Early failure of hydroxyapatite-coating in total knee arthroplasty

A case report

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We observed early loosening of a hydroxyapatite-coated tibial component in a total knee arthroplasty in a randomized study comparing HA-coating with cement fixation. Symptoms of loosening started 8 weeks after surgery. Roentgen stereophotogrammetric analysis revealed stability during the initial 6 weeks followed by a pronounced subsidence up to 6 months after surgery when revision was done. At revision, the HA-coating was found to have separated from the medial part of the tibial component. The synovium was abundant with macrophages and multinucleated giant cells containing HA-crystals. Overloading of the prosthesis and suboptimal quality of the HA-coating was believed to have caused the loosening process.

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A 66-year-old man weighing 83 kg with a right medial gonarthrosis, Grade 4, (Ahlbäck 1968) underwent a Tricon II tricompartmental knee arthroplasty (Smith & Nephew Richards, Memphis, Tennessee, U.S.A.). The tibial component of this design is made of titanium alloy. The undersurface has several large grooves and is coated with a 200-µm-thick layer of hydroxyapatite performed by Cerasiv (formerly Feldmühle, Germany). According to the manufacturer the HA-coating has a purity of 98 percent, a porosity of 20 percent and a tensile bond strength of 35 MPa. A polyethylene tibial tray with a thickness of 12 mm was used in this patient. The chromium-cobalt porous-coated femoral component was inserted without cement, whereas the all-polyethylene patellar component was cemented (Palacos® with Gentamicin). At the operation, the tibia and the polyethylene tibial component were prepared for the subsequent roentgen stereophotogrammetric analysis by the insertion of 0.5 and 0.8 mm tantalum markers. The operation was performed by an experienced surgeon. No peroperative complications occurred. Postoperative radiographs showed that the components were well aligned and the HKA angle was 177°. The postoperative period was uneventful and the patient was sent home after 11 days. According to our routine postoperative treatment of uncemented knee arthroplasties, partial weight bearing was allowed as soon as the patient found it comfortable. 2 crutches were used for 6 weeks.

At 6 weeks, the patient was pain-free during weight bearing, but reported slight pain after exercise. 2 weeks later he suddenly felt pain after a twist of the knee when he was carrying his sick wife. Thereafter, the pain during weight bearing and at rest gradually increased during the following months. At 7 months after the insertion, revision was performed.

Up to 6 weeks after surgery, the RSA investigations revealed small migration (0.4 mm MTPM; Ryd 1986), equal to the mean value in the other 28 patients operated with HA-coated prostheses in the study (Nilsson and Kärrholm 1993). The central and anteromedial parts of the tibial component were the most stable, displaying subsidence of 0.16–0.20 mm at 6 weeks. Thereafter, the migration increased dramatically. At 3 months, it was 5.5 mm and at 6 months, 9.4 mm (Figure 1). Prior to revision, the tibial component had rotated 2.1° anteriorly, 3.3° externally, and 3.0° into varus, corresponding to a subsidence of 7.1 and 2.7 mm at the medial and lateral edges, respectively, and an anterior subsidence of 6 mm (Figure 2).

At revision the synovium was markedly thickened, discolored by grey-black metallosis and had a crunchy sensation on palpation. The tibial component seemed to pop off spontaneously from the bone when the tibia was displaced anteriorly, whereas the femoral and patellar components were firmly fixed. The polyethylene of the tibial and patellar components did not show any macroscopic evidence of wear. The HA-coating had separated from the medial part of the tibial component (Figure 3). Grey-black stained fibrous mem-

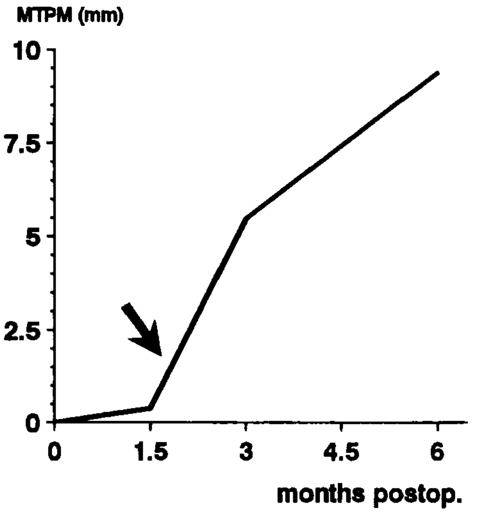

Figure 1. Maximum migration (MTPM) of the tibial component from the RSA evaluation. The migration was small during the initial 6 postoperative weeks. Thereafter the migration increased tremendously. The arrow indicates when the symptoms from the knee commenced.

brane was found on the lateral part of the resected proximal tibia and in both screw holes. Obvious signs of osteolysis could not be seen. Multiple intraoperative cultures were negative. After synovectomy, a cemented Tricon II tibial component was inserted.

Histological analysis. Samples for histological analysis were obtained from the thickened synovium, the greyish membrane on the lateral part of the proximal tibia. One cm long bone biopsies were taken from the medial and lateral parts of the resected proximal tibia. The synovium was markedly vascularized and infiltrated by mononuclear histiocytes and multinucleated giant cells. 3 distinct types of foreign material were identified: (1) small (0.1–14.0 μm) black metallic particles, (2) oblong fiber-like (1-300 μm), strongly birefringent fragments, and (3) irregular, greyish, and slightly birefringent crystalline particles (0.1–3.0 μm). Energy-dispersive x-ray microanalysis (EDAX) of the crystalline particles showed a calcium to phosphate ratio (1.728:1) similar to that of hydroxyapatite. All 3 types of particulate were found interstitially, but mainly in the cytoplasm of the mononuclear histiocytes and the multinucleated giant cells. Frequently, up to 30 μm large clusters of HA crystals were seen in the cytoplasm of giant cells. The amount of particulate varied between grades 2+ and 3+ according to Bloebaum and Dupont (1993). Particularly heavy deposits were observed in perivascular areas in the subsynovial connective tissue. The membrane obtained from the lateral part of the proximal tibia showed similar but less pronounced deposits of the foreign particles. The medial bone biopsy contained mainly necrotic, partly compressed and fragmented cancellous bone. The lateral bone biopsy demonstrated essentially normal viable cancellous bone. There was no cellular reaction or presence of foreign material in either bone biopsy.

Discussion

The early stability of the tibial component in our patient suggests that at least some areas of the coated tibial undersurface may have been bonded to the bone. The sudden increase in migration after 6 weeks coincided with the initiation of symptoms indicating that in

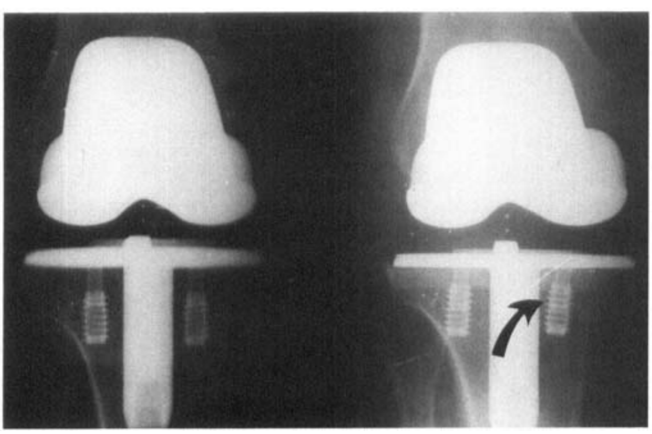

Figure 2. The right knee at 1 week postoperatively (left) and 6 months postoperatively (right). Notice the radiolucent zone under the tibial component. The screws slid and tilted (arrow) as a result of subsidence and varus rotation. Reduction of the distance between the tibial tray and the tantalum markers in the proximal medial tibial metaphysis is obvious.

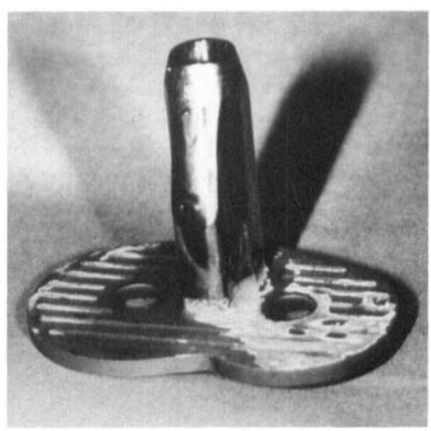

Figure 3. The HA-coating had separated from under the medial part of the tibial component (to the left).

this patient the loosening process did not start immediately after surgery as has been suggested by Ryd et al. (1993). The reason for the early loosening may have been that too small an area of the prosthetic undersurface was attached to the bone in combination with an overloading of the implant. The quality of the coating used may have been another important factor.

In pull-out tests the HA-prosthesis interface has been shown to be weaker (Brunski et al. 1991, Klein et al. 1991) than the HA-coating itself (Brunski et al. 1991), especially if the coating is thicker than 50 µm (Kester et al. 1991). The interface between HA and bone always seems to be the strongest (Brunski et al. 1991, Klein et al. 1991). Moreover, the coating porosity is also of importance. Manley et al. (1993) observed decreasing strength with increasing porosity from 5 to 15 percent when examining coatings corresponding to those available on the market. The HA-coating used in this patient was rather thick, had a comparatively high porosity, and was attached to a non-porous-coated surface. The tibial component of a knee prosthesis is subjected to high forces, often resulting in multiplanar migration. The pattern of micromotion in our patient and the findings at revision support the hypothesis that fracture of the HA-coating or separation at the HA-prosthesis interface was the initiator of the process of loosening. Once the prosthesis loosened, the combined effects of overload and progressively increased varus malalignment of the knee resulted in necrosis of the bone. This necrosis, being most pronounced medially, may explain the dramatic subsidence.

The large amount of HA crystals found in histiocytes and giant cells in the thickened synovium has several implications. Presence of HA particles in cells has sometimes been found to induce synovitis similar to gout in human joint tissues (Alwan et al. 1989). Moreover, in vitro studies have shown that HA crystals are able to stimulate synovial macrophages producing osteolytic activity (Alwan et al. 1989), and severe osteolysis has been found in a loosened HA-coated hip prosthesis years after surgery (Bloebaum and Dupont 1993). Whether the large subsidence recorded was due to osteolysis of the tibial metaphysis, pure overload of the bone due to mechanical reasons, or a combination of these factors was not possible to establish in this patient. HA crystals have also been found to aggravate wear of the polyethylene by becoming embedded in the polyethylene (Bloebaum and Dupont 1993). In our patient, macroscopically obvious wear was not found, probably due to the short period in which the prosthesis was in service.

HA-coating has a potential for substantially improving the initial fixation of uncemented prostheses. For the long-term stability of total knee arthroplasties, the optimum characteristics of such a coating and the prosthetic surface to which it should be bonded, has so far not been completely established. Therefore, general use of HA-coated implants should be avoided until controlled clinical studies of implants with well-defined coatings have been performed.

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