■ SHOULDER AND ELBOW

Total shoulder arthroplasty with a second-generation tantalum trabecular metal-backed glenoid component

CLINICAL AND RADIOGRAPHIC OUTCOMES AT A MEAN FOLLOW-UP OF 38 MONTHS

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Aims

We evaluated clinical and radiographic outcomes of total shoulder arthroplasty (TSA) using the second-generation Trabecular Metal (TM) Glenoid component. The first generation component was withdrawn in 2005 after a series of failures were reported. Between 2009 and 2012, 40 consecutive patients with unilateral TSA using the second-generation component were enrolled in this clinical study. The mean age of the patients was 63.8 years (40 to 75) and the mean follow-up was 38 months (24 to 42).

Methods

Patients were evaluated using the Constant score (CS), the American Shoulder and Elbow Surgeons (ASES) score and routine radiographs.

Results

Significant differences were found between the pre- and post-operative CS ($p = 0.003$), ASES ($p = 0.009$) scores and CS subscores of pain ($p < 0.001$), strength ($p < 0.001$) and mobility items ($p < 0.05$). No glenoid or humeral components migrated. Posterior thinning of the keel and slight wear at the polyethylene-TM interface was observed in one patient but was asymptomatic. Radiolucent lines were found around three humeral (< 1.5 mm) and two glenoid components (< 1 mm) and all were asymptomatic.

Discussion

TSA with the second-generation TM Glenoid component results in satisfactory to excellent clinical performance, function, and subjective satisfaction at a mean follow-up of about three years. Radiographic changes were few and did not affect the outcome.

Take home message: This paper highlights that the second generation Trabecular Metal Glenoid has better outcomes than those reported with the first-generation component.

Cite this article: *Bone Joint J* 2016;98-B:75–80.

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doi:10.1302/0301-620X.98B1.36620 $2.00

Bone Joint J 2016;98-B:75–80.
Received 1 June 2015; Accepted after revision 14 August 2015

Since the introduction of total shoulder arthroplasty (TSA) by Neer in 1974,[1] several designs of glenoid component have been used with varying results.[2] Despite advances in implant technology and surgical techniques, the optimal management of the glenoid remains controversial. Failure of the glenoid component is recognised as the weak link in TSA with loosening being the most frequent long-term complication.[2] High rates of loosening have prompted alterations in the design of the glenoid component[3,4] and the exploration of new materials to improve its fixation to bone.[5-7]

A new porous tantalum biomaterial, Trabecular Metal (TM) (Zimmer, Warsaw, Indiana), allows osteogenesis to occur in a porous scaffold.[8,9] This replicates the porosity, strength, and flexibility of trabecular bone.[6,9,5] The first-generation TM Glenoid component (Zimmer) was introduced in 2003 as a press-fit, uncemented metal-backed polyethylene component but was withdrawn in 2005 after failures were reported.[10] The design was later changed and re-introduced in 2009. To our knowledge, the clinical effectiveness of the second-generation TM Glenoid has not been reported.

The purpose of this study was to evaluate retrospectively early clinical and radiographic outcomes of TSA with the second-generation TM Glenoid component in a series of patients

Table I. Patient characteristics of 40 patients receiving the second generation (Gen II) Trabecular Metal glenoid component assessed in the current study (Zimmer, Warsaw, Indiana)

Variable	Data
Number of patients (and shoulders)	40
Mean age (yrs) (SD: range)	63.8 (7.3: 40 to 75)
Gender (male/female) (%)	24/16 *(60/40)*
Dominant shoulder (n; %)	37 *(92)*
Mean BMI (kg/m^2) (SD)	26.5 (3.4)
Osteoarthritis grade (n) (%)	
Mild	0 *(0)*
Moderate	5 *(13)*
Severe	35 *(87)*
Mean follow-up (mths) (SD: range)	38 (2.9: 24 to 42)

Osteoarthritis was graded as mild, moderate and severe according to Samilson-Prieto criteria[11]
SD, standard deviation; BMI, body mass index

Fig. 1

Photographs of the second generation trabecular tantalum metal glenoid component (Zimmer, Warsaw, Indiana).

with primary osteoarthritis (OA) of the shoulder at a minimum of two years post-operatively.

Patients and Methods

This was a multicentre study involving two institutions (Unit of Shoulder and Elbow Surgery, D. Cervesi Hospital, Cattolica, Italy and University of British Columbia, Vancouver, Canada). Ethical approval was obtained from independent review boards at each site (Prot. N°. 3980/2012 I.5/126 CEAV/IRST Meldola, Italy and Prot. N°. H12-03219 University of British Columbia Clinical Research Ethics Board). A total of 47 consecutive patients (47 shoulders), who received a TSA with a TM Glenoid component between May 2009 and July 2012, were screened for eligibility. Patients were included if they were aged > 18 years, had a pre-operative diagnosis of OA and had a minimum follow-up of 24 months. There were no specific exclusion criteria. A total of six patients declined to be studied and one had incomplete clinical and radiographic data, leaving 40 patients (40 shoulders) with a mean age of 63.8 years (40 to 75) in the study. The demographic data of the patients are shown in Table I.

The patients had a standardised assessment including anteroposterior (AP) and axillary radiographs, a series of questionnaires and a physical examination. OA of the shoulder was classified as mild, moderate or severe according to the Samilson-Prieto criteria[11] and the morphology of the glenoid was evaluated on axial CT scans using the criteria described by Walch et al;[12] (A1: symmetric minor erosion; A2: major symmetric erosion; B1: posterior erosion and humeral head subluxation; B2: biconcave glenoid; C: dysplastic glenoid, retroversion > 25°). Demographic, baseline, and peri-operative data were obtained from the medical records.

The first- and second-generation TM Glenoid components have a tantalum TM backing with an articular surface manufactured from ultra-high molecular weight polyethylene (UHMWPE) (Fig. 1). The first generation was a monoblock design with a porous tantalum keel and three posts. The second generation had two additional posts (anterior and posterior) with polyethylene cones in all five posts (Fig. 2). The second-generation design has a cruciform keel with the UHMWPE compression moulded onto the tantalum keel itself. The keeled base of the component was designed to be press-fitted in the glenoid to improve bone in-growth.[13] In the United States, the TM Glenoid must use cement fixation. However, in other countries including the sites in this study, it can be implanted without cement. The component offers a radial mismatch (i.e. the difference between the radius of curvature of the glenoid and of the humeral head, ranging from 0 mm to 4 mm). The articulating surface is the same as the first-generation TM Glenoid and the standard all polyethylene pegged or keeled glenoid component (used with a standard humeral component) from the Bigliani-Flatow Total Shoulder System (Zimmer).

Active range of movement (ROM) was measured with a goniometer with the patient standing by two raters (GM and PC). Strength in abduction was recorded using a mechanical dynamometer and expressed in pounds (lbs). The Constant score (CS)[14] and American Shoulder and Elbow surgeons (ASES)[15] score were used to assess function and the EuroQoL (EQ-5D) visual analogue scale (VAS) was scored on a 0 to 100 metric scale and administered for assessment of quality of life and general health profile together with the derived index value of the EQ-5D which is composed of five different questions.[16]

Standard AP and axillary radiographs were taken at follow-up visits to assess the glenoid and humeral components for wear and loosening using standardised criteria adapted to TM prostheses.[17,18] Radiolucency was assessed in five zones for the glenoid component and in eight zones for the humeral component according to the Sperling Classification system[17] (Fig. 3). Both components were also assessed for acromio-humeral distance, subsidence, tilt, polyethylene wear, migration, fractures and stability (Fig. 4). Osteophytes were identified and heterotopic ossification (HO) classified from grade 1 to 4.[19]

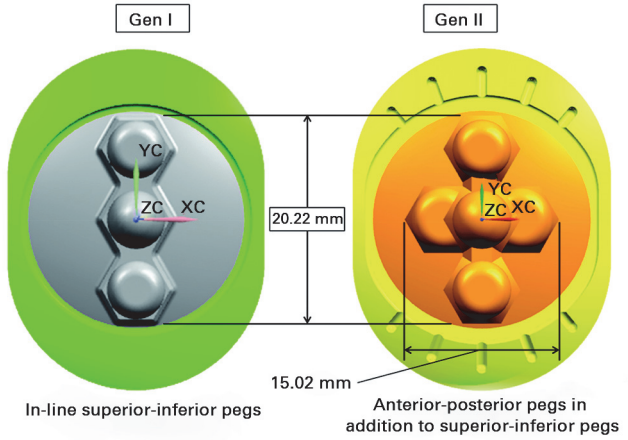

Fig. 2

Drawings representing the posterior view of the first (Gen I) and second generation (Gen II) of trabecular tantalum metal Glenoid. The original design with the In-line superior-inferior pegs was changed by adding two pegs (anterior and posterior). The line ZC-YC represents the in-line superior-inferior pegs of the first and second generation glenoids. The line ZC-XC represents the in-line anterior-posterior pegs of the second generation glenoids.

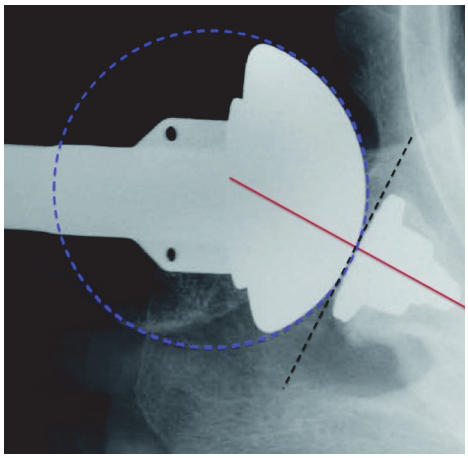

Fig. 4

Axillary view radiograph used to assess the stability of the humeral component in the axial plane according to the criteria of Sperling et al.[22] The humeral head is centred in the glenoid with an optimal relationship with the tuberosities. The dotted circle shows the restored humeral head morphology. The dotted lines describe the position of the TM glenoid related to the humeral component.

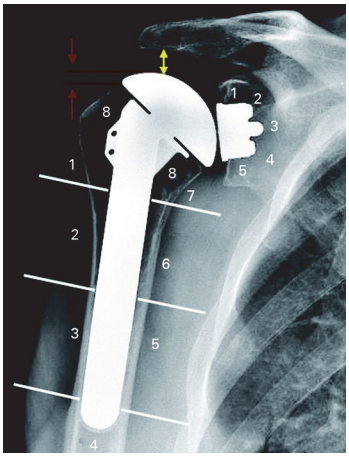

Fig. 3

Anterioposterior (AP) Grashey view radiograph ("true" AP) of a right total shoulder arthroplasty with a Trabecular Metal Glenoid component. The numbers represent the zones where the radiolucency was assessed around the humeral and glenoid component. Red arrows indicate the height of the humeral head (normal about 5 mm) used to assess subsidence; yellow double arrow shows the acromio-humeral interval, used to assess the integrity of the rotator cuff.

Operative technique. The shoulder was exposed using a standard deltopectoral approach with osteotomy of the lesser tuberosity (27 patients, 27 shoulders) or subscapularis tenotomy (13 patients, 13 shoulders). Osteotomy of the humeral head was carried out at 30° of retroversion and the glenoid was exposed. A circumferential capsular release and total excision of the labrum was performed. The orientation of the glenoid was defined and the centre peg hole drilled for centreing the reamer. Reaming was performed down to subchondral bone for an effective bone-prosthesis bond. Reaming was a crucial step to correct the orientation of the glenoid, being careful not to remove an excessive amount of subchondral bone. A cannulated drill was used to create a pilot hole for the drill guide. Superior and inferior holes were then created followed by the anterior and posterior holes. A slotted opening for the TM was created with a chisel to join the four holes, followed by insertion of a trial glenoid component to confirm that its seating was flush against the prepared surface. The definitive component was impacted to achieve a press-fit fixation. Cement was not used.

The humeral component was introduced after selecting the appropriate size. A press-fit stem was used in 38 patients (38 shoulders) and cement fixation in two (two shoulders). An offset humeral head was selected matching the articular surface of the glenoid to obtain a stable reconstruction. The subscapularis was re-attached with bone sutures if an osteotomy having been undertaken and by end-to-end tendon repair if tenotomy alone had been performed. The wound was closed and the arm was immobilised in a sling for four to six weeks. Passive mobilisation in the scapular plane was allowed from the first postoperative day. Active assisted exercises, including internal and external rotation of the shoulder were initiated at four to six weeks and strengthening exercises were allowed at eight weeks.

Statistical analysis. Summary statistics including numbers, percentages, means and standard deviations (SDs) were used to describe the data. Differences between the continuous variables of the measurements pre-operatively and at the last available follow-up were assessed using the Mann–Whitney U test. Statistical significance was set at a p-value of < 0.05. No p-values were adjusted for multiplicity of testing.

Table II. The mean (standard deviation) for the pre- and post-operative clinical scores

Clinical scores	Baseline	Post-operative	p-value (Mann–Whitney U test)
CS	23.2 (6.4)	69.8 (13.2)	< 0.001
ASES	24.1 (10.7)	93.4 (6.8)	0.009
EQ-5D			
Health state	15.0 (14.6)	93.0 (11.5)	< 0.001
Index value	0.1 (0.1)	0.9 (0.2)	< 0.001

CS, constant score; ASES, American Shoulder and Elbow Surgeons score; EQ-5D Health state, EuroQoL Visual Analogue Scale; Index value, Derived EQ-5D scale

Table III. Constant-Murley subscores: mobility, pain, strength. Values are presented as mean points (standard deviation) as assigned by the Constant-Murley scoring system[14]

Variable	Pre-operative	Post-operative	p-value (Mann–Whitney U test)
Mobility			
AAE	5.4 (2.1)	9.4 (1.5)	0.037
ALE	4.7 (1.7)	9.0 (1.4)	< 0. 001
AER	2.3 (0.7)	4.5 (3.5)	< 0.001
AIR	3.3 (1.5)	7.2 (1.9)	< 0.001
Pain	2.1 (2.3)	14.6 (0.7)	< 0.001
Strength	1.4 (0.9)	7.6 (3.8)	< 0.001

AAE, active anterior elevation: 2 points assigned per 30° of movement (0 points = 0° to 30° and 10 points = 151° to 180°)
ALE, active lateral elevation: 2 points assigned per 30° of movement (0 points = 0° to 30° and 10 points = 151° to 180°)
AER, active external rotation: 2 points = hand behind head with elbow held forward and 10 points = all listed ER movements up to and including full elevation from on top of head
AIR, active internal rotation: 0 = dorsum of hand to lateral thigh and 10 = dorsum of hand to interscapular region
Pain: 0 = severe; 5 = moderate; 10 = mild; 15 = none
Strength: score reflects the number of pounds resisted up to a maximum of 25

Results

The clinical scores at a mean follow-up of 38 months (SD 2.9; 24 to 41) are shown in Table II.

There was a significant difference between the pre- and post-operative clinical scores, with a mean change of 46.6 points (SD 12.5; 95% confidence interval (CI) 36.4 to 46.5) ($p < 0.001$) for the CS and 69.3 points (SD 11.7; 95% CI 66.6 to 75.6) ($p < 0.001$) for the ASES. There were also significant improvements for the CS subscores of pain, strength and all mobility items ($p < 0.05$, Mann–Whitney U test) (Table III).

Analysis of the activities of daily living showed return to full work in 31 patients (77.5%) and to recreation/sports in 19 (47.5%). The mean change in EQ-5D was 78 (SD 17.9; 95% CI 71.7 to 85.5) for the VAS ($p < 0.001$) and 0.8 (SD 0.2; 95% CI 0.8 to 0.9) for derived EQ-5D scale (index value) ($p < 0.001$, Mann–Whitney U test).

One patient with an intact glenoid had a massive rotator cuff tear on clinical examination six months post-operatively with static superior subluxation of the humeral component in relation to the glenoid component. Although the patient was pseudoparalytic (unable to actively elevate arm above 90°), there was no pain in the affected shoulder and the patient had a CS of 68 points and ASES of 75. When reviewed three years post-operatively, there was no indication for further surgery for this patient. There were no other peri-operative complications.

OA was graded as moderate radiographically in five patients (13%) and severe in 35 (87%). The pre-operative wear pattern of the glenoid included the following types: A2 (32%), B1 (61%) and B2 (7%). At 24 months post-operative follow-up, there was no evidence of glenoid or humeral component migration. Thinning of the posterior keel and slight wear at UHMWPE-TM interface was seen in one patient with a type A2 glenoid and was asymptomatic with the patient having a CS of 91 and an ASES score of 97 (Fig. 5).

Radiolucent lines were found in three patients around the humeral component (< 0.5 mm involving two zones in two patients with an uncemented component and < 1.5 mm involving eight zones in one patient with a cemented component). In two patients, radiolucent lines were noted around the glenoid component which were < 1 mm wide in three zones (zones 1, 2 and 3). All patients with radiolucencies were asymptomatic. No significant correlation was found between abnormal radiographic findings and clinical scores ($p > 0.05$). Grade 1 HO was found in four patients around the humeral neck and the inferior rim of the glenoid. There were no patients with radiographic evidence of implant failure.

Discussion

The clinical performance and rate of failure of the second-generation TM Glenoid component for TSA have not been previously reported. Our early post-operative findings suggest satisfactory performance, function and subjective satisfaction at a mean of 38 months (21 to 41) post-operatively. The most promising finding in this retrospective series is the radiographic evaluation. There were no catastrophic failures or evidence of metal debris, migration,

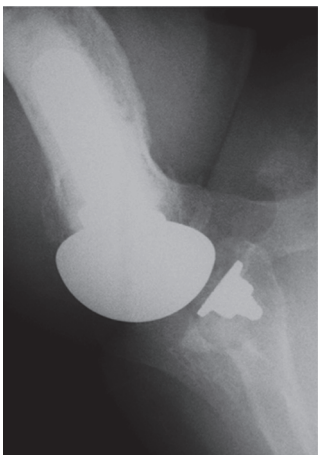

Fig. 5a

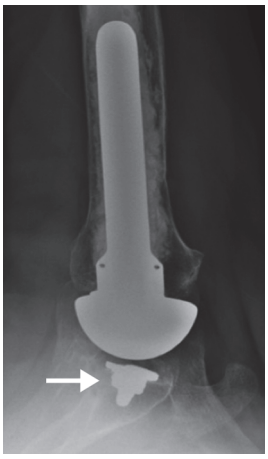

Fig. 5b

Axillary radiographs of the patient with thinning of the posterior keel a) one day post-operatively and b) 24 months post-operatively (arrow).

or gross evidence of loosening. Radiolucent lines were found in two patients around the glenoid component but clinically the patients were unaffected.

New biomaterials, such as TM, have been introduced in an attempt to improve fixation to bone. The structure of TM closely resembles that of trabecular bone. The porous tantalum has an elastic modulus (stiffness) close to that of the surrounding bone (cancellous bone: 0.15 GPa to 1.5 GPa; porous tantalum: 3.3 GPa) and has been shown to induce bone ingrowth and fibrous tissue formation inside the component.[21] In a series of 19 patients with a first generation TM backed glenoid component all but one patient had complete ingrowth of the porous tantalum keel at a mean follow-up of 38 months (24 to 64).[10]

Recent evidence supports the theory that metal backed glenoid components are superior to polyethylene implants with respect to fixation.[21] A 2014 systematic review involving 43 studies (1571 patients with metal backed implants and 3035 patients with all polyethylene implants) reported 77% of polyethylene glenoid revisions were attributed to loosening compared with 38% of metal backed implants.[22] However, the rate of revision for metal backed components was three-times higher than for polyethylene (14% *vs* 3.8%, respectively) five to seven years post-operatively.[22] Most of metal backed glenoid component revisions (> 60%) were attributed to UHMWPE wear, instability, or dissociation. These findings suggest that although metal backed components have succeeded in reducing loosening, there are new, potentially more severe, problems. Despite UHMWPE implants having considerably lower rates of revision than metal backed implants, statistically greater rates of radiolucent lines were found around the UHMWPE components. This finding highlights the fact that radiolucency and loosening may offer valuable insights when monitoring the performance of a component, but the ultimate determinant of success or failure should be the requirement for revision surgery.

A patient's ability to tolerate a suboptimal glenoid component is an important factor to consider when deciding whether or not a revision should be undertaken. Based on the literature, patients appear to be more tolerant of a poorly performing UHMWPE glenoid than a metal backed glenoid.[20-23]

We did not find any evidence of catastrophic failure, gross migration, or loosening. One patient had thinning of the posterior keel. The clinical significance at this finding is unknown. The patient remains asymptomatic and has maintained satisfactory functional scores. Radiolucent lines were detected in two patients around the glenoid. Although asymptomatic at the time of our review, rates of failure tend to increase at seven years post-operatively, and therefore the long-term situation for our patients should be monitored.[22]

With respect to comparisons between the first and second-generation TM Glenoid, a 2013 study by Budge et al[10] found four of 19 first-generation glenoids (21%) failed at a mean of three years post-operatively by fracture at the keel-glenoid junction as manifested by the presence of tantalum particulate debris and/or migration of the glenoid component.[10] Based on our early findings, the second-generation component does not exhibit the problems seen with the first-generation and results in better outcomes. Our mean post-operative ASES score was > 20 points higher than that reported by Budge et al[10] (93 *vs* 70, respectively). Pain, strength and ROM, however, were measured using different methods and thus, do not permit comparison. The improved performance is likely attributable to a more solid and stable construct. The new shape has a cruciform keel with five central porous tantalum pegs. The added posts may contribute to the improved early performance by allowing better seating of the component but this is purely supposition.

Attempts to compare post-operative function and patient reported outcomes are challenging owing to the lack of standardised reporting and the use of uniform outcomes in the literature.[2,22] Litchfield et al[24] conducted a Level 1 study comparing cemented and uncemented humeral components with either a keeled or pegged cemented polyethylene glenoid. Although the glenoid components were different than in the current study, they used the same TSA system (Bigliani/Flatow) and reported pre- and post-operative ASES scores. Their patients were slightly older (mean 68 years in uncemented group and 69 years in cemented group), however, the baseline mean ASES scores were almost identical (cemented humeral component: ASES 26 points, uncemented humeral component: ASES 23 points, compared with our study: ASES 24 points). At two years post-operative, their mean ASES scores were 69 and 34 for the cemented and uncemented humeral components, respectively. However, it should be noted that the mean ASES score of the uncemented group declined sharply from 64.8 at 18 months to 34.7 at two years which may suggest a reporting anomaly. Most patients (38/40) in our series

had an uncemented humeral component. Although we cannot draw any firm conclusions from these data, patients with the second-generation TM Glenoid from the same TSA system had a relatively higher post-operative ASES score than a sample of patients with a cemented all UHMWPE glenoid.

We advise caution when comparing the current findings with previously published literature on metal backed components as most studies are longer-term (> five years) and involve older metal backed glenoid components with cemented *versus* press-fit fixation. There is only one study to our knowledge[10] that used a glenoid component made with the new porous TM. All studies on metal backed glenoids included in the 2014 systematic review by Papadonikolakis and Matsen[22] were Level IV evidence or lower emphasizing the need for higher quality studies on these newer implants.

It is likely that surgical expertise and technique, patient characteristics, and the integrity of the rotator cuff all play a role in the outcome regardless of the design of the components.[2] These variables should be considered when interpreting findings as well as the subjective nature of radiographic interpretation and its limited ability to detect early loosening.

The main limitations of this study are its retrospective design, absence of control group, limited number of patients, and short follow-up. Long-term randomised controlled trials are now in progress[25] to understand better the progressive nature of clinical data and symptoms over a ten-year period.

Despite the limitations of our study we conclude that the second-generation TM Glenoid component for TSA resulted in good to excellent clinical performance, function and satisfaction at a mean of 38 months post-operatively. Radiographic changes around the tantalum coating of the glenoid were few and did not affect clinical outcomes. The second-generation TM Glenoid has better outcomes than those reported with the first-generation component. Long-term follow-up is required to judge fully the safety and efficacy of these components.

Author contributions:
G. Merolla: Study protocol preparation, data collection, data analysis, performed surgeries, writing the paper.
P. Chin: Data collection, data analysis, performed surgeries, writing paper.
T. M. Sasyniuk: Data collection, data analysis, writing paper.
P. Paladini: Writing paper.
G. Porcellini: Writing paper.

The authors (G. Merolla, P. Chin and T. Sasyniuk) have received benefits from a commercial party (Zimmer Inc) related directly or indirectly to the subject of this article.

This article was primary edited by G. Scott and first proof edited by J. Scott.

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