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Mind the gaps!

Clinical and technical aspects of PCL-retaining total knee replacement with the balanced gap technique

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Contents

List of papers

This thesis is based on the following papers:

1. Christen B, Heesterbeek P, Wymenga A, Wehrli U. Posterior cruciate ligament balancing in total knee replacement: the quantitative relationship between tightness of the flexion gap and tibial translation. J Bone Joint Surg [Br] 2007; 89-B: 1046-50.

2. Heesterbeek PJC, Keijsers NLW, Jacobs WCH, Verdonschot N, Wymenga AB. Posterior cruciate ligament recruitment affects antero-posterior translation during flexion gap distraction in total knee replacement. Intra-operative study in 50 patients. Acta Orthop 2010; 81: 471-477.

3. Heesterbeek PJC, Verdonschot N, Wymenga AB. In vivo knee laxity in flexion and extension: a radiographic study in 30 older healthy subjects. Knee 2008; 15: 45-49.

4. Heesterbeek PJC, Keijsers NLW, Wymenga AB. Ligament releases do not lead to increased postoperative varus-valgus laxity in flexion and extension: a prospective clinical study in 49 TKR patients. Knee Surg Sports Traumatol Arthrosc 2010; 18: 187-193.

5. Heesterbeek PJC, Wymenga AB. Correction of axial and rotational alignment after medial and lateral releases during balanced gap TKA. A clinical study of 54 patients. Acta Orthopaedica 2010; 81: 347-353.

6. Heesterbeek PJC, Jacobs WCH, Wymenga AB. Effects of the balanced gap technique on femoral component rotation in TKA. Clin Orthop Relat Res 2009; (497): 1015-1022.

7. Heesterbeek PJC, Beumers MPC, Jacobs WCH, Havinga ME, Wymenga AB. A comparison of reproducibility of measurement techniques for patella position on axial radiographs after total knee arthroplasty. Knee 2007; 14: 411-416.

8. Heesterbeek PJC, Keijsers NLW, Wymenga AB. Femoral component rotation after balanced gap total knee replacement is not a predictor for postoperative patella position. Knee Surg Sports Traumatol Arthrosc 2011; 2011;19:1131-1136.

9. Clinical and functional results of patients with a total knee replacement compared to the healthy elderly. Unpublished data.

Introduction

In this thesis several aspects and consequences of the balanced gap implantation technique for total knee replacement (TKR) will be described and analyzed. Although this technique was introduced as early as in 1976 by Insall (Insall et al. 1976) thanks to modern technologies it has further evolved which has raised this TKR procedure to a higher level. This introduction starts by describing the relevant anatomy and biomechanics of the knee necessary to understand the subsequent studies. In addition, a short description of osteoarthritis of the knee and the total knee replacement as a choice of treatment will be given. The two main implantation philosophies around the total knee replacement will also be explained, and the balanced gap technique will be introduced and described. In conclusion the issues around the balanced gap implantation technique – which lead to the main research questions that will be addressed in the subsequent studies of this thesis – will be outlined.

Anatomy and biomechanics of the knee

Anatomy

The knee joint is the largest and one of the most complex joints in the human body. A unique interaction of bones, muscles, menisci, and ligaments results in a compromise between stability and mobility: the knee has to withstand stresses from body weight and (muscle) lever forces while at the same time it has to enable mobility to produce movement.

The knee consists of two articulations: one between the femur and tibia, the tibia-femoral joint, and one on the anterior side: the patella-femoral joint.

The joint surfaces of the femur, tibia, and patella are covered with a thin layer of articular cartilage. The synovial membrane seals the joint and secretes synovial fluid to reduce the friction during movement. The medial and lateral menisci also have this function and they further act as shock absorbers and pressure distributors.

The knee is a pivotal hinge joint, which permits flexion and extension as well as limited internal and external rotation. The shape of the bones together with the ligaments around the knee facilitates these movements.

The bony architecture of the femur consists of two asymmetrical rounded prominences, the femoral condyles (Figure 1). The posterior condyles have a circular geometry (Eckhoff 2005) and are separated by a space called the intercondylar notch. The femoral condyles join anterior and proximally in the femoral trochlear groove. The patella articulates here with the femur. The sulcus is the lowest point of the trochlear groove and lies lateral to the midplane of the distal femur.

The proximal tibia is a 3-dimensional asymmetrical structure (Figure 2). The medial articular surface is concave whereas the lateral articular surface is convex. The menisci, which are located on top of the articular surfaces of the tibia, guide the femoral condyles on the tibia surface during flexion and extension. The natural slope of the tibia plateau is 3 degrees down from lateral to medial and 5–10 degrees down from anterior to posterior (Vail and Lang 2006).

The patella is the largest sesamoid bone in the body. It is oval shaped and 2–2.5 cm thick. The lateral facet is larger than the medial facet and lies slightly lateral of the femoral midplane. The most important function of the patella is to increase the

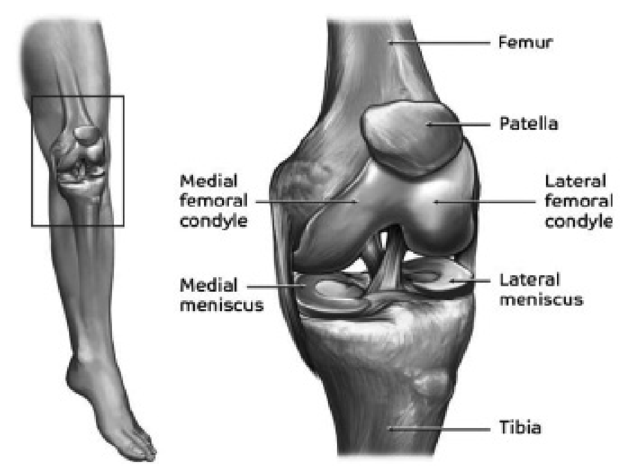

Figure 1. Bony anatomy of the distal femur and proximal tibia. Medical Illustration © 2010 Nucleus Medical Media, Inc., www.nucleusinc.com.

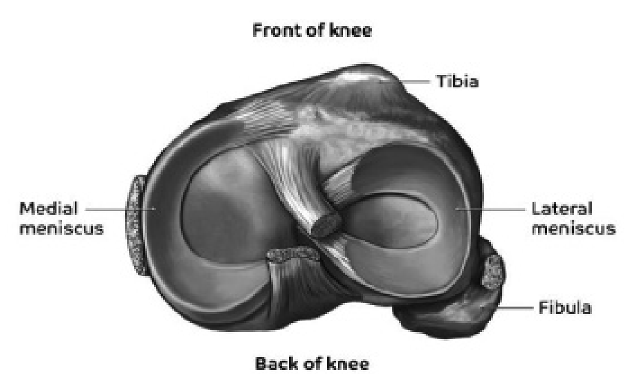

Figure 2. Top view of the proximal tibia. Medical Illustration © 2010 Nucleus Medical Media, Inc., www.nucleusinc.com.

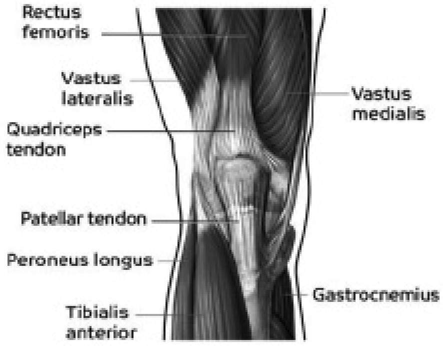

Figure 3. Quadriceps muscle and tendons around the knee, anterior view. Medical Illustration © 2010 Nucleus Medical Media, Inc., www.nucleusinc.com.

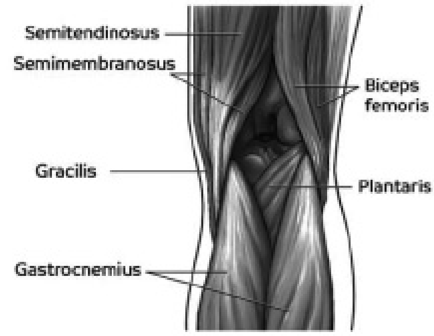

Figure 4. Hamstrings muscle and tendons, posterior view. Medical Illustration © 2010 Nucleus Medical Media, Inc., www.nucleusinc.com.

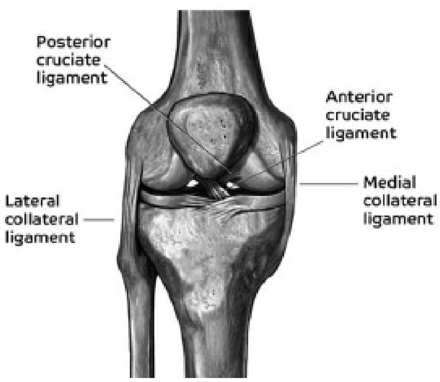

Figure 5. The ligaments of the knee, anterior view. Medical Illustration © 2010 Nucleus Medical Media, Inc., www.nucleusinc.com.

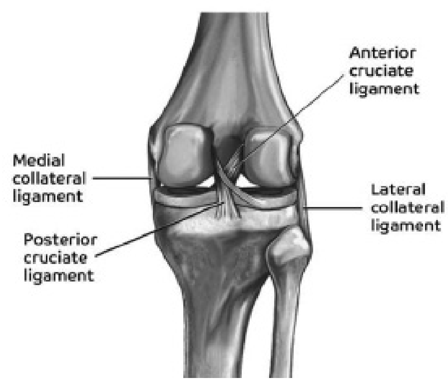

Figure 6. Ligaments of the knee, posterior view. Medical Illustration © 2010 Nucleus Medical Media, Inc., www.nucleusinc.com.

moment produced by the already strong quadriceps femoris muscle by increasing the lever arm by increasing the distance of the quadriceps tendon from the flexion axis of the knee. The retinaculum and synovium are attached to the patella and the patella tendon and pass around the medial and lateral aspects of the knee to the distal femur and proximal tibia. The soft tissue sleeve that runs from hip to ankle acts as a protector and provides nutritional support to the knee. In addition to skin, fat, capsule and synovium, a network of vessels and nerves is present at the posterior aspect of the knee.

The major extensor mechanism on the anterior aspect of the knee is formed by the m. quadriceps (Figure 3). This muscle group consists of the rector femoris, vastus lateralis, vastus intermedius, and the vastus medialis; it originates from the pelvis (rectus femoris) and proximal femur (vasti), and inserts via the patella tendon to the anterior proximal tibia.

The muscle-tendon complexes of the hamstrings, the main knee flexors and the rotators of the knee lie on the posterior aspect of the knee. The lateral hamstring (biceps femoris) and medial hamstrings (semitendinosis and semimembranosis) run from the pelvis to the fibular head (biceps femoris) or medial aspect of the tibia (Figure 4). Another bi-articular muscle present at the posterior aspect of the knee is the gastrocnemius muscle. This muscle originates proximal and posterior to the femoral condyles and inserts to the calcaneus through the Achilles tendon. The popliteal muscle serves as a static and dynamic posterolateral knee joint stabilisator and runs from the posterolateral femur to the posterolateral tibia. The iliotibial (IT) band runs from the lateral pelvis to the antrolateral tibia and inserts at Gerdy's tubercle. The IT band serves as an exorotator of the tibia.

Four important ligaments join the femur and the tibia: two collateral ligaments and two cruciate ligaments (Figure 5).

The medial collateral ligament (MCL) consists of the deep MCL and the superficial MCL. The deep MCL originates from the area of the medial epicondyle and inserts onto the medial meniscus and the proximal medial tibia plateau. The superficial MCL has the same origin but no meniscal attachment and inserts more distally along the medial tibia. The MCL runs obliquely from posterior proximal to anterior distal.

The lateral collateral ligament (LCL) originates on the femur on the area of the lateral epicondyle and inserts onto the fibular head. Opposite to the MCL, the LCL runs obliquely from anterior proximal to posterior distal. The femoral origins of the MCL and the LCL lie on an axis through the medial and lateral epicondyle: the epicondylar line.

The anterior cruciate ligament (ACL) originates from the lateral wall of the femoral intercondylar notch and inserts onto the mid-tibia between the articular surfaces. The sagittal slope of the ACL runs from posterior proximally to anterior distally. The ACL is commonly excised during total knee replacement.

The posterior cruciate ligament (PCL) originates from the medial wall of the intercondylar notch and inserts onto the posterior aspect of the tibia (Figure 6). The sagittal slope of this ligament is opposite to that of the ACL and runs from anterior proximal to posterior distal. The origins of the ACL and PCL lie approximately on an axis through the centres of the femoral condyles: the condylar line. The PCL can be either retained or substituted during total knee replacement. The clinical significance of the specific insertions of the four most important ligaments of the knee lies in their ability together with the geometry of the articular surfaces to restrict the laxity of the knee in different flexion angles.

Biomechanics

Knee flexion can be divided into three stages: the screw-home arc, the functional active arc, and the passive deep flexion arc (Williams and Phillips 2005). The first stage, the screw-home arc, refers to the movement from 20 degrees of flexion to extension. Little is known about the functional significance of this segment of the flexion arc. The shapes of the medial and lateral femoral condyles, which participate in the articulation of these low flexion angles are highly asymmetrical and guide the movement in this range of flexion. The lateral femoral condyle rotates internally during the screw-home arc.

The second stage, the functional active arc, covers the range from 20 to 120 degrees of flexion. In this range, longitudinal, or, axial rotation is not obligatory and depends on the activity and amount of muscular control as well as the position of the foot (Freeman and Pinskerova 2003). The knee may act as a uniaxial hinge (Hill et al. 2000) there is no roll-back of the medial femoral condyle (Freeman and Pinskerova 2003).

The third stage, the passive deep-flexion arc refers to the segment between 120–140 degrees of flexion and is the result of an external force (mostly body weight). Both the medial and the lateral condyles move posteriorly (medial condyle approximately 9 mm, lateral condyle an additional 10 mm) and seem to subluxate slightly (Iwaki et al. 2000, Williams and Phillips 2005). The tension of the extensor mechanism and the posterior anatomical impingement control the movement of the femur relative to the tibia in these high flexion angles.

Before open access MRI scanners were available and before 3-dimensional imaging of the 3-dimensional movements of the knee had been made possible, there was the "illusion" of femoral rollback on the available lateral projections. Actually, the longitudinal axial rotation (internal tibial rotation or external femoral rotation) seen during deeper knee flexion takes place around an axis through the medial compartment (Komistek et al. 2003, Williams and Phillips 2005). Roll-back exists only for the lateral condyle; the medial condyle demonstrates a "spinning on the spot", instead of "rolling" (Iwaki et al. 2000, Williams and Phillips 2005). Only the first 5 degrees of external femoral rotation are obligatory between 0 and 10 degrees of flexion, further external rotation of the femur can be suppressed by applying external rotation to the tibia with muscular force (Iwaki et al. 2000).

Another previously adapted model is the four-bar linkage model. That model was first described by Zuppinger in 1904 (Williams and Logan 2004). It was thought that the cruciate ligaments guided tibiofemoral motion when taut. Furthermore, the model depended on the bars being straight, taut, rigid, and arranged in a single plane (Williams and Logan 2004). However, further research has provided arguments to discredit the four-bar linkage model. Although the PCL is arranged mainly in the sagittal plane, the ACL is a multiplanar structure. Furthermore, in extension the PCL is curved around the posterior tibia, thereby being neither rigid nor taut. Recently, studies have demonstrated that the cruciate ligaments only guide during excessive application of force as in sports (Logan et al. 2004a, Logan et al. 2004b). Basically, the ACL assists in controlling rotation and static weight-bearing tibiofemoral position in both compartments, whereas the PCL acts similarly mainly in the medial compartment. Articular geometry is a more potent factor driving tibiofemoral positioning during knee kinematics (Williams and Phillips 2005). Kinematic analyses of typical activities of daily living, such as walking, stair climbing, deep knee flexion, show that knee motion is activity dependent (Andriacchi and Dyrby 2005).

Osteoarthritis

Pain is the predominant symptom with which patients present themselves to the physician, accompanied by swelling and loss of function and motion of the knee. In cases of mild osteoarthritis, the pain is usually relieved by rest, without night pain or morning stiffness. When the osteoarthritis is more advanced, patients typically have pain at the beginning of movement. It is unclear which structure transmits the pain to the neural system. Since cartilage has no nerve supply, probably the subchondral bone, or the other intra- and periarticular structures as the synovium, menisci or ligaments may act as pain sensors.

Clinical examination shows pain (during passive and active movement of the knee), local tenderness, crepitus, joint swelling, and osteophytosis or adverse bone remodelling. Often muscle atrophy of the m. quadriceps is present due to secondary disuse, and secondary axis deviations (genu vara or valga) due to asymmetrical cartilage wear are also found.

The diagnosis osteoarthritis can be confirmed by radiographic imaging of the three compartments of the knee. A weight-bearing anteroposterior view, a mediolateral and a skyline view of the patella can show joint space narrowing, subchondral bone sclerosis and osteophytes (Figure 7). There is a poor correlation between clinical findings and radiographic

Figure 7. Left: Anteroposterior view of a knee with osteoarthritis. On the medial side, narrowing of the joint space is clearly visible, as well as osteophytes.

Right: Sagittal view of a knee with patellofemoral osteoarthritis. Bone sclerosis (white) as well as joint space narrowing is visible in this patient.

Figure 8. Knee with total knee replacement. (Adapted from: http://nosleepingdogs.wordpress.com/2009/06/10/total-knee-replacement-surgery-the-second-time-around-learn-from-experience/).

changes. A CT- or MRI scan can help to define the degree or nature of damage to the cartilage, subchondral bone or soft tissues (Wenham and Conaghan 2009).

Treatment of osteoarthritis depends on the stage of the disease. Non-medical approaches include patient instruction, weight loss and restoring muscle strength. The medical approach consists of treating pain with pain relieving drugs or intra-articular injections with corticosteroids. So far, there seems to be some preliminary evidence as to whether nutritional supplements as glucosamine or hyaluronic acid injections will help (Black et al. 2009, Vangsness, Jr. et al. 2009, Bannuru et al. 2009).

Surgical options for treatment include tissue repair (including cartilage repair), and arthroscopic debridement. When the osteoarthritis is limited to just one knee compartment, the surgeon may decide for an unicompartmental knee replacement or osteotomy. The osteotomy may help to unload the diseased knee compartment through an alignment correction. In case of progressive osteoarthritis, a total knee replacement (TKR) may be the option of choice (Figure 8).

Total knee replacement

During a TKR procedure the articulating surfaces of the knee are replaced within the existing soft tissue envelope. The TKR as presently known is a condylar type implant, consisting of a femoral component, a tibial component, and sometimes a patellar component. This condylar implant was first introduced in 1970's (Robinson 2005). The femoral component is usually made of metal, articulating on a polyethylene component which is connected to a metal tibial tray. The components can be fixed to the bone by bone cement or in a press-fit manner, allowing fixation by bone-ingrowth into the prosthetic surface.

TKR survivorship is good; rates of 91% at ten years, 84% at 15, and 78% at 20 years have been reported (Rand et al. 2003). Several factors that can affect the survival are implant type, age and gender of the patient, diagnosis, type of fixation, and design of the patellar component (Rand et al. 2003). Although TKR results are good, on-going development of adapted designs for the components and implantation techniques to improve the functional outcome of the active (younger) patient continues.

Computer navigation

At the end of the 1990s, computer assisted surgery became available for the surgical treatment of orthopaedic trauma and total joint arthroplasty. The need to improve precision and accuracy is apparent since traditional implant alignment methods with manual instrumentation rely on extensive visual referencing of bony landmarks and the use of jigs and aiming instrumentation. Critical bony landmarks such as the epicondyles and the original joint surface are sometimes difficult to identify during surgery (Jerosch et al. 2002, Jenny and Boeri 2004) these and other factors such as variations in anatomy, difficulty with exposure or significant bone loss, can lead to deviations from correct alignment. Although surgeons who do not use navigation during TKA indicate that they are not convinced that navigation improves clinical outcome and alignment of the prosthesis (Friederich and Verdonk 2008) a meta-analysis by Mason and colleagues presents results in favour of navigation with respect to component alignment (Mason et al. 2007). In that review of both randomized controlled trials (RCTs) and prospective and historical nonrandomized controlled trials, the authors found that the use of computer navigation during TKR results in significantly fewer outliers for the mechanical axis, the frontal femoral and tibial component alignment, and the femoral and tibial slope. Hence, navigation significantly reduces the number of alignment outliers and improves component orientation. However, whether these improvements in alignment are directly translated into improved implant longevity and improved clinical outcome still needs to be shown in the coming decade.

Computer navigation was used during the TKR surgeries described in this thesis (studies 2, 4, 5, and 8). Improving implant alignment was not the primary purpose for using navigation; rather we used it as a measurement device to investigate the relative movements of the femur and tibia and to study implant position more accurately.

Two surgical philosophies of TKR implantation

In TKR there exist 2 main surgical philosophies: the measured resection technique and the balanced gap technique. These two distinct techniques developed as a result of two approaches toward implants and instruments during the early days of knee arthroplasty. Although these techniques originate from fundamentally different concepts, over time the instruments were developed that incorporated aspects from both philosophies, thus obscuring the distinctions. Nowadays these techniques differ mainly in the procedure for rotational alignment of the femoral component.

Measured resection technique

The measured resection technique was introduced in 1978 by Hungerford, Kenna & Krackow (Hungerford et al. 1982, Hungerford and Hungerford 2005). That technique originated from surgeons and engineers who aimed for anatomical resurfacing and who were advocates of retaining the PCL (Robinson 2005). The principle of this technique is to resect the amount of distal and posterior femoral bone that will be replaced by prosthetic components. The goal is to attain articular surfaces at the same level as those in the natural knee; i.e. anatomical cuts. First, the tibia cut comprised a 3 degree mediolateral slope, comparable to the natural knee. Since the cuts had to be symmetric, the femoral cut also had a 3 degree mediolateral slope. Later, surgeons found that a perpendicular tibia cut was easier to perform and this became the standard. To compensate for lateral laxity during flexion, the anterior and posterior femoral cuts had to be exorotated 3 degrees. In addition to referencing with regard to the posterior condyles, more variation in this fixed, 'measured' reference was introduced with the use of the transepicondylar axis and the antero-posterior line, or Whiteside's line, as bony landmarks for femoral component rotation. Measured resection techniques independently osteotomize the tibia and femur, aiming to remove only enough bone to accommodate the component; ligament releases to achieve correct leg alignment are usually performed after implanting the prosthesis (Berger et al. 1993, Whiteside and Arima 1995, Poilvache et al. 1996, Olcott and Scott 2000, Katz et al. 2001, Vail and Lang 2006). This philosophy is the most commonly used practice nowadays and has been integrated into the majority of the available TKR systems. The thickness of the implant is still the reference for the bone cuts and for most patients this is the proper solution. Today, the PCL can either be retained or substituted.

Figure 9. Bi-compartmental tensor of the balanSys™ system.

Balanced gap technique

The balanced gap technique, or the classic alignment method, was introduced by Insall and Freeman in the '70s (Insall et al. 1976) and originated with those surgeons aiming for functional replacement by resecting the PCL (Robinson 2005). This technique also builds from a tibia cut perpendicular to the mechanical axis of the tibia. In extension this approach is partly comparable to the measured resection technique; the thickness of the implant determines the amount of resected bone. However, the specific philosophy of the gap technique is that the ligaments are tensioned after the initial soft tissue correction. Thereafter gap resection is performed (Vail and Lang 2006). During flexion, this technique differs the most from the measured resection technique: the soft tissues are tensioned with laminar spreaders or tensors and determine the rotation of the femoral component. Theoretically, this technique results in stable and balanced (i.e. rectangular) extension and flexion gaps.

At present, surgical instruments often include a tensor or spreader to distract the extension and flexion gaps. Insall introduced a prototype of the modern spreader in his publication in 1976 and described it in more detail in 1985 (Insall et al. 1976, Insall et al. 1985). At that time, Freeman also described a spreader (Moreland et al. 1979). The balanced gap technique used for all patients in this thesis was the balanSys™ system (Mathys Ltd, Bettlach, Switzerland). The instrumentation for this system uses either conventional (manual) alignment references or computer navigation and the PCL is retained. There are several possible approaches but the surgical technique used in the studies of this thesis starts with a proximal tibia cut 6–8 mm below the unworn compartment perpendicular to the mechanical axis, with a dorsal slope of 7°. After osteophyte removal, a bi-compartmental tensor is inserted into the knee in extension (Figure 9). Frontal alignment of the leg is controlled by ligament tension. Releases of the collateral ligaments are performed when necessary to achieve correct leg alignment. Thereafter the distal femoral cut is performed parallel to the tibia cut. Subsequently, the tensor is inserted into the joint at

90° flexion to balance the PCL. The femur rotates guided by the ligaments; if the medial side is looser then the femur will exorotate. In the other extreme, if the lateral side is looser, then the femur will show endorotation. Subsequently, the ventral and dorsal femoral cuts are performed parallel to the tibial resection. Hence, the tension in the soft tissue structures determines the posterior femoral cut, and therefore, rotation of the femoral component can vary.

Issues

As described above, the knee is a complex joint, and replacing part of it by an implant requires an in-depth understanding of the complex interaction that takes place within and around the joint. Several issues are related to the balanced gap technique due to its specific approach focusing on soft tissue management.

The overall aim of this thesis is to investigate the effects of the balanced gap implantation technique on knee stability. Furthermore, technical issues such as releases, femoral component rotation, and balancing of the posterior cruciate ligament and the consequences of these aspects are addressed. Below, the several issues are introduced further and explained, resulting in the outline of this thesis, given in Figure 10.

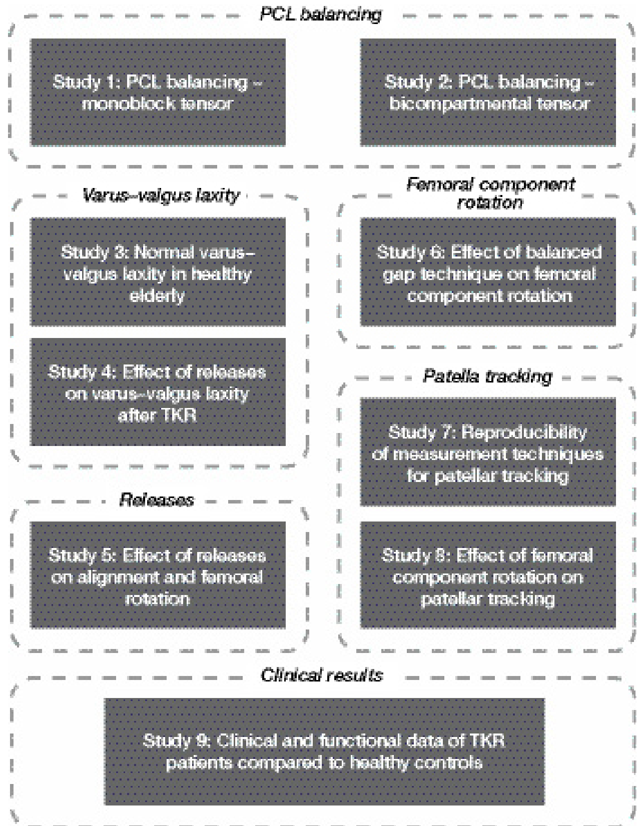

Figure 10. Schematic illustration of the outline of this thesis.

PCL balancing (Studies 1 and 2)

There is still no consensus whether the PCL should be retained or substituted. The scientific evidence is limited although a meta-analysis showed 8 degrees more range of motion in favour of PCL substitution (Jacobs et al. 2005). However, the methodological quality of studies reviewed was variable; the outcome seemed to be dependent on correct PCL balancing and implant design. Those in favour of resection have found that the use of a substituting design resulted in increased flexion (Victor et al. 2005). Furthermore, the surgical technique was reported to have become easier, especially the ligament balancing, and kinematics were expected to be more in line with those of healthy knees (Victor et al. 2005). Advocates for both PCL substitution and PCL retention can point to excellent clinical and radiographic results in the literature. Furthermore, findings in the areas of biomechanics, histology, and gait analysis do not show convincing evidence for one technique above the other (Pagnano et al. 1998a). However, a factor of major importance is PCL balancing. To function properly, the PCL must be accurately tensioned during knee replacement. Several authors did discuss about their finding that PCL insufficiency might be an explanation for some inferior results (Victor et al. 2005, Cromie et al. 2008). Furthermore, studies paying careful attention to an accurate balance of the flexion and extension gaps reported that no significant differences were found between retaining or substituting the PCL based on clinical, functional, or radiographic outcome (Pagnano et al. 1998a, Tanzer et al. 2002) or for the weight-bearing range of motion and kinematic patterns (Cates et al. 2008). In addition, implant design and surgical technique could be more crucial for a successful TKR (Komistek et al. 2008). Thus far, little scientific data have been published regarding balancing issues related to the PCL, but it seems crucial that the PCL be placed under appropriate tension such that the kinetic benefits of its retention can be enhanced and at the same time the adverse effects of either an excessively tight or a lax PCL can be avoided. Furthermore, a too tight PCL may result in decreased ROM, potentially affect PE wear and implant fixation due to posterior loading (Ritter et al. 1988, Nozaki et al. 2002, Vail and Lang 2006). On the other hand, a PCL that is slack over a wide range of flexion angles may lead to AP-instability which could result in pain, effusion, impaired function, and higher contact stresses that might also induce wear (Bellemans et al. 2002, Vail and Lang 2006). If the PCL is retained, a balanced situation with correct AP positioning of the femur on the tibia remains complicated to achieve. A clinical surgical test, the "pull-out-lift-off test", has been published (Scott and Chmell 2008) but it still fails to quantify gap balancing appropriately. More knowledge is required to investigate what happens during PCL balancing. Due to the oblique orientation of the PCL, distraction of the flexion gap may also result in anterior movement of the tibia. In Study 1 the results are described when the flexion gap is distracted with a mono-block tensor. In Study 2 the flexion gap was distracted with a bi-compartmental tensor and the 3-dimensional movements of the femur and tibia were registered using a navigation system.

Varus-valgus laxity (Studies 3 and 4)

Up to 20% of TKR revision is performed due to tibiofemoral instability (Fehring and Valadie 1994). One of the reasons is ligamentous imbalance and incompetence; thus, accurate ligament balancing is a key determinant of postoperative stability (Fehring and Valadie 1994, Parratte and Pagnano 2008). Studies with healthy Asian subjects demonstrated that lateral laxity is greater than medial laxity in both extension and flexion (Tokuhara et al. 2004, Okazaki et al. 2006). However, since the implants do not yet have an anatomical medial-lateral slope, it remains questionable whether the surgeon should aim for laterally lax knees after TKR. It remains controversial as to which laxity leads to a functionally good TKR. Several authors claim that more loosely balanced knees have a better range of motion (Edwards et al. 1988, Warren et al. 1994, Matsuda et al. 2005b) whereas others state that too much laxity is a cause of persistent pain and catastrophic long-term results (Fehring and Valadie 1994, Pagnano et al. 1998b, Waslewski et al. 1998). Patients appear to prefer the laxer knee in bilateral TKR (Kuster et al. 2004). Bellemans and co-workers found that during surgery, soft tissue relaxation has occurred within 30 minutes and that the knee becomes looser in the earliest phase after TKR (Bellemans et al. 2006). Gap balancing seems to be very delicate with great effects on the tibiofemoral force for a slight gap increase (Jeffcote et al. 2007). Therefore, it is not clear how much laxity the surgeon should aim for during TKR. One approach is to aim for normal stability as found in healthy knees of older individuals. But what is the normal stability of an older knee? In Study 3 varus- and valgus laxity values of the knee are reported for healthy, older individuals.

In some patients releases of the collateral ligaments are necessary to achieve correct leg alignment. However, ligament releases needed to align the leg should not compromise varus-valgus stability. Study 4 addresses the question whether knees become less stable if ligament releases have been performed during TKR.

Releases (Studies 4 and 5)

As described earlier in the balanced gap philosophy for surgical technique releases of soft tissue structures are sometimes necessary during TKR to achieve correct leg alignment. Insall described release techniques in 1985 (Insall et al. 1985). From then on several studies have been published on ligament releases; in which cases should the surgeon release which structure? In particular Whiteside and colleagues published several papers on this topic (Whiteside 1999, Whiteside et al. 2000, Whiteside 2002). These papers focused on finding the most optimal release sequence when measured resection techniques are used. Whiteside and colleagues proposed releases in extension and flexion to adapt the gaps to conform to the chosen implant position. In contrast, the balanced gap technique uses releases in extension to correct alignment to a neutral axis and no releases in flexion are performed. Instead, the soft tissues determine the rotation of the femoral component. Both from lab studies and clinical studies we have learned that releases of structures in extension can have an even larger effect in flexion (Whiteside et al. 2000, Saeki et al. 2001, Mihalko et al. 2003) and therefore, the effects of releases in combination with the balanced gap technique need to be studied in both extension and flexion.

Instead of releasing structures according to a fixed sequence, the surgeon can also choose to release according to the "tightest-structure-first"-principle. To date, no papers have been published on the effects of this strategy on the frequency of releases, leg alignment, or femur rotation in flexion. Study 5 describes the effects of stepwise ligament releases during TKR on leg alignment and femoral rotation.

Rotation femoral component (Studies 6 and 8)

The most important consequence of the balanced gap technique is that rotational alignment of the femur component is "free": because no pre-determined amount of bone is resected from the femur, the rotation of the femoral component may vary (Olcott and Scott 2000). Internal rotation of the femoral component has been associated with patellar tracking problems (Berger et al. 1998, Barrack et al. 2001). External rotation could result in an abnormally tight popliteus tendon complex which could lead to a loss of rotational laxity during knee flexion (Nagamine et al. 1995). Romero and colleagues found in a case-controlled study that the femoral component in patients with lateral flexion instability was more internally rotated compared to the controls (Romero et al. 2007). Although in the measured resection technique the femoral component is rotationally aligned to bony landmarks, even this "fixed" rotational alignment method shows errors and variation (Siston et al. 2005). It is therefore questionable whether variable femoral component rotation is detrimental for the TKR. As there is still no consensus about the consequences of variable femoral component rotation and because results may depend on the implantation technique, more prospective clinical data are necessary. Study 6 describes the effects of the balanced gap technique on the rotation of the femoral component.

Patellar tracking (Studies 7 and 8)

Variable femoral component rotation can have consequences for patellar tracking, an important parameter for clinical function. Studies suggest that an endorotated femoral component is disadvantageous for patellar tracking while an exorotated femoral component would be preferable (Berger et al. 1998, Barrack et al. 2001). However to a certain extent, endorotation of the femoral component could be tolerated without negative side effects (Zihlmann et al. 2005). Other studies have shown that endorotation of the tibial component may even be more detrimental, resulting in patellofemoral complications (Barrack et al. 2001, Kienapfel et al. 2003). From lab experiments in which femoral component rotation was varied a few degrees more towards more extreme rotation values, we learned that endorotation of the femoral component can lead to significant changes in patellar tracking pattern, and exorotation was considered favourable (Rhoads et al. 1990, Anouchi et al. 1993). With the balanced gap technique, variation of femoral component rotation will, theoretically, be increased, thus resulting in higher values for femoral component endo- and exorotation. The majority of published studies on this topic describe the results from bone-oriented implantation techniques; to date no studies have been published on patellar tracking problems after the balanced gap technique. To measure patella position after the balanced gap technique, a reproducible measurement technique was needed. Study 7 evaluates 5 measurement techniques for patella position on regular skyline patella radiographs. After TKR with the balanced gap technique, patients were followed for 2 years and the effect of femoral component rotation on patella position was assessed in Study 8.

Clinical results (Study 9)

Study 9 summarizes the major clinical and functional results for patients with a total knee replacement with the balanced gap technique. In addition, these results will be compared to those of healthy older subjects.

Methods and findings

Study 1. Posterior cruciate ligament balancing in total knee replacement: the quantitative relationship between tightness of the flexion gap and tibial translation

During TKR with the balanced gap technique the following observation has been made when the flexion gap was distracted by a tensor: the tibia moved anteriorly and the size of the gap increased.

Since no data describing this phenomenon were available in the literature, the aim of this prospective clinical study was to describe the relationship between the size of the flexion gap and the anterior translation of the tibia during the implantation of a PCL-retaining total knee prosthesis. A total of 91 knees (83 patients) undergoing a TKR was included. During surgery after the tibia was cut, a monoblock tensor was inserted in the knee at 90° of flexion and a force of 100 N, 150 N, and 200 N was applied sequentially. Using the scales on the spacer, the size of the flexion gap and the translation of the tibia were measured in millimetres for the three distraction forces. The progressive differences in the size of the gap and anterior tibial translation between 100 N and 150 N, and between 150 N and 200 N were calculated. The mathematical slopes ("AP/gap slope") were calculated and indicated the amount of tibial translation when the size of the gap increased by 1 mm.

The mean AP/gap slope was 1.25 (SD 0.79, 95% CI 1.13 to 1.37). This means that for each increase of 1 mm in the flexion gap, a mean increase of 1.25 mm in anterior tibial translation occurred while the flexed knee was distracted with a force between 100 N and 200 N.

Study 2. Posterior cruciate ligament recruitment affects antero-posterior translation during flexion gap distraction in total knee replacement. Intra-operative study in 50 patients

The first goal of this study was to quantify the changes in the parameters for the flexion gap (gap height, tibial antero-posterior translation, medio-lateral displacement and femoral rotation) when the knee is distracted with a tensor intraoperatively during TKR and to determine whether knees with ligament releases have different dynamics. The second goal was to determine the orientation of the PCL in the gap and to assess whether flexion gap kinematics can be predicted from PCL orientation. During a TKR procedure in 50 knees (50 patients) with the balanced gap technique, a CT-free navigation system was used for both the surgery and the measurements. With the pointer of the navigation system, the insertions of the PCL on the femur and tibia were digitised. The flexion gap was distracted with a double-spring tensor with 100 N and 200 N after the tibia had been cut and the movements of the reference frames of the tibia and femur as a consequence of the tension forces applied were registered by the camera of the navigation system. The dynamics of the flexion gap were described by the change in gap height, anterior translation, medial-lateral displacement, and femoral rotation when the flexion gap was distracted. PCL elevation was calculated as the angle between the digitised PCL (line between insertion points on femur and tibia) and the transverse plane of the tibia. All ligament releases performed needed to align the leg were recorded.

During flexion gap distraction, the greatest displacement was seen in anterior-posterior direction. The least amount of movement was seen in the medial-lateral direction and rotation of the femur remained limited. Mean ratio between gap height increase and tibial translation was 1 to 1.9. PCL elevation angle significantly affected the ratio between gap height increase and anterior tibial translation; in knees with a steep PCL, AP translation increased more for each mm of increase in gap height (gap/AP ratio was 1:2.3 (SD 0.63)) compared to knees with a flat PCL (gap/AP ratio was 1:1.7 (SD 0.50)). There was no significant difference in mean ratio of gap height increase and anterior tibial translation between knees with a release and knees without, although knees with a release had a greater increase in PCL elevation as the distracting force increased from 100 N to 200 N. When the flexion gap is distracted with a bi-compartmental tensor, every extra mm that the flexion gap is distracted can be expected to move the tibia anteriorly by at least 1.7 mm (flat PCL), or even more if the PCL is oriented steeply relative to the transverse plane of the tibia.

Study 3. In vivo knee laxity in flexion and extension: a radiographic study in 30 older healthy subjects

The objective of this study was to determine knee laxity in extension and flexion in healthy, non-arthritic, knees of older subjects. Thirty healthy older subjects (mean age 62 (SD 6.4) were recruited for participation with one randomly selected knee in this study to determine in vivo knee laxity. Stress radiographs were made to assess varus and valgus laxity. In extension stress was applied by the Telos device (15 Nm). For medial and lateral flexion laxity, a custom made stress device (the Flexilax) was used to stress the knee in 70° of flexion (15 Nm) and to produce objective laxity measurements. Radiographs were made with the X-ray direction parallel to the tibia joint surface in the conditions varus, valgus or no moment applied. The angle between a tangent line on the femur condyles and a line through the deepest tibial joint surfaces was determined on the varus, valgus and neutral radiographs. Valgus laxity was defined as the difference between the medial stress radiographs and the neutral radiographs, varus laxity as the difference between the lateral stress radiograph and the neutral radiograph. In addition, the passive range of motion and active flexion were assessed.

Mean passive ROM was 132° (SD 7.3), mean active flexion was 116° (SD 15.2). Mean varus laxity in extension was 2.8° (SD 1.3, range 0.6–5.4°), mean valgus laxity was 2.3° (SD 0.9, range 0.2–4.1°). In flexion, mean varus laxity was 3.1° (SD 2.0, range 0.1–7.0°) and mean valgus laxity was 2.5° (SD 1.5, range 0.0–6.0°). There was no significant gender difference, nor was there any significant association between age and varus or valgus laxity in extension. In flexion, there was a statistically significant association between age and varus laxity with higher varus laxity with higher age. Varus and valgus knee laxity in extension and flexion were comparable.

Study 4. Ligament releases do not lead to increased postoperative varus-valgus laxity in flexion and extension: a prospective clinical study in 49 TKR patients

This prospective clinical cohort study investigated whether ligament releases in combination with a balanced gap technique using a tensor lead to a higher varus-valgus laxity in flexion and extension after implantation of the prosthesis and after 6 months. Furthermore, the postoperative varus-valgus laxity of the TKR was compared with normal laxity in the healthy elderly. Fifty patients (50 knees) were included in the study and underwent navigated TKR with the balanced gap approach. Before any bone cut or ligament balancing was performed, varus-valgus laxity was assessed using the navigation system when 15 Nm varus and valgus stress was applied with a calibrated spring tensor. Movements in the reference frames of the tibia and femur – as a consequence of the applied stresses – were registered by the navigation system and varus and valgus laxity could be calculated afterwards. The extension and flexion gap were distracted with 150 N force exerted with the tensor in extension and 100 N in flexion. Ligament releases were performed in extension, if necessary to achieve neutral leg alignment, according to the tightest structure first approach. All releases performed were registered and catalogued into lateral releases or medial releases including either the posteromedial capsule (PMC) or the superficial medical collateral ligament (SMCL). After implantation of the prosthesis, varus and valgus laxity were registered again according to the same procedure. Postoperative varus-valgus laxity was determined at 6 months after surgery by stress radiographs. For varus-valgus laxity in extension the Telos device was used, for varus-valgus laxity in flexion we used the Flexilax; a custom-made stress device. The same amount of stress (15 Nm) was applied as during the intraoperative measurements. Furthermore, postoperative varus-valgus laxity was compared to the healthy control group described in Study 3.

At surgery, before and after implantation of the prosthesis, there was no difference in varus or valgus laxity in extension and flexion between knees that did not need a ligament release, knees with a lateral release, knees with a medial SMCL releases, and knees with medial PMC releases. Also 6 months after surgery, varus or valgus laxity in extension and flexion was not significantly different between the release categories. Postoperative laxity in extension at 6 months did not differ from varus and valgus laxity in the healthy elderly. However, valgus laxity in flexion was significantly higher after TKR and varus laxity in flexion showed a trend for increased laxity in the TKR group compared to the controls. The most important finding of this study was that there was no difference in varus or valgus laxity in extension and flexion between knees with or without releases.

Study 5. Correction of axial and rotational alignment after medial and lateral releases during balanced gap TKA. A clinical study of 54 patients

The peroperative effect of stepwise soft tissue releases following the "tightest structure first" on leg axis in extension and femur rotation in flexion was investigated with a cohort study. 54 patients participated and during their navigated PCL-retaining TKA with a balanced gap technique measurements were performed with the CT-free navigation system. Leg alignment and femoral rotation were measured when a tensor with 150 N and 100 N was inserted into the extended and the flexed knee, respectively. When the leg axis was 180º (straight leg) during distraction of the extension gap, no ligament releases needed to be performed. When leg axis deviated from a straight leg, the surgeon chose the tightest ligament at that moment and released it. Subsequently, the leg axis in extension and femoral rotation in 90º flexion were recorded again with the navigation system with the tensor in place. This procedure was repeated as necessary for a second or third ligament structure until the leg axis in extension was 180º. For multiple releases, the sequence of the released structures was recorded. Analyses were performed to determine the effect of each release step on leg axis and femoral rotation.

In more than half of the patients, 1 or more releases were necessary. There was no significant difference in the alignment-correcting effect of a release depending upon the sequence in which this structure was released. Of all releases that were performed, the effects were the greatest for the extension gap. When the posteromedial condyle was released, this led to a minor effect on leg axis in extension and on femoral rotation in flexion. Release of the superficial medial collateral ligament corrected the leg axis in extension a few degrees, and had a small effect on femoral rotation in flexion. On the lateral side, release of the iliotibial tract led to a small correction of leg alignment in extension. The "tightest structure first"-approach worked with the balance gap technique: all patients achieved neutral leg alignment and the effects on femoral rotation remained limited.

Study 6. Effects of the balanced gap technique on femoral component rotation in TKA

With this prospective clinical cohort study we investigated whether ligament releases in extension lead to a different amount of femoral component rotation using the balanced gap technique in PCL-retaining TKA. Furthermore, the effect of the side and extent of the ligament releases on femoral component rotation was determined, as well as the effect of preoperative leg alignment. 83 patients participated with 87 knees in this study. All knees received a PCL-retaining TKA using the balanced gap technique with 200 N applied with the tensor in extension and 150 N in flexion. If necessary to align the knee, ligament releases were performed in extension, according to the 'tightest ligament first'-approach. To determine femoral component rotation, a cutting jig with 3º external rotation was used referenced from the posterior condyles. The tensor was inserted into the flexion gap and 150 N was applied. A goniometer was attached to the external tibial alignment system and the angle between the 3º exorotation and the amount of rotation using the balanced gap technique was measured. After calculation femoral component rotation using the balanced gap technique referenced from the posterior condyles was known. Knees were divided into 2 categories: knees without ligament release and knees with any ligament release. This last category was further subclassified into major and minor, medial and lateral releases.

We found that mean femoral component rotation for knees with ligament releases did not differ from that for knees that did not need releases. There was a high interpatient variability in femoral component rotation; ranging from 4º endorotation to 13º exorotation. Within the release-group, the type of release influenced femoral component rotation; knees with major medial releases showed the least external rotation whereas knees with minor lateral releases had the most external rotation. Preoperative alignment had no influence on femoral component rotation for both knees either with or without releases.

Study 7. A comparison of reproducibility of measurement techniques for patella position on axial radiographs after total knee arthroplasty

For this reliability study, 50 axial radiographs of the patellofemoral joint were selected to determine the intra- and interobserver reproducibility of measurement techniques that could be used to quantify the patella position after TKA. These radiographs were randomly selected and had been taken during normal clinical practice. Five measurement techniques were selected because all necessary landmarks were visible on standard axial radiographs: the Congruence Angle, the Lateral Patellar Displacement, the Lateral Patellofemoral Angle, the Lateral Patellar Tilt, and the Patellar Displacement. Each radiograph was measured using each of the 5 techniques, by 2 independent observers. One observer carried out the measurements twice to determine the intraobserver variability. Inter- and intraobserver variability were assessed according to Bland and Altman's method. Furthermore, 3 orthopaedic surgeons reviewed the images independently from each other and scored them as normal patellar tracking or patellar maltracking. These clinical observations were used as a golden standard to perform a validity study.

The Lateral Patellar Displacement, the Lateral Patellar Tilt, and the Patellar Displacement were reproducible and valid measurement techniques. The Congruence Angle was a difficult technique to apply and appeared to be irreproducible. The Lateral Patellofemoral Angle was reproducible, but less valid. Based on our study we recommend that the most reproducible and clinically relevant method for measuring tilt is Lateral Patellar Tilt (with >10º as cut-off point); to measure displacement, one should use the Patellar Displacement (with ≥4 mm as cut-off point) technique.

Study 8. Femoral component rotation after balanced gap total knee replacement is not a predictor for postoperative patella position

The goal of this prospective cohort study was to investigate whether femoral component rotation influenced patella position after primary TKR with the balanced gap technique. We investigated 49 patients who received a PCL-retaining TKR, performed using a CT-free navigation system. The navigation system was also used as a measurement device. From the surface model of the femur and the documented dorsal femur cut we calculated femoral component rotation as the angle between the posterior condylar axis and the plane through the dorsal femur cut. For all patients patellar radiographs were performed preoperatively and at the two-year follow-up. Patellar tilt and displacement were measured using the Lateral Patellar Tilt and the Patellar Displacement measurement techniques, with 10º and 4 mm as cut-off points for tilt and displacement, respectively. A logistic regression analysis was performed on femoral component rotation and preoperative patella position to identify predictors for postoperative patellar tilt and displacement. Although femoral component rotation varied from 4º endorotation to 12º exorotation, we could not statistically relate it to postoperative tilt or displacement. The only statistically significant predictor found was preoperative patella displacement; a preoperatively displaced patella led in 50% of the cases to a postoperatively displaced patella.

Study 9. Clinical and functional results of patients with a total knee replacement compared to the healthy elderly

A total of 49 patients (same as Study 2, 4, 5, and 8) were evaluated to summarize clinical outcome of patients with a TKR implanted with the balanced gap technique. Their scores were compared with the clinical outcome and functional test results of 30 healthy controls of the same age. Several scores were obtained by an independent research nurse at various follow-up moments; activity level, ability to stand and walk, ROM, knee flexion, AP stability, the Knee Society Score, functional performance tests, and VAS scores on daily-living activities.

For the patients, activity level improved after surgery and was comparable to the healthy controls. The ability to stand and walk improved as well after surgery, but walking was still less feasible than for the healthy controls. Active flexion and ROM were significantly higher for the healthy controls than for the patients at the 12-month follow-up. Postoperative active flexion and ROM was comparable to the preoperative situation. AP laxity decreased significantly after TKR and was lower for the patients compared to the controls. The KSS showed significant improvement for the patients during most stages of follow-up. At the 12-month follow-up there was no difference in clinical KSS between patients and controls, although the healthy elderly scored better on the functional and total KSS. The patients were significantly faster on all functional performance tests compared to the preoperative situation, but still slower than the healthy controls. Patients still experienced some pain after TKR but this decreased during follow-up until 1 year. Instability scores were low. Rising from a deep chair, and kneeling remained difficult. Patients were satisfied after surgery.

General discussion

In this thesis several issues and consequences of the balanced gap technique for total knee replacement have been analysed and described. In this General Discussion the major outcomes will be discussed and placed into a clinical perspective. Finally, as during the course of this project new questions have risen; one paragraph will be dedicated to possible future research related to the balanced gap technique. This discussion will end with the overall conclusions of this thesis.

Main findings and clinical implications

PCL balancing

In Studies 1 and 2 it has been shown that balancing the flexion gap is an extremely delicate technique; a few millimetres more or less gap distraction can make a difference and that directly influences gap balancing. It is much more critical than we had anticipated before these studies. In addition to gap distraction collateral ligament releases and variation in PCL elevation angle also have been shown to play a role in PCL balancing.

In both studies we observed that when the gap is distracted, the tibia moves in a more forward direction than the expected axial direction. With the mono-block tensor a ratio between gap height increase and anterior tibial translation of 1 to 1.25 was found; for the bi-compartmental tensor a higher variable ratio, ranging from 1 to 1.9, was found. Hence, a 2-mm change in bone cut or PE-insert thickness can make a difference between a perfectly balanced PCL and one that has been too tightly balanced.

Balancing is difficult due to the great interpatient variation in gap height increase and anterior tibial translation. Both the PCL elevation angle and collateral ligament releases influence the ratio between gap height increase and tibial translation. Another source of variation that affects PCL balancing might be the type of implant used. A femoral component is designed to articulate at the deepest point of the articular insert, conform the congruence between the femoral and tibial component. Different implant systems may have different configurations and have different 'prescribed' tibiofemoral contact points. The surgeon should be aware that the balancing performed should be implant specific. Hence, this is another factor which could influence, and complicate, PCL balancing, but one that has not been included in our studies. Anteroposterior movement between femur and tibia has direct consequences for the tibiofemoral contact point, and therefore, PCL tensioning directly controls the tibiofemoral contact point (Freeman and Pinskerova 2003, Komistek et al. 2003). Furthermore, it is also known that tibiofemoral contact point changes affect the range of flexion (Banks et al. 2003) and that normal kinematics can be obtained when the contact point of the medial condyle has been restored.

The clinical results for the TKR patients treated with the balanced gap technique as presented in Study 9 are satisfying in terms of range of motion, varus-valgus stability in extension and flexion, AP stability, clinical scores, and activity level. Hence, a distracting force with the bi-compartmental tensor of 150 N in extension and 100 N in flexion used as a first approximation should produce the desired effect. However, we observed that the anteroposterior (AP) laxity of the knees of healthy elderly was significantly higher than that of the patients. Perhaps, the forces used resulted in the TKR knees being a bit too tightly balanced. To evaluate this possibility, further clinical trials to titrate the correct tension with respect to the ideal AP laxity are needed. It is also speculative whether slightly less tension in flexion would have increased the range of motion of the TKR. In our series the average ROM was 120 degrees which is in accordance with the average ROM of a cruciate retaining TKR reported in the literature (Conditt et al. 2004, Wyss et al. 2008, Harato et al. 2008). However, a number of patients who seem to have correct balancing and tensioning had up to 130 degrees of flexion whereas others had a more limited flexion. Our impression is that with a 100 N distracting force in flexion some individual patients were simply too tightly balanced.

Since flexion gap balancing has apparently such narrow margins, the following question arises. What is more critical: a TKR for which the ligament tensioning is a little tight or one for which it is a little loose? With a TKR that is tensioned too tightly, the tibiofemoral contact point will be closer to the posterior lip of the polyethylene insert. Most inserts used today are dished. Consequently, this could result in undesirably high pressures on the PE. Furthermore, tight knees could result in limited flexion and pain, and a higher PCL strain (Mahoney et al. 1994). On the other hand, a slightly loose balanced PCL could result in a more anterior contact point. Although this would lead to some decrease of patella moment arm and a slight increase in AP laxity, in such a situation flexion will not be limited. The PE stresses on the anterior side in a looser knee will usually also be lower than those on the posterior side produced by a tight knee since for most inserts the anterior form of the dish is not as curved. However, whether higher shearing motions actually do occur in relatively loose knees and what the potential clinical consequences would be remains unknown. In summary, when the surgeon has to compromise between one extreme or the other in planning the flexion gap tension, our opinion is that a slightly loose flexion gap is preferred above a too tight flexion gap.

Regarding femur rotation in relation to the value of the distraction forces in the flexion gap, we had hypothesized that the femur would rotate more internally when the gap was distracted with a higher force since the lateral ligaments of the knee are expected to be more lax. However, from the results of Study 2 one can conclude that the amount of the distracting force has virtually no influence on femur rotation. The varus-valgus laxity during flexion for our patient group with 100 N distraction force, in comparison to reports in the literature, had rather tight knees. However, their varus-valgus laxity values appeared to be in line with those of the cohort of healthy elderly studied in Study 3. In conclusion, flexion gap tensioning with respect to femoral rotation can be safely applied as no major effects in a PCL-retaining TKR were found; in addition, we do not expect large changes in rotation or in varus-valgus laxity if the force would be reduced to 70–80 N. Whether the above results can also be applied to PCL-substituting implants remains to be investigated.

For a PCL-retaining TKR, the question remains as to how one should balance the PCL. Although thus far, we have not yet found an optimal force with which to distract the gap, we have gained more insight into the dynamic character of the flexion gap. Based on the work and the subsequent clinical findings reported in this thesis, one may conclude that the use of a tensor works well, but our impression is that a fixed distraction force of 100 N is not suitable for every type of patient. Several sources of variation influence flexion gap dynamics and different approaches can be taken to optimise PCL balancing for the individual patient. These approaches will be discussed in more detail in the section *Future perspectives*.

Although, we do not yet have a recipe for what can be considered perfect balancing, another study by our group showed that the contact point of normal, asymptomatic knees, lies at 68% of the anteroposterior distance on the tibia plateau (de Jong et al. 2010). We believe that a correct restoration of the contact point is the key to normal tibiofemoral and patellofemoral kinematics and good clinical results. There are good arguments to implement this natural contact point in future prosthetic designs. If during the operation, the surgeon observes that the tibia has an extreme anterior position, indicating that the contact point will have an extreme posterior position, the flexion gap has to be increased. The surgeon can achieve this by either increasing the posterior slope by a few degrees or by downsizing the femur and resecting a few more mm from the posterior condyles. Either technique will not affect the extension gap. If the gap is too loose a thicker spacer should be used, and the extension gap should be adapted to this spacer by making a re-cut on the distal femur.

Although much more knowledge on flexion gap dynamics has been gained through the present work, surgical techniques to achieve correct PCL balancing need further research. Only with a correctly tensioned PCL as well as correct tension in the collateral ligaments, proper balancing is possible. Apparently, the collateral ligaments will have to be tensioned in concert with the PCL while the gap is distracted. The question of how the soft tissue structures work together and which role the individual ligaments play opens up another research direction.

Varus-valgus laxity

Although the goal of a TKR is to relieve pain and to restore joint kinematics and stability to a normal level, what ‘normal stability’ really is has not yet been defined. It is also not clear whether laxity values of healthy knees can serve as a reference for TKR, since modern implant designs do not yet resemble a “normal” knee. However, the laxity of healthy knees seems a reasonable starting point.

The laxity values found in the control group of healthy elderly reported in Study 3 seem a bit lower than those for the younger populations given in the literature (Tokuhara et al. 2004, Okazaki et al. 2006). In addition, the TKR patients (reported in Study 4) demonstrated slightly higher varus and valgus laxity in flexion, compared to the healthy elderly. It is possible that the techniques used to measure laxity underestimate normal laxity in the collateral ligaments. With the devices used in the presented studies we measured laxity of the complete knee. It is known that human living cartilage is compressed when it is loaded (Eckstein et al. 2006). Because of this cartilage compression, the femur and tibia approach each other and the ligaments may become slacker (Victor et al. 2009). The subjects in Study 3 were assessed when lying supine; therefore, the measured laxity may be slightly less compared to that in a weight-bearing situation. A 3-5% cartilage compression on a 6 cm wide tibia plateau results in 0.2 to 0.3 degrees additional laxity of the knee (Adam et al. 1998, Eckstein et al. 2006). If these corrections were made to the values for the healthy elderly, the laxity in the collateral ligaments would be even more different from those of the patients; although the patients’ laxity was measured with the same device in the same supine, position no cartilage compression takes place between the metal femoral component and the PE insert.

The varus-valgus laxity found in the TKR patients is slightly higher than that measured in the older healthy subjects. However, this slight increase seems clinically acceptable. The patients performed well and did not report feeling unstable when standing and walking (Study 9). From previous work it is known that 3 to 4 degrees of varus or valgus laxity results in a good functional outcome for PCL-retaining TKR,(Ishii et al. 2003, Matsuda et al. 2005a, Ishii et al. 2007) and the patients described in Study 4 fulfil these criteria. Although not statistically demonstrated in the present studies (because the peri- and postoperative measurement devices were not comparable), it seems as if laxity in flexion increased during the postoperative period. The mechanism is unclear and could not be identified from the present studies. We hypothesize that ligaments adapt to changing situations and that perhaps directly after surgery the knees were initially too tightly tensioned during flexion since stress relaxation of ligaments and subsequent the increased laxity can be substantial (Bellemans et al. 2006).

In contrast to what was expected, ligament releases made during surgery did not lead to increased varus-valgus laxity. It had been hypothesized that in particular releases of the MCL, an important medial stabilizer, would lead to increased valgus laxity if stress were applied, but this effect was not confirmed. Two possible mechanisms to elucidate this discrepancy can be suggested. Firstly, it is possible that distraction and recruitment of the (remaining) peripheral soft tissue envelope results in sufficient stability. A second possible mechanism may be that after a medial release, the central structure, the PCL, prevents laxity along with a lateral compartment that is completely filled and has been tensioned with an implant.

Because of the in vivo nature of the study setup, we could not detect whether released ligaments reattach to the bone. It is possible that after a release in extension, ligament insertions shift due to the distracting force during flexion. It may, however, not be important since the knees were stable immediately after surgery. It should be noted that extensive lateral releases including complete detachments of the lateral collateral ligament and popliteal tendon were not analysed in this study; in such cases the results could be different. Although it remains, to a certain extent, a black box mechanism, the balanced gap approach can be safely used and those ligament releases needed to align the leg in extension will not lead to an increase in varus-valgus laxity.

Releases

In addition to the effect of releases on varus-valgus stability when stress is applied, the alignment correcting effects of individually released structures has been investigated. In contrast to what could have been expected from the literature, ligament releases performed in extension for alignment correction did not lead to great effects on femoral rotation in flexion (Matsueda et al. 1999, Krackow and Mihalko 1999a and b, Mihalko et al. 2003, Luring et al. 2006). Apparently, in flexion, gap distraction causes recruitment of all the surrounding soft tissue structures and that the effect of one released ligament on femoral rotation remains small. Also the PCL as the central structure holds the flexion gap together. Whereas in a cadaver study a single release would lead to much more laxity, it is plausible that in a clinical situation other structures comprising the soft tissue envelop in combination with the tendons, muscles and skin ensure stability. In addition, the difference between clinical and laboratory studies may result because of the different ways of measuring gap and axis changes after ligament releases, varying from distraction with tensors to varus-valgus stress methods.

The method of releasing the tightest structure first, described in Study 5, is actually a patient-specific approach in which the surgeon only releases the tightest structure at that moment. In this thesis this stepwise technique has been applied and shown to work in combination with the balanced gap technique; we are confident that the effects found are not limited to the balanced gap technique but can also be applied during a measured resection technique. Probably the PCL, the secondary medial stabilizer, being intact during surgery is the important prerequisite.

Rotation femoral component

The most specific characteristic of the balanced gap technique is the free femoral rotation. In this thesis it was hypothesized that femoral component rotation would be variable between patients. This has been investigated and described in Study 6. It can be confirmed that femoral component rotation following the balanced gap technique was indeed variable, thereby confirming the hypothesis. Femoral component rotation, referenced from the posterior condyles, varied from 4 degrees endorotation to 13 degrees exorotation. Knees that needed collateral ligament releases had no different average or range for femoral component rotation compared to knees without releases. However, when releases were needed, major medial releases did lead to slightly endorotated femoral components.

Evidently, there is more variation in femoral component rotation with the balanced gap technique than with a measured resection technique. With the latter, the surgeon usually places the implant first and if necessary, corrects leg alignment with ligament releases in extension. In addition, ligament releases in flexion can occasionally be performed to adapt the flexion gap (Whiteside 2002). It is questionable whether balanced extension and flexion gaps will be achieved with a measured resection technique that has a fixed femoral component rotation. Presumably this is possible in 70–80% of the cases without additional releases as Whiteside proposes, but it does depend on the amount of laxity that the surgeon finds acceptable, and there is no clear consensus on this topic. With the balanced gap technique as performed in the present work, both extension and flexion gaps were balanced, with the accompanying relatively high variation in femoral component rotation. The knees perform well (Study 9) and are stable, both in extension and flexion (Study 4). However, a disadvantage of the balanced gap technique may be that for a limited number of patients, the result is an endorotated femoral component with a potentially disadvantageous effect for patellar tracking (Berger et al. 1998). This will be described in more detail in the next section.

Patellar tracking

Technically, patella position would have been a better heading for this section, since patellar tracking has been defined as the motion of the patella relative to the femur or femoral groove during knee flexion and extension (Katchburian et al. 2003). Unfortunately, to date no single valid and reproducible method has been reported to measure patellar tracking in patients. However, as reported in Study 7, the Patellar Displacement and the Lateral Patellar Tilt methods were found to be the most reproducible and clinically relevant measurement technique for patellar displacement and tilt, respectively; these can be applied on a standard skyline radiograph. Using these techniques, femoral component rotation as a predictor for patella malposition after balanced gap TKR was investigated. This was not found to be the case: femoral component rotation was not a predictor for either patellar tilt or patellar displacement. Only preoperative patella position was identified as a risk factor for postoperative patella displacement, although the confidence interval was broad.

The most intriguing finding reported in Study 8 is that femoral component rotation has much less effect on patella position than has commonly been suggested in the literature. Could this be the effect of the balanced gap technique or do other mechanisms play a role? With a measured resection technique in theory one would expect more knees with a certain amount of flexion laxity. Knees that are laterally loose in flexion would show a lift off of the lateral condyle in flexion, and thereby endorotate the femur component in relation to the tibia. Theoretically this could cause more patella subluxation, although in daily practice this mechanism has not actually been observed as a clinical phenomenon.

Probably a better explanation, as Berger reported (Berger et al. 1998) is that both femoral and tibial component rotation play a role. Only the combination of an endorotated tibia component with an endorotated femoral component can be detrimental for patellar tracking. In most cases an endorotated femoral component alone, as we have found, is not enough to produce problems. Furthermore, the 4 degrees of maximum endorotation as found in the present work is probably not enough to produce patella problems as has been suggested in various experimental studies conducted on this topic. Even if the two different cohorts of Studies 6 and 8 were combined, the maximum of 'free' endorotation remains restricted. Therefore, we feel that the surgical technique is safe with respect to patellar tracking, certainly for PCL-retaining implants and if careful attention is given with regard to the tibial component rotation.

The patients reported on in both Studies 6 and 8 had no extreme deformities because both exclusion criteria as well as implant indications exclude extreme deformities. These are companied with leg alignments that deviate from normal due to serious cartilage defects and bone loss. Theoretically, it is possible that with greater deformities the results would have been different. However, as the results of Study 6 have shown, preoperative alignment has no influence on femoral component rotation. In addition to implant indication, surgical technique may also prevent patellar problems. Rotation of the tibial component was performed accurately, precisely aiming on the medial 1/3 of the tibial tubercle. Furthermore, soft tissues were carefully balanced, correct tensioning of the medial retinaculum, and closing with non-resorbable sutures could also play a role in preventing patella malposition or dislocation.

Pre-existing patella maltracking can indeed play an important role in the postoperative situation. The surgeon can correct several factors at the knee joint level, but some patients with longstanding patellofemoral maltracking also have aberrant muscular attachments and development, as well as femur malrotations which have been found to have an important effect in maintaining maltracking. Furthermore, for these cases it is also worthwhile to investigate hip rotation since the working line of the muscular force plays a crucial role in distributing pressures between the patella and the anterior distal femur.

Future perspectives

Although we have considerably furthered our knowledge pertaining to the TKR performed with the balanced gap technique, even more questions were triggered along the way. This section suggests some major topics for future research to take the balanced gap technique to the next level.

The first topic is optimal balancing. As yet no ideal recipe or protocol to balance the knee is acknowledged as the optimal method. Two approaches can be distinguished. The first approach assumes the same, optimal, distracting force for all patients. It still has to be determined what this force should be. Presumably to ensure good stability and at the same time good range of motion, this would be slightly lower than 150 N during extension and 100 N during flexion that was used in the studies reported here. But the appropriateness of lower values needs to be confirmed in future clinical studies. Until now only the extension and flexion gaps have been balanced since these gaps directly influence bone cuts. It probably makes sense to also add 'midflexion balancing' in order to better evaluate balance throughout the complete range of motion to ensure perfect stability during all knee flexion angles. Although several, unpublished, attempts have already been made along this line of reasoning, more research and development is required concerning how to adapt the implantation system or even the implant to ensure such a postoperative balanced situation. The second approach starts from a different perspective, namely that all aspects quantified in the present work vary so much that no one average distraction force would be appropriate for each patient. It is plausible that new techniques such as intraoperative measurement of soft tissue stress-strain curves need to be developed which would allow the implantation technique to be individualized for patients so that specific patient-characteristics could be used as input. When ligaments are stretched during joint distraction, a force-length-relationship can determine the nonlinear part in which the fibres are gradually tensioned and the linear part in which the fibres are stretched. Perhaps the transition point between the two segments of the curve could be used to determine the optimal distracting force for an individual patient. A second variation that might be useful in this individualized approach would be to distract the flexion gap with a tensor and to focus on the point where the tibia starts anterior movement. From the work presented here, we know that the tibia will move forward only when the PCL is tensed. One could stop gap distraction when the tibia moves forward a couple of mms. One could hypothesize that with an appropriately tensioned PCL, the relative positions of tibia and femur resemble the natural knee and thereby a correct contact point would automatically be achieved. As previously mentioned, the articulating prosthetic design should accommodate the location of the physiological contact point. A third variation in this individualized approach makes use of spacers. This method still needs to be worked out in more detail, but hypothetically one could calculate the desired tibiofemoral contact point for a certain implant. After making the bone cuts using a measured resection technique, the surgeon would insert a spacer with an mm-scale and measure the step off between the distal femur cut and the anterior edge of the tibia in 90 degrees of flexion, and check whether this distance corresponds to the contact point that had been calculated by the implant designers. Furthermore, the individual musculoskeletal system varies considerably. Hence, individuals with laxer knees may have other neuromuscular control features than patients with naturally stiff knees. Therefore, it is likely that patients would benefit the most from a TKR system and implantation technique that is more individualized. How this individualization process should be executed and what factors play a crucial role remains subject for further study. Also the recent development of patient-matched cutting blocks will be of major interest in the search to match the technique to the individual's anatomy.

A second topic that has to be resolved in the near future is the question where and how the released ligaments reattach to the bone. Perhaps they do not attach to the bone, but merge into the other soft tissue structures around the knee, and form a flexible system to restrain passive laxity. It would be highly challenging to design clinical studies in living patients to investigate this topic since healing cannot be studied using in vitro models. This topic may not seem an urgent one since the current work does not show laxity problems after releases. However, to advance soft tissue healing some fundamental knowledge is needed.

The third topic comprises patellar tracking. Although we found that 'free' femoral component rotation did not predict patellar displacement or tilt, there were still a few malpositioned patellae. Since maltracking is a dynamic process, a dynamic measurement technique must be considered. Measuring patellar tracking with standard gait laboratory techniques is difficult, since skin movements induce artificial patella movements. Perhaps the future lies in fluoroscopic measurements, possibly with RSA markers, but this would have disadvantageous radiation consequences for patients. New open MRI scan techniques may also be helpful. Combined with a 3-dimensional measurement technique for their patient groups, researchers could use challenging every-day tasks that are sensitive to very small changes or adaptations in surgical technique.

The fourth, and last, topic concerns the ultimate question whether the implantation technique (whether a measured resection or a balanced gap technique) can influence clinical outcome and implant longevity. To find out whether balanced gaps make sense, one could conduct a randomised experiment with a balanced gap and a measured resection technique. An interesting question would be whether, using an implant suitable for both techniques, equally stable and functional knees can be achieved using both implantation philosophies. To ensure a successful trial, an objective surgeon, experienced in both techniques would be needed in addition to the "neutral" implant that has equal possibilities with both techniques. Otherwise, the introduction of bias into the study is inevitable.

Continuous developments in implants and surgical techniques are mainly company driven. A disadvantage is that commercial motives lead to the fact that well-functioning implants with an excellent long-term survival are no longer available when the 15-years survival can be reported. On the other hand, new legal developments around medical implants result in shorter timelines for improving the effectiveness and safety of the implant. Therefore, more objective and precise measurement methods need to become available, accompanied with surgical techniques that can easily be adapted to the surgeons' preference, whether a measured resection or a balanced gap technique. From the start, the balanced gap technique has been developed to improve proprioception and stability by balanced gaps and has focussed mainly on the tibiofemoral joint. The measured resection techniques were developed to resolve patellofemoral problems by improving patellar tracking through optimal femoral component rotation. It is most plausible that the "golden technique" will be a mix of the best from two philosophies and that the "mix-and-match"-trend that has been established during the past decades will continue with the ultimate goal being to utilize the best technique with optimal implant designs and materials to realize a near-normal functioning knee replacement for the individual patient.

Conclusion

In this thesis a deeper comprehension in the use of the balanced gap technique has been reached. The issues mentioned in the Introduction have been addressed and can be highlighted in the following summarizing conclusions.

PCL balancing by flexion gap distraction has definitive consequences for the relative tibiofemoral position; it is dependent on the presence of releases and the PCL elevation angle. Varus-valgus laxity is not increased by ligament releases and laxity in extension compares perfectly to that of healthy elderly, whereas flexion laxity is slightly less in TKR patients. Releases needed to align the leg in extension can be performed with a gradual effect using the "tightest structure first"-

approach, and the effect on femoral rotation is limited. The balanced gap technique leads to a relatively high range of femoral component rotation. Releases themselves do not change rotation of the femoral component; however, knees with major medial ligament releases do have a more endorotated femoral component compared to knees with lateral releases. This variable femoral component rotation does not predict postoperative patellar malposition, whereas a preoperatively existing patella malposition was identified as a risk factor. In summary, the balanced gap technique for TKR is a surgical method focusing on the stability of the soft tissue structures of the knee. The work in this thesis adds to the knowledge about the balanced gap technique and has identified some areas that require further exploration to take TKR to the next level in achieving near-normal function for a replaced knee.

Summary

The knee joint is the largest and one of the most complex joints in the human body. The *Introduction* describes the relevant anatomy and biomechanics of the knee. In addition, osteoarthritis was explained, followed by the total knee replacement (TKR) as treatment of choice. The two main surgical philosophies in TKR were introduced: the measured resection approach and the balanced gap technique. The balanced gap technique focuses on soft tissue management before bone cuts are performed. Several issues are related to this specific approach. The overall aim of this thesis was to investigate these issues; the effect of the balanced gap implantation technique on knee stability was investigated. Furthermore, technical issues such as releases, femoral component rotation, and balancing of the posterior cruciate ligament as well as the consequences of these techniques were addressed.

The goal of *Study 1* was to examine the relation between gap size and anterior translation of the flexion gap during implantation of a PCL-retaining total knee prosthesis. In 91 knees the flexion gap and anterior tibial translation were measured intra-operatively using a mono-block, custom-made, flexible tensor-spacer device. The results showed that each mm increase in the flexion gap produced a correspondingly greater increase in the anterior tibial translation, on average a 1:1.25 (SD 0.79, CI_{95}: 1.13–1.37) relation. When placing a PCL-retaining TKR, the surgeon needs to be aware of the consequences for the tibiofemoral contact point related to his/her choice for the thickness of the polyethylene insert: when the flexed knee is distracted with a force between 100 and 200 N, an additional 2 mm polyethylene would result in an average additional 2.5 mm anterior translation of the tibia.

Because of the PCL's oblique orientation it is conceivable that flexion gap distraction could lead to anterior movement of the tibia relative to the femur. This tibiofemoral repositioning would influence the tibiofemoral contact point, which in turn would affect the kinematics of the TKR. *Study 2* quantitatively describes the flexion gap parameters when during implantation of a PCL-retaining TKR, the knee is distracted using a bicompartmental tensor. Furthermore, the effect of PCL elevation (steep or flat) and collateral ligament releases on the flexion gap parameters were studied. During a ligament-guided TKR procedure, the flexion gap was distracted with a double-spring tensor with 200 N in 50 knees after the tibia had been cut. The flexion gap height, anterior tibial translation and femoral rotation were measured intra-operatively using a CT-free navigation system. During flexion gap distraction, the greatest displacement was seen in anterior-posterior direction. The mean ratio between gap height increase and tibial translation was 1:1.9, and was the highest for knees with a steep PCL (1:2.3). Knees with a flat PCL and knees with a ligament release had a larger increase in PCL elevation when the gap was distracted. When the PCL is tensioned, every extra mm that the flexion gap is distracted can be expected to move the tibia anteriorly by at least 1.7 mm (flat PCL), or even more if there is a steep PCL. The surgeon must not ignore this as it has consequences for the tibiofemoral contact point and polyethylene wear.

In order to determine how "tight" a total knee prosthesis should be implanted, it is important to know the amount of laxity in a healthy knee. The objective of *Study 3* was to determine knee laxity in extension and flexion in healthy, non-arthritic knees of subjects similar in age to patients undergoing a TKR and thus, to provide guidelines for the orthopaedic surgeon to restore the stability of an osteoarthritic knee to the normal condition. Thirty healthy subjects were included in this study. For each subject one, randomly selected, knee was stressed in extension and in 70° flexion (15 Nm). Varus and valgus laxity in extension and flexion were measured on radiographs. The passive range of motion and active flexion angle were assessed. Mean valgus laxity in extension was 2.3° (SD 0.9, range 0.2–4.1°). In extension mean varus laxity was 2.8° (SD 1.3, range 0.6–5.4°). In flexion, mean valgus laxity was 2.5° (SD 1.5, range 0.0–6.0°) and mean varus laxity was 3.1° (SD 2.0, range 0.1–7.0°). Varus and valgus knee laxity in extension and in flexion were comparable. The results in this study showed that the normal knee in this age group has an inherent degree of varus-valgus laxity. Whether the results of the present study can be used to optimise the TKR implantation technique requires further investigation.

The prospective *Study 4* investigated whether ligament releases necessary during TKR lead to a higher varus-valgus laxity during intra-operative examination after implantation of the prosthesis and after 6 months. The laxity values of TKR patients were also compared to healthy controls. Varus-valgus laxity was assessed intra- and postoperatively in extension and 70° flexion in 49 patients undergoing TKR, using a balanced gap technique. Knees were catalogued according to ligament releases performed during surgery. Postoperative varus-valgus laxity and laxity after 6 months had not increased following release of the posteromedial capsule, iliotibial tract, and the superficial medial collateral ligament. The obtained postoperative laxity compared well with the healthy equally-aged control group. It can be concluded that the balanced gap technique results in stable knees and that releases can safely be performed to achieve neutral leg alignment without causing postoperative laxity.

Ligament releases can be performed to achieve restoration of mechanical alignment after TKR. Several previously

described sequences and results achieved on cadaver knees with measured resection implantation techniques are not be applied to the balanced gap technique. In *Study 5* the peroperative effect of stepwise, soft tissue releases following the "tightest structure first" on leg axis in extension and femur rotation in flexion was investigated. During PCL-retaining TKR using a balanced gap technique in 54 patients, we determined the effect of each ligament release using a navigation system while the knee was distracted with a tensor in extension and flexion. The effect on alignment in extension and on femoral rotation in flexion was measured separately after each release. In more than half of the patients, one or more ligament releases were necessary. Release of the posteromedial condyle led to a minor effect on leg axis in extension and femoral rotation in flexion; release of the superficial medial collateral ligament, to a few degrees, mainly in extension. Release of the iliotibial tract led to a small correction of leg alignment in extension. There was no statistically significant difference in the alignment-correcting effect of a release dependent upon the sequence in which the structure was released. In PCL-retaining TKR a step-wise "tightest structure first" protocol for ligament releases in extension with the balanced gap technique results in an effective, gradual, alignment correction in extension, and limited femoral rotation effects in flexion.

The most specific characteristic of the balanced gap implantation technique is that, within the restrictions produced by soft tissue structures, femoral component rotation can vary freely. Since internal rotation might cause patella problems, the effect of ligament releases on femoral component rotation was prospectively assessed in *Study 6*. Femoral component rotation was measured intra-operatively with a tensor applied in flexion at 150 N in 87 knees. A great interpatient variability was found; femoral component rotation, referenced from the posterior condyles, ranged from -4° to 13°. There was no difference in femoral component rotation between knees with or without ligament releases in extension. However, knees with major medial releases had less external femoral component rotation than knees with minor lateral releases. Pre-operative alignment had no influence on femoral component rotation. Theoretically, the use of the balanced gap implantation technique will result in a balanced flexion gap, but the amount of femoral component rotation will be variable as a result of patient variability and variation in ligament releases. Whether this has consequences for patellar tracking needs to be investigated.

Patella position can be measured on axial radiographs and many measurement techniques have been described in the literature. *Study 7* evaluates the inter- and intra-observer reproducibility of suitable measurement techniques for patients with a knee prosthesis found in the literature. Fifty axial patella radiographs from knee prostheses were used to measure the reproducibility of five measurement techniques. Reproducibility was calculated using the Bland and Altman method. Lateral Patellar Tilt (>10°) and Patellar Displacement (≥4mm) methods were found to be the most reproducible methods to measure patellar tilt or displacement, respectively.

The goal of *Study 8* was to investigate whether femoral component rotation influenced patella position after a primary total knee replacement with the balanced gap technique. In this prospective cohort study, a primary TKR was implanted in 49 patients using a balanced gap technique and a CT-free navigation system. Femoral component rotation referenced from the posterior condyles was measured using the navigation data of the distal femur cut. At the 2-year follow up, lateral patellar tilt and patellar displacement were measured on axial patella radiographs. Logistic regression analysis on femoral component rotation and pre-operative patella position was conducted to identify predictors for postoperative patellar tilt and displacement. Femoral component rotation, which varied between –3 and 12 degrees exorotation was not a predictor for postoperative tilt and displacement. Only pre-operative displacement of the patella significantly predicted postoperative patella displacement. Although the balanced gap implantation technique resulted in a wide interpatient variability for femoral component rotation, this variable rotation was not found to be associated with abnormal patellar position. Preoperative displacement results in a higher risk at a postoperatively displaced patella.

After assessing several rather technical issues concerning PCL-retaining TKR with the balanced gap technique, it remained to be seen what the clinical and functional results of the surgery were, and whether these compare to persons of the same age without a knee problem. The goal of *Study 9* was to summarize clinical outcome of patients with TKR implanted with the balanced gap technique and to compare the clinical outcome and functional test results to equally-aged healthy controls. A total of 49 patients were available for follow-up; thirty healthy controls of the same age category were assessed for comparison. An independent research nurse assessed activity scores, knee flexion, the Knee Society Score (KSS), and AP stability. In addition, three functional tests (the Get-Up-and-Go-test, the 20m walk test, and the stair climbing test) were performed. Furthermore, a questionnaire on pain, instability and daily life activities was completed. The results showed that TKR patients did well 6 and 12 months after surgery; their activity level was comparable to that of the healthy controls. Pain was diminished and both clinical and functional KSS were good. Compared to healthy controls, patients were still not (yet) normal, with exception of the clinical KSS for which there was no difference between patients and controls. Functional tests showed a difference between patients and healthy controls; perhaps co-morbidities had an influence. Clinical examination showed very stable knees, even more stable than those of the control group. Range of motion of TKR patients at 1 year follow-up was 118 degrees; active flexion was 103 degrees, which was good, although lower than that of the healthy controls. Although patients did not function "normally", the majority was quite satisfied.

Finally, the *General discussion* addresses the main findings of the studies and places them into a clinical perspective. Furthermore, new questions related to future research on the balanced gap technique that have risen during the course of the project were posed. The overall conclusions of this thesis were formulated.

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