A hydroxyapatite-coated total knee replacement

PROSPECTIVE ANALYSIS OF 1000 PATIENTS

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We prospectively reviewed 1000 consecutive patients who underwent a cementless, hydroxyapatite-coated, stemless, total knee replacement over a period of nine years. Regular post-operative clinical follow-up was performed using the Knee Society score. The mean pre-operative score was 96, improving to 182 and 180 at five and ten years, respectively. To date, there have been seven (0.5%) cases which required revision, primarily for septic loosening (four cases), with low rates of other post-operative complications. The cumulative survival at ten years with revision as the end-point, was 99.14% (95% confidence interval 92.5 to 99.8). These results support the use of hydroxyapatite in a cementless total knee replacement since it can give reliable fixation with an excellent clinical and functional outcome.

Total knee replacement (TKR) is a successful operation for the treatment of advanced degeneration of the knee. Cemented fixation has been used because of its reliable long-term results and excellent rates of survival.¹⁻³

Cementless prostheses were initially designed to provide greater durability, preserve bone stock and to remove the need for cement. Some early flaws in the design including failure to maintain tibial cortical contact and osteolysis from the use of titanium femoral components have undermined the efficacy of such prostheses. Modified cementless designs have overcome these errors so that their medium- and long-term results have been as good as those for a cemented TKR.⁴⁻¹⁰

In order to improve the quality of cementless fixation bioceramics such as hydroxyapatite (HA) have been introduced. The effectiveness of HA in augmenting uncemented fixation of a TKR has been proven¹¹⁻¹⁵ since it encourages bone growth on to porous-coated prostheses. Our aim was to report prospectively the medium- to long-term outcome of the use of an uncemented, HA-coated TKR in a consecutive series of 1000 patients.

Patients and Methods

Between 1992 and 2001, 1000 patients underwent a primary TKR using a cementless, HA-coated, posterior-cruciate-ligament-retaining, stemless prosthesis. All the operations were performed by the senior author (MJC) using a standard technique. The Knee Society clinical

rating score¹⁶ with a maximum possible score of 200 was used to record the outcome. Clinical examination was carried out by independent examiners throughout the study, either an orthopaedic fellow, orthopaedic registrar or qualified researcher. After establishing a pre-operative score, reviews were performed at three and six months post-operatively, and at one, two, five and ten years thereafter.

At two years, routine fluoroscopic images of the prosthesis-bone interface were taken of the first 200 patients. In order to standardise the protocol, the same two radiographers examined all patients in the same fluoroscopy suite. The position of lucent or sclerotic lines¹⁷ was noted independently by independent examiners who were unconnected with the clinical management of the patients in this study. A line was said to be present if noted by either of them, in order to minimise the false-negative observation rate.

Of the 1000 patients, 479 were men and 521 were women. Their mean age was 68 years (34 to 93). The mean follow-up was 6.6 years (2.5 to 11.3). A total of 1429 procedures had been undertaken (571 unilateral, 858 bilateral). Of the 858 bilateral operations, 658 had been performed simultaneously and 200 as staged procedures. Osteoarthritis was the primary diagnosis in 940 (94%) of the patients. Forty-seven (4.7%) had undergone an earlier high tibial osteotomy on their operated knee.

Prosthesis. We used the Active uncemented TKR system (Australian Surgical Design and

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Table I. Mean knee scores and range of movement (°) at follow-up

	Knee score (maximum 200)	Range of movement (°)
Pre-operative	96	6 to 115
3 mths	169	3 to 107
6 mths	177	2 to 109
1 yr	181	1 to 113
2 yrs	183	1 to 113
5 yrs	182	1 to 113
10 yrs	180	0 to 115

Table II. Treatment of patients with deep infection

Treatment	Number of patients	Mean time after surgery (mths)
Revision	4	18.0
Open synovectomy	3	0.0
Arthroscopic synovectomy	6	26.4
Arthroscopic washout	3	40.3
Antibiotics	1	0.0

Manufacture Pty Ltd, Sydney, Australia). The HA-coated, cobalt-chrome (CoCrMo) femoral component is designed with its beads recessed into the distal end of the prosthesis and encourages bone ongrowth on its anterior, posterior, and chamfer-cut surfaces by growth into these beads. The HA is 70 µm thick (crystallinity 75%, porosity 20%), which facilitates penetration of the porous beads by osteoblasts without blocking the pores.

The titanium alloy (Ti6Al4V) tibial component uses three methods of fixation as follows: 1) four press-fit lugs which provide rotational stability and initial fixation; 2) cortical and cancellous bone screws which prevent lift-off; and 3) HA which accelerates bone ingrowth for long-term biological fixation. Placement of the lugs is related to the size of the tray with an outer diameter of 12.5 mm and an inner diameter of 6.5 mm. Bone screws are coated with titanium nitride, which reduces the potential for the production of wear particles from micromovement. The fixation screws have a standard 4-mm hexagonal head, with sizes ranging from 20 to 50 mm in length. An ultra-high-molecular-weight polyethylene (UHMWPE) fixed-bearing meniscal insert was used in all patients, with a cemented polyethylene patellar component when required.

Statistical analysis. With revision of the prosthesis selected as an end-point a life table was calculated and survival rates presented using Kaplan-Meier survival analysis (SPSS version 10.0, Chicago, Illinois).

Results

Sixty-four patients died after surgery (32 men, 32 women) at a mean age of 78 years (31 to 88) and at a mean of 4.1 years (3 to 12) after operation. The mean pre-operative knee score was 96, which had improved to 182 by review at five years and 180 by ten years, with a mean range of movement of 0° to 115° (Table I).

Table III. Post-operative complications

Complication	Number of patients
Cardiac	
Peri-operative death	2
Arrhythmia	18
Myocardial infarction	5
Thromboembolic	
Pulmonary embolism	25
Asymptomatic DVT*	148
Symptomatic DVT	5
Infection	17
Supracondylar fracture	5

* DVT, deep-vein thrombosis

Table IV. Complications requiring surgery

Complication	Number of knees
Revision	7
Deep infection	16
Subsequent patellar replacement	20
Polyethylene exchange	2
Arthrolysis	7
MUA*	16
ORIF† for supracondylar fracture	2

* MUA, manipulation under anaesthesia

† ORIF, open reduction and internal fixation

Post-operative complications, and those requiring further surgery, are reported in Tables II to IV. Revision of the prosthesis was required in seven cases. The reasons for revision were septic loosening (four), malrotation (one), aseptic loosening (one) and supracondylar fracture (one). Retrieval of the prosthesis from a revision for septic loosening was possible in one case. Histological examination of this showed good osseointegration into the porous surfaces (Fig. 1). There were 17 knees which developed a deep infection (1.2%). Of these, four required revision of the prosthesis while the remainder were retained by means of open synovectomy (three), arthroscopic synovectomy (six), arthroscopic washout (three) and long-term antibiotics (one). Thromboembolic complications, normally diagnosed by routine Doppler ultrasound seven days after surgery, were the most common post-operative problems and affected 178 (17.8%) of patients. Cardiac complications, primarily arrhythmias, affected 2.5% of the total group.

The follow-up rate at five years was 96% (571 of 592 patients) and at ten years 94% (101 of 107 patients). Routine fluoroscopic interface views performed on the initial series of 200 patients revealed minimal evidence of radiolucent lines. There was no evidence of tibial or femoral osteolysis and no patient showed subsidence of the tibial tray. There has only been one case of clinical loosening which has required revision to date, 7.4 years post-operatively in a patient whose TKR was performed after a high tibial osteotomy.

Histological view of a specimen retrieved at revision (Stevenels Blue). Beads are 0.4 to 0.6 mm in diameter.

Fig. 1

Fig. 2

Survival curve using revision as an end-point.

At ten years the cumulative survival with revision as the end-point was 99.14% (95% confidence interval 92.5 to 99.8) (Fig. 2).

Discussion

The medium to long-term results of this consecutive series of primary, HA-coated, cementless TKRs are good. Cementless TKR has proven results which are comparable with cemented TKR and has the added advantages of preservation of bone stock and reduced operating time. If the initial fixation of HA-coated implants is secure a strong and enduring implantation can be obtained. The use of HA offers a clinically relevant advantage over simple porous coating and provides adequate fixation to prevent mechanical loosening of a TKR.¹¹⁻¹⁵ It has the theoretical benefits of osteoconduction, acceleration of bony ingrowth and biological fixation compared with the use of press-fit or porous coating alone.

In order to examine accurately bony ingrowth we monitored an initial group of 200 patients by fluoroscopy. Few studies have examined the interfaces in this way.^{8,18} A true lateral radiograph of the prosthesis, which can vary from a standard lateral view, was thus obtained in order to identify any lucent lines. The results from this screening were sufficient to avoid further unnecessary radiation exposure of all our patients. They are now routinely screened at assessment at ten years in order to examine the prosthesis-bone interface, or earlier if their symptoms demand it.

Retrieval of the component during a single revision for septic loosening allowed the degree of osseointegration to be assessed. The specimen was obtained from a 74-year-old man in July 1995, 2.2 years after simultaneous, bilateral primary TKR for osteoarthritis. Histological examination of the interface of the femoral component (Fig. 1) demonstrated trabecular bone surrounding the distal porous-coated surface and which had also penetrated to the very edge of the prosthesis.

The rate of infection for our study (1.2%) is in keeping with accepted levels. Of key interest was the ability to retain the prosthesis within this subgroup. Of the 17 deep infections which occurred, only four (23.5%) required revision. Other work has suggested that the ideal treatment for a deep infection in a well-fixed uncemented prosthesis is an arthroscopic synovectomy because of the absence of an avascular prosthesis-cement interface.¹⁹ This is an area which clearly warrants further investigation.

Age was not a discriminating factor when deciding whether or not to use an uncemented TKR in older patients. This prosthesis has been previously shown to produce similar results in patients over the age of 75 years when compared with those younger patients.²⁰ Function after surgery has already been reported, with a number of

patients being able to return to recreational sports and to kneel on the replaced knee without discomfort.^{21,22} The range of movement (Table I) achieved was comparable with that obtained with other posterior-cruciate ligament-retaining designs.

Our consecutive series of 1000 patients supports the use of HA in uncemented TKR, which can produce a reliable fixation at a mean of 6.6 years post-operatively. It is comparable with cemented fixation, as demonstrated by the low rates of revision and complications and the low incidence of loosening (one case of aseptic loosening in 1429 knees). The cumulative survival rate of 99.14% at ten years suggests reliable long-term results. This design of TKR produces excellent clinical results, with good functional outcomes in the medium to long term.

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References

1. Duffy GP, Berry DJ, Rand JA. Cement versus cementless fixation in total knee arthroplasty. *Clin Orthop* 1998;356:66-72.
2. Lachiewicz PF. Cement versus cementless total knee replacement: is there a place for cementless fixation in 2001? *Curr Opin Orthop* 2001;12:33-6.
3. Scuderi GR, Insall JN, Windsor RE, Moran MC. Survivorship of cemented knee replacements. *J Bone Joint Surg [Br]* 1989;71-B:798-803.
4. Hofmann AA, Evanich JD, Ferguson RP, Camargo MP. Ten- to 14-year clinical followup of the cementless Natural Knee system. *Clin Orthop* 2001;388:85-94.
5. Bassett RW. Results of 1,000 performance knees: cementless versus cemented fixation. *J Arthroplasty* 1998;13:409-13.
6. Khaw F, Kirk LM, Morris RW, Gregg PJ. A randomised, controlled trial of cemented press-fit condylar total knee replacement. *J Bone Joint Surg [Br]* 2002;84-B:658-66.
7. Rosenberg AG, Barden R, Galante JO. A comparison of cemented and cementless fixation with the Miller-Galante total knee arthroplasty. *Orthop Clin North Am* 1989;20:97-111.
8. Nielsen PT, Hansen EB, Rechnagel K. Cementless total knee arthroplasty in unselected cases of osteoarthritis and rheumatoid arthritis: a 3-year follow-up study of 103 cases. *J Arthroplasty* 1992;7:137-43.
9. Door L. Fixation for the millennium: the knee. *J Bone Joint Surg [Br]* 2002;84-B(Suppl II):172.
10. Schroder HM, Berthelsen A, Hassani G, Hansen EB, Solgaard S. Cementless porous-coated total knee arthroplasty: 10-year results in a consecutive series. *J Arthroplasty* 2001;16:559-67.
11. Gejo R, Akizuki S, Takizawa T. Fixation of the NexGen HA-TCP-coated cementless, screwless total knee arthroplasty: comparison with conventional cementless total knee arthroplasty of the same type. *J Arthroplasty* 2002;17:449-56.
12. Toksvig-Larsen S, Jorn P, Ryd L, Lindstrand A. Hydroxyapatite-enhanced tibial prosthetic fixation. *Clin Orthop* 2000;370:192-200.
13. Nelissen R, Valstar ER, Rozing PM. The effect of hydroxyapatite on the micro-motion of total knee prosthesis: a prospective, randomized, double-blind study. *J Bone Joint Surg [Am]* 1998;80-A:1665-72.
14. Onsten I, Nordqvist A, Varlsson AS, Besakov J, Sholt S. Hydroxyapatite augmentation of the porous coating improves fixation of tibial components: a randomised RSA study in 116 patients. *J Bone Joint Surg [Br]* 1998;80-B:417-25.
15. Cross M, Roger G, Holt M, et al. Enhanced fixation of uncemented knee replacement with hydroxyapatite. *Key Eng Mat* 2003;240-2:773-6.
16. Insall JN, Door MD, Scott RD, Scott WN. Rationale of the Knee Society clinical rating system. *Clin Orthop* 1989;248:13-14.
17. Ewald FC. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system. *Clin Orthop* 1989;248:9-12.
18. Mintz AD, Pilkington CA, Howie DW. A comparison of plain and fluoroscopically guided radiographs in the assessment of arthroplasty of the knee. *J Bone Joint Surg [Am]* 1989;71-A:1343-7.
19. Dixon P, Parish EN, Cross MJ. Arthroscopic debridement in the treatment of the infected total knee replacement. *J Bone Joint Surg [Br]* 2004;86-B:39-42.
20. Dixon P, Parish EN, Chan B, Chitnavis J, Cross MJ. Hydroxyapatite-coated cementless, total knee replacement in patients aged 75 years and over. *J Bone Joint Surg [Br]* 2004;86-B:200-4.
21. Palmer S, Servant CT, Maguire J, Parish EN, Cross MJ. Ability to kneel after total knee replacement. *J Bone Joint Surg [Br]* 2002;84-B:220-2.
22. Bradbury N, Borton D, Spoo G, Gross MJ. Participation in sports after total knee replacement. *Am J Sports Med* 1998;26:530-5.