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

TEN-YEAR SURVIVAL ANALYSIS

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We have carried out a long-term survival analysis of a prospective, randomised trial comparing cemented with cementless fixation of press-fit condylar primary total knee replacements. A consecutive series of 501 replacements received either cemented (219 patients, 277 implants) or cementless (177 patients, 224 implants) fixation.

The patients were contacted at a mean follow-up of 7.4 years (2.7 to 13.0) to establish the rate of survival of the implant. The ten-year survival was compared using life-table and Cox's proportional hazard analysis.

No patient was lost to follow-up. The survival at ten years was 95.3% (95% CI 90.3 to 97.8) and 95.6% (95% CI 89.5 to 98.2) in the cemented and cementless groups, respectively. The hazard ratio for failure in cemented compared with cementless prostheses was 0.97 (95% CI 0.36 to 2.6). A comparison of the clinical outcome at ten years in 80 knees showed no difference between the two groups.

The survival of the press-fit condylar total knee replacement at ten years is good irrespective of the method of fixation and brings into question the use of more expensive cementless implants.

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As the demand for knee replacement surgery increases resources need to be allocated to implants with the best long-term clinical outcome and survival rates.

Liow and Murray[1] reported that 54% of knee prostheses, which were available in the UK did not have functional or survival results published in peer-reviewed journals. In their report, there were only five implants (13%) with published survival analyses of ten years or more and only five (13%) for which a functional outcome at more than five years was available. This paucity of data concerning the long-term outcome after total knee replacement (TKR) is alarming considering the rapid rise in the number of different designs of prostheses which are available.

There is considerable debate regarding the possible benefits of using cementless fixation in joint replacement surgery. These include preservation of bone stock, ease of revision, the avoidance of complications of cementation and lastly, but most importantly, improved long-term survival of the implant. Although it is now clear that aseptic loosening is mainly related to wear debris rather than to cemented fixation, the question remains as to whether cementless implants have an improved long-term survival. This can only be answered by a randomised trial comparing the two methods of fixation. For TKR no such reports have been published in peer-reviewed journals. Our aim therefore was to compare the long-term survival, in a prospective randomised trial, of cemented with cementless fixation, using the press-fit condylar TKR system.

Patients and Methods

Between June 1987 and February 1997 all patients requiring primary TKR using the press-fit condylar 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. They were included in the trial only if they were suitable for both methods. Thus, the choice of implant was randomised during the operation only after the joint surfaces had been prepared. Before March 1993, pseudorandomisation according to year of birth was carried out for 320 implants. After March 1993, a more satisfactory method of randomisation[2] using computer-generated random numbers was

Table I. Reasons for exclusion from randomisation for cemented or cementless press-fit condylar TKR

Reason	Number of implants	Comments
Bone loss	45	Grossly porotic bone or bone defects not requiring grafting
Bone cuts	18	Bone cuts not sufficiently accurate for a cementless prosthesis
Bone graft	15	Bone defects sufficiently large to warrant bone grafting
Error	6	
Religion	3	Jehovah's Witnesses
Medical	2	Previous cerebrovascular accident and therapeutic anticoagulation required
Unavailable	4	Prosthesis unavailable
Consent	5	Consent not given

Table II. Details of the patients in the cementless (177) and cemented (219) groups who received press-fit condylar TKRs

	Press-fit condylar TKR	
	Cemented	**Cementless**
Total number	219	177
Gender		
Male	98	74
Female	121	103
Diagnosis		
Osteoarthritis	199	163
Rheumatoid arthritis	17	13
Other	3	1
Mean age in years (range)	70 (41 to 87)	71 (49 to 88)
Mean follow-up in years (range)	7.3 (2.9 to 13.0)	7.4 (2.7 to 12.8)

used (181 implants). All patients undergoing one-stage bilateral TKR (28) and most patients undergoing bilateral staged TKR (77 of 81) had the same method of fixation on both sides.

Of a consecutive total of 599 TKRs (454 patients) 98 (85 patients) were excluded for reasons given in Table I. Twenty-three of the excluded implants were in patients whose contralateral knees were included in the trial. Thus, 501 TKRs (392 patients) were studied; there were 277 (219 patients) cemented and 224 (177 patients) cementless implants. Four patients with bilateral TKRs had implants with both methods of fixation. Details of the patients are given in Table II.

All TKRs were carried out by, or under the direct supervision of, the senior author (PJG). Antibiotic cover was used routinely, but no chemical thromboprophylaxis was given. In all knees, the prosthesis used was a press-fit condylar posterior-cruciate-ligament (PCL)-sparing TKR. This 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. The posterior-lipped polyethylene insert is gently curved in both sagittal and coronal sections, providing a degree of conformity. The cementless implants are porous-coated and the cemented prostheses have a smooth non-porous finish. Both have the same geometry and are introduced using the same instrumentation. The polyethylene insert (GUR412) was manufactured from compressed moulded sheets and sterilised by gamma irradiation in air. All components were used before their five-year expiry dates.

A standard surgical technique was used with a longitudinal incision and a medial parapatellar approach. The bone cuts were made using the manufacturer's jigs. 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. In these knees, a cruciate-sparing tibial implant was still 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. The number of 10 mm inserts used is not known, since it was not routine practice to record the thickness of polyethylene inserts in the operative notes.

In the cemented group, both the femoral and tibial components were implanted using cement of normal viscosity. This was layered over the proximal tibia by hand and inserted into the slot 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 onto bone. The knee was held in extension until the cement had set. The patella was not resurfaced. The knee was immobilised in a Robert Jones bandage for two days followed by a standard rehabilitation programme after review of the wound.

Although this study was primarily an analysis of survival, it was thought important to collect clinical data for those patients who reached the ten-year endpoint since not all the implants which remain in situ may be functioning satisfactorily. An independent clinical review using the Nottingham data collection system[3] was undertaken by a research physiotherapist (LMGK). This knee assessment score uses a five-point scale to evaluate pain, mobility and function. The assigned scores range from 1 to 5, where 1 corresponds to the worst and 5 the best level of performance. For the assessment of pain, the frequency, severity and that experienced at night were recorded. Functional evaluation included the ability to walk, the use of aids, stability, standing, ascending and descending steps, and sitting and rising from a chair. Clinical measurements were made of flexion contracture, total flexion and extensor lag. The patients were assessed before operation and post-operatively at six months, one year, annually for five years and, most recently, at ten years. At the ten-year review, they were also asked to comment on the change in their knee compared with the preoperative status.

Standard anteroposterior (AP) and lateral radiographs of

Table III. Details of all reoperations after either cemented or cementless press-fit condylar TKR

Indication	Time to revision (yrs)	Age (yrs)	Gender	Diagnosis*	Procedure	Comments†
Cemented						
Aseptic loosening	6.2	69	F	OA	1-stage revision	Loose femoral component and extensive polyethylene wear
Infection	0.3	73	F	OA	2-stage revision	*Strep. faecalis* infection
Infection	0.8	70	F	OA	Arthrodesis	Patient's choice
Infection	1.1	65	M	OA	2-stage revision	Evacuation of haematoma and quadriceps rupture repair at 4 weeks Group A-*Strep.* infection
Infection	1.1	85	F	OA	2-stage revision	*Staph. albus* infection
Infection	2.1	75	M	OA	2-stage revision	*Staph. aureus* infection
Patellar malalignment	1.2	72	F	OA	Exchange of polyethylene insert	Extensive realignment of extensor apparatus Thicker polyethylene insert used
Patellar malalignment	7.9	63	M	OA	Patellar resurfacing Exchange of insert	Patella resurfaced at 1.2 years. Fractured patellar button 6.7 years later. During retrieval, insert found to be worn and therefore replaced
Polyethylene wear	6.5	77	M	OA	1-stage revision Patellar resurfacing	Extensive polyethylene wear debris. Tibial and femoral components well fixed
Anterior knee pain	0.7	79	F	OA	Patellar resurfacing	
Anterior knee pain	2.6	72	F	OA	Patellar resurfacing Arthroscopic washout	Unexplained symptoms, no evidence of infection or loosening. Revision surgery not felt to be indicated
Anterior knee pain	4.3	73	M	OA	Patellar resurfacing	
Cementless						
Aseptic loosening	1.2	70	M	OA	1-stage revision	Haematoma evacuated two weeks postoperatively No infection confirmed
Aseptic loosening	2.0	73	M	OA	1-stage revision	Tibial component revised
Aseptic loosening	6.4	61	M	OA	Tibial component revised	Loose tibial component. Medial wear of polyethylene insert
Infection	1.0	70	F	OA	Arthrotomy washout	*Staph.* infection. Successfully treated with debridement and flucloxacillin
Infection	2.1	81	F	OA	2-stage revision	Delayed wound healing after index operation
Infection	4.6	77	M	OA	Arthrotomy washout	Coagulase-negative *Staph.* resolved with debridement and clindomycin
Instability	1.0	84	F	OA	1-stage revision	Gross instability after fall and quadriceps avulsion. Components revised but not found to be loose
Patellar malalignment	2.2	51	F	OA	Patellar realignment	
Anterior knee pain	1.2	64	F	OA	Patellar resurfacing	
Anterior knee pain	1.4	87	F	OA	Patellar resurfacing	
Anterior knee pain	2.0	74	F	RA	Patellar resurfacing Exchange of insert Femoral component downsized	Femoral component not loose but deemed to be too large
Anterior knee pain	2.3	65	F	RA	Patellar resurfacing	
Anterior knee pain	3.4	49	F	OA	Patellar resurfacing	
Anterior knee pain	7.5	64	F	OA	Patellar resurfacing Exchange of insert	Thicker insert exchanged to correct recurvatum deformity after patellar replacement

* OA, osteoarthritis; RA, rheumatoid arthritis
† *Strep., Streptococcus; Staph., Staphylococcus*

the knee were obtained and radiolucent lines were assessed using the Knee Society Scoring System[4] on those taken at ten years.

During a 12-month period between January and December 2000, all surviving patients were contacted. Those who could not be contacted directly were traced through their general practitioner (GP). In the case of deceased patients, hospital and GP records were reviewed and relatives were contacted to ascertain the survival of the implant. The interval of follow-up for surviving implants was recorded as the interval between the date of the operation and the date of either the death of the patient or confirmation of survival of the implant.

Statistical analysis. We used life-table analysis, as detailed by Armitage and Berry.[5] Asymmetrical binomial confidence limits, as described by Rothman,[6] were calculated using the 'effective number at risk' described by Murray, Carr and Bulstrode.[7] These statistical techniques are useful in the survival analysis of joint replacement surgery in which low rates of failure are expected. The endpoint was defined as revision surgery to remove any of the original implant components. These were analysed in three groups of indications for revision: 1) aseptic loosening; 2) infection; and 3) all other indications. A comparison of the cumulative survival rates for the two groups was made using Cox's proportional hazards regression analysis[5] with age, gender and diagnosis as covariates.

The clinical outcome of the two groups was compared. The scores for each parameter, with the exception of range of movement, were categorised into two groups, improved and not improved. Comparisons were made using a chi-squared test. For comparisons when the expected values are small (i.e. <5), a chi-squared test was used with correction for continuity as recommended by Cochran.[8] The change in range of movement, which is not considered to follow a normal distribution, was compared using the Wilcoxon-Mann-Whitney[9,10] non-parametric test for two independent samples with correction for tied values.

Results

At the last review, 78 (36%) patients (87 TKRs) in the cemented group and 51 (29%) (67 TKRs) in the cementless group had died. In addition, two cementless implants had been lost because of above-knee amputations, one after a traumatic fracture of the shaft of the femur and one for distal gangrene secondary to diabetes mellitus. For the purpose of life-table survival analysis, both these patients were withdrawn from the series, which is equivalent to the loss of an implant due to death. All surviving patients were contacted and there was no loss to follow-up. The survival of the implants was ascertained at a mean of 7.4 years (2.7 to 12.8) after surgery in the cementless and of 7.3 years (2.9 to 13.0) in the cemented group.

Reoperations. A total of 26 knees required further surgery (Table III), 12 in the cemented and 14 in the cementless group. In the cemented group, the components were revised for aseptic loosening in one, for infection in five, polyethylene wear debris in one and for exchange of polyethylene inserts during procedures for patellar malalignment in two. Patellar resurfacing was undertaken for anterior knee pain in three cases; these were not included in the survival analysis. In the cementless group, components were revised for aseptic loosening in three, for infection in one and for exchange of polyethylene inserts in three implants. In one of these last three, the femoral component was deemed to be too large and was changed. Seven other reoperations were not included in the survival analysis. Patellar resurfacing was undertaken for anterior knee pain in four knees. Proven infection was successfully treated by arthrotomy, lavage and systemic antibiotics in two knees, and secondary patellar realignment was undertaken in one. No patient was awaiting revision surgery.

Life-table analysis and survival curves. The all-knee analysis included revision surgery for aseptic loosening, infection and exchange of the tibial polyethylene insert as the endpoint. Life-table analysis (Tables IV and V) showed a ten-year survival of 95.3% (95% confidence interval (CI), 90.3 to 97.8) in the cemented group and 95.6% (95% CI 89.5 to 98.2) in the cementless. Figure 1 shows the survival curve. Cox's analysis showed no apparent difference in the hazard of failure between the two groups (hazard ratio 0.97, 95% CI 0.36 to 2.60, p = 0.95). Adjustment for age, gender and diagnosis made no difference.

Using revision for aseptic loosening as the endpoint, the survival rates at ten years were 99.2% (95% CI 95.8 to 99.9) and 98.2% (95% CI 93.2 to 99.5) in the cemented and cementless groups, respectively. This difference was not statistically significant (hazard ratio 0.25, 95% CI 0.03 to 2.37, p = 0.23).

A greater number of cemented implants (5 cemented, 1 cementless) were revised for infection. Using revision for infection as the endpoint, the ten-year survival rates were 98.1% (95% CI 94.1 to 99.4) in the cemented group and 99.5% (95% CI 95.3 to 99.9) in the cementless. This difference was not statistically significant (hazard ratio 4.31, 95% CI 0.50 to 37.14, p = 0.18). Two other cementless implants, not included as revisions for the purpose of survival analysis, were complicated by deep infection, which was successfully treated by arthrotomy, debridement and lavage.

Table IV. Life-table survival analysis of the cemented press-fit condylar TKR with revision for all causes as endpoint

Years since operation	Number at start	Number revised	Withdrawn	Lost to follow-up	Number at risk	Effective number at risk	Annual failure rate (%)	Annual success rate (%)	Survival rate (%)	Confidence interval (%)
0 to 1	277	2	5	0	274.5	274.5	*0.7*	*99.3*	*99.3*	*97.4 to 99.8*
1 to 2	270	3	9	0	265.5	269.9	*1.1*	*98.9*	*98.1*	*95.7 to 99.2*
2 to 3	258	1	11	0	252.5	263.9	*0.4*	*99.6*	*97.8*	*95.2 to 99.0*
3 to 4	246	0	41	0	225.5	253.1	*0.0*	*100.0*	*97.8*	*95.1 to 99.0*
4 to 5	205	0	32	0	189.0	237.0	*0.0*	*100.0*	*97.8*	*95.0 to 99.0*
5 to 6	173	0	27	0	159.5	219.3	*0.0*	*100.0*	*97.8*	*94.8 to 99.0*
6 to 7	146	2	28	0	132.0	200.3	*1.5*	*98.5*	*96.3*	*92.7 to 98.1*
7 to 8	116	1	31	0	100.5	178.2	*1.0*	*99.0*	*95.3*	*91.2 to 97.6*
8 to 9	84	0	18	0	75.0	154.6	*0.0*	*100.0*	*95.3*	*90.8 to 97.7*
9 to 10	66	0	17	0	57.5	132.2	*0.0*	*100.0*	*95.3*	*90.3 to 97.8*
10 to 11	49	0	29	0	34.5	105.2	*0.0*	*100.0*	*95.3*	*89.4 to 98.0*
11 to 12	20	0	12	0	14.0	68.2	*0.0*	*100.0*	*95.3*	*87.5 to 98.3*
12 to 13	8	0	8	0	4.0	28.2	*0.0*	*100.0*	*95.3*	*80.8 to 99.0*

Table V. Life-table survival analysis of the cementless press-fit condylar TKR with revision for all causes as endpoint

Years since operation	Number at start	Number revised	Withdrawn	Lost to follow-up	Number at risk	Effective number at risk	Annual failure rate (%)	Annual success rate (%)	Survival rate (%)	Confidence interval (%)
0 to 1	224	1	10	0	219.0	219.0	*0.5*	*99.5*	*99.5*	*97.5 to 99.9*
1 to 2	213	3	7	0	209.5	214.1	*1.4*	*98.6*	*98.1*	*95.3 to 99.3*
2 to 3	203	1	5	0	200.5	209.4	*0.5*	*99.5*	*97.6*	*94.6 to 99.0*
3 to 4	197	0	26	0	184.0	202.4	*0.0*	*100.0*	*97.6*	*94.5 to 99.0*
4 to 5	171	0	23	0	159.5	192.1	*0.0*	*100.0*	*97.6*	*94.4 to 99.0*
5 to 6	148	0	23	0	136.5	179.9	*0.0*	*100.0*	*97.6*	*94.2 to 99.0*
6 to 7	125	1	26	0	112.0	165.5	*0.9*	*99.1*	*96.8*	*92.8 to 98.6*
7 to 8	98	1	35	0	80.5	146.2	*1.2*	*98.8*	*95.6*	*90.9 to 97.9*
8 to 9	62	0	22	0	51.0	121.1	*0.0*	*100.0*	*95.6*	*90.3 to 98.0*
9 to 10	40	0	6	0	37.0	98.7	*0.0*	*100.0*	*95.6*	*89.5 to 98.2*
10 to 11	34	0	19	0	24.5	77.4	*0.0*	*100.0*	*95.6*	*88.4 to 98.4*
11 to 12	15	0	12	0	9.0	47.4	*0.0*	*100.0*	*95.6*	*85.5 to 98.7*
12 to 13	3	0	3	0	1.5	13.0	*0.0*	*100.0*	*95.6*	*70.9 to 99.5*

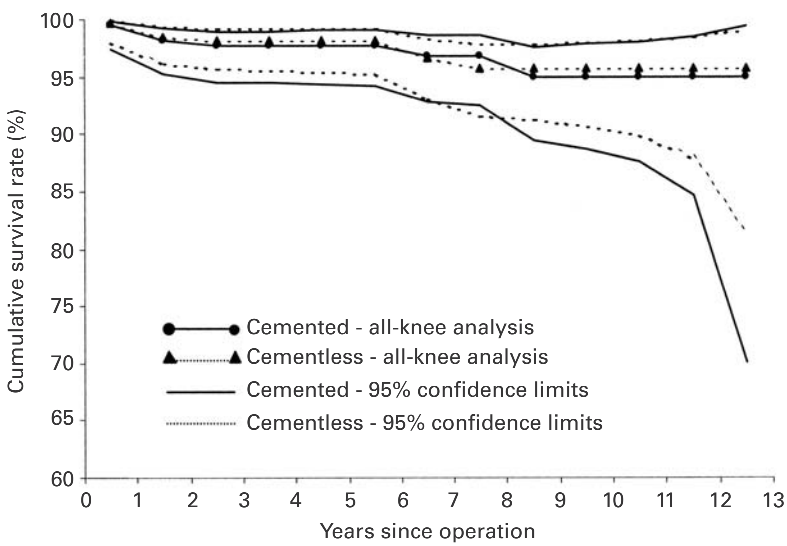

Fig. 1

Survival curves for all-knees analysis comparing cemented and cementless fixation.

The analysis was repeated for knees replaced before and after March 1993 because of the changes in the method of randomisation, which was introduced at that time. In each knee, adjustment was made for the effects of age, gender and diagnosis. No statistically significant difference was found in either time period.

Clinical outcome. Pre- and postoperative clinical outcome data were available for all patients, and the five-year outcome for this cohort has previously been reported.[11] Although an attempt was made to assess all patients clinically a complete ten-year clinical assessment was only made for 74 knees (44 cemented, 30 cementless), using the Nottingham Data Collection system.[3] Partial assessment was also possible for six knees (three in each group) in patients who were unable to attend for assessment but were interviewed over the telephone to obtain scores for parameters which did not require physical examination. Thus, some indication of clinical outcome was possible in 80 knees. We were not able to assess 11 knees in patients who were physically or mentally incapacitated.

In most knees in both groups, the scores for pain and mobility had improved at ten years. These are summarised in Figure 2. Using the Wilcoxon signed-rank test to compare the ten-year with the preoperative scores, there was a significant improvement in all parameters apart from the use of walking aids in which the improvement was not statistically significant (Table VI). A supplementary question regarding the use of walking aids at the ten-year assessment showed that most patients who used such an aid did so for reasons which were not related to the TKR.

In the cemented group, the mean change in the range of movement (ROM) at ten years was 10.1 ± 23.5° (SD) (-35 to 54); 28 of 44 implants had an improvement in ROM. Using the Wilcoxon signed-rank test, this improvement was significant ($p = 0.03$). In the cementless group, the mean change of range of movement at ten years was 0.0 ± 18.4° (SD) (-41 to 36); only 13 of 30 implants had an improved ROM. The change in ROM was not statistically significant. The evidence for a difference in the mean change in ROM between the groups was weak ($p = 0.07$) using the Wilcoxon-Mann-Whitney test.

During their clinical assessment, patients were asked how their knee felt compared with before surgery. In the cemented group, 42 patients were much improved, three

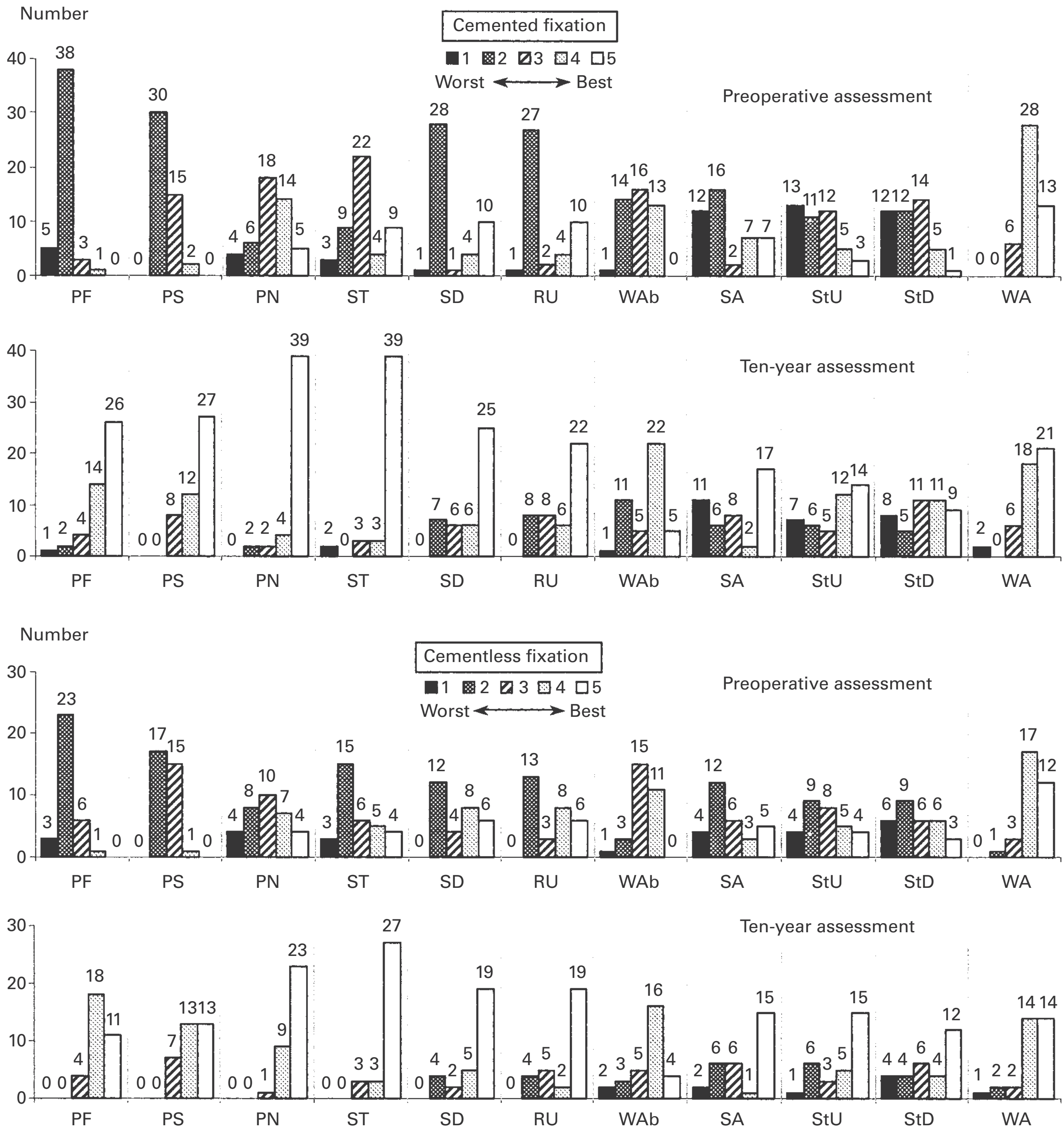

Fig. 2

Comparison of preoperative and ten-year assessment scores in parameters of the Nottingham Data Collection system (PF, pain frequency; PS, pain severity; PN, pain at night; ST, stability; SD, sitting down; RU, rising up; WAb, walking ability; SA, standing ability; StU, ability to step up; StD, ability to step down; WA, use of walking aids).

improved, one unchanged and one had deteriorated slightly. In the cementless group, 30 patients were much improved, two improved and one was unchanged. Using the Wilcoxon-Mann-Whitney test, there was no significant difference between the two groups ($p = 0.90$).

Radiological outcome. Radiographs were available for 74 knees (44 cemented and 30 cementless) at the ten-year review, and it was possible to evaluate radiolucent lines. The width of these lines was measured around both components on lateral radiographs and also around the tibial component on AP radiographs. The Knee Society scoring system[4] was used. In the cemented group, 41 knees scored 4 or less (no radiological indication for revision), three scored between 5 and 9 (requiring observation for progression) and none scored over 9, which is a score that implies impending failure regardless of symptoms. In the cement-

Table VI. Changes in outcome assessment at ten years after either a cemented or cementless press-fit condylar TKR compared with preoperative scores

	Nottingham Data Collection score*										
Group	**PF**	**PS**	**PN**	**WAb**	**WA**	**SD**	**RU**	**SA**	**StU**	**StD**	**ST**
Cemented											
Improved	43	45	39	21	12	26	24	20	29	25	34
No change	3	2	6	17	29	17	18	14	11	11	12
Deteriorated	1	0	2	6	6	1	2	10	4	8	1
Cementless											
Improved	31	29	28	14	8	19	19	18	17	17	28
No change	2	4	3	12	18	4	4	8	13	9	4
Deteriorated	0	0	2	4	7	7	7	4	0	4	1
p value between groups†	0.40	0.38	0.32	0.43	0.32	0.32	0.32	0.34	0.41	0.35	0.32

* PF, pain frequency; PS, pain severity; PN, pain at night; ST, stability; SD, sitting down; RU, rising up; WAb, walking ability; SA, standing ability; StU, ability to step up; StD, ability to step down; WA, use of walking aids

† comparison between cemented and cementless groups using a 2 × 2 chi-squared test. An unimproved group, formed by combining the no change and deteriorated group, was compared with the improved group

less group, 28 scored 4 or less, two scored between 5 and 9 and none scored over 9.

Discussion

Our study has shown that the long-term survival of the press-fit condylar knee prosthesis is very good. The ten-year survival rates, using revision for all causes as the endpoint, were 95.3% and 94.9% in the cemented and cementless groups, respectively. These rates compare well with the survivorship of 92% reported by the originators of the press-fit condylar knee.[12] The indication for many of their revision procedures was polyethylene wear of metal-backed patellar components, and the method of fixation included both cemented and cementless techniques.

The ten-year survival rates reported for other cemented prostheses are also comparable. These range from 92% to 99%; 92% for the Kinematic Condylar (Howmedica, Rutherford, New Jersey),[13] 95% for the Kinematic Stabiliser (Howmedica),[14] 98% for the Anatomical Graduated Components (Biomet Inc, Warsaw, Indiana),[15] and 92% and 99% for the Total Condylar Knee (Johnson & Johnson, New Brunswick, New Jersey and Howmedica).[16,17]

There are few long-term survival rates for cementless TKR in the literature. Jordan, Olivo and Voorhorst[18] reported an eight-year survival of 94.6% for the cementless meniscal-bearing low-contact-stress knee. The PCL-retaining low-contact-stress knee has a survival rate of 98% at six years,[19] but the number of prostheses in this cohort (57) was small. The performance knee has a survival rate at five years of 99%.[20] These are comparable with that of the cementless press-fit condylar knee in our series.

In our series, there was no loss to follow-up, which is probably due to the prospective recruitment and annual contact. Many survival analyses of TKR include a number of patients lost to follow-up ranging from 3% to 13% of the initial cohort.[13-17] The reported cumulative survival rates in these series may be an overestimation of the true survival rate.[21] Implant survival data for patients who have died are often not included and some of these prostheses may have been revised before death. We recommend that future reports should specify status of the implant in deceased patients.

Survival analysis is a widely accepted statistical method of reporting the long-term survival of implants in vivo. Clinical assessment is also an important indicator of outcome, and we have reported the clinical results at ten years in our cohort with reference to a preoperative baseline assessment. Other published survival analyses include only limited data concerning clinical outcome. In these reports either clinical assessment is collected and not reported,[22] postoperative scores are reported but not compared with preoperative scores,[14,17,23] or only preoperative scores are included.[13,16] The number of implants with clinical assessment at ten years in our series is only 16% of the original cohort and therefore represents only a minor indication of the clinical outcome. We plan to continue to review these patients for a larger sample for clinical outcome at ten years.

In our prospective, randomised controlled trial, there was no significant difference between cemented and cementless fixation both for survival rates after years and in clinical outcome. This concurs with a short-term retrospective matched-pair analysis of clinical outcome on a small cohort of press-fit condylar knees reported by Rand.[24] A longer-term outcome study on these patients[25] showed a significant deterioration in the survival of cementless implants. The survival rate at ten years was 94.2% and 72.7% in cemented and cementless fixation, respectively. The groups, however, contained small numbers of patients and were not well matched with regard to age; the cementless group was significantly younger, by about ten years. Rorabeck, Bourne and Nott[26] compared cemented and cementless fixation and reported better results with cemented fixation. Unlike the present study, their implants were of two different designs, which may account for the difference in survival. Collins et al[27] compared the method of fixation using implants of similar design and reported no difference in the short-term clinical outcome. Migration studies comparing the two methods of fixation have shown mixed results. Nilsson et al[28] described a computerised radiological analysis of the tibial component fixed with or without cement and concluded that there was no difference in the migration after two years. A later study showed no difference in migration of the femoral component after two years.[29] Albrektsson et al[30] showed significantly less migration of cemented implants at one year. More implants in the cementless group required revision at three years in this series. Önsten et al[31] showed cemented fixation to be superior to porous-coated cementless implants at the one- to two-year interval, but equivalent to cementless hydroxyapatite-augmented porous-coated implants.

In our series, although there were differences in the indication for revision between the two groups, these were not significant. The number of deep infections in the cemented (5) was greater than in the cementless group (1). The higher infection rate using cemented fixation cannot easily be explained. The use of cement with antibiotics is reported to be associated with lower rates of infection in total hip arthroplasty[32,33] when compared with the use of cement without antibiotics, but why this should be different when compared with cementless implants is uncertain. Nevertheless, infection remains a major cause of failure in the present series and efforts to minimise its incidence should continue.

The method of randomisation was changed during the study from pseudorandomisation according to year of birth, to the use of random numbers. The earlier assignment of treatment according to the year of birth resulted in an imbalance in numbers in each group. There was no apparent difference between the groups with either method of randomisation. Out of a consecutive series of 599 implants, 98 were excluded for reasons detailed in Table I, mostly because of unsuitability for cementless fixation as a result of poor bone stock, inadequate bone cuts or the need for bone grafting. It is possible that a high proportion would have received a cementless implant had they been included. Thus the cementless implants which were included may have been a select group. In this case, the study may therefore have been biased in favour of cementless implants. Despite this, no evidence of benefit of using cementless implants was found.

This randomised, controlled trial has failed to show significant differences in clinical outcome or ten-year rates of survival between cemented and cementless fixation using the press-fit condylar knee. In the UK, cementless implants are generally more expensive than their cemented counterparts and the difference is usually substantially larger than would simply be accounted for by the additional cost of cement. According to the confidence intervals, the lowest possible survival at ten years for cemented knees was 90.3%, compared with a highest possible survival of 98.2% for cementless knees. For every 100 cementless prostheses implanted, there could be eight fewer revisions required during a period of ten years. If the extra cost of 100 cementless prostheses compared with 100 cemented implants is greater than the cost of eight revisions, there is no clinical or economic justification for the use of cementless knee implants. Even if cementless prostheses are justified under this most optimistic view, it should be appreciated that our data have shown no evidence of benefit for cementless prostheses over cemented ones.

One or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

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