Degradation of hydroxyapatite coating on a well-functioning femoral component

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We carried out a histological study of a proximally hydroxyapatite (HA)-coated femoral component, retrieved after 9.5 years of good function. The HA coating had completely degraded. Bone was in direct contact with the titanium surface in all the areas which had been coated, with no interposing fibrous tissue. There were no signs of particles, third-body wear, adverse tissue reactions or osteolysis. Bone remodelling was evident by the presence of resorption lacunae; tetracycline labelling showed bone laid down six years after implantation.

The loss of the HA-coating had no negative effect on the osseo-integration of the stem. We conclude that the HA coating contributes to the fixation of the implant and that its degradation does not adversely affect the long-term fixation.

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Because of its osteoconductive effect, hydroxyapatite (HA) coating has been used to improve the osseo-integration and thus fixation of uncemented implants for more than a decade. The midterm results of HA-coated total hip replacement have been very promising.¹⁻³ The clinical use of HA-coated stems, however, remains a topic of debate because of concern about the stability of HA in the biological environ-

ment and the consequences on osseo-integration in the long term.⁴

HA on the surface of an implant may degrade as a result of mechanical abrasion or delamination, phagocytosis or dissolution due to low pH, the presence of proteins or cell-mediated resorption.⁵⁻¹³ There is evidence that HA particles may lead to cell-mediated osteolysis and subsequent loosening of the implant, or wear of the joint surfaces.^{14,15} Not all examples of the degradation of HA have been detrimental. New bone can form in direct contact with a metal surface as HA is degraded, creating an osseo-integrated surface.⁹ Furthermore, third-body wear does not seem to be more of a problem with HA-coated than with uncoated uncemented implants.¹⁶

Previous reports have documented the histological results of HA-coated stems retrieved after a maximum of 6.2 years.⁹ Our study presents the radiological and histological results of a retrieved HA-coated stem 9.5 years after implantation.

Case report

A 61-year-old male farmer weighing 120 kg with chronic obstructive pulmonary disease and diabetes (type II), received a total hip arthroplasty for primary osteoarthritis of the right hip. The implants were an uncemented 13 mm ABG femoral stem and a 54 mm ABG I acetabular cup (Howmedica, Staines, UK) with a polyethylene liner. The femoral stem was made from titanium alloy (Ti6Al4V). The proximal third of the stem had a macro-relief texture and was coated with commercially pure titanium (roughness between 3 and 4 μm Ra) and subsequently with HA by vacuum plasma spraying to a thickness of 60 μm . The HA coating had a purity of more than 90%, a crystallinity of approximately 75% and a Ca:P ratio of 10:6.

There were no complications after the surgery or during the follow-up period. Radiographs were taken immediately after operation and four years later. The patient received long-term prophylactic treatment with tetracycline for pulmonary infection, six years after the surgery. He died from cardiac arrest, after the prosthesis had been in situ for 9.5 years and functioning very well. Permission to retrieve the prosthesis had been obtained from the patient and from his next of kin.

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Fig. 1

Radiograph of the prosthesis fixed within the shaft of the retrieved femur indicating the areas from which the sections shown in Figures 2 to 6 have been taken.

Retrieval and processing. The proximal femur was removed *en bloc* at post mortem and fixed in 10% buffered formalin. The upper half of the femur, containing the whole stem, was radiographed before being cut into multiple blocks. Each specimen was later processed according to the technique described by Stich.¹⁷ Specimens were sectioned and ground down to a thickness of between 10 and 30 μm .

We took histomorphometric measurements from scanned light-microscopic photographs (original magnification $\times 6$) using the computer software Corel Photopaint (Version 9; Corel Corporation, Ottawa, Canada). We determined the proportion of bone-implant contact from a calibrated grid (2 $\times$ 2 mm) superimposed above the section image. Because of the small number of sections analysed these measurements are useful only as a rough guide.

Results

Both stem and cup were secure within the shaft of the femur and the acetabulum, respectively. There was no macroscopic evidence of loosening, metallosis on the inner surface of the joint capsule, or wear on the surface of the polyethylene inlay of the cup.

Radiological examination. The stem was well integrated, with no surrounding radiolucent lines (Fig. 1). During the

Fig. 2

Photomicrograph through zone 1 showing bone (B) in direct contact with the rough titanium (Ti) surface (O, osteocyte; Light Green and Basic Fuchsin $\times 150$).

Fig. 3

Photomicrograph through zone 1 showing a remodelling canal (RC) in a bone trabeculum (B) (Light Green and Basic Fuchsin $\times 50$).

9.5 years since surgery it had subsided by 4 mm, as measured from the shoulder of the prosthesis. There was slight corticalisation of the cancellous bone in Gruen zones 3 and 5 (Fig. 1). Bone in Gruen zone 6 seemed to be atrophic. These features were not observed on the radiographs taken at four years after operation. All other zones showed normal bone density.

Histological examination. All the sections of Gruen zones 1 and 7 which were analysed showed no sign of the HA coating remaining on the surface of the implant, indicating

Fig. 4

Photomicrograph through zone 1 taken under ultraviolet light showing tetracycline (TC)-labelled bone (B) adjacent to the implant (I) (x 20).

that it had been completely degraded. Bone trabeculae were in direct contact with the titanium surface in all areas from which the HA coating had been removed with no interposing fibrous tissue (Fig. 2), indicating a mechanically stable interface. The presence of resorption lacunae gave evidence of active remodelling (Fig. 3). The fact that remodelling continued well beyond the initial years after implantation was also demonstrated by the traces of tetracycline visible within the bone on microscopic views taken with ultraviolet light (Fig. 4). There were no wear particles or inflammatory cells in any section studied and no evidence of osteolysis. The surrounding bone was mildly atrophic in zones 1 and 7. In the transitional region between zone 1 (distal) and zone 2 (proximal), the surrounding bone appeared to be hypertrophic. In zone 7, the cortex showed signs of cancellisation (Fig. 5). The 'fish-scale' macrotexture of the stem resulted in increased gaps between the surface of the implant and the surrounding bone; no bone had crossed these gaps. Bone-to-implant contact was approximately 23% in zone 7 (Fig. 5), 30% in zone 1 and 54% in the transitional region between zones 1 and 2.

In the distal Gruen zones 2 to 6, an interposing fibrous tissue layer, which was quite thick in some areas, was seen between the bone trabeculae and the surface of the implant (Fig. 6). The proportion of bone-to-implant contact distally was approximately 7%. There was no bone marrow in direct contact with the surface of the implant. There appeared to be a ring of comparatively dense bone in the peri-implant region (Fig. 6) where the bone trabeculae were orientated in a radial fashion. In zones 3 and 5, the surrounding bone was hypertrophic, but there was no hypertrophic bone (no reactive lines) distal to the tip of the stem. There was evidence of continuing active and previous bone remodelling by resorption lacunae and tetracycline staining. Cortical and cancellous bone atrophy seen on radiographs of zone 6 was

Fig. 5

Photomicrograph of a horizontal section through the calcar area showing cancellisation of the cortex. Approximately 23% of the surface is in contact with bone (Light Green and Basic Fuchsin x 1.25).

Fig. 6

Photomicrograph of horizontal section through zones 3 and 5. Most of the implant circumference is in contact with fibrous tissue (F) (Light Green and Basic Fuchsin x 1).

also evident histologically and this suggests stress shielding.

Discussion

This investigation shows the radiological and histological appearances of a well-functioning, proximally HA-coated, femoral stem retrieved after 9.5 years. The HA coating had been completely removed and the proximal third of the prosthesis was well integrated with bone trabeculae. The design of the stem relies on proximal fixation, which is confirmed by the histological and radiological examinations.

The removal of the entire HA coating had no negative effect on osseointegration of the stem. The coating was not replaced by fibrous tissue on the surface of the implant and there were no adverse tissue reactions (eg. granulomata, osteolysis, etc) or third-body wear of the polyethylene liner associated with HA particles in the joint. This confirms findings of other retrieval studies.^{6,8,9,18-20} After degradation of the HA coating, bone trabeculae were in direct contact with the surface of the implant, as reported by other authors.^{9,19,21} It is therefore important that the surface of the metal underneath the HA coating encourages osseointegration by virtue of its material and texture.⁹ In our implant, there was an underlying coating of commercially pure titanium with a rough surface which was ideal for this purpose.^{22,23}

The process of degradation of the HA coating seems to have occurred in the course of bone remodelling without loss of fixation, with osteoclasts probably playing a major role. It is likely that degraded amorphous HA at the interface induced new formation of bone. Bone remodelling depends on load transfer (Wolff's law), and is an ongoing process during the lifetime of the prosthesis. In our subject this was demonstrated by tetracycline staining of bone laid down six years after implantation. Some authors have reported that degradation only occurs in areas with no bone-implant contact.^{8,9} We found that all the HA coating had been removed, suggesting that degradation occurred in areas where there must have been bone-implant contact. Although the mechanisms of degradation of HA are speculative, phagocytosis and cell-mediated resorption (i.e. dissolution) are possible explanations.

The radiological and histological findings show proximal fixation and osseointegration of the stem. Stress seemed to be uniformly distributed over the length of the stem and femur with little evidence of stress shielding. The concept of this proximally-coated stem is to provide proximal fixation by osseointegration, allowing transfer of transitional load from proximal to distal.³

The average bone-implant contact of the originally coated part of the stem (34%) was lower than in other retrieval studies (31% to 90%).^{6,9,18} The time of implantation of these stems was shorter, between one and six years, and there was still some HA present. In our subject, the amount of bone on the surface of the implant may have been

reduced in the natural process of bone remodelling.²¹ Coating resorption and bone remodelling have resulted in an extent of bone-implant contact which is typical of uncoated titanium implants.^{18,24}

We have shown that the stem, distally, was covered by a layer of fibrous tissue. This tissue layer was demonstrated histologically, but was too thin to be detected radiologically as a radiolucent line. Radiographs therefore do not seem to be a reliable means of distinguishing between microscopic bone and fibrous tissue.²⁵

We conclude that the loss of the HA coating has no negative effect in terms of loosening of the implant, adverse tissue reactions, osteolysis, third-body wear or formation of interposing fibrous tissue. Bone trabeculae were in direct contact with the underlying metal surface.

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