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Cemented versus uncemented fixation of second-generation Trabecular Metal glenoid components: minimum 5-year outcomes

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Background: Total shoulder arthroplasty (TSA) with second-generation Trabecular Metal™ implants (Zimmer, Warsaw, IN, USA) has shown good short-term outcomes. Differences in outcomes between cemented and uncemented fixation are unknown. This study compared the clinical, radiographic, and patient-rated outcomes of TSA with cemented vs. uncemented TM glenoids at minimum 5-year follow-up.

Methods: Patients who underwent anatomic TSA with second-generation TM glenoid components for primary osteoarthritis were identified for minimum 5-year follow-up. The patients were divided into 2 groups: cemented and uncemented glenoid fixation. Outcome measures included implant survival, patient-rated outcome scores (Patient-Reported Outcomes Measurement Information System [PROMIS] and American Shoulder and Elbow Surgeons scores), shoulder range of motion, and radiographic analysis. Findings were compared between groups.

Results: The study included 55 shoulders: 27 in the cemented group (21 with full radiographic follow-up) and 28 in the uncemented group (22 with full radiographic follow-up). Both groups had similar follow-up times (6.6 years in cemented group vs. 6.7 years in uncemented group, $P = .60$). Moreover, the groups did not differ significantly in sex composition, age at the time of surgery, or preoperative Walch glenoid grade distribution. No patients required revision surgery. The 2 groups had similar preoperative range of motion, but patients in the uncemented group had greater follow-up forward flexion ($P = .03$), external rotation ($P < .01$), and lateral elevation ($P = .03$) than did patients in the cemented group. PROMIS scores were not significantly different between groups. American Shoulder and Elbow Surgeons scores were similar (89.8 in cemented group vs. 94.1 in uncemented group, $P = .21$). Mid-term radiographs showed a metal debris rate of 24% in the cemented group and 27% in the uncemented group. Although these values were not significantly different ($P = .90$), the frequency of mild metal debris (grade 1-2), when present, was greater in the uncemented group (grade 2 in 6 shoulders) than in the cemented group (grade 1 in 4 and grade 2 in 1, $P = .02$). There was a greater presence of mild (grade 1) radiolucent lines in the uncemented group (64%) than in the cemented group (29%, $P < .01$). No glenoid had evidence of loosening (defined by a change in position or radiolucent lines > 2 mm). The presence of metal debris and radiolucent lines did not have a significant effect on clinical outcomes.

Conclusion: At minimum 5-year follow-up, TSA patients with TM glenoids demonstrated excellent clinical and patient-reported outcomes with a 100% implant survival rate, regardless of cemented vs. uncemented fixation. However, the uncemented group showed a significantly higher rate of radiolucent lines and a higher frequency of mild metal debris. These radiographic findings did not affect the clinical outcomes, and their implications for long-term outcomes and prosthesis survival is unknown.

This study and all study-related documents were reviewed and approved by the University of Rochester Research Subjects Review Board (study no. RSRB00071615).

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In 2003, the first-generation Trabecular Metal™ (TM)–backed polyethylene glenoid component (Zimmer, Warsaw, IN, USA) was introduced. Metal-backed glenoids were seen as a potential option to address glenoid loosening, improve glenoid fixation, and provide long-term durability. TM is a tantalum biomaterial with a structure similar to trabecular bone and has decreased metal stiffness and high porosity to allow for osseointegration.[1,5,16] This material showed favorable results in total hip and knee arthroplasty, as well as reverse total shoulder arthroplasty (TSA).[2,8,15] Unfortunately, the first-generation TM-backed glenoid components exhibited an unacceptably high failure rate due to fracture at the component keel–tantalum disc interface and was taken off the market in 2005.[5]

After redesign, the second-generation TM glenoid was introduced in 2009 and is currently in widespread use throughout the world. Short-term clinical studies (minimum 2-year follow-up) investigating the performance of the second-generation TM glenoid have yielded good to excellent patient outcomes.[9,16,17,20,22] Mid-term outcomes (minimum 5-year follow-up), however, are sparse. Furthermore, some short-term studies reported radiographic metal debris formation at rates as high as 44% associated with these TM glenoid components, raising concern for possible future implant failure.[9,22] Other short-term studies did not find similar results, reporting 0% metal debris rates.[19] It is important to note that there was heterogeneity among these short-term studies regarding whether the TM glenoid component was implanted in a cemented or uncemented fashion. It is currently unknown whether the TM glenoid implantation technique affects metal debris rates or other clinical and radiographic outcomes.

Therefore, the purpose of this study was to compare the clinical, radiographic, and patient-rated outcomes, at minimum 5-year follow-up, in patients who underwent TSA using second-generation TM glenoids with cemented vs. uncemented glenoid fixation. We hypothesized that mid-term outcomes would be similar between the cemented and uncemented groups. Furthermore, this study aimed to provide further mid-term data for the TM glenoid, as prior studies have reported primarily on shorter-term outcomes.

Materials and methods

Patients who underwent anatomic TSA with a porous tantalum glenoid component (second-generation TM; Zimmer Biomet, Warsaw, IN, USA) from January 2009 to August 2013 were retrospectively reviewed. Patients were identified using Current Procedural Terminology code 23472. The query was performed between September 2018 and March 2019 to ensure a minimum follow-up time of 5 years after surgery. Chart review of all patients identified by Current Procedural Terminology code was then performed to determine which patients would qualify for the study. Patients were included in the study if their operative notes stated that they underwent primary anatomic TSA using a TM-backed glenoid component system for the treatment of primary glenohumeral osteoarthritis. Patients were excluded from the study if their operative notes stated that they required glenoid bone grafting or augmentation or underwent reverse TSA, hemiarthroplasty, or revision shoulder arthroplasty. No patients with a history of fracture or infection of the shoulder girdle or previous rotator cuff repair were included in this study. Included patients were then split into 2 groups depending on if their operative notes stated that the glenoid component was placed with a cemented or uncemented technique and were contacted by telephone and asked to return to the clinic for radiographic and patient-rated outcome studies. Patients who declined to return for clinical evaluation were given the option of answering patient-reported outcome questionnaires over the phone. Informed consent was provided to all patients who chose to participate in this study.

Outcomes between groups were then compared. The primary outcome measure was implant survival, as defined by the need for revision surgery owing to glenoid component loosening or fracture. Secondary outcome measures were patient-rated outcome scores, radiographic findings, and clinical shoulder range-of-motion (ROM) findings. Patient-rated outcome measures (PROMs) included the American Shoulder and Elbow Surgeons (ASES) score; ASES pain score; and PROMIS T-scores for Physical Function (PF), Upper Extremity (UE), Pain Interference (PI), and Depression (D). All patients who returned to the clinic underwent radiographic evaluation of the operative shoulder with anteroposterior, oblique, and axillary lateral radiographs. In addition, shoulder ROM was measured with a goniometer, specifically forward flexion (FF), external rotation with the arm at the patient's side (ER), and lateral elevation (LE). A chart review was performed of all patients who agreed to participate in the study to capture demographic information (age, sex), preoperative imaging of the involved shoulder, immediate postoperative shoulder radiographs, and preoperative shoulder FF and ER measurements.

Operative technique

All patients included in this study underwent primary anatomic TSA using the Zimmer Bigliani/Flatow Total Shoulder system with a second-generation TM-backed glenoid component (Zimmer Biomet) for the treatment of primary glenohumeral osteoarthritis. All patients had satisfactory rotator cuff integrity at the time of surgery given that none had a full-thickness rotator cuff tear based on preoperative magnetic resonance imaging or intraoperative assessment. All surgical procedures were performed by 2 fellowship-trained shoulder surgeons. The glenoid component

was either cemented or fixed in a press-fit manner without cement. Cementation was performed per the manufacturer's guidelines, with cement applied on the component's backside, covering only the peripheral polyethylene surface. One surgeon routinely cemented the glenoid component and used a lesser tuberosity osteotomy for exposure. The second surgeon routinely implanted the glenoid component without cement and used a subscapularis peel. Surgery was otherwise performed in a similar fashion in all patients. A standard deltopectoral approach was used, and biceps tenodesis was performed in all cases. Humeral and glenoid preparation was similarly performed in all cases. Postoperative rehabilitation was the same in all cases and consisted of initial shoulder immobilizer protection for 4 weeks, with early gradual passive ROM and active-assisted ROM exercises, followed by active ROM and gradual progressive resistance exercises at 6-12 weeks.

Radiographic analysis

All radiographs were evaluated independently by 2 fellowship-trained shoulder surgeons. All radiographs were blinded of all patient-identifying information. Preoperative imaging was reviewed, and the glenoid wear pattern was graded per the Walch classification. Postoperative radiographs were evaluated for 4 main radiographic outcome measures: evidence of metallic debris, presence of radiolucent lines, superior humeral head subluxation, and anterior-posterior (AP) humeral head subluxation.

Metal debris was graded using the method of Endrizzi et al.[9] A grade from 0 to 4 is assigned, in which grade 0 indicates no radiographic evidence of metallic debris; grade 1, debris noted only at the bone-metal interface; grade 2, debris noted in the soft tissues intra-articularly; grade 3, incomplete fracture or cracking of the tantalum component; and grade 4, complete component fracture and displacement. Radiolucent lines were graded using the method of Lazarus et al.[12] The TM glenoid component was graded as a keeled implant, similarly to prior studies.[9] Grading is performed on a 0-5 scale, with grade 0 representing no radiolucency; grade 1, radiolucency at the superior and/or inferior flange; grade 2, radiolucency at the keel; grade 3, complete radiolucency ≤ 2 mm wide around the keel; grade 4, complete radiolucency > 2 mm wide around the keel; and grade 5, gross loosening. Superior humeral subluxation was measured with the method of Torchia et al[21] and was defined as none, mild, moderate, or severe. The classification is dependent on the position of the center of the prosthetic humeral head relative to the center of the glenoid component and measured in terms of the diameter of the prosthetic head. No subluxation means that the center of the humeral head and glenoid are exactly identical, mild subluxation means that the distance between the head and glenoid is less than one-quarter the diameter of the humeral head, moderate subluxation is defined as translation of between one-quarter and one-half the diameter of the head, and severe subluxation is defined as translation of more than half the diameter of the humeral head. Finally, AP humeral subluxation was measured using the same definitions of Torchia et al described earlier but in the axial plane as opposed to the coronal plane.

A grade for all 4 radiographic outcome measures was independently assigned for all radiographs by the 2 reviewers. The findings were then independently compared by a separate author, and differences in interpretation were noted. For discordant grades, the radiographs were re-evaluated and discussed until a consensus was reached.

Statistical analysis

All statistical analyses were performed using GraphPad Prism software (GraphPad, La Jolla, CA, USA). Descriptive statistics were performed on PROMs and clinical shoulder ROM findings for both groups. Findings between groups were compared using the Fisher exact test for nominal data and independent t test for numerical data. Correlation between the preoperative Walch glenoid classification and presence of metal debris and radiolucent lines was determined using the Fisher exact test. Descriptive statistics were also performed on the entire cohort, combining the 2 groups. Differences in PROMs and ROM findings were compared between patients with radiographic grade 0 metal debris and those with grade 1 metal debris or higher via the Mann-Whitney U test. In a similar fashion, differences in PROMs and ROM findings were determined between patients with grade 0 radiolucency and those with grade 1 radiolucency or higher. Statistical significance was defined as $P < .05$ for all tests.

Furthermore, Cohen κ coefficient analysis was performed to determine the inter-rater reliability for all radiographic grading measures. The κ results were interpreted as follows: 0.01-0.20, no to slight agreement; 0.21-0.40, fair agreement; 0.41-0.60, moderate agreement; 0.61-0.80, substantial agreement; and 0.81-1.00, nearly perfect agreement.[14]

An a priori power analysis was performed and determined that 32 patients total (16 in each arm) would be needed to achieve 80% power with an α of .05 and to detect a 9-point difference in the ASES score, assuming a standard deviation of 10. The minimal clinically important difference in the ASES score was previously shown to be 9 points.[23] A second a priori power analysis determined that 36 patients (18 in each arm) were needed to identify a radiographic difference of 1 grade with 80% power and an α of .05. Patients were successfully recruited for the study to achieve sufficient power.

Results

We identified 77 patients who underwent anatomic TSA with placement of a TM glenoid component from 2009-2013. Of these 77 patients, 10 had died; moreover, 9 patients (or patients' families) declined to participate in the study, and 5 patients were unable to be contacted. The remaining 53 patients agreed to take part in the study. Two patients had bilateral shoulders included in the study.

Of the 53 included patients, 27 patients (27 shoulders) had cemented glenoid fixation and 26 patients (28 shoulders) had uncemented fixation. In the cemented group, 21 patients returned to the office for radiographs, physical examination measurements, and PROM questionnaires whereas 6 patients agreed to phone administration of PROM surveys. In the uncemented group, patients returned for radiographs, physical examination measurements, and PROM questionnaires for the assessment of 22 shoulders whereas patients agreed to phone administration of

PROM surveys for 6 shoulders. In total, a 70% follow-up rate (55 of 79 shoulders) was achieved for minimum 5-year follow-up.

The mean follow-up time in the cemented group was 6.6 ± 1.1 years; this was similar to that in the uncemented group (6.7 ± 0.8 years, $P = .60$). The groups were not significantly different in terms of sex composition (70% male patients in cemented group vs. 65% male patients in uncemented group) or age at the time of surgery (68.5 ± 8.2 years in cemented group vs. 69.0 ± 7.8 years in uncemented group). There was a 100% implant survival rate in both groups, with no revision surgical procedures performed on any of the 55 shoulders included in the study. No cases of component fracture or gross component failure occurred. No major surgical complications were noted in all included patients. No shoulders had evidence of metallic debris on immediate postoperative imaging.

Table I summarizes shoulder ROM and PROM findings for both groups. The 2 groups had similar preoperative ROM and all patients made significant gains in ROM after surgery, but the uncemented group had greater postoperative FF (143° vs. 130°, $P = .03$), ER (75° vs. 53°, $P < .01$), and LE (145° vs. 127°, $P = .03$) than did the cemented group. PROMIS PF, UE, PI and D scores were not significantly different between groups. ASES pain scores and ASES overall scores (89.8 in cemented group vs. 94.1 in uncemented group, $P = .21$) were also similar.

Table II summarizes radiographic findings for both groups. Radiographic analysis showed the presence of metal debris in 24% of cemented shoulders (5 of 21) and 27% of uncemented shoulders (6 of 22). Although these values were not significantly different ($P = .90$), the frequency of mild (grade 1-2) metal debris, when present, was greater in the uncemented group (grade 2 in 6 shoulders) than in the cemented group (grade 1 in 4 and grade 2 in 1) ($P = .02$). There was a significantly greater presence of mild radiolucent lines in the uncemented group (64%, grade 1 in all) compared with the cemented shoulders (29%, grade 1 in 4 and grade 2 in 2) ($P < .01$). Evidence of superior migration was found in all cemented shoulders (mild in 18 and moderate in 3), which was significantly greater than in the uncemented group (59%, mild in all) ($P < .01$). Similar rates of AP migration were found between groups (86% in cemented group vs. 77% in uncemented group, $P = .70$). Analysis of the κ coefficient revealed excellent inter-rater reliability for grading of metal debris ($\kappa = 0.94$; 95% confidence interval [CI], 0.88-1.00), radiolucent lines ($\kappa = 0.96$; 95% CI, 0.92-1.00), and superior subluxation ($\kappa = 0.84$; 95% CI, 0.75-0.93). Substantial inter-rater reliability was observed for grading of AP subluxation ($\kappa = 0.65$; 95% CI, 0.50-0.80). Radiographic examples from each group are shown in Figures 1 and 2.

Evidence of TM component erosion was noted in 1 patient in the cemented group, as shown in Figure 3. Radiographs at 5.7 years' follow-up showed superior wear of the glenoid component and intra-articular metal debris without component fracturing (grade 2), grade 2 radiolucent lines (no evidence of gross component loosening), moderate superior migration (evidence of rotator cuff dysfunction), and mild AP subluxation. This patient had the worst radiographic grades of all study patients but still

Table I Clinical outcomes of TSA with TM glenoid: comparison of cemented vs. uncemented groups

Outcome measure	Cemented	Uncemented	*P* value
Preoperative ROM, °			
FF	89 (16)	102 (31)	.09
ER	17 (18)	23 (14)	.21
Postoperative ROM, °			
FF	130 (20)	143 (17)	.03*
ER	53 (22)	75 (11)	<.01*
LE	127 (29)	145 (24)	.03*
PROM score			
PROMIS PF	48.4 (8.5)	47.4 (7.1)	.60
PROMIS UE	47.6 (9.9)	49.8 (10.1)	.42
PROMIS PI	48.0 (8.2)	48.6 (8.2)	.81
PROMIS D	43.4 (8.3)	43.0 (8.8)	.87
ASES pain	45.6 (9.2)	47.6 (5.4)	.35
ASES	89.8 (10.3)	94.1 (9.1)	.21

ROM, range of motion; *FF*, forward flexion; *ER*, external rotation; *LE*, lateral elevation; *PROM*, patient-rated outcome measure; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *PF*, Physical Function; *UE*, Upper Extremity; *PI*, Pain interference; *D*, Depression; *ASES*, American Shoulder and Elbow Surgeons.

Data are presented as mean (standard deviation).

* Statistically significant.

Table II Radiographic grades of TSA with TM glenoid: comparison of cemented vs. uncemented groups

Radiographic grade	Cemented	Uncemented
Metal debris		
0	16	16
1	4	—
2	1	6
3	—	—
4	—	—
Radiolucent lines		
0	15	8
1	4	14
2	2	—
3	—	—
4	—	—
5	—	—
Superior migration		
None	—	9
Mild	18	13
Moderate	3	—
Severe	—	—
AP migration		
None	3	5
Mild	18	16
Moderate	—	1
Severe	—	—

TSA, total shoulder arthroplasty; *TM*, Trabecular Metal; *AP*, anterior-posterior.

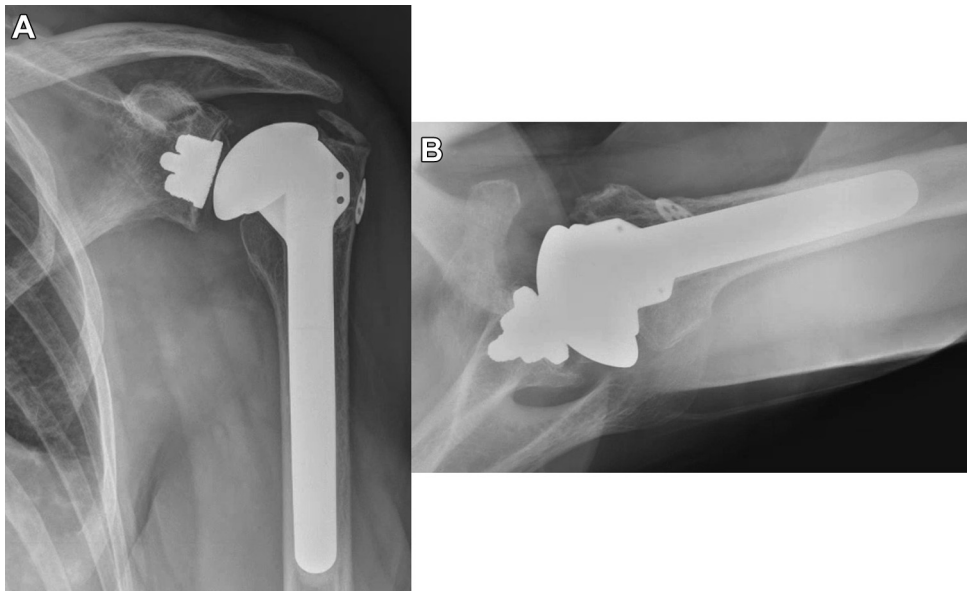

Figure 1 **(A, B)** Example of study patient with cemented Trabecular Metal glenoid component. Mild superior migration is present, but there is no evidence of metal debris or radiolucent lines.

demonstrated excellent clinical outcomes, with an ASES score of 95, FF to 152°, ER to 58°, and LE to 153°.

Preoperative imaging was available for 19 of the 21 cemented shoulders that presented for mid-term radiographs, including all 5 patients who had evidence of metal debris and all 6 patients with evidence of radiolucent lines. All 22 uncemented shoulders had preoperative imaging available. Preoperative glenoid morphology types and the associated presence of metal debris and radiolucent lines in each group are shown in Table III. No significant difference

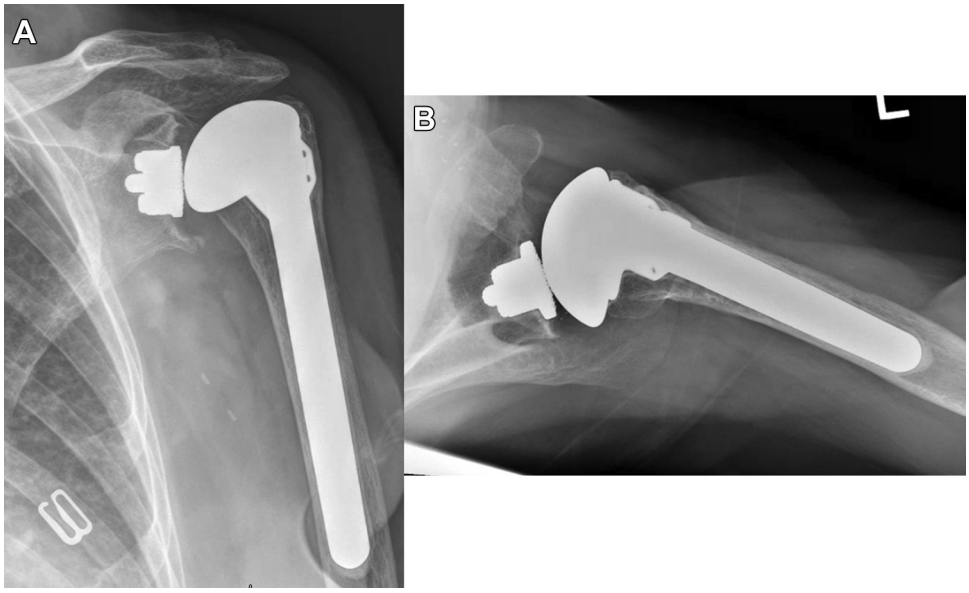

Figure 2 **(A, B)** Example of study patient with uncemented Trabecular Metal glenoid component. Intra-articular metal debris (grade 2) and grade 1 radiolucency, as well as mild superior and anterior-posterior migration, are present.

in the preoperative Walch glenoid grade distribution was noted between groups ($P = .66$). There was no significant correlation between the preoperative Walch classification and the development of metal debris ($P = .51$) or development of radiolucent lines ($P = .61$) in the cemented group. Similarly, there was no significant correlation between the preoperative Walch classification and the development of metal debris ($P = .84$) or development of radiolucent lines ($P = .43$) in the uncemented group. Walch grading showed excellent inter-rater reliability ($\kappa = 0.86$; 95% CI, 0.79-0.93).

Combining the 2 groups yielded generalized data describing the outcomes of the second-generation TM glenoid at minimum 5-year follow-up. The overall mean follow-up time was 6.7 ± 0.9 years. The overall mean age at the time of surgery was 68.8 ± 7.5 years, and 69% of total patients were male patients. Preoperative FF (96° ± 26°) improved to 137° ± 20° at mid-term follow-up ($P <$

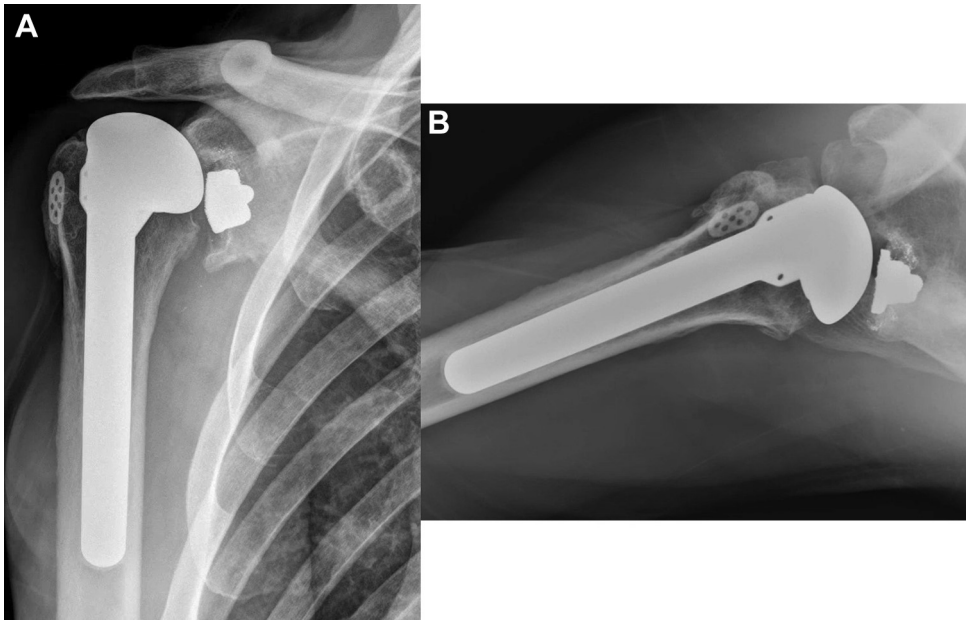

Figure 3 **(A, B)** Trabecular Metal component erosion in patient with cemented Trabecular Metal glenoid at 5.7 years' follow-up. Intra-articular metal debris, grade 2 radiolucency, evidence of rotator cuff dysfunction, and mild anterior-posterior subluxation are present. Despite having the most concerning radiographic findings, this patient demonstrated excellent clinical outcomes.

Table III Preoperative Walch glenoid types and associated radiographic findings at mid-term follow-up

Walch glenoid type	No. of shoulders	No. of shoulders with any metal debris	No. of shoulders with any radiolucent lines
Cemented			
A1	7	1	3
A2	2	—	—
B1	2	1	1
B2	8	3	2
C	—	—	—
Uncemented			
A1	5	2	4
A2	2	—	2
B1	5	1	2
B2	10	3	6
C	—	—	—

.01). Preoperative ER (20° ± 16°) improved to 65° ± 20° ($P < .01$). LE was 136° ± 28° at mid-term follow-up. At minimum 5-year follow-up, patients had a mean PROMIS PF score of 47.9 ± 7.8; UE score, 48.7 ± 10.0; PI score, 48.3 ± 8.1; and D score, 43.2 ± 8.5. The mean ASES score was 92.0 ± 12.5. We observed an overall metal debris rate of 26% and overall radiolucent line rate of 46%. As a whole, there was no significant correlation between the preoperative Walch classification and the development of metal debris ($P = .74$) or development of radiolucent lines ($P = .90$). When we compared all patients with grade 0 metal debris vs. those with grade 1 metal debris or higher, there were no significant differences in shoulder ROM, PROMIS, and ASES outcomes ($P > .05$ for all). Similarly, when we compared patients with grade 0 radiolucency vs. those with findings of grade 1 radiolucency or higher, there were no significant differences in any shoulder ROM, PROMIS, or ASES outcomes ($P > .05$ for all).

Discussion

The second-generation TM glenoid has shown promising short-term clinical and radiographic outcomes in several prior studies. At a mean follow-up of 38 months, Merolla et al[16] found a mean ASES score of 93.4. There was a 0% incidence of glenoid implant failure, with no evidence of metal debris on any follow-up radiographs. Styron et al[20] also showed good clinical results at a mean 50-month follow-up, but their cohort included a combination of first- and second-generation TM-backed glenoid components. Panti et al[17] found good clinical outcomes (mean ASES score, 88.5) with no patients requiring revision surgery at 43 months' follow-up. Other short-term studies also demonstrated good clinical outcomes but raised concern about metal debris rates associated with the implant. Endrizzi et al,[9] at a minimum 2-year follow-up time and mean follow-up of 53 months, found a mean ASES score of 89.7 but showed a 44% incidence of metal debris that appeared to increase with longer follow-up periods. Watson et al,[22] at a mean follow-up of 34 months, described a 25% incidence of debris or osteolysis, with a mean ASES score of 69.2. Comparison of these studies shows that there was heterogeneity not only in the metal debris rate (0%-44%) but also in the use of cement during glenoid fixation. Both Endrizzi et al and Watson et al, who reported the highest metal debris rates, primarily used a press-fit technique without cement. Furthermore, the aforementioned studies were all short-term investigations at minimum 2-year follow-up. Therefore, it is unknown whether the choice of cementation technique when implanting the second-generation TM glenoid affects outcomes at mid-term follow-up.

The findings from our study showed that, at minimum 5-year follow-up, patients who underwent TSA with TM glenoids demonstrated excellent clinical and patient-reported outcomes, regardless of cemented vs. uncemented fixation. No patients in either group required revision surgery or had evidence of component fracture or gross loosening on follow-up imaging. However, the uncemented group demonstrated a higher rate of mild radiolucent lines (64%) than the cemented group (24%). Metal debris rates were similar between groups (27% in uncemented group vs. 24% in cemented group), but when metal debris was present, the uncemented group had a higher frequency of mild (grade 1-2) metal debris. The groups were similar in terms of age, sex distribution, follow-up period, surgical implants, and preoperative Walch glenoid types.

Endrizzi et al[9] reported a 36% radiolucency rate for the same implant examined in our study, and a prior systematic review showed an overall 35% radiolucency rate for metal-backed glenoids.[18] Although the presence of radiolucent lines has not been directly correlated with poor outcomes, surgeons generally agree that radiolucency should be

avoided if possible, as the presence of radiolucent lines may be a precursor to future glenoid loosening.[19] In this light, the increased radiolucent line rate in the uncemented group is important to highlight. All of the radiolucent lines in the uncemented group were grade 1. It has been shown biomechanically that initial fixation of the TM glenoid component is greater with cement.[4] This may explain the mild lucent lines noted in the uncemented group. None of the components in the uncemented group had a higher degree of loosening, which is encouraging. It is possible that once bone incorporation into the TM component occurs, stability is achieved and radiolucent lines do not progress.

The uncemented group also demonstrated a higher frequency of mild metal debris grades. The exact mechanism of metal debris formation in these implants is unknown. A decrease in fixation strength at time 0 between the TM glenoid backside and the bony glenoid surface could potentially be a cause. Prior studies have suggested that cementation of metal-backed glenoid components yields greater fixation strength. Budge et al[4] demonstrated biomechanically that cementation of the TM glenoid yielded greater stability than press-fit implantation and suggested that cementation may enhance the osseointegration of the implant. Prior reports of other uncemented metal-backed glenoid designs found high clinical and radiographic complication rates as well, especially with early metal-backed designs.[3,10,13,19] Given our findings, uncemented implantation of TM glenoids may be more prone to generation of mild metal debris until osseointegration takes place. None of the components in this study showed evidence of lack of osseointegration.

Interpretation of other radiographic findings showed that the cemented group had a significantly greater presence of superior humeral migration. At the time of surgery, no patient had a full-thickness rotator cuff tear based on preoperative magnetic resonance imaging or intraoperative assessment. Superior migration is an indirect measure of rotator cuff integrity. Secondary rotator cuff dysfunction was defined as moderate or severe superior migration per the definition of Torchia et al.[21] In the cemented group, 3 patients had moderate migration, yielding an overall rate of 14%, which is comparable to the 17% rate of secondary rotator cuff dysfunction at long-term follow-up of anatomic TSA patients found by Young et al.[24] There was no significant difference between groups in terms of AP migration rates, with all patients demonstrating either no AP migration or mild migration, except for 1 patient with moderate migration. This finding likely signifies that subscapularis function was intact and that the lesser tuberosity osteotomies and subscapularis peels healed appropriately. Finally, preoperative Walch glenoid grade did not have a significant effect on the formation of metal debris or presence of radiolucent lines in either group.

Both groups demonstrated excellent patient-reported outcomes and significant improvements in shoulder ROM. The 2 groups had similar preoperative ROM, but the uncemented group achieved greater ROM at follow-up. The improvements in shoulder ROM described in this study are similar to those in prior studies investigating the same implant.[16,22] The PROM scores were not significantly different between groups. The ASES scores in both groups compared favorably with those in the previously discussed short-term studies of this implant, with mean scores ranging from 69.2 to 93.4, and signified a good functional outcome after TSA.[9,16,17,20,22] The PROMIS scores in our study are similar to those in a recent study that demonstrated that patients had mean PROMIS T-scores of 44.1 for PF, 52.6 for PI, and 45.5 for D at early (minimum 3-month) postoperative follow-up after TSA.[6] These findings suggest not only that patients had satisfactory patient-reported outcomes after use of the TM glenoid but also that these patient-reported results are enduring, as our outcomes were obtained at >6 years' follow-up.

With the data taken as a whole, our cohort is the largest reported cohort of second-generation TM glenoids at minimum 5-year follow-up. The patients maintained significant gains in ROM and demonstrated excellent PROM scores (mean ASES score, 92.0). The overall metal debris rate was 26%, significantly lower than the rate of 44% reported by Endrizzi et al.[9] The component fracturing and catastrophic failures associated with the first-generation implant were not seen on any follow-up radiographs of this cohort, and no patients required revision surgery. Clinical outcomes were not significantly different between patients with and patients without radiographic evidence of metal debris or radiolucency. Prior studies have shown that the presence of radiolucent lines does not directly correlate with poor outcomes,[19] as similarly found in this study. Also similarly to our findings, prior clinical studies of the second-generation TM glenoid found that the presence of metal debris did not correspond to poor patient outcomes.[9,16] Further studies are needed to elucidate the long-term sequelae of radiographic metal debris related to this implant. Our findings show that at a mean of 6.7 years' follow-up, although metal debris and radiolucent lines were present, patients with second-generation TM glenoids exhibited excellent clinical and patient-reported outcomes.

This study had certain limitations. First, this study was limited by loss to follow-up. A portion of patients who met the inclusion criteria were unable to participate in the study. This could in part be due to the more elderly patient population but also due to the longer-term minimum follow-up time that was desired. Multiple patients were deceased or medically unfit to participate in the study. Next, this study was limited by factors inherent to all retrospective studies, including the inability to control for baseline differences

between groups prior to group assignment. A matched, case-control design would have been desirable, but this was not feasible given our study numbers. However, patients in both groups were not significantly different in terms of age, sex distribution, length of follow-up, and preoperative Walch glenoid type distribution. All patients underwent similar operative procedures with the same humeral and glenoid implant, with the major difference being cement placement during glenoid fixation. The groups also differed in terms of subscapularis management, but prior prospective and retrospective studies have shown no significant differences in clinical outcomes between patients who underwent lesser tuberosity osteotomy and patients who underwent subscapularis peel.[7,11] Subscapularis management therefore likely did not significantly influence the study results. It is possible that other factors not captured in this study influenced the significant radiographic differences found between the groups, but given the similarity between the groups, we believe that our findings can be primarily attributed to the glenoid fixation technique. Furthermore, the patients in this study all underwent TSA for primary osteoarthritis and, therefore, the findings of this study may not be generalizable to patients undergoing surgery for other indications. Finally, although the follow-up length in this study was significantly greater than that in previous studies investigating the same implant, even longer follow-up periods are desirable to determine true implant safety and survivorship. We plan to continue following up our cohort of patients to further elucidate the long-term durability of the second-generation TM-backed glenoid component.

Conclusion

At minimum 5-year follow-up, patients who underwent TSA with second-generation TM glenoids demonstrated excellent clinical and patient-reported outcomes with a 100% implant survival rate, regardless of cemented vs. uncemented fixation. There was no evidence of glenoid loosening or component fracture. The uncemented group showed a higher rate of mild radiolucent lines (64%) and a higher frequency of mild metal debris than the cemented group. This did not affect the clinical outcomes, and the long-term implications of these findings are unknown.

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