

# Midterm results of cemented Press Fit Condylar Sigma total knee arthroplasty system

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## ABSTRACT

**Purpose.** To evaluate the midterm results of 50 patients who underwent total knee replacement using Press Fit Condylar (PFC) Sigma system.

**Methods.** We retrospectively reviewed 87 consecutive cases (50 patients with 37 bilateral cases) of PFC Sigma total knee replacement performed between January 1998 and December 1999. Patients were evaluated clinically and radiographically by an independent observer. The American Knee Society Score, Oxford Knee Score, and Knee Society radiographic assessment were used to rate knee function and to determine the satisfaction level of each patient.

**Results.** The mean age of the patients at the time of operation was 65 years (range, 41–85 years). The mean follow-up period was 5.4 years (range, 4.5–6.4 years). 44 patients (79 knees) were available for follow-up, 3 patients (3 knees) were lost to follow-up, and 3

patients (5 knees) died of unrelated causes. At the final follow-up, the mean Oxford Knee Score was 22. Using the American Knee Society Score, 88% of the knees were rated excellent, 4% good, 2% fair, and 6% poor. Five knees required revision surgery, the indications being infection in 4 knees and aseptic loosening in one knee. The survival rate of the implants was 94% at 6 years.

**Conclusion.** The PFC Sigma total knee arthroplasty system has demonstrated good midterm results at our institution.

**Key words:** arthroplasty, replacement, knee; knee prosthesis; prostheses and implants; prosthesis design

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## INTRODUCTION

Total knee replacement is becoming increasingly popular worldwide due to improvements in the

technology and durability of implants. In the United States, the number of knee replacements has surpassed the number of hip replacements.<sup>1</sup> The prevalence of arthritis, including osteoarthritis and rheumatoid arthritis, continues to increase with age for people 65 years or older. Clinical decisions for selecting one implant over another must be supported by clinical results.<sup>2</sup>

The design of the Press Fit Condylar (PFC) Sigma (DePuy, Warsaw [IN], US) total knee arthroplasty (TKA) prosthesis was based on the earlier PFC implant. Design features include modularity to improve intra-operative adaptability, and a deep and extended trochlear groove with a matching single radius dome patella, allowing the patellar component to maintain maximum contact of up to and beyond 90° of flexion. This implant was introduced to our institution in late 1997. This study evaluates the midterm clinical and radiological results of TKA using the PFC Sigma prostheses.

## METHODS

We retrospectively reviewed 87 TKAs performed by a number of surgeons in 50 patients (46 women and 4 men) using the PFC Sigma prostheses at the University of Malaya Medical Centre between January 1998 and December 1999. All cases used cemented fixation.

### Clinical evaluation

Knees were stratified into 3 categories according to Halley and Charnley<sup>3</sup>: 36 in category A (unilateral or bilateral TKA), 8 in category B (one knee symptomatic but not replaced), and 6 in category C (multiple arthritis or medical infirmity). At follow-up, patients were evaluated clinically by an independent observer using the American Knee Society Score<sup>4</sup> and the Oxford Knee Score.<sup>5</sup>

The American Knee Society scoring system<sup>4</sup> comprises a knee score and a functional score. Knees are examined for range of motion, flexion contractures, extension lag, alignment, and stability in the anteroposterior and mediolateral plane. The maximum score for each of the knee and functional scores is 100 points. The knee score includes pain (50 points), range of motion (25 points), and anteroposterior and mediolateral stability (25 points). Deductions are made for flexion contracture, extension lag, and alignment. The functional score includes walking (50 points) and stair climbing (50 points). Deductions are given for walking aids. Scores of 80 to 100 were rated as excellent, 70 to 79 good, 60 to 69 fair, and less than 60 poor.

The Oxford Knee Score<sup>5</sup> is a patient-based outcome assessment of patient response to surgery. It consists of 12 questions, each with 5 items. The highest score is 12 points and the lowest is 60. Patients are asked to complete a questionnaire about their symptoms with the assistance of a nurse.

### Radiographic evaluation

Weight-bearing radiographs of the knees were analysed for loosening and evidence of failure according to the Knee Society radiographic assessment.<sup>6</sup> This assessment includes evaluation for radiolucent lines on anteroposterior and lateral radiographs, and of alignment of the prosthesis. A radiolucent line of greater than 2 mm around the entire circumference of the prosthesis, subsidence of the component, or a change in alignment from a previous radiograph signified a radiographically loose prosthesis.

## RESULTS

Of the 50 patients (46 women and 4 men), 37 underwent simultaneous bilateral TKA. The mean age of the patients at the time of index operation was 65 years (range, 41–85 years). The indications for surgery were osteoarthritis in 44 patients and rheumatoid arthritis in 6 patients. 44 patients (79 knees) were able to return for clinical evaluation. Three patients (5 knees) died of unrelated causes and 3 patients (3 knees) were lost to follow-up. The mean follow-up period was 5.4 years (range, 4.5–6.4 years). The posterior cruciate ligament (PCL)-retaining implant was used in 53 knees, while the PCL-substituting implant was used in 26 knees. The patella was resurfaced in 34 knees and was not resurfaced in 45 knees. The implant survival rate was 94% at 6 years.

### Clinical results

At the final clinical assessment, using the American Knee Society scoring system, the mean knee score was 87 points (range, 48–99; standard deviation [SD], 11.06). The mean functional score was 72 points (range, 0–100; SD, 20.27); 88% of knees were rated excellent, 4% good, 2% fair, and 6% poor. Five knees in 3 patients were rated poor. Two of these patients had undergone bilateral TKA for rheumatoid arthritis, and both were homebound because of multiple joint problems and medical illness. The third patient had a functioning unilateral knee but remained homebound because

**Table 1**  
Oxford Knee Score

Oxford Knee Score	No. of patients, n=44
12–17	10
18–23	23
24–29	6
30–35	2
36–41	1
42–47	2

**Table 2**  
Comparison between patients with osteoarthritis and rheumatoid arthritis\*

	Osteoarthritis	Rheumatoid arthritis	p value
American Knee Society scores			
Knee score	88 (10)	79 (14)	0.10
Functional score	73 (19)	57 (25)	0.03
Oxford Knee Score	21 (6)	30 (10)	0.006

\* Values are expressed in mean (SD) unless otherwise stated

**Table 3**  
Comparison between patients with and without resurfaced patella\*

	Resurfaced patella		p value
	No	Yes	
American Knee Society scores			
Knee score	88 (9)	85 (13)	0.26
Functional score	72 (16)	71 (25)	0.76
Oxford Knee Score	22 (7)	22 (7)	0.90

\* Values are expressed in mean (SD) unless otherwise stated

**Table 4**  
Comparison between posterior cruciate ligament-retaining and -substituting implants\*

	PCL retaining	PCL substituting	p value
American Knee Society scores			
Knee score	88 (9)	85 (14)	0.43
Functional score	75 (17)	66 (24)	0.38
Oxford Knee Score	21 (6)	24 (8)	0.21

\* Values are expressed in mean (SD) unless otherwise stated

of severe spinal stenosis. The mean Oxford Knee Score was 22 (range, 16–46; SD, 6.76) [Table 1].

We compared the American Knee Society knee and functional scores and the Oxford score between patients diagnosed with osteoarthritis and rheumatoid arthritis using the Student's *t* test. No significant difference was found between the 2 groups on knee score ( $p=0.10$ ) or functional score ( $p=0.03$ ); the only statistically significant difference was found with the Oxford Knee Score ( $p=0.006$ ) [Table 2]. When comparing patients who underwent resurfacing of the patella with those who did not, no significant difference was found between the 2 groups on knee score ( $p=0.26$ ), functional score ( $p=0.76$ ), or Oxford Knee Score ( $p=0.90$ ) [Table 3]. When comparing patients who received PCL-retaining implants with those who received PCL-substituting implants, again, no significant difference was found between the 2 groups on knee score ( $p=0.43$ ), functional score ( $p=0.38$ ), or the Oxford Knee Scores ( $p=0.21$ ) [Table 4].

At the most recent follow-up, relief of pain was excellent in most patients: 82% had no pain or very mild pain, 13% had pain while climbing stairs, and 5% had moderate pain; 59% could walk farther than

10 blocks or more than one hour, and 91% did not use assistive devices for ambulation.

At final clinical assessment, the mean active flexion was 105° (range, 20°–130°). The mean flexion contracture was 0.6° (range, 0°–15°). 21 knees had more than 5° of mediolateral instability, and only one knee had more than 10 mm of anteroposterior instability.

### Radiographic results

The tibiofemoral angle was 5° to 8° valgus in 64 knees, 0° to 4° valgus in 8 knees, and 0° to 8° varus in 7 knees. The mean femoral component alignment from the anteroposterior view was 96° (range, 94°–99°; SD, 0.97°), and the mean tibial component alignment from the anteroposterior view was 90° (range, 87°–95°; SD, 2.19°). The mean posterior slope of the tibia was 1.03° (range, 0°–7°; SD, 1.75°).

No knees were found to have aseptic loosening of the tibial, femoral, or patellar components by American Knee Society criteria at final follow-up. Radiolucent lines of 1-mm thick were present around zones 1 and 2 in 6 tibial components, and around zone 1 in 4 femoral components.

## Revision operations

Five knees (4 patients) required revision surgery: 4 knees (3 patients) because of deep infection and one knee due to aseptic loosening of the tibial component.

Of patients with deep infection, one presented with swelling and erythema around the knee at postoperative 2 months. A 2-stage revision was performed after 6 months. At the final follow-up, the patient's knee and functional scores were 76 and 60 points, respectively. The second patient presented with a history of pain in both knees for more than one year and was scheduled for simultaneous bilateral TKA. During the surgery, slough was found in the left knee. The knee surgery was aborted and tissue was sent for culture and histopathology. The cultures were negative, and the histopathology report indicated chronic inflammatory disease. The operation was resumed 4 weeks later. One week postoperatively, the patient developed fever and had discharge from the left knee. An arthrotomy and washout was performed, and tissue was taken for culture. The cultures grew methicillin-resistant *Staphylococcus aureus* (MRSA). The patient was given intravenous vancomycin for 6 weeks, and was then discharged and received oral fusidic acid and rifampicin for 3 months. After 2 years, the patient presented with pain in the left knee, this time with loosening of the implant. A one-stage revision was carried out after infection was ruled out by intra-operative frozen section and gram stain. At final follow-up, the patient's knee and functional scores were 78 and 60 points, respectively. The third patient also underwent simultaneous bilateral TKA, and presented at postoperative one month with a discharging sinus on the left knee; aspirate cultures grew MRSA. A 2-stage revision was performed. The patient presented again 2 years later with swelling of the right knee; aspirate culture grew MRSA. A 2-stage revision was subsequently performed on the right side as well. At final follow-up, this patient's knee score was 87 for the left side and 89 for the right side, and his functional score was 90.

One patient with rheumatoid arthritis required revision of the tibial component after 2 years because of aseptic loosening; the tibial component had been inserted in 8° of varus at the primary surgery. At final follow-up, the patient's knee and functional scores were 69 and 55 points, respectively.

## DISCUSSION

TKA can provide excellent pain relief and restoration of function for patients. The success of the prosthesis

is based on implant survival, in addition to pain relief and restoration of function. This study found good-to-excellent midterm results with the PFC Sigma implant: 88% of the knees were rated excellent. There was only one failure because of technical problems: the tibial component was implanted in 8° of varus, which resulted in early aseptic loosening.

Infection was the major cause of failure. The high rate of infection can be attributed to the fact that the University of Malaya Medical Centre is a teaching university hospital with large turnover of medical personnel at all levels. The surgeries were performed by a number of surgeons with different levels of expertise. The infection rate has subsequently been improved with better training and the use of body exhaust suits. All 4 cases of infection arose in patients undergoing simultaneous bilateral knee replacements. It is difficult to say if bilateral operations resulted in higher rate of infection, because only 13 of the 50 patients underwent unilateral procedures. Bilateral knee replacements have been common at our hospital because these allow us to better cope with the demand for TKA. It has been shown that patients undergoing bilateral knee replacement are subjected to a minimally increased morbidity.<sup>7</sup> In spite of this, many of our patients with severe bilateral symptoms were grateful that they needed to endure only one admission, an attitude that has been noted in other studies.<sup>8</sup>

The overall infection rate in this series was comparable with those reported in other studies. Font-Rodriguez et al.<sup>9</sup> reported 3 failures, all due to infection, among 49 implants (Insall-Burstein II prostheses), with an overall 10-year success rate of 89%. In a series of 94 knees replaced with anatomic graduated component total knee implants, Alemparte et al.<sup>10</sup> reported 3 knees requiring revision, 2 due to infection, over a follow-up period of 2 to 8 years.

Respectively, American Knee Society mean knee and functional scores in the present study were 87 and 72 points with a mean follow-up period of 5.4 years, whereas Martin et al.<sup>11</sup> reported 88 and 72 points with a mean follow-up period of 6.5 years, Alemparte et al.<sup>10</sup> reported 89 and 64 points, and Buehler et al.<sup>12</sup> reported 96 and 68 points with a mean follow-up period of 9 years.

The mean Oxford Knee Score of this series was 22. The patients' scores were reduced largely because of their inability or unwillingness to kneel. Patients were routinely advised by their surgeons not to do so. The mean score on question 7 (Have you been able to kneel in the last 4 weeks?) was 5 (impossible). There was also some confusion between simple

kneeling (as during prayer in church) and kneeling with deep knee bends (as in the mosque) and squatting.

In this retrospective study, we did not have preoperative knee scores to compare with the final knee scores. Polyethylene wear was not reported because we were not able to confidently measure the liners due to rotation of some radiographs. Nonetheless, visual inspection of radiographs showed little discernable wear of the polyethylene liners. No evidence of osteolysis was seen. Three (6%) patients were lost to follow-up despite extensive efforts to contact them; Tooma et al.<sup>13</sup> reported 31% of patients lost to follow-up over 2.5 years, Martin

et al.<sup>11</sup> reported 5% over 6.5 years, and Alemparte et al.<sup>10</sup> reported 3.2%. Because the current failure rate of primary TKA was small, this small percentage of missing patients could have markedly affected the final results.

## CONCLUSION

The PFC Sigma total knee prosthesis continues to function well during a mean follow-up period of 5.4 years. These results are comparable to those of other midterm studies. We plan to continue monitoring this cohort for long-term analysis.

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