Failure of HA coating on a gritblasted acetabular cup

155 patients followed for 7–10 years

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ABSTRACT – We report the outcome of 191 acetabular gritblasted titanium cups with a hemispherical design for press-fit insertion and coated with hydroxyapatite. The prosthesis was made of gritblasted titanium entirely coated with hydroxyapatite. 155 patients aged 15–78 years were operated on during the years 1991–1993 and followed for 7–10 years. During this period, 39 cups were revised because of mechanical loosening, a further 9 had radiolucent lines and 2 focal osteolysis. None of these 11 patients had clinical symptoms. Failure was associated with age, wear and radiolucency/osteolysis. At revision, we found that the soft tissues were discolored, and that most of the coating had disappeared. This design of hydroxyapatite-coated cups has a high rate of debonding and failure.

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In uncemented hip replacement, various methods can be used to achieve bioactivity and anchorage of the prosthesis (Lewis and Galante 1985, Haddad et al. 1987, Poss et al. 1988). Hydroxyapatite (HA) has an attractive biological profile when plasma-sprayed onto a titanium implant (DeGroot et al. 1987, Geesink et al. 1987, Kay et al. 1987, Cook et al. 1988). However, the long-term biological effects of HA-coated prostheses remain uncertain (Morscher 1991). The stability of the coating in terms of bonding to bone and adherence to titanium has been questioned. Our results with femoral stems coated with HA have been good. In this study, we report our 7–10-year experience using a gritblasted titanium cup with a hemispherical design for press-fit insertion, which was plasma-sprayed with HA.

Patients and methods

During the years 1991–1993, we performed 191 primary total hip replacements in 155 patients (103 women) with mean age 47 (15–78) years. The diagnoses were primary (idiopathic) arthrosis (32 cases), and secondary arthrosis due to failed femoral neck fracture (5), congenital dislocation (56), congenital dislocation with luxation (62), Calvé-Legg-Perthes disease or epiphysiolysis (8) and various other conditions (28).

We used a straight stem and a hemispherical press-fit cup secured by 2–3 screws. The components were made of gritblasted $TiAl_6V_4$ (Landos Corail, Landanger, Chaumont, France), and the outer surfaces were entirely plasma-sprayed with a 155 ± 35 μm layer of HA. The purity of the HA was reported to be greater than 97%, the density between 1.2 and 1.6 g/mL, the crystallinity greater than 50% and the porosity less than 10%. The surface roughness of the coating was characterized as Ra (arithmetical mean roughness value) between 7.5 and 9.5 μm and Rt (maximum profile height) between 50 and 65. The surface roughness of the gritblasted metal was characterized as Ra between 4 and 6 μm and Rt between 25 and 40. The bonding strength of the coating on the metal was reported to be more than 10MPa. The technical data have been described by the manufacturer.

We used cups of sizes 46 in 20 cases, 48 in 34, 50 in 35, 52 in 36, 54 in 34, 56 in 18, 58 in 9, 60 in 4 and 64 in 1 case. The polyethylene liners were reported to fulfil ISO standard F648. Sterilization was done with gamma irradiation in a dose of 25–35 kGy in air. The head, which had a diam-

Table 1. Kaplan-Meier table for observation time

Time (year)	Cumulative survival	Cumulative failure	At risk	95% CI
1	1	0	190	
2	0.99	0.005	188	0.98–1.0
3	0.99	0.011	184	0.98–1.0
4	0.98	0.016	183	0.97–1.0
5	0.96	0.038	178	0.94–0.99
6	0.91	0.087	165	0.87–0.95
7	0.87	0.13	150	0.82–0.92
8	0.78	0.22	71	0.71–0.85
9	0.68	0.32	29	0.59–0.78
10	0.65	0.35	5	0.54–0.76

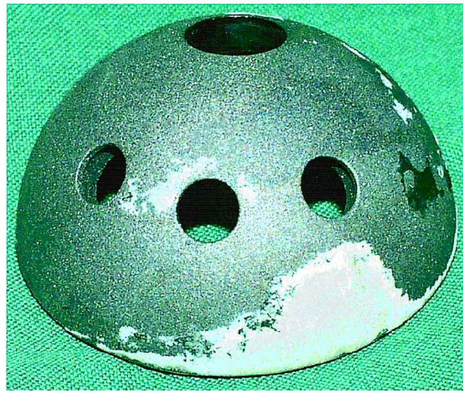

Figure 1. Revised acetabular cup with loss of most of the HA coating.

eter of 28 mm, was made of stainless steel (Inox) in 169 cases and of Al_2O_3 (Biolox) in 22.

Surgery was performed in a standardized manner, using the direct lateral approach, without trochanteric osteotomy. We advised patients to avoid weight bearing for 3 months postoperatively.

The patients have been followed 7–10 years after the operation with radiographic and clinical examinations. During the follow-up, 6 patients died and 5 patients refused to return for the follow-up examination; they were censored at their last control examination.

Radiographic evaluation included assessment of cup inclination, polyethylene wear, osteolysis and fixation of the acetabular cup. Linear measurements were made on the AP radiograph, using a caliper and corrected by checking the diameter of the femoral head. Polyethylene wear was measured with Livermore et al.'s method (1990). Radiolucent lines and osteolytic lesions were classified on the basis of size and regional location with DeLee and Charnley's method (1976). Loss of cortical or trabecular bone was considered evidence of osteolysis. We determined a focal area of bone loss to permit approximation of the area with the formula for an ellipse (Zicat et al. 1995). Radiographic bony incorporation was defined as extensive intimate bone-implant contact, periprosthetic bone formation and remodeling, and the absence of migration. We modified the criteria of Massin et al. (1989) for cup loosening, using a variation of more than 5 mm or 5 degrees.

Kaplan-Meier survival analysis was used with removal of the component as the endpoint and the Cox proportional hazard model for covariations. $P < 0.05$ was considered significant.

Results

During the follow-up period 38 cups were revised, none because of infection (Table 1). At follow-up, 3 more cups had become loose. This was confirmed at revision.

In 11 cases, revision was done due to sudden onset of pain in a hip that had been pain free for years. These cases showed no radiographic signs of loosening or osteolysis, but at revision, slight hammering of the cup after removal of the screws revealed that it was loose. In 4 cases, revision was necessary due to a sudden and total change in position of the cup, but without preceding radiological signs of loosening or osteolysis. Pain was associated with a radiolucent line around the cup ranging from 1 to 4 mm in 14 cases. The radiolucency was located in regions 1, 2 and 3 in 8 cases, regions 1 and 2 in 2 and regions 2 and 3 in 4. In 1 case, a radiolucent line of 1 mm in regions 1, 2 and 3 was associated with proximal and medial migration. Focal osteolysis ranging from 25 to 1575 mm^2 was found in 11 cases. The osteolysis was located in region 1 in 1 case, region 2 in 3, region 3 in 2, regions 1 and 2 in 3 and regions 2 and 3 in 2 cases.

At revision, we found that the soft tissues were discolored and that most of the coating had disappeared (Figure 1). The acetabular bone was hard and sclerotic, and in many cases it seemed to be

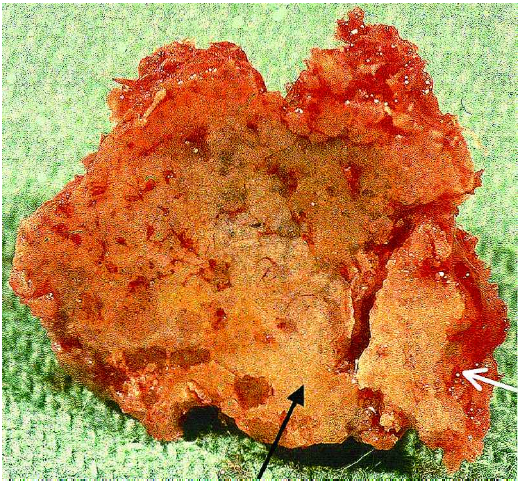

Figure 2. Revision biopsy from the acetabular floor with HA (black arrow) anchored to the bone (white arrow), but detached from the cup, as seen in Figure 1.

coated with HA that had been delaminated from the metal backing (Figure 2).

In 118 hips, wear measured between 0.5 and 6.5 mm. At revision, internal wear of the upper part was confirmed. In general, the surfaces were smooth, except in cases where the polyethylene had been worn through with cracks and delaminations.

Wear and age were significantly associated with revision ($p < 0.0001$ and 0.0005, respectively) (Table 2). There were no associations between revision and gender, diagnosis, cup size or inclination of the cup.

Radiographic examinations of the surviving cups showed a radiolucent line from 1 to 5 mm in 9 cases. The radiolucent line was located in regions 1, 2 and 3 in 3 cases, regions 2 and 3 in 4 and region 1 and 3 in 2. Focal osteolysis was seen in 2 cases—i.e., 24 and 816 mm^2 in regions 3 and 1, respectively. The remaining 139 cups showed bony incorporation seen as intimate bone-implant contact with periprosthetic bone formation and remodeling.

Discussion

The fixation of cemented acetabular cups gradually deteriorates after 5 years (Johnsson et al. 1994), and cementless fixation has become commoner, especially in younger patients. However, hardly any data show that uncemented cups are better than cemented ones. The results with threaded screw cups have, in general, been disappointing (Fox et al. 1994, Bruijn et al. 1995), but some reports indicate good results with porous press-fit cups at 10 years (Bohm and Bosche 1998, Clohishy and Harris 1999).

Table 2. Odds ratio (OR), 95% confidence interval (CI) and significance (P-value) of Cox proportional hazards analysis

	OR	CI	P-value
Sex	0.49	0.20–1.2	0.1158
Age (year)	0.95	0.91–0.98	0.0005
Diagnosis	1.1	0.90–1.3	0.3867
Cup size (mm)	1.0	0.94–1.1	0.4276
Cup inclination (°)	0.98	0.94–1.0	0.3097
Wear (mm)	1.67	1.3–2.1	< 0.0001

Most of our patients were young with dysplastic hips. We used a HA-coated prosthesis on the basis of experimental studies indicating that HA has osteoconductive properties which improve early bone ingrowth and mechanical fixation of implants (Cook et al. 1988). Numerous clinical short-term studies have also shown promising results (Furlong and Osborn 1991, Kroon and Freeman 1992, Capello 1994, Geesink and Hoefnagel 1995, Rossi et al. 1995, Onsten et al. 1996)—e.g., that HA reduces early migration of the components more than uncoated implants. However, hardly any clinical long-term follow-up studies have been done, and several concerns have been expressed about HA-coated implants, such as resorption and delamination of the coating as failure mechanisms. Our medium-term results confirm these concerns, especially in younger patients.

In our experience, there is a typical pattern of failure. The HA coating is resorbed and/or delaminated from the implant. This causes micromotion or at least instability of the implant at a molecular level, with fretting of titanium particles which cause discoloration and granulomatous inflammation of the tissues and pain. At about this time in the process, the implant loosens from its bony bed, with or without osteolysis. The presence of a titanium screw may increase the likelihood of fretting and ingress of joint fluid. It also provides a fulcrum about which rotation can occur.

The pattern of osteolysis in our series resembles that seen in prostheses without HA. Osteolysis due to severe granulomatosis in cemented THR is relatively common, and also occurs in association with uncemented acetabular components (Maloney et al. 1993, Zicat et al. 1995). The main cause of osteolysis is ascribed to the presence of particulate polyethylene wear, resulting in a foreign body reaction. Activation of macrophages and possibly osteoclasts produces an acidic environment which may cause osteolysis and dissolution of HA coatings. Wear, resorption of HA and osteolysis are factors that influence each other in a continuous process. Presence of bone marrow has been shown to increase HA resorption compared to more compact bone (Overgaard et al. 1997). Resorption of HA may cause micromotion with an increase in shear stresses, resulting in delamination of HA, especially on the medial side of the cup. Release of HA particles may induce a foreign body reaction and third-body wear.

The stability of HA in vivo has been questioned (Morscher 1991). It depends on chemical composition, texture and the underlying surface of the implant (Overgaard 2000). Our observations indicate that the effect of disintegration of the coating becomes clinically evident after 5–6 years, at least when gritblasted acetabular prostheses have been used. In 15 cases, loosening was not associated with granulomatosis or radiolucent lines around the cup. They experienced sudden pain suggesting fracture or delamination as the ultimate failure mechanism. However, in 4 of these the sudden pain was associated with a complete change in position of the cup. It is uncertain what will happen to the surviving cups in the long run. The few surviving cups with radiolucency or focal osteolysis are certainly at risk of clinical failure.

In the discussion about HA coating of implants, two views have been presented: one that believes a stable coating enhances bonding between bone and implant, and another that believes a resorbable coating enhances bone ingrowth into a textured implant surface. The present study addresses these views. If the HA coating bonds to bone in a stable situation, we found that stresses on the coating can induce underlying failure by delamination between the coating and implant surface. On the other hand, if the coating is resorbed, implant fixation must rely on incorporation between metal and bone. Our prosthesis had a gritblasted structure which was fairly smooth. Therefore, hardly any bony ingrowth can occur and a porous-coated structure would be better under the HA coating to allow secondary fixation by ingrowth. Subsequently, surface stresses become more complex which should reduce the risk of delamination.

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