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ORIGINAL ARTICLE

Radiographic and clinical comparison of pegged and keeled glenoid components using modern cementing techniques: midterm results of a prospective randomized study

Christopher M. Kilian, MD[a,*], Cyrus M. Press, MD[b], Kevin M. Smith, MD[c], Daniel P. O'Connor, PhD[d], Brent J. Morris, MD[a], Hussein A. Elkousy, MD[a], Gary M. Gartsman, MD[a], T. Bradley Edwards, MD[a]

[a]*Fondren Orthopedic Group, Texas Orthopedic Hospital, Houston, TX, USA*
[b]*Nova Orthopaedic and Spine Care, Woodbridge, VA, USA*
[c]*Houston Methodist Hospital, Houston, TX, USA*
[d]*Health & Human Performance, University of Houston, Houston, TX, USA*

Background: Glenoid component loosening remains a significant issue after anatomic shoulder arthroplasty. Pegged glenoid components have shown better lucency rates than keeled components in the short term; however, midterm to long-term results have not fully been determined. We previously reported early outcomes of the current randomized controlled group of patients, with higher glenoid lucency rates in those with a keeled glenoid. The purpose of this study was to evaluate the radiographic and clinical outcomes of these components at minimum 5-year follow-up.

Methods: Fifty-nine total shoulder arthroplasties were performed in patients with primary glenohumeral osteoarthritis. Patients were randomized to receive either a pegged or keeled glenoid component. Three raters graded radiographic glenoid lucencies. Clinical outcome scores and active mobility outcomes were collected preoperatively and at yearly postoperative appointments.

Results: Of the 46 shoulders meeting the inclusion criteria, 38 (82.6%) were available for minimum 5-year radiographic follow-up. After an average of 7.9 years, radiographic lucency was present in 100% of pegged and 91% of keeled components ($P = .617$). Grade 4 or 5 lucency was present in 44% of pegged and 36% of keeled components ($P = .743$). There were no differences in clinical outcome scores or active mobility outcomes between shoulders with pegged and keeled components at last follow-up. Within the initial cohort, 20% of the keeled shoulders (6 of 30) and 7% of the pegged shoulders (2 of 29) underwent revision surgery ($P = .263$). Kaplan-Meier analysis showed no significant difference in survival rates between groups ($P = .560$).

Conclusion: At an average 7.9-year follow-up, non-ingrowth, all-polyethylene pegged glenoid implants are equivalent to keeled implants with respect to radiolucency, clinical outcomes, and need for revision surgery.

This study was approved by the Texas Orthopedic Hospital Institutional Review Board (protocol TOH 040).

*Reprint requests: Christopher M. Kilian, MD, Fondren Orthopedic Group, Texas Orthopedic Hospital, 7401 S Main St, Houston, TX 77030, USA.
E-mail address: cmk12985@gmail.com (C.M. Kilian).

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Management of end-stage glenohumeral arthritis with anatomic total shoulder arthroplasty continues to increase.[16] The most frequent indication for revision total shoulder arthroplasty is loosening of the glenoid component,[13-15,18,24,27,31,35,41,43] which has been correlated radiographically with the appearance of lucencies around the glenoid component.[1-3,23,27,34,38]

Early radiolucent lines around the glenoid component have been shown to occur at significantly higher rates in shoulders in which radiographic loosening eventually develops.[34] After ways to improve cementing techniques were examined,[6,17,23,25,32] the focus transitioned toward glenoid component design. Early biomechanical and animal studies showed the superiority of pegged components over keeled components.[18,29,41] Subsequently, outcomes comparing retrospective and prospective early and midterm radiographic results of pegged versus keeled glenoid components have also favored pegged components.[5,9,17,19] This observation was found in the early results of the current cohort of patients: the rate of glenoid lucency was significantly higher in patients with keeled components (46%) compared with patients with pegged components (15%) ($P = .003$) at an average of 26 months.[5]

Perhaps the true test of superiority does not lie in radiographic assessment but rather in clinical outcomes. Furthermore, these qualities are not readily apparent in the short term and may require longer follow-up to delineate subtle differences. The purpose of this study was to follow up a previous randomized controlled population that received a non-ingrowth, all-polyethylene pegged component or keeled implant using modern cementing techniques[5] and attempt to determine both radiographic and clinical outcomes at a minimum of 5 years postoperatively. On the basis of the findings from the previous randomized study, our working hypothesis was that both radiographic and clinical outcomes at the midterm would prove to be superior in pegged implants.

Materials and methods

Subjects

Participating patients signed informed consent forms. The study consisted of the same 50 patients who were enrolled in our prospective randomized trial previously.[5] Patients undergoing total shoulder arthroplasty were included if they had a diagnosis of primary glenohumeral osteoarthritis and a glenoid that did not require bone grafting. Patients with a history of shoulder trauma (fracture or soft-tissue injury), instability (surgically or nonsurgically treated), or shoulder surgery were excluded. In addition, we excluded patients with marked rotator cuff disorders of the shoulder, as indicated by acromiohumeral arthritis, a massive rotator cuff tear, or a rotator cuff tear involving the infraspinatus or subscapularis, because the cause of their shoulder disease may not have been primary glenohumeral osteoarthritis.

All patients underwent complete preoperative radiographic assessment, including an anteroposterior radiograph and computed tomographic arthrography, for evaluation of the rotator cuff and morphologic features of the glenoid. Glenoid morphology was described according to the classification of Walch et al.[37] Shoulder function scores and active mobility outcomes were evaluated preoperatively and at yearly postoperative appointments. The clinical information was retained in a secure password-protected server. Additional surgery or revision procedures were recorded.

A simple randomization technique using a number table with glenoid component type placed in sealed envelopes (with odd numbers indicating pegged and even numbers indicating keeled) was used. The design of the glenoid component, pegged versus keeled, was determined by opening a randomly selected envelope immediately preoperatively without any specific indication.

The initial study's power analysis showed that 18 patients in each group were needed to identify a radiographic difference of 1 level.[5] In the initial study, 50 patients (53 shoulders) with an average age of 69 ± 11 years were enrolled. Surgical procedures were performed between December 2004 and December 2005. Six patients later underwent contralateral total shoulder arthroplasty as late as November 2008 and were included in the randomization. Therefore, 59 shoulders in 50 patients were enrolled, with 29 pegged and 30 keeled components implanted. Patients who had undergone revision surgery or died before evaluation were excluded. Minimum 5-year follow-up was required for inclusion of radiographic and clinical evaluation.

Surgical procedure

Fifty-nine total shoulder arthroplasties were performed in patients with primary glenohumeral osteoarthritis who agreed to participate in the initial study.[5] All cases were performed at a single, high-volume shoulder arthroplasty center by a single surgeon (T.B.E.) using a uniform implant system (Wright Medical, Memphis, TN, USA). A deltopectoral surgical approach was used, with management of the subscapularis through a tenotomy at the anatomic neck of the humerus. Subscapularis mobilization was achieved through releases of the glenohumeral ligaments and capsule. On dislocation and removal of osteophytes, the humerus was prepared to accept a press-fit prosthesis with a corresponding humeral head size (39-50 mm).

Glenoid visualization and preparation were carried out through a release of the capsule at the inferior portion of the glenoid and drilling of a center hole. After assessment of the native radius of curvature of the glenoid surface, a concentric reamer was used with care taken to avoid excessive subchondral bone removal. Either the non-ingrowth, all-polyethylene pegged (Fig. 1, *A*) or keeled (Fig. 1,

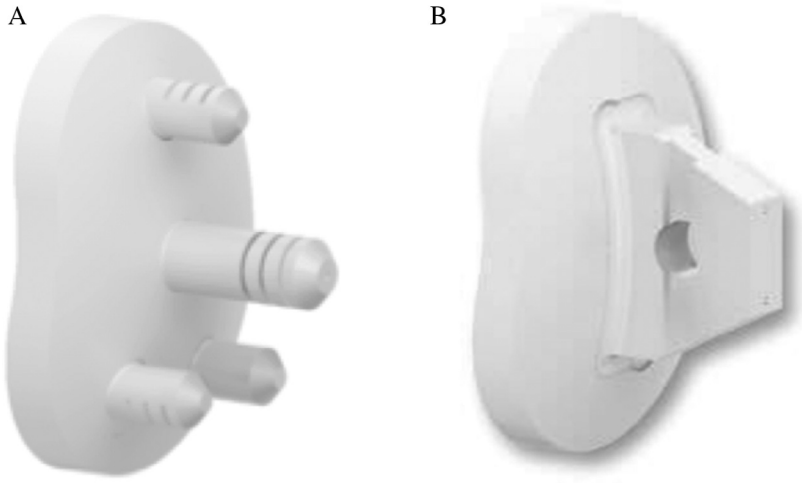

Figure 1 **(A)** Non-ingrowth, all-polyethylene pegged glenoid component (Aequalis; Tornier, Edina, MN, USA). **(B)** Non-ingrowth, all-polyethylene keeled glenoid component (Aequalis).

B) glenoid component was implanted using modern pressurization techniques with a catheter-tipped syringe.[44]

Once the glenoid and humeral components were placed, the subscapularis was repaired with transtendinous and transosseous nonabsorbable sutures, followed by a running absorbable suture. The rotator interval was closed, and the wound was closed in layers. The patients were given a simple sling and were enrolled in an aquatic rehabilitation program approximately 1 week postoperatively to begin gentle shoulder range-of-motion exercises.

Radiographic lucency

Radiographic assessment of glenoid components was performed in a fashion similar to previously published studies at our institution.[5,9] Radiographs were obtained 1 week postoperatively, as well as at interval visits, using fluoroscopic and magnification-controlled techniques to ensure that the beam was perpendicular to the bone-implant interface. Lucency about the glenoid component was graded according to the classification of Lazarus et al,[19] which was a modification of the original classification proposed by Franklin et al.[8] The images were viewed using a digital radiographic viewer (SwissVision Workstation; SwissRay, East Brunswick, NJ, USA) that allowed for on-screen annotation as well as contrast modification to ensure optimal visualization. These high-resolution images were viewed at a single viewing station under standard lighting conditions. Radiographs at last follow-up were evaluated by 3 raters who independently reviewed all images. The final lucency grade used in data analysis was the grade assigned independently by at least 2 of the 3 raters (ie, a single discordant grade was ignored). In no case did all 3 raters disagree on the lucency grade.

Clinical and statistical analysis

All patients were assessed using Constant,[4] American Shoulder and Elbow Surgeons,[22] Western Ontario Osteoarthritis of the Shoulder,[20] and Single Assessment Numeric Evaluation scores.[40] The κ statistic was used to evaluate interobserver agreement for the radiographic ratings. Preoperative-to-postoperative changes in outcome scores were compared between groups using a 2-way (group by time) repeated-measures analysis of variance. Exact χ^2 tests were used to assess differences in sex and shoulder dominance. The IBM SPSS Statistics statistical software application (IBM, Armonk, NY, USA) was used for data analysis. Statistical significance was set at $P < .05$.

Results

Of the 50 patients (59 shoulders) initially enrolled, 10 died; moreover, 3 shoulders underwent revision surgery before 5-year follow-up. Therefore, 46 shoulders (38 patients) met the inclusion criteria. Eight shoulders were considered lost to follow-up because the patients did not return for follow-up at a minimum of 5 years. At an average of 7.9 years, 38 of 46 shoulders (30 patients) were available with minimum 5-year follow-up (82.6%) with the original glenoid implant in place (16 pegged and 22 keeled). The average follow-up time was 7.4 years in the pegged group and 8.2 years in the keeled group (range, 5-12 years) ($P = .159$). There were significantly fewer women in the pegged group than in the keeled group ($P = .010$). As a result, glenoid size ($P = .021$) and head size ($P < .001$) in the included patients were also statistically significantly different. However, there were no differences in age ($P = .919$), shoulder dominance ($P = .590$), glenoid morphology ($P = .515$), or glenohumeral mismatch ($P = .560$) (Table I).

On radiographic evaluation at minimum 5-year follow-up, a score of 2 or higher was considered clinically relevant. Rater agreement on lucency was moderate to good (κ of 0.48-0.71). Radiographic lucency was present in all pegged components (16 of 16) and 91% of keeled components (20 of 22) ($P = .617$). Grade 4 or 5 lucency, considered to indicate a glenoid at risk of failure, was present in 44% of the pegged components (7 of 16) (Fig. 2, *A*) and 36% of the keeled components (8 of 22) (Fig. 2, *B*) ($P = .743$).

At last follow-up, shoulders at risk of failure had significantly worse clinical outcome scores and active mobility

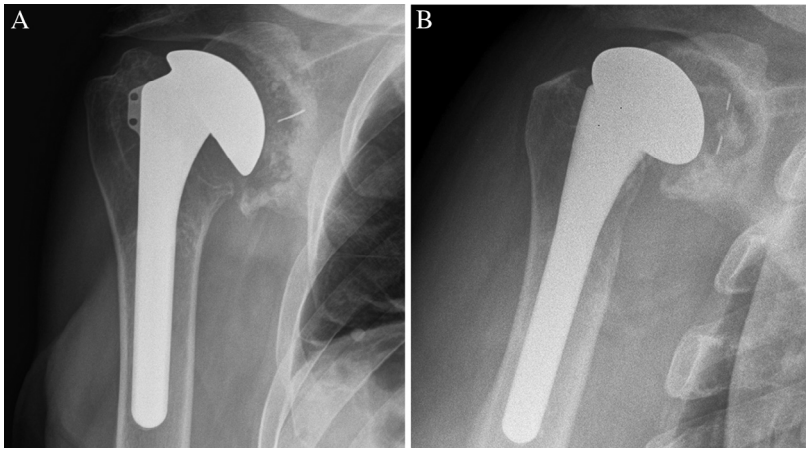

Figure 2 **(A)** Pegged component with grade 4 radiographic lucency. **(B)** Keeled component with grade 5 radiographic lucency.

Table I Patient demographic characteristics

	Pegged (n = 16)	Keeled (n = 22)	*P* value
Age at surgery, y	68 ± 10.8	68.0 ± 12.2	.919
Dominant side, n	7	10	.590
Sex, n			
Male	12	7	
Female	4	15	.010
Glenoid morphology, n			
A1	10	15	.515
A2	3	1	
B2	3	5	
C	0	1	
Glenoid size, n			
Small	1	3	.021
Medium	2	11	
Large	8	7	
Extra large	5	1	
Head size, n			
39 mm	1	3	<.001
41 mm	1	1	
43 mm	1	12	
46 mm	4	5	
48 mm	7	0	
50 mm	2	1	
Mismatch (mm)	7.7 ± 0.9	7.6 ± 0.7	.560

outcomes than shoulders not at risk of failure, with the exception of external rotation (Table II). There were no differences in clinical outcome scores or active mobility outcomes between shoulders with pegged components and those with keeled components (Table III).

Failures

In the initial cohort, 20% of the keeled shoulders (6 of 30) and 7% of the pegged shoulders (2 of 29) underwent revision surgery ($P = .263$). These were considered failures.

Table II Combined pegged and keeled shoulder outcomes for glenoids at risk of failure (grade 4 or 5) and not at risk of failure (grade 3 or lower)

Outcome	Mean (at last follow-up)		*P* value
	Glenoids at risk of failure	Glenoids not at risk of failure	
Constant score	46.4	67.3	.015
ASES score	54.5	76.0	.031
WOOS score	48.8	20.2	.004
SANE score	42.8	76.4	.003
FF, °	124.6	151.1	.008
ABD, °	123.9	150.2	.007
ER, °	38.6	48.2	.058

ABD, abduction; ASES, American Shoulder and Elbow Surgeons; ER, external rotation; FF, forward flexion; SANE, Single Assessment Numeric Evaluation; WOOS, Western Ontario Osteoarthritis of the Shoulder.

Table III Comparison of shoulder outcomes between pegged and keeled components

Outcome	Mean (at last follow-up)		*P* value
	Shoulders with pegged components	Shoulders with keeled components	
Constant score	59.7	58.9	.728
ASES score	68.5	67.0	.635
WOOS score	32.6	31.6	.501
SANE score	58.7	66.6	.247
FF, °	138.7	142.4	.599
ABD, °	138.3	141.2	.674
ER, °	42.0	46.2	.430

ABD, abduction; ASES, American Shoulder and Elbow Surgeons; ER, external rotation; FF, forward flexion; SANE, Single Assessment Numeric Evaluation; WOOS, Western Ontario Osteoarthritis of the Shoulder.

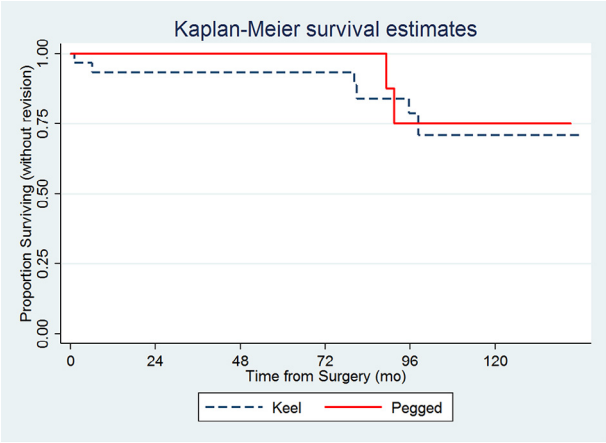

Figure 3 Kaplan-Meier survival estimates.

In 3 shoulders in the keeled group, failure occurred before 5-year follow-up. In 1 of these patients, failure occurred because of a fall resulting in posterior dislocation; revision to a reverse total shoulder arthroplasty was performed. In another patient, failure occurred because of a fracture of the glenoid component, after a fall. The third patient in the keeled group with failure before 5-year follow-up underwent revision surgery at an outside hospital for unclear reasons. Among the shoulders with minimum 5-year follow-up, failure occurred in 2 of the pegged (13%) and 3 of the keeled shoulders (14%), each with grade 4 or 5 lucency on the last examination ($P = .999$). Aseptic glenoid loosening was the presumed mode of failure. Two of the keeled component failures occurred in the same patient. Revision of the failed pegged components occurred at 89 months and 93 months postoperatively, and revision of the 3 keeled failures occurred at 91, 96, and 98 months postoperatively. Kaplan-Meier analysis showed no significant difference in survival rates between the 2 groups ($P = .560$) (Fig. 3).

Discussion

Our initial short-term radiographic data supported the use of pegged over keeled glenoid components.[5] We reassessed the same patient population, evaluating both radiographic and clinical outcomes, to determine whether our initial conclusion is valid for midterm follow-up. To our knowledge, this is the first study evaluating clinical and radiographic outcomes of pegged and keeled glenoid components in a randomized prospective manner with a minimum of 5 years' postoperative follow-up.

Surprisingly, we found that at an average of 7.9 years, all but 2 keeled shoulders showed at least grade 2 lucency and approximately 40% of shoulders in each group showed either grade 4 or 5 lucency. This result deviates from our past conclusion in the short term, showing significantly less radiolucency in pegged components at an average of 26 months' follow-up.[5] In the current study, we added an analysis of clinical outcome scores and active mobility outcomes to obtain a more complete picture of this prospective randomized population. Our results showed no statistically significant difference between patients with pegged components and those with keeled components. Any shoulders with grade 4 or 5 lucency showed worse clinical outcome scores and worse active mobility outcomes than those with lower lucency grades. In addition, all total shoulder arthroplasty failures and aseptic loosening–related failures were similar between groups. Therefore, our hypothesis that pegged glenoid components would continue to outperform keeled glenoid components in terms of radiolucency, clinical outcomes, and revisions was not supported.

The debate over pegged versus keeled components in total shoulder arthroplasty has taken place in the literature for more than a decade. Lazarus et al[19] retrospectively reviewed the initial postoperative radiographs of 328 patients who had undergone total shoulder arthroplasty (289 pegged and 39 keeled) and noted the "extremely common" evidence of radiolucencies and incomplete seating around the components with a statistically significant difference favoring improved cementation of pegged components over keeled components. Only 2 of the 328 cases were deemed to have "perfect" cementation. The study did not mention specific cementing techniques and included the outcomes of 17 surgeons.

In a randomized prospective study, Rahme et al[30] compared keeled glenoid components with inline pegged components with a follow-up period of 2 years. They implanted 13 keeled components and 14 pegged components. No statistically significant difference in clinical outcomes was noted, nor was there any difference in component migration at any time point or in any axis of rotation. At final follow-up, 10 of 13 keeled and 8 of 14 pegged components had lucencies ($P = .429$), although none displayed grade 4 or 5 lucency.

Fox et al[7] retrospectively reviewed the outcomes of multiple glenoid designs, including Cofield 2 all-polyethylene keeled and pegged components, during a 20-year span at the Mayo Clinic. Revision for either instability or aseptic loosening was required in 11 patients, including 1 pegged and 10 keeled components. However, these data may be confounded by the 3-fold difference in follow-up time for keeled components versus pegged components (6.7 years vs 2.3 years). The authors concluded pegged components had a slight advantage. Gartsman et al[9] also looked at Cofield glenoid prostheses in a prospective evaluation of 23 keeled and 20 pegged components, assessing radiographic lucency. There was an 8-fold greater incidence of grade 2 or higher lucency with keeled components (14 of 23) compared with pegged components (1 of 20). These findings were observed at 6 weeks postoperatively, and longer follow-up was not included.

Nuttall et al[26] examined both clinical and radiostereometric analyses in 10 keeled and 10 pegged components. Although clinical results at 2 years showed a statistically significant clinical difference from preoperative levels, no differences were noted between groups. There were statistically significant differences in the motion detected between the 2 groups. While

both types of components showed movement on radiostereometric analysis, keeled components moved more frequently and in all 3 planes of motion.

Throckmorton et al[33] found no clinical or radiographic differences between pegged and keeled components in a retrospective case-controlled study performed at the Mayo Clinic, with 51.3 months and 45.7 months of follow-up, respectively. With 50 patients in each group, the authors concluded that while radiolucent lines became more apparent with time, there was not a statistically significant difference between the 2 groups.

The data from the aforementioned studies have been synthesized in a meta-analysis performed by Vavken et al.[36] Their aim was to evaluate cost-effectiveness based on glenoid design when looking at radiolucency, loosening, and revision surgery. The final 8 studies (which included 2 from our institution) were assessed against each other for study quality, heterogeneity, and publication bias. The pooled risk ratio for radiolucency (or severe radiolucency) was not significant; however, this ratio with respect to revision surgery was significant ($P = .028$) in favor of pegged components. The risk ratio for component loosening showed borderline significance ($P = .051$) in favor of pegged components. When cost-effectiveness was factored in, the number needed to treat was between 23 and 115 patients with pegged components to avoid 1 revision surgery. The authors believed that pegged components warranted consideration by surgeons, especially those in higher-volume centers. Given the similarity in cost to produce either glenoid component, they advocated the use of pegged components from a cost-effectiveness perspective. However, it must be noted that most of the studies included in the analysis only included short-term follow-up, with the longest follow-up period included being 6 years.

More recently, McLendon et al[21] at the Mayo Clinic retrospectively reviewed 287 total shoulder arthroplasties with pegged glenoid components at a mean follow-up of 7.2 years. Their analysis showed that 43% were considered loose based on radiographic evaluation. The rate of glenoid component survival free from revision at 10 years was 83%. McLendon et al concluded that long-term radiographic and clinical failure rates are markedly similar between pegged and keeled glenoid component designs. These results are strikingly similar to those of our randomized controlled trial showing similar rates of radiographic lucency between pegged and keeled glenoid components, as well as nearly half of patients in both groups at risk of failure by the 7- to 8-year period.

Before drawing conclusions, one must consider implant-related factors that may contribute to these results. First, there is significant variability in the radiographic evaluation between the pegged and keeled components themselves. The design of the keeled component may lend itself to an easier evaluation of lucency than that of a pegged design. Given the nonlinear peg configuration, an unavoidable overlap between pegs makes visualization of lucency more difficult. In addition, new pegged designs have gained significant popularity, with possible bony ingrowth. These include components with a finned polyethylene cementless central peg, as well as hybrid designs with a central highly porous metal post. Early clinical results have shown either no difference or the possible superiority of these newer designs.[10-12,28,39,42] More high-level studies with longer follow-up are needed to help ascertain how these newer designs will perform. The pegged design in our study included cement fixation of all pegs, thus preventing ingrowth and potentially affecting long-term fixation.

Limitations of this study include a reduced number of patients available for minimum 5-year follow-up. Of 59 shoulders studied, only 8 were lost to follow-up. However, 3 shoulders underwent revision before 5 years and 10 patients had died at the time of data collection, limiting our analysis. Although 1 patient is known to have received revision surgery at another institution, other patients lost to follow-up also may have undergone revision elsewhere. In addition, the number of patients in the pegged group (ie, 16 patients) is less than the number desired in our initial power analysis (ie, 18 patients). Therefore, the chance of a 1–lucency grade type II error between groups is higher. However, it is unlikely that an effect size of 2 lucency grades or greater is truly present. Even with smaller sample sizes, a large effect size would be detectable with high (>80%) power. Although rates of revision surgery were not statistically significantly different between groups, power analysis was performed to observe a difference in lucency between groups, not failures. A much larger number of patients would be required to adequately power this analysis. Last, we were unable to obtain institutional review board approval to obtain postoperative computed tomography scans, given the extra burden and risk of radiation exposure to the patients. This may have allowed more accurate evaluation of lucency, as opposed to relying exclusively on postoperative radiographs. Strengths of this study include the prospective randomized nature of the initial design, which allows additional investigation to continue into the midterm. In addition, confounding variables brought on by different surgeons and different prosthetic implants were avoided through the use of a single surgeon and single implant system.

Conclusion

At an average 7.9 years' follow-up, non-ingrowth, all-polyethylene pegged glenoid implants do not show superiority to keeled implants with respect to radiolucency, clinical outcomes, or need for revision surgery. However, given that biomechanical data have shown pegged glenoid superiority, with clinical and radiographic data showing improved early results, we continue to use pegged glenoid components. Further high-level studies evaluating newer design features will help elucidate the optimal choice for prosthetic replacement.

Disclaimer

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