The Metasul metal-on-metal articulation in primary total hip replacement

CLINICAL AND RADIOLOGICAL RESULTS AT TEN YEARS

We report the clinical and radiological outcome at ten years of 104 primary total hip replacements (100 patients) using the Metasul metal-on-metal bearing. Of these, 52 had a cemented Stuehmer-Weber polyethylene acetabular component with a Metasul bearing and 52 had an uncemented Allofit acetabular component with a Metasul liner. A total of 15 patients (16 hips) died before their follow-up at ten years and three were lost to follow-up.

The study group therefore comprised 82 patients (85 hips).

The mean Oxford score at ten years was 20.7 (12 to 42). Six of 85 hips required revision surgery. One was performed because of infection, one for aseptic loosening of the acetabular component and four because of unexplained pain. Histological examination showed an aseptic lymphocytic vasculitis associated lesion-type tissue response in two of these. Continued follow-up is advocated in order to monitor the long-term performance of the Metasul bearing and tissue responses to metal debris.

In the 1960s, both metal-on-metal and metal-on-polyethylene bearings were used in total hip replacement (THR). In the United Kingdom, THR using a metal-on-polyethylene articulation was pioneered and popularised by Charnley.1,2 Implants with metal-on-metal bearings were developed and used by McKee and Watson-Farrar3 in the 1960s, and McKee and Chen4 and Ring5 throughout the 1970s. By the end of the 1970s there was a widespread perception that the metal-on-polyethylene articulation gave better clinical results1,2 and this became the preferred articulation for primary THR throughout the 1980s.

Despite this trend, Weber6 in Switzerland observed that a proportion of Müller-McKee metal-on-metal THRs implanted in the late 1960s, continued to function well at their review at ten years. He questioned whether the reported high rate of loosening of prostheses with a metal-on-metal bearing was because of the unsuitability of the bearing materials and suggested that appropriately-manufactured metal-on-metal articulations would offer dramatically lower wear than that of metal-on-polyethylene. Weber secured the support of Sulzer Brothers Limited (Sulzer Inc., Winterthur, Switzerland) to manufacture the Metasul-bearing couple and was able to use this articulation from 1988 onwards.

We have implanted the Metasul bearing, in selected cases, from the beginning of 1995 and now report the clinical and radiological outcome at ten years for our first 100 patients.

Patients and Methods

Between January 1995 and June 1997, 476 primary THRs were undertaken at our institution. Of these, the Metasul articulation was used in 100 patients (104 hips) in whom we were unable to undertake hip resurfacing, but who were active, had good bone quality and required an implant with a long life.

There were 60 women (64 hips) and 40 men (40 hips) with a mean age at surgery of 61.6 years (44 to 84) and a mean length of follow-up of 10.8 years (10.2 to 12.2).

A polished, cannulated, Allopro CF30 femoral component (Sulzer) was used in all the THRs. Alignment was controlled during insertion by the removable, central guide-wire which was screwed distally into the central channel through the Allopro cement plug. A third-generation, retrograde cementing technique was used with two mixes of Palacos R bone cement (Schering-Plough Ltd, Welwyn Garden City, United Kingdom). A long, medium or short 28 mm Metasul femoral head was selected in order to optimise leg length and tissue tension.

A Stuehmer-Weber polyethylene acetabular component with a Metasul bearing was cemented with a single mix of Palacos R cement in 52 THRs. The mean outer diameter
of these components was 52 mm (44 to 64). An Allofit uncemented component (Sulzer) with a Metasul insert was implanted in the other 52. The mean outer diameter of these components was 54.2 mm (48 to 60).

Three consultant orthopaedic surgeons (REF, TGK, JKK) undertook 87% of the procedures and the remaining 13% were carried out by a total of eight trainees. All the procedures were performed in laminar-airflow operating theatres, with the patients in the lateral de cubitus position. The anterolateral approach to the hip was used in 77 hips and the posterior approach in 27.

Pre-operatively, the diagnoses were osteoarthritis in 97 hips, inflammatory arthritis in two, developmental dysplasia in two, congenital dislocation of the hip in one, old osteomyelitis in one and avascular necrosis of the hip in one.

All the patients were given three doses of intravenous antibiotic prophylaxis (cefuroxime 750 mg) and low-molecular-weight heparin (enoxaparin 20 mg, subcutaneously, once daily) was prescribed for five days after surgery. Unrestricted weight-bearing was from the first post-operative day.

In 1999, we established a joint replacement register and surveillance programme into which the patients who had received a Metasul prosthesis were enrolled. Formal clinical and radiological evaluation was only undertaken for the final 12 hips, at two years post-operatively. Patients were also evaluated annually, from 1999, by postal questionnaire using the Oxford hip score.7

Table I. Pre-revision assessment of five patients undergoing revision

<table>
<thead>
<tr>
<th>Patient</th>
<th>Interval to onset of symptoms (mths)</th>
<th>Interval to revision (mths)</th>
<th>Radiological findings</th>
<th>Inflammatory markers</th>
<th>Isotope bone scanning</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11</td>
<td>13</td>
<td>No evidence of loosening</td>
<td>NA</td>
<td>Increased tracer uptake at the neck and tip of the femoral prosthesis, greater trochanter and acetabulum</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inclination of acetabular cup: 44°</td>
<td></td>
<td>White cell scan: inflammatory process at the upper end of the prosthesis</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>26</td>
<td>No evidence of loosening</td>
<td>ESR 56 CRP 116</td>
<td>Increased uptake around femoral neck and acetabulum</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inclination of acetabular cup: 42°</td>
<td></td>
<td>White cell scan normal</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>54</td>
<td>No evidence of loosening</td>
<td>ESR 29 CRP 12</td>
<td>Normal</td>
</tr>
<tr>
<td>4</td>
<td>44</td>
<td>48</td>
<td>No evidence of loosening</td>
<td>ESR 56 CRP 24</td>
<td>Normal</td>
</tr>
<tr>
<td>5</td>
<td>103</td>
<td>108</td>
<td>No evidence of loosening</td>
<td>ESR 48 CRP 13.1</td>
<td>Increased uptake over greater trochanter and medial aspect of the neck</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inclination of acetabular cup: 41°</td>
<td></td>
<td>White cell scan normal</td>
</tr>
</tbody>
</table>

NA, not available, ESR, erythrocyte sedimentation rate (mm/hr); CRP, C-reactive protein (mg/l)

Acetabular radiolucent lines were measured according to the zones described by DeLee and Charnley.10 Femoral radiolucent lines were analysed as described by Gruen, McNiece and Amstutz.11 A radiolucent line was recorded only if it occupied at least 50% of the zone. Migration of the acetabular component was measured using the inter-teardrop line and Kohler’s line as reference.12 Migration of the acetabular component was defined as significant if there was a > 3 mm linear change (medial, superior or both) in relation to either Kohler’s or the inter-teardrop line.12 Heterotopic ossification was evaluated using the criteria described by Brooker et al.13 Measurements of wear were not performed. The acetabular inclination angle was measured on a post-operative standing pelvic radiograph.

For a non-randomised comparison group, we investigated the revision rate for 372 primary metal-on-polyethylene THRs in 355 patients with a mean age of 73.3 years (48 to 91) and mean follow-up of 11.3 years (10 to 12.5) performed during the same study period.

Statistical analysis. Survivorship analysis was performed using Graph Pad Prism statistical software version 5.0 for Windows (Graph Pad Software Inc, San Diego, California). The survival rate was calculated using Kaplan-Meier survivorship curves with 95% confidence intervals (CI).

Results

Of the 100 patients, 15 died before their ten-year review. In each of these cases, the cause of death was obtained and none was related to the THR and all had well-functioning hips at the time of their demise. In five, cancer was cited as a contributory factor in their death. No patient had a local tumour. This incidence of cancer-related deaths is consistent with the expected incidence in the United Kingdom.14 Three patients were lost to follow-up. Consequently, 82 patients (85 hips) were available for complete clinical, radiological and self-assessment at ten years after their operation.
Table II. Operative finding at revision and outcome in five patients undergoing revision

<table>
<thead>
<tr>
<th>Indication for revision</th>
<th>Tissue appearance at revision</th>
<th>Cultures</th>
<th>Histological findings</th>
<th>Component stability</th>
<th>Revised to</th>
<th>Outcome of revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>Abscess arising from the prosthesis</td>
<td>Staphylococcus aureus with multiple sensitivities</td>
<td>NA*</td>
<td>2-stage revision</td>
<td>Pain-free. Oxford score 16 at ten years post revision</td>
<td></td>
</tr>
<tr>
<td>Suspected infection</td>
<td>Clear bursal sac fluid No pus in joint Necrotic tissues</td>
<td>No growth in multiple tissue specimens</td>
<td>NA</td>
<td>2-stage revision</td>
<td>Died two years post-revision with well-functioning hip in situ</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>Invasive and florid grey-stained synovitis and thick white subsynovial layer Synovium dissecting soft tissues from peri-acetabular bone</td>
<td>No growth in multiple tissue specimens</td>
<td>Both acetalular and femoral components well fixed</td>
<td>Metasul liner exchanged with polyethylene liner</td>
<td>Underwent re-revision for instability two years post-revision Oxford score 12 at five years after second revision</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>No evidence of infection</td>
<td>No growth in multiple tissue specimens</td>
<td>ALVAL†-type changes</td>
<td>Revised to un cemented ANCA fit cup and Profemur R Stem‡</td>
<td>Pain-free. Oxford score 22 at eight years post-revision</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>Inflamed synovium</td>
<td>No growth in multiple tissue specimens</td>
<td>ALVAL-type changes</td>
<td>Both acetalular and femoral components well fixed</td>
<td>Metasul liner exchanged to polyethylene liner</td>
<td>Pain-free. Oxford score 12 at two years after exchange of liner</td>
</tr>
</tbody>
</table>

* NA, not available
† ALVAL, aseptic lymphocytic vasculitis associated lesion
‡ ANCA fit uncemented cup and Profemur R revision stem (Wright Cremascoli Ortho Ltd, Chester, UK)

Surgical complications. Three patients had a dislocation during the early post-operative period. All were treated by closed reduction and had no sequelae. One had deep-vein thrombosis and was treated with warfarin. Three developed a superficial wound infection which resolved after antibiotic therapy. Two required further surgery to excise heterotopic bone.

Revision. Of the 85 hips (7.1%; six patients) underwent revision surgery. Five of these revisions were undertaken at our hospital. In only one were we able to culture an organism which was believed to be clinically significant. This was *staphylococcus aureus* with multiple sensitivities. A two-stage revision proved to be successful and the patient remained well with a revision Metasul hip replacement. Her Oxford score was 16 at ten years after the revision surgery.

Tables I and II give the pre-revision assessment, operative findings and results after revision in five patients.

The sixth patient had undergone THR at the age of 44 years and developed further symptoms 7.5 years later. Plain radiography showed loosening of the cemented Stuehmer-Weber acetabular component, although inflammatory markers such as the erythrocyte sedimentation rate (ESR) and level of C-reactive protein (CRP) were not elevated. The patient had moved to France and elected to have his hip revised there. We were unable to obtain details of the revision procedure.

In one patient (case 5) the operative appearance was unusual. The synovium appeared to be inflamed throughout the joint. Multiple specimens were taken for frozen section, culture and sensitivity. None revealed any signs of infection. Neither the un cemented Allofit acetalular component nor the femoral component appeared to be loose. However, there was marked resorption of the medial calcar (Fig. 1). The Metasul acetabular liner was replaced by a polyethylene liner. Histological examination of the synovium showed perivascular T-cell infiltrate and haemosiderin-laden macrophages, consistent with metal sensitivity.

Oxford hip scores. The mean Oxford hip score at ten years was 20.7 (12 to 42) and the mean scores throughout the follow-up period are shown in Figure 2.

Radiological findings. Of the 79 hips (76 patients) which remained in situ, radioluencies were identified at the implant-bone interface of 14 cemented (13 patients) and three uncemented acetabular components (3 patients). Of these, 13 (13 patients) had a radiolucent line in one zone and four in two zones. None had a circumferential radioluency affecting all three zones and all radiolucent lines were < 2 mm thick. No hip had radiological evidence of pelvic osteolysis and we were unable to detect migration of any acetabular component.

On the femoral side, a radiolucent line was seen in at least one zone of the cement-bone interface in 47 components (45 patients). Of these, 16 (16 patients) had a radiolucent line in one zone, 13 (13 patients) in two zones, nine (nine patients) in three zones, four in four zones (four patients), four in five zones (four patients) and one in six zones. None had a circumferential radioluency and no radiolucent lines were seen at the cement-prosthetic interface.
The formation of heterotopic bone, classified according to Brooker et al., was grade 0, 1, 2 and 3 in 57 (54 patients), 16 (16 patients), four (four patients) and two hips (two patients), respectively. No femoral component was loose and there was no evidence of cortical hypertrophy, endosteal calcification or focal osteolysis.

The mean acetabular inclination angle was 44.5° (30.0° to 59.4°) with 94% (74 hips) of acetabular components having an inclination angle of between 35° and 55°. The inclination angles of the bearings which failed were 44°, 42°, 41°, 41° and 50°. There was no relationship between the radiolucent lines as seen on plain radiographs and the acetabular inclination angle.

Digital radiological analysis of the position of the femoral component showed that 75 (95%) were in neutral alignment, two were in 2° valgus and two in 2° varus. There was no relationship between the position of the component, Oxford hip score and radiolucent lines.

Failures and survivorship analysis. Kaplan-Meier survivorship curves for the Metasul bearing, with revision for any reason as an endpoint are shown in Figure 3 and show survivorship of 94% at ten years. Using aseptic loosening as the endpoint, the survival of the acetabular component at ten years was 99% and that of the femoral component was 100%. Using revision for any reason as the endpoint, the survival at ten years was 96% for both the acetabular and femoral components.

As an indirect comparison, 26 (7%) of 372 primary THRs implanted at our institution during the same period as those in our study, were revised.

Discussion

Several studies describing the short- to medium-term results of second-generation metal-on-metal Metasul THRs have been published. To date, the study of Sharma et al provides the longest follow-up with a mean of 7.33 years.
To our knowledge, our study is the first to report the results of the Metasul metal-on-metal articulation with a minimum follow-up of ten years.

Dorr et al.\(^1\) reported a rate of aseptic loosening of the acetabular component of 2% in a study of 56 prostheses with a mean follow-up of 5.2 years. Long et al.,\(^1\) whose patients were followed up for a mean of 6.3 years, reported a revision rate of 3.7%. However, none of the revisions were a result of aseptic loosening. Two acetabular components were revised because of suspected hypersensitivity. Histological examination in these patients did not confirm lymphocyte-mediated hypersensitivity. Saito et al.\(^1\) reported a survival of 99% at a mean follow-up of 6.4 years. Sharma et al.,\(^1\) with a mean follow-up of 7.33 years, reported a survival of 95.5%, with aseptic loosening as the endpoint. These studies indicate that the early and mid-term clinical results with this prosthesis are as good as those for conventional metal-on-polyethylene implants, and were better than first-generation metal-on-metal implants. None of the previous studies of the Metasul hip described an aseptic lymphocytic vasculitis associated lesion (ALVAL) or hypersensitivity reactions in their patients.

In our direct comparison group, metal-on-polyethylene THRs were generally implanted in patients who were older than those with the Metasul hips and this was a non-randomised group. However, using revision for any reason as the endpoint, the Metasul group did not show a higher rate of failure at ten years.

A limitation of the radiological analysis of metal-on-metal implants is the inability to measure articular wear from plain radiographs. However, we did not observe any evidence of dissociation of the metal liner from the surrounding polyethylene.\(^2\) We were unable to obtain pre-operative Oxford scores for our series since this only became available towards the end of our recruitment period and was not adopted at our institution until 1998. The mean Oxford score at ten years was 20.7 (SD 9.5) and the mean scores during the follow-up period (Fig. 3) were consistent with the expected level after a THR.\(^3\) A third potential criticism was that we initially used the cemented Stuehmer-Weber acetabular component and changed to the Allofit uncemented component during the study period. Our series comprised equal numbers of the two components and we did not identify a significant difference in the outcome of the two types of component.

Some McKee-Farrar implants demonstrated an unacceptable rate of early acetabular loosening.\(^4,22\) Radiological evidence of acetabular loosening was only present in one of our six revisions and this took over seven years to develop. One of the remaining five acetabular components was removed easily, the remainder were firmly fixed. Of these, two were revised and two had exchange of the liner. With regard to the femoral components, we observed lucency in a varying number of Gruen zones but always of < 2 mm and without associated radiological evidence of loosening. We interpreted the calcar bone loss shown in Figure 1 as a form of osteolysis, but this was non-cavitatory and there was no compromise of the implant-bone interface. The histological finding of T-cell infiltration would be consistent with an ALVAL-type response.\(^23\) Histological examination demonstrated ALVAL-type changes in two of our six failures (revision cases 4 and 5). In three further cases we were unable to obtain histological reports, but this diagnosis remains likely, based upon our pre-operative investigations and operative findings. A possible total failure rate of 5% from ALVAL is of concern since metal hypersensitivity/ALVAL as a mechanism of failure in THR is less likely with metal-on-polyethylene bearings. The time to onset of symptoms for our two patients with histological confirmation of an ALVAL-type response was 44 and 103 months. If these cases were caused by the local load of metal debris then such a late onset in previously asymptomatic joints may indicate increasing wear long after the bearing’s initial ‘wearing-in’ phase.

The failure rate demonstrated in our series falls well within recommended targets specified by the National Institute for Clinical Excellence\(^24\) and the Orthopaedic Data Evaluation Panel.\(^25\) It remains to be seen whether the Metasul bearings will continue to perform satisfactorily during the next decade. The lucencies around the cement-bone interface of both femoral and cemented acetabular components are of interest. The aetiology of a lucent line is not fully understood and it will be interesting to see whether those observed in our patients remain static or progress. In the event of further revisions, we will seek to determine whether polyethylene and/or metal debris is present in the membrane at the cement-bone or implant-bone interfaces. A similar study would be valuable on any post-mortem retrievals which might be obtained. An unusual pattern of calcar resorption has been seen in conjunction with ALVAL-like histological changes. Again, it will be interesting to see whether this problem changes in prevalence in the second and third post-operative decades.
We wish to thank Mrs J. Riordan for running the Joint Replacement Review Programme at St Helier Hospital, Carshalton. Her dedication and diligence have ensured that we were able to undertake this review. We also thank Mr T. G. Kavanagh and Mr J. K. Klosok for allowing us to include their patients in this review.

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References