Improving surgical techniques and functional outcome in total knee arthroplasty

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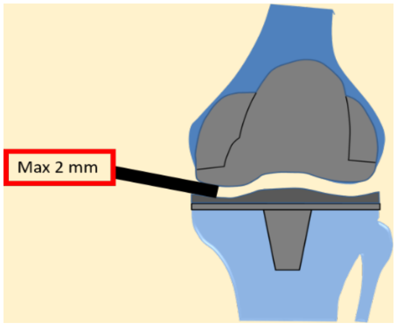
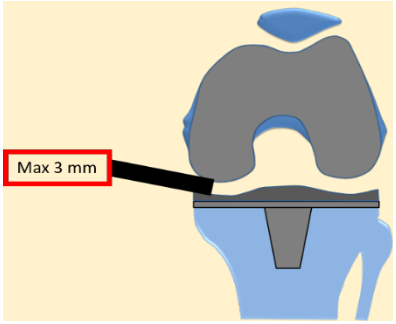
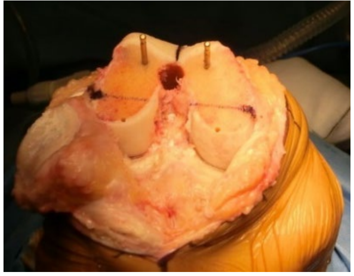
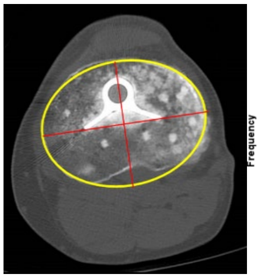
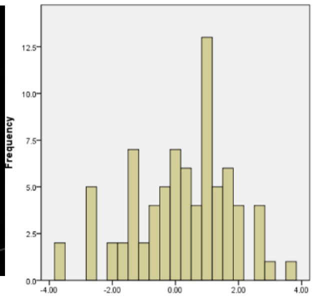
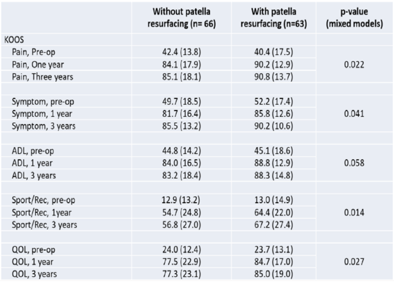












	Without patella resurfacing (n= 66)	With patella resurfacing (n=63)	p-value (mixed models)
KOOS			
Pain, Pre-op	42.4 (13.8)	40.4 (17.5)	0.022
Pain, One year	84.1 (17.9)	90.2 (12.9)	
Pain, Three years	85.1 (18.1)	90.8 (13.7)	
Symptom, pre-op	49.7 (18.5)	52.2 (17.4)	0.041
Symptom, 1 year	81.7 (16.4)	85.8 (12.6)	
Symptom, 3 years	85.5 (13.2)	90.2 (10.6)	
ADL, pre-op	44.8 (14.2)	45.1 (18.6)	0.058
ADL, 1 year	84.0 (16.5)	88.8 (12.9)	
ADL, 3 years	83.2 (18.4)	88.3 (14.8)	
Sport/Rec, pre-op	12.9 (13.2)	13.0 (14.9)	0.014
Sport/Rec, 1year	54.7 (24.8)	64.4 (22.0)	
Sport/Rec, 3 years	56.8 (27.0)	67.2 (27.4)	
QOL, pre-op	24.0 (12.4)	23.7 (13.1)	0.027
QOL, 1 year	77.5 (22.9)	84.7 (17.0)	
QOL, 3 years	77.3 (23.1)	85.0 (19.0)	

1 Contents

2 Preface

Total knee arthroplasty (TKA) is one of modern surgery's most effective means of relieving chronic pain and dysfunction, and it is the treatment of choice in severely damaged knee joints when other treatment options have failed. TKA has for the last four decades developed from being a dangerous operation with a high risk of major complications, to be a relatively predictable procedure with a good chance of pain relief and recovery of knee function. However, 10%-20% of patients operated with TKA suffer from knee pain, joint stiffness and poor function. In some of the unsuccessful cases the reason for failure can be identified and corrected, but in many cases the cause of failure remains unknown and the patient is left with the problem. The reason for failed TKA can be divided into patient dependent factors, implant dependent factors and surgeon dependent factors.

After many years of clinical experience and study of the available scientific literature related to TKA, I realized that many important decisions made throughout TKA surgery were based on the surgeons' subjective feel, with little or no support for these decisions to be found in evidence-based literature. It was reasonable to assume that further insight into these surgeon-dependent, unresolved problems could diminish the number of unsuccessful TKAs. The most prominent unresolved questions I identified were related to ligament balancing, the patellofemoral joint and rotational alignment of the prosthetic components. Therefore, in 2007, I started to plan a series of studies in the hope of providing more evidence-based information into some of these unresolved problems.

In this thesis I introduce and validate the spatula method, which is a novel method developed at our institution, designed to measure ligament laxity intraoperatively. With this method, it was possible to generate objective data about ligament laxity, and thereafter to evaluate the association between ligament laxity measured intraoperatively and functional outcome. Based on this new data, recommendation on how much ligament laxity orthopaedic surgeons should aim for can be given. The effect of the surgical trauma induced by ligament balancing on functional outcome after TKA is also estimated, and its implication on the choice of alignment strategy and gap-balancing strategy is discussed.

The most effective treatment of the patello-femoral joint during TKA remains controversial, and there is a remarkable variation between countries in whether the patella is resurfaced or not. However, recent research on outcomes after TKA has raised the question of the ability of traditional outcome measures to distinguish between treatments. Therefore, a randomized double-blind study with a more contemporary and sensitive outcome measure was performed.

Malrotation of the femoral and tibial prosthetic components is known to be associated with poor functional outcome and complications. Existing techniques for rotational alignment of the prosthetic components are found to be unreliable. Consequently, a new method to guide rotational position of the femoral component was developed and tested, and the association between rotational alignment of the prosthetic components and functional outcome was further evaluated.

Until now, 8 clinical studies have been completed. At the beginning, this research was not intended as a doctoral thesis, however it gradually became clear that both funders and colleagues expected me to follow through with a thesis or dissertation of this material. Although a strange idea at the beginning, after some years it became an inspiring drive in my project. Having planned and performed my research at a local hospital, without supervision or any formal affiliation to a university, it was evident that the project was more suitable for a Dr.Philos. degree than for a PhD program.

According to the University of Oslo, “The Dr.Philos. degree (Doctor Philosophiae) may be awarded to academics who have qualified for a doctoral degree on their own, without formal supervision. The candidates have no formal affiliation to the University until their application for the doctoral examination has been approved.”

This book contains a monography based on the contents of eight scientific studies and on my clinical experience and literature studies through the years. As of now (september 2018) six studies have been published in recognized international medical journals. All eight studies have been presented live at national and/or international congresses.

3 Acknowledgments

The first topic in this thesis, ligament balancing, was not much heeded in Norwegian orthopaedic research society 10 years ago. Stephan Maximillian Röhrl, associate professor at University of Oslo and head of CIRRO (Center for Implant and Radiostereometric Research Oslo) was the first to show interest in my research. I am grateful for his inspiration when the work became hard, for his work as a coauthor and for his enthusiasm throughout the entire project.

Careful outcome assessment, essential in clinical research, was accomplished with outstanding reliability and amiability by Grethe Næss, coauthor and Physiotherapist at the Department for Ergotherapy and Physiotherapy at SI Lillehammer hospital.

I also want to thank coauthors Thomas Kibsgård, John Clarke-Jenssen, Daniel Østergaard, Arn Meland and Ketil Dalheim for their help with data collection and revision of manuscripts. Thanks also to coauthors Lien My Diep MSc, statistician at Oslo University Hospital and Leiv Sandvik, Dr. Philos at Oslo Centre for Biostatistics and Epidemiology, for their indispensable help when statistics became difficult.

I acknowledge the nurses in the operating theatre at SI Lillehammer hospital for their crucial effort in optimizing the conditions necessary for high quality surgery. A special thank to Magnar Øien for his help in designing and manufacturing the spatulas, the new tool that was essential for our research on ligament balancing.

I would also like to thank the heads of our surgical department Roar Rønning, Ellen Henriette Pettersen and Arn Meland for incorporating this piece of clinical research into our busy daily practice. Roar should also be acknowledged for the design of the advanced relation database in MS Access that made data management safe and effective. I also acknowledge the service from the Department of Radiology accountable for hundreds of high quality X-rays and CT scans.

A special thanks to Jacob Nakling Dr. Med. and specialist in Obstetrics and Gynecology for carrying the burden of scientific responsibility of a project dedicated to orthopaedic surgery. Thanks also to Kari Lillehaug, adviser at the research unit at SI Innlandet for her careful and friendly follow-up throughout the research period.

A warm acknowledgement goes to the patients who accepted the inconvenience of extra examinations and follow-up visits that resulted in 98% follow-up at three years.

I am glad the funding from Helse Sør-Øst and Sykehuset Innlandet hospital trust made it possible to work in daylight at least one day a week.

Thanks also to James Feher, Orthopaedic surgeon at Sykehuset Innlandet, Lillehammer for his help with proofreading of this monography.

Combining clinical surgery and research is a lifestyle, not only for the surgeon, but also for his whole family. Therefore, my greatest thanks goes to my wife Helen Juel who supported me throughout my career and whose strength and care have been vital for the well-being of our family and myself. Without her efforts, this work would not have been possible. Besides being my wife, Helen has also played an important professional role as an operating theatre nurse at SI Lillehammer hospital working with the complex entities of orthopaedic equipment and logistics. We both thank our children Elisabeth and Håvard (deceased in the mountains of Jotunheimen, July 2010) for their love and tolerance.

4 Definitions

Condylar lift-off: The distance between the medial femoral and medial tibial condyles and between the lateral condyles when the ligaments are stretched to their full length by a valgus or varus force as in a standard clinical knee ligament testing.

Combined malrotation: The sum of the rotational alignments in the femoral and tibial components.

Component mismatch: The degree of divergence in rotational alignment between the femoral and the tibial components.

CT derived surgical transepicondylar axis (CTsTEA): was defined by drawing a line from the lateral epicondyle to the sulcus in the medial epicondyle (Fig. 16A).

Femoral component rotational axis (FCRA): was defined by drawing the common tangent of the two pegs on the inside of the femoral component (Fig. 16B).

Femoral component rotational angle (FCR-angle): The angle between the CTsTEA and the FCRA (Fig. 16).

Instability: 1) A physical sign of abnormal mobility of a joint. 2) A subjective symptom of giving-way.

Kinematics: The branch of classical mechanics that describes the motion of points, bodies, and systems of bodies without consideration of the masses of those objects nor the forces that may have caused the motion. Knee kinematics describe the movements of the knee joint through the full range of motion.

Kinetics: The branch of classical mechanics that is concerned with the relationship between the motion of bodies and its causes, namely forces and torques.

Ligament balance: The degree of symmetry between the medial and lateral stabilizing structures

Ligament laxity: Slackness or lack of tension in a ligament. See also condylar lift-off.

Opposite rotation of prosthetic components: occurs if one component is rotated internally and the other externally. See also combined malrotation and component mismatch above.

Patello-femoral arthroplasty: A surgical procedure in which only the anterior compartment (the joint surfaces between the patella and the femur) are replaced with artificial implants.

Statics: The branch of mechanics that is concerned with the analysis of loads (force and torque, or “moment”) acting on physical systems that do not experience an acceleration, but rather, are in static equilibrium with their environment.

Stiffness: is the rigidity of an object — the extent to which it resists deformation in response to an applied force.

Strain: Percentage change in length.

Stress: Load per cross-sectional area (N/m^2 = Pascal)

Stress–strain curve: The amount of deformation (strain) at distinct intervals of tensile or compressive loading (stress).

Total knee arthroplasty = Total knee replacement = Total knee prosthesis: A surgical procedure in which the native knee joint surfaces and underlying bone is replaced with artificial implants. Coexisting bony deformities as well as the soft tissue (capsule, ligaments and tendons) deformities are adjusted. The replacement of both the distal femur and the proximal tibia is mandatory. Replacement of the patella is optional.

Unicompartmental arthroplasty (UNI): A surgical procedure in which only the medial or the lateral compartment of the knee is replaced with artificial implants.

5 Abbreviations

ACL: Anterior cruciate ligament
APA: Antero-posterior axis (Whiteside‘s line)
BMI: Body mass index
CAOS: Computer assisted orthopaedic surgery
CI: Confidence interval
CRA: Clinical rotational axis
CRA-method: Clinical rotational axis method
CT: Computer tomography
CTsTEA: CT-derived surgical transepicondylar axis
DOF: Degree of freedom
FCRA: Femoral component rotational axis.
FCR-angle: Femoral component rotational angle
HKA: Hip-knee-ankle
HKFS: Hip-knee-femoral shaft
ICC: Intra-class correlation coefficient
ICRS: International Cartilage Repair Society
KOOS: Knee injury and osteoarthritis outcome score.
KSS: American knee society score
LCL: Lateral collateral ligament
MCL: Medial collateral ligament
MPCI: Minimal perceptible clinical improvement
OKS: Oxford knee score. The original score range from 12 to 60 points, 12 being the best score. More recently, the scale has been inverted so that 12 is the worst score and 60 is the best score. The inverted scale is used in paper IV.
PCL: In paper V in this thesis; Posterior condylar line. Elsewhere; Posterior cruciate ligament.
PLC: Posterior-lateral corner
PROM: Patient reported outcome measure
PSI: Patient specific instruments
ROM: Range of motion
RSA: Radiostereometric analysis
SD: Standard deviation
sTEA: surgical Transepicondylar axis
TEA: Transepicondylar axis
TKA: Total knee arthroplasty = Total knee replacement
TKR: Total knee replacement = Total knee arthroplasty
UNI: Unicompartmental arthroplasty
VAS: Visual analog scale

6 Aims of this thesis

6.1 Overall aim

Improve functional outcome of total knee arthroplasty (TKA) by developing new techniques and testing existing controversies faced by orthopaedic surgeons in daily practice.

6.2 Specific aims

Paper I: Introduce a new method to measure medial and lateral ligament laxity intra-operatively during TKA, and provide objective data on ligament laxity after implantation of all prosthetic components.

Paper II: Identify how ligament laxity measured intraoperatively is related to functional outcome one year after TKA, and thereby replacing subjective judgement with objective targets during surgery.

Paper III: Estimate the effect of patellar eversion on ligament laxity measured intraoperatively after the implantation of the prosthetic components in cruciate-retaining TKAs. In addition, to find out whether or not the effect of patellar eversion on ligament balance is clinically relevant.

Paper IV: To find out if the surgical trauma imposed by ligament balancing has detrimental effects on functional outcome after TKA. Thereafter to discuss the impact of ligament balancing on different alignment strategies,

Paper V: Comparison of functional outcome in osteoarthritic patients operated with TKA, with and without patellar resurfacing in a randomized, double-blind study. Thereafter to discuss the impact of ceiling effects and other distribution effects in different outcome measures on the results of a clinical trial.

Paper VI: First, to present and validate a new method for rotational alignment of the femoral component in the axial plane. Second, to investigate the association between femoral component rotation and functional outcome 3 years after operation.

Paper VII: Investigate the effect of tibial component rotation on functional outcome after TKA and give recommendations on how the tibial component should be aligned in the axial plane. Then to discuss the value of Berger’s method to measure rotational alignment in individual patients and finally to discuss the value of the Intraclass Correlation coefficient (ICC).

Paper VIII: Explore the effects of combined rotation of the femoral and tibial components and patellar tilt on functional outcome in TKA.

7 Thesis at a glance

Paper	Aim of the study	Design and publication status	Number of knees investigated	Follow-up	Main findings
I	1) To introduce a new method to measure medial and lateral ligament laxity intra-operatively during TKA. 2) To provide objective data on ligament laxity after implantation of all prosthetic components.	Validation of a new method Try-out of the new method Arc Orhop Trauma Surg (2012) 132:1173-81	Validation: 96 measurements in 24 knees Try out: 100 knees	Not relevant	This new method for measuring ligament balance is reliable and provides valuable information in assessing laxity intra-operatively. This method may become a useful tool in further research on the relationship between ligament balance, function and survival of TKA.
II	To find out how ligament laxity measured intraoperatively is related to functional outcome one year after TKA, and thereby replacing subjective judgement with objective targets during surgery.	Prospective cohort study Knee Surg Sports Traumatol Arthrosc (2015) 23: 1684-92	122 knees	1 year	The mechanical axis in the coronal plane was found to interact on the effect of ligament laxity on outcome. Medial laxity more than 2 mm in extension and 3 mm in flexion should be avoided in neutral and valgus-aligned knees.
III	1) To estimate the effect of patellar eversion on ligament laxity measured intraoperatively after the implantation of the prosthetic components in cruciate-retaining TKAs. 2) To find out whether the effect of patellar eversion on ligament balance is clinically relevant.	Observational cross sectional study Prospective cohort study Arc Orhop Trauma Surg (2017) 137(3): 387-92	49 knees	Not relevant 1 year	An increase of 0.6 mm in lateral ligament laxity in flexion was identified when the patella was repositioned compared to everted. No differences were found in extension or medially in flexion. The effect of patellar eversion on ligament laxity measurement is too small to be considered clinically relevant.
IV	1) To find out if the surgical trauma imposed by ligament balancing have detrimental effects on functional outcome after TKA.	Cohort study	129 knees	3 years	No detrimental effects of ligament balancing on functional outcome was observed.

	2) To discuss the effect of ligament balancing in mechanically aligned versus anatomically or kinematically aligned TKAs.	Acta Orthopaedica June 2018			The results indicate that the need for additional ligament-balancing is not a valid argument against mechanical alignment in TKA.
V	1) To compare the functional outcome in osteoarthritic patients operated with TKA, with and without patellar resurfacing. 2) Additionally, to discuss the impact of ceiling effects in different outcome measures on the results of a clinical trial.	Randomized double-blind study Acta Orthopaedica (2016) 87(2): 158-64	129 knees	3 months, 1 year and 3 years	The KOOS indicated that patellar resurfacing is beneficial in TKA. Unacceptable high ceiling effects were observed for the KSS, the patient satisfaction score (VAS), and for the ADL sub-score in KOOS.
VI	1) To present and validate a new method for rotational alignment of the femoral component in the axial plane. 2) To investigate the association between femoral component rotation and functional outcome 3 years after the operation.	Description and validation of a new method. Cohort study Acta Orthopaedica (2017) 88(6):657-63	80 knees	3 years	The CRA method proved to be simple and very accurate with a low grade of scatter compared to earlier techniques. The fact that no statistically significant association was found between the degree of malrotation and functional outcome indicate that the CRA method is a safe method for intraoperative estimation of femoral component rotation.
VII	To investigate the effect of tibial component rotation on functional outcome after TKA and to give recommendations on how the tibial component should be aligned in the axial plane.	Cohort study	80 knees	3 years	Internal rotation of the tibial component has negative effect on functional outcome after TKA. The rotation of the tibial component should be guided by bony landmarks (medial third of the tibial tubercle) rather than by a dynamic self-seeking technique.

	A discussion of the usefulness of Berger’s method to measure rotational alignment is added, and finally the value of ICC in clinical practice is discussed.	Manuscript submitted			Berger’s method to measure tibial component rotation on individual patients is not very reliable and should be interpreted with caution. The interpretation of ICC is probably not very intuitive. Histograms or frequency tables may be more informative.
VIII	To study the effects of different combinations of malrotation of the femoral and tibial components on functional outcome. Thereafter to explore the relationship between malrotation and patellar tilt and the effect of patellar tilt on functional outcome.	Cohort study Manuscript in progress	80 knees	3 years	1) Combined internal rotation of the femoral and tibial components have negative effect on functional outcome. 2) Opposite rotation and mismatch of the femoral and tibial components did not affect functional outcome. 3) No correlation between individual, combined or opposite malrotations and patella tilt were found. 4) In knees with patella tilt more than 4° all outcome scores were significantly lower than in knees with 4° or less patella tilt.

8 Introduction

Total knee arthroplasty (TKA) is the preferred treatment when knee pain and poor knee function is due to damaged articular surfaces, and less invasive treatment options have failed. TKA has proved to be one of the most efficient treatments in orthopaedic surgery and more than a million operations are performed each year worldwide. However, it is a major surgical intervention and the patients must be physically and psychologically fit. Patient selection, surgical technique and choice of implants are crucial requirements for successful outcome. Thorough understanding of knee anatomy, biology and mechanics, as well as the effect of general health factors on the surgical patient is mandatory.

8.1 Hyaline cartilage

The load-bearing surfaces in the knee joint consists of a 2-5 mm thick layer of hyaline cartilage, a highly specialized tissue made up mainly by chondrocytes, proteoglycans and collagen (Figure 1). The tissue has no vascularization and depends on oxygen supply and nutrients from the joint fluid (synovial fluid). The composition and structure of hyaline cartilage provides extreme biomechanical properties when exposed to motion and load. The low friction coefficient (0.002) and viscoelastic properties allows the articular cartilage to withstand millions of load cycles year after year without degeneration. Unfortunately, the ability of hyaline cartilage to regenerate after trauma or disease is very limited and the lack of a healthy load-bearing articular surface in the knee may cause pain and functional loss [1].

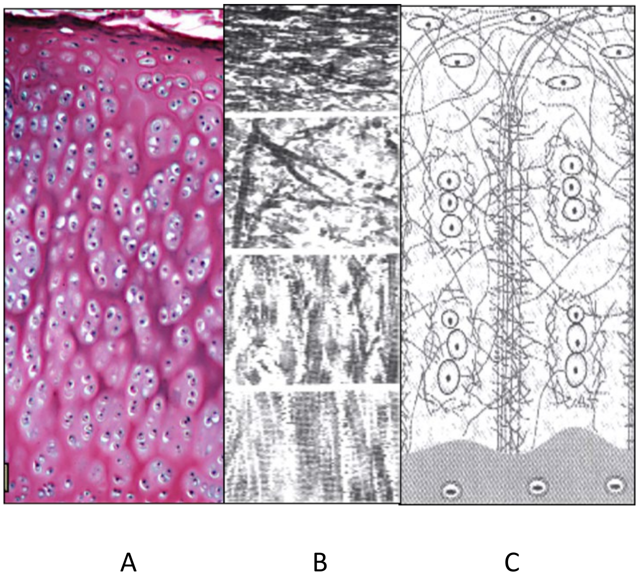


Figure 1. A: Histologic picture of hyalin cartilage. B: Electron-microscopic picture showing the orientation of the collagen fibers in different layers. C: Drawing illustrating the organization of chondrocytes, collagen fibers and matrix.

8.2 Osteoarthritis

Osteoarthritis (OA), also called degenerative joint disease or arthrosis is the result of breakdown of hyaline cartilage. Macroscopically the smooth, delicate white surface is transformed to a fibrillated or cracked surface and in the more severely affected knee, the subchondral bone is exposed and bony and soft tissue deformities occur. Histologically, fibrillation, cell proliferation and cell death can be seen, as well as loss of matrix, delamination and erosion [2]. In the clinical setting hyaline cartilage damage can be graded according to the International Cartilage Repair Society (ICRS) [3] where grade 1 and 2 represent damage within the superficial one half of the cartilage thickness and grade 4 penetrates the subchondral bone. Long-standing knee OA frequently leads to skeletal deformities in varus or valgus. Subsequent contractures or failure of ligamentous and capsular structures may increase deformities and lead to lac of motion and/or instability. OA is a frequent cause for disabling pain and dysfunction in the knee of middle aged and elderly people.

In younger people, another entity of cartilage damage is frequently found: Isolated focal cartilage lesions can be seen in association with injuries to the cruciate and collateral ligaments [4]. The natural history of these lesions is largely unknown. However, small lesions surrounded by healthy cartilage may have a good prognosis, but bigger lesions may result in OA.

OA is described as primary or idiopathic when no obvious underlying causal factor is recognized. Secondary OA may be initiated by congenital lesions, trauma, infections, inflammatory arthritis, neuropathic or metabolic disorders. The etiology is multifactorial, and the complex interactions between genetic, metabolic and local factors are not fully understood. However, a common factor in the causal pathways to OA is non-physiologic mechanical stresses. Among the most important risk factors are obesity. In obese patients, a relative risk for having a knee arthroplasty has been estimated to 6.2 in men and 11.1 in women, comparing the highest versus the lowest quarter of BMI [5]. In the same study, the relative risk of having a knee arthroplasty in patients with intensive physical activity at work was 2.4 for men and 2.3 for women compared to patients with sedentary activity at work [5]. The role of malalignment in initiating OA is unclear, but a strong association has been documented between malalignment and progression of OA [6].

In the Global Burden of Disease 2010 study, hip and knee OA was ranked as the 11th highest contributor to global disability among the 291 conditions investigated, and knee OA was by far the most prevalent of the two [7]. The prevalence is increasing with age and women are more frequently affected than men are. In a Swedish study the prevalence of radiographic knee osteoarthritis in the age group 56-84 years was 25% and 15% were symptomatic [8]. An American study estimated the lifetime risk of symptomatic knee OA to be 45% in the general population and 57% for those with a history of knee injury. Obese patients had a lifetime risk of 61% [9].

8.3 Ligaments and soft tissues

The bony and cartilaginous structures of the knee are surrounded by a soft tissue envelope consisting of the joint capsule, menisci, ligaments, and tendons that guide knee movements and provides stability. Ligaments and other soft tissue structures therefore are crucial for knee function. It is somewhat surprising that the basic properties of the ligament structures around the knee have achieved a relative limited attention in TKA literature.

Ligaments are viscoelastic structures made of connective tissues consisting mainly of collagen and fibroblasts. Ligaments have three properties that affect their ability to limit knee motion; the localization of the distal and proximal insertion points, laxity (just taught length) and stiffness [10]. The insertion points determines the direction of the ligament forces, and it determines the more or less isometric behavior of the ligament. The laxity is the amount of joint movement necessary to tighten up the slack and activate ligament forces. Ligament stiffness represents the resistance offered by the ligament to further elongation [11]. Figure 2 shows a typical force-elongation curve were the "too-phase" represents the ligament laxity. The linear part of the curve is the elastic region ending at a yield point where plastic deformation starts and finally a failure point where the ligament ruptures. It is also important to note that collagen fibers are not highly elastic and fails at a low level of elongation (8-12%), indicating that ligaments around the knee can fail if they are stretched a few millimeters. In ligaments the collagen fibers are parallel and load is therefore relatively equally distributed between the fibers. This results in a high maximum load to failure followed by an abrupt failure. In contrast, in capsular structures the collagen fibers are oblique to each other's resulting in a lower maximum load to failure and a more gradual failure mechanism [10]. Knee ligaments also contain nerve-endings with mechanoreceptors and nociceptors indicating that ligaments are important structures for proprioception and perception of joint pain [12].

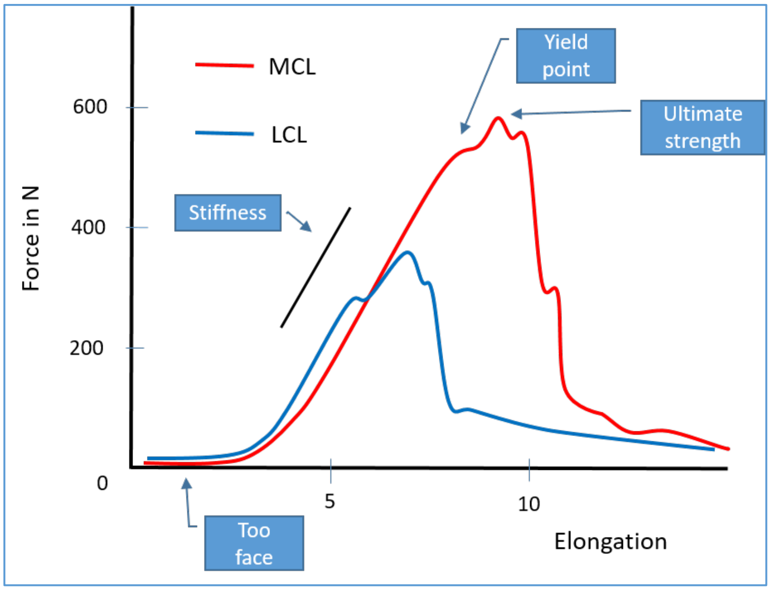


Figure 2. Hypothetic force-elongation curves for the medial and lateral collateral ligaments. The too-phase represent the ligament laxity, and the linear part of the curve represent the elastic region. The slope characterizes the stiffness of the ligament.

8.4 Native knee kinematics

The knee joint was originally considered a hinged articulation, with movements around one single axis like a hinged door. Modern research did not find it so. Knee motion is a very complex combination of flexion/extension, rotation, translation, rolling and gliding. The tibia moves around the femur with six degrees of freedom (DOF) guided by the articular surfaces, menisci, multiple ligaments and the joint capsule. Muscles and tendons impose forces to the skeleton and to soft tissue structures adding to the complexity of knee joint biomechanics. The most apparent patterns of knee joint kinematics are as follows: During flexion, the femoral condyles rotate and glide resulting in posterior translation of the femur on the tibia. This posterior rollback is much more prominent on the lateral side (18mm) compared to the medial side (1,5mm), resulting in internal rotation of the tibia in flexion. The degree of tibial rotation from full extension to full flexion has been found to be about 18° [13]. At the end of knee extension, an inversed rotation occurs as the tibia rotates externally, the so-called "screw home" mechanism.

8.5 Treatment options for knee osteoarthritis

Many possible pathways for prevention and treatment of OA have been suggested. Blocking the degeneration of the hyaline cartilage with glucosamine, chondroitin sulfate, hyaluronic acid, doxycycline, and matrix metalloproteinases have been tested in clinical trials with varying results [14]. Other investigators have focused on treating the subchondral pathology with bisphosphonates and reported some transient effect on pain [15]. The effect of Calcitonin have also been tested in humans, but no clinical benefits were documented [16].

The choice of treatment of knee osteoarthritis depends on the severity of the disease and the disability of the patient. In early stages of OA, many conservative (non-surgical) treatment options exist and evidence-based, consensus guidelines have been developed [17]. Recommendations for non-surgical management of knee OA include weight reduction, activity modifications, exercise and strength training, intraarticular corticosteroids, NSAIDs and paracetamol. Biomechanical interventions like unloading knee braces and canes are also recommended. The effect of these interventions are pain reduction and for some interventions increased knee function.

8.6 Surgical treatment

When discussing surgical treatment it is important to distinguish between focal cartilage lesions and OA. Some selected acute cases with focal cartilage lesions and a loose osteochondral fragment can be successfully treated with refixation of the fragment. In the majority of cases however, no loose fragment, suitable for refixation can be found, and many alternative treatment options for these focal cartilage lesions have been proposed. The mostly used options nowadays are; debridement, bone marrow stimulation (microfracture), osteochondral graft transplantation (mosaic plasty), autolog chondrocyte implantation and mesenchymal stem cell implantation with or without scaffolds. However, it may be questioned whether any of these methods with certainty have been proven superior to the natural history of focal cartilage lesions [4]. Some patient with focal cartilage lesions develop OA over time.

Cases with OA localized solely in the medial or lateral compartment and moderate deformity can be treated with osteotomy [18]. The osteotomy aims at realigning the leg so that the main load through the knee joint is transferred from the sick to the healthy compartment. By doing so most patient can expect less pain and better function for many years. Another option for patients with unicompartmental OA is UNI-prosthesis, which is prosthetic replacement of only the medial or the lateral knee compartment [19]. For a few patients suffering from OA mainly in the anterior compartment (the patella-femoral joint), an isolated patella-femoral prosthesis can be a good option [20]. However, a common consequence for knees treated with osteotomies or partial prosthesis is the tendency to develop OA in the rest of the knee joint. Therefore, many of these patients will experience increasing pain and dysfunction after many years, and will become candidates for TKA.

8.7 Total knee arthroplasty

Total knee arthroplasty (TKA) is the treatment of choice for disabling end-stage OA. More than 7000 TKAs were performed in Norway in 2017 [21]. In the USA the estimated number is more than 600 000 TKAs per year, and the number is still increasing [22]. The obesity epidemic in the western world and the development of advanced medical services in the Far East will probably multiply the need for total knee surgery worldwide. Medical research and modern engineering have given insight into the biology and mechanics of the native knee and made possible the development of new implants, instrumentations, surgical techniques and strategies. The ability of TKA to relieve patients from pain and to improve knee function and quality of life is demonstrated in this thesis (Figure 3). However, the proportion of unsuccessful TKA‘s and unhappy patients has been estimated to as much as 20% [23] The reason for this may be inherent limitations in concept and design of total knee prosthesis or insufficient surgical techniques. In this thesis, the focus is on surgical techniques and other surgeon-dependent factors.

The ultimate goal of TKA is a pain-free, well-functioning knee throughout the patient's life. In the real world, the outcome diverges from amputation and death at one extreme to a perfect functioning and everlasting knee at the other extreme. A great number of factors influence the outcome. Patient related factors such as cardiovascular disease, KOLS, diabetes, obesity, neurological, and immunological diseases must be optimized before surgery, and in some cases represent an absolute contraindication to TKA. Local factors that may affect the outcome include the degree of deformities in bone and soft tissues, infections and impaired peripheral circulation. Of major importance is also the quality of the skin. An additional skin incision in an area with scarring from previous surgery or trauma will make the skin vulnerable to ischemia, necrosis and subsequent deep infection and loss of tissues covering the knee joint.

TKA is a major surgical intervention with potential for serious adverse events and the surgeon should share all relevant information with the patient in order to make the patient capable of making a true informed decision based on hers/his personal priorities [24, 25].

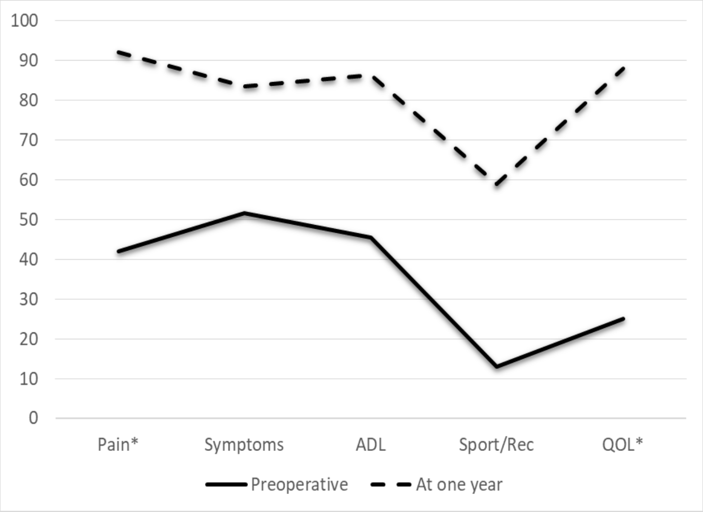


Figure 3. KOOS (including five sub-scores) measured preoperatively and at 1 year follow up in 122 knees. Δ-values are statistically significant for all subscores (p<0.001).

ADL: Activities of daily living. Sport/Rec: Sport and recreation. QOL: Knee related quality of life. * Median values

8.7.1 Basic principles in total knee arthroplasty

Three basic elements are essential for successful TKA. These are alignment, component positioning and soft tissue balance.

8.7.2 Alignment and component positioning

Alignment of the lower limb is the relative positions of the hip, knee and ankle joints in three planes and has been described in detail by Dror Paley [26]. Alignment is best demonstrated by the mechanical axes, the anatomical axes and the joint orientation lines (Figure 4). The mechanical axis of the lower limb is a straight line from the center of the hip joint to the center of the ankle. In the frontal plane of the native knee, this line passes average 8 mm medial to the center of the knee. In the sagittal plane, the distance between the mechanical axis of the lower limb and the knee center increases with increasing knee flexion. The mechanical axis of the femur is a straight line from the center of the hip joint to the center of the knee, and the mechanical axis of the tibia is a straight line from the center of the knee to the center of the ankle. The anatomical axes of the femur and tibia follows the mid-diaphyseal line of the bones. The mechanical and anatomical axes of the tibia are almost parallel, but in the femur the anatomic axis deviates in average 7° from the mechanical axis in the frontal plane (Figure 4).

In the frontal plane the knee has two joint orientation lines (Figure 4). One connects the centers of the medial and lateral tibial plateaus and the other connects the most distal points of the medial and lateral femoral condyles. In the normal, bipedal weight bearing position these lines are almost parallel, and their inclination in relation to the horizontal plane average 2°-3°, lowest medially.

In TKA, three different principles for frontal plane alignment exist. Classical mechanical alignment [27, 28], anatomic alignment [27, 29] and kinematic alignment [27, 30, 31]. In the studies presented in this thesis all patients were operated following the principle of mechanical alignment: In the frontal plane, the goal is to place the center of the prosthetic joint at the mechanical axis of the lower limb and to place the femoral and tibial joint lines perpendicular to the mechanical axis of the femur and tibia respectively. This non-anatomical alignment in extension must be compensated for in flexion by externally rotating the femoral component 2-3° (Figure 5). The degree of acceptable frontal plane malalignment has long been considered to be ± 3°, however more recent studies comparing TKAs with ≤ ± 3° postoperative mechanical axis with outliers did not find any significant difference in 15 years implant survival [32, 33].

In contrast to mechanical alignment, anatomic and kinematic alignment aims at reestablishing the patients' natural premorbid alignment, and thereby mimic normal knee kinematics. However, the scientific support for the use of anatomic and kinematic alignment in TKA is currently scarce and mechanical alignment remains the gold standard [34, 35]. Different alignment techniques and their relations to ligament balancing are further discussed in **paper IV**.

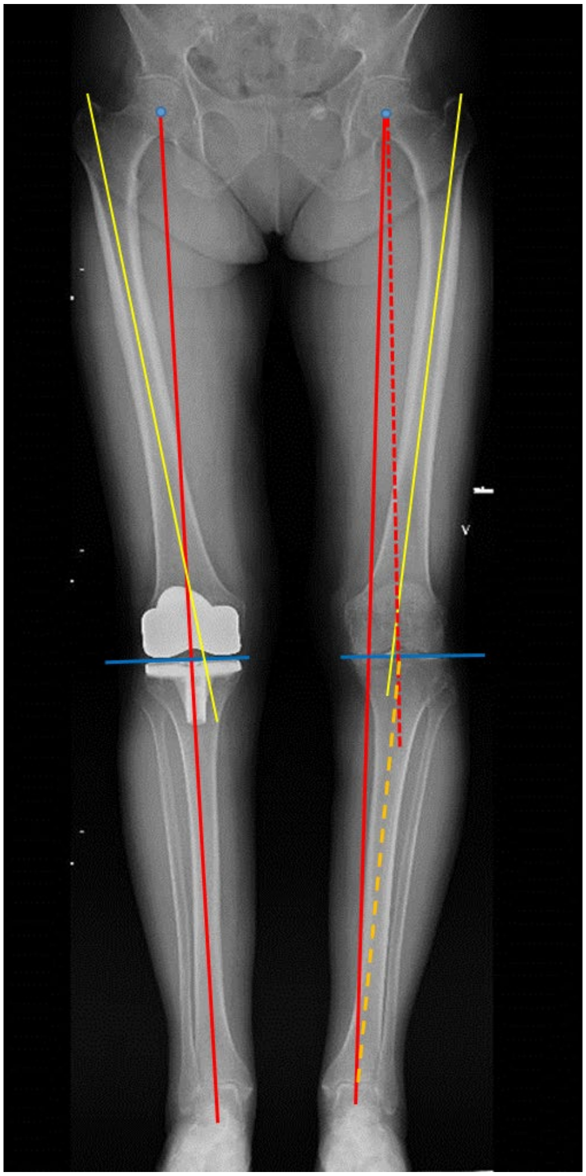


Figure 4. Standing HKA radiograph of both legs of a 69 year old woman operated with TKA in her right knee. The left knee suffers from arthrosis and has a small varus deformity. The previous varus deformity of the right knee has been corrected and the tibial and femoral components are placed perpendicular to the mechanical axes.

Red continuous lines: The mechanical axes the lower limb.

Red stippled line: The mechanical axis of the left femur.

Yellow lines: The anatomical axes of the femur.

Orange stippled line: Mechanical axis of the left tibia.

Blue lines: The joint orientation lines

In the sagittal plane, the femoral component is normally placed perpendicular to the mechanical axis of the femur. Malalignment in the sagittal plane may compromise the pseudo-isometric characteristics of the knee ligaments, and if hyperextended, lead to notching of the anterior cortex.

On the tibial side, the sagittal plane joint line in the native knee is on average at 10°of posterior slope compared to the tibial mechanical axis. The position of maximal loading in normal gait is 20° of flexion, which brings the joint line parallel to the floor [36]. In the prosthetic knee, where one or both cruciate ligaments are removed, the tibial slope is manipulated to compensate for potential sagittal instability. Therefore, the preferred tibial slope in TKA differs with different prosthetic designs. Malalignment or mal-positioning of the tibial component will affect the relative positions of the insertion points of the ligaments and thereby knee kinematics and kinetics.

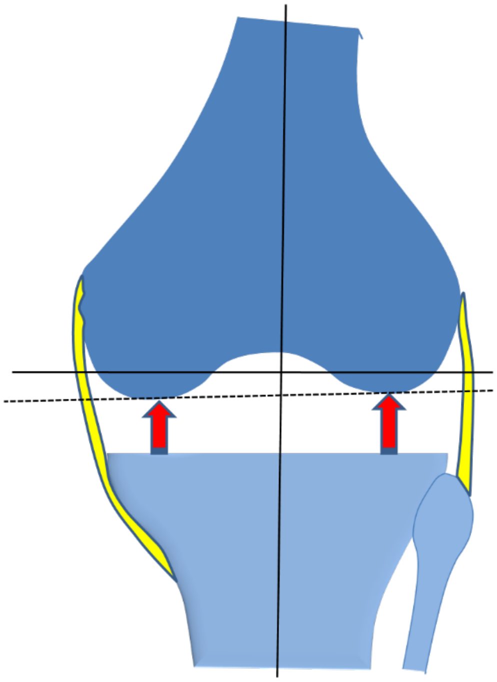


Figure 5 A. Left knee in extension, frontal plane.

The stippled line shows the original joint orientation line 2°-3° in valgus. The tibial cut has been done perpendicular to the mechanical axes. The continuous line shows the planned distal femoral cut perpendicular to the mechanical axis and parallel to the tibial cut, thereby creating a rectangular extension gap.

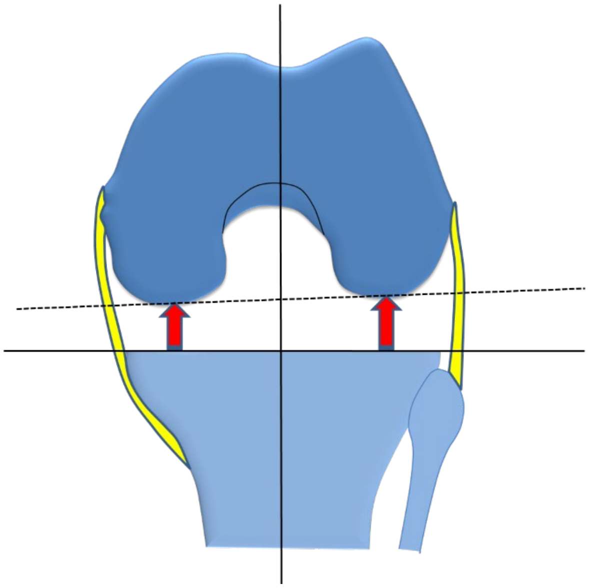


Figure 5 B. Left knee in flexion. The tibia is seen in the frontal plane and the femur in the axial plane.

The stippled line shows the original joint orientation line which is in 2°-3° valgus.

In order to obtain a rectangular flexion gap the posterior femoral cut must be made parallel to the proximal tibial cut, which means that the femoral component wil be 2°-3° externally rotated.

In the horizontal (axial) plane, the rotational alignment of the femoral component is of particular interest because it affects varus/valgus alignment and joint stability in 90° of knee flexion, as well as the conformity between the components and patello-femoral tracking (Figure 6). Malrotation may therefore influence load distributions and lead to instability, increased wear, patellar subluxation, pain and early failure. Several surgical techniques as well as new surrogate axes or anatomical lines have been proposed to improve accuracy and precision when placing the femoral component [37-44], but unfortunately, rotational malalignment is still a significant problem. **Paper VI** in this thesis presents a new simple method to overcome this problem.

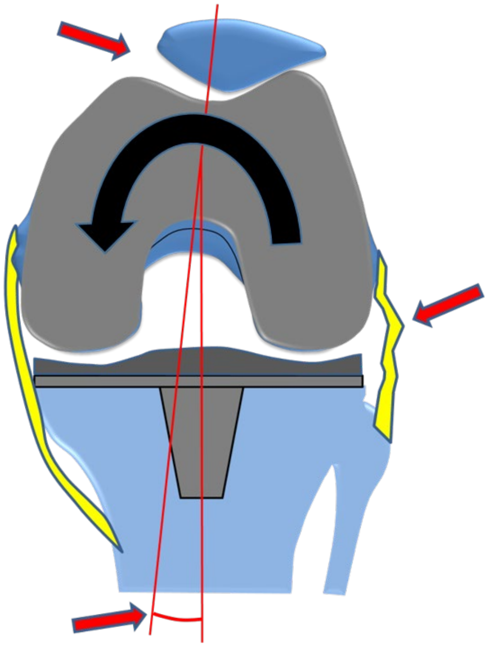


Figure 6. Internal malrotation of the femoral component is the result of over-resection of the posterior lateral femoral condyle. It leads to lateral tracking of the patella, lateral ligament laxity in flexion and valgus mal-alignment in flexion.

Rotational alignment of the tibial component may also affect functional outcome and prosthetic survival after TKA, and many different techniques to guide the tibial component into correct rotational alignment have emerged [45-49]. A systematic review and correlation analysis by Valkering et al. [50] found a medium positive correlation between tibial component external rotation and functional outcome. However, a very recent study by Thielemann et al. [51] did not find any significant correlation between tibial component malrotation and functional outcome. **Paper VII** highlights this issue and contributes important information to total knee surgeons.

Perfect rotational alignment of the femoral and tibial component is difficult to obtain. It is therefore expected that many prosthetic knees will end up with different combinations of malrotation. Earlier studies have demonstrated that some of these combinations of malrotation can affect outcome in TKA. In their frequently cited paper from 1998, Berger et al. [52] compared 30 knees undergoing revision TKA because of isolated patellofemoral complications with 20 patients with well-functioning total knee replacements. They reported that the group with patellofemoral complications had excessive combined (tibial plus femoral) internal component rotation and that combined internal rotation was directly proportional to the severity of patellofemoral complications: Small amounts of combined internal rotation (1°-4°) correlated with lateral tracking and patellar tilting. Moderate combined internal rotation (3°-8°) correlated with patellar subluxation. Large amounts of combined internal rotational (7°-17°) correlated with early patellar dislocation or late patellar prosthesis failure [52]. Barrack et al. [53] compared 14 knees in patients with anterior knee pain and a control group of 11 pain free knees. They found that patients with anterior knee pain had average 4.7 degrees combined internal rotation compared with 2.6 degrees external rotation in the pain free knees, but they did not find a significant difference in the degree of radiographic patellar tilt or patellar subluxation between the two groups. Bell et al. [54] compared 56 patients with unexplained pain following posterior stabilized TKA with a matched control cohort of 56 patients. They found that internal rotation of the tibia and femoral components individually as well as in combination affected outcome negatively. They did also find that component rotation mismatch (the degree of divergence in rotation between the femoral and the tibial components) was a factor in pain following TKA. The effects of different combinations of malrotation of the femoral and tibial components on functional outcome and patellar tilt are evaluated in **paper VIII**.

The classical alignment theories are based on a static model with equal load on each knee. Nevertheless, in one leg stance during normal gait, the joint orientation line change from average 3° compared to the horizontal plane to neutral (parallel to the horizontal plane). In an attempt to decrease shear forces and to introduce more natural biomechanics some surgeons prefer so called kinematic or anatomical alignment, which means positioning the joint orientation line of the femoral and tibial components into an anatomical (native) position [55]. However, a recent level I study was unable to demonstrate an advantage of kinematic alignment in terms of pain or function [56].

The concept of lower limb alignment has been further elaborated with three dimensional CT and MRI, and a more complex understanding of this topic comprises dynamic variables including gait patterns and analysis of the ground reaction forces and muscle joint reaction forces [26].

Positioning of the prosthetic components in TKA is a complex task. Each component should be positioned within acceptable limits along three axis, which means six degrees of freedom. In TKA these movements consists of three translational movements; anterior/posterior, medial/lateral, proximal/distal and three rotational movements; rotation in the frontal plane (varus/valgus), rotation in the sagittal plane (flexion/extension) and rotation in the horizontal plane (external rotation/internal rotation). The rotational movements affect alignment. Translational movements have limited effect on alignment but do affect the relationship between the extension and flexion gap, ligament mechanics and joint line level. Joint line preservation, implies keeping the height of the joint line at the original level. If the distal femur is over-resected, the femoral component is translated proximally end the tibial insert must be thicker. The result is an elevated joint line. This leads to proximalisation of the rotational axes of the knee and distortion of ligament mechanics. Another consequence is patella baja and a tight flexion gap necessitating further posterior femoral cuts and so-called downsizing of the femoral component that again can reduce knee flexion.

Near perfect alignment and component positioning in all three planes is mandatory to minimize wear on the articular surfaces and the supporting structures of the knee. Malalignment in one or more planes leads to increasing load and shear forces on the implants and on the interfaces between bone and implants. Malalignment also result in uneven tensile stresses on the surrounding ligaments, capsule and tendons. Like the native knee, the reconstructed prosthetic knee has limited load-bearing capacity over time, and residual malalignment may result in early failure. However, the exact limits for acceptable alignment and component positioning are debated, and dependent on many other variables like body weight, activity level, muscular strength, ligament status, prosthetic design and type of polyethylene. In this thesis, alignment and component positioning was measured on standing HKA x-rays, standard antero-posterior and medio-lateral x-rays, and standing patella axial views taken both preoperatively and postoperatively. Rotational alignment was assessed on computer tomography (CT).

8.7.3 Mechanical, anatomical and kinematic alignment

Mechanical alignment is still considered a gold standard [34, 35] however, anatomic and kinematic alignment have gained increasing popularity in the last decade [55] and there is an ongoing debate as to what is the best alignment goal. Classical mechanical alignment was introduced in order to secure equal distribution of loads between the medial and lateral compartments of the knee and to reduce shear forces at the interfaces between implants and bone (Figure 7) [28, 57, 58]. However, some recent studies have failed to show a relationship between coronal plane alignment and prosthetic survival [32, 33]. Therefore, in the hope of improving knee function after TKA a growing enthusiasm for anatomic and kinematic alignment have emerged. However, an important matter to take into consideration is the ability of current surgical techniques to reach the exact alignment goal. Although outliers from the mechanical axis up to 5°-6° may be acceptable, the same amount of divergence in varus from the natural axis is probably not compatible with long-term survival and good knee function. Consequently, in order to prevent unacceptable outliers, the use of anatomic or kinematic alignment presume surgical techniques with a very high degree of accuracy and precision.

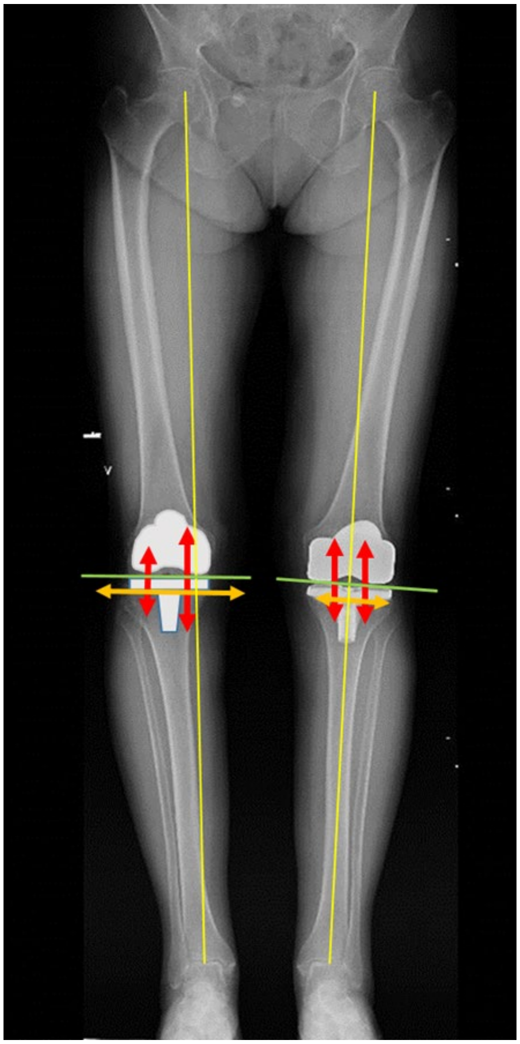


Figure 7. The left knee is mechanically aligned with the mechanical axis of the lower limb (yellow line) passing through the center of the knee and the joint orientation line (green line) is perpendicular to the mechanical axis.

The right knee is anatomically aligned with the mechanical axis of the lower limb passing through the medial knee compartment and the joint line is in 2°-3° varus.

Red arrows illustrate the load distribution between the medial and lateral compartments, and the orange arrows illustrates the share forces in the interfaces between bone and implants.

The aim of anatomic and kinematic alignment is to replicate normal knee anatomy more closely (Figure 7) and thereby mimic normal knee kinematics [29-31]. However, anatomic alignment do not necessarily lead to more natural knee joint kinematics in TKA. It must be remembered that almost all total knee designs sacrifice one or both cruciate ligaments. The lack of well-functioning cruciate ligaments have profound impact on knee kinematics [59], and non-anatomic prosthetic design features are needed to compensate for the lack of the cruciate ligament and secure stability. It is therefore the authors opinion that, in the current context, the term kinematic alignment is too optimistic.

If a gap-technique is used instead of measured resection technique the need for ligament balancing in flexion is reduced [60]. However, in a varus knee with medial soft-tissue contractures this will lead to external rotation of the femoral component and varus alignment in flexion. In a valgus knee, it will result in internal rotation of the femoral component, potential maltracking of the patella and valgus deformity in flexion.

8.7.4 Soft tissue balancing (ligament balancing)

Soft tissue balancing, also called ligament balancing is the adaptation of the static and dynamic stabilizing structures around the knee to the new geometry of the knee obtained after correction of the osteochondral deformities. Soft tissue balancing is also an essential part of the treatment of flexion and extension contractures. The actual soft tissues are the posterior cruciate and collateral ligaments, the joint capsule, the popliteus tendon, the ileo-tibial band, the pes anserinus, and in rare occasions the semimembranosus, the biceps tendon, the gastrocnemius muscles and the extensor mechanism. Too loose ligaments may lead to instability, poor function, pain and polyethylene wear. Too tight ligaments may lead to reduced range of motion, pain and accelerated wear (Figure 8). Ligamentous deformities can be caused by osteophytes tenting the ligaments, elongation of the ligament on the convex side of the deformity or by contracture on the concave side of the deformity. Many different techniques and algorithms for balancing the ligaments have been developed [60-67]. Most of these techniques are based on elongation of the ligaments on the concave side rather than shortening ligaments on the convex side. In the present papers, the method developed by Whiteside et al. was used [66-68]: First, the bony cuts are guided by bony landmarks according to the measured resection technique, and all osteophytes are removed. Then ligament balancing is performed following a pseudo-algorithmic sequential release of soft tissue structures based on the properties of each structure. For example, if the knee is tight medially in flexion and well-balanced in extension, the anterior part of the medial collateral ligament is stripped from its tibial attachments. The posterior part of the medial collateral ligament act as a secondary stabilizer and prevent instability. Another more complex example could be a knee that is severely tight medially both in extension and in flexion after all osteophytes have been removed: Because the anterior portion of the medial collateral ligament is considered the most isometric structure it is released first. If this is not sufficient, the rest of the medial collateral ligament is released. The posterior cruciate ligament now act as the secondary stabilizer in flexion. In the case were the knee is still tight in extension the posterior medial capsule can be released and in some rare cases the semimembranosus and the pes anserinus. The sequential releases results in larger flexion and extension gaps that are filled with a higher polyethylene component.

It is remarkable that the optimal degree of ligament laxity and the effects of ligament laxity on functional outcome after TKA have not been clearly described in the literature, and that defining optimal ligament laxity during TKA is still mostly based on the surgeon's ‘‘feel’’ and personal experience. Answers to these fundamental problems and detailed discussions of the topic is given in **papers I, II and III**.

Figure 8. Retrieved prosthesis from a 60 year old man who short after the initial operation suffered from poor knee flexion. 5 years later, his knee was painful, swollen and poor functioning. The picture illustrates the consequence of poor gap balancing. The knee was too tight in flexion, but seemingly symmetric medio-laterally.

8.7.5 Three important terms: The gaps – gap balancing – gap balancing technique

The extension gap and the flexion gap are essential concepts in TKA. The extension gap refers to the void that is created between the distal femoral cut and the proximal tibial cut after the surgeon has performed the saw cuts on the bones, and the ligaments have been stretched out to full length. Similarly, the flexion gap refers to the void between the posterior femoral cut and the proximal tibial cut when the knee is in 90° of flexion. According to traditional theories in TKA, these gaps should be rectangular and with equal height.

Gap balancing is the exercise of surgery aimed at modifying the shape of the gaps in order to make them rectangular and equal. This can be done in two very different ways; either by altering the length of the ligaments (soft tissue balancing), or by revising the femoral saw cuts (gap resection).

The gap balancing technique is one out of two main principles for gap balancing. The other principle is the measured resection technique.

8.7.6 The measured resection technique

In extension, the bony cuts are made perpendicular to the mechanical axes of the femur and tibia. In flexion the bony cuts are guided by anatomic bony landmarks. These are the femoral epicondyles, the posterior condyles and the femoral antero-posterior line (Whiteside line). The amount of prosthetic material to be implanted should equal the amount of bone to be resected in addition to the amount of bone and cartilage that is lost by wear. If no soft tissue deformities existed before surgery this technique should restore near native gaps. In the case of a varus or valgus deformity the ligaments and other soft tissues on the concave side are often contracted. In these cases, the gaps will appear markedly trapezoidal and it may be a significant difference between the extension gap and the flexion gap. In order to make these gaps rectangular and equal in size, the length of the collateral ligaments, the capsule, the posterior cruciate ligament and other soft tissues around the knee must be adjusted by soft tissue balancing. The result of these procedures should, in theory be a perfectly aligned knee in extension and flexion with equally tensioned ligaments on the medial and lateral sides. However, ligament balancing is not always a precise procedure, and some medial-lateral asymmetry will often occur. In addition, the height of the flexion gap do not always exactly equal the extension gap, as demonstrated in **paper I** in this thesis. In a few cases, after medial-lateral symmetry is obtained there is still an important difference between the heights of the flexion and the extension gaps and additional bone cuts according to the contingency table developed by Monts et al. should be performed [69].

8.7.7 The gap balancing technique

Alternatively, the bony cuts can be guided by the length of the ligaments and other soft tissues. First, the tibia is cut perpendicular to its mechanical axes in the frontal plane, then the soft tissues are stretched out to their full length and the femoral cuts are made parallel to the tibial cut. In a knee without any ligamentous deformities, this should result in precise alignment and ligament balance. However, in knees with soft tissue contractures this approach will replicate the présurgical deformity. Therefore, in order to avoid malalignment in extension, hybrid techniques involving ligament balancing in extension have been developed: The distal femoral cut is performed perpendicular to the mechanical axis, like in the measured resection technique. Then ligament balancing is performed in extension. In flexion, no ligament balancing is performed, but instead the ligaments are stretched out and the posterior femoral cut is made parallel with the tibial cut at a depth that equals the height of the extension gap. This will result in rectangular and equal flexion- and extension gaps, but if ligamentous contracture in flexion was present before surgery, varus- or valgus malalignment in flexion will occur, and patella-femoral mal-tracking is induced. This malalignment is also referred to as malrotation of the femoral component, and this problem is assessed in **paper VI**.

8.7.8 The patella

The first types of knee replacements were bicompartmental, resurfacing only the distal femur and the proximal tibia. In the late 1960s, patellar resurfacing became an option, but the early designs were hampered with problems like anterior knee pain, patella-femoral incongruity, instability, and polyethylene wear. Later on, better understanding of patella-femoral joint kinetics have led to so called patella friendly femoral components, more durable patella implants and better surgical techniques. However, there is still a remarkable variation between surgeons and between countries as to whether the patella is resurfaced or not. In Norway and Sweden, only 2% of the TKAs have their patella resurfaced [21, 70]. In the USA, 98% of TKAs registered in the Kaiser Permanente Registry in 2011 were performed with patellar resurfacing [71].

The effect of patellar resurfacing can be viewed in three different perspectives; risk of reoperation, anterior knee pain and knee function. Four meta-analysis comparing patellar resurfacing and non-resurfacing have concluded that resurfacing reduces the risk of reoperation [72-75]. (Figure 9).When it comes to anterior knee pain and functional outcome it has not been possible to conclude on which treatment is the best. It is noteworthy that all these studies were based on classical outcome assessment tools like the Knee Society clinical rating system (KSS), the Hospital for Special Surgery (HSS) and the Western Ontario and McMaster osteoarthritis index (WOMAC). However, observations at our institution in the late 1990s indicated that the KSS had very high ceiling effects. Our observation has later been confirmed by several authors [76-79]. In an attempt to overcome this problem we decided to perform a prospective, randomized and double-blinded study based on more contemporary outcome tools with higher discriminating capacity. This topic is discussed in detail in **paper V**.

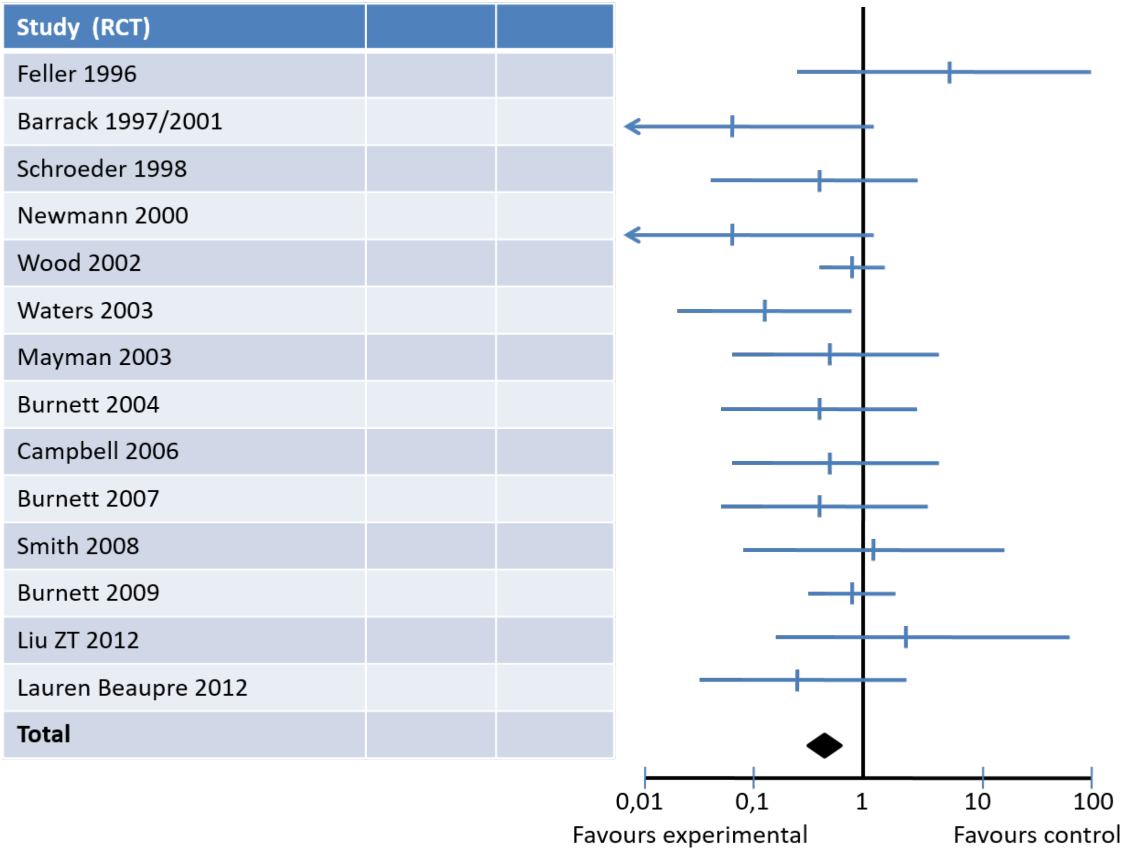


Figure 9: Forrest plot from a meta-analysis of randomized controlled trials comparing the risk of reoperation for total knee arthroplasties performed with and without patellar resurfacing. The horizontal axis indicate risk-ratio. (Kai Chen et al. 2013, International Orthopaedics (SICOT) 37: 1075-1083)

In traditional surgical approaches for TKA the patella is usually everted to gain optimal view of the knee. Many earlier studies have postulated that eversion of the patella may have detrimental effects on the quadriceps and cause pain and reduced knee function. More recently, several randomized controlled studies have concluded that patellar eversion does not adversely affect postoperative quadriceps recovery, range of motion, pain scores, or patient reported knee outcome scores including generic scores [80-82]

The position of the patella (everted, laterally retracted or in situ) during the operation has also been shown to influence on the measurements of ligament balance [83-85], but it is unknown whether this effect is of clinical importance for the functional outcome after TKA. The study presented in **paper III** discusses and offers an answer to this question.

8.7.9 Conformity and the degree of constraint

The freedom of movement between the femoral, tibial and the patellar components depend on the mechanics of the articulation between the components and on the soft tissues. Some early generations of TKA were hinged like a door hinge. This highly constrained design allows only one degree of freedom, namely flexion and extension. On the other extreme is a non-constrained design were nothing but the ligaments and other soft tissues can guide the movements between the femoral and the tibial components. In-between the extremes are different semi constrained designs intended to limit certain movements. Examples are deep-dished conforming polyethylene components (figure 10B) and cam and post designs (figure 10C) that limit antero-posterior movements. Peg and box designs (figure 11A) or rotating hinges (figure 11B) also limit varus/valgus movements and thereby compensate for non-functioning collateral ligaments.

The articular surfaces of the native knee are non-constrained and the natural movements are very much guided by the soft tissues. Therefore, the kinematics in the native knee is a complex combination of flexion, extension, rotation, medial-lateral movements, rolling and gliding. If a highly constrained prosthesis is introduced into this soft tissue envelope, a conflict will arise between the prosthetic constraint and the forces induced by the soft tissues. This will result in shear forces at the interfaces between the prosthesis and the bone, and eventually lead to increased wear and early loosening of the components. The two mostly used prosthetic designs in primary TKA are the cruciate retaining (CR) design (figure 10A), which is non- constrained and the posterior stabilized (PS) design (figure 10C), which can be considered low constrained.

In brief, in order to prevent instability, a constrained prosthesis is a good choice in knees with poor ligaments, and a non-constraint design is the preferred choice in knees with well-functioning ligaments. The degree of constraint needed depends on the degree and type of ligament failure. In the studies presented in this thesis all patient were operated with a non-constrained, posterior cruciate retaining (CR) prosthesis.

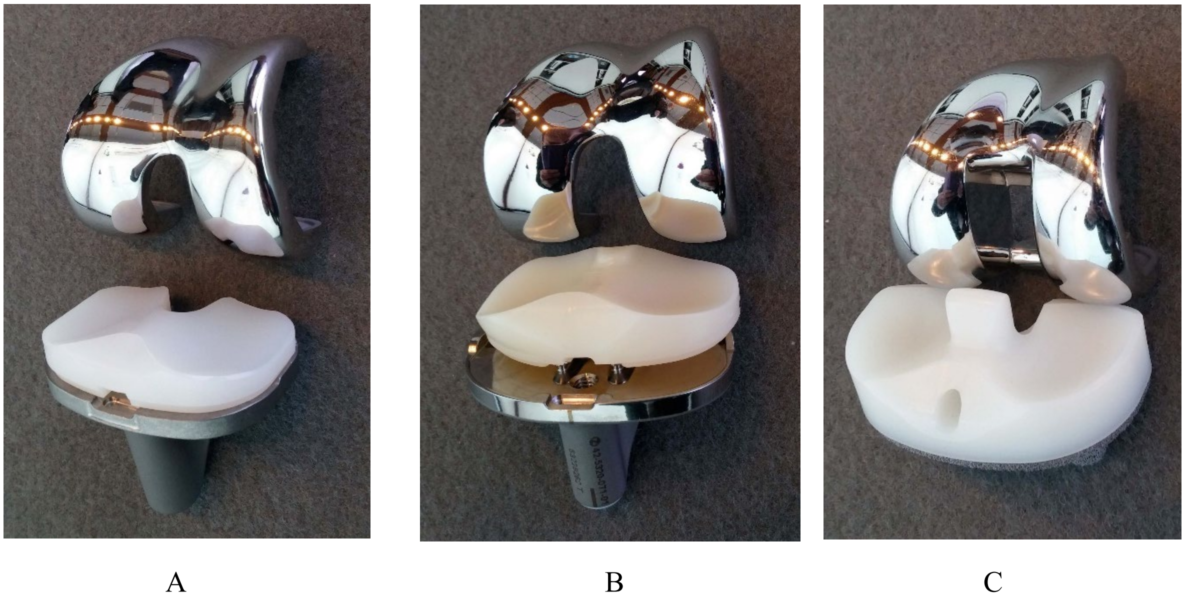
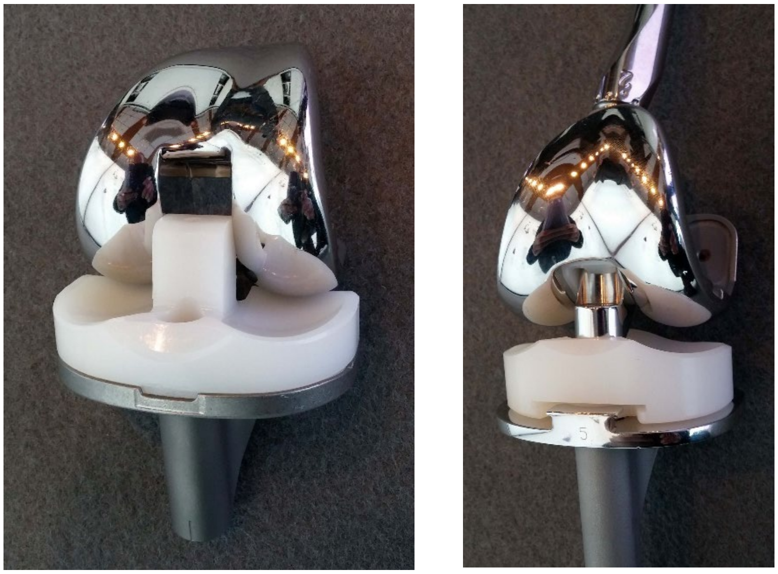


Figure 10. A: Minimally constrained posterior cruciate retaining (CR) knee prosthesis. B: Deep dished design limiting the antero-posterior translation between the components. C: Posterior stabilized (PS) prosthesis with a cam and post design limiting posterior translation of the tibia.



A B

Figure 11. A: Condylar constrained knee (CCK). The peg and box design limits posterior translation and varus-valgus movements.

B: Rotating hinge. The central metal cylinder prevents translational movements in the horizontal plane and varus- valgus movements, but allows rotation and telescoping

8.7.10 The sacrifice of the anterior cruciate ligament

Although the aim of TKA is to replicate the normal knee as close as possible, the current total knee designs are far from anatomical copies of the native knee, but rather the result of a series of compromises resulting in non-physiologic kinetics and kinematics. The most important compromise in TKA is the sacrifice of the anterior cruciate ligament (ACL). Normal knee function necessitate intact anterior and posterior cruciate ligaments, but the creation of a functional bicruciate retaining prosthesis (figure 12A) has so far proven to be very difficult because of limitations in engineering and surgical techniques [86].

Having sacrificed the ACL, a cascade of challenges appears. First, the knee becomes unstable in the sagittal and horizontal plane. To prevent this instability a constraint is introduced by making the tibial condyles concave and conforming. The resulting build up in the posterior polyethylene prevents lateral rollback and internal rotation of the tibia in flexion. This again affect patello-femoral tracking and the kinetics of the lateral collateral ligament. The introduction of a constraint that is in conflict with the soft tissue kinetics generate increased forces on the polyethylene and the interfaces that may result in potential wear and loosening. In order to allow for lateral femoral rollback and internal tibial rotation in flexion some manufacturers have introduced medial pivot designs where the medial condyles are more conforming than the lateral condyles, thereby allowing more rollback laterally. Another option is mobile polyethylene bearings (figure 12B), which means the tibial polyethylene tray is allowed to rotate on the tibial platform. However, the introduction of an additional gliding surface may increase polyethylene wear. The real mobility of the mobile platforms in vivo have also been questioned, and so far, no benefits in functional outcome or prosthetic survival have been documented [87].

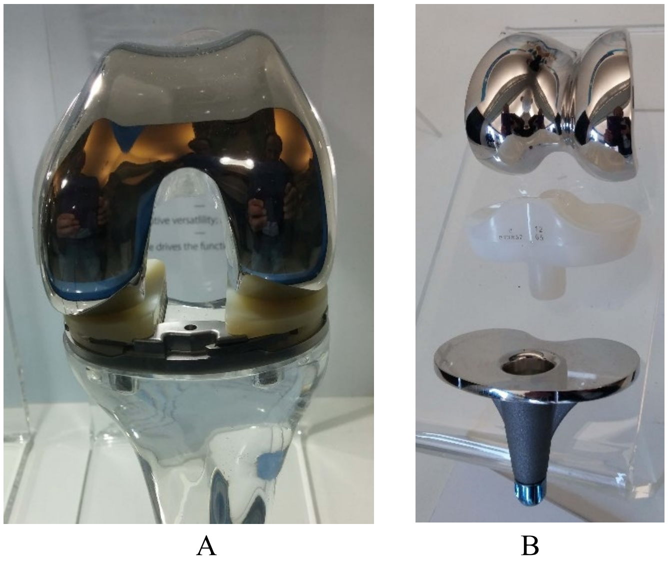


Figure 12. A: Bicruciate retaining design.

B: Rotating platform. A minimally constrained prosthesis with an extra articulation between the tibial tray and the polyethylene

8.7.11 Cemented or cementless fixation

Bonding between the prosthetic components and the bone is essential in order to prevent loosening of the prosthesis. Fixation with bone cement (polymethylmethacrylat) is the gold standard in TKA [88, 89]. However, relatively high rates of aseptic loosening in younger, active and obese patients have been reported [90, 91], and consequently a search for more reliable fixation of the prosthetic components are requested. Cementless fixation have the potential of a more biologic fixation with ingrowth of bone into porous coated components. Cementless fixation may also have other advantages like shorter operating time, reduced third body wear of the polyethylene and easier implant removal in the case of revision.

The first experiences with cementless TKA was bothered with high complication rates and early loosening [92, 93]. Insufficient bonding between metal and bone, poor polyethylene, and metal-backed patellar components contributed to osteolysis and poor result. However, these design flaws have later been corrected, leading to an increased interest for cementless TKA. Short and medium term results equal to those of cemented TKA have been reported [94, 95]. Only one RCT have reported long-term survival with minimum 16 years follow-up: No difference in KSS knee score, WOMAC score, ROM, patient satisfaction, radiological results or component survival was found between cemented and uncemented TKAs [96]. The shortage of long-term follow-up of new prosthetic designs and operative techniques can, to some degree be compensated for by radiostereometric analysis (RSA). RSA is a highly accurate, three-dimensional method to quantify micromotion between a prosthetic component and bone [97, 98]. Measurements of implant migration over two years can provide a surrogate for longer term follow-up and predict mechanical loosening of the prosthesis [99]. RSA studies have demonstrated promising results with equal magnitude and pattern of migration of cemented and uncemented femoral components during two years follow-up [100]. On the tibial side, one RSA study reported different migration patterns between cemented and uncemented hydroxyapatite-coated implants [101]: While uncemented implants migrated the first three months and stabilized thereafter, cemented implants continued to migrate. The authors concluded that uncemented fixation using hydroxyapatite-coated implants seems to be the best solution for the younger patient. Although the results of cementless fixation are promising, there is still a need for high quality long-term studies. All prosthetic implants reported in this thesis were cemented.

8.7.12 Computer guided surgery, patient specific instruments and robotics

Computer navigation or computer assisted orthopaedic surgery (CAOS) was introduced in total knee surgery in the 1990s with the intention to make navigation in three planes easier and more precise. Imageless computer-navigation made it possible to determine the center of the hip joint with a high degree of accuracy and thereby improving alignment of the lower limb in the frontal plane [102]. However, CAOS do not offer any other extra information necessary for alignment in the axial plane. The need for computers, infrared cameras and trackers add to the total cost and results of randomized controlled trials are still conflicting as to whether CAOS represents any advantages in patient reported outcomes and prosthetic survival [103-107]. However a very recent level 1 study by Petursson et al. found that computer navigation provided better pain relief and restored better function than conventional surgical technique at 2 years after TKA [108].

Computer software facilitating three-dimensional (3-D) reconstruction on CT and MRI images inspired the development of patient specific instruments (PSI) in the beginning of this millennium [109]. This technology allows individual characteristics from each specific patient to be built into templates or cutting guides. Based on preoperative CT or MRI, two guides are designed to match precisely with the patient's distal femur and proximal tibia, and because of the built in preoperative information the bone cuts can be performed taking into account five of the six degrees of freedom. There is no need for conventional sizing- or alignment jigs. However, a crucial point in this technique is an exact and unambiguous match between the guide and the patient's knee. Another problem is that only the skeletal deformities are addressed, not the soft tissues. So far, no significant radiological and clinical benefit have been demonstrated in level I studies [110, 111].

Robotic-assisted surgery has the potential to enhance accuracy and precision of surgery and to control a high number of variables essential for successful arthroplasty. Robotic systems can be active, semi active or passive. So-called haptic robotics are semi-active, permitting the surgeon to maintain control of the movements, but the robotic arm restricts the space in which the movements can be done [112]. Preliminary outcomes of robotic-assisted surgery are promising, but more studies are needed in order to evaluate patient outcomes [113, 114].

Computers and robots may help surgeons to achieve their objectives with a high degree of precision. However, the details of each surgical step must be accurately defined and programmed into the computer. If not, the computer or robot may still be precise, but inaccurate, introducing systematic bias and poor outcome. Unfortunately, in total knee surgery, many details in surgical technique are still controversial or poorly defined. This lack of knowledge must be addressed in order to program the robots with accurate information.

8.7.13 Challenges and controversies

Advances in biology and genetics, modern engineering and clinical research as well as computer-assistance and robotics have refined surgical implants, surgical techniques and our understanding of the complexity of knee biology and biomechanics. However, experienced total knee surgeons still face many important questions during surgery that remain unresolved. Among these are:

1. How can ligament laxity be easily measured during surgery?
2. How tight should the ligaments be balanced?
3. How do patellar eversion affect ligament laxity measurements?

4. Does the surgical trauma induced by ligament balancing have negative effects on functional outcome after TKA?
5. Should the patella be replaced or not in routine total knee arthroplasty?
6. How can rotational alignment of the femoral component be easily controlled during surgery, and how does rotational malalignment affect functional outcome?
7. What is the best method to ensure correct rotational alignment of the tibial component and what is the effect of malrotation on functional outcome?
8. What are the effects of combined rotation of the femoral and tibial components and patellar tilt on functional outcome in TKA?

The goal of this thesis is to try to answer these questions in order to provide objective information and develop better surgical procedures to improve functional outcome in patients with TKA.

9 Materials and methods

9.1 Context

All studies were conducted at Sykehuset Innlandet Hospital Trust, Lillehammer, which is a community teaching hospital in Norway that serves a population of roughly 100 000 inhabitants from urban and rural societies. The orthopaedic department covers a wide spectrum of traumatology, other acute conditions, elective operations, and performs 50–70 primary TKAs per year.

9.2 Study population

The complete study population:

After sample size calculation a total of 153 consecutive patients scheduled for primary TKA at our institution between November 2007 and March 2011 were assessed for eligibility into the randomized controlled trial (RCT) presented in paper V in this thesis. Inclusion criteria were patients younger than 85 years with primary knee osteoarthritis. Exclusion criteria were knees with patellar thickness less than 18 mm measured on calibrated digital radiographs, knees with isolated patello-femoral arthrosis and knees with posterior cruciate deficiency. Also excluded were knees with secondary osteoarthritis (except for meniscal sequelae), previous surgery on the extensor mechanism, patients with a severe medical disability preventing them from climbing one level of stairs, and patients who were not able to fill out the patient-reported outcome measures (KOOS and Oxford knee score). Finally, knees with severe bone and/or ligament deformity that made them unsuitable for a standard cruciate-retaining prosthesis were excluded, or more precisely: Bone deformity to such a degree that the bone cuts would damage the ligamentous attachments on the epicondyles; Ligament laxity without a firm end point or to such a degree that ligament releases on the concave side would result in a need for more than 20 mm polyethylene thickness; The combination of bone deformity and ligament laxity resulting in the need for more than 20 mm polyethylene thickness.

The reasons for exclusion were as follows (with number of patients in parentheses): severe deformity (1), isolated patello-femoral arthrosis (3), previous surgery on the extensor mechanism (6), severe medical disability (3), inability to fill out the patient-reported outcome measures (2), and refusal to participate in the study (8). An old woman declined follow-up visits after 3 months because she was living in a remote area and had not experienced any problems with her operated knee. Between the follow-up visits at 1 year and 3 years, 2 patients died from heart disease. For these two patients, the data from the 1-year follow-up were carried forward to the 3-year follow-up. As a result, 129 knees were investigated (in 73 women and 56 men). Mean age was 70 year (42-82) and mean BMI 29 (20-43). 14 patients underwent bilateral TKA. 66 knees were randomized to TKA without patellar resurfacing, and 63 knees to TKA with resurfacing. Baseline characteristics in the two groups were similar. One patient who suffered from anterior knee pain was réoperated with patellar resurfacing 20 months after the initial operation. In the final analysis, her data were kept in the original allocation group (intention to treat principle).

The patients included in the other seven studies were selected consecutively from the complete study population at a number that was considered sufficient and practical for the progression of the studies in the clinical setting.

9.3 Study designs and patients

9.3.1 Paper I

This study presents a new measuring device (a set of 4 spatulas with increasing thickness) and a new method (the spatula-method) for measuring ligament laxity intraoperatively with the prosthetic components implanted. Furthermore, it reports on the results of a try-out of this method and its inter-observer reliability. Technical details of this new measuring method is described in detail in the surgical technique paragraph below. One-hundred knees in 90 patients, of which 56 were women, were operated consecutively. Mean (range) age was 70 (42-83) years, and mean (range) body mass index (BMI) was 29 (22-43). In 70 knees ligament balancing according to Whiteside et al. [66-68] were undertaken because of unsymmetrical gaps. In 30 knees ligament balancing was considered unnecessary. The number and type of ligament releases were registered. Medial and lateral ligament laxity (condylar lift-off) in extension and 90° of flexion in knees with and without ligament balancing was measured. Medial–lateral symmetry in extension and in flexion was calculated, as well as the difference in size between the extension and the flexion gap. In all knees, the measurements were done with the patella everted. To evaluate the reliability of the method, an inter-rater analysis was performed in 96 consecutive measurements (24 knees) by two surgeons blinded from each other's measurements.

9.3.2 Paper II

Prospective cohort study, examining the association between ligament laxity measured intraoperatively with the prosthetic components implanted, and the patient's functional outcome one year after TKA. Ligament laxity was measured with the spatula-method described in paper I, and functional outcome was measured with the KOOS as the primary outcome measure, and the KSS, Oxford knee score and patient satisfaction (VAS) as the secondary outcome measures. The relationship between ligament laxity and outcome scores was examined by median regression analyses. 122 knees in 108 patients (63 women and 45 men) were investigated. The median (range) age of the patients was 70 (42–83) years, and the median (range) BMI of the patients was 29 (22–43) kg/m².

9.3.3 Paper III

Observational cross sectional study investigating the influence of patellar eversion on medial and lateral ligament laxity measurements performed intra-operatively in total knee arthroplasty. 49 knees (27 female) with mean (range) age 70 years (42–83) and mean (range) BMI of 29 (22-38) were operated consecutively. After implantation of the prosthesis, medial and lateral condylar lift-off (ligament laxity) were measured in extension and in 90° of flexion with the spatula-method described in paper I. First measurements were performed in the standard way with the patella everted. Thereafter, the measurements were repeated with the patella repositioned. The difference in laxity measurements with the patella everted and repositioned was calculated. Because some authors prefer to describe the gaps by referring to the inclination between the femoral and tibial cuts measured in degrees and height of the gaps measured in millimeters, we did also calculate the corresponding changes in inclination and gap height.

9.3.4 Paper IV

In this cohort study, it was hypothesized that the surgical trauma induced by ligament balancing may have detrimental effects on the functional outcome after TKA. In total, 129 knees were investigated (73 female and 56 male). Mean (range) age was 69 (42-82) years. Mean (range) BMI was 29 (20-43). First all ligament releases were registered intraoperatively. Second, outcome scores at 3 years follow up in knees with and without ligament balancing were compared. Third, the change in outcome scores from preoperative to the 3 year follow up in each group was compared. Fourth, the material was split into varus knees and valgus knees and separate comparisons within these groups were performed. Finally, the correlation between increasing number of ligament releases and functional outcome was estimated.

9.3.5 Paper V

Randomized, double-blind study comparing functional outcome in osteoarthritic patients operated with TKA, with and without patellar resurfacing, using four different outcome measures. The study was conducted according to the CONSORT guidelines (Figure 13).

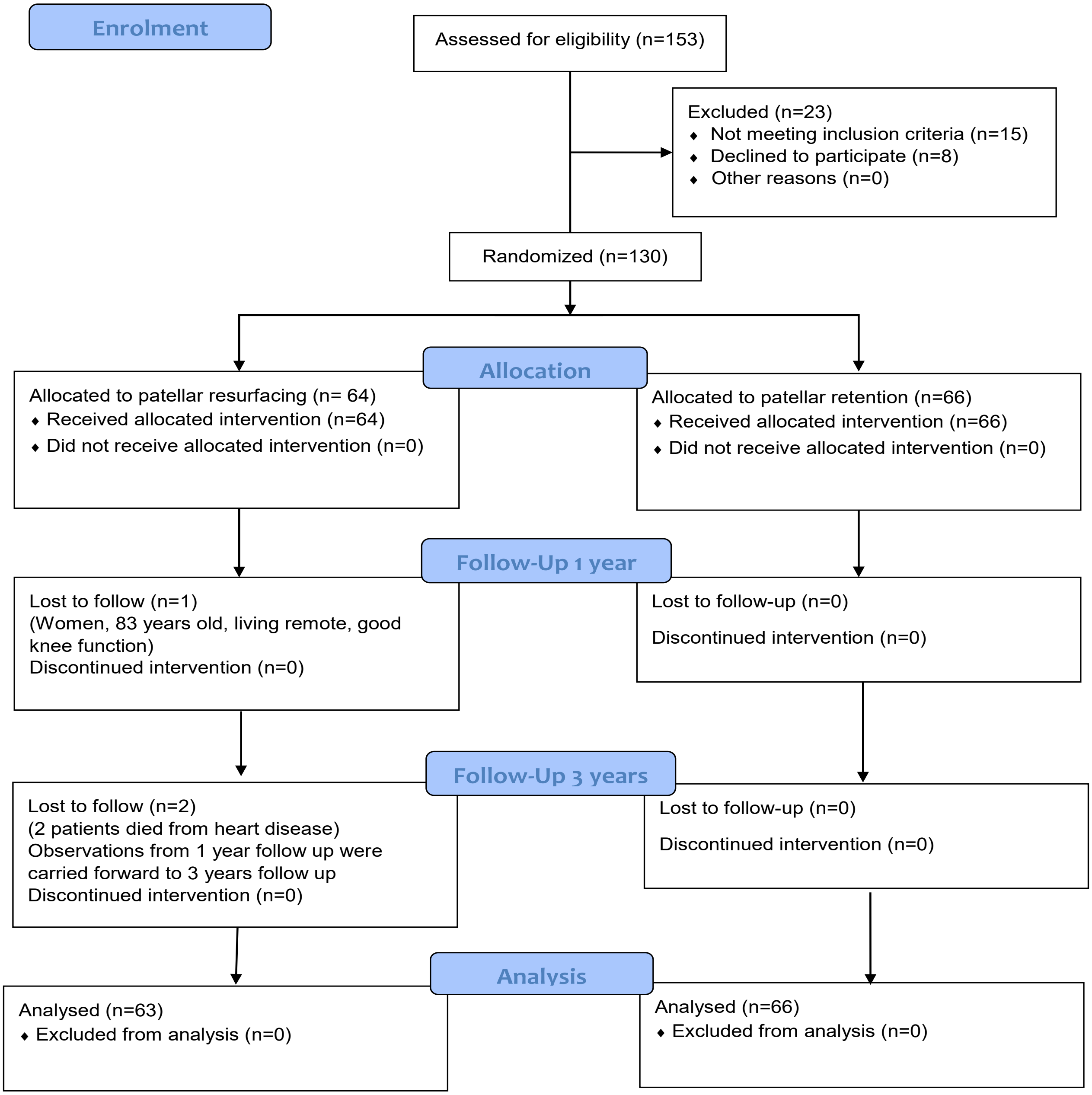
129 knees were investigated (in 73 women and 56 men). Mean (range) age was 70 (42-82) years and mean (range) BMI was 29 (20-43). 14 patients underwent staged bilateral TKA. 66 knees were randomized to TKA without patellar resurfacing, and 63 knees to TKA with resurfacing.

Randomization and blinding:

Computerized random numbers in blocks with randomly selected block sizes were generated by a third party at the Norwegian University of Science and Technology in Trondheim. The randomization of each knee was performed by the surgeon or the assistant immediately before the operation through internet connection with the randomization server. The patients and the assessor of outcome were blinded regarding the randomization allocation throughout the study.

The primary outcome measure was the KOOS and secondary outcome measures were the KSS, the Oxford knee score, and patient satisfaction. The scores were recorded preoperatively and at follow-up after 1 and 3 years. Functional outcomes in the two treatment groups, were compared with mixed-models analysis. In addition, we calculated ceiling effects and interquartile ranges (IQRs) at 3 years for all outcome measures.

Figure 13. The RCT described in paper V was conducted according to the CONSORT guidelines.



9.3.6 Paper VI

In this paper, a new method for rotational positioning of the femoral component in TKA is presented. We called it the Clinical rotational axis method (CRA-method). The accuracy, the variability and safety of the new method was evaluated in a prospective cohort study. The new method is described in detail in the surgical technique paragraph below. At 3 years follow-up, the rotation of the femoral components was compared to the accepted gold standard, the CT-derived surgical transepicondylar axis (CTsTEA) by three observers. The inter-rater variability of the CT-measurements were calculated. Then the accuracy and variability of the new method was estimated. Thereafter the association between rotational positioning of the femoral component and functional outcome at 3 years follow-up was assessed in 2 ways: initially by comparing KOOS, OKS, and patient satisfaction 3 years after the operation between internally rotated knees (group 1), and neutral and externally rotated knees (group 2). Thereafter, the knees were split into two new groups: knees with any degree of malrotation of the femoral component (group 3) and knees with perfectly rotated (< 1°) femoral components (group 4).

The subjects included 80 knees (46 female) with mean (range) age of 69 (42-81) years, and mean (range) BMI 29 (20-43). The primary functional outcome was the KOOS, and secondary outcomes were the OKS and patient satisfaction (VAS).

9.3.7 Paper VII

Cohort study investigating the association between rotational positioning of the tibial component and functional outcome in the same study population as in paper VI. At the operation, the rotation of the tibial component was normally oriented along a line drawn from between the tibial eminences to the medial one third of the tibial tubercle. In cases where this method lead to obvious mismatch between rotational alignment of the femoral component and the tibial component, the knee was taken through a full range of motion and the tibial component was allowed to rotate into a conforming position with the femur. Then a mark was placed with cautery midway between this position and the medial third of the tibial tubercle.

At 3 years follow-up, the rotational position of the tibial components was measured on axial CT-scans, and functional outcome was assessed with the KOOS, the OKS and patient satisfaction (VAS). The knees were categorized into internally or externally rotated and the outcome scores of the two groups were compared. Based on the experience from this study a discussion on the reliability of Berger's method to measure tibial component rotation is added. Finally, the interpretability of the intraclass correlation coefficient (ICC) in clinical practice is discussed.

9.3.8 Paper VIII

The same cohort as in paper VI and VII was further explored. The effects of combined and opposite malrotation of the prosthetic components on functional outcome and patella tilt was investigated. The following terms and definitions were used: Opposite rotation occurs if one component is rotated internally and the other externally. Component mismatch is the degree of divergence in rotation between the femoral and the tibial components [115]. Combined malrotation is the sum of the rotations in the femoral and tibial components [52]. Four different issues were investigated: 1) The effect of combined rotation of the femoral and tibial components on functional outcome after TKA, 2) the effect of opposite rotation and mismatch of the femoral and tibial components on functional outcome, 3) the association between component rotation and patella tilt, and 4) the effect of patellar tilt on functional outcome.

9.4 Surgical techniques

The operations were performed in spinal/epidural anesthesia and bloodless field, with a tourniquet on the proximal part of the thigh set between 250 and 350 mmHg depending on the patient's blood pressure and soft tissues. No intra-articular anesthesia was used.

All knees were operated on through a standard midline incision and a medial parapatellar arthrotomy, using a cruciate-retaining, fixed-bearing prosthesis (NexGen; Zimmer, Warsaw, IN) and a measured resection technique with anterior referencing. All components were cemented. In order to create a neutral mechanical axis, the valgus angle of the femoral component was set at 5–8°, depending on the hip-knee-femoral shaft angle, as measured on preoperative standing hip-knee-ankle (HKA) radiographs [116]. Rotational alignment of the femoral component was performed with the CRA-method described in detail in paper V and shortly repeated here.

9.4.1 The CRA-method

First, the surgical transepicondylar axis (sTEA) was established by marking the most prominent point of the lateral epicondyle and the sulcus on the medial epicondyle with cautery. Secondly, the antero-posterior axis (APA) was marked from the highest point in the intercondylar notch to the deepest point of the trochlea. Third, after distal femoral resection, a line 3° externally rotated compared to the posterior condylar line (PCL) was marked with two pins on the distal femoral cut (Figures 14 A-C). Theoretically, the sTEA and thePCL+3° should now be parallel, and these two lines should be at 90° angle to the APA. The parallelism between the sTEA and the PCL+3° was judged with a ruler (Figure 14 B), and the orthogonality between these two lines and the APA was judged with a transparent angle-measuring device (Figure 14 C). In the cases were perfect correlation between the lines was achieved (parallelism between the PCL+3° and the sTEA, and orthogonality (90° angle) between these two lines and the APA) the rotation was accepted. If it was agreement between two of the lines, these were accepted. If disagreement between all the three lines occurred, the in between line was preferred. In the case of visible bony attrition (ICRS grade 4) (severely damaged articular surface through the subchondral bone)), on one or both posterior condyles, the PCL was excluded from the work out. The PCL was also excluded in cases with posterior lateral condylar dysplasia.

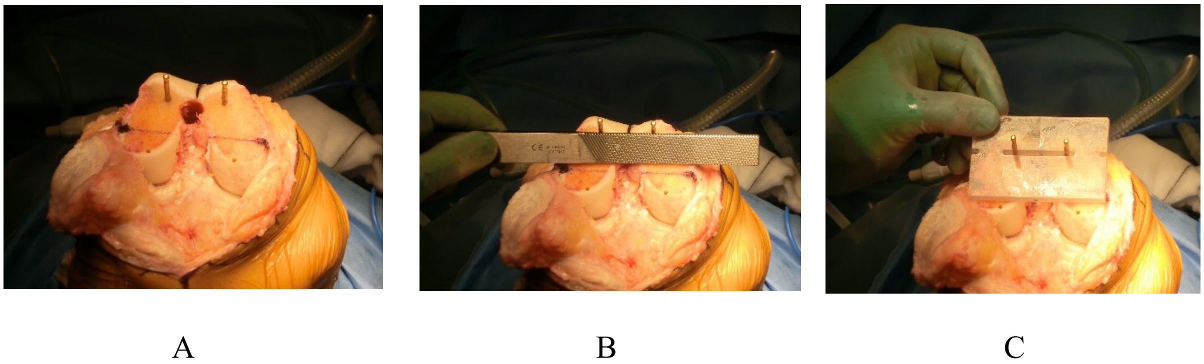


Figure 14. The Clinical Rotational Axis method (CRA-method)
A. Before the distal resection of the femur, the sTEA was established by marking the most prominent point of the lateral epicondyle and the sulcus on the medial epicondyle with cautery. Thereafter, the APA was marked from the highest point in the intercondylar notch to the deepest point of the trochlea. Then, after distal femoral resection, a line 3° externally rotated compared with the PCL was marked with two pins on the distal femoral cut.
B. The parallelism between the sTEA and the PCL+3° was judged with a ruler.
C. The orthogonality between the sTEA and the APA and between the PCL+3° and the APA was judged with a transparent angle-measuring device.

9.4.2 Rotational alignment of the tibial plateau

Our preferred standard method for rotational alignment of the tibial component is to align the tibial platform according to anatomic landmarks. That is aligning the antero-posterior axes of the tibial component with a line drawn from between the tibial eminences to the medial third of the tibial tubercle. However, in cases were a seemingly important rotational mismatch between the tibial and the femoral component was observed the tibial plateau was allowed to rotate into position guided by the femoral component as the knee was taken through a full range of motion (the self-seeking or dynamic technique). The midpoint between the anatomic and the dynamic points were finally selected.

9.4.3 Ligament balancing

Ligament balancing was performed using the technique described by Whiteside and colleagues [66-68]. The aims of the ligament balancing were medial and lateral laxities of 1–3 mm in both extension and 90° of flexion, and equal and rectangular flexion and extension gaps. The indication for ligament balancing was laxities outside these limits. If there was a persistent mismatch between the extension and the flexion gap heights after ligament balancing, additional bone cuts according to the contingency table proposed by Mont and Delanois [69] were performed.

9.4.4 The patella

The patella was everted, and cartilage damage to the patella was graded according to the ICRS [3] and documented. Patellar resurfacing was performed with the onlay technique, removing bone of the same thickness as the prosthetic component, and accepting up to 1 mm over- or under-resection (measured with calipers before and after resection). In the non-resurfaced patellas, osteophytes were removed. Circumferential cauterization was not performed. After implantation of all components, ligament laxity was measured with the spatula-method described in detail in paper I and briefly repeated here:

9.4.5 The spatula-method

A set of four polyethylene spatulas with thicknesses ranging from 2 to 5 mm was used to measure the medial and lateral lift-off when the knee was stressed in varus or valgus. With the knee in extension (not hyperextension), lift-off (ligament laxity) was defined as the distance in the frontal plane from the deepest point of the polyethylene tray to the most distal point of the femoral condyle. With the knee in 90° of flexion, the same measurements were done between the deepest point of the polyethylene tray to the most posterior point of the femoral condyle (Figure 15).

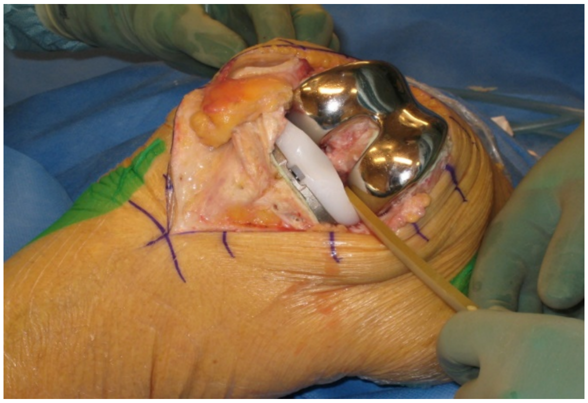


Figure 15. The picture illustrates the measurement of condylar lift-off (ligament laxity) medially in 90° of flexion. The measurement was performed with the leg in a reversed crossed-leg position under passive varus-stress from the weight of the lower leg with the thickest spatula that could be introduced without force

9.5 Postoperative rehabilitation

Epidural analgesia was discontinued one or two days after the operation depending on pain. Patients were mobilized the day after surgery under the supervision of a physiotherapist educated in TKA rehabilitation. After discharge from hospital, the patients spent one or two weeks in a rehabilitation institution, that specializes in training patients with musculoskeletal disorders.

9.6 Outcome measures

9.6.1 KOOS

The Knee injury and osteoarthritis outcome score (KOOS) is a knee-specific, patient-reported outcome measure (PROM) developed to detect changes in knee function in patients with knee injuries or osteoarthritis [117]. It has five separately scored subscales for pain, other symptoms, activities of daily living (ADL), function in sport and recreation, and knee-related quality of life (QoL). Scores are transformed to a 0–100 scale, with 0 representing extreme knee problems and 100 representing no problems. The minimal perceptible clinical improvement (MPCI) for KOOS has been suggested to be 8–10 points [118].The KOOS has been validated for use in TKA and has been shown to be a valid, reliable, and responsive measure [117].

9.6.2 OKS

The Oxford knee score (OKS) is a PROM containing 12 questions about activities of daily living. It was developed to assess function and pain after TKA [119]. Originally, the scores ranged from 12 points to 60 points, 12 being the best score. More recently, the scale has been inverted so that 12 is the worst score and 60 is the best score [120]. A second modification also exist with scores from 0 (worst score) to 48 (best score). In this thesis, the original score is used in all but paper IV were the inverted modification is used.

9.6.3 KSS

The Knee Society Score (KSS) is an observer-reported outcome tool, and is one of the most commonly used scores for reporting the results of knee arthroplasty [121]. The KSS scoring is performed by an observer (for example a physiotherapist) through an interview and physical examination. The KSS consists of three sections; the Knee score, the Function score and a patient classification system. The Knee score (0-100 points) evaluate pain, range of motion, stability, flexion contracture, extensor lag and alignment. The Function score (0-100 points) measures the patients ability to walk and to climb and descend stairs. The patient classification system, assign patients to one out of three different categories referring to functional deficiency related to medical impairment other than the actual knee.

9.6.4 Other outcome measures

Range of motion (ROM) was measured in degrees with a goniometer by a physiotherapist.

Ligament laxity was measured in mm`s with the spatula-method described in detail in paper I and II.

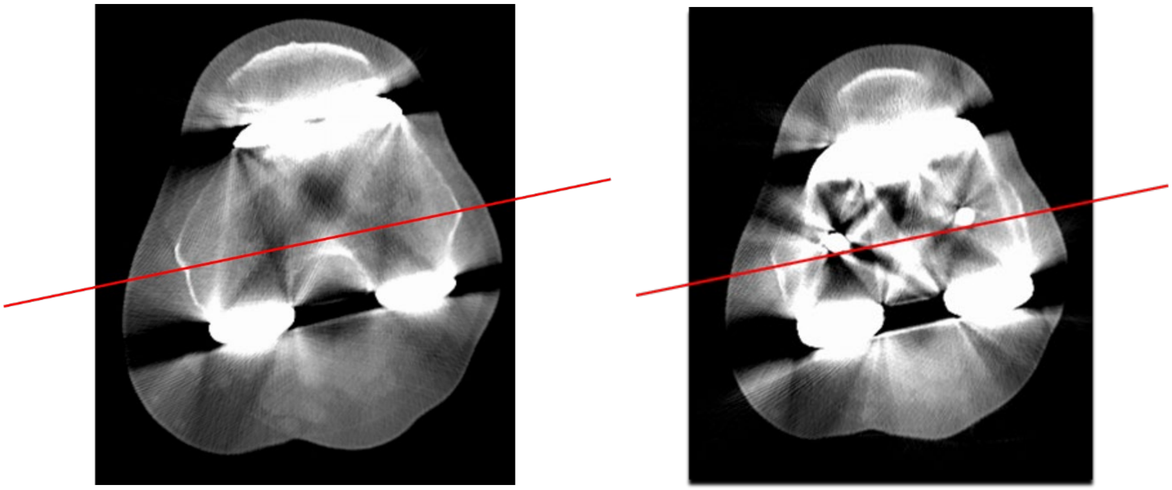
In order to measure patient satisfaction, the patients were asked to indicate how satisfied they were with the operated knee on a visual analog scale (VAS) from 0 to 100 (0 is worst).

Complications were registered at follow-up three months, 1 year and three years after the operation, and reported as frequencies.

The patient-administered questionnaires, KOOS, Oxford knee score, and the VAS score for patient satisfaction, were completed by the patient alone. In bilateral cases, the patients were encouraged to consider the knee under investigation when answering the questions. A physiotherapist who was blinded to the randomization group performed the KSS scores.

9.6.5 CT and radiographic measurements

Rotational alignment of the femoral component was measured with the method described by Berger et al. [52]. The CT scans were evaluated independently by three observers; one radiologist and two experienced orthopaedic surgeons: First, the CT derived surgical transepicondylar axis (CTsTEA) was defined by drawing a line from the lateral epicondyle to the sulcus in the medial epicondyle (Figure 16A). Secondly, the femoral component rotational axis (FCRA) was defined by drawing the common tangent of the two pegs on the inside of the femoral component (Figure 16B). Finally, the angle between these two lines, called the femoral component rotational angle (FCR-angle) was measured. No corrections or eliminations of outliers were performed. Inter-rater reliability for the measurements performed by the three observers was estimated and accuracy and precision of the CRA-method was calculated.



A

B

Figure 16 A. The CT derived surgical transepicondylar axis (CTsTEA) is the line drawn from the most prominent part of the lateral epicondyle to the sulcus in the medial epicondyle. B Femoral component rotation is defined by the femoral component rotational axis (FCRA), the common tangent of the two pegs on the inside of the femoral component. Then the CTsTEA from figure 2A was superimposed, and the femoral component rotational angle (FCR-angle) was measured. In this case, the angle was 0°.

Rotational alignment of the tibial component was based on three axial CT scans (Figure 17), the first at the level of the tibial tuberosity, the second through the native tibial plateau just beneath the tibial base-plate, and the third through the tibial base-plate as described by Berger et al. [52]. The center of the native tibial plateau was defined as the center of the best-fit ellipse at the second scan. The first scan was superimposed on the second scan, and the line from the center of the ellipse to the top of the tibial tubercle was drawn. This line was rotated 18° inward, defining the rotational axis of the native tibia. The rotational axis of the tibial component was drawn on the third CT-scan and finally the angle between the native rotational axis and the tibial components rotational axis could be measured.

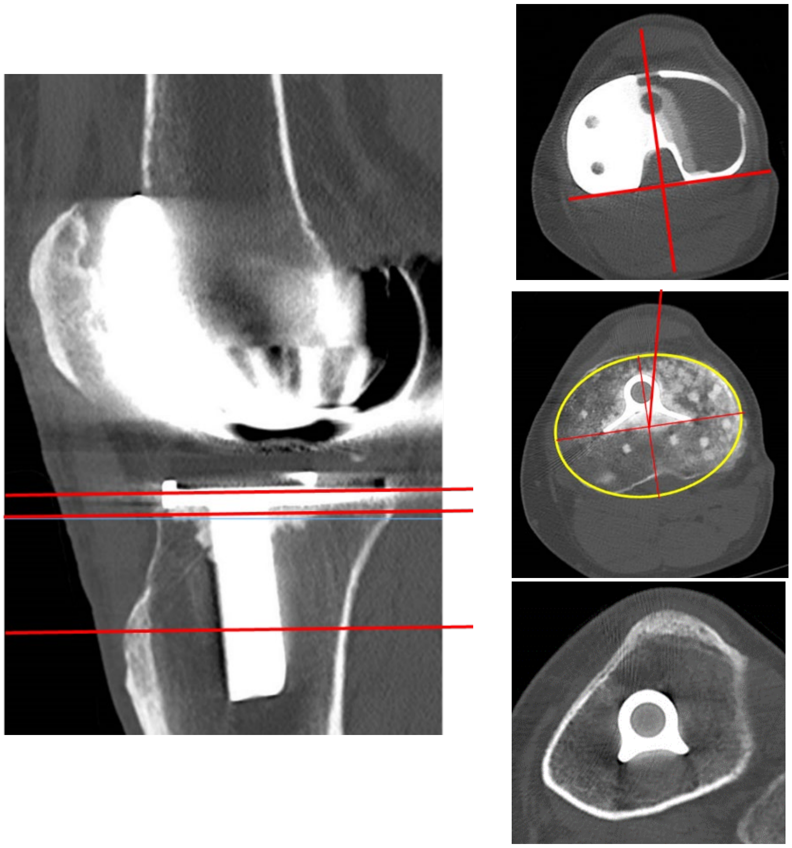


Figure 17. Rotational alignment of the tibial component was measured on tree axial CT scans. One at the level of the tibial tuberosity, the second through the tibial plateau just beneath the tibial base-plate, and the third through the tibial base-plate. Refer to the text for more detailed description.

Patella tilt was measure at weight-bearing patella axial radiographs [116]. On native patellas a line was drawn through the equator of the patella (Figure 18 B). On resurfaced patellas the line was drawn through the interface between the patella component and bone (Figure 18 A). A second line was drawn between the most anterior points of the medial and lateral femoral condyles. The angle between the two lines defined the patella tilt.

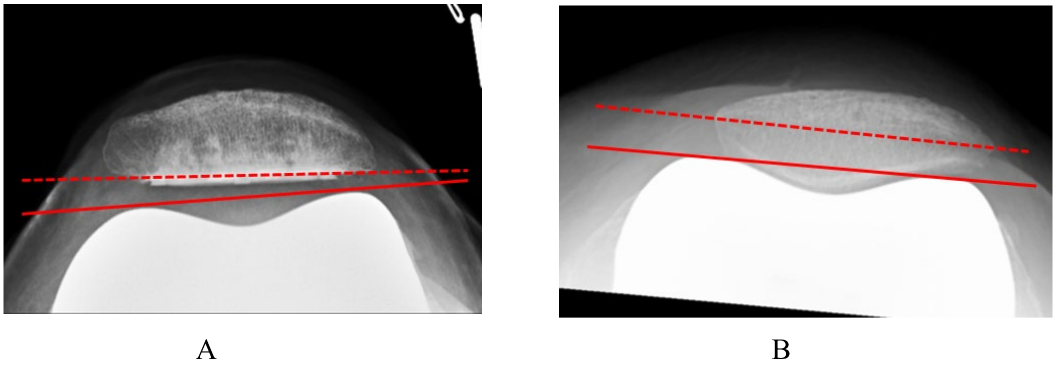


Figure 18. Patella tilt was defined as the angle between the common anterior tangent of the femoral component and the interface-line on the resurfaced patella (A) or the equator-line of the native patella (B).

9.7 Statistical analysis

Data was initially registered on paper forms. Thereafter the data was transferred into specially adapted forms and tables designed in Microsoft Access® database (Microsoft, Redmond, Washington, USA). Statistical analysis was performed in SPSS v.20.0 -25.0 software (SPSS Inc., Chicago, IL) for Windows or with STATA 9.2 statistical software for Windows (Stata Corp LP, College Station, TX).

Only one patient was lost to follow-up. She declined follow-up visits after 3 months because she was living in a remote area and had not experienced any problems with her operated knee. This patient (one knee) was excluded from the study.

Two patients died from heart disease between the follow-up visits at 1 year and 3 years. For these patients the data from the 1-year follow-up were carried forward to the 3-year follow-up.

One patient who suffered from anterior knee pain after the index operation was réoperated with patellar resurfacing after 20 months. In the final analysis, her data was kept in the original allocation group according to the intention to treat principle.

The self-administered questionnaires (KOOS, Oxford knee score, and VAS score for patient satisfaction) were checked for completeness before the patient left the consultations. If incomplete, the patient was encouraged to fulfil the questionnaires. Nevertheless, there was still some missing data, and imputations were done according to the recommendations given by the inventors of the PROMs.

Numbers and percentages were calculated for categorical variables. For continuous data the mean, standard deviation and range, or median and interquartile range, was given as appropriate. Additionally, 95% confidence interval (CI) were given when considered adequate. Two-sided p values <0.05 were considered to be significant.

9.7.1 Paper I

The distribution of data on ligament laxity (condylar lift-off) was analyzed with the Kolmogorov–Smirnov test. For the comparisons of lift-off between ligament-balanced and non-ligament-balanced knees, we used the independent samples t- test for normally distributed data and the Mann–Whitney test for skewed data. Inter-observer agreement between raters of condylar lift-off was calculated with intraclass correlation statistics (ICC) for single measures.

9.7.2 Paper II

Initially, the associations between laxity measurements and outcome scores were assessed by Spearman's rank correlation. Thereafter, confounding variables and effect modifiers known from prior research and biological plausibility were examined statistically using Spearman's rank correlation. Finally, the relationships between laxity measurement and the outcome scores were investigated by median regression analysis, adjusting for significant confounders and stratifying on the effect modifier. A median regression model was chosen because of highly skewed data and outliers.

9.7.3 Paper III

In this study, each measurement was performed twice on the same subject, with the patella everted and repositioned. Comparisons between paired data was tested with paired samples t-test for normally distributed data and with the Wilcoxon signed rank test for skewed data.

9.7.4 Paper IV

A post hoc sample size estimation was performed: The minimal clinically important difference (MCID) in KOOS was set at 10 points and the mean SD of all KOOS sub-scores at 3 years was set at 16. The ratio of sample sizes was set at 0.5, the 2-sided CI at 95% and the power at 90%. Given these data, the total sample size was calculated to be 122 with 41 in one group and 81 in the other.

Median values and interquartile ranges (IQR) for functional outcome for ligament-balanced and non-ligament-balanced knees at 3 years follow-up were calculated and compared with the Mann-Whitney U test. Thereafter, mean and SD change in outcome scores from baseline to the 3 years follow up in ligament-balanced and non-ligament-balanced knees were calculated and compared with the independent samples t-test. The association between the number of ligaments released and outcome was estimated with Spearman's correlation analysis.

9.7.5 Paper V

Sample size estimation: The minimal perceptible clinical improvement (MPCI) for KOOS has been suggested to be 8–10 points [118]. The power was set to 90%, the level of significance (p) at 5%, and the standard deviation at 16, resulting in a sample size of 55 knees in each treatment group. Allowing for some dropouts after 3 years of follow-up, it was decided to include 130 knees.

Data was checked visually for normality based on histograms, using the findings in a publication by Fagerland and Sandvik [122]. Comparison of means was performed using the independent-samples t-test for normally distributed data and the Mann-Whitney U-test for skewed variables. Fisher's exact test was used when analyzing categorical variables.

When comparing the functional outcome variables in the two treatment groups from before surgery up to 3 years postoperatively, repeated measures, mixed-models analysis was used.

9.7.6 Paper VI

The femoral component rotational angle (FCR-angle) was measured independently by three observers. The inter-rater reliability of the measurements was estimated with intra-class- correlation coefficient (ICC), two way mixed models.

Accuracy of the CRA-method was expressed as the mean FCR-angle and its 95% confidence interval (CI). The variability was expressed as the standard deviation (SD) and range of the FCR-angle. At last, the 95% CI of the SD was calculated.

The difference in effect of femoral component rotation on functional outcome between group 1 and 2 and between group 3 and 4 was tested with the independent samples t-test.

The length of the 95% CI of the FCR-angle was used as an indicator of sample size adequacy [123].

9.7.7 Paper VII

The rotational alignment of the tibial component was measured independently by two observers. The inter-rater reliability for the measurements was estimated with intra-class- correlation coefficient (ICC), two way mixed models, absolute agreement.

The difference in functional outcome between knees with internally rotated tibial platforms and knees with neutral or externally rotated platforms were tested with the Mann-Whitney u-test.

9.7.8 Paper VIII

A post hoc power analysis was performed with the OpenEpi, Version 3, open source calculator. The 2-sided CI was set at 95%. The minimal clinically important difference (MCID) in KOOS was set at 10 points and the mean SD of all KOOS sub-scores at 3 years was set at 16. The sample sizes for each group was 45 and 35. Given these data, the power was calculated to be 79.2%. Differences in functional outcome between groups were tested with the Mann-Whitney U-test. Pearson or Spearman correlation analysis was chosen depending of the distribution pattern of the data. Proportions of dichotomized variables were analyzed with the Fisher exact test.

9.8 Ethics

The protocol was approved by the Regional Committee of Research Ethics at the University of Oslo (REK: 1.2007.952) and registered at ClinicalTrials.gov (identifier: NCT00553982). Later additions to the protocol was approved by the same committee (ID number: S-07172d 1.2007.952) and (2010/1678 D 33-07172b 1.2007.952 with changes 05.03.2012). All the patients signed an informed consent form.

10 Summary of results

TKA had a major positive impact on patients pain, symptoms, activities of daily living, sport/recreation and knee related quality of life ($p<0.001$ for all sub-scores) (Figure 3). At 3 years follow-up, only one patient reported that knee related quality of life had declined. Four patients declined in symptoms sub-score and five patient declined in sport/recreation sub-score (all women ≥ 70 years of age). In summary, in 10 knees (7.8%) at least one sub-score was inferior at 3yeas compared with preoperatively. Oxford knee score declined in only two knees.

10.1 Paper I

The new spatula-method to measure ligament laxity intraoperatively in TKA was feasible in all operated knees. Inter-observer agreement among raters was high with an intraclass correlation coefficient for single measures of 0.88 (95 % confidence interval 0.82–0.92). Absolute agreement was achieved in 60.4 % of measurements. In only one out of 96 measurements, the difference between observers reached 2 mm.

In 70 out of 100 knees, ligament balancing was found to be necessary because of asymmetric gaps. The most frequently released ligament structures in varus knees were the anterior and posterior part of the MCL, the PCL and the medial posterior capsule. In valgus knees the popliteus tendon and the PCL was the most frequently released soft tissue structures (Table 1).

Table 1. Number of ligaments released in varus and valgus deformed knees

Ligament	Varus knees (n=63)	Valgus knees (n=6)
MCL		
anterior part	49	
posterior part	39	
Medial posterior capsule	10	
Semi-membranosus	2	
Pes anserinius	-	-
PCL	27	3
LCL	1*	1
Popliteus tendon	4*	3
Posterolateral corner		1
Ileo-tibial tract		2
Lateral posterior capsule		2

*Compensatory release in varus knees.
MCL: medial collateral ligament, PCL: posterior cruciate ligament, LCL: lateral collateral ligament.

Table 2. Medial and lateral ligament laxity (lift-off) in extension and 90 degrees of flexion in knees with and without ligament balancing. N=100. Values are expressed in millimeters as means, (95 % CIs), and ranges

Knee alignment	Position		Without ligament balancing	With Ligament balancing	p Value	Total
Varus knees		n	18	63		81
	Extension	Medial	1.6 (1.2-1.9) 1-3	1.9 (1.7-2.1) 1-4	0.17	
		Lateral	2.0 (1.6-2.4) 1-3	2.1 (1.9-2.3) 1-5	0.90	
	Flexion	Medial	2.7(2.2-3.2) 0-4	3.4 (2.9-3.9) 1-9	0.30	
		Lateral	3.2 (2.6-3.9) 1-5	3.5 (3.1-3.9) 1-10	0.74	
Valgus knees		n	9	6		15
	Extension	Medial	2.0 (1.6-2.4) 1-3	2.7 (1.4-3.9) 1-4	0.25	
		Lateral	1.7 (1.1-2.2) 1-3	1.7 (0.2-3.1) 0-4	1.00	
	Flexion	Medial	2.4 (1.6-3.3) 1-4	3.7 (0.9-6.5) 1-8	0.33	
		Lateral	3.0 (1.7-4.3) 1-7	4.3 (2.9-5.8) 2-6	0.12	
Neutral knees		n	3	1		4
	Extension	Medial	2.3 (-) 1-3	1.0		
		Lateral	1.3 (-) 0-3	3.0		
	Flexion	Medial	3.3 (-) 2-4	2.0		
		Lateral	2.3 (-) 0-5	3.0		

No statistically significant difference in condylar lift-off between the ligament-balanced and the non-ligament-balanced group were found (Table 2), however, there was a tendency to more outliers in flexion in the ligament-balanced group.

In extension, medial–lateral symmetry within 2 mm was obtained in 96 % of the knees undergoing ligament balancing and in 97 % of the knees not undergoing ligament balancing. In flexion, medial–lateral symmetry within 2 mm was obtained in 70 % of the ligament-balanced knees and in 89 % of the knees without ligament balancing. Flexion gaps were equal to extension gaps in 29 % of the ligament-balanced knees and in 23 % of the knees where no ligament surgery was performed. In the knees with unequal gaps, 98 % of the ligament-balanced knees were tightest in extension and 91 % of the non ligament- balanced knees were tightest in extension.

10.2 Paper II

Intraoperative ligament laxity was found to influence on functional outcome one year after TKA. The postoperative mechanical axis proved to interact significantly on the association between ligament laxity and outcome. The material was therefore stratified into knees with perfect alignment or valgus alignment (n = 58) and knees with varus alignment (n = 64).

In perfectly aligned and valgus-aligned TKAs, there was a negative correlation between medial laxity and all subscores in KOOS. Medially in extension the most important regression coefficient (β) was recorded for ADL ($\beta = -7.32$, $p < 0.001$), sport/recreation ($\beta = -6.9$, $p = 0.017$) and pain ($\beta = -5.9$, $p = 0.006$). Medially in flexion the most important regression coefficient (β) was recorded for ADLs ($\beta = -3.11$, $p = 0.023$) and sport/recreation ($\beta = -4.18$, $p = 0.042$).

In varus-aligned knees, lateral laxity in extension and flexion had a statistically significant negative effect on the symptom subscore in KOOS ($\beta = -5.0$, $p = 0.023$ in extension and $\beta = -3.0$, $p = 0.041$ in flexion), but this pattern was not consistent through all subscores. The regression coefficients for the KSS and Oxford Knee Score were lower and less consistent than for the KOOSs and did not reach statistical significance.

10.3 Paper III

A statistically significant increase of 0.6 mm ($p < 0.001$) in condylar lift-off (ligament laxity) laterally in flexion was found when measurements were performed with the patella repositioned compared to everted. No differences were found in extension or medially in flexion. Correspondingly the flexion gap inclination increased by 0.6° ($p = 0.002$) when the patella was repositioned, and the flexion gap increased 0.4 mm ($p < 0.001$) when the patella was repositioned. In only two of 196 measurements the difference between laxity measurements performed with and without patellar eversion was more than two mm. Recalling the results from paper II it appears that the effect of patellar eversion on ligament laxity measurements is too small to be considered clinically relevant.

10.4 Paper IV

Preoperatively 103 knees had a varus deformity, 21 knees had valgus deformity and 5 knees were neutral. 86 knees were ligament-balanced and 43 knees were not. Ligament-balanced varus knees had statistically significant more preoperative deformity than varus knees without ligament balancing ($p=0.01$). No significant differences in the distribution of patella-resurfaced knees were found between the groups ($p= 0.46$) or between the subgroups ($p=0.66$ for varus knees, $p=0.18$ for valgus knees).

In the ligament-balanced knees, mean (range) 2 (1-4) ligament structures were released per knee. There was no statistical difference in outcome scores between ligament-balanced and non-ligament-balanced knees at 3 years follow-up, and there was no statistical difference in change in outcome score from baseline to follow up between the two groups (table 3). When varus and valgus knees were investigated separately, there was still no difference between ligament-balanced and non-ligament-balanced knees observed. No correlation was found between increasing numbers of soft tissue structures released and KOOS, OKS or patient satisfaction.

Table 3. Mean (SD) change in outcome scores for all knees (N=129) from baseline to the 3 years follow up in ligament-balanced and non-ligament-balanced knees.

	Change in score from baseline to 3 years follow-up		
	Without ligament-balancing (n=43)	**With ligament-balancing (n=86)**	p*
KOOS			
Pain	42 (18)	48 (19)	0.09
Symptomes	36 (17)	37 (20)	0.7
ADL	38 (19)	42 (21)	0.33
Sport/recreation	48 (27)	49 (30)	0.76
QOL	55 (22)	58 (25)	0.45
Oxford knee score**	18 (7)	20 (8)	0.37

* Independent samples t-test**.** ** **Inverted scale:** the worst score is 12 and the best score is 60. KOOS: Knee injury and Osteoarthritis Outcome Score, 0-100. Best score is 100. ADL: Activities of daily living. QOL: Knee related quality of life.

10.5 Paper V

The mean subscores for the primary outcome measure, the KOOS, were in favor of patellar resurfacing. The greatest difference between the two groups at 3 years after surgery was seen in the subscore sport/recreation, with a 10-point difference between the groups (p = 0.01). In the other subscores, the differences were 8 points for knee-related QoL (p = 0.03), 6 points for pain (p = 0.02), and 5 points for symptoms (p = 0.04). In the subscore for ADL, there was a 5-point difference between the two groups, but this was not statistically significant (p = 0.06). No statistically significant differences between the two groups were observed for the secondary outcome measures (KSS knee score, KSS function score, Oxford knee score, and patient satisfaction). For detailed information, refer to table 4.

At 3 years follow-up, the smallest ceiling effect was found for the sport/recreation subscore of the KOOS (6%). The highest ceiling effects were observed for the KSS function score (48%) and patient satisfaction (40%).

Table 4. On next page. Clinical outcome with pre-operative, one-year post-operative and 3 year post-operative scores expressed as means (standard deviation). The pre-operative scores did not differ significantly between the treatment groups.
*Mixed models including data from all time points. **Mann-Whitney U-test
KOOS: Knee injury and Osteoarthritis Outcome Score (0-100), 100 is the best score.
KSS: Knee Society Clinical Rating System (0-100), 100 is the best score.
Oxford score: Oxford knee score (12-60), 12 is the best score.
ADL: activities of daily living. QOL: knee related quality of life. Pre-op: pre-operative (baseline) score.

Table 4. Clinical outcome scores expressed as mean (SD) in patients operated with and without patellar resurfacing in 129 TKAs. Refer to the previous page for explanations

	Without patella resurfacing (n= 66)	**With patella resurfacing (n=63)**	**p-value***
KOOS			
Pain, Pre-op	42.4 (13.8)	40.4 (17.5)	
Pain, One year	84.1 (17.9)	90.2 (12.9)	0.022
Pain, Three years	85.1 (18.1)	90.8 (13.7)	
Symptom, pre-op	49.7 (18.5)	52.2 (17.4)	
Symptom, 1 year	81.7 (16.4)	85.8 (12.6)	0.041
Symptom, 3 years	85.5 (13.2)	90.2 (10.6)	
ADL, pre-op	44.8 (14.2)	45.1 (18.6)	
ADL, 1 year	84.0 (16.5)	88.8 (12.9)	0.058
ADL, 3 years	83.2 (18.4)	88.3 (14.8)	
Sport/Rec, pre-op	12.9 (13.2)	13.0 (14.9)	
Sport/Rec, 1year	54.7 (24.8)	64.4 (22.0)	0.014
Sport/Rec, 3 years	56.8 (27.0)	67.2 (27.4)	
QOL, pre-op	24.0 (12.4)	23.7 (13.1)	
QOL, 1 year	77.5 (22.9)	84.7 (17.0)	0.027
QOL, 3 years	77.3 (23.1)	85.0 (19.0)	
KSS			
KSS knee, pre-op	35.4 (14.5)	34.2 (17.6)	
KSS knee, 1 year	84.1 (15.1)	88.8 (11.8)	0.103
KSS knee, 3 years	90.0 (14.2)	92.0 (8.5)	
KSS function, pre-op	64.6 (18.5)	68.7 (20.1)	
KSS function, 1 year	87.4 (15.7)	87.9 (17.0)	0.984
KSS function, 3 years	83.4 (20.7)	83.1 (20.8)	
Oxford score, pre-op	37.0 (6.4)	36.9 (7.3)	
Oxford score, 1 year	18.8 (6.5)	17.1 (5.5)	0.168
Oxford score, 3 years	18.3 (6.5)	17.2 (6.4)	
Satisfaction, 1 year	89.6 (20.5)	95.0 (11.0)	0.114**
Satisfaction, 3 years	90.0 (16.4)	92.2 (15.4)	0.426**

10.6 Paper VI

In this study the accuracy and variability of the Clinical rotational axis method (CRA-method) was evaluated by comparing the femoral component rotation to the gold standard (CTsTEA). Thereafter, the relationship between femoral component rotation and functional outcome at 3 years follow-up was assessed.

No statistical difference in preoperative patient characteristics were observed between group 1 and 2 or between group 3 and 4.

The mean (95% CI) angular deviation of the femoral component from the gold standard was 0.2° (-0.15°-0.55°). The standard deviation was 1.58° and the 95% CI of the SD vas 1.36°-1.85°. Maximum and minimum values for angular deviation from the gold standard were 3.7° external rotation and 3.7° internal rotation.

Malrotation of the femoral component did not affect functional outcome at 3 years follow-up (Table 5).

Table 5. Comparison of functional outcome measures at 3 years follow up between groups. First knees were split into two groups: Group 1; internally rotated femoral components and Group 2; neutral and externally rotated femoral components. Thereafter, knees were split into two new groups: Group 3; knees with >1° malrotation of the femoral component in any direction and Group 4; knees with ≤ 1° malrotation of the femoral component in any direction. Median (range) values are given for all scores.

	Group1 (n=29)	**Group 2 (n=51)**	**p***		**Group 3 (n=39)**	**Group 4 (n=41)**	**p***
KOOS							
Pain	89 (58-100)	94 (33-100)	0.31		94 (33-100)	94 (39-100)	0.80
Symptoms	89 (64-100)	93 (32-100)	0.89		93 (54-100)	89 (32-100)	0.21
ADL	97 (53-100)	93 (31-100)	0.49		97 (53-100)	91 (31-100)	0.14
Sport/recreation	70 (0-100)	70 (5-100)	0.98		70 (5-100)	65 (0-100)	0.40
QOL	88 (31-100)	94 (19-100)	0.05		88 (31-100)	94 (19-100)	0.97
OKS	16 (12-37)	15 (12-43)	0.23		16 (12-37)	15 (12-43)	0.90
Patient satisfaction	96 (70-100)	99 (10-100)	0.26		99 (41-100)	98 (10-100)	0.68

*Mann-Whitney U test.

10.7 Paper VII

In 46 knees, the tibial component was in neutral position or externally rotated mean (range) 4° (0°-15°). In 34 knees, the tibial component was internally rotated mean (range) -4.5° (-1°- -14°). Preoperatively there was no difference between the groups in KOOS, Oxford knee scores or demographic data except for BMI that was significantly higher (p=0.001) in the group of internally rotated tibial components.

At three years follow-up all scores favored knees with neutral or externally rotated tibial platforms (Table 6). However, the difference was not statistically significant for pain and ADL.

Table 6. Scores at three years follow-up for knees with internally rotated tibial components and knees with neutral or externally rotated tibial components. N=80.

	Internal rotation (n=34)	**Neutral or external rotation (n=46)**	**Δ**	**p***
KOOS				
Pain	83	92	9	0.06
Symptomes	84	91	7	0.02
ADL	82	90	8	0.13
Sport/recreation	55	72	17	0.02
QOL	74	89	15	0.002
Oxford knee score	19	16	3	0.02
Patient satisfaction	88	95	7	0.03

* Mann-Whitney U test

10.8 Paper VIII

1) Mean (SD) combined rotation of the femoral and tibial components was 0° (5.5°) with range from 16° internal rotation to 15° external rotation. All outcome scores were statistically significant better in knees with combined external rotation (Table 7). 2) Opposite rotation of the femoral and tibial components occurred in 35 knees. The difference in rotation between the femoral and tibial components ranged from 1° to 14°. There was no statistically significant difference in outcome scores in patients with knees with opposite component rotation compared to knees with rotation in the same direction. The degree of mismatch did not correlate with any outcome measure. 3) Mean patella tilt was 1.8° external rotation with a range from 4° internal rotation to 10° external rotation. There was no statistically significant correlation between individual or the different combinations of malrotation and patella tilt. (Pearson correlation coefficient for tibia 0.1 (p=0.38), femur 0.05 (p=0.67), combined 0.09 (p=0.45) and mismatch 0.1 (p=0.35)). 4) Patella tilt correlated negatively with the KOOS subscores for pain, symptoms and quality of life. Patella tilt more than 4° occurred in 9 knees. All these knees were without patella resurfacing and all outcome scores were statistically significant and clinical relevant inferior compared to knees with 4° or less patella tilt (Table 8).

	External rotation (n=43)	**Internal rotation** (n=37)	p*
KOOS			
Pain	97	92	0.011
Symptoms	93	89	0.019
ADL	97	93	0.049
Sport/Rec	80	65	0.032
QOL	94	81	0.002
OKS	15	16	0.010
Patient satisfaction	100	95	0.019

*Mann-Whitney U test

Table 7. Outcome scores at 3 years follow-up in knees with combined external and internal rotation of the femoral and tibial components. Median values are given. KOOS: Knee injury and osteoarthritis outcome score. 0-100. Best score is 100. ADL: Activities of daily living. QOL: Knee related quality of life. OKS: Oxford knee score. 12-60. Best score is 12.

	Patella tilt ≤ 4° n=71	**Patella tilt > 4° n=9**	**p***
KOOS			
Pain	97	67	0.001
Symptomes	93	71	0.002
ADL	94	76	0.012
Sport/Recreation	70	35	0.007
QOL	94	56	0.002
OKS	15	22	0.008
Patient satisfaction	99	90	0.001

*Mann-Whitney U test

Table 8. Knee function at 3 years follow-up in a subgroup with more than 4° patella tilt compared to those with ≤ 4°patella tilt.

10.9 Complications

In the complete study population five perioperative complications occurred. Three were caused by inadvertent saw cuts: one to the popliteal tendon, one to the medial collateral ligament and one to the posterior cruciate ligament. There was one case of atrial fibrillation, and one patient had a small myocardial infarction. A further 7 complications were registered within the first three years: three patients had stiffness requiring arthroscopic arthrolysis and mobilization under anesthesia. One of these had a poor result. It was one minimally displaced patella fracture and one partial quadriceps tendon rupture which did not need any additional treatment and had very good outcomes. One patient with lateral knee pain underwent neurolysis of the fibular nerve and had a fairly good outcome. Finally, one acute hematogenous infection that occurred two years after the index operation was treated successfully with soft tissue debridement. The number of complications were equally distributed between randomization groups. Both complications related to the patello-femoral joint were in the non-patella-resurfaced group.

11 Discussion

11.1 External and internal validity

External validity is the extent to which the results of a study can be generalized to other situations and to other people. *Internal validity* is the extent to which a causal conclusion based on a study is warranted [124].

Effectiveness is the extent to which an intervention produces an outcome under ordinary day-to-day circumstances whereas *efficacy* is the extent to which an intervention produces a beneficial result under ideal conditions [125].

A *pragmatic study* test effectiveness in everyday practice with relatively unselected participants and under flexible conditions. In contrast, an *explanatory study* test efficacy in a research setting with highly selected participants and under highly controlled conditions [126].

Consequently, pragmatic studies favors external validity and describes the effectiveness of a treatment. On the other hand, an explanatory study favors internal validity and describe efficacy.

External validity presumes that the study population (sample) is representative for the general population to which the researcher want to infer the results. Another prerequisite is that the treatment given to the study population can be replicated by other surgeons performing total knee surgery. Therefore, in theory, no exclusions should be allowed and the operations should be performed by multiple teams with different degrees of experience representing the overall collegial community. Such pragmatic studies will satisfy the demands for generalizability, but at the risk of blurring out the effect of technical details that may be of interest. In contrast, the aim of an explanatory study design is to remove as much “noise” as possible and find out whether a treatment works under ideal circumstances. How pragmatic or explanatory a study is, is a matter of subjective judgement.

The outcome of total knee surgery is highly influenced by a number of known and unknown confounders, bias, effect modifiers and random errors that might result in spurious results and disguise interesting differences between treatment options. Therefore, an effort to reduce this “noise” is warranted.

Inclusion/exclusion criteria, consistency in surgical technique, as well as the study design are important factors that contribute to the amount of confounding and systematic bias. In the present studies, the exclusion criteria first of all excludes patients that do not fit the typical primary TKA population and a few patients that for physical or psychological reasons could not convey their outcome through the given outcome measures. It is not very likely that these exclusion criteria induce a significant selection bias.

So-called expert bias is another factor that may reduce the external validity. In the present studies the operations were performed by both experienced orthopaedic surgeons and trainees, but the first author (EA) was either operating or assisting in every operation. This arrangement was introduced in order to replicate the daily routine in many teaching hospitals and to ensure consistency in surgical technique, thereby favoring both the external and internal validity to a reasonable extent.

Random allocation to different treatment groups, like in paper V, is the most powerful way to reduce confounding and bias. Confounding can also be controlled in regression analysis as in paper II, however only recognized confounders can be controlled.

In paper II, another potential threat to internal validity is demonstrated: Interaction, or effect modification, occurs when the magnitude of the effect of an exposure of interest differs depending on the level of a third variable. This problem was resolved by stratifying the material on the interacting variable (mechanical axis).

11.2 Outcome measures (Outcome assessment instruments)

Trustworthy outcome measures are of fundamental importance in clinical research. Given the abundance of available tools or instruments developed to assess outcome in knee surgery the selection of outcome measures can be difficult and not without the risk of jeopardizing the validity of otherwise well designed studies.

Outcome measures can be categorized into generic and specific. Generic instruments assess overall health related quality of life and typically include questions about physical, mental and social function and health. Examples of generic outcome tools are the Short form 36 (SF-36) [127] and the Euro Qual five dimensions questionnaire (EQ5D) [128]. Generic measures can be used to compare the impact of treatments across patients with different diseases. It is therefore an important tool for health care providers when prioritizing resources between different groups of patients. However, generic outcome tools have limited sensitivity and responsiveness to changes in a specific body region or a specific disease.

Specific outcome measures can be further categorized into joint specific, disease specific and performance based measurements. These are more sensitive to changes induced by a disease or treatment within a specific region and are therefore suitable for comparisons between groups of patients with the same disease. Among the most frequently used knee joint specific outcome tools are the Western Ontario and McMaster Universities (WOMAC) score [129], the Knee Society score (KSS) [130], the Oxford Knee score OKS [119]and the Knee Injury and Osteoarthritis Outcome Score (KOOS) [131]. Performance based instruments commonly in use are the Timed Up and Go Test (TUG) [132], the Stair Climbing Test (SCT) [133] and the Six Minute Walk Test (6MW) [134]. Performance based instruments measure capability objectively, are virtually free from floor- and ceiling effects, but they do not consider any comorbidities that may inhibit function.

Outcome measures can also be categorized into assessor reported outcome measures and patient reported outcome measures (PROMs). In the first case, the assessor, usually the surgeon or a physiotherapist performs testing and interviews of the patient. In the second case, the patient answers questions and judge their own capacities without the influence of another person. Therefore, PROMs are less prone to assessor-induced bias. OKS and KOOS are typical examples of PROMs.

Outcome measures must be valid, reliable and responsive to changes. Validity means that it measures what it is supposed to measure. To do so, the tool must reflect all facets of interest, so called content validity, and it must be able to predict outcome, termed criterion validity. Reliability is the extent to which scores on an instrument is reproducible [135]. It can be measured by intraclass correlation coefficient (ICC) as in paper I, VI and VII. Responsiveness of an outcome measure is the ability of an instrument to detect true changes in the patients' status, for example before and after operative treatment [136]. It can be assessed by the standardized response mean (mean change score divided by the standard deviation of the change score).

The choice of outcome measures in this thesis was based upon many considerations. The KSS was chosen because it is assessor-reported and include objective items like ROM, stability, contractures and alignment. Furthermore, it was in frequent use and highly recommended at the time these studies were planned. Oxford knee score was included because it was a well-established and validated PROM. KOOS was added because it was more contemporary, developed for patients that are more active and therefore potentially more responsive to changes in the high end of the score. Patient satisfaction score was expected to reflect the overall success with the surgical procedure.

Indications for, and outcomes of surgery are likely to change over time. Therefore, outcome measure that was found to be valid 30 years ago is not necessarily valid today. In paper V in this thesis, we demonstrate and discuss some important characteristics of the outcome tools that may threaten their validity. For example, we observed unacceptably high ceiling effects for the KSS function score, patient satisfaction score, and for the ADL sub-score in KOOS. We also found very low standard deviations and inter-quartile ranges for the KSS knee score and the Oxford knee score. The high ceiling effects may in part be attributed to a shift in the TKA population over the decades from elderly, sedentary to younger and more active patients with higher expectations as well as to improved surgical techniques and better implants. It is evident that high ceiling effects reduce the ability of a scoring system to reveal differences in the high end of the scales. It is also likely that very small SDs and IQRs indicate that only small parts of the scoring scales are in use. The consequence of these undesirable distribution effects is reduced ability to discriminate between treatment effects, hence reduced internal validity of a study.

Comparisons between different treatments is often based on differences in PROMs and on whether these differences are statistically significant and clinically relevant. In paper V, we compared outcomes in patella resurfaced and non-resurfaced TKAs by repeated measures mixed model and the mean differences between treatment groups where compared to the minimal clinically important difference (MCID). However, the MCID is a metric that is based on differences in individual patients, not on mean differences between groups [137]. A more appropriate use of the MCID could have been to perform responder analyses [138]. In responder analysis, the number of patients that reach the MCID in each treatment group is calculated. Thereafter, the proportions of responders in each group is compared. Nevertheless, it has been showed that the calculation of MCID is highly dependent on the method used to calculate it, and that it can vary up to tenfold depending on the calculation method [137]. Hence, the interpretation of responder analyses is not always straightforward.

Outcome assessment in total knee surgery has many facets, some quantitative and some qualitative. Typical quantitative measurements are prosthetic survival (measured in years), range of motion (measured in degrees), ligament laxity (measured in mm or degrees) and muscle strength (measured in kg or Nm). In contrast, the patient's perception of pain, knee function, or knee related wellbeing during activities of daily living and during sports and recreation are qualitative issues. In order to quantify these qualitative issues, questionnaires rating qualitative items on Likert scales or visual analogue scales (VAS) were developed. Yet, this conversion of qualitative properties to quantitative ones is a fundamental and very difficult task that have resulted in the development of a new scientific discipline within the field of psychometrics [139].

Based on the experience from the studies in this thesis it is the authors opinion that development of better outcome measures that are more valid, reliable and responsive to change is mandatory for meaningful clinical research in total knee surgery in the future.

11.3 Ethics

All studies were performed in consistence with the Helsinki declaration‘s ethical principles for medical research involving human subjects [140]. The fundamental principles of the declaration are respect for the individual, their right to self-determination, and that the subject’s welfare must always take precedence over other interests.

In papers I-III the patients were exposed to measurements of ligament laxity. It is not likely that these simple manipulations would result in any harm to the patients. In contrast, in paper V, the patients were exposed to a trial comparing different treatments. In studies where the treatment options do not appear to be equal, the consequence is that one study group have received the less effective intervention, which is of course an ethical dilemma. To compensate for this unpleasant fact the study design and statistics should aim to minimize the number of patients at risk of inferior treatment. The randomized, double-blind study design with an a priori sample size estimation is the most effective way to define the minimal number of patients at risk, and still enable the researcher to demonstrate a significant difference between treatments with a reasonable power. In the present study, the statistical significance level was set at 5% and the power at 90%, which are generally accepted limits in medical clinical research. An interim analysis was also performed in order to stop the inclusions of patient in the case of unacceptable results in one of the patient groups.

In RCTs, the details in study design should not be manipulated after the initiation of a trial. Doing so may threaten the validity of the study. In order to document adherence to this principle the RCT presented in paper V was registered in Clinical trials.gov. before the recruitment of patients started (identifier: NCT00553982). Such registries enable editors of medical journals to check that important details in prospective trials have not been manipulated during the study. It also enables the medical society to discover selective publication practice.

In paper VI, VII and VIII 80 patients underwent CT-scans of the knees. Ionizing radiation has potential adverse effects to human health. The typical effective radiation dose from a CT-scan of the knee is 0.16 milli-Sievert (mSV), which is equivalent to 8 chest x-rays or to one month natural background radiation [141]. In comparison, the radiation dose of one CT of the lumbar spine is 19 mSv, equivalent to 8.8 years background radiation [141]. The patient´s age must also be taken into account. The mean age in this study was 69 years and the youngest patient 42 years. Subsequently, the potential risks of the CT scans was considered negligible.

11.4 Paper I

The first goal of this study was to present a new method to measure ligament laxity. The second goal was to report on the results of the direct measurements, the degree of medial–lateral symmetry in extension and in flexion, and the equality of the extension gaps and flexion gaps in 70 ligament-balanced and 30 non ligament-balanced TKAs.

The spatula-method is the first method to measure, intra-operatively directly in millimeters, medial and lateral condylar lift-off in extension and 90° of flexion with all components implanted. The measuring procedure was easy to perform, and the measurements take no more than 1 or 2 minutes.

Despite many different devices designed to assist in ligament balancing including spacers [60], tensors [60, 142, 143], electronic instruments [144-148], and computers [149-152], defining optimal ligament balance during TKA has until now, been based on the surgeons ‘‘feel’’, and the association between ligament laxity and functional outcome was apparently unknown. The reason why this important topic has been so sparsely investigated is unclear, but it could be that the previously developed devices to measure ligament balance were cumbersome and/or expensive and therefore of limited use.

Ideally, the spatula-method should have been tested against a gold standard, but unfortunately, no gold standard for measuring ligament laxity intraoperatively exist. Instead, the inter-observer reliability of the new method was measured with intraclass correlation statistics. The ICC (95% CI) for single measures was 0.88 (0.82–0.92). According to Cicchetti [153], an ICC less than 0.40 is poor, between 0.40 and 0.59 is fair, between 0.60 and 0.74 is good and between 0.75 and 1.00 is excellent. However, the ICC can be calculated in many ways and the interpretation of the ICC values depends on the assumptions that are built into the calculations [154]. A more comprehensive discussion of the ICC follows in paper VII. Nevertheless, the excellent reliability of the spatula method is supported by the fact that absolute agreement between the observers was found in 60.4% of the cases and that 2 mm disagreement was observed in only one out of 96 measurements.

An important advantage of the spatula-method is that it measures ligament laxity directly with all components in situ. That is in a near normal biomechanical situation. Spreading devices, tensioners and spacer blocks allow measurements of gaps between osteotomies in a very different and non-physiologic biomechanical situation, without the prosthesis in place. For example, using a tensor Muratsu et al. found a decrease of as much as 5.3 mm in joint gap in extension and a reduction of varus ligament imbalance of 3.1° with the femoral trial prosthesis in place compared to measurements without [155].

The second part of the study provides objective information on the degree of ligament laxity that can be expected after TKA performed with a generally accepted technique. It also provide information on how balanced surgically ligament-balanced knees become compared to the knees that did not need ligament balancing. It is promising that with the knee in extension the raw laxity measurements of medial-lateral symmetry and flexion-extension gap ratio is almost identical for ligament balanced and non-ligament-balanced knees. With the knee in 90° of flexion a small non-significant difference between ligament-balanced and non-ligament-balanced knees and a higher number of outliers may indicate that ligament balancing in flexion is more difficult than in extension.

The fact that no statistically significant difference in ligament-laxity between the ligament-balanced and the non-ligament-balanced group were found indicate that ligament balancing according to the Whiteside technique is a safe method, however a small risk for over-release in flexion can be suspected.

A potential limitation of the spatula-method is that manual loading of the ligaments in valgus and varus may not give an accurate and reproducible tension to the ligaments during measurements of ligament laxity. However, LaPrade et al. [156] compared the lateral compartment gapping on stress radiographs before and after sequential lateral ligament sectioning in ten cadavers. Varus stress was applied either by a clinician or by a force-application device delivering a 12 Nm moment to the knee. They concluded that both standardized 12 Nm moments and clinician- applied varus stress radiographs provide objective and reproducible measures of lateral compartment gapping. The reason for this may be that ligaments are not very elastic and that ligament laxity mostly represents “the too phase” of the stress strain curve for the ligament. Another possible bias of the measuring method is the dished contour of the polyethylene leading to an oblique introduction angle (10–15°) of the spatulas and overestimation of the lift-off of 3–4 %. It is the authors' opinion that ligament-balancing surgery is not so fine-tuned that measurement-errors of this magnitude are clinically relevant. Finally, no power analysis was performed, indicating that type 2 errors cannot be excluded.

The generalizability of the results from this study is a matter of concern, because expert bias can be suspected. The spatula method was found to be very reliable with an ICC of 0.88. This indicate excellent internal validity because agreement within different observers who performed measurements was high. However, the observers were trained by the same senior surgeon (EA) and therefore relatively homogeneous results is expected. In a different context, some degree of systematic deviations could be expected and therefore some degree of performance (expert) bias reducing the external validity is likely. Consequently, the method is more valid for comparisons within one expert group than across different research groups in different hospitals. The laxity measurements in extension are very sensitive to the positioning of the knee. If the measurement is performed in hyperextension, the posterior capsule will tighten and block varus/valgus motion. The posterior capsule must therefore be slackened by avoiding hyperextension.

The experiences from this study created a fundament for further research on the effect of ligament balancing on outcome in TKA.

11.5 Paper II

Previous studies that investigated the relationship between ligament laxity and functional outcome performed laxity measurements clinically or radiographically after the operation [157-159]. In order to correct unacceptable results before the end of the surgical procedure, orthopaedic surgeons need information on the relationship between laxity measured intraoperatively and functional outcome.

This is the first study to demonstrate a relationship between ligament laxity measured intraoperatively and functional outcome after TKA. The spatula-method (paper I) was used to measure ligament laxity, and subsequently the association between ligament laxity and functional outcome at one-year follow-up was calculated with a quantile regression model.

The interpretation of the regression coefficient (β) may not be evident to everyone. For that reason, a short explanation follows: The value of the regression coefficient (β) represent the change in outcome score that is induced by one millimeter change in ligament laxity. Moreover, it is repeated that the minimum perceptible clinical improvement in KOOSs is 8–10 points. Thus, it seems that only a 1–2 mm increase in medial laxity may have a clinically significant impact on the subscores in KOOS for ADL, sport/recreation and pain in patients with perfectly aligned or valgus-aligned knees.

Hence, the main findings in this study were that in perfectly aligned and valgus-aligned TKAs, medial laxity more than approximately 2 mm in extension and 3 mm in flexion have statistically significant and clinically relevant negative effect on functional outcome at one-year follow-up. In the varus-aligned knees, the results were not conclusive, however a trend in disfavor of increasing lateral laxity can be suspected. The data also indicate that more laxity is tolerated (or preferred) laterally and in flexion. This opinion is supported by the fact that the native knee is slacker laterally and in flexion [160], and by the fact that lateral posterior femoral rollback require a certain degree of lateral laxity. All taken together, our findings may support a new hypothesis arguing that the ideal gaps in TKA should not be equal and rectangular, but rather trapezoidal and unequal. This standpoint has later been supported by a very recent study by Jacobs et al. who measured medial and lateral ligament tension with an instrumented trial tibial liner in 50 TKAs [161]. They concluded that recreating greater forces in the medial compartment may yield improved patient-reported outcomes.

Some old studies that assessed the effect of ligament balance on outcome found better function in laxer knees [157, 158]. Edwards et al. measured ligament laxity with clinical examination in 50 knees average four years after the index operation. They found a consistent increase in a modified HSS score through categories of laxity from 1° to 15° unilateral laxity in varus or valgus [157]. Kuster et al. measured laxity on stress X-rays at a mean follow up of 4.5 years in 22 patients with bilateral TKA. The results showed that patients with a preferred side felt significantly more comfortable on the laxer side. It should be noted that the laxity measurements in these studies were performed in 20° and 30° of flexion respectively. This might have resulted in an unknown number of knees with poor function due to too much tightness in extension and/or in 90° of flexion. In a more recent study, Okamoto et al. [162] concluded that the extension gap needs more than 1 mm laxity to avoid postoperative flexion contracture. All these findings strengthens the opinion that some laxity is beneficial for the knee function.

The interpretations of the findings in our paper is supported by two recent studies from 2017. Ismalidis et al. [163] stated that a flexion gap increase of 2.5 mm might have a positive effect on postoperative flexion and patient satisfaction after TKA. Furthermore, Tsukiyama et al.[164] measured knee laxity with postoperative stress radiographs in flexion and extension in 50 TKAs. They found that medial rather than lateral knee instability correlates with inferior patient satisfaction and knee function after TKA.

In the present study, all laxity measurements were performed intra-operatively after the implantation of the prosthetic components. The importance of these details is that spreading devices, tensioners and spacer blocs commonly used allow measurements in a non-anatomic and non-physiologic biomechanical situation that might bias the results. For example, using a tensor Muratsu et al. found a decrease of as much as 5.3 mm in joint gap in extension and a reduction of varus ligament imbalance of 3.1° with the femoral trial prosthesis in place compared to measurements without [155]. Recent papers have described new methods combining patient-specific instruments and a balancer device, but also in these studies ligament tension was measured without the prosthetic components implanted [165, 166]. In contrast, the spatula-method allows for laxity measurements with all prosthetic components implanted, that is with the knee in its ultimate biomechanical situation.

The topic of this paper is very complex and the study has some limitations. Functional outcome in TKA is multifactorial, influenced by a large number of known and unknown confounding factors, and the ability of our outcome instruments to register important differences is far from perfect (see discussion in paper V). Consequently, there is a risk for type 2 errors.

Even more evident is the risk of type I errors. Multiple testing was performed on the association between ligament laxity and functional outcome. Out of 40 tests, eight tests were found to be statistically significant. However, we can anticipate that two tests were found to be significant by chance, resulting in a so called “false discovery rate” of 25%. Nevertheless, it is important to bear in mind that all tests were targeted and planned in advance. It is also essential to ask whether our results are plausible. From a clinical standpoint, it seems reasonable to accept that varus alignment may protect patients with modest degrees of medial laxity from medial instability events, at least in patients with low-grade physical activity. This presumption is supported by gait analysis that has demonstrated that the knee adduction moments are correlated with the mechanical axis of the knee [167]. It is likely that the relatively high adduction moments in varus knees reduce the effect of medial laxity. Vice versa, the low adduction moment in valgus knees may contribute to instability in knees with medial laxity. Accordingly, one could expect a negative effect of lateral laxity on varus-aligned knees.

11.6 Paper III

The position of the patella (everted, laterally retracted or in situ) has been shown to influence on the measurements of ligament balance [83-85], but so far it has been unknown whether this effect is of clinical importance for the functional outcome after TKA. We can recall from paper II that only one regression coefficient laterally in flexion was statistically significant (KOOS Symptoms $\beta = -3.0$ ($p = 0.04$)). We also recall that the MPCI in KOOS is 8-10 points, which indicate that at least 2-3 mm additional laxity laterally in flexion is needed to produce a clinically relevant change in the KOOS Symptom score. Therefore, the very small increase of 0.6 mm ($p < 0.001$) in ligament laxity laterally in flexion when measurements were performed with the patella repositioned compared to everted should not be considered clinically relevant. However, on an individual basis the mean values have limited importance. Therefore, a frequency table was included in paper III. The table revealed only one patient (2%) with >3 mm change in laxity laterally in flexion. Taking into account that no other KOOS subscore was statistically significant, the risk for underestimating lateral laxity in flexion is probably negligible.

This study has some limitations. First, all knees were operated with a posterior cruciate retaining prosthesis. The results may not apply to posterior cruciate sacrificing prosthetic designs because the posterior cruciate ligament is known to play a part in medial and lateral laxity. Another possible limitation is that our method to measure ligament laxity is based on manual loading of the ligaments in valgus and varus. This limitation is discussed in paper I.

In a more general context, it is important to understand that the consequences of erroneous measurements of ligament balancing in TKA depend on the surgical technique. If measured resection technique is used, like in our study, ligament balancing performed with the patella everted will lead to underestimation of ligament laxity laterally in flexion; that is, after reduction of the patella lateral laxity in flexion will increase average 0.6 mm. If a pure gap technique is used, and the flexion gap is tensioned with the patella everted, a 0.6-mm over-resection of the posterior lateral femoral condyle will follow, resulting in internal rotation of the femoral component of approximately 0.7°. Theoretically, this results in valgus-malalignment in flexion and lateral tracking of the patella.

11.7 Paper IV

The effect of the surgical trauma induced by ligament balancing on functional outcome after TKA is by far unknown. However, the need for ligament balancing and the extent of ligament releases varies in different alignment- and gap balancing techniques. For that reason, objective data on the effect of the trauma induced by ligament balancing on knee function is of fundamental interest for surgeons that have to choose between mechanical and anatomic alignment and between measured resection and gap-balancing technique.

The findings in this study indicate that the surgical trauma imposed by ligament balancing do not have detrimental effect on knee function 3 years after the operation. Despite the fact that the majority of the ligament-balanced knees had more deformity at baseline than the non-ligament-balanced knees, no negative effect of ligament balancing could be found in our data.

Although TKA has proved to relieve knee pain effectively in most patient with end stage osteoarthritis and inflammatory arthritis, it is well documented that as much as one fifth of TKA patients are unsatisfied with their TKA [23]. The majority of TKAs have until now been aligned according to the principle of mechanical alignment. However, it has been shown that most native knees are slightly varus-aligned [26] and that 32% of men and 17% of women have constitutional varus knees with a natural mechanical alignment of $\geq 3°$ degrees varus [168]. Based on this information, it has been speculated that the reason for dissatisfaction with TKA can be that mechanical alignment does not recreate the patient's premorbid natural alignment [55, 168] and that the increased need for ligament balancing in mechanically aligned varus-knees can be detrimental to the functional outcome [168]. Our findings do not support this theory indicating that the need for additional soft tissue releases is not a valid argument against mechanical alignment in TKA.

Mechanical alignment is still considered a gold standard [34, 35] however, anatomic and kinematic alignment have gained increasing popularity in the last decade [55] and there is an ongoing debate as to what is the best alignment goal. Classical mechanical alignment was introduced in order to secure equal distribution of loads between the medial and lateral compartments of the knee and to reduce shear forces at the interfaces between implants and bone [28, 57, 58]. However, some recent studies have failed to show a relationship between coronal plane alignment and prosthetic survival [32, 33]. Therefore, in the hope of improving knee function after TKA a growing enthusiasm for anatomic and kinematic alignment has emerged. However, an important matter to take into consideration is the ability of current surgical techniques to reach the exact alignment goal. Although outliers from the mechanical axis up to 5°-6° may be acceptable, the same amount of divergence in varus from the natural axis is probably not compatible with long-term survival and good knee function. Consequently, in order to prevent unacceptable outliers, the use of anatomic or kinematic alignment presume surgical techniques with a very high degree of accuracy and precision.

The aim of anatomic and kinematic alignment is to replicate normal knee anatomy more closely and thereby mimic normal knee kinematics [29-31]. However, anatomic alignment does not necessarily lead to more natural knee joint kinematics in TKA. It must be remembered that almost all total knee designs sacrifice one or both cruciate ligaments. The lack of well-functioning cruciate ligaments have profound impact on knee kinematics [59], and non-anatomic design features are needed to compensate for the lack of the cruciate ligament and secure stability. It is therefore the author's opinion that, in the current context, the term kinematic alignment is too optimistic.

If a gap-technique is used instead of measured resection technique, the need for ligament balancing in flexion is reduced [43]. However, in a varus knee this will lead to external rotation of the femoral component and varus alignment in flexion. In a valgus knee, it will result in internal rotation of the femoral component and potential malt racking of the patella and valgus deformity in flexion.

There are some limitations to this study. First, when the study population was subdivided into varus- and valgus-deformed knees the subsequent comparisons between ligament balanced and non-ligament balanced knees are underpowered, increasing the risk of a type 2 error. However, no trends in favor of the non-ligament-balanced knees were observed. Second, we do not know how the ligament-balanced knees would have performed without ligament balancing. Nevertheless, the fact that no differences between the groups were found in change in scores from preoperative to follow-up, and that no correlation was found between increasing numbers of released soft tissue structures and outcome suggest the positive effects of ligament balancing surpass eventual negative effects. Although an RCT could have been preferred, given the huge amount of literature pointing out the importance of proper ligament balancing in deformed knees with soft tissue contractures, it is our opinion that an RCT on this population would be unethical. Third, ligament balancing was performed according to the methods described by Whiteside et al. The results of our study are therefore not valid for other ligament-balancing techniques.

11.8 Paper V

This is the first randomized, double-blind trial that compares patellar resurfacing and non-resurfacing in TKA using KOOS as the primary outcome. The main finding was that according to the primary outcome measure, resurfacing of the patella gave a statistically significant better functional outcome during the 3 years follow-up. The secondary outcome measures did not show a statistically significant difference between the groups. The effect size at 3 years of follow-up in KOOS sub scores was 10 points for sport/recreation, 8 points for QoL, 6 points for pain, and 5 points for symptoms and ADL. The minimal perceptible clinical improvement (MPCI) for KOOS has been suggested to be 8–10 points [118]; therefore, the clinical relevance of the observed effect sizes in our study is disputable.

We found a striking dissimilarity in outcomes measured with the KOOS and with the more classical outcome scores. The reason for this is unclear, but it is remarkable that the sport/recreation sub score in KOOS had the lowest ceiling effect (6.3%) and that very high ceiling effects were found in the KSS function score (48%) and VAS for patient satisfaction (40%) (Table 9). The KSS knee score and the Oxford knee score had near-acceptable ceiling effects, but these items showed small IQRs and relatively small standard deviations, which might indicate clustering of data within a limited fraction of the outcome scales. In contrast, the KOOS sub scores for pain, ADL, and QoL had higher standard deviations and IQRs, indicating less clustering of data and therefore higher discriminative capacity. Terwee et al. [169] suggested that ceiling effects should be considered present in a health status measure if 15% or more of responders report the highest value. However, any ceiling effect is likely to reduce the responsiveness of an assessment tool.

Table 9. Detailed description of the different outcome scores at 3 years follow-up (n=129)

	Range	**Mean**	**Std. Deviation**	**Ceiling effect in %**	**IQR**
KOOS					
Pain 3 years	31-100	87.8	16.3	35.7	18
Symptoms 3 years	32-100	87.8	12.2	18.6	14
ADL 3 years	31-100	85.7	16.9	24.0	23
SportRec 3 years	0-100	61.9	27.6	6.3	45
QOL 3 years	19-100	81.1	21.5	28.7	31
KSS					
Knee score 3 years	31-100	91.0	11.8	16.3	12
Function score 3 years	-10-100	83.3	20.7	47.7	30
Oxford Score 3 years	12-43	17.7	6.5	16.3	8
Satisfaction (VAS) 3 years	10-100	91.1	15.9	40.0	10

KOOS: Knee injury and Osteoarthritis Outcome Score (0-100), 100 is the best score.
KSS: Knee Society Clinical Rating System (0-100), 100 is the best score.
Oxford score: Oxford knee score (12-60), 12 is the best score.
IQR: inter quartile range, ADL: activities of daily living. QOL: knee related quality of life.

Important ceiling effects in the most commonly used outcome measures for total knee surgery have also been reported in previous papers: Jenny et al. [79] tested 100 patients operated on for TKA with more than 1 year of follow-up. They found that the ceiling effect for the KSS was 53%, and 33% for the Oxford Knee score. Na et al. [170] studied 201 well-functioning knees in patients who had undergone primary TKA. The ceiling effect for the KSS knee score was 25% and for the KSS function score 43%. Impellizzeri et al. [171] documented profound ceiling effects from 41% to 67%, and modest floor effects from 10% to 19%, 6 months after TKA for the pain, stiffness, and function subscales in WOMAC. For the Oxford Knee score, these authors found a 27% ceiling effect 6 months after the operation.

Another important issue considering the responsiveness of the KOOS compared to the older KSS and Oxford knee scores is that today's patients tend to be younger and more physically active than in the past. KOOS was developed for patients that are more active. In the sport/recreation sub score, patients are asked about difficulties when squatting, kneeling, running, jumping, and twisting. These are demanding activities, which may explain why only a few patients reach the "ceiling". Thus, it is likely that this measure is better than others to distinguish between patients with high scores.

Fourteen patients in the present study underwent staged bilateral TKA. It has been argued that the principle of statistical independence is violated if left and right side measures within a subject are considered independent. However, the effect of bilateral cases depends on the study design [172]. The present study was randomized and the bilateral cases were equally distributed between the two groups. Furthermore, studies comparing outcome after arthroplasty have concluded that inclusion of bilateral cases does not alter the outcome [173, 174].

Although this level I randomized double-blinded study seems to favor patellar resurfacing, a final question rests. Are the results applicable to the general TKA-population treated by the average TKA-surgeon? In order to answer this question the generalizability of the study must be assessed. As pointed out earlier in this thesis the study was a priori planned to be a relatively pragmatic study. However, this judgement is not straightforward and implies many variables. In order to help clinicians, healthcare funders, and patient to make decisions based on RCTs, new tools have recently been developed [175-177]. The Pragmatic—explanatory continuum indicator summary (PRECIS-2) is a tool that can help researchers designing RCTs and support readers interpreting the study results [176]. PRECIS-2 define nine domains that express the degree of generalizability of a trial. Each domain is scored on a Lickert-scale from 1 to 5, were 1 indicates "very explanatory" and 5 indicates "very pragmatic". The assessment is summarized graphically on a wheel diagram. This diagram offers a rapid overview that enables the researcher or reader to appraise the pragmatic—explanatory continuum for each domain. Although still somewhat subjective, the diagram is a useful fundament for discussions of the applicability of the study. Figure 20 illustrates a PRECIS-2 diagram of the current study.

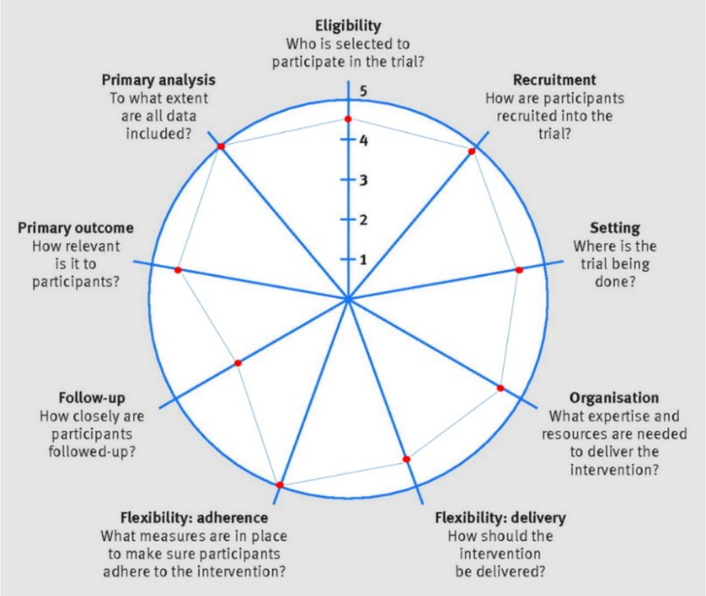


Figure 20. PRECIS-2 wheel-diagram (Pragmatic-Explanatory Continuum Indicator Summary 2). 1 indicate very explanatory and 5 indicate very pragmatic

11.9 Paper VI

The rotational positioning of the femoral component is intimately integrated with ligament balancing, alignment in flexion and patello-femoral tracking. Internal rotation of the femoral component result in slack ligaments on the lateral side, valgus alignment in flexion and lateral tracking of the patella. The opposite is the consequence of external rotation. These mechanisms make the rotational alignment of the femoral component a potential source for many undesired results and complications. Therefore, femoral component rotation is a crucial factor in TKA. Technical innovations including CAOS and PSI were developed to improve alignment in TKA, but so far, these methods have not been shown to improve rotational alignment. The reason for this is unclear, but it seems evident that CAOS does not bring any supplementary information about rotation as long as the information programmed into the computer is delivered from the operating surgeon's hand, which is exactly the same information that would be used in a classical technique. PSI have also not been found superior to conventional techniques in securing correct alignment, probably because of inaccurate fit between the patient specific cutting blocs and the bone.

The literature on this topic is abundant, and the controversies are many. However, when it comes to surgical methods for securing correct rotational alignment of the femoral component only a few studies (Table 10) have compared their results to the accepted gold standard, the CTsTEA [38, 40-42]. None of these methods is perfect.

Table 10. Data from the present and previous studies that compare the rotational alignment of the femoral component to the gold standard (CTsTEA).

Author	**Methode**	**Number of knees**	**Rotational alignment deviation from the gold standard in degrees***		**Comments**
			Mean	**SD (range)**	
Aunan et al. 2017 Acta Orthopaedica	The Clinical rotational axis method (CRA-method)	80	0.2°	1.6° (-3.7° – 3.7°)	
Talbot, Dimitriou et al. 2015 KSSTA	Sulcus line	181	0.6°	2.9° (-7.2° – 6.7°)	28 knees excluded due to poor CT scans, and 19 excluded due to unidentified sulcusline
Inui, Taketomi et al. 2013, J Arthroplasty	Transepicondylar axis, Whiteside axis and the condylar twist angle	26	0.3°	1.7° (-3° – 3°)	Preoperative x-ray in 90° knee-flexion and computer navigation
Luyckx, Peeters et al. 2012 JBJS Am	Gap-technique	48	2.4	2.5° (-2.8° – 6.9°)	Gap-technique
Luyckx, Peeters et al. 2012 JBJS Am	PCL adapted to preoperative CT	48	1.7°	2.1° (-2.5° – 6.5°)	Preoperative CT of the knee
Seo, Moon et al. 2012 KSSTA	Mechanical axis-derived rotational axis	120	1.6°	2.2° (-4.8° – 7.9°)	Preoperative x-rays of both hips. Customized graduated ruler and extramedullary alignment jig

*Positive values represent external rotation and negative values represent internal rotation. PCL: Posterior condylar line

The clinical rotational axis method (CRA-method) is a new method to guide the femoral component into correct rotational positioning developed at our institution. When tested against the gold standard the method was found to be very accurate with mean (95% CI) angular deviation of 0.2° (-0.15°-0.55°) from the gold standard. Even the extreme values of the 95% CI (-0.15° – 0.55°) were close to the supposed gold standard and the small SD (1.58°) indicate a low variability compared to earlier described methods. An important advantage of this method is its simplicity with no need for additional preoperative x-ray or CT-imaging and no need for computer navigation, customized equipment or alignment jigs (Table 10).

A limitation to this study is that the reliability of Berger's method [52] for measuring femoral component rotation on postoperative CT-scans is not perfect. The ICC-values vary considerably between studies, and may depend on whether data are given for single measurements or average measurements, on which statistical model that was chosen and on whether consistency or absolute agreement is reported [154]. This information is missing in many studies, making comparison between studies difficult. In the current study, we have specified the model, type and definition of the ICC.

The first part of this study concluded that the CRA-method is efficacious with a very high degree of accuracy and precision. The second part of the study can be regarded as a safety study because no statistical significant association was found between the degree of malrotation observed in the study and functional outcome at 3 years follow-up. This strong side of the study leads to another limitation of the study: Only three femoral components were malrotated more than 3°, which means that we cannot judge the effect of malrotation at this level. Another limitation to this part of the study is that we used a symmetric tibial platform with fixed bearing and minimal constraint. Our results on functional outcome may therefore not be valid for prosthesis with an asymmetric tibial platform, mobile platform and/or more constraint.

11.10 Paper VII

Many different techniques to guide the tibial component into correct rotational alignment have been described. In order to obtain maximal bony support for the tibial tray some surgeons strive for the best coverage of the proximal tibia [49, 178]. In another method, the so-called self-seeking technique (also called the range-of-motion or dynamic method), the tibial trial component is allowed to rotate spontaneously as the knee is brought through a full range of motion, and thereby secure the most conforming position in relation to the shape and position of the femoral component [47]. A third option is to rotate the tibial tray in line with anatomical landmarks. The mostly used anatomical landmarks are the medial border of the tibial tubercle [45] and the medial third of the tibial tubercle [48]. More recently, other methods have been suggested: the anatomical axis [46], the anteroposterior tibial axis [45] and the posterior condylar axis [179]. The use of extra-articular anatomical landmarks like the second metatarsal of the ankle and the transmaleolar axis of the ankle are essentially abandoned [45].

Comparative studies have shown that the self-seeking method leads to a relative internal rotation of the tibial platform compared to the anatomical landmarks [180]. Another work reported that maximizing tibial coverage resulted in tibial component internal malrotation in a large percentage of cases [181], and that this effect was strongest for symmetric tibial plateau designs.

In our study, the use of anatomical landmarks (the medial third of the tibial tubercle) was the preferred method. Nevertheless, in knees were the surgeon observed a considerable “mismatch” between the tibial and femoral components a modified self-seeking method were used.

Although many methods to secure alignment of the tibial component in the axial plain have been described, only a few studies have focused on the effect of tibial component rotation on functional outcome. A systematic review and correlation analysis by Valkering et al. [50] found a medium positive correlation between tibial component external rotation and functional outcome. The analysis was based on five studies (250 knees) assessed with postoperative CT and the KSS. However, four of the studies included in this correlation analysis [53, 115, 182, 183] investigated selected patients with knee pain after TKA retrospectively and the studies are very heterogeneous. Bell et al. [54] also found internal rotation of the tibial component to be a factor in pain following TKA. They compared the rotational alignment of components in a cohort of 56 patients with unexplained pain following TKA with a matched control cohort of 56 patients. In contrast, a recent study by Thielemann et al. [51] did not find any significant correlation between tibial component malrotation and functional outcome assessed with KSS and KOOS in 55 patients followed for 5-7 years. Similarly, Kawahara et al. [184] found that tibial component malrotation did not affect any of the subscores of the relatively new 2011 KSS. Kim et al. [185] studied the relationship between the survival of TKA at average 16 years and alignment of the prosthetic components. They found that external rotational alignment of the femoral and tibial components less than 2 degrees was a risk factor for failure of the prosthetic components.

The reason for the disagreement between these studies is unclear. In the study by Thielemann et al. [51] the component orientation was not measured with Berger’s method, but it was expressed as the angle between the posterior of the tibial baseplate and the tibial condyles. The agreement between these two methods is unknown. Differences in prosthetic design may also play a role as cruciate retaining and rotating platforms probably are more forgiving for malrotation than more constraint designs. It is also remarkable that most of the earlier studies investigates selected populations with pain and dysfunction after TKA in a retrospective manner. In contrast, our study is a prospective cohort study on an unselected sample recruited consecutively from our daily practice.

The main findings in this study was that all sub-scores in KOOS, the Oxford knee score and the VAS score for patient satisfaction were in favor of knees with neutral or externally rotated tibial platforms. However, 2 out of 7 scores did not reach statistical significance, and one subscore (symptoms) was below the MPCI (Table 6). Our findings are in concordance with those from Valkering et al. [50] and Bell et al. [54] mentioned above.

Interestingly, in our study we found that the preoperative BMI was statistically significant higher (p=0.001) in the group with internally rotated tibial components. The p-value is so low that this observation is probably not due to chance, indicating that there might be a correlation between high BMI and internal rotation of the tibial platform. The reason for this is unknown, but it could be argued that correct rotational alignment of the tibial plateau is technically more difficult in obese patients. Keeping in mind that there is also a week correlation between BMI and functional outcome, a confounding effect of BMI can be suspected.

The reliability of Bergers method [52] to measure tibial platform rotation on CT-scans is a matter of concern. We tested the inter-rater reliability of the method with intra-class correlation (ICC) two way mixed models, absolute agreement, and found that the ICC (95% CI) coefficient for average measurements was 0.77 (0.63–0.85) and for single measurements the ICC (95% CI)) was 0.62 (0.46–0.74). According to Cicchetti [153], Less than 0.40 is poor, between 0.40 and 0.59 is fair, between 0.60 and 0.74 is good and between 0.75 and 1.00 is excellent. The 95% CI for the ICC in our study indicate that the interrater-reliability for average measurements is good to excellent and the interrater-reliability for single measurements is fair to good. The implication of this is that in order to judge the reliability of a method (like in this paper), Bergers technique for measuring the rotation of the tibial component is probably very good. However, when it comes to measurements on a single knee performed by one examiner, the reliability is only fair or good. Consequently, the judgment of rotational alignment on an individual basis should be done with caution. For example, when ruling out the cause of knee pain in a painful TKA the examiner should not rely too much on a single measurement of tibial component rotation performed by one assessor. Our findings are supported by the study of Konigsberg et al. [186] who found the interobserver reliability of two-dimensional CT scan for tibial component malrotation to be 0.67 (0.47-0.80). The authors were concerned about whether CT scan is diagnostic in the assessment of component malrotation after TKA.

The ICC is widely used in orthopaedic research, but the interpretation of the ICC is not straightforward. At least 10 forms of ICC have been described and the reader should focus on the “model”, “type” and “definition” in order to interpret the data [154]. Still, the interpretation of the ICC values is probably not intuitive to all readers. It is the author’s opinion that a histogram or a frequency table may be more informative. The histogram below (Figure 21) demonstrate the difference between the two observers in this study (one radiologist and one orthopaedic surgeon). Table 11 shows the frequency of different degrees of disagreement between the two observers. According to this table, there is a likelihood of 35% that the measurements of two observers differ more than 3° and a likelihood of 15% that the measurements differs more than 5°. As much as 10° or more between observers difference can be assumed in 6% of the knees. This uncertainty must be taken into consideration when a revision is considered based on the measurements of rotational alignment on CT scans.

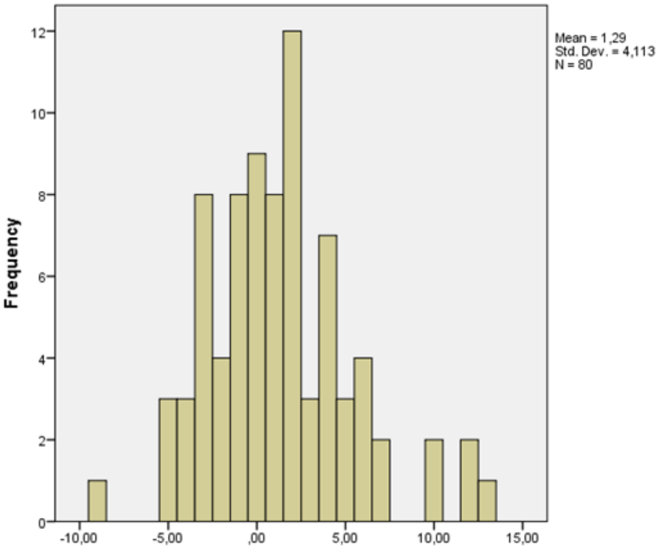


Figure 21. Disagreement between two observers (one radiologist and one orthopaedic surgeon) who measured rotational alignment of the tibial component on CT in 80 knees. Measurements in degrees. Negative values indicate internal rotation and positive values indicate external rotation.

A limitation to this study is that the choice between the modified dynamic method, and the anatomical landmark method was dependent on the surgeons' subjective judgment and that the choice was not registered in advance. Therefore, the study do not prove that one method is better than the other, however, based on clinical experience and earlier literature [180, 181] it is reasonable to assume that the majority of internally rotated tibial components were placed with the modified dynamic method. Another limitation is related to the choice of implant design. We used a cruciate retaining tibial component with fixed platform, and our results may not be true for other prosthetic designs.

A strong side of this study is the relatively high number of knees and the prospective design The big difference in scores between the two groups, demonstrate that internal rotation of the tibial component have a statistically significant and clinically relevant negative effect on functional outcome after TKA. The study also indicates that the dynamic method to guide tibial platform rotation should be avoided, and finally measurement of tibial component rotation performed with ordinary two-dimensional CT on individual patients is not very reliable and should be interpreted with caution.

Table 11. Disagreement between two observers (one radiologist and one orthopaedic surgeon) who measured rotational alignment of the tibial component on CT in 80 knees. The difference in measurements between the observers is given in degrees.

Difference in degrees	Frequency	Percent	Cumulative percent
0	9	11.3	11.3
1	16	20.0	31.3
2	16	20.0	51,3
3	11	13.8	65.1
4	10	12.5	77.7
5	6	7.5	85.3
6	4	5.0	90.3
7	2	2.5	92.8
8	0	0	92.8
9	1	1.3	94.1
10	2	2.5	96.6
11	0	0	96.6
12	2	2.5	99.1
13	1	1.3	100
Total	80	100	100

11.11 Paper VIII

In this study, we found that knees with combined internal rotation of the tibial and femoral components had statistically significant lower outcome scores than knees with combined external rotation of the components. This finding is supported by earlier studies [53, 54], however in the present study, the minimal perceptible clinical improvement (MPCI) for KOOS (8–10 points) was achieved only for sport/recreation and knee related quality of life.

Component rotational mismatch and opposite rotation did not influence outcome in our study. This is in contrast to the findings of Bell et al. [54]. One reason for this controversy may be that we used a cruciate retaining prosthesis and Bell et al. used a posterior stabilized implant that can be considered slightly constrained and thereby induce mechanical conflict between the components when rotated in opposite direction to each other. However, it should be noticed that in our data, there is a trend in favor of rotation in the same direction for all scores, and although the power is 79%, there is an obvious risk of a type 2 statistical error.

We did not find any correlation between component rotation and patellar tilt. So – if not caused by component malrotation, what is the causal mechanism of patellar tilt? It should be emphasized that in the present study population the maximal malrotation of the femoral component was very small (± 3.7°) compared to other studies and a plausible explanation could be that malrotation of the femoral component must exceed 3°- 4° in order to induce patellar tilt. Still, it seems that tibial component rotation has little influence on patellar tilt. In an additional analysis, we found a strong association between patellar tilt and valgus alignment and between patellar tilt and patellar resurfacing (Table 12). Furthermore, eight out of nine severely tilted patellas were in women. This was not statistically significant (p=0.07) but a type 2 error can be suspected. Thus, it is likely that the cause for patellar tilt is multifactorial including preoperative alignment, resurfacing or not of the patella, gender and probably femoral component rotation. It is however remarkable that even pronounced tibial component rotation does not seem to produce patella tilt.

Another possible interpretation of these findings is that patellar resurfacing in some way seems to protect the patient against patellar tilt and thereby from pain and dysfunction. The reason for this is unclear, but it can be argued that the exercise of patellar resurfacing introduce an extra tool to the surgeon that make balancing of the patella-femoral joint easier. For example, residual lateral tracking of the patella after positioning the tibial and femoral components can be corrected by a few mm´s over-resection of the patellar bone and by medializing a relatively small patellar button. It may also be that non-resurfaced patella-femoral joints when tilted, for some reason is more painful. These findings may add to the understanding of the effect of patellar resurfacing in TKA and it may explain to some extent why patellar resurfacing favored functional outcome in paper V.

Table 12. The association between knees with patella tilt >4° and gender, alignment and patellar resurfacing.

	Female/ male	p	Valgus/Varus	p	Without/with patellar component	p*
Patella tilt >4°	8/1	0.07	6/3	0.0007	9/0	0.002

*Fisher exact test.

It should be noticed that our results are in conflict with the findings of Berger et al. [52] who found that combined internal rotation was directly proportional to the severity of patellofemoral complication. Furthermore, Berger stated that small amounts of combined internal rotation (1°-4°) correlated with lateral tracking and patellar tilting, moderate combined internal rotation (3°-8°) correlated with patellar subluxation and large amounts of combined internal rotational (7°-17°) correlated with early patellar dislocation or late patellar prosthesis failure. The reason for the discrepancy between Berger's and our results is unclear, but it is remarkable that Berger investigated a highly selected group of patients with isolated patellofemoral complications already scheduled for revision arthroplasty. This is also the case in other previous studies [53, 54] that investigated the relationship between component rotation, patellar tilt and outcome. A common characteristic in all these previous studies is that the patients' outcome was known in advance and a retrospective analysis were performed in order to find a causal variable. In contrast, in our study, a prospective analysis were performed on 80 unselected consecutive knees.

Table 13. Outcome scores at 3 years follow-up in knees with patella tilt ≤ 4° and in knees with patella tilt > 4°

	Patella tilt ≤ 4° (n=71)	**Patella tilt > 4°** (n=9)	p*
KOOS			
Pain	97	67	0.001
Symptoms	93	71	0.002
ADL	94	76	0.012
Sport/Rec	70	35	0.007
QOL	94	56	0.002
OKS	15	22	0.008
Patient satisfaction	99	90	0.001

*Mann-Whitney U test

The last finding in this study was that knees with more than 4° patellar tilt had much worse outcome than knees with less patella tilt (Table 13). The number of knees was small, but the p-values very low, indicating that the findings are not due to chance. However, the effect size is so great that confounding must be suspected. As demonstrated in table 12 additional analysis revealed that all knees with more than 4° patellar tilt had their patellas non-resurfaced and valgus alignment was dominating. However, alignment was not correlated with outcome in this material, indicating that alignment is not a confounder, but it seems that non-resurfacing of the patella is a confounding variable that adds to the negative effect of patellar tilt on outcome.

12 Conclusions

The spatula method designed to measure ligament laxity intraoperatively **(paper I)** is reliable, simple, and easy to use. It provides valuable information when assessing ligament laxity intra-operatively. The method has proved to be useful in the research on the relationship between ligament laxity and knee function. Given the results in paper II, the spatula method can be recommended in order to enable surgeons to perform ligament balancing based on more objective data, and thereby avoiding complications due to poor ligament balance.

In **paper II**, postoperative varus/valgus alignment was found to interact on the association between ligament laxity and functional outcome. In order to improve the functional outcome after TKA, orthopaedic surgeons should monitor mechanical axis and ligament laxity intraoperatively and avoid medial laxity more than 2 mm in extension and 3 mm in flexion in neutral and valgus-aligned knees. Varus-aligned knees seem to be more forgiving for medial laxity.

In **paper III**, a statistically significant increase of 0.6 mm in ligament laxity laterally in flexion was found with the patella repositioned compared to everted. No differences were found in extension or medially in flexion. Based on the results from paper II and III, it can be concluded that the effect of patellar eversion on ligament laxity measurements is too small to be considered clinically relevant.

In **paper IV**, no negative effect of ligament balancing on knee function after 3 years was observed, indicating that the need for additional ligament balancing is not a valid argument against mechanical alignment and measured resection technique.

In the double-blinded randomized controlled trial **(paper V)**, the primary outcome measure (KOOS) indicated that patellar resurfacing is beneficial for knee function in TKA during the first 3 years follow up. The secondary, classical outcome measures, including KSS, Oxford knee score and patient satisfaction recorded on a VAS, did not reveal any statistically significant differences between the groups. This study also point out unacceptably high ceiling effects for the KSS function scores and the VAS score for patient satisfaction. These findings indicate that the conclusions from earlier studies that used only classical outcome measures may be questionable, and that future investigations should include assessment tools with limited ceiling effects, which are responsive enough to discriminate between active patients performing demanding activities in their daily lives.

The CRA-method for rotational alignment of the femoral component in TKA described in **paper VI** appeared to be simple, safe, accurate and precise. Additionally, malrotation of the femoral component within ±3.7 ° did not affect outcome 3 years after TKA. The CRA-method should be recommended in order to avoid complications like postoperative pain, patellofemoral mal-tracking and malalignment in flexion.

Internal rotation of the tibial component has a statistically significant and clinically relevant negative effect on functional outcome after TKA **(paper VII)**. The rotation of the tibial component should be guided by bony landmarks (medial third of the tibial tubercle) rather than by a dynamic self-seeking technique. Berger's method to measure tibial component rotation on individual patients is not very reliable and the results should be interpreted with caution.

In **paper VIII**, we concluded that 1) Combined internal rotation of the femoral and tibial components have statistically significant negative effect on functional outcome. 2) Opposite rotation and mismatch of the femoral and tibial components did not affect functional outcome. 3) It was no statistically significant correlation between individual, combined or opposite malrotations and patella tilt. 4) Patella tilt correlated negatively with the KOOS subscores for pain, symptoms, quality of life and for patient satisfaction. In knees with more than 4° patella tilt all outcome scores were statistically significant and clinically relevant lower than in knees with 4° or less patella tilt. There was a strong association between patella tilt and preoperative valgus alignment and between patellar tilt and patellar resurfacing.

13 Future areas of research in TKA

Knee osteoarthritis is one of the leading causes of global disability [7]. Although TKA is a good treatment option for painful end stage osteoarthritis and inflammatory arthritis, it does not reproduce normal knee function in all patients. Moreover, TKA can result in serious complications and end up with wear and loosening of the implants. Therefore, cartilage repair and prevention of osteoarthritis is the ultimate goal. Tissue engineering and gene therapy represent future options for treatment of cartilage disease. Tissue engineering have been in clinical use for many years by means of autologous chondrocyte implantation combined with scaffolds and growth factors, but there are still serious concerns regarding the efficacy of these procedures [187]. So far, gene therapy focus on identification of important genes, methods of transfer, target cells, and expression control. However, studies using gene therapy to prevent OA in animal models are limited [188, 189]. As long as prevention of OA fail and recreation of damaged hyaline cartilage is impossible, there is still a need for surgical treatment of knee OA, and the demand for TKA is expected to grow.

The number of TKAs have increased steadily the last decades [21], and by 2030, the demand for primary total knee arthroplasties in the USA is projected to grow to 3.48 million procedures per year [190]. The burden of revision total knee surgery is expected to increase equally [190].

Further development in reconstructive knee surgery should focus on innovations in prosthetic design, surgical technique, computer assistance and robotics. Additionally, wear characteristics of different materials and their immunological interactions with human tissues are important factors in TKA research. Innovative study designs and valid outcome measures are essential in order to disclose real changes in outcome when different treatments are compared.

The majority of the existing TKA designs sacrifice one or both cruciate ligaments. However, the cruciate ligaments are essential for normal knee kinematics, and the potential for improved function in anterior and /or posterior cruciate sacrificing designs may be limited. Continued development of bicruciate retaining designs may open new opportunities to mimic natural knee function.

Anatomic and kinematic alignment techniques are interesting options with the potential of improving outcome in TKA. Careful follow-up with radio-stereometric analysis (RSA) is mandatory in order to disclose complications due to changes in force transmission through the knee and increased share forces on the interfaces.

Ligament balance is typically measured as ligament laxity or as ligament tension. Tension and laxity are mutually exclusive concepts and there is a need for studies that clarify the association between ligament laxity and tension and whether the two concepts lead to different outcomes. Another challenge in ligament balancing is the lack of fine-tuned predictable ligament balancing techniques.

The results from computer assisted orthopaedic surgery (CAOS) are conflicting. Nevertheless, some very recent studies report better pain relief and function, and superior accuracy in implant positioning after CAOS compared to conventional techniques [106, 108]. Patient specific instruments (PSI) have not generated obvious benefits until now [110, 111]. A problem with the PSI-methods is the lack of perfect match between the PSI and the patient's knee. This problem can probably be by-passed with the development of more sensitive CT and MRI technology.

Robotic surgery has been available for a decade. It has the potential of improving accuracy and precision, and to control a high number of variables. However, it has not been shown to improve patient outcomes and further research is needed [114, 191].

The stiff and painful prosthetic knee is an unpleasant enigma for a few patients and all total knee surgeons. The etiology of this devastating complication is probably multifactorial. From a surgical point of view, investigations on the relationship between ligament tension and neurologic response is an interesting matter. The etiology should also be searched for in the field of biology, immunology and genetics.

As discussed earlier in this thesis, some classical outcome measures have limited responsiveness and the conclusions from earlier studies that used these classical tools may be questionable, especially when considering non-significant or nearly significant results. There is a need for better outcome assessment tools, which are valid, reliable, without ceiling effects, and responsive enough to discriminate between active patients performing demanding activities in their daily lives.

Pragmatic study designs are often preferred in order to increase the generalizability of a study. However, patients undergoing TKA are very heterogeneous with wide ranges in age, BMI, comorbidities, activity level and expectations. This diversity induce much statistical noise (confounding, bias and interaction) that might blur out important differences between treatment groups. Future studies should be designed and powered to allow stratification of subjects, into groups with different expectations and demands. Moreover, if an explanatory study performed in a highly specialized environment demonstrate important differences between a traditional surgical technique and a new more complex treatment option, and a pragmatic study does not, it is not evident that the new complex method should be abandoned.

Good knee function depends on complex interactions between anatomic, physiologic, biomechanical and psychologic factors. More complex, scientific approaches including collaboration with other specialties may be needed in order to improve the results of total knee surgery.

14 References

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15 Norske sammendrag (Abstracts in Norwegian language)

15.1 Innledning

Totalproteseoperasjon i kneleddet (engelsk: Total Knee Arthroplasty (TKA) eller Total Knee Replacement (TKR)) innebærer at de ødelagte leddflatene i kneleddet erstattes av kunstige leddflater som er bygget opp av stållegeringer, titanlegeringer og kryssbundet polyetylen med svært høy molekylvekt. I tillegg korrigeres deformiteter i skjelettet, leddbånd, leddkapsel og sener. TKA kan tilbys pasienter med smerter og dårlig knefunksjon på grunn av artrose (slitasjegikt) eller andre skader eller sykdommer som har ødelagt kneleddet. En viktig forutsetning er at andre mindre inngripende behandlingsmetoder ikke har hatt tilfredsstillende effekt. TKA har i løpet av de siste 40 årene utviklet seg fra å være en svært risikabel operasjon med usikkert utfall til å bli en relativt forutsigbar prosedyre der de fleste pasientene får et godt resultat.

TKA er en stor og ressurskrevende operasjon som utføres av høyt spesialisert personell. I 2017 ble det gjort ca. 7000 kneproteseoperasjoner i Norge og på verdensbasis gjøres anslagsvis en million operasjoner per år. Antallet øker raskt og det forventes fortsatt rask vekst på grunn av fedmeepidemien og økende andel gamle mennesker i befolkningen. Det forventes også en sterk økning i antall operasjoner i den fjerne Østen og i utviklingsland der økonomien vokser.

Resultatet av TKA bedømmes ut i fra ulike parametere. Tradisjonelt har det blitt lagt størst vekt på proteseoverlevelse, det vil si hvor lang tid det går fra protesen blir operert inn til den må skiftes eller fjernes på grunn av slitasje, løsning eller andre komplikasjoner. Nasjonalt register for leddproteser på Haukeland universitetssykehus har registrert nesten alle kneproteseoperasjoner operert i Norge siden 1994 og utgir årlige rapporter om proteseoverlevelse og et stort antall andre viktige parametere relatert til primære og sekundære proteseoperasjoner. Tilsvarende kvalitetsregistre finnes nå etter hvert også i mange andre land. Registerdataene sier oss imidlertid svært lite om hvordan det kunstige kneet fungerer og hvordan pasienten opplever det nye kneet. Dette vurderes best ved hjelp av tester, ytelsesmålinger og såkalte pasientrapporterte utfallsmålinger (engelsk: Patient Reported Outcome Measures (PROMs)). Forskning på kneets biologi og biomekanikk samt forskning for å utvikle bedre proteseimplantater og bedre kirurgisk teknikk har ført til store fremskritt. Allikevel, på tross av omfattende forskning gjennom mange tiår er det vist at 15%-20% av pasientene ikke oppnår et tilfredsstillende resultat etter TKA.

Etter mange år med klinisk arbeid og litteraturstudier forstod jeg at mange viktige beslutninger under operasjonene måtte gjøres på grunnlag av subjektive vurderinger fordi det ikke fantes evidensbasert kunnskap. De mest iøynefallende problemene i min praksis omfattet ligamentbalansering, patellofemoralleddet og protesekomponentenes rotasjonsstiling i horisontalplanet. I en betydelig andel av de mislykkede operasjonene er årsaken knyttet til de ovenfor nevnte problemene. Det var derfor rimelig å anta at man ved å utvikle mer objektiv kunnskap innenfor disse områdene ville kunne redusere antall mislykkede operasjoner.

I 2007 startet jeg derfor planleggingen av en serie studier som søkte å finne svar på følgende spørsmål:

1. Hvordan kan ligamentlaksitet måles peroperativt på en enkel, praktisk og reproduserbar måte?
2. Finnes det en sammenheng mellom ligamentlaksitet målt under operasjonen og pasientenes knefunksjon etter ett år, og er det mulig å komme frem til objektive anbefalinger for hvor løst eller stramt et protesekne bør balanseres under operasjonen?
3. Påvirkes ligamentlaksitetsmålingene av hvorvidt patella er evertert eller ikke under operasjonen?
4. Er det kirurgiske tilleggstraumet som ligamentbalansering påfører pasienten skadelig for knefunksjonen?
5. Bør patellas leddflate rutinemessig skiftes ut under totalproteseoperasjon?

6. Hvordan kan man best sikre at femurkomponenten kommer i riktig rotasjonsstilling i horisontalplanet, og hvordan er sammenhengen mellom rotasjonsstillingen og knefunksjonen etter operasjon?
7. Hvordan kan man best sikre at tibiakomponenten kommer i riktig rotasjonsstilling i horisontalplanet, og hvordan er sammenhengen mellom rotasjonsstillingen og knefunksjonen etter operasjon?
8. Hvordan påvirker ulike kombinasjoner av rotasjonsfeilstillinger i protesekomponentene pasientens knefunksjon, og hvilken betydning har patellas posisjon?

Svarene på disse spørsmålene fremkommer i 9 sammendrag (abstracts) som her er gjengitt nedenfor og som tidligere er presentert på Norsk Ortopedisk forenings høstmøter i form av foredrag. Innholdet i disse resymeene representerer en kortversjon av denne avhandlingen som legges frem til vurdering for en Dr. Philos grad ved Universitetet i Oslo.

15.2 Spatelmetoden, en ny metode for intraoperativ måling av ligamentbalanse i kneproteser. Validering og resultater av laksitetsmålinger i 100 knær

Eirik Aunan, Kirurgisk avdeling, Sykehuset Innlandet, Lillehammer. Thomas Kibsgård, John Clarke-Jenssen, Stephan M Röhrl, Oslo Universitetssykehus

Bakgrunn: Riktig ligamentbalanse anses som en forutsetning for god funksjon og proteseoverlevelse etter total kneprotesekirurgi (TKA), men det er ikke enighet om hvordan ligamentbalansen best kan måles under TKA. Graden av stabilitet man kan forvente å oppnå etter ulike balanseringsteknikker er for det meste ukjent.

Hensikt: Denne studien presenterer en ny metode for å måle ligamentbalanse intraoperativt i TKA. Metodens inter-observer reliabilitet og resultater fra en utprøving av metoden på 100 kneproteseoperasjoner presenteres.

Metode og pasienter: Polyethylen-spatler med ulike tykkelser ble benyttet til å måle medial og lateral ”condylar lift-off” i ekstensjon og fleksjon i 70 ligamentbalanserte knær og i 30 knær der ligamentbalansering ikke var nødvendig. Inter-observer reliabilitet for den nye metoden ble beregnet ved hjelp av intraclass korrelasjons koeffisient. Graden av medio-lateral symmetri i ekstensjon og fleksjon samt likheten mellom ekstensjons-gap og fleksjons-gap ble kalkulert.

Resultater: Metoden viste seg å være enkel i bruk under alle operasjonene. Inter-observer reliabiliteten var svært god med en intraclass korrelasjonskoeffisient på 0,88. Det var ingen signifikant forskjell i condylar lift-off mellom ligamentbalanserte og ikke ligamentbalanserte knær, men det var en tendens til flere ”outliers” i fleksjon i gruppen som ble ligamentbalansert.

Diskusjon: Det kan hevdes at manuell belastning av ligamentene ikke gir en nøyaktig og reproduserbar oppstramming av ligamentene, men en tidligere studie på effekten av sekvensiell lateral ligament-frigjøring der det ble utført både instrumentell og manuell belastning av ligamentene viste at manuell oppstramming ga reproduserbare mål for lateral condylar lift-off (La Prade et al. JBJS am, 2008). Validering av en ny metode bør helst foregå mot en gullstandard. Det er vår oppfatning at en slik ikke finnes for måling av condylar lift-off. Spacere, tensjons-instrumenter og elektroniske apparater måler gapene i en svært ufysiologisk biomekanisk situasjon uten hele protesen implantert. En studie av Muratsu et al. (Clin. Biomech. 2010) viste en svært stor endring av ekstensjonsgapet og varus-valgus balansen før og etter implantasjon av femurkomponenten. Laksitetsmåling med computer navigasjon er nærliggende, men det er vår erfaring at denne metoden overestimerer laksiteten, kanskje på grunn av benvevets visco-elastiske egenskaper.

Konklusjon: Den nye metoden (spatelmetoden) er reliabel og gir kirurgen verdifull intraoperativ informasjon om ligamentbalansen i protesekneet. Metoden er også et nyttig verktøy i videre forskning på sammenhengen mellom ligamentbalanse, knefunksjon og proteseoverlevelse.

15.3 Ligamentær laksitet målt intraoperativt påvirker funksjonsskår etter totalprotesekirurgi i knær

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Bakgrunn: Det finnes lite kunnskap om hvilken betydning ligamentær laksitet har på de funksjonelle resultatene etter totalproteseoperasjon i kneleddet (TKA) og det finnes ingen godt dokumenterte anbefalinger for hvor stramt en total kneprotese bør balanseres. Graden av ligament-laksitet avgjøres fremdeles i stor grad av kirurgens personlige preferanse, og praksis er svært ulik.

Hensikt: Målet ved denne studien var å beregne sammenhengen mellom ligament-laksitet målt intraoperativt og funksjonelle resultater etter ett år.

Metode og pasienter: Ved hjelp av Spatelmetoden ble medial og lateral ”Condylar lift-off” i ekstensjon og 90° fleksjon målt peroperativt i 122 konsekutivt opererte TKA (Nexgen® CR, bakre korsbåndsbevarende, fixed plattform). Gjennomsnittlig alder var 70 år (42-83). Alle pasienter ble skåret preoperativt og etter ett år med Knee Injury and Osteoarthritis Outcome Score (KOOS), Oxford Knee Score, Knee Society Score (KSS) og pasienttilfredshet. Quantil median regresjonsanalyse ble utført i STATA® for å beregne sammenhengen mellom peroperative laksitetsmål og resultatmål ved ett-års kontroll.

Resultater: Mekanisk akse (varus-valgus) målt ved ett-års kontrollen viste seg å være en signifikant effektmodifikator. Materialet ble derfor splittet i to: Knær med nøytral akse eller valgusakse (n = 58) og knær med varusakse (n=64). Kjønn, BMI og alder var ”confounders” og ble justert for i analysen. I knær med nøytral akse eller valgusakse var condylær lift-off medialt i ekstensjon og fleksjon en negativ prediktor for alle fem subskårene i KOOS. Medialt i ekstensjon var regresjonskkoeffisientene statistisk signifikante for Smerte (c=-5,9) (p=0,006), ADL (c=-7,3) (p<0,001) og Sport/Rekreasjon (c=-6,9 (p=0,017). Medialt i fleksjon var koeffisientene signifikante for ADL (c=-3,1) (p=0.023) og Sport/Rekreasjon (-4,2) (p=0,042). Condylær lift-off lateralt i ekstensjon og fleksjon var ikke signifikante prediktorer for funksjonsskår. Det var ingen systematisk, signifikant sammenheng mellom laksitetsmål og funksjonsskår for knær med varusakse. KSS, Oxford score og tilfredshet ble ikke signifikant påvirket av laksitetsmålene.

Diskusjon: Tradisjonelt har målet for ligamentbalanseringen vært rektangulære og like store fleksjons- og ekstensjonsgap. Denne studien antyder at sammenhengen mellom gapenes geometri og knefunkjonen er mer sammensatt og blant annet avhengig av ekstremitetens mekaniske akse.

Relevans/Konklusjon: Den minste klinisk interessante effekten av subskårene i KOOS er 8 poeng. Det betyr f. eks. at 1-2 mm økning i medial laksitet i ekstensjon predikerer et klinisk signifikant dårligere resultat hos pasienter som har endt opp med perfekt mekanisk akse eller en lett valgusdeformitet. Dette er antagelig den første studien som dokumenterer effekten av condylær lift-off målt intraoperativt på funksjonelle resultater etter TKA. Ved ligamentbalansering av TKA bør kirurgen sikte mot medial laksitet fra 1 til 2-3 mm.

15.4 Eversjon av patella under ligamentbalansering av totalproteser i kne medfører ikke klinisk relevante forskjeller i ligamentlaksitet

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Innledning: Riktig ligamentbalanse er avgjørende for god knefunksjon og proteseoverlevelse etter totalproteseoperasjon i kneleddet. Ligamentbalansering blir ofte utført med patella evertert, men effekten av patellaeversjon på ligamentlaksiteten er lite kjent og ingen har tidligere vist om denne effekten er klinisk relevant. Hensikten med denne studien var å måle effekten av patellaeversjon på medial og lateral ligamentlaksitet i ekstensjon og fleksjon, og å finne ut om den har en klinisk relevant betydning.

Pasienter og metoder: Totalt 49 knær (27 hos kvinner) med gjennomsnitts alder 70 år (42-83) og gjennomsnitts BMI på 28,5 kg/m² (22-38) ble operert konsekutivt med en bakre korsbåndsbevarende protese (Nexgen CR). Medial og lateral ligamentlaksitet ble målt i ekstensjon og 90° fleksjon ved hjelp av en nylig validert metode (spatel-metoden). Målingene ble gjort etter at protesen var implantert, først med patella evertert, deretter med patella reponert. Forandringene i fleksjonsgapets og ektensjonsgapets høyde samt gapenes inklinasjon ble så beregnet. Basert på tidligere forskningsresultater ble så den minste interessante forskjellen i ligamentlaksitet sammenliknet med funnene i denne studien.

Resultater: Målinger med patella reponert viste en statistisk signifikant økning på 0,6 mm (p<0,001) i lateral laxitet i fleksjon i forhold til når målingene ble gjort med patella evertert. Ingen statistiske signifikante forskjeller ble funnet i ekstensjon eller medialt i fleksjon. Tilsvarende, beregnede endringer i fleksjonsgapet var 0,4 mm (p<0,001) økning i høyde og 0,6° (p=0,002) økning i varusinklinasjon. Vi har i tidligere forskning vist at 1-2 mm økning i medial laxitet kan føre til klinisk relevant reduksjon i knefunksjon 1 år etter TKA, og at lateralsiden er mer tilgivende for endringer i laksitet.

Diskusjon: «Measured resection teknikk» ble benyttet i denne studien. Resultatene kan ikke uten videre anvendes dersom man bruker en ren «gap teknikk», fordi feilmålinger i ligamentlaksitet da vil få andre konsekvenser som akseendringer og skjev sporing av patella.

Betydning/relevans: Effekten av patellaeversjon på ligamentlaksiteten rundt kneleddet er så liten at den antagelig ikke påvirker knefunksjonen etter TKA.

15.5 Ingen skadelig effekt av ligamentbalansering på knefunksjonen etter totalprotesekirurgi. En prospektiv kohort studie på 129 knær operert med mekanisk alignment

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Innledning: Ligamentbalansering anses som en avgjørende faktor ved totalprotesekirurgi i kneleddet (TKA) for å sikre stabilitet, bevegelighet, lang proteseoverlevelse, og for å unngå smerter. Ligamentbalansering innebærer et ekstra kirurgisk traume og enkelte kneprotesekirurger har ment at dette traumet kan forårsake redusert funksjon i proteseleddet. Behovet for ligamentbalansering kan reduseres ved å sikte mot anatomisk eller kinematisk alignment fremfor tradisjonell mekanisk alignment. En ulempe ved anatomisk og kinematisk alignment er ulik vektoverføring mellom mediale og laterale leddkammer, og større skjæringskrefter mellom ben og protese, noe som på lengre sikt kan føre til økt slitasje og redusert levetid for protesen. Ingen tidligere studier har undersøkt om ligamentbalansering kan bidra til redusert funksjon i proteseleddet.
Målet ved denne studien var å sammenlikne knefunksjonen i proteseknær med og uten ligamentbalansering, og å finne ut om økende grad av ligamentfrigjøring reduserer funksjonsnivået.
Pasienter og metode: 130 knær ble operert konsekutivt. En pasient trakk seg fra studien. I 86 knær ble det utført ligamentbalansering a.m. Whiteside. I 43 knær ble ligamentbalansering ansett som unødvendig. Pasientenes knefunksjon ble vurdert før operasjonen og 3 år etter operasjonen med Knee injury and Osteoarthritis Outcome Score (KOOS) og Oxford Knee Score (OKS). Ved 3-års kontrollen ble også pasienttilfredshet (VAS) registrert.
Resultater: Før operasjon var det i gruppen varusknær større grad av deformitet blant ligamentbalanserte enn blant ikke ligamentbalanserte ($p = 0.01$). I gruppen valgusknær var det ingen slik forskjell. I gruppen med ligamentbalansering ble det frigjort gjennomsnittlig 2 (1-4) ligamentstrukturer per kne. For hele materialet var det ved 3-års kontrollen ingen statistisk signifikant forskjell i KOOS, OKS eller pasient-tilfredshet (VAS) mellom ligamentbalanserte og ikke ligamentbalanserte knær. Det ble hellere ikke påvist noen forskjell i endring av skår fra preoperativt til 3-års kontrollen mellom de to gruppene. Det ble så gjort separate analyser for varus- og valgusknær, uten at det ble det påvist noen forskjell mellom gruppene. Det var heller ingen korrelasjon mellom økende antall frigjorte ligamentstrukturer på den ene siden og KOOS, OKS eller pasienttilfredshet på den andre siden.
Diskusjon: Effekten av ligamentbalansering på knefunksjon er vanskelig å studere fordi man ikke vet hvordan utfallet ville blitt uten ligamentbalansering og fordi en randomisert undersøkelse på betydelig deformerte knær antagelig vil være uetisk. Denne studien viser at ligamentbalanserte knær skårer like godt som ikke balanserte knær etter 3 år. Dette på tross av at de balanserte knærne hadde større deformitet préoperativt. Det er velkjent at manglende ligamentbalansering kan føre til instabilitet, smerter, redusert bevegelighet og tidlig proteseløsning.
Betydning/Relevans: Det synes derfor rimelig å konkludere med at riktig utført ligamentbalansering a.m. Whiteside ikke har relevante skadelige effekter som kan trumfe de positive effektene av ligamentbalanseringen.

15.6 Implantasjon av patellakomponent gir bedre knefunksjon etter totalproteseoperasjon. En prospektiv, randomisert og dobbelt blind undersøkelse med 3 års oppfølging.

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Innledning: Bruken av patellakomponent ved totalprotesekirurgi i knær (TKA) varierer fra 2% til 98% i ulike land. Dagens kunnskap om effekten av patellakomponent på smerte og knefunksjon etter totalprotesekirurgi i knær (TKA) er basert på randomiserte, kontrollerte studier som anvender relativt gamle, klassiske skåringsverktøy som Knee Society Score (KSS), Hospital for Special surgery score (HSS) og Western Ontario and McMaster Osteoarthritis Index (WOMAC). I den senere tid har det blitt stilt spørsmål om disse og andre verktøys evne til å skille mellom gode og veldig gode resultater. Hensikten med denne studien var å sammenlikne resultatene etter TKA med og uten patellakomponent ved hjelp av 4 ulike skåringsverktøy. I tillegg beregnet vi takeffekter og interquartile range (IQR) ved 3-års kontrollen for alle skåringsverktøyene.

Pasienter og metoder: 129 knær hos 115 pasienter med gjennomsnitts alder 70 år (42 til 82), derav 67 kvinner (58 %) med kneleddsartrose ble inkludert i denne dobbelt blindede, randomiserte kontrollerte studien som ble gjennomført i henhold til CONSORT-reglene. Pasientene ble randomisert til TKA med eller uten implantasjon av patellakomponent ved hjelp av en internettbasert randomiseringstjeneste like før operasjonsstart. Alle pasienter fikk implantert Nexgen® CR totalprotese gjennom medial parapatellar tilgang. I gruppen med patella ble patellakomponenten satt inn med «onlay» teknikk. I gruppen uten patellakomponent ble det fjernet osteofytter.

Primært effektmål var Knee injury and Osteoarthritis Outcome Score (KOOS). Sekundære effektmål var KSS, Oxford knee score og pasienttilfredshet (VAS). Alle pasienter ble undersøkt og skåret dagen før operasjon, ved 1-års kontroll og ved 3-års kontroll av en blindet undersøker. Resultatene i de to gruppene ble så sammenliknet ved hjelp av «repeated measures mixed models» analyser.

Resultater: Alle subskårene i KOOS gikk i favør av implantasjon av patellakomponent: Sport/Rekreasjon ($p = 0.014$), smerte ($p = 0.022$), kne-relatert livskvalitet ($p = 0.027$), symptomer ($p = 0.041$) og aktiviter i hverdagen ($p = 0.058$). Det var ingen statistisk signifikant forskjell mellom gruppene for KSS, Oxford knee score eller pasient-tilfredshet. Flere av skåringsverktøyene viste betydelig takeffekter.

Diskusjon: Det var en påfallende diskrepans mellom resultatene målt med KOOS og de klassiske skåringsverktøyene. Dette kan blant annet skyldes høye takeffekter i de klassiske verktøyene.

Betydning/Relevans: KOOS tyder på at patellakomponent bør implanteres ved primær, bakre korsbåndsbevarende TKA hos artrosepasienter.

15.7 En enkel metode for presis og nøyaktig bestemmelse av femurkomponentens rotasjon i total kneprotesekirurgi

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Innledning: Den CT-påviste kirurgiske transepicondylære akse (sTEA) ansees av de fleste som gullstandard for kneets rotasjonsakse. Peroperativt kan denne aksen være vanskelig å lokalisere, og et stort antall anatomiske og dynamiske surrogatakser (referanselinjer) har derfor blitt foreslått. De mest brukte linjene er sTEA, bakre condyllinje (PCL) og anterior-posterior aksen (APA) (Whitesides linje). Mange studier har vist at disse linjene er lite reproduserbare og at femurkomponentens plassering i axialplanet (rotasjon) derfor kan bli feil og medføre problemer for pasienten. Målsetting: Vi ønsket å evaluere presisjon og nøyaktighet av vår egen metode for rotasjonsbestemmelse av femurkomponenten under totalproteseoperasjon i kneledd (TKR).

Materialer og metoder: Rotasjonen av femurkomponenten beregnes under operasjonen ved at vi tegner opp sTEA, APA og til slutt PCL+3° på distale femur. Teoretisk skal da sTEA og PCL+3° være parallelle og APA skal stå vinkelrett på disse. Dersom dette er tilfelle aksepteres målene og benkuttene fullføres. Dersom bare to linjer stemmer over ens utelukkes den tredje. Dersom alle linjer gir forskjellig resultat velges den midterste. Dersom det foreligger grov hypoplasi eller blankskurt ben på en eller begge bakre femurcondyler utelukkes PCL fra beregningen. 80 knær (46 kvinner) operert konsekutivt med TKR fikk utført CT undersøkelse tre år etter operasjonen. Pasientenes gjennomsnittsalder var 69 år. Det var 65 varusknær med 1°- 22° deformitet, 14 valgusknær med 2°-13° deformitet og ett nøytralt kne. Femurkomponentens rotasjon ble målt på CT bilder av 3 ulike observatører. Først tegnet man sTEA på CT-bildene, deretter fellestangenten til femurkomponentens to "pegger". Vinkelen mellom de to linjene ble så målt. Inter-rater-reliabilitet for målingene ble beregnet med intraclass correlasjonskoeffisient (ICC) "two-way mixed model". Gjennomsnittsverdien for målingene ble så brukt til å beregne presisjon (uttrykt som SD og spredning) og nøyaktighet (uttrykt ved gjennomsnittlig avvik fra sTEA) av plasseringen av femurkomponenten.

Resultater: ICC (95% CI) for rotasjonsmålingene var 0,62 (0,51-0,72) for enkeltmålingene og 0,83 (0,76-0,89) for gjennomsnittsmålingene. Femurkomponentens gjennomsnittlige rotasjon i forhold til sTEA var 0,2° (utrotasjon) med en standarddeviasjon på 1,6 og spredning fra -3,7° til 3,7°. Det var ingen "outliers".

Diskusjon: Vår metode for beregning av femurkomponentens rotasjon viste seg svært nøyaktig og presis i forhold til tidligere rapporterte data. Det kan skyldes at vi anvender informasjon fra flere referanselinjer og at vi ser bort fra informasjon som er åpenbart usikker.

Betydning/relevans: For å oppnå høy grad av nøyaktighet og presisjon ved bestemmelse av femurkomponentens rotasjon i TKR bør kirurgen kombinere informasjon fra sTEA, APA og PCL.

15.8 Påvirker små rotasjonsfeil i femurkomponentens plassering knefunksjonen etter totalproteseoperasjoner i kneledd?

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Innledning: Femurkomponentens rotasjon i axialplanet anses som en avgjørende faktor for god knefunksjon og proteseoverlevelse etter totalproteseoperasjon i kneledd (TKR). Rotasjonen påvirker gap-symmetrien og derfor også ligamentbalansen og stabiliteten. Feilrotasjon kan også medføre skjev sporing av patella og medfølgende smerter, subluksasjon eller luksasjon. Videre gir feilrotasjon akseavvik i fleksjon med mulig økt plastslitasje og redusert proteseoverlevelse. Så lite som en grad intern rotasjon er hevdet å påvirke knefunksjonen. Hensikten med denne studien var å finne ut om relativt små rotasjonsfeil (±3º) av femurkomponenten påvirker knefunksjonen etter TKR.

Materialer og metoder: 80 knær (46 kvinner) operert konsekutivt med TKR fikk utført CT undersøkelse tre år etter operasjonen. Pasientenes gjennomsnittsalder var 69 år. Det var 65 varusknær med 1º- 22º deformitet, 14 valgusknær med 2º-13º deformitet og ett nøytralt kne. Femurkomponentens rotasjon ble målt på CT bilder av 3 ulike observatører. Først tegnet man sTEA på CT-bildene, deretter fellestangenten til femurkomponentens to ”pegger”. Vinkelen mellom de to linjene ble brukt som uttrykk for femurkomponentens rotasjon i axialplanet. Negative verdier representerer innrotasjon. Metoden har i en tidligere studie vist høy grad av presisjon og nøyaktighet. Knefunksjonen ble underesøkt preoperativt og ett år etter proteseoperasjonen med Knee injury and osteoarthritis outcome score (KOOS), Oxford knee score, Knee Society Score (KSS). I tillegg ble pasienttilfredshet undersøkt med visuell analog skår (VAS) ved ett års kontrollen. Sammenhengen mellom femurkomponentens rotasjon og knefunksjon ble først undersøkt med Spearmans korrelasjonsanalyse. Deretter ble materialet delt i 2 grupper. Gruppe 1: ingen eller minimal feilrotasjon (<1º) (n=26). Gruppe 2: feilrotasjon ≥1º (n=56). Maksimal feilrotasjon var 3,7º. Gruppene ble sammenliknet med Mann-Whitney U test.

Resultater: Det var ingen korrelasjon mellom femurkomponentens rotasjon og funksjonsskår. Det var ingen statistisk signifikant forskjell mellom gruppe 1 or 2 for noen av de 9 testede skårene og subskårene.

Diskusjon: Hvor stor feilrotasjon som kan toleres uten at det går ut over knefunksjonen er ukjent. Enkelte forfattere vurderer den samlede rotasjonen av tibiakomponenten og femurkomponenten. I denne studien har vi kun sett på femurkomponentens rotasjon En svakhet ved studien er at bare 13 knær (16%) hadde mer enn 2º feilrotasjon. De statistiske beregningene blir derfor usikre.

Betydning/Relevans: Vi fant ingen korrelasjon mellom femurkomponentens rotasjon og funksjonsskår i vårt materiale som utgjøres av knær med maksimalt 3,7º feilrotasjon.

15.9 Hvordan bør tibiakomponentens rotasjon bestemmes under totalproteseoperasjon i kneleddet?

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Innledning: Det finnes ingen gullstandard for hvordan tibiakomponentens rotasjon skal bestemmes under totalproteseoperasjoner i kneleddet (TKR).

Målsetting: Målet ved denne undersøkelsen var å undersøke sammenhengen mellom tibiakomponentens rotasjon og knefunksjonen 3 år etter operasjonen.

Materialer og metoder: 80 knær (46 hos kvinner) ble operert konsekutivt med en bakre korsbåndsbevarende Nexgen totalprotese. Pasientenes gjennomsnittsalder var 69 år. Det var 65 varusknær med 1º- 22º deformitet, 14 valgusknær med 2º-13º deformitet og ett nøytralt kne. Tibiakomponentens rotasjon ble under operasjonen bestemt ved at metallplatåets antero-posteriore akse ble plassert over en linje trukket fra midten av tuberositas tibias mediale 1/3 til laterale begrensning av bakre korsbånd. I knær med stor diskrepans mellom femur- og tibiakomponentens rotasjon tillot vi en begrenset grad av dynamisk tilpasning av rotasjonen ved å gjøre gjentatte fleksjonsbevegelser i kneet. Dette medførte alltid noe innrotasjon av tibiakomponenten. Tre år etter operasjonen ble pasientene skåret med KOOS, Oxford knee score og pasienttilfredshet (VAS). Det ble gjort CT undersøkelse av alle knær og tibiakomponentens rotasjon ble målt på CT bilder ved hjelp av Bergers metode av 2 uavhengige observatører. Inter-rater reliabilitet for målingene ble beregnet med intraclass correlasjonskoeffisient ICC. Deretter sammenliknet man de ulike skårene i knær med innroterte tibiakomponenter i en gruppe, og nøytrale eller utroterte tibiakomponenter i en annen gruppe.

Resultater: ICC (95% CI) for rotasjonsmålingene var 0.62 (0.46-0.74) for enkeltmålinger og 0.77 (0.63-0.85) for gjennomsnittsmålinger. Det var 46 nøytrale og utroterte tibiakomponenter med gjennomsnittlig rotasjon på 4°(0°-15°) og 34 innroterte tibiakomponenter med gjennomsnittlig rotasjon på -4.5° (-1°- -14°). Knær med nøytrale og utroterte tibiakomponenter hadde bedre skår enn knær med innroterte tibiakomponenter: KOOS: Smerte 92 vs 82 (p=0.06), Symptomer 91 vs 84 (p=0.02), ADL 90 vs 82 (p=0.13), Sport og fritid 72 vs 55 (p=0.02) og livskvalitet 89 vs 74 (p=0.002). Oxford knee score 16 vs 19 (p=0.02), og pasienttilfredshet 95 vs 88 (p=0.03).

Diskusjon: Denne undersøkelsen viser at innrotasjon av tibiakomponenten bør unngås og at midten av tuberositas tibias mediale 1/3 kan være et fornuftig siktepunkt når tibiakomponentens rotasjon skal bestemmes. Studien ble gjort med en bakre korsbåndsbevarende protese med fast plattform og resultatene kan ikke uten videre anvendes på andre protesedesign. ICC for enkeltmålinger er relativt lav, hvilket innebærer at tolkningen av en rotasjonsmåling hos en pasient som utredes for smerter etter TKR må gjøres med forsiktighet. Vi fant også at kroppsmasseindeks (BMI) var høyere i gruppen med innroterte tibiakomponenter hvilket kan bety at BMI har en konfunderende effekt.

Betydning/relevans: Knær med innroterte tibiakomponenter hadde dårligere resultater enn de med nøytrale og utroterte komponenter. Tibiakomponentens rotasjon bør bestemmes av ossøse landemerker fremfor ved bruk av dynamisk tilpasning.

15.10 Er CT undersøkelse pålitelig nok til å rettferdiggjøre revisjonsoperasjon ved mistanke om feilrotasjon av tibiakomponenten i et protesekne?

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Introduksjon: Feilrotasjon av tibiakomponenten anses som en viktig årsak til smerter og redusert funksjon etter TKA. Tidligere studier har konkludert med at feilrotasjon på noen få grader kan medføre feilsporing av patella og at revisjonsartroplastikk kan være en løsning på pasientens problemer selv ved svært beskjedne feilrotasjoner. Hos pasienter med dårlig resultat etter TKA uten kjent årsak er det vanlig å måle eventuell feilrotasjon med todimensjonal CT undersøkelse (2D CT). Påliteligheten av slike CT målinger blir ofte karakterisert med intra-class correlation coefficient (ICC). Resultatene av våre rotasjonsmålinger på gruppenivå (80 knær) er tidligere presentert på høstmøtet. Hensikten med denne presentasjonen er å diskutere verdien av vanlig 2D CT ved utredning av feilrotasjon som årsak til smerter og redusert funksjon etter TKA på individuelt nivå.

Materialer og Metoder: 80 knær ble operert konsekutivt med en bakre korsbåndsbevarende kneprotese med symmetrisk og fast plattform. Rotasjonsstillingen av tibiakomponenten ble undersøkt med Bergers metode på CT etter 3 år av to uavhengige observatører. Inter-rater reliabiliteten ble undersøkt med ICC. Graden av forskjell i rotasjonsmålingene mellom de to observatørene blir så vist i en frekvenstabell.

Resultater: ICC (95% CI) for gjennomsnittsmålinger var 0.77 (0.63-0.85) (exellent) og for enkeltmålinger 0.62 (0.46-0.74) (good). Frekvensanalysen viste ca. 35% sannsynlighet for at forskjellen mellom to observatører er inntil 3°, 15% sannsynlighet for en forskjell på inntil 5° og 6% sannsynlighet for en forskjell på 10° eller mer.

Diskusjon: Våre ICC resultater samsvarer godt med funn i tidligere undersøkelser. ICC er mye brukt i ortopedisk litteratur der en ønsker å undersøke reliabiliteten av ulike målemetoder, men tolkningen av ICC er komplisert. Det finnes minst 10 ulike varianter av ICC og resultatene kan variere betydelig avhengig av hvilken “modell”, “type” og “definisjon” som velges. En enklere måte å anskueliggjøre påliteligheten av en målemetode kan være å sette opp et histogram eller en enkel frekvenstabell. Man ser da umiddelbart at det er relativt stor sannsynlighet for «feilmålinger» opp til 10°. Disse funnene støttes også av en studie utført av Konigsberg et al. (CORR, 2014) som fant at inter- og intrarater reliabiliteten ved rotasjonsmålinger av protesekomponentene var bekymringsfullt dårlig.

Konklusjon/relevans: Vurderingen av mulige rotasjonsfeil i protesekomponentene har stor betydning for pasienten, og for eventuelle medicolegale beslutninger. Rotasjonsmålinger av tibiakomponenten har stor feilmargin og enkeltmålinger på individuelle pasienter må tolkes med forsiktighet. Revisjonsinngrep bør antagelig bare utføres der flere uavhengige observatører finner store avvik og der også andre kriterier taler i retning av feilrotasjon.

15.11 Effekter av kombinert rotasjon av protesekomponentene og patella-tilt på knefunksjonen etter totalprotesekirurgi i knær.

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Vi har tidligere vist at innrotasjon av tibiakomponenten har statistisk og klinisk signifikant negativ effekt på knefunksjonen, og at feilrotasjon av femurkomponenten innenfor ±3 grader antagelig ikke har signifikant effekt på knefunksjonen etter totalprotese i knær. I denne studien vurderes effekten av: 1) Samlet rotasjon (rotasjon av femurkomponenten + rotasjon av tibiakomponenten) og 2) Omvendt rotasjon (innrotert femurkomponent og utrotert tibiakomponent eller vice versa) på knefunksjonen. Deretter analyseres: 3) Sammenhengen mellom komponentrotasjon og patella-tilt og 4) Effekten av patella-tilt på knefunksjonen.

Pasienter og metode: 80 knær (46 hos kvinner) ble operert konsekutivt med en minimalt stabilisert, bakre korsbåndsbevarende totalprotese. Pasientenes gjennomsnittsalder var 69 år. Det var 65 varusknær med 1°-22° deformitet, 14 valgusknær med 2°-13° deformitet og ett nøytralt kne. Etter 3 år ble tibia- og femurkomponentenes rotasjon målt på CT med Bergers metode. Patella-tilt ble målt på aksiale røntgenbilder og pasientenes knefunksjon ble målt med KOOS (5 ulike subskår), Oxford knee score og pasienttilfredshet (VAS).
Resultater:
1) Gjennomsnittlig (SD) samlet rotasjon var 0° (5.5°) med spredning fra 16° innrotasjon til 15° utrotasjon. Alle 7 skår var signifikant dårligere for knær med samlet innrotasjon (p-verdier fra 0.002 til 0.049).
2) I 35 knær var en komponent rotert ut og den andre inn. Forskjellen i rotasjon var 1°-14°, men dette medførte ikke dårligere knefunksjon i forhold til knær med rotasjon samme vei.
3) Median patella-tilt var 1.5° (-4°-10°) utrotasjon. Det var ingen korrelasjon mellom individuell eller samlet rotasjon av femur- og tibiakomponentene og patella-tilt.
4) Patella-tilt >4° (5° -10°) ble observert i 9 knær. Disse hadde statistisk signifikant og klinisk relevant dårligere knefunksjon.
Diskusjon: I dette materialet er det svært liten spredning i femurkomponentens rotasjon (±3.7°), og relativt stor spredning i tibiakomponentens rotasjon (-14°-14°). Vi tror det kan være en årsak til at vi ikke fant korrelasjon mellom samlet rotasjon og patella-tilt. Sett i lys av tidligere forskning kan dette tyde på at rotasjon av femurkomponenten er en viktigere årsak til patella-tilt enn tibiarotasjonen.
Konklusjon/Relevans: 1) Samlet innrotasjon av komponentene må unngås. 2) Minimalt stabiliserte protesedesign er antagelig tilgivende for omvendt rotasjon (mismatch). 3) Vi fant ingen sammenheng mellom individuell eller samlet komponentrotasjon og patella-tilt i dette materialet. 4) Patella-tilt >4° har negativ effekt på knefunksjonen.

16 The papers

Arch Orthop Trauma Surg (2012) 132:1173–1181
DOI 10.1007/s00402-012-1536-1

KNEE ARTHROPLASTY

A new method to measure ligament balancing in total knee arthroplasty: laxity measurements in 100 knees

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Received: 5 January 2012 / Published online: 13 May 2012

Abstract
Background Ligament balancing is considered a prerequisite for good function and survival in total knee arthroplasty (TKA). However, there is no consensus on how to measure ligament balance intra-operatively and the degree of stability obtained after different balancing techniques is not clarified.
Purpose This study presents a new method to measure ligament balancing in TKA and reports on the results of a try-out of this method and its inter-observer reliability.
Methods After the implantation of the prosthesis, spatulas of different thickness were used to measure medial and lateral condylar lift-off in flexion and extension in 70 ligament-balanced knees and in 30 knees were ligament balancing was considered unnecessary. Inter-observer reliability for the new method was estimated and the degree of medial–lateral symmetry in extension and in flexion, and the equality of the extension gaps and flexion gaps were calculated.
Results The method was feasible in all operated knees, and found to be very reliable (intraclass correlation coefficient = 0.88). We found no statistically significant difference in condylar lift-off between the ligament-balanced and the non ligament-balanced group, however, there was a tendency to more outliers in flexion in the ligament-balanced group.
Conclusions Our method for measuring ligament balance is reliable and provides valuable information in assessing laxity intra-operatively. This method may be a useful tool in further research on the relationship between ligament balance, function and survival of TKA.

Keywords Total knee arthroplasty · Ligament balance · Soft tissue balance · Flexion–extension gap · Surgical technique · Equipment design

Introduction

Symmetric ligament balance is considered a prerequisite for good function and endurance in total knee arthroplasty (TKA) [1–4]. Lack of medial–lateral symmetry in the flexion or extension gaps, or both, may lead to instability, poor function and wear. Inequality between the flexion gap and the extension gap may cause decreased range of motion or instability.

The immediate consequences of poor ligament balance differ depending on the implantation technique. If measured resection technique is used poor ligament balance can lead to asymmetric medial and lateral condylar lift-off. If the balanced gap technique is used, the ligament balance in flexion will influence on the rotation of the femoral component [5, 6].

Many surgical techniques for ligament balancing have been developed [7–15], and different devices designed to assist in ligament balancing have emerged. These include spacers [9], tensors [9, 16, 17], electronic instruments [18–22], and computers [23–27]. Despite the availability of these devices, defining optimal ligament tension during TKA is still mostly based on the surgeons "feel" and personal experience. Proper intra-operative laxity is

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typically judged subjectively, rather than measured [1, 28]. We believe one reason for this may be a lack of a simple method to measure ligament balance during surgery. There is also little objective information in the literature to what degree ligament balance can be achieved by different techniques for soft tissue release.

The primary goal of this study is to introduce a new, simple method to measure medial and lateral condylar lift-off in extension and in 90° of flexion intra-operatively during TKA. The inter-observer reliability of the new method is measured.

The second goal is to report on the results of the direct measurements, the degree of medial–lateral symmetry in extension and in flexion, and the equality of the extension gaps and flexion gaps in 70 ligament-balanced and 30 non ligament-balanced TKAs.

Patients and methods

One-hundred knees in 90 patients, of which 56 were women, were operated consecutively. Patient demographics and Knee Society score (KSS) at baseline are shown in Table 1. Details of preoperative alignment and deformity are summarized in Table 2.

All patients were consecutively recruited from another ongoing prospective, randomized and double-blind study (comparing patella resurfacing to no resurfacing). Inclusion criteria were patients <85 years scheduled for TKA because of osteoarthritis. Exclusion criteria were knees with severe deformity not suitable for standard cruciate-retaining prosthesis, rheumatoid arthritis, patellar thickness below 18 mm and severe medical disability limiting the ability to walk. The protocol was approved by the Regional Committee of Research Ethics, and before enrolment, all patients signed an informed-consent form. Operations were undertaken between October 2007 and November 2010 in a community hospital doing about 50 TKAs per year. To assure conformity in surgical technique, the first author (EA) was either operating or assisting in every operation.

Surgical technique

All knees were operated through a standard midline incision and a medial parapatellar arthrotomy, using a cruciate-retaining prosthesis (NexGen, Zimmer, Warsaw, IN, USA). We used measured resection technique which involves resecting the amount of bone from the distal and posterior femur and the proximal tibia that will be replaced by the prosthetic components. The valgus angle of the femoral component was set at 5–8°, depending on the hip–knee–femoral shaft angle (HKFS) as measured on preoperative standing hip–knee–ankle (HKA) X-rays. Rotation of the femoral component was established by combining information from the anterior-posterior axis of the femur (Whiteside's line), the transepicondylar line and the

Table 1 Patient demographics and Knee Society Score (KSS) at baseline divided in groups with and without ligament balancing

Variable	Without ligament balancing ($n = 30$)	With ligament balancing ($n = 70$)	p value	Total
Gender (female)	17 (56.7 %)	39 (55.7 %)		100
Age[a]	71.0 (7.3) 53 to 83	69.2 (8.4) 42–81	0.30	69.7 (8.1) 42–83
BMI[a]	28.8 (3.5) 22 to 34	29.5 (4.0) 23–43	0.41	29.3 (3.9) 22–43
KSS knee score[a]	36.3 (20.4) −5 to 95	31,9 (14.3) 5–67	0.22	33.2 (16.4) −5–95
KSS function score[a]	64.8 (18.5) 30 to 100	64.9 (20.6) 30–100	0.98	64.9 (19.9) 30–100

[a] Data are presented as means, (SDs), and ranges

Table 2 Alignment and deformity at baseline divided in groups with and without ligament balancing

Alignment	Without ligament balancing		With ligament balancing		p value	Total
	n	Deformity[a]	n	Deformity[a]		
Varus knees	18	7.4 (5.2) 1–21	63	10.0 (4.5) 3–22	0.04	81
Valgus knees	9	5.9 (1.8) 3–9	6	5.0 (1.8) 2–7	0.37	15
Neutral knees	3	0	1	0	–	4
Total	30		70			100

[a] Deformity was measured in degrees and defined as the deviation from the ideal mechanical axis on HKA X-rays. Data are presented as means, (SDs), and ranges

posterior condylar line. Osteophytes were resected. With an intramedullary guide in the femur and an extramedullary guide on the tibia, saw-blocks were fit into place. After the saw cuts were performed, posterior osteophytes were removed. With a trial prosthesis implanted, the ligament balance was evaluated. If asymmetric, the knee was balanced using the technique described by Whiteside, Saeki, Mihalko, Kanamiya et al. [12, 13, 29, 30]. The aims of the ligament balancing were medial and lateral condylar lift-off of 1–3 mm in both extension and 90° of flexion, and equal and rectangular flexion and extension gaps. When forced to choose, we went for a bigger gap laterally and/or in flexion. If anterior lift-off was observed in less than 100° of flexion, after ligament balancing was accomplished, the posterior cruciate ligament was released with a small tibial bone block. If there was a persistent mismatch between the extension and the flexion gap of more than 5 mm, additional bone cuts, according to the contingency table proposed by Mont and Delanois [31], were performed. All operations were performed in bloodless field with a tourniquet on the proximal part of the thigh.

The new method to measure ligament balance

After implantation of the prosthesis, we used a set of four polyethylene spatulas with thicknesses from 2 to 5 mm to measure the medial and lateral gaps (Fig. 1a). With the knee in extension, lift-off was defined as the distance in the frontal plane from the deepest point of the polyethylene tray to the most distal point of the femoral condyle. With the knee in 90° of flexion, the same measurements were done between the deepest point of the polyethylene tray to the most posterior point of the femoral condyle. With the knee in extension, the surgeon stressed the ligaments in valgus and varus until a firm endpoint was felt. Lift-off was measured by inserting the thickest spatula possible (Fig. 1b). If the thinnest spatula could not be inserted and there still was a visible gap, the gap was recorded as 1 mm, in the case of no visible gap, 0 mm was recorded. If the gap was more than 5 mm two spatulas were appositioned. In flexion, measurements were performed in the positions described by Tokuhara et al. [32]: lateral lift-off in 90° of flexion was measured in the unilateral cross-legged position under passive valgus stress by the weight of the lower leg. Medial lift-off in flexion was measured in a similar way with the leg in a reversed cross-leg position (Fig. 1b).

Measurements

Medial and lateral lift-off was measured in extension and in 90° of flexion, and then, medial–lateral symmetry in extension and in flexion was calculated. The difference in size between the extension and the flexion gap was calculated by subtracting the mean values of medial and lateral lift-off in flexion from the mean values of the medial and lateral lift-off in extension. In all knees, the measurements were done with the patella everted.

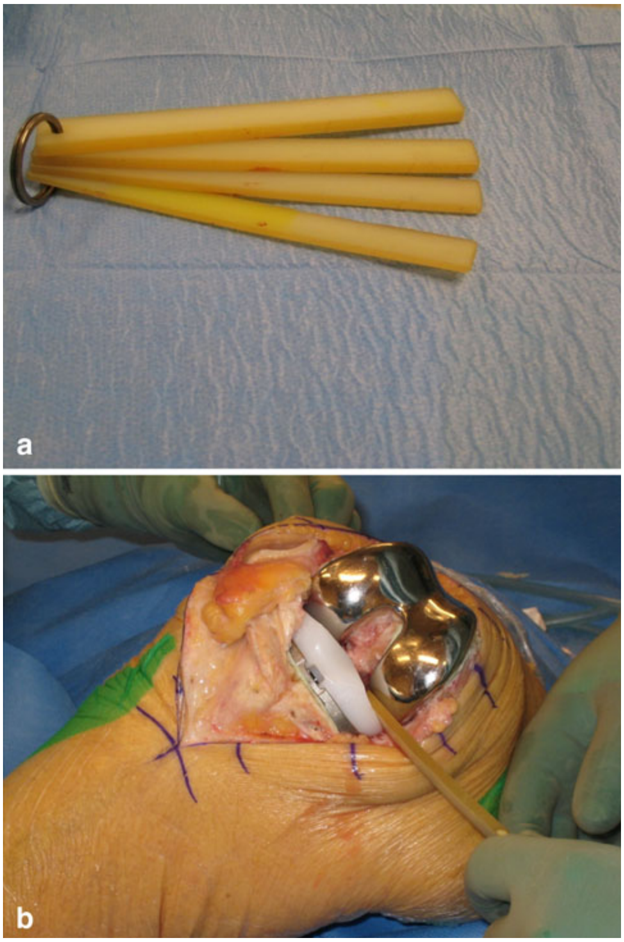

Fig. 1 **a** The tool for measuring condylar lift-off consists of four spatulas made of polyethylene, from 2 to 5 mm thick. **b** With the knee in 90° of flexion medial condylar lift-off was defined as the distance in the frontal plane from the deepest point of the polyethylene tray to the most posterior point of the femoral condyle. The measurement was performed with the leg in a reversed crossed-leg position under passive varus-stress from the weight of the lower leg with the thickest spatula that could be introduced without force

Inter-observer reliability

To evaluate the reliability of the method, an inter-rater analysis was performed in 96 consecutive measurements (24 knees). First the assisting surgeon measured the gaps while the operating surgeon stressed the knee ligaments. To assure blinding between the observers, the operating surgeon turned his head away from the field while the measurements were performed by the assisting surgeon. The results of the measurements were communicated to the circulating nurse by finger signs. Thereafter, the two surgeons changed roles. Four different assistants with very dissimilar experience in total knee surgery and the senior surgeon performed the measurements in this part of the study.

Statistics

Data were stored and analyzed with use of Microsoft Access® (Microsoft, Redmond, Washington, USA) and SPSS® software (SPSS, Chicago, IL, USA). To determine inter-observer agreement between raters of condylar lift-off intraclass correlation statistics for single measures was performed. The distribution of data on condylar lift-off was analyzed with a Kolmogorov–Smirnov test. For the comparisons of lift-off between ligament-balanced and non ligament-balanced knees, we used the independent samples test for normally distributed data and the Mann–Whitney test for skewed data.

Results

Inter-observer reliability

Inter-observer agreement among raters was high with an intraclass correlation coefficient for single measures of 0.88 (95 % confidence interval 0.82–0.92). Absolute agreement was achieved in 60.4 % of measurements. In only one case, the difference between observers reached 2 mm.

Ligament-balancing procedures

In 70 out of 100 knees, ligament balancing was undertaken, and in 30 knees, ligament surgery was deemed unnecessary. Among the ligament-balanced knees, 63 knees were deformed in varus, 6 were deformed in valgus and 1 knee was without preoperative deformity. The numbers of ligaments that were released in the varus- and valgus-deformed knees are presented in Table 3. Although the deep and superficial medial collateral ligaments are two anatomical structures, the current technique for ligament balancing regards the two layers as one functional unit with an anterior part that tightens in knee flexion and a posterior part that tightens in knee extension [12].

Table 3 Number of ligaments released in varus and valgus deformed knees

Ligament	Varus knees (*n* = 63)	Valgus knees (*n* = 6)
MCL		
Anterior part	49	
Posterior part	39	
Medial posterior capsule	10	
Semimembranosus	2	
Pes anserinus	–	–
PCL	27	3
LCL	1[a]	1
Popliteus tendon	4[a]	3
Posterolateral corner		1
Iliotibial tract		2
Lateral posterior capsule		2

MCL medial collateral ligament, *PCL* posterior cruciate ligament, *LCL* lateral collateral ligament

[a] Compensatory release in varus knees

Additional bone cuts were performed in ten cases; six re-cuts on the tibia, one recut on the distal femur and three cases of downsizing of the femur.

Laxity measurements

There was no statistically significant difference between ligament-balanced knees and non ligament-balanced knees in medial and lateral condylar lift-off in extension and 90° of flexion for varus and valgus knees (Table 4).

In extension, medial–lateral symmetry within 2 mm was obtained in 96 % of the knees undergoing ligament balancing and in 97 % of the knees not undergoing ligament balancing (Fig. 2). In flexion, medial–lateral symmetry within 2 mm was obtained in 70 % of the ligament-balanced knees and in 89 % of the knees without ligament balancing (Fig. 2).

Flexion gaps were equal to extension gaps in 29 % of the ligament-balanced knees and in 23 % of the knees where no ligament surgery was performed (Fig. 3). In the knees with unequal gaps, 98 % of the ligament-balanced knees were tightest in extension and 91 % of the non ligament-balanced knees were tightest in extension (Fig. 3).

Complications

Three intra-operative complications occurred. In one case, the popliteus tendon was cut, probably by the oscillating saw, while performing the posterior, lateral bone cut. In another case, the medial collateral ligament was damaged by the saw when performing the proximal tibial bone cut. The last was an inadvertent saw cut to the posterior cruciate ligament.

Discussion

The new method

Our method measures, intra-operatively directly in millimeters, medial and lateral condylar lift-off in extension and 90° of flexion. We consider the measuring procedure as easy to perform, and the measurements take no more than 1 or 2 min.

Table 4 Medial and lateral lift-off in extension and 90° of flexion in knees with or without ligament balancing

Knee alignment	Position	Without ligament balancing	With ligament balancing	*p* value	Total
Varus knees		$n = 18$	$n = 63$		81
	Extension				
	Medial	1.6 (1.2–1.9) 1–3	1.9 (1.7–2.1) 1–4	0.17	
	Lateral	2.0 (1.6–2.4) 1–3	2.1 (1.9–2.3) 1–5	0.90	
	Flexion				
	Medial	2.7 (2.2–3.2) 0–4	3.4 (2.9–3.9) 1–9	0.30	
	Lateral	3.2 (2.6–3.9) 1–5	3.5 (3.1–3.9) 1–10	0.74	
Valgus knees		$n = 9$	$n = 6$		15
	Extension				
	Medial	2.0 (1.6–2.4) 1–3	2.7 (1.4–3.9) 1–4	0.25	
	Lateral	1.7 (1.1–2.2) 1–3	1.7 (0.2–3.1) 0–4	1.00	
	Flexion				
	Medial	2.4 (1.6–3.3) 1–4	3.7 (0.9–6.5) 1–8	0.33	
	Lateral	3.0 (1.7–4.3) 1–7	4.3 (2.9–5.8) 2–6	0.12	
Neutral knees		$n = 3$	$n = 1$		4
	Extension				
	Medial	2.3 (–) 1–3	1.0		
	Lateral	1.3 (–) 0–3	3.0		
	Flexion				
	Medial	3.3 (–) 2–4	2.0		
	Lateral	2.3 (–) 0–5	3.0		

With the knee in extension the surgeon stressed the collateral ligaments until a firm endpoint. Lift-off was defined as the distance in the frontal plane from the deepest point of the polyethylene tray to the most distal point of the femoral condyle. With the knee in 90° of flexion, the same measurements were done between the deepest point of the polyethylene tray and the most posterior point of the femoral condyle while the collateral ligaments were stressed by gravity (see text). Values are expressed in millimeters as means, (95 % CIs), and ranges

One might argue that this method will not give an accurate and reproducible tension to the ligaments during measurements of condylar lift-off. However, in every knee in this study, there was a firm endpoint when exposed to valgus and varus stress, and there is some evidence in the literature that clinician-applied stress to quantify the lift-off is quite reliable. LaPrade et al. [33] compared the lateral compartment gapping on stress radiographs before and after sequential lateral ligament sectioning in ten cadavers. Varus stress was applied either by a clinician or by a force-application device delivering a 12 Nm moment to the knee. They concluded that both standardized 12 Nm moments and clinician-applied varus stress radiographs provide objective and reproducible measures of lateral compartment gapping.

Another possible bias of the measuring method is the dished contour of the polyethylene leading to an oblique introduction angle (10–15°) of the spatulas and overestimation of the lift-off of 3–4 %. It is our opinion that ligament-balancing surgery is not so fine-tuned that measurement-errors of this magnitude are clinically relevant.

It is widely accepted that good ligament balance is a cornerstone for good function and survival after TKA. However, it is problematic that there is no consensus on how stability should be measured intra-operatively. Many principles for evaluation of ligament balance during TKA have been developed, but they do not address the same problem. Different spacers, including trial components and blocks may assist in stretching the ligaments. The medial and lateral lift-off can then be measured by eye or indirectly by a computer in millimeters or degrees. Tensors and spreaders apply tension to the ligaments in a more or less controlled manner and electric instruments measures compressive loads. Most of these devices are expensive, add to the complexity of the surgery and are time consuming. Up to now, computer-assisted surgery has been the only established way to measure condylar lift-off intra-operatively. Although available for more than a decade, only a small part of TKAs are performed with computer assistance, probably due to high costs and prolonged operation time.

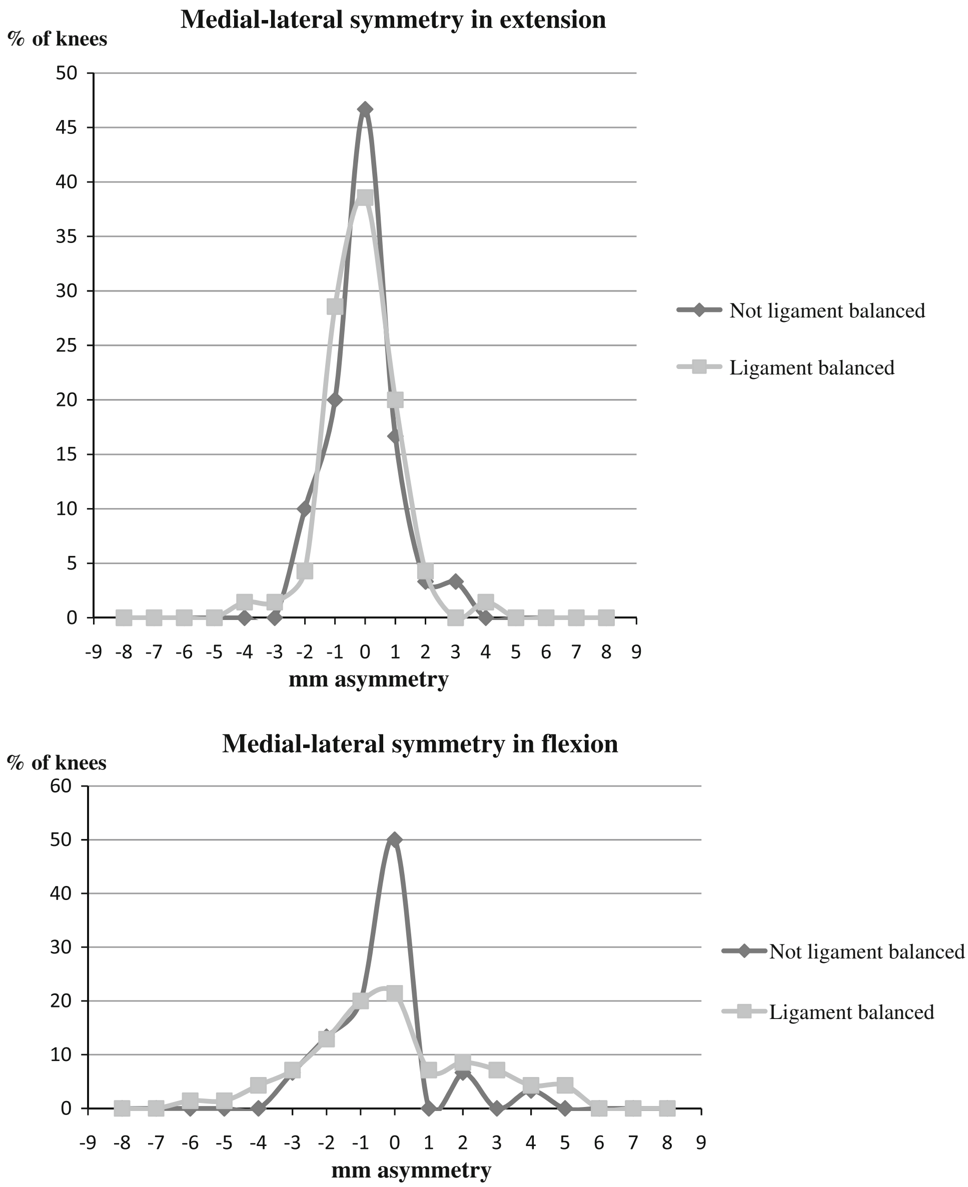

Fig. 2 The degree of medial–lateral symmetry in lift-off that was achieved after implantation of the prosthesis, in knees where ligament balancing was not necessary ($n = 30$) and in knees that were ligament balanced according to the Whiteside method ($n = 70$). *Negative values* represent more lift-off laterally than medially. *Positive values* mean more lift-off medially than laterally

Validation

The intraclass correlation coefficient was found to be high (0.88), indicating that the interobserver reliability is very good. This conclusion is strengthened by the high number of tests (96) and by the fact that the measurements were undertaken by five different assessors whose experience in total knee surgery ranged from 14 years to some months.

Ideally, validation of the new method should have been performed against an established gold standard. However, we believe that there is no absolute gold standard. Spreading devices, tensioners and spacer blocks allow measurements of gaps between osteotomies in a very different and non physiologic biomechanical situation without the prosthesis in place. Using a tensor Muratsu and Matsumoto found a decrease of as much as 5.3 mm in joint gap in extension and a reduction of varus ligament imbalance of 3.1° with the femoral trial prosthesis in place compared to measurements without [34]. We planed to compare our laxity measurements with those from computer-assisted surgery, but early trials found that this method overestimates the lift-off substantially. The reasons for this are unclear but might be related to the visco–elastic properties of bone.

Ligament balancing

This part of the study was a tryout of the new method to measure ligament balancing on 100 TKAs. We found no statistically significant difference between ligament-balanced knees and non ligament-balanced knees in medial and lateral condylar lift-off in extension and 90° of flexion

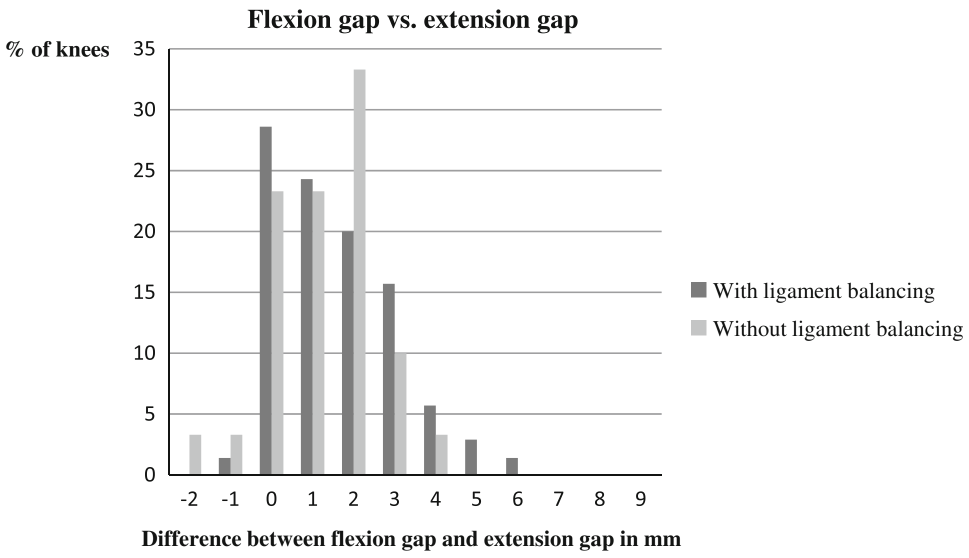

Fig. 3 The relationship between the flexion gap and the extension gap. *Positive values* mean the flexion gap is larger than the extension gap. *Negative values* mean the extension gap is larger. *Zero* means the two gaps are of equal size

for varus and valgus knees (Table 4). No power analysis was performed and the number of knees tested is limited, so this conclusion must be drawn with caution.

Accepting 2 mm difference in medial and lateral condylar lift-off as a reasonable definition of medial–lateral symmetry, we found a high proportion of well-balanced knees, especially in extension (Fig. 2). It is, however, difficult to evaluate these results, because the limits for acceptable symmetry and laxity are so poorly defined in the literature. Further research is needed to find out if there is a connection between ligament-balance and function and prosthetic survival after TKA.

There is no consensus in the literature on how tight a TKA should be balanced. Our method for assessing ligament balance rests on the belief that some degree of visible lift-off is beneficial. This is in accordance with the findings of Edwards et al. [35]. They reported on 63 TKAs and found that lax knees showed better results in Hospital for Special Surgery Score (HSS) and pain, than stable knees. The stability was measured clinically at follow-up, 12–84 months after the operation. Kuster et al. [36] evaluated 22 patients with bilateral knee arthroplasties clinically and radiologically at a mean follow-up of 4.5 years. A modified HSS score (excluding laxity), varus and valgus stress X-rays in 30° of knee flexion, and the subjective outcome of both knees were compared. A knee was considered tight when it opened <4° and lax if it opened 4° or more on stress X-ray. Their results showed that patients with a preferred side felt significantly more comfortable on the laxer side.

Most orthopaedic surgeons agree that one goal for ligament balancing is to obtain rectangular gaps (that is equal medial and lateral lift-off). This goal was by far obtained in extension, but in flexion, it was some outliers (Fig. 2). Our tendency to obtain bigger gaps laterally may be due to the fact that we did not want to over-correct the varus knees and to the fact that native knees are looser laterally than medially in flexion. Tokuhara et al. [32] studied the flexion gap in 20 normal knees with MRI imaging. Under valgus stress, the mean medial gap was 2.1 ± 1.1 mm (0.2–4.2). When a varus stress was applied, the mean lateral gap was 6.7 ± 1.9 mm (2.1–9.2), indicating that the flexion gap is not rectangular but trapezoidal. The effect of such lateral laxity on prosthetic knee joints is unknown.

Another goal was to achieve equal extension and flexion gaps. As shown in Fig. 3, we were not able to reach this goal in the majority of the ligament-balanced knees. Nevertheless, the results were virtually the same for the not ligament-balanced knees, and there is some support in the literature that the flexion gap is bigger than the extension gap in normal, native knees. Van Damme et al. [27] quantified the ligament laxity in non-arthritic cadaver knees with a fluoroscopy assisted navigation system. In extension, the medial joint-line opening was on average 2.6 ± 1.0 mm and the lateral joint-line opening averaged 3.1 ± 0.8 mm. In 90° of flexion the medial join-line opening was on average 7.1 ± 1.4 mm and the lateral joint-line opening averaged 8.1 ± 1.0 mm.

When a mismatch between extension and flexion gap was present in our study, 98 % of the knees were tightest in extension. This is in contrast to the work of Griffin et al. [37] who found that less than 50 % of the knees were tightest in extension. We believe the reason why we generally obtained bigger flexion gaps is that we used a measured resection technique with anterior referencing and our policy to go down in size when forced to choose between femoral component sizes.

Recently Heesterbeek et al. [38] reported on varus–valgus laxity in extension and 70° of flexion in 49 TKAs implanted with a balanced gap technique. Ligament balancing was performed by releasing the tightest ligament first and laxity was measured with computer navigation while the knees were stressed to 15 Nm with a spring load. In extension, they found 2.6° (±1.1) (SD) valgus laxity and 2.8° (±1.6) varus laxity, and in flexion, 2.3 (±1.5)° valgus laxity and 2.7° (±1.8) varus laxity. Using a balanced gap technique, these authors succeeded in creating almost equal extension and flexion gaps, but their data are mean values and do not give any information on medial–lateral symmetry. Laxity outliers were not described and the results represent a selected group of patients with median age 60 years and knees with fixed varus- or valgus-alignment more than 10° and patients with BMI > 30 were excluded.

Effect of patella eversion

In this study, all measurements of condylar lift-off were performed with the patella everted. There is some evidence in the literature show that patellar eversion affects ligament balance. Kamei et al. [39] assessed soft tissue balance by the gap technique in TKA, and found that gap inclination at 90° of flexion was higher with the patella in situ compared to with patella everted. Matsumoto and Muratsu measured the effect of ligament balance with a tensor and a navigation system. Their results are diverging with different results for cruciate retaining and posterior-stabilized knees [40]. Our method can easily be performed with the patella repositioned. An ongoing study is focusing on the effect of patellar eversion on condylar lift-off.

The present study has some limitations. First, our measuring tool do not distinguish between differences <1 mm, but ligament balancing surgery is not so exact that we feel a need for a more fine-tuned measuring device. Second, our method for measuring medial and lateral lift-off in extension is based on manual loading of the ligaments in valgus and varus. This is accounted for earlier in this paper. Third, the number of knees is limited, especially for valgus knees, thus firm conclusions cannot be drawn in the comparison between ligament-balanced and not ligament-balanced knees.

The strong points of this study are that it is prospective, the patients were recruited consecutively and inclusion criteria were well defined. The new method was tested on five different surgeons with different background and experience in total knee surgery. No data are missing.

In this study, the patients were operated with the measured resection technique, and therefore, less than perfect ligament balance becomes visible as lack of medial–lateral symmetry in condylar lift-off. Proper ligament balance is also important when the balanced gap technique is used, because in such cases, poor ligament balance in flexion can influence on the femoral component rotation [5, 6].

We conclude that our measuring device is reliable, simple, and easy to use. It enables the surgeon to document data on ligament balance objectively. Such data may be useful in further research on the relationship between ligament balance, function and survival of TKA.

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Knee Surg Sports Traumatol Arthrosc (2015) 23:1684–1692
DOI 10.1007/s00167-014-3108-0

Intraoperative ligament laxity influences functional outcome 1 year after total knee arthroplasty

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Received: 9 August 2013 / Accepted: 29 May 2014 / Published online: 12 June 2014

Abstract

Purpose To find out if there is an association between ligament laxity measured intraoperatively and functional outcome 1 year after total knee arthroplasty (TKA).

Methods Medial and lateral ligament laxities were measured intraoperatively in extension and in 90° of flexion in 108 patients [122 knees; median age 70 (range 42–83) years]. Mechanical axes were measured preoperatively and at 1-year follow-up. Outcome measures were the Knee Injury and Osteoarthritis Outcome Score (KOOS), the Knee Society Clinical Rating System, the Oxford Knee Score and patient satisfaction. The relationships between laxity and outcome scores were examined by median regression analyses.

Results Post-operative mechanical axis had a significant effect on the association between ligament laxity and KOOS. Therefore, the material was stratified on post-operative mechanical axis. In perfectly aligned and valgus-aligned TKAs, there was a negative correlation between medial laxity and all subscores in KOOS. The most important regression coefficient (β) was recorded for the effect of medial laxity in extension on activities of daily living (ADLs) ($\beta = -7.32$, $p < 0.001$), sport/recreation ($\beta = -6.9$, $p = 0.017$) and pain ($\beta = -5.9$, $p = 0.006$), and for the effect of medial laxity in flexion on ADLs ($\beta = -3.11$, $p = 0.023$) and sport/recreation ($\beta = -4.18$, $p = 0.042$).

Conclusions In order to improve the functional results after TKA, orthopaedic surgeons should monitor ligament laxity and mechanical axis intraoperatively and avoid medial laxity more than 2 mm in extension and 3 mm in flexion in neutral and valgus-aligned knees.

Level of evidence II.

Keywords Total knee replacement · Joint instability · Ligament balancing · Monitoring, intraoperative · Knee osteoarthritis · Reference values

Introduction

The effects of ligament laxity on functional outcome after total knee arthroplasty (TKA) are not clearly described in the literature, and defining optimal ligament laxity during TKA is still mostly based on the surgeon's "feel" and personal experience. Many methods for ligament balancing (soft tissue balancing) have been developed [3, 6, 11, 14, 21, 23, 24, 36, 37], and the current recommendations for ligament balancing are that the gaps should be rectangular and equal. However, it is still not known what the optimal degree of laxity is, and actual intraoperative laxity is typically judged subjectively rather than measured [20, 22].

The deleterious effect of gross instability on prosthetic survival is well documented, and instability is still among the most important reasons for revision knee arthroplasty [27]. The negative effect of overly tight ligaments on knee motion and prosthetic survival has also been described previously [1, 17, 31, 35]. A few studies have reported the influence of

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ligament balance measured postoperatively on functional outcome after TKA [9, 18, 20]. They concluded that relatively loose knees perform better than tight knees. However, the degree of laxity that leads to subjective instability and poor function is unknown. It is important to bear in mind that instability may also depend on other factors than laxity alone. For example, different adduction moments during walking in varus- and valgus-deformed knees are likely to modify the patient's perception of laxity.

Most previous studies investigated laxity that was measured clinically or radiographically postoperatively [9, 18, 20, 33]. In order to correct unacceptable results before the end of the surgical procedure, orthopaedic surgeons need information on the relationship between laxity measured intraoperatively and outcome.

Although the literature on the relationship between laxity and functional outcome is non-conclusive, it is likely that such a relationship exists, and if so, it is important for the operating surgeon to have objective data on how and to what degree intraoperative laxity influences outcome. To our knowledge, this is the first study to investigate the relationships between ligament laxity measured intraoperatively, final mechanical axis and functional outcome. The aim of the study was to find out how laxity measured intraoperatively is related to functional outcome 1 year after TKA.

Materials and methods

Inclusion criteria were patients with primary knee osteoarthritis who were younger than 85 years. Exclusion criteria were patients with severe deformity of the knee, defined as: Bone deformity to such a degree that the bone cuts would damage the ligamentous attachments on the epicondyles; Ligament laxity without a firm end point or to such a degree that ligament releases on the concave side would result in a need for more than 20 mm polyethylene thickness; The combination of bone deformity and ligament laxity resulting in the need for more than 20 mm polyethylene thickness. Excluded were also knees with posterior cruciate deficiency, isolated patella-femoral arthrosis, previous surgery on the knee (except from meniscal surgery and proximal tibial osteotomy) and patients with a severe medical disability preventing them from climbing one level of stairs. Patients not able to fill out the patient-reported outcome measures (KOOS and Oxford knee score) were also excluded.

One hundred and thirty-two patients met the inclusion criteria and twenty-three of these patients were excluded. The reasons for exclusions were as follows (number of patients in parentheses): Severe deformity (1), isolated patella-femoral arthrosis (3), prior surgery on the knee (6), severe medical disability (3), not able to fill out the patient-reported outcome measures (2) and finally, eight patients refused to participate in the study. One 83-year-old woman declined a follow-up visit at 1 year because she was living in a remote area and had experienced no problems with her operated knee. As a result, 122 knees in 108 patients (63 women and 45 men) were investigated. The median age of the patients was 70 (range 42–83) years, and the median body mass index (BMI) of the patients was 29 (range 22–43) kg/m^2.

All patients underwent surgery consecutively between October 2007 and November 2010 at one community hospital. To ensure conformity in surgical technique, one surgeon (E.A.) was either operating or assisting in every operation.

Surgical technique

All knees were operated on through a standard midline incision and a medial parapatellar arthrotomy, using a cruciate-retaining prosthesis (NexGen®; Zimmer, Warsaw, IN) and a measured resection technique. In order to create a neutral mechanical axis, the valgus angle of the femoral component was set at 5°–8°, depending on the hip–knee–femoral shaft angle, as measured on preoperative standing hip–knee–ankle (HKA) radiographs [10]. Rotation of the femoral component was established by drawing the epicondylar line, the anteroposterior line and the posterior condylar line + 3 degrees external rotation at the distal femoral cut. The average of the three lines was considered to be the true rotational axis. In cases with obvious dysplasia or bony attrition of one or both posterior condyle(s), the posterior condylar line was excluded from the estimation.

Ligament balancing was performed using the technique previously described by Whiteside and colleagues [36, 37]. The aim of the ligament balancing was to achieve medial and lateral condylar lift-off of 1–3 mm in both extension and 90° of flexion.

All operations were performed in a bloodless field with a tourniquet on the proximal part of the thigh.

Laxity measurements

The method for measuring ligament laxity has previously been described in detail [2]. After implantation of the prosthesis we used a set of four polyethylene spatulas with thicknesses from 2 to 5 mm to measure the medial and lateral laxity (Fig. 1a). With the knee in extension, laxity was defined as the distance in the frontal plane from the deepest point of the polyethylene tray to the most distal point of the femoral condyle. With the knee in 90 degrees of flexion, the same measurements were done between the

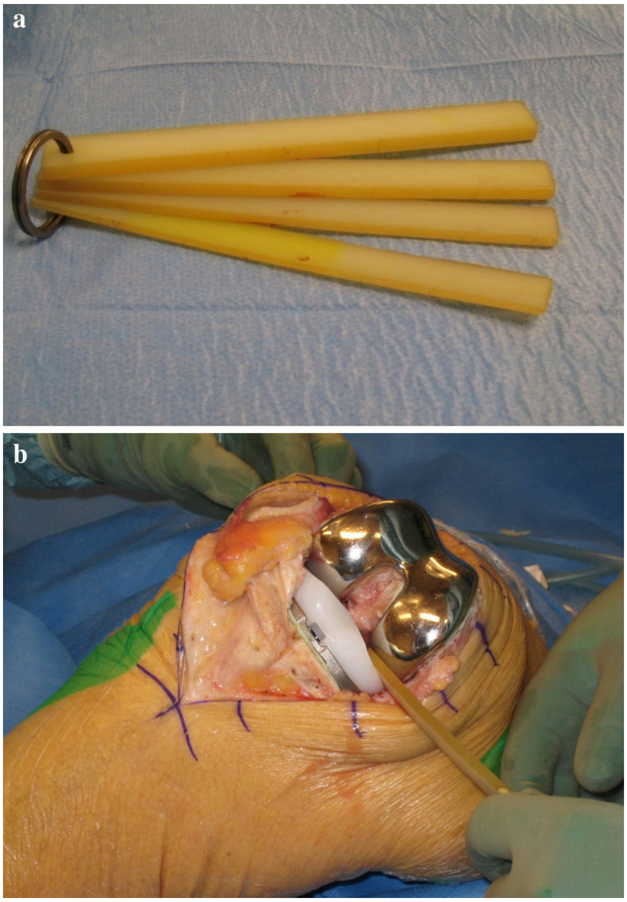

Fig. 1 **a** The tool for measuring ligament laxity (condylar lift-off) consists of four spatulas made of polyethylene of increasing thickness [2]. **b** With the knee in 90 degrees of flexion, medial laxity (condylar lift-off) was defined as the distance in the frontal plane from the deepest point of the polyethylene tray to the most posterior point of the femoral condyle. The measurement was performed with the leg in a reversed crossed-leg position under passive valgus stress from the weight of the lower leg with the thickest spatula that could be introduced without force [2]

deepest points of the polyethylene tray to the most posterior point of the femoral condyle. With the knee in extension, the surgeon stressed the ligaments in valgus and varus until a firm end point was felt. Laxity was measured by inserting the thickest spatula possible without using force. If the thinnest spatula could not be inserted and there still was a visible gap, laxity was recorded as 1 mm, in the case of no visible gap, zero was recorded. If laxity was more than 5 mm two or more spatulas were appositioned. In flexion, measurements were performed in the positions described by Tokuhara et al. [34], as follows: Lateral laxity in 90° of flexion was measured in the unilateral cross-legged position under passive varus stress by the weight of the lower leg. Medial laxity in flexion was measured in a similar way with the leg in a reverse cross-legged position (Fig. 1b). All measurements were performed with the patella everted. The reliability (precision) of the measuring method has been tested, and the inter-observer agreement among raters proved to be high with an intraclass correlation coefficient for single measures of 0.88 (95 %confidence interval 0.82–0.92) [2].

Outcome scores

All patients were clinically evaluated with the Knee Injury and Osteoarthritis Outcome Score (KOOS) [29, 30], the Oxford Knee Score [8] and the Knee Society Clinical Rating System (KSS) [15] preoperatively and at 1-year follow-up. Patient satisfaction was measured on a visual analogue scale (VAS) at 1-year follow-up.

KOOS is a knee-specific, patient-reported outcome measure consisting of 42 questions. It has five separately scored subscales for pain, other symptoms, activities of daily living (ADLs), function in sport and recreation, and knee-related quality of life (QOL). The KOOS has been validated for use in TKR and has been shown to be valid, reliable and responsive [7, 28–30].

The self-administered questionnaires (KOOS, Oxford Knee Score and VAS score) were completed by the patient alone. In bilateral cases (28 knees), the patients were encouraged to consider the knee under investigation when answering the questions.

A physiotherapist, who was blinded to the laxity measures and other details from the operation, assessed the KSS scores including range of motion (ROM).

Mechanical axes were measured preoperatively and at 1-year follow-up on HKA radiographs using the method described by Ewald [10].

The protocol was approved by the Regional Committee on Research Ethics on the University of Oslo (ID number: S-07172d 1.2007.952), and all patients gave their informed consent prior to inclusion in the study.

Statistical analysis

The mean, standard deviation and range, or median and interquartile range, were given for laxity and outcome scores as appropriate. Numbers and percentages were calculated for categorical variables. The differences between preoperative scores and outcome scores at 1 year were tested with the paired samples *t* test or the Wilcoxon signed-rank test depending on the distribution of paired data.

Initially, the associations between laxity measurements and outcome scores were assessed by Spearman's rank correlation. Thereafter, confounding variables and effect modifiers known from prior research and biological plausibility were examined statistically using Spearman's rank correlation. Finally, the relationships between each laxity measurement and the outcome scores were investigated by median regression analysis, adjusting for significant confounders and stratifying on the effect modifier. A median regression model was chosen because of highly skewed data and outliers. The effects of medial and lateral laxity in extension and in flexion on KOOSs are expressed as median regression coefficients. The regression coefficients represent the median changes in outcome scores that can be expected for a 1 mm change in laxity. Two-sided p values of <0.05 were considered to be significant. SPSS v.20.0 software (SPSS Inc., Chicago, IL) for Windows was used to carry out descriptive analyses. Median regression analyses were performed with STATA 9.2 statistical software for Windows (StataCorp LP, College Station, TX).

Results

Alignment and deformity improved from preoperatively to 1 year after surgery (Table 1). Intraoperative ligament laxity measurements showed a tendency towards more laxity in flexion than in extension (Table 2).

All function scores improved significantly ($p < 0.001$) at 1 year (Fig. 2; Table 3).

Range of motion (ROM) preoperatively and at 1 year is presented in Table 3. Four knees ended up with less than 90° of flexion and four knees had more than 10° of flexion contracture at the final follow-up.

It was not statistically significant correlation between preoperative mechanical axis or the amount of correction of mechanical axis (from preoperative to postoperative) and outcome measures.

It was no statistical significant correlation between medial and lateral laxity in extension and in flexion and alignment prior or after surgery.

The relationships between laxities and function scores were evaluated in the median regression model: The postoperative mechanical axis proved to interact significantly on the association between medial laxity and outcome for pain (in extension $p < 0.001$ and in flexion $p < 0.001$) and ADL (in extension $p = 0.008$ and in flexion $p = 0.028$) subscores in KOOS. The material was therefore stratified into knees with perfect alignment or valgus alignment ($n = 58$) and knees with varus alignment ($n = 64$) (Table 4). The analyses were adjusted for age, sex and BMI.

In perfectly aligned and valgus-aligned TKAs, there was a negative correlation between medial laxity and all subscores in KOOS (Table 4). The most important regression coefficient (β) was recorded for the effect of medial laxity in extension on ADLs ($\beta = -7.32$, $p < 0.001$), sport/recreation ($\beta = -6.9$, $p = 0.017$) and pain ($\beta = -5.9$, $p = 0.006$), and for the effect of medial laxity in flexion on ADLs ($\beta = -3.11$, $p = 0.023$) and sport/recreation ($\beta = -4.18$, $p = 0.042$) (Table 4).

In varus-aligned knees, lateral laxity in extension and flexion had a significant negative effect on the symptom subscore in KOOS ($p = 0.023$ in extension and $p = 0.041$ in flexion), but this pattern was not consistent through all subscores (Table 4). The regression coefficients for the KSS and Oxford Knee Score were lower and less consistent than for the KOOSs and did not reach statistical significance.

Complications

Five perioperative complications occurred. Three were caused by inadvertent saw cuts: one to the popliteal tendon, one to the medial collateral ligament and one to the posterior cruciate ligament. There was one case of atrial fibrillation, and one patient had a small myocardial infarction.

A further two complications were registered within the first year: one patient with lateral knee pain and stiffness underwent neurolysis of the fibular nerve and arthroscopic arthrolysis and mobilization, and one patient with stiffness underwent arthroscopic arthrolysis because of arthrofibrosis, but had poor results and range of motion (8°–78°) at 1 year.

Discussion

The main finding in this study was that in knees with neutral or slight valgus alignment functional outcome

Table 1 Alignment and deformity measured as deviation from normal mechanical axis in degrees, mean (SD) and range, preoperatively and at 1-year follow-up

	Alignment						*N* (%)
	Varus		Valgus		Neutral		
	Deformity	*n* (%)	Deformity	*n* (%)	Deformity	*n* (%)	
Preoperatively	9.0° (4.8) 1°–22°	98 (80.3)	5.9° (2.7) 2°–13°	20 (16.4)	0	4 (3.3)	122 (100)
At 1 year	2.7° (1.5) 1°–7°	64 (52.5)	2.2° (1.0) 1°–4°	27 (22.1)	0	31 (25.4)	122 (100)

Table 2 Ligament laxity (condylar lift-off) measured medially and laterally in extension and in flexion after ligament balancing and implantation of the prosthesis, before closure of the wound, in 122 TKAs. All measurements were performed with the patella everted

	Ligament laxity (mm)	
	Median (IQR)	Range
Extension		
Medially	2 (1–2)	1–5
Laterally	2 (1–3)	0–5
Flexion		
Medially	3 (2–4)	0–9
Laterally	3 (2–4)	0–10

IQR inter quartile range

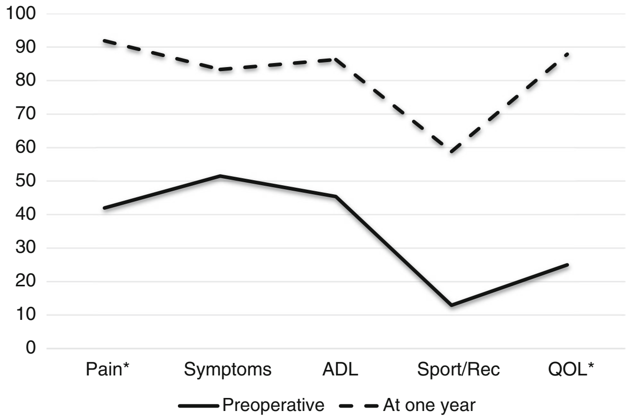

Fig. 2 KOOS (including five sub-scores) measured preoperatively and at 1-year follow-up. Mean values are given when Δ values (change from preoperative to follow-up at 1 year) where normally distributed, and median values are given when the Δ values were skewed. Δ values are statistically significant for all subscores ($p < 0.001$). ADL Activities of daily living. Sport/Rec Sport and recreation. QOL knee-related quality of life. * Median values

1 year after TKA was affected negatively by increasing medial laxity in extension and flexion. Additionally, the study shows that postoperative varus/valgus alignment interacts on the association between laxity and functional outcome. This means that the effect of laxity on function depends on the postoperative mechanical axis. It appears that perfectly aligned and valgus-aligned TKAs are more sensitive to increasing medial laxity than varus-aligned TKAs. From a clinical standpoint, it seems reasonable to accept that varus alignment may protect patients with modest degrees of medial laxity from medial instability events, at least in patients with low-grade physical activity. This presumption is supported by gait analysis that has demonstrated that the knee adduction moments are correlated with the mechanical axis of the knee [13]. It is likely that the relatively high adduction moments in varus knees reduce the effect of medial laxity. Vice versa, the low adduction moment in valgus knees may contribute to instability in knees with medial laxity.

Accordingly, one could expect a negative effect of lateral laxity on varus-aligned knees; however, this effect was less pronounced and less consistent through the different subscores (Table 4).

The size of the regression coefficients may be regarded as a measure of the clinical relevance of laxity on function. The minimum perceptible clinical improvement in KOOSs is 8–10 points [30]. Thus, it seems that only a 1–2 mm increase in medial laxity may have a clinically significant impact on subscores in KOOS for ADLs, sport/recreation and pain in patients with perfectly aligned or valgus-aligned knees.

The findings in this study differ from those in earlier reports where functional outcome was found to be better in lax knees. In the studies by Kuster et al. [18] and Edwards et al. [9] laxity measurements were performed in 30° and

Table 3 Knee Society scores, Oxford knee score, knee flexion, knee flexion contracture and patient satisfaction (VAS) measured preoperatively and at 1-year follow-up

	Preoperative	At 1 year	Δ (change)	*p*
KSS knee score	34.7 (16.3)	86.2 (13.3)	51.6 (19.0)	<0.001
KSS function score*	67.5 (50.0–80.0)	90.0 (80.0–100.0)	22.5 (10.0 to 36.3)	<0.001**
Oxford knee score§	36.90 (7.0)	18.0 (5.8)	−19.0 (8.0)	<0.001
Knee flexion*	120° (110°–128°)	115° (110°–122°)	−5° (−12° to 5°)	0.002**
Knee flexion contracture*	8° (5°–11°)	0° (0°–5°)	−5° (−10° to 0°)	<0.001**
Patient satisfaction (VAS)*		98 (90–100)		

Mean and standard deviation (SD) are given when Δ values (change from preoperative to follow-up at 1 year) where normally distributed and as median and interquartile ranges (IQR) when the Δ values were skewed. *p* values were tested with paired samples t test if no other indicated

* Skewed data

** Wilcoxon signed-rank test

§ Oxford score from 12 to 60, the best score is 12

VAS visual analogue scale (0–100)

Table 4 The relationship between ligament laxity (condylar lift-off) and outcome at 1-year follow-up expressed as median regression coefficients with 95 % CI and their *p* values

Outcome (KOOS)	Pain		Symptoms		ADL		Sport/recreation		QOL	
	Coefficient (95 % CI)	*p**	Coefficient (95 % CI)	*p**	Coefficient (95 % CI)	*p**	Coefficient (95 % CI)	*p**	Coefficient (95 % CI)	*p**
Laxity split by axis										
Medial in extension										
Valgus/neutral $n = 58$	−5.9 (−10.1 to −1.7)	0.006	−2.7 (−8.8 to 3.4)	n.s.	−7.3 (−11.2 to −3.5)	<0.001	−6.9 (−12.5 to −1.3)	0.017	−1.7 (−9.6 to 6.3)	n.s.
Varus $n = 64$	1.2 (−1.1 to 3.4)	n.s.	−0.1 (−6.4 to 6.3)	n.s	2.7 (−0.4 to 5.9)	n.s.	4.2 (−3.8 to 12.0)	n.s.	−0.9 (−7.7 to 5.9)	n.s.
Medial in flexion										
Valgus/neutral $n = 58$	−2.4 (−5.1 to 0.3)	n.s.	−1.9 (−4.3 to 0.4)	n.s	−3.1 (−5.8 to −0.5)	0.023	−4.2 (−8.2 to −0.2)	0.042	−2.2 (−6.0 to 1.6)	n.s.
Varus $n = 64$	0.2 (−1.0 to 1.3)	n.s.	0.4 (−2.4 to 3.2)	n.s	1.0 (−0.9 to 2.8)	n.s.	2.1 (−3.5 to 7.6)	n.s.	−0.8 (−4.2 to 2.5)	n.s.
Lateral in extension										
Valgus/neutral $n = 58$	−1.3 (−5.8 to 3.1)	n.s	−3.0 (−7.4 to 1.4)	n.s	2.2 (−2.3 to 6.7)	n.s.	7.0 (1.0 to 3.0)	0.024	−0.9 (−5.8 to 4.0)	n.s.
Varus $n = 64$	0.1 (−2.7 to 2.9)	n.s.	−5.0 (−9.2 to −0.8)	0.023	0.5 (−4.6 to 5.6)	n.s.	5.6 (−7.6 to 18.8)	n.s.	−3.0 (−10.1 to 4.2)	n.s.
Lateral in flexion										
Valgus/neutral $n = 58$	−0.7 (−3.0 to 1.6)	n.s.	−0.5 (−4.4 to 3.3)	n.s.	−1.8 (−4.8 to 1.2)	n.s.	−2.5 (−6.8 to 1.9)	n.s.	−2.0 (−4.5 to 0.6)	n.s.
Varus $n = 64$	0.1 (−1.4 to 1.5)	n.s	−3.0 (−5.8 to −0.1)	0.041	−1.7 (−5.2 to 1.8)	n.s.	−3.3 (−9.6 to 3.1)	n.s.	−2.7 (−5.9 to 0.4)	n.s.

Ligament laxity was measured intra-operatively medially and laterally in extension and in flexion. Outcome was measured with KOOS (including five subscores). The patients were stratified into two groups depending on the postoperative mechanical axis (alignment) of the operated knee: 58 valgus or neutral knees and 64 varus knees. The analysis was adjusted for age, sex and BMI

* *p* value for the regression coefficient, not corrected for multiple testing. ADL Activities of daily living. QOL knee-related quality of life

20° of flexion, respectively. This might have caused an unknown number of knees with poor function due to too much tightness in extension and/or in 90° of flexion. In a very recent study, Okamoto et al. [26] concluded that the extension gap needs more than 1 mm laxity to avoid postoperative flexion contracture. This finding strengthens the opinion that some laxity is beneficial for the knee function. In our study, we tried to avoid laxity less than one mm and only four out of 488 measurements showed less than one mm laxity.

In the study by Widmer et al. [38] computer navigation was used to assess intraoperative ligament balance. They found a poor association between ligament balance and outcome scores at 1 year. Ligament balance was only assessed with the knee in extension, and in the analysis on the effect of ligament balance on functional outcome, ligament balance was expressed as the change (Δ values) in manually tested maximum varus and valgus before and after prosthetic implantation. We consider absolute data on laxity to be more appropriate because the change in ligament balance does not reflect the actual laxity in the knee at the time of functional testing.

Medial–lateral laxity and the mechanical axis were focused on in this study. Subjective stability probably also depends on other factors. Recently, Seah et al. [32] studied the relationship between anteroposterior translation and functional outcome in 100 knees that were replaced with a cruciate-retaining total knee prosthesis. At 2 years of follow-up, patients with a 5–10 mm anteroposterior translation reported significantly better Oxford Knee Scores than patients with less than 5 mm or more than 10 mm anteroposterior translation ($p = 0.045$). Although the loosest knees had the greatest range of motion, they also had the greatest proportion of knees with hyperextension of more than 10°.

In this study, all knees were operated with the measured resection technique and a stepwise ligament-balancing technique where each step increases laxity from roughly zero to 4–5 mm. In order to avoid too tight ligaments or overcorrection (too lax ligaments) some degree of laxity had to be accepted. In contrast, if a pure gap technique is used, laxity can be fine-tuned by further bone cuts. A possible downside of this technique is that these additional bone cuts affect alignment of the knee.

Another important implication of the measured resection technique is that after the mechanical axis has been restored and ligament balancing performed, there should be no correlation between the preoperative degree of deformity and postoperative laxity. This is in concordance with our findings: we found no statistical significant correlation between the preoperative degree of deformity and medial and lateral laxity in extension and in flexion.

The effect of laxity on functional outcome is a major concern in TKA, but it has proved difficult to investigate. There may be various reasons for this. First, the general TKA population is very heterogeneous, with a huge range in age, BMI, physical fitness, activity interests and activity levels. Gender and comorbidities may also be important variables. It is not evident whether all these patients benefit from the same degree of laxity. Second, the choice of outcome measures may be decisive in order to reveal a relationship between laxity and functional outcome after TKA. In this study, the degree of association between laxity and outcome was strongest for the ADL subscore, the sport and recreation subscore and the pain subscore in KOOS. It was not possible to draw firm conclusions based on the KSS score and Oxford Knee Score alone. This may be attributed to a profound ceiling effect in these scores [16], leading to low discriminative capacity.

How tightly should a total knee replacement be balanced? Some authors have proposed guidelines for orthopaedic surgeons to restore normal stability in TKA. Based on a radiographic study measuring knee laxity in 30 healthy, elderly subjects with non-arthritic knees, Heesterbeek et al. [12] recommended varus laxity in flexion between 0° and 7.1° and valgus laxity between 0° and 5.5°. In extension, they suggest that surgeons should aim for varus laxity between 0.2° and 5.4° and valgus laxity between 0.7° and 3.9°.

Bellemans et al. [4] assumed ligament balance to be successful when a 2–4 mm medial–lateral joint line opening was obtained in extension and a 2–6 mm one in flexion.

Our results indicate that medial laxity of more than 2 mm in extension and more than 3 mm in flexion should be avoided. Lateral laxity seems to be more forgiving, especially in knees with neutral or valgus alignment. Varus-aligned knees also seem more forgiving to some minor degree of laxity. Our results also emphasize the importance of having maximal control on the mechanical axis when deciding on the degree of laxity during ligament balancing.

There are several limitations to this study. First, the patient sample was recruited from a general population of TKA patients. Although favourable for the external validity of the study, this also implies that the number and size of confounding factors are high. These confounding factors may disguise possible associations that are not so strong. Second, we observed visible condylar lift-off in almost every measurement. Only four out of 488 measurements recorded no condylar lift-off. When no lift-off is visible, the surgeon does not know how tight the soft tissues are, unless the tension in the ligaments is measured with some kind of mechanical or electronic device. Thus, the results of this study do not apply to knees without visible lift-off when tested for ligament laxity intraoperatively. Third, 14 patients in this study underwent bilateral TKA, and statistical independence between bilateral cases can be questioned. The influence of bilaterality depends on study design and context. In studies comparing outcome after arthroplasty, like in our study, recent papers have concluded that inclusion of bilateral cases does not alter the outcome [5, 25]. Fourth, our method to measure laxity do not distinguish between differences below 1 mm, but in our experience ligament-balancing surgery is not so exact that we feel a need for a more fine-tuned measuring device. The method is based on manual loading of the ligaments in valgus and varus. However, LaPrade and Heikes compared the lateral compartment gapping before and after sequential lateral ligament sectioning on radiographs when varus stress was applied either by a clinician or by a force-application device delivering a 12 Nm moment to the knee [19]. They concluded that both standardized 12-Nm moments and clinician-applied varus stress radiographs provide objective and reproducible measures of lateral compartment gapping.

Fifth, in this study we used CR knees and measured resection technique and our results may not be valid for other types of implants or surgical techniques. Finally, due to the lack of information on the effect size of laxity on functional outcome in former literature sample size calculation was not possible.

The strengths of the present study are its prospective design and the strict consecutive inclusion of patients according to inclusion criteria. Only one patient was lost to follow-up, and no other data are missing. Laxity measurements were performed intraoperatively both in extension and in flexion, enabling the surgeon to correct unacceptable results before finishing the procedure. To the best of our knowledge, this study is the first to describe the effects of ligament laxity, measured directly intraoperatively in millimetres, on functional outcome after TKA.

In a general TKA population, it is likely that many variables will obscure the effect of laxity on outcome, and all patients probably do not benefit from the same degree of laxity. Current outcome scores may not detect instability symptoms adequately. Consequently, further research on the effect of ligament laxity on functional outcome after TKA should focus on more selected patient groups, and both patient-reported outcome measures and performance measures sensitive to instability should be considered.

Until now, the literature has been indecisive on how a TKA should be balanced and surgeons had to depend on their personal experience. This study provides new information enabling orthopaedic surgeons to base their decisions during ligament balancing in TKA on more objective data.

Conclusion

Final mechanical axis needs consideration during ligament balancing and medial laxity more than 2 mm in extension and 3 mm in flexion must be avoided in neutral and valgus-aligned knees. Varus-aligned knees seem to be more forgiving for medial laxity.

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Arch Orthop Trauma Surg
DOI 10.1007/s00402-017-2625-y

KNEE ARTHROPLASTY

Minimal effect of patella eversion on ligament balancing in cruciate-retaining total knee arthroplasty

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Received: 12 May 2016

Abstract

Purpose The effect of patellar eversion on ligament laxity measurements is still unclear. The purpose of this study was to investigate the influence of patellar eversion on medial and lateral ligament laxity measurements performed intra-operatively in total knee arthroplasty (TKA).

Methods A total of 49 knees (27 female) with mean age 70 years (42–83) and mean body mass index of 28.5 were operated consecutively with a cruciate-retaining prosthesis. Medial and lateral ligament laxity in extension and in 90° of flexion was measured with the spatula-method intra-operatively after implantation of the prosthetic components with the patella everted and thereafter with the patella repositioned. The corresponding changes in gap height and inclination were calculated.

Results A statistically significant increase of 0.6 mm ($p<0.001$) in ligament laxity (condylar lift-off) laterally in flexion was found with the patella repositioned compared to everted. No differences were found in extension or medially in flexion. Correspondingly, the flexion gap increased by 0.4 mm ($p< 0.001$) and the flexion gap inclination increased by 0.6° ($p=0.002$) when the patella was repositioned.

Conclusions Earlier research has shown that ligament laxity must be at least 1–2 mm to cause inferior function after TKA. In the current study, we found that the effect of patellar eversion on ligament laxity measurements is too small to be considered clinically relevant.

Prospective study evaluating the effect of patient characteristics Level II.

Keywords Total knee arthroplasty · Patella · Joint instability · Ligament balancing · Patella eversion

Introduction

Ligament balance is mandatory for good function and survival in total knee arthroplasty (TKA) [1–5]. Instability is still among the most important reasons for revision knee arthroplasty [3, 4] and overly tight ligaments may have negative effect on knee motion and prosthetic survival [6–9]. Ligament laxity also affects functional outcome [5, 10], and earlier research has shown that ligament laxity must be at least 1–2 mm to cause inferior function after TKA [5].

The position of the patella (everted, laterally retracted or in situ) has been shown to influence on the measurements of ligament balance [11–13], but it is unknown whether this effect is of clinical importance for the functional outcome after TKA. In addition, the effect of the patella position on ligament laxity may depend on many factors such as the measuring device, whether the measurements are done before or after implantation of the prosthetic components, the integrity of the posterior cruciate ligament, the prosthetic design and the ligament balancing technique.

The aim of this study was to estimate the effect of patellar eversion on ligament laxity measured with the "spatula-method" [5, 14] after the implantation of the prosthetic components in cruciate-retaining TKAs balanced according to the technique described by Whiteside et al. [15, 16].

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Table 1 Patient demographics, knee alignment and deformity at baseline

		SD
Mean (range) age (years)	70 (42–83)	8.8
Gender (% female)	55%	
Side (% right)	49%	
Mean (range) BMI (kg/m²)	29 (22–38)	3.5
Pre-operative alignment		
Number of varus knees (%)	41 (83.7%)	
Mean deformity (range)	10° (1–22)	5.0
Number of valgus knees (%)	7 (14.3%)	
Mean deformity (range)	5° (2–9)	2.3
Number of neutral knees (%)	1 (2.0%)	
Mean deformity	0°	

Alignment and deformity was measured on long hip–knee–ankle (HKA) X-rays. Knees with 180° HKA angle was defined as neutral. Any deviation in varus was defined as a varus knee, and any deviation in valgus was defined as a valgus knee

SD standard deviation

Table 2 Ligament releases were performed in 33 out of 41 varus-deformed knees, in 3 out of 7 valgus-deformed knees, and in one out of one neutral knee

Ligament release	Varus knees ($n = 33$)	Valgus knees ($n = 3$)	Neutral knees ($n = 1$)
MCL			
Anterior part	26	–	1
Posterior part	20	–	–
Medial posterior capsule	5	–	–
Semi-membranous	1	–	–
Pes anserinus	–	–	–
PCL	13	2	–
LCL	–	1	–
Popliteus tendon	–	1	–
Posterolateral corner	–	–	–
Ileo-tibial tract	–	1	–
Lateral posterior capsule	–	1	–

MCL medial collateral ligament, *PCL* posterior cruciate ligament, *LCL* lateral collateral ligament

Patients and methods

A total of 49 knees (27 female and 22 male) with mean age 70 years (42–83), mean body mass index (BMI) of 28.5 were operated consecutively. Patient demographics, knee alignment and deformity at baseline are detailed in Table 1.

All patients were recruited consecutively from another ongoing prospective study evaluating the effect of ligament laxity on functional outcome in TKA 1 year after the operation. Inclusion criteria were patients less than 85 years old scheduled for TKA because of osteoarthritis. Exclusion criteria were knees with severe deformity not suitable for standard cruciate-retaining prosthesis, inflammatory arthritis, and severe medical disability limiting the ability to walk. The regional committee of research ethics approved the protocol and before enrolment, all patients signed an informed-consent form.

Surgical technique

All knees were operated through a standard midline incision and a medial parapatellar arthrotomy, using a cruciate retaining prosthesis (NexGen, Zimmer, Warsaw, IN, USA). We used measured resection technique. The valgus angle of the femoral component was set at 5°–8°, depending on the hip–knee–femoral shaft angle (HKFS) as measured on preoperative standing hip–knee–ankle (HKA) X-rays. Rotation of the femoral component was established by combining information from the anterior–posterior axis of the femur (Whiteside's line), the transepicondylar line and the posterior condylar line. Osteophytes were resected. With an intramedullary guide in the femur and an extramedullary guide on the tibia, saw-blocks were fit into place. After the saw cuts were performed, posterior osteophytes were removed. With a trial prosthesis implanted the ligament balance was evaluated. If asymmetric, the knee was balanced using the technique described by Whiteside et al. [15, 16]. The numbers of ligaments released are given in Table 2. The aims of the ligament balancing were medial and lateral condylar lift-off of 1–3 millimeters in both extension and 90° of flexion, and equal and rectangular flexion and extension gaps. If there was a persistent mismatch between the extension and the flexion gap of more than 5 mm additional bone cuts, according to the contingency table proposed by Mont and Delanois [17], were performed. All operations were done in bloodless field with a tourniquet on the proximal part of the thigh.

Laxity measurements

After implantation of the prosthesis medial and lateral condylar lift-off (ligament laxity) were measured with the "spatula-method" [14] in extension and 90° of flexion. In the "spatula-method" a set of polyethylene spatulas with increasing thicknesses (Fig. 1) are used to measure the distance from the deepest points of the polyethylene tray to the most distal and posterior points of the femoral condyles medially and laterally in extension and flexion (Fig. 2), while the knee is stressed in valgus and varus. The method have proved to be very reliable [14]. First measurements were performed in the standard way with the patella everted. Thereafter, the measurements were repeated with the patella repositioned.

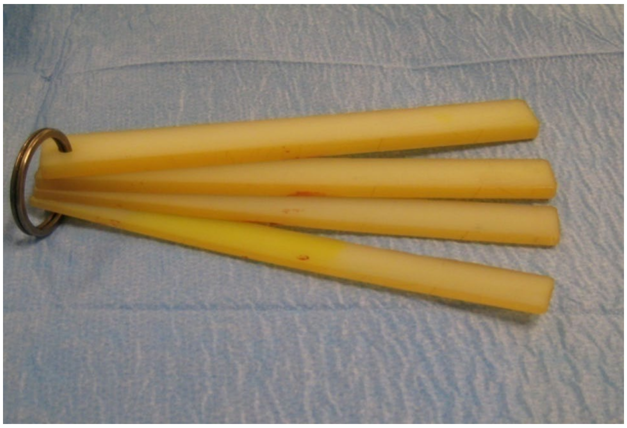

Fig. 1 The tool for measuring condylar lift-off consists of four spatulas made of polyethylene of increasing thickness

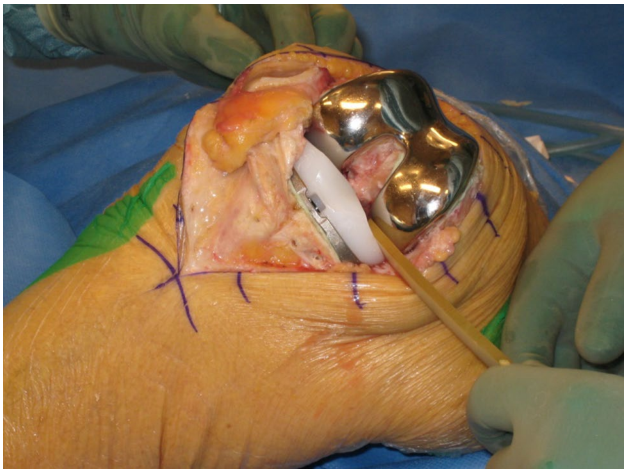

Fig. 2 The picture demonstrates measurement of medial condylar lift-off in flexion with the patella everted: with the knee in 90° of flexion medial condylar lift-off was defined as the distance in the frontal plane from the deepest point of the polyethylene tray to the most posterior point of the femoral condyle. The measurement was performed with the leg in a reversed crossed-leg position under passive varus stress from the weight of the lower leg with the thickest spatula that could be introduced without force

Some authors prefer to describe the gaps by referring to the inclination between the femoral and tibial cuts measured in degrees and height of the gaps measured in millimeters. In our study, inclination of the extension gap and the flexion gap was calculated from the laxity measurements (medial and lateral condylar lift-off) and the average distance between femoral condyles. Positive values indicate varus and negative values indicate valgus. The height of the extension gap and the flexion gap was defined as the mean value of medial and lateral condylar lift-off.

Statistical analysis

Categorical data are given in numbers and percent. Condylar lift-off was measured in millimeters and is presented as means, standard deviations and ranges. Comparisons between pared data were tested with paired samples *t* test for normally distributed data and with the Wilcoxon signed rank test for skewed data. Two-sided *p* values of <0.05 were considered to be statistically significant. Data were analyzed with SPSS v.22 software (SPSS Inc, Chicago, IL, USA) for Windows.

Results

A statistically significant increase of 0.6 mm ($p < 0.001$) in condylar lift-off (ligament laxity) laterally in flexion was found when measurements were performed with the patella repositioned compared to everted. No differences were found in extension or medially in flexion. (Table 3). Correspondingly the flexion gap inclination increased by 0.6° ($p = 0.002$) when the patella was repositioned (Table 4), and the flexion gap increased 0.4 mm ($p < 0.001$) when the patella was repositioned (Table 4). In only 2 of 196 measurements the difference between laxity measurements performed with and without patellar eversion was more than 2 mm (Table 5). More results are detailed in Tables 3, 4 and 5.

Discussion

The main finding in the present study is that ligament laxity laterally in 90° of flexion is underestimated by

Table 3 Medial and lateral laxity (condylar lift-off) in extension and 90° of flexion measured both with the patella everted and repositioned

Parameter	Patella everted	Patella repositioned	Δ	*p* value*
Extension medially	1.7 (0.7)1–4	1.8 (0.8)1–4	0.1	0.26
Extension laterally	2.1 (0.9)1–5	2.2 (1.0)1–5	0.1	0.56
Flexion medially	3.0 (1.5)1–8	3.1 (1.5)1–8	0.1	0.20
Flexion laterally	3.6 (1.7)1–10	4.2 (2.1)1–11	0.6	<0.001

The values are given in millimeters as means (SDs), and ranges (see text)

$N = 49$

Δ The difference in laxity measurements with the patella everted and repositioned

*Wilcoxon signed rank test

Table 4 Height and inclination of the flexion gap and the extension gap with the patella everted and repositioned

Parameter	Patella everted	Patella repositioned	Δ	*p* value
Extension gap in mm (SD)	1.9 (0.6)	2.0 (0.7)	0.1	0.315*
Flexion gap in mm (SD)	3.3 (1.3)	3.7 (1.5)	0.4	<0.001**
Extension gap inclination in degrees (SD)#	0.5° (1.2)	0.5° (1.42)	0.0°	0.796*
Flexion gap inclination in degrees (SD)#	0.8° (2.4)	1.3° (2.4)	0.6°	0.002**

N=49

*Wilcoxon signed rank test

**Paired samples *t* test

#Positive values indicate varus, negative values indicate valgus

Table 5 Frequency table showing the numbers of each delta value (Δ) for laxity measurements in mm

Δmm	Number of delta values (Δ) (%)			
	Medially in extension	Medially in flexion	Laterally in extension	Laterally in flexion
−2		1 (2.0)		
−1	2 (4.1)	5 (10.2)	5 (10.2)	5 (10.2)
0	42 (85.7)	30 (61.2)	37 (75.5)	19 (38.8)
1	5 (10.2)	13 (26.5)	7 (14.3)	17 (34.7)
2				6 (12.2)
3				1 (2.2)
4				1 (2.2)

196 measurements were performed in 49 knees

ΔDifference in ligament laxity measurements performed with the patella everted and with the patella repositioned

average 0.6 mm when ligament balance is measured with the patella everted, and that laxity medially in flexion and medially and laterally in extension is not significantly affected by patellar eversion. Additionally, only two outliers were observed (Table 5), one in a varus knee and one in a valgus knee. Both outliers were observed laterally in flexion. Earlier research had shown that medial laxity must be at least 1–2 mm to cause inferior functional results, and that the lateral side is even more forgiving [5]. Based on these earlier findings, it seems reasonable to assume that the very small changes in ligament laxity induced by patellar eversion in the current study are without clinical relevance.

This is to our knowledge the first study to compare the effect of patellar eversion on ligament laxity when all laxity measurements were performed intra-operatively after the implantation of the prosthetic components. The importance of these details is that spreading devices, tensioners and spacer blocs allow measurements in non-anatomic and non-physiologic biomechanical situation that might bias the results. For example, using a tensor Muratsu et al. found a decrease of as much as 5.3 mm in joint gap in extension and a reduction of varus ligament imbalance of 3.1° with the femoral trial prosthesis in place compared to measurements without [18]. Recent papers have described new methods combining patient-specific instruments and a balancer device, but also in these studies ligament tension was measured without the prosthetic components implanted [19, 20]. In contrast, the spatula-method allows for laxity measurements with all prosthetic components implanted, that is with the knee in its ultimate biomechanical situation.

Our findings are supported by some earlier studies. Kamei et al. [12] observed a statistically significant increase in gap inclination of 0.9° in 90° of flexion when the patella was repositioned. Measured in millimeters this corresponds to 0.8 mm increase in laxity laterally in flexion [21]. The study was performed with gap technique on 24 posterior-stabilized (PS) knees, and the measurements were done after the bone cuts on the proximal tibia and the distal femur without the prosthetic components implanted.

Mayman et al. studied the influence of patellar eversion versus reduction on medial and lateral gaps in ten cadaver knees using a computer-controlled distractor [11]. They found that in knees with the PCL intact, the lateral gap in 90° of flexion increased by 0.7 mm (from 4.2 to 4.9 mm) when the patella was reduced, and they also found a statistically significant increase of 1 mm medially in flexion. The study was performed on cadaver knees without deformity and no prosthetic components were implanted.

In a recent paper, Yoon et al. reported on medial and lateral gap measurements in extension and 90° of flexion, performed with the patella in three positions; reduced, subluxated (laterally retracted) and everted [22]. They found a significant decrease of 4 mm in the lateral joint gap in flexion when the patella was everted compared to reduced. No statistically significant differences were found laterally in extension or medially. Measurements were done with a computer navigation system and a force controlled spreader on 50 posterior cruciate-sacrificing TKAs before the prosthetic components implanted. The relatively high decrease in gap joint (4 mm) laterally in flexion may be attributed to the sacrifice of posterior cruciate ligament.

In contrast to the aforementioned papers, Matsumoto et al. observed a 1.8-mm greater gap laterally in flexion when the patella was everted in 20 cruciate-retaining TKA [23]. They measured the soft tissue balance with a tensor fixed to the proximal tibial bone by its lower part and the upper part fitted into the femoral trial component. However, the same research group found a 1.6° increase in varus imbalance when the patella was reduced compared to retracted in a study on posterior-stabilized TKA with a quadriceps-sparing approach [24]. The reason for this controversy remains unclear.

The consequences of erroneous measurements due to patellar eversion during ligament balancing in TKA depend on the surgical technique. If measured resection technique is used, like in our study, ligament balancing performed with the patella everted will lead to underestimation of ligament laxity laterally in flexion; that is, after reduction of the patella lateral laxity in flexion will increase average 0.6 mm. If a pure gap technique is used, and the flexion gap is tensioned with the patella everted, a 0.6-mm over-resection of the posterior lateral femoral condyle will follow, resulting in internal rotation of the femoral component of approximately 0.7°. Theoretically, this results in valgus-malalignment in flexion and lateral tracking of the patella.

Our study has some limitations. First, all knees were operated with a posterior cruciate-retaining prosthesis. The results may not apply to posterior cruciate-sacrificing prosthetic designs, because the posterior cruciate ligament is known to play a part in medial and lateral laxity. Another possible limitation is that our method to measure ligament laxity is based on manual loading of the ligaments in valgus and varus. However LaPrade et al. compared the lateral compartment gapping before and after sequential lateral ligament sectioning on radiographs when varus stress was applied either by a clinician or by a force-application device delivering a 12 N m moment to the knee [25]. They concluded that both standardized 12-Nm moments and clinician-applied varus stress radiographs provide objective and reproducible measures of lateral compartment gapping. In another study, Mayman et al. determined the influence of load magnitude on gap symmetry and balance in ACL-deficient knees [11]. They found that increasing the load from 50 to 100 N increased the mean gap by only 0.5 mm. It is our opinion that such small differences are beyond clinical importance, because current ligament balancing techniques are not so fine-tuned. In our study, laxity measurements were performed in epidural anesthesia. In a very recent study, Tsukeoka et al. found that varus and valgus laxity was significantly increased when the stress tests were performed with anesthesia as compared to without anesthesia [26]. However, ligament laxity cannot be modified without anesthesia, so in the context of this study, ligament laxity measurements performed under anesthesia is the most relevant. Finally, the lower limit of precision for our measuring method is 1 mm. This means that on an individual basis our measuring method is not able to detect differences below 1 mm.

The strength of this study is that all laxity measurements were performed after the prosthetic components were implanted, that is in the ultimate anatomical and biomechanical situation. Another strength of this study is the prospective, pragmatic design including patients with deformed knees representing the general TKA population. The relatively high number of knees also adds to the credibility of this study.

Based on the results of the current study and earlier research, we conclude that the effect of patellar eversion on ligament laxity measurements is too small to be considered clinically relevant.

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No detrimental effect of ligament balancing on functional outcome after total knee arthroplasty: a prospective cohort study on 129 mechanically aligned knees with 3 years' follow-up

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Submitted 2018-04-22. Accepted 2018-05-21.

Background and purpose — In the classical mechanical alignment technique, ligament balancing is considered a prerequisite for good function and endurance in total knee arthroplasty (TKA). However, it has been argued that ligament balancing may have a negative effect on knee function, and some authors advocate anatomic or kinematic alignment in order to reduce the extent of ligament releases. The effect of the trauma induced by ligament balancing on functional outcome is unknown; therefore, the aim of this study was to investigate this effect.

Patients and methods — 129 knees (73 women) were investigated. Mean age was 69 years (42–82), and mean BMI was 29 (20–43). Preoperatively 103 knees had a varus deformity, 21 knees had valgus deformity, and 5 knees were neutral. The primary outcome measure was the Knee injury and Osteoarthritis Outcome Score (KOOS). Secondary outcome measures were the Oxford Knee Score (OKS) and patient satisfaction (VAS). All ligament releases were registered intraoperatively and outcome at 3 years' follow-up in knees with and without ligament balancing was compared

Results — 86 knees were ligament balanced and 43 knees were not. Ligament-balanced varus knees had more preoperative deformity than varus knees without ligament balancing ($p = 0.01$). There were no statistically significant differences in outcomes between ligament-balanced and non-ligament-balanced knees at 3 years' follow-up. No correlation was found between increasing numbers of soft tissue structures released and outcome.

Interpretation — We did not find any negative effect of the trauma induced by ligament balancing on knee function after 3 years.

Symmetric ligament balancing, creating equal and rectangular gaps, has traditionally been considered a prerequisite for good function and endurance in total knee arthroplasty (TKA) (Sharkey et al. 2002, Matsuda et al. 2005, Graichen et al. 2007, Delport et al. 2013). The need for and the extent of ligament balancing is influenced by patient-dependent factors and surgical factors. The most important patient-dependent factors are the degree of knee deformity and the status of the ligaments and other soft tissues around the knee. The predominant surgical factors are the alignment goal, and whether a measured resection technique or a gap technique is used.

3 different principles for alignment exist. Classical mechanical alignment (Insall et al. 1985), anatomic alignment (Hungerford and Krackow 1985), and kinematic alignment (Hollister et al. 1993, Eckhoff et al. 2005). In mechanical alignment, the aim is to place the center of the femoral and tibial components at the mechanical axis of the lower extremity and the joint line perpendicular to the mechanical axis. In contrast, anatomic and kinematic alignment aim to reestablish the patient's natural premorbid alignment, that is with the mechanical axis passing on average 8 mm medial to the joint center and the joint line in 2°–3°varus (Paley 2003). Consequently, by using anatomical or kinematic alignment in a varus knee, less angular correction of the bone is needed and the extent of medial ligament releases is reduced. However, the scientific support for anatomical and kinematic alignment is currently scarce and mechanical alignment remains the gold standard (Abdel et al. 2014, Gromov et al. 2014).

The extent of ligament balancing can also be reduced by using a gap technique rather than a measured resection technique. When a measured resection technique is used, ligament balancing is performed both in extension and in flexion. In contrast, with a classical gap technique, ligament balancing is performed only in extension (Insall and Easley 2001).

DOI 10.1080/17453674.2018.1485283

Hence, the extent of ligament releases in varus knees can be reduced by aiming at anatomical or kinematic alignment and/or by using a gap technique. Nevertheless, a possible downside is that the knee will be left with the mechanical axis passing medially to the center of the knee and the joint line in varus. In return, this will lead to uneven distribution of loads through the medial and lateral compartments of the knee and increased share forces on the interfaces between implants and bone. These factors may possibly threaten the longevity of the prosthetic knee (Ritter et al. 2011, Kim et al. 2014).

The exercise of ligament balancing induces an additional surgical trauma to the knee and it could be hypothesized that this trauma is deleterious to functional outcome after TKA. Each surgeon must choose between mechanical, anatomic, or kinematic alignment techniques and between measured resection and gap technique. The effect of the trauma induced by ligament balancing on functional outcome after TKA has not been described in the literature. However, it is a crucial factor to consider when the surgeon will decide whether to perform ligament balancing or not, and which alignment strategy and gap-balancing strategy to use. Therefore, we investigated the effect of the trauma imposed by ligament balancing on functional outcome after TKA.

Patients and methods

All patients participating in another prospective, randomized, and double-blind study comparing TKA with and without patellar resurfacing (Aunan et al. 2016) were included in this study. Inclusion criteria were patients less than 85 years old scheduled for TKA because of osteoarthritis. Exclusion criteria were knees with severe deformity defined as: bone deformity to such a degree that the bone cuts would damage the ligamentous attachments on the epicondyles; ligament laxity without a firm end-point or to such a degree that ligament releases on the concave side would result in a need for more than 20 mm polyethylene thickness; the combination of bone deformity and ligament laxity resulting in the need for more than 20 mm polyethylene thickness. Excluded were also knees with posterior cruciate deficiency, inflammatory arthritis, and severe medical disability limiting the ability to walk or to fill out the patient-recorded outcome documents. Also excluded were patients with patellar thickness less than 18 mm measured on calibrated digital radiographs, isolated patello-femoral arthrosis, knees with secondary osteoarthritis (except for meniscal sequelae), and knees with previous surgery on the extensor mechanism. 2 patients died before the 3-year follow-up. In these patients, outcome scores 1 year after the operation were carried forward.

Standard radiographs and standing hip–knee–ankle (HKA) radiographs were taken preoperatively and at follow-up. A knee was considered in neutral alignment when the mechanical axis of the lower extremity passed through the center of the tibial spines of the knee and any deviation was termed varus or valgus deformity according to the definitions recommended by Paley (2003).

Surgical technique

All knees were operated through a standard midline incision and a medial para-patellar arthrotomy, using a posterior cruciate-retaining prosthesis (NexGen, Zimmer, Warsaw, IN, USA) and measured resection technique. Classical mechanical alignment was aimed for by setting the valgus angle of the femoral component at 5–8 degrees, depending on the hip–knee–femoral shaft angle (HKFS) as measured on preoperative HKA radiographs.

Rotation of the femoral component was decided with the clinical rotational axis (CRA) method, described by Aunan et al. (2017). The tibial component was aligned to the medial third of the tibial tubercle or with a modified self-seeking technique. Ligament balancing was performed using the technique described by Whiteside and colleagues (Whiteside 1999, Whiteside et al. 2000). The aims of the ligament balancing were medial and lateral laxities of 1–3 mm in both extension and 90° of flexion, and equal and rectangular flexion and extension gaps. The indication for ligament balancing was laxities outside these limits. If an important difference in the height of the flexion and extension gap was still observed after ligament balancing, the gaps were corrected according to the contingency table described by Mont et al. (1999). Medial and lateral ligament laxity in extension and 90° of flexion was measured with the spatula method (Aunan et al. 2012, 2015). This method has demonstrated a very high inter-rater reliability with an intraclass correlation coefficient equal to 0.88.

Outcome measures

The primary outcome measure was the Knee injury and Osteoarthritis Outcome Score (KOOS) (Roos and Toksvig-Larsen 2003). Secondary outcome measures were the Oxford Knee Score (Dawson et al. 1998) and patient satisfaction measured on a visual analog scale (VAS). The primary and secondary outcome measures were recorded preoperatively and at 3 years of follow-up. VAS was recorded at 3 years.

First all ligament releases were registered intraoperatively. Second, outcome scores at 3 years' follow-up in knees with and without ligament balancing was compared. Third, the change in outcome scores from preoperative to the 3-year follow-up in each group was compared. Fourth, the change in outcome scores for varus knees and valgus knees was analyzed separately. Finally, the correlation between increasing number of ligament releases and functional outcome for all ligament-balanced knees was estimated.

Statistics

A post hoc sample size calculation was performed with the OpenEpi, Version 3 (http://www.openepi.com/Menu/OE_Menu.htm), open source calculator. The minimal clinically

Table 1. Baseline data for knees with and without ligament balancing. Values are mean (range) unless otherwise specified

Factor	With ligament balancing (n = 86)	Without ligament balancing (n = 43)	p-value
All knees:			
Age	69 (42–81)	70 (53–82)	0.4 [a]
BMI	29 (23–43)	29 (20–38)	0.8 [a]
Women/men, n	50/36	23/20	0.7 [b]
Patellar resurfacing yes/no, n	40/46	23/20	0.5 [b]
Varus knees:			
Number of knees	75	28	
Age	70 (48–81)	70 (53–82)	0.9 [a]
BMI	29 (23–43)	30 (22–38)	0.4 [a]
Women/men, n	41/34	13/15	0.5 [b]
Deformity [c]	10° (4.4) 2–22	7° (5.1) 1–21	0.01 [a]
Patellar resurfacing yes/no, n	38/37	16/12	0.7 b
Valgus knees:			
Number of knees	10	11	
Age	65 (42–79)	72 (63–82)	0.1 [a]
BMI	32 (26–38)	28 (20–34)	0.06 [a]
Women/men, n	9/1	8/3	0.6 [b]
Deformity [c]	5° (3.2) 2–13	7° (3.0) 3–13	0.3 [a]
Patellar resurfacing yes/no, n	2/8	6/5	0.2 [b]
Neutral knees:			
Number of knees	1	4	
Age	69	70 (65–79)	
BMI	32	30 (25–34)	
Women/men, n	0/1	2/2	
Patellar resurfacing yes/no, n	0/1	1/3	

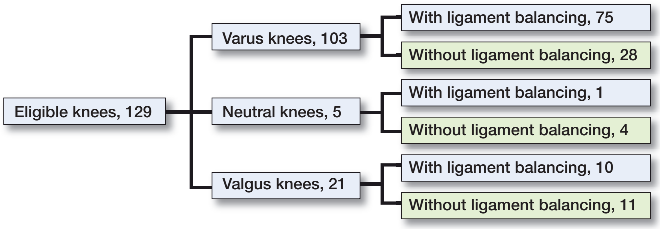
[a] Independent samples t-test.
[b] Fisher's exact test.
[c] Mean (SD) and range

important difference (MCID) in KOOS was set at 10 points and the mean SD of all KOOS sub-scores at 3 years was set at 16. The ratio of sample sizes was set at 0.5, the 2-sided CI at 95%, and the power at 90%. Given these data, the total sample size was calculated to be 122 with 41 in one group and 81 in the other.

Data were checked visually for normality based on histograms. Means or median values are presented depending on the distribution of data. Comparison of mean and median values was performed using the independent-samples t-test for normally distributed data and the Mann–Whitney U-test for skewed variables. Fisher's exact test was used when analyzing categorical variables. The association between the number of ligaments released and outcome was estimated with Spearman's correlation analysis. A significance level of 5% was used and the analyses were performed with IBM SPSS 22 software (IBM Corp, Armonk, NY, USA).

Ethics, funding, and potential conflicts of interest

The patients included in this study was recruited from another randomized and double-blind trial that was approved by the Regional Committee of Research Ethics at the University of Oslo (REK: 1.2007.952) and registered at ClinicalTrials.gov (identifier: NCT00553982). Later additions to the protocol was approved by the same committee (ID number: S-07172d 1.2007.952) and (2010/1678 D 33-07172b 1.2007.952 with changes 05.03.2012). All the patients signed an informed consent form. The first author has received funding from Sykehuset Innlandet Hospital trust. There are no conflicts of interest.



Number of knees with and without ligament balancing in different alignment groups.

Table 2. Frequency of soft tissue releases in 86 ligament-balanced knees

Structure released	Varus knees	Valgus knees	Neutral knees
MCL, anterior part	57	2 [a]	1
MCL, posterior part	47	1 [a]	0
Medial posterior capsule	11	0	0
Semimembranosus	2	0	0
Pes anserinius	0	0	0
Popliteus tendon	5	4	0
Lateral collateral ligament	1	1	0
Tractus ileotibialis	0	4	0
Posterior-lateral corner.	0	2	0
Lateral posterior capsule	0	4	0
Posterior cruciate ligament	33	3	0
Total	156	21	1

[a] Compensatory releases.
MCL: Medial collateral ligament.

Results

129 knees were investigated (Table 1). Preoperatively 103 knees had a varus deformity, 21 knees had valgus deformity, and 5 knees were neutral (Figure). Ligament-balanced varus knees had statistically significantly more preoperative deformity than varus knees without ligament balancing. No other statistically significant differences in baseline data were observed.

86 knees were ligament balanced and 43 knees were not. In the ligament-balanced knees, mean 2 (1–4) ligament structures were released per knee (Table 2).

Table 3. Median (IQR) values for functional outcome for ligament-balanced and non-ligament-balanced knees at 3 years follow-up

Factor	Without ligament balancing (n = 43)	With ligament balancing (n = 86)	p-value [a]
KOOS:			
Pain	92 (17)	97 (19)	0.3
Symptoms	89 (14)	93 (14)	0.9
ADL	93 (24)	94 (24)	0.7
Sport/recreation	70 (45)	65 (41)	0.9
QOL	88 (38)	88 (27)	0.9
Oxford Knee Score	56 (10)	57 (7)	0.3
Patient satisfaction	98 (10)	98 (10)	0.6

[a] Mann-Whitney U test.
KOOS: Knee injury and Osteoarthritis Outcome Score, 0–100. Best score is 100. ADL: Activities of daily living. QOL: Knee related quality of life.
Oxford knee score, 12-60. Best score is 60.

Table 4. Mean (SD) change in outcome scores for all knees (N = 129) from baseline to the 3 years follow up in ligament-balanced and non-ligament-balanced knees

Factor	Without ligament balancing (n = 43)	With ligament balancing (n = 86)	p-value [a]
KOOS:			
Pain	42 (18)	48 (19)	0.09
Symptoms	36 (17)	37 (20)	0.7
ADL	38 (19)	42 (21)	0.3
Sport/recreation	48 (27)	49 (30)	0.8
QOL	55 (22)	58 (25)	0.5
Oxford Knee Score	18 (7)	20 (8)	0.4

[a] Independent samples t-test.
Abbreviations: See Table 3.

There were no statistically significant differences in outcome scores between ligament-balanced and non-ligament-balanced knees at 3 years' follow-up (Table 3), or in change of outcome score from baseline to follow-up between the 2 groups (Table 4). When varus and valgus knees were investigated separately, still no difference between ligament-balanced and non-ligament-balanced knees was observed (Table 5). No correlation was found between increasing numbers of soft tissue structures released on the one hand and KOOS, OKS or patient satisfaction on the other.

Table 5. Mean (SD) change in outcome scores from baseline to the 3 years follow up for varus-deformed and valgus-deformed knees in ligament-balanced and non-ligament-balanced knees

Factor	Without ligament balancing (n = 43)	With ligament balancing (n = 86)	p-value [a]
Varus knees (n = 103), n	**28**	**75**	
KOOS:			
Pain	46 (19)	49 (18)	0.6
Symptoms	37 (16)	36 (20)	0.9
ADL	40 (21)	41 (20)	0.8
Sport/recreation	52 (26)	50 (29)	0.7
QOL	60 (20)	58 (25)	0.7
Oxford Knee Score	20 (8)	20 (8)	1.0
Valgus knees (n = 21), n	**11**	**10**	
KOOS:			
Pain	35 (12)	45 (26.)	0.3
Symptoms	38 (12)	41 (18)	0.7
ADL	37 (11)	45 (22)	0.3
Sport/recreation	44 (25)	42 (33)	0.8
QOL	49 (20)	56 (31)	0.6
Oxford Knee Score	15 (5)	19 (11)	0.3

[a] Independent samples t-test.
Abbreviations: See Table 3.

Discussion

Our findings indicate that the surgical trauma imposed by ligament balancing does not have a detrimental effect on knee function as assessed 3 years after the operation. The majority of the ligament-balanced knees had more deformity at baseline than the non-ligament-balanced knees, indicating a less favorable prognosis. Nevertheless, despite multiple releases in many knees, we could not find any negative effect of ligament balancing.

It is well documented that as much as one-fifth of TKA patients are unsatisfied with their TKA (Bourne et al. 2010). The majority of TKAs have until now been aligned according to the principle of mechanical alignment. However, it has been shown that most native knees are slightly varus-aligned (Paley 2003) and that one-third of men and one-fifth of women have constitutional varus knees with a natural mechanical alignment ≥ 3° degrees varus (Bellemans et al. 2012). Based on this information, it has been speculated that one reason for dissatisfaction with TKA can be that mechanical alignment does not recreate the patient's premorbid natural alignment (Bellemans et al. 2012, Lee et al. 2017), and that the increased need for ligament balancing in mechanically aligned varus knees can be detrimental to the functional outcome (Bellemans et al. 2012, Gu et al. 2014). Our findings do not support this theory, indicating that the need for additional soft tissue releases is not a valid argument against mechanical alignment in TKA.

Kinematic alignment reduces the need for ligament and other soft tissue releases in 2 different ways: first, in traditional mechanical ligament balancing the goal is to obtain rectangular and equal flexion and extension gaps (Sharkey et al. 2002, Matsuda et al. 2005, Graichen et al. 2007, Delport et al. 2013). In kinematic alignment theory, the aim is to restore the native laxity of the knee ligaments (Lee et al. 2017). Native knee ligament laxity is more pronounced laterally than medially and more laxity is present in flexion than in extension (Tokuhara et al. 2004, Van Damme et al. 2005, Nowakowski et al. 2012). Consequently, by preserving these native properties the need for medial soft tissue releases in a varus-deformed knee is reduced as compared with traditional mechanical balancing. Second, in kinematically and anatomically aligned TKAs the need for soft tissue releases in varus deformed knees is reduced because less correction of the varus deformity is needed, thus less tension is generated in the medial soft tissues.

The degree of ligament balancing in flexion can also be reduced if a gap technique is used instead of a measured resection technique (Insall and Easley 2001). However, in a varus knee this will lead to external rotation of the femoral component and varus alignment in flexion. In a valgus knee, it will result in internal rotation of the femoral component and potential maltracking of the patella and valgus deformity in flexion.

Mechanical alignment is still considered a gold standard (Abdel et al. 2014, Gromov et al. 2014) but anatomic and kinematic alignment have gained increasing popularity in the last decade (Lee et al. 2017) and there is an ongoing debate as to what is the best alignment goal (Lee et al. 2017, Young et al. 2017). Classical mechanical alignment was introduced in order to secure equal distribution of loads between the medial and lateral compartments of the knee and to reduce shear forces at the interfaces between implants and bone (Insall et al. 1985). However, some recent studies have failed to show a relationship between coronal plane alignment and prosthetic survival (Parratte et al. 2010, Bonner et al. 2011). Therefore, in the hope of improving knee function after TKA growing enthusiasm for anatomic and kinematic alignment has emerged. Nevertheless, an important matter to consider is the ability of current surgical techniques to reach the exact alignment goal. Although outliers from the mechanical axis ≥ 3° may be acceptable (Parratte et al. 2010, Bonner et al. 2011), the same amount of divergence in varus from the natural axis is probably not compatible with long-term survival and good knee function. Consequently, in order to prevent unacceptable outliers, the use of anatomic or kinematic alignment presumes surgical techniques with a high degree of accuracy and precision. Another limitation to the kinematic alignment theory is that replication of normal alignment and ligament laxity does not necessarily lead to more natural knee joint kinematics in TKA. It must be remembered that almost all total knee designs sacrifice 1 or both cruciate ligaments. The lack of well-functioning cruciate ligaments has profound impact on knee kinematics (Scanian and Andriacchi 2017), and non-anatomic prosthetic design features are needed to compensate for the lack of the cruciate ligament(s) and secure stability. It is therefore the authors' opinion that, in the current context, the term kinematic alignment is too optimistic.

There are some limitations to this study. First, when the study population was subdivided into varus- and valgus-deformed knees (Table 5) the subsequent comparisons between ligament balanced and non-ligament balanced knees are underpowered, increasing the risk of a type 2 error. However, we observed no trends in favor of the non-ligament-balanced knees. Second, we do not know how the ligament-balanced knees would have performed without ligament balancing. Nevertheless, the fact that no differences between the groups were found in change in scores (Δ-values) (Tables 4 and 5) and that no correlation was found was found between increasing numbers of released soft tissue structures and outcome suggests that no real difference between the groups exists. Although an RCT could have been preferred, given the huge amount of literature pointing out the importance of proper ligament balancing in deformed knees with soft tissue contractures, it is our opinion that an RCT on this population would be unethical. Third, ligament balancing was performed according to the methods described by Whiteside et al. (Whiteside 1999, Whiteside et al. 2000). The results of our study are therefore not valid for other ligament-balancing techniques. Finally, optimal ligament balancing has until recently been unknown. Some earlier reports that compared lax and tight TKAs found better functional outcomes in lax knees (Edwards et al. 1988, Kuster et al. 2004). However, during the last decade different research groups have come to conclusions or recommendations that seem to resemble each other. For example, Heesterbeek et al. (2008) recommended 0.7–3.9° valgus laxity and 0.2–5.4° varus laxity in extension. In flexion they recommended between 0° and 7.1° varus laxity and between 0° and 5.5° valgus laxity. Bellemans et al. (2010) assumed ligament balance successful when 2–4 mm medial–lateral joint line opening was obtained in extension and 2–6 mm in flexion. Okamoto et al. (2014) concluded that the extension gap needs more than 1 mm laxity to avoid postoperative flexion contracture in a clinical study. Our research group studied the effect of ligament laxity measured intraoperatively on functional outcome at 1-year follow-up (Aunan et al. 2015). We concluded that medial laxity more than 2 mm in extension and 3 mm in flexion should be avoided in neutral and valgus-aligned knees and that the lateral side is more forgiving. These findings are supported by a recent study by Ismailidis et al. (2017) that found a positive effect on postoperative flexion and patient satisfaction in knees where the flexion gap exceeded the extension gap by 2.5 mm. Furthermore, Tsukiyama et al. (2017) reported that medial rather than lateral knee instability correlates with inferior patient satisfaction and knee function after TKA.

In summary, the potential detrimental effect of the surgical trauma imposed by ligament balancing is an important determinant that must be considered when surgeons choose between different principles for alignment and gap balancing. It is also a crucial factor in cases where the need for ligament releases is debatable. We did not find any negative effect of ligament balancing on knee function after 3 years.

EA: conception, design, data collection, analysis, interpretation, and writing of manuscript. SMR: Revision and approval of the manuscript.

Acta thanks Kirill Gromov and Kjell G Nilsson for help with peer review of this study.

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Patellar resurfacing in total knee arthroplasty: functional outcome differs with different outcome scores

A randomized, double-blind study of 129 knees with 3 years of follow-up

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Submitted 2015-06-21. Accepted 2015-09-14.

Background and purpose — Recent research on outcomes after total knee arthroplasty (TKA) has raised the question of the ability of traditional outcome measures to distinguish between treatments. We compared functional outcomes in patients undergoing TKA with and without patellar resurfacing, using the knee injury and osteoarthritis outcome score (KOOS) as the primary outcome and 3 traditional outcome measures as secondary outcomes.

Patients and methods — 129 knees in 115 patients (mean age 70 (42–82) years; 67 female) were evaluated in this single-center, randomized, double-blind study. Data were recorded preoperatively, at 1 year, and at 3 years, and were assessed using repeated-measures mixed models.

Results — The mean subscores for the KOOS after surgery were statistically significantly in favor of patellar resurfacing: sport/recreation, knee-related quality of life, pain, and symptoms. No statistically significant differences between the groups were observed with the Knee Society clinical rating system, with the Oxford knee score, and with visual analog scale (VAS) for patient satisfaction.

Interpretation — In the present study, the KOOS—but no other outcome measure used—indicated that patellar resurfacing may be beneficial in TKA.

The most effective treatment of the patello-femoral joint during total knee arthroplasty (TKA) remains controversial, and according to different national arthroplasty registries there is a remarkable variation between countries in whether the patella is resurfaced or not. In Norway and Sweden, only 2% of the TKAs have their patellas resurfaced (Norwegian Arthroplasty Registry 2014, Swedish Knee Arthroplasty Registry 2014). In Denmark, 76% of the patellas are resurfaced (Danish Knee Arthroplasty Registry 2014) and in Australia 54% are resurfaced (Australian National Joint Registry 2013). In the USA, 98% of TKAs registered in the Kaiser Permanente Registry were performed with patellar resurfacing (Paxton et al. 2011). Advocates of patellar resurfacing emphasize cost-effectiveness, a reduced number of reoperations, and less anterior knee pain (Helmy et al. 2008, Clements et al. 2010, Murray et al. 2014). Proponents of patellar retention claim that patellar resurfacing offers no advantages in functional outcome, reoperation rate, or total healthcare cost (Burnett et al. 2009, Group et al. 2009, Breeman et al. 2011), and that it is associated with more complications (Ogon et al. 2002).

Since 2011, 4 meta-analyses of randomized controlled trials (RCTs) comparing patellar resurfacing and non-resurfacing have been published (Fu et al. 2011, He et al. 2011, Pavlou et al. 2011, Chen et al. 2013). They all concluded that patellar resurfacing reduces the risk of reoperations. Concerning anterior knee pain and knee function, it was not possible to conclude whether patellar resurfacing is beneficial or not. In the meta-analyses, the assessment of knee function was based on 14 RCTs. In 11 of these studies, knee function was measured with the Knee Society clinical rating system (KSS), while the Hospital for Special Surgery (HSS) score was used in 2 studies and the Western Ontario and McMaster osteoarthritis index (WOMAC) in 1 study. However, in recent years, the discriminating capacity of these classical outcome measures has been questioned because of high ceiling effects (Hossain et al. 2011, Jenny et al. 2014, Hossain et al. 2015, Aunan et al. 2015). This may obscure differences between patients with high scores, and bias research results. New scoring systems have been developed in an attempt to avoid this problem (Roos and Toksvig-Larsen 2003, Behrend et al. 2012, Na et al. 2012, Noble et al. 2012, Hossain et al. 2013, Jenny et al. 2014).

We compared the functional outcome in osteoarthritic patients operated with TKA, with and without patellar resurfacing, using 4 different outcome measures. The primary outcome measure was the knee injury and osteoarthritis outcome

DOI 10.3109/17453674.2015.1111075

score (KOOS) (Roos and Lohmander 2003) and secondary outcome measures were the KSS, the Oxford knee score, and patient satisfaction. These were recorded preoperatively and at follow-up after 1 year and 3 years. In addition, we calculated ceiling effects and interquartile ranges (IQRs) at 3 years for all outcome measures.

Patients and methods

Design

This was a single-center, randomized, double-blind study. It was conducted according to the CONSORT guidelines. All patients underwent surgery at Sykehuset Innlandet Hospital Trust, Lillehammer, Norway, which is a community teaching hospital that performs 50–70 primary TKAs per year. To ensure consistency in surgical technique, 1 surgeon (EA) was either operating or assisting at every operation.

Inclusion and exclusion

153 consecutive patients scheduled for primary TKA at our institution between November 2007 and March 2011 were assessed for eligibility for this study. Inclusion criteria were patients younger than 85 years with primary knee osteoarthritis. Exclusion criteria were knees with severe deformity of bone and/or ligaments that made them unsuitable for a standard cruciate-retaining prosthesis, patellar thickness less than 18 mm measured on calibrated digital radiographs, and isolated patello-femoral arthrosis. Also excluded were knees with secondary osteoarthritis (except for meniscal sequelae), previous surgery on the extensor mechanism, patients with a severe medical disability preventing them from climbing 1 level of stairs, and patients who were not able to fill out the patient-reported outcome measures (KOOS and Oxford knee score).

Randomization and blinding

Computerized random numbers in blocks with randomly selected block sizes were generated by a third party, and randomization of each knee was performed by the surgeon or the assistant immediately before the operation, through internet connection with the randomization server. The patients and the assessor of outcome (GN) were blind regarding the randomization allocation throughout the study.

Surgical technique

All knees were operated on through a standard midline incision and a medial parapatellar arthrotomy, using a cruciate-retaining, fixed-bearing prosthesis (NexGen; Zimmer, Warsaw, IN) and a measured resection technique. All components were cemented. In order to create a neutral mechanical axis, the valgus angle of the femoral component was set at 5–8°, depending on the hip-knee-femoral shaft angle, as measured on preoperative standing hip-knee-ankle (HKA) radiographs (Ewald 1989). Ligament balancing was performed using the technique described by Whiteside and colleagues (Whiteside 1999, Whiteside et al. 2000). The patella was everted, and cartilage damage to the patella was graded according to the International Cartilage Repair Society (ICRS) (Brittberg and Winalski 2003) and documented. Patellar resurfacing was performed with the onlay technique, removing bone of the same thickness as the prosthetic component, and accepting up to 1 mm over- or under-resection (measured with callipers before and after resection). In the non-resurfaced patellas, osteophytes were removed. Circumferential cauterization was not performed. In 2 cases, both in the non-resurfaced group, lateral release of the patellar retinaculum was performed. All operations were performed in a bloodless field, with a tourniquet on the proximal part of the thigh set between 250 and 350 mmHg depending on the patient's blood pressure and soft tissues. No intra-articular anesthesia was used.

Outcome measures

The primary outcome measure was the KOOS (Roos and Toksvig-Larsen 2003). Secondary outcome measures were the KSS (Insall et al. 1989), the Oxford knee score (Dawson et al. 1998), and patient satisfaction measured on a visual analog scale (VAS). The primary and secondary outcome measures were recorded preoperatively and at 1 year and 3 years of follow-up. VAS was recorded at 1 year and 3 years. In addition, complications were recorded at all observation points.

The KOOS is a knee-specific, patient-reported outcome measure developed for more active patients. It has 5 separately-scored subscales for pain, other symptoms, activities of daily living (ADL), function in sport and recreation, and knee-related quality of life (QoL). Scores are transformed to a 0–100 scale, with 0 representing extreme knee problems and 100 representing no problems. The KOOS has been validated for use in TKA and has been shown to be a valid, reliable, and responsive measure (Roos and Toksvig-Larsen 2003).

The self-administered questionnaires (KOOS, Oxford knee score, and VAS score for patient satisfaction) were completed by the patient alone. In bilateral cases (28 knees), the 14 patients were encouraged to consider the knee under investigation when answering the questions. A physiotherapist who was blind as to the randomization group assessed the KSS scores. Range of motion was measured with a goniometer. Mechanical axes were measured on HKA radiographs preoperatively and at 1 year of follow-up, using the method described by Ewald (1989).

Finally, the ceiling effects—defined as the proportion of patients reaching the top score—and IQRs for all the outcome measures were calculated for the entire group.

Statistics

The minimal perceptible clinical improvement (MPCI) for KOOS has been suggested to be 8–10 points (Roos and Lohmander 2003). The power was set to 90%, the level of signifi-

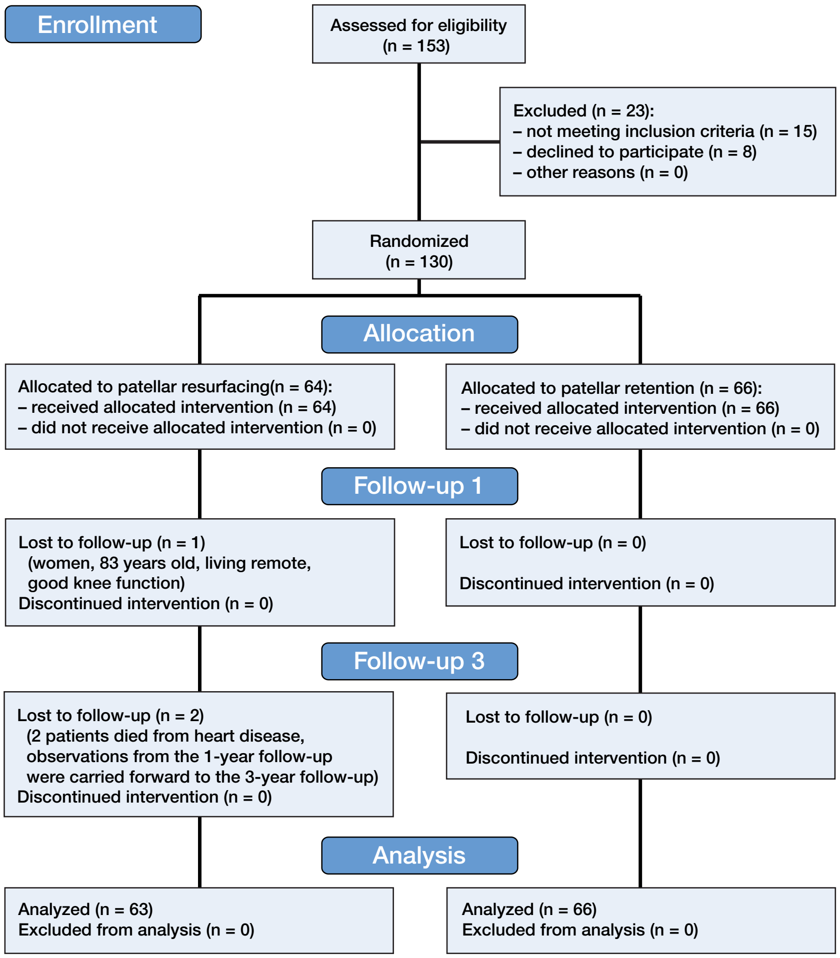

Figure 1. CONSORT 2010 flow diagram.

cance (p) at 5%, and the standard deviation at 16, resulting in a sample size of 55 knees in each treatment group. Allowing for some dropouts after 3 years of follow-up, we decided to include 130 knees.

Data were checked visually for normality based on histograms, using the findings in a recent publication by Fagerland and Sandvik (2009). Comparison of means was performed using the independent-samples t-test for normally distributed data and the Mann-Whitney U-test for skewed variables. Fisher's exact test was used when analyzing categorical variables. When comparing the functional outcome variables in the 2 treatment groups from before surgery up to 3 years postoperatively, mixed-models analysis was used. The assumptions underlying this model were checked and found to be adequately met. No adjustments for multiple testing were performed and a significance level of 5% was used. Data analyses were performed with IBM SPSS 22 software.

Ethics

The protocol was approved by the Regional Committee of Research Ethics at the University of Oslo (REK: 1.2007.952) and registered at ClinicalTrials.gov (identifier: NCT00553982). All the patients signed an informed consent form.

Results

153 knees met the inclusion criteria and 23 of these knees were excluded (Figure 1). The reasons for exclusion were as follows (with number of patients in parentheses): severe deformity (1), isolated patello-femoral arthrosis (3), previous surgery on the extensor mechanism (6), severe medical disability (3), inability to fill out the patient-reported outcome measures (2), and refusal to participate in the study (8).

An old woman declined follow-up visits after 3 months because she was living in a remote area and had not experienced any problems with her operated knee. Between the follow-up visits at 1 year and 3 years, 2 patients died from heart disease. For these 2 patients , the data from the 1-year follow-up were carried forward to the 3-year follow-up. As a result, 129 knees were investigated (in 73 women and 56 men). 14 patients underwent bilateral TKA. 66 knees were randomized to TKA without patellar resurfacing, and 63 knees to TKA with resurfacing. Baseline characteristics in the 2 groups were similar (Table 1). 1 patient who suffered from anterior knee pain was reoperated with patellar resurfacing 20 months after the index operation. In the final analysis, her data were kept in the original allocation group (intention to treat principle).

Table 1. Baseline data for 129 knees

	Without patellar resurfacing (n = 66)	With patellar resurfacing (n = 63)
Mean age (range)	69 (42–82)	70 (48–82)
Number of females	38	35
Mean BMI (range)	29 (22–43)	30 (20–38)
Mean ASA score (range)	2.0 (1–3)	2.0 (1–3)
Mean ICRS score (range)	2.95 (1–4)	2.92 (1–4)
Number of bilateral knees	13	15
Preoperative alignment		
Varus, number of knees	49	54
Mean deformity (range)	9.2° (2–21)	8.6° (1–22)
Valgus, number of knees	13	8
Mean deformity (range)	6.2° (2–13)	5.9° (3–13)
Neutral, number of knees	4	1
Mean deformity	0°	0°

ASA: American Society of Anesthesiologists;
ICRS: International Cartilage Repair Society.

Table 2. Clinical outcome with preoperative, 1-year postoperative, and 3-year postoperative scores expressed as mean (SD). The preoperative scores were not significantly different between the treatment groups

	Without patellar resurfacing (n = 66)	With patellar resurfacing (n = 63)	p-value [a]
KOOS			
Pain, preop.	42 (14)	40 (18)	0.02
Pain, 1 year	84 (18)	90 (13)	
Pain, 3 years	85 (18)	91 (14)	
Symptoms, preop.	50 (19)	52 (17)	0.04
Symptoms, 1 year	82 (16)	86 (13)	
Symptoms, 3 years	86 (13)	90 (11)	
ADL, preop.	45 (14)	45 (19)	0.06
ADL, 1 year	84 (17)	89 (13)	
ADL, 3 years	83 (18)	88 (15)	
Sport/rec, preop.	13 (13)	13 (15)	0.01
Sport/rec, 1 year	55 (25)	64 (22)	
Sport/rec, 3 years	57 (27)	67 (27)	
QoL, preop.	24 (12)	24 (13)	0.03
QoL, 1 year	78 (23)	85 (17)	
QoL, 3 years	77 (23)	85 (19)	
KSS			
Knee, preop.	35 (15)	34 (18)	0.1
Knee, 1 year	84 (15)	89 (12)	
Knee, 3 years	90 (14)	92 (9)	
Function, preop.	65 (19)	69 (20)	1.0
Function, 1 year	87 (16)	88 (17)	
Function, 3 years	83 (21)	83 (21)	
Oxford score			
Preop.	37 (6)	37 (7)	0.2
1 year	19 (7)	17 (6)	
3 years	18 (7)	17 (6)	
Satisfaction (VAS), 1 year	90 (21)	95 (11)	0.1 [b]
Satisfaction (VAS), 3 years	90 (16)	92 (15)	0.4 [b]

[a] Mixed models including data from all time points.
[b] Mann-Whitney U-test.
KOOS: knee injury and osteoarthritis outcome score (0–100); 100 is the best score.
KSS: Knee Society clinical rating system (0–100); 100 is the best score.
Oxford score: Oxford knee score (12–60); 12 is the best score.
ADL: activities of daily living; QoL: knee-related quality of life; preop.: preoperative (baseline) score.

Functional outcome

The mean subscores for the primary outcome measure, the KOOS, were in favor of patellar resurfacing (Table 2). The greatest difference between the 2 groups at 3 years after surgery was seen in the subscore sport/recreation, with a 10-point difference between the groups (p = 0.01). In the other subscores, the differences were 8 points for knee-related QoL (p = 0.03), 6 points for pain (p = 0.02), and 5 points for symptoms (p = 0.04). In the subscore for ADL, there was a 5-point difference between the 2 groups, but this was not statistically significant (p = 0.06).

No statistically significant differences between the 2 groups were observed for the secondary outcome measures (KSS knee score, KSS function score, Oxford knee score, and patient satisfaction) (Table 2).

Table 3. Complications

Allocation group	Complication	n	Treatment	VAS
Without patellar resurfacing				
	Patellar fracture with minimal displacement	1	None	95
	Stiffness	1	AA and MUA	50
	Partial quadriceps tendon rupture	1	Nonoperative treatment	95
With patellar resurfacing				
	Stiffness	1	AA and MUA	10
	Lateral knee pain and stiffness	1	Neurolysis of the fibular nerve, AA and MUA	80
	Hematogenous infection 2 years after the index operation	1	Soft tissue debridement	79

VAS: Patient satisfaction at final follow-up with visual analog scale (0–100); 100 is the best score.
AA and MUA: arthroscopic arthrolysis and mobilization under anesthesia.

Table 4. Detailed description of the different outcome scores at 3-year follow-up (n = 129)

3-year outcome	Range	Mean	SD	Ceiling effect, in %	IQR
KOOS					
Pain	31–100	88	16	36	18
Symptoms	32–100	88	12	19	14
ADL	31–100	86	17	24	23
Sport/rec	0–100	62	28	6	45
QoL	19–100	81	22	29	31
KSS					
Knee score	31–100	91	12	16	12
Function score	–10 to 100	83	21	48	30
Oxford score	12–43	18	7	16	8
Satisfaction (VAS)	10–100	91	16	40	10

For abbreviations and explanations, see Table 2.
IQR: interquartile range.

4 complications occurred in 3 patients who were operated on with patellar resurfacing, and there were 3 complications in 3 patients who were operated on without (Table 3).

Ceiling effects

At 3 years of follow-up, the smallest ceiling effect was found for the sport/recreation subscore of the KOOS (6%). The highest ceiling effects were observed for the KSS function score (48%) and patient satisfaction (40%). More details of the outcome measures are given in Table 4.

Discussion

To our knowledge, this is the first randomized, double-blind trial to compare patellar resurfacing and non-resurfacing in TKA using KOOS as the primary outcome. The main finding was that resurfacing of the patella gave a statistically significantly better functional outcome. However, the clinical relevance of the differences between the groups is debatable. In contrast, the KSS knee score, the KSS function score, the Oxford knee score, and patient satisfaction did not show any statistically significant differences between the 2 groups.

A similar situation has been observed in several recent papers. Hossain et al. (2011) reported on a randomized controlled trial comparing 2 different prosthetic designs for TKA—by KSS, Oxford knee score, WOMAC score, SF-36, and a new score, the total knee function questionnaire (TKFQ). TKFQ is designed to assess demanding physical activities. The authors found that although there were statistically significant differences for range of motion, the TKFQ, and the physical component of SF-36, no significant differences were observed in KSS, total WOMAC, or Oxford knee score. They suggested that the lack of response in these 3 outcome measures could be attributable to ceiling effects, and that high-demand activities, such as sport and recreation, are not addressed. In a comparative study comparing patellar retention and patellar replacement in TKA, Van Hemert et al. (2009) found a statistically significant functional advantage for patients with resurfaced patella, using accelerometers fixed to the patients while they were performing a set of motion tasks mimicking daily activities, whereas no difference in KSS was found. Consequently, the authors recommended complementing the classical evaluation tools with objective functional tests. A recent study evaluating the influence of ligament laxity on functional outcome after TKA found a statistically significant association between ligament laxity and KOOS, but no such association was observed for the KSS, the Oxford knee score, or patient satisfaction. (Aunan et al. 2015).

Today's patients tend to be younger and more physically active than in the past, and even in the elderly population aged between 60 and 80 years, a substantial proportion of patients participate in sports activity on a regular basis (Mayr et al. 2015). Functional assessment after TKA should therefore include measuring tools that take sports activities and other demanding activities into account. In a recent paper, Hossain et al. (2015) reviewed some of the current challenges using patient-reported outcome measures (PROMs) to evaluate TKA, and pointed out that ceiling effects, and lack of important considerations including ability in sports and recreational activities, may limit the power of PROMs to distinguish between treatments. These authors also highlighted alternative methods to improve the assessment of outcome: for example, more contemporary PROM-based instruments measuring high-demand function, and performance-based outcome measures.

Terwee et al. (2007) suggested that ceiling effects should be considered to be present in a health status measure if 15% or more of responders report the highest value. Many investigators have observed ceiling effects in the most commonly used outcome measures for TKA. Jenny et al. (2014) tested 100 patients who were operated on for TKA with more than 1 year of follow-up. They found that the ceiling effect for the KSS was 53%, and that it was 33% for the Oxford knee score. Na et al. (2012) studied 201 well-functioning knees in patients who had undergone primary TKA. The ceiling effect for the KSS knee score was 25%, that for the KSS function score was 43%, and that for the WOMAC score was 0%. Impellizzeri et al. (2011) documented profound ceiling effects from 41% to 67%, and modest floor effects from 10% to 19%, 6 months after TKA for the pain, stiffness, and function subscales in WOMAC. For the Oxford knee score, the authors found a 27% ceiling effect 6 months after the operation.

Giesinger et al. (2014) studied the comparative responsiveness of different outcome measures for TKA at different time intervals up to 2 years after surgery. They reported a decreasing responsiveness over time, especially beyond 1 year, and substantial ceiling effects for KSS and WOMAC scores 1 year after the index operation. The "forgotten joint score-12" (Behrend et al. 2012) was the most responsive of the tools assessed in their study.

We included KOOS, which is a more contemporary outcome measure developed for more active patients. In the sport/recreation subscore of the KOOS, patients were asked about difficulties when squatting, kneeling, running, jumping, and twisting. These are demanding activities, which may explain why only a few patients reach the "ceiling". Thus, it is likely that this measure is better than others to distinguish between patients with high scores. It is noteworthy that the greatest effect size in our study was recorded for the sport/recreation score. Steinhoff et al. (2014) found higher responsiveness and lower ceiling effects in KOOS than in the KSS function score, and concluded that the KOOS should be used to measure TKA outcomes.

We found a striking dissimilarity in outcomes measured with the KOOS and with the classical outcome scores. The reason for this is unclear, but it is remarkable that the sport/recreation subscore in KOOS had the lowest ceiling effect (6.3%) and that very high ceiling effects were found in the KSS function score (48%) and VAS for patient satisfaction (40%). However, the KSS knee score and the Oxford knee score had near-acceptable ceiling effects. On the other hand, these items showed small IQRs and relatively small standard deviations, which might indicate clustering of data within a limited fraction of the outcome scales. In contrast, the KOOS subscores for pain, ADL, and QoL had higher standard deviations and IQRs, indicating less clustering of data and therefore higher discriminative capacity (Table 4). Finally, it should be considered that KSS is an assessor-reported outcome tool, and the KSS knee score is calculated from a combination based on pain score, flexion and extension scores, stability scores, and alignment scores.

In this study, the effect size at 3 years of follow-up in KOOS subscores was 10 points for sport/recreation, 8 points for QoL, 6 points for pain, and 5 points for symptoms and ADL. The minimal perceptible clinical improvement (MPCI) for KOOS has been suggested to be 8–10 points (Roos and Lohmander 2003); therefore, the clinical relevance of the observed effect sizes in our study is disputable. Nevertheless, the relatively small effect sizes observed for pain, symptoms, and ADL might be attributable to ceiling effects. Moreover, the exact definition of the MPCI remains controversial (Revicki et al. 2008).

14 patients in the present study underwent bilateral TKA, so the statistical independence between bilateral cases must be considered. However, the effect of bilateral cases depends on the study design (Park et al. 2010). Our study was randomized and the bilateral cases were equally distributed between the 2 groups (Table 1). Furthermore, in recent studies comparing outcome after arthroplasty, as in the present study, the authors have concluded that inclusion of bilateral cases does not alter the outcome (Bjorgul et al. 2011, Na et al. 2013).

A limitation of our study was that the results may not have been true for all prosthetic designs. We used a posterior cruciate-retaining design with fixed platform (Nexgen CR). Sacrificing the posterior cruciate ligament and introducing mobile bearings or other design alternatives might alter mechanics in the patello-femoral joint, and therefore the effect of patellar resurfacing may not be the same. The strengths of our study include the RCT design with blinding of patients and the outcome assessor, and the low number of dropouts. The wide inclusion criteria strengthened the generalizability of the study.

In summary, the primary outcome measure in our study (KOOS) indicated that patellar resurfacing may be beneficial for knee function in TKA, whereas the secondary, classical outcome measures—including KSS, Oxford knee score, and patient satisfaction recorded on a VAS—did not reveal any statistically significant differences between the groups. These findings indicate that the conclusions from earlier studies that used only classical outcome measures may be questionable, and that future investigations should include assessment tools with limited ceiling effects, which are responsive enough to discriminate between active patients performing demanding activities in their daily lives. In addition, patients undergoing TKA are heterogeneous; thus, future studies should be designed and powered to allow stratification of subjects into groups with different expectations and demands.

EA: conception, design, data collection, analysis, interpretation, and writing of manuscript. GN: assessment of all patients preoperatively and at follow-up. JCJ and TK: approval of the study protocol and contribution to critical revision of the final manuscript. LS: approval of the study protocol and performance of the mixed model analysis.

No competing interests declared.

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OPEN ACCESS

Acta Orthopaedica 2017; 88 (6): 657–663

A simple method for accurate rotational positioning of the femoral component in total knee arthroplasty

A prospective study on 80 knees with 3 years' follow-up with CT scans and functional outcome

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Submitted 2017-02-26. Accepted 2017-06-15.

Background and purpose — There are many techniques for placing the femoral component in correct rotational alignment in total knee arthroplasty (TKA), but only a few have been tested against the supposed gold standard, rotation determined by postoperative computed tomography (CT). We evaluated the accuracy and variability of a new method, the clinical rotational axis (CRA) method, and assessed the association between the CRA and knee function.

Patients and methods — The CRA is a line derived from clinical judgement of information from the surgical transepicondylar axis, the anteroposterior axis, and the posterior condylar line. The CRA was used to guide the rotational positioning of the femoral component in 80 knees (46 female). At 3 years follow-up, the rotation of the femoral component was compared with the CT-derived surgical transepicondylar axis (CTsTEA) by 3 observers. Functional outcome was assessed with the Knee Injury and Osteoarthritis Outcome Score (KOOS), the Oxford Knee Score (OKS) and patient satisfaction (VAS).

Results — The mean (95% CI) rotational deviation of the femoral component from the CTsTEA was 0.2° (–0.15°–0.55°). The standard deviation (95% CI) was 1.58° (1.36°–1.85°) and the range was from 3.7° internal rotation to 3.7° external rotation. No statistically significant association was found between femoral component rotation and KOOS, OKS, or VAS.

Interpretation — The CRA method was found to be accurate with a low grade of variability.

■

Rotational alignment of the femoral component in the axial plane affects knee kinematics, function and prosthetic survival after total knee arthroplasty (TKA) (Berger et al. 1998, Olcott et al. 1999, Barrack et al. 2001, Hanada et al. 2007, Romero et al. 2007, Victor 2009, Kim et al. 2014). Excessive internal rotation may lead to pain (Barrack et al. 2001, Bell et al. 2014), patella-femoral instability (Berger et al. 1998), failure of the patellar component (Berger et al. 1998), tibiofemoral instability in flexion (Romero et al. 2007) and valgus malalignment in flexion (Hanada et al. 2007). Excessive external rotation may cause laxity in flexion (Olcott et al. 1999) and varus malalignment in flexion (Hanada et al. 2007).

2 principles for placing the femoral component in correct rotation exist, the gap-balancing technique and the measured resection technique (Vail et al. 2012). In the pure gap-balancing technique, femoral rotation is determined by the soft tissue tension in the flexed knee. If the soft tissues are contracted malrotation can occur (Lee et al. 2011). In the measured resection technique, femoral component rotation is based on anatomical bony landmarks. These landmarks may be difficult to localize during surgery. Current surgical techniques are often hybrids taking advances from both principles, thus both principles depend more or less on bony landmarks (Vail et al. 2012).

The CT derived surgical transepicondylar axis (CTsTEA) is considered the gold standard for rotational alignment (Asano et al. 2005, Victor et al. 2009, Seo et al. 2012, Talbot et al. 2015). This axis can be drawn on axial CT scans, but is not visible intraoperatively. Therefore, several surrogate axis or anatomical lines have been suggested to help navigate the femoral component into correct rotational alignment during surgery. However, these axes depend on anatomical landmarks that might be hard to define precisely intraoperatively.

The most widely used surrogate axes (secondary reference axes) are the posterior condylar line (PCL) (Laskin 1995), the surgical transepicondylar axis (sTEA) (Berger et al. 1993) and the antero-posterior axis (APA) (Whiteside's line) (Whiteside

DOI 10.1080/17453674.2017.1362733

Table 1. Patient characteristics and preoperative coronal plane alignment (n = 80)

	Group 1 (n = 29)	Group 2 (n = 51)	p-value	Group 3 (n = 39)	Group 4 (n = 41)	p-value
Mean age (range)	69 (48–79)	69 (42–81)	0.9 [a]	70 (42–81)	69 (49–81)	0.6 [a]
Number of women	18	28	0.6 [b]	23	23	0.8 [b]
Mean BMI (range)	28 (20–36)	29 (23–43)	0.3 [a]	30 (20–43)	28 (22–34)	0.2 [a]
Preoperative coronal alignment						
Varus, number of knees	21	44	0.1 [b]	32	33	1.0 [b]
mean deformity (range)	9° (4°–22°)	10° (1°–21°)	0.8 [a]	10° (3°–22°)	9° (1°–21°)	0.3 [a]
Valgus, number of knees	8	6	0.1 [b]	7	7	1.0 [b]
mean deformity (range)	6° (2°–13°)	7° (2°–13°)	0.4 [a]	7° (3°–13°)	5° (2°–11°)	0.2 [a]
Neutral, number of knees	0	1		0	1	
mean deformity (range)	–	0		–	0	
Number of knees with patella resurfacing	17	23	0.4 [b]	22	18	0.4 [b]

First, knees were split into 2 groups: Group 1, internally rotated femoral components and Group 2, neutral and externally rotated femoral components. Thereafter, knees were split into two new groups: Group 3, knees with ≥ 1° malrotation of the femoral component in any direction and Group 4, knees with < 1° malrotation of the femoral component in any direction.
[a] Independent samples t-test. [b] Fisher's exact test.

and Arima 1995). The PCL is easy to define and normally it is internally rotated 3–4 degrees relative to the sTEA, but in in knees with deformity due to osteoarthritis or condylar dysplasia there might be substantial variations. The sTEA is considered a good reference for femoral component rotation, but it may be difficult to define in the surgical field. Kinzel et al. (2005) reported that the epicondyles were correctly identified in only 75% of the knees, with a wide range of malrotation from 6 degrees of external rotation to 11 degrees of internal rotation. The APA is also a widely used landmark to determine rotation, but this line too can be hard to draw correctly. Yau et al. (2007) found a wide range of error from 15 degrees of external rotation to 17 degrees of internal rotation.

More recently new and more reliable surrogate axes have been described (Victor et al. 2009, Talbot et al. 2015), and some studies combine information from 2 or more axes (Siston et al. 2008, Inui et al. 2013, Paternostre et al. 2014). Additionally, some techniques add information from preoperative CT scans or conventional radiographs (Luyckx et al. 2012, Seo et al. 2012, Inui et al. 2013), and some require special alignment jigs, computer navigation or patient-specific instruments (Seo et al. 2012, Inui et al. 2013, Parratte et al. 2013).

Postoperative CT scan is the only widely accepted method to determine both the ideal and the actual rotational alignment of the femoral component (Berger et al. 1998, Olcott et al. 1999, Asano et al. 2005, Oussedik et al. 2012, Talbot et al. 2015).

In this prospective cohort study, the rotation of the femoral component was determined intraoperatively with the clinical rotational axis (CRA) method. The CRA is established by clinical judgement of information from three surrogate axes: the sTEA, the APA and the PCL. Our aim was twofold: first, to evaluate the accuracy of the CRA method; second, to investigate the association between femoral component rotation and functional outcome 3 years after the operation.

Patients and method

All patients were consecutively recruited from another ongoing prospective, randomized and double-blind study comparing TKA with and without patellar resurfacing (Aunan et al. 2016). The patients were operated between January 2009 and June 2011. Inclusion criteria were patients less than 85 years old scheduled for TKA because of osteoarthritis. Exclusion criteria were knees with severe deformity not suitable for standard cruciate-retaining prosthesis, rheumatoid arthritis, and severe medical disability limiting the ability to walk or to fill out the patient-recorded outcome documents.

80 consecutive knees (46 female) were investigated at 3 years' follow-up. Mean age was 69 (42–81) years. Mean BMI was 29 (20–43). 65 knees had varus deformity ranging from 1° to 22°, 14 knees had valgus deformity from 2° to 13° and 1 knee was without deformity (Table 1).

Surgical technique

All knees were operated through a standard midline incision and a medial parapatellar arthrotomy, using a posterior cruciate-retaining prosthesis (NexGen, Zimmer, Warsaw, IN). We used the measured resection technique, which involves resecting the amount of bone from the distal femur and the proximal tibia that will be replaced by the prosthetic components. The valgus angle of the femoral component was set at 5–8 degrees, depending on the hip–knee–femoral shaft angle (HKFS) as measured on preoperative standing hip–knee–ankle (HKA) radiographs. To assure conformity in surgical technique the first author (EA) was either operating or assisting in every operation.

Description of the CRA method

Rotation of the femoral component was established by combining information from the PCL, the sTEA and the

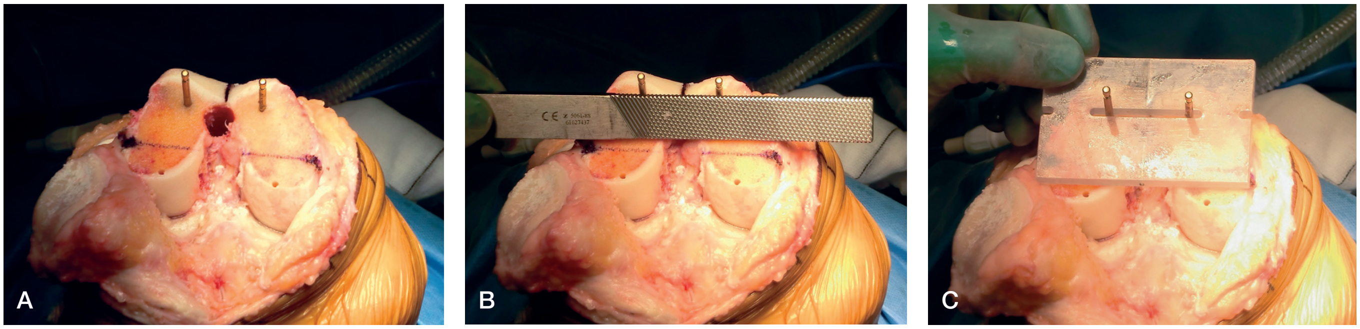

Figure 1. A. Before the distal resection of the femur the sTEA was established by marking the most prominent point of the lateral epicondyle and the sulcus on the medial epicondyle with cautery. Thereafter, the APA was marked from the highest point in the intercondylar notch to the deepest point of the trochlea. Then, after distal femoral resection, a line 3° externally rotated compared with the PCL was marked with two pins on the distal femoral cut.

B. The parallelism between the sTEA and the PCL+3° was judged with a ruler.

C. The orthogonality between the sTEA and the APA and between the PCL+3° and the APA was judged with a transparent angle-measuring device.

APA. First, the sTEA was established by marking the most prominent point of the lateral epicondyle and the sulcus on the medial epicondyle with cautery. Second, the APA was marked from the highest point in the intercondylar notch to the deepest point of the trochlea. Third, after distal femoral resection, a line 3° externally rotated compared with the PCL was marked with 2 pins on the distal femoral cut. Theoretically, the sTEA and the PCL+3° should now be parallel, and these 2 lines should be at a 90° angle to the APA. The parallelism between the sTEA and the PCL+3° was judged with a ruler, and the orthogonality between these 2 lines and the APA was judged with a transparent angle-measuring device (Figure 1). In the cases where perfect correlation between the lines was achieved (parallelism between the PCL+3° and the sTEA, and orthogonality (90° angle) between these 2 lines and the APA) the rotation was accepted. If there was agreement between 2 of the lines, these were accepted. If disagreement between all three lines occurred, the in-between line was selected. In the case of visible bony attrition (International Cartilage and Repair Society (ICRS) grade 4) on 1 or both posterior condyles, the PCL was excluded from the work-up. The PCL was also excluded in cases with posterior lateral condylar dysplasia. Dysplasia was suspected in knees with distal femoral valgus deformity on HKA radiographs and no noticeable valgus deformity on the tibial side. If, during the operation, a visible valgus deformity in 90° of flexion was present, the posterior lateral condyle was considered dysplastic. In the cases were 2 lines remained and were not parallel, the average angle between these 2 lines was preferred.

Outcome measures

At 3 years' follow-up 80 knees were examined with CT for rotational alignment of the femoral prosthetic components. Scans were performed using the Philips Ingenuity 128-row multidetector scanner (Philips Healthcare, Andover, MA) with our standard knee protocol (140 kV, 150 mAs; rotation time 0.5 s, pitch 0.485/0.391; slice thickness 0.9 mm, interval 0.45 mm). The imaging material was evaluated using the Philips Intellispace system (Philips Healthcare, Andover, MA) and measurements were done as described by Berger et al. (1998). Standard radiographic evaluation with antero-posterior, hip–knee–ankle (HKA), sagittal and patella-axial radiographs was also performed. All patients were clinically evaluated with the Knee Injury and Osteoarthritis Outcome Score (KOOS) (Roos et al. 1998, 2003), the Oxford Knee Score (OKS) (Dawson et al. 1998) and patient satisfaction (visual analogue scale (VAS)) at the 3-year follow-up.

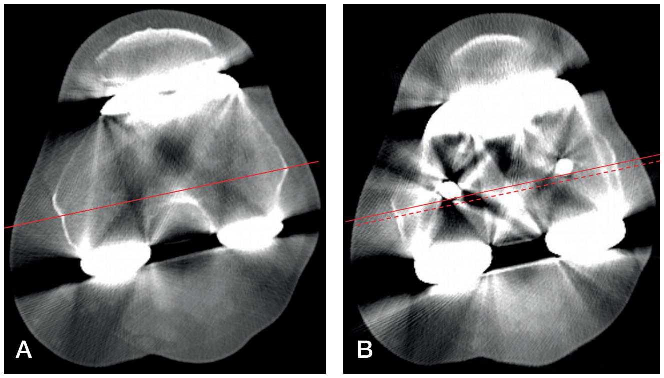

Figure 2. A. The CT-derived surgical transepicondylar axis (CTsTEA) is the line drawn from the most prominent part of the lateral epicondyle to the sulcus in the medial epicondyle.

B. Femoral component rotation is defined by the femoral component rotational axis (FCRA), the common tangent of the 2 pegs on the inside of the femoral component (continuous red line). Then the CTsTEA (stippled red line) from Figure 2A was superimposed, and the femoral component rotational angle (FCR angle) was measured. In this case the angle was 0°.

The CT scans were evaluated independently by 3 observers: 1 radiologist (DØ) and 2 experienced orthopedic surgeons (EA and AM). First the CTsTEA was defined by drawing a line from the lateral epicondyle to the sulcus in the medial epicondyle. Second, the femoral component rotational axis (FCRA) was defined by drawing the common tangent of the

2 pegs on the inside of the femoral component (Figure 2). Finally, the angle between these two lines, called the femoral component rotational angle (FCR angle), was measured. No corrections or eliminations of outliers were performed. Inter-rater reliability for the measurements performed by the 3 observers was estimated and accuracy and precision of the CRA method was calculated.

The effect of femoral component rotation on functional outcome was assessed in 2 ways: initially by comparing KOOS, OKS, and patient satisfaction 3 years after the operation between internally rotated knees (group 1), and neutral and externally rotated knees (group 2). Thereafter, the knees were split into 2 new groups: knees with any degree of malrotation of the femoral component (group 3) and knees with perfectly rotated (< 1°) femoral components (group 4).

Statistics

Inter-rater reliability for the measurements was estimated with intra-class correlation coefficient (ICC), 2-way mixed models, and absolute agreement. ICC (95% CI) for inter-rater reliability was 0.62 (0.51–0.72) for single measurements and 0.83 (0.76–0.89) for average measurements. Accuracy of the CRA method was expressed as the mean FCR angle and its 95% confidence interval (CI). The variability was expressed as the standard deviation (SD) and range of the FCR angle. Finally, the 95% CI of the SD was calculated. Negative values were given for internal rotation of the femoral component and positive values for external rotation.

The effect of femoral component rotation on functional outcome between groups 1 and 2 and between groups 3 and 4 was tested with the independent samples t-test or Fisher's exact test. The length of the 95% CI of the FCR angle was used as an indicator of sample size adequacy (Machin et al. 2009). Statistical significance was defined as p-values below 0,05. Statistical analyses were performed with IBM SPSS® 22 software (IBM, Chicago, IL, USA).

Ethics, funding, and potential conflicts of interest

The protocol was approved by the regional committee of research ethics (2010/ 1678 D 33-07172b 1.2007.952 with changes 05.03.2012) and before enrolment all patients signed an informed-consent form. The study was funded by the Sykehuset Innlandet Hospital trust and the authors have no competing interests to declare.

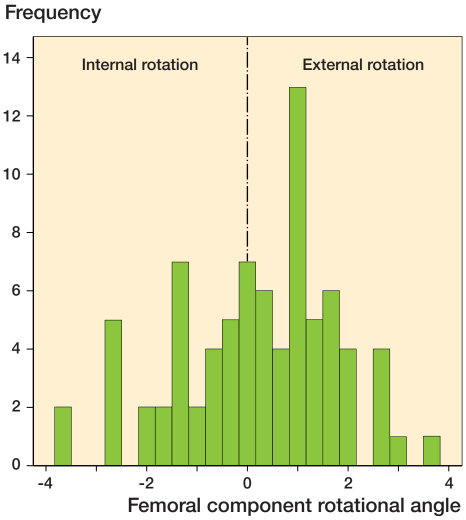

Figure 3. The femoral component rotational angle (FCR angle) relative to the CT-derived surgical transepicondylar axis (CTsTEA) in 80 knees.

Results

Patient characteristics and preoperative coronal plane alignment are given in Table 1. The mean (95% CI) FCR angle was 0.2° (–0.15°–0.55°). The standard deviation was 1.58° and the 95% CI of the SD was 1.36°–1.85°. Maximum and minimum values were 3.7° external rotation and 3.7° internal rotation. The distribution of the FCR angles for all knees is presented in Figure 3.

No statistically significant difference was found between group 1 and group 2, or between group 3 and group 4 in KOOS, OKS, or patient satisfaction (VAS) at follow-up 3 years after the operation (Table 2).

Table 2. Comparison of functional outcome measures at 3 years' follow-up between groups

	Group 1 (n = 29)	Group 2 (n = 51)	p-value [a]	Group 3 (n = 39)	Group 4 (n = 41)	p-value [a]
KOOS						
Pain	89 (58–100)	94 (33–100)	0.3	94 (33–100)	94 (39–100)	0.8
Symptoms	89 (64–100)	93 (32–100)	0.9	93 (54–100)	89 (32–100)	0.2
ADL	97 (53–100)	93 (31–100)	0.5	97 (53–100)	91 (31–100)	0.1
Sport/recreation	70 (0–100)	70 (5–100)	1.0	70 (5–100)	65 (0–100)	0.4
QOL	88 (31–100)	94 (19–100)	0.05	88 (31–100)	94 (19–100)	1.0
OKS	16 (12–37)	15 (12–43)	0.2	16 (12–37)	15 (12–43)	0.9
Patient satisfaction [b]	96 (70–100)	99 (10–100)	0.3	99 (41–100)	98 (10–100)	0.7

For Groups, see Table 1
KOOS: Knee Injury and Osteoarthritis Outcome Score (0–100); the best score is 100. ADL activities of daily living. QOL knee-related quality of life.
OKS: Oxford Knee Score (48–12); the best score is12.
[a] Mann–Whitney U test. [b] VAS scale (0–100); the best score is 100.

Table 3. Data from the present and previous studies that compare the rotational alignment of the femoral component with the gold standard (CTsTEA)

Author	Method	Number of knees	Rotational alignment [a] mean	SD (range)	Number of measurements [b]	Comments
The present study	The clinical rotational axes method (CRA method)	80	0.2°	1.6° (–3.7°–3.7°)	3	
Talbot et al. 2015	Sulcus line	181	0.6°	2.9° (–7.2°–6.7°)	2	28 knees excluded due to poor CT scans, and 19 excluded due to unidentified sulcus line.
Inui et al. 2013	Transepicondylar axis, Whiteside axis and the condylar twist angle	26	0.3°	1.7° (–3°– 3°)	2	Preoperative radiographs in 90° knee flexion. Computer navigation
Luyckx et al. 2012	Gap technique	48	2.4	2.5° (–2.8°–6.9°)	6 [c]	Gap technique
Luyckx et al. 2012	PCL adapted to preop. CT	48	1.7°	2.1° (–2.5°–6.5°)	6 [c]	Preoperative CT of the knee
Seo et al. 2012	Mechanical axis-derived rotational axis	120	1.6°	2.2° (–4.8°–7.9°)	3	Preoperative radiographs of both hips. Customized graduated ruler and extramedullary alignment jig

[a] Positive values represent external rotation and negative values represent internal rotation.
[b] The number of measurements and observers may influence the values for rotational alignment. See text for further information.
[c] 3 observers, 2 measurements each
PCL = posterior condylar line.

Discussion

The CRA method generated results very close to the gold standard with a low grade of scatter. The fact that no statistically significant association was found between the degree of malrotation and functional outcome indicate that the CRA method is a safe method for intraoperative estimation of femoral component rotation. However, because only 3 knees were malrotated more than 3° and only 13 knees more than 2°, the effect of more than 2° malrotation cannot be judged in this study.

The length of the 95% CI of the FCR angle was only 0.7°, indicating that the sample size of our study is adequate (Machin et al. 2009).

The CTsTEA is widely accepted as the gold standard for rotational alignment of the femoral component. Many studies have investigated different anatomical rotational axes, but as long as they do not refer to postoperative CT scans and the CTsTEA the results are hard to interpret. Table 3 presents data from the present and earlier studies that compared femoral component rotation with the CTsTEA. Talbot et al. (2015) described a new surrogate axis called the sulcus line by marking the deepest part of the trochlear groove with multiple diathermy points from the anterior edge of the intercondylar notch to the proximal trochlear groove. In another study, Inui et al. (2013) determined the rotational alignment of the femoral component by combining information from the computer navigation system and preoperative radiographs in 90° of knee flexion. This method has much in common with our method: both methods combine information from the sTEA, the APA and the PCL, and both methods accept that the PCL differs, to some degree predictably, with varus and valgus deformities. The main difference between the methods is that in our method the determination of the PCL is done by clinical judgement intraoperatively and does not depend on computer navigation and preoperative radiographs at 90° knee flexion. Luyckx et al. (2012) compared the classical gap technique and the so-called adapted measured resection technique in which the native rotation of the distal femur measured on preoperative CT scans was taken into account. They did not find a statistical significant difference between the 2 methods. Seo et al. (2012) defined the "the mechanical axes derived rotational axis" with a combination of preoperative radiographs of the pelvis to determine surface landmarks and an extramedullary alignment jig. They found that "the mechanical axes derived rotational axis" was on average 1.6° externally rotated compared with the sTEA. They also concluded that the method was relatively time-consuming and complicated.

When comparing data in Table 3 it is important to bear in mind that the number of measurements performed at each CT scan may affect the level of accuracy and precision. Averaging data from 2 or more measurements may result in mean values closer to the truth, but the ranges and the standard deviations (SD) will tend to decrease. In our study we used 3 observers, so for completeness and in order to make the data of our study easier to interpret we also calculated mean values, ranges, and SDs for all 3 combinations of 2 observers: Mean values: 0.1°, 0.5°, and 0.2°. Ranges: –4°–3°, –4°–4°, and –4°–4°. Standard deviations: 1.7°, 1.7°, and 1.6°. Therefore, in our study the effect of 3 versus 2 observers did not seem to affect the results to an important degree.

In a recent review article, Valkering et al. (2015) performed a correlation analysis based on 490 patients. They found a large positive correlation between femoral component external rotation and better functional outcome. In contrast, we did not find any statistically significant effect of femoral component malrotation on the outcome measures. The reason for this may be the very few and small deviations in rotation found in our study (maximum ± 3.7°).

Our study has some limitations. First, the reliability of Berger's method for measuring femoral component rotation on postoperative CT scans is not perfect (Luyckx et al. 2012, Inui et al. 2013). The ICC values vary considerably between studies depending on whether data are given for single measurements or average measurements, and on which statistical model was chosen. This information is missing in many studies, making comparison between studies difficult. In our study, we have specified ICC values for the most conservative options. Second, due to the low number of malrotated femoral components we cannot estimate the effect of malrotation above 2° on functional outcome. Third, half of the knees had the patella resurfaced. Therefore, patella resurfacing is a potential effect modifier (interaction). Stratifying the material on patellar resurfacing revealed a trend in disfavor of internally rotated femoral components in the group without patellar resurfacing. However, multiple testing without correction were performed and the numbers were small; 12 femoral components were internally rotated and 28 were neutral or externally rotated. Finally, we used a tibial platform with fixed bearing and minimal constraint. Our results on functional outcome may not be valid for prostheses with mobile platforms and/or more constraint.

The validity of our study is strengthened by the fact that no knees were excluded and no corrections or exclusions were done because of outliers or disagreement between observers.

A major advance of the CRA method is its simplicity. There is no need for additional preoperative radiographs or CT imaging and no need for computer navigation. Likewise, customized equipment or alignment jigs are not required.

In summary, the CRA method for rotational alignment of the femoral component in TKA appears to be simple, safe, accurate, and precise.

EA: Conception, design, data collection, statistical analysis, interpretation and writing of the manuscript. DØ, AM and KD: Data collection. LS: Statistical analysis. All the authors took part in revision of the manuscript.

Acta thanks Kaj Knutson and Stephan Röhrl for help with peer review of this study.

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Internal rotation of the tibial component has negative effect on functional outcome after total knee arthroplasty, but revision arthroplasty because of malrotation based on CT-evaluation may not be warranted

80 knees with 3 years follow-up with CT-scans and functional outcome

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Introduction: In total knee arthroplasty (TKA) the effect of tibial component rotation on functional outcome is controversial, but revision arthroplasty is often recommended if malrotation is demonstrated on CT scans in a painful TKA. The aim of this study was to investigate the effect of tibial component rotation on functional outcome and to discuss the reliability of Bergers method to measure tibial component rotation in individual patients.

Patients and methods: Eighty consecutive knees (46 female) with mean (range) age 69 (42-81) years and mean (range) BMI 29 (20-43) underwent TKA. At three years follow up all knees were examined with CT scans for rotational alignment of the tibial components by two independent observers. Inter-rater reliability for the measurements was estimated with intra-class-correlation coefficient (ICC) and visualized in a frequency table. The functional outcome in knees with neutral or externally rotated tibial components, and knees with internally rotated tibial components was compared with the Knee Injury and Osteoarthritis Outcome Score (KOOS), the Oxford Knee Score (OKS) and patient satisfaction.

Results: In 46 knees, the tibial component was in neutral position or externally rotated mean (range) 4° (0°-15°). In 34 knees, the tibial component was internally rotated mean (range) -4.5° (-1°- -14°). All outcome scores favored knees with neutral or externally rotated tibial components; however, 2 out of 7 scores did not reach statistical significance. The ICC (95% CI) was 0.62 (0.46–0.74) for single measurements and 0.77 (0.63–0.85) for average measurements. In 35% of the knees, the measurements of the two observers differed more than 3°, in 15% the measurements differed more than 5° and in 6% the measurements differed 10° or more.

Interpretation: Internal rotation of the tibial component have a statistically significant and clinically relevant negative effect on functional outcome after TKA. Measurements of tibial component rotation on individual patients is not very reliable and should be interpreted with caution.

There is no gold standard for intraoperative targeting of the rotational alignment of the tibial component. Many different techniques to guide the tibial component into correct rotational alignment have emerged. In order to obtain maximal bony support for the tibial tray, some surgeons prefer the best coverage technique [1, 2]. Another option is to secure the best conformity with the femoral component (the range-of-movement or self-seeking technique) [3]. A third option is to rotate the tibial tray in line with anatomical landmarks. The mostly used anatomical landmarks are the medial border of the tibial tubercle [4] and the medial third of the tibial tubercle [5]. More recently, many other methods have emerged: the anatomical tibial axis [6], the anteroposterior axis [4] and the posterior condylar axis [7]. The use of extra-articular anatomical landmarks like the second metatarsal of the ankle and the transmaleolar axis of the ankle are essentially abandoned [4]. Comparative studies have shown that the self-seeking method leads to a relative internal rotation of the tibial platform compared to the anatomical landmarks method [8, 9]. More recently, Martin et al. reported that maximizing tibial coverage resulted in tibial component internal malrotation in a large percentage of cases [10], and that this effect was strongest for symmetric (no difference between right and left) tibial plateau designs.

Although many methods to secure alignment of the tibial component in the axial plain have been described, only a few studies have focused on the effect of tibial component rotation on functional outcome. A systematic review and correlation analysis by Valkering et al. [11] found a medium positive correlation between tibial component external rotation and functional outcome. The analysis was based on five papers (250 patients) that were assessed with postoperative CT and the Knee Society score (KSS). In contrast, a recent study by Thielemann et al. [12] did not find any significant correlation between tibial component malrotation and functional outcome assessed with KSS and Knee injury and osteoarthritis outcome score (KOOS) in 55 patients followed for 5-7 years.

The aim of the current study was to investigate prospectively the effect of tibial component rotation on functional outcome in an unselected sample recruited consecutively form our daily practice, and if possible, to give recommendations on how the tibial component should be aligned in the axial plane. Based on the experience from this study a discussion on the reliability of Bergers method to measure tibial component rotation in individual patients is added. Finally, the interpretability of the intraclass correlation coefficient (ICC) in clinical practice is questioned.

Patients and methods

Eighty consecutive knees (46 female) were investigated at 3 years follow-up. Mean (range) age was 69 (42-81) years. Mean (range) BMI was 29 (20-43). Sixty-five knees had varus deformity ranging from 1° to 22°, 14 knees had valgus deformity from 2° to 13° and one knee was without deformity.

All patients were consecutively recruited from another ongoing prospective, randomized and double blind study. The patients were operated between January 2009 and June 2011.Inclusion criteria were patients less than eighty-five years old scheduled for TKA because of end-stage osteoarthritis. Exclusion criteria were knees with severe deformity not suitable for standard cruciate-retaining prosthesis, rheumatoid arthritis, and severe medical disability limiting the ability to walk or to fill out the patient-recorded outcome documents.

Surgical technique

All knees were operated through a standard midline incision and a medial parapatellar arthrotomy. A posterior cruciate retaining prosthesis (NexGen, Zimmer, Warsaw, IN) was implanted with measured resection technique. The valgus angle of the femoral component was set at 5-8 degrees, depending on the hip-knee-femoral shaft angle (HKFS) as measured on preoperative standing hip-knee-ankle (HKA) x-rays.

Rotation of the femoral component was established with the clinical rotational axis method (CRA-method) by combining information from the posterior condylar line, the surgical transepicondylar axis, and the antero-posterior axis [13]. The tibial component was oriented along a line drawn from between the tibial eminences to the medial one third of the tibial tubercle. In cases where this method lead to obvious mismatch between rotational alignment of the femoral component and the tibial component, the knee was taken through a full range of motion and the tibial component allowed rotating into a conforming position with the femur (self-seeking technique). Then a mark was placed with cautery midway between this position and the medial third of the tibial tubercle. To assure conformity in surgical technique the first author (EA) was either operating or assisting in every operation.

Outcome measures

At three years follow up 80 knees were examined with a computed tomography for rotational alignment of the tibial components. Scans were performed using the Philips Ingenuity 128-row multidetector scanner (Philips Healthcare, Andover, MA) with our standard knee protocol (140 kV, 150 mAs,; rotation time 0,5 s, pitch 0,485/0,391; slice thickness 0,9 mm, interval 0,45 mm). The imaging material was evaluated using the Philips Intellispace system (Philips Healthcare, Andover, MA) and measurements were done as described by Berger et al. [14]. Standard radiographic evaluation with antero-posterior, hip-knee-ankle (HKA), sagittal and patella-axial x-rays were also performed. All patients were clinically evaluated with the Knee Injury and Osteoarthritis Outcome Score (KOOS) [15, 16] and the Oxford Knee Score (OKS) [17] preoperatively and at 3 years follow-up. Patient satisfaction was measured on a visual analogue scale (VAS) at 3 years follow-up.

Rotational alignment of the tibial components was measured on CT scans by two independent observers (one radiologist and one experienced orthopaedic surgeon) with the method described by Berger [14]. Inter-rater reliability for the measurements was estimated with intra-class-correlation coefficient (ICC) and a table demonstrating the frequency of different degrees of disagreement between the two observers was prepared. The knees were divided into two groups: Knees with neutral or externally rotated tibial components, and knees with internally rotated tibial components. KOOS, Oxford knee score and Patient satisfaction in the two groups was compared.

Statistics

The rotational alignment of the tibial components was measured independently by two observers. The inter-rater reliability for the measurements was estimated with intra-class- correlation coefficient (ICC), two way mixed models, absolute agreement for single and average measurements. Differences between the groups at baseline were tested with independent samples t-test, Fisher's exact test or the Mann-Whitney U test as appropriate.

The difference in functional outcome between knees with internally rotated tibial platforms and knees with neutral or externally rotated platforms were tested with the Mann-Whitney u-test. Statistical significance was defined as p-values below 0.05. Statistical analyses were performed with IBM SPSS® 22 software (IBM, Chicago, IL, USA).

Results

In 46 knees, the tibial component was in neutral position or externally rotated. The mean (range) rotation in this group was 4° (0°-15°). In 34 knees, the tibial component was internally rotated mean (range) -4.5° (-1°- -14°). Preoperatively there was no difference between the groups in KOOS, Oxford knee scores or demographic data except for BMI that was significantly higher in the group of internally rotated tibial components. (Table 1).

At three years follow-up all scores favored knees with neutral or externally rotated tibial platforms (Table 2). However, 2 out of 7 scores did not reach statistical significance, and one sub score (symptoms) was below the minimal perceptible clinical improvement (MPCI) for KOOS.

Table 1. Baseline data for knees with internally rotated tibial components and knees with neutral or externally rotated tibial components. N=80

	Internal rotation (n=34)	Neutral or external rotation (n=46)	p
Age	68	71	0.16[a]
Women/Men	19/15	27/19	0.82[b]
BMI	31	28	0.001[a]
Deformity (grades)	8	9	0.22[a]
With/without patella component	18/16	22/24	0.82[b]
KOOS			
Pain	39	44	0.22[c]
Symptomes	53	51	0.78[c]
ADL	45	47	0.71[c]
Sport/recreation	11	15	0.25[c]
QOL	24	25	0.64[c]
Oxford knee score	38	36	0.14[c]

[a]Independent samples t-test. [b]Fisher's exact test. [c]Mann-Whitney U test. QOL: knee related quality of life.

Table 2. Scores at three years follow-up for knees with internally rotated tibial components and knees with neutral or externally rotated tibial components. N=80.

	Internal rotation (n=34)	**Neutral or external rotation (n=46)**	**Δ**	**p***
KOOS				
Pain	83	92	9	0.06
Symptomes	84	91	7	0.02
ADL	82	90	8	0.13
Sport/recreation	55	72	17	0.02
QOL	74	89	15	0.002
Oxford knee score	19	16	3	0.02
Patient satisfaction (VAS)	88	95	7	0.03

* Mann-Whitney U test. QOL = knee related quality of life. KOOS = Knee Injury and Osteoarthritis Outcome Score (0-100), the best score is 100. Oxford knee score (60-12), the best score is 12.

The ICC (95% CI) was 0.62 (0.46–0.74) for single measurements and 0.77 (0.63–0.85) for average measurements. In 35% of the knees, the measurements of the two observers differed more than 3°, in 15% the measurements differed more than 5° and in 6% the measurements differed 10° or more (Table 3).

Discussion

The main findings in this study was that the KOOS, the Oxford knee score and the VAS score for patient satisfaction were in favor of knees with neutral or externally rotated tibial platforms. However, 2 out of 7 scores did not reach statistical significance, and one subscore (symptoms) was below the MPCI.

Our findings are in concordance with those in the systematic review by Valkering et al. [11] who found a medium positive correlation between tibial component external rotation and functional outcome. However, four of the studies included in their correlation analysis [18-21] investigated selected patients with knee pain after TKA retrospectively. Bell et al. [22] also found internal rotation of the tibial component to be a factor in pain following TKA. They compared the rotational alignment of components in a cohort of 56 patients with unexplained pain following TKA with a matched control cohort of 56 patients. In contrast, a recent study by Thielemann et al. [12] did not find any significant correlation between tibial component malrotation and functional outcome assessed with KSS and KOOS in 55 patients followed for 5-7 years. Similarly Kawahara et al. [23] found that tibial component malrotation did not affect any of the subscores of the relatively new 2011 KSS. Kim et al. [24] studied the relationship between the survival of TKA at average 16 years and alignment of the prosthetic components. They found that external rotational alignment of the femoral and tibial components less than 2 degrees was a risk factor for failure of the prosthetic components.

The reason for the disagreement between these studies is unclear. In the study by Thielemann et al. [12] the component orientation was not measured with Berger's method, but it was expressed as the angle between the posterior of the tibial baseplate and the tibial condyles. The agreement between these two methods is unknown. Differences in prosthetic design may also play a role as cruciate retaining and rotating platforms could be more forgiving for malrotation than more constraint designs. It is also remarkable that most of the earlier studies investigates selected populations with pain and dysfunction after TKA in a retrospective manner. In contrast, our study is a prospective cohort study.

Interestingly, in our study we found that the preoperative BMI was statistically significant higher (p=0.001) in the group with internally rotated tibial components (Table 1). The p-value is so low that this observation is probably not due to chance, indicating that there might be a correlation between high BMI and internal rotation of the tibial platform. The reason for this is unknown, but it could be argued that correct rotational alignment of the tibial plateau is technically more difficult in obese patients. Keeping in mind that there is also a week correlation between BMI and functional outcome, a confounding effect of BMI can be suspected.

The reliability of Berger's method [14] to measure tibial platform rotation on CT-scans is a matter of concern. We tested the inter-rater reliability of the method with intra-class correlation (ICC) two way mixed models, absolute agreement, and found that the ICC (95% CI) coefficient for average measurements was 0.77 (0.63–0.85) and for single measurements the ICC (95% CI)) was 0.62 (0.46–0.74). According to Cicchetti [25], Less than 0.40 is poor, between 0.40 and 0.59 is fair, between 0.60 and 0.74 is good and between 0.75 and 1.00 is excellent. The 95% CI for the ICC in our study indicate that the interrater-reliability for average measurements is good to excellent and the interrater-reliability for single measurements is fair to good. The implication of this is that in order to judge the reliability of a method (like in this paper), Berger's technique for measuring the rotation of the tibial component is probably good or excellent. However, when it comes to measurements on a single knee performed by one examiner, the reliability is only fair or good. Consequently, the judgment of rotational alignment on an individual basis should be done with caution. For example, when ruling out the cause of knee pain in a painful TKA the examiner should not rely too much on a single measurement of tibial component rotation performed by one assessor. This argumentation is supported by the study of Konigsberg et al. [26] who found the interobserver reliability of two-dimensional CT scan for tibial component malrotation to be 0.67 (0.47-0.80). The authors were concerned about whether CT scan is diagnostic in the assessment of component malrotation after TKA.

The ICC is widely used in orthopaedic research, but the interpretation of the ICC is not straightforward. At least 10 forms of ICC have been described and the reader should focus on the "model", "type" and "definition" in order to interpret the data [27]. Still, the interpretation of the ICC values is probably not intuitive to all readers. It is the author's opinion that a histogram or a frequency table may be more informative. The histogram below (Figure 1) demonstrate the difference between the two observers in this study. Table 6 shows the frequency of different degrees of disagreement between the two observers. In 35% of the knees, the measurements of the two observers differed more than 3°, in 15% the measurements differed more than 5° and in 6% the measurements differed 10° or more. This uncertainty must be taken into consideration when a revision is considered based on the measurements of rotational alignment on CT scans.

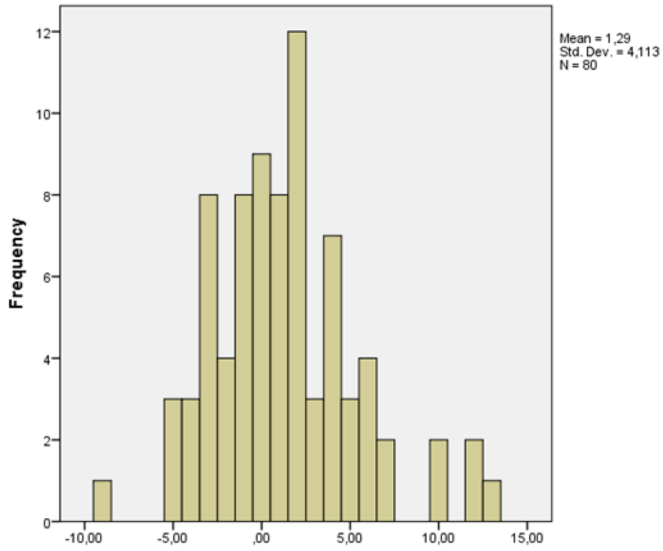

Figure 1. Disagreement between two observers (one radiologist and one orthopaedic surgeon) who measured rotational alignment of the tibial component on CT in 80 knees. Negative values indicate internal rotation and positive values indicate external rotation.

A limitation to this study is that the choice between the modified dynamic method, and the anatomical landmark method was dependent on the surgeons' subjective judgment and that the choice was not registered in advance. Therefore, the study do not prove that one method is better than the other, however, based on clinical experience and earlier literature [8, 10] it is reasonable to assume that the majority of internally rotated tibial components were placed with the modified dynamic method. Another limitation is related to the choice of implant design. We used a cruciate retaining tibial component with fixed platform, and our results may not be true for other prosthetic designs.

A strong side of the study is the relatively high number of knees and the prospective design.

In conclusion, the big difference in scores between the two groups, indicate internal rotation of the tibial component have a statistically significant and clinically relevant negative effect on functional outcome after TKA. The study also suggest that the dynamic method to guide tibial platform rotation should be avoided. Finally, measurements of tibial component rotation performed with ordinary two-dimensional CT on an individual patient is not very reliable and should be interpreted with caution.

Table 3. The frequency of different degrees of disagreement between two observers (one radiologist and one orthopaedic surgeon) who measured rotational alignment of the tibial component on CT scans in 80 knees.

Difference in degrees	Frequency	Percent	Cumulative percent
0	9	11.3	11.3
1	16	20.0	31.3
2	16	20.0	51,3
3	11	13.8	65.1
4	10	12.5	77.7
5	6	7.5	85.3
6	4	5.0	90.3
7	2	2.5	92.8
8	0	0	92.8
9	1	1.3	94.1
10	2	2.5	96.6
11	0	0	96.6
12	2	2.5	99.1
13	1	1.3	100
Total	80	100	100

EA: conception, design, data collection, analysis, interpretation, and writing of manuscript. DØ, AM and KD: Data collection.

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Effects of combined and opposite malrotation of the prosthetic components on functional outcome and patella tilt in total knee arthroplasty

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Abstract

Background/Purpose – The effect of different combinations of malrotation of the prosthetic components in total knee arthroplasty (TKA) is controversial. The purpose of this study was to investigate 1) the effect of combined rotation of the femoral and tibial components on functional outcome after TKA, 2) the effect of opposite rotation and mismatch of the femoral and tibial components on functional outcome, 3) the association between component rotation and patella tilt, and 4) the effect of patellar tilt on functional outcome.

Patients and Methods – 80 consecutive knees (46 female) were operated with a posterior cruciate-retaining prosthesis. Mean age was 69 (42–81) years and mean BMI was 29 (20–43). At 3 years follow-up, all knees were examined with CT for rotational alignment of the femoral and tibial prosthetic components and patella tilt was measured on patella-axial radiographs. All patients were clinically evaluated with the Knee Injury and Osteoarthritis Outcome Score (KOOS) the Oxford Knee Score (OKS) and patient satisfaction.

Results – 1) All outcome scores were in favor of combined external rotation. 2) It was no statistically significant difference in outcome scores between knees with opposite component rotation and knees with rotation in the same direction. 3) It was no statistically significant correlation between individual, combined or opposite malrotations and patella tilt. 4) Patella tilt correlated negatively with the KOOS subscores for pain, symptoms, quality of life and for patient satisfaction. In knees with more than 4° patella tilt all outcome scores were statistically significant and clinical relevant lower than in knees with 4° or less patella tilt.

Interpretation – Combined internal rotation of the femoral and tibial components as well as patellar tilt should be avoided in TKA.

The effect of different combinations of malrotation of the prosthetic components in total knee arthroplasty (TKA) is only scarcely described and the results are conflicting. Perfect rotational alignment of the components is difficult to obtain. Consequently, many prosthetic knees will end up with different combinations of malrotation. Opposite rotation occurs if one component is rotated internally and the other externally. Component mismatch is the degree of divergence in rotation between the femoral and the tibial components [1]. Combined malrotation is the sum of the rotations in the femoral and tibial components [2].

Rotational alignment of the femoral component in the axial plane affects knee kinematics, knee function and prosthetic survival after total knee arthroplasty [2-8]. Excessive internal rotation may lead to pain [3, 9], patella-femoral instability [2], failure of the patellar component [2], tibiofemoral instability in flexion [7] and valgus malalignment in flexion [4]. Excessive external rotation may cause medial laxity in flexion [6] and varus malalignment in flexion [4]. Several surgical techniques as well as new surrogate axes or anatomical lines have been proposed to improve accuracy and precision when placing the femoral component [10-18], but unfortunately, rotational malalignment is still a significant problem. A recent study from our research group did not find any correlation between malrotation of the femoral component and functional outcome after 3 years [18].

Rotational alignment of the tibial component may also affect functional outcome and prosthetic survival after TKA, and many different techniques to guide the tibial component into correct rotational alignment have emerged [19-23]. A systematic review and correlation analysis by Valkering et al. [24] found a medium positive correlation between tibial component external rotation and functional outcome. However, a very recent study by Thielemann et al. [25] did not find any significant correlation between tibial component malrotation and functional outcome.

Combined malrotation was studied by Berger et al. [2] who compared 30 knees undergoing revision TKA because of isolated patellofemoral complications with 20 patients with well-functioning total knee replacements. In their frequently cited paper, they reported that the group with patellofemoral complications had excessive combined (tibial plus femoral) internal component rotation and that combined internal rotation was directly proportional to the severity of patellofemoral complications: Small amounts of combined internal rotation (1°-4°) correlated with lateral tracking and tilting of the patella. Moderate combined internal rotation (3°-8°) correlated with patellar subluxation. Large amounts of combined internal rotational (7°-17°) correlated with early patellar dislocation or late patellar prosthesis failure [2].

Barrack et al. [3] compared 14 knees in patients with anterior knee pain and a control group of 11 pain free knees. They found that patients with anterior knee pain had average 4.7 degrees combined internal rotation compared with 2.6 degrees external rotation in the pain free knees, but they did not find a significant difference in the degree of radiographic patellar tilt or patellar subluxation between the two groups.

Nicoll et al. studied 39 painful and 26 painless fixed-bearing TKAs and found that 56% of the painful TKAs had internal rotational errors involving the femoral, the tibial or both components {Nicoll, 2010 #186}.

Bell et al. [9] compared 56 patients with unexplained pain following posterior stabilized TKA with a matched control cohort of 56 patients. They found internal rotation of the tibia and femoral components individually as well as the combined component rotation and component rotation mismatch to be a factor in pain following TKA.

In all these earlier studies, the patients' outcome was known in advance and retrospective analyses were performed in order to find a causal variable. In contrast, the current study is a prospective analysis performed on an unselected group of consecutive TKA patients. The aim of the current study was to investigate: 1) the effect of combined rotation of the femoral and tibial components on functional outcome 3 years after TKA, 2) the effect of opposite rotation and mismatch of the femoral and tibial components on functional outcome, 3) the association between component rotation and patella tilt, and 4) the effect of patellar tilt on functional outcome.

Patients and Methods

All patients were consecutively recruited from another ongoing prospective, randomized and double-blind study comparing TKA with and without patellar resurfacing [26]. Inclusion criteria were patients less than 85 years old scheduled for TKA because of end-stage osteoarthritis. Exclusion criteria were knees with severe deformity not suitable for standard cruciate-retaining prosthesis, rheumatoid arthritis, and severe medical disability limiting the ability to walk or to fill out the patient-recorded outcome documents. 80 consecutive knees (46 female) were investigated at 3 years' follow-up. Mean age was 69 (42–81) years. Mean BMI was 29 (20–43). 65 knees had varus deformity ranging from 1° to 22°, 14 knees had valgus deformity from 2° to 13° and one knee was without deformity. In 40 knees, the patella was resurfaced.

Surgical technique

All knees were operated through a standard midline incision and a medial parapatellar arthrotomy, using a posterior cruciate-retaining prosthesis (NexGen, Zimmer, Warsaw, IN). Measured resection technique, anterior referencing and ligament balancing according to Whiteside et al. [27, 28] was used in order to obtain a balanced knee in mechanical alignment. The valgus angle of the femoral component was set at 5–8 degrees, depending on the hip–knee–femoral shaft angle (HKFS) as measured on preoperative standing hip–knee–ankle (HKA) radiographs. To assure conformity in surgical technique the first author (EA) was either operating or assisting in every operation.

The rotational alignment of the femoral component was determined with the clinical rotational axis (CRA) method [18]. The rotational alignment of the tibial component was guided by conventional methods (medial third of the tibial tubercle or a modified self-seeking method).

Outcome measures

At 3 years' follow-up 80 knees were examined with CT for rotational alignment of the femoral and tibial prosthetic components. Scans were performed using the Philips Ingenuity 128-row multidetector scanner (Philips Healthcare, Andover, MA) with our standard knee protocol (140 kV, 150 mAs; rotation time 0.5 s, pitch 0.485/0.391; slice thickness 0.9 mm, interval 0.45 mm). The imaging material was evaluated using the Philips Intellispace system (Philips Healthcare, Andover, MA). Measurements were done as described by Berger et al. [2]. Patella tilt was measured on patella-axial radiographs according to Gomes [29]. Standard radiographic evaluation with antero-posterior, hip–knee–ankle (HKA) and sagittal views was also performed. All patients were clinically evaluated with the Knee Injury and Osteoarthritis Outcome Score (KOOS) [30, 31], the Oxford Knee Score (OKS) [32] and patient satisfaction (visual analogue scale (VAS)) at the 3-year follow-up.

The CT scans were evaluated independently by two observers (tibial components) or three observers (femoral components), one radiologist and one or two experienced orthopedic surgeons. Interrater reliability for the measurements performed by the observers was estimated. The effect of individual and combined rotations, opposite rotation and rotational mismatch on functional outcome and patellar tilt was then assessed. Thereafter the correlation between patellar tilt on functional outcome scores was estimated. Then functional outcome scores in knees with more than 4° patella tilt was compared to those with patellar tilt $\leq 4°$.

Statistics

KOOS, OKS and patient satisfaction are given as median values and ranges. Normally distributed values are given as mean and standard deviation (SD). A post hoc power analysis was performed with the OpenEpi, Version 3, open source calculator. The 2-sided CI was set at 95%. The minimal clinically important difference (MCID) in KOOS was set at 10 points and the mean SD of all KOOS sub-scores at 3 years was set at 16. The sample sizes for each group was 45 and 35. Given these data, the power was calculated to be 79.2%.

Inter-rater reliability for the measurements was estimated with intra-class correlation coefficient (ICC), 2-way mixed models, absolute agreement. For the measurements on the femoral components the ICC (95% CI) for inter-rater reliability was 0.62 (0.51–0.72) for single measurements and 0.83 (0.76–0.89) for average measurements. For the tibial components the ICC (95% CI) was 0.62 (0.46–0.74) for single measurements and 0.77 (0.63–0.85) for average measurements.

Comparison of outcome scores between groups were analyzed with Mann-Whitney U-test. The association between patellar tilt and component rotation was assessed with Pearson correlation. The correlation between the degree of patellar tilt and functional outcome score was assessed with Spearman's correlation analysis. The relationship between dichotomized values for patellar tilt and other dichotome variables were analyzed with the Fisher exact test.

Results

1) Mean (SD) combined rotation of the femoral and tibial components was 0° (5.5°) with range from 16° internal rotation to 15° external rotation. All outcome scores were statistically significant better in the group with combined external rotation of the components (table 1).

	External rotation (n=43)	Internal rotation (n=37)	p*
KOOS			
Pain	97	92	0.011
Symptoms	93	89	0.019
ADL	97	93	0.049
Sport/Rec	80	65	0.032
QOL	94	81	0.002
OKS	15	16	0.010
Patient satisfaction	100	95	0.019

* Mann-Whitney U-test

Table 1. Outcome scores at 3 years follow-up in knees with combined external and internal rotation of the femoral and tibial components. Median values are given. KOOS: Knee injury and osteoarthritis outcome score. 0-100. Best score is 100. ADL: Activities of daily living. QOL: Knee related quality of life. OKS: Oxford knee score. 12-60. Best score is 12.

2) Opposite rotation of the femoral and tibial components occurred in 35 knees. The difference in rotation between the femoral and tibial components ranged from 1° to 14°. It was no statistically significant difference in outcome scores in patients with knees with opposite component rotation and knees with rotation in the same direction (table 2). The degree of mismatch did not correlate with any outcome measure.

	Rotation in the same direction (n=45)	Opposite rotation (n=35)	p*
KOOS			
Pain	97	94	0.18
Symptoms	93	89	0.60
ADL	96	93	0.52
Sport/Rec	75	65	0.34
QOL	94	88	0.67
OKS	15	16	0.25
Patient satisfaction	99	95	0.27

* Mann-Whitney U-test

Table 2. Outcome scores at 3 years follow-up in knees with the femoral and tibial components rotated in the same direction and in opposite direction. Median values are given. See table 1 for abbreviations.

3) Mean patella tilt was 1.8° external rotation with a range from 4° internal rotation to 10° external rotation. It was no statistically significant correlation between individual or the different combinations of malrotation and patella tilt (table 3). However, it was a strong association between patella tilt on one side and preoperative alignment and patellar resurfacing on the other side (table 4).

Table 3. Correlation coefficients for the relationship between different combinations of malrotation of the prosthetic components and patellar tilt

	Tibial component rotation	Femoral component rotation	Combined rotation	Mismatch
Patella tilt	Pearson r = 0.1 (p = 0.38)	Pearson r = 0.05 (p = 0.67)	Pearson r = 0.09 (p = 0.45)	Pearson r = 0.1 (p = 0.35)

Table 4. Association between knees with patellar tilt >4° and gender, varus/valgus alignment and patellar resurfacing. Among 80 knees, 9 knees had patellar tilt > 4°

	Female/ male	p*	Valgus/Varus	p*	Without/with patellar component	p*
Patella tilt >4°	8/1	0.07	6/3	0.0007	9/0	0.002

* Fisher exact test

4) Patella tilt correlated negatively with the KOOS subscores for pain, symptoms and quality of life, and for patient satisfaction. Patella tilt more than 4° occurred in 9 knees. All these knees were without patella resurfacing and all outcome scores were statistically significant, and clinical relevant inferior compared to knees with 4° or less patella tilt (table 5).

Table 5. Outcome scores at 3 years follow-up in knees with patella tilt ≤ 4° and in knees with patella tilt > 4°

	Patella tilt ≤ 4° (n=71)	Patella tilt > 4° (n=9)	p*
KOOS			
Pain	97	67	0.001
Symptoms	93	71	0.002
ADL	94	76	0.012
Sport/Rec	70	35	0.007
QOL	94	56	0.002
OKS	15	22	0.008
Patient satisfaction	99	90	0.001

*Mann-Whitney U test

Discussion

In this study, we found that knees with combined internal rotation of the tibial and femoral components had statistically significant lower outcome scores than knees with externally rotated components (Table 1). However, the minimal perceptible clinical improvement (MPCI) for KOOS (8–10 points) was achieved only for sport/recreation and knee related quality of life [33]. This finding is supported by earlier studies [3, 9]. Component rotational mismatch and opposite rotation (Table 2) did not influence outcome in our study. This is in contrast to the findings of Bell et al. [9]. One reason for this controversy may be that we used a cruciate retaining prosthesis and Bell et al. used a posterior stabilized implant that can be considered slightly constrained, and therefore can induce a mechanical conflict between the components. However, it should also be noticed that in our data, there is a trend in favor of rotation in the same direction for all scores, and although the power is 79%, there is an obvious risk of a type 2 statistical error.

We did not find any correlation between component rotation and patellar tilt (Table 3). This is in conflict with the findings by Berger et al. [2]. The reason for this discrepancy is unclear, but it is noteworthy that Berger investigated a highly selected group of patients with isolated patellofemoral complications already scheduled for revision arthroplasty. In our study, an unselected sample of consecutive TKA-patients were investigated. It is also important to remember that in this material the rotational positioning of the femoral component was determined by the Clinical rotational axis (CRA) method [18]. Due to the very high degree of accuracy and precision of this method the maximal malrotation of the femoral component in this material was very small (± 3.7°) compared to other studies. Additionally, we found a strong association between patellar tilt and preoperative valgus alignment and between patellar tilt and patellar resurfacing (Table 4). Furthermore, eight out of nine severely tilted patellas were in women. This was not statistically significant (p=0.07) but a type 2 error can be suspected. Thus, it is likely that the cause of patellar tilt is multifactorial including preoperative alignment, resurfacing or not of the patella, gender and probably femoral component rotation. It is however remarkable that even pronounced tibial component rotation does not seem to produce patella tilt.

Another possible interpretation of these findings is that patellar resurfacing in some way seems to protect the patient against patellar tilt and thereby from pain and dysfunction. The reason for this is unclear, but it can be argued that the exercise of patellar resurfacing introduce an extra tool to the surgeon that make balancing of the patella-femoral joint easier. For example, residual lateral tracking of the patella after positioning the tibial and femoral components can be corrected by a few mm´s over-resection of the patellar bone and by medializing a relatively small patellar button. It may also be that non-resurfaced patella-femoral joints when tilted, for some reason is more painful.

The last finding in this study was that knees with more than 4° patellar tilt had much worse outcome than knees with less patella tilt. However, the effect size was so big that confounding should be suspected. Additional analyses showed that non-resurfacing of the patella, was negatively correlated to outcome, but preoperative valgus alignment was not correlated with outcome. Thus, non-resurfacing of the patella is a confounding variable that adds to the negative effect of patellar tilt on outcome, but valgus alignment is not a confounder.

Limitations to this study are the low number of patients in some of the subanalyses, indicating a risk for type 2 statistical errors. Another limitation is the relatively low ICC for measurements of tibial component rotation on CT images. A strong side of this study compared to most earlier studies is the unselected study population.

In summary, combined internal rotation of the femoral and tibial components and patellar tilt more than 4° should be avoided in order to obtain good functional outcome after TKA.

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