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Radiographic comparison of finned, cementless central pegged glenoid component and conventional cemented pegged glenoid component in total shoulder arthroplasty: a prospective randomized study

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Background: Radiographic lucency of the glenoid component remains a problem after cement fixation in primary total shoulder arthroplasty. Glenoid component design likely contributes to rates of glenoid lucency. The purpose of this study was to prospectively compare radiographic lucency between a finned, cementless central pegged glenoid component (CL component) and a conventional cemented pegged glenoid component (P component) on immediate postoperative and minimum 2-year follow-up radiographs.

Methods: Fifty-four patients undergoing total shoulder arthroplasty were prospectively randomized to receive an all-polyethylene CL component or a conventional all-polyethylene P component. Three raters graded glenoid lucency and bone interdigitation on immediate postoperative and latest follow-up radiographs. Patients who had undergone revision surgery or had died before evaluation were excluded. Minimum 2-year follow-up was required for inclusion of radiographic evaluation.

Results: Fifty patients met inclusion criteria; 42 patients (84%; 20 CL and 22 P) were available for follow-up with the original glenoid implant in place. The mean follow-up duration was 35 months (24-64 months). There were no significant differences in glenoid radiolucency between CL (1/20 [5%]) and P (2/22 [9%]) components at last follow-up ($P = .999$). Five patients (25%) in the CL group had bone interdigitation. No instances of aseptic glenoid loosening occurred.

This study, TOH 102, was approved by the Texas Orthopedic Hospital Institutional Review Board.

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Conclusion: There were no significant differences in the rate of glenoid lucency between the 2 groups at immediate or an average 35-month follow-up. Both techniques appear to be viable options for initial glenoid component fixation, with CL components allowing possible osseointegration, imparting potential long-term stability.

Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

Keywords: Cementless central pegged; pegged glenoid; radiolucency; total shoulder arthroplasty; CortiLoc; aseptic loosening, finned peg

Glenoid component loosening is the most common cause of failure after total shoulder arthroplasty (TSA).[2,4,5,8,9,14,17,18,22] Radiolucency around the glenoid component has been correlated with loosening and failure of the prosthesis.[12,25] Radiographic lucency has been reported to range from 0% to 5% on immediate postoperative radiographs, up to 15% at 2-year follow-up, and as high as 79% at 7-year follow-up using conventional pegged components.[11,18] Overall, radiolucency has been estimated to occur at an average rate of 7% and 1% per year for symptomatic and asymptomatic patients, respectively, after TSA.[19]

Although modern cementing techniques have improved glenoid fixation, glenoid design significantly contributes to rates of glenoid lucency.[11,12,15,16,21,24,25,32] Furthermore, techniques for glenoid preparation have evolved, with evidence suggesting less aggressive glenoid reaming that preserves more subchondral bone may be important for glenoid implant longevity.[23,28]

A glenoid component with a finned, cementless central peg was first introduced by Wirth et al in a canine model because of continued concerns about glenoid component loosening.[30] Retrospective studies using a similar component have reported variable rates of radiographic lucency ranging from 0% to 31% at minimum 2-year follow-up and up to 25% at minimum 5-year follow-up.[1,7,14,20,29] However, there have been no prospective randomized studies comparing a conventional cemented pegged glenoid component (P component) with a finned, cementless central pegged component (CL component).

The purpose of this study was to prospectively compare radiographic lucency between a CL component and a P component on immediate postoperative and minimum 2-year follow-up radiographs. The authors hypothesized that there would be no difference in radiographic lucency between groups on immediate postoperative radiographs and at last follow-up.

Materials and methods

There were 54 patients who were prospectively enrolled from January 2012 to October 2012. All cases were performed at a single, high-volume shoulder arthroplasty center by a single surgeon (T.B.E.). All patients signed informed consent before entering the study and were enrolled in a prospectively collected shoulder arthroplasty registry. Patients with an intact rotator cuff and primary glenohumeral osteoarthritis, inflammatory arthritis, or instability arthropathy electing to undergo primary TSA were eligible for study enrollment. Patients were excluded if they had a history of skeletal dysplasia or prior shoulder infection.

A power analysis conducted before the study determined that 20 patients per group would be required to identify an average difference of 1 lucency grade between the CL and P glenoid components with a power of 80%.

The design of the glenoid component was randomly selected immediately before surgery. Randomization was performed using a random numbers table (odd = CL, even = P) with the glenoid component type sealed in an envelope. Twenty-eight shoulders were randomized to receive a polyethylene CL component, and 26 shoulders were randomized to receive a polyethylene P component.

The Aequalis Ascend Flex (Wright Medical, Memphis, TN, USA) shoulder arthroplasty system was used for all patients during the study period. The TSA technique used during the study period is well described, and a standardized postoperative rehabilitation protocol was followed.[13] A subscapularis tenotomy was used, with transtendinous and transosseous repair performed at the end of the procedure.

The polyethylene CL component has 3 peripheral pegs and a larger finned central peg (Fig. 1). The polyethylene P component consists of 4 pegs of the same size with 1 central peg and 3 peripheral pegs (Fig. 2). Both glenoid components have the same size options—small, medium, large, and extra-large. Humeral head diameters were matched with their respective glenoid components with sizes ranging from 38 to 50 mm. Radii of curvatures were obtained from the manufacturing technique guide.

Glenoid reaming was completed using previously described methods.[23,28] Preparation of the glenoid was completed with a powered, concentric and convex-shaped reamer. The reamer matched the size of the chosen glenoid component (small, medium, large, or extra-large). Minimal reaming was performed to preserve

Figure 1 Finned, cementless central pegged glenoid component. By permission of Wright Medical Group, Inc. All rights reserved.

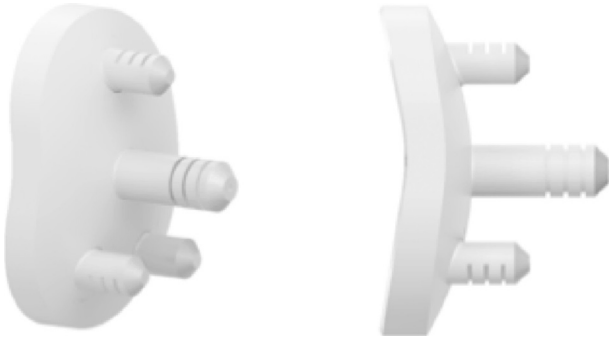

Figure 2 Conventional cemented pegged glenoid component. By permission of Wright Medical Group, Inc. All rights reserved.

subchondral bone while creating a congruent base for the convex back of the glenoid components. Any necessary deformity correction was determined preoperatively with computed tomography (CT) arthrography and confirmed intraoperatively. Glenoid biconcavity was corrected to physiologic version as determined by the surgeon (T.B.E.) by reaming of the anterior side or "high" side while still attempting to preserve as much subchondral bone as possible.

Cementing for all cases was completed using described modern pressurization techniques.[10] The prepared glenoid was irrigated with saline solution using bulb syringe and dried with suction and sponges. A 60-mL catheter tip syringe was used to introduce the cement under manual pressure. Non–antibiotic-loaded fast-setting cement was used for all cases (DePuy CMW2 Bone Cement; DePuy Synthes, Warsaw, IN, USA) with a recommended setting time of 6 minutes.

The 3 peripheral pegs were cemented in the CL component, but the finned central peg was not cemented. No bone was added to the central peg before implantation. All 4 pegs of the P component were cemented. All P components had manual pressure applied until cement setting was complete (6 minutes). All CL components were properly seated, and no manual pressure was applied after proper insertion.

All patients underwent complete preoperative radiographic assessment with an anteroposterior view in the plane of the scapula, scapular Y view, and axillary view. In addition, all patients completed preoperative CT arthrography for evaluation of the rotator cuff and morphologic features of the glenoid, which were classified according to Walch et al.[26]

Radiographs were obtained within 7 days of the operative procedure and at each subsequent follow-up visit. Radiographic views included anteroposterior in the plane of the scapula, scapular Y, and axillary views. All radiographs were obtained using standardized fluoroscopic and magnification control to ensure that the x-ray beam was perpendicular to the plane of the bone-glenoid implant interface, as determined by the embedded wire in the polyethylene components.

Grading of radiographic lucency of the CL and P components was completed according to criteria described by Lazarus et al (Table I).[16] According to this method, radiolucency was graded on a scale of 0-5, with 0 indicating no radiolucency and 5 indicating gross loosening (Fig. 3). Those with grade 1 findings were considered to have negligible lucency and further grouped with grade 0 to provide more in-depth analysis of those with significant lucency.

The CL component has 3 peripheral pegs with small slots and a larger finned central peg, and the P component consists of 4 pegs with small slots of the same size with 1 central peg and 3 peripheral pegs. Bone interdigitation was assessed on CL component radiographs only as no interdigitation was expected on the fully cemented pegs in the P group. Patients were determined to have bone interdigitation if there was bone adjacent to the large fins and radiodensity within the large fins on radiographs as described by Wirth et al (Fig. 4).[31] This was evaluated only at last follow-up.

Table I Grading scale for radiolucencies about pegged glenoid components[16]

Grade	Finding
0	No radiolucency
1	Incomplete radiolucency around 1 or 2 pegs
2	Complete radiolucency (≤2 mm wide) around 1 peg only, with or without incomplete radiolucency around 1 other peg
3	Complete radiolucency (≤2 mm wide) around 2 or more pegs
4	Complete radiolucency (≥2 mm wide) around 2 or more pegs
5	Gross loosening

Reprinted from: Lazarus MD, Jensen KL, Southworth C, Matsen FA 3rd. The radiographic evaluation of keeled and pegged glenoid component insertion. J Bone Joint Surg Am 2002;84:1174-82 with permission from Wolters Kluwer.

The radiographs were graded using a digital radiographic viewer (SwissVision Workstation; Swissray, East Brunswick, NJ, USA). Radiographic lucency was measured using the digital caliper within the radiographic viewer. All radiographs were independently graded by 3 raters (C.M.K., M.M.G., and K.R.S.). The senior author did not grade the radiographs to eliminate any bias. The immediate postoperative and most recent follow-up radiographs were randomly viewed to avoid "side-by-side" comparisons. The final radiographic 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). There were no cases in which 2 of 3 raters disagreed on the lucency grade. If a patient underwent revision surgery or died before evaluation, that patient was excluded. Minimum 2-year follow-up was required for inclusion of radiographic evaluation.

Demographics (age, follow-up, gender, hand dominance, glenoid morphology, humeral head size, glenoid component size, and glenohumeral prosthetic mismatch) were compared between groups. The Lazarus radiographic grade, rate of radiographic lucency (grade 2 or higher), and complication rates were compared between groups. Continuous variables were compared using the Student *t*-test; categorical variables were compared using an exact χ^2 test and analysis of variance with P value < .05. Interobserver reliability of the radiographic grade and bone interdigitation was evaluated using intraclass correlation coefficients.

Results

Of the original 54 patients enrolled, 3 patients underwent revision surgery before 2-year follow-up and 1 patient died. These patients were excluded from analysis. Forty-two (20 CL and 22 P) of the 50 patients (84%) meeting inclusion criteria completed minimum 2-year radiographic follow-up. The

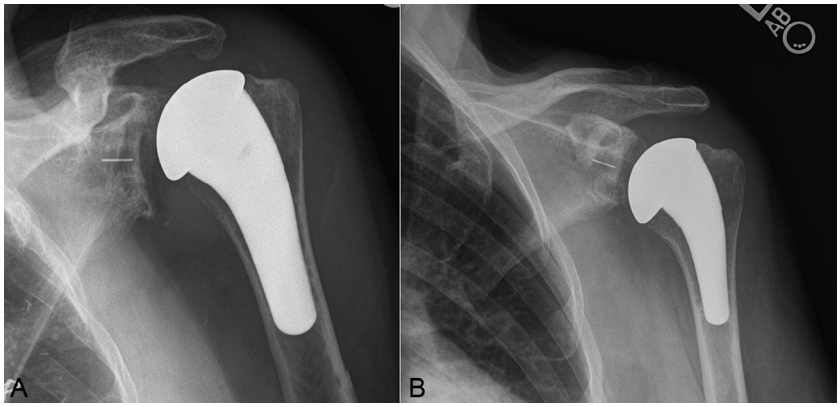

Figure 3 (**A**) Anteroposterior radiograph with grade 0 lucency. (**B**) Anteroposterior radiograph with grade 2 lucency.

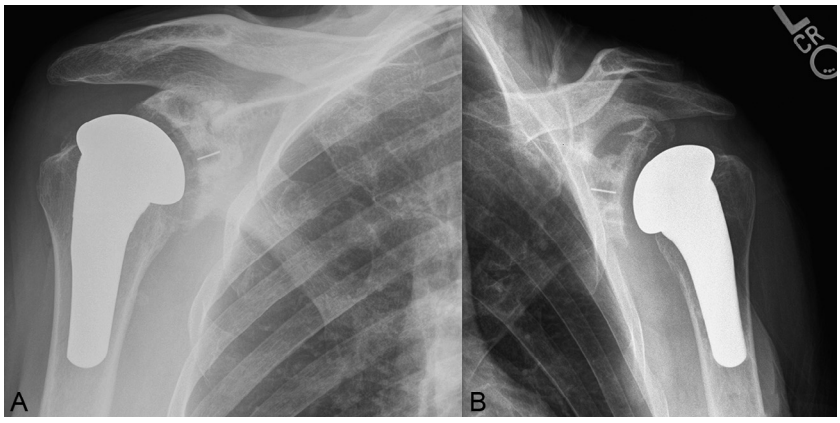

Figure 4 (**A**) Anteroposterior radiograph with no glenoid bone interdigitation. (**B**) Anteroposterior radiograph with central pegged glenoid bone interdigitation.

mean duration of follow-up was 35 months (range, 24-64 months). The mean age at time of surgery was 66.1 ± 10.1 years. Twenty-three (55%) patients were male, and 20 (48%) patients had involvement of the dominant extremity. There were no differences between the 2 groups regarding age at time of surgery ($P = .455$), follow-up duration ($P = .793$), gender ($P = .551$), dominant-side surgery ($P = .999$), glenoid morphology ($P = .324$), glenoid size ($P = .278$), humeral head size ($P = .465$), glenohumeral prosthetic mismatch ($P = .946$), or diagnosis ($P = .443$) (Table II).

None of the patients in either group had lucency noted on immediate postoperative radiographs. There were no significant differences in Lazarus grade ($P = .595$) and glenoid radiolucency between the CL group (1/20 [5%]) and P group (2/22 [9%]) at last follow-up ($P = .999$). Five patients (25%) in the CL group had bone interdigitation. In addition, glenoid morphology was associated with lucency ($P = .018$), with A1 being less likely to have lucency compared with the others. Overall, excellent agreement on lucency ratings was achieved by 2 of 3 reviewers for immediate postoperative and minimum 2-year radiographic review ($\kappa = 0.76$), but both had only fair to moderate agreement with the other rater ($\kappa = 0.36$ and 0.38).

Seven complications occurred in the 54 patients initially enrolled in the study. Six occurred in the CL group with 1 in the P group. Of the patients completing minimum 2-year follow-up, 2 patients in the CL group and 1 patient in the P group had complications. One patient in the CL group had an intraoperative proximal humerus metaphyseal fracture caused during retraction; this did not require further treatment. The second complication in the CL group was a postoperative traumatic rupture of the subscapularis tendon that was treated with a pectoralis major tendon transfer. One patient in the P group had an intraoperative nondisplaced greater tuberosity fracture that did not require further treatment.

The remaining 4 patients did not complete the minimum follow-up. Two CL patients sustained glenohumeral dislocations (1 anterior and 1 posterior) necessitating revisions to a reverse TSA. The anterior dislocation was atraumatic in nature, whereas the posterior dislocation occurred after a fall. One CL patient developed a postoperative infection requiring staged revision and eventual resection arthroplasty. One CL patient sustained a small anterior glenoid fracture that occurred during glenoid reaming. The fracture did not alter glenoid component placement or stability, and it required no

Table II Patient demographics

	CortiLoc (n = 20)	Pegged (n = 22)	*P* value comparing groups
Age at surgery (y)	65 ± 11	67 ± 9	.455
Follow-up time (mo)	35 ± 13	34 ± 13	.793
Gender			
Male	12	11	.551
Female	8	11	
Dominant-side surgery	10	10	.999
Glenoid morphology			
A1	11	12	.324
A2	3	7	
B1	2	0	
B2	4	3	
Glenoid size			
Small	4	5	.278
Medium	10	6	
Large	4	10	
Extra-large	2	1	
Head size (mm)			
38	1	1	.465
40	3	1	
42	4	6	
44	1	4	
46	7	3	
48	3	4	
50	1	3	
Mismatch (mm)	7.3 ± 1.2	7.3 ± 0.9	.946
Diagnosis			
Primary OA	14	16	.443
Instability	3	4	
RA	2	0	
Non-RA inflammatory	0	1	
Malunion	1	0	
AVN	0	1	
Lazarus score			
0	13	16	.595
1	6	4	
2	1	2	
Lucency (1 or higher)	7	6	.741
Lucency (2 or higher)	1	2	.999
Complications	2	1	.493

OA, osteoarthritis; *RA*, rheumatoid arthritis; *AVN*, avascular necrosis.

additional treatment. None of these complications were related to aseptic loosening of the glenoid. Aseptic loosening did not occur in either group.

Discussion

The purpose of this study was to prospectively compare radiographic lucency between a CL component and a P component on immediate postoperative and minimum 2-year follow-up radiographs. We found no significant differences in the rate of glenoid lucency between the 2 groups at immediate or average 35-month follow-up, and our hypothesis was supported.

The evaluation of radiolucent lines around the pegged glenoid component has been graded by Lazarus et al.[16] Prior studies using conventional pegged components and minimum grade 2 Lazarus score demonstrated radiographic lucency in 4%-15% of TSAs at early follow-up and up to 54% at 7-year follow-up.[3,11,12,18] Other studies investigating the radiolucency of a CL component found that lucency was visible on radiographs in 0%-18% at minimum 2-year follow-up and 5% at minimum 5-year follow-up.[1,7,14,20,29] However, no study has directly compared the lucency rates between these glenoid components. This study did not demonstrate a significant difference between the P component (9%) and a CL component (5%) at an average 35 months. This result is similar to that of previously studied lucency rates.

Similar demographics were noted between both groups regarding age, follow-up, gender, glenoid morphology, and glenohumeral prosthetic mismatch. This is important to note as a recent systematic review demonstrated that female gender and glenoid morphology are associated with significant risk of failure after TSA.[19] Another study by Walch et al found that poor glenohumeral prosthetic mismatch (<6 mm and >10 mm) was associated with glenoid radiolucency.[27] This study had an average mismatch of 7.2 mm and 7.3 mm in the CL and P groups, respectively, indicating appropriate component sizing. As such, these factors can be eliminated as confounding variables in comparing the 2 components.

The CL component allows bone interdigitation that may potentially help stabilize the glenoid component. Previous studies have shown the existence of bone interdigitation on a similar finned peg with rates ranging from 29% to 91%.[1,7,14,29,31] This was higher than the interdigitation found in our study, as only 25% of patients treated with the CL component demonstrated bone interdigitation. However, the higher rates found in the prior studies are likely to be secondary to the use of postoperative CT for analysis. This study was unable to obtain Institutional Review Board approval to perform postoperative CT because of potentially unnecessary radiation exposure in asymptomatic patients, thus potentially affecting our results.

In addition, the finned central peg allows a faster operative time (6 minutes) on average as the necessity to hold pressure during cement polymerization is eliminated. Given that this component is less reliant on cement for fixation, the impact of alterations in cementing technique may be lowered. This is especially important as studies have shown that failure of cemented implants occurs at the cement-implant interface.[28] This study did not demonstrate radiographic evidence of any detrimental effects from not applying manual pressure until cement polymerization for the CL component.

Seven (13%) complications occurred in the 54 patients initially enrolled in the study. This is similar to previous reports in which complication rates ranged from 12% to 14% at minimum 2-year follow-up.[4,6] The most commonly reported complications are loosening (39%), instability (30%), rotator cuff tear (8%), intraoperative fracture (7%), and infection (5%).[4] This study had 3 intraoperative fractures, 2 dislocations, 1 rotator cuff tear, and 1 infection. Six of the complications occurred in patients with the CL component but do not appear to be related to the glenoid component. However, only 3 patients with complications achieved 2-year follow-up; thus, no differences were noted between the groups regarding complications. There were no instances of glenoid aseptic loosening in any of our study patients.

Limitations of the study are acknowledged. Blinding of the surgeon to component design at implantation was not possible. Although we reached the minimum number of patients needed in our power analysis, the numbers remain relatively low, making type II error a possibility. In addition, an underestimation of radiolucency may occur at minimum 2-year radiographic follow-up, especially given the expected longevity of a TSA. As discussed earlier, radiolucency is likely to be progressive, with some data suggesting 50%-60% grade 2 lucency or higher at 7-8 years of follow-up.[18] With our shorter duration of follow-up, it is difficult to determine ultimate radiolucency and therefore differences between these components. However, the previously mentioned study used a "3 in-line" pegged component. Thus, long-term evaluation will be needed to delineate the eventual longevity of these implants. Last, we were not able to obtain postoperative CT scans to further assess bone interdigitation and relied exclusively on postoperative radiographs, probably underestimating interdigitation.

Several strengths of the study are noted. This is the first study directly evaluating the differences between these 2 glenoid component designs. Direct comparison of these designs will provide deeper insight in selection between these 2 commonly used components. The senior author did not participate in radiographic grading, preventing potential bias. In addition, the prospective, randomized design ensured homogeneous groups of patients, which was confirmed statistically. Furthermore, the study was limited to a single surgeon using a standardized surgical technique and the same postoperative protocols.

Conclusion

This is the first prospective randomized study evaluating a CL component compared with a P component. There were no significant differences in the rate of glenoid lucency between the 2 groups at immediate or an average 35-month follow-up. The CL component allows shorter cementation time as there was no radiographic evidence of detrimental effects from not applying manual pressure until cement polymerization for the CL component. Both techniques appear to be viable options for initial glenoid component fixation, with CL components allowing osseointegration, imparting potential long-term stability.

Disclaimer

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