



■ SHOULDER & ELBOW

Two-year results of a multi-centre, randomized controlled trial comparing a second-generation uncemented trabecular metal-backed versus cemented polyethylene glenoid component in total shoulder arthroplasty

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Aims

To report early (two-year) postoperative findings from a randomized controlled trial (RCT) investigating disease-specific quality of life (QOL), clinical, patient-reported, and radiological outcomes in patients undergoing a total shoulder arthroplasty (TSA) with a second-generation uncemented trabecular metal (TM) glenoid versus a cemented polyethylene glenoid (POLY) component.

Methods

Five fellowship-trained surgeons from three centres participated. Patients aged between 18 and 79 years with a primary diagnosis of glenohumeral osteoarthritis were screened for eligibility. Patients were randomized intraoperatively to either a TM or POLY glenoid component. Study intervals were: baseline, six weeks, six-, 12-, and 24 months postoperatively. The primary outcome was the Western Ontario Osteoarthritis Shoulder QOL score. Radiological images were reviewed for metal debris. Mixed effects repeated measures analysis of variance for within and between group comparisons were performed.

Results

A total of 93 patients were randomized (46 TM; 47 POLY). No significant or clinically important differences were found with patient-reported outcomes at 24-month follow-up. Regarding the glenoid components, there were no complications or revision surgeries in either group. Grade 1 metal debris was observed in three (6.5%) patients with TM glenoids at 24 months but outcomes were not negatively impacted.

Conclusion

Early results from this RCT showed no differences in disease-specific QOL, radiographs, complication rates, or shoulder function between uncemented second-generation TM and cemented POLY glenoids at 24 months postoperatively. Revision surgeries and reoperations were reported in both groups, but none attributed to glenoid implant failure. At 24 months postoperatively, Grade 1 metal debris was found in 6.5% of patients with a TM glenoid but did not negatively influence patient-reported outcomes. Longer-term follow-up is needed and is underway.

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Introduction

Total shoulder arthroplasty (TSA) is an effective surgical procedure to manage patients suffering from end-stage shoulder arthritis with an intact rotator cuff. Issues related to the glenoid implant, however, remain a common complication affecting both clinical and patient-based outcomes.^{1,2}

TSA is often deemed a success or failure based on revision surgery, but what happens if the patient's expectations are not met? Restoring a patient's quality of life (QOL) is an important treatment goal of TSA and warrants consideration.³ QOL is a multidimensional concept that considers various aspects of life such as physical, mental, emotional, and social functioning.⁴ Developed in 2001, the Western Ontario Osteoarthritis of the Shoulder (WOOS) score is a rigorously validated disease-specific QOL instrument. It was designed for patient evaluation but also for research, specifically, to serve as the primary outcome in clinical trials involving glenohumeral osteoarthritis (OA).^{5,6}

All-polyethylene glenoid implants have been used for decades in primary TSA. A porous tantalum biomaterial, trabecular metal (TM) component was developed to address problems seen with the cemented polyethylene implants, notably chronic loosening. The first-generation TM glenoid was recalled due to high failure rates,⁷ and a second-generation, constructed from the same materials (ultra-high-molecular-weight polyethylene (UHMWPE) and TM) was introduced but with two distinctly different design features. The UHMWPE portion was compression-moulded into a TM keel, with a cavity within each peg to expand the area of interdigitation creating a monoblock design, and an anterior and posterior peg were added increasing the number of pegs from three to five.⁸ The second-generation design is the subject of our study (Figure 1).

Published studies comparing all-polyethylene and TM glenoid components are retrospective in design; some involve the first-generation TM implant, and although most report joint-specific or general health outcomes, none report disease-specific QOL using the WOOS questionnaire.⁸⁻¹⁴ The authors designed a randomized controlled trial to compare patient-reported outcomes including the WOOS, as well as clinical and radiological outcomes in patients undergoing a TSA with a second-generation uncemented TM glenoid versus a cemented polyethylene (POLY) glenoid at five years postoperatively. The purpose of the current paper is to report early (two-year) findings from this trial with a null hypothesis that there will be no statistical difference in disease-specific QOL WOOS scores between groups at two years postoperative.

Methods

Approval to conduct this randomized controlled trial was granted by the University of British Columbia Clinical Research Ethics Board and the study was registered with clinicaltrials.gov (Identifier: NCT01539122). Five fellowship-trained surgeons (PYKC, WDR, DP, ZDZ,



Fig. 1

The second-generation Trabecular Metal glenoid.

and FL) from three centres participated. Patients were screened for eligibility and had surgery between June 2012 and December 2016 (Table I). Final eligibility was determined intraoperatively prior to randomization.

Surgical procedures. Patients were positioned in a beach chair position and received a general anaesthetic with or without a brachial plexus regional block. A deltopectoral approach was used, and biceps tenodesis performed. The subscapularis tendon was treated according to surgeon preference (tenotomized or peel off the lesser tuberosity). Osteophytes were removed and the humeral head osteotomized. The humeral canal was progressively reamed, and the trial-broaching stem left in situ to protect the proximal humerus during glenoid exposure. Once complete glenoid exposure was achieved, the glenoid bone stock was assessed for eligibility in the study. If adequate bone stock was identified (adequate defined as a contained defect suitable for an anatomical keeled implant), patients were randomized to either an uncemented second-generation TM glenoid (Zimmer Biomet, USA) or a cemented all-polyethylene glenoid (Zimmer Biomet). Randomization was performed using a data centre (EmPOWER Health Research, Canada) and stratified by surgeon. All patients received an uncemented Bigliani-Flatow humeral prosthesis (Zimmer Biomet). Placement of the glenoid component was carried out and no cement was used for the TM glenoid. The subscapularis was repaired and the incision closed.

Postoperatively, patients in both groups were admitted to hospital overnight and discharged the next day with routine postoperative instructions and rehabilitation protocols. Follow-up intervals were: six weeks, six-, 12-, and 24 months postoperatively. Patients were blinded to their treatment assignment.

Outcomes. The primary outcome was the Western Ontario Osteoarthritis of the Shoulder (WOOS) Index score. The WOOS is a patient-reported, disease-specific instrument measuring quality of life.⁶ An overall score

Table I. Study inclusion and exclusion criteria.

Inclusion
Aged between 19 and 79 yrs
Diagnosis of primary glenohumeral osteoarthritis
Exclusion
Significant glenoid bone loss on a preoperative CT scan or intraoperatively*
Major joint trauma
Avascular necrosis
Rotator cuff or inflammatory arthropathy
Chronic dislocations
Massive cuff tear
Previous shoulder surgery (other than arthroscopic debridement or acromioplasty)
Active joint or systemic infection, muscle paralysis
Charcot arthropathy
Life expectancy < 2 yrs
Unable to read or speak English

*Final assessment made intraoperatively prior to randomization.

from 0 to 100 is obtained where 0 represents a major dysfunction in shoulder-related quality of life and 100 represents the best possible score.

Secondary patient-reported outcome measures (PROMs) including the American Shoulder and Elbow Surgeons (ASES) score,¹⁵ the 12-Item Short Form Health Survey Questionnaire (SF-12),¹⁶ and the EuroQol-five dimensions (EQ-5D).¹⁷ The ASES is a shoulder-specific functional assessment tool and is scored out of 100 points, where 100 signifies maximum function and no pain. The SF-12 is patient-reported measure of global health status. Two summary scales can be derived. The Mental Component Summary (MCS) is based on questions related to vitality, social functioning, emotional, and mental health items while the Physical Component Summary (PCS) is based on physical functioning, bodily pain, physical, and general health items.¹⁸ The EQ-5D is a patient-reported, standardized measure of health-related quality of life.

Clinical assessment. Clinical examination included active range of motion (ROM), shoulder strength, and stability. A goniometer was used for ROM measurements. Complications, revisions, and reoperations were also documented. Revision surgery was defined as partial or complete arthroplasty of an original prosthesis due to component failure or infection, and reoperation was defined as surgery to address a soft-tissue problem.¹⁹

Radiological evaluation. Plain radiological images included anteroposterior (AP), axillary, and lateral views, and were evaluated by the treating surgeon for radiolucency, as well as implant subsidence, position, and migration. Radiolucent lines (RLLs) around the glenoid implant and humeral stem were categorized as present/absent and severity reported in millimetres. Metal debris was assessed by one surgeon, the principal investigator (PYKC), according to Endrizzi et al⁹ (Table II). Glenoid morphology

Table II. Endrizzi et al⁹ metal debris classification system.

Grade 0	No evidence of metallic debris
Grade 1	Debris at the bone-metal interface
Grade 2	Intra-articular soft tissue metallic debris
Grade 3	Visible, but incomplete fracture of the metal component
Grade 4	Component breakage and displacement

was classified according to Walch on preoperative CT images.²⁰

Sample size calculation. Sample size was based on the following parameters: the primary outcome (WOOS), a two-sided test, significance level of 0.05, and power of 0.8. The final endpoint was 24 months postoperatively. Estimates for the WOOS mean, standard deviation (SD), and a minimally clinical importance difference of 15% were based on a similar population of patients published by JOINTS Canada.²¹ These parameters resulted in the need for 34 patients per treatment group. An additional 18 patients per group were recruited to account for pre- and post-randomization attrition resulting in 104 patients in total.

Statistical analysis. Continuous variables were described via means and SDs, and quantiles, while categorical variables were described per frequency tables. Descriptive statistics were generated overall as well as stratified by group and study interval. Comparisons of primary and secondary outcome variables, within and between groups, were made via mixed effects repeated measures analysis of variance (ANOVA). Standardized residuals demonstrated normality per normal quantile-quantile (Q-Q) plots. All analyses were performed using SAS v9.4 (SAS Institute, USA). A p-value < 0.05 was considered statistically significant.

Results

A total of 93 patients were randomized intraoperatively to either a TM (46) or POLY (47) glenoid component. Patient flow through the study is presented in Figure 2. Patient demographic details, previous surgery, and glenoid morphology were similar between groups. (Table III)

Clinically significant improvements from baseline to 24 months postoperatively were seen in both groups across all patient-reported outcomes (Table IV). No statistically significant differences in WOOS scores were observed between groups at 24 months, however a statistical difference was detected at six months postoperatively in favour of the TM group (TM = 90.8 vs POLY = 84.9; $p = 0.030$, mixed effects repeated measures ANOVA). Interestingly, findings with SF-12 Mental scores were similar to the WOOS. A significant difference was found at six months postoperatively favouring the TM group (TM = 59.0 vs POLY = 55.3; $p = 0.013$, mixed effects repeated measures ANOVA), however no other

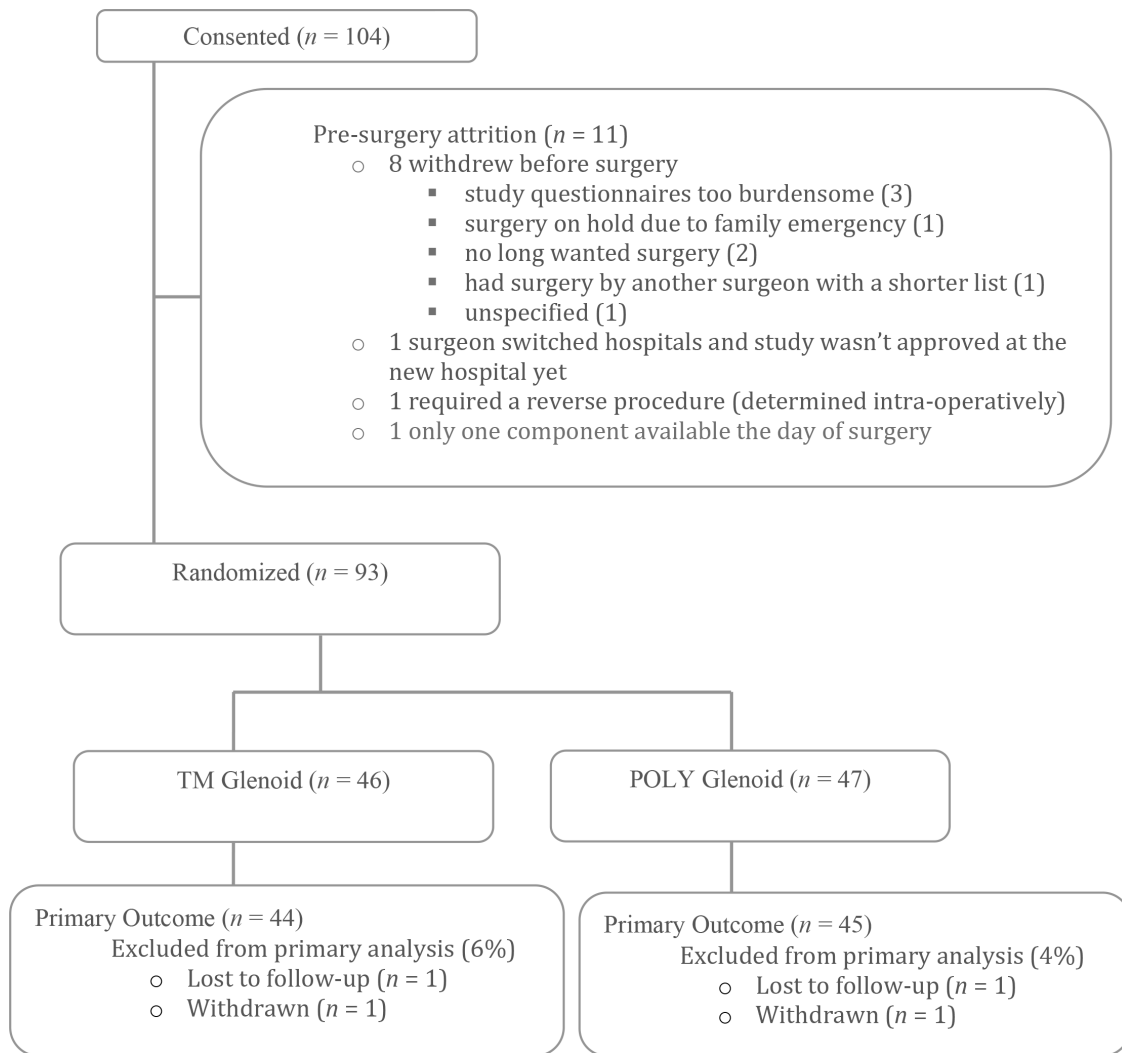


Fig. 2

CONSORT flow diagram.

differences were detected. With respect to the ASES, SF-12 Physical, and EQ-5D index and VAS, no statistical or clinically important differences were detected between groups during the 24-month follow-up period.

Active forward elevation and external rotation improved in both groups from baseline and there were no clinically significant differences between groups at any postoperative interval (Table V).

Table VI presents strength at baseline and 24 months postoperatively. The greatest difference between groups was seen with external rotation at 24 months, where 57% of TM patients versus 67% of POLY patients achieved full strength. Six complications (12.8%) occurred in the POLY group and five (10.9%) in the TM group (Table VII). No glenoid implant failures or revisions were observed in either group.

Grade 1 metal debris was detected in three patients (6.5%) at 24 months. There was no evidence of debris in these patients prior to the 24-month interval and their

mean WOOS scores were not negatively impacted (mean 24-month WOOS score = 89.7 (standard deviation (SD) 11)).

There was no radiological evidence of glenoid component migration in either group. At 12 months postoperatively, one patient in the POLY group had superior migration of the humeral implant in keeping with a rotator cuff tear. RLL around the glenoid implant were observed in eight patients (17%) in the POLY group but the severity was minor in most patients (6 = 1 mm; 1 = 2 mm; 1 = 6 mm). In the TM group, 'possible' lucency around the glenoid was reported in one patient.

With respect to the humeral stem, subsidence was observed in four (8.5%) patients in the POLY group and seven (15.2%) in the TM group and RLLs were observed in three (6.4%) and five (10.9%) patients in the POLY and TM groups, respectively.

Table III. Patient demographic details.

Characteristic	TM (46)	POLY (47)
Sex, n (%)		
Male	24 (52)	23 (49)
Female	22 (48)	24 (51)
Mean age, yrs (SD)	66.5 (6.4)	68.4 (5.5)
Mean BMI, kg/m ² (SD)	28.8 (5.8)	28.3 (5.3)
Mean duration of symptoms, mths (SD)	57.8 (49.5)	63.6 (57.7)
Dominant arm, n (%)		
Left	6 (13)	5 (11)
Right	38 (83)	41 (87)
Ambidextrous	1 (2)	1 (2)
Not reported	1 (2)	0 (0)
Operative limb, n (%)		
Right	21 (46)	27 (57)
Left	25 (54)	20 (43)
Smoking status, n (%)		
No	44 (96)	46 (98)
Yes	2 (4)	1 (2)
Alcohol status, n (%)		
No	22 (48)	18 (38)
Yes	24 (52)	28 (60)
Not reported	0	1
Previous surgery on study shoulder, n (%)		
No	45 (98)	45 (96)
Yes	1 (2)	2 (4)
Previous surgery type, n		
Tendon shortening	1	N/A
Subacromial decompression	N/A	1
Debridement	N/A	1
Walch classification of glenoid morphology, n (%)		
A1	8 (17)	9 (19)
A2	6 (13)	5 (10.5)
B1	4 (9)	5 (10.5)
B2	27 (59)	28 (60)
Not reported	1	0

Demographics of those eligible but not randomized (n = 11): mean age 65.5 yrs (SD 8.3); male/female: 7/4; mean BMI 32.3 kg/m² (SD 6.7). N/A, not applicable; SD, standard deviation.

Discussion

Early postoperative findings from this randomized trial comparing an uncemented second-generation TM versus cemented POLY glenoid showed no clinically relevant differences with respect to disease-specific QOL, pain, or shoulder function at two years postoperatively. No revisions or reoperations were attributed to the glenoid in either group during the 24-month study period, and complication rates were similar between groups. Metal debris was identified in 6.5% of patients (n = 3) with a TM glenoid however the severity of debris was of the lowest grade (Grade 1) and did not negatively influence QOL or shoulder function.

Table IV. Patient-reported outcome measures for each group over time.

Mean outcome (SD)	TM	POLY	Adjusted MD (95% CI)	p-value*
WOOS				
Preop	32.1 (21)	26.6 (15)	5.5 (-1.9 to 13.0)	0.143
6 wks	60.3 (21)	59.1 (17)	1.2 (-6.7 to -9.1)	0.763
6 mths	90.8 (10)	84.9 (14)	5.9 (0.6 to 10.8)	0.030
12 mths	90.4 (16)	91.3 (14)	-0.9 (-6.6 to 5.5)	0.848
24 mths	91.9 (13)	93.1 (11)	-1.2 (-6.1 to 3.8)	0.641
ASES Patient Portion				
Preop	35.8 (16)	37.1 (14)	-1.3 (-8.7 to 6.0)	0.716
6 wks	61.4 (19)	64.1 (15)	-2.7 (-9.9 to 4.3)	0.437
6 mths	86.2 (16)	81.9 (14)	4.3 (-2.2 to 10.8)	0.187
12 mths	88.7 (14)	89.0 (11)	-0.3 (-5.1 to 5.3)	0.971
24 mths	88.8 (15)	89.1 (13)	-0.3 (-6.0 to 5.7)	0.961
SF-12 Physical				
Preop	35.8 (8)	36.5 (7)	0.7 (-4.3 to -2.3)	0.551
6 wks	39.9 (9)	38.5 (7)	1.4 (-2.0 to 4.5)	0.461
6 mths	48.5 (9)	46.8 (9)	1.7 (-2.9 to 4.6)	0.659
12 mths	47.0 (11)	49.1 (8)	-2.1 (-5.7 to 2.4)	0.415
24 mths	47.8 (11)	47.8 (8)	0.0 (-3.6 to 4.4)	0.840
SF-12 Mental				
Preop	54.1 (10)	52.9 (10)	1.2 (-2.9 to 5.5)	0.549
6 wks	56.6 (9)	55.7 (8)	0.9 (-2.8 to 4.2)	0.701
6 mths	59.0 (5)	55.2 (8)	3.8 (0.8 to 6.6)	0.013
12 mths	56.5 (6)	55.7 (8)	0.8 (-1.9 to 3.9)	0.505
24 mths	56.5 (7)	56.2 (6)	0.3 (-2.0 to 3.2)	0.656
EQ-5D Index Scale				
Preop	0.62 (0.2)	0.64 (0.2)	-0.02 (-0.10 to 0.06)	0.615
6 wks	0.79 (0.1)	0.80 (0.1)	-0.01 (-0.06 to -0.03)	0.587
6 mths	0.90 (0.1)	0.86 (0.1)	0.04 (-0.07 to -0.08)	0.100
12 mths	0.89 (0.1)	0.88 (0.1)	0.02 (-0.03 to -0.07)	0.475
24 mths	0.88 (0.1)	0.89 (0.1)	-0.01 (-0.06 to -0.05)	0.778
EQ-5D VAS Slider				
Preop	72.0 (17.4)	72.3 (15.9)	-0.3 (-7.0 to 6.5)	0.944
6 wks	72.4 (23.8)	78.9 (15.0)	-6.5 (-14.6 to 1.8)	0.127
6 mths	83.7 (15.9)	83.6 (13.4)	0.1 (-6.4 to 5.8)	0.923
12 mths	78.5 (16.8)	81.9 (18.1)	-3.4 (-10.0 to 4.6)	0.458
24 mths	80.0 (15.3)	83.0 (9.9)	-3.0 (-7.6 to 3.2)	0.421

*Mixed effects repeated measures analysis of variance.

ASES, American Shoulder and Elbow Surgeons score; CI, confidence interval; EQ-5D, EuroQol five-dimension questionnaire; MD, mean between-groups difference; POLY, polyethylene component; SD, standard deviation; SF-12, 12-Item Short Form Health Survey; TM, trabecular metal; VAS, visual analogue scale; WOOS, Western Ontario Osteoarthritis of the Shoulder score.

While data from retrospective studies and case series are valuable and necessary, randomized trials provide more powerful data and are needed to determine efficacy of a new technique or implant. Results from our randomized trial support the findings from seven retrospective case-series involving the second-generation TM glenoid. These studies had longer follow-up periods, ranging from 38 to 80 months, but their conclusions were consistent with our trial: there were no catastrophic implant failures with the second-generation TM implants, and

Table V. Active range of motion for operative and nonoperative arm by group over time.

Timepoint	Mean TM ROM, ° (SD)		Mean POLY ROM, ° (SD)	
	Operative	Non-op	Operative	Non-op
Forward elevation				
Preop	103 (25)	144 (20)	103 (29)	146 (25)
6 wks	90 (21)	145 (26)	98 (25)	143 (27)
6 mths	132 (16)	145 (22)	129 (19)	146 (20)
12 mths	138 (16)	144 (26)	138 (16)	145 (17)
24 mths	136 (21)	141 (28)	142 (17)	147 (20)
External rotation (at side)				
Preop	14 (18)	47 (22)	19 (22)	47 (23)
6 wks	26 (16)	47 (21)	23 (17)	46 (24)
6 mths	45 (19)	50 (22)	47 (26)	51 (27)
12 mths	49 (18)	57 (32)	46 (20)	49 (19)
24 mths	52 (19)	47 (22)	50 (19)	53 (29)
External rotation (abduction)				
Preop	17 (30)	56 (28)	19 (30)	52 (28)
6 wks	19 (25)	58 (27)	18 (23)	52 (32)
6 mths	50 (24)	60 (26)	47 (24)	55 (28)
12 mths	53 (25)	56 (30)	54 (21)	62 (23)
24 mths	58 (25)	56 (30)	60 (21)	62 (24)

POLY, polyethylene component; ROM, range of motion; SD, standard deviation; TM, trabecular metal.

good patient outcomes were reported with respect to pain, satisfaction, and function.⁸⁻¹⁴ The patient-reported outcomes documented in these studies were either joint-specific or general health measures and are valuable for broad comparisons. However, none reported the disease-specific QOL WOOS, which has been referenced by some as the best instrument for assessing shoulder arthroplasty.²²

Our trial is the first to compare a second-generation TM versus POLY glenoid using WOOS data and demonstrates that disease-specific QOL significantly improves with both implants after TSA, and that no differences between implants were detected at two years postoperatively. At six months postoperatively, a statistical difference in the WOOS and SF-12 Mental scores favoured the TM group. The clinical relevance of 5.9 points on the WOOS and 3.8 on the SF-12 Mental Score is unclear, particularly when all other clinical and functional outcomes were comparable between groups at all other timepoints.

It is well documented that TSA survivorship declines over time. The Australian Orthopaedic Association National Joint Arthroplasty Registry (AOANJRR) 2019 Annual Report documented TSA revision rates (all prostheses) of: 2.9% (two yrs), 7.8% (five yrs), 12.4% (ten yrs), and 14.9% (12 yrs).²³ These rates are similar to an American prospective cohort, involving 2,588 TSAs performed between 1976 to 2008, that showed revision rates of 5.8%, 9.8%, and 18.6% at five, ten, and 20 years, respectively.²⁴ Another large American-based cohort study involving 5,566 patients and over 30 glenoid

Table VI. Strength (Grade 1 to 5) by group at baseline and 24 months postoperatively.

Variable	TM, n (%)		POLY, n (%)	
	Baseline	24 mths	Baseline	24 mths
Forward elevation				
1	0	1 (2)	0	0
2	3 (7)	0	1 (2)	0
3	6 (13)	0	10 (21)	0
4	25 (54)	10 (22)	21 (45)	13 (28)
5	9 (17)	31 (67)	11 (23)	31 (66)
Not reported	4 (9)	4 (9)	4 (9)	3 (6)
Abduction				
1	0	1 (2)	0	0
2	4 (9)	0	1 (2)	0
3	8 (17)	0	14 (30)	1 (2)
4	21 (46)	14 (30)	19 (40)	12 (26)
5	9 (20)	27 (60)	9 (19)	31 (66)
Not reported	4 (9)	4 (9)	4 (9)	3 (6)
External rotation				
1	0	1 (2)	0	0
2	5 (10)	0	2 (4)	0
3	6 (13)	1 (2)	11 (23)	0
4	23 (50)	14 (30)	25 (55)	13 (28)
5	8 (17)	26 (57)	4 (9)	31 (67)
Not reported	4 (8)	4 (9)	4 (9)	3 (6)
Internal rotation				
1	0	1 (2)	0	0
2	2 (4)	0	3 (7)	0
3	7 (15)	0	11 (23)	0
4	20 (44)	9 (20)	18 (38)	12 (26)
5	13 (28)	32 (70)	11 (23)	32 (68)
Not reported	4 (9)	4 (9)	4 (9)	3 (6)
Pain with testing?				
No	3 (7)	37 (80)	7 (15)	39 (83)
Yes	39 (85)	5 (11)	36 (77)	5 (11)
Not reported	4 (9)	4 (9)	4 (9)	3 (6)

Not reported - missing or patient couldn't perform.

POLY, polyethylene component; TM, trabecular metal.

designs offers evidence that implant design is associated with differential risks of revision.²⁵ Systematic review and registry data have shown higher failure rates with metal-backed glenoids versus all-polyethylene implants, and that uncemented glenoids are five times more likely to require revision than cemented.^{23,26,27} The importance of exercising caution when interpreting and comparing these cohort studies and registry data cannot be overstated. Many of the datasets include first-generation non-porous metal-backed components. Further, they include a diverse range of patient characteristics, implantation techniques, and follow-up periods. A recent systematic review highlights these factors by reporting no difference in failure rates between cemented polyethylene glenoids and 'modern' metal-backed glenoids in the mid-term follow-up period (< 36 months), however in the longer term (> 72 months) the modern metal-backed glenoids had lower rates of failure, RRLs, and loosening.²⁸

Table VII. Complications and, when relevant, modes of failure for each group.

Group	Age, yrs	Time of AE, mths	Complication type (traumatic or atraumatic; humeral or glenoid implant)	Treatment and outcome	WOOS score at AE	WOOS score at 24 mths	Metal debris
TM	64	0 Intraop	Periprosthetic fracture; atraumatic; humeral stem	Nonoperative; fracture healed	24.2	100	None
TM	62	6	Periprosthetic fracture and instability; traumatic (patient fell); posterior subluxation and humeral fracture	Reoperation; ORIF and inferior capsule shift	71.9	76.0	None
TM	67	21	Loosening - aseptic; atraumatic; humeral stem	Revision to cemented humeral stem (glenoid: no change)	56.8	56.8	None
TM	71	22	Instability; atraumatic (posterior dislocation while patient was stretching); humeral	Nonoperative; reduced; no further treatment	91.2	91.2	None
TM	67	24	Loosening - aseptic; atraumatic; humeral stem	Revision to cemented humeral stem (glenoid: no change)	50.0	50.0	None
POLY	75	0 Intraop	Periprosthetic fracture; atraumatic; glenoid	Nonoperative	55.5	100	N/A
POLY	61	2	Subscapularis and supraspinatous tear; traumatic (patient fell)	Revision; rotator cuff repair and downsizing of humeral head	55.6	96.8	N/A
POLY	78	3	Periprosthetic fracture; atraumatic (patient was doing exercises and felt a pop); greater tubercle fracture	Nonoperative	6.8	91.6	N/A
POLY	67	3	Subscapularis and supraspinatous tear; atraumatic	Reoperation; conversion to rTSA.	53.1	97.7	N/A
POLY	67	5	Periprosthetic fracture; traumatic (accident); humeral stem only	Nonoperative	49.3	94.7	N/A
POLY	59	5	Subscapularis failure; traumatic	Reoperation; major shoulder contracture release + subscapularis repair	16.5	42.8	N/A

AE, adverse event; N/A, not applicable; ORIF, open reduction and internal fixation; POLY, polyethylene component; rTSA, reverse total shoulder arthroplasty; TM, trabecular metal; WOOS, Western Ontario Osteoarthritis Shoulder.

The issue of periprosthetic metal debris is a growing concern with TM components. Metal debris preceded implant failure with some first-generation TM and metal-backed designs, and warrants monitoring.^{9,19} Our study found a lower rate of debris (6.5%) and severity (Grade 1) when compared to the literature, and might be attributed to our shorter follow-up period. Chen et al¹⁰ identified debris in 24% of patients in their series at a mean 80 months with four patients categorized as Grade 1 and one patient as Grade 2. A subsequent retrospective study by the same author explored differences in metal debris between cemented and uncemented second-generation TM glenoids.¹¹ Although there was no difference in debris rate between groups, the cemented glenoids had more severe debris (Grade 2 and 4) than uncemented (Grade 1 to 2). Our early findings are similar to those seen in Chen et al's¹¹ uncemented cohort. Endrizzi et al⁹ observed Grade 1 to 3 metal debris in 44% of patients at five years postoperatively. The incidence and severity of debris increased over time, and there was no relationship between the presence of debris and outcomes, radiolucency, glenoid size, or preoperative Walch classification.

Watson et al¹³ reported 11% of patients with metal debris at 34 months' follow-up, however the authors did not use the Endrizzi grading system to categorize debris severity. The correlation between higher rates of debris and longer-term follow-up is further supported by an unpublished retrospective series that documented 18 of 40 (45%) of patients with metal debris at 65 months' follow-up (Grade 1 = 15, Grade 2 = 3).²⁹ Metal debris was not correlated with worse outcomes in all studies mentioned above, and this is consistent with our trial. A correlation between metal debris and implant failure may exist, but requires longer-term follow-up.

The presence or progression of RLL at the implant-bone interface following TSA can denote component loosening. RLLs were not appreciated with the uncemented TM implant in our trial, which was in direct contrast with the 17% RLL seen in our cemented POLY group, and also with Chen et al,¹¹ who reported statistically greater RLLs with uncemented versus cemented TM glenoids (64% and 29%, respectively). Endrizzi et al⁹ also reported RLL with cemented TM implants at a rate of 36%. These differences may be attributed to a

variety of factors such as glenoid wear, implantation technique, or follow-up duration.

Revising TM components can be difficult and deserves consideration. Despite the many benefits of biological fixation, it can make prosthesis removal extremely difficult resulting in significant bone loss.^{13,30} Additionally, one cannot leave the metal tray in place and only replace the polyethylene implant due to the TM monoblock design.^{30–32}

Limitations of this study include the short-term follow-up period, variability with multiple surgeons performing the surgeries, and only one surgeon performing the metal debris evaluations. Future studies should consider reliability of metal debris assessment. Longer-term follow-up is needed to understand implant survivorship and whether RLL or metal debris rates increase over time.

In conclusion, early results from this randomized controlled trial comparing an uncemented TM versus cemented POLY glenoid showed no differences with respect to disease-specific QOL, radiological outcomes, complication rates, or shoulder function between groups. Revision surgeries and reoperations were reported in both groups, but none attributed to glenoid implant failure. Grade 1 metal debris was found in 6.5% of patients with a TM glenoid but did not negatively influence QOL. Longer-term follow-up is needed and is currently underway.



Take home message

- Level 1 evidence to guide total shoulder arthroplasty glenoid implant selection.
- Early findings suggest no major concerns with the second-generation trabecular metal glenoid.
- Disease-specific quality of life data using a validated instrument (Western Ontario Osteoarthritis of the Shoulder Index).

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