normal activities gradually, using caution to avoid sudden large or painful joint movements.

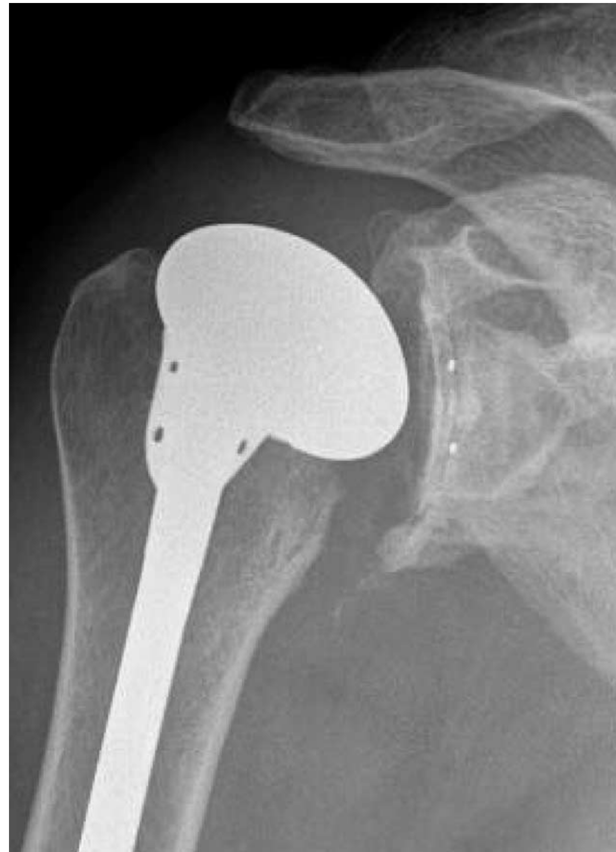

Figure 1 Postoperative radiograph showing a keeled glenoid component with lucency grade 0.

Radiographic lucency

Radiographic lucency of the keeled glenoid components was graded according to criteria previously described by Franklin et al,[7] and the pegged components were graded according to the modification described by Lazarus et al.[14] True anteroposterior radiographs obtained within the first 6 weeks after surgery were evaluated. The keeled components were graded between 0 and 5 (Figures 1 and 2). A grade of 0 represented no lucency.

Grades 1 through 5 were as follows:

1. Radiolucency at inferior and/or superior flange
2. Incomplete radiolucency at keel
3. Complete radiolucency of less than 2 mm in width around keel
4. Complete radiolucency of 2 mm or greater in width around keel
5. Gross loosening

The pegged components were also graded between 0

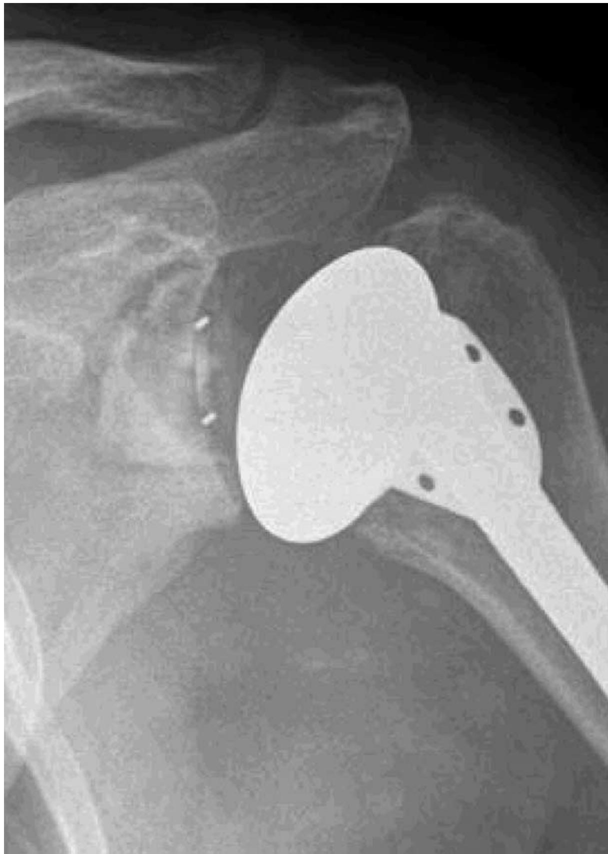

Figure 2 Postoperative radiograph showing a keeled glenoid component with lucency grade 4.

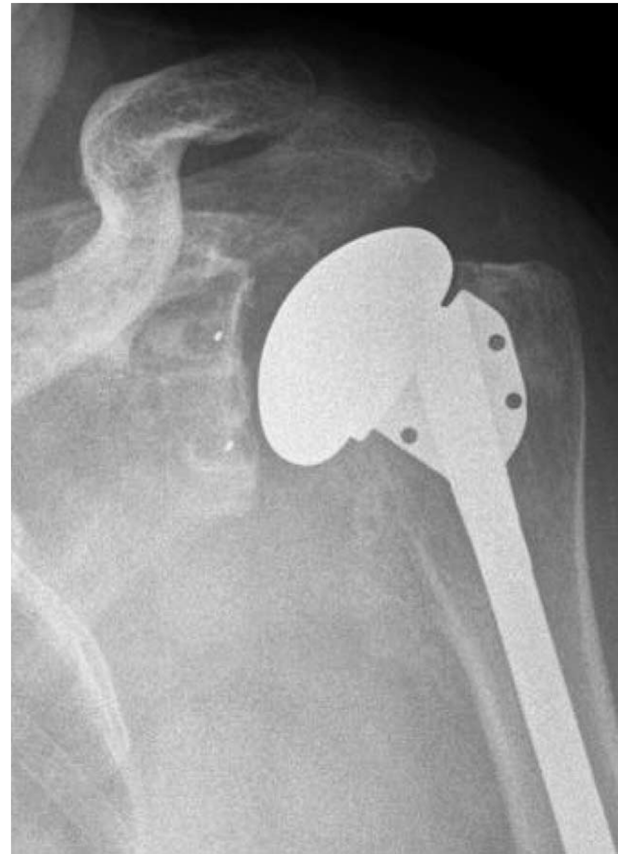

Figure 3 Postoperative radiograph showing a pegged glenoid component with lucency grade 0.

and 5, with 0 representing no lucency (Figures 3 and 4). The remaining grades were as follows:

1. Incomplete radiolucency around 1 or 2 pegs
2. Complete radiolucency of less than 2 mm in width around 1 peg only, with or without incomplete radiolucency around 1 other peg
3. Complete radiolucency of less than 2 mm in width around 2 or more pegs
4. Complete radiolucency of 2 mm or greater in width around 2 or more pegs
5. Gross loosening

The radiographs were evaluated by 3 raters (2 orthopaedic surgeons and 1 radiologist). The orthopaedic surgeon who had performed the arthroplasties was not a rater. These raters had participated in a training session in which they graded the radiographs of 30 patients with total shoulder arthroplasty who had not been enrolled in this study. The training session allowed the raters to confer during the grading to ensure that each rater was using consistent criteria. The raters then independently graded the radiographs for each of the patients in this study.

Data analysis

Intertester reliability was evaluated by use of intraclass correlation coefficients of Shrout and Fleiss type (3,1); this estimate represents the reliability of the composite (average) lucency score of the raters. The χ^2 test was used to determine whether the glenoid component types differed with respect to the presence of lucency. We used the same definition of lucency as described by Lazarus et al[14]: glenoid components with ratings of grade 0 or 1 were classified as having no lucency, and components with ratings of grade 2 or higher were classified as having lucency. Analysis of variance, including patient age, gender, and glenoid size as covariates, was used to determine whether the glenoid component types differed with respect to radiographic lucency.

RESULTS

Subjects

The study consisted of 27 men with a mean age of 67.8 years (SD, 8.1 years) and 16 women with a mean age of 69.9 years (SD, 7.2 years) at the time of arthroplasty. There were 23 keeled glenoid components implanted in 8 women and 15 men and 20 pegged glenoid components implanted in 8 women and 12 men.

There were 3 small, 6 medium, and 14 large keeled glenoid components and 1 small, 6 medium,

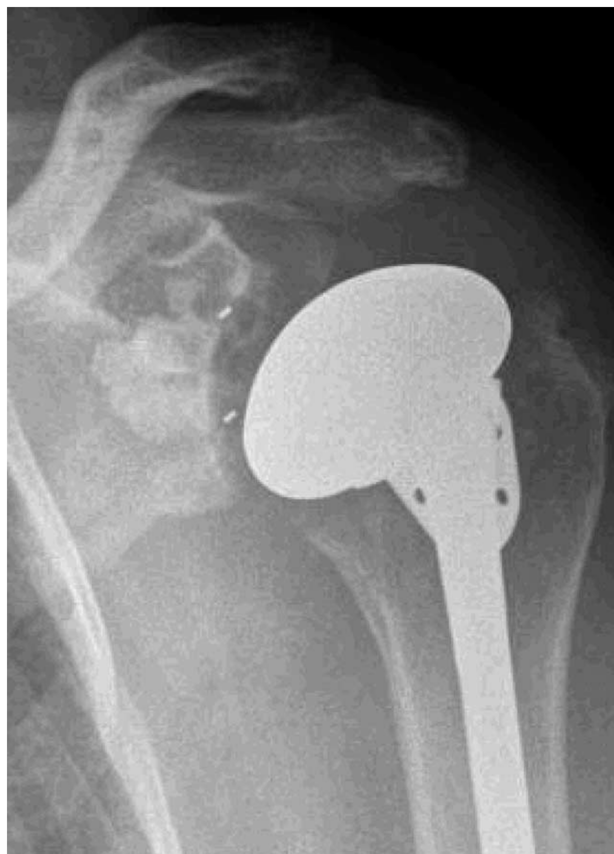

Figure 4 Postoperative radiograph showing a pegged glenoid component with lucency grade 3.

and 13 large pegged glenoid components. All of the men but 1 had received a large-sized glenoid component; 4 of 16 women had received small glenoid components, 11 had received medium components, and 1 had received a large component. Gender ($P = .971$), patient age ($P = .958$), and glenoid size ($P = .999$) did not differ significantly between the 2 glenoid types.

Six patients (five in the pegged group and one in the keeled group) had partial rotator cuff tears that were treated by debridement only, and the remainder of the patients had intact rotator cuffs. In the 6 patients with partial rotator cuff tears, 2 glenoid components received a grade of 0 and 4 received a grade of 1. Hence, with the numbers available, there did not appear to be worse lucency ratings among patients with partial rotator cuff tears.

Intertester reliability

On the basis of the composite of the scores of the 3 raters, the intertester reliability was 0.88 for the lucency ratings. All 3 raters were in perfect agreement for 81% of the radiographs.

Effect of glenoid type

Of the 23 keeled glenoid components, 14 (39%) demonstrated radiographic lucency of grade 2 or higher, whereas only 1 of 20 pegged components (5%) demonstrated lucency of grade 2 or higher (Table I). This difference was statistically significant ($P = .023$).

The keeled components had a mean lucency rating of 1.4 on a scale of 0 (no lucency) to 5 points (gross loosening); 9 (39%) had no signs of radiographic lucency (grade 0), and 14 (61%) had signs of lucency. The pegged components had a mean lucency rating of 0.5 on a scale of 0 (no lucency) to 5 points (gross loosening); 14 (70%) had no signs of radiographic lucency (grade 0), and 6 (30%) had signs of lucency. Patient age, gender, and glenoid size did not significantly affect glenoid component lucency ($P > .05$).

Of the 23 keeled glenoid components, 1 had complete lucency of 2 mm or greater in width (grade 4) and 2 had complete lucency of less than 2 mm in width (grade 3). Nine keeled components had no lucency (grade 0), five had lucency at the inferior or superior flange only (grade 1), and six had incomplete lucency at the keel (grade 2). None of the keeled glenoid components had gross lucency (grade 5) that was evident on the radiographs.

Of the 20 pegged glenoid component, 1 had complete lucency of less than 2 mm in width (grade 3). Five pegged glenoid components had complete lucency of less than 2 mm in width of 1 peg only (grade 2), and fourteen had incomplete lucency around only 1 or 2 pegs (grade 1). None of the keeled or pegged glenoid components had gross lucency (grade 5).

DISCUSSION

We found that the keeled glenoid components had a higher incidence and higher overall grade of radiographic lucency postoperatively than did the pegged glenoid components. We assumed in formulating our hypothesis that eliminating selection bias with a randomized prospective study would equalize the incidence of radiographic lucency between the keel and peg designs. This was not the case. Our results confirm previous animal, biomechanical, and retrospective studies that have reported that pegged glenoid components have less lucency in patients with glenohumeral osteoarthritis than do keeled glenoid components.[13,14,28,33]

We found lucency rates of 39% for keeled glenoid components and 5% for pegged glenoid components evaluated within 6 weeks of surgery. Lucency rates in the literature range from 30% to 96%; however, these previous data do not account for other variables such

Table I Immediate postoperative radiolucency grade for 43 glenoid components

Component	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Keeled	9 (39%)	5 (22%)	6 (26%)	2 (9%)	1 (4%)	0 (0%)
Pegged	14 (70%)	5 (25%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)
Total	6 (14%)	19 (44%)	14 (33%)	3 (7%)	1 (2%)	0 (0%)

Grade 0 indicates no lucency and grade 5 indicates gross component loosening evident on radiograph.

as glenoid design, time after surgery, underlying pathology, or cementing. The only other study in the literature that compared lucency rates between cemented pegged and cemented keeled components immediately after surgery was a retrospective multicenter study published by Lazarus et al.[14] They found that keeled components had a lucency rate (grade 2 lucency or higher) of 72% (11/39 components) whereas pegged components had a lucency rate of only 38% (180/289 components). They also reported a mean lucency rating of 1.8 points for keeled components and 1.3 points for pegged components. We found mean lucency ratings of 1.4 points for keeled components and 0.5 points for pegged components. Our study differed from their study by evaluating the results of only 1 surgeon in a prospective randomized format.

Our randomized trial design eliminated several threats to internal and external validity present in previous trial designs. These would include initial differences among patients (eg, severity of disease, quality of glenoid bone) and selection biases (ie, the surgeon chooses the glenoid component based on clinical or anatomic features).[14,28] However, our data still suffer from the same inherent problem of radiographic evaluation. We followed prior evaluation protocols, but it is not clear how keel and peg radiographic evaluation correlate. Our study, however, did demonstrate a high level of intraobserver and interobserver consistency not seen in prior studies. This is likely related to the pre-evaluation testing done on nonstudy radiographs to develop a consensus for grading.

In summary, we found that keeled glenoid components have higher grades of radiographic lucency (39%) immediately after surgery than pegged glenoid components (5%) in a randomized group of patients. Controversy still exists as to the relationship between glenoid lucency and clinical failure of the glenoid component. However, the long-term study by Torchia et al[27] suggests a positive correlation. With these data in mind, orthopaedic surgeons should balance the technical difficulty of implanting pegged components with the potential long-term benefits.

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