

Excellent results of HA coating on a grit-blasted stem

245 patients followed for 8–12 years

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ABSTRACT We report the outcome of a grit-blasted titanium stem designed for press-fit insertion and entirely plasma sprayed with HA. During the years 1988–1993, we performed 323 primary total hip replacements in 276 patients (189 women) with a HA-coated prosthesis. Their mean age was 48 (15–79) years. During the follow-up, 12 patients died. 19 other patients did not attend the follow-up examination, but had no major symptoms according to telephone interviews and written replies. Thus, 245 patients (291 hips) were followed for a mean of 10 (8–12) years with radiographic and clinical examinations.

Only 1 stem was revised due to mechanical failure. None were revised because of infection. Osteolysis was significantly associated with wear, and wear was significantly associated with the size of the femoral head. We found a small amount of proximal bone loss (37/291) and a low incidence of distal hypertrophy of the bone (23/291). These observations indicate an essentially physiological weight distribution from the stem to the femoral bone. The changes in the bone confirmed that the femoral component was well fixed in asymptomatic patients. To conclude, we found excellent 8–12-year results with a fully HA-coated femoral prosthesis designed for press-fit insertion.

fixation. Osseointegration into metal depends on surface structure and characteristics of the implant. Titanium alloys are usually selected as the metallic substrate because of their low elastic modulus, good mechanical properties and good corrosion resistance (Deligianni et al. 2001). Hydroxyapatite as a coating is one of the most generally accepted and commercialized bioactive materials (Chang et al. 2001). Although promising experimental results have been reported with hydroxyapatite (HA)-coated implants, concern has been expressed about porosity, low fatigue strength, degradation and delamination during implantation for a long period (Bloebaum et al. 1994). Loose HA particles may also cause a foreign body reaction with osteolysis.

Good clinical results have been reported with HA-coated prostheses after a follow-up of 5–10 years (Røkkum and Reigstad 1999), but hardly any clinical long-term follow-up studies have been done (McNally et al. 2000, D'Antonio et al. 2001). Although we have had poor results with a grit-blasted HA-coated cup (Reikerås and Gunderson 2002), our clinical experience with a HA-coated stem have been very good. In the present study, we report our 8–12-year results with a grit-blasted and HA-coated titanium stem designed for press-fit insertion.

Aseptic loosening of cemented hip prostheses is a recognized long-term problem, especially in males and younger patients (Johnsson et al. 1994, Bourne et al. 1995, Callaghan et al. 1997, Herberts and Malchau 1997, Sochart and Porter 1997). Much energy, therefore, has been used to develop new prostheses designed for cementless

Patients and methods

During the years 1988 to 1993, we performed 323 primary total hip replacements in 276 patients (mean age 48 (15–79) years, 189 women) with a HA-coated prosthesis. Their diagnoses were

primary osteoarthritis (57 cases) and secondary osteoarthritis due to failed femoral neck fracture (12), congenital dislocation (95), congenital dislocation with luxation (94), Calvé-Legg-Perthes' disease or epiphysiolysis (23) and various other conditions (42).

In all cases, we used a straight stem designed for press-fit insertion. In 195 cases, we inserted a hemispherical cup with press-fit and in 128 cases, a hemispherical screw cup. Both the acetabular and femoral components were made of grit-blasted TiAl_6V_4 (Landos Corail, Landanger, Chaumont, France), and the outer surfaces were entirely plasma-sprayed with a $155 \pm 35 \mu\text{m}$ layer of HA. The purity of the HA was reported to be more than 97%, the density between 1.2 and 1.6 g/mL, the crystallinity more than 50% and the porosity less than 10%. The surface roughness of the coating, as characterized by Ra (arithmetical mean roughness value), varied between 7.5 and 9.5 μm , and Rt (maximum profile height) between 50 and 65. The surface roughness of the grit-blasted metal varied between 4 and 6 μm (Ra) and Rt between 25 and 40. The bonding strength of the coating to the metal is reportedly more than 10 MPa. These data were provided by the manufacturer.

We used stems of sizes 6 in 2 cases, 8 in 3, 9 in 27, 10 in 44, 11 in 42, 12 in 65, 13 in 46, 14 in 59, 15 in 19 and 16 in 16 cases. The head was made of stainless steel (Inox) with a diameter of 28 mm in 206 cases and 32 mm in 94 cases. In 23 cases, the head was made of Al_2O_3 (BioloX) and had a diameter of 28 mm. The polyethylene liners met the ISO standard for F648. Sterilization had been carried out by gamma irradiation with a dose of 25 to 35 kGy in air.

Surgery was standardized, using the direct lateral approach, without trochanteric osteotomy. We recommended no weight bearing for 3 months postoperatively.

During the follow-up, 12 patients died. 19 others failed to come for the follow-up examination. They were doing quite well with their prostheses according to a telephone interview and written reply. These patients were censored at their last check-up. This leaves 245 patients (291 hips) followed for mean 10 (8–12) years after the operation by radiographic and clinical examinations. They were rated clinically, using d'Aubigné and Postel's clas-

sification, as modified by Charnley (1972). Each patient was asked specifically about thigh pain and was instructed to grade such pain on a scale from 1 to 6 with 1 as the worst and 6 as no pain at all.

Radiographic evaluation included assessment of polyethylene wear, bone remodeling, osteolysis and fixation of the stem. Linear measurements were made on the AP radiograph, using a caliper, and corrected with reference to the diameter of the femoral head. Subsidence of the femoral component was compared with the vertical distance from the tip of the trochanter to the lateral shoulder of the prosthesis, with a variation of more than 5 mm. This limit of migration was arbitrarily set, but based on analysis of manual measurements of migration of hip prostheses (Malchau et al. 1995). Polyethylene wear was measured, using Livermore et al.'s method (1990). Alignment of the femoral component was classified as valgus (the tip of the stem engaged the medial cortex), neutral or varus (the tip of the stem engaged the lateral cortex). Analysis of radiolucent lines was performed as described by Gruen et al. (1979) (Figure 1). The degree of adequacy of biological fixation of the stem was assessed by a modification of the criteria described by Engh et al. (1987). Radiographic bony incorporation was defined as extensive intimate bone-implant contact, periprosthetic bone formation and remodeling, and the absence of migration. Femoral remodeling was regarded as a change in bone density, either as cortical or endosteal bone formation. A reduction in bone density was called atrophy and an increase as hypertrophy. Radiodense lines that roughly paralleled the surface contour of the implant, but was separated from it by a complete radiolucent zone (line) of varying thickness, was classified as fibrous ingrowth. A focal area of cortical or trabecular bone loss was considered evidence of osteolysis and assessed by approximating the area, using the formula for an ellipse (Zicat et al. 1995).

Kaplan-Meier survival analysis was used with removal of a component as the endpoint. Logistic regression analysis was employed to compare independent and dependent data. $P < 0.05$ was considered significant.



Figure 1. Radiographic follow-up of a HA-coated stem at 11 years. Gruen regions are indicated. Note the slight bone atrophy (calcar rounding) in regions 7 and 1, radiolucency adjacent to the stem proximally in region 1 and endosteal bone hypertrophy in region 4.

Results

During 8–12 years of follow-up, 42 press-fit cups and 9 screw cups were revised, none because of infection. Survival analyses indicated a cumulative survival of the HA-coated press-fit cup of 0.69 (0.59–0.79) at 11 years, with no patients at risk. The cumulative survival of the HA-coated screw cup was 0.92 (0.86–0.98) at 11 years, with 68 patients at risk.

1 stem was revised due to mechanical failure. This was a woman with arthrogryposis who was operated on when she was 32 years old. After 8 years she fell on her operated hip, and afterwards she had constant pain. On revision, the stem was loose, and all HA coating had disappeared. No other stems were revised because of mechanical loosening or infection. Therefore we did not have enough uncensored variables to compute survival analysis for the stem.



Figure 2. Radiographic follow-up of a HA-coated stem at 11.5 years. Note wear and osteolysis proximally in region 1. Apart from this, the prosthesis is well osseointegrated along the entire HA coating.

Stem subsidence exceeding 5 mm was not recorded in any case. Fibrous ingrowths with radiolucency adjacent to the stem with a thickness of 1–3 mm were found in 16 cases (Table). These were located in region 1 in 10 cases (Figure 1), region 7 in 2, regions 1 and 7 in 2 cases and to region 3 in 2 cases. Bone atrophy was found in 37 cases. This occurred in region 1 in 5 cases, region 7 in 23 and regions 1 and 7 in 9 (Figure 1). Bone hypertrophy, generally in the form of endosteal condensation around the tip of the stem in region 4, was found in 21 cases (Figure 1). In another 2 cases with a valgus position of the stem, cortical hypertrophy was found in region 5, where the tip of the stem engaged the cortex. Bone hypertrophy was associated with a larger stem ($p < 0.001$). Focal osteolysis, ranging from 25 to 1750 mm², was found in 28 cases. This was located in region 1 in 11 cases (Figure 2), region 7 in 12 and regions 1 and 7 in 5. Osteolysis was

Relation between the Gruen regions and the distribution of femoral bone radiolucency, atrophy, hypertrophy and osteolysis around the stem

	Region						
	1	2	3	4	5	6	7
Radiolucency	12		2				4
Atrophy	14						32
Hypertrophy				21	2		
Osteolysis	16						17

significantly associated with wear ($p < 0.001$) (Figure 2).

In 184 hips, we found 0.5–6.5 mm linear wear, no wear was recorded in the other cups. Mean linear wear was 0.80 (SD 1.03) mm with the 28 mm metal head, 0.86 (SD 1.49) mm with the ceramic head and 1.24 (SD 1.69) mm with the 32 mm metal head ($p < 0.001$).

Hips with mechanical loosening were excluded from the clinical evaluation of hip function, as recommended by Charnley (1972) and adopted from d'Aubigne and Postel. Pain ranged from 5 to 6, with a mean of 6, motion ranged from 4 to 6, with a mean of 5 and walking also ranged from 4 to 6, with a mean of 5. No patient had thigh pain. The rating varied from 5 to 6 in all cases.

Discussion

We started to use a HA-coated prosthesis in 1988. This was because of inferior results with porous-coated prostheses and experimental studies, which showed that HA has osteoconductive properties that improve early bone ingrowth and mechanical fixation of the implants (Cook et al. 1988). Preliminary clinical reports on HA-coated implants have been encouraging (Furlong and Osborn 1991, D'Antonio et al. 1992a, b, Kroon and Freeman 1992, Geesink and Hoefnagels 1995, Rossi et al. 1995, Tonino et al. 1995, Önsten et al. 1996, Røkkum and Reigstad 1999). They indicate that HA reduces early migration of the components more than uncoated implants. However, only a few long-term clinical follow-up studies have been done (McNally et al. 2000, D'Antonio et al. 2001), and there has been some concern about the long-term results of HA-coated implants. Resorp-

tion and delamination of the HA coating have been suggested as the reasons for failure.

In a recent paper (Reikerås and Gunderson 2002), we reported failure of a HA-coated press-fit cup. In the present series, the cumulative survival of the HA-coated screw cup was 0.92 at 11 years. With only one stem revision, however, there were not enough uncensored variables to analyze the survival of the stem. Since most of our patients were revised because of mechanical failure of the acetabular component, we could not determine the overall clinical outcome. We therefore focused on thigh pain related to the femoral component. The patients were mainly in the younger age groups with abnormalities of the hip, and belonged to a risk group. Nevertheless we found very good clinical and radiographic results at a mean follow-up of 10 years with a HA-coated stem. Reliable primary stability for a rapid bone response to HA was probably ensured by the wedge-shaped design of the stem.

Most cementless stems have been coated proximally. The clinical effects of proximal coating are uncertain. However, with unacceptable rates of stem revision with proximal porous coating, Engh et al. (1989) concluded that the fixation of fully coated stems is better than a proximal coating. We used an entirely coated stem, and our results accord with the recent long-term results of McNally et al. (2000). On the other hand, in a multicenter study of 436 proximally HA-coated stems, D'Antonio et al. (1992a) revised 0.46% of the stems because of loosening and found subsidence of another 6% at a follow-up of 3 years. In another study of proximally HA-coated stems, 1% were revised after 2–3 years and 8% experienced subsidence (D'Antonio et al. 1992b). However, other authors have reported fairly good results with proximal HA coating (Tonino and Rahmy 2000, Oosterbos et al. 2001).

Radiolucency adjacent to a prosthesis has been correlated histologically with a fibrous layer between the bone and the prosthesis (Engh et al. 1987, Pidhorz et al. 1993). We found radiolucent lines adjacent to the stem in 16 cases. In all except 2 cases, radiolucency was located in the proximal zones. The central and distal zones of the prostheses otherwise were well osseointegrated. Our explanation for proximal radiolucency is that a

well-bonded implant may have some proximal micromovement during loading. Wear particles with a foreign body reaction at the proximal level of the stem may also be of importance. In any case, these observations indicate that an extensive coating may give reliable fixation.

Thigh pain has been a considerable problem in proximally and fully-coated uncemented stems. The cause of thigh pain has been considered to be multifactorial. Cortical hypertrophy around the distal part of an uncemented press-fit stem has been reported in up to 70% of cases by Amstutz et al. (1989). This has been ascribed to distal stress transfer to cortical bone and an unphysiological load has been thought to account for mid-thigh pain. A striking finding in our series is the absence of thigh pain. The absence of radiolucent lines in the diaphysis suggests marked diaphyseal bonding. Furthermore, formation of new bone adjacent to the prosthesis was associated with a very moderate degree of bone remodeling. Since we found hardly any loss of bone proximally and a very low incidence of cortical hypertrophy distally, it can be assumed that: 1) no significant stress occurred from the proximal to the distal part of the femur, and 2) the weight distribution from the stem to the femoral bone was fairly physiological. The bone changes, therefore, confirm that the asymptomatic femoral component was well fixed. Radiographic measurements of remodeling of bone have been considered inaccurate. Kilgus et al. (1993), however, found a close correlation between dual energy X-ray absorptiometry and radiography.

Wear and osteolysis due to aggressive granulomatosis are a major problem with cemented and uncemented prostheses (Maloney et al. 1993, Zicat et al. 1995). The main cause of osteolysis has been ascribed to the presence of particulate polyethylene wear, which causes a foreign body reaction. In an uncemented prosthesis with an outer acetabular shell of metal, the polyethylene is less thick than in a cup of full thickness polyethylene for cementing (Owen et al. 1994). This may affect the degree of wear. In our study, osteolysis was significantly associated with wear, and wear was significantly associated with the size of the femoral head.

It is well accepted that young age, male gender and a high activity level increase the risk of accelerated wear, osteolysis and mechanical failure

(Dorr et al. 1994, Johnsson et al. 1994, Herbert and Malchau 1997). The prevalence of femoral osteolysis in uncemented prostheses has been reported to vary between 40% and 50% and even up to 60% in younger age groups (Engh et al. 1997, Xenos et al. 1999, Kawamura et al. 2001), which is much higher than that found in our material.

Wear particles activate macrophages and possibly osteoclasts, which may produce an acidic environment that can dissolve HA coatings. Resorption of HA may induce micromotion with an increase in shear stresses, and delamination of HA. The release of HA particles may cause a foreign body reaction. Wear, resorption of HA and osteolysis are probably closely related to one another and the stability of the HA coating is of primary importance. As there were only one revision in our series, we can not answer any question about stability of the HA coating on the stem. In a previous study, we found a marked loosening and dissolution of the HA coating on the cups (Reikerås and Gunderson 2002). This difference may be due to a greater tendency to dissolution of HA on the acetabular than on the femoral side. The presence of bone marrow increases resorption of HA more than compact bone (Overgaard et al. 1997). Moreover, the wedge-shaped design of the stem gives reliable stability on the femoral side that is difficult to obtain on the acetabular side.

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