Fixation of a hydroxyapatite-tricalcium phosphate-coated cementless knee prosthesis

CLINICAL AND RADIOGRAPHIC EVALUATION SEVEN YEARS AFTER SURGERY

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Miller-Galante II total knee arthroplasty (MG II TKA) was performed on 32 knees in 30 patients. On both the femoral and tibial components, the fibre-metal area was plasma-sprayed with hydroxyapatite-tricalcium phosphate (HA-TCP). The clinical and radiographic outcome was evaluated. A mean pre-operative knee score of 26.0 ± 18.6 (SD) increased to 97.5 ± 3.5 and a mean pre-operative functional score of 21.7 ± 15.0 (SD) increased to 83.4 ± 12.4 at follow-up of seven years. Clear zones were common around the components at one month post-operatively but had completely disappeared after six months. An autopsy of a patient who underwent MG II TKA with HA-TCP two years previously, showed osteogenesis in all parts of the fibre-metal, and bone tissue comprised 77.7% of the interface. This coated prosthesis has good early fixation which is maintained at seven years with good clinical and radiographic outcomes.

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A total knee arthroplasty (TKA) may be cemented or uncemented. Cement provides good early fixation and may prevent the migration of polyethylene debris into the interface between the implant and bone. The advantages of cementless fixation are that more bone can be retained, infection is more likely to be controlled without removal of the implant, and post-arthroplasty fracture can be treated more easily.1,2 The main disadvantages are that an extremely accurate osteotomy is required and bony ingrowth takes time.3-5 Migration of polyethylene wear debris into the bone-implant interface may also occur.6 With regard to the components, the use of titanium alloy gives good fixation but may be associated with increased wear. We have used a prosthesis in which the femoral component is made of cobalt chrome (CoCr) alloy and the tibial component of titanium-6 aluminum-4 vanadium (Ti-6Al-4V) alloy. In both components, the fibre-metal surface is coated with hydroxyapatite-tricalcium phosphate (HA-TCP) in order to improve fixation. This study assesses the fixation achieved by HA-TCP at seven years after TKA using the HA-TCP-coated Miller-Galante II knee prosthesis, based on clinical and radiographic evaluation and reports the histological fixation of an HA-TCP-coated TKA at autopsy of a patient who died two years after operation.

Patients and Methods

Thirty patients (32 knees) underwent HA-TCP-coated Miller-Galante II total knee arthroplasty between January 1994 and February 1995. The femoral component is made of CoCr alloy and fibre metal, and the tibial component which has four pegs is made of Ti-6Al-4V alloy and fibre metal. The fibre metal on both components is plasma-sprayed with HA-TCP (70% HA and 30% TCP) to a thickness of 70 µm (Fig. 1). The femoral and tibial components were introduced without cement. The ultrahigh molecular weight polyethylene patellar component was fixed with cement. There were five men and 25 women. Osteoarthritis was the diagnosis in 25 patients (27 knees) whose mean age...
was 76.1 ± 4.9 years and whose mean weight was 56.6 ± 9.9 kg (43 to 78) at the time of operation. Rheumatoid arthritis was the diagnosis in five patients (five knees) whose mean age was 75.0 ± 7.1 years and whose mean weight was 48.7 ± 7.1 kg (37 to 58). All patients were followed up prospectively. At five years, two patients (two knees) had died due to unrelated reasons and at seven years three further patients (three knees) had died and two patients (two knees) could not be evaluated due to cerebral infarction and femoral neck fracture. Thus at seven years, 23 patients (25 knees) were available for assessment.

Surgical procedure and post-operative management. All operations were performed by the same surgeon (SA) using a standard technique. A midline longitudinal skin incision was made and the knee joint exposed via a medial-parapatellar incision. The posterior cruciate ligament was retained. Cancellous bone chips were placed at the site of osteotomies and the tibial component was fixed using screws. Continuous passive motion exercises were started on the second post-operative day and full weight-bearing with the knee in extension using a brace started after one week.

Clinical and radiographic evaluation. Patients were assessed before surgery and at one, three, six, nine and 12 months and regularly thereafter until seven years. For clinical evaluation, the Knee Society Clinical Rating System, knee and functional scores were used and the range of movement was recorded. For radiographic evaluation standard non-weight-bearing anteroposterior (AP) and lateral views of the fully extended knee, and a lateral view with the knee flexed to 40° were used. In order to assess the fixation of the components, the width of any clear zone in the five femoral and tibial regions shown in Figure 2 was measured. The total width of the clear zones was divided by the number of regions in order to calculate the mean width of the clear zone per region. The incidence of clear zones in each region was also calculated. The screw-bone interface was evaluated for evidence of osteolysis.

Results

Clinical assessment. The mean knee score showed a significant increase (Student’s t-test, t = 20.8, p < 0.001) from 26.0 ± 18.6 (SD) before surgery to 97.0 ± 3.7 at one year, 97.8 ± 3.4 at five years and 97.5 ± 3.5 at seven years after surgery. The mean functional score also showed a significant increase (Student’s t-test, t = 22.1, p < 0.001) from 21.7 ± 15.0 before surgery to 82.7 ± 12.3 at one year, 83.4 ± 12.3 at five years and 83.4 ± 12.4 at seven years after surgery.
Range of movement. The mean flexion contracture before surgery was 20.5 ± 12.4°. This decreased to 0.2 ± 0.7° at one year and to 0 ± 0° at five and seven years. The mean maximum flexion was 124.0 ± 17.8° before surgery, 119 ± 17.0° at one year, 123.0 ± 12.3° at five years and 123.4 ± 13.5° at seven years. Thus there was a significant improvement (Student’s t-test, t = 3.08, p < 0.01) in the mean range of movement from 103.5 ± 24.6° before surgery to 119.0 ± 16.8° at one year, 123.0 ± 12.3° at five years and 123.4 ± 13.5° at seven years.

Clear zones. The mean width of the clear zones in all regions around the femoral component decreased from 0.19 ± 0.21 mm (SD) at one month after surgery to 0.04 ± 0.08 mm at three and 0.0 ± 0.01 mm at six months. They disappeared by 12 months and none were seen at five or seven years (Fig. 3). For the tibial component, the mean width of the clear zones was 0.04 ± 0.10 mm at one month, 0.04 ± 0.14 mm at three and 0.02 ± 0.08 mm at six months. They disappeared at 12 months and none were seen at five or seven years (Fig. 4).

The mean width of the clear zones in each of the five areas around the femoral and tibial components was compared. For the femoral component, the mean width of the clear zones in the distal femur (C) and around the adjacent chamfer (B) was 0.47 ± 0.48 mm and 0.34 ± 0.56 mm, respectively. From three months after surgery, these zones decreased rapidly, and had disappeared by 12 months and none were seen at seven years after surgery. For the tibial component, the mean width of clear zones along the medial margin (A) was 0.08 ± 0.25 mm and along the lateral margin (E) 0.06 ± 0.24 mm at one month. Their mean width reduced by a half at six months and had almost disappeared by 12 months and remained unchanged at seven years.

The number and incidence of clear zones in each of the five regions around the femoral and tibial components was studied. For the femoral component, 17 patients (51%) had clear zones in the distal femur (C) and 12 (40%) had them around the chamfer (B) at one month after surgery. At three months, they were seen in five (17%) and two (7%) patients, respectively, and at six months only one patient (3%) had clear zones at each site. At 12 months, and at seven years none had clear zones. For the tibial component, they were seen in three patients (10%) at the medial margin (A) and in two (7%) at the lateral (E) and central regions (C) at one month. At six months, they were only seen in one patient (3%) at these three sites. At 12 months and at seven years, none had clear zones. There was no osteolysis around the screws at any follow-up period.

Case report of autopsy. In May 1994, an 84-year-old woman with rheumatoid arthritis underwent bilateral TKA. She gained a knee and function score of 98 and 80, respectively. Two years post-operatively, she died of acute fat embolism. We examined the histological findings at the junction between the tibial tray and bone. The specimen was mounted in a cold-curing plastic base and was embedded in methylmethacrylate in preparation for undecalcified histological studies. Coronal sections of approximately 200 µm were cut and stained with toluidine blue and basic fuchsin. A contact radiograph of each section was produced on high-resolution film. The bone-implant interface was evaluated using histomorphometric techniques which have been previously described. The interface between the porous coating of the tray and pegs and the proximal tibia was divided into 1 mm fields and each characterised as either bone, cartilage, fibrous tissue, necrotic tissue, or particle-induced foreign body granuloma. The tissues within the porous coating were also similarly characterised. The presence or absence of HA-TCP coating on the surface of the fibre metal was recorded for each field. The extent of each tissue and the presence of HA-TCP were expressed as a percentage of the total field.

AP and lateral radiographs of the gross specimen suggested a stable component without radiolucencies. In the stained section, there was ingrowth of bone into the fibre-metal coating in all regions of the tray and all four pegs (Fig. 5a). The tissue within the porous coating of tray and pegs was 81.1% bone, 6.7% marrow, and 4.5% fibrous tissues. The remaining 7.7% consisted of aggregates of metal.
fibres. HA-TCP coating was present on the surface of the fibre metal in 96.5% of the fields (Fig. 5b). The bone-implant interface was composed of 77.7% bone, 21.3% marrow, and 1% fibrous tissue. All four screws were in contact with trabecular bone and there were no granulomas (Fig. 5c).

Discussion

A combination of resistance of polyethylene to abrasion, and durable fixation of the implant is required in order to achieve good, long-term results of TKA. The advantage of cementing the components is that strong primary fixation is obtained. The disadvantages, however, include the toxicity of cement, decreased bone stock at the time of revision, difficulty in the treatment of infection and weakening of fixation over time. Cementless fixation avoids these complications and good, mid-term and long-term results have been obtained. The main disadvantage, however, is poor early fixation. Beads of fibre or metal may be used at the implant-bone interface to promote osteogenesis and improve fixation. However, bony ingrowth may take some months so the issue with cementless fixation is how to obtain stable early fixation. Osteogenesis around the tibial component is partly dependent upon the material and design of the implant. HA-coated implants were introduced in an attempt to provide early as well as long-term fixation. According to Burr et al, Tisdel et al, and Dean et al, HA-TCP coating of fibre metal results in increased osteoconduction to the surface of the implant. Soballe et al reported that the fixation with HA-coated implants is three times stronger than that with titanium alloy porous-coated implants. Excellent osteoconduction of HA-TCP has been shown in various experiments. Regner et al showed that there was significantly less subsidence of an HA-TCP-coated tibial component compared with uncoated implants, and less migration and displacement at follow-up of five years after TKA.

Recently, we have reported a series of 59 patients (92 knees) who underwent Nexgen (Zimmer Inc, Warsaw, Indiana) cruciate-retaining TKA. At 12 months post-operatively, there was a clear zone around the femoral and tibial components of 56.5% and 32.6% of the control uncoated components, respectively. However, in the HA-TCP group, there was a clear zone at the medial aspect of the tibial component in only one knee. These results suggested that there was good, early fixation with HA-TCP-coated components. In the present study, the clear zones which were seen one month after surgery decreased significantly by three months and had almost dis-

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Fig. 5

(A) Photomicrographs of the proximal tibia retrieved two years after TKA in an 84-year-old woman. (B) Note the presence of bone ingrowth into the porous fibre-metal HA-TCP coating some of which can still be seen (arrow). T, trabecular bone; p, porous; b, tibial base plate; arrow, HA-TCP. (C) All screws were in contact with trabecular bone, and there were no granulomas around the screws (toluidine blue and fuchsin stain, original magnification A: ×1, B: ×8, C: ×88).
appeared by six months. Regner et al. reported that HA-coated implants have less subsidence and anterior-posterior tilt at two months and become stable by between six and 12 months after surgery. Thus it seems that strong bone-implant fixation via HA-TCP is established at about this time.

The source of osteolysis was thought to be polyethylene wear from the tibial and patellar components. The presence of screw holes in the baseplate was thought to be a factor in the development of osteolysis on the tibial side rather than the femoral side. Polyethylene debris may migrate through the screw holes and the presence of local osteolysis would suggest that polyethylene failure has occurred. However, the presence of a radiolucent line may simply indicate micromovement between the screw and bone. Lewis et al. reported that radiolucent lines were seen around the screws in about 20% of cementless MG II, but not HA-TCP-coated prostheses. In our study, no osteolysis was found around a screw at any period of follow-up.

At autopsy of a patient who had received a MG II prosthesis with an HA-TCP-coated fibre metal surface two years previously, we found bony ingrowth in all areas of the fibre metal, and bone tissue comprised 77.7% of the interface. HA-TCP was seen on 96.5% of the coated fibre-metal surface, and the newly-formed bone covered the HA-TCP. These findings also indicate that early, firm fixation is achieved.

Some complications may occur after cementless fixation of the femoral component. The use of cobalt chrome alloy may be associated with less osteogenesis unless it is covered with HA-TCP. Furthermore, in view of the superior osteoinduction by HA-TCP, there may be less migration of wear debris, such as polyethylene particles. Some particles of HA may separate from the component, and the bone density may be reduced by stress shielding. It is not known whether these factors will influence the long-term survival of the implant. Despite these potential limitations, un cemented HA-TCP-coated knee prostheses have many advantages over cemented prostheses.

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Reference


