Polyethylene wear with an entirely HA-coated total hip replacement

79 hips followed for 5 years

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We measured the eccentricity of the femoral head in the metal backing annually during 5 years in 79 consecutive total hip replacements (73 patients). The mean age of the patients was 57 (32–73) years and the female/male ratio 63/22. The prostheses were entirely coated with hydroxyapatite. Modular 32 mm stainless steel heads and hemispherical, self-tapping screw cups with polyethylene liners were used.

We found accelerating eccentricity throughout the observation period. The mean eccentricity at 5 years was 0.71 mm (95% CI 0.53–0.90), resulting in a mean eccentricity rate of 0.14 mm (0.11–0.18) per year. The 5-year eccentricity was 0.5 mm or less in 45 hips and more than 1.5 mm in 13 hips, 2 in the latter group apparently having worn through the polyethylene liner. The true wear may be twice as great.

The use of 32 mm stainless steel heads and thin polyethylene inlays may have aggravated the wear problems. These HA-coated prostheses must all be checked regularly, so that cases with excessive polyethylene wear can be reoperated on before wear-through of the liner.

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Preliminary reports on hydroxyapatite (HA)-coated hip prostheses are encouraging (D'Antonio et al. 1992, Geesink and Hoefnagels 1995, Rossi et al. 1995, Tonino et al. 1995). However, uncertainty exists as to the stability of the coating and the long-term effects of HA, including the possibility of HA particles entering the joint space and destroying the articulating surfaces (Morscher 1991).

We assessed the polyethylene wear in an entirely HA-coated total hip replacement, by annually measuring the eccentricity of the femoral head in the acetabular cup during the first 5-year follow-up.

Patients and methods

We studied the first 85 consecutive primary total hip replacements (Landos Corail, Landanger, Chaumont, France) with modular 32 mm stainless steel heads (Inox®), performed between February 1989 and February 1991 (Table 1). The surface roughness of the steel heads was characterized as Ra = 0.05 µm. Both the straight tapering stem and the hemispherical screw cup were made of $TiAl_6V_4$. The outer surfaces were entirely plasma-sprayed with a 155 ± 35 µm layer of HA, having a purity greater than 98%, a density between 1.2 and 1.6 g/mL, and a crystallinity between 50 and 70%, according to the manufacturer. The bonding strength was reported to range from 20 to 30 MPa and the surface roughness was characterized by Ra being about 10 µm and Rt between 60 and 65 µm. We used cups of sizes 48 mm (20), 50 mm (20), 52 mm (19), 54 mm (16), 56 mm (4), 58 mm (3) and 60 mm (3). The minimum thicknesses of the liners fitting the 48/50 mm cups (40 hips), the 52/54/56 mm cups (39 hips), and the 58/60 mm cups (6 hips) were 3, 5 and 7 mm, respectively (Figure 1). The liners had been machined from the base resin GUR 412 (Chirulen, Germany), having a molecular weight of 4.5 million and a density of 0.934 g/cc. The polyethylene was reported to fulfil the ISO standards 5834/1 and 5834/2, and the ASTM standard F648. Sterilization had been carried out by a gamma irradiation dose of 25 to 35 kGy in air.

Table 1. Patient characteristics

Mean age (range)	57 (32–73)
Gender F/M	63/22
Mean body weight (range), kg	72 (46–105)
Diagnoses – Primary arthrosis	60
Secondary arthrosis	20
Inflammatory disease	5
Patient grade (Charnley 1979) – A	27
B	48
C	10

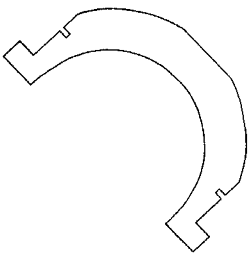

Figure 1. A cross-section through the polyethylene liner matching the 48 and 50 mm cups. The partly cylindrical outer side and the spherical excavation resulted in a gradual reduction in thickness from the bottom of the inlay to the rims, where the minimum thickness was located in all sizes of insert.

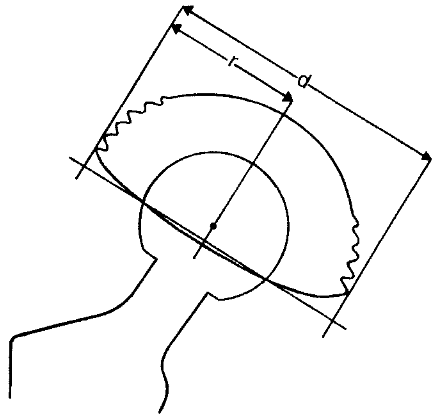

Figure 2. Assessment of eccentricity of the femoral head in the metal backing. The center of the femoral head was determined by a template with concentric circles. A line was drawn through the points of intersection of the femoral head and the periphery of the metal backing. Perpendiculars were raised through the center of the femoral head and at the extreme medial and lateral borders of the metal backing. The distances d and r were measured to the nearest 0.1 mm by use of a caliper. The eccentricity of the femoral head in the metal backing was calculated by the formula d/2 – r. Using the 3-week control as the reference, increased eccentricity due to polyethylene wear could be assessed at the subsequent controls.

Surgery was standardized, using the direct lateral approach, without trochanteric osteotomy (Hardinge 1982). We recommended no weight bearing for 3 months postoperatively.

Radiographic evaluation was carried out at 3 weeks, 4 months, 12 months and yearly thereafter until 5 years. 9 and 6 cases failed to appear for the 3- and 4-year reviews, respectively; otherwise, all hips were reviewed in accordance with the schedule. 3 patients, 1 of them bilaterally operated, died after 4 months (1), 3 years (2) and 4 years (1). 2 cups, which loosened after the 3- and 4-year controls, were excluded from the study thereafter. There were no reoperations for polyethylene wear during the observation period. Hence, 79 hips reached the final 5-year follow-up.

Measurement technique

All radiographs were evaluated by the same orthopedic surgeon. Anteroposterior radiographs of the pelvis, centered over the pubis, were standardized by using the same film quality, developing process, exposure, target distance, magnification, field and keeping the leg in the same position. All measurements were corrected for magnification of the radiographs, using the diameter of the head of the femoral component as reference.

We modified the technique of Livermore et al. (1990) for detection of maximum polyethylene wear for cemented cups, by measuring only the eccentricity of the head in the metal backing (Figure 2). The accuracy of our measurements was estimated by independently determining the eccentricity of 30 hips twice. The mean difference between the 2 evaluations was 0.17, SD 0.32 mm (range 0–0.55).

Due to the irregular outer surface of the metal backing, we could not determine the direction of wear. Livermore et al. (1990) found that the mean direction of maximum linear wear in cemented prostheses with 32 mm heads was cephalad and 15° medial to a vertical line. We measured the lateral angle of our cups as 46°, SD 7.7°, assessed by the inter-teardrop line and a line through the intersections of the head and the metal backing. On the basis of these data, we estimated the true linear polyethylene wear in our hips at approximately twice the eccentricity that we measured.

The corresponding volumetric wear (v) was estimated by the formula $v = \pi r^2 w$, in which r is the radius of the femoral head and w is the measured linear migration of the head through the polyethylene (Livermore et al. 1990).

Statistics

The data were analyzed with the two-tailed Mann-Whitney test. Relations between continuous variables were analyzed with Spearman's rank correlation. Statistical significance was set at $p < 0.05$ and adjusted to $p < 0.01$, using Bonferroni's correction for multiple comparisons.

Results

The mean eccentricity of the femoral head in the metal backing at the 3-week radiography was 0.15 mm (95% CI 0.09–0.20). Using this as the starting point, we found accelerating eccentricity throughout the observation period (Figure 3). The mean eccentricity at 5 years was 0.71 mm (CI 0.53–0.90), resulting in a mean eccentricity rate of 0.14 mm (CI 0.11–0.18) per

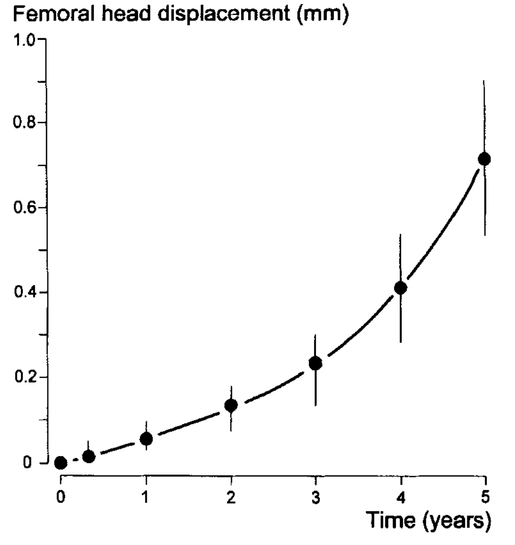

Figure 3. Accelerating eccentricity of the femoral head in the metal backing (mean, 95% CI), demonstrating significantly increasing eccentricity between every second registration point.

year. This corresponds to an estimated true wear of approximately 0.28 mm in the direction that Livermore et al. (1990) reported. The corresponding estimate of 5-year volumetric wear was approximately 1100 mm^3, giving an average volumetric wear rate of approximately 230 mm^3 per year. No statistically significant association was found between eccentricity and gender ($p = 0.9$, Mann-Whitney), age (Spearman's r_s 0.24, $p = 0.04$), body weight (Spearman's r_s 0.14, $p = 0.2$) or cup inclination (Spearman's r_s 0.13, $p = 0.3$). The mean eccentricities of polyethylene inserts with minimum thicknesses of 3, 5 and 7 mm were 0.91 mm (CI 0.59–1.24, n 38), 0.53 mm (CI 0.34–0.72, n 37) and 0.48 mm (CI 0.02–0.93, n 4), respectively. No statistically significant difference was found between inserts with minimum thicknesses of 3 and 5 mm ($p = 0.1$, Mann-Whitney).

45 hips had an eccentricity of 0.5 mm or less, whereas 13 hips in 12 patients had an eccentricity exceeding 1.5 mm, 2 of the latter apparently having worn through the 3 mm minimum of their polyethylene liners (Table 2). The 13 hips with wear exceeding 1.5 mm had a greater eccentricity from 2 years on than the remaining 66 hips ($p = 0.0004$, Mann-Whitney). Based on the 5-year results, the average annual eccentricity rates of these 13 hips and the remainder were 0.45 mm (CI 0.11–0.18) and 0.08 mm (CI 0.36–0.53), respectively ($p < 0.0001$, Mann-Whitney). 1 bilaterally operated patient developed a 5-year eccentricity of 1.8 mm in the latest-operated hip only, whereas the contralateral hip had an eccentricity of 0.2 mm. The same cup size had been used, and the lateral angle was exactly 5° greater in the hip with excessive wear.

Discussion

The accuracy of our wear measurements did not attain the level reported by Livermore et al. (1990). The radiographic contour of our screw cup should be as distinct as that of a cemented cup, although the thin tips of the threads appeared a little unclear in some projections. In some cases, the metal backing obscured most of the head, possibly reducing the precision of the head-center determination. Generally, greater uncertainty accompanies wear measurements during the first 5 years, due to the small distances involved (Callaghan et al. 1995).

The true polyethylene wear of our prostheses was certainly higher than the eccentricity that we measured along the cup inclination plane. Livermore et al. (1990) found the mean direction of linear wear in prostheses with 32 mm heads to be 15° medial to a vertical line. If this were the true direction of wear in our prostheses, the true amount of wear would be approximately twice the eccentricity that we measured. However, such an estimate of true wear is attended with uncertainty. Hence, a wear directed even more medially would mean a further increase in true wear, whereas a strictly vertical direction would correspond to an increase of approximately 50%.

A mean linear polyethylene wear rate of 0.05–0.21 mm per year has been found with cemented prostheses (Charnley and Cupic 1973, Charnley and Halley 1975, Griffith et al. 1978, Cupic 1979, Wroblewski 1985, Livermore et al. 1990, Bankston et al. 1993, 1995b, Cates et al. 1993, Callaghan et al. 1995, Nashed et al. 1995, Izquierdo-Avino et al. 1996). An-

Table 2. Distribution of eccentricities at 5 years

	Eccentricity (mm)							
	0	0.1–0.5	0.6–1.0	1.1–1.5	1.6–2.0	2.1–2.5	2.6–3.0	>3.0
Hips (n 79)	17	28	13	8	6	3	2	2

nual wear rates of 0.15 and 0.22 mm were observed with the cementless Universal cup design (Biomet, Warsaw, Indiana, USA) when articulating with cemented and cementless femoral components, respectively (Hernandez et al. 1994). Wear rates of 0.07 mm and 0.14 mm per year have been reported with the Harris-Galante cup (Callaghan et al. 1995, Woolson and Murphy 1995). With the Biologic Ingrowth Anatomic System (Zimmer, Warsaw, Indiana, USA), wear rates of 0.17 and 0.25 mm were reported, respectively, with use of cobalt chromium and titanium heads (Nashed et al. 1995). A 2-year radiostereometry study showed 0.37 mm polyethylene wear in the HA-coated Osteonic prosthesis, which was not significantly different from the Charnley hip (Önsten et al. 1996). Hence, our estimated true annual wear rate lies at the upper extreme of the ranges reported with both cemented and cementless prostheses.

Only some of our hips contributed to the high annual wear rate. Owen et al. (1994) noted severe wear of the polyethylene liner in 14% of 226 PCA hips, and Kim and Kim (1993) found excessive polyethylene wear in 17% of 116 PCA hips, mean 7.4 (5–11) mm. The average wear rate in these cases was 1.3 mm per year. Berry et al. (1994) described catastrophic failure of the polyethylene liner in 10 cases of 3 different uncemented sockets (DePuy, PCA and Osteonics), all with a minimum polyethylene thickness of less than 5 mm. Bono et al. (1994) found catastrophic failure in 15 of 72 AML+ acetabular components. The wear rate in the failure group was 0.77 mm yearly. Geesink and Hoefnagels (1995) revised only 1 HA-coated acetabular cup due to excessive polyethylene wear. This demonstrates that excessive polyethylene wear is a problem with cementless cups of various designs. It is uncertain whether the problem is greater with HA-coating than with other surfaces.

Increased polyethylene wear has been reported with the use of metal backing (Cates et al. 1993, Bankston et al. 1995a), which is partly explained by wear or plastic deformation taking place on the convex side of the polyethylene (Huk et al. 1994). Other factors that have been associated with increased polyethylene wear, such as machined polyethylene inlays (Bankston et al. 1995b), cementless fixation (Hernandez et al. 1994) and ageing following gamma irradiation (Rimnac et al. 1994, Fisher et al. 1995, Sutula et al. 1995), may also have contributed to the polyethylene wear in our hips. We found no significant associations between wear and parameters like gender, age and body weight, which have been demonstrated by others (Griffith et al. 1978, Kim and Kim 1993, Berry et al. 1994, Bono et al. 1994, Callaghan et al. 1995, Nashed et al. 1995, Woolson and Murphy 1995).

The use of 32 mm femoral heads was clearly inadvisable. It reduced the available polyethylene layer. A minimum thickness of only 3 mm, which was the situation in almost half of our hips, proved insufficient. Thicker inlays may reduce the contact stress and wear rate of polyethylene (Bartel et al. 1986). The cylindrical geometry of the polyethylene liner localized the minimum thickness to the superior rim, thereby increasing the stress, especially with steep cups (Berry et al. 1994, Bono et al. 1994). However, we found no significant difference in wear between polyethylene inlays with minimum thicknesses of 3 and 5 mm, and no association between wear rate and cup inclination.

At 5 years, more than half of the hips showed an eccentricity of only 0.5 mm or less. This speaks against any general explanation of our excessive wear problems, such as inferior polyethylene quality and suggests that severe wear was related to one or more specific factors. This finding is supported by the bilaterally operated patient, who developed excessive wear in one hip only. From 2 years on, we found a statistically significant difference in wear between the excessive wear group and the remainder, implying a wear factor that was active even early postoperatively.

The accelerating wear might suggest third-body wear, possibly increasing the wear rate along with increasing damage of the articulating surfaces. The most probable third bodies in this setting are HA particles, which may well have been released obscurely in varying amounts. The HA coating could have been detached during insertion, especially from the screw cup. This is in agreement with the human retrieval study by Lintner et al. (1994), which showed separately osseointegrated HA lamellae, obviously having been flaked off during implantation. Our findings also agree with those of Bloebaum and DuPont (1993) and Bloebaum et al. (1994) , who reported excessive polyethylene wear with HA-coated prostheses. Their retrieval analysis showed HA, polyethylene and metal particles throughout the soft tissue and in osteolytic lesions, while HA and metal particles were embedded in the articulating surface of the polyethylene inserts. They hypothesized that parts of HA exposed to bone marrow and soft tissues could dissociate by hydrolysis or other cellular or bone remodeling events. Human retrieval studies have shown resorption of the HA coating and HA particles in macrophages in the adjacent bone marrow (Bauer et al. 1991, Hardy et al. 1994). Whether released by the mentioned mechanisms or by others, some of this HA coating could have entered the joint.

The 155 μm HA coating of our prosthesis was thicker than most other clinically employed coatings.

Bloebaum and DuPont (1993), Bloebaum et al. (1994) and Geesink and Hoefnagels (1995) examined prostheses with HA coating thicknesses of 70–100 and 45–65 µm. Poorer mechanical properties with thick coatings (Geesink et al. 1987, Wang et al. 1993) might increase the risk of HA abrasion or delamination. In addition, a thick coating provides a greater reservoir of HA, which may be a source of HA particles.

Our findings indicate that these HA-coated prostheses must all be checked regularly. Since the minimum thickness of the polyethylene inlay was near the upper rim, our measurements of eccentricity could be useful in selecting a correct time for reoperation, before wear-through of the liner. At reoperation, we also recommend replacing the femoral head with a smaller one, allowing the use of a thicker polyethylene inlay.

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