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RESEARCH ARTICLE

# Performance of Hi-Flex Femoral Component in Total Knee Arthroplasty - A Randomized Control Study

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## Abstract

**Background:** Total knee replacement (TKR) is a surgical procedure for intractable degenerative disease of the knee joint. Despite continued evolution in prosthesis design and surgical procedures, restricted range of motion and functional performance is still common in patients undergoing TKR. Posterior stabilized TKR aims to maintain a more reproducible roll back than cruciate retaining and mobile bearing knees, possibly leading to better flexion and function.

The aim of this study was to compare the performance of De-Puy posterior-stabilized rotating platform TKR prosthesis (PS-RP) with the newer Hi-Flex PS-RPF system. In particular, the two prostheses were compared for patient satisfaction and functional outcome.

**Methods:** Seventy physically active patients with unilateral knee osteoarthritis, allocated for primary TKR were recruited into the study. Patients were randomly allocated to one of the two treatment groups. The pre and post-operative data (functional outcome and patient satisfaction) was statistically analysed between the two groups.

**Results:** There were no statistical subjective differences between the 2 groups at 6 weeks and 12 months post-operative. There was a significant difference between knee flexion of patients in the Hi-Flex TKR group at 12 months post-operative, achieving higher mean flexion (123.8 ± 7.8 deg compared to 116.4 ± 14.1 deg; $p < 0.013$). However, this group also had better preoperative flexion suggesting direct correlation between the preoperative and postoperative knee flexion angles, in keeping with current literature.

**Conclusion:** Therefore, we concluded that there are no significant subjective or objective differences between hi-flex and standard knee replacements after 12 months of follow-up.

## Keywords

Total knee replacement, Primary, Functional outcome, Range of motion, Knee flexion

## Introduction

Total Knee Replacement is a very successful treatment for painful osteoarthritis of the knee. Follow-up studies shows implant survival rate *in situ* of about 95% after 10 years and 84% after 15 years [1,2]. However, despite the good results in terms of pain relief and longevity, there are still certain aspects, which require further consideration, in particular patient satisfaction, knee function, and component wear.

If a TKR gave pain relief and functioned like a healthy knee for many years, most patients would be very satisfied with it. A problem in clinical studies has, however, always been to grade the degree of success. Long-term studies focus on prosthesis survival, which is important - but if the function is poor or the knee painful, it is certainly more a long-term problem than a success. To better grade success in terms of function and pain relief, various knee scores are used.

In pursue of excellence, several types of implants and techniques have been used. Significant controversy exists in TKR surgery whether to retain, sacrifice, or substitute the posterior cruciate ligament (PCL). Likewise, there is no consensus whether superior function is achieved with a mobile tibial polyethylene insert or one of the new knee designs which aim to improve medial

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stability and lateral rollback. Therefore, there is a need for prospective randomized clinical studies comparing efficacy and patient satisfaction with the different TKR designs.

Moreover, when knee flexion increases with better function or if a more constrained knee implant is used, the forces acting on the implant-bone interface will increase [3]. Whether these will indeed, lead to inferior implant fixation and inferior longevity is not known and should be the focus of prospective studies.

In recent years, the population of the patients in Asia and the Middle East, where lifestyle and religious activities demand full flexion, has been increasing. Even in areas such as America and Europe, the requirement for deep flexion is increasing to perform daily activities [4]. Generally, knee implants were designed to accommodate flexion up to 125 degrees. Under these circumstances, many types of high-flexion artificial knee systems have been introduced, and various modifications have been attempted to improve the longevity of the implant. In high flexion knee system, the anterior part of the polyethylene insert is deeply cut to minimise the impingement of the patella tendon in deep flexion, and a number of other modifications have been made to the polyethylene insert in order to obtain the excellent tibio-femoral kinematics and tibio-femoral conformity. Spine and cam mechanism and tibial insert design provide controlled rollback for full flexion without posterior impingement. HI-Flex (PFC-RP) knees claim to accommodate deep flexion of up to 155 degrees. Many activities of daily living including religious and recreational require this range of motion, such as climbing stairs (75-140 degrees), sitting in a chair and standing up again (90-130 degrees), and squatting (130-150 degrees) [5].

Theoretically, an increased range of motion can be achieved without resecting more posterior bone than is required for a standard TKR.

Application of a mobile polyethylene insert in Hi-Flex TKR could permit greater conformity of the tibio-femoral joint, thereby reducing contact stress without reducing the knee's range of motion [6]. The decreased contact stress made possible by mobile bearing designs is believed to increase longevity of the prosthesis by reducing wear.

The primary purpose of this study was to evaluate the performance of the new Hi-Flex PS-RPF TKR in a prospective randomized way and compare to a well-known and well functioning standard, the De-Puy mobile-bearing PS (PS-RP). Our hypothesis was that, Hi-Flex will show better functional outcome and patient satisfaction. Of the two types of implants, we decided to compare the following parameters - patient satisfaction, functional outcome, postoperative knee flexion, complications and difficulties.

The two type of implants share a similar shape and identical mechanical behaviours during the first 100 degrees of flexion; however, the high-flexion design has the theoretical advantage of being able to accommodate larger flexion angles. It has an extended sagittal curve and a thicker posterior femoral condyle to maintain contact area and impart less stress on the insert in high flexion. The tibial post is located 1 to 2 mm more posteriorly in order to guide femoral rollback during high flexion.

## Material and Methods

We recruited 70 consecutive patients for TKR between 2006 and 2008. All were physically active patients affected by osteoarthritis and were scheduled for primary TKR.

We excluded patients with previous major knee surgery, previous infection, BMI > 35, age > 80 years, pre-operative range of movement of < 80° (flexion) and > 15° fixed flexion deformity or varus/valgus deformity.

Three senior orthopaedic surgeons were involved. All the surgeons used an anterior midline skin incision, medial parapatellar arthrotomy and medial soft tissue release for the exposure. The posterior cruciate ligament was resected in all cases. Hybrid fixation was used involving press-fit femur and fully cemented tibial base-plate. All knees were navigated. The rehabilitation program was also the same in both the groups. Immediately after surgery, patients were encouraged to begin quadriceps-strengthening exercises. Continuous passive motion was used and tolerable weight bearing was started. We also encouraged ROM and straight leg raising exercises. Patients were discharged on average within 10-12 days, postoperative.

A power study involving 5 Hi-Flex knees was done before including knees in this study. Data for the first 5 Hi-Flex knees was saved and used as a learning curve. We randomized using closed envelopes technique to either of the 2 groups (Hi-Flex PS-RPF or PS-RP groups). All investigators were blinded for the choice of implant except the operating surgeon.

Data was collected from patient's hospital records, kinematic logs from navigation machine and clinical scores. This data was put on forms with only code numbers as identification, which were mailed to DePuy monthly. Code number, patient name, date of birth and randomization was kept locally by every surgeon. All other facts were entered into the database by DePuy secretary and continuously updated and reported to participating surgeons. SPSS 12 software was used for statistical analysis to test distribution, compare continuous variables, repeated measures and Stepwise linear regression to investigate the influence of other variables on outcome and function.

Of the seventy patients recruited in our study, 37 patients were randomised to Group 1 (HI-Flex TKR) and 33 patients to Group 2 (PFC-RP). Demographic data for the

**Table 1:** Demographic data.

| | | Group 1 (HF) | | Group 2 (PFC) | | p (p < 0.05) |
|---|---|---|---|---|---|---|
| | | Mean | SD | Mean | SD | |
| **Prosthesis** | *Model* | ***Hi-Flex PFC-RPF*** | | ***PFC-RP*** | | |
| **Patients** | *n* | 37 | - | 33 | - | |
| **Gender** | *Males* | 16 | - | 10 | - | 0.338 |
| | *Females* | 21 | - | 23 | - | |
| **Age at surgery** | *Years* | 68.7 | 9.8 | 68.8 | 9.6 | 0.482 |
| **ASA** | *Score* | 2.2 | 0.5 | 2.3 | 0.6 | 0.414 |
| **Height** | *cm* | 163.6 | 8.3 | 164.4 | 8.8 | 0.350 |
| **Body Weight** | *Kg* | 80.7 | 18.2 | 87.9 | 18.3 | 0.053 |
| **BMI** | *Kg/m²* | 30.0 | 5.7 | 32.6 | 6.8 | **0.045*** |

SD: Standard deviation; *Significant p-value < 0.05; HF: High flex.

**Table 2:** Individual Oxford Scores.

| | Hi-Flex | | PS-RP | | P-Value |
|---|---|---|---|---|---|
| | Pre Op | 12 months | Pre Op | 12 months | |
| **Oxford 8** | 3.2 | 1.4 | 3.1 | 1.5 | 0.325 |
| **Oxford 9** | 4.2 | 3.8 | 4.5 | 4.2 | 0.139 |

SD: Standard deviation; Significant p-value < 0.05; HF: High flex.

patient cohort are shown in Table 1. Data was collected regarding size of prosthesis components used, surgical time and location, and length of hospital stay. Clinical and functional scores (Oxford/SF 12) were recorded preoperatively to compare them with postoperative scores at six weeks and twelve months mark.

## Results

While there were no significant differences between the groups on age or ASA score at time of surgery, Group 2 (PFC-RP) had a significantly higher Body Mass Index than Group 1 (p = 0.045). There was no difference in operative time between the two groups.

### Pre-operative

Comparisons were made between groups on the total Oxford score and on each individual element of the questionnaire. There was a significant difference between the groups on Oxford-4 (night pain), with Group 2 experiencing higher levels of night pain (p = 0.044). Patients receiving the PFC prosthesis also had a higher total Oxford score (p = 0.016). While flexion range of motion did not reach statistical significance (p = 0.054), patients in the Hi-Flex knee group generally had a higher average knee range of movement before surgery.

### Postoperative

There were no significant differences on any clinical variables between the groups at 6 weeks post-operative. There was a significant difference between knee flexion range of motion of patients at 12 months post-operative, with patients in Group 1 achieving higher mean flexion (123.8 ± 7.8 deg compared to 116.4 ± 14.1 deg; p < 0.013). There were no other differences between the groups. Interestingly, patients with higher ASA score generally had a poorer range of motion in extension at 12 months post-surgery.

Patients starting with fixed flexion, Hi-flex group started with a mean of 11 degrees fixed flexion compared to the PS-RP group who started with 9 degrees. After 12 months, this was reduced to less than 2 degrees for both groups with no statistical difference between the 2 groups.

We know from previous studies such as the one done by Merrill, et al. that the strongest predictor of flexion post TKR is pre-op flexion followed by intra-op flexion [7]. This graph shows that patients in both groups had an improvement in knee flexion after 12 months, but the hi-flex group of patients started with better flexion thus ended up with better post-op flexion. We found that there was no statistical difference in flexion between these 2 groups with a p-value of 0.097.

Total oxford knee score analysis showed that there was an improvement in both groups after 12 months post-op with no statistical difference between them (Table 2). The individual scores such as oxford 8 and 9, showed no difference between the groups with both improving after knee arthroplasty but still not being perfect.

The results of the visual analogue score showed improvement in the level of pain in both patient groups after 12 months post-op, with no statistical difference between them after 1 year.

Finally the results of the SF 12, show that prior to surgery patients in both groups were evenly matched and were able to perform their normal duties on the whole better after having their knee replacements, but after 12 months post-op the non hi-flex group had a higher mean SF 12 score, which on testing is not statistically significant.

With regards to the mental part of the SF 12 there was improvement in patient mental health in both groups after receiving TKR but no difference between the groups.

## Discussion

To study kinematics of both normal and TKR knees is challenging. Recently, several papers have been published comparing kinematics of different concepts for TKR by the use of fluoroscopy. It seems more or less a consensus that posterior-stabilized (PS) TKR obtain a more normal and reproducible roll back than cruciate retaining and mobile bearing knees do, possibly leading to better flexion and function [8,9].

New constructions such as the Medial Pivot Knee hold promise, but the new Hi-Flex knee (De-Puy International) goes even further in its attempt to obtain "normal" kinematics. The Hi-Flex is a PS knee where the post, the cam, and the shape of both femoral and tibial components are designed to guide the knee into normal movements.

A very important aspect of TKR function is the range of flexion. The typical range of motion of most TKR recipients is 110 degrees [10]. Although the postoperative knee flexion is highly dependent on factors such as preoperative knee flexion, the design of most contemporary TKR does not safely allow knee flexion beyond 120 degrees [7,11].

To enable knee flexion of 130 to 155 degrees, the Hi-Flex TKR is designed differently compared to the standard TKR. The radii of the femoral component are increased and the patellofemoral groove deepened. The articulation between tibia and femur provides stability both in extension and maximal flexion, and at the same time accommodates the 25 degrees of tibio-femoral rotation that should occur at 150 degrees of knee flexion [9,12]. Gupta, et al. in a matched pair study of 50 PFC Sigma RP-F (rotating-platform, high flexion) prostheses and 50 PFC RP devices, found that 28 patients with less than 120 degrees of motion benefited from the high flexion design [13]. However, the cited authors did not mention maximum flexion but rather compared range of motion (ROM) values, which are affected not only by preoperative flexion deficit alone but also by preoperative flexion contracture. Victor, et al. reported on 201 consecutive TKRs using the Journey prosthesis (Smith & Nephew, Memphis, TN) and found that patients with the least preoperative flexion (< 90 degrees) gained the most postoperative flexion (26 degrees), concluding that use of a high-flexion implant in TKR is indicated in patients with poor preoperative ROM [6]. However, the cited authors did not compare their results with those of patients receiving standard implants.

Although polyethylene wears and osteolysis traditionally has been more associated with total hip arthroplasty, wear is also an important issue in total knees. Subsurface cracks, de-lamination and wear through are typical findings of major importance for loosening of the implant. Wear in knees can be expected to become an even more important issue in the near future. First, more and more young patients are being operated with knee arthroplasty, and second, the newer designs with higher knee flexion, mobile bearings and posterior stabilized knees may theoretically induce more wear [14].

The high-flexion version of the De-Puy posterior stabilized total knee prosthesis is designed to allow safe deep flexion. The advantage of the high-flexion design may not be obvious if the pre-operative knee flexion is low, and hence the anticipated post-operative flexion range, is poor.

There have been only a few clinical trials using high-flexion type prostheses, and there are only few reports in the literature dealing with large numbers of knees [15]. The mean ROM after TKR using the High flexion prosthesis (Zimmer, NexGen) has been reported to be 138 degrees and 80% of the patients were able to squat. However, this report consisted of relatively small number of cases: Limited to 25 cases.

Our study was limited by the short follow-up period (12 months) and no radiological data included. We recommend long-term follow-up to reassess subjective & objective findings, and to include radiological scoring. Long-term results are necessary, including survival rate of the prosthesis to determine whether the increased posterior translation, which has not been studied in this paper, but shown during *in-vivo* kinematic studies, and loads on the knee during deep flexion will lead to greater wear of the insert or loosening of components.

Despite several limitations, the present study provides some valuable information. Some authors are of the view that high-flexion implants will have little effect in patients who could not attain a satisfactory flexion angle preoperatively [7,13]. However, the present study shows that a high-flexion implant might not be contraindicated in osteoarthritis patients with severe preoperative stiffness. On the contrary, surgeons would give more chances to obtain notable improvement in flexion after TKR in such patients when high-flexion prostheses are employed, rather than standard implants.

## Conclusion

We conclude that the Hi flex knees do not result in better flexion than standard knee replacements and there is no statistical difference in patient satisfaction and functional outcome at short term follow up. The only factor affecting postoperative ROM at 1 year was preoperative ROM.

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## References


1. Rand JA, Trousdale RT, Ilstrup DM, Harmsen WS (2003) Factors affecting the durability of primary total knee prostheses. J Bone Joint Surg Am 85: 259-265.
2. Robertsson O, Knutson K, Lewold S, Lidgren L (2001) The Swedish Knee Arthroplasty Register 1975-1997: An update with special emphasis on 41,223 knees operated on in 1988-1997. Acta Orthop Scand 72: 503-513.
3. Nagura T, Dyrby CO, Alexander EJ, Andriacchi TP (2002) Mechanical loads at the knee joint during deep flexion. J Orthop Res 20: 881-886.
4. Hassaballa MA, Porteous AJ, Newman JH, Rogers CA (2003) Can knees kneel? Kneeling ability after total, unicompartmental and patellofemoral knee arthroplasty. Knee 10: 155-160.
5. Weiss JM, Noble PC, Conditt MA, Kohl HW, Roberts S, et al. (2002) What functional activities are important to patients with knee replacements? Clin Orthop Relat Res 172-188.
6. Victor J, Ries M, Bellemans J, Robb WM, Van Hellemondt G (2007) High-flexion, motion-guided total knee arthroplasty: Who benefits the most? Orthopedics 30: 77-79.
7. Ritter MA, Harty LD, Davis KE, Meding JB, Berend ME (2003) Predicting range of motion after total knee arthroplasty. Clustering, log-linear regression, and regression tree analysis. J Bone Joint Surg Am 85: 1278-1285.
8. Yoshiya S, Matsui N, Komistek RD, Dennis DA, Mahfouz M, et al. (2005) In vivo kinematic comparison of posterior cruciate-retaining and posterior stabilized total knee arthroplasties under passive and weight-bearing conditions. J Arthroplasty 20: 777-783.
9. Argenson JN, Scuderi GR, Komistek RD, Scott WN, Kelly MA, et al. (2005) In vivo kinematic evaluation and design considerations related to high flexion in total knee arthroplasty. J Biomech 38: 277-284.
10. Miner AL, Lingard EA, Wright EA, Sledge CB, Katz JN, et al. (2003) Knee range of motion after total knee arthroplasty: How important is this as an outcome measure? J Arthroplasty 18: 286-294.
11. Sultan PG, Most E, Schule S, Li G, Rubash HE (2003) Optimizing flexion after total knee arthroplasty: Advances in prosthetic design. Clin Orthop Relat Res 167-173.
12. Bellemans J, Banks S, Victor J, Vandenneucker H, Moemans A (2002) Fluoroscopic analysis of the kinematics of deep flexion in total knee arthroplasty. Influence of posterior condylar offset. J Bone Joint Surg Br 84: 50-53.
13. Gupta SK, Ranawat AS, Shah V, Zikria BA, Zikria JF, et al. (2006) The P.F.C. sigma RP-F TKA designed for improved performance: A matched-pair study. Orthopedics 29: S49-S52.
14. McEwen HM, Barnett PI, Bell CJ, Farrar R, Auger DD, et al. (2005) The influence of design, materials and kinematics on the in vitro wear of total knee replacements. J Biomech 38: 357-365.
15. Huang HT, Su JY, Wang GJ (2005) The early results of high-flex total knee arthroplasty: A minimum of 2 years of follow-up. J Arthroplasty 20: 674-679.