



## Medium term results with the Press Fit Condylar (PFC) Sigma knee prosthesis The Wrightington experience

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The PFC Sigma total knee was introduced in 1997, incorporating a number of design changes. We report the mid-term results of a consecutive series of PFC Sigma knee arthroplasties performed between November 1997 and December 1998. Out of a total of 156 patients (166 knees), 5 patients (5 knees) were lost to follow-up and 6 patients (6 knees) died of unrelated causes. This left 145 patients (155 knees), 90 female and 55 male, with a mean age of 70 years (range, 53-88) and an average follow-up of 90 months (range, 84-96). Posterior cruciate retaining components were used in 136 knees (88%) and posterior-stabilized in 19 (12%). The patella was resurfaced in 74 (48%) knees. Follow-up was at 3, 6 and 12 months, then yearly. Preoperative American Knee Society and Oxford scores were compared with follow-up scores. The Knee Society radiological score was used for radiographic assessment.

One knee (0.6%) was revised due to aseptic loosening. One knee (0.6%) had superficial wound infection, which settled with oral antibiotics. Two knees became deeply infected. Of these, one resolved following early debridement, the other developed chronic infection. Using revision for any reason as the end-point our cumulative success rate was 99.4%. The mean preoperative Knee score improved from 45 (30-65) to 84 (45-92), Functional score from 38 (25-55) to 73 (50-95) and Oxford score from 43 (33-52) to 17 (14-29). Radiographic review showed radiolucent lines in 54 (35%) tibial and 17 (11%) femoral components. The Radiological Knee Society score was less than 4 in all except one tibia where the score was 7.

**Our study shows excellent clinical results with the PFC Sigma total knee replacement after almost eight years follow-up.**

**Keywords :** total knee arthroplasty ; PFC Sigma ; mid-term results.

### INTRODUCTION

Total knee arthroplasty (TKA) is a standard and dependable method of treating severe knee arthritis (2, 4, 5, 10, 11, 13, 14, 16, 17, 18). It is becoming increasingly popular worldwide due to improvements in the technology and durability of implants. There are many different total knee replacements in the marketplace. Most have undergone design changes since their introduction. The design of the Press-Fit Condylar (PFC) total knee prosthesis (Johnson & Johnson, Raynham, Massachusetts, USA) was based on earlier successful implants

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such as the Total Condylar and Kinematic knees (12, 15). The Press Fit Condylar (PFC) was later changed to PFC Sigma with the main design changes being a deep and extended trochlear groove with a matching single radius dome all-polyethylene patella. The patellar articular surface has a central convexity and peripheral concavities to allow better patello-femoral contact.

In our institution, we started using the PFC Sigma implant in November 1997. Our study presents clinical and radiological results of the prosthesis implanted in the first year of its use, from November 1997 to December 1998.

### PATIENTS AND METHODS

Between November 1997 and December 1998 a consecutive series of 166 TKAs (156 patients) were carried out using the PFC Sigma total knee replacement system at Wrightington Hospital. The indications for operation were advanced degenerative change with severe pain on weight-bearing, impaired function, and limitation of daily activities. Out of the 156 patients, 5 patients (5 knees) were lost to follow-up and 6 patients (6 knees) died of unrelated causes. This left 145 patients (155 knees) with a mean follow-up of 90 months (range 84-96 months). Preoperative diagnosis was primary osteoarthritis in 136 knees (88%), rheumatoid arthritis in 14 (9%) and post-traumatic arthritis in five (3%). The mean age was 70 years (range, 53-88 yrs). There were 90 female and 55 male patients. A posterior cruciate-retaining prosthesis was used in 136 (88%) and a posterior stabilized in 19 (12%) knees. The patella was resurfaced in 74 (48%) knees. Indications for patellar resurfacing included rheumatoid arthritis, sero-negative inflammatory arthropathy and bony eburnation.

#### Surgical technique

All arthroplasties were performed in clean air operating theatres using body exhaust suits. Antibiotic prophylaxis was used routinely. Cefuroxime 1.5 gm i.v was given at induction with two post op doses of 750 mg, eight hours apart. The knees were exposed through a midline skin incision and medial parapatellar approach. Appropriate soft-tissue releases were done. Femoral preparation was done using an intramedullary alignment jig; an extramedullary jig was used for tibial preparation. Following the bone cuts, a trial reduction was done and the knee checked for soft tissue balance, flexion/

extension gaps and stability. Bone surfaces were washed using pulsatile lavage and dried. Definitive components were implanted using CMW 1 cement (De Puy, UK). Drains were placed routinely and removed 24 hours later. DVT prophylaxis was with daily subcutaneous Enoxaparin, until discharge from the hospital.

Physical therapy, comprising active and passive range of motion with weight-bearing as tolerated was started during hospitalization and continued upon discharge. All patients were followed prospectively at 3 months, 6 months, one year and then yearly. Clinical evaluation was done using the American Knee Society (7) and Oxford knee scores (3). The American Knee Society scoring system comprises a knee score and a functional score. The maximum score for each is 100. The knee score is divided between, pain (50 points), range of motion (25 points), and stability (25 points). Points are deducted for flexion contracture, alignment and extensor lag. The functional score includes walking (50 points) and stair climbing (50 points). Points are deducted for walking aids. Scores of 80-100 are rated as excellent, 70-79 as good, 60-69 as fair and less than 60 as poor. The Knee society score (6) was used to assess the radiographs. These included immediate postoperative and subsequent follow-up radiographs. The thickness of the radiolucent lines was graded and a total score was assigned by adding the radiolucent lines in each of the zones. Progression of a radiolucent line was defined as an increase of 1 mm on sequential radiographs.

### RESULTS

The mean knee score according to the Knee Society scoring system improved from a mean preoperative value of 45 (range, 30-65) to a postoperative value of 84 points (range, 45-92). The mean preoperative functional score was 38 (range, 25-55), and the postoperative functional score was 73 points (range, 50-95).

According to the final scoring, 90% of the knees were rated excellent, 4% good, 4% fair and 2% poor.

The mean preoperative Oxford knee score was 43 (range 33-52) and the mean postoperative score was 17 (14-29). Range of motion improved from a mean of 90° (range, 50-125) to 100° (range, 65-130).

There was no significant difference ( $p = 0.03$ ) in the American Knee Society score and Oxford knee



**Fig. 1.** — AP radiograph of PFC Sigma total Knee arthroplasty 6 weeks post-operatively.



**Fig. 2.** — Lateral radiograph of PFC Sigma total Knee arthroplasty 6 weeks post-operatively.

score when comparing patients with and without resurfacing of the patella and PCL-retaining with PCL-substituting implants.

One knee (0.6%) was revised within 18 months due to aseptic loosening and catastrophic tibial stem subsidence. One knee (0.6%) had superficial wound infection which cleared with oral antibiotics.

Two patients (2 knees) developed deep infection out of which one resolved following early debridement, the other went on to develop a chronic infection requiring long-term suppressive antibiotics.

Three patients had proven below knee deep venous thrombosis ; one of them developed a non-fatal pulmonary embolism.

Radiological review (figs 1-4) using radiological Knee Society scoring showed radiolucent lines in

54 (35%) tibial components and 17 (11%) femoral components.

The radiological Knee Society score was less than 4 in all except one where the tibia had a score of 7. For survivorship analysis, the actuarial life-table method, as described by Armitage (1), was used with calculation of the numbers at risk and the survival rates at annual intervals (table I). The 95% confidence limits were calculated by the method of Rothman (17) as used by Murray *et al* (9). The survivorship at the end of the eight-year follow-up was 99.40% (table II). The end point was taken as the decision to revise or the revision itself, due to any reason.

None of the patellar components failed and no patients required secondary patellar resurfacing for patellofemoral problems.



*Fig. 3.* — AP radiograph of PFC Sigma total knee arthroplasty after 8 years follow-up.

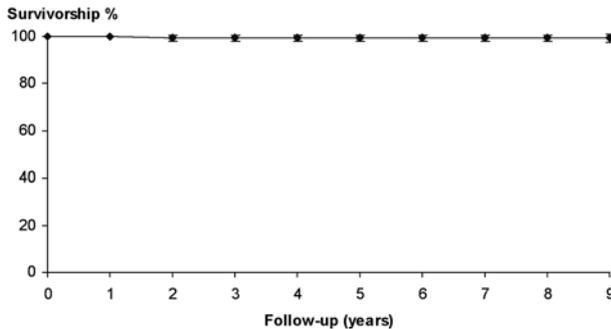


*Fig. 4.* — Lateral radiograph of PFC Sigma total knee arthroplasty after 8 years follow-up.

Table I. — The actuarial life-table to show the survival of total knee arthroplasties at end of each year of follow-up

Follow-up	Number at start	Withdrawn	Failure	Number at risk	Cumulative Success rate	Confidence limits		Standard error
						Higher	Lower	
0	166	0	0	100	100.00	100.00	100.00	0.000
1	166	0	0	166	100.00	100.00	100.00	0.000
2	166	0	1	166	99.40	100.57	98.22	0.006
3	165	2	0	164	99.40	100.58	98.22	0.006
4	163	2	0	162	99.40	100.59	98.21	0.006
5	161	1	0	160.5	99.40	100.59	98.20	0.006
6	160	1	0	159.5	99.40	100.59	98.20	0.006
7	159	3	0	157.5	99.40	100.60	98.19	0.006
8	156	2	0	155	99.40	100.61	98.18	0.006
9	154	0	0	154	99.40	101.12	97.67	0.009

Table II. — Survivorship analysis graph of PFC Sigma total knee arthroplasty with revision as the end-point



## DISCUSSION

The success of prosthesis is based on pain relief, restoration of function and implant survival. Survival analysis is an accepted means of assessing implant survival. Survivorship can be defined with various endpoints which include revision and radiological or functional failure. In most series of total knee replacements, survivorship of between 90% to 99% has been reported at ten years (2, 10, 11, 13, 9, 8). Our results shows similar survival rate after a mean follow-up of eight years, during which we did not find any problems with polyethylene wear, osteolysis and loosening of the prosthesis. Ninety four percent of the knees were rated good to excellent.

We conclude that the PFC Sigma total knee prosthesis continues to function well after a mean follow-up of 8 years. We plan to continue monitoring this cohort of patients for long-term analysis.

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