HISTOLOGY OF TISSUE ADJACENT TO AN HAC-COATED FEMORAL PROSTHESIS

A CASE REPORT

F. LINTNER, G. BÖHM, M. HUBER, R. SCHOLZ

From the Baumgartner Höhe Institute of Pathological Bacteriology and the University Institute for Clinical Pathology, Vienna and Leoben General Public Hospital, Styria, Austria

We studied the fixation of a cementless titanium femoral prosthesis partially coated with hydroxyapatite ceramic (HAC) 10.4 months after implantation. Histomorphological investigation showed extensive new bone formation between the HAC coating and the bone bed; morphometry showed bone contact indices of up to 91.60%. There were a number of resorption lacunae on the HAC coat with depths of up to 76.6 µm and widths of up to 453 µm.

Our results confirmed that considerable bone remodelling had taken place and that the apatite-coated prosthesis had united with bone despite the lack of appreciable immediate press-fit. Hydroxyapatite particles which had been released did not appear to show any negative effects on the stability of the implant.

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In orthopaedics, hydroxyapatite is used in a ceramic form (HAC, hydroxyapatite ceramic) (Dörre 1989; Willmann 1990) and is regarded as bioactive, stimulation of bone growth having been confirmed experimentally (Geesink, De Groot and Klein 1987; Cook et al 1988; Søballe et al 1990, 1992; Ogiso et al 1992; Malik et al 1992; Massas, Pitaru and Weinreb 1993; Neo et al 1993). There are,

however, few morphological studies providing quantitative data after long-term implantation in patients (Bloebaum et al 1993; Hofmann, Bachus and Bloebaum 1993).

We have examined one case in detail, studying bone growth on to the hydroxyapatite coating, and the processes of resorption.

CASE REPORT AND METHODS

An 80-year-old woman sustained a fracture of the neck of the right femur on 14 January 1992. The following day total hip arthroplasty was performed using a 52 mm AHS socket and a 13 mm AHS shaft. The AHS endoprosthesis (Fig. 1; Ehall et al 1992) is a cementless hip implant developed by Logimed, Austria-Styria (Logimed-Medizinische Spezialprodukte Gesellschaft mbH, Leoben, Austria). The straight femoral shaft is of wrought titanium alloy (Ti-6Al-4V) with the proximal two-thirds coated with HAC (Osprovit; Feldmühle AG, now Cerasiv GmbH, Plochingen, Germany). The thickness of the coating tapers from 0.15 mm to 0.2 mm proximally to zero distally. The spherical polyethylene socket also has a titanium alloy backing which is HAC coated.

In our patient, socket loosening resulted from a *Staphylococcus aureus* infection and revision was performed on 21 October 1992 using a 66 mm AHS socket and fixation screw, leaving the unloosened femoral component in place. The patient died on 19 November 1992 from cardiac failure, when the femoral shaft had been in situ for 10.4 months.

The proximal femur was removed immediately at post-mortem and fixed in 10% buffered formalin. After radiography (Fig. 2), the specimen was cut into 12 transverse segments on a band saw (Exakt-Apparatebau Hermann, Norderstedt, Germany) and these were embedded in methylmethacrylate under vacuum (Fig. 3). Sections 100 µm thick were cut and ground from the blocks and microradiographs were taken.

Further grinding down was performed to about 10 µm thickness and the sections were polished on a PM2 polisher (Logitech, Glasgow, UK). Staining was with toluidine blue.

Single sections were then measured and investigated

F. Lintner, MD, Professor of Pathology
M. Huber, MD
Institute of Pathological Bacteriology, Baumgartner Höhe 1, 1140 Vienna, Austria.

G. Böhm, MD
Institute for Clinical Pathology, University of Vienna, Währingergürtel 18-20, Vienna 1090, Austria.

R. Scholz, MD, Head, Department of Surgery
Leoben General Hospital, Vordernbergerstrasse 42, 8700 Leoben, Styria, Austria.

Correspondence should be sent to Professor F. Lintner.

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Fig. 1

General appearance of the partially HAC-coated titanium prosthesis.

Table I. Detailed findings for each of 12 segments from proximal (1) to distal (12) (see Fig. 3)

Segment	Bone contact index (per cent)	Number of contacts with cancellous bone	Number of lacunae
1	80.70	27	16
2	81.60	35	21
3	69.50	39	22
4	86.00	18	11
5	83.50	20	15
6	91.60	17	13
7	79.50	Contacts only with the inner side of the cortical bone	—
8	26.40		—
9	15.10		—
10	26.60		—
11	19.10		—
12	23.97		—

using a semiquantitative AMS evaluation system (Leitz-Wetzlar) to measure the following parameters (Table I):

- 1) percentage of bony covering (BCI, bone contact index),
- 2) number of cancellous bone contacts with the surface of the prosthesis,
- 3) number of resorption lacunae on the HAC coating in each segment,
- 4) the greatest depth of the lacunae in any segment, and
- 5) the greatest width of the lacunae in any segment.

RESULTS

Histomorphology and microradiography. The shaft of the prosthesis was in an ideal position, with its oval longitudinal axis parallel to the cortical bone in the

Fig. 2

Radiographs of the specimen removed 10.4 months after implantation. There is a good fit with no signs of loosening.

proximal region. The cancellous bone architecture was homogeneous throughout, but the cortical bone had become slightly cancellous (Fig. 3), although with no change in width.

There were typical elongated narrow bony ridges with a lamellar configuration in the entire region of the HAC coating, with occasional bony foot-like processes anchoring the coating to the cancellous bone (Figs 4 and

Fig. 6

There are several adjacent resorption lacunae in the newly-formed bone on the HAC coating and also on the HAC coating itself (arrows). There is an increase in nuclear density (macrophages containing apatite) in the region of the lacunae (dotted line) (toluidine blue, non-decalcified $\times 12$).

Fig. 7

Resorption lacunae in the HAC coating, which have interrupted the bony continuity (toluidine blue, non-decalcified $\times 40$).

cancellous region of the femoral bone was between 17 and 39. There were between 11 and 22 osteoclast lacunae. The greatest depth of the lacunae was $76.6 \mu\text{m}$, the greatest width was $453 \mu\text{m}$.

DISCUSSION

In previous reports of good incorporation of HAC-coated prostheses, there are very few studies of the stability of the coating. Primary interest is in the technique of application of the coating and the significance of its thickness, since flaking-off is possible with alternating

loading or deformation of the support (Willmann 1990). A secondary consideration is the restructuring of the HAC layer in vivo. Willmann, Richter and Wimmer (1993) showed by rotating and bending tests that flaking-off does not occur in coated test specimens of different thicknesses.

As regards restructuring of the coating, previous morphological studies have described the early growth of new bone at the HAC surface with an intimate bond between the bone and the coating, in particular the absence of a layer of connective tissue (Osborn 1987, 1988, 1989; Bauer et al 1991; Furlong and Osborn 1991; Hardy et al 1991; Jansen et al 1991; Søballe et al 1991; Lintner, Huber and Scholz 1992; Bloebaum et al 1993; Hofmann et al 1993). This has also been shown radiologically (Geesink 1990), with double contours in the uncoated part indicating the formation of an intermediate layer of connective tissue (D'Antonio, Capello and Jaffe 1992). This was confirmed by our investigation.

Böhm et al (1990, 1992) first reported morphometric investigations on removed specimens of cementless titanium prostheses with rough surfaces, specifying the percentage of BCI. Our morphometric investigation had a highest value for rates of bony covering of 91.6% in segment 6 (Table I). This confirms excellent appositional bone growth at 10.4 months after implantation. Bauer et al (1991) and Bloebaum and Dupont (1993) have also shown that HAC-coated implants were largely covered by bone, confirming the excellent osseointegration.

Osborn (1987) describes the formation of new bone on the HAC coating as 'bilateral' since the cells which form bone tissue appear to arise both without intermediary pre-existing bone on the surface of the HAC and also by accretion on the osseous structures opposite the HAC coating. The crucial addition of new bone appeared to be independent of attached bone structure. This was confirmed by the number of cancellous bone contacts on the HAC surface, since a high BCI was found even when there were relatively few cancellous bone contacts.

Experimental studies which compared titanium surfaces with and without HAC coating showed intense osseoneogenesis with HAC coating, but no faster increase in the bone mineral content. This indicates that HAC does not affect the cell metabolism of osteogenic cells (Hofmann et al 1993). In our specimen, the uncoated but smooth titanium part of the prosthesis showed only occasional and delicate metal contacts with the inner cortical layer under press-fit conditions. This was confirmed by the marked decrease in BCI in segments 8 to 12 (Table I). An interpolated fibrous tissue was shown between metal and cancellous bone or the more distant inner cortical bone layer (Hardy et al 1991).

Straight cementless titanium prostheses with a rough surface show extensive bony covering under press-fit conditions, as demonstrated morphologically by Lintner, Zweymüller and Brand (1986) and Lintner et al (1988, 1990) and morphometrically by Böhm et al (1990, 1992). After 14 months, the BCI reached an average of 49.5%;

Fig. 8

Irregularly formed HAC surface (resorption; arrows). There are contiguous abundant macrophages (MP) and no resorption of the bone (toluidine blue, non-decalcified x60).

Fig. 9a

Fig. 10a

Fig. 9b

Fig. 10b

Figure 9 – Segment 2. a) Detached HAC coating; some new bone has grown around the detached HAC lamella (HAC), and bone has also covered the original HAC layer (OHAC). b) At one point the two bone layers are connected (toluidine blue, non-decalcified x13). Figure 10 – Details from the uncoated smooth part of the prosthesis. a) The newly-formed arcuate bone trabeculae are clearly separated from the metal surface (M) by a fine layer of connective tissue (CT, arrows) (toluidine blue, non-decalcified x13). b) The bone tissue is clearly separate from the metal surface. At only one point, a delicate bone process reaches the metal surface (toluidine blue, non-decalcified x26).

in occasional segments there was 71% bony covering (Böhm et al 1992). Our investigation of an HAC-coated prosthesis after 10.4 months showed a very much higher BCI in terms both of the average and the peak values.

It can therefore be assumed that the favourable results with titanium surfaces are attributable to both the press-fit technique and the rough surface. An HAC-coated prosthesis shows much faster osseointegration without accurate press-fit, because of its special properties. Other authors have confirmed this (Søballe et al 1990; Jansen et al 1991); they showed better bone formation on the HAC coating even in the absence of direct bone contacts.

Our investigation showed that the coating may flake off, at least focally, during implantation. The flakes, however, undergo osseointegration, provided that there is primary stability and immobility at the implant bed (Søballe et al 1992). These flakes do not have a negative effect on healing. We consider, however, that HAC-coated prostheses should be introduced by 'gentle pressure' only; they do not need 'hammering-in' to attain osseointegration, although absolute primary stability should be achieved.

The question of resorption of the HAC coating by bone remodelling has not been adequately addressed. Bauer et al (1991) described occasional focal resorption with release of some calcium phosphate into the extracellular fluid but little change in the thickness of the HAC coating. Jansen et al (1991), however, reported a decrease in the thickness of HAC coating as a result of resorption and degradation. Bloebaum and Dupont (1993) also described release of particles from the HAC coating into periprosthetic tissues and into the hip capsule 3.3 years

after implantation of a press-fit prosthesis. These particles were combined with other attrition products, especially polyethylene. The significance of these HAC particles in the osteolysis which had occurred was not established.

We could find no specific quantitative data on active resorption caused by osteo(ceramo)clasts. This is important since it is possible that such resorption could degrade the HAC coating down to its metal base. In our specimen the coating was 150 to 200 µm thick proximally, with a regular decrease to zero distally. The deepest lacuna which we found had a depth of 76.6 µm, and could have penetrated down to the metallic surface in the distal sections of the shaft of the prosthesis. The maximum width of lacunae was 453 µm, which indicates that resorption may take place over large areas. Osteoclast counts were increased above the normal values found in the human skeleton; this indicated that osseointegration was not complete and that adaptation was continuing.

In contrast to Osborn (1987) and Furlong and Osborn (1991) we found small macrophage beds with incorporated HAC particles in the regions of resorption (Lintner et al 1992) but there were no signs of resorption on the adjacent bone. In our specimen there were also indications of 'filling-up' of occasional lacunae by newly-formed osteoid.

Further investigations are required to establish whether the formation of such resorption lacunae and the release of HAC particles can cause weakening of the fixation with consequences to the long-term fixation of the implant.

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