

**CLINICAL EVALUATION OF TOTAL KNEE
ARTHROPLASTY USING PRESS FIT CONDYLAR
SIGMA PROSTHESIS: MIDTERM RESULTS.**



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Abstract

Background: To evaluate the midterm results of 25 patients who underwent total knee arthroplasty using Press Fit Condylar (PFC) Sigma system.

Materials and Methods: 28 TKA performed by various surgeons using PFC Sigma prosthesis at All India Institute of Medical Sciences, New Delhi, India between June 2002 to Dec 2002 were retrospectively reviewed by us clinically and radiologically. The American knee society score and Knee society radiographic assessment were used to rate the knee function and these were compared with the pre-operative scores.

Results: The mean age of patients at the time of index procedure was 58.7 years, while average follow-up was for 62 months. 2 patients were lost to follow-up and 23 patients (26 knees) were available at the time of final follow-up. Using American society score at the most recent follow-up 61% of knees were rated as excellent, 27% as good, 8% as fair and 4% as poor. One patient had infection which was controlled with debridement and long term antibiotic therapy. Radiographic review showed radiolucent lines in 38% of tibial components and 12% of femoral components. Survival rate of implants was 96% at 5years.

Conclusion: The PFC Sigma total knee prosthesis resulted in excellent relief of pain, range of motion, and restoration of function as well as a low prevalence of patellofemoral complications and continues to function well during a mean follow-up period of 61 months. These results are comparable to those of other midterm studies.

Key words: arthroplasty, replacement, knee, PFC Sigma.

Introduction

Total knee arthroplasty (TKA) is becoming increasingly popular worldwide due to improvements in technology and durability of implants and has become a standard and dependable method of treating severe knee arthritis.^{1,2,3,4,5} The prevalence of arthritis including osteoarthritis (OA) and rheumatoid arthritis (RA) continues to increase with age. Decisions for appropriate use of prosthesis for TKA has to be supported by clinical results in literature.^{1,2,3}

The design of Press Fit Condylar (PFC) Sigma (DePuy, Warsaw (IN), US) was based on earlier successful implants namely Total Condylar and Kinematic Knee.^{2,6} PFC was later changed to PFC Sigma. The condylar geometry of the total condylar prosthesis (TCP) was adapted by adjusting the length and the radius of the curvature of the posterior condyles. In addition, a tibial post-and-cam mechanism that substituted for the posterior cruciate ligament was added to provide greater clearance for the posterior aspect of the tibial component with the knee in full flexion and to optimize the contact area for improved contact stresses on the polyethylene. The trochlear groove was deepened, and its congruency with the patellar component was optimized to allow a broad surface of contact, which extended the range of motion to 110°, and thereby reduced the compressive and shear forces of the patellofemoral articulation. Modular components, such as optional stems, wedges, and augments as well as more constrained polyethylene inserts, were included in the design to allow greater intraoperative versatility.^{2,4,5}

The use of this implant in our institution started in early 1998. This study however evaluates the midterm clinical and radiological results of TKA using PFC Sigma prosthesis used in 2002.

Materials and Methods

We retrospectively reviewed 28 TKA performed by various surgeons using PFC Sigma prosthesis at All India Institute of Medical Sciences, New Delhi, India between June 2002 to Dec 2002.

The indications for surgery were advanced degenerative changes with severe pain on weight bearing, impaired function with limitation in daily activities. The patients with serious medical illnesses, infected arthritis, Charcot's arthropathy were excluded.

All surgeries were performed with midline incision and medial parapatellar approach. Appropriate soft tissue releases were done. Femoral preparation was done with an intramedullary jig while tibial preparation with an extramedullary jig. Following the bone cuts, a trial reduction was done and the knee checked for soft tissue balance, flexion/extension gaps and stability. All implants were of posterior cruciate ligament (PCL) substituting design and had cemented fixation. None of the cases had patellar resurfacing. 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 up at regular intervals by American Knee Society Score.^{7,8}

The American Knee Society scoring system⁷ 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 score⁹ was used to assess the immediate postoperative and subsequent follow-up weight-bearing radiographs of the knees for loosening and evidence of failure. It included 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.

Outcomes and Analysis

Of the 25 patients who were operated during the study period two were lost to follow-up. These left 23 patients of whom 3 underwent bilateral TKA and hence 26 knees were analyzed with a mean duration of follow-up of 62 months (range, 60 – 65 months). Of the selected patients 14 had OA 9 had RA. The mean age (*Figure 1*) at the time of index procedure was 58.7 years (range, 35 – 79 years), however the mean age for RA group was 52 years (Range 35 – 60years) and for OA was 63 years (Range 52 – 79years). There were 15 female and 8 male patients.

Clinical results

Pre-operatively the mean knee score was 29 points (range, 0 – 53) and mean functional score was 31 points (range, 0 – 70). At the time of final clinical assessment, the mean knee score was 87 points (range, 71 – 95) and mean functional score was 73 points (range, 0 – 100). The clinical result at the time of most recent follow-up was 61% of knees were rated as excellent, 27% as good, 8% as fair and 4% as poor. A comparison of knee society scores between OA and RA is given in *Table 1* while a literature review of knee society scores for PFC sigma at midterm follow up is given in *Table 2*

Pain

Pre-operatively 14 (54%) knees had severe pain while walking and another 10 (40%) knees had severe pain even at rest. Post-operatively none of the patients had any pain at rest. 8 (30%) knees reported discomfort in the knee and of these 5 (19%) had mild and occasional pain of whom 4 had RA. 2 (7%) had moderate pain that necessitated analgesic use occasionally and one (3%) patient was house bound had continuous moderate pain. Pain in 3 patients was in anterior aspect of the knee and presumed to be referable to patellofemoral articulation.

Range of motion

The mean pre-operative range of flexion of the knee was 61° (Range 5° – 110°), while that of patients with osteoarthritis was 67° (Range 5° – 110°) and rheumatoid arthritis was 53° (Range 35° – 100°). The mean post-operative range of flexion was 104° (Range 78° – 136°), while that for osteoarthritis was 107° (Range 86° – 136°) and rheumatoid arthritis was 91° (Range 78° – 127°). (*Figure 2*)

Pre-operatively 22 (85%) knees had a flexion contracture with a range of 5° – 50° . Of them 3 had 5° , 6 had 10° , 3 had 15° , 5 had 20° and 5 had $>20^{\circ}$. Post-operatively 6 (23%) knees had a flexion contracture persisting with 5 having between 5° – 10° and one having 20° . Pre-operatively 2 patients had an extensor lag while none had in post-operative period.

Ability to walk

Pre-operatively 6 patients were unable to walk, 5 were housebound, 4 were 1 – 5 blocks, 7 were 5 – 10 blocks and one had unlimited walking ability. Post operatively at latest follow-up one patient was house bound, 5 were 1 – 5 blocks, 13 were 5 – 10 blocks while 4 were unlimited walkers. 4 patients with decreased ability to walk had polyarticular RA which impeded their ability to walk while one patient with OA was 84 years who due to age and another 73years with associated medical co-morbid conditions had decreased ability to walk. Pre-operatively 14 patients used cane support and 5 patients used walker while post-operatively 9 patients used single cane support and one used a walker.

Complications

One patient had infection which was debrided 2 times and put on long term suppressive antibiotic therapy for 6months following which there was no discharge. Patient's ability to walk was severely restricted and also there was lysis around the tibial component. However the patient was house bound due to involvement of additional joints and refused any other procedure for his knee.

Radiological Results

The tibiofemoral angle was 5° to 8° valgus in 10 knees, 0° - 4° in 11 knees and 0° - 5° varus in 5 knees. The mean femoral component alignment for anterior posterior view was 95° (Range 93° – 99°) and mean tibial component alignment for the same view was 89° (Range 87° – 95°). In the lateral view the mean posterior slope of tibia was 4° (Range 0° – 8°) while the femoral component was positioned in a mean of 5° of flexion (Range 0° – 10°).

The anteroposterior radiographs at the latest follow-up showed on tibial side 3 radiolucent lines in zone 1, 2 in zone 2, 2 in zone 3 and 3 in zone 4. On lateral view 2 patients had radiolucent line in zone 2, while on the femoral side 2 were seen in zone 2 and one in zone 3. All these lucencies were less than 2mm in size. One patient had radiolucency involving all zones of tibia and zone 2 and 3 of femur.

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. The PFC prosthesis was designed by modifying the geometry of the TCP with a slight reduction in the radius of the curvature of the posterior femoral flange and with the addition of the posterior stabilized mechanism to allow femoral rollback. Compared with that associated with the total condylar prosthesis, motion was improved appreciably from a mean of 90° to 95° ^{2,10} to a mean of 104° in the present series, with 65 per cent of the knees attaining motion beyond 100° . If the knee does not flex at least 90° , the functional result is poor.¹¹ Because, this much is needed to get in and out of chair and climbing chairs.¹¹ Lack of flexion may be due to quadriceps adhesion or contracture or placing too big material between femoral condyles and top of tibia causing ligaments tight in flexion, making flexion difficult.¹¹ The decreased movement in RA, could be due to long standing disease status causing permanent muscle atrophy, adhesions, soft tissue fibrosis, poor compliance and poor motivation.

Pain relief with TKA has been excellent. In our series 90% of the patients had severe pain while post-operatively 70% had no pain at end of 5 years while another 20% had mild occasional pain. In a study by Ranawat et al² 79% of patients had no pain. Pain is an important parameter not only as an indication for TKA, but also for the evaluation of the results¹¹. Pain can be categorized into mild, moderate and severe based on the intensity, duration and response to medication. The pain parameter was given 50 points in Knee Society Score. This indicates its significance. Pain has an influence on other parameters of functional evaluation, as it is associated with physical activity. Hence, alleviation of pain is the prime criteria of TKA. 3 of our patients complained of anterior knee pain which was presumed to be due to patellofemoral articulation. All the 3 patients had RA and progress in disease process may have led to onset of pain. In a study by Kanijo et al¹³ simultaneous bilateral TKA was performed in twenty-six patients who had RA, and a patellar replacement was performed concurrently in one randomly selected knee in each patient and at follow-up at end of 6 years came to a conclusion that individual scores for pain, function, range of motion, muscle strength, flexion contracture, and instability were not significantly different between the knees that had had a patellar replacement and those that had not. However, pain on standing and on ascending or descending stairs as well as tenderness of the patellofemoral

joint were only noted in knees that had not had a patellar replacement. These findings suggest that, in order to diminish pain on standing and on using stairs, replacement of the patella during TKA is preferable for patients who have RA.¹³

One of the objectives of TKA is to correct the fixed flexion deformity (FFD). It is usually severe in RA than OA. Full extension may be inhibited by pain or effusion & later by contracture of capsule, hamstrings, gastrocnemius & PCL. Weight bearing may put an excessive load on the back of femoral condyles and cause them to sink into the back of tibial condyles ultimately causing contact between the femoral intercondylar notch and tibial intercondylar eminence creating further block to the extension.¹⁴ FFD also has adverse effects on other functions.¹⁴ Weight bearing in an extended knee is more stable and requires less muscle action. While loading in flexion require considerable action by quadriceps with consequent increase in forces across the patellofemoral and tibiofemoral joint. Similarly walking, stair climbing, transfer are also affected. These patients with severe FFD may remain house bound or walk with walking aid. A severe FFD also poses a problem in correcting it completely without resecting more bone from femoral side. Severe FFD also creates severe posterior tibial and femoral condylar defects, which require a good pre-operative planning for the defect management.¹⁴ It also dictates the proper design selection. This is because in severe flexed knee the soft tissue tension will be higher on flexor side than on the extension side, despite the efforts to balance the soft tissue by extensive release. This causes greater propensity to posterior subluxation. TCP design which does not have inherent constraint for posterior subluxation in the absence of PCL will have a high incidence of dislocations. The PFC sigma have features of central post which prevents this problem.¹⁵ Flexion contractures have been classified as mild, moderate and severe deformities. (FFD 20°-mild to moderate, FFD more than 30° -severe deformity).¹⁵ whether flexion contractures correct with time after surgery remains a matter of debate. McPherson et al¹⁶ evaluated 29 patients with flexion contractures less than 30° and found that all resolved. Tanzer and Miller¹⁷ evaluated patients with a mean flexion contracture of less than 15° postoperatively and found that these resolved as well. However, in 41% of these cases they did a posterior capsular stripping at the time of primary surgery. In contrast, Firestone et al¹⁸ found that any patient left with a significant residual flexion contracture at the end of the procedure (average, 8.6°) deteriorated with time, increasing to an average flexion contracture of 13.4°. Tew and Forster¹⁹ and Schurman et al²⁰

in separate reports found no improvement in flexion contractures beyond what could be corrected at the time of surgery.

The radiographic results in our study confirmed the results that have been reported for arthroplasties performed with other contemporary condylar, metal backed designs.^{2,21} The radiolucent lines that occurred were found exclusively at the margins of the cement-bone interface and were non-progressive. With use of a uniform operative technique²² aseptic loosening has not been a source of failure at the time of intermediate-term follow-up. Ranawat et al² report on the AP view, the average femoral flexion angle was 96° (Range 91°-103°). The average tibial angle was 89° (Range 82°-95°). While in lateral view the femoral component was positioned in a mean of 5° (Range 0° – 16°) of flexion and the angle of the tibial component was a mean of 85° (Range 78° – 97°), or 5° of posterior tilt. Sixty knees had no evidence of radiolucent lines around any of the components. Therefore, the prevalence of radiolucent lines around at least one component was 39 per cent (thirty-nine knees).

Conclusion

The PFC Sigma total knee prosthesis resulted in excellent relief of pain, range of motion, and restoration of function as well as a low prevalence of patellofemoral complications and continues to function well during a mean follow-up period of 61 months. These results are comparable to those of other midterm studies.

Figures and Tables

Figure 1

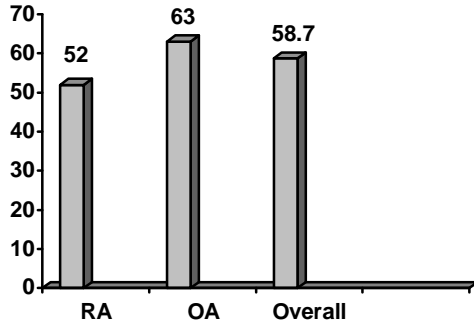


Figure 2

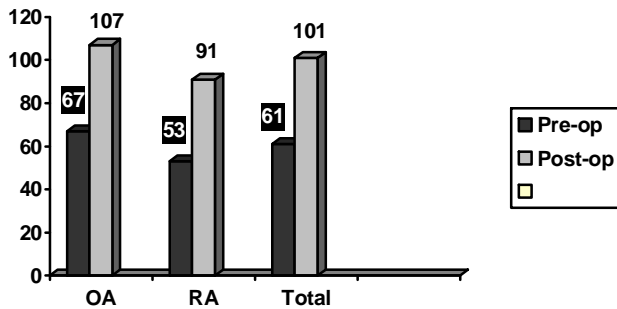


Table 1

American Knee Society Scores	OA	RA	Over-all
Knee Score	90.6	83.6	87
Functional Score	74.3	78.5	73

Table 2

Series	Knee score	Functional score
Ranawat et al ²	93	78
Zaki et al ⁴	84	72
Asif & Choon ⁵	87	72
Present series	87	73

Legends

Figure 1: Comparison of mean age (in years) at index procedure between OA and RA groups

Figure 2: Comparison of pre and post operative range of motion (in degrees) between patients with OA and RA groups

Table 1: Comparison of American knee society score between OA and RA groups

Table 2: Literature review of knee society scores with PFC sigma at midterm followup

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