Confirmation of Long-term In Vivo Bearing Mobility in Eight Rotating-platform TKAs

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Abstract

Background Posterior-stabilized rotating-platform prostheses for TKAs were designed to improve contact mechanics at the femoral-polyethylene (PE) interface. Short-term followup studies have shown that the PE bearings rotate with respect to the tibia but might not necessarily track with the femur. It is important to know how kinematics in these designs change owing to long-term in vivo use.

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Questions/purposes We asked whether there is a significant change in the in vivo kinematic performance of a posterior-stabilized rotating-platform prosthesis at as much as 10 years postoperative. We specifically examined (1) relative femoral component-PE bearing and relative PE bearing-tibial tray motion; (2) relative AP motion of the femoral condyles with respect to the tibial tray; and (3) relative femorotibial condylar translations.

Methods In vivo three-dimensional kinematics were evaluated for eight patients at 3 months, 15 months, 5 years, and 10 years after TKA with primary implantation of a posterior-stabilized rotating-platform prosthesis. Each patient performed deep knee bend activity, and three-dimensional kinematics were reconstructed from multiple fluoroscopic images using a three-dimensional to two-dimensional registration technique. Once complete, relative component axial rotation patterns, medial and lateral condyle motions throughout flexion, and the presence of femoral condylar lift-off were analyzed.

Results Overall, tibial bearing rotation was maintained at 10 years postoperatively. There was no statistical difference between postoperative periods for any kinematic parameter except for femoral component-PE bearing axial rotation, which was reduced at the 10-year evaluation versus other assessment periods ($p = 0.0006$). The lack of statistical difference between postoperative evaluation

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periods indicates sustained overall implant kinematic performance.

Conclusions Our study showed that PE bearing-tibial tray mobility was maintained and that femoral component-PE bearing rotation was reduced at the 10-year followup. This suggests that the overall kinematic performance of this mobile-bearing implant is not negatively affected 10 years postoperatively.

Level of Evidence Level III, retrospective study. See the Instructions for Authors for a complete description of levels of evidence.

Introduction

Some authors believe that a goal of successful knee implant design is to reproduce normal knee kinematics [1, 5]. Various kinematic evaluations of the normal knee have documented posterior translation of the femoral condyles and external rotation of the femur with respect to the tibia with increasing knee flexion [7, 16, 18]. It has been shown that increased posterior femoral rollback and normal axial rotation lead to better extensor mechanism mechanics and better outcomes [2, 3, 5, 7, 8, 16, 27]. In vivo kinematic patterns of patients having a TKA vary considerably from the normal knee. It has been reported that knees with implants commonly experience axial rotation patterns opposite those of the normal knee [2, 3, 5, 7, 15, 16, 26, 27]. This has prompted development of various femoro-tibial articulation geometries and UHMWPE bearing designs, each aiming to achieve greater magnitudes of posterior femoral translation and more normal axial rotation patterns.

One such design variant is the rotating-platform mobile-bearing knee prosthesis, in which the polyethylene (PE) bearing can freely rotate atop the tibial tray. By design, the PE bearing is highly conforming to the femoral component in the coronal plane, which allows the femoral component to guide rotation of the PE bearing. Increasing the conformity and adding the extra rotational degree of freedom allows these designs to be more tolerant to rotational misalignment during surgery and enables the PE component to remain congruent with the femoral component throughout flexion [6, 20]. By doing so, the cross-directional motion characteristics (attributable to translation and axial rotation) of the femoral component with respect to the PE bearing observed in fixed-bearing prostheses can be

decoupled into unidirectional motions (AP translation on the top surface and rotation on the bottom surface of the PE bearing) [6]. Thus, by maintaining long-term bearing mobility and reducing this cross-directional motion, mobile-bearing implant designs potentially could lead to reductions in PE contact stresses and thereby improvement in the lifetime of the implant [10, 12, 28].

Previous studies have validated that bearing mobility occurs throughout the full range of knee flexion and that this mobility is maintained for up to 3 years postoperatively [6, 13, 17, 21]. Another study also validated the occurrence of bearing mobility but showed that TKAs with mobile-bearing prostheses do not necessarily increase the amount of in vivo axial rotation compared with TKAs with fixed-bearing prostheses and that the overall in vivo axial rotation magnitudes remain substantially lower for TKAs compared with normal knees [29]. Unfortunately, most of these studies have relatively short followups.

The question therefore remains whether there is a significant change in the in vivo kinematic performance of TKAs with mobile-bearing prostheses at postoperative times up to 10 years. To answer this question, we specifically asked: (1) Is there a significant change between femoral component-PE bearing rotational alignment and the PE bearing-tibial tray axial rotation patterns as followup time increases? (2) Is the AP motion of the medial and lateral condyles of the femur with respect to the tibia affected by followup time? (3) Do the frequency and incidence of femoral condylar lift-off change with followup time? We hypothesized that the rotational motion of the PE bearing and the AP motion of the femoral condyles would not be affected detrimentally by 10 years of in vivo use, therefore the overall kinematic performance of the TKA with a mobile-bearing prosthesis would remain the same.

Patients and Methods

Initially, the study was started on 10 patients. Two patients died before the 10-year followup. Therefore we report data for eight patients studied at four followup times (3 months, 15 months, 5 years, and 10 years). All patients had implantation of a P.F.C.[®] Sigma[®] posterior stabilized rotating platform prosthesis (DePuy Orthopaedics Inc, Warsaw, IN, USA) by one fellowship-trained surgeon (DAD) using the same surgical technique. Because PE is radiolucent, the PE inserts for these patients were specially designed with four tantalum beads strategically placed to ensure that at least three beads were always visible during fluoroscopy [6]. To participate in the study, patients were required to have clinically successful, well-functioning implants (The Knee Society scores > 90) without evidence

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of ligamentous laxity or function-limiting pain. At each evaluation period, the patients were asked to perform a deep knee bend activity from full extension to maximum knee flexion while under single planar fluoroscopic surveillance in the sagittal plane. The patients were asked to do the activity at a pace that was comfortable to them, in a manner where they felt confident and stable without holding onto any support. Institutional review board approval was obtained for each phase of the study, and informed consent was obtained for each patient before any data collection at any phase of the study.

Individual fluoroscopic frames at 10° increments of flexion from full extension to maximum knee flexion for the deep knee bend activity were digitized from the fluoroscopic video and corrected for distortion. Using a three-dimensional (3-D) to two-dimensional (2-D) image registration approach, the relative 3-D poses of the femoral and tibial knee implant components were determined using the fluoroscopy image in the sagittal plane and registration of the component computer-aided design models in 3-D space [4, 14, 19]. The process involved two stages. Initially, the 3-D orientations of the femoral and tibial components were positioned manually by an operator in an approximate position corresponding to the respective silhouettes in the digitized fluoroscopic image. Then, an automated global optimization algorithm, based on a weighted measure of edge intensity, used intensity-based matching to finalize the best orientation of the models [4, 14]. The 3-D orientation of the radiolucent PE bearing then was determined by matching the beads embedded in the PE insert with their observed fluoroscopic silhouettes. Existing error analyses of this 3-D to 2-D registration technique have shown that this technique has a rotational error less than 0.5° and a translational error less than 0.5 mm [19].

After completion of the registration process, a kinematic analysis was conducted to assess the following three parameters: (1) relative axial rotations between the femoral component and PE bearing and between the PE bearing and the tibial tray; (2) the AP motion of the medial and lateral condyles of the femur with respect to the tibia; and (3) the incidence and magnitude of femoral condylar lift-off. For consistency, all measurements of interest are reported with respect to the inferior component reference frame.

The lowest points on each of the femoral condyles, measured with respect to the tibial plateau, were used to track AP movement of the femoral condyles. The same points were used to calculate axial rotation of the femoral component with respect to the tibia. First, a line was created from the medial point to the lateral point, and then a second line was constructed bisecting the center of the tibial component in the coronal plane. The angle created between these two lines was considered the axial rotation angle. The axial rotation of the PE bearing was directly

calculated from the relative transformation of the PE bearing with respect to the tibia [4, 6, 16, 19].

Changes in axial rotation as a function of change in flexion angle were determined by subtracting the axial rotation angle at the first desired flexion angle from the axial rotation angle at the last desired flexion angle. A positive value of axial rotation represents external rotation of the superior component (either the femoral component or the PE bearing) with respect to the tibia with increasing flexion (normal rotation), while a negative value represents reverse (nonphysiologic) axial rotation. The amounts of axial rotation from full extension to 90° flexion and from full extension to maximum flexion were evaluated for all patients at all four phases of the study.

Femoral condylar lift-off was assumed if there was greater than a 1 mm difference in the superoinferior positions between the medial and lateral condyles of the femoral component [26]. The maximum weightbearing ROM was recorded for each patient at all four study phases. Overall, the ROM for each patient was well maintained many years after implantation. The average weightbearing ROM was between 93° and 106° for all four followup times, with the single minimum ROM between 64° and 90° and the single maximum ROM between 107° and 130°. There were no significant differences between followup intervals. A previous analysis showed that weightbearing flexion is typically 10° to 20° less in magnitude than when knee flexion is evaluated using a passive, nonweightbearing method [9].

Statistical analyses were conducted to determine significant differences in axial rotation at the femoral component-tibial tray, femoral component-PE bearing, and PE bearing-tibial tray articulations from full extension to 90° flexion and from full extension to maximum flexion across the various followup times. Additionally, absolute maximum relative component rotations, medial and lateral femorotibial contact positions, average ROM, and instances of condylar lift-off were compared between followup intervals. In all cases, the dataset was first checked for normality. In the event of normal distribution, a parametric, all-pairs Tukey-Kramer honestly significant difference test was conducted. Otherwise, a nonparametric, each-pair Wilcoxon method comparison was used. Testing of the hypothesis was performed at the 95% confidence level ($\alpha = 0.05$) using the JMP® Statistical Discovery™ (SAS Institute Inc, Cary, NC, USA) software package.

Results

For all postoperative phases in this study, the PE bearing generally rotated externally with respect to the tibia from

Fig. 1 The mean ($\pm$ SD) of the variations in axial rotation patterns of the polyethylene (PE) bearing with respect to the tibial tray as a function of flexion angle are plotted for eight patients at the four

followup times. External rotation of the PE bearing with respect to the tibia is presented as positive.

Table 1. Relative component axial rotation for all four study phases

Postoperative time (study phase)	Femur/tibia (degrees)		PE/tibia (degrees)		Femur/PE (degrees)	
	0°–90°	0°–maximum	0°–90°	0°–maximum	0°–90°	0°–maximum
3 months						
Mean	5.2	4.5	2.9	2.8	2.3	1.6
Range	0.1–11.2	0.0–11.3	–0.4 to 12.4	–0.5 to 12.1	–1.7 to 4.9	–1.7 to 4.8
SD	3.8	4.0	4.8	4.0	3.0	2.8
15 months						
Mean	2.3	3.4	2.1	2.5	0.2	1.0
Range	–4.1 to 11.5	–4.1 to 11.8	–3.3 to 12.6	–3.3 to 11.0	–1.2 to 3.0	–0.8 to 4.2
SD	5.3	5.1	6.0	5.4	1.5	1.9
5 years						
Mean	6.0	6.2	4.9	4.6	1.2	1.7
Range	1.4–15.6	1.4–16.6	–0.3 to 12.1	–0.3 to 12.5	–0.5 to 3.6	–0.5 to 4.1
SD	5.1	5.3	4.6	4.4	1.5	1.6
10 years						
Mean	4.3	6.1	3.8	6.0	0.4	0.1
Range	1.0–9.4	0.2–17.6	0.3–8.6	0.2–18.0	–0.3 to 1.0	–0.4 to 0.8
SD	3.0	5.7	3.0	5.8	0.5	0.5

PE = polyethylene

full extension to maximum knee flexion (Fig. 1). In general, external PE bearing rotation with respect to the tibia was more consistent with increased followup duration. At the 3-month and 15-month followups, high instances of internal PE rotation were observed (between 90° and 110° flexion and between 30° and 60° flexion, respectively). Moreover, the maximum average PE bearing-tibial tray axial rotation magnitude was the least during the 3-month postoperative phase, and the remaining three evaluation

periods were similar. The differences in PE bearing-tibial tray rotation from full extension to 90° flexion and from full extension to maximum flexion were found not to differ across the different followup times, which might be attributable to the high standard deviations observed (Table 1). In general, however, the amount of axial rotation was greater at longer followup times (5 years and 10 years) compared with shorter followup times (3 months and 15 months). Among all subjects, the maximum amount of

Fig. 2 Individual patient axial rotation data from full extension to maximum knee flexion are shown for the 10 year followup. External rotation of the superior component with respect to the inferior component is positive.

Fig. 3 The mean ($\pm$ SD) of the variations in axial rotation patterns of the femoral component with respect to the polyethylene (PE) bearing as a function of flexion angle are plotted for eight patients at the four

followup times. External rotation of the femoral component with respect to the PE bearing is positive.

PE bearing-tibial tray axial rotation from full extension to maximum flexion was 18° , which was observed at the 10-year followup (Fig. 2). Interestingly, the amount of relative axial rotation between the femoral component and the PE insert decreased with the increase in postoperative time (Fig. 3). Relative axial rotation of the femoral component with respect to the PE bearing was greater at the 3- and 15-month followups compared with the 5- and 10-year followups. At the 10-year followup, the PE bearing more consistently remained in a congruent position with the femoral component and thus the relative axial rotational

magnitudes of this articulation interface were smaller compared with magnitudes at the other three followups ($p = 0.0006$ in all three cases) (Fig. 3).

On average, from full extension to maximum knee flexion, the patients' knees consistently exhibited posterior femoral translation of the lateral condyle (Fig. 4). Although no statistical difference was observed, the general trend seemed to be that the lateral condyle stayed more posterior at longer followup times when compared with shorter followup times. On average, the femoral medial condyles tended to move slightly anterior with increasing

Fig. 4 The mean ($\pm$ SD) of the variations in the average femoral lateral condylar motion with respect to the tibial tray as a function of flexion angle are plotted for eight patients at the four followup times.

Fig. 5 The mean ($\pm$ SD) of the variations in the average femoral medial condylar motion with respect to the tibial tray as a function of flexion angle are plotted for eight patients at the four followup times.

flexion until approximately 100° flexion (Fig. 5). Similar to the lateral condyles, no difference was observed in the anterior motion of the medial condyles when compared across the various followup times. Nonetheless, the most anterior location of the medial condyles was observed at the 10-year followup.

During the 3-month postoperative phase of the study, two patients (four instances, two each) experienced femoral condylar lift-off. For the 15-month and 5-year phases, one patient stopped exhibiting lift-off and only one patient

exhibited condylar lift-off. At the 10-year followup, all patients stopped exhibiting any lift-off.

Discussion

Some analyses have been conducted to evaluate the kinematic performance of a knee with a TKA compared with a normal knee [7, 16, 18], and others have aimed specifically at examining the mobility of the rotating PE bearing with

mobile-bearing TKA designs [6, 11, 17, 21]. However, to our knowledge, no study has yet to confirm the continued *in vivo* bearing mobility in TKAs with mobile-bearing prostheses at postoperative times greater than 3 years. The results from our study answer the questions of component motion and kinematic performance at postoperative times of up to 10 years for one mobile-bearing design, the P.F.C.® Sigma® posterior stabilized rotating platform prosthesis. Our analyses show that relative femoral component-tibial tray and PE bearing-tibial tray rotations are maintained and that femoral component-PE bearing rotational misalignment decreases as postoperative time increases. Furthermore, the results confirm that the overall kinematic performance of the P.F.C.® Sigma® posterior stabilized rotating platform prosthesis, including AP motion (ie, femoral rollback patterns) and condylar lift-off, does not significantly change as postoperative time increases.

Limitations of this study include the limited number of patients tested at each study phase, which restricts the statistical power of the results. Similarly, we concentrated on analyzing the average motion and general movement trends as exhibited by patients' knees and did not delve into patient-specific variations in the data. Another limitation of this study is that only one specific type of rotating platform prosthesis was analyzed. Therefore, conclusions drawn from this particular implant may not necessarily pertain to different models and/or designs of mobile-bearing prostheses. Likewise, only patients with well-functioning knees were recruited to be part of the study, therefore, our results may not necessarily pertain to patients with more poorly functioning implants. In addition, only a weightbearing deep knee bend activity was tested, and therefore the results from this study might not translate to other activities which have different loading conditions. Finally, the repeatability of the weightbearing deep knee bend activity has not been tested for this study. The protocol used during data collection ensures that the patients remain comfortable and stable and can do the activity without any additional support. We did not ask the patient to modify their activity for the sake of the data, therefore this might induce a certain level of arbitrariness to the data.

Rotating platform TKA prostheses are believed to be self-correcting as the PE bearing has the ability to axially rotate and stay with the femur [6, 20]. This is advantageous because the design can compensate for any slight rotational implantation mismatches that may have occurred between the femoral and tibial components [6, 20]. The results from our study suggest that the relative axial rotation between the femoral component and the PE bearing in TKAs with rotating platform prostheses decreases with increasing followup time, which further implies that while PE bearings may inconsistently rotate with the femur immediately after surgery, given a sufficient period of *in vivo* use, the

bearings do have the ability to adjust to the rotational nature of the femur. When congruent femoral-PE rotation occurs, the majority of axial rotation (unidirectional motion) occurs on the inferior aspect of the mobile PE bearing, between the PE bearing and the tibial tray, whereas the majority of AP translation (unidirectional) occurs on the superior aspect of the bearing, between the PE bearing and the femoral component. This is in contrast to fixed-bearing designs in which all axial rotation and AP translation (multidirectional motion) occur on the superior aspect of the PE insert [6]. Preserved PE-bearing mobility may contribute to improving implant longevity [10, 12, 28] by enabling less constrained motion of the femoral component during normal daily activities [3, 12]. When the PE bearing rotates with the femur, conformity built into the femoral-PE interface tends to be preserved, leading to improved contact mechanics and reduced contact stresses [23, 24]. Additionally, since the relative rotation between the PE bearing and the femur decreases, it can be inferred from the data that the amount of axial rotation of the femur with respect to the tibia increases. Increased normal axial rotation leads to better patellofemoral tracking and improved extensor mechanism mechanics [2, 3, 5, 7, 8, 16, 27]. However, the overall magnitudes of axial rotation were well below those observed in normal knees and were similar in magnitudes reported by Wasielewski et al. [29]. Finally, femoral-PE rotational congruency results in the femoral cam contacting the center of the PE post more consistently during flexion [30]. This is beneficial in the long term because the consistent central contact, in a region where the post is the thickest, may help to reduce overall stress and long-term fatigue failure effects that the cam might have on the post. Therefore, it is important for bearing mobility to be maintained throughout the entire flexion domain and the entire lifespan of the implant.

The ability of the PE bearing to rotate congruently with the femur does not seem to come at the expense of *in vivo* translational kinematics, as the AP movement of the femoral condyles tended to be similar at all followup times. The posterior motion of the lateral condyle and the minimal anterior movement of the medial condyle are similar in pattern as observed in normal knees [7, 16] and are consistent with data reported for TKAs with posterior stabilized-type prostheses during deep knee bending [5, 8]. Posterior motion of the lateral condyle has been shown to increase flexion by preventing impingement of the femoral condyles on the tibia [1, 7, 8] and by increasing the moment arm of the extensor mechanism, thereby reducing the forces [22, 25]. Reduction of the forces in the extensor mechanism leads to lower femorotibial contact forces and less resistance to movement and flexion [22, 25].

The data from our study seem to suggest that as followup time increases, the patients have improved stability and

therefore a decrease in the incidences of femoral condylar lift-off. At the 10-year followup no patient exhibited any incidence of lift-off. However, owing to the low number of patients who exhibited lift-off initially, there is no statistical significance to support such a claim, and the relationship between the frequency and occurrence of condylar lift-off with postoperative duration cannot be suitably established.

The results of the current study support the results of previous kinematic studies [6, 11, 17, 21] in that the mobile PE insert in a TKA with a posterior-stabilized rotating platform prosthesis does rotate relative to the tibial tray. Specifically, our study confirmed that even 10 years post-operatively, the PE bearing continues to rotate smoothly and in congruence with the femoral component. The translational kinematics remain unchanged.

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