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Original research

# Minimum 5-year follow-up results and functional outcome of rotating-platform high-flexion total knee arthroplasty: A prospective study of 701 knees

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#### ABSTRACT

*Background:* To evaluate the midterm clinical outcome, functional outcome, associated complications, and survivorship of high-flexion posterior-stabilized rotating-platform total knee arthroplasty. *Methods:* We prospectively analyzed 701 knees in 501 patients, who underwent total knee arthroplasty using high-flexion posterior-stabilized rotating-platform prosthesis. Patients were assessed preoperatively and postoperatively for their ability to kneel, do full squats, do half squats, and sit cross-legged by using a patient-administered questionnaire.

*Results:* Significant improvement was seen in patient-reported outcomes at the mean follow-up of 5.5 (range, 5-7) years. Mean flexion achieved postoperatively was  $135^{\circ}$  (range,  $120^{\circ}$ - $150^{\circ}$ ) from a mean preoperative flexion of  $108.8^{\circ}$  (range,  $90^{\circ}$ - $120^{\circ}$ ). Ninety-five percent of patients were able to sit cross-legged, 90% were able to kneel, 70% were able to perform a half squat, and 20% were able to perform a full squat.

*Conclusions:* Posterior-stabilized, rotating-platform, high-flexion design provides good postoperative flexion, functional outcome, and good midterm survivorship.

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#### Introduction

Total knee arthroplasty (TKA) is a dependable and universally used operation. Primarily intended to alleviate pain in patients with severe arthritis, the procedure has undergone several modifications with respect to implant designs and surgical techniques with the sole motive of providing long-term success rates of about 85% at 10-to 15-year follow-up [1]. Initially introduced in 1978 by Insall et al. [2], the "posterior-stabilized condylar total knee prosthesis" had post-and-cam mechanism to achieve femoral rollback so as to achieve better flexion. The average flexion procured by this prosthesis was 107°-115°. Although this was a noteworthy refinement, it was not enough to achieve flexion which is essential for activities such as sitting cross-legged or squatting which is common in Asian population [3].

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The PFC Sigma, rotating-platform, high-flexion system (PSRPHF; DePuy Synthes, Warsaw, IN) is a mobile-bearing design which has changes in both the femoral component and the tibial insert. This was done with purpose so as to allow increased flexion without compromising the stability of the component in full flexion. Mobile-bearing design was inculcated, as there is theoretically decreased constraint to tibial rotation during flexion. The sole intention of this combination was to increase flexion and stability of TKA throughout the range of motion of knee to facilitate activities such as squatting and kneeling [4].

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The aim of our study was to evaluate midterm clinical outcome, functional outcome, any significant complication, and survivorship of PSRPHF design in a significant sample size of 701 patients, with follow-up of 5-7 years.

#### Material and methods

This study is a prospective, open-labeled observational clinical study, approved by the institutional ethics committee and consented by patients participating. All patients who were operated using PSRPHF system between March 2005 and December 2007 for TKA were included in this study (701 knees, 501 patients). Patients with

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primary osteoarthritis who were well motivated and had high functional demands were selected. Patient with a preoperative range of motion of  $\geq$ 90°, body mass index <25, with varus and flexion deformity <15°, and hyperextension <5° were included in this study. Patients excluded were those having adjacent joint disorder (such as hip, knee, ankle, spine involvement), knee arthritis other than primary osteoarthritis, patients not willing to participate in the study, and patients with dementia or other neurologic disorders.

Two hundred patients who underwent a bilateral simultaneous TKA and 301 who underwent unilateral TKA were included. Out of 501 patients, approximately 81% (n = 370), were female and 19% (n = 131) were male with mean age of 66 (55-84) years. All the patients were operated by single senior experienced surgeon using a medial parapatellar approach and computer navigation (Brainlab, Feldkirchen, Germany).We used a pneumatic tourniquet and midline skin incision. A standard surgical technique for TKA was used. None of the knees required lateral patellar retinacular release.

Pain management and rehabilitation protocol was followed as shown in Table 1.

Patients were called for follow-up 2 weeks postoperative and were further advised to continue physiotherapy under supervision of a physiotherapist at home with an aim to gain flexion range of 130° without extensor lag up to 3-6 weeks postoperatively. The patients were reviewed at 6 weeks, 3 months, 6 months, 1 year, and annually thereafter. All patients were evaluated preoperatively and postoperatively by Knee Society Score (KSS; clinical + functional), Hospital for Special Surgery (HSS) Knee Score, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), flexion range, and Fulkerson and Bristol patellar scores at 6 weeks, 3 months, 6 months, 1 year, and annually. Bristol and Fulkerson scores were included separately to assess patellofemoral functioning as at higher degree of flexion patellofemoral contact stress increases. The tibiofemoral angle was measured as the angle formed at the knee by intersection of the femur shaft anatomical axis and the mechanical axis of the lower limb. Any deviation of the line from the center of the femoral head to the center of the knee and of the line from the center of the knee to the center of the ankle was considered varus or valgus deformity.

Mean follow-up of our patients was 5.5 (range, 5-7) years. All the patients were separately evaluated by using a patientadministered questionnaire for their ability to kneel, do a full squat, do a half squat, and sit cross-legged preoperatively and postoperatively regularly during their follow-up. Individuals gathering the data were not blinded. The tibiofemoral axis was calculated on table by using the navigation system itself at the end of surgery. Knee joint range of motion for knee extension and flexion was assessed in the operated knees. The participant was asked to actively extend or flex their knee, and the examiner measured the joint range with the goniometer. Placing the axis of a goniometer at the intersection of the thigh and shank at the knee joint center of rotation, that is, the lateral femoral condyle, the stationary arm is placed along the lateral aspect of the thigh, following the line from the knee joint to the greater trochanter at the hip. The movable arm is placed along the lateral aspect of the fibula (from the knee center of rotation to the lateral malleolus at the ankle). Measurement was done with the participant in supine position on an examination table long enough to support the legs and in sitting position on a chair too.

Statistical analysis was performed with SPSS software (IBM Corp., Armonk, NY) using regression analysis and the paired *t* test.

#### Results

The results at the end of mean follow-up period of 5.5 years (range, 5-7; standard deviation, 0.75 years) showed that there was improvement in the activity level of all the patients. Preoperative mean KSS, HSS, WOMAC, Fulkerson, and Bristol scores were 120.331, 65.99, 88.34, 63.35, and 67.13 respectively. The improved postoperative mean KSS, HSS, WOMAC, Fulkerson, and Bristol scores were 158.57, 90.84, 51.30, 80.92, and 77.97, respectively (Table 2). Out of the 701 TKAs performed, 95% of patients were able to sit cross-legged, 90% of patients were able to kneel down comfortably, 70% were able to perform a half squat, and only 20% of patients were able to do full squatting without any help (Figs. 1-3). There was significant improvement in the flexion range postoperatively at the end of follow-up with minimum postoperative flexion being 120° and maximum postoperative flexion achieved being 150° from a mean preoperative flexion of 108.8° (90°-120°: Fig. 4). Mean postoperative flexion achieved was 134.95° which is more than that achieved by the standard design prosthesis for total knee replacement. All knees postoperatively were well aligned with the mean postoperative alignment of 5° valgus. There was a significant decrease in patellofemoral pain as evident by improvement in Fulkerson and Bristol scorings postoperatively. Table 2 shows results in detail with statistical analysis.

Complications included 3 infections. One patient with bilateral TKA has a late hematogenous infection 1 year postoperative initially treated with irrigation and debridement and later with knee arthrodesis elsewhere, 1.5 years postoperatively. An immunocompromised patient has a late hematogenous infection 2 years postoperatively and was treated successfully with irrigation and debridement wound and intravenous antibiotics. Three patients (3 knees) had patellar clunk syndrome, all of which were treated arthroscopically. There were 2 cases of tibial component aseptic loosening. One of these patients sustained a fall 6 years after the surgery and required revision using stemmed tibial components. Another case of tibial component loosening occurred 5 years postoperatively and required complete revision using a constrained implant. One patient had posttraumatic avulsion of the medial ligament complex from its

Table 1

Pain management and rehabilitation protocol.

Days (postop)	Pain management	Rehabilitation protocol
0 (Day of surgery)	Continuous titrated dose of epidural analgesia (0.1% Sensorcaine and 2 mikes/mL/h fentanyl)	Ankle pump exercises, straight leg raising exercises
1	Continuous titrated dose of epidural analgesia (0.1% Sensorcaine and 2 mikes/mL/h fentanyl)	In addition to above, quadriceps strengthening exercises, sitting on chair, standing and walking with aid of walker. Active and passive knee flexion of $0^{\circ}$ -45° and gradually increasing
2	1 g of paracetamol twice a day intravenous	In addition to above, commode training and walking for longer distance with aid of walker and active and passive knee flexion from 0° to 60°
3	1 gm of paracetamol twice a day intravenous	In addition to above, stairs climbing (up and down) training was given. Walking with walker and active and passive knee flexion of $0^{\circ}$ - $90^{\circ}$
4	Oral analgesic as per requirement	Same as above

Table 2						
	Final statistical	results	of all	variables.		

Table 2

	Preoperative (mean)	Postoperative (mean)	P value	T value	95% CI	Conclusion
WOMAC score	88.3	51.3	0	251.87	36.744, 37.321	Difference is significant indicating improvement as relation is inverse
HSS score	65.9	90.8	0	-135.91	-25.214, -24.495	Difference is significant indicating improvement
KSS (clinical and functional)	120.3	158.5	0	-82.12	-39.154, -37.325	Difference is significant indicating improvement
Visual analogue scale score	8.3	0.6	0	293.15	8.1923, 8.3027	Difference is significant indicating improvement
Fulkerson Score	63.3	80.9	0	-80.74	-17.994, -17.139	Difference is significant indicating improvement
Bristol Score	67.1	77.9	0	-56.02	-11.222, -10.462	Difference is significant indicating improvement
Flexion (°)	108.8	134.9	0	-64.21	-27.701, -26.057	Difference is significant indicating improvement

femoral attachment. This patient was treated with reconstruction of the medial ligament complex using anchor sutures and immobilization for 6 weeks postoperatively. No mortality was reported in our series.

#### Discussion

For people with high functional demands and for some recreational and daily activities such as getting out of bathtub, kneeling, sitting cross-legged, and squatting >110° of knee flexion in required. Activities such as sitting cross-legged, kneeling, and squatting are more common in Asian population [5]. Therefore, although TKA is accepted worldwide, restriction of postoperative range of motion is its one of the major limitations [6].

The PSRPHF prosthesis was introduced in 2005 and sought to help with this limitation. The high-flexion design has a smaller

femoral radius of curvature, thicker posterior condyle, and modified conforming post-cam mechanism to increase the contact area between the posterior femoral condyle and the tibial insert. All modifications were made to accommodate increased shear forces, increased jump distance so as to avoid dislocation at deeper flexion angles and insure a predictable posterior femoral rollback. An anterior cutout slope in the polyethylene insert diminishes patellofemoral impingement and accommodates extensor mechanisms for proper patellar tracking in deep flexion. These changes were introduced to achieve higher degrees of flexion, optimal tibiofemoral contact area, and better congruency, while simultaneously minimizing the stress created in camand-post mechanism and between tibial and femoral components. As high-flexion prosthesis mimics near-normal knee kinematics, there is less of a "digging effect" on the tibial polythene as studied by Kelly [7]. It has also been reported that



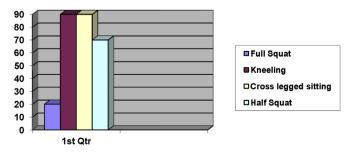
Figure 1. Figure showing 7-year follow-up radiograph of posterior-stabilized rotating-platform high-flexion TKA and patients clinical radiographs showing cross-legged sitting, knee bending of 140°, and half squats.



Figure 2. Figure showing patients performing various routine activities such as full squatting, praying (Namaz), and kneeling.

mobile-bearing high-flexion prostheses are superior to fixed bearing in terms of wear [8]. In our study, none of the knee showed measurable wear or osteolysis at midterm. In our series, we experienced 2 cases of tibial loosening, but during revision, we found no evidence of cam or post wear.

A study by Kim et al. [9] have shown that at 2-year follow-up, knees with a standard prosthesis had a mean range of motion of 135.8° (range, 105°-150°) and those with a high-flexion prosthesis had a mean range of motion of 138.6° (range, 105°-150°). Kim et al have shown that there were no significant differences between the standard conventional and high-flexion TKAs with regard to range of motion or clinical and radiographic parameters. In a systematic review done by Murphy et al [10] that included 9 different studies representing a total of 399 high-flexion knee arthroplasties in 370 patients, the investigators found insufficient evidence of improved range of motion or functional performance after high-flexion knee arthroplasty. Certain other level II studies have shown no significant improvement in flexion range of



**Figure 3.** Graph showing percentage of patients in our study able to do various clinical activities such as full squat, half squat, kneeling, and cross-legged sitting.

motion compared to standard conventional posterior-stabilized knee prosthesis [11,12].

The results of our case series are differ in regard to some of these findings and are contradictory to other published articles. On the other hand, many studies concluded an improved postoperative flexion range of motion by at least 10° [3,13]. Our study showed significant improvement in mean knee range of motion from approximately 108.8° preoperative to 135° postoperative. This high-flexion design successfully achieved a 15°-25° increase in postoperative flexion as compared to preoperative flexion.

Postoperative range of motion depends on several factors as suggested by Kawamura et al [14] such as preoperative flexion, tibiofemoral varus/valgus, patellar tilt angle, use of patellar resurfacing, body mass index, age, and surgical approach and technique. All these factors may act as confounding factors, and hence, results may vary in every study. Our study showed significant improvements in KSS, HSS, and WOMAC scoring postoperatively. We also noted improvement in Bristol and Fulkerson scores

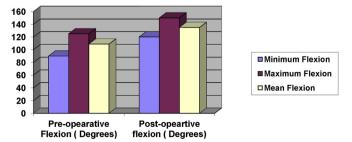


Figure 4. Graphical representation of preoperative and postoperative flexion range.

postoperatively making it evident that high-flexion total knee replacement relieves patellofemoral symptoms irrespective of increased patellofemoral contact stress in high degree of flexion. Posterior-stabilized, high-flexion, rotating-platform prosthesis in our study gave a mean postoperative flexion of 135° (range, 120°-150°) with a good functional outcome and midterm survivorship. Ninety-five percent patients were able to sit cross-legged, 90% of patients were able to kneel down comfortably, 70% were able to perform half squat, and 20% of patients were able to do full squatting without any help. Although lifestyle modification was required in all patients who participated in our study, almost all of them performed all activities of daily living satisfactorily.

Certain level 2 or level 3 studies have demonstrated that mobilebearing TKA may have lower wear and longer survivorship [9,10,15,16]. However, a level 1 multicenter study by Kalisvaar et al [17] has demonstrated that mobile-bearing TKA was reliable and durable but had no difference when compared to fixed-bearing inserts with respect to flexion, functional outcome, and long-term durability in North American patients. In our study, we combined a rotating-platform design with the posterior-stabilized highflexion knee prosthesis and expected both low wear rates and higher survivorship [18].

The downside of the rotating-platform design was the occurrence of subluxation or dislocation of the bearings (ie, "spin-out") due to uncontrolled mobility of the insert. Certain studies have reported spinout rate of rotating platform between 0% and 9.3% [19,20]. There were no incidences of spinoff, liftoff, or femoral component loosening in our study as compared to certain other studies [16,21]. Tibial component loosening is rare but exists and incidence increases after 10-15 years of surgery [8]. We came across 2 cases of loosening of tibial components and could not ascertain any cause for the same. In rotating-platform patella, a clunk may be due to its box cut which is extended to the anterior aspect of the proximal femur with an edge that sharply curves anterior to the intercondylar notch [22]. We reported 3 cases of patellar clunk syndrome, all of which were treated arthroscopically, and they did well later.

The bone size, that is, "distal femur and proximal tibia," in case of Asian and Indian population is found to be smaller as compared to Western and European population. Studies have shown that more bone stock is removed in high-flexion TKA so it has been theoretically implicated that revision in case of high-flexion TKA would be cumbersome [8]. As more bone stock is removed in highflexion TKA especially in Asian/Indian population with smaller bone size and gross deformities, final posterior cut comes very close to the origin of the medial collateral ligament which may lead to injuries as seen in our series.

All high-flexion designs are not the same. We feel that results of various studies on high-flexion knee prosthesis have given variable conclusions because of aforementioned reasons.

There are many confounding factors that are responsible for variable reported results. First, most studies only report one particular design, for example, the NexGen high-flexion LPS (Zimmer, Inc., Warsaw, IN) prosthesis has not been evaluated in prospective randomized double blinded trials using 2 different concepts of high-flexion prosthesis. Next, daily living activities of high flexion such as kneeling, squatting, sitting cross-legged, and so forth are not reported uniformly as range of flexion, WOMAC, and KSS scores do not directly suggest functioning of high-flexion design. Finally, patient satisfaction questionnaires related specifically to activities that require high flexion have not yet been formulated nor studied.

Our study showed improved results in a larger sample size with less confounding factors. Drawback of our study is that, it is not a comparative study or double-blinded trial and no control group had been assigned. Also, our study has very stringent criteria for patient selection. This was implemented so as to avoid any-patient related bias in our study. Being a midterm follow-up study, no conclusions can be made regarding long-term survivorship of the implant. This design is able to achieve satisfactory results in terms of kneeling and sitting cross-legged, but results with respect to full squatting and half squatting are not much encouraging. All these activities are essential for Asian population. Proper patient selection and standard and precise surgical technique are important factors in achieving good functional outcome and better survivorship of this implant.

#### Conclusions

Our study suggests that posterior-stabilized, rotating-platform, high-flexion prosthesis provides subjective data with respect to increases in patient's ability to perform functions such as sitting cross-legged, kneeling, and squatting. It provides better midterm survivorship rates and good functional outcomes, although their long-term survival rates are questionable as no study has conclusively proved its longevity for more than 15-20 years. Further refining of currently available designs to get anatomical knee prosthesis is awaited so as to meet high functional demands, high survivorship, fewer complications, and lower revision rates.

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