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Bone presence between the central peg's radial fins of a partially cemented pegged all poly glenoid component suggest few radiolucencies

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Background: Cement penetration problems and/or cement-induced bone necrosis may contribute to glenoid component failures. An all polyethylene component was developed that promotes biologic fixation between radial fins of its central peg and utilizes minimal cement fixation for its peripheral pegs, but it has little published data. We hypothesized better bone presence between the radial fins would be associated with less overall radiolucencies. This study's purpose was to utilize computed tomography (CT) and plain films to assess for bone between the central peg's radial fins and to assess overall component radiolucencies.
Materials and methods: Thirty-five of 48 consecutively performed total shoulder arthroplasties (TSA) for primary glenohumeral osteoarthritis were in patients able to participate a minimum 2 years after surgery. All had reamed humeral head bone packed between radial fins of the central peg and minimal cement for the peripheral pegs. Thin cut (0.625 mm) CT scans, standardized plain films, Simple Shoulder Tests (SST), and Constant scores were obtained. A musculoskeletal radiologist calculated Yian CT scores, bone presence between fins on CT, and Lazarus radiolucency scores.
Results: At a mean of 43 months, by CT: 1) better Yian scores correlated with more bone between fins, and 2) bone was present in 6/6 inter-fin compartments in 23/35 shoulders, averaging 4.5/6 overall. Mean Lazarus radiolucency score was 0.45. Mean SST and Constant scores were 10.3 and 81.3, respectively.
Conclusion: TSA utilizing autologous bone in inter-fin compartments of the central peg and minimal peripheral peg cement maintained bone presence a minimum 2 years post-op. More bone imparted fewer overall component radiolucencies.
Level of evidence: Level IV, Case Series, Treatment Study.

Keywords: Total shoulder arthroplasty; glenoid loosening; shoulder replacement; glenoid; CT scan; radiolucencies

Since its evolution, total shoulder arthroplasty (TSA) has become an effective treatment for primary glenohumeral arthritis, as measured by shoulder-specific and general health-specific outcomes metrics.[1,8,9,18,19,22,26,28] Yet, cemented all polyethylene glenoid component loosening remains a problem.[1-3,8,11,13,22,24,27,29,30,36] Radiolucent lines

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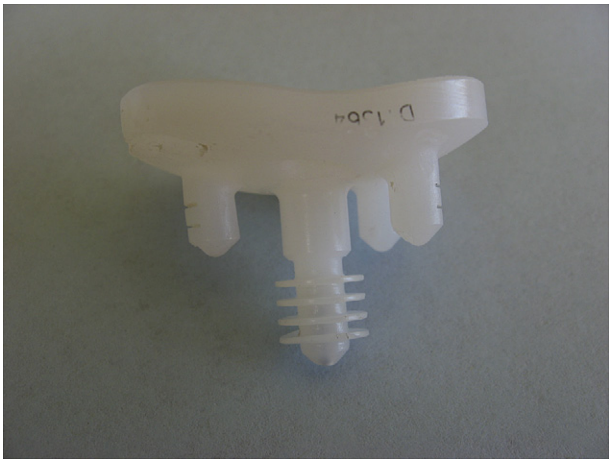

Figure 1 DePuy anchor peg glenoid component (Warsaw, IN).

surrounding cemented all polyethylene glenoid components may be present as early as the recovery room and suggest suboptimal cementing technique.[1,4,7,10,12,13,20] Gartsman et al found radiolucenies evident in 39% of keeled and 5% of pegged components in radiographs performed within 6 weeks of surgery.[12] It is also possible that cemented-induced thermal necrosis may contribute to osteocyte death and radiolucent lines.[5] Unfortunately, cementless metal-backed glenoids components have suffered similar loosening fates,[20,21,33,34] such that cemented all polyethylene glenoids, regardless of the configuration, are the current standard of care.

In an attempt to decrease cement utilization but to avoid problems associated with metal-backed glenoid components, Wirth et al designed a cementless all polyethylene component for use in canines. In their model, the component allowed for radiographically-proven and histologically-proven bone growth between the radial fins of the peg used to anchor the glenoid component in bone.[37] A component for utilization in humans based upon the canine counterpart was designed and has been used extensively. Its central peg is similar to the canine model with respect to the radial fins, but the human component also has 3 peripheral pegs. It is a hybrid component, as the central peg is placed in cementless fashion while the peripheral 3 pegs are placed in cemented fashion (Figure 1). Its premise is to allow bone growth between the radial fins of the central peg (as it did in the canine model) in a controlled fracture response-like fashion. Yet, little radiographic or clinical data exists for this prosthesis in humans despite its widespread use for almost 10 years.[6] And, to date, no computed tomography (CT) data exists for this prosthesis, despite the fact that CT interpretation of glenoid components has been shown to be more reliable than plain radiography and fluoroscopically-guided images.[38] We hypothesized that better bone presence between the radial fins of the central peg of this prosthesis would be associated with less overall component radiolucencies. Therefore, the purpose of this study was to assess for bone presence between the radial fins of this hybrid glenoid component's central peg, as well as for overall component radiolucencies with thin cut CT scans and plain radiographs.

Materials and methods

We asked patients in whom the senior author (EVF) had performed primary total shoulder replacements for primary glenohumeral arthritis without previous surgery to return a minimum of 2 years, following their procedures performed between July of 2003 and July of 2007.

All patients had been invited to participate; but, because of distance to travel (some >200 miles), illness, lack of financial resources, or unwillingness to participate in a study that required nearly ≥½ day of the patient's time, only 35 (29 patients) of the 48 shoulders replaced with a total shoulder arthroplasty for 1 diagnosis (primary glenohumeral osteoarthritis) were studied. Twenty of 35 shoulders were in males. No shoulder has been re-operated to date.

All replacement procedures were performed with a consistent technique and prosthesis (Depuy Global Advantage with an Anchor Peg glenoid; Depuy, Warsaw, IN) (Figure 1) that utilizes a humeral head-glenoid radial mismatch of 3 mm according to the manufacturer's recommendations. We did not deviate from this product's designated mismatch in any case. We utilized a deltopectoral approach and a beach chair position. We released the subscapularis tendon from the lesser tuberosity along with underlying capsule, and subsequently repaired them together with #2 braided polyester with simple and interrupted suture fixation via bone tunnels in the humeral neck after component placement. At the time of surgery, with a glenoid reamer, we attempted to create a glenoid concavity that would support, in intimate fashion, the backside of the glenoid component. Prior to glenoid component implantation, we packed bone between the radial fins of the component's central peg. This bone was obtained by reaming the cut surface side of the osteotomized humeral head after drilling a pilot hole to accept the central tip of the reamer. Reaming allowed the creation of a "bone paste" that was left between the reamer blades. We applied this paste easily and efficiently between the radial fins. We used minimal cement for the peripheral 3 pegs, but placed it in pressurized fashion with a 60-cc Toomey syringe. While in the hospital, a physical therapist taught each patient to perform a standardized home therapy program that patients were to continue for 12 weeks postoperatively. We chose not to grade glenoid morphology for this study because of the many variables involved in grading glenoid preoperatively, particularly those without pre-op CT scans. None of the patients in this study had a pre-op CT scan.

A 5th-year orthopaedic surgery resident, blinded as to the minimum 2-year radiographic study results, examined each patient. He obtained a health history, a Simple Shoulder Test (SST) score, and an absolute Constant score. Unfortunately, preoperative SST scores and absolute Constant scores had not been obtained. Plain radiographs were obtained for each shoulder. They were standardized and included a conventional axillary view as well as a Grashey (AP) view with 30° of shoulder external rotation with the elbow at the side. CT scans (helical scans with 0.625 x 0.625-mm slice thickness and interval; 120 kv; mA varied by patient size; 0.8 sec rotation time; 25 FOV) were also obtained for each; the patient was positioned supine with the arm at the side. Images were acquired in the axial plane. Reconstruction images were then performed in oblique coronal and sagittal planes

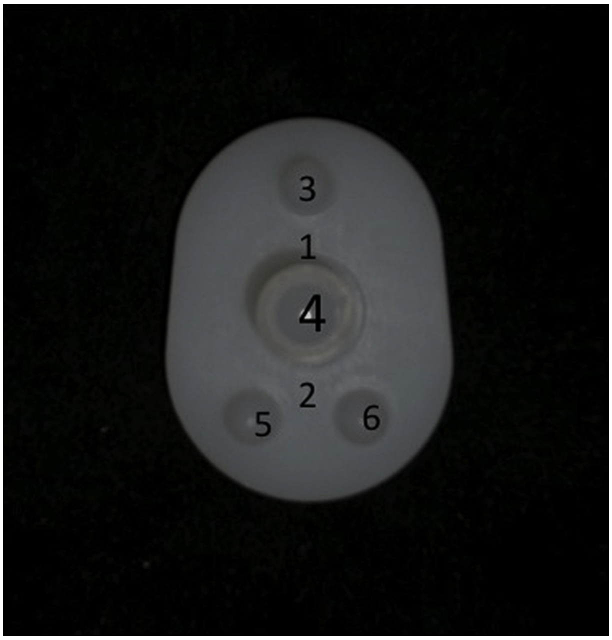

Figure 2 Zones 1 through 6 utilized for Yian scoring on CT scans.

Table I Yian scoring system for each zone of glenoid component on CT scan

0	No lucency presence
1	1 mm of lucency
2	2 mm of lucency
3	Gross lucency

aligned to the glenoid orientation. All images were used to evaluate the glenoid component.

A fellowship-trained musculoskeletal radiologist with greater than 20 years of clinical experience, blinded as to the purpose of the study as well as to patient identities, evaluated for bone presence between radial fins as well as component radiolucencies based upon thin CT scan axial cuts, as described by Yian et al.[38] These authors previously utilized CT scans with 3-mm axial cuts to establish a new gold standard for glenoid component radiolucency evaluation.[38] The same radiologist also evaluated all plain radiographs to obtain a Lazarus radiolucency score[17] for each.

Yian CT-based radiolucency scores were originally described and calculated based upon a cemented 4-pegged all polyethylene glenoid design.[38] For the component in our study, the 4 pegs are in the same configuration, as that described by Yian et al (Figure 2); but, the component in our study's central peg was placed in uncemented fashion and it has radial fins. Yian scores range from 0 to 18 with 0 representing no radiolucencies and 18 being the maximum (worst) (Table I). The CT scans in Yian's study were performed with 3-mm axial cuts; our CT scans had 0.625-mm axial cuts. Moroever, our radiologist utilized not only the thin axial cuts but the reconstructions as well for glenoid component evaluation.

The Lazarus radiolucency scoring system (Figure 3) was originally described for a cemented, pegged, all polyethylene glenoid component based upon plain radiographs. Scores range from 0 to 5, with 0 being no radioluciencies[17] (Table II).

With the prosthesis in this study, there are 6 ''compartments'' between the radial fins of the central peg in which one could visualize bone on plain radiographs (Figure 4) and/or CT scans (Figures 5 and 6). For the purpose of this study, each ''side'' of the core diameter of the central peg (eg, above and below) was treated independently. Thus, although there are 4 radial fins and 3 potential compartments in a 3-dimensional analysis, we divided each of the 3 compartments in half as they were studied with 2-dimensional radiographic studies. We asked our radiologist to assess all CT scan cuts for bone presence or absence in these ''compartments.'' Bone presence in all 6 compartments scored a 6; the minimum score (no bone present in any compartment) was 0.

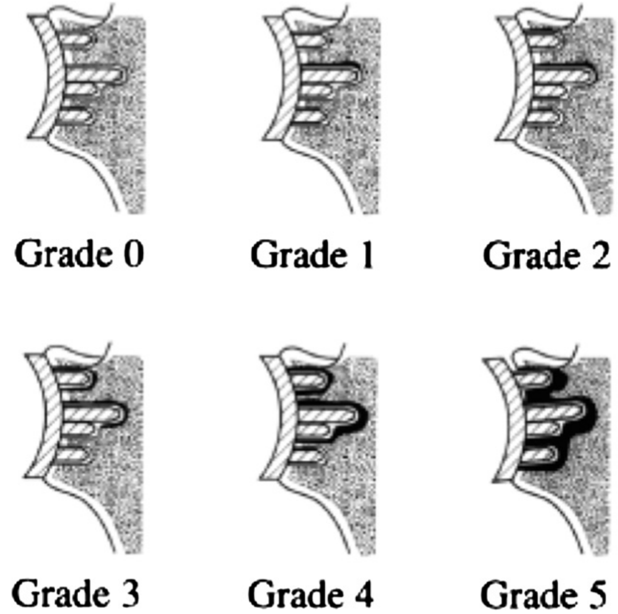

Figure 3 Lazarus scoring system for radiolucencies about pegged glenoid components. (Courtesy of Lazarus et al. and Rockwater, Inc.[17])

Table II Lazarus scoring for glenoid component on plain radiograph

0	No radiolucency
1	Incomplete radiolucency around 1 or 2 pegs
2	Complete radiolucency (</= 2 mm wide) around 1 peg only, with or without complete radiolucency around 1 other peg
3	Complete radiolucency (</= 2 mm wide) around 2 or more pegs
4	Complete radiolucency (>2mm wide) around 2 or more pegs
5	Gross loosening

Statistical analysis

A statistical analysis was then performed to test the hypotheses that: 1) more bone between the central peg's radial fins was associated with better (lower) modified Yian scores, and 2) less bone was associated with increasing age. As a baseline for future study, we also obtained absolute Constant and SST scores. We wished to see whether absolute Constant and SST

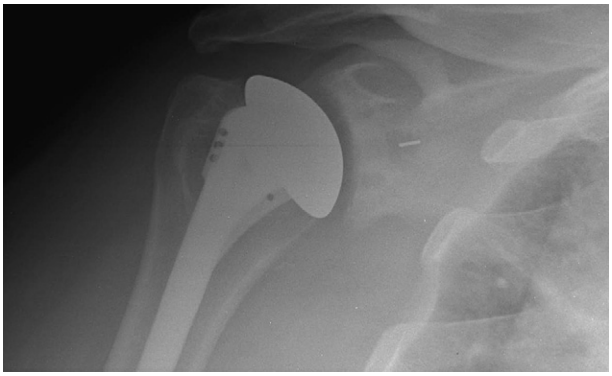

Figure 4 Standard radiograph of glenoid component for Lazarus scoring. Lazarus Grade 0/5.

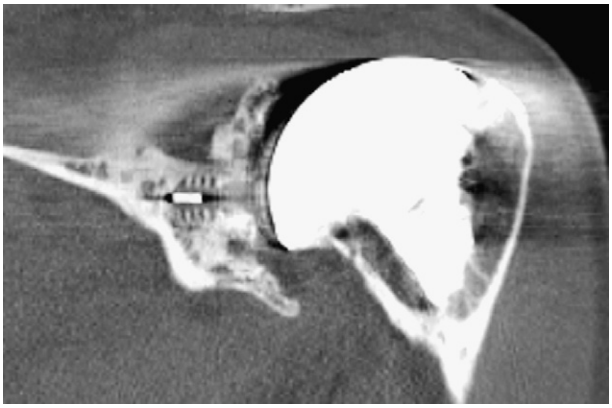

Figure 5 CT scan evaluation of glenoid component demonstrating bone between radial fins of central peg. Yian score = 0/18. Bone presence between central fins score = 6/6.

scores were associated with more bone and whether those scores depended on the Yian score in this medium-term follow-up period. Finally, a Spearman rank correlation was performed to test whether Yian scores correlated with Lazarus scores.

Data were analyzed with the QUANTREG and LOGISTIC procedures with SAS software (version 9.2; SAS Institute Inc., Cary, NC). Quantile regression extends the linear regression model (based on least squares and residuals that are normally distributed) to conditional quantiles of the response variable; in the results presented here, the median.[39] Its main advantages over least squares regression with these data are its flexibility for working with outliers, response values that are within strict boundaries, and with distributions that do not exhibit constant variance. Logistic regression determines if the proportion of successes depend on one or more explanatory variables. Because of the small sample size, the Firth option was applied to reduce estimation bias.[14]

Results

Having a dataset with a mean patient age at the time of surgery of 70 years (range, 49-89) and with measurements collected at an average 43 months (range, 24-66) after surgery, the following results (Table III) were found with respect to each proposed hypothesis: 1) By CT, better bone presence between the radial fins of the central peg was associated with better (lower) Yian scores ($P < .001$) (Figure 7). Also by CT, bone was present in 6/6 radial fin compartments in 23/35 shoulders. On average (when considering all 35), bone compartment presence was 4.5/6 (range, 0-6). Only 3 shoulders had no bone present in any of the compartments (score of 0). The mean Lazaus radiolucency scores of these 3 shoulders without bone was a 1.0. 2) Logistic regression indicated bone presence and age at surgery ($P = .957$) or months since surgery ($P = .153$) were not significantly associated with one another.

With respect to the functional data, neither absolute Constant ($P = .489$) nor SST ($P = .550$) scores were associated with bone presence by CT. Neither higher SST ($P = .160$) nor absolute Constant ($P = .415$) scores were associated with better (lower) Yian scores. However, this may have been due to no cases of loosening. The mean Lazarus radiolucency

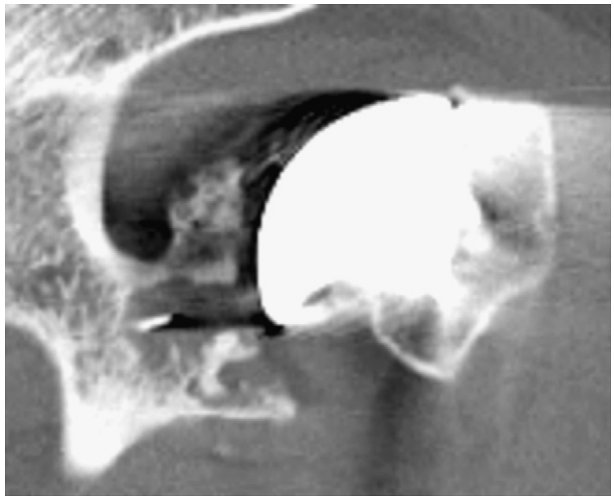

Figure 6 CT scan evaluation of glenoid component demonstrating bone between radial fins of central peg. Yian score = 6/18. Bone presence between central fins score = 0/6.

Table III Results

Patients	29
Shoulders	35
Follow-up	43 months
SST	10.3 (range, 6-12)
Constant Score	81.3 (range, 69-96)
Mean Lazarus Score (0-5)	0.45
# of Lazarus 0	24
# of Lazarus 1	6
# of Lazarus 2	5
# of Lazarus 3-5	0
Mean Yian Score	3.29
Central peg compartments with bone (0-6)	4.5
Shoulders with bone in all 6 compartments	23

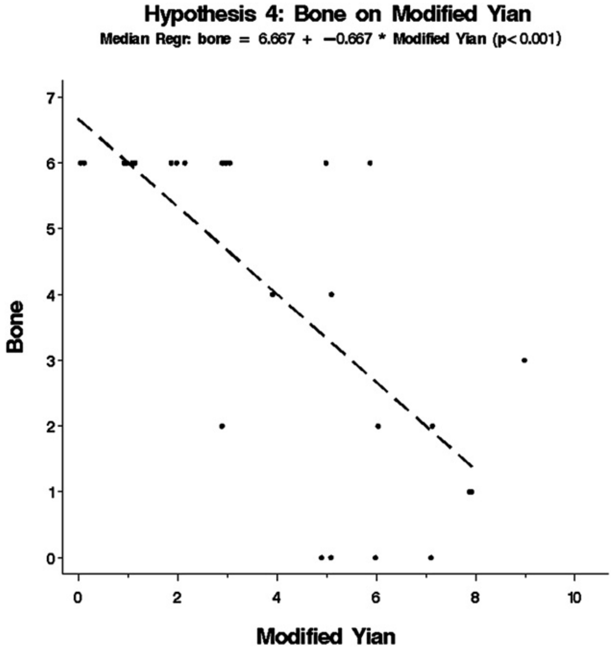

Figure 7 More bone between the radial fins of the central peg correlates with better (lower) Yian scores. (Note: x axis maximum is 10 for simplicity; maximum is 18, but highest score was 9 in this study; y axis is number of compartments filled with bone.)

score (0-5 with 0 = no lucency) was 0.45. Mean SST score was 10.3 while the mean absolute Constant score was 81.3. With regard to the relationship between Yian scores and Lazarus scores, the Spearman rank correlation was 0.62 ($P =$ .0001), indicating the 2 variables have a positive association with each other. No complications were experienced. No glenoid component was radiographically loose according to the Lazarus classification.[17] No shoulder has been revised. No other phenomena were noted about the central peg.

Discussion

Glenoid component loosening remains a major concern following total shoulder arthroplasty.[8,35] Wirth et al designed the all polyethylene glenoid described in our study that utilizes less bone cement at the time of its implantation and encourages bone growth between the radial fins of its central peg.[37] Despite this component's widespread use in humans, limited literature exists regarding its radiographic and/or clinical outcomes, and the radiographic studies were confined to plain radiographs.[6] The purpose of this study was to assess for bone presence between the radial fins of this hybrid glenoid component's central peg, as well as for overall component radiolucencies with thin cut CT scans and plain radiography.

Historically, concern over glenoid bone stock loss related to cemented components led to interest in cementless, metal-backed glenoid components that unfortunately did not improve radiographic outcomes.[8, 10, 20, 31] Radiolucencies that surround glenoid components, regardless of associated clinical function, are cause for concern. Unfortunately, 1 report demonstrated a nearly 20% incidence of radiolucent lines in cemented glenoids within 2 weeks of surgery,[8] and many have reported these radiolucencies to be present in recovery room radiographs as well.[1,4,13,15,16,24,32] Gartsman et al demonstrated these initial radiographic lucencies to be further dependent upon the glenoid design, finding initial radiolucencies in 39% of keeled components and 5% of pegged components.[12] Recent studies have also confirmed a higher survival rate for pegged components compared to their keeled counterparts.[10,17,37]

Years ago, Neer suggested that initial radiolucencies were attributable to poor cementing technique rather than loosening.[25] Although the advent of modern glenoid cementing techniques have shown slight decreases in the development of radiographic loosening, it has been shown that these radiolucent lines are still present and that they are progressive over time.[23,27,32] A 2004 study by Churchill et al demonstrated that heat production during methylmethacrylate curing is significant enough to result in thermal necrosis of bone.[5] This necrosis may be a cause or contributor of immediate and/or progressive radiolucent lines. Churchill suggested that limiting the amount of cement used during glenoid insertion might be beneficial in decreasing osteocyte death and, therefore, radiolucencies and likely associated loosening.[5] In their study, greater than 2 grams of cement led to significant thermal necrosis. The component in our study was designed to utilize limited bone cement with the 3 peripheral pegs while attempting to achieve acute and, ultimately, long-term biologic fixation with the central peg.

For many years, the primary method of evaluation of glenoid radiolucencies and loosening was plain radiography. Neer et al noted in 1982 that a high degree of variability exists in the presence of early radiolucencies surrounding cemented keel components due to the variations of radiographic technique and inter-observer error.[24] In 2002, Lazarus et al described a plain radiographic classification system to evaluate pegged glenoid components for radiolucencies.[17] Yian et al following their CT scan study to evaluated pegged glenoid components utilizing 3-mm CT cuts, concluded that "computed tomography scans were a more sensitive and reproducible tool for the assessment of loosening of pegged glenoid components than was fluoroscopically-guided conventional radiography. Further improvement in implant design and fixation technique appears to be necessary for long-term success of cemented glenoid components.[38] These authors did note that some pegs were difficult to analyze due to artifact from the humeral component. Our radiologist noted that some pegs were more difficult to evaluate than others because of artifact. However, because he had CT scans with 0.625 mm axial cuts as well as the coronal and sagittal reconstructions, he felt that he could adequately evaluate every peg. He felt the reconstruction images were critical in the assessment of some of the more difficult to visualize pegs.

Also as part of their study, Yian et al performed intra- and inter-observer reliability testing. The overall scoring reliability was higher for the computed tomography scores than for the Lazarus plain radiographic radiolucency scores. This was true for both intra-observer reliability (0.95 for CT, 0.70 for Lazarus) and inter-observer reliability (0.89 for CT, 0.51 for Lazarus).[38] Churchill et al recently demonstrated low rates of radiolucencies based upon Lazarus radiolucency scores at a minimum 5-year follow-up with the prosthesis described in our study. However, only 2/20 (10%) of their shoulders were assessed with CT scans.[6] In our study, we used CT scans with 0.625-mm cuts in an effort to further improve the evaluation of radiolucencies described as small as 1 mm. While we would not necessarily advocate CT scans for routine follow-up of total shoulder replacements, we do feel it is an excellent (and more accurate) adjunct to plain radiographs for more in-depth study of glenoid components.

In Wirth et al's component designed for canines, by plain radiographic and histological analysis, they found what looked like bone radiographically between the radial fins on the centralized peg, and it turned out to be just that in all cases histologically.[37] As with our study, they did not suggest a means of quantifying the bone present between the radial fins. Rather, they reported whether bone was or was not present between the radial fins. The human component counterpart that we studied here also has 3 cemented peripheral pegs in addition to the central peg; but the central peg principles remain the same as those in the canine study: a fracture-healing response to a controlled fracture that is created with a drill bit. Based upon our study, it is unclear whether the bone graft placed between the radial fins of the central peg is necessary for bone incorporation. Churchill et al did not utilize bone graft in their cases[6]; however, we found it simple and quick to obtain and place at the time of surgery.

There are several limitations to our study. First, it was performed in retrospective fashion. Second, we included bilateral shoulders for 6 patients. In cases of bilateral procedures, one is faced with the decision to include both, randomly include 1, or include neither. Our thought was that although one's clinical outcome on one side may be affected by the outcome of the other, due to many variables including the bias of the patient of 1 shoulder on the other, bone incorporation would not be affected by nearly as many of these variables including patient bias. Third, there is potential for minor irregularities of alignment in our radiographs due to a lack of fluoroscopic guidance. This is principally why we utilized CT scans as well. Fourth, there is no currently accepted means of quantifying bone incorporation between the fins of the central peg. We have accepted that, if present, the bone was viable as all cases were a minimum of 2 years after surgery. Our assumption was that necrotic bone or bone that was not being loaded would not be present beyond 2 years. Fifth, our mean follow-up was only 43 months. It is likely that loosening rates will increase with longer follow-up. Sixth, we did not have an ability to obtain serial CT scans on each shoulder and the follow-up serial plain radiographic analysis was inconsistent. Thus we are unable to comment on whether radiolucencies were or were not progressive. Seventh, the interpretation of the findings on plain radiographs and CT scans can be complicated. In the present study, a single observer (with over two decades of musculoskeletal radiology experience) other than the surgeon of record assessed all images. Given that Yian et al performed intra- and inter-observer reliability testing and found that the overall scoring reliability was significantly higher for the computed tomography scores than for the Lazarus plain radiographic radiolucency scores, we used CT scans and 1 observer with extensive experience. We did not repeat intra- and inter-observer reliability testing given the excellent reliability scores in Yian et al's study, particularly with CT scans. These limitations may diminish the value of this attempt to determine whether bone presence between the central peg's radial fins is associated with better glenoid component medium term fixation in this partially cemented all polyethylene glenoid component.

Conclusion

Primary total shoulder arthroplasty for primary glenohumeral osteoarthritis utilizing minimal glenoid peripheral peg cement and autologous reamings placed between radial fins of the central peg allowed for persistent central peg bone presence at a minimum 2 years after surgery. Better bone presence imparted fewer overall component radiolucencies.

Disclaimer

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Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.jse.2010.05.025.

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