What have we learned from 100% success of press fit condylar rotating platform posterior stabilized knees? A 5-10 years followup by a nondesigner

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ABSTRACT
Background: Total joint arthroplasties of the hip and knee represent a remarkable feat of modern medicine in terms of reducing pain and restoring function to millions of patients afflicted with severe arthritis. Oftentimes, the performance and longevity of new implants and devices are based on limited data. This is the first study by a non-designer on the press fit condylar rotating platform posterior stabilized (PFC-RP-PS) design with 100% success. This has a relevance, vis-à-vis bias that one may have in terms of reproducibility of technique and funding from the manufacturer. We associate our excellent mid-term results to intra operative technical aspects and stringent intra operative exclusion criteria.

Materials and Methods: Our study includes a cohort of 121 selected knees operated between January 2003 and October 2010. We used cemented, posterior stabilized (PS), mobile bearing (MB), and RP prosthesis from the same manufacturer in all these 121 knees. The patients were evaluated bi-annually with the calculation of their Knee Society Scores (KSS) and a radiological assessment for loosening/osteolysis.

Results: 120 knees were available for followup. The average Knee Society clinical and functional scores, respectively, were 27 points and 40 points preoperatively and 93 points and 95 points postoperatively. This indicates a mean increase of about 71% in the clinical score and about 58% in the functional score, which is statistically significant. The mean postoperative flexion was 124°, a mean increase of 23° from the preoperative flexion of 101°. There were no revisions (Kaplan–Meier survivorship of 100%).

Conclusions: We feel durable and reproducible results of PFC-RP-PS design knees are very technique sensitive. The way ahead with the PFC-RP-PS knees looks promising when the exclusion criteria for this design are strictly met. Coming from a non-designer, this study acquires a higher degree of relevance without any designer’s or manufacturer’s bias.

Key words: Midterm results, nondesigner, rotating platform, total knee arthroplasty

MeSH terms: Arthroplasty, replacement, knee, knee joint, knee prosthesis

INTRODUCTION
Total joint arthroplasties of the hip and knee represent a remarkable feat of modern medicine in terms of reducing pain and restoring function to millions of patients afflicted with severe arthritis. While the evolution of implants in many cases has resulted in marked improvements for patients, there are noticeable, high profile failures that have occurred during the same period. Often times the performance and longevity of new implants and devices are based on limited data. These data are commonly in the form of reported case series in the literature where many of these studies are funded by the manufacturers of the implant and/or conducted by designers of the implant, both of whom have an inherent conflict of interest. This undoubtedly can introduce bias into the results of these studies.

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Mobile bearing (MB) knee design has got remarkable success when followed for more than 20 years, low contact stress (LCS) design introduced in 1977, has been proved very successful with maximum followup of 31 years in the hands of designer, Buechel et al. Based on its success, same manufacturer (DePuy Orthopaedics Inc., Warsaw, IN, United States) introduced press-fit condylar (PFC) knee with rotating platform (RP) with two main variants – PFC-RP-cruciate retaining (PFC-RP-CR) and PFC-RP-posterior stabilized (PFC-RP-PS) in year of 2000. While there has been enough literature on CR variant, we could only come across two papers, with minimum 5 years followup with at least 100 knees in the cohort for PS variant.

These are Meftah et al. (designer for DePuy) with 97.7% success rate at the end of 10 years of followup Maniar et al. lead author (designer for DePuy PFC-PS-RP) with 100% success rate at the end of 8 years followup. Incidentally, for the available studies of PS variant of PFC-RP one of the co-authors is the designer himself for DePuy (Ranawat CS, Maniar, RN respectively). The design features of this implant are an improvement over the LCS-RP by DePuy Orthopaedics Inc., Warsaw, IN, United States knee. The 4.8 mm thick chrome baseplate was designed to accept a unidirectional tibial insert with 16 mm high post, and full conformity in both coronal and sagittal planes.

This is the first study by a non-designer on the PFC-RP-PS design with 100% success. This has a relevance, vis-à-vis bias that one may have in terms of reproducibility of technique and funding from the manufacturer. We associate our excellent mid-term results to intraoperative technical aspects and stringent intraoperative exclusion criteria.

**Materials and Methods**

We started performing PFC-RP-PS knees since 2003, with very selective intraoperative criteria, in choosing the patients for this implant. One hundred and twenty one selective knees in 83 patients were operated for PFC-RP-PS total knee arthroplasty (TKA) between January 2003 and October 2010. A written informed consent was taken for every knee that if there were unsatisfactory intraoperative technical conditions, we would not go ahead with PFC-RP-PS design and may have to revert to fixed bearing (FB) design. All knees having an inadequate balancing of flexion and extension gap, knees with severe osteolysis and those with trapezoidal gap were excluded intraoperatively and an FB design was implanted. Moreover, knees having extreme deformities where balancing could not be up to a satisfactory level were excluded intraoperatively in favor of FB design. We used cemented, PS, RP prosthesis from the same manufacturer (PFC-RP-PS Sigma, DePuy Orthopaedics Inc., Warsaw, IN, United States) in all these 121 knees. The patella was resurfaced in 100% knees with a cemented polyethylene component.

After losing 1 patient (1 knee) to followup as patient died of myocardial infarction, we retrospectively analyzed 120 knees in 82 patients in our study [Figures 1 and 2]. The average age of the patient at the time of surgery was 62.5 years (range 38–83 years). There were fifty five female patients (66.3%) and 28 male patients (33.7%). The diagnosis was osteoarthritis in 68 knees (80.8%) and rheumatoid arthritides in 15 knees (19.2%). Varus deformity was seen in 67 knees (82.0%) and valgus deformity was seen in 11 knees (18.0%). Mean preoperative flexion was 101° (range 75°–125°). About 44 patients (53%) were either overweight (body mass index [BMI] 25.00–29.99) or obese (BMI ≥ 30.00). The mean BMI of the patients in the study was 31.7 (range 23.9–39.6). Periarticular surgeries were previously performed in none of the cases. Minimum followup was of 5 years and 1 month (range 5 years and 1 month to 11 years and 10 months).

**Operative procedure**

All the surgeries were performed by the lead author through a standard central skin incision with a midvastus approach. Tibial cuts were taken first. An intramedullary guide was used in case of a femur while an extramedullary jig was used for tibia. Balancing was done first in extension using spacer blocks. For creation of a rectangular flexion space, posterior condyle cut parallel to tibial condyle or the “gap balancing” technique was used, the efficacy of which has been published by the lead author. This is a modification of the original gap-balancing technique. In this technique, the proximal tibia is the first cut at 90°. The distal femur is cut at 5° of valgus for a varus knee or 3° of valgus for a valgus knee. The soft tissues are first balanced in extension (up to 2 mm of equal mediolateral opening was accepted). Then, the knee is flexed to 90°.
the osteophytes were thoroughly removed, especially the posterior ones, prior to soft tissue releases for coronal plane balancing. An anteroposterior (AP) femoral cutting block of appropriate size is placed on the cut surface of distal femur and preliminarily fixed with pins. A lamina spreader is then applied between posterior margins of the block and cut tibial surface with the knee at 90° flexion to create even tension in the collaterals. The block is then rotated and/or shifted anteroposteriorly with stylus on the upper edge (to make sure that the notching is prevented) until a rectangular gap is created equal to the extension gap. In an ideal case, both extension and flexion gaps form a perfect rectangle. Equal laxity of 1–2 mm mediolateral, in flexion of 90° with spacer block in, with varus and valgus stress testing, respectively, should be desirable. Any flexion gap of more than 2 mm in the formation of a rectangular flexion space on stretching with lamina spreader was not accepted.

The balanced extension and flexion gaps so obtained were confirmed by corroborating with transepicondylar axis and Whiteside’s line (AP axis), which are other accepted methods of confirming rotation of the femoral component.

An FB implant was used in the following situations:

- The balancing in flexion was not satisfactory despite efforts to fit appropriate size femoral implant and moving the AP cutting block as needed or the flexion balancing remaining more than 2 mm loose. Obviously, the AP cutter block cannot be shifted further posteriorly (which would tighten the flexion space) for fear of notching
- A trapezoidal flexion gap developed (on the medial side height more than lateral, in typical varus deformity, after it is released, and balanced in extension) despite rotating the femoral AP cutting jig. This can particularly happen in extreme deformities or combination of flexion + varus deformities
- Substantial incompetence of the collateral ligaments, especially in cases of severe bone loss or extensive posteromedial release, including semimembranosus.

No undue attempt was made to fit in the PFC-RP-PS prosthesis in any of these unacceptable scenarios. Authors abandoned the PFC-RP-PS prosthesis and went ahead to perform FB implant if the above criteria were not met. The advantage of the instrumentation allowed the switch over to FB implant, efficiently, as the femoral component for both, the RP and the FB implant, are the same, requiring only tibial fin cut changes intraoperatively. Thus, all the knees were either “PFC Sigma RP PS” or “PFC Sigma FB PS” for this project.

We resurfaced patellar component in all the cases and it was done with a free-hand technique. In all the cases, the patellar thickness was measured with a vernier caliper and suprapatellar synovial fold was resected. Patella was held with the help of two towel clips, in an everted position so that it lies with its equator parallel to the floor. Saw blade was passed through substance at a particular level so that after patellar component implantation the original thickness of patella is created; taking care that at least 14 mm of native patellar bone is left behind after the cut. Final patellar button implantation was done a little medially so that the button lies adequately medial to the anterior lateral flange of the femoral component; in an effort to recreate the normal patellofemoral biomechanics. Under no circumstances, was the patella undercut or overcut or the patellar button put eccentrically. We do this step with a logical presumption that every time we overcut to leave a thinner or smaller patella than before, the quadriceps tendon will have natural tendency to rub its surface against the metal at the femoral component notch. This, we feel, is the most common cause related to the surgical technique, which can lead to crepitus or clunk, postoperatively. Similarly, undercutting and leaving a larger patella causes overstuffing of the joint. Abnormal patellar button placement or tilt affects the patellofemoral tracking.

All components were cemented with Palacos-R (a nonantibiotic impregnated low-viscosity cement). Wound closure was performed with the knee in 90° flexion. Absorbable monofilament subcuticular closure was opted in all cases. Drain was kept for all knees for 48 h. Postoperative protocols were the same for all the patients. Full weight bearing mobilization started from the day following the surgery. No continuous passive motion machine was used. All patients received routine antibiotics and thrombosis prophylaxis therapy and were usually discharged on the 3rd postoperative day and asked to followup as per routine schedule.
The patients were discharged on 3rd postoperative day and were called for followup on 10th day and 3rd week for inspection of surgical site and stitch removal. Then, they were followed monthly for 6 months then 6 monthly. Thus, patients were evaluated biannually with calculation of their Knee Society Scores (KSSs) and a radiological assessment for loosening/osteolysis (by dividing the periarticular region into various zones as described in the Knee Society X-ray Scoring System), spin-offs or any other abnormalities by getting true-sized AP, lateral and oblique weight-bearing radiographs, and an axial view of patella. A Kaplan–Meier analysis was done for the survivorship. The “Wilcoxon signed rank” statistical test was done for statistical analysis of our results (Figures 3 and 4).

**RESULTS**

Of the 121 knees (n = 83) included in the study, we could followup 120 knees (n = 82), one died due to myocardial infarction at 7 years followup. The average followup of our patients came to about 6.25 years. The average Knee Society clinical and functional scores, respectively, were 27 points (range: 7–50 points) and 40 points (range 5–60 points) preoperatively and 93 points (range 64–100 points) and 95 points (range 70–100 points) postoperatively. This indicates a mean increase of about 71% (mean absolute increase of 66 points) in the clinical score and about 58% (mean absolute increase of 55 points) in the functional score, which is statistically significant. The mean postoperative flexion was 124° (range 99–134°), a mean increase of 23° from the preoperative flexion of 101° (range 75–125°).

Three knees (3.61%) had anterior knee pain of which 2 resolved over a period of 6–9 months while 1 still has mild but persistent pain (6 years followup). Two knees (2.40%) had crepitus which resolved over a period of 9–12 months after supervised physiotherapy and vastus medialis obliquus strengthening exercises. Two knees (2.40%) showed a superficial skin infection (stitch abscess) which were treated with oral antibiotics and dressing and did not necessitate a wash. Two knees (2.40%) showed a nonprogressive osteolytic line (1 in number) on the femoral side. Both the lines were 2 mm in diameter and located in femoral zone 2. One patient with bilateral knees done sequentially fared lower on her second (right) knee score as she developed a psychiatric illness during her rehabilitation period unrelated to the surgery, which prevented her from pursuing the physiotherapy. She developed a postoperative extension lag of 5° in her right knee, which lead to a deduction of 5 points from her good postoperative clinical score of 81. However, her first knee (left) continues to do very well.

*Figure 3:* Anteroposterior view of the tibial component. Suggested guidelines for assignment of zones are: 1 and 2 for medial plateau, 3 and 4 for lateral plateau, and 5 to 7 for the stem fixation or the central fixation if there is no stem.

*Figure 4:* Lateral view of the femoral component. Suggested guidelines for the assignment of zones are: 1 and 2 for the anterior flange, 3 and 4 for the posterior part, and 5 to 7 for the stem fixation or the central fixation if there is no stem.
There were no revisions (Kaplan–Meier survivorship of 100%), periprosthetic fractures, neurovascular complications, thromboembolic phenomena or deep infections, and the followup radiographs revealed no gross osteoysis/loosening.

The comparison of the mean clinical score and functional score before and after surgery and the analysis of the results are given in Tables 1-5 and Figure 5.

Thus, in the above statistical analysis it is clear that in all the 120 cases of PFC-RP-PS knees the postoperative clinical and functional scores are higher than the preoperative scores (negative ranks – 0/120, positive ranks – 120/120). Using Wilcoxon signed ranks test, the PFC-RP-PS knees, have a \( P = 0.000 \) (\( P < 0.05 \)), giving a success rate of 100% in terms of significant improvement in clinical and functional postoperative scores. The Kaplan–Meier analysis, done for the minimum followup of 5 years, gave a 100% survivorship (0/78 revision).

**Discussion**

Numerous studies till date have shown successful results with the RP design knees. The meta-analysis by Hopley et al.\(^ {11} \) and Carothers et al.\(^ {12} \) and the landmark study by Buechel et al.\(^ {7} \) on LCS-RP knees have demonstrated excellent results as good, if not better, as those with FB knees. Buechel et al., one of the earliest designers of MB knees, have the longest followup of up to 31 years. These knees were introduced with the goal of providing an implant that would allow increased congruity without compromising motion. The implant was made more conforming, in both the sagittal and coronal planes, at the tibiofemoral articulation, thereby decreasing the contact stresses. Motion at the polyethylene tibial component interface was designed to avoid the compromise in knee range of motion (ROM) expected with increased articular conformity with FB designs. In theory, this design would provide an ideal biomechanical situation-decreased polyethylene back wear from increased articular conformity while improving knee ROM with the addition articulation at the tibial polyethylene interface.\(^ {13,14} \)

**The press fit condylar-rotating platform-posterior stabilized knee design**

The PFC-RP-PS knee was introduced by the same manufacturer (DePuy Orthopaedics Inc., Warsaw, IN, United States) in order to decrease the high spin out rates in some of the earlier studies. The PFC-RP-PS prosthesis is said to be an improvement over the LCS-RP variety. The tibial component is a highly polished 4.8 mm thick cobalt-chromium baseplate with the poly having nearly full conformity in the sagittal and coronal plane. There is a 16 mm post in the PS variety, apparently reducing the risk of spin-outs. The PFC-RP-PS knee was introduced after the success of its FB variant. Clinically, the results of the limited number of PFC-RP-PS followup studies, including the KSS

![Figure 5: A bar diagram showing preoperative and postoperative functional and clinical scores](image-url)
and mean ROM, have been better than that seen in many of the LCS studies.6,7

Reduced poly wear

One of the main reasons for the failure of TKA in the long run is the premature polyethylene wear (backwear)15,16 with subsequent surrounding bone osteolysis as a result of “condylar lift-off” and subsurface movement at the “back” of tibial poly insert.17-19 This is the place where the PFC-RP-PS knees can be highly advantageous. They allow increased conformity both sagittal and coronal (esp. coronal conformity with regards to FB) and increased contact area without dramatically increasing the fixation stresses.20-23 They decrease the paradoxical sliding/shear and are more tolerable of femoral condylar lift off. It is a known fact that multidirectional motion accelerates the poly wears, while unidirectional motion reduces the same. There is multidirectional motion (rotational, translational, and flexion extension) of the femoral component relative to the tibial bearing surface in FB-TKA, all occurring at the single superior surface of the poly. However, in the PFC-RP-PS knees, the superior surface experiences purely flexion extension (unidirectional) and the inferior surface has purely rotational (unidirectional) movements. Thus, these movements are decoupled and the wear is largely diminished.24,25 The phenomenon of rotational medial and lateral postimpingement in PS systems are reduced in PFC-RP-PS knees due to postrotating with the femoral box instead of rotating against it leading due reduction of cam-postwear. However, the long term followups are awaited. Though PFC-RP-PS knees have an additional articulating surface between the poly and tibia, the concerns of generation of extra polyethylene debris and consequent rapid poly wear have not been validated till date,15,16 which can be explained by the fact of decoupling of joint motion as mentioned earlier [Figures 1 and 2].

**Better patellar tracking**

The self aligning feature of PFC-RP-PS helps the facilitation of central patellar tracking.20 By means of bearing motion, the rotating poly provides for greater self correction of component malalignment in cases of substantial malfraction of tibial component (internal rotation). A little medial implantation of the patellar button subsequently results in favorable patellar biomechanics. This significantly reduces the risk of patellar subluxation.

**When not to do a rotating platform?**

We believe that an important reason for such good results in our study was known exactly when not to do the PFC-RP-PS knee [Table 6]. We never compromised on the perfect soft tissue balancing of extension-flexion gap. Any deviation from the same leads to the conversion to FB implant. This is a very important factor in the success of PFC-RP-PS knees. Most of the complications of this implant such as the spin-offs or patellofemoral pain can be attributed to imperfect balancing.

We as a policy, as mentioned earlier, plan for PFC-RP-PS knees to begin with. However, no attempt is made to fit in the prosthesis if balancing is not satisfactory and the exclusion criteria, as mentioned earlier, are followed strictly.

We compared our results with publications by two authors on PFC-RP-PS design, both members of the designer team [Table 7]. This study differs from them by having stricter exclusion criteria for the selection of RP over FB knees. This has helped us achieve a significant improvement of the postoperative ROM over the preoperative ROM up to a mean of 23°. This is higher by 8° than the previous similar study, having 100% survivorship, by Maniar et al.,9 which had a mean increase of 150. The author attributes the improvement in postoperative ROM to stricter knee selection and surgical steps like the removal of posterior femoral osteophytes, restoration of patellar thickness, and accepting up to 2 mm of extra space in flexion as compared to an extension.

We also compared our results with other studies done for RP knee designs, which include two meta-analyses with 10 years-plus duration of the index surgery. The outcome compares favorably for the PFC-RP-PS knees as illustrated in the following table [Table 8].
Bedair et al. compared the survivorship of hip and knee implants recorded by the designers and the national registries separately, 32% of comparisons performed demonstrated greater survivorship in the designer series compared to the registry, while 0% reported lower, and 68% demonstrated no difference ($P < 0.01$).27 The performance and longevity of new implants and devices are based on limited data. These data are commonly in the form of reported case series in the literature where many of these studies are funded by the manufacturers of the implant and/or conducted by designers of the implant, both of whom have an inherent conflict of interest. This undoubtedly can introduce bias into the results of these studies. A common and prevailing sentiment is that the results reported in these types of studies may portray an overly optimistic picture of the implant’s performance. The earlier studies on the followup and survivorship of PFC-RP-PS knees were designer series in essence.

Maniar and Ranawat studies have excellent midterm results (100% and 97%, respectively), but both are by designers of the implant manufactured by DePuy6 [Table 7]. A recent study by Lee et al. in 2016 reported excellent midterm results of a success rate of 96.7% over 10 years.28 As per Bedair et al., there is no concordance in terms of bias and authority when the excellent results are published by designers. Our study and its excellent results should stand out as it is not done by designers or manufacturers nor is it funded by them.

Possible pitfalls with press fit condylar-rotating platform-posterior stabilized knee design

One of the controversial points, whether to internally rotate the femoral component for the achievement of a flexion rectangular gap is highly debatable. As per Boldt et al., most of the complications after internal rotation of femur resulted when it exceeded 5°. They stated that optimal amount was up to 3°. We in all the cases followed the same religiously, i.e. never internal rotate beyond the epicondylar line.

Patellar clunk syndrome was not encountered in our operated cases. The extra femoral cut during extension gap balancing which is the cause behind the patellar clunk can be avoided by proper technique and adhering to the exclusion criteria.

**Conclusions**

Authors feel durable and reproducible results of PFC-RP-PS design knees are very technique sensitive. A surgeon should know before starting to operate, the possibility of changing over to FB implant, if stringent criteria of flexion extension spaces and patella-femoral joint balancing are to be met with. The way ahead with the PFC-RP-PS knees looks promising when the exclusion criteria for this design are given their fair share of importance. Coming from a nondesigner, this study acquires a higher degree of relevance without any designer’s or manufacturer’s bias.

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**Table 6: Total knee arthroplasties done by year**

| Year   | Total knees signed up | Rotating platforms | Fixed bearings | Rotating platform as a percentage in all knees signed up |
|--------|-----------------------|--------------------|----------------|-------------------------------------------------------|
| 2003   | 27                    | 2                  | 25             | 7                                                     |
| 2004   | 38                    | 3                  | 35             | 8                                                     |
| 2005   | 45                    | 4                  | 41             | 9                                                     |
| 2006   | 59                    | 7                  | 52             | 12                                                    |
| 2007   | 72                    | 10                 | 62             | 14                                                    |
| 2008   | 100                   | 17                 | 83             | 17                                                    |
| 2009   | 175                   | 35                 | 140            | 20                                                    |
| 2010   | 176                   | 33                 | 144            | 18                                                    |
| Total  | 692                   | 121                | 438            | 15                                                    |

**Table 7: Comparison with studies by designers**

| Studies     | Number of knees | Pre-CS | Post-CS | Pre-FS | Post-FS | Survival (maximum followup) %, (years) | Average followup |
|-------------|-----------------|--------|---------|--------|---------|----------------------------------------|------------------|
| Our study   | 120             | 26.6   | 92.6    | 39.7   | 94.7    | 100 (12)                               | 6.25             |
| Maniar et al.6 | 118         | 27     | 96      | 51     | 83      | 100 (8)                                | 6.5              |
| Meftah et al.6 | 117       | 44     | 94      | -      | -       | 97.7 (11)                              | 10               |

Pre-CS=Preoperative clinical score, Pre-FS=Preoperative functional score, Post-CS=Postoperative clinical score, Post-FS=Postoperative functional score, PFC-FB=Press fit condylar-fixed bearing

**Table 8: Comparison with other studies by non designers**

| Studies         | Number of knees | Pre-CS | Post-CS | Pre-FS | Post-FS | Survival (followup) %, (years) |
|-----------------|-----------------|--------|---------|--------|---------|-------------------------------|
| Our study       | 120             | 26.6   | 92.6    | 39.7   | 94.7    | 100 (11)                      |
| Buechel et al.6 | 373*            | -      | -       | -      | -       | 97.7 (20)                     |
| Callaghan et al.20 | 119       | 30     | 90      | 44     | 75      | 98 (12)                       |
| Huang et al.26  | 267*            | -      | 87      | -      | 75      | 92.1 (12)                     |
| Meftah et al.6  | 117             | 44     | 94      | -      | -       | 97.7 (10)                     |
| Argenson et al.5 | 116        | 34     | 94      | 55     | 88      | 98.5 (10)                     |
| Hopley et al. meta-analysis11 | 6437 | 34     | 89      | 39     | 78      | 98.1 (10)                     |
| Carothers et al. meta-analysis12 | 3506 | 62.6   | increase in the total score | 96.5 (10) |
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Conflicts of interest
There are no conflicts of interest.

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