A randomised controlled trial of cemented *versus* cementless press-fit condylar total knee replacement

15-YEAR SURVIVAL ANALYSIS

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We report the long-term survival of a prospective randomised consecutive series of 501 primary knee replacements using the press-fit condylar posterior cruciate ligament-retaining prosthesis. Patients received either cemented (219 patients, 277 implants) or cementless (177 patients, 224 implants) fixation. Altogether, 44 of 501 knees (8.8%) underwent revision surgery (24 cemented vs 20 cementless). For cemented knees the 15-year survival rate was 80.7% (95% confidence interval (CI) 71.5 to 87.4) and for cementless knees it was 75.3% (95% CI 63.5 to 84.3). There was no significant difference between the two groups (cemented vs cementless; hazard ratio (HR) 0.83, 95% CI 0.45 to 1.52, $p = 0.55$). When comparing the covariates there was no significant difference in the rates of survival between the side of operation (HR 0.58, $p = 0.07$), age (HR 0.97, $p = 0.10$) and diagnosis (HR 1.25 $p = 0.72$). However, there was a significant gender difference, with males having a higher failure rate with cemented fixation (HR 2.48, $p = 0.004$). Females had a similar failure rate in both groups.

This single-surgeon series, with no loss to follow-up, provides reliable data of the revision rates of one of the most commonly-used total knee replacements. The survival of the press-fit condylar total knee replacement remained good at 15 years, irrespective of the method of fixation.

There are currently 33 different types of total condylar knee prosthesis being implanted in England and Wales.¹ According to the National Joint Registry's database, in addition, ten types of unicondylar prosthesis, three types of patellofemoral replacement prosthesis and seven different hinged prostheses are in contemporary use. It is imperative that surgeons know the long-term outcome and possibility of survival for the wide variety of implants they are using. Such information may also be useful for health-care commissioners in modelling the future provision of revision knee surgery.

Some previous reports comparing cemented and cementless fixation for knee replacement have suggested that both clinical outcome and long-term survival are inferior for cementless prostheses.²⁻⁵ However, these studies were not randomised and had methodological flaws, which may account for the differences seen.

Previously, we published a ten-year survival analysis of a prospective randomised trial comparing cemented and cementless fixation of press-fit condylar (PFC) primary total knee replacement (TKR)⁶ which showed good survival at ten years irrespective of the method of fixation. We now present a longer term analy-

sis of this cohort, comparing the survival over a 15-year period.

Patients and Methods

Between June 1987 and February 1997, all patients requiring primary TKR using the PFC posterior cruciate ligament (PCL)-retaining knee replacement system (Johnson & Johnson Professional Inc., Raynham, Massachusetts) under the care of the senior author (PJG) were recruited into a randomised controlled trial in order to compare cemented and cementless fixation. Inclusion in the trial depended on the patient's suitability for both methods of fixation to be used, so that the choice of implant could be randomised during the operation only after the bone surfaces had been prepared. Before March 1993, randomisation according to year of birth was carried out for 320 implants, with allocation into each of the two groups depending upon whether their year of birth ended in an odd or an even number. After March 1993, a more satisfactory method of randomisation⁷ using computer-generated random numbers was used for 181 implants.

A total of 28 patients undergoing single-stage bilateral TKR and 77 of 81 patients

Table I. Reasons for exclusion from randomisation for cemented or cementless press-fit condylar total knee replacement

Number of implants	Reason for non-randomisation
45	Grossly porotic bone or bone defects not requiring grafting
18	Bone cuts not sufficiently accurate for a cementless prosthesis
15	Bone defects sufficiently large to warrant bone grafting
6	Error of randomisation
5	Consent not provided
4	Prosthesis unavailable
3	Jehovah's witness
2	Patient on therapeutic anticoagulation following previous cerebrovascular accident

Table II. Details of the patients

	Cemented	Cementless
Patients (TKRs)*	219 (277)	177 (224)
Gender		
Male	98	74
Female	121	103
Diagnosis		
Osteoarthritis	199	163
Rheumatoid arthritis	17	13
Other	3	1
Mean age in yrs (range)	70 (41 to 87)	71 (49 to 88)

* TKRs, total knee replacements

undergoing bilateral staged TKR had the same method of fixation on both sides. The other four patients with bilateral TKRs had a cemented implant in one knee and cementless in the other.

Of a consecutive total of 599 TKRs (481 patients), 98 knees (85 patients) were excluded for reasons given in Table I. Jehovah's witnesses and patients on anticoagulation were excluded, as it was the senior author's experience that cementless TKRs tended to have a greater blood loss than cemented knees. He therefore preferred to perform cemented TKR in these patients. Thus, 501 TKRs (396 patients) were studied, with 277 cemented (219 patients) and 224 cementless (177 patients). Details of the patients are given in Table II.

All TKRs were carried out by, or under the direct supervision of, the senior author. The TKR used is a modular prosthesis with a cobalt-chrome femoral component articulating with a polyethylene insert which is mounted on a titanium tibial tray with a cruciform stem. Both the cemented and the cementless implants have the same geometry and are introduced using the same instrumentation. Cementless implants have a coating of porous beads for contact with the bone cuts, and were not hydroxyapatite-coated.

A standard surgical technique was used, with a longitudinal incision and a medial parapatellar approach. The

bone was prepared using the manufacturer's cutting guides. In most knees the PCL was left intact, but in a few with a severe fixed-flexion deformity it was released from the posterior aspect of the tibia and a cruciate-sparing tibial component was used. A polyethylene insert with a thickness of at least 8 mm was routinely used, but one of 10 mm thickness was occasionally required to achieve stability.

In the cemented group, the components were implanted using cement of normal viscosity. This was layered over the proximal tibia by hand and inserted into the recess for the stem of the prosthesis. Cement was applied to the back of the femoral component except for the anterior chamfer and flange. In these regions cement was applied directly on to the bone. The knee was held in extension until the cement had polymerised. The patella was not resurfaced. The knee was immobilised in a Robert Jones bandage⁸ for two days, followed by a standard rehabilitation programme after review of the wound.

During a ten-month period between November 2003 and September 2004, all surviving patients were contacted by telephone by a research physiotherapist (LMGK) with the aim of establishing implant survival. Those who could not be contacted directly were traced through their general practitioner. In the case of deceased patients, hospital and general practitioner records were reviewed and relatives were contacted by telephone to ascertain the survival of the implant. The interval of follow-up was recorded as the interval between the date of the operation and the date of either the death of the patient or confirmation of the survival of the implant.

Statistical analysis. We used life-table analysis, as detailed by Armitage and Berry.⁹ Asymmetrical binomial confidence intervals as described by Rothman¹⁰ were calculated using the 'effective number at risk' method described by Murray, Carr and Bulstrode.¹¹ The endpoint (revision) was defined as further surgery, irrespective of indication, that involved replacement of any of the three original components (femoral component, tibial tray, polyethylene insert). A comparison of the cumulative survival rates for the two groups was made using Cox's proportional hazards regression analysis,⁹ with operation, gender, age, diagnosis and operative side as covariates. Statistical significance was set at $p < 0.05$.

Fig. 1

Radiographs of a cementless total knee replacement showing gross osteolysis prior to revision.

Fig. 2

Photograph of an explanted cementless prosthesis showing debonding of the porous-bead coating.

Results

At the last review 97 patients (126 knees) in the cemented group and 85 (106 knees) in the cementless group had died. In addition, two cementless implants had been lost because of above-knee amputation, one after fracture of the femur and one for gangrene secondary to diabetes mellitus. For the purpose of life-table survival analysis, both of these patients were withdrawn from the series, which is equivalent to the loss of an implant due to death. All 214 surviving patients (269 knees) were contacted, with no loss to follow-up. The survival of the implants was ascertained at a mean

Table III. Anderson Orthopaedic Research Institute (AORI) grades for 13 of the 26 knees revised for aseptic loosening

AORI grade*	Cemented (n = 5)	Cementless (n = 8)
Tibial		
1	3	2
2a	1	-
2b	1	4
3	-	2
Femoral		
1	1	1
2a	1	-
2b	3	6
3	-	1

* Grade 1: Intact and full metaphyseal bone and flare. No component subsidence or osteolysis. Intra-operatively: No augments (> 4 mm), structural grafts, or > 1 cm cement fill required

Grade 2: Damaged metaphysis, shortened metaphyseal flare. Intra-operatively: Joint line restored with either an augmented component (> 4 mm), particulate autograft or allograft, or > 1 cm fill. (One condyle = grade 2a, both condyles = grade 2b)

Grade 3: Deficient metaphyseal segment. Intra-operatively: Need to reconstruct condyle or plateau with structural graft, augment, cement or hinged components

follow-up of 8.9 years (5.8 to 16.8) in the cemented group and 8.7 years (6.9 to 16.6) in the cementless group.

A total of 54 of 501 knees (10.8%) required further surgery, 27 of 277 (9.7%) in the cemented group and 27 of 224 (12.1%) in the cementless group. Of these re-operations, 44 were revision procedures (24 of 277 (8.7%) cemented *vs* 20 of 224 (8.9%) cementless). In the cemented group components were revised for infection in seven patients (2.5%), for aseptic loosening in 14 (5%), for polyethylene wear debris in one (0.4%), and for exchange of polyethylene insert during a procedure for patellar realignment in two (0.7%). Patellar resurfacing was undertaken for anterior knee pain in three cases; these patients were not included as revisions, as the original components were not revised. In the cementless group, components were revised for infection in four patients (1.8%), for aseptic loosening in 12 (5.4%), for instability in two (0.9%), and for exchange of polyethylene insert during a procedure for anterior knee pain in two (0.9%). A further seven operations were not included as revisions. Patellar resurfacing was undertaken for anterior knee pain in four cases. Proven infection was successfully treated by arthrotomy, lavage and systemic antibiotics in two knees without loss of the components, and secondary patellar realignment was undertaken in one. At the time of follow-up seven patients were awaiting revision surgery for aseptic loosening (four cemented and three cementless).

Of the 26 revisions performed for aseptic loosening additional information was available for 13 procedures (five cemented, eight cementless) performed by one of the authors (CNAE). At the time of revision there was no difficulty in removing the components, irrespective of the method of fixation. Cementless fixation was associated

Table IV. Life-table analysis of cemented press-fit condylar total knee replacements with revision for all causes as the endpoint (no patients were lost to follow up)

Years since operation	Number at start	Number revised	Withdrawn	Number at risk	Effective number at risk	Annual failure rate (%)	Annual success rate (%)	Survival rate (%)	95% confidence interval
0 to 1	277	2	5	274.5	274.5	0.7	99.3	99.3	97.4 to 99.8
1 to 2	270	3	9	269.5	269.9	1.1	98.9	98.1	95.7 to 99.2
2 to 3	258	1	7	254.5	264.6	0.4	99.6	97.8	95.2 to 99.0
3 to 4	250	0	11	244.5	259.3	0.0	100.0	97.8	95.1 to 99.0
4 to 5	239	0	9	234.5	253.9	0.0	100.0	97.8	95.1 to 99.0
5 to 6	230	0	21	219.5	247.4	0.0	100.0	97.8	95.1 to 99.0
6 to 7	209	2	12	203.0	239.9	1.0	99.0	96.8	93.7 to 98.4
7 to 8	195	4	28	181.0	230.5	2.2	97.8	94.7	91.0 to 96.9
8 to 9	163	1	28	149.0	217.3	0.7	99.3	94.0	90.1 to 96.5
9 to 10	134	3	23	122.5	201.7	2.4	97.6	91.7	87.1 to 94.8
10 to 11	108	1	18	99.0	184.3	1.0	99.0	90.8	85.8 to 94.2
11 to 12	89	1	22	78.0	165.5	1.3	98.7	89.6	93.4 to 84.1
12 to 13	66	3	16	58.0	144.9	5.2	94.8	85.0	78.3 to 89.9
13 to 14	47	2	15	39.5	121.7	5.1	94.9	80.7	72.8 to 86.7
14 to 15	30	0	16	22.0	93.5	0.0	100.0	80.7	71.5 to 87.4
15 to 16	14	0	9	9.5	60.2	0.0	100.0	80.7	69.0 to 88.7
16 to 17	5	1	4	3.0	26.7	33.3	66.7	53.8	35.6 to 71.0

Table V. Life-table analysis of cementless press-fit condylar total knee replacements with revision for all causes as the endpoint (no patients were lost to follow-up)

Years since operation	Number at start	Number revised	Withdrawn	Number at risk	Effective number at risk	Annual failure rate (%)	Annual success rate (%)	Survival rate (%)	95% confidence interval
0 to 1	224	1	10	219.0	219.0	0.5	99.5	99.5	97.5 to 99.9
1 to 2	213	3	7	209.5	214.1	1.4	98.6	98.1	95.3 to 99.3
2 to 3	203	1	3	201.5	209.8	0.5	99.5	97.6	94.6 to 99.0
3 to 4	199	0	7	195.5	206.0	0.0	100.0	97.6	94.5 to 99.0
4 to 5	192	0	8	188.0	202.1	0.0	100.0	97.6	94.5 to 99.0
5 to 6	184	0	11	178.5	197.8	0.0	100.0	97.6	94.4 to 99.0
6 to 7	173	1	13	166.5	192.6	0.6	99.4	97.0	93.6 to 98.7
7 to 8	159	2	26	146.0	185.2	1.4	98.6	95.7	91.8 to 97.8
8 to 9	131	2	17	122.5	175.2	1.6	98.4	94.2	89.6 to 96.8
9 to 10	112	1	11	106.5	164.6	0.9	99.1	93.3	88.4 to 96.2
10 to 11	100	3	23	88.5	152.7	3.4	96.6	90.1	84.3 to 93.9
11 to 12	74	2	26	61.0	135.7	3.3	96.7	87.2	80.5 to 91.8
12 to 13	46	2	17	37.5	112.9	5.3	94.7	82.5	74.5 to 88.4
13 to 14	27	2	8	23.0	88.3	8.7	91.3	75.3	65.4 to 83.1
14 to 15	17	0	8	13.0	63.7	0.0	100.0	75.3	63.5 to 84.3
15 to 16	9	0	7	5.5	38.3	0.0	100.0	75.3	59.8 to 86.2
16 to 17	2	0	2	1.0	11.3	0.0	100.0	75.3	46.2 to 91.6

with significant osteolysis (Fig. 1) and debonding of the porous-bead coating (Fig. 2), and there was a fibrous layer below the tibial component in all cases. The only place where the femoral components were well-fixed, if anywhere, was anteriorly. In both cemented and cementless fixation there was a significant loss of bone from the posterior femoral condyles. The bone loss has been graded according to Anderson Orthopaedic Research Institute grades¹² for these 13 revisions (Table III).

Survival analysis used revision surgery, with exchange of any of the three originally inserted components (femoral, tibial, polyethylene insert), as the endpoint. Life-table analysis (Tables IV and V) showed a 15-year survival of

80.7% (95% confidence interval (CI) 71.5 to 87.4) for cemented knees, with a ten-year survival of 91.7% (95% CI 87.1 to 94.8). For cementless knees 15-year survival was 75.3% (95% CI 63.5 to 84.3), with a ten-year survival of 93.3% (95% CI 88.4 to 96.2). Figures 3 and 4 show the respective survival curves. Although the 15-year survival for cementless knees was lower, Cox's analysis showed no apparent difference in the hazard of failure between the two groups (hazard ratio (HR) = 0.83 (95% CI 0.45 to 1.52), $p = 0.55$).

The life tables in this analysis differ considerably from those seen in our previous ten-year analysis⁶ reflecting the longer follow-up. At the time of the previous analysis the

Fig. 3

Survival curve with binomial 95% confidence intervals for cemented press-fit condylar total knee replacement with revision for all causes as the endpoint.

Fig. 4

Survival curve with binomial 95% confidence intervals for cementless press-fit condylar total knee replacement with revision for all causes as the endpoint.

minimum follow-up was 2.7 years and in the current analysis the minimum follow-up is 5.8 years. This explains why differences are observed from the third year of the life table onwards in the current study.

When comparing the covariates (side of operation, age, diagnosis, gender), there was no significant difference between the side of operation (HR = 0.58 (95% CI 0.32 to 1.05), $p = 0.07$), age (HR = 0.97 (95% CI 0.92 to 1.01), $p = 0.10$), or diagnosis (osteoarthritis *vs* non-osteoarthritis, HR = 1.25 (95% CI 0.38 to 4.12), $p = 0.72$). However, there was a significant gender difference (males *vs* females, HR = 2.48 (95% CI 1.34 to 4.61), $p = 0.004$), more males

having a revision following a cemented procedure than after cementless procedure (16 *vs* 12 revisions). In comparison, the female patients had the same number of revisions in both the cemented and cementless groups (eight in each group).

In the 'worst-case scenario' including seven patients awaiting revision, the 15-year survival for the cemented group was 78.3% (95% CI 68.9 to 85.4) and 72.0% (95% CI 59.9 to 81.5) for the cementless group.

Discussion

The study reports the long-term survival of the PCL-sparing knee prosthesis at 15 years. Using revision surgery that involved replacement of any of the three original components irrespective of indication as the endpoint, the 15-year survival rates were 80.7% and 75.3% in the cemented and cementless groups, respectively.

A total of 44 knees (8.8%) required revision surgery. The indication for the majority of revision procedures was aseptic loosening, which occurred in 26 revisions (59.1%). Overall, the indications for revision between the two groups were comparable. This is in contrast to our ten-year analysis, where the indications for many of the revision procedures was infection.⁶ At the time of the ten-year analysis only four implants had been revised for aseptic loosening.

Our 15-year survival rate is comparable to those in other reports of longer term survival of cemented TKRs. Rates of survival of 87% at 12 years¹³ and 82% at 14 years¹⁴ have been reported for the Kinematic Condylar Knee (Howmedica, Rutherford, New Jersey), 87% at 13 years¹⁵ for the Kinematic Stabiliser (Howmedica), and 96.9% at 14 years¹⁶ for the Anatomical Graduated Components (Biomet Inc., Warsaw, Indiana). In these series, loss to follow-up ranged from 1% to 8.2%. A worst-case analysis performed on the total condylar posterior stabilised prosthesis (Johnson & Johnson, New Brunswick, New Jersey) reported a 14-year survival of 93.1% for implants with a metal-backed tibia and a 16-year survival of 90.3% for implants with an all-polyethylene tibia.¹⁷ A 20-year survival rate of 91.9% has been reported with the total condylar knee (Johnson & Johnson).¹⁸ This series did, however, have a 15.9% loss to follow-up, which may partly explain this high rate of survival.

There are relatively few longer term survival rates for cementless prostheses in the literature. A few series have reported ten-year survival, with rates including 93.4% for the natural knee (Zimmer Inc, Warsaw, Indiana),¹⁹ 97% for the anatomical graduated components (Biomet Inc.)²⁰ and 94% for the Ortholoc I (Biomet Inc.).²¹ One series²² reported a 13-year survival rate of 96.7% with the Osteonics knee (Stryker, Mahwah, New Jersey), but this was from a small series with a 9.2% loss to follow-up. A survivorship of 93% at 13 years has also been reported using the hydroxyapatite (HA)-coated Insall Burstein II TKR²³ (Cremascoli Fry Ortho Ltd., Surrey, United Kingdom). Epinette

and Manley²⁴ assessed the longer term survival of the partially HA-coated Omnifit knee prosthesis Series 3000 (Stryker) and the fully HA-coated series 7000 (Stryker). At 11 years, the cumulative survival, using retrieval for any cause as the endpoint, was 94.1% and 94.4% in the two respective groups. These results are comparable with our ten-year survival rate of 93.3%.

Many survival analyses of TKR include a number of patients who have been lost to follow-up. This can lead to overestimation of the true survival rate.²⁵ In the previously mentioned series,¹³⁻²² loss to follow-up ranged between 1% and 15.9%. This is possibly why our longer term survival seems to be lower than previously reported rates. In our series, owing to the prospective design there was no loss to follow-up. Our reported survival rates should therefore be an accurate reflection of the expected survival of the PFC replacement at 15 years.

In this series there was no significant difference between the survival rates for cemented and cementless fixation. This is in keeping with the findings from our earlier ten-year analysis.⁶ Longer term comparative studies of cemented and cementless fixation for knee replacement have suggested that cementless implantation is associated with a poorer survival and clinical outcome. A retrospective case-matched series undertaken by Duffy et al⁵ reported survival rates of 94.2% and 72.7% at ten years for cemented and cementless fixation, respectively. However, the groups contained small numbers and were poorly matched, especially with regard to age, the cementless group being approximately ten years younger. Chockalingham and Scott² compared cemented and cementless fixation of the femoral component of the Freeman-Samuelson prosthesis and found a significant difference in the results at six years when the failure rates were 0.6% and 9.8% for cemented and cementless fixation, respectively. This series was a non-randomised design, had unequal group sizes, and it is not clear to what extent the groups were matched for age, gender and underlying diagnosis. This makes it difficult to interpret the findings. Nafei et al⁴ found a higher revision rate in a small cohort of patients who underwent cementless TKR fixation compared with cemented fixation. They also found that patients who had cementless fixation were more likely to have residual pain (24% vs 4%). Improved clinical results with cemented over cementless fixation have also been described by Rorabeck et al.³ Unlike ours, their study used two different designs of implant, which could partly account for their findings.

In this analysis the ten-year survival rates were 91.7% and 93.3% for cemented and cementless knees, respectively. These rates are lower than those reported in our previous paper,⁶ when the survival rates were 95.3% and 95.6%. It is assumed that the observed decrease is a function of the longer follow-up in this current study, in which a larger proportion of the original cohort had reached ten years. The results reported in this paper are therefore a

more accurate reflection of the ten-year survival rates for the different methods of fixation of this implant.

One limitation with this study was our inability to collect more clinical information, including data relating to patient outcome measures of pain and functional limitation. Although this would have provided useful additional data, the current study was undertaken with the sole aim of establishing and analysing the 15-year survival of the PFC TKR. We recognise that survival data are the measure most likely to be applied if the National Institute for Clinical Excellence were to develop guidance for TKR surgery as it has for total hip replacement.

This study provides surgeons with reliable longer term data for the revision rates of the most commonly-used TKR. It demonstrates that the survival of the press-fit condylar TKR remains good at 15 years, irrespective of the method of fixation in this series where randomisation of fixation was delayed until the suitability of either method of fixation was confirmed after preparation of the bone.

Supplementary material

Tables showing details of the revisions and re-operations in both the cemented and cementless groups are available with the electronic version of this article on our website at www.jbjs.org.uk

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