

Functional outcome of PFC Sigma fixed and rotating-platform total knee arthroplasty. A prospective randomised controlled trial

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Abstract The aim of this study was to determine whether there is a difference in functional outcome between the PFC Sigma fixed-bearing and rotating-platform total knee replacement systems. One hundred twenty patients were randomised to receive either a fixed-bearing or rotating-platform PFC Sigma total knee replacement. Range of movement (ROM), Oxford knee score (OKS) and Knee Society score (KSS) were assessed independently before and one year after surgery. Weight-bearing X-rays were taken immediately and one year post surgery to determine the incidence of osteolysis and loosening. At a mean follow-up of 13.4 months there was no statistically significant difference in mean ROM, OKS and KSS between the two groups. There was no evidence of osteolysis or loosening in either of the groups and no revision for infection or implant failure. This study shows that there is no statistically significant difference in functional outcome between the two types of implants at short-term follow-up.

Introduction

Mobile bearings in total knee arthroplasty have been developed with the aim to better reproduce the complex function and kinematics of the knee joint [1]. They allow a more natural tibial rotation during flexion than fixed-bearing implants. Their designs provide articulation at both

the upper and lower surfaces of the bearing, improving congruency and thus leading to a reduction of polyethylene contact stresses. Simulator studies have shown that this significantly lowers the wear rate compared to standard fixed-bearing knee replacements [2]. It has also been suggested that mobile bearings minimise stress at the tibial bone–prosthesis interface [3].

To date, however, there has been no convincing evidence that these theoretical advantages lead to an improvement in clinical outcomes and survivorship. Various studies have been published comparing mobile- and fixed-bearing knee replacements [4–10], but often different types and designs of prostheses were compared. The studies also differ in methodology, patient selection, operative technique and outcome measures. The Cochrane Review, published in 2004 [11], found that studies failed to report information in a standardised way and concluded that good quality clinical trials were needed to enable comparison between surgical techniques and prosthesis design.

In recent years a number of studies have investigated the functional outcome of the PFC Sigma fixed-bearing and PFC Sigma rotating-platform total knee replacement systems [12–17]. Only three of these are randomised controlled trials [15–17]. In two of these studies [15, 16] the patella was routinely resurfaced; in the third study the resurfacing status of the patella was not reported.

We carried out a randomised controlled trial comparing the functional outcome and survivorship between the fixed-bearing and rotating-platform PFC Sigma knee replacement systems. To our knowledge no prospective study has been published comparing these two designs without resurfacing of the patella using posterior cruciate ligament (PCL) retaining implants.

This study was approved by the local research ethics committee.

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Patients and methods

Between November 2001 and July 2005 patients who underwent a primary total knee arthroplasty for osteoarthritis under the care of two orthopaedic surgeons (senior authors) were invited to take part in this study. Patients were included if they were suitable for treatment with either a fixed- or mobile-bearing knee replacement system and had given written informed consent. Patients with rheumatoid arthritis and patients undergoing revision arthroplasty, requiring tibial component augmentation or a constrained prosthesis were excluded from the study.

The primary outcome measure was active range of motion (ROM) at one year after surgery. Secondary outcome measures were active flexion, active extension, Oxford knee score (OKS) [18], Knee Society score (KSS) [19] and survivorship at one year.

Patients were randomised to receive either a press-fit condylar Sigma fixed-bearing or rotating-platform knee replacement system (PFC Sigma or PFC Sigma RP, DePuy, Warsaw, Indiana). Two different randomisation schedules were used as the first 32 patients also took part in the Knee Arthroplasty Trial (KAT) [20]. The randomisation schedule for the KAT trial was generated by the Health Services Research Unit, University of Aberdeen, using a minimisation technique. For the subsequent patients a further randomisation schedule, blocked and stratified for treatment only, was produced by a biostatistician at DePuy International Ltd. The treatment allocation was concealed in sequentially numbered, darkened, sealed envelopes. The allocated envelope was opened on the day before surgery by the operating surgeon after consent had been obtained. Patients were not blinded to the knee type implanted.

The operations were performed by or under direct supervision of the two orthopaedic surgeons. All operating surgeons were experienced in the use of the PFC Sigma knee system and its instrumentation. The operation was carried out through a midline incision using a medial parapatellar approach. Intramedullary referencing was used for the femur and extramedullary referencing for the tibia. All femoral and tibial components were cemented. The posterior cruciate ligament (PCL) was retained in all cases. The patella was not resurfaced. A tourniquet was applied routinely. All patients received perioperative antibiotic and thromboprophylaxis.

All patients were mobilised fully weight-bearing using a walking frame or crutches for support from the first postoperative day. They followed a standard postoperative rehabilitation protocol.

Data about patient demographics, activity level, previous knee surgery, other joint pathologies, concomitant medical problems and medication were collected prior to surgery. A clinical assessment was carried out preoperatively and at a

minimum of one year after surgery. The functional outcome was evaluated by an independent physiotherapist or specialist nurse practitioner who was not blinded to the knee implanted, using range of motion, Oxford knee score (range 12–60) [18] and Knee Society (KSS) knee and function subscores (range 0–100) [19]. Range of motion was measured using a goniometer with the patient in the supine position. The pain subscore of the OKS was calculated summarising the score of all questions regarding pain (Q1, Q4, Q5, Q8, Q9 [score range 5–25]) and the function subscore summarising the score of all questions regarding function (Q2, Q3, Q6, Q7, Q10, Q11, Q12 [range 5–35]). Pain was quantified using the KSS pain subscore (range 0–50) and the pain subscore of the OKS (range 5–25). A low score in the OKS and a high score in the KSS indicate a good outcome.

Weight-bearing radiographs, anterior-posterior and lateral of the knee, were taken immediately postoperatively and at the follow-up assessment. They were analysed for osteolysis and signs of loosening by an independent radiograph reviewer using the Knee Society roentgenographic evaluation and scoring system [21].

Statistical analysis

Statistical analysis was performed with the use of SAS software (v9.1.3; SAS Institute, Cary, North Carolina, USA).

The collected data were summarised using descriptive statistics. Data were analysed on an intention-to-treat analysis. If the statistical assumption for normality was valid a two-sample *t*-test was used to compare PFC Sigma and PFC Sigma RP, otherwise a Wilcoxon rank sum test was used. *P*-values of less than 0.05 were considered to be statistically significant.

The sample size was calculated based on detecting a difference of 20 degrees in the postoperative range of motion (ROM) between the fixed- and mobile-bearing knee systems. This difference in range of motion was seen as clinically significant by the two operating surgeons. Assuming a two-sample *t*-test was used for the primary analysis, 48 patients in each treatment group were needed to identify a 20-degree difference based upon a significance level of 0.05, a power of 0.97 and a standard deviation of 25. To allow for an expected attrition rate of 25% we aimed to recruit 60 patients in each treatment group.

Results

One hundred twenty patients were recruited for this study. Twelve patients were lost to follow-up—six patients did not attend the follow-up clinics, four patients died within the first year after surgery of causes unrelated to the operative

procedure and two patients withdrew consent. Four patients were randomised to a mobile-bearing, but received a fixed-bearing implant due to problems with implant availability. Three patients had to be excluded from analysis. One patient sustained a patella fracture after a fall within the first year after surgery and in two cases tibial augmentation was necessary, which constituted a protocol violation.

This left 105 patients for analysis. Fifty-five patients received a fixed-bearing prosthesis and 50 patients a rotating-platform prosthesis. Mean age at surgery was 69.3 years (range 57–86) in the fixed-bearing group and 70 years (range 47–85) in the rotating-platform group. Demographics were similar in both groups with the exception of the gender ratio (Table 1).

Preoperative range of motion, flexion, Oxford knee score and Knee Society score did not differ between the two groups (Table 2). There was a statistically significant difference in extension between the groups ($p=0.017$), with the fixed-bearing group showing a greater mean fixed flexion deformity.

At a mean follow-up of 13.4 months (range 9.3–28.3 months) there was no statistically significant difference in range of motion between the fixed-bearing and rotating-platform groups. Mean flexion did not increase in either group, but mean extension improved significantly in both groups. The improvement in mean extension was statistically significantly higher in the fixed-bearing group ($p=0.041$). Ten patients (five in each group) had a persisting fixed flexion deformity with a mean of 6.6° (range 5–10°) at follow-up.

We found no statistically significant differences in any of the secondary outcomes including the OKS and KSS subscores with a similar improvement in both groups (Table 2). We observed no radiographic evidence of osteolysis or loosening in any knee in either group.

There were no intraoperative complications. In the postoperative period nine patients experienced complica-

tions. Two patients required drainage and washout of their knee due to infection (both rotating platform). The prostheses were found to be well fixed and without evidence of loosening in both cases. Three patients underwent a manipulation under anaesthesia for persistent stiffness within three months of operation (two rotating platform, one fixed bearing), and four patients developed a deep vein thrombosis or pulmonary embolism (three rotating platform, one fixed bearing).

There were no revisions at the one-year time point for early infection, loosening or bearing dislocation in either of the groups.

Discussion

The theoretical advantages of a mobile bearing design are attractive, but there has been no convincing evidence that these theoretical advantages translate into a benefit for the patient and deliver a better outcome in the short or long terms.

The Cochrane Review [11] highlighted that there were only few comparative studies with acceptable methodological quality [4, 5]. Inconsistent reporting did not allow for meta-analysis of the data. These findings were reiterated in a meta-analysis by Oh et al. [22]. It was therefore recommended that further trials needed to be undertaken, with a particular emphasis on patient selection from a homogenous group.

Since publication of the Cochrane review further studies have been reported, comparing mobile and fixed-bearing knee replacement systems. These include randomised controlled trials [6–8, 15–17, 23], prospective case series [9, 10] and retrospective reviews [12–14, 24]. In these studies a variety of knee replacements have been used, but often prostheses of different design and different manufacturers were compared with each other [6–10]. None of these studies showed a statistically significant difference between the mobile and fixed bearing, but the use of different types and designs of implants may have affected the clinical outcome as has previously been acknowledged by Biau et al. [24] and Kim et al. [15].

In the last few years a number of studies have been published comparing the results of a fixed and mobile bearing total knee arthroplasty using a similar design of prosthesis, i.e. the PFC Sigma total knee replacement system [12–17]. All of these studies, however, differ with regards to PCL status, implantation techniques (cemented or hybrid) and resurfacing of the patella (Table 3).

Ranawat et al. [12] reported results of a retrospective matched-pair analysis of 26 patients with osteoarthritis (25 patients) and rheumatoid arthritis (one patient) who had undergone a staged bilateral total knee arthroplasty (TKA).

Table 1 Patient demographics

Demographic	PFC Sigma	PFC Sigma RP
Number of patients	55	50
Gender ratio: male/female	33/22	20/30
Mean age (SD)	69.4 (7.9)	70 (8.4)
Mean height (SD)	167.4 (9.4)	165.5 (8.7)
Mean weight (SD)	81.9 (14.8)	82.1 (13.5)
Mean BMI (SD)	29.9 (5.4)	29.7 (6.1)
KSS category A	21	25
KSS category B	33	24
KSS category C	1	1

SD standard deviation, BMI body mass index, KSS Knee Society score

Table 2 Pre- and postoperative scores and difference in mean change between pre- and postoperative scores

Mean outcome scores	Preoperative			Oneyear follow-up			Difference in mean change (95% CI)	
	PFC Sigma	PFC Sigma RP	<i>p</i> -value	PFC Sigma	PFC Sigma RP	<i>p</i> -value	Sigma RP - Sigma	<i>p</i> -value
Range of motion (ROM) (°)								
Total ROM (SD)	95.7 (12.9)	96.5 (20.1)	0.404 ^a	100.8 (10.1)	101.0 (11.0)	0.910 ^a	-0.27 (-7.3 to 6.8)	0.941 ^c
Flexion (SD)	102.9 (11.1)	101.7 (17.5)	0.783 ^a	101.5 (9.8)	101.7 (10.7)	0.923 ^a	1.63 (-4.6 to 7.8)	0.605 ^b
Extension (SD)	7.2 (5.3)	5.2 (5.0)	0.017 ^a	0.7 (2.0)	0.7 (2.3)	0.681 ^a	1.89	0.041 ^a
Oxford knee score								
Total score (SD)	40.4 (7.6)	40.2 (7.8)	0.867 ^b	21.4 (7.0)	21.0 (6.2)	0.752 ^a	-0.66 (-4.3 to 3.0)	0.720 ^b
Pain subscore (SD)	17.3 (3.2)	17.6 (3.5)	0.572 ^b	8.1 (3.9)	7.9 (3.4)	0.946 ^a	-0.81 (-2.6 to 1.0)	0.368 ^b
Function subscore (SD)	23.1 (5.1)	22.5 (5.1)	0.608 ^b	13.3 (3.6)	13.1 (3.6)	0.677 ^a	0.12 (-2.0 to 2.2)	0.909 ^b
Knee Society score								
Total knee score (SD)	36.7 (11.9)	42.9 (14.6)	0.086 ^b	84.5 (16.2)	84.3 (15.8)	0.721 ^a	3.66	0.940 ^a
Total function score (SD)	43.5 (20.4)	44.5 (22.0)	0.854 ^a	76.7 (18.2)	76.4 (21.3)	0.758 ^a	0.25 (-9.1 to 9.7)	0.986 ^b
Pain score (SD)	7.3 (9.2)	6.9 (8.7)	0.831 ^a	41.7 (13.9)	42.6 (13.2)	0.616 ^a	1.87	0.387 ^a

Difference in mean change = Sigma RP - Sigma. 95% confidence interval (CI) only available through two-sample *t*-test

^a Wilcoxon rank sum

^b Two-sample *t*-test (equal variances)

^c Two-sample *t*-test (unequal variances)

All implants were posterior stabilised, cemented and the patella was resurfaced in all cases. However, in the fixed-bearing group metal-backed as well as all-polyethylene tibial components were used. There was also a statistically significant difference in preoperative scores between the groups, but no difference in postoperative scores. No analysis for improvement in scores was reported.

Luring et al. [14] investigated joint stability and muscular function in a retrospective matched-pair analysis of 40 patients with osteoarthritis. All patients received a PCL retaining prosthesis which was implanted using a computer-assisted technique. The patella was not replaced in either group. The authors showed no statistically significant difference in postoperative knee scores, but

Table 3 Overview of published studies comparing fixed-bearing and rotating-platform PFC Sigma knee replacement systems

Author	Year	PCL status	Cement	Patella	Methodology	<i>N</i> ^a	Side	Dx	Outcomes	Follow-up
Cheng et al. [17]	2009	Retained	Not available	Not available	RCT	76 knees	Uni- and bilateral	OA	ROM, flexion, extension	1 and 4 years
Laedermann et al. [16]	2008	Post stabilised	Cemented	All resurfaced	RCT	90 knees	Unilateral	OA	KSS, VAS, SF-12, X-ray	Mean 7.1 y
Kim et al. [15]	2007	Retained	Cemented	All resurfaced	RCT	174 patients	Bilateral	OA, RA	KSS, HSS	Mean 5.6 y
Evans et al. [13]	2006	Retained	Mixed	All resurfaced	Retrospective review	190 knees	Mixed	OA	Flexion, ROM	Min 2 y
Luring et al. [14]	2006	Retained	Not available	Not resurfaced	Retrospective matched-pair	40 knees	Unilateral	OA	KSS, Womac	2 y
Ranawat et al. [12]	2004	Post stabilised	Cemented	All resurfaced	Retrospective matched-pair	26 patients	Bilateral	OA, RA	KSS, X-ray	46/16 months

PCL posterior cruciate ligament, RCT randomised controlled trial, Dx diagnosis, OA osteoarthritis, RA rheumatoid arthritis, KSS Knee Society score, ROM range of motion, VAS visual analogue scale, HSS Hospital for Special Surgery Score

^a Number of patients included in final analysis

found statistically significantly better results for isokinetic muscle force in flexion and medio-lateral stability in flexion for the rotating bearing group.

Evans et al. [13] carried out a retrospective review of 170 patients (223 knees) with osteoarthritis. The PCL was retained and the patella resurfaced in all patients. The implantation technique, however, was not consistent and the analysis included all-cement and hybrid (femoral component uncemented) fixation. There was no statistically significant difference in change in range of motion at a minimum follow-up of two years.

Kim et al. [15] reported the results of a randomised controlled trial of 174 patients (348 knees) with osteoarthritis and rheumatoid arthritis (one patient) who underwent simultaneous bilateral TKA. The PCL was retained and the patella resurfaced in all patients. All implants were cemented. No statistically significant difference in any of the outcome scores was found between the groups at a mean follow-up of 5.6 years. The study population, however, was derived from an Asian population with a comparably low mean height and weight. Results may therefore not be transferable to a western European population.

A further randomised controlled trial was carried out by Laedermann et al. [16] including 90 patients with osteoarthritis who underwent a unilateral TKA. In all patients a posterior-stabilised implant was used and the patella resurfaced. All prostheses were cemented. There was no statistically significant difference in clinical and radiological outcomes between the groups at a mean of 7.1 years.

The most recent randomised controlled trial by Higuchi et al. [17] reported the results of 68 patients (76 knees) with osteoarthritis who underwent unilateral or bilateral TKA. The PCL was retained in all patients, but neither patella resurfacing status nor implant fixation technique have been reported. The trial showed a statistically significantly greater improvement in extension at one year in the mobile bearing group. There was however no difference in ROM at four years between the groups.

Our randomised controlled trial of 120 patients who underwent unilateral knee replacement for osteoarthritis showed no statistically significant difference in functional outcome and survivorship between the mobile-bearing and rotating-platform in the PFC Sigma total knee replacement at a mean of 13.4 months. However, in our trial the PCL was retained in all cases, all implants were cemented and the patella was not resurfaced. Results of this combination have not been previously reported.

As in previous trials we found no statistically significant difference in overall range of motion between the groups. The fixed-bearing group however showed a statistically significantly greater improvement in extension compared to

the mobile-bearing group. This may be explained by the fact that the fixed-bearing group had a statistically significantly greater preoperative mean flexion deformity. It has recently been shown by Cheng et al. [25] that subjects with a pre-existing fixed flexion deformity had a statistically significantly greater improvement in extension than subjects without, due to operative correction of the deformity.

Many different designs for mobile bearings exist, based on a glide or rotating mechanism with uni- or multidirectional motion. The rotating platform, as used in the PFC Sigma RP knee replacement system, has unidirectional motion which has been shown to have less volumetric wear than other mobile designs [12]. In our short-term follow-up we found no evidence of increased wear, loosening or osteolysis for either the mobile or fixed bearing. We also did not encounter any bearing dislocations, which has been described as a potential complication of mobile-bearing implants in other studies [26, 27].

The strengths of this study include its design as a randomised controlled trial with adequate power. Also, we reduced confounding factors by the use of two prostheses of similar design from the same manufacturer, consistent PCL status, inclusion of patients with the same form of arthritis and independent assessment of clinical and radiological outcome scores. We also used common outcome measures and aimed to report data in a standardised way to enable inclusion of the data in future meta-analyses.

The weaknesses of our trial include a relatively high rate of exclusion from analysis and loss to follow-up. Patients and assessors were not blinded with regards to the implant they received, which could have influenced the outcome in favour of the mobile bearing. This however seems unlikely as the use of the mobile bearing was not associated with a better outcome.

In conclusion, our study showed no statistically significant difference in functional outcome and survivorship between the fixed-bearing and mobile-bearing design of the PFC Sigma knee replacement system in the short-term. Long-term follow-up will determine if there is an increased rate of wear or loosening in either group. Based on the current results no type of bearing can be recommended over the other.

Conflict of interest This study has been sponsored by DePuy International who have provided resources to cover the additional costs of conducting the research over and above standard clinical practice as well as statistical support. None 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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