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**Dr. Ashootosh Hiranand Batra**  
Senior Resident, Department of  
Orthopedics, Indira Gandhi ESI  
Hospital, Delhi, India

## Evaluation of results of cemented total knee replacement in 30 arthritic knee joints: Short term results (mean 26 months)

**Dr. Ashootosh Hiranand Batra**

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### Abstract

**Background:** Total Knee replacement surgery, also called Knee arthroplasty, is a surgical procedure to resurface a knee damaged by arthritis. This study investigates the short-term outcomes of total knee replacement surgeries employing the PFC Sigma Rotating-Platform, posterior-stabilized knee prosthesis. The aim is to assess the clinical and radiological effectiveness of this surgical approach in patients with arthritic knees.

**Aim:** The primary objective of this study is to evaluate the short-term clinical and radiological outcomes of total knee replacement surgeries performed using the PFC Sigma Rotating-Platform, posterior-stabilized knee implant.

**Methods:** A total of 30 knee replacements were conducted in 24 patients, including bilateral total knee arthroplasties, by a single surgical team at Indira Gandhi ESI Hospital, Delhi. Pre- and post-operative Knee Society scores, range of motion, walking ability, and radiological results were assessed at intervals up to 2 years post-surgery. Complications were monitored, and patient subgroups of Osteoarthritis (OA) and Rheumatoid Arthritis (RA) were analyzed separately.

**Results:** Pre-operatively, the mean knee score was 31 points, and the mean functional score was 34 points. Post-surgery, significant improvements were observed, with a mean knee score of 85.68 points and a mean functional score of 71.94 points at final clinical assessment. Clinical outcomes demonstrated 53.33% excellent, 33.33% good, 10% fair, and 3.33% poor results. Analysis of OA and RA subgroups revealed distinct responses to the surgical intervention.

**Conclusion:** The utilization of the PFC Sigma Rotating-Platform, posterior-stabilized knee implant yielded positive short-term outcomes in patients with arthritic knees. Marked enhancements in pain relief, range of motion, walking ability, and overall quality of life were evident. These findings underscore the efficacy of the surgical approach in alleviating symptoms and improving functional capacity in arthritic knee patients.

**Keywords:** Total knee replacement, PFC sigma implant, short-term outcomes, knee society scores, arthritic knees, clinical assessment, fixed flexion deformity, complications of total knee replacement

### Introduction

Total knee replacement (TKR), also referred to as total knee arthroplasty (TKA), is a surgical procedure where worn, diseased, or damaged surfaces of a knee joint are removed and replaced with artificial surfaces. Survival rates for modern total knee replacements (TKR) of 80%-95% after 10 years have been reported. The restoration of the physiological alignment of the lower limb is an accepted prognostic factor for long-term survival<sup>[1, 2]</sup>. Materials used for resurfacing of the joint should not only be strong and durable but also optimal for joint function hence should produce as little friction as possible. TKR has established itself as a standard and dependable method of treating severe knee arthritis<sup>[3, 4, 5, 6, 7]</sup>. Decisions for appropriate use of prosthesis for TKR has to be supported by clinical results in literature<sup>[3, 4, 5]</sup>.

**Corresponding Author:**  
**Dr. Ashootosh Hiranand Batra**  
Specialist Orthopedic Surgeon,  
Department of Orthopedics,  
Medeor Hospital, Abu Dhabi,  
UAE, P.O. Box 7400

The ultimate goal of all TKRs is to produce a well aligned prosthesis with good ligament balance. One without the other is unacceptable.

PFC Sigma rotating-platform, posterior-stabilized total knee prosthesis [DePuy, Warsaw(IN), US] is based on the principle of the mobile-bearing knee, which unlike traditional, fixed-bearing knee implants, are designed to mimic the natural movement of knee rotation during flexion. This rotation reduces the stress and wear on the implant<sup>[8]</sup>. *Doug Noiles*, an engineer with US Surgical Corporation, was probably the first in the United States to recognize that a dual-articulation rotating-platform prosthesis would resolve the kinematic conflict between a low-stress articulation and high bearing conformity. This knee system eventually evolved into the P.F.C. Sigma rotating-platform prosthesis (DePuy Orthopaedics, Inc, Warsaw, Ind). Other principles of PFC Sigma are retained in this implant. 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. A tibial post-and-cam mechanism that substituted for the posterior cruciate ligament is present 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.

This study evaluates the short term clinical and radiological results of 30 Total Knee Replacement surgeries in 24 patients with arthritic knees operated between 1st January 2008 to 31st December 2008 at Indira Gandhi ESI Hospital, Delhi using the PFC Sigma Rotating-Platform, posterior-stabilized knee implant by a single surgical team. (followed upto August 2010).

A total of thirty Total Knee Arthroplasties in 24 patients (6 of the patients had bilateral TKA's) operated between 1st Jan to 31st Dec 2008 at Indira Gandhi ESI Hospital, Jhilmil, Delhi by a single surgical team using PFC Sigma Rotating Platform, Posterior Stabilized prosthesis were reviewed and followed up till August 2010.

The indications for surgery were advanced degenerative changes with severe pain on weight bearing and impaired function with limitation in daily activities.

#### Exclusion Criteria for this study were

- Patients requiring revision total knee arthroplasty surgery.
- Patients with any tibial deformity requiring tibial component augmentation.
- Patients that in the opinion of the clinical investigators require a constrained prosthesis.
- Patients with a known history of poor compliance to medical treatment.
- Patients who are known drug or alcohol abusers.

Combined spinal epidural anesthesia was used and epidural catheter was kept post-operatively to aid in post-operative analgesia. Midline incision and standard medial para-patellar approach was used in all cases after application of tourniquet. Tibial cuts were taken first using extra-medullary jig followed by femoral preparation and cuts using intra-medullary jig. Appropriate soft tissue balancing was then done and flexion and extension gaps checked using blocks. 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 with a rotating platform tibial insert and had cemented fixation. Pulse lavage was carried out in all cases and cement was mixed by hand. None of the cases had patellar resurfacing. Osteophytes of the patella, if present, were nibbled out. Closure was carried over drain No 14, and a Jones bandage was applied. Quadriceps strengthening and ankle pumping were started immediate post op as soon as the patient permitted it. Drain was removed after 48 hours and injectable iv antibiotics given for 7 days followed by oral antibiotics till stitch removal (14-18th post op day). Bedside knee bending active and assisted, was started after removal of drain and walking with walker initiated within one week in most patients. Patients were discharged after stitch removal once they were able to do straight leg raising and knee bending upto 90°. All patients were followed up at regular intervals by American Knee Society Score<sup>[9,10]</sup> and X-rays. The American Knee Society scoring system comprises a knee score and a functional score. The maximum score for each is 100. Criteria for knee score are 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. Since all the surgeries were carried out by a single surgical team using a single technique, intra-surgeon variations were minimized.

The Knee society score<sup>[11]</sup> was used to assess the immediate postoperative and follow up function of the operated knees and subsequent follow-up weight-bearing radiographs of the knees were evaluated for loosening of implant 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

All 24 patients were followed up and none was lost in follow up. As six of these had bilateral TKA's, a total of 30 knees were followed up over mean duration of 26 months (20-32 months) both clinically and radiologically.

All of the patients were followed up clinically, radiologically and with questionnaires for Knee Society score at 15 days, 2 months, 6 months, 1 year, and 2 years post operatively. Of the selected patients 14 had Osteoarthritis (OA) [9 male and 5 females] and 10 had Rheumatoid Arthritis (RA) [1 male and 9 females]. 3 patients of OA and 3 patients of RA, underwent bilateral TKA's which were carried out in a single sitting. The mean age (Figure 1) at the time of index procedure was 59 years (range, 41-75 years), however the mean age for RA group was 49 years (Range 41-58 years) and for OA was 64 years (Range 52-75years). There were 14 female and 10 male patients (Figure 2).

#### Clinical results

Pre-operatively the mean knee score was 31 points (range, 0-55) and mean functional score was 34 points (range, 0-65). At the time of final clinical assessment, the mean knee score was 85.68 points (range, 70-95) and mean functional score was

71.94 points (range, 40-95). The clinical result at the time of most recent follow-up was 16 knees(53.33%) were rated as excellent, 10 knees (33.33%) as good, 3 knees (10%) as fair and 1 knee (3.33%) as poor (Figure 3). 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 is given in Table 2.

### Pain

In this study pre-operatively 16(53.33%) knees had severe pain on walking and another 10(33.33%) knees had severe pain even at rest. Post-operative results indicated none of the patients had any pain at rest. 10(33.33%) knees reported discomfort in the knee and of these 6(20%) had mild and occasional pain of whom 3 had RA. 2(6.66%) had moderate pain that necessitated analgesic use occasionally and one (3.33%) patient was house bound and had continuous moderate pain. Pain in 6 patients was in anterior aspect of the knee and presumed to be preferable to patellofemoral articulation. All 6 of these patients had RA. All the patients had improvement in pain as compared to preoperative analysis.

### Range of motion

The mean pre-operative range of flexion of the knee was 70(Range 20o-110o). The patients with osteoarthritis had a mean of 74o (Range 20o-110o) and rheumatoid arthritis had a mean of 55o (Range 40o-100o). The mean post-operative range of flexion was 102o (Range 80o-120o), while that for osteoarthritis was 105o (Range 90 o-120 o) and rheumatoid arthritis was 100 o (Range 80 o - 110 o) (Figure 4). Pre-operatively % knees had a flexion contracture with a range of 5 o-30 o. Of them 4 had 5 o, 7 had 10 o, 3 had 15 o, 5 had 20 o and 3 had >20 o. Post-operatively 8 (26.66%) knees had a flexion contracture persisting between 5°-10°. Pre-operatively 3 patients had an extensor lag while in 2 it persisted in post-operative period. The extensor lag in most patients responded to vigorous active physiotherapy. Continuous Passive Motion was not used in any case.

### Ability to walk

Pre-operatively 4 patients were unable to walk, 9 were housebound, 6 were 1-5 blocks, 5 were 5-10 blocks and none had unlimited walking ability. Post operatively at latest follow-up 2 patients was house bound, 10 were 1-5 blocks, 12 were 5-10 blocks while none were unlimited walkers. Pre-operatively 15 patients used cane support and 5 patients used walker while post-operatively 9 patients used single cane support and 2 used a walker.

### Complications

None of the patients had clinically significant infection. One of the patients had medial femoral condylar split while taking femoral cuts, which was fixed by cancellous screw fixation intraoperatively after reduction. Weight bearing in this patient was postponed till 30 days post operatively. Follow-up x-ray of this patient at 3 months and 12 months showed no change in implant orientation or evidence of loosening.

### Radiological Results

While the concept of 'treat the patient and not the X-ray' was followed, however radiological followup of the operated cases

demonstrated a marked improvement in knee alignment and also gave clues to impending loosening. The preoperative tibiofemoral angle was 5 o to 8 o valgus in 3 knees, 0 o to 4o valgus in 12 knees and 0o to 10 o varus in 15 knees. Postoperatively the physiological valgus was achieved in 24 knees while 6 of the knees were in neutral. None of the knees were aligned in varus. The mean femoral component alignment for anterior posterior view was 95 o (Range 92 o - 99 o) and mean tibial component alignment for the same view was 88 o (Range 86 o - 95 o). In the lateral view the mean posterior slope of tibia was 3 o (Range 0 o - 7 o) while the femoral component was positioned in a mean of 5 o of flexion (Range 0 o - 10 o). The anteroposterior radiographs at the latest follow-up showed on tibial side 3 radiolucent lines in zone 1, 3 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. Two patients had radiolucency involving all zones of tibia and zone 2 and 3 of femur.

TKA has established itself as a treatment modality of the arthritic knee associated with severe pain and/or deformity. It can provide excellent pain relief and restoration of function of the arthritic knee joint. The indications for joint replacement are Pain and Loss of Function. Joint Replacement Surgery is warranted when degeneration and destruction of the knee creates disabling pain and severely limits the functional use of the extremity. The success of the surgery is based on implant survival, in addition to pain relief and restoration of function. The PFC Sigma prosthesis was designed by modifying the geometry of the Total Condylar Prosthesis 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. The concept of rotating platform tibial insert was then added to mimic the natural movement of knee rotation during flexion which reduces the stress and wear on the implant [8].

### Pain

Pain relief with TKA has been excellent and has been one of the primary indications for surgery. Even though the pain relief was excellent in the broader outlook of our study, however immediate post-operative pain was a significant component of patient's experience after total knee arthroplasty (TKA). It was severe in 60% of patients and moderate in 30%, which hindered early physical therapy. In our series almost 100% of the patients had severe pain preoperatively while post-operatively nearly 70% had no pain at end of 2 years while 30% had mild occasional pain. In a study by Ranawat *et al*, [3]. 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 results [13]. On the basis of the amount of pain, it is categorized into mild, moderate and severe pain based on the intensity, duration and response to medication. The pain parameter was given 50 points in Knee Society Score indicating 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 primary criteria in evaluation of TKA. Six of our patients complained of anterior knee pain which was presumed to be due to patellofemoral articulation. All these patients had RA and progress in disease process may have led to onset of pain. Findings of a study done by Kanijo *et al*, [15] 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 [15]. The best data regarding the results of patellar resurfacing is derived from randomized, prospective studies of patellar resurfacing. Using meta-analysis of nine randomized, prospective series, there were 518 resurfaced and 542 unresurfaced patellae followed for 2-10 years [16-24]. Anterior knee pain was present in 38 (7.3%) of the resurfaced and 118 (21.8%) of the unresurfaced patellae. Knee scores were similar in both groups. Patellar complications occurred in 14 (2.7%), leading to reoperation in ten (1.9%) of the resurfaced patellae. This is in contrast to patellar complications in 37 (6.8%) of unresurfaced patellae, leading to reoperation in 36 (6.6%) [16-24].

### Range of Motion

The major goal of total knee arthroplasty is relief of pain. Almost as important, however, is the restoration of function, and that function depends primarily on an adequate arc of motion in the knee. Extension and flexion following a knee arthroplasty are dependent upon a multitude of factors related to surgical technique, the implant used, the physical therapy program, and the patient him- or herself. Compared with that associated with the Total Condylar Prosthesis, motion using PFC Sigma RP posterior stabilized knee was improved appreciably from a mean of 90° to 95° [3, 12] to a mean of 102° in the present series, with 60 per cent of the knees attaining motion beyond 100°. If the knee does not flex at least 90°, the functional result is poor [13] as this much of knee flexion is needed to get in and out of chair and climbing stairs. 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 [13]. 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.

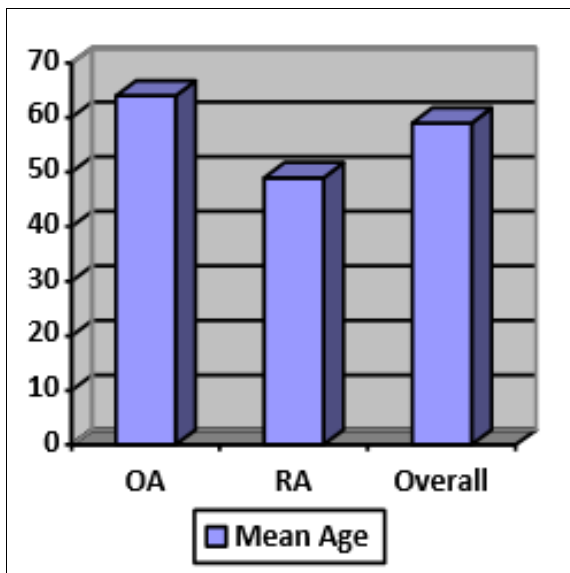
### Radiological evaluation

The radiolucent lines that occurred were found exclusively at the margins of the cement- bone interface and were non-progressive. The radiographic results in our study confirmed the results that have been reported for arthroplasties performed with other contemporary condylar, metal backed designs [3, 33]. With use of a uniform operative technique [34] aseptic loosening has not been a source of failure at the time of short-term follow-up. Ranawat *et al* [3] 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.

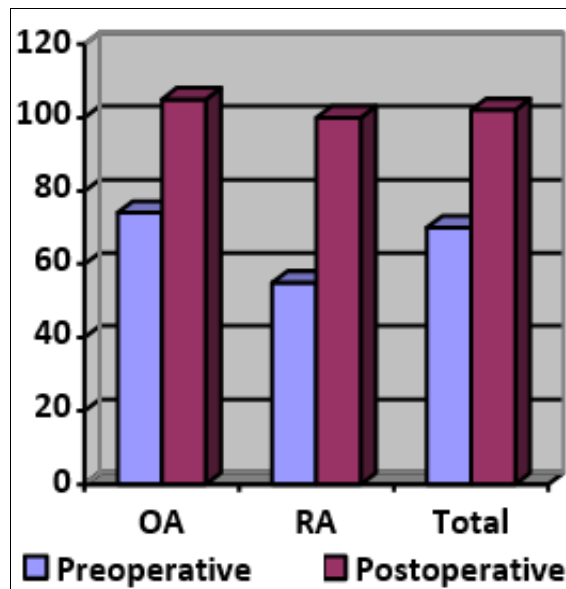
### Fixed Flexion Deformity

One of the objectives of TKA is to correct the fixed flexion deformity (FFD). It is usually more 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

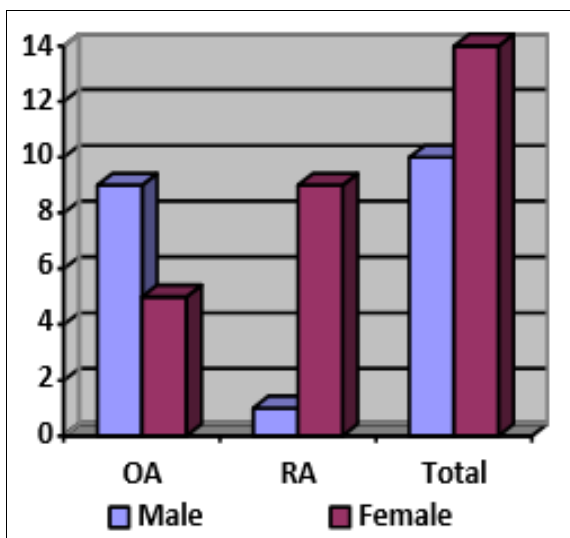
femoral condyles and cause them to sink into the back of tibial condyles ultimately causing contact between the femoral intercondylar notch and tibial intercondylar eminence creating further block to the extension [25]. FFD also has adverse effects on other functions [25]. Weight bearing in an extended 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. Severe FFD also creates severe posterior tibial and femoral condylar defects, which require a good pre-operative planning for the defect management [25]. 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 with a fixed flexion contracture, the shortened posterior soft tissues block full extension. The first step in correcting such a contracture is to recreate the normal posterior capsular recesses of the knee joint by stripping the adherent posterior capsule proximally off the femur a short distance above the femoral condyles posteriorly. This usually is done after the posterior condylar cuts are made, allowing access to this space. Another technique of correcting flexion contracture involves removing additional bone from the distal femur to enlarge the narrowed extension gap. This technique should be used only with persistent flexion contracture after posterior capsular release and posterior osteophyte removal, because the removal of additional distal femur results in joint line elevation. 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 [26]. Flexion contractures have been classified as mild, moderate and severe deformities. (FFD 20°-mild to moderate, FFD more than 30° -severe deformity) [26]. Whether flexion contractures correct with time after surgery remains a matter of debate. McPherson *et al*, [27] evaluated 29 patients with flexion contractures less than 30° and found that all resolved. Tanzer and Miller [28] 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. Ritter and Stringer [29] similarly reported an improvement of postoperative flexion contracture with time. These results are in direct contrast to the studies performed by Tew and Forster [30], Schurman, Parker, and Ornstein [31], and Firestone *et al*. [32], who found that the maximal correction of flexion contracture occurred in the operating room and did not improve with time. Firestone *et al*. [32] and others have mentioned reduction of severe flexion contractures with preoperative serial casting.



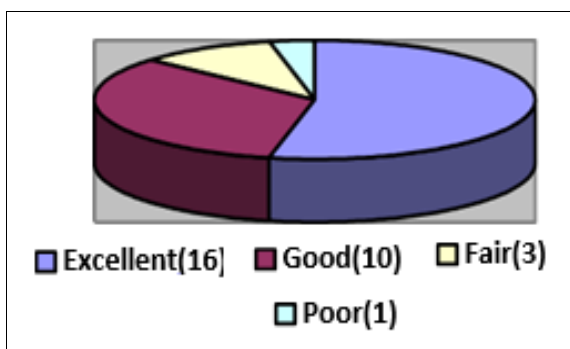
**Fig 1:** Comparison of mean age (in years) at index procedure between OA and RA



**Fig 4:** Comparison of pre and post-operative ROM between OA and RA patients



**Fig 2:** Comparison of sex distribution of OA and RA patients in this study



**Fig 3:** Clinical Results of the post-operative follow up of the operated knees

**Table 1:** Comparison of American Knee Society score between OA and RA groups

American Knee Society Score	Osteoarthritis	Rheumatoid Arthritis	Over all
Knee Score	88.8	81.6	85.68
Functional Score	73.8	69.5	71.92

**Table 2:** Literature review of knee society scores with PFC sigma at follow up

Series	Knee Score	Functional Score
Ranawat <i>et al</i>	93	78
Asif and Choon	87	72
Zaki <i>et al</i>	84	72
Present series	86	72

**Conclusions and Recommendations**

The PFC Sigma Rotating Platform Posterior stabilized knee prosthesis resulted in excellent relief of pain, range of motion and restoration of function as well as a low prevalence of patellofemoral complications. However as the study gives short term results (average 26 months) further follow up is needed. Also the need for selective patellar resurfacing on a case to case basis especially in inflammatory arthritis needs to be kept in mind. Patient selection is of utmost importance. Rheumatoid arthritis patients in general seem to have lesser knee score as compared to osteoarthritic patients and also have more patellofemoral issues.

**Conflict of Interest**

Not available

**Financial Support**

Not available

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