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Leiden  
The Netherlands

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

Garling, E.H.

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# **Objective Clinical Performance Outcome of Total Knee Prostheses**

**A study of mobile bearing knees using fluoroscopy,  
electromyography and roentgenstereophotogrammetry**

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Garling, E.H.

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# **Objective Clinical Performance Outcome of Total Knee Prostheses**

**A study of mobile bearing knees using fluoroscopy,  
electromyography and roentgenstereophotogrammetry**

PROEFSCHRIFT

ter verkrijging van  
de graad van Doctor aan de Universiteit Leiden,  
op gezag van Rector Magnificus prof.mr. P.F. van der Heijden,  
volgens besluit van het College voor Promoties  
te verdedigen op donderdag 13 maart 2008  
klokke 15.00 uur

door  
**Eric Harald Garling**  
geboren te Alkmaar  
in 1972

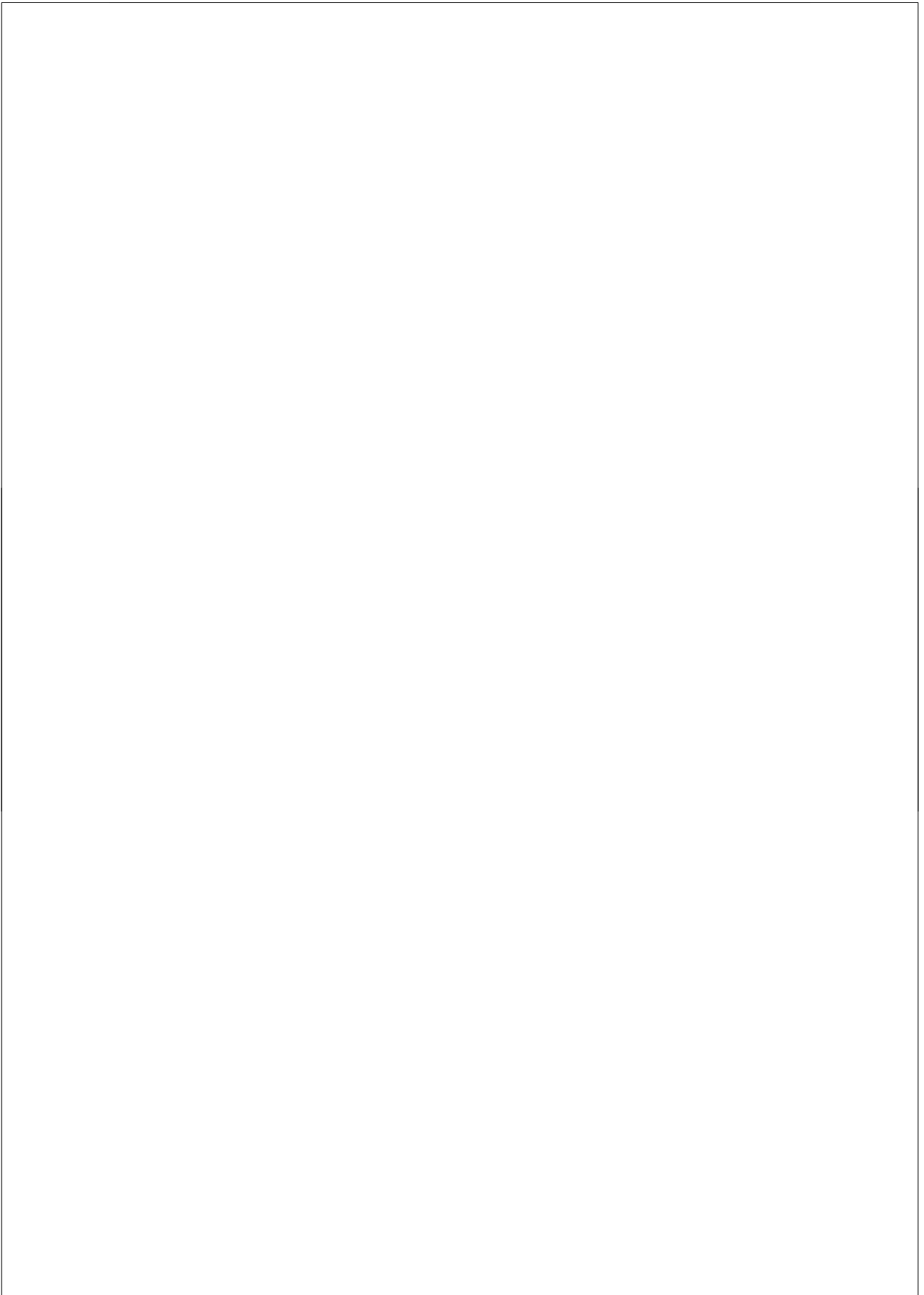
### **Promotiecommissie**

Promotor: Prof. dr. R.G.H.H. Nelissen  
Copromotor: Dr. ir. E.R. Valstar  
Referent: Prof. dr. A. van Kampen (UMC St. Radboud, Nijmegen)  
Overige leden: Dr. S. Banks (University of Florida, USA)  
Prof. dr. F. Catani (Istituto Orthopedici Rizzoli, Bologna)  
Prof. dr. ir. J.H.C. Reiber  
Dr. H.E.J. Veeger (Vrije Universiteit, Amsterdam)

*‘Wird der centrale und periphere Stumpf eines reserzirten Gelenkes mit je einem in die Markhöhle eingerammten Elfenbeincylinder armirt, so kann durch ein zwischen den Elfenbeincylindern eingeschaltetes Charnier, wie bei den orthopädischen Apparaten unserer Instrumentenmacher, die Feststellung des Charniers die inamovible Fixation der Fragmente gewährleisten, die Beweglichkeit desselben arthroplastischen Zwecken dienen’.*

Temistophores Gluck, 1890

*Voor mijn dames*

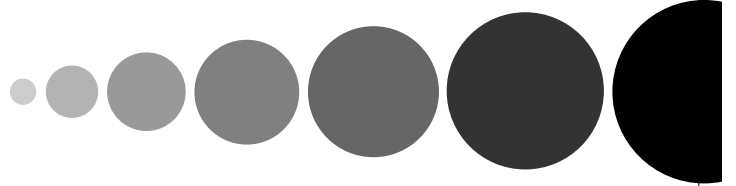


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# Chapter 1



## **Introduction**

## **1.1 Objective evaluation tools**

### **1.1.1 Background**

Although, the total of knee prostheses designs available for the surgeon to implant is almost unlimited, every year numerous new knee prostheses are released to the market. However, historic data has shown that knee prostheses have a 10-15 year survival of over 90% (Robertsson, 2001; Keating et al., 2002), with some reports of survivorship as high as 98% at 20 years (Gill et al., 1999; Buechel, 2002). Although these survival rates of total knee prostheses are impressive, there is still a need to improve function and fixation, to reflect the increasing activity demands of a growing population of (younger) patients. Wear has been identified as one of the critical factors limiting the long-term success of total knee prostheses in the past (Wimmer & Andriacchi, 1997). To minimise wear, mobile bearing knees have been developed. The defining feature of a 'mobile bearing knee' is the presence of a moving polyethylene bearing that articulates with both the femoral condyle and the tibial tray, hereby dispersing contact stresses over a greater area, thus potentially reducing wear. The only mobile-bearing knee prosthesis with long-term results is the LCS rotating-platform prosthesis (J&J DePuy, Warsaw, Indiana, USA; Figure 3A, Chapter 2). This design shows survival rates of 98.3% at 18 years (Buechel et al., 2002; Buechel, 2004, Stiehl, 2002).

In order to advance the current state of the art in total knee arthroplasty and to comply with strict regulatory requirements, there are a series of challenges that need to be addressed. New total knee prostheses will have to focus on improving functionality without compromising longevity. Since the differences between knee prostheses are small, this stresses a significant challenge in appropriate, objective and accurate evaluation tools to assess important clinical performance outcome parameters like kinematics, muscle activity and micromotion.

### **1.1.2 Kinematics**

Knowledge regarding joint and segment kinematics is important for the understanding of normal movement and function, as well as to target clinical musculoskeletal or postoperative problems. Several studies have related the variations in (abnormal)

kinematic patterns after TKA to the design of the articulating surfaces (Dennis et al. 1998; Kärrholm et al., 1994; Nilsson et al., 1997) and the aetiology of prosthetic loosening (Hilding et al., 1995). The most widely accepted non-invasive method to study knee kinematics is stereophotogrammetry using skin-mounted markers (Leardini et al., 2005). However, soft tissue and structures surrounding the knee conceal the actual underlying kinematics (Della Croce et al., 2005; Luchetti et al., 1998). To avoid the error introduced by soft tissue artefacts in kinematic analyses, kinematic data can be obtained via invasive techniques (Ramsey & Wretenberg, 1999; Fuller et al., 1997), exoskeletal attachment systems (Sati et al., 1996a; Ganjikia et al., 2000), computed tomography (Hagemeister et al., 1999), magnetic resonance imaging (Patel et al., 2004), or elimination of this error through mathematical correction (Sati et al., 1996b; Luchetti et al., 1998). However, not all of these techniques are applicable to study TKA kinematics because of disadvantages like risk of infection, pain, loss in freedom of movement, high exposure to radiation, or the inaccuracy of the method and are therefore only a valuable tool for *in vitro* studies. Fluoroscopy has been used in numerous studies for assessing knee arthroplasty kinematics. This technique matches virtually projected boundaries (contours) of a 3D model of the prosthesis onto the actually detected contours of the prosthesis in the fluoroscopic roentgen image.

Fluoroscopic analyses of various mobile-bearing total knee prostheses have demonstrated already numerous kinematic patterns of the femoral component with respect to the tibial component (Banks et al., 2003; Callaghan et al., 2000; Dennis et al., 1997; Saari et al., 2003; Stiehl et al., 1997; Walker et al., 2002). However, it remains unclear if and how the polyethylene bearing actually moves in mobile-bearing knees with respect to the tibial component during dynamic activities. Most kinematic studies of the mobility of the mobile bearing have been conducted under *in vitro* conditions using cadavers (D'lima et al., 2000; Lewandowski et al., 1997; Stukenborg et al., 2002) or under non-invasive *in vivo* conditions using gait analysis (Andriacchi et al., 1982; Catani et al., 2003). *In vitro* simulation techniques are practical to set-up but the results are not a true resemblance of *in vivo* kinematics. Therefore, the *in vivo* kinematics of a mobile bearing needs to be assessed. Since the polyethylene mobile bearing component can be visualised in roentgen images by using tantalum beads, a marker based fluoroscopic technique needs to be developed and validated.



### **1.1.3 Muscle activity**

Surface electromyography (EMG) is an objective technique to assess the activity of muscles surrounding the knee. Since mobile bearing knees have a polyethylene bearing that articulates with both the femoral condyle and the tibial tray, there is an increased dependence upon preserved ligaments and active structures to provide stability. Therefore, one can hypothesize that the muscle groups surrounding the knee should show more activity in patients with a mobile bearing prosthesis compared to patients with a fixed bearing prosthesis. By co-contracting the agonist and antagonist muscle groups surrounding the knee one could increase joint instability (Akjaer et al., 2003). Co-contraction of agonist and antagonist muscle groups is also a common strategy adopted to reduce strain and shear forces at the joint. However, it also increases joint torque and axial load (O'Conner, 1993). These larger forces, resisted by the ligaments in the intact knee, are transmitted at the bone-component interface. This might influence the micromotion of the tibial components and therefore long term survival of the components (Grewal et al., 1992). A better understanding of the differences in function between knee prostheses can be gathered by assessing the activity and co-contraction of muscles surrounding the knee after arthroplasty.

### **1.1.4 Micromotion**

All prostheses will become loose after a period of time due to a progressive micromotion of the prosthesis. This micromotion of prostheses can be very accurately assessed using Roentgen Stereophotogrammetric Analysis (RSA). RSA can be used to assess prosthetic stability with a high accuracy (Ryd, 1986; Selvik, 1989; Valstar, 2001; Valstar et al., 2000). The value of RSA is -besides high accuracy- its predictive value for future prosthesis loosening (Freeman and Plante-Bordeneuve, 1994; Kärrholm et al., 1994; Ryd et al., 1995). On theoretical grounds one would expect less micromotion of mobile bearing designs compared to fixed bearing designs. Especially the better wear characteristics and the assumption that torque and shear forces in a mobile bearing prosthesis will be better dissipated from the prosthesis-bone interface by the motion of the bearing would express this expectation (Buechel and Pappas, 1990; Goodfellow and O'Connor, 1992; Callaghan et al., 2001).

Cemented fixation of the components is still the most frequently used way of fixation. The advantages of a cemented design are the immediate implant stability, and the fact that the cement will act as a barrier for wear particles migration into the bone-prosthesis interface. Advantages of cement less designs are that more bone is preserved, which is of special importance to younger patients (Hofman et al., 2002), and that peri-prosthetic fracture treatment can be performed more easily, which is important to the elderly patients. The addition of a calcium phosphate coating on prosthetic components improves the bone-prosthesis fixation compared to non-cemented and uncoated components (Nelissen et al., 1998). The influence of component design (fixed or mobile) and fixation method (cemented, coated, non-coated) on micromotion and consequently future prosthesis loosening needs to be assessed.

Definite conclusions about the function and fixation of current concepts and new designs should be drawn only by looking at experimental results from *in vivo* studies conducted with validated objective methods accurate enough to detect the claimed features.

## 1.2 Aim of this thesis

The aim of this thesis is to assess with accurate and objective methods the function and fixation of total knee prostheses with special emphasis on mobile bearing total knee designs.

## 1.3 Outline of the thesis

In **Chapter 2**, a short introduction to the anatomy of the knee and how a healthy knee joint functions is given. Osteoarthritis and knee arthroplasty as one of its interventions to treat osteoarthritis is introduced. Also the current concepts in mobile bearing knee prostheses are described in more detail.



In **Chapter 3**, a marker based fluoroscopic technique is validated that is able to accurately estimate the pose of an implant or bone represented by tantalum markers using single plane roentgen images or fluoroscopic images. In **Chapter 4** the *in vivo* motion of the tibial insert relative to the tibial base plate in a mobile bearing knee is assessed by using this fluoroscopy technique. The purpose of this study is to assess the tibiofemoral kinematics and the *in vivo* axial rotation of the polyethylene bearing of a rotating platform total knee design.

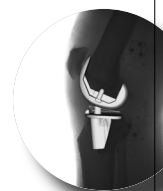
In **Chapter 5** the problem of soft tissue artefacts in gait analysis is assessed by using the fluoroscopic technique. Two external marker fixation methods are compared during a step-up task and the effects of the soft tissue artefacts on joint kinematics are quantified.

In **Chapters 6** and **7** gait analysis was used to identify adaptations of the patients following mobile bearing arthroplasty and to identify differences between patients with mobile bearing knee prostheses, posterior stabilised prostheses and control subjects regarding electromyography levels of the muscles surrounding the knee and co-activation patterns.

In **Chapter 8** through **10** Roentgen Stereophotogrammetric Analysis is used to assess the influence of fixation method and articulating surface design on the amount of micromotion. In **Chapter 8** the effect of augmenting a peripatite coating on the tibial stem on the micromotion of the tibial tray is assessed in an osteoarthritic patient group. Subsequently, in **Chapter 9** the effect of this peripatite coating on the micromotion of tibial components in a rheumatoid arthritis patient group is assessed. In **Chapter 10**, the three-dimensional micromotion of the tibial components is assessed in a prospective randomised RSA study comparing cemented fixed bearing and a mobile bearing total knee prosthesis in a predominantly rheumatoid arthritis patient group.

In **Chapter 11** the retrieved articular surfaces of nine total knees are analysed using scanning electron microscopy. Issues concerning wear of polyethylene and corrosion of metal prosthetic components are discussed.

**Chapter 12** provides a general discussion and conclusion of the work presented in this thesis. Furthermore, recommendations and some directions for future research are given.



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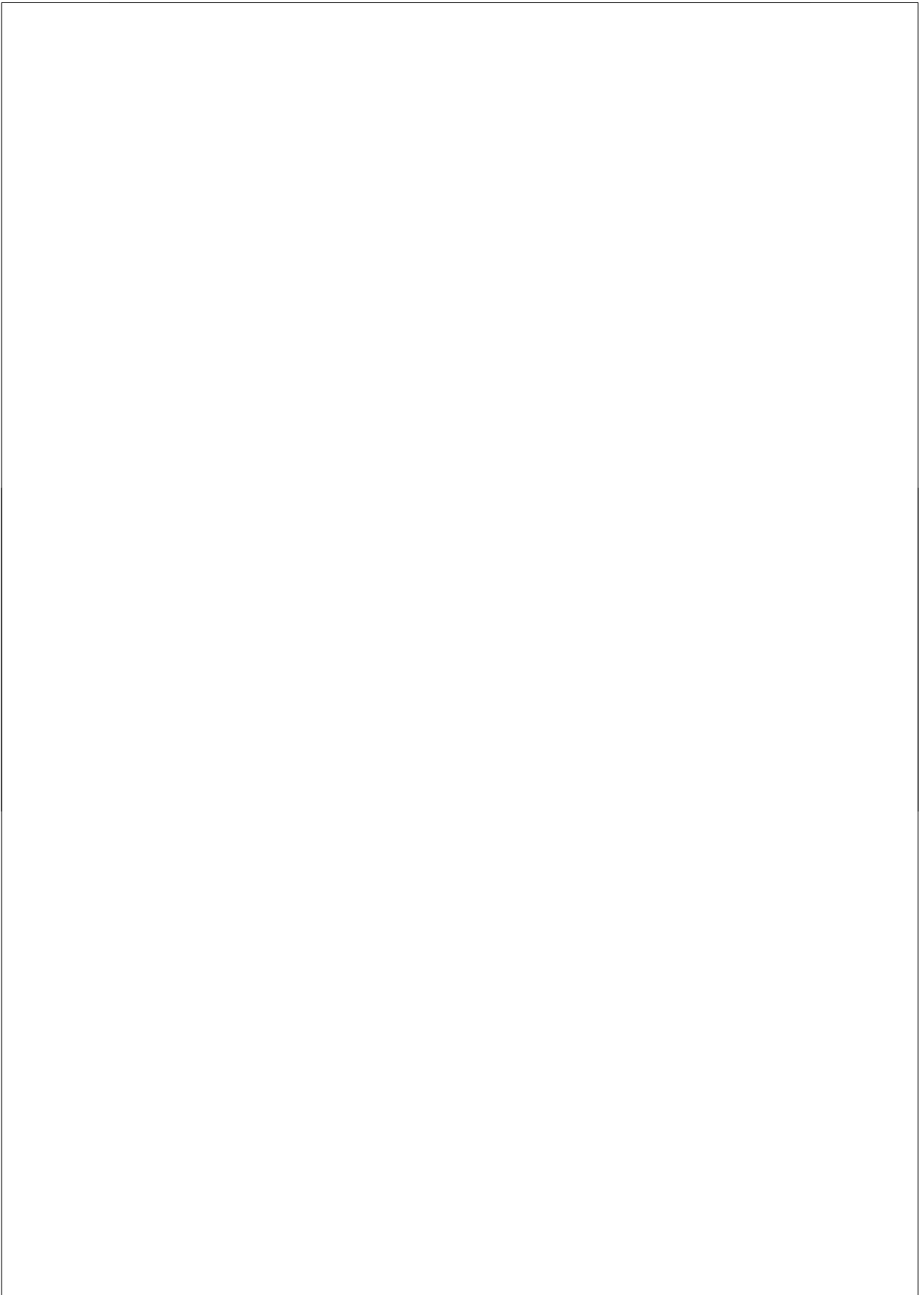
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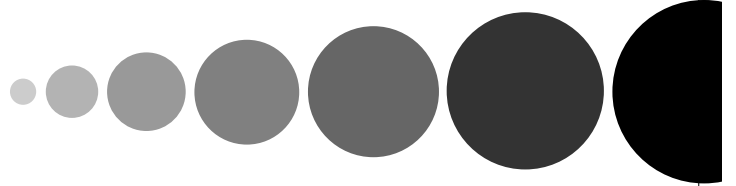
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# Chapter 2



**Knee anatomy,  
function and disorder**

## 2.1 Anatomy of the knee joint

The bony skeleton of the lower limb consists of the femur, tibia, fibula, patella and the bones of the foot (Figure 1). Each bone consists of relatively hard cortical bone externally and spongy bone internally. Posterior of the distal femoral bone end, there are two condyles. Each is roughly spherical in shape and one is medial and the other lateral of the central notch. The femoral condyles touch or articulate on the proximal tibial bone end. The tibial surface is mostly a plateau with a slightly concave medial depression and a slightly convex lateral surface, separated by central area prominences.

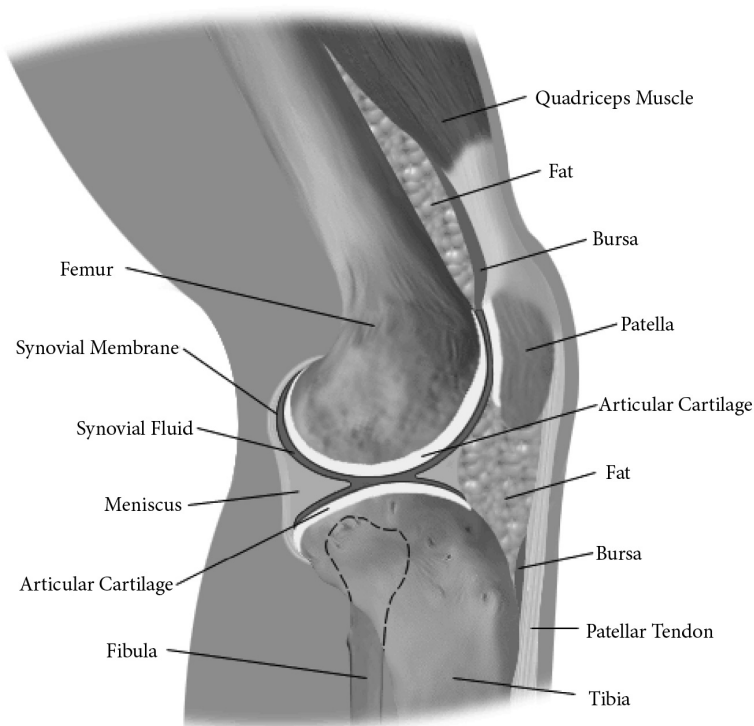


**Figure 1.** Anatomy of the knee. Source: [www.rush.edu/rumc/images/ei\\_0276.gif](http://www.rush.edu/rumc/images/ei_0276.gif)

The knee joint consists of a patello-femoral articulation and a tibio-femoral articulation. In this joint, the areas of inter-bone contact of the femur, tibia and patella

are covered in cartilage. Cartilage has a very low coefficient of friction and secretes a water lubricant under pressure. Menisci in the medial and lateral compartments of the knee provide a cushion between the articulating surfaces of the femur and the tibia.

The quadriceps tendon inserts into the proximal border of the patella and the distal apex of the patella is connected to the anterior aspect of the proximal tibia at the tibial tuberosity by the patellar ligament. The patella tracks in the trochlear groove of the femur during knee flexion and extension. The synovial membrane regulates and contains the lubricating synovial fluid of the knee and the tibia and femur are connected by ligaments.

The ligaments maintain knee stability and guide the motion of the femur relative to the tibia. They connect the tibia to the femur and transfer load across the joint space and protect the knee. The four primary ligaments of the knee are the cruciate or 'crossing' ligament pair in the mid-sagittal plane of the joint and the collateral ligament pair (medial and lateral).

Fibres of the anterior cruciate ligament (ACL) pass postero-laterally from its distal end attachment on the anterior aspect of the proximal tibia to its proximal end attachment on the medial aspect of the lateral femoral condyle (Figure 2). The posterior cruciate ligament (PCL) links the posterior of the tibial plateau to the antero-lateral aspect of the medial femoral condyle.

The anterior muscles of the knee act primarily as knee extensors. The quadriceps femoris muscle is the principle muscle involved in knee extension. This muscle can be divided into four distinct parts: the rectus femoris, vastus medialis, vastus lateralis, and the vastus intermedius. All four parts of this muscle come together to insert on the proximal edge of the patella, which then transfers their action, by way of the patellar tendon, to the tibia.

The principle muscles involved in knee flexion are the hamstring muscle group. This group is comprised of the biceps femoris, semitendinosus, and the semimembranosus muscles. Their insertion occurs on the proximal tibia and head of the fibula. The biceps femoris muscle has an additional action of externally rotating the tibia. While the semitendinosus and semimembranosus muscles also have an additional role of internally rotating the tibia. Other muscles participating in knee flexion and internal rotation are the sartorius, and gracilis muscles. The popliteus



muscle also serves to internally rotate the knee in a non-weight bearing position. Additional muscles involved in isolated knee flexion include the gastrocnemius and plantaris muscles.

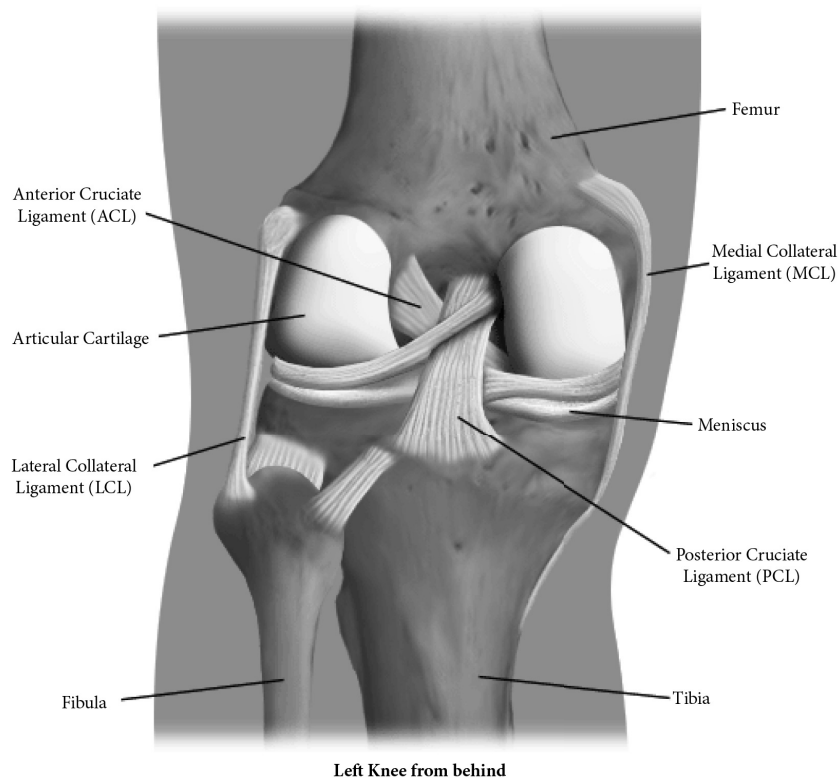


**Figure 2.** Knee joint ligaments. Source: [www.summithealth.org/greystone\\_images/es\\_0277.gif](http://www.summithealth.org/greystone_images/es_0277.gif)

## 2.2 Knee joint kinematics

Movement of the knee joint can be classified as having six degrees of freedom – three translations: anterior/posterior, medial/lateral, and inferior/superior and three rotations: flexion/extension, internal/external, and abduction/adduction. The movements of the knee joint are determined by the shape of the articulating

surfaces of the tibia and femur and the orientation of the four major ligaments of the knee joint: the anterior and posterior cruciate ligaments and the medial and lateral collateral ligaments functioning as a four bar linkage system.

Knee flexion/extension involves a combination of rolling and sliding called 'femoral roll back' which is an ingenious way of allowing increased ranges of flexion. Because of asymmetry between the lateral and medial femoral condyles the lateral condyle rolls a greater distance than the medial condyle during the first 20 degrees of knee flexion. This causes coupled external rotation of the tibia which has been described as the 'screw-home mechanism' of the knee which locks the knee into extension (Blankevoort et al., 1988; Lafortune et al., 1992).

The primary function of the medial collateral ligament is to restrain valgus rotation of the knee joint with its secondary function being control of external rotation. The lateral collateral ligament restrains against varus rotation as well as resisting internal rotation.

The primary function of the ACL is to resist anterior displacement of the tibia on the femur when the knee is flexed and control the 'screw home mechanism' of the tibia in terminal extension of the knee. A secondary function of the ACL is to resist varus or valgus rotation of the tibia, especially in the absence of the collateral ligaments. The ACL also resists internal rotation of the tibia.

The main function of the PCL is to allow femoral rollback in flexion and resist posterior translation of the tibia relative to the femur. This is also important for improving the lever arm of the quadriceps mechanism with flexion of the knee. The PCL also controls external rotation of the tibia with increasing knee flexion.

The movement of the patello-femoral joint can be characterized as gliding and sliding. During flexion of the knee the patella moves distally on the femur. This movement is governed by its attachments to the quadriceps tendon, ligamentum patellae and the anterior aspects of the femoral condyles. The muscles and ligaments of the patello-femoral joint are responsible for producing extension of the knee. The patella acts as a pulley in transmitting the force developed by the quadriceps muscles to the femur and the patellar ligament. It also increases the mechanical advantage of the quadriceps muscle relative to the instant centre of rotation of the knee.



The mechanical axis of the lower limb is an imaginary line through which the weight of the body passes. It runs from the centre of the hip to the centre of the ankle through the middle of the knee. This allows normalisation of gait and protects the tibia from eccentric loading.

### **2.3 Knee disorder**

Knee disorder can result from wear and tear, infection, trauma or disease. Osteoarthritis is the most common form of knee disorder. It is also known as degenerative joint disease. It is characterized by the breakdown of the articular cartilage within the joint. While the exact cause is unknown, there are known to be several possible causes including: injury, age, congenital predisposition, obesity, metabolic or constitutional attack and involves new tissue production in response. Part of the body's response is to produce osteophytes. The most common inflammatory type is rheumatoid arthritis. It primarily affects the synovium, which thickens and secretes chemicals damaging the cartilage and other tissue (Doherty et al., 2001). In the Netherlands, up to one quarter of all people over 55 have osteoarthritis of the knee, and a further one-seventh have rheumatoid arthritis (Schouten et al., 2003). Severe pain during daily activities and inflammation of the joints are indications for treatment. Medicines, weight loss and physiotherapy can only treat moderate forms of arthritis. When these conservative treatments fail, (total) joint replacement is the intervention for patients with pain, limitation of motion, and/or deformities.

Although in 1890 the first endoprosthesis with any success was reported (Gluck, 1890), the modern history of knee arthroplasty began in the 1940's, and is today second only to the hip as the most commonly replaced joint. World wide more than 750,000 primary and revision knee arthroplasties are performed each year.

Knee arthroplasty involves resurfacing of the condylar and tibial surfaces. There are a large number of total knee arthroplasty (TKA) designs available for the surgeon to implant, depending on the age and expected activity level of the patient, and on the preoperative deformity and stability of the knee. If the arthritis or other abnormal condition (such as avascular necrosis or fracture) affects only the medial or lateral

compartment of the knee, a unicompartmental arthroplasty may be performed, in which only the condylar and tibial surfaces of that particular compartment are replaced. If both the medial and lateral compartment are involved, a TKA is performed, which may or may not involve resurfacing of the patella (Barrack et al., 2001).

All total knee prostheses sacrifice the anterior cruciate ligament. Some also sacrifice or substitute for the posterior cruciate ligament while others retain the PCL. All of these devices are considered unconstrained or partially constrained, depending on the degree of stability they provide to the knee joint. Fully constrained devices act like simple hinges and provide complete stabilization to a knee that no longer has any inherent stability, but are used in less than 5% of the cases (Vince, 1996).

Although total knee replacements have excellent long term survival (Buechel, 2002; Gill et al., 1999; Keating et al., 2002), wear is one of the critical factors limiting the long-term success of total knee prostheses (Wimmer & Andriacchi, 1997). Retrieval studies of tibial inserts have shown that low-conformity and the thicknesses of the polyethylene insert are associated with increased wear (Bartel et al., 1986; Collier et al., 1991; Wright et al., 1992). To reduce excessive wear, one should increase the contact area between the tibial and femoral components (Sathasivam et al., 2001). Even in the most highly evolved designs of fixed bearing knees there is an intrinsic conflict between the need for dispersing contact forces over a greater range of the polyethylene tibial component in order to reduce wear, and the reduction in mobility that results from the more highly conforming polyethylene.

The introduction of mobile bearing knees in the late 1970's was intended to address this 'kinematic conflict' with designs that combined a highly conforming surface and a mobile polyethylene tibial component (Buechel and Pappas, 1990; Jordan et al., 1997). The highly conforming surface disperses contact stresses over a greater area, thus potentially reducing wear. At the same time, the mobile polyethylene bearing allows a degree of motion that has the potential to reduce implant to bone interface stresses. Such stresses have been shown to lead to implant loosening in highly conforming fixed-bearing knee designs. The defining feature of a 'mobile bearing knee' is the presence of a moving polyethylene bearing that articulates with both the femoral condyle and the tibial tray.



## 2.4 Mobile bearing prostheses

Today, there are nearly fifty different mobile bearing knee designs in use. They utilize a number of design variations that attempt to achieve low contact stress while maintaining near natural mobility (Callaghan et al., 2001). These design variations include:

### *Type of bearing surface*

*Platform:* a single polyethylene bearing that rotates in the transverse plane, with or without anterior-posterior motion (rotating only or multidirectional platform – Figures 3A and 3B, 4 and 5).



**Figure 3A.** Low Contact Stress (LCS) Rotating Platform (J&J DePuy, Warsaw, Indiana, USA).



**Figure 3B.** TRAC Mobile Bearing Knee System (Biomet, Bridgend, UK).

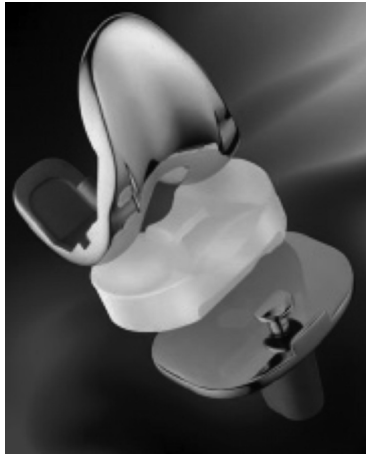


**Figure 4.** Mobile Bearing Knee (Zimmer, Warsaw, ID, USA).

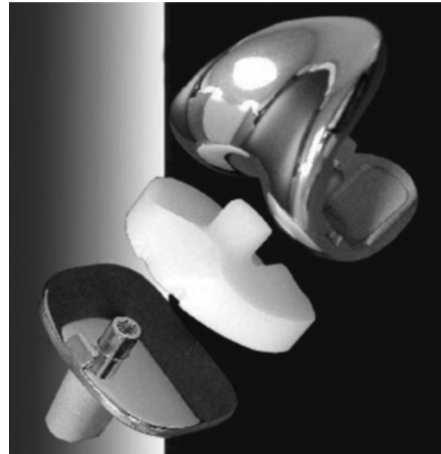


**Figure 5.** LPS-Flex Mobile Knee (Zimmer, Warsaw, ID, USA).

*Meniscal bearing:* separate medial and lateral polyethylene bearings that slide independently in arced tracks that run anteriorly and posteriorly in the fixed, metal tibial component (Figure 6).



**Figure 6.** Low Contact Stress (LCS) Meniscal Bearings (J&J DePuy, Warsaw, Indiana, USA).

*Unicondylar meniscal bearing:* an implant in which only the medial or lateral compartment of the knee is replaced. The polyethylene may run in a track as described above, or may move freely, held in place only by its reciprocal shape and the tension of the surrounding ligaments (Figure 7).



**Figure 7.** Oxford Unicompartmental Knee (Biomet, Bridgend UK).

***Type of constraint***

*Cone-in-cone design:* incorporates a tapered projection of the polyethylene insert that inserts into a reciprocal concavity in the tibial tray (Figure 3).

*Tibial tray post:* A post extending from the superior surface of the tibial tray fits into a recess on the polyethylene insert (Figure 4, 5).

*Longitudinal curved sliding tracks:* Movement of the platform or meniscus is limited by a track formed in the upper surface of the tibial tray (Figure 6).

*Stops:* Elevated rim of the tibial tray that limits excessive anterior-posterior translation or rotation (Figure 5).

*Unconstrained bearing:* designs that lack a mechanical limit to movement, but instead rely on the conformity of the polyethylene mobile bearing to the femoral condyle and the tension of the soft tissues (Figure 7).

***Directional mobility of the bearing surfaces***

The mobile polyethylene bearing has been utilized in a variety of designs that permit mobility in one or more directions. Some have only rotational mobility, which permits internal and external movement in the transverse plane. Some have multidirectional mobility, which may include anterior/posterior and medial/lateral movement in addition to rotational mobility. Designs can be characterized



as “unconstrained”, “semi-constrained”, and “constrained”. Unconstrained are those designs characterized by very low constraint forces over the entire range of normal (physiologic) displacements. Semi-constrained are those that have near physiologic constraint that rises over the range of normal displacements. Constraint forces that exceed physiologic levels and rise sharply over the range of displacements characterize constrained designs.

Rotation in the transverse plane (internal/external rotation) is a primary requirement of normal gait (Lafortune et al., 1992; Andriacchi & Dyrby, 2005). Constrained and semi-constrained medial/lateral mobility is characteristic of both mobile and fixed bearing knee designs, and does not adversely affect clinical performance (Banks et al., 2003; Dennis et al., 1998; Stiehl et al., 1997).

### ***Congruence***

Fully congruent mobile bearing knees are those that have a high degree of conformity between the femoral condyle and the polyethylene bearing surface, over a wide range of flexion (approximately 120 degrees). The congruence is achieved over this range by providing a constant sagittal femoral radius. These prostheses have a theoretical range of flexion of 120 degrees, limited by posterior impingement of the tibial component. A fully congruent prosthesis has a large contact area between the femoral condyle and the bearing surface, which disperses contact forces. This can result in reduced polyethylene wear.

During gait congruent or partially congruent mobile bearing knees have large contact areas in the first 20 degrees of flexion. The contact area decreases with flexion due to a decreasing sagittal radius. These prostheses maximize contact areas in the more important low end of the flexion range, while decreasing the sagittal radius to improve flexion range.

### ***PCL management***

Mobile bearing knees are available in PCL-retaining, PCL-sacrificing and PCL stabilizing designs (respectively Figure 3A, 4 and 5). In general, knees with only rotating mobility utilize a PCL sacrificing or PCL-stabilizing design, while multidirectional platform knees generally are PCL-retaining. Based on the radiological knee joint destruction, one should decide to retain or sacrifice the PCL (Nelissen and Hogendoorn, 2001).

In summary, there are numerous mobile bearing knee designs on the market worldwide that are designed with two common purposes. The first is to increase contact area in order to reduce long-term wear. The second is to reduce implant-to-bone interface stresses and allow good kinematics by the mobility of the polyethylene bearing on the tibial plate. The number of variations of mobile bearing knee designs available proves the interest in evaluating the clinical success and performance of current designs with the aim to improve the mobile bearing alternative to traditional fixed bearing knees. Since the differences between (mobile bearing) total knee designs are small, this requires objective and accurate performance assessment and evaluation tools.



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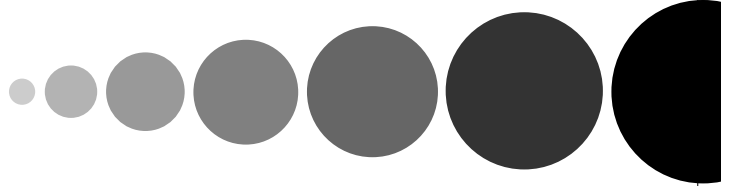
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# Chapter 3



## **Marker configuration model based roentgen fluoroscopic analysis**

**Accuracy assessment by phantom tests and computer simulations**

Eric H. Garling<sup>1</sup>, Bart L. Kaptein<sup>1</sup>, Koos Geleijns<sup>2</sup>,  
Rob G.H.H. Nelissen<sup>1</sup>, Edward R. Valstar<sup>1,3</sup>

<sup>1</sup> Department of Orthopaedics Leiden University Medical Center, The Netherlands

<sup>2</sup> Department of Radiology, Leiden University Medical Center, The Netherlands

<sup>3</sup> Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials  
Engineering, Delft University of Technology, The Netherlands

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## Abstract

It remains unknown if and how the polyethylene bearing in mobile bearing knees moves during dynamic activities with respect to the tibial base plate. Marker Configuration Model-Based Roentgen Fluoroscopic Analysis (MCM-based RFA) uses a marker configuration model of inserted tantalum markers in order to accurately estimate the pose of an implant or bone using single plane Roentgen images or fluoroscopic images. The goal of this study is to assess the accuracy of (MCM-Based RFA) in a standard fluoroscopic set-up using phantom experiments and to determine the error propagation with computer simulations.

The experimental set-up of the phantom study was calibrated using a calibration box equipped with 600 tantalum markers, which corrected for image distortion and determined the focus position. In the computer simulation study the influence of image distortion, MC-model accuracy, focus position, the relative distance between MC-models and MC-model configuration on the accuracy of MCM-Based RFA were assessed.

The phantom study established that the in-plane accuracy of MCM-Based RFA is 0.1 mm and the out-of-plane accuracy is 0.9 mm. The rotational accuracy is 0.1 degrees. A ninth-order polynomial model was used to correct for image distortion. Marker-Based RFA was estimated to have, in a worst case scenario, an *in vivo* translational accuracy of 0.14 mm (x-axis), 0.17 mm (y-axis), 1.9 mm (z-axis), respectively, and a rotational accuracy of 0.3 degrees.

When using fluoroscopy to study kinematics, image distortion and the accuracy of models are important factors, which influence the accuracy of the measurements. MCM-Based RFA has the potential to be an accurate, clinically useful tool for studying kinematics after total joint replacement using standard equipment.

### 3.1 Introduction

Fluoroscopy and Roentgen Stereophotogrammetric Analysis (RSA) studies of knee replacements have demonstrated a broad range of kinematic patterns of the femur with respect to the tibia during dynamic activities (Banks, et al., 2003; Callaghan et al., 2001; Dennis et al., 1998; Fantozzi et al., 2003; Saari et al., 2003; Stiehl et al., 1997; Walker et al., 2002). In one of these studies, the motion of the polyethylene bearing in mobile bearing (MB) knees was derived from the relative position of the femoral component and the tibial component assuming motion of the bearing due to the congruency with the femoral component (Stiehl et al., 1997). However, it is still unknown if and how the polyethylene bearing actually moves in MB knees with respect to the tibia during dynamic activities. Since functional capabilities of patients are affected by the knee kinematics, it is important to know how the different parts of the total knee replacement are moving and if they work beneficial or detrimental to the knee function.

In order to assess the kinematics of the MB, its position in roentgen images needs to be well defined (Yuan et al., 2002). To visualise the polyethylene bearing in roentgen images, the bearing can be marked with tantalum beads. In this article, a technique called Marker Configuration Model Based Roentgen Fluoroscopic Analysis (MCM-based RFA) is presented. MCM-based RFA uses a marker configuration model (MC-model) of inserted tantalum markers in order to accurately estimate the pose of an implant or bone using single plane roentgen images or fluoroscopic images.

Before applying MCM-based RFA in a clinical experiment, it is necessary to validate this technique. The goal of this study is to assess the accuracy of MCM-based RFA in a standard fluoroscopic set-up using phantom experiments and to determine the error propagation of the accuracy of 3D marker position reconstruction with computer simulations.



### 3.2 Method

MCM-based RFA uses an MC-model to estimate the pose of a rigid body from single focus roentgen images or fluoroscopic images. This MC-model describes the positions of the markers in the rigid-body relative to each other, and this can be assessed by the reconstructed 3D positions of the markers from one, or more, RSA radiographs using RSA software (RSA-CMS, Medis, The Netherlands).

The 2D positions of the marker projections in the fluoroscopy images are automatically detected with an algorithm based on the Hough-transform for circle detection (Duda and Hart, 1972). For obtaining a more accurate location of each 2D marker projection, a parabolic model of the marker is fitted to the marker's grey value profile (Vrooman et al., 1998).

The 3D position of the roentgen focus is calculated by the same procedure as in RSA using a calibration box (Selvik, 1989). For each marker projection, a 3D projection line is defined between the 2D marker projection and this roentgen focus. For calculating the pose of the MC-model, its position and orientation are optimised so that the markers in the MC-model have a minimum distance to their corresponding projection lines. This distance is defined as:

$$D_i = \min_{j=1-n_p} (||X_i - X_i^{pj}||) \quad (1)$$

In this formula,  $D_i$  is the distance between marker  $i$  and its closest projection line,  $n_p$  is the number of projection lines,  $X_i$  is the 3D position of marker  $i$  and is  $X_i^{pj}$  the perpendicular projection of marker  $i$  on projection line  $j$ .

Because the markers in the MC-model can be occluded, the number of markers in the MC-model is on the whole higher than the number of corresponding projection lines. Therefore, some markers of the MC-model will be projected on the same projection line. To solve this problem, the markers are sorted according to their distances, and a number of markers is selected equal to the number of projection lines, thus excluding the markers with larger distances. This procedure automatically eliminates the markers of the MC-model that have no corresponding projection line in the matching procedure. Occasionally projection lines that have

no corresponding marker in the MC-model need to be manually removed from the matching procedure.

The mean of the distances between the markers defines the difference that is to be minimised:

$$E = \frac{\sum_{i \in \text{selected}} D_i}{n_{\text{selected}}} \quad (2)$$

In this formula,  $n_{\text{selected}}$  is the number of selected markers, which is in this study always equal to the number of projection lines.

To make sure that each marker is related to its corresponding projection line in an image, it is important that the initial pose of the MC-model is close to its final pose. This prevents local minima in the solution space. Setting this initial pose is done manually by a human operator with the help of a 3D visualisation of the MC-models and the actual projections of the markers. For minimising the difference  $E$ , we used a combination of the downhill Simplex method with a simulated annealing algorithm (Press et al., 1994). This robust algorithm was used to avoid remaining local minima in the solution space. The total duration of the manual initial pose estimation followed by the automated pose estimation takes less than 2 minutes.

### **Calibration**

To be able to correct for pincushion distortion and calibrate the set-up a specially designed 400x400 mm Perspex calibration box (BAAT Engineering B.V., Hengelo, The Netherlands) was used. The fiducial plane consists of 553 fiducial markers and the control plane of 45 control markers. The fiducial markers were placed in a chequered 10 mm pattern covering the fluoroscopic field of view of 280 mm in diameter (Figure 1). By subtracting the known grid coordinates from the measured 2D grid coordinates in the fluoroscopic images, the distortion was quantified and correction parameters were calculated by using a two-dimensional N-degree polynomial model:



$$\begin{aligned}
 X &= \sum_{i=0}^m \sum_{j=1}^i a_{ij} x^i y^{j-i} \\
 Y &= \sum_{i=0}^m \sum_{j=1}^i b_{ij} x^i y^{j-i}
 \end{aligned}
 \tag{3}$$

Where (X,Y) are the known grid coordinates, (x,y) are the coordinates of the corresponding measured 2D grid coordinates and a,b are the polynomial coefficients.

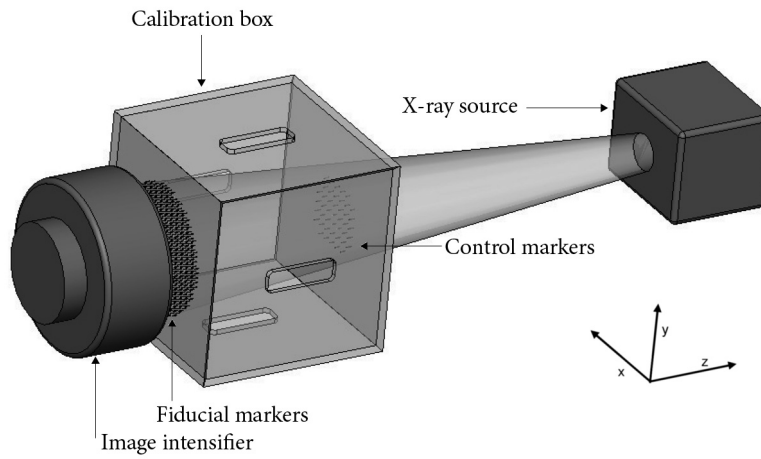


**Figure 1.** Fluoroscopy calibration set-up with Perspex calibration box containing 553 fiducial markers (film plane) and 45 control markers.

In the phantom experiments, the calibration box was utilized to obtain the 3D position of the focus and to define the coordinate system. The field of view of the fluoroscopic system (Super Digital Fluorography (SDF) system, Toshiba Infinix-NB: Toshiba, Zoetermeer, The Netherlands) was aligned with the calibration box. The maximum focus-to-film distance was limited by the system, and corresponded to an approximate distance of 1.25 m. The nominal X-ray spot size was 0.3 mm<sup>2</sup> minimising the geometric unsharpness (penumbra). To assess the distortion and to calibrate the set-up, an image run of three seconds of the calibration box was made with 15 frames/sec and a pulse width of 1 ms. An 1024×1024 image matrix was used,

and the calibration images were recorded once before, and once after the phantom experiment. All images were digitally stored, and the 2D positions of the projected markers in the images were automatically detected.

Increasing degrees of the polynomial models were used to identify the effect of image distortion on the accuracy MCM-based RFA.

### 3.2.1 Phantom experiments

The phantom used in this study was made of carbon fibre sandwich plates, containing seventeen 1-mm tantalum beads attached to its edges. Within the phantom, two rigid bodies defined two MC-models. One MC-model represented a configuration of the MB similar representing the actual *in vivo* MB. To obtain a highly accurate MC-model, an average MC-model was determined from four RSA radiographs of the phantom. The phantom box was connected to a pendulum and was swung in front of the image intensifier field ( $\pm 0.4$  m/sec). Subsequently two image runs of three seconds were made of the phantom.

The relative change in position and orientation between the two MC-models was calculated by comparing their relative pose in two consecutive images. Since the actual relative motion between the models defined inside the phantom is zero, they are defined within one rigid phantom, the relative changes in position and orientation indicate the error (henceforth measurement error) of the MCM-based RFA method (Ranstam et al., 2000).

### 3.2.2 Computer simulations

Based on the results of the phantom study, the error propagation of MCM-based RFA was assessed by computer simulations using MATLAB (The Mathworks Inc, Natick, Massachusetts).

Two virtual MC-models were defined. The first MC-model represented an *in vivo* situation of tibia markers consisting of two trapeziums perpendicular to each other (Figure 2). This way, eight markers were evenly distributed in a geometrical space of 40 x 40 mm. The second MC-model represented a polyethylene bearing consisting of a trapezium with the longest side of 50 mm in length and an additional two markers 5 mm out-of-plane. The condition numbers, for the MC-models of the tibia and the



bearing, were 9.8 and 18.2 respectively (Söderkvist and Wedin, 1993). Both MC-models were positioned 150 mm out of the image plane. The markers of the MC-models were mathematically projected on the fiducial plane with the focus position set at 1150 mm (based on the focus-to-film distance calculated in the phantom experiments).

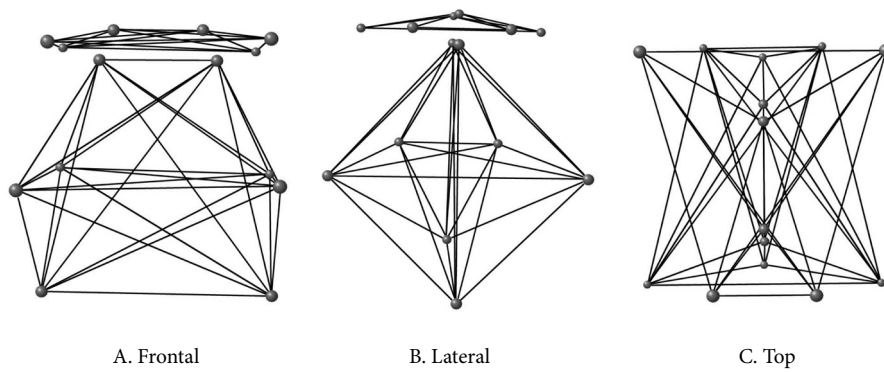


**Figure 2.** The MC-models used in the computer simulations (A. frontal, B. lateral, C. top-view). The MC-model of the tibia consists of two trapeziums perpendicular to each other and the MC-model of the bearing consisting of one trapezium and two out-of-plane markers. The relative distance between the two MC-models is 50 mm.

Five types of simulations were performed to separately assess the influence of image distortion, MC-model accuracy, focus position, the relative distance between MC-models, and MC-model configuration on the accuracy of MCM-based RFA (Table 1). In each type of simulation, ten levels of normally distributed noise with zero mean and set standard deviation (SD) was added to the data of the tested parameters. The SD's of the noise levels were based on the results of the phantom experiments.

MC-models were virtually translated and rotated in ten poses (range translations: -100 mm to 50 mm; range rotations: 0 to 90 degrees) and noise was added. After mathematically projecting the MC-models, their poses were reconstructed using MCM-based RFA. Using a cross table, all motions between the MC-model of the bearing and the MC-model of the tibia were calculated between all ten calculated



orientations. This resulted in 45 migrations per noise level and was repeated 50 times. In total, 22500 calculations per type of simulation were done.

In the first simulation, the influence of image distortion was assessed by adding noise, with a SD range of 0.02 mm to 0.3 mm, to the simulated error-free projections of the MC-model markers.

In the second simulation, model distortion was simulated by adding noise to the 3D positions of the MC-model markers. Since the accuracy of RSA, used to assess the MC-models, is two times lower in the out-of-plane (Valstar, 2001; Kaptein et al., 2003), the added noise of the in-plane direction ranged from SD 0.002 to SD 0.1 mm, and in the out-of-plane direction from SD 0.004 mm up to SD 0.2 mm.

**Table 1.** Test conditions for the accuracy assessment of MCM-based RFA.

|                      | Test conditions | Results   | Description                                                                                                                 |
|----------------------|-----------------|-----------|-----------------------------------------------------------------------------------------------------------------------------|
|                      | Calibration     | Figure 3  | Pincushion distortion corrected using increasing polynomial models.                                                         |
|                      | Phantom         | Table II  | Phantom containing two MC-models connected to a pendulum in front of image intensifier.                                     |
| Computer simulations | Condition 1     | Table III | Normally distributed noise levels on the marker coordinates.                                                                |
|                      | Condition 2     | Table IV  | Normally distributed noise levels on the MC-models.                                                                         |
|                      | Condition 3     | Table V   | Normally distributed noise levels on the focus-to-film distance.                                                            |
|                      | Condition 4     | Table VI  | Increasing the relative distance between CPG's. Noise levels were added on the MC-models (0.02 mm) and the image (0.04 mm). |
|                      | Condition 5     | Table VII | Decreasing number of markers in the MC-model. Noise levels were added on the MC-models (0.02 mm) and the image (0.04 mm).   |

In the third simulation, the influence of the error in the calculated focus position was assessed. The results of the phantom experiments showed that the accuracy

of MCM-based RFA is three times lower in the out-of-plane direction than in the in-plane direction; the noise added in this direction was set three times higher compared to the noise in the in-plane directions. Therefore the normally distributed noise for the in plane direction ranged from SD 0.3 to SD 20 mm and in the out-of-plane direction from SD 1 mm to SD 60 mm.

In the fourth and the fifth simulation, the noise (SD 0.02 mm) was added to the 3D marker positions of the MC-models and the noise (SD 0.04 mm) was added to the 2D positions of the marker projections in the image plane. The noise levels were based on the results of the phantom experiments. In these last two experiments, no noise was added to the focus position.

In the fourth simulation, the distance between the centre of gravity of the MC-model of the tibia and the insert was increased along the x-direction to 100 mm with 10 mm intervals. Since it can be stated that relative motions can be composed of two unrelated absolute motions between rigid bodies, the reconstruction error in the 3-D position might increase the measurement error of the relative motion between two rigid bodies (Spoor and Veldpaus, 1980).

In the fifth simulation, one to five markers were chosen randomly and deleted, in no particular order, from the MC-model of the tibia before the pose estimation. Since the MC-model of the tibia consisted of eight markers, at least three markers remained in the MC-model of the tibia. When the marker configuration is symmetrical or when a small number of markers are used to define the MC-models, measurement errors are expected in the relative motion between the MC-models (Söderkvist and Wedin, 1993; Yuan et al., 1997).

### **3.3 Results**

#### **3.3.1 Phantom experiments**

The mean difference between the known grid coordinates and the measured grid coordinates before correction was  $1.50 \pm 0.76$  mm (range -3.90 – 4.19 mm). The highest distortion was found at the borders of the field of view. The distortion was corrected using increasing polynomial models (Figure 3). By correcting the distortion using a ninth order polynomial fit, the mean length of the difference

vector decreased to 0.05 mm. With this correction, the residual error vectors did not have a systematic component and were randomly distributed in both length and orientation. A tenth order correction polynomial slightly decreased the mean length of the difference vector compared to the ninth order correction polynomial from 0.051 mm to 0.050 mm. However, the standard deviation increased respectively from 0.0248 mm to 0.0250 mm. When using a tenth order correction, noise is modelled too, thus decreasing the accuracy.

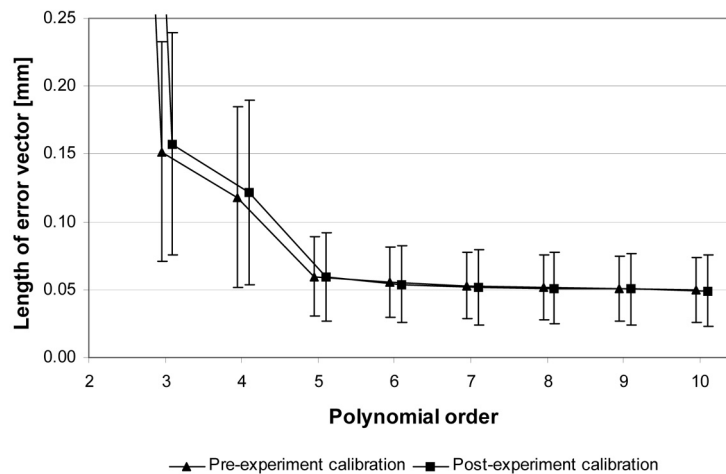


**Figure 3.** Calibration experiment: length of the error vector between the known grid points and the measured grid points after correction with increasing degrees of polynomial models (mean  $\pm$  SD) for the pre experiment calibration and post experiment calibration.

After a ninth order correction for image distortion, the relative motion between the models defined inside the phantom decreased in comparison with the situation when using a fifth order correction for image distortion was used in the out-of-plane direction from  $-0.270 \pm 1.404$  mm to  $-0.221 \pm 0.856$  mm (Table 2). No significant differences in distortion were found between the calibration run made before the phantom experiment and the calibration run made after the experiment. Thus, the calibration parameters assessed before the phantom runs made an adequate correction possible. The calculated focus-to-film distance using the calibration box was 1066 mm.

**Table 2.** Phantom experiment: error in the relative position and orientation of the two MC-models in the phantom, when comparing consecutive images ( $n=9$ ; 9<sup>th</sup> order correction). Translations are labelled  $x$ ,  $y$ ,  $z$  (in mm) and rotations are labelled  $R_x$ ,  $R_y$ ,  $R_z$  (in degrees).

|       | $x$   | $y$   | $z$    | $R_x$ | $R_y$ | $R_z$ |
|-------|-------|-------|--------|-------|-------|-------|
| Mean  | 0.017 | 0.008 | -0.221 | 0.014 | 0.003 | 0.011 |
| Stdev | 0.093 | 0.060 | 0.856  | 0.080 | 0.085 | 0.051 |

### 3.3.2 Computer simulations

In Figure 4, a graphical representation shows the influence of noise in the first three simulations. The magnitudes of the measurement errors in the out-of-plane ( $z$ -) direction displayed in the graph are confirmed in the simulation experiments.

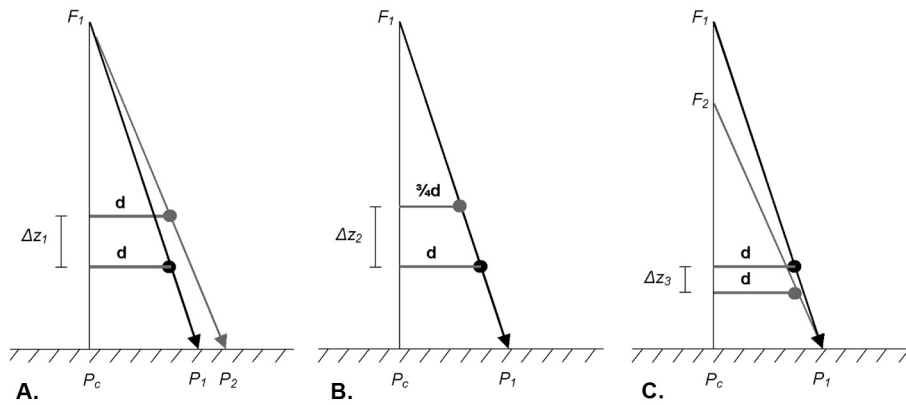


**Figure 4.** Error propagation in the out-of-plane direction following image distortion (A), configuration model distortion (B) and focus position distortion (C). (A) The configuration model  $d$ , is fitted between the central projection line ( $P_c$ ) and the marker projection line ( $P_1$ ). When 25% image distortion is added the marker projection line shifts towards  $P_2$ . The new optimal fit between  $P_c$  and  $P_2$  result in the out-of-plane error  $\Delta z_1$ . (B) When 25% of noise is added on  $d$  this result in an error  $\Delta z_2$ . (C) Decreasing the focus position  $F_1$  with 25% to  $F_2$  results in an out-of-plane error of  $\Delta z_3$ .

**Table 3.** *Condition 1:* error in the relative position and orientation of the two simulated MC-models with normally distributed noise on the marker coordinates. Translations are labelled x, y, z (in mm) and rotations are labelled Rx, Ry, Rz (in degrees).

| SD of noise<br>[mm] |      | x      | y      | z      | Rx     | Ry     | Rz     |
|---------------------|------|--------|--------|--------|--------|--------|--------|
| 0.005               | Mean | 0.002  | -0.003 | 0.033  | 0.009  | -0.017 | -0.003 |
|                     | SD   | 0.028  | 0.032  | 0.087  | 0.028  | 0.042  | 0.012  |
| 0.010               | Mean | -0.003 | 0.009  | -0.046 | 0.015  | -0.018 | 0.002  |
|                     | SD   | 0.055  | 0.041  | 0.228  | 0.081  | 0.065  | 0.020  |
| 0.020               | Mean | -0.013 | -0.044 | 0.079  | 0.003  | -0.038 | -0.007 |
|                     | SD   | 0.165  | 0.180  | 0.603  | 0.186  | 0.141  | 0.044  |
| 0.040               | Mean | 0.125  | 0.119  | -0.177 | -0.283 | -0.026 | 0.035  |
|                     | SD   | 0.369  | 0.478  | 1.241  | 0.428  | 0.286  | 0.077  |
| 0.060               | Mean | 0.119  | 0.113  | 0.127  | -0.262 | 0.223  | 0.050  |
|                     | SD   | 0.335  | 0.438  | 1.082  | 0.698  | 0.544  | 0.180  |
| 0.080               | Mean | 0.043  | 0.129  | 0.060  | 0.286  | -0.060 | 0.041  |
|                     | SD   | 0.422  | 0.404  | 1.579  | 0.893  | 0.523  | 0.181  |
| 0.100               | Mean | -0.038 | -0.055 | -0.279 | -0.103 | -0.085 | -0.036 |
|                     | SD   | 0.515  | 0.439  | 2.092  | 0.875  | 0.718  | 0.239  |
| 0.150               | Mean | 0.188  | -0.077 | 0.281  | 0.208  | 0.139  | 0.012  |
|                     | SD   | 0.733  | 0.713  | 2.727  | 1.088  | 1.086  | 0.395  |
| 0.200               | Mean | -0.174 | -0.713 | 1.582  | -0.379 | 0.020  | 0.074  |
|                     | SD   | 1.604  | 1.622  | 6.042  | 1.949  | 1.578  | 0.635  |
| 0.300               | Mean | 0.516  | 0.830  | -1.055 | -0.089 | -0.001 | 0.021  |
|                     | SD   | 2.195  | 2.686  | 7.418  | 3.042  | 2.114  | 0.666  |

As expected, the out-of-plane measurement error was the most sensitive when noise was added. The measurement error of MCM-based RFA is linearly related to the amount of image distortion and the amount of model distortion. Adding image distortion resulted in an increase of the measurement error in the out-of-plane direction by a factor of three (Table 3) relative to the in-plane (x-y plane) direction,



whereas in the simulations where model distortion was added this effect was a factor two (Table 4). In addition, systematic errors in the out-of-plane direction appeared only when the noise level added to the image plane was more than 0.150 mm. Thus, image distortion has the largest influence on the accuracy of the method. However, when the noise level of the focus-to-film distance was set at 60 mm, the measurement error only slightly increased in the out-of-plane direction to SD 0.2 mm (Table 5). No apparent systematic measurement errors have been observed in this simulation.

**Table 4.** *Condition 2:* error in the relative position and orientation of the two simulated MC-models with normally distributed noise levels on the MC-models. Translations are labelled x, y, z (in mm) and rotations are labelled Rx, Ry, Rz (in degrees).

| SD of noise<br>[mm] |      | x      | y      | z      | Rx     | Ry     | Rz     |
|---------------------|------|--------|--------|--------|--------|--------|--------|
| 0.004               | Mean | 0.000  | 0.000  | 0.006  | 0.005  | -0.001 | 0.000  |
|                     | SD   | 0.024  | 0.023  | 0.047  | 0.028  | 0.022  | 0.006  |
| 0.006               | Mean | -0.005 | 0.003  | -0.018 | 0.001  | -0.020 | -0.004 |
|                     | SD   | 0.023  | 0.019  | 0.099  | 0.055  | 0.058  | 0.020  |
| 0.008               | Mean | 0.000  | -0.007 | -0.015 | 0.016  | 0.007  | 0.001  |
|                     | SD   | 0.054  | 0.051  | 0.085  | 0.066  | 0.065  | 0.018  |
| 0.020               | Mean | 0.004  | -0.004 | 0.004  | -0.012 | 0.023  | 0.002  |
|                     | SD   | 0.109  | 0.131  | 0.287  | 0.158  | 0.144  | 0.037  |
| 0.040               | Mean | 0.003  | 0.055  | 0.008  | 0.029  | -0.064 | -0.019 |
|                     | SD   | 0.344  | 0.403  | 0.742  | 0.341  | 0.317  | 0.079  |
| 0.060               | Mean | 0.024  | 0.075  | -0.206 | -0.071 | -0.075 | -0.020 |
|                     | SD   | 0.256  | 0.221  | 0.864  | 0.384  | 0.367  | 0.113  |
| 0.080               | Mean | 0.027  | 0.043  | -0.265 | 0.143  | -0.142 | -0.034 |
|                     | SD   | 0.406  | 0.386  | 0.997  | 0.566  | 0.497  | 0.144  |
| 0.100               | Mean | -0.007 | 0.056  | 0.161  | -0.054 | 0.031  | 0.000  |
|                     | SD   | 0.515  | 0.535  | 1.164  | 0.653  | 0.545  | 0.125  |
| 0.200               | Mean | -0.046 | -0.077 | -0.040 | -0.010 | 0.063  | 0.009  |
|                     | SD   | 0.988  | 0.988  | 2.316  | 1.211  | 1.464  | 0.545  |

**Table 5.** *Condition 3:* error in the relative position and orientation of the two simulated MC-models with normally distributed noise levels on the focus-to-film distance. Translations are labelled x, y, z (in mm) and rotations are labelled Rx, Ry, Rz (in degrees).

| SD of noise<br>[mm] |      | x      | y      | z      | Rx     | Ry     | Rz     |
|---------------------|------|--------|--------|--------|--------|--------|--------|
| 1                   | Mean | -0.001 | -0.001 | 0.000  | 0.001  | 0.000  | 0.000  |
|                     | SD   | 0.003  | 0.004  | 0.007  | 0.002  | 0.002  | 0.001  |
| 5                   | Mean | 0.000  | 0.000  | -0.002 | 0.000  | -0.001 | 0.000  |
|                     | SD   | 0.003  | 0.004  | 0.018  | 0.005  | 0.006  | 0.002  |
| 10                  | Mean | 0.001  | 0.001  | 0.000  | 0.002  | -0.001 | 0.000  |
|                     | SD   | 0.011  | 0.012  | 0.030  | 0.009  | 0.009  | 0.004  |
| 15                  | Mean | -0.001 | -0.003 | -0.007 | -0.001 | -0.009 | -0.004 |
|                     | SD   | 0.016  | 0.017  | 0.052  | 0.017  | 0.019  | 0.007  |
| 20                  | Mean | 0.000  | -0.003 | 0.008  | 0.001  | 0.005  | 0.001  |
|                     | SD   | 0.031  | 0.032  | 0.074  | 0.025  | 0.031  | 0.011  |
| 25                  | Mean | -0.001 | 0.000  | 0.013  | 0.001  | 0.004  | 0.002  |
|                     | SD   | 0.028  | 0.033  | 0.085  | 0.023  | 0.027  | 0.013  |
| 30                  | Mean | -0.003 | -0.010 | 0.021  | 0.003  | 0.006  | 0.000  |
|                     | SD   | 0.044  | 0.049  | 0.119  | 0.038  | 0.042  | 0.019  |
| 40                  | Mean | -0.008 | -0.018 | 0.023  | 0.001  | 0.009  | 0.002  |
|                     | SD   | 0.068  | 0.084  | 0.129  | 0.051  | 0.059  | 0.024  |
| 50                  | Mean | 0.006  | 0.009  | 0.017  | 0.009  | 0.009  | 0.006  |
|                     | SD   | 0.060  | 0.065  | 0.181  | 0.064  | 0.062  | 0.022  |
| 60                  | Mean | 0.000  | 0.010  | -0.024 | 0.001  | -0.031 | -0.006 |
|                     | SD   | 0.073  | 0.077  | 0.199  | 0.065  | 0.080  | 0.028  |



**Table 6.** *Condition 4:* error in the relative position and orientation of the two simulated MC-models when increasing the relative distance between CPG's. Normally distributed noise levels were added on the models and the image of respectively 0.02 and 0.04 mm. Translations are labelled x, y, z (in mm) and rotations are labelled Rx, Ry, Rz (in degrees).

| Distance<br>[mm] |      | x     | y      | z     | Rx     | Ry     | Rz     |
|------------------|------|-------|--------|-------|--------|--------|--------|
| 0                | Mean | 0.002 | 0.001  | 0.029 | -0.012 | -0.025 | 0.003  |
|                  | SD   | 0.061 | 0.026  | 0.723 | 0.234  | 0.244  | 0.038  |
| 10               | Mean | 0.025 | -0.040 | 0.470 | 0.008  | -0.013 | 0.006  |
|                  | SD   | 0.065 | 0.056  | 0.783 | 0.226  | 0.267  | 0.040  |
| 20               | Mean | 0.061 | -0.071 | 0.996 | 0.004  | -0.045 | 0.002  |
|                  | SD   | 0.095 | 0.108  | 1.264 | 0.278  | 0.195  | 0.052  |
| 30               | Mean | 0.092 | -0.128 | 1.584 | 0.010  | -0.042 | -0.005 |
|                  | SD   | 0.137 | 0.165  | 1.867 | 0.263  | 0.254  | 0.045  |
| 40               | Mean | 0.106 | -0.157 | 1.712 | 0.027  | 0.000  | -0.003 |
|                  | SD   | 0.195 | 0.217  | 2.455 | 0.205  | 0.246  | 0.044  |
| 50               | Mean | 0.130 | -0.188 | 2.058 | 0.034  | -0.081 | -0.003 |
|                  | SD   | 0.222 | 0.285  | 2.972 | 0.369  | 0.280  | 0.077  |
| 60               | Mean | 0.174 | -0.237 | 2.656 | 0.002  | 0.039  | 0.005  |
|                  | SD   | 0.247 | 0.331  | 3.543 | 0.221  | 0.236  | 0.057  |
| 80               | Mean | 0.238 | -0.340 | 3.710 | 0.075  | -0.078 | -0.002 |
|                  | SD   | 0.400 | 0.445  | 4.985 | 0.860  | 0.610  | 0.090  |
| 100              | Mean | 0.377 | -0.362 | 5.017 | -0.084 | -0.110 | 0.015  |
|                  | SD   | 0.625 | 0.562  | 6.688 | 0.658  | 0.672  | 0.124  |

When the distance between the MC-models was increased, the translatory measurement errors increased (Table 6). Especially in the z-direction, a systematic error was clearly present. In studying femorotibial kinematics, the relative distance between the centres point of gravities of the tibia and the femur is approximately 100 mm. This will have substantial influence on the accuracy in medial-lateral direction. The estimated distance between the centres of gravity of the MB and the tibia markers



in patients with a MB design is about 30 mm. When the image distortion and model distortion in the simulation were set at the same level as found in the phantom study – respectively SD 0.02 and 0.04 – the measurement errors were comparable between the two studies (Table 6). This indicates that the simulation study was appropriate in representing in vitro measurements and estimating the *in vivo* accuracy of MCM-based RFA. Given the results of the fourth experiment, the *in vivo* measurement accuracy for translations is estimated to be 0.14 mm (x-axis), 0.17 mm (y-axis), and 1.9 mm (z-axis) respectively and for all rotations 0.3 degrees.

**Table 7.** *Condition 5:* error in the relative position and orientation of the two simulated MC-models when decreasing the number of markers in the MC-model of the tibia. Normally distributed noise levels were added on the models and the image of respectively 0.02 and 0.04 mm. Translations are labelled x, y, z (in mm) and rotations are labelled Rx, Ry, Rz (in degrees).

| Number of markers |      | x      | y      | z      | Rx     | Ry     | Rz     |
|-------------------|------|--------|--------|--------|--------|--------|--------|
| 8                 | Mean | 0.002  | 0.001  | 0.029  | -0.012 | -0.025 | 0.003  |
|                   | SD   | 0.061  | 0.026  | 0.723  | 0.234  | 0.244  | 0.038  |
| 7                 | Mean | -0.003 | -0.004 | -0.086 | -0.037 | -0.020 | 0.008  |
|                   | SD   | 0.233  | 0.237  | 0.860  | 0.300  | 0.304  | 0.084  |
| 6                 | Mean | 0.014  | 0.004  | 0.028  | 0.049  | 0.010  | 0.007  |
|                   | SD   | 0.225  | 0.214  | 0.882  | 0.290  | 0.295  | 0.083  |
| 5                 | Mean | 0.022  | -0.009 | 0.159  | 0.02   | 0.058  | -0.006 |
|                   | SD   | 0.228  | 0.236  | 0.885  | 0.369  | 0.312  | 0.103  |
| 4                 | Mean | 0.030  | 0.023  | 0.064  | 0.014  | 0.031  | 0.013  |
|                   | SD   | 0.254  | 0.246  | 1.041  | 0.332  | 0.323  | 0.098  |
| 3                 | Mean | 0.014  | -0.032 | -0.126 | 0.014  | 0.002  | -0.006 |
|                   | SD   | 0.334  | 0.338  | 1.658  | 0.521  | 0.589  | 0.182  |

Since the centres of gravity of the MC-models of the tibia in the configuration simulation did not coincide, comparable in-plane errors as in the fourth simulation were observed when a small relative distance was set between the centres of gravity

(Table 7). Condition numbers of the generated MC-models of the tibia varied between 10.2 and 27.5. When only three markers were used to describe the configuration of the tibia, an increase in rotational errors was observed. This can be explained by looking at the virtual projections of the MC-models. In some poses, the projection appeared as a line on the image plane. The noise added to both model and image plane caused consequently a rotation error about the axes directed in the same direction as the projection line. The z-direction was therefore the least sensitive to this error.

### 3.4 Discussion

Roentgen Stereophotogrammetric Analysis (RSA) has been proven a well-developed research tool with a high accuracy (Börlin et al., 2002; Valstar, 2001). RSA studies have mainly focused on the fields of prosthetic fixation, joint stability, and fracture stability. Also efforts have been made to apply RSA to *in vivo* kinematic analysis using film exchangers together with a biplane RSA set-up (Kärrholm et al., 2000; Kärrholm et al., 1994; Saari et al., 2003). However, a biplane set-up limits the space available for skeletal movement, making it difficult to apply. Additionally, the tantalum markers in the mobile bearing become hidden behind tibial tray during flexion-extension motion when using dual projections. In addition, the required equipment that uses film exchangers is expensive and not widely available. Attempts have been made before MCM-based RFA to combine RSA information and single plane fluoroscopic data (Yuan et al., 2002). This single plane technique also employs three-dimensional position data from RSA-radiographs, together with two-dimensional marker coordinates from single focus images, to compute the three-dimensional position of markers from said images. However, a prerequisite is that three-dimensional coordinates of markers are assigned to corresponding projections in the fluoroscopic images. If projected markers are hard to identify leading to two or more markers swapping positions, results will be erroneous. This method proved, inherent to its mathematical technique, to be highly sensitive for focus position accuracy, object point distance to the film, and two-dimensional marker position accuracy (Yuan et

al., 2002). The marker projection accuracy, in particular, will have large influence on the accuracy of the method when applied in a standard fluoroscopic set-up because of the presence of pincushion distortion (Zwet et al., 1995).

The most commonly used fluoroscopic technique minimises the difference between the virtual projection of a 3-D surface model or a library of geometries of the implanted prostheses and the actual projection of the implant as it appears in a fluoroscopic image (Banks and Hodge, 1996; Dennis et al., 1996). Reported accuracies are approximately  $1^\circ$  for rotations while the accuracy of translation in the sagittal plane were approximately 0.5 mm (Banks and Hodge, 1996). However, large errors up to 8.3 mm were reported in the out-of-plane translation. Hoff et al. found rotation errors averaging  $0.35^\circ$ , in-plane translation errors of 0.5 mm, and out-of-plane errors up to 2.25 mm (Hoff et al., 1998). In fluoroscopic studies where the 3-D surface model-fitting technique is used, the out-of-plane accuracy is influenced by the accuracy of the model, the symmetry of the implant, and image quality. The influence of the latter is clearly shown in a study of Fukuoka et al. (1999). When the technique was used in a static situation using single focus X-ray images, the reported accuracy was 0.09 mm for in-plane translations and 0.87 mm out-of-plane. The prime advantages of standard X-ray images over fluoroscopic images are the absence of pincushion distortion and the high contrast resolution of the images. The contour of orthopaedic implants is not as well defined than the centre of tantalum beads. Therefore, the reported accuracies in the out-of-plane direction of the fluoroscopic studies using the 3-D surface model-fitting technique are lower compared to MCM-based RFA whereas the accuracy reported by Fukuoka et al. in a static situation is similar to the accuracy of MCM-based RFA.

Although computer simulations and phantom studies might overestimate the *in vivo* accuracy of a method, by this approach it is possible to evaluate sources of error in a systematic way and derive the *in vivo* accuracy. In the present study, the computer simulations revealed that MCM-based RFA is highly sensitive for image distortion and MC-model accuracy. In this study, a commercially available fluoroscopic system with image intensifier was used. In most fluoroscopic studies, the fluoroscope is adapted by fixing a high-speed camera behind the image intensifier to record the images. This implies a special experimental set-up not widely available. This study



showed that it is possible to capture the 3D kinematics of marker configurations using fluoroscopic equipment potentially available in almost every hospital. Although image intensifiers are still the well-established technology for fluoroscopy, flat-panel detectors are just beginning to make an entrance into this field (Yaffe and Rowland, 1997). Characteristics of flat-panel detectors – such as the availability of distortion-free images, the excellent contrast resolution, the large dynamic range, and the high sensitivity to X-rays – provide the basis for even more improvement in accuracy with tools like MCM-based RFA. Surprisingly, the influence of the focus position and configuration of the MC-models on the accuracy was low. Like RSA, focus-to-film distance variation did not prove a significant source of error when calculating the relative motion between two MC-models (Soavi et al., 1999). Although the focus-to-film distance was set at 1.25 m, the calculated distance was 1.07 m. Thus, one needs to calibrate the set-up to remove this source of error. In RSA, condition numbers can account for well over 90% of the variability in the mean rotational accuracy (Ryd et al., 2000). In our simulations of the *in vivo* situation, the condition numbers of the generated MC-models were too low to find this relation for MCM-based RFA. However, the results of the simulations when carried out with three markers in the MC-models did show the importance of isotropic distributed markers.

Since the magnitude of the relative translations and rotations (range translations: -100 mm to 50 mm; range rotations: 0 to 90 degrees) affect the accuracy of the measurements (Yuan et al., 1997), the large translations and rotations that were simulated resulted in a lower accuracy compared to the phantom study. In the phantom study, the phantom moved parallel to the image plane and the sampling frequency diminished the effect of large differences between poses of the MC-models in consecutive image frames. Errors in the pose estimation of objects moving parallel to the image plane at the edge of the field of view are mainly affected by image border effects when applying a polynomial model to correct for image distortion. The measurement accuracy of motions perpendicular to the image plane is mainly affected by the magnification of the inaccuracy of the MC-model. In our fluoroscopic set-up, translations perpendicular to the image plane corresponds to medial/lateral displacements of the knee prosthesis. This inaccuracy does not pose a serious limitation for the measurement of mobile bearing knee kinematics. This is

due to the very small magnitude of medial/lateral translations, which are allowed by the design of the tibial plateau. Since reported femorotibial translations and rotations are lower than the simulated translations and rotations (Callaghan et al., 2001), the actual *in vivo* accuracy of MCM-based RFA will be better than observed in the fourth experiment (Table 6; translations: 0.14 mm (x-axis), 0.17 mm (y-axis), and 1.9 mm (z-axis) and for all rotations 0.3 degrees). In other kinematic applications of MCM-based RFA where large changes in position and orientation are expected, one should take care that during the experiment the motion of interest is in the in-plane directions.



### 3.5 Conclusion

When using fluoroscopy to study kinematics, image distortion and the accuracy of models are the most important factors influencing the accuracy of the measurements. Considering the allowed mobility by design of most MB implants, MCM-based RFA is well suited to study the 3D kinematics of the polyethylene bearing in MB knees. MCM-based RFA has the potential to be an accurate, clinically useful tool for studying kinematics after total joint replacement using standard equipment.

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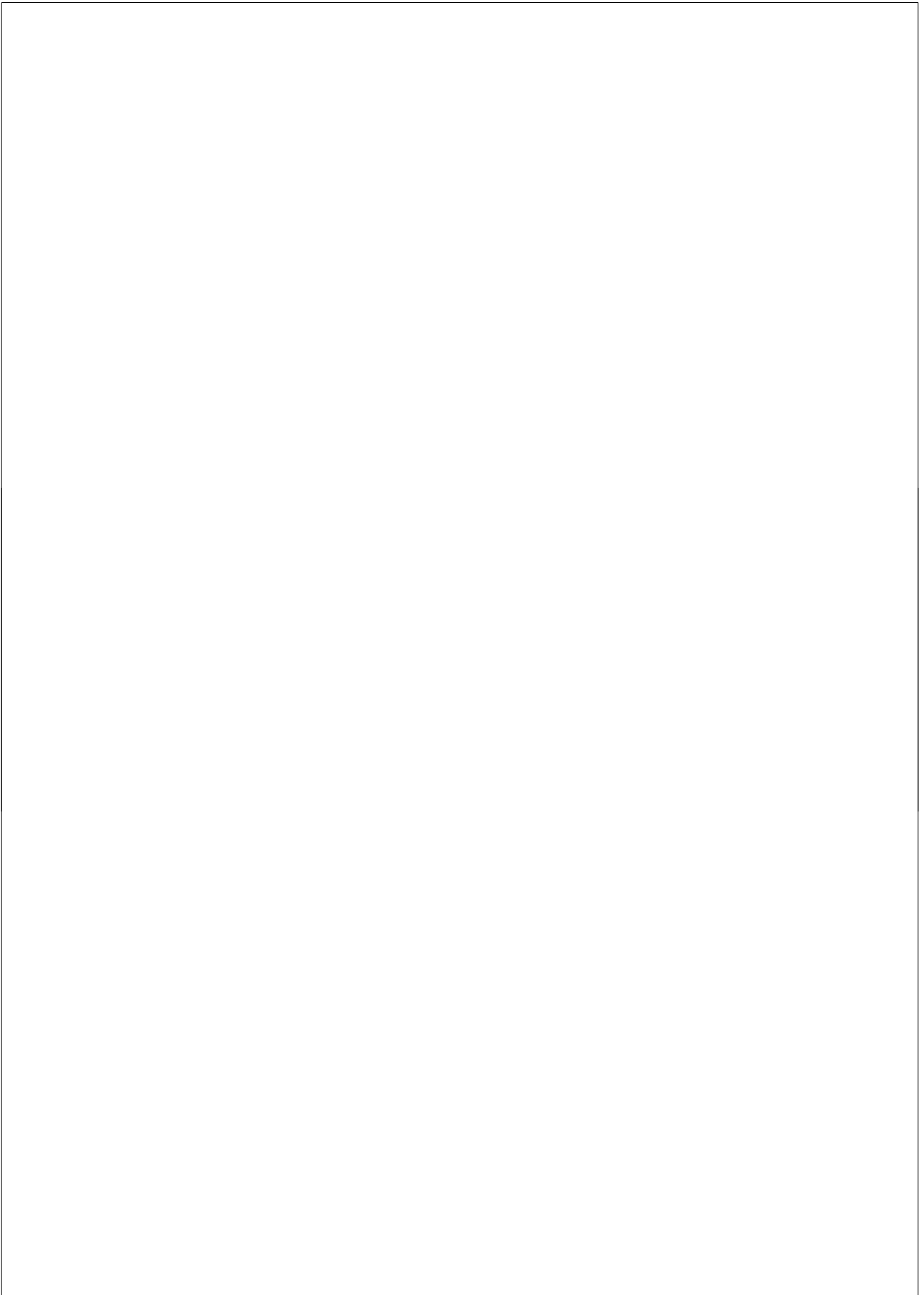
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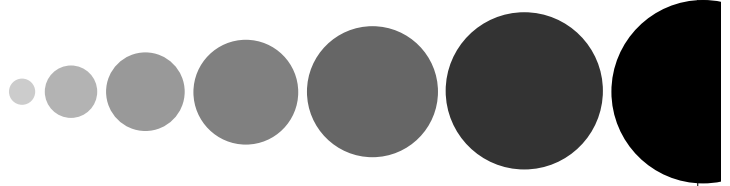
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# Chapter 4



## **Limited rotation of the mobile-bearing in a rotating platform total knee prosthesis**

Eric H. Garling<sup>1,2</sup>, Bart L. Kaptein<sup>1,2</sup>, Rob G.H.H. Nelissen<sup>1</sup>,  
Edward R. Valstar<sup>1,3</sup>

<sup>1</sup> Department of Orthopaedics Leiden University Medical Center, The Netherlands

<sup>2</sup> Department of Radiology, Division of Image Processing, Leiden University Medical Center, Leiden, The Netherlands

<sup>3</sup> Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials Engineering, Delft University of Technology, The Netherlands

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## **Abstract**

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

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

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

## 4.1 Introduction

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

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

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

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



## 4.2 Materials and Methods

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

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

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

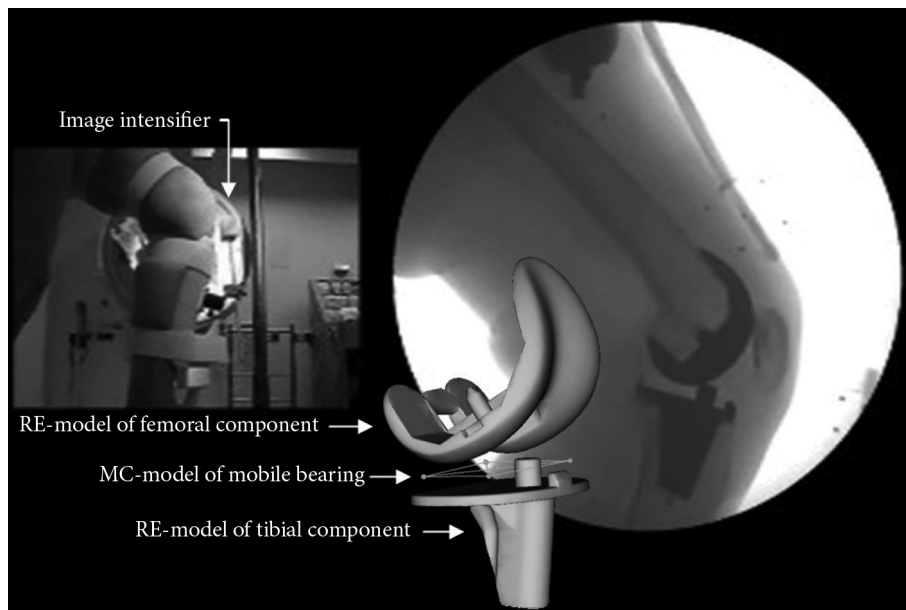


**Figure 1.** The experimental set-up is shown with the knee centered in front of the fluoroscope. The MC model of the mobile-bearing insert and RE models of the tibia and femur component were matched on the 2-D projections of the fluoroscopy image.

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

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

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

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

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

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

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

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

#### 4.4 Results

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

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

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



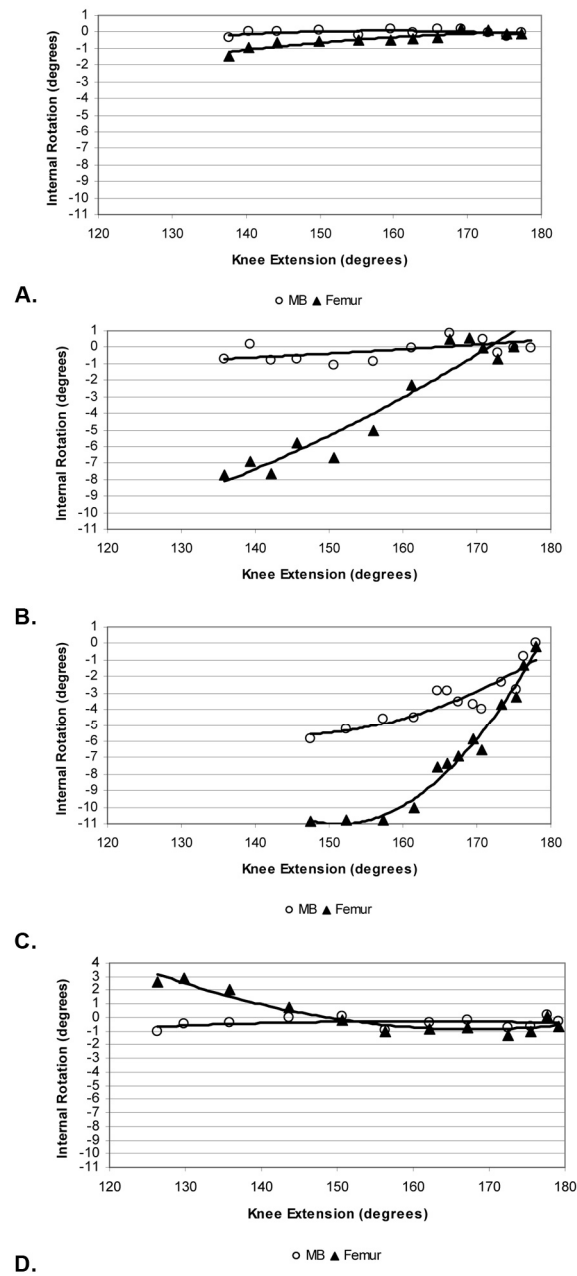


**Figure 2A-D.** Graphs show the relative axial rotation of the mobile-bearing insert and the femoral component with respect to the tibial component during extension: (A) No axial rotation of the components. (B) Mobile-bearing insert is fixed and femoral component is rotating internally. (C) Both components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

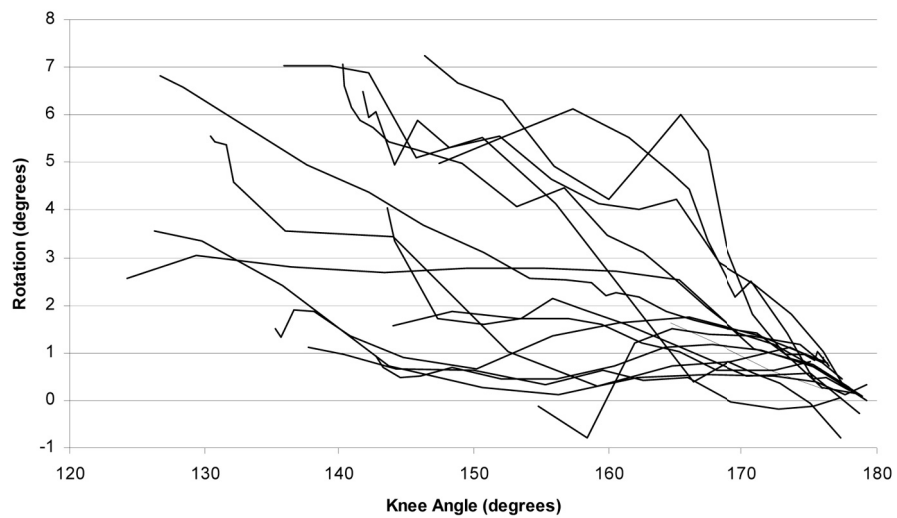


**Figure 3.** A graph shows the difference in axial rotation of the femoral component relative to the mobile-bearing insert.

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

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

#### 4.4 Discussion

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

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

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

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



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

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

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

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

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

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



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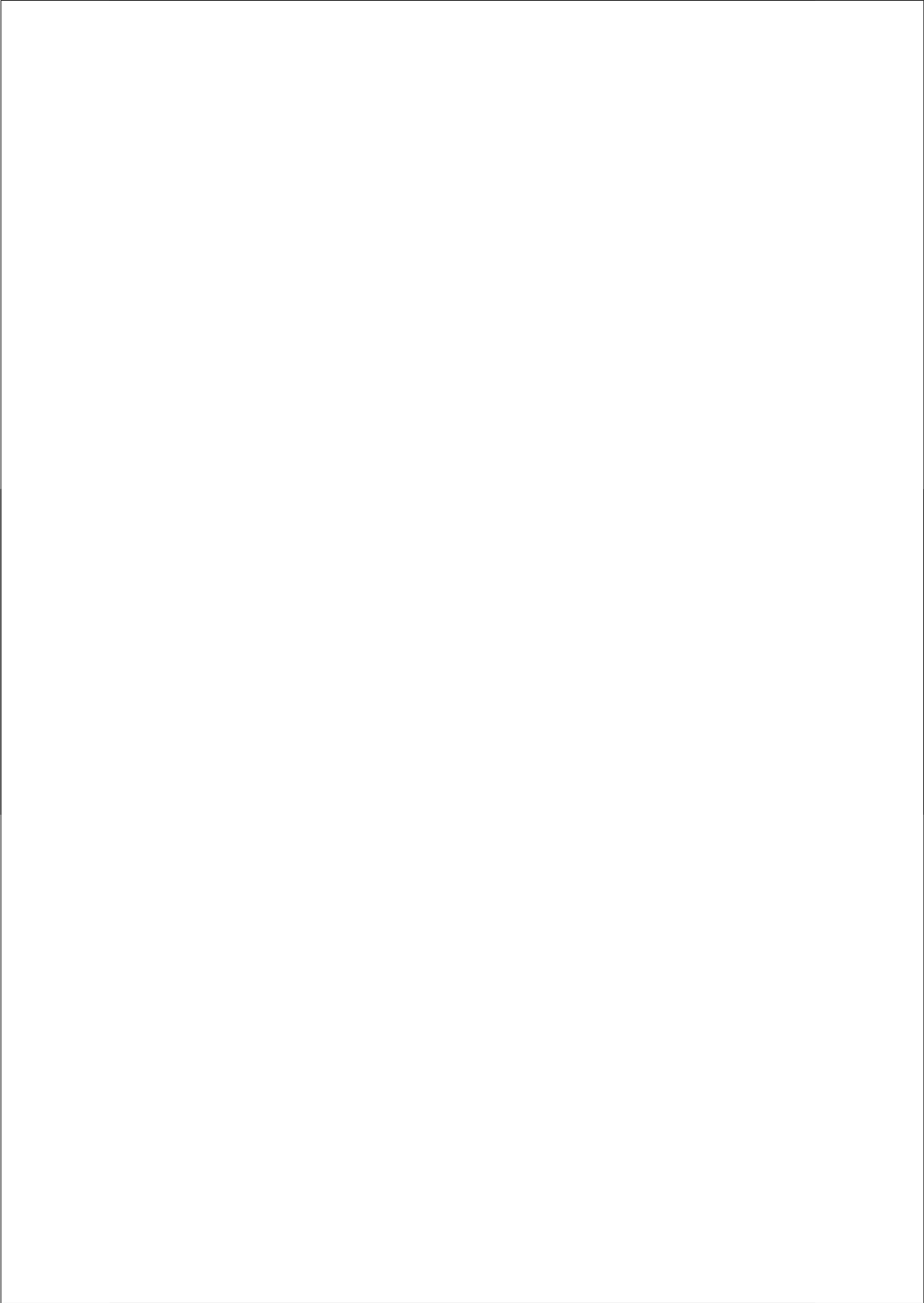
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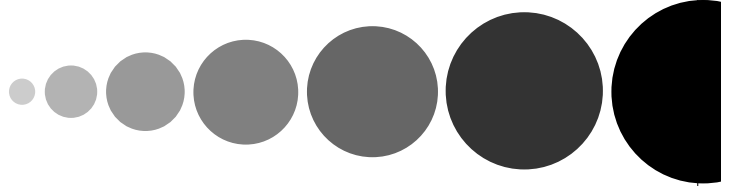
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# Chapter 5



## **Soft tissue artefact assessment during step-up using fluoroscopy and skin mounted markers**

Eric H. Garling<sup>1,2</sup>, Bart L. Kaptein<sup>1,2</sup>, Bart Mertens<sup>3</sup>, Willemijn Barendregt<sup>4</sup>,  
Dirk-Jan Veeger<sup>4</sup>, Rob G.H.H. Nelissen<sup>1</sup>, Edward R. Valstar<sup>1,5</sup>

<sup>1</sup> Department of Orthopaedics Leiden University Medical Center, The Netherlands

<sup>2</sup> Department of Radiology, Division of Image Processing, Leiden University Medical Center, Leiden, The Netherlands

<sup>3</sup> Department of Medical Statistics and Bioinformatics, Leiden University Medical Center, The Netherlands

<sup>4</sup> Faculty of Human Movement Sciences, Vrije Universiteit, Amsterdam, The Netherlands

<sup>5</sup> Department of Biomechanical Engineering, Faculty of Mechanical Maritime and Materials Engineering, Delft University of Technology, The Netherlands

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## Abstract

When measuring knee kinematics with skin mounted markers, soft tissue and structures surrounding the knee are hiding the actual underlying segment kinematics. Soft tissue artefacts can be reduced when plate-mounted markers or marker trees are used instead of individual unconstrained mounted markers. The purpose of this study was to accurately quantify soft tissue artefacts and to compare two marker cluster fixation methods by using fluoroscopy of knee motion after total knee arthroplasty during a step-up task.

Ten subjects participated six months after their total knee arthroplasty. The patients were randomised into (1) a plate-mounted marker group and (2) a strap-mounted marker group. Fluoroscopic data were collected during a step-up motion. A three-dimensional model fitting technique was used to reconstruct the *in vivo* 3D positions of the markers and the implants representing the bones.

The measurement errors associated with the thigh were generally larger (maximum translational error: 17 mm; maximum rotational error 12 degrees) than the measurement errors for the lower leg (maximum translational error: 11 mm; maximum rotational error 10 degrees). The strap-mounted group showed significant more translational errors than the plate-mounted group for both the shank (respectively  $3 \pm 2.2$  mm and  $0 \pm 2.0$  mm:  $p = 0.025$ ) and the thigh ( $2 \pm 2.0$  mm and  $0 \pm 5.9$  mm:  $p = 0.031$ ). The qualitative conclusions based on interpretation of the calculated estimates of effects within the longitudinal mixed-effects modelling evaluation of the data for the two groups (separately) were effectively identical. The soft tissue artefacts across knee flexion angle could not be distinguished from zero for both groups. For all cases, recorded soft tissue artefacts were less variable within subjects than between subjects.

The large soft tissue artefacts when using clustered skin markers, irrespective of the fixation method, question the usefulness of parameters found with external movement registration and clinical interpretation of stair data in small patient groups.



## 5.1 Introduction

To identify causes for knee dysfunction, related to diagnosis, treatment, rehabilitation programs and prosthesis design a complete understanding of knee kinematics is necessary (Ramsey and Wretenberg, 1999). The most widely accepted non-invasive method to study knee kinematics is stereophotogrammetry using skin-mounted markers (Leardini et al., 2005). However, soft tissue and structures surrounding the knee interfere with the actual underlying kinematics. Task dependent displacements of individual skin-mounted markers relative to the underlying bone of more than twenty millimetres are reported (Cappozzo et al., 1996; Fuller et al., 1997; Holden et al., 1997; Manal et al., 2000; Sati et al., 1996a; Sati et al., 1999b; Stagni et al., 2005). The location of the skin-mounted markers is another important factor influencing the error (Della Croce et al., 2000; Sati et al., 1996b). Soft tissue artefacts can be reduced when plate-mounted markers or marker trees -defining the individual body segments- are used instead of individual unconstrained mounted markers (Manal et al., 2000). In addition to gait data, stair data are often used in kinematical studies since stair climbing provides an approximation to other activities involving the flexed knee under high load during daily activities.

The most accurate measurement technique for *in-vivo* performance of total knee replacement prosthesis is 3D fluoroscopic analysis (Banks and Hodge, 2005; Dennis et al., 1998). The position and orientation of 3D computer models of total knee components are manipulated so that their projections on the image match those captured during the *in vivo* knee motion. If tantalum markers are used as alternative for standard skin-based markers, this technique can be used to determine the accuracy of skin-mounted marker fixation systems (Garling et al., 2005).

The purpose of this study was to accurately quantify soft tissue artefacts and to compare two marker cluster fixation methods by using fluoroscopy of subjects after total knee arthroplasty during a step-up task.

## 5.2 Material and Methods

Ten patients were included six months after a total knee arthroplasty (Table 1). Inclusion criteria were the ability to perform a step-up task without the help of bars or a cane, scored ‘none’ or ‘slight’ in the Knee Society pain score during activity. Exclusion criteria were a functional impairment of any other lower extremity joint besides the operated knee, the use of walking aids and the inability to walk more than 500 meters. The institutional medical-ethical committee approved the study and all subjects gave written informed consent.

**Table 1.** Anthropometric data for the two groups (median, min-max)

|                          | Plate mounted group (n=5) | Strap mounted group (n=5) |
|--------------------------|---------------------------|---------------------------|
| Age [years]              | 75, 65-82                 | 71, 53-79                 |
| BMI [kg/m <sup>2</sup> ] | 30, 27-35                 | 29, 26-34                 |
| Sex [F/M]                | 3/2                       | 3/2                       |

The patients were randomised into two groups: (1) a plate-mounted (PM) marker group and (2) a strap-mounted (SM) marker group. The PM group received contour moulded Thermoplast marker-plates containing six 3-mm stainless steel beads, mimicking the normally used reflecting markers, at the lateral side of the femur (14 x 24 cm) and the medial-frontal border of the tibia (12 x 24 cm). The marker plates were attached with Velcro straps (Figure 1A). To create a fluoroscopic depiction, the plates had extensions with marker-configurations (4x4x3 cm polystyrene blocs containing six 2-mm stainless steel beads) attached to them.

The SM group received two polystyrene squares (4x4x3 cm) attached to elastic straps containing six 2-mm RVS beads. The straps were positioned at the distal part of the lateral femur and at the proximal part of the lateral tibia (Figure 1B).

Reversed engineered models of the tibia component and the femoral component were used to assess the poses of the femur and the tibia bones assuming that the components were fixed in the bones [16].



**Figure 1.** The plate mounted markers configuration with adjustable extensions for visualisation (A). Strap mounted marker configurations in the polystyrene blocs (B).

### 5.2.1 Experimental set-up

The patients were asked to perform a step-up task in front of the fluoroscope. The step-up platform (riser height 18 cm) was centered between the image intensifier and the focus of the fluoroscope. The patients' knee was positioned in front of the image intensifier. The height of the image intensifier was adjusted to the height of the patient by centering the field of view at the lateral side of the joint cavity of the knee. The patients were asked to perform the step-up task in a controlled manner without the use of holding bars. At the start of the step-up, the leg with the total knee prosthesis was positioned on top of the step-up. The step-up was finished when the contra-lateral leg was on top of the step-up. The patient performed five step-ups in total, the first two step-ups were used to gain comfort with the experimental set-up and during the last three runs data were collected.

### 5.2.2 Data analysis

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

The 2D positions of the marker projections in the fluoroscopy images were automatically detected with an algorithm based on the Hough-transformation for circle detection (Duda and Hart, 1972). For obtaining a more accurate location of each 2D marker projection, a parabolic model of the marker is fitted to the marker's grey value profile (Vrooman et al., 1998). Marker configuration model based roentgen fluoroscopic analysis (Medis specials, Leiden, The Netherlands) was used to estimate the pose of the marker configurations from this 2D data (Garling et al., 2005). This method requires the 3D models of the defined rigid bodies. To assess 3D models of the marker configurations of both the strap markers and the marker plate markers, two RSA radiographs were made directly after the measurements and analysed using RSA-CMS software (Medis, Leiden, The Netherlands). These radiographs were also used to assess the relationship between the marker-configurations at the marker plates and the marker-configurations at the extensions.

The coordinate system was defined by the local coordinate system of the femoral component (Figure 2). Positive directions of rotations about these axes followed the right hand rule. Since prostheses are placed using alignment instrumentation, this local coordinate system is highly reproducible between subjects. The plate markers and the strap markers of the thigh and shank were defined with respect to this coordinate system.

With the assessed 3D positions of the bones, strap markers and plate markers, the relative rotations about all axes of the shank with respect to the thigh were calculated with extension (0 degrees) as the reference (Söderkvist and Wedin, 1993). Positive directions for rotations about the coordinate axes were defined as posterior tilt, external rotation and valgus rotation.

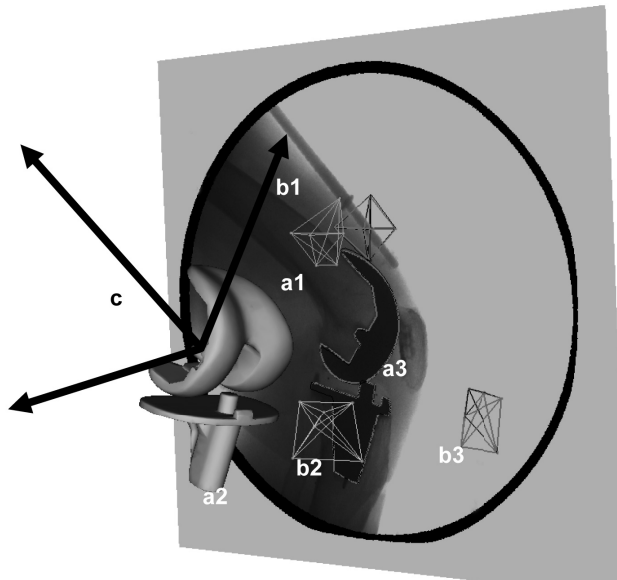


**Figure 2.** An analysed fluoroscopic image of the PM group showing the reversed engineered models of the femoral component (**a1**), and tibial component (**a2**) and their 2D projections (**a3**). In addition, the marker configuration models of the plate mounted markers on the femur (**b1**), tibia (**b2**) and their 2D projections are visible (**b3**). The orientation of the coordinate system is defined by the local coordinate system of the femoral component (**c**).

The measurement error i.e. soft tissue artefact was defined as the difference between the joint rotations of the bones and the joint rotations of the strap or plate markers.

### 5.2.3 Statistical analysis

The non-parametric Mann Whitney U-test was used to compare the differences in anthropometric data between the SM group and the PM group. For all statistical analyses, significance was set as a p-value of less than 0.05.

For both knee internal-external rotation and knee joint adduction-abduction a linear mixed-effects model for longitudinal data was used for analysis, augmented with a penalized spline with within-patient random (spline) effect to evaluate and adjust for possible deviation from the linear effects assumption. We refer to Durban

et al., (2005) for a full description of the model and data-analytic approach (Durban et al., 2005). The model assumes a subject-specific linear trend of observed outcome (internal-external rotation and adduction-abduction of the knee joint) with knee flexion angle and adds a patient-specific penalized spline to counter for possible subject-specific non-linear deviation from the global linear trend. For the linear component of the model, results may be summarized through the population intercept and slope of the global linear trend (i.e. the population mean) as well as within- and between- patient-specific random effects for slope and intercept. With respect to the non-linear (spline) component of the model it was found that fitted effects were effectively zero and may therefore be ignored from any further qualitative interpretation or discussion of results.

### 5.3 Results

The measurement errors associated with the thigh, presented in Table 2, were generally larger (maximum translational error: 17 mm; maximum rotational error 12 degrees) than the measurement errors for the lower leg (maximum translational error: 11 mm; maximum rotational error 10 degrees). The SM group showed significant more translational errors than the PM group for both the shank (respectively  $3 \pm 2.2$  mm and  $0 \pm 2.0$  mm:  $p = 0.025$ ) and the thigh ( $2 \pm 2.0$  mm and  $0 \pm 5.9$  mm:  $p = 0.031$ ). Rotational errors up to 12 degrees were found for the SM group.

However, it is more important to assess how the soft tissue artefact propagates to knee arthrokinematics. Especially the non-sagittal plane joint movements are of interest. In Figures 3 and 4, the difference between the bone and the SM and PM markers for knee joint internal/external rotation and adduction/abduction are presented. During higher flexion angles, the internal-external rotation of the shank was over-estimated by the skin mounted markers groups. During extension the internal-external rotation error between skin and bone decreased. In two cases in the PM group, the skin markers under-estimated the actual internal-external rotation of the shank. In general, the adduction-abduction of the shank was over-estimated by the skin mounted marker groups.

**Table 2.** Relative motion of the plate and strap mounted markers with respect to the underlying bone.

|       |       | Shank                |                        | Thigh                |                        |
|-------|-------|----------------------|------------------------|----------------------|------------------------|
|       |       | Translations<br>[mm] | Rotations<br>[degrees] | Translations<br>[mm] | Rotations<br>[degrees] |
| Plate | Mean  | -0.1                 | 0.4                    | 0.2                  | -0.4                   |
|       | Stdev | 2.0                  | 1.8                    | 5.9                  | 2.9                    |
|       | Min   | -6.9                 | -8.3                   | -17.4                | -10.2                  |
|       | Max   | 10.9                 | 9.6                    | 16.6                 | 5.2                    |
| Strap | Mean  | 3.0                  | -0.8                   | 1.8                  | -0.7                   |
|       | Stdev | 2.2                  | 2.8                    | 2.0                  | 3.7                    |
|       | Min   | -0.8                 | -7.2                   | -1.6                 | -11.8                  |
|       | Max   | 8.3                  | 3.6                    | 7.5                  | 7.7                    |

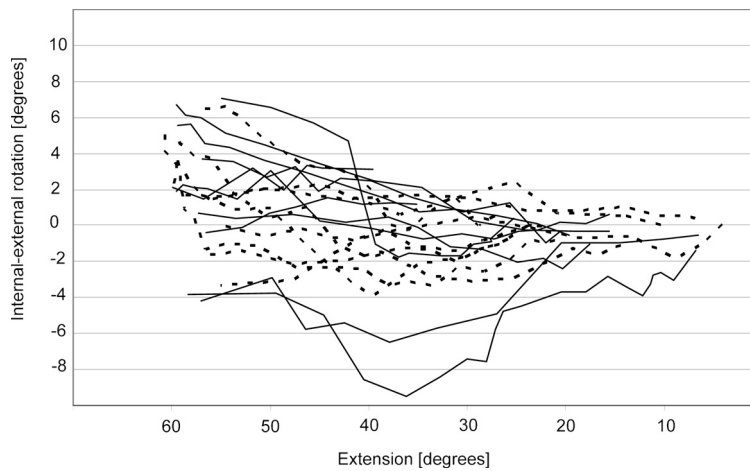


**Figure 3.** Difference between the bone and either plate (-) or strap (- -) mounted markers resulting in internal-external rotation of the shank with respect to the thigh. Positive values describe an over-estimation, zero described perfect agreement and negative values describe an under-estimation of the skin mounted marker derived knee joint rotations.

Table 3. Summary of the calculated estimates of the linear effect

|                                   | Plates                                          |                                |                                     | Straps                |                                |                                     |
|-----------------------------------|-------------------------------------------------|--------------------------------|-------------------------------------|-----------------------|--------------------------------|-------------------------------------|
|                                   | Estimate<br>[degrees]                           | Standard<br>error<br>[degrees] | Confidence<br>interval<br>[degrees] | Estimate<br>[degrees] | Standard<br>error<br>[degrees] | Confidence<br>interval<br>[degrees] |
| <b>Internal-external rotation</b> | Intercept                                       | 8.22                           | -42.92 : 59.09                      | -2.66                 | 21.68                          | -45.67 : 39.28                      |
|                                   | Slope                                           | 0.28                           | 0.61 : -0.90 : 1.48                 | -0.02                 | 0.53                           | -1.06 : 1.01                        |
|                                   | Reproducibility intercept                       | 0.75                           |                                     | 0.68                  |                                |                                     |
|                                   | Reproducibility slope                           | 0.93                           |                                     | 0.93                  |                                |                                     |
|                                   | Standard error within patient effect intercept  | 0.61                           | 0.18                                | 0.65                  | 0.20                           | 0.34 : 1.10                         |
|                                   | Standard error within patient effect slope      | 0.15                           | 0.01                                | 0.15                  | 0.01                           | 0.12 : 0.17                         |
|                                   | Standard error between patient effect intercept | 1.06                           | 0.62                                | 0.94                  | 0.51                           | 0.38 : 2.25                         |
|                                   | Standard error between patient effect slope     | 0.55                           | 0.23                                | 0.54                  | 0.23                           | 0.28 : 1.12                         |
| <b>Adduction-abduction</b>        | Intercept                                       | 17.48                          | -32.07 : 67.17                      | 0.14                  | 18.60                          | -36.75 : 37.18                      |
|                                   | Slope                                           | 0.28                           | 0.60 : -0.89 : 1.45                 | -0.02                 | 0.44                           | -0.89 : 0.83                        |
|                                   | Reproducibility intercept                       | 0.53                           |                                     | 0.64                  |                                |                                     |
|                                   | Reproducibility slope                           | 0.93                           |                                     | 0.95                  |                                |                                     |
|                                   | Standard error within patient effect intercept  | 1.03                           | 0.54                                | 0.62                  | 0.17                           | 0.35 : 0.99                         |
|                                   | Standard error within patient effect slope      | 0.15                           | 0.01                                | 0.12                  | 0.01                           | 0.11 : 0.15                         |
|                                   | Standard error between patient effect intercept | 1.09                           | 0.70                                | 0.83                  | 0.41                           | 0.37 : 1.98                         |
|                                   | Standard error between patient effect slope     | 0.54                           | 0.22                                | 0.52                  | 0.19                           | 0.28 : 1.00                         |

From a qualitative point of view, the calculated summary estimates (systematic linear population effect, within and between patient estimates and variability) are identical (Table 3). The mean population deviation (as longitudinal trend) could not be distinguished from zero (linear population effect) for both groups. For all cases the errors were less variable within subjects, than between subjects. Taking the small sample size in the current study into account, we must therefore conclude that the studied effect is either small, or absent.

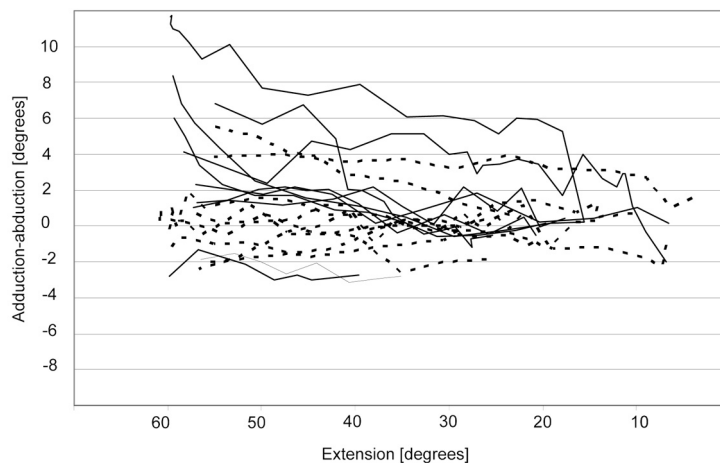


**Figure 4.** Difference between the bone and either plate (-) or strap (- -) mounted markers resulting in adduction-abduction of the shank with respect to the thigh. Positive values describe an over-estimation, zero described perfect agreement and negative values describe an under-estimation of the skin mounted marker derived knee joint rotations.

Paradoxical movements were registered when e.g. the movement of the plate-mounted markers was compared with the underlying bone kinematics. For instance, Figure 5 shows an external rotation of the tibia with respect to the femur while the plate markers show a movement pattern that can be compared with the screw-home phenomenon or external rotation of the tibia in extension with internal rotation as the angle of flexion increases. In the first phase of extension, the plate markers attached to the tibia rotate internally while in the end phase these plate markers rotate externally.

There was no relationship between Body Mass Index (BMI) and the error in knee angles for either group.

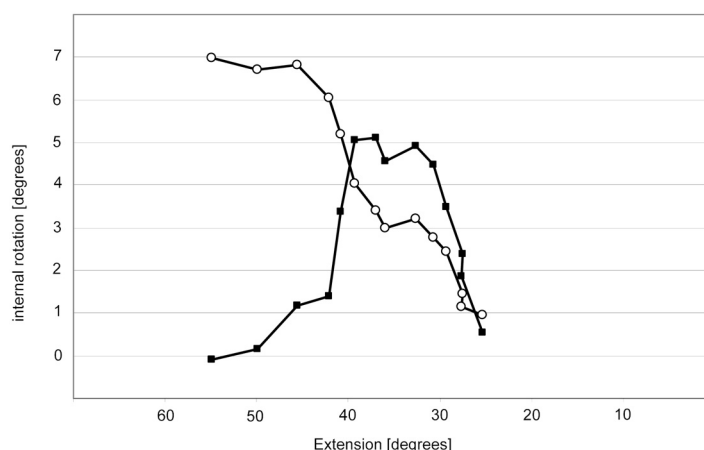


**Figure 5.** Example of an individual subject showing a paradoxical internal-external rotation of plate mounted markers (■) and the underlying prosthesis (○) of the tibia with respect to the femur.

## 5.4 Discussion

To avoid the error component of soft tissue artefacts in kinematic analyses, kinematic data have been obtained via invasive techniques (Fuller et al., 1997; Ramsey and Wretenberg, 1999), exoskeletal attachment systems (Ganjikia et al., 2000; Sati et al., 1996a), computed tomography (Hagemeister et al., 1999), magnetic resonance imaging (Patel et al., 2005), elimination of this error through mathematical correction (Lucchetti et al., 1998; Sati et al., 1996b), Roentgen Stereophotogrammetric Analysis (RSA) and fluoroscopy (Banks and Hodge, 19996; Fantozzi et al., 2003). However, not all of these techniques are applicable to study knee kinematics because of disadvantages like risk of infection (especially applicable after TKA), pain, loss in freedom of movement, high exposure to radiation, or the inaccuracy of the method.



Fluoroscopy seems to be the most accurate and accepted method to study kinematics after total knee replacement. Fluoroscopic data can be utilised in an experimental environment to validate kinematic acquisition methods or validate dynamic models of body segments. However, besides the patients' exposure to radiation it would not be practical as a clinical tool due to the limitation of analysis to a single joint and the extensive image data processing. Optimising the use of stereophotogrammetric systems and providing insight into the measurement accuracy would therefore be the goal to aim for. The most appealing solution to correct for the skin movement error would be to filter out the contaminating soft tissue movement. However, no regular systematic pattern of marker displacement was found in this study for both marker attachment methods. Absence of a regular pattern was also reported in several other studies (Holden et al., 1997; Manal et al., 2003; Sati et al., 1996b). The absence of a regular pattern makes accurate mathematical correction of marker positions impossible. The frequency content of the soft tissue moving relative to the bones lies within the same spectra as the actual motion of the bones itself (Fuller et al., 1997; Stagni et al., 2005). Next to this several *in vivo* kinematic studies of TKA have demonstrated that femorotibial kinematics in itself is not predictable in patients with a total knee prosthesis (Banks and Hodge, 2004; Dennis et al., 1998; Hill et al., 2000).

Most studies quantifying soft tissue artefacts used walking, running or cycling as the motor task for healthy subjects. It can be concluded from these studies that there is -like in the present study- a large variability between subjects and in the task performed. Therefore, it is not possible to compare the error found with the marker attachment methods used in this study with the errors found in the literature. An explanation for the variability between subjects in this study might be deviations in orientation of the femoral component from the actual epicondylar axis after implantation despite the use of alignment instrumentation (Chauhan et al., 2004). This will cause deviations between subjects in the reference local coordinate system defined by the femoral component.

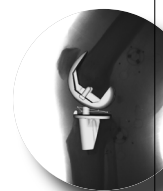
Two other studies have also used fluoroscopy to quantify skin movement artefacts. Cappozzo et al. (1996) compared movement of anatomical skin markers during walking and movement of the external fixation devices patients had due

to a fracture of the tibia or femur. They reported skin marker displacements of up to 40 mm and rotations of 4-10 degrees and 6-20 degrees with respect to the tibia and femur respectively. Anatomical landmarks were used as reference, thereby introducing another source of error (Della Croce et al., 2005). This might explain the larger displacements compared to our study. Sati et al. (1996a) compared individual skin markers and geometric parameters of the bone to quantify skin movement on the femur during dynamic flexion. Maximal ranges of the soft tissue artefacts in the in plane directions found were 42.5 mm and 20 mm. The use of a simplified fluoroscopic technique and the use of unconstrained markers might explain the differences with the current study.

Further study, including expanding the patient group may reveal systematic errors allowing mathematical correction for skin artefacts in specific tasks that were not found in this study due to the small sample size and inherently large between-subject variability. A recently developed technique for fluoroscopy using digital reconstructed radiographs will provide accurate data of the *in vivo* kinematics of healthy subjects in the near future (Mahfouz et al., 2005). A database of this accumulated data may provide accurate dynamic models and insight in skeletal kinematics.

## 5.5 Conclusion

The large soft tissue artefacts when using clustered skin markers, irrespective of the fixation method, question the usefulness of parameters found with external movement registration and clinical interpretation of stair data in small patient groups. Results of femorotibial kinematics derived from skin-mounted markers during a stair task should be interpreted and presented within the margin of error presented in this study.



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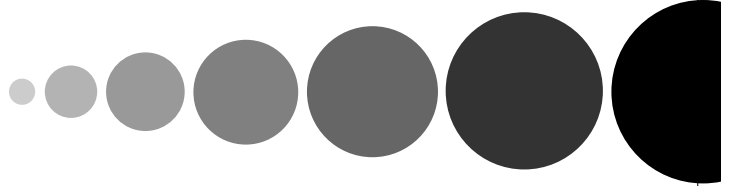
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# Chapter 6



## **Increased muscle activity to stabilise mobile bearing knees in patients with Rheumatoid Arthritis**

Eric H. Garling<sup>1</sup>, Mirjam van Eck<sup>2</sup>, Tessa Wedding<sup>2</sup>, Dirk-Jan Veeger<sup>2</sup>,  
Edward R. Valstar<sup>1,3</sup>, Rob G.H.H. Nelissen<sup>1</sup>

<sup>1</sup> Department of Orthopaedics, Leiden University Medical Center, The Netherlands

<sup>2</sup> Department of Human Movement Sciences, Vrije Universiteit Amsterdam, The Netherlands

<sup>3</sup> Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials  
Engineering, Delft University of Technology, The Netherlands

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## **Abstract**

The aim of this study was to assess the differences in muscle activity (surface EMG) between a posterior stabilised (PS) total knee design and a mobile bearing (MB) posterior cruciate ligament retaining design in rheumatoid arthritis (RA) patients during a step-up task.

Four patients with a PS total knee prosthesis and three patients with a MB total knee prosthesis were selected based on pain score, knee function, range of motion and joint stability.

Clinical scores and functional scores were comparable between the two groups preoperatively and at the one-year follow-up. Visual analysis of the EMG activity of the main flexor and extensor muscles showed that the activity of both extensor and flexor muscles of the MB group was on average higher compared to the PS group. When the maximum activities of the muscles were compared, the patients in the MB group showed a significant higher maximum peak activity ( $p < 0.05$ ) of the Vastus Medialis, Vastus Lateralis and Semitendinosus during step-up than the patients in the PS group. Also the instance of activation of the Vastus Medialis and the Vastus Lateralis was significant earlier in the MB group compared to the PS group.

Since the differences between the PS and the MB group didn't only show an increase of muscle activity but also an earlier activation of the flexor muscles, this may express compensation by coordination. Rehabilitation programs for RA patients should include besides muscle strength training, elements of muscle-coordination training.



## 6.1 Introduction

The success of total knee arthroplasty (TKA) is influenced by a complex interaction between the geometry of the implant and the active and passive soft-tissue structures that surround the articulation (Callaghan et al., 2000). Knee joint kinematics after TKA influence the performance and lifespan of the prosthesis. Several studies have related variations in the abnormal gait patterns after TKA to the design of articulating surfaces (Dennis et al., 1998; Kärrholm et al., 1994; Nilsson et al., 1991) and the aetiology of prosthetic loosening (Hilding et al., 1995).

PS total knee prostheses substitute for the posterior cruciate ligament by a post-and-cam mechanism, which causes rollback when the knee is flexed, translating the femorotibial contact area posterior and thereby increasing the quadriceps extension moment. However, this central cam also imposes some restrictions towards the kinematics. The PS total knee is designed to provide passive stability and therefore improves postoperative function and prevents posterior subluxation of the tibia (Stern and Insall, 1992).

MB total knee prostheses have polyethylene inserts that can translate and rotate with respect to the tibial plateau. The MB knee is designed to allow the kinematic advantages of large and highly congruent surface contact and low contact pressures, while preserving flexion, extension and rotation in knee motion (Kaper et al., 1999). In the mobile bearing knee design, there is an increased dependence upon preserved ligaments and active structures to provide stability. Therefore, it is hypothesized that the muscle groups surrounding the knee should show more active stabilisation in patients with a MB prosthesis, whereas in patients with a PS prosthesis the knee joint is stabilised primarily by the intrinsic constraint of the design and thus would need less muscle activation.

The aim of this study was to assess the differences in muscle activity between RA patients with either a PS total knee design or a MB posterior cruciate ligament retaining design during a step-up task.

## 6.2 Methods

Four patients with a PS total knee prosthesis and three patients with a MB total knee prosthesis were selected based on pain score, knee function, range of motion and joint stability (Table 1), from a larger group of patients included in a previous study comparing MB and PS total knees (Garling et al., 2005). All the patients included in this study suffered from rheumatoid arthritis. The patients were included at one year postoperatively, and they had to be able to perform a step-up movement. Furthermore, they had to have a unilateral total knee replacement, the ability to walk more than one kilometre, and not use walking aids and/or a functional impairment of any other lower extremity joint besides the operated knee. All recorded data was coded.

**Table 1.** Clinical data and functional scores at the one-year follow-up evaluation.

|    | Age     | BMI                  | Knee<br>Score | Function<br>Score | Flexion | M-L<br>instability | A-P<br>instability | Fem-Tib<br>Angle |     |
|----|---------|----------------------|---------------|-------------------|---------|--------------------|--------------------|------------------|-----|
|    | [years] | [kg/m <sup>2</sup> ] | [pts]         | [pts]             | [°]     | [°]                | [mm]               | [°]              |     |
| MB | 1       | 74                   | 32.2          | 85                | 100     | 130                | < 5                | 10-14            | 183 |
|    | 2       | 74                   | 27.7          | 94                | 100     | 120                | < 5                | < 5              | 178 |
|    | 3       | 63                   | 31.2          | 88                | 15      | 90                 | 5-10               | < 5              | 179 |
| PS | 1       | 62                   | 24.8          | 85                | 80      | 90                 | < 5                | 6-9              | 183 |
|    | 2       | 63                   | 23.6          | 87                | 100     | 100                | < 5                | < 5              | 183 |
|    | 3       | 57                   | 32.1          | 97                | 30      | 110                | < 5                | < 5              | 183 |
|    | 4       | 76                   | 31.2          | 89                | 70      | 125                | < 5                | < 5              | 188 |

In the PS group the patients had received the Interax Posterior Stabilised total knee prosthesis (Stryker-Howmedica, Rutherford, New Jersey, USA). In the MB knee group, the Interax Integrated Secure Asymmetric (ISA) total knee prosthesis was used. This mobile bearing total knee design is only conforming in extension and permits anterior/posterior sliding and rotation of the inlay on the tibial tray. The maximum possible movement of the inlay center is 8.5 mm anterior/posterior and 18 degrees of axial rotation relative to the tibial tray.

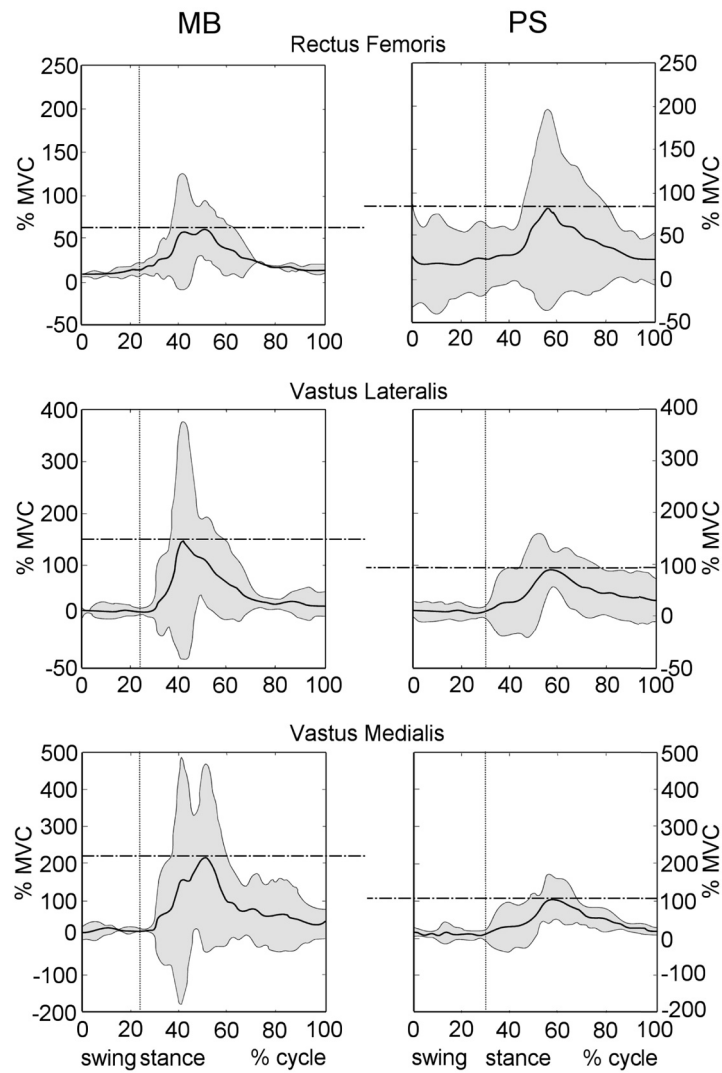


**Figure 1.** Smoothed rectified EMG of the extensors around the knee during step-up. The EMG signal is averaged and normalised to the MVC for all subjects in each group (MB: n=3; PS: n=4). The greyed area indicates the 95% confidence interval. The start of the stance phase is visualised by the dotted vertical line

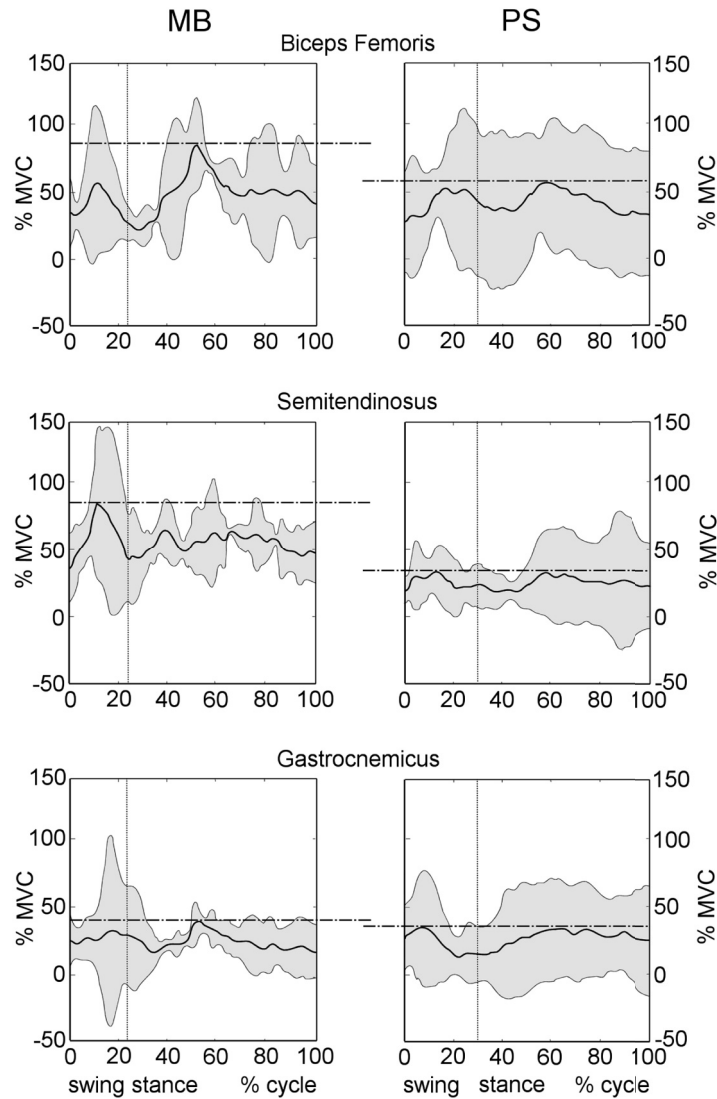


**Figure 2.** Smoothed rectified EMG of the flexors around the knee during step-up. The EMG signal is averaged and normalised to the MVC for all subjects in each group (MB:  $n=3$ ; PS:  $n=4$ ). The greyed area indicates the 95% confidence interval. The start of the stance phase is visualised by the dotted vertical line. The dashed-dotted line indicates the difference between the two groups of the EMG signal for each muscle.

External movement registration (Optotrak: Northern Digital inc., Canada) was used to determine the beginning and the end of the step-up cycle. A force plate was used to determine the onset of the stance phase during the step-up. All measurement systems were time-synchronised. The activity was performed barefoot without the aid of bars. Prior to the recordings, functional and anthropometrical measurements were taken. Patients were assessed clinically by an orthopaedic surgeon using radiographic and functional evaluation using the Knee Society Score (Ewald, 1989).

Surface EMG of the most important stabilising muscles of the knee was recorded at a sample frequency of 1000 Hz. The muscles recorded were the Rectus Femoris (RF), Vastus Lateralis (VL), Vastus Medialis (VM) as the major extensor muscles; the Biceps Femoris (BF) and Semitendinosus (ST) as two major flexor muscles; and the Gastrocnemius Medialis (GM). Electrode placement for the different muscles used in this study was similar as described by Nelissen et al. (1995). Before placing the electrodes, the skin was shaved, slightly braided and cleaned with alcohol to reduce skin resistance. EMG data were processed with Matlab (The Mathworks Inc., Natick, USA). After removing movement artefacts the raw data was high-pass filtered (Butterworth, 10 Hz) and full-wave rectified. This full-wave rectified signal was filtered with a low-pass filter using a second-order recursive Butterworth filter with a cut off frequency of 2 Hz. The recorded EMG was normalised to the Maximum Voluntary Contraction (MVC). This MVC was determined by an isometric contraction of each muscle prior to the experiment. The average of three isolated MVC's of each muscle was used to normalise the recorded EMG.

Telemetric Light Emitting Diodes (LED's) were placed on the operated leg of each patient, located at anatomical landmarks, and were recorded with a frame rate of 100 Hz. The LED's were attached at the anterior superior iliac spines, the lateral malleolus, the lateral side of the fifth metatarsal and the lateral aspect of the calcaneus. Two cameras of the Optotrak system were positioned lateral-frontal and lateral-dorsal of the patients operated side. When markers were occluded during the measurements the missing values were replaced by means of interpolation.

A strain gauge force plate with a surface area of 1 m<sup>2</sup> was used to measure at a frame rate of 500 Hz the ground reaction forces in all directions. The force plate was calibrated prior to the measurements (Pijnappels et al., 2001).



At the beginning of the step-up the patient was asked to stand, feet together, at a distance of 15 cm in front of the 18-cm-high force plate platform, and step onto the platform using the limb with the implant under investigation. The start of the movement cycle (0%) was defined as the first change in position (movement speed  $> 0.01$  m/s) of one of the foot markers. The end of the movement cycle (100%) was defined as the maximum height of the Spina Iliaca Anterior Superior (end of single limb support). The movement cycle was divided into a swing phase and a stance phase. The swing phase was defined as the first part of the movement cycle until the instant of support (force on platform  $> 10$  N). The stance phase was defined from the moment of support until the end of the movement cycle. After a brief orientation session, the patient performed the step-up three times, with a rest period of 2 minutes between trials.

Non-parametric tests were used to determine the differences in maximum activity of the recorded muscles between the two groups. Statistical differences were defined as significant at an alpha level of 0.05.

### **6.3 Results**

The preoperative and one year follow-up clinical scores and functional scores were comparable between the two groups (Table 1). Patient 3 of the MB group had a poor function score. The Knee Function Score showed that this patient was unable to walk more than one kilometre at the time of the measurements and used a rail to step-down from the stairs. However, the patient was pain free and had no impairments when climbing stairs. Two patients had a limited flexion of 90 degrees of the knee joint. These patients had no flexion contracture but a small lateral femoral component flexion angle (0-1 degree). When this angle is (too) small, high flexion of the knee will result in early impingement of the femoral component with the tibia.

No difference in co-contraction was observed between the two groups. In Figure 1, the mean EMG data of the extensor muscles is presented as a percentage of the MVC, of all patients in each group during the step-up task. For the BF and ST – as the flexor muscles – the data is presented in Figure 2. Visual analysis shows that the



activity of both extensor and flexor muscles of the MB group is on average higher compared to the PS group. Only the RF showed on visual basis a higher activity in the PS group compared to the MB group. However, this difference was not significant. When the maximum activities of the muscles were compared, the patients in the MB group showed a higher maximum peak activity of the VM ( $p = 0.023$ ), VL ( $p = 0.029$ ) and ST ( $p = 0.011$ ) during step-up than the patients in the PS-group. Also the instance of activation of the VM and the VL was significant earlier in the MB group compared to the PS group (respectively  $p=0.043$  and  $p=0.049$ ). The VM and VL in the MB group and the RF in the PS group showed a large 95% confidence interval, showing not only the inter-individual differences but also intra-individual differences.

Two patients of the MB group reported a subjective unstable feeling in the knee. The EMG data of these two patients showed also a high maximum activity of VM and VL.

#### 6.4 Discussion

Differences in kinematics between the PS and the MB group were analysed during a step-up movement. Stairs and steps are frequently encountered during the course of daily activity and are important aspects in functional assessment. In comparison to normal walking stair climbing is a more stressful activity, which requires a greater flexion of the knee. Therefore, during this activity it is possible to stress differences between different knee replacement designs more clearly (Andriacchi et al., 1982).

Although the study population was a homogeneous group, the inclusion criteria bias the outcome of the study since the selected patients represent the 'best' patients of the original knee prostheses cohort (Garling et al., 2005). Patients with MB total knees will benefit from well functioning active and passive soft-tissue structures surrounding the knee joint preoperatively, since preoperative function and general condition of the patient are important factors determining the postoperative function after TKA (Nelissen, 1995). However, no significant differences in clinical and function scores between the two groups were observed preoperatively. Only 7

patients in this rheumatoid group sufficed the inclusion criteria. This emphasises that a prerequisite for patients after TKA is a good muscle function to be able to perform a step-up at all. Statistical analysis showed a low power i.e. more false negative outcome, because of this small number of patients and the large observed confidence intervals in the EMG data. Nevertheless, the EMG data supported our hypothesis.

The maximum voluntary contraction (MVC) was used in this study to normalise the muscle activity. The EMG data of the MB group showed activity of the VM and VL larger than 100%. This might be explained by a sub maximal contraction of the patients during the MVC measurements due to improper activation of the isolated muscle. Another explanation could be avoidance for pain during contraction, however the patients reported no pain during the measurements. Furthermore, enforced tasks during daily activities may often require higher activation levels of the muscles than patients are willing to give during a MVC measurement. Recently, a different method of normalising EMG data was published (Doorenbosch and Harlaar, 2003). The EMG data was normalised using a limited number of isokinetic contractions of the knee during the entire range of motion. The normalised data showed a high discriminating power. It is advised to normalise EMG data for TKA patients by means of this method in the future.

*In vivo* fluoroscopic studies have shown an abnormal anteroposterior translation during flexion and extension of the knee in both mobile and fixed bearing designs (Callaghan et al., 2000; Dennnis et al., 1998; Stiehl et al., 1997). This paradoxical movement is responsible for unfavorable kinematics of the extensor mechanism. The predominant shear force during gait and stair climbing is directed posterior on the tibia, which normally is resisted by the posterior cruciate ligament, preventing an anterior movement of the femorotibial contact point (Andriacchi and Hurwitz, 1997). At lesser degrees of flexion, the direction of the patellar ligament pull is anterior on the tibia. The anterior cruciate ligament normally resists this anterior directed shear force on the tibia. Since the anterior cruciate ligament is absent in both the PS and MB designs, the femorotibial contact point will shift to anterior especially in a MB design where there is no central cam preventing anterior translation. As a consequence of this anterior movement of the tibia, the quadriceps efficiency is reduced by a



decrease of the moment arm about the condylar contact point (Andriacchi et al., 1982). Higher levels of activity of the quadriceps are expected in patients who have this anterior translation of the tibia at the beginning of extension. In this study we also found more activity in the VM and VL muscles. Fluoroscopy could be the appropriate technique to confirm the anterior translation of the femorotibial contact point in patients with high EMG activity of the quadriceps (Dennis et al., 1998; Stiehl et al., 1997; Banks et al., 1997).

Since the cruciate ligaments are disrupted after TKA, normal physiological knee joint kinematics cannot occur (O'Connor et al., 1996). Soft tissue and muscles acting on the knee substitute for the absence of the anterior cruciate ligament and or the posterior cruciate ligament. One of the difficulties described in PCL-retaining designs is tensioning of the posterior cruciate ligament. If the tension of the PCL is not restored properly, the ligament will lose its stabilising function (Dennis et al., 1998; Nelissen, 1995). The importance of the PCL is higher with larger flexion angles. Inadequate tension could also be an explanation for the higher compensatory activity of the quadriceps during extension in the MB group. The EMG data of the MB group showed a statistically significant higher maximum activity of the VM and VL during the stance phase of step-up. In normal subjects the VL is also an important stabiliser of the knee during stair ascent (McFayden and Winter, 1988).

The early onset of hamstring activity, especially the lateral hamstrings (BF), is due to the dynamic stabilisation of the knee in preparation for foot contact with the ground (Lass et al., 1991). In the MB group the BF showed a higher activity than in the PS group before the stance phase. This anticipation before contact with the ground was further emphasized in the total movement time of the step-up. The BF pulls the tibia into a position so that the knee joint is stable during extension.

Higher EMG levels of the main stabilisers of the knee (i.e. quadriceps and hamstrings) in the MB group indicate that compensatory muscle activity is used to stabilise the femur with respect to the tibia. It has been shown that simultaneous contraction of the knee muscles increase the stiffness of the joint and reduces anterior-posterior laxity up to 50 percent of the normal value (Markolf et al., 1987). This kind of protective knee stabilisation in MB knees has also been observed in a study comparing a MB and a fixed bearing TKA design (Catani et al., 2003). In

that study a decrease in the frontal external knee moments in the MB group was observed suggesting that compensatory mechanism seemed to be adopted especially during stair ascending.

The mobile bearing design is more forgiving during surgery, self-correcting the slight axial mal-rotations between the actual anatomy and the total knee prosthesis. Furthermore, slight mal-rotations between the femoral and tibial component will be adjusted as well. However it seems that a MB design is more demanding for the RA patient requiring a better preoperative and postoperative status of the ligaments and the muscles consuming more energy.

Since the differences between the PS and the MB group didn't only show an increase of muscle activity but also an earlier activation of the flexor muscles, this may express compensation by coordination (Rutherford, 1988). Rehabilitation programs for RA patients should include besides muscle strength training, elements of muscle-coordination training.



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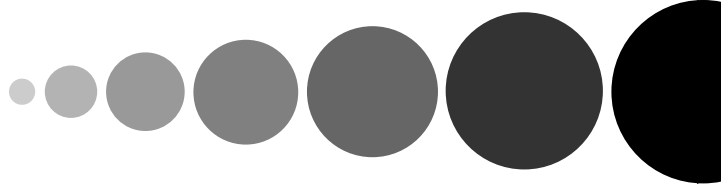
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# Chapter 7



## **The effect of a mobile bearing total knee prosthesis on co-contraction during a step-up task in patients with rheumatoid arthritis**

Eric H. Garling<sup>1,2</sup>, Nienke Wolterbeek<sup>1</sup>, Sanne Velzeboer<sup>4</sup>, Rob G.H.H. Nelissen<sup>1</sup>, Edward R. Valstar<sup>1,3</sup>, Caroline A. Doorenbosch<sup>4</sup>, Jaap Harlaar<sup>4</sup>

<sup>1</sup> Department of Orthopaedics, Leiden University Medical Center, Leiden, The Netherlands

<sup>2</sup> Department of Radiology, Division of Image Processing, Leiden University Medical Center, Leiden, The Netherlands

<sup>3</sup> Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials Engineering, Delft University of Technology, The Netherlands

<sup>4</sup> Department of Rehabilitation Medicine, VU University Medical Center, Amsterdam, The Netherlands

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## **Abstract**

It was hypothesized that rheumatoid arthritis (RA) patients with a total knee prosthesis that allows axial rotation of the bearing (MB) will show more co-contraction to stabilize the knee joint during a step-up task than RA 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). Surface 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 ROM during the step-up task than the patient group, 96 vs 88 degrees ( $p = 0.007$ ). 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, however co-contraction levels were not different. Compared to the control group arthroplasty 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-contrast approximately 20% later compared to the MB group.

RA patients after total knee arthroplasty show 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. MB and FB patients showed no difference in co-contraction levels, although coordination in FB is closer to controls than MB subjects. Since visual analysis revealed a timing difference between the MB and FB group, this may express compensation by coordination. Rehabilitation programs for RA patients should include besides muscle strength training, elements of muscle-coordination training.



## 7.1 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 & 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 (Akjaer et al., 2003).

Many clinical, biomechanical and modeling 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 (Doorenbosch and Harlaar, 2004).

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.

## 7.2 Methods

### 7.2.1 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 5 controls were compared with 5 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 (sd 0.04) versus a CCI of 0.25 (sd 0.07) for the controls. Based on this information a sample size of 9 patients versus 8 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 Stabilised (MB group) prosthesis was implanted and in four patients a FB NexGen Legacy Posterior Stabilised (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 center of rotation of the bearing. The slot in the plastic 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 degrees and induces mechanical rollback while inhibiting posterior subluxation of the tibia. In the frontal plane, the component has a dished

articulation, providing a large contact area even in up to 7 degrees varus/valgus mal alignment. 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.



**Table 1.** Subjects data 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.

|                          | <b>MB group</b><br>median,<br>min-max | <b>p</b>     | <b>FB group</b><br>median,<br>min-max | <b>Patient group</b><br>median,<br>min-max | <b>p</b>     | <b>Control group</b><br>median,<br>min-max |
|--------------------------|---------------------------------------|--------------|---------------------------------------|--------------------------------------------|--------------|--------------------------------------------|
| Age [years]              | 64, 46–74                             | ns           | 67, 60–81                             | 66, 46–81                                  | <b>0.002</b> | 30, 19–54                                  |
| BMI [kg/m <sup>2</sup> ] | 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 [degrees]            | 87, 64–92                             | ns           | 90, 84–95                             | 88, 64–95                                  | <b>0.007</b> | 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                                  | <b>0.003</b> | 25, 17–61                                  |
| Mflex [Nm]               | -28, -30– -27                         | ns           | -18, -43– -16                         | -28, -43– -16                              | <b>0.012</b> | -17, -25– -6                               |
| Mnet [Nm]                | -12, -15– -8                          | ns           | 0, -26–4                              | -12, -26– -4                               | <b>0.005</b> | 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                               | <b>0.009</b> | 0.5, 0.2–0.8                               |
| Mext [Nm]                | 24, 22–31                             | ns           | 28, 28–30                             | 28, 22–31                                  | <b>0.001</b> | 44, 32–105                                 |
| Mflex [Nm]               | -32, -43– -27                         | <b>0.025</b> | -21, -24– -14                         | -28, -43– -14                              | ns           | -15, -36– -6                               |
| Mnet [Nm]                | -10, -18.2–4                          | <b>0.049</b> | 7, 4–17                               | -1.4, -18.2–17                             | <b>0.005</b> | 27, 3–98                                   |

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. Furthermore, they had to have a unilateral total knee replacement.

Prior to the experiment, the Knee Society Pain Score and anthropometric data was assessed for all three groups.

### **7.2.2 Experimental protocol**

The subjects performed the step-up task barefoot, straightforward in a controlled manner with a self-selected, comfortable speed. 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 2 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. Prior to the step-up task, the EMG levels were calibrated towards mechanical units.

### **7.2.3 Calibration of the EMG force processing**

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, deg s<sup>-1</sup>). Contractions were randomly ordered and rest pauses of 2 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.

#### 7.2.4 Electromyography

Surface EMG electrodes (Meditrace Ag–AgCl; lead-off area 1 cm<sup>2</sup>; center-to-center 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.

#### 7.2.5 Kinematics and kinetics

During the step-up task, the vertical and fore-aft 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 per 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 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 per second for visual inspection of undesirable postural compensation strategies.

#### **7.2.6 Data analysis**

The start of the movement cycle (0%) was defined as the first change in position (knee angle > 5 degrees). 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 et al., 2005; Doorenbosch and Harlaar, 2004; Doorenbosch and Harlaar, 2003). 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 (Doorenbosch et al., 2005; Doorenbosch and Harlaar, 2003).

$$CCI = 1 - \frac{[(Magonist) - (Mantagonist)]}{[(Magonist) + (Mantagonist)]} \quad (1)$$



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.

#### 7.2.7 Statistical analysis

A non-parametric Mann-Whitney U Test and Spearman's  $\rho$  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, USA).

### 7.3 Results

The most important variables and p-values are listed in Table 1. Mean time after operation was 9.6 months (sd 3.5 months, 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 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 ROM during the step-up task than 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 than in the patient group (Figure 1). Since the control subjects used higher extension moments, this resulted in a higher net joint moment. No differences between the MB and FB group were observed. The differences between the FB group and controls 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 group 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 (1st and 2nd peak of the CCI) in the single limb support phase compared to the MB group (Figure 2).

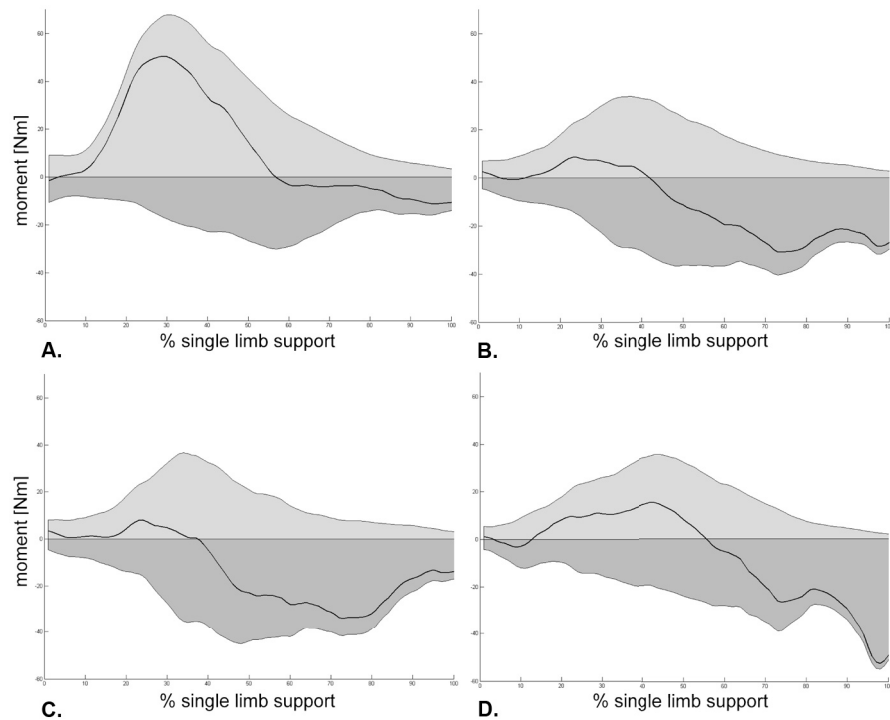


**Figure 1.**  $M_{\text{flexion}}$  (dark grey),  $M_{\text{extension}}$  (light grey) and  $M_{\text{net}}$  (line) for all four groups (A. control; B. patient; C. MB; D. FB) during the entire single limb support phase.

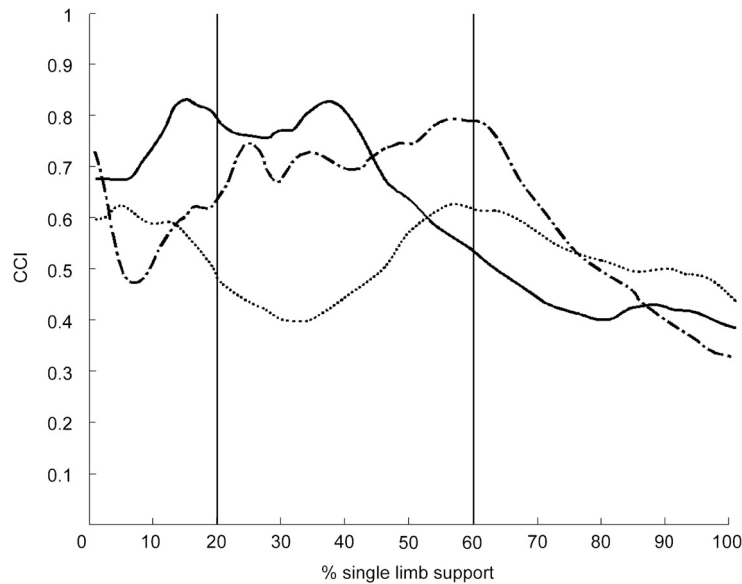


**Figure 2.** CCI values for the MB group (line), the FB group (dash-dotted) and the control group (dotted) during the single limb support phase. The 20%-60% interval is also indicated.

#### 7.4 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 a 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 AP 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., 2005). 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 TKA (Doorenbosch et al., 2005; Doorenbosch and Harlaar, 2004). 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. (2005) 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 center of rotation. Femoral rollback with flexion will increase the moment arm of the quadriceps. When an intrinsic AP constraint is absent, the hamstrings can be recruited as secondary AP stabilisers. 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., 2007). 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 where 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 stabilises the knee (Lass et al., 1999). 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 TKA design during stair ascending, a decrease in the frontal external knee moments in the MB group was observed suggesting a compensatory loading mechanism (Byrne et al., 2002).

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 (Catani et al., 2003; Andriacchi et al., 1982; Benedetti 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 were 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 ROM 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 ROM during step-up for the RA patients of about 10-15%, without differences in duration of the step-up (Catani et al., 2003; Andriacchi et al., 1982; 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 TKA 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.

## **7.5 Conclusion**

RA 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 MB and FB groups show no difference in co-contraction levels, although coordination in patients with a FB is closer to controls than patients with a MB. Timing differences between the MB and FB group, may express compensation by coordination. Rehabilitation programs for RA patients should include besides muscle strength training, elements of muscle-coordination training.



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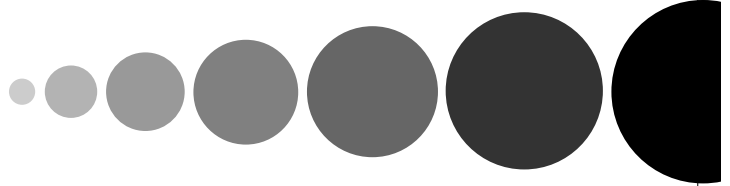
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# Chapter 8



## **The effect of periapatite on the micromotion of total knee arthroplasty tibial components in osteoarthritis**

**A controlled prospective, randomized RSA study in 90 patients**

Mathys J.A. van der Linde<sup>1</sup>, Eric H. Garling<sup>2</sup>, Edward R. Valstar<sup>2,3</sup>,  
Rob G.H.H. Nelissen<sup>2</sup>, Alfons J. Tonino<sup>1</sup>

<sup>1</sup> Department of Orthopaedic Surgery and Traumatology, Atrium Medisch Centrum Heerlen,  
The Netherlands

<sup>2</sup> Department of Orthopaedics, Leiden University Medical Center, The Netherlands

<sup>3</sup> Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials  
Engineering, Delft University of Technology, The Netherlands

### **Abstract**

Both cemented and cementless total knee designs produce excellent clinical results. However, for specific patient groups, the cementless knees could have advantages. The way of bonding of the prosthesis to the adjacent bone remains a topic in total knee arthroplasty (TKA), especially in the younger patient population. Furthermore, the question of the value of adding a calciumphosphate coating to the prosthesis surface remains.

A controlled randomized prospective study was performed on 90 Duracon TKA, to evaluate the effect of a Periapatite (PA) coating on the fixation of the tibial tray using micromotion (as measured with roentgen stereophotogrammetric analysis) as evaluation method. Twenty-five cemented components were included as the control group.

The coated and the non-coated groups matched perfectly well for sex, age, weight, length, BMI and Insall score. Stage of osteoarthritis according to Ahlback, preoperative and postoperative femorotibial angle (FTA) and the mechanical leg axis showed no statistical differences. The non-coated tibial components showed more subsidence at two years  $0.5 \pm 0.63$  mm (range, -0.50 to 2.07 mm), than the PA coated tibial components:  $0.1 \pm 0.60$  mm (range, -0.34 to 2.75 mm); ( $p = 0.047$ ). Also the medial-lateral motion of the non-coated group was significantly larger ( $p = 0.003$ ). Translation and rotation migration data for the other axes were not significantly different. As expected the control group – cemented components – showed no subsidence after two-years follow-up:  $-0.1 \pm 0.17$  (range, -0.44 to 0.22 mm).

This study shows that periapatite augmentation improves the fixation of the Duracon total knee prosthesis, thus preventing mechanical loosening and subsequent long-term revision.



## 8.1 Introduction

Nowadays, total knee arthroplasty is considered a routine procedure for degenerative changes of the knee joint. Cemented fixation of the components is still the most frequently used way of fixation. The advantages of a cemented design are the immediate implant stability, and the fact that the cement will act as a barrier for wear particles migration into the bone-prosthesis interface. Advantages of cementless designs are that more bone is preserved, which is of special importance to younger patients (Hofmann et al., 2002), and that peri-prosthetic fracture treatment can be performed more easily, which is important to the elderly patients.

However, studies on the long-term results of cementless designs (Akizuki et al., 2003; Gejo et al., 1988; Nilsson et al., 1999) show the same – and sometimes even better – favorable clinical results as with cemented designs (Buechel, 2002; Whiteside, 2001). The addition of a calcium phosphate coating might even augment the bone-prosthesis fixation and may also act as a barrier for ingress of wear-particles by sealing of the interface through periprosthetic bone ingrowth (Rahbek et al., 2000).

Since these cementless designs have to osteointegrate for enduring fixation, this process of bonding between bone and prosthesis is the crucial issue for failure apart from polyethylene failure. Osteointegration is reflected by the absence of progressive micromotion (Nelissen et al., 1998; Ryd et al., 1995), absence of radiolucent lines and bone remodeling next to the prosthesis (Fuiko et al., 2003). The addition of a hydroxyapatite (HA) coating on the tibial tray may reduce micromotion in a cementless design even more (Akizuki et al., 2003; Nelissen, 1995; Onsten et al., 1998; Regnner et al., 2000; Toksvig-Larsen et al., 2000). Early migration as measured with roentgen stereophotogrammetric analysis (RSA) has been shown to be related to long-term implant survival (Grewal et al., 19992; Ryd et al., 1995).

The purpose of this study was to examine the amount of three-dimensional micromotion of the tibial component in a prospective randomized RSA study, comparing uncoated tibial components and tibial components coated with periapatite (PA). Cemented tibial components were used as a control group.

## **8.2 Materials and Methods**

### **8.2.1 Patients**

Ninety consecutive primary total knee arthroplasties (TKA) (eighty-two patients) were included in this prospective, randomized RSA study. During surgery, a randomization scheme selected the patients for either the PA coated group or the uncoated group (Duracon: Stryker Howmedica Osteonics). Subsequently twenty-five cemented TKA's of the same design were included as a control group to validate the measurements. All patients had osteoarthritis. The PA group consisted of 44 knees and the uncoated group of 46 knees. The institution's ethics committee approved the study, and the patients gave informed consent.

#### ***Tibial components***

The Duracon prosthetic design consists of a posterior cruciate retaining, non-constrained system. All tibial baseplates had a cruciform keel for rotational stability and the same porous coated multiple layer beads ingrowth surface. In general, HA coating is applied with a plasma spraying process (Nelissen et al., 1998; Onsten et al., 1998), but this technique is not appropriate to coat the deeper layers of a porous surfaced prosthesis. The Duracon porous coated surface consists of a multiple layer beads (diameter 0.4 mm) with a porosity of 35%, a mean pore size of 425 micrometer and a thickness of 1.5 mm. During the PA coating technique, the prosthesis is submerged in a watery bath of calcium and phosphate at regulated pH (7.4) and temperature (80°). As result of this process nucleation of the calcium phosphate as calcium deficient HA (similar to the process of bone mineralization) on the metal surface will take place. The PA technique reveals a pure single crystallized precipitated HA coating with a thickness of 20 micrometer in all layers of the porous surfaced prosthesis. No other calcium phosphate phases are present with this type of coating technique.

In all knee replacements a PA porous coated femoral component and a full polyethylene cemented patellar prosthesis was used. The femorotibial design is a biconcave polyaxial radiated design with elongated posterior condyles and is medial-lateral stabilized with two pegs. The anatomically shaped patella component

articulates in a proximal elongated trochlear groove. The exchangeable UHMW polyethylene insert, minimal thickness 11 mm, is fixed with an anterior and posterior lipping mechanism on the tibial tray (Figure 1).

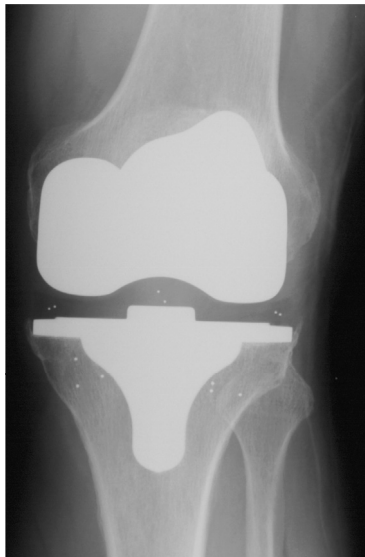


**Figure 1.** Radiograph of Duracon total knee prosthesis. Six tantalum markers are visible in the polyethylene inlay and in the tibia bone.

#### ***Operative technique and after-treatment***

In all knee replacements, the same standard surgical procedure under tourniquet control was used. After a straight midline incision the knee was opened with a medial Payer approach. The tibial cutting surface was extramedullary aligned (classical prosthetic alignment perpendicular to the talocrural joint) and the distal femoral cut intra medullary aligned and was adjusted to the femoral anatomy both based on long standing X-rays. Soft tissue releases were performed when necessary. In the implants were bone cement (Genta Palacos, Biomet-Merck, Sjöbo, Sweden) was used, the bone surfaces were cleaned with a pulse lavage system.

During operation three to eight tantalum beads (1 millimeter diameter) were inserted in preselected places in the metaphysial bone of the tibia. The insert of the tibial tray was manufactured with six tantalum balls (Howmedica Inc., Rutherford, USA). The locking mechanism between the insert and the tibial tray was pre-tested and showed no movement between the two parts.

After one day of bed rest patients were mobilized with two crutches and partial weight bearing during 6 weeks. Anti-trombotic prophylaxis was performed using acenocoumarol (6 weeks), peri operatively patients received three doses of Cefamandol intravenously for infection prevention.

### **8.2.2 Radiographs and RSA**

The patients were evaluated preoperatively, and at one week before mobilization, three months, six months, one year, and two years postoperatively. At each evaluation the clinical status was assessed and radiographs for RSA were made. Immediately after the operation, at the one-year, and at the two-year follow-up, standard anterior/posterior (AP) were taken with the patient standing. Lateral radiographs as well as axial radiographs of the patella were made supine. The femorotibial angle, the lateral and AP position of the tibial and femoral component were measured as well as the leg axis (Ewald, 1989).

The RSA set-up consisted of two synchronized roentgen tubes positioned approximately 1.5 meter above a roentgen cassette (35x43 cm) at a 20° angle to the vertical. Both roentgen tubes simultaneously exposed the roentgen film. A calibration box made of Perspex™ was used to define the three-dimensional (laboratory) coordinate system. For this purpose 38 tantalum 1-mm markers were positioned in the lower plane of the box (fiducial markers). In order to calculate the focus position, 20 1-mm tantalum markers were positioned in the upper plane of the box (control markers).

With a Vidar VXR-12 scanner (Vidar, Lund, Sweden), the radiographs were scanned at 150 dots per inch resolution and eight-bit gray scale resolution. The measurement of marker coordinates in the digitized radiographs, the three-dimensional reconstruction of the marker positions, and the micromotion analysis was done with RSA-CMS (Medis, Leiden, The Netherlands), a software package that performs the RSA procedure automatically in digitized or digital radiographs (Valstar, 2001; Vrooman et al., 1998).

In order to assess the micromotion of the implant with a high accuracy, the bone markers need to be well fixated in the bone. Bone markers were defined unstable when they moved more than 0.3 mm with respect to the other bone markers. Unstable markers were excluded from analysis.



The first RSA examination served as the reference baseline. All subsequent evaluations of micromotion were related to the relative position of the prosthesis with respect to the bone at that the time of the evaluation. In 30 knees (16 PA and 14 uncoated) the first RSA radiograph was not made within 5 days after operation but at six weeks. As a consequence this radiograph was used as the reference baseline. Micromotion of the components was expressed as translation of the center of gravity of the prosthesis makers and rotation of the rigid body defined by the prosthesis markers about this center of gravity. Positive directions for translations along the orthogonal axes were: transverse (medial-lateral), longitudinal (caudal-cranial), and sagittal (posterior-anterior). Positive directions for rotations about the coordinate axes were anterior tilt (transverse axis), internal rotation (longitudinal axis), and varus (sagittal axis).

When an integrated bone-prosthesis interface exists, the implant should be stable and a stable implant would not be at risk for aseptic loosening. In an RSA study of Ryd et al. (1995), a micromotion rate of 0.2 mm or more during the second postoperative year was identified to be a predictor for loosening of total knee implants at ten-year follow-up with a predictive power of about 85%. In this study, implants were defined to be at risk for aseptic loosening when the translation rate during the second postoperative year was larger than 0.5 mm along one or more coordinate axes (Ryd et al., 1995) and/or the rotation rate was larger than one degree about one or more coordinate axes.

The reproducibility of the RSA measurements was determined by means of double examination of twenty patients (Table 1). Double examination consists of two RSA examinations of the same patient exposed within a time interval of about ten minutes. Because of the short time-interval between these two radiographs, the assumption is made that the implant did not migrate between these two exposures relative to the surrounding bone. By comparing these two radiographs, the accuracy of the micromotion parameters can be assessed (Ranstam et al., 2000).

In some cases problems occurred with respect to the marking of the tibia. In six cases, the bone was either marked with less than three markers, or the markers were positioned so that they were occluded by the component. These cases were excluded from the analysis.

**Table 1.** Accuracy of the RSA measurements based on double examinations. Presented numbers are the upper limits of the 95%-confidence interval (N = 20).

|      | Translation (mm) |      |      | Rotation (°) |      |      |
|------|------------------|------|------|--------------|------|------|
|      | Trans            | Long | Sag  | Trans        | Long | Sag  |
| Stem | 0.25             | 0.15 | 0.44 | 0.48         | 0.41 | 0.26 |

### 8.2.3 Statistical methods

Mean values and standard deviations were calculated for all variables. For comparison of the mean values of the two groups, a Kruskal-Wallis test was used. In order to explore the effects of the two types of fixation on the amount of micromotion after two-years a linear regression was used with migration at the two years follow-up as the dependent variable and the fixation type and the base-line examination (directly postoperative or 6 weeks post operative) as co-variables. Levene's test for homogeneity of variance was used to determine the differences of the group variances in the micromotion data. For all analyses, significance was determined by a p-value of less than 0.05.

## 8.3 Results

### 8.3.1 Clinical results

The two groups and the cemented control group matched perfectly well for sex, age, weight, length, BMI and Insall score. Stage of osteoarthritis according to Ahlback, preoperative and postoperative femorotibial angle (FTA) and the mechanical leg axis showed no statistical differences (Table 2). The average operating time was 79 minutes (SD 18) for the uncemented knees and 81 minutes (SD 15) for cemented knees.

During follow-up 5 PA coated, 3 uncoated and 1 cemented knee (9 patients) were lost to follow-up (not knee related). In the PA group 3 patients died, all after one year follow-up, one other patient had a cerebrovascular accident within two weeks after operation and the fifth patient moved abroad after 6 month follow-up. Based on the RSA results at the last follow-up, these knees were judged as stable.



In the uncoated group one patient died and one moved after one year follow-up. Both knees were stable based on RSA examination. The third patient underwent an upper limb amputation because of vascular problems in another hospital. For this patient, RSA follow-up was too short for defining stability, which was the same for the patient in the cemented group who died after 6 month follow-up. Otherwise there was no evidence of clinical or radiographic failure in any of these patients.

Clinical results by means of Insall score, active knee flexion and active extension lag showed no statistical difference among the two groups and the cemented control group during follow-up (Table 3).

**Table 2.** Preoperative patient data (mean and standard deviations).

|                 | PA coated        | Uncoated          | Cemented         |
|-----------------|------------------|-------------------|------------------|
| Sex F/M         | 33/10            | 31/12             | 14/11            |
| Age             | 71 ( $\pm$ 7.8)  | 71 ( $\pm$ 7.27)  | 72 ( $\pm$ 6.6)  |
| Weight (kg)     | 78 ( $\pm$ 13.3) | 79 ( $\pm$ 12.57) | 79 ( $\pm$ 11.4) |
| Length (cm)     | 165 ( $\pm$ 8.6) | 166 ( $\pm$ 8.53) | 168 ( $\pm$ 7.8) |
| BMI             | 29 ( $\pm$ 4.7)  | 30 ( $\pm$ 4.9)   | 29 ( $\pm$ 4.9)  |
| Insall          | 53 ( $\pm$ 14.9) | 49 ( $\pm$ 14.6)  | 60 ( $\pm$ 13.8) |
| Ahlbäck 1-5 (N) | 6/18/10/6/2      | 9/13/13/5/3       | 4/15/4/2         |
| FTA             | 184 ( $\pm$ 8.9) | 183 ( $\pm$ 8.6)  | 181 ( $\pm$ 4.9) |
| Leg axis        | 177 ( $\pm$ 8.6) | 177 ( $\pm$ 8.4)  | 174 ( $\pm$ 4.5) |

**Table 3.** Clinical results during follow-up (mean and standard deviations).

|           | PA coated              |                         | Uncoated                |                         | Cemented               |                         |
|-----------|------------------------|-------------------------|-------------------------|-------------------------|------------------------|-------------------------|
|           | Post                   | 2 yrs                   | Post                    | 2 yrs                   | Post                   | 2 yrs                   |
| Insall    | 81.8<br>( $\pm$ 11.76) | 88.5<br>( $\pm$ 8.35)   | 83.0<br>( $\pm$ 8.80)   | 88.5<br>( $\pm$ 9.02)   | 82.2<br>( $\pm$ 13.04) | 90.6<br>( $\pm$ 6.98)   |
| Flexion   | 98.5<br>( $\pm$ 13.82) | 102.4<br>( $\pm$ 12.67) | 100.1<br>( $\pm$ 10.74) | 106.0<br>( $\pm$ 12.66) | 97.0<br>( $\pm$ 10.10) | 107.1<br>( $\pm$ 12.59) |
| Extension | 1.5<br>( $\pm$ 3.62)   | 0.2<br>( $\pm$ 0.93)    | 2.5<br>( $\pm$ 5.04)    | 0.6<br>( $\pm$ 2.00)    | 2.4<br>( $\pm$ 5.42)   | 0.6<br>( $\pm$ 2.24)    |

### 8.3.2 Radiographic results

Routine radiographs of the knee revealed no radiolucent lines of two millimeters or more around the tibial, femoral or patellar component in any knees of the three groups at the two-year follow-up evaluation. Sclerotic lines around the keel of the tibia tray were seen in 8 knees, 1 in the PA group and 7 in the uncoated group ( $P < 0.05$ ; Pearson Chi Square test).

**Table 4.** Radiographic results (mean and standard deviations) or number of knees.

|                                  | PA coated               |                         | Uncoated                |                         | Cemented                |                         |
|----------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
|                                  | Post                    | 2 yrs                   | Post                    | 2 yrs                   | Post                    | 2 yrs                   |
| FTA                              | 186.0<br>( $\pm 4.37$ ) | 185.3<br>( $\pm 3.98$ ) | 187.5<br>( $\pm 3.59$ ) | 186.4<br>( $\pm 3.81$ ) | 187.0<br>( $\pm 2.85$ ) | 186.3<br>( $\pm 2.75$ ) |
| Hip-knee-ankle axis              | 179.6<br>( $\pm 4.66$ ) | 178.4<br>( $\pm 3.77$ ) | 180.8<br>( $\pm 3.28$ ) | 179.8<br>( $\pm 3.77$ ) | 180.0<br>( $\pm 2.58$ ) | 180.0<br>( $\pm 2.75$ ) |
| Hip-knee-ankle axis<br><177° (n) | 10                      | 12                      | 5                       | 10                      | 2                       | 1                       |
| Hip-knee-ankle<br>axis >183° (n) | 6                       | 6                       | 5                       | 4                       | 6                       | 5                       |

**Table 5.** Component position on AP and lateral radiographs (mean and standard deviation).

|               | PA coated           |                     | Uncoated            |                     | Cemented            |                      |
|---------------|---------------------|---------------------|---------------------|---------------------|---------------------|----------------------|
|               | Post                | 2 yrs               | Post                | 2 yrs               | Post                | 2 yrs                |
| Femur AP (°)  | 98<br>( $\pm 2.6$ ) | 98<br>( $\pm 2.4$ ) | 99<br>( $\pm 2.6$ ) | 99<br>( $\pm 2.7$ ) | 99<br>( $\pm 2.3$ ) | 98<br>( $\pm 2.1$ )  |
| Femur lat (°) | 2<br>( $\pm 2.5$ )  | 1<br>( $\pm 2.0$ )  | 2<br>( $\pm 2.4$ )  | 2<br>( $\pm 2.7$ )  | 10<br>( $\pm 2.3$ ) | 1.3<br>( $\pm 2.2$ ) |
| Tibia AP (°)  | 88<br>( $\pm 2.6$ ) | 88<br>( $\pm 2.5$ ) | 89<br>( $\pm 2.2$ ) | 89<br>( $\pm 1.8$ ) | 89<br>( $\pm 3.2$ ) | 89<br>( $\pm 2.7$ )  |
| Tibia lat (°) | 87<br>( $\pm 2.8$ ) | 86<br>( $\pm 2.9$ ) | 87<br>( $\pm 2.7$ ) | 86<br>( $\pm 2.4$ ) | 85<br>( $\pm 2.5$ ) | 86<br>( $\pm 2.5$ )  |



The average femoral-tibial angle was not different for the two groups and did not change substantially during follow-up (Table 4). The radiographic results of the components, evaluating the surgical technique for all groups individually by component position on standardized plain radiographs showed no differences between the three groups. In the cemented control group the FTA, legaxis and component positioning did not significantly differ from the other two groups (Table 5).

### 8.3.3 RSA results

The migration of the tibial components in millimeters at the two years follow-up is presented in Table 6. The graphs of the migration data showing the patterns of how the components in the two randomized groups and the control group migrated during the two-year follow-up are presented in Figures 2–7.

At two year follow-up the non-coated tibial components showed more subsidence  $0.5 \pm 0.63$  mm (range, -0.50 to 2.07 mm), than the PA coated tibial components:  $0.1 \pm 0.60$  mm (range, -0.34 to 2.75 mm); ( $p = 0.047$ ). In the first six weeks after implantation the uncoated implants already subsided 0.3 mm, while the PA coated group subsided only 0.1 mm. Also the medial-lateral motion between the two groups was significantly different ( $p = 0.003$ ).

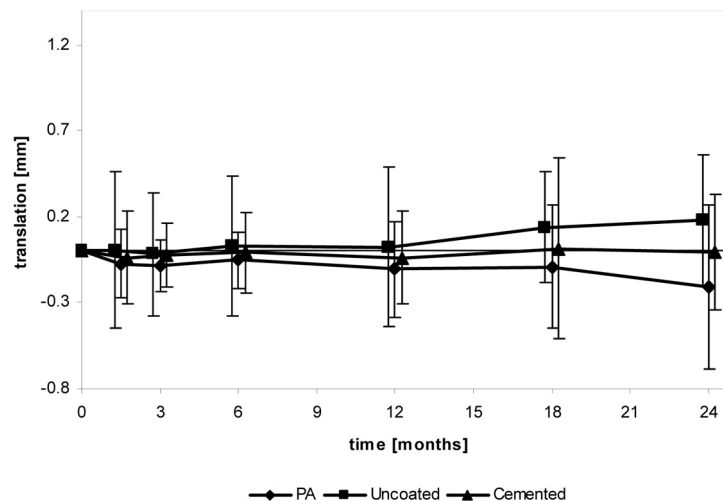


**Figure 2.** Medial-lateral translations of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

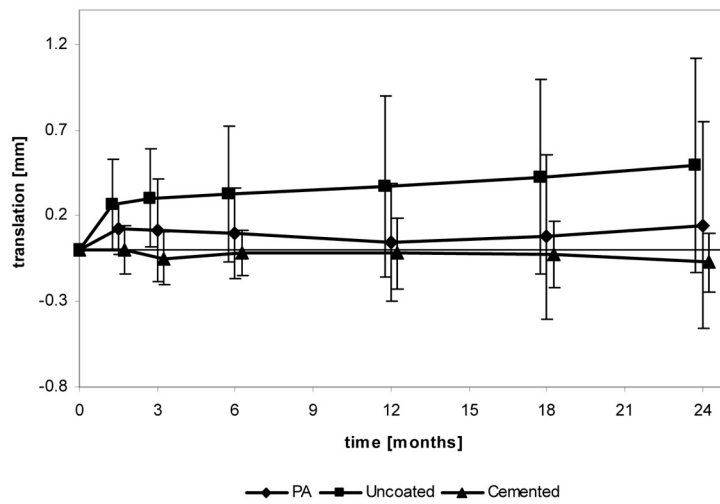


**Figure 3.** Caudal-cranial translations of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

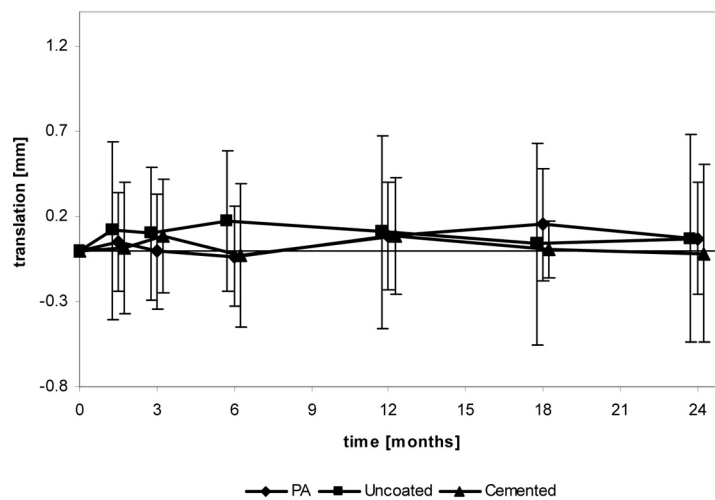


**Figure 4.** Posterior-anterior translations of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

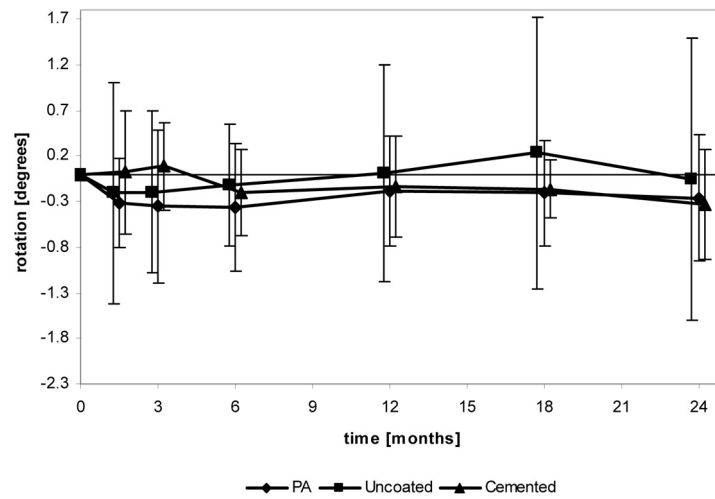


**Figure 5.** Anterior tilt of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

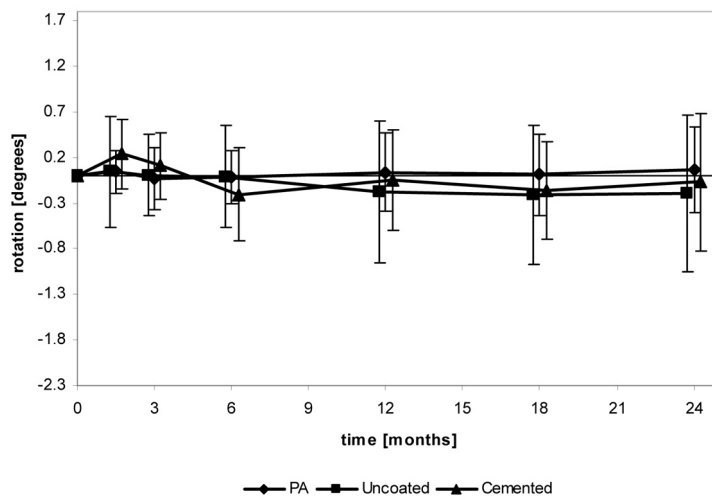


**Figure 6.** Internal rotations of the PA coated, uncoated and cemented tibial components (mean and standard deviation).



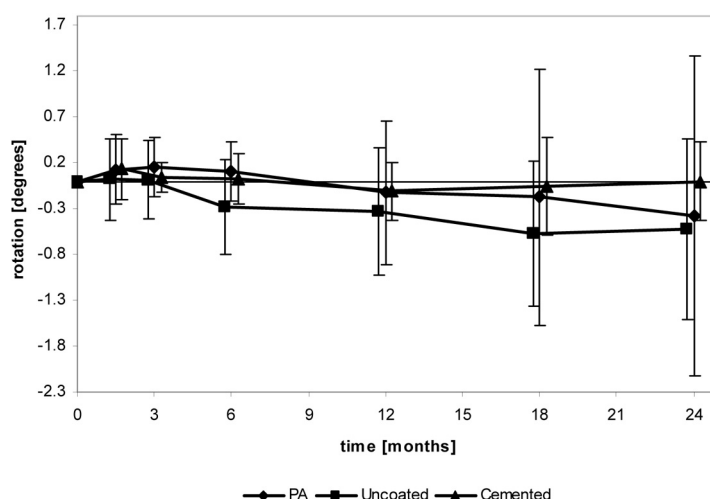


**Figure 7.** Varus rotation of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

Translation along the other 2 axis and rotation around all three axis migration data along the other axes were not significantly different among the groups. The effect of the other co-variable 'base-line examination' was not significant ( $p > 0.2$ ) for all directions. This indicates that there was no difference between the delayed base-line examination group on the total amount of micromotion from 6 weeks post operatively up to the two year examination compared with the completely examined group. As in the group with the baseline within 5 days post operatively as in the group with the baseline at six weeks, it was possible to identify the stable tibial trays and the migrating tibial trays at risk for late aseptic loosening.

The two groups showed no differences in the rotational migration data. However, the uncoated group showed a significant higher variance in anterior tilt compared to the PA coated components (Levene's test:  $p = 0.01$ ). The tibial slope was not of influence on the amount of tilting of the components. The PA coated group showed also a high variance in varus rotation. This could be explained by one of the components in that group showing a high varus (7.7 degrees) tilt at the two years follow-up. This varus rotation of that tibial tray was also clearly visible on the plain



radiographs. However, clinically there were no signs of failure of this component at two year follow-up. No relation between the femoral-tibial angle and varus/valgus rotation of the components could be found.

The significant difference in the micromotion data between the two groups in medial-lateral direction can also be explained by the varus/valgus rotations of the components. These rotations are expressed by a medial-lateral motion of the center point of gravity of the markers in the polyethylene. Therefore it is very important to present three-dimensional micromotion data, not limited to in-plane translations that are actually caused by rotations of the components.

As expected the control group showed no subsidence after two-years follow-up:  $-0.1 \pm 0.17$  mm (range,  $-0.44$  to  $0.22$  mm). Only a small posterior tilt of  $0.3$  degrees was observed. Four of the cemented components showed a posterior tilting of the component and three components an anterior tilt. The results of the control group validated the RSA measurements in this study.

A total of 11 tibial trays from the PA group (26%), and 29 tibial trays from the uncoated group (63%) could be identified as at risk according to the definition given in the Materials and Methods section of this paper.

**Table 6.** Migration (mean and standard deviation) of the PA coated, uncoated and cemented tibial components at the 2-year follow-up evaluation.

|              |                    | PA coated        | Uncoated         | Cemented         |
|--------------|--------------------|------------------|------------------|------------------|
| Translations | medial-lateral     | $-0.21 \pm 0.48$ | $0.18 \pm 0.38$  | $-0.01 \pm 0.34$ |
|              | caudal-cranial     | $0.15 \pm 0.60$  | $0.49 \pm 0.63$  | $-0.07 \pm 0.17$ |
|              | posterior-anterior | $0.07 \pm 0.33$  | $0.07 \pm 0.61$  | $-0.02 \pm 0.52$ |
| Rotations    | anterior tilt      | $-0.26 \pm 0.69$ | $-0.05 \pm 1.55$ | $-0.33 \pm 0.60$ |
|              | internal rotation  | $0.07 \pm 0.47$  | $-0.19 \pm 0.86$ | $-0.07 \pm 0.75$ |
|              | varus rotation     | $-0.38 \pm 1.75$ | $-0.53 \pm 0.98$ | $-0.00 \pm 0.43$ |

## 8.4 Discussion

The loosening process of total knee implants seems to start with the tibial component. Continuous micromotion during the first two years after implantation in one or more directions detected by RSA, a validated tool to measure micromotion *in vivo*, reflects the start of this process (Grewal et al., 1992; Kärrholm et al., 1994; Ryd et al., 1995). General requirements for good fixation are close apposition of bone to the porous surface and a lack of movement at the developing interface between bone and implant. Optimization of the interface between bone and implant is therefore of paramount importance. In a cemented design, suboptimal conditions of both surfaces are corrected by the cement, but in cementless designs, apart from the type of ingrowth surface (calciumphosphate and/or metal pore diameter) the status of the prepared bone surfaces, bone quality and the gap between bone and implant are of high importance. In a comparative study of human cancellous bone remodeling to titanium and hydroxylapatite (HA) coated implants, Hofman showed that HA increases the percentage of the implant surface with ingrowth of bone (Hofmann et al., 1993). Ongrowth or ingrowth of human cancellous bone is possible in gaps smaller than 50  $\mu\text{m}$  while HA had no metabolic influence on bone mineral apposition rate. In another study, Bloebaum showed the same maximum gap healing properties (max 50  $\mu\text{m}$ ) of surrounding human cancellous bone in the absence of HA on the titanium implants and found that bone apposition on non coated titanium implants needed a minimal time of 12 weeks (Bloebaum et al., 1971). Taking the assumption that HA coating accelerates bone ingrowth or ongrowth in time, it will create a higher area percentage bone-prosthesis contact. This could be an explanation for the higher level of migration of the uncoated implants observed in our RSA results and the faster stabilisation of the peripatite implants after an initial period of subsidence.

From animal experiment it was already known that a thin lining of bone is present on the implant surface at three weeks, while at 6 weeks the implant is histologically osteointegrated (Geesink et al., 1988). In human, Hardy (Hardy et al., 1991) and Frayssinet (Frayssinet et al., 1993) showed intimate contact between woven bone and the hydroxyapatite coated hip prosthesis before six weeks after implantation. This study is in agreement with an earlier study by Nelissen on RSA measurement



in TKA which also showed favorable results of adding a calcium-phosphate coating to the surface of uncemented tibial trays in TKA. In that study the noncoated components subsided significantly more than the coated and cemented components (Nelissen et al., 1998). In our study and the study by Nelissen the coated implants show stabilization after a short initial period of subsidence projecting the ingrowth phase, where as the uncoated implants show ongoing subsidence. Major difference between that study and the current study is the amount of subsidence observed in the uncoated groups, 0.73 mm vs 0.5 mm respectively at two years follow-up. One explanation for this difference could be the non-homogenous patient selection in the study by Nelissen. They included a mix of patients with rheumatoid arthritis and osteoarthritis. In generally patients with rheumatoid arthritis have more osteoporosis induced by the use of corticosteroids resulting in a weaker foundation for the tibial tray. Li and Nilsson acknowledged this observation by showing a significant relationship between lower average BMD and more migration of the tibial component in TKA (Li and Nilsson, 2000).

The greater variability in the migration profile of the uncemented tibial trays as found in this study stresses more the individual differences in bone ongrowth to the prosthesis, a factor not only determined by the available bone mass, but also dependent on the distance between bone and prosthesis immediate after implantation as well the intrinsic mechanical stability. Technically optimized instrumentation is necessary especially in uncemented TKA not only for creating correct alignment but also for exact bone cuts to create immediate implant stability without gaps. So, addition of the calcium phosphate PA did enhance initial component stability comparable to cemented TKA. Several other studies also acknowledge the beneficial effect of calcium phosphates (Akizuki et al., 2003; Fuiko et al., 2003; Nelissen et al., 1998; Nilsson et al., 1999; Onsten et al., 1998; Toksvig-Larsen et al., 2000).

Looking at the different migration profiles of the cementless TKA designs described in these studies, the profile of the porous surface of the TKA seems also to be a factor related with migration. The titanium PFC design described by Önsten et al. had a porous surface with a pore diameter of 120-220 micrometer (Onsten et al., 1998), while the vitallium Interax total knee described by Nelissen et al. had a fiber mesh surface with pore diameter of 1690 micrometer. The first mentioned

uncoated design showed a mean subsidence of  $0.71 \pm 0.56$  mm (coated  $0.87 \pm 0.56$ ), while the components in the latter study subsided  $0.73 \pm 0.92$  mm at the two-year follow-up (coated  $0.06 \pm 0.17$  mm) in a rheumatoid arthritis patient group. In our series with a homogenous osteoarthritic patient group, the uncoated tibial trays, (pore size 425 micrometer) subsided  $0.5 \text{ mm} \pm 0.63 \text{ mm}$  (range -0.50 to 2.07 mm) while the coated subsided  $0.1 \text{ mm} \pm 0.60 \text{ mm}$  (range -0.34 to 2.75). One reason for this difference might be their patient selection but another reason may be the quality of the pore size. In experiments with calcium aluminate, Klawitter showed that a minimal pore diameter of 100  $\mu\text{m}$  is necessary for the ingrowth of bone (Klawitter et al., 1971). A minimal pore diameter of 50  $\mu\text{m}$  is needed for ingrowth of osteoid and smaller pore sizes of about 5  $\mu\text{m}$  to 15  $\mu\text{m}$  result in ingrowth of fibrous tissue. If coatings are added to the porous surface more open structures may be required to keep the structure open. The Duracon prosthesis in this study has a porous surface with a pore diameter of 425  $\mu\text{m}$  and after adding the 20  $\mu\text{m}$  periapatite layer a remaining pore size diameter of 385  $\mu\text{m}$ , which should be enough for ingrowth of bone according to the results of Klawitter. The small remaining pore size diameter (120-220 micrometer) in the PFC study by Önsten could be the explanation for the high amount of subsidence in their coated group ( $0.87\text{mm} \pm 0.56 \text{ mm}$ ). It must be emphasized that for all surface gap sizes reported in the literature, the addition of a calciumphosphate coating improved fixation, independent of the initial migration. A randomized RSA study comparing calciumphosphate coated tibial components with different gap sizes should further prove this effect. It is expected that when calciumphosphate coated implants sustain the forces that threaten the fixation in the early period after implantation, a strong and enduring fixation will be obtained. The influence of the local BMD on migration patterns of cemented and non cemented tibial trays is another subject of further analysis.

## 8.5 Conclusion

This study shows that periapatite augmentation improves the fixation of the Duracon total knee prosthesis, thus preventing mechanical loosening and subsequent long-term revision. Uncemented non coated tibial trays in TKA are not advised to use.



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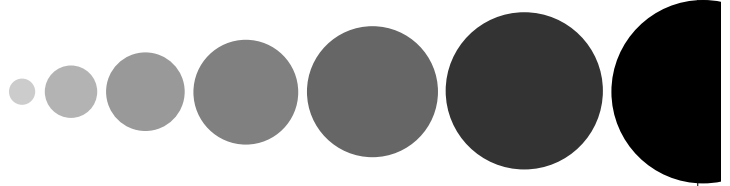
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# Chapter 9



## **Periapatite may not improve micromotion of knee prostheses in rheumatoid arthritis**

Matthys J.A. van der Linde<sup>1</sup>, Eric H. Garling<sup>2</sup>, Edward R. Valstar<sup>2,3</sup>,  
Alfons J. Tonino<sup>1</sup>, Rob G.H.H. Nelissen<sup>2</sup>

<sup>1</sup> Department of Orthopaedic Surgery and Traumatology, Atrium Medisch Centrum, Heerlen

<sup>2</sup> Department of Orthopaedics, Leiden University Medical Center, Leiden

<sup>3</sup> Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials  
Engineering, Delft University of Technology, The Netherlands

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## **Abstract**

Prosthesis migration in bone inevitably occurs in cemented and uncemented total knee arthroplasty tibial components. Cemented designs as the gold standard give immediate fixation whereas cementless designs need a period of bone ingrowth onto the surface irregularities of the implants. The addition of bioactive coatings may enhance this process of ingrowth.

A controlled randomized prospective RSA study was carried out on 26 Duracon implants in a rheumatoid arthritis patient group to evaluate the effect of a peripatite coating on the fixation of the tibial tray. The coated and the noncoated groups were matched for sex, age, body mass index, and HSS Knee Score. Stage of preoperative joint destruction and preoperative and postoperative mechanical leg axis showed no differences. We saw no differences in migration between the two groups, but a trend for lesser translations along and rotations about all three axes in the peripatite group. The peripatite-coated components showed a lower variance in subsidence than did the uncoated components. Both groups also showed a high variance in anterior tilting of the components.

The cementless PA-coated Duracon prosthesis used in patients with RA may provide improved fixation of tibial components although we could not demonstrate improvement in this small controlled series.



## 9.1 Introduction

Prosthetic joint replacement in patients with rheumatoid arthritis (RA) has a major impact on the quality of life of these patients (Nelissen, 2003). Problems that are specific to patients with RA as opposed to patients with osteoarthritis typically include younger age and more osteoporotic bone, both of which have a negative effect on prosthesis fixation. Although acrylic bone cement is the primary load-bearing material used for the attachment of orthopaedic devices to adjoining bone, degradation of acrylic-based cements in time results in a loss of structural integrity of the bone-cement-prosthesis interface and limits the longevity of cemented orthopaedic implants (Hoffmann et al., 1997; Sabokbar et al., 1997; Shardlow et al., 2003). Next to the cement deterioration itself, these small cement particles will also cause locally osteolysis with subsequent prosthesis loosening. In a rat model, titanium implants surrounded by bone showed less fibrous tissue interface after injection of PE particles than did partially ingrown implants. Within this fibrous tissue interface, foreign-body granulomas with macrophages differentiating into bone-resorbing cells are active (Brooks et al., 2000; Weir et al., 1996). Monocytes and macrophages are capable of differentiating into osteoclastic bone-resorbing cells in reaction to bone cement particles. Radio-opaque additives like barium sulphate ( $\text{BaSO}_4$ ) and, to a lesser degree, zirconium dioxide ( $\text{ZrO}_2$ ) or bone cement without radio-opaque additives are associated with bone resorption (Sabokbar et al., 1997; Wimhurst et al., 2001).

A potential advantage of cementless prostheses is that a good bone-prosthesis interlock will last longer, which will be especially of value in the younger population. However, these cementless knee prostheses account for only 2% of implants listed in the Swedish knee registry. In the Swedish registry, the most common diagnosis in patients younger than 55 years was RA (Robertsson et al., 2001). Enhancement of cementless prosthesis fixation is possible with hydroxyapatite (HA), which stabilizes initially unstable prostheses by osteoconduction through the calcium phosphate coating. Furthermore, HA is beneficial in gap healing of up to 2 mm and it converts fibrous tissue to bone around loaded implants (Søballe et al., 1993). The latter is advantageous in more osteoporotic bone that is commonly seen in patients with RA.

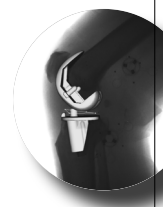
The importance of early prosthesis fixation is stressed by its relation to long-term survival of the prosthesis (Ryd et al., 1995). HA can increase the percentage ingrowth of bone into cementless implants. This bony interlock with the coating also seals off the prosthesis–bone interface, creating a barrier for PE wear particles, which are known to be another source of osteolysis and prosthetic loosening in the long term (Rahbek et al., 2001). The latter phenomenon will cause prosthesis migration and, in the longer term, prosthesis loosening. Thus, by enhancing the bone-prosthesis fixation with a calcium phosphate coating, less migration can be expected than without coating.

We hypothesized augmentation of a calcium phosphate coating to tibial components will provide a better fixation than noncoated component in a RA population.

## **9.2 Materials and methods**

We prospectively enrolled 21 consecutive patients with RA undergoing primary cementless TKA (26 knees) and compared component migration RSA study. A power analysis based on data reported in a previous RSA study (Nelissen et al., 1998), suggested a significant difference in subsidence of 0.3 mm could be observed when 12 knees were included in each group. During surgery, patients were randomized to receive an uncoated Duracon (Stryker, Montreux, Switzerland) implant or a Duracon implant coated with PA. There were 11 patients (14 knees) in the PA group and 10 patients (12 knees) in the uncoated group. Descriptive statistics of the two groups (sex, age, body mass index [BMI], Hospital for Special Surgery [HSS] Knee Score and stage of radiographic arthritis [Insall et al., 1976]) showed no differences between the two groups supporting the homogeneity of the groups (Table 2). The preoperative and postoperative mechanical leg axes were similar in the two groups. One patient died unrelated to the knee prosthesis procedure, before the 1-year follow-up; no other patients were lost to follow-up.

The Duracon knee implant is a posterior cruciate ligament (PCL)-retaining nonconstrained knee replacement system. All tibial base plates had a cruciform keel



for rotational stability and the same porous-coated multiple-layer bead ingrowth surface. In general, HA coating is applied with a plasma-spraying process (Nelissen et al., 1998; Onsten et al., 1998), but this technique is not appropriate to coat the deeper layers of a porous-surfaced prosthesis. The Duracon porous-coated surface consists of multiple layer beads (diameter 0.4 mm) with a porosity of 35%, a mean pore size of 425  $\mu\text{m}$ , and a thickness of 1.5 mm. During the PA coating technique, the prosthesis is submerged in a watery bath of calcium and phosphate (pH 7.4, 80° Celsius). As a result of this process, nucleation of the calcium phosphate as calcium-deficient HA (similar to the process of bone mineralization) on the metal surface will take place. The PA technique reveals a pure, single, crystallized precipitated HA coating with a thickness of 20  $\mu\text{m}$  in all layers of the porous-surfaced prosthesis. No other calcium phosphate phases are present with this type of coating technique.

**Table 1.** Preoperative Patient Data (Means and Standard Deviations)

| Variables                  | PA Coated       | Uncoated        |
|----------------------------|-----------------|-----------------|
| Sex (F/M)                  | 10/2            | 8/2             |
| Age (years)                | 65 $\pm$ 8.3    | 62 $\pm$ 2.0    |
| BMI                        | 25 $\pm$ 4.3    | 26 $\pm$ 2.9    |
| Knee Score <sup>1</sup>    | 39 $\pm$ 12.2   | 47 $\pm$ 15.2   |
| Larsen grades <sup>2</sup> | 1/3/2/4/1       | 0/5/0/4/0       |
| Range of Motion            | 94° $\pm$ 17.5° | 93° $\pm$ 18.9° |
| Mechanical Axis            | 183° $\pm$ 5.3° | 185° $\pm$ 5.2° |

<sup>1</sup>Hospital for Special Surgery Knee Score

F = Female; M = Male; BMI = Body mass index

<sup>2</sup> Presented numbers are the number of patients per Larsen grade (1 till 5)

In all TKA surgeries, PA porous-coated femoral components and full PA cemented patellar components were used. The femorotibial design is a biconcave polyaxial radiated design with elongated posterior condyles and is stabilized mediolaterally with two pegs. The anatomically shaped patella component articulates in a proximal elongated trochlear groove. The exchangeable ultra-high molecular weight (UHMW) PE insert with a minimum thickness of 11 mm was fixed with an anterior and posterior lipping mechanism on the tibial tray.

We used the same standard surgical procedure under tourniquet control in all patients. After a straight midline incision was made, the knee was opened by a medial arthrotomy. The tibial cutting surface was aligned extramedullary (prosthetic alignment perpendicular to the talocrural joint) and the distal femoral was cut intramedullary, aligned, and was adjusted to the femoral anatomy based on long, standing radiographs. Soft tissue releases were done when necessary.

During surgery, three to eight tantalum beads (1 mm in diameter) were inserted in preselected places in the metaphyseal bone of the tibia. The insert of the tibial tray was manufactured with six tantalum balls. The locking mechanism between the insert and the tibial tray was pre-tested and showed no movement between the two parts.

After one day of bed rest, patients were allowed to walk using two crutches with partial weight bearing for 6 weeks. Antithrombotic prophylaxis was performed using acenocoumarol (oral acenocoumarol was combined with subcutaneous heparin until an INR [International Normalized Ratio] value between 2.5 and 3.5 was reached), after which acenocoumarol was continued for 6 weeks. At induction of anesthesia and postoperatively for 24 hours, patients received a total of three doses of cefamandole intravenously for infection prevention.

The patients were evaluated preoperatively, at 1 week after mobilization, and 3 months, 6 months, 1 year, and 2 years postoperatively. At each evaluation the clinical status was assessed and radiographs for RSA were made in supine position. Immediately after the operation, at the 1-year follow-up, and at the 2-year follow-up standard anteroposterior (AP) radiographs were taken with the patient standing. Lateral radiographs and axial radiographs of the patella were performed with the patient supine. The lateral and AP positions of the tibial and femoral components were measured as was the mechanical leg axis (Ewald, 1989).

The RSA setup consisted of two synchronized roentgen tubes positioned approximately 1.5 meter above a roentgen cassette (35x43 cm) at a 20° angle to the vertical. Both roentgen tubes simultaneously exposed the roentgen film. A calibration box made of Perspex™ was used to define the three-dimensional (laboratory) coordinate system. For this purpose 38 tantalum 1-mm markers were positioned in the lower plane of the box (fiducial markers). In order to calculate the focus position, 20 1-mm tantalum markers were positioned in the upper plane of the box (control markers).



Using a Vidar VXR-12 scanner (Vidar, Lund, Sweden), the radiographs were scanned at 150 dpi resolution and 8-bit grayscale resolution. The measurement of marker coordinates in the digitized radiographs, the 3-D reconstruction of the marker positions, and the micromotion analysis were done with RSA-CMS software (Medis, Leiden, The Netherlands), a software package that performs the RSA procedure automatically on digitized or digital radiographs (Vrooman et al., 1998). To assess the micromotion of the implants with a high accuracy, the bone markers need to be well fixed in the bone. Bone markers were defined as unstable when they moved more than 0.3 mm with respect to the other bone markers. Unstable markers were excluded from analysis.

The first RSA examination served as the reference baseline. All subsequent evaluations of micromotion were related to the relative position of the prosthesis with respect to the bone at the time of that evaluation. In 6 patients (10 knees; three from the PA group and seven from the uncoated group) the first RSA radiograph was not done within 5 days after surgery, but at 6 weeks postoperatively. As a consequence, in these patients, this radiograph was used as the reference baseline. Micromotion of the components was expressed as translation of the center of gravity of the prosthesis makers and rotation of the rigid body defined by the prosthesis markers about this center of gravity. Positive directions for translations along the orthogonal axes were transverse (lateral-medial), longitudinal (caudal-cranial), and sagittal (posterior-anterior). Positive directions for rotations about the coordinate axes were anterior tilt (transverse axis), internal rotation (longitudinal axis), and varus (sagittal axis).

The reproducibility of the RSA measurements was determined by means of replicate examination of 10 patients (Table 2). Replicate examination consisted of two RSA examinations of the same patient within about 10 minutes of each other. Because of the short time interval between these two radiographs, the assumption is made that the implant did not migrate between these two exposures relative to the surrounding bone. By comparing these two radiographs, the accuracy of the micromotion parameters can be assessed (Ranstam et al., 2000; Ryd et al., 2000).

Outcome measures used in this study to discriminate between the two groups were RSA results after two years follow-up, radiographic measurements and clinical scores (HSS). The observers were blinded to the results.

**Table 2.** Accuracy of the RSA Measurements Based on Double Examinations\*

| Component | Translation (mm)   |                   |                  | Rotation (°)       |                   |                  |
|-----------|--------------------|-------------------|------------------|--------------------|-------------------|------------------|
|           | Trans <sup>1</sup> | Long <sup>1</sup> | Sag <sup>1</sup> | Trans <sup>2</sup> | Long <sup>2</sup> | Sag <sup>2</sup> |
| Stem      | 0.132              | 0.126             | 0.335            | 0.426              | 0.511             | 0.247            |

\*Presented numbers are the upper limits of the 95% CI (N = 10)

<sup>1</sup>Trans = Transverse plane (medial-lateral); Long = Longitudinal plane (caudal-cranial or subsidence); Sag = Sagittal plane (posterior-anterior)

<sup>2</sup>Trans = Transverse plane (anterior tilt); Long = Longitudinal plane (internal rotation); Sag = Sagittal plane (varus rotation)

For comparison of the mean values of the two groups, a nonparametric Mann–Whitney U test was used. In order to explore the effects of the two types of fixation on the amount of micromotion after 2 years, a linear regression was used with migration at the 2-year follow-up as the dependent variable and the fixation type and the baseline examination (directly postoperative or 6 weeks postoperative) as covariables. Levene's test for homogeneity of variance was used to determine the differences of the group variances in the micromotion data. For all analyses, significance was determined by a p value of less than 0.05. All statistical analyses were performed using a commercial software package SPSS 12.0 (Chicago, IL, US).

### 9.3 Results

Follow-up clinical results (HSS score), and range of motion (ROM) were similar between the two groups (Table 3). The knee prosthesis of the patient who died showed no radiographic signs of loosening at 1-year follow-up.

Routine radiographs of the knees revealed no radiolucent lines of 2 mm or more around the tibial, femoral or patellar component in any knees of the two groups at the 2-year follow-up evaluations. Radiolucent lines with a maximum of 1 mm were seen in eight uncoated tibial components, whereas in the PA group no radiolucent lines beneath the tibial tray were detected. Two of the eight uncoated knees showed 4 zones with nonprogressive radiolucencies (medial/lateral/anterior and posterior) with a maximum of 1 mm between the tibial base plate and the tibial bone. Sclerotic

lines around the keel of the tibial tray were seen in two knees, one in the PA group and one in the uncoated group.

**Table 3.** Clinical results during follow-up (Means and Standard Deviations).

| Variables       | PA Coated            |                      | Uncoated             |                      |
|-----------------|----------------------|----------------------|----------------------|----------------------|
|                 | 6 Weeks <sup>1</sup> | 2 Years <sup>1</sup> | 6 Weeks <sup>1</sup> | 2 Years <sup>1</sup> |
| HSS Knee Score  | 77 ± 19.3            | 88 ± 10.2            | 80 ± 9.0             | 88 ± 9.7             |
| Range of Motion | 90° ± 16.7           | 108° ± 18.4          | 86° ± 9.9            | 107° ± 18.3          |

<sup>1</sup>Postoperative time points

HSS = Hospital for Special Surgery

The average mechanical leg axis was similar for the two groups at the 2-year follow-up. The radiographic orientation of the components showed no differences between the two groups (Table 4). Cortical rim support of the tibial base plate judged on plain AP and lateral radiographs was considered insufficient in four knees (two from the PA group and two from the uncoated group). However, these four knees showed no radiographic evidence of radiolucencies around the tibial component.

**Table 4.** Mechanical Axis and Component Orientation (Means and Standard Deviations)\*

| Variables       | PA Coated   | Uncoated    |
|-----------------|-------------|-------------|
| Mechanical Axis | 179° ± 2.5° | 180° ± 3.0° |
| Femur (AP)      | 98° ± 2.5°  | 99° ± 1.2°  |
| Femur (Lateral) | 1° ± 2.8°   | 3° ± 3.1°   |
| Tibia (AP)      | 88° ± 2.0°  | 88° ± 1.5°  |
| Tibia (Lateral) | 86° ± 2.4°  | 86° ± 1.9°  |

\*Results are from the 2-year follow-up examinations

AP = Anteroposterior

Results of the replicate RSA examinations showed that the upper limits of the 95% confidence intervals of the translation and rotation variables (Table 1) were below 0.35 mm for translations and below 0.51 for rotations. Confounding of the difference in baseline examination had no influence on migration along the three orthogonal



axes. This indicates there was no difference between the delayed baseline examination groups on the total amount of micromotion from 6 weeks postoperatively up to the 2-year examination compared with the postoperative RSA examination.

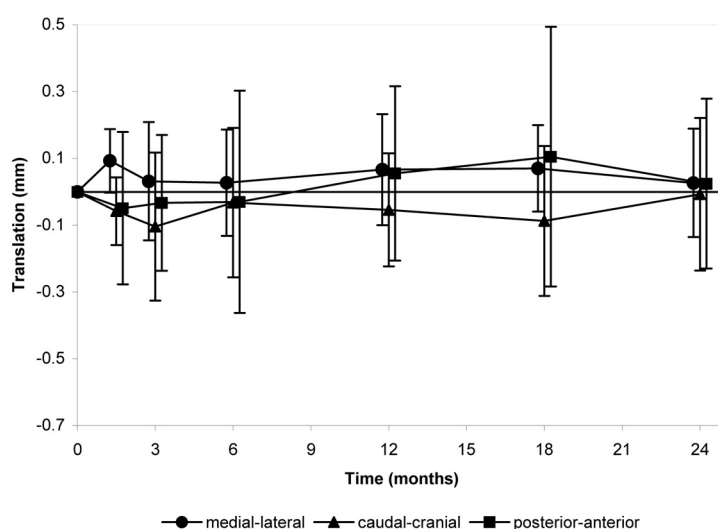


**Figure 1A.** Translations of the PA coated tibial components along the three orthogonal axes (mean and standard deviation).

We observed no difference in migration patterns or in the translations and rotations. Power analysis showed that a statistical power was reached of 0.68. For the PA-coated tibial components, these results were  $0^\circ \pm 0.23^\circ$  (95% CI,  $-0.45^\circ$  to  $0.45^\circ$ ) and  $-0.2^\circ \pm 0.38^\circ$  (95% CI,  $-0.74^\circ$  to  $0.54^\circ$ ), respectively (Figure 1A, Figure 2A and Table 5). For noncoated components, mean subsidence was  $-0.15 \pm 0.47$  mm (95% confidence interval [CI],  $-1.07$  to  $0.77$  mm) and mean valgus rotation was  $-0.6^\circ \pm 0.49^\circ$  (95% CI,  $-1.56^\circ$  to  $0.36^\circ$ ) respectively (Figure 1B, Figure 2B and Table 5). However, the uncoated components had a higher ( $p = 0.007$ ) variance in subsidence compared with the PA-coated components. Both groups showed also a high variance in anterior tilting of the components (range for the PA group,  $-1.44^\circ$  to  $1.57^\circ$ ; range for the uncoated group,  $-0.90^\circ$  to  $2.52^\circ$ ). No correlation was found between the postoperative mechanical leg axis of all pooled data and varus or valgus rotations of the components.

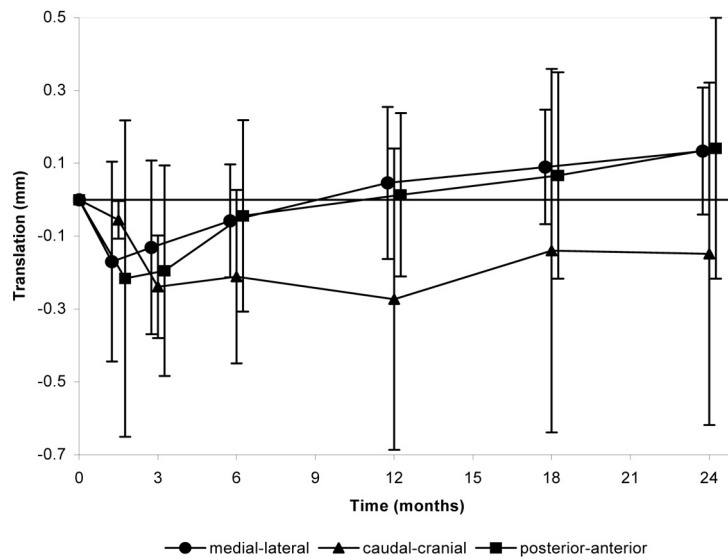


**Figure 1B.** Translations of the uncoated tibial components along the three orthogonal axes (mean and standard deviation).

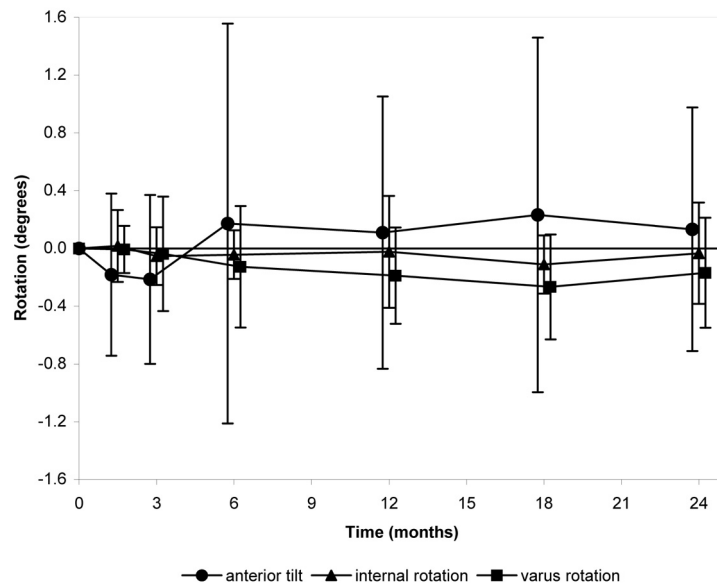


**Figure 2A.** Rotations of the PA coated tibial components about the three orthogonal axes (mean and standard deviation).



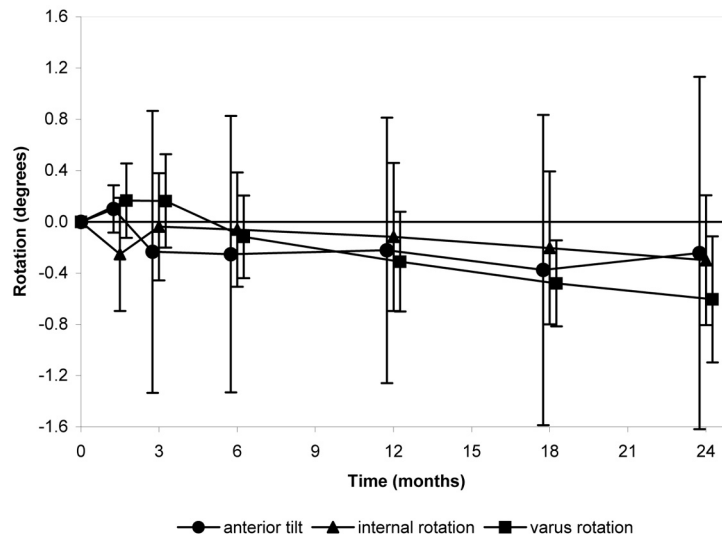
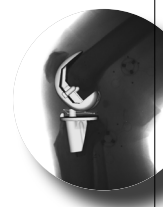


**Figure 2B.** Rotations of the uncoated tibial components about the three orthogonal axes (mean and standard deviation).

**Table 5.** Migration of the PA-Coated and Uncoated Tibial Components (Means and Standard Deviations)\*

| Variables          |                    | PA Coated      | Uncoated       |
|--------------------|--------------------|----------------|----------------|
| Translation (mm)   | Medial-Lateral     | 0.027 ± 0.162  | 0.134 ± 0.174  |
|                    | Caudal-Cranial     | -0.007 ± 0.229 | -0.149 ± 0.470 |
|                    | Posterior-Anterior | 0.025 ± 0.254  | 0.141 ± 0.358  |
| Rotation (degrees) | Anterior Tilt      | 0.133 ± 0.844  | -0.243 ± 1.374 |
|                    | Internal Rotation  | -0.034 ± 0.351 | -0.299 ± 0.507 |
|                    | Varus Rotation     | -0.169 ± 0.381 | -0.605 ± 0.492 |

\*Results are from the 2-year follow-up examinations



## 9.4 Discussion

We hypothesized augmentation of a calcium phosphate coating (PA) to cementless tibial components in a RA patient group would enhance the fixation of these components when compared to cementless, non-coated components. The addition of a calcium phosphate coating to the currently studied TKA gave less variability in prosthesis migration. We were unable to support the hypothesis although noted a trend suggesting addition of a calcium phosphate coating (i.e. PA) might decrease tibial component migration. This might be because of the overall high variability of the mean migration in these patients with RA, which might be a reflection of the variability in their bone quality. Prevalence of RA in the general population is low. In the Swedish knee arthroplasty register (Robertsson et al., 2001), patients with RA made up 10% of the total of 45,000 knee prostheses. Authors of a study in the United States showed a prevalence of only 3.6% (4533 patients) of patients with RA in a total of 125,000 TKAs done in 2000 (Nizar et al., 2005). Patients with RA differ from patients with osteoarthritis patients not only because of the systemic character of their disease (e.g., more osteoporosis), but generally they also are younger.

We note several limitations. Most importantly is the limited number of patients. A power analysis before the study showed, based on data reported in a previous RSA study (Nelissen et al., 1998), that a significant difference in subsidence of 0.3 mm could be observed when 12 patients were included in each group. The power analysis after conducting the study showed a statistical power of 0.68 because of the slightly larger standard deviation than previously assumed. The loss of 7 patients in the uncoated group and 3 in the PA group at the 5 day RSA baseline would intuitively lead to a reduction of the variability and the mean subsidence resulting in an underestimation of the differences between the two groups. However, statistical analysis using a regression analysis showed that there was no effect of delaying the baseline examination to 6 weeks.

Although acrylic bone cement is the primary load-bearing material used for the attachment of orthopaedic devices to adjoining bone, a potential negative effect is its known degradation during long-term follow-up (Hoffmann et al., 1997) and stimulation of osteolysis caused by particulate debris (Brooks et al., 2000; Sabokbar

et al., 1997; Shardlow et al., 2003; Wimhurst et al., 2001). Enhancement of bone ingrowth into cementless knee prostheses using calcium phosphate coatings has been advocated (Nelissen et al., 1998; Nilsson et al., 1999; Søballe et al., 1993). Furthermore, the sealing effect of these coatings for the prosthetic interface from particulate debris also would be advantageous (Rahbek et al., 2001).

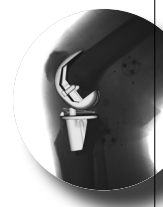
A potential negative effect of calcium phosphate coatings is delamination and third-body wear (Wang et al., 1997). Thick calcium phosphate layers (greater than 100  $\mu\text{m}$ ) have a tensile bond strength of only 35 MPa with subsequent risk for delamination (Nilsson et al., 1994; Røkkum et al., 2002). The Duracon prosthesis, with its double-layer beaded surface, is coated with a PA coating at a mean thickness of 20  $\mu\text{m}$  with a tensile bond strength of 65 MPa. In addition to the bioactive coating, prosthesis design also is important to implant survival in cementless prostheses. The Duracon knee has a risk ratio for revision of 1.05 compared with its predecessor, the PCA cementless uncoated knee, which had a risk ratio for revision of 2.28 (Furnes et al., 2002; Robertsson et al., 2001). These differences probably are accounted for because of design changes of the tibial base plate in these two devices.

Prosthetic failure also is related to insufficient bone contact. The supportive cortical bone in healthy knees is 6% of the total tibial surface and the cancellous ingrowth areas are 18% (Bloebaum et al., 1994). Bone quality in the patients with RA generally is reduced; they have thinner cortical bone and reduced cancellous bone. Migration results of the PA group in this study and in other studies in which different calcium phosphate coatings were used (Nelissen et al., 1998; Nilsson et al., 1994; Oliver et al., 2005) are favorable. Furthermore, no effect of bone quality on migration (Tagil et al., 2003) or revision rate (Therbo et al., 2003) was found. Although in our series the differences in migration between uncoated and PA groups did not differ, we found less variability in PA group. A trend could be detected toward a more stable fixation in the PA group.

Prosthetic position also influences TKA survival (Bargren et al., 1993; Ecker et al., 1987). However, we could not find a correlation between prosthetic malalignment ( $< 176^\circ$ ,  $> 184^\circ$ ), and increased micromotion after two years, probably because of absence of extreme outliers in the postoperative mechanical axes in this study.

Authors of two RSA studies comparing migration results between uncoated, HA-coated, and cemented tibial implants showed a higher rate of migration in the uncoated groups compared with the HA and the cemented implants in patients with OA and RA (Nelissen et al., 1998; Nilsson et al., 1999). After a settling period, stabilization of the HA-coated implants occurred. Although the PA-coated implants we studied tended to act similarly to these HA-coated implants, the variation in migration in the current study is greater (Nelissen et al., 1998; Nilsson et al., 1999; Onsten et al., 1998). Initial migration during the first 3 to 6 months is highest; after that the PA components tend to stabilize. Although others showed bone ingrowth continues up to 9 months after implantation (Hughes et al., 2003), the micromotion curve suggests earlier mechanical stability. The uncoated groups show progressive micromotion along the orthogonal axes throughout the 2-year follow-up. It has not been determined yet whether this results in long-term failure. The ability of calcium-phosphate-coated implants to sustain the forces that threaten fixation early after implantation and to remain stable in the longer term is supported with excellent 10-year survival data (90–98% survival) in patients with RA (Illgen et al., 2004; Robertsson et al., 2001; Watanabe et al., 2004; Weir et al., 1996; Whiteside, 1994; Wright et al., 2004).

Although we noted no differences in migration between uncoated and PA-coated implants, we saw a trend for less subsidence and anterior tilting in patients with PA-coated implants. We observed lower variance in migration when PA-coated implants were used. Different implant designs will have different impacts on migration. The influence of these individual prosthetic designs can be evaluated accurately with RSA.



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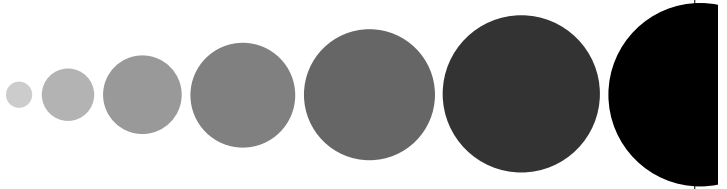
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# Chapter 10



## **Micromotion of mobile bearing versus posterior stabilized total knee prostheses**

**Randomized RSA study of 40 knees followed for 2 years**

Eric H. Garling<sup>1</sup>, Edward R. Valstar<sup>1,2</sup>, Rob G.H.H. Nelissen<sup>1</sup>

<sup>1</sup> Department of Orthopaedics, Leiden University Medical Center, Leiden, The Netherlands

<sup>2</sup> Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials Engineering, Delft University of Technology, The Netherlands

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## **Abstract**

On theoretical grounds mobile bearing total knees should reduce the micromotion of the tibial component relative to the bone.

We used radiostereometric analysis to measure the three-dimensional micromotion in 42 tibial components during 2 years of follow-up. The patients had been randomized as to whether they would receive a mobile bearing (MB) or posterior stabilized (PS) design. We expected that the MB knee would facilitate dissipation of forces from the prosthesis-bone interface by the motion of the bearing and by load sharing with the soft tissues, leading to less micromotion. In the PS designs, limited free rotation caused by the cam-post articulation might cause additional stress at the boneprosthesis interface.

We found no significant differences between the MB and PS group at the 2-year follow-up evaluation with respect to Knee Society scores and radiographic results. The PS group had a higher variability in subsidence and anterior-posterior tilting of the component than the MB group.

The low variability of the data in the MB knee prosthesis group suggests that this design is more predictable and forgiving with respect to micromotion of the tibial component.



## 10.1 Introduction

Wear is one of the critical factors limiting the long-term success of total knee prostheses (TKP). Retrieval studies of tibial inserts have shown that low-conformity and the thickness of the polyethylene insert are associated with increased wear (Bartel et al., 1986; Collier et al., 1991; Wright et al., 1992). One design option which deals with this problem is the mobile bearing (MB) insert, combining high conformity with maximized range of motion (Buechel and Pappas, 1990; Jordan et al., 1997). In contrast to this mobile design the fixed bearing posterior stabilized (PS) TKP, which has a high degree of internal constraint and has during some periods been most frequently used (Aglietti et al., 1999; Stern et al., 1992; Li et al., 1999).

The better wear characteristics of the MB prostheses are based on the relatively large contact area of these designs, thus the contact stresses in the polyethylene are lower compared to the PS designs. Furthermore, if the femoral component and tibial components are malaligned and slight orientation differences are present between the components, the fixed-bearing PS insert will be forced in a certain direction during the range of motion. Contrary, differences between component rotation and the actual knee joint will be corrected by a movable bearing. PS implants will show additional polyethylene wear debris (Puloski et al., 2001), while the MB designs result in less wear of the polyethylene (Jones et al., 1999).

Also torque and shear forces in a MB TKP will be better dissipated from the prosthesis-bone interface by the motion of the bearing and by load sharing with the ligaments and other soft tissue structures (Buechel and Pappas, 1990; Goodfellow and O'Connor, 1992; Callaghan et al., 2001). While in the PS design the limited free rotation caused by the cam-post articulation might cause additional stress at the bone-prosthesis interface.

Early micromotion of implants has been shown to be related to implant survival (Grewal et al., 1992). This micromotion can be very accurately assessed using Roentgen Stereophotogrammetric Analysis (RSA). The value of RSA is -besides high accuracy- its predictive value for future prosthesis loosening (Kärrholm et al., 1994; Ryd et al., 1995; Selvik, 1989). The purpose of our study was to examine the amount of three-dimensional micromotion of the tibial component in a randomized RSA study, comparing a PS fixed with a MB design.

## 10.2 Patients and methods

42 Consecutive primary cemented TKP (33 patients; 21 female, 12 male) were included. During surgery, a randomization scheme selected the patients for either a PS or MB prosthesis. If a patient was operated bi-laterally the randomization scheme was followed starting with the right leg. In each group two patients received in both knees the same implant design. Patients with a deformity of more than 20 degrees in any plane were excluded from the study. The institution's ethics committee approved the study, and the patients gave informed consent.

In each group 21 cemented implants were included. The PS group consisted of 15 knees of patients with rheumatoid arthritis and 6 knees of patients with osteoarthritis. The MB group consisted of 14 knees of patients with rheumatoid arthritis and 7 knees of patients with osteoarthritis. The two groups were similar with regard to age (66 SD 12 years), body mass index (27 SD 5 kilogram per square meter), or stage of osteoarthritis: Ahlbäck 4, (min-max: 3-4) and Larsen 4, (min-max: 3-5) (Ahlback, 1968; Larsen et al., 1977).

The prosthesis used was the Interax Posterior Stabilized TKP (Stryker-Howmedica, Rutherford, New Jersey, USA) and the Interax Integrated Secure Asymmetric (ISA) TKP, a MB design (Figure 1). The Interax system provides a tibiofemoral articulation surface of the femoral prosthesis, which is spherically shaped in both the frontal and sagittal planes. The base plate of the Interax system is manufactured from cast Vitallium and has a highly polished surface. The articulating surface used in both designs is made of ultra-high-density-molecular-weight polyethylene (UHMWP). The PS design has a fixed articulating surface with a central cam providing medial-lateral stability.

The knee prosthesis with the MB insert permits anterior/posterior sliding and rotation of the inlay on the tibial tray. Two metal pins guide movement of the inlay on the tibial tray, which match the profile of a corresponding groove on the underside of the inlay. Movement of the MB insert is guided by this metal pin, which matches the profile of a corresponding groove on the underside of the inlay. The maximum possible movement of the inlay center is 8.5 mm anterior/posterior and 18 degrees of axial rotation relative to the tibial tray.

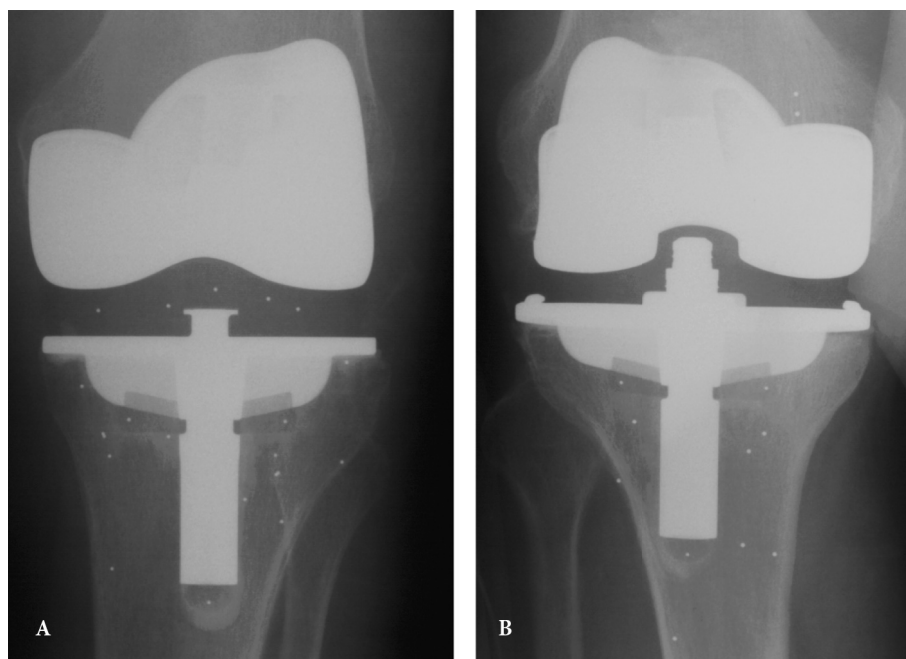


**Figure 1.** Anterior-posterior radiograph of a MB (A) and a PS (B) total knee prosthesis used in this study.

During the knee arthroplasty 6 to 8 tantalum markers ( $\varnothing = 1$  mm; Industrial Techtonics, Ann Arbor, Michigan, USA) were inserted by a specialized instrument into the tibial metaphysis of each patient. The manufacturer inserted two one-millimeter-diameter tantalum markers into a polyethylene wing, which was rigidly connected between the tibial base plate and the stem. A third implant marker was attached at the tip of the stem in a polyethylene notch.

A patellar component made of UHMWP was used in all TKR. The operation was performed through a standard mid-line incision with a medial arthrotomy. Ligament tensioning and balancing of the MB knee group was standardized during surgery using the Monogram Knee Balancer (Stryker-Howmedica, Rutherford, New Jersey, USA). After soft-tissue releases, the prosthesis was implanted according to the manufacturer's instructions. During surgery the stability of each PS knee was assessed in extension and 90 degrees of flexion. Discrepancies of less than 2 mm were accepted after medial and lateral stressing of the knee.

The cut bone surfaces were mechanically pulse-lavaged with a device manufactured by Zimmer (Warsaw, Indiana, USA) before Palacos bone cement (Schering, Kenilworth, New Jersey, USA) was applied. The tibial base plate and the central stem were cemented in all patients. Post operatively, all of the knees were fitted with a Jones bandage.

The patients were evaluated pre operatively, at 1 week, 3 weeks, 6 weeks, 3 months, 6 months, 1 year, and 2 years post operatively. At each evaluation the clinical status was assessed and radiographs for RSA were exposed. Immediately after the operation, at the 1-year, and at the 2-year follow-up, standard anterior/posterior exposures were taken with the patient standing (Ewald, 1989). Lateral radiographs as well as axial radiographs of the patella were made supine. The femoral tibial angle was determined based on a preoperative and one-year hip-knee-ankle radiograph. 2 patients (one PS and one MB) were lost to follow-up before the final follow-up evaluation of the study due to severe mobility restrictions unrelated to the knee prosthesis (severe rheumatoid arthritis with multiple joint involvement).

The RSA set-up consisted of two synchronized roentgen tubes positioned approximately 1.5 meter above a roentgen cassette (35x43 cm) at a 20° angle to the vertical. Both roentgen tubes simultaneously exposed the roentgen film. A calibration box made of Perspex™ was used to define the three-dimensional (laboratory) coordinate system. For this purpose 26 tantalum 1-mm markers were positioned in the lower plane of the box (fiducial markers). In order to calculate the focus position, 16 1-mm tantalum markers were positioned in the upper plane of the box (control markers).

With a Vidar VXR-12 scanner (Vidar, Lund, Sweden), the radiographs were scanned at 150 dots per inch resolution and eight-bit gray scale resolution. The measurement of marker coordinates in the digitized radiographs, the three-dimensional reconstruction of the marker positions, and the micromotion analysis was done with RSA-CMS (MEDIS, Leiden, The Netherlands). This software package performs the RSA procedure automatically using digitized or digital radiographs (Vrooman et al., 1998; Valstar et al., 2000; Valstar, 2001).

In order to assess the micromotion of the implant with a high accuracy, the bone markers need to be well fixated in the bone. Bone markers were defined unstable



when they moved more than 0.3 mm with respect to the other bone markers. Unstable markers were excluded automatically from analysis.

The first RSA examination served as the reference baseline. All subsequent evaluations of micromotion were related to the relative position of the prosthesis with respect to the bone at that time of the evaluation. Micromotion of the components was expressed as translation of the center of gravity of the prosthesis makers and rotation of the rigid body defined by the prosthesis markers about this center of gravity. Positive directions for translations along the orthogonal axes were: transverse (medial-lateral), longitudinal (caudal-cranial), and sagittal posterior-anterior). Positive directions for rotations about the coordinate axes were anterior tilt (transverse axis), internal rotation (longitudinal axis), and varus (sagittal axis).

The reproducibility of the RSA measurements was determined by means of double examination of a subgroup of patients (Table 1). Double examination consists of 2 RSA examinations of the same patient exposed within a time interval of about 10 minutes. Because of the short time-interval between these two radiographs, the assumption is made that the implant did not migrate between these two exposures relative to the surrounding bone. By measuring, analyzing, and comparing these two radiographs, the accuracy of the micromotion parameters can be assessed (Ranstam et al., 2000).

**Table 1.** Precision of the RSA measurements based on double examinations. Presented numbers are the upper limits of the 95%-confidence interval (translations n=22; rotations n=16).

| Translation (mm) |      |      | Rotation (°) |      |      |
|------------------|------|------|--------------|------|------|
| Trans            | Long | Sag  | Trans        | Long | Sag  |
| 0.07             | 0.06 | 0.28 | 0.45         | 0.42 | 0.16 |

### 10.2.1 Statistics

Mean values and standard deviations were calculated for all variables. For comparison of the median values of the two groups, Mann-Whitney U-test was used. This test was used to compare the micromotion data between the two types of bearing designs at the 2 year follow-up. Levene's test was used to determine whether the

group variances for the micromotion were equal. For all analyses, significance was determined by a p-value  $\leq 0.05$ .

### 10.3 Results

#### 10.3.1 Clinical results

There were no significant differences between the two groups in the pre operative Hospital for Special Surgery Score (HSS), Knee score and Functional score according to the system of the Knee Society (Table 2), or at the 2-year follow-up evaluation. The mean pre operative flexion of both groups was 111, (SD 16) degrees (range, 80 to 135 degrees), which increased to 116, (SD 13) degrees (range, 90 to 140 degrees) at the 2-year follow-up evaluation. The medio-lateral instability scores, based on the Knee Society are presented in Table 3.

**Table 2.** HSS, Knee Society Scores and Functional Scores (mean, SD) preoperatively, at the 6-month, 1 year and 2-year follow-up for the MB knee (n=21) and PS group (n=21).

|               | HSS score |         | Knee Society Score |         | Function score |         |
|---------------|-----------|---------|--------------------|---------|----------------|---------|
|               | MB        | PS      | MB                 | PS      | MB             | PS      |
| Pre operative | 40 (13)   | 40 (12) | 24 (14)            | 18 (13) | 26 (18)        | 19 (18) |
| 6 months      | 89 (6.2)  | 76 (23) | 88 (14)            | 87 (23) | 71 (28)        | 55 (36) |
| 1 year        | 90 (7.2)  | 86 (11) | 92 (7.2)           | 89 (12) | 74 (29)        | 58 (34) |
| 2 years       | 92 (5.8)  | 83 (13) | 85 (17)            | 85 (23) | 70 (25)        | 62 (34) |

One patient from the MB group (RA treated with corticosteroids and methotrexate), developed skin necrosis with secondary patella tendon necrosis and deep infection. After removal of the prosthesis, debridement and treatment with antibiotics, an arthrodesis was performed.

**Table 3.** Medio-lateral instability according to the system of the Knee Society. Number of patients scored pre operatively and post operatively.

|                         | MBK |      | PS  |      |
|-------------------------|-----|------|-----|------|
|                         | Pre | Post | Pre | Post |
| Category I (<5°)        | 2   | 16   | 6   | 17   |
| Category II (6°- 9°)    | 6   | 2    | 3   | 3    |
| Category III (10°- 14°) | 6   | 1    | 2   | –    |
| Category IV (>14°)      | 2   | –    | 5   | –    |

### 10.3.2 Radiographic results

Routine radiographs of the knee revealed no radiolucent lines of 2 mm or more around the tibial, femoral or patellar component in either of the two groups at the two-year follow-up evaluation. In 2 knees from the MB group and 3 knees from the PS group, non-progressive radiolucent lines of 1 mm were observed in the first two medial zones of the anterior-posterior radiograph according to the Knee Society. In one PS knee, the lateral radiograph revealed a radiolucent line of 1 mm in the posterior zone and in another PS knee a radiolucent line of 1 mm in the anterior zone was discovered.

**Table 4.** Radiographic results (mean (SD) for the MB knee (n=21) and PS (n=21) tibial components at the 2-year follow-up evaluation.

|                       | MB (°)    | PS (°)    |
|-----------------------|-----------|-----------|
| Tibial angle          | 87 (2.2)  | 87 (1.9)  |
| Tibial slope          | 86 (3.2)  | 85 (3.1)  |
| Femoral flexion (AP)  | 94 (2.3)  | 95 (2.6)  |
| Femoral flexion (LAT) | 3.0 (2.6) | 2.6 (3.0) |

No significant differences in the radiographic results were observed between the MB and PS group. The mean pre operative femoral-tibial angle was for the two groups 181, (SD 8.4) (range, 152 to 192) degrees. At the postoperative evaluation the mean flexion contracture for the MB group was 1.3, (SD 3.3) degrees (range, 5 to 10)



compared to 0.0, (SD 3.3) (range, -5 to 10) degrees for the PS group. At the two-year follow-up evaluation, the femoral-tibial angle was 178, (SD 3.2) (range, 176 to 186) degrees. 4 MB knee prostheses and 1 PS prosthesis had a varus deformity of more than three degrees at the two-year follow-up evaluation (Table 4).

### **10.3.3 RSA results**

The micromotion data of the tibial components is presented in Table 5 and Table 6. In some cases problems occurred with respect to the marking of the tibia. In 3 cases (2 MB, 1 PS), the bone was either marked with less than three markers, or the markers were positioned so that they were occluded by the component. These cases were excluded from the analysis. In 9 components (6 PS, 3 MB) one of the markers, either at the medial or lateral side of the tibial tray, was occluded. As a result only the translations of these specific tibial components could be calculated (Table 7).

No significant differences in translations and rotations were found between the MB group and the PS group. At the 2-year follow-up evaluation, the PS components had subsided 0.10, (SD 0.18) (range, -0.01 to 0.59) mm; the mobile bearing components had subsided 0.06, (SD 0.09) (range, -0.01 to 0.20) mm. The mean anterior-posterior tilting of the component at two-year follow-up was for MB components -0.09, (SD 0.27) (range, -0.39 to 0.35) degrees and for the PS components -0.06, (SD 0.86) (range, -1.42 to 1.75) degrees. 6 patients had a rotation of more than 0.30° about this axis. Three of these patients also had the highest body mass index (BMI) of the PS group. The PS group showed a significant higher variability in subsidence (Levene's test,  $p = 0.04$ ) and rotation about the transverse axis (Levene's test,  $p = 0.05$ ) compared to the MB group. This indicates that some PS components showed a relatively high micromotion (e.g. maximum anterior tilt or posterior tilt) compared to the components in the MB group.

All tibial components with radiolucent lines of one millimeter rotated about the longitudinal axis 0.4 degrees or more. Components without radiolucent lines rotated less.

**Table 5.** Mean translations (95% CI, Lower Bound – Upper Bound) of the PS and MB tibial components during 2-year follow-up.

|           | Translations (mm)    |                      |                       |                     |                      |                      |
|-----------|----------------------|----------------------|-----------------------|---------------------|----------------------|----------------------|
|           | Lateral-Medial       |                      |                       | Caudal-Cranial      |                      |                      |
|           | PS                   | MB                   | PS                    | MB                  | PS                   | MB                   |
| 3 weeks   | -0.00 (-0.05 – 0.04) | 0.06 (0.01 – 0.103)  | 0.01 (-0.037 – 0.06)  | 0.04 (-0.01 – 0.08) | -0.00 (-0.05 – 0.05) | -0.10 (-0.32 – 0.12) |
| 6 weeks   | 0.02 (-0.03 – 0.07)  | 0.01 (-0.03 – 0.05)  | -0.03 (-0.01 – 0.07)  | 0.04 (0.00 – 0.07)  | -0.04 (-0.12 – 0.03) | 0.03 (-0.06 – 0.12)  |
| 3 months  | -0.02 (-0.08 – 0.04) | 0.02 (0.00 – 0.04)   | 0.02 (-0.03 – 0.07)   | 0.03 (-0.01 – 0.07) | -0.05 (-0.08 – 0.01) | 0.03 (-0.02 – 0.08)  |
| 6 months  | -0.02 (-0.07 – 0.03) | -0.00 (-0.08 – 0.08) | -0.04 (-0.04 – -0.02) | 0.02 (-0.02 – 0.06) | -0.02 (-0.08 – 0.04) | 0.03 (-0.09 – 0.15)  |
| 12 months | -0.05 (-0.11 – 0.00) | -0.01 (-0.07 – 0.05) | 0.05 (-0.04 – 0.14)   | 0.06 (-0.02 – 0.12) | -0.06 (-0.12 – 0.00) | 0.02 (-0.07 – 0.11)  |
| 24 months | -0.05 (-0.10 – 0.01) | -0.02 (-0.10 – 0.05) | 0.09 (-0.02 – 0.20)   | 0.06 (-0.01 – 0.12) | -0.00 (-0.08 – 0.08) | 0.02 (-0.08 – 0.11)  |

**Table 6.** Mean rotations (95% CI, Lower Bound – Upper Bound) of the PS and MB tibial components during 2-year follow-up.

|           | Rotations (degrees)  |                      |                      |                      |                      |                      |
|-----------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
|           | Anterior tilt        |                      |                      | Internal rotation    |                      |                      |
|           | PS                   | MB                   | PS                   | MB                   | PS                   | MB                   |
| 3 weeks   | -0.03 (-0.40 – 0.33) | 0.06 (-0.28 – 0.39)  | -0.06 (-0.21 – 0.01) | 0.04 (-0.84 – 0.91)  | 0.03 (-0.04 – 0.11)  | 0.03 (-0.15 – 0.20)  |
| 6 weeks   | 0.14 (-0.21 – 0.48)  | 0.05 (-0.23 – 0.33)  | -0.00 (-0.19 – 0.18) | 0.03 (0.16 – 0.22)   | 0.01 (-0.11 – 0.13)  | 0.07 (0.00 – 0.13)   |
| 3 months  | 0.09 (-0.23 – 0.42)  | -0.02 (-0.18 – 0.14) | 0.10 (-0.10 – 0.29)  | 0.12 (-0.03 – 0.26)  | -0.02 (-0.14 – 0.09) | 0.03 (-0.14 – 0.08)  |
| 6 months  | 0.08 (-0.31 – 0.46)  | -0.08 (-0.31 – 0.16) | 0.02 (-0.19 – 0.22)  | -0.00 (-0.23 – 0.23) | -0.04 (-0.15 – 0.08) | 0.03 (-0.14 – 0.19)  |
| 12 months | -0.16 (-0.49 – 0.75) | -0.07 (-0.29 – 0.15) | -0.02 (-0.27 – 0.24) | 0.02 (-0.19 – 0.23)  | 0.00 (-0.16 – 0.17)  | 0.04 (-0.08 – 0.16)  |
| 24 months | -0.06 (-0.60 – 0.49) | -0.09 (-0.30 – 0.12) | -0.01 (-0.28 – 0.26) | 0.01 (-0.28 – 0.29)  | 0.00 (-0.16 – 0.16)  | -0.07 (-0.21 – 0.06) |

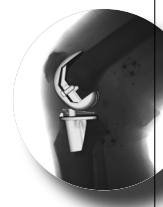


**Table 7.** Number of observations that could be used for migration calculation for each follow-up examination.

|          | MB           |           | PS           |           |
|----------|--------------|-----------|--------------|-----------|
|          | Translations | Rotations | Translations | Rotations |
| 3 weeks  | 19           | 10        | 20           | 11        |
| 6 weeks  | 19           | 13        | 20           | 12        |
| 3 months | 19           | 16        | 20           | 13        |
| 6 months | 19           | 14        | 20           | 15        |
| 1 year   | 19           | 16        | 20           | 14        |
| 2 years  | 19           | 16        | 20           | 15        |

#### 10.4 Discussion

Wear causes aseptic loosening of the prosthesis due to the osteolytic activity around the prosthesis induced by wear particles and fluid pressure (Schmalzried et al., 1992; Santavirta et al., 1993; Vis, 1997). Because of the relatively small contact area of fixed bearing designs, the contact stresses in the polyethylene can be high leading to excessive wear. Especially for patients with a high BMI the contact pressure on the posterior part of the tibial tray increases rapidly during flexion, due to a posterior translation of the femoral-tibial contact point (Stiehl et al., 1999) which can explain the observed anterior-posterior tilting of the component in this study (Stukenborg et al., 2002). However, in MB designs wear is also observed between the polyethylene bearing and the tibial tray. The mechanical solutions proposed to restrict bearing motion to a unidirectional motion by rotating platforms or to entrap meniscal bearings in curved tracks (Lewandowski et al., 1997), may induce erratic movements with polyethylene on metal impingement. A prerequisite for a good load distribution in mobile bearing knees is a continuous motion over time of the polyethylene insert during flexion. However, the mobile bearing may be encapsulated by soft-tissue after a period of time or may have erratic movements (Hartford et al., 2001). Consequently,



the advantage of the mobility of the polyethylene insert – which should prevent excessive wear – is cancelled out, and could induce even more wear.

In cam-post articulation of PS implants an additional source of polyethylene wear debris is present. The stabilizing cam acts as a contact guide in limiting tibial subluxation and ensuring appropriate femoral rollback. Therefore the most polyethylene wear will occur over the posterior surface of the post (Li et al., 1999). Pre operative function and general condition of the patient are important factors determining the post operative function after TKA (Nelissen et al., 1995). The preoperative function score was only slightly higher for the MB group compared to the PS group. Although in the beginning of the follow-up the Knee Society function score was higher for the MB group, at the two-years evaluation no differences were observed.

Nelissen et al. (1998), showed a subsidence rate after two-years of cemented fixed bearing tibial components of the Interax total knee prosthesis of  $-0.05 \text{ mm} \pm 0.11 \text{ mm}$ , which is comparable with the subsidence in the results of the MB prostheses ( $0.08 \text{ mm} \pm 0.09 \text{ mm}$ ). In the former study a low-conformity, posterior cruciate retaining TKP was used, allowing more rotation than the Interax PS design. Apparently a low conformity design as well as a higher conformity MB design give less variability in the subsidence data compared to the PS design (Nelissen et al., 1998).

Three clinical factors could explain the variability in the micromotion between the two groups: the bone-cement interface, ligament balancing and alignment of the components.

A good bone-cement interface implies a stable cemented prosthesis. Interface motions stresses the bone/cement, which will induce loosening of the prosthesis. Especially the variability in the tilting of the components was large for the PS knees. In high flexion, the posterior cam of the femoral component slides against the polyethylene post and pushes the tibial component into an anterior tilt. Inducible displacements caused by this cam-post mechanism leads to increased interface motions (Uvehammer and Kärrholm, 2001).

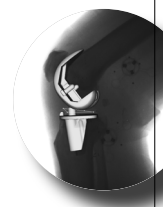
The second clinical factor causing variability in TKP micromotion data is improper ligament balancing. Some knees might be more lax in extension and tight in flexion causing high contact pressures posterior of the tibial tray or at the

cam-post contact point (Uvehammer and Kärrholm, 2001). Patients with a flexion contracture stress the posterior part of the tibial tray continuously resulting in a rotation of the component about the transverse axis (i.e. anterior tilt of the tibial tray). However, in this study no significant difference in flexion contracture was noted between groups. Finally, postoperative collateral medio-lateral stability scores were similar comparing the MB and the PS knee prostheses. However, for the MB prostheses, load inequality between the medial and lateral condyles resulting from an adduction moment during gait (Schipplein and Andriacchi, 1991; Yu et al., 1997) or improper balancing of the knee (Vedi et al., 1999) is expected to be less at the tibial component due to the mobility of the bearing. If alignment can be restored to normal anatomy, load sharing gives positive remodeling at the bone level (Wolff's Law) and at the soft tissue level (Roux's Law) (Malone et al., 2002). Appropriate tensioning of the soft tissues will not only enhance stress distribution reducing bone-implant interface stresses, but will also provide appropriate knee stability and improved function. There is a low margin of error allowed during surgery. Even small errors could result in increased wear due to high contact stresses and could undermine theoretical benefits of prosthesis designs. The mobile bearing design is more forgiving, by correcting slight rotation differences between the actual anatomy and the TKP, but also correcting for slight rotation differences between the femoral and tibial component.

A third clinical factor affecting micromotion is alignment of the TKP. Residual varus deformity following TKP has been shown to create a substantial load imbalance, resulting in the type of stress eventually leading to tibial component loosening (Schipplein and Andriacchi, 1991; Stiehl et al., 1999; Perillo-Marcone et al., 2000). In a finite element analysis, the contact stresses in a 3 degrees varus knee increased by 45% in comparison to a neutral alignment of the component (Liau et al., 2002). In the MB group, 4 prostheses had a varus deformity of more than 3 degrees. These components might be at risk for high contact stresses in the medial compartment of the bearing resulting in abnormal kinematics and a high polyethylene wear rate. However, no increased micromotion (i.e. rotation of the tibial component about the sagittal axis) was found in these prostheses during the two-year follow-up. Stresses are dissipated away through the movable insert of the MB design.

We found no evidence of periprosthetic osteolysis on the plain radiographs when defining 2 mm of radiolucency as a risk of radiologic loosening (Pilliar et al., 1986; Søballe et al., 1993; Reading et al., 1999). When traditional radiographs are used for assessment, the rate of early loosening is underestimated. The PS components with a partial radiolucency of one millimeter also showed a substantial rotation about the longitudinal axis (i.e. external rotation). Rotations about this axis are hard to discriminate in traditional radiographs. The rotations about the longitudinal axis of the PS components can be explained by the femoral component bouncing against the cam during flexion. This cam prevents internal and external rotation of the tibia during flexion or walking (Lafortune et al., 1992). Puloski et al. (2001) observed surface damage on the tibial posts of PS tibial components caused by cam-post articulation. Damage on the tibial posts will result in long-term failure of the PS knees through excessive wear, delamination, or even lead to fatigue fracture of the tibial component.

The low variability of the data in the MB knee prosthesis group suggests that implantation of a MB design is more predictable and forgiving with respect to micromotion of the tibia component in the bone after two-year follow-up compared to fixed bearing PS designs.



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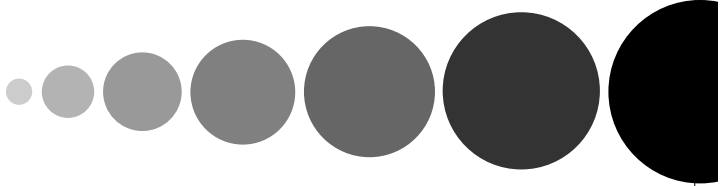
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# Chapter 11



## **Observations on retrieved articular surfaces of total knee prostheses**

Eric H. Garling<sup>1</sup>, Henk K. Koerten<sup>2</sup>, Edward R. Valstar<sup>1,3</sup>, Rob G.H.H. Nelissen<sup>1</sup>

<sup>1</sup> Department of Orthopaedics, Leiden University Medical Center, The Netherlands

<sup>2</sup> Department of Microscopic Imaging and Technology, Leiden University Medical Center, The Netherlands

<sup>3</sup> Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials Engineering, Delft University of Technology, The Netherlands

## **Abstract**

It is of interest to observe and document the wear characteristics of explanted knee bearings to see how various kinematic phenomena *in vivo* manifest in wear and damage of different articular surfaces over extended time. The evaluation in this study included two mobile bearing, three posterior stabilized and four fixed bearing total knee prostheses. Two total knee prostheses served as control components.

Polishing marks and randomly oriented residual polishing scratches were visible on the surface of all control components. However, also large polyethylene fibrils next to the articulating surface were observed on the inserts.

The two revised mobile bearing inserts showed striations at the tibial articulating surface indicating rotational movement of the insert *in vivo*. Most of the particles on the mobile bearing insert surfaces could be characterized as granules in combination with beads

One post of the tibial insert was fractured and severe fatigue wear with subsurface deformation and removal of the surface was observed. All the fixed bearing tibial inserts showed severe delamination at the posterior parts of the condylar articulating surface

Imaging X-ray microanalysis showed composing elements Co, Cr and Mo. However, in three femoral components small round holes were visible in the surface at various locations. In one of these holes a Ti particle could be observed indicating severe pollution of the metal compound. This will induce galvanic corrosion with subsequent increased metal particle release and osteolysis.



## 11.1 Introduction

The most common causes for failure after more than 2 years after primary total knee surgery are polyethylene wear and aseptic loosening (Dennis, 2004; Fehring et al., 2001; Sharkey et al., 2002). The primary wear mechanisms acting on the articulating surfaces of a knee prostheses are abrasive wear, adhesive wear, third body wear and fatigue wear (Figure 1). Since the total knee prosthesis comprehends articulation between a metal femoral component and a polyethylene tibial insert, wear debris will be mainly polyethylene particles, while metal debris is far less. Also cement and bone particles are involved in the third body wear pattern through a possible interposition between the components.

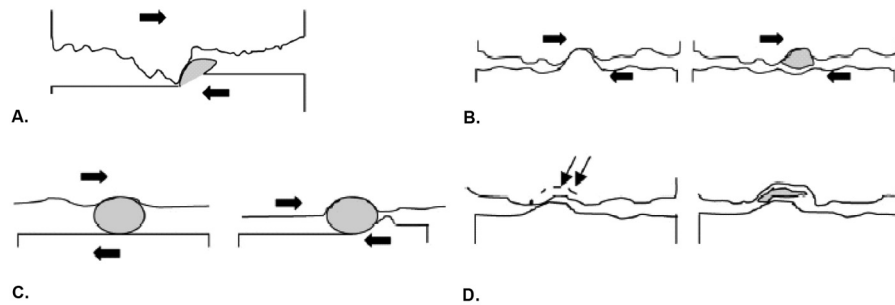


**Figure 1.** (A) *Abrasive wear*: removal of material from one surface by the other. Local high points or ‘asperities’ on the surface of the harder material will scrape into the softer material and produce wear particles. (B) *Adhesive wear*: localised bonding of the two surfaces occurs such that the attachment force is stronger than the yield strength of the material. (C) *Third body wear*: damage is caused by a particle caught between the two surfaces (such as a particle of cement). These third bodies can become embedded in the polyethylene and lead to scratching of the metal surface which, in turn, leads to accelerated abrasive wear. (D) *Fatigue wear*: subsurface stresses in the polyethylene, which can lead to subsurface cracks (arrows) propagating and flaking off of particles from the surface. High subsurface stresses can also be caused by third bodies between the two articulating surfaces leading to accelerated fatigue wear.

The effect of particles on the artificial joint is directly related to the osteolysis which can appear around the prosthesis even one year after its implantation (Colliza et al., 1995). Factors influencing the process of osteolysis are the number of the particles, their size and surface chemistry and the actual material that they are made of (Wroblewski, 1979; Schmalzried et al., 1994; Hirakawa et al., 1996). Because all particles originate from the prosthetic surface, analysis of their genesis is important. The objective of the current study was to observe wear patterns and wear particles in retrieved total knee prostheses.

## **11.2 Method**

All studied knee components were retrieved from patients that underwent revision surgery at Leiden University Medical Center. The evaluation included nine total knee components (Table 1). After retrieval, the components were cleaned in a solution containing 5.25 % sodium hypochlorite (pH 10) to digest the tissue surrounding the retrieved implants. Thereafter, the implants were rinsed in distilled water, air dried and subsequently transferred to the specimen stage of a Philips SEM 525M scanning electron microscope. The large size of the SEM specimen room allowed analysis of complete femoral and tibial components.

Two of the shelf femoral components and two tibial inserts (one mobile bearing and one posterior stabilised: Interax, Stryker-Howmedica) served as a reference. These control implants were treated in exactly the same way as the retrieved implants. Consequently a total of 11 femoral and tibial inserts were scanned. Imaging X-ray microanalysis (XRMA) was performed on interesting locations of the components by using a Voyager XRMA system (NORAN Instruments, Madison, WI, USA).

Also the polyethylene tibial inserts of the prostheses were retrieved. These polyethylene inserts were gold-blasted to make them electron conductive. Types of particle morphology were characterized according to Schmalzried et al. (1997), as granular (diameter < 1  $\mu\text{m}$ , aspect ratio < 4), bead (diameter > 1  $\mu\text{m}$ , aspect ratio < 4), fibril (diameter < 1  $\mu\text{m}$ , aspect ratio > 4) and larger shred (diameter > 1  $\mu\text{m}$ , aspect ratio > 4).

**Table 1.** Detailed data for the nine retrieved total knee prostheses.

|                                 | Side<br>[L/R] | Sex<br>[M/F] | Age<br>[years] | BMI | Prosthesis  | In situ<br>[months] |
|---------------------------------|---------------|--------------|----------------|-----|-------------|---------------------|
| <b>Mobile<br/>Bearing</b>       | R             | F            | 72             | 24  | Interax ISA | 3                   |
|                                 | L             | M            | 81             | *   | Interax ISA | 8                   |
| <b>Posterior<br/>Stabilised</b> | R             | F            | 72             | 27  | Interax     | 60                  |
|                                 | R             | F            | 81             | 28  | Zimmer LPS  | 14                  |
|                                 | L             | F            | 70             | 28  | Interax     | 49                  |
| <b>Fixed<br/>Bearing</b>        | L             | M            | 76             | 27  | AGC         | 18                  |
|                                 | R             | F            | 47             | 28  | IB2         | 49                  |
|                                 | R             | M            | 68             | 28  | IB2         | 90                  |
|                                 | R             | F            | 71             | 32  | IB2         | 30                  |

\* Information not available

### 11.3 Results

Eight tibial and femoral components were explanted for reasons other than polyethylene failure (aseptic loosening, infection). One posterior stabilized total knee was revised due to polyethylene failure.

#### *Control components*

XRMA of the surface of all the control implants showed composing elements Co, Cr and Mo. This was according to the specification of the devices by the manufacturers (Figure 2). Si could be present in spectra from all implant surfaces, irrespective of the morphology, but Si in a particulate form was never observed.

Polishing marks and randomly oriented residual polishing scratches were visible on the surface of all metal components (Figure 3A and 3B). Regular polishing scratches were also clearly visible on the polyethylene inserts. However, also large polyethylene fibrils next to the articulating surface were observed (Figure 4).

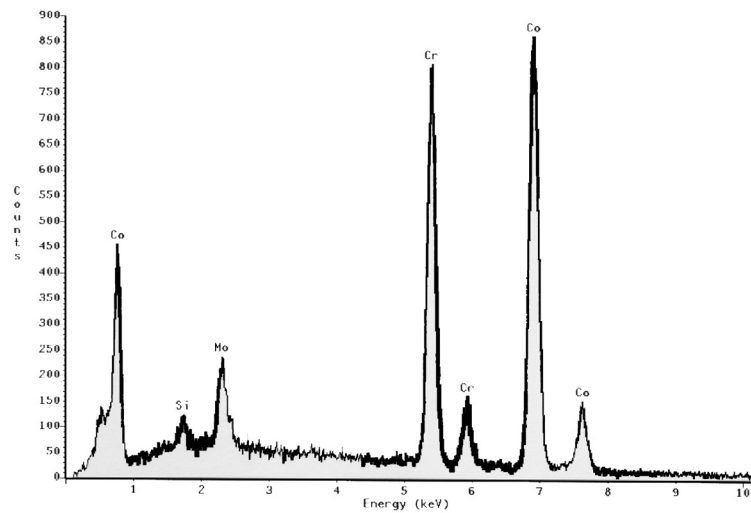


**Figure 2.** Imaging X-ray microanalysis of a control femoral component surface. Clear peaks of Co, Cr and Mo elements can be observed. Also the element Si is present.

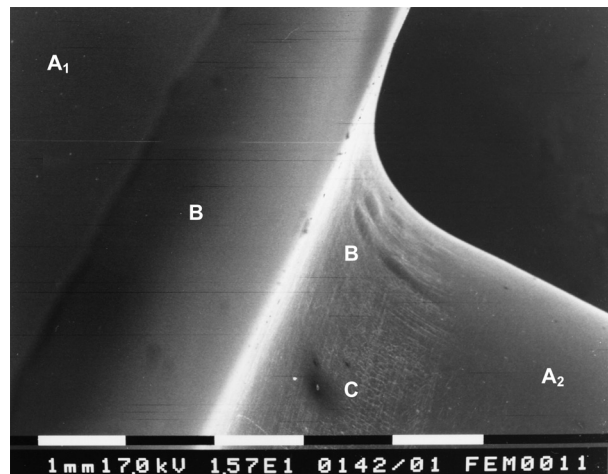


**Figure 3A.** Scanning electron micrograph of a control femoral component surface around the condylar notch. Polishing differences between articular surface (A1, A2) and rougher non-articular surface (B) including small particles (C) can be distinguished.

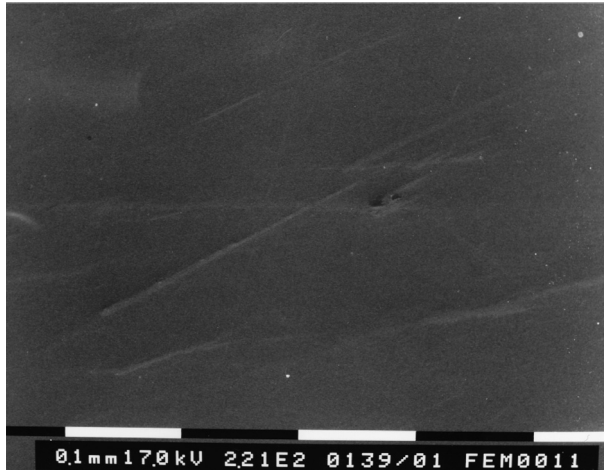


**Figure 3B.** Scanning electron micrograph of a control femoral component articular surface. Randomly oriented residual polishing scratches and small pits can be observed.

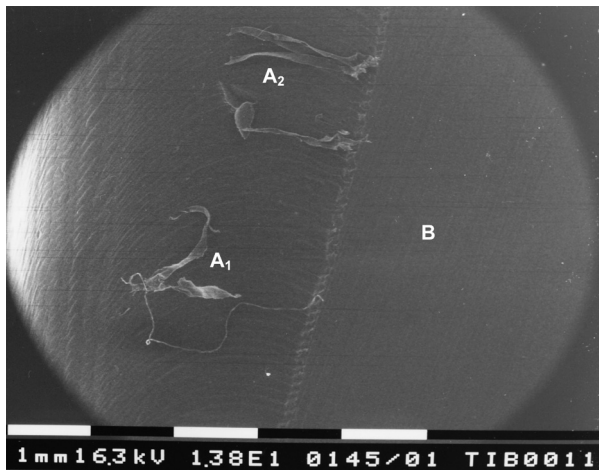


**Figure 4.** Scanning electron micrograph of a control polyethylene tibial insert. Large polyethylene fibrils (A1, A2) next to the articulating surface (B) are observed.

### ***Retrieved components***

The surfaces of the retrieved femoral components showed all abrasive-adhesive wear patterns (Figure 5). However, in three femoral components small round holes were visible in the surface at various locations. Although the XRMA spot analysis showed that affected areas around these holes contained the same composition as in the control samples (Co, Cr, Mo), in one of these holes a Ti particle could be observed indicating severe pollution of the metal compound (Figure 6A and 6B).



**Figure 5.** Scanning electron micrograph detail of a retrieved femoral component showing abrasive-adhesive wear (A) scratching and wear residue (B).

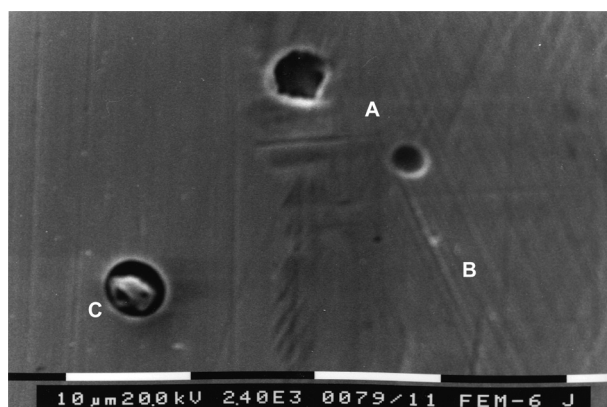


**Figure 6A.** Scanning electron micrograph of a retrieved femoral component articular surface. Small round holes (A) and randomly oriented scratches (B) are visible. One of the holes contains a Ti article (C: Figure 6B).

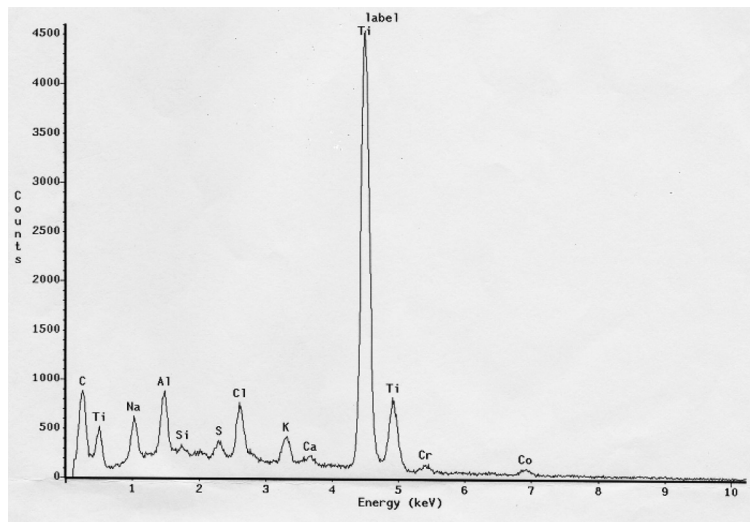


**Figure 6B.** Imaging X-ray microanalysis of a Ti particle in a small round hole of a retrieved femoral component articular surface.

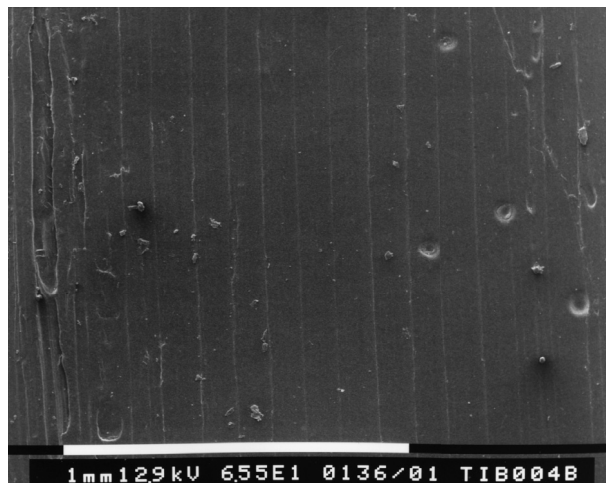


**Figure 7.** Scanning electron micrograph of a retrieved polyethylene mobile bearing tibial insert. Straight polishing marks and the presence of predominantly granular polyethylene particles are visible.



**Figure 8A.** Photo of the back surface of a retrieved mobile bearing tibial insert showing a rotating striation.

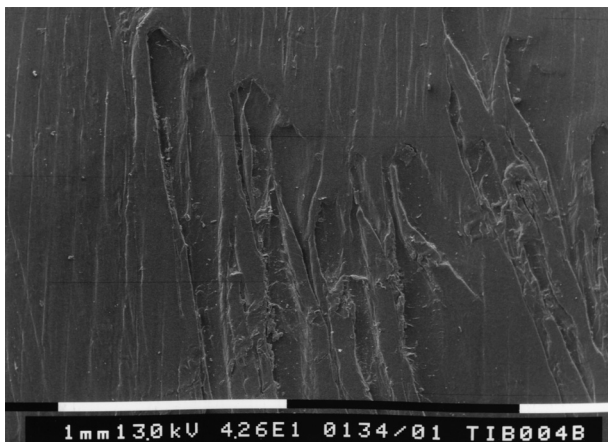


**Figure 8B.** Scanning electron micrograph detail of the back surface of a retrieved mobile bearing tibial insert showing abrasive wear.

The morphology of polyethylene particles observed at the back surface of a retrieved mobile bearing insert is shown in Figure 7. Most of the particles on the mobile bearing insert surfaces could be characterized as granules in combination with beads. On the fixed bearing insert surfaces also fibrils and larger shred could be observed. The size of the bead particles was about 0.6  $\mu\text{m}$ . Fibril dimensions varied

from 5  $\mu\text{m}$  till 7  $\mu\text{m}$ . The two revised mobile bearing inserts showed striations at the tibial articulating surface. The striation revealed that the insert was predominantly rotating (Figure 8A and 8B). Although the mobile bearing design also allowed posterior-anterior sliding, no clear wear patterns could confirm this was occurring *in vivo*. At the condylar articulating surface on several locations scratching and burnishing was observed (Figure 9). At the anterior part of the condylar articulating surface polishing marks were noted.

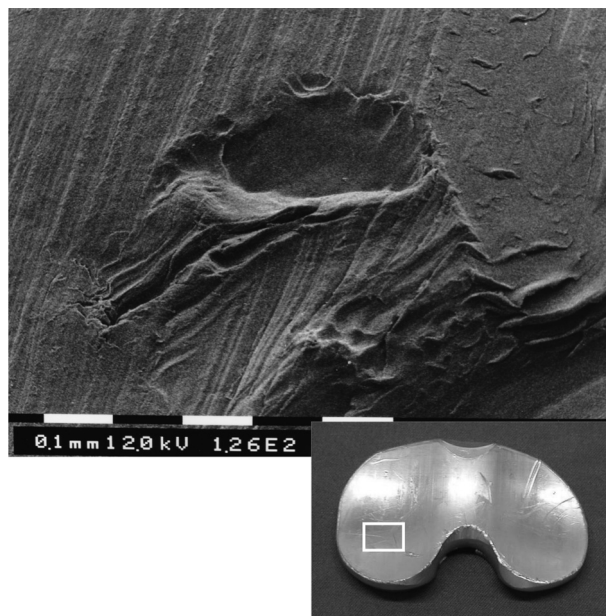


**Figure 9.** Scanning electron micrograph detail of the articulating surface of a retrieved mobile bearing tibial insert showing burnishing.

One of the posterior stabilized knee prostheses was revised because of instability and pain after 60 months. The post of the tibial insert was fractured and severe fatigue wear with subsurface deformation and removal of the surface was observed at the anterior part of the post (Figure 10). In addition to this, at the posterior-medial and lateral part of the condylar articular surface severe fatigue wear or delamination was observed. The cam of the corresponding femoral component showed also severe scratches at the surface where the cam interacts with the tibial post. The

other two posterior stabilised insert surfaces demonstrated at the post some form of deformation, with adhesive wear, or burnishing, being the most encountered wear mechanism. The most predominant location of the wear was the posterior surface, but wear over the anterior, medial and lateral surfaces was also visible.

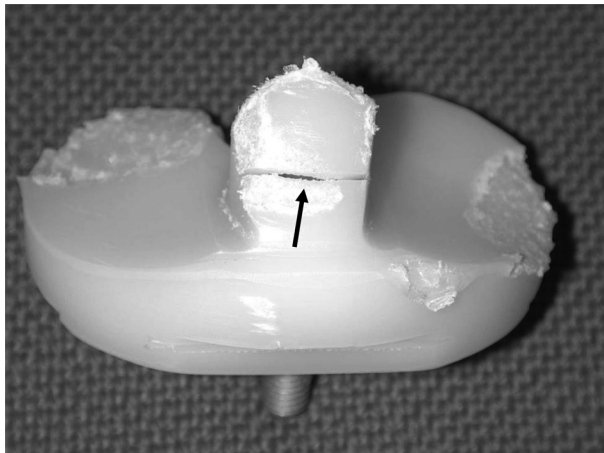


**Figure 10.** Photo of a retrieved posterior stabilized tibial insert. The post is fractured and severe anterior wear can be observed. At the posterior-medial and lateral part of the condylar articular surface severe fatigue wear or delamination was observed

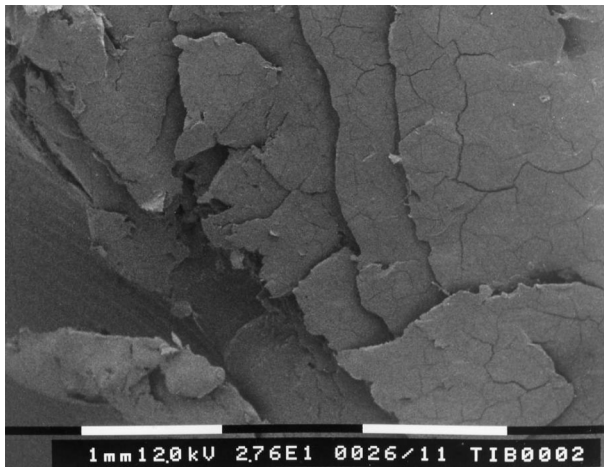


**Figure 11.** Scanning electron micrograph detail of a retrieved fixed bearing tibial insert showing severe delamination.

All the fixed bearing tibial inserts showed severe delamination at the posterior parts of the condylar articulating surface (Figure 11).

#### 11.4 Discussion

Findings from kinematic studies have been variable and have sometimes given conflicting indications of kinematic phenomena. Therefore, it is of interest to observe and document the wear characteristics of explanted knee bearings to see how various kinematic phenomena identified in fluoroscopy studies are manifest in wear and damage of different articular surfaces over extended time *in vivo*.

The chemical composition of the metal surfaces studied showed the expected Co, Cr, Mo compound. But also Si was found at several locations. Si can be introduced when the implants are polished with Si containing agents (Koerten et al., 2000). The presence of Ti particles is more concerning. It has been described that Ti-based compounds can form a galvanic element with Co, Cr, Mo alloys (Jacobs et al., 1998). Galvanic elements in combination with electrolytes may be the basis for galvanic corrosion. This will release ions and corrosion particles thereby inducing abrasive wear and the release of additional particles that will accelerate osteolysis (Koerten et al., 2000). The release of ions can not only cause adverse local effects like osteolysis but even cause the development of malignant tumors.

Tibial component wear patterns and severity are associated with clinical and mechanical factors such as articular surface design, component size and position, knee alignment and ligament balance. The alignment or pattern of striations at the subsurface of the mobile bearing inserts can be related to the tibial-femoral contact mechanics *in vivo* (Wimmer et al., 1998). It can be hypothesized that the polyethylene bearing of the two described mobile bearing knees moved predominantly in internal and external tibial rotation during daily activity. The anterior-posterior translation caused by the femoral rollback phenomenon could not be confirmed by the striated pattern at the backside of the mobile bearing. When this occurs the femoral component must have slid across the condylar surface of the tibial insert. However, polishing was found at the anterior part of the condylar surfaces. Polishing may result from cyclic loading and micromotion which leads to progressive obliteration



of the original factory surface finish. This indicates that the femoral component remained mainly at the anterior part of the polyethylene condylar surface during flexion-extension of the knee joint. The scratches and burnishing might have been caused by high impacts or forced translations. The particles observed in the mobile bearing inserts were in general smaller compared to the particles found at the fixed bearing surfaces. More congruent articular surface wear in combination with under surface wear are possible explanations (Huang et al., 2002). Smaller particles are more biologically active and therefore more inductive for an osteolytic response.

One expects the most wear at the posterior part of the tibial posts of posterior stabilized total knees, where the cam of the femoral component interacts with the cam as it guides femoral rollback. Probably due to high impact in combination with improper alignment and/or ligament balancing the post broke entirely. The anterior wear that was observed can be explained when the post resists hyperextension in combination with a tibial component slope. Dependent on the location and geometry of the cam-post complex one should observe distinctive wear patterns. It is not unexpected that severe wear of the post coincided with similar wear over the condylar articular surface of the tibial insert. The polyethylene of these implants might be predisposed to fatigue as a result of intrinsic factors such as oxidation, crystallinity, or manufacturing method. It maybe secondary to operative factors such as mal-alignment or instability of the components. Posterior stabilized implants contribute to additional wear debris (Puloski et al., 2001). Ultra-high-conforming design might be a good alternative since highly conformed geometries of the tibial polyethylene, matched with appropriately sized condyles, have less point contact stress and therefore less wear. Although component wear is unavoidable consequence, optimization of the design should seek to maximize contact area while minimizing post yield region. Congruency can give all this advantages and combined with a mobile bearing insert kinematic advantage one can reach to a solution of the conflicting mechanical requirements of total knee prostheses.

Delamination and cracking have been associated with polyethylene embrittlement attributable to gamma radiation sterilisation (Williams et al., 1998). All the retrieved fixed bearing components were sterilized using this gamma irradiation. The older generation flat-on-flat designs are also known to produce more delamination



due to high point stresses (Jones et al., 1992). A decreased conformity can result in substantially increased contact stresses that can exceed the yield strength of polyethylene.

Cumulative 10 year revision rates of total knee arthroplasty (according to the Swedish Knee register report) have generally decreased over the past 25 years probably due to improvements in polyethylene quality, implant design and more accurate instrumentation. However, there is a general trend towards treating younger patients and these younger and probably more active patients are likely to generate more wear and hence this may contribute to a new increase of wear and revision rates seen in (younger) patients. Therefore, it would seem logical to develop alternative bearing surfaces in total and partial knee replacements to attempt to reduce wear and consequently potentially improve survivorship of these implants. However, abrasive and adhesive wear will remain the silent killer of any articulating surface. It is caused by a function of contact pressure, material properties, and kinematics (Blunn et al., 1997; Sathasivam and Walker, 1998; Wimmer et al., 1998; Harman et al., 2001). Recent developments in new materials are highly cross-linked polyethylene bearings (Wroblewski et al., 1999) and more scratch-resistant ceramic femoral articular surfaces (Heimke et al., 2002). However, these materials may reduce, but will never eliminate, these wear mechanisms.

### 11.5 Conclusion

The main factors that influence implant wear are complex and include patient activity and weight, polyethylene thickness and quality, methods of sterilisation, degree of implant conformity, surgical alignment, and ligament and soft tissue balancing. Many of the observed wear patterns in the retrieved implants of this study corresponded with literature. Most remarkable observation was the large fibrils in the control polyethylene tibial insert. Also the presence of Ti elements is worrying since it will induce galvanic corrosion with subsequent increased metal particle release and osteolysis.

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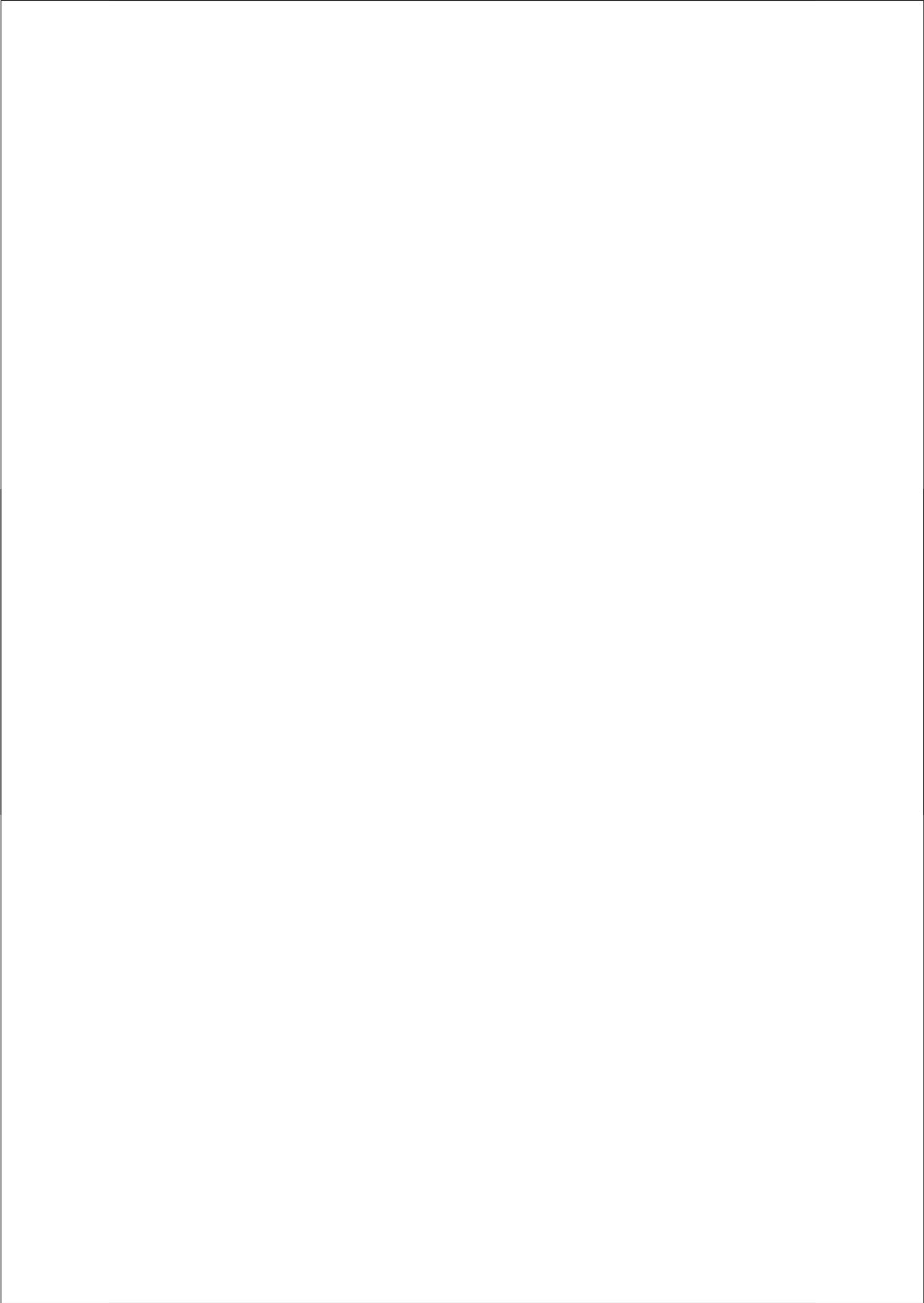
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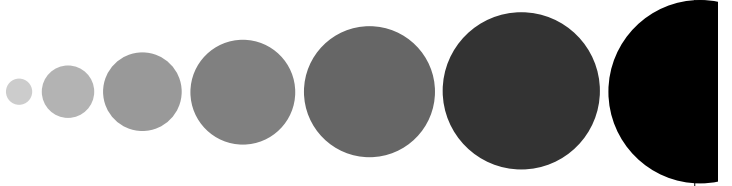
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# Chapter 12



## **General discussion and conclusion**

## 12.1 Discussion

The original hinge and surface replacement knee prostheses have evolved to the modern fixed and mobile-bearing designs. However, past experience has demonstrated that so-called design improvements may not always result into clinical success. Therefore, every surgeon should base implant selection on well-controlled, long-term follow-up studies using objective outcome parameters. The frequency of implantation of contemporary total knee arthroplasty designs in progressively younger patients makes a critical review of longevity and durability of total knee arthroplasty devices all the more important. In addition, the higher demands placed on these implants by the younger, typically more active patient population emphasizes the importance for prostheses that show consistent long-term results. The constant introduction of new modifications of older knee designs can make this process complex. It is not uncommon that satisfactory clinical results are obtained in the short term (5 years). However, longer follow-up (>10 years) often demonstrates shortcomings and reveals designs that actually have stood the test of time (Mc Bride et al., 2000).

These factors have lead amongst others to an important new directive from the European Commission. On August 11, 2005, a long-anticipated Reclassification Directive for hip, knee and shoulder joint replacements was published (Official Journal, 2005/50/EC). This Directive reclassifies these implants from Class IIB to Class III, the highest risk category for medical devices in the European Union (EU). The Directive must be transposed into the national laws of all EU Member States by 1 March 2007 and will apply to all new products being launched on the market from 1 September 2007. The upward classification of joint replacements renders them subject to a more burdensome set of regulatory requirements, most importantly, requiring direct scrutiny of pre-market clinical data used to support performance claims. Before the Reclassification Directive for Class IIB devices, a notified body needed only to assess the orthopaedic device manufacturer's procedures for evaluating its clinical data (post-market surveillance) when introducing new or modifications to implant designs. The Global Harmonization Task Force (founding members: EU, United States, Canada, Japan and Australia) is responsible for the international



harmonization in the regulation of medical devices. It is expected that the members of this task force will follow the EU's Reclassification Directive in the near future. In order to reduce costs and decrease timelines when introducing new products on the market from September 2007 onwards, joint replacement manufacturers will need objective outcome measurement tools that will deliver reliable clinical results evaluating device performance in a short period of time. RSA, fluoroscopy and gait analysis will become more important measurement tools for the short term evaluation of (new) total joint replacements.

Due to the high accuracy, RSA studies on the fixation of joint prostheses can be performed in small study groups with a short follow-up period, while maintaining the sensitivity to accurately assess the fixation of these implants (Chapters 8, 9 and 10). However, more prospective RSA studies are needed that correlate the short-term results of implants with specific design characteristics (e.g. material, coating, geometrical shape etc.) with the long term clinical results. It is expected that many of these RSA studies will be published the coming years since RSA has been widely used after introduction of digital RSA analysis systems in the mid nineties (Börlin et al., 1997; Gill et al., 1998; Vrooman et al., 1998) so that more long-term clinical data can be collected and related to the short-term RSA results.

A very important development in RSA is the Model-based RSA technique (Kaptein et al., 2003; Kaptein et al., 2004). The methodology used by Model-based RSA is based on matching virtually projected boundaries (contours) of a 3D model of the prosthesis onto the actually detected contours of the prosthesis in an RSA radiograph. The position and orientation of the prosthesis are calculated by changing the orientation and position of this model such that the virtually projected contours form an optimal match with the actual contours. The reported accuracy of Model-based RSA for a total knee prosthesis (95% confidence interval) ranges between 0.1 and 0.3 mm for translations and between 0.1° and 0.2° for rotations (Kaptein et al., 2003). With the Model-based RSA technique the position and orientation of prostheses can be highly accurately assessed, without the demand for specific manufacturing adjustments to these prostheses. It is therefore relatively easy, cost effective and time efficient to set-up RSA studies. It is expected that Model-based RSA will be used by the industry and clinicians as being the golden standard for

the evaluation of joint prostheses. In addition to the Reclassification Directive, initiatives from our group towards the International Standardisation Organisation Working Group 4, should lead for a standard of pre-market clinical evaluation using (Model-based) RSA (CEN/TC 285/WG4).

The 2D/3D matching technique used in Model-based RSA can also be applied in fluoroscopy studies (Chapters 3, 4 and 5). The main difference between RSA and fluoroscopy is the use of a single focus set-up and dynamic image acquisition. Since the Model-based RSA technique is commercialized (Medis specials b.v., Leiden, The Netherlands) and initiatives from the group of Banks (University of Florida) to make fluoroscopy software on-line available will lead to a wider use of these techniques. When efforts are made to standardize fluoroscopy protocols and experimental set-ups including an agreement about coordinate systems, the goal should be to build a knowledge base of knee prostheses kinematic behaviour. Using this information the next step for research would be to focus on the development of knowledge based software capable of providing orthopaedic surgeons involved with knee arthroplasty with the ability to simulate pre-operatively, and intra-operatively assess the optimal prosthetic configuration and position in order to maximise the effectiveness of the procedure and therefore to offer the best possible surgical outcome for the patient.

However the use of the fluoroscopy technique has several pitfalls and limitations that one should be aware of when interpreting fluoroscopy results and when one would like to start fluoroscopy studies. Although many studies have been published using the fluoroscopy technique (Banks, et al., 2003; Callaghan et al., 2000; Dennis et al., 1998; Fantozzi et al., 2003; Saari et al., 2003; Stiehl et al., 1997; Walker et al., 2002) not always a thorough validation of the technique precedes or joins these publications (Dennis et al., 1998, Stiehl et al., 1997, Komistek et al., 2000). The accuracy of the technique (like for Model-based RSA) is mainly dependent on the geometrical characteristics of the prosthesis, accuracy of the CAD or RE model, and the pincushion distortion of the image (Chapter 3; Kaptein et al., 2003). Especially the out-of plane accuracy of the fluoroscopy technique is very sensitive for measurement errors and limits therefore the applicability of the technique and interpretation of results. A validation study about the accuracy of the technique applied to the specific implant(s) used in a fluoroscopy study should therefore always be preceded by a

validation study or at least be included in the 'Materials and Methods' section of the publication.

Only recently flat-panel detectors have been introduced that nullifies measurement error caused by image distortion. Also large flat panel detectors have been introduced increasing the diameter of the field of view from about 25cm to 40cm. However, the fluoroscopy studies always involve dynamic tasks related to daily activity. For these activities the field of view is still too limited and restricts the subject's movement pattern. Therefore, one actually needs a system that is able to follow the joint over a movement trajectory. Several systems are currently under development that will allow the assessment of knee kinematics during gait and/or other complex tasks. A research group in Zürich developed a mobile fluoroscopy unit that follows the knee joint during level walking using an external marker registration system (Zihlmann et al., 2006). Another and more flexible approach is the use of a robot arm to track the knee joint (Banks et al., 2006). By real time tracking of the joint, the robot arm that holds the fluoroscopic system is able to follow the knee in 3D space. This fluoroscopic approach also allows the postoperative functional assessment of other joints and other complex joint movements. As mentioned, the out-of plane direction is very sensitive for measurement errors. To overcome this error component, the group of Tashman in Detroit has developed a stereo fluoroscopic system which allows high speed assessment of kinematics by using high speed film camera's instead of image intensifiers. The accuracy when using this kind of set-up approaches that of RSA (Bey et al., 2006).

Accurate and easy to use software needs to be developed that is not only applicable in a research setting but also in the clinical setting. Surgeons need easy to use and objective tools beyond the patient's experience to tell them whether the surgical technique or approach worked as intended and whether the patient risks new or additional damage. Gait analysis, with skin mounted marker tracking and force plates, is a well-established objective method for the acquisition of kinematic and kinetic data of total knee arthroplasty *in vivo* and for non-invasive estimation of joint function. However, joint rotations and resultant moments at the knee joint are inaccurate with this method, due to large skin movement artefacts (Chapter 5). Therefore, methodologies need to be developed by which patient specific data



(anthropometry, ankle centre, knee flexion axis etc.) can be integrated and related to the fluoroscopy knowledge base. The development of accurate dynamic models that mathematically correct for skin artefacts by using patient's specific data will allow the development of easy to use gait analysis systems for the clinical setting to postoperatively monitor functional outcome.

In addition to that, real time feedback and visualization of dynamic joint motion is essential to make a clinician work with these advanced measurement tools and consequently apply the techniques in a clinical setting.

It has been shown that there is a strong relation between pre- and post operative function of total knee arthroplasty patients (Nelissen, 1995). Therefore, it is also important to assess both the preoperative kinematics as well as possible kinematic changes over time. A new technique that is under development for RSA and fluoroscopy uses digital reconstructed radiographs of CT datasets to reconstruct the position and orientation of the registered segments. This technique will provide accurate data of the *in vivo* kinematics of healthy subjects and preoperative kinematics of patients with joint disorders and accurate dynamic models made with accumulated data will provide detailed insight in skeletal kinematics (de Bruin et al., 2006; Mahfouz et al., 2005). The aim is to pre-, and intra-operatively assess the optimal prosthetic configuration and position in order to maximise the effectiveness of surgery.

The integration of RSA, fluoroscopy and EMG, preferably in combination with other imaging modalities like CT and MR for visualisation, results in a more or less holistic research approach. More insight into the relation between parameters can be obtained when measurement techniques are combined and when many parameters are assessed. One should aim to set-up randomized clinical studies that will combine fluoroscopy and gait analysis including electromyography. Electromyographic data provides also important information about total knee replacement functioning, co-contraction and control of movements (Chapter 6 and 7). Including the micromotion data assessed by RSA with this data will complete the variables related to the outcome of the specific total knee replacement and relations between the different outcome parameters can be established. Using this holistic approach where also CT could be included as imaging modality, even controversies like the rotational positioning of



the tibial component can be studied and the optimal orientation of the components in relation to functional outcome can be assessed (Barrack et al., 2001; Berger and Rubash, 2001; Uehara et al., 2002). Dual energy X-ray absorptiometry (DEXA) was not used in the studies of this thesis. This technique is an established standard for measuring bone mineral density and adds important information about bone remodelling or bone loss to prosthesis fixation studies and should also be included to complement the holistic approach.

A rotational mismatch between the tibial and femoral components may lead to patellar complications. It must be noted that almost no attention has been given towards the kinematics of the patella in this thesis. Due to practical issues with a fluoroscopy set-up applied to patellar kinematics like the out-of plane inaccuracy and visualisation of the patella during the range of motion there are no validated publications of *in vivo* patellar kinematics after total knee replacement. However, the patellofemoral joint is a major source of problems after total knee replacement. As many as one-half of all re-operations are done for extensor mechanism or patellar-related problems (Price et al., 2006). Patellofemoral geometry and orientation has a significant effect on knee kinematics (Barink et al., 2006). Especially the quadriceps moments in the joint are dependent of the orientation of the prosthesis relative to the patella (Chapter 7; Andriacchi et al., 1997). Forces several times body weight are transferred across the patellofemoral joint when one climbs stairs or rises from a chair. Future research using fluoroscopy should clarify the *in vivo* kinematics of the patella in different femoral component designs in both patella resurfacing or non-resurfacing variants.

## 12.2 Conclusion

The goal of this thesis was to assess with accurate and objective methods the function and fixation of current total knee prostheses concepts, in particular of mobile bearing total knee designs. Some methods like marker-based fluoroscopy were validated to determine its feasibility and accuracy. Subsequently the *in vivo* clinical performance of several total knee prostheses was reported. Already established methods like RSA

were used in randomized trials to assess the differences in micromotion between total knee prostheses.

Findings from kinematic studies of knee prostheses have been variable and have sometimes given conflicting kinematic patterns. Various studies have indicated posterior-medial rollback, posterior-lateral rollback, anterior translation with flexion, and both internal and external tibial rotation (in Chapter 4). Analysis of the presence of femoral-tibial anterior/posterior mobility in the literature reveals a wide range of constraints in prostheses, with unconstrained designs prevailing. Also mobile bearings have shown controversial kinematic patterns or limited motion (Chapter 4). Therefore, an alternative design would be a mobile bearing prosthesis that is not hindered by a locking mechanism (pivot point or curved tracks) which may also lead to polyethylene on metal impingement and increased wear (Chapter 11). Highly conformed geometries of the tibial polyethylene, matched with appropriately sized condyles, have less focal contact stress and therefore less wear. Also has been shown that low conformity knee prostheses as well as a higher conformity mobile bearing knees give less variability in the migration data compared to fixed bearing posterior-stabilised prostheses (Chapter 10; Nelissen et al., 1998). Therefore a highly congruent bearing-femur articulation (in both media-lateral as posterior-anterior direction) in combination with a tibia-bearing articular surface that is flat-on-flat would on theoretical grounds be a good solution. This articulation would provide the needed axial rotation and translations needed to avoid unnecessary constraint without preventing congruent flexion. In order to achieve joint stability with a lower level of constraint, competent soft tissue, including balanced collateral ligaments and the posterior cruciate ligament are necessary. Therefore soft tissue deficiency together with an uncorrectable extensor mechanism deficiency would be an absolute contra-indication for this type of knee prostheses since mobile bearing prostheses are more demanding for the soft tissue surrounding the knee compared to fixed bearing prostheses (Chapter 6 and 7). This might limit patient selection of this type of prosthesis towards the younger patient with less deterioration of the joint.

Although, ultra-high molecular weight polyethylene is the current material of choice for use as a bearing surface in total joint replacement, the recently introduced cross-linked polyethylene is currently marketed as the material of choice based on

initial wear tests and short term-results of congruent articulating surfaces (Chapter 11). However, this type of polyethylene might also be too brittle in the knee joint during focal loading of the surface or in less congruent ranges of motion. Despite all the mechanical tests and wear simulation studies, long-term clinical results should clarify the benefits of this new type of polyethylene.

Cemented total knee arthroplasty is still accepted as the gold standard. However, apatite coated implants show excellent mid-term (RSA) results and offers the advantage of bone preservation in the event of need for revision. Based on the results from Chapters 8 and 9 and the publications of others (Nelissen et al., 1998; Onsten et al., 1998), a calcium coating augmented with a plasma spraying process or a porous coated surface consisting of multiple layer beads showed to be an excellent and promising alternative to cemented fixation. It was concluded that this type of fixation would benefit survival of any total knee design. However, uncemented fixation of components requires the necessity for a precise fit of the component. Computer assisted surgery systems (CAS) are being developed to improve the precision of prosthesis placement. Recently, several studies have shown improved alignment of the leg and orientation of the components compared to the conventional technique when using computer navigation (Bathis et al., 2004; Decking et al., 2005; Luring et al., 2006; Sparmann et al., 2003). However, there has not yet been any prove of better patient outcome, function or longevity of the implant (Luring et al., 2006; Sikorski and Chauhan, 2003). Also minimal invasive techniques have been introduced in an effort to reduce tissue damage and shorten rehabilitation period. A prospective randomized trial comparing CAS in combination with minimal invasive surgery and conventional techniques should clarify the benefits when using these methods. The benefits offered by total knee arthroplasty in terms of pain relief and restoration of function have resulted in ever increasing demand for this surgery during the past 2 decades. Satisfactory knee function is usually restored following total knee arthroplasty, and the majority of patients are able to return to low-impact sporting activity. The focus of total knee arthroplasty and the development of new implants has shifted from pain relief towards functional restoration of normal kinematics for the growing and more demanding (younger) population. However, one should question what are 'normal kinematics' of patients and in particular of rheumatoid



patients? In addition to that, it is doubtful to aim at restoring 'normal kinematics'. From kinematic studies we may generally conclude that knee kinematics after total knee arthroplasty do not replicate 'normal knee kinematics' (Chapter 4, Chapter 7). The gain in survival of total knee prostheses can only be marginal with survival rates of 91-96% at 14-15 years follow-up. However, technological advances in materials, operative procedures, product design and manufacturing processes will always drive to new prosthesis development. Nearly every orthopaedic device manufacturer has introduced new (mobile bearing) knee prostheses within the last years. Many orthopaedic device manufacturers are marketing something new claiming it to be better. However, surgeons as well as patients should be critical towards the evidence and the used methods and be aware that new is not always better.



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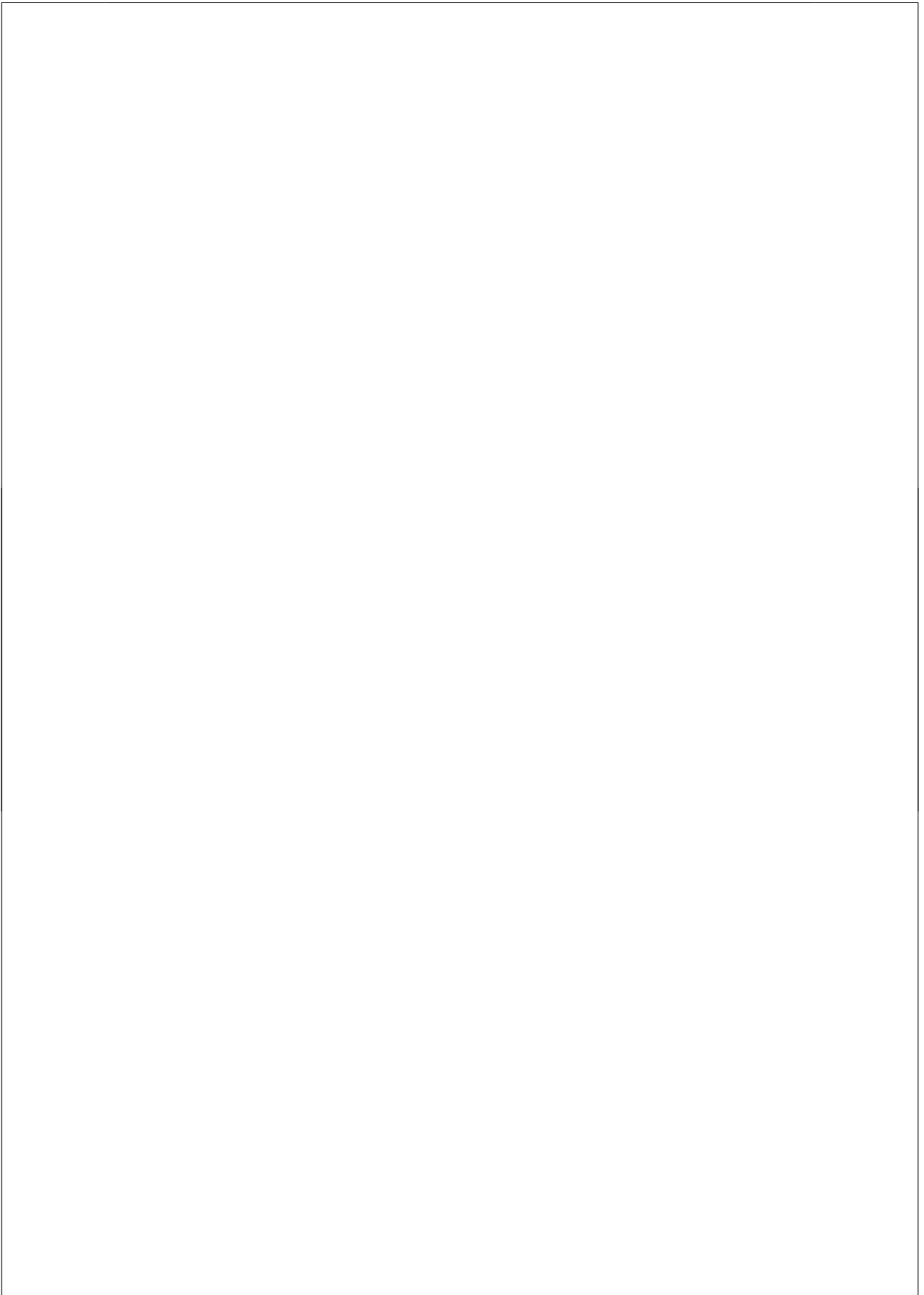
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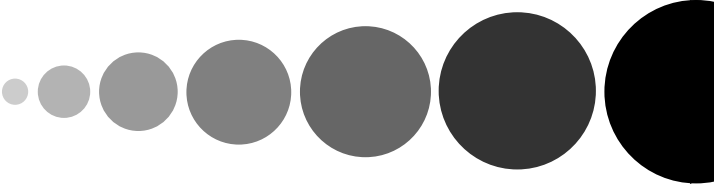
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**Summary**



In *Chapter 1*, a short introduction towards the aim of the work described in this thesis was given. The aim of this thesis was to assess with accurate and objective methods the function and fixation of total knee prostheses with special emphasis on mobile bearing total knee designs.

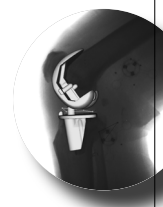
The four main methods that haven been used in this thesis are:

1. Fluoroscopy: imaging technique that takes a real time x-ray ‘movie’ of the body to study moving body structures
2. Electromyography: a method for measuring muscle activity via the electrical signals produced by muscles when they are stimulated
3. Roentgen Stereophotogrammetric Analysis (RSA): accurate stereo radiographic technique for the assessment of three-dimensional micromotion of orthopaedic implants
4. Scanning electron microscopy: a type of electron microscope capable of producing high resolution images of a sample surface at high magnification by means of electron lenses.

In *Chapter 2*, a description of the knee anatomy and knee disorder is given. When medicines, weight loss and physiotherapy fail, joint replacement is the intervention for patients with pain, limitation of motion, and/or deformities. Several types of total knee prostheses are introduced while the mobile bearing total knee prosthesis is presented in more detail.

Mobile bearing total knee prostheses allow the polyethylene insert to move with respect to the tibial base plate. Numerous variations are on the market but all are designed with two common purposes. The first is to increase contact area in order to reduce long-term wear. The second is to reduce implant-to-bone interface stresses and to allow good kinematics by the mobility of the polyethylene bearing on the tibial plate.

*Chapter 3* introduces the fluoroscopy technique that is applied to reconstruct the 3D position and orientation of markers inserted in (body) segments. A thorough validation established that the in-plane accuracy of the technique is 0.1 mm and the rotational accuracy is 0.1 degrees. The simulated *in vivo* out-of-plane accuracy was about 1.9 mm. Accuracy of the marker models and image distortion showed to be



the most important factors influencing the out-of-plane measurement error as the most sensitive direction for measurement errors.

In *Chapter 4* fluoroscopy was used to assess the axial rotation of a polyethylene bearing in a rotating platform total knee prosthesis during a step-up task. In all patients, the femur showed more axial rotation than the mobile-bearing insert indicating the femoral component was sliding on the polyethylene of the rotating platform during the step-up motion. The theoretical advantages of mobile bearing total knee prostheses are challenged by the *in vivo* measured movements in this study.

In *Chapter 5* the problem of soft tissue artefacts during gait analysis was addressed by using the fluoroscopic methodology. The measurement errors of two different external marker fixation methods commonly used in gait analysis were assessed. The measurement errors associated with the thigh were generally larger (maximum translational error: 17 mm; maximum rotational error: 12 degrees) than the measurement errors for the lower leg (maximum translational error: 11 mm; maximum rotational error: 10 degrees). Errors up to 10 degrees were observed for knee joint internal/external rotation and adduction/abduction. The large soft tissue artefacts when using clustered skin markers, irrespective of the fixation method, question the usefulness of parameters found with external movement registration and clinical interpretation of stair data in small patient groups.

Another important parameter assessed during gait analysis is electromyography of muscles. In *Chapter 6* the differences of electromyography activity of the muscles stabilizing the knee joint between patients with a mobile bearing knee prosthesis and a posterior stabilized knee prostheses was assessed. The differences between the two groups group didn't only show an increase of muscle activity for the mobile bearing group but also an earlier activation of the flexor muscles which in turn may express compensation by coordination. In *Chapter 7* a new normalization method for electromyography data was used to study differences in co-contraction. Surface electromyography, kinematics and kinetics about the knee were recorded during a step-up task of a mobile bearing group, a fixed bearing group and a control group. The total knee arthroplasty groups showed 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. Mobile bearing and fixed bearing patients showed no difference in co-contraction levels, although coordination in fixed bearing subjects is closer to controls than mobile bearing subjects.

In *Chapter 8* it was shown that periapatite augmentation on a tibial stem improved the fixation of the total knee prosthesis in a osteoarthritis group after two years follow-up. In *Chapter 9* the differences in migration between uncoated and periapatite coated groups did not differ in a rheumatoid arthritis patient group. The periapatite group showed less variability of micromotion. A trend could be detected toward a more stable fixation in the periapatite group.

In *Chapter 10* it was hypothesized that torque and shear forces in a mobile bearing total knee prosthesis would be better dissipated from the prosthesis-bone interface by the motion of the bearing and by load sharing with the ligaments and other soft tissue structures. A prospectively randomized RSA study comparing a mobile bearing total knee prostheses group and a posterior stabilized prosthesis group showed that the mobile bearing group had a significant lower variability in the subsidence and anterior-posterior tilting of the tibial component after two-year follow-up.

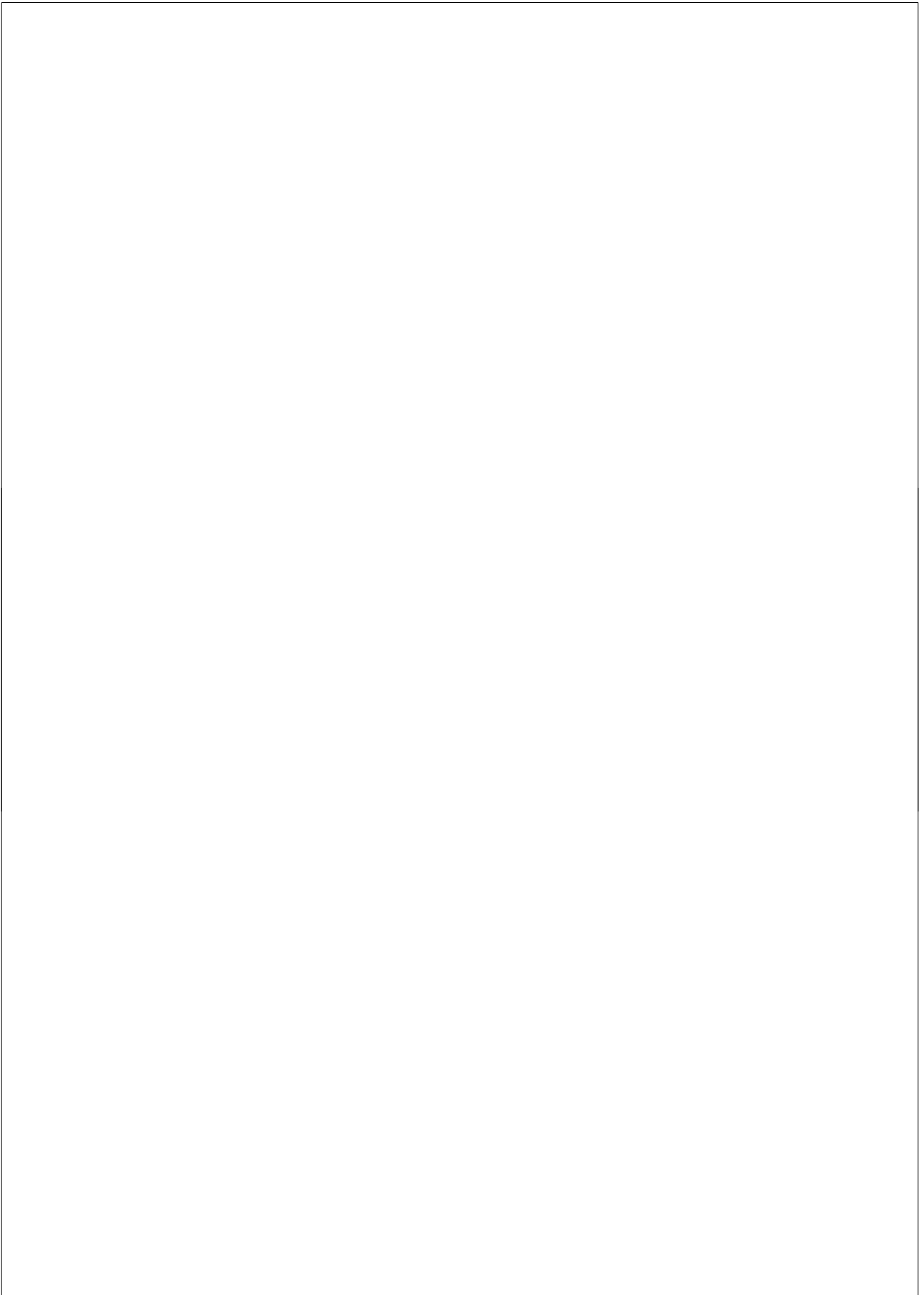
In *Chapter 11* scanning electron microscopy was used to observe wear mechanism on the surfaces of retrieved total knee prostheses. In the control polyethylene insert, large polyethylene fibrils next to the articulating surface were observed. Two mobile bearing inserts showed striations at the tibial articulating surface indicating rotational movement of the insert *in vivo*. The fixed bearing tibial inserts showed severe delamination at the posterior parts of the condylar articulating surface. Imaging X-ray microanalysis showed the expected composing elements Co, Cr and Mo. However, in three femoral components small round holes were visible in the surface at various locations. In one of these holes a Ti particle could be observed indicating severe pollution of the metal compound.

Grouping the main findings of this thesis led to a general discussion and conclusion in *Chapter 12*. The mobile bearing of a rotating platform design showed limited motion or no motion during a step-up task thereby nullifying the theoretical advantages of a mobile bearing prosthesis. Apatite coated implants show excellent mid-term RSA results and offer some clinical advantages above cemented total

knee arthroplasty. A prospective RSA study also revealed that the studied mobile bearing design is more predictable and forgiving with respect to micromotion of the tibial component than a posterior stabilised prosthesis. However, mobile bearing prostheses showed to be more demanding for the soft tissue structures surrounding the knee joint.

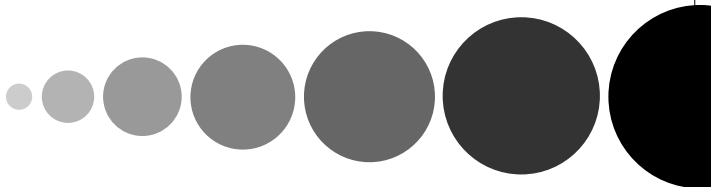
The techniques used in gait analysis and fluoroscopy are sensitive for measurement errors. This restricts the applicability and interpretation of the results acquired when using these methods. In general one needs to be aware of the limitations of measurement tools since one needs accurate and objective methods to assess evidence about the clinical performance of (new) total knee prostheses.





# Samenvatting

(Dutch Summary)



In *hoofdstuk 1* wordt een korte inleiding gegeven eindigend in het doel van dit proefschrift. Het doel van dit proefschrift was om met behulp van nauwkeurige en objectieve meetmethoden de functie en fixatie van totale knieprotheses te bepalen, met een speciale nadruk op totale knieprotheses met een beweegbaar lager.

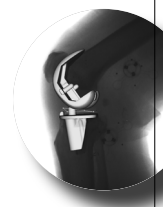
De vier belangrijkste meetmethoden die hiervoor gebruikt zijn:

5. Fluoroscopie: beeldvormende techniek dat een röntgenfilm maakt van het lichaam en het mogelijk maakt om bewegende lichaamsstructuren te bestuderen.
6. Electromyografie: een methode om spieractiviteit te meten door middel van de elektrische signalen die spieren produceren wanneer zij actief zijn.
7. Röntgen Stereofotogrammetrische Analyse (RSA): nauwkeurige meetmethode om de driedimensionale microbewegingen van orthopedische implantaten te bestuderen.
8. Elektronen microscopie: een type microscoop dat, door gebruik te maken van elektronen lenzen, hoge resolutie beelden met een grote vergrotingsfactor kan maken van oppervlakten.

In *hoofdstuk 2* wordt een beschrijving gegeven van de knieanatomie en de belangrijkste knie aandoeningen. Als medicatie, gewichtsverlies en fysiotherapie niet afdoende zijn om de klachten te verhelpen, is gewrichtsvervanging de manier om patiënten met pijn, beperkte bewegingsmogelijkheden en/of misvormingen te helpen. Verschillende typen knieprotheses worden geïntroduceerd waarbij de knie prothese met een beweegbaar lager in meer detail wordt beschreven.

Knieprotheses met een beweegbaar lager laten een beweging toe van het polyethyleen lager ten opzichte van het scheenbeen component van de prothese. Diverse variaties zijn op de markt verkrijgbaar welke echter allemaal twee doelen nastreven. Het eerste doel is het vergroten van het contactoppervlak om zo de lange termijn slijtage te verkleinen. Het tweede doel is het verkleinen van de krachten die optreden tussen de prothese en het bot terwijl de kinematica van het gewricht behouden blijft door de beweegbaarheid van het lager.

*Hoofdstuk 3* introduceert de fluoroscopietechniek die gebruikt is om de driedimensionale positie en oriëntatie van de met kogeltjes gemarkeerde (lichaams)



segmenten te reconstrueren. Via grondige validatie werd vastgesteld dat de nauwkeurigheid in het meetvlak voor translaties 0.1 mm en 0.1 graden voor rotaties is. De gesimuleerde data toonde een nauwkeurigheid aan voor metingen uit het meetvlak van 1.9 mm. De nauwkeurigheid van markermodellen en de grootte van de beeldverstoring bleken de meeste invloed op de nauwkeurigheid voor metingen uit het meetvlak te hebben.

In *hoofdstuk 4* werd de fluoroscopietechniek toegepast om de axiale rotatie van een polyethyleen lager in een totale knieprothese met roterend lager te bestuderen gedurende een opstapbeweging. In alle patiënten liet het bovenbeen een grotere axiale rotatie zien dan het roterende lager waarmee werd aangetoond dat het bovenbeen component van de prothese glijdt over het beweegbare lager tijdens deze opstapbeweging. De theoretische voordelen van een knieprothese met een beweegbaar lager worden in twijfel getrokken door de in deze studie gemeten *in vivo* beweging van het lager..

In *hoofdstuk 5* werd het probleem van huidbewegingen gedurende gangbeeldanalyse bestudeerd door middel van de fluoroscopietechniek. De meetfouten van twee verschillende externe markerbevestigingsmethoden, die gebruikelijk zijn bij gangbeeldanalyse, werden bepaald. De meetfout van de op het dijbeen aangebrachte markers bleek over het algemeen groter (maximum translatiefout van 17 mm; maximum rotatiefout van 12 graden) dan de meetfout behorende bij markers op het onderbeen (maximum translatiefout van 11 mm; maximum rotatiefout van 10 graden). Meetfouten van 10 graden werden gevonden voor endo-/exorotatie en adductie/abductie in het kniegewricht. De grote meetfouten die optreden bij het gebruik van markers op de huid, onafhankelijk van de gebruikte fixatiemethode, betwist de bruikbaarheid van parameters die gevonden worden met gangbeeldanalyse en de klinische interpretatie van data van een opstapbeweging in een kleine patiëntengroep.

Een andere belangrijke parameter dat tijdens gangbeeldanalyse wordt gebruikt, is de spieractiviteit. In *hoofdstuk 6* worden de verschillen in activiteit in gewrichtsstabiliserende spieren gemeten tussen patiënten met een knieprothese met een beweegbaar lager en patiënten met een aan de achterkant gestabiliseerde knieprothese. De data liet niet alleen een verhoogde activiteit zien in de beweegbare

lager groep, maar ook werden de spierflexoren eerder geactiveerd wat kan duiden op een compensatie mechanisme middels coördinatie. In *hoofdstuk 7* werd een nieuwe normalisatiemethode voor electromyografiedata gebruikt om verschillen in co-contractie te bestuderen. Oppervlakte electromyografie, kinematica en kinetica van het kniegewricht werden geregistreerd gedurende een opstapbeweging van een groep patiënten met een beweegbaar lager, een groep met een vast lager, en een controle groep. De totale gewrichtsvervangingsgroep had een lager netto kniemoment en liet meer co-contractie zien dan de controle groep. Dit toonde aan dat er sprake was van een vermindering van gewrichtsbelasting en een actieve stabilisatie van het kniegewricht. Er werd geen verschil in co-contractie aangetoond tussen de vaste lager en de beweegbare lager groep, hoewel de spiercoördinatie van patiënten met een vast lager knieprothese meer lijkt op die van de controle groep dan die met een beweegbaar lager.

In *hoofdstuk 8* werd aangetoond dat het aanbrengen van een peri-apatite coating op het onderbeencomponent in een osteoarthrose groep de fixatie van de component verbeterde. In *hoofdstuk 9* werd geen verschil gevonden in de migratie van ongecoate of peri-apatite gecoate componenten in een reuma patiëntengroep. De peri-apatite groep liet wel een kleinere variatie in de microbewegingen zien. Een trend naar een meer stabiele fixatie voor de peri-apatite groep kon worden waargenomen.

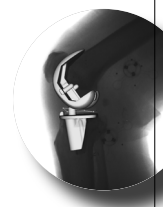
In *hoofdstuk 10* werd de hypothese gesteld dat draai en glijkrachten in een prothese met een beweegbaar lager beter worden overgedragen op de prothese-bot overgang door de beweging van het lager en doordat de belasting wordt gedeeld met ligamenten en ander zacht weefsel rond het kniegewricht. Een prospectief gerandomiseerde studie toonde aan dat na twee jaar de groep met een beweegbaar lager een significant kleinere variatie had in zowel de inzakking als voorachterwaartse kanteling van het onderbeencomponent.

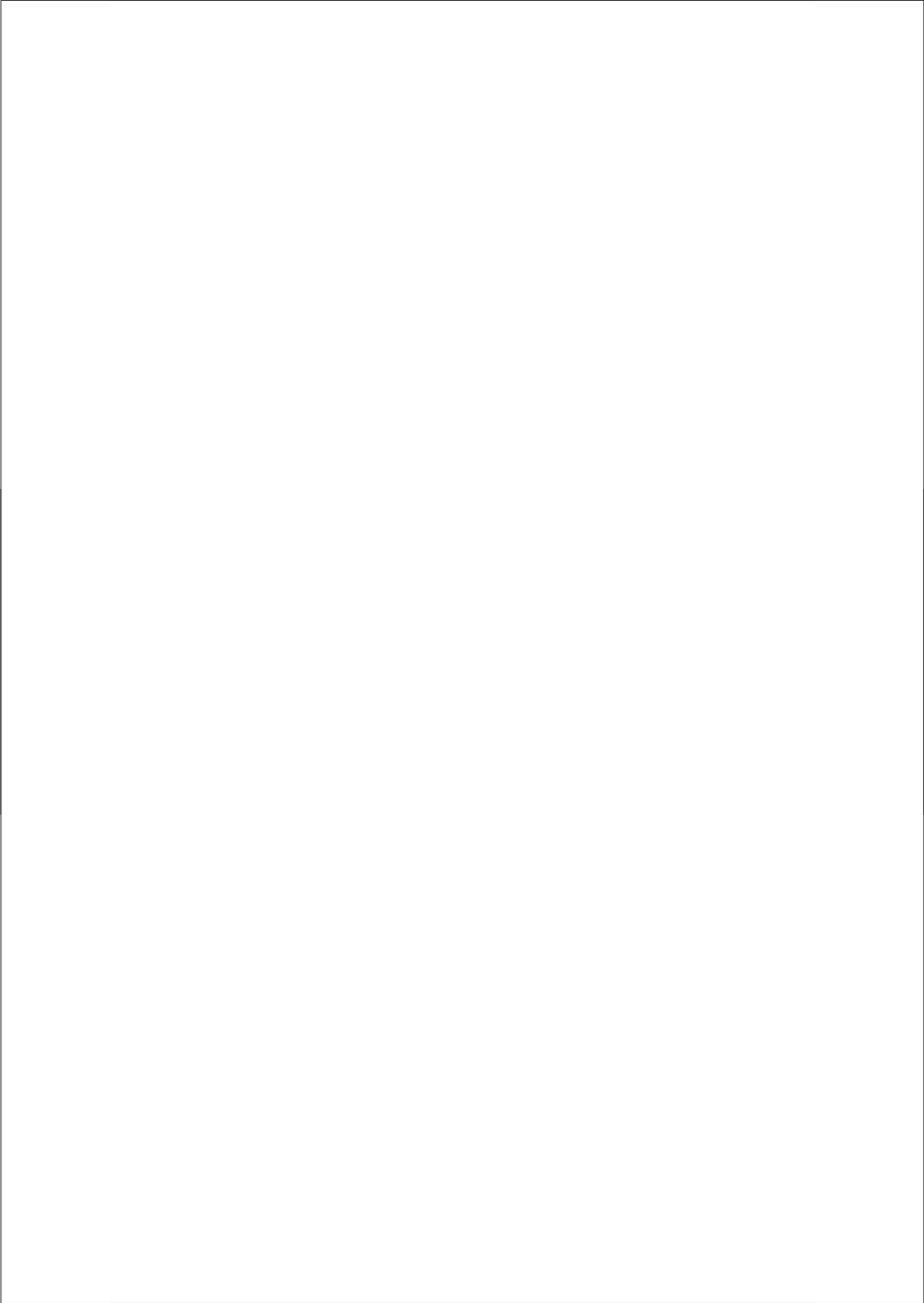
In *hoofdstuk 11* werd elektronen microscopie gebruikt om de slijtage patronen op oppervlakten van gereviseerde totale knieprothesen te bestuderen. In een controle polyethyleen lager werden grote polyethyleen fibrillen vlak naast het articulerend oppervlak waargenomen. Twee beweegbare lagers lieten slijtpatronen zien welke duiden op beweging in vivo van het lager. De vaste lagers lieten delaminatie zien aan de achterzijde van het articulerend oppervlak. Röntgen micro-analyse toonde

de verwachte elementen Co, Cr en Mo. Echter, in drie bovenbeen componenten waren op verschillende locaties kleine ronde gaatjes zichtbaar in het oppervlak. In één van deze gaatjes was een Ti partikel zichtbaar, wat op ernstige vervuiling van de metaallegering duidt.

De belangrijkste bevindingen in dit proefschrift leidden tot een algemene discussie en conclusie in *hoofdstuk 12*. Het beweegbare lager in een knieprothese met een beweegbaar lager roteerde niet of nauwelijks waarmee de theoretische voordelen van een prothese met een beweegbaar lager teniet worden gedaan. Apatite gecoate implantaten laten uitstekende middellange termijn RSA resultaten zien en hebben bovendien enkele klinische voordelen boven gecementeerde kniegewrichtsvervanging. Een prospectieve RSA studie toonde bovendien aan dat knieprothesen met een beweegbaar lager voorspelbaarder en vergevingsgezinder zijn voor de micro-beweging van het onderbeencomponent dan een aan de achterzijde gestabiliseerde knieprothese. Echter, prothesen met een beweegbaar lager zijn belastender voor het zachte weefsel rond het kniegewricht.

De technieken die gebruikt worden in gangbeeldanalyse en fluoroscopie zijn gevoelig voor meetfouten. Dit beperkt de toepasbaarheid en interpretatie van de resultaten die verkregen zijn met behulp van deze methoden. In het algemeen dient men zich bewust te zijn van de beperkingen van de gebruikte meetmethoden. Alleen nauwkeurige en objectieve methoden komen in aanmerking voor het verzamelen van data over het klinisch functioneren van een (nieuwe) totale knieprothese.







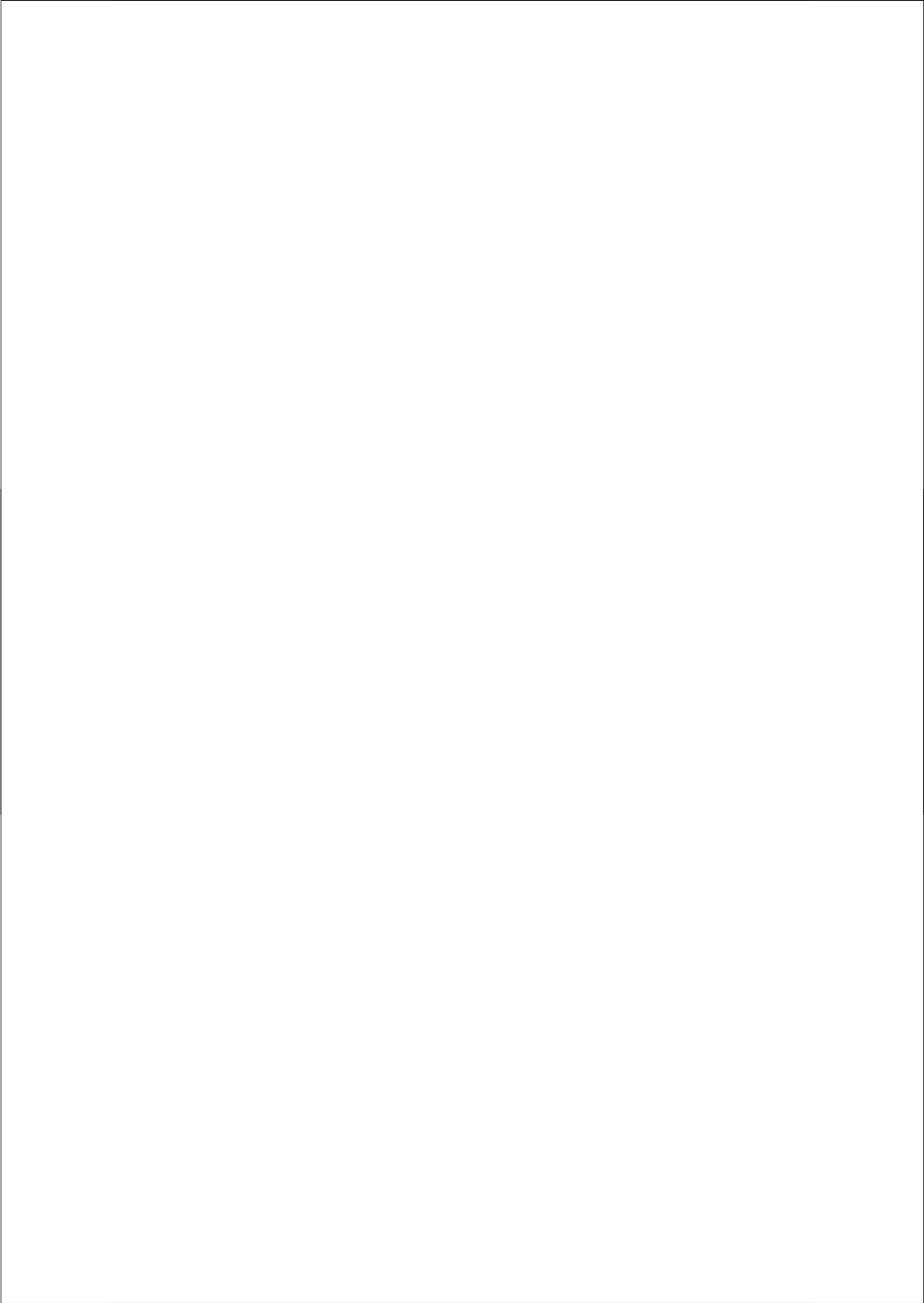
## Acknowledgements

This thesis was prepared at the Department of Orthopaedics (head: prof. dr. R.G.H.H. Nelissen) under supervision of dr. ir. E.R. Valstar, head of the Biomechanics and Imaging group, of the Leiden University Medical Center.

I would like to express my sincere gratitude to Bart Kaptein who gave the fluoroscopy projects an extra impetus with his excellent accomplishments in developing the Model-based RSA software. His positive, can-do attitude was very motivating.

I am also indebted to many people who have contributed in some way to this thesis:

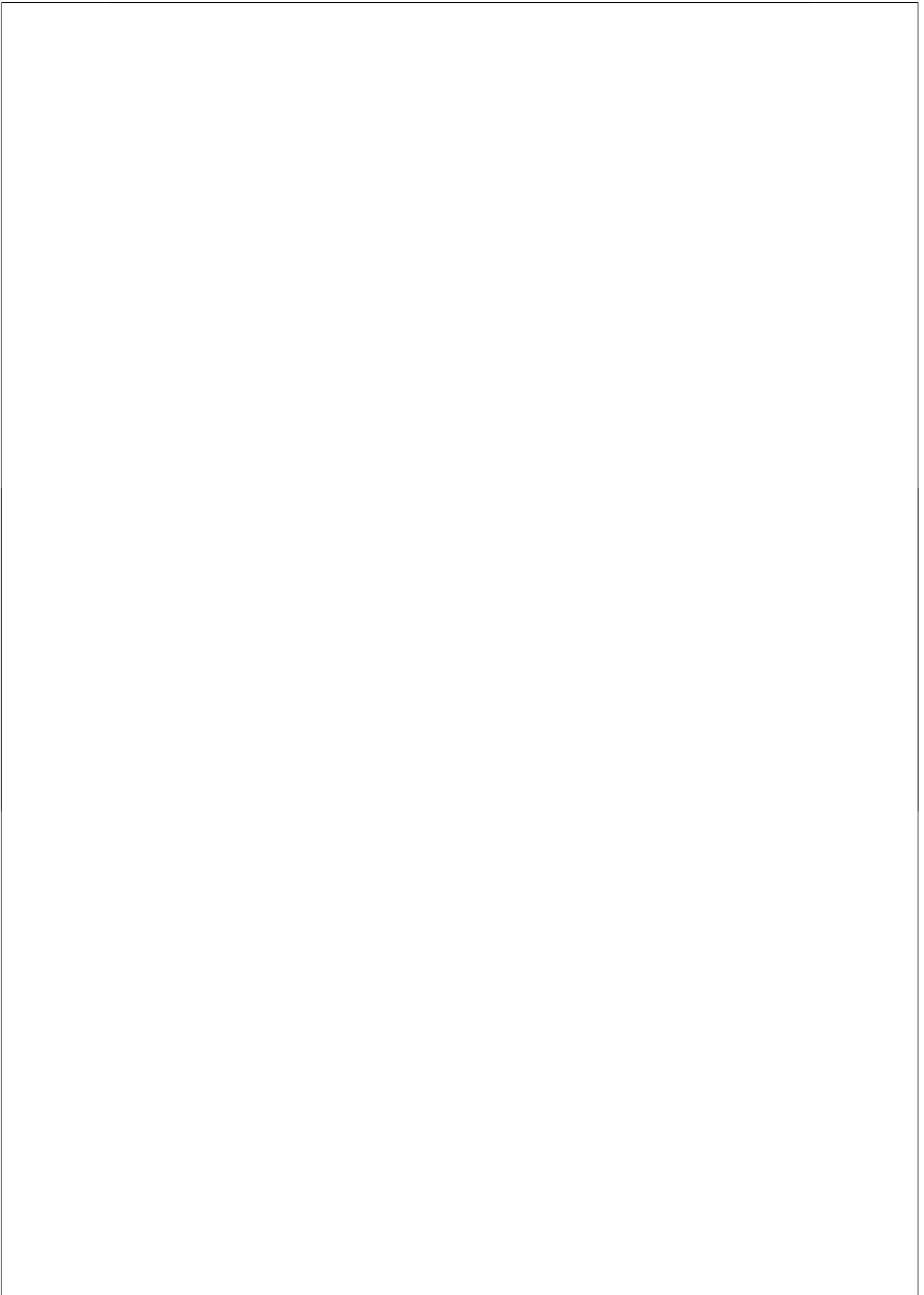
Jaap Harlaar and Caroline Doorenbosch (Vrije Universiteit Medical Center, Amsterdam), who made it possible for me to work in their fantastic gait lab. Nienke, Sanne, Mirjam, Tessa, Liane, Caroline, and Willemijn of the Department of Human Movement Sciences, Vrije Universiteit Amsterdam, who made a considerable contribution to several projects within this thesis. Staff and residents from the Department of Orthopaedics for their clinical contributions. Staff and roentgen assistants from the Department of Radiology. Especially, Dirk Zweers and Koos Geleijns for their advice and assistance during the experimental and clinical fluoroscopy studies. Hans Fraterman, Arie de Vos and Bram Visser who have been extremely helpful for developing and manufacturing devices and experimental set-ups that have been used for this research project. Administrative staff of the Department of Orthopaedics for general assistance. My colleagues at Medis for making it possible to continue to work in a challenging environment.



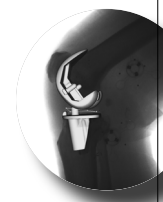
## Curriculum Vitae

Eric Garling was born on April 7, 1972 in Alkmaar, The Netherlands. After graduation from the 'Murmellius Gymnasium' in Alkmaar, he started his academic career with studying Public Administration at the Leiden University. In 1995, he made a career change in a life-science oriented direction and started studying Human Movement Sciences at the Vrije Universiteit of Amsterdam. He specialized in Human Movement in the context of Sports and Biomechanics. He carried out his Master of Science work under supervision of dr. ir. E.R. Valstar and dr. H.E.J. Veeger. The title of his master's thesis was *Mobile bearing knee kinematics*. After graduation in 1999, he began to work as a researcher in a number of projects at the Department of Orthopaedics of the Leiden University Medical Center (head: prof. dr. P.M. Rozing), which eventually evolved into this thesis. He currently holds a position at Medis medical imaging systems b.v. as a strategic account manager and at Medis specials b.v. as a business development manager.





# Publications



## Publications related to this thesis

**Garling EH, Kaptein BL, Geleijns K, Nelissen RGHH, Valstar ER.** Marker Configuration Model Based Roentgen Fluoroscopic Analysis. *J Biomech* 2005; 38(4): 893-901.

**Garling EH, Kaptein BL, Mertens B, Barendregt W, Veeger HEJ, Nelissen RGHH, Valstar ER.** Soft-tissue artefact assessment during step-up using fluoroscopy and skin-mounted markers. *J Biomech* 2007; 40(1): S18-S24.

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**Garling EH, van Eck M, Wedding T, Veeger HEJ, Valstar ER, Nelissen RGHH.** Increased muscle activity to stabilise mobile bearing knees in patients with Rheumatoid Arthritis. *Knee* 2005; 12(3): 177-82.

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**Linde van der MJA, Garling EH, Valstar ER, Tonino AJ, Nelissen RGHH.** The effect of peripatite on the micromotion of total knee arthroplasty tibial components in rheumatoid arthritis patients. *Clin Orthop Rel Res* 2006; 448:122-128.

## Publications not related to this thesis

**Beumer A, Valstar ER, Garling EH, Leeuwen WJ, Sikma W, Niesing R, Ranstam J, Swierstra BA.** External rotation stress imaging in syndesmotic injuries of the ankle. Lateral radiography and radiostereometry compared in a cadaveric model. *Acta Orthop Scand* 2003; 74(2): 201-205.

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**Beumer A, Valstar ER, Garling EH, Niesing R, Ginai AZ, Ranstam J, Swierstra BA.** Effects of ligament sectioning on the kinematics of the distal tibiofibular syndesmosis. A radiostereometric study of 10 cadaveric specimens focused on presumed trauma mechanisms and possibilities of treatment. *Acta Orthop Scand* 2006; 77(3):531-40.

**Beumer A, Valstar ER, Garling EH, Niesing R, Heijboer RP, Ranstam J, Swierstra BA.** Kinematics before and after reconstruction of the anterior syndesmosis of the ankle. A prospective radiostereometric and clinical study in 5 patients. *Acta Orthop Scand* 2005; 76(5): 713-720.

**Koning OHJ, Oudegeest OR, Valstar ER, Garling EH, Linden van den E, Hinnen JW, Hamming JF, Vossepoel AM, van Bockel JH.** Roentgen Stereophotogrammetric Analysis: an accurate tool to assess endovascular stentgraft migration. *J Endovasc Therap* 2006; 13(4): 468-475.

**Koning OHJ, Garling EH, Hinnen JW, Kroft LJM, van der Linden E, Hamming JF, Valstar ER, van Bockel JH.** Accurate detection of stent-graft migration in a pulsatile aortic model using roentgen stereophotogrammetric analysis. *J Endovasc Therap* 2007; 14(1): 30-38.

**Koning OHJ, Garling EH, Hinnen JW, Kroft LJM, van der Linden E, Hamming JF, Valstar ER, van Bockel JH.** Roentgen Stereophotogrammetric Analysis to detect stentgraft migration in an animal model. *J Endovasc Therap* 2007; in press.

**Koning OHJ, Kaptein BL, Garling EH, Hinnen JW, Hamming JF, Valstar ER, Bockel JH.** Assessment of three-dimensional stent-graft dynamics by using fluoroscopic roentgenographic stereophotogrammetric analysis. *J Vasc Surg* 2007; 46(4): 773-779.

**Nelissen RGHH, Garling EH, Valstar ER.** Influence of cement viscosity and cement mantle thickness on migration of the Exeter total hip prosthesis. *J Arthroplasty* 2005; 20(4): 521-528.

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**Valstar ER, Garling EH, Rozing PM.** Micromotion of the Souter-Stratchclyde total elbow prosthesis in patients with rheumatoid arthritis. *Acta Orthop Scand* 2002; 73(3): 257-263.