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Panti, Juan Paulo, Tan, Simon, Kuo, Warren, Fung, Sebastian, Walker, Kim, Duff, Jed. "Clinical and radiologic outcomes of the second-generation Trabecular Metal (TM) glenoid for total shoulder replacements after 2-6 years follow-up", Published in Archives of Orthopaedic and Trauma Surgery Vol. 136, Issue 12, p. 1637-1645 (2017)

Available from: <u>http://dx.doi.org/10.1007/s00402-016-2562-1</u>

This is a post-peer-review, pre-copyedit version of an article published in Archives of Orthopaedic and Trauma Surgery. The final authenticated version is available online at: http://dx.doi.org/10.1007/s00402-016-2562-1

Accessed from: http://hdl.handle.net/1959.13/1331477

Clinical and radiologic outcomes of the 2nd Generation Trabecular Metal[™] glenoid for Total Shoulder Replacements after two to six years follow-up.

ABSTRACT

Background: A porous tantalum glenoid component for Total Shoulder Replacements was introduced in 2003 to promote biologic ingrowth. However, reports of component failure prompted design modifications. The purpose of this study is to present the largest series to date, of TSR with the 2nd generation Trabecular Metal[™] glenoid component.

Method: A radiologic and clinical evaluation of the 2nd generation TM glenoid was conducted in consecutive cases of 76 shoulders (66 patients) with a mean follow up of 43.2 mos (range: 24-72 mos). Pre-operative VAS score, patient self-assessed ASES score, active shoulder range of motion and radiologic assessment were recorded. Patients were recalled for latest follow-up clinical and radiologic evaluation.

Results: On latest follow up, the mean VAS scores (Pre-op: 6.4 - latest: 0.9) and ASES scores (Pre-op: 36.9 - latest: 88.5) improved. Active range of motion improved in all planes. There was no report of glenoid component migration, loosening, or humeral stem subsidence. The incidence of non-progressive radiolucency in the glenoid was 6.6% (Franklin 1: 3 cases, Franklin 2: 2 cases). Post-operative complications involved dislocation (n=2) which were reduced in ED, post-operative stiffness (n= 1), transient axillary nerve neuropraxia (n=1), and supraspinatus tear which underwent arthroscopic repair at 16 months post-op. There were no revision surgeries for implant loosening nor glenoid component fracture at the peg-base plate junction.

Conclusions: The modifications established in the 2^{nd} generation TM glenoid resulted to improve early to mid-term survivorship and clinical outcomes in TSR, with promise of long term implant stability through bony ingrowth.

Level of evidence: Level IV, Case series, Treatment study

Keywords: 2nd generation TM glenoid; Total Shoulder Replacement; Tantalum

INTRODUCTION

Total Shoulder Replacement (TSR) is a successful operation in relieving pain and improving function in patients with moderate to severe arthritis of the glenohumeral joint. According to the Australian Orthopaedic Association National Joint Registry Report (AOANJRR) 2015, there have been 8,906 primary total conventional shoulder replacements done in Australia since the inception of the shoulder registry, of which 93.8% are attributed to primary osteoarthritis.¹ Based on their data, the total eight year cumulative rate of revision of a conventional total shoulder arthroplasty for primary osteoarthritis is 10.5%. Component loosening/lysis is a common reason for revision, responsible for 17.5% of revision surgeries.¹

Currently, a cemented all-polyethylene (AP) glenoid component is still the benchmark of practice for conventional TSR's by the majority of shoulder surgeons in Australia¹ and around the world. This is despite numerous publications showing rates of clinical loosening of cemented glenoid implants up to 44% at mid to long-term follow up.²⁻¹² Failure of the glenoid component can be attributed to several different causes including polyethylene wear, rotator cuff insufficiency, inadequate initial fixation, inability to fully seat the implant, failure to handle eccentric loading, deficient glenoid bone stock, and cement fatigue leading to failure.¹³ Historically, metal-backed (MB) glenoid components have mixed results and some designs have not fared better due to a larger number of revision surgeries compared to their cemented counterpart.^{14-17,19} Dissociation of polyethylene from the metal base was an additional

drawback in some reports.¹⁸⁻²² Despite the TSR's success, chronic loosening of the glenoid component presents as a worrying complication.

A new glenoid metal backed design using Tantalum was developed in an attempt to decrease the risk of glenoid loosening, provide the stability and rigidity of a metal backed plate, and promote permanent fixation due to long-term biologic ingrowth between the implant and glenoid bone stock. Numerous biomechanical and clinical studies have reported that tantalum implants or augmentations can provide a good substrate for attachment, formation, and ingrowth of bone tissue in vivo even under difficult conditions.²³⁻²⁶ The 1st generation monoblock porous Tantalum MB glenoid component (Trabecular MetalTM) with three in-line conjoined pegs developed by Zimmer Biomet® (Warsaw, IN, USA) was launched in 2003. The device is considered a monoblock due to a 1.5mm uniform interdigitation of polyethylene into the Trabecular MetalTM (TM) material.

To date, the only available clinical report regarding the use of the 1st generation TM glenoid component in a conventional Total Shoulder Arthroplasty was presented by *Budge et al.* (2013).²⁷ Their prospective series involved 19 patients with a mean follow-up of 38 months, wherein clinical and radiologic outcomes were evaluated. All glenoid components except one, had complete in-growth on latest follow-up. Despite the favourable early clinical results, there were four patients (21%) who had a glenoid component failure due to fracture at the glenoid peg-base plate junction. Prior to the manufacturer's change of glenoid component design, there were 6 known implant fractures out of 430 implantations. From manufacturer's data, the company commenced numerous lab studies to replicate the observed failure pattern and concluded that the amount of antero-posterior humeral head translation was underestimated. This left the TM material struts vulnerable to cyclic compression and tensile forces. A strut

fracture on the outside edge of the material would propagate across the TM disk, leading to catastrophic failure.

The second-generation Trabecular MetalTM Glenoid (Zimmer Biomet, Warsaw, IN, USA) component was introduced in 2009 in which modifications include addition of conjoined anterior and posterior pegs, shortening the central peg, and incorporating divots into all five pegs for expanded polyethylene interdigitating (**Figure 1A, 1B, 1C**). The improvement in the component design aimed to increase resistance to fatigue and fracture, which was demonstrated in a biomechanical performance evaluation.²⁸ Since its release, this glenoid design has been implanted in 13,000 patients worldwide. The paper by *Obermeyer et al. (2015)* presented a case series of 12 shoulders with a mean follow-up of 20 months, using either a 1st or 2nd generation TM glenoid for primary TSR.²⁹ In all cases, there was no evidence of radiographic lucency on standard shoulder views nor was there any evidence of clinical loosening. Recently, *Merolla et al. (Jan 2016)*, published a series of 40 unilateral TSR cases entirely with the 2nd generation TM glenoid, with a mean follow-up of 38 months. There were no reports of catastrophic implant failure or loosening. Radiolucent lines (<1mm) were noted in 2 glenoid components, although they were asymptomatic.

Our paper aims to present the largest series to date, of the 2nd generation TM glenoid component in primary TSR's with mid-term clinical and radiologic outcomes.

METHODS

From September 2009 up to November 2013, the 2^{nd} Generation Trabecular Metal GlenoidTM (Zimmer Biomet, Warsaw) was implanted in 91 shoulders (80 patients) by either of two fellowship-trained shoulder surgeons (ST & WK) working in a group practice. Before initiation

of the study, the project (Project R 68) was approved by our institution's Practice Development and Research Council. A retrospective review of the clinic database was performed to document pre-operative clinical and radiologic evaluation, pre-op shoulder functional outcome scores, intra-operative findings, complications, and post-operative follow-ups. Each patient was then contacted to arrange a current follow-up at the clinic along with standard shoulder radiographs (Grashey anteroposterior, Scapular Y, and axillary views). A total of 76 shoulders (66 patients) were available for review and assessment. A written participant consent form was signed by each patient during the latest evaluation. Fourteen patients (15 shoulders) were unable to have a minimum of 2 years follow-up and were excluded in the study due to the following causes: 4 patients (5 shoulders) have died due to unrelated reasons, 3 patients (3 shoulders) refused participation, and 7 patients (7 shoulders) were lost to follow-up.

The indications for TSR was predominantly primary glenohumeral osteoarthritis (90.5%), followed by rheumatoid arthritis (4.1%), OA secondary to humeral head avascular necrosis (4.1%), and post-traumatic arthritis (1.4%). Pre-operatively, patients were assessed clinically for a competent and well-functioning rotator cuff. A shoulder MRI or a CT arthrogram was requested to verify the rotator cuff integrity, glenoid morphology and version. All patients had well-functioning rotator cuff, although there were two shoulders that had a previous arthroscopic cuff repair (Supraspinatus tear). Glenoid pre-operative morphology was taken into consideration using the Walch Classification, as a type B2 and C on axial CT scans were not considered appropriate for this type of glenoid implant. Other exclusion criteria for the 2nd generation TM Glenoid would be any revision shoulder replacement and ongoing shoulder sepsis. Patients with history of osteoporosis were not excluded from receiving a TM glenoid.

The surgery was performed in all cases by using a semi-beach chair position with a standard Deltopectoral approach under general anaesthesia. The long head of the biceps tendon was cut and sutured to surrounding soft tissue using absorbable sutures. Subscapularis tenotomy was performed to expose the joint followed by appropriate releases. During glenoid preparation, reaming was performed to but not beyond subchondral bone for structural support of the implant. All cases used the Trabecular Metal Humeral stemTM and the 2nd Generation Trabecular Metal Glenoid component TM (Zimmer Biomet, Warsaw, IN, USA). Both components were inserted using an entirely un-cemented press-fit technique, contrary to previous studies by Budge et al.²⁷ and Obermeyer et al.²⁹ in which a small amount of polymethylmethacrylate was placed at the tip of the keel or at the periphery of the glenoid polyethylene respectively. Subscapularis was repaired with either a transosseous technique using number 5 Ethibond® (Ethicon, USA) sutures in 46 cases (ST), or with number 2 Fiberwire® (Arthrex, Fl, USA) using an interrupted Figure of 8 technique in 28 cases (WK) as per surgeon preference. A suction drainage was secured prior to skin closure. All patients had a regular arm sling with body strap post-operatively for 2 weeks. Post-operative rehabilitation followed the Neer protocol and the Subscapularis repair was protected for 6 weeks. Followup appointments post-operatively were at 2 weeks, 1 month, 3 months, 6 months, and annually thereafter.

On latest follow-up, all participants were requested to complete a current patient-self-assessed American Shoulder and Elbow Society questionnaire and visual analog pain scale (VAS). Most recent clinical assessment was done by an orthopaedic surgeon (JPP) not involved with the shoulder replacement surgery. Patients were assessed for any evidence of instability, impingement symptoms, and shoulder atrophy. Active range of motion was recorded using a standard goniometer. The latest radiologic evaluation was performed by independent assessors, JPP and a fellowship-trained Musculoskeletal Radiologist (SF). The plain films were scrutinized by both assessors for any evidence of radiolucency, glenoid osteophytes, heterotopic ossification, glenoid component migration, humeral stem subsidence, or fracture. Radiolucency was defined as a discrete area behind the implant which is lucent and devoid of any bony trabeculae. Since the 2nd generation glenoid design is unique and there has been an addition of antero-posterior pegs since its predecessor, we decided to create our own modified Sperling's zones for periprosthetic radiolucency in the glenoid. ³⁰ Aside from zones 1-5 in the Grashey AP view, we incorporated zones 6-10 in the axillary view to note for any loosening or radiolucency in the anteroposterior pegs as well (**Figure 2A and 2B**). The grading scale by Franklin et. al's⁷ for radiolucencies around pegged glenoid components was utilized. Humeral radiolucencies were documented using the classic Sperling's zones.

RESULTS

There were 76 cases (66 patients) available for review, with a mean age of 69.6 years (52-81yrs) during the time of surgery. The study population was comprised of 26 males and 40 females, with a mean body mass index of 29.4 kg/m² (19.6-42.7 kg/m²) pre-operatively. The TSR was performed in 34 right and 42 left shoulders, with 23 cases involving the dominant side and 10 patients with staged bilateral surgeries. The mean follow-up was 43.2 months (24-72 mos). There were three intra-operative complications reported consisting of glenoid component not fully seated (**Figure 3**) to bone (n=1), an undisplaced fracture at the antero-inferior quadrant of the glenoid (n=1), and a longitudinal split in the humeral shaft which was fixed using a cerclage wire (n=1). There was one patient that had intra-operative tissue sent for frozen section following previous history of shoulder infection which returned a negative

result. No growth was noted in culture medium thereafter. Post-operative complications consisted of glenohumeral dislocation reduced in the emergency department (n=2), shoulder stiffness requiring a manipulation under anaesthesia (n=1), transient axillary neuropraxia which resolved 3 months post-operatively (n=1), and an arthroscopic supraspinatus repair at 16 months post-op for a 2x2 cm full thickness tear (n=1).

Clinical evaluation of the patients recorded an improvement in pain, range of motion, and functional outcome scores. The mean VAS score improved from a pre-operative score of 6.4 (0-10) to 0.9 (0-10) on latest follow-up. The mean active forward elevation improved from 108.4° (15-170°) to 162.9 ° (90-180°), while the mean abduction improved from 84.3° (0-170°) to 166.6° (6-180°). Active external rotation improved from 21.0° (0-90°) to 61.7° (40-90°). The patient assessed ASES score improved from 36.5 (5-85) to 88.1 (18.3-100) on latest follow-up (**Table 1**). There were only 3 patients with ASES score less than 50 on latest follow-up and all of them have symptoms of anterior impingement. The mean VAS score of these three patients was 8.3. One of the patients opted to have a subacromial corticosteroid injection which offered initial relief, while the other two opted conservative management and refused injections or surgery for the anterior impingement. There were no revision shoulder replacement surgeries for glenoid component failure due to fracture at peg-base plate junction, implant loosening, instability, or rotator cuff failure.

Latest shoulder plain radiographs revealed an incidence of glenoid non-progressive radiolucency in 5 cases (6.8%). No radiolucency was more than 2mm on both AP and axillary views. The location of the glenoid radiolucencies involved Zone 1 (n=3), Zone 2 (n=1), Zone 3 (n=2), Zone 4 (n=4), Zone 5 (n=4), and Zone 6 (n=1). There were no radiolucency observed in glenoid zone 7-10. The glenoid lucencies were allocated to Franklin 1(n=3) and Franklin 2

(n=2) types. There was an observed osteopenia behind the glenoid plate and pegs in Grashey AP views of 8 patients (**Figure 4**), suggestive of stress shielding of the glenoid bone stock. There was an inferior glenoid bone spur observed in 5 cases due to a retained inferior rim osteophyte. There was no glenoid component migration by comparison of immediate post-op films to latest follow-up films. There were also 5 cases suggestive of heterotopic ossification at the triceps attachment. No humeral stem subsidence was observed on latest radiographs.

DISCUSSION

Glenoid component failure in anatomic Total Shoulder Replacements continues to be an unwelcome complication often leading to substandard clinical results. The quest for the optimal glenoid design and fixation still remains. A recent systematic review was published comparing the incidence of peri-implant radiolucent lines, component loosening, and revision surgeries between 1571 metal-backed (MB) and 3035 all-polyethylene (AP) glenoid components in primary anatomic Total Shoulder Replacements.³¹ Based on the review, MB components have a lower incidence of lucent lines (MB=34.9%, AP=42.5%) and component loosening (MB=16.8%, AP=21.1%) compared to AP components on latest radiographs. However, revisions rates and component failures were considerably higher with MB components (MB=14.0%, AP=3.8%). It is interesting to note that glenoid loosening is the mode of failure for 77% of revisions surgeries for primary Total Shoulder Replacements with AP components, compared to only 38% of revisions for MB's. Other modes of failure for a variety of MB glenoid designs were polyethylene dissociation from metal plate, metal plate fracture, screw breakage, back-side polyethylene wear from modular components, instability, and cuff failure. ¹³ A similar trend was shown in the recent Australian National Joint Registry 2015, wherein the cumulative 3 year revision rate of a cemented AP glenoid was 3.0% compared to 15.8% in an uncemented modular MB glenoid. About 88.7% of revisions involving modular MB glenoid were due to replacement of the modular polyethylene with a glenosphere and conversion to a Reverse Total Shoulder Replacement. Curiously when the SMR glenoid (Lima Corporate, Villanova, Italy) was excluded from the data due to its higher than anticipated rate of revision, the 3 yrs cumulative revision rate for an uncemented modular MB glenoid increased to 23.2%. On the other hand, a MB glenoid with a fixed polyethylene has a 3 year cumulative revision rate of 4.4% which compares closely to a cemented AP glenoid.¹

Given that the etiology of MB glenoid failures is varied and mainly associated with implant design and materials, it is reasonable to presume that design advancements could improve survivorship and clinical outcomes. Pitfalls in previous MB designs were discussed in numerous publications. In the lone prospective, double blinded, randomized control trial, comparing cemented AP versus uncemented glenoid components by Boileau P, et. al,¹⁴ there were 3 revisions for MB component loosening due to asymmetric posterior polyethylene wear. The MB design was a hyrdroxyapatite coated porous 3mm metal tray with two expansion screws. Boileau postulated that the failures were due to four factors: Insufficient thickness of PE insert (4mm), excessive thickness of glenoid component metal tray (7mm), stress shielding of bone due to rigidity of MB trays, and posterior load on the glenoid even after TSR. Martin et.al,³² reported the clinical and radiographic results of 140 TSRs using a plasma-sprayed, screw-fixed, uncemented MB glenoid tray with a mean follow-up of 7.5 years. In their series, there were 16 clinical failures including fractured metal trays (n=2), polyethylene delamination (n=9), and aseptic loosening (n=5). There were also 16 screw breakages in 15 patients, and osteolysis around 13 of the screws were documented as well. The implant used similarly had a thick metal plate, and lack of bone in-growth capability around the screws might have contributed to the high number of screw loosening and breakage. A mid to long-term follow up in 83 uncemented MB glenoids was reported by *Taunton and colleagues*³³ using a porous

coated titanium alloy metal tray with 3 columns projecting to the glenoid and fixed with two titanium cortical screws. The porous coating however only extended over the surface of the metal tray and not the columns. With a mean clinical follow-up of 9.5 years, the revisions due to the glenoid component were as follows: Polyethylene wear (n=15), glenoid metal wear (n=12) and glenoid component loosening (n=9). There were 33 cases with evidence of radiographic glenoid loosening in their report. Dissociation of polyethylene from the metal tray was also a pitfall observed in some uncemented modular MB designs. *Wallace and colleagues*²⁰⁻²¹ postulated that the dissociations might have been caused by eccentric stresses of the shoulder directly affecting the polyethylene-metal interface. A biomechanical analysis has shown that the thicker width of the metal plate in previous MB designs added to the polyethylene width, will result into a thicker entire glenoid component hence resulting into a greater susceptibility to eccentric stress. ³⁴ We have tabulated a summary of clinical studies involving various uncemented, bone in-growth MB glenoid components highlighting radiographic findings and revisions (**Table 2**).

In an effort to improve bone ingrowth and decrease the rate of loosening, a MB glenoid implant using porous Tantalum was introduced. Trabecular MetalTM has been reported to have a large propensity for bone in-growth under physiologic stress due to low modulus of elasticity and high volumetric porosity (70-80%).²⁴⁻²⁶ It has been used previously in spinal fusions, ³⁵ hip ³⁶ and knee joint replacements ³⁷ with success. The 1st generation Trabecular MetalTM glenoid was described as monoblock with three in-line porous tantalum pegs and was designed to have no metal backing at the glenoid face so as to maximize the polyethylene thickness. The polyethylene had a round back and the articular surface a conforming central and non-conforming peripheral geometry. However, initial clinical reports showed failures due to fracture of the tantalum metal at the peg-base plate junction.²⁷

The design modifications in the second generation Trabecular Metal[™] glenoid were intended to improve on the key points of its predecessor, while at the same time eliminate the incidence of glenoid component fracture at the peg-base plate junction as reported previously.²⁷ The objective of our investigation is to determine whether the 2nd generation Trabecular Metal glenoid has a better survivorship and outcomes than the 1st generation and other MB glenoid designs. We present the largest reported series to date, of porous Tantalum used for the glenoid component in anatomic TSRs. Both reports by *Budge et. al*²⁷ and *Obermeyer et. al*,²⁹ have used a limited cementing technique (at the tip of the pegs or at the periphery of the polyethylene) for their TM glenoid components since it is approved by the USA FDA for cemented implantation only. Such is not the case in Australia and thus all of our glenoids were implanted entirely uncemented via a press-fit technique, relying solely on the bone in-growth capability and stability of this implant design. Based on our results, there has been no report of metal fracture, polyethylene dissociation or revision surgeries due to component loosening. The addition of the antero-posterior pegs and shortening of the central peg seems to provide enhanced stability to counteract rocking-horse loosening from eccentric glenoid loading.³⁸⁻⁴⁰ The expanded interdigitation of the PE to the tantalum metal prevented dissociation or fracture of these components.

Our clinical outcomes shows improvement in pain, function, and range of motion consistent with expected results from a TSR. The absence of revision surgeries in our series are slightly better than the cumulative 3 year revision rate of 4.4% for fixed polyethylene MB glenoid. The presence of asymptomatic radiolucent lines in our report (6.8%) is comparable to the reported rate of 7.3% per year as shown in a systematic review of 27 articles. The aforementioned review by *Papadonikolakis, et. al* noted that symptomatic glenoid loosening occurred at 1.2% per year,

and surgical revision occurred at 0.8% per year.⁴¹ We also observed osteopenia behind the pegs in 8 cases, suggestive of stress shielding. However we have not further investigated this with more stringent radiographic techniques such as radiostereometric analysis which could demonstrate a more precise gauge of implant stability.

Limitations of our study includes the lack of a long-term follow up and control group. Lately, radiostereometric analysis has been suggested as a more accurate measure of component displacement and loosening.⁴² However, it is not widely available and it involves implantation of small metal beads in the patient to take the radio-stereograph.

The primary investigator has proposed an addition to standard AP radiographic assessment of TSA utilizing the axillary lateral view. The added Zones 6-10 incorporate the anterior and posterior pegs in to the classification. This is very relevant considering the current design of glenoid components.

In conclusion, our mid-term clinical and radiographic results with the 2nd generation Trabecular Metal glenoid are comparable to available literature on TSR. There was, however, improved implant survivorship with promise of long term implant stability through bony ingrowth. Further long term follow up will be necessary to determine if the lower rates of component loosening are sustained.

REFERENCES

 Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. Adelaide:AOA; 2015.

- Neer CS 2nd, Watson KC, Stanton FJ. Recent experience in total shoulder replacement. J Bone Joint Surg Am. 1982;64(3):319-337.
- Cofield RH. Total shoulder arthroplasty with the Neer prosthesis. J Bone Joint Surg Am 1984;66:899-906.
- 4. Barrett WP, Franklin JL, Jackins SE, Wyss CR, Matsen FA 3rd. Total shoulder arthroplasty. J Bone Joint Surg Am 1987;69:865-72.
- Brems J. The glenoid component in total shoulder arthroplasty. J Shoulder Elbow Surg 1993;2:47-54.
- 6. Torchia ME, Cofield RH, Settergren CR. Total shoulder arthroplasty with the Neer prosthesis: long-term results. J Shoulder Elbow Surg. 1997;6(6):495-505.
- Lazarus MD, Jensen KL, Southworth C, Matsen FA. The radiographic evaluation of keeled and pegged glenoid component insertion. J BoneJoint Surg Am 2002;84:1174-82.
- Gartsman GM, Elkousy HA, Warnock KM, Edwards TB, O'Connor DP. Radiographic comparison of pegged and keeled glenoid components. J Shoulder Elbow Surg 2005;14:252-7. <u>http://dx.doi.org/10.1016/j.jse.2004.09.006</u>
- Fox TJ, Cil A, Sperling JW, Sanchez-Sotelo J, Schleck CD, Cofield RH. Survival of the glenoid component in shoulder arthroplasty. J Shoulder Elbow Surg 2009;18:859-63. http://dx.doi.org/10. 1016/j.jse.2008.11.020.
- Edwards BT, Lavriola JE, Stanley RJ, O'Connor DP, Elkousy HA, Gartsman GM. Radiographic comparison of pegged and keeled glenoid components using modern cementing techniques: a prospective randomized study. J Shoulder Elbow Surg 2010;19:251-7. <u>http://dx</u>. doi.org/10.1016/j.jse.2009.10.013.

- 11. Kasten P, Pape G, Raiss P, et al. Mid-term survivorship analysis of a shoulder replacement with a keeled glenoid and a modern cementing technique. J Bone Joint Surg Br. 2010;92(3):387-392.
- 12. Walch G, Young AA, Elis B, Gazielly D, Loew M, Boileau P. Results of a convexback cemented keeled glenoid component in primary osteoarthritis: multicenter study with a follow-up greater than 5 years. J Shoulder Elbow Surg 2011;20:385-94. <u>http://dx.doi.org/10.1016/j.jse.2010.07.011</u>.
- Matsen FA III, Clinton J, Lynch J, Bertelsen A, Richardson ML. Glenoid Component Failure in Total Shoulder Arthroplasty. J Bone Joint Surg Am. 2008; 90:885-896. doi:10.2106/JBJS.G.01263.
- 14. Boileau P, Avidor C, Krishnan SG, Walch G, Kempf J, Mole D. Cemented polyethylene versus uncemented metal-backed glenoid components in total shoulder arthroplasty: a prospective, double-blind, randomized study. J Shoulder Elbow Surg 2002;11:351-9. <u>http://dx</u>. doi.org/10.1067/mse.2002.125807.
- 15. Montoya F, Magosch P, Scheiderer B, Lichtenberg S, Melean P, Habermeyer P. Midterm results of a total shoulder prosthesis fixed with a cementless glenoid component. J Shoulder Elbow Surg. 2013;22(5):628-635.
- Clement ND, Duckworth AD, Colling RC, Stirrat AN. An uncemented metal-backed glenoid component in total shoulder arthroplasty for osteoarthritis: factors affecting survival and outcome. J Orthop Sci (2013) 18:22–28. DOI 10.1007/s00776-012-0308-7.
- 17. Clement ND, Mathur K, Colling RC, Stirrat AN. The metal-backed glenoid component in rheumatoid disease: Eight-to fourteen-year follow-up. J Shoulder Elbow Surg 2010;19:749-756.

- 18. Burkhead WZ. Cementless shoulder arthroplasty. In: Friedman RJ, editor. Arthroplasty of the shoulder. New York: Thieme Medical;1994. p. 281-309.
- 19. Cofield RH. Uncemented total shoulder arthroplasty: a review. Clin Orthop 1994;307:86-93.
- 20. Wallace AL, Walsh WR, Sonnabend DH. Dissociation of the glenoid component in cementless total shoulder arthroplasty. J Shoulder Elbow Surg 1999;8:81-4.
- 21. Wallace AL, Phillips RL, MacDougal GA, Walsh WR, Sonnabend DH. Resurfacing of the glenoid in total shoulder arthroplasty. A comparison, at a mean of five years, of prostheses inserted with and without cement. J Bone Joint Surg Am. 1999;81:510-8.
- 22. Cheung EV, Sperling JW, Cofield RH. Polyethylene insert exchange for wear after total shoulder arthroplasty. J Shoulder Elbow Surg. 2007;16:574-8.
- 23. Budge MD, Kurdziel M, Baker K, Wiater JM. A biomechanical analysis of initial fixation options for porous-tantalum-backed glenoid components. J Shoulder Elbow Surg (2013) 22, 709-715.
- 24. Balla VK, Bodhak S, Bose S, Bandyopadhyay A. Porous tantalum structures for bone implants: fabrication, mechanical and in vitrobiological properties. Acta Biomater 2010 Aug;6(8):3349-59.
- 25. Balla VK, Bodhak S, Bose S, Bandyopadhyay A. Direct laser processing of tantalum coating on titanium for bone replacement structures. Acta Biomater 2010;6:2329-34.
- 26. Bobyn JD, Stackpool GJ, Hacking SA, Tanzer M, Krygier JJ. Characteristics of bone ingrowth and interface mechanics of a new porous tantalum biomaterial. J Bone Joint Surg [Br] 1999;81-B:907-14.
- 27. Budge MD, Nolan EM, Heisey MH, Baker K, Wiater M. Results of total shoulder arthroplasty with a monoblock porous tantalum glenoid component: a prospective minimum 2-year follow-up study. J Shoulder Elbow Surg (2013) 22, 535-541.

- Mroczkowski ML. Performance evaluation of the Trabecular Metal Glenoid. 2009 Zimmer, Inc.p.1-4.
- 29. Obermeyer T, Cagle P, Parsons B, Flatow E. Midterm Follow-Up of Metal-Backed Glenoid Components in Anatomical Total Shoulder Arthroplasties. Am J Orthop. 2015;44(9):E340-E342.
- 30. Sperling JW, Cofield RH, O'Driscoll S, Torchia M, Rowland C. Radiographic assessment of ingrowth total shoulder arthroplasty. Journal of Shoulder Elbow Surg 2000;9:507-13.
- 31. Papadonikolakis A and Matsen F. Metal-Backed Glenoid Components Have a Higher Rate of Failure and Fail by Different Modes in Comparison with All-Polyethylene Components: A Systematic Review. J Bone Joint Surg Am. 2014;96:1041-7.
- 32. Martin SD, Zurakowski D, and Thornhill T. Uncemented Glenoid Component in Total Shoulder Arthroplasty SURVIVORSHIP AND OUTCOMES. J Bone Joint Surg Am 2005:87-A:No 6: 1284-1291. doi:10.2106/JBJS.C.00947.
- 33. Taunton MJ, McIntosh AL, Sperling J, Cofield RH. Total Shoulder Arthroplasty with a Metal-Backed, Bone-Ingrowth Glenoid Component Medium to Long-Term Results. J Bone Joint Surg Am (2008);90:2180-8. doi:10.2106/JBJS.G.00966.
- 34. Collins D, Tencer A, Sidles J, Matsen F 3rd. Edge displacement and deformation of glenoid components in response to eccentric loading. The effect of preparation of the glenoid bone. J Bone Joint Surg Am. 1992;74:501-7.
- 35. Hanc M, Fokter SK, Vogrin M, Molicnik A, and Recnik G. Porous tantalum in spinal surgery: an overview. Eur J Orthop Surg Traumatol (2015). DOI 10.1007/s00590-015-1654-x.

- 36. Grappiolo G, Loppini M, Longo U, Traverso F, Mazziota G, Denaro V. Trabecular Metal Augments for the Management of Paprosky Type III DefectsWithout Pelvic Discontinuity. The Journal of Arthroplasty 30 (2015) 1024–1029.
- 37. Minoda Y, Kobayashi A, Iwaki H, Ikebuchi M, Inori F, Takaoka K. Comparison of Bone Mineral Density Between Porous Tantalum and Cemented Tibial Total Knee Arthroplasty Components. Bone Joint Surg Am 2010;92:700-6.
- 38. Anglin C, Wyss UP, Pichora DR. Mechanical testing of shoulder prostheses and recommendations for glenoid design. J Shoulder Elbow Surg. 2000;9:323-31.
- 39. Nagels J, Valstar ER, Stokdijk M, Rozing PM. Patterns of loosening of the glenoid component. J Bone Joint Surg [Br] 2002;84-B:83-7.
- 40. Fukuda K, Chen CM, Cofield RH, Chao EYS.Biomechanical analysis of stability and fixation strength of total shoulder prosthesis. Orthopedics.1988; 11: 141-9.
- 41. Papadonikolakis A, Neradilek MB, Matsen F. Failure of the Glenoid Component in Anatomic Total Shoulder Arthroplasty A Systematic Review of the English-Language Literature Between 2006 and 2012. J Bone Joint Surg Am. 2013;95:2205-12.
- Streit J, Shishani Y, Greene M, et al. Radiostereometric and Radiographic Analysis of Glenoid Component Motion After Total Shoulder Arthroplasty. Orthopedics. 2015; 38(10):e891-e897.

FIGURES

- Side by side pictures of 1st (Left) and 2nd generation (Right) Trabecular Metal[™] glenoid components, highlighting its modifications.
 - A.) Addition of conjoined anterior and posterior pegs.
 - B.) Shortening the central peg.

A

C.) Incorporation of divots into all five pegs for expanded polyethylene interdigitation.

B



С



 Modified radiographic zones for peri-prosthetic radiolucency in antero-posterior view (2A) and axial view (2B).



 Latest shoulder AP radiograph of a case wherein the glenoid was not fully seated down to bone during time of implantation. Note the sclerotic rim around the periphery of the tantalum pegs.



4. Latest shoulder AP radiograph showing osteopenia behind the tantalum pegs suggestive of stress shielding.



TABLES

 Comparison of pre-operative and latest clinical outcomes in patients with 2nd generation Trabecular Metal[™] glenoid.

Outcome measure	Pre-operative	Post-operative	Difference
	Mean (SD)	Mean (SD)	Mean
Active forward flexion	108.4° (15-170°)	162.9 ° (90-180°)	+54.5
Active abduction	84.3° (0-170°)	166.6° (6-180°)	+82.3
Active external rotation	21.0° (0-90°)	61.7° (40-90°)	+40.7
VAS score	6.4 (0-10)	0.9 (0-10)	-5.5
Subjective ASES score	36.5 (5-85)	88.1 (18.3-100)	+51.6

2.) Summary of published clinical studies involving various uncemented, bone in-growth

MB glenoid components highlighting radiographic findings and revisions.

Author/ Publication /Year	In-growth metal backed glenoid component description	No. of cases	Mean Follow-up	Radiographic findings	Glenoid complications
McElwain JP & English E CORR, 1987	English-McNab component (porous coated metal-backed glenoid with orthocrome screws and acromial pins)	13	37 mos (12-66 mos)	Significant radiolucent lines (RLL) and component loosening of glenoid component (n=1)	Dislocation with glenoid loosening and component migration(n=1), PE loosening from metal base (n=1)
Weis AP, et.al, CORR 1999	English-McNab component; cemented Neer prosthesis	9 EM, 37 Neer	4.9 yrs (3- 10yrs)	Presence of RLL in English-McNab component (n=1)	No revision surgeries for EM components
Wallace A, et.al JBJS 1999	Cofield uncementd MB glenoid; cemented AP components	26 MB , 28 AP	56 mos (MB), 71 mos (AP)	Presence of RL in MB components (n=6); component loosening (n=1)	Revision surgeries in MB components (n=5): Dissociation of PE to metal tray (n=2), early instability (n=3)
Sperling JW et.al, JSES 2000	Cofield component (titanium-alloy porous coated metal tray with three columns penetrating subchondral bone, fixed with 2 cortical screw)	62	4.6 yrs	Presence of RLL completely surrounding glenoid (n=4); RLL incompletely surrounding glenoid (n=22)	Revision surgeries for glenoid: component loosening (n=1), PE wear and displacement (n=3), infection (n=1)
Boileau P et.al, JSES 2002	Aquelis shoulder system (hydroxyapatite coated porous metal backed tray, fixed with expansion screws; 4mm thick polyethylene)	20 cemented AP, 20 uncemente d MB	38.4 mos (MB group)	Presence of RLL (n=5) with component loosening and medial migration in 4 implants	Revision surgeries MB group (n=4):glenoid component loosening (n=3), Subscapularis tear (n=1)
Martin SD et.al, JBJS(Am) 2005	Kirschner II-C Glenoid component (plasma- sprayed, screw-fixed, metal tray)	140	7.5 yrs	Presence of RLL 1- 2mm (n=40) and >2mm (n=2) in glenoid components; Osteolysis around metal tray (n=6), and screws (n=13)	Revision surgeries (n=16): fractured metal trays (n=2), polyethylene delamination (n=9), and aseptic loosening (n=5). There were 16 screw breakages
Taunton MJ, et.al, JBJS(Am) 2008	Cofield component (titanium-alloy porous coated metal tray with three columns penetrating subchondral bone, fixed with 2 cortical screw)	83	Mean clinical ff. up: 9.5 yrs; mean radiologic ff.up: 7.1 vrs	Glenoid loosening (n=33),evidence of RLL >1.5mm (n=33), <1mm (n=17)	Revision surgeries due to glenoid: PE wear (n=15), glenoid metal wear (n=12) glenoid component loosening (n=9)

		1			
Clement ND et. al, JSES, 2010	Biomodular TSR (porous- coated modular, metal- backed, screw-fixed glenoid component)	36	132mos (96- 168mos)	Glenoid loosening (n=1), presence of glenoid RLL (n=4)	Revision surgeries (n=5): worn out PE and loose glenoid (n=1), infection (n=1), pain (n=3).
Castagna A, et.al, JBJS(Br) 2010	SMR system (porous titanium coated with Hydroxyapatite, with large hollow central peg and two 6.5mm cancellous screws)	35	75.4 mos (48-154 mos)	Presence of RLL (n=8) in 22.9% cases.	No glenoid component loosening, no PE glenoid disassembly, no revision surgeries documented.
Fucentese SF, et. Al, JSES 2010	Soft Metal Backed Glenoid (highly porous titanium plate, multiple layers of unalloyed titanium mesh, with 4 pegs)	22	50 mos (range, 24- 89 mos)	Glenoid loosening due to fractured glenoid pegs (n=3);RLL incompletely surrounding glenoid (n=2)	Revision surgeries due to fractured glenoid component (n=3)
Montoya F, et.al, JSES 2013	Univers glenoid (modular cobalt-chrome metal-backed, bone- ingrowth glenoid component with titanium alloy central cage screw)	53	64 mos (26-85 mos)	Glenoid loosening due to breakage of central cage screw (n=5), presence of RLL (n=4)	Revision surgeries (n=6): PE wear (n=1), central screw breakage (n=5)
Katz D, et.al, EJOST 2013	ARROW system (modular; metal plate and keel covered with Hydroxyapatite with 3.5 mm PE, fixed with 2 axial screws and additional sagittal screw if needed)	37	38.3 mos (24–75)	No presence of RLL; inferior screw positioned under the scapula (n=5)	Early dissociations of PE from metal tray, before glenoid component was redesigned (n=3), conversion of small metal tray to a larger size (n=1)
Budge M, et.al, JSES 2013	1 st gen Trabecular Metal Glenoid (monoblock; porous, Tantalum- backed glenoid with three in-line conjoined pegs)	19	38 mos (24-64 mos)	Presence of grade 2 RLL (n=1)	Revisions due to component fracture at keel-face plate glenoid (n=4), no clinical loosening
Obermeyer T, et.al, AMJO 2015	1 st or 2 nd gen Trabecular Metal Glenoid (monoblock; porous, Tantalum-backed glenoid)	12	20 mos (6- 84 mos)	No presence of RLL	No glenoid component loosening, no PE glenoid disassembly, no revision surgeries documented.
Merolla G, et. al, BJJ 2016	2 nd gen Trabecular Metal Glenoid (monoblock; porous, Tantalum-backed glenoid)	40	38 mos (24-42)	Presence of RLL (<1mm) in n=2	No glenoid component loosening, no PE glenoid disassembly, no revision surgeries.