# High survival rate of hydroxyapatite-coated hip prostheses

## 100 consecutive hips followed for 10 years

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**ABSTRACT We followed 100 consecutive primary total hip replacements with a proximal hydroxyapatite coating for 10 years. No patient was lost to follow-up. 29 patients (32 hips) died before the 10-year follow-up was done; none of their hips had been revised. Thigh pain on activity occurred in 3 hips. We found no radiographic signs of loosening of the femoral components. In course of time the location of dense bone around the femoral stem, which would suggest implant/bone stress transfer, moved distally in 51 of 67 stems after 10 years. No linear or distal osteolysis occurred around the stem. Revision of 1 stem was performed because of thigh pain, but it was found fixed to bone proximally, while 3 cups were revised because of acetabular osteolysis. The 10-year survival of the stem and cup, using revision or pending revision as endpoint, was 100% (95% CI: 99–100) and 97% (95% CI: 94–99), respectively.**

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HA-coated implants have osteoinductive properties because they enhance direct bone formation at the interface without forming an intermediate layer of fibrous tissue (Bauer et al. 1991, Hardy et al. 1991, Frayssinet et al. 1993, Søballe et al. 1993, Overgaard et al. 1997, Tonino et al. 1999, 2001). Bonding to living bone occurs over a relatively short period of time even under loaded conditions (Geesink et al. 1988, Bauer et al. 1991, Hardy et al. 1991, Søballe et al. 1991, 1993, Frayssinet et al. 1993, Donnelly et al. 1997, Overgaard et al. 1997, Tonino et al. 1999, 2001). We studied an uncemented stem with proximal HA coating designed to load only the proximal part of the femur. To inhibit distal stress transfer, the stem was anatomically shaped, which permitted distal overreaming. Our prospective one-center study describes the clinical and radiographic results of the first 100 consecutive primary total hip arthroplasties (THA). The first aim was to determine radiographically whether the stem functioned as intended. The second aim was to assess whether the appearance of the implant/bone interface was compatible with circumferential bony fixation and if this prevented femoral diaphyseal osteolysis.

## Patients and methods

Between May 1990 and January 1992, 100 consecutive primary uncemented THAs were performed on 91 patients by 3 senior consultants. We had no specific patient selection, except for the exclusion of patients more than 85 years of age. The average age of the patients at the time of surgery was 72 (55–84) years. 25 hips were implanted in men and 75 in women. Their mean body weight and height were 70 (39–108) kg and 1.66 (1.30–1.85) cm, respectively. The left hip was replaced in 46 cases, the right in 54. Primary osteoarthrosis was the most common diagnosis (88 cases), next to rheumatoid arthritis (5 cases), avascular necrosis (2 cases), femoral neck fracture (2 cases) and 3 other diagnoses.

### *Prosthesis*

We used the Anatomique Benoist Girard (ABG, Stryker, Newbury, England) hip prosthesis. The stem is made of a titanium alloy (Ti6Al4V) and is available in 9 sizes (from 3 to 7). The proximal third is HA-coated and has a structured scaled surface. The scales on the anterior, posterior, and medial surfaces were designed to transform shear forces into compression forces. There is an area of transition between the coated metaphysis and the uncoated diaphysis of the stem to avoid chipping of the HA during insertion. To accommodate the proximal anatomic press-fit, there is a 7° curvature starting 1 cm distal to this transition point, while the neck has a further 5° antetorsion, which results in a total of 12° anteversion. This feature is important to obtain proximal rotational stability regardless of diaphyseal fill. The stem has a grit-blasted surface distally (roughness 2.59 μm), which tapers only slightly. The acetabular component is a hemispherical, entirely HA-coated press-fit cup available in 14 sizes (we used the sizes between 46 and 60 mm). This first-generation cup has numerous holes for screws and/or spikes. 95 cups were inserted with 2 spikes and 5 with screws. We used a hooded polyethylene insert and a 28 mm cobalt-chromium head in all cases.

### Hydroxyapatite coating

The HA coating was applied with a vacuum plasma-spray torch on a sublayer of pure titanium, to improve the tensile adhesion of the HA to the implant. This vacuum treatment maximized the quality and homogeneity of the coating. The HA had a chemical purity of 100% crystallinity before coating, as determined by x-ray diffraction at low speed, and > 75% crystallinity after coating. Its porosity was < 10%. The tensile bond strength was 62–65 MPa, and thickness 60 (± 20) μm. The roughness of the HA-coated parts was 3–4 μm. Each batch was tested to ensure that the specifications were met.

Surgery was performed in a standard operating room. Systemic prophylactic antibiotics (amoxicillin/clavulan 2000/200) and oral anticoagulation (acenocoumarol) were given routinely. Lateral (Hardinge, 63 cases) and anterolateral (Watson-Jones, 37 cases) approaches were used. The distal femur was reamed to a diameter of 1–1.5 mm, which was greater than the diameter of the stem that was to be inserted. Weight bearing was allowed as tolerated, but crutches were used for 4–6 weeks to prevent the patient from falling.

### Follow-up

We reviewed all patients clinically and radiographically at 3, 6 and 12 months after surgery and yearly thereafter. Function was assessed with the Merle d'Aubigné system, as modified by Charnley. In the femur, all changes were related to the Gruen regions (Gruen et al. 1979) and in the acetabulum, to the De Lee and Charnley regions (DeLee and Charnley 1976). Polyethylene wear was measured with Livermore et al.'s method (1990). An increase in wear was defined as a linear wear rate of > 0.15 mm/year (Mont and Hungerford 1997). Osteolysis was defined as a scalloped erosion exceeding 2 mm in diameter at the bone-prosthesis interface. A decrease or increase in bone density (resorption or densification) was not quantified, but graded as present or absent on the AP and lateral radiographs as compared to the postoperative radiographs. The stem was considered to be in varus or valgus when there was a deviation of ≥ 3° from the neutral position. Likewise, using a radiographic template, we measured cranial and medial migration of the socket and head on standing AP radiographs. The stem was regarded as completely filling the medullary canal when less than 1 mm gap was measured on both sides between the stem and the inner cortex on the first postoperative AP radiograph. The components were considered stable when there was no subsidence or migration (> 5 mm) and no radiolucent or radiodense line along the HA-coated portions of the prosthesis.

### Statistics

ANOVA was used. Kaplan-Meier survival curves were calculated, using revision or pending revision due to loosening or osteolysis as the definition of failure. Statistical significance was set at $p < 0.05$.

## Results

### Complications

Peroperatively 4 fissures of the proximal femur and 2 fractures of the greater trochanter occurred. 1 trochanteric fracture was treated with internal fixation. There were 5 wound hematomas, no superficial infections, but 2 deep infections, which were treated successfully with the implant in situ. 1 transient lesion of the femoral nerve was seen, and

Merle d'Aubigné score, median (range)

| | Pain | Range of motion | Ability to walk | Total |
|---|---|---|---|---|
| Preoperative (n = 100) | 1.6 (0–4) | 4.0 (2–5) | 3.1 (1–5) | 9 (4–12) |
| 3 months (n = 99) | 5.5 (4–6) | 5.4 (4–6) | 4.0 (2–6) | 14 (10–17) |
| 10 years (n = 68) | 5.6 (4–6) | 5.7 (5–6) | 5.5 (5–6) | 17 (14–18) |

2 early dislocations. None developed into a recurrent dislocation. 1 stem was revised after 1 year due to thigh pain. At revision, the stem was fixed to bone proximally.

### Clinical results

None of the patients was lost to follow-up. At the 10-year follow-up, 29 patients (32 hips) had died. None of them had been revised. The clinical scores at their last annual assessment were similar to those in the living patients. 68 hips were available for evaluation at 10 years. At that time, 67 original stems and 65 original cups were still in situ.

The clinical results had improved after 3 months and showed no signs of deterioration at 10 years (Table). Thigh pain throughout the 10 years of follow-up occurred in 3 hips.

### Radiography

The inclination of the metal acetabular component on the postoperative standing AP radiographs varied between 40° and 55° in 84 hips. In 16, this angle was 55° or more. None of the acetabular components showed migration or radiolucent lines. After 10 years signs of increased polyethylene wear were noted in 13 of 65 living patients, including the 3 previously revised cases. 3 cases could not be evaluated. 4 of 13 cases with increased PE wear and 2 of 52 with normal wear had osteolytic cysts. The areas of osteolysis appeared in all Charnley-DeLee regions. 3 of the 13 cups with an increase in PE wear had been revised between 8 and 10 years because of this acetabular osteolysis and 1 cup revision was pending at the latest follow-up. These 4 cups had a postoperative inclination between 57° and 61°. At revision, the osteolytic cysts were more extensive than expected. We found more cases with radiographically-detected acetabular cysts in the group with increased PE wear (4 of 13) than in the group with normal wear (2 of 52) ($p = 0.006$), and more cases with increased wear in the group with a cup inclination of > 55° (4 of 11) than in those with a normal inclination (9 of 54, $p = 0.01$).

On the first postoperative radiograph, 12 femoral stems were in varus and 1 in valgus. No significant change in position occurred during the follow-up. Slight distal migration of the stem (< 5 mm) was seen in 1 patient at 3 months, but this subsidence had stopped at 6 months.

Structural changes in the femoral bone became apparent between 3 and 6 months after THA. Densifications of cancellous bone were visible along the femoral stem at the point of transition between the coated and uncoated parts of the stem in Gruen regions 2 and 6, from 3 months onwards. The frequency of these endosteal bone densifications increased and after 1 year, these areas of bone apposition slowly expanded distally into the upper parts of Gruen regions 3 and 5 in 51 of 67 hips (Figure 1A).

Endosteal reactive (radiopaque) lines became visible on radiographs in Gruen zone 4, between the first and second year postoperatively. Their incidence increased from 46% after 1 year to 82% after 3 years, and it decreased to 43% after 10 years.

We also found some other changes: a reduction in bone density in Gruen regions 7A and 1 (Figure 1B), densification of cortical bone (Figure 1C), thickening of femoral cortex (Figure 1D) and formation of small (< 5 mm in diameter) cysts. These cysts were seen in Gruen region 7A in 8 cases at 10 years and in Gruen region 1 in 4. However, we found no radiolucent lines around the HA-coated parts of any femoral component and no signs of impending failure.

Periarticular ossifications were noted using the Brooker (Brooker et al. 1973) grading system. At the last visit, 40% of the hips had grade I ossifications, 5% grade II, 1% grade III and none grade IV.

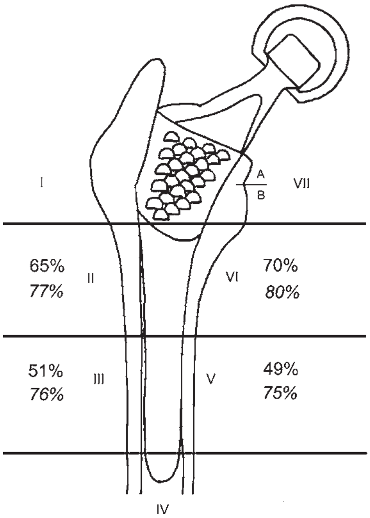
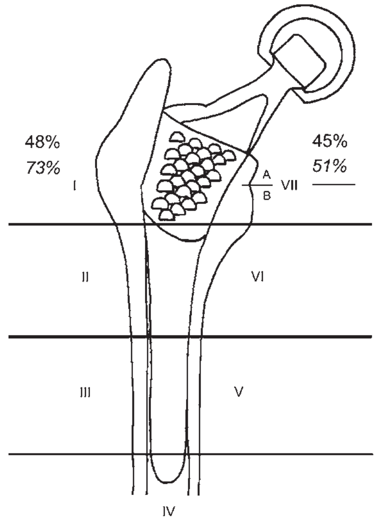
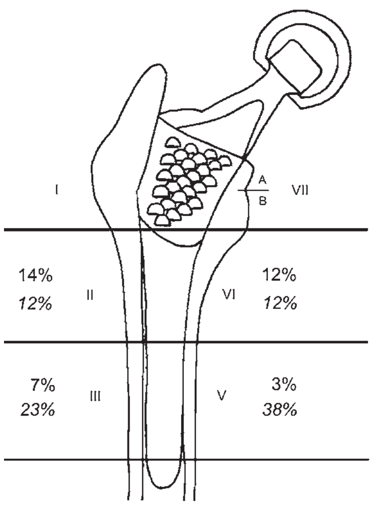


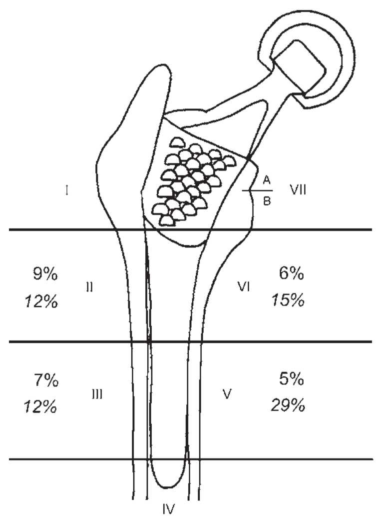

Figure 1A. Endosteal bone densifications. Frequency of endosteal bone densifications in the Gruen regions after 5 (plain, n = 91) and 10 years (italics, n = 67).




B. Bone resorption. Frequency of reduced bone density in Gruen regions after 5 (plain, n = 91) and 10 years (italics, n = 67). Note that no resorption was observed in regions 2–6.




C. Cortical bone densification. Frequency of densification of cortical bone in Gruen regions after 5 (plain, n = 91) and 10 years (italics, n = 67).




D. Cortical thickening. Frequency of thickening of the cortex in Gruen regions after 5 (plain, n = 91) and 10 years (italics, n = 67).

### *Survival*

The cumulative survival at 10 years was 97% for the acetabular component (95% CI: 94–99) and 100% for the femoral stem (95% CI: 99–100) using revision or pending revision due to loosening or osteolysis as an endpoint (Figure 2).

## Discussion

Previous studies have documented the 10-year results of many other designs of uncemented stems (Malchau et al. 1996, Engh et al. 1997, McLaughlin and Lee 1997, Hellman et al. 1999, Eingartner et al. 2000, McNally et al. 2000, Delaunay and

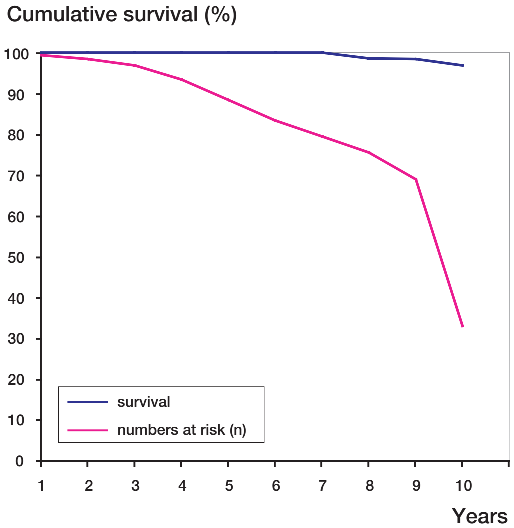
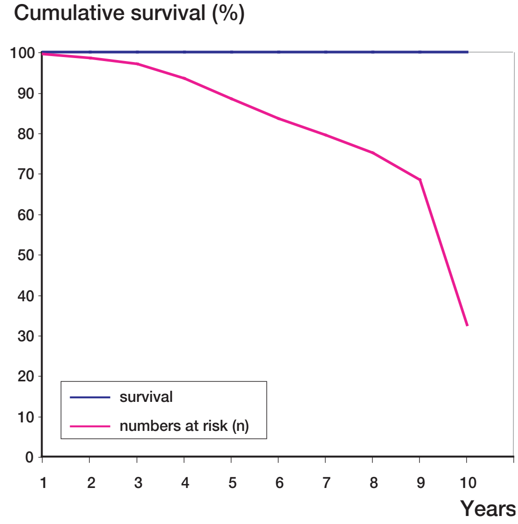



Figure 2A. Survival of the acetabular component. Confidence limits at 8 (97–100), 9 (97–100), and 10 years (94–99).




B. Survival of the femoral component. Confidence limits throughout the follow-up (99–100).

Kapandji 2001). According to our radiographic evaluation, bony fixation seemed to be consistently achieved with the ABG stem. This means that the view concerning bone growth onto this proximal HA-coated stem is valid for long term fixation. It is also supported by histological and histomorphometric examinations of autopsy-retrieved specimens after years of successful hip functioning (Tonino et al. 1999, 2001).

The radiographic bone remodeling was characterized by a specific pattern of bony features in the proximal femur. During the first 3 years, endosteal bone apposition occurred in Gruen regions 2 and 6. This suggests that the transfer of a load from stem to femoral bone occurs mainly in these areas. Between the third and fifth years, areas of reduced bone density were seen in the region of the lesser and greater trochanters. In our opinion, the concomitant formation of a reactive line around the distal part of the stem in Gruen regions 3, 4 and 5 is consistent with the presence of a local fibrous interface due to micromotion in this area with no substantial stress transfer to the endocortex. These three characteristic radiographic features confirmed the primary goal of the design of the femoral stem: that osseointegration should occur mainly proximally. However, with time, new bone growth onto the stem was also noted distally in Gruen regions 3 and 5. With declining incidence of the reactive line around the distal part of the stem after the 5-year follow-up (the line disappeared in almost half of the cases), the incidence of cortical thickening and, especially of cortical densification, clearly increased, especially in Gruen regions 3 and 5. This also indicates a shift from proximal to distal loading. Other authors have found more cortical thickening around HA-coated stems at a much earlier stage. D'Antonio et al. (1996) observed 47% cortical thickening in Gruen region 5 along with 63% calcar resorption 6 years after surgery with a proximally-coated stem. Geesink and Hoefnagels (1995), using the same design of prosthesis, reported similar figures. Vedantam and Ruddlesdin (1996), who inserted a completely HA-coated stem, reported 26–46% cortical hypertrophy in Gruen regions 3 and 5 after only 2 years with femoral neck resorption in more than 57% of cases. The phenomenon of cortical hypertrophy was also noted with cementless, non-HA-coated stems—e.g., Mulliken et al. (1996) found it in 35% of their patients, especially in Gruen regions 3 and 5. In uncemented porous coated hips, it was shown that poorly fitting stems were less likely to become fixed by ingrowth. The authors recommended: 1) the stem should be implanted with a tight fit at the isthmus, 2) the medullary canal should be completely filled to achieve predictable fixation, and 3) the largest possible stem should be used. In a previous study (Oosterbos et al. 2001) we showed that the view of transitional load transfer from proximal to distal is morphologically determined by the way the concept fills the medullary canal. In a study of 416 uncemented THAs, Mulliken et al. (1996) could not explain this finding, but Whiteside (1989) observed that 24 of 67 patients with a tight distal stem had distal cortical hypertrophy and none of 38 patients with a loose distal fit did. Therefore, the ABG prosthesis does not primarily aim at diaphyseal fill and this may explain why we found less than 30% distal cortical thickening in Gruen regions 3 and 5 after 10 years of follow-up and the low incidence of activity-bound thigh pain, which is ascribed to a different modulus of elasticity between the bone and distal stem. Nevertheless, anatomical shape, slight distal overreaming and a proximal HA coating did not prevent most stems from achieving distal fixation with time.

We found no cases of distal or linear osteolysis around the stem after 10 years. Even in patients with increased PE wear, only 8 developed very moderate local cystic osteolysis in the proximal femur. This can be due only to a complete proximal sealing of the medullary cavity by circumferential bone ongrowth. Histological examination of retrieved autopsy specimens and animal studies have confirmed that this occurs with proximally osseointegrated stems (Tonino et al. 1999, Rahbek et al. 2000).

The high (13 of 65) incidence of an increase in PE wear was a cause of concern, as it has been with other uncemented hips (Engh et al. 1997). We found a relationship between aseptic cup loosening and an increase in wear, but excessive (> 55°) inclination of the cup also resulted in early revision of the cup. It is not understood why all patients with such an increase do not develop acetabular cysts. Histological studies suggest that this may be due to the individual reaction of patients to PE particles since only half of the empty screw holes are sealed with a bony bridge (Tonino et al. 2001). Inflammatory fluid debris can oscillate through these holes and increase acetabular osteolysis. We therefore believe that there should be no open holes in the cup. In a later design of the cup, the spikes have been attached to the outer surface of the shell.

In conclusion, our findings confirm that lasting fixation occurs by means of bone growth onto this proximally HA-coated hip prosthesis. Radiographic follow-up showed that bone remodeling around the stem was an ongoing process with early proximal bone formation followed by proximal resorption, and mainly distal endoteal densifications between 5 and 10 years. This pattern of distal stress transfer is at variance with the original views about this prosthesis. The sealing effect of fast proximal fixation of the stem to bone seems to prevent distal osteolysis during the first 10 years after surgery.

No competing interests declared.

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