KNEE ARTHROPLASTY

A comparative analysis between fixed bearing total knee arthroplasty (PFC Sigma) and rotating platform total knee arthroplasty (PFC-RP) with minimum 3-year follow-up

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Abstract

Background Since the introduction of mobile bearing total knee designs nearly 30 years back, many studies have been done to evaluate its long-term result. Comparison with fixed bearing designs has been done in the past, but the studies were confounded by variables such as disease, surgeon, bone quality, pain tolerance, etc. We attempt to eliminate these variables in this study.

Methods A total of 50 patients who had bilateral arthritis of the knee with similar deformity and pre-operative range of motion on both sides agreed to have one knee replaced with mobile bearing total knee design (PFC-RP) and the other with a fixed bearing design (PFC Sigma) were prospectively evaluated. Comparative analysis of both the designs was done at a mean follow-up of 40 months, minimizing patient, surgeon and observer related bias. Clinical and radiographic outcome, survival and complication rates were compared.

Results At a mean follow-up of 40 months (range 36–47 months), no benefit of mobile bearing (PFC-RP) over fixed bearing design (PFC Sigma) could be demonstrated with respect to Knee Society scores, pain scores, range of flexion, subject preference or patello-femoral complication rates. Radiographs showed no difference in prosthetic alignment. No patient required a revision surgery till last follow-up.

Conclusions Our study demonstrated no advantage of the mobile-bearing arthroplasty over fixed bearing arthroplasty with regard to clinical results at short-term follow-up.

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However, longer follow-up is necessary to confirm whether these results are sustained.

Keywords Mobile bearing \cdot Fixed bearing \cdot Rotating platform \cdot Knee score

Introduction

Long-term result of total knee arthroplasty (TKA) with symmetric fixed bearing design has shown high degree of clinical success especially in older and less active individuals [1-5]. However, concern continues regarding problems related to patello-femoral articulation, polyethylene wear and osteolysis. Mobile bearing knee was introduced with the aim of reducing polyethylene wear and related osteolysis, which was seen with some fixed bearing designs [6]. Congruency between femoral component and superior surface of the rotating polyethylene in a mobile bearing design was intended to reduce polyethylene wear, while rotation between the inferior polyethylene surface and metal tray was thought to reduce stress on the metal tray and tibial bone interface. Increasing conformity in a fixed bearing decreases polyethylene wear, but transfers excessive stresses to the implant bone interface causing loosening of the tibial component [7, 8]. Mobile bearing design theoretically removes these drawbacks by providing a dual surface articulation between the metallic femoral prosthesis and tibial tray. Another advantage of mobile bearing designs is that they are more forgiving in terms of tibial malrotation as some rotatory movement is allowed between the polyethylene insert and the tibial tray. The amount of malrotation tolerable, though, is only minimum to the extent of movement between the insert and tray.

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However, no previous controlled comparison has been able to show any advantage of mobile bearing over fixed bearing total knee prosthesis either in clinical function or longevity [9].

In October 2000, the press-fit condylar Sigma rotating platform (PFC Sigma RP) TKA (DePuy Orthopedics, Warsaw, IN) was introduced in the United States after a multicenter, preclinical trial in Europe in more than 3,000 knees. The design features of the PFC Sigma RP take advantage of improvements over the PFC modular TKA (DePuy Orthopedics) introduced in 1990 and the 20-year experience gained with the New Jersey lowcontact stress (LCS) mobile-bearing knee (DePuy Orthopedics) [10]. Currently, these are the only two primary rotating platform knee implants with US Food and Drug Administration (FDA) approval. The PFC Sigma RP uses the same formula component as the existing PFC Sigma knee, and is part of its integrated total knee system. The tibial component is a highly polished, 4.8-mm thick chromium cobalt baseplate. Other advantages include almost full conformity in both the coronal (1.03:1) and sagittal (1.021:1) planes and a 16-mm post in the posterior-stabilized version to protect against bearing dislocation.

The aim of this prospective study is to compare the results of PFC (rotating platform) and PFC Sigma (fixed bearing) prosthesis in patients undergoing bilateral TKA with regards to clinical and radiologic outcome and complication rate with special emphasis on instability and patello-femoral complications.

Materials and methods

A prospective study of 50 patients suffering from bilateral knee arthritis with similar deformity and pre-operative range of motion on both sides were offered simultaneous total knee replacement and were invited to have one knee replaced with PFC (rotating platform) and other with PFC Sigma (fixed bearing). They were also requested to agree to random selection by lottery as to which knee would receive PFC Sigma (fixed bearing) and which one PFC (rotating platform) prostheses.

Patients were evaluated pre- and post-operatively at intervals of 2 weeks, 3 months, 1 year and yearly, thereafter, according to the American Knee Society recommendation. However, the 2 weeks post-operative evaluation was necessarily related to wound complications as no meaningful difference in terms of clinical performance of the two prostheses can be expected so early in the post-operative period.

Pre-operative evaluation

The pre-operative evaluation included detailed clinical and radiological evaluation. The data obtained included demographic data, pre-operative diagnosis, the patient symptoms and clinical evaluation as per Knee Society clinical rating system [11]. Note was made regarding ambulatory status of the patient.

The pre-operative range of motion of the knees was measured using a goniometer with 30 cm movable arms and scale marked in 2° increments. The patello-femoral mobility was evaluated to assess exposure options. The angular deformity of the limb and the condition of the overlying skin including any previous scars were documented. The neurovascular status of the limb and its quadriceps power were assessed. In addition, the patients' desire and ability to comply with post-operative therapy were also evaluated.

All patients were subjected to evaluation by Knee Society scoring system in terms of knee score as well as function knee score. Pain scoring of each knee was also done according to the Hospital for Special Surgeries pain scoring scale [12]. Note was also made of any deformity in the knee with regard to flexion and medio-lateral malalignment.

Radiographic evaluation included an antero-posterior view (standing if possible), lateral view and a skyline patellar view, according to the guidelines of the Knee Society. Evaluation was done regarding the limb alignment, the bone loss, the bone quality and the relationship of patella to the joint line. Presence of sub-chondral cystic areas, if any, was also noted.

Written and informed consent was sought and obtained in all the cases. Patients were informed regarding the high risk of complications including superficial wound necrosis, deep infection, anterior knee pain or post-operative instability particularly bearing dislocation as a few cases have been reported in the knees with mobile bearing designs.

Operative technique

The operations were carried out in laminar air flow operating room. Antibiotic prophylaxis with intravenous cefotaxime (2 g, half an hour before inflation of the tourniquet followed by 1 g each 8 h for 3 days) and anti-thrombotic prophylaxis with subcutaneous enoxaparin (40 mg, once a day from the night before surgery and continued till the tenth post-operative day) were used in all patients.

We routinely used combined spinal and epidural anaesthesia and maintained the patients on continuous epidural infusion post-operatively for 48 h for post-operative pain relief. Range of motion of knees and ligamentous stability were reassessed under anaesthesia. Surgeries were performed under tourniquet.

An anterior midline skin incision was used in all the cases. A medial para-patellar arthrotomy was used in all the cases. The posterior cruciate ligament was sacrificed in all the cases. Hoffa's fat pad was removed routinely. Extra-medullary alignment jig for tibia and intra-medullary alignment jig for femur were used. The tibial cut is made first and the femoral rotation is according to the flexion gap and is confirmed by the bony landmarks. In case of any discrepancy, we go back and check the tibial cut and if that is still found satisfactory, the femoral rotation is confirmed according to the flexion gap to ensure stability in flexion. Mostly, however, they coincide and reassure the surgeon. Patella was not replaced. Patelloplasty was done in all cases which included soft tissue release from lateral patella, division of patellofemoral ligament, patellar rim cautery to provide partial denervation and osteophyte removal. In all the rheumatoid knees and in OA with thick and deformed patella, 2-4 mm of the articular surface of patella was removed and medial and lateral facets were recreated. Note was made regarding tourniquet time, blood loss, need for extensive releases, additional distal femoral cuts and the size of implant used.

Both the tibial and femoral components were cemented. Pulsatile lavage was used before cementing the implants. The post-operative regimen included epidural analgesia, immobilization in knee immobilizer for 2 days, gravity assisted regaining of flexion from the third day and walking with support from the fourth post-operative day. Progressive resisted exercises to strengthen the quadriceps were started in the second week and continued through the first year following arthroplasty. All patients used support while walking for 3 months following surgery.

Post-operative evaluation

Post-operatively patients were called to the out patient department at pre-determined intervals for assessment. These evaluations were blinded to prevent bias.

Patients were subjected to assessment according to the American Knee Society [11] recommendation in both the knees. However, the comparison between the two sides was made only by the Knee Society score, as the function scores which require bipedal activities such as walking and stair climbing could not be used in our patients.

Clinical evaluation of patello-femoral joint articulation was done and knees were graded by a system developed by Stern and Insall [13].

Radiographic evaluation

Antero-posterior and lateral radiographs were made both pre-operatively and post-operatively with the patient standing. On the pre-operative antero-posterior radiographs, varus or valgus alignment, as defined by the mechanical axis of the knee relative to the center of the hip joint, was measured. On the pre-operative lateral radiographs, the perpendicular distance from the tibial tubercle to a line parallel to the weight-bearing surface of the tibial plateau was measured.

The change in the relative position of the joint line preoperatively and post-operatively was defined as the difference between the perpendicular distance from the weight-bearing surface of the tibial plateau to the tibial tubercle of the natural tibia and the perpendicular distance from the weight-bearing surface of the prosthetic tibial component to the tibial tubercle.

Also, in the pre- and post-operative radiographs, Insall–Salvati [14] and Blackburne–Peel ratio was noted [15].

Distances between joint line and medial epicondyle and between fibular styloid and joint lines were measured on anterior–posterior radiographs both pre- and post-operatively. The perpendicular distance from the inferior pole of the patellar implant to the line parallel to the weightbearing surface of the prosthetic tibial plateau was measured.

Patellar height measurement was done to detect possible impingement by rotating platform as well as the fact that patello-femoral symptoms are a concern with rotating platform. Also, many of our joints are severely deformed and correction is often associated with an alteration of the joint line and the patellar height. Hence, we routinely looked for it post-operatively.

Position of individual prosthesis and location of radiolucent lines at the cement bone interface were analyzed according to the guidelines of Knee Society [16]. A loose prosthesis was diagnosed by progressive lucency of >2 mm surrounding the entire circumference of prosthesis, subsidence of component or change in alignment of the prosthesis compared to its previous status. Patellar tilt, subluxation or dislocation if any was assessed by the skyline patellar view.

Statistical analysis

Two groups of knees were compared overall and diagnosis wise with respect to pre- and post-operative knee score, pain score and range of motion achieved post-operatively using paired t test. Chi-square test was used to evaluate overall complication rates and incidence of radiolucent lines in two groups. Significance was tested with P value

<0.05. The statistical analysis was performed using SPSS software.

Observation and results

Demographic data

In this study, 50 patients with similar range of motion and deformity in both knees were invited to have one knee implanted with fixed bearing and other with mobile bearing variants of same TKA prosthesis. Clinical and radiologic parameters between the two designs were compared. The mean follow duration was 40 months (range 36–47 months).

There were 10 males (20%) and 40 females (80%). The mean age in our study group was 64.46 (range 47–73). Osteoarthritis was the most common (44 patients) diagnosis. All of these patients had primary degenerative arthritis. Rheumatoid arthritis (six patients) was the other diagnosis.

Clinical observation and results

Range of motion

The mean range of motion in the fixed bearing group pre-operatively was 100° (range $60^{\circ}-120^{\circ}$). At 3 months follow-up the mean range of motion was 95° (range $75^{\circ}-110^{\circ}$). Range of motion improved to a mean of 107° (range $85^{\circ}-120^{\circ}$) at 1 year and 110° (range $85^{\circ}-120^{\circ}$) at 3 years.

In the rotating platform group the mean pre-operative range of motion was 10 [19] (range $70^{\circ}-120^{\circ}$). At 3 months follow-up the mean range of motion was 96.6° (range $70^{\circ}-110^{\circ}$). Range of motion improved to a mean of 106° (range $70^{\circ}-120^{\circ}$) at 1 year and 11 [19] (range $80^{\circ}-120^{\circ}$) at 3 years.

The difference in the improvement in the arc of flexion for the two designs of prostheses was found to be statistically insignificant (P > 0.05) at each follow-up (Table 1).

Knee Society score

The mean pre-operative Knee Society score in the fixed bearing group was 55.72 (range 32–64) and it improved to a mean score of 70.62 (range 32–64), 79.92 (range 46–78)

Table 1 Range of motion in each group

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ROM (deg)	Fixed bearing (SD)	Rotating platform (SD)
Pre-operative	100 (14)	102.0 (12)
3 months	95.0 (12)	96.0 (10)
1 year	107 (9)	106 (11)
3 years	110 (11)	112 (11)

Table 2	Knee	Society	score	in	the	two	groups
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Knee Society score	Fixed bearing (SD)	Rotating platform (SD)
Pre-operative	55.72 (8.78)	56.40 (9.01)
3 months	70.62 (5.38)	71.77 (5.47)
1 year	79.92 (4.91)	80.36 (4.92)
3 years	86.94 (9.24)	87.60 (9.16)

and 86.94 (range 64–92) at 3 months, 1- and 3-year followup, respectively.

The mean pre-operative Knee Society score in the rotating platform group was 56.40 (range 29–64), which improved to 71.77 (range 29–64) at 3 months, 80.36 (range 64–87) at 1 year and 87.60 (range 64–91) at 3-year follow-up (Table 2). The improvement in knee scores was compared and it was found that the improvement in each group was not significant statistically (P > 0.05).

Pain score

The mean pain score in the fixed bearing group on a scale with maximum 30 points during pre-operative period was 11.4 (range 5–15) and it improved to 21.6 (range 20–25) at 3 months, 23.6 (range 20–30) at 1 year and 25.4 (range 20–30) at 3-year follow-up. The mean pain score in the rotating platform group in pre-operative period was 11.7 (range 5–15). This score improved to a mean of 21.8 (range 20–25) at 3 months, 24.4 (range 20–30) at 1 year and 26.1 (range 20–30) at 3-year follow-up (Table 3). The improvements in pain score were analyzed, and no significant difference was found statistically (P > 0.05).

Radiological results

Patellar height was recorded with all three criteria, i.e. mean Insall–Salvati ratio (IS), Blackburne–Peel ratio (BP) and from joint line (PH). Joint line levels were recorded from medial epicondyle (ME), fibular styloid (FS) and from tibial tuberosity (TT). No significant elevation of joint line and alteration in patellar height were seen in the fixed bearing group as compared to rotating platform group (P > 0.05) (Table 4).

The comparison between radiological parameters was made at 1-year follow-up to avoid excessive radiation exposure to the patient unless clinically indicated.

Table 3 Pain score in the two groups

Pain score	Fixed bearing (SD)	Rotating platform (SD)
Pre-operative	11.4 (3.03)	11.7 (3.58)
3 months	21.6 (3.61)	21.8 (3.75)
1 year	23.6 (3.03)	24.4 (3.86)
3 years	25.4 (3.91)	26.1 (4.14)

Table 4 Radiological results among the two groups

	Fixed pre-op	Fixed post-op	Rotating pre-op	Rotating post-op
IS	0.98	0.95	0.98	0.95
BP	0.92	0.86	0.93	0.85
PH (mm)	19	17.5	19	17
ME (mm)	23	22	24	22
FS (mm)	12	14	11	13
TT (mm)	20	22	20	22

Mean tibio-femoral angle was 4° valgus (range $0^{\circ}-10^{\circ}$) in both fixed and mobile bearing groups post-operatively.

Complications

Four knees in the rotating platform group and two knees in the fixed bearing group developed persistent discharge from the wound in the early post-operative period (average 3rd to 4th day). Out of these six knees that had haematoma formation and discharge from the wounds, two cases were bilateral (hence two fixed and two rotating platform knees). Both these patients were taken to operation theatre for debridement and irrigation of joint. Samples were collected from the joint and sent for culture and sensitivity. Patients were continued on intravenous antibiotics for 2 weeks. Culture reports from all four knees were sterile, and patients were investigated for any possible coagulation defects. The incidence of wound complication with the numbers available is not significant on statistical parameters (P > 0.05).

The incidence of anterior knee pain was 14 and 12% in mobile-bearing and fixed bearing groups, respectively. However, all these patients whether in fixed or rotating platform group had Grade 1 complication only.

There was no evidence of tibio-femoral joint instability or dislocation of bearing, as well as massive osteolysis (lesions of more than 1 cm) in either group till last followup. Six knees, three in the fixed bearing group and three in the mobile bearing group, had a pre-operative flexion deformity of an average 15° (range $5^{\circ}-30^{\circ}$). The diagnosis in all these cases was rheumatoid arthritis. A mean flexion deformity of 5° (range $2^{\circ}-10^{\circ}$) persisted in the mobile as well as in the fixed bearing group. These patients were managed with skin foam traction during night and active mobilization during day (Table 5).

Discussion

Numerous comparative studies have been published in the literature analyzing the results of mobile bearing TKA with fixed bearing [9, 17–27]. Most of these studies compared

 Table 5
 Various complications in each group

Complication	Fixed bearing	Rotating platform
Wound necrosis/discharge	2	4
Anterior knee pain	6	7
Dislocation	-	_
Radiolucent lines	2	2
Osteolysis	-	_

the results of these two implants either in different patient groups or in same patient who received both the implants, the design was different for the two variants [9, 17–27]. However, comparisons are more meaningful if confounding is minimal. In this study, simultaneous bilateral TKA using fixed and mobile bearing variants of PFC Sigma (DePuy) was performed in same patient. The only variable in this study is the design of tibial insert. We have minimized confounding variables relating to disease, surgeon, bone quality, type of prosthesis and pain tolerance of individual and post-op rehabilitation.

We could find only three studies in the literature where fixed and mobile bearing TKA of same design were implanted in the same patient [28–30]. Kim and colleagues [28] demonstrated that both PFC Sigma mobile and fixed gearings were functioning well at mean follow-up of 5.6 years with no superiority of mobile bearing variant over fixed bearing variant both clinically and radiologically. Price et al. [29] compared the results of AGC fixed bearing (Biomer, Merck) and TMK (Biomer, Merck) mobile bearing prosthesis implanted in same patients and followed for 1 year. Their study revealed small but significant clinical advantage of the mobile bearing design; however, there was no difference in the range of motion.

Relevance of our study in reporting short-term results of this comparative analysis is to establish whether mobile bearing designs improve clinical performance of the knee significantly. We could not demonstrate this theoretical advantage in our clinical results as one would expect the maximal knee flexion and anterior knee pain to show shortterm improvement with the use of mobile bearing design.

Wohlrab et al. [31] evaluated Hospital for Special Surgery (HSS) score in 30 patients each implanted with NexGen LPS and NexGen LPS flex mobile, respectively, at 3 months and found that mobile bearing designs showed better results in scores of pain range of motion, and overall HSS. But these results were not sustained at a later followup after 3 years when there was no difference in all scores. We expect a knee replacement to serve for about a decade and half to two, and the superior performance of one design should be permanent.

Ranawat and colleagues [30] also compared the results of fixed bearing and rotating platform designs implanted in same patients. However, they performed these surgeries

during different anaesthetic time, thereby resulting in an unequal follow-up for these two designs. They have reported the clinical outcomes to be similar for the two prostheses.

Implant related complication also affect patient satisfaction as well as survival in TKA. The concept of selfalignment of mobile bearing is expected to lower the incidence of anterior knee pain, and hence improve overall patient satisfaction. We could not demonstrate any significant reduction in anterior knee pain in the mobile bearing group, whereas Breugem and colleagues [32] reported an incidence of only 4.3% in the mobile bearing group compared to 18.9% in the fixed bearing designs.

Further, early revision due to bearing spin out is a potential disadvantage of mobile bearing prosthesis. Bhan and Malhotra [33] have reported an incidence of 4.9% of bearing dislocation with the use of LCS mobile bearing prosthesis; however, no dislocation was seen in the present study. This lower incidence of bearing spin out may also be attributed to learning curve with the use of mobile bearing designs. Moreover, clinical and radiological results of earlier study conducted by senior authors using the IB II (fixed bearing) and LCS knee (mobile bearing) [34] have also shown no advantage of mobile bearing design.

Medium- and long-term follow studies are needed to evaluate more important theoretical advantage of mobile bearing prosthesis which reduced polyethylene wear and loosening. Callaghan et al. [35] have reported 9- to 12-year follow-up of mobile bearing design with no radiographic evidence of loosening in 66 knees available for final follow-up. Kim et al. [9] published a comparison of fixed and mobile bearing design after 6–8 years and found no difference in the rate of polyethylene wear and osteolysis, whereas Huang and colleagues [36] demonstrated higher (47%) incidence of osteolysis in mobile bearing prosthesis compared to the fixed bearing group.

Thus, various theoretical advantages of mobile bearing prosthesis viz. improved functional performance, reduction of mechanical failures, allowing younger patients to be more active and reduced wear rates as a result of improved congruency between the articulating surface which could not be statistically substantiated with any of the studies published till date as well as the present study; however, a longer follow would be necessary to compare the performance of two designs.

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