Osteolysis with a cementless second generation metal-on-metal cup in total hip replacement

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Abstract This study examined the long-term results of a metal-on-metal total hip replacement with a Metasul-lined cup. Twenty-nine total hip arthroplasties were performed in 27 young patients (mean age 49 years). Twenty-two patients (23 hips) were available for clinical and radiographic analysis after a mean duration of 99 months. Mean preoperative Harris hip score of 60 improved to 93 at most recent follow-up. One patient required revision of his cup for periacetabular osteolysis. Radiographic analysis showed osteolysis in another four hips. The high rate of osteolysis found in this series has not previously been reported with this type of implant. The length of follow-up in this series is greater than other reports in the literature and may explain this difference.

Résumé Cette étude permet d'examiner les résultats à long terme des prothèses totales de hanche métal/métal de type Métasul. 29 prothèses totales de hanche ont été réalisées chez 27 patients relativement jeunes (âge moyen 49 ans). 22 patients (23 hanches) ont des résultats utilisables avec revue radiographique après un temps moyen post-opératoire de 99 mois. Le score moyen de Harris pré-opératoire a été amélioré de 60 à 93 au dernier suivi. Un patient a nécessité une révision de la cupule du fait d'une ostéolyse acétabulaire. L'analyse radiographique a montré une ostéolyse dans 4 autres hanches. Le taux important d'ostéolyse dans cette série n'a jamais été rapporté avec ce type d'implants. Le

temps de surveillance de cette série est plus important que dans les autres séries de la littérature et peut expliquer cette différence.

Introduction

Wear-related osteolysis with metal-on-polyethylene articulations [23] has led to a resurgence of interest in metal-on-metal bearings. Second generation metal-on-metal bearings have evolved after recognition of the causes of failure of the first generation McKee–Farrar and Ring prostheses [4, 22].

Some current designs of metal-on-metal cups include a polyethylene interface (sandwich) between the metal bearing surface and titanium shell and may be cemented [5, 22] or cementless [1, 2, 10, 14, 15, 18] fixation.

The potential for osteolysis remains, related to metal wear debris from the primary articulation [12, 17], polyethylene wear debris from backside wear [21, 25], and the pumping of fluid through the hole in the shell [19, 20]. We therefore studied the results of one such implant to assess the long-term clinical outcome and the risk of osteolysis and loosening.

Materials and methods

From November 1995 to November 1996, a consecutive series of 27 young patients (29 hips) underwent total hip arthroplasty with a Metasul metal-on-metal bearing using a polyethylene sandwich cup design.

Twenty-one patients (76%) were male and six (22%) were female. Mean age was 49 years (range 35–63 years). Average weight was 84 kg (range 48–115 kg) and average height was 174 cm (range 152–185 cm). Average BMI was

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28 (range 21–38). The right hip was involved in 14 patients, the left hip in 11 patients, and two patients had staged bilateral hip replacements. There were 22 cases of primary osteoarthritis; osteoarthritis was secondary to avascular necrosis in three cases, developmental dysplasia in two cases, and slipped capital femoral epiphysis and trauma in one case each. All patients were operated upon by a single surgeon (WKW) through a posterior approach.

A modular cementless femoral stem with a grit blasted surface (CLS, Sulzer, Winterthur, Switzerland), a modular cup with a titanium shell and a polyethylene insert with a Metasul inlay (both Fitek, Sulzer, Winterthur, Switzerland), as well as a 28 mm Metasul head were used in all patients. Primary fixation was achieved by press-fit in all cases, without screws; however, all shells had a polar hole.

Patients were instructed to fully weight-bear as tolerated. Clinical and radiographic review was recommended at six weeks, one year, two years, five years, and ten years postoperatively. Patients completed a questionnaire based on the “Standard System of Terminology for Reporting Results” [9] which includes modified Harris hip scores [6]. Periprosthetic radiolucent lines were defined as lucencies that had not been present on the immediate postoperative radiograph and were defined using DeLee and Charnley and Gruen zones [3]. The presence and volume of focal bone resorption was assessed on plain radiographs in all cases and was further investigated using multi slice axial computerised tomography (CT) in 13 patients to assess for evidence of osteolysis [11]. Liner wear could not be accurately assessed because it was not possible to determine the interface between components, both having the same radiographic opacity.

All data was collected prospectively and entered into a database at the time of assessment.

Despite an exhaustive search there were two patients (three hips) completely lost to follow-up. There was one death unrelated to surgery. Two patients developed a deep infection and were excluded from further analysis. One of these patients developed an infection after a dental abscess 54 months after the index procedure and underwent two stage revision after drainage and antibiotic treatment failed to resolve the infection. Histological analysis following revision surgery showed evidence of acute infection, and no evidence of metal hypersensitivity. The other patient developed a deep infection five months following index procedure and underwent surgical drainage and retention of a well fixed prosthesis. There was clinical evidence of chronic infection at the time of most recent follow-up but the patient had elected not to undergo revision surgery. One patient moved away and was unable to attend for radiographs. Clinical data was obtained for this patient using a postal survey. Clinical follow-up data was therefore available for 22 patients (23 hips); radiographic follow-up was available for 22 hips.

Clinical results

Average length of clinical follow up was 105 months (range 26–128 months).

The Harris hip score improved from a mean preoperative score of 60 (range 16–89) to 93 (33–100) at most recent follow-up. There were 22 patients (96%) with good or excellent scores at final follow-up and one patient with a poor score. This patient had concurrent lumbar spine problems and her pain has improved with physiotherapy since her most recent visit. Twenty-two patients (96%) had none or mild pain at final follow-up. Function, assessed by walking ability and use of walking aids, was good with 22 patients (100%) walking without a limp and 21 patients walking without a cane or crutch at final follow-up.

Average flexion was to 105 degrees flexion (range 35–140). No patients had significant leg length discrepancy as determined by clinical examination.

One patient complained of audible squeaking from his replaced hip. This occurred transiently. It was first noticed immediately postoperatively and lasted for three months. It did not then squeak for a number of years but occurred on one occasion ten years postoperatively when dressing. The squeak tended to occur under load in mid range of flexion and was audible to the patient and to observers. There are no plans to revise the component as the implants are well fixed and the patient is otherwise asymptomatic. CT scan shows that the cup is slightly retroverted with respect to the anterior pelvic plain. It also shows a small volume of central retroacetabular osteolysis (discussed below).

One patient was revised for osteolysis and is discussed below.

Radiographic results

Average length of radiographic follow-up was 92 months (range 26–129 months).

Osteolysis

Osteolysis was found in five out of 22 hips (23%). Location of osteolysis was in the periacetabular region in three cases and in the femur in two cases (Figs. 1 and 2). Each of these cases were assessed with plain radiographs and CT scan. The eight remaining patients who underwent CT scan had no evidence of osteolysis.

Table 1 summarises the radiographic features of each case of osteolysis with regard to site and size of osteolytic lesion, pain, and activity levels at most recent follow-up and treatment.

None of these lesions was present on preoperative radiographs; four were noted to be expansile on sequential

Fig. 1 Locations of osteolysis for cases 1–4

radiographs. CT scans demonstrated the presence of a communication pathway in all cases—between the lesion and the joint space around the periphery of the implant (cases 1, 3, and 4), through the polar hole in the cup (case 2), or via both routes (case 5).

Fig. 2 Location of osteolysis for case 5

One case (case 5) underwent revision of the acetabular component at 124 months (Fig. 2). At operation a retro-acetabular lesion was identified which communicated with the joint through a small superior pathway. The cup was otherwise well fixed and was stable. After removal of the

Table 1 Patient characteristics and radiographic features for each case of osteolysis

Case (see Figs. 1 and 2)	Age at surgery	Gender	Weight (kg)	Follow-up (months)	Pain on activity	Activity level ^a	Location of osteolytic lesion	Size of lesion [17]	Treatment
1	55	Male	74	107	Nil	4	Femur, zone VII	Small	Observation
2	41	Male	96	124	Nil	5	Pelvis, zones II and III	Small	Observation
3	48	Male	85	122	Nil	5	Femur, zone VIII	Moderate	Observation
4	47	Male	48	122	Nil	5	Pelvis, zone I	Small	Observation
5	49	Male	90	124	N/A	N/A	Pelvis, zones I and II	Large	Revision cup

^a Activity level: 1 bedridden/ wheelchair-bound; 2 limited to the house only; 3 light work only (e.g. sit down job); 4 no restrictions, able to carry out normal work; 5 very active including farm work, yard work, or sports

cup, the cavity was curetted and was found to contain friable brown tissue, which was sent for histological analysis with a sample of anterior capsule.

Radiolucent lines

All cups showed stable fixation with bony ingrowth at final follow-up with no radiolucent lines reported in any zone in any patient. The polar region of the cup (zone II) does not gain immediate contact with the acetabular bone at the time of implantation because the cup is deliberately flattened at the pole to encourage rim fixation. In all cases, therefore, this defect filled in over time. There were no femoral radiolucent lines reported in any zone in any patient.

Stress shielding was present in the proximal femur in nine cases. This was limited to zones one and seven in eight cases and extended to zones two and six in one case.

Histological findings

The tissue from the retro-acetabular cavity of the revised case was composed of granular debris, much of which had a fibrinoid degenerative appearance. This tissue was associated with fibro-vascular tissue in which numerous histiocytes were present, the histiocytes containing abundant granular grey/brown debris which was nonpolarisable.

No polyethylene or metal particles were present. There were intracellular inclusions in keeping with old haemorrhage. The capsular specimen again showed areas of extensive fibrinoid change and no wear particles.

Discussion

This is the longest follow-up report of this type of bearing (cementless metal-on-metal with polyethylene sandwich cup). Average length of follow-up in published series ranges from 45 to 85 months [1, 2, 5, 10, 14, 15, 18].

In our series nearly 25% of patients developed focal osteolytic lesions despite the previously low rates of osteolysis reported with cementless polyethylene sandwich cups [2, 4, 10, 13–15, 18] (summarised in Table 2).

All of these reports have included significant numbers of cups with large holes either for screws or for implantation instrumentation. The shell used in this series has no screw holes but has a small polar hole. Two of the cases of acetabular osteolysis in this series had evidence of osteolysis behind the polar region (zone II), although in the revised case the majority of the bone loss was superiorly (zone I). Osteolysis is known to occur in relation to screw holes, which provide a pathway for the passage of polyethylene debris [19, 20]. In the case that was revised for osteolysis, however, there were very few polyethylene

Table 2 Reported rates of osteolysis with cementless polyethylene sandwich cups

Authors, year	Cup fixation	Bearing surface	Number in series	Average length of follow-up (months)	Rate of osteolysis (%)
Dorr et al. [4], 2000	Cemented	Metasul	56	62	0
Wagner and Wagner [18], 2000	Cementless	Metasul	47	60	0
Migaud et al. [14], 2004	Cementless	Metasul	39	69	0
Delauney [2], 2004	Cementless	Metasul	98	72	3
Kim et al. [10], 2004	Cementless	Metasul	84	68	3
Milosev et al. [15], 2006	Cementless	Sikomet	640	85	3 ^a
Lazennec et al. [13], 2007	Cemented	Metasul	97	96	12

^a Osteolysis only stated in hips that were revised; overall radiographic rate not stated

particles evident on histological examination of tissue from the cavity.

A recent report of a series of 97 cemented Metasul lined polyethylene sandwich cups (with cemented titanium stems) reported a high rate of acetabular osteolysis at eight years. Seven cups were revised for osteolysis and a further three cups were awaiting revision [13]. A previous report of cemented cups showed a rate of osteolysis of 0%, but follow-up was limited to 62 months [5].

There is evidence that hypersensitivity to metal particles may play a role in loosening of implants with a metal-on-metal bearings [24], although the relationship is not yet fully established [8]. The hypersensitivity reaction is characterised by chronic inflammation and the presence of perivascular lymphoid aggregates on histology. There was no evidence for this finding in our revised case and metal particles were not seen on histological examination.

Both of the cases of femoral osteolysis in our series were in the proximal femoral metaphysis in continuity with the joint. This is a pattern that has been reported with cementless metal-on-polyethylene implants and is consistent with an aggressive response to particulate debris [26]. The size of the lesions in our series is such that further intervention has not been warranted and histological analysis has not been possible on any but one case.

The question as to whether or not the pelvic lesions identified in this series represent osteolysis can be addressed by assessment according to the criteria set out by Kitamura et al. [11]. Their study demonstrated that the presence of communication pathways between the lesion and the joint was the best predictor of a true osteolytic lesion. Communication pathways were present in all lesions reported as osteolysis in our series.

It should be noted that the patients who developed osteolysis reported that they have returned to a high level of activity (Table 2). Whilst these patients do not have a statistically higher activity level than the patients who did not develop osteolysis, there is a trend. Activity levels have been shown to be related to polyethylene wear in metal-on-polyethylene bearings [16], but not to the generation of metal ions in metal-on-metal arthroplasty [7]. Whether backside polyethylene wear related to high activity levels plays a role in our series is not clear.

There are two main limitations of our study. The first is the small sample size. This series reports the total number of this type of bearing that the senior author implanted, which was used in young active patients before ceramic bearings became widely available.

Secondly, this study uses CT scanning to help with diagnosis of osteolytic lesions. Without the use of CT, three cases may not have been detected (cases 2, 3, and 4). Whilst two of these cases were visible on plain radiographs (cases 2 and 3), the plain radiographic abnormality was

subtle and was only evident after the CT scan had brought the lesions to light. The use of CT scanning has however given a more accurate assessment of these lesions and is therefore likely to have allowed a truer assessment of the rate of osteolysis than plain radiographs alone.

Conclusion

This small series shows an excellent clinical outcome with this implant but a high rate of radiographically defined osteolysis. The cause for osteolysis is not evident from histological analysis of the only patient who required re-operation.

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