Uncemented metal-on-metal acetabular component

Follow-up of 112 hips for a minimum of 5 years

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Submitted 06-07-16. Accepted 06-11-13

Background Aseptic loosening is the major cause of implant failure. In cemented hip arthroplasty, failure of the acetabular side is mainly due to lysis caused by wear particles. By using an implant with low wear characteristics and by enhancing acetabular fixation using an uncemented implant, we aimed to reduce acetabular lysis and thereby loosening.

Patients and methods This was a retrospective cohort study of 119 hips (101 patients) that had the Uncemented Fitmore cup (Sulzer Orthopedics). In 66 patients, the femoral component was CF-30 (Sulzer) used with cement. In the remaining 35 patients, thrust plate prosthesis (TPP) (Sulzer) was used. Of the 101 patients, 94 (112 hips) were available for study. Mean follow-up of the 94 patients was 7 (5–13) years.

Results The mean preoperative Harris hip score was 38 and the mean postoperative Harris hip score was 89 at the last follow-up. Taking aseptic loosening as the endpoint, the survival rate of the Fitmore cup was 100% at 11 years.

Interpretation The uncemented Fitmore acetabular cup with second generation metal-on-metal articulation showed good results with regard to aseptic loosening in the medium term.

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Metal-on-polyethylene articulation is still the most commonly used articulation in total hip arthroplasty. Survival with this type of coupling is around 92–95% at 10 years (Havelin et al. 2000). The main reason for implant failure is osteolysis leading to aseptic loosening. The wear rate of metal-on-polyethylene articulation ranges from 0.06 mm per year to 0.2 mm per year (Bankston et al. 1995, Devane et al. 1995, Semlitsch et al. 1997).

Alternative joint bearing surfaces are being tried to reduce the wear rate. Metal-on-metal bearings have been in use since 1970s, when McKee and Farrar introduced them. These earlier metal-on-metal implants failed not because of the bearing surface, but because of other factors—such as implant design, manufacturing process, and surgical techniques (Schmalzried et al. 1996, Zahiri et al. 1999). Retrieval studies of McKee-Farrar implants have shown that the bearing surfaces performed well with little wear even after 20 years (Campbell et al. 2003). Time and time again, there is repeated mention in the literature about the low volume of inflammatory tissue seen in the retrieved metal-on-metal implants as compared to metal-on-polyethylene implants (Schmalzried et al. 1996, Doorn et al. 1996, Higuchi et al. 1997, Doorn et al. 1998, Campbell et al. 2003).

In 1988, Weber along with Sulzer Medical Technology Switzerland introduced the Metasul bearing, made from CoCrMo alloy that had been metallurgically refined. Since 1988, the Metasul metal-on-metal bearing has been used in over 250,000 hip replacements. Retrieval studies of Metasul metal-on-metal implants have shown a volumetric rate of wear 60–100 times less than that of metal-on-polyethylene implants (Anissian et al. 1999, Sieber et al. 1999). Retrieval studies have also shown a low linear wear rate of approximately 5 μm/year (Sieber et al. 1999), which can be compared to a

DOI 10.1080/17453670710014103

Figure 1. The Fitmore cup.

rate of 0.1–0.2 mm/year for metal-on-polyethylene (Wroblewski 1985, Kabo et al. 1993). Early studies with Metasul implants have shown a low revision rate ranging from 0–2% at a mean follow-up time of 7 years (Dorr et al. 2000, Wagner and Wagner 2000, Kim et al. 2004). Since 1993, the senior author (MSB) has been using the Metasul articulation in different settings. The rationale is that metal-on-metal hips with a low wear rate will lead to less osteolysis and reduce the incidence of aseptic loosening. We report on the medium-term results with this uncemented acetabular cup. The rationale in using an uncemented acetabular component is to eliminate the problem of late loosening, which is known to occur in cemented acetabular components—especially in younger patients (Harris 1996).

Patients and methods

Between 1994 and 2000, the senior author performed more than 600 primary hip replacements. In 119 hips (101 patients) the acetabular component used was the Fitmore (Sulzer/Zimmer Orthopaedics Inc.) uncemented cup (Figure 1). This is a titanium hemispherical shell with the outer surface covered by a 4-layered sulmesh grid made of sand-blasted pure titanium, which has a porosity of 65% (corresponding to that of cancellous bone tissue), thus facilitating osteointegration. The cup is inserted press-fit. It has 2 screw cones, giving additional stability and which also allows the use of additional screws. The cup comes in different sizes: in 2-mm increments from 42 mm to 68 mm. The insert is made of polyethylene with a 3-mm cobalt chrome metal articulation (Metasul) embedded within.

In 66 of the 109 patients, the femoral component was CF-30 (Sulzer/Zimmer). This is a polished tapered stem used with cement. In 35 patients, thrust plate prosthesis (TPP) (Sulzer/Zimmer) was used. This is a bolt-type device, which is fixed on to the neck; the femoral canal is not violated. The femoral head was a 28-mm Metasul head.

The approach was posterolateral. The acetabulum was prepared by reaming sequentially and the appropriate-sized shell was inserted. Screws were only used if there was some doubt about the stability of the implant. 35 patients had 1 screw and 10 patients had 2 screws for additional stability. Low molecular weight heparin (Fragmin) was administered along with TED stockings. Intravenous third-generation cephalosporin (Cefuroxime) was administered at induction, along with 2 further doses postoperatively. Follow-up was at 6 weeks, 3 months, and 1 year—and then at 2-yearly intervals. Outcome scoring was done using Harris Hip score at follow-up visits. All patients (except those with fractured femoral necks) had Harris hip scoring preoperatively. Radiographic assessment (anteroposterior) was done at 1 year postoperatively and then at subsequent visits.

Of the 101 patients (119 hips), 5 patients died during the follow-up period, 4 of them before 5 years of follow-up. None of them had revision of the acetabular cup. 3 patients were lost to follow-up. They were lost at 1 year, 3 years and 6 years, respectively: 1 patient did not attend because of severe medical problems, 1 patient moved away and could not be traced, and 1 patient declined follow-up. 1 patient was contacted by phone and she denied any problems with the hip. The available radiographs of these patients were reviewed. None of these patients had revision of the cup.

4 patients had Boneloc cement for fixation of the femoral component. 2 of these patients had revision of the femoral components, which is not surprising considering the poor performance of the Boneloc cement (Nilsen and Wiig 1996, Walczak et al. 2000). The cup was not revised in any of these patients.

94 patients (57 females; 112 hips, 18 bilateral) had at least 5-years of follow-up. The average duration of the follow-up was 7 years. The mean age was 56 (21–79) years. Primary osteoarthritis was the commonest diagnosis (Table 1).

Table 1. Preoperative diagnosis of patients

Diagnosis	No. of patients
Primary osteoarthritis	62
Rheumatoid arthritis	7
Psoriatic arthropathy	1
Other inflammatory	2
Avascular necrosis	5
Dysplasia	7
Perthe's disease	3
Fracture	3
Ankylosing spondylitiis	1
Others	3

Of the 18 patients who had bilateral THR, 12 were in the hybrid total hip arthroplasty group and 6 were in the TPP group. Fitmore cups of sizes 52 mm and 54 mm were the most commonly used. 41% of hips had at least 1 screw for stabilization. The study was conducted retrospectively. Sequential radiographs were reviewed. Immediate postoperative films were used to measure the cup inclination. Subsequent radiographs were assessed for change in cup inclination. For 3 patients, the initial radiographs were not available for review due to an earlier protocol in our radiology department to destroy radiographs more than 5 years old unless otherwise requested. In these patients, cup angle was assessed from the earliest available radiograph.

The radiographs were analyzed by two of the authors (UV and SS) who were not involved in the primary procedure. Acetabular radiolucent lines were measured in the 3 DeLee and Charnley regions (DeLee and Charnley 1976). Failure was defined as either revision or a progressive radiolucent line more than 2 mm in size in all 3 DeLee regions. Patients who had a non-progressive 1-mm radiolucent line were clinically correlated with their Harris hip scores. Radiolucent lines and osteolysis around the femoral stem were analyzed according to the zones described by Gruen. The cement mantle around the femoral stem was graded according to Barrack et al. (1992). The TPP is an uncemented implant. Radiolucent lines are common in the central bolt along the neck. Heterotrophic ossification was graded according to Brooker et al. (1973).

Table 2. Local complications

Complications	No. of patients
Groin discomfort	2
Dislocation	5
Periprosthetic fracture	4
Infection	2
Loose stem (TPP)	3
Sciatic nerve palsy	1
Dislodged cup	1
Dissociated liner	1

Statistics

A survivorship analysis was done for the total cohort of patients who underwent revision of the acetabular component for whatever reason, and also for patients who underwent revision of the acetabular component for aseptic loosening. Patients who died were also included in the analysis.

Results

Intraoperative complications

2 patients had acetabular perforation, which required grafting. 3 patients developed proximal fissuring in the femur, but none had any additional procedure. These patients were kept from weight bearing for 6 weeks postoperatively.

Postoperative complications (Table 2)

2 patients had persistent discomfort in the groin, but had normal results on screening for infection. 1 of them was revised to a cemented cup after 6 years. The cup was well fixed but was overhanging anteriorly, which may have caused impingement. Intraoperative cultures were negative. The patient's symptoms were partially resolved. The other patient who had a TPP declined revision.

Posterior dislocation occurred in 5 patients. 3 patients dislocated in the immediate postoperative period; 1 was reduced open (TPP patient). 1 of these patients went on to have 2 further dislocations 6 years after the first one, and was revised. 1 patient had late dislocations at 5 and 6 years, which were managed with closed reduction; she has remained stable till now. 1 patient had a missed dislocation that was noted at 1-year follow-up. His hip was

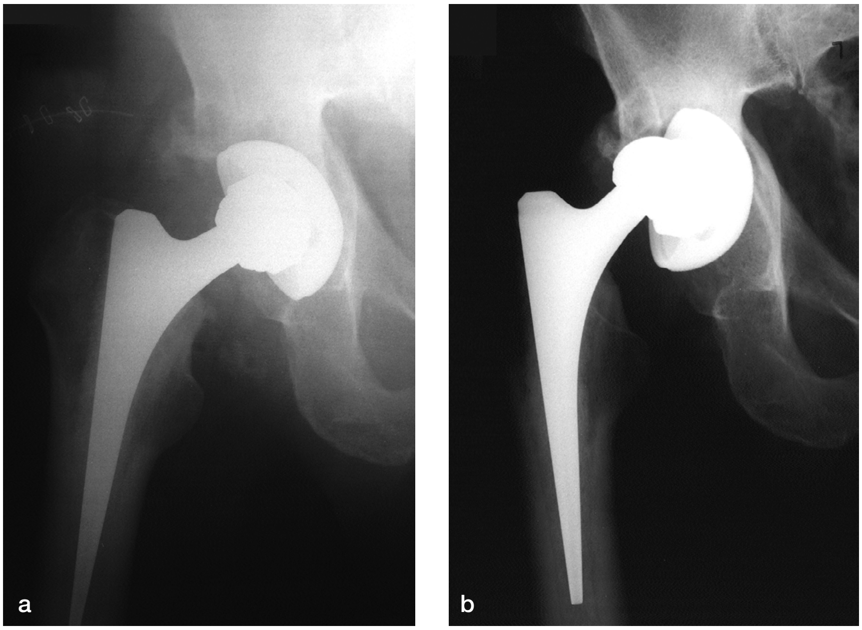

Figure 2. Immediate postoperative radiograph (a) showing the superior defect and the dislodged cup (b).

normal at 3-month follow-up. He was mobilizing well with a stick—although with a shortened leg—and declined any further surgery.

Periprosthetic fractures occurred in 4 patients. All were due to falls. Deep infection occurred in 2 patients. 1 patient developed a thigh abscess 7.5 years after primary surgery, which was drained; she went on to develop a persistent sinus. Because of co-morbid conditions, she was managed with long-term suppressive antibiotic therapy. Another patient developed septic loosening 3 years after the primary procedure, which was revised in 2 stages. 3 patients with TPP developed loosening of the stem. 2 patients were revised at 3 and 6 years, respectively. 1 patient who was seen recently after 9 years of follow-up is awaiting revision.

In 1 patient, the cup dislodged 1 year after implantation. There was an uncontained defect superiorly in the acetabulum and a Fitmore shell was implanted without the use of bone graft or additional screws at the first operation, since the shell was thought to be stable. Follow-up proved that this was not the case and the shell dissociated itself from the acetabulum within a year (Figure 2). The superior defect in the acetabulum was bone grafted and a revision cup was used along with 2 additional screws for stability of the shell. The bone graft incorporated well and the patient did well thereafter.

Other complications include dissociation of the liner from the cup (1), sciatic nerve palsy (1), trochantric bursitis (1), deep vein thrombosis (4), and pulmonary embolism (1). Heterotrophic ossification was seen in 5% of patients.

Preoperative Harris hip score was not available for fracture patients for obvious reasons. Mean preoperative Harris hip score was 38 (4–83). Mean postoperative Harris hip score at 5 years was 91 (62–100). Mean preoperative pain component of the Harris hip score was 14 (0–30). Mean postoperative pain score at 5 years was 42 (30–44). Outcome scoring could not be accomplished for all patients at every follow-up visit. All patients had outcome scoring on at least 2 of the first 4 follow-up visits, however, and most patients had hip scores at all visits.

Complete sets of radiographs were available for 91 patients. As mentioned earlier, 3 patients did not have adequate radiographs. Acetabular inclination was between 36º and 55º in 68% of patients (Table 3).

Non-progressive radiolucent lines were observed in 1 or more De Lee zones in 5 acetabular cups, but none were circumferential. 1 patient who had

Table 3. Distribution of acetabular cup alignment

Inclination angle	No. of patients (%) (n = 116) [a]
≤ 35°	1 (1)
36°–55°	79 (68)
56°–65°	30 (26)
> 65°	6 (5)

[a] excludes patients lost to follow-up.

progressive radiolucent lines of more than 2 mm was found to have infection. Calcar osteopenia was observed in 13 hips (17% of the cemented stems).

Survivorship analysis

With revision for aseptic loosening as the endpoint, there was 100% survival of the Fitmore cup at 10 years. None of the cups showed any evidence of radiolucent lines suggestive of loosening. 4 cups were revised in the follow-up period. 1 was the dislodged cup mentioned earlier. 1 patient was revised for persistent groin discomfort and 1 for septic loosening, and the fourth one for recurrent dislocation. With revision of the cup for all causes as the endpoint, 82% of the cups had survived at 10 years (Figure 3).

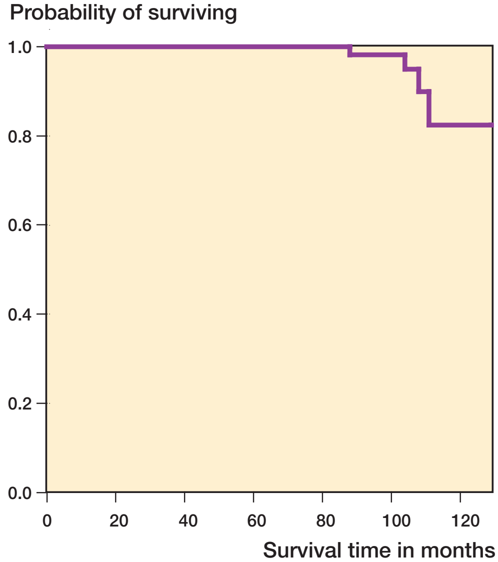

Figure 3. Kaplan-Meier curve with revision of cup for all reasons as endpoint.

Discussion

Longevity of hip arthroplasty depends on several patient- and surgeon-related factors, materials, method of fixation, and bearing surface. Long-term results with metal-on-polyethylene cups have shown a revision rate of 10–22% at 15 years (Barrack et al. 1992, Mulroy et al. 1995, Havelin et al. 2000, Klapach et al. 2001, Wroblewski et al. 2002, 2005, Nercessian et al. 2005). Aseptic loosening of one or both components averages around 1% per year (Welch et al. 1988, Wroblewski et al. 2005). It is well known that the acetabular component fails earlier than the femoral component in cemented hip arthroplasty with a metal-on-polyethylene articulation (Eftekhar and Nercessian 1988, Mulroy et al. 1995, Klapach et al. 2001, Nercessian et al. 2005). This led to the development of uncemented implants for acetabular fixation while maintaining the cemented stem (hybrid THA). Hybrid hip replacements have given variable results (Table 4).

Whether it is cemented or uncemented, and porous or hydroxyapatite-coated, the common factor in all these implants is the metal-on-polyethylene articulation.

Table 4. Hybrid hip replacements, revision of cup for aseptic loosening

Study	No. of patients	Mean follow-up (years)	Revision rate (%)	Comments
Goldberg et al. (1996)	125	8.6	0	4% had osteolysis
Clohisy et al. (1999)	86	10	1	5 hips had osteolytic lesions
Engh et al. (1997)	167	10	2	10 patients had reoperation for excessive wear of polyethylene liner
Zicat et al. (1995)	74	8.7		18% had osteolytic lesions
Fox et al. (1994)	52	6	31	

Table 5. Follow-up studies of metasul metal-on-metal THR

Study	No. of patients	Mean follow-up (years)	Revision rate for aseptic loosening (%)
Dorr et al. (2000)	56	5.2	2
Kim et al. (2004)	62	7	0
Long et al. (2004)	154	6.5	0

Long-term survival results with McKee-Farrar metal-on-metal hip replacements have shown almost identical survival when compared with Charnley low-friction arthroplasty. 20-year probability of implant survivorship of 84% and a 28-year implant survivorship of 74% was reported in a study of 129 patients who had McKee- Farrar hip replacement (Brown et al. 2002). Another study reported a 20-year implant survivorship of 77% in 107 McKee-Farrar arthroplasties, as compared to a 20-year survivorship of 73% for Charnley low-friction arthroplasty for a similar population (Jacobsson et al. 1996). This has led to renewed interest in metal-on-metal bearings to reduce wear rate.

Weber and Fiechter (1989) re-introduced the concept of metal-on-metal hip replacement with their metasul articulation, with a medium-term revision rate of 0–2% for aseptic loosening (Table 5). A retrieval analysis of 118 Metasul arthroplasties showed a 60-fold decrease in volumetric wear compared to metal-on-polyethylene bearings with no failures due to osteolysis (Sieber et al. 1999). Recent reports of the Sikomet metal-on-metal hip replacements (Korovessis et al. 2006, Milosev et al. 2006) do suggest that osteolysis and aseptic loosening can be a problem in these types of implants. Metal hypersensitivity has been suggested as the possible etiological factor responsible for the osteolysis. Metal hypersensitivity has also been reported for other types of metal-on-metal implants. Histological changes similar to delayed-type hypersensitivity have been seen in tissues revised for aseptic loosening. Willert et al. (2005) first described these in periprosthetic tissues in patients who had metal-on-metal hip replacements.

In our study of 108 hips with a mean follow-up time of 7 years, no acetabular cups were revised for aseptic loosening. Non-progressive radiolucent lines less than 2 mm were seen in 5 hips. None of these lines were circumferential and none of these hips were symptomatic. Their Harris hip score averaged 94. Osteolysis, commonly seen in metal-on-polyethylene hips, was conspicuously absent (Figure 4). None of the patients had osteolysis suggestive of metal hypersensitivity. The stems that

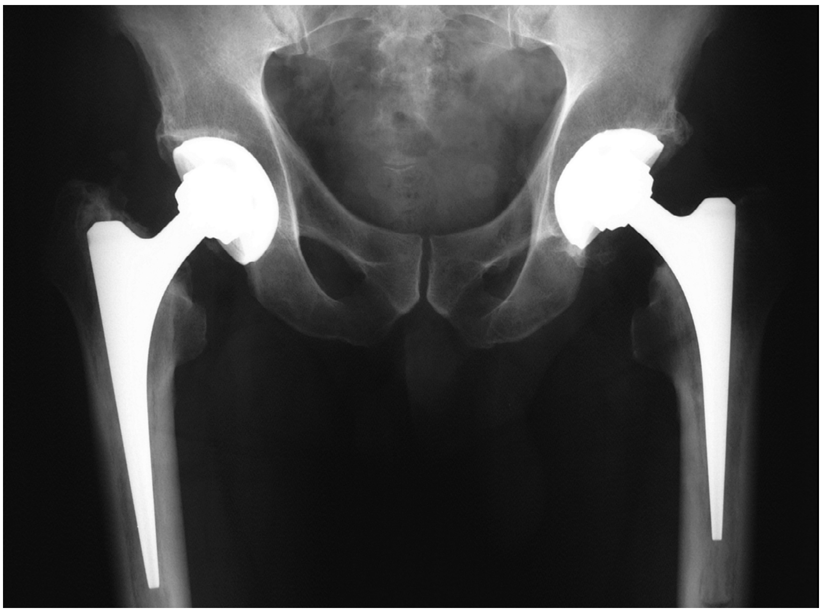

Figure 4. 10-year follow-up radiograph with no radiolucent lines suggestive of osteolysis.

were revised were all TPP and the mode of failure was gradual collapse into varus, not osteolysis. We did not have any stem revisions due to aseptic loosening in the cemented CF-30 stem (other than the patients with Boneloc cement). In patients revised for other reasons, no obvious metallosis of the periarticular tissues was seen. Schmalzried et al. (1996) analyzed 6 first-generation metal-on-metal hip arthroplasties revised at an average of 21 years, and did not find metallic staining of tissues except in one patient (due to impingement wear).

In a retrieval study of metal-on-metal implants, the linear wear rate was found to be around 5 μm per year, which is 20 times less than metal-on-polyethylene cup. The volumetric wear rate of 0.3 mm^3 per year is at least 60 times lower than metal-on-polyethylene cup (Seiber et al. 1998). Another study showed that the steady-state wear rates for metal-on-metal bearings were almost 100 times less than those for the metal-on-polyethelene bearings (Anissian et al. 1999). Willert et al. (1996) found that the cellular reaction to metal wear particles was always lower than that to cement and polyethelene. Metal wear particles have a smaller diameter (< 0.1 μm) than polyethelene particles (0.5 μm) (Doorn et al. 1996). The smaller metal particles are removed from the periprosthetic tissue by dissolution and dissemination. Metal wear particles, because of their smaller size, do not seem to stimulate the production of multinucleate giant cells (Doorn et al. 1996). Only polyethylene particles of a defined size (0.5–10 μm) can induce secretion of interleukin-6 in macrophages, with subsequent formation of granuloma and osteolysis (Green et al. 1998).

With the resurgence of interest in the use of metal-on-metal bearings—and especially due to their use in young patients—concerns have been raised about the potential for increased metal ion generation and its systemic effects A 9-fold elevation in serum chromium, 35-fold elevation in urine chromium, and 3-fold elevation in serum cobalt concentrations was found in patients with long-term use (> 20 years) of McKee-Farrar hip arthroplasties, as compared to controls (Jacobs et al. 1996). Similar findings have been reported for metasul articulation (Brodner et al. 1997). Metallic particles have been shown to disseminate to the liver, spleen, and abdominal lymph nodes of patients with hip and knee replacements (Urban et al. 2000). There are concerns about the effect of these metal particles, both locally and systemically. A study from Finland did find a slightly increased incidence of leukemia in patients who had metal-on-metal replacements when compared to patients with metal-on-polyethylene replacements (Visuri et al. 1996). An epidemiological study done in Sweden showed that hip implant patients had similar rates of most types of cancer to those in the general population. Long-term follow-up (> 15 years) did reveal an excess of multiple myeloma and a statistically non-significant increase in bladder cancer (Signorello et al. 2001). A causal relationship between metal implants and cancer has yet to be proven. Further long-term epidemiological studies are required to investigate the possibility of such a relationship.

In our cohort of patients, we did not find any systemic side effects. The drawback of our study is that it was a retrospective cohort study of non-consecutive patients. Within the limitations of this study, however, we can conclude that the Fitmore metal-on-metal acetabular cup gives good results in the medium term as far as aseptic loosening is concerned, and further long-term results appear promising because of the relative rarity of osteolysis.

Contributions of authors

MSB: organized the study and edited the manuscript. UTV: wrote the manuscript and analyzed the data. SS: collected the data and did the analysis. KC: collected the data and helped in the analysis.

The authors thank Ms Tracy Young, Sheffield, for helping with the statistical analysis.

No competing interests declared.

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