An Original Study

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.

Fixation of the glenoid component is the limiting factor in modern total shoulder arthroplasty (TSA). Glenoid loosening, the most common long-term complication, necessitates revision in up to 12% of patients.[1-4] By contrast, humeral component loosening is relatively uncommon, affecting as few as 0.34% of patients.[5] Multiple long-term studies have found consistently high rates (45%-93%) of radiolucencies around the glenoid component.[3,6,7] Although their clinical significance has been debated, radiolucencies around the glenoid component raise concern about progressive loss of fixation.

Since TSA was introduced in the 1970s, complications with the glenoid component have been addressed with 2 different designs: conforming (congruent) and nonconforming. In a congruent articulation, the radii of curvature of the glenoid and humeral head components are identical, whereas they differ in a nonconforming model. Joint conformity is inversely related to glenohumeral translation.[8] Neer's original TSA was made congruent in order to limit translation and maximize the contact area. However, this design results in edge load-

Authors' Disclosure Statement: Dr. Bigliani reports that he helped design the Zimmer Biomet prosthesis discussed in this article and has received royalties from Zimmer Biomet and Innomed. Columbia University, where Dr. Levine and Dr. Ahmad are employed, receives royalties from Zimmer Biomet, and Dr. Levine reports that he is an unpaid consultant to Zimmer Biomet. The other authors report no actual or potential conflict of interest in relation to this article.

ing and a so-called rocking-horse phenomenon, which may lead to glenoid loosening.[9-13] 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,[14] it allows more translation and reduces the relative contact area of the glenohumeral joint. As a result, more contact stress is transmitted to the glenoid component, leading to polyethylene deformation and wear.[15,16]

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 nonconforming 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.[17] 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.

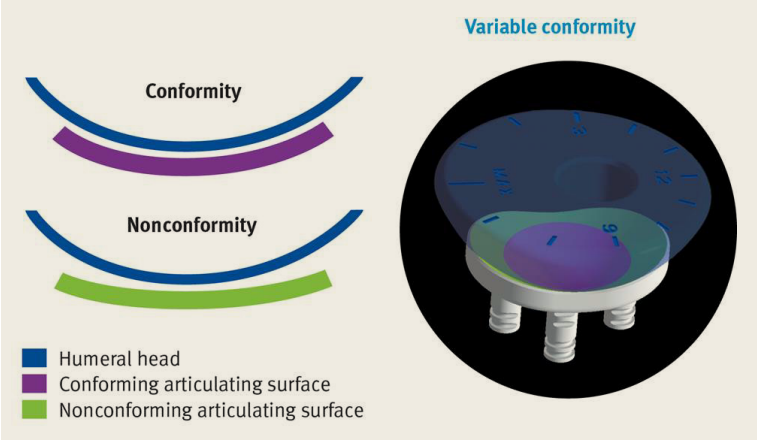

Figure 1. In this hybrid glenoid component (Bigliani-Flatow; Zimmer Biomet), a central conforming zone is surrounded by a nonconforming zone. This design reduces edge loading and associated glenoid wear.
Image acquired with the permission of Zimmer Biomet.

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.[18] 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 nonconforming 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.

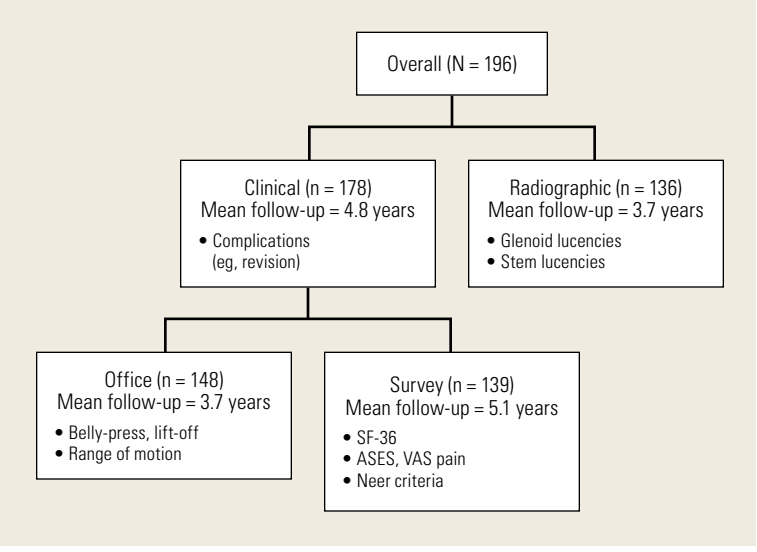

Figure 2. Breakdown of 4 major study cohorts and data analyzed by cohort. N represents number of shoulders per cohort. The clinical office and clinical survey subgroups of the overall clinical cohort were used to assess complication rates; however, the sum of the subgroups does not equal the overall cohort because the majority of patients were in both subgroups.

Abbreviations: ASES, American Shoulder and Elbow Surgeons; SF-36, 36-Item Short Form Health Survey; SST, Simple Shoulder Test; VAS, visual analog scale.

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.

Table 1. **Lazarus Classification for Glenoid Radiolucencies[23]**

	Component	
Grade	**Pegged**	**Keeled**
0	No radiolucency	No radiolucency
1	Incomplete radiolucency around 1 or 2 pegs	Radiolucency at superior and/or inferior flange
2	Complete radiolucency (≤2 mm wide) around 1 peg with or without incomplete radiolucency around 1 other peg	Incomplete radiolucency at keel
3	Complete radiolucency (≤2 mm wide) around ≥2 pegs	Complete radiolucency (≤2 mm wide) around keel
4	Complete radiolucency (>2 mm wide) around ≥2 pegs	Complete radiolucency (>2 mm wide) around keel
5	Gross loosening	Gross loosening

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, 69% follow-up) had radiographic follow-up at a mean of 3.7 years (range, 1.0-9.4 years) after surgery.

All radiographs were independently assessed by 2 blinded physicians who were not involved in the index procedure. Any disputed radiographs were reassessed by these physicians together, until consensus was reached. Radiographs were reviewed for the presence of glenoid lucencies around the pegs or keel and were scored using the

system of Lazarus and colleagues[23] (**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

Table 2. **Patient Operative Demographics by Study Cohort**

Demographic Factor	Cohort[a] Overall (n = 196)	Clinical (n = 178)	Radiographic (n = 136)
Mean (SD), y			
Age at time of surgery	68.1 (10.2)	67.9 (10.0)	67.4 (10.6)
Duration of symptoms before surgery	5.2 (4.1)	5.2 (4.1)	5.1 (4.3)
% (n)			
Male	57% (111)	57% (102)	60% (81)
Prior history of ipsilateral shoulder surgery	23% (45)	24% (42)	25% (34)
Total shoulder arthroplasty on dominant arm	58% (114)	59% (105)	56% (76)

[a]Overall cohort consisted of all patients who had primary glenohumeral arthritis and underwent total shoulder arthroplasty with hybrid glenoid component; clinical subgroup patients had minimum 1-year clinical follow-up (office or questionnaire); radiographic subgroup patients had minimum 1-year radiographic follow-up.

Table 3. **Post-Total Shoulder Arthroplasty Complications That Required Surgery**

Surgery Type	Shoulders, n	Clinical Study Population,[a] %
Overall	18	10.1
Subscapularis tendon repair	6	3.4
Acromioplasty	5	2.8
Posterior-inferior capsular shift	2	1.1
Subacromial lysis of adhesions	2	1.1
Glenoid component revision	2	1.1
Humeral component revision	1	0.6
Removal of methylmethacrylate	1	0.6
Arthroscopic washout for superficial infection	1	0.6

[a]178 shoulders; mean follow-up, 4.8 years.

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-

Table 4. **Outcomes in Patients With Post-Total Shoulder Arthroplasty Implant Revision, Capsular Shift for Dislocation, or Subscapularis Repair**

Outcome Measure	Patients	
	All (n varies)	Complication[a] (n = 11)
Mean (SD), final		
Forward elevation	159.0° (29.4°)[b]	137.3° (45.5°)
External rotation in abduction	84.7° (9.1°)[b]	86.9° (9.6°)
Internal rotation	T9 (3.7 levels)[b]	T9 (3.5 levels)
36-Item Short Form Health Survey score	73.6 (17.1)[c]	66.2 (20.5)
American Shoulder and Elbow Surgeons score	82.7 (17.7)[c]	69.8 (19.3)
Visual analog scale pain score	1.4 (2.1)[c]	3.3 (2.3)
Simple Shoulder Test score	9.7 (2.2)[c]	8.4 (2.4)
Patients, % (n)		
Satisfied or very satisfied with function of operative shoulder	93.5% (130)[c]	72.7% (8)
Glenoid lucency score was 0	63.2% (86)[d]	72.7% (8)
Stem lucency score was 0	66.9% (91)[d]	72.7% (8)

[a]These surgical complication patients underwent a revision, capsular shift, or subscapularis repair procedure any time after the index total shoulder arthroplasty.
[b]Clinical office follow-up group, 148 patients; mean follow-up, 3.7 years.
[c]Clinical survey follow-up group, 139 patients; mean follow-up, 5.1 years.
[d]Radiographic follow-up group, 136 patients; mean follow-up, 3.7 years.

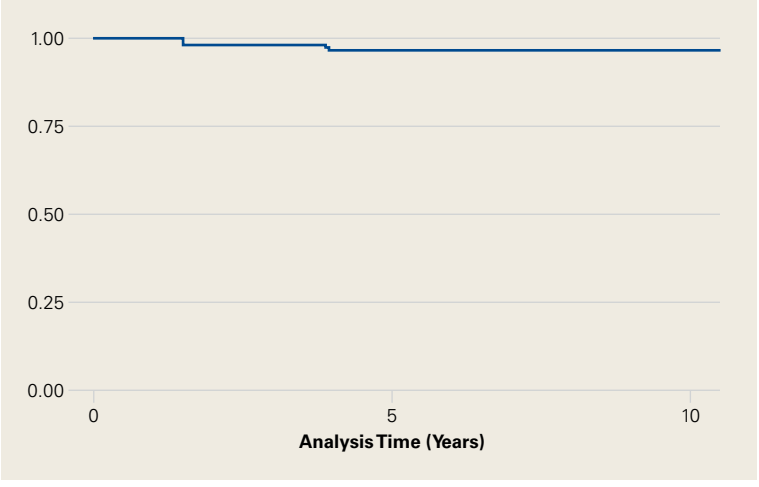

Figure 3. Kaplan-Meier survival curve of overall implant loosening.

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-Meir 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] In

a review of 73 Neer TSAs, Cofield[7] 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[3] 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[27] found similar lucency and radiographic loosening rates and a 7% glenoid revision rate. These data suggest glenoid radiolucencies may progress to component loosening.

Degree of joint congruence is a key factor in glenoid loosening. Neer's congruent design increases the contact area with concentric loading and reduces glenohumeral translation, which leads to reduced polyethylene wear and improved joint stability. In extreme arm positions, however, humeral head subluxation results in edge loading and a glenoid rocking-horse effect.[9-13,17,29-31] Conversely, nonconforming implants allow increased glenohumeral translation without edge loading,[14] though they also reduce the relative glenohumeral contact area and thus transmit more contact stress to the glenoid.[16,17] A hybrid glenoid component with central conforming and peripheral nonconforming zones may reduce the rocking-horse effect while maximizing ROM and joint stability. Wang and colleagues[32] studied the biomechanical properties of this glenoid design and found that the addition of a central conforming region did not increase edge loading.

Additional results from our study support the efficacy of a hybrid glenoid component. Patients' clinical outcomes improved significantly. At 5.1 years after surgery, 93.5% of patients were satisfied or very satisfied with their procedure and reported less satisfaction (86%) with the nonoperative shoulder. Also significant was the reduced number of radiolucencies. At 3.7 years after surgery, the overall percentage of shoulders with ≥1 glenoid radiolucency was 37%, considerably lower than the 82% reported by Cofield[7] and the rates in more recent studies.[3,16,33-36] Of the 178 shoulders in our study, 10 (5.6%) had subscapularis tears, and 6 (3.4%) of 178 had these tears surgically repaired. This 3.4% compares favorably with the 5.9% (of 119 patients) found by Miller and colleagues[37] 28 months after surgery. Of our 178 shoulders, 27 (15.2%) had clinically significant postoperative complications; 18 (10.1%) of the 178 had these complications surgically treated, and 9 (5.1%) had them managed nonoperatively. Bohsali and colleagues[27] 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 4 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.[38] These tests may be positive in up to two-thirds of patients after 2 years.[39] 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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This paper will be judged for the Resident Writer's Award.