

# Two-year outcome of hydroxyapatite-coated prostheses

## Two femoral prostheses retrieved at autopsy

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We performed a histological study of the bone-implant interface on 2 human femurs implanted with a hydroxyapatite-coated self-locking stem for 2 years. Extensive bone formation with no intervening fibrous tissue was noted around the entire circumference of the 2 prostheses. The newly-formed bone had 2 morphotypes: an alveolar disposition

with a continuous contact between bone and hydroxyapatite, and a digitiform one where distinct bony trabeculae were in contact with the ceramic coating or with the bone marrow. Partial or even total resorption of the hydroxyapatite coating was clearly identified, these areas showing bone in contact with the metal.

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A new generation of hydroxyapatite(HA)-coated prostheses designed for cementless fixation is gaining clinical application. However, human histological data of the bone-HA interface are few; previous reports deal with early observations (Osborn 1987, Furlong and Osborn 1991, Hardy et al. 1991), but little is known about events after 1 year (Bauer et al. 1991). We report the histological findings in 2 well-functioning femoral prostheses retrieved after 24 and 26 months of implantation.

## Material and methods

### Case 1

An 83-year-old woman was admitted with a displaced femoral neck fracture. A HA-coated hemiarthroplasty with a UNILOK bipolar cup was inserted. 12 days after surgery, intraprostatic dislocation of the bipolar head occurred and the bipolar cup was converted to a BHP-Zimmer cup. Despite massive heterotopic ossifications and multiple medical complications, she regained minimal walking ability 6 months after surgery. She died 26 months later of a bronchopneumonia.

### Case 2

An alert 88-year-old woman, with no previous medical history, sustained a displaced femoral neck frac-

ture and was treated with an HA-coated hemiarthroplasty. Her postoperative period was uneventful and 2 months later she was able to walk up to 1 km every day. 2 years later, a colonic neoplasm was discovered. She died some days after colon resection.

In both cases the femoral prosthesis was made of TiAl<sub>6</sub>V<sub>4</sub> alloy and coated with a layer of 155 ± 35 µm of hydroxyapatite. This coating contains 97% of hydroxyapatite, of which 57–62% are in crystalline form, traces of CaO and tricalcium phosphate.

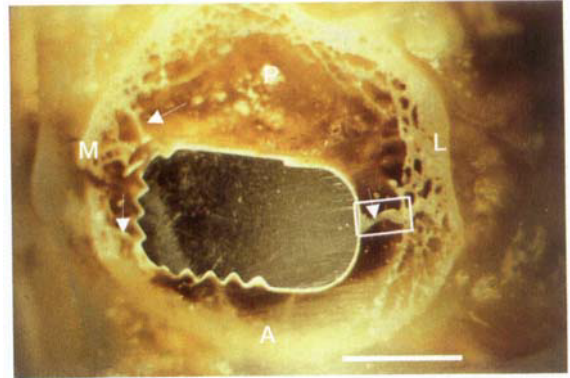
### Histological procedure

A one-piece specimen was obtained from each patient by transection of the femur 5 cm below the tip of the prosthetic stem and isolation of the acetabulum with 3 saw cuts through the pelvic bones. Radiographs were made of each specimen. Toluidine blue, basic fuchsin and silver methenamine were used for histologic observation in transmitted light. Some unstained sections were also examined under reflected light, using a Reichert Polyvar microscope (Hardy et al. 1991). Topographic data are given according to the Gruen division in seven zones (Gruen et al. 1979). To assess the extent of bone coverage, a digitizing pad and a microcomputer with image-processing software (Productim Image, AES, France) were used. The fractional linear extent of the coverage is expressed as a percentage of the whole perimeter. 2–7 sections were considered for each of

Figure 1. Case 1. 83-year-old woman.



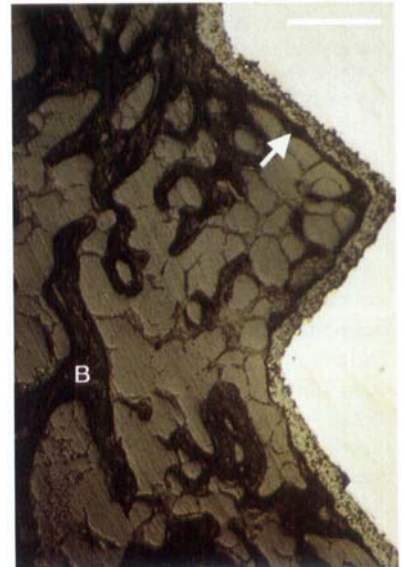
The stem is slightly undersized and tilted in a varus position.



Metaphyseal section of the femur. New bone made of isolated bony trabeculae (arrows) is seen on the medial and the lateral aspects of the implant. (A) anterior, (P) posterior, (M) medial and (L) lateral sides; square = microscopic field of lower left close up, bar = 1 cm.



Sigmoid-shaped bone trabecula. Bone is of lamellar structure, but Haversian remodeling is noted close to the HA coating (arrows). Around the bone, the bone marrow is in direct contact with the HA layer. I implant, B bone trabecula, M bone marrow. Reflected light microscopy, bar = 1 mm.



Alveolar morphotype on the lateral aspect of the tip of the stem. A continuous sleeve of bone (arrows) runs along the HA coating. I implant, B bone. Reflected light microscopy, bar = 1 mm.

the Gruen zones. Arithmetic means of the percentages were calculated for each section. Values concerning the whole implant consist of the length of bone coverage related to the total length of the observed prosthetic perimeter.

**Results**

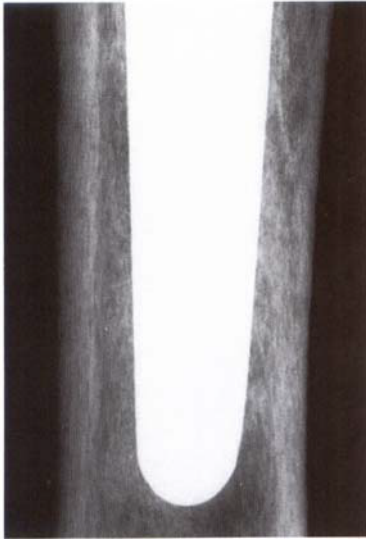
*Case 1 (Figure 1)*

The radiograph shows a rather tiny network of bone

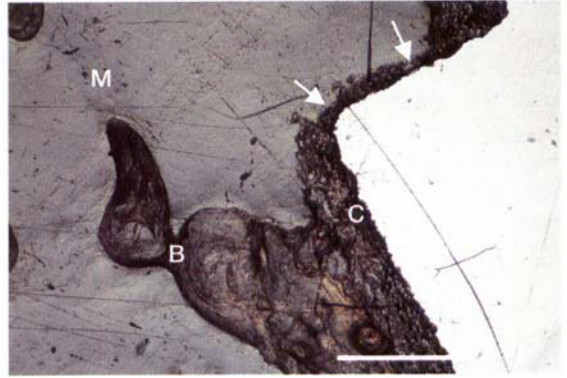
trabeculae at the tip of the stem between the implant and the endosteum.

A macroscopic view of the metaphyseal area (Gruen Zones I and VII) showed scattered trochanteric cancellous bone with very thin cortical shells. On the lateral and the medial aspects of the implant, isolated and often sigmoid-shaped trabeculae could be identified, up to 1 mm thick. Microscopic examination showed that they were made of lamellar bone. Haversian remodeling was visible close to the HA coating. Direct contact between bone and ceramic

Figure 2. Case 2. 88-year-old woman.



The tip of the stem. Extensive new bone formation is visible all around the implant. Note the high degree of osteoporosis of the cortices.



Resorption of the coating (arrows) in the bone marrow–ceramic interface areas. I implant, C ceramic layer, B bone tissue, M bone marrow cavity. Reflected light microscopy, bar = 200  $\mu$ , diaphyseal section.

was evident. No changes in the coating could be seen in this area at a light microscopic level.

The interfacial bone found in Zones II, III, V, and VI were of a digitiform morphotype. Superficial irregularities were noted in the segment of the coating in contact with bone marrow, while its original thickness was preserved in the bone-HA interface. In these areas of degradation, several osteoclasts were found, forming resorptive lacunae. In no place was complete degradation of the coating down to the metallic substrate observed.

The tip of the stem, which constitutes Zone IV, was completely surrounded by newly-formed bone tissue. A bony sleeve was running continuously around the tip of the stem (an alveolar morphotype). No degradation of the coating was visible. The marrow tissue in the meshes of this cancellous bone contained rather fatty involuted tissue with very few cells.

As regards the entire femoral implant, approximately 40 percent of the surface interfaces with bone, while the remaining 60 percent is in contact with bone marrow. No fibrous tissue was found adjacent to the implant.

#### Case 2 (Figure 2)

Radiographically, this stem seemed tightly fitted into the medullary canal. A detail of the tip of the stem showed bone formation. From a histological standpoint, two major differences from Case 1 could be

outlined: a more pronounced ceramic degradation and a highly cellularized bone marrow.

In most places where the coating faced bone tissue, the original thickness of the ceramic was preserved. Extensive resorption of the coating was observed in areas without bone covering, where marrow cells had access to the apatite coating. Macrophages with a cytoplasm that was charged with ceramic debris were seen in the areas of resorption as well as free particles of ceramics in the extracellular fluid. This degradation process may or may not leave a thin remnant of ceramic, the metal being in contact with bone marrow. In several places, secondary formation of immature bone tissue was found to occur on the ceramic remnant. Secondary mineralization took place, leaving a mature bone tissue interfacing with the prosthesis.

On the whole, the implant interfaced with bone for approximately 30 percent of its total surface, with a total absence of fibrous interface.

#### Discussion

The majority of studies involving HA coatings have focused on two major properties: formation of an early direct bond with living bone and maintenance of the integral structure of the coating.

In vivo animal experiments confirm the high osteophilic potential of HA, both in cortical and in can-

cellous bone. They indicate a faster and stronger attachment of bone to HA-coated implants, as compared with uncoated implants (Cook et al. 1988, Søballe et al. 1992). The histologic findings in this study and in our previous report confirm the results obtained in animal experiments and demonstrate new bone formation directly onto the HA coating. The osteophilic nature of HA is affirmed by the deposition of bone, even in areas where initial contact with bone is not present.

What we call alveolar morphotype has previously been described around HA-coated dental implants (deLange and Donath 1989) and orthopedic implants (Geesink et al. 1987). With such a layout, load transfer should probably be optimal. On the other hand, a discontinuous bone-HA interface equivalent to the so-called digitiform morphotype was also previously reported by Buser et al. (1991). Likewise, these authors described resorptive phenomena of the ceramic component located at the bone marrow-HA interface.

The presence of bone trabeculae between HA and cortical shell on the trochanteric area is of clinical importance. Their sigmoid shape and their overall shroud-like disposition is due to their load-transmitting ability. It has been shown that this area is subject to relatively low stresses. However, the presence of the anatomical continuity between bone and prosthesis allows forces to be transmitted to the metaphyseal area, perhaps preventing stress-shielding.

Bio-resorbability of calcium phosphate ceramic implants has been extensively reported in the literature (Uchida et al. 1985, Kwong et al. 1989). Osteoclasts, macrophages, monocytes, synovial cells and fibroblasts have been shown to solubilize bone mineral *in vitro* (Holtrop et al. 1982, Evans et al. 1984, Uchida et al. 1985, Ziats et al. 1988). In the present study, multinucleated osteoclast-like cells and macrophage-like cells showed phagocytosis of the ceramic component. However, the exact role played by each of these cell types and the physiological sequence of the resorption process are not known. The clinical relevance of the resorption of HA is unknown. The loss of fixation due to resorption of HA is possibly counterbalanced by the re-formation of bone on the remnants of the ceramic, or even directly on the metallic substrate itself. After disappearance of HA, the risk of ion release is of major concern (Ducheyne and Healy 1988).

Finally, a few comments should be made about the large amount of ceramic fragments released. Morscher (1991), in an editorial devoted to hydroxyapatite coatings, discussed the potential hazards that could damage joint tissues, if disintegration of the

ceramic mantle occurred. No intraarticular hydroxyapatite granules could be found in any of our specimens, either macroscopically or microscopically. Similarly, serial sections through ectopic ossifications failed to disclose any calcium phosphate body. This study and our previous one (Hardy et al. 1991) indicate that degradation of the coating is nearly absent before one year post-operatively, where heterotopic bone formation takes place.

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