Polyethylene wear, osteolysis and acetabular loosening with an HA-coated hip prosthesis

A FOLLOW-UP OF 94 CONSECUTIVE ARTHROPLASTIES

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We have followed up for a period of seven to nine years 100 consecutive arthroplasties of the hip in which an entirely HA-coated implant had been used. The clinical results were excellent and bony incorporation was extensive in all components. No stem became loose or subsided but five cups were revised because of loosening after 3.8 to 5.5 years, having functioned painlessly and shown radiological ingrowth.

Revision procedures because of excessive polyethylene wear have been performed on 18 hips and are planned for six more. Two eroded metal backings with worn-through polyethylene were exchanged; six hips showed metallosis without polyethylene wear-through. There were two cases of granulomatous cysts in the groin and 66 hips had osteolysis located perarticularly, in the greater trochanter or in the acetabulum.

Our aim was to study the medium-term results of a consecutive series of total hip replacements (THRs) using a prosthesis with a stem and cup completely coated with HA.

Patients and Methods

We examined 100 consecutive primary THRs before operation and at three weeks, four months, 12 months and annually thereafter. Four patients died, leaving 94 hips with a follow-up of between seven and nine years (Table I).

Prosthesis. The whole stem and metal backing were made of Ti6Al4V (Landos Corail; Landanger, Chaumont, France). They were plasma-sprayed with a layer of HA of mean thickness of 155 ± 3.5 µm. The HA had a purity greater than 98%, a density between 1.2 and 1.6 g/ml, and a crystallinity of between 50% and 70% (Fig. 1). The

Table I. Details of 94 hips (82 patients) operated upon between 1989 and 1991

| Mean age in years (range) | 56.1 (32 to 73) |
| Male:female              | 23:71          |
| Mean body-weight in kg (range) | 71.1 (46 to 105) |

Diagnoses

Primary osteoarthritis | 64 |
Arthritis secondary to dysplasia | 14 |
Rheumatoid arthritis | 5 |
Arthritis secondary to Developmental dysplasia of the hip | 3 |
Septic arthritis | 2 |
Traumatic hip dislocation | 2 |
Fracture of the femoral neck | 1 |
Epiphysiodesis | 1 |
Ankylosing spondylitis | 1 |
Legg-Calvé-Perthes disease | 1 |

Previous operations

None | 80 |
Arthrodesis | 5 |
Acetabuloplasty | 3 |
Osteosynthesis of fracture of the neck of the femur | 2 |
Intertrochanteric osteotomy | 2 |
Schanz osteotomy | 1 |
Smith-Petersen cup arthroplasty | 1 |

Charnley grade | 19 |
A | 30 |
B | 53 |
C | 11 |

Animall studies have demonstrated the capacity of hydroxyapatite (HA) to bond with bone without toxic or inflammatory effect.\(^1\)\(^-\)\(^7\) Plasma spraying of thin and dense coatings of HA on titanium implants may combine the beneficial effects of HA with the mechanical strength that is required of prostheses for human use.\(^2\)\(^,\)\(^3\)\(^,\)\(^8\)\(^-\)\(^11\) Preliminary reports on HA-coated hip prostheses are encouraging,\(^12\)\(^-\)\(^17\) but uncertainty exists about the stability of the coating and possible complications, including that of particles entering the joint space and damaging the articulating surfaces\(^18\).
bonding strength was 20 to 30 MPa, and the surface roughness had an Ra (average roughness/arithmetic average) of about 10 µm and Rt (maximum peak-to-valley height of the profile) between 60 and 65 µm. The stem and cup were available in eight and nine sizes, respectively, with reamers appropriate to each.

The diameter of the head was 32 mm in 92 prostheses and 22.2 mm in two; eleven were made of Al₂O₃ (Biolox) and 83 of 316L stainless steel (Inox). All had the same surface roughness (Ra = 0.05 µm).

The polyethylene liner had a cylindrical outer surface, resulting in a gradual decrease in thickness from the bottom of the inlay to the rim. Liners with minimum thicknesses of 3, 5, 6 and 7 mm were used in 47, 37, 2 and 8 hips, respectively. The inlays had been machined from the base resin GUR 412 (Chirulen, Germany) with a molecular weight of \(4.5 \times 10^6\) and a density of 0.934 g/cc, fulfilling the ISO standards 5834/1 and 5834/2, and the ASTM standard F648. Sterilisation had been carried out by gamma irradiation of 25 to 35 kGy in air.

Radiological evaluation. A standardised anteroposterior (AP) radiograph was taken of each pelvis and femur centred over the pubis, and a lateral view of the femur. Linear measurements were made using a calliper and corrected by reference to the diameter of the femoral head. Any gap between the metal backing and the acetabular bone and any deficiency of bone covering the cup laterally were measured in relation to lines through the centre of the femoral head. The angle of the cup laterally was determined using the interteardrop line and a line through the intersections of the head and the metal backing. We assessed the formation of radiopaque double lines\(^{20}\) and the eccentricity of the femoral head within the acetabulum.\(^{21}\) Migration was calculated using the outline of the components and the bony contours. Radiological bony incorporation was defined as extensive intimate bone-implant contact, periprosthetic bone formation and remodelling, and the absence of migration. Loosening of the implant was denoted by a change in position exceeding 2 mm or 2°, combined with the appearance of a double line.

Osteolysis was described as any focal area of bone loss adjacent to the prosthesis. Rounded or scalloped lesions extending away from the surface of the implant were classified as ‘expansile osteolysis’. Double lines adjacent to the prosthesis were classified as ‘linear osteolysis’ when the lucency exceeded 1 mm.\(^{22}\) Endosteal lysis of the femoral cortex was noted separately. Osteolysis was also categorised as periarticular or remote from the joint.\(^{22}\) The maximum diameter and the widest area perpendicular to this diameter were measured with a calliper on the AP radiograph, allowing approximation of the area using the formula for an ellipse.\(^{22}\)

We performed Kaplan-Meier survival analysis with removal of a component as the endpoint.

Results

The clinical results were excellent. Radiologically, there was bony incorporation of all components. Double lines slowly developed adjacent to the stems in 82 arthroplasties, starting proximally, usually extending laterally and anteriorly, but never along the distal two-thirds of the stem. No stem migrated or loosened. Thin partial lines appeared adjacent to two cups. The clinical and radiological results have been described elsewhere.\(^{23}\)

Acetabular loosening. In five female patients the cup which initially had been incorporated and functioned without pain, became loose (Fig. 2 and Table II). At revision, we found discoloration of the soft tissues and disappearance of most of the HA coating from the proximal parts of each femoral stem. The acetabular bone was hard and sclerotic. In one patient (case 5), we suspected that there was a low-grade infection, and both the loose cup and the well-fixed stem were removed. As in all the other ‘revised’ hips, bacterial cultures were negative.

Polyethylene wear. Eighteen hips with excessive polyethylene wear required surgery (Table III), and six are awaiting revision. Two patients (cases 14 and 16) developed tender cysts in the groin (Fig. 3). One (case 12) who had
Case 4. Acetabular loosening. Figure 2a – Radiograph showing a well-positioned and integrated cup four years after operation. Figure 2b – At 6.2 years, the cup has loosened revealing a radiopaque double line medially and minor lateral tilting. Figure 2c – The retrieved cup. There is material of an uncertain nature in some threads, but otherwise no HA coating remains.

Table II. Details of acetabular loosening

<table>
<thead>
<tr>
<th>Case</th>
<th>Diagnosis*</th>
<th>Age (yr)</th>
<th>Weight (kg)</th>
<th>Cup Angle (degrees)</th>
<th>Cup Size (mm)</th>
<th>Lack of Coverage (degrees)</th>
<th>Postoperative Gap (mm)</th>
<th>Eccentricity (mm)</th>
<th>Time to Symptoms (yr)</th>
<th>Time to Revision (yr)</th>
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<td>87</td>
<td>Steel</td>
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* DDH, developmental dysplasia of the hip; OA, osteoarthritis

Table III. Details of patients revised for excessive polyethylene wear. In cases 1 and 2, the polyethylene was worn through

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<th>Weight (kg)</th>
<th>Femoral Head</th>
<th>Cup Angle (degrees)</th>
<th>Cup Size (mm)</th>
<th>Minimum PE Thickness (mm)</th>
<th>Eccentricity (mm)</th>
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* OA, osteoarthritis; DDH, developmental dysplasia of the hip
had almost identical bilateral arthroplasties performed at different times, developed excessive wear of polyethylene in one hip only. Two patients had both hips revised (cases 4/7 and 9/16). Moderate pain unrelated to loading was encountered in 12 hips (Table III), the symptoms starting six months or less before revision was undertaken. Two patients (cases 1 and 3) had episodes of instability.

At revision, all prostheses were firmly anchored to bone, and the polyethylene inlays were secure in their metal backings. The inserts showed internal wear superiorly. The load-bearing surfaces were smooth, except where the liners were seen to be worn through with cracks and delamination of the polyethylene. The outer surfaces of the superior aspect of removed inlays were smooth and slightly depressed, except for the areas directly underlying holes in the backing, where the markers of machining were still visible. In two patients (cases 1 and 2) the femoral head had worn right through the polyethylene inlay on to the metal backing (Fig. 4). In six of the 16 cases without polyethylene wear-through, we found substantial dark grey discoloration of the bursal lining (Table III and Fig. 5a). Some scoring of the steel heads was found, but not of the ceramic ones. We found no wear of the taper cone or the inner aspect of the metal backing, and there was no evidence of impingement. At revision, all reactive inflammatory or stained soft tissue was removed, including the two groin

Table IV. Patterns of osteolysis. Most hips showed more than one pattern. Several areas of destruction were seen in more than one zone \( ^{24-26} \) and therefore patterns 3a to 3b, 4a to 4b and 5a and 5d were probably manifestations of the same lesions

<table>
<thead>
<tr>
<th>Pattern</th>
<th>Illustration</th>
<th>Location</th>
<th>Zone</th>
<th>Lesion</th>
<th>Relation to joint</th>
<th>Hips</th>
<th>Median size (mm (^2 ); range)</th>
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<td>Fig. 4a</td>
<td>Acetabulum AB</td>
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<td>Remote</td>
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<td>Femur 8</td>
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<td>337 (141 to 754)</td>
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<td>4a</td>
<td>Fig. 8</td>
<td>Femur 7</td>
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<td>Periarticular</td>
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<td>5a</td>
<td>Fig. 9</td>
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We extracted the two metal backings which had been exposed to wear and inserted 28 mm ceramic heads. Osteolysis. Osteolysis was found in 66 hips, including all those reoperated on for excessive polyethylene wear. Five principal patterns were seen (Table IV): 1) expansile destructions, located superiorly to the cup without dissection around the bone-implant interface in eight (Fig. 4a and pattern 1 in Table IV); 2) periarticular expansile lesions lateral to the cup, starting from the joint and eroding bone adjacent to the stem of the implant in 23 (Fig. 6 and pattern 2 in Table IV); 3) expansile lesions in the greater trochanter, laterally and often anterior to the stem in 12 (Fig. 7 and pattern 3a and 3b in Table IV); 4) scalloping excavations of the calcar in 42 (Fig. 8 and pattern 4a to 4b in Table IV); and 5) linear osteolysis adjacent to the stem in 60 (Fig. 9 and pattern 5a to 5d in Table IV); this extended distally from the upper lateral corner, anteriorly, and in two cases completely enveloped the upper part of the stem. All linear osteolysis was confined to the proximal one-third of the stem. No diaphyseal endosteal lysis was found. All lesions increased in size, especially patterns 1 and 3a and 3b in which extensive polyethylene wear required revision. No other reoperation for osteolysis was performed.

At the time of operation, the acetabular defects were seen to be more extensive than appeared radiologically; five pattern-1 lesions communicated with the central hole in the metal backing, and three connected with a pattern-2 lesion. The granulomatous content of osteolytic lesions contained particulate metal when there was intra-articular metallosis (Fig. 5a). We performed a thorough pulsatile lavage. Autogenous bone was grafted into the pattern-1 and pattern-3a-to-3b lesions, but generally not into other defects.

Survivorship. The survival rate of the stem at eight years was 98.9% (95% CI 96.9 to 100), of the acetabular metal backing 92.6% (95% CI 87.3 to 97.9), and of the polyethylene liner 77.5% (95% CI 69.0 to 86.0) (Fig. 10).

Discussion

Stem fixation. No stem loosened or subsided which is a satisfactory result for a cementless stem in which high rates of loosening have been reported. Reliable primary stability with the wedge-shaped design of stem, extensive coating and a rapid bone response with HA may have contributed to this outcome.

Acetabular loosening. Our incidence of acetabular loosening (5%) exceeded that of cemented cups, the Harris-Galante cup and preliminary reports on HA-coated cups. In our series acetabular loosening occurred late, after the cup had functioned painlessly and shown extensive bony ingrowth as far as could be demonstrated radiologically. This contrasts with porous-coated cups for which a high incidence of early lucent lines has been reported, suggesting poorer bonding.

Fig. 5a
Case 3. Severe but incomplete polyethylene wear of the liner 5.9 years after operation. Figure 5a – At reoperation, there is extensive metallosis. In the greater trochanter a black stained intraosseous expansile osteolytic lesion is seen (pattern 3a-b). Almost no HA remains on the visible part of the stem. Figure 5b – The head in the liner showing the wear.

Fig. 6
Radiograph showing an expansile periarticular osteolytic lesion above the cup (pattern 2) six years after operation.

cysts. We extracted the two metal backings which had been exposed to wear and inserted 28 mm ceramic heads.

Osteolysis. Osteolysis was found in 66 hips, including all those reoperated on for excessive polyethylene wear. Five principal patterns were seen (Table IV): 1) expansile destructions, located superiorly to the cup without dissection around the bone-implant interface in eight (Fig. 4a and pattern 1 in Table IV); 2) periarticular expansile lesions lateral to the cup, starting from the joint and eroding bone adjacent to the stem of the implant in 23 (Fig. 6 and pattern 2 in Table IV); 3) expansile lesions in the greater trochanter, laterally and often anterior to the stem in 12 (Fig. 7 and pattern 3a and 3b in Table IV); 4) scalloping excavations of the calcar in 42 (Fig. 8 and pattern 4a to 4b in Table IV); and 5) linear osteolysis adjacent to the stem in 60 (Fig. 9 and pattern 5a to 5d in Table IV); this extended distally from the upper lateral corner, anteriorly, and in two cases completely enveloped the upper part of the stem. All linear osteolysis was confined to the proximal one-third of the stem. No diaphyseal endosteal lysis was found. All lesions increased in size, especially patterns 1 and 3a and 3b in which extensive polyethylene wear required revision. No other reoperation for osteolysis was performed.

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Acetabular loosening. Our incidence of acetabular loosening (5%) exceeded that of cemented cups, the Harris-Galante cup and preliminary reports on HA-coated cups. In our series acetabular loosening occurred late, after the cup had functioned painlessly and shown extensive bony ingrowth as far as could be demonstrated radiologically. This contrasts with porous-coated cups for which a high incidence of early lucent lines has been reported, suggesting poorer bonding.

Fig. 5a
Case 3. Severe but incomplete polyethylene wear of the liner 5.9 years after operation. Figure 5a – At reoperation, there is extensive metallosis. In the greater trochanter a black stained intraosseous expansile osteolytic lesion is seen (pattern 3a-b). Almost no HA remains on the visible part of the stem. Figure 5b – The head in the liner showing the wear.

Fig. 6
Radiograph showing an expansile periarticular osteolytic lesion above the cup (pattern 2) six years after operation.

cysts. We extracted the two metal backings which had been exposed to wear and inserted 28 mm ceramic heads.

Osteolysis. Osteolysis was found in 66 hips, including all those reoperated on for excessive polyethylene wear. Five principal patterns were seen (Table IV): 1) expansile destructions, located superiorly to the cup without dissection around the bone-implant interface in eight (Fig. 4a and pattern 1 in Table IV); 2) periarticular expansile lesions lateral to the cup, starting from the joint and eroding bone adjacent to the stem of the implant in 23 (Fig. 6 and pattern 2 in Table IV); 3) expansile lesions in the greater trochanter, laterally and often anterior to the stem in 12 (Fig. 7 and pattern 3a and 3b in Table IV); 4) scalloping excavations of the calcar in 42 (Fig. 8 and pattern 4a to 4b in Table IV); and 5) linear osteolysis adjacent to the stem in 60 (Fig. 9 and pattern 5a to 5d in Table IV); this extended distally from the upper lateral corner, anteriorly, and in two cases completely enveloped the upper part of the stem. All linear osteolysis was confined to the proximal one-third of the stem. No diaphyseal endosteal lysis was found. All lesions increased in size, especially patterns 1 and 3a and 3b in which extensive polyethylene wear required revision. No other reoperation for osteolysis was performed.

At the time of operation, the acetabular defects were seen to be more extensive than appeared radiologically; five pattern-1 lesions communicated with the central hole in the metal backing, and three connected with a pattern-2 lesion. The granulomatous content of osteolytic lesions contained particulate metal when there was intra-articular metallosis (Fig. 5a). We performed a thorough pulsatile lavage. Autogenous bone was grafted into the pattern-1 and pattern-3a-to-3b lesions, but generally not into other defects.

Survivorship. The survival rate of the stem at eight years was 98.9% (95% CI 96.9 to 100), of the acetabular metal backing 92.6% (95% CI 87.3 to 97.9), and of the polyethylene liner 77.5% (95% CI 69.0 to 86.0) (Fig. 10).

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HA coating. Histological studies of HA-coated prostheses retrieved from patients have shown no resorption of HA up to nine months after implantation. Other studies have shown partial loss of coating up to 26 months after implantation, and complete resorption of an HA coating 60 µm thick after four years. Our coating was thicker, but the follow-up was longer, and therefore complete degradation of HA could yet have taken place. If reaction to particles causes loosening, we would have expected this to have been preceded by the development of lucent lines. This was not seen, which suggests disruption between the implant and bone. Thick HA coatings may have poorer mechanical properties than thin ones, and the HA-to-metal interface is thought to be the weak point. We observed that loose cups had almost completely lost their HA coating, consistent with loosening between the coating and metal. Fatigue failure between the smooth metal surface and the HA coating in response to prolonged distractive stress medially could be responsible for the separation of the socket from the bone, in contrast to the stem in which compressional forces are acting inside the medullary canal. It is less likely that the coating had been resorbed after loosening, since the time from loosening to reoperation was short. Abrasion of the coating after loosening would have been expected cranially rather than globally, as in all our loosenings.

Polyethylene wear. Our observation of polyethylene wear and acetabular loosening was worse than for cemented and some cementless cups. Excessive polyethylene wear is reported with various cementless cups, with or without HA coating. Our results confirm those of Bloebaum et al and Bloebaum and Dupont who found both HA and metal particles embedded within the polyethylene surface.

Metallosis in hips with incomplete polyethylene wear implies third-body wear. The most probable third bodies
are particles of HA which may detach during insertion, specially from the threads of a screw cup. A human retrieval study has shown osseointegrated HA lamellae, which had separated during implantation.\textsuperscript{53} HA lost from surfaces uncovered by bone could more easily enter the overload of particles probably provokes pain.\textsuperscript{150} The poor mechanical properties of our thick coating\textsuperscript{150} may have enhanced HA abrasion and provided a source of HA particles.

Machined polyethylene inlays,\textsuperscript{54} cementless fixation,\textsuperscript{55} ageing after gamma irradiation,\textsuperscript{56} and wear or deformation of the convex side of the polyethylene\textsuperscript{57} may also have influenced our results. Femoral heads of 32 mm diameter and cylindrical acetabular inlays may be unfavourable in that they reduce the available polyethylene layer, particularly at the superior rim.\textsuperscript{51,52} Thicker inlays reduce the contact stress and wear rate of polyethylene\textsuperscript{58} a thickness of 5 mm or less proved to be insufficient. There is uncertainty as to the linear wear with 32 mm heads compared with smaller ones,\textsuperscript{54,55,59-64} but higher volumetric wear with 32 mm heads has been substantiated.\textsuperscript{61,65} Ceramic heads do not prevent polyethylene wear and osteolysis.

**Osteolysis.** We believe that the biological response to the wear particles, mainly polyethylene\textsuperscript{66,70} but also including steel and HA,\textsuperscript{43,46,66} has been responsible for the osteolytic lesions and granulomatous cysts. The latter has not been reported previously around HA-coated prostheses. The largest lesions were in the cancellous bone. The gap often seen lateral to the proximal part of the stem could be a route for the transport of particles into the greater trochanter whereas the hole in the metal backing could have provided access to the acetalabular bone. The smaller scalloping calcar excavations and metaphyseal linear osteolysis were not considered equally alarming, although the gradual extension of the latter may represent a threat to the diaphyseal seal. The complete absence of femoral endosteal cortical osteolysis in spite of the abundance of particles is reassuring. The explanation may be that the extensive HA coating of the stem seals the whole interface and blocks the passage of particles. Osteolysis of the femoral cortex has often been found with both porous-coated and cemented stems.\textsuperscript{29,32-35,66,71-74} Osteolysis around cementless acetalabular components seems to appear most often in hips with abundant particles such as we encountered.\textsuperscript{15,22,33,35,51,52,67} The continuous increase in the size of the lesions has been reported by others.\textsuperscript{74-76} The inflammatory response to the overload of particles probably provokes pain.

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**References**


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