# Poor outcome of the PCA and Harris-Galante hip prostheses

## Randomized study of 171 arthroplasties with 9-year follow-up

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**155 patients (171 hips) with a mean age of 50 years (24–64) were randomized to uncemented PCA (84 hips) or Harris-Galante type I (87 hips) total hip arthroplasty. Clinical and radiographic evaluations were done regularly. The improvements in the Harris hip and pain scores did not differ. Osteolysis developed in 5 PCA and 17 Harris-Galante hips. 13 hips in the PCA and 16 in the Harris-Galante (HG) group were revised because of mechanical failures and 1 hip (HG) because of infection after a mean follow-up of 9 years. Decreased 10-year survival rate, based on revision as end-point, was noted for the PCA (85%), compared with the Harris-Galante cup (99%). The corresponding survival rate of the PCA stem (96%) was higher than that observed for the Harris-Galante design (86%). When radiographic failures were included, the survival rates of the 4 different components dropped to between 73% and 94%. These findings indicate that further revisions will be necessary and continuous radiographic follow-up is indicated to enable revision before severe bone destruction has occurred. Although the PCA and the Harris-Galante designs differed as regards the survival of the individual components, the overall clinical and radiographic survival rates of these cementless total hip arthroplasties were poor.**

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Cementless hip systems were introduced in the late 1970s because of early and high failure rates of cemented implants, especially in young and active patients (Chandler et al. 1981, Dorr et al. 1983). Alternative solutions to the problem of fixation were suggested on the basis of experimental studies of bony ingrowth into porous surfaces (Galante et al. 1971, Pilliar et al. 1975, Pilliar 1987) and clinical experiences of stress-shielding observed around cementless stems entirely coated with a porous surface (Bobyn et al. 1987). The PCA (Howmedica Inc, Rutherford, NJ, USA) and the Harris-Galante I (Zimmer Inc, Warzaw, IA, USA) prostheses were two examples of this new fixation concept, including a porous-coated hemispherical cup and a stem with a proximal porous coating. These implants, representing the second generation of cementless hip implants, were believed to solve the fixation problem and they spread rapidly in the orthopedic community. At the time of their introduction both designs addressed the problem of cementless fixation in two ways, using different alloys, type of porous coatings, stem design and fixation principles for the cup. This prospective and randomized study aimed to evaluate which of these concepts could most efficiently fulfil the requirements of a young patient population.

## Patients and methods

155 patients (78 women) were included in the study. They were operated with uncemented total hip arthroplasties between 1985 and 1989. All patients had been admitted to our hospital. The criteria for entering the study were disabling hip disease with duration of at least 6 months and positive radiographic findings. Exclusion criteria were age above 65 years, corticosteroid treatment for more than 3 months or insufficient bone stock. The patients gave informed consent to participate. The mean age was 50 (24–64) years, the mean weight 72 (41–107) kg and the mean preoperative Harris score 41 (9–83). 16 patients (11 women) received bilateral prostheses and thus 171 hips were included. Primary osteoarthrosis, the commonest diagnosis, was present in half of the cases. 50% of the patients had unilateral and 37% bilateral hip disease. 13% of the patients had a multiple joint disease (Table 1).

84 hips were randomized to a PCA (Porous-Coated Anatomic) and 87 to a Harris-Galante I prosthesis. The randomization procedure was performed preoperatively, using closed envelopes. Both groups were similar regarding the Charnley classification, the type of diagnosis and the preoperative hip and pain scores.

Table 1. Preoperative data

| | PCA | HG |
|---|---|---|
| Age [a] | 51 (24–64) | 52 (21–64) |
| Gender: female/male | 48/36 | 41/46 |
| Weight [a] | 72 (46–100) | 74 (41–107) |
| Diagnosis, n | | |
| Primary osteoarthrosis | 46 | 42 |
| Pediatric disease | 16 | 18 |
| Trauma | 10 | 14 |
| Arthritis | 4 | 3 |
| Idiopathic osteonecrosis | 2 | 5 |
| Miscellaneous | 6 | 5 |
| Preop Harris score [a] | 40 (9–80) | 40 (10–83) |
| Preop Harris pain [a] | 10 (0–30) | 10 (0–40) |
| Charnley category, n | | |
| A | 37 | 47 |
| B | 36 | 27 |
| C | 11 | 13 |

[a] median (range)

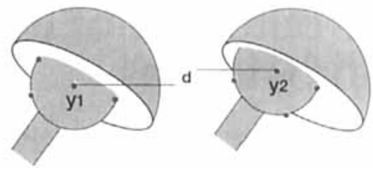



Figure 1. Wear measurements according to **method a**. Proximal wear is defined as the difference (d) between the 2 head center coordinates (y2–y1).

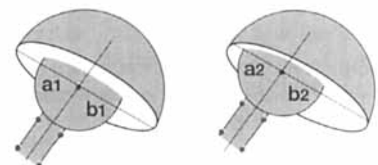



Figure 2. Wear measurements according to **method b**. Proximal–lateral wear is defined as: (a1–a2) + (b2–b1) / 2.

The PCA prosthesis is made of chrome-cobalt alloy. The press-fit cup is entirely porous-coated and has two pegs for additional fixation. The femoral component is anatomically designed, with a circumferential porous coating on its proximal third. The Harris-Galante I prosthesis (HG) is made of titanium alloy, with pure titanium fiber mesh surfaces for bone ingrowth. The acetabular component is hemispherical and completely covered with a titanium fiber mesh. It has multiple holes for additional screw fixation. The straight stem has medial collar and ingrowth pads on the anterior, posterior and medial surfaces of the proximal third of the implant.

A modified anterolateral approach, according to Hardinge, was used in all but 2 cases with a posterior approach. A 32 mm femoral head made of chrome cobalt was used in all hips, apart from 1 with a 22 mm head. 4 surgeons did the operations. Peroperative calcar fissures were noted in 6 patients (4 HG, 2 PCA). 1 patient (HG) was treated with closed reduction because of postoperative dislocation.

Postoperatively, the patients were partially weight bearing for 6–8 weeks. Clinical and radiographic follow-up were performed 1, 3, 5, 7 and 10 years after the operation. The Harris (1969) hip score was used at the clinical evaluation by an unbiased observer. Radiographic examination included anteroposterior, lateral and pelvic views. Classification into acetabular and femoral regions was made according to DeLee and Charnley (1976) and Gruen et al. (1979). Femoral osteolysis was defined according to Goetz et al. (1994). In addition, the presence of osteolytic lesions in Gruen zones 1 and 7 (calcar and trochanteric granulomas) was recorded. The sizes of the osteolytic lesions in each acetabular or femoral region were measured on a digitizing table. Lateral displacement of the distal end of the stem was recorded, as well as presence of distal cortical hypertrophy in Gruen zones 3, 4 and 5. Radiolucent lines were classified as not present, including less than 50%, 51–99% or 100% of the interface. Radiolucencies around the stem were recorded only on the AP view. We considered the quality of the lateral view of the stem to be too poor in most cases for an adequate analysis. The migration of the implants was measured on digitized radiographs (Malchau et al. 1995). Proximal migration of acetabular and subsidence of femoral components were regarded as significant if they exceeded 5 mm. Components with significant migration, surrounded by a complete radiolucent line or cortical osteolysis larger than 1 $cm^2$, were defined as radiographic failures. Polyethylene wear (here: same as penetration of the femoral head) was measured in two ways on the digitizing table. The two-dimensional coordinates of the center of the cup and femoral head were determined on the postoperative and follow-up radiographs. The difference in length between these two points along the longitudinal axis of the body was calculated. This difference represented proximal wear (method a, Figure 1). Since the metal-backing hid the head in most of the PCA cups, an alternative method to measure the wear was used. A center line through the neck of the femoral component and a line between the most lateral and medial edges of the opening of the cup were reconstructed. The displacement of the intersection of these lines between 2 examinations (proximal-lateral penetration) was used to represent wear (method b, Figure 2).

Two of the authors (JT, JK), who had not been involved in the surgery screened all radiographs, using a predetermined protocol. One of us (JT) did the measurements of wear, radiolucencies and osteolyses. Further, a single unbiased observer measured the migration of the implants.

Cox regression and the Mann-Whitney U-test were used for statistical analysis. Survival analysis was performed according to Kaplan-Meier. Survival rates and the 95% confidence intervals were calculated based on revision only or revision and/or radiographic failure as end-points. If only the polyethylene liner was exchanged, this was defined as a cup revision. One hip revised because of infection was excluded from these calculations.

In the bilaterally operated patients (n 16), only the first operated hip was included in the calculations of the Harris hip and pain scores. In the survival and regression analyses, the total material is presented. Exclusion of the second operated hip did not change these results.

Revision was recommended for patients with progressive wear or osteolysis, even if they had no symptoms. During the follow-up, 30 patients (30 hips) were revised and 7 patients (8 hips) died. In the remaining 133 hips, the mean follow-up time was 9.4 (7.7–11.4) years. None of the patients was lost to follow-up.

Table 2. Data of the 30 revised patients

| A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|
| 0.8 | Harris-Galante | 55 | 76 | M | 2 | 2 |
| 2.0 | Harris-Galante | 55 | 60 | F | 4 | 1 + 2 |
| 2.1 | Harris-Galante | 62 | 82 | M | 2 | 3 |
| 2.3 | Harris-Galante | 52 | 65 | F | 3 | 3 |
| 4.8 | Harris-Galante | 51 | 80 | F | 2 | 3 |
| 5.1 | PCA | 44 | 60 | F | 2 + 3 | 1 |
| 5.2 | PCA | 57 | 75 | F | 3 | 4 |
| 5.6 | PCA | 43 | 84 | M | 2 | 1 + 2 |
| 5.6 | PCA | 46 | 60 | M | 3 | 4 |
| 5.8 | Harris-Galante | 32 | 58 | W | 3 | 4 |
| 6.6 | PCA | 48 | 8 | M | 2 | 1 |
| 7.0 | PCA | 61 | 72 | M | 1 + 2 | 3 |
| 7.0 | PCA | 59 | 106 | M | 3 | 4 |
| 7.2 | PCA | 58 | 73 | M | 1 | 1 + 2 |
| 7.3 | PCA | 60 | 70 | F | 2 | 1 |
| 7.3 | Harris-Galante | 54 | 68 | M | 1 + 2 | 3 |
| 7.3 | Harris-Galante | 56 | 68 | F | 2 | 3 |
| 7.8 | Harris-Galante | 43 | 90 | M | 2 | 3 |
| 7.9 | PCA | 52 | 80 | F | 2 | 1 |
| 8.0 | Harris-Galante | 49 | 65 | F | 1 | 3 |
| 8.4 | Harris-Galante | 53 | 86 | M | 2 | 3 |
| 8.4 | PCA | 50 | 78 | F | 2 | 1 |
| 9.0 | Harris-Galante | 57 | 93 | M | 1 | 3 |
| 9.3 | PCA | 53 | 64 | F | 2 | 1 |
| 10.2 | PCA | 54 | 73 | M | 1 + 3 | 1 + 2 |
| 10.3 | Harris-Galante | 53 | 85 | M | 2 | 3 |
| 10.5 | Harris-Galante | 58 | 78 | F | 1 + 3 | 3 |
| 10.7 | Harris-Galante | 56 | 78 | M | 3 | 4 |
| 11.0 | Harris-Galante | 50 | 65 | F | 1 + 2 | 3 |
| 11.1 | Harris-Galante | 46 | 63 | F | 1 | 3 |

A Years between index and revision surgery
B Type of prosthesis
C Age at index surgery
D Weight (kg) at index surgery
E Gender
  F female
  M male
F Reasons for revision
  1 Osteolysis
  2 Aseptic loosening
  3 Wear
  4 Infection
G Revised components
  1 Cup
  2 Stem
  3 Stem and liner
  4 Liner

## Results

### *Unrevised hips*

At the latest follow-up, the median Harris score was 93 (55–100) in the PCA and 95 (61–100) in the HG group ($p = 0.1$). The corresponding figure for the Harris pain score was 44 (20–44) in both groups ($p = 0.06$). The changes in the Harris hip and Harris pain scores between the preoperative assessment and the latest follow-up did not differ ($p = 0.2$, 0.2). 5 patients with PCA hips and none with an HG prosthesis had thigh pain ($p = 0.03$).

### *Revised hips*

13 patients in the PCA and 17 in the HG group underwent revision surgery (Table 2). The main indications for revision were radiographic loosening (17), excessive wear of the polyethylene liner (9) and osteolysis (9). The mean postoperative interval until revision was 7.1 years in both groups (range: PCA 5.1–10.3; HG 0.8–11.1). One patient was revised because of infection (*staphylococcus epidermidis*). This case was the only one in the Harris-Galante group where the metallic shell was exchanged.

Survival analysis with revision as end-point revealed 10-year survival rates of 85% for the PCA and 99% for the HG cups (Table 3). The stem survival rates with the same interval were 96% and 86% (PCA/HG). There was no difference between the two designs (Figure 3). More cups were revised in the PCA group because of mechanical failures (12 PCA/2 HG; $p = 0.02$) and more stems in the HG group (4 PCA/14 HG; $p = 0.03$; Cox regression). Other variables included in the regression analysis (age, gender, weight, primary/secondary arthrosis) had no statistically significant influence on the survival rates.

At the time of this evaluation, 4 additional patients were scheduled for revision surgery (1 PCA hip with a radiographically loose femoral stem and 3 HG hips: 2

Table 3. Survivorship according to Kaplan-Meier at 8 and 10 years, with revision as end-point. Survival rates in percent and with 95% confidence intervals

| | Years | PCA | | HG | |
|---|---|---|---|---|---|
| | | Survival rate | Number at risk | Survival rate | Number at risk |
| Cup | 8 | 89 ± 6.8 | 66 | 99 ± 2.4 | 65 |
| | 10 | 85 ± 8.2 | 24 | 99 ± 2.4 | 27 |
| Stem | 8 | 96 ± 4.2 | 66 | 92 ± 6.0 | 65 |
| | 10 | 96 ± 4.2 | 24 | 86 ± 8.2 | 27 |
| Cup and stem | 8 | 88 ± 7.0 | 66 | 90 ± 6.3 | 65 |
| | 10 | 84 ± 8.4 | 24 | 85 ± 8.4 | 27 |

with femoral and 1 with acetabular osteolysis). With these patients included, the crude revision rates were 17% in the PCA and 24% in the HG group after a mean follow-up of 9.4 years.

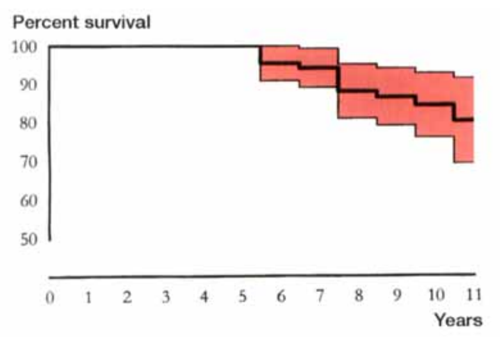
## Radiography

### *Unrevised hips*

5 cups in the PCA group were defined as radiographically loose (100% radiolucency or proximal migration > 5 mm) compared to 2 in the HG group, with a mean radiographic follow-up of 8.2 years (7–10; p = 0.3). Radiolucencies were more extensive on the lateral view among the PCA cups (p = 0.04), but there was no difference in frequency of occurrence (p = 0.1, Table 4). Acetabular osteolysis was detected around 2 of the PCA (0.8–1.4 cm$^2$) and 2 of the Harris-Galante cups (0.8–4.2 cm$^2$). 10 PCA and 4 HG stems were radiographically loose at the latest follow-up (p = 0.1). Focal femoral osteolyses between 0.6 and 3.6 cm$^2$ were found around 6 HG stems (p = 0.01). In 13 cases in the PCA group, the tip of the stem had displaced laterally and in 25 cases, cortical hypertrophy was present in Gruen zones 3 and 5. The corresponding figures in the HG group were 9 and 17 cases (p = 0.5/0.2). Loose beads, a sign of insufficient porous coating, were seen around 6 PCA cups and 7 PCA stems.

### *All patients*

The presence and amount of osteolysis were recorded at the latest follow-up or before the reoperation. Osteolysis developed in 5 PCA and in 17 Harris-Galante hips. Retrospective review of the consecutive series of radiographs revealed that the osteolysis could be detected as early as 2 years after the operation in 1 patient with the Harris-Galante design and in the other cases between 3 and 10 years (median: 6.5 years). Acetabular osteolyses were found in 4 PCA hips (0.9–8.1 cm$^2$). 3 patients presented osteolytic lesions in the acetabulum around the Harris-Galante cup (0.8–4.2 cm$^2$). Femoral osteolyses were found around 14 HG stems and 1 PCA stem (p = 0.001), mostly in Gruen zones 3 and 4 (Figure 4). The total size of the femoral osteolyses varied between 0.6–11 cm$^2$. The preva-



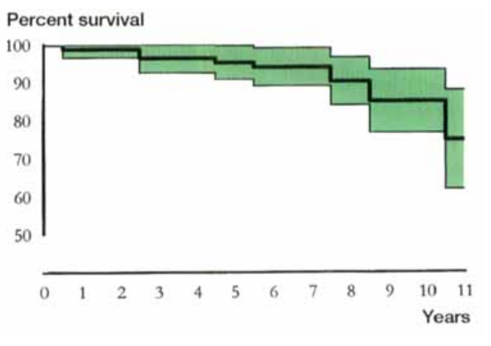




Figure 3. Survival of the PCA (left) and HG design (right), using **revision** of cup and/or stem as end-point. 95% confidence limits are indicated.

Table 4. Radiolucencies at latest follow-up in unrevised patients. Number of patients in the different categories: 0%, 50%, 50-99% and 100% of the bone implant interface

| | PCA [a] | | | | HG | | | |
|---|---|---|---|---|---|---|---|---|
| | 0 | < 50 | 50–99 | 100 | 0 | < 50 | 50–99 | 100 |
| Cup anteroposterior | 22 | 25 | 18 | 2 | 12 | 32 | 17 | 4 |
| Cup lateral | 17 | 28 | 18 | 4 | 25 | 27 | 12 | 1 |
| Stem anteroposterior | 3 | 46 | 18 | 0 | 9 | 37 | 17 | 2 |

[a] Radiographs missing in 1 hip

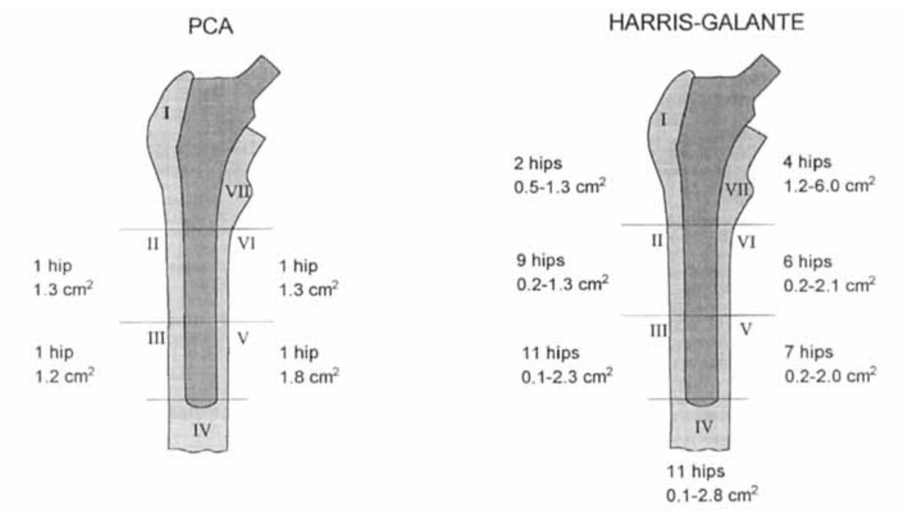



Figure 4. Femoral osteolysis in various Gruen regions (I–VII). Revised and unrevised patients.

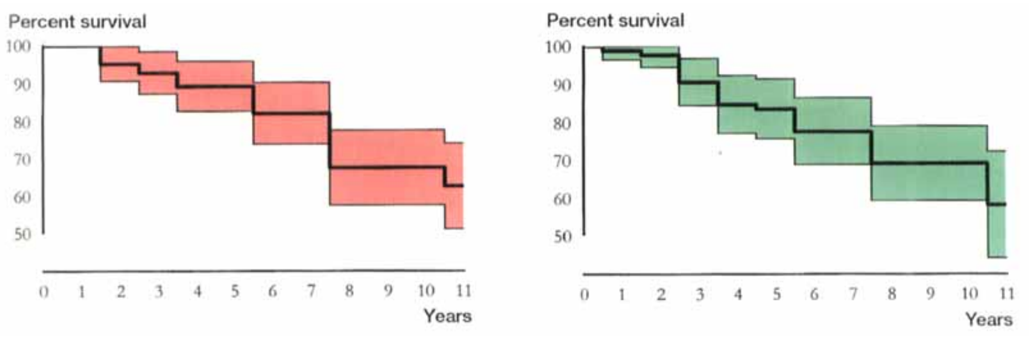



Figure 5. Survival of the PCA (left) and HG design (right), using **mechanical failure** of cup and/or stem as end-point. 95% confidence limits are indicated.

lence and mean size of granulomas in the calcar region (PCA/HG: 21% and 0.8 $cm^2$/22% and 0.7 $cm^2$) and in the greater trochanter (PCA/HG: 12% and 2.3 $cm^2$/7% and 2.5 $cm^2$) did not differ between the 2 groups ($p = 0.9/0.3$).

### *Mechanical failure (Table 5, Figure 5)*

With revision, aseptic loosening or osteolysis (> 1 $cm^2$) as end-points, the 10-year survival rates dropped to 74% for the PCA and 94% for the HG cups ($p = 0.02$; Cox regression). The stem survival rates were 84% and 72% (PCA/HG: $p = 0.05$). The combined survival rate (cup and/or stem) did not differ ($p = 0.6$). The patient-related variables listed above had no significant influence on the results.

### *Wear*

Polyethylene wear was evaluated at 7 years and 10 years and, in case of revision, at the latest follow-up. Comparisons between the 2 groups were made on wear measurements up to 7 years (Table 6). There was no difference in wear between the two groups, independently of the method used for measurements (method a/b: $p = 0.9/0.06$). The mean proximal wear was 1.1 mm in the PCA and 1.0 mm in the HG groups, corresponding to an annual wear of 0.15 and 0.16 mm (method a). The corresponding mean wear rates, according to method b, were 0.9 and 1.1 mm.

**Table 5. Survivorship (Kaplan-Meier) at 8 and 10 years, with mechanical failure as end-point. Survival rates in percent and with 95% confidence limits**

| | | PCA | | HG | |
|---|---|---|---|---|---|
| | Years | Survival rate | Number at risk | Survival rate | Number at risk |
| Cup | 8 | 77 ± 10.9 | 34 | 94 ± 5.2 | 26 |
| | 10 | 74 ± 10.9 | 32 | 94 ± 5.2 | 26 |
| Stem | 8 | 87 ± 7.4 | 31 | 73 ± 9.5 | 20 |
| | 10 | 84± 8.7 | 31 | 73 ± 9.5 | 20 |
| Cup and stem | 8 | 68 ± 10 | 29 | 69 ± 9.9 | 19 |
| | 10 | 68 ± 10 | 27 | 69 ± 9.9 | 19 |

Table 6. Wear (femoral head penetration) in mm in hips with available 7-year radiographs and with visible and distinct landmarks necessary for measurements. Method a: Proximal (+) and distal (–) directions. Method b: Proximal-lateral (+) and distal-medial (–) directions

| | PCA | | HG | |
|---|---|---|---|---|
| | Number | Wear | Number | Wear |
| Method a | 28 | 1.1 (-0.4–5.1) | 74 | 1.1 (-0.2–4.3) |
| Method b | 76 | 0.9 (-1.0–7.5) | 55 | 1.1 (-0.2–3.8) |

## Discussion

The PCA and Harris-Galante prostheses are well documented in the literature (Lachiewich et al. 1992, Kim and Kim 1992, 1993), but there is no randomized comparison. We found unacceptably high revision and failure rates for both designs, which has been reported separately for the PCA (Heekin et al. 1993, Owen et al. 1994, Malchau et al. 1997) and the Harris-Galante prostheses (Kim and Kim 1992, Martell et al. 1993). In contrast, Petersilge et al. (1997) reported a 98% survival rate of the Harris-Galante stem at 8 years, with revision as end-point, but the incidence of osteolysis was high, 12%.

Osteolysis around stable and loose uncemented implants has been seen with increasing frequency. Martell et al. (1993) reported 18% osteolysis around loose and 3% around stable Harris-Galante I prostheses. Osteolytic lesions are likely to increase in size with time. According to Tanzer et al. (1992), they become more severe in femora with loose implants. It is generally accepted that polyethylene is the major source of particles. Implant motion can also result in the release of titanium (Kärrholm et al. 1994) or cobalt-chromium particles (Skipor et al. 1996), which may increase third-body wear (Urban et al. 1994). These metallic particles can themselves activate the immune system (Bennet et al. 1991, Jacobs et al. 1995), resulting in the stimulation of osteoclastic bone resorption.

In our study, osteolytic lesions were common, especially around Harris-Galante femoral stems. This is probably related to the stem design, which facilitates migration of particles down to the distal part of the interface (Tanzer et al. 1992, Urban et al. 1996). The small proximal pads aimed for bone ingrowth are also insufficient for adequate fixation (Kim and Kim 1992). The titanium alloy used in this design is softer than cobalt-chromium alloy. When subjected to micromovements, abrasive wear will more easily occur. The use of a polished surface distal to the pads, as in later generations of this design, would have prevented this effect to some extent. The effect of such a change, however, is difficult to predict. The possibility of bony fixation to the matte stem surface would disappear and the joint fluid would still more easily penetrate the interface.

There are also other factors that may have influenced the failure pattern of the two designs. The metallic particles from the two alloys could have had different effects on the immune system and might also have generated different amounts and sizes of polyethylene particles in the process of third-body wear.

The overall frequency of osteolysis may also have been influenced by the use of 32 mm heads. Apart from increased polyethylene wear, a large head will also require use of a thinner plastic insert. A higher prevalence of osteolysis has been reported for the PCA cup, when a thin polyethylene liner was combined with a 32 mm femoral head (Astion et al. 1996). Even if we agree that thin polyethylene inserts should not be used, we could not in our study document a relation between small cups and an increased risk for revision.

Osteolytic lesions developed between 2 and 10 years after the operation. Similar observations were made by Tanzer et al. (1992) as regards stable Harris-Galante stems. It seems that osteolysis appears earlier around cementless than with cemented stems (Maloney et al. 1990). The varying period between implantation and the development of osteolysis might have a multifactorial background related to the patient, the implant design and the pattern of failure.

When the polyethylene wears down, the femoral head will assume an eccentric position in the cup and the risk of impingement will increase. During motion, asymmetrical loading of the insert occurs, which puts more strain on its fixation to the shell. This fixation mechanism has proved unsatisfactory for both of these prosthetic designs (Brien et al. 1990, Astion et al. 1996, Incavo et al. 1996). The PCA liner in some versions does not conform to the metallic shell and luxations of the plastic insert have been described (Ries et al. 1992). The quality of the polyethylene varies because of differences in manufacturing the PCA liner (Alexander et al. 1995). The liner in the Harris-Galante design may rotate inside the metallic shell, which has been described in radiostereometric studies (Kärrholm et al. 1994), and even complete dislocations may occur (Retpen and Solgaard 1993). These motions can cause wear between the liner and the metallic shell, which will increase the number of particles.

Addition of ceramic coatings to cementless implants may improve the results in future. Geesink and Hoefnagels (1995) reported 100% survival of hydroxyapatite-coated stems and very few reactive lines around the HA-coated parts after 6 years. After a mean follow-up of 6 years, D'Antonio et al. (1996) reported a low incidence of osteolysis (0.4%) and minimum frequency of radiolucent lines (0–2%, depending on the Gruen region). Hydroxyapatite seems to effectively seal the bone-implant interface, thereby minimizing the distal migration of wear debris. However, long-term results are not available and there is a possibility that degradation and delamination of ceramic coatings generate an increased release of particles promoting three-body wear.

In our study, the Harris-Galante cup was better than the PCA cup but, on the femoral side, the situation was reversed. There are several reasons for these differences related to choice of materials and design. The main factors are probably the use or non-use of circumferential stem coating, different polyethylene quality and liner locking mechanisms and the different fixation principles used in two cup designs. The 10-year survival rates of 68–84% for the PCA and 69–85% for the Harris-Galante designs, depending on the definition of end-points, are disappointing. Cementless THA must still be considered as an experimental procedure. Osteolysis is a major complication, often asymptomatic, and patients must be followed prospectively with radiographic examinations, to detect impending failures before severe bone destruction has occurred.

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