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The Influence of Soft Tissue Balancing on Postoperative In Vivo Tibiofemoral Contact Kinematics in Total Knee Arthroplasty

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Abstract

We performed a prospective imaging study to investigate whether there are differences in *in vivo* tibiofemoral contact kinematics between patients that received minimal amounts of medial soft tissue balancing and patients that required more extensive balancing during total knee arthroplasty. At 100° of flexion, patients that received extensive release had more anterior tibiofemoral contact on the lateral condyle (mean difference = 1.77 mm, p=0.02). No other statistically significant differences in tibiofemoral contact positions or excursions on the medial or lateral condyles were found throughout flexion from 0° to 120° . Postoperative patient-reported outcome scores were not different. Correcting severe varus deformities with extensive medial soft tissue release largely did not alter patients' tibiofemoral contact kinematics or clinical outcome scores compared to those with minimal soft tissue release.

Keywords

Total knee arthroplasty, soft tissue balancing, contact kinematics, osteoarthritis, varus, radiostereometric analysis

Co-Authorship Statement

This study was designed in collaboration with Drs. Bryant, Teeter, and Lanting. I was solely responsible for executing the study protocol including patient identification and recruitment, data collection, and data analysis. I wrote the original draft of this thesis document. Towards the final submission Drs. Bryant, Teeter, and Lanting made comments and suggestions that contributed to the improvement of this manuscript.

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Chapter 1

1 Introduction

Total knee arthroplasty (TKA) aims to produce a functional and stable prosthetic knee for individuals suffering from debilitating arthritis. This procedure produces excellent outcomes for most, however, dissatisfaction has been reported in approximately 19% of patients[1,2]. Additionally, as the prevalence of TKA rises and the average age of patients decreases, the rate of revision surgeries has been steadily increasing[3]. The primary mechanisms of failure requiring revision surgery reported for contemporary TKA designs include aseptic loosening, infection, instability, and polyethylene wear[4,5]. In response to these concerns, investigators have examined aspects of surgical technique that may contribute to undesired outcomes.

One theory addresses the uncertainty about the amount of correction in coronal plane alignment that occurs during TKA. Currently, most surgeons alter a patient's natural alignment to a mechanically neutral position (mechanical axis angle of 0^o +/- 3^o) to balance the loading forces exerted on the medial and lateral condyles of the tibial baseplate. Compared to varus aligned knees, neutral alignment has demonstrated decreased surface wear and longer implant survivorship[6,7].

However, there are important considerations associated with correcting all patients to neutral alignment. First, some surgeons believe correcting patients with long-standing varus deformities to neutral alignment during TKA may produce an unnatural feeling, which may be reported by patients as dissatisfaction[8]. Second, increased medial soft tissue balancing is often required when correcting varus deformities, which may compromise knee kinematics and stability.

Soft tissue balancing in a varus knee involves the surgical release of medial ligaments and tendons to equalize the medial and lateral gaps between the femur and tibia. The amount of balancing required between patients varies and typically increases as preoperative varus deformities increase[9]. Soft tissue balancing has been widely regarded as an essential aspect of TKA that serves to optimize joint kinematics and stability beyond what can be achieved through bone cuts and implant design[9-11]. The majority of studies that have assessed ligament contributions to TKA stability[12] and the effect of sequential medial releases on tibiofemoral flexion and extension gaps[13,14] are cadaveric biomechanical studies although a few clinical studies have also been reported. These studies have primarily focused on intraoperative and post-operative measures of tibiofemoral gaps, stability, and alignment after medial release[15-17]. However, despite the current body of literature on medial soft tissue balancing in primary TKA, a lack of consensus between surgeons as to the method and best sequence of ligament release still exists[18]. Additionally, there is a paucity of literature examining the role soft tissue balancing has on postoperative, clinically important outcomes.

Studies of contact kinematics have provided valuable *in vivo* biomechanical information by examining changes from pre- to post-TKA knees and differences between implant designs and surgical techniques. Teeter *et al.*[19] performed a study using radiostereometric analysis that compared patients' (n=24) tibial implant component migration with *in vivo* tibiofemoral contact kinematics from 0° to 60° of flexion at one-year post-operation. Associations were found between the contact positions and tibial component varus-valgus tilt, anterior-posterior tilt, and anterior-posterior translation in a single-radius, posterior-stabilized TKA design suggesting contact kinematics can influence tibial component migration via altered force transmission. They also noted that patients with continuous tibial component migration (n=4) were found to have atypical contact kinematics. Given the intrinsic relationship between ligament balancing and knee kinematics and stability, a study investigating the influence of soft tissue balancing on contact kinematics is warranted.

Thus, the purpose of this study was to examine the *in vivo* tibiofemoral contact kinematics throughout knee flexion between patients with minimal or additional required amounts of soft tissue balancing in a single radius, posterior-stabilized TKA design.

Chapter 2

2 Literature Review

The following literature review focuses primarily on four topics: knee anatomy, osteoarthritis, total knee arthroplasty, and tibiofemoral contact kinematics. The knee anatomy section will describe general characteristics of the knee joint and the specific medial soft tissue structures relevant to the surgical technique examined in this thesis. Then, osteoarthritis of the knee will be discussed including prevalence, diagnosis, and available non-surgical and surgical treatment options. Next, the technique of total knee arthroplasty and the importance of soft tissue balancing will be described. Finally, the typical pre- and post-operative *in vivo* weight-bearing tibiofemoral contact kinematics will be discussed.

2.1 Anatomy of the Knee

The knee joint is the largest joint in the body, consisting of the patella, the distal femur, and the proximal tibia. These bones articulate to form three functional compartments: the patellofemoral articulation and the medial and lateral tibiofemoral articulations. The patellofemoral articulations involve the patellar trochlea of the anterior femur and the posterior surface of the patella. This compartment is a partly arthrodial joint that allows superior and inferior gliding of the patella during knee extension and flexion, respectively. The medial and lateral tibiofemoral articulations involve the ovoid surfaces of the femoral condyles that are received by the elliptical cavities of the tibial plateau. Together, the knee functions as a complex, modified hinged joint allowing for flexion and extension, translation, and slight internal and external rotation[20].

The knee is a synovial joint. The three compartments are enclosed by an articular joint capsule that creates a synovial cavity. The synovial membrane, the innermost layer of the articular capsule, secretes synovial fluid which lubricates the articulating surfaces, assists in load distribution, and provides nutrient and waste transportation[21]. The articulating surfaces of the posterior patella, distal femur, and proximal tibia are covered by articular cartilage. Articular cartilage is a smooth layer of hyaline cartilage that covers the articulating surfaces of bones involved in synovial joints. Articular cartilage acts to dissipates joint forces and reduce friction between articulating surfaces[21,22]. Composed primarily of a dense extracellular matrix, articular cartilage is without nervous or vascular structures, which limits its ability to heal if damaged[22].

The fibrous outer layer of the articular joint capsule spans the entire circumference of the joint line and acts to passively stabilize the knee in multiple directions[21]. The capsule extends several centimetres superior and inferior to the joint line and thickens posteriorly. The thick posterior capsule acts primarily to limit hyperextension and is a secondary stabilizer of multiple other movements[21].

Tibiofemoral articulation is aided by involvement of the medial and lateral meniscus. The menisci are C-shaped disks of fibrous cartilage that sit upon the tibial condyles and are fixed to the synovial membrane at the perimeter. These structures serve to absorb load and deepen the articulating surfaces of the shallow elliptical cavities of the tibial condyles[20,21].

Anterior and posterior stability is primarily offered by two intracapsular ligaments: the anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL). The ACL extends from the anterior intercondylar area of the tibia to the posterior part of the medial surface of the lateral condyle of the femur. The ACL acts to limit anterior translation of the tibia relative to the femur[21]. The PCL extends from the posterior intercondylar area of the tibia to the anterior part of the lateral surface of the medial condyle of the femur. The PCL acts to limit posterior translation of the tibia on the femur[21].

The knee is further stabilized by two extracapsular ligaments: the lateral collateral ligament (LCL) and the medial collateral ligament (MCL). The LCL extends from the lateral epicondyle of the femur to the head of the fibula. The LCL is the primary restraint to varus stress and is a secondary restraint to anterior-posterior translation[21]. The MCL consists of the deep MCL (dMCL) and the superficial MCL (sMCL). The dMCL consists of the meniscofemoral and meniscotibial ligament components. The meniscofemoral component extends from the posterior aspect of the medial femoral condyle to the medial meniscus, whereas the meniscotibial component extends from the medial meniscus to the edge of the medial tibial plateau[23]. The dMCL provides passive rotational stability in extension and early flexion, and acts as a secondary restraint to valgus force[24].

The sMCL originates from the posterior aspect of the medial femoral condyle, superior to the origin of the dMCL. The sMCL has two tibial insertions. The proximal insertion inserts on the semimembranosus tendon and the distal insertion is anterior to the posteromedial crest of the tibia[23]. The sMCL is the primary restraint to valgus forces and is recognized as being one of the primary static stabilizers of the knee[69], assisting in joint control throughout the entire range of motion. Specifically, the sMCL acts to limits anterior translation of the medial tibia[24,69].

The sole medial muscle involved in the surgical technique examined in this thesis is the semimembranosus. The semimembranosus is a long muscle found on the posterior aspect of the thigh that originates from the ischial tuberosity. Distally, the semimembranosus has several expansions that insert on the posteromedial aspect of the medial tibial condyle and other medial soft tissue structures[23]. The actions of the semimembranosus include knee flexion, hip extension, and medial rotation of the tibia. When the knee is flexed, the semimembranosus contributes to medial knee control via active stabilization[21,25].

The final relevant medial structure is the posterior oblique ligament (POL). The POL consists of superficial, central, and capsular arms that branch from the distal tendon of the semimembranosus. The POL has a femoral attachment distal and posterior to the adductor tubercle and its three arms course distally to the semimembranosus tendon and the tibia[23]. Primarily, the function of the POL is to limit medial rotation of the tibia in knee extension and to resist valgus forces while the knee is extending[26].

2.2 Osteoarthritis

Osteoarthritis (OA) is a degenerative disorder of movable joints, most commonly involving the weight-bearing joints of the lower extremities such as the hip and knee. OA is characterized by extracellular matrix degradation and cell stress resulting from micro- and macro-injury that activates maladaptive repair responses[27]. The disease typically progresses from molecular derangement (altered metabolism) to anatomic and physiologic derangement (cartilage degradation, joint inflammation, bone remodelling). The manifestation of molecular and anatomic derangement can culminate in illness characterized by stiffness, joint pain, and swelling that leads to disability and reduced quality of life[27-30].

OA is the most common form of arthritis. In the 2015 Global Burden of Disease report, it was estimated that nearly 240 million people are living with symptomatic hip and knee OA worldwide, a 33% increase from 2005[31]. The same study estimated that OA accounted for approximately 13 million years living with disability (YLDs) globally. However, the prevalence and impact of OA has been thought as underestimated because OA in joints other than the hip and knee have not been considered in these calculations[32]. OA is also associated with increased comorbidity and increased mortality.

2.2.1 Osteoarthritis of the Knee

OA develops more frequently in the knee joint than any other weight-bearing joint in the body[33]. Second to low back and neck pain, symptomatic OA of the knee is one of the leading causes of worldwide physical disability[32]. Global age-standardized prevalence of knee OA has been reported as 3.8%[33], but lifetime risk of developing symptomatic knee OA has been estimated to be as high as 45%[34]. With increases in obesity rates partnered with the aging population, the physical disability and economic burden associated with knee OA is expected to grow[28].

2.2.2 Risk Factors

As there is no known cure or disease modifying drug currently available for OA, it is important to understand the risk factors that may accelerate the development and progression of knee OA. Risk factors are numerous, and the interaction between risk factors is complex. Generally, knee OA risk factors can be divided into systemic and local categories.

Systemic risk factors influence the knee through biochemical and physiological mechanisms that act to predispose an individual to knee OA. Systemic risk factors can be subdivided into modifiable and non-modifiable categories. Non-modifiable systemic risk factors include age, sex, genetics and ethnicity, whereas modifiable systemic risk factors include obesity, diet, and bone metabolism[29,30].

Local risk factors have a mechanical influence on the knee joint that act to make the joint susceptible to OA. These factors include muscle strength, physical activity/occupation, joint injury, joint alignment, obesity, and leg length inequality. All of these local risk factors are modifiable to some extent[29,30].

In a systematic review and meta-analysis, Silverwood *et al.* reviewed the current available evidence on risk factors for knee OA in adults over the age of 50. They found the four main factors associated with the onset of OA were having a previous knee injury (pooled odds ratio [OR] 2.83, 95% confidence interval [CI] 1.91-4.19), obesity (pooled OR 2.66, 95% CI 2.15-3.28), being overweight (pooled OR 1.98, 95% CI 1.57-2.29), and being of female gender (pooled OR 1.68, 95% CI 1.37-2.07)[35].

Additionally, Murphy *et al.* used 3068 participants from the Johnston County OA Project to estimate the lifetime risk of symptomatic knee OA using a logistic regression model. They found the lifetime risk of symptomatic knee OA in this cohort was 44.7% (95% CI 40.0 – 49.3%), and this risk increased to 56.8% (95% CI 48.4 – 65.2%) with history of knee injury, and increased further to 60.5% (53.0 – 68.1%) with obesity[34].

To assess patient characteristics that predict knee OA progression, Chapple *et al.* performed a systematic review of prognostic studies. They found that age, presence of OA in multiple joints, radiographic features, and varus knee alignment had were strong predictors of knee OA progression, and that BMI was a strong predictor for long-term (>3 years) progression of OA[36].

2.2.2.1 Alignment

Among the risk factors identified as most strongly associated with knee OA progression by Chapple *et al*, varus knee alignment has been a focus of many research groups. Knee alignment is an important factor to predict disease development and progression, and to identify potential treatment options[36- 38].

There are three categories of knee alignment: neutral, varus, and valgus. To best assess knee alignment, full length hip-to-ankle standing anteroposterior radiographs are recommended. Using these radiographs, axes can be drawn on the lower-limb that classify the individual to an alignment category. The most common measure is known as the mechanical axis angle (MAA). To find the MAA, a line is drawn from the center of the head of the femur to the center of the talus. If the line passes through the tibial spines, the individual has neutral alignment. If the line passes medial or lateral to the tibial spines, then the individual would be classified as varus or valgus, respectively. The MAA can be subdivided into the femoral mechanical axis (center of femoral head to intercondylar notch of femur) and the tibial mechanical axis (tibial spines to center of talus)[39]. The angle between the mechanical axes of the femur and tibia provides a continuous variable that indicates the severity of deformity.

Sharma *et al.* found a four-fold increase in the odds of medial OA progression in individuals with varus deformities after adjusting for sex, age and body mass index (Adjusted OR, 4.09; 95% CI, 2.20-7.62). They also found the severity of varus deformity was correlated with joint space loss over 18 months (R=0.52; 95% CI, 0.40-0.62). Finally, bilateral 5° deformity or greater was associated with significant physical function deterioration over an 18 month period compared with individuals with less than 5° bilateral deformity at baseline[37].

Additionally, patients with varus deformities of approximately 10° or greater were found to have intrinsic shortening of the medial collateral ligaments and lengthening of the lateral soft tissues[40]. This has important implications for physical function and needs to be considered if the patient progresses to operative treatment options.

2.2.3 Diagnosis

As there are no available laboratory tests to diagnose early OA, knee OA is diagnosed with a combination of clinical and radiographic assessments. Clinical assessments typically follow the guidelines of Altman *et al.* They describe the clinical findings required to diagnose OA as knee pain and one of the following: over the age of 50, crepitus (cracking or popping sounds or sensations in a joint), or morning stiffness lasting no longer than 30 minutes[41].

Radiographic assessments commonly follow the Kellgren-Lawrence grading scale for evaluating radiographic evidence of OA (Table 1). The scale grades OA severity from zero to four (0 – None; 1 – Doubtful; 2 – Minimal; 3 – Moderate; 4 – Severe) based on three key radiographic findings: joint space narrowing, osteophytes, and subchondral sclerosis[42]. Joint space narrowing is a proxy measure for the amount of cartilage in the joint because cartilage does not appear on radiographic images. The amount of joint space narrowing generally represents the amount of cartilage lost due to OA. Osteophytes are bony outgrowths that are typically found at the joint margins. They are associated with the ongoing remodelling process of damaged cartilage and can contribute to functional limitations and clinical symptoms. Subchondral sclerosis presents on radiographs as an area of increased density deep to the articular cartilage. Similar to osteophytes, subchondral sclerosis is thought to develop due to the remodelling processes associated with damaged cartilage.

Table 1: Kellgren-Lawrence scale for evaluating radiographic evidence of OA

Grade	**Description**
0	No radiographic features of OA are present
1	Doubtful joint space narrowing, possible osteophytic lipping
2	Possible joint space narrowing on anterior-posterior weight-bearing radiograph, definite osteophytes
3	Definite joint space narrowing, multiple osteophytes, some subchondral sclerosis, possible bony deformation
4	Marked joint space narrowing, large osteophytes, severe subchondral sclerosis, definite bony deformation

Altman *et al.* found that combining clinical and radiographic assessments achieved 91% sensitivity and 86% specificity for the differentiating between patients with idiopathic knee OA and non-arthritic controls[41].

2.2.4 Treatment Options for Knee Osteoarthritis

Following the diagnosis of OA, the patient has several available treatment options targeted at managing symptoms of the disease and improving physical function. These treatment options range from lifestyle changes to surgical interventions depending on the severity of knee OA at the time of diagnosis. Unfortunately, no cure or disease modifying drug exists for OA and conservative management does not provide long-term symptom relief, leaving patients few options except for the eventual total joint replacement.

2.2.4.1 Conservative Management

Conservative management is the first-line treatment for knee OA and there are several options. The effectiveness of conservative treatment options varies depending on individual and disease factors. A plethora of evidence exists for the various conservative management options for knee OA. This led the Osteoarthritis Research Society International (OARSI) to perform a systematic review and create guidelines for the non-surgical management of symptomatic knee OA[43]. Several treatment modalities were deemed appropriate for all individuals with knee OA including biomechanical interventions (walking canes, knee braces, knee sleeves), intra-articular corticosteroid injections, aerobic and strength training exercise, weight management, and education. Additional non-surgical treatment modalities of acetaminophen, oral and topical non-steroidal anti-inflammatory drugs (NSAIDs), balneotherapy, and capsaicin were deemed appropriate for patients without relevant comorbidities[43].

These conservative management modalities do not cure OA, nor do they alter the biochemical changes associated with OA. Rather these modalities are focused on symptom management and removing factors that are known to accelerate knee OA progression. Often, multiple conservative treatment modalities are used concurrently. The selection of the most appropriate treatments are made together by the clinician and patient based on symptom and disease severity, and personal preference[43].

2.2.4.2 Surgical Management

For patients in later stages of the disease, where conservative treatment options have been exhausted and no longer provide symptom relief, a referral to an orthopaedic surgeon is appropriate. Surgical options for knee OA include arthroscopic debridement, high tibial osteotomy (HTO), unicompartmental knee arthroplasty (UKA) and total knee arthroplasty (TKA).

Arthroscopic debridement is a minimally invasive procedure that involves the removal of damaged cartilage and bone that may be the cause of OA symptoms. HTO is considered for younger patients (<60) with OA affecting either the medial or lateral tibiofemoral compartments of the knee and have an accompanying lower limb malalignment. HTO involves making a controlled break of the proximal tibia to shift the weight-bearing load of the joint away from the affected tibiofemoral compartment. The goal of this procedure is to slow the progression of knee OA and to relieve symptoms[44]. Selecting appropriate patients for this procedure is crucial to its success, and it is recommended that those with OA affecting multiple knee compartments, above 60 years old, and have pain at night or rest are better candidates for TKA[45]. While HTO certainly has its place in the surgical management of knee OA, the current gold-standard surgical treatment is TKA.

UKA is a surgical procedure used for patients with OA affecting only one of the knee compartments, typically the medial or lateral compartment. The damaged surfaces of the affected compartment are removed and replaced with metal and plastic components, while the unaffected compartment is left alone.

2.3 Total Knee Arthroplasty

Total knee arthroplasty is primarily used as a surgical treatment for patients with severely arthritic knees whose quality of life can no longer be maintained using non-surgical options. The procedure corrects any pre-existing knee malalignment and replaces the damaged articular surfaces of the distal femur and proximal tibia with metal components that are separated by a polyethylene insert. The goal of TKA is to provide the patient with a long-lasting, painless and functional knee[9,46].

The concept of TKA, first termed total condylar knee prothesis, was developed independently in the United States and overseas during the early 1970s[47]. While the basic tenants of the procedure have remained unchanged, development and refinement of TKA over the past 40 years have produced tremendous improvements to the surgical technique and implant design.

2.3.1 Preoperative Assessment

Preoperative assessment is important to ensure the patient is an appropriate candidate for TKA. A detailed medical history and radiographs are commonly used to identify the severity of OA and to identify comorbidities. Indication for TKA is considerable pain and disability that can no longer be managed with nonoperative treatment modalities[9]. There are also several contraindications for TKA. The most common of these include insufficient pain or disability, inadequate attempts at nonoperative management, active joint or skin infection, extensor mechanism dysfunction, and severe medical comorbidities[9]. As TKA is an elective procedure, the ultimate decision to proceed with TKA requires agreeance from both patient and surgeon.

Once deemed an appropriate candidate for TKA, a comprehensive physical history, similar to that of other surgical procedures, is completed to help reduce the risk of intra- and post-operative complications. Additionally, a full-limb standing anteroposterior (AP) radiograph is taken preoperatively for templating purposes. Several axes are drawn on this radiograph that guide intraoperative bone cuts.

2.3.2 Surgical Technique

Differences in surgical technique for TKA exist between surgeons. The surgeons at University Hospital, London Health Sciences Centre, currently utilize the following surgical technique for TKA.

An anterior midline incision is completed with the knee in flexion. The incision begins from six to ten centimeters proximal to the superior pole (base) of the patella and extends longitudinally to medial border of the tibial tuberosity (approximately six centimeters distal to the inferior pole (apex) of the patella). The incision is continued deep to expose the quadriceps tendon, medial border of the patella, and medial border of the patellar tendon[48].

Following the initial skin incision, joint exposure is attained using the medial parapatellar approach. The medial parapatellar incision begins along the length of the quadriceps tendon, continues around the medial side of the patella, and extends approximately four centimeters distally along the medial border of the patellar tendon. To gain medial exposure, the anteromedial capsule and 50% of the dMCL are subperiosteally elevated off the tibia. The knee is then extended and the infrapatellar fat pad is excised, allowing the patella to evert and be flipped laterally. To gain full exposure to the entire knee joint, the knee is flexed to 90°[48].

After adequate knee joint exposure is attained, the distal femur and proximal tibial bone cuts are made. The selected angle of the various bone cuts are made with the goal of achieving a preselected alignment and are guided by the preoperative template images. Both coronal and sagittal alignment must be considered to ensure long-lasting implant survivorship[9].

In the coronal plane, most surgeons aim to correct alignment to a neutral mechanical axis angle of $0° \pm 3°$ to balance the loading forces exerted on the medial and lateral condyles of the tibial baseplate. To achieve this alignment, the distal femur is cut perpendicular to the mechanical axis (6° valgus to the anatomic axis) of the femur, and the proximal tibia is cut perpendicular to the mechanical axis of the tibia[40]. Varus alignment of the tibial component has demonstrated increased wear in retrieval analyses[6] and shorter survival rates[7] when compared with neutral alignment.

In the sagittal plane, the distal femur is cut perpendicular to the intramedullary canal of the femur. The sagittal cut of the tibia, termed the posterior tibial slope, is dependent on the selected implant design. Generally, the posterior tibial slope is cut to 3°, however, when using cruciate-retaining implants, a greater slope (>3°) may be necessary[9].

The final bone cuts are then made to the anterior surface and posterior condyles of the femur. These cuts have important implications for femoral component sizing and rotation, and there are several techniques available to perform these cuts. Regardless of the technique used to set femoral component positioning, the goal is to achieve placement parallel to the transepicondylar axis, perpendicular to the anteroposterior axis, slight lateralization to aid in patellar tracking, and 3° to 4° of external rotation relative to the posterior condylar axis[9].

The previously made bone cuts create what are known as the extension and flexion gaps. The extension and flexion gaps are defined by the joint space between the resected femur and tibia when in extension and in 90° of flexion, respectively. Achieving rectangular gaps that are equal in magnitude when in flexion and extension is desirable, however, tightness of medial soft tissue structures in varus knees often prevent the gaps from being rectangular following bone cuts alone. To address this issue, the surgeon can selectively release medial soft tissues to widen the medial aspect of the joint gaps to create rectangular gaps. The process of sequentially releasing medial structures to correct flexion and extension gaps is called soft tissue balancing.

After the knee is deemed appropriately balanced, the implant components can be installed. The femoral component fits tightly over the femoral condyles and is fixed using either a cemented or uncemented technique. The tibial component requires an intramedullary hole to be drilled with additional space for the medial and lateral metal flares of the tibial component. A trial tibial component is inserted to ensure proper fit and balance prior to cementing and impacting the final tibial component. Layer-by-layer closure of the exposed knee completes the procedure.

2.3.2.1 Soft Tissue Balancing

Soft tissue balancing in the varus knee is an essential step in TKA as the flexion and extension gaps cannot be effectively balanced using bone cuts and implant manipulation alone. Flexion and extension gap imbalance can occur in two ways. First, the gap may not be rectangular, meaning the magnitude of separation between the femur and tibia is different between the medial and lateral condyles. Secondly, the magnitude of separation between the flexion gap and extension gaps may be different. The latter of these inequalities is largely influenced by femoral component sizing and positioning, while the former (the focus of this thesis) is managed in the varus knee using medial soft tissue release.

The sequence of structures the surgeons releases varies between surgeons. A review of the medial release methods was completed by Hunt *et al.* who found that over 20 sequences have been published[18]. This illustrates the subjectivity of handling soft tissues in TKA.

The surgeons at University Hospital typically utilize the following sequence of medial release in the varus knee. As part of the previously described technique for exposing the knee joint, a subperiosteal elevation of approximately 50% of the dMCL is completed. Next, any tibial and femoral osteophytes are removed. It is important to remove osteophytes before continuing with the surgical release of any structures because they can “tent” ligaments, giving the surgeon a false sense of ligamentous tightness.

If further correction is needed, the release of the dMCL is continued until the entire distal attachment is lifted from the tibia. Typically, these few releases are sufficient for patients that presented with minimal preoperative varus deformities. For those with greater deformities, further release may be required to create rectangular gaps.

Following release of the complete dMCL, the medial posterior capsule is the next structure released. Given the anterior approach to TKA, release of the medial posterior capsule is achieved by an intra-articular approach.

If releasing the medial posterior capsule is insufficient to achieve balance, this release can be continued posteriorly to release the semimembranosus and POL. These two structures are in close proximity to each other making it difficult to release one without the other.

Modification of the sMCL may be required if the patient has a severe preoperative varus deformity that cannot be managed with the previous releases. The surgeon has a few options when modifying the tension of the sMCL. They can shave away a portion of the proximal medial tibia (medial tibial reduction osteotomy; MTRO) to decrease the distance the superficial structures must travel, which decreases ligament tension. Alternatively, they can surgically release the sMCL directly.

The surgeons involved in this thesis prefer to first us the MTRO technique before releasing the sMCL directly as this can preserve the stabilization properties of this ligament. If balance cannot be achieved using the MTRO or another factor prevents the surgeon from using this technique, the surgeon may release the sMCL directly. The sMCL can be surgically released using two methods. First, the ligament can be released using a scalpel to make small horizontal cuts to "pie-crust" the ligament. Alternatively, the surgeon can perform a similar technique that was utilized for the dMCL release. This "deep" sMCL release technique uses a blunt instrument to lift the distal attachment from the tibia.

Finally, if all other releases are unable to create a balanced knee, the use of a medial epicondyle osteotomy may be considered. The osteotomy allows the epicondyle to move distally, decreasing the tension of the attached soft tissues, and increasing medial joint space[49]. This release is rarely used in practice, but if used, a more constrained implant should be considered to account for instability this release may cause.

After each step of the medial soft tissue release sequence, the balance is assessed to avoid excessive release. Balance is commonly tested by inserting a spacer block or trial tibial component into the flexion and extension gap and then applying varus and valgus stress on the knee to assess medial and lateral joint space opening. Achieving perfectly rectangular and equal flexion and extension gaps is difficult. Griffen *et al.* examined the ability to achieve rectangular and equal flexion and extension gaps in 104 consecutive posterior-stabilized TKA. They found rectangular flexion and extension gaps were obtained within 1 mm in 84% to 89% of cases, but creating flexion and extension gaps of equal magnitude proved more difficult, with only 47% to 57% of cases within 1 mm[16].

Soft tissue balancing is widely regarded as an essential component of the TKA procedure to ensure long-term stability and implant survivorship[10,11,13-17]. Ligament imbalance has been shown to be associated with negative effects on the outcomes of primary TKA including instability[51], radiolucent lines[52], and increased severity of wear at revision[53].

Typically, the amount of medial soft tissue release required intraoperatively is correlated with the extent of the patient's preoperative varus deformity[9]. Few studies have investigated postoperative outcomes between patients that require little or no release, and those that need extensive release. One study, by Unitt *et al.* collected pre- and post-operative patient-reported outcomes of patients that received none/minimal (n=173), moderate (n=122), and extensive (n=115) releases intraoperatively. They found patients requiring extensive release had greater change scores preoperatively to postoperatively compared to patients with none/minimal release, but had similar postoperative outcomes and complication rates[54].

2.3.3 Implant Design

Several types of TKA implant designs available, but the most common implants used in primary TKA are cruciate-retaining (CR) and posterior-stabilized (PS). In CR-TKA, the patient's ACL is excised and the PCL is left in place. In PS-TKA, both the ACL and PCL are excised. The role of the PCL is fulfilled by an interaction between a post that extends vertically from the polyethylene spacer and inserts into the cam of the femoral component. When near 60° to 80° of flexion, the posterior aspect of the femoral cam engages with the posterior surface of the tibial post, restricting anterior femoral translation. As the knee continues to flex, the cam-post interaction drives posterior translation of the femur on the tibia.

The fixation of the polyethylene tibial liner may also differ between implant designs. Most commonly, a fixed-bearing design is used. Here, the tibial liner is fixed to the metal tibial implant component and does not move. Recently, mobile-bearing designs have been introduced that allow axial rotation of the polyethylene liner on the tibial implant component[55].

2.3.3.1 Posterior-Stabilized Triathlon

The implant used in the present study was a posterior-stabilized Triathlon implant (Stryker, Mahwah, NJ) with cemented fixation. This implant has a fixed-bearing tibial component. In the sagittal plane, the femoral component has a single radius of curvature from 10° to 110° flexion. The short, flared posterior condyles are designed to allow internal-external rotation of 20° and flexion to 150°.

2.4 Tibiofemoral Contact Kinematics

Numerous studies have investigated *in vivo* tibiofemoral contact kinematics of native knees and of postoperative knees that have underwent TKA using a variety of implant designs. Nonoperative native knee contact kinematic studies are useful to understand the normal knee movements and to provide a gold-standard pattern that TKA implants can strive towards. Many studies have demonstrated kinematics post-TKA generally do not replicate native knee kinematics[48-52]. Nevertheless, contact kinematics post-TKA provide valuable information related to implant function, wear, and migration[56-58].

2.4.1 Radiostereometric Analysis

Radiostereometric analysis, or RSA is an imaging technique originally developed by Selvik *et al.*[59]. Although most commonly used to measure orthopaedic implant migration, RSA techniques can be applied to acquire *in vivo* tibiofemoral contact kinematics of individuals that underwent TKA. RSA utilizes two X-ray focus points that capture images simultaneously to create a “stereo” image. These images, along with markers projected onto each image from a calibration cage, are used to generate accurate 3D representations of implant positions and orientations. Although other methods are commonly used to collect kinematic data, a strength of RSA is its accuracy. It has reported errors of only 0.52° for rotations and 0.19 mm for translations[60].

2.4.2 Pre- and Postoperative Tibiofemoral Contact Kinematics

In vivo tibiofemoral contact kinematics have been measured in normal healthy knees and in arthritic knees prior to undergoing TKA during a deep knee bend activity. These studies have found that non-implanted knees typically have a medial pivot position. This means that as the knee is flexed, most axial rotation of the tibia happens about the medial condyle. There is a combination of tibial rotation and translation that characterizes a normal knee bend contact pattern. Dennis *et al.* used a model-fitting technique that utilized fluoroscopy combined with computed tomography (CT) to assess contact patterns of ten healthy knees performing a deep knee bend from 0° to 90°. They found all participants had posterior translation of the lateral condyle throughout flexion, and nine patients had posterior translation of the medial condyle throughout flexion. They found from full extension to 90° of flexion the medial condyle had an average posterior translation of 3.4 mm ± 4.6 mm, whereas the lateral condyle saw more dramatic average posterior translation of 19.2 mm ± 8.4 mm. Eight of these patients were noted to have a medial pivot position, one patient was noted with lateral pivot, and the final patient was absent of a pivot pattern[56].

Similar results were found by Li *et al.* who used a similar model-fitting technique, except with magnetic resonance imaging (MRI). Li *et al.* assessed contact patterns of 11 OA patients with Kellgren-Lawrence grade III and IV during a deep knee bend activity just prior to, and approximately 8-months following CR-TKA. They reported contact translations as a percent change, with 100% representing the entire AP width of the tibial plateau. In the OA knee, they also found a medial pivot position with consistent posterior translation of both the medial (-10.7% ± 6.6%) and lateral condyles (-17.0% ± 6.4%) throughout flexion. Again, more dramatic translation of the posterior condyle was found. In the CR-TKA knee, the medial condyle demonstrated a stable contact position until approximately 30° of flexion before moving anteriorly, whereas the lateral condyle moved slightly anterior throughout flexion. The range of anteroposterior translation was dramatically smaller in TKA knees. On the medial condyle, the range was 12.8% and 3.1% for OA and TKA knees, respectively. On the lateral condyle, the range was 16% and 1.6% for OA and TKA knees, respectively[59].

An issue with TKA knees is often their failure to control paradoxical roll-forward, or anterior translation of the femoral condyles as the knee is flexed. Not only does this paradoxical roll-forward have negative implications for polyethylene wear, anterior contact positions in deep flexion has been negatively associated with achieving higher maximum flexion angles as it may lead to early impingement of the posterior tibial component on the posterior thigh[62]. Posterior-stabilized implants, such as the implant used in this thesis, may be used to attain posterior translation of the femur at higher flexion angles. *In vivo* cam-post engagement has been studied by Pandit *et al.* They used a fluoroscopic assessment of 11 patients performing a deep knee bend activity to find the average flexion angle the cam and post engaged in the Triathlon PS-TKA. They found engagement occurred at a wide range of flexion angles across the cohort (32° to 96°), with average engagement at 63° ± 24°[64].

Tibiofemoral contact kinematics of PS-TKA have also been studied. Dennis *et al.* used a fluoroscopic three-dimensional model-fitting technique to investigate the tibiofemoral contact kinematics of 163 patients that received various PS-TKA. During a deep knee bend from 0° to 90°, they found approximately 70% of patients demonstrated a medial pivot position. Average posterior motion of the medial condyle was 1.0 mm ± 2.7 mm and the lateral condyle was 3.7 mm ± 3.3 mm. The average contact positions on the lateral condyle became more posterior as flexion increased from 0° to 30° and then remained relatively stable from 30° to 90°. However, on the medial condyle, posterior translation was seen from 0° to 30°, but at 60° and 90° the contact position had translated anteriorly to a position between the 0° and 30° positions[56].

These contact position patterns of the medial and lateral condyles described by Dennis *et al.* have been similarly reported independently by Okamoto *et al.*[63] and Teeter *et al.*[57] in the Triathlon PS-TKA. Both authors described anterior translation of the medial condyle and an approximately stable lateral contact position from 20° to 60° of flexion during a weight-bearing knee bend.

2.5 Summary

Osteoarthritis of the knee is a severely debilitating whole joint disease characterized by changes in the cartilage and bone that result in pain and a loss of function. There is no cure for OA and the disease will typically progress to the point of surgical necessity. Total knee arthroplasty is the gold-standard operative treatment for knee OA that corrects lower-limb malalignment while replacing the damaged articular surfaces of the distal femur and proximal tibia with metal components that are separated by a polyethylene spacer.

In varus knees, an essential aspect of TKA is the soft tissue release of the medial stabilizing structures so that effective correction of coronal plane deformities can be achieved. While the release of medial stabilizing structures may be necessary to achieve the desired neutral coronal plane alignment, the releases may act to destabilize the knee and be associated with unwanted outcomes.

Tibiofemoral contact kinematics have been studied extensively to assess healthy and arthritic knees, to compare TKA surgical techniques, and to compare between TKA designs. Mimicking healthy knee kinematics post-TKA is desirable, but is rarely achieved. Medial stabilizing structures aid in guiding tibiofemoral knee kinematics and extensive releases that are necessary to correct varus deformities may compromise stability.

Currently, no literature exists that examines the weight-bearing postoperative *in vivo* tibiofemoral contact kinematics of patients that received little or extensive soft tissue releases intraoperatively. Further study of the postoperative implications of extensive soft tissue release is needed.

Chapter 3

3 Objectives

Our primary objective was to compare the postoperative *in vivo* tibiofemoral contact kinematics of a single-radius, posterior-stabilized TKA design between patients that received minimal amounts of medial soft tissue balancing intraoperatively and patients that required more extensive releases. Our secondary objectives were to compare these groups using the following patient-reported outcomes: The Short-Form 12, the Western Ontario and McMaster Osteoarthritis Index, and the Knee Society Score. Our final objective was to investigate if an association exists between anterior-posterior excursion of the contact position and patient satisfaction.

We hypothesized that in this particular implant design, the *in vivo* tibiofemoral contact kinematics would be different for patients that received minimal soft tissue release versus patients that required additional soft tissue release. We also hypothesized that no differences would be found in any of the collected patient-reported outcomes, and no association will be found between excursion and patient satisfaction.

Chapter 4

4 Materials and Methods

4.1 Study Design

This was a single-centre, prospective imaging study that took place in London, Ontario between January 2017 and March 2018. This study involved patients with end-stage osteoarthritis undergoing a primary total knee arthroplasty that received different amounts of soft tissue modifications to correct a varus deformity. Prospectively collected baseline data were collected approximately one month prior to surgery at the patients' preadmission clinic visit. The imaging follow-up visit took place at least one-year postoperatively. Surgery and clinical follow-up visits were completed at London Health Sciences Centre's (LHSC) University Hospital and imaging was completed in Robarts Research Institute. Twenty-two patients from a previous study[57] that met the eligibility criteria of the present study were also included in the analysis. This study was approved by Western University's Health Sciences Research Ethics Board (Appendix A).

4.2 Eligibility Requirements

Eligible patients for the present study were those over the age of 18 who received primary total knee arthroplasty for osteoarthritis and presented with a preoperative varus deformity. In addition, patients must have received a fixed-bearing, single-radius, posterior-stabilized Triathlon knee system (Stryker, Mahwah, NJ) with cemented fixation by one of two surgeons (JLH or BAL) to be considered eligible. Patients were excluded if their soft tissue and bone modifications were not recorded intraoperatively, if they were physically unable to perform the imaging protocol, or if they were unable to provide informed consent.

4.3 Intervention

4.3.1 Surgical Approach

The goal postoperative mechanical axis angle of all patients was $0^{o} \pm 3^{o}$. Each knee was exposed using a standard midline incision followed by a medial parapatellar arthrotomy. One surgeon (JLH) used a measured resection technique, setting femoral rotation to 3^{o} of external rotation relative to the posterior condylar axis before making bone cuts based on anatomic landmarks. Following the bone cuts, soft tissue releases and bone resections were performed to create balance in flexion and extension. One surgeon (BAL) used a gap balancing technique, where preoperative templating and anatomic landmarks are used to complete the distal femur and proximal tibia bone cuts. Following the bone cuts, soft tissue releases and bone resections were performed to balance the joint in extension using spacer blocks. Once balance in extension was achieved, the magnitude of the previously completed tibial resection was used to set femoral component rotation using a McBride tensioner to achieve flexion and extension spaces of equal magnitude. Identical fixed-bearing, single-radius, posterior-stabilized TKA (Triathlon, Stryker, Mahwah, NJ) with cemented fixation was implanted in all patients. Similar tibiofemoral contact kinematic patterns have been found between measured resection and gap balancing techniques for this implant system[57].

4.3.2 Medial Soft Tissue Balancing

Coronal plane ligament balance was assessed using a spacer block. When the medial extension gap was tighter than the lateral extension gap, the sequence of medial soft tissue releases and bone resections shown in Table 2 were used to attain a rectangular gap space. During initial knee exposure, all patients received 50% release of the deep medial collateral ligament to the midcoronal plane of the tibia. Additionally, tibial and femoral osteophytes were removed in all patients to ensure osteophytes were not tenting the tightened medial structures. Following each step in the medial release sequence, a spacer block was inserted to assess gap symmetry. In patients where medial tightness persisted, the next step in the sequence was utilized. This process was repeated until gap symmetry was achieved.

Table 2: Authors' stepwise medial release sequence for correcting varus deformities

Soft Tissue Release / Bone Modification
1. 50% Deep MCL (Mid-coronal plane)
2. Osteophytes
3. Complete Deep MCL
4. Posterior Capsule
5. Semimembranosus & Posterior Oblique Ligament
6. Tibial Reduction Osteotomy
7. Superficial MCL
8. Medial Epicondyle Osteotomy

Abbreviation. MCL = Medial Collateral Ligament

4.3.3 Postoperative Protocol

A standardized rehabilitation protocol was used for all patients. In-patient physiotherapy began immediately following surgery, consisting of full weight-bearing and an initial set of exercises focused on maintaining range of motion and blood flow. Upon discharge patients were instructed to weight-bear as tolerable and encouraged to follow-up with a physiotherapist within two weeks. Out-patient physiotherapy generally continued until three months post-surgery. Patients could cease the use of a gait aid at any time. Postoperative clinic evaluations were at two weeks, six weeks, three months, one-year, and yearly as needed.

4.4 Outcome Measures

4.4.1 Primary Outcome Measure

The primary outcome, tibiofemoral contact kinematics, was measured at least one-year postoperative using a radiostereometric analysis system (RSA), which is located on the 2nd Floor Imaging Centre of the Robarts Research Institute in London, Ontario.

4.4.1.1 Imaging Set-up

An RSA system with computed radiography (CR) cassettes was used in the present study. We used a uniplanar technique and calibration cage (cage 43, RSA Biomedical, Umea, Sweden) to obtain images. A uniplanar technique was used instead of a biplane technique because a biplane technique was unable to obtain images at high flexion angles. The CR cassettes were positioned side-by-side behind a calibration cage. The calibration cage is a radiolucent material that contains two sets of radio-opaque markers: fiducial markers and control markers. When an examination is completed, both sets of markers are projected onto the cassettes along with the object of interest. The visibility of the markers on the obtained image are essential to the ability to perform 2D to 3D registration. There are two sets of fiducial markers, one on each half of the calibration cage. These markers are used to define the position and orientation of the global coordinate system. There is a single set of control markers, positioned perpendicular and central to the fiducial markers. The control markers are used to determine the position of the focus points and where the X-ray beams intersect. The system in Robarts Research Institute has a 0.1 mm pixel pitch and a 10-bit grey-scale level.

In the present study, two mobile X-ray tubes were positioned at the height of the patient's knee joint and directed towards the patient's knee (Figure 1). The two X-rays were taken simultaneously for each examination, providing two images of the knee from different focus points.

Figure 1: Representation of RSA set-up with participant in full extension

4.4.1.2 Imaging Protocol

Patients underwent weight-bearing radiographic stereo examinations of a deep knee bend with the aforementioned RSA system. Examinations were taken starting in full extension (0^{o}) and in 20^{o} increments of flexion to a maximum of 120^{o}. For each examination, patients stood upright between the two X-ray tubes and the calibration cage with their knee of interest centralized. The X-ray technician would adjust the patient's position to ensure the entire knee would be visible on both X-ray cassettes.

To obtain high flexion angles, the deep knee bend was separated into two techniques. The first four examinations (0^{o}, 20^{o}, 40^{o}, 60^{o}) were taken with patients facing the calibration cage. At 0^{o}, the patient was instructed to stand upright with their knees straight and weight equally distributed between limbs. For examinations at 20^{o} to 60^{o}, patients were instructed to squat with their heel on the ground until they reached the desired flexion angle as measured by a manual goniometer, again with weight equally distributed between limbs. The final three images (80^{o}, 100^{o}, 120^{o}) were taken with the patient rotated 90 degrees relative to the previous images, with the knee of interest closest to the calibration cage and elevated with a small step-stool. Patients were instructed to lunge until they reached the desired flexion angle with their body weight supported primarily by the leg being studied, again measured by a manual goniometer. A handrail was available during all examinations. Patients were asked to use the handrail if needed for balance. All examinations and goniometer measurements were completed by a single X-ray technician. Because a CR system was used, the cassettes had to be read and cleared between each examination resulting in a slight delay between examinations.

4.4.1.3 Image Processing

Each examination for each patient resulted in two images taken from a non-orthogonal angle that required 2D to 3D registration. Images and manufacturer's computer-aided design (CAD) models were imported into model-based RSA software (RSAcore, Leiden, Netherlands). The CAD models used were specific to the femoral and tibial implant component sizes of each patient. The fiducial and control markers were identified for each image and the femoral and tibial implant component contours were outlined. The software then fits the shadow of the CAD models with the contours of the implant components of each image. This results in a 3D representation of the position and orientation of the tibial and femoral implant CAD models. This model-based registration technique has been found to be very accurate, with errors of 0.52° for rotations and 0.19 mm for translations[64].

The position and orientation coordinates of the registered CAD models were then imported into in-house software[57] to calculate the contact positions between the femoral and tibial components of the medial and lateral condyles. This software calculates the magnitude of separation between the surface geometries of the tibial and femoral components. The position with the shortest magnitude of separation between components was considered to be the contact position. Contact positions were recorded using a coordinate system specific to the tibial baseplate. Negative values represent posterior contact position translation relative to the AP centre of the tibial baseplate, while positive values represent anterior contact position translation. To account for differences in component sizes and operative side between patients, all coordinates were normalized to a size three, right knee tibial baseplate.

Several measures of contact kinematics can be calculated using the contact positions. The two primary measures of contact kinematics used in the present study were average anterior-posterior (AP) contact position translation and average AP excursion. AP contact position translation describes how the average contact positions on the medial and lateral condyles change throughout flexion. AP excursion is a measure of the maximum AP range the contact position travels throughout flexion, calculated by subtracting the most posterior contact position from the most anterior.

4.4.2 Secondary Outcome Measures

We measured patients' secondary outcomes preoperatively at their pre-admission clinic appointment and postoperatively at the imaging timepoint.

4.4.2.1 Short Form-12

The Short Form-12 (SF-12) is a generic 12-item patient-reported questionnaire designed to measure health-related quality of life. Items are rated on a three-to-five-point ordinal scale and used to calculate physical and mental health composite scores (PCS and MCS, respectively). The PCS and MCS are standardized and range from 0 to 100, where higher scores represent better health. The SF-12 was not designed to target a specific disease group or age range. It has been used extensively across many domains of health research as a valid, reliable, and responsive measure[65,66].

The SF-12 has been found to have good reliability for the physical component and excellent reliability for the mental component in TKA patients with ICC values of 0.81 and 0.90, respectively. The minimal detectable changes in this patient population have been reported as 9.7 points for PCS and 8.0 points for the MCS when measured preoperatively and six-months postoperatively[65].

4.4.2.2 Western Ontario McMaster Osteoarthritis Index

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a patient reported questionnaire consisting of 24 items used to measure changes in physical function as a result of treatment interventions for patients with osteoarthritis. The WOMAC uses three subscales to assess distinct dimensions of health including pain (five items), stiffness (two items), and physical function (17 items). Each item can be answered using response options of none, mild, moderate, severe, and extreme. Responses correspond to an ordinal scale from zero to four. Scores for individual subscales are summed with maximum totals of 20 points for pain, eight points for stiffness, and 68 points for physical function. By summing the individual subscales, a global health score can also be obtained. Typically, higher scores on the WOMAC represent worse health outcomes, however, at our institution scores are inverted so that higher scores represent better health outcomes.

The WOMAC's measurement properties have been examined in a literature review performed by McConnell et al[67]. They found that in total knee arthroplasty populations the WOMAC is a valid and reliable tool to detect health related changes after surgery. High internal consistency was found for all subscales, while physical function and pain subscales demonstrated high test re-test reliability[67]. The WOMAC was also found to be responsive in this population with large effect sizes in pain (0.95-41), stiffness (0.88-24), and physical function (1.01-23.9) subscales.

4.4.2.3 Knee Society Score

The Knee Society Score (KSS) is a patient reported scoring system for measuring patient's functional ability after TKA. There are two versions of the KSS; one administered preoperatively and the other postoperatively. The patient questionnaire consists of four subscales: symptoms score (three items; 25 points), satisfaction scores (five items; 40 points), expectation score (three items; 15 points), and functional activity score (19 items; 100 points). Subscales can be interpreted individually or summed for a total score. The new version of the KSS described above was created in 2011 to better assess the contemporary population of TKA patients, and was used in the present study. It has been found to be a valid and reliable measure in this population[68].

4.5 Patient Grouping

Because of the exploratory nature of this study, we grouped patients in two ways, depending on the amount of soft tissue balancing they received intraoperatively. For the first analysis, patients were allocated to those who received only the complete deep medial collateral ligament release (minimal group), or those who received more than the complete deep medial collateral ligament (extensive group) (see Table 3).

For the second analysis, patients were allocated to one of three groups. The first group included patients who received up to and including osteophyte removal (mild group); the second group included patients who received up to and including complete release of the deep MCL to release of the semimembranosus and posterior oblique ligament (moderate group). The final group of patient included those who received a medial tibial reduction osteotomy or beyond (extensive group).

4.6 Statistical Analysis

Data analysis was performed using GraphPad Prism version 7.0d (GraphPad Software, Inc). All data was assessed for normality using the D'Agostion and Pearson omnibus normality test.

We used descriptive statistics to present patient demographic characteristics. Means and standard deviations were used for continuous variables (age, height, mass, BMI, HKA angle) and proportions for nominal variables (sex, operative limb).

We used descriptive statistics to present the average AP contact position and excursion throughout flexion on the medial and lateral condyle for each release type and across the entire cohort by using means and standard deviations. Average excursion on the medial and lateral condyles for each release type and across the entire cohort were also presented using means and standard deviations.

We used linear regression to determine the magnitude of the association between medial and lateral excursion and patients' postoperative satisfaction score from the KSS. The independent variable was contact position excursion and the dependent variable was the satisfaction score. Residual plots were assessed for normality and tested for homoscedasticity. Regression was reported with the beta coefficient and corresponding 95% confidence intervals, and the adjusted R-square.

In the first analysis (two-group), AP positions were presented with means and 95% confidence intervals. Excursion was presented with boxplots. Both were compared between groups using unpaired t-tests or Mann-Whitney tests when appropriate. Patient-reported data was presented using means and standard errors and compared between groups using unpaired t-tests or Mann-Whitney tests when appropriate. Preoperative to postoperatively, data was compared using paired t-tests or Wilcoxon matched pairs tests when appropriate.

In the second analysis (three-group), AP positions were presented with means and 95% confidence intervals. Excursion was presented with boxplots. Both were compared between groups using ordinary one-way analysis of variance tests or Kruskal-Wallis tests when appropriate. Patient-reported data was presented using means and standard errors and compared between groups using ordinary one-way analysis of variance tests or Kruskal-Wallis tests when appropriate. Preoperatively to postoperatively, data was compared using paired t-tests or Wilcoxon match pairs tests when appropriate.

Chapter 5

5 Results

5.1 Participant Flow

Participant flow of this study is outlined in Figure 2. From January 2017 to March 2018, 153 patients were screened for eligibility. Seventy nine of these patients were deemed ineligible because they had an ineligible implant (n=65), the means to achieve soft tissue balance was not recorded in sufficient detail (n=13), or they were deceased (n=3).

Thirty-three patients provided informed consent for this study. One patient withdrew prior to imaging with concerns of radiation exposure. The first patient of the study was excluded because we altered the imaging protocol and set-up after they completed the study. Finally, two patients were excluded because calibration markers could not be identified in the images.

A sample of patients (n=22) from a previous prospective imaging study[57] were also included in this analysis. The inclusion criteria of this study was receiving a posterior-stabilized Triathlon implant with cemented fixation. Exclusion criteria was a history of alcoholism, a language barrier, pregnancy, or undergoing simultaneous bilateral TKA. Patients were recruited consecutively and randomized at the time of referral to one of the two surgeons involved in the present thesis. They underwent the same kinematic and patient-reported outcome protocol as the present study, and this data was included in the analysis.

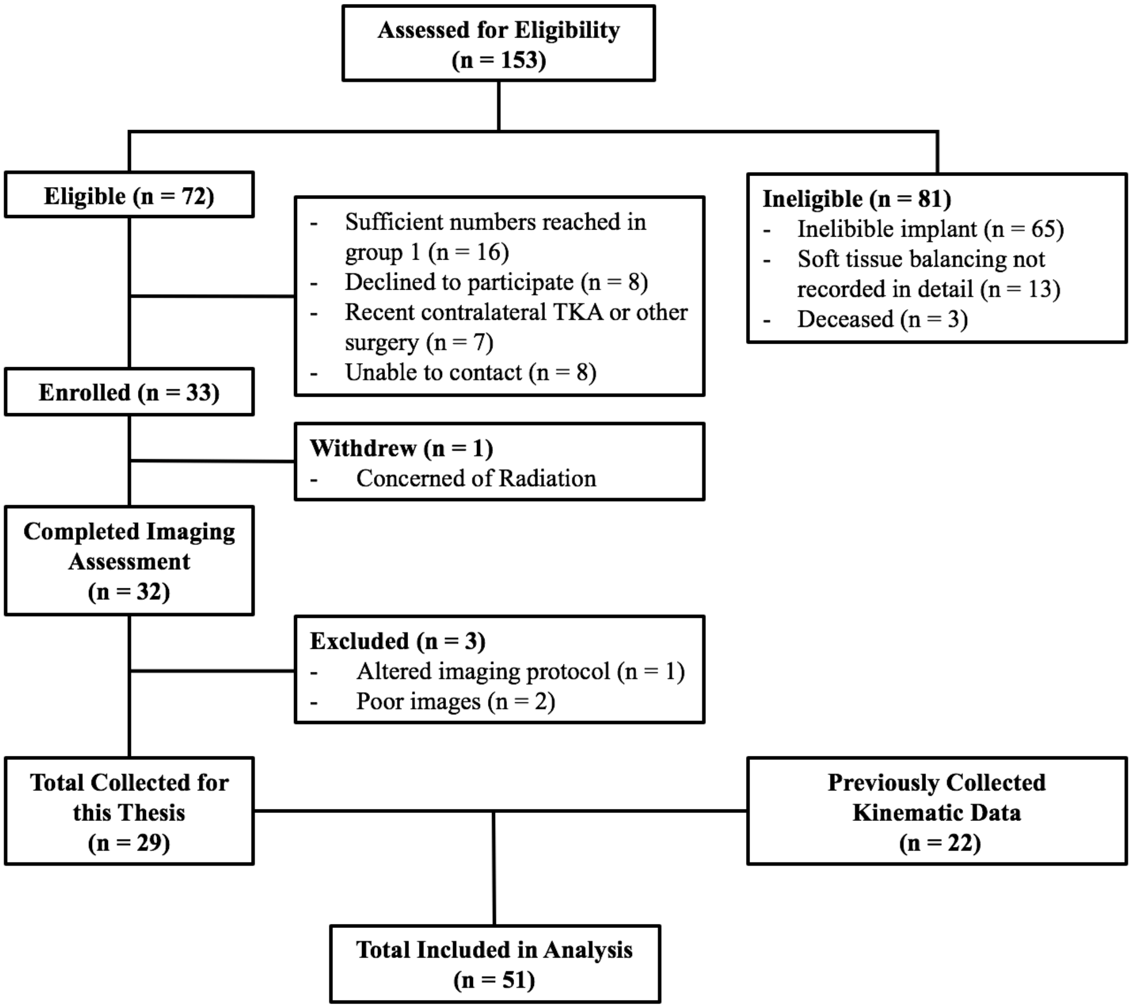

Figure 2: Participant flow through this study

5.2 Surgical Balancing Characteristics

The number of releases completed intraoperatively for this cohort are given in Table 3. Patients were organized by the maximum level of balancing they required to attain a balanced knee. One patient received release up to the complete deep medial collateral ligament before the surgeon opted to perform a tibial reduction osteotomy without first releasing the posterior capsule, semimembranosus, or posterior oblique ligament. All other patients had releases performed sequentially through the progression of Table 3 until the knee was appropriately balanced.

Table 3: Sequential completed soft tissue balancing of the entire cohort

Release Progression	Number of Patients
1. 50% Deep MCL (Mid-coronal plane)	0
2. Osteophytes	24
3. Complete Deep MCL	7
4. Posterior Capsule	3
5. Semimembranosus & Posterior Oblique Ligament	6
6. Tibial Reduction Osteotomy	10
7. Superficial MCL	1
8. Medial Epicondyle Osteotomy	0

Abbreviation. MCL = Medial Collateral Ligament

5.3 Ungrouped Analysis

5.3.1 Tibiofemoral Contact Kinematics

Average anterior-posterior (AP) contact positions across flexion angles for each release type are given in Table 4. Cohort averages show the medial contact position translates posteriorly from 0° to 20°, anteriorly from 20° to 80°, and posteriorly from 80° to 120°. On the lateral condyle, the contact position translates posteriorly from 0° to 20°, stays stable from 20° to 60°, and translates posteriorly from 60° to 120°. From 0° to 20°, greater posterior translation is seen on the lateral condyle indicating external femoral rotation as the knee begins flexion from full extension.

Table 4: Average (mean + standard deviation) medial and lateral condyle anterior-posterior contact kinematics by release type

		Release Group						
		Osteophytes (n = 24)	**100% dMCL (n = 7)**	**Posterior Capsule (n = 3)**	**SM/POL (n = 6)**	**Tibial Reduction Osteotomy (n = 10)**	**sMCL (n = 1)**	**Average (n = 51)**
Medial Condyle AP Position	**0°**	-8.0 ± 3.7	-9.5 ± 2.5	-7.3 ± 1.8	-8.0 ± 2.9	-8.1 ± 2.9	-8.8	-8.2 ± 3.1
	20°	-10.6 ± 2.5	-11.2 ± 1.2	-8.7 ± 2.1	-10.1 ± 1.7	-10.3 ± 3.3	-12.9	-10.5 ± 2.4
	40°	-8.8 ± 3.5	-9.8 ± 0.7	-8.7 ± 1.2	-9.8 ± 0.9	-9.3 ± 3.1	-10.1	-9.2 ± 2.8
	60°	-8.3 ± 2.0	-8.4 ± 1.3	-7.5 ± 0.7	-7.8 ± 0.9	-9.0 ± 2.5	-10.4	-8.4 ± 1.9
	80°	-8.0 ± 1.5	-8.6 ± 1.9	-9.4 ± 0.5	-6.6 ± 1.1	-8.5 ± 2.5	-7.8	-8.2 ± 1.8
	100°	-9.8 ± 0.9	-10.5 ± 1.7	-11.3 ± 1.2	-8.9 ± 1.3	-11.0 ± 2.5	-13.8	-10.3 ± 1.8
	120°	-12.0 ± 2.3	-11.8 ± 1.7	11.6 ± 1.5	-10.7 ± 0.3	-11.8 ± 2.4	-14.3	-11.7 ± 1.9
	Average	-9.3 ± 1.5	-9.9 ± 1.3	-9.2 ± 1.7	-8.8 ± 1.5	-9.7 ± 1.4	-11.2 ± 2.5	-9.5 ± 1.4
	Excursion	5.4 ± 3.1	5.0 ± 1.0	4.9 ± 1.4	4.7 ± 1.0	4.8 ± 2.1	6.5	5.1 ± 2.4
Lateral Condyle AP Position	**0°**	-6.7 ± 2.9	-6.2 ± 2.1	-7.0 ± 2.1	-7.8 ± 2.6	-5.7 ± 2.6	-8.8	-6.6 ± 2.6
	20°	-10.7 ± 1.9	-9.7 ± 1.9	-8.7 ± 1.0	-10.6 ± 2.7	-10.5 ± 3.0	-9.1	-10.4 ± 2.2
	40°	-10.9 ± 2.4	-9.9 ± 2.0	-8.8 ± 0.3	-10.2 ± 2.1	-9.7 ± 2.7	-8.0	-10.2 ± 2.3
	60°	-10.5 ± 2.2	-10.0 ± 1.7	-9.4 ± 0.9	-10.2 ± 1.2	-9.8 ± 2.7	-9.5	-10.2 ± 2.0
	80°	-11.6 ± 2.0	-10.6 ± 1.9	-9.3 ± 1.2	-12.0 ± 2.1	-10.7 ± 2.3	-12.3	-11.0 ± 2.0
	100°	-13.1 ± 1.70	-13.4 ± 0.7	-11.6 ± 3.0	-12.0 ± 2.2	-10.9 ± 2.4	-12.7	-12.3 ± 2.0
	120°	-14.4 ± 2.3	-13.2 ± 1.1	-12.3 ± 2.0	-13.2 ± 1.3	-12.1 ± 3.1	-12.8	-13.1 ± 2.2
	Average	-11.1 ± 2.4	-10.4 ± 2.5	-9.6 ± 1.8	-10.9 ± 1.8	-9.9 ± 2.0	-10.5 ± 2.1	-10.5 ± 2.1
	Exc	6.0 ± 3.4	7.2 ± 2.8	5.7 ± 2.8	5.1 ± 1.9	7.4 ± 3.5	4.8	6.3 ± 3.0

Abbreviations. AP = Anterior-Posterior; dMCL = Deep Medial Collateral Ligament; SM = semimembranosus; POL = Posterior Oblique Ligament; sMCL = Superficial Medial Collateral Ligament

5.3.2 Excursion and Satisfaction

The KSS satisfaction score was not associated with medial condyle contact position excursion (beta coefficient = -0.06, 95% CI -0.11 to 0.07, adjusted R^2 -0.02). The KSS satisfaction score was also not associated with lateral condyle contact position excursion (beta coefficient = 0.23, 95% CI -0.25 to 0.21, adjusted, R^2 of 0.03).

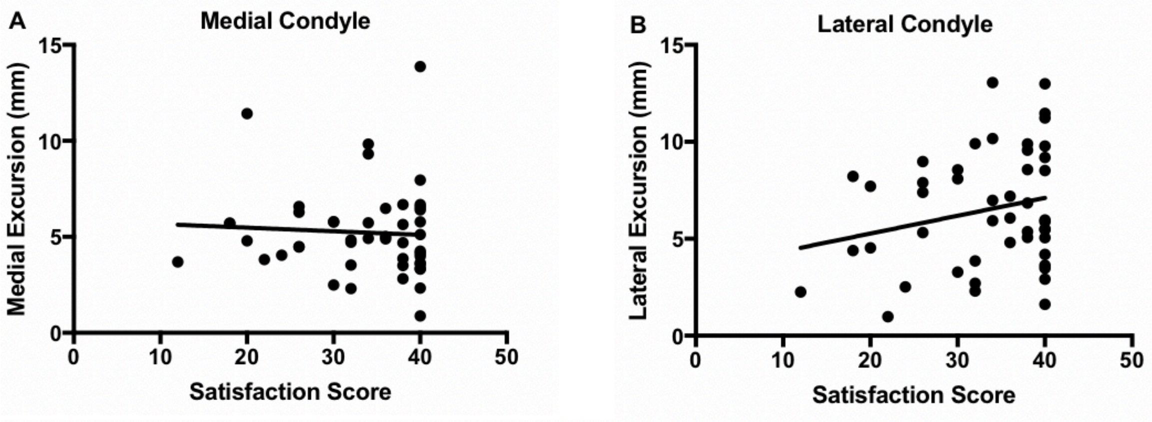

Figure 3: Linear regression of KSS satisfaction score versus medial condyle (A) and lateral condyle (B) contact position excursion from 0° to 120° of knee flexion

5.4 Grouped Analysis One: Two Groups

5.4.1 Demographic Information

The first grouped analysis consisted of two groups: those that received minimal release (group one; n = 31) and those that received more extensive release (group two; n = 20). Demographic characteristics are presented in Table 5. Only preoperative hip-knee-ankle (HKA) was compared using inferential statistics. Preoperative HKA angle was significantly more varus in group two ($p < 0.01$).

Table 5: Baseline participant demographics of grouped analysis 1 (mean ± standard deviation)

Demographic	**Minimal Release (n = 31)**	**Extensive Release (n = 20)**
Sex	21 females, 10 males	6 females, 14 males
Age at Surgery, years	67.9 ± 7.3	69.1 ± 7.5
Height, cm	166.0 ± 8.7	170.3 ± 9.8
Mass, kg	92.6 ± 18.7	94.0 ± 23.0
Body Mass Index, kg/m^2	33.7 ± 6.9	32.3 ± 7.0
Operative limb	20 right, 11 left	8 right, 12 left
Surgical Technique	17 MR, 14 GB	10 MR, 10 GB
Preoperative HKA Angle (°)	-6.7 ± 4.3	-10.5 ± 4.1

Abbreviation. HKA = Hip-Knee-Ankle; MR = Measured Resection; GB = Gap Balancing

*Negative HKA angle indicated varus deformity

5.4.2 Primary Outcome: Tibiofemoral Contact Kinematics

5.4.2.1 Average Contact Positions

Medial and lateral AP positions of group one and group two throughout flexion are presented in Figure 4. On the medial condyle, there were no differences in average AP position at any flexion angle indicating both groups follow the same pattern of contact. Both groups translated posteriorly from 0° to 20°, then anteriorly to 80°, and again posteriorly to 120°. On the lateral condyle, there were no differences in average AP position at all flexion angles, except for 100° where the group with the greater number of releases (group two) was more anterior ($p = 0.02$). The mean difference at this flexion angle was 1.77 mm and the 95% confidence interval was 0.32 mm to 3.22 mm. Both groups translated posteriorly from 0° to 20°, then remained approximately stable until 60° before translating posteriorly to 120°.

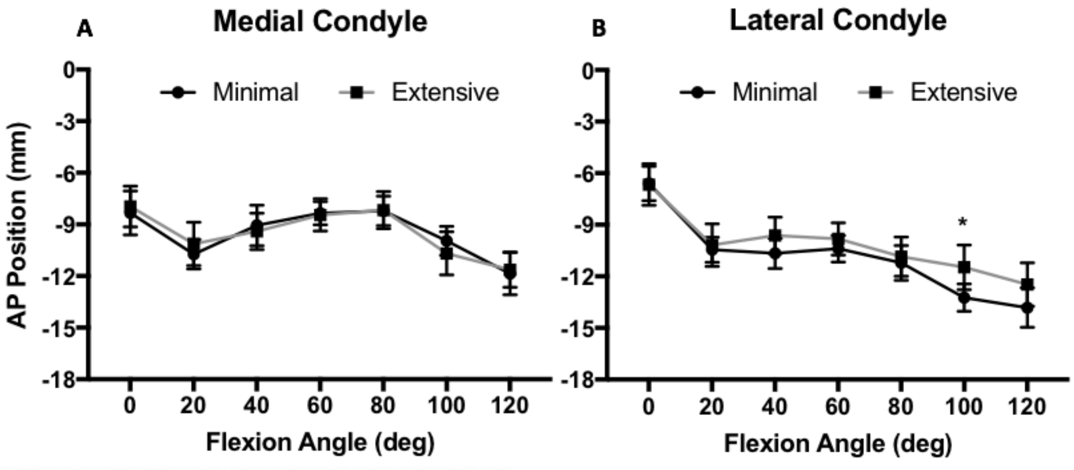

Figure 4: Anterior-posterior (AP) translation (mean ± 95% confidence interval) on the medial condyle (A) and lateral condyle (B) between the minimal release group and extensive release group from 0° to 120° of knee flexion

Both cohorts demonstrated more posterior translation of the contact position on the lateral condyle than the medial condyle (Figure 4 & 5) indicating external rotation and medial pivot. There was no difference (p = 0.43) in external rotation between group one (2.11° ± 2.46°) and group two (1.55° ± 3.34°) from 0° to 20°.

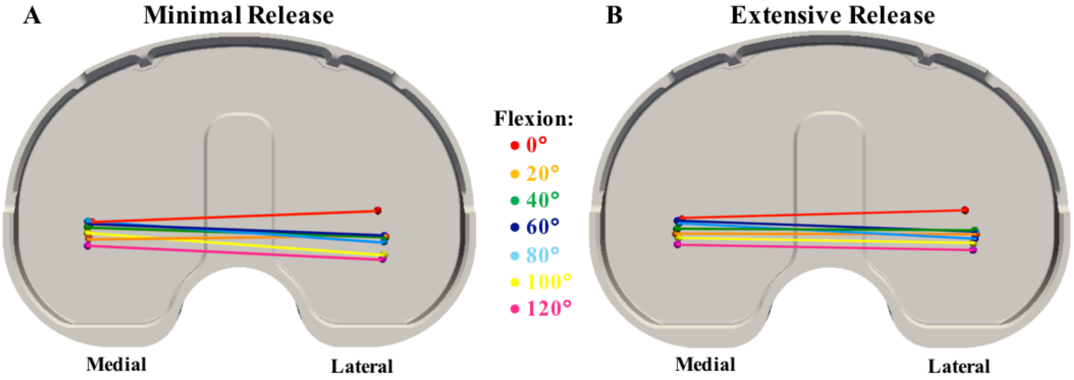

Figure 5: Superior view of a tibial baseplate representing the average medial and lateral contact positions for the minimal release group (A) and the extensive release group (B) from 0° to 120° of knee flexion.

The tibiofemoral contact pattern for the patient that received sMCL release relative to the mean and 95% confidence intervals of the extensive group is shown in Figure 6. On the medial condyle, the sMCL patient demonstrated posterior contact beyond the limits of the confidence intervals at 20°, 60°, 100°, and 120° of flexion. On the lateral condyle, the sMCL patient was posterior to the confidence interval at 0° of flexion, and anterior at 40°.

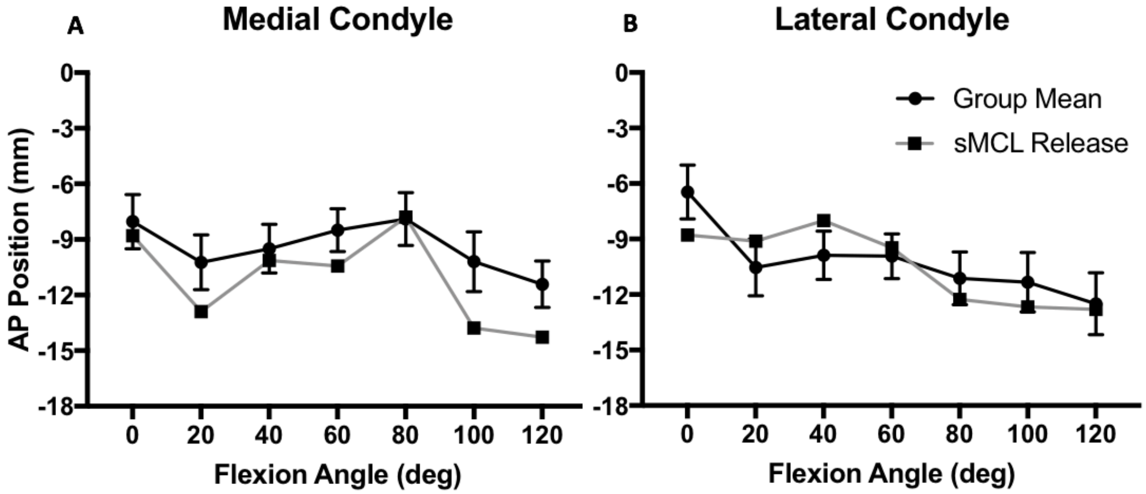

Figure 6: Contact pattern on the medial (A) and lateral (B) condyles for the one patient that received a superficial MCL release. The mean contact pattern for the extensive release group (without sMCL patient included) is presented with upper and lower bounds of their 95% confidence intervals

5.4.2.2 Excursion

Contact position excursion of the medial and lateral condyles of the two groups are presented in Figure 7. Between groups, there was no difference in the average excursion of the contact position on the medial condyles (p = 0.50) or lateral condyles (p=0.97). There was no difference in average excursion between the medial and lateral condyles within group one (p=0.23) or group two (p=0.09).

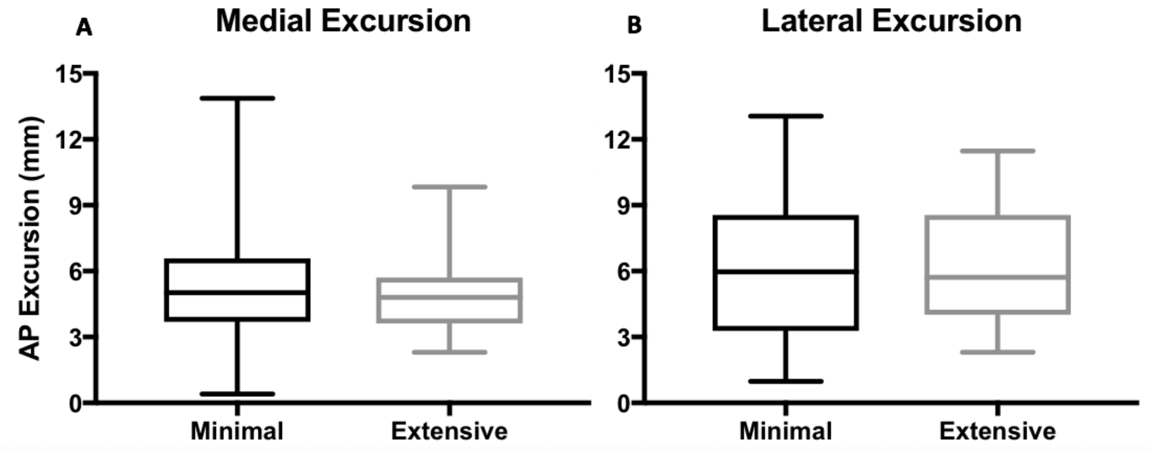

Figure 7: Boxplots of contact position excursion of the medial condyle (A) and the lateral condyle (B) between the minimal release group and extensive release group from 0° to 120° of knee flexion

5.4.3 Secondary Outcome: Patient-Reported Outcomes

Minimal and extensive release groups significantly improved in all patient-reported outcomes preoperatively to postoperatively (p<0.001), except in SF-12 MCS (minimal group p=0.42; extensive group p=0.71).There were no differences between groups in the SF-12, WOMAC, or KSS outcome scores, preoperatively or postoperatively (Table 6).

Table 6: Patient-reported outcome scores (mean ± standard error)

Time	Outcome Measure	Minimal	Extensive	p-value
Preop	SF-12			
	PCS	30.4 ± 2.0	31.8 ± 2.2	0.80
	MCS	57.2 ± 2.7	56.2 ± 3.1	0.94
Postop	SF-12			
	PCS	37.7 ± 1.9	46.1 ± 1.7	0.13
	MCS	48.6 ± 2.2	56.4 ± 2.3	0.45
Preop	WOMAC			
	Pain	46.5 ± 2.8	49.4 ± 3.4	0.46
	Stiffness	43.6 ± 3.8	40.5 ± 3.6	0.57
	Function	48.3 ± 2.9	46.0 ± 3.7	0.81
	Total	48.1 ± 2.7	48.0 ± 3.5	0.76
Postop	WOMAC			
	Pain	84.0 ± 3.0	87.4 ± 2.3	0.68
	Stiffness	78.5 ± 3.8	72.4 ± 4.1	0.19
	Function	82.0 ± 2.6	82.0 ± 2.6	0.66
	Total	83.4 ± 2.7	85.2 ± 2.6	0.98
Preop	KSS			
	Symptoms	08.4 ± 1.1	09.0 ± 1.2	0.66
	Satisfaction	14.3 ± 1.5	14.7 ± 1.4	0.61
	Expectations	14.0 ± 0.3	13.8 ± 0.4	0.67
	Function	34.9 ± 3.5	40.0 ± 3.8	0.18
	Total	71.5 ± 5.3	77.4 ± 5.6	0.34
Postop	KSS			
	Symptoms	20.6 ± 0.9	21.5 ± 0.8	0.75
	Satisfaction	32.0 ± 1.7	35.2 ± 1.1	0.60
	Expectations	09.3 ± 0.7	10.7 ± 0.6	0.11
	Function	72.0 ± 3.3	76.7 ± 3.1	0.39
	Total	133.1 ± 6.2	144.0 ± 4.9	0.36

Abbreviations. SF = Short Form; PCS = Physical Component Score; MCS = Mental Component Score; WOMAC = Western Ontario McMaster Osteoarthritis Index; KSS = Knee Society Score

5.5 Grouped Analysis Two: Three Groups

5.5.1 Demographic Information

The second analysis consisted of three groups; those patients with mild soft tissue balancing (Group one; n = 24), moderate soft tissue balancing (group two; n = 16), and extensive soft tissue balancing (group three; n = 11). Demographic characteristics are given in Table 7. Only preoperative hip-knee-ankle (HKA) angles were compared using inferential statistics. Preoperative hip-knee-ankle angle was not significantly different between group one and group two ($p = 0.29$), but was significantly different between groups one and three ($p < 0.001$) and groups two and three ($p = 0.01$).

Table 7: Baseline participant demographics of grouped analysis 2 (mean ± standard deviation)

Demographic	Mild (n = 24)	Moderate (n = 16)	Extensive (n = 11)
Sex	17 females, 7 males	8 females, 8 males	2 females, 9 males
Age at Surgery, years	68.1 ± 7.3	67.5 ± 7.6	69.7 ± 7.5
Height, cm	166.5± 8.5	166.5 ± 9.1	171.7 ± 10.9
Mass, kg	90.8 ± 18.9	95.0 ± 22.3	94.0 ± 21.8
Body Mass Index, kg/m^2	32.9 ± 6.9	34.3 ± 7.8	31.6 ± 5.4
Operative limb	16 right, 8 left	8 right, 8 left	4 right, 7 left
Surgical Technique	11 MR, 13 GB	13 MR, 3 GB	3 MR, 8 GB
Preoperative HKA Angle* (°)	-6.2 ± 4.4	-8.2 ± 3.3	-12.7 ± 3.6

Abbreviation. HKA = Hip-Knee-Ankle; MR = Measured Resection; GB = Gap Balancing

*Negative HKA angle indicated varus deformity

5.5.2 Primary Outcome: Tibiofemoral Contact Kinematics

5.5.2.1 Average Contact Positions

Medial and lateral AP positions of group one, two, and three throughout flexion are presented in Figure 8. The pattern of contact for all groups was similar; there were no significant differences between average AP contact positions between groups at any flexion angle.

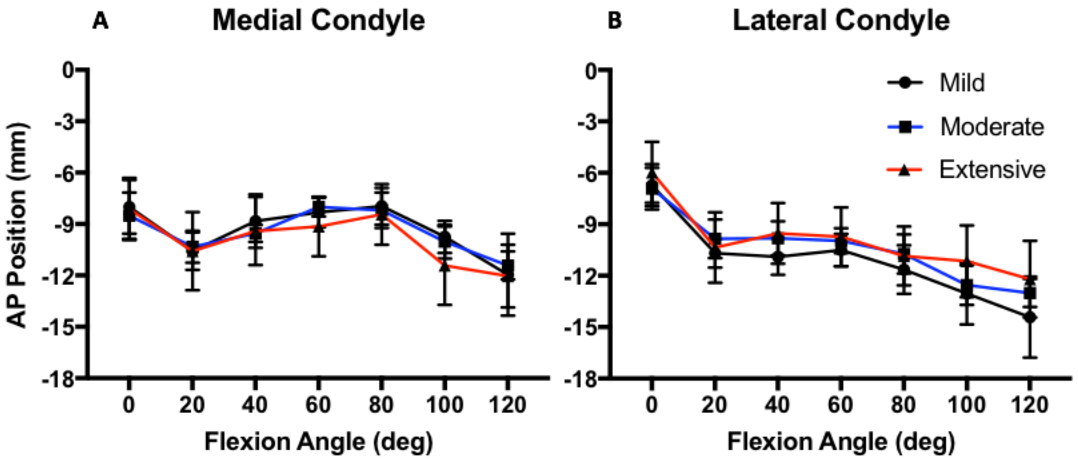

Figure 8: Anterior-posterior (AP) translation (mean ± 95% confidence interval) on the medial condyle (A) and lateral condyle (B) between the mild, moderate, and extensive release groups from 0° to 120° of knee flexion

All groups demonstrated more posterior translation of the contact position on the lateral condyle than the medial condyle (Figure 8 & 9) indicating external rotation and medial pivot. There was no difference (p = 0.76) in external rotation between group one (2.04° ± 2.40°), group two (1.47° ± 2.48°) and group three (2.24° ± 4.16°) from 0° to 20°.

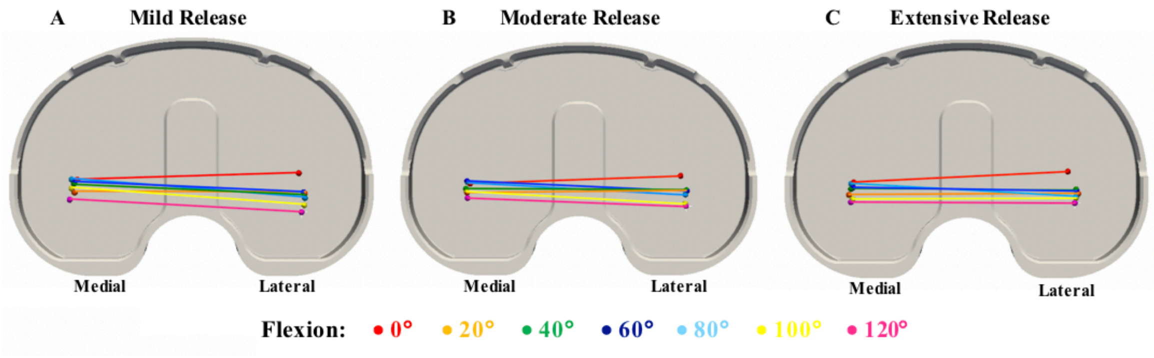

Figure 9: Superior view of a tibial baseplate representing the average medial and lateral contact positions for the mild (A), moderate (B), and extensive (C) release groups from 0° to 120° of knee flexion.

5.5.2.2 Excursion

Contact position excursion of the medial and lateral condyles of the three groups are presented in Figure 10. Between groups, there was no difference in the average excursion of the contact position on the medial condyles (p = 0.85) or lateral condyles (p = 0.55). There was no difference in average excursion between the medial and lateral condyles within group one (p = 0.60), group two (p = 0.08), or group three (p = 0.06).

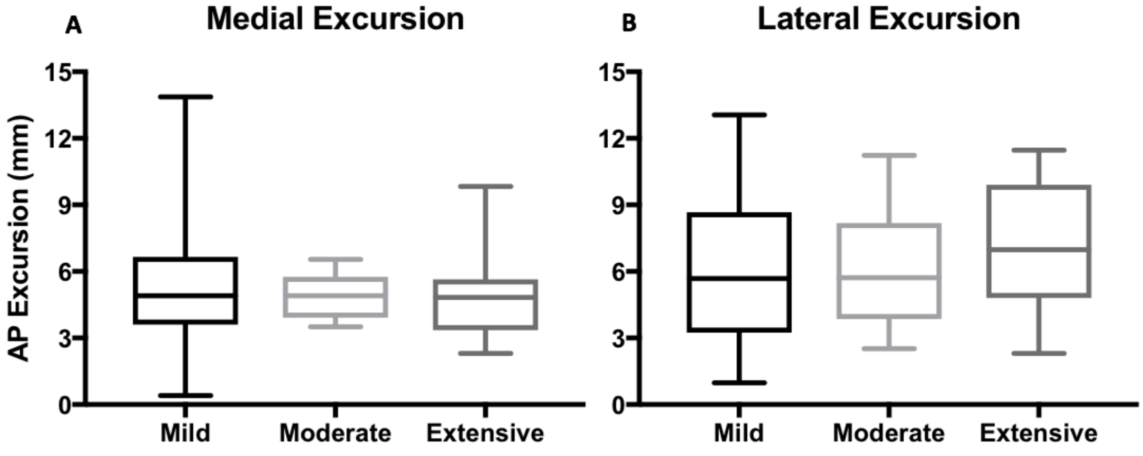

Figure 10: Average contact position excursion of the medial condyle (A) and the lateral condyle (B) between mild, moderate, and extensive release groups from 0° to 120° of knee flexion

5.5.3 Secondary Outcome: Patient-Reported Outcomes

Minimal, moderate, and extensive release groups significantly improved in all patient-reported outcomes preoperatively to postoperatively ($p<0.001$), except in SF-12 MCS (minimal group $p=0.67$; moderate group $p=0.37$; extensive group $p=0.37$). There were no differences between groups in the SF-12, WOMAC, or KSS outcome scores, preoperatively or postoperatively (Table 8).

Table 8: Patient-reported outcome scores (mean ± standard error)

Time	Outcome Measure	Mild	Moderate	Extensive	p-value
Preop	SF-12				
	PCS	32.3 ± 2.3	29.0 ± 2.5	31.9 ± 2.5	0.56
	MCS	57.8 ± 3.2	57.0 ± 3.2	54.9 ± 4.6	0.99
Postop	SF-12				
	PCS	43.2 ± 2.2	42.2 ± 2.5	45.6 ± 2.3	0.66
	MCS	52.1 ± 2.7	54.6 ± 2.9	58.9 ± 2.3	0.27
Preop	WOMAC				
	Pain	49.2 ± 3.3	44.6 ± 4.1	50.1 ± 3.4	0.54
	Stiffness	47.8 ± 4.2	38.8 ± 4.2	38.6 ± 5.3	0.25
	Function	52.0 ± 3.4	43.1 ± 4.0	46.0 ± 4.4	0.23
	Total	51.2 ± 3.2	44.8 ± 3.9	48.1 ± 4.2	0.45
Postop	WOMAC				
	Pain	85.9 ± 3.3	81.9 ± 4.0	89.3 ± 1.8	0.72
	Stiffness	80.0 ± 4.7	74.1 ± 3.8	71.0 ± 6.3	0.43
	Function	83.5 ± 3.1	80.8 ± 3.2	80.9 ± 3.5	0.79
	Total	84.6 ± 3.2	83.0 ± 3.4	85.1 ± 3.2	0.91
Preop	KSS				
	Symptoms	08.8 ± 1.2	08.1 ± 1.5	09.3 ± 1.5	0.85
	Satisfaction	15.0 ± 1.8	13.5 ± 1.7	15.0 ± 2.0	0.84
	Expectations	14.1 ± 0.4	13.9 ± 0.5	13.5 ± 0.3	0.14
	Function	34.3 ± 3.9	38.9 ± 5.1	38.9 ± 4.0	0.70
	Total	72.3 ± 5.7	74.4 ± 7.4	76.7 ± 7.1	0.91
Postop	KSS				
	Symptoms	21.0 ± 0.9	20.3 ± 1.3	21.8 ± 0.7	0.97
	Satisfaction	32.5 ± 2.1	32.9 ± 1.9	35.6 ± 0.9	0.52
	Expectations	08.9 ± 0.7	11.3 ± 0.8	09.7 ± 0.7	0.09
	Function	74.0 ± 3.8	71.8 ± 4.3	77.1 ± 3.7	0.70
	Total	135.4 ± 7.2	136.2 ± 7.7	144.3 ± 5.1	0.89

Abbreviations. SF = Short Form; PCS = Physical Component Score; MCS = Mental Component Score; WOMAC = Western Ontario McMaster Osteoarthritis Index; KSS = Knee Society Score

Chapter 6

6 Discussion

Although soft tissue balancing is universally recognized as a crucial component of primary TKA success, little data has been reported on the postoperative outcomes of patients that required different amounts of medial soft tissue release. In this study, we compared the *in vivo* tibiofemoral contact kinematics of a posterior-stabilized TKA during a deep knee bend in patients that ranged in the amount of soft tissue balancing they received intraoperatively as a result of a preoperative varus alignment deformity. We hypothesized that when compared to minimal soft tissue balancing, increased release of the active and passive stabilizing structures of the medial knee would produce more medial laxity, and therefore cause a corresponding change in contact position and contact position excursion throughout 0° to 120° of flexion. The most important findings from this study were that we found no statistically significant differences between groups in average contact position of the medial condyle at any flexion angle and no differences in AP excursion on the medial or lateral condyles throughout flexion. These results indicate that despite some individuals requiring extensive medial soft tissue release, contact kinematics are similar to those individuals requiring little medial soft tissue release.

Appropriate soft tissue balancing to produce rectangular gaps in flexion and extension is an essential aspect of TKA to ensure proper knee kinematics and stability. A study by Griffin *et al.* measured the medial and lateral gap height differences in flexion and extension after soft tissue balancing to determine surgeons' accuracy in 104 knees. They determined achieving perfect balance is difficult, but a rectangular gap was obtained within 1 mm in 84% to 89% of knees[16]. Improper soft-tissue balancing has been associated with several adverse outcomes including increases in radiolucent lines[52], instability[51], and an increased severity of wear found at revision[53]. All knees of the present study were considered to be appropriately balanced and stable after a stepwise medial release.

In both grouped analyses, we found no differences in average medial condyle contact position at any flexion angle. It is likely that we found little difference in contact position between groups because a primary surgical objective was to achieve approximately rectangular flexion and extension gaps across the entire range of this cohort's varus deformities. The ligament release is certainly an important aspect of soft tissue balancing, however, contact positions may also have been influenced by other techniques that can aid in ligament balance. Femoral component sizing, positioning, and rotation are all important considerations of soft tissue balancing as each of these factors can influence the flexion and extension gaps[9].

On the lateral condyle, the only difference we observed was between those with minimal and extensive soft tissue release at 100° of flexion. Here, those patients with soft tissue release were more anterior than those without (mean difference = 1.77 mm, 95% CI 0.32 – 3.22, $p = 0.02$). This difference may be explained by the larger preoperative varus deformity of the soft tissue release group. In an observational study, Bellemens *et al.* performed measured intraoperative varus-valgus stress testing of 35 consecutive TKA patients with preoperative varus deformities. They found the medial collateral structures are intrinsically shortened and the lateral soft tissues are stretched when patients' preoperative varus deformity is approximately 10° or greater[40]. In the present study, the group that underwent soft tissue release had an average preoperative varus deformity of 10.5° ± 4.1°, whereas those without soft tissue release had a preoperative varus deformity of 6.7° ± 4.3° ($p < 0.01$). Those with soft tissue release likely experienced more lateral laxity than those who did not. This residual lateral structure laxity found in patients with severe preoperative varus deformities may have contributed to the difference in contact position at 100° between groups, rather than the increased medial soft tissue release. Had this difference been on the medial condyle as we expected, it may have been attributed to the increased medial release patients with large varus deformities often require.

The superficial medial collateral ligament (MCL) is a very important structure for controlling medial laxity after TKA. Recently, Athwal *et al.* tested eight non-arthritic intact fresh-frozen knees in a robotic simulator, administering AP forces, varus-valgus torques, and internal-external rotational torques at multiple flexion angles. Half of these knees were then implanted with cruciate-retaining TKA and the other half were implanted with posterior-stabilized TKA and the testing protocol was repeated. They found the superficial MCL was the primary medial restraint to anterior translation, valgus torque, and both internal and external rotation in the intact knee, and in the cruciate-retaining and posterior-stabilized knee implants[69]. Given the importance of the superficial MCL for stability following TKA, the authors of the present study avoid superficial MCL release if possible. Only one patient of the eligible 74 had their superficial MCL released. While only one patient is not representative of a population of patients, this patient did exhibit dramatic posterior translation of the medial condyle compared to the group average. Increasing the number of patients in this group would provide valuable *in vivo* data to support the superficial MCL's importance for postoperative medial stability.

To preserve the integrity of the superficial MCL while still achieving coronal plane mechanical alignment, authors of this study utilize the medial tibial reduction osteotomy (MTRO) technique. During MTRO, the proximal medial tibial is shaved away, shortening the distance superficial structures (such as the superficial MCL) must travel. Two studies have compared the use of MTRO with other medial balancing techniques. First, Ahn and Back compared their standard medial release progression (n=20) with bony resection of the proximal medial tibia (n=20) in patients with ≥10° anatomical varus deformity. They assessed total operation time, tibiofemoral medial-lateral gap ratios at 0°, 90°, and 130°, and Hospital for Special Surgery scores. They found the bony resection group to have significantly shorter operating room times (mean difference 19.3 minutes) and a significantly smaller tibiofemoral medial-lateral gap ratio at 130° (mean difference 0.12). At 6-months, there were no differences between groups for range of motion or HSS scores, aligning with the patient-reported findings of our study[70]. The second study was a retrospective study by Martin *et al.* that compared 67 MTRO patients and 67 matched controls that did not require an MTRO. They found the MTRO group had significantly better postoperative KSS scores and produced similar corrections to coronal alignment as the control group[9]. However, medial tibia bone resorption was seen in 64% of the MTRO group. In both of these studies, the sequence of medial release was described for the control groups, but the frequency of the releases actually performed intraoperatively was not.

These studies suggest MTRO is an acceptable alternative to superficial MCL release when balancing severely varus patients. A concern of this technique is the required lateralization and downsizing of the tibial component to allow space for the medial osteotomy, which may alter kinematics and present problems if revision surgery is needed. The group of patients that received MTRO in the present study demonstrated similar tibiofemoral contact kinematics to cohort averages and to groups of patients that required minimal releases. Our results support the use of MTRO as a promising technique for patients undergoing TKA with large preoperative varus deformities.

Anterior-posterior excursion was not different on the medial or lateral condyles in any of our analyses. AP excursion has been investigated by Johnson *et al.* in laboratory gait cycle simulation study to determine its contribution to polyethylene wear. They found that with force and rotation inputs retained, reducing AP translation input by 50% reduced the polyethylene wear rate from 17.0 mg per million cycles to 10.6 mg per million cycles. When AP translation input was eliminated, wear rate was further reduced to 1.7 mg per million cycles[72]. While the results of this wear simulation and *in vivo* contact kinematics do not directly translate, we could theoretically expect all groups of the present study to have similar wear rates if only considering AP excursion. However, wear is influenced by many factors in addition to AP excursion including activity level and joint loading[58].

Among the entire cohort, we found no association between medial or lateral condyle excursion and the KSS satisfaction score. Many patients indicated complete satisfaction which produced a ceiling effect for this outcome score. Further exploration of the interactions between contact kinematics and metrics of patient satisfaction should be considered.

Consistent with our expectations, the preoperative varus deformity was larger in the groups that required more extensive soft tissue balancing. All patient-reported outcome scores improved preoperatively to postoperatively, except for the SF-12 MCS, which was expected because this is a generic measure of mental health. A large multicentre prospective study by Unitt *et al.* examined clinical outcome score differences in patients that received none or minimal (n=173), moderate (n=122), and extensive (n=115) amounts of soft tissue balancing during primary TKA. Across multiple outcome measures, they found the extensive release group had significantly greater preoperative to postoperative change scores than the other groups but had similar postoperative outcomes at 12-months[54]. Finding no differences in postoperative patient-reported outcomes is consistent with our findings. The study by Unitt et al included participants with neutral, valgus, and varus alignment, and therefore studied both medial and lateral balancing. There were also differences in the sequence of tissues released making their results not directly transferable to the present study.

The evidence surrounding soft tissue balancing in primary TKA has been primarily limited to cadaveric and clinical intraoperative studies, and the few studies assessing postoperative outcomes have focused mainly on outcomes of stability assessments and alignment. A challenge lies in the variability of release sequences used between institutions. In a recent literature review on medial release methods in TKA by Hunt *et al.,* approximately 20 unique sequences have been published describing the management of medial soft tissue in primary TKA[18]. The variability seen is likely due to differences in surgical training and the lack of evidence surrounding this topic. There is little consensus as to the how to best perform medial soft tissue balancing which makes finding comparable literature difficult. For this reason, the results of this study may not be directly applicable to institutions that perform a medial release sequence different from our institution.

The results of the present study represent a single-radius, posterior-stabilized TKA design. In posterior-stabilized TKA designs, the role of the posterior cruciate ligament (PCL) is fulfilled by a cam-post interaction that occurs between the femoral and tibial components. This interaction has been found to begin at approximately 82° ± 16° of flexion in the PS Triathlon implant, which drives posterior femoral rollback in deep flexion[64]. This posterior translation of the contact position was seen in our results, however, the exact flexion angle of post-cam engagement in the present study is unknown as images were taken in 20° increments. In cruciate-retaining implant designs, the PCL is intact, and its tension contributes to the height of the flexion gap. The PCL often requires release in addition to the medial soft tissue structures and therefore the interpretation of the results of the present study should not be extended to cruciate-retaining implant designs.

6.1 Limitations

There were several limitations of the present study. One limitation was the small sample size. While this study meets or exceeds the sample size of other *in vivo* studies of tibiofemoral contact kinematics, release groups including the posterior capsule, the semimembranosus and posterior oblique ligament, and superficial medial collateral ligament had few participants. Filling these groups would allow for detailed analyses of the individual release types rather than resorting to grouped analysis as in the present study. The number of patients available to be recruited decreases as the number of releases required increases that made filling specific groups difficult. The small sample size may have limited our ability to detect differences in tibiofemoral contact positions. However, 95% confidence intervals surrounding AP positions were narrow, extending approximately 1-2 mm around the means. This indicates reasonable precision was achieved for our primary outcome even with this small sample. Additionally, a threshold for differences in contact position becoming clinically relevant has not been established. We were certainly underpowered to detect differences in patient-reported outcomes.

A second limitation was that a selection bias may have been present as a result of the physical demand of the imaging protocol. Patients without pain or physical limitations may have been more likely to participate in this study, which may have influenced our results. A less physically demanding protocol may be necessary to capture patients that are less functional following TKA.

Another limitation was that kinematic data was collected using a quasi-static technique instead of a continuous dynamic technique. The quasi-static technique was used because our RSA imaging system cannot acquire continuous images. However, compared to an imaging system that can acquire continuous images, our method produces higher accuracy of implant position. Saevarsson *et al.* collected weight-bearing contact kinematics of ten subjects using both static and dynamic techniques to investigate if differences exist between the image acquisition techniques. They found that static and dynamic kinematics were comparable for all patients except one patient that demonstrated a difference of 5-8° in internal/external rotation[73]. The kinematic patterns of the present study were consistent with other studies of the same implant design indicating our image acquisition technique was acceptable.

Finally, the time between surgery and imaging for this study was not standardized, because our group of eligible patients ranged from one to approximately three years postoperative at the time of recruitment. Patients at different time-points in their recovery may differ in muscle strength and activation, which may influence patient-reported outcome scores and possibly our kinematic data.

Chapter 7

7 Conclusion

Contact kinematics and clinical outcome scores were largely unaffected by greater levels of medial soft tissue release. This suggests that correcting severely varus patients to mechanically neutral coronal alignment does not compromise tibiofemoral contact kinematics or patient-reported satisfaction.

7.1 Future Directions

In the future, attaining a sufficient sample of patients in each individual release type would allow for a more robust analysis. The present study did not find differences between releases when grouped, however differences between individual release types may exist. Comparison of the medial tibial reduction osteotomy group with the superficial medial collateral release group would be of particular interest.

A follow-up study of similar design but using a true dynamic imaging system to capture tibiofemoral contact kinematics in more challenging dynamic movements such as stair climbing or walking with perturbations may be useful. The higher impact activities would not allow participants the same control as they had in our quasi-static protocol which may expose specific instabilities within release groups.

Future studies in this area should aim to compare contact kinematics of patients with different amounts of soft tissue release in a cruciate-retaining implant design as the present study is not generalizable beyond single-radius, posterior-stabilized TKA designs.

Finally, a lack of consensus remains surrounding the best sequence of medial soft tissue balancing. Future work should focus on building a base of comparable literature on a specific sequence of medial soft tissue releases and to compare existing release sequences for superiority.

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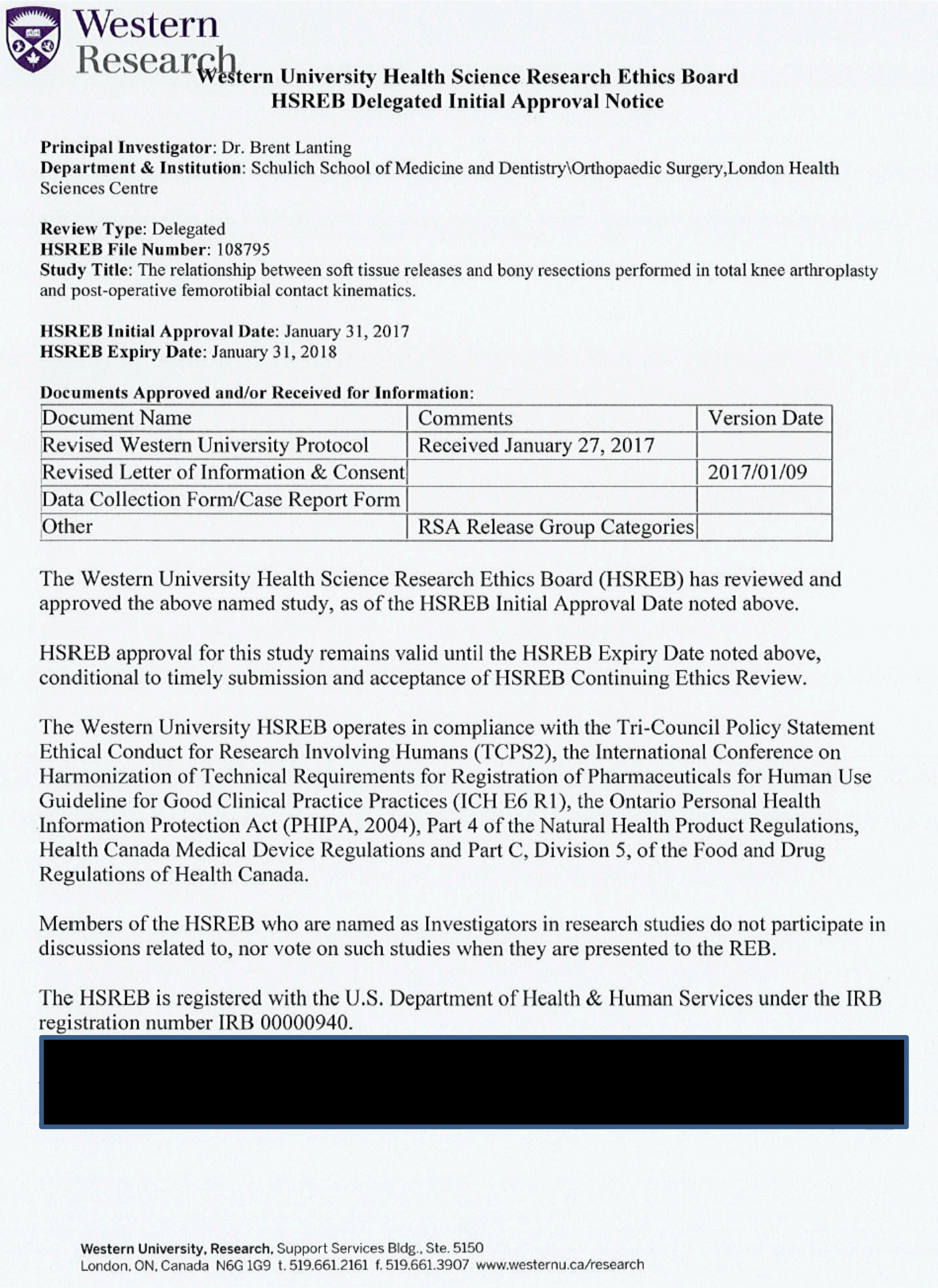
Appendices

Appendix A: Ethics Approval



Western Research

Western University Health Science Research Ethics Board
HSREB Delegated Initial Approval Notice

Principal Investigator: Dr. Brent Lanting
Department & Institution: Schulich School of Medicine and Dentistry\Orthopaedic Surgery,London Health Sciences Centre

Review Type: Delegated
HSREB File Number: 108795
Study Title: The relationship between soft tissue releases and bony resections performed in total knee arthroplasty and post-operative femorotibial contact kinematics.

HSREB Initial Approval Date: January 31, 2017
HSREB Expiry Date: January 31, 2018

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Revised Western University Protocol	Received January 27, 2017	
Revised Letter of Information & Consent		2017/01/09
Data Collection Form/Case Report Form		
Other	RSA Release Group Categories	

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

[redacted]

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EDUCATION

Master of Science (Candidate)

Integrative Biosciences in Kinesiology
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September 2016 - Present

Bachelor of Arts

Honors Specialization in Kinesiology
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REASEARCH EXPERIENCE

Western University
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Thesis Project
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University Hospital
Under the supervision of Dr. Dianne Bryant, Dr. Matthew Teeter and Dr. Brent Lanting.

A prospective cohort study investigating the relationship between soft tissue releases and bony resections performed during total knee arthroplasty and post-operative femorotibial contact kinematics.

Western University
London, ON
Student Research Assistant
Sept. 2016 - Present

University Hospital
Under the supervision the orthopedic research team: Drs. Somerville, Lanting, Howard, Vasarhelyi, and MacDonald.

A prospective cohort study investigating the relationship between soft tissue releases and bony resections performed during total knee arthroplasty and post-operative patient pain and satisfaction.

CONFERENCES

Victoria, BC
Poster
June, 2018

Canadian Orthopaedic Association
Contributed a poster outlining work regarding the influence of posterior femoral offset on tibiofemoral contact kinematics in total knee arthroplasty.

Liverpool, UK
Poster
April, 2018

Osteoarthritis Research Society International
Contributed a poster outlining thesis work regarding the the influence of soft tissue balancing on tibiofemoral contact kinematics in total knee arthroplasty.

London, ON
Presentation
May, 2017

Kinesiology Graduate Research Symposium
Presented thesis work regarding the influence of soft tissue balancing on tibiofemoral contact kinematics in total knee arthroplasty.

London, ON
Presentation
Feb, 2017

Health and Rehab Sci Graduate Research Conference
Presented thesis work regarding the influence of soft tissue releases on tibiofemoral contact kinematics in TKA.

TEACHING EXPERIENCE

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AWARDS AND CERTIFICATIONS

Kinesiology Travel Award	2016-2017
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Ontario Graduate Scholarship	2016-2017
The Western Scholarship of Excellence	2012