Novel insights in cruciate-retaining total knee arthroplasty

Albert H. van Houten

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- Voor Hannah en Olivier -

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Chapter 1

General introduction and thesis outline

Anatomy of the knee

The knee joint is one of the most complex joints in the body. The combination of bones, ligaments, menisci, muscles and cartilage work together to create stability and mobility under high loading conditions. The knee joint consists of three bones: femur, tibia and patella. The interaction between these bones results in two articulations: the tibiofemoral and patellofemoral joint. The bones are covered with cartilage which smoothens the surface and aids in reducing friction during movement.

The knee joint is stabilized by multiple ligamentous structures (Figure 1). The anterior cruciate ligament (ACL) is positioned centrally in the knee joint and attaches the posterior aspect of the medial wall of the lateral femoral condyle to the central-anterior aspect of the tibia. It is a ribbon-like structure with one part that stretches in knee-flexion and one part in knee-extension [62]. Due to its position, it primarily resists anterior tibial translation in relation to the femur [31]. Its secondary function is resisting tibial internal, valgus and varus rotational forces on the knee joint [31].
The posterior cruciate ligament (PCL) acts as a counterpart in relation to the ACL. It is also centrally positioned and attaches the lateral wall of the medial femoral condyle to the central posterior aspect of the tibia (Figure 2). It consists of two parts: the anterolateral bundle (ALB) and the posteromedial bundle (PMB) in which the ALB is taught in 90 degrees of flexion and the PMB in 0 degrees of flexion [20, 27]. It is thicker and stronger than the ACL and resists posterior translation in relation to the femur [8, 52]. The medial collateral ligament (MCL) complex consists of multiple structures: (superficial) MCL, deep MCL, posteromedial capsule (PMC)) [71]. The sMCL is the primary static medial stabilizer of the knee and resists valgus forces in 20-30 degrees of flexion [30, 40, 55]. In 0 degrees of flexion the PMC has an important stabilizing effect [55]. Secondary function of the sMCL and dMCL is resisting anteromedial rotatory instability [3].
The posterolateral corner (PLC) of the knee consists of multiple (musculo)ligamentous structures which act as a static or dynamic restraint for varus movement and exorotatory forces [14]. The passive stabilizers are the lateral collateral ligament (LCL), popliteus tendon, popliteofibular ligament and arcuate ligament complex [28, 30]. Dynamic structures of the PLC are the biceps femoris, popliteus muscle, iliotibial band and lateral gastrocnemius [41].
These four ligamentous entities create stability of the knee in different flexion angles and are the main stabilizers.

Knee joint kinematics

The tibiofemoral joint has six degrees of freedom (DOF) which can be divided in three rotations and three translations. The three rotations consist of flexion/extension, varus-valgus and exo- and endorotation (Figure 3).

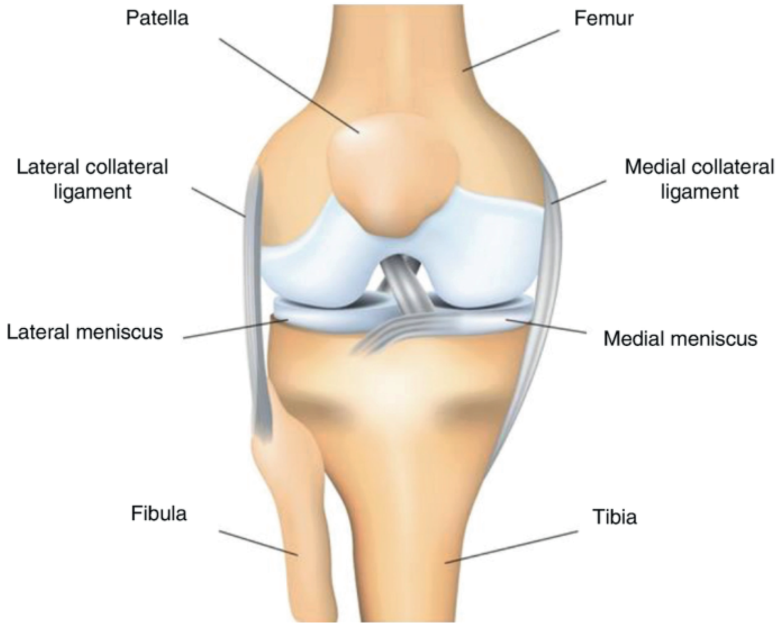

Figure 1. Anatomy of the knee joint (Reproduced with permission and copyright ©) [51]

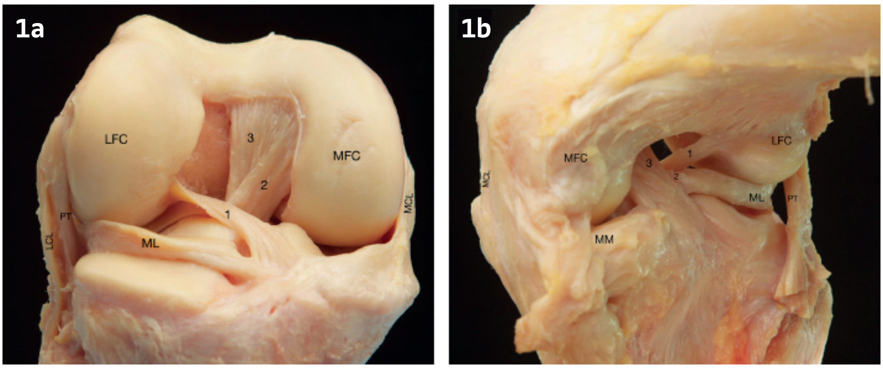

Figure 2. (**1a**) Cadaveric dissection of right knee joint, patella is removed, view from the front. LFC=lateral femoral condyle, MFC=medial femoral condyle, ML=lateral meniscus, MCL=medial collateral ligament, LCL=lateral collateral ligament, PT=popliteus tendon, 1=anterior cruciate ligament, 2=anterior menisco-femoral ligament (Humphrey ligament), 3=posterior cruciate ligament. Notice: flat, ribbon-like appearance of ACL, very low femoral attachment, reaching to articular surface of lateral femoral condyle. (**1b**) View from postero-medial side (Reproduced with permission and copyright ©) [75]

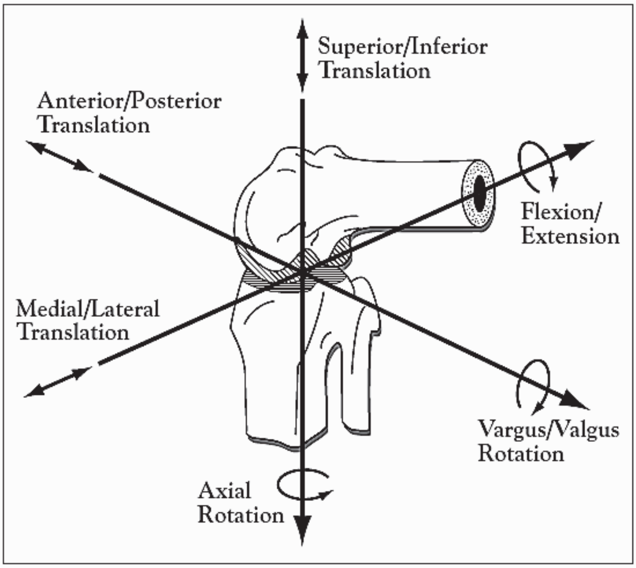

Figure 3. Six degrees of freedom of the knee joint, which include 3 rotational and 3 translational motions (Reproduced with permission and copyright ©)[38]

Anterior-posterior (AP) translation, medio-lateral translation and proximal-distal translation are the three types of translation.

In the normal knee, the femoral condyles undergo a combination of rolling, sliding, and rotation on the tibial plateau during flexion [1]. With increasing flexion, the posterior translation of the tibiofemoral contact point is typically greater on the lateral plateau compared to the medial plateau. This is partly due to the larger radius of curvature of the lateral femoral condyle. This well-established asymmetry in condylar motion during knee flexion imposes passive internal rotation of the tibia with flexion. The opposite rotational motion ("screw home" rotation) occurs when the tibia passively externally rotates during knee extension as the medial femoral condyle articular surface is wider than the lateral one [1].

Regarding patellofemoral joint kinematics, the knee flexion angle has been used as a reference to describe the 6 DOF movement of patella in most studies.

Numerous factors can affect patellofemoral kinematics, including trochlear groove morphology, muscular and retinacular stretch, and tibial rotation. At the initial period of flexion, soft tissues (quadriceps, patellar tendon, and medial and lateral retinaculum) play a vital role in patellar tracking. During further flexion, the status of the patella is determined by the morphology of the trochlear groove and patellar facet [74].

Osteoarthritis of the knee

Osteoarthritis of the knee is a common condition where typically the protective cartilage of the distal femur and proximal tibia wears down over time. Classical symptoms are pain, stiffness, swelling, and reduced range of motion in the affected knee joint. While it often occurs as people age, it can also develop as a result of injury or overuse of the knee joint.

Non-operative treatment for osteoarthritis of the knee typically involves a combination of lifestyle changes, medications, physical therapy and intra-articular injections. Lifestyle changes may include weight loss, exercise, and avoiding activities that aggravate the knee joint. Medications such as pain relievers, anti-inflammatory drugs, or injections of corticosteroids or hyaluronic acid may help manage symptoms. Physical therapy can improve strength and flexibility of the knee joint.

Surgical treatment can be considered in more advanced cases in which daily activities are prohibited. When the osteoarthritis is limited to one compartment (medial or lateral), the surgeon may advise an osteotomy or an unicompartmental knee replacement. With a femoral and/or tibial osteotomy, the affected knee compartment is (partly) unloaded by a correction of the leg alignment. In unicompartmental knee replacement only one compartment is replaced and the central stabilizers of the knee (ACL/PCL) are preserved. In progressive osteoarthritis, involving more than one compartment, a total knee arthroplasty is the preferred treatment.

Historical perspective on total knee arthroplasty [50, 56]

The advent of total knee arthroplasty (TKA) was an important milestone in orthopedic surgery. The first TKAs were performed by Theophilus Gluck in the 1890s [56]. It was an ivory hinged design fixed with plaster. Due to infection and insufficient fixation it rapidly failed. The hinge knee from cobalt chrome was developed in 1958 by Walldius and used till the 1970s (Figure 4) [36]. The Bousquet-Trillat prothesis was an evolution of the hinge and allowed rotational movements. It provided the stability of a hinged unit by a contained ball-and-socket joint and allowed transaxial motion [66]. The concept was that it reduced stress at the bone-cement interface and theoretically improving the longevity of the implant. The high mechanical failure rates from its inherent constrained design led to the development of less constrained designs: the condylar knee system.

Condylar knee arthroplasty essentially resurfaces the tibiofemoral joint and is less constrained. They require less bone resection compared to the hinged design. Besides, additional surgical instrumentation was needed to aid in soft-tissue balancing.

Professor Sav Swanson and dr. Michael Freeman of Imperial college London Hospital (ICLH) pioneered the ICLH knee which sacrificed the ACL and PCL in order to correct large deformities and maximize tibiofemoral contact area to reduce wear [65]. Furthermore, Freeman introduced the concept of equal and parallel flexion and

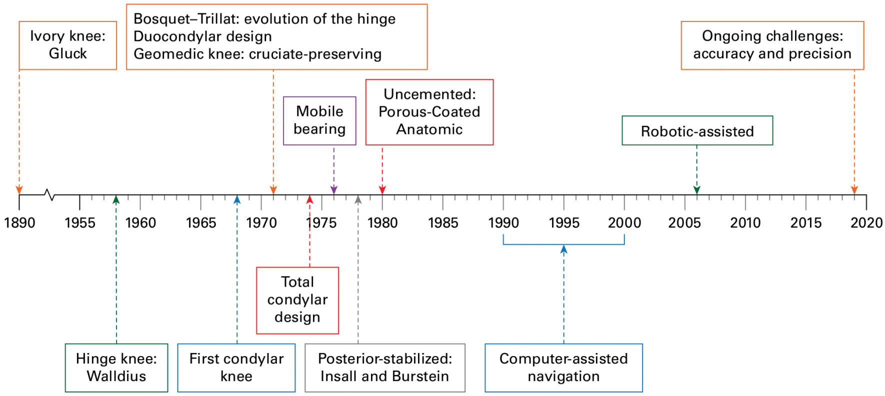

Figure 4. A timeline showing important events in the history of total knee arthroplasty (Reproduced with permission and copyright © of the British Editorial Society of Bone & Joint Surgery) [50]

extension spaces, which later were called gaps by John Insall [50]. The concept of ligament balancing and soft-tissue release were introduced by him, which, are even nowadays essential in primary TKA.

Currently, we still use a condylar type implant, with a femoral component, tibial component and an optional patellar component. Between the femoral and tibial component, a polyethylene insert is present which is connected to the tibial component. The components can be fixed to the bone by the use of polymethyl methacrylate (PMMA or 'bone cement') or in a cementless fashion. In the cementless fixation the components are fixed by biological fixation (bony ingrowth) by the use of coatings and porous metals.

Arthroplasty of the knee

There are several forms or types of knee arthroplasty, each designed to address different aspects of knee osteoarthritis. Grossly, they can be divided in partial knee arthroplasty (PKA) and total knee arthroplasty (TKA). In PKA a single compartment of the knee is replaced, either the medial, lateral or patellofemoral compartment. In recent years, there is increasing attention for bicompartmental knee arthroplasty (BKA) in which two compartments are replaced and ligaments and bone stock is more preserved. Up till now, it is debatable if this technique leads to an improved result in terms of survival rates and higher patient satisfaction [22].

Due to increasing life expectancy, increasing world-wide population and demand for more active lifestyle, there is a significant increase in the numbers of performed total knee arthroplasties of the knee. Currently, around 1 million TKAs are now performed

annually in the United States, with projections to be 3.48 million in 2030 [39]. In the Netherlands 26.708 TKAs were performed in 2022 of which the majority were women (62%) with an average age of 69.9 years (LROI rapportage 2023).
TKA is a successful surgical procedure with a survival of 94% at 14 years (LROI 2023) regardless of fixation type or implant design. Although the results in terms of survival are considered to be good, there is room for improvement regarding functional outcomes and patient satisfaction. However, despite substantial technique and technological advances in primary TKA, numerous studies suggest that only 82% to 89% of patients are satisfied with the results. Bourne et al. confirmed that approximately one in five (19%) of 1,703 primary TKA patients were not satisfied with their outcome at approximately 1 year after surgery [7]. Recently, this percentage was re-evaluated and questioned [17]. The strongest predictors for patient dissatisfaction were unmet expectations, lower preoperative Kellgren-Lawrence scores and poor patient coping skills [17, 48]. From these studies it also became clear that definitions of poor response to TKA are heterogeneous and there is need for an unambiguous definition of poor response to draw conclusion about the prevalence of poor-responders to TKA [46].
The last decades long-term survival of TKA has been improved [47]. However, as previously mentioned, there is still room for improvement regarding decreasing the numbers of patient with a poor response to TKA. In search of improvement of clinical outcomes, designs and surgical techniques are continuously under development. One of the main goals is to restore the native anatomy, as much as possible, with an anatomical implant and strive for near-normal tibio-femoral kinematics and physiological loading of the soft-tissue structures of the knee joint.

Surgical philosophies in TKA

The prosthetic components can be positioned in the knee according to different philosophies. These can be separated in two distinct alignment methods: the measured resection technique and gap balancing technique [16].
In the measured resection technique, bony landmarks are used to guide resections equal to the distal and posterior femoral thickness of the femoral component of the prosthesis. This technique was developed by surgeons and engineers aiming for an anatomical resurfacing and retaining the PCL [56]. Bony landmarks such as the trans-epicondylar axis (TEA), the anteroposterior (AP) axis and the posterior condylar axis (PCA) are used to set femoral component rotation when using a measured resection technique. Unlike gap balancing, bone cuts are initially made independent of soft tissue tension.
The balanced gap technique was introduced by Insall and Freeman in the 1970s [35]. The goal of gap balancing is to optimize flexion and extension gap symmetry. Gap balancing depends on attaining symmetric tension on the ligaments in extension

and subsequently setting femoral component rotation based on achieving a symmetric flexion gap. The soft tissues are tensioned with laminar spreaders or tensor devices and they determine the rotation of the femoral component. The balanced gap technique involves performing soft-tissue releases to equalize the flexion and extension gaps before making bony resections [35]. Proponents of gap balancing believe that balanced gaps are the most important determinants of TKA outcomes [19].
In more recent years, alternative alignment philosophies were introduced but are essentially a further development of the above-mentioned techniques.

Types of total knee arthroplasty

Currently there are two major implant types. The posterior cruciate ligament (PCL) involved in the knee joint is commonly either retained or replaced by artificial structures during total knee arthroplasty surgery, i.e., posterior cruciate ligament retention (CR) and posterior stabilized (PS). Several randomized studies comparing two designs have been conducted from the early 90s up to now, but the debate continues today in terms of the significance of preserving the PCL in TKA surgery [54, 64, 68]. It is generally assumed that CR design could increase range of motion and knee flexion by restoring anatomical femoral rollback and normal knee kinematics, but some studies show a lack of posterior femorotibial translation with knee flexion in patients with a CR design [18, 43]. Besides, several studies also show that preservation of the PCL in TKA surgery does not guarantee a proper function of this ligament [13, 58]. The technique of ligament balancing (tensioning of the PCL and determining rotational alignment of the femoral component during flexion balancing with a tensioner) is challenging and no objective instructions exists on how to balance the ligaments [15, 32, 33].
The PS design has a cam-post mechanism to substitute the PCL and guides rollback of the femoral component on the tibial component during flexion. Its proponents argue that the posterior translation of the femur theoretically creates more knee flexion [69]. Many studies have reported that both designs show satisfactory results, but the specific importance of PCL retention has yet to be confirmed, and the particular advantages of one design over the other have not been documented [42, 68]. The perfectly balanced PCL might lead to a superior clinical result compared to the PS design.
In traditional TKA the ACL is most often resected and PCL function can be compensated for by balancing the PCL (CR) or by implant design (PS). Due to the assumed loss of proprioception by resecting the ACL in combination with the commonly seen paradoxical anterior femoral translation in mid- and near-extension led to the further development of bi-cruciate retaining (BCR) TKA to optimize results, especially in the young and demanding patient [72]. Whether this will lead to a better functional result is on debate and the surgical technique is challenging. In concordance with

the previously mentioned techniques, optimal implant placement, soft tissue balancing, and alignment are key factors for a good clinical outcome. Preclinical and clinical research suggest, however, that the BCR-TKA has a potential benefit to achieve improved kinematics in the young and active arthroplasty patient and warrants future research for new-generation designs with optimal (tibial) fixation and reproducible (robotic assisted or navigated) surgical placement [72].

Types of bearing in CR-TKA

Commonly, there is a polyethylene (PE) bearing between the femoral and tibial component on which the surface of the tibial component articulates with the femoral component. Fixed bearing (FB) and mobile bearing (MB) are two types of bearing designs for TKA [26]. FB are relatively flat and, therefore, allow some small rotations and translations, but much less compared to the MB [53]. Although this configuration allows for some axial rotation, it might result in high contact stress (and subsequent wear) between the femoral and tibial surface. Because of these circumstances, the concept of a MB insert was introduced [10]. Due to its motion at the tibia-insert interface, greater tibiofemoral congruency can be achieved, potentially reducing bearing stresses and wear of the PE and reproducing more natural kinematics of the knee. Furthermore, due to the high mobility of the MB, knee forces and kinematics are not accompanied by an increase of stress levels at the bone-implant interface [12], possibly resulting in increased durability and knee function. However, the increased mobility with sliding and rotation of the MB could potentially lead to more backside polyethylene wear and subsequently result in (aseptic) loosening.
Balancing the PCL combined with either a FB or a MB (AP glide and limited rotational freedom) in CR-TKA showed good clinical outcomes and limited complications and revisions on the mid-term follow-up [60]. However, PCL balancing combined with either a FB or a MB is not a forgiving system and the long-term results might be less predictable. Meta-analyses investigating survivorship did not find any clinically relevant differences in revision rates between FB and MB TKA [70, 76]. In these studies no specific analyses were performed for measured resection versus ligament balancing implantation techniques [70, 76]. Besides, the follow-up was shorter than 10 years. Hence, there is need for a long-term follow-up study to determine of survival of the two bearing types in PCL balanced TKA according to the balanced gap technique. It has been hypothesized that long-term survival and clinical outcomes will be equal for the FB and MB in the well-balanced TKA.

Insert geometry (anatomical vs. non-anatomical)

To obtain near-normal knee kinematics in CR-TKA, the native articulating position of the medial femoral condyle on the tibia should be restored [34]. Next to a correct tibiofemoral contact point, appropriate PCL balancing will help to reproduce normal anteroposterior (AP) translation. As mentioned before, a PCL which is too loose in flexion results in increased AP translation in flexion and paradoxical forward femoral sliding [73]. However, the optimal AP and varus-valgus (VV) laxity after TKA, and their relation with postoperative satisfaction, postoperative range-of-motion (ROM) and knee function are unclear [45, 57].

In addition to appropriate PCL-balancing by adjusting the tibial slope and restoring the natural tibial step-off [34], a well-designed implant is an important factor for a successful TKA. Symmetrical inserts have been used in vivo for years without concerns regarding longevity or stability. Recently, new implants have been introduced that have more resemblance with the native anatomy of the knee. Some of these implants have 3° degrees of joint line obliquity in the coronal plane and an accommodating insert. In this more anatomical design, the medial surface of the insert is concave and the lateral surface is convex (Figure 5), more consistent with the anatomy of the tibial plateau surface. However, a convex lateral insert surface geometry could result in more lateral AP translation due to the less constraining design compared to a more dished like surface geometry. The effect of a more anatomical insert design on AP and VV laxity has not been extensively investigated in CR-TKA. Furthermore, whether a more anatomical insert design leads to superior patient outcomes and long-term survival remains to be investigated.

Patellofemoral joint in total knee arthroplasty

One of the major challenges after TKA is anterior knee pain (AKP) and this is also one of the major reasons for revision [2, 11, 23, 44]. The incidence varies and is reported to be between 4 and 49% but also the intensity of pain varies [9, 25, 37]. Daily activities such as climbing stairs, cycling, getting up from a chair or even normal walking can be impaired due to this type of pain.

The pathogenesis remains unclear and several determinants have been proposed [21, 37]. One of the major supposed causes is abnormal patellofemoral tracking. Patellar kinematics can be disturbed after TKA. However, several studies did not find an association between the amount of patellar tilt, subluxation and the development of AKP [37]. Other factors that could contribute to the development of AKP are native patellofemoral anatomy that is different from the trochlear anatomy of the implant, positioning of the femoral component and trochlear groove orientation, prosthetic design with respect to the trochlear groove, femoral and tibial component rotation and tibial slope in CR-TKA.

Few studies described the relationship between AKP and patella position in CR-TKA [4, 24]. In one of those studies the patella was resurfaced [24]. The correlation between the presence of AKP and radiological position of the patella in CR-TKA, especially when the patella is not resurfaced is not known.

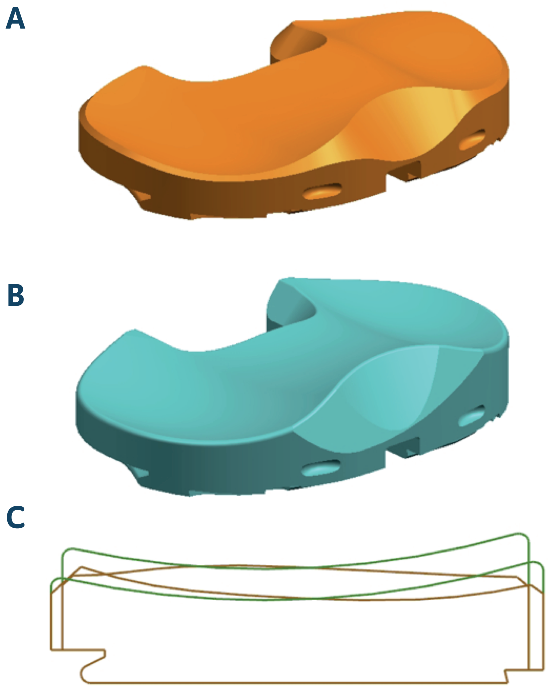

Figure 5. Design of anatomical insert with medial concave and lateral convex surface geometry (**A**), and design of symmetrical insert (**B**) and projections of the contour lines of both inserts (**C**). Rim heights are given with respect to the corresponding sulcus. The medial sulcus lies 2.5 mm lower than the lateral sulcus for the anatomical insert.

From the native knee it is known that rotation malalignment of the femur, increased tibial tuberosity–trochlear groove distance and patella height are factors that can contribute to AKP [5]. Patella alta (a high positioned patella relative to the femur) is associated with increased patellofemoral contact force, but several studies did not find a correlation between patellar height and AKP in TKA [37].
The type of tibiofemoral bearing might also influence outcomes in different patellar kinematics and subsequently development of AKP. Several studies have demonstrated a potential benefit of MB compared to the FB TKA [9, 11, 63]. This could be due to the expected lower patellofemoral contact pressures in the mobile bearing design [59, 61].
The tibiofemoral contact point (CP) is another suggested potential determinant for development of AKP: a more anterior positioning of the tibiofemoral CP leads to a reduced lever arm of the extensor mechanism and leads to higher patellofemoral

pressure [49]. Therefore, it seems important to restore the original CP of the native knee when performing CR-TKA.

Radiological evaluation after TKA

In the 'unhappy' TKA patient it is common to perform a thorough work-up including anamnesis, physical examination and radiological evaluation. Conventional radiographic imaging consists of a weight-bearing anteroposterior view, mediolateral view and a skyline view of the patella. In addition, lower limb alignment is determined by full-length standing radiograph in an anteroposterior (AP) projection. Rotational alignment of the tibial and femoral component is most often determined by utilizing 2D computed tomography (CT) scans. Rotational malalignment of the femoral and/or tibial component after TKA, may provoke pain, synovitis, stiffness and patellofemoral complications. However, the relation between (mal)alignment and clinical outcomes is not clear and the amount of rotation to cause clinical symptoms is unknown [29, 67]. The optimal method to determine rotation of the tibia and femoral component while performing surgery is a matter of debate. To quantify tibial component rotation various anatomical land marks have been suggested such as: the medial third of the tibial tubercle, the posterior condylar line, transverse axis of the tibia, patellar tendon, the malleolar axis and the second metatarsal. The method described by Berger, using the medial third of the tubercle, is most frequently used to determine tibial rotation on CT-scans [6]. The anatomical tibial axis (ATA) can alternatively be used but the relationship between the ATA and the method of Berger has never been investigated. In addition to the ATA and Berger's tibial angle the tibial tuberosity trochlear groove (TT-TG) distance can be used to determine combined femoral and tibial rotation. Nevertheless, none of the methods is recognized as the ultimate reference [29]. Furthermore, the reliability of, and correlation between, the different measurement techniques for rotational alignment after TKA is unclear.

Thesis aims and overview

The purpose of this thesis is to evaluate multiple factors that may affect the clinical success in total knee arthroplasty. The aims of this thesis were focused on investigation of the role of a more anatomical knee design and to compare it to the native knee. Secondly, long-term results of a CR-TKA with two different insert designs and the associated incidence of anterior knee pain were evaluated. Finally, the reliability of, and correlation between, the different measurement techniques for rotational alignment after TKA were investigated.
This resulted in the following contents of the thesis:

Chapter 2 compares the effect of insert articular surface geometry (anatomical versus conventional insert design) on anteroposterior translation and varus-valgus laxity in balanced CR retaining TKA in a human cadaveric knee.

Chapter 3 presents the (clinical) outcomes of a multi-centre retrospective cohort study investing the 12-years results of a primary CR-TKA using a balanced gap technique. In this study two different types of bearings (inserts) were used (fixed and mobile) and they were compared in terms of survival and clinical performance.

Chapter 4 presents a prospective cohort study in which we investigated the incidence of anterior knee pain 10 years after CR-TKA. The surgery was performed according the balanced gap technique. Possible determinants for the development of anterior knee pain were evaluated.

Chapter 5 assesses the reliability of different measurement techniques for determining tibial and femoral component rotation after TKA. The correlation between these different measurement techniques is unclear and also their clinical relevance.

Finally, **Chapter 6** of this thesis discusses the methods, results and implications of the presented studies, followed by recommendations for future research.

Through the studies presented in this thesis, we aim to contribute to the ongoing efforts to enhance clinical outcomes following TKA.

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Chapter 2

Limited effect of anatomical insert geometry on in vitro laxity in balanced anatomic posterior cruciate ligament retaining total knee arthroplasty

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Abstract

Purpose The present study assessed the effect of insert articular surface geometry (anatomical versus conventional insert design) on anteroposterior (AP) translation and varus-valgus (VV) laxity in balanced posterior cruciate ligament (PCL) retaining total knee arthroplasty (TKA). Secondly, we evaluated if the AP translation and VV laxity in the reconstructed knee resembled the stability of the native knee.

Methods Nine fresh-frozen full-leg cadaver specimens were used in this study. After testing the native knee, anatomical components of a PCL-retaining implant were implanted. The knee joints were subjected to anteriorly and posteriorly directed forces (at 20° and 90° flexion) and varus-valgus stresses (at 20°, 45° and 90° flexion) in both non-weightbearing and weightbearing situations in a knee kinematics simulator. Measurements were performed in the native knee, TKA with anatomical insert geometry (3° built-in varus, medial concave, lateral convex), and TKA with symmetrical insert geometry.

Results In weightbearing conditions, anterior translations ranged between 2.6 and 3.9 mm at 20° flexion and were < 1 mm at 90° flexion. Posterior translation at 20° flexion was 2.7 mm for the native knee versus 4.0 mm ($p = 0.047$) and 7.0 mm ($p = 0.02$) for the symmetrical insert and the anatomical insert, respectively. Posterior translation at 90° flexion was < 1.1 mm and not significantly different between the native knee and insert types.

In non-weightbearing conditions, the anterior translation at 20° flexion was 5.9 mm for the symmetrical and 4.6 mm for the anatomical insert (n.s.), compared with 3.0 mm for the native knee ($p = 0.02$). The anterior translation at 90° flexion was significantly higher for the reconstructed knees (anatomical insert 7.0 mm; symmetrical insert 9.2 mm), compared with 1.6 mm for the native knee (both $p = 0.02$). Varus-valgus laxity at different flexion angles was independent of insert geometry. A valgus force in weightbearing conditions led to significantly more medial laxity (1°–3° opening) in the native knee at 45° and 90° flexion compared with the reconstructed knee for all flexion angles.

Conclusions Insert geometry seems to have a limited effect with respect to AP translation and VV laxity, in the well-balanced PCL-retaining TKA with an anatomical femoral component. Secondly, AP translation and VV laxity in the reconstructed knee approximated the laxity of the native knee.

Keywords: cruciate-retaining total knee arthroplasty; PCL-retaining total knee arthroplasty; total knee arthroplasty; anteroposterior translation; varus-valgus laxity; spacer technique

Introduction

Posterior cruciate ligament (PCL) retention in total knee arthroplasty (TKA) may lead to better proprioception compared with PCL-sacrificing (PS) TKA, due to the presence of mechanoreceptors in the ligament [4, 13]. To obtain near normal knee kinematics in PCL-retaining TKA, the normal articulating position of the medial femoral condyle on the tibia should be restored [6]. Next to a correct contact point, proper PCL balancing will help to reproduce healthy/normal anteroposterior (AP) translation; a PCL which is too loose in flexion results in increased translation in flexion and paradoxical forward femoral sliding [2, 23].

Good functional outcomes have been reported with an AP translation less than 10 mm [15, 17]. However, the optimal anteroposterior and varus-valgus laxity after TKA, and its relation with postoperative achieved patient satisfaction, postoperative ROM, and knee function are unclear [12, 14]. Seah et al. reported that patients obtain a beneficial result from surgery if they have less than 5° of combined varus-valgus laxity postoperatively [16].

In addition to proper PCL-balancing by adjusting the tibial slope and restoring the natural step-off, a well-designed implant is an important factor for a successful TKA [18]. Recently, implants were introduced that resemble the anatomy of the native knee. These implants have 3° of joint line obliquity in the coronal plane and an accommodating insert. In the anatomical design, the medial surface of the insert is concave and the lateral surface is convex, consistent with the native anatomy of the tibia surface. However, a convex lateral insert surface geometry could result in more lateral AP translation due to the less constraining design compared to a dished insert, but may be compensated for by the concave medial surface with a clear posterior rim.

To date, the effects of anatomical insert design on anteroposterior and varus-valgus laxity have not been investigated in PCL-retaining TKA. However, several in vitro studies have investigated the amount of laxity after non-anatomical TKA compared to the native knee [1, 5, 8, 11]. Hunt et al. found comparable laxity in the single radius PCL-retaining TKA compared to the native knee in a cadaveric study [8] whereas Lo et al. found [11] increased posterior laxity in PCL-retaining TKA with symmetrical inserts compared to the native knee and the bicruciate-retaining (BCR) TKA.

Therefore, the aim of the present study was to test the anterior–posterior and varus-valgus stability of the anatomical insert and evaluate the effect of anatomical insert geometry (medial concave – lateral convex), compared to the conventional symmetrical concave insert design on anterior–posterior (AP) translation and varus-valgus (VV) laxity in PCL-retaining TKA. We hypothesized that (1) an anatomical insert results in similar anteroposterior translation compared with the symmetrical insert, (2) AP translation in the reconstructed knee resembles the stability of the native knee, and (3) VV laxity is independent of insert design.

Materials and methods

In this cadaveric study, knee joints were subjected to anteriorly and posteriorly directed forces and varus-valgus stresses under different flexion angles in both non-weightbearing and weightbearing situations using a knee kinematics simulator. AP translation and varus-valgus laxity were recorded using six infrared motion capture cameras. The measurements were repeated for the native knee, TKA with anatomical insert geometry, and TKA with symmetrical insert geometry (Figure 1). Trials were performed in triplicate and the averages of the three measurements were calculated and used for further analysis.

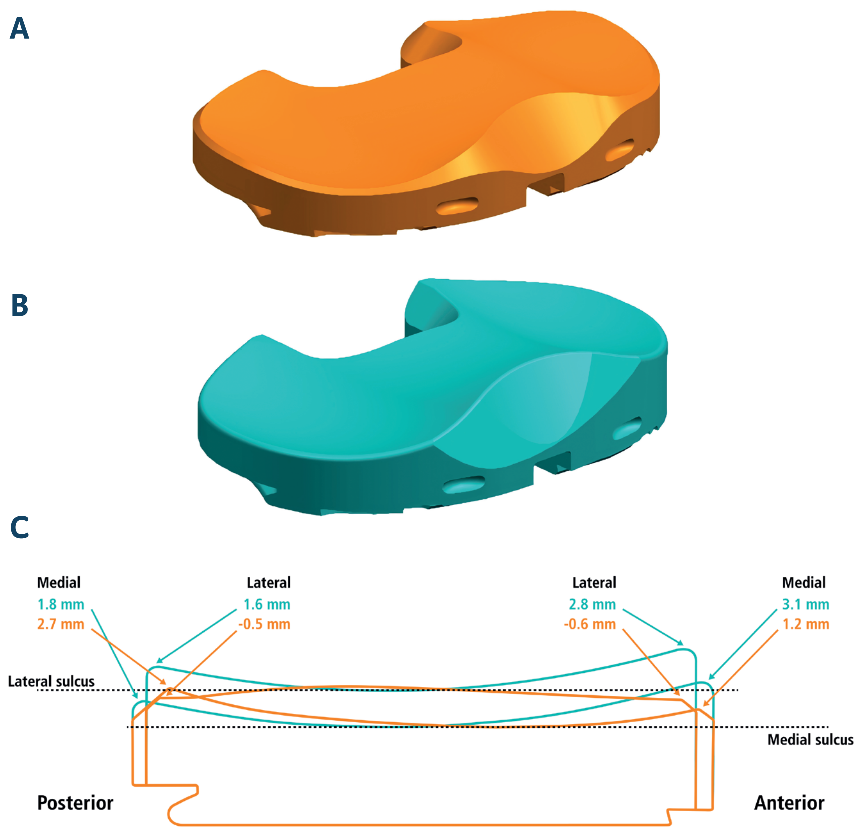

Figure 1. Design of anatomical insert with medial concave and lateral convex surface geometry (**A**), and design of symmetrical insert (**B**) and projections of the contour lines of both inserts (**C**). Rim heights are given with respect to the corresponding sulcus. The medial sulcus lies 2.5 mm lower than the lateral sulcus for the anatomical insert.

Specimens

A total of nine freshly frozen, full-leg cadaver specimens were used. Medical records of the donors showed that they had no known history of musculoskeletal problems at the investigated knee joint. Four specimens were left specimens; two specimens were from female donors. The donors' ages ranged from 61 to 80 years, with an average of 71 (SD 8.7) years.

Experimental setup and specimen preparation

The experimental setup and methodology have been described in detail previously [6, 20]. In short, after identifying the centres of the femoral head and the ankle with the navigation system, the femoral head and ankle were removed and the femur and tibia plus fibula were cut to lengths of 32 and 28 cm, respectively. Both bones were cleaned and embedded in aluminum fixtures with PMMA, ensuring proper alignment in the coronal and sagittal planes. Afterwards, the quadriceps tendon was dissected, stripped from all muscle tissue and securely fixed in a clamp. Also, the medial (semitendinosus and semimembranosus) and lateral (biceps femoris) hamstrings tendons were dissected, and suture wires were attached to enable loading of the hamstrings (50 N on medial and 50 N on the lateral side) during testing [20].

Surgical technique and implant

After measurements (see detailed description below) of the native knee, the knee was opened and the integrity of the PCL in the specimens was confirmed visually as well as by posterior laxity testing at 90° flexion. Subsequently, components of a Journey CR-TKA (Smith and Nephew, Memphis, TN, USA) were implanted. The Journey CR-TKA is an anatomically designed implant, with an asymmetrical tibial baseplate and an accommodating insert with a concave medial and a convex lateral surface geometry (Figure 1a). The femoral component has an extended posterior condyle facilitated by an upslope posterior bone cut [6]. A computer navigation system (PiGalileo, Smith and Nephew, Memphis, TN, USA) was used to assist with the bone cuts. The knee prosthesis was implanted using a measured resection technique, removing an amount of bone of femur and tibia equal to the prosthesis thickness in extension and flexion. First, mediolateral balancing in extension was performed with a spacer. A 3° external rotation jig was used to determine the femoral component rotation. A bony island around the PCL attachment on the tibia was preserved, and all ligaments were intact after finishing the bone cuts. No releases of the collateral ligaments or the PCL were performed. In this study, we used the spacer technique to balance the PCL, which has previously been described in detail [6, 22]. In essence, by reconstructing the natural step-off, the PCL will be balanced. If the step-off is too large after the bone cuts, the PCL is too tight. Where applicable, this was corrected by performing a recut of the tibia with the addition of slope.

To test the effect of insert surface geometry, the anatomical insert was removed and replaced by a symmetrical insert (Genesis 2, Smith and Nephew, Memphis, TN, USA). The test symmetrical inserts (Figure 1b) were custom adapted by the manufacturer (Smith and Nephew, Memphis, TN, USA) to the anatomic knee system by changing the joint line from perpendicular to the tibial axis to 3° angulation to fit with the anatomic system. The surface geometry was not changed.

Measurements

After preparation, the specimen was mounted in a dynamic knee simulator system, based on the Oxford Rig, which was designed to simulate and record motions and loads during squatting [6].
The knee was brought to the required flexion angle by moving the hip joint down over the predefined distance. When the correct knee flexion angle was reached, the hip position was fixed. Where a weightbearing laxity test was performed, the hamstring tendons were hooked to the constant force springs and the quadriceps motor then started pulling gently on the tendon until the 3D force sensor, which was mounted underneath the ankle joint of the simulator registered the correct vertical ankle force of 130 N. If the laxity test was done in the non-weightbearing condition, no tension was applied to the quadriceps nor to the hamstring tendons. Previously, Victor et al. showed that this technique is sufficiently accurate and precise [19].
Trials were performed in triplicate and the averages of the three measurements were calculated and used for further analysis.

Laxity measurements

Anteroposterior translation

AP translation was tested by manually applying an anterior pulling force (i.e., anterior drawer) and posterior pushing (i.e., posterior drawer) force of 89 N at 20° flexion and 90° flexion, respectively, with a dynamometer. Anterior pulling was performed with a hook on the dynamometer, perpendicular to the tibia just below the joint line. Posterior pushing was performed with an adaptor on the dynamometer and perpendicular to the tibia. For the laxity test, AP translation of the specimens was defined as the difference in position of the femoral knee centre relative to the tibial knee centre. AP translation was reported in millimeters (mm). The marker trajectories during testing were recorded using six infrared motion capture cameras (Vicon, Oxford, UK) at 100 Hz.

Varus-valgus laxity

Varus-valgus stress tests were performed at 20°, 45° and 90° flexion with a force of 50 N perpendicular to the tibia at 30 cm below the joint line creating an external moment of 15 Nm by pulling with a dynamometer [FMI-220C5 Force Gauge (range

0–500 N, resolution 0.1 N) Alluris, Germany]. Weightbearing and non-weightbearing measurements for all laxity measurements were recorded. Varus-valgus laxity was reported in degrees. The marker trajectories during testing were recorded using six infrared motion capture cameras (Vicon, Oxford, UK) at 100 Hz.

Statistical analysis

Descriptive statistics were used to summarise the data. Differences in AP translation and varus-valgus laxity between the native knee, and the reconstructed knee with anatomical and symmetrical insert were tested using Friedman's one-way repeated measures analysis of variance by ranks, followed by pairwise comparisons using Wilcoxon signed rank tests. Holm's procedure was used to correct for multiple testing. Results were reported as median (interquartile range). Statistical analyses were performed using R version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria). $p < 0.05$ was considered statistically significant.

Results

Anterior-posterior translation - weightbearing conditions

Median anterior translation at 20° flexion was 2.6 mm (1.4-3.3 mm) for the native knee versus 2.7 mm (1.7-3.5 mm) for the reconstructed knee with symmetrical insert, and 3.9 mm (2.1-4.9 mm) for the reconstructed knee with anatomical insert (Figure 2). Median anterior translations for all tested knee conditions at 90° flexion were below 1.0 mm (Figure 2).

There were no statistically significant differences in anterior translation between the native knee and the two insert types for the anterior drawer test at 20° and 90° flexion.

Median posterior translation at 20° flexion was 2.7 mm (2.2-4.9 mm) for the native knee, versus 4.0 mm (3.7-5.2 mm) for the reconstructed knee with symmetrical insert (n.s.). In the reconstructed knee with anatomical insert, a median posterior translation of 7.0 mm (6.2-7.9 mm) was measured at 20° flexion (Figure 2). This was statistically significantly higher compared to the native knee ($p = 0.047$), as well as compared to the reconstructed knee with symmetrical insert ($p = 0.02$).

Median posterior translation at 90° flexion was 0.8 mm (0.6-1.1 mm) for the native knee, versus 0.3 mm (0.2-0.3 mm) for the reconstructed knee with symmetrical insert ($p = 0.02$). In the reconstructed knee with anatomical insert, a median posterior translation of 0.4 mm (0.3-0.8 mm) was recorded at 90° flexion. Compared to the native knee, this was not significant (n.s.). No statistically significant difference was found between the two insert types (n.s.).

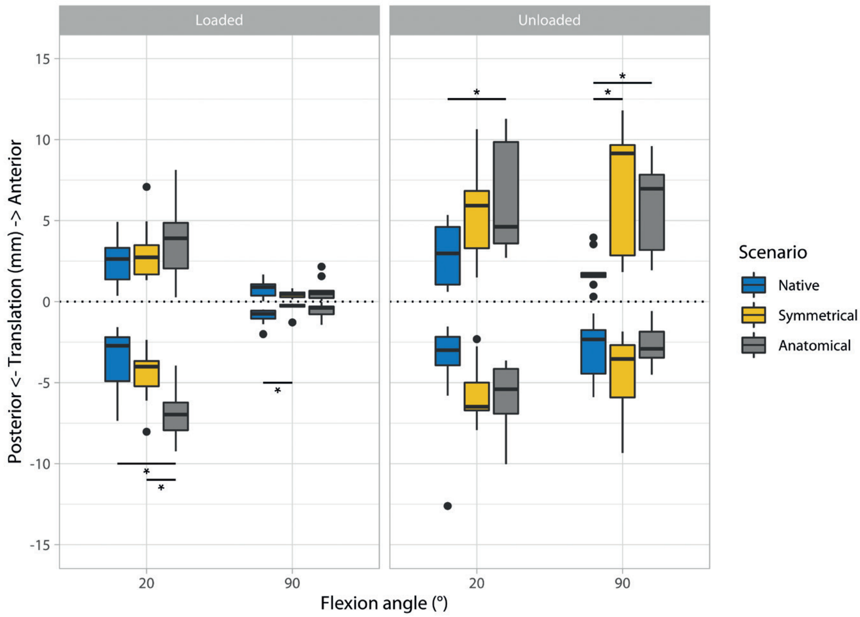

Figure 2. Translation in mm in response to anterior and posterior drawer test for different loading conditions at 20° and 90° flexion for the three tested knee scenarios. Asterisk indicates statistically significant difference.

Anterior-posterior translation - non-weightbearing conditions

Median anterior translation at 20° flexion was 3.0 mm (1.1-4.6 mm) for the native knee, versus 5.9 mm (3.3-6.8 mm) for the reconstructed knee with symmetrical insert (n.s.), and 4.6 mm (3.6-9.9 mm) for the anatomical insert (Figure 2). The anterior translation in the anatomical insert was significantly higher compared with the native knee ($p = 0.02$), but no statistically significant difference was found between the two insert types (n.s.).
Median anterior translation at 90° flexion was 1.6 mm (1.5-1.8 mm) for the native knee, versus 9.2 mm (2.9-9.7 mm) for the reconstructed knee with the symmetrical insert and 7.0 mm (3.2-7.8 mm) for the anatomical insert (Figure 2). The anterior translation for both insert types was also significantly higher compared to the native knee (anatomical insert $p = 0.02$; symmetrical insert $p = 0.02$), but no statistically significant difference was found between the two insert types (n.s.).

Median posterior translation at 20° flexion was 3.0 mm (2.2-3.9 mm) for the native knee, versus 6.5 mm (5.0-6.7 mm) for the reconstructed knee with a symmetrical insert (n.s.), and 5.4 mm (4.2-6.9 mm) for the anatomical insert (Figure 2). There was no statistically significant difference between the anatomical insert and the native knee (n.s.). No statistically significant difference was found between the two insert types at 20° flexion (n.s).

Median posterior translation at 90° flexion was 2.3 mm (1.8-4.4 mm) for the native knee, versus 3.5 mm (2.7-5.9 mm) for the symmetrical insert (n.s.), and 2.9 mm (1.9-3.5 mm) for the anatomical insert (Figure 2). There was no statistically significant difference between the anatomical insert and the native knee nor between the two insert types at 90° flexion (n.s.).

Varus-valgus laxity - weightbearing conditions

There were no statistically significant differences in varus laxity in response to a varus force between the anatomical and symmetrical insert and the native knee (Figure 3).

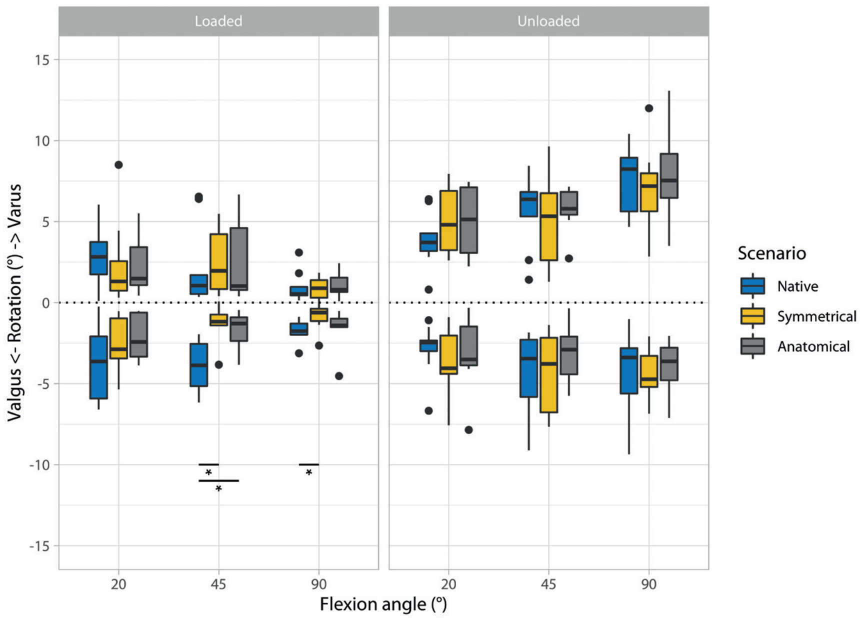

Figure 3. Varus-valgus laxity in degrees for different loading conditions at 20°, 45° and 90° flexion for the three tested knee scenarios. Asterisk indicates statistically significant difference.

Median valgus laxity in 20° flexion was 3.6° (2.1°-5.9°) for the native knee, versus 2.9° (1.0°-3.4°) for the reconstructed knee with symmetrical insert, and 2.4° (0.6°-3.3°) for the anatomical insert (Figure 3). No statistically significant difference was found

between the native knee and the symmetrical insert and between the two insert types (n.s.). There was no statistically significant difference between the native knee and the anatomical insert (n.s.).
Median valgus laxity at 45° flexion was 3.9° (2.5°-5.2°) for the native knee, versus 1.2° (0.7°-1.4°) for the reconstructed knee with symmetrical insert, and 1.3° (0.9°-2.4°) for the reconstructed knee with anatomical insert (Figure 3). A statistically significant difference was found between the native knee and the symmetrical insert ($p = 0.02$), and for the native versus anatomical insert ($p = 0.03$).
Median valgus laxity at 90° flexion was 1.8° (1.3°-2.0°) for the native knee, versus 0.6° (0.4°-1.1°) for the reconstructed knee with symmetrical insert, and 1.4° (1.0°-1.5°) for the reconstructed knee with anatomical insert (Figure 3). A statistically significant difference was found between the native knee and the symmetrical insert ($p = 0.047$), but not for the symmetrical insert versus anatomical insert (n.s.).

Varus-valgus laxity - non-weightbearing conditions
There was no statistically significant difference in medial and lateral laxity in response to a valgus or varus force for the anatomical and symmetrical insert versus the native knee (Figure 3).

Discussion

The most important finding in this study was that the anatomical insert had a very limited effect on anterior-posterior translation compared with the symmetrical insert in PCL-retaining (CR) TKA. Only the posterior translation at 20° flexion was slightly higher (3 mm) for the anatomical insert under weightbearing conditions compared with the symmetrical insert. Secondly, anteroposterior translation for the anatomical insert was slightly increased in non-weightbearing conditions, with more anterior translation at 20 and 90° flexion compared to the native knee. Thirdly, varus-varus laxity was independent of insert type.
Anteroposterior translation of the anatomical insert resembled the amount of translation of the symmetrical insert. This is an important finding, because the lateral convex design is intrinsically less constrained. Only the posterior translation at 20° flexion in weightbearing conditions was increased compared to the symmetrical insert. This can be explained by the lower anterior rim of the anatomic insert combined with limited resistance of the PCL to posterior translation at 20° flexion. Apparently, the amount of dishing of the medial concave surface in combination with an increased posterior rim is sufficient to prevent extreme anterior translation. The symmetrical inserts have been used in vivo for years without concerns regarding longevity or stability. Whether the anatomical insert design translates into superior patient outcomes and long-term survival remains to be investigated in clinical studies.

Anteroposterior translation was mildly increased for the reconstructed knee compared to the native knee, especially in non-weightbearing conditions. The increased anterior translation can be explained by the effect of resection of the ACL [1]. Furthermore, at 20° flexion, the increase in anterior translation was less than 6 mm for the reconstructed knee. However, this increased laxity is less than previous biomechanical studies reported [5, 9, 11], although Arnout et al. found slightly decreased laxity in anatomical CR-TKA [1]. In weightbearing conditions, these differences diminished. Posterior translation at 20° flexion in loaded conditions was increased for the anatomical insert compared to the native knee. As mentioned above, this can be explained by the less constrained design on the anteromedial side. In contrast, at 90° flexion in weightbearing conditions, posterior translation was higher for the native knee compared to the reconstructed knee independent of insert type. However, all conditions showed below 1 mm translation, so this difference seems not be clinically relevant. In our opinion, precise PCL balancing, by restoring the natural step-off, is an important contributor to the prevention of posterior translation.

Overall, at 90° flexion in weightbearing conditions, the native and reconstructed knee were very stable. This is in accordance with previous studies [19, 21]. In the present biomechanical study, this may be explained by the stabilising effect of the quadriceps force pushing the femoral and tibial articular surfaces (native and reconstructed) together and leading to less AP translation as a result.

Several biomechanical studies report inferior results in terms of AP translation in PCL-retaining TKA compared to the native knee [5, 11]. This is in contrast to our results, in which AP translation in the reconstructed knee resembled the translation of the native knee, independent of insert geometry. The total AP laxity after TKA in this study was slightly increased in the non-weightbearing knee at 20° flexion, but within the limits of the clinically-advised 10 mm [15, 17]. In our opinion, proper balancing of the PCL, for example with a spacer [6], is the key to a posteriorly stable knee and good kinematics. Unfortunately, most other studies do not report details about their PCL balancing technique [5, 11].

The currently tested insert designs differ from the medial pivot design. In medial pivot knees (and dished inserts in general), the dished shape leads to a ball and socket effect. Since the lowest point of the insert on the medial side is typically located in the posterior third of the AP distance of the tibia [3], this causes the femur to move posteriorly in extension. The design of the anteromedial side of the anatomical insert of the used implant system is much flatter in order to prevent this subluxation effect in extension [18]. Nevertheless, Jones et al reported better sagittal stability and higher PROMs in medial pivot knees in vivo at 30 and 90° flexion when compared to non-medial pivot knees [10]. Further research is needed to clarify the clinical outcomes for these different designs.

The varus-valgus laxity was independent of insert design. This was to be expected, because only surface geometry was changed; thickness of the inserts was unchanged and therefore there was no difference in gap filling. This presumably results in a similar amount of ligament tension. With respect to varus-valgus laxity, we found that valgus laxity in the reconstructed knee was decreased compared to the native knee at 45 and 90° flexion under weightbearing conditions. However, the absolute differences are small, and this seems not to be clinically relevant. Decreased varus-valgus laxity in the reconstructed knee compared to the native knee is in accordance with other in vitro studies [1, 7, 9]. An explanation could be that the relative elasticity of the cartilage of the native knee is replaced by stiffer polyethylene, resulting in less laxity. A second explanation could be the relative loss of cartilage, but in the present study the human cadavers had no signs of osteoarthritis.

Limitations

Some potential limitations of this study must be discussed. Firstly, AP translation was measured from the centre of the femur; therefore it is possible that increased AP translation could be caused by increased lateral rotation in the reconstructed knee with anatomical insert geometry due to the lateral convex surface. However, Arnout et al., who studied the same implant, did not find significant differences between the medial and lateral compartment in AP translation [1].

Secondly, one might argue that it is better to report AP translation in percentages instead of millimetres. We investigated this, and found no correlation between AP laxity and the size of the knee. Besides, comparison with existing literature is more feasible when using millimeters.

Currently, there is no gold standard for in vitro testing in terms of amount of loading. As a result, absolute numbers in terms of translation and laxity are difficult to compare due to different amounts of loading or absence of hamstring loading. Therefore, we present the weightbearing and non-weightbearing results.

The results of the anatomical insert in PCL-retaining TKA in this study are promising in terms of laxity. Furthermore, Heesterbeek et al. found tibiofemoral kinematics close to the native knee with this anatomical insert [6]. Whether this combination translates into superior patient outcome and long-term survival remains to be investigated.

Conclusions

Insert geometry seems to have a limited effect with respect to anterior-posterior translation and varus-valgus laxity in the well-balanced PCL-retaining TKA with an anatomical femoral component. Secondly, anterior-posterior translation and varus-valgus laxity in the reconstructed knee approximate the laxity of the native knee.

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Chapter 3

Superior long-term survival for fixed bearing compared with mobile bearing in ligament-balanced total knee arthroplasty

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Abstract

Purpose Only few long-term data on ligament-balanced cruciate-retaining total knee arthroplasty (CR-TKA) are currently available. Either a mobile or fixed bearing insert can be chosen, which showed good mid-term outcome and few complications and revisions. This multi-centre retrospective cross-sectional cohort study investigated the 12-year results of primary TKA using a balancing gap technique and compared survival and clinical outcome between fixed and mobile inserts.

Methods In this retrospective cross-sectional cohort study, 557 cases of three clinics (2 Swiss, 1 Dutch) operated between 1998 and 2003 with the first series of a TKA implanted with a balanced gap technique (433 (77.7%) fixed, 124 (22.3%) mobile (anterior-posterior gliding (7-9 mm) and rotational (15°) degrees of freedom) inserts) were included for survival analysis (Kaplan–Meier, by insert type). At the 12-year follow-up (FU) examination of 189 cases, range of motion, knee society score (KSS), numeric rating scale (NRS) for pain and satisfaction were determined and radiographs were evaluated by median tests, by insert type.

Results Of 521 cases available for analysis, 28 (5.4%; 11 fixed, 17 mobile bearing) were revised. Mean cumulative survival after 12.4 years was 97.0% (95% CI 94.7-98.4) for fixed bearings and 85.4% (95% CI 77.5-90.7) after 12.2 years for mobile bearings, $p < 0.0001$. Patients' mean age at 11.0 years FU ($n = 189$) was 78.0 (range 54.5-97.3) years. Mean total KSS was 157.8 (24-200) points, and mean passive flexion was 114° (45-150); no clinical score differed significantly between fixed and mobile bearings.

Conclusion This study showed a superior survival for fixed bearing compared with mobile bearing in a CR-TKA using a ligament-balanced technique after more than 12 years. Clinical outcomes are excellent to good after long-term follow-up, and similar for fixed and mobile bearing.

Level of evidence: Therapeutic studies - retrospective cohort study, Level III.

Keywords: Total knee arthroplasty; Ligament balancing; Dependent gap total knee arthroplasty; Balanced gap technique; Survival; Long-term follow-up; Fixed bearing; Mobile bearing; Clinical outcome

Introduction

Meta-analyses show that cruciate-retaining (CR) and posterior-stabilized (PS) total knee arthroplasty (TKA) can have similar clinical outcomes with regard to knee function and postoperative knee pain [9, 12]. Registry data show superiority of CR designs over PS designs on the mid-term survival. The technique of ligament balancing (tensioning of the PCL and determining rotational alignment of the femoral implant during flexion balancing with a tensioner) is difficult [4–6] and no objective instructions existed on how to balance the ligaments. Short- to mid-term results of TKA using the ligament balanced technique with either a fixed bearing (FB) or a mobile bearing (MB; anterior-posterior (AP)-gliding (7-9 mm) and rotational (15°) degrees of freedom) showed good outcome and few complications and revisions [17, 20]. Ligament balancing combined with either a fixed or a mobile bearing insert is not a forgiving system, and the long-term results might be less predictable.

In general, mobile bearing inserts in TKA have been claimed to reduce polyethylene wear by increasing conformity of the articulating bearing surface and hereby minimizing the stress transmitted to the implant-bone interface. Whether this increased mobility eventually leads to superior survival and outcome remains to be investigated. Meta-analyses investigating survivorship did not find any clinically relevant differences in revision rates between MB and FB TKA [18, 21]. In these studies, no specific analyses were performed for measured resection versus ligament balancing implantation techniques, and the follow-up was shorter than 10 years. Hence, there is need for a long-term follow-up study [21] of a cross-sectional multi-centre cohort, to determine survival of ligament-balanced TKA.

The purpose of this multi-centre cohort study was to compare long-term survival between fixed and mobile bearing inserts in a primary TKA using a ligament balancing technique and investigate the 12-year clinical outcome in a subset of the cohort. It has been hypothesized that long-term survival and clinical outcome will be equal for the fixed and mobile bearing inserts. This is the first long-term study on ligament-balanced TKA, and the results may be generalizable to national or regional community-based practices, and can assist surgeons in making choices on implantation technique and help in managing patient expectations with regard to long-term clinical outcome of a ligament-balanced TKA.

Materials and methods

In this retrospective cross-sectional cohort study, patients of three clinics receiving the first series of a ligament balanced TKA (balanSys, CR knee system Mathys Ltd, Bettlach, Switzerland) with either a fixed (Figure 1a) or a mobile bearing (anterior-posterior gliding (7-9 mm) and rotational (15°) degrees of freedom, Figure 1b, c) were included. Between 1998 and 2003, 557 cases (501 patients) were operated in two Swiss and one Dutch clinic using a balanced gap technique [20] according to the hospital's databases. With the balanced gap technique, the tibia was cut first and subsequently the rotational alignment (anterior and posterior bone cuts) of the femoral implant was determined during flexion balancing using a tensioner. These 557 cases formed the survival study, and for these cases all efforts were made to contact the patient (or relatives) to verify whether the implant was in situ (by phone, sending letters, contacting known relatives, contacting the general practitioner). Dates of death were verified from the hospital's information system, or from information provided by the patients' general practitioners or relatives, and we verified whether the implant was in situ at the time of death.

A subset of the total cohort of 557 patients was recruited for the cohort determining clinical outcome after 10-year follow-up. All patients were contacted, starting with the patients who were operated first, and those who were able and willing to visit the clinic for a follow-up (FU) visit provided informed consent. For logistic and financial reasons, we stopped with inclusion for follow-up after reaching one third of the total number of patients in the cohort, at a total of 189 cases (Figure 2). Patients of the Dutch cohort were asked about anterior knee pain, and their radiographs were used

Figure 1. balanSys CR Knee system with a a fixed bearing, and b, c a mobile bearing (anterior-posterior (AP)-gliding (7-9 mm) and rotational (15°) degrees of freedom)

to measure patella position in a previously published paper [8]. As summarized in Figure 2, out of 557 cases, 174 were lost to FU due to death and 31 due to unknown address. Four hundred and thirty-three patients (77.7%) received a fixed bearing, and in 124 patients (22.3%) a mobile bearing was used. The study population attending the FU examination consisted of 189 cases (158 patients, 106 female, 52 men) with a mean age of 78.0 (range 54.5–97.3) years at FU.

There were 31 bilateral cases. The mean time to FU was 11.0 (range 8.6–13.6) years after surgery. In 132 cases, a fixed bearing and in 57 cases a mobile bearing was implanted. Patients with a mobile bearing were statistically significantly younger. In seven cases, the patella was resurfaced; in one patient during primary surgery, in five patients during a second surgery—during which one patient also had a simultaneous insert exchange (this case was not included in the FU cohort)—and in one case the time point of replacement was unknown.

Characteristics of the study population who attended FU examination are summarized in Table 1. The most frequent indication for TKA for the FU cohort was primary osteoarthritis (n = 164, 87%) (Table 1). In 64 cases, no previous surgery had been performed on the study knee. For 75 cases, one or more previous surgeries were documented; osteotomy (n = 27), arthroscopy (n = 39), other type, including meniscectomy (n = 25), not documented (n = 50).

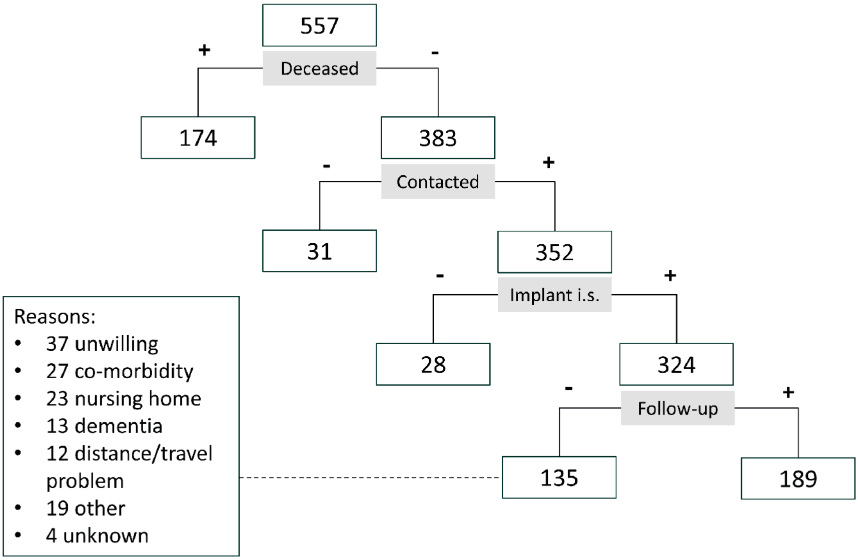

Figure 2. Flow diagram of patient enrolment for the long-term clinical follow-up visit (number of patients)

Table 1. Demographics of the follow-up cohort; values represent frequencies, or mean (SD)

Parameter	Total cases	Fixed bearing	Mobile bearing
N	189	132	57
Age @ surgery (years)	67.1 (44.6-84.2)	69.0 (50.8-84.2)	62.5 (44.6-79.7)*
Gender (m/f)**	52/106	33/75	19/31
BMI (kg/m2)**	28.6 (15.7-40.0)	28.7 (15.7-40.0)	28.4 (20.8-37.6)
Side (L/R)	81/108	57/75	24/33
Diagnosis			
Primary osteoarthritis	164	115	49
Secondary osteoarthritis after trauma	14	7	7
Rheumatoid arthritis	6	5	1
Other***	5	5	
Surgical approach			
Medial	145	101	44
Lateral	39	26	13
Unknown	5	5	0

* statistically significant difference between fixed and AP-glide bearing ($p < 0.001$) .
** total was 158, bilateral cases counted only once.
*** Morbus Ahlbäck (2), preliminary arthrodesis due to multifragmentary fracture, meniscectomy with arthroscopy, Ehlers-Danlos Syndrome.

Follow-up examination

Patients visited the clinic where they had been operated more than 10 years ago and were examined by independent physicians (not their surgeons). Information was collected from the medical charts on indication for surgery, previous surgery, and surgical details including bearing type. In addition, patients were asked about major postoperative complications, re-operations and (partial) revisions. Clinical examination consisted of the knee society score (KSS) with active and passive knee flexion with a standard goniometer and scored to the nearest 5 degrees. Pain and satisfaction scores were assessed with a numerical rating scale (NRS) (0–10) with for pain a 0 representing no pain and for satisfaction a 10 representing very satisfied. Patients were asked whether feelings of instability, clicking and impingement in association with movement were present (yes/no). Radiographs (AP and lateral) were performed to score radiolucent lines (defining radiolucent lines as the distance of the bone-implant interface >2 mm) around the implant.

Statistical analysis

For the calculation of the survival rate, only cases with a known endpoint were included. Implant survival was estimated with the use of the Kaplan–Meier method, reporting the estimates of the cumulative probability of remaining free of revision and 95% confidence intervals (CI). Two analyses were performed: one for all cases, and one by insert type. Differences in survival curves for fixed and mobile bearing were tested with the log-rank test.

Descriptive statistics are reported as means (range), or as frequencies and percentages when appropriate. Comparisons between fixed and mobile bearings were performed with the use of a nonparametric median test, because of the different group sizes. STATA10.1 was used for all analyses. The alpha level was set at ≤0.05 for significance. This study was approved by two ethical committees: Kantonale Ethikkommission, Bern, application number 202/10, and Independent Review Board Nijmegen, application number NL37085.072.11, IRBN2011019.

Because of the descriptive nature of this study, no sample size calculation was performed. The number of patients included was a consequence of searching in databases for eligible patients. After having defined the study population for the survival cohort, 1/3 of the patients were contacted for invitation for the clinical follow-up visit, starting with patients operated on in 1998 in order to have the longest follow-up.

Results

Of the available 521 cases for analysis, 28 (5.4%) were revised; of 36 patients no known endpoint or survival time was available. The total number of revised implants was 28 (fixed bearing n = 11; mobile bearing n = 17). Reasons for revision are presented in Table 2. Instability was the most frequent reason for revision.

The survival rates for all cases and for each bearing type are shown in Figures 3 and 4. The mean cumulative survival after 12.3 years was 94.2% (95% CI 91.6–95.9) for the total group. For the fixed bearing, the mean cumulative survival after 12.4 years was 97.0% (95% CI 94.7–98.4) and 85.4% (95% CI 77.5–90.7) for the mobile bearings after 12.2 years. Survival was significantly different for cases with a fixed bearing compared with a mobile insert ($p < 0.0001$).

Table 2. Reasons for revisions (n) out of 557 cases

Reasons for revision	Total cases	Fixed bearing	Mobile bearing
Instability*	9	4	5
Limited ROM and/or pain	6	2	4
Loosening	4	2	2
Infection	3	1	2
Prosthesis size	2	1	1
Other**	4	1	3
Total	28	11	17

* Reported feeling of instability with/without pain
** Persisting irritated synovitis and retropatellar symptoms (1), suspicion allergic reaction material prosthesis (1), fall and dislocated trans and supracondylar femur stem fracture (1), internal rotation malalignment and pain (1)

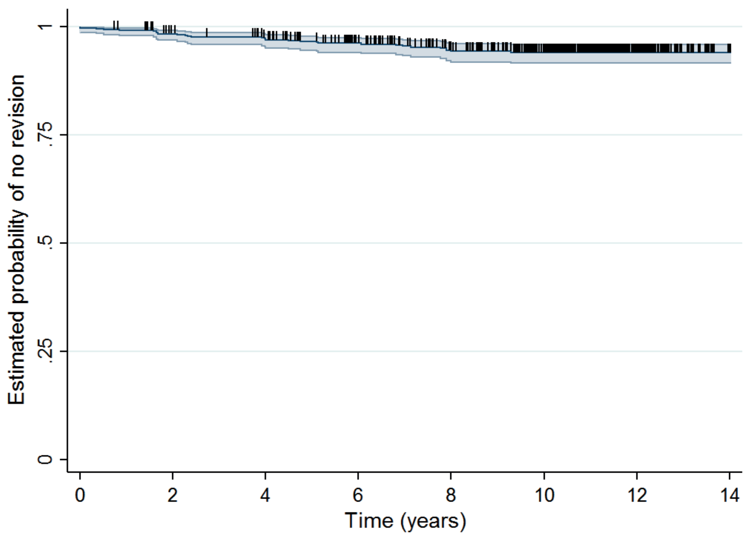

Figure 3. Cumulative survival of 521 TKAs (total group) with revision surgery defined as failure event. The small vertical spikes represent the censored data

Eleven years after TKA, mean KSS for the total group was 158 points (24-200) and passive knee flexion was 114° (45-150). There were no significant differences in KSS, knee flexion, NRS pain and satisfaction scores between the patients with a fixed and mobile bearing, neither for all KOOS subscales. Patients with a mobile bearing reported 'clicking during movement' significantly more often compared to those

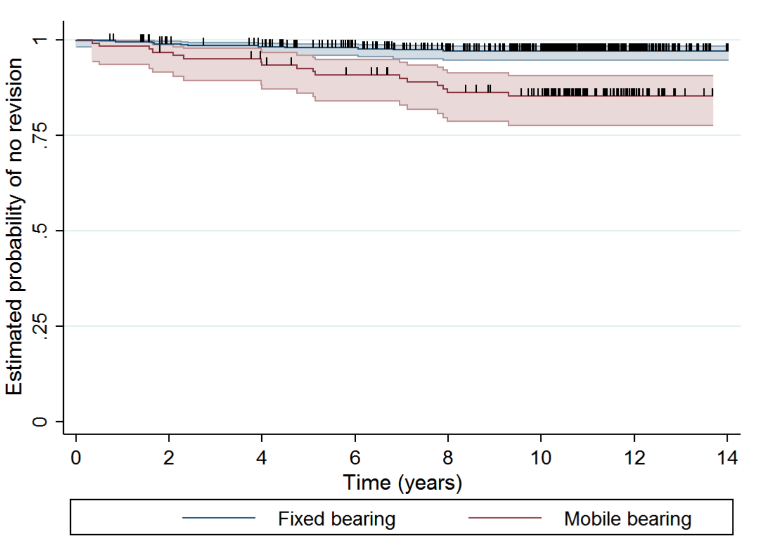

Figure 4. Cumulative survival of 521 TKAs for fixed bearings and mobile bearings separately, with revision surgery defined as failure event. The small vertical spikes represent the censored data

having a fixed bearing; 19 of 57 (33.3%) versus 19 of 132 (14.4%), respectively ($p = 0.011$). In Table 3, the clinical results are summarized and presented for the total group and specified for bearing type as well. In total, 41 complications were reported. Three patients reported two complications. Seventeen falls, eight mobilizations under anaesthesia, two infections, and fourteen other complications were reported. In Table 4, the cases are summarized and stratified by bearing type. There is no significant difference between the number of cases reporting one or more complications between fixed bearing (n = 11) and mobile bearing (n = 17; n.s.). Radiolucent lines (>2 mm) behind the femoral component were found in 1 case with fixed bearing (0.8%) and 2 cases (3.5%) with mobile bearing (n.s.). For the tibia, the number of cases showing one or more radiolucent lines on the AP-view was 5 (3.8%) for the fixed and 1 (1.8%) for the mobile bearing (n.s.). Also, no significant difference on the lateral view of the tibia between the inlay types in the number of cases showing one or more radiolucent lines were found: 2 (1.5%) and 1 (1.8%) for fixed and mobile bearings, respectively.

Table 3. Clinical parameters at long-term follow-up; values represent means (range)

Clinical parameter	Total cases	Fixed bearing	Mobile bearing
KSS (points)	157.8 (24-200)	155.8 (24-200)	162.5 (90-200)
KSS clinical (points)	87.7 (34-100)	88.3 (34-100)	86.4 (48-100)
KSS functional (points)	70.1 (-10-100)	67.5 (-10-100)	76.1 (0-100)
Passive knee flexion (°)	114.1 (45-150)	113.0 (45-150)	116.7 (85-130)
Active knee flexion (°)	110.8 (45-135)	110.0 (45-135)	112.5 (75-135)
NRS pain (0=no pain)	1.7 (0-10)	1.7 (0-10)	1.7 (0-8)
NRS satisfaction (10=very satisfied)	8.6 (0-10)	8.6 (0-10)	8.4 (1-10)
KOOS pain	81.5 (8.3-100)	81.6 (8.3-100)	81.1 (38.9-100)
KOOS symptoms	81.9 (32-100)	82.6 (32.1-100)	79.7 (32-100)
KOOS activities of daily living	77.7 (10.3-100)	77.1 (10.3-100)	79.4 (40-100)
KOOS sports and recreation function	47.1 (0-100)	49.7 (0-100)	40.2 (0-95)
KOOS knee-related quality of life	69.6 (0-100)	70.2 (0-100)	67.2 (25-100)
Feeling instability, n (%)	21 (11.1)	12 (9.1)	9 (15.8)
Feeling impingement, n (%)	22 (11.6)	15 (11.4)	7 (12.3)
Hear clicking, n (%)	38 (20.1)	19 (14.4)	19 (33.3)*

KSS=Knee Society Score; NRS=numeric rating scale
*p=0.011

Table 4. Complications of patients who attended the long-term follow-up

Complications	Total cases*	Fixed bearing	Mobile bearing
None	149	106	43
Fall	17	12	5
Manipulation under anaesthesia	8	4	4
Infection**	2	2	0
Patella subluxation	1	1	0
Other***	11	7	4
Total of number complications	39	26	13

*2 missing
**not leading to revision
***including 4 cases with secondary patella resurfacing

Discussion

The most important finding of the present study was that implant survival was superior for fixed bearing compared with mobile bearing in ligament-balanced TKA after 12.3 years. The survival rate of the mobile bearing is unsatisfactory (85.4%). Our hypothesis could not be confirmed. Instability was the most frequent reason for the revisions of the mobile bearing group. The failure mechanism remains unknown, but perhaps a combined AP-glide and rotating mechanism in these mobile bearings, in combination with a possible higher demand of the younger patients, resulted in too many degrees of freedom. In a previous paper on the same implant, a difference in favour of the fixed bearing design in stair climbing has been reported [9]. This (unexplained) difference may be caused by a mid-flexion instability, and a paradoxical roll-back of the femur causing fat-pad impingement in mobile bearings [2]. With the introduction of this system, ligament balancing got started and publications on this difficult technique were yet to come [4, 6, 10]. The mobile bearing of the combined AP-glide and rotating insert has already been withdrawn from the market by the company in 2009. The major problems were instability and problems with the patella, resulting in revisions. However, the patients who still have this mobile bearing type insert in situ were similarly satisfied and had equal clinical outcomes as those with the fixed bearing. In a number of patients, the mobile (AP-glide + rotating) bearing was replaced by a rotating-platform insert of the same system, which was available some years later and was accompanied by an easy revision technique, which worked well. Recent reports demonstrate comparable clinical outcome in fixed and mobile bearing (rotating platform) CR-TKA [13].

The findings of the present study are consistent with those found by Namba et al. [14] who reported highest survival rates for fixed bearing inserts and a higher risk for revision of mobile CR inserts, based on data of a total joint replacement registry. However, data up until 7 years of FU were available and implants of multiple manufacturers with different implantation techniques were included. The conclusions of the meta-analysis by Van der Voort et al. [18] were in contrast to the findings of the present study. They reported no differences in revision rates at 5 and 10 years between fixed bearings and all kinds of mobile bearings. Again, that meta-analysis did not include this specific implant with ligament balancing technique and also included PS-TKA. Possibly, implantation technique and implant type play a role. Furthermore, as Carothers et al. [3] showed, the different types of mobile bearings showed a different fifteen-year survivorship.

Clinical outcome after over 12 years of follow-up of a cohort of patients with an average age of nearly 80 is good to excellent. The scores on the KOOS subscales pain, symptoms, activities in daily living and knee-related quality of life are close to reference data of an equally aged population [15]. With an average passive knee flexion of 114° and an active knee flexion of 111° for the total group, these results indicate that the aim of 110° of knee flexion of a suitable knee rehabilitation has been well met [16]. No clinical differences between the two bearing types were found, as also confirmed by others with different implant systems [1, 7, 11]. The higher frequency of radiolucent lines in mobile bearing TKA (rotating platform) as found by Bailey et al. [1] could not be confirmed by the present study.

Wyatt et al. reported the New Zealand Joint Registry data suggest that CR fixed bearing and mobile bearing TKR designs implanted without resurfacing of the patella are superior to fixed bearing PS designs in terms of rates of secondary patellar resurfacing. These results imply that the patella can be left unresurfaced if using a mobile bearing design [19]. For the present study, secondary patella resurfacing was not counted as total system revision.

A limitation of the present study is the potential for selection bias. It is possible that a particular surgeon's criteria for using an AP-glide bearing design for an individual patient may be related to activity level, or a particularly high demand for knee motion, sporting activity, or other anticipated patient goals. Our data were not detailed enough to capture this degree of surgical indications. A second limitation might be the finding that patients with a mobile bearing were statistically significantly younger than patients with a fixed bearing and this might have biased the results, as functional difficulties increase with age [15]. This phenomenon follows logically from the fact that mobile bearing inserts in TKA were developed for younger patients, based on the idea to gain a bit more flexion and reducing polyethylene wear by increasing conformity of the articulating bearing surface [14]. After performing a logistic regression analysis with revision as dependent variable, and age at surgery and insert type as independent variables, only insert type was a statistically significant predictor for revision. Therefore, we believe that age was not a confounder for the survival analysis in the present study. A third limitation might be that including only the living and healthy patients for attending the FU visit, the clinical results can be biased into an overestimation. In addition, multiple centres and surgeons were involved in the study. While some may consider this a drawback, we see this as a benefit because we were able to obtain sufficient power for analysis. Furthermore, our study accurately replicates the community scenario, in which multiple surgeons of various centres are using similar implants in regular clinical practice, resulting in better generalizability. The results of this study show that this ligament-balanced CR-TKA system is safe to use and works in the long term, and delivers clinical results comparable to other standard TKA systems.

Conclusion

The results of this study showed a superior survival for fixed bearing (97.0%) compared with mobile bearing (AP-glide and rotating) (85.4%) in ligament-balanced TKA. Clinical outcomes are good, and close to population reference values, after 11 years of follow-up.

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Chapter 4

Patella position is not a determinant for anterior knee pain 10 years after balanced gap total knee arthroplasty

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Abstract

Purpose Incidence of anterior knee pain after total knee arthroplasty (TKA) is reported to be between 4 and 49 %. The incidence of AKP at long-term follow-up and possible determinants after cruciate cruciate-retaining TKA were investigated.
Methods A 10-year follow-up of a cohort of 55 patients (63 TKAs), who received the balanSys™ cruciate-retaining total knee system (Mathys Ltd, Bettlach, Switzerland) between 1999 and 2002, was performed. Patients had undergone the balanced gap technique, with either a fixed bearing or an AP-glide bearing. Standardised diagnostic questions regarding AKP were collected and categorized into two groups: those with and without AKP. The lateral patellar tilt, patellar displacement measurement and modified Insall-Salvati ratio were used for patella position evaluation on skyline radiographs. The Knee Society Score (KSS), the Knee Osteoarthritis Outcome Score (KOOS) and Numerical Rating Scales (NRS) for pain and satisfaction were obtained at follow-up.
Results Sixteen patients in the study population experienced AKP. Incidence of AKP (fixed bearing 13/44; AP-glide bearing baring 3/17) was not dependent on type of insert (n.s.). There were no statistical differences in patella position and tibiofemoral contact point between the AKP group and the no AKP group (n.s.). KSS, KOOS, NRS-pain and NRS-satisfaction were significantly lower for the patients with AKP (all $p < 0.05$).
Conclusion Twenty-six percentage of the patients experienced AKP 10 years after balanced gap TKA. Postoperative patella positioning was not found to be a determinant for anterior knee pain after TKA. However, patellar displacement does not seem completely favourable. Moreover, type of bearing was not found a determinant for AKP at long-term follow-up.

Level of evidence: Lower quality prospective cohort study (<80 % follow-up, patients enrolled at different time points in disease), Level II.

Keywords: Knee arthroplasty; Anterior knee pain; Patella position; Balanced gap technique

Introduction

Anterior knee pain (AKP) is one of the major challenges after total knee arthroplasty (TKA) and one of the major reasons for revision surgery [1, 3, 10, 11, 28]. Incidence of AKP after TKA is reported to be between 4 and 49 % [1, 9, 22, 32, 35]. The intensity of pain tends mostly to be mild to moderate [29]. Daily activities such as climbing stairs, cycling, getting up from a chair or even normal walking are impaired due to this type of pain.

The pathogenesis remains unclear, but several potential determinants have been proposed. One of the supposed causes is abnormal patellofemoral tracking. Retropatellar pressure and patella tracking can be disturbed after TKA [28]. Altered patellar kinematics after TKA can potentially contribute to patellar complications in TKA. A couple of studies did not find an association between the amount of patellar tilt and subluxation and AKP [35]. There was only one study that described the patella position in cruciate-retaining (CR) TKA and related it to AKP; no correlation was found. In that study, at index surgery they performed a resurfacing of the patella [17]. However, there has been no published study that correlates the presence of AKP with patella positioning in CR-TKA, according to the balanced gap implantation technique, without resurfacing of the patella.

Patellar height is another factor that could influence the occurrence of AKP. Patella baja could lead to AKP, although the incidence of patella baja after TKA is low [12]. Patella alta is associated with a higher patellofemoral contact force compared to the normal patella position. However, several studies did not find a correlation between patella height and the development of AKP [35].

The type of bearing might also influence results in different patellar kinematics and subsequently in AKP. A few studies have demonstrated a potential benefit of mobile bearing TKA compared to the fixed bearing TKA [8, 10, 32, 37]. However, some suggested that the performance of the mobile bearing might decline over time [1, 9]. Some studies reported lower patellofemoral contact stresses in the mobile bearing design compared to the fixed bearing design [31].

The tibiofemoral contact point (CP) is another suggested potential determinant for AKP [15, 36]. As previously mentioned, greater anterior positioning of the tibiofemoral CP leads to a reduced lever arm of the extensor mechanism and leads to higher patellofemoral pressure [27]. Femoral component and tibial rotation are also believed to be factors influencing patellar-tracking behaviour [3, 5, 29].

There are only a few studies that report the incidence of AKP, with a reasonable sample size, at long-term follow-up after TKA without resurfacing of the patella. Furthermore, until today there has been no study that correlates AKP with radiological reproducible measurement techniques for patella positioning, 10 years after CR-TKA according to the balanced gap technique. Therefore, the purpose of the present study was fourfold. The first goal was to describe the incidence of AKP, clinical outcome and satisfaction in a cohort 10 years after balanced gap CR-TKA without resurfacing of the patella. Secondly, an altered position of the patella being: displacement ≥4 mm, patellar tilt ≥10°, patella alta or baja was hypothesised to be a determinant for AKP. Thirdly, a more anterior positioned contact point could was hypothesized to lead to AKP. Finally, fixed bearing in CR-TKA was hypothesised to be a determinant for AKP.

Materials and methods

A ten-year follow-up of patients, who received a PCL-retaining total knee prosthesis using the balanced gap technique between 1999 and 2002, was performed. A total of 129 patients (149 TKAs) were operated on between 1999 and 2002. Eight patients received bilateral TKA. Fifty-five patients (63 TKAs) were eligible for the 10-year follow-up (Figure 1). Two patients were retrospectively excluded. One was excluded because the indication for TKP was invalidated due to medial compartment arthritis after lateral unicompartmental knee arthroplasty (UKA). The second patient was excluded because the patient received a patella button prior to follow-up. One patient suffered from a cerebrovascular stroke, which resulted in incomplete data

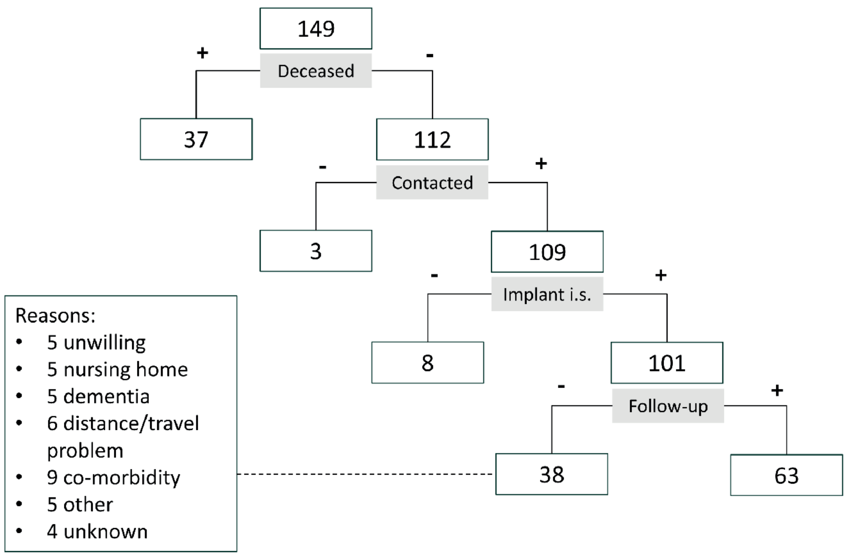

Figure 1. Flow chart of follow-up

but was included for analysis. All participating patients provided written informed consent. At the outpatient clinic, an independent observer evaluated and scored all patients (AvH).

Operation technique

All patients received the same knee prosthesis. The balanSys™ cruciate-retaining total knee system (Mathys Ltd, Bettlach, Switzerland) was implanted according the balanced gap technique [34]. At the time of the index surgery, no patellar components were placed. All the patients received the same postoperative regimen.
Of the total study population, 44 knees received a fixed bearing and 17 knees received an AP-glide-bearing TKA. The AP-glide bearing was introduced in our clinic in the year 2000 and used predominantly in younger and more physically active patients. The femoral component was identical in design for the fixed and the AP-glide bearings. Orthopaedic surgeons specialising in TKA performed the operations in all patients.

Outcome parameters

The patients' medical reports, operative reports and postoperative radiographs were collected and reviewed by one author (AvH). Follow-up consisted of a one-time visit and included clinical, physical and radiographical evaluation. Classic questions regarding AKP were asked of all patients in a standardised fashion (Table 1).
The American Knee Society Score (AKSS) was used to determine function, pain, range of motion (ROM) and stability of the knee [21]. The Knee Osteoarthritis Outcome Score (KOOS) was used as patient-reported outcome score [14].
The radiographical evaluation consisted of anterior-posterior and lateral conventional radiographs of the operated knee. For patellofemoral imaging, the leg was set in a leg holder with a knee flexion of 20°–30°. For patellar tilt, the lateral patellar tilt measurement technique (cut-off point ≥10°) was chosen, and for displacement, the patellar displacement measurement was chosen (cut-off point ≥4 mm) [12, 26]. These techniques are the most reproducible ones for measuring patellar tilt and displacement on skyline patellar radiographs after TKA [19]. The modified Insall-Salvati ratio was used to determine real patellar height on the postoperative lateral radiograph [18]. The Blackburne-Peel ratio was used to determine pseudo-patellar height [7, 13]. The postoperative tibiofemoral CP was measured in all patients on the lateral radiograph [15]. Measurements were taken to the nearest degree.
The local medical ethical committee approved the study design [Independent Review Board Nijmegen (IRBN), Wijchen, The Netherlands (NL37085.072.11)].

Table 1. Questionnaire for AKP

Questions	Answer
Are you experiencing anterior knee pain?	Yes / No
Does the pain in your knee get worse when standing up from a chair?	Yes / No
Does the pain in your knee get worse when climbing stairs?	Yes / No
Does the pain in your knee get worse when cycling against the wind?	Yes / No
Does the pain get worse when getting in or out of a car?	Yes / No

Statistical analysis

An a priori sample size calculation could not be performed; all available patients who received this specific implant were invited for participation. Patients were divided into two groups: AKP or no AKP. AKP was scored if the patient responded yes for two or more items on the questionnaire in Table 1. All potential risk factors and radiological scores were compared between these groups using cross-tabs with Fisher's exact tests or two-sample t tests with unequal variances. 95 % Confidence intervals for the differences in proportions and means are given. Significance was set at a level of <0.05.

Results

In total, 16 patients experienced AKP (26 %). In 44 patients, there was an absence of AKP. Demographic data are presented in Table 2. Forty-four patients received a fixed bearing and 17 an AP-glide bearing (Table 3). In the fixed bearing group, 13 patients experienced AKP. Three patients experienced AKP in the AP-glide group. There was no statistical difference between the incidences of AKP between the two groups (difference 12.6, 95 % CI [−10.2 to 35.3]); n.s. indicating that type of insert was not a confounding variable. Patients who received the AP-glide bearing were significantly younger ($p = 0.005$). There was no significant difference in AKSS regarding range of motion between patients either with or without AKP, although the total AKSS seemed to be higher for patients without AKP (Table 2).

Patellar displacement and the lateral patellar tilt were not statistically different between the two groups (Table 4), although a patellar displacement might be unfavourable (difference 23, 95 % CI [−8.7 to 54.7]). There was also no difference in patellar height measured according the modified Insall-Salvati ratio and the Blackburne-Peel ratio. In addition, the tibiofemoral CP was not different between the patients with AKP versus an absence of AKP (Table 4). The tibiofemoral CP was 62.5 % (SD 5.5) for the fixed bearing compared to 53.6 % (SD 5.4) for the AP-glide bearing. This resulted in a significant difference ($p < 0.001$).

Table 2. Demographic data [mean (SD)] with difference (95 % CI)

	Absence of AKP (n= 44)[a]	AKP (n= 16)[a]	Difference (95%CI); p-value
Age	64.1 (10.0)	63.5 (7.6)	0.5 (-4.5 to 5.4); p=0.85
Male: female	11:33	4:12	p=1.0
Follow-up (years)	10.7 (0.8)	10.6 (0.6)	0.1 (-0.3 to 0.5); p=0.56
AKSS (points)	154 (34)	133 (39)	21 (-2 to 44); p=0.071
Passive flexion (degrees)	112 (12)	111 (12)	1 (-6 to 8); p=0.75
Passive extension (degrees)	0.3 (4)	0.9 (7)	-0.6 (-5 to 3); p=0.76

[a]= 1 missing

Table 3. Anterior knee pain; number of patients

Type of bearing	Absence of AKP	AKP	Percentage AKP
Fixed	30	13	30.2%
AP-glide	14	3	17.7%
Difference (95% CI)			12.5% (-10.2 to 35.3); p=0.32

The groups with AKP scored significantly worse on the subscales of the KOOS for pain, symptoms, ADL and quality of life (Figure 2). The subscale for sport and recreational activity showed no statistical difference. Patients with AKP had significantly more pain and were less satisfied compared with patients without AKP (Figure 3).

Table 4. Radiological outcomes; mean (SD), number of patients

	Absence of AKP	AKP	Incidence AKP (%)	Difference in percentage (95%CI); p-value
Patellar displacement <4mm	38	11	22.5%	23% (-55 to 9); n.s.[a]
Patellar displacement ≥4mm	6	5	45.5%	
Patellar tilt <10°	34	10	22.7%	0.4% (-26 to 26); n.s.[a]
Patellar tilt >10°	10	3	23.1%	
Modified Insall-Salvati ratio[c]	1.44 (0.2), 44	1.48 (0.2), 16		-0.035 (-0.15 to 0.085); n.s.[b]
Blackburne-Peel ratio[c]	0.53 (0.1), 41	0.59 (0.1), 15		-0.056 (-0.14 to 0.034); n.s.[b]
Tibiofemoral contact point[c]	59.3 (7.1), 43	62.0 (5.8), 16		-2.7 (-6.4 to 0.95); n.s.[b]

[a] Two-sample test of proportions
[b] Two-sample t test, unequal variances
[c] Modified Insall-Salvati 1 missing, Blackburne-Peel ratio 4 missing, Tibiofemoral contact point 1 missing

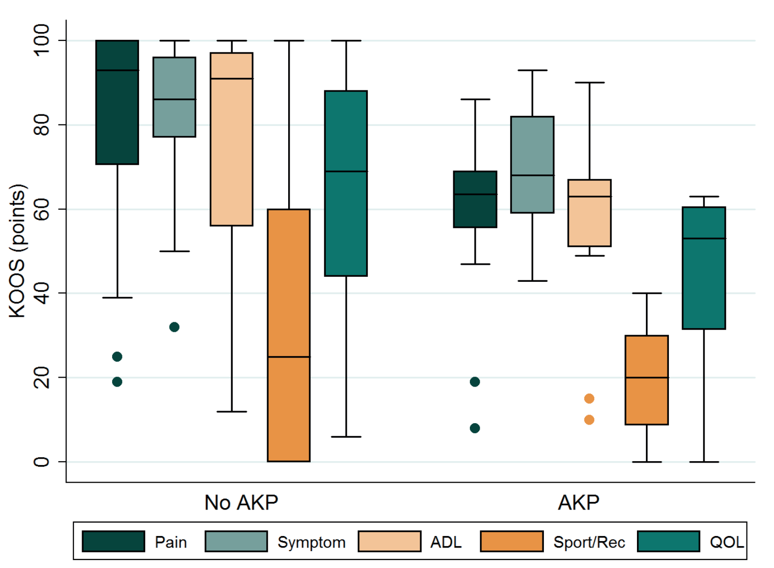

Figure 2. Different subscales for the KOOS questionnaire for patients with and without AKP

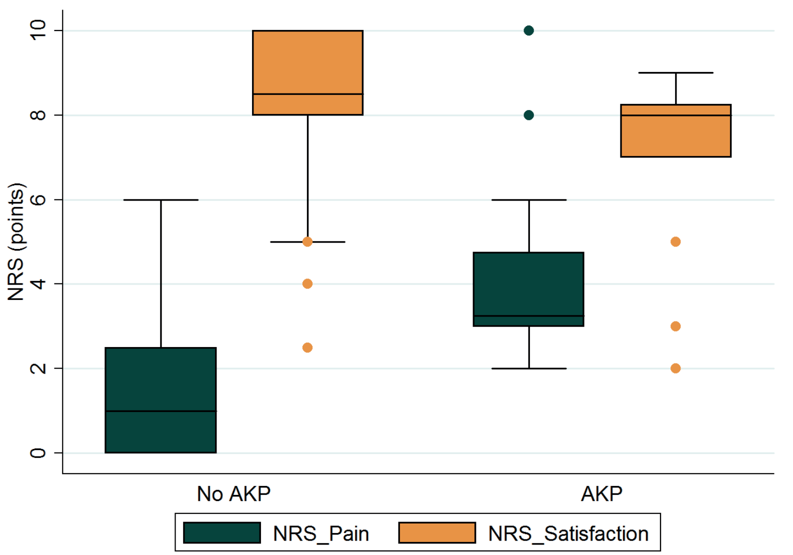

Figure 3. NRS-pain and NRS-satisfaction for patients with and without AKP

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Discussion

The most important finding of this cohort study was that 26 % of the patients experienced AKP 10 years after balanced gap CR-TKA with non-resurfacing of the patella. AKP could not be explained by a radiographically abnormal position of the patella or patellar height. Furthermore, type of bearing was not a determinant for AKP 10 years after TKA according to the balanced gap implantation technique. Tibiofemoral CP was not different in patients with AKP compared to patients without AKP. Finally, patients with AKP had significantly lower clinical outcome scores.

This study is one of the few studies that report long-term incidence of AKP after TKA. Only one study reported the incidence of AKP 10 years postoperative after CR–TKA [11]. In that study, 43 % of the patients (n = 28) reported AKP. Besides, patients with AKP were not categorized based on standardised questions related to AKP. Another study described an incidence of 7.5 % of AKP after posterior stabilised TKA (PS–TKA) with a follow-up of more than 10 years [22].

Although some biomechanical studies showed that patellofemoral pressure was significantly higher in CR than in posterior stabilised arthroplasty, the incidence of AKP in the present study corresponded with the numbers reported in the literature [4, 31]. Becher et al. [4] suggested kinematic differences between cruciate-retaining and posterior stabilised arthroplasty with a greater and more consistent posterior femoral rollback and less paradoxical anterior sliding of the femur for subjects having a PS–TKA. However, a meta-analysis showed no difference in postoperative pain between CR–TKA and PS–TKA up to 5 years of follow-up [25]. A recent published study reports a lower incidence of AKP [22]. However, that study does not clearly report how AKP is defined or categorised.

Patients with AKP had significantly lower clinical scores compared to patients without AKP. The importance of the subject was emphasised by the present results, showing that AKP resulted in higher reported pain and significantly lower satisfaction. However, in general patients with AKP were significantly less satisfied although they quantitatively scored fair to good. Nevertheless, AKP is one of the common reasons for reoperation or revision [28].

The amount of patellar displacement or patellar tilt could not be related to an increase in incidence of AKP as consistent with previous studies [35]. Therefore, it seems that patella position was not a relevant determinant for AKP. However, in those previous studies, concerning TKA without resurfacing of the patella, it is not described which method is used for measuring patella displacement and patellar tilt. In the present study, we used the measurement techniques with the highest reproducibility [19]. Because of the rather broad confidence interval and the smaller AKP, we cannot rule out patellar displacement >4 mm being a determinant completely. Furthermore, in those past studies and the present study, the patellar displacement and patellar tilt were measured in a non-weight-bearing situation. A weight-bearing situation might lead to a different conclusion [2]. In contrast, contraction of the thigh muscles may result in centralisation of the patella into the trochlear groove and potentially lead to less patellar displacement and patellar tilt. Patellar height was not different between the two groups and therefore was not considered a determinant. In the present study, none of the operations led to a patella baja.

The type of bearing was not a determinant of AKP in the present study. This was in contrast with several studies reporting that the mobile bearing TKA might lead to a lower incidence of AKP [6]. The studies that reported these findings were mainly short-term follow-up studies [8, 24]. In the literature, the ability of the mobile bearing to self-align and to correct small mismatches perhaps decline over time [1, 9, 30, 35]. The present study showed that in long-term follow-up, there was no advantage or disadvantage for a mobile bearing insert type in the TKA with non-resurfacing of the patella, using the balanced gap technique. Although the AP-glide bearing had been used predominantly in younger patients, age was not a confounding factor in the relationship between AKP and type of bearing.

The tibiofemoral CP was also not statistically different between the two groups. The hypothesis that a more anterior positioned CP led to a higher incidence of AKP could therefore not be confirmed. The CP in the AP-glide bearing group was significantly more anterior as mentioned in the literature [36]. However, the absolute difference was small and it seems that with this CP, the PCL seemed to be well balanced [36].

One of the main limitations in the present study was that a validated instrument for measuring AKP was not used. Unfortunately, the Kujala AKP score had not yet been validated when this study was conducted, but this seems to be a reliable and valid instrument for measuring AKP after knee arthroplasty [23]. However, standardised questions regarding AKP were used; this is in contrast to several studies reporting on AKP that solely asked for presence of AKP or did not define their definition of AKP [35]. The amount of patients eligible for follow-up was limited. A larger study with more patients with AKP might find other determinants for AKP. However, up till today there are no larger studies that evaluated AKP and patella position 10 years after CR-TKA [35].

Another limitation of the present study was that there were some missing data (maximum of 7 %) in the radiographical analysis due to poor conventional radiographs on which patella position could not be measured reliably. Furthermore, it would have been interesting to compare the preoperative patella position compared with the postoperative position [19]. At the time of the index surgery, patella skyline views were not obtained routinely, and therefore, a comparison was not possible. Also, it would have been interesting to use CT scans in patients with AKP to measure the component rotation although a femoral component rotation between −3° and 12°

does not lead to an altered patella position in CR-TKA according the balanced gap technique [20].
The exact pathogenesis of AKP still remains unclear and is probably multifactorial. A potential factor could be the variation in the amount of anterior femur cut during standard TKA implantation. A small anterior femur cut could lead to overstuffing of the patellofemoral compartment, while an increased anterior femur cut could perhaps result in the opposite. This might lead to a different trochlear orientation and to different patellofemoral kinematics compared to the native knee. How much the femoral component design can compensate for this can be argued. A study by Dejour et al. [16] supports this theory. They noted that some femoral component designs exhibit characteristics of trochlear dysplasia. Furthermore, mediolateral positioning of the femoral component could be an influencing factor. A recent study showed that a more medial position of the femoral component leads to a significantly better postoperative outcome in terms of pain and satisfaction at mid- to long-term follow-up [33]. This can probably be explained by the non-physiological lateral orientation of the trochlear groove in TKA designs.
A recent systematic review suggested that only a weak recommendation can be made for femoral components with a posterior centre of rotation, resection of Hoffa's fat pad, patellar rim electrocautery and preventing combined component internal rotation [35]. In addition, decreased strength of thigh, hip and trunk stabilising muscles is functional causes of AKP and may be responsible for dynamic valgus malalignment. This could potentially result in patellar maltracking [28].
Based on the evidence provided by this study and those previously published, the authors conclude that an abnormal radiographical position of the patella will not necessarily result in AKP. Furthermore, incidence in AKP at long-term follow-up is high and this need to be informed preoperatively to the patient to manage expectations.

Conclusion

In conclusion, 26 % of the patients experienced AKP 10 years after TKA, without resurfacing of the patella, using the balanced gap technique. No determinants were found that could explain the incidence of AKP 10 years after TKA, although patellar displacement >4 mm might be unfavourable. In long-term follow-up, type of bearing seems not to be a factor of influence. The clinical outcomes scores were significantly lower for patients with AKP.

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Chapter 5

Measurement techniques to determine tibial rotation after total knee arthroplasty are less accurate than we think

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Abstract

Background The present study assessed the inter- and intra-observer reliability of tibial and femoral rotation measures after total knee arthroplasty (TKA), and evaluated the correlation between these measurement techniques and their clinical relevance.
Methods Femoral rotation and tibial rotation were determined on 42 2D-CT-scans made three months after TKA. Reliability of the radiological measurements (including Berger's method, the anatomical tibial axis and the tibial tuberosity trochlear-groove) was assessed with 15 randomly selected patients measured twice by three observers. Functional outcomes were scored one-year postoperatively with the KSS, VAS pain, VAS satisfaction, KOOS, and Kujala.
Results The inter- and intra-observer reliability of the rotational measurements ranged from good to excellent (ICC 0.67–0.98). Tibial rotation measured with the Berger technique was most reliable (ICC inter = 0.91; ICC intra = 0.96). No strong correlations were found between the different rotational measures or the clinical outcomes and rotational outliers.
Conclusions Tibial rotation is most reliable measured with the technique described by Berger. There were no strong correlations found between the different tibial rotation measures or between the clinical outcomes and the rotational outliers. Further research is needed to gain more insight into optimal positioning and measuring rotation in TKA for clinical practice.

Keywords: Rotational alignment; Total knee arthroplasty (TKA); Total knee replacement; Tibial rotation; 2D CT-scan; Computed tomography

Introduction

Malalignment due to an internally rotated femoral component, after total knee arthroplasty, may provoke knee pain, synovitis and patellofemoral complications [1,2]. Whereas internal rotation of the tibial component has been associated with postoperative knee stiffness and pain [3–7]. Although no consistent guidelines exist for malalignment after total knee arthroplasty (TKA), generally it is recommended to avoid internal rotation of the tibial component and to place the femoral component in two to five degrees of external rotation [6]. However, the relation between (mal) alignment and clinical outcomes is not clear and the amount of rotation to cause clinical problems is unknown [6,8].

The optimal method to determine rotation of the tibia and femoral component is a matter of debate [9–12]. The medial third of the tibial tubercle, the posterior tibial condylar line, transverse axis of the tibia, patellar tendon, the malleolar axis and the second metatarsal have all been described as anatomical landmarks for correct tibial component rotation [13]. The method described by Berger, using the medial third of the tubercle, is used most frequently to determine tibial rotation [1,2]. An alternative is the anatomical tibial axis (ATA), first described by Cobb et al. [14]. One might expect that the ATA would be more reliable compared to Berger's tibial angle since the measurement seems less complex; fewer CT-slides and fewer steps are needed. Although the ATA and Berger both determine the tibial rotation, the relationship between these two radiological measurements has never been investigated. In addition to the ATA and Berger's tibial angle, the tibial tuberosity–trochlear groove (TT–TG) distance can be used to determine combined femoral and tibial rotational alignment. The TT–TG is often used in patellofemoral pathology to diagnose patellar maltracking. Nevertheless, none of the methods is recognized as the ultimate reference [6,12].

Besides the optimal method, the optimal imaging modality (2D-CT or 3D-CT-scans) to determine rotation of the tibial and femoral component is a matter of debate [10,11,15,16,8]. Recently, 3D-CT-scans gained popularity and showed more reliable and reproducible assessment of tibial and femoral rotation alignment than 2D-CT [10,8,17]. However, 3D-CT is less commonly used in daily clinical practice due to limited availability of specialized software and limited experience in performing these measurements on 3D-CT.

In our search for a feasible, reliable and clinically relevant radiological technique to measure rotation, we proposed three consecutive aims for this study. The first aim was to investigate the intra- and inter-observer reliability of measurements used to assess the femoral and tibial rotation alignment with 2D-CT-scans (e.g., Berger's transepicondylar axis and tibia angle, the ATA and the TT–TG) after TKA. Secondly, the correlation between the tibial rotation measurement techniques (Berger's angle and

ATA) was evaluated. Finally, the effect of rotational alignment on clinical outcome was examined. We hypothesized that patients with an alignment within the recommended range had better clinical outcomes.

Patients and methods

Patients

Forty-two patients (22 left and 20 right knees) were included in this retrospective study; 20 males and 22 females with an average age of 63 ± 4 years [18]. The patients had received a cemented posterior stabilized (PS) TKA because of degenerative joint disease (Genesis II™, Smith and Nephew, Memphis, TN, USA). 2D-CT-scans obtained three months postoperatively and clinical outcomes scored one year postoperatively were available for all patients. Approval of the hospital's investigational review board and the Medical Ethical Review Board of Slotervaart and Reade was obtained and patients gave their written consent.

Outcome measures

Radiological measurements

An extensive description of the measurement protocol is presented in **Appendix I.** Femoral rotation was determined using the method described by Berger, measuring the angle between the posterior condylar axis and the surgical epicondylar axis [2]. Measurements evaluating the tibial rotation included Berger's angle, the ATA and the tibial tubercle trochlear groove distance (TT–TG) [1,2,14,19]. Berger's angle is based on the geometric centre of the proximal tibial plateau, the distal level of the tibial tubercle and the posterior axis of the tibial component [1]. The ATA is the angle calculated from the axis between the lateral condylar centre and medial condylar centre, and the posterior axis of the tibial component [14]. To determine the geometric centre of the proximal tibial plateau for Berger's angle and the lateral and medial condylar centre for the ATA, the slide just below the cement interface was used in which the circumferential tibial cortex was clearly identifiable. The TT–TG is defined as the distance between the deepest point of the trochlea and the centre of the tibial tubercle [19,20]. CT-scans were obtained to assess the component rotation of both femur and tibia. Imaging was performed with a helical 2D-CT-scanner (Aquilion 32, Toshiba Medical Systems Corporation, Tokyo, Japan): 135 kV, slice thickness 0.5 mm, and 250 mA. Radiological measurements were performed using IMPAX software (Agfa Healthcare, Mortsel, Belgium), measurements were done to the nearest 0.1°/mm.

Inter- and intra-observer reliability

To evaluate intra- and inter-observer reliability, three independent observers performed the radiological measurements twice, with an interval of at least two weeks, in 15 randomly selected patients. The observers were an orthopaedic resident, a fellow musculoskeletal radiologist and a researcher in the orthopaedic field.

Functional outcomes

Functional outcomes were scored one year postoperatively with the Knee Society Score (KSS), VAS pain, VAS satisfaction, the
patella score (Kujala) and the Knee injury and Osteoarthritis Outcome score (KOOS) with the five subscales pain, symptoms, ADL, sports and quality of life.

Statistical analyses

Intra- and inter-observer agreement was evaluated using a Bland-Altman analysis, calculating limits of agreement (LoA) [21]. In addition, the margin of equivalency (MoE) within and between the observers was determined by calculating the proportion of outcome values of the same measurement falling within 5°/mm of each other [11]. Intra-class correlation (ICC) was used to determine intra-observer reliability (ICC: one-way random, absolute agreement) and inter-observer reliability (ICC: two-way random, consistency). ICC values >0.80 represents excellent reliability, 0.60–0.80 good reliability, 0.40–0.60 moderate reliability, and <0.40 poor reliability [22].
To investigate whether a relationship existed between the tibial radiological measures, and between the radiological outcomes and functional outcomes, correlation coefficients were calculated. Furthermore, based on literature the recommended ranges were defined as presented in Table 1 for rotational measures [1,14,15,23,24]. Since reference data for the TT-TG after TKA is lacking the mean ± SD of the obtained values in the present study was used to define outliers. The Mann-Whitney U test was used to compare clinical outcome scores between patients classified within or without the preferred ranges defined in literature.
The analyses were performed using statistical package STATA 13.0 (StataCorp, College Station, Texas). A p value <0.05 was considered statistically significant.

Table 1. Mean and ranges for radiological measurements techniques. Cut-off points based on mean ± SD

Measurement technique	Mean (standard deviation)	Preferred range
Berger's angle femur (°)	3 (3)	0 to 6
Berger's angle tibia (°)	0 (3)	-3 to 3
Anatomical tibial axis (°)	-6 (3)	-9 to -3
Tibial tubercle - trochlear groove distance (mm)	4 (3)	1 to 7

Results

Inter- and intra-observer reliability

The smallest LoA between the observers were found for Berger's angle of the femur (3.3°) and the TT-TG (3.5 mm), with 98% falling within the MoE. Within observers, the LoA were also smallest for Berger's angle of the femur (2.6°) and the TT-TG (2.2 mm), with 100% falling within the MoE. The LoA between and within observers were larger for Berger's angle of the tibia and the ATA (Table 2), with the MoE ranging between 67% and 93%.

Based on the ICC, the intra-observer reliability varied between 0.67 and 0.91 and inter-observer reliability between 0.82 and 0.96 for all measurement techniques (Table 2).

Correlation tibia rotation measures

The correlation coefficient between Berger's tibia angle and the ATA was 0.52 (Figure 1).

Clinical outcomes

Clinical outcome scores of all 42 patients were obtained one year postoperatively (Table 3). The correlation coefficients obtained for the clinical outcomes and radiological measurements ranged between 0 and 0.44. The strongest correlations were found between the Berger tibia angle and the KSS function (r= 0.44) and the Kujala score (r= 0.41).

Considering the cut-off points from Table 1 defining preferred alignment, a remarkable large number of outliers for Berger's tibia angle and the ATA were found, with 34 and 36 outliers out of 42, respectively (Table 2). No significant differences were found for the clinical outcomes between patients marked as outliers and patients within the preferred alignment.

Table 2. The median (range) values and number of outliers (N Out) of the radiological measures and the inter- and intra-observer reliability of those measures are presented as the limits of agreement (LoA), the margin of equivalency (±5) and the intra-class correlation (ICC).

			Inter-observer[b]			Intra-observer[b]		
Radiological measure	Median (range)[a]	N Out[a]	LoA	± 5	ICC (95% CI)	LoA	± 5	ICC (95% CI)
Mechanical axis (degrees)	0.7 (-4.4 to 5.3)							
Femur – Berger's angle (degrees)	2.6 (-2.8 to 5.8)	6	3.3	98%	0.80 (0.61-0.92)	2.6	100%	0.88 (0.49-0.93)
Tibia – Berger's angle (degrees)	3.8 (-12.6 to 15.7)	34	7.6	67%	0.91 (0.80-0.97)	6.1	93%	0.96 (0.96-0.99)
Tibia – Anatomical tibial axis (degrees)	2.2 (-15.8 to 11.8)	36	9.4	73%	0.67 (0.40-0.86)	5.1	89%	0.82 (0.70-0.90)
Tibial tuberosity – Trochlear Groove (mm)	3.0 (0 to 12.6)	16	3.5	98%	0.85 (0.68-0.94)	2.2	100%	0.93 (0.88-0.96)

[a] Based on 42 patients; [b] Based on 15 patients

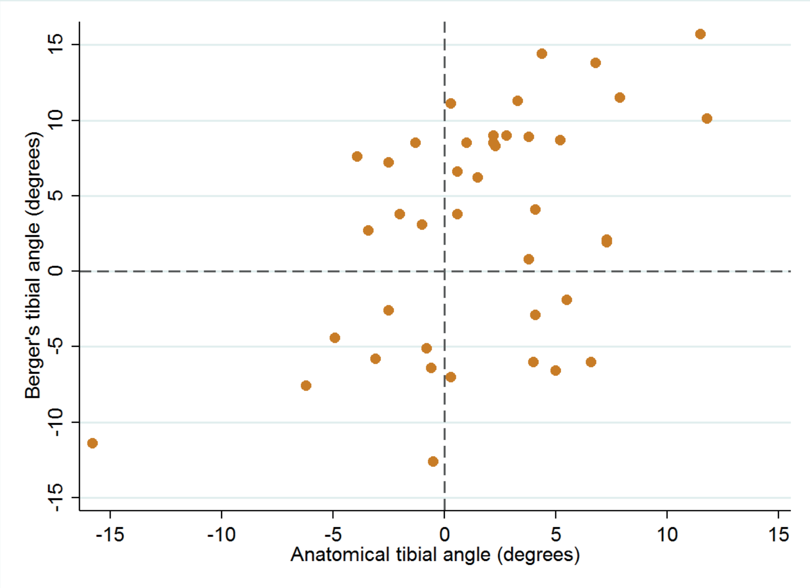

Figure 1. Presentation of the Berger tibia angle and ATA for each individual patient.

Table 3. Clinical outcome scores.

	Median (range)
KSS	
Total (points)	180 (115 - 200)
Clinical (points)	95 (63 - 100)
Functional (points)	83 (50 - 100)
KOOS	
Symptoms (points)	80 (36 - 100)
Pain (points)	91 (33 - 100)
ADL (points)	89 (28 - 100)
Sports (points)	40 (0 - 100)
QOL (points)	66 (6 - 94)
Kujala (points)	70 (33 - 100)

Discussion

Seeking a feasible, reliable and clinical relevant radiological rotational measurement technique after TKA, we found that (1) all rotational measurement techniques were reliable, (2) no strong correlation between the two tibia rotation measurement techniques existed, and (3) no associations were found between the rotational measures and clinical outcomes. This study is the first comparing three different measurement techniques (e.g. Berger's technique, ATA, TT–TG) to determine tibial rotation after TKA.

Interestingly, the LoA found in our study were relatively large. Resulting in a large number of measurements found outside the MoE, a margin of 5°/mm, and multiple outliers considering the recommended ranges described in literature [6]. Our results are in line with the results of Konigsberg et al., who recommended caution with measurements on 2D-CT-scans when attributing symptoms or indicating a revision surgery to component malalignment [11]. Considering the large LoA, it seems that the recommended alignment ranges described in literature are too narrow for daily orthopaedic practice.

The inter- and intra-observer reliabilities determined with the ICC were good to excellent for all measurement techniques. The most reliable tibia measurements were performed with the tibial rotation measured according to Berger (ICC inter-observer 0.91; ICC intra-observer 0.96). We expected that the ATA would be measured more reliable due to the less complex character of the measurement and excellent reported inter-observer reliability in the native knee (ICC 0.94) [14]. A possible explanation might be that the irregular shape of the tibia cortex after TKA causes poorer inter-observer reliability. In the original paper of Cobb et al. the determination of the medial condyle centre was described as most challenging [14]. In contrast, we found, while reviewing the repeated measurements, that determining the centre of the lateral articular surface was most challenging (**Appendix I**). Considering the obtained ICC values of the tibia rotation measurements, Berger's technique is recommended. In contrast to Berger's technique for measuring tibial rotation, literature about the use of the ATA in a postoperative setting is scarce [16]. Surprisingly, no strong correlation was found between the ATA and Berger's tibial angle. Higher variability of the position of the tibial tubercle between and within patients has been mentioned as a possible explanation [14].

No correlations were found between patient and clinician reported outcome measures and the variations in rotational alignment. In addition, no difference in clinical outcome between patients with aligned knees within the preferred ranges and knees outside the preferred ranges was observed. The results are in contrast with the review of Valkering et al. reporting a moderate positive correlation between external rotation of the tibia and femoral component and the total score on the KSS

[16]. Nicoll et al. reported in their study a cut-off point for tibial internal rotation of larger than nine degrees, which was associated with pain. However, the painful group in that cohort study had a large range of tibial rotation and a large number of patients had combined internal rotation. Furthermore, recent (review) studies were unable to recommend for a precise cut-off value for tibial malrotation [7,16,8]. Based on Berger's measurement technique, it is suggested to avoid excessive internal rotation of the tibial component [3-7,25]. In contrast, a recent study by Young et al. suggested caution with interpretation of >9° of tibial internal rotation in the painful TKA [26]. In their study unexplained painful TKA versus well-functioning TKA patients were compared. Fifty-nine percent of patients in the painful group had tibial component rotation >9° of internal rotation vs. 49% in the control group [7].

In the present study, regardless of which measurement technique was used, the tibial component was positioned in slight external rotation. Probably, larger variability in rotational component alignment can be tolerated and other factors, such as muscle strength, stability and kinematic alignment, could influence the clinical outcomes.

The TT–TG technique had an excellent inter-observer and intra-observer reliability (ICC and LoA). Up till now, the TT–TG has mostly been used in patellofemoral instability to decide if the lateralisation of the tuberosity referenced to the trochlea is pathological. A TT–TG of more than 15–20mm is proposed as pathological in the native knee with patellofemoral instability and maltracking [19]. However, TT–TG has not been used as a measurement for determining rotation of the tibia and femur after total knee arthroplasty. We did not find pathological values in this TKA cohort and also no correlation with the patient and clinician reported outcome measures. To gain more insight into the clinical relevance of the TT–TG after TKA more research is required.

Currently, 3D-CT-scans with sophisticated software are preferred to 2D-CT-scans due to their reliable results [10,14,8,17]. Software programs that re-orientate the tibia and femur before performing the measurements might lead to more accurate results. Hirschmann et al. presented results in favour of measuring femoral rotation by using 3D-CT-scans [10]. Nevertheless, in the present study 2D-CT-scans and a standard radiology package were used and the reliability ranged from good to excellent for the different rotational measurement techniques. Moreover, the intra-observer reliability was in favour of our results compared to Hirschmann et al. using 3D-CT-scans (ICC 0.96 vs. ICC 0.73) [10]. The ICC values in the present study were surprisingly high compared to other studies investigating the reliability of rotational measures using 2D-CT-scans [10,11,15,8]. This might be explained by the extensive measurement protocol (**Appendix I**) and the use of more accurate software programs for analysis than in the past.

The measurements performed seem reliable and feasible for clinical practice and can be performed with a standard radiology package instead of specialized software.

Furthermore, the 2D-CT-scan measurements are less time-consuming and more feasible for daily clinical practice than the 3D-CT-scan.
Unfortunately, clinical relevance of the measurement techniques was not demonstrated. The clinical outcomes were generally good in this cohort study. A wider range of clinical outcomes combined with a larger sample size, might provide more insight into the importance of rotational alignment for clinical outcomes. Additionally, mid- to long-term follow-up could have resulted in a wider range of clinical outcomes.

Conclusions

In conclusion, the reliability of the different rotational measurements (Berger, ATA, TT–TG) assessed in this study was good to excellent. Repeatability and reproducibility on 2D-CT-scans were excellent and higher than existing literature, and comparable to techniques using 3D-CT-scans. Although due to the broad LoA many knees fell outside the preferred alignment ranges described in literature, no differences between well-aligned and malaligned knees were found in the clinical outcomes. Berger's technique to measure rotational alignment seems most feasible and reliable for use in clinical practice.

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5

Chapter 6

General discussion and future perspectives

Introduction

In this thesis, various aspects related to TKA were evaluated. Firstly, insert design and its effect on tibiofemoral kinematics and laxity profiles were assessed in the balanced PCL-retaining (CR) TKA. Secondly, the long-term survival and clinical outcomes of two different insert designs (fixed and mobile bearing) were evaluated. Thirdly, the incidence of anterior knee pain after balanced gap CR-TKA and its potential risk factors for developing AKP was established. Finally, the (inter/intra-observer) reliability of different tibial and femoral rotation measurement techniques after TKA on 2D-CT-scans and their clinical relevance were assessed.
The general discussion in this chapter reflects on the papers presented in this thesis, particularly on aspects such as implant design, PCL balancing and its impact, recognizing the third (patellofemoral) compartment of the knee, and identification of directions for future research relative to knee implants. This discussion will end with the overall conclusions of this thesis.

Main findings and clinical implications

As mentioned in the general introduction **(Chapter 1)**, there is room for improvement regarding clinical outcomes in TKA [13]. One of the main topics of interest is further development of the implant design towards a more anatomical shape and function and eventually better clinical outcomes. Preserving the PCL and balancing the flexion gap has been shown to be a delicate and challenging technique [19, 30, 33]. In addition to proper PCL balancing by adjusting the tibial slope and restoring the natural tibial step-off, a well-designed implant is an important factor for a successful TKA [81].

Insert geometry

In this thesis we found very limited effect of an anatomically shaped insert geometry on anterior-posterior (AP) translation and varus-valgus laxity compared with the more traditional symmetrical insert design in a cadaveric study (**Chapter 2**). We observed that in the more anatomical design, with a medial concave and lateral convex surface geometry, the quantity of AP translation was very limited. This is an important finding, because the lateral convex design is intrinsically less constrained. Apparently, the level of dishing of the medial concave surface in combination with an increased posterior rim is sufficient to prevent extreme anterior translation in the absence of the anterior cruciate ligament. Besides, in 90 degrees of flexion in weightbearing conditions, the native and reconstructed knees were even more stable and this may

be explained by the stabilizing effect of the quadriceps force resulting in tibiofemoral compression. Varus-valgus laxity was independent of insert design.
Several in vivo studies reported inferior clinical outcomes in patients with >10mm AP translation in 90 degrees of flexion in CR-TKA [73, 74]. In those studies the PCL balancing technique was not described and different type of bearings (fixed and mobile) were used. However, AP translation in 90 degrees of flexion is clinically relevant and the aim is to resemble the native knee laxity. This is in concordance to our results from **Chapter 2**, in which AP translation in the reconstructed knee resembled the translation of the native knee, independent of insert geometry. We found a stable medial compartment in flexion and extension using a computer assisted surgical (CAS) navigation technique and mechanical alignment philosophy. Using the CAS navigation technique we positioned this more anatomical femoral component to resemble the original medial femoral geometry, without elevation of the tibiofemoral joint line. The CAS navigation has aided in the accurate placement of the components resulting in tibiofemoral joint kinematics and laxity profiles close to the native knee [23].
Appropriate PCL balancing, for example with a spacer, is key to a posterior stable knee in 90 degrees of flexion and good tibiofemoral joint kinematics [33, 52]. The goal of balancing the PCL in CR-TKA is restoration of the patient individual tibiofemoral step-off. This can be performed in 90 degrees of flexion with the spacer technique, by measuring the native tibial step-off. The flexion gap can be balanced with adjustments of the tibial slope. For example, increasing the tibial slope slackens the PCL and results in a decrease of tibiofemoral step-off [19, 33]. Restoration of the original tibiofemoral contact point (CP) is only possible with an insert which can accommodate this. For example, if the bearing is deep dished or ultracongruent with a more anterior CP, it will lead to a lower moment arm of the extensor apparatus and is likely to result in higher patellofemoral pressures [16, 20, 49, 63].
In general, the orthopedic surgeon needs to be aware that implant design and bearing types influence stability and the method of balancing the knee. Therefore, surgeons require knowledge about the preferred off-the-shelf implant to allow for compensation for its limitations because these types of implants will not precisely mimick the anatomy of the patient.
In the native knee, the medial compartment of the knee is typically the more stable compartment in most patients with a relatively fixed contact point at the posterior 1/3 of the tibia plateau in AP-direction and taking higher intra-articulair compartmental loads compared with the lateral compartment [23, 35, 49, 80]; this remains true even in a neutrally aligned limb [80]. To adhere to a more medially fixed contact point, medial pivoting (MP) knee designs have been developed. The geometry of the components in the medial compartment in the MP design has an increased congruency providing increased sagittal stability while laterally the less congruent articulation permits the

lateral condyle to roll and slide posteriorly with flexion of the knee [11]. As a result of the increased sagittal stability, it may compensate for a less optimal balanced or absent PCL. The difference between the anatomical insert from **Chapter 2** and these MP designs is the more flattening of the anteromedial side of the anatomical insert design to prevent subluxation in extension [81].

There are several limitations regarding the biomechanical study in **Chapter 2**. Firstly, testing protocols in biomechanical studies for TKA lack a gold standard. As a result, absolute numbers in terms of translation and laxity are difficult to compare with literature due to different loading protocols or differences in experimental set-up. Secondly, results of biomechanical studies may not reflect real-life loading conditions in a patient. To circumvent these shortcommings, we included the native knee which should serve as an adequate reference and allows for qualitative comparisons with the prosthetic cases. Thirdly, in recent years, different (coronal) alignment techniques have been introduced such as kinematic aligment [42, 50]. It has been demonstrated, both experimentally and in vivo, that mechanical alignment could result in less femoral rollback and less laxity than kinematic alignment and that functional results may be inferior when mechanical alignment is used with medial pivot components [47, 55]. However, whether this applies to all knee phenotypes remains to be investigated. In our study, the implant was placed with a mechanical alignment technique, and with a kinematic alignment we could have had different results regarding AP translation and varus-valgus laxity. However, the results from **Chapter 2** are promising in terms of laxity but whether this combination of an anatomical insert design with a more anatomical femoral component leads to superior patient outcomes and long-term survival remains to be investigated.

In the future, we may aim for restoration of the original anatomy of femur and tibia with patient-specific implants. Ideally, the surface geometry of the insert is restored to the original configuration. It is yet to be determined if this applies to all knee phenotypes. Further improvement could be achieved with a design in which the shape and therefore function of the meniscus is recreated. Furthermore, perhaps using other materials than polyethylene with more shock-absorbing (elastic) characteristics (such as the native cartilage) could improve knee function.

A bi-compartimental tensioner in combination with a CAS navigation technique / robotic-assisted TKA (RATKA) could identify the patient's individual stiffness transition point (STP) which could aid in pretension the ligaments of the knee [32]. By using a bi-compartmental tensioner the surgeon is able to pretension the ligaments and combined with CAS / RATKA one can perhaps find the amount of force in which the force gap curve changes from a non-linear to a linear curve, this is called the STP [32]. This could lead to optimized laxity profiles and prevent over- or undertensioning of the (primary) stabilizing ligaments of the knee. These concepts justify further research.

Fixed vs. mobile bearing in CR-TKA

The long-term survival rates for fixed and mobile bearings in a CR-TKA were investigated in **Chapter 3**. We found a superior implant survival for fixed bearing (FB) compared with the mobile bearing (or AP-glide). Furthermore, the survival rate for mobile bearing (MB) was below expectations [82]. Our results are in contrast to a previously published meta-analysis in which no difference in revision rates was found between fixed and all different types of mobile bearings at more than 10 years of follow-up [28, 65, 82]. However, it is important to emphasize that CR-TKA as well as PCL substituting (PS) TKAs were included in those studies. In one meta-analysis, the revision rates in the MB group were lower than those in the FB group, and the subgroup analysis showed that this tendency in the MB group was much stronger in the PS subgroup than in the CR subgroup [28]. A potential explanation for the differences could be that at that time PCL-balancing was difficult. Little information was available how to achieve a good balanced PCL and herewith not optimally use the potential of CR-TKA. The design of the MB in **Chapter 3** was a combination of an AP-glide and rotation insert and was eventually withdrawn from the market in 2009 due to higher reported revision rates. This is in accordance with the results of **Chapter 3** in which instability was the most frequent reason for revision for the mobile bearing type. Perhaps the combination of a combined AP-glide and rotating mechanism in a younger and higher demand population resulted in too much antero-posterior (AP) and rotatory laxity. In combination with the, at that time, limited knowledge regarding PCL balancing, this could have led to more outliers with clinical instability and eventually resulting in revision.

Clinical outcomes were good to excellent at 12 years follow-up and no clinical differences between the two bearing types were found in the present study. This is consistent with the results of two meta-analyses [28, 65]. However, these studies had a small number of patients and only a few patients with a CR implant. The applicability of these results remains to be debated due to the heterogeneity in prosthetic design and scarce description of the surgical technique. However, in general we can conclude that in our study long-term survival rates were unsatisfactory for the mobile bearing type.

Therefore, consistent with currently available implants, the role of the MB in contempory TKA is limited. With the introduction of highly cross-linked polyethylene (HXPLE) and improved sterilization methods minimizing presence of free oxygen radicals, the focus for reduction of wear characteristics has shifted from a more mobile design to a change in use of materials and sterilization process. However, currently there is no conclusive favorable evidence for use of HXPLE compared with traditional PE [51]. Recently, newer implants were developed with more native surface geometry of the bearing and with more natural tibiofemoral joint kinematics, leading to a decreased interest in mobile bearings.

Patellofemoral joint in total knee arthroplasty

The patellofemoral compartment is often called 'the third space' [2, 5]. The name third space derives from the historical focus of knee surgeons on the first and second spaces of the joint, namely the flexion and extension gaps of the tibiofemoral joint. The third space is becoming increasingly established as an important part of TKA, particularly in its role in determining the function and satisfaction of the patient post-surgery [5].

Anterior knee pain was present in 1 out of 4 patients 10 years after balanced gap CR-TKA without resurfacing of the patella. The presented results in **Chapter 4** showed no correlation with the radiological position of the patella, type of bearing or tibiofemoral contact-point (CP). The tibiofemoral CP in the AP-glide bearing group was significantly more anterior as also mentioned in the literature regarding its specific implant and bearing type [78]. Patient with AKP had lower clinical scores, higher reported pain and significantly lower satisfaction rates. The pathogenesis of development of AKP remains unclear and is probably multifactorial. The amount of patellar displacement or patellar tilt could not be related to the development of AKP as presented in **Chapter 4**, consistent with the literature [48]. However, in those studies the measurement techniques were not described.

In **Chapter 4** we used the measurement technique with the highest reproducibility [31]. For radiographical evaluation, anterior-posterior and lateral conventional radiographs were used in our study, while in recent years the use of 2D and 3D-CT-scans were introduced for evaluation of the patellofemoral compartment. Furthermore, regarding patellar tilt and patellar displacement, imaging is mostly performed in a non-weight bearing situation. A weight-bearing situation might lead to a different conclusion due to the medializing effect caused by contraction of the quadriceps muscles, especially the vastus medialis [3, 36]. Besides, axial malalignment of the lower extremity was not evaluated in our study which seems a relevant factor in development of AKP after TKA [70].

Additionally, we did not find that type of bearing was a determinant for the occurrence of AKP. This was in contrast to other studies reporting that MBs might lead to a lower incidence of AKP [10, 15, 54]. Those studies had shorter follow-up and one of the mentioned cohorts reported no difference in AKP at long-term follow-up [14]. The perceived ability to correct small rotational mismatches might decline over time and in the long-term, we did not find an advantage for a mobile bearing, using the balanced gap technique. A recent meta-analysis concluded that there is a higher incidence of AKP in CR implants compared to PS implants and subsequently that resurfacing of the patella led to lower incidence of AKP [75]. Previously, suggested kinematic differences between CR and PS-TKA were a larger and more consistent femoral rollback and less paradoxical anterior sliding of the femur with PS-TKA [6, 34].

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Limited rollback leads to a lower extensor moment arm for the extensor apparatus resulting in higher patellofemoral forces and subsequently pain [16]. However, in most studies the method of PCL balancing has not been described and this could influence tibiofemoral joint kinematics.
Furthermore, there is much variation in prosthetic design regarding the patellofemoral compartment with respect to the trochlear orientation and conformity [71]. In recent years, there is more attention for the patellofemoral compartment and modern implants seem to be more “patella friendly” [18, 24]. Precise positioning of the femoral component and the subsequent orientation of the trochlear groove plays an important role. In the AP direction for instance, a small anterior femoral cut could lead to overstuffing of the patellofemoral compartment and an increased anterior femoral cut might lead to the opposite. In addition, flexing the femoral component increases the knee extensors moment arm and reduces the quadriceps and patellofemoral contact forces in posterior referencing CR-TKA [62].
The varus-valgus position of the femur has also a large effect on the orientation of the trochlea angle and the line of quadriceps force [29]. In the last decade, different alignment philosophies were introduced and this makes comparisons more difficult with historical literature in which most often mechanical alignment technique was used. The positioning of the femoral component in terms of mediolateral position, changes in the coronal plane and femoral rotation are also potential factors that might influence the clinical outcomes with respect to patella complications. Patellofemoral alignment/orientation is extremely variable in the native osteoarthritic knees [29, 40]. A more detailed knowledge of the complex relationship between the patella and the trochlea preoperatively, for example by performing weight-bearing radiological evaluation, may help to better diagnose patellofemoral malalignment in patients considered for TKA with the aim of improving overall outcome and reducing the incidence of postoperative AKP [40]. It has been suggested that standard resurfacing of the patella might be a solution to address the clinical patellofemoral problems, but it remains debatable whether resurfacing the patella actually leads to better clinical outcomes [26]. Knees that do not receive patellar resurfacing are more likely to receive a reoperation, most often for secondary resurfacing [26]. However, the disease burden linked to the various complication profiles in resurfacing and non-resurfacing groups is still not well understood [79]. Besides, routinely resurfacing of the patella would lead to higher healthcare cost without a clear clinical benefit.
Therefore, it seems that we need to better understand the ‘third space’. Native patella tracking varies greatly among individuals and to reconstruct it with off-the-shelf implants aiming for physiological loading seems a challenge. Furthermore, the quantity of trochlea resection or patella resection using standard cutting guides does not always match the implant dimensions. As mentioned above, this could result in under- or overstuffing of the patellofemoral joint and non-physiological soft tissue

tensions [5]. Moreover, almost each off-the-shelf implant has been designed for a mechanical alignment philosophy. The question arises whether these implants are suitable for different coronal alignment philosophies that create more varus in the femur component and medialize the trochlea in varus phenotypes. It is also known that the range of trochlear angle relative to the distal femoral angle is highly variable [29, 71]. With the introduction of personalized implants we can perhaps restore the native anatomy of the tibiofemoral and patellofemoral joint more precisely and improve patellofemoral tracking and avoid under- and overstuffing. Further development of patella pressure sensor devices could aid in balancing the 'third space' of the knee by showing dynamic patellofemoral pressures over full range of motion intra-operatively [5].

In summary, a comprehensive approach seems mandatory which could start with preoperative (3D) imaging (preferably under loaded conditions) including evaluation of rotational (mal)alignment of the whole lower limb, identification of native alignment phenotype, compensation for osseous wear to replicate a native shape and finally manufacturing of patient-specific implants which restore the tibiofemoral and patellofemoral joint in terms of native trochlear orientation, kinematics and contact pressures.

Radiological evaluation after TKA

In presence of an unsatisfying clinical result after TKA, it is recommended to perform a standardized work-up regarding potential malalignment. The results in **Chapter 5** showed that the reliability of the different rotational measurements on 2D-CT-scans as assessed in this study were good to excellent and higher than existing literature, and comparable to techniques using 3D-CT-scans. The most reliable measurement technique for tibial rotation was Berger's tibial angle [9]. Although all measurement techniques were reliable, there was no strong correlation between the techniques measuring tibial rotation **(Chapter 5)**. Interestingly, we found a large number of measurements for femoral and tibial rotation outside the recommended ranges described in literature [27]. This is consistent with the findings of Konigsberg et al, who recommended caution with measurement on 2D-CT-scans when attributing symptoms or indicating revision surgery to component malalignment [56].

Furthermore, several studies were unable to recommend a precise cut-off point for tibial malrotation although it is suggested to avoid excessive internal rotation of the tibia component [4, 7, 27, 53, 66, 69], while this too has been debated [85]. Probably, a larger variability in component alignment can be tolerated and other factors such as native anatomy, muscle strength, stability, (coronal) alignment philosophy could influence the clinical outcomes. With the introduction of the different alignment

philosophies, it is questionable whether these previously mentioned preferred ranges remain applicable. Currently, 3D-CT-scans are preferred over 2D-CT-scans for radiological evaluation after TKA due to their reliable results [39, 76]. However, the reliability of the measurement techniques on 2D-CT-scans (**Chapter 5)** are surprisingly high and comparable to literature on 3D-CT-scans [39, 76]. Therefore, the measurements on 2D-CT-scans seem reliable, feasible and are less-time consuming when done according to a well described measurement protocol.
Nevertheless, it is debatable if we are performing the correct radiological evaluations if we assess only in a static and passive manner. Most patients have pain during weight-bearing or at least in a dynamic situation. When for instance looking at a radiological measurement like the tibial tuberosity to trochlea groove (TT-TG) distance, weight-bearing tends to decrease the TT-TG distance and patellar tilt in loaded upright CT-scan and thus gives incorrect values when measured passively [36].
Furthermore, most radiological evaluation studies focused on defining malalignment only in the knee. For a good understanding of rotational malalignment, the overall lower leg axial limb alignment analysis including pelvis/hip and foot/ankle should be performed. From a dynamic approach it would be interesting to combine clinical findings, radiological evaluation and gait analysis to detect the functional deficits and to correlate them [79].
Separately from the radiological evaluation, one should not forget to do a thorough clinical evaluation of the unsatisfied painfull TKA which should include assessment of the presence of neuroma or exclude other extra-articular causes [25]. A preoperative assessment of patients with factors associated with more pain after TKA (lower mental health, pain catastrophizing, high level of preoperative pain) should be performed [68]. Development of predictive models to gain knowledge and identify these patients may improve TKA outcomes.

Future perspectives

With an increasing worldwide demand for knee arthroplasty and with an increasing life expectancy and desire for higher functional demand, there will be an ongoing search for improvement of clinical outcomes. Determining the ideal coronal, sagittal and axial alignment for individuals undergoing total knee arthroplasty (TKA) is one of the great challenges in reconstructive knee surgery. The 'mechanical alignment' (MA) method [46] has been the gold-standard technique since early days in TKA development, with good historic long-term survivorship [22]. MA, however, disregards the significant variability in coronal alignment that exists across individuals [8, 37, 57] and the biomechanical sequelae that may result from this 'one-size-fits- all' approach [12, 59, 61, 67]. The pursuit of improvement in patient satisfaction has led some to suggest a shift in technique favoring recronstruction of a patient's constitutional (healthy, pre-arthritic) alignment, possibly resulting in more natural knee movements [12, 61, 67] and more physiological loading of the soft-tissue structures around the knee [17, 21, 41, 44, 59]. This is commonly termed the 'kinematic alignment' (KA) method and introduced by Howell [42]. However, there remains room for debate about alignment targets, optimal kinematic surgical techniques, and choice of suitable patients [1, 17, 41, 43, 44, 64, 83, 86]. To develop a uniform classification and to identify potential phenotypes which will benefit for KA or MA to optimize soft-tissue balancing, the Coronal Plane Alignment of the Knee (CPAK) classification was developed [58, 60]. This has been further developed to define normal and 'abnormal' values for coronal alignment [38]. This can be seen as an important first step towards a safe transition from the conventional one-size-fits-all to a more personalized coronal alignment target.

However, currently all introduced alignment philosophies primarily focus on the coronal plane and there is scarce interest in the sagittal and axial plane. There should be a paradigm shift with focus on truly individualized anatomy taking into account the coronal, sagittal and axial plane and the patellofemoral compartment. Recently, a study was published identifying anatomic outliers in search of understanding the high dissatisfaction rates after TKA [84].

In addition to personalized alignment, we could additionally aim for a more individualized reconstruction of the healthy pre-diseased anatomy by restoration of femoral and tibial geometry with patient specific implants. In that respect, we need further development of personalized inserts, that fits the phenotype of the patient, which could include materials other than PE, with more flexibility resembling te original cartilage and meniscus elastic properties.

With the introduction of CAS navigation technique, patient-specific instrumentation and RATKA, the precision of TKA placement has been improved, but it lacks substantial improvement in clinical outcomes and (currently) does not balance the additional costs.

In summary, we have the technology to aid the surgeon in TKA, but optimal targets in terms of alignment, laxity profiles are not known. The potential benefits of personalized (custom-made) implants are optimisation of bone-implant fit, the decoupling of the tibiofemoral (TF) and patellofemoral (PF) joint and the restoration of the native condylar curvature [72]. In combination with a tibiofemoral tensioner and contact pressure devices we might identify optimal individual targets for balancing all three compartments of the knee and this warrants further investigation [5, 32]. As a result, this could lead to a more physiological loading of the ligaments and capsulous structures of the knee with near native joint kinematics and laxity profiles. CAS or robotic-assisted techniques can aid in achieving an accurate individualized position of these implants.

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As the technology advances, new regulations (European Union Medical Device Regulation (EU-MDR)) regarding medical devices have been introduced to enhance safety and transparency. There is concern that these regulations may have negative consequences in the treatment of patients, as a result of the negative effects on innovation (speed and costs) in Europe. Clinicians, academics, healthcare policy-makers, managers, and industry partners will need to work in close collaboration and use the EU-MDR to maintain high standards of quality and safety for orthopedic devices, but also ensure the administrative and research bottlenecks do not delay the delivery of novel and innovative technologies to patients [45, 77]. There will be a need for substantial clinical improvement to justify the increase of healthcare costs. It raises the question if we are too focused on technological improvements to provide better clinical outcomes. Next to technological improvements, further development of identifying patient characteristics which negatively influence the outcomes and managing patients' expectations might be equally important. Personalisation of the TKA process can be more successful if it is applied in combination with a holistical assessment of the patient which includes evaluation of muscular strength, mental health, and patient coping strategies.

Conclusion

In this thesis, various aspects in (CR) TKA were evaluated. The issues mentioned in the introduction have been addressed and can be summarized with the following conclusions.

1. Insert geometry was found to have limited effect with respect to AP translation and varus-valgus laxity, in the well-balanced CR-TKA with an anatomical femoral component. In the presented in vitro study, AP translation and varus-valgus laxity in the reconstructed knee approximated the laxity of the native knee. Precise PCL-balancing, by restoring the natural tibial step-off, for example with a spacer, is key to obtain a posteriorly stable knee and good kinematics.
2. The long-term results of a fixed bearing in CR-TKA were superior to that of the mobile bearing (MB) type. Furthermore, survival of MB was unsatisfactory in our study. Therefore, consistent with currently available implants, the role of the mobile bearing is limited.
3. Incidence of anterior knee pain was 26% at >10 years after CR-TKA (without resurfacing of the patella), using the balancing gap technique. No determinants were found that could explain the incidence of AKP and clinical outcomes were significantly lower in patients with AKP. Incidence of AKP at long-term follow-up is high and patients need to be informed preoperatively to manage expectations.

4. The reliability of different rotational measurement techniques after TKA on 2D-CT-scans was good to excellent and comparable to literature using 3D-CT-scans. However, unfortunately, clinical relevance of the measurement techniques has not been demonstrated, possibly due to the generally good clinical outcomes in our study cohort.

The work in this thesis adds to the process of further improvement of implant design, importance of PCL balancing in CR-TKA and the clinical relevance of the 'third space' of the knee. Furthermore, this thesis identifies areas for further research to gain more insight in the relation between clinical outcomes and radiographical rotational outliers in TKA patients.

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Chapter 7

Summary

Total knee arthroplasty (TKA) is one of the most frequently performed orthopedic surgical procedures in the world. **Chapter 1** presents a general introduction focusing on the anatomy of the knee joint, knee joint kinematics and development of osteoarthritis. Furthermore, the historical development of TKA into different TKA types and designs was described. The chapter concluded by describing the purpose of this thesis which aimed to evaluate multiple factors that may affect clinical success of TKA. These aims were focused on investigation of a more anatomical knee design and compared it to the native knee. Secondly, long-term results of a PCL-retaining (CR) TKA with two different insert types were evaluated with the accompanying incidence of anterior knee pain. Finally, the reliability of, and correlation between, the different measurement techniques for rotational alignment after TKA was investigated.

Chapter 2 explored the effect of different insert articular surface geometries (anatomical versus conventional insert design) on anteroposterior (AP) translation and varus-valgus (VV) laxity in CR-TKA. Additionally, it aimed to determine whether the reconstructed knee, using these different inserts, reproduced the stability of a native knee.

To investigate this, nine fresh-frozen full-leg cadaver specimens were used. The native knees were first tested to obtain baseline data. Subsequently, CR knee implants with anatomical components were inserted. The knee joints were then subjected to anterior and posterior forces at 20° and 90° flexion, as well as varus-valgus stresses at 20°, 45°, and 90° flexion, both under weightbearing and non-weightbearing conditions, using a kinematic knee simulator. Measurements were performed on the native knee, TKA with anatomical insert geometry (3° built-in varus, medial concave, lateral convex), and TKA with symmetrical (concave) insert geometry.

The results showed that in weightbearing conditions, anterior translations ranged from 2.6 to 3.9 mm at 20° flexion and were less than 1 mm at 90° flexion for all three tested conditions (native knee, anatomical insert, non-anatomical insert). Posterior translation at 20° flexion was 2.7 mm (2.2-4.9 mm) for the native knee, compared to 4.0 mm (3.7-5.2 mm) for the symmetrical insert and 7.0 mm (6.2 – 7.9 mm) for the anatomical insert. At 90° flexion, posterior translation was minimal (<1.1 mm) and similar across all cases. In non-weightbearing conditions, anterior translation at 20° flexion was higher in the reconstructed knees than in the native knee. Varus-valgus laxity was generally unaffected by insert geometry, although the native knee exhibited more medial laxity in response to valgus force during weightbearing at higher flexion angles.

In conclusion, these findings suggest that insert geometry has a limited effect on AP translation and VV laxity in a well-balanced CR-TKA with an anatomical femoral component. Furthermore, the AP translation and VV laxity observed in the reconstructed knee closely approximated that of the native knee, indicating that the stability of the reconstructed knee was similar to that of the native knee, despite minor variations in specific conditions.

The multi-center retrospective cross-sectional cohort study in **Chapter 3** investigated the 12-year outcomes of primary CR-TKA performed using a balanced-gap technique. The study aimed to compare the survival rates and clinical outcomes between fixed bearing and mobile bearing inserts. A total of 557 (501 patients) cases from three clinics (two in Switzerland and one in the Netherlands), performed between 1998 and 2003, were included. Of these, 433 (77.7%) were fixed bearing and 124 (22.3%) were mobile bearing inserts. After a follow-up period of more than 12 years, the survival analysis revealed a significantly higher survival rate for fixed bearing inserts (97.0%) compared to mobile bearing inserts (85.4%). Out of 521 cases available for analysis, 28 revisions (5.4%) were required, with 11 in the fixed bearing group and 17 in the mobile bearing group. At the 12-year follow-up examination, 189 cases were assessed for clinical outcomes. The mean age of patients was 78 years, with a mean Knee Society Score (KSS) of 157.8 points and a mean passive flexion of 114°. No significant differences were found in clinical scores, range of motion, pain, or patient satisfaction between the two insert types. In conclusion, this study demonstrated superior long-term survival for fixed bearing inserts compared to mobile bearing inserts in CR-TKA using a ligament-balanced technique. Both groups showed excellent to good clinical outcomes after 12 years, with comparable patient satisfaction and knee function.

Chapter 4 presents the long-term incidence of anterior knee pain (AKP) and its potential determinants in patients who underwent cruciate-retaining total knee arthroplasty (TKA). The 10-year follow-up included 55 patients (63 TKAs) who received the balanSys™ CR-TKA between 1999 and 2002, using either a fixed bearing or an AP-glide bearing insert with a balanced gap technique. Patients were assessed for AKP through standardized diagnostic questions and divided into two groups: those with and without AKP.
The study found that 26% of patients experienced AKP after 10 years. The incidence of AKP was not statistically significantly associated with the type of insert (fixed bearing vs. AP-glide bearing). Additionally, no significant differences were found in patellar position or tibiofemoral contact point between the AKP and no AKP groups. However, patients with AKP had significantly lower scores on the Knee Society Score (KSS), Knee Osteoarthritis Outcome Score (KOOS), and Numerical Rating Scales (NRS) for pain and satisfaction.
In conclusion, AKP affected a substantial portion of patients 10 years post-TKA, but patella positioning and bearing type were no significant determinants of this

outcome. Although patellar displacement did not seem entirely favorable, it was not identified as a key factor in the development of AKP over the long term.

The goal of the study in **Chapter 5** was to evaluate the inter- and intra-observer reliability of tibial and femoral rotation measurements after TKA and investigated the correlation between these measurements and their clinical relevance. Tibial and femoral rotations were assessed using 42 2D-CT-scans taken 3 months post-TKA. Reliability of various radiological measurement techniques, including Berger's method, the anatomical tibial axis, and the tibial tuberosity trochlear-groove, was tested with 15 randomly selected patients measured twice by three observers. Functional outcomes were assessed one year postoperatively using the Knee Society Score (KSS), Visual Analog Scale (VAS) for pain and satisfaction, Knee Osteoarthritis Outcome Score (KOOS), and Kujala score.
The results showed that inter- and intra-observer reliability for rotational measurements ranged from good to excellent (ICC 0.67-0.98), with Berger's technique demonstrating the highest reliability for tibial rotation (ICC inter = 0.91; ICC intra = 0.96). No strong correlations were found between different rotational measurement techniques or between rotational outliers and clinical outcomes. Further research is needed to better understand optimal positioning and measurement techniques for tibial rotation in TKA to enhance clinical practice.

Finally, **Chapter 6** presents a general discussion of the main findings of the studies presented in this thesis. Particular emphasis is placed on aspects such as implant design, PCL balancing and its impact, recognizing the third (patellofemoral) compartment of the knee, and identification of directions for future research relative to knee implants. The general discussion ends with the following conclusions of this thesis.

1. Insert geometry had a limited effect on AP translation and varus-valgus laxity in well-balanced CR-TKA with anatomical femoral components, with precise PCL balancing being crucial for posterior stability.
2. Long-term results favored fixed bearing over mobile bearing (MB) in PCL-retaining TKA, with MB showing unsatisfactory survival. Therefore, the role of MB is limited.
3. Anterior knee pain (AKP) occurred in 26% of patients 10+ years after CR-TKA, without clear determinants, highlighting the need for preoperative patient counseling.
4. The reliability of rotational measurement techniques on 2D-CT-scans after TKA was good to excellent and comparable to 3D-CT-scans results. However, their clinical relevance remains unclear, likely due to the generally positive clinical outcomes in the study cohort, making it difficult to draw a clear connection between rotational alignment and patient outcomes.

Chapter 8

Samenvatting

De plaatsing van een totale knieprothese (TKP) is een van de meest uitgevoerde orthopedische operaties ter wereld. **Hoofdstuk 1** geeft een algemene inleiding met focus op de anatomie en kinematica van het kniegewricht en de ontwikkeling van artrose. Ook wordt de historische ontwikkeling van de TKP naar verschillende soorten knieprothesen en ontwerpen beschreven. **Hoofdstuk 1** eindigt met een beschrijving van het doel van dit proefschrift, dat zich richt op de evaluatie van meerdere factoren die van invloed kunnen zijn op het klinische succes van de TKP. Het doel was de effecten van verschillende ontwerpen van inserts op o.a. stabiliteit in een meer anatomisch knieprothese design te onderzoeken en deze te vergelijken met de natieve (intacte) knie. Daarnaast worden de langetermijnresultaten van een achterste kruisband sparende (CR) TKP met twee verschillende typen inserts geëvalueerd, evenals de bijbehorende incidentie van anterieure kniepijn (AKP). Ten slotte worden de betrouwbaarheid en correlatie tussen de verschillende meetmethoden voor rotatie-uitlijning na TKP onderzocht.

In **Hoofdstuk 2** wordt het effect onderzocht van verschillende ontwerpen van insert oppervlakken (anatomisch versus een conventioneel insert ontwerp) op voor-achterwaartse (VA) translatie en varus-valgus (VV) laxiteit in CR-TKP, waarbij de achterste kruisband gespaard blijft. Een ander doel van deze studie was om te bepalen of de gereconstrueerde knie, met behulp van deze verschillende inserts, de stabiliteit van een natuurlijke knie kan reproduceren. Om dit te onderzoeken werden negen volledige beenpreparaten gebruikt. De natieve (intacte, niet gereconstrueerde) knieën werden eerst getest om referentiewaarden te genereren. Vervolgens werden CR knie-implantaten met een anatomisch ontwerp geplaatst. De kniegewrichten werden onderworpen aan voorwaarts en achterwaarts gerichte krachten bij 20° en 90° knieflexie, evenals varus-valgus stress bij 20°, 45° en 90° knieflexie, zowel onder belaste als onbelaste condities. Deze experimenten konden worden uitgevoerd middels een kinematische kniesimulator. Metingen werden uitgevoerd op de natieve knie, op een TKP met een anatomisch insert ontwerp (3° ingebouwde varus, mediaal concaaf, lateraal convex) en op een TKP met een symmetrisch (concave) insert ontwerp.
De resultaten tonen aan dat bij belasting de voorwaartse translaties variëren van 2.6 tot 3.9 mm bij 20° knieflexie en minder dan 1 mm bij 90° knieflexie voor alle drie de geteste condities (natieve knie, anatomische insert, niet-anatomische insert). De achterwaartse translatie bij 20° knieflexie was 2.7 mm (2.2-4.9 mm) voor de natieve knie, vergeleken met 4.0 mm (3.7-5.2 mm) voor de symmetrische insert en 7.0 mm (6.2-7.9 mm) voor de anatomische insert. Bij 90° knieflexie was de achterwaartse translatie minimaal (<1.1 mm) en vergelijkbaar voor alle drie de geteste condities. Bij onbelaste omstandigheden was de voorwaartse translatie bij 20° knieflexie groter in de gereconstrueerde knieën dan in de natuurlijke knie. Varus-valgus laxiteit werd over het algemeen niet beïnvloed door het ontwerp van de insert, hoewel de

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natuurlijke knie meer mediale laxiteit vertoonde als reactie op valgus stress tijdens belasting bij hogere flexiehoeken.
Samenvattend suggereren deze bevindingen dat de insert ontwerpen een beperkt effect hebben op VA translatie en VV laxiteit in een goed gebalanceerde CR-TKP met een anatomische femur component. Bovendien benaderen de AP-translatie en VV-laxiteit in de gereconstrueerde knie de laxiteit van de natuurlijke knie, wat aangeeft dat de stabiliteit van de gereconstrueerde knie vergelijkbaar is met die van de natuurlijke knie, ondanks kleine variaties in specifieke omstandigheden.

Het multicenter retrospectieve dwarsdoorsnede cohortonderzoek in **Hoofdstuk 3** onderzocht de 12-jaars uitkomsten van primaire CR-TKP, uitgevoerd middels een gap-balancing techniek. De studie had als doel de overlevingspercentages en klinische resultaten te vergelijken tussen een CR-TKP met een fixed bearing (FB) en een mobile bearing (MB). In totaal werden 557 TKP's (501 patiënten) uit drie klinieken (twee in Zwitserland en één in Nederland), geplaatst tussen 1998 en 2003, geïncludeerd. Hiervan hadden er 433 (77.7%) een fixed bearing en 124 (22.3%) een mobile bearing insert. Na een follow-up periode van meer dan 12 jaar toont de overlevingsanalyse een significant hoger overlevingspercentage voor FB (97.0%) in vergelijking met MB (85.4%). Van de 521 TKP's die beschikbaar waren voor analyse, werden er 28 revisies (5.4%) uitgevoerd, waarvan 11 in de FB-groep en 17 in de MB-groep. Bij het 12-jaars follow-up onderzoek werden 189 TKP's beoordeeld op klinische resultaten. De gemiddelde leeftijd van deze patiënten in de 12 jaar follow-up periode was 78 jaar, met een gemiddelde Knee Society Score (KSS) van 157.8 punten en een gemiddelde passieve flexie van 114°. Er werden geen significante verschillen gevonden in klinische scores, flexie/extensie, pijn of patiënt tevredenheid tussen de twee verschillende inserts.
Samenvattend toont deze studie aan dat de FB op de lange termijn minder vaak gereviseerd wordt dan de MB in CR-TKA, uitgevoerd met een gap-balancing techniek. Beide groepen vertonen uitstekende tot goede klinische resultaten na 12 jaar, met vergelijkbare patiënttevredenheid en kniefunctie.

Hoofdstuk 4 beschrijft de lange termijnincidentie van anterieure (voorste) kniepijn (AKP) en de mogelijke determinanten daarvan bij patiënten die een CR-TKP hebben ondergaan. Deze studie had een 10-jaar follow-up en omvatte 55 patiënten (63 TKP's) die tussen 1999 en 2002 de balanSys™ CR-TKP kregen, met ofwel een fixed bearing (FB) ofwel een AP-glide mobile bearing (MB), geplaatst met de gap-balancing techniek. Patiënten werden beoordeeld op AKP door middel van gestandaardiseerde diagnostische vragen en werden onderverdeeld in twee groepen: met en zonder AKP. De resultaten van de studie laten zien dat 26% van de patiënten na 10 jaar AKP hadden ontwikkeld. De incidentie van AKP was niet statistisch significant geassocieerd met

het type insert (FB versus AP-glide MB). Bovendien werden er geen significante verschillen gevonden in de positie van de patella of het tibiofemorale contactpunt tussen patiënten met en zonder AKP. Echter, patiënten met AKP hadden significant lagere scores op de Knee Society Score (KSS), Knee Osteoarthritis Outcome Score (KOOS) en NRS voor pijn en tevredenheid.
Samenvattend heeft een aanzienlijk deel van de patiënten 10 jaar na TKA anterieure kniepijn, maar patella positie en type bearing zijn geen significante determinanten van deze uitkomst. Hoewel de positie van de patella in relatie tot de trochlea (patellar displacement) niet geheel gunstig leek, lijkt het geen belangrijke determinant voor de ontwikkeling van AKP op de lange termijn.

Het doel van de studie beschreven in **Hoofdstuk 5** was om de inter- en intrabeoordelaarsbetrouwbaarheid van tibiale en femorale rotatiemetingen na TKP te evalueren en de correlatie tussen deze verschillende metingen en hun klinische relevantie te onderzoeken. Tibiale en femorale rotaties werden gemeten op 42 2D-CT-scans, drie maanden na plaatsing van de TKP. De betrouwbaarheid van verschillende radiologische meetmethoden, waaronder de Berger-methode, de anatomische tibiale as en de tibiale tuberositas-trochlea groeve afstand (TT-TG) werden getest met CT-scans van 15 willekeurig geselecteerde patiënten die tweemaal werden gemeten door drie waarnemers. Functionele uitkomsten werden één jaar postoperatief beoordeeld met behulp van de Knee Society Score (KSS), Visuele Analoge Schaal (VAS) voor pijn en tevredenheid, Knee Osteoarthritis Outcome Score (KOOS) en Kujala-score.
De resultaten tonen aan dat de inter- en intrabeoordeelbaarsbetrouwbaarheid voor rotatiemetingen varieerden van goed tot uitstekend (ICC 0.67-0.98), waarbij de Berger-techniek de hoogste betrouwbaarheid heeft voor het bepalen van tibiale rotatie (ICC inter = 0.91; ICC intra = 0.96). Er werden geen sterke correlaties gevonden tussen de verschillende rotatiemeetmethoden of tussen rotatie-afwijkingen en klinische uitkomsten. Verdere studies zijn nodig om beter inzicht te krijgen in optimale positionering van de componenten en meetmethoden voor tibiale rotatie in TKA om de klinische praktijk te verbeteren.

Ten slotte is **Hoofdstuk 6** een algemene discussie over de belangrijkste bevindingen van de studies in dit proefschrift. Er wordt nadruk gelegd op aspecten zoals implantaatontwerp, balanceren van de achterste kruisband en de impact daarvan op de stabiliteit van de knie, het erkennen van het derde (patellofemorale) compartiment van de knie, en het vaststellen van richtingen voor toekomstig onderzoek met betrekking tot knie-implantaten. De algemene discussie eindigt met de volgende conclusies van dit proefschrift:

1. Het ontwerp van de insert oppervlakken heeft een beperkt effect op de AP-translatie en varus-valgus laxiteit bij goed gebalanceerde CR-TKP's met een anatomische femur component, waarbij nauwkeurige balancering van de achterste kruisband cruciaal is voor posterieure stabiliteit.
2. Langetermijnresultaten zijn beter bij een fixed bearing vergeleken met een mobile bearing (MB) in CR-TKP, waarbij MB een onbevredigende levensduur vertoonde. Daarom zouden MB's beperkt geplaatst moeten worden bij TKP.
3. Anterieure kniepijn kwam voor bij 26% van de patiënten meer dan 10 jaar na plaatsing van CR-TKP, zonder duidelijk aanwijsbare risicofactoren, wat het belang van goede preoperatieve patiëntvoorlichting m.b.t. de mogelijkheid van het ontstaan van deze pijnklachten benadrukt.
4. De betrouwbaarheid van rotatie meettechnieken op 2D-CT-scans na TKP is goed tot uitstekend en vergelijkbaar met 3D-CT resultaten. De klinische relevantie hiervan blijft echter onduidelijk. Dit wordt waarschijnlijk veroorzaakt door de over het algemeen positieve klinische resultaten in de onderzoeksgroep, waardoor het moeilijk is een duidelijke relatie te leggen tussen rotatie-uitlijning en patiënt-resultaten.

Appendices

Appendix I. Appendices with Chapter 5

We present in this appendix in more detail our techniques for measuring rotation of the femur and tibia after total knee arthroplasty.

1. Measurement technique for determining rotation of the femur according Berger's method [2].

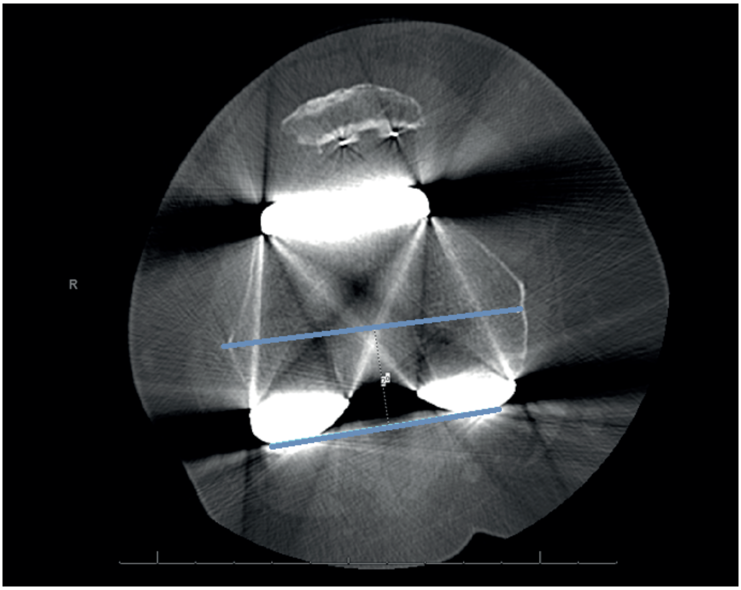

Figure A.1

1. Take the axial slides of the 2D CT-scan images.
2. Use the slide in which the medial sulcus is visible.
3. Draw a line from the medial sulcus to the lateral epicondyle. This is called the surgical epicondylar axis [2].
4. Draw a tangent line connecting the medial posterior condyle to the lateral posterior condyle, this is called the posterior condylar line (PCL)
5. Measure the angle between the PCL and the surgical epicondylar axis. This is called Berger's angle for femur rotation (figure A.1) [2].

2. Measurement technique for determining the rotation of the tibia according Berger's method [1].

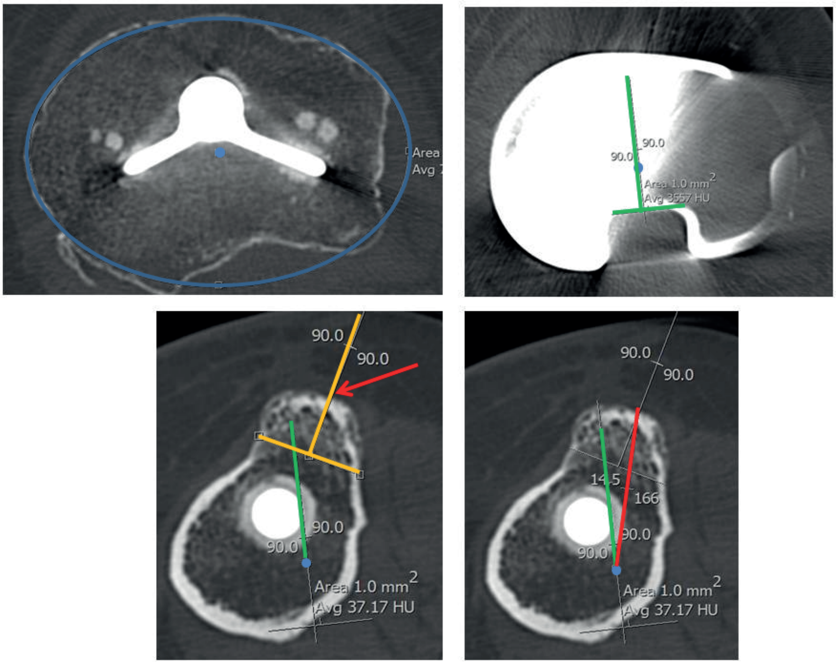

Figure A.2

1. Take the axial slides of the 2D-CT-scan images.
2. Use the slide under the cement interface; the complete tibia circumference has to be visible.
3. Draw an oval circle covering most of the circumference of the tibia (blue circle).
4. Determine the centre of the oval circle.
5. Find the axial slide where the box of the tibia component is good visible. Mark the line of the box as shown in figure A.2.
6. Draw a perpendicular line from the center of the box to the center of the tibia (green line).
7. Find the axial slide where the tip of the tibial stem visible is at the most distal point.
8. Determine the center of the tibial tuberosity by drawing a line from the medial to lateral side of the tibial tuberosity (yellow lines)
9. Draw a perpendicular line (yellow line)) from the center of the tibial tuberosity to the apex (red arrow) of the tibial tuberosity.
10. Draw a line (red line) from the apex (red arrow) of the tibial tuberosity to the previously determined centre of the oval circle.
11. Finally, measure the angle between green and the red line. This is called the Berger's angle for tibia rotation.

3. Measurement technique for determining rotation of the tibia using the anatomical tibial axis (ATA) [3].

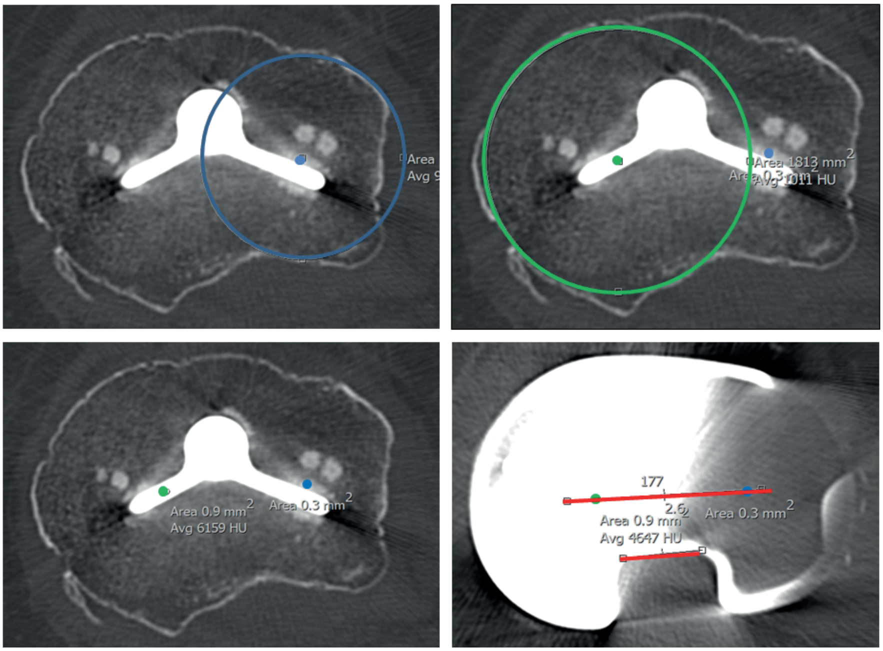

Figure A.3

1. Take the axial slides of the 2D CT-scan images.
2. Use the slide under the cement interface; the complete tibia circumference has to be visible.
3. Determine the centre of the lateral tibia condyle, with a circle (blue circle). Make sure the circle follows the tibia cortex as close as possible. Determine the centre of the circle (blue dot).
4. Use the same procedure for the medial tibia condyle (green circle / green dot).
5. Draw a line between the center of the lateral (blue dot) condyle and the center of the medial (green dot).
6. Find the axial slide where the box of the box of the tibia component is good visible. Mark the line of the box as presented in figure 3 (red line).
7. Measure the angle between the BOX line and the line connecting the centers of the medial and lateral condyle. This is called the anatomical tibial axis (ATA).

4. Measurement technique for determining the tibial tubercle – trochlear groove distance (TT-TG) [4].

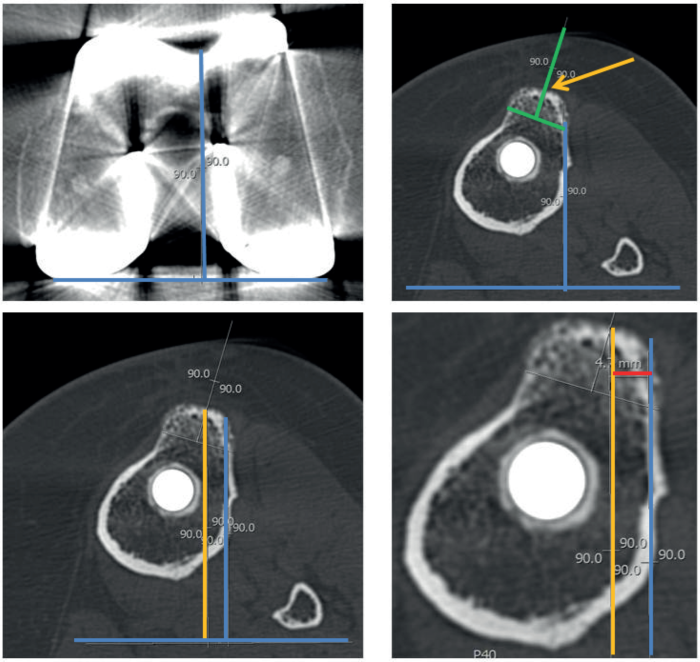

Figure A.4

1. Take the axial slides of the 2D CT-scan images.
2. Take the axial slide in which the deepest point of the trochlea visible is in combination with a symmetrical projection of the posterior condyles of the femur.
3. Draw a tangent line connecting the medial posterior condyle to the lateral posterior condyle (posterior condylar line).
4. Next, draw a line perpendicular to the posterior condylar line to the deepest point of the trochlea (blue line).
5. Find the axial slide where the tip of the tibial stem visible is at the most distal point.
6. Determine the center of the tibial tuberosity by drawing a line from the medial to lateral side of the tibial tuberosity (green line).
7. Draw a perpendicular line (green line) from the midpoint of the green line to the apex of the tibial tuberosity.
8. Next, draw a line perpendicular from the posterior condylar line to the point that line intersect with the cortex of the tibial tuberosity (yellow line).
9. Finally, measure the distance between blue and yellow line. This is called the tibial tuberosity – trochlear groove distance (TT-TG) [4].

References

1. **Berger RA, Crossett LS, Jacobs JJ, Rubash HE.** Malrotation causing patellofemoral complications after total knee arthroplasty. Clin Orthop Relat Res 1998:144–53.
2. **Berger RA, Rubash HE, Seel MJ, Thompson WH, Crossett LS**. Determining the rotational alignment of the femoral component in total knee arthroplasty using the epicondylar axis. Clin Orthop Relat Res 1993(286):40–7.
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4. **Koëter S, Horstmann WG, Wagenaar FCBM, Huysse W, Wymenga AB, Anderson PG.** A new CT scan method for measuring the tibial tubercle trochlear groove distance in patellar instability. Knee 2007; 14:128–32.

Appendix II. Description of the Research Data Management

General information about the data collection

This thesis is based on the results of research involving human cadavers and human participants which were conducted in accordance with relevant national and international legislation and regulations, guidelines, and codes of conduct.
Furthermore, research data management was conducted according to FAIR principles. The paragraphs below specify in detail how this was achieved.

Ethics and privacy

This thesis is based on the results of human studies, which were conducted in accordance with the principles of the Declaration of Helsinki.
For **Chapter 2** ethical approval was not required according to the Dutch Medical Research Involving Human Subjects Act.
For **Chapter 3** the study was approved by two ethical committees: Kantonale Ethik-kommission, Bern, application number 202/10 and Independent Review Board Nijmegen (IRBN), application number NL37085.072.11, IRBN 20110119. The IRBN granted an approval for the study in **Chapter 4,** under the same application number NL37085.072.11, IRBN 20110119. For **Chapter 5** the Sint Maartenskliniek's institutional review board approved the study. Data was also used from another study, that was approved by the Medical Ethical Review Board of Slotervaart and Reade (NL32953.048.11). That trial is registered under the number NTR3585 at the Dutch trial register.
The privacy of the participants from **Chapter 3 to 5** was warranted by the use of pseudonymization.

Funding

Specimen and materials used in **Chapter 2** were arranged by the former European Center of Knee Research (owned by Smith & Nephew). Smith & Nephew partially financed this study (payment to institution of author). The study in **Chapter 3** was partly funded by Mathys Ltd. (Institutional research grant). The studies from **Chapter 4** and **5** received no funding.

Data collection and storage

Data from Chapters **2, 3, 4, and 5** were collected, analyzed, pseudonymized, and stored on a secure server at the Sint Maartenskliniek, Nijmegen, accessible only to project members with restricted access for local study team members.
These secure storage options ensure the availability, integrity and confidentiality of the data.

Data sharing

Although the datasets of **Chapters 2** through **5** could be suitable for reuse, patients (**Chapters 3-5**) did not give permission for sharing of the data within the informed consent, which prevent publication of the datasets. Moreover, due to the very specific type of implants used **in Chapter 3 and 4**, which is only placed in limited numbers in the Netherlands, anonymity cannot be guaranteed. Due to contractual agreements, we are unable to disclose the data from **Chapter 2.**

The data is stored securely and sustainable at the Sint Maartenskliniek (**Chapters 2-5**). Since the participants did not provided consent for sharing and reuse of their data, it is not allowed to request and share the data via the secretariat or via the researchers of the institute. Data was archived by adding sufficient documentation according to local standard operating procedures for archiving. All data not suitable for reuse will be archived for 15 years after termination of the studies.

Appendix III. PhD portfolio of A.H. van Houten

Department: Orthopaedic surgery, Radboud Institute for Health Sciences
PhD period: **01/07/2014 – 01/12/2024**
PhD Supervisor(s): **prof. dr. ir. N.J.J. Verdonschot**
PhD Co-supervisor(s): **dr. P.J.C. Heesterbeek, dr. A.B. Wymenga**

Training activities	Hours
Courses	
- Scientific Integrity, Radboudumc (2020)	28
- BROK cursus, NFU (2020)	42
- Followed courses for orthopaedic training (ATLS provider and advanced, AO Trauma basic and advanced course, CCOC-courses (9x), Groninger Dissectiecursus, heupprothesiologie cursus (Radboudumc Health Academy), Northern Osteotomy Masterclass, NVA Arthroscopy of the knee / schoulder, OTV IV Advanced Pediatrics, Oxford UKP course (2014-2018)	392
- Followed courses for knee fellowship at OCON (NVA Advanced Knee Course)	14
- Balans Werk en Privé. PAO Heyendael (2015)	6
- Medical Business Masterclass (2015)	6
- Coach de Co, AMC (2017)	5
Conferences	
- Oral Presentation: EFORT congress (2014)	56
- 2x Poster Presentation ESSKA (2014)	56
- 1x Poster Presentation World Arthroplasty Congress (2015)	28
- 1x Poster Presentation American Association of Hip and Knee surgeons (AAHKS) Annual Meeting (2016)	28
- 1x Poster Presentation European Knee Society (2017)	56
- Visiting scientific congresses (ESSKA (3x), BKS/DKS meeting, ISAKOS (1x), NOV (3x), NVA Jaarcongres (3x), VOCA congress (2x), World Arthroplasty Congress (2x)	392
Other	
- Visiting weekly seminars and lectures during residency (2014-2018)	224
- Visiting weekly seminars and lectures during fellowship OCON (2019) and as staff member	56
- Review scientific publications (2018-2024)	11
- Organizing OCON FBK Games Sportmedisch Congres (2023 and 2024)	28
- Member of the fellowship committee (NVA-AGA fellowship) of the NVA (2023-2024)	56

Teaching activities	
Lecturing	
- Journal clubs and clinical presentations during residency (2014-2018)	112
Supervision of internships / other	
- Supervision and guidance of technical medicine students from the University of Twente (2019-2020)	28
- Supervision of medical students, research project with focus on complications after ACL reconstruction (University of Groningen)	28
- Supervision of Medical student and Senior House Officer from OCON (2019-2024)	28
Total	**1680**

Appendix IV. Dankwoord

Een proefschrift schrijf je nooit alleen. Hoewel mijn naam op de kaft staat, is dit onderzoek tot stand gekomen dankzij de hulp, steun en inspiratie van velen. Met veel dankbaarheid kijk ik terug op de afgelopen jaren en wil ik graag enkele personen in het bijzonder bedanken.

Mijn copromotoren en promotor

Dr. A.B. Wymenga, beste Ate, het was een voorrecht om jou als leermeester, mentor en copromotor te hebben. Jouw passie voor het kniegewricht, onderzoek en klinische toepassingen is aanstekelijk en heeft geleid tot meerdere onderzoeksprojecten én uiteindelijk dit proefschrift. Dank voor je onmisbare hulp en, vooral, voor het delen van je theoretische en technische kennis van het kniegewricht—kennis waar ik nog dagelijks profijt van heb. Ik wens je de komende jaren nog een behouden vaart.

Dr. P.J.C. Heesterbeek, beste Petra, jij was de drijvende kracht achter dit proefschrift. Dankzij jouw inzet, betrokkenheid en enthousiasme is het gelukt. De pragmatische route bleek uiteindelijk de verstandigste, ook al moest ik daar zelf eerst aan wennen. Je hebt al ongelooflijk veel betekend voor de orthopedie, zowel nationaal als internationaal, en begeleidt promovendi met toewijding. Je wist me steeds op het juiste moment weer te motiveren, dank daarvoor.

Prof. dr. ir. N.J.J. Verdonschot, beste Nico, jij bent in een latere fase bij dit proefschrift betrokken geraakt, maar je impact was groot. Ik heb je leren kennen als een scherp onderzoeker met een helder overzicht, pragmatische aanpak en een sterke brug tussen technologische kennis en de klinische praktijk. Ik betreur het dat we de laatste beoogde studies niet hebben kunnen uitvoeren, maar ik heb enorm genoten van jouw begeleiding en kritische blik. Hopelijk zetten we in de toekomst samen nog een mooi onderzoeksproject op.

Mijn paranimfen

Kasper Bernardt, beste Kasper, onze vriendschap begon als ANIOS in de Sint Maartenskliniek en groeide uit tot een gedeelde reis door de hele opleiding. Als ‘buurman en buurman lossen het op’ in Apeldoorn tot collega’s in ROGO Oost, met heel wat lol en een indrukwekkende verzameling Europese cursussen achter de rug. Jouw motto—*dan gaan wij dat nu regelen*—en persoonlijkheid maakt het volkomen logisch dat jij mijn paranimf bent. Ik heb veel respect voor hoe jij werk en privé combineert en steeds nieuwe uitdagingen aangaat.

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De manuscriptcommissie

Beste **prof. dr. A.C.H. Geurts, prof. dr. S.K. Bulstra en prof. dr. ir. G.J. Verkerke**, hartelijk dank voor het lezen en beoordelen van dit proefschrift.

Mijn medeauteurs

Beste **Bernard Christen, Henk Eijer, Gerjon Hannink, Nienke Kosse, Joachim Klenk, Luc Labey, Andreas Schuster** en **Mascha Wessels**, dank voor jullie bijdragen aan dit proefschrift.

De patiënten

Een klinische studie is onmogelijk zonder de deelname van patiënten. Mijn grote dank aan hen en hun familieleden voor hun bereidheid om deel te nemen en data beschikbaar te stellen. Ik hoop dat de resultaten uit dit proefschrift bijdragen aan de verbetering van de operatieve behandeling van knie-artrose.

Orthopedisch chirurgen en AIOS ROGO Oost

Tijdens mijn opleiding en promotieonderzoek heb ik veel steun gehad van alle orthopedisch chirurgen en AIOS van ROGO Oost. Met veel plezier kijk ik terug op mijn opleidingstijd en daar wil ik jullie graag voor bedanken. Een speciale dank aan de leden van de jaarclub **Stijn, Kasper, Bram** en 'de mama's' **Akkie en Floortje.**

Research & Orthopedie Sint Maartenskliniek

Mijn dank aan alle medewerkers die hebben geholpen bij het uitvoeren van de klinische studies. Een speciale dank aan **Saskia Susan** en **Jolanda Rubrech** voor hun coördinatie en inzet bij de dataverzameling.

Team OCON

Aan de vakgroepen orthopedie, sportgeneeskunde en anesthesiologie, directie, managementteam en alle medewerkers van OCON: dank voor de inspirerende werkomgeving. Sinds mijn start als fellow kniechirurgie in 2019 voelde ik me hier direct thuis. Ik beschouw het als een groot voorrecht om als staflid binnen een hooggespecialiseerde kliniek te mogen werken, waar professionaliteit en betrokkenheid hand in hand gaan. Laten we dat samen blijven voortzetten.

Omnivagus

Beste **Thomas Dobbe, Corneel Jonkers, Chris van Rey, Thomas Metz, Robert Verhoek, Thomas Otten** en **Bram Konings†**, we kennen elkaar inmiddels al ruim 20 jaar en hebben veel meegemaakt. Ondanks de fysieke afstand blijven we een hechte groep. Jullie vriendschap, steun en humor betekenen veel voor me.

Vrienden van Geneeskunde & Partners

Beste **Max & Sally, Maarten & Sanne, Jeroen & Suzanne, Mark & Rosanne, Laurens & Myrthe, Geert & Lonneke, Ward & Anniek en Tom & Saskia**, wat hebben we in de loop der jaren veel gedeeld: van geboortes, huwelijken tot nieuwe banen over het hele land, van fiets- en vriendenweekenden tot wintersport en roadtrips. Dank voor jullie luisterend oor en de broodnodige afleiding.

Mijn familie

Harrie en Franca, lieve schoonouders, dank voor jullie steun, interesse en nuchterheid. Jullie staan altijd klaar voor ons wanneer dat nodig is.

Len & Cindy en Ron, ik voel me al jaren welkom in jullie familie en heb me zelfs een beetje geïntegreerd in het Brabantse leven. Dat is niet eenvoudig voor iemand uit de randstad, dank voor jullie hulp hierbij.

Victor, lieve broer, we hebben vaak weinig woorden nodig, maar begrijpen elkaar toch. Jij dromerig, ik serieus, jij stadsmens, ik van beide werelden— maar allebei erg precies en vaardig. Jouw brede interesses, humor en intelligentie maken onze gesprekken en samenzijn als vanouds. Samen met **Floor** hou je van reizen, design en grapjes. Het 'Dream Team' is letterlijk present. Dank voor jullie aanwezigheid in mijn leven.

Lieve **Hessel en Jenny,** papa en mama, jullie gaven me een onbezorgde jeugd in Den Haag, vol aandacht, varen, stad, strand, zee en duinen. Dankzij jullie kreeg ik de vrijheid om mijn eigen pad te kiezen, met eindeloze steun, interesse en inspiratie. Dank voor alles.

Mijn gezin

Lieve Hannah en Olivier, wat bof ik om jullie vader te mogen zijn. Jullie zijn nu nog jong, onbevangen en meestal vrolijk, en het is prachtig om te zien hoe snel jullie je ontwikkelen. Vader zijn van jullie is meestal makkelijk, maar niet altijd—soms nemen jullie een creatieve afslag die ik niet zag aankomen. Maar juist dat maakt het zo leuk. Ik geniet elke dag van jullie en hoop dat jullie later net zo vrij en vol vertrouwen je eigen koers bepalen.

Lieve Geke, wat is de tijd snel gegaan. We zijn al zoveel jaren samen en toch is geen dag hetzelfde. Onze verschillen maken ons sterk: jij bent een duizendpoot, een harde werker, efficiënt, georganiseerd, charmant en sportief. Als ik het zo samenvat, zou je net zo goed chirurg kunnen zijn in plaats van klinisch geriater. Dat we uiteindelijk niet in Nijmegen bleven wonen, vergde aanpassingen van jou, zowel professioneel als privé, en ik bewonder hoe je dat hebt gedaan. Thuis hebben we het relatief weinig over werk, en dat is maar goed ook—er zijn zoveel andere mooie dingen in het leven om te bespreken. Na mijn verdediging gaan we meteen door naar een nieuw groot avontuur: een nieuw thuis creëren, waar we als gezin nooit meer weg hoeven. Ik kan niet wachten om daar de rest van ons leven samen door te brengen. Schatje, ik hou van je.

Appendix V. List of publications

1. Welling W, Paalman J, Speerstra R, **Van Houten AH**, Hoogeslag RAG.
Monitoring hamstring and quadriceps strength using handheld dynamometry in patients after ACL reconstruction: A prospective longitudinal study.
Journal of Orthopedics. 2025;59:128–136

2. Gokeler A, Zandbergen MA, Hoogeslag RAG, **van Houten AH,** Nijmeijer EM, Heuvelmans P.
Neurocognitive demands reduce jump distance and coordination variability of the injured leg in athletes after anterior cruciate ligament reconstruction.
Knee Surgery, Sports Traumatology, Arthroscopy. Published online August 27, 2024. doi:10.1002/ksa.12439

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4. Laven IEWG, Schröder FF, de Graaff F, Rompen JC, Hoogeslag RAG, **van Houten AH.**
Accuracy, inter- and intrarater reliability, and user-experience of high tibial osteotomy angle measurements for preoperative planning: manual planning PACS versus semi-automatic software programs.
Journal of Experimental Orthopaedics. 2022;9(1):44

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Limited effect of anatomical insert geometry on in vitro laxity in balanced anatomic posterior cruciate ligament retaining total knee arthroplasty.
Knee Surgery, Sports Traumatology, Arthroscopy. 2022;30(4):1273-1281

6. Mens R, **van Houten AH**, Brokelman RBG, Hoogeslag RAG.
Iatrogenic common peroneal nerve injury during harvesting of semitendinosus tendon for anterior cruciate ligament reconstruction.
BMJ Case Reports. 2021;14(4):e240736

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What Is the Reliability of a New Classification for Bone Defects in Revision TKA Based on Preoperative Radiographs?
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10. **van Houten AH**, Heesterbeek PJC, Wymenga AB.
    Patella position is not a determinant for anterior knee pain 10 years after balanced gap total knee arthroplasty.
    Knee Surgery, Sports Traumatology, Arthroscopy. 2016;24(8):2656-2662

11. **van Houten AH**, Heesterbeek PJC, van Heerwaarden RJ, van Tienen TG, Wymenga AB.
    Medial open wedge high tibial osteotomy: can delayed or nonunion be predicted?
    Clinical Orthopaedics and Related Research. 2014;472(4):1217-1223

12. Iriuchishima T, Ingham SJM, Tajima G, Horaguchi T, Saito A, Tokuhashi Y, **van Houten AH**, Aerts MM, Fu FH.
    Evaluation of the tunnel placement in the anatomical double-bundle ACL reconstruction: a cadaver study.
    Knee Surgery, Sports Traumatology, Arthroscopy. 2010;18(9):1226-31

13. Tajima G, Iriuchishima T, Ingham SJM, Shen W, **van Houten AH**, Aerts MM, Shimamura T, Smolinski P, Fu FH.
    Anatomic double-bundle anterior cruciate ligament reconstruction restores patellofemoral contact areas and pressures more closely than nonanatomic single-bundle reconstruction.
    Arthroscopy - Journal of Arthroscopic and Related Surgery. 2010;26(10):1302-1310

Appendix VI. Curriculum vitae

Albert van Houten was born on August 10 1985, in Rotterdam, the Netherlands. He attended primary and secondary school in the Hague, where he graduated from highschool (Vrijzinnig Christelijk Lyceum, The Hague) in 2003. After spending one year at university in Leuven, Belgium, he began his medical studies at Radboud University Nijmegen.

His interest in orthopaedic surgery as a specialty emerged during his medical studies, particularly after attending lectures by dr. Micha Holla. Before starting his clinical rotations, he completed a research internship at the Department of Orthopaedic Surgery at the University of Pittsburgh Medical Center (UPMC) under the supervision of world-renowned dr. Freddie Fu. He then proceeded with his clinical rotations and completed his final internship at the Sint Maartenskliniek Nijmegen in 2010.

In 2011, he began working as a resident not in training, first at Medisch Centrum Alkmaar and later at the Sint Maartenskliniek Nijmegen. In 2013, he started his residency in orthopaedic surgery. He completed his general surgery rotation at Gelre Hospital in Apeldoorn (dr. P. van Duijvendijk) and his orthopedic rotations at the Sint Maartenskliniek in Nijmegen (dr. A.B. Wymenga and dr. V.J.J.F. Busch), Radboud UMC Nijmegen (dr. M.C. de Waal Malefijt), and Rijnstate Hospital Arnhem (dr. W.J. Rijnberg). During his residency, he developed a particular interest in the diversity and complexity of the knee joint.

Following his residency, in 2019, Albert completed a fellowship in knee (sports) surgery at the Centre for Orthopaedic Surgery and Sports Medicine (OCON) in Hengelo, the Netherlands. In 2020, he started working as a consultant orthopaedic surgeon specialising in knee surgery at OCON. His primary focus is on treating ligamentous, cartilage, and meniscus injuries, although he also enjoys managing the full spectrum of knee disorders, including lower leg osteotomy, patellofemoral stabilisation, and both partial and total knee arthroplasty. In the coming years, he aims to initiate and conduct research projects within OCON and in collaboration with regional stakeholders.

In his free time, Albert enjoys cycling, fitness, exploring new hobbies and projects, and spending time with his children, family, and friends. He and his partner, Geke van den Elsen, live in Gorssel with their two children, Hannah (born in 2018) and Olivier (born in 2020). At the beginning of 2026, they hope to move into their new home in Joppe.

Appendix VII. Theses Sint Maartenskliniek

Ensink, C. (2025) Sensing the path to mobility - advancing gait rehabilitation with sensor technology. Radboud University Nijmegen, Nijmegen. The Netherlands.

Ulijn, E. (2025) Evaluating the (over)use of diagnostics in rheumatoid arthritis care. Radboud University Nijmegen, Nijmegen. The Netherlands.

Van der Togt, C. (2025) Further optimising treatment with biologicals and JAK-inhibitors in inflammatory arthritis: Focus on vaccine effectiveness and cost-effectiveness. Radboud University Nijmegen, Nijmegen. The Netherlands.

Van Rensch, P. (2025) Revision total knee arthroplasty. Optimizing the journey. Radboud University Nijmegen, Nijmegen. The Netherlands.

Zwijgers, E. (2025) Improving walking capacity after spinal cord injury. Radboud University Nijmegen, Nijmegen. The Netherlands.

Boekesteijn, R. (2024) Evaluating walking in lower-extremity osteoarthritis: Beyond the lab, towards the real world. Radboud University Nijmegen, Nijmegen. The Netherlands.

Den Broeder, N. (2024) More than tapering, less than full dose - Efficient use of biologics in the treatment of rheumatoid arthritis. Radboud University Nijmegen, Nijmegen. The Netherlands.

Kuijpers, R. (2024) Adapt your step: Clinical assessment and training of walking adaptability in children with mild motor disorders. Radboud University Nijmegen, Nijmegen. The Netherlands.

Te Molder, M. (2024) The unhappy patient after TKA. A paradigm shift in assessing outcome. Radboud University Nijmegen, Nijmegen. The Netherlands.

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Pelle, T. (2021). Beating osteoarthritis by e-self management in knee or hip osteoarthritis. Radboud University Nijmegen, Nijmegen. The Netherlands.

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Willems, L. (2015). Non-pharmacological care for patients with systemic sclerosis. Radboud University, Nijmegen, The Netherlands.

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