Mid-term results of a metal-backed glenoid component in total shoulder replacement

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Total shoulder replacement is a successful procedure for degenerative or some inflammatory diseases of the shoulder. However, fixation of the glenoid seems to be the main weakness with a high rate of loosening. The results using all-polyethylene components have been better than those using metal-backed components. We describe our experience with 35 consecutive total shoulder replacements using a new metal-backed glenoid component with a mean follow-up of 75.4 months (48 to 154).

Our implant differs from others because of its mechanism of fixation. It has a convex metal-backed bone interface and the main stabilising factor is a large hollow central peg. The patients were evaluated with standard radiographs and with the Constant Score, the Simple Shoulder Test and a visual analogue scale. All the scores improved and there was no loosening, no polyethylene-glenoid disassembly and no other implant-related complications.

We conclude that a metal-backed glenoid component is a good option in total shoulder replacement with no worse results than of those using a cemented all-polyethylene prosthesis.

Although it was the first joint to be replaced,1 replacement of the shoulder is a less common procedure than other joint replacements such as of the hip or knee. However, it is the treatment of choice for degenerative and some inflammatory pathologies of the gleno-humeral joint and for certain proximal humeral fractures. Total shoulder replacement (TSR) leads to better relief of pain, range of movement (ROM) and patient satisfaction than hemiarthroplasty.2

Despite the high success rate of shoulder replacements3-10 complication rates of 10% to 15% are reported in the literature.11-14 Complications are various including intra-operative fracture, dislocation, loosening, heterotopic ossification, sepsis, vascular or neurological injury, fracture, dissociation of the components and polyethylene wear. While the absence of complications does not guarantee a good clinical result and some complications such as intra-operative fracture or dislocation do not necessarily lead to a bad outcome, loosening of either component results in a failure of the implant in the majority of cases.15

Matsen et al12 concluded that loosening is the most common complication of TSR with a 32% incidence of progressive glenoid loosening. Hasan et al15 found that 59% of failed TSRs had loosening of the glenoid component. Sperling, Cofield and Rowland16 identified radiolucent lines adjacent to 59% of glenoid components and Torchia and Cofield,17 analysing 89 TSRs at a mean follow-up of 12 years, found radiolucencies around 75 glenoid components (84%) and reported 39 glenoid loosenings (44%). Glenoid replacement is thus the weak link in shoulder replacement.

According to the experience of Neer in the 1970s, the early glenoid prostheses implanted were cemented all-polyethylene components and after the poor results of these implants, metal-backed uncemented glenoids were gradually introduced.18

The experience with these prostheses was initially good, but complications increased significantly at mid-term follow-up.19,20 The current focus has therefore returned to all-polyethylene cemented components. However, the few published studies on metal-backed glenoid components are related to similar designs with a flat shape and fixation with two screws.19,20

The aim of this study was to evaluate the stability of a metal-backed glenoid component that has a significantly different design at a mid-term follow-up.
Patients and Methods

We followed a series of 35 consecutive TSRs (35 patients) with a new design of metal-backed glenoid component (SMR System, Lima Corporate, Villanova, Italy), implanted between 1996 and 2005.

The aetiology was rheumatoid arthritis (RA) in three patients (8.6%), post-traumatic arthritis in five (14.2%) and idiopathic osteoarthritis in 27 (77.1%). There were 19 (54.3%) women and 16 (45.7%) men with a mean age at the time of operation of 62.7 years (55.3 to 70.1). All patients had pre-operative true anteroposterior (AP) and axillary view radiographs and MR scans. Radiographs were taken with the patient in an upright position with their back to the film which was rotated through 45° so that the glenohumeral joint was projected as a line. All the images were pre-operatively evaluated by a single observer (MB).

The shape of glenoid erosion was classified according to the criteria of Walch using an MRI standardised protocol. We found 27 glenoid type A1-A2, 15 (42.8%) type A1 and 12 (34.3%) type A2, six (17.0%) type B1 and two (5.7%) type B2. MRI was used also to evaluate the rotator cuff. For this operation we selected those with no cuff tear. We evaluated fatty infiltration according to the MRI modified classification of Goutallier. A total of 30 patients (85.7%) had a grade 0 to 1 fatty degeneration of the infraspinatus (11 grade 0 and 19 grade 1), two patients (5.7%) had grade 2 fatty degeneration, while the three (8.6%) with RA had grade 3.

The Constant Score, the simple shoulder test and a visual analogue scale (VAS) to evaluate the pain were recorded on the day before the operation.

All the evaluations were performed by a single experienced orthopaedic surgeon (MB) and the strength for the Constant score was evaluated with a Lafayette Manual Muscle Test System dynamometer (Lafayette Instrument Company, Lafayette, Indiana).

Surgical technique. The implant. A press-fit cementless humeral component was used with the cementless metal-backed glenoid component. This has a titanium alloy shell coated with porous titanium and hydroxyapatite (SMR System) (Fig. 1). It has a slightly convex backing with a concave glenoid-polyethylene surface in order to reproduce the normal anatomy of the glenoid with a non-conforming and less constrained interface.

The prosthesis is available in three sizes: Small R, Small and Standard. There is no difference in the radius of curvature between the metal back and the bone in the three sizes and the value is 28.5 mm. The radius of curvature of the ‘liner’ between the polyethylene and the humeral head is 32.5 mm in the Small R and Small glenoid and 35 mm in the Standard size (Fig. 2). As the humeral heads have different sizes with different radii of curvature and can be used with every size of glenoid, the mismatch between the humeral head and the surface of the glenoid is variable (Table I).
cancellous screws are inserted superiorly and inferiorly and a standard polyethylene insert is positioned.

The humeral component is then inserted and after reduction of the shoulder, the subscapularis is repaired with four Ethibond number 2 sutures (Ethibond Ethicon, Somerville, New Jersey).

The arm is rested in a sling for four weeks, passive movement then follows for two to three weeks and then active movement is initiated.

**Evaluation.** The patients were followed clinically and radiologically with a true AP radiograph and an axillary view at three months, six months, one year, and then annually. The mean follow-up was 75.4 months (48 to 154).

One surgeon (RG) assessed the Constant score, the simple shoulder test, and pain at every clinical evaluation. For the radiological evaluation, the positioning of the glenoid implant and the presence of radiolucent lines were evaluated according to the Molè classification adapted to the shape of this glenoid. In particular on the AP radiograph, six zones around the component were defined, and the width of the radiolucent lines in all the six zones measured (Fig. 3). Radiological loosening was defined as a progressive translucency around the glenoid component of ≥ 2 mm or more in one zones or a change in the position of the component.

Two independent observers, a surgeon and a radiologist not involved with the study, who were blinded to the identity and clinical outcomes of the patients, separately reviewed the radiographs with a minimum follow-up of four years and discussed their analyses until both had agreed a final score.

**Statistical analysis.** This was performed using the Mann-Whitney U test to evaluate significant differences between the pre- and post-operative values of the Constant scores with a p-value set at p < 0.05.

**Results**

There were no intra-operative or immediate post-operative complications and no superficial or deep infections. At the last follow-up, periprosthetic radiolucent lines < 2 mm with reactive bone sclerosis near the peg were found in eight patients (22.9%). In three of these there was also an area of resorption near the superior screw. In three cases the radiolucent lines progressed during the first two years and then stopped by the next follow-up. In the other 27 patients (77.1%) no radiolucent lines were observed (Fig. 4).

No shift or tilt of the glenoid and no polyethylene-glenoid disassembly were found. In three patients (8.6%) the superior screw was seen to be outside the glenoid in the immediate post-operative radiograph, but the central peg and the inferior screw were in the correct position in all the patients.

In five patients (14.3%) there was minor posterior subluxation of the humeral head, but the clinical scores were satisfactory.

The mean VAS improved from 7.8 (6 to 19) to 3.1 (1 to 6). The mean Constant score improved from 35.2 (14 to 48) to 70.8 (53 to 84). The mean simple shoulder test score changed from a negative answer of 8.4 (6 to 11) to 4.4 (3 to 7).

Improvement in the Constant score was highly significant (p < 0.001) (Mann-Whitney U test). We did not find any correlation between the clinical scores and the position of the glenoid, the screws or the humeral head. None of the patients underwent a revision operation in the period of follow-up.

All the patients were satisfied with the operation and would choose the same procedure again. Three patients subsequently underwent replacement of the other shoulder.
Their second procedure is not included in this study because of insufficient follow-up.

Discussion

TSR is a satisfactory treatment for the painful and severely osteoarthritic glenohumeral joint although there has been some dispute about its long-term outcome.2

The main concern is loosening of the glenoid component, which can be difficult to diagnose and is usually a radiological diagnosis. Sometimes it can be seen easily on a standard AP radiograph with a shift of the component, but in most cases it can only be inferred by the presence of radiolucent lines. In a few cases, there is no radiological evidence of glenoid loosening but its presence is assumed because of pain or a sudden reduction of the range of movement. In such cases, the failure is revealed only at the time of the revision operation.

In the literature, the prevalence of radiolucent lines in TSR is reported to range from 22% to 95%, and they are present in both cemented and uncemented glenoids. However, measurements of radiolucency using plain radiographs are prone to error and standardisation of the position of the patient is difficult because of scapular mobility and individual anatomical variation. The absence of a standardised scoring system makes a comparison of the results difficult. Clinical and radiological studies with cemented designs have indicated an incidence of progressive radiolucent lines at the cement-bone interface of between 33% and 50%.

There are few studies addressing outcomes using uncemented glenoid components. Early clinical and radiological observations with such implants have shown encouraging results with a low prevalence of loosening. In particular, Wallace et al. analysed 32 cemented glenoids and 26 uncemented glenoids at a mean follow-up of five years and found that, despite a higher rate of early complications related to dissociation of the polyethylene component from the metal tray and instability, the fixation of the glenoid without cement provided a clinical outcome comparable to fixation with cement in terms of relief of pain, subjective functional capacity and range of movement. Radiolucent lines and the proportion of implants classified as ‘probably loose’ was higher in the group with cemented glenoids.

Other studies have reported failure of different types of metal-backed implant by loosening of the baseplate and polyethylene wear. In particular, Boileau et al. in a prospective, double-blind randomised study, analysed 20 metal-backed with 20 all-polyethylene cemented glenoids and concluded that, at a minimum of three years of follow-up, the functional results were better in the non-cemented group; the rate of radiolucent lines was higher in the cemented group (85% compared with 25% in the metal-backed group), but the survivorship of a cementless metal-backed glenoid was inferior to a cemented all-polyethylene component. Revision was required in 20% of the metal-backed group compared with 0% in the all-polyethylene cemented prostheses.

Cofield reported his experience of 180 tissue in-growth glenoid components, with less than two years of follow-up in 88 shoulders. He recorded nine complications in 28 cases (16%) including rotator cuff failure, glenohumeral instability, fracture and neuropraxia. Radiolucent lines were present in six cases (3.3%). In one case (0.5%) there was a glenoid shift, but in five (2.7%) he found a dissociation between the polyethylene and the metal tray.

Martin et al. described their experience with an uncemented glenoid component in 140 shoulders with a mean follow-up of 7.5 years. They reported radiolucent lines in 53 cases (37.8%) with 21 (15%) radiological failures and 16 (11.4%) clinical failures, ten of which were also radiological failures. In 11 shoulders (7.8%) there was...
radiological failure without clinical symptoms. However, the 16 clinical failures included two fractured metal-backed glenoid components and nine polyethylene delaminations-dissociations and only five cases of aseptic loosening.

Finally, Fox et al.,38 in a recent review of the Mayo Clinic experience, examined 1542 primary arthroplasties performed between 1984 and 2004. There were 99 all-polyethylene (Neer II), 254 metal-backed (Neer II), 316 metal-backed (Cofield 1), 18 all-polyethylene (Cofield 1), and 855 all-polyethylene (Cofield 2) glenoid components. The number of glenoid revision or removals was 121 (7.8%), but the revision for a glenoid-related cause, including polyethylene or metal wear and loosening, was 77% (4.9%). Analysing this data in the five groups, they found that the revision rate for an all-polyethylene glenoid was 15% (1.5%) and 62% (10.8%) for a metal-backed component. Revisions for polyethylene or metal wear were only in the metal-backed groups. He concluded that the causes for failure of the metal-backed glenoid were wear of the polyethylene or metal, loosening related to osteolysis, instability due to asymmetric polyethylene wear and to the thickness of the glenoid component which can create a Bankart-like lesion.

There are several possible explanations for our good results using this new metal-backed glenoid component. The first is the shape of the glenoid. Wirth et al.39 suggested that the most critical implant-related features are size, the conformity of the articular surface and the type of fixation in the scapula. Hertel and Ballmer40 concluded that the glenoid components commonly available may cover an excessive amount of the humeral head and that this may result in limitation of glenohumeral movement with and abutment of the humerus against the glenoid rim and a high risk of glenoid loosening.

Other studies have shown that implants with a more conforming design have increased constraint which limits translation of the humeral head during movement which can stress the fixation. However, less conforming designs have a lower surface area which can lead to increased wear. This leads to the conclusion that implants with a radial mismatch of 6 mm to 7 mm provide the best clinical results with the lowest incidence of radiolucent lines.41,42

Szabo et al.43 evaluated the radiological results of flat- and curved-back glenoids in 66 TSRs and found that in the immediate post-operative period 65% of curved-back glenoids had no radiolucent lines compared with 26% of the flat-back components. After two years radiolucent lines were present in 100% of the implanted glenoids, but the radiolucency scores were worse in the flat-back group.43

Anglin, Wyss and Pichora44 conducted a laboratory analysis comparing the resistance to loosening associated with flat- and curved-back designs of glenoid when subjected to cyclic, eccentric loading. He concluded that curved-back glenoids were associated with nearly 50% less distraction than that of the flat-back implant.44

The second issue is the polyethylene component which can create two different, but related problems, namely polyethylene wear and overstuffing of the joint.

The use of a highly stiff and thick metal-backing (5 mm) offered rigidity to the implant with reduced stresses in the polyethylene component and the underlying bone, but these reductions depend on the thickness and the shape of the metal backing. The positive effect is that stresses in the polyethylene component are reduced by 20% in comparison to the cemented total polyethylene design, with a decrease in the risk of polyethylene wear, but the negative effect is that using thicker metal-backing resulted in higher metal-bone and polyethylene-metal interface stresses, which may lead to an interface disruption with separation of the component from bone or separation of polyethylene from the metal-backing.45,46

It is difficult to evaluate polyethylene wear in the absence of radiological changes so the surgeon may have to rely on clinical suspicion raised by reduced movement. Our data seem to be stable over time with no sudden changes and so in the absence of other evidence we consider our rate of wear to be clinically significant.

Wirth et al.47 compared the wear properties of polyethylene sterilised with gas plasma with polyethylene sterilised with 50 kGy gamma irradiation using the same glenoid design. He found that the second group had an 85% reduction in gravimetric wear compared with the first group.

The third and probably the main issue for our results is the fixation of the glenoid. Previous results,19,20,37 referred to a flat implant fixed only with screws. In our design the two screws are only important for the initial fixation; the main stabilising element is the central hollow peg that provides durable anchorage due to bone ingrowth.

A weak point of this study is the short follow-up. However, the incidence of radiological loosening of the glenoid components after nine years is between 24% and 44%,17,30,48 and after three years3,5,6,29,49 it is between 0% and 15%. Other studies19,37 have reported a mean time to glenoid revision of between 2 to 3 years so a mean follow-up of 6.2 years in our study may be enough to give an indication of the potential loosening of this component.

We believe that metal-backed cementless implants can still be considered for glenoid replacement and that the results obtained are no worse that those with the cemented all-polyethylene glenoid.

Supplementary material

A table showing the patient details is available with the electronic version of this article on our website at www.jbjs.org.uk

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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References


