Prospective Analysis of 1000 Patients with Hydroxyapatite-coated Total Knee Replacements

Mervyn J Cross, OAM, MD, MBBS, FRACS

Erin N Parish, MHSc

Australian Institute of Musculo-Skeletal Research, Sydney, Australia

Address for Correspondence:

Dr MJ Cross

286 Pacific Highway

Crows Nest, Australia, 2065

Phone: +61 2 9437 5999

Fax: +61 2 9906 1060

Email: mervcros@ozemail.com.au

Prospective Analysis of 1000 Patients with Hydroxyapatite-coated Total Knee Replacements

Abstract

One thousand consecutive patients that underwent a cementless, hydroxyapatite (HA) coated, stemless, total knee replacement (TKR) over a 9 year period were prospectively studied. Regular postoperative clinical follow up was conducted using the Knee Society score. Mean pre-operative score was 96 which improved to 182 and 180 at 5 and 10 years respectively. To date, there have been 7 (0.5%) cases requiring revision, primarily for septic loosening (4 cases) with low rates of other post-operative complications. Cumulative survival for this group at 10 years with revision selected as the endpoint was 99.14% (95% Confidence Interval (CI) 92.5 to 99.8). These results support the use of HA in a cementless TKR produces reliable fixation with excellent clinical and functional outcomes.

Introduction

Total knee replacement (TKR) is a safe and successful operation for the treatment of advanced knee joint degeneration. Cemented fixation is used due to its reliable long-term results. It has represented the gold standard for TKR due to its proven long-term results and excellent survival rates[1-3].

Cementless prostheses were initially designed to provide greater durability, preserve bone stock and remove the need for the use of cement. Design flaws in some early designs, including failure to maintain tibial cortical contact and the use of titanium femoral components leading to metal osteolysis, resulted in the undermining of the efficacy of such prostheses. Modified cementless designs have overcome these errors with the

medium and long-term results from cementless TKR as good as results found with cemented designs[4-10].

To improve the quality of fixation with the cementless designs bioceramics such as hydroxyapatite (HA) have been introduced. The effectiveness of HA in augmenting uncemented TKR fixation has been proven[11-15]. The presence of HA has been shown to encourage bone growth onto the porous coated prostheses. The purpose of this study was to prospectively report on the medium to long-term outcomes of an uncemented, HA coated, TKR in a consecutive series of 1000 patients.

Methods

Between 1992 and 2001, 1000 patients requiring a primary TKR were treated with a cementless HA coated, posterior cruciate ligament retaining, stemless prosthesis implanted by the senior author (MJC) using a standard technique. The Knee Society clinical rating score[16] was used to record the outcome of the surgery (maximum score of 200). Clinical examination was conducted by independent examiners for the duration of the study (either an orthopaedic fellow, orthopaedic registrar or qualified researcher). Following a preoperative score, regular clinical reviews were carried out at three and six months post operatively and then 1, 2, 5 and 10 years thereafter.

At two years, routine fluoroscopic interface images where taken of the initial 200 patients. Screened views of the bone-prosthesis interface were taken under fluoroscopic positioning. To standardize the protocol, the same two radiographers examined all

patients in the same fluoroscopy suite. The position and presence of lucent or sclerotic lines[17] were noted independently by two (independent) orthopaedic surgeons unconnected with the clinical management of the patients in the study. A line was said to be present if noted by either of the two observers ensuring the false negative rate was as low as possible.

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

Prosthesis. The prosthesis used was the Active (ASDM, Sydney, Australia) uncemented TKR system. The cobalt chrome (CoCrMo) femoral component is designed with the beads recessed into the distal end of the prosthesis. The HA coated femoral component encourages bone ongrowth onto the anterior and posterior surfaces and the chamfer cut surfaces of the femoral component with ingrowth into the distal porous beads. The HA is 70μm thick (crystallinity 75%, porosity 20%), which facilitates osteoblast penetration of the porous beads without blocking the pores.

The titanium alloy (Ti6Al4V) tibial component utilises three methods of fixation. Four press fit lugs, provide rotational stability and initial fixation, the cortical and cancellous bone screws prevent lift off and the HA accelerates bone ingrowth into beads for long-term biological fixation. The lug placement is proportional to the tray size, with an outer diameter of 12.5mm and an inner diameter of 6.5mm. Bone screws are coated with

titanium nitride, which reduces potential wear particles from micro-motion. The screw heads are the standard 'AO' 4mm hex head, with sizes ranging from 20-50mm in length. A medical grade ultra high molecular weight polyethylene (UHMWPE) fixed bearing meniscal insert was used in all cases and with a cemented polyethylene patella component when required.

Results

One thousand patients (male:female 479:521) were included in the study with a mean follow up was 6.6 years (2.5-11.3 years). Details of the patients can be seen in Table 1. Osteoarthritis was the primary diagnosis in 94 percent of the patients. Forty-seven patients (4.7%) had previously undertaken a high tibial osteotomy on the operated knee. The majority of the patients (60% of knees) were done either as a simultaneous or staged bilateral procedure with 1429 knees in total for this series. Sixty-four patients have died since the surgery (32 male, 32 female, average age 78 years, average time from surgery; 4.1 years). The average preoperative knee score was 96 and improved to 182 by the five year review with a range of movement of 113 degrees (Table 2).

Post-operative complications and complications requiring further surgery are reported in Tables 3-5. Revision of the prosthesis was required in 7 cases. Reasons for revision were septic loosening (4), malrotation (1), aseptic loosening (1) and supracondylar fracture (1). Retrieval of the prosthesis from a revision for septic loosening was possible in one case Histological examination showed good osteoinduction into the porous surfaces (Fig 1). There were seventeen knees that developed a deep infection (1.2%). Of these, four

required revision of the prosthesis while the remainder were retained by means of open synovectomy (3), arthroscopic synovectomy (6), arthroscopic washout (3) and long-term antibiotics (1). Thromboembolic complications of varying degrees were the most common post operative sequelae affecting 16.6 percent of patients. All patients receive routine Doppler ultrasound screening 7-days post-operatively. Cardiac complications, primarily arrhythmias, affected 2.5 percent of the total group.

The follow up rate at five years was 96 percent (571 of 592 patients) and at 10 years was 94 percent (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 none with any subsidence of the tibial tray. There has only been one case of clinical loosening requiring revision to date (7.4 years post operatively). This patient had a TKR performed following a high tibial osteotomy.

A survival analysis was conducted on the series of patients. At 10 years 101 patients (94%) were successfully followed up. The cumulative survival with revision set as the end-point was 99.14% (95% CI 92.5 to 99.8) (Fig 2).

Discussion

The results of this consecutive series of primary HA-coated, cementless TKR are good in the medium to long-term stage of follow up. Cementless TKR have proven results that are comparable with cemented TKR and also have the advantages of preserving bone stock and reduced operative time. If initial fixation of HA-coated implants is secure in the

early implantation period, then a strong and enduring fixation can be obtained. The use of a HA coating offers a clinically relevant advantage over simple porous coating and provides adequate fixation to prevent mechanical loosening of TKR[11-15]. The use of a HA coating has the theoretical advantages of osteoconduction, acceleration of bone ingrowth and biological fixation compared to the use of press-fit or porous-coating alone.

To examine accurate bone ingrowth onto the prosthesis this study monitored the initial group of patients via means of fluoroscopic screening. 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 screened into position in order to reveal the presence of lucent lines. The results from screening the initial 200 patients were sufficient to not warrant further unnecessary radiation exposure to all patients. Patients are now routinely screened at the 10 year evaluation to examine bone/prosthetic interface (earlier if patients present symptomatically).

Retrieval of the components during a revision procedure for septic loosening made it possible to examine the osseointergration that had occurred. The specimen was obtained from a 74 year old male patient in July 1995 (2.2 years following an initial simultaneous bilateral primary TKR procedure in May 1993 for osteoarthritis). Histological examination of the bone/prosthesis interface of the femoral component is shown in Figure 1. Osseointergration of the trabecular bone can be seen surrounding the distal porous coated beaded surface which has also penetrated through to the edge of the prosthesis (inset).

The rate of infection for this study (1.2%) is in keeping with other results that have been published in the literature. Of key interest was the ability to retain the prosthesis within this subgroup. Of the 17 deep infections that occurred, only 4 required revision (23.5% of all infections). Other work has suggested that the ideal method of treatment for a deep infection in a well fixed uncemented prosthesis if certain criteria are met is an arthroscopic synovectomy due to the absence of the avascular cement-prosthesis interface[19]. While it is not possible to give a definitive conclusion, it is an area that warrants further investigation.

Patient age was not a discriminating factor in deciding to use an uncemented TKR in older patients. This prosthesis has been shown previously to produce similar results in patients over the age of 75 years when compared to patients in the same cohort under the age of 75 years[20]. Patient function after surgery in this series has previously been reported with a number of patients able to return to recreational sports and have the ability to kneel on the knee without discomfort[21, 22]. The range of movement (Table 2) achieved is comparable to the standard range that is achieved with other PCL retaining designs. Achieving an average of at least 110 degrees of flexion may account for a greater activity and mobility level in the patients.

This consecutive series of 1000 patients supports the use of HA in uncemented TKR which produces reliable fixation at a mean 6.6 years post operatively. It is comparable to cemented fixation, as demonstrated with minimal revision and complication rates and

incidence of loosening (1 case of aseptic loosening in 1429 knees). The cumulative survival rate of 99.14% at 10 years (95% CI 92.5 to 99.8) with revision set as an end-point reveals reliable results in this initial group for the long-term period. It produces excellent clinical results and range of movement with good medical and functional outcomes in the medium to long-term follow-up.

Table 1. Patient details

	Number
Percent female	52.1%
Average Age	68 years (range 34-93)
Unilateral TKR **Bilateral TKR** - *Simultaneous* - *Staged*	571 858 *658* *200*
Total Number of Knees	1429
Average Follow Up	6.6 years (range 2.5-11.3 years)
Diagnosis – OA	94%
Deceased	64

Table 2. Average follow up combined knee scores and range of movement

	Knee Score (Max 200)	**Flexion (Degrees)**
Pre Operative	96	6-115
3 Month	169	3-107
6 Month	177	2-109
1 year	181	1-113
2 year	183	1-113
5 year	182	1-113
10 year	180	0-115

Table 3. Treatment of patients with deep infection

Treatment	**Number of Patients**	**Average Time from Op (months)**
Revision	3	18.0
Open Synovectomy	1	0
Arthroscopic Synovectomy	8	26.4
Arthroscopic Washout	4	40.3
Antibiotics	1	-

Table 4. Post-operative complications

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

Table 5. Complications requiring surgery

Complication	**Number**
Revision	7
Deep Infection	16
Subsequent Patella Replacement	20
Poly Exchange	2
Arthrolysis	7
MUA	16
ORIF (for supracondylar fracture)	2

Figure 1: Histologic view of specimen retrieved at autopsy

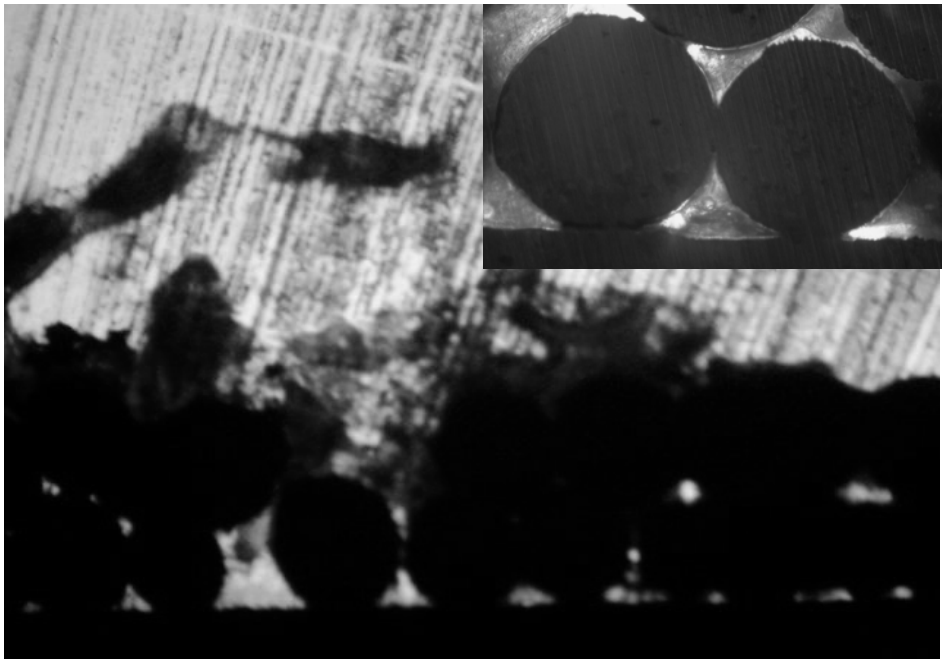
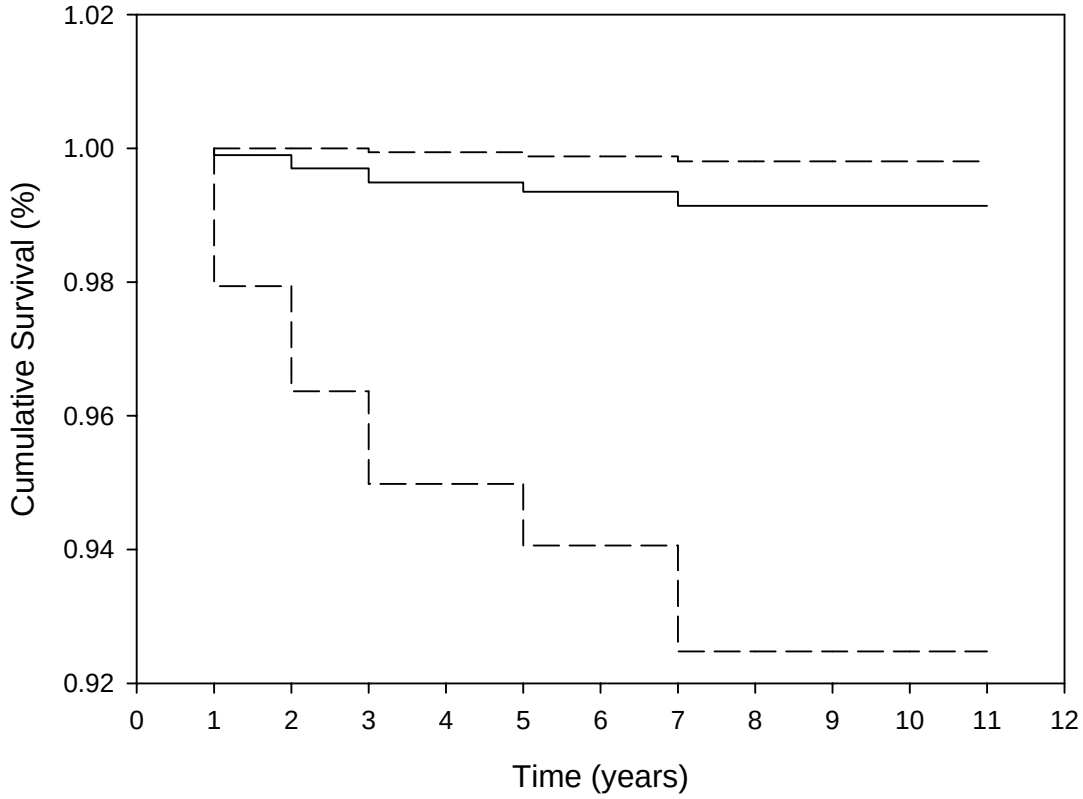


Figure 2: Survival curve using revision as an end-point



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? *Current Opinion in Orthopaedics* 2001; 12(1): 33-36.

3 Scuderi GR, Insall JN, Windsor RE, Moran, MC. Survivorship of cemented knee replacements. *J Bone Joint Surg* 1989; 71-B(5): 798-803.

4 Hofmann AA, Evanich JD, Ferguson RP, *et al.* Ten- to 14-year clinical follow up 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(4): 409-13.

6 Khaw F, Kirk LM, Morris, RW, Gregg PJ. A randomised, controlled trial of cemented versus cementless press-fit condylar total knee replacement. *JBJS (Br)* 2002; 84B(5): 658-666.

7 Rosenburg AG, Barden R, Galante JO. A comparison of cemented and cementless fixation with the miller-galante total knee arthroplasty. *Orthop Clin Nth Am* 1989; 20(1): 97-111.

8 Nielsen PT, Hansen EB, Rechnagel K. Cementless total knee arthroplasty in unselected cases of osteoarthritis and rheumatoid arthritis. *J Arthroplasty* 1992; 7(2): 137-143.

9 Door L. Fixation for the millennium - The Knee. *J Bone Joint Surg, Supp II* 2002; 84B(172.

10 Schroder HM, Berthelsen A, Hassani G, et al. Cementless porous-coated total knee arthroplasty: 10-year results in a consecutive series. *J Arthroplasty* 2001; 16(5): 559-67.

11 Gejo R, Akizuki S, Takizawa, T. Fixation of the NexGen HA-TCP-Coated cementless, screwless total knee arthroplasty. *J Arthroplasty* 2002; 17(4): 449-456.

12 Toksvig-Larsen S, Jorn P, Ryd, L et al. Hydroxyapatite-enhanced tibial prosthetic fixation. *Clin Orthop* 2000; 370(192-200.

13 Nelissen R, Valstar ER, Rozing, PM. The effect of hydroxyapatite on the micromotion of total knee prothesis: A prospective, randomized, double-blind study. *J Bone Joint Surg* 1998; 80-A(11): 1665-1672.

14 Onsten I, Nordqvist A, Carlsson AS, et al. Hydroxyapatite augmentation of the porus coating improves fixation of tibial components: A randomised RSA study in 116 patients. *J Bone Joint Surg* 1998; 80-B(3): 417-425.

15 Cross M, Roger G, Holt, M, Bradbury N, Dixon P, Parish EN. Enhanced fixation of uncemented knee replacement with hydroxyapatite. *Key Engineering Materials* 2003; 15(240-242.

16 Insall JN, Door MD, Scott RD, et al. 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* 1989; 71-A(9): 1343-1347.

19 Dixon P, Parish EN, Cross MJ. Arthroscopic synovectomy - A viable option in the treatment of the infected total knee replacement. *J Bone Joint Surg* 2004; 86-B (1):39-42.

20 Dixon P, Parish EN, Chan B, Chitnavis J, Cross MJ. Minimum 5-year follow up of a hydroxyapatite coated, cementless, total knee replacement in patients aged 75 years and over. *J Bone Joint Surg* 2004 86-B (2):200-4.

21 Palmer S, Servant CT, Maguire J, Parish EN, Cross MJ. Ability to kneel after total knee replacement. *J Bone Joint Surg* 2002; 84-B(220-222.

22 Bradbury N, Borton D, Spoo G, et al. Participation in sports after total knee replacement. *AJSM* 1998; 26(4): 530-535.