Reverse total shoulder arthroplasty using a trabecular metal glenoid base plate

FUNCTIONAL AND RADIOLOGICAL OUTCOMES AT TWO TO FIVE YEARS

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Aim
We present the medium-term clinical results of a reverse total shoulder arthroplasty with a trabecular metal glenoid base plate.

Patients and Methods
We reviewed 125 consecutive primary reverse total shoulder arthroplasties (RTSA) implanted in 124 patients for rotator cuff arthropathy. There were 100 women and 24 men in the study group with a mean age of 76 years (58 to 89). The mean follow-up was 32 months (24 to 60). No patient was lost to follow-up.

Results
There were statistically significant improvements in the mean range of movement and Oxford Shoulder Score (p < 0.001). Kaplan-Meier survivorship at five years was 96.7% (95% confidence interval 91.5 to 98.7) with aseptic glenoid failure as the end point.

Radiologically, 63 shoulders (50.4%) showed no evidence of notching, 51 (40.8%) had grade 1 notching, ten (8.0%) had grade 2 notching and one (0.8%) had grade 4 notching. Radiolucency around the glenoid base plate was found in one patient (0.8%) and around the humeral stem in five (4.0%). In all, three RTSA (2.4%) underwent revision surgery for aseptic mechanical failure of the glenoid within 11 months of surgery due to malseating of the glenosphere.

Conclusion
The clinical results of this large independent single unit series are comparable to those from previous series of RTSA reported in the literature. A trabecular metal base plate is safe and effective in the medium-term.

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Reverse total shoulder arthroplasty (RTSA) is used to relieve the pain from a number of conditions. These include cuff tear arthropathy, proximal humeral fracture and massive cuff tears in elderly patients.1,2 The modern RTSA was initially introduced by Grammont for patients with cuff tear arthropathy.3 The semi-constrained nature of the design, there remain concerns about the risk of wear and loosening, particularly of the glenoid base plate.5,6

The Trabecular Metal (TM) RTSA (Zimmer Biomet, Warsaw, Indiana) is designed to achieve both initial and long-term stability of the base plate by a unique combination of screw fixation and ingrowth into a porous tantalum base plate. There are only two small previous reports which deal with this design of baseplate. These are of the same cohort of patients and come from the designer group.7,8

Our aim was to report a large independent series of TM RTSAs from a single centre in patients with cuff tear arthropathy. We present the clinical and radiological outcomes with focus on the performance of the novel design of the base plate.

Patients and Methods
This review was approved by the Derby Teaching Hospitals NHS Trust audit process and forms an ongoing service evaluation and post-market surveillance of this RTSA.

We retrospectively reviewed all 243 TM RTSAs recorded in our prospectively collected database (Microsoft, Redmond, Washington) on the 1 June 2015. Patients were then excluded if they had a diagnosis of fracture (18), dislocation (one), revision TSA (41),
inflammatory joint disease without cuff tear arthropathy (three) and follow-up of less than two years (180). Patients were included if they had a minimum follow-up of two years and a diagnosis of cuff tear arthropathy.

There were a total of 125 TM RTSAs in 124 patients (100 women and 24 men). The mean age of the patients was 76 years (58 to 89) and the mean follow-up 32 months (24 to 60) (Table I). Each procedure was carried out by one of four experienced upper limb fellowship-trained surgeons (AT, ME, TC, DIC) at the Royal Derby Hospital, Derbyshire, United Kingdom, between April 2009 and June 2013.

The validated Oxford Shoulder Score (OSS)\textsuperscript{9} which rates pain, function and psycho-social components on a scale from 0 (worst) to 48 (best), clinical examination, including the assessment of range of movement using a goniometer, and radiological assessment were prospectively recorded. The Constant and Murley shoulder score (CMS) has recently (September 2013) been included in our routine collection of data. This enabled us to present a post-operative evaluation and to compare these to series which have been reported using this score.\textsuperscript{10} We used the full CMS score as originally described with a range between 0 and 100 points. The power of abduction was measured using a myometer (Mecmesin Ltd, West Sussex, United Kingdom) with 1 pound equaling 1 point, to a maximum of 25 points. If patients were unable to achieve 90° abduction they scored 0 for the strength component. In the three patients (three TM RTSAs) who had died, the medical records and the general practitioner were consulted for evidence of failure. They had all died after the minimum two-year follow-up and were therefore included in the analysis.

Table I. Demographic details of the 124 patients (125 reverse shoulder arthroplasties)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Patients (n, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male:female</td>
<td>24 (19) Male: 100 (81) female</td>
</tr>
<tr>
<td>Surgery side</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>72 (58)</td>
</tr>
<tr>
<td>Left</td>
<td>53 (42)</td>
</tr>
<tr>
<td>Bilateral RTSA</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Number of previous ipsilateral shoulder procedures</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>87 (70)</td>
</tr>
<tr>
<td>1</td>
<td>27 (22)</td>
</tr>
<tr>
<td>2</td>
<td>10 (8)</td>
</tr>
<tr>
<td>American Society of Anesthesiologists grades</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>3 (2)</td>
</tr>
<tr>
<td>2</td>
<td>78 (62)</td>
</tr>
<tr>
<td>3</td>
<td>44 (36)</td>
</tr>
</tbody>
</table>

RTSA, reverse total shoulder arthroplasty

Fig. 1

Four year post-operative anteroposterior radiograph showing a fully integrated grade A baseplate.

In summary, the humeral head is dislocated and divided using the humeral cutting guide in 0° to 20° of retroversion.
Preparation of the glenoid consists of a 360° capsular release and excision of labrum. A 2.5 mm guide wire is inserted just inferior and anterior to the centre of the long axis of the glenoid: 36 mm sclerotic and peripheral reamers are passed over the guide wire and the rest of the articular cartilage is removed down to subchondral bone. The wire is removed and the centre hole is widened with a 7.5 mm drill to a depth of 15 mm to accept the central post of the TM baseplate. This is impacted with the peg into the 7.5 mm hole and secured with one inferior and one superior screw, which is later locked using a locking screw cap. A 36 mm glenosphere is impacted onto the tapered baseplate. The humerus is prepared sequentially with hand reamers and rasps in 0° to 20° of retroversion. A total of 117 (92.8%) of the TM RTSA had an uncemented press-fit humeral stem (proximal grit-blasted design): the rest had cemented stems. If the stem was cemented, either Palacos R&G (Heraeus Medical, Wehrheim, Germany) or Simplex (Stryker, Mahwah, New Jersey) with Erythromycin was used, according to surgeon preference. Cement was used if the surgeon felt that primary stability was not achievable with an uncemented component. A humeral polyethylene trial was used to ensure correct tension after reduction of the prosthesis. The definitive humeral polyethylene was subsequently introduced and the shoulder reduced. The subscapularis was reattached with Ultrabraid (Smith & Nephew, London, United Kingdom) sutures. The arm was immobilised in a sling for four weeks when supervised physiotherapy was started. The patients were reviewed at two weeks, three months and one year post-operatively and annually thereafter.

**Statistical analysis.** This was performed using Microsoft Excel for Student's t-test and the Stata version 11 statistical package (StatCorp., College Station, Texas) for Kaplan–Meier survivorship with 95% confidence intervals (CI). A p-value of < 0.05 was considered statistically significant.

**Results.**

A total of three patients died of unrelated causes more than two years post-operatively; none had undergone a revision procedure.

In all, eight RTSAs (eight patients, 6.4%) were revised at a mean of 16.3 months (one to 41) post-operatively; four for aseptic mechanical failure of the glenoid, two for dislocation, one for pain and one for deep infection. Kaplan–Meier analysis revealed a five-year rate of survival of 90.3% (95% CI 78.9 to 95.7) for revision in all causes (12 at risk) and 96.7% (95% CI 91.5 to 98.7) for aseptic failure of the glenoid (15 at risk) (Fig. 2).

The four patients who underwent revision for aseptic failure of the glenoid did not have any evidence of RLLs around the glenoid on radiographs prior to revision. Three of these revisions were attributed to malalignment of the glenosphere (Fig. 3) leading to early mechanical failure with a mean time to revision of 10.3 months (10 to 11). In one patient, early failure of the glenoid component was attributed to a superiorly-placed baseplate which failed at 11 months. All patients with mechanical failure of the glenoid were revised to a large head hemiarthroplasty.

Two patients had a dislocation at a mean time to revision of 8.8 months (one to 16). One underwent revision to a large head hemiarthroplasty: in the other a +6 mm medial offset polyethylene liner was introduced to replace one with a 0 mm offset.

One patient underwent revision for pain: radiographs suggested RLLs around the baseplate but no evidence of infection. At the time of revision, it was noted that the baseplate was fully integrated with the glenoid bone and could not be removed after removing the screws. The screws and glenosphere were exchanged and a +6 mm medial offset polyethylene liner was introduced to replace one with a 0 mm offset. The patient’s pain was improved after revision surgery.
One patient had a deep infection and underwent a two-stage revision at 31 months post-operatively. The infecting organism was Staphylococcus epidermidis. Treatment involved removal of the prosthesis and introduction of a cement spacer followed by intravenous Teicoplanin for six weeks. A TM RTSA was used at the second stage and the infection resolved.

There were four complications that did not require further surgery. All were related to fractures around the shoulder. There was one fracture of the acromion diagnosed four months post-operatively (no trauma) and one of the spine of the scapula after a fall 16 months post-operatively. Two humeral periprosthetic fractures occurred intra-operatively: in these cases the stem was cemented and augmented with cerclage wires. Overall, the complication rate was 9.6% (12/125) when revision and fractures were included.

The mean pre- and post-operative ranges of movement are shown in Table II. These indicate improvement in mean active flexion and abduction (Student’s t-test, both p < 0.001). A statistically significant improvement in the mean OSS of 19 points was also found (t-test, p < 0.001). As the collection of the CMS data has only started recently, no pre-operative comparative scores were available (Table II). The latest post-operative scores, with a breakdown of the subsections of the CMS, are presented in Table III and compared with the post-operative pooled data from a recent systematic review of RTSA for patients with cuff tear arthropathy.

The grades of scapular notching are shown in Table IV. All patients with scapular notching were asymptomatic.

A total of five patients had RLLs in all zones around the humerus. These were non-progressive and asymptomatic. One patient had RLLs around the base plate but at revision surgery it was found to be fully integrated and was not revised, as described above.

The most recent radiographs were assessed for integration of bone into the base plate on AP and axillary lateral radiographs. A total of 124 glenoids were grade A (Fig. 1) and one was grade C. No glenoids were grade B.

<table>
<thead>
<tr>
<th>Notching Grade</th>
<th>Patients (n, %)</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>63 (50.4)</td>
</tr>
<tr>
<td>1</td>
<td>51 (40.8)</td>
</tr>
<tr>
<td>2</td>
<td>10 (8)</td>
</tr>
<tr>
<td>3</td>
<td>0 (0)</td>
</tr>
<tr>
<td>4</td>
<td>1 (0.8)</td>
</tr>
</tbody>
</table>

Discussion

This study shows that TM RTSA improved active flexion and abduction as well as the OSS: this is in line with previous reports.\(^2\),\(^12\) The mean post-operative OSSs showed both a statistically significant improvement and minimal clinically important difference (MCID) when compared to the mean pre-operative OSSs. A MCID of six for the OSS has been established as the smallest change in score that patients perceive to be important.\(^13\) In this study the mean difference was 19 points, which is more than three times the MCID, proving that the TM RTSA significantly improves pain and function in patients with cuff tear arthropathy. All components of the post-operative CMS scores (Table III) including pain, function, movement and strength were comparable to the pooled results of a recent systematic review of patients undergoing RTSA for cuff tear arthropathy.\(^2\)

To our knowledge, this study is one of the largest single-centre series reporting on any design of RTSA.\(^1\),\(^12\) It is also the only single-centre independent (non-designer) cohort reporting on this design of RTSA. The rate of complications...
and revision are comparable if not better than some contemporary studies on RTSA in patients with cuff tear arthropathy (Table V).4,8,14,15 The overall five-year all-cause survival is comparable to those which have been previously reported in the literature.

Sirveaux et al6 reported one of the earliest series of RTSA performed for cuff tear arthropathy and found a rate of survival of the implant of 91.3% at five years (80 RTSA). Guery et al5 reported a rate of survival of the implant of 91% at a minimum follow-up of five years, with a substantially better rate of survival in patients with arthropathy associated with a massive cuff tear as compared to other indications such as trauma, cuff tear without arthritis, recurrent dislocations in the elderly: they therefore suggested that cuff tear arthropathy was the best indication for a RTSA. The Norwegian Arthroplasty Register reported on a total of 225 RTSAs, all of which were the Delta III (DePuy) with a five-year survival of 90%.16 The most common reason for revision was aseptic loosening of the glenoid.

The National Joint Registry (NJR) in the United Kingdom started collecting data for all shoulder arthroplasties in 2012 and five-year survival data are not yet available. The 12th Annual NJR report shows a 2.5-year estimate of survival of about 97% (213 at risk) for all brands of RTSA for all elective indications.17 They report only 70 TM RTSAs for all elective indications: no separate analysis was performed on this design or the clinical indication.

The five-year survival of this prosthesis with revision for aseptic glenoid failure as the end-point was only 96.7% in our series. This is significantly better than that reported by Guery et al5 who had a rate of survival of the glenoid of 84% with loosening as the end-point at a minimum five-year follow-up for 80 arthroplasties. In their series four patients were revised for aseptic loosening of the glenoid component in the Delta RTSA.

In a series of 60 patients, Frankle et al18 found a rate of failure of the glenoid baseplate of 12% at a mean follow-up of 21.4 months, and attributed it to the use of 3.5 mm peripheral screws for fixation. Harman et al19 found that using peripheral screws of 5 mm diameter reduced micro-motion at the baseplate-bone interface to < 150 μm, which is generally the accepted threshold for bony ingrowth.20 In their follow-up study (114 RTSA), Cuff et al21 secured the baseplate with 5 mm screws and found no cases of loosening at a mean of 27.5 months. A further study evaluated 96 RTSAs, in which the baseplate was secured with locking screws: no failures were identified at a mean follow-up of two years.10 Frankle et al18 found that their eight failures in 60 RTSA occurred because of metal fatigue of the screws holding the baseplate at a mean of 21.4 months: they suggested that the first two years was a critical period because failure of bony ingrowth could result in early failure.18

In our series, three patients had early mechanical failure of the glenoid component attributed to malalignment of the glenosphere on the Morse taper of the base plate (Fig. 3). This occurred within the first year of using this system in our department. At the time, the manufacturer issued a notice highlighting the problem and we have had no further failures because of this. We developed a number of surgical tips to prevent this happening, including 360° exposure of the glenoid at the time of surgery and ensuring that the glenosphere is inserted in line with the Morse taper and impacted concentrically so that it is seated equally and in contact with the base plate as confirmed by palpation.

<table>
<thead>
<tr>
<th>Study</th>
<th>Joints (n)</th>
<th>Brand</th>
<th>Mean follow-up (mths)</th>
<th>Complications (%)</th>
<th>Revisions (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valenti et al15</td>
<td>76</td>
<td>Arrow (FHI)</td>
<td>44</td>
<td>18.4</td>
<td>13</td>
</tr>
<tr>
<td>Werner et al14</td>
<td>17</td>
<td>Delta III (Depuy)</td>
<td>38</td>
<td>50</td>
<td>33</td>
</tr>
<tr>
<td>Naveed et al6</td>
<td>60</td>
<td>Delta III (Depuy)</td>
<td>39</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>Wiater et al8</td>
<td>64</td>
<td>TM RTSA (Zimmer)</td>
<td>32</td>
<td>7.8</td>
<td>4.7</td>
</tr>
<tr>
<td>Current Series</td>
<td>125</td>
<td>TM RTSA (Zimmer)</td>
<td>32</td>
<td>9.8</td>
<td>6.4</td>
</tr>
</tbody>
</table>

FHI, Fournitures Hospitalières Industrie; TM, Trabecular Metal; RTSA, reverse total shoulder arthroplasty
The designer centre have published their results of 64 TM RTSAs with a mean follow-up of 32 months (Wiater et al). In all, three patients had instability which required revision. One patient with instability and recurrent dislocation underwent revision more than three years post-operatively. The other two revisions were in the same patient: one two months post-operatively because of dislocation after a fall and again five months after the revision because of recurrent instability. All revision operations for instability consisted of replacing an unconstrained liner with a thicker constrained liner. The second revision in a patient with an uncemented stem consisted of exchange of the baseplate, glenosphere and polyethylene as well as the use of a modular, metallic humeral spacer. They carried out no survival analysis but had five major complications (a 7.8% complication rate); two systemic complications (myocardial infarction, deep venous thrombosis) and three cases of late prosthetic instability requiring revision surgery (4.7% revision rate). These complication and revision rates are similar to ours using the same design of baseplate although our series had more than double the number of TM RTSAs and included a survival analysis. Furthermore, we analysed the final radiographic findings and assessed integration of bone into the baseplate, which was not done by Wiater et al. They had no radiographic baseplate loosening and we only had one, which was subsequently found to be fully integrated at the time of revision surgery.

Scapular notching was seen in 49.6% of our series, which is comparable to, if not slightly lower than, previously reported rates for RTSAs which have ranged from 44% to 96%. We did not have any complications as a result of scapular notching. The clinical relevance of notching is controversial. Some authors have reported no impact on post-operative function and others have described a negative correlation between scapular notching and outcome. We had a relatively low incidence compared to that described in the literature. The patients with notching were, however, asymptomatic and we conclude that scapular notching has little clinical impact under these circumstances.

In our series, five TM RTSAs had RLLs around an uncemented humeral stem in all Gruen zones. These were non-progressive and asymptomatic. Bogle et al and Wiater et al, in their studies of the same baseplate, found RLLs in two RTSAs, one in Gruen zones 1 and 7 and the other in zones 4 and 5. These were also asymptomatic. However, they used the TM proximally-coated humeral stem whereas we used a proximal grit-blasted stem. We believe that humeral loosening is not as common as glenoid loosening in RTSAs. This is also reflected in the literature. Revision surgery for glenoid loosening is more common than that for humeral loosening.

We had a high rate of glenoid bone integration: 124 of 125 glenoid components were fully integrated (Grade A) onto the TM baseplate at final follow-up. This is the first study to assess this for a porous-coated RTSA glenoid component. Bogle et al and Wiater et al who used the same baseplate did not formally analyse bony integration in their smaller series. The high level of integration may explain the low rate of loosening and high rate of survival of the glenoid component in our series. A recent systematic review of pooled results of RTSAs for patients with cuff tear arthropathy which included 1016 patients, showed a rate of loosening of the glenoid of 3.2% with an all-cause rate of revision of 5.4%.

The study has its limitations. These include a relatively short mean follow-up of 32 months, although this is comparable if not longer than in some series of RTSA in patients with cuff tear arthropathy. The availability of post-operative CMS scores only with no pre-operative scores means that the change or improvement could not be calculated although the latest scores have been compared with those in the literature. The grading of the integration of bone into the baseplate used in this study has also not been validated and may not be as accurate as CT imaging. However, in view of the porous nature of the baseplate, we believe that some attempts should be made to assess the integration of bone. Early to medium-term results are justified given the paucity of literature on this combination of TM glenoid baseplate and design of humeral stem.

The main strength of this study is the large cohort of patients from a single centre, with a single design of arthroplasty used for a single indication. Continued monitoring of the outcomes is warranted with particular focus on RLLs around the humeral stem and the long-term clinical performance of the glenoid component.

In conclusion, we found that adequate and reliable fixation can be achieved using the TM RTSA in patients with cuff tear arthropathy. The results are similar to those in systematic reviews which use other devices for this indication. Medium-term clinical outcomes show reliable pain relief with improvement in functional outcome and movement of the shoulder.

Take home message:
RTSA using a trabecular metal glenoid base plate is safe and effective with good medium-term clinical outcomes and survivorship which are comparable with other designs of reverse shoulder prosthesis.

Author contributions:
K. Theivendran: Data Collection, Data analysis, Writing paper, Literature search.
M. Varghese: Data Collection, Data analysis, Writing paper, Literature search.
M. Large: Data Collection, Data analysis, Writing paper, Literature search.
D. I. Clark: Study design, Performed operations, Literature search.
M. Bateman: Study design, Data collection and analysis.
M. Morgan: Study design, Data collection and analysis.
A. Tambe: Study design, Performed operations, Literature search.
M. Espag: Study design, Performed operations, Literature search.
T. Cresswell: Study design, Performed operations, Literature search.

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References


