

# **Objective clinical performance outcome of total knee prostheses.** A **study of mobile bearing knees using fluoroscopy, electromyography and roentgenstereophotogrammetry** Garling, E.H.

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### Limited rotation of the mobilebearing in a rotating platform total knee prosthesis

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#### Abstract

The hypothesis of this study was that the polyethylene bearing in a rotating platform total knee prosthesis shows axial rotation during a step-up motion, thereby facilitating the theoretical advantages of mobile bearing knee prostheses.

We examined ten patients with rheumatoid arthritis who had a rotating platform total knee arthroplasty (NexGen LPS mobile, Zimmer Inc. Warsaw, USA). Fluoroscopic data was collected during a step-up motion six months postoperatively. A 3D-2D model fitting technique was used to reconstruct the *in vivo* 3D kinematics.

The femoral component showed more axial rotation than the polyethylene mobile-bearing insert compared to the tibia during extension. In eight knees, the femoral component rotated internally with respect to the tibia during extension. In the other two knees the femoral component rotated externally with respect to the tibia. In all ten patients, the femur showed more axial rotation than the mobilebearing insert indicating the femoral component was sliding on the polyethylene of the rotating platform during the step-up motion. Possible explanations are a too limited conformity between femoral component and insert, the anterior located pivot location of the investigated rotating platform design, polyethylene on metal impingement and fibrous tissue formation between the mobile-bearing insert and the tibial plateau.

#### 4.1 Introduction

Since, functional capabilities of patients and survival of total knees are affected by knee kinematics, it is important to know how the different components of total knee prostheses move and whether this motion is beneficial or detrimental to the knee function and device longevity. Fluoroscopic analyses of various mobile-bearing total knee prostheses (TKP) have demonstrated differing kinematic patterns of the femoral component with respect to the tibial component (Banks et al., 2003; Callaghan et al., 2000; Fantozzi et al., 2004; Haas et al., 2002; Saari et al., 2003; Stiehl et al., 1997; Walker et al., 2002).

Rotating platform mobile-bearing knee prostheses are on the market for about 25 years and have excellent long-term results (Buechel, 2004). A rotating platform ostensibly allows increased tibiofemoral articular conformity without restricting axial rotation of the polyethylene bearing. The presumption is that the axial rotation of the polyethylene bearing during frequently encountered daily activities is an important factor in these excellent clinical results.

Only one study reports the 3D *in vivo* motion of a mobile bearing intended for axial rotation and anterior posterior translation (Fantozzi et al., 2004). In that study a relatively small motion of the bearing during various activities was observed. Presumably the mobility of a mobile bearing permits increased articular conformity between the femoral and tibial components, reducing contact stresses and thus reducing polyethylene wear compared to fixed bearing total knee prostheses. When the motion of the mobile bearing is limited or even absent this presumption is questionable.

The hypothesis of this study was that the polyethylene bearing in a rotating platform total knee prosthesis shows axial rotation during a step-up motion, thereby facilitating the theoretical advantages of mobile bearing knee prostheses.

#### 4.2 Materials and Methods

We selected ten rheumatoid arthritis patients from a prospectively randomized Roentgen Stereophotogrammetric Analysis (RSA) study in our specialized rheumatoid arthritis clinic six months after a total knee arthroplasty (6 females and 4 males, median age 73 years (range: 53-82); median BMI 30 range: 26-35). Inclusion criteria were the ability to perform a step-up without the help of bars or a cane, symptom less any other lower extremity joint besides the operated knee and no or slight pain during activity according to the Knee Society pain score (Ewald, 1989). Exclusion criteria were the use of walking aids and the inability to walk more than 500 meters. A 80% power analysis in combination with an expected measurement error of 0.3 degrees (Garling et al., 2005), showed that relative motions of 0.3 degrees could be detected when 10 patients were included in the study. The institutional medical-ethical committee approved the study and all subjects gave informed consent.

In all patients, a NexGen Legacy Posterior Stabilised (LPS) mobile bearing prosthesis was implanted (Zimmer Inc. Warsaw, USA). All components were fixed using cement. The tibial articular surfaces are made of net-shape molded UHMW polyethylene. The tibial bearing component is snapped onto an anterior-central located trunion at the polished cobalt chromium base plate, which prevents tilting and determines the center of rotation of the bearing. The slot in the plastic allows for 25° of internal-external rotation of the NexGen LPS mobile bearing, limited by an anterior bar. In addition to that, there is a rotational freedom of  $\pm 12^{\circ}$  between the femoral and articular surface. During surgery tantalum beads were inserted in predefined non-weight bearing areas of the mobile bearing insert with a specially designed insertion device. Holes of 2 mm depth and a diameter of 0.8 mm were pre-drilled, so that the 1 mm tantalum beads were press fitted in the predefined non-critical areas of the insert. The cam of the femoral component engages the tibial spine at approximately 75 degrees and induces mechanical rollback while inhibiting posterior subluxation of the tibia. In the frontal plane, the component has a dished articulation, providing a large contact area even in up to 7 degrees varus/ valgus malalignment. In addition to the cam/spine mechanism, the LPS femoral



component has a large distal radius and smaller posterior radius to help facilitate femoral rollback on the tibia during lower flexion angles. A ligament balancer applying 40 lbs tension in flexion and extension to both condyles was used during operation (V-Stat, Zimmer Inc. Warsaw, USA) to provide optimal stability in flexion and extension and to guarantee reproducible ligament balancing between patients.



**Figure 1.** The experimental set-up is shown with the knee centered in front of the fluoroscope. The MC model of the mobile-bearing insert and RE models of the tibia and femur component were matched on the 2-D projections of the fluoroscopy image.

Prior to the experiment, knee stability tests were performed to assess the anteriorposterior and medial-lateral stability (Knee Society Score). The patients were asked to perform a step-up task with bare feet in front of the fluoroscope. Considering the loading and the range of motion of the knee joint, a step up motion was considered as a worst case representation of gait as a frequently encountered activity during daily living. The step-up platform (riser height 18 cm) was centered between the image intensifier and the focus of the fluoroscope. The patients' knee was positioned

next to the image intensifier. The height of the image intensifier was adjusted to the length of the patient by centering the field of view at the lateral side of the joint cavity of the knee. At the start of the step-up motion, the leg with the total knee prosthesis was positioned on top of the riser (Figure 1). The step-up motion was finished when the contra-lateral leg was on top of the riser. The patient was asked to perform the step-up motion in a controlled manner without the use of holding bars. The patient performed four step-ups in total, the first two step-ups were used to gain comfort with the experimental set-up and during the last two runs the data was collected.

Prior to the measurements, the fluoroscopic set-up (Super Digital Fluorography (SDF) system, Toshiba Infinix-NB: Toshiba, Zoetermeer, The Netherlands) was calibrated. To calibrate the fluoroscopic system and to correct for image distortion an image run of three seconds of a specially designed calibration box (BAAT Engineering B.V., Hengelo, The Netherlands) was made before each experiment (15 frames/sec; 1024×1024 image matrix; pulse width of 1 ms).

The 2D positions of the marker projections in the fluoroscopy images were automatically detected with an algorithm based on the Hough-transform for circle detection. For obtaining a more accurate location of each 2D marker projection, a parabolic model of the marker is fitted to the marker's grey value profile (Vrooman et al., 1998). Marker Configuration Model Based Roentgen Fluoroscopic Analysis (MCM-based RFA) was used to estimate the position and orientation of the marker configurations from this 2D data. This technique showed to have a rotational accuracy of 0.3 degrees (Garling et al., 2005). MCM-based RFA requires the 3D models of the defined segments. In order to assess accurate 3D MC-models of the markers of the mobile bearing, two RSA radiographs of the subjects – all were also involved in an RSA study- were used and analyzed using RSA-CMS software (Medis, The Netherlands). Reversed engineered (RE) 3D models of the tibia component and the femoral component were used to assess the poses of the femur and the tibia (Kaptein et al., 2003).

With the assessed 3D position and orientation of the femoral and tibial components and the markers in the mobile bearing both the relative rotation of the mobile bearing with respect to the tibial component was calculated and the relative rotation of the femoral component with respect to the tibial component (Söderkvist

and Wedin, 1993). The coordinate system was defined by the local coordinate system of the tibial component.

A paired-samples T-test was used to compare the differences between the axial rotation of the femoral component and the mobile-bearing insert with respect to the tibia. Pearson's correlation coefficient was used to assess the relation between the varus/valgus angle and the observed kinematics.

For all analyses, significance was determined by a p-value of less than 0.05.

#### 4.4 Results

The femoral component showed more (p < 0.0003) axial rotation than the mobilebearing insert with respect to the tibial component during extension. In all ten subjects, the femur showed more (p < 0.05) axial rotation than the mobile-bearing insert (Figure 2A–D and 3). This indicates the femoral component was sliding on the polyethylene of the rotating platform during the step-up motion in this study. In eight cases, the femoral component rotated internally with respect to the tibia during extension (maximum internal rotation of these femoral components was 10.8°, compared to 5.9° of the mobile-bearing insert). The maximum observed external rotation of the femoral component in the other two knees was 2.8°, compared to 1.4° of the mobile-bearing insert.

All patients had an anterior-posterior laxity of less than 5 mm and only two patients had a medial-lateral laxity of  $5^{\circ} - 9^{\circ}$  at the 6 months evaluation. No large deviations were observed in the components' orientation in the AP and lateral radiographs (Table 1). Three patients had a small varus angle.

The maximum observed varus angle was 178°. The varus/valgus angle did not influence the tibiofemoral kinematics or tibial component mobile-bearing insert kinematics. The average range of motion during the step-up was  $45^\circ \pm 8^\circ$ . All patients reached nearly full knee extension (177° ± 1.3°).



Figure 2A-D. Graphs show the relative axial rotation of the mobile-bearing insert and the femoral component with respect to the tibial component during extension: (A) No axial rotation of the components. (B) Mobilebearing insert is fixed and femoral component is rotating internally. (C) Both components rotate internally, however the mobile-bearing insert shows half the rotation of the femoral component. (D) The femoral component rotates externally and the mobile-bearing insert is fixed

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**Figure 3**. A graph shows the difference in axial rotation of the femoral component relative to the mobile-bearing insert.

Table 1. Radiographic results for 10 patients based on two follow-up examinations

Parameter	Mean ± Standard Deviation
Tibial slope	85.6° ± 3.1°
Tibial angle	86.9° ± 2.2°
Femoral flexion (anteroposterior)	95.2° ± 2.3°
Total valgus (femoral-tibial) angle	182° ± 3.2°
Femoral flexion (lateral)	$2.8^{\circ} \pm 2.7^{\circ}$

#### 4.4 Discussion

The relative rotation between the femoral component and the polyethylene insert found in this study is in contrast with the hypothesis that the clinical results of the studied rotating platform mobile bearing knee prosthesis will benefit from the axial rotation of the insert during step-up thereby improving the conformity of the articulating surface.

The results presented in the current study are not conclusive to understand the effect of a rotating platform on total knee functioning and device longevity. Especially when one wants to understand the effect of the spine-cam mechanism on the axial rotation of the rotating platform, kinematics during motor tasks with a range of motion of at least 80° – 90° need to be assessed. Although one needs to keep in mind that when assessing mobile bearing knee kinematics the goal is not to prove the bearing is moving – like in deep knee bending- but how it moves during the most frequently encountered daily activities.

Although it is a valid goal of TKA design to mimic normal knee kinematics, for knees that have had severe arthritis with a prolonged period of bone and soft tissue changes, achieving normal motion after TKA may be unrealistic. Even slight arthritic changes in the knee have been shown to influence gait (Murray et al., 1985). The motion patterns in our study were variable among subjects during step-up. During gait analysis the rotation pattern of a rotating platform design varies also considerably among patients (Stiehl et al., 1999). However, the results of these rotating platform designs and other total knee designs suggest the broad range of tibiofemoral motion patterns are well accommodated by patients (Banks et al., 2004). It must be stressed in all fluoroscopic studies the included subjects are surgeon-selected, typically satisfied patients with good clinical and functional outcomes. Thus, results of kinematic studies are in general biased.

Our data confirms that of an in vitro study of the NexGen LPS flex mobile knee that demonstrated a limited internal rotation of 3.8 degrees at 30 degrees flexion (Most et al., 2003). Other studies also report reduced tibiofemoral axial rotations when compared to the axial rotations of the normal knee (Fantozzi et al., 2004; Haas et al., 2002; Kärrholm et al., 1994; Reuben et al., 1989). In cases of reduced axial



rotation, a rotating platform mobile-bearing total knee design may still have an advantage over fixed bearing designs, in that individual knees can determine their own neutral rotational position reducing the constraint at the bearing surfaces and shear forces at the fixation interfaces. Maximum contact pressures are reduced in malaligned mobile-bearing total knee designs compared to fixed designs (Cheng et al., 2003). *In vivo* data suggest under static loading, a tibial malalignment of 3 degrees or more in varus or valgus can greatly alter the distribution of pressure and the load between the medial and lateral compartments. Consequently, internal/external and adduction/abduction motions are affected by the coronal malalignment (Werner et al., 2005). Since the tibiofemoral motion patterns are well accommodated by subjects and the mobile-bearing design is forgiving by its self-alignment capabilities (Fantozzi et al., 2004), implant designers and surgeons will have some latitude in designing new knee prostheses and the placement of mobile-bearing total knees (Banks and Hodge, 2004).

The literature contains limited information regarding the long-term results of different rotating platform designs. The only rotating mobile bearing design with long-term results is the LCS rotating-platform design (DePuy Orthopedics, Warsaw, IN). This design has a survival rate of 98.3% at 18 years (Buechel, 2004; Buechel et al., 2001; Stiehl, 2002). However, one cannot extrapolate these results to the NexGen rotating platform design since the LCS compensates for the absence of the posterior cruciate ligament by a deep dish rotating platform with an anterior-posterior constraint and an elevated posterior rim and not by a post-cam interaction as in the NexGen. In addition, the pivot point of the mobile-bearing insert of the LCS is located central and not anterior as in the NexGen design. These characteristics will result in different tibiofemoral motion and bearing motion. At present, the short-term clinical results of the NexGen prosthesis are good (Ip et al., 2003). Additional long-term survival results and retrieval data should clarify the effect of the observed sliding phenomenon of the femoral component with respect to the polyethylene mobile-bearing.

Three explanations can be given for the observed limited axial rotation of the NexGen LPS rotating platform. The first explanation could be the conformity between the femoral component and insert. This conformity is low enough that

the femoral component is allowed to translate with respect to the insert without forcing the insert to rotate. The second explanation could be the location of the pivot point of the rotating platform. The design rationale of the NexGen LPS mobile was to maximize polyethylene support and minimize overhang as the mobile-bearing insert rotates throughout the range of motion by the anterior location of the trunion. The anterior location was also based on a cadaveric study were an anterior pivot point was observed at approximately the insertion of the anterior cruciate ligament (Hollister et al., 1993). However, it seems more logical to have a lateral located pivot point instead of an anterior located pivot point. In other in vivo fluoroscopic studies, eighty-six percent of mobile-bearing knee implants with translation and rotation freedom and rotating-only bearings had a lateral center of rotation (Banks and Hodge, 2004). Total knees with post-cam substitution of the posterior cruciate ligament tend to show a more medial center of rotation during stair-climbing (Banks et al., 2003). The knee center of rotation tends to migrate from medial to lateral with decreasing AP constraint of the implant but the direction and amount of axial rotation seem unaffected by the location of the center of rotation (Banks and Hodge, 2004). In another in vivo study the actual motion of the mobile bearing in a cruciate retaining mobile bearing design was assessed (Fantozzi et al., 2004). Although the mobile bearing design in that study allowed not only axial rotation but also anteriorposterior translation resulting in a medially located pivot mechanism, the mobile bearing showed also a limited motion with respect to the tibia component. When the location of the pivot point is fixed like in rotating platform designs and the pivot point does not coincide with the actual tibiofemoral rotation point, torsion forces at the cam-bearing articulation will even result into an increase of wear and/or polyethylene on metal impingement. Additional torsion forces might occur when the mobile-bearing tibial component is placed in internal rotation in combination with an anatomic tibial exotorsion (Bramer et al., 2004). The maximum allowed motion of the mobile-bearing insert is than limited by the anterior rotational stop. A prospective randomized study comparing the kinematics of the NexGen and the LCS total knee prostheses would clarify the effect of the mobile bearing pivot point location.

A third explanation for the relatively small motion of the bearing is that it is caused by fibrous tissue formation between the tibial plateau and the rotating platform. As with any surgical procedure, fibrous tissue is formed around prosthetic components (Carro and Suarez, 1999). Presence of this tissue at the edge of mobilebearing insert articulating surfaces will limit their freedom of movement.

The value of the current kinematic data is that theoretical advantages are challenged by *in vivo* measured movements. When combining more *in vivo* kinematic data, with micro-motion data at the prosthesis-bone interface, long-term clinical data and retrieval observations, one can better predict expectations for the patient and device performance. This information is useful for a continued improvement of knee arthroplasty designs.



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