Clinical and Radiographic Outcomes of Total Shoulder Arthroplasty With a Hybrid Dual-Radii Glenoid Component

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Abstract

In total shoulder arthroplasty (TSA), glenoid prostheses have conforming or nonconforming designs. A hybrid glenoid was designed with dual radii of curvature: a central conforming region surrounded by an outer nonconforming region.

We retrospectively reviewed the cases of 169 patients who underwent 196 hybrid glenoid prosthesis TSAs for primary glenohumeral arthritis. Clinical data, retrieved for 178 shoulders at a mean follow-up of 4.8 years, included physical examination, 36-Item Short Form Health Survey (SF-36), American Shoulder and Elbow Surgeons (ASES), Simple Shoulder Test (SST), subjective Neer criteria, and postoperative complication data. Radiographic data were retrieved for 136 shoulders at a mean of 3.7 years. Kaplan-Meier survivorship analysis was performed with glenoid or humeral revision as the endpoint.

All range of motion and survey measures improved in a statistically significant manner (P < .001). Of 139 respondents, 130 (93.5%) stated they were satisfied or very satisfied with their TSA. Of 178 patients, only 3 (1.7%) required revision for component loosening: 2 glenoid and 1 humeral. Of 136 shoulders, 86 (63.2%) had no glenoid lucencies, and 91 (66.9%) had no humeral stem lucencies.

Use of a hybrid-congruency glenoid prosthesis had excellent intermediate clinical and radiographic outcomes in the treatment of primary glenohumeral osteoarthritis.

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ing and a so-called rocking-horse phenomenon, which may lead to glenoid loosening. Surgeons therefore have increasingly turned to nonconforming implants. In the nonconforming design, the radius of curvature of the humeral head is smaller than that of the glenoid. Although this design may reduce edge loading, it allows more translation and reduces the relative contact area of the gleno-humeral joint. As a result, more contact stress is transmitted to the glenoid component, leading to polyethylene deformation and wear.

A desire to integrate the advantages of the 2 designs led to a novel glenoid implant design with variable conformity. This innovative component has a central conforming region and a peripheral non-conforming region or “translation zone” (Figure 1). Dual radii of curvature are designed to augment joint stability without increasing component wear. Biomechanical data have indicated that edge loading is not increased by having a central conforming region added to a nonconforming model. The clinical value of this prosthesis, however, has not been determined. Therefore, we conducted a study to describe the intermediate-term clinical and radiographic outcomes of TSAs that use a novel hybrid glenoid component.

Materials and Methods
This study was approved (protocol AAAD3473) by the Institutional Review Board of Columbia University and was conducted in compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations.

Patient Selection
At Columbia University Medical Center, Dr. Bigliani performed 196 TSAs with a hybrid glenoid component (Bigliani-Flatow; Zimmer Biomet) in 169 patients between September 1998 and November 2007. All patients had received a diagnosis of primary glenohumeral arthritis as defined by Neer. Patients with previous surgery such as rotator cuff repair or subacromial decompression were included in our review, and patients with a nonprimary form of arthritis, such as rheumatoid, posttraumatic, or post-capsulorrhaphy arthritis, were excluded.

Operative Technique
For all surgeries, Dr. Bigliani performed a subscapularis tenotomy with regional anesthesia and a standard deltopectoral approach. A partial anterior capsulectomy was performed to increase the glenoid’s visibility. The inferior labrum was removed with a needle-tip bovie while the axillary nerve was being protected with a metal finger or narrow Darrach retractor. After reaming and trialing, the final glenoid component was cemented into place. Cement was placed only in the peg or keel holes and pressurized twice before final implantation. Of the 196 glenoid components, 168 (86%) were pegged and 28 (14%) keeled; in addition, 190 of these components were all-polyethylene, whereas 6 had trabecular-metal backing. All glenoid components incorporated the hybrid design of dual radii of curvature. After the glenoid was cemented, the final humeral component was placed in 30° of retroversion. Whenever posterior wear was found, retroversion was reduced by 5° to 10°. The humeral prosthesis was cemented in cases (104/196, 53%) of poor bone quality or a large canal.

After surgery, the patient’s sling was fitted with an abduction pillow and a swathe, to be worn the first 24 hours, and the arm was passively ranged.

Take-Home Points
- The authors have developed a total shoulder glenoid prosthesis that conforms with the humeral head in its center and is non-conforming on its peripheral edge.
- All clinical survey and range of motion parameters demonstrated statistically significant improvements at final follow-up.
- Only 3 shoulders (1.7%) required revision surgery.
- Eighty-six (63%) of 136 shoulders demonstrated no radiographic evidence of glenoid loosening.
- This is the first and largest study that evaluates the clinical and radiographic outcomes of this hybrid shoulder prosthesis.
Patients typically were discharged on postoperative day 2. Then, for 2 weeks, they followed an assisted passive range of motion (ROM) protocol, with limited external rotation, for promotion of subscapularis healing.

**Clinical Outcomes**
Dr. Bigliani assessed preoperative ROM in all planes. During initial evaluation, patients completed a questionnaire that consisted of the 36-Item Short Form Health Survey\(^{19,20}\) (SF-36) and the American Shoulder and Elbow Surgeons\(^{21}\) (ASES) and Simple Shoulder Test\(^{22}\) (SST) surveys. Postoperative clinical data were collected from office follow-up visits, survey questionnaires, or both. Postoperative office data included ROM, subscapularis integrity testing (belly-press or lift-off), and any complications. Patients with <1 year of office follow-up were excluded. In addition, the same survey questionnaire that was used before surgery was mailed to all patients after surgery; then, for anyone who did not respond by mail, we attempted contact by telephone. Neer criteria were based on patients’ subjective assessment of each arm on a 3-point Likert scale (1 = very satisfied, 2 = satisfied, 3 = dissatisfied). Patients were also asked about any specific complications or revision operations since their index procedure.

Physical examination and office follow-up data were obtained for 129 patients (148/196 shoulders, 76% follow-up) at a mean of 3.7 years (range 1.0-10.2 years) after surgery. Surveys were completed by 117 patients (139/196 shoulders, 71% follow-up) at a mean of 5.1 years (range, 1.6-11.2 years) after surgery. Only 15 patients had neither 1 year of office follow-up nor a completed questionnaire. The remaining 154 patients (178/196 shoulders, 91% follow-up) had clinical follow-up with office, mail, or telephone questionnaire at a mean of 4.8 years (range, 1.0-11.2 years) after surgery. This cohort of patients was used to determine rates of surgical revisions, subscapularis tears, dislocations, and other complications. Acromioplasty, performed in TSA patients who had subacromial impingement stemming from improved ROM, represented a second operation, and therefore the need for this surgery was deemed a complication as well.

**Figure 2** breaks down the 4 major study cohorts. A clinical office and clinical survey subgroups of the overall clinical cohort were used to assess complication rates; however, the sum of the subgroups does not equal the overall cohort because the majority of patients were in both subgroups.

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**Table 1. Lazarus Classification for Glenoid Radiolucencies\(^{23}\)**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Component</th>
<th>Pegged</th>
<th>Keeled</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No radiolucency</td>
<td>No radiolucency</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Incomplete radiolucency around 1 or 2 pegs</td>
<td>Radiolucency at superior and/or inferior flange</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Complete radiolucency (≤2 mm wide) around 1 peg with or without incomplete radiolucency around 1 other peg</td>
<td>Incomplete radiolucency at keel</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Complete radiolucency (≤2 mm wide) around ≥2 pegs</td>
<td>Complete radiolucency (≤2 mm wide) around keel</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Complete radiolucency (&gt;2 mm wide) around ≥2 pegs</td>
<td>Complete radiolucency (&gt;2 mm wide) around keel</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Gross loosening</td>
<td>Gross loosening</td>
<td></td>
</tr>
</tbody>
</table>

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**Radiographic Outcomes**
Patients were included in the radiographic analysis if they had a shoulder radiograph at least 1 year after surgery. One hundred nineteen patients (136/196 shoulders, 76% follow-up) had radiographic follow-up at a mean of 3.7 years (range 1.0-10.2 years) after surgery. Surveys were completed by 117 patients (139/196 shoulders, 71% follow-up) at a mean of 5.1 years (range, 1.6-11.2 years) after surgery. Only 15 patients had neither 1 year of office follow-up nor a completed questionnaire. The remaining 154 patients (178/196 shoulders, 91% follow-up) had clinical follow-up with office, mail, or telephone questionnaire at a mean of 4.8 years (range, 1.0-11.2 years) after surgery. This cohort of patients was used to determine rates of surgical revisions, subscapularis tears, dislocations, and other complications. Acromioplasty, performed in TSA patients who had subacromial impingement stemming from improved ROM, represented a second operation, and therefore the need for this surgery was deemed a complication as well.

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**Figure 2** breaks down the 4 major study cohorts.
system of Lazarus and colleagues²³ (Table 1). The humerus was assessed for total number of lucent lines in any of 8 periprosthetic zones, as described by Sperling and colleagues.²⁴

**Statistical Analysis**

Statistical analysis was performed with Stata Version 10.0. Paired t tests were used to compare preoperative and postoperative numerical data, including ROM and survey scores. We calculated 95% confidence intervals (CIs) and set statistical significance at \( P < .05 \). For qualitative measures, the Fisher exact test was used. Survivorship analysis was performed according to the Kaplan-Meier method, with right-censored data for no event or missing data.²⁵

**Results**

**Clinical Analysis of Demographics**

In demographics, the clinical and radiographic patient subgroups were similar to each other and to the overall study population (Table 2). Of 196 patients overall, 16 (8%) had a concomitant rotator cuff repair, and 27 (14%) underwent staged bilateral shoulder arthroplasties.

**Clinical Analysis of ROM and Survey Scores**

Operative shoulder ROM in forward elevation, external rotation at side, external rotation in abduction, and internal rotation all showed statistically significant \( (P < .001) \) improvement from before surgery to after surgery. Over 3.7 years, mean (SD) forward elevation improved from 107.3° (34.8°) to 159.0° (29.4°), external rotation at side improved from 20.4° (16.7°) to 49.4° (11.3°), and external rotation in abduction improved from 53.7° (24.3°) to 84.7° (9.1°). Internal rotation improved from a mean (SD) vertebral level of S1 (6.0 levels) to T9 (3.7 levels).

All validated survey scores also showed statistically significant \( (P < .001) \) improvement from before surgery to after surgery. Over 5.1 years, mean (SD) SF-36 scores improved from 64.9 (13.4) to 73.6 (17.1), ASES scores improved from 41.1 (22.5) to 82.7 (17.7), SST scores improved from 3.9 (2.8) to 9.7 (2.2), and visual analog scale pain scores improved from 5.6 (3.2) to 1.4 (2.1). Of 139 patients with follow-up, 130 (93.5%) were either satisfied or very satisfied with their TSA, and only 119 (86%) were either satisfied or very satisfied with the nonoperative shoulder.

**Clinical Analysis of Postoperative Complications**

Of the 178 shoulders evaluated for complications, 3 (1.7%) underwent revision surgery. Mean time to revision was 2.3 years (range, 1.5-3.9 years). Two revisions involved the glenoid component, and the third involved the humerus. In one of the glenoid cases, a 77-year-old woman fell and sustained a fracture at the base of the trabecular metal glenoid pegs; her component was revised to an all-polyethylene component, and she had no further complications. In the other glenoid case, a 73-year-old man’s all-polyethylene component loosened after 2 years and was revised to a tra-
becular metal implant, which loosened as well and was later converted to a hemiarthroplasty. In the humeral case, a 33-year-old man had his 4-year-old index TSA revised to a cemented stem and had no further complications.

Of the 148 patients with office follow-up, only 8 had a positive belly-press or lift-off test. Of all 178 clinical study shoulders, 10 (5.6%) had a subscapularis tear confirmed by magnetic resonance imaging or a physician. Of these 10 tears, 3 resulted from traumatic falls. Four of the 10 tears were managed nonoperatively, and the other 6 underwent surgical repair at a mean of 2.9 years (range, 0.3-7.8 years) after index TSA. In 2 of the 6 repair cases, a 46-mm humeral head had been used, and, in the other 4 cases, a 52-mm humeral head. Of the 6 repaired tears, 2 were massive, and 4 were isolated to the subscapularis. None of these 6 tears required a second repair. Seven (4%) of the 178 shoulders experienced a clinically significant posterosuperior subluxation or dislocation; 5 of the 7 were managed nonoperatively, and the other 2 underwent open capsular shift, at 0.5 year and 3.0 years, respectively. Table 3 lists the other postoperative complications that required surgery.

Table 4 compares the clinical and radiographic outcomes of patients who required subscapularis repair, capsular shift, or implant revision with the outcomes of all other study patients, and Figure 3 shows Kaplan-Meier survivorship.

Postoperative Radiographic Analysis

**Glenoid Component.** At a mean of 3.7 years (minimum, 1 year) after surgery, 86 (63%) of 136 radiographically evaluated shoulders showed no glenoid lucencies; the other 50 (37%) showed ≥1 lucency. Of the 136 shoulders, 33 (24%) had a Lazarus score of 1, 15 (11%) had a score of 2, and only 2 (2%) had a score of 3. None of the shoulders had a score of 4 or 5.

**Humeral Component.** Of the 136 shoulders, 91 (67%) showed no lucencies in any of the 8 humeral stem zones; the other 45 (33%) showed 1 to 3 lucencies. Thirty (22%) of the 136 shoulders had 1 stem lucency zone, 8 (6%) had 2, and 3 (2%) had 3. None of the shoulders had >3 periprosthetic zones with lucent lines.

**Discussion**

In this article, we describe a hybrid glenoid TSA component with dual radii of curvature. Its central portion is congruent with the humeral head, and its peripheral portion is noncongruent and larger. The most significant finding of our study is the low rate (1.1%) of glenoid component revision 4.8 years after surgery. This rate is the lowest that has been reported in a study of ≥100 patients. Overall implant survival appeared as an almost flat Kaplan-Meier curve. We attribute this low revision rate to improved biomechanics with the hybrid glenoid design.

Symptomatic glenoid component loosening is the most common TSA complication.1,26-28
a review of 73 Neer TSAs, Cofield found glenoid radiolucencies in 71% of patients 3.8 years after surgery. Radiographic evidence of loosening, defined as component migration, or tilt, or a circumferential lucency 1.5 mm thick, was present in another 11% of patients, and 4.1% developed symptomatic loosening that required glenoid revision. In a study with 12.2-year follow-up, Torchia and colleagues found rates of 84% for glenoid radiolucencies, 44% for radiographic loosening, and 5.6% for symptomatic loosening that required revision. In a systematic review of studies with follow-up of ≥10 years, Bohsali and colleagues systematically reviewed 33 TSA studies and found a slightly higher complication rate (16.3%) 5.3 years after surgery. Furthermore, in our study, the 11 patients who underwent revision, capsular shift, or subscapularis repair had final outcomes comparable to those of the rest of our study population.

Our study had several potential weaknesses. First, its minimum clinical and radiographic follow-up was 1 year, whereas most long-term TSA series set a minimum of 2 years. We used 1 year because this was the first clinical study of the hybrid glenoid component design, and we wanted to maximize its sample size by reporting on intermediate-length outcomes. Even so, 93% (166/178) of our clinical patients and 83% (113/136) of our radiographic patients have had ≥2 years of follow-up, and we continue to follow all study patients for long-term outcomes. Another weakness of the study was its lack of a uniform group of patients with all the office, survey, complications, and radiographic data. Our retrospective study design made it difficult to obtain such a group without significantly reducing the sample size, so we divided patients into four data groups. A third potential weakness was the study’s variable method for collecting complications data. Rates of complications in the 178 shoulders were calculated from either office evaluation or patient self-report by mail or telephone. This data collection method is subject to recall bias, but mail and telephone contact was needed so the study would capture the large number of patients who had traveled to our institution for their surgery or had since moved away. Fourth, belly-press and lift-off tests were used in part to assess subscapularis function, but recent literature suggests post-TSA subscapularis assessment can be unreliable. These tests may be positive in up to two-thirds of patients after 2 years. Fifth, the generalizability of our findings to diagnoses such as rheumatoid and posttraumatic arthritis is limited. We had to restrict the study to patients with primary glenohumeral arthritis in order to minimize confounders.

This study’s main strength is its description of the clinical and radiographic outcomes of using a single prosthetic system in operations performed by a single surgeon in a large number of patients. This was the first and largest study evaluating the clinical
and radiographic outcomes of this hybrid glenoid implant. Excluding patients with nonprimary arthritis allowed us to minimize potential confounding factors that affect patient outcomes. In conclusion, our study results showed the favorable clinical and radiographic outcomes of TSAs that have a hybrid glenoid component with dual radii of curvature. At a mean of 3.7 years after surgery, 63% of patients had no glenoid lucencies, and, at a mean of 4.8 years, only 1.7% of patients required revision. We continue to follow these patients to obtain long-term results of this innovative prosthesis.

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