Hydroxyapatite-coated total knee replacement

CLINICAL EXPERIENCE AT 10 TO 15 YEARS

This study describes 146 primary total knee replacements, either fully or partially coated with hydroxyapatite of which 74 knees in 68 patients were available for clinical and radiological assessment at a mean of 11.2 years (10 to 15). The global failure rate was 1.37% and survival rate with mechanical failure as the end-point was 98.14%. Radiological assessment indicated intimate contact between bone and the hydroxyapatite coating. Over time the hydroxyapatite coating appears to encourage filling of interface gaps remaining after surgery. Our results compare favourably with those of series describing cemented or porous-coated knee replacements, and suggest that fixation with hydroxyapatite is a reliable option in primary total knee replacement.

The use of hydroxyapatite (HA) in total hip replacement has shown good long-term clinical results.1 The role of HA in total knee replacement (TKR) is less clear. More than ten years ago Verhaar2 and Epinette3 showed promising early results with HA-coated knees. More recently, Nilsson et al4 published a prospective randomised comparison of HA-coated and cemented tibial components with a five-year follow-up using roentgenstereophotogrammetric analysis (RSA). They concluded that the HA group potentially offered longer lasting stability than the cemented implants. Other studies comparing the outcomes of cemented versus un cemented knees have reported both favourable and poor results5-8 but overall the performance of HA-coated components has been at least equivalent to that of cemented implants.7,9,10

This study is a long-term review of two designs of prosthesis, the HA Omnifit Knee Prosthesis-Series 3000 (Stryker Orthopaedics, Mahwah, New Jersey), which was partially HA-coated, and the Series 7000 which was fully coated (Stryker).

Patients and Methods

Between June 1990 and December 1995, 197 HA-coated primary posterior cruciate-retaining knee replacements were implanted consecutively. Of these, 51 knees were classified as ‘hybrids’ because they received a Series 3000 femoral component and a Series 7000 tibial component, and were excluded from this study. The remaining 146 knees were divided into two homogenous groups, with 50 (group 1) receiving a partially HA-coated implant and 96 (group 2) a fully HA-coated implant. During this period the use of HA implants was restricted to knees without deficiency of the posterior cruciate ligament, because posterior cruciate-substituting designs were not available.

These 146 knees were implanted in 132 patients, with 14 cases being bilateral. There were 21 men and 111 women with a mean age of 69.87 years (43 to 89).

Only 11 patients (8.3%) had a normal weight (body mass index (BMI) < 25). Obesity was mild (BMI 25 to 29.9) in 55 patients (41.7%), medium (BMI 30 to 39.9) in 58 patients (43.9%) and severe (BMI ≥ 40) in the remaining 8 patients (6.1%). The mean BMI was 31.02 (17.3 to 49.8). At the latest follow-up 40 knees (27.4%) were in group A of the Charnley classification,11 22 (15.1%) in group B with the other knee affected and 84 (57.5%) in group C with significant other disability. Osteoarthritis was the main diagnosis in 128 knees (87.7%), rheumatoid arthritis in 15 (10.3%) and necrosis in 3 (2.0%). A single surgeon (JAE) used an identical surgical technique throughout.

The knees were manufactured from cobalt chromium and both femoral and tibial components were plasma sprayed with HA upon a waffle-pattern grit-blasted surface. Between 1990 and 1992, the partially HA-coated Series 3000 Omnifit femoral component was implanted into 50 knees (group 1). These were...
coated on the distal aspects of the femur in radiological zones 2 and 3 as defined by the International Knee Society Score while zones 1 (anterior) and 4 (posterior) were uncoated. The tibial component had HA coating on the tray only, while the keel was uncoated. Between 1993 and 1995, 96 HA-coated, Series 7000 HA Omnifit implants with a fully-coated femoral surface and tibial component, with a delta keel design were implanted (group 2). All knees used fixed-bearing tibial components. Titanium non-HA-coated screws were used routinely (two screws in the Series 3000 and four screws in the Series 7000) in order to enhance fixation of the tray. In group 1 a cemented polyethylene non-metal-backed button was used in 44 knees (88%), with simple reshaping to fit the trochlear groove in the remaining six knees (12%). In group 2, replacement of the patellar with a PE button was carried out in 21 knees (21.9%) with reshaping in the remaining 75 (78.1%). Lateral retinacular release was undertaken as a routine procedure.

The mean follow-up was 11.2 years (10 to 15). At the time of review 52 patients (59 knees, 40.4%) had died before the 10-year visit, one (one knee) was lost to follow-up. Partial weight-bearing was permitted immediately after operation and all patients had early mobilisation, physiotherapy, and continuous passive motion. Full weight-bearing was achieved by between four and eight weeks.

Clinical and radiological follow-up was undertaken at six weeks, at four to six months and yearly thereafter. The data were entered into a database (OrthoWave, Aria Software, Bruay Labuissiere, France), which allowed easy access to clinical and statistical information. Clinical assessment was by the operating surgeon and two uninvolved persons using the International Knee Society score, which includes both the 100-point knee and the 100-point function score. The range of movement and stability were recorded clinically. Survivorship was calculated according to the Kaplan-Meier method. Radiographs were obtained post-operatively at six weeks, three months, and yearly thereafter and included anteroposterior (AP) and mediolateral, weight-bearing, skyline and standing views. The radiological zones were assessed using the International Knee Society criteria. The bone component interface was examined carefully for the presence of radiolucent lines or radiolucenties. Particular attention was given to obtaining tangential beams in lateral films of femoral components and AP and lateral views of tibial components, in order to assess the specific radiological patterns of cementless implants.

Results

Is this study of 146 knees, we observed good long-term fixation and few radiolucent lines at the bone-implant interface (Fig. 1). Although only 74 knees of the 146 knees were available for clinical assessment, each patient who died was followed until death. Their records up until death demonstrated no difference between their results and those of the survivors. Complications were recorded for all 146 knees in the series.

There were no peri-operative adverse events. Post-operative complications included deep venous thrombosis in 12 knees (8.2%; 12 patients) with pulmonary emboli in two (1.3%; two patients), delayed wound healing in ten (6.8%; 10 patients), a deep haematoma in three (2.1%; three patients) and a superficial wound infection in two (1.3%; two patients). No significant difference was recorded between the two groups with respect to these various complications. We also noted no difference in the outcomes for elderly patients when compared with those for younger patients (Fig. 2).

Six knees (4.1%) in five patients developed complications which required re-operation. In group 2 five knees in four patients required a second procedure to introduce a patellar button at a mean of 23.6 months (5 to 66) for pain experienced after reshaping of the patella at the primary procedure. A further patient, in group 2 required synovectomy and debridement for a stiff knee, with a good result at ten years.

Of both groups combined, seven knees (4.8%) were revised in five patients, two knees from group 1 and five from group 2. Two were revised following supracondylar fracture, three for infection and two following mechanical failure. Infection occurred at one, nine and 12 years after operation secondary to distal infected skin lesions. Mechanical failure occurred in one patient in group 1 five years after operation with loosening and severe chondrocalcinosis. In the second case of mechanical failure (group 2), a flare-up of rheumatoid disease at seven years led to loss of bone density and pain on the femoral side of the articulation while the tibial side remained intact. In both cases successful revision was achieved using cemented prostheses.
Of the 50 knees in group 1, 34 patients (35 knees) had died by the latest follow-up. Four of these (four patients) had been assessed at over 10 years follow-up before they died. Clinical and radiological assessments were done on 19 knees (15 living, 4 dead) in this group after the tenth year of follow-up with a mean follow-up of 13.05 years (10 to 15). In three knees in three of the 19 patients, neurological disease or poor general health prevented consistent functional assessment although their knees appeared to be functioning well with no significant pain or stiffness. In the remaining 16 knees eligible for clinical assessment in group 1, 15 (94%) had no pain and one had only mild pain on walking. The mean flexion for these patients was 112.8° (90° to 130°). The mean International Knee Society score was 23.2 (0 to 42) before operation and 96.2 (88 to 100) at final follow-up. The mean function score was 25.3 (0 to 70) before operation and 86.7 (60 to 100) at final follow-up.

Radiological examination in the 19 eligible knees in group 1 showed that the mechanical axis lay between 2° of varus and 3° of valgus in 72.3% (13 knees of 18; one was not interpretable because of abnormal rotation of the leg). In these 19 partially HA-coated femoral components, the uncoated zones 1 and 4 demonstrated some lines or lucencies in the femoral lateral view, four knees (21%) in zone 1 and five knees (26%) in zone 4. In the femoral lateral view coated zones 2 and 3 radiolucent lines were present in only (two knees) (10%) in zone 2 and (one knee) (5%) in zone 3, respectively. No radiolucent lines were seen around the pegs in any case, suggesting that all of these implants were stable. The tibial components also had some radiolucent lines on the smooth, uncoated areas of the cruciate keels. Two cases of lysis in zones 1 and 4 were seen within the first six months but did not show further extension or modification.

Fig. 2

The medial aspect of a hydroxyapatite-coated Omnifit 7000 tibial plateau. Computer-generated (Imagika software, Greystone, France) three-dimensional serial views from standard radiographs were taken immediately post-operatively, at 3 months, 2 years, and 6 years. There is a) no gap post-operatively, while b) a severe gap is shown at 3 months, c) filled in spontaneously through a remodeling process at 2 years, di leading to an intimate contact between bone and metal at 6 years, and demonstrating an excellent transmission of load. The insert pictures show the post-operative follow-up periods superimposed on the actual radiographs from which the three-dimensional images were calculated.
None of the femoral or tibial components which had lines was clinically loose.

Of the 96 knees in group 2, 27 patients (28 knees) had died before the 10-year visit and one was lost to follow-up. In this group, 62 knees (56 patients) had been clinically and radiologically assessed after the tenth year, either at their most recent follow-up or before their death. However, due to severe low back pain in one patient (one knee) and poor general health in three, consistent functional assessment could not be performed, leaving 58 knees in 52 patients for clinical assessment. The mean age at the most recent review was 79.18 years (61 to 97). The mean follow-up was for 10.6 years (10 to 13); 49 patients (54 knees) had osteoarthritis and three (four knees) had rheumatoid disease. In these latter three patients, the knee implants appeared to be functioning well with no significant pain or stiffness and no difference with arthritic knees. Of the 58 knees, 94.8% (55 knees) had no pain, and the remaining three knees, mild discomfort when walking. None was unstable. The mean flexion was 115° (60° to 160°). The mean knee score\(^1\) was 22.5 points (0 to 42) before operation and 95 (80 to 100) at final follow-up. The mean function score\(^2\) was 39.4 points (0 to 80) before and 88.4 points (60 to 100) at final follow-up.

Radiological assessment of the 62 knees showed better bone apposition for both the fully-coated femoral and tibial components compared with the partially coated implants in group 1. Femoral lines or lucencies were seen in only one knee in group 2 and no osteolysis was observed. No lucencies were seen around the pegs. On the tibial side, radiolucent lines were seen at the tip of the fully coated delta keel in two knees on the AP view and in one knee (2%) at zones 1 and 4 (AP view) and zone 1 (lateral) of the tibial tray. No osteolysis was seen. None of these knees was clinically loose. The post-operative mechanical axis showed a mean value of 1° varus (5° valgus to 8° varus) with 41 knees (66%) lying between 2° varus and 3° valgus. Seventeen knees (27%) were assessed either at 3° varus or between 4° and 5° valgus. The four remaining knees (7%) with varus of 4° to 8° did not demonstrate instability or radiological loosening.

In 16 (19.75%) of the 81 knees in both groups which were available for radiological assessment, bone completely filled in areas under the tibial tray that had, at two to three months post-operatively, exhibited lytic patterns approximately 2 mm to 3 mm thick caused by a fibrous tissue layer. All 16 knees showed excellent bone-implant contact on radiographs taken immediately post-operatively. It took between six months and three years for the new bone to fill the lytic areas completely.

The cumulative survival rate, according to Kaplan-Meier analysis,\(^3\) was calculated for the 50 knees in group 1, the 96 knees in group 2 and then for the 146 knees overall. Considering retrieval for any cause as the end-point, the cumulative survival rate at 11 years with more than 30 patients remaining at risk at the end was 94.1% (SD 0.087) and 94.4% (SD 0.071), respectively for groups 1 and 2, and that for the entire series at 12 years was 90.1% (SD 0.109).

Taking mechanical failure as the end-point, the optimal cumulative survival rate was 100% in group 1, and 97.4% (SD 0.037) in group 2. The survival rate for the entire study, with retrieval for mechanical failure at 12 years as the end-point, was 98.1% (SD 0.026).

**Discussion**

This study indicates that TKRs do equally well whether partially- or fully-coated with HA. The cumulative survival rate of 98.1% at 12 years using mechanical failure from loosening, wear or osteolysis as an end-point compares favourably with previous studies of cemented or porous-coated knees replacements.\(^5,7,15,16\)

The principal limitation of our study is the difficulty of assessing long-term clinical results in older patients. The low rate of survival of patients at ten years reflects the mean age at operation (almost 70 years), and the frequent comorbidity which makes functional results in the elderly difficult to assess. Although only 16 knees of 50 from group 1 and 58 of 96 from group 2 were available for clinical assessment, each of the patients who died was followed up until death, and their records until then demonstrated no difference between their results and those of the survivors. Complications were also recorded for the entire 146 TKRs in the series. Only one patient (0.68%) was lost to follow-up. Dixon et al\(^17\) compared their results at five years in patients older than 75 years who underwent an HA-coated TKR with those under this age with the same procedure and found that the outcome for the elderly was just as good as for the younger patients. We also found this to be the case.

Our main aim was to study the behaviour of the HA-bone interface, so radiological analysis was critical, both for global findings and differences between the partial and full coatings. Radiological assessment showed very good interfaces between bone and the HA implant with intimate bony apposition in the HA-coated zones. Few lytic lines were observed on HA-coated surfaces, and no extensive lysis was evident, especially beneath the tibial plateau and around the keel or screws. McCaskie et al\(^7\) and Nilsson et al\(^15\) also reported fewer lytic lines in HA compared with cemented components. More lytic lines have been reported with non HA-coated uncemented knee components when compared with cemented components.\(^3\) We believe the HA coating provides the early tibial fixation needed for long-term success and the findings of Nilsson et al\(^15\) support this.

Reactive lines are thin, dense lines located approximately 1 mm away from the implant surface with identical bone density on both sides of the line. There is no radiological void and no fibrous tissue along the metal-bone interface, which is seen with radiolucent lines.

For the femoral components, reactive lines and lucencies were seen more frequently (21% and 26%, respectively) on the smooth non-coated areas (zones 1 and 4) of the par-
tially coated implants (group 1), compared with the same zones in fully HA-coated components (2%) in group 2. Similarly, with the tibial components, lines occurred more frequently (26%) in the smooth, uncoated areas of the cruciate keel design, compared with the HA-coated delta keel design where they were scarcely seen (less than 6% of knees). Bone bonding afforded by the proximal coating was assessed as excellent, be it isolated or in combination with distal coating. While the enhanced stability provided by the delta keel of the Omnifit 7000 series may have also contributed substantially to overall stability, these radiological findings clearly indicate the virtue of full HA coating of both femoral and tibial components.

We were impressed by the ability of bone to fill in areas where lytic patterns from a fibrous tissue layer under the tibial tray were observed early after operation. This occurred in 20% of our cases and was followed by progressive new bone filling in the gap completely, usually two to three years later. We had no clear explanation for this lytic reaction, since the post-operative films showed very intimate bone-implant contact upon tangential beams. Because of the short time interval, it is doubtful if the lysis resulted from polyethylene wear or any other debris-related cause. However, the lines beneath the tibial plateau and lytic zones might be explained by a reaction to kinases caused by the joint fluid, and research by Schmalzried, Jasty and Harris,18 Schmalzried et al19 and Whiteside20 on the lytic properties of joint fluid appears to support this concept. One explanation can be found in the work of Soballe et al,21 which demonstrated that the fibrous tissue beneath an HA interface contains collagen fibres which are usually perpendicular to the metallic surface and can guide secondary bony ongrowth. Conversely, the random distribution of collagen fibres in the presence of a porous coating prevents bone from filling in the gap. This finding is an advantage of HA over porous coatings and cemented interfaces.

We observed good long-term fixation and few radiolucent lines at the bone-implant interface, which confirms our short-term findings reported in 1995.22 This corresponds to a recent long-term study by Oliver et al23 which describes favourable long-term results for HA knee replacements at a mean follow-up of 11 years. Based on these observations, we suggest that HA-coated implants for TKR be fully coated over the entire fixation interface.

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References