Diss. ETH No. 25026

Challenges in the Design of Biomimetic Orthopaedic Implants

Next Generation Knee Arthroplasty

A thesis submitted to attain the degree of

DOCTOR OF SCIENCES of ETH ZURICH

(Dr. sc. ETH Zurich)

presented by

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2018

To medicine and science

“Anyone who has never made a mistake has never tried anything new”

Albert Einstein

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Acknowledgement

My way from Boston to Zurich with a thesis across oceans would not have been possible without the flexibility and support of many.

First, I would like to thank Prof. Stephen J. Ferguson for his openness to accept me as a doctoral candidate in his group, following my project proposal for an external dissertation, without knowing much about my skills and personality. This enabled the continuation of my previously started work in Boston before moving back to Switzerland. On the other side of the Atlantic, I would like to thank Prof. Orhun K. Muratoglu, for endorsing the integration of their implant development projects into my thesis. I very much appreciated the supervision and guidance by Orhun and Stephen, providing support for the projects of this thesis, as well as planning of my career. I was very fortunate to receive the freedom for my personal development in all aspects of this thesis and count on their advice and experience when needed.

I am very grateful for conducting my thesis in two laboratories providing a reproductive working environment. I was privileged for being part of the Technology Implementation Research Center at the Department of Orthopaedic Surgery at Massachusetts General Hospital (MGH) in Boston for the first projects of my thesis. Moving back to Switzerland I was able to join the Laboratory for Orthopaedic Technology at the Institute for Biomechanics (IfB) for the second part of my thesis. I would like to thank ETH Zurich and the Department of Health Sciences and Technology (HEST), for permitting me to conduct part of my studies as an external dissertation in Boston, where I found valuable opportunities at MGH and the Harvard system.

I was very fortunate to benefit from the experience in joint biomechanics and implant design of Dr. Kartik Mangudi Varadarajan at MGH and Dr. Renate List at the Institute for Biomechanics. Renate and Kartik introduced me to the unique measurement methods in the respective laboratories and had always an open door for discussions regarding detailed findings of our research.

I would like to thank everyone who was contributing to the excellent setting in the IfB motion lab over the years with either hardware or software development. Special thanks goes to all IfB members, who were helping during the measurements of my studies. I feel fortunate, for supervising two excellent master theses by Lorena and Adrian, and a bachelor thesis by Luca, that were integrated into my project.

Furthermore, I would like to express my sincere gratitude for many enjoyable interactions with my colleagues and friends at MGH and ETH, responsible for a productive, professional and pleasant atmosphere. After-work sailing on the Charles in Boston or jumping into the Limmat, were fantastic ways to end a hardworking day at the office. I will always remember colorful hikes in the White Mountains or weekend trips to New York City. Skiing the Swiss Alps, backcountry skiing on Mt. Washington or climbing via ferratas will be great memories with colleagues. These experiences would not have been possible, without friendships lasting beyond work. I am looking forward to onsite visits, or reunions in different parts of the world at a conference or on vacation.

I would like to thank all clinical collaborators at MGH and Schulthess Klinik for their valuable input. I appreciated introductions and education in orthopaedic surgery to understand and recognize knee anatomy and function through a clinical perspective.

All funding sources for these projects are greatly acknowledged. Among departmental funding sources, industry support from MAKO Surgical (Stryker) for some of the projects in Boston and from DePuy Synthes for the Projects at ETH were critical for the achievements of this thesis.

Last but not least, I would like to thank my family and friends for their encouragement all through my life. Particularly I am grateful for the support my parents Beatrice and Hans provided in the first part of my life, and how my girlfriend Aleksandra has been keeping up with me, during all my ventures.

Hasliberg, January 2018
Thomas Zumbrunn

Summary

Designing orthopaedic implants to reconstruct native anatomy and function continues to be a major challenge in the development of new products. This thesis provides insights and suggestions for designing next generation knee arthroplasty with a focus on native joint kinematics. Like in many other specialties, biomimetics is the ultimate objective in joint reconstruction.

Knee arthroplasty is the most successful treatment option for severe osteoarthritis, providing patients with a reliable solution to relief pain and regain mobility. However, native joint function is not fully restored and for an aging population with growing interest in demanding activities, several limitations are present. Particularly, existing total knee arthroplasty (TKA) delivers kinematic deficits, associated with abnormal feeling of the knee, following joint surgery. These limitations are related to sacrificed ligaments, and none-anatomic geometries of current implant designs. Mostly, the anterior cruciate ligament (ACL) is sacrificed and its function is lost. Therefore, a biomimetic process was implemented to reverse engineer articular surfaces, by directly incorporating native knee kinematics.

For the first aim, we designed a biomimetic implant that would preserve all major ligaments of the native knee joint. Therefore, an anatomically designed femoral component was virtually moved through native knee kinematics, to carve out a tibial articular surface, through the biomimetic process. This anatomical surface was incorporated into a novel implant, specifically designed to preserve the native ACL.

For the second aim, we established a dynamic simulation platform to reliably evaluate implant design variations and the effect of ligaments. Knee kinematics, driven by ligament function and contacting implant geometry, allowed for comparison of different knee arthroplasty systems, against in vivo and simulated native knee motion. The first computational study revealed that a biomimetic, bi-cruciate retaining (BCR) implant provides activity dependent kinematics, similar to healthy knees in vivo, during deep knee bend, chair sit and level walking. This was in contrast to symmetric BCR systems, which nonetheless showed kinematic improvements over ACL-sacrificing implants. This indicates that restoring anatomic knee geometry together with ACL preservation is required for optimal implant function. The second computational study showed that a novel ACL-substituting mechanism could improve kinematic deficits of contemporary PCL-retaining (ACL-sacrificing) implants. ACL-substituting and ACL-retaining implants both provided similar improvements over the ACL-sacrificing implant in comparison to a native knee model. This was shown during walking, stair-ascent, chair-sit and deep knee bend simulations, indicating that ACL-substitution may be a valuable treatment option when ACL preservation is not feasible.

For the third aim, we evaluated an extended treatment indication for unicompartmental knee arthroplasty (UKA), via in vivo kinematic analysis, using a moving fluoroscope. UKA is known for better functionality over TKA due to ACL retention and partial preservation of the native articulation. An ACL-deficient population, undergoing an altered surgical technique, with appropriate adaptation of implant placement, was compared against conventional UKA patients, with an intact ACL. The first in vivo study showed kinematic similarities between ACL-deficient and conventional UKA patients, in contrast to TKA. A posterior femoral shift was observed with ACL-deficient UKA, while kinematic trends and range of motion were similar during deep knee bend, downhill walking, level walking and stair descent. Based on kinematics, this confirms that the indication for UKA can be extended to include selected ACL-deficient patients. The second kinematic study revealed no differences in ground reaction forces between ACL-deficient and conventional UKA patients. Adequate kinematic and kinetic symmetries among implanted and contralateral leg indicate that UKA may not always be a contraindication due to ACL deficiency.

In summary, this thesis outlines the importance of biomimetic implants for the objective of “forgotten knees”, following joint arthroplasty. Native knee function may be restored with anatomic geometries and ligament retention. Preservation or substitution of either the articular geometry or the ACL, results in kinematic improvements over conventional TKA. Long-term clinical outcome studies will be required for the ultimate proof of this concept.

Zusammenfassung

Implantate zu entwickeln, welche die natürliche Anatomie und Funktion wiederherstellen ist eine grosse Herausforderung. Diese Dissertation beabsichtigt Empfehlungen für die Entwicklung zukünftiger Implantate zu geben. Wie in vielen anderen Fachgebieten ist die Biomimetik das ultimative Ziel eines Gelenkersatzes.

Der künstliche Gelenkersatz stellt die erfolgreichste Intervention bei Gelenkarthrose dar. Obschon Schmerzlinderung und Wiedererlangen der Mobilität erfolgreich erreicht werden, bleiben einige Limitationen bestehen, vor allem bei anforderungsreichen Aktivitäten. Die Totale Knie Endoprothetik (TKE) hat kinematische Defizite, welche mit einem unnatürlichen Bewegungsgefühl assoziiert sind. Diese Limitationen entstehen wegen dem Verlust der Bänderfunktion und einem nichtanatomischen Implantat Design, im speziellen das vordere Kreuzband (VKB) wird meist nicht erhalten. Deshalb wurde ein biomimetischer Prozess eingeführt, welcher die natürliche Kinematik direkt in das Design der Artikulationsflächen miteinbezieht.

Als erstes Ziel haben wir ein biomimetisches Implantat entworfen, welches alle wichtigen Bänder des nativen Kniegelenkes erhaltet. Dazu wurde eine anatomisch geformte Femur Komponente virtuell durch die Kniekinematik bewegt, um eine tibiale Oberfläche zu generieren. Diese anatomische Oberfläche wurde zu einem neuartigen Implantat verarbeitet, das speziell für die Erhaltung des VKB entwickelt wurde.

Als zweite Absicht haben wir eine stabile Simulationsplattform etabliert, um den kinematischen Effekt von Implantat Geometrien und Bänderfunktion zu evaluieren. So konnte die Kniekinematik verschiedener Implantat Systeme mit simulierten und gemessenen Bewegung des natürlichen Knies verglichen werden. Die erste Simulationsstudie zeigte, dass ein biomimetisches Implantat, welches beide Kreuzbänder erhaltet, aktivitätsabhängige Kinematik, ähnlich zum natürlichen Knie vorweist. Dies im Gegensatz zu konventionellen kreuzbanderhaltenden Systemen, welche jedoch kinematische Verbesserungen gegenüber VKB-opfernden Implantaten aufwiesen. Dies bedeutet, dass Wiederherstellung anatomischer Artikulationsflächen,

sowie Erhaltung des VKB für eine optimale Implantat Funktion erforderlich sind. Die zweite Simulationsstudie zeigte, dass ein künstlicher Mechanismus als Ersatz des vorderen Kreuzbandes die kinematischen Defizite von Knieimplantaten ohne VKB verbessern kann. VKB-erhaltende und VKB-substituierende Implantate zeigten ähnliche Verbesserungen gegenüber dem VKB-defizitären Implantat, im Vergleich zu einem anatomischen Kniemodell. Dies suggeriert, dass die VKB-Substitution eine wertvolle Behandlungsoption sein kann, wenn die VKB-Erhaltung nicht durchführbar ist.

Als dritte Zielsetzung haben wir eine erweiterte Behandlungsindikation der partiellen Knie Endoprothetik (mediales Uni) anhand der Kinematik, gemessen durch ein bewegtes Fluoroskop, evaluiert. Teilprothesen sind bekannt für bessere Kinematik im Knie, resultierend aus dem Kreuzbanderhalt und der Teilerhaltung von Artikulationsflächen. Patienten mit VKB-Insuffizienz, behandelt durch eine geänderte Operationstechnik mit angepasster Implantat Positionierung, wurden mit Patienten mit konventioneller Teilprothese und VKB-Erhalt verglichen. Die erste in vivo Studie zeigte eine vergleichbare Kinematik zwischen den zwei Gruppen mit Teilprothesen, im Gegensatz zu Patienten mit einer Totalprothese. Eine posteriore Femur Verschiebung wurde beobachtet, während kinematische Tendenzen und Bewegungsumfang bei tiefem Kniebeugen, abwärts Gehen, ebenem Gehen und Treppenabsteigen ähnlich waren. Dies bestätigt, dass in Bezug auf die Kinematik, die Indikation für Teilprothesen auf ausgewählte Patienten mit VKB-Insuffizienz, ausgedehnt werden kann. Die zweite kinematische Studie zeigte keine Unterschiede in den Bodenreaktionskräften zwischen VKB-insuffizienten und konventionellen Uni Patienten. Weiter deuten angemessene Symmetrien zwischen implantiertem und kontralateralem Bein darauf hin, dass VKB Insuffizienz nicht immer eine Kontraindikation für Teilprothesen ist.

Zusammenfassend zeigt diese Arbeit die Bedeutung biomimetischer Implantate für das Ziel eines «vergessenen Knies» nach einer Gelenk Endoprothetik. Die natürliche Kniefunktion ist von anatomischen Geometrien und Erhaltung der Bänder abhängig. Erhaltung oder Substitution von entweder Gelenkgeometrie oder VBK führt zu kinematischen Verbesserungen in der totalen Endoprothetik. Für den endgültigen Nachweis dieses Konzepts sind langfristige klinische Studien nötig.

1 Introduction

1.1 Thesis motivation

Osteoarthritis is one of the most common diseases in elderly, and with the aging population, prevalence is expected to increase exponentially in the coming years [1]. Impact on daily living and economic burden of osteoarthritis are tremendous, and the knee joint is particularly affected due to its load accepting purpose. The overall population prevalence is up to 2%, with over 10% in people 80 years and older. This results in more than 600,000 implantations yearly in the United States alone [2,3].

Patient reported outcome studies and kinematic evaluations reveal that hip replacements are more successful than knee replacements in restoring native joint function [4–7]. While both procedures are effective in pain reduction and basic mobility, functionality required for more demanding activities is challenging with knee implants. Native knee kinematics are associated with activity-dependent joint function, which may not be retained following knee arthroplasty [7–9]. The hip functions as a ball-and-socket joint that can accurately be replaced by means of joint arthroplasty, whereas the knee joint is less constrained and relays on soft-tissues for stability and proper function.

There is a large variety of implant systems available, following different design philosophies, including partial and total knee arthroplasty with fixed and mobile bearing surfaces that either sacrifice or retain native knee ligaments. There is no clear gold standard and multiple implant types are equally effective for clinical use, however, unicompartmental knee arthroplasty (UKA) patients generally achieve better knee function [10,11]. Total knee arthroplasty (TKA) designs are generally not based on native knee function and articular designs may fundamentally conflict with such native knee kinematics for the benefit of added joint stability. This is in contrast to hip arthroplasty patients, reporting higher satisfaction following surgery with less difficulty during activities in daily living [4,12]. Therefore, the “forgotten joint” following implantation may be more prevalent in hip arthroplasty than in knee arthroplasty. Patient reported outcome studies reveal that up to 20% of patients following TKA are dissatisfied with their prosthesis [6,10,13]. Particularly functionally demanding activities pose difficulties for many patients.

Current knee arthroplasty systems are not meeting the clinical need of preserving native joint function following surgery [7]. Therefore, the motivation of this thesis was to address this clinical need through innovation of biomimetic implants. The challenge to develop next generation knee arthroplasty for better functional outcome and improved quality of live is very motivating.

1.2 Thesis aims

The aim of this thesis was to provide recommendations for implant design and treatment indication, based on biomechanical principles. The objective was to improve contemporary implant design, via biomimetic articular surfaces, based on healthy knee kinematics, and to extend current treatment indication, through adjusted surgical technique.

1.2.1 Biomimetic implant design

The first aim was to design a biomimetic implant that preserves all major ligaments of the native knee joint, including the anterior cruciate ligament (ACL). This was done with a process, allowing to reverse engineer biomimetic articular surfaces, implicitly compatible with healthy knee motion. Via this biomimetic process, an anatomically designed femoral knee component was moved through deep knee flexion kinematics of in vivo native knees, to carve out a tibial implant. The aim was that this tibial articular surface would allow healthy knee kinematics. The objective was to improve knee articulation of contemporary implants, which do not consider actual kinematics of native knees.

1.2.2 Dynamic simulations for implant design evaluation

The second aim was to establish a robust dynamic simulation platform for the evaluation of implant design variations and effects of ligaments. This allowed the comparison of knee kinematics, driven by ligament function and contacting implant geometry, of different knee arthroplasty systems, against simulated and in vivo native knee motion. A new implant design could be further modified, based on the kinematic simulation output. A specific aim was to evaluate a biomimetic knee arthroplasty that preserves both cruciate ligaments (bi-cruciate retaining), by means of dynamic simulations, and compare kinematics against a variety of contemporary implant systems. Another evaluation was the concept of an ACL-substituting mechanism, compensating for an absent ACL. Therefore, a common articular surface was simulated with an intact ACL, a substituted ACL and without an ACL. A native articular cartilage model (including an intact ACL) served as reference comparison.

1.2.3 In vivo evaluation of extended treatment indication

The third aim was to evaluate an extended treatment indication for UKA, via in vivo kinematic analysis, using a moving fluoroscope. A specific aim was to investigate, if kinematics in ACL-deficient knees undergoing UKA implantation, with adjusted implant positioning (tibial slope reduction), would show similar kinematics to conventional UKA, with an intact ACL. Another aim was to evaluate gait symmetries between implanted and contralateral leg, based on kinematic and kinetic parameters. The objective was to show that ACL-deficiency would not always be a contraindication for UKA.

1.3 Thesis outline

This thesis is structured in seven chapters, including motivation, aims, background and philosophy, four specific analyses, achievements and overall conclusion.

Chapter 1: Motivation of this work, specific aims and outline of the thesis.

Chapter 2: Description of native knee anatomy and function, as well as joint disease due to osteoarthritis.

Overview of current implant types, including clinical relevance and conflict to native knee anatomy and function.

Challenges in the design of new knee implants, with a focus on native structures and function.

Introduction of a reverse-engineering process, for creation of biomimetic articular surfaces, through in vivo native knee kinematics.

Effects of articular surface design and ACL function, concerning knee kinematics in dynamic simulations.

Chapter 3: Geometric abnormalities in contemporary knee arthroplasty, in contrast to anatomic articular surface and ACL retention.

Hypothesis: Design of a biomimetic implant with ACL retention, for restauration of native knee kinematics.

Kinematic comparison of the biomimetic TKA to various contemporary implant systems, by means of dynamic simulations.

Activity dependent kinematics of the biomimetic TKA, with ACL retention, similar to healthy knees in vivo, in contrast to contemporary systems.

Kinematic improvements of implants, with ACL preservation but absence of anatomic articular surface, over implants without an ACL.

Anatomic articular surface together with ACL preservation, resulting in normal knee function.

Chapter 4: Kinematic abnormalities of contemporary TKA due to ACL resection.

Technical challenges of ACL preservation, or prevalence of ACL deficiency in current practice.

Hypothesis: Novel ACL-substituting implant, for improvement of kinematic deficits in ACL-sacrificing TKA.

Dynamic simulations of a common articular geometry with ACL substitution, ACL preservation or without an ACL.

Similarities of ACL substitution and ACL preservation, in comparison with healthy knee simulations and in contrast to ACL deficiency.

Implant design with ACL substitution, as a valuable treatment option improving limitations in contemporary TKA.

Chapter 5: Functional advantages of partial knee systems, over total implants due to ACL retention and partial preservation of native articulation.

Hypothesis: ACL deficient UKA with adaptation of implant placement, for similar kinematics to conventional UKA with intact ACL.

In vivo kinematic assessment of UKA patients with an intact ACL, and a deficient ACL during daily activities.

Posterior femoral shift in UKA with ACL deficiency in a standing position.

Minimal differences in kinematics between the two UKA groups for all activities.

Additional comparison of TKA patients, showing different kinematic trends and range of motion reduction.

ACL deficiency, with tibial slope reduction in UKA, as a viable treatment option, for patients with rotational stability.

Chapter 6: Better functionality of UKA and a less invasive procedure in contrast to TKA implantation.

Controversy of ACL necessity in partial knee arthroplasty, with posterior tibial slope reduction compensating for instability.

Aim: Kinematic and kinetic investigation of conventional UKA and ACL-deficient UKA patients for analysis of gait symmetries.

No leg asymmetries in kinematics of UKA patients with an intact ACL and a deficient ACL, for level walking, ramp descent and stair descent.

Minimal asymmetries in kinetics between ipsilateral and contralateral leg, in ACL-deficient group, for level walking and stair descent.

ACL deficiency not always a contraindication for patients with translational laxity and rotational stability.

Chapter 7: Discussion of overall results with a biomimetic focus.

Specific achievements of this thesis.

Implication of the findings in relation to clinical needs.

Limitations of the outcomes of this thesis.

Conclusion with impact and challenges of implant design and surgical technique.

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2 Background

Portions of this chapter are published as
K. Mangudi Varadarajan[1], T. Zumbrunn[1,2], HE. Rubash[1], H. Malchau[1], OK. Muratoglu[1], G. Li[1]
Reverse Engineering Nature to Design Biomimetic Total Knee Implants
J Knee Surg, Oct 2015; 28(5), 363-9
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2.1 Native Knee

2.1.1 Knee Anatomy

Native knees consist of the tibiofemoral and patella femoral joint, thus, there are three bones involved (tibia, femur and patella). The focus of this thesis is on the tibiofemoral joint, which consists of the medial and lateral compartment (**Figure 2-1A**). Both compartments include a femoral condyle articulating against a separate tibial articular surface. The interacting areas are covered with articular cartilage, providing smooth low-friction contact. While both femoral condyles comprise of a multi-radius sagittal profile with an almost cylindrical shape of the posterior condyles, the tibia has a concave (dished) profile on the medial side, in contrast to a convex profile on the lateral side [1,2] (**Figure 2-1B**).

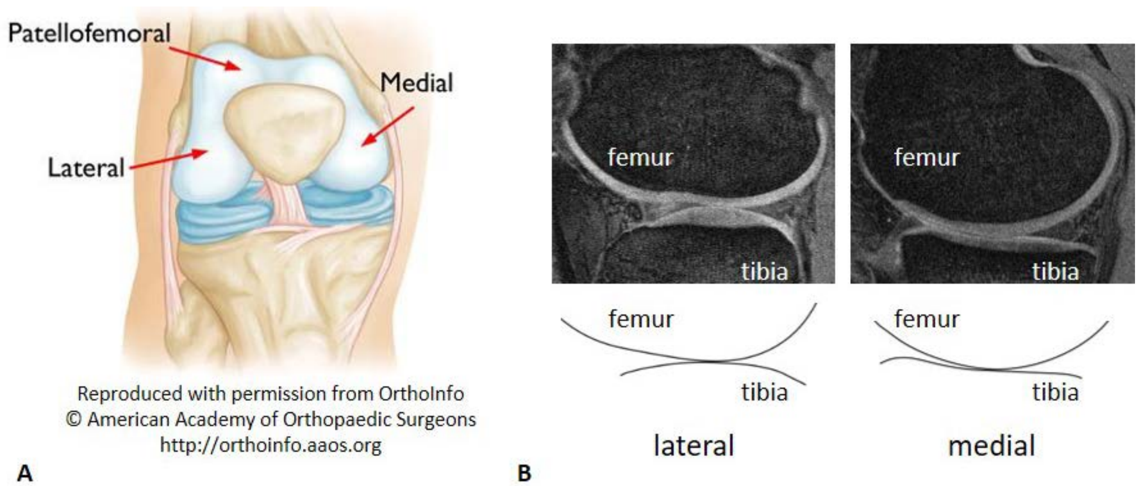

Figure 2-1: *Schematic indicating the three knee compartments (A), and sagittal view of lateral and medial condyles on MRI and average native knee model (B)* [3].

In addition to the cartilage covered bones, the contact areas are supported with medial and lateral menisci (**Figure 2-2**). The menisci distribute load across the incongruent femoral and tibial contact, and therefore serve an important role in the knee joint [4]. The medial meniscus provides more stability, with attachment sites (horns) located anteriorly and posteriorly on the tibia, while the lateral meniscus is attached more centrally on the tibia, allowing rotational freedom. The lateral meniscus is capable of sliding off the posterior margin of the convex tibia in contrast to the medial meniscus that is further attached to the medial collateral ligament (MCL), hence increasing stability of the medial tibiofemoral joint [5]. The MCL together with the lateral collateral ligament (LCL) provides stability to the knee joint throughout knee flexion by connecting femur and tibia on both sides of the joint [6]. Anterior and posterior cruciate ligament (ACL and PCL) connect femur and tibia in a crossing manner inside the joint capsule and are responsible for stability during different portions of knee flexion (**Figure 2-2**) [7–9]. Together with the joint capsule, additional small structures provide overall joint stability, including connections to the patellar bone that are not further discussed herein.

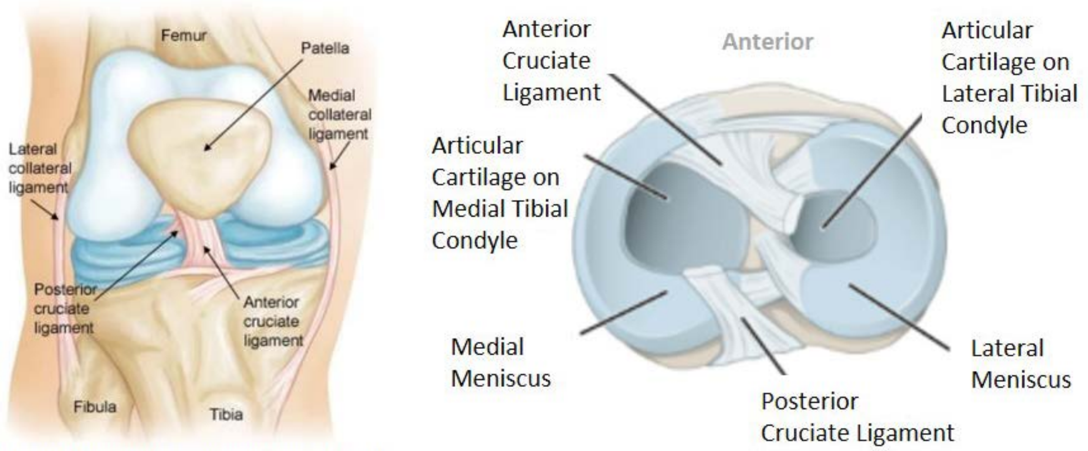

Figure 2-2: *Schematic of the native knee showing relevant soft-tissue structures including menisci, collateral and cruciate ligaments.*

2.1.2 Knee Function

Due to the variety of anatomical structures, the knee joint provides complex motion with six-degree of freedom kinematics, consisting of all three rotations and translations [3,10,11]. The predominant function of the knee joint is flexion and extension in the sagittal plane. Additionally, there is substantial internal/external (IE) rotation in the native knee joint. IE rotation is mainly fostered by the asymmetric tibial articular surface and the cruciate ligaments. While the ACL is associated with a so-called "screw-home" ration in extension, the PCL is responsible for posterior femoral rollback in deep flexion. Both Cruciate ligaments provide mid-flexion stability in the healthy knee [7–9]. As a result of the increased laxity in the lateral compartment, ligament and muscle function induce IE rotation. Joint asymmetry and ligaments also affect anteroposterior (AP) translation of medial and lateral compartments [12,13]. The lateral compartment allows increased motion over the medial side, which nonetheless tolerates appreciable AP translation. Hence, the native knee joint can neither be approximated by a hinge joint nor by a ball-in-socket joint.

With proper MCL and LCL function, varus/valgus (VV) rotation in the knee joint is stabilized as well as superior/inferior (SI) translation (also referred to proximodistal). The combination of VV rotation and SI translation could however generate lift-off in one or the other compartment of the knee joint [14,15]. This would primarily occur in unloaded scenarios, such as the swing phase during gait cycles. Mediolateral (ML) translation is not particularly relevant in a healthy knee joint, stabilized by intact anatomical structures (ligaments, menisci, etc.).

Native knees present asymmetric kinematics with greater femoral rollback on the lateral side, resulting in femoral external rotation (also referred to as tibial internal rotation), particularly in deep knee flexion as reported by Johal et al. (**Figure 2-3**, [3]).

Several other in vivo and in vitro studies have reported knee kinematics of native knees with variability in kinematics based on knee flexion, activity and patient specific factors [10,11,16,17]. Therefore, it is important to recognize the complex anatomy and kinematics of healthy knees when designing implants that are replacing the articular surface of the knee joint.

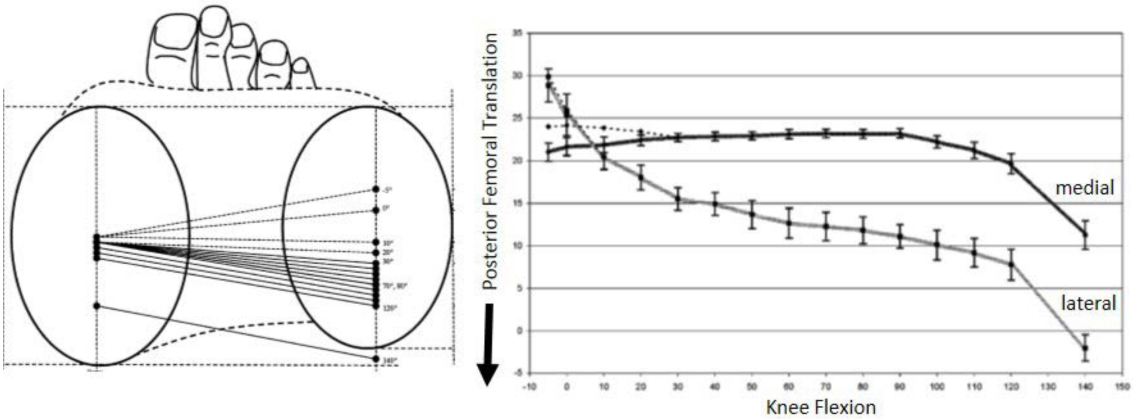

Figure 2-3: *In vivo kinematics of native knees showing femoral condyle motion in respect to the tibia when looking top-down on the tibial plateau* [3].

2.2 Arthritis

Osteoarthritis is a common disease affecting predominantly elderly people. With aging, articular cartilage is prone to degeneration due to enduring deterioration [18,19]. With worn cartilage surfaces, bone-on-bone articulation, which is not optimized for friction-less interaction, occurs in the affected joint. Bone-on-bone contact (and articulation) can cause formation of osteophytes (also called bone spurs), resulting in impingement and consequently impaired joint motion, followed by a decreased activity level (**Figure 2-4**).

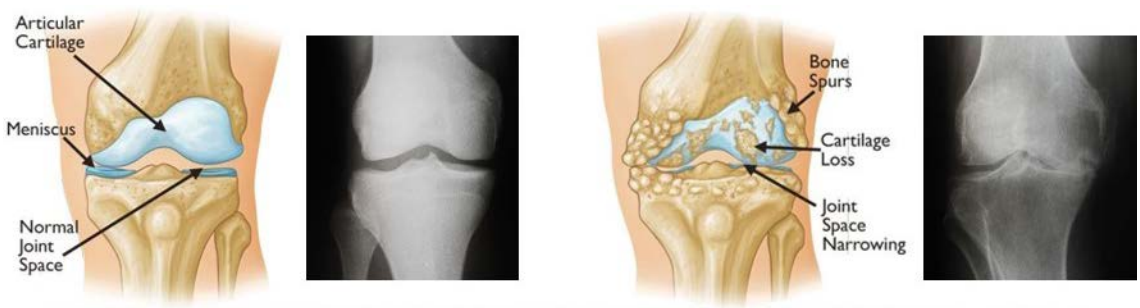

Figure 2-4: *Schematic and coronal x-ray of the intact knee joint with normal joint space (left) and osteoarthritic knee joint showing joint space narrowing and formation of osteophytes (right).*

Osteoarthritis can either affect one or both bones associated with a joint, and in the knee joint specifically, also one or all three compartments. Knee osteoarthritis is most commonly prevalent in the medial tibiofemoral compartment. Higher load transmitted thought the medial compartment compared to the lateral compartment due to the nature of the mechanical axis is likely associated with this higher incidence [20,21]. Additionally, malalignment and prior trauma are related to the site and progression of osteoarthritis. For example, ACL injury may be linked to osteoarthritis, because of increased joint mobility due to a missing ACL and its related stability. However, there is conflicting information regarding the causation of ACL injury and osteoarthritis [22,23]. Alternatively, a degenerative ACL can develop secondary to osteoarthritis [24,25].

Increasing prevalence of obesity, and high activity levels in elderly people can both result in greater occurrence of osteoarthritis [19]. These two subpopulations are exemplary for two main factors related to osteoarthritis: load and motion. Hence, with a well-balanced lifestyle osteoarthritis can be prevented to a certain extent. Genetic factors play a further role in the disease manifestation, however, age related "wear and tear" are more predictable factors [19,26].

Since cartilage is not visible on x-ray images, this offers a simple and fast way for disease detection. The joint space is significantly narrowed in a diseased state, which is well detectable for the tibiofemoral joint, on an anteroposterior radiograph (**Figure 2-4**). This view also allows separation of the disease between the medial and lateral compartment of the knee joint. Patellofemoral arthritis is detectable on a transfers x-ray relative to the tibia at 90° knee flexion.

2.3 Joint Replacement

Knee arthroplasties have been evolving continuously since the 1960s. Many materials and designs have been explored and as many have failed suitable application. Nowadays, most implants consist of a metal femoral component (mostly cobalt-chrome), a metal tibial baseplate (cobalt-chrome or titanium) and a tibial insert (also called inlay) located between the two metal components. Existing designs include replacement of a single compartment of the knee joint, with unicompartmental knee arthroplasty (UKA), or replacement of all three compartments, with total knee arthroplasty (TKA), which is the most used implant type in clinical practice (**Figure 2-5**).

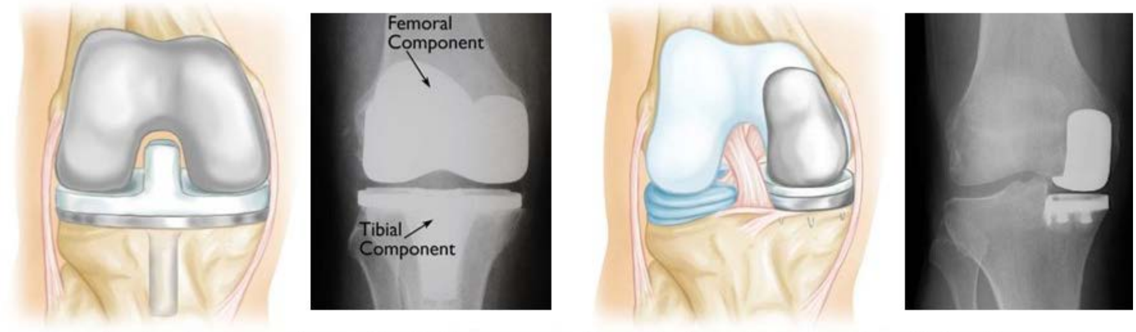

Figure 2-5: *Schematic and coronal x-ray image of TKA (left) and UKA (right) showing the different components of the prosthesis.*

Inserts are generally manufactured of ultrahigh molecular weight polyethylene (UHMWPE) and articulate against one or both metal parts. Inserts have gained attraction in the last decades due to wear, when articulating against a metal counterpart. UHMWPE has been associated with delamination due to oxidation, and wear debris causing osteolysis. Osteolysis reduces bone density, resulting in implant loosening and higher risk of bone fracture [27,28]. Recent advancements in material development offer second and third generation UHMWPE undergoing cross-linking and anti-oxidizing methods (e.g. vitamin-E) for prolonged wear resistant material properties [29–31].

Design improvements have been rare during the past decade, however, there is a large variety of knee arthroplasty types in clinical use. TKA offers different options regarding articular design and preservation of soft tissues. For the vast majority of current TKA designs, the ACL is sacrificed and its contribution to stability and kinematics is lost following implantation. So-called cruciate retaining (CR) TKA with PCL preservation (sacrificed ACL), and posterior-stabilized (PS) TKA, with PCL substitution through a post-cam mechanism (ACL and PCL sacrificing), are most widely used in todays practice [32]. Design philosophies include mobile and fixed bearing variations, cemented and uncemented fixation, as well as less popular designs that retain the ACL or include articular asymmetries (e.g. medial pivot with lateral freedom and medial compartment ball-and-socket articulation) [2,33–35]. However, native knee anatomy and function are used to a limited extent for few patient specific options or so called “anatomic” implants restricted to an anatomic tibial baseplate. Therefore, UKA remains a more physiologically functioning treatment option, in contrast to contemporary TKA [36,37].

2.4 Reverse Engineering Nature to Design Biomimetic Total Knee Implants

While contemporary total knee arthroplasty (TKA) provides tremendous clinical benefits, the normal feel and function of the knee is not fully restored. To address this, a novel design process was developed to reverse engineer "biomimetic" articular surfaces that are compatible with normal soft-tissue envelope and kinematics of the knee. The biomimetic articular surface is created by moving the TKA femoral component along in vivo kinematics of normal knees and carving out the tibial articular surface from a rectangular tibial block. Here, we describe the biomimetic design process. In addition, we utilize geometric comparisons and kinematic simulations to show that; (1) tibial articular surfaces of conventional implants are fundamentally incompatible with normal knee motion, and (2) the anatomic geometry of the biomimetic surface contributes directly to restoration of normal knee kinematics. Such biomimetic implants may enable us to achieve the long sought after goal of a "normal" knee post-TKA surgery.

2.4.1 Introduction

The utilization of total knee arthroplasty (TKA) for treatment of severe knee joint arthritis continues to grow rapidly, and a wide range of implants based on various design philosophies are available on the market [26,38–40]. However, in vivo and in vitro biomechanical studies have shown that knee kinematics with contemporary TKA implants differs significantly from that of the normal healthy knee [12,41–43]. These kinematic abnormalities have been associated with decreased functional outcomes and patient dissatisfaction, with patients frequently reporting that their knees do not feel normal following knee replacement surgery [44–47]. Therefore, there is growing interest in the development of innovative TKA implants, which together with the advancements in surgical technologies could provide a more "normal" feeling and functioning knee, for an increasingly younger and more active patient population [48,49].

While surgical placement and ligament balancing directly influence knee kinematics, the key question from a design perspective is whether contemporary implants have a fundamental limitation that prevents restoration of normal kinematics even when optimal soft-tissue balancing and component placement are achieved. Contemporary implants are based on design philosophies that only partially incorporate elements of native knee biomechanics. For example, implants with single-radius femoral designs assume that the medial/lateral collateral ligament (MCL/LCL) tension is symmetric and isometric (constant through flexion) [38]. However, in the normal knee the MCL and LCL have been shown to have substantially different tension patterns that vary with flexion [6,50]. Implants with multi-radius femoral designs attempt to accurately match the native femoral anatomy, but mate these anatomic femoral designs with nonanatomic tibial articular surfaces [39]. Other implants, such as gender-specific and high-flexion TKA were developed to match native knee size better and to increase contact area in deep flexion, respectively [40,51,52]. However, these implants retain the tibial articular geometry of prior conventional designs and have not been shown to provide improved knee function relative to conventional implants [51–54]. Furthermore, while contemporary designs incorporate some aspects of normal knee anatomy, normal knee kinematics is not directly used in the design process. This has resulted in an inefficient and iterative approach to implant design that has been unsuccessful in restoring normal knee kinematics post-TKA. If the ultimate objective is to restore normal knee kinematics, it is logical to utilize this information directly in the design process to achieve compatibility with normal knee motion.

With modern imaging techniques, such as magnetic resonance imaging (MRI) and fluoroscopy, we now have very accurate knowledge of the three-dimensional (3D) in vivo knee kinematics through the full range of knee flexion [3,10,11,16,17,55]. To address the kinematic limitations of contemporary TKA implants, we developed a novel design process that directly utilizes 3D anatomy and in vivo kinematics of normal knees to reverse engineer “biomimetic” implant articular surfaces. This methodology allows for hand-in-hand design of femoral and tibial articular surfaces, takes into consideration component orientation relative to native anatomy, and ensures compatibility of the articular surfaces with normal in vivo kinematics and ligament tension patterns.

In this study, we describe the biomimetic design process and evaluate the hypotheses that (1) tibial articular surfaces of conventional implants are fundamentally incompatible with normal knee motion, and (2) the anatomic geometry of the biomimetic surface contributes directly to restoration of normal knee kinematics. To evaluate the first hypothesis we compared the tibial articular geometry of a variety of contemporary implants to the biomimetic articular surface and the native anatomy. To evaluate the second hypothesis we tested the effect of altering the biomimetic articular geometry on simulated deep knee bend kinematics.

2.4.2 Materials and Methods

2.4.2.1 Overview of Biomimetic Design Process

The overall concept involves moving a TKA femoral component in virtual space along in vivo kinematics pathway of healthy knees to carve out a biomimetic tibial articular surface compatible with the normal knee motion. Since the tibiofemoral motion used in this process is that of normal knees, the underlying soft-tissue tension may also be considered as “normal” or “ideal.” Therefore, if the articular geometry of a contemporary implant differs from such biomimetic geometry, it could conflict with normal knee motion. For example, if the contemporary implant articular surface is proud relative the biomimetic surface it could increase soft-tissue tension and constrain or prevent femoral motion.

2.4.2.2 Capturing In Vivo Kinematics during Full Range of Knee Flexion

A total of 40 subjects (24 males and 16 females) were recruited following approval by our institute review board (IRB), and informed consent was obtained from all subjects. Only one knee from each subject was studied and the choice of side was made randomly (22 right, 18 left). There was no significant difference in the age or body mass index (BMI) of the male and female subjects (age: males = 30.6 ± 10.2 years vs. females = 28.9 ± 9.1 years, $p = 0.606$; BMI: males = 25.8 ± 2.9 vs. females = 22.6 ± 7.5, $p = 0.69$). Clinical evaluation and MRI were used to confirm absence of ligamentous instability, flexion contracture, sagittal or axial limb deformities, soft-tissue injuries, osteoarthritis or other knee pathology. MRI combined with biplanar fluoroscopy was used to measure in vivo knee kinematics during a lunge activity as described in several previous studies [12,55].

2.4.2.3 Biomimetic Design Process

The combined MRI and biplanar fluoroscopy technique provided a 3D representation of each subject's knee at discrete flexion angles from full extension to maximum flexion. The individual bone and cartilage models of femur and tibia were aligned and scaled to maintain individual shapes, and subsequently averaged to create an average knee model. The 3D kinematics data were normalized for knee size and averaged to determine the average normal knee kinematics. A multi-radius femoral component was mounted on the average femur following standard surgical protocol. A tibial template in the form of a rectangular box was mounted on the tibia with 5 degree posterior tibial slope in the sagittal plane. The femoral component was then moved in 3D space through average normal knee kinematics from -5 degree flexion to 150 degree flexion in 70 increments. At each increment, corresponding material from the tibial template was removed via a Boolean subtraction operation to "carve" out an articular surface compatible with the kinematic pathway of the femur (**Figure 2-6**). The raw carved geometry was simplified and parameterized to form the final biomimetic articular surface.

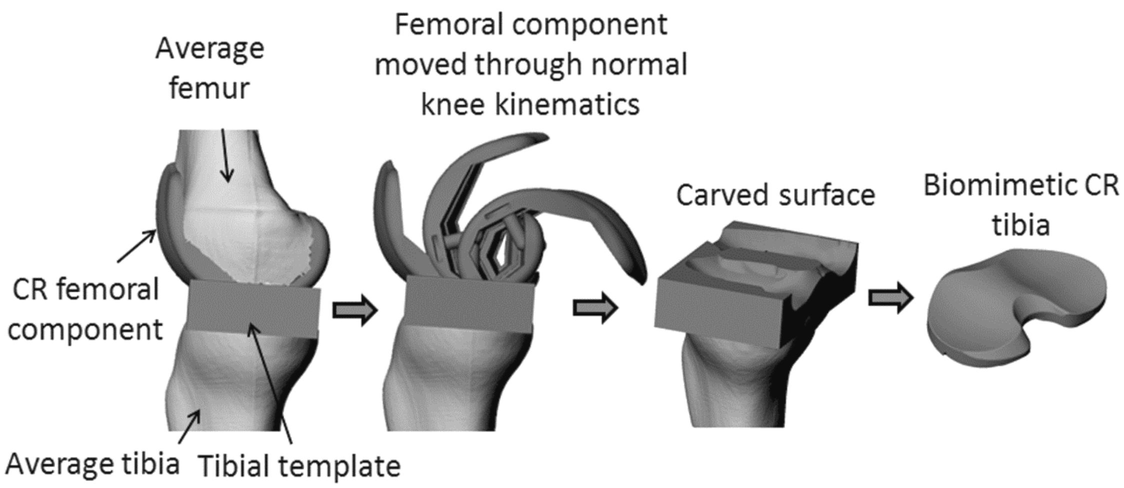

Figure 2-6: *Design process used to generate biomimetic tibial articular surface by mounting TKA femoral component on average normal knee and moving it though the average normal knee kinematics to carve the compatible "biomimetic" tibial surface.*

2.4.2.4 Geometric Comparisons to Contemporary Implants

The sagittal plane geometry of the biomimetic tibia was compared with that of the average native tibia, and four contemporary CR tibias (NexGen CR, Zimmer Inc., Warsaw, IN; Vanguard CR, Biomet Inc., Warsaw, IN; Triathlon CR, Stryker Corp., Kalamazoo, MI; Sigma CR, DePuy-Synthes, Warsaw, IN). The contemporary implants were mounted as per manufacturer recommendations to restore the native joint line, with 7 degree posterior tibial slope for NexGen CR, and 3 degree posterior tibial slope for Vanguard CR, Triathlon CR, and Sigma CR.

2.4.2.5 Deep Knee Bend Kinematics Simulations

LifeModeler KneeSIM (San Clemente, CA) was used to simulate deep knee bend kinematics of the biomimetic articular surface with anterior and posterior cruciate retention (biomimetic BCR), and with posterior cruciate retention alone (biomimetic CR) [56–58]. Further, these kinematics were compared with that of a symmetric and an asymmetric articular surface with posterior cruciate retention (symmetric CR, asymmetric CR; **Figure 2-7**). All articular surfaces had the same medial profile, but differed in the geometry of the lateral compartment. The biomimetic surface had a convex lateral profile, the asymmetric surface had a flat lateral profile, and the symmetric surface had a dished lateral profile matching the medial side. All surfaces articulated with the same femoral component.

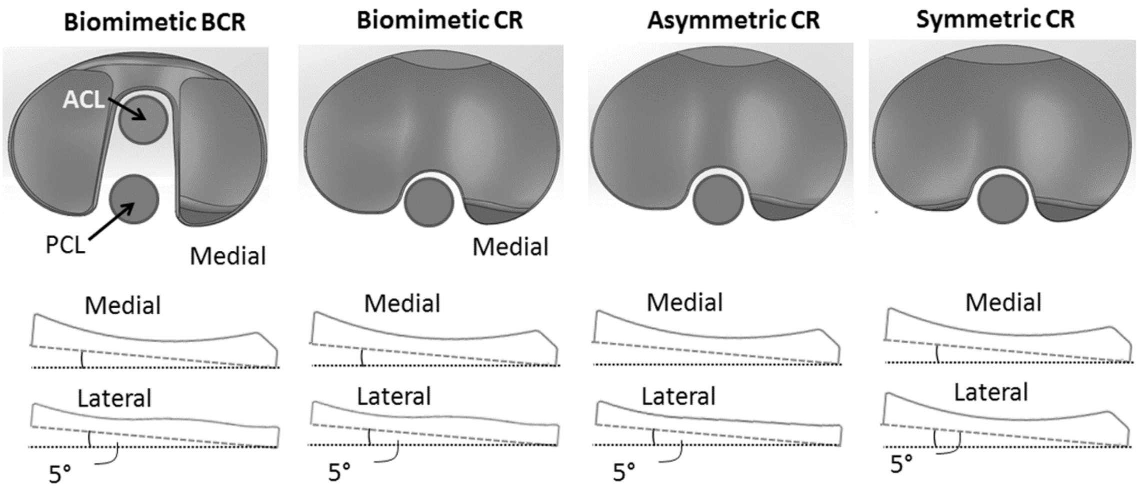

Figure 2-7: *Biomimetic BCR, biomimetic CR, asymmetric CR, and symmetric CR implants evaluated in LifeModeler KneeSIM (San Clemente, CA) software.*

In the present study, anteroposterior (AP) motion of the medial and lateral femoral condyle centers was measured relative to a tibial origin at the center of the tibial insert. The implants were mounted on the average knee model created from the MRI of the 40 healthy knees. The tibial implants were placed at 5 degree posterior slope. The MCL and LCL, posterior cruciate ligament (PCL), quadriceps mechanism, hamstrings, and the overall capsular tension were modeled. The soft-tissue insertions were obtained from the MRI-based average knee model, and tissue mechanical properties were obtained from the literature [59–62]. All ligaments were modeled as nonlinear springs. The MCL was modeled with two bundles and other ligaments (LCL, PCL) were modeled with one bundle. The quadriceps angle was set to 14 degrees based on average literature values [63], and wrapping of quadriceps tendon around the femoral components was modeled.

2.4.3 Results

2.4.3.1 In Vivo Motion of Normal Knees Used in Biomimetic Design Process

In the average normal knee, the medial femoral condyle showed appreciable AP motion, although it was substantially less than the motion of the lateral femoral condyle (7.4 mm medial vs. 19.8 mm lateral, **Figure 2-8**). Between 0 and 70 degrees flexion, the femur pivoted about a center located near the eminence of the medial tibial plateau. Above 70 degree flexion, the pivot center shifted medial beyond the medial edge of the tibia resulting in parallel motion of medial and lateral condyles. When considering the full range of knee motion, the pivot center was located approximately 16 mm medial to the medial plateau edge.

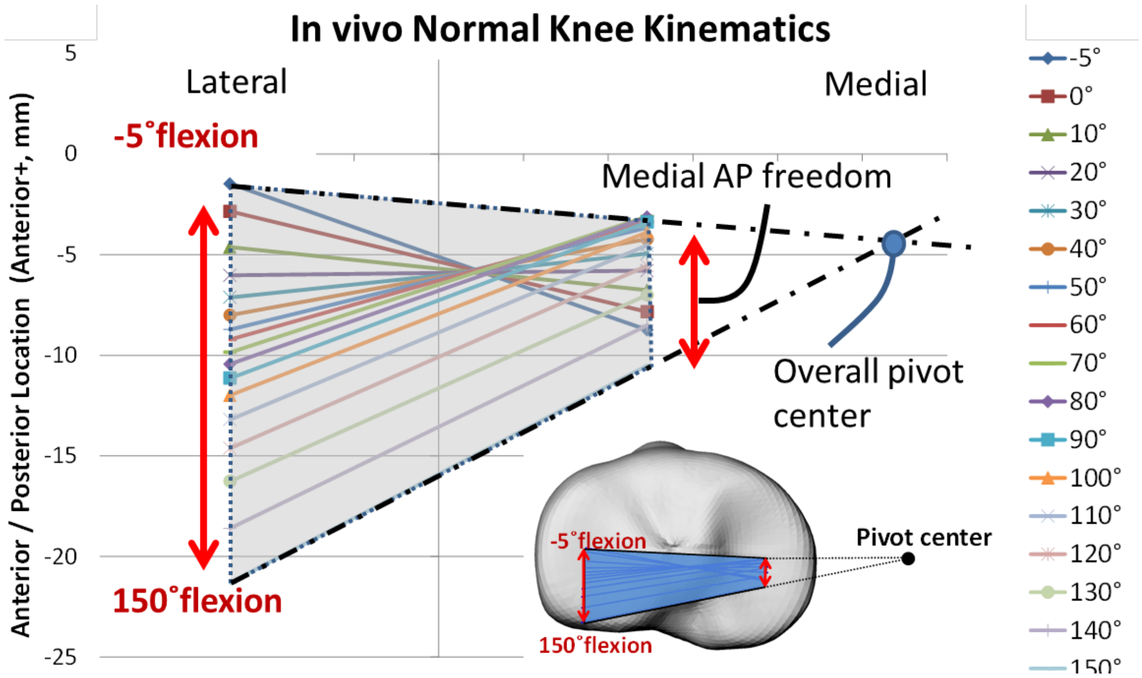

Figure 2-8: *Average in vivo kinematics of 40 healthy knees during single leg bend captured using biplanar fluoroscopy and MRI.*

2.4.3.2 Biomimetic versus Contemporary Implant Articular Geometry

The biomimetic tibia had a moderately dished medial plateau and a convex lateral plateau similar to the native tibia, with anterior and posterior lips analogous to the native menisci (**Figure 2-9**). The anterior and posterior lips were carved by the femoral component at its fully extended and flexed position, respectively. In contrast, while the medial geometries of NexGen CR and Triathlon CR tibias were similar to the biomimetic tibia, the lateral geometries were significantly different (**Figure 2-9A, B**). The high anterior lip on the lateral side of NexGen CR and Triathlon CR tibias (3 mm proud relative to biomimetic surface) conflicted with anterior location of the lateral femoral condyle in extension. The high posterior lip on the lateral side of NexGen CR and Triathlon CR tibias (~2 mm proud) conflicted with posterior rollback of the lateral femoral condyle in flexion. On the medial side, the Vanguard CR tibia had an anterior lip height similar to that of the biomimetic CR, but the posterior lip height was minimal (**Figure 2-9C**). On the lateral side, the Vanguard CR tibia had a higher anterior lip (~4 mm proud), which conflicted with anterior location of the lateral femoral condyle in extension. Sigma CR differed significantly from the biomimetic surface both medially and laterally (**Figure 2-9D**). On the medial side Sigma CR was proud of the biomimetic surface both anteriorly (~1.5 mm) and posteriorly (~1.8 mm) indicating higher level of AP constraint. On the lateral side, Sigma CR was again proud of the biomimetic surface both anteriorly (~4mm) and posteriorly (~3 mm) leading to conflict with anterior femoral location in extension and posterior rollback in flexion.

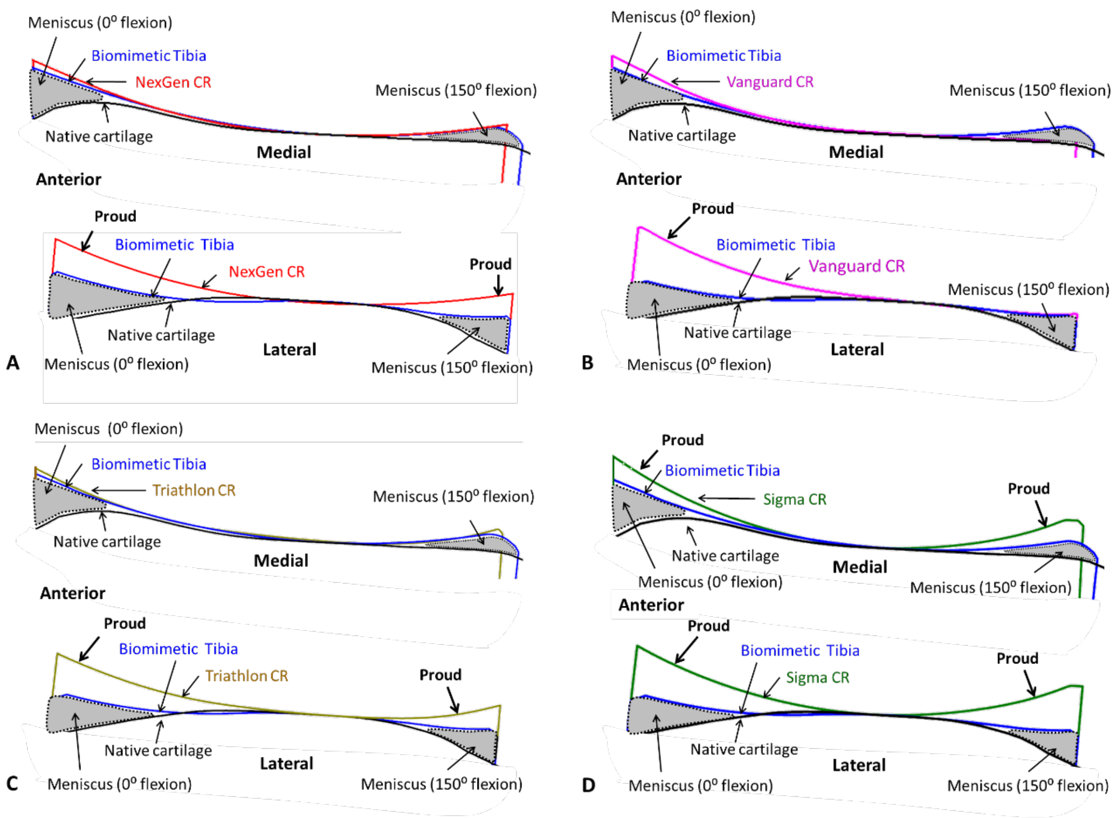

Figure 2-9: *Geometric comparison of the biomimetic and native tibial anatomy versus (A) NexGen CR (Zimmer Inc., Warsaw, IN), (B) Vanguard CR (Biomet Inc., Warsaw, IN), (C) Triathlon CR (Stryker Corp., Kalamazoo, MI), and (D) Sigma CR (DePuy-Synthes, Warsaw, IN) tibias.*

2.4.3.3 Effect of Modifying Biomimetic Geometry on Knee Kinematics

During the simulated deep knee bend, both biomimetic BCR and biomimetic CR showed overall medial pivot motion with greater rollback of the lateral than medial femoral condyle (biomimetic BCR: 8.9 mm medial, 15.0 mm lateral; biomimetic CR: 6.4 mm medial, 11.4 mm lateral, **Figure 2-10**). However, absence of the ACL in biomimetic CR leads to posterior shift of the femoral condyles in extension. The asymmetric CR also showed medial pivot motion, but to a lesser extent (6.6 mm medial condyle vs. 9 mm lateral condyle, **Figure 2-10**). In particular, relative to the biomimetic CR, the femur shifted slightly posterior in extension, rollback of lateral femoral condyle was reduced, and the medial femoral condyle showed slight anterior sliding from 0 to 60 degrees flexion. The symmetric CR showed no medial pivot (7.7 mm medial condyle vs. 6.2 mm lateral condyle, **Figure 2-10**). Relative to the biomimetic CR, the femur was shifted posteriorly in extension, the rollback of lateral femoral condyle was significantly reduced, and both medial and lateral femoral condyle showed anterior sliding from 0 to 60 degrees flexion.

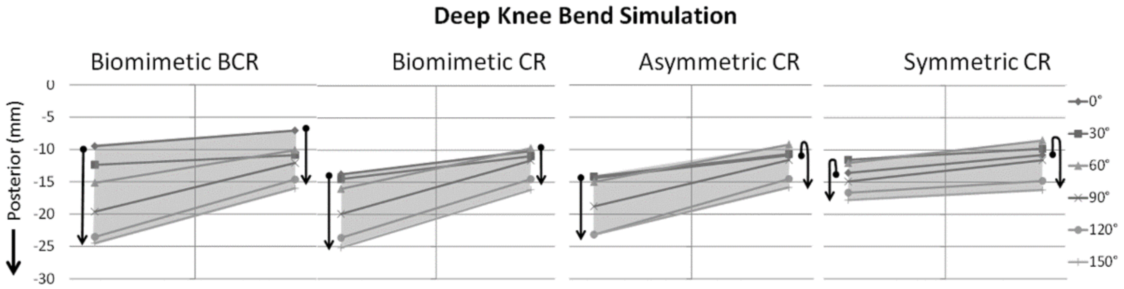

Figure 2-10: *Simulated deep knee bend kinematics of biomimetic BCR (ACL and PCL retaining), biomimetic CR (PCL retaining), asymmetric CR, and symmetric CR. All articular surfaces have the same medial compartment geometry but differ in geometry of the lateral compartment. ACL, anterior cruciate ligament; PCL, posterior cruciate ligament.*

2.4.4 Discussion

Due to the growing utilization of TKA, a wide range of implant designs have become available on the market today [26,38–40]. However, these designs have had limited success in restoration of normal knee feel and function, in large part due to their failure to incorporate important aspects of normal knee biomechanics. In this article, we described a novel approach to design “biomimetic” articular surfaces directly from in vivo kinematics of healthy knees. Such biomimetic surfaces are inherently compatible with normal knee kinematics and soft-tissue envelope. The geometric comparisons of the biomimetic surface to contemporary designs showed that articular surfaces of contemporary implants are fundamentally incompatible with normal knee motion. Further, kinematic simulations showed that the anatomic geometry of the biomimetic surface directly contributes to restoration of normal knee kinematics.

The geometric comparison of contemporary CR tibias to the biomimetic surface and native anatomy showed that all contemporary CR tibias (NexGen CR, Vanguard CR, Triathlon CR, and Sigma CR) conflicted with normal knee motion and anatomy. On the lateral side, all contemporary implants had high anterior lips, which conflicted with anterior location of lateral femoral condyle in extension. NexGen CR, Triathlon CR, and Sigma CR implants also had a prominent posterior lip on the lateral side that conflicted with lateral condyle rollback in flexion. Vanguard CR had minimal posterior lip on the medial side, which could lead to insufficient AP constraint of the medial femoral condyle. On the other hand, Sigma CR had prominent anterior and posterior lip on the medial side, which could lead to excessive AP constraint of the medial femoral condyle. These geometric conflicts are corroborated by prior in vivo and in vitro studies [12,64–68]. For example, Yue et al noted paradoxical anterior sliding from 0 to 45 degrees flexion, reduced femoral rollback, and significant reduction in tibial internal rotation in patients with NexGen CR-flex implant compared with normal subjects [12]. Bertin et al observed minimal axial rotation and limited posterior translation of medial and lateral condyles in patients with NexGen CR implant [65]. Fiacchi et al reported greater anterior translation of medial than lateral condyle during a chair activity for patients with Triathlon CR (5 mm medial, 2.5 mm lateral) [66]. Shimizu et al reported anterior translation of both medial and lateral condyle with greater translation of medial condyle (6.3 mm medial vs. 4 mm lateral) in knees with Triathlon CR implant [68]. Delport et al reported paradoxical anterior femoral slide, and minimal and symmetric medial/lateral condyle rollback in patients with Sigma CR implant [69]. Varadarajan et al showed absence of medial pivot in both Vanguard CR and NexGen CR, reduced femoral rollback in NexGen CR, and increased AP motion of medial condyle in Vanguard CR, during a simulated deep knee bend [64]. Such kinematic conflicts reflect fundamental design limitation of contemporary implants, which cannot be addressed via optimization of soft-tissue balancing or component placement during surgery.

The kinematic simulations in the present study confirmed that the specific medial and lateral geometry of the biomimetic articular surface are together responsible for the resto-ration of normal medial pivot kinematics. In particular, changing the convex geometry of the lateral compartment in the biomimetic CR to a flat geometry in the asymmetric CR leads to reduced medial pivot rotation and lateral femoral rollback, and changing the geometry to dished profile in the symmetric CR, leads to complete loss of medial pivot rotation, together with posterior femoral shift in extension, paradoxical anterior sliding in early flexion, and significant reduction in lateral condyle rollback.

The reverse engineering approach described herein to generate biomimetic surfaces utilized normal knee kinematics during a deep knee bend activity. This activity was selected because it covers the full range of knee motion under a loaded condition, as opposed to a limited range of flexion with other activities, such as chair-sit, stair climbing, walking, etc. Although the pivot center varied with knee flexion in the normal knees, overall it was located outside the medial tibial plateau (~16 mm medial to the tibial edge). This overall location of the pivot center in the native knee provided the medial femoral condyle with appreciable AP freedom, while allowing greater AP motion of the lateral femoral condyle. This is consistent with the in vivo kinematics of normal knees reported in other studies (**Figure 2-8**) [3]. Because the normal knee kinematics used to engineer the biomimetic articular surface included appreciable AP motion of the medial femoral condyle, the biomimetic implant had a moderately dished medial surface that avoided over constrain of medial condyle motion. The moderately dished medial compartment is advantageous for providing laxity to accommodate pivot center variations during activities of limited flexion, as well as to accommodate intrasubject variations in knee kinematics [3,17,41,70,71]. Such kinematic variations may not be accommodated by the strict ball-in-socket articulation of traditional "medial-pivot" implants.

Walker et al have described the design of tibial articular surfaces by moving the femoral component through in vitro kinematics of the native knee, and by moving the femoral component according to equations describing the laxity and stability of the natural knee [72,73]. However, the kinematics and stability data used to generate the designs were based on in vitro testing of cadaver knees under simplified loading conditions that may not represent in vivo motion of the knee joint. In addition, these prior studies incorporated motion of femur only in the transverse plane of the tibia, and consequently did not capture the anatomic convexity of the lateral tibial plateau in the sagittal plane [72,73].

There are several limitations to the current study. Implant kinematics were evaluated by using computational simulations, which may not fully represent in vivo function. Further, the simulations were conducted only for an average knee model, which may not account for patient-specific factors. Nonetheless, virtual simulations provide a cost- and time-effective method for side-by-side comparison of multiple implants. The KneeSIM simulation tool in particular has been used in several previous studies and validated via comparisons to in vivo data [57,58]. The present study also improved upon the basic KneeSIM setup by utilizing soft-tissue insertion locations from MRI of healthy knees rather than default values provided within the software. Future studies should include simulations of other activities, as well as kinematic evaluations in cadaver specimens.

While the biomimetic articular surface was designed from kinematics of healthy knees with an intact ACL, this study largely focused on ACL sacrificing CR implants. This was because the vast majority of TKA cases are done with ACL-sacrificing implants, and therefore we wanted to evaluate the benefit of such biomimetic surfaces for these devices. The kinematic results show that even in the absence of the ACL the biomimetic surface provides more normal kinematics than conventional symmetric and asymmetric CR designs. In a prior study Zumbrunn et al showed that ACL-retaining implants with biomimetic surfaces provide more normal knee kinematics than contemporary ACL-retaining implants with symmetric nonanatomic geometries [74]. This shows that bio-mimetic articular surfaces can significantly improve kinematic performance of both ACL-retaining and ACL-sacrificing implants.

In the current study, we discussed the biomimetic design approach primarily in context of the tibial articular surface design. However, the biomimetic process can also be applied to design a femoral articular surface since the geometry of the carved tibia depends on the geometry of the femoral component.

2.4.5 Conclusion

In conclusion, in this article we described how in vivo kinematics of healthy knees can be directly used to reverse engineer biomimetic articular surfaces compatible with normal knee motion. For the first time, we have a comprehensive approach to designing TKA implants by (1) ac-counting for normal knee anatomy as well as kinematics,(2) allowing hand-in-hand design of femoral and tibial articular surfaces, (3) allowing design of articular surfaces in accordance with their positioning in standard surgical practice. Biomimetic implants obtained through this design process may help us attain the long sought after goal of a normal feeling knee post-TKA. This may prove to be a new standard of care especially for the high-demand active and younger patient population.

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3 Regaining Native Knee Kinematics following Joint Arthroplasty: A Novel Biomimetic Design with ACL and PCL Preservation

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Regaining Native Knee Kinematics Following Joint Arthroplasty: A Novel Biomimetic Design with ACL and PCL Preservation
J Arthroplasty, Dec 2015; 30(12), 2143-8
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Lack of ACL and non-anatomic articular surfaces in contemporary total knee implants result in kinematic abnormalities. We hypothesized that such abnormalities may be addressed with a biomimetic bi-cruciate retaining (BCR) design having anatomical articular surfaces. We used dynamic computer simulations to compare kinematics among the biomimetic BCR, a contemporary BCR and cruciate-retaining implant for activities of daily living. During simulated deep knee bend, chair-sit and walking, the biomimetic BCR implant showed activity dependent kinematics similar to healthy knees in vivo. Restoring native knee geometry together with ACL preservation provided these kinematic improvements over contemporary ACL-preserving and ACL-sacrificing implants. Further clinical studies are required to determine if such biomimetic implants can result in more normal feeling knees and improve quality of life for active patients.

3.1 Introduction

In the native knee, the anterior- and posterior cruciate ligaments (ACL and PCL) play a major role in joint stability and kinematics throughout the range of motion (ROM), [1,2]. The native ACL is under tension in extension contributing to the so-called “screw-home" mechanism that is associated with anterior femoral location and internal femoral rotation at low knee flexion angles. In mid-flexion, the ACL provides anteroposterior [3] stability in conjunction with the PCL, while at higher flexion the ACL is relaxed and the PCL is responsible for posterior femoral rollback [1,2,4].

Significant portion of patients undergoing total knee arthroplasty (TKA) possess a functional ACL [5]. While importance of ACL in normal joint feel and function is well recognized, the vast majority of TKA procedures involve resection of the ACL. In contrast to ACL sacrificing implants, bi-cruciate retaining (BCR) and bi-unicompartmental procedures (medial and lateral unicompartmental knee arthroplasty) for multi-compartmental joint replacement preserve the ACL. These procedures have been performed since the 1970s and have not gained popularity primarily due to the challenging nature of the surgery requiring balancing of the collateral ligaments as well as both ACL and PCL, together with limited joint exposure [6]. Further, there were concerns regarding strength of the tibial baseplate design (narrow metal bridge connecting the medial and lateral compartments), wear of polyethylene components and fracture of the bony tibial eminence [7,8]. With the availability of next generation materials and advancements in surgical tools such as navigation, robotics and patient specific instrumentation (PSI), there is resurgence in interest for BCR implants.

While contemporary BCR implants provide more natural kinematics due to the preservation of ACL, they do not fully restore normal knee kinematics. Stiehl et al. reported improved AP kinematics with a more anterior femoral location in extension and absence of paradoxical anterior sliding with greater posterior translation of the lateral condyle in knees reconstructed by retaining both cruciate ligaments in comparison to when the ACL was sacrificed. However, the net amount of femoral rollback was very similar between the medial and lateral sides with the contemporary BCR implant; and the medial pivot motion of native knees was not reproduced [9]. The results of Banks et al. also showed that while ACL preservation in bi-unicompartmental procedures was able to address posterior femoral subluxation seen in ACL sacrificing implants, the posterior motion of medial and lateral femoral condyles was symmetric resulting in minimal axial rotation. In contrast, unicondylar knees that replaced only the medial compartment and retained the native lateral compartment had greater axial rotation, resulting in more medial pivot motion as observed in native knees [10].

BCR implants preserve the ACL but like contemporary cruciate retaining (CR) implants, they do not restore the native tibial anatomy [11,12]. In the native knee in addition to the ACL, the anatomy of the tibia determines the asymmetric AP motion of the medial and lateral femoral condyles. The native tibial geometry consists of a shallow medial tibial plateau and a convex lateral side, which makes the knee anatomy asymmetric [13, 14]. Further, the medial and lateral menisci provide differential medial and lateral constraint (more mobile lateral meniscus) contributing to the differential AP kinematics of medial and lateral femoral condyle through the range of motion (ROM) [13,15].

Knee kinematics following TKA surgery is influenced by various factors including implant design, surgical- and patient factors. For this research we focused on implant design, particularly on the geometry of the articular surfaces together with cruciate retention. We hypothesized that a BCR implant, designed with a biomimetic tibial articular surface mimicking native knee geometry would better restore normal knee kinematics. We tested this hypothesis by using computational simulations to evaluate kinematics during a variety of daily activities such as deep knee bend, chair-sit and normal gait. Additionally, we investigated the wear performance of the biomimetic BCR design using a knee simulator, to determine whether adequate wear performance could be obtained with such anatomic surfaces. The design methodology and results of the wear study are detailed in Appendix A-1.

3.2 Materials and Methods

3.2.1 Biomimetic Implant Design and Rationale

The biomimetic articular surface was designed by using average in vivo kinematics and anatomy of normal knees. In vivo knee kinematics of 40 healthy subjects was collected using bi-planar fluoroscopy and magnetic resonance imaging (MRI). Data of 24 males (age = 30.6 ± 10.2 years; BMI = 25.8 ± 2.9) and 16 females (age = 28.9 ± 9.1

years; BMI = 22.6 ± 7.5) from previously conducted IRB approved studies was obtained to create average bone and cartilage models (**Figure 3-1**) together with an average kinematic dataset [17].

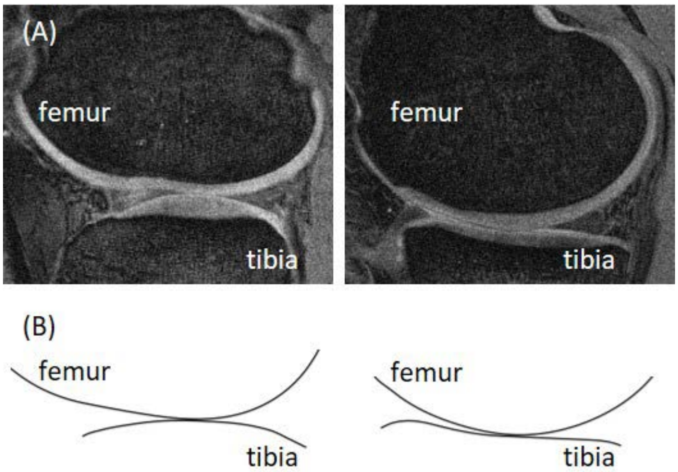

Figure 3-1: *Sagittal cross-section through the center of the native lateral (left) and medial (right) tibial plateau for (A) single MRI scan and (B) average native knee model showing the convex lateral and concave medial asymmetry.*

A femoral component was mounted on the average knee model following standard surgical technique and moved through the average normal tibiofemoral kinematics to create the tibial articular surface by removing (or carving) material from a tibial template [18]. By using this procedure the implant design also intended to restore the native joint constraint and ensure compatibility with normal ligament function (**Figure 3-2**).

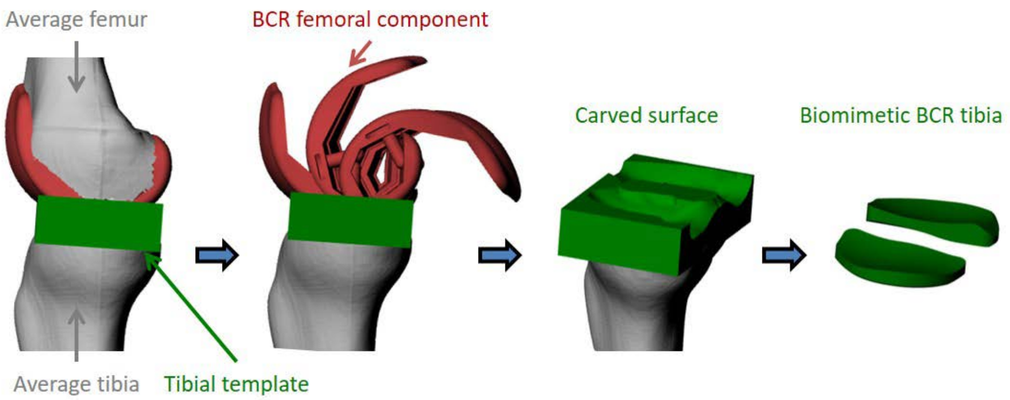

Figure 3-2: *Tibial carving process to reverse engineer the novel biomimetic BCR implant based on average in vivo kinematics.*

3.2.2 Dynamic Activity Simulations

A previously established software tool based on Oxford-rig type setup (KneeSIM; LifeModeler, San Clemente, CA) was used to analyze implant performance [19-21]. Like in an Oxford-rig, a vertical load is applied at the hip joint and the quadriceps muscle is used to control the knee flexion angle. All six degrees of freedom are allowed at the knee joint with femoral flexion and SI motion allowed at the hip joint, and tibial flexion, IE, VV, and ML motions allowed via degrees of freedom provided at the ankle joint.

The loading conditions built-in within KneeSIM software vary across different activities, for example during deep knee bend a constant load of 180 N is applied to the proximal femur over a 155° range of knee flexion. Similarly for chair-sit the same vertical load is applied in combination with a variable anterior-posterior [3] load at the ankle joint. During walking simulation the vertical load varies throughout the gait cycle reaching a maximum of 1100 N at heel strike which is combined with a time varying adduction/abduction moment and tibial IE torque profile. Both quadriceps and hamstring muscles were modeled with a 180 N “relaxed tension” at full extension.

The basic KneeSIM model was customized by including the average in vivo anatomical landmarks from the dataset of 40 healthy subjects. The insertion locations for medial/lateral collateral ligaments (MCL, LCL) and cruciate ligaments (ACL, PCL) as well as patellar tendon were extracted from MRI and the average bone models. Quadriceps insertions were chosen such that the Q-angle measured 14° based on average literature values [22-24] and wrapping of the quadriceps tendon around the femoral component was modeled. Average stiffness values reported in the literature were used to define ligament properties in KneeSIM (**Table 3-1**), [25-28]. All ligaments and capsular compression of the tibiofemoral and patellofemoral joints were modeled as non-linear, tension-only springs. While there was a preload applied to the collateral ligaments (as happens during surgery), the ACL was modeled with tension at full extension, and the PCL with a slack at the neutral starting position (**Table 3-1**), [4,29].

Table 3-1: Soft-tissue material properties with initial slack (+) / tension (-) or preload (+) used for the knee model setup in KneeSIM

Soft Tissue	Material Properties [N/mm]	Initial Preload / Slack
ACL	184	-0.79 mm slack
PCL	239.3	3.51 mm slack
MCL	92.7	44.5 N preload
LCL	86.9	44.5 N preload
Capsule (tibiofemoral)	6.1	89 N preload
Capsule (patellofemoral)	1.8	44.5 N preload

A contemporary CR (NexGen CR; Zimmer, Warsaw, IN), a symmetric BCR (TKO BCR; Biopro, Port Huron, MI), and a bi-uni system (MCK UKA; MAKO Surgical, Fort Lauderdale, FL) were compared to the biomimetic BCR design. The NexGen CR implant represented a typical contemporary symmetric TKA with concave medial and lateral tibial articulating surfaces. The TKO BCR device consists of a symmetric shallow dished medial and lateral tibia, while the MCK UKA components have a flat profile (**Figure 3-3**). All components were mounted onto the average bone model perpendicular to the mechanical axis following standard surgical technique. The tibial components were placed at 5° posterior slope for all ACL retaining devices and 7° for the CR implant. Various activities were simulated in KneeSIM including deep knee bend (DKB), sitting on a chair and walking. For DKB the knee was flexed to the highest flexion angle of 155°. Chair-sit (105° flexion) and walking (65° flexion) were also included in this analysis to evaluate the TKA design for an envelope of daily activities with different ROM.

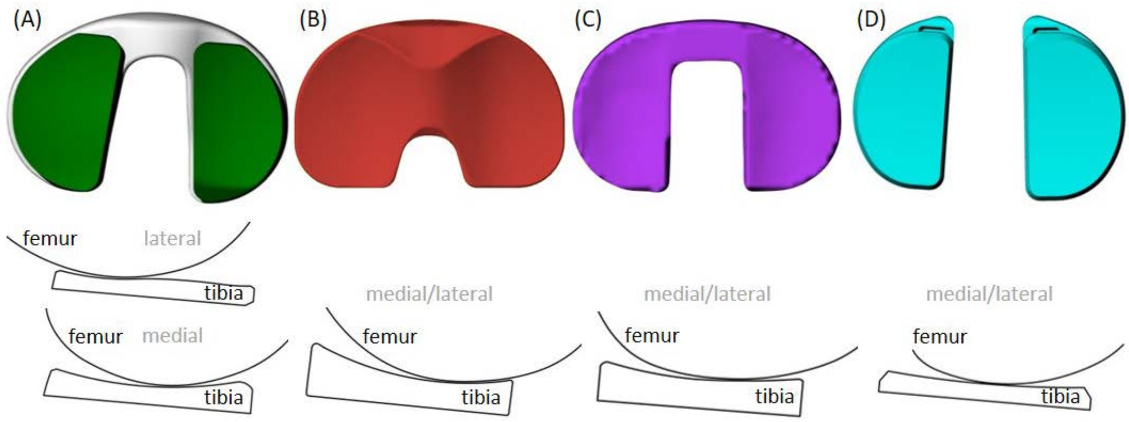

Figure 3-3: *3D model and sagittal cross-section through the center of the lateral and medial tibial plateau for (A) biomimetic BCR design, (B) symmetric dished CR (Zimmer NexGen), (C) symmetric, shallow dished BCR (Biopro TKO) and (D) flat bi-uni system (MAKO MCK).*

Tibiofemoral motion was quantified as motion of medial and lateral femoral condyle centers (flexion facet centers, FFC) relative to tibia for different implant design comparison. In vivo knee kinematics of healthy subjects and patients with bi-uni implant systems from published literature served as reference [10,13,15].

3.3 Results

3.3.1 Biomimetic Implant Design

The reverse engineering process using in vivo kinematics of healthy knees [18] resulted in an asymmetric tibial articular surface. The sagittal cross-section through the medial tibial insert had a concave geometry similar to the native medial tibial cartilage including a shallow curvature to compensate for the stability provided by the missing meniscus. The lateral insert of the biomimetic implant had a convex sagittal cross-section matching the lateral plateau of the native cartilage, and included minimal anterior and posterior lips to compensate for the missing meniscus. The anterior and posterior lips/curvatures result from the femoral component position at the extremes of knee motion in extension (anterior lip) and full flexion (posterior lip). Overall the articular surface of the biomimetic tibial component closely matched the asymmetric geometry of the native knee (**Figure 3-3**).

3.3.2 Deep Knee Bend and Chair-Sit Simulations

During simulated deep knee bend, the ACL sacrificing NexGen CR implant showed 12 mm of posterior femoral subluxation at full extension relative to the biomimetic BCR implant. With continuous knee flexion the femur slid 6 mm anteriorly relative to the tibia until 90° flexion. Beyond 90° flexion the NexGen CR implant showed symmetric rollback of both femoral condyles (5 mm).

Retention of the ACL in the symmetric TKO BCR implant lead to a more anterior location of the femur relative to the NexGen CR implant in extension (7 mm). With knee flexion, 4 mm of posterior rollback of the femoral condyles occurred, however, medial pivot rotation was not observed. Beyond 90° flexion no further rollback was achieved for the TKO BCR. Very similar motions were recorded for the bi-uni system, with 3 mm posterior shift relative to the biomimetic BCR implant, 4 mm rollback, and no observable medial pivot (**Figure 3-4**).

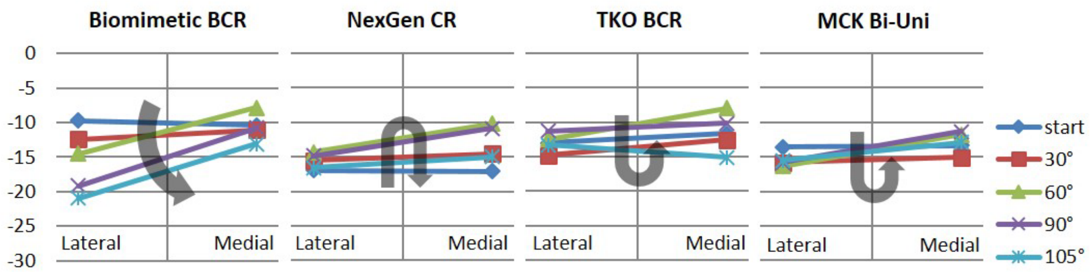

Figure 3-4: *Motion of medial and lateral femoral condyles relative to tibia of biomimetic BCR design, contemporary CR, contemporary BCR and bi-uni system for simulated deep knee bend.*

In contrast, the biomimetic BCR implant showed knee motion similar to that reported for healthy knees in vivo (**Figure 3-5**), [13]. At full extension the femur was located in the center portion of the tibia and with continuous knee flexion the femoral condyle centers showed posterior rollback with a greater rollback on the lateral side (16 mm lateral vs. 11 mm medial). Particularly until 90° flexion medial pivot rotation was observed due to greater lateral rollback, while above 90° flexion both condyles showed posterior motion through high flexion until 155° (**Figure 3-4**).

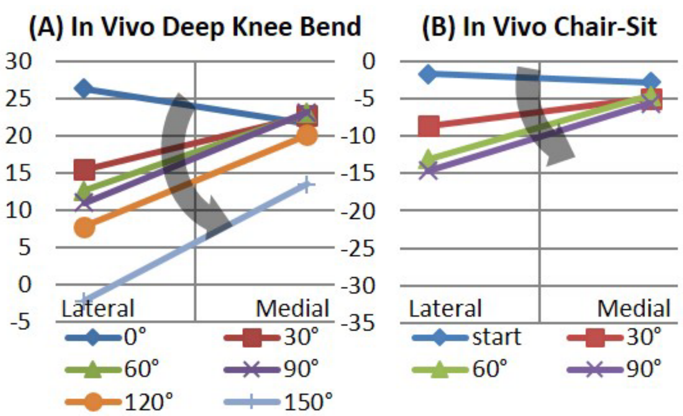

Figure 3-5: *Replotted kinematics of posterior motion (-)relative to tibia for native in vivo knees of (A) medial and lateral femoral condyles for deep knee bend [13], and (B) contact points for chair-sit [15].*

Another motion simulated in KneeSIM was chair-sit, which showed similar trends. Again, the biomimetic BCR implant showed kinematics similar to those reported for healthy knees in vivo (**Figure 3-5**), [15] including medial pivot rotation with 5 mm medial, 11 mm lateral rollback. All contemporary implants showed knee motion similar to the DKB activity. The ACL sacrificing design showed posterior femoral subluxation in extension (7 mm), followed by anterior femoral sliding (5 mm) and no medial pivot motion during chair-sit (**Figure 3-6**). While the contemporary ACL retaining solutions (TKO BCR, MCK bi-uni) did not show posterior subluxation and initial anterior sliding; neither did they achieve medial pivot rotation, showing minimal posterior rollback.

During both simulated activities the ACL was active in low flexion angles for all ACL retaining implants. In particular, the ACL was active between full extension and 26° to 42° depending on the activity and implant. The PCL was active in mid- to high flexion (between 56° to 78°, and full flexion) for all implants including the contemporary CR TKA.

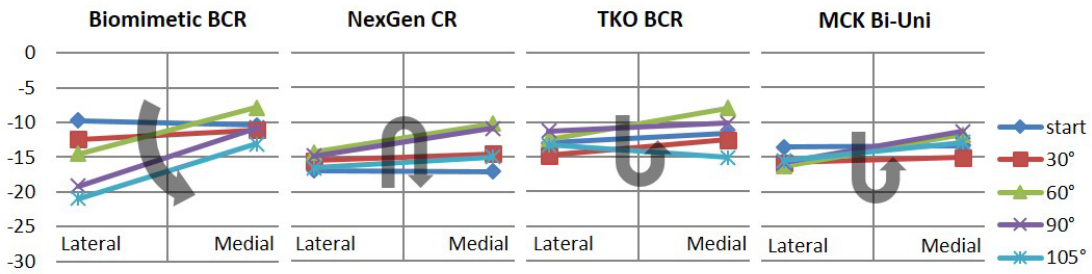

Figure 3-6: *Motion of medial and lateral femoral condyles relative to tibia of biomimetic BCR design, contemporary CR, contemporary BCR and bi-uni system for simulated chair-sit.*

3.3.3 Walking Simulation

Walking was the third activity analyzed in this study, which was simulated with a maximum flexion angle of 65°. Consistent with in vivo kinematics of native knees and knees of patients with bi-uni implants, during this low flexion activity the excursion of biomimetic BCR implant was smaller than during the other two activities. There was a smaller extent of anteroposterior motion, internal-external (IE) rotation and a more steady location of the femoral condyle centers relative to the tibia. The TKO BCR was located 3 mm more posterior and the bi-uni 7 mm more posterior compared to the biomimetic BCR (**Figure 3-7**). For the ACL sacrificing NexGen CR implant the femur was posteriorly subluxated in extension (10 mm) compared to the more natural location in the center of the tibia for the biomimetic design. Similar to the deep knee bend and chair-sit activities, the ACL sacrificing CR implant showed more anterior sliding (7 mm) of the femur with increasing knee flexion than all simulated ACL retaining implants and published in vivo kinematics of bi-uni knees during walking [10].

During walking, the ACL was active between full extension and 17° to 25° flexion for all ACL preserving implants. Thus the ACL guided joint motion over stance phase of the gait cycle. The PCL was not active during the stance phase of gait due to the low flexion angles (< 30°), but it was active over the swing phase.

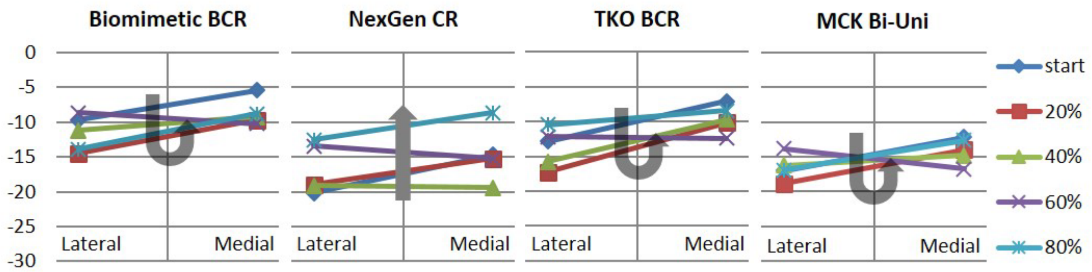

Figure 3-7: *Motion of medial and lateral femoral condyles relative to tibia of biomimetic BCR design, contemporary CR, contemporary BCR and bi-uni system for simulated walking.*

3.4 Discussion

Restoring native knee function following total knee arthroplasty is the ultimate goal of advanced knee implant designs. One step in this direction is to preserve the native ligaments in the knee joint, particularly the ACL which is resected with contemporary TKA implants [9,30,31]. In the native knee, ACL and asymmetric shape of the tibial articular surface together contribute to the controlled differential medial/lateral femoral rollback and activity dependent kinematics. The results of this simulation study confirmed the hypothesis that a biomimetic surface together with ACL preservation could more consistently restore normal activity dependent kinematics of the knee. Further, wear tests showed that such designs do not compromise wear performance relative to contemporary unicompartmental implants (**Appendix A-1**).

In the native knee the ACL tension keeps the lateral femoral condyle anteriorly in extension [13]. In mid-flexion both ACL and PCL are active, while at higher flexion angles the PCL is responsible for posterior rollback [4]. This was also seen in our simulations with the ACL function driving an anterior location of the femur in low knee flexion angles

(0° - 42°) and the PCL being responsible for femoral rollback in mid- to high flexion angles (53° - 155°). Resection of the ACL in contemporary TKA surgery causes abnormal posterior femoral subluxation in extension. As the knee goes into flexion the femur slides forward due to imbalance between soft-tissue and muscle forces [16,32]. High anterior lips in contemporary CR TKA are intended as a mechanism to prevent the femur from sliding anteriorly, which is caused by the abnormal initial posterior location in extension due to the missing ACL.

In the biomimetic BCR, the anatomic convexity of the lateral tibial articular geometry is restored, which, together with ACL preservation, allow for natural location of the femur in extension and flexion (**Figure 3-1** and **3-3**). In contemporary UKA, bi-uni and BCR TKA implants the natural asymmetry of the tibial articular surface, particularly the lateral convexity, is not restored. A flat or dished lateral tibial surface in these implants creates a constant or decreasing slope resulting in a posteriorly directed joint force opposing the anterior pull of the ACL. In contrast, a convex surface provides a leveled anterior portion, allowing anterior femoral location in extension, and a gradually increasing slope, encouraging posterior rollback with flexion. Specifically the biomimetic design allowed internal/external rotation and greater lateral rollback similar to native knees, which was inhibited in contemporary CR and BCR implants due to non-anatomic articular geometries. The biomimetic articular surface was generated by native knee kinematics and associated ligament function.

Kinematic analysis of the biomimetic implant in KneeSIM revealed more normal knee kinematics with the biomimetic design compared to contemporary ACL-retaining and ACL-sacrificing TKA. Particularly during deep knee bend and chair-sit activities, which capture a large knee ROM, significant differences were apparent between designs. In the NexGen CR implant, posterior subluxation and paradoxical anterior sliding of the femur in early flexion, followed by symmetric motion, was seen. This was due to the sacrificed ACL and a symmetric dished tibia with posteriorly located medial and lateral concavity low-points drawing the femoral location in equilibrium (**Figure 3-3**). These results from the computational simulations reported herein are consistent with in vivo kinematics found for the NexGen CR implant by Yue et al. [16]. The symmetric BCR and bi-uni implants avoided posterior subluxation and paradoxical sliding due to the preserved ACL. However, in these implants medial pivot motion and posterior femoral rollback was not restored due to the non-anatomic symmetric articular surfaces. These kinematic improvements of ACL preserving implants over ACL sacrificing implants are consistent with results observed in several in vivo studies [9,10,30,31]. Stiehl et al. reported absence of posterior subluxation and anterior femoral sliding in in BCR compared to CR implants in low flexion. However, they found no differences in IE rotations between BCR and CR implant [9]. Moro-oka et al. showed greater femoral posterior translation, and IE rotation in BCR implants compared to CR implants in high flexion activities. However, they noted that both IE rotation and lateral rollback seen in native knees were not restored even by BCR implants [31]. In the present study we found that the only implant showing motion similar to healthy knees in vivo during DKB and chair-sit was the biomimetic BCR design (**Figures 3-4** to **3-6**). The biomimetic BCR showed medial pivot motion and greater femoral rollback compared to any of the contemporary implants, due to the retention of ACL and the asymmetric medial/lateral articular surface design. This confirmed our hypothesis that ACL preservation together with an anatomic articular surface is required to restore native knee motion.

The most common daily activity is normal walking, which involves a relatively low knee flexion range. The pivot patterns during walking seem to be unclear, with various publications describing walking as either medial pivot motion, lateral pivot motion or with no defined center of IE rotation [30,31,33,34]. Nonetheless, analyzing the kinematics of this activity allowed us to verify whether the biomimetic design could accommodate an envelope of motion patterns across different activities without forcing individual knees to a certain kinematic constraint. Overall, all ACL preserving implants showed similar kinematics during walking, with the femur being more anteriorly located at full extension in contrast to the ACL sacrificing NexGen implant (**Figure 3-7**). The retention of the ACL also prevented paradoxical anterior sliding seen in the NexGen implant. These kinematic features of the ACL retaining implants during the simulated walking were consistent with those observed in patients with bi-uni and contemporary BCR implants [10,31].

Other implant designs aim to provide normal kinematic function post-TKA surgery via guided knee motion instead of ACL/PCL retention. For example, with a highly conforming medial and a more lax lateral tibia [35], or a shallow medial and convex lateral tibia together with ACL and PCL substitution via an anterior and posterior cam-post contact [14]. While these implants may provide kinematic improvements over conventional CR/PS designs, perhaps proprioceptive function of the retained cruciate ligaments may be an added benefit for ACL retaining implants. It may be debated whether restoration of normal native knee kinematics should be the goal for the osteoarthritic knee. However, studies have shown that while osteoarthritis affects knee kinematics, the kinematics of OA knees are still more similar to that of normal knees than after TKA implantation [16]. Therefore, we believe that it is an appropriate goal to try and restore normal knee motion.

This study has several limitations. For the simulations in KneeSIM, only an average knee model was used and we could not evaluate effect of patient specific factors such as variation in ligamentous properties. Though not a part of this study, we did investigate effect of variation in component placement on implant kinematics, particularly tibial component internal/external rotation. In general, while kinematics for all implant designs varied with component position, the characteristics motion patterns were maintained. This implies that the general conclusions of this study hold even if variation in component placement is considered. We also simulated the BCR implants with an inactive ACL (worst case) to evaluate the effect of impaired ACL function. For the biomimetic design, some of the kinematic benefit, in particular anterior location of femur in extension, was lost when the ACL was not active. However, even in absence of ACL function kinematic improvements such as medial pivot rotation were achieved with the biomimetic design. In contrast, conventional BCR implants without a functional ACL showed kinematic abnormalities similar to conventional CR implants (e.g. paradoxical anterior sliding). To further verify the kinematic benefits of the biomimetic BCR implant design, patient specific simulations should be conducted in the future.

Perhaps the most important limitation of this study is that we cannot fully predict how implants will perform in vivo based on simulation results. This is true even though KneeSIM has been validated against in vivo data and used extensively for purpose of implant design [19,21]. Therefore, in vitro studies using cadaver specimens and eventually in vivo studied should be conducted. Further, clinical studies will be essential to understanding both the contribution of implant design to improving knee kinematics relative to patient/surgical factors, as well as how such improvement relate to clinical and patient reported outcomes.

3.5 Conclusion

In conclusion, the results of this computational study showed that restoring the native geometry of the knee in TKA implants and preservation of the ACL may result in marked kinematic improvements over contemporary ACL preserving and ACL sacrificing implants. Further, clinical / in vivo studies are required to determine whether such biomimetic BCR designs could truly help achieve a more naturally functioning and normal feeling knee for patients following TKA surgery [36-38].

Acknowledgements

The work reported herein was supported by departmental grants at Massachusetts general Hospital and funding received from MAKO Surgical (Stryker).

We would like to thank Brad Micheli and Keith Wannomae from the Harris Orthopaedic Laboratory for their contributions with the wear test simulations.

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4 ACL Substitution May Improve Kinematics of PCL-Retaining Total Knee Arthroplasty

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ACL substitution may improve kinematics of PCL-retaining total knee arthroplasty
Knee Surg Sports Traumatol Arthrosc, 2016 Nov; Epub ahead of print
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Purpose One of the key factors responsible for altered kinematics and joint stability following contemporary total knee arthroplasty (TKA) is resection of the anterior cruciate ligament (ACL). However, ACL retention can present several technical challenges, and in some cases may not be viable due to an absent or nonfunctional ACL. Therefore, the goal of this research was to investigate whether substitution of the ACL through an anterior post mechanism could improve kinematic deficits of contemporary posterior cruciate ligament (PCL) retaining implants.

Methods Kinematic analysis of different implant types was done using KneeSIM, a previously established dynamic simulation tool. Walking, stair-ascent, chair-sit, and deep knee bend were simulated for an ACL-substituting (PCL-retaining) design, a bi-cruciate-retaining and ACL-sacrificing (PCL-retaining) implant, as well as the native knee. The motion of the femoral condyles relative to the tibia was recorded for kinematic comparisons.

Results The ACL-substituting and ACL-retaining implants provided similar kinematic improvements over the ACL-sacrificing implant, by reducing posterior femoral shift in extension and preventing paradoxical anterior sliding. During all simulated activities, the ACL-sacrificing implant showed between 7 and 8 mm of posterior shift in extension in contrast to the ACL-retaining implant and the ACL-substituting design, which showed overall kinematic trends similar to the native knee.

Conclusion The absence of ACL function has been linked to abnormal kinematics and joint stability in patients with contemporary TKA. ACL-substituting implants could be a valuable treatment option capable of overcoming the limitations of contemporary TKA, particularly when retaining the native ACL is not feasible or is challenging.

4.1 Introduction

In the native knee, anteroposterior stability is granted by the anterior cruciate ligament (ACL), primarily in early flexion and in conjunction with the posterior cruciate ligament (PCL) throughout knee motion. The ACL contributes to the so-called screw-home mechanism that is associated with anterior location of the femur on the tibia near full extension, while the PCL drives posterior femoral rollback in high flexion [1–4]. Hence, in the native knee, both ACL and PCL play a major role in joint stability and kinematics.

Current efforts to restore native knee function following total knee arthroplasty (TKA) aim to retain both ACL and PCL through the use of bi-cruciate-retaining (BCR) implants or bi-unicompartmental procedures. In vivo, in vitro (cadaver), and computational studies have shown that ACL preservation provides more normal kinematics than contemporary ACL-sacrificing TKA [5–9].

Several studies investigating TKA implants found the tibiofemoral contact to be shifted to the posterior portion of the tibia when the ACL was not present [10–12]. This is in contrast to studies investigating ACL-retaining implants [8,13]. In functional outcome studies, TKA patients with contemporary ACL-sacrificing implants have reported abnormal feeling knees after joint replacement, which may be linked to these kinematic impairments [14,15].

However, in spite of potential benefits of ACL retention, ACL-retaining total knee arthroplasty is currently not part of standard TKA practice. This is due to perceived technical difficulties in retaining and balancing both ACL and PCL, lack of availability of such implants, and clinical contraindications including the absence of a functional ACL at surgery. Patients undergoing TKA often present with an absent or nonfunctional ACL at the time of surgery due to the progression of arthritis or due to prior trauma.

Incidence of a functional ACL at the time of TKA surgery is reported to range from 25 to 86% of the patients [16,17]. Concerns have also been raised about the tibial baseplate design changes required to accommodate the ACL, specifically reduction in surface available for implant fixation and the strength of the tibial baseplate [18,19]. Further, these designs create a tibial bone island around the ACL attachment, which could fracture [20], particularly in the presence of osteoporotic bone or due to improper ligament balancing resulting in increased ACL tension [21].

The hypothesis of this study was that an ACL-substituting tibial implant designed with an anterior post mechanism to replace the ACL function while allowing retention of the PCL (ASCR: ACL-substituting, cruciate (PCL)-retaining) could improve the kinematics of contemporary cruciate-retaining (CR) designs. The primary purpose of such an ACL-substituting implant would be to locate the femur anteriorly in extension like in native knees, while allowing the PCL to guide knee motion at higher flexion angles. An implant incorporating this new concept of an ACL-substituting post that also allows for PCL retention may be of significant clinical value. Such an implant may satisfy surgeons desire to improve kinematic abnormalities of CR implants, without the challenges posed by attempting to retain the native ACL.

4.2 Materials and Methods

This hypothesis was tested by using dynamic computational simulations performed in KneeSIM software (LifeModeler, San Clemente, CA) to evaluate kinematics of implant designs that either retain (BCR), substitute (ASCR), or sacrifice the ACL (CR) in comparison with the native knee simulation.

KneeSIM is a previously validated software tool that mimics an oxford-type physical test set-up (**Figure 4-1**) commonly used to test/analyze kinematics of knee implant designs in cadaver specimens [22]. This software tool uses rigid body dynamics coupled with elastic foundation contact modelling to simulate knee mechanics and has been used by several researchers to analyze kinematics of different knee implant designs, effect of variation in component positioning, etc. [9,23–25]. In particular, Colwell et al. validated their computational model within KneeSIM using experimentally measured kinematic and kinetic data, and found major trends plotted as function of knee flexion angle to be similar between the computational and experimental results [23]. Magnetic resonance imaging (MRI) data from a previous IRB-approved study (2003P000337) was used to create average bone and cartilage models of tibia, femur, and patella, and identify average insertion locations for medial/lateral collateral ligaments (MCL/LCL), cruciate ligaments (ACL/PCL), and the patellar tendon [9]. The quadriceps angle was determined to be 14.0° based on the average literature values [26,27] and the proximal quadriceps insertion was chosen accordingly.

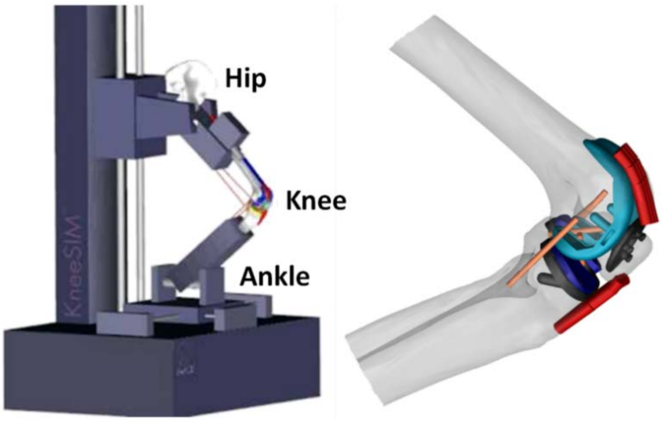

Figure 4-1: *Graphical visualization of the KneeSIM set-up modelling an oxford-type physical test including a detailed image of the knee joint*

The kinematics of an ACL-substituting implant (ASCR) was compared to that of the same tibial articular surface without a post but with an intact ACL (BCR). This allowed for a direct comparison of the kinematic function of the ACL-substituting post, and the modelled ACL, for a given femoral and tibial articular surface design (identical for all tested implants). The ACL-substituting design tested in this study included an anterior tibial post that substitutes for the native ACL by interacting with the anterior portion of the femoral intercondylar notch. This concept of replacing the native ACL function is analogous to the concept of replacing PCL function in posterior stabilized (PS) implants using a post–cam interaction. The ACL-substituting post is also designed to accommodate the intact PCL (**Figure 4-2**).

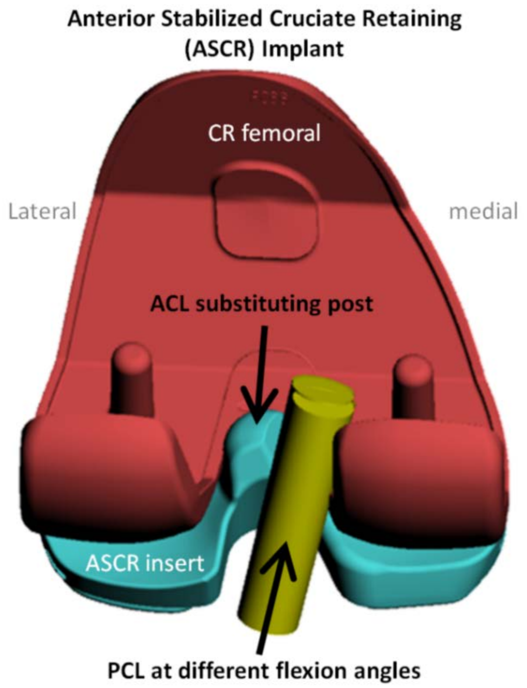

Figure 4-2: *Schematic showing the novel implant design with an ACL-substituting post and retention of the native PCL, the PCL is shown at different flexion angles*

Kinematics of the ASCR implant were also compared to the ACL-sacrificing CR implant that consisted of the same articular surface but without an ACL or ACL-substituting post. Additionally, simulations were performed for the average native knee using the average articular cartilage geometry (femur tibia and patella) derived from MRI data (the "native knee"). The native knee model included ACL and PCL. **Figure 4-3** shows a model and cross sections of all the implants and the native knee tested in this study. In Appendix A-2, there is a further comparison of the ASCR design to a commercially available BCR and CR implant.

Several activities were simulated to capture activities of daily living involving different ranges of knee motion (ROM): walking (60° flexion), stair-ascent (90° flexion), sitting on a chair (105° flexion), and deep knee bend (DKB, 135° flexion). These simulations were carried out with ideal (normative) component placements. The components were mounted perpendicular to the mechanical axis on the average bone models to restore the joint line on the lateral side according to standard surgical technique. The tibial posterior slope was 7.0° for all implants.

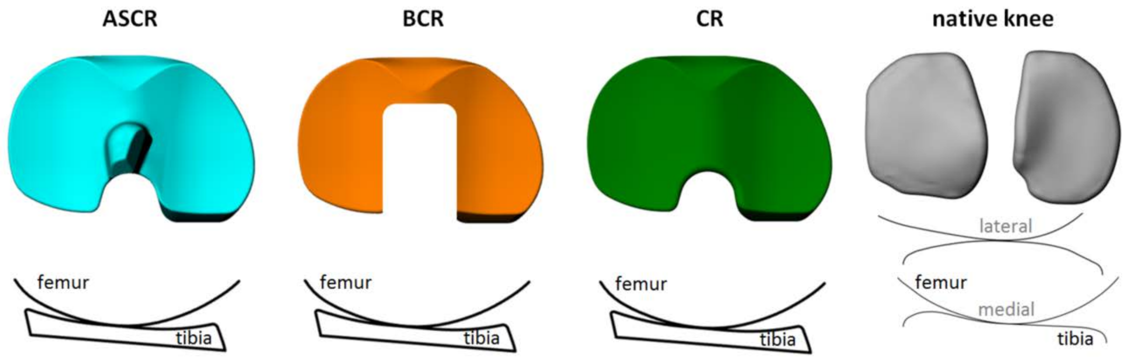

Figure 4-3: *Implants tested in KneeSIM (ASCR, BCR, CR, and native knee) together with a sagittal cross section of the femur on the tibia*

Ligaments were modelled as nonlinear, tension-only springs, with average stiffness values obtained from the literature (**Table 4-1**), [28–30]. An initial preload was applied to the collateral ligaments to simulate a balanced knee joint during surgery. The ACL was modelled with initial tension at full extension, while the PCL was modelled to be slack at the starting position (**Table 4-1**), [31,32]. For a given knee flexion, the knee joint was free to move in all other degrees of freedom (internal/external and varus/valgus rotation as well as all translations), and no forces were imposed on the level of the knee joint for any activity. Tibiofemoral contact forces and knee kinematics are interdependent, and are in turn driven by implant geometry, implant placement, soft-tissue properties, and quadriceps muscle forces. Within KneeSIM, different combinations of built-in loading conditions are available to simulate a variety of activities, with the muscle loads being automatically modulated to balance forces applied to the hip/ankle joint center. For deep knee bend, a constant load of 180.0 N was applied to the hip joint center, while for chair-sit the same constant load at the hip joint was applied in conjunction with a varying anteroposterior (AP) load at the ankle joint. For stair-ascent, a variable vertical hip load was applied, with a peak force of 670.0 N. For walking simulation, a variable vertical hip load with a peak of 1100.0 N, together with a variable ankle torque around the tibia and an adduction/abduction moment, was applied.

Table 4-1: *Initial slack (+) or tension (-) and preload of ligaments and capsule used for the knee model setup in KneeSIM*

Soft Tissue	Material Properties [N/mm]	Initial Preload / Slack
ACL	184.0	-0.8 mm slack
PCL	239.3	3.5 mm slack
MCL	92.7	44.5 N preload
LCL	86.9	44.5 N preload
Capsule (tibiofemoral)	6.1	89 N preload
Capsule (patellofemoral)	1.8	44.5 N preload

For all simulations, tibiofemoral kinematics were reported as the average of medial and lateral femoral condyle motions relative to the tibia. The posterior femoral shift in extension, defined as shift of the midpoint between the medial and lateral condyle centers relative to KneeSIM's built-in local tibial coordinate system, was of particular interest for the purpose of this study. Furthermore, the range of knee flexion angles where ACL and PCL were under tension, and range of knee flexion angles where there was contact between the femoral component and the ACL-substituting post were also reported.

4.3 Results

4.3.1 Walking Simulation

During walking, the results for the CR implant revealed notable posterior femoral shift in extension (**Figure 4-4**) relative to the native knee (4.9 mm), and predominantly anterior femoral motion with increasing knee flexion (6.2 mm). Neither the ACL-retaining nor ACL-substituting implants showed this posterior femoral shift in extension relative to the native knee during the gait cycle (**Table 4-2**). Both ACL-retaining and ACL-substituting implants showed more similar motion trends compared to the native knee than the ACL-sacrificing implant. During walking simulations, the ASCR post was engaged with the intercondylar notch of the femoral component throughout the stance phase of gait (effective flexion range over which the "ACL substitute" was functional), which was similar to the portion over which the ACL was under tension in the BCR simulation and the native knee (**Table 4-3**).

Table 4-2: *Femoral posterior rollback (average of medial and lateral condyle) relative to full extension in KneeSIM [mm]*

Knee Flexion	15°	30°	60°	90°	105°	120°	135°
Walking							
ASCR	3.7	1.1	0.7				
BCR	3.0	1.5	1.0				
CR	-0.3	-2.9	-6.2				
native knee	3.0	3.7	2.2				
Stair-ascent							
ASCR	1.7	-2.0	-1.2	3.1			
BCR	2.2	-0.7	0.2	4.4			
CR	-3.0	-6.7	-5.9	-1.6			
native knee	4.0	5.9	5.3	5.4			
Chair-sit							
ASCR	0.7	0.1	-2.0	0.8	5.0		
BCR	0.6	1.5	-0.4	2.3	6.6		
CR	0.4	-2.3	-4.5	-1.8	2.4		
native knee	0.0	5.0	8.0	8.0	10.4		
DKB							
ASCR	3.2	3.5	2.0	4.3	5.8	7.3	8.0
BCR	2.5	3.7	2.9	5.2	6.7	8.2	8.9
CR	0.3	-2.4	-4.2	-2.0	-0.4	1.0	1.7
native knee	2.3	5.2	11.5	15.5	17.0	18.8	20.8

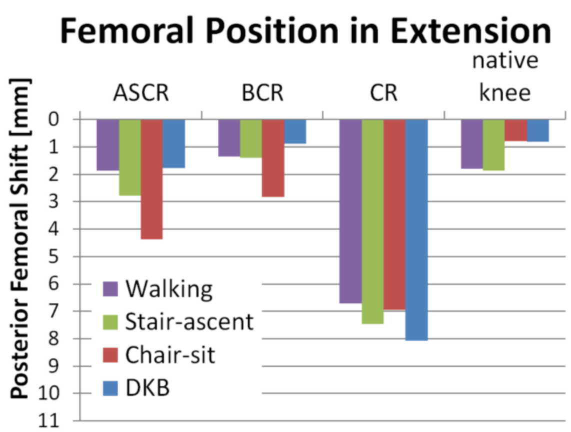

Figure 4-4: *Extended femoral position of all implants and activities relative to the tibia showing significant posterior femoral shift for the CR TKA*

4.3.2 Stair-ascent Simulation

For the stair-ascent simulation, the CR implant data again showed posterior femoral shift in extension relative to the native knee (5.6 mm) followed by paradoxical anterior sliding. In contrast to ASCR and both BCR implant and native knee that showed posterior femoral rollback, the CR implant had a more anterior location (1.6 mm) of the femur on the tibia at 90° flexion compared to full extension (**Table 4-2**).

Table 4-3: *Range of knee flexion [deg] over which the ACL post is in contact with the femoral component or ACL/PCL are under tension*

	ACL-Post contact	ACL tension	PCL tension	ACL-Post contact	ACL tension	PCL tension
Activity		**Walking**			**Stair-ascent**	
ASCR	0.0 - 16.7		58.2 - 60.0	0.0 - 15.8		65.6 - 90.0
BCR		0.0 - 23.1	58.2 - 60.0		0.0 - 30.6	65.6 - 90.0
CR			no tension			65.6 - 90.0
native knee		0.0 - 31.7	no tension		0.0 - 45.6	73.6 - 90.0
Activity		**Chair-sit**			**DKB**	
ASCR	0.0 - 17.6		60.0 - 105.0	0.0 - 17.4		65.6 - 135.0
BCR		0.0 - 27.3	60.0 - 105.0		0.0 - 28.9	65.6 - 135.0
CR			60.0 - 105.0			65.6 - 135.0
native knee		0.0 - 60.0	72.7 - 105.0		0.0 - 73.7	93.9 - 135.0

4.3.3 Chair-sit Simulation

The ASCR implant again showed motion similar to the BCR with net posterior femoral rollback of 5.0 mm for ASCR and 6.6 mm for BCR, respectively. The CR data for chair-sit again showed substantial posterior femoral shift in extension relative to the native knee (6.2 mm, **Figure 4-4**), followed by anterior femoral sliding of 4.5 mm until 60° before rollback occurred with higher knee flexion (**Table 4-2**).

4.3.4 Deep Knee Bend Simulation

During deep knee bend, the whole range of knee flexion was covered, and the comparison of all implants and the native knee is shown in detail in **Figure 4-5**. Like for all the other simulated activities in low flexion (<30°), the ASCR tibial post-femoral notch interaction provided a similar kinematic effect to that of the retained ACL in the BCR simulation unlike the CR simulation. At higher flexion angles when there was no contribution from either the tibial post in ASCR or the ACL in the BCR implant, the kinematics for all designs were virtually identical. The simulations for the native knee showed very similar trends in low flexion until around 30° knee flexion. With further knee flexion, the native knee showed more femoral rollback than any of the implants

(**Figure 4-5**, **Table 4-2**). **Table 4-3** shows the range of knee flexion angles where the tibial post was in contact with the femoral component in the ASCR implant, and where the ACL/PCL were under tension in the BCR/CR implants and the native knee.

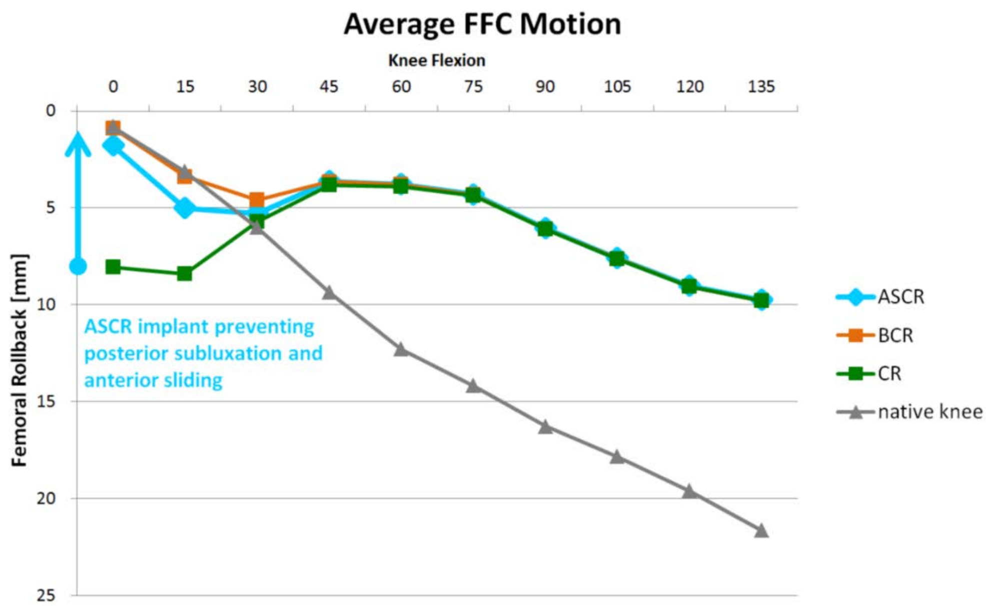

Figure 4-5: *Average motion of the femur relative to tibia during DKB showing initial posterior rollback of the ASCR and BCR implants unlike for the CR implant, compared to the native knee showing continuous femoral rollback*

4.4 Discussion

The most important finding of the present study was that within the simulation environment, the kinematic function of the ACL in low knee flexion was successfully replicated by ACL substitution involving engagement of a tibial post with the femoral component. The anterior substituting cruciate-retaining (ASCR) design showed kinematics close to that of the BCR design, which had the same articular surface geometry as the ASCR design. Thus, like the BCR design, the ASCR implant was able to improve the kinematic abnormalities of the CR implants across the simulated activities in this study (**Figures 4-4**, **4-5**; **Table 4-2**). In all activities, the CR implant showed substantial posterior femoral shift in extension (**Figure 4-4**) followed by paradoxical anterior sliding. These findings for the CR implant are consistent with various in vivo, in vitro (cadaver), and simulation studies [7,9,11,12,33]. Further, we have also compared kinematics of the ASCR design to a commercial BCR and CR device in Appendix A-2. This confirmed the original hypothesis of this study.

The abnormal posterior femoral location in CR implants is largely due to the missing ACL, which is under tension in extension and holds the femur anteriorly on the tibia (**Figure 4-6**). Following this posterior shift, the force imbalance within the joint causes paradoxical anterior sliding of the femur in early flexion. As explained by Blaha, the line of action of the body weight in early flexion lies behind the knee joint. This is balanced by quadriceps activation, and the absence of the ACL and slack state of the PCL in early flexion causes anterior femoral sliding [34]. To reduce such paradoxical anterior sliding, contemporary TKA implants often utilize increased anterior tibial lips, which also cause the femur to sit posteriorly on the tibia in extension. With increased flexion, a reduced tibiofemoral constraint allows additional laxity, and paradoxical anterior sliding occurs until the PCL is adequately tensioned in mid-flexion to guide femoral posterior rollback.

In contemporary CR TKA, the ACL is resected and its function is lost, which alters native knee kinematics following TKA surgery [7–9]. ACL retention is one way to overcome these kinematic abnormalities but presents several challenges as previously discussed. Therefore, the goal of this study was to determine whether the kinematic abnormalities of CR implants could be improved by substituting for the resected ACL. This is achieved by the interaction of a tibial post with the intercondylar notch of the femoral component at low flexion angles to provide anteroposterior stability similar to that provided by the ACL in the native knee (**Figure 4-6**), [4]. Further, the ACL-substituting tibial post is intended to work in conjunction with the native PCL. At higher flexion angles, the ACL post is designed to disengage from the femoral component and allow motion/stability to be governed by the native PCL

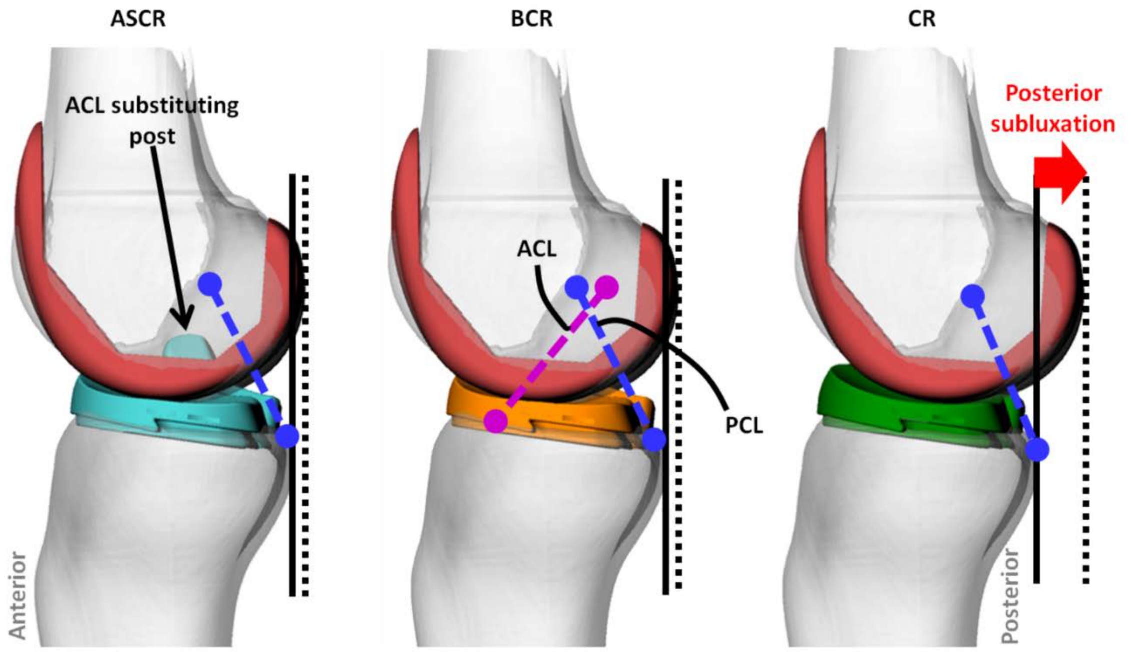

Figure 4-6: *Schematic showing the posterior femoral shift at full extension for contemporary CR implants relative to the posterior aspect of the tibia (vertical lines) in contrast to a centrally located femur for the ASCR and BCR designs*

Liu et al. [35] proposed ACL reconstruction following TKA as a different way to improve kinematics in CR implants based on the results of their computational simulations. Other attempts to provide improved knee kinematics through implant design include a bi-cruciate substituting (BCS) device with an anterior and posterior cam–post interaction (Smith and Nephew, London, UK). Publications related to this design have shown kinematic improvements over contemporary PS implants where both ACL and PCL are resected. While the kinematics of this implant has been compared to other contemporary devices and native knees, the effectiveness of the ACL- and PCL-substituting mechanism relative to the actual ligaments has not been directly evaluated [24,36]. Another commercially available design uses a ball-and-socket-like joint on the medial side to provide AP stability while allowing greater AP motion on the less constrained lateral side also intends to improve joint stability and kinematics (Wright Medical Group, Arlington, TN, USA). Generally, these medially constrained designs are indicated for PCL-sacrificing applications, and use articular surface constraint instead of a post–cam mechanism to substitute for ligament function. Some publications have even debated whether PCL function either through retention (CR) or through substitution (PS) is necessary [37]. Nonetheless, CR and PS both are established and successful treatment options. Our research aimed to analyze the effect of direct substitution for the ACL with an ACL post while leaving the PCL intact providing an improved alternative to contemporary CR implants.

There are several limitations to the present study: The first limitation is that the kinematics evaluated in this study are based on the simulations of an average knee model in KneeSIM. The extent to which kinematics of an individual knee can be replicated by an ACL-substituting post designed for the average population is unclear. Therefore, subject-specific simulation studies should be conducted in future to evaluate inter-subject variations in knee kinematics for the different designs. The second limitation is that while the native knee simulations included geometry of the average articular cartilage, the simulation package did not allow for modelling of the menisci. However, the results for the native knee across different activities showed kinematic trends similar to published in vivo data of normal knees, particularly the activity depended range of AP translation showed very similar trends [38–40]. Another limitation of this study is although KneeSIM and other such computational tools have been used for design and evaluation of TKA implants, it is still uncertain whether such tools can fully predict kinematic behavior of knees in vivo. Therefore, continued analysis of this concept via cadaver testing, more advanced full-body musculoskeletal simulations, and eventually in vivo kinematic evaluation is required. Another limitation of this study is also that the effect of articular geometry on implant kinematics was not evaluated. This was because we wanted to achieve a direct comparison of ACL substitution versus ACL retention and ACL sacrifice, without the confounding effect of articular surface variation. Prior studies have shown important effect of articular geometry on kinematics of BCR and CR implants [9,41]. Therefore, future studies relating to the ASCR should evaluate the effect of changes in articular geometry coupled with the presence and absence of the ACL-substituting post.

The results of the present study suggest that the ASCR post can substitute for kinematic function of the ACL and provide a more natural location of the femur on the tibia. However, proprioception provided by the ACL would still be lost, which may have important implications for joint function [42,43]. This may be a possible limitation of the ACL substitution concept.

While TKA procedures provide excellent pain relief, a significant portion of patients remain dissatisfied due to functional limitations, residual symptoms, and perception of joint instability [14,15]. ACL has long been recognized as a missing puzzle in the quest for addressing these clinical challenges. However, retention of native ACL in TKA poses many challenges, and may also necessitate the use of advanced tools to obtain reliable outcomes. The proposed concept of ACL substitution may be an alternative to ACL retention, particularly for patients with an absent or non-functional ACL. If the kinematic improvements seen here are replicated in vivo, improved patient outcomes could be achieved with such ACL-substituting designs compared to contemporary CR implants. This would allow surgeons to provide better outcomes for their patients, without encountering challenges of ACL retention.

4.5 Conclusion

In conclusion, an ACL-substituting design that retains the native PCL showed important kinematic improvements over a CR TKA during dynamic simulations. Particularly, the abnormal posterior femoral shift and paradoxical anterior sliding in low knee flexion seen with the CR implants were addressed with the ASCR design through replacement of the native ACL by an ACL-substituting post. The kinematic results of the ASCR design were similar to an ACL-retaining implant and the native knee.

Acknowledgement

The work reported herein was supported by departmental grants at Massachusetts general Hospital. The authors would also like to thank Rajan Patel for technical assistance with various aspects of the analysis.

One or more co-authors are listed inventors on a patent application related to the technology analyzed as part of this research.

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5 Indication for Medial Unicompartmental Knee Arthroplasty in ACL-Deficient Knees: In Vivo Kinematic Evaluation Using a Moving Fluoroscope

Submitted as
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Indication for Medial Unicompartmental Knee Arthroplasty in ACL-Deficient Knees: In Vivo Kinematic Evaluation Using a Moving Fluoroscope
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UKA is functionally superior to TKA with kinematics similar to native knees, in contrast to TKA. Despite superior function, UKA implants are used in less than 10% of cases. While the advantages of UKA are recognized, ACL-deficiency is generally considered a contraindication. The hypothesis of this study was that UKA in ACL-deficient knees, with appropriate adaptation of implant placement, would result in similar kinematic trends to conventional UKA with an intact ACL.

Ten conventional UKA patients were compared to eight patients with the same implant but a deficient ACL. A 50% tibial slope reduction was applied to compensate for instability resulting from the deficient ACL. Knee kinematics were evaluated using a moving fluoroscope allowing horizontal and vertical tracking of the knee joint during deep knee bend, level walking, ramp descent and stair descent. The results of level walking and stair descent were further compared to six TKA patients.

In a standing position, a posterior shift of the femur was observed for the ACL-deficient UKA patients compared to conventional UKA patients. This posterior shift was also present during the first 25% of deep knee bend. Most parameters revealed no difference in range of motion across all activities between the two UKA groups. This is

in contrast to TKA patients showing different motion trends and decreased range of motion.

Despite the posterior femoral shift due to ACL-deficiency, both UKA groups showed similar kinematic trends, indicating that posterior tibial slope reduction can partially compensate for ACL function. This confirmed our hypothesis that UKA can be a viable treatment option for selected ACL-deficient patients, allowing patient specific kinematics. While anteroposterior laxity can be compensated, rotational stability is a prerequisite for this approach.

5.1 Introduction

Native knees possess a complex anatomy resulting in rotational and translational motion with 6-degrees of freedom kinematics [1–3]. The medial and lateral tibial compartments are asymmetric, with a concave (dished) sagittal profile on the medial side and a convex lateral tibial contour [1,2]. In addition to the articular geometry, anterior cruciate and posterior cruciate ligaments (ACL and PCL) guide and constrain the kinematics of the knee joint [4,5]. Hence, the native knee joint relies on the interplay of soft tissues and asymmetric articular surfaces for proper functioning.

Total knee arthroplasty (TKA) is the preferred treatment option for osteoarthritis by replacing the worn articular cartilage surfaces to regain mobility and avoid painful bone-on-bone articulation [6]. In contrast to pain relief and increased patient mobility, knee kinematics are altered and some proprioceptive feedback is lost with TKA [7–10]. This is mainly due to cruciate ligament resection in combination with the altered articular surface of the joint [11–13]. Yue et al. found that, knee kinematics of arthritic knees (pre-operative) were more similar to healthy controls than the kinematics following TKA surgery (post-operative) [7].

Unicompartmental knee arthroplasty (UKA) is an alternative treatment option to TKA, where only the diseased compartment (mostly medial) is replaced, while the rest of the joint retains its natural structures [14,15]. UKA surgery is technically more demanding than TKA, however improved surgical techniques and implant design provide reliable outcomes [16]. Several in vitro and in vivo studies have shown that UKA provides superior clinical outcomes in comparison to TKA and kinematics were reported similar to native knees, in contrast to TKA, during daily activities including treadmill gait, step up/down, and lunge [14,16–21]. This is mainly due to the retained ACL and the intact lateral (or medial) compartment. Despite superior function, the proportion of UKA implants is below 10% when compared to TKA, even though potential indication covers up to 50% of patient population [22,23].

A common co-morbidity of knee osteoarthritis is ACL-deficiency. It has been reported that up to 40% of patients undergoing joint arthroplasty show evidence of a deficient ACL [24,25]. ACL-deficiency has also been linked to a posterior tibial wear pattern in the medial compartment of the knee, in contrast to patients with an intact ACL showing anterior tibial wear pattern [24,25].

While the advantages of UKA in knees with predominantly medial osteoarthritis are recognized, a sign of ACL-deficiency (in otherwise UKA indicated knees) is seen as a contraindication by most orthopaedic surgeons, resulting in a TKA procedure. This contraindication is common practice in joint arthroplasty, though largely derived from early experiences with mobile bearing UKA (floating tibial insert) and older, less wear resistant polyethylene inserts [26–28]. However, there have been conflicting reports in the literature regarding the use of UKA in ACL-deficient knees based on clinical evaluation [26,29–33]. Hernigou et al. found that posterior tibial slope has a major effect on anteroposterior (AP) stability, with increased laxity for higher slope. They reported higher revision rates with increased tibial slope for both ACL-intact and ACL-deficient UKA [29]. In a cadaveric study, Suero et al. reported similar AP stability of the medial knee compartment in ACL-deficient UKA with a decreased posterior tibial slope compared to conventional UKA (intact ACL) matching the native slope. This is in contrast to AP stability in ACL-deficient UKA with a matching and increased tibial slope relative to the native slope [34].

To our knowledge, no study has investigated dynamic functionality in patients implanted with UKA in ACL-deficient knees. The hypothesis of this study was that UKA in ACL-deficient knees, implanted with a reduced posterior tibial slope, would result in similar kinematic trends to conventional UKA with an intact ACL during daily activities.

5.2 Materials and Methods

Ten patients following conventional medial fixed bearing UKA implantation, and eight patients after an alternative surgical approach, using a UKA implant in ACL-deficient knees were recruited from two different centers (**Table 5-1**). Informed consent was obtained from each patient for this study, approved by the institutional review board and the Zurich cantonal ethics committee (BASEC-No. 2016-00438). For the conventional UKA group the tibial implant slope was matching the patients' native anatomy. For the ACL-deficient UKA group, the tibial baseplate was implanted with a 50% reduced posterior slope (relative to native knee). The tibial slope reduction intended to compensate for translational AP instability, while rotational stability during a clinical examination was a prerequisite for this procedure [34].

Table 5-1: *Inclusion criteria and patient demographics for conventional UKA, ACL-deficient UKA and TKA groups*

Inclusion Criteria	**Conventional UKA**	**ACL-Deficient UKA**	**TKA**
Implant (DePuy Synthes, Raynham, MA)	SIGMA High Performance Partial Knee System,	SIGMA High Performance Partial Knee System	SIGMA Total Knee System
ACL	intact/functional ACL	deficient ACL	N/A
Cartilage defect	Medial OA	Medial OA central/posterior wear pattern (preop MRI)	Knee OA
Functional outcome (Knee Injury and Osteoarthritis Outcome Score)	KOOS > 70 (0-100, average of all five subscales)	KOOS > 70 (0-100, average of all five subscales)	KOOS > 70 (0-100, average of all five subscales)
Pain score (Visual Analog Scale)	VAS < 2 (0-10)	VAS < 2 (0-10)	VAS < 2 (0-10)
BMI	BMI < 32	BMI < 32	BMI < 32
Postoperative time	> 1 year postop	> 1 year postop	> 1 year postop
Demographics			
Gender	2 female/8 male	5 female/3 male	1 female/5 male
Age (range)	67 years (52-80)	63 years (57-75)	73 years (57-80)
BMI (range)	25.3 (21.2-29.8)	26.9 (24.2-29.9)	24.3 (22-28)
Postoperative time	21 months (12-28)	76 months (72-87)	50 months (14-121)

Knee joint kinematics were obtained using a moving fluoroscope capturing x-ray images at 25 Hz [35–38]. A modified video-fluoroscopy C-arm (BV Pulsera, Philips

Medical Systems) was mounted onto an instrumented trolley with horizontal and vertical actuators that allowed dynamic positional tracking of the knee joint during various activities. A wire sensor was used to provide the knee reference position for proper horizontal and vertical alignment of fluoroscope throughout the whole motion task (**Figure 5-1**).

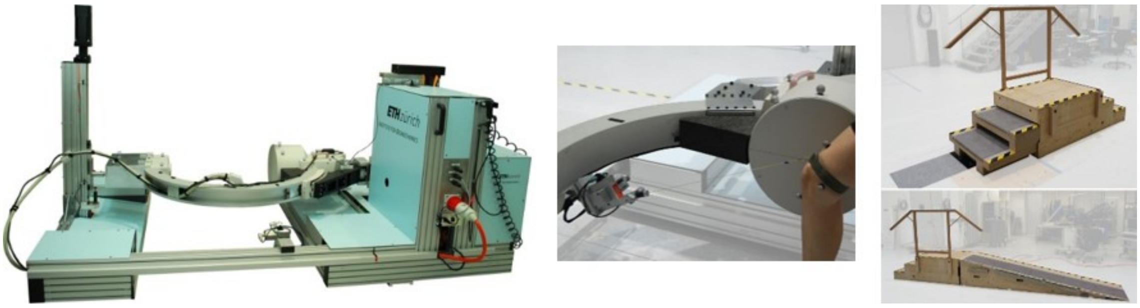


Figure 5-2: *Moving fluoroscope (left), wire sensor setup providing knee reference for tracking throughout motion tasks (center), stair and ramp setup (right).*

Standing trials from lateral and frontal views (x-ray) were captured for initial alignment. Flexion/extension and varus/valgus angles were normalized to the standing position for each patient as a baseline. All activities were performed at a patient-selected velocity within the capabilities of the measurement setup. For deep knee bend (DKB), patients were stepping down posteriorly from a 31 cm high box and were bending the knee as far as they felt comfortable. Additionally, a cane was provided for stability. During level walking, downhill walking and stair descent the fluoroscope was tracking the knee horizontally and vertically (downhill and stair descent). For downhill walking, patients were walking down a ramp with a 10° slope and the staircase consisted of three steps.

Kinematics for all activities were analyzed using a previously developed 2D/3D registration method [39]. After initial manual matching of the 3D implant outline on each 2D x-ray image, an automated intensity based 2D/3D registration was applied (**Figure 5-2**) [39,40]. The process was validated for this specific implant via a three-dimensional fixture containing metal beads. Root-mean-square-errors (RMSE) of in-plane translations and rotation were below 1 mm and 1° respectively and below 3° for the out of plane rotations. Out-of-plane translation was in the mediolateral (ML) direction for all activities and not of interest for the analysis of this study.

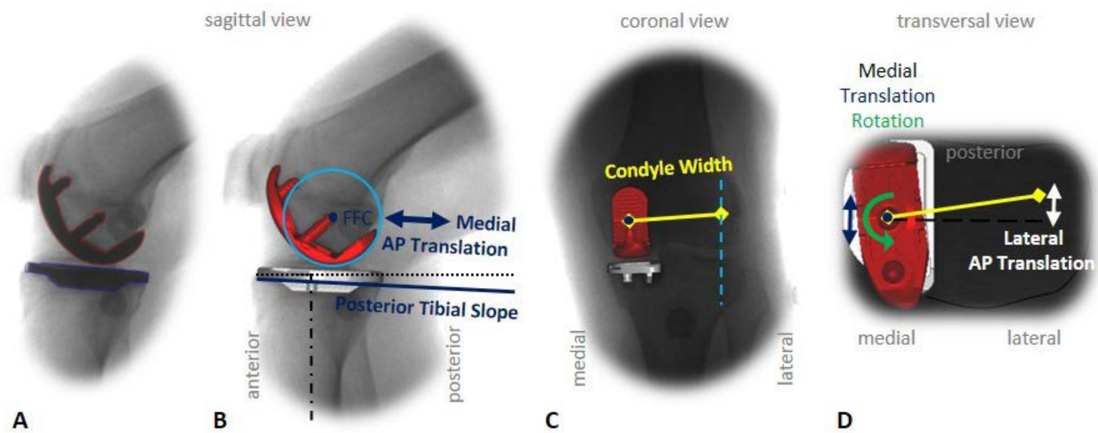


Figure 5-2: *Implant outline (A), AP translation of posterior femoral condyle centers (FFC) relative to tibial implant base (B), femoral condyle width in coronal view (C) and calculation of lateral AP translation based on medial AP translation/IE rotation and condyle width relative to tibial implant (D).*

For each patient, the average motion curve of five valid trials was used for a given activity. Flexion/extension (FE), internal/external (IE) and varus/valgus (VV) rotation together with medial and lateral AP translations were compared over the whole motion cycle for conventional UKA (UKAI) and ACL-deficient UKA (UKAD) patients. Additionally, the range of motion (ROM) was analyzed for all parameters, accounting for individual differences that could be overlooked when taking the average of all patients over the motion cycle (e.g. different rhythm). Joint angles were calculated according to Grood and Suntay [41]. Medial AP translation was based on the posterior condyle center (flexion facet center, FFC) and reported parallel to the tibial baseplate. Lateral AP translation was calculated parallel to the tibial baseplate using medial AP translation and IE rotation based on the condyle width determined on a frontal x-ray (**Figure 5-2**).

For level walking and stair descent, the results of the two UKA groups were further compared to a previously conducted study [38], analyzing six TKA patients implanted with a conventional ACL-sacrificing/PCL-retaining (CR) design (**Table 5-1**).

The statistical parametric mapping (SPM) method [42,43] with integrated t-test and one-way ANOVA was applied to evaluate differences that would occur in specific temporal regions of motion cycles (e.g. stance phase of gait). The significance level was adjusted to 0.01 (from 0.05) according to Bonferroni Correction considering the analysis of four activities. The data was checked for normality but to account for the small sample size, a non-parametric statistical test (Mann-Whitney U-test) was applied to the ROM analysis. The analysis was performed using open-source spm1d code (v.M0.1, www.spm1d.org) and MATLAB (The MathWorks, Inc. Natick, MA, USA).

5.3 Results

The baseline of the femoral condyle locations relative to the tibia was determined using a standing trial for both groups showing a more posterior location of the femur for ACL-deficient UKA (**Figure 5-3**). The posterior shift of the medial and lateral femoral condyles relative to the tibia was 5.8 mm and 9.5 mm respectively compared to the conventional UKA group (p-values = 0.010 and 0.043).

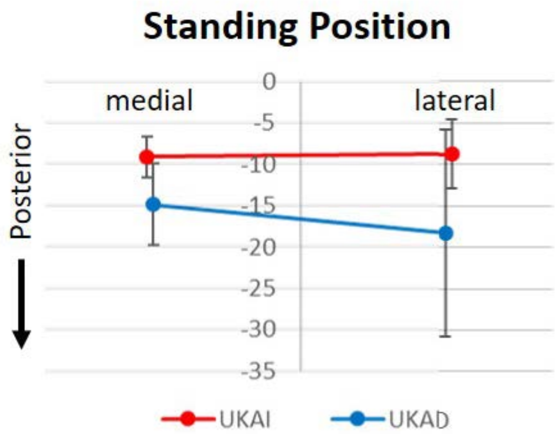


Figure 5-3: *Average standing position of conventional UKA (red) and ACL-deficient UKA (blue) including standard deviation for the medial and lateral condyles.*

Average kinematics of each UKA group revealed no significant differences for any parameters across all activities except for AP translation of the medial condyle during deep knee bend. Using SPM, a significant posterior femoral shift was detected through the first 25% of the motion cycle (flexion between 0° and around 30°) for the ACL-deficient group with a p-value of 0.001 (**Figure 5-4**).

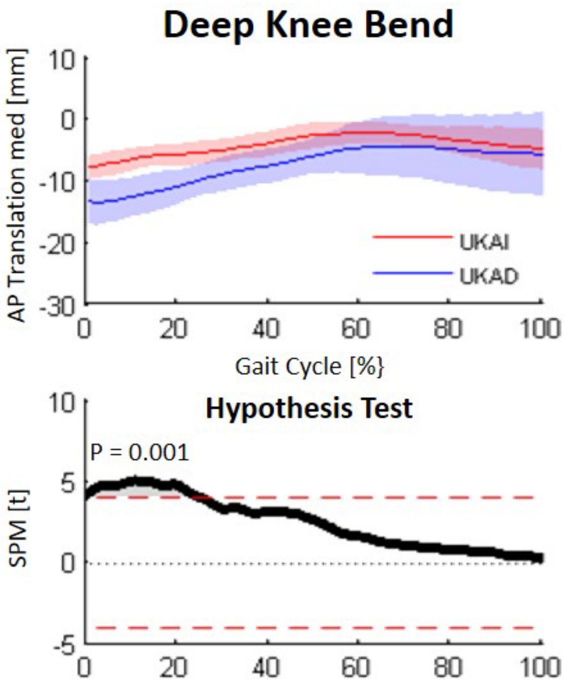


Figure 5-4: *Analysis of medial AP translation showing a posterior shift for the ACL-deficient UKA group (top, blue) in low knee flexion during DKB Hypothesis Test with SPM analysis (bottom) including the significance level of 0.01 (dotted redline)*

Range of motion (ROM) analysis revealed no significant difference for any parameters across all activities except for the medial AP translation during DKB and stair descent (**Table 5-2**). An increased ROM of 3.5 mm in the ACL-deficient UKA group was found for both activities ($p = 0.001$ and $p = 0.005$ respectively).

Average IE rotation and medial AP translation of conventional UKA, ACL-deficient UKA and TKA groups during stair descent, downhill walking and level walking are shown in **Figure 5-5** and **5-6** together with individual patient data.

Table 5-1: *Range of motion (ROM) ±SD data of conventional UKA, ACL-deficient UKA and conventional TKA [38] patients including standard deviation for all analyzed activities (#: difference between UKA groups, *: difference between TKA and UKA groups, $p < 0.01$)*

Activity	Parameter	UKAI	UKAD	TKA
DKB	Flexion/Extension	123.6 ±15.1	122.7 ±14.4	
	IE Rotation	8.4 ±3.4	11.6 ± 3.4	
	VV Rotation	5.8 ±2.7	7.1 ±2.6	
	AP Trans med#	6.5 ±2.1	10.0 ±2.5	
	AP Trans lat	10.3 ±2.3	11.0 ±5.2	
Ramp Descent	Flexion/Extension	73.1 ±4.7	72.3 ±4.6	
	IE Rotation	12.9 ±3.0	11.0 ±4.6	
	VV Rotation	5.0 ±1.6	5.5 ±1.7	
	AP Trans med	9.9 ±1.3	12.4 ±2.9	
	AP Trans lat	15.5 ±3.1	15.2 ±6.2	
Stair Descent	Flexion/Extension*	90.9 ±2.8	95.1 ±5.8	80.7±4.8
	IE Rotation	13.4 ±5.0	12.1 ±5.3	6.8~±2.5
	VV Rotation*	5.8 ±1.7	5.0 ±1.5	2.1±0.6
	AP Trans med#	9.9 ±1.3	13.4 ±2.5	8.9 ±2.4
	AP Trans lat	16.4 ±5.3	15.9 ±8.5	7.7 ±1.3
Level Walking	Flexion/Extension*	62.9 ±4.7	65.7 ±3.8	56.8±4.3
	IE Rotation	10.0 ±3.8	12.4 ±3.8	6.5~±1.3
	VV Rotation*	5.0 ±1.8	6.6 ±2.1	2.2±1.0
	AP Trans med*	9.5 ±2.2	10.8 ±2.0	6.9±1.5
	AP Trans lat	14.5 ±2.1	13.3 ±4.1	7.1#±1.6

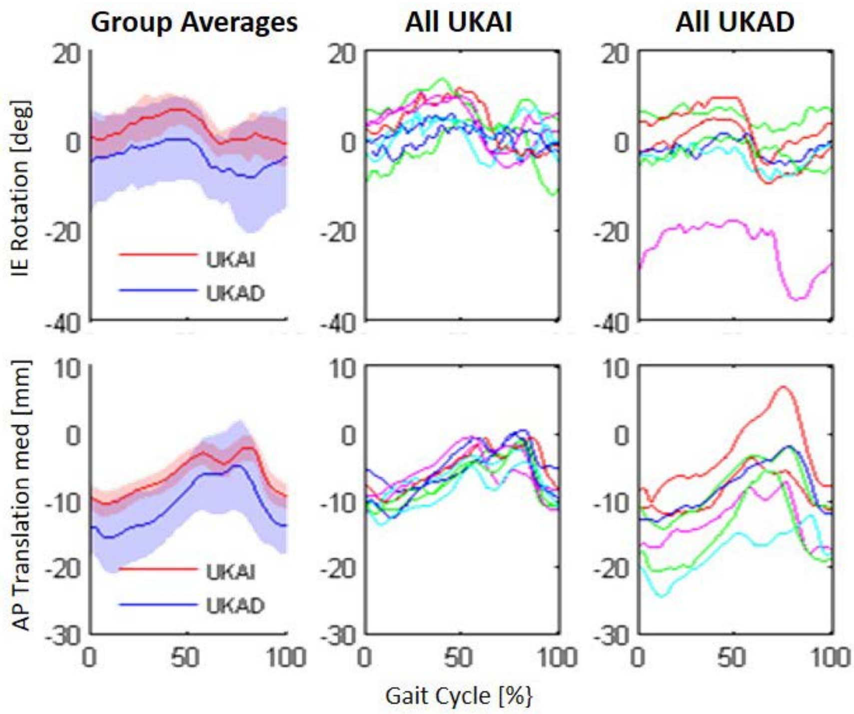
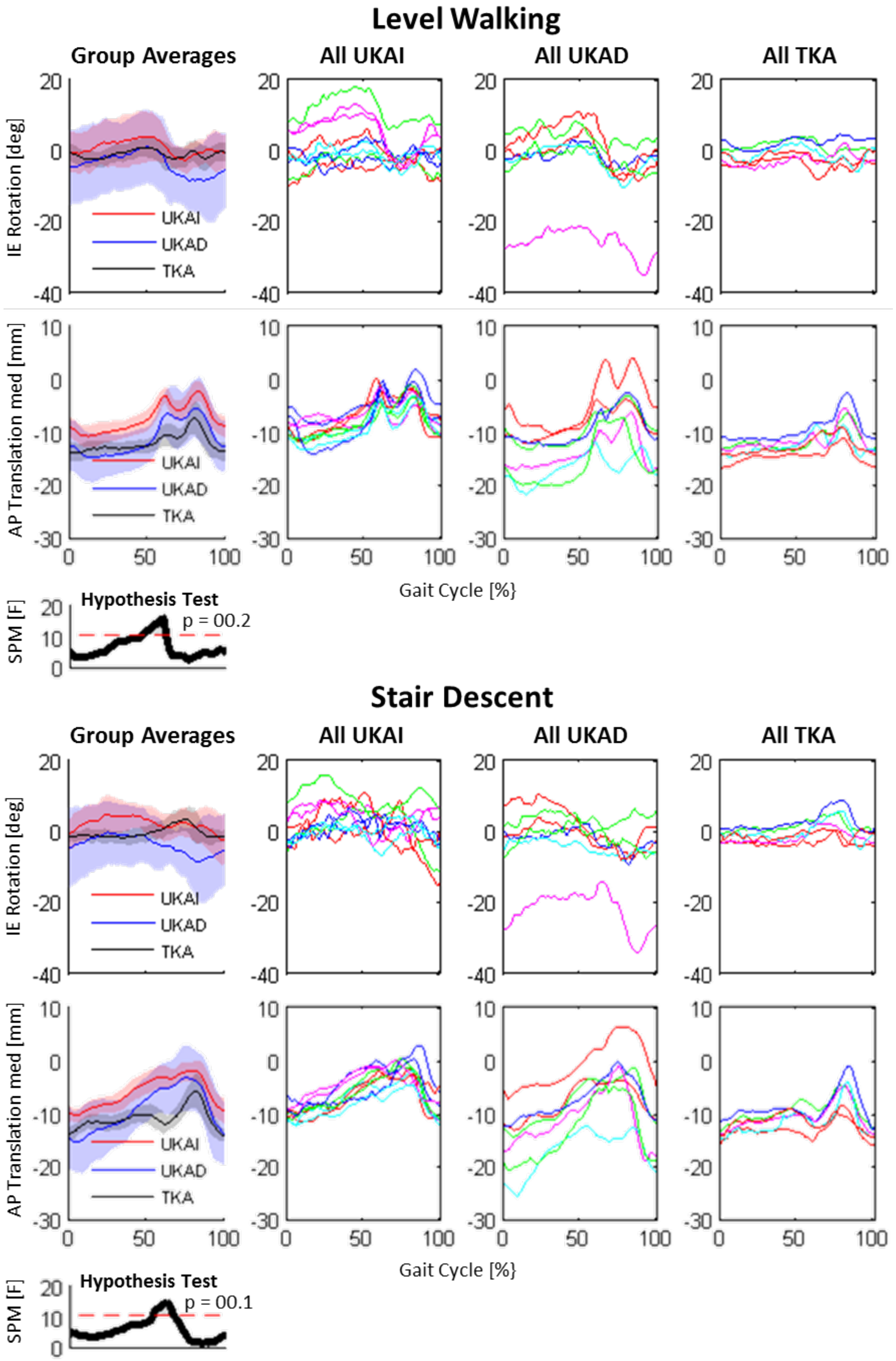


Figure 5-5: *Top: IE rotation (+ femur internal), bottom: medial AP translation (+ femur anterior) during downhill walking. Left: group averages with SD, center and right: individual patient data for conventional (UKAI) and ACL-deficient (UKAD) UKA groups.*

The comparison of TKA patients to both UKA groups for stair descent and level walking revealed significant differences for medial AP translations in the transition from stance to swing phase (50% - 70% gait cycle) between TKA und conventional UKA group for both activities (p = 0.001 and p = 0.002 respectively, **Figure 5-6**). ANOVA of the ROM during level walking revealed significant difference of the TKA group for all parameters except IE rotation (p = 0.018). For stair descent AP translation ROM was not analyzed due to proven difference between the UKA groups. Flexion and VV ROM were again significantly different while IE rotation was not significant (p = 0.036, **Table 5-2**).

Figure 5-6: *IE rotation (+ femur internal) and medial AP translation (+ femur anterior) during level walking and stair descent showing the group average with SD and individual patient data for two UKA groups and TKA. SPM ANOVA hypothesis test showing significant differences for AP translation in the transition of stance and swing phase during both activities.*


Level Walking
Group Averages
All UKAI
All UKAD
All TKA
IE Rotation [deg]
AP Translation med [mm]
UKAI
UKAD
TKA
Gait Cycle [%]
SPM [F]
Hypothesis Test
p = 00.2
Stair Descent
Group Averages
All UKAI
All UKAD
All TKA
IE Rotation [deg]
AP Translation med [mm]
UKAI
UKAD
TKA
Gait Cycle [%]
SPM [F]
Hypothesis Test
p = 00.1

5.4 Discussion

This comprehensive kinematic analysis covered a variety of daily activities with different flexion angles (**Figure 5-7**). The main finding of this study was the suitability of UKA in ACL-deficient knees from a kinematic point of view. There was a posterior femoral shift in the ACL-deficient group compared to conventional UKA, however, the motion trends revealed similarities across all activities between the two UKA groups (**Figure 5-6**). The TKA group showed different kinematic trends with a reduced range of motion compared to both UKA groups.

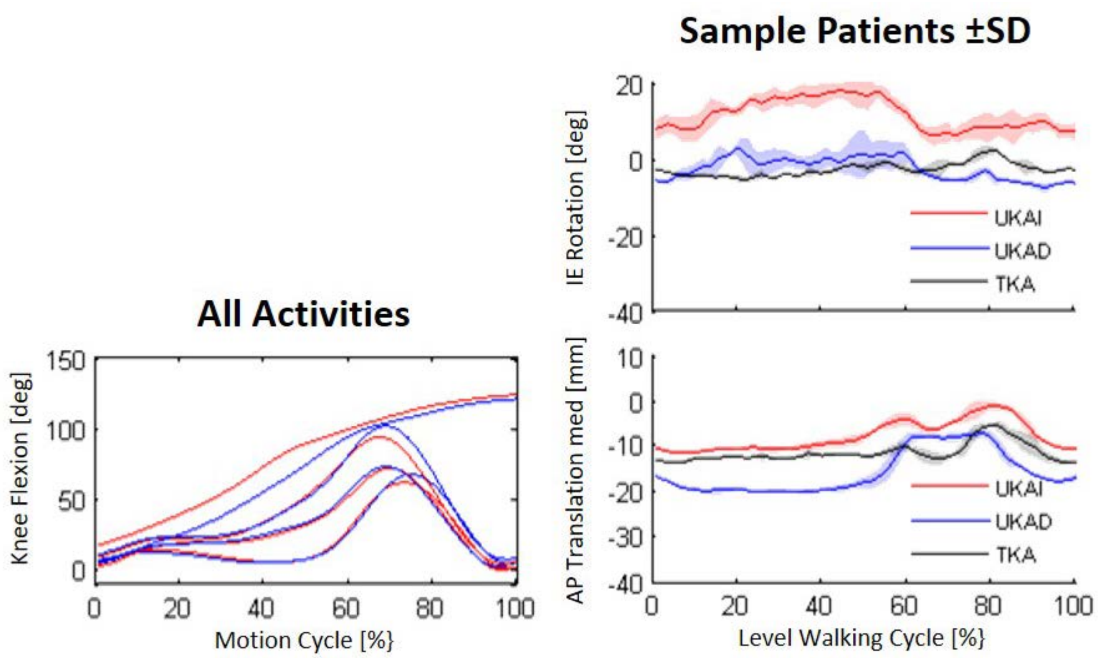


Figure 5-7: *Flexion profile with increasing ROM of level walking, downhill walking, stair descent and deep knee bend for UKAI (red) and UKAD (blue), and a sample patient of each group showing trial average ±SD for IE rotation and AP translation.*

The standing trial was used to define full extension for each patient to account for variations in component placement (tibial slope). Deep knee bend revealed that there was no difference in the maximum flexion angle between the two UKA groups. Both groups were able to perform a high flexion activity with a maximum knee flexion of 102.5° to 151.7° for the UKAI group and 108.8° to 145.7° for the UKAD group. The similar maximum flexion between groups (123.6° vs. 122.7°) indicates that the reduction in posterior tibial slope did not negatively affect maximum flexion, despite potential for increased constraint on the posterior tibia, which was ensured through a dorsal precut to soften the flexion gap. Knee flexion for both groups, and particularly some patients presenting flexion up to 150°, was higher than what is commonly achieved with TKA [3,7]. It was surprising that, for both UKA groups, IE rotation and AP translation ROM during DKB were smaller compared to other activities with lower knee flexion.

To fully visualize the collected data, individual patient curves were described in addition to the mean of each group. This was mostly relevant for IE rotation and AP translation, since there was substantial variation across patients, particularly in the ACL-deficient group. For clarity, patient standard deviation across trials was omitted (Example of each group in **Figure 5-7**). Both UKA groups showed individual patient trends, in contrast to TKA (**Figure 5-6**). Differences in AP translation for the TKA group were significant for both activities in the transition from stance to swing phase as well as ROM during level walking. Reduced IE rotation ROM of TKA patients was close to the significance level compared to the two UKA groups for both activities ($p = 0.018$ and $p = 0.036$). In view of the small sample size, power analysis of IE rotation predicts a patient population to around twelve is required for appropriate power. Overall, these results indicate that there is more patient variability within UKA than TKA, which can be explained by the symmetric dished TKA design providing constraint for the medial and lateral compartments. Despite ACL-deficiency in UKAD, both UKA groups retained the native articular geometry in the lateral compartment with an unconstrained and convex tibia, which contributes to knee kinematics, together with ligament interactions and menisci. The patellofemoral joint also remained intact in both UKA groups.

Banks et al. found that the ACL provided AP stability, while there was less IE rotation in bi-UKA patients (medial and lateral UKA) compared to conventional UKA patients during similar activities in a comparable study [20]. This is likely due to the replacement of the convex lateral tibia with a flat tibial design, identical to the medial side. Varadarajan et al. showed the effects of both, articular geometry and ACL function on knee kinematics using computer simulations of implant design variations. They concluded that anatomically shaped articular surfaces showed more natural kinematics over conventional TKA even in the absence of ACL function [11]. Similar to this study they found that ACL-deficiency resulted in a posterior femoral shift while motion patterns were preserved.

We consider the treatment of ACL-deficient patients with UKA for suitable candidates based on pre-operative evaluation. Suitable candidates show a posterior wear pattern on the medial tibial plateau due to ACL-deficiency, but present rotational stability of the knee joint. With this study, we were able to quantify the functional outcome of these patients, showing comparable results to conventional UKA patients. Nevertheless, there was one patient showing increased femoral external (tibial internal) rotation across all activities. Possibly this was due to rotational instability, but then motion pattern and ROM were comparable to other patients (**Figure 5-6**). Overall, ACL-deficient knees showed a more posterior location of the condyles indicating that the posterior femoral shift was not fully compensated by tibial slope reduction. The kinematic patterns in our study were in line with conventional UKA knees and no functional restrictions were observed. Also considering the correlation between decreased tibial slope and AP stability found by Suero et al. [34], tibial slope may be further reduced compared to our current practice.

Small sample size was a limitation of this study, particularly for the ACL-deficient UKA group due to the narrow indication of this procedure. While the two groups were comparable for age and BMI, ACL-deficient patients dated back several years and we could not recruit more participants at this point. One patient of the UKAD group had to be excluded for this analysis due to an all-poly tibia, which is not visible on x-ray. While patients were moving at self-selected velocity, the moving fluoroscope was limited to slow walking velocities (~0.9 m/s compared to ~1.3 m/s without the fluoroscope). Another limitation was the variable standing position chosen as a common baseline due to patient specific implant placement. There was no implant on the lateral condyle and therefore the lateral AP translation was calculated from the medial side, hence, comparison to the medial AP translation was omitted due to deviation in measurement method. Comparison to TKA patients was limited to level walking and stair descent (no deep knee bend and downhill walking were performed).

5.5 Conclusion

In conclusion, the motion trends during several daily activities were similar between conventional UKA patients (with an intact ACL) and ACL-deficient UKA patients. Exception was the occurrence of a posterior femoral shift, despite the posterior tibial slope reduction with ACL-deficient UKA. These results confirm our hypothesis that UKA can be a viable treatment option for selected patients with ACL-deficiency, providing a less invasive procedure and allowance of patient specific kinematics. It is important to state that patient selection is critical and while AP laxity can be partially compensated by tibial slope reduction, rotational stability is a prerequisite for this approach. Future analysis including long-term outcomes and further slope reduction in ACL-deficient UKA will be of interest for comprehensive evaluation of this surgical approach.

Acknowledgement

This study was funded by the Mäxi Foundation, departmental grants of ETH Zurich and Schulthess Klinik, together with industry support from DePuy Synthes.

The authors of this manuscript would like to thank all members of the Institute for Biomechanics for their help during the experiments or establishing the required hardware and software processes. Specifically, we would like to thank Lorena Suter and Adrian Roth for the 2D/3D registration, Luca Kiener for the validation experiments, Donato Papillo for his help with patient recruitment and all patients for participating in this study.

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6 Is ACL deficiency always a contraindication for medial UKA? Kinematic and Kinetic Analysis of implanted and contralateral knees

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Is ACL deficiency always a contraindication for medial UKA? Kinematic and Kinetic Analysis of implanted and contralateral knees
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Prevalence of knee osteoarthritis increases because life expectancy continues to rise with an active patient population. Hence, the concept of unicompartmental knee arthroplasty (UKA) has regained popularity as a treatment option for unicompartmental knee osteoarthritis. Anterior cruciate ligament (ACL) deficiency is widely considered as a contraindication for UKA, however, there are conflicting reports. If otherwise indicated, some surgeons consider UKA for ACL-deficient patients using a modified surgical technique, with a reduction of posterior tibial slope. The purpose of this study was to evaluate outcomes in UKA patients with ACL deficiency in comparison to a conventional UKA group (intact ACL) by the measurement of knee kinematics and kinetics.

Methods: Ten patients with conventional UKA and an intact ACL and eight patients with an ACL-deficient UKA and a 50% reduced posterior tibial slope relative to the native knee were recruited. Three-dimensional joint kinematics of the knee were measured, using skin markers and an infrared optical motion capture system. Ground reaction forces (GRF) were measured with force plates in all three directions. Level walking, ramp descent and stair descent were analyzed, comparing implanted and contralateral native knees and the two UKA groups.

Results: No significant differences in kinetics and kinematics were observed between conventional UKA and ACL-deficient UKA groups for any of the activities. However, some asymmetries in GRF between the implanted and contralateral side were present for the ACL-deficient group, during level walking (unloading rate) and stair descent (stance time).

Significance: Promising outcomes of the ACL-deficient UKA group suggest that ACL deficiency may not always be a contraindication. Therefore, ACL-deficient UKA could be an alternative treatment option to total knee arthroplasty for an appropriate surgeon selected patient population.

6.1 Introduction

In the United States alone, around 4.7 million individuals live with a total knee arthroplasty (TKA) [1] and more than 600’000 knee implantations are performed yearly [2]. These numbers are increasing with the aging population [1] and a growing desire for improved mobility and quality of life. The main indication for knee arthroplasty is advanced osteoarthritis (OA), with approximately 13% of women and 10% of men older than 60 years suffering from symptomatic knee OA [3]. With isolated OA in the medial or lateral compartment of the knee joint, unicompartmental knee arthroplasty (UKA) is a common treatment option [4], mostly performed in the medial tibiofemoral compartment [5]. UKA has gained popularity with its smaller surgical procedure and intact lateral (or medial) compartment, including soft-tissue preservation. Functional advantages of UKA, compared to TKA, are greater postoperative range of motion (ROM) and preservation of normal kinematic function [4,6,7]. Nonetheless, fewer than 10% of all primary knee replacements are UKAs [4,8], even though up to half of all patients are potential UKA candidates [4].

In the native knee, the anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL) play a major role in knee kinematics and joint stability [9]. In neutral tibial rotation, the ACL is the primary restraint for anterior drawer and the PCL for posterior drawer [9]. In extension, the ACL is under tension and responsible for the so-called “screw-home” mechanism, while the PCL is not under tension [10]. In mid-flexion both

ACL and PCL, provide knee joint stability and at high flexion, the PCL is responsible for posterior femoral rollback [11–13]. Additionally, other passive restraints are present, nevertheless, the main stabilizing and restraint mechanism in anteroposterior (AP) tibial translation is provided by the ACL [14,15].

Some studies stated that ACL deficiency is a relative contraindication for UKA implantation, leading to high failure rates [16,17], whereas others showed no increase in revision rates compared to conventional UKA [18,19]. It has been shown that the ACL is intact in around 61% -78% of OA knees [20,21], resulting in a substantial proportion of ACL-deficient knees undergoing TKA. The ACL forces after UKA are comparable to those in native knees, indicating a similar role of the ACL in knees following UKA [22]. Suggs et al. demonstrated in cadaveric knees that AP stability of the knee after UKA with an intact ACL was similar to that of the native knee, while UKA with a deficient ACL showed more than twice the knee movement under anterior tibial loading [22]. On the other hand, Boissonneault et al. proposed that a functionally intact ACL is not always an essential prerequisite for a successful UKA [19]. To improve stability in the ACL-deficient knee, the posterior tibial slope can be reduced [23]. With an increased tibial slope the resting position of the femur shifts posteriorly and the posterior femoral rollback in normal and ACL-deficient knees increases along with tibial shear forces [23–26]. A decreased tibial slope in ACL-deficient UKA results in similar femoral rollback compared to healthy knees [27] and a more stable knee in flexion [18].

The aim of this study was to investigate the kinematics and kinetics in conventional medial UKA patients with an intact ACL, and medial UKA patients with a deficient ACL, during various daily activities. Additionally, we analyzed the contralateral native knee for symmetry comparison.

6.2 Materials and Methods

For this study, ten patients (8 male, 2 female; 67 years ±10 years; BMI 25.3 ±2.7; postop 21 months ±5 months) were recruited with a contemporary, fixed bearing medial UKA (SIGMA High Performance Partial Knee System), implanted following standard surgical technique, and with an intact ACL. Additionally, eight patients (3 male, 5 female;

63 years ±7 years; BMI 26.9 ±2.2; postop 76 months ±16 months) were recruited with a deficient ACL and following an altered surgical technique. Patients were recruited at least one year postoperatively from two different centers. Preoperative assessment of ACL deficiency was identified clinically by means of Lachman test, through imaging including lateral knee radiographs and magnetic resonance imaging (MRI), as well as intraoperative assessment. With an intact ACL, the tibial component of the UKA was implanted matching the native tibial slope, and with a deficient ACL, the posterior tibial slope was reduced by 50% compared to the native tibial slope. A detailed description of inclusion and exclusion criteria is given in Table 1. All patients provided their written informed consent prior to data collection, and the institutional review board and the Zurich cantonal ethics committee (BASEC-No. 2016-00438) approved this study.

Table 6-1: *Inclusion and Exclusion Criteria.*

	Inclusion Criteria	**Exclusion Criteria**
Universal	*BMI < 32*	*Significant problem on lower extremities*
	Good functional outcome, KOOS > 70	*Misaligned UKA*
	No or very low pain, VAS < 2	*Severe joint instability*
	Follow-up at least one year postop	*Any other arthroplasty at the lower extremities*
	Standardized general health survey score (SF-12) within the normal range	*Pregnancy*
Conventional UKA	*Intact/ functional ACL*	*Deficient/ suboptimal ACL (Lachman Test)*
ACL-deficient UKA	*Deficient/ suboptimal ACL*	*Intact/ functional ACL*
	Central to posterior wear of medial tibial plateau (preop MRI)	
	50% reduced tibial posterior slope after UKA (post-op radiograph)	

Kinetics and Kinematics of level walking, ramp descent and stair descent were evaluated at self-selected velocity by means of skin marker and ground reaction force measurements. All motion tasks were performed with a moving fluoroscope tracking the patient's knee [28], used for other aspects of this study. The instrumented stairs had a standard inclination of 31.8° with a run of 29 cm and a rise of 18 cm, while the instrumented ramp consisted of a downward slope of 10° [28]. Each patient performed five valid gait cycles for all analyzed motion tasks.

6.2.1 Kinematics

The 3D motion analysis system comprised 22 infrared-cameras (Vicon MX system, Oxfords Metrics Group, UK) with a capture frequency of 100 Hz. The Institute for Biomechanics (IfB) lower body Marker-Set of 55 skin markers was used [29]. The instrumental root mean square error of marker positions was ≤1 mm [29]. The segmental position and orientation was determined based on a least squares fit of marker point clouds [30]. The clinical description of Grood and Suntay was used for intersegmental joint rotations [31]. Four basic motion tasks [29] were performed to functionally determine ankle, knee and hip joint centers, respectively axes. Thus, the influence of anatomical landmark misplacement was decreased and higher joint center accuracy was obtained [32]. The ankle and hip joints were modelled as ball-and-socket joints and the knee as a hinge joint. Furthermore, all kinematic data were normalized over a gait cycle. Flexion/extension, internal/external (IE) rotation and varus/valgus (VV) rotation were analyzed.

6.2.2 Kinetics

Five integrated, and two mobile force plates (Kistler Instrumentation, Winterthur, Switzerland) were used in a setup, mechanically decoupled from the surroundings to limit noise of force measurements [33]. Ground reaction force (GRF) was recorded in the vertical, anteroposterior (AP) and mediolateral (ML) direction, with a frequency of 2 kHz over the stance phase of gait cycles, and normalized to body weight (BW).

6.2.3 Symmetry Index

For the kinetic comparison of the ipsilateral and contralateral leg the symmetry index (SI) [34] was used, which was calculated as:

$$SI = \frac{2*(x_{ipsi}-x_{cont})}{(x_{ipsi}+x_{cont})} * 100$$

x_{ipsi}= value of variable for ipsilateral side, x_{cont}= value of variable for contralateral side.

Asymmetry was defined as a mean SI below or above an arbitrary cut-off value of ±10% [34]. Additionally, the SI needed to be outside the 95% confidence Interval to be considered asymmetric. The confidence interval was calculated as $t_{df;(0.05)}$*Standard Deviation(SD) [35].

6.2.4 Statistical Analysis

An open-source one-dimensional statistical parametric mapping code (v0.4, www.spm1d.org), was used for statistical analysis, evaluating the entire waveform of gait cycles [36,37]. SPM integrated paired two-tailed t-tests were applied for analysis of the ipsilateral and contralateral leg within the same subject. SPM with unpaired two-tailed t-tests were used for the comparison of the two UKA groups. Additionally, a Bonferroni correction was applied for post hoc multiple comparisons, considering the analysis of three activities (significance level adjusted from 0.05 to 0.02). To check the repeatability of gait cycles within activities of each patient, the coefficient of multiple correlation was calculated for the ipsilateral and contralateral side over all trials [38]. All calculations were performed in Matlab (Mathworks, Inc., Natick, USA).

6.3 Results

6.3.1 Level Walking

Knee flexion, IE rotation and VV rotation during level walking over the whole gait cycle were recorded for the conventional UKA patients (**Figure 6-1**) and for ACL-deficient UKA patients (**Figure 6-2**). All kinematic and kinetic waveforms were similar throughout the gait cycle without any significant differences between conventional and ACL-deficient UKA patients. For comparison within patients (ipsilateral vs. contralateral), none of the kinematic waveforms showed any differences (**Figures 6-1** and **6-2**), and kinetic asymmetry was only found for the unloading rate in the ACL-deficient UKA group (**Table 6-2** and **6-3**). In the conventional and ACL-deficient UKA groups, level walking was performed with an average gait velocity of 0.87 ±0.05 m/s and 0.85 ±0.12 m/s respectively.

Table 6-2: Kinetic parameters of conventional (UKAI) and ACL-deficient (UKAD) UKA groups for UKA implanted (ipsi) and contralateral (cont) side. Reported are stance time (T), first peak (Max1), second peak (Max2), local minimum (Min), loading rate(Lr), unloading rate (Ur), ratio of accelerating and decelerating impulse in walking direction (Acc/Dec), Maximum AP Force (APMax) and Minimum AP Force (APMin). Loading rate and unloading rate were defined as a straight line through 80% of first peak or second peak respectively, according to Stüssi and Debrunner[39].

Motion Task	**Group**	**Side**	**T [s]**	**Max_1** [BW]	**Max_2** [BW]	**Min** [BW]	**L_r** [BW/s]	**U_r** [BW/s]	**Acc /Dec**	**AP_{Max}** [BW]	**AP_{Min}** [BW]
Level Walking	UKAI	Ipsi	0.91 ±0.09	1.07 ±0.06	1.04 ±0.06	0.91 ±0.05	5.22 ±0.97	-5.78 ±0.79	0.65 ±0.18	0.11 ±0.02	-0.14 ±0.02
		Cont	0.91 ±0.09	1.11 ±0.08	1.09 ±0.07	0.91 ±0.05	5.14 ±1.3	-6.28 ±1.04	1.42 ±0.32	0.16 ±0.02	-0.13 ±0.02
	UKAD	Ipsi	0.91 ±0.11	1.03 ±0.03	1.03 ±0.03	0.90 ±0.03	4.90 ±1.11	-5.45 ±0.88	0.73 ±0.22	0.13 ±0.02	-0.14 ±0.02
		Cont	0.92 ±0.11	1.07 ±0.04	1.06 ±0.03	0.91 ±0.05	4.77 ±1.44	-6.13 ±0.95	1.19 ±0.23	0.15 ±0.02	-0.13 ±0.03
Ramp Descent	UKAI	Ipsi	0.92 ±0.10	1.13 ±0.13	0.99 ±0.08	0.87 ±0.06	5.36 ±1.66	-5.88 ±0.76	1.43 ±0.28	0.16 ±0.02	-0.11 ±0.03
		Cont	0.89 ±0.08	1.21 ±0.14	1.01 ±0.08	0.85 ±0.06	7.82 ±2.29	-6.12 ±1.30	1.52 ±0.11	0.19 ±0.02	-0.14 ±0.04
	UKAD	Ipsi	0.91 ±0.10	1.07 ±0.05	0.98 ±0.05	0.85 ±0.03	4.86 ±0.78	-5.84 ±1.20	1.69 ±1.03	0.16 ±0.02	-0.11 ±0.03
		Cont	0.87 ±0.08	1.13 ±0.09	1.01 ±0.05	0.85 ±0.04	7.52 ±1.85	-6.49 ±0.93	1.31 ±0.25	0.20 ±0.03	-0.15 ±0.05
Stair Descent	UKAI	Ipsi	0.98 ±0.13	1.29 ±0.16	0.98 ±0.08	0.84 ±0.07	8.91 ±3.49	-4.90 ±1.25	1.15 ±0.29	0.13 ±0.02	-0.15 ±0.02
		Cont	0.87 ±0.10	1.41 ±0.25	0.98 ±0.07	0.82 ±0.05	11.42 ±3.22	-6.76 ±1.27	2.67 ±1.16	0.21 ±0.04	-0.13 ±0.02
	UKAD	Ipsi	0.99 ±0.16	1.27 ±0.16	0.96 ±0.05	0.83 ±0.05	8.76 ±3.05	-4.99 ±1.00	1.23 ±0.21	0.15 ±0.02	-0.13 ±0.02
		Cont	0.86 ±0.10	1.43 ±0.19	0.98 ±0.05	0.81 ±0.04	11.11 ±2.61	-6.11 ±1.02	2.31 ±0.95	0.19 ±0.03	-0.13 ±0.03

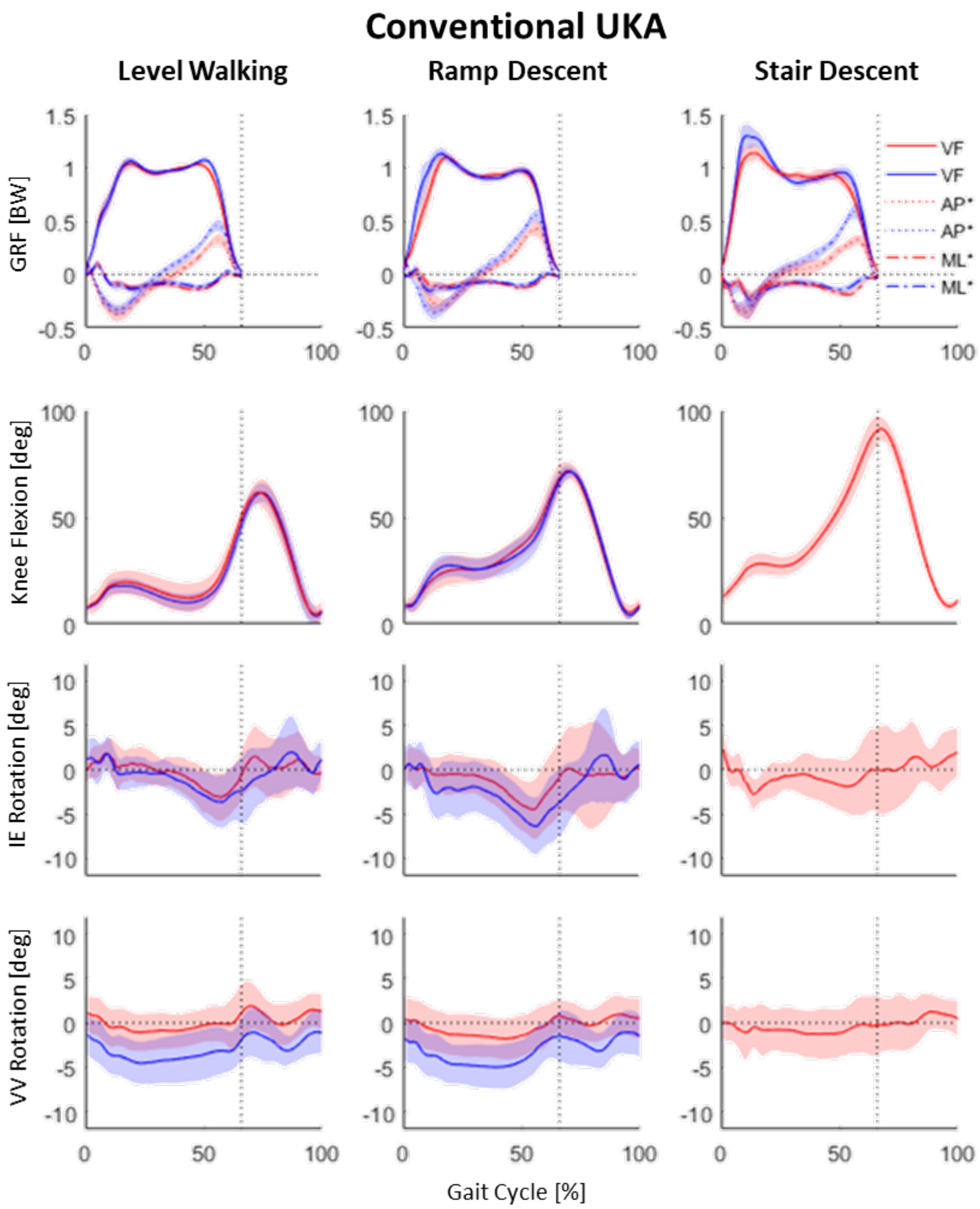

Figure 6-1: *Ipsilateral (red) and contralateral (blue) graphs of conventional UKA patients. First column: Level walking, second column: Ramp descent, third column: Stair descent. First row: Average GRF normalized to BW (* visualized threefold, VF: vertical force, AP: + anterior, ML: + medial). Second row: Knee Flexion, third row: IE Rotation (+ femur internal), fourth row: VV Rotation (+ varus).*

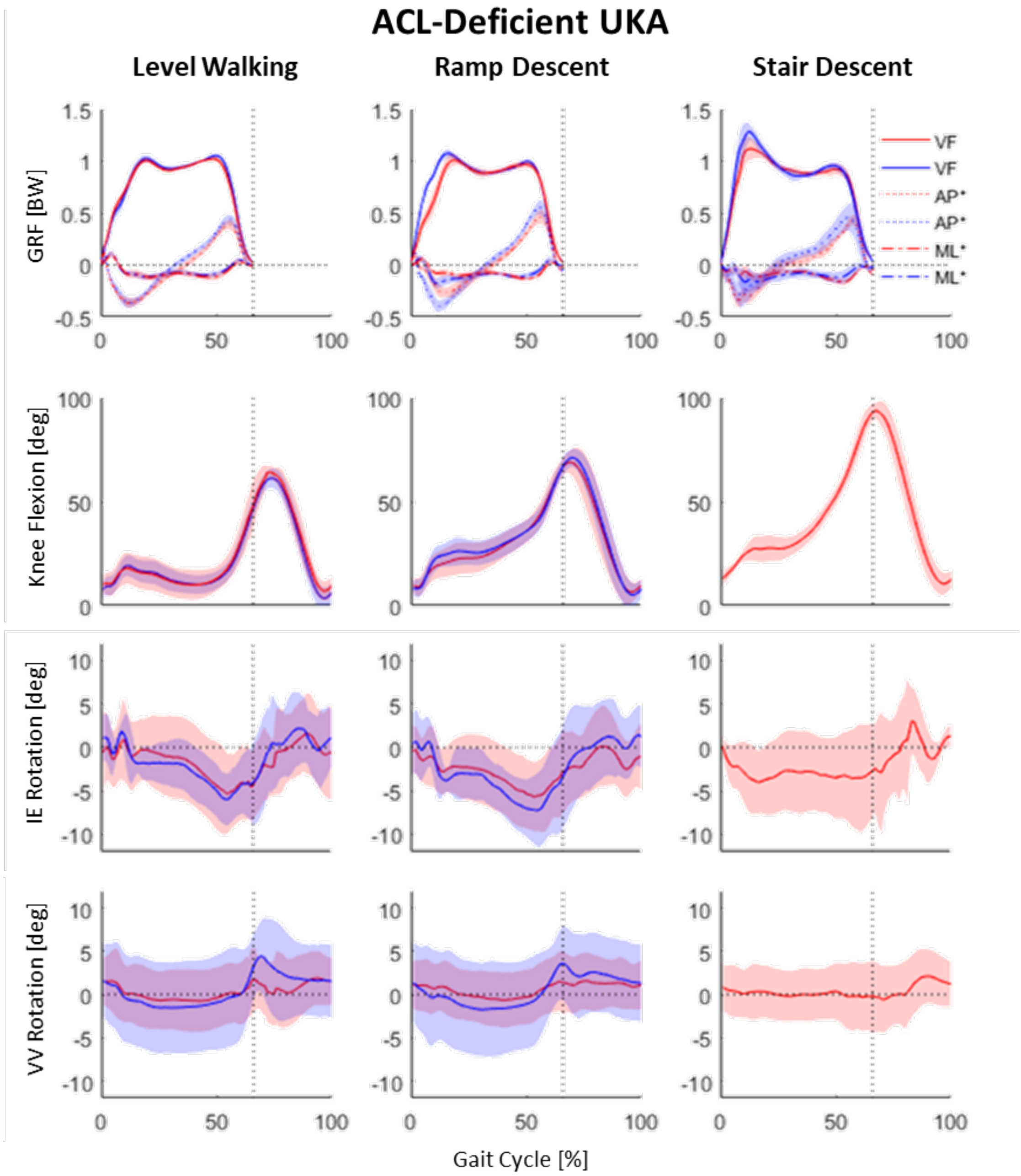

Figure 6-2: Ipsilateral (red) and contralateral (blue) graphs of ACL-deficient UKA patients. First column: Level walking, second column: Ramp descent, third column: Stair descent. First row: Average GRF normalized to BW (* visualized threefold, VF: vertical force, AP: + anterior, ML: + medial). Second row: Knee Flexion, third row: IE Rotation (+ femur internal), fourth row: VV Rotation (+ varus).

Table 6-3: *Symmetry Index (Mean ±SD) based on kinetics during level walking, ramp and stair descent for conventional UKA and ACL-deficient UKA groups. Positive values = higher for ipsilateral side, negative values = lower for ipsilateral side, ** asymmetry.*

Motion Tasks	Group	T	Max_1	Max_2	Min	L_r	U_r
Level Walking	Conventional UKA	0 ±4	-3 ±4	-4 ±2	-1 ±2	3 ±18	-8 ±8
	ACL-deficient UKA	-1 ±3	-4 ±2	-3 ±2	0 ±3	4 ±19	-12 ±6**
Ramp Descent	Conventional UKA	-4 ± 3	-7 ±6	-2 ±4	2 ±3	-37 ±19	-3 ±12
	ACL-deficient UKA	-5 ±4	-6 ±5	-4 ±2	0 ±5	-41 ±25	-11 ±15
Stair Descent	Conventional UKA	12 ±7	-8 ±13	-1 ±7	3 ±5	-28 ±29	-33 ±24
	ACL-deficient UKA	14 ±5**	-11 ±8	-1 ±5	1 ±4	-27 ±18	-20 ±25

6.3.2 Ramp Descent

The three-dimensional joint kinematics of ramp descent were similar over the whole gait cycle for both UKA groups. No significant differences were found between the groups for kinematic and kinetic waveforms (**Figure 6-1** and **6-2**). Within patients, there was no kinematic difference between ipsilateral and contralateral waveforms and none of the symmetry parameters for the kinetic analysis showed any differences (**Table 6-2** and **6-3**).

6.3.3 Stair Descent

During stair descent, the experimental set up limited investigation of kinematics to the implanted leg, only allowing comparison between the two UKA groups. No significant differences were found in kinematics and kinetics throughout the whole gait cycle between the two groups (**Figure 6-1** and **6-2**). Asymmetries in GRF were only present for stance time of ACL-deficient patients (**Table 6-2** and **6-3**).

The coefficient of multiple comparison (CMC) across all parameters revealed good trial repeatability within patients for a given activity. In the conventional UKA group, the range of CMC was 85% - 99% for kinematics, and 76% - 99% for kinetics. In the ACL-deficient group, the range of CMC was 64% - 100% (with an outlier of one parameter showing 27%) for kinematics and 73% - 99% for kinetics.

6.4 Discussion

There were no significant differences in kinematics and in kinetics between the two UKA groups across all three motion tasks. For all activities, flexion, internal/external (IE) rotation and varus/valgus (VV) rotation show similarities between ipsilateral and contralateral legs as well as between the two groups. However, it appears that the standard deviation is larger for IE and VV rotation, in contrast to flexion and kinetic parameters. This may be linked to skin marker artefacts, less prevalent for the large range of flexion, in contrast to other rotations in the knee joint (e.g. rotation around long axis of limbs).

Significant differences were measured in the vertical GRF when comparing the two walking velocities of walking with and without the moving fluoroscope as a control setting (1.3 ±0.17 m/s), during mid stance-phase and push-off, with lower and higher values respectively, for level walking without the fluoroscope (**Figure 6-3**). Hitz et al. stated, that gait characteristics, when walking with the moving fluoroscope, are comparable to walking with slow velocities [40].

Collectively, these data represent a common knee joint kinematics pattern in agreement with previous reports on human level walking and human sloped walking [41,42]. The GRF patterns during level walking were comparable to healthy [39,43], however, of lesser magnitude due to the reduced walking velocity, which also resulted in a less pronounced “double peak” shape. In both groups, the decelerating (braking) impulse in the walking direction at the beginning of stance phase was higher and over a longer portion of stance phase for the ipsilateral leg, in contrast to the contralateral leg. Generally, the accelerating and decelerating impulse in the walking direction are reported of equal magnitude during normal gait, at constant velocity and similar loading of the legs [39,44]. This indicates a different loading behavior of the implanted legs for both UKA groups. With higher velocities in the control setting, the loading was more balanced, indicating that the difference partially resulted from the lower velocities or the presence of the moving fluoroscope.

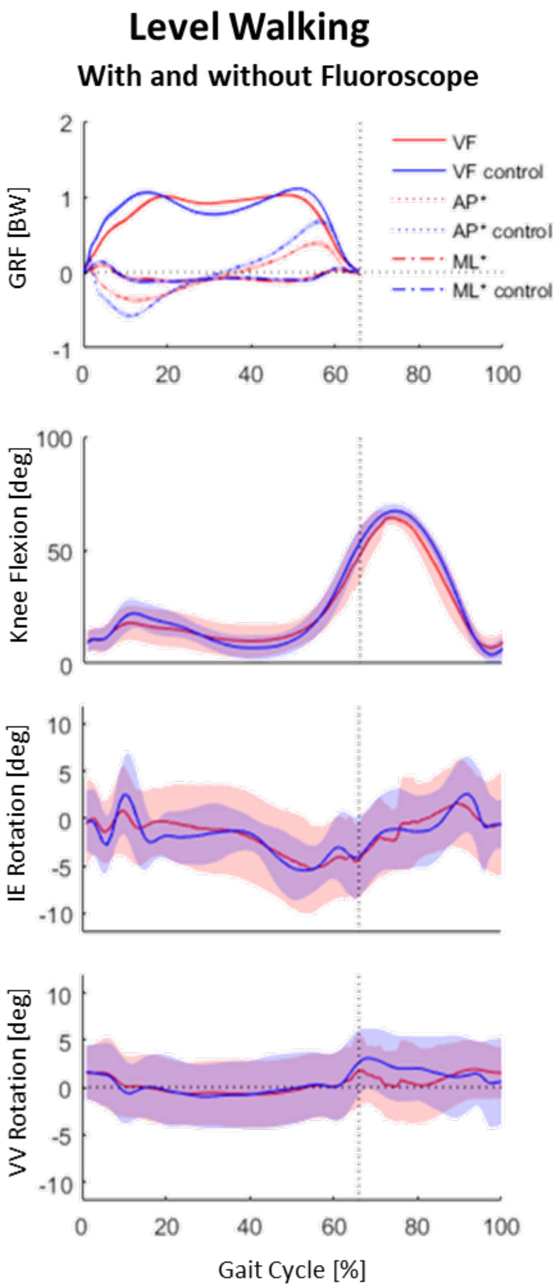

Figure 6-3: ACL-Deficient UKA Level Walking with (red) and without fluoroscope (blue; control setting), first row: Average GRF normalized to BW (* visualized threefold, VF: vertical force, AP: + anterior, ML: + medial). Second row: Knee Flexion, third row: IE Rotation (+ femur internal).

Asymmetries in the GRF, measured during level walking, indicate a trend of reduced push off with the implanted side. Since the asymmetries disappeared with higher walking velocities in the control setting, it may be attributed either to the slow walking velocity or to the presence of the moving fluoroscope. In another study, healthy subjects showed symmetrical peak values of the vertical GRF, with no significant differences during stance phase [45]. In contrast, UKA patients showed increased asymmetry during heel strike in another study [43]. It is important to notice the large SD, especially for loading and unloading rates, across all three motion tasks, showing individual differences of the SI towards either leg. Therefore, no overall asymmetry was observed, indicating no implant specific trend towards the ipsi or contralateral leg.

During downhill walking, the first force peak was increased compared to level walking due to higher impact [41]. However, it was surprising that for the ipsi and contralateral side in both groups the forward propulsion of the body was higher than the decelerating impulse. This is in contrast to the results of Lay et al. showing higher decelerating forces in healthy, due to increased braking forces when walking downhill [41]. The greater acceleration and decreased deceleration of both UKA groups could result from the moderate angle and the short distance of the ramp, causing no particular need for deceleration. Another reason could be the measurement of the GRF right after movement initiation, where acceleration is needed to increase velocity.

During stair descent, with the highest maximum knee flexion and ground reaction forces, there were no significant differences between the two groups. Another study investigated the kinematics during stair descent between TKA and a matched control group and found significantly lower peak of knee flexion for the TKA group (90.97° vs. 94.05°) [46]. Their results are comparable to our study (conventional UKA: 94.0°, ACL-deficient UKA: 97.3°), particularly indicating that ACL-deficient UKA did not show reduced knee flexion during stair descent, compared to conventional UKA. This is in contrast to TKA when compared against a control group. In a longitudinal evaluation study of stair walking between ACL-intact and ACL-deficient patients, Lepley et al. found no differences for any frontal or sagittal plane joint angles at peak or initial contact [47]. These findings are in line with our hypothesis that ACL-deficient UKA patients show similar function to conventional UKA patients. Nonetheless, a difference in IE rotation during swing phase seems to be detectable especially during stair descent, presenting an increase in internal femoral rotation, peaking in the middle of swing phase [Figure 2]. This may be explained by a low muscle activity during swing phase, in combination with a missing ACL, resulting in higher IE rotation. However, there was no difference in IE rotation throughout the whole gait cycle.

The force magnitudes of the first peak during stair descent were higher for both groups compared to level walking and ramp descent. This is in accordance with Stacoff et al. showing increased vertical forces for both healthy and UKA when comparing to level walking. This indicates achievability to accept high forces with the UKA operated leg during more demanding activities [43]. The accelerating impulse is higher than the decelerating and over a longer portion of stance phase for ipsi- and contralateral side in both groups, indicating gain in velocity over the three steps, similar to ramp descent.

The present work has several limitations, especially linked to other aspects of the study. The moving fluoroscope limits gait velocity due to the acceleration limit of the machine. Further, a band was used for the connection of the position sensor to the implanted leg, which may have an influence on the movement pattern. Furthermore, the maximum elevation height of the moving fluoroscope was 1 m and therefore, only three steps were measured during stair descent, which limits the examination to one full gait cycle. For stair descent and ramp descent, the measurement started short after movement initiation, which can result in lower magnitudes of GRF because of reduced velocity, and higher acceleration to gain speed.

Using optical tracking systems, with skin marker related soft-tissue artefacts, is another limitation. The movement of the skin as well as the muscle contraction do not allow an exact tracking of the underlying bone and consequently influences the results.

It is important to notice our small sample size of only ten and eight patients for the conventional UKA and ACL-deficient UKA group respectively. Due to the limited indication for the ACL-deficient UKA group it was not feasible to increase the sample size at this time.

6.5 Conclusion

The most important finding of this study was that there were no differences in kinematics and kinetics between patients undergoing conventional medial UKA, and patients with a medial UKA presenting ACL deficiency. Overall, more differences were observed in kinetics between the implanted and the contralateral native side, than between the two UKA groups. UKA with a 50% reduction in posterior tibial slope, relative to the native knee, may be an alternative treatment option, for carefully selected patients. It is important to note, that tibial slope reduction intends to compensate for translational instability, while rotational stability of the knee is required for this procedure. Our results indicate good functional outcome of ACL-deficient UKA, however, long-term clinical results are needed to offer specific guidelines for UKA in ACL-deficient patients.

Acknowledgements

This study was funded by the Mäxi Foundation, departmental grants of ETH Zurich and Schulthess Klinik, together with industry support from DePuy Synthes.

The authors would like to thank all IfB members for their previous work establishing hardware and software for the motion laboratory as well as Barbara Postolka and Fabio D'Isidoro for their help during the measurements.

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7 Synthesis

7.1 Achievements and discussion

Osteoarthritis is one of the most prevalent diseases in today's aging population and carries a high economic burden. Current treatment with joint arthroplasty is successful for pain relief and basic mobility, however, patient satisfaction and demanding functionality have room for improvement. While partial knee implants provide good outcomes with similar kinematics to native knees, total knee arthroplasty (TKA) exhibits kinematic abnormalities, resulting in unnaturally feeling knees.

In chapter 2 it was shown that articular surfaces of contemporary knee implants are fundamentally conflicting with native knee anatomy. Therefore, kinematics driven by said implant geometries show abnormalities, in contrast to kinematics resulting from native anatomy, in conjunction with knee ligaments. Contemporary TKA kinematics are known for reduced range of internal/external (IE) rotation and related translational abnormalities, in differential medial and lateral anteroposterior (AP) translation.

Unicompartmental knee arthroplasty (UKA) does not show these kinematic abnormalities due to preservation of the anterior cruciate ligament (ACL), and replacement limited to damaged knee compartments. Hence, UKA is known for better functionality and similar kinematics to healthy native knees. In contrast, the ACL is resected in contemporary TKA and its function is lost, unless otherwise substituted, which is not part of current practice, with the exception of one implant type, substituting for both cruciate ligaments.

Patient expectations are increasing with younger, more active patients requiring joint replacement. With current implant systems, these expectations are not met, unless UKA is indicated and available as a treatment option. These functional benefits over TKA are well known, nonetheless, UKA is used in less than 10% of cases, even though possible indication is reported up to 50% [1,2]. Thus, there is a clinical need for next generation biomimetic TKA designs.

7.1.1 Biomimetic implant design

The first achievement of this thesis was the creation of a biomimetic implant that retains all major ligaments of the knee joint, including the ACL. This was achieved through a biomimetic process that enables the creation of articular surfaces, directly incorporating specific kinematic inputs. The tibial implant was essentially carved out by the native motion of the femoral component. This resulted in a lateral compartment that allows substantial anteroposterior (AP) freedom with a convex surface, and a medial compartment with a concave surface, which comprised of considerable laxity. These findings were consistent with reported differential medial and lateral tibial geometries of native knees [3]. Furthermore, the average cartilage anatomy of our MRI cartilage models was in line with the biomimetic surface.

7.1.2 Dynamic simulations for implant design evaluation

The second achievement was the establishment of a robust computational setup that allows the evaluation of articular surface design and effect of ligament function, with direct comparison to existing implant geometries. While the KneeSIM software was commercially available, it was modified based on the anatomy of the healthy subjects corresponding to the average kinematics used for the biomimetic process.

A biomimetic implant, with ACL and PCL preservation, revealed activity depended kinematics, similar to healthy knees in vivo, in contrast to existing implant systems that retain the PCL, and either preserve or sacrifice the ACL. The ACL sacrificing design showed abnormal kinematics, while the existing ACL-retaining systems showed some improvements, however, to a lesser extent than the biomimetic design (chapter 3). In vivo studies described the importance of the ACL and the effect of implant design on knee kinematics. Banks et al. specifically showed benefits of retaining the ACL, using a similar symmetric implant system (bi-uni), while reporting rotational deficits due to the non-anatomic lateral tibia, in contrast to patients with an implanted medial UKA [4].

Another specific achievement using KneeSIm was the proof of concept for an ACL-substituting mechanism, engaging between femur and tibia, during low knee flexion, when the ACL is active. Simulations of a common articular surface either with a simulated ACL, an absent ACL or with the designed ACL-substituting mechanism revealed similar kinematics between the ACL-substituting mechanism and the simulated ACL. Additionally, these similarities were in line with simulations of an average cartilage model, despite reduced femoral rollback due to required implant constraint. This was in contrast to the simulations without an ACL, showing a posterior femoral shift and abnormal knee motion (chapter 4). Consistently, other simulation studies reported similar effects with substitution of both cruciate ligaments [5,6]. In vitro studies showed femoral shift after ACL resection, and in vivo studies reported abnormalities in ACL-deficient healthy knees and ACL-sacrificing TKA [7–10].

7.1.3 In vivo evaluation of extended treatment indication

A unique setup, consisting of a moving fluoroscope, was used for kinematic evaluation of conventional (intact ACL) and ACL-deficient UKA patients during daily activities. The third achievement of this thesis was the functional justification that ACL-deficiency may not always be a contraindication for UKA implantation. Patients with rotational knee stability and translational laxity due to a deficient-ACL received a UKA, while undergoing a modified surgical technique. By reducing the posterior tibial slope, joint stability was compensating for the missing ACL.

Kinematic analysis revealed minimal differences between the two UKA groups, besides a posterior femoral shift for the ACL-deficient group, particularly present in low knee flexion. However, motion trends remained similar, in contrast to conventional TKA patients, which presented reduced range of motion following the same kinematic evaluation. Ground reaction forces also revealed no differences between the two UKA groups, and minimal implant related asymmetries were found between the ipsi and contralateral leg in either group (chapter 5 and 6). These findings suggest that, from a functional point of view, the indication for UKA can be extended to selected ACL-deficient patients, providing a less invasive treatment option. Considering the posterior femoral shift in ACL-deficient UKA, the tibial slope might be further reduced, following the principles found in vitro by Suero et al. [11]. The effects of ACL deficiency are consistent with other in vivo studies [8–10] and the simulation results in previous chapters. Particularly, the ACL-deficient UKA group provided the opportunity to evaluate the kinematic effect of an anatomical articular surface (intact lateral compartment) in vivo. In ACL-deficient UKA, kinematics are more depending on the articular joint geometry, while conventional UKA kinematics are driven by ACL function. The fact that both UKA groups preserved kinematic trends and range of motion, in contrast to conventional TKA, supports the findings in chapter 2 that a biomimetic surface with an absent ACL can achieve more natural kinematics, than conventional TKA. A posterior femoral shift was also observed for ACL-sacrificing biomimetic TKA in comparison to a simulated ACL, while overall kinematic trends were retained. On the contrary, conventional TKA simulations showed abnormal kinematics with limited range of motion. Therefore, the outcomes of this in vivo study might not only provide useful guidelines regarding UKA in ACL-deficient knees, but also the importance of articular surfaces in general. Hence, improved kinematics following joint arthroplasty may either be achieved by a native joint compartment in UKA (e.g. lateral), or a biomimetic articular surface in TKA, even with an absent or deficient ACL.

7.1.4 Special achievement

A special achievement was the acceptance of a patent (Methods and Devices for Knee Joint Replacement with Anterior Cruciate Ligament Substitution, US 9005299B2) for the ACL-substituting mechanism.

7.2 Limitations and outlook

While this thesis provides novel ways of implant design, and addresses questions regarding the development of next generation knee arthroplasty, there are several limitations to this work.

The process for the creation of biomimetic articular surfaces was based on average kinematics of 40 subjects during one activity. The kinematic influence of individual subjects on the articular surface would be of great value, and the extent of surface variation would be worth evaluating. Additionally, activity dependent kinematics is a known phenomenon as shown by Banks et al. [12], and the effect of using different activities for the creation of biomimetic surfaces would be of interest. However, a high flexion activity was required to allow the whole range of knee motion. Alternatively, individual kinematics or different activities could carve out additional material from the baseline surface, even though the carving process may reduce specific implant features if excessively applied.

Dynamic simulations have general limitations regarding the effectiveness of predicting clinical implications. It is generally unclear if findings from simulations transfer clinical outcomes. Nevertheless, it is a starting point for implementing new technology while in vitro and in vivo evaluations would further strengthen the prediction of clinical success. While not a focus of this thesis, a biomimetic implant designed for PCL-retaining (ACL-sacrificing) TKA has been clinically implemented for an investigational design exemption study in a limited patient population. No biomechanical and kinematic results are currently available for comparison. Our simulations are based on an average model, the output may not represent the average of a population [13]. This means, our kinematic results of the average knee model might not predict average kinematics of individual knee models. Hence, it would be desirable to include individual patient models.

Fluoroscopy provides a valuable tool for in vivo kinematic evaluation of various implant types. Nonetheless, comprehensive analysis is time intensive and expensive, resulting in small sample sizes. Additionally, this study was bound to a small sample size due to a patient population with a limited treatment indication. The use of single plane fluoroscopy poses limitations for accuracy in component placement particularly relevant for this study with UKA implants only replacing one condyle of the knee joint. This results in a higher error for out-of-plane rotations due to the limited component width and features in the out-of-plane direction, when measuring from a lateral view. However, accuracy was validated indicating a reasonable error for kinematic evaluation. A clinical limitation was the prediction of long-term effects related to implant longevity due to the reduced posterior slope and the posterior femoral shift found in this analysis.

While ACL-deficient UKA is not equivalent to any of the designs evaluated with dynamic simulations, the comparison to conventional UKA with an intact ACL provides valuable findings, adding to the philosophy of biomimetic implant design. Unfortunately, in vivo analysis of the simulated implants could not be achieved as part of this thesis.

7.3 Overall conclusions

This thesis identified required changes in implant design to meet the clinical need of normal feeling knees, following joint arthroplasty.

ACL preservation and anatomic articular surface are crucial for normal knee function, following joint arthroplasty. However, if either the ACL or anatomic surface is retained, patients can benefit from improved functionality. This implies that, treatment indications of UKA can be extended for selected ACL-deficient patients, providing a functional benefit. Next generation implants should be designed based on anatomy and kinematics, and if ACL preservation is not a viable treatment option, ACL-substitution and biomimetic articular surfaces may additionally improve ACL-deficient TKA.

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Appendix

A-1 Knee Simulator Wear Test (Chapter 3)

The wear performance of the biomimetic BCR design manufactured from vitamin-E stabilized highly cross-linked ultra-high molecular weight polyethylene (UHMWPE) was compared to that of a bi-uni system (MCK UKA; MAKO Surgical, Fort Lauderdale, FL) manufactured from the same material using knee simulator wear tests. Additionally the same bi-uni design was tested with tibial inserts manufactured from conventional UHMWPE. All sets of tibial bearings articulated against corresponding CoCr femoral components and for all implant systems the largest available size pairings were used for all tests. All inserts were tested on an AMTI 6-station displacement controlled knee simulator (AMTI, Watertown, MA) for 5 million cycles (MC) of simulated walking at a rate of 1 Hz. The wear test study was conducted according to ISO 14243-3 with an increased compressive peak load of 3200 N. Gravimetric assessment of wear was conducted to calculate the average wear rate through linear regression between 0.5 MC and 5 MC.

The data from the wear test showed an average incremental wear rate of 14.23 ± 0.87 mg/MC for the biomimetic BCR design and 12.86 ± 1.35 mg/MC for the bi-uni system machined from the same advanced material. The average incremental wear rate for the bi-uni system machined from the conventional material was 78.85 ± 17.63 mg/MC (Figure A-2-1). T-test statistical analysis showed no significant difference in wear rate between the biomimetic BCR implant and the bi-uni system ($p=0.210$), both manufactured from vitamin-E stabilized highly cross-linked UHMWPE. However, significant differences were found between the wear rates for the bi-uni system manufactured from vitamin-E stabilized UHMWPE vs. conventional UHMWPE ($p<0.01$). This ensures that the use of a biomimetic design does not affect the wear benefits of such advanced polyethylene materials.

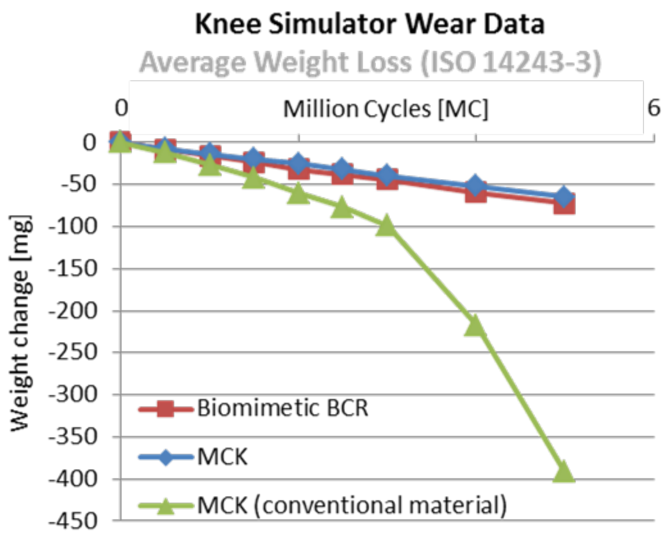

Figure A-2-1: *Wear test results of the biomimetic BCR design and the MCK bi-uni system (vitamin-E stabilized polyethylene) as well as the MCK bi-uni system with conventional polyethylene for 5 MC of simulated walking.*

There was a geometric difference in the femoral component used for the wear test experiments due to the nature of the tested implant types (BCR vs. bi-uni), which may or may not have an effect on wear performance. Another limitation is the use of standard ISO kinematics for wear testing, which may not represent true in vivo motions considering different implant designs. However, the ISO kinematics for wear testing is an industry-wide standard used to assess wear behavior of tibial components.

A-2 Additional KneeSIM Simulations (Chapter 4)

Methods

Further implants were tested by using dynamic computational simulations performed in KneeSIM software (LifeModeler, San Clemente, CA) to evaluate kinematics of the ACL-substituting design (ASCR) against commercially available implants.

Therefore, kinematics of the ASCR implant were also compared to that of a widely used contemporary ACL-sacrificing CR TKA (NexGen CR, Zimmer, Warsaw, IN), and an existing ACL-retaining implant (TKO BCR, Biopro, Port Huron, MI). The implant geometries and sagittal cross-sections are shown in **Figure A-3-1** and the same activities were simulated.

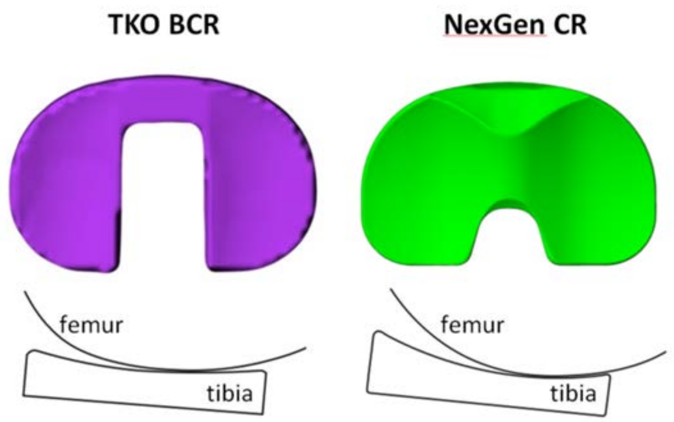

Figure A-3-1: *Additional implants tested in KneeSIM (TKO BCR and NexGen CR) together with a sagittal cross-section of the femur on the tibia*

The simulations were also carried out with ideal (normative) component placements, mounted perpendicular to the mechanical axis on the average bone models with a tibial posterior slope of 7°. The same tibiofemoral kinematic parameters were analyzed for a direct comparison to the ASCR implant and the native knee with a particular interest in posterior femoral shift in extension relative to KneeSIM's built-in local tibial coordinate system.

Results

The results for the NexGen CR implant revealed notable posterior femoral shift in extension relative to the native knee for all simulated activities (7 mm - 10 mm), which was the most of all tested implants (**Figure A-3-2**). The TKO BCR implant did not show this posterior femoral shift in extension relative to the native knee, which is in line with the ASCR and BCR implants analyzed in this study. Overall, the NexGen CR implant showed similar abnormalities to the tested CR implant in this study, including posterior femoral shift in extension followed by paradoxical anterior sliding. The femur only moved posterior on the tibia with deeper knee flexion and no overall femoral rollback was observed in any activity. The TKO BCR showed results more closely resembling the native knee as well as the ACL-substituting and ACL-retaining implants of this study. Particularly, there was no excessive posterior femoral shift in extension; however, reduced femoral rollback was observed compared to the implants evaluated in this study and the native knee (**Table A-3-1**).

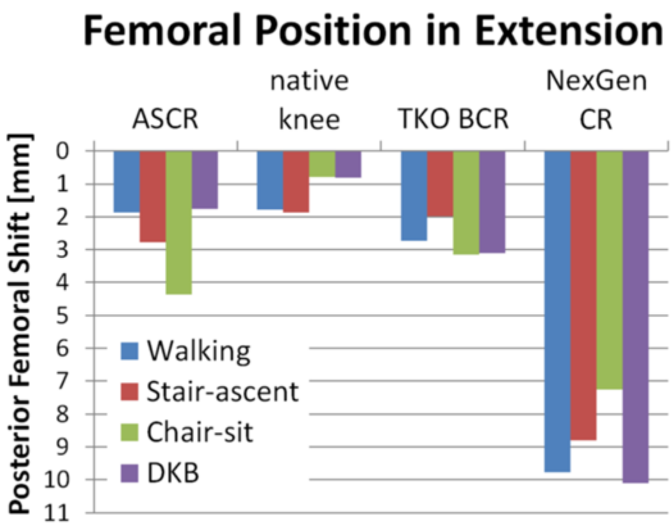

Figure A-3-2: *Additional implants tested in KneeSIM (TKO BCR and NexGen CR) together with a sagittal cross-section of the femur on the tibia*

Table A-3-1: *Femoral posterior rollback (average of medial and lateral condyle) relative to full extension in KneeSIM [mm]*

Knee Flexion	15°	30°	60°	90°	105°	120°	135°
Walking							
ASCR	3.7	1.1	0.7				
native knee	3.0	3.7	2.2				
TKO BCR	1.3	0.2	-0.3				
NexGen CR	-2.4	-5.2	-9.0				
Stair-ascent							
ASCR	1.7	-2.0	-1.2	3.1			
native knee	4.0	5.9	5.3	5.4			
TKO BCR	1.1	-1.0	-0.7	2.3			
NexGen CR	-3.4	-7.2	-8.6	-5.3			
Chair-sit							
ASCR	0.7	0.1	-2.0	0.8	5.0		
native knee	0.0	5.0	8.0	8.0	10.4		
TKO BCR	0.1	2.0	0.4	0.1	2.9		
NexGen CR	0.1	-2.0	-4.8	-4.3	-1.3		
DKB							
ASCR	3.2	3.5	2.0	4.3	5.8	7.3	8.0
native knee	2.3	5.2	11.5	15.5	17.0	18.8	20.8
TKO BCR	0.2	1.9	4.5	3.0	3.2	2.9	2.4
NexGen CR	-1.4	-3.9	-5.7	-6.0	-4.8	-3.8	-2.8

Course Work

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- T Zumbrunn, K Varadarajan, H Rubash, H Malchau, G Li, O Muratoglu; Is ACL retention together with an anatomical articular surface required to restore normal, activity dependent knee kinematics?; *EFORT*, Prague, CZE, 2015
- T Zumbrunn, H Malchau, H Rubash, O Muratoglu, K Varadarajan; An Anatomical Test Setup for Evaluation of Anterior Cruciate Ligament Strength in Cadaver Knees; *EFORT*, Prague, CZE, 2015
- K Varadarajan, **T Zumbrunn**, M Duffy, R Patel, H Rubash, H Malchau, A Freiberg, O Muratoglu; Large Femoral Heads Used in Traditional Total Hip Arthroplasty Can Impinge Against the Iliopsoas; *EFORT*, Prague, CZE, 2015
- A Nebergall, A Freiberg, M Greene, H Malchau, O Muratoglu, S Rowell, **T Zumbrunn**, K Varadarajan; Soft-Tissue Impingement of Dual Mobility Liners as a Proposed Mechanism of Intraprosthetic Dislocation; *EFORT*, Prague, CZE, 2015
- T Zumbrunn, K Varadarajan, H Rubash, H Malchau, G Li, O Muratoglu; Can Simulated Activities Confirm the Need of Anatomical Articular Surface Together with ACL Preservation to Restore Normal Activity Dependent Knee Kinematics?; *MGH SAC*, Boston, MA, 2015
- A Nebergall, A Freiberg, M Greene, H Malchau, O Muratoglu, S Rowell, T Zumbrunn, K Varadarajan; Soft-Tissue Impingement in Dual Mobility Components: A Proposed Mechanism of Intraprosthetic Dislocation using Cadaver Models and Retrievals; *MGH SAC*, Boston, MA, 2015
- T Zumbrunn, K Varadarajan, H Rubash, H Malchau, G Li, O Muratoglu; Can Simulated Activities Confirm the Need of Anatomical Articular Surface Together with ACL Preservation to Restore Normal Activity Dependent Knee Kinematics?; *ORS*, Las Vegas, NV, 2015
- T Zumbrunn, K Varadarajan, M Duffy, H Rubash, H Malchau, A Freiberg O Muratoglu; Simulations Based on Various In Vivo Activities to Analyze Micro-Separation in Total Hip Implants; *ORS*, Las Vegas, NV, 2015
- K Varadarajan, T Zumbrunn, M Duffy, H Rubash, H Malchau, A Freiberg, O Muratoglu; Anatomically Contoured Dual Mobility Insert Mitigates Soft-tissue Impingement and Insert Entrapment: A Cadaver Verification Study; *ORS*, Las Vegas, NV, 2015
- K Varadarajan, T Zumbrunn, H Rubash, H Malchau, G Li, O Muratoglu; Kinematic and Wear Performance of a Novel Cruciate Retaining Biomimetic Implant Manufactured from Advanced Vitamin-E Stabilized Material; *ORS*, Las Vegas, NV, 2015
- S Rowell, M Duffy, T Zumbrunn, K Varadarajan, O Muratoglu; Frictional Torque In Highly Cross-liked Acetabular Liners After In Vivo Service; *ORS*, Las Vegas, NV, 2015
- A Nebergall, A Freiberg, M Greene, J Langlois, H Malchau, O Muratoglu, S Rowell, A Troelsen, T Zumbrunn, K Varadarajan; Assessment Of The Mechanisms Of Rim Damage In Dual Mobility Polyethylene Inserts Using Retrievals And Cadaver Models; *ORS*, Las Vegas, NV, 2015
- K Varadarajan, T Zumbrunn, M Duffy, H Rubash, H Malchau, O Muratoglu; Can Anterior Cruciate Substitution Address Abnormal Kinematics of Posterior Cruciate Retaining Implants?; *AAOS*, Las Vegas, NV, 2015
- K Varadarajan, T Zumbrunn, M Duffy, H Rubash, H Malchau, **O Muratoglu**; A Novel Anterior Cruciate Substituting Implant Can Address the Abnormal

Femoral Sliding in Contemporary Cruciate Retaining Total Knee Arthroplasty; *ISTA*, Kyoto, JPN, 2014

- K Varadarajan, T Zumbrunn, M Duffy, H Rubash, H Malchau, A Freiberg, **O Muratoglu**; Anatomically Contoured Dual Mobility Insert Mitigates Soft-Tissue Impingement and Insert Entrapment: A Cadaver Verification Study; *ISTA*, Kyoto, JPN, 2014
- O Muratoglu, T Zumbrunn, K Varadarajan, M Duffy, H Rubash, H Malchau, A Freiberg; Simulated Micro-Separation in Total Hip Implants Based on Various In Vivo Activities; *The Hip Society Meeting*, Durham, NC, 2014
- T Zumbrunn, K Varadarajan, H Rubash, H Malchau, G Li, B Micheli, K Wannomae, O Muratoglu; Biomimetic Total Knee Arthroplasty with Anterior Cruciate Ligament Preservation Restores Normal Kinematics and Reduces Implant Wear; *WCB*, Boston, MA, 2014
- K Varadarajan, T Zumbrunn, H Rubash, H Malchau, O Muratoglu, G Li; Reverse Engineering Nature to Design Biomimetic Total Knee Arthroplasty Implants; *WCB*, Boston, MA, 2014
- M Duffy, K Varadarajan, T Zumbrunn, K Wannomae, D Chan, B Micheli, H Rubash, A Freiberg, H Malchau, O Muratoglu; A Novel Large Diameter Femoral Head for Soft-tissue Relief Maintains Load Bearing Contact Area, Frictional Characteristics and Wear Performance in Ceramic on Poly Articulation; *WCB*, Boston, MA, 2014
- K Varadarajan, M Duffy, T Zumbrunn, A Freiberg, H Rubash, H Malchau, O Muratoglu; A Novel Anatomically Contoured Dual Mobility Insert To Alleviate Soft Tissue Impingement; *EFORT*, London, GBR, 2014
- M Duffy, K Varadarajan, K Wannomae, D Chan, B Micheli, T Zumbrunn, H Rubash, A Freiberg, H Malchau, O Muratoglu; Anatomical Contouring Of Large Diameter Heads For Soft-Tissue Relief Does Not Impact Load Bearing Contact Area And Wear Performance In Ceramic On Polyethylene Articulation; *EFORT*, London, GBR, 2014
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- T Zumbrunn, K Varadarajan, H Rubash, H Malchau, G Li, B Micheli, K Wannomae, O Muratoglu; Biomimetic Total Knee Arthroplasty with Anterior Cruciate Ligament Preservation Restores Normal Kinematics and Reduces Implant Wear; *ORS*, New Orleans, LA, 2014
- K Varadarajan, T Zumbrunn, H Rubash, H Malchau, G Li, O Muratoglu; Total Knee Arthroplasty (TKA) Implant Should be designed with Pivot Center Located beyond the Medial Edge of the Tibia; *ORS*, New Orleans, LA, 2014
- K Varadarajan, T Zumbrunn, M Duffy, H Rubash, H Malchau, O Muratoglu; A Novel Anterior Cruciate Substituting Implant can address the Abnormal Femoral Sliding in Contemporary Cruciate Retaining Total Knee Arthroplasty; *ORS*, New Orleans, LA, 2014
- B Micheli, K Varadarajan, T Zumbrunn, K Wannomae, O Muratoglu; In-vitro Comparison Of Aged Conventional CR Tibial Bearings Vs Aged Vitamin E Biomimetic Bearings; *ORS*, New Orleans, LA, 2014

- K Varadarajan, M Duffy, T Zumbrunn, A Freiberg, H Rubash, H Malchau, O Muratoglu; A New Soft Tissue Friendly Femoral Head may also Reduce Frictional Torque in Ceramic-on-Ceramic Articulation; *ORS*, New Orleans, LA, 2014
- M Duffy, K Varadarajan, D Chan, K Wannomae, B Micheli, T Zumbrunn, H Rubash, A Freiberg, H Malchau, O Muratoglu; Anatomical Contouring of Large Diameter Heads for Soft-tissue Relief Does Not Impact Load Bearing Contact Area and Wear Performance in Ceramic on Poly Articulation; *ORS*, New Orleans, LA, 2014
- K Varadarajan, T Zumbrunn, H Rubash, H Malchau, G Li, O Muratoglu; Total Knee Arthroplasty (TKA) Implant Should be designed with Pivot Center Located beyond the Medial Edge of the Tibia; *AAOS*, New Orleans, LA, 2014
- T Zumbrunn, K Varadarajan, H Rubash, H Malchau, G Li, O Muratoglu; Biomimetic Total Knee Arthroplasty with Anterior Cruciate Ligament (ACL) Preservation Restores Normal Kinematics; *ISTA*, Palm Beach, FL, 2013
- T Zumbrunn, K Varadarajan, H Rubash, H Malchau, G Li, O Muratoglu; Role of Articular Surface Design in Posterior Cruciate Ligament (PCL) Sacrificing Total Knee Arthroplasty Implants; *ISTA*, Palm Beach, FL, 2013
- T Zumbrunn, K Varadarajan, M Duffy, H Rubash, H Malchau, A Freiberg, O Muratoglu; Anatomically Shaped Large Femoral Heads Can Reduce Hip Dislocation Risk while Avoiding Soft Tissue Impingement; *ISTA*, Palm Beach, FL, 2013
- T Zumbrunn, K Varadarajan, M Duffy, H Rubash, H Malchau, A Freiberg, O Muratoglu; An Anatomically Shaped Dual Mobility Liner Can Reduce Dislocation Risk and Soft Tissue Impingement; *ISTA*, Palm Beach, FL, 2013
- K Varadarajan, T Zumbrunn, H Rubash, H Malchau, O Muratoglu, G Li; Reverse Engineering Nature to Design Total Knee Arthroplasty (TKA) Implants that Allow More Normal Knee Motion; *ISTA*, Palm Beach, FL, 2013
- K Varadarajan, T Zumbrunn, H Rubash, H Malchau, G Li, O Muratoglu; Cruciate Retaining Biomimetic Implant Can Restore Normal Kinematics following Total Knee Arthroplasty (TKA); *ISTA*, Palm Beach, FL, 2013
- K Varadarajan, T Zumbrunn, M Duffy, H Rubash, H Malchau, A Freiberg, O Muratoglu; A New Anatomically Contoured Dual Mobility Insert to Alleviate Soft Tissue Impingement in Total Hip Arthroplasty; *ISTA*, Palm Beach, FL, 2013
- K Varadarajan, M Duffy, T Zumbrunn, H Rubash, H Malchau, A Freiberg, O Muratoglu; A New Anatomically Contoured Large Diameter Femoral Head to Alleviate Soft-Tissue Impingement in Hip Arthroplasty; *ISTA*, Palm Beach, FL, 2013
- M Duffy, K Varadarajan, T Zumbrunn, H Rubash, H Malchau, A Freiberg, O Muratoglu; Large Diameter Heads Can Be Anatomically Contoured for Soft-Tissue Relief Without Affecting Their Contact Area; *ISTA*, Palm Beach, FL, 2013
- M Duffy, K Varadarajan, T Zumbrunn, H Rubash, H Malchau, A Freiberg, O Muratoglu; Anatomically Contoured Dual Mobility Liner for Soft-Tissue Relief Maintains Head Retention and Contact Area; *ISTA*, Palm Beach, FL, 2013
- K Varadarajan, T Zumbrunn, M Duffy, **H Rubash**, H Malchau, A Freiberg, O Muratoglu; A New Anatomically Contoured Dual Mobility Insert to Alleviate Soft Tissue Impingement in Total Hip Arthroplasty; *The Hip Society Meeting*, Charleston, SC, 2013

- K Varadarajan, T Zumbrunn, **H Rubash**, H Malchau, G Li, O Muratoglu; Cruciate Retaining Biomimetic Implant Can Provide More Normal Kinematics following Total Knee Arthroplasty (TKA); *The Knee Society Meeting*, Toronto, CAN, 2013
- T Zumbrunn, B MacWilliams, B Johnson; Single Leg Balance in Typically Developing Children and Patients with CEV; *JEGM*, Miami, FL, 2010

AWARDS

- Best poster awards (3rd place); *ISTA*, Kyoto, JPN (2015)
- Nicholas Rhinelander Spirit in Service Award, *Harvard University* (2015)
- CD Reddish Memorial Leadership Award, *University of Utah* (2010)
- Athletic Scholarship NCAA Division I Skiing, *University of Utah* (2007-10)
- NCAA All Academic Scholar (2007-10)
- MWC Scholar Athlete (2007-10)
- Outstanding performance Award, *University of Utah* (2009)
- RMISA All Conference Team (2007-09)

MEMBERSHIPS

- Gait and Clinical Movement Analysis Society, GCMAS (2010-12)
- European Society for Biomechanics, ESB (2016-17)

LANGUAGES

- **German**, **English**, French

EXTRACURRICULAR ACTIVITIES

Head of Alpine Skiing at Swiss University Sports, SHSV (2016-present)

Chief of Alpine Skiing at Swiss Academic Skiclub, SAS (2016-present)

Ski Instructor at Schweizer Skischule Meiringen-Hasliberg (2012-17)

Volunteer Coach at Harvard University Ski Team (2010-15)

Member of University of Utah Ski Team (2007-2010)

Board Member at Swiss Academic Skiclub, SAS Zurich (2006-09)

Executive Staff Assistant; Civil Protection, Swiss Confederation; SUI (2005-present)

Personal Trainer (2005-17)

Member of Swiss Academic Ski Team (2004-11)

Member of Swiss National Ski Team (2002-03)