A hydroxyapatite-coated Insall-Burstein II total knee replacement

11-YEAR RESULTS

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We report the clinical and radiographic outcome of a consecutive series of 138 hydroxyapatite-coated total knee replacements with a mean follow-up of 11 years (10 to 13). The patients were entered into a prospective study and all living patients (76 knees) were evaluated. The Hospital for Special Surgery knee score was obtained for comparison with the pre-operative situation. No patient was lost to follow-up. Radiographic assessment revealed no loosening. Seven prostheses have been revised, giving a cumulative survival rate of 93% at 13 years. We believe this to be the longest follow-up report available for an hydroxyapatite-coated knee replacement and the first for this design of Insall-Burstein II knee.

Hydroxyapatite (HA) coatings have been used in total hip arthroplasty since 1985, and in wider orthopaedic surgery since 1981. Outstanding results have been reported. Encouraged by our own experience with this technology, we modified the cemented Insall-Burstein II knee replacement (Cremascoli Fry Ortho Ltd, Surrey, UK) for HA coating.1-3 This required a new chrome cobalt femoral design which eliminated the cement-compressing lip on the undersurface of the component although the articulating surface remained unchanged. Full coating of both tibial and femoral surfaces was performed with an 80 µm vacuum plasma-spray technique. Holes in the tibial base plate allowed the option of screw fixation if required. We present the ten- to 13-year results of this design of total knee replacement (TKR) and believe this to be the first report of the Insall-Burstein knee replacement using this technology and the longest follow-up of any HA-coated TKR.

Patients and Methods

Between March 1990 and August 1993, 138 consecutive primary TKRs were performed in 106 patients using a fully HA-coated Insall-Burstein II prosthesis (Cremascoli Fry). There were 74 women and 32 men. All patients were indexed and documented prospectively. The indications for surgery were osteoarthritis (130 knees; 1 case was post-traumatic), rheumatoid arthritis (five knees), pigmented villonodular synovitis (two knees) and previous trauma (one knee). The mean age of the patients at surgery was 72.5 years (32 to 92). Bilateral procedures were performed simultaneously in 28 patients and staged in four. Selection was on clinical grounds, as is standard practice in our unit for TKR. There were no exclusions.

Surgery, through a medial parapatellar approach, was carried out by or under the supervision of the senior authors (BLH and JANS). The original design of femoral cutting block was modified in order to improve the fit of the femoral component and cemented patellar resurfacing was only undertaken when the wear of the patellar was considered to be exceptional.

In three knees, the tibial component was cemented and in four knees cement augmentation of the anterior femur was used. These seven knees were excluded from the series.

Antibiotic prophylaxis was always used and patients were treated in a compression bandage for two days after surgery. Full weight-bearing was allowed immediately with patients being discharged at a mean of 6.5 days after their TKR.

All knees were assessed pre-operatively using the Hospital for Special Surgery (HSS) scoring system.4 Post-operative review was at six, 12, 24, and 52 weeks, and annually thereafter in a dedicated research clinic. Two authors (MCO and ODK-B) undertook this review. All knees were rescoped and standard weight-bearing anteroposterior, lateral and skyline radiographs were obtained and assessed using the American Knee Society guidelines.5
Survival analysis was calculated using a life table.\textsuperscript{6,7} Failures were withdrawn in the year in which they failed. Failure rates were calculated with revision, or pain and knee score as end-points.

**Results**

Our follow-up was 100\% and included those patients who had moved out of the region. We can thus be confident of our survival analysis.\textsuperscript{8} A total of 57 patients (76 knees) survived; 51 (68 knees) of whom had a current radiographic examination available. Six elderly patients were assessed in their residences and had radiographs available from within the previous three years. We included these in our radiographic assessment. One demented patient was unable to complete the assessment form. Of the 49 patients who had died, 34 had undergone a full review during the year of their death. The exceptions were one patient who had been reviewed four years earlier, seven patients three years earlier and a further seven patients two years earlier. None of the deceased patients’ records indicated problems with their knee replacement. These patients were withdrawn from analysis in the year of their death.

The HSS knee score\textsuperscript{4} combines symptoms with functional outcome. As patients become older, general debility and other conditions can cloud the knee score. A score of 85 to 100 was rated excellent, 70 to 84 good, 60 to 69 fair and less than 60 points poor. The mean pre-operative score was 55 points (23 to 77), but at the latest review the mean post-operative score was 83 (0 to 95).

Six surviving knees (7.9\%) scored below 70. Of these, two were because of unrelated functional impairment, one had technically failed because of tibial subsidence, one had recurrence of pigmented villonodular synovitis, one had a previous synovectomy, and one showed no technical reason but had a pre-operative HHS of 43. The poor specificity of the HSS scoring system is recognised.\textsuperscript{9}

Persistent anterior knee pain can plague the successful outcome of a TKR. It has been extensively debated whether or not to resurface the patella.\textsuperscript{10-13} In our study, by the latest review, 30 patellae had been primarily resurfaced, with a mean HSS score of 84.4 ± 18.4 (0 to 95). The 42 knees with their original, unresurfaced patellae scored a mean of 79.9 ± 19.5 (0 to 93). There was no significant statistical difference between the two groups (p > 0.05, Mann-Whitney U test). Two patients, with bilateral TKRs, required subsequent patellar resurfacing seven years post-operatively. This improved one patient’s symptoms but only marginally assisted the other.

After surgery, 28 TKRs developed a complication (Table I). Seven underwent a revision procedure between five months and nine years after surgery (Table II). One patient developed aseptic loosening of the patellar component two years post-operatively and underwent revision of this. This patient has been included in Table I but not in Table II.
Survival analysis was performed by constructing a life table (Table III) and using the statistical software package, SPSS (SPSS Inc, Chicago, Illinois) in order to generate a Kaplan-Meier survival curve (Fig. 1).

**Radiographic assessment.** The incidence of radiolucent lines in our study was very low. No radiographs had a Knee Society score greater than 4 around the tibial component. It has been previously reported that the detection of subsidence and radiolucent lines on plain radiographs is less accurate than when roentgen stereophotogrammetric analysis and fluoroscopic guidance are used, especially in relation to the femoral component. However, the tibial component, especially the stem, can be assessed more consistently with plain radiography. Our results show evidence of bone apposition around the stem with 72% of knees demonstrating spot welding or buttress formation around the distal stem (Fig. 2). There were minor lucencies (≤ 1 mm) around two tibial components in zones 5 to 7 and around three femoral components in zones 1, 2 and 6. Overall this demonstrated solid fixation. Standard radiographs have been used in several published series and justify their use in our study as a method of comparison.

**Discussion**

HA-coating has been shown to enhance bone growth across a gap in both stable and unstable conditions, and also to convert a movement-induced fibrous membrane into a bony anchorage. A meta-analysis of the available literature to compare matching implants with and without HA-coatings provides overwhelming support for the value of the material. Very encouraging long-term results have been published for HA-coated total hip replacements. To our knowledge, our study is the first to document a ten- to 13-year follow-up of HA-coated Insall-Burstein TKRs. Our results are, at the very least, comparable with those for a cemented design.

Li et al reported a cumulative survival rate for the cemented Insall-Burstein TKR of 92% at 11 years while Insall et al reported an even better result, of 98% at 11 years. A study of cementless press-fit knee prostheses had disappointing results, with 72% survival at ten years.

Pain is the principle indication for joint replacement and we contend that this should also be the criterion for failure. Three surviving knees (3.9%) suffered moderate to severe pain although 52 (68%) had no pain at their last review. Published results for a series of cemented Insall-Burstein II knee replacements reported that 17% of knees had moderate to severe pain at eight years follow-up. Another series reported that 79% of patients had no pain, 13% mild pain, 7% moderate pain and one patient had severe pain that was unrelated to the knee prosthesis at the ten-year follow-up. However, pain is a subjective phenomenon, prone to patient and doctor bias, and may not always be related to the prosthesis. In our series for example, one case with severe pain was in a terminally ill patient with metastatic disease. We found no evidence of differing pain outcomes between the HA-coated and cemented versions of this implant.

The design shape that was used in this series was not originally intended for biological bonding. Alterations would improve the initial stability. The Insall-Burstein II knee was designed for cemented fixation and included features specific to that application. There is clearly scope for potential improvement. Our early cases used a femoral cutting jig which did not achieve a sound interference fit on the femur and we are surprised that more of these early cases did not show femoral loosening. Positioning the tibial tray in line with the patellar tendon is necessary for patellofemoral tracking, but frequently leaves the implant resting on cortical bone laterally and cancellous bone medially. This may result in subsidence.

Roentgen stereophotogrammetric analysis has been used to investigate the early stability of HA-coated prostheses in comparison with cementless prostheses and has shown that HA-coated components migrate less than porous-coated devices. HA-coated components do show increased early movement but, subsequently less movement between one and two years after surgery when compared with cemented prostheses. Lack of movement at this stage is a good predictor of long-term results.

In our series the age of the patient was not used as an exclusion criterion. We believe that our two early failures
with tibial subsidence were related to poor bone quality. These patients were aged 79 and 80 years, one of whom had rheumatoid arthritis. It has been shown that low bone mineral density is related to increased subsidence in a cementless prosthesis and would be a relative contraindication. Poor bone quality requires careful pre-operative planning and, if a long-stem tibial component is used, subsidence may possibly be avoided.

One revision was for infection in a 62-year-old man with osteoarthritis. We explored his knee ten months post-operatively for unexplained pain. The findings were of a thickened synovium but no loosening of the components. Six years later, the knee was explored again for continuing discomfort. At that stage all components were loose and looked infected, although no growth was obtained from the microbiology swabs. The knee was debrided and a revision arthroplasty performed. Post-operatively, there was a superficial wound infection but this was successfully treated with antibiotics and the revision TKR continued to perform well.

Good long-term results for cemented TKRs have already been published. However, our study demonstrates that comparable long-term clinical and radiological results can be achieved when using HA-coating with the Insall-Burstein TKR.

The potential advantages of HA include fixation by bone ingrowth (Fig. 3), preservation of bone stock, speed of surgery and the avoidance of intramedullary pressurisation and possible fat embolisation. We consider that the HA-coating provides enhanced bone fixation when compared with other, uncoated cementless designs. The consistent finding on serial radiographs taken over the follow-up period suggests that these knees will continue to function well. We feel these results could be improved further with better technique, better design and materials and the specific exclusion of patients with poor bone quality. Our good results with a HA-coated TKR will continue to challenge the outcome of cemented designs both now and in the future.

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References


