OSTEOLYSIS AROUND CEMENTLESS POROUS-COATED ANATOMIC KNEE PROSTHESSES

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We report the incidence of osteolysis in the femur, tibia, and patella of 44 consecutive patients (60 knees) who were followed for more than seven years after cementless knee arthroplasty with a Porous-Coated Anatomic prosthesis. The average age of the patients was 56.5 years (17 to 73); the operative diagnosis was osteoarthritis (33 knees), rheumatoid arthritis (17), tuberculous arthritis (7) and post-traumatic arthritis (3). All patellae were resurfaced.

No femoral or tibial component was loose at the final follow-up examination. Thirty patellar components were loose of which six had been revised. Radiographs revealed osteolysis in 90% of the tibial plateaux and in 80% of the 30 intact patellar prostheses. No osteolysis was seen around any femoral component. In 50 knees (83%) the average wear of the polyethylene liner was 2.5 mm in the medial compartment and 1.7 mm in the lateral compartment. Four of 60 knees (6.7%) were revised for complete wear of the polyethylene liner of the tibial component.

Fixation of the tibial and patellar components without cement fails to seal the interface between bone and prosthesis and allows the migration of polyethylene particulate debris which causes osteolysis.

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Periprosthetic osteolysis has been largely unrecognised after total knee replacement (TKR) despite the fact that retrieval studies have often shown substantial wear of the polyethylene components (Rostoker, Chao and Galante 1978, Engh 1988; Lombardi et al 1988; Wright et al 1988), nor has it been reported as a complication or as a cause of failure in long-term studies of cemented TKR (Townley 1985; Ranawat and Boachie-Adjei 1988).

Peters et al (1992) demonstrated osteolysis after cementless TKR in which titanium screws had been used for fixation of the tibial component but the duration of their follow-up was less than five years. To our knowledge, no information is available for series of cementless knee replacements followed up for more than seven years.

Our aim was to document periprosthetic osteolysis in 60 knees followed for a minimum of seven years after arthroplasty with an uncemented prosthesis.

PATIENTS AND METHODS

In Seoul, Korea, 55 consecutive patients had primary TKR with an uncemented Porous-Coated Anatomic (PCA) prosthesis. The tibial component had a porous-coated central tibial stem (Howmedica, Rutherford, New Jersey). Eleven patients were lost to follow-up; 44 have been studied. Of these, 28 had unilateral (right 12, left 16) and 16 had bilateral arthroplasties, giving a total of 60 knees. Of the bilateral procedures, seven were one-stage operations and nine two-stage, with an average interval of 14 days between the operations (10 days to 11 months). The mean age of the patients was 56.5 years (17 to 73). There were nine men and 35 women.

The diagnosis was osteoarthritis in 33 knees, rheumatoid arthritis in 17, tuberculous arthritis in 7 and post-traumatic arthritis in 3. No patient had had a previous operation on the involved knee. The indications for operation were disabling pain and/or limited motion. All patellae were resurfaced.

All the operations were carried out by the senior author (Y-HK) and performed under general anaesthesia using a pneumatic tourniquet. An anterior midline approach was used in 59 knees. A medial curved parapatellar incision was used in one of the knees with tuberculous arthritis to excise the scar of a healed draining sinus.

Lateral release was performed if the patellar component subluxed or dislocated laterally when the knee was tested.
through the range of movement. It was performed from within the joint, preserving the superolateral genicular artery. Vastus medialis obliquus muscle was not advanced.

We used 40 small, 17 medium and 3 large femoral components and 32 small, 25 medium, and 3 large tibial components. We implanted 42 small and 18 medium patellar components. The thickness of the polyethylene on the tibial components ranged from 7 to 13 mm (average 8.2).

The average follow-up was 86.6 months (84 to 96). We used the Hospital for Special Surgery (HSS) knee form (Insall et al 1976) preoperatively and at 3 months, 6 months, and yearly thereafter. Function before and after the operation was recorded as limp, distance walked, use of support, stair-climbing, and ability to get in and out of a chair.

The alignment and stability of the knee were assessed by clinical examination in extension and at 30° flexion. Standing and supine anteroposterior, lateral and skyline radiographs of each knee were obtained, taking care that the standardised beam distance and knee position were maintained constant. At the follow-up examinations, fluoroscopy was used to ensure that the radiographs gave optimum visualisation of the bone-implant interfaces. Detailed analysis of the radiographs assessed alignment of the knee and of the components, coverage of the upper tibial surface, radiodense or radiolucent lines in each of the 20 zones (Kim 1990), evidence of periprosthetic osteolysis, and loose beads.

The thickness of the polyethylene liner of the tibial component was measured on the anteroposterior radiographs made three months after the operation and at later examinations for evidence of wear. The measurements were made between the femoral component and the tibial plate, at the medial edge of the metal marker in the tibial component for medial compartment wear and its lateral margin for lateral compartment wear. They were corrected for magnification using the known width of the tibial plate.

Loosening of the component was diagnosed if there was a change of position or complete periprosthetic radiolucency wider than 2 mm. Periprosthetic osteolysis was defined as any localised lucency or bone resorption, absent on the postoperative films taken immediately after the preceding TKR which developed around the components. The location of osteolysis was recorded in each of 20 zones (Kim 1990).

Scintigraphy was used to supplement plain radiography, using an intravenous injection of 99mTc phosphate at the final follow-up examination. Anterior, posterior and lateral views were obtained four hours after the injection.

In nine patients (ten knees), at the time of revision surgery, wear of the polyethylene articulating surfaces of the tibial and patellar components was evaluated by the HSS system (Hood, Wright and Burstein 1983). Wear of the tibial components was correlated with that on the radiographs.

Histological examination by polarised light and electron microscopy was performed in the ten cases revised, and in 40 on tissue obtained by needle biopsy from osteolytic areas in the tibia.

RESULTS
At the final follow-up no femoral or tibial component was loose. Thirty patellar components (50%) were loose (Fig. 1) of which six (10%) had been revised.

Osteolysis was present in the tibia on the anteroposterior view in 54 knees (90%) and on the lateral view in 45 (75%). There was osteolysis of the patella visible on the skyline view (Fig. 2) and on the lateral view around 24 of the 30 well-fixed patellar prostheses (80%), and around all the loose patellar prostheses. There was no osteolysis around any femoral component.

On the anteroposterior radiographs, there was osteolysis in 54 knees (90%) in the middle of the tibial plateau with an average width of 20 mm (19 to 22), in 30 knees (50%)
in the medial tibial plateau with an average width of 6 mm (5 to 9), and in 51 knees (85%) in the lateral tibial plateau with an average width of 8.3 mm (6 to 11). On the lateral radiographs osteolysis was present in 21 knees (35%) in the anterior tibial plateau with an average width of 8.5 mm (6 to 11) and in 22 (37%) in the posterior tibial plateau with an average size of 8 mm (6 to 10). The average extent of osteolysis around the patellar prosthesis was 8 mm (6 to 10) in the medial facet, 8.5 mm (5 to 12) in the lateral facet, 7.5 mm (1.5 to 15) in the superior pole and 5.7 mm (5 to 6) in the inferior pole (Fig. 3). After five years osteolysis was found in all knees; the average time to the radiographic diagnosis of osteolysis was 65 months (60 to 70).

In the patients who had tibial osteolysis the distribution according to gender was similar to that of the study population as a whole (chi-squared test, p = 0.175).

The age of the patients who had osteolysis ranged from 56 to 69 years (average 60) and of those with no osteolysis from 17 to 73 years (average 54.5) (unpaired two-tailed Student’s t-test, p = 0.78). The weight of the patients with osteolysis ranged from 35 to 81 kg (average 54.7) and of those with no osteolysis from 42 to 84 kg (average 56.8) (unpaired two-tailed Student’s t-test, p = 0.78).

The average range of motion in all the knees was 112° (75 to 140). In knees with an intact patellar prosthesis it was 113° (75 to 140) and in those with a loose patellar component 111° (100 to 130). The average range of motion of the knees with osteolysis was 114° (78 to 137) and of those with no osteolysis 110° (105 to 125).

The average knee score at the final follow-up examination was 81 points (54 to 100). In those with osteolysis it was 82 (54 to 100) and in those without, 70 (60 to 100) (unpaired two-tailed Student’s t-test, p = 0.76). The average score of the 30 knees with intact patellar prostheses was 92 points (80 to 100) and of the 30 knees with loose patellar components 71 (54 to 75).

Eight knees with radiological evidence of osteolysis had tibiofemoral malalignment outside the accepted limits of 6 ± 3° of valgus angulation. Five were in 3° varus and three in 12° valgus. The frequency of malalignment was similar in the patients with and without osteolysis (chi-squared test, p = 0.36). There was no relationship between malalignment and the site of the osteolysis.

None of the demographic parameters was found to be statistically different in the patients with osteolysis compared with those without.

There were four (7%) knees with full-thickness wear of the polyethylene liner which required revision. Fifty knees (83%) had wear of the liner averaging 2.5 mm (2 to 3.2) in the medial compartment and 1.7 mm (1 to 2) in the lateral compartment. In the nine patients (ten knees) revised the radiological measurement of tibial polyethylene wear did not accurately match the degree of wear actually found at the time of revision. All these ten polyethylene liners, however, were severely damaged.

All the tibial components covered the entire upper tibia. A new subchondral bone plate had reappeared in the upper tibia in all cases after about one year, and no bone resorption attributable to stress-shielding of the tibial plateau has been seen.

Six tibial components showed three to ten loose beads within three months, but there were no additional loose beads at the final follow-up examination. One femoral component had three loose beads within three months of
the operation, but their number did not increase. The 30 loose patellar components all showed some loose beads (1 to 8) after three months.

Radionuclide uptake in the bone around the central stem of the tibial component was normal in all knees. Increased uptake was noticed in all the tibial plateaux whether there was osteolysis or not. Increased uptake was also demonstrated around all the patellar components whether they were loose or not or had osteolysis or not. There was a moderately increased uptake in the distal femur in all cases (Fig. 4).

Examination of the ten revised knees revealed that the synovium was discoloured and showed multiple villous projections. Subsynovial infiltrates consisted of histiocytes and giant cells. Polyethylene debris was seen in those knees in which there was failure of the patellar component. Polyethylene and metallic debris was seen in those knees in which there was complete wear of the polyethylene of the tibial component.

Histological examination of the 40 specimens of osteolytic tissue obtained by needle biopsy from the tibia revealed histiocytes and giant cells with polyethylene particles within their cytoplasm (Fig. 5). Polarised light microscopy and electron microscopy confirmed many intracellular particles of polyethylene, ranging in size from less than 1 μm to 3 μm. Larger particles were seen engulfed by giant cells.

DISCUSSION

In our series there was a very high incidence of osteolysis in the tibia and the patella but some of the factors believed to be associated with this, such as gender, age, weight of the patient, range of motion of the knee, knee score, and tibiofemoral malalignment, did not correlate with the osteolytic changes.

It has been reported that the incidence of osteolysis after total hip replacement increases with patient weight, male gender and young age (Huddleston 1988; Maloney et al

Fig. 4
Scintigram of the knees of a 56-year-old woman with rheumatoid arthritis 96 months after bilateral arthroplasty. On the left there is normal uptake in the bone around the tibial implant and in the patella. On the right there is increased uptake around the patella, although the patellar component is intact.

Fig. 5a
Histological findings in a specimen obtained by needle biopsy from an osteolytic lesion of the tibia. Figure 5a – Polarised light photomicrograph shows birefringent intracellular polyethylene particles, less than 1 μm in size (haematoxylin and eosin × 200). Figure 5b – Granular electron-dense particles in a phagolysosome. The material has the properties of polyethylene (× 1200).
1990a,b) but Peters et al. (1992) found no such correlations and our series does not suggest that any of these variables is a risk factor for osteolysis in the knee.

The range of motion and the knee score are measurements of the level of the patient’s activity and may correlate with the rate of wear but in our series these factors were not statistically different in the patients who had osteolysis and in those who did not. Nor did we find that malalignment of the implant was any more frequent in patients with osteolysis than in those without.

Maloney et al. (1990a,b) found that osteolysis was present in only one of their patients less than two years after hip replacement. In all the others it was found only after three years, and they suggested that it might become more prevalent as the follow-up became longer. Peters et al. (1992) found a 16% incidence of osteolysis of the tibia in knee replacements and in their series the average time to the radiological diagnosis of osteolysis was 35 months (14 to 59). In our patients, osteolysis was present in every case followed for five years. The high incidence of osteolysis in our series is probably the result of the longer follow-up.

Osteolysis is usually attributed to tissue reaction to foreign particulate debris and in our series, 90% of the plastic liners exhibited wear as measured on the radiographs. Wear was confirmed in the ten revised knees and histological examination revealed polyethylene particles in all the osteolytic regions. These findings confirm that polyethylene particulate debris is the most likely cause.

Features of the design of an implant such as the conformity of its articulating surfaces influence the rate of polyethylene wear. Unlike hip replacements, the tibial and femoral components of most artificial knees have small contact areas which lead to high contact stresses (Bartel, Wright and Edwards 1983; Bartel, Bicknell and Wright 1986). There is also concern over the quality of implanted polyethylene (Black et al. 1990; Collier et al. 1990).

In the newer designs of cementless knee replacement, the tibial implant is metal-backed necessitating the use of thinner polyethylene for any given level of bone resection. Because preservation of bone stock is advocated, the thinnest insert available has often been the most popular although Bartel et al. (1986) and others have shown that the combination of high stress and thin polyethylene can cause a devastating rate of wear (Engh 1988; Lombardi et al. 1988; Collier et al. 1990; Engh, Dwyer and Hanes 1992). The design of the implant, lack of conformity of its articulating surfaces, and modularity may all have increased the rate of generation of particulate debris in our patients.

Jacobs et al. (1991) reported that radiographically secure hip implants were associated with a higher incidence of osteolysis than were those with loose components: Jasty et al. (1986) reported that loose stems were associated with increased osteolysis. Peters et al. (1992) demonstrated a similar incidence of osteolysis in stable and loose cementless knee prostheses. In our study tibial osteolysis was always associated with a stable tibial prosthesis but patellar osteolysis was present in knees with stable and loose prostheses.

It is not understood why osteolysis occurs predominantly in the tibia and the patella. We speculate that there are three factors that may be involved. First, the posteroentral slot of the tibial implant provides an avenue for the migration of polyethylene debris into the bone. Secondly, gravity tends to localize the particulate polyethylene on the tibial side. Revell et al. (1978) and Peters et al. (1992) also noted this tibial accumulation in ICLH knee prostheses. Thirdly, unlike the tibia and the patella, the femoral implant-bone interface is radio-graphically obscured and only extensive resorption of bone can be seen there.

Restoration of the subchondral bone plate, which apparently resulted from joining of the cut trabeculae at the plane of the bone section, suggests that stress-shielding of the tibial plateau had not occurred.

There is at present no agreement on how to treat osteolysis around hip and knee prostheses. Huddleston (1988) recommended revision of a cemented hip implant as soon as osteolysis was diagnosed. Maloney et al. (1990a,b) recommended that patients with osteolysis but no loosening should be followed carefully and only revised if the osteolysis progressed rapidly. In most of their patients, the osteolysis progressed slowly. In our patients, osteolysis progressed more rapidly after five years suggesting that patients should be most carefully observed after this time.

The incidence of tibial osteolysis in our series is alarmingly higher than that reported by others after cemented or cementless total knee or hip arthroplasty (Harris, Barrack and Mulroy 1992). Fixation without cement appears not to seal the interface between bone and prosthesis, allowing migration into the gap of polyethylene particulate debris which causes osteolysis.

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REFERENCES


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