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Assessing the Impact of Surgical Technique on Implant Migration, Tibiofemoral Contact Kinematics, and Functional Recovery Following Uncemented Total Knee Arthroplasty

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Abstract

The standard of care treatment for end-stage osteoarthritis of the knee joint is a total knee arthroplasty (TKA). As we move towards a younger TKA patient cohort, implant longevity is of increasing concern. Porous hydroxyapatite coated uncemented implants provide a promising alternative to cemented fixation methods. Currently, a lack of consensus exists regarding which surgical technique is best suited to the uncemented TKA procedure. This thesis sought to examine the impact of surgical technique on tibial and femoral component migration. Additionally, we investigated the impact of technique on post-operative kinematics and functional recovery. The results of this thesis indicate no significant effect of surgical technique on one year migration of the tibial and femoral components or on post-operative kinematics, condylar liftoff, and function. In conclusion, this thesis provides support for the use of a single-radius cruciate-retaining porous hydroxyapatite coated uncemented implant as a viable alternative to cemented TKA.

Keywords

Osteoarthritis; Total Knee Arthroplasty; Orthopaedic Surgery; Gap Balancing; Measured Resection; Radiostereometric Analysis; Implant Migration; Knee Kinematics; Function; Timed-Up-and-Go Test

Co-Authorship Statement

This study was designed by Drs. Matthew Teeter and Brent Lanting. I was solely responsible for executing the study protocol. This included patient screening/identification and recruitment. Additionally, I was responsible for all data collection, radiostereometric image analysis, and data analysis. I was also responsible for the draft of this thesis document. Drs. Teeter and Lanting provided commentary and suggestions throughout the experimental process, guidance on data interpretation, and editorial insight. Drs. Brent Lanting and James Howard were responsible for performing the surgeries in the gap balancing and measured resection groups, respectively.

This thesis is written as an integrated article thesis. Chapters 2 and 3 will be combined and submitted as one article which details the impact of a gap balancing or measured resection surgical technique on both implant migration and tibiofemoral contact kinematics.

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List of Abbreviations

ACL	Anterior Cruciate Ligament
APA	Anterior-Posterior Axis
CR	posterior Cruciate Retaining
GB	Gap Balancing
HA	Hydroxyapatite
HRQOL	Health Related Quality of Life
IMUs	Inertial Measurement Units
KSS	Knee Society Score
LCL	Lateral Collateral Ligament
MCL	Medial Collateral Ligament
dMCL	Deep Medial Collateral Ligament
sMCL	Superficial Medial Collateral Ligament
MSK	Musculoskeletal
MR	Measured Resection
MTPM	Maximum Total Point Motion
OA	Osteoarthritis
PCA	Posterior Condylar Axis
PCL	Posterior Cruciate Ligament
PCWL	Productivity Costs of Work Lost
PROMs	Patient Reported Outcome Measures
PS	Posterior Stabilized or Posterior Cruciate Sacrificing
RSA	Radiostereometric Analysis
ROM	Range of Motion
SF-12	Short Form 12
TEA	Transepicondylar Axis
TKA	Total Knee Arthroplasty
TUG	Timed-up-and-go Test
UCLA	University of California, Los Angeles Activity Score
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

Chapter 1

1 Introduction

1.1 Osteoarthritis

1.1.1 Etiology

Osteoarthritis (OA) is a chronic degenerative disease of the articular synovial joint.[1,2] Under healthy conditions, cartilage provides a smooth lubricated surface for articulating movement and facilitates the proper transmission of load throughout the joint.[2] Healthy cartilage can tolerate enormous amounts of repetitive physical loads.[1] OA arises when the dynamic equilibrium between the breakdown and regeneration of joint tissues becomes unbalanced, shifting in favour of catabolic processes.[1] Over time, the joint experiences extensive deterioration of the articular cartilage and subsequent structural and functional changes to the joint space which can involve subchondral bone remodelling, osteophyte formation, and synovial inflammation.[1] As debilitating symptoms are often what prompts patients to seek assistance from a medical professional, diagnosis is often made in the later stages of disease. Using plain film radiography, hallmarks of end-stage disease such as cartilage degradation, narrowing of the joint space, osteophyte formation, and subchondral sclerosis can be identified.[1]

Insight into OA development is provided from large population based longitudinal studies.[1] The disease is known to have a multifactorial pathophysiology involving genetic, biomechanical, and environmental components.[1,2] Major risk factors previously identified include female biological sex, age, obesity, and the presence of cardiovascular disease, Type II diabetes, or metabolic disease.[2] Abnormal biomechanical load transmission within a susceptible joint can place additional stress on that joint resulting in further destabilization. Load transmission is impacted by anatomical and functional factors, such as tibial and femoral bone morphology, quadricep strength, lower limb alignment, and leg length discrepancy.[2] Thus, a heightened risk can result from the interaction between atypical joint biomechanics and genetic, systemic, and environmental factors. The complexity of OA has resulted in a lack of complete understanding of the disease etiology which only adds to the burden of this disease.

1.1.2 Burden of Disease

In the province of Ontario, musculoskeletal (MSK) conditions represent 40% of all chronic conditions and 54% of all long term disability.[3] The most common MSK disease worldwide is OA.[4] More prevalent in females than males and in older individuals, the World Health Organization estimates that 10% of males and 18% of females over the age of 60 report having symptomatic OA.[5] The level of disability that accompanies OA is highly individualized. Detrimental physical and psychological problems and socioeconomic effects are observed for the affected individual, their families, and society.[6] This burden is expected to rise dramatically as we have both a greater number of older people and a continual trend towards the adoption of more sedentary lifestyles, secondary to obesity.[3]

Specifically, with respect to OA, physical impairments can contribute to large declines in patient functioning. Patients often experience immense pain and joint stiffness in their large weightbearing joints resulting in significant levels of disability.[3,6] In turn, the performance of self-care and instrumental activities of daily living, such as walking, standing, lifting, stair ascension and descension, and getting up and down, become very taxing. Affected individuals often must rely on caregivers for assistance, which places further limitations on their independence.[7] While OA does not result in mortality, the health-related quality of life (HRQOL) impact of the disease on older individuals is considered comparable to patients with advanced cancer.[8,9]

The link between physical impairment as a result of pain and poor functioning and psychological well-being amongst OA patients is well established.[10] Physical limitations are often found to be the mediator between physical pain and a more depressed affect.[10] Furthermore, due to physical restrictions patients report reduced participation in social activities, such as visiting friends and shopping, which in turn, contributes to a greater likelihood of exhibiting depressive symptomology.[10] Under these assumptions, the physical disability one experiences, secondary to OA, also becomes a social disability and restricts their performance of customary and valued social activities.[10]

As a result of the widespread physical and psychological burden of OA on both a national and global level, the disease subsequently has a substantial economic burden. Healthcare resource utilization is the primary contributor to the direct costs of OA. In Canada, it is projected that by 2031 the direct cost of OA will increase to $7.6 billion.[11] Of this $5.8 billion will be spent on hospitalization, outpatient services, prescription drugs, and rehabilitation (all monetary values presented in Canadian Dollars).[11] The economic implications of OA are further intensified indirectly by the productivity costs of work lost (PCWL). PCWL associated with OA include, for example, long-term sick leave, disability, or early retirement for OA related disability.[12] As both the working population and OA prevalence continues to grow, this cost is expected to substantially rise. Current projections estimate that by 2031 the PCWL associated with OA will rise to $17.5 billion dollars, with almost 30% of the labour force reporting symptomatic OA by the year 2040.[12,13]

1.1.3 Treatment Options

Once a diagnosis of OA is made there are various non-surgical and surgical treatment options available. Unfortunately, because of the complex multi-factorial etiology of OA, no disease modifying osteoarthritic drugs exist. Even if pharmaceutical agents capable of preventing OA progression are developed, it will be years before the efficacy of these agents can be established and developed for public use.[2]

Conservative non-surgical treatment options involve lifestyle modifications, such as weight loss management through diet and exercise, pain management, intra-articular injections, and bracing.[14] While the full benefit of lifestyle modifications needs to be better elucidated, weight loss and improvements in muscle strength and aerobic capacity have shown to improve OA symptomology while benefiting cardiovascular health and all-cause mortality.[4,14] Pharmaceutical pain management is centred around non-steroid anti-inflammatory agents which are used to reduce joint inflammation.[4,14] Intra-articular injections involving corticosteroids or growth factors have been shown to improve symptoms but do not contribute to any structural modification within the joint space.[2]

In most cases, non-surgical treatment options do not provide long-term effective relief of OA symptomology. For patients who have exhausted all non-operative options, several surgical options exist and include: a high tibial osteotomy, a unicompartmental knee arthroplasty, and a total knee arthroplastsy.[15,16] Nonetheless, the gold standard treatment for end-stage knee OA is a total knee arthroplasty (TKA).[15]

1.2 Total Knee Arthroplasty

1.2.1 Basic Knee Anatomy

In order to better understand the goals and principles of the TKA procedure, a basic understanding of knee anatomy is required. The knee joint combines bone, cartilage, menisci, ligaments, tendons, synovium, a joint capsule, and synovial fluid to create an articular surface between the upper and lower leg.[17] More specifically, the knee is comprised of a condylar joint between the femoral condyles and tibia and a saddle joint between the posterior surface of the patella and the anterior articular surface of the distal femur.[17] Therefore, conceptually, the knee is comprised of two joints, a tibiofemoral joint and a patellofemoral joint.[18] Together, the knee acts as a modified hinge joint, allowing for flexion, extension, translation, and slight internal and external rotation. Knee joint anatomy is depicted in Figure 1.

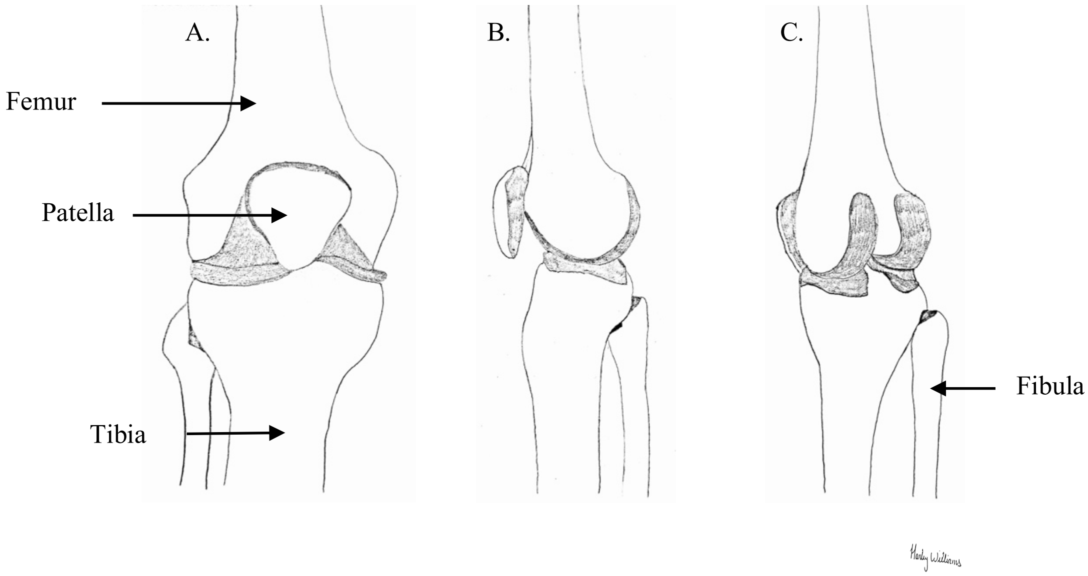

Figure 1: Bone anatomy of the knee (A) anterior, (B) lateral, and (C) posterior views.

The tibiofemoral joint is the primary joint of the knee. The dynamic and static stability of the tibiofemoral joint results from a complex interplay of various structures within and around the joint.[18] Dynamically, muscles acting on or across the joint, such as the quadriceps and hamstrings, provide dynamic stability to the anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL).[17,18] The ACL originates from the lateral femoral condyle and inserts on the medial and anterior aspect of the tibial plateau.[19] The ACL resists anterior displacement of the tibia relative to the femur.[18] The PCL originates from the antero-lateral aspect of the medial femoral condyle in the area of the intercondylar notch and inserts over the back of the tibial plateau.[19] The PCL resists posterior displacement of the tibia relative to the femur.[18] Soft tissue anatomy is depicted in Figure 2. Muscles are also involved in the stability of the joint, in addition to the medial and lateral collateral ligaments and the two menisci.[18,19]

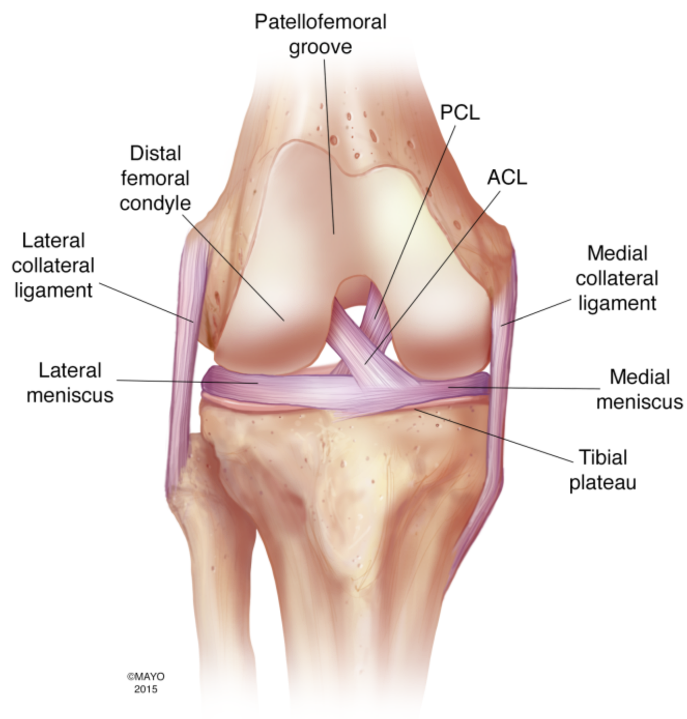

Figure 2: Soft tissue anatomy of the knee. Reproduced with permission from Dr. Kevin Perry.[19]

The medial meniscus is broader and more c-shaped than its lateral counterpart, however, and it is thinner throughout the body and anchored firmly to the anterior surface of the tibia, medial collateral ligament, and joint capsule.[18] The lateral meniscus is more circular than the medial meniscus and covers a greater portion of the lateral articular surface. Unlike the medial meniscus, the lateral meniscus does not attach onto the lateral collateral ligament and attaches less firmly to the joint capsule. This makes the lateral meniscus more mobile than the medial meniscus and less likely to tear.[17,18] Both meniscal structures are made of fibrocartilaginous tissue and have a number of biomechanical funtions.[18] The meniscal structures primarily act to absorb load and deepen the shallow elliptical cavities of the tibial condyles which provides stability and helps facilitate articular movement within the joint.[18]

The extracapsular ligaments are the medial collateral ligament (MCL) and the lateral collateral ligament (LCL) which further stabilize the joint by resisting varus and valgus rotation.[19] The MCL is composed of both a deep (dMCL) and superficial (sMCL) component. The dMCL is responsible for providing passive rotational stability to the joint in a position of extension and early flexion.[20]. The sMCL is acknowledged as a primary stabilizer of the knee and is responsible for minimizing any anterior translation of the medial tibia.[20,21] Together, the dMCL and sMCL act antagonistically to any applied valgus force.[20] The responsibilities of the LCL are twofold: primarily, it is responsible for providing restraint to any applied varus forces and secondarily, limiting anterior-posterior translation of the tibia.[19]

The muscles surrounding the knee are the final structures relevant to understanding the functionality of the articulating joint. The quadriceps, located on the anterior aspect of the thigh or upper leg, are responsible for extension of the tibia.[18] The hamstrings, located on the posterior aspect of the thigh or upper leg, are responsible for facilitating knee flexion.[18]

The knee joint is a very complex system that relies on proper functioning components in order to facilitate the wide variety of movement the joint is capable of performing. Consequently, this complexity makes joint replacement an extremely difficult task.

1.2.2 Principles of Total Knee Arthroplasty

A TKA, or the surgical reconstruction of the knee joint through the implantation of artificial components, is the standard of care treatment for end-stage OA of the knee.[22] For patients, a TKA is reserved as the final step to restore their quality of life and joint function and is a viable option when conservative non-operative treatments have failed to mitigate their symptoms.[11]

In general, the procedure involves replacing the diseased distal femur and proximal tibia, and occasionally the patella, with artificial components.[23] Thus, the prosthesis is comprised of both a metal femoral and tibial component. The femoral component has two spheroidal condylar bearing surfaces, mimicking the natural anatomy of the medial and lateral femoral condyles.[24] The tibial component includes a flat tibial platform.[24] Placed in between the metal femoral condylar bearing surface and tibial platform is an ultra high molecular weight polyethylene insert. Depending on the design of the prosthetic components, the polyethylene insert is either free floating (mobile) or fixed to the tibial component.[25] The polyethylene acts to reduce the frictional force between the two components and aids in establishing smooth articulation between the implanted prosthesis (Figure 3).[25,26] In situations where the patella is replaced, a dome-shaped polyethylene cap is also implanted.[24]

Figure 3: Total knee arthroplasty prosthesis components.

While many nuances of the TKA procedure are disputed between arthroplasty surgeons, there is a basic set of procedure goals that are widely accepted amongst them. Firstly, adequate visualization of the entire joint is required for successful implantation of the prosthesis.[27,28] The medial parapatellar incisional approach is the most commonly used incisional approach for TKA, primarily for its simplicity and excellent exposure of all three joint compartments.[29]

Another widely held assumption amongst arthroplasty surgeons is that following TKA the mechanical axis of the lower limb should be realigned to a neutral position. This involves correcting any pre-operative deformities (either a varus or valgus alignment) to a neutral position. Common variations in lower limb alignment are demonstrated in Figure 4. When the knee is in a neutral position the load applied across the joint is equally distributed between the medial and lateral articulating surfaces. Malalignment post-TKA has been linked to increased polyethylene wear rates, decreased function, and early implant failure, and therefore a neutral position is desired.[30–32] Neutral alignment is achieved through a combination of both bone resection and soft tissue release.

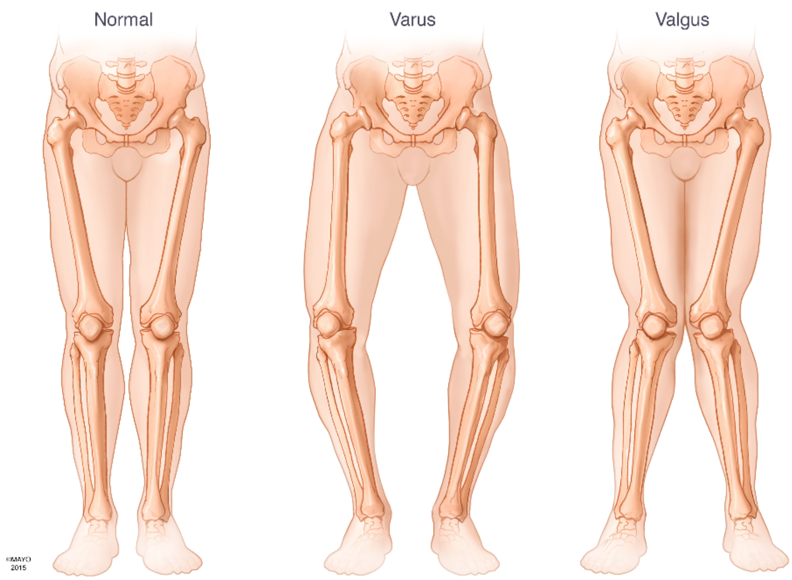

Figure 4: Demonstrating valgus, neutral, and varus alignment of the lower limb. Reproduced with permission from Dr. Kevin Perry.[19]

Accordingly, balancing the soft tissues around the knee joint is a goal of TKA surgery.[33] Additionally, surgeons aim to achieve balanced gaps within the joint space with the limb in a position of flexion and extension. This involves establishing equal symmetrical gaps between the femur and tibia in both the medial and lateral compartments of the knee. When the tissues are balanced correctly, the knee is said to be in a stable position. Balance assessment by the surgeon is subjective and the sequence of releases varies based on personal preference. Nevertheless, surgeons aim to achieve symmetrical balanced gaps in the joint space in order to improve implant longevity and patient outcomes.[34]

Consequently, the standard of care intraoperative objectives for a TKA are to: achieve a neutral limb alignment, restore and maintain the joint line, obtain well positioned stable femoral and tibial components, and achieve proper soft tissue balancing.

1.3 Surgical Technique

1.3.1 Controversy in TKA

A TKA is a very popular procedure with successful outcomes for most patients.[35] Nevertheless, dissatisfaction remains post-operatively in one in every five patients.[22] As a result, surgeons have sought improvements in their surgical technique. Improvements are typically centred around improving either soft-tissue balancing, component positioning, or both.[36,37]

In order to achieve the standard of care objectives of a TKA, two modern surgical approaches have been developed: gap balancing (GB) and measured resection (MR). Since their introduction, these techniques have become effective and reproducible means for performing a TKA. A number of studies have directly compared the two surgical approaches.[38–40] Nevertheless, neither technique has been shown to produce superior outcomes across a number of domains.

1.3.2 Gap Balancing

Historically, very few anteroposterior femoral component sizes were available for use. In order to utilize the available sizes, surgeons often made larger posterior femoral condyle bone resections. A consequence of these resections was that gap differences were often observed between a position of flexion and extension, leading to long term instability of the knee joint. In order to address this instability, the GB surgical technique was introduced in the 1980’s by Drs. Michael Freeman and John Insall.[41]

In modern times, whether the flexion or extension space is balanced first is left up to surgeon discretion. Proponents of GB suggest that by setting femoral component rotation based off of the proximal tibia resection, as opposed to a predetermined anatomical landmark, offers greater coronal plane stability.[35]

1.3.2.1 Technique

Central to the GB surgical technique is that ligamentous releases are conducted prior to bone resection.[42] As previously mentioned, surgeons may elect to balance either the flexion or extension gap first. The most common strategy is to balance the knee first in a position of extension, followed by flexion. This allows surgeons to achieve symmetrical tension on ligamentous structures in extension, then set femoral implant rotation to ensure a symmetrical flexion gap. In this case, balance of the extension gap is first established by resection of the proximal tibial and distal femur articular surfaces.[43] The proximal tibial resection is conducted at 90° to the longitudinal tibial axis.[42] The posterior slope of the tibial resection is dependent upon implant design. The distal femoral resection is made with the achievement of a neutral mechanical axis in mind.[42] The thickness of each resection varies between patients. Appropriate cutting guides, such as intramedullary instrumentation, are utilized for the resections.

Once the resections of the proximal tibial and distal femoral surfaces have been made, all femoral and tibial osteophytes must be removed.[42] It is imperative osteophyte removal occurs prior to any soft-tissue releases as their presence can alter soft tissue tension, thus affecting implant positioning and extension-flexion gap symmetry. Once removed, soft-tissue releases are conducted to achieve a neutral limb alignment and a symmetric or balanced extension gap.[42]

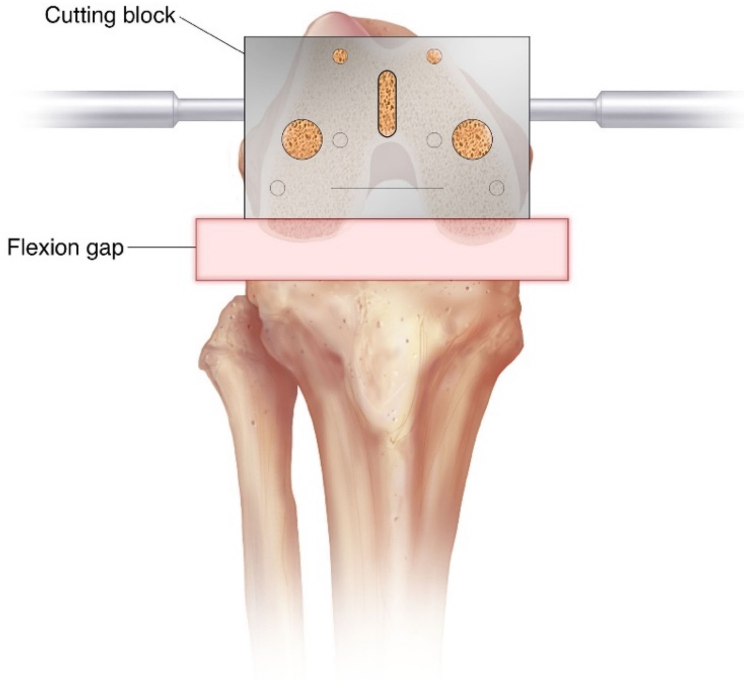

Figure 5: Placement of the anteroposterior femoral cutting block. Reproduced with permission from Dr. Kevin Perry.[19]

The next step is to create a flexion gap with the same dimensions as the extension gap. First, the knee is positioned to be in a position of 90° of flexion. Next, surgeons utilize implant-specific tensioners or laminar spreaders to tension the collateral ligaments of the joint. With the tensioners in place, the flexion gap is compared to the extension gap. Once confirmed to be rectangular and of the same magnitude of the extension space, the posterior femoral condyles can be resected. An anteroposterior cutting block is placed for the resection. This cutting block is depicted in Figure 5. The rotation of the femoral component is set based on the proximal tibial resection made previously. If no more osteophytes are removed and no more soft-tissues are released, flexion-extension gap symmetry can be ensured.

Alternatively, if surgeons elect to balance the joint space in a position of flexion prior to a position of extension, the implant-specific tensioners are used immediately following the resection of the proximal tibia. After flexion balancing, the limb is brought to a position of extension. Tensioners are once again used to help balance the joint space. The distal femur resection is made in order to match the balanced flexion gap.

1.3.2.2 Advantages and Disadvantages

Proponents of GB suggest that the approach results in improved flexion gap stability and flexion-extension gap symmetry.[43] An *in vivo* study analyzing flexion-extension gap symmetry found that among 84 TKAs completed with a GB approach, no knees had a flexion extension gap mismatch of greater than 3 mm.[44] Furthermore, supporters of the GB approach suggest the technique results in greater coronal plane stability as observed by a smaller likelihood and magnitude of femoral condylar liftoff.[40]

A limitation of the GB approach is that occasionally joint line preservation and anatomic femoral rotation are foregone in order to achieve symmetrical and balanced flexion and extension gaps.[42] This change in joint line has been shown to result in instability in the midrange of flexion and cause complications with patellofemoral mechanics.[45] Additionally, nonanatomic femoral rotation, specifically internal rotation, has been associated with the GB approach if collateral ligament tension is abnormal or asymmetric.[42] Abnormal tension can result from residual femoral or tibial osteophytes.

1.3.3 Measured Resection

The MR technique was introduced in 1980 by Drs. Robert Kenna, Kenneth Krackow, and David Hungerford.[46] There are two main principles that govern the MR technique. Firstly, the amount of bone resected should be equivalent to the thickness of the prosthesis being implanted.[42] Secondly, femoral component position is determined based on three predetermined anatomical landmarks: the transepicondylar axis (TEA), the anterior-posterior axis (APA), and the posterior condylar axis (PCA).[42] Anatomical landmarks used for MR are depicted in Figure 6. The TEA connects the bony prominence of the lateral epicondyle with the sulcus of the medial epicondyle.[42] These bone landmarks are also the origin of the lateral and medial collateral ligaments on the femur. The APA, also known as Whiteside's line, begins from the trochlear sulcus on the anterior portion of the femur, and ends posteriorly at the intercondylar notch. In the majority of cases, the APA lies 90° to the TEA. The PCA connects the most posterior part of the medial and lateral femoral condyles. As the posterior condyles of the femur are easy to identify, most femoral instrumentation relies on this landmark.

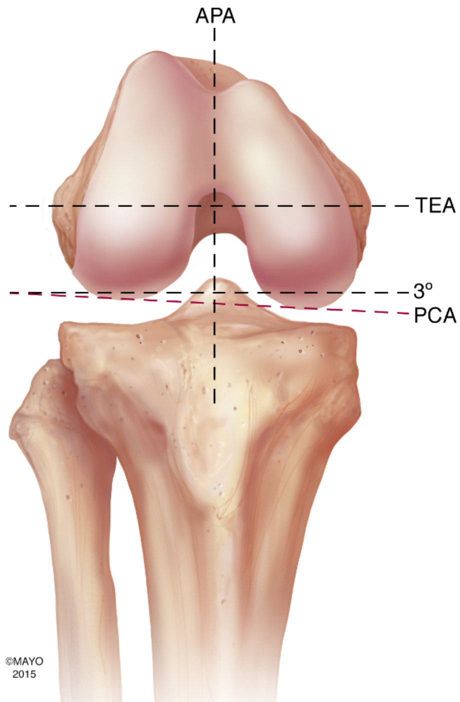

Figure 6: Measured resection anatomical landmarks. Reproduced with permission from Dr. Kevin Perry.[19]

1.3.3.1 Technique

In modern day, the MR technique includes a tibial resection in either a neutral position or in 90° of flexion.[42] Historically in the majority of patients, more bone is resected from the lateral side of the tibia compared to the medial due to the varus geometry of the proximal tibia. This was thought to permit a greater degree of rotational freedom on the lateral side.[42]

The MR approach involves performing bone resections before ligamentous balancing. As the tibial and femoral resections are done independently, the order of resection is up to the discretion of the surgeon.[42] The tibial resection is made perpendicular to the anatomical and mechanical axis of the tibia. Resection of the distal femur is done to achieve a neutral mechanical alignment, which often requires a position of approximately 5° to 7° of valgus alignment.[42] Following appropriate sizing of the femoral component, AP femoral resection is performed parallel to the TEA and perpendicular to the APA.[42] This allows proper and accurate femoral rotation to be determined. Common practice involves utilizing instrumentation that references the PCA to make the AP femoral resection. It is crucial that effort is made to match the thickness of the prosthesis being implanted to the amount of bone resection performed.

In order to ensure a rectangular flexion gap, the femoral component often must be externally rotated in relation to the TEA.[42] Following bone resections, all femoral and tibial osteophytes are removed, trial prosthesis components are placed and tested throughout an entire range of motion (ROM).[42]

1.3.3.2 Advantages and Disadvantages

Proponents of MR suggest the technique's preservation of joint line position as one of its main advantages.[35] Furthermore, the approach respects the native anatomy of the knee and multiple anatomical landmarks provide a number of ways to assess femoral component rotation.[47]

Technical pitfalls of the MR technique derive from the use of anatomical landmarks to set femoral component rotation. Femoral anatomy varies significantly from one patient to another, making accurate identification of anatomical landmarks a difficult task. This results in considerable variability in femoral component rotation between patients.[42] While the TEA is suggested as the standard landmark, critics of the MR technique suggest it be used with caution. A study analyzing interindividual reproducibility in the identification of the TEA between eight arthroplasty trained surgeons found a high interindividual discrepancy in defining the TEA.[48] The maximal distance between locations marked on the lateral and medical epicondyles were 13.8mm and 22.3mm respectively. As improper femoral component malalignment is a major cause of persistent post-operative anterior knee pain, this variance must be considered.[48] Critics of the MR technique also believe that the MR approach is associated with a greater likelihood of coronal plane instability. A study comparing the incidence and magnitude of femoral condylar liftoff, a measure of coronal plane instability, found that when compared to the GB approach the MR technique showed greater liftoff at 0º, 30°, 60°, and 90° of flexion.[40]

1.4 Implant Design

1.4.1 Fixation Method

TKA implant components may be fixated to host bone through either cemented, uncemented, or hybrid (cementless femur with a cemented tibia) fixation methods.[49] With the advancements in prosthetic design and instrumentation seen over the past decade, optimal fixation for primary TKA has become an increasingly common debate amongst arthroplasty surgeons.[50] As the TKA procedure gains popularity with a younger patient demographic and younger patients expect to achieve greater post-operative activity levels, the goal of long-term implant survivorship is being pushed to the forefront. The demands of this patient population could potentially predispose them to more mechanical complications and needs for revision surgery. Thus, uncemented implant systems may provide an appealing alternative to cemented systems.

1.4.1.1 Cemented Fixation

Cemented TKA has historically been the gold standard method for fixation in primary TKA cases.[51] Cemented TKAs have been associated with excellent post-operative clinical outcomes.[52] While capable of providing strong initial levels of fixation, questions have been raised about long-term cement durability.[49] TKA failure after 5 years is becoming more common, especially among younger, more active, and heavier patient populations.[51] Aseptic loosening is cited as one of the primary reasons.[52] Often in this case, osteolysis at the bone-cement interface is observed.[53] Aseptic loosening is an indication for revision surgery which can be complicated by the removal of cement. Additionally, cement has been shown to degrade over time and deform which imparts a weakened resistance to loads applied to the implant, such as tension and shear forces, leading to further need for revision surgery.[49,54,55] These methods of failure will continue to challenge arthroplasty surgeons as the largest growth in prospective TKA patients is amongst a patient population under the age of 65 years.[51] It is projected that patients under the age of 65 years will comprise over 50% of the primary TKA burden between 2010 and 2030.[56] This coupled with a rise in life expectancy creates a greater interest in long-term implant fixation, such as rates seen in uncemented total hip arthroplasty.[57]

1.4.1.2 Uncemented Fixation

Proponents of uncemented prostheses suggest that the ease of revision surgery, preservation of bone stock, shorter operative times, avoidance of cement complications, and potential for greater long-term durability and thus, increased implant survivorship as benefits of the implant fixation method.[58] Historically, studies examining uncemented TKA have reported inferior levels of fixation compared to cemented implants for a multitude of reasons, including poor patch porous coating and tibial locking mechanisms.[51] With an understanding of these failure mechanisms and advances in biomaterials and additive manufacturing, previous design flaws have been changed.[51] These changes have led to improved rates of implant survivorship amongst uncemented implant systems.[59] The tibial component is often the component of concern when loosening is observed within an uncemented implant system.[60] Current uncemented implants use a porous metal with a biological material, such as hydroxyapatite, as the tibial fixation surface.[50] This surface is designed to morphologically and mechanically resemble native trabecular bone. The porous surface supports bone ingrowth and has been shown to be effective in supplementing the osseointegration of the implant to host bone.[60] Variations in pore size and coating thickness have been shown to impact the process of osseointegration.[60] Some uncemented tibial components have pegs or provide the opportunity for additional screw fixation. A pegged tibial design increases the surface area available for bone fixation.[60] A pegged implant with a porous tibial underside can be seen in Figure 7. The addition of screws is to help provide immediate stability to the implanted component. However, uncemented implants without screw fixation have been shown to perform equivalently to uncemented implants with screw fixation.[59]

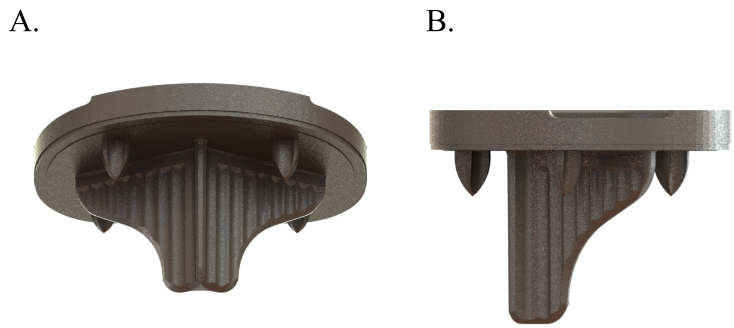

Figure 7: Cementless, highly porous pegged tibial baseplate.

1.4.2 Ligament Retention or Sacrifice

Another controversy that is prominent in joint replacement operations is whether or not to retain or sacrifice the PCL.[61] Available literature does not suggest that either ligament retention or sacrifice results in superior clinical outcomes post-operatively.[61] As such, whether or not a patient receives a posterior cruciate retaining (CR) or posterior cruciate sacrificing also known as a posterior stabilized (PS) implant depends largely on surgeon preference. A CR implant is displayed in Figure 3.

1.4.2.1 Cruciate Retaining

Proper knee kinematics and joint stability throughout various positions of flexion and extension are requirements for the clinical post-operative success of a TKA. The PCL plays a very important role in determining knee stability, specifically in the anteroposterior or coronal plane and in ensuring femoral rollback.[62] Additionally, CR designs are thought to correlate with better post-operative knee proprioception and kinesthesia.[63] While it is desirable to reproduce the natural kinematics of the knee, critics of CR designs suggest the implant style leads to a reduced ROM post-operatively.[63] Furthermore, balancing the PCL can be a very complicated task and consequently can take more time, thus resulting in a longer and more technically demanding surgical procedure.[62] If balanced improperly patients have a greater likelihood of joint instability, pain, and increased wear rates.[64,65] Nevertheless, when compared to alternative implant designs, no significant difference in knee scores, ROM, radiographic kinematics, and complication rates are consistently observed.[63]

1.5 Radiostereometric Analysis

With a number of different surgical techniques and implant systems available, it is important to measure *in vivo* implant performance. The gold standard way of measuring implant performance is through a stereo x-ray technique called radiostereometric analysis (RSA). Since its introduction in 1974 by Selvik, RSA has become the gold standard method for the assessment of orthopaedic implants.[66,67] The RSA imaging technique allows for the highly accurate assessment of three-dimensional movement between an implanted prosthesis and host bone by using biological and component landmarks.[66]

RSA uses two mobile x-ray tubes simultaneously to create a three-dimensional image. In RSA a single object is imaged on two films which include all the necessary information required to determine the location of the implant in space. This is possible as we know where both the sources and detectors are relative to one another. Tracing a line between the projected images back to their source will provide the location of the object in three dimensional space as the intersection of the lines.[68] This can be visualized in Figure 8.

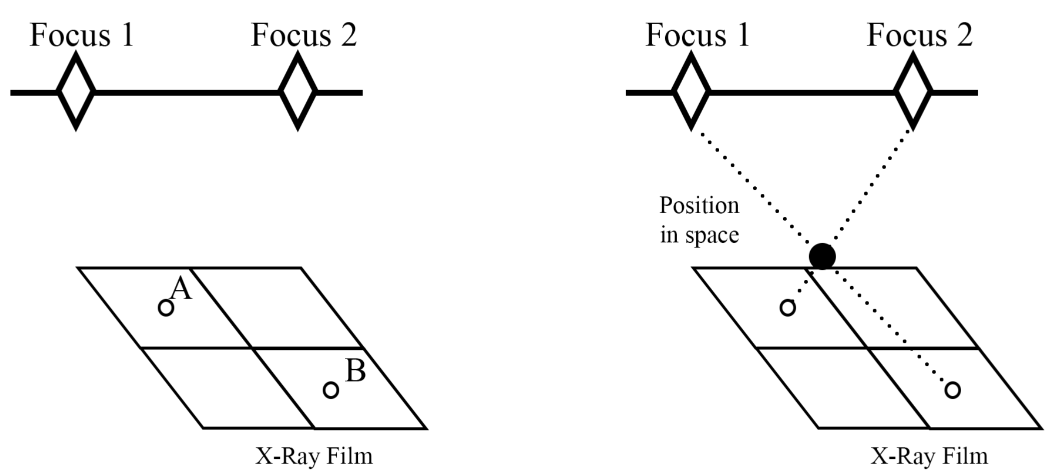

Figure 8: Three-dimensional object location determination using two stereo x-ray projections. Reproduced with permission from Maxwell Perelgut.[68]

RSA can use a biplanar technique to examine the migration of TKAs. In a biplanar set up, the two film cassettes or digital x-ray detectors are placed at a 90° relative to one another.[66] This allows for an anterior-posterior and lateral-medial view of the prosthesis to be obtained. Rather than having a set distance between the x-ray sources and film cassettes or detectors, modern day RSA techniques involve the use of a calibration cage. The calibration cage has both control and fiducial markers which helps to define the position and orientation of the mobile x-ray tubes and allows for the creation of a three-dimensional global coordinate system. Figure 9 details a biplanar RSA arrangement.

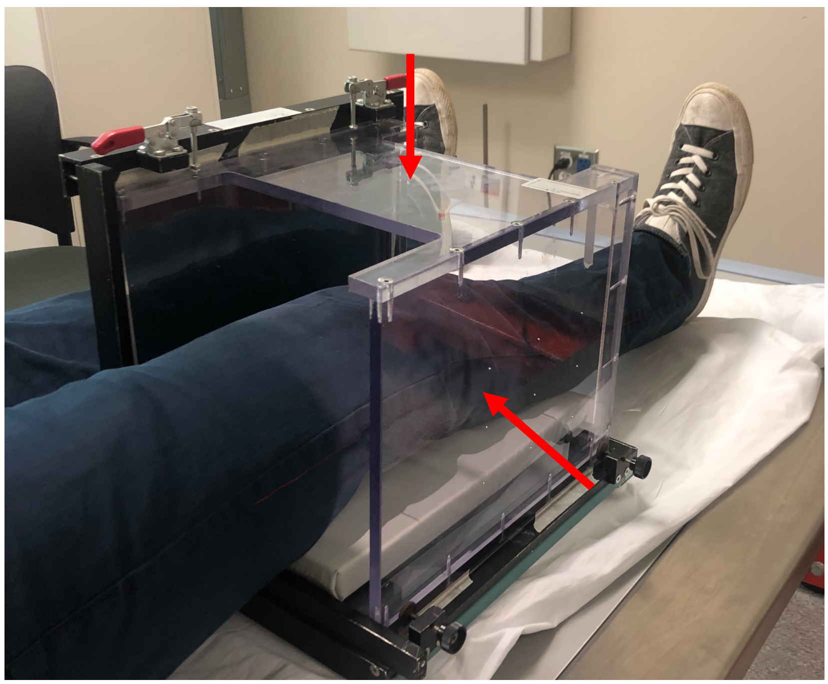

Figure 9: Biplanar RSA set up (red arrows demonstrating direction of x-ray projections).

Alternatively, a uniplanar technique can be utilized in which the recording media are placed side by side.[66] A calibration cage with control and fiducial markers is once again used to determine source location and identify the position and orientation of the global coordinate system. Figure 10 demonstrates a uniplanar RSA set up.

Figure 10: A uniplanar RSA arrangement. Reproduced with permission from Maxwell Perelgut.[68]

The RSA technique relies upon the assumption that the components of the implant and their immediate environment are made up of rigid bodies. A rigid body is a solid body with no or negligible deformity. We can therefore assume that the distance between two points on a rigid body are constant over time. RSA allows us to measure changes in position of rigid bodies. Under our circumstances one rigid body is assigned to the implanted prosthesis and another to the host bone. To create well-defined landmarks within the bone, surgeons intraoperatively implant spherical tantalum markers into the bone surrounding the prosthesis.[66] These markers appear radiopaque on x-ray. When the beads are implanted into the surrounding bone, the position of the prosthesis is determined by matching the radiographic projections of the prosthesis to a virtual projection of a three-dimensional model of the prosthesis.[69] When assessing the movement of the prosthesis over time, the spherical markers are used as reference points.

In order to use the host bone as a rigid body, three non-colinear beads are required.[66,67] Unfortunately, the tantalum beads are not always visible. For example, in an AP projection of the knee joint, the femoral component often blocks the beads, making them undetectable. To overcome this, approximately eight beads are inserted into the bone to form the rigid body. It is important to not only have a minimum of three non-colinear beads but to have a large distance between the beads.[66,67] The more linear the beads are inserted into the bone and the smaller number of beads visible, the less accurate the measurement will be.[66,67] Figure 11 illustrates the tantalum bead placement following uncemented TKA.

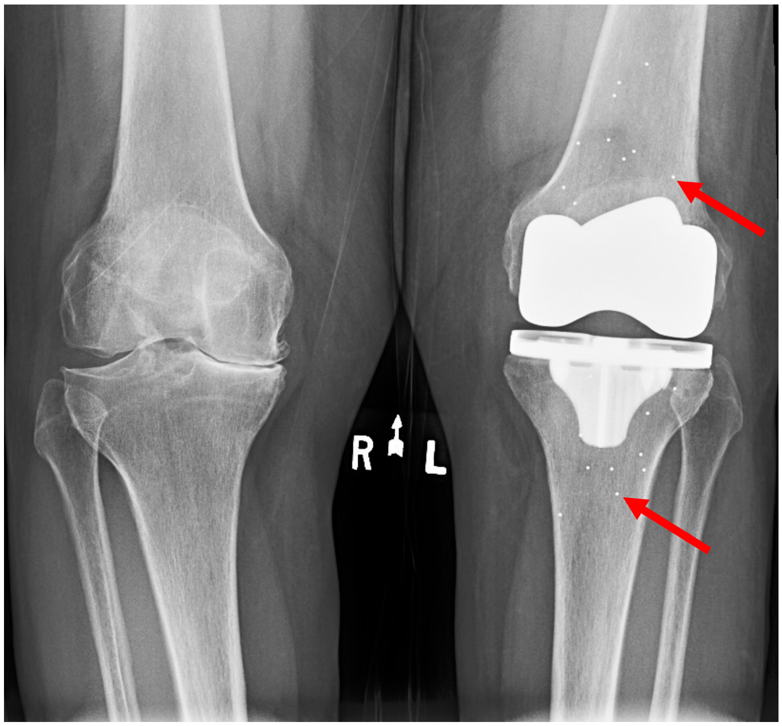

Figure 11: An anterior-posterior x-ray illustrating tantalum bead placement around a left uncemented TKA (red arrows pointing to beads).

Historically, tantalum markers were also attached to the prosthesis itself, but several developments have been made in order to avoid this, such as model-based RSA techniques. Model-based RSA utilizes a three-dimensional model of the implant, created using special model-based RSA software, where the implant model is matched to the actual radiographic projections of the prosthesis (RSAcore, Leiden, the Netherlands). This can be visualized in Figure 12.

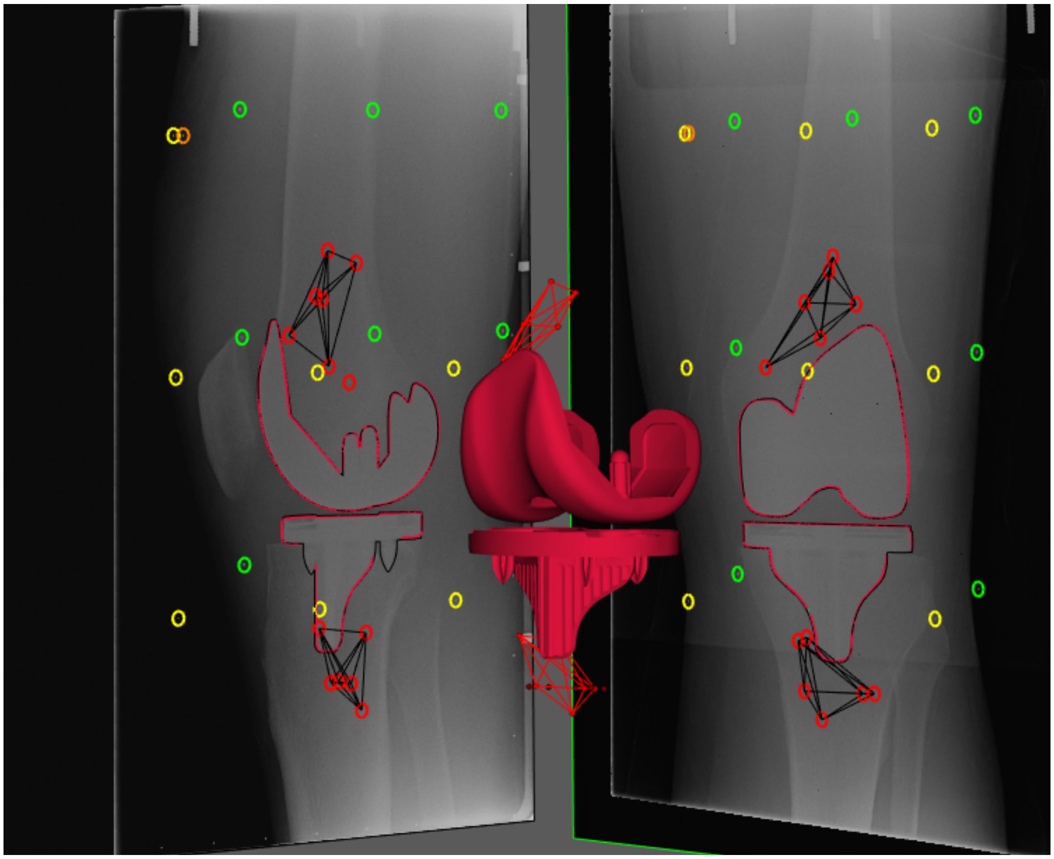

Figure 12: Model-based RSA software demonstrating the implant's position in three-dimensional space (RSAcore, Leiden, the Netherlands). A virtual surface model of the prosthesis is matched to contour projections from the actual radiographic images.

The strength of the RSA imaging technique lies in its accuracy. Reported standard deviations for any translations and rotations are 0.19 mm and 0.52°, respectively.[69] Obtaining RSA images at multiple post-operative time points allows for the tracking of implant migration, specifically translations and rotations. The level of accuracy of the RSA modality allows for the detection of migration before clinical manifestation of symptoms.[66] Established RSA thresholds can then be used to predict implant loosening.[70]

1.5.1 RSA Analysis of Joint Kinematics

In addition to assessing implant motion, RSA can be utilized to assess *in vivo* tibiofemoral contact kinematics of patients who have undergone TKA. Native knee contact kinematics provide a normative model for TKA implants to strive towards replicating. In order for a normal knee to go from a position of extension to deep flexion, internal rotation of the tibia around a medial pivot point and posterior femoral rollback are observed. While both condyles experience some amount of rollback, the lateral condyle experiences much larger amounts. This asymmetry helps to create the medial pivot point.[71]

It is well documented in the literature that the tibiofemoral contact kinematics following TKA do not replicate those of a native knee joint.[35,72–74] A common issue with TKA knees is their inability to prevent paradoxical anterior translation. Meaning, as the knee undergoes active flexion, the contact position between the femur and tibia move to a more anterior position. This action translates the flexion axis of the joint anteriorly and can result in a reduced ROM post-operatively. Understanding how articular contact kinematics following TKA are related to implant migration, function, and polyethylene wear is important in understanding the mechanisms of TKA component failure.[75]

To analyze contact kinematics using RSA in a research setting, a weight-bearing quasi-static imaging protocol can be followed. A quasi-static protocol consists of image acquisition at 0º, 20º, 40º, 60º, 80º, 100º, and 120º of knee flexion. At each position the patient is required to hold the position for approximately five seconds. Dual x-ray images are acquired from a posteroanterior oblique view at 0º to 60º of knee flexion and a mediolateral oblique view from 80º-120º of knee flexion. The angle between the x-ray sources is approximately 40º. Kinematic evaluation still utilizes control and fiducial beads, however, a uniplanar calibration cage is required (RSA Biomedical, Umea, Sweden). This is displayed in Figure 10. Following acquisition, model-based software is once again utilized. The images are registered to the manufacturer's computer-aided design models for both the tibial and femoral components using a model-based RSA software called RSAcore (Leiden University Medical Centre, the Netherlands). After the position and orientations are obtained for the femoral and tibia components, a model of the implanted polyethylene liner is attached to the tibial component. An in-house software program is then used to find the point of shortest distance between the articular surfaces for both the medial and lateral condyles. The magnitude of this distance and contact area of the components are recorded. A difference in tibiofemoral distance between the condyles of 0.5 mm is set as the threshold of condylar liftoff, matching previous studies where RSA was used to acquire kinematic data following TKA.[35]

1.6 Functional Assessment Methods

1.6.1 Clinician Assessment

Arthroplasty surgeons carefully assess the TKA patient pre- and post-operatively. This can include an assessment of wound healing, functionality, and overall patient experience. Tasks could involve reviewing x-rays, taking a detailed past medical history, or physical joint examination.[76] Surgeon to surgeon assessment of the same patient can vary to a great extent and is inherently biased.[77] As a result, evaluation of patient outcomes should be comprehensive and holistic; clinician assessment as well as patient perspective must be included in the evaluation.

1.6.2 Patient Reported Outcome Measures

Patient reported outcome measures (PROMs) are administered to patients in the form of questionnaires and aim to quantify their quality of life, pain, functional status, and satisfaction level. In the setting of a TKA, PROMs are used both pre- and post-operatively to assess patients across these domains. The Short Form 12 (SF-12), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the Knee Society Score (KSS) are three such questionnaires that can be administered to assess these outcomes. The SF-12 is a generic assessment of a patients general health, encompassing both a physical and mental well-being component.[78] The WOMAC is a disease specific questionnaire which measures symptoms and physical disability resulting from OA.[79] The questionnaire has three subscales for pain, stiffness, and physical function, as well as an overall score. The KSS is a joint-specific questionnaire that includes a patient and physician derived component.[80] Together, the patient and physician generate subscores to represent the patient’s symptoms, satisfaction, expectations, functionality, and objective knee indicators.[80] The SF-12, WOMAC, and KSS are validated measures and can be used across different sexes, ages, activity levels, and implant designs.[78–81]

While PROMs are a simple, cost, resource, and time efficient method for quantifying a number of TKA domains of interest, they have limitations.[81] One disadvantage of PROMs is how they are prone to floor and ceiling effects.[82] This means that when participants select the lowest or highest scores available, it is very difficult to detect subtle differences between them. Additionally, PROM answers are categorical and therefore clump patients together who may indeed have very different levels of function. These small undetectable distinctions could be important in predicting the long-term success of the TKA procedure. Additionally, the subjective nature of PROMs means that they are greatly influenced by pain, which reduces the functional content validity of the questionnaires.[83]

1.6.3 Functional Performance Tests

Functional performance tests are a very common method of assessment used in research. Physical function relates to one's ability to move around and perform activities of daily living.[84,85] In contrast to PROMs, performance-based tests evaluate what individuals can do, rather than what they think they can do.[85] It is suggested that performance-based assessments may be better suited to distinguish subtle differences in pain and function than PROMs.[86] However, it is important to see PROMs and functional performance tests as complementary assessment methods when evaluating the functional outcomes of the TKA procedure for OA patients.[84] While the inclusion of functional performance-based tests is well supported, there is no clear consensus regarding which types of tests best assess the physical function of OA patients.[84]

1.6.3.1 The Timed-up-and-go Test

The Timed-up-and-go test (TUG) has been previously used to assess the physical performance level of TKA patients pre- and post-operatively.[87] The TUG test is a simple, time and resource efficient test that can easily be implemented into the clinical workflow. The test requires patients to start from a seated position, stand up, walk 3 metres towards a goal, turn around, walk back to the chair, and assume a seated position once again.[83] Patients are allowed to use the armrests of the chair, wear their desired footwear, and use any mobility aid during test administration. As the test is less physically demanding than other functional performance assessments, such as the 6-minute walk test and ascending/descending stair assessment, patients can complete the assessment earlier on in the post-operative timeline. The components of the TUG test assess the basic motor activities considered to be important in the successful completion of a variety of activities of daily living.[87,88] Furthermore, pre-operatively, many TKA patients cite the most important areas they wish to see improvements post-operatively are in their pain and walking capacity.[89] Thus, administering the TUG test allows us to objectively assess domains important for patient satisfaction and expectations, while quantifying functional mobility in a way that is useful for following clinical change over time.[87] The TUG test has high test-retest reliability with a change of at least 2.27 seconds indicating a “real” clinical change in a TKA patient’s functional status.[87] The TUG test has previously been used to discern between healthy and OA populations and provides a global, yet basic, assessment of functional mobility.[87]

1.6.4 Wearable Motion-Based Sensors

Typically, human motion analysis or gait analysis is done using complex, high-speed, optical tracking systems.[90] To successfully track the movement patterns of different body parts and dynamically analyze different physical behaviours, one requires a large amount of space, a great deal of money, and a wealth of experience in human motion analysis. Thus, this standard method of analysis is limited to laboratory research and is extremely difficult to apply in real life environments.

Wearable sensors systems are an emerging concept that provides an appealing alternative to optical tracking systems. Wearables are a more cost- and user-friendly way to track and analyze human movement outside of a controlled laboratory environment.[91] Inertial sensors, a type of wearable sensors, are becoming increasingly more common.[92] Inertial measurement units (IMUs) are comprised of three systems: a gyroscope, a magnetometer, and an accelerometer. Together the data retrieved from IMUs such as linear accelerations, angular velocities, and stride length can be used to determine a range of patient-specific spatiotemporal and kinematics metrics.[93] Additionally, if subjects wear IMUs on the lower and upper legs, calibration procedures which take into consideration joint constraints can be applied in order to determine quantitative joint angle data.[94] In fact, previous in-house laboratory studies have proposed and validated a method of deriving novel functional metrics as a subject performs the TUG test using wearable sensor technology.[95,96] Validation involved evaluating the measurement repeatability of IMU derived joint angles of a robotic leg phantom and comparison of said data to angular data collected using both a three-dimensional motion capture system and electro-goniometer.[96] The study determined the system had acceptable repeatability levels in addition to determining optimal sensor placement. These measurements of knee joint flexion and extension angles can be calculated during dynamic activities, such as walking and running, or the basic motor activities, such as rising from a chair, performed during the TUG test. While the orientation data collected from the IMUs is a relative assessment compared to the absolute assessment one would get from an optical motion analysis system, the correlation coefficient between data obtained from optical tracking systems and data obtained from wearable IMUs approaches 0.9.[90,97]

1.7 Thesis Objectives and Hypothesis

The primary objectives of this thesis are to determine how a GB or MR surgical technique may impact the (1) migration patterns of the tibial and femoral components, and (2) post-operative *in vivo* tibiofemoral contact kinematics of a cruciate-retaining uncemented TKA design. Our secondary objective was to implement the TUG test with wearable sensor technology in a population of TKA patients pre- and post-operatively to assess the relationship between novel sensor derived metrics and clinically meaningful improvements in functionality.

We hypothesize that the majority of implant migration will occur in the early post-operative period as the biological fixation between the host bone and implanted prosthesis develops. Therefore, we expect that the magnitude of migration throughout the first six months of the follow up period to be greater than the magnitude expected during this time period for cemented prostheses. We hypothesize that there will be larger overall amounts of migration for those patients who had their TKA completed using an MR technique as there may be greater medial-lateral imbalance in joint forces in TKA performed with the MR technique. Additionally, we hypothesize that there will be differences in the *in vivo* tibiofemoral contact kinematics, specifically condylar liftoff, between the MR and GB surgical approach groups. Lastly, we hypothesize that the novel joint-specific wearable sensor-derived metrics will provide more insight into patient functional restoration than that currently provided by total time to complete the test alone.

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Chapter 2

2 The impact of surgical technique on implant migration for an uncemented total knee arthroplasty

2.1 Introduction

Total knee arthroplasty (TKA) is becoming more popular with a 15.5% increase in the total number of procedures over the past five years in Canada, totaling over 67,000 in the 2016-2017 year.[1] With a rising number of individuals undergoing TKA's annually, it is imperative that surgical technique and implant design be examined in order to optimize the treatment provided to the TKA patient population and to ensure long-term procedure success. The main goals of the TKA procedure are to achieve a neutral lower limb alignment, to restore and maintain the joint line, to obtain well positioned femoral and tibial components, and to balance the joint's soft tissues. While these goals are not disputed amongst arthroplasty surgeons, what remains controversial is the surgical technique employed to achieve said goals. Most commonly, arthroplasty surgeons utilize either a gap balancing (GB) or measured resection (MR) surgical approach. In a GB surgical approach, surgeons conduct ligamentous releases prior to making bone resections.[2] Surgeons balance ligament tension in both a position of flexion and extension and utilize this balancing to guide their final bone resections.[3] Whereas, in a MR surgical approach, surgeons first make bone resections according to pre-determined anatomical landmarks and conduct soft tissue releases afterwards.[2] The amount of bone resected is equal to the distal and posterior thickness of the femoral component.[3] Supporters of the GB technique suggest that the technique results in superior coronal plane stability.[2,4,5] However, commonly cited disadvantages include elevation of the joint line and greater femoral component rotation variability. Supporters of the MR technique suggest that the techniques emphasis on the natural anatomy of the knee contributes to its superiority.[2,6] Depending on patient presentation, it may be exceedingly difficult to accurately determine the location of the pre-determined anatomical landmarks used for bone resection, as such, the technique is criticized for issues with precision.[2,6] Still debated is whether or not the GB or MR surgical approach is best suited to achieving the standard of care objectives for the TKA procedure.

Historically, cemented fixation has been the most common method used to fixate the implanted tibial and femoral components to the host bone.[7] While cemented fixation has shown to have excellent survivorship outcomes, studies report bone resorption, osteolysis, and aseptic loosening at the bone-cement interface, especially in younger patient cohorts.[7–11] However, a Cochrane Review concluded that while cemented tibial components had a lower risk of initial migration, uncemented tibial components were less likely to experience aseptic loosening in the future.[12,13] With an increasingly younger cohort requiring TKA alongside advances in prosthetic design the durability of cemented fixation and the subsequent impact on implant longevity have been brought into question. An uncemented implant system provides a promising alternative to the cemented TKA approach and may be better suited to a younger patient cohort with greater demands for post-op function. Porous and hydroxyapatite coated implants can theoretically assist host bone in osseous ingrowth, ultimately providing a stronger more durable bonded interface between the implanted component and host bone.

It is important to understand the impact of a GB or MR surgical approach on the implant migration of an uncemented TKA system as early migration thresholds can be used for predictions of successful fixation between the host bone and implanted components. While clinical x-rays can be used for this task, the amount of migration that must occur for detection is greater than 1.0 mm.[14,15] Rather, a stereo x-ray technique called radiostereometric analysis (RSA) is the gold standard for assessing in-vivo migration. RSA may detect translational motion between 0.05 and 0.5 mm and rotations between 0.15º and 1.15º and is thus a much more accurate way to assess this type of motion.[16,17] The predictive ability of early migration values, such as migration one year post-operatively is well documented within the literature.[13] Established thresholds for cemented implants indicate that one year maximum total point motion greater than 0.5 mm indicates an implant is “at risk” for failure and values greater than 1.6 mm indicate “unacceptable” migration levels.[13,18] Higher one year migration values are expected with uncemented implant systems as osseointegration occurs. Additionally, it has been suggested six month migration values can be used with uncemented implants instead due to the minimal amount of migration that is expected to occur once osseointegration is established.[13,19]

The objective of this study was to compare the amount of implant migration of an uncemented implant system when a GB or MR surgical approach is utilized for a primary TKA. We hypothesize that the majority of implant migration will occur in the early post-operative period as osseointegration develops. Additionally, we hypothesize that the MR surgical approach will experience more implant migration than a GB approach as there is a greater likelihood of medial-lateral imbalance in joint force distribution in TKAs performed with a MR approach.

2.2 Methods

2.2.1 Study Design

Research ethics board approval was obtained from the institutional review ethics board (The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects, File No. 109486). All patients provided written informed consent prior to study participation. Patients scheduled for a primary unilateral TKA were recruited pre-operatively between September 2017 – May 2018. Prospectively collected baseline data was collected at time of pre-admission appointment which was within one month of patients' surgical dates. Surgical and clinical follow-up appointments were completed at the Rorabeck Bourne Joint Replacement Clinic at London Health Sciences Centre, University Campus. Imaging follows up were completed at Robarts Research Institute, Western University. Participant flow through study is illustrated in Figure 13.

2.2.2 Eligibility Requirements

Thirty-nine patients (n=39) were recruited for the study and were randomly assigned on referral to either a surgeon who performs TKA with a GB or MR surgical approach. Patients were excluded if their surgery was not being performed by one of the two participating surgeons in this study. The primary inclusion criteria were a diagnosis of end-stage OA requiring a primary unilateral TKA and a minimum age of 18 years.

Exclusion criteria included a diagnosis of inflammatory arthritis, prior knee surgery, if the patient was pregnant or planning on becoming pregnant, cognitive impairment, a neuromuscular disorder preventing the completion of a walking test, an inability to understand English, a history of alcoholism (defined as more than 15 standard drinks per week for males and 8 for females), or age greater than 75 years. Patient demographics are listed in

Table **1**. There was no significant difference in age, height, body mass index, sex, or operative side between the two surgical approach groups; however, patients in the MR group were significantly heavier (p=0.035).

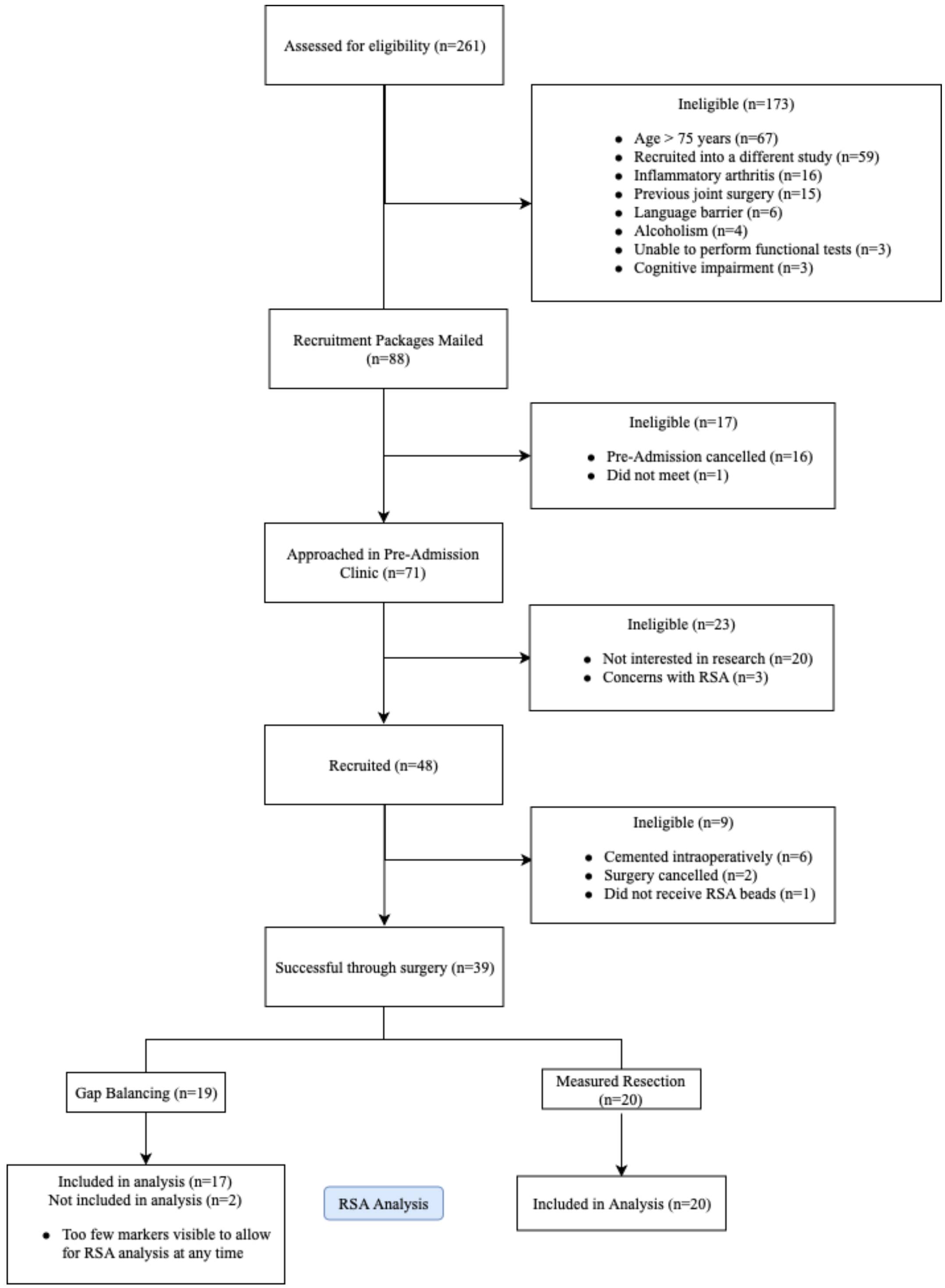

Figure 13: Participant flow through study.

Table 1: Patient demographics, presented as mean ± standard deviation.

	Gap Balancing	Measured Resection	p-value
Age, y	62.0 ± 7.4	62.9 ± 6.6	0.70
Height, cm	167.0 ± 7.8	170.0 ± 7.8	0.39
Weight, kg	92.4 ± 19.5	107.0 ± 19.6	0.03
BMI, kg/m^2	33.0 ± 6.4	37.3 ± 6.8	0.06
Sex	7 males: 10 females	10 males: 10 females	0.74
Side	9 right: 8 left	10 right: 10 left	0.99

BMI, body mass index

2.2.3 Intervention

All patients received a standard midline incision followed by a medial parapatellar arthrotomy. The surgeon who utilized a MR approach sets femoral rotation to 3º of external rotation relative to the posterior condylar axis of the femur before making bone resections. Following bone resection, soft tissue releases are conducted to balance the joint space in a position of flexion and extension. The surgeon who utilized a GB approach conducts soft tissue releases after resecting the bone of the proximal tibia and distal femur, balancing the extension space. Following osteophyte removal, bone cuts are made with the knee in flexion to match the flexion space to the extension space. Additionally, all patients received an identical fixed-bearing, cruciate-retaining beaded peri-apatite coated uncemented femoral component and a highly porous uncemented tibial baseplate (Triathlon, Stryker, Mahwah, NJ). The same post-operative protocol was followed for all patients. Furthermore, a standardized rehabilitation protocol was used. Post-operative follow up visits were scheduled at two weeks, six weeks, three months, six months, and one year post-operatively.

2.2.4 Image Analysis Follow-Up

In order to complete RSA analysis post-operatively, a minimum of eight 1.0 mm diameter tantalum beads were implanted intraoperatively into both the distal femur and proximal tibia. Baseline RSA exams were conducted two weeks post-operatively, with additional follow up visits at six weeks, three months, six months, and one year post-TKA. All RSA exams were conducted with the patient in a standardized supine position with their knee within a biplanar calibration cage (RSA Biomedical, Umea, Sweden).

This standardized position is depicted in Figure 14. The RSA images were analyzed using a commercial model-based RSA software (RSAcore, Leiden, the Netherlands). The mean error of rigid body fitting for the tibial and femoral components of all patients at all time points was less than the 0.35 mm threshold proposed by Valstar et al.[20] Additionally, the condition number, which indicates the distribution of the tantalum beads, for all measurements was less than the upper limit of 150 also suggested by Valstar et al., indicating that our measurements are reliable and sufficient for determination of implant migration.[20]

Figure 14: Supine patient exam positioning.

Maximum total point motion (MTPM) was calculated at each time point and compared to the baseline position. Individual segment translations and rotations were also calculated. Positive translations were defined as lateral in the axial (x) plane, superior in the coronal (y) plane, and anterior in the sagittal (z) plane. Positive rotations were defined as anterior tilt about the axial (x) plane, external rotation about the coronal (y) plane, and valgus rotation about the sagittal (z) plane. Figure 15 details positive translation and rotation directions of the tibial component.

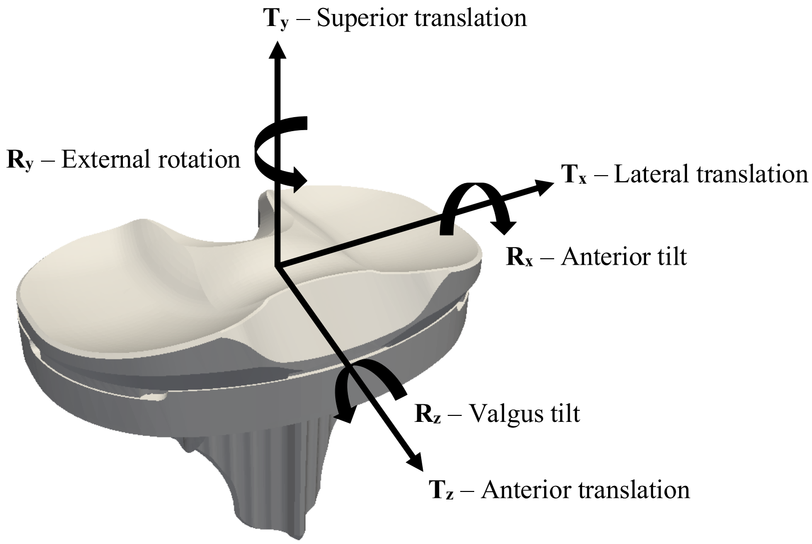

Figure 15: Indicating positive direction axial translations and rotations.

2.2.5 Patient Reported Outcome Measures

All patients completed a standardized set of patient reported outcome measures (PROMs) in the form of a series of questionnaires. The Short Form 12 (SF-12) assessed general health and well-being. The disease specific Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) assessed pain, stiffness, and physical function. The Knee Society Score (KSS) is a joint specific questionnaire which assessed symptoms, satisfaction, expectations, function, and objective knee indicators. The University of California, Los Angeles activity score (UCLA) asked patients to rate their activity levels in the 24 hours prior to clinical evaluation.

2.2.6 Statistical Analysis

All data were assessed for normality using the D'Agostino and Pearson omnibus normality test. Depending on normality, demographics and baseline PROMs were compared between groups using either an unpaired t-test (parametric) or using a Mann-

Whitney test (non-parametric), whereas the ratio of males:females and right:left knee were compared between groups using a Fisher exact test. A paired t-test (parametric) or Wilcoxon matched pairs signed rank test (non-parametric) was used to compare baseline and one year PROMs within groups. RSA migrations are provided as medians and range. RSA migration was compared between groups using an unpaired t-test (parametric) or Mann-Whitney test (non-parametric) depending on normality. MTPM at six months and one year was compared between groups and within groups using a mixed effects model for repeated measures data. Level of significance was set at $p<0.05$. All statistical tests were conducted using GraphPad Prism v8.0 (GraphPad Software, La Jolla, CA).

2.3 Results

2.3.1 Patient Reported Outcome Measures

There were no differences pre-operatively or one year post-operatively in SF-12, WOMAC, KSS, or UCLA Activity Score (Table 2) between the MR and GB cohorts.

Table 2: Patient reported outcome measures, presented as mean ± standard deviation.

	Gap Balancing	Measured Resection	p-value
SF-12 MCS			
Pre-Operation	50.0 ± 10.6	53.5 ± 11.4	0.350
1 Year	50.3 ± 11.3	53.9 ± 10.6	0.343
SF-12 PCS			
Pre-Operation	35.2 ± 8.6	29.9 ± 7.5	0.054
1 Year	44.0 ± 8.4	46.1 ± 10.0	0.559
WOMAC			
Pre-Operation	43.3 ± 16.5	43.3 ± 18.7	0.870
1 Year	80.2 ± 20.2	81.0 ± 15.6	0.894
KSS			
Pre-Operation	114.0 ± 35.3	104.0 ± 30.7	0.428
1 Year	136.0 ± 34.2	137.0 ± 29.6	0.952
UCLA			
Pre-Operation	4.5 ± 2.1	4.5 ± 2.5	0.970
1 Year	6.2 ± 0.84	6.2 ± 1.6	0.981

SF-12, short form 12; MCS, mental component score; PCS, physical component score; WOMAC, Western and McMaster Universities Osteoarthritis Index, KSS, knee society score; UCLA, University California, Los Angeles activity score

In the GB group, there was significant improvements pre- to post-operatively in the SF12 PCS (p=0.0006), WOMAC (p=0.0007), and UCLA (p=0.006). No significant improvement in the SF12 MCS (p=0.66) or KSS (p=0.13) was observed. In the MR group, significant improvements were observed with respect to SF12 PCS (p<0.0001), WOMAC (p<0.0001), KSS (p=0.04), UCLA (p=0.037). No significant improvement in the SF12 MCS (p=0.90) was observed.

2.3.2 Migration

There was no significant difference in tibial component translation in the x, y or z axial directions at any time point between the two cohorts. Additionally, no significant difference was observed in rotation around the y or z axis at any time point. There was a significant difference (p=0.01) in rotation around the x axis at the six month follow up with the MR group reporting more posterior tilt than the GB cohort. However, this difference was not observed at one year follow up visit. Median tibial translation and rotations for each group can be found in

Table **3**. Furthermore, no significant difference was observed at any time point between the groups in terms of their MTPM (Figure 16).

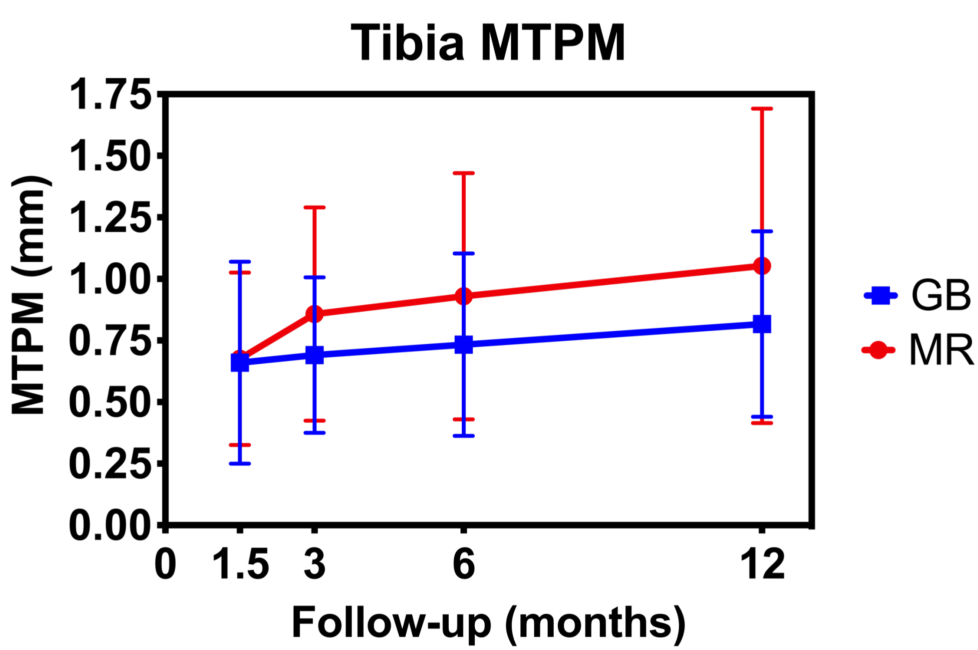

Figure 16: Maximum total point motion of the tibial component.

Table 3: Migration of the tibial component (median and range presented).

	Gap Balancing	Measured Resection	p-value
X Translation (mm)			
6 weeks	-0.04 (-0.37 to 0.12)	-.006 (-0.28 to 0.27)	0.82
3 months	-0.04 (-0.61 to 0.06)	-0.03 (-0.22 to 0.22)	0.49
6 months	-0.02 (-0.69 to 0.15)	0.01 (-0.18 to 0.51)	0.38
1 year	-0.07 (-1.02 to 0.15)	0.02 (-0.27 to 0.76)	0.09
Y Translation (mm)			
6 weeks	0.03 (-0.10 to 0.28)	0.02 (-0.21 to 0.35)	0.61
3 months	0.05 (-0.28 to 0.23)	0.02 (-0.29 to 0.30)	0.90
6 months	0.05 (-0.49 to 0.37)	-0.02 (-0.20 to 0.38)	0.19
1 year	0.13 (-0.95 to 0.30)	0.11 (-0.38 to 0.57)	0.99
Z Translation (mm)			
6 weeks	-0.03 (-0.18 to 0.10)	0.02 (-0.42 to 0.45)	0.34
3 months	0.07 (-0.18 to 0.36)	0.19 (-0.41 to 0.57)	0.56
6 months	0.02 (-0.18 to 0.37)	0.06 (-0.63 to 0.57)	0.30
1 year	0.11 (-0.21 to 0.26)	0.03 (-1.04 to 0.46)	0.51
X Rotation (º)			
6 weeks	-0.02 (-1.60 to 0.84)	-0.04 (-0.85 to 0.68)	0.38
3 months	-0.05 (-1.14 to 1.20)	-0.30 (-1.78 to 1.59)	0.06
6 months	0.13 (-0.46 to 1.04)	-0.32 (-1.83 to 0.78)	0.01*
1 year	0.57 (-0.51 to 0.74)	0.08 (-1.72 to 1.50)	0.17
Y Rotation (º)			
6 weeks	0.30 (-1.69 to 1.38)	-0.06 (-0.90 to 1.74)	0.29
3 months	0.52 (-0.51 to 1.31)	0.56 (-0.85 to 1.79)	0.78
6 months	0.11 (-0.86 to 1.22)	-0.32 (-1.83 to 0.78)	0.35
1 year	-0.16 (-1.29 to 1.01)	0.16 (-2.40 to 1.49)	0.79
Z Rotation (º)			
6 weeks	-0.11 (-0.65 to 0.52)	0.04 (-0.45 to 1.04)	0.50
3 months	-0.08 (-0.63 to 0.37)	-0.15 (-1.26 to 0.72)	0.86
6 months	-0.21 (-1.30 to 0.68)	-0.16 (-1.28 to 0.58)	0.86
1 year	-0.08 (-1.32 to 0.76)	-0.17 (-1.05 to 1.20)	0.72
MTPM			
6 weeks	0.57 (0.20 to 1.69)	0.71 (0.15 to 1.30)	0.60
3 months	0.69 (0.16 to 1.28)	0.77 (0.32 to 1.73)	0.24
6 months	0.68 (0.20 to 1.45)	0.81 (0.38 to 1.95)	0.24
1 year	0.77 (0.40 to 1.70)	1.00 (0.32 to 2.82)	0.38

MTPM; maximum total point motion; * denotes significance

No significant difference was found with respect to the change in tibial MTPM from the six month to the one year follow up between the GB (mean difference: 0.08mm, p=0.71) or MR (mean difference: 0.12mm, p=0.56) cohorts. This plateau can be visualized in Figure 16.

There was no significant difference (p>0.05) in femoral component x, y, and z translations and x and y rotations between the two surgical approach groups. There was a significant difference in the amount of rotation in the z plane between surgical approach groups at the three month (p=0.04) and six month (p=0.003) follow up visits. This was trending towards significance one year (p=0.14) post-op. Median femoral translation and rotations for each group can be found in Table 4. No difference was found in femoral MTPM between the groups at six weeks, three months, six months, or one year post-operatively (Figure 17).

Table 4: Migration of the femoral component (median and range presented).

	Gap Balancing	Measured Resection	p-value
X Translation (mm)			
6 weeks	0.05 (-0.10-0.23)	0.05 (-0.16-0.22)	0.71
3 months	0.17 (-0.35-0.27)	0.11 (-0.16-0.28)	0.98
6 months	0.11 (-0.13-0.52)	0.07 (-0.66-0.17)	0.17
1 year	0.13 (-0.05-0.92)	0.08 (-0.14-0.41)	0.31
Y Translation (mm)			
6 weeks	-0.02 (-0.15-0.11)	-0.0005 (-0.11-0.09)	0.60
3 months	-0.05 (-0.16-0.32)	0.002 (-0.21-0.65)	0.85
6 months	-0.05 (-0.23-0.30)	-0.05 (-0.19-0.06)	0.38
1 year	-0.009 (-0.11-0.37)	-0.02 (-0.33-0.14)	0.78
Z Translation (mm)			
6 weeks	-0.05 (-0.57-0.23)	0.02 (-0.24-0.49)	0.19
3 months	-0.003 (-0.43-0.40)	0.002 (-0.21-0.65)	0.61
6 months	-0.02 (-0.43-0.48)	0.06 (-0.29-1.07)	0.21
1 year	-0.09 (-0.50-0.28)	0.12 (-0.46-0.52)	0.29
X Rotation (º)			
6 weeks	0.01 (-0.55-0.25)	-0.01 (-0.27-0.32)	0.34
3 months	-0.15 (-0.55-0.50)	0.01 (-0.68-0.47)	0.42
6 months	0.05 (-0.37-0.64)	0.09 (-1.33-0.32)	0.97
1 year	-0.05 (-0.42-0.63)	0.04 (-0.37-0.32)	0.77
Y Rotation (º)			
6 weeks	0.01 (-0.59-0.64)	-0.02 (-1.03-0.57)	0.56
3 months	0.14 (-0.69-0.96)	-0.11 (-1.50-0.51)	0.48
6 months	0.08 (-0.90-0.93)	-0.34 (-1.39-0.40)	0.28
1 year	0.07 (-0.44-0.58)	-0.31 (-1.30-0.90)	0.22
Z Rotation (º)			
6 weeks	0.12 (-0.30-0.36)	-0.03 (-0.29-0.22)	0.18
3 months	0.07 (-0.20-0.64)	0.03 (-0.40-0.15)	0.04*
6 months	0.22 (-0.11-0.67)	-0.13 (-0.57-0.07)	0.003*
1 year	0.17 (-0.24-0.99)	-0.005 (-0.22-0.19)	0.14
MTPM			
6 weeks	0.41 (0.25-1.1)	0.44 (0.07-1.18)	0.71
3 months	0.53 (0.35-1.34)	0.51 (0.18-1.68)	0.69
6 months	0.55 (0.33-1.49)	0.60 (0.28-1.72)	0.57
1 year	0.49 (0.19-1.80)	0.84 (0.23-1.43)	0.51

MTPM; maximum total point motion; * denotes significance

No significant difference was found in the amount of MTPM from 6 months to one year post-operatively between the GB (mean difference: 0.016mm, p=0.46) or MR (mean difference: 0.029mm, p=0.70) cohorts.

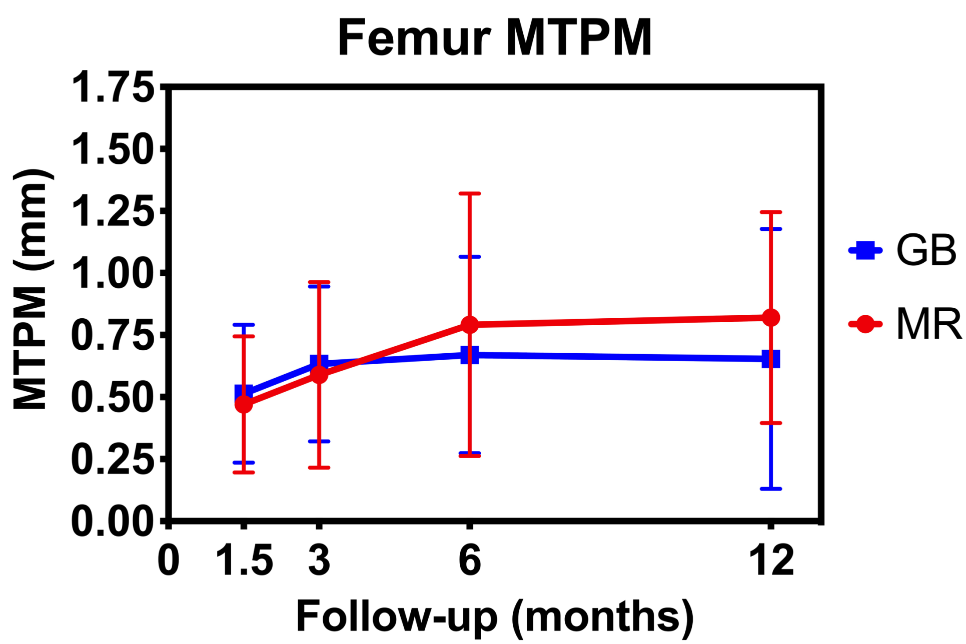

Figure 17: Maximum total point motion of the femoral component.

2.4 Discussion

In the last decade we have seen a substantial rise in the number of patients under the age of 60 undergoing TKA.[21,22] A higher risk of revision surgery has been observed in patients of this age demographic.[23] This cohort tends to have higher functional demands and therefore applies more stress on their prosthesis.[21] Besides polyethylene wear, aseptic loosening is the major cause of revision surgery in these patients. While cemented fixation methods provide strong initial stability, over time the cement may degrade and result in implant loosening at either the cement-bone or cement-implant interfaces.[21] In older patient populations not concerned about the potential of revision surgery this may not be of issue, but with younger patients the presence of cement can make revision surgery more difficult. Uncemented fixation methods provide a promising alternative.

Implants with uncemented fixation are vulnerable during the early post-operative period but may be better suited to providing good long-term stability to younger patient cohorts.

We have demonstrated in this study that for an uncemented single-radius cruciate-retaining highly porous tibial component and beaded peri-apatite coated femoral component, TKA surgical technique has no significant impact on the MTPM observed within the first post-operative year. In a study conducted by Laende et al., examining one and two year post-operative stabilization of uncemented tibial components an average MTPM of 0.85 mm was observed at one year with a predecessor implant to the one used in our study.[13] This is comparable to the amount of MTPM observed within our cohort at one year. The study also reported a median MTPM of 0.5 mm (range 0.11-4.17 mm). While we reported higher median levels of MTPM of 0.77 mm in the GB cohort and 1.00 mm in the MR cohort, the range of our MTPM calculations was smaller within both the GB (0.40 – 1.70 mm) and MR cohort (0.32 – 2.82 mm). Furthermore, a meta-analysis conducted by Pijls et al., examined one year MTPM values for a range of hydroxyapatite (HA) coated, trabecular metal, porous coated, and uncoated uncemented tibial components.[24] Our study uses a 3D printed porous tibial component. Pijls et al. reported mean one year MTPM values with porous tibial components of 1.13 mm (CI: 0.87-1.38 mm) which is higher than what we observed in our cohort.

While aseptic loosening of the femoral component occurs much less frequently than loosening of the tibial component, it is still important to consider the magnitude and pattern of migration of uncemented femoral components.[21] There was no significant difference between surgical approach groups in any axial translation observed and in rotation about the x and y directions. However, there was a significant difference in the rotation about the z axis at three months ($p=0.04$) and six months ($p=0.003$) post-operatively. Not all patients have returned for their one year post-op exams affecting our ability to detect significance at the one year mark. Nevertheless, the difference in varus-valgus rotation at one year is trending towards significant. A study conducted by Uvehammer et al., used RSA to compare rotation of the femoral component over the early post-operative period. One of the implants examined was an HA coated uncemented femoral component similar as ours. Two years post-operatively they observed a median rotation of -0.16º (range: -2.57-2.86). One year post-operatively we observed a median rotation of -0.005º (range: -0.24-1.0) in the GB cohort and 0.17º (range: -0.22-0.19) in the MR cohort. While a time point difference of a year exists, uncemented implants are proposed to be stable during the one and two year post-operative period. Thus, we presume the position of our implant at one year is comparable to the position we will observe two years post-operatively. Furthermore, we observed less variability in varus-valgus rotation than did Uvehammer et al., who reported no significant impact of femoral component rotation on long term femoral component fixation.[25] No difference in MTPM at any time point existed between the GB and MR cohorts. Gao et al., conducted a comparison of MTPM of cemented and uncemented CR-TKA without HA coating with a maximum of two year follow up.[21] They observed a median one year MTPM of 0.87 mm (range: 0.47-1.10 mm). We observed 0.49 mm (range: 0.19-1.80 mm) in the GB cohort and 0.84 mm (0.23-1.43 mm) in the MR cohort. Well documented within the literature is the stability benefits of HA coatings.[26] It is hypothesized that we observed lower median levels of femoral MTPM at one year due to the presence of a peri-apatite coating on our femoral component.

Migration of the tibial component appears to plateau at approximately three months post-operatively. Whereas, the femoral component appears to continue to migrate between the three month and six-month follow ups, becoming stable and plateauing at approximately six months post-op. The similarity observed between the six month MTPM and one year MPTM provides further support to previous suggestions in the literature to use 6 month MTPM values as opposed to one year MPTM values for RSA testing thresholds of implant fixation with uncemented implant designs.[24] Pijls et al. further indicates that if six month MTPM is used for RSA testing thresholds, migration thresholds currently used for one to two year stability can be applied to observed migrations between six months and one year.[24] However, they suggest this be used with caution and reiterate that the observed migration between one year and two years should be used as an extra safeguard assessment for long term stability.

Historically, MTPM migration values have been used to identify implants at higher risk for revision at the five year mark. Pijls et al. concluded in a meta-analysis that MTPM migration at one year less than 0.5 mm was considered “acceptable” and greater than 1.6 mm was representative of “unacceptable” future risk for revision.[27] Implants that fell between 0.5 mm and 1.6 mm would be considered “at risk” for revision. These thresholds however were determined based off of TKAs with cemented fixation. Laende et al., has previously indicated that these thresholds are not applicable to uncemented TKAs.[13] Higher one year MTPM values are expected for uncemented implants as there is a “settling” period before bone growth begins to occur.[13] Once osseointegration has occurred between the host bone and implanted prosthesis, long term fixation of uncemented components is good, whereas with cemented components we must be concerned about cement-related durability concerns.[28] According to the guidelines set by Pijls et al., 60% of our cohort would be considered “at risk” or “unacceptable”. These results would be concerning and illustrative of poor fixation. However, in the study conducted by Laende et al., of the 32 implants analyzed which were similar to our study implant, zero migrated above the threshold amount 0.2 mm between one year to two years despite having an average one year MTPM of 0.85 mm.[13] Thus, we feel it is not acceptable to infer revision risk from the RSA thresholds determined with cemented TKAs to our uncemented CR-TKA cohort.

No significant difference was found at any time point between groups in terms of PROMs. All patients, regardless of approach, saw improvement in PROMs from pre-operatively to one-year post-op.

This study is not without limitations. Firstly, there is a significant difference in weight between the two cohorts but there is no statistically significant difference in their BMIs. It is unlikely that differences in weight over 90kg and BMI greater than 30 has substantial clinical relevance as the patient population is already considered obese. Additionally, we studied a single implant design (with a single radius femoral component). This may prevent our results from being applicable to other implant designs but was required in order to isolate the impact of surgical technique. While the size of our study population is consistent with typical RSA studies, we examined a small number of people (37 knees included in analysis). Nevertheless, there is nothing that suggests we would have observed different results if we had examined a larger number of patients. Furthermore, we have yet to have all patients complete the one year follow up exam and no patients have reached the two year post-operative time point. While this is an important time point for established RSA thresholds of future revision risk, the long-term stability of this implant design can only be confirmed with a longer follow up period. Lastly, we experienced a great deal of difficulty with femoral bead occlusion. We were only able to visualize enough beads to calculate component translations, rotations, and MTPM in 10 patients from the GB group and 14 patients from the MR group at the one year time point. While RSA studies in the literature have reported cohorts of this size being able to determine these values for all study patients would add strength to our results. A strength of this study is the high-resolution imaging technique utilized which adds to the reliability of our results.

In conclusion, there was no significant difference in the magnitude of migration or pattern of migration with a single-radius uncemented CR-TKA design between a GB and MR surgical approach. We observed higher levels of migration during the early post-operative period of both the tibial and femoral component as osseointegration developed between the host bone and implant components. Migration of both components plateaued by six months post-operatively indicating that the process of osseointegration had occurred. The similarity between six month and one year MTPM values supports the use of established RSA migration thresholds six months following uncemented TKA. The RSA findings suggest that an uncemented single-radius cruciate-retaining highly porous tibial baseplate and beaded peri-apatite coated femoral component are stable constructs as demonstrated in this patient cohort.

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Chapter 3

3 The impact of surgical technique on contact kinematics for an uncemented cruciate-retaining total knee arthroplasty.

3.1 Introduction

Success of the total knee arthroplasty (TKA) procedure can be measured through a variety of functional and durability parameters determined by patient-, surgeon-, and implant-related factors.[1] One surgeon-related variable is TKA surgical technique. As a result of dissatisfaction rates (reported by up to 20% of patients post-operatively[2,3]) surgeons have sought improvements in surgical technique, most often centred around component alignment, balance of the joint space, and intraoperative soft tissue releases.[3,4] Two TKA surgical approaches, gap balancing (GB) and measured resection (MR), are commonly used to achieve the goals of the TKA procedure and optimize component position, joint balance, and treatment of joint soft tissues. In a GB approach, soft tissue releases are first conducted to ensure neutral alignment of the limb. Afterwards bone resection enables the creation of symmetrical balanced rectangular joint spaces with the limb in a position of flexion and extension.[3] In a MR approach, bone resections are first made based on predetermined anatomical landmarks.[3] Subsequent soft tissue releases are conducted to balance the joint space. Neither technique has consistently shown superiority across a number of clinical outcomes of interest.[3,5]

Irrespective of surgical technique surgeons, aim to achieve precise rotational alignment of the femoral component.[6] The technique best suited to optimize component alignment is a commonly held debate amongst arthroplasty surgeons. Improper femoral component rotation has been associated with a number of undesirable outcomes such as anterior knee pain, condylar liftoff, and altered joint kinematics.[6,7] Fluoroscopic studies can be used to assess condylar liftoff following TKA. It is hypothesized that condylar liftoff is a result of instability within the coronal plane and improper femoral component rotation.[6,8,9] When condylar liftoff is present unequal load distribution is observed across the medial and lateral compartments of the joint. This increase in applied stress can result in greater rates of polyethylene wear in one of the aforementioned compartments, ultimately leading to an increased risk for revision surgery.[8–10] Previous studies have shown greater rates of condylar liftoff in TKA's performed using a MR technique when compared to a GB technique.[6,11] Additionally, rates of condylar liftoff tend to be higher when a cruciate-retaining TKA is performed compared to a posterior-stabilized TKA.[6,12]

Fluoroscopy can also be utilized to assess a joint's tibiofemoral contact kinematics post-TKA. When a normal knee is in a position of extension, the lateral femoral condyle tends to sit slightly more anteriorly on the tibia compared to the medial femoral condyle.[12] During active flexion a healthy knee experiences posterior femoral rollback and slight internal rotation of the tibia around a medial pivot point. Implant design and surgical technique have been observed to impact tibiofemoral contact kinematics.[12] Ligamentous structures within the joint are responsible for facilitating natural knee joint kinematics. In a cruciate-retaining implant design, native structures remain responsible for joint kinematics. There is potential for these ligamentous structures to be damaged within end-stage disease states. Thus, abnormal tibiofemoral kinematics can be observed when relying on their continued function.[12]

The objective of this study was to compare: 1) the location and pattern of tibiofemoral contact from a position of extension to deep flexion and 2) the frequency of condylar liftoff between patients undergoing a TKA using either a GB or MR surgical approach with an uncemented, cruciate-retaining design.

3.2 Methods

3.2.1 Study Design

Ethics approval was obtained from The University of Western Ontario Ethics Board for Health Services Research Involving Human Subjects (REB#109486). Prior to participation written informed consent was obtained from all study participants. All patients scheduled for a primary unilateral TKA between September 2017 and May 2018 were screened for inclusion and exclusion criteria. Surgical follow up appointments were completed at the Rorabeck Bourne Joint Replacement Clinic at London Health Sciences Centre, University Campus. Radiographic images required to assess tibiofemoral contact kinematics and condylar liftoff were taken at the Robarts Research Institute, Western University. Figure 18 shows participant flow through study. The patient cohort evaluated is the same as in Chapter 2.

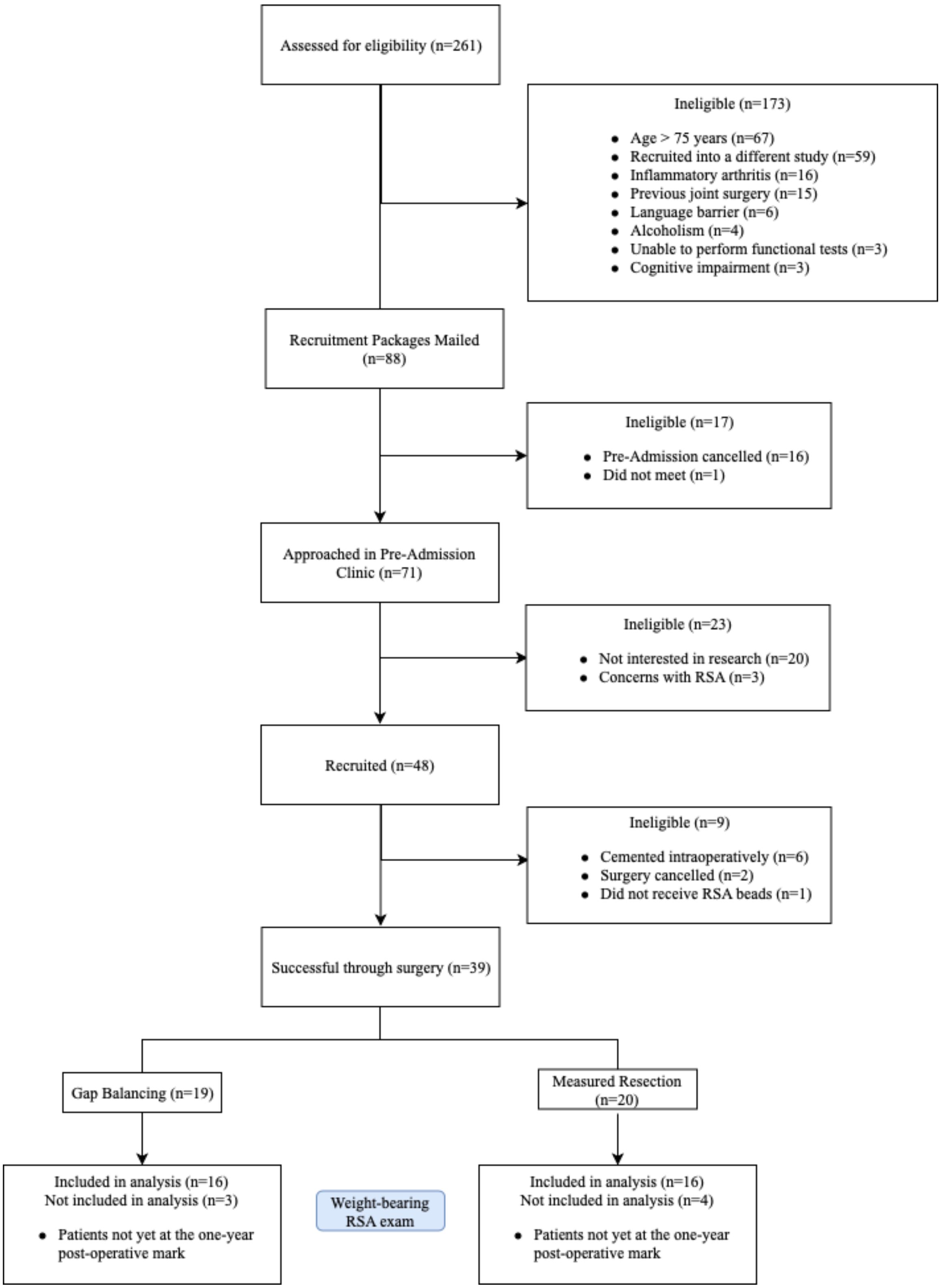

Figure 18: Participant flow through study.

3.2.2 Eligibility Requirements

To be eligible patients had to be a minimum of 18 years old and had to have received a diagnosis of OA. Exclusion criteria were: prior knee surgery, a diagnosis of inflammatory arthritis, age greater than 75 years, if the patient was pregnant or trying to become pregnant, cognitive impairment, neuromuscular impairment causing an inability to complete a walking test, language barrier preventing completion of questionnaires, a history of alcoholism, or if the patient was undergoing a simultaneous, bilateral TKA.

Thirty-nine patients were recruited to participate in the study. Patients were assigned to either a GB or MR surgical approach based on referral to a surgeon who performed one of the prescribed techniques. Patient demographics are listed in Table 5. No significant differences were found between groups in terms of age, height, weight, body mass index, sex, or operative limb.

Table 5: Patient demographics, presented at mean ± standard deviation.

	Gap Balancing	Measured Resection	p-value
Age, y	61.7 ± 7.7	62.2 ± 6.18	0.84
Height, cm	168.0 ± 8.1	170.0 ± 6.4	0.52
Weight, kg	95.4 ± 19.5	109.0 ± 21.3	0.072
BMI, kg/m^2	34.0 ± 6.9	37.9 ± 7.3	0.13
Sex	6 males: 10 females	8 males: 8 females	0.72
Side	9 right: 7 left	8 right: 8 left	0.99

BMI; body mass index

3.2.3 Surgical Intervention

All patients had their surgery performed by a fellowship trained arthroplasty surgeon and received an identical fixed-bearing, cruciate-retaining TKA (Triathlon, Stryker, Mahwah, NJ) with uncemented fixation. The Triathlon single-radius femoral component has short external condyles to enable deep flexion of up to 150º. Both patient cohorts had a standard midline incision with a medial parapatellar arthrotomy. In the MR cohort, femoral component rotation was based off of the posterior condylar axis at 3º of external rotation. All patients received the same post-operative protocol and standard of care rehabilitation.

3.2.4 Imaging Protocol

Image acquisition occurred one-year post-operatively. Each patient underwent a weight-bearing stereo x-ray examination with two mobile x-ray sources. The sources were positioned to acquire posteroanterior projections with approximately a 40º angle between them at 0º, 20º, 40º, and 60º of flexion. The two mobile tubes were positioned to acquire mediolateral oblique views at 80º, 100º, and 120º of flexion. All quasi-static radiostereometric analysis (RSA) exams used a uniplanar calibration cage (RSA Biomedical, Umea, Sweden). Imaging set up can be visualized in Figure 19. A model-based RSA software was used to register CAD models for the femoral and tibial components to the pair of x-rays taken at each 20º angle increment (RSACore, Leiden, the Netherlands). The accuracy of the model-based software is well documented, with translational errors of 0.19 mm and rotational errors of 0.52º.[13] Using the position and orientation data obtained from the CAD model registration, a model of the polyethylene liner of the implanted thickness was attached to the tibial component. Afterwards, the shortest distance between the femoral and the tibial component with poly was computed for both the medial and lateral compartments using an in house software. This is considered to be the contact point(s) of the weight-bearing surfaces. The magnitude of distance between the surfaces at the identified point was also considered in order to measure condylar liftoff. A difference in distance greater than 0.5 mm was considered to be condylar liftoff. Within the literature, values of liftoff are often considered between 0.5 mm and 1.0 mm.[3,14] Due to the high accuracy of the RSA imaging modality, the lower end of this range was found to be more appropriate, with higher ranges being more acceptable for single plane fluoroscopic studies.

Figure 19: Patient positioning for image acquisition of (A) 0º to 60º projections and (B) 80º to 120º projections

3.2.5 Statistical Analysis

All data were assessed for normality using the D'Agostino and Pearson omnibus normality test. To compare baseline demographics between groups either an unpaired t test or Mann-Whitney was used. However, the ratios of male:female and right:left were compared using a Fisher exact test. The frequency of condylar liftoff between the groups was also compared using a Fisher exact test. At each degree of flexion, an anterior-posterior (AP) contact point was calculated. AP excursion, or the amount of AP translation, was calculated by finding the range between the minimum and maximum AP positions. Medial and lateral AP excursion was compared within groups using either a paired t-test or a Wilcoxon matched pairs test depending on if the data was normalized or not. AP excursion was compared between groups using an unpaired t-test or a Mann-Whitney test. Level of significance was set at $p<0.05$. All statistical tests were conducted using GraphPad Prism v8.0 (GraphPad Software, La Jolla, CA).

3.3 Results

3.3.1 Tibiofemoral Contact Kinematics

On the medial condyle, at 0º the GB group displayed a more anterior contact location than the MR group (mean difference: 2.48 mm), however the locations did not differ significantly between groups (p=0.20). The AP position for the GB group moved 4.79 mm posteriorly from 0º to 20º, whereas the MR group experienced only 1.14 mm of posterior translation. From a position of 40º to 100º of flexion, both the MR and GB groups showed similar AP contact position (p<0.05). The MR group had a slightly more anterior contact position on the medial condyle than the GB group. The average magnitude of this difference ranged from 1.10 mm at 40º to 2.96 mm at 100º Figure 20A). In both groups, the medial contact position moved anteriorly from 20º to 80º before shifting posteriorly from 80º to 100º.

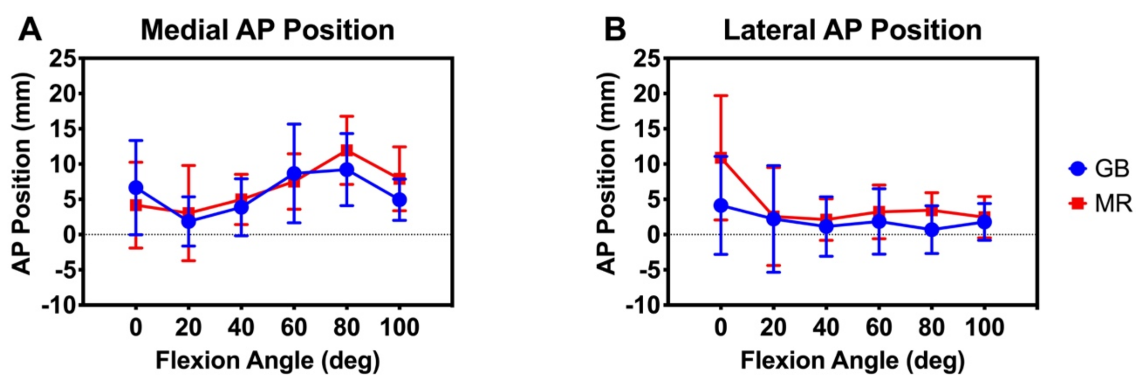

Figure 20: AP translation (mean ± standard deviation) on the medial condyle (A) and lateral condyle (B) between the MR and GB groups throughout flexion from 0º to 100º.

On the lateral condyle, at 0º the MR group displayed a significantly more anterior contact location than the GB group (mean difference: 6.90 mm, p=0.02). Both groups experienced a posterior shift in contact location from 0º to 20º, with the magnitude of difference for the MR group being 8.40 mm and 1.90 mm for the GB group. No significant difference in contact position was observed from 20º through 60º or at 100º of flexion between the groups (p>0.05). At 80º of flexion, the contact position of the MR group was more anteriorly located than the GB group (mean difference: 2.70 mm, p=0.03). The MR group had a slightly more anterior contact position on the lateral condyle compared to the GB group. The average magnitude of this difference ranged from 0.40 mm at 20º to 2.70 mm at 80º (Figure 20B). The contact position of both groups moved posteriorly from 0º to 40º. From 40º to 60º the contact position of both groups moved anteriorly. This anterior translation continued for the MR group until 80º of flexion, whereas for the GB group from 60º to 80º of flexion posterior translation was observed. From 80º to 100º the MR group displayed posterior translation in contact location. The GB group displayed anterior translation from 80º to 100º of flexion. Contact kinematic patterns are displayed in Figure 21 for both the GB (A) and MR (B) cohorts.

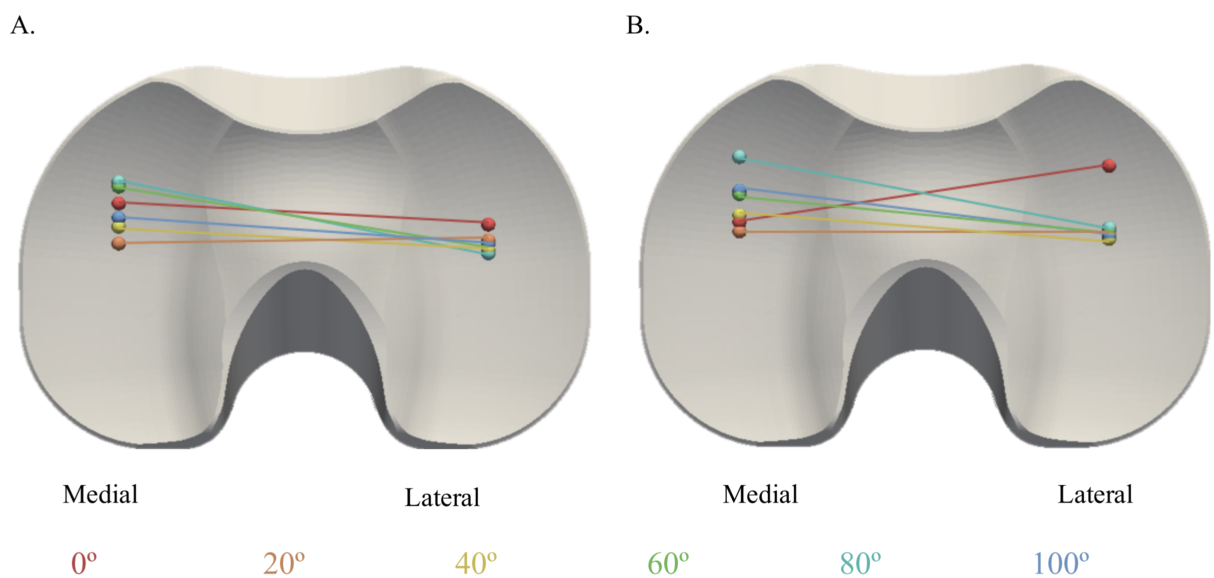

Figure 21: Contact kinematic maps for the GB(A) and MR(B) cohorts.

There was no significant difference (p=0.80) in the average amount of medial excursion between the GB group (11.11 ± 3.75 mm) and MR group (10.75 ± 4.14 mm). Additionally, there was no significant difference (p=0.21) in the average amount of lateral excursion between the GB group (7.86 ± 5.83 mm) and MR group (10.82 ± 7.75 mm). There was no difference in the magnitude of excursion medially vs. laterally for the

MR group (p=0.98) or the GB group (p=0.13). Amount of AP excursion displayed in Figure 22.

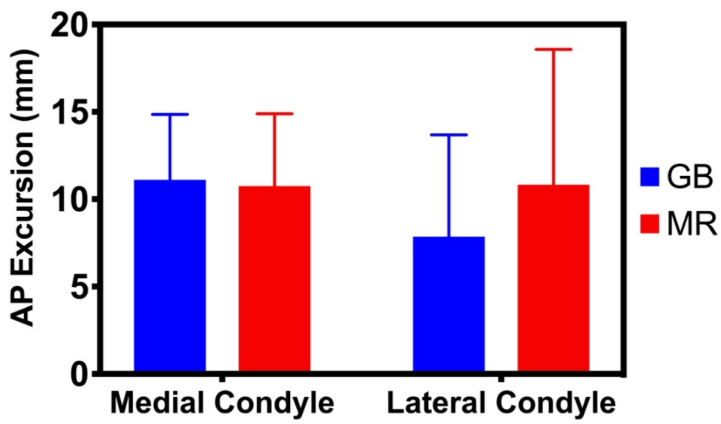

Figure 22: AP excursion of the medial and lateral condyles between the GB and MR surgical approach groups.

3.3.2 Condylar Liftoff

The incidence of coronal instability (femoral condylar liftoff) occurring at any flexion interval analyzed (0º, 20º, 40º, 60º, 80º, or 100º) was comparable between groups (p>0.999). With a threshold of 0.5 mm, 13 of 16 (81.3%) in the GB group and 13 of 16 (81.3%) in the MR group recorded condylar liftoff. In the GB group, five patients had lateral liftoff, two had medial, and six had both lateral and medial. In the MR group, seven had lateral liftoff, two had medial, and four had both. Femoral condylar liftoff greater than 1.0 mm was also comparable between groups (p=0.65). It was observed within two patients in the GB group and four patients in the MR group. In the GB group, one patient had lateral liftoff and one medial. In the MR group, three patients had lateral liftoff and one medial.

3.4 Discussion

The primary goal of the TKA procedure is to reduce pain and restore joint function. In order to achieve this, it is imperative that the tibiofemoral joint be stable throughout its full range of motion.[15] Additionally, obtaining satisfactory stability in the coronal plane is crucial to the long term success of a TKA. Past research has shown that the post-operative kinematics of the knee are influenced by the patient's condition, surgical technique employed, and design features inherent to the implant used.[16]

It is well documented within the literature that there are a number of differences that exist between pre-operative and post-operative TKA knee kinematics. Native knee kinematics describe an asymmetrical rollback of the femur during flexion, predominantly of the lateral femoral condyle, giving way to a medial pivot point and tibial internal rotation.[17] Common phenomena described of TKA knees include posterior femoral rollback, paradoxical anterior translation of the femur, and condylar liftoff.[18] Posterior femoral rollback occurs when the posterior contact position between the tibial surface and femoral condyles translates posteriorly.[19] It is often associated with a greater range of motion as the rollback delays the impingement of the femur on the tibia, a movement that normally limits flexion capabilities.[19] On the other hand, paradoxical anterior translation occurs when the flexion axis of the joint translates anteriorly. This translocation reduces the range of motion of the joint. Condylar liftoff or condylar separation between the femoral component and the polyethylene insert indicates laxity or an unbalanced gap in the joint space. It has been suggested that the joint kinematics following TKA may be partially responsible for the dissatisfaction reported in approximately 20% of patients post-operatively.[2] Additionally, a correlation between abnormal tibiofemoral contact kinematics and the amount of tibial component migration has been observed, where patient's recording more atypical movement tended to have greater amounts of component migration.[20] Thus, abnormal kinematics are thought to play a role in long-term implant loosening.

Previously documented in the literature is the difficulty of CR implants to replicate normal joint kinematics during the early post-operative period. The results from this study echo this observation, irrespective of surgical technique. We believe this is a result of the contact pattern being primarily driven by implant design as opposed to whether a GB or MR approach was utilized. Regardless of flexion degree, the tibiofemoral contact position was anteriorly located. A CR implant relies on the preserved PCL to prevent anterior positioning of the femur. It has been suggested previously, that in a diseased OA knee the PCLs functional capability may be suboptimal. From a position of 20º to 60º of flexion we observed anterior translation medially and maintained position laterally. Thus, both groups demonstrated paradoxical anterior translation during mid flexion. Stiehl et al., compared normal knees to CR-TKAs with fluoroscopy and also reported anterior translation of the condylar contact location with flexion.[21] A multi-centre in vivo study conducted by Dennis et al., examining CR- and PS-TKA, reported paradoxical anterior translation in the majority of patients who received a CR implant.[22] A study conducted by Okamoto et al., using a similar implant system to the one used in this study, reported the same contact pattern within their cohort.[23] However, the contact location observed by Okamoto et al., was consistently more posterior than that observed in our study. It is important to note however that the study cohort from Okamoto et al., was comprised of 10 knees, 8 CR-TKAs and 2 PS-TKAs, with cemented fixation. It is possible that the posterior contact location observed by Okamoto was driven by the PS-TKAs analyzed. It is well documented in the literature that PS-TKAs tend to have more posterior contact locations than CR-TKAs. Okamoto et al., did not report the differences between the PS-TKAs and CR-TKAs included in the study. Rather they reported them as one cohort with a single-radius femoral component compared to 10 CR-TKAs with a multi-radius femoral component. An uncemented CR-TKA is less forgiving than a cemented TKA in terms of any minor residual imbalance in soft tissues. With an uncemented TKA, residual imbalance could impact the position of the implant and thus contact location before osseointegration develops, potentially resulting in a more anterior contact location.

There was no significant difference within our surgical groups in terms of the amount of AP excursion observed or in the magnitude of medial or lateral excursion between the two groups. It has been reported previously in the literature that a kinematically normal knee will experience approximately 6.9 mm and 27.4 mm of posterior translation on the medial and lateral condyles, respectively.[24] The difference in posterior femoral rollback between the medial and lateral condyles gives way to a medial pivot point. Other studies have also reported similar amounts of posterior rollback on the lateral condyle and even less on the medial.[25] Thus, by analyzing the amount of AP excursion we can infer if we observed posterior femoral rollback or anterior femoral rollforward. Our study found that those who received a CR-TKA with a GB approach had medial and lateral excursion of 11.1 and 7.9 mm, respectively, whereas those who received a CR-TKA with an MR approach had 10.8 mm of medial excursion and 10.8 mm of lateral excursion. The AP excursion was in the anterior direction, indicating anterior femoral rollforward. Additionally, the results of our study do not support a medial pivot point. Rather, with deep knee flexion our results indicate a lateral pivot point. This observation is not uncharacteristic for CR-TKAs. In a study conducted by Stiehl et al., a lateral pivot point was also identified in most cases.[26] Fitz and colleagues compared the kinematic differences between 9 patients who underwent a CR-TKA with a traditional GB approach, comparable to the one used in our study, and 10 patients who underwent a CR-TKA with a modified GB approach.[12] The modified approach aimed to address the absence of a medial pivot point often seen within CR-TKAs by completing a more anatomical reconstruction of the medial femoral condyle. The traditional approach involves bone resection which results in symmetrical medial and lateral femoral condyles. In a natural knee, the condyles are asymmetrical. The larger medial condyle bears more weight and facilitates rotation of the smaller lateral condyle, thus resulting in a medial pivot point. The results of this study found that patients who received a traditional symmetrical CR-TKA were more likely to experience a lateral pivot point than those who underwent the modified GB approach.[12] As the implant we used had symmetrical femoral condyles the observable lateral pivot point may be inherent to the implant's design.

When examining the tibiofemoral contact maps of both the GB and MR cohorts, the screw home mechanistic phenomenon is much easier to visualize within the MR group. At 0º of flexion, the contact location of the medial condyle is more posteriorly located compared to the lateral contact location. As flexion occurs, the medial contact location becomes more anteriorly located than the lateral contact position, indicating that the femur has indeed experienced external rotation. Constraint of rotational movement in TKA is well documented in the literature as a cause of early implant failure.[27] It has been previously suggested that the flexion axis of the joint and the PCL play a vital role in maintaining this kinematic observation.[28] A reduced prominence of this rotational mechanism has been observed following TKA.[29] Furthermore, a lateral axis of rotation, paradoxical femoral condylar roll-forward, and absence of the screw home mechanism have been reported in CR-TKA.[30] Within both cohorts we observed an anterior contact location, a lateral pivot point, and paradoxical anterior translation of the femur with joint flexion.

When examining the rates of coronal plane instability, determined by the presence of condylar liftoff between the two surgical approach groups, no significant difference was observed. The majority of the cohort experienced separation between the femoral component and polyethylene liner of greater than 0.5 mm. With this threshold, we had an 81.25% rate of condylar liftoff. Dennis et al. examined the rates of coronal instability or femoral condylar liftoff between patients who received a CR-TKA and a PS-TKA. Within their cohort, 80% of patients with CR-TKAs experienced liftoff greater than 0.75 mm and 70% greater than 1.0 mm.[6] With a 1.0 mm threshold however, we saw separation in only six patients (18.8%). It should be noted that Dennis et al. used an alternate method to calculate liftoff than we did, using the femoral component and tibial tray, as opposed to the polyethylene liner. However, the implant used in both Dennis et al., and our current study are symmetrical. Thus, it is unlikely this is the cause of the discrepancy. When examining liftoff location, our results follow the same trend as Dennis et al.[6] High variability was observed in liftoff location within the cohort with some patients reporting medial liftoff, some lateral, and some both depending on the angle of flexion. While there were no significant differences in liftoff location, lateral liftoff tended to be more common than medial liftoff. We hypothesize that this is due to the fact that the PCL originates from the lateral origin of the medial femoral condyle. When comparing the instances of lateral liftoff with a 0.5 mm threshold to the migration patterns observed in Chapter 2, it is interesting to note that there were more instances of lateral liftoff in the MR cohort who reported significantly more varus tilt (negative tilt in the sagittal plane) of the tibial component than the GB cohort. Varus tilt would lend itself to lateral liftoff. On the contrary, medial liftoff was more common in the GB cohort who reported significantly more valgus tilt (positive tilt in the sagittal plane) of the tibial component than the MR cohort. Valgus tilt would lend itself to medial liftoff.

It is important to note the limitations of this study. All images were taken using a quasi-static protocol rather than under dynamic conditions. Nevertheless, the similarity between static and dynamic study protocols is well documented in the literature. The slight variations one may see in results does not contribute to any meaningful differences in functional outcomes.[31,32] Variations have been reported between the two modalities with respect to differences in foot position, however, standardizing our imaging set up and patient position has helped to minimize this. Therefore, we feel the clinical relevance of quasi-static exams is high and our results can be compared to weight-bearing studies using dynamic imaging protocols. Additionally, the imaging set up switched from posteroanterior images at 0º, 20º, 40º, and 60º to mediolateral oblique views at 80º, 100º, and 120º of flexion. The positioning change was made to help accommodate deep knee flexion. While this switch may impact the generalizability of our results to alternate studies, it would not influence our ability to detect kinematic differences between the surgical approach groups examined in this study. Furthermore, the CR-TKA surgery is a technically demanding operation. Our surgeons are fellowship trained and have very high yield surgical practices. Thus, we cannot conclude if the same kinematic results would be achieved following CR-TKA with less experienced surgeons. Lastly, only one implant design system was used. This prevents the results from being able to be generalized to the CR-TKA procedure. However, in order to minimize the bias imparted by implant design and focus solely on the impact of surgical technique, it was imperative only one implant system was used.

In conclusion, we found no difference in the frequency of condylar liftoff between single radius, cruciate-retaining uncemented TKA performed using a GB or MR surgical technique. The pattern of motion of the contact location during flexion was similar between groups as we hypothesize this is driven by implant design. The only difference in contact location was found to be at 0º and 80º of flexion on the lateral condyle, with the MR group reporting a more anterior contact position. The contact location on both condyles throughout the entire range of deep flexion was anterior to the mid sagittal plane of the tibial component. Both the MR and GB cohort reported improvements in clinical outcome scores from the pre-operative to one year post-operative time point. Therefore, for this particular implant design system, the GB and MR surgical techniques appear to produce similar *in vivo* kinematics.

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Chapter 4

4 Novel joint-specific metrics derived from instrumented Timed-up-and-go test allows for better characterization of patient functional status pre- and post-TKA

4.1 Introduction

One in five patients report dissatisfaction with their total knee arthroplasty (TKA) for reasons such as, limited functional improvement and persistent disability.[1,2] As the commonality of the TKA procedure is on the rise, it is imperative that we develop a better understanding of what is at the root of this dissatisfaction. Patient satisfaction is determined by a multitude of factors.[3] Clinical results and satisfaction are currently assessed using a range of objective and subjective measures.[4]

Patient reported outcome measures (PROMs) are an important tool for measuring patient outcomes and TKA effectiveness as they consider the most prominent participant in the TKA procedure, the patient. In general, PROMs aim to assess patient pain, function, and satisfaction. PROMs have become a popular way to assess these qualities as they are easy to administer, inexpensive, and convenient to use in longitudinal follow up.[5] Unfortunately, they are not without their disadvantages. PROMs are subject to biases and ceiling and floor effects, as functional differences are often masked by patient pain.[5,6] While pain management is a very important outcome from the perspective of the patient, pain is a subjective measure and has been shown to be influenced by socioeconomic and psychosocial factors.[5,7] PROMs are administered in the form of questionnaires. The categorical outcomes group patients together despite potentially having different symptoms and responses to treatment.[8,9] The trend of the TKA patient demographic is moving towards patients who are younger and often interested in higher levels of post-operative function. Thus, function is becoming an increasingly important outcome to accurately and effectively measure due to higher expectations and a greater demand for post-op function. As PROMs are unable to fully capture the functional abilities of relevance to the TKA patient population, additional measures must be included in the assessment of function.[5]

Performance based outcome measures are an objective way to assess function. Physical performance tests focus on what a patient can actually do, rather than on what they perceive they can do.[6] While both PROMs and performance-based measures aim to assess function, only low to moderate correlations with one another have been observed.[5,10] The absence of a strong correlation suggests that each measure provides distinct but potentially supplementary information about patient function. Therefore, including functional performance-based assessments in the clinical environment allows for better characterization of functional capability. Physical performance tests are simple to implement, require minimal resources and staff, and can be completed quickly. The timed-up-and-go (TUG) test has been shown to demonstrate reliable functional improvements post-operatively amongst TKA populations.[11–13] The TUG test requires patients to start in a seated position, stand up, walk three metres, turn around, walk back to the chair, and assume the seated position once again. Historically, measurements have been solely focused on the overall time to complete the TUG test. While this singular temporal parameter does relate to patient function, it is unable to capture subtle differences in functionality besides completing the test at a quicker rate.

The use of wearable sensors to measure complex joint kinematics has become increasingly popular over the last few years.[14] These sensors systems are economically feasible, portable, user friendly, and easily allow for the assessment of three-dimensional motion. An easy and popular way to collect joint kinematic data is through the use of inertial measurement units (IMUs). Using a gyroscope, accelerometer, and magnetometer joint angles can be calculated with good accuracy.[14,15] IMUs have been used to obtain biomechanical data in healthy, OA, and TKA populations.[9,16,17] IMUs can be used to collect acceleration, velocity, and orientation data at much less cost than with traditional motion capture systems. These sensors have a very small physical size which makes positioning them on the body during the completion of physical activity uncomplicated. Research studies have begun to implement wearable sensors into the TUG functional performance test for younger and older adults, as well as patients with Parkinson's disease.[18–21]

In prior work, our research group has identified links between wearable sensor derived TUG test metrics and satisfaction.[22,23] Additionally, using these metrics we have identified links between pre-operative function and functional capacity at three months post-op within a TKA population.[24] The purpose of this study is to implement IMUs into the TUG performance test amongst a cohort of patients undergoing a primary unilateral TKA through either a GB or MR surgical approach. By instrumenting the TUG test pre- and post-operatively amongst this cohort we aim to identify how sensor-derived metrics change from pre- to post-TKA and identify any relationship between early and late functional performance following TKA. We hypothesize that over the duration of the follow up period we will see significant improvements in overall time to complete the TUG and the temporal segments of the test. Additionally, we hypothesize that the previously identified sensor metrics important for satisfaction and function will improve over the follow up period and that correlations will exist between pre-operative levels and future performance. The novel sensor derived metrics will provide a deeper understanding of patient functional capacity and allow for more detailed assessment of movement patterns than total TUG time alone.

4.2 Methods

4.2.1 Study Design

Institutional ethics approval was obtained from The University of Western Ontario Ethics Board for Health Services Research Involving Human Subjects (REB#109486). Prior to participation in the study, written and informed consent was obtained from all participating patients. Patients scheduled for a primary unilateral TKA between September 2017 and May 2018 were screened for inclusion and exclusion criteria. Surgical and research related follow up visits were completed in the Rorabeck Bourne Joint Replacement Clinic at London Health Sciences Centre, University Hospital. Figure 23 details participant flow through study. The patient cohort evaluated is the same as in Chapters 2 and 3.

4.2.2 Eligibility Requirements

Patient eligibility required that they be over the age of 18, had received a diagnosis of osteoarthritis, and be scheduled for a primary unilateral TKA. Patients were excluded if their surgery was not to be performed by one of the two participating surgeons. Additionally, patients were excluded if they were over the age of 75 years, received a diagnosis of inflammatory arthritis, had a cognitive impairment or language barrier preventing competition of PROMs, a neuromuscular impairment causing an inability to complete the TUG test, were pregnant or trying to become pregnant, had a history of alcoholism, or if the patient was undergoing simultaneous bilateral TKA. Patient demographics are listed in Table 6. No significant difference in terms of age, height, BMI, sex, or operative side. There was a significant difference between groups with respect to weight (p=0.04).

4.2.3 Intervention

All patients received a midline incision with a medial parapatellar arthrotomy. All surgeries were performed by a fellowship trained arthroplasty surgeon. Patients received fixed-bearing, cruciate-retaining implant systems (Triathlon, Stryker, Mahwah, NJ) with uncemented fixation. Study related visits occurred pre-operatively (within one month of surgery), two weeks, six weeks, three months, six months, and one year post-op. At all study visits patients completed three trials of the instrumented TUG test while wearing IMUs. For the TUG test, patients were instructed to start in a seated position, stand up, walk three meters, turn around, walk back, and assume a seated position once again. They were instructed to complete the test at a comfortable pace and to stand up/sit down without the use of arm rests, whenever possible. Participants were allowed to use any gait aids used pre- or post-operatively (cane, crutch, walker, etc.) while completing the test trials. The chair used during the TUG test was standardized and used for all trials, at all follow ups, for all patients. At the pre-operative, six week, three month, six month, and one year visits patients completed patient-reported outcome measures in the form of a series of questionnaires. The questionnaires included the SF-12, WOMAC, the KSS, and the UCLA Activity score.

Table 6: Patient demographics, presented as mean ± standard deviation.

	Gap Balancing	Measured Resection	p-value
Age, y	62.3 ± 7.4	62.9 ± 6.7	0.78
Height, cm	167.4 ± 8.0	170.1 ± 7.8	0.42
Weight, kg	93.6 ± 18.9	107.1 ± 7.8	0.04
BMI, kg/m^2	33.4 ± 6.5	37.3 ± 6.8	0.08
Sex	7 males: 12 females	10 males: 10 females	0.53
Side	11 right: 8 left	10 right: 10 left	0.75

BMI; body mass index

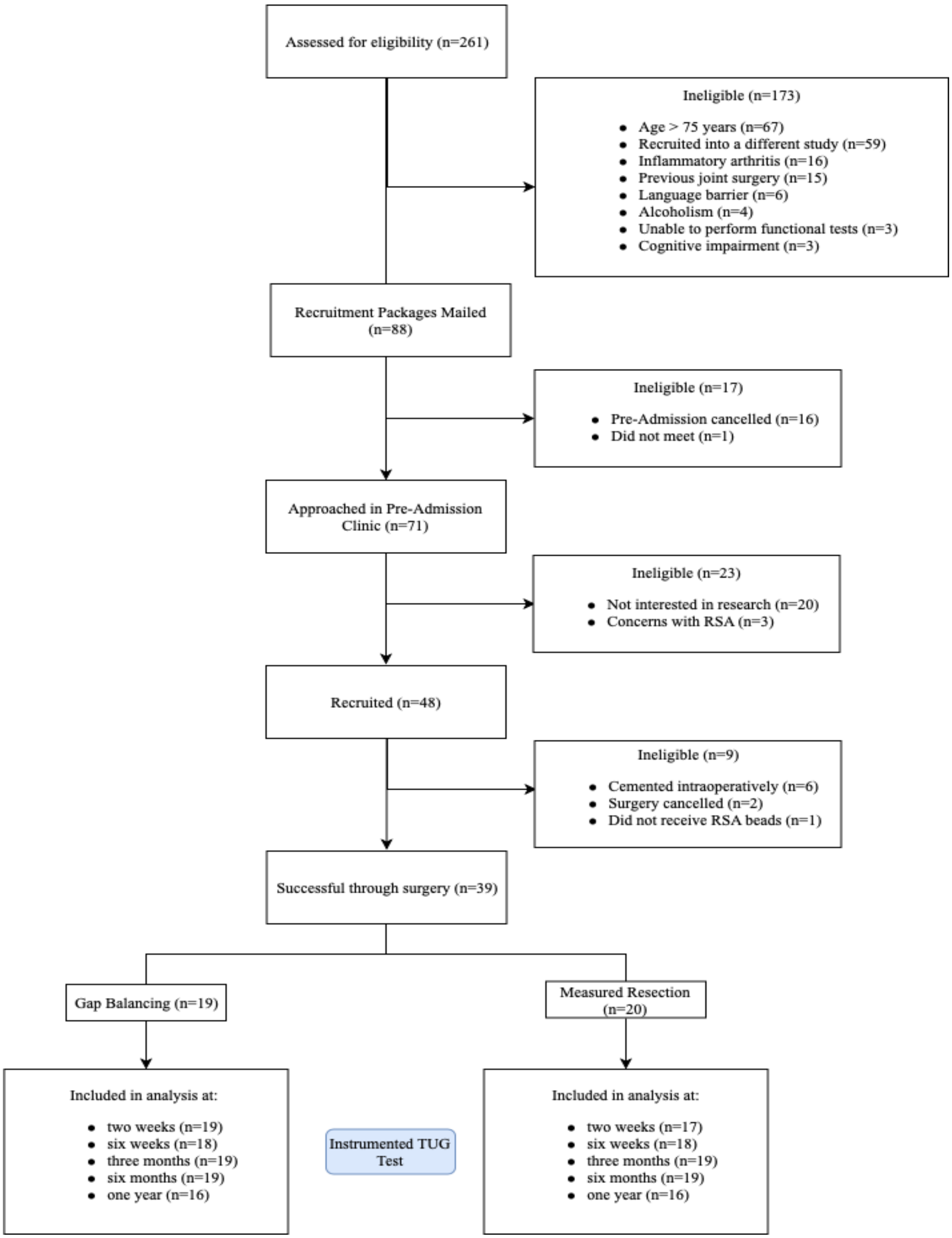

Figure 23: Participant flow through study.

4.2.4 Sensor Setup

Four wearable sensors were used during the instrumented TUG test. IMUs were affixed to the anterior side of both the operative and non-operative limb both above and below the knee joint. This is displayed in Figure 24.

Figure 24: Wearable sensor placement.

Each wearable sensor consists of an IMU development board (MetaMotionR, MBientLab, San Francisco, CA) and a rechargeable lithium-polymer battery. Both were housed in a custom plastic 3D printed case with the approximate dimensions of 1.2 cm x 3.0 cm x 4.0 cm. In order to affix the sensor to the patient, two wings were constructed on either side of the sensor with slots for an elastic strap. The 3D printed case was concave in shape to help with placement on the anterior side of the lower limb and to decrease motion artifacts. The size of the sensor case is depicted in Figure 25.

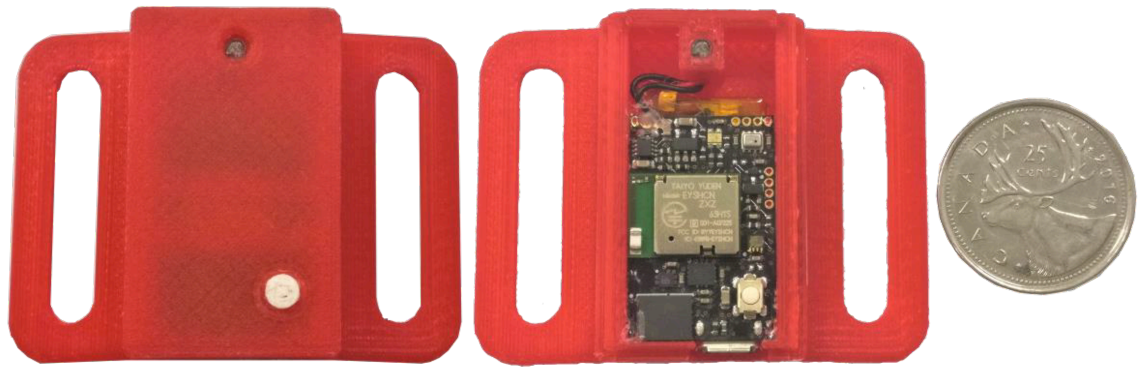

Figure 25: Custom 3D printed case for wearable sensors, quarter for scaling purposes. Reproduced with permission from Riley Bloomfield.

The sensors were programmed to transfer data via Bluetooth to an Apple iPod touch at the end of each TUG test trial. The iPod was configured to store raw data without a persistent connection to a wireless network. Custom software was developed to use raw sensor data (orientations) and calculate joint angles. This occurred at a sampling rate of approximately 25 Hz.[22]

4.2.5 Sensor-derived Metrics

Novel sensor-derived metrics of function previously identified, tested, and validated through other in-house studies were collected from instrumented TUG test performance.[22,23] Temporal metrics included Total TUG time, Sit-to-Stand time, Walk-to-Goal time, Turning-at-Goal time, Walk-to-Chair time, and Turn-to-Sit time. Other spatiotemporal metrics included step counts for the operative (SC_{OP}) and non-operative (SC_{NON}) limbs and total step count (SC_{TOT}). Angular metrics included specific angles and angle ranges for both the operative and non-operative limbs, such as Start-TUG and End-TUG flexion and extension angles and their asymmetry, and average step maximum flexion angle and flexion range. Velocity and acceleration metrics were calculated for the average step of the operative and non-operative limb and included flexion and extension velocity and acceleration.

Metrics specific to the sensors used in this study were determined using orientation data and were based on values of flexion/extension, internal/external rotation, and varus/valgus rotation. Additionally, metrics representing movement in all three axial directions of each individual sensor (i.e. upper and lower sensors) on the operative and non-operative limbs were determined. An Additive Angular Displacement (ADD) value was calculated by summing the differences in angles from one sampling time to another sampling time over a given sampling period. In the case of this study, the sampling period is either one gait cycle (one step) or the entire TUG test. Patients with greater motion over the sample period will have higher ADD values. All sensor derived metrics are listed and described in Table 7.

Table 7: List of sensor metrics and descriptions.

Sensor Metrics	Description
Spatiotemporal	
Total TUG Time	Total time (s) taken to complete one trial of the TUG test
Sit-to-Stand	Time (s) taken to go from a seated to standing position
Walk-to-Goal	Time (s) taken to walk from starting chair to goal, distance 3 metres
Turn-at-Goal	Time (s) taken to turn at goal
Walk-to-Chair	Time (s) taken to walk from the turnaround point back to the chair, distance 3 metres
Turn-to-Sit	Time (s) taken from the start of the turn to a seated position
Step Count (SC_{OP}, SC_{NON}, SC_{TOT})	Number of steps (gait cycles) taken during TUG test
Angular	
Start-TUG Flexion Angle ($_{OP}$ and $_{NON}$)	Knee joint angle (º) of operative or nonoperative limb in seated position at start of TUG test
End-TUG Flexion Angle ($_{OP}$ and $_{NON}$)	Knee joint angle (º) of operative or nonoperative limb in seated position at end of TUG test
Average Step Max. Flexion Angle	Average maximum flexion angle (º) of the knee during TUG test for the operative or nonoperative limb

Average Step Flexion Range	Average difference between the minimum and maximum flexion angles (º) of the knee during the TUG test of the operative and nonoperative limb.
Velocity	
Average Step Flexion Velocity (OP and NON)	Average flexion angular velocity (º/s) of all steps taken during TUG test of operative or nonoperative limb
Average Step Extension Velocity (OP and NON)	Average extension angular velocity (º/s) of all steps taken during the TUG test of operative or nonoperative limb
Acceleration	
Average Step Flexion Acceleration (OP and NON)	Average flexion angular acceleration ($º/s^2$) of all steps taken during the TUG test of operative or nonoperative limb
Average Step Extension Acceleration (OP and NON)	Average extension angular acceleration ($º/s^2$) of all steps taken during the TUG test of operative or nonoperative limb
Additive Angular Displacement	
Total Flexion-Extension Additive Angular Displacement ($TAAD_{OP}^{F/E}$ and $_{NON}^{F/E}$)	General motion (º) of the knee joint in the flexion-extension axis over the entire TUG test of the operative or nonoperative limb
Total Internal-External Additive Angular Displacement ($TAAD_{OP}^{I/E}$ and $_{NON}^{I/E}$)	General motion (º) of the knee joint in the internal/external rotation axis over the entire TUG test of the operative or nonoperative limb
Total Varus-Valgus Additive Angular Displacement ($TAAD_{OP}^{V/V}$ and $_{NON}^{V/V}$)	General motion (º) of the knee joint in the varus-valgus axis over the entire TUG test of the operative or nonoperative limb
Sensor Specific Total Additive Angular Displacement ($TAAD_{OP}^{LOW}$, $_{OP}^{HIGH}$, $_{NON}^{LOW}$ and $_{NON}^{HIGH}$).	General motion (º) of the shank (LOW) and thigh (HIGH) over the entire TUG test of the operative or nonoperative limb
Step Flexion-Extension Additive Angular Displacement ($SAAD_{OP}^{F/E}$ and $_{NON}^{F/E}$)	General motion (º) of the knee joint in the flexion-extension axis of an average step of the operative or nonoperative limb
Step Internal-External Additive Angular Displacement ($SAAD_{OP}^{I/E}$ and $_{NON}^{I/E}$)	General motion (º) of the knee joint in the internal/external rotation axis of an average step of the operative or nonoperative limb
Step Varus-Valgus Additive Angular Displacement ($SAAD_{OP}^{V/V}$ and $_{NON}^{V/V}$)	General motion (º) of the knee joint in the varus-valgus axis of an average step of the operative or nonoperative limb

Sensor Specific Step Additive Angular Displacement ($SAAD_{OP}^{LOW}$, $_{OP}^{HIGH}$, $_{NON}^{LOW}$ and $_{NON}^{HIGH}$).	General motion (°) of the shank ($_{LOW}$) and thigh ($_{HIGH}$) of an average step of the operative or nonoperative limb

Previous studies by our research group have identified metrics important for post-operative function and satisfaction levels.[22,23] Specifically: total TUG time, sit-to-stand time, walk-to-goal time, walk-to-chair time, operative limb step count, average step flexion range of the operative limb, $SAAD_{OP}^{F/E}$, $SAAD_{OP}^{Low}$, $SAAD_{NON}^{Low}$, $SAAD_{OP}^{High}$, $SAAD_{NON}^{High}$. Special attention in the analyses will be brought to these previously identified metrics and their improvement over time.

4.2.6 Statistical Analysis

Baseline demographics and PROMs were tested for normality using the D'Agostino and Pearson omnibus normality test. One year PROMs were compared to baseline levels using a paired t test or Wilcoxon matched pairs signed rank test depending on normality. Sensor metrics were compared at different time points using an ANOVA with mixed effects analysis. A Tukey post-hoc test was used to correct for multiple comparisons. Correlations between metrics at different follow up times were calculated using Pearson's correlation coefficient (r). Correlations were then classified as being either weak (|0.20| – |0.39|), moderate (|0.40| – |0.79|), or strong (|0.80|-|1.00|). Level of significance was set at $p<0.05$. All statistical tests were conducted using GraphPad Prism v8.0 (GraphPad Software, La Jolla, CA).

4.3 Results

No significant differences were found between GB and MR surgical techniques in terms of PROMs or sensor-derived metrics; thus, GB and MR patients were combined and results are presented as one cohort. Significant improvements in the SF-12 PCS ($p<0.0001$), WOMAC ($p<0.0001$), KSS ($p<0.0001$), and UCLA Activity Score ($p=0.0002$) were observed one year post-operatively from baseline values. No improvement in SF-12 MCS was observed ($p=0.72$). Means and standard deviations for all questionnaires at the pre-operative and one year follow up visit can be found in Table 8.

Table 8: Patient reported outcome measures, presented as mean ± standard deviation.

	Pre-Op	1 year	p-value
SF-12 MCS	51.7 ± 11.3	52.2 ± 10.6	0.72
SF-12 PCS	32.0 ± 8.3	45.3 ± 8.8	0.0001
WOMAC	43.6 ± 17.2	80.7 ± 17.0	0.0001
KSS	108.5 ± 32.4	203.7 ± 31.1	0.0001
UCLA	4.5 ± 2.2	6.0 ± 1.4	0.0002

SF-12, short form 12; MCS, mental component score; PCS, physical component score; WOMAC, Western and McMaster Universities Osteoarthritis Index, KSS, knee society score; UCLA, University California, Los Angeles activity score

A significant effect of time (p<0.001) was observed when examining total TUG performance time and temporally segmented components of the TUG test over the duration of the study. This is demonstrated in Figure 26. A significant increase in pre-operative total TUG time was observed at the two week assessment (mean difference: 7.90s, p=0.02). Total TUG performance time at six weeks was comparable to pre-operative levels (mean difference: -1.25s, p=0.64). By three months post-operatively, total TUG performance time was significantly faster than pre-operative performance (mean difference: -3.41s, p=0.0031). No further significant improvements in total TUG performance time were observed between three and six months (mean difference: -0.42s, p=0.78) or six months and one year (mean difference: 0.20s, p=0.90). Total TUG

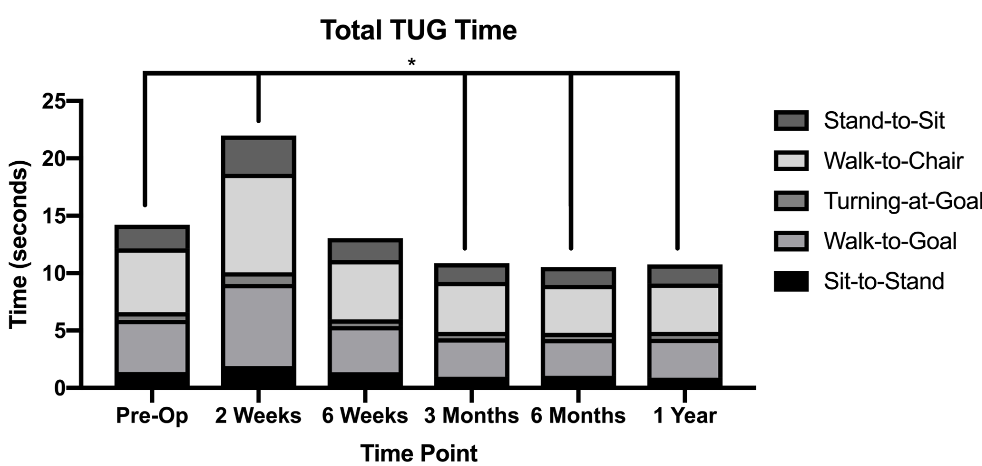

Figure 26: Average total TUG performance time.

performance time remained significantly faster than pre-operative performance at six months (mean difference: -3.83s, $p=0.0003$) and one year (mean difference: -3.63s, $p=0.004$).

The same effect of time was observed for temporally segmented TUG times of walk-to-goal, walk-to-chair, and stand-to-sit ($p<0.0001$). The mean differences in walk-to-goal, walk-to-chair, and stand-to-sit times between the pre-operative time point and three month time point were -1.19s ($p<0.0001$), -1.18s ($p=0.02$), and -0.45s ($p=0.03$), respectively. No significant improvement in these components was observed between three months and six months or six months and one year ($p>0.05$). Sit-to-stand time saw significant improvement from pre-operative levels at one year (mean difference: -0.51s, $p=0.03$). Turn-at-goal time saw significant improvements from pre-operative levels at six months (mean difference: -0.51s, $p=0.01$).

No significant effect of time was observed with respect to the number of steps taken with the operative limb during a trial performance of the TUG. A significant effect of time was observed in the mean step flexion range of the operative limb ($p=0.0002$). The earliest time point to demonstrate significant improvement from pre-operative levels was six months post-op (mean difference: 8.27°, $p=0.0006$). At one year post-op the mean improvement in flexion range of the operative knee was 9.33°, representing a 25% increase in pre-op mean step flexion range.

A significant effect of time ($p<0.05$) was also observed in a number of step additive angular displacement metrics: $SAAD_{OP}^{F/E}$, $SAAD_{OP}^{Low}$, $SAAD_{NON}^{Low}$, $SAAD_{OP}^{High}$, and $SAAD_{NON}^{High}$. Mean difference in $SAAD_{OP}^{F/E}$ from pre-op to six months was 18.55° ($p=0.0001$). No significant difference was observed from six months to one year ($p=0.69$). All additive sensor metrics representing movement in three planes of the lower or upper leg segments followed the same trend of improvement. $SAAD_{OP}^{Low}$, $SAAD_{NON}^{Low}$, $SAAD_{OP}^{High}$, and $SAAD_{NON}^{High}$ saw improvement at three months from pre-operative levels with mean differences of 14.12 ($p=0.005$), 12.68 ($p=0.02$), 9.86 ($p=0.02$), and 10.84 ($p=0.005$) respectively. No further significant improvement was observed in $SAAD_{OP}^{Low}$, $SAAD_{NON}^{Low}$, $SAAD_{OP}^{High}$, and $SAAD_{NON}^{High}$ at six months from three months ($p=0.69$, $p=0.20$, $p=0.71$, and $p=0.14$) or at one year from six months ($p=0.99$, $p=0.94$, $p=0.99$, and $p=0.94$). Mean, standard deviation, minimums and maximums of metrics previously identified as important to patient satisfaction are displayed in Table 9.

Table 9: Means, standard deviations, and ranges for metrics identified from previous laboratory studies.

	Pre-op	2 weeks	6 weeks	3 months	6 months	1 year	p-value
Total TUG time (s)	14.92 ± 5.13 (8.35-32.20)	22.81 ± 13.91 (9.11-81.95)	13.66 ± 3.08 (8.34-37.79)	11.51 ± 3.08 (7.65-24.97)	11.09 ± 2.24 (7.71-18.70)	11.29 ± 2.57 (7.15-20.15)	<0.0001
Sit-to-Stand (s)	1.38 ± 0.84 (0.61-5.29)	1.91 ± 1.50 (0.65-8.60)	1.37 ± 0.99 (0.56-5.21)	0.96 ± 0.32 (0.61-2.45)	0.91 ± 0.29 (0.58-1.97)	0.88 ± 0.25 (0.56-1.88)	<0.0001
Walk-to-Goal (s)	4.55 ± 4.57 (2.48-9.42)	7.14 ± 0.84 (2.82-28.95)	4.01 ± 1.28 (2.23-8.60)	3.35 ± 0.98 (2.25-7.98)	3.23 ± 0.78 (2.05-6.20)	3.41 ± 0.92 (1.82-6.34)	<0.0001
Walk-to-Chair (s)	5.56 ± 1.99 (2.81-12.90)	8.59 ± 4.98 (3.77-26.51)	5.16 ± 1.65 (2.62-10.71)	4.38 ± 1.29 (2.40-9.25)	4.17 ± 1.022 (2.45-7.36)	4.21 ± 1.11 (2.37-7.89)	<0.0001
Op. Step Count	5.80 ± 1.92 (4.00-9.00)	5.64 ± 2.32 (1.50-9.67)	5.34 ±1.50 (1.33-8.00)	5.38 ± 1.25 (3.00-9.00)	5.12 ± 1.22 (1.67-7.67)	5.38 ± 1.52 (2.00-9.00)	0.06
Op. Step Flexion Range (°)	37.66 ± 9.31 (21.32-62.08)	31.00 ± 7.62 (21.57-44.79)	37.46 ± 7.79 (21.11-52.90)	40.46 ± 6.83 (22.52-55.82)	45.93 ± 9.43 (25.08-72.44)	46.99 ± 23.05 (24.17-166.30)	0.0002
$SAAD_{OP}^{F/E}$	77.88 ± 18.03 (45.96-126.30)	62.20 ± 14.50 (43.12-90.57)	75.64 ± 14.77 (43.16-98.90)	83.13 ± 14.96 (42.77-118.90)	96.43 ± 18.54 (56.11-163.10)	91.40 ± 14.50 (57.23-120.50)	<0.0001
$SAAD_{OP}^{Low}$	117.50 ± 20.80 (69.90-154.00)	94.69 ± 16.78 (69.62-134.70)	116.0 ± 17.92 (74.42-157.70)	131.60 ± 17.93 (78.64-182.30)	135.30 ± 24.42 (64.54-148.20)	136.20 ± 6.73 (89.21-183.20)	<0.0001
$SAAD_{NON}^{Low}$	120.80 ± 20.78 (77.06-158.30)	105.00 ± 19.97 (48.50-148.20)	126.30 ± 18.64 (84.47-172.20)	133.50 ± 15.61 (88.24-164.50)	137.70 ± 19.20 (8693-171.70)	136.10 ± 16.63 (89.75-167.50)	<0.0001
$SAAD_{OP}^{High}$	85.39 ± 19.41 (28.69-124.60)	66.98 ± 14.08 (46.97-98.57)	84.36 ± 15.87 (3.26-112.20)	95.24 ± 15.65 (52.75-132.40)	98.32 ± 17.90 (46.01-130.60)	97.83 ± 15.96 (57.97-131.10)	<0.0001
$SAAD_{NON}^{High}$	84.34 ± 17.74 (59.26-124.20)	71.04 ± 16.00 (29.15-109.20)	88.97 ± 16.11 (57.95-127.20)	95.18 ± 14.78 (60.03-128.50)	99.37 ± 14.71 (66.20-131.0)	97.84 ± 16.15 (61.14-135.30)	<0.0001

Correlations over time were examined for the metrics from Table 9 with a significant effect of time.

Weak to moderate yet significant correlations were found between pre-operative total TUG performance time and performance time at all follow up time points. Strong, significant correlations were observed between two week total TUG performance and six week ($p=0.002$), three month ($p=0.0005$), six month ($p=0.01$), and one year ($p=0.007$) performance. As follow up time progressed, stronger correlations between performance time at subsequent visits were generally observed. Pearson correlation matrix displayed in Table 10.

Table 10: Pearson correlation matrix of total TUG performance times, all correlations listed have a p<0.05.

Pre-op	2 Week	6 Week	3 Month	6 Month	1 Year	Pearson (r)
	0.30	0.42	0.36	0.36	0.32	Pre-op
		0.76	0.79	0.64	0.73	2 Week
			0.83	0.75	0.73	6 Week
				0.77	0.74	3 Month
					0.90	6 Month

All metrics from Table 9 showed at least one significant correlation between performance at a given time point and future performance. Sit-to-stand, mean flexion range of the operative joint, $SAAD_{OP}^{F/E}$, and $SAAD_{OP}^{High}$ showed only weak to moderate correlations over time, but walk-to-goal, walk-to-chair, $SAAD_{OP}^{Low}$, $SAAD_{NON}^{Low}$, and $SAAD_{NON}^{High}$ metrics demonstrated strong correlations over time and those are shown in Tables 11-15.

Table 11: Pearson correlation matrix of walk-to-goal time, all correlations listed have a p<0.05.

Pre-op	2 Week	6 Week	3 Month	6 Month	1 Year	Pearson (r)
	0.42	0.53	0.56	0.58	0.53	Pre-op
		0.60	0.77	0.68	0.68	2 Week
			0.77	0.64	0.65	6 Week
				0.79	0.77	3 Month
					0.90	6 Month

Table 12: Pearson correlation matrix of walk-to-chair time, all correlations listed have a p<0.05.

Pre-op	2 Week	6 Week	3 Month	6 Month	1 Year	Pearson (r)
						Pre-op
		0.67	0.65	0.54	0.60	2 Week
			0.80	0.68	0.64	6 Week
				0.74	0.72	3 Month
					0.86	6 Month

Table 13: Pearson correlation matrix of $SAAD_{OP}^{Low}$, all correlations listed have a $p<0.05$.

Pre-op	2 Week	6 Week	3 Month	6 Month	1 Year	Pearson (r)
			0.41			Pre-op
		0.69	0.43			2 Week
			0.66	0.61	0.66	6 Week
				0.79	0.81	3 Month
					0.71	6 Month

Table 14: Pearson correlation matrix of $SAAD_{NON}^{Low}$, all correlations listed have a $p<0.05$.

Pre-op	2 Week	6 Week	3 Month	6 Month	1 Year	Pearson (r)
	0.34	0.44				Pre-op
		0.80	0.73	0.65	0.71	2 Week
			0.83	0.74	0.63	6 Week
				0.82	0.74	3 Month
					0.82	6 Month

Table 15: Pearson correlation matrix of $SAAD_{NON}^{High}$, all correlations listed have a $p<0.05$.

Pre-op	2 Week	6 Week	3 Month	6 Month	1 Year	Pearson (r)
	0.47	0.56	0.49	0.54		Pre-op
		0.77	0.69	0.69	0.54	2 Week
			0.80	0.6	0.50	6 Week
				0.77	0.60	3 Month
					0.81	6 Month

4.4 Discussion

Through the instrumentation of the TUG performance test with wearable sensors amongst a primary TKA population, novel spatiotemporal, velocity, acceleration, and angular metrics related to functional performance were examined. The absence of strong correlations between PROMs and physical performance outcomes provides further support to the differences which exist between subjective and objective function and the inability of PROMs to paint a complete picture of patient function.[9] By including the TUG test in clinical follow up, we are able to gather important information about post-operative function and thus develop a better understanding of the TKA recovery process.

The Osteoarthritis Research Society International has recommended a core set of three performance based outcome measures for use in OA research and clinical practice.[25] They are the 30s chair stand, 40m fast-paced walk, and a stair-climb test. The TUG test and six minute walk test are indicated to be complementary, yet supplementary performance based outcome measures because of the redundancy of activity themes if all are performed. It can be difficult under some circumstances however to complete all of these functional performance tests and completing the 30s chair stand, 40m fast-paced walk, or stair-climb test alone risks providing a superficial understanding of patient function. As the stair-climb test was not feasible to administer within our clinical environment and the 40m fast-paced walk test can be difficult for TKA patients to complete comfortably at early post-operative time points, the TUG test was selected as our functional outcome measure due to the overlap of activity themes (i.e. involves chair stand and walking components).[25,26] Only a surface level understanding of patient function would be obtained from using performance based assessment(s) that do not evaluate a number of basic motor activities important for activities of daily living, such as walking ability and the ability to rise from a chair.

Significant changes over time were observed with respect to total TUG time and all temporal segments of the TUG test. The significant increase in total TUG performance time at the two week follow up period is understandable as the early post-operative period is a time of acute pain and swelling. As this subsides and physical rehabilitation becomes a more prominent part of daily patient life, function begins to be restored with performance equivalent to pre-operative levels being observed at the six week follow up period. The mean magnitude of performance improvement in total TUG time over the duration of the follow up period was 3.83s. This improvement is greater than the minimal clinically important difference of 2.27s previously described in the literature and thus, represents a "real" clinical change in patient function.[12] As current clinical practice suggests that total TUG time can be used as a predictor of fall risk within elderly community dwelling populations this improvement is important to note.[27] Furthermore, Greene et al., analyzed fall risk using the TUG test and found patients that have fallen to have a mean time of 15.6s ± 6.5s and non-fallers 12.4s ±5.1s.[27] With respect to our cohort, pre-operatively patients had total TUG times more similar to that of fallers (14.92s ± 5.1s). whereas post-operative performance was quicker paced than the non-faller group (11.09s ± 2.2s). As the economic burden of falls is substantial, the functional improvement observed within our cohort benefits both the patient themselves and the Canadian healthcare system.

A particular strength of this study is that patients were assessed at multiple time points, allowing for more detailed analysis of functional behaviour and recovery. Well documented within the literature is the relationship between pre-operative functional ability and post-operative function.[28] Fortin et al., examined patients presenting for either hip or knee arthroplasty with low pre-operative functional ability and high pain scores.[29] They observed that patients who presented with low pre-operative function had a lower magnitude of functional improvement six months post-operatively than patients who presented with higher levels of baseline function.[29] This effect persisted one year following surgery. While we did observe a significant correlation between pre-operative, six month, and one year performance levels, the correlation was weak. Other studies previously completed in our laboratory with larger cohorts of patients, have identified specific TUG related metrics (total TUG time, sit-to-stand, walk-to-goal, walk-to-chair, step count of the operative limb, mean operative step flexion range, $SAAD_{OP}^{F/E}$, $SAAD_{OP}^{Low}$, $SAAD_{NON}^{Low}$, $SAAD_{OP}^{High}$, and $SAAD_{NON}^{High}$) that can be used to discern high function patients from low function patients at three months and satisfied from dissatisfied patients at one year.[9,24] Once again, only weak to moderate correlations were observed between these novel metrics pre-operatively and function post-operatively. All identified metrics besides step count of the operative limb saw significant improvement over the duration of the study to more favourable values. Thus, objective functional outcomes do improve following TKA demonstrating an improvement in patient functional capacity.

Interestingly, however, were the strong significant correlations between two week TUG performance and performance levels at six months and one year post-op. This pattern was observed for total TUG time, temporal TUG test segments, and the novel additive angular displacement metrics of the upper and lower sensors. The importance of patient function at two weeks post-operation is not well documented within the literature or well supported by current clinical practice. Many tertiary care centres, such as ours, service a large geographical area and as such patients often do not report to our fellowship trained arthroplasty surgeons at the two week time point and rather for convenience report to their local general practitioners. Historically, the reasoning behind the acute two week visit is for staple removal and to check for signs of surgical site infection or evidence of a thromboembolic event. The results of our study suggest that more attention should be paid to patient functional ability at the two week time point. It is unclear if it would be feasible for general practitioners to administer functional testing at this point in time and if so, if they would be able to interpret the outcome parameters in a way that supports further clinical decision making. Nonetheless, this relationship indicates that the two week post-operative visit provides a favourable time for functional assessment and potentially subsequent intervention, such as personalized physical therapy programming, to prevent poor long term functional outcomes.

The information provided by instrumenting the TUG test with inertial based sensors is crucial for providing a deeper level of functional understanding than time alone. While time represents general function, solely it is unable to capture detailed disease-specific mechanisms impairing function.[5] For example, two people may complete the TUG test with equivalent performance times, however one of them may have an abnormal gait cycle or an asymmetric limping pattern. Power-related metrics such as velocity and acceleration and movement-related metrics such as ROM or additive angular displacement, would differentiate between these two individuals and capture their specific functional disabilities.[5] Capturing these specific metrics pre- and post-operatively has allowed us to visualize gait improvements over the course of recovery as we observe more symmetrical movement-related parameters. This reiterates the importance of assessing not only the speed, but the quality of movement as well. In the future these specific metrics could be used within clinical practice to identify patients who are at risk for post-operative dissatisfaction as a result of poor functional ability. While total TUG time calculated using a stop watch could be used to accomplish this, novel sensor-derived metrics, such as mean step additive angular displacement, will identify at-risk patients with greater specificity.

While TKA improvements can be observed up to two years post-operatively, the early post-op phase is important from a health economic perspective. As we are expecting to observe a rise in the total number of joint replacements performed annually, arthroplasty has become a target of payment reform efforts.[30] In the United States under Model 2 of Medicare's Bundled Payments for Care Improvement Program, hospitals are fiscally responsible for complications, readmissions, and any costs incurred above the procedures target bundle price from the time of hospitalization for TKA until 90 days following TKA.[31] Under this model, hospitals are reimbursed for costs saved from patients who will require less frequent care or who utilize less resources, for example shorter length of stay in hospital or those discharged home rather than to respite care. The lack of significant difference observed between three month performance levels and one year performance levels add credence to bundled care programs and the importance of early functional improvement.

This study has some limitations that should be noted when interpreting the results presented. Firstly, these observations were made within a small cohort of patients. The number of patients included may have impacted the strength of correlations observed. Additionally, the patients included are from a single tertiary care centre. Patients included were also a part of an imaging study which required ample time investment, potentially biasing the subject population to patients who are more likely to be well educated on the TKA procedure and post-operative expectations and are therefore more knowledgeable about the importance of physical rehabilitation and more satisfied with their outcomes. Thus, the results may not be generalizable to larger populations. Lastly, a few patients only completed part of the booklet of questionnaires administered at a given follow up visit rendering some data incomplete. This is likely a result of the significant time and effort required to fully complete a number of PROMs. However, we believe that there was no systematic nature to the non-responders that would bias our results. Nevertheless, this study is prospective in nature and uses a standardized performance-based assessment method to assess validated and reliable novel outcome parameters from wearable IMUs to gather a more detailed understanding of post-operative TKA functional restoration.

In conclusion, both PROMs and the TUG performance test were responsive to functional improvements following TKA, regardless of surgical approach group. However, the responsiveness differed considerably depending on outcome measure. This study provides further support to the idea that only a superficial understanding of functional ability can be obtained from PROM administration alone. Furthermore, our study echoes the importance of including both self-reported and performance-based measures in the assessment of TKA patient function. Additionally, the results indicate that objective functional assessment should occur pre-operatively as well as post-operatively at a number of time points during the recovery process. For the GB and MR patients examined in this study, the acute post-operative time may provide an opportunity to intervene and prevent poor long-term function. Future work will stress the importance of routinely evaluating the effect of TKA intervention on functional recovery in order to optimize both the recovery process and long term satisfaction and function.

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Chapter 5

5 Conclusions and Future Directions

5.1 Overview of Objectives

Over the past decade we have observed a change in the TKA patient population to include younger patients. This cohort places unique demands on their implanted prosthesis, such as the application of greater loads, the requirement of more long-term fixation, and an interest in higher levels of post-operative function. Historically, cemented fixation methods have been utilized in TKA and have been shown to provide strong initial stability. What is worrisome is the potential of bone resorption over time at the cement-bone interface, thus resulting in aseptic loosening and the need for revision surgery. Uncemented implant systems provide a promising alternative to cemented fixation methods as an osteoconductive component surface promotes bony ingrowth between the host bone and implanted component. It is currently unknown what TKA surgical technique may be best suited to an uncemented implant system in terms of minimizing implant migration and optimizing tibiofemoral contact kinematics and patient function. Thus, the specific objectives of this thesis were to examine the impact of total knee arthroplasty surgical technique with an uncemented implant on implant migration, *in vivo* kinematics, and functional restoration.

5.2 Summary of Results

In Chapter 2 of this thesis, the implant migration patterns for a single-radius fixed-bearing cruciate-retaining uncemented TKA performed with either a GB or MR surgical technique were assessed. Translations and rotations of both the tibial and femoral components were measured using radiostereometric analysis (RSA) at six weeks, three months, six months, and one year post-operatively using a baseline two week exam. The maximum total point motion was also calculated at each time point. It was concluded that surgical technique had no impact on the amount of migration observed over the first post-operative year. The majority of migration observed occurred during the first six months of the follow up period as osseointegration developed. Once osseointegration was established between the host bone and implanted component migration plateaued, indicating that this process had occurred. Comparing the amount of migration within the first year to well established RSA thresholds for implant migration indicated 60% of our cohort to be at heightened risk for future revision surgery. These guidelines, established through observation of primarily cemented implant systems, may be inappropriate comparisons for uncemented implant systems. The negligible level of migration that occurred during the six month to one year period can potentially be used as a surrogate measure to illustrate adequate levels of fixation between the uncemented prothesis and host bone.

In Chapter 3, the impact of uncemented TKA surgical technique on tibiofemoral contact kinematics was examined by conducting a quasi-static RSA exam one year post-operatively. This study demonstrated that similar contact patterns are observed throughout flexion on both the medial and lateral condyles regardless of surgical technique. Contact locations between the approach groups were comparable on the medial condyle. However, on the lateral condyle, the MR group reported a more anterior contact location than the GB cohort at a position of full extension and 80º of flexion. The amount of anterior-posterior excursion between the medial and lateral condyles, between groups and within groups, was comparable. Regardless of flexion degree and surgical approach, the tibiofemoral contact location was located anterior to the midline of the sagittal plane. Coronal plane stability was inferred from the amount of condylar liftoff. Both groups had comparable levels of condylar liftoff and observed liftoff of both medial and lateral femoral condyles. Both cohorts demonstrated paradoxical anterior translation of the femur, coronal plane laxity, and a lateral pivot point during deep flexion.

In Chapter 4, novel temporal and joint specific metrics were examined from the information obtained from wearable sensor technology during the TUG functional performance test. This experiment demonstrated weak to moderate correlations between objective measures of function pre- and post-operatively. However, strong correlations between functional performance levels two weeks post-operatively and functional ability six months and one year following TKA were observed for total time to complete the TUG test and other, novel metrics. This observation demonstrates the importance of functional assessment two weeks post-operation to identify those at risk for poor long term functional outcomes. Furthermore, we examined the recovery of angular metrics previously identified to be important in the determination of patient satisfaction and function and how these metrics change over time. The inclusion of the instrumented TUG test could help clinicians provide patients with more realistic procedure expectations, help identify those at risk for poor function long-term, and lead to greater rates of post-operative patient satisfaction.

5.3 Future Directions

This Master's thesis examined implant migration, tibiofemoral contact kinematics, and functional restoration for patients undergoing an uncemented TKA using either a gap balancing or measured resection surgical approach. While this thesis provides important insight into implant behavior during the early post-operative period, a longer follow up duration is required to best understand the long term stability of this implant system. More long term data will allow for the establishment of implant migration thresholds better suited to predicting the risk of future revision when uncemented implant systems are used. Additionally, it would be of interest to compare the results we observed with those observed within a cohort of smaller body mass index. People of larger body mass tend to place larger amounts of stress on their joints, potentially imparting differences in migration and kinematic patterns. Further work may also include conducting the instrumented TUG test on larger cohorts of patients and patients with different implant styles. This will provide the information on the impact this implant fixation style and surgical approach has on long term implant stability and long term recovery.

5.4 Conclusions

This thesis set out to examine the impact of surgical technique for uncemented total knee arthroplasty on implant migration, tibiofemoral contact kinematics, and functional restoration. The results indicate that surgical approach has no impact on one year migration levels, articular contact kinematics, or functional capacity assessed through the timed-up-and-go physical performance assessment. Additionally, the results provide preliminary support for the use of uncemented total knee arthroplasty as a viable alternative to cemented fixation methods. This thesis provides evidence of a strong relationship between acute post-operative function and long-term functionality. Incorporating the findings of this thesis into care planning will assist us in optimizing the TKA procedure in ways which result in meaningful differences for our patients.

Appendices

Appendix A: Ethics Approval Notice

LAWSON FINAL APPROVAL NOTICE

LAWSON APPROVAL NUMBER: R-17-327

PROJECT TITLE: The Impact of Total Knee Arthroplasty Surgical Technique with Cementless Implants on Coronal Plane Motion

PRINCIPAL INVESTIGATOR: Dr. Brent Lanting

LAWSON APPROVAL DATE: Tuesday, 5 September 2017

Health Sciences REB#: 109486

ReDA ID: 2921

Please be advised the above project was reviewed by Lawson Administration and the project:

Was Approved

Please provide your Lawson Approval Number (R#) to the appropriate contact(s) in supporting departments (eg. Lab Services, Diagnostic Imaging, etc.) to inform them that your study is starting. The Lawson Approval Number must be provided each time services are requested.

Dr. David Hill
V.P. Research
Lawson Health Research Institute

All future correspondence concerning this study should include the Lawson Approval Number and should be directed to Sherry Paiva, Research Approval Officer, Lawson Health Research Institute, 750 Baseline Road, East, Suite 300.

cc: Administration

Appendix B: Letter of Information and Consent

London Health Sciences Centre

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Letter of Information and Consent Form

The impact of total knee arthroplasty surgical technique with cementless implants on coronal plane motion.

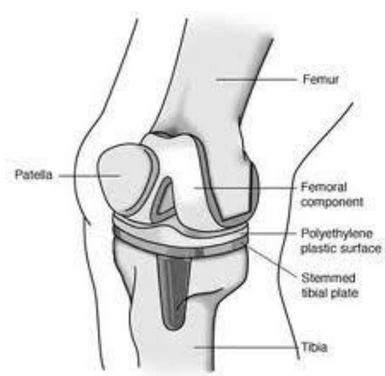
Principal Investigator:
Dr. Brent Lanting

Co-Investigators:
Dr. James Howard
Dr. Matthew Teeter

Study Coordinators:
Harley Williams
Jordan Broberg
Maxwell Perelgut
Bryn Zomar

You are being invited to participate in a research study designed for patients who will receive a primary total knee replacement under Dr. Brent Lanting's or Dr. James Howard's care. This letter of information describes the research study and your role as a participant. The purpose of this letter is to provide you with the information you require to make an informed decision about participating in this research. Please read this form carefully.

Anatomy of the Knee



Total Knee Replacement Implant

Study Purpose

How stable a total knee replacement (TKR) is depends on the correct and precise rotation of the femoral component. Abnormal femoral component rotation has been associated with numerous adverse conditions including knee instability, knee pain, scar tissue, and abnormal knee motion. Controversy exists, however, regarding the most favorable surgical technique to determine accurate femoral component rotation. Some doctors prefer a measured resection technique in which landmarks on the femur bone are used to determine where to place the femoral component. Others recommend a gap-balancing technique in which the femoral component is positioned by balancing the ligaments of the knee and placing it in the position where each ligament is equally strained.

The purpose of this study is to examine the impact of the measured resection and gap-balancing surgical techniques, used with cementless implants, on how the total knee replacement moves and patient knee outcome scores. Knee outcome scores are assessed from the responses given by patients to questions about outcomes associated with total knee replacement related to pain, symptoms, activities of daily living, sport and recreational function, and knee-related quality of life. We aim to include a total of 48 participants in this study, 24 in each group.

Procedure

If you decide to participate in this study you will be operated on using the surgical technique used routinely by your surgeon. You will have the same knee replacement parts implanted regardless of what surgical technique is used by your surgeon. During your surgery you will have tantalum beads inserted into the end of your femur, top of your tibia and patella. These beads are the size of the head of a pin and will have no impact on how your knee will function after the surgery. The tantalum beads will be used as markers to assess for any microscopic movement of the implant. To measure this movement, we will ask you to have a special kind of x-ray called radiostereometric analysis (RSA) taken after surgery at 2 weeks, 6 weeks, 3 months, 6 months and 2 years. At your 1 year follow-up we will perform a series of RSA x-rays at multiple degrees of knee flexion to measure the position of your implant components relative to each other. A member of the study team will escort you to Robarts Research Institute (attached to University Hospital) where the x-rays will be taken, and a wheelchair will be provided for you if needed. The x-ray will take less than 15 minutes to complete.

You will be asked to complete questionnaires that will assess your functional ability and quality of life. The questionnaires will be collected at your preadmission visit, 2 weeks, 6 weeks, 3 months, 6 months, 1 year and 2 years after surgery. These questionnaires will take approximately 15 minutes to complete.

You will also be asked to perform the Timed Up and Go (TUG) at each visit. Any gait aids (such as a cane, crutches or walker) that are normally used will be permitted during the TUG. The TUG involves getting up from a chair, walking 3 metres to a point marked on the floor, turning around and returning to sitting in the chair. During the TUG we will have you wear sensors that will measure speed, step length, stride length, etc.

Risk

There is always a slight chance of cancer from excessive exposure to radiation. However, special care is taken during x-ray examinations to use the lowest radiation dose possible while producing the best images for evaluation.

The scientific unit of measurement for radiation dose is the millisevert (mSv). People are exposed to radiation from natural sources all the time. The average person receives an effective dose of about 3 mSv per year from naturally occurring radioactive materials and cosmic radiation from outer space. Each RSA examination of the knee will expose the patient to 0.001 mSv (or 1 uSv) of ionizing radiation, or 0.033% of the background radiation we are all exposed to yearly. The RSA exam at 1-year post-operation requires a maximum of 8 images (0°, 20°, 40°, 60°, 80°, 100°, 120°, and 140° of flexion). Therefore, the sum total of radiation exposure across the 14 RSA images possibly required for the study is 0.014 mSv (14 uSv), equivalent to approximately 0.46% of yearly background radiation exposure.

There is also a small risk of falling as the x-rays are taken in weight-bearing positions and the TUG test involves walking and sitting. This risk is minimized by providing a handrail to be used as a support during imaging.

Data from your medical record will be gathered for this study. There is a risk for breaching confidentiality of this information; however procedures are set in place to minimize this risk (see below).

Benefits

Participation in this study will provide no known benefit to you. Information learned from this study may help lead to improvements TKR procedures in the future.

Compensation

There will be no compensation for your participation in this study.

Voluntary Participation

Your participation in this study is voluntary. You may refuse to participate or discontinue your participation at any time without affecting the care being provided to you. Should you choose to withdraw, no further information will be collected. The data you have contributed to that point will be used to help answer our research question.

Confidentiality

All information will be kept confidential to the best of our ability. All RSA image data and TUG data will be stored on a password protected computer in a secure facility (Robarts Research Institute and Sandy Kirkley Centre for Musculoskeletal Health Research, respectively) and will contain only your unique identifying number and no personal identifiers. Even with this high level of security, there is always a remote chance that your information could be breached by someone without permission to your information. The chance that this information will be accidentally released is minimal. In any publication, presentation or report, all results will be de-identified and any information that would reveal your identity will not be published.

You will be given a copy of this letter of information and consent form once it has been signed. You do not waive any legal rights by signing the consent form. Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

Qualified representatives of the Lawson Quality Assurance Education Program may look at your medical/clinical study records at the site where these records are held, for quality assurance (to check that the information collected for the study is correct and follows proper laws and guidelines).

If you have any questions about your rights as a research participant or the conduct of the study you may contact the Patient Experience Office at LHSC at ext. or access the online form at:

If you have any questions about your surgery, please contact your orthopaedic surgeon. If you have any questions about this research, please contact the research coordinator Harley Williams at , or the principal investigator Dr. Brent Lanting at or

Sincerely,

Dr. Brent Lanting, MD, FRCSC
Dr. James Howard, MD, FRCSC
Dr. Matthew Teeter, PhD
Bryn Zomar, MSc, PhD(c)
Harley Williams, Master's Student
Maxwell Perelgut, Master's Student
Jordan Broberg, Master's Student

London Health Sciences Centre

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The impact of total knee arthroplasty surgical technique with cementless implants on coronal plane motion.

Principal Investigator: Dr. Brent Lanting

Informed Consent Form

Agreement of Participant

I have read the accompanying letter of information regarding this study and give my informed consent to participate. All questions have been answered to my satisfaction.

____

Print Participant's Full Name

____

Participant's Signature Date

____

Name of Person Obtaining Consent

____

Signature of Person Obtaining Consent Date

Appendix C: Short Form 12 (SF-12)

Study ID: ___________

Date: _______________

SF-12

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:	Excellent (1)	Very Good (2)	Good (3)	Fair (4)	Poor (5)

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much:

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	1	2	3
3. Climbing several flights of stairs.	1	2	3

During the past 4 weeks have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	YES	NO
4. Accomplished less than you would like.	1	2
5. Were limited in the kind of work or other activities.	1	2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	YES	NO
6. Accomplished less than you would like.	1	2
7. Didn't do work or other activities as carefully as usual.	1	2

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at All (1)	A little bit (2)	Moderately (3)	Quite a bit (4)	Extremely (5)

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks?

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	1	2	3	4	5	6
10. Did you have a lot of energy?	1	2	3	4	5	6
11. Have you felt downhearted and blue?	1	2	3	4	5	6

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc)?

All of the time (1)	Most of the time (2)	Some of the time (3)	A little of the time (4)	None of the time (5)

Version: 22-Jun-2017

Appendix D: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Study ID: ___________

Date: _______________

WOMAC

A. Think about the ***pain*** you felt in your hip/knee during the last 48 hours.

Question: How much pain do you have?	None	Mild	Moderate	Severe	Extreme
1. Walking on a flat surface	0	1	2	3	4
2. Going up or down stairs	0	1	2	3	4
3. At night while in bed, pain disturbs your sleep	0	1	2	3	4
4. Sitting or lying	0	1	2	3	4
5. Standing upright	0	1	2	3	4

B. Think about the ***stiffness*** (not pain) you felt in your hip/knee during the last 48 hours. Stiffness is a sensation of ***decreased*** ease in moving your joint.

	None	Mild	Moderate	Severe	Extreme
6. How ***severe*** is your ***stiffness after first awakening*** in the morning?	0	1	2	3	4
7. How ***severe*** is your stiffness after sitting, lying, or resting ***later in the day***?	0	1	2	3	4

C. Think about the ***difficulty*** you had in doing the following daily physical activities dues to your hip/knee during the last 48 hours. By this we mean your ***ability to move around and look after yourself***.

Question: What degree of difficulty do you have?	None	Mild	Moderate	Severe	Extreme
8. Descending stairs	0	1	2	3	4
9. Ascending stairs	0	1	2	3	4
10. Rising from sitting	0	1	2	3	4
11. Standing	0	1	2	3	4
12. Bending to the floor	0	1	2	3	4
13. Walking on a flat surface	0	1	2	3	4
14. Getting in and out of a car, or on or off a bus	0	1	2	3	4
15. Going shopping	0	1	2	3	4
16. Putting on your socks or stockings	0	1	2	3	4
17. Rising from bed	0	1	2	3	4
18. Taking off your socks or stockings	0	1	2	3	4
19. Lying in bed	0	1	2	3	4
20. Getting in or out of the bath	0	1	2	3	4
21. Sitting	0	1	2	3	4
22. Getting on or off the toilet	0	1	2	3	4
23. Performing heavy domestic duties	0	1	2	3	4
24. Performing light domestic duties	0	1	2	3	4

Version 22-Jun-2017

Appendix E: Knee Society Score (patient portion)

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SYMPTOMS (To be completed by patient)

1- Pain with level walking (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

2- Pain with stairs or inclines (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

3- Does this knee feel "normal" to you? (5 points)

○ Always (5 pts) ○ Sometimes (3 pts) ○ Never (0 pts)

Maximum total points (25 points)

PATIENT SATISFACTION

1- Currently, how satisfied are you with the pain level of your knee while sitting? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

2- Currently, how satisfied are you with the pain level of your knee while lying in bed? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

3- Currently, how satisfied are you with your knee function while getting out of bed? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

4- Currently, how satisfied are you with your knee function while performing light household duties? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

5- Currently, how satisfied are you with your knee function while performing leisure recreational activities? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

Maximum total points (40 points)

PATIENT EXPECTATION (To be completed by patient)

Compared to what you expected before your knee replacement:

1- My expectations for pain relief were... (5 points)

- O Too High- "I'm a lot worse than I thought" (1 pt)
- O Too High- "I'm somewhat worse than I thought" (2 pts)
- O Just Right- "My expectations were met" (3 pts)
- O Too Low- "I'm somewhat better than I thought" (4 pts)
- O Too Low- "I'm a lot better than I thought" (5 pts)

2- My expectations for being able to do my normal activities of daily living were... (5 points)

- O Too High- "I'm a lot worse than I thought" (1 pt)
- O Too High- "I'm somewhat worse than I thought" (2 pts)
- O Just Right- "My expectations were met" (3 pts)
- O Too Low- "I'm somewhat better than I thought" (4 pts)
- O Too Low- "I'm a lot better than I thought" (5 pts)

3- My expectations for being able to do my leisure, recreational or sports activities were... (5 points)

- O Too High- "I'm a lot worse than I thought" (1 pt)
- O Too High- "I'm somewhat worse than I thought" (2 pts)
- O Just Right- "My expectations were met" (3 pts)
- O Too Low- "I'm somewhat better than I thought" (4 pts)
- O Too Low- "I'm a lot better than I thought" (5 pts)

Maximum total points (15 points) ☐

FUNCTIONAL ACTIVITIES (To be completed by patient)

WALKING AND STANDING (30 points)

1 - Can you walk without any aids (such as a cane, crutches or wheelchair)? **(0 points)**

O Yes O No

2 - If no, which of the following aid(s) do you use? **(-10 points)**

O wheelchair (-10 pts) O walker (-8 pts) O crutches (-8 pts) O two canes (-6 pts)

O one crutch (-4 pts) O one cane (-4 pts) O knee sleeve / brace (-2 pts)

O other

3 - Do you use these aid(s) because of your knees? **(0 points)**

O Yes O No

4 - For how long can you stand (with or without aid) before sitting due to knee discomfort? **(15 points)**

O cannot stand (0 pts) O 0-5 minutes (3 pts) O 6-15 minutes (6 pts)

O 16-30 minutes (9 pts) O 31-60 minutes (12 pts) O more than an hour (15 pts)

5 - For how long can you walk (with or without aid) before stopping due to knee discomfort? **(15 points)**

O cannot walk (0 pts) O 0-5 minutes (3 pts) O 6-15 minutes (6 pts)

O 16-30 minutes (9 pts) O 31-60 minutes (12 pts) O more than an hour (15 pts)

Maximum points (30 points)

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STANDARD ACTIVITIES (30 points)

How much does your knee bother you during each of the following activities?	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	I never do this	
1 - Walking on an uneven surface	o	o	o	o	o	o	o	☐
2 - Turning or pivoting on your leg	o	o	o	o	o	o	o	☐
3 - Climbing up or down a flight of stairs	o	o	o	o	o	o	o	☐
4 - Getting up from a low couch or a chair without arms	o	o	o	o	o	o	o	☐
5 - Getting into or out of a car	o	o	o	o	o	o	o	☐
6 - Moving laterally (stepping to the side)	o	o	o	o	o	o	o	☐

Maximum points (30 points) ☐

ADVANCED ACTIVITIES (25 points)

1 - Climbing a ladder or step stool	o	o	o	o	o	o	o	☐
2 - Carrying a shopping bag for a block	o	o	o	o	o	o	o	☐
3 - Squatting	o	o	o	o	o	o	o	☐
4 - Kneeling	o	o	o	o	o	o	o	☐
5 - Running	o	o	o	o	o	o	o	☐

Maximum points (25 points) ☐

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DISCRETIONARY KNEE ACTIVITIES (15 points)

Please check 3 of the activities below that you consider *most important* to you.
(Please do not write in additional activities)

Recreational Activities

- ☐ Swimming
- ☐ Golfing (18 holes)
- ☐ Road Cycling (>30mins)
- ☐ Gardening
- ☐ Bowling
- ☐ Racquet Sports (Tennis, Racquetball, etc.)
- ☐ Distance Walking
- ☐ Dancing / Ballet
- ☐ Stretching Exercises (stretching out your muscles)

Workout and Gym Activities

- ☐ Weight-lifting
- ☐ Leg Extensions
- ☐ Stair-Climber
- ☐ Stationary Biking / Spinning
- ☐ Leg Press
- ☐ Jogging
- ☐ Elliptical Trainer
- ☐ Aerobic Exercises

Please copy all 3 checked activities into the empty boxes below.

How much does your knee bother you during each of these activities?

Activity (Please write the 3 activites from list above)	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	
1.	○	○	○	○	○	○	☐
2.	○	○	○	○	○	○	☐
3.	○	○	○	○	○	○	☐

Maximum points (15 points) ☐

Maximum total points (100 points) ☐

Appendix F: Knee Society Score (clinician portion)

KNEE SOCIETY SCORE: POST-OP

•to be completed by staff

PAIN	Right	Left
None	50	50
Mild or Occasional	45	45
Stairs Only	40	40
Walking and Stairs	30	30
Moderate Occasional	20	20
Moderate Continual	10	10
Severe	0	0

Range of Motion	Right	Left
Start of Flexion (Degrees)- Extension		
End of Flexion (Degrees)		

Anterior/ Posterior Instability: ***Measured at 90°***

	R	L		R	L
<5mm			None		
5-10mm			Moderate <5mm		
10mm			Severe >5mm		

Medial/ Lateral Instability: ***Measured in Full Extension***

	R	L		R	L
<5°			None		
6-9°			Little <5mm		
10-14°			Moderate 5mm		
15°			Severe >5mm		

Flexion Contracture

	R	L		R	L
<5°			1-5°		
5-10°			6-10°		
10-15°			11-15°		
16-20°			>15°		
>20°					

Extension Lag

	R	L		R	L
None			<10°		
<10°			10 20°		
10-20°			>20°		
>20°					

Walking	Right	Left
Unlimited	50	50
>10 blocks	40	40
5-10 blocks	30	30
<5 blocks	20	20
House Bound	10	10
Unable	0	0

Stairs	Right	Left
Normal Up and Down	50	50
Normal Up; Down with Rail	40	40
Up and Down with Rail	30	30
Up with Rail; Unable Down	15	15
Unable	0	0

Support	Right	Left
None	0	0
Cane	-5	-5
Two Crutches	-10	-10
Crutches or Walker	-20	-20

Charnley Functional Classification

A B1 B2 C1 C2 C3

A: Unilateral Knee Arthritis
B1: Unilateral TKA, Opposite Knee Arthritic
B2: Bilateral TKA
C1: TKA, but remote arthritis affecting ambulation
C2: TKA, but medical condition affecting ambulation
C3: Unilateral or Bilateral TKA with Unilateral or bilateral THA

RADIOGRAPHIC FINDINGS

Alignment: ***Measured on AP Xray***

	R	L		R	L
5-10° Valgus			Neutral: 2-10° valgus		
4-11° Valgus			Varus: <2° Valgus		
3-12° Valgus			Valgus: >10° Valgus		
2-13° Valgus					
1-14° Valgus					
0-15° Valgus					
Varus OR >15° Valgus					

Radiosclerotic Lines (cementless)

Right: No Yes: *Femur Tibia (AP) Tibia (Lat) Tibial Screws Patella (skyline)*	**Left:** No Yes *Femur Tibia (AP) Tibia (Lat) Tibial Screws Patella (skyline)*

Radiolucent Lines (cemented)

Right: No Yes: *Femur Tibia (AP) Tibia (Lat) Patella (skyline)*	**Left:** No Yes *Femur Tibia (AP) Tibia (Lat) Patella (skyline)*

Loosening

Right: No Possible *T F P* Probable *T F P* Definite *T F P*	**Left:** No Possible *T F P* Probable *T F P* Definite *T F P*

Implant Problems

Right: No Yes: Wear Osteolysis: *T F P* Patella: *tilted subluxed dislocated fracture AVN*	**Left:** No Yes: Wear Osteolysis: *T F P* Patella: *tilted subluxed dislocated fracture AVN*

Adverse Events

Right: Deep Infection Superficial Infection Stiff Knee DVT/PE Other:______	**Left:** Deep Infection Superficial Infection Stiff Knee DVT/PE Other:______

ANTERIOR KNEE PAIN

Right: No Yes: *Daily Weekly Monthly* 0 1 2 3 4 5 6 7 8 9 10	Left: No Yes: *Daily Weekly Monthly* 0 1 2 3 4 5 6 7 8 9 10

Comments:____________________

Examiner:____________________

Appendix G: University of California, Los Angeles (UCLA) Activity Score

Study ID: ___________

Date: _______________

UCLA Activity Score

Check one box that best describes current activity level.

◯ 1: Wholly Inactive, dependent on others, and can not leave residence

◯ 2: Mostly Inactive or restricted to minimum activities of daily living

◯ 3: Sometimes participates in mild activities, such as walking, limited housework and limited shopping

◯ 4: Regularly Participates in mild activities

◯ 5: Sometimes participates in moderate activities such as swimming or could do unlimited housework or shopping

◯ 6: Regularly participates in moderate activities

◯ 7: Regularly participates in active events such as bicycling

◯ 8: Regularly participates in active events, such as golf or bowling

◯ 9: Sometimes participates in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor or backpacking

◯ 10: Regularly participates in impact sports

Version: 22-Jun-2017

Appendix H: Image Permission

Harley Williams
GBMR Image Permission
To: [redacted] Cc: [redacted]

April 15, 2019 at 2:26 PM
Details
HW

Hi Dr. Perry,

My name is Harley Williams and I am currently a second year MSc. student working with Drs. Teeter and Lanting. My MSc. project is actually the second wave of your MSc. study using the uncemented Triathlon system. I just wondered if I could have permission from you to use some of the images you included in your final thesis in my MSc. thesis?

If you have any further questions, please let me know!

All the best.

Regards,
Harley Williams

Perry, Kevin I., M.D.
RE: GBMR Image Permission
To: Harley Williams

April 15, 2019 at 2:26 PM
KP

Of course, no problem at all

See More from Harley Williams

Schulich
MEDICINE & DENTISTRY

Tuesday, June 11th, 2019

RE**: Image Permission**

Dear Harley Williams,

I provide you with this letter to provide permission for you to include Figure 25 from my unpublished work in your MSc. thesis titled Assessing the Impact of Surgical Technique on Implant Migration, Tibiofemoral Contact Kinematics, and Functional Recovery Following Uncemented Total Knee Arthroplasty.

Sincerely,

Riley Bloomfield,
PhD Candidate

Schulich School of Medicine & Dentistry, Western University, Building, Rm. 222
1111 Street Name St. London, ON, Canada A1A 2B2
t. 519.111.1111 ext. 22222 f. 519.111.3333 www.schulich.uwo.ca

Western

Schulich
MEDICINE & DENTISTRY

Tuesday, June 11th, 2019

RE**: Image Permission**

Dear Harley Williams,

I provide you with this letter to provide permission for you to include Figure 8 and 10 from my unpublished work in your MSc. thesis titled Assessing the Impact of Surgical Technique on Implant Migration, Tibiofemoral Contact Kinematics, and Functional Recovery Following Uncemented Total Knee Arthroplasty.

Sincerely,

Maxwell Perelgut, MESc
Student Research Associate

Schulich School of Medicine & Dentistry, Western University, Building, Rm. 222
1111 Street Name St. London, ON, Canada A1A 2B2
t. 519.111.1111 ext. 22222 f. 519.111.3333 www.schulich.uwo.ca

Western

Curriculum Vitae

Harley Williams

UNIVERSITY EDUCATIONAL BACKGROUND

Bachelor of Science, Honours Specialization in Kinesiology 2013-2017
School of Kinesiology and Health Studies, Queen's University, Kingston, ON

Master of Science, Department of Medical Biophysics, Sept. 2017 - Present
Schulich School of Medicine & Dentistry, Western University, London, ON

- Thesis Title: Assessing the Impact of Surgical Technique on Implant Migration, Tibiofemoral Contact Kinematics, and Functional Recovery Following Uncemented Total Knee Arthroplasty.
- Supervisor: Dr. Matthew Teeter
- Degree expected: June 2019

Collaborative Training Program in Musculoskeletal Health Research, Sept. 2017 - Present
Bone and Joint Institute, Western University, London, ON

- Specialization acknowledges the musculoskeletal focus of graduate research project.
- Certificate awarded upon confirmation of graduate degree.

Doctor of Medicine, Schulich School of Medicine & Dentistry, Sept. 2019
Western University, London, ON

Research-specific Honours, Scholarships and Awards during University

Kidney Cancer Research Network of Canada Summer Studentship Award, Department of Surgery, Division of Urology, May 2016 – Aug. 2018
University Health Network, Toronto, ON

- Annual value: $5,000.00

Western Graduate Research Scholarship, School of Graduate & Postdoctoral Studies, Western University, London, ON Sept. 2017 – Present

- Annual value: $4500.00

Collaborative Training Program in Musculoskeletal Health Research Trainee Stipend, Bone and Joint Institute, Western University, London, ON Sept. 2017 – Present

- Annual value: $500.00

Ontario Graduate Scholarship, Schulich School of Medicine & Dentistry, Western University, London, ON Sept. 2018 – Present

- Annual value: $15,000.00

Williams, Harley

RESEARCH EXPERIENCE

Research Associate, London Health Sciences Centre, Department of Surgery, Division of Urology, Western University, London, ON — May 2016 – Dec. 2018

- Supervisor: Dr. Nicholas Power
- Funding source: Kidney Cancer Research Network of Canada
- Responsible for data collection and entry for national kidney cancer database, quality assurance, and answering data queries.

Small Cell Carcinoma of the Bladder, London Health Sciences Centre, Department of Surgery, Division of Urology, Western University, London, ON — May 2016 – Oct. 2018

- Time range of project: May 2016 – Present
- Supervisor: Dr. Nicholas Power
- Project Title: The Oncologic Outcomes of Small Cell Carcinoma of the Bladder
- Responsible for ethics submission, chart reviewal, data collection, data entry, and manuscript preparation.

Independent Study Project, Cardiovascular Stress Response Lab, School of Kinesiology and Health Sciences, Queen's University, Kingston, ON — Sept. 2016 – May 2017

- Supervisor: Dr. Kyra Pyke
- Project Title: Exploring the impact of isometric handgrip training on arterial stiffness in young, healthy, normotensive males.
- Responsible for participant recruitment, exercise supervision, data collection and analyses, thesis preparation, and oral poster presentation.

Master of Science Thesis Project, London Health Sciences Centre, University Hospital and Robarts Research Institute, Western University, London, ON — May 2016 – Present

- Supervisor: Dr. Matthew Teeter
- Project Title: The impact of total knee arthroplasty surgical technique with cementless implants on coronal plane stability.
- Responsible for participant screening and recruitment, pre- and post-operative subject testing which includes functional performance assessments and x-ray imaging, data entry, image and statistical analyses, and thesis and publication preparation.

Student Research Assistant, London Health Sciences Centre, Department of Surgery, Division of Orthopaedics, Western University, London, ON — Sept. 2017 - Present

- Supervisors: Dr. Matthew Teeter
- Project Title: Various projects

Williams, Harley

- Assist with data collection and patient follow up visits for a variety of arthroplasty projects being conducted within the Division of Orthopaedics.

Total Knee Arthroplasty and Post-Operative Alignment, London Health Sciences Centre, Department of Surgery, Division of Orthopaedics, Western University, London, ON — Dec. 2017 – Aug. 2018

- Supervisor: Dr. Brent Lanting
- Project Title: The impact of residual varus alignment following total knee arthroplasty on patient outcome scores in a constitutional varus population.
- Responsible for data extraction and analysis and manuscript preparation.

Total Hip Arthroplasty Surgical Approach and Muscle Atrophy, London Health Sciences Centre, Department of Surgery, Division of Orthopaedics, Western University, London, ON — Jan. 2018 – Present

- Supervisors: Dr. Brent Lanting and Dr. Edward Vasarhelyi
- Project Title: The impact of total hip arthroplasty surgical technique on post-operative muscle atrophy.
- Responsible for patient reported outcome measure data collection, all data analyses, and manuscript preparation.
- Funding sources: London Health Sciences Centre Department of Surgery, Internal Research Fund and the Physician Services Incorporated Foundation.

PUBLICATIONS, PRESENTATIONS, AND ABSTRACTS

a. Articles, Peer Reviewed:

1. Lanting BA, **Williams HA**, Matlovich NF, Vandekerckhove PJ, Teeter MG, Vasarhelyi EM, Howard JL, and Somerville LE. The Impact of Residual Varus Alignment Following Total Knee Arthroplasty on Patient Outcome Scores in a Constitutional Varus Population. *The Knee*, 25(6), 1278-1282.
2. **Williams HA** and Power NE. Book Review – Zen Slaps from a Cancer Warrior: A Pissant's Perspective. *Canadian Urological Association Journal*, submitted to editor. September 4, 2018.
3. **Williams H**, Punjani N, Khan O, and Power N. The Oncologic Outcomes of Small Cell Carcinoma of the Bladder. *Canadian Urological Association Journal,* Epub ahead of print, 13(8). December 3, 2018. https://doi.org/10.5489/cuaj.5579
4. Vasarhelyi EM, **Williams HA**, Howard JL, Petis S, Barfett J, and Lanting BA. The Impact of Total Hip Arthroplasty Surgical Technique on Post-Operative Muscle Atrophy. *Orthopedics,* submitted. May 8, 2019.
5. Bloomfield RA, **Williams HA**, Broberg JS, Lanting BA, McIsaac KA, and Teeter MG. Machine Learning Groups Patients by Early Functional Improvement Likelihood Based on Wearable Sensor Instrumented Preoperative Timed-Up-and-Go Tests. *Journal of Arthroplasty*, accepted. May 31, 2019.

Williams, Harley

b. Abstracts and Presentations at Scientific Meetings, Peer Reviewed:

1. **Williams HA**, Bloomfield RA, Howard JL, Lanting BA, and Teeter MG. Wearable sensors: identifying quantitative metrics to better assess pre- and post-operative TKA patient functional status. Abstract, Imaging Network of Ontario Symposium. Toronto, ON. March 28-29, 2018.
2. **Williams HA**, Bloomfield RA, Howard JL, Lanting BA, and Teeter MG. Identifying temporal and spatial metrics with wearable sensors to better assess pre- and post-operative TKA patient functional status. Abstract, Canadian Bone and Joint Conference. London, ON. May 10-12, 2018.
3. **Williams HA**, Howard JL, Lanting BA, and Teeter MG. Cementless total knee replacements: Does surgical technique impact coronal plane stability? Oral presentation, Robarts Research Day Symposium, Robarts Research Institute, Western University, London, ON. June 1, 2018.
4. **Williams HA**, Bloomfield RA, Howard JL, Lanting BA, and Teeter MG. Wearable Sensors: Identifying new temporal and joint-specific metrics to improve the characterization of patient functional capacity pre- and post-TKA. Abstract, Department of Surgery Research Day, Schulich School of Medicine & Dentistry, Western University. June 15, 2018.
5. **Williams HA**, Bloomfield RA, Yuan X, Howard JL, Lanting BA, and Teeter MG. Cementless Total Knee Arthroplasty: Does surgical technique impact implant migration? Abstract, Imaging Network of Ontario Symposium. London, ON. March 28-29, 2019.
6. Bloomfield RA, **Williams HA**, Lanting BA, McIsaac KA, and Teeter MG. Machine learning functional metrics for recovery path analysis following total knee replacement. Abstract, Imaging Network of Ontario Symposium. London, ON. March 28-29, 2019.
7. **Williams HA**, Bloomfield RA, Yuan X, Howard JL, Lanting BA, and Teeter MG. Cementless Total Knee Arthroplasty: Does surgical technique impact implant migration? Abstract, London Health Research Day. London, ON. April 30, 2019.
8. **Williams HA**, Broberg JS, Howard JL, Vasarhelyi EM, Naudie DR, Lanting BA, and Teeter MG. Wearable Sensors: Providing a New Perspective to Post-Operative TKA Functional Recovery. International Combined Orthopaedic Research Societies. Montreal, QC. June 19-22, 2019.
9. Lanting BA, **Williams HA**, Matlovich NF, Vandekerckhove PJ, Teeter MG, Vasarhelyi EM, Howard JL, and Somerville LE. A Residual Varus Alignment Following Total Knee Arthroplasty in a Constitutional Varus Population Does Not Lead to Improved Patient Outcome Scores. International Combined Orthopaedic Research Societies. Montreal, QC. June 19-22, 2019.
10. Vasarhelyi EM, **Williams HA**, Howard JL, Petis S, Barfett J, and Lanting BA. Minimally Invasive Direct Anterior Surgical Approach Leads to Less Post-Operative Muscle Atrophy Following Total Hip Arthroplasty. International Combined Orthopaedic Research Societies. Montreal, QC. June 19-22, 2019.

c. Abstracts and Presentations, Non-Peer Reviewed:

1. **Williams HA**, Silvester MD, and Pyke KE. Exploring the Impact of Isometric Handgrip Training on Arterial Stiffness in Young, Healthy, Normotensive Males. Abstract,

Williams, Harley

Independent Study Project Showcase, School of Kinesiology and Health Studies, Queen's University, Kingston, ON. March 27, 2017.

2. **Williams HA**, Howard JL, Lanting BA, and Teeter MG. Cementless Total Knee Replacements: Does surgical technique impact coronal plane stability? Oral presentation, Graduate Seminar, Department of Medical Biophysics, Schulich School of Medicine & Dentistry, Western University, London, ON. March 8, 2018.
3. "What's the Big Deal About Grad School?" Invited speaker, Undergraduate summer seminar series, Collaborative Program in Musculoskeletal Health Research, Bone and Joint Institute, Western University, London, ON. July 31, 2018.
4. **Williams HA**, Howard JL, Lanting BA, and Teeter MG. Cementless Total Knee Replacements: Does surgical technique impact implant migration? Oral presentation, Graduate Seminar, Department of Medical Biophysics, Schulich School of Medicine & Dentistry, Western University, London, ON. November 20, 2018.
5. **Williams HA**, Howard JL, Lanting BA, and Teeter MG. Assessing the Impact of Surgical Technique on Implant Migration, Tibiofemoral Contact Kinematics, and Functional Recovery Following Uncemented Total Knee Arthroplasty. Master of Science Public lecture, Department of Medical Biophysics, Schulich School of Medicine & Dentistry, Western University, London, ON. June 4, 2019.