



## Unsatisfactory results with the cementless Omnifit acetabular component due to polyethylene and severe osteolysis

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A high incidence of acetabular osteolysis (43%), associated with osteolytic lesions in the proximal femur (22.6%) and leading to a high revision rate, was experienced with the Omnifit total hip prosthesis. We reviewed the clinical and radiological results with 429 Omnifit total hips in 356 patients after a mean follow-up of 60 months. Time to revision and wear of the polyethylene liner with different acetabular shell types were specifically analysed.

Pelvic osteolysis first became manifest in the acetabular bone opposite to the holes in the metal shell. Osteolysis occurred predominantly adjacent to the central hole in the metal shell of threaded cups; widespread and larger defects were found in press fit cups with peripheral screw holes.

Kaplan Meier survival analysis demonstrated a higher probability for retaining the threaded cup at 6 years (96% ; 95%-confidence interval : 93-99%) compared to the survival of the press fit cup (66% ; 95%-CI : 56-77%).

The results suggest a negative relationship between backside wear, the larger number of holes in the cup, the extent of osteolysis and survival rate of the press fit cups.

Based on these findings and supported by similar reports about osteolysis related to the same cup design, it was hypothesised that backside wear due to the insufficient locking mechanism of the Omnifit acetabular cup was the major cause of the unsatisfactory results in our patients. For this reason we discontinued using this type of uncemented socket.

## INTRODUCTION

Wear of the polyethylene liner is now recognised as the most common cause of osteolysis and prosthetic failure in uncemented total hip replacement (5). Theoretical models and retrieval analyses have shown that the rate of volumetric wear of polyethylene acetabular components increases with an increase in the femoral head diameter (11). A highly significant correlation has been demonstrated between the depth of polyethylene wear and periprosthetic osteolysis and subsequent loosening of the acetabular component (14). Distal migration

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of polyethylene wear debris may result in osteolytic lesions around the femoral component (13). Pelvic bone loss is associated with a younger age (28), vertical positioning of the acetabular cup, and high volumetric wear of the polyethylene liner (22). Bone resorption may be asymptomatic until loosening of the acetabular component or even pelvic fracture occurs (20). Other concerns are wear of the modular polyethylene liner against the metal shell, so-called backside wear, and fretting of fixation screws placed through the shell (10, 25). Several authors believe that there is an interaction between specific design and implantation variables in the occurrence of pelvic osteolysis (21).

Uncemented total hip arthroplasties are used in our practice in patients younger than 65 years. The problem of pelvic lysis and a high revision rate of the acetabular component became of such magnitude that we decided to review our clinical and radiographic results.

#### PATIENT AND METHODS

Using a posterolateral approach, we performed 429 consecutive uncemented total hip arthroplasties (Omnifit-HA, Osteonics Corporation, Allendale, NJ, USA) in 356 patients. Eleven Patients (2.6%, 11 hips) were lost to follow-up within one year of surgery and were excluded from the study. The present study included 418 hips in 345 patients (123 men, 222 women) with a mean age of 57 years (range : 23 to 73). The average follow-up period was 60 months (range : 12 to 124). Fifteen patients (19 hips) died of causes unrelated to their hip surgery after an average postoperative period of 66 months (range : 25 to 112). Primary osteoarthritis was the preoperative diagnosis in 353 hips (84.4%), secondary osteoarthritis in 36 hips (8.6%), osteonecrosis in 19 hips (4.5%) and miscellaneous in 10 hips (2.4%).

The acetabular components used in this study included 145 (34.7%) threaded cups (mean follow-up 82 months) and 273 (65.3%) press fit (Dual Radius) cups (mean follow-up 48 months). Both designs were hydroxyapatite coated. Their outer diameters varied from 46 to 64 mm. Both types had the same general design except that the screw ring had a large central dome hole and threads around the periphery, whereas the Dual Radius cup had a small threaded apex hole and 8 separate peripheral screw holes. The patented locking mechanism of the Omnifit insert however is the same for

both sockets, securing the polyethylene liner to the metal shell by an incomplete metal wire-retaining ring, which was preassembled with the polyethylene insert. The polyethylene liners were all sterilised in ethylene oxide.

From January 1989 to August 1995 a 32-mm cobalt chromium alloy femoral head with variable neck length was used (n = 339) ; from there we changed to 28-mm heads (n = 79). The modular femoral component used in all patients was a double wedge design, collarless, straight titanium alloy implant with a proximal peripheral coating of hydroxyapatite.

All patient records and radiographs were retrospectively analysed by one independent investigator (JN). The surgical records, postoperative data and data obtained at every follow-up visit were assessed and recorded with special reference to the level of activity, complaints and satisfaction. Anteroposterior and lateral radiographic examination of the replaced hip was performed immediately after surgery, at 6 weeks, 6 months postoperatively and then annually at each clinical attendance.

Classification into acetabular regions was made according to DeLee and Charnley (4). Radiolucencies were defined as gaps between the implant and bone, not present on the initial postoperative radiographs. Osteolysis was defined as non-linear radiolucencies with a width of 3 mm or more, without sclerosis. Vertical cup migration was assessed on sequential radiographs by referencing a line through the centre of the femoral head perpendicular to the interteardrop line. Measuring the distance from the intersection of this perpendicular line to the teardrop assessed the horizontal migration. The inclination or abduction of the acetabular component was measured on the anteroposterior radiographs of the pelvis. Sockets showing a change in position, migration of more than 3 mm, or a complete radiolucency between implant and bone were considered loose.

Polyethylene wear of the acetabular liners was measured using the validated technique of Livermore *et al* (18) in which the centre of the femoral head was determined by using a series of concentric rings. The distance from the hip centre to the edge of the acetabular component was measured on the initial postoperative radiograph and compared with the shortest distance (maximum wear) on the radiograph of the final follow-up visit. The measurement was corrected for magnification by using the known diameter of the femoral head. Linear acetabular wear per year was calculated by dividing the total wear by the number of years after surgery.

The femoral components were assessed for radiographic demarcation and osteolysis using the zonal system of Gruen *et al* (7). Definite loosening was present if subsidence of more than 5 mm was noted or continuous demarcation was depicted around the stem. Probable loosening was defined as the presence of a radiolucent line in three or more Gruen zones.

One-way analysis of variance (ANOVA) was used to test differences in the mean linear wear rate between multiple groups for statistical significance. ANOVA was used to study the influence of the type of cup, gender, radiographic variables, level of activity, satisfaction of the patient, prosthetic variables for statistical significance on the linear acetabular wear per year. Accordingly the least square means with 95% confidence intervals (95% CI) were presented. The Kaplan-Meier estimate with 95% CI for both types of cup was calculated to estimate the time to revision. Revisions of either prosthetic component for any reason was used as endpoint ; those who had no revision within the study period or who were lost to follow-up were considered to be censored at the date of the last visit.

Univariate Cox regression models were used to study effects (i.e. gender, radiographic variables, level of activity, satisfaction of the patient, prosthetic variables) on the time to revision. Multivariate Cox regression models with stepwise selection procedures were used to indicate the most important explanatory variables, in addition to the type of cup used.

## RESULTS

Of 418 hip replacements, 73 had been revised and 28 were qualified as fair or poor by the patients, due to pain, limp, recurrent dislocation, limitation in daily activities or otherwise. The remaining 317 hips (75.8%) were clinically well functioning at follow-up. Radiographic assessment of these 317 hip prostheses yielded one threaded cup loosening with vertical subsidence, and progressive migration of 15 radiologically loose press fit cups into abduction.

### Radiography

Acetabular osteolytic lesions near the apical zone of the threaded cup (n = 70) were seen at a mean of 32 months (range : 11 to 49) and adjacent to the press fit cups (n = 108) at a mean of



**Fig. 1.** — Axial radiograph of the hip, showing extensive osteolysis mainly in zone 2 already appearing 4 years post-THA with a threaded cup.

27 months (range : 8 to 44). Acetabular osteolysis was present around 69 threaded cups (47.6%), predominantly in zone II (84%) (fig 1), whereas 112 press fit cups (41%) showed osteolytic lesions more evenly distributed, with 31% in zone I, 42% in zone II and 27% in zone III (fig 2).

Femoral osteolysis was found in 41 hips with a threaded cup (28%) and in 54 with a press fit cup (20%). In both groups the femoral osteolysis was consistently associated with acetabular osteolysis ; it was confined to Gruen zones 1 (43%), 6 (21%), 7 (48%) and the greater trochanter (36%) (table I).

Table I. — Radiological evidence of loosening, subsidence and osteolysis in 418 hips

		Threaded cups	Press fit cups	All
Total number		145	273	418
Mean follow-up (months)		82	48	60
Femoral head	32 mm	145	194	339
	28 mm	0	79	79
Cup loosening/migration		3 (2.1%)	16 (5.9%)	19 (4.5%)
Stem subsidence		7 (4.8%)	8 (2.9%)	15 (3.5%)
Osteolysis	Acetabular	70 (48.3%)	108 (39.6%)	178 (42.6%)
	Femoral	43 (29.7%)	55 (20.1%)	98 (23.4%)

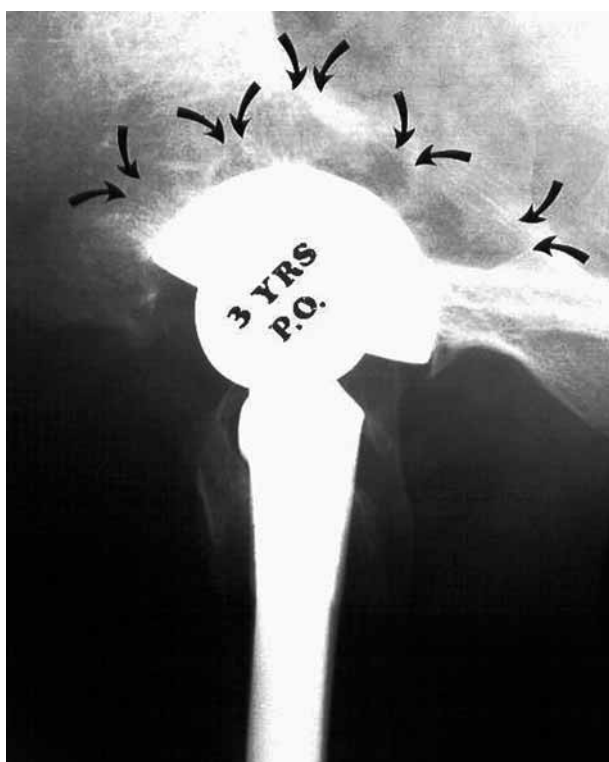


Fig. 2. — Axial radiograph of the hip, showing extensive osteolysis in zone 1, 2 and 3 already appearing 3 years post-THA with a press fit cup.

### Annual polyethylene linear wear rate

The average total polyethylene linear wear in the acetabular cups ( $n = 418$ ) was 0.77 mm (range: 0.00 to 6.00), and the annual linear polyethylene

wear rate averaged 0.16 mm (range 0.00 to 1.57). As expected, total linear wear increased in a statistically significant manner with increasing duration of *in situ* implantation (Pearson correlation test,  $r = 0.30$ ,  $p < 0.001$ ), whereas the annual linear wear rate was independent of the duration of *in situ* implantation (Pearson correlation test,  $r = -0.07$ ,  $p = 0.15$ ). The mean annual wear of the threaded cup was significantly lower than that of the press fit cup: 0.11 mm/year (95% CI: 0.09-0.13) versus 0.18 mm/year (95% CI: 0.16-0.20; t-test:  $p < 0.001$ ).

The mean wear rate was significantly different for the size of the femoral head (t-test,  $p = 0.03$ ), but not for the abduction angle and the femoral offset.

We found that the mean annual wear rate was significantly higher when the press fit cup was used in combination with a 32-mm femoral head (0.22 mm/yr; 95% CI: 0.20-0.24) compared to either the threaded cup in combination with a 32-mm head (0.12 mm/yr; 95% CI: 0.10-0.14) or the press fit cup used in combination with a 28-mm femoral head (0.11 mm/yr; 95% CI: 0.09-0.14). The mean wear rates in the last two combinations were not significantly different. The threaded cup was not used in combination with a 28-mm femoral head.

Table II shows the mean annual wear rate by metal shell type, by femoral head and by cup diameter. A two-way ANOVA showed that there were no significant differences for the different acetabular cup sizes (46-50 mm, 52-58 mm, 60-64 mm),

Table II. — Mean wear rate of the acetabular polyethylene liner in mm/year by metal shell type, by femoral head and by cup diameter

	Cup size	46-50 mm		52-58 mm		60-64 mm	
	Fem head	N	Mean (95% CI)	n	Mean (95% CI)	N	Mean (95% CI)
Threaded	32 mm	27	0.10 (0.08-0.13)	108	0.11 (0.09-0.12)	10	0.14 (0.10-0.19)
Press fit	32 mm	17	0.20 (0.16-0.23)	55	0.11 (0.09-0.14)	7	0.03 (0.00-0.09)
	28 mm	33	0.26 (0.21-0.28)	153	0.20 (0.19-0.21)	8	0.20 (0.15-0.25)

Table III. — Overview of wear and revision rates

	Threaded cups	Press fit cups	Total
Number	145	273	418
Follow-up (months)	82	48	60
Mean wear rate (mm/yr)	0.11	0.18	0.16
Average total wear (mm)	0.76	0.77	0.77
Mean time to revision (months)	82	54	62
Revision of acetabular cup	21 (14.5%)	50 (18.3%)	71 (17%)
Revision of femoral stem	11 (7.6%)	14 (5.1%)	25 (6%)

Table IV. — Crude risk ratio of the revision (univariate Cox regression model)

		Risk ratio	95% CI
Cup	Threaded	1.00	Reference
	Press fit	10.38	4.59-23.46
Gender	Female	1.00	Reference
	Male	0.804	0.465-1.391
Abduction angle <i>Flat/normal/steep</i>		0.935	0.566-1.571
Femoral neck <i>-5, 0, +5, +10 mm</i>		1.13	1.05-1.21
Femoral offset <i>&lt; 125, 125-145, &gt; 145</i>		1.013	0.689-1.488
Level of activity <i>Low/normal/high</i>		0.125	0.068-0.230

although the mean wear rate was higher in the smallest cup size class (0.19 mm/yr; 95% CI: 0.17-0.20) compared to both other classes (0.14 mm/yr; 0.13-0.15 and 0.13 mm/yr; 0.10-0.16, respectively).

The annual wear rate was not significantly influenced by gender. A high annual wear rate was associated with a low level of satisfaction (t-test,  $p < 0.001$ ) and a higher level of pain ( $p < 0.001$ ).

The results of the radiographic variables were studied with regard to the mean wear rate. The presence of pelvic osteolysis was associated with a higher annual polyethylene linear wear rate, independent of the metal shell type (two-way ANOVA,  $p < 0.001$ ). Similar correlations were found for the change in acetabular cup positioning, fixation of the cup and femoral osteolysis.

### Revision

Revision of the acetabular component was carried out in 70 hips (16.7%), whereas the femoral stem was revised in 25 cases (6%). The most frequent indication for revision was progressive wear with periprosthetic osteolysis and pain ( $n = 58$ , 79.5%) and radiological loosening of the cup with radiolucencies, but without osteolytic defects ( $n = 8$ , 11%). A total of 22 threaded cups (15.8%) and 51 press fit cups (18.5%) were revised after a mean survival of 82 and 52 months respectively. The majority of the revised cups were 52 mm in diameter or larger (81.8% of the revised threaded cups and 74.5% of the revised press fit cups respectively). Although gross liner damage occurred during removal from the metal shell at the time of revision, it was noted that the concave surface of the liners

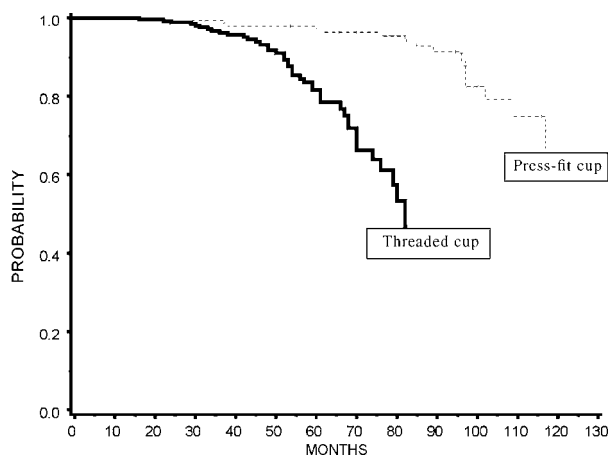


Fig. 3. — Kaplan-Meier curve of the survival of the threaded cup and the press-fit cup.

demonstrated significant burnishing in the superior part where the femoral head contacts with the liner during weight bearing. There were no signs of rim wear consistent with neck impingement in any of the revised hips. Five polyethylene inserts (1.2%) were incompletely seated in the metal shell; one liner was fractured (0.2%).

In most cases, the acetabular osteolytic lesions appeared to be far more widespread and extensive than was anticipated from the preoperative radiographs. Behind the threaded cup, bone resorption predominantly expanded into the cancellous bone of the pelvis in Charnley zone II, corresponding with the central apical hole in the shell. Osteolysis behind the press fit cups was consistently found to originate from the screw holes in the metal shell. In particular in the latter group, severe acetabular osteolysis occurred, frequently with large cavitory defects involving the ilium, ischium and pubic bone. Nevertheless, most of the acetabular components were still osseointegrated at their periphery.

Histologically, the granulation tissue from the osteolytic defects showed no evidence of acute inflammation. Under polarised light, birefringent particles were consistently found, representing polyethylene wear debris.

### Statistical analysis

The probability for retaining the THA was significantly higher in the group with the threaded cup implant compared to the press fit cup implant (Log-rank,  $p < 0.001$ ). A Kaplan-Meier estimate (12) (fig 3) showed that the probability for retaining the THA at 6 years was 96% (95% CI : 93-96%) when the threaded cup was used, compared to 66% (range : 56 to 77) at 6 years when the press fit cup was used. If a 32-mm femoral head was used with a press fit cup, the probability for retaining the THA was significantly lower than in combination with a threaded cup (Log-Rank test,  $p < 0.001$ ).

### DISCUSSION

Various materials used in cemented and uncemented arthroplasties, including cement, metal and polyethylene, may generate particulate wear debris gaining access to the bone-prosthesis interface. Subsequently, a cascade of biologic responses is elicited at the cellular and tissue levels, resulting in periprosthetic osteolysis.

Although the success of uncemented acetabular components with polyethylene liners is well established, the greatest concern is wear over time. Increased polyethylene wear in cementless THA has been associated with patient age, gender, polyethylene source, type of femoral component, head size and composition, head roughness, acetabular component orientation, sterilisation techniques, packaging methods and shelf-life of polyethylene (2, 5).

The long-term rate of linear wear of polyethylene in cementless THA has been reported to range from 0.07 to 0.25 mm per year (3, 5). The mean linear wear rate of 0.16 (range : 0.15 to 0.17) mm in this study lies within this range.

It has been generally accepted that polyethylene wear is one of the major causes of periprosthetic osteolysis in cementless THA (8). In our series, pelvic osteolysis was encountered in 43.1% and accompanying femoral osteolysis in 22.6% of the 418 reviewed hips. This is unacceptably high in comparison with other series, in which the prevalence of osteolysis varies from 7 to 24% (26). In our

series, revision surgery was performed in 40.8% of the hips with pelvic osteolysis and pain. However, 59.2% of the remaining hips with pelvic osteolysis were asymptomatic at the time of study and were not revised.

Astion *et al* (1) found an increased risk of osteolysis developing in cups with an outer diameter of 55 mm or less, corresponding to a polyethylene thickness of 8.5 mm or less. Learmonth *et al* (15) encountered osteolysis only with the 32-mm head where the outer diameter of the metal-backed cup was 52 mm or less. They concluded that inadequate polyethylene thickness, rather than head size, should be implicated as the major cause of polyethylene particle mediated osteolysis. Although the same trend for 32-mm heads was recognised in our study, the majority (almost 80%) of the metal shells we revised had an outer diameter of 52 mm or more. In spite of the fact that the follow-up of the THA's in which we used 28-mm heads was too short to draw definite conclusions, it is at least alarming that pelvic osteolysis already occurred after an average of 15 months in a relatively high percentage of these hips (11.2%).

Sanchez-Sotelo *et al* (20) reported 2 cases of severe early osteolysis causing periprosthetic fracture after implantation of Dual Geometry Omnifit cups with 28-mm femoral heads. In 76 cementless Omnifit hips with an average 10-year follow-up, 61.8% of the hips either had radiological evidence of osteolysis (32 hips) or had undergone revision surgery (15 hips) because of progressive osteolysis (9). Most of the cups had a polyethylene liner with an inner diameter of 26 mm, the remaining were 32 mm. Lee *et al* (16) evaluated the results of 240 cementless porous coated femoral components (Osteonics, Allendale) with 26-mm heads and 110 hips which received a 32-mm head, in combination with Omnifit sockets. A high incidence of osteolysis was encountered in 24% and 48% respectively, after a mean follow-up of 4 years. They concluded that the use of a large head, but also the poor prosthetic design, appeared to be responsible for the unsatisfactory early results of the cementless Omnifit acetabular component. Schwelow *et al* (23) reported catastrophic results of the acetabular component with 66 revisions out of

154 implanted cups after a mean of 75 months, and high annual wear rates.

These reports underline that the use of 32-mm heads is not an exclusive cause of periprosthetic osteolysis. With cemented all polyethylene cups, wear occurs at the articular surface only and may be affected primarily by femoral head size. In modular uncemented cup there are two surfaces that can generate wear debris.

It has been well accepted that insufficient liner locking mechanisms, the amount of micromotion present, and the metal finish contribute to backside wear and release of polyethylene particles, resulting in pelvic osteolysis (6, 22).

Several specific prosthetic designs, such as the Harris Galante I cup and gamma radiated Hylamer liners have been associated with backside wear and osteolysis (8, 24). Different authors (16, 17, 19) have reported specific complications of the liner locking system in Omnifit acetabular components. Lee *et al* (17) found polyethylene wear on both surfaces of the liners that were revised. In their opinion, the polyethylene liners in Omnifit cups do not fully contact the metal shell, with the potential risk of excessive edge stresses on the locking system, in particular when polyethylene thickness falls below 8 mm. These reports strikingly agree with the results from our study, supporting the hypothesis that backside wear and pelvic osteolysis were mainly due to poor conformity between the liner and the metal shell. This also explains why the frequency and extent of acetabular osteolytic lesions in our revisions were consistently related to the holes in the metal shell, as has been reported by others (24, 26). The difference in survivorship at 6 years between the threaded cup (one apical hole) and the press fit cup (8 peripheral holes) fits into this hypothesis.

Being confined to the proximal zones, femoral osteolysis in our study was considered to be secondary to acetabular wear and distal migration of polyethylene debris (13). The proximal hydroxyapatite coating of the stem and local bone condensation apparently blocked the stretch of effective joint space, preventing further extension of osteolysis and progressive loosening of the implant.

As a result of our study, we abandoned the use of all variants of the metal backed Omnifit sockets,

which have an identical polyethylene liner locking mechanism. We expect that with a longer follow-up of this system, osteolytic defects will increase in size and number. Clinical results are misleading, since the implants remain stable in spite of large bony defects that are often not visible on standard AP radiographs. "Faux profil" radiographs or CT scans may be more revealing in these cases.

New designs have tried to address this issue by an improved locking mechanism, a polished and closed inside of the metal shell and optimised congruency against the liner (25). However, the expected effect on reducing polyethylene wear and osteolysis still has to be demonstrated in further clinical studies.

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