The sense or nonsense of mobile-bearing total knee prostheses

Wolterbeek, N.

Chapter 4

Integrated assessment techniques for linking kinematics, kinetics and muscle activation to early migration: A pilot study

Nienke Wolterbeek[1], Eric H. Garling[1], Henrica M.J. van der Linden[1], Rob G.H.H. Nelissen[1], Edward R. Valstar[1,2]

[1]*Department of Orthopaedics, Leiden University Medical Center*
[2]*Department of Biomechanical Engineering, Delft University of Technology*

Submitted.

Abstract

The goal of this pilot study was to develop and test an integrated method to assess kinematics, kinetics and muscle activation of total knee prostheses during dynamic activities, by integrating fluoroscopic measurements with force plate, electromyography and external motion registration measurements.

Subsequently, this multi-instrumental analysis was then used to assess the relationship between kinematics, kinetics and muscle activation and early migration of the tibial component of total knee prostheses.

This pilot study showed that it is feasible to integrate fluoroscopic, kinematic and kinetic measurements and relate findings to early migration data. Results showed that there might be an association between deviant kinematics and early migration in patients with a highly congruent mobile-bearing total knee prosthesis.

Patients that showed high levels of coactivation, diverging axial rotations of the insert and a deviant pivot point showed increased migration and might be at higher risk for tibial component loosening. In the future, to confirm our findings, the same integrated measurements have to be performed in larger patient groups and different prosthesis designs.

4.1 Introduction

In vivo functional testing is performed frequently and seems extremely useful in optimising knee implant designs for better function, better fixation and improved long-term results (Andriacchi et al., 1982; Banks and Hodge, 2004b). Three-dimensional (3D) fluoroscopic analysis is the most accurate measurement technique to examine the *in vivo* kinematics of total knee prostheses under weight-bearing activities (Banks et al., 1997b; Garling et al., 2005a; Stiehl et al., 1999). The position and orientation of 3D computer models of the knee components are manipulated so that their projections on the image match those captured during the *in vivo* knee motions (Kaptein et al., 2006).

Electromyographic (EMG) data provides important information about co-activation, control of movements and insight into the integration of the prosthesis within the musculo-skeletal system (Benedetti et al., 2003; Garling et al., 2005c). This information is particular relevant when combined with information about the *in vivo* kinematics (Benedetti et al., 2003). Muscle activation is influenced by aspects of an implant design. For instance, the extra degree of freedom in mobile-bearing knees might require higher muscle activity levels of the quadriceps and hamstrings muscles to stabilize the knee. However, moving with excessive muscle activations and co-activations is inefficient and large forces are transmitted to the bone-implant interface which could lead to migration of the tibial component (Grewal et al., 1992).

Roentgen stereophotogrammetric analysis (RSA) can be used to accurately assess the migration of the components and gives an indication about the quality of component fixation (Grewal et al., 1992; Mjoberg et al., 1986; Ryd et al., 1995). Progressive migration after the first post-operative year indicates a higher risk with a predictive power of 85% for future component loosening (Ryd et al., 1995). By combining migration data and external motion registration data, Hilding et al. (1996) showed a correlation between knee joint loading and an increased risk for future tibial component loosening. Unfortunately, data acquired with external motion registration systems is inaccurate because of problems in locating anatomical landmarks and soft tissue artefacts (Stagni et al., 2005; Garling et al., 2007a; Peters et al., 2009). Zihlmann et al. (2006) improved the measurement accuracy of external motion registration by using fluoroscopic images to determine the knee centre and thereby providing a better basis for inverse dynamic calculations. Some studies combine fluoroscopy with a force plate or with external motion registration systems, however, in most studies the measurements are not performed simultaneous (Catani et al., 2009; Fantozzi et al., 2003; Fernandez et al., 2008; Isaac et al., 2005; Stagni et al., 2005; Zihlmann et al., 2006).

The goal of this pilot study was to develop and test an integrated method to assess kinematics, kinetics and muscle activation of total knee prostheses during dynamic activities, by integrating fluoroscopic measurements with force plate, electromyography and external motion registration measurements. Subsequently, this multi-instrumental analysis was then used to assess the relationship between kinematics, kinetics and muscle activation and early migration of the tibial component of total knee prostheses.

4.2 Materials and Methods

4.2.1 Subjects

Nine rheumatoid arthritis patients [4 male, 5 female; age 62 years (σ 12.3); BMI 29.6 (σ 4.4)] were measured simultaneously using fluoroscopy, EMG, force plate registration and external motion registration while performing three step-up and lunge motions 7 months (σ 1.2) post-operatively. Inclusion criteria were the expected ability to perform a step-up and lunge motion without the help of bars and the expected ability to walk more than 1 km. All patients gave informed consent and the study was approved by the local medical ethics committee (ClinicalTrials.gov: *NCT*01102829).

A ROCC® mobile-bearing prosthesis was implanted (Biomet, Europe BV, The Netherlands) in all patients. The polyethylene insert of this prosthesis has a centrally located trunnion and allows for pure rotation on the tibial component. There is a high congruency between the insert and femoral component between 0° and 70° of flexion. The patellae were not resurfaced. The insert was made of compression moulded UHMW polyethylene. During surgery 1 mm tantalum markers were inserted into the tibia bone and into predefined non-weight bearing areas of the insert to visualise the polyethylene.

4.2.2 Tasks

At the start of the step-up motion, the patient was standing with the contra-lateral leg one step lower (height 18 cm) than the leg of interest. The motion was finished when the contra lateral leg was on the same level as the leg of interest. For the lunge task, the patient started with both feet on the highest step (on top of the force plate) and was asked to step back with the contra-lateral leg, bending the knee as far as comfortable possible (Figure 4.1). Patients were instructed to keep their weight onto the leg of interest and to perform the motions in a controlled manner.

4.2.3 Fluoroscopy

Fluoroscopy was used to determine anterior-posterior translation and axial rotation of the insert and the femoral component with respect to the tibial component. Reverse engineered 3D models of components were used to assess their position and orientation in the fluoroscopic images (Infinix, Toshiba, Zoetermeer, The Netherlands) (15 frames/sec, resolution 1024×1024 pixels, pulse width 1 msec). Contours of the components were detected and the 3D models were projected onto the image plane and a virtually projected contour was calculated (Model-based RSA, Medis specials b.v., The Netherlands) (Kaptein et al., 2003). The global fluoroscopy coordinate system was defined within the local coordinate system of the tibial component. RSA was used to create accurate 3D models of the markers of the inserts to assess position and orientation of the polyethylene in the fluoroscopic images. At maximal extension, the axial rotation of the insert was defined to be

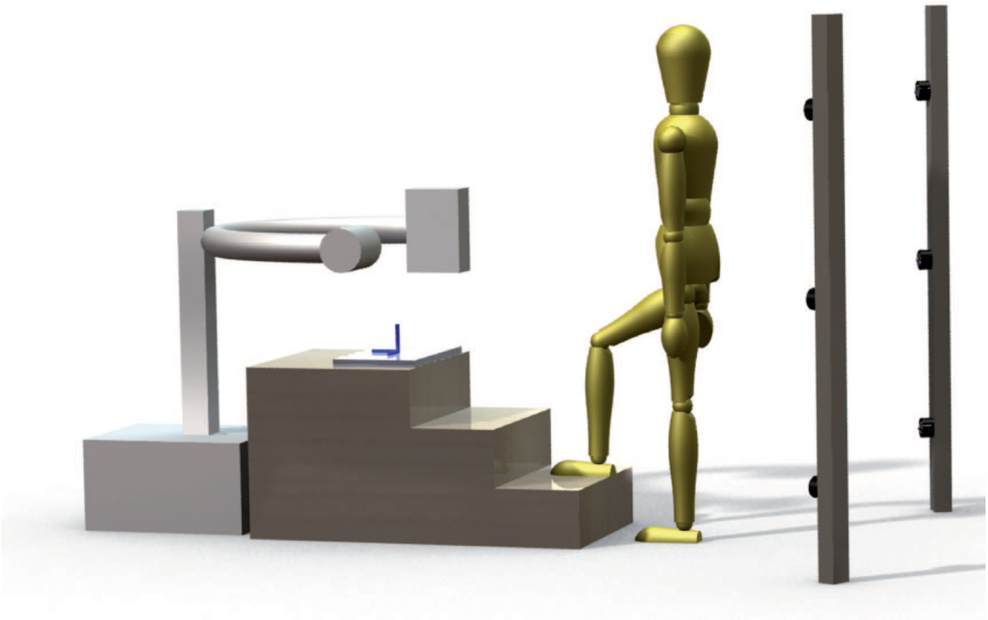

Figure 4.1: Experimental set-up including stairs, force plate, two external motion registration cameras and the image intensifier and X-ray source of the fluoroscope.

zero. The minimal distance between the femoral condyles and the tibial base plate was calculated independently for the medial and lateral condyle and projected on the tibial plane to assess the anterior-posterior motion of the femoral component with respect to the tibial component.

4.2.4 Electromyography

To determine muscle activation patterns and coactivation, bipolar surface EMG (Delsys, Boston, USA) data of the flexor and extensor muscles around the knee was collected (2500 Hz). The muscles recorded were the M. Rectus Femoris, M. Vastus Lateralis, M. Vastus Medialis, M. Biceps Femoris, M. Semitendinosus and M. Gastrocnemius Medialis. Electrodes were placed according to the recommendations of the Seniam project (www.seniam.org). The recorded EMG was filtered using a high-pass Butterworth filter, rectified and smoothed using a low-pass filter. The signals were normalised to their own maximal values.

4.2.5 External motion registration

An external motion registration system (Optotrak Certus, Northern Digital Inc., Canada) was used to record data ($>$ 100 Hz) on the posture of the subjects during the step-up and lunge motions. Technical clusters of three markers were attached to the pelvis, upper leg, lower leg and foot. Anatomical landmarks were indicated in order to anatomically calibrate the technical cluster frames (Cappozzo et al., 2005). An embedded right-hand Cartesian coordinate system is used for describing the position and orientation of the segments.

4.2.6 Force plate

A portable force plate (400×600 mm, Kistler AG, Switzerland) was used to measure ground reaction forces (2500 Hz) and was placed on the highest step of the stairs. From these signals the external knee joint moments were calculated. The knee joint centre, generally calculated from the external motion registration data, was extracted from the fluoroscopic images for a more accurate calculation of the external knee joint moments (Zihlmann et al., 2006). All external joint moments are presented as percentage of body weight times height (%BW$\times$Ht) to minimize the influence of height and weight. The laboratory's global coordinate system's origin was set in the centre of the force plate (Figure 4.1).

4.2.7 Synchronisation

The fluoroscopy, EMG, force plate and external motion registration measurements were synchronised temporally and spatially. EMG, force plate and external motion registration systems were synchronised temporally in a conventional way, provided

Figure 4.2: An analyzed fluoroscopic image showing the reversed engineered models of the femoral and tibial component and the marker model of the insert and their 2D projections. In addition, the custom made box with X-ray sensitive photocells (upper left corner) used for temporal synchronisation, and three EMG electrodes placed on the upper leg are visible.

by the manufactures. For temporally synchronising the fluoroscopic images with the EMG system a custom made box with X-ray-sensitive photocells was used (Figure 4.2). The force plate and external motion registration system were synchronised spatially using a standard calibration cube, which was part of the external motion registration system. Subsequently, an object with markers, both visible in the external motion registration system and in the fluoroscopic images, was used to synchronise spatially the fluoroscopic images with the laboratory's global coordinate system located in the centre of the force plate. All data was processed using Matlab (The MathWorks, Inc., Natick, USA).

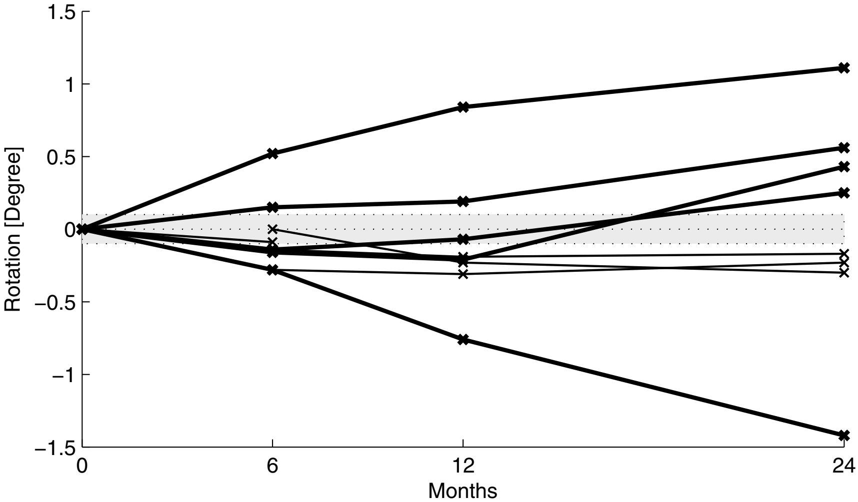

Figure 4.3: Rotation (°) around the z-axis (varus-valgus tilt) measured with RSA for the individual patients 6, 12 and 24 months post-operatively. Precision for varus-valgus tilt is 0.1° (grey area is 95% confidence interval). In this direction, five patients (thick lines) showed continuous migration.

4.2.8 RSA

RSA (Model-based RSA, Medis specials b.v., The Netherlands) was used to determine the migration of the prosthesis with respect to the bone. The first RSA examination, two days after surgery and before mobilization, served as reference baseline. Subsequent evaluations of migration (6, 12 and 24 months post-operatively) were related to the relative position of the prosthesis with respect to the bone at the time of the first evaluation. In one patient, the baseline RSA radiograph was of poor quality and for that reason the second radiograph was used as reference baseline. One patient was dissatisfied and underwent revision in another hospital despite having normal clinical indicators, and was therefore excluded from the RSA study after 6 months.

Table 4.1: Mean migration and standard deviation (σ) of the tibial component with respect to the bone 1 and 2 years post-operatively. Directions are corrected for side. Precision of the RSA measurements, by means of double examinations 1 year post-operatively, is also presented (95% confidence interval).

		1 year		2 year		Precision
		Mean	σ	Mean	σ	
Translation (mm)	**Medial-Lateral**	-0.09	0.27	-0.21	0.36	0.1
	Subsidence	0.13	0.19	0.11	0.25	0.1
	Anterior-Posterior	0.09	0.41	0.30	0.42	0.3
Rotation (°)	**Anterior-posterior tilt**	0.08	0.53	0.62	0.33	0.4
	Axial rotation	0.17	0.56	0.20	0.60	0.4
	Varus-valgus tilt	0.03	0.49	0.13	0.70	0.1

4.3 Results

4.3.1 RSA

The precision of the RSA measurements was determined by means of double examinations at the one-year follow-up examination (Table 4.1). After an initial period of rapid migration, in 4 of the 9 patients the tibial component migration slowed down and stabilized. The other components showed continuous migrations (> 0.5 mm and $> 0.5°$) in one or more directions (Figure 4.3). The direction of migration was irregular. Mean Maximum Total Point Motion (MTPM) at 1 year was 0.87 mm (range 0.46 – 1.64) and at 2 year 1.09 mm (range 0.54 – 2.13).

4.3.2 Fluoroscopy

Fluoroscopic data showed that the insert and femoral component had comparable axial rotations between 0° and 60° of flexion (Table 4.2). Beyond 60° of flexion the axial rotations of the femoral component and insert diverged. In two knees, the

Table 4.2: The range of axial rotation (°) of the femoral component and the insert and the range of anterior-posterior translation (mm) for the medial and lateral condyle are presented for the step-up and lunge motion (mean, standard deviation (σ), minimal and maximum).

Range	Axial rotation (°)				AP translation (mm)			
	Femoral component		Insert		Medial condyle		Lateral condyle	
	Step-up	Lunge	Step-up	Lunge	Step-up	Lunge	Step-up	Lunge
Mean	8.6	5.6	7.8	6.9	5.6	5.9	7.0	6.7
σ	4.4	2.0	4.0	2.8	1.2	1.5	1.6	2.0
Min	2.2	1.9	2.3	3.0	3.5	3.7	4.5	4.0
Max	18.4	11.3	16.1	12.5	9.0	9.0	11.0	11.0

difference in axial rotation increased to more than 10°. Paradoxical internal rotation followed by external rotation between 40° and extension were seen in two patients. During the lunge motion, two different patients showed paradoxical external rotation after 50° of flexion. One patient showed almost no axial rotation of the insert and femoral component during both motions ($< 3°$). This patient had also virtually no anterior-posterior motions.

During the lunge motion, the knees first showed axial rotations and after approximately 50° of knee flexion they shifted to paradoxical anterior translations. In all knees, except one (medial pivot), there was a central pivot point of axial rotation. The knee with the medial pivot point was one of the knees with diverging axial rotations of the femoral component and the insert. This patient showed large continuous migration in axial rotation (0.51°) and in medial-lateral translation (0.23 mm). The other knee with diverging axial rotations had also continuous migrations in these directions (respectively 0.71° and 0.69 mm) as well as large varus-valgus tilt (1.11°) and anterior-posterior tilt (0.98°).

4.3.3 Electromyography

During the step-up motion, all patients showed the same extensor muscles activity pattern with a peak around 30° of flexion. The activity of the flexor muscles was variable showing continuous activity, an increase or a decrease in activity during extension. During the lunge motion, the extensor muscles were active in all patients and the activity levels decreased with increasing flexion angle (around 50°). The flexor muscles were either continuously active on a low level or their activity were similar to the extensor muscles and also decreased with increasing flexion angle. One patient had high levels of coactivation during both motions (antagonists were active at high levels ($> 40\%$) in the same pattern as the agonists), while 3 patients had high levels of coactivation during either the step-up or the lunge motion. All the patients with high levels of coactivation had tibial component migration in one or more directions.

4.3.4 External movement registration and force plate

One patient performed the step-up and lunge motion with much higher ($> 6\%$BW×Ht) extension moments then the other patients. This patient had also high adduction moments ($> 2\%$BW×Ht) and high internal rotation moments ($> 0.2\%$BW×Ht). This patient had large and continuous migrations in the direction of anterior-posterior translation (1.27 mm), medial-lateral translation (0.94 mm) and varus-valgus tilt (0.57°). Another patient had relative low extension moments ($< 4\%$BW×Ht) during the motions, but high internal rotation moments during the step-up motion and low external rotation moments ($< 0.1\%$BW×Ht) during the lunge motion. This was the only patient who had external rotation moments. This patient had migration in the direction of anterior-posterior tilt (0.82°). A third patient had high internal rotation moments during both motions, but low extension and ab-adduction moments. This is the same patient as described above with the medial pivot point and diverging axial rotation patterns.

4.4 Discussion

The goal of this pilot study was to develop and test the concept of simultaneously obtaining kinematic, kinetic and muscle activation data during dynamic activities, by integrating fluoroscopic measurements with force plate, electromyography and external motion registration measurements. This method was used to accurately assess the relationship between knee joint kinematics, kinetics and muscle activations and early migration of the tibial component of total knee prostheses. A modest association between deviate kinematics and early migration in patients with a highly congruent mobile-bearing total knee prosthesis was found.

The fluoroscopic results confirm the high congruency between the femoral component and the insert until approximately 60° of flexion. Beyond 60° of flexion the difference between the axial rotation of the insert and of the femoral component increases which supports the decreasing congruency with increasing knee flexion. This prosthesis has a centrally located trunnion and therefore a central pivot point of axial rotation is expected. However, one patient has a medial pivot point. This could be related to the divergent axial rotation patterns of the insert and femoral component beyond 50° of flexion and the high internal rotation moments also seen in this patient. In this study, all inserts except one showed axial rotation during motion. The knee with no axial rotation had also virtually no anterior-posterior translations. There is no clear explanation for the lack of axial rotation and anterior-posterior translation in this patient as the patient did not suffer from a stiff knee, excessive scar tissue or a flexion limitation. However, large migrations were seen in 4 directions which indicate severe friction between components.

The paradoxical anterior translations beyond 50° of knee flexion and the divergent axial rotations beyond 60° of flexion indicate that as soon as the congruency decreases the femoral component is not longer forced in a certain position by the insert and moves to a self-imposed position. This indicates that in this prosthesis, the high congruency leads to undesired restrictions of motions which in turn might lead to high stresses between the components and the bone. Despite high-flexion being generally less performed during daily living, paradoxical kinematics might have implications in long-term failure of prostheses (Argenson et al., 2002; Banks and Hodge, 2004a; Benedetti et al., 2003; Li et al., 2006; Sansone and da Gama, 2004; Shi et al., 2008).

Possible patient related reasons for early migration are incomplete cortical support, low bone quality and insufficient initial fixation. In this study, according to the surgeon, all patients had good cortical support, bone quality and initial fixation of the implants. A non-patient related reason for early migration is stresses on the bone-implant interface due to the design of the implant. This tibial component has a keel which provides both fixation and stability and thus withstands small stresses. Therefore, high stresses on the bone-implant interface seem to be the main reason for the relatively large early migrations.

The presence of prolonged coactivation of the flexor (hamstrings) and extensor (quadriceps) muscles may indicate skeletal instability of the knee joint, motor control deficiencies or intrinsic instability of the prosthesis (Fantozzi et al., 2003; Garling et al., 2005c; Lloyd et al., 2005). Muscle contractions can produce dynamic stability of the knee and thereby unload soft tissue but it could also cause abnormal kinematics and high stresses at the bone-implant interface (Andriacchi et al., 1982; Andriacchi and Dyrby, 2005). The 4 patients with high levels of coactivation showed large continuous migration in one or more directions. The patient who showed no axial rotation of the femoral component and the insert or anterior-posterior translation during motion had large migrations around all 3 rotational axes and in subsidence. Instability of the tibial component might explain the high levels of coactivation (active stabilizing the knee joint).

As far as we know this is the first study simultaneously measuring fluoroscopy, ground reaction forces, joint kinematics and EMG and relate the findings with RSA data. Using fluoroscopic images to extract the knee joint centre to calculate external knee joint moments is more accurate than using external skin markers (Zihlmann et al., 2006). However, the out of plane error in fluoroscopic analysis, depending on the prosthesis design and the quality of the used 3D models of the components (Prins et al., 2010), might have a major influence on the accuracy of this method. An error in the out of plane direction (medial-lateral position of the components) has a direct effect on the length of the lever arm between the knee centre and the ground reaction force vectors and thus an effect on the calculations of the external knee joint moments.

Unfortunately, it was not possible to replicate the accuracy measurements of Zihlmann et al. (2006) due to visibility problems of the external motion registration markers. During the measurements particularly the pelvis and upper leg markers were difficult to keep into view and therefore it was not always possible to accurately recreate the segments and calculate the external moments around the joints. These problems were caused by the limited space available in the X-ray room, resulting in a suboptimal position of the external motion registration cameras.

Despite the small sample size and relative short follow-up, there seems to be an association between deviant kinematics and early tibial component migration. Until now, patients did not have clinical symptoms. However, it seems reasonable to consider that continuation of this initial migration will develop into clinical loosening and becomes of clinical significance. RSA evaluations of these patients will continue at yearly intervals to monitor these patients carefully and determine the long-term fixation of the components in the bone.

Conclusion

This pilot study showed that it is feasible to integrate fluoroscopic, kinematic and kinetic measurements and relate findings to early migration data. Results showed that there might be an association between deviant kinematics and early migration in patients with a highly congruent mobile-bearing total knee prosthesis. Patients that showed high levels of coactivation, diverging axial rotations of the insert and a deviant pivot point showed increased migration and might be at higher risk for tibial component loosening. In the future, to confirm our findings, the same integrated measurements have to be performed in larger patient groups and different prosthesis designs.