The sense or nonsense of mobile-bearing total knee prostheses

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Co-promotores:	Dr. ir. E.R. Valstar
	Dr. E.H. Garling
Overige leden:	Prof. M. Taylor (University of Southampton, UK)
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Our purpose is to explain what may appear to be a paradox: that a condylar replacement prosthesis may best confer stability upon the living joint if it is itself completely unstable.

Goodfellow and O'Connor, *The journal of Bone and Joint Surgery, 1978*

Aan mijn ouders

Contents

Chapter 1

General introduction

1.1 Development of total knee prostheses

In the late 1960's and early 1970's the first modern total knee prostheses were developed based on hinged and unicondylar implants which were already available (Freeman et al., 1977; Insall et al., 1979a,b; Yamamoto, 1979). Current total knee prostheses are directly derived from these first prostheses and represent variations of the basic concepts introduced. Intrinsic constraints, including the shapes of the articular surfaces, post-cam mechanisms and insert mobility, have been altered to reproduce the form and function of the healthy knee (Banks and Hodge, 2004b; Pandit et al., 2005). The importance of the development in prosthetic design relates directly to the fact that the aspiration of total knee arthroplasty moved from that of a salvage operation for pain control, only performed in extreme cases, to an intervention to improve the quality of life and functionality. Pain and loss of function due to osteoarthritis and rheumatoid arthritis are nowadays the main indicators for replacement of the knee joint. The objective one hopes to achieve with total knee arthroplasty are long-lasting pain relief and restoration of functionality of the knee joint in terms of stability, mobility and load-bearing capacity (Banks et al., 2003b; Catani et al., 2006; Kim et al., 2001).

The maximum lifespan of total knee prostheses is limited; survival rates between 78% to 98% at twenty years have been reported (Buechel, 2002, 2004; Gill et al., 1999; Keating et al., 2002; Rand et al., 2003; Stiehl, 2002). Survival rates are dependent on gender, age and diagnosis of the patient, as well as, prosthetic design and fixation method (Rand et al., 2003). Reasons for revision are septic loosening (infection), aseptic loosening (associated with component malalignment and soft tissue imbalance) and wear of the polyethylene insert.

Total knee prostheses consist of a femoral component, a tibial component, an insert and in some cases also a patellar button. The first total knee prostheses had J-curved or multi-radius femoral components which means that the components had a variable sagittal curvature. This results in artificial joints with multiple axes of rotation through the arc of flexion. In these so-called multi-radius knees, the motion of the knee is mainly guided by the shape of the articulating surfaces.

The first post-operative kinematic problems that were encountered in the mid 1970's with total knee prostheses were limited flexion and the lack of posterior roll-back of the femoral component on the tibial component, resulting in paradoxical anterior translations. Posterior-stabilized prostheses were developed to prevent these paradoxical anterior translations during flexion. The post-cam mechanism in posterior-stabilized knee prostheses replaces the function of the posterior cruciate ligament and induces posterior displacement of the femoral component on the tibial component during flexion. This posterior displacement will avoid impingement and thereby improves the range of motion of the knee (Insall et al., 1982).

Mechanical loosening and wear of the polyethylene insert are the primary complications in knee replacement. In the late 1970's and early 1980's, mobile-bearing prostheses were introduced to prevent these complications. The mobility of the mobile insert allows a higher congruency between the femoral component and the polyethylene insert, which results in an increased contact area and subsequent lower contact stresses in the insert compared to non-congruent fixed-bearings (Andriacchi, 1994; Blunn et al., 1997; Dennis et al., 2005; Stiehl et al., 1997; Uvehammer et al., 2007).

Joint instability in mid-flexion and the belief that there is only one flexion-extension axis fixed in the femur led to the latest large adaptation made in total knee implants. Single-radius prostheses have been developed in the mid 1980's as an alternative for the multi-radius prostheses. A single-radius design allows the ligaments to guide the motion of the knee on the articulating surfaces. The single axis of rotation is aligned with the transepicondylar axis providing ligament isometry and a substantial contact area throughout the entire range of motion. This provides a more uniform motion, lower contact stresses on the insert, improved mid-flexion stability and more efficient muscle activity (Kessler et al., 2007; Wang et al., 2006).

1.2 Theoretical considerations for mobile-bearing total knee prostheses

There are numerous mobile-bearing knee prostheses on the market worldwide, most of them based on the mobile-bearing concept of the LCS-prosthesis. Mobile-bearing knees vary in type of bearing surface (single platform, separate meniscal bearings or an unicondylar meniscal bearing), type of motion constraint (cone-in-cone, tibial tray post, stops or unconstrained bearing) and type of mobility (rotating platform or multidirectional mobility). The models with rotating platforms are often based on a conventional prosthesis and share the same femoral components with the fixed-bearing prosthesis.

Mobile-bearing knee prostheses were designed to mimic the function of the human meniscus by accommodating the natural combination of rolling and sliding movements (Goodfellow and O'Connor, 1978). The intact meniscus is relatively free to distort and can be displaced forwards and backwards upon the tibial condyles in order to take up and distributes the stresses between the non-conforming surfaces of the tibial and femoral joint surfaces.

The essential point of the mobile-bearing knee prosthesis is that the polyethylene insert can move with respect to the underlying tibial component and does not restricts the natural movements of the femoral component. The mobility of the insert allows a higher congruency between the insert and the femoral component, which leads to an increased contact area and thus lower contact stresses and wear in comparison with non-conforming fixed inserts (Andriacchi, 1994; Blunn et al., 1997; Buechel, 2004; Dennis et al., 2005; Matsuda et al., 1998; Li et al., 2006; Stiehl et al., 1997; Uvehammer et al., 2007). Furthermore, the unrestricted movement of the insert uncouples the forces generated at the articulation from the prosthesis-bone interface. This could have a positive effect on the fixation of the prosthesis to the bone and thereby decreases the risk for loosening (Garling et al., 2005b; Henricson et al., 2006; Huang et al., 2007). Another potential advantage of a mobile-bearing over the fixed-bearing knee, stated in literature, is self-adjustment of the insert to accommodate surgical malalignment. This self-adjustment might improve patellar tracking and maximal knee flexion (Cheng et al., 2003; Huang et al., 2007; Matsuda et al., 1998; Pagnano et al., 2004). However, surgeons should not select a mobile-bearing knee prosthesis based on the assumption that their surgery does not need to be as accurate as that of a surgery using a fixed-bearing knee prosthesis.

Mobile-bearing total knee prostheses have also potential disadvantages. First, mobile-bearing implants are less forgiving for imbalance in soft tissue compared with fixed-bearing implants. An accurate surgical technique is essential for a good result since the knee stability depends on well balanced ligaments and soft tissues around the new knee joint. Soft tissue instability might also lead to dislocation of the polyethylene insert (Callaghan, 2001).

A second disadvantage is that the polyethylene insert has two potential wearing surfaces: the upper surface in contact with the femoral component and the lower surface in contact with the tibial component. No evidence exists whether this two sided polyethylene wear is less than the one sided polyethylene wear of fixed-bearing knee prostheses. *In vitro* simulator studies show reduced wear rates in mobile-bearing knee prostheses compared to fixed-bearing knees due to redistribution of knee motion to two articulating interfaces with more linear motions at each interface (Haider and Garvin, 2008; McEwen et al., 2005). However, it is not clear if this also applies *in vivo*. Polyethylene debris (wear particles) has been implicated as the cause of osteolysis and subsequent implant failure. As the body attempts to clean up these wear particles it triggers an autoimmune reaction which causes resorption of living bone. Osteolysis seems to be dependent on the size of wear particles. The particles in mobile-bearing knees are claimed to be smaller, inducing more bone resorption compared to fixed-bearing knees (Huang et al., 2002).

A third disadvantage concerns mechanical failures of mobile-bearing knee prostheses like (partial) dislocation and even breakage of the polyethylene insert (Callaghan, 2001).

1.3 Clinical considerations for mobile-bearing total knee prostheses

The concept of mobility in total knee prostheses is attractive. Most orthopaedic surgeons and researchers have an explicit preference for one or the other but this is mainly based on eminence based knowledge in stead of on strong evidence based medicine. There has been no convincing evidence that the theoretical advantages of mobile-bearing knee prostheses translate into a benefit for the patient and deliver a better clinical outcome in the short (i.e. better functionality) or long-term (i.e. less wear). Better long-term survivorship and better clinical function compared to the fixed-bearing designs, have not yet been demonstrated in any outcome studies (Hamai et al., 2008; Hansson et al., 2005; Hanusch et al., 2010).

The reasoning behind mobile-bearing knee prostheses is that the mobility permits increased articular congruency between the femoral component and the insert, reducing contact stresses and thus reducing polyethylene wear compared to fixed-bearing knees. Therefore, for mobile-bearing knee prostheses to be considered successful, the polyethylene bearing should accommodate rotation during frequently encountered daily activities. Only a few studies are performed to evaluate the *in vivo* three-dimensional motion of the insert (Fantozzi et al., 2004; Garling et al., 2007b). In those studies a relatively small motion of the bearing was observed during various activities which questions the benefit of the mobile-bearing. When there is no or minimal rotation at the tibial-insert interface, the theoretical advantages which should lead to reduced contact stresses and polyethylene wear will not be accomplished and could even lead to longevity problems. However, if mobile-bearing knee prostheses are inserted with the same precision as fixed-bearing knee prostheses, the clinical outcome should be at least comparable (Callaghan, 2001).

Each total knee prosthesis has its own theoretical advantages and disadvantages. However, it is no exception that knee implants do not show *in vivo* the advantages they are designed for. Better understanding the influence of design parameters on *in vivo* kinematics, stability and muscle activation is fundamental for improving current total knee prostheses to reach the objectives of long-lasting pain relief and restoration of knee joint stability, mobility and load-bearing capacity (Andriacchi et al., 1982; Banks and Hodge, 2004a; Taylor and Barrett, 2003; Wang et al., 2006). This is of importance because of the growing population of younger patients who will require not only an implant to function for at least two decades, but also one that is adapted to the higher physical demands of the younger patient.

1.4 Aim of this thesis

The aim of this study is twofold. First, to study if the *in vivo* kinematics of mobile-bearing total knee prostheses was consistent with the kinematics intended by the design and second to determine the additional value of insert mobility and thus 'the sense or nonsense' of mobile-bearing total knee prostheses.

1.5 Outline of this thesis

In **Chapter 2** a short introduction of normal knee joint kinematics and knee prosthesis kinematics is given.

In **Chapter 3** gait analysis was used to identify differences in muscle activity levels and co-activation patterns between patients with a mobile-bearing prosthesis or a fixed-bearing prosthesis and healthy controls.

The goal of **Chapter 4** was to develop and test an integrated method to assess kinematics, kinetics and muscle activation of total knee prostheses during dynamic activities. 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.

In **Chapter 5** and **6** the tibiofemoral kinematics, including the *in vivo* axial rotation of the polyethylene insert, of two mobile-bearing total knee prostheses was assessed using fluoroscopy. The purpose of these studies was to determine the change in tibiofemoral kinematics over time and to show the importance of re-evaluating knee kinematics.

In **Chapter 7** a prospective randomized study was performed to compare a fixed-bearing and mobile-bearing single-radius total knee prosthesis and study the effect of a mobile-bearing on early migration of the tibial component and knee kinematics.

In **Chapter 8** different total knee prostheses were compared to determine if *in vivo* kinematics was consistent with the kinematics intended by design.

Chapter 9 provides a general discussion and conclusion of the work presented in this thesis.

Chapter 2

Knee joint kinematics

2.1 Normal knee joint kinematics

The knee joint can be seen as a pivotal hinge joint. It consists of four bones: femur, tibia, fibula and patella bone and two articulations: between the femur and tibia, and between the femur and patella. The lack of congruency between the bony surfaces allows six degrees of freedom of motion about the knee including 3 translations (anterior-posterior, medial-lateral, proximal-distal) and 3 rotations (flexion-extension, internal-external, varus-valgus). The total range of motion is dependent on several parameters such as muscle activation and soft tissue restraints.

The healthy knee employs a passive system of ligaments and menisci to provide stability and intrinsic control of knee motions over the functional range of motion. The four primary ligaments of the knee are the anterior and posterior cruciate ligaments located in the centre of the knee joint and the medial and lateral collateral ligaments. The anterior cruciate ligament (ACL) resists anterior displacement and the posterior cruciate ligament (PCL) resists posterior displacement of the tibia on the femur during flexion. The ACL also controls the screw-home mechanism of the tibia in terminal extension of the knee. The PCL controls external rotation of the tibia with increasing knee flexion and guides femoral rollback in flexion. The main function of the medial and lateral collateral ligaments is to restrain respectively valgus and varus rotation of the knee and external and internal rotation of the tibia.

Kinematics of the knee during frequently occurring activities, like walking and ascending and descending stairs, has been thoroughly studied. However, the exact *in vivo* kinematics of the knee is still not entirely resolved. Flexion-extension, the predominant motion of the knee, involves a combination of rolling and sliding. During flexion the femoral condyles move posterior with respect to the tibia, called ‘femoral rollback’. At the beginning of flexion, the knee ‘unlocks’ with internal rotation of the tibia with respect to the femur. Axial rotations of more than 10° occur at the knee during daily activities. Axial rotation is feasible because of asymmetry between the lateral and medial femoral condyles. The lateral condyle being smaller allows the condyle to roll a greater distance than the medial condyle during the first

20° of knee flexion (Dennis et al., 2005; Lafortune et al., 1992).

The hamstrings and quadriceps are the main muscle groups that control the motions of the knee. The quadriceps muscle group is located in the front of the thigh and controls extension of the knee. The hamstrings muscle group, in the back of the thigh, controls flexion of the knee. Normal muscle activation patterns are characterized by a pattern of activation and relaxation related to the function of the muscle group during a specific activity. Co-activation of agonist and antagonist muscle groups is a common strategy adopted to reduce strain and shear forces at the joint. However, it also increases joint torque and axial load (O'Connor, 1993). The forces across the normal knee joint are complex and involve loads in axial compression, torsion and shear.

2.2 Knee prosthesis kinematics

Normal function of the knee joint requires a high degree of mobility and stability while sustaining high loads during daily activities. Therefore, the knee joint is vulnerable to changes in alignment or loss of passive and active soft tissue stability. After total knee replacement surgery, joint resistance to external force and torque must be guaranteed primarily by the articulating surfaces and by the ligaments throughout the functional range of motion. Also, one wants to achieve 'normal' mobility and stability at the replaced joint (Andriacchi, 1994; Bellemans et al., 2002; Catani et al., 2006).

In vivo functional testing seems extremely useful in optimizing 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 analyses are the most accurate measurement technique to examine the *in vivo* kinematics of total knee prostheses under weight-bearing activities (Banks et al., 1997b; Dennis et al., 1996, 1998; Garling et al., 2005a; Stiehl et al., 1999). The position and orientation of 3D computer models of total knee components are manipulated so that their projections on the images match those captured during the *in vivo* knee motions (Garling et al., 2005a; Kaptein et al., 2006). Because of the high accuracy of fluoroscopy, small patient cohorts are in general sufficient to study the parameters of interest.

Fluoroscopic studies of total knee prostheses have shown a broad range of kinematic patterns of the femur with respect to the tibia during dynamic activities and a significant proportion of implanted knees has abnormal kinematics (Banks et al., 2003a; Callaghan et al., 2000; Callaghan, 2001; Dennis et al., 1998, 2003; Morra et al., 2008; Pandit et al., 2005; Saari et al., 2005; Stiehl et al., 1997, 1999; Walker et al., 2002). Abnormal kinematics found in fixed-bearing designs, such as paradoxical anterior-posterior translations and reversed axial rotations, are common and also found in mobile-bearing designs. Paradoxical anterior-posterior translations may lead to accelerated wear of the polyethylene insert and may restrict flexion (Krichen et al., 2006; McEwen et al., 2005; Sansone and da Gama, 2004). Abnormal kinematics, which the knee prosthesis is not designed for, may even result in a feeling of instability and excessive stresses at the bone-implant interface leading to aseptic loosening (Taylor and Barrett, 2003; Hilding et al., 1996).

Electromyographic (EMG) data can provide important information about total knee prosthesis functioning like co-activation and control of movements (Andriacchi, 1994; Benedetti et al., 2003; Garling et al., 2005c). Knowledge of the muscular control of knee prosthesis provides insight into the integration of the prosthesis within the musculo-skeletal system. This information is particular relevant when combined with information about the implant kinematics (Benedetti et al., 2003). Muscle activation is not only influenced by aspects of an implant design but also by long lasting adaptations to a destructed knee joint. 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. Also, early muscle activation or anticipatory stabilization of the knee joint is seen in patients with a mobile-bearing knee (Catani et al., 2003; Garling et al., 2005c, 2008). Anticipatory stabilization and co-activation are mechanisms to protect the soft tissue from external loads by increasing the stiffness of the knee (Andriacchi, 1994). 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 micromotion of the tibial component (Grewal et al., 1992).

Different total knee prosthesis designs result in different *in vivo* knee joint kinematics. Joint kinematics are highly dependent on the intrinsic prosthetic constraint (Andriacchi et al., 1982; Kessler et al., 2007). The argument as to whether posterior cruciate knee ligaments should be preserved or sacrificed continues to this day (Nelissen and Hogendoorn, 2001). Long-term follow-up studies do not show any significant differences, although gait appears to be less abnormal if ligaments are preserved, especially when walking up and down stairs. Posterior-stabilized knee prostheses have been introduced on the basis that the post-cam system might induce femoral rollback during flexion. The post-cam mechanism drives tibiofemoral contact towards the posterior edge of the insert, allowing for higher flexion prior to impingement (Banks et al., 2003a; Dennis et al., 2003; Morra et al., 2008). However, others report that the posterior-stabilized mechanism fails to prevent paradoxical anterior-posterior translations and does not contribute to initial or increasing rollback during flexion (van Duren et al., 2007; Pandit et al., 2005).

The rotational freedom and higher congruency between the femoral component and the insert in a mobile-bearing knee could provide better kinematic behaviour by minimizing the paradoxical anterior-posterior sliding of the femoral component in flexion (Sansone and da Gama, 2004). Rotational mobility of the insert could also allow a better reproduction of internal tibial rotation during flexion (Delport et al., 2006). However, rotation centres inconsistent with the insert's pivot location are no exception in mobile-bearing knees, probably caused by insufficient congruency and will result in a less optimal congruency between the femoral and tibial component (Banks and Hodge, 2004a).

2.3 Motion of the mobile insert

Using fluoroscopy it is also possible to analyse the *in vivo* kinematics of marked polyethylene inserts in mobile-bearing knee prostheses (Garling et al., 2005a). Axial rotation of the insert is not only affected by internal-external rotation of the femoral component but also by the anterior-posterior and medial-lateral translations of the femoral component (Hamai et al., 2008). The broad range of kinematics patterns seen in mobile-bearing knees could be explained by the absence of motion or occurrence of erratic motion of the polyethylene insert. This will enhance wear of the polyethylene surface and could increase the torsional forces at the bone-implant interface, induce more aseptic loosening (Garling et al., 2005a; Henricson et al., 2006). The mobile insert may also be encapsulated by soft tissue after a period of time. As a consequence, the mobility of the mobile-bearing which should prevent wear of the mobile-bearing is cancelled out, and might even induce more wear when it is fixed in an abnormal position. However, the discussion whether the mobile insert is moving during knee motion and if it copies the natural movement of the healthy knee is still ongoing. A number of studies show that the polyethylene insert keeps its mobility over time (Sansone and da Gama, 2004; Uvehammer et al., 2007) while other studies show limited or no motion of the insert at all (Fantozzi et al., 2004; Garling et al., 2007b).

Chapter 3

Co-contraction in RA patients with a mobile-bearing total knee prosthesis during a step-up task

Eric H. Garling[1], Nienke Wolterbeek[1], Sanne Velzeboer[3], Rob G.H.H. Nelissen[1], Edward R. Valstar[1,2], Caroline A.M. Doorenbosch[3], Jaap Harlaar[3]

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

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Abstract

It was hypothesized that rheumatoid arthritis (RA) patients with a mobile-bearing (MB) total knee prosthesis will have more co-contraction to stabilize the knee joint during a step-up task than patients with a fixed-bearing total knee prosthesis (FB) where this rotational freedom is absent while having the same articular geometry.

Surface EMG, kinematics and kinetics about the knee were recorded during a step-up task of a MB group ($n = 5$), a FB group ($n = 4$) and a control group ($n = 8$). EMG levels of thigh muscles were calibrated to either knee flexion or extension moments by means of isokinetic contractions on a dynamometer. During the step-up task co-contraction indices were determined from an EMG-force model.

Controls showed a higher active range of motion during the step-up task than the patient group, 96° versus 88° ($p = 0.007$). In the control group higher average muscle extension, flexion and net moments during single limb support phase were observed than in the patient group. During the $20 - 60\%$ interval of the single limb support, MB patients showed a significant higher level of flexor activity, resulting in a lower net joint moment. Compared to the control group patients showed a 40% higher level of co-contraction during this interval ($p = 0.009$). Control subjects used higher extension moments, resulting in a higher net joint moment. Visual analysis revealed a timing difference between the MB and FB group. The FB group seems to co-contract approximately 20% later compared to the MB group.

RA patients after total knee arthroplasty show a lower net knee joint moment and higher co-contraction than controls indicating avoidance of net joint load and an active stabilization of the knee joint. MB and FB patients showed no difference in co-contraction levels, although coordination in FB is closer to controls. Visual analysis revealed a timing difference between the MB and FB group. This may express compensation by coordination. Rehabilitation programs should include besides muscle strength training, elements of muscle-coordination training.

3.1 Introduction

The aim of total knee replacement is relief of pain and functional improvement. The two most common implanted total knee designs are the fixed-bearing (FB) posterior-stabilized (PS) total knee and the mobile-bearing (MB) total knee prosthesis. The fixed-bearing PS total knee prosthesis was designed to provide passive stability for the knee joint (Aglietti et al., 1999; Li et al., 1999; Stern and Insall, 1992). The post and cam interaction stabilizes the joint in medial-lateral direction and facilitate femoral rollback when the knee is flexed. MB total knee prostheses have polyethylene inserts that can rotate and/or translate with respect to the tibial plateau. Therefore, a MB total knee has less internal stability and depends more upon preserved ligaments and active structures to provide stability of the knee joint compared to a FB total knee design. It has been shown that joint instability can lead to high levels of muscle co-contraction of agonist and antagonist muscle groups surrounding the knee (Alkjaer et al., 2003).

Many clinical, biomechanical and modelling studies support the hypothesis about higher levels of co-contraction of the quadriceps and hamstrings during dynamic tasks to provide an active stabilization of the knee to compensate for the loss of passive structures e.g. the cruciate ligaments after total knee arthroplasty (Baratta et al., 1988; Boerboom et al., 2001; Bulgheroni et al., 1997; Imran and O'Connor, 1998; Kellis, 1998; O'Connor, 1993; Pandy and Shelburne, 1998; Roberts et al., 1999; Shelburne and Pandy, 1998). The use of surface EMG is an independent technique to assess co-contraction, but is hindered by the complex relation between muscle force and EMG. However, EMG-to-force processing can be applied in dynamic tasks, such as a step-up, when combining an EMG-to-activation model with a (physiologic) muscle model of muscle kinematics (Hof et al., 1987). It has also been shown that sub maximal contractions can be used to calibrate EMG to force (Doorenbosch et al., 2005), which makes this technique applicable to patients after total knee arthroplasty (Garling et al., 2005c).

In this study, it was hypothesized that subjects with a total knee prosthesis that allows axial rotation of the bearing will show more co-contraction to stabilize the knee joint during a step-up task than subjects with a FB total knee prosthesis where this rotational freedom is absent while having the same articular geometry.

3.2 Methods

3.2.1 Subjects

The power calculation for the number of subjects in this study is based on the study of Doorenbosch and Harlaar (2003). In that study, five controls were compared with five anterior cruciate ligament deficient subjects and they found a significant difference in co-contraction index (CCI) between the two groups. The mean CCI for patients was 0.54 (σ 0.04) versus a CCI of 0.25 (σ 0.07) for the controls. Based on this information, a sample size of nine patients versus eight controls would be sufficient to detect a difference of 0.05 between controls and patients. Unfortunately, no literature is available about differences in CCI between two prosthesis groups. Therefore in this study, nine patients suffering from rheumatoid arthritis (RA) were included in our specialized rheumatoid arthritis clinic approximately six months after total knee arthroplasty. The institutional medical-ethical committee approved the study and all subjects gave informed consent. In five patients, a MB NexGen Legacy Posterior stabilized (MB group) prosthesis was implanted and in four patients a FB NexGen Legacy Posterior stabilized (FB group) (Zimmer Inc. Warsaw, USA). As a control group, eight healthy persons were selected who had no functional impairment of any lower extremity joint. For the control group, the data of the non-preferred leg was acquired. The 'non-preferred' leg for the controls was chosen for comparability, assuming that patients with a total knee prosthesis preferred the non-operated leg.

The tibial articular surfaces of the MB group are made of net-shape moulded UHMW polyethylene. The tibial bearing component is snapped onto an anterior-centrally located trunnion at the polished cobalt chromium base plate, which prevents tilting and determines the centre of rotation of the bearing. The slot in the plastic

Table 3.1: Subjects data (median and range) and kinetic parameters for the MB knee group ($n = 5$), FB group ($n = 4$), the combined patient group ($n = 9$) and control group ($n = 8$) during the single limb support phase and $20-60\%$ interval of the single limb support phase (ns=not significant).

	MB	p	FB	Patients	p	Controls
Age (years)	64 46 - 74	ns	67 60 - 81	66 46 - 81	0.002	30 19 - 54
BMI (kg/m^2)	30 21 - 34	ns	28 22 - 32	29 21 - 34	ns	23 20 - 32
Sex (F/M)	4/1	ns	1/2	5/3	ns	4/4
Side (L/R)	2/3	ns	3/0	5/3	ns	1/7
Duration (sec)	2 1.8 - 2.4	ns	2 2.1 - 2.4	2 1.8 - 2.4	ns	2 1.9 - 2.5
ROM (°)	87 64 - 92	ns	90 84 - 95	88 64 - 95	0.007	96 89 - 106
Single Limb						
CCI	0.6 0.4 - 0.7	ns	0.6 0.5 - 0.7	0.6 0.4 - 0.7	ns	0.5 0.3 - 0.7
Mext (Nm)	17 12 - 20	ns	18 17 - 20	17 12 - 20	0.003	25 17 - 61
Mflex (Nm)	-28 -30 - -27	ns	-18 -43 - -16	-28 -43 - -16	0.012	-17 -25 - -6
Mnet (Nm)	-12 -15 - -8	ns	0 -26 - 4	-12 -26 - 4	0.005	9 -1 - 54
20-60% Single Limb						
CCI	0.7 0.6 - 0.8	ns	0.7 0.7 - 0.8	0.7 0.6 - 0.8	0.009	0.5 0.2 - 0.8
Mext (Nm)	24 22 - 31	ns	28 28 - 30	28 22 - 31	0.001	44 32 - 105
Mflex (Nm)	-32 -43 - -27	0.025	-21 -24 - -14	-28 -43 - -14	ns	-15 -36 - -6
Mnet (Nm)	-10 -18.2 - 4	0.049	7 4 - 17	-1.4 -18.2 - 17	0.005	27 3 - 98

allows for 25° of internal-external rotation of the mobile-bearing, limited by an anterior bar. In the FB group, this rotational freedom of the tibial bearing is absent. For both prosthesis groups, the cam of the femoral component engages the tibial spine at approximately 75° 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° varus-valgus malalignment. In addition to the cam-spine mechanism, the femoral component has a large distal radius and smaller posterior radius to help facilitate femoral rollback on the tibia during lower flexion angles. Inclusion criteria for the prosthesis groups for the study were the ability to perform a step-up without the help of bars or a cane, the ability to walk more than 1 km, not use walking aids, symptom less with no apparent functional impairment of 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). Furthermore, they had to have a unilateral total knee replacement. Prior to the experiment anthropometric data was assessed for all three groups (Table 3.1).

3.2.2 Experimental protocol

The subjects performed the step-up task barefoot, in a controlled manner with a self-selected, comfortable speed. The motion had to be linear and smooth. At the beginning of the step-up, the patient was asked to stand, feet together, at a distance of 5 cm in front of the 18-cm-high platform, and step onto the platform using the limb with the implant under investigation. After a brief orientation session, the patient performed at least three step-ups with a maximum of five, with a rest period of two minutes between trials. In all cases an assistant was near the patient during the measurements for safety reasons. During the step-up task knee kinematics, EMG of thigh muscles and ground reaction forces were measured.

3.2.3 Calibration of the EMG force processing

Prior to the step-up task, the EMG levels were calibrated towards mechanical units. All subjects were instructed to exert maximal isokinetic knee flexion and extension contractions with their leg on an isokinetic dynamometer (Kin-Com 500 H, Chattex Corp., Chattanooga, TE, USA). During the experiments, subjects were seated with their hips flexed at maximal flexion. The trunk and upper leg of the subject were rigidly fixated to the chair. A part of the seat was especially designed with a hole, to keep the electrodes at the dorsal side of the thigh free and prevent contact artefacts. The projection of the knee axis of flexion and extension at the lateral condyle was aligned with the rotation axis of the dynamometer. The rotatable arm of the dynamometer was fixed to the tibia at a distal position. The dynamometer angle offset was set to reflect on an anatomical knee angle, defined by the line of lateral malleolus, knee axis and greater trochanter. For the calibration, concentric isokinetic flexion and extension contractions were performed at three different velocities (30°, 60°, $90^\circ\,s^{-1}$). Contractions were randomly ordered and rest pauses of two min were between each of them. The exerted moment, processed EMG signals, range of motion and angular velocity were recorded (100 Hz) during each isokinetic flexion and extension movement of the knee.

3.2.4 Electromyography

Surface EMG electrodes (Meditrace Ag-AgCl; lead-off area 1 cm^2; centre-to-centre distance 2.5 cm) were used to record the activation of five thigh muscles. EMG of the following muscles were recorded: M. Rectus Femoris; M. Vastus Lateralis; M. Vastus Medialis; M. Semitendinosus; M. Biceps Femoris c. Longum. The electrodes were placed longitudinally over the muscle bellies after standard preparation of the skin (Doorenbosch and Harlaar, 2004). A reference-electrode was placed on a bony part of the shank. Surface EMG was recorded by a bipolar lead-off and online removal of artefacts by high pass filtering at 20 Hz. Simultaneously, the EMG signals were shown on screen for on line visual inspection to check for undesirable co-activation during the calibration contractions. Offline, the EMG signals were rectified and low pass filtered at 2 Hz to obtain the EMG envelopes.

3.2.5 Kinematics and kinetics

During the step-up task, the vertical and horizontal components of the ground reaction forces and moments during the step-up were recorded by means of a force plate (AMTI, Boston, MA, USA) and sampled at 1000 Hz. From these signals, the magnitude, direction and point of application of the force vector were calculated. Simultaneously, the 3D kinematics was assessed with an optoelectronic motion analysis system (Optotrak: Northern Digital inc., Canada) at a frame rate of 100 frames/second. A three segment-model was used including the upper leg, lower leg and foot. To define local coordinate systems of the lower leg and the upper leg, a triangle at each segment containing three light-emitting diodes (LED's) was attached with straps. The third triangle defining the foot segment was attached with tape on the instep of the foot. With a stylus anatomical landmarks were defined relatively to the local coordinate system of the triangle into an anatomical coordinate system: trochanter major, lateral femur condyle, medial femur condyle, tuberositas, caput fibulae, lateral malleolus, medial malleolus, lateral side of the foot on the fifth metatarsal, medial side of the foot on the first metatarsal and the calcaneus. Kinematics in the sagittal plane were also obtained with a video camera operating at 25 frames/second for visual inspection of undesirable postural compensation strategies.

3.2.6 Data analysis

The start of the movement cycle (0%) was defined as the first change in position (knee angle $> 5°$). The end of the movement cycle (100%) was defined when the change in knee angle was zero. The co-contraction index (CCI) was determined during the single limb support phase. The single limb support phase starts on the first moment of weight loading on the platform. This phase ends at the last moment of single limb support on the top of the platform determined by the onset of the ground reaction force moving back to the centre of the platform. Also the $20-60\%$ interval of this phase was analyzed separately. An EMG-force model was used to calculate muscle moments and the CCI. This model has been thoroughly validated (Doorenbosch and Harlaar, 2003, 2004; Doorenbosch et al., 2005). In general, the isokinetic measurements are used to include length and velocity influences on the EMG to force relation, to obtain estimated moments of agonists and antagonist muscles (Magonist, Mantagonist) separately. To quantify the amount of co-contraction or active stabilization, Magonist and Mantagonist were used in defining the CCI according to

$$CCI = 1 - \left\{ \frac{[(Magonist) - (Mantagonist)]}{[(Magonist) + (Mantagonist)]} \right\} \tag{3.1}$$

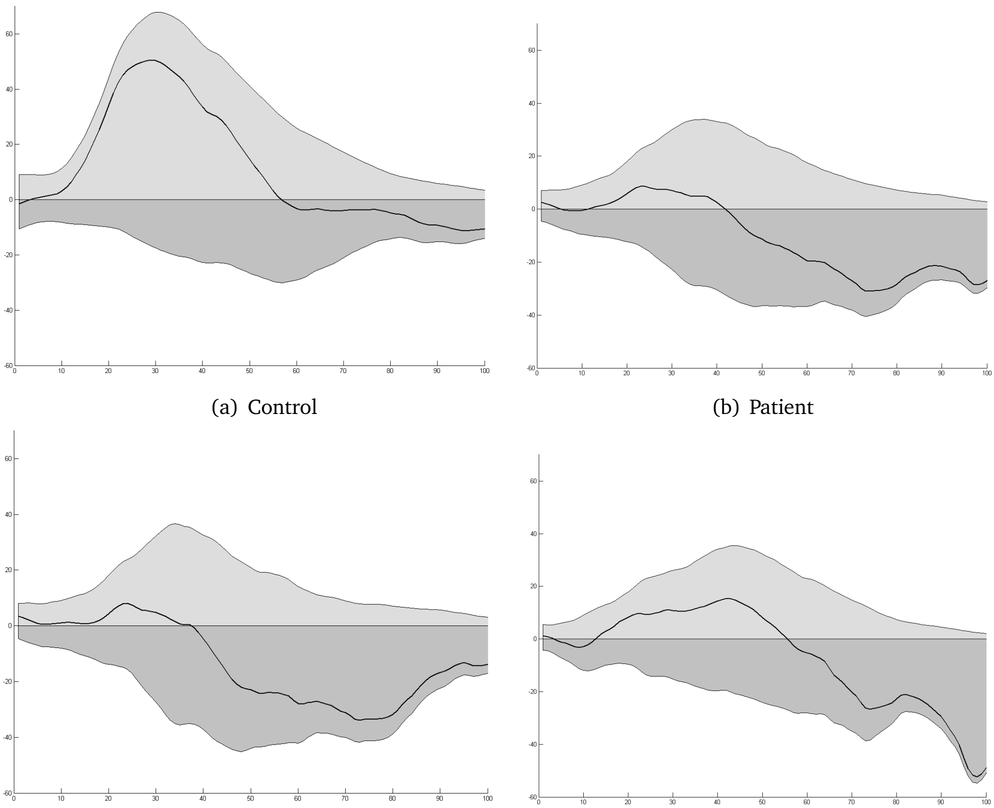
The CCI ranges between 0 and 1. CCI values close to 1 indicate a high level of co-contraction of agonists and antagonists and a CCI value of 0 indicates a pure reciprocal activation. For each individual subject, the CCI was calculated as the mean value of the muscle moments during the single limb support phase of the step-up task.

3.2.7 Statistical analysis

A non-parametric Mann-Whitney U test and Spearman's ρ were performed. Significance was accepted at an alpha level of $p < 0.05$. All statistical computations are performed with a commercial statistical package (SPSS, SPSS Inc, USA).

3.3 Results

The most important variables and p-values are listed in Table 3.1. Mean time after operation was 9.6 months (σ 3.5, range $5-17$ months). The questionnaire showed that 38% of the patients declare their operated leg as their leg of preference. The duration of the step-up task was comparable for all groups. In addition, the



(a) Control (b) Patient

(c) MB (d) FB

Figure 3.1: Knee moments (y-axis; Nm) for all four groups during the entire single limb support phase (x-axis; %Single limb support). Mflexion (dark grey), Mextension (light grey) and Mnet (line).

phases defined during the step-up: foot-lift, foot-placement, double-stance and single limb support were similar between groups. Controls showed a higher active range of motion during the step-up task then the patient group ($p = 0.007$). In the control group higher average muscle extension, resulting in higher net moments, and higher flexion moments during single limb support phase was observed (Figure 3.1). Since the control group used higher extension moments, this resulted in a higher net joint moment. No differences between the MB and FB group were observed.

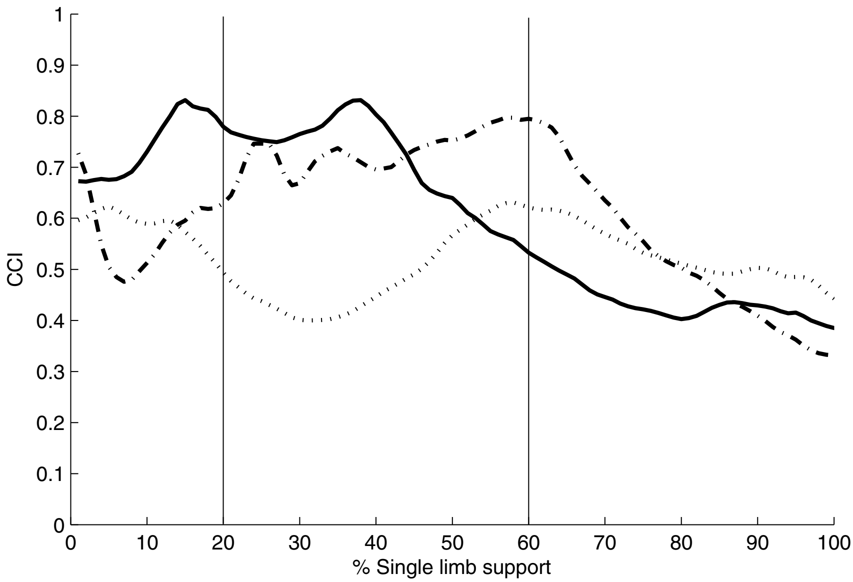


Figure 3.2: CCI values for the MB group (line), the FB group (dash-dotted) and the control group (dotted) during the single limb support phase. The $20-60\%$ interval is also indicated.

The differences between the FB and control group for the variables muscle flexion moments, extension moments and net knee joint moments were smaller than between the MB group and controls. In the interval from twenty to sixty percent $(20-60\%)$ of the single limb support, all individual subjects showed the peak muscle extension moment. In this interval there was a significant difference between the MB and FB group in the knee flexion moment and the net knee moments (respectively $p = 0.025$ and $p = 0.049$). The MB patients showed a significant higher level of flexor activity, resulting in a lower net joint moment. However, co-contraction levels were not different. A significant difference was found for co-contraction between the patient and the control group (average CCI was respectively 0.7 and 0.5, $p = 0.009$). Visual analysis revealed a timing difference between the MB and FB group. The FB group seems to co-contract approximately 20% later (first and second peak of the CCI) in the single limb support phase compared to the MB group (Figure 3.2).

3.4 Discussion

In this study an EMG-force model has been used to answer the question about if there are differences in co-contraction between RA patients with MB or FB total knee prostheses. Although coordination in FB patients is closer to controls than MB subjects, the latter could not be confirmed during the step-up task. This might be caused by the small patient groups. However, there was a significant difference in co-contraction between the patient group and the control group. To increase power of studies using an EMG-to-activation model in patients after total knee arthroplasty, larger patient groups are recommended. Also, a MB design that allows besides rotation, also anterior-posterior translation, might show more distinctive differences between the two designs. In a previous study, maximal voluntary contraction was used to calibrate the EMG signals (Garling et al., 2005c). Avoidance for pain and higher activation levels forced during daily activity tasks than subjects are willing to give during isolated contractions lead to an improper maximal activation of isolated muscles. The new method used in the current study using an EMG-force model calibrated with sub-maximal contractions showed to be suitable for patients after total knee arthroplasty (Doorenbosch and Harlaar, 2004; Doorenbosch et al., 2005). Although this method has proven to have a high discriminating power (Doorenbosch and Harlaar, 2003), differences between the two prostheses could not be observed during the step-up task.

In the study of Garling et al. (2005c) it was shown that subjects with a MB design show higher EMG levels compared to subjects with a PS fixed-bearing design. However, no difference in co-contraction was observed between the two groups. One of the differences between that study and the current study is the use of a MB design with more degrees of freedom of the inlay. The MB knee design in the previous study permits both anterior-posterior sliding as rotation of the inlay on the tibial tray. It can be expected that a MB that allows also anterior-posterior sliding of the inlay result in more co-contraction than the MB used in the current study that only allows axial rotation of the inlay. Tibiofemoral translations affect the quadriceps moment arm by changing the instantaneous centre of rotation. Femoral rollback with flexion will increase the moment arm of the quadriceps. When an intrinsic anterior-posterior constraint is absent, the hamstrings can be recruited as secondary anterior-posterior stabilizers. Consequently, co-contraction will be increased. Another explanation for the same amount of co-contraction between the two designs found in this study is the actual mobility of the mobile-bearing inlay. It has been shown that the amount of axial rotation of the MB design used in the current study is very limited or even absent (Garling et al., 2007b). The kinematics of the inlay and consequently the tibiofemoral kinematics can be compared to a fixed-bearing total knee design with the same articular geometry were no motion of the bearing occurs.

The FB group showed a peak co-contraction approximately 20% later during the stance phase than the MB group. In preparation for foot contact with the ground, an early hamstring activity stabilizes the knee (Lass et al., 1991). The hamstrings pull the tibia into a position so that the knee joint is stable during extension. The patient group showed also a lower net knee joint moment and a higher co-contraction than controls indicating avoidance of net joint load and an active stabilization of the knee joint. In another study comparing a MB and a fixed-bearing total knee prosthesis design during stair ascending, a decrease in the frontal external knee moments in the MB group was observed suggesting a compensatory loading mechanism (Catani et al., 2003).

An abnormal negative net knee moment was found in the whole single limb support phase in the MB group and FB group. In the $20-60\%$ interval, only the MB group has a negative net knee moment. The large muscle flexion moments are an explanation for this negative net knee moments. This would imply that flexion is accomplished while extension is actually performed. During analysis of the videotape made during step-up, it appeared that patients did not use another step-up strategy than the controls. However, even a slight forward lean (e.g. 3 cm) of the patients' trunk would already explain this change in net joint moment. The same patterns for the net knee moment were found in other studies (Andriacchi et al., 1982; Benedetti et al., 2003; Catani et al., 2003). Another possibility of the large flexion moments is a neglect of the bi-articular nature of the hamstrings in our model. The force-length relationship of the muscles during measurements with the dynamometer assumes hip flexion. Hip extension during step-up could influence the length dependence of the EMG to force model considerably.

Patellofemoral geometry has a significant effect on knee kinematics. Especially the quadriceps moments in the joint are dependent of the orientation of the prosthesis relative to the patella (Andriacchi et al., 1997; Andriacchi and Hurwitz, 1997). Andriacchi et al. (1997) evaluated two different groups of patients during stair climbing that only differed in the curvature of the femoral trochlea. The group with a design that had non-anatomical tracking of the patella had a higher than normal flexion moment of the knee during late stance phase. In the current study the patellofemoral kinematics are not explored but the results show resembling high flexion moments when extension is expected for the patients, without significant differences between the MB and the FB group.

Patients with rheumatoid arthritis have used medication for years, which has effect on bone strength and the function of soft tissue surrounding the prosthesis. Although the other joints of the patients were symptom less and showed no functional impairment it cannot be guaranteed that the kinematics where not influenced. Abnormal kinematics and eventual dysfunction of the prosthesis might be a result of the decreased bone and tissue quality (Chmell and Scott, 1999). Even in the most clinically successful cases of non-RA patients treated by total knee replacement cannot achieve normal joint function over time. In most cases gait remains slower than normal, muscle strength is decreased, less work is produced, the treated knee has limited range of motion both during stance and the swing phase and muscle moments are changed (Benedetti et al., 2003; Byrne et al., 2002; Kaufman et al., 2001). Although other studies show comparable results with the current study regarding a decreased active range of motion during step-up for the RA patients of about $10\% - 15\%$, without differences in duration of the step-up (Andriacchi et al., 1982; Catani et al., 2003; Costigan et al., 2002), co-contraction can be added to changes in joint function of after total knee arthroplasty based on the findings of this study. Continuing follow-up of the patients after total knee arthroplasty should clarify whether the active stabilization of the knee joint is a lasting adaptation or changes over time. Staircase data provides an approximation to other activities involving a flexed knee position under high load, such as sitting and rising from a chair or bed and using a toilet. Knee flexion and exerted moments are higher in activities like sitting and rising from a chair. Further research should therefore focus at other activities as well to describe possible functional differences between MB and FB total knee prostheses.

Conclusion

Rheumatoid arthritis patients after total knee arthroplasty show lower net knee joint moment and higher co-contraction than controls indicating avoidance of net joint load and an active stabilization of the knee joint. The mobile-bearing and fixed-bearing groups show no difference in co-contraction levels, although coordination in patients with a fixed-bearing is closer to controls than patients with a mobile-bearing. Timing differences between the mobile-bearing and fixed-bearing group, may express compensation by coordination. Rehabilitation programs for rheumatoid arthritis patients should include besides muscle strength training, elements of muscle-coordination training.

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

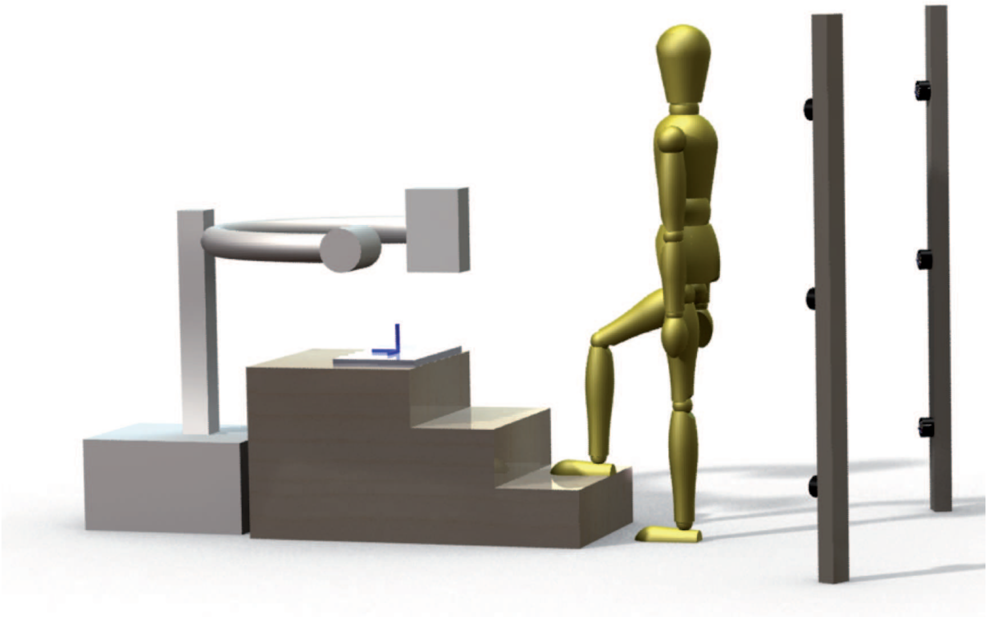


Figure 4.1: Experimental set-up including stairs, force plate, two external motion registration cameras and the image intensifier and X-ray source of the fluoroscope.

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).

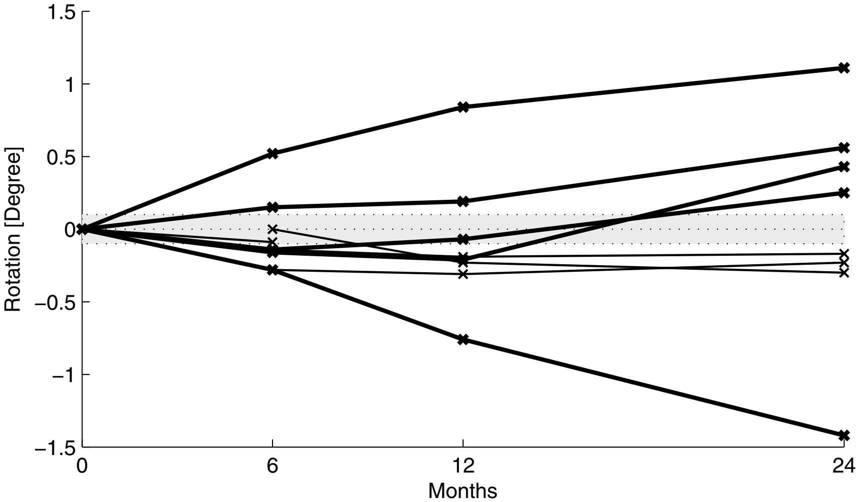


Figure 4.3: Rotation (°) around the z-axis (varus-valgus tilt) measured with RSA for the individual patients 6, 12 and 24 months post-operatively. Precision for varus-valgus tilt is 0.1° (grey area is 95% confidence interval). In this direction, five patients (thick lines) showed continuous migration.

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).

	Axial rotation (°)				**AP translation (mm)**			
Range	**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.

Chapter 5

Insert mobility in a high congruent mobile-bearing total knee prosthesis

Nienke Wolterbeek[1], Eric H. Garling[1], Bart J.A. Mertens[2], Henrica M.J. van der Linden[1], Rob G.H.H. Nelissen[1], Edward R. Valstar[1,3]

[1]*Department of Orthopaedics, Leiden University Medical Center*

[2]*Department of Medical Statistics and Bioinformatics, Leiden University Medical Center*

[3]*Department of Biomechanical Engineering, Delft University of Technology*

Submitted.

Abstract

Limited or absent axial rotation of the mobile insert of total knee prostheses could lead to high contact stresses and stresses at the bone-implant interface, which in turn might lead to implant loosening. It is hypothesized that there will be adequate axial rotation of the insert in a highly congruent mobile-bearing total knee prosthesis and that the insert remains mobile in the course of time. Therefore, the aim of this study was to assess knee kinematics and muscle activation and their possible change over time in patients with a highly congruent, mobile-bearing total knee prosthesis.

A prospective series of 11 rheumatoid arthritis patients was included to participate in this fluoroscopic and EMG study. Kinematic evaluations took place 7 months, 1 and 2 years post-operatively.

Knee kinematics and muscle activation did not change in the first 2 post-operative years. The insert remained mobile and followed the femoral component from 0° until approximately 60° of knee flexion. Diverging and reversed axial rotations and translations were seen during the dynamic motions.

Reversed and divergent axial rotations with increasing knee 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. At lower knee flexion angles, the femoral component is obstructed by the highly congruent insert and is not able to move freely. This leads to high stresses at the insert which will be transferred to the bone-implant interface.

5.1 Introduction

High congruency between the insert and the femoral component in combination with free rotation of the insert in mobile-bearing total knee prostheses (TKP) is assumed to benefit the longevity of the implant. This combination results in an increased contact area, lower contact stresses and reduced wear compared to non-congruent fixed inserts (Buechel, 2004; Dennis et al., 2005; Matsuda et al., 1998; Stiehl et al., 1997; Uvehammer et al., 2007). Furthermore, the unrestricted movement of the insert prevents transfer of the forces generated at the insert to the bone-implant interface. This is assumed to improve the fixation of the prosthesis and to decrease the risk for loosening (Garling et al., 2005b; Henricson et al., 2006; Huang et al., 2007).

Only a few studies have evaluated the *in vivo* three-dimensional (3D) motion of the insert during activities of daily life (Fantozzi et al., 2004; Garling et al., 2007b; Wolterbeek et al., 2009). In those studies, insert rotation was limited or absent which means that the insert remained in the same position on top of the tibial component during knee motion and was not forced by the femoral component to rotate.

When the mobility of the insert is limited or absent, force transmission to the polyethylene and fixation interface increases because of increased congruency of the insert typically present in mobile-bearing total knee prostheses (Dennis et al., 2005). If the congruency of the insert is not increased compared to fixed-bearing knees, absence or reduced rotation of the insert makes the implants very similar to fixed-bearing prostheses and clinical results are expected to be comparable.

The lack of insert motion in those previous studies can be explained by the relative low congruency of the implants used. It is hypothesized that there will be adequate axial rotation of the insert in a highly congruent mobile-bearing TKP and that the insert remains mobile in the course of time. Therefore, the aim of this study is to assess the knee kinematics and muscle activation and their possible change over time in patients with a highly congruent, mobile-bearing total knee prosthesis.

Table 5.1: Patient characteristics pre-operatively and for follow-up 1 (FU1), follow-up 2 (FU2) and follow-up 3 (FU3) are presented (mean and range).

	Follow-up (months)	Number of patients	Gender	Age (years)	BMI	Knee Score	Function Score
Pre-op	0	11	4 male 7 female	64 (45-86)	29.2 (22.1-36.3)	45 (25-55)	53 (10-80)
FU1	7 (5-9)	9	4 male 5 female	62 (45-79)	29.6 (22.5-35.3)	81 (47-94)	68 (30-90)
FU2	13 (11-16)	7	3 male 4 female	63 (55-79)	28.5 (22.5-36.7)	87 (62-100)	79 (60-90)
FU3	25 (24-26)	7	3 male 4 female	63 (55-79)	28.9 (22.5-38.6)	86 (62-92)	79 (40-100)

5.2 Methods

A prospective series of 11 rheumatoid arthritis patients (4 male, 7 female; mean age 64 years) was included to participate in this study (Table 5.1). Inclusion criteria were the ability to perform a step-up motion without the help of bars and the ability to walk more than 1 km. Pain during activity was an exclusion criterion. All patients gave informed consent and the study was approved by the local medical ethics committee. The study was registered at ClinicalTrials.gov (*NCT*01102829). Patients' reported functional ability (knee score and function score) were quantified pre- and post-operatively using the Knee Society Score (KSS) (Ewald, 1989). One year post-operatively long-leg X-rays were acquired to determine leg alignment. Sagittal and anterior-posterior weight bearing X-rays were taken 6, 12 and 24 months post-operatively and were used to assess radiolucent lines along the components.

In all patients, a ROCC® (ROtating Concave Convex) mobile-bearing prosthesis (Biomet, Europe BV, The Netherlands) was implanted (Figure 5.1). The insert has a centrally located trunnion and allows for pure rotation on the tibial component. The design has a high congruency between the insert and femoral component between 0° and 70° of flexion. Anterior-posterior sliding displacement is limited. The tibial component has a finned stem for enhanced rotational stability. CT-free computer navigation was used during surgery (BrainLAB AG, Germany). All components

Figure 5.1: The ROCC knee (Biomet, Europe BV, The Netherlands). A high congruent, mobile bearing total knee prosthesis.

were fixed using cement (Palacos R cement, Heraeus Medical GmbH, Germany) and the patellae were not resurfaced. The tibial-articular surfaces are made of compression moulded UHMW polyethylene. During surgery four 1 mm tantalum markers were inserted in predefined non-weight bearing areas of the insert to model the polyethylene in the fluoroscopic images (Garling et al., 2005a).

After surgery, two patients were lost to follow-up. One patient dropped out because of severe spinal complaints and one because of general health reasons. After the first fluoroscopic evaluation (FU1; mean 7 months post-operatively, range: $5 - 9$), two more patients were lost to follow-up. One dropped out because of personal reasons and the other patient was dissatisfied and underwent revision in another hospital despite having normal clinical indicators. Seven patients participated in the second (FU2; mean 13 months post-operatively, range: $11 - 16$) and third (FU3; mean 25 months post-operatively, range: $24 - 26$) fluoroscopic evaluation (Table 5.1).

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

5.2.1 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 (super digital fluorography system, Toshiba Infinix, Toshiba, Zoetermeer, The Netherlands) (15 frames/sec, resolution 1024×1024, field of view 40 cm high by 30 cm wide, pulse width 1 msec). Fluoroscopic images were processed using a commercially available software package (Model-based RSA, Medis specials b.v., The Netherlands). Reverse engineered 3D models of the components were used to assess the position and orientation of the components in the fluoroscopic images (Kaptein et al., 2003). Roentgen stereophotogrammetric analysis (RSA) was used to create accurate 3D models of the markers of the inserts to assess position and orientation of the insert in the fluoroscopic images (Garling et al., 2005a). Both techniques showed to have an axial rotation accuracy of 0.3° (Garling et al., 2005a). The global coordinate system was defined with the local coordinate system of the tibial component. At maximal extension, the axial rotation was defined to be zero. The minimal distance between the femoral condyles and the tibial base plate was calculated independently for the medial and lateral condyle. The lowest points of each frame were projected on the tibial plane to show the anterior-posterior motion and the pivot point of rotation of the femoral component with respect to the tibial component.

5.2.2 Electromyography

To determine muscle activation patterns and coactivation, bipolar surface electromyography (EMG) (Delsys, Boston, USA) data of the flexor and extensor muscles around the knee was collected (2500 Hz). The extensor muscles recorded were the M. Rectus Femoris, M. Vastus Lateralis and M. Vastus Medialis. The flexor muscles recorded were the M. Biceps Femoris, M. Semitendinosus and M. Gastrocnemius Medialis. Electrodes were placed according to the recommendations of the Seniam project (www.seniam.org). The EMG data was filtered using a high-pass Butterworth filter, then rectified and smoothed using a low-pass filter. The signals were normalised to their own maximal values. All data was processed using Matlab (The MathWorks, Inc., Natick, USA). Measurements were temporal synchronized using a custom made box with X-ray sensitive photocells.

5.2.3 Statistical analysis

A two-tailed Student's t-test was used to compare the knee flexion ranges and anterior-posterior translation ranges between follow-ups. A linear mixed-effects model for longitudinal data was used to compare the differences between the axial rotation of the femoral component and the insert over the follow-ups. The model assumed a linear trend of axial rotation versus knee flexion angle within each follow-up. A patient random effect as well as a trial-within-patient nested random effect was incorporated in the model for both the intercept and slope coefficients of the linear trend. The first random effect was included to account for between-patient heterogeneity in observed differences, while the latter effect was included to take into account differences in the number of analysable trials per patient between follow-ups. It is a key characteristic of the model that differences in range of motion between trials are taken into account with respect to the fitting of the population linear effect within each follow-up. The model was fit using a fully Bayesian formulation via Markov chain Monte Carlo within the package WinBUGS (Lunn et al., 2000). Model-based residuals were investigated to detect potential mismatch between the observed data and the assumed model, which could adversely affect conclusions. Based on the model, the fitted mean population linear trends were calculated for the rotation of the insert, the femoral component and the difference between them versus knee flexion angle, together with standard errors for each follow-up.

5.3 Results

The mean KSS knee score increased from 45 points pre-operatively to 81 points 7 months post-operatively. There is a small increase between 7 and 13 months post-operatively to 87 points, and the improvement maintained 2 years post-operatively. The mean KSS function score increased from 53 points pre-operatively to 68 points 7 months post-operatively and 79 points 1 and 2 years post-operatively (Table 5.1). The pre-operative and 7 months post-operative scores include the patients who were lost to follow-up. There was no difference in scores when those patients were excluded from analysis. None of the patients had a flexion contracture or an extension lag. No clinical relevant deviations were observed in the post-operative alignment of the components (all between $175^\circ - 180^\circ$). Also no radiolucent lines along the components were seen 2 years post-operatively.

5.3.1 Fluoroscopy

There are no significant changes in axial rotations between follow-up moments for the femoral component as well as the mobile insert (Figure 5.2 and 5.3). During the step-up motion, all patients showed merely external rotation of the tibial component during knee extension. However, in three patients, reversed (paradoxical) internal rotation was seen at one of the follow-up moments at the start of the motion (knee flexion angle $> 40^\circ$). During the lunge motion, five patients showed internal rotation of the tibial component during knee flexion, while four patients had internal rotation at the start of the motion but showed paradoxical external rotation beyond 40° of knee flexion. There was a small variation in axial rotation patterns over the different follow-ups within patients. The variation was larger in the step-up motion compared to the lunge motion.

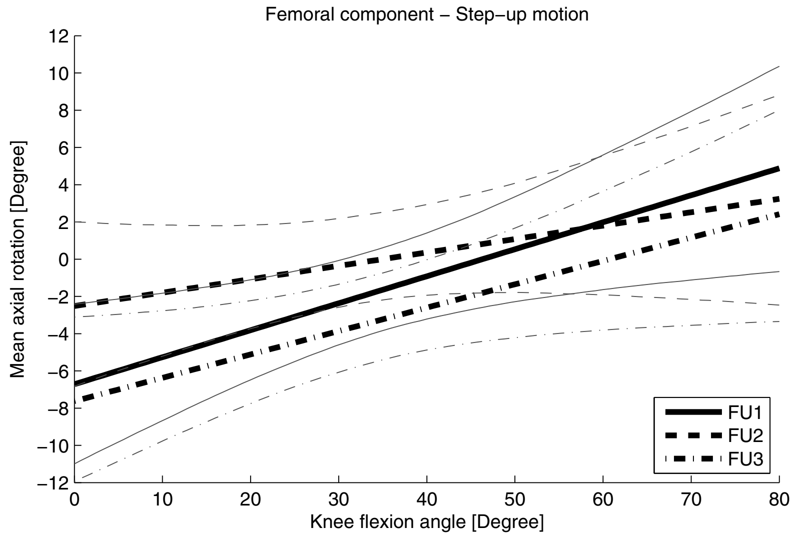
The insert follows the femoral component during motion until approximately 60° of knee flexion. Beyond 60° of knee flexion, diverging axial rotations were seen. In three knees, the diverging effect even started around 40° of knee flexion and the difference in axial rotation between insert and femoral component increased to more than 10°.

Deviant pivot points of axial rotation of the femoral component with respect to the tibial component were seen. One knee had a lateral pivot point during the lunge motion of the last follow-up and two knees had a medial pivot point of rotation, respectively, during the lunge motion of follow-up 1 and 3 and during the step-up motion of follow-up 2 and the lunge motion of follow-up 3.

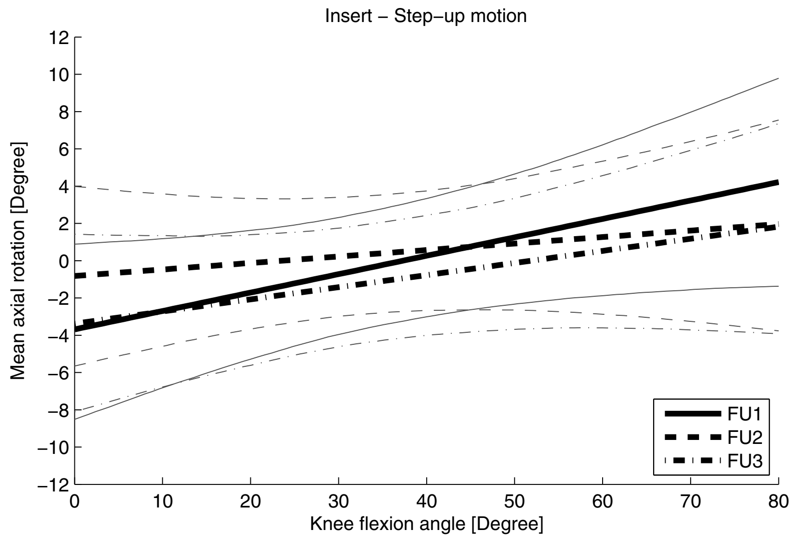
The mean range of knee flexion increased over time for the step-up motion as well as for the lunge motion (Table 5.2). For the step-up motion, the mean range of flexion was significant larger ($p = 0.000$) in FU2 (54.8°) and FU3 (59.0°) compared to FU1 (44.3°). For the lunge motion, the mean range of flexion was significant larger in FU3 (79.4°) compared to FU1 (56.9°) and FU2 (63.5°), respectively, $p = 0.000$ and $p = 0.010$. The range of anterior-posterior translation of the medial condyle was significant larger in FU3 compared to FU1 for the step-up ($p = 0.029$) and lunge motion ($p = 0.039$). The rest of the anterior-posterior translation ranges of the medial and lateral condyle were not significant different. Patterns of anterior-posterior translation are rather consistent within patients between trails and follow-ups but vary considerably between patients. The variation is larger in the step-up motion compared to the lunge motion. Also more reversed or paradoxical translations were seen in the step-up motion (respectively, 6 versus 2 knees) (Table 5.3).

5.3.2 Electromyography

EMG patterns within patients and within each follow-up were very consistent. However, they were less consistent among follow-ups as well as among patients. During the step-up motion, all patients showed the same extensor muscles (agonists) activity with a peak between 30° and 40° of knee flexion. The activity of the flexor muscles (antagonists) was variable showing continuous activity, an increase or a decrease in activity during extension. During the lunge motion, the extensor muscles (antagonists) were active in all patients and the activity levels decreased with increasing flexion angle (peak between 40° and 50° of knee flexion). The activity of

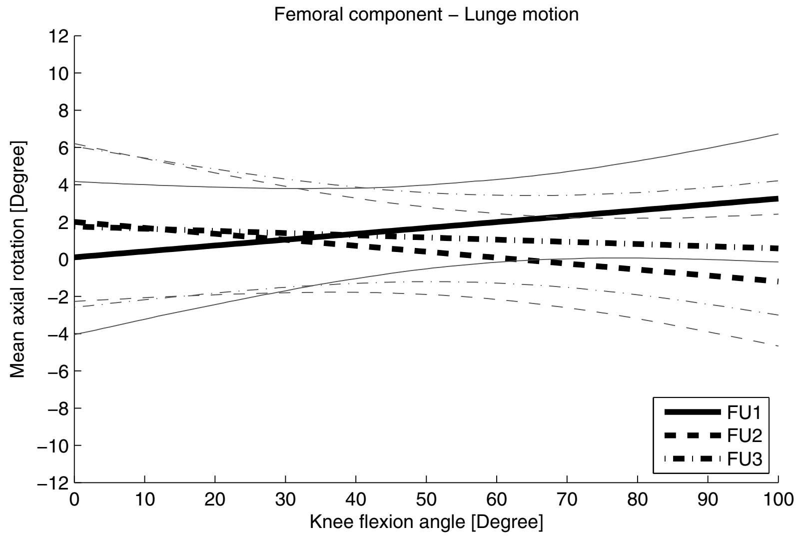


(a)

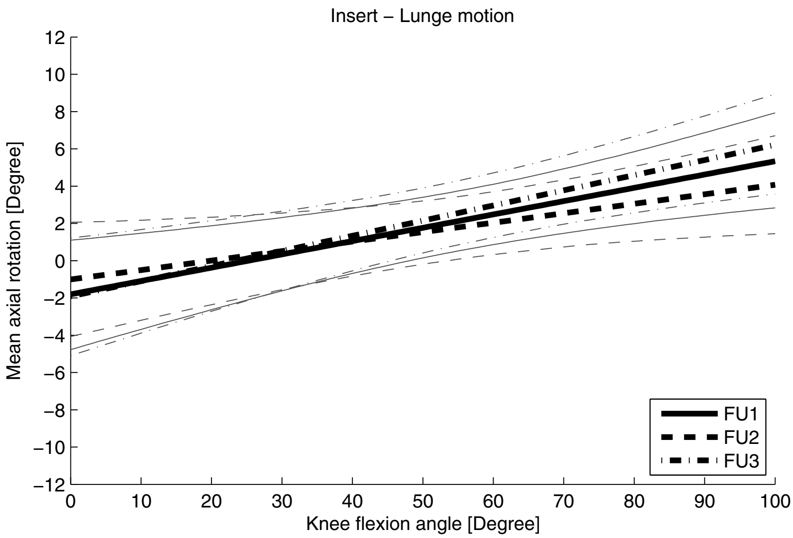


(b)

Figure 5.2: Calculated mean axial rotation and 95% confidence interval of the femoral component (a) and the inset (b) during the step-up motion for follow-up 1 (solid), follow-up 2 (dashed) and follow-up 3 (dotted).



(a)



(b)

Figure 5.3: Calculated mean axial rotation and 95% confidence interval of the femoral component (a) and the inset (b) during the lunge motion for follow-up 1 (solid), follow-up 2 (dashed) and follow-up 3 (dotted).

Table 5.2: Fluoroscopic results for follow-up 1 (FU1), follow-up 2 (FU2) and follow-up 3 (FU3). Mean and standard deviation (σ) of the knee flexion range (°), the axial rotation ranges (femoral component and insert (°) and anterior-posterior translation ranges (medial and lateral condyle (mm) are presented for the step-up (SU) and lunge motion.

	Knee flexion		**Axial rotation**				**AP translation**			
			Femoral comp.		**Insert**		**Med. cond.**		**Lat. cond.**	
	SU	**Lunge**	**SU**	**Lunge**	**SU**	**Lunge**	**SU**	**Lunge**	**SU**	**Lunge**
FU1	44.3	56.9	8.6	5.6	7.8	6.9	5.6	5.9	7.0	6.7
	(8.4)	(15.3)	(4.4)	(2.0)	(4.0)	(2.8)	(1.2)	(1.5)	(1.6)	(2.0)
FU2	54.8[1]	63.5	6.9	6.6	5.5	5.4	5.8	6.4	6.0	6.5
	(6.1)	(20.2)	(3.1)	(3.3)	(3.4)	(2.9)	(2.2)	(3.2)	(2.0)	(2.5)
FU3	59.0[1]	79.4[1,2]	10.4	9.7	7.5	7.8	6.9[3]	7.8[4]	7.0	7.8
	(10.3)	(14.0)	(5.5)	(2.8)	(4.1)	(3.4)	(2.5)	(3.9)	(2.1)	(2.0)

[1] Significant larger than in FU1 ($p = 0.000$)
[2] Significant larger than in FU2 ($p = 0.010$)
[3] Significant larger than in FU1 ($p = 0.029$)
[4] Significant larger than in FU1 ($p = 0.039$)

the flexor muscles (agonists) was either on a low level or similar to the activity of the extensor muscles including the decrease with increasing flexion angle. Performing a step-up or lunge motion, there was no clear change in muscle activity over time.

5.4 Discussion

The aim of this study was to assess knee kinematics and muscle activation in the first two post-operative years, in patients with a highly congruent, mobile-bearing total knee prosthesis. Fluoroscopic and EMG evaluations were performed three times using exactly the same measurement set-up, assuming no influence of extrinsic factors.

For the dynamic motions, there was no apparent change in muscle activity over time. This indicates that there is no change in dynamic stabilization of the knee by the muscles. The mean range of knee flexion increased significantly over time, for the step-up and lunge motion, indicating an improvement in the ability to move freely. This might be a result of reduced post-operative swelling and increased patient comfort and confidence in their artificial joint (Chouteau et al., 2009). This finding

Table 5.3: Paradoxical anterior-posterior (AP) translation and paradoxical axial rotation (AR) for follow-up 1 (FU1), follow-up 2 (FU2) and follow-up 3 (FU3) for the step-up and lunge motion. Also deviant pivot points and diverging axial rotation patterns are reported. No remark means that there were no deviant or paradoxical motions seen in that patient during that specific follow-up moment. Missing fluoroscopic data is indicated with an 'x'.

	Step-up			**Lunge**		
	FU1	**FU2**	**FU3**	**FU1**	**FU2**	**FU3**
1	AP	x	x	-	x	x
2	-	AP	AP	-	-	-
3	-	-	-	AR Diverging AR	AR Diverging AR	x
4	AP AR	x	x	-	x	x
5	-	-	-	-	-	-
6	AR	Medial pivot	-	-	-	Medial pivot
7	-	AP	AP	-	-	AP AR
8	-	AP	AP Diverging AR	AR	AP AR	Lateral pivot AR
9	-	AP AR	Diverging AR	Medial pivot AR	AR Diverging AR	Medial pivot AR

was also supported by the improved KSS knee scores and function scores.

Tibial and femoral component axial rotations and anterior-posterior translations did not change among follow-ups. Diverging axial rotation patterns were seen beyond 60° of knee flexion, confirming the high congruency of this prosthesis until approximately 60° of flexion. Beyond 60° of flexion the difference between the axial rotation of the insert and of the femoral component increases. These diverging patterns were less pronounced in the step-up motion, probably because of the smaller range of knee flexion. The comparable axial rotations of the insert and the femoral component between 0° and 60° of knee flexion indicates a reduction of multidirectional wear on the femoral aspect of the insert in this range of motion compared to less congruent designs (Buechel, 2004; Dennis et al., 2005; McEwen et al., 2001). The diverging axial rotations could explain the deviant pivot points of axial rotation found in this study. A central pivot point of axial rotation between the femoral and tibial component was expected because of the combination of the high congruency and the centrally located trunnion of the insert in this specific prosthesis. However, lateral or medial pivot points of axial rotation were seen in three knees. In two of these knees, the deviant pivot point coexists with reversed and diverging axial rotations. In the third knee, no other deviating patterns were seen. Another explanation for the deviant pivot points might be laxity of the surrounding ligaments. However, no manifest laxity was seen in these patients.

Several studies show that in non-conforming TKP the motion of the insert is limited (Fantozzi et al., 2004; Garling et al., 2007b; Wolterbeek et al., 2009). When the congruency between the femoral component and the insert is not high enough, translation of the femoral condyles on the insert is allowed and axial rotation of the insert will be limited or absent. In this study, the insert remains mobile, probably due to the high congruency in this specific prosthesis. Because of the high congruency, the mobile insert is forced by the femoral component to rotate. Fibrous tissue formation between the insert and the tibial component seems not to be an issue.

Another advantage of high congruency is that there will be more intrinsic stability of the knee joint compared to a knee with a flatter polyethylene insert (Blunn et al., 1997). A disadvantage, however, is that a high degree of congruency could lead to high contact stresses if the congruency is disrupted or when the axial rotation of the insert is limited. Furthermore, the high congruency could obstruct the motion of the femoral component on the insert. This would result in increased force transmission to the bone-implant interface (Blunn et al., 1997; Dennis et al., 2005; Hamai et al., 2008). High stresses might result in a large amount of early migration and therefore an increased risk for future component loosening. The obstruction of motion of the femoral component by the insert becomes apparent in this study. The reversed axial rotations beyond 40° of knee flexion and the divergent axial rotations beyond 60° of knee 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.

Several studies found, as in this study, reversed or paradoxical kinematic patterns as knee flexion increased (Chouteau et al., 2009; Oakeshott et al., 2003; Stiehl et al., 1997). Despite motions beyond 60° of flexion being generally less performed in daily living, paradoxical kinematics might have implications in long-term failure of prostheses. They may lead to a feeling of instability, excessive stresses and accelerated wear of the polyethylene and therefore need to be prevented or kept to a minimum (Argenson et al., 2002; Dennis et al., 1996; Li et al., 2006; Sansone and da Gama, 2004; Taylor and Barrett, 2003).

The lunge task is chosen for kinematic studies because it is assumed that the knee is more stressed and knee stability is more challenged. In this study, there was a larger range of knee flexion performing the lunge motion compared to the step-up motion. However, the maximal knee flexion angles found during the lunge task were not the absolute maximal knee flexion angles. This difference is caused by the experimental set-up in this study. Patients were standing on the stairs with the contra-lateral foot one step lower than the other foot. Because of the small horizontal distance between the feet it was difficult for the patients to reach maximal flexion. This also explains the muscle activity patterns during the lunge motion. The EMG results indicate that the antagonists controlled and guided the motion and beyond 50° of knee flexion the motion became largely passive. Most of the weight is transferred to the contralateral leg and the leg of interest was not as loaded as intended. Despite the fact that there was a larger range of motion and less variability in axial rotation and anterior-posterior translations, the lunge motion performed in this study does not resembles a daily activity task and the relevance of using this specific motion in kinematic studies is questionable.

Conclusion

Knee kinematics and muscle activation did not change in the first 2 post-operative years. In this study, the insert remains mobile. The comparable axial rotations of the insert and the femoral component between 0° and 60° of knee flexion indicates a reduction of multidirectional wear in this range of motion compared to less congruent implants. The reversed and divergent axial rotations with increasing knee 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. At lower knee flexion angles, the femoral component is obstructed by the highly congruent insert and is not able to move freely. This leads to high stresses at the insert which will be transferred to the bone-implant interface. Therefore, the question remains, does a movable insert yield any profit if it is at the expense of the fixation of the tibial component?

Chapter 6

Mobile-bearing kinematics change over time

A fluoroscopic study in rheumatoid arthritis patients

Nienke Wolterbeek[1], Eric H. Garling[1], Bart J.A. Mertens[2], Edward R. Valstar[1,3], Rob G.H.H. Nelissen[1]

[1]*Department of Orthopaedics, Leiden University Medical Center*

[2]*Department of Medical Statistics and Bioinformatics, Leiden University Medical Center*

[3]*Department of Biomechanical Engineering, Delft University of Technology*

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Abstract

In a previous fluoroscopy study the motion of a mobile-bearing total knee prosthesis was evaluated. That study showed that the axial rotation of the insert was limited. Three possible explanations are given for the limited rotation: low conformity between the femoral component and insert, the fixed anterior position of the insert-tibia pivot point leading to impingement and fibrous tissue formation. While the effect of the conformity on the axial rotation will not change over time, the effect of impingement and fibrous tissue is likely to increase, and thereby further decreasing the axial rotation.

In order to accurately assess changes in axial rotation over time in a mobile-bearing total knee prosthesis rheumatoid arthritis patient group, patients were evaluated 8 months and 3 years postoperatively using fluoroscopy.

In comparison with the 8 months evaluation, the rotation of the femoral component (range: $-10.8°$ to $2.8°$) and the insert (range: $-5.9°$ to $1.4°$) were further limited at 3 years (respectively, $-5.9°$ to $4.9°$ and $-2.8°$ to $5.4°$). Patterns of axial rotation for the femoral component and insert varied considerably between the trials within patients while at the 8 months evaluation no significant difference within patients was observed.

This study shows the importance of re-evaluating knee kinematics over time. The axial rotation of both the femoral component as the insert decreased over time, indicating a kinematic change caused by intrinsic factors. The decline in rotation of the insert could be explained by increased impingement and the formation of fibrous tissue.

6.1 Introduction

During the last decade, mobile-bearing (MB) knee prosthesis designs have become increasingly popular. In theory, the mobility of a MB permits increased articular conformity between the femoral and tibial components, reducing contact stresses and thus reducing polyethylene wear compared to fixed-bearing (FB) total knee prosthesis (TKP) (Cheng et al., 2003; Henricson et al., 2006; Li et al., 2006). There are many studies that evaluate the performance of MB TKP (Banks et al., 2003a; Bhan et al., 2005; Callaghan, 2001; Catani et al., 2003; Delport et al., 2006; Dennis et al., 2005; Garling et al., 2007b; Jones and Huo, 2006). Most kinematic studies focus on osteoarthritis patients.

The underlying pathology is of importance as it may have an effect on knee kinematics. For example, patients suffering from osteoarthritis may have different kinematic and coordination patterns compared to TKP patients suffering from rheumatoid arthritis (RA) (Chmell and Scott, 1999). RA causes degenerative loss of skeletal muscle mass and strength and selective muscle atrophy may have occurred (Chmell and Scott, 1999; Keenan et al., 1991; Meireles et al., 2002; Tjon et al., 2000). It is also reported that RA patients have an increased postural sway and that the quality of sensory information from the lower limbs is affected (Tjon et al., 2000). In most cases, RA has also affected other joints. All these factors influence the knee function of the patient.

In a previous fluoroscopy study the motion of a mobile-bearing TKP in 10 RA patients was evaluated 8 months postoperatively (Garling et al., 2007b). That study showed that the axial rotation of the insert was limited - or even absent - and that in all cases the femoral component rotated more than the insert. In Garling et al. (2007b), three possible explanations are given for the limited rotation. Firstly, the low conformity between the femoral component and insert of this specific design allows the femoral component to rotate and translate with respect to the insert without forcing the insert to rotate. Secondly, the fixed anterior position of the insert-tibia pivot point may lead to torsion forces at the cam-insert articulation, because the pivot point does not coincide with the actual tibiofemoral rotation point, resulting in polyethylene on metal impingement. The third explanation is that fibrous tissue formation between the tibial plateau and the insert limits the freedom of motion of the insert. While the effect of the conformity on the axial rotation will not change over time, the effect of impingement and fibrous tissue is likely to increase, and thereby further decreasing the axial rotation.

Knowledge about the kinematic changes of knee prostheses over time in patients is very limited. It is important to measure the kinematics of patients over times to assess possible changes in kinematics. Two studies have been published, but they focus on FB prostheses and not on MB prostheses (Collopy et al., 1977; Steiner et al., 1989). Therefore, in this study patients with a mobile-bearing total knee prosthesis that have been evaluated 8 months postoperatively in a previous fluoroscopy study are now re-evaluated 3 years postoperatively in order to accurately assess changes in axial rotation over time.

6.2 Methods

Ten rheumatoid arthritis patients were selected from a prospectively randomized Roentgen stereophotogrammetric analysis (RSA) study in our specialized rheumatoid arthritis clinic. Patients were measured using fluoroscopy while performing a step-up task 8 months after total knee arthroplasty (Garling et al., 2007b). From the original group of patients, seven patients were able to participate with the second follow-up (six females and one male). The mean follow-up time was 8 months (range: $2 - 13$) for the first follow-up and 43 months (range: $33 - 51$) for the second. The mean age during surgery was 67 years (range: $51 - 73$) and the mean body mass index (BMI) was 30 (range: $26 - 35$) at both follow-ups (Table 6.1). Three patients were lost to follow-up. One patient died, one was not able to participate because of psychological reasons and one patient could not be tracked down. Inclusion criteria were the ability to walk more than 500 m and to perform a step-up task without the help of bars. Exclusion criteria were the use of walking aids, functional impairment at any other

Table 6.1: Patient Characteristics: mean, standard deviation (σ) and range ($n = 7$).

	Age at surgery (years)	Follow-up time (months)		BMI (kg/m^2)	
		8 months	3 years	8 months	3 years
Mean	67	8	43	30	30
σ	8.2	4.4	7.7	3.5	3.1
Range	51-73	2-13	33-51	26-35	26-35

lower extremity joint besides the operated knee and pain during activity according to the knee society pain score (KSS) (Ewald, 1989). All patients gave informed consent and the study was approved by the local medical ethics committee.

In all patients, a NexGen legacy posterior stabilized (LPS) mobile-bearing prosthesis was implanted (Zimmer Inc., Warsaw, USA). All components were fixed using cement. The tibial-articular surfaces are made of compression moulded polyethylene. During surgery 1 mm tantalum markers were inserted in predefined non-weight bearing areas of the insert to visualize the polyethylene (Garling et al., 2005a). The insert has an anterior-central located trunnion and allows for 25° internal-external rotation on the tibia limited by an anterior bar. The curvature of the femoral component permits internal-external rotation to 12° in maximum flexion. In the NexGen LPS mobile-bearing knee, there is a limited degree of conformity of the insert surface. The conformity of the insert of the MB and the FB design of this prosthesis are the same, the only difference between the designs is the additional point of rotation in the MB design.

The patients were asked to perform a step-up task (height 18 cm) with bare feet in front of a fluoroscope (super digital fluorography (SDF) system, Toshiba Infinix-NB: Toshiba, Zoetermeer, The Netherlands). At the start of the step-up motion, the leg with the TKP was positioned on top of the riser. 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 five step-ups in total, the first two were used to gain comfort with the experimental set-up and during the last three runs data was collected. Prior to the measurements, the fluoroscopic set-up was calibrated using a specially designed calibration box (BAAT Engineering B.V. Hengelo, The Netherlands) (Garling et al., 2005a). In order to assess accurate three-dimensional (3D) models of the markers of the insert, two RSA radiographs of the subjects were used. These marker models of the insert were used to assess position and orientation of the insert in the fluoroscopic images. Reverse engineered 3D models of the tibia component and the femoral component were used to assess the position and orientation of the femur and the tibia. Contours of the implants were detected and the 3D models of the implants were projected onto the image plane and a virtually projected contour was calculated (Kaptein et al., 2003).

All images are processed using a commercially available software package (Model-based RSA, Medis specials b.v., The Netherlands). With the assessed 3D position and orientation of the femoral and tibial components and the markers in the insert both the relative rotation of the insert with respect to the tibial component and the relative rotation of the femoral component with respect to the tibial component were calculated. This technique showed to have an axial rotation accuracy of 0.3° (Garling et al., 2005a). In this study, motions smaller than 0.6° (95% confidence interval) were denoted as measurement error. The coordinate system was defined by the local coordinate system of the tibial component (internal rotation is defined as negative; 0° is extension). At maximal extension the axial rotation is set to zero. For both follow-ups this is done separately. This means that 'zero' axial rotation in the first follow-up might not be the same as in the second follow-up. To overcome possible differences in relative positions of the insert and femur component with respect to the tibia component, the relative change in rotation is presented.

6.2.1 Statistical analysis

A linear mixed-effects model for longitudinal data was used to compare the differences between the axial rotation of the femoral component and the insert at both follow-ups. The model assumes a linear trend of axial rotation of the predicted means of axial rotation versus knee angle within each follow-up. A patient random effect as well as a trial-within-patient nested random effect was incorporated in the model for both the intercept and slope coefficients of the linear trend. The first random effect was included to account for between-patient heterogeneity in observed differences, while the latter effect was included to take into account differences in the number of analysable trials per patient between follow-ups. It is a key characteristic of the model that differences in range of motion between trials are taken into account with respect to the fitting of the population linear effect within each follow-up. The model was fit using a fully Bayesian formulation via Markov chain Monte Carlo within the package WinBUGS (Lunn et al., 2000). Model-based residuals were investigated to detect potential mismatch between the observed data and the assumed model, which could adversely affect conclusions. Based on the model, the fitted mean population linear trends were calculated for the rotation of the insert, the femoral component and the difference between them versus knee angle, together with standard errors for each follow-up. Similarly, the probabilities were calculated of mean differences at the 8 months follow-up being larger than those at 3 years, for each knee angle within the range of the data. In interpreting those numbers, it should be noted that a probability of 0.5 means that the axial rotation at both follow-ups is the same. A probability between 0.5 and 1 indicates that the mean axial rotation of follow-up one is larger than the mean axial rotation of follow-up two.

6.3 Results

Clinical parameters determined with the KSS did not change between follow-ups (respectively, 155 ($\pm$46.8) and 161 ($\pm$44.5) points of the 200). At both follow-up moments patients were able to perform complete knee extension (0°). The range of knee flexion during the step-up task was the same at both follow-ups (mean 40° ($\pm$11°) versus 43° ($\pm$14°)). All axial rotation patterns were erratic and in most cases the axial rotations of the insert were smaller than the measurement error ($\pm$0.6°). A remarkable observation at the 3 years follow-up was that patterns of axial rotation for

Table 6.2: Maximal axial rotations and range for follow-up one and two ($n = 7$).

		8 months	3 years
Femoral component	Internal rotation	-10.8°	-5.9°
	External rotation	2.8°	4.9°
	Range	13.6°	10.8°
Insert	Internal rotation	-5.9°	-2.8°
	External rotation	1.4°	5.4°
	Range	7.3°	8.2°

both the femoral component and insert varied considerably between the trials within patients (Figure 6.1) while at the 8 months evaluation no significant difference within patients was observed. At both follow-ups, in all subjects, the femoral component showed more axial rotation than the insert (Table 6.2, Figures 6.2, 6.3).

The 8 months results show that the axial rotation of the insert was limited. In comparison with the 8 months evaluation, the 3 years rotation of the femoral component ($-10.8°$ to $2.8°$) and the insert ($-5.9°$ to $1.4°$) was further decreased (respectively, $-5.9°$ to $4.9°$ and $-2.8°$ to $5.4°$) (Table 6.2, Figures 6.2, 6.3). The large external rotation of the insert at the second follow-up is caused by one deviant trial (Figure 6.2) and gives a distorted picture of the range of axial rotation. The other two trials of this patient were not atypical. The trial was not excluded. The decrease in axial rotation of the femoral component and insert at 3 years is also presented in figures 6.4. In these figures, the predicted mean ($\pm\sigma$) according to the mixed-model approach is shown for the axial rotation of the femoral component and insert for both follow-ups. Also the probability that the mean axial rotation of the second follow-up is smaller than the mean axial rotation at the 8 months evaluation is visualized. The probabilities are above 0.5, which indicates that the mean axial rotation after 8 months is larger compared to the mean axial rotation at 3 years.

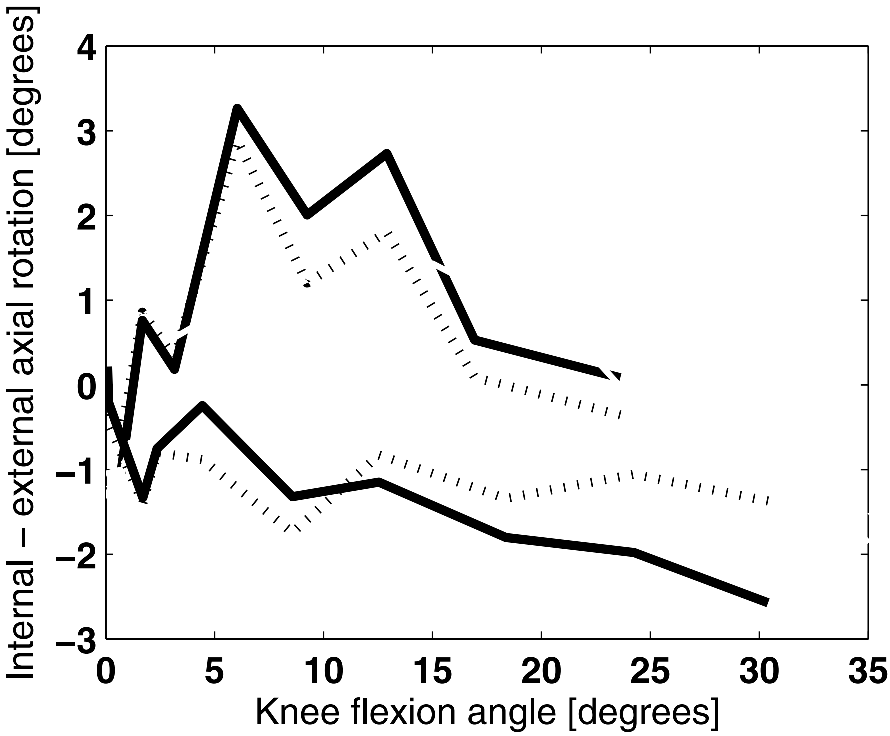


Figure 6.1: Example of variation in axial rotation patterns at the 3 years follow-up between trials of the femoral component (solid) and the insert (dotted) within one subject.

6.4 Discussion

In order to accurately assess changes in axial rotation over time in a mobile-bearing total knee prosthesis RA patient group, knee kinematics of seven patients were evaluated 8 months and 3 years postoperatively using fluoroscopy. The rotation of the polyethylene insert proved to be limited at 8 months postoperatively and even decreased over time. It seems that the insert becomes more fixed after a few years. The experimental set-up was exactly the same at both follow-ups, assuming no influence of extrinsic factors. Therefore, all differences found can be interpreted as differences caused by intrinsic factors. The effect of the underlying pathology is

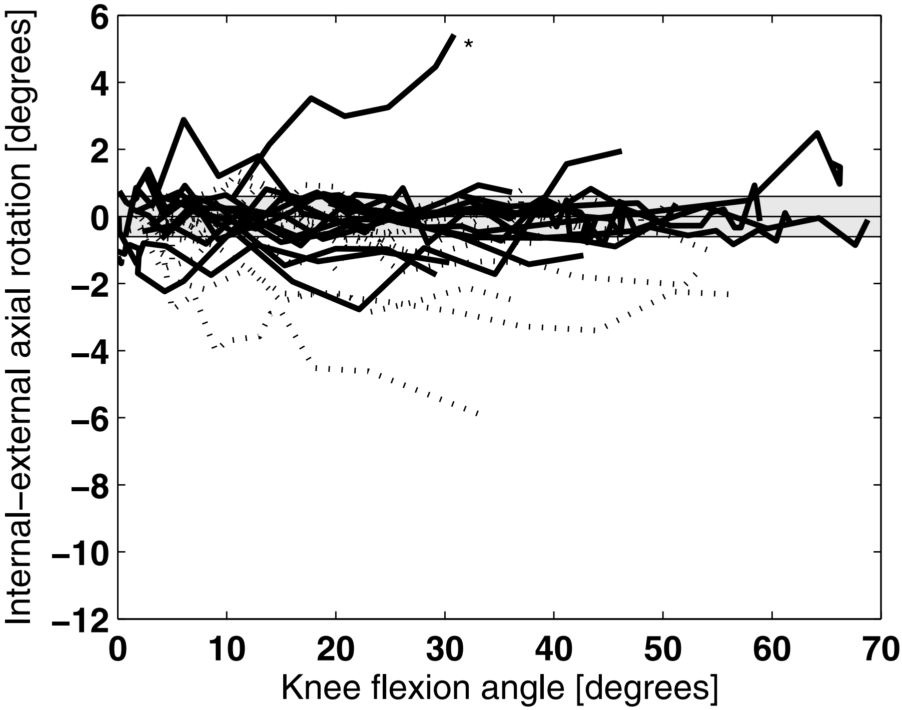


Figure 6.2: Rotation of the insert of all individual trials of all patients ($n = 7$) at 8 months (dotted) and 3 years (solid). The grey area represents the measurement error ($\pm 0.6°$). One deviant trial (*) (3 years follow-up) is visible.

limited by excluding patients with functional impairment of any other lower extremity joint besides the operated knee. In this study, the maximum knee extension did not change over time, but axial rotation of the femoral component and the insert decreased. The decrease in femoral axial rotation indicates a kinematic change over time. A remarkable observation at the 3 years follow-up was that patterns of axial rotation for both the femoral component and insert varied considerably between the trials within patients (Figure 6.1) while at the 8 months evaluation no significant difference within patients was observed. The increase in variability at 3 years may imply a decrease in muscle control.

The high variability and the observed reversed patterns might be caused by the

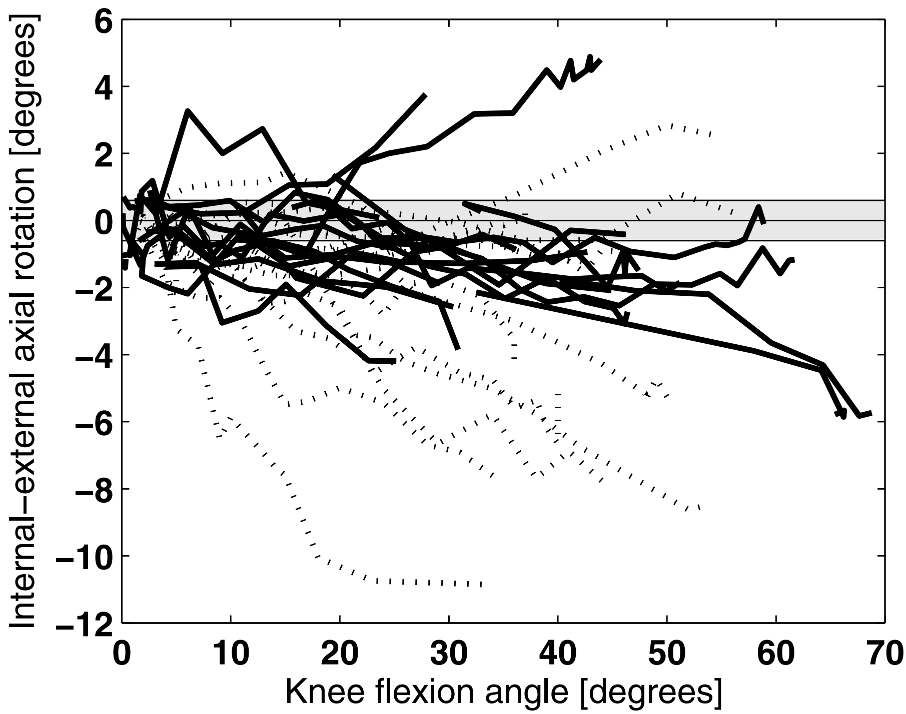
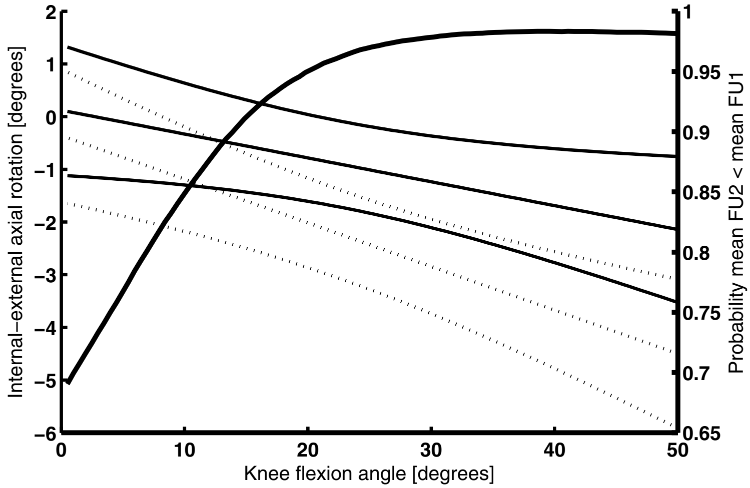
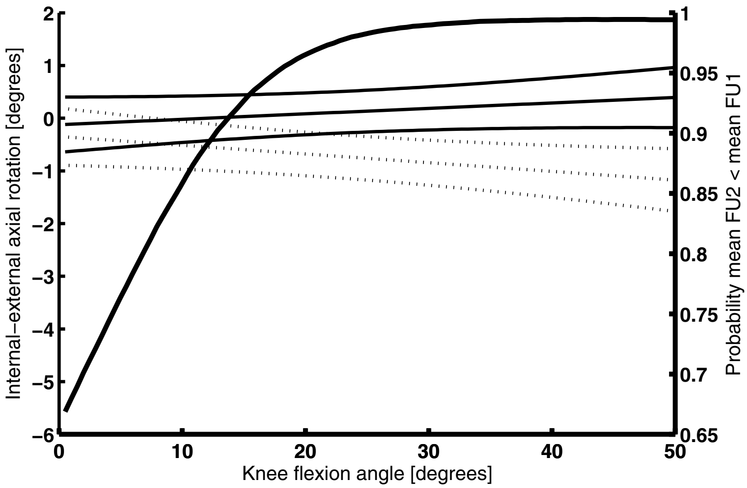


Figure 6.3: Rotation of the femoral component of all individual trials of all patients ($n = 7$) at 8 months (dotted) and 3 years (solid). The grey area represents the measurement error ($\pm 0.6°$).

location of the trunnion of the tibial-insert which is placed anterior in this design and does not coincide with the actual tibiofemoral rotation point. The high variability in axial rotation patterns among patients observed in this study is in accordance with the literature. Knee joint kinematics are highly unpredictable (Banks et al., 2005; Dennis et al., 1998; Huang et al., 2007; Stiehl et al., 1995, 1999) and often abnormal compared with healthy knees (Callaghan, 2001). In most studies tibiofemoral axial rotations are reduced compared to the axial rotation of the normal knee (Fantozzi et al., 2004; Haas et al., 2002; Most et al., 2003). Also reversed axial rotation patterns compared to normal kinematics are common after total knee arthroplasty (Callaghan, 2001). These reversed patterns are undesirable and can have an adverse effect on the



(a)



(b)

Figure 6.4: Predicted mean and standard deviation (σ) for the axial rotation of the femoral component (a) and for the insert (b) for 8 months follow-up (dotted) and 3 years follow-up (solid) on the left y-axis. On the right y-axis, the probability that the mean axial rotation of the second follow-up (FU2) is smaller than the axial rotation of the first follow-up (FU1) is shown.

range of motion because of reduced posterior femoral rollback of the lateral femoral condyle and patellar stability (Callaghan, 2001; Dennis et al., 2005).

In Garling's short term follow-up study, three explanations were given for the observed limited rotations. The first is the low conformity between the femoral component and insert. The conformity is not subjected to change over time and therefore not responsible for the observed decline in axial rotation. The other two explanations, respectively, increased polyethylene on metal impingement at the cam-insert articulation and increased formation of fibrous tissue at the edge of the insert, could explain the decline in axial rotation of the insert at the latter follow-up. Until now, no revision surgery was necessary in our patient group. However, retrieval data could clarify possible fibrous tissue formation and also show the effect on wear of the observed sliding phenomenon of the femoral component with respect to the insert (Harman et al., 2001).

Several studies show that 'normal' knees have a smooth motion during knee flexion, while implanted knees produce erratic, discontinuous motions (Sakauchi et al., 2001; Stiehl et al., 1995). This erratic motion is also visible in this study. In most trials, at both follow-ups, the femoral component and the insert rotate in the same direction but the rotation of the insert is much smaller. This indicates sliding of the femoral component over the insert during flexion. In two other fluoroscopic studies comparable results are found using different designs (Dennis et al., 2005; Fantozzi et al., 2004). If this sliding occurs without rotating the insert, a MB TKP becomes a FB TKP. In the NexGen LPS mobile-bearing knee, there is a limited degree of conformity of the insert surface. This allows for sliding of the femoral component with respect to the insert ($\pm 12^\circ$ of rotation). However, the philosophy behind a MB design is that axial rotation occurs at the tibial-insert interface to reduce multidirectional wear on the superior (i.e. femoral) aspect of the insert (Dennis et al., 2005). The mobility of a MB permits increased articular conformity between the femoral and tibial components. If the conformity is not increased but kept the same as the conformity of a FB prosthesis, as is the case for the NexGen LPS mobile-bearing knee, this will result in minimal or no rotation at the tibial-insert interface. In this non-conforming prosthesis, the effect of limited axial rotation will be compensated for with sliding of the femoral component on the insert. Therefore, the patient might not experience any functional limitations in daily living. However, the theoretical advantages of having a rotating platform which should lead to reduced contact stresses and wear will not be accomplished and could even lead to longevity problems.

The conformity of the femoral-tibial contact area should be high enough to make sure that the insert is following the motion of the femoral component thereby facilitating the philosophy of the MB design. The only theoretical advantage remaining of this MB design over a FB design seems to be the assumed forgiveness for surgical rotational misalignment. In this study, the exact positions of the markers in the insert are not known, In future studies it would be interesting to place the markers with a submillimetre accuracy to evaluate the actual axial rotation instead of the relative axial rotations. This would also provide more insight in the theory that MB inserts find their own optimal position and correct for femoral component misalignment.

A limitation of this study is the small patient group. For the first evaluation, an 80% power analysis in combination with an expected measurement error of 0.3° showed that relative motions of 0.3° could be detected when ten patients were included in the study. Unfortunately, three patients were lost to follow-up which has a negative effect on the power of this study. Patients included in fluoroscopic studies are surgeon-selected and therefore kinematic results in general biased. Although this is the first study presenting changes in mobile-bearing knee kinematics of RA patients, one has to be careful generalizing these findings to other patient groups and/or other implant designs. The characteristics of this NexGen design will result in implant specific tibiofemoral and insert kinematics.

Conclusion

It is important to assess knee kinematics for the most frequently encountered daily activities, as functional capabilities of patients and survival of TKP are affected by knee kinematics. This study shows the importance of re-evaluating knee kinematics over time, as knee kinematics continue to adapt to intrinsic factors and physiological changes. In an identical experimental set-up the axial rotation of both the femoral component as the insert decreased over time, indicating a kinematic change caused by intrinsic factors. The decline in rotation of the insert could be explained by increased impingement and the formation of fibrous tissue.

Chapter 7

Kinematics and early migration in single-radius mobile- and fixed-bearing total knee prostheses

Nienke Wolterbeek[1], Eric H. Garling[1], Bart J.A. Mertens[2], Rob G.H.H. Nelissen[1], Edward R. Valstar[1,3]

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

Submitted.

Abstract

The mobile-bearing variant of a single-radius design is assumed to provide more freedom of motion compared to the fixed-bearing variant because the insert does not restrict the natural movements of the femoral component. This would reduce the contact stresses and wear which in turn may have a positive effect on the fixation of the prosthesis to the bone and thereby decreases the risk for loosening. The aim of this study was to evaluate early migration of the tibial component and kinematics of a mobile-bearing and fixed-bearing total knee prosthesis of the same single-radius design.

Twenty Triathlon single-radius posterior-stabilized knee prostheses were implanted (9 mobile-bearing and 11 fixed-bearing). Fluoroscopy and roentgen stereophotogrammetric analysis were performed 6 and 12 months post-operatively.

The 1 year post-operative roentgen stereophotogrammetric analysis results showed considerable early migrations in 3 mobile-bearing patients (33%) and 1 fixed-bearing patient (9%). The range of knee flexion was the same for the mobile-bearing and fixed-bearing group. The mobile insert was following the femoral component during motion.

Despite the mobile insert was following the femoral component during motion, and therefore performed as intended, no kinematic advantages of the mobile-bearing total knee prosthesis were seen. The fixed-bearing knee performed as good as the mobile-bearing knee and maybe even slightly better based on less paradox and reversed motions and less early migrations.

7.1 Introduction

The conventional knee implant is designed with several axes of rotation, the so called multi-radius designs. In multi-radius designs the motion of the knee is guided by the shape of the articulating surfaces (Banks et al., 1997a; Kessler et al., 2007; Pandit et al., 2005). During knee motion, the contact area between the femoral component and the insert decreases which can lead to excessive stresses in the polyethylene (Blunn et al., 1997). Because of the change in radii of the femoral component, strain on the ligaments is not consistent during motion. This ligament instability tends to cause the femoral component to skid forward rather than roll back during flexion (paradoxical anterior motion). This may lead to impingement during deep flexion thereby limiting the range of motion. Alternatively, single-radius designs have been developed allowing the ligaments to guide the motion of the knee on the articulating surfaces. According to the design rationale of a single-radius design, centering the axis of rotation about the transepicondylar axis provides ligament isometry and a substantial contact area throughout the entire range of motion. This provides a more uniform motion, lower contact stresses on the insert, better mid-flexion stability and more efficient muscle activity (Blunn et al., 1997; Hollister et al., 1993; Kessler et al., 2007; Mahoney et al., 2002; Wang et al., 2005, 2006).

The mobile-bearing variant of this single-radius design is assumed to provide more freedom of motion compared to the fixed-bearing variant because the insert can move with respect to the tibial component and does not restrict the natural movements of the femoral component. This would reduce the contact stresses and polyethylene wear even further. Furthermore, reduced contact stresses will lead to reduced stresses at the bone-implant interface. This may have a positive effect on the fixation of the prosthesis to the bone and thereby decrease the risk for loosening (Garling et al., 2005b; Henricson et al., 2006; Huang et al., 2007).

The aim of this study was to evaluate early migration of the tibial component and kinematics of a mobile-bearing and fixed-bearing total knee prosthesis of the same single-radius design.

7.2 Methods

The patients included in this fluoroscopic study were part of a larger prospective randomized roentgen stereophotogrammetric analysis (RSA) trial studying the long-term fixation of the tibial component of the Triathlon total knee prosthesis (Stryker Orthopaedics, USA). All osteoarthritic and rheumatoid arthritic patients of our hospital undergoing primary total knee arthroplasty were included, except those having a flexion or varus-valgus contracture of 15° or more. Prospectively, the first 20 patients of the larger RSA study, who met the inclusion criteria for this fluoroscopic study, were included. Based on a previous fluoroscopy study, relative motions of 0.3° could be detected when ten patients were included in each group (Kaptein et al., 2003). Inclusion criteria were the expected ability to perform a step-up and lunge motion in a controlled manner without the use of bars and walk more than 1 km. Pain during activity was an exclusion criterion. Twenty knees (17 patients: 11 female; 6 male) were included and evaluated using fluoroscopy while performing a step-up and lunge motion 6 (FU1) and 13 (FU2) months after total knee arthroplasty (Table 7.1). Three knees were randomly selected to receive a mobile-bearing knee, however, by decision of the surgeon they were implanted with a fixed-bearing knee. Analysis is performed according to 'applied treatment'. All patients gave informed consent and the study was approved by the local medical ethics committee. Patients' reported functional ability (knee score and function score) were quantified pre- and post-operatively using the Knee Society Score (KSS) (Ewald, 1989). All patients were considered clinically successful without significant pain or measurable ligamentous instability.

The Triathlon total knee prosthesis is a single-radius posterior-stabilized knee prosthesis. The femoral component was the same for the mobile-bearing and fixed-bearing implant with a single-radius resulting in a fixed instant centre of rotation. All components were fixed using cement and the patellae were not resurfaced. The inserts were made of compression moulded ultra high molecular weight polyethylene. The mobile-bearing implant has a central guiding mechanism in the form of a

Table 7.1: Patient details. Mean (SD) of age at surgery (years), body mass index (BMI), follow-up moment (FU) in months and pre- and post-operative Knee Society knee score (KS) and function score (FS) are presented for the mobile-bearing (MB), the fixed-bearing (FB) and the total group.

Gender (male/female)		Age	BMI	FU1/2	FU0		FU1		FU2	
					KS	FS	KS	FS	KS	FS
MB	2/7	63 (9.6)	29.3 (6.7)	7 / 13 (1.5 / 1.1)	50 (19.5)	49 (12.2)	90 (4.3)	81 (25.9)	93 (1.9)	78 (16.9)
FB	5/6	66 (9.1)	29.6 (5.9)	6 / 12 (1.6 / 1.0)	43 (12.5)	52 (17.8)	89 (7.0)	77 (21.0)	92 (4.0)	73 (23.9)
Total	7/13	65 (9.2)	29.5 (6.1)	6 / 13 (1.5 / 1.1)	46 (15.9)	51 (15.2)	90 (6.0)	79 (22.4)	92 (3.3)	75 (20.8)

‘mushroom’ that fits into a slot of the polyethylene undersurface. During surgery 1 mm tantalum markers were inserted in predefined non-weight bearing areas of the mobile insert to visualize the polyethylene in the fluoroscopic images.

7.2.1 RSA

RSA was used to determine the migration of the prosthesis with respect to the bone (Model-based RSA, Medis specials b.v., The Netherlands). The first RSA examination, two days after surgery and before mobilization, served as reference baseline. Subsequent evaluations of migration (6 and 12 months post-operatively) were related to the relative position of the prosthesis with respect to the bone at the time of the first evaluation. The precision of the RSA measurements was determined by means of double examinations at the 1 year follow-up.

7.2.2 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 (super digital fluorography system, Toshiba Infinix, Toshiba, Zoetermeer, The Netherlands) (15 frames/sec, resolution 1024×1024, pulse width 1 msec). The patients were asked to perform three step-up and lunge motions (height 18 cm) with bare feet in front of a flat panel fluoroscope. Patients were instructed to keep their weight on the leg of interest. Fluoroscopic images were processed using a commercially available software package (Model-based RSA, Medis specials b.v., The Netherlands). Reverse engineered three-dimensional (3D) models of the components were used to assess the position and orientation of the components in the fluoroscopic images (Kaptein et al., 2003). RSA was used to create accurate 3D models of the markers of the inserts to assess position and orientation of the insert in the fluoroscopic images. Fluoroscopy showed to have an accuracy of 0.3° and $0.3\,\mathrm{mm}$ (Garling et al., 2005a). At maximal extension, the axial rotation was defined to be zero. The minimal distance between the femoral condyles and the tibial base plate was calculated independently for the medial and lateral condyle. The lowest points of each frame were projected on the tibial plane to show the anterior-posterior motion and the pivot point of rotation of the femoral component with respect to the tibial component.

7.2.3 Statistical analysis

Two-tailed Student's t-tests were used to compare the clinical scores, knee flexion ranges and anterior-posterior translation ranges between follow-ups and between implant groups. Mean and standard deviations were presented. A linear mixed-effects model for longitudinal data was used to compare the differences between the axial rotation of the femoral component and the insert over the follow-ups. The model assumed a linear trend of axial rotation versus knee flexion angle within each follow-up. A patient random effect as well as a trial-within-patient nested random effect was incorporated in the model for both the intercept and slope coefficients of the linear trend. The first random effect was included to account for between-patient heterogeneity in observed differences, while the latter effect was included to take into account differences in the number of analysable trials per patient between follow-ups. It is a key characteristic of the model that differences in range of motion between trials are taken into account with respect to the fitting of the population linear effect within each follow-up. The model was fit using a fully Bayesian formulation via Markov chain Monte Carlo within the package WinBUGS (Lunn et al., 2000). Model-based residuals were investigated to detect potential mismatch between the observed data and the assumed model, which could adversely affect conclusions. Based on the model, the fitted mean population linear trends were calculated for the rotation of the insert, the femoral component and the difference between them versus knee flexion angle, together with standard errors for each follow-up.

7.3 Results

Age at surgery, length, weight, body mass index (BMI), pre- and post-operative KSS knee score and function score were not statistically different between the mobile-bearing and fixed-bearing group (Table 7.1). Knee scores and function scores significantly improved post-operatively in both groups. For the total group, the mean KSS knee score increased from 46 points pre-operatively to 90 points 6 months post-operatively and the improvement remained 1 years post-operatively. The mean KSS function score increased from 51 points pre-operatively to 79 points at 6 months and 75 points at 1 year post-operatively. None of the patients had post-operatively a flexion contracture or an extension lag. No clinical relevant deviations were observed in the post-operative alignment of the components.

7.3.1 RSA

The precision of the RSA measurements was determined by means of double examinations at the 1 year follow-up ($n = 16$). There was no difference in precision between the mobile-bearing and fixed-bearing group. Significant rotations at the 95% significant level were $> 0.25°$ for anterior-posterior tilt, $> 0.5°$ for axial rotation and $> 0.15°$ for varus-valgus tilt. The values for significant translations were > 0.06 mm for both medial-lateral translation and subsidence and > 0.18 mm for anterior-posterior translation.

The 1 year post-operative RSA results showed considerable early migrations in 3 mobile-bearing patients (33%) and 1 fixed-bearing patient (9%) (1 rheumatoid

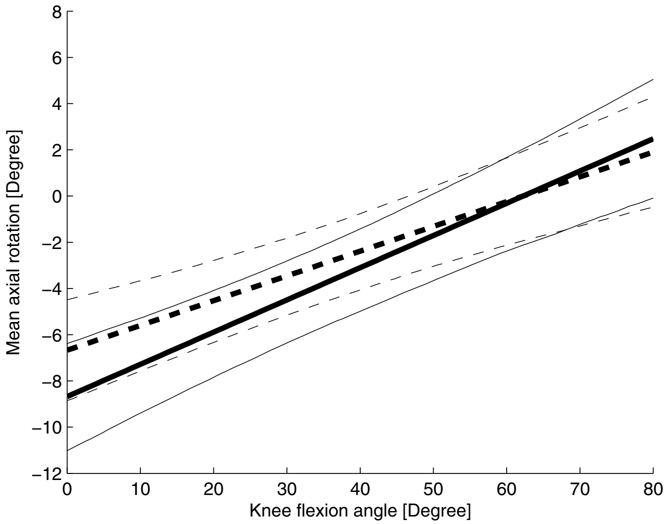
Table 7.2: Knee flexion range (°) and axial rotation range (°) of the femoral component (mean and standard deviation) for follow-up 1 (FU1) and follow-up 2 (FU2) for the mobile-bearing (MB), the fixed-bearing (FB) and the total group.

	Step-up				**Lunge**			
	Knee Flexion		**Axial rotation femoral component**		**Knee Flexion**		**Axial rotation femoral component**	
	FU1	FU2	FU1	FU2	FU1	FU2	FU1	FU2
MB	59.8	61.0	9.9	8.7	71.9	80.2	7.2	8.0
	(11.4)	(13.5)	(4.6)	(3.7)	(19.7)	(13.9)	(2.2)	(3.1)
FB	58.0	59.9	7.6	8.4	78.4	82.2	6.2	6.6
	(8.2)	(7.0)	(2.2)	(2.8)	(13.6)	(17.3)	(2.3)	(2.7)
Total	58.8	60.4	8.6	8.5	75.6	81.4	6.6	7.2
	(9.7)	(10.2)	(3.6)	(3.2)	(16.7)	(15.9)	(2.3)	(2.9)

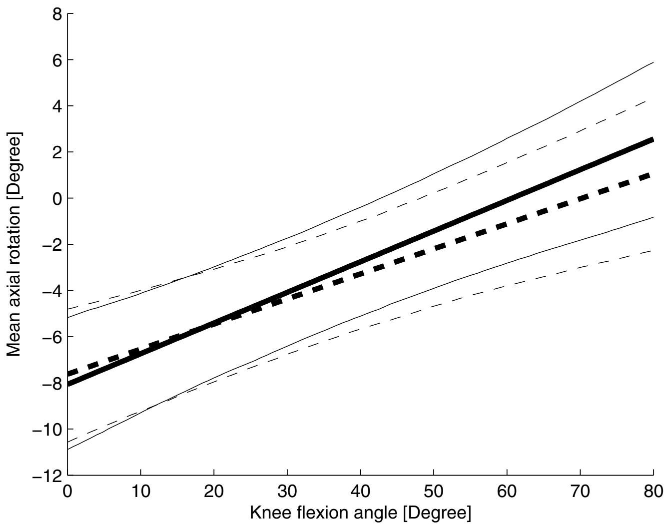
arthritis and 3 osteoarthritis patients, all women). In three of these patients, radiolucent lines were visible on the 1 year post-operative X-rays. The other patients had insignificant migrations below the measured threshold or stabilized after 6 months. The migrations were more prominent for the rotations than for the translations. Mean Maximum Total Point Motion (MTPM) at 1 year was 0.92 mm (SD: 0.92) for the total group (0.84 mm (SD: 1.03) for the fixed-bearing and 1.02 mm (SD: 0.81) for the mobile-bearing group).

7.3.2 Fluoroscopy

The mean range of knee flexion during the step-up and lunge motion was the same for the mobile-bearing and fixed-bearing group and for FU1 and FU2 (Table 7.2, Figure 7.1). Performing the step-up motion, all patients showed external rotation of the tibial component while extending, like expected. Performing the lunge motion, all the patients started with internal rotation of the tibial component while flexing the knee. Beyond 60° of knee flexion, external rotations were seen in all fixed-bearing patients and 50% of the mobile-bearing patients, ranging from returning to their starting position to 5° to 10° beyond their starting position.



(a) Mobile-bearing (solid) and the fixed-bearing (dotted) at follow-up 1



(b) Mobile-bearing follow-up 1 (solid) and mobile-bearing follow-up 2 (dotted)

Figure 7.1: Mean axial rotation of the femoral component and confidence intervals for the step-up motion.

7.3.3 Axial rotation mobile insert

The mobile insert and femoral component had comparable axial rotations during flexion and extension during both follow-ups and both motions. Hence, the mobile insert was following the femoral component during motion. Despite this fact, medial, lateral and central pivot points of rotations of the femoral component with respect of the tibial component were measured, whereas a central pivot point of rotation was expected according to design. The range of axial rotation of the mobile insert did not change with follow-ups. The axial rotation during the step-up motion was 9.3° (SD: 4.5°) and 8.0° (SD: 4.8°), respectively for FU1 and FU2. During the lunge motion axial rotation of the insert was 6.6° (SD: 4.0°) and 7.0° (SD: 3.1°) for respectively FU1 and FU2.

7.3.4 Anterior-posterior translation

For both the step-up and lunge motion, the range of anterior-posterior translation of the medial condyle did not change with follow-ups and was not different between mobile-bearing and fixed-bearing groups (Table 7.3). For the lateral condyle, the range of translation was significantly larger for the fixed-bearing group during the lunge motion at 6 months (7.1 mm versus 5.8 mm, $p = 0.024$) and during the step-up motion at 12 months (7.2 mm versus 6.0 mm, $p = 0.031$).

For each individual patient, the patterns of anterior-posterior translation were essentially the same 6 months and 1 year post-operatively. The lateral condylar translations were anterior throughout knee extension and medial condylar translations posterior. In the mobile-bearing group, one patient showed atypical translations while performing the step-up motion, namely posterior translation of both condyles during extension. Throughout flexion, the lateral condyle was expected to move posterior and the medial condyle anterior or in case of no or minimal axial rotation both condyles were expected to move posterior. However, 63% of the mobile-bearing group and 27% of the fixed-bearing group showed anterior translation of both condyles during flexion.

Table 7.3: Range of anterior-posterior translation (mean and standard deviation in mm) of the medial and lateral condyle for follow-up 1 (FU1) and follow-up 2 (FU2) for the mobile-bearing (MB), the fixed-bearing (FB) and the total group.

	Anterior-posterior translation							
	Step-up				**Lunge**			
	medial condyle		**lateral condyle**		**medial condyle**		**lateral condyle**	
	FU1	FU2	FU1	FU2	FU1	FU2	FU1	FU2
MB	7.1	6.7	6.5	6.0	8.4	8.0	5.8	6.9
	(2.7)	(2.2)	(1.9)	(2.1)	(2.9)	(3.0)	(2.0)	(2.0)
FB	6.4	6.6	6.5	7.2*	7.5	7.5	7.1**	7.5
	(2.1)	(1.7)	(2.1)	(2.0)	(2.5)	(3.0)	(1.9)	(1.8)
Total	6.7	6.6	6.5	6.6	7.9	7.7	6.5	7.3
	(2.4)	(1.9)	(2.0)	(2.1)	(2.7)	(3.0)	(2.1)	(1.9)

* $p = 0.031$
** $p = 0.024$

7.4 Discussion

The aim of this study was to evaluate early migration of the tibial component and kinematics of a mobile-bearing and fixed-bearing total knee prosthesis of the same single-radius design. The mobile-bearing and fixed-bearing group showed approximately the same range of knee flexion and axial rotation of the femoral component with respect to the tibial component. Hence, the mobile-bearing variant did not add additional mobility to the knee joint which could be assumed based on theoretical grounds. However, supposedly the additional mobility was not necessary during the range of motion of the functional tasks performed in this study.

For the lateral condyle, the range of translation was significantly larger for the fixed-bearing group during the lunge motion at 6 months and during the step-up motion at 12 months. This means that the mobile-bearing group had a smaller sliding distance and therefore a reduced surface area of polyethylene being worn. The anterior-posterior translation in this study was assessed by the lowest points of the femoral condyles with respect to the tibial component. In determining the anterior-posterior translations, the motion of the insert in the mobile-bearing group was not taken into account. Because the mobile insert was following the femoral component during motion, the actual sliding of the condyles in the mobile-bearing group is even smaller. However, more paradoxical anterior-posterior translations were seen in the mobile-bearing group compared to the fixed-bearing group during the dynamic tasks. Throughout knee flexion both condyles translated anterior instead of posterior. Lack of engagement of the cam-post mechanisms in activities that require less flexion could explain these paradoxical motions. Paradoxical motions are assumed to increase wear (Banks and Hodge, 2004b; Benedetti et al., 2003; Krichen et al., 2006; Taylor and Barrett, 2003; van Duren et al., 2007).

Medial, lateral and central pivot points of axial rotation of the femoral component with respect to the tibial component were found. Because of the centrally located trunnion in the mobile-bearing variant, a centrally located pivot point of rotation was expected. The medial and lateral pivot points may be caused by low congruency between the insert and femoral component and by laxity of the surrounding ligaments (Banks and Hodge, 2004b). No manifest laxity was seen in these patients.

In several RSA studies evaluating other total knee prostheses, initial migration was seen during the first 3 to 6 months. After this period the components tend to stabilize (Therbo et al., 2008; van der Linde et al., 2006). The preliminary RSA data of this study confirm early migration and latter stabilization of the tibial component in most patients. The larger MTPM of the mobile-bearing group imply that the mobile insert does not improve initial fixation of the prosthesis to the bone, as intended by mobile-bearing designs. Additionally, early migration in 33% of the mobile-bearing group versus 9% in the fixed-bearing group indicates that early migration of the tibial component is worse in the mobile-bearing group. Until now, patients did not have clinical symptoms. However, it seems reasonable to consider that continuation of the large initial migration seen in 4 patients might develop into clinical loosening and becomes of clinical significance. RSA evaluations of all patients will continue at yearly intervals to determine the long-term fixation of the components in the bone.

Comparable studies are not able to prove or disprove the theoretical working principle of mobile-bearing designs or find significant differences in clinical or radiological outcomes (Breugem et al., 2008; Callaghan, 2001; Haider and Garvin, 2008; Huang et al., 2007; Jacobs et al., 2001; Oh et al., 2009; Post et al., 2010; Rossi et al., 2009; Smith et al., 2010; Van der Bracht et al., 2010). In this study, the fixed-bearing knee performed as good as the mobile-bearing knee and maybe even slightly better based on less paradox and reversed motions and less early migrations. Retrieval studies showing wear patterns and particles (sizes) and large, long-term RSA studies assessing the effect of prosthesis-bone interface stresses on migration of the components should be combined with kinematic studies to clarify differences in design variations and the benefit of on prosthesis above another. If no superiority of one of the designs concerning revision rate, survival and outcome can be found, one might question the added value of a mobile-bearing knee taking into account the added costs, complexity for implantation and persisting concerns about dislocation and breakage of the polyethylene insert (Callaghan, 2001; Hanusch et al., 2010; Pagnano and Menghini, 2006). Development and use of improved wear resistant triple cross linked polyethylene for fixed-bearing total knees might be preferred over the use of mobile-bearing knees. These inserts will limit wear that occurs during sliding of the femur on the tibial articulating surface.

Conclusion

Despite the mobile insert was following the femoral component during motion, and therefore performed as intended, no kinematic advantages of the mobile-bearing total knee prosthesis were seen. The fixed-bearing knee performed as good as the mobile-bearing knee and maybe even slightly better based on less paradox and reversed motions and less early migrations.

Chapter 8

No differences in *in vivo* kinematics between six different types of knee prostheses

Nienke Wolterbeek[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*

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Abstract

The aim of this study was to compare a broad range of total knee prostheses with different design parameters to determine whether *in vivo* kinematics was consistently related to design. The hypothesis was that there are no clear recognizable differences in *in vivo* kinematics between different design parameters or prostheses.

At two sites, data were collected by a single observer on 52 knees (49 subjects with rheumatoid arthritis or osteoarthritis). Six different total knee prostheses were used: multi-radius, single-radius, fixed-bearing, mobile-bearing, posterior-stabilized, cruciate retaining and cruciate sacrificing. Knee kinematics was recorded using fluoroscopy as the patients performed a step-up motion.

There was a significant effect of prosthetic design on all outcome parameters; however post-hoc tests showed that the NexGen group was responsible for 80% of the significant values. The range of knee flexion was much smaller in this group, resulting in smaller anterior-posterior translations and rotations.

Despite kinematics being generally consistent with the kinematics intended by their design, there were no clear recognizable differences in *in vivo* kinematics between different design parameters or prostheses. Hence, the differences in design parameters or prostheses are not distinct enough to have an effect on clinical outcome of patients.

8.1 Introduction

Many studies have characterized the *in vivo* motions of total knee prostheses. Major conclusions are that there is a broad range of kinematics and that specific prostheses have specific advantages and disadvantages (Andriacchi et al., 1982; Banks and Hodge, 2004b; Wang et al., 2006). For example, posterior-stabilized knee prostheses were developed to prevent reversed anterior translations of the femoral condyles during flexion seen in cruciate sacrificing prostheses. The induced posterior displacement will avoid impingement and thereby improve the range of motion of the knee (Insall et al., 1982). However, it is no exception that the actual *in vivo* kinematics of knee prostheses is not in line with the desired kinematics as intended by the design. Understanding the effect of design choices on *in vivo* kinematics, stability and muscle activation has become more important because of the increasingly clear connection between knee prosthesis kinematics and clinical performance. Therefore, the aim of this study was to compare a broad range of total knee prostheses with different design parameters (multi-radius, single-radius, fixed-bearing, mobile-bearing, posterior-stabilized, cruciate retaining and cruciate sacrificing) to determine whether *in vivo* kinematics was consistently related to design. The hypothesis was that there are no clear recognizable differences in *in vivo* kinematics between different design parameters or prostheses.

8.2 Materials and Methods

At two sites, data were collected by a single observer on 52 knees (49 subjects with rheumatoid arthritis or osteoarthritis). Six different total knee prostheses were used (Table 8.1). Total knee replacements were performed by five surgeons at three hospitals in two countries (the Netherlands and United Kingdom). All surgeons were specialized in total knee arthroplasty, and prostheses were implanted according to the operative techniques described by the manufacturer. Based on a previous fluoroscopy study, relative motions of 0.3° could be detected when ten patients were included in each group (Garling et al., 2007b). Knee kinematics was recorded using fluoroscopy as the patients performed a step-up motion. The experimental set-up was the same for all patients. Patients' reported functional ability (knee score and function score) was quantified pre- and post-operatively for the prospective patients using the Knee Society Score (KSS) (Ewald, 1989). The study was approved by the respective local medical ethics committees and all patients gave informed consent.

8.2.1 Fluoroscopy

The patients were asked to perform a step-up motion (height 18 cm) with bare feet in front of a flat panel fluoroscope (15 frames/sec, resolution 1024×1024, pulse width < 3.2 msec). Patients were instructed to keep their weight onto the leg of interest and to perform the motions in a controlled manner. Three-dimensional (3D) models (reverse engineered or computer aided design) of the tibial and femoral components were used to assess the position and orientation of the components in the fluoroscopic images (Kaptein et al., 2003). In case of a mobile-bearing prosthesis, during surgery 1 mm tantalum markers were inserted in predefined non-weight bearing areas of the mobile insert to visualize the polyethylene. Roentgen stereophotogrammetric analysis (RSA) was used to create accurate 3D models of the markers of the inserts to assess position and orientation of the mobile insert in the fluoroscopic images. This technique showed to have an axial rotation accuracy of 0.1° and 0.1 mm (Kaptein et al., 2003). The coordinate system was defined as the local coordinate system of the tibial component. At maximal extension, the axial rotation is defined as 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 show the anterior-posterior motions. This line was projected onto the transverse plane of the tibial plateau for each fluoroscopic frame. All images were processed using a commercially available software package (Model-based RSA, Medis specials b.v., Leiden, The Netherlands).

Table 8.1: Overview of the prostheses used, congruency of the insert and number of knees and patient characteristics (mean and standard deviation). Missing data is indicated with an 'x'.

Prosthesis	Design parameters	Number of knees	Follow-up (months)	Male/ female	Age (years)	BMI (kg/m^2)	Pre-operative Function score	Pre-operative Knee score	Post-operative Function score	Post-operative Knee score
Duracon[1]	Multi-radius Fixed-bearing Cruciate retaining	10	21 (8.9)	3/7	68 (10.9)	29 (3.7)	x	x	88 (13)	95 (3)
Triathlon FB[1]	Single-radius Fixed-bearing Posterior-stabilized	11	13 (1.0)	5/6	66 (9.1)	30 (6.2)	52 (18)	43 (13)	73 (24)	92 (4)
Triathlon MB[1]	Single-radius Mobile-bearing Posterior-stabilized	9	12 (2.5)	2/7	63 (9.6)	31 (7.5)	48 (13)	49 (21)	71 (26)	90 (11)
PFC-Sigma[2]	Multi-radius Fixed-bearing Posterior-stabilized	8	5 (1.0)	4/4	67 (7.6)	31 (5.1)	x	x	x	x
NexGen[3]	Multi-radius Mobile-bearing Posterior-stabilized	7	43 (7.7)	1/6	67 (8.2)	30 (3.1)	43 (16)	44 (24)	74 (30)	84 (18)
ROCC[4]	Multi-radius Mobile-bearing Cruciate sacrificing	7	25 (0.8)	3/4	63 (10.9)	29 (5.6)	50 (26)	47 (12)	79 (22)	86 (11)

[1] Stryker, Kalamazoo, MI, USA
[2] DePuy Orthopaedics Inc., Warsaw, In, USA
[3] Zimmer Inc., Warsaw, In, USA
[4] Biomet, Europe BV, Dordrecht, The Netherlands

8.2.2 Statistical analysis

A chi-square test (Cramer's V) was used to test whether the prosthesis groups were different on variables, such as age, gender, BMI and functional and knee scores. An ANOVA was used to test for differences in outcome variables among the prosthetic groups. Levene's test was used to test for homogeneity of variances between prosthetic groups. For femoral axial rotation ($p = 0.006$) and insert axial rotation ($p = 0.001$) the variances were not equal. To correct for this unequal variance and to correct for the different group sizes, Brown-Forsythe correction was used. When a significant effect of prosthetic design on an outcome variable was found, post hoc tests were performed to test which groups were different.

8.3 Results

Age at surgery, BMI, pre-operative KSS knee score and function score did not differ significantly between groups (Table 8.1). The PFC-Sigma patients had no pre- or post-operative scores. The Duracon patients were included retrospectively. Therefore, no pre-operative clinical scores were available. There was no difference in post-operative KSS function score between groups. However, there was a small significant difference in post-operative KSS knee score ($p = 0.045$). Post-operatively, the Duracon patients (multi-radius fixed-bearing cruciate retaining) scored highest on both KSS function score and knee score. In all groups, the KSS function score and knee score increased post-operatively. All patients were considered clinically successful without significant pain or measurable ligamentous instability. Also, no clinical deviations were reported, such as extension lags or flexion contractures.

8.3.1 Knee flexion angle

The NexGen group had significant smaller knee flexion angles compared to the other prosthetic groups (Triathlon MB $p = 0.005$; Triathlon FB $p = 0.004$; Duracon $p = 0.003$; ROCC $p = 0.007$; PFC-Sigma $p = 0.017$). There were no significant differences

Table 8.2: Mean and standard deviation of the range of knee flexion (°), axial rotation of the femoral component and the insert (°) and anterior-posterior (AP) translation (mm) of the lateral and medial condyle during the step-up motion for each prosthetic group. Also, the results of the Levene's test and ANOVA are presented. There was a significant effect of prosthetic design on all outcome variables.

		Axial rotation		AP-translation	
Prosthesis	**Knee flexion**	**Femoral component**	**Mobile insert**	**Medial condyle**	**Lateral condyle**
Duracon	59.7 (9.3)	8.6 (2.3)	-	9.0 (2.1)	11.1 (3.4)
Triathlon FB	60.3 (5.4)	8.3 (2.7)	-	6.6 (1.5)	7.1 (1.8)
Triathlon MB	62.0 (12.9)	9.6 (4.3)	8.7 (4.9)	6.8 (2.0)	6.0 (1.6)
PFC-Sigma	56.5 (9.9)	8.3 (4.5)	-	5.3 (1.9)	6.8 (2.5)
NexGen	34.5 (10.3)	3.0 (0.5)	2.0 (0.7)	3.9 (2.1)	4.8 (1.8)
ROCC	59.0 (8.8)	10.4 (5.4)	7.3 (2.8)	6.9 (2.0)	7.0 (1.5)
Levene's test	0.83	3.80	9.60	0.31	1.74
	n.s.	p=0.006	p=0.001	n.s.	n.s.
ANOVA	F(5,36.7)=8.38	F(5,25.1)=3.56	F(2,13.2)=9.11	F(5,40.7)=6.46	F(5,34.6)=8.55
Brown-Forsythe	p=0.000	p=0.014	p=0.003	p=0.000	p=0.000

-: fixed-bearing prosthesis; therefore no 'mobile insert' data
n.s. Not significant

between the other groups (Table 8.2).

8.3.2 Axial rotation

The NexGen group had significantly smaller femoral axial rotation compared to the Duracon group ($p = 0.000$), the Triathlon MB group ($p = 0.024$) and Triathlon FB group ($p = 0.001$). There were no differences in axial femoral rotation between the rest of the groups. The mean range of axial rotation of the insert of the NexGen patients was also significantly smaller (limited to 2.0°) than the mean range of axial rotations of the inserts of the Triathlon MB and ROCC groups ($p = 0.010$ and $p = 0.006$, respectively). There was no difference in axial insert rotation between the Triathlon and ROCC group. The mobile insert of the ROCC followed the motion of the femoral component until approximately 60° of knee flexion. Beyond 60° of knee flexion, 3 of 7 ROCC patients showed paradoxical axial rotations. The insert of the Triathlon patients followed the femoral component during the complete motion (maximum

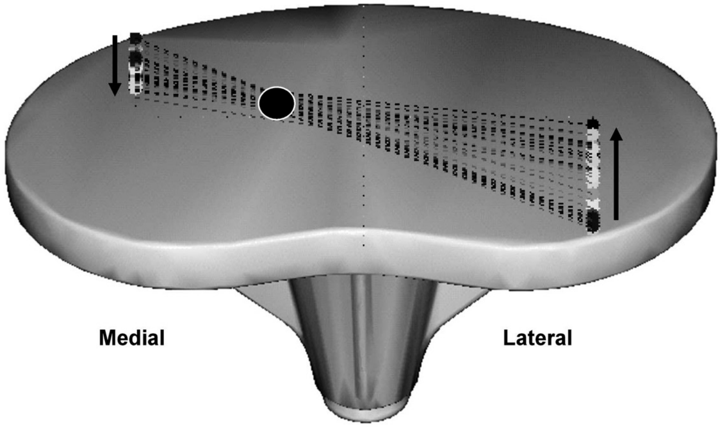

Figure 8.1: Example of a medial pivot point of axial rotation. The medial condyle moves to posterior and the lateral condyle to anterior during knee extension.

knee flexion during step-up was 80°), without showing paradoxical axial rotations.

8.3.3 Pivot point of rotation

Under the assumption that the inserts will follow the femoral component, a centrally located pivot point of axial rotation of the femoral component was expected. In all groups, except for the ROCC patients, the measured pivot point of axial rotation varied between a medial, central or lateral position. All the ROCC patients had a central point of rotation, except for one subject having a medial pivot point of axial rotation (Figure 8.1).

8.3.4 Anterior-posterior translation of the contact points

The translations of the lateral condylar were essentially anterior throughout knee extension and translations of the medial condylar mainly posterior. The ROCC patients showed most reversed anterior-posterior motions. Six of seven patients had paradoxical motions at some point. One Triathlon MB patient had paradoxical motion, namely posterior translation during extension. The NexGen, Duracon, PFC-Sigma and Triathlon FB patients showed no paradoxical anterior-posterior motions. The Duracon group had larger translations of the medial condyle compared to the PFC-Sigma group ($p = 0.021$) and the NexGen group ($p = 0.005$) and of the lateral condyle compared to the Triathlon MB group ($p = 0.015$) and NexGen group ($p = 0.003$). Between the rest of the groups, there were no significant differences in anterior-posterior translation.

8.4 Discussion

The aim of this study was to compare different total knee prostheses (multi-radius, single-radius, fixed-bearing, mobile-bearing, posterior-stabilized, cruciate retaining and cruciate sacrificing) to determine whether *in vivo* kinematics is consistently related to kinematics intended by the knee prosthesis design. According to several authors, *in vivo* knee kinematics after total knee arthroplasty is directly related to the constraints of the design of the prosthesis (Banks and Hodge, 2004a,b; Delport et al., 2006). On the other hand, several studies found aberrant and highly unpredictable kinematics, and there was no distinction in clinical results and kinematics between different types of prostheses (Delport et al., 2006; Hall et al., 2008; Hilding et al., 1996; Pandit et al., 2005; Saari et al., 2005, 2006; Snider and MacDonald, 2009). This study showed that despite kinematics being generally consistent with the kinematics intended by their design, there were no clear recognizable differences in *in vivo* kinematics between different design parameters or prostheses.

Patients with a cruciate sacrificing prosthesis (ROCC) cannot rely on the cruciate ligaments to provide stability. To compensate for this, the congruency of the insert is increased, providing more intrinsic stability between the insert and the femoral component. The increased congruency is also expected to lead to increased axial rotation of the mobile insert. This is supported by our fluoroscopic data, showing that the insert was following the femoral component until approximately 60° of knee flexion. Beyond 60° of knee flexion, diversion between the insert and the femoral component and reversed axial rotations occurred. Despite the lower congruency, the Triathlon MB group showed equal motion of the insert and femoral component during the whole range of flexion, without occurrence of reversed axial rotations. This suggests a more uniform motion in this group. A more uniform motion may reduce wear of the polyethylene, due to a reduction in shear forces at the liner interface (Blunn et al., 1997; McEwen et al., 2001).

According to knee simulator studies, the reduction in sliding distance reduces the surface area of polyethylene being worn which in turn reduces wear (McEwen et al., 2001, 2005). The cruciate retaining group (Duracon) had the largest anterior-posterior motions, without revealing any reversed femoral tibial motion patterns. This is in accordance with the intended kinematics, keeping the posterior ligament to preserve normal rollback. The retained posterior ligament is assumed to increase joint stability compared to cruciate sacrificing total knees. This assumption is supported by the Duracon group having the highest post-operative KSS knee and function scores. Possibly, this patient group had also better function pre-operatively. Pre-operative scores and function are good indicators for post-operative scores and functions. Unfortunately, pre-operative scores were not quantified for these patients.

All total knees showed comparable axial rotations of the femoral component with respect to the tibial component, except for the NexGen patients. The mobile inserts did not add additional mobility to the knee joint compared to the fixed-bearing groups. However, additional mobility was possibly not needed during the step-up motion performed. The inserts of two of the three mobile-bearing groups moved as predicted on theoretical grounds. The absence or reduced mobility in the NexGen patients makes this implant very similar to a fixed-bearing prosthesis. This absence or reduced mobility will also enhance wear of the polyethylene and could induce a higher incidence of loosening by transmitting larger forces to the bone-implant interface (Andriacchi, 1994; Blunn et al., 1997; Bottlang et al., 2006; Dennis et al., 2005; Garling et al., 2005b; Stiehl et al., 1997; Uvehammer et al., 2007).

In all three mobile-bearing prostheses used, the centrally located trunnion imposed a centrally located pivot point of rotation of the insert on top of the tibial plateau. Under the assumption that the inserts will follow the femoral component, a centrally located pivot point of axial rotation of the femoral component was expected. Only the ROCC patients had a measured central pivot point of axial rotation of the femoral component with respect to the tibial component. In the other two mobile-bearing groups, patients showed also medial and lateral pivot points of axial rotation. These deviant pivot points might be caused by low congruency between the insert and femoral component and by laxity of the surrounding ligaments (Banks and Hodge, 2004b). However, no manifest laxity was seen in these patients.

A possible limitation of this and other multicenter studies, which could explain the variability in kinematics, is patient diversity (osteoarthritis and rheumatoid arthritis), pre-operative deformities, muscle adaptations and the different surgeons (Banks et al., 2003b). It is known that surgeons are still the biggest variable in outcome after total knee arthroplasty. Factors that play a major role in dysfunction of any knee and are determined by the surgeon are frontal plane malalignment, axial malrotation of the prosthesis, sagittal overstuffing of the knee, inappropriate level of joint space, inappropriate constraint or ligamentous imbalance and poor initial fixation of the implant (Banks et al., 2003b; Callaghan, 2001; Rousseau et al., 2008).

Statistics showed that there was a significant effect of prosthetic design on all outcome parameters; however, post hoc tests showed that the NexGen group was responsible for 80% of the significant values. In this group, the range of knee flexion was much smaller, resulting in smaller anterior-posterior translations and rotations. It is not clear whether and why this patient group performed the step-up task differently.

This study showed that the *in vivo* kinematics of most included total knee prostheses were consistent with the kinematics intended by their design. However, some prostheses showed reversed or paradoxical kinematics in some parts of their functional range of motion. If the theoretical kinematics is not in accordance with the *in vivo* kinematics, the manufacture should optimize the new prosthetic design to prevent large scale polyethylene wear with subsequent prosthesis loosening. This is of importance because of the growing population of younger patients who will require an implant to function for at least two decades. Because of the high accuracy, it is recommended that fluoroscopy is used for evaluating the kinematics of new total knee prostheses before introducing the new knee worldwide on the market.

Conclusion

Despite kinematics being generally consistent with the kinematics intended by their design, there were no clear recognizable differences in *in vivo* kinematics between different design parameters or prostheses. Hence, the differences in design parameters or prostheses are not distinct enough to have an effect on clinical outcome of patients.

Chapter 9

Discussion and conclusion

9.1 Introduction

The focus of this thesis was if the *in vivo* kinematics of total knee prostheses was consistent with the kinematics intended by design and to determine the additional value of insert mobility and thus 'the sense or nonsense' of mobile-bearing knee prostheses. The added value of this thesis to the current literature is the integration of different measurement techniques. The majority of studies exploring differences in total knee prostheses include only questionnaires and radiological examinations or just knee kinematics using fluoroscopy or motion analysis. Questionnaires like the WOMAC[1], KSS[2] and SF-36[3] are not objective and accurate enough to detect potentially functional differences in total knee prostheses and therefore more objective and accurate measurement tools to detect subtle functional differences should be developed (Harrington et al., 2009). Better understanding the influence of design parameters on *in vivo* kinematics, stability and muscle activation is fundamental for improving current knee implant designs (Andriacchi et al., 1982; Banks and Hodge, 2004b; Taylor and Barrett, 2003; Wang et al., 2006). In this thesis, fluoroscopy is combined with RSA and motion analysis techniques to fully understand the *in vivo* knee kinematics beyond which can be obtained by either technique alone. In this chapter the major conclusions of this thesis are discussed and some limitations and recommendations for future research are describes.

Worldwide, there is a wide diversity of total knee prosthesis designs, including numerous mobile-bearing implants. Each implant is developed with specific properties and with a specific patient group in mind and therefore has its own theoretical advantages and disadvantages. There is a long-standing controversy on which type of total knee prosthesis provides better kinematics and clinical outcome. A huge number of kinematic studies have been performed to evaluate the performance of total knee prostheses. Total knee arthroplasty has proven to be a successful and durable solution; however, it is still not clear if the restoration of normal knee

[1] Westren Ontario and McMaster Universities index
[2] Knee Society Score
[3] Short-Form Health Survey

kinematics is possible or necessary. The fundamental goal of total knee arthroplasty is to give the patients what they need for their everyday activities: pain relief, a good post-operative range of motion and stability (Costigan et al., 2002).

9.2 Fluoroscopy

In vivo functional testing seems extremely useful in optimizing knee implant designs for better function, better fixation and improved long-term results (Andriacchi et al., 1982; Banks and Hodge, 2004b; Taylor and Barrett, 2003). Three-dimensional (3D) fluoroscopic analyses is the most accurate measurement technique to examine the *in vivo* kinematics of total knee prostheses under weight-bearing activities (Banks et al., 1997b; Dennis et al., 1996; Garling et al., 2005a; Stiehl et al., 1999). Besides the big advantage of the high accuracy of fluoroscopy, there are also a few drawbacks. Firstly, the small field of view confines the analysis to only a single joint. Secondly, a mayor difficulty is to measure weight-bearing knee kinematics other than stair ascent and descent due to the rigid fluoroscopic equipment. Activities such as gait cannot be performed easily because the knee moves out of the field of view. Gait is the most performed every day activity and therefore to study knee kinematics, fluoroscopy studies evaluating gait would be preferred. In our measurement set-up it was not possible to study gait because of the rigid c-arm. Currently, the University of Florida and the University of Zurich are developing movable c-arms by which the number of activities can be enlarged and gait can also be studied. Thirdly, a drawback of fluoroscopy is the patient exposure to radiation. Despite the exposure being very low, patients often experience problems with other joints, and are also under medical treatment for additional disorders, getting multiple radiological examinations a year.

Despite the high accuracy of fluoroscopy, in clinical studies large enough patient groups have to be included to reach sufficient statistical power. Unfortunately, the number of patients receiving total knee prostheses in our hospital was too small to create large patient groups. Approximately 40 patients a year are considered for total knee arthroplasty and not all patients are suited to participate in a clinical study.

Furthermore, the excessive post-processing of the fluoroscopic images per patient (3 days per patient) discourages large patient groups. Further automating the post-processing software would solve this problem (A.H. Prins, thesis 2012). Another software and measurement improvement would be to know the starting orientation of the mobile insert. Using the tantalum markers inserted in the polyethylene, change in orientation of the insert with respect to the orientation of the insert in the reference image can be calculated. Knowing the starting orientation would make it possible to model the insert between the tibial and femoral component and calculate contact points, impingement points and the accurate anterior-posterior translation patterns of the femoral component on the insert.

9.3 Kinematics

This thesis showed that *in vivo* kinematics of most included total knee prostheses were consistent with the kinematics intended by their design. However, some prostheses showed reversed or paradoxical kinematics in parts of their functional range of motion. If the theoretical kinematics is not in accordance with the *in vivo* kinematics, the manufacture should optimize the new prosthetic design to prevent excessive polyethylene wear with subsequent prosthesis loosening. This is of importance because of the growing population of younger patients who will require an implant to function for at least two decades (**Chapter 8**).

The variability in kinematics, seen in the literature as well as in this thesis, could be explained by patient diversity (osteoarthritis and rheumatoid arthritis), pre-operative deformities, muscle adaptations and the different surgeons (Banks et al., 2003a). It is known that surgeons are still the largest variable in outcome after total knee arthroplasty. Factors that play a major role in dysfunction of any knee, and are related to the surgical procedure, are frontal plane malalignment, axial malrotation, sagittal overstuffing of the knee, inappropriate level of joint space, inappropriate constraint or ligamentous imbalance and poor initial fixation of the implant (Banks et al., 2003b; Callaghan, 2001; Nozaki et al., 2002; Rousseau et al., 2008).

9.4 Muscle activations

Knowledge of the muscular control of knee prosthesis provides insight into the integration of the prosthesis within the musculo-skeletal system. After total knee arthroplasty, rheumatoid arthritis patients showed lower net knee joint moment and higher co-contraction than healthy controls indicating avoidance of net joint load and an active stabilization of the knee joint (**Chapter 3**). Anticipatory stabilization and co-activation are mechanisms to protect the soft tissue from external loads by increasing the stiffness of the knee (Andriacchi, 1994). 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 micromotion of the tibial component (Grewal et al., 1992) (**Chapter 4**).

The extra degree of freedom in mobile-bearing knees might require higher muscle activity levels of the extensor (quadriceps) and flexor (hamstrings) muscles to stabilize the knee. However, in this thesis, mobile-bearing and fixed-bearing groups had the same co-contraction levels, although coordination in patients with a fixed-bearing was closer to healthy controls than patients with mobile-bearing total knee prostheses (**Chapter 3**). Muscle activity timing which was different for the mobile-bearing and fixed-bearing groups, may express compensation by coordination (**Chapter 3**). Furthermore, muscle activation did not change in the first two post-operative years (**Chapter 5** and **6**). Therefore, to prevent problems caused by excessive muscle activations and co-activations, rehabilitation programs for patients with total knee prostheses should include besides muscle strength training, elements of muscle-coordination training.

9.5 Patella

Despite the patella being an important part of the knee joint, the patella was not included in this thesis due to practical issues with the fluoroscopic set-up. The out-of-plane inaccuracy and visualisation problems of the patella in the fluoroscopic images made it impossible to include the patella in the measurements performed. Osteoarthritis and rheumatoid arthritis cause changes not only in the knee joint but also on the back of the patella. If the patella is damaged, it needs to be resurfaced during total knee arthroplasty. The patella (resurfaced or not) interacts with the patellar groove of the femoral component. Malalignment of the femoral component in a more internally or externally rotated position will have an effect on patellar tracking and knee kinematics. Furthermore, reversed axial rotations seen after total knee arthroplasty can cause patellofemoral instability and maltracking of the patella (Dennis et al., 2004, 2005; Most et al., 2003). In turn, this will cause increased contact pressure at the lateral aspect of the patella and influences the quadriceps moment arm (Andriacchi et al., 1997; Andriacchi and Hurwitz, 1997; Most et al., 2003). Therefore, in future studies evaluating kinematics and clinical outcome of total knee prostheses, it is recommended to also take the patella into account.

9.6 Motion of the mobile insert

High congruency between the insert and the femoral component in combination with free rotation of the mobile insert is assumed to be beneficent for the longevity of the prosthesis by reducing multidirectional wear on the femoral aspect of the insert and friction at the bone-implant interface. However, in **Chapter 4** and **5**, high congruency of the insert seems to lead to undesired restrictions of motions of the femoral component which in turn might be a disadvantage for the functioning and long-term survival of that specific total knee prosthesis design. At lower knee flexion angles, the femoral component is obstructed by the highly congruent insert and is not able to move freely. This leads to high stresses at the insert which will be transferred to the bone-implant interface.

Furthermore, this thesis shows that high congruency does not guarantee adequate insert rotation. Reversed and divergent axial rotations with increasing knee flexion were seen in patients with the ROCC total knee prosthesis. The single-radius Triathlon total knee prosthesis including a less congruent insert showed preferable axial rotation of the insert compared to that of the high congruent ROCC total knee prosthesis (**Chapter 4**, **5**, **8**). Based on these results, an optimal level of congruency between the insert and femoral component should be found.

The inserts of two (Triathlon and ROCC) of the three mobile-bearing groups moved as predicted on theoretical grounds and remained mobile several years post-operatively. The comparable axial rotations of the insert and the femoral component supports the assumption of redistributing the knee motion to two articulating interfaces with a more linear motions at each interface leading; pure rotation at the lower surface and anterior-posterior motions at the upper surface. The absence or reduced mobility seen in one of the mobile-bearings knees makes this implant very similar to a fixed-bearing prosthesis (**Chapter 6**). This absence or reduced mobility will also enhance wear of the polyethylene and could induce a higher incidence of loosening by transmitting larger forces to the bone-implant interface (Andriacchi, 1994; Bottlang et al., 2006; Blunn et al., 1997; Dennis et al., 2005; Stiehl et al., 1997; Uvehammer et al., 2007; Garling et al., 2005c). In this thesis, the mobile inserts did not add additional mobility to the knee joint compared to the fixed-bearing groups. However, additional mobility was possibly not necessary during the dynamic motions performed.

Chapter 7 shows early migration in 33% of the mobile-bearing group versus 9% in the fixed-bearing group. This indicates that early migration of the tibial component is worse in the mobile-bearing group. Despite the mobile insert was following the femoral component during motion, and therefore performed as intended, no kinematic advantages of the mobile-bearing total knee prosthesis were seen. The fixed-bearing knee performed as good as the mobile-bearing knee and maybe even slightly better based on less paradox and reversed motions and less early migrations.

9.7 Final Conclusions

In this thesis, fluoroscopy was combined with RSA and motion analysis techniques to fully understand the *in vivo* knee kinematics beyond which can be obtained by either technique alone. Results demonstrate that the integration of different measurement techniques was indeed of great value to comprehend the *in vivo* knee kinematics.

This thesis showed that the *in vivo* kinematics of most included total knee prostheses were consistent with the kinematics intended by their design. However, some prostheses showed reversed or paradoxical kinematics in some parts of their functional range of motion. Because of the high accuracy, it is recommended that fluoroscopy is used for evaluating the kinematics of new total knee prostheses before introducing it to the market.

Based on this thesis, it was also possible to determine the additional value of insert mobility and thus 'the sense or nonsense' of mobile-bearing knees. It is concluded that a mobile-bearing insert in single-radius total knee prostheses is redundant and will not lead to additional benefits. Finally, at the current time there is no compelling reason for the widespread use of mobile-bearing total knee prostheses over successful fixed-bearing total knee prostheses either in terms of improved kinematics, early migration, clinical and radiological success.

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Summary

The focus of this thesis was if the *in vivo* kinematics of total knee prostheses was consistent with the kinematics intended by design and to determine the additional value of insert mobility and thus ‘the sense or nonsense’ of mobile-bearing knee prostheses. The added value of this thesis to the current literature is the integration of different measurement techniques. Fluoroscopy is combined with RSA and motion analysis techniques to fully understand the *in vivo* knee kinematics beyond which can be obtained by either technique alone. Results demonstrate that the integration of different measurement techniques was indeed of great value to comprehend the *in vivo* knee kinematics.

Knowledge of the muscular control of knee prosthesis provides insight into the integration of the prosthesis within the musculo-skeletal system. After total knee arthroplasty, rheumatoid arthritis patients showed lower net knee joint moment and higher co-contraction than healthy controls indicating avoidance of net joint load and an active stabilization of the knee joint (**Chapter 3**). Anticipatory stabilization and co-activation are mechanisms to protect the soft tissue from external loads by increasing the stiffness of 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 micromotion of the tibial component (**Chapter 4**). Muscle activation did not change in the first two post-operative years (**Chapter 5** and **6**). Therefore, to prevent problems caused by excessive muscle activations and co-activations, rehabilitation programs for patients with total knee prostheses should include besides muscle strength training, elements of muscle-coordination training.

High congruency between the insert and the femoral component in combination with free rotation of the mobile insert is assumed to be beneficent for the longevity of the prosthesis by reducing multidirectional wear on the femoral aspect of the insert and friction at the bone-implant interface. However, high congruency of the insert seems to lead to undesired restrictions of motions of the femoral component which in turn might be a disadvantage for the functioning and long-term survival of that specific total knee prosthesis design (**Chapter 4** and **5**).

Furthermore, high congruency does not guarantee adequate insert rotation. Reversed and divergent axial rotations with increasing knee flexion were seen in patients with the ROCC total knee prosthesis. The single-radius Triathlon total knee prosthesis including a less congruent insert showed preferable axial rotation of the insert compared to that of the high congruent ROCC total knee prosthesis (**Chapter 4**, **5**, **7**, **8**). Based on these results, an optimal level of congruency between the insert and femoral component should be found.

Early migration in 33% of the mobile-bearing group versus 9% in the fixed-bearing group indicates that early migration of the tibial component is worse in the mobile-bearing group. It implies that the mobile insert does not improve initial fixation of the prosthesis to the bone, as intended by mobile-bearing designs (**Chapter 7**). Despite the mobile insert was following the femoral component during motion, and therefore performed as intended, no kinematic advantages of the mobile-bearing total knee prosthesis were seen.

In vivo kinematics of most included total knee prostheses were consistent with the kinematics intended by their design (**Chapter 8**). However, some prostheses showed reversed or paradoxical kinematics in some parts of their functional range of motion. At the current time there is no compelling reason for the widespread use of mobile-bearing total knee prostheses over successful fixed-bearing total knee prostheses either in terms of improved kinematics, early migration, clinical and radiological success.

Samenvatting (Dutch summary)

Het doel van dit proefschrift was om vast te stellen of de *in vivo* kinematica van totale knieprotheses consistent is met de kinematica zoals bedoeld door het concept. Tevens wilden we nagaan of een beweegbaar lager toegevoegde waarde heeft voor patiënten en dus 'de zin of onzin' van totale knieprotheses met een beweegbaar lager. De toegevoegde waarde van dit proefschrift ten opzichte van de al bekende literatuur is de integratie van verschillende meetsystemen. Fluoroscopie (röntgenvideo) is gecombineerd met RSA (3D microbewegingen van implantaten) en bewegingsanalysetechnieken om de *in vivo* kinematica van de knie volledig te kunnen begrijpen, meer dan elk systeem afzonderlijk kan doen. De resultaten laten zien dat de integratie van de verschillende meetsystemen inderdaad van grote waarde was om de *in vivo* kinematica van de knie volledig te kunnen begrijpen.

Kennis over spieractiviteit rond totale knieprotheses geeft inzicht in de integratie van de prothese in het spierskeletsysteem. Na totale knie-arthroplastie lieten patiënten met reumatoïde artritis lagere netto momenten rond het kniegewricht zien en meer cocontractie in vergelijking met de gezonde controlegroep. Dit impliceert dat de patiënten belasting van het kniegewricht ontwijken en dat er meer actieve stabilisatie (door het aanspannen van spieren) is van het kniegewricht (**Hoofdstuk 3**). Anticiperende stabilisatie en cocontractie zijn mechanismen die de weke delen beschermen tegen externe krachten door stijfheid van de knie te laten toenemen. Echter, bewegen met overbodige spieractiviteit en cocontractie is inefficiënt en kan leiden tot grote krachten tussen het bot en prothese. Deze krachten kunnen leiden tot microbewegingen van de onderbeencomponent (**Hoofdstuk 4**).

Het gebruik van de spieren bleef onveranderd in de eerste twee jaar na operatie (**Hoofdstuk 5** en **6**). Zodoende, om problemen door overbodige spieractiviteit en cocontractie te voorkomen, dienen revalidatieprogramma's voor patiënten met een totale knieprothese naast spierkrachttrainingen ook spiercoördinatietrainingen te bevatten.

Er wordt aangenomen dat hoge congruentie tussen het beweegbare lager en bovenbeencomponent in combinatie met vrije rotatie van het beweegbare lager, voordelen heeft voor de levensduur van de prothese. Er zou sprake zijn van minder slijtage op het bovenste vlak van het beweegbare lager en minder wrijvingskrachten tussen bot en prothese. Echter, hoge congruentie van het beweegbare lager lijkt te leiden tot ongewenste beperkingen van de beweging van de bovenbeencomponent wat weer nadelig is voor het functioneren en de langetermijnoverleving van die specifieke totale knieprothese (**Hoofdstuk 4** en **5**).

Bovendien, hoge congruentie tussen bovenbeencomponent en beweegbaar lager garandeert geen adequate lagerrotatie. Omgekeerde en uiteenlopende axiale rotaties met toenemende kniebuiging werd gezien in patiënten met een ROCC totale knieprothese. De Triathlon totale knieprothese met enkele radius heeft een minder congruent beweegbaar lager maar liet axiale rotatie zien die te verkiezen is boven die van de hoog congruente ROCC totale knieprothese (**Hoofdstuk 4**, **5**, **7**, **8**). Op basis van deze resultaten kan geconcludeerd worden dat een optimaal niveau van congruentie tussen beweegbaar lager en bovenbeencomponent nog gevonden moet worden.

Vroege migratie in 33% van de knieprotheses met een beweegbaar lager ten opzichte van 9% in de knieprotheses met een vast lager geeft aan dat vroege migratie een groter probleem is in knieprotheses met een beweegbaar lager. Het impliceert dat het beweegbare lager niet de initiële fixatie verbeterd tussen de prothese en het bot, wat wel de bedoeling is volgens het concept (**Hoofdstuk 7**). Ondanks het feit dat het beweegbare lager de bovenbeencomponent volgt tijdens beweging, en dus functioneert zoals bedoeld, werden er geen kinematische voordelen gezien bij totale knieprotheses met een beweegbaar lager.

In vivo kinematica van de meeste totale knieprotheses gemeten in dit proefschrift was consistent met de kinematica zoals bedoeld door het concept (**Hoofdstuk 8**). Echter, sommige protheses lieten omgekeerde of paradoxale kinematica zien in bepaalde stukken van hun functionele bewegingsbereik. Op dit moment is er geen overtuigende reden voor het wereldwijd gebruik van de totale knieprothese met een beweegbaar lager ten opzichte van de succesvolle totale knieprothese met een vast lager, in termen van verbeterde kinematica, vroege migratie, klinische en radiologische succes.

List of publications

Wolterbeek N, Garling EH, Mertens BJA, Nelissen RGHH, Valstar ER (2011). Kinematics and early migration in single-radius mobile- and fixed-bearing total knee prostheses. *Submitted*

Wolterbeek N, Garling EH, van der Linden HMJ, Nelissen RGHH, Valstar ER (2011). Integrated assessment techniques for linking kinematics, kinetics and muscle activation to early migration: A pilot study. *Submitted*

Wolterbeek N, Garling EH, Mertens BJA, van der Linden HMJ, Nelissen RGHH, Valstar ER (2011). Insert mobility in a high congruent mobile-bearing total knee prosthesis. *Submitted*

Wolterbeek N, Nelissen RGHH, Valstar ER (2011). No differences in *in vivo* kinematics between six different types of knee prostheses. *Knee Surgery, Sports Traumatology, Arthroscopy* Accepted.

Zürcher AW, Wolterbeek N, Valstar ER, Nelissen RGHH, Pöll RG, Harlaar J (2011). The Femoral Epicondylar Frame to track femoral rotation in optoelectronic gait analysis. *Gait and Posture* 33(2), 306-308.

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Curriculum Vitae

Nienke Wolterbeek was born on March 15, 1981 in Amsterdam, The Netherlands. After graduating from the 'Spinoza Lyceum' in Amsterdam in 1999 she started her Human Movement Science studies in 2000 at the 'Vrije Universiteit' of Amsterdam. She specialized in Human Movement in the context of Rehabilitation. Her Master's project at the Motion Lab of the VU Medical Center was a joint effort between the Department of Orthopaedics of the Leiden University Medical Center and the Department of Rehabilitation Medicine of the VU Medical Center under supervision of dr. ir. J. Harlaar, dr. C.A.M. Doorenbosch and dr. E.H. Garling.

After graduation in 2004, she began to work as a junior researcher at the Motion Lab of the Department of Rehabilitation Medicine of the VU Medical Center. In 2006 she started a Ph.D.-project at the Biomechanics and Imaging Group at the Department of Orthopaedics at the Leiden University Medical Center (Head: prof. dr. R.G.H.H. Nelissen). This Ph.D.-project was part of the European DeSSOS-project. The objective of the DeSSOS-project was to develop decision support software for orthopaedic surgery so as to reduce variability in surgical outcome and maximise the longevity of orthopaedic devices and in particular, total knee replacements.

After finishing her Ph.D.-project, she started working as research coordinator at the Department of Orthopaedics at the St. Antonius Hospital in Nieuwegein and Utrecht.

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