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Comparison of the PFC Sigma Fixed-Bearing and Rotating-Platform Total Knee Arthroplasty in the Same Patient

Short-Term Results

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Abstract: This study compares the fixed-bearing PFC Sigma Total Knee Arthroplasty to the recently introduced rotating-platform version of the same design in 26 patients. At an average follow-up time of 46 months for the fixed-bearing side and 16 months for the rotating-platform side, no significant differences were found in terms of knee preference, knee pain, range of motion, overall satisfaction, or Knee Society scores (KSSs). No revisions, subluxations, dislocations, or infections were seen. Also no radiographic evidence of component loosening, osteolysis, or malalignment was found in any knee. The results of cementing the PFC Sigma rotating-platform, posterior-stabilized total knee show excellent patient satisfaction at 1 year and comparable clinical and radiographic results to the fixed-bearing version. **Key words:** total knee arthroplasty, mobile-bearing, rotating-platform, fixed-bearing, patient outcomes.

In October 2000, the press-fit condylar Sigma rotating-platform (PFC SigmaRP) total knee arthroplasty (TKA) (DePuy Orthopedics, Warsaw, IN) was introduced in the United States after a multicenter, preclinical trial in Europe in more than 3,000 knees (Fig. 1). The design features of the PFC SigmaRP take advantage of improvements over the PFC modular TKA (DePuy Orthopedics) introduced in 1990 and the 20-year experience gained with the New Jersey low-contact stress (LCS) mobile-bearing knee (DePuy Orthopedics) [1].Currently, these are the only 2 primary rotating-platform knee implants with US Food and Drug Administration (FDA) approval. The purpose of this study was to compare the fixed-bearing and rotating-platform designs of the PFC Sigma total knee system in the same patient.

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Materials and Methods

Between December 2000 and October 2001, 3 surgeons performed 163 consecutive primary total knee arthroplasties with the PFC SigmaRP in 141 patients. In this consecutive series, only 2 patients received fixed-bearing TKA (one because of patient choice and one because of surgeon choice as a result

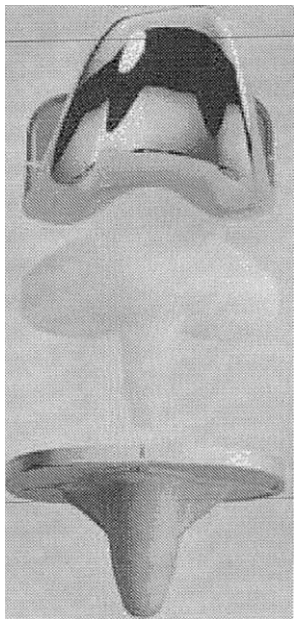

Fig. 1. Photograph of the PFC Sigma rotating-platform prosthesis.

of post-traumatic arthritis with significant preoperative instability). From this prospective cohort, 26 patients were identified in whom the fixed-bearing version of the same PFC Sigma design had been previously implanted in the opposite knee. In this patient-matched series, 16 of the fixed-bearing knees were metal-backed and 10 were all-polyethylene. Seventeen patients (34 knees) were women, and 9 patients (18 knees) were men. The average patient age at surgery was 74 years (range, 50–89 years). The diagnosis was osteoarthritis in 25 patients and rheumatoid arthritis in one patient. Coronal deformity was varus in 44 knees and valgus in 8 knees.

The procedure, described by the senior author (C.S.R.), has been well documented [2]. All components were fixed with cement. All patellae were resurfaced with a polyethylene button. All implants were posterior stabilized. All patients followed the same postoperative rehabilitation protocol, described elsewhere [3].

Patients were evaluated with self-administered patient assessment questionnaires that include analogue scales (rated 0 through 10) to determine levels of knee pain, knee preferences, and overall satisfaction. Additionally, patients were directly questioned on which knee bends more and how many blocks they can walk. When patients could not complete the form during follow-up visits, further information was acquired via phone interview. The patients and the assessor (R.R., I.L.) were blinded with respect to type of implant. Clinical and radiographic evaluations were assessed using the KSS in an unblinded fashion by the senior surgeon (C.S.R.) [4,5]. Clinical range of motion (ROM) was measured using a combination of visual inspection and goniometer recordings by the senior surgeon (C.S.R.). Data were collected and tabulated using Microsoft Excel (Redmond, WA). Mann-Whitney testing of continuous variables for KSS, pain scores, satisfaction scores, and ROM were performed using GraphPad InStat statistical software (GraphPad Software, San Diego, CA). P values less than .05 were considered significant.

Preoperative, early postoperative, and final follow-up standing anteroposterior, lateral, and Merchant views radiographs were evaluated, according to the method of the Knee Society, for radiolucency at the bone–cement interfaces around the 3 components, any change in the position of the components, femorotibial alignment in the coronal plane, and osteolysis [5].

Results

At an average follow-up time of 46 months (range, 18–132 months) for the fixed-bearing side and 16 months (range, 13–21 months) for the rotating-platform side, 12 of 25 patients (48%) could not distinguish between the 2 designs with respect to preference or range of motion. No patient was lost to follow-up evaluation. One patient had incomplete questionnaire data and was excluded from analysis. Nonetheless, clinical KSS and radiographic evaluations were performed on all 26 patients.

Average knee pain was rated 0.80 and 0.92 for the fixed-bearing and rotating-platform sides, respectively (0, no pain; 10, severe pain; $P = .94$). Overall satisfaction was rated 8.9 and 9.2, respectively (10, completely satisfied; 0, unsatisfied; $P = .66$). Five patients preferred the rotating-platform side. Eight patients preferred the fixed-bearing side (2 were all-polyethylene; 6 were metal-backed).

The average preoperative clinical and functional KSS for the fixed-bearing side were 56 points (range, 40–70 points) and 50 points (range, 20–80 points), respectively, and the average scores at final follow-up evaluation were 96 points (range, 83–100 points) and 96 points (range, 65–100 points), respectively. The average clinical and functional KSS for the rotating-platform side were 49 points (range, 24–77 points) and 48 points (range, 30–60 points), respectively, preoperatively and 96 points

(range, 60–100 points) and 95 points (range, 65–100 points), respectively, at the final follow-up evaluation. Preoperatively, the rotating-platform side was significantly worse than the fixed-bearing side (combined KSS rotating-platform = 97, fixed-bearing = 106, p = 0.01). There were no significant differences between the two sides post-operatively (combined KSS rotating-platform, 191; fixed-bearing, 192; $P = .63$).

The preoperative femorotibial angle in the coronal plane for the fixed-bearing side averaged 4° of varus (range, 20° of valgus to 20° of varus), and at the final follow-up evaluation averaged 5° of valgus (range, 6° of valgus to 3° of valgus). The preoperative femorotibial angle in the coronal plane for the rotating-platform side averaged 3° of varus (range, 11° of valgus to 20° of varus), and at the final follow-up evaluation averaged 5° of valgus (range, 9° of valgus to 3° of valgus).

The average active range of motion for the fixed-bearing side was from 2° (range, 0° to 15°) to 116° (range, 100° to 130°) preoperatively and from 0° (range, 0° to 5°) to 119° (range, 110° to 125°) at final follow-up evaluation. The average active range of motion for the rotating-platform side was from 2° (range, 0° to 10°) to 119° (range, 70° to 130°) preoperatively and from 0° (range, 0° to 5°) to 120° (range, 110° to 125°) at the final follow-up evaluation. No significant difference was seen between preoperative or postoperative ROM for the 2 sides ($P = .15$ and $P = .24$, respectively).

Based on patient responses to questionnaires, 19 fixed-bearing knees were not painful (pain rating, 0 or 1), 5 were mildly painful (pain rating, 2, 3, or 4), one was moderately painful (5, 6, or 7), and none had severe pain (9 or 10). On the rotating-platform side, 19 knees were not painful, 4 were mildly painful, 2 were moderately painful, and none had severe pain. Nine patients could walk an unlimited distance, 6 patients could walk between 10 and 20 blocks (one half to one mile), and 10 patients could walk between 5 and 10 blocks. No patients were limited to household ambulation.

No revisions or infections occurred. Additionally, no subluxations or dislocations of any bearings were seen. One rotating platform knee underwent successful manipulation. No other complications occurred.

Radiographs of the 52 knees showed little radiolucency at the bone–cement interfaces around the components (Fig. 2). No knee had any circumferential radiolucency around any of the 3 components. No knee had radiolucency in more than 2 zones around the tibial or femoral component. In one fixed-bearing knee, a radiolucent line was seen in 2 zones around the patellar component without evidence of osteolysis or synovitis. One mild patellar tilt was seen in each of the 2 groups.

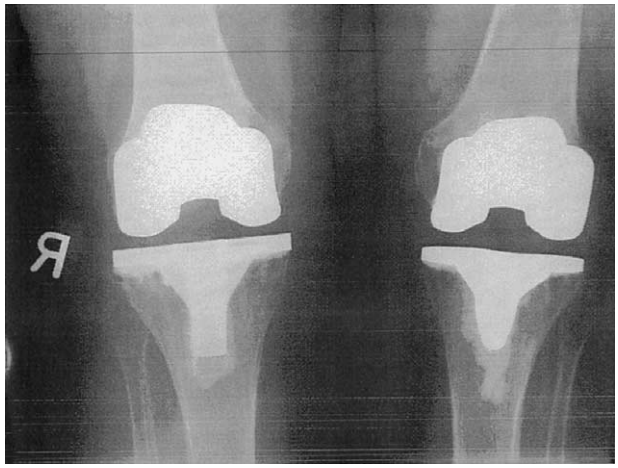

Fig. 2. Radiograph of 3 year follow-up of PFC Sigma fixed-bearing on the right and 1 year follow-up of the PFC Sigma rotating-platform on the left.

Discussion

Many different designs, whether fixed-bearing or mobile-bearing, have documented long-term durability [6–14]. The "gold standard" at our center has been a one-piece, posterior-stabilized, all-polyethylene tibial component fixed with cement. This fixed-bearing design has produced excellent long-term results, with survivorship of 95% at 15 years and 90% at 20 years [15].

Nonetheless, in response to published biomechanical studies supporting metal-backed tibial components, we have also frequently cemented modular designs with metal tibial baseplates starting in the early 1980s [16]. Several reports have documented an increased incidence of backside polyethylene wear with these modular components [17,18]. We chose to implant a consecutive series of the recently introduced PFC SigmaRP design in December of 2000 with the hope of addressing this issue. To our knowledge, this is the first published report using this prosthesis.

The PFC SigmaRP uses the same femoral component as the existing PFC Sigma knee and is part of its integrated total knee system. The tibial component is a highly polished, 4.8-mm thick, chromium-cobalt baseplate. Other advantages include almost full conformity in both the coronal (1.03:1) and sagittal (1.021:1) planes and a 16-mm post in the posterior-stabilized version to protect against bear-

Table 1. Summary of Results

	Fixed-Bearing	Range	Rotating-Platform	Range	*P* Value
Preoperative KSS	56	40–70	49	24–77	
Preoperative KSFS	50	20–80	48	30–60	
Postoperative KSS	96	83–100	96	60–100	
Postoperative KSFS	96	65–100	95	65–100	
Combined preoperative scores	106		97		.01
Combined postoperative scores	192		191		.63
Average follow-up	46	18–132 mo	16	13–21 mo	
Average knee pain	.80	0–10	0.92	0–10	.94
Satisfaction	8.9	0–10	9.2	0–10	.66
Preoperative deformity	4° varus	20° valgus-20° varus	3° varus	11° valgus-20° varus	
Postoperative deformity	5° valgus	3–6° valgus	5° valgus	3–9° valgus	
Preoperative ROM	2–116°	0–15°, 100–130°	2–119°	0–10°, 70–130°	.15
Postoperative ROM	0–119°	0–5°, 110–125°	0–120°	0–5°, 110–125°	.23

Abbreviations: KSS, knee society score; KSFS, knee society functional score; ROM, range of motion.

ing dislocation, which is always a concern with these designs. No dislocations occurred in this study group, and only 2 cases of mild, temporary subluxation were seen in the entire cohort of 368 knees. We believe this is also an indication of our meticulous attention to flexion gap stability.

Unlike some other mobile-bearing designs found mainly in Europe, the PFC SigmaRP knee has unidirectional motion that has been shown to produce significantly less wear than multidirectional knees [19]. Thus, it is safe to say that not all mobile-bearing designs are alike. That being said, McEwan et al. has shown significantly decreased volumetric wear (3 times less) with a unidirectional, rotating-platform design (LCS) compared with the fixed-bearing PFC Sigma knee in knee simulator studies (internal data, DePuy International, Leeds, UK). Other similar studies have also documented significant theoretical advantages of the highly conforming rotating-platform design in terms of wear reduction and improved kinematics [20–24]. Nonetheless, no clinical study to date has shown superior results with the rotating-platform design over a fixed-bearing one [25]. According to Callaghan [26], "if mobile-bearing knee replacements are inserted with the same precision as fixed-bearing knee replacements, the results should at least be comparable." This patient-matched study has confirmed that notion.

Some improvement appeared to occur in overall ROM with the newer PFC SigmaRP design compared with the LCS rotating knee. Two separate studies have shown an average ROM of 102° and 110° with the cemented LCS rotating-platform, which was often considered a short-coming of this design [6,8]. Our average ROM is at least 10° more than previously reported for cemented rotating-platform knees. One reason for this may be the improved design characteristics of the PFC Sigma femoral component and its optimal post to cam placement on the tibial plateau.

However, several weaknesses can be noted with our study. First, our small study group was extracted from a larger consecutive cohort. This selection can confound results and may not be applicable to the group as a whole. This was done as an initial review of our experience with this new prosthesis. The 2-year follow-up results of the entire cohort will be published in 2004. Second, the demographics of our select group suggest a somewhat older patient population with a moderate activity level and associated comorbidities. Finally, we are comparing the 1-year follow-up data of the rotating-platform design with the 4-year follow-up data of the fixed-bearing design, with its attendant differences. Nevertheless, studying 2 knee designs in the same patient eliminates variability by means of an internal control and, therefore, provides a more meaningful comparison.

Whether or not the PFC SigmaRP design is a significant improvement over the existing fixed-bearing version remains to be seen. Our initial experience has shown excellent patient satisfaction at 1 year and comparable clinical and radiographic results.

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