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The Association Between Soft Tissue Releases and Bony Resections Performed During Total Knee Arthroplasty and Patients' Pain and Satisfaction Postoperatively

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A thesis submitted in partial fulfillment of the requirements for the degree in Master of Science

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THE ASSOCIATION BETWEEN SOFT TISSUE RELEASES AND BONY
RESECTIONS PERFORMED DURING TOTAL KNEE ARTHROPLASTY AND
PATIENTS' PAIN AND SATISFACTION POSTOPERATIVELY

(Thesis format: Monograph)

by

Matthew Carter

Graduate Program in Kinesiology

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science

The School of Graduate and Postdoctoral Studies
The University of Western Ontario
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Abstract

Total knee arthroplasty (TKA) is a surgical treatment for degenerative knee conditions such as osteoarthritis to reduce pain and increase function. Intraoperative soft tissue releases (STRs) and bony resections (BRs) are necessary for a balanced and aligned TKA. It is possible that the degree of STRs and BRs is related to final outcome following TKA and thus there may be implications for patient rehabilitation, patient expectations, pain medications, and timelines for recovery. Thus, our primary objective was to examine the association between the number of STRs and BRs performed intraoperatively and patients' satisfaction and pain at three months. We performed an interim analysis on 100 patients who had undergone a TKA. Using multiple regression models, we showed no association between degree of releases and satisfaction or pain. These results were limited by sample size such that we are unable to make definitive conclusions about the relationship between STRs and BRs and outcome following TKA.

Keywords

Osteoarthritis, total knee arthroplasty, total knee replacement, soft tissue, soft tissue release, bony resection, pain, satisfaction.

Co-Authorship Statement

With the assistance of Drs. Bryant, Somerville, Lanting, Howard, Vasarhelyi, and MacDonald, I designed a prospective cohort study. We collaborated in the selection and creation of the patient questionnaires and operative recording form, respectively, while I was solely responsible for identifying and recruiting patients; identifying issues, problem solving, and implementing solutions. I wrote the original draft of the manuscript while Dr. Bryant and Dr. Somerville made suggestions and comments that contributed to this thesis document. The thesis was sent to the other committee members for their comments and suggestions toward the final submission.

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Acronyms

BMI- Body mass index

CI- Confidence interval

CR- Cruciate retaining

DMCL- Deep medial collateral ligament

HRQOL- Health related quality of life

KL- Kellgren Lawrence

KSS- Knee society score

MGT- Medial gastrocnemius tendon

MPFL- Medial patellofemoral ligament

NPRS- Numeric pain rating scale

OA- Osteoarthritis

OPL- Oblique popliteal ligament

PCL- Posterior cruciate ligament

POL- Posterior oblique ligament

PS- PCL sacrificing

ROM- Range of motion

SD- Standard deviation

SE- Standard error

SF-12- Short form 12 survey

SM- Semimembranosus

SMCL- Superficial medial collateral ligament

STRs- Soft tissue releases

TKA-Total knee arthroplasty

VMO- Vastus medialis obliquus

WOMAC- Western Ontario and McMaster Universities Osteoarthritis Index

Chapter 1

1 Introduction

Osteoarthritis (OA) is the most common joint disorder and occurs in one in ten people in Canada¹. End stage OA develops a number of ways, but is more commonly seen as a result of ‘wear and tear’, or primary OA². Regardless of how it is developed, OA presents as a painful and debilitating disease that can lead to severely reduced quality of life^{3,4}. Lower limb alignment may be a contributor to the development of knee OA. People that have varus alignment, or are ‘bow-legged’, are prone to increased progression of OA because varus alignment causes an increased load on the medial compartment of the knee joint⁵. Currently there is no cure for OA, but there are several treatment options available to help improve quality of life.

The gold standard treatment for knee OA is a total knee arthroplasty (TKA)^{6,7}. A TKA involves removing the damaged articular surfaces and replacing them with a tibial and femoral component. These implants work together as a new weight bearing surface for the knee. In some cases, the patella is also replaced or resurfaced. The implants replace the arthritic natural articular surfaces with an artificial articular surface, which alleviates pain and improves functionality of the knee.

During a TKA, several surrounding soft tissues, such as ligaments and tendons, are cut, or released, to achieve a balanced knee⁸⁻¹³. The standard of care for a TKA involves correcting lower limb alignment to neutral ($+3^{\circ}$ to -3° in the coronal plane), while balancing the knee by keeping the space between the femur and tibia, in the medial and lateral compartments, equal^{6,14,15}. The number of releases varies for each individual and is primarily based on their preoperative alignment.

Post-surgery quality of life, pain, function and satisfaction are important considerations when evaluating the outcome of TKA^{7,16-19}. The literature suggests that about 20% of patients who have undergone TKA are dissatisfied at one year post-surgery²⁰⁻²⁴. It is unclear whether the intraoperative procedures to correct alignment influence these patient important postoperative outcomes.

Currently there are no published studies evaluating the relationship between patient-important outcomes following TKA and the extent of soft tissue release or bony resection. Thus the purpose of our study was to evaluate the relationship between soft tissue releases and bony resections performed during a TKA to achieve neutral lower limb alignment and the patients' pain and satisfaction up to one year. Further, if the extent of soft tissue release and bony resection is associated with outcome following TKA, then there are implications for patient rehabilitation, patient expectations, pain medications, and timelines for recovery. Depending on the strength of the association, there may also be implications for research and whether or not future studies should stratify or adjust the analyses of outcomes for this factor.

Chapter 2

2 Literature Review

2.1 Osteoarthritis

Osteoarthritis (OA) is a chronic degenerative disease, and is the most common form of arthritis. OA can affect any joint within the body, although it is commonly observed in the knees, hips, and hands^{1,4,25}. OA progresses gradually and worsens over time. There is currently no cure for OA, but treatments exist that slow the progression and improve quality of life with the disease²⁵.

OA is painful and is characterized by structural changes to the joint, such as loss of cartilage, meniscal damage, osteophyte formation, and inflammation^{1,3-5}. In the knee, OA can present both unilaterally and bilaterally⁴. Symptoms of OA include stiffness, decreased range of motion (ROM), tenderness, and pain. People experiencing OA of the knee will also complain of functional limitations such as symptomatic squatting, kneeling, and climbing stairs^{3,4}.

Osteoarthritis can be classified into two different groups: primary or secondary². These two classes share similar characteristics, however the cause of the arthritis is what differentiates them. Primary OA is associated with aging and is more commonly diagnosed than secondary. It is sometimes referred to as “wear and tear” OA. Secondary OA originates from a specific cause such as injury, obesity, or other diseases².

There are three distinct areas where OA presents in the knee: medial tibiofemoral, lateral tibiofemoral, and patellofemoral compartments. Medial tibiofemoral OA is most commonly diagnosed and may be associated with varus alignment⁵. Varus, or bow-legged, alignment is determined by drawing a line from the centre of the femoral head (hip) to the centre of the talus (ankle) to determine the load bearing axis²⁶. Varus alignment is diagnosed when the load bearing axis lies medial to the knee. This alignment results in increased load on the medial tibiofemoral compartment which causes accelerated progression of OA⁵. Valgus, or knock-kneed, alignment is the opposite of

varus. This occurs when the weight bearing axis lies lateral to the knee, which can cause issues in the lateral tibiofemoral compartment^{5,26}.

2.1.1 Diagnosis

Diagnosis of OA is primarily accomplished by diagnostic imaging. Although a variety of imaging techniques (e.g. magnetic resonance imaging, ultrasound) can be used to diagnose OA, radiographic imaging (x-ray) is utilized most often due to its low cost and ease of use^{25,27}.

OA is radiographically defined by the presence of osteophytes within the joint, but the degree of joint space narrowing is most commonly used to assess the severity of OA^{4,27}. Osteophytes are bony protrusions, also known as bone spurs, which occur in degenerative joints²⁸. These osteophytes are a reparative response to the destruction of cartilage within the joint. Cartilage does not appear on x-rays, but the amount of cartilage in the joint is represented by the space between the bones, or joint space width^{4,25,27}. The Kellgren and Lawrence (KL) grading system is used to assess and define radiographic findings for the severity of OA based on the presence of osteophytes and joint space narrowing. The KL system grades include: Grade 0 (no evidence) – no osteophyte formation or joint space narrowing; Grade 1 (doubtful) – minimal osteophytes, possible joint space narrowing; Grade 2 (minimal) – definite osteophytes, possible joint space narrowing; Grade 3 (moderate) – multiple and larger osteophytes, moderate diminution of joint space; Grade 4 (severe) – large osteophyte formation, joint space greatly impaired with sclerosis of subchondral bone²⁹.

Clinical evaluation coupled with radiographic assessment is useful for making the diagnosis of OA. Clinical review involves the clinician taking a detailed history which includes asking about symptoms and the mechanism of these symptoms. Specifically, pain during rest, pain at night, and pain while climbing stairs are key indicators of OA progression. Other symptoms such as stiffness, loss of ROM, inflammation, and joint tenderness are also noted during the clinical examination^{4,30}. If necessary, lab tests such as blood tests and joint fluid analysis can also be done to eliminate other diseases such as rheumatoid arthritis, gout, or infection²⁵. Clinical examination in conjunction with

radiographic evaluation is the most widely used method to diagnose and assess the severity of OA, which is a necessary step in developing a treatment plan.

2.2 Treatment

When a person is diagnosed with OA, there are various treatment options that may be considered. Non-surgical treatments consist of weight loss management, exercise, pain medications, and intra-articular injections. After non-surgical treatments are exhausted, only then are patients considered for surgical options. Several surgical options exist; such as high tibial osteotomy and unicompartmental knee arthroplasty, but the gold standard for knee OA treatment is a total knee arthroplasty (TKA)^{6,7}.

The design for the modern TKA implant was developed by Dr. John Insall and his colleagues out of The Hospital for Special Surgery in 1970^{31,32}. The design of the implant has been modified slightly over the years, but the overall concept still remains the same; replace the knee joint with implants that mimic the articular surfaces of the knee. Since the beginning of the development of the procedure, both patient and clinical evaluations have reported good results. Initial reports (two to five years post-surgery) found that 93% of patients scored excellent or good using the Special Surgery Knee Scoring System^{31,32}. In a 15 year implant survivorship study by Ranawat *et al.*, they found that 92% of patients reported scores of 'good' or better³³, which is comparable to the initial five year report. Overall survivorship of the implant was found to be 94.6% at 15 years³³. All of the patients were treated in the same centre, by the same consultants and it was a small sample size which resulted in an underpowered study. Further validated outcome measures would need to be used to evaluate the effectiveness of TKA in multiple centres and with a larger sample size.

In 2004, Ethgen *et al.* published a systematic review that reported health related quality of life (HRQOL) outcome measures of TKAs between six to twelve months postoperatively. They found early benefits from TKA¹⁶, but their study was limited by the relatively small sample size of included studies, as well as inconsistent follow-up period and lack of standardization of outcome measures across studies. A recent meta-analysis from 2015, conducted by Shan *et al.*, verified that TKA is the gold standard for

knee OA treatment. This analysis pooled all studies which used HRQOL outcome measures when evaluating TKAs with at least three years of follow-up. When combining multiple HRQOL measures, the pooled effect size was greater than 1.0⁷. In statistical analysis, an effect size of greater than 0.8 is considered large³⁴, which in turn indicates that TKA is very effective at improving HRQOL³⁵. This study had one major limitation which was the limited number of studies that fit their criteria. Of 243 articles identified, only 19 were eligible to be included. Although this is a small proportion of published studies, this meta-analysis is strongly indicative of the effectiveness of TKA in improving HRQOL⁷.

Patient satisfaction is as equally important as functional outcomes following TKA. Although TKA is the most effective way to treat knee OA, it has been found that only 75% to 89% of people are satisfied with their knee replacement^{20-24,36,37}. The majority of these studies retrospectively conducted their satisfaction questionnaires and reported overall satisfaction with TKA. Nakahara *et al.* found that functional activities such as climbing stairs, getting in and out of a car, and walking and standing were key determinants in patients satisfaction following TKA²³.

2.3 Total Knee Arthroplasty

There are many criteria in which a patient must fit before they can be considered eligible for a TKA. The patient must demonstrate a significant amount of pain and/or disability from OA and must have also failed conservative (non-operative) treatment⁶. There are many contraindications to receiving a TKA: joint infections, neurological deficit, extensor mechanism deficiency, insufficient pain and/or disability, inadequate attempts of conservative treatment, and severe medical risks due to other comorbidities⁶.

Several types of TKA implants can be used which is primarily based on surgeon preference. The posterior cruciate ligament (PCL) is a ligament that provides stability from posterior translation of the tibia. The surgeon can decide their preference for a cruciate retaining (CR) or a posterior stabilized (PS) TKA. In a CR knee, the PCL is not removed and acts as it normally would within the knee after surgery. In a PS procedure, the PCL is excised and the tibial component has a PCL substitute called the 'post'. These

two approaches have shown similar outcomes, as described in two large meta-analyses. Bercik *et al.*, found that both PS and CR TKAs had excellent long-term results. The only difference between the two implants was that PS TKAs showed a slight increase in ROM, but this difference was negligible and unlikely to have any clinical significance³⁸. Another meta-analysis of randomized controlled trials by Li *et al.*, found similar results in regards to ROM, as well as no difference in Knee Society Scores and complications at two and five years³⁹. Due to these results, PS vs CR is a surgeon dependent variable that should be decided based on surgeon preference and not based on difference in outcome.

Patellar resurfacing is another decision that a surgeon must consider when performing a TKA. Patellar resurfacing involves resecting the articular portion of the patella, which is affected by OA in some patients, and replacing it with a polyethylene articular component⁴⁰. Surgeons approach patellar resurfacing similarly to PS vs CR TKAs; mainly by preference. Some surgeons will resurface all of the time, others none of the time, while some will choose based on the severity of the patellar OA⁴¹. Multiple studies have looked at outcomes at various time points and they have consistently found that there is no difference between knee scores, knee pain, or radiographic outcomes following patellar resurfaced or patellar retained TKAs^{40,42-44}.

Regardless of the type or technique used, the ultimate goal of TKA is to create a functional, painless knee as well as providing long term survival of the joint⁶. To ensure the longevity and proper functionality of the knee replacement, correct limb alignment is vital to allow for even wear on the hardware. To ensure even wear, limb alignment is corrected to neutral alignment (-3° to $+3^{\circ}$), eliminating varus and valgus forces^{6,14,15}. After all necessary corrections are made to the alignment, prosthetic components are installed on the distal femur and proximal tibia (Figure 1).

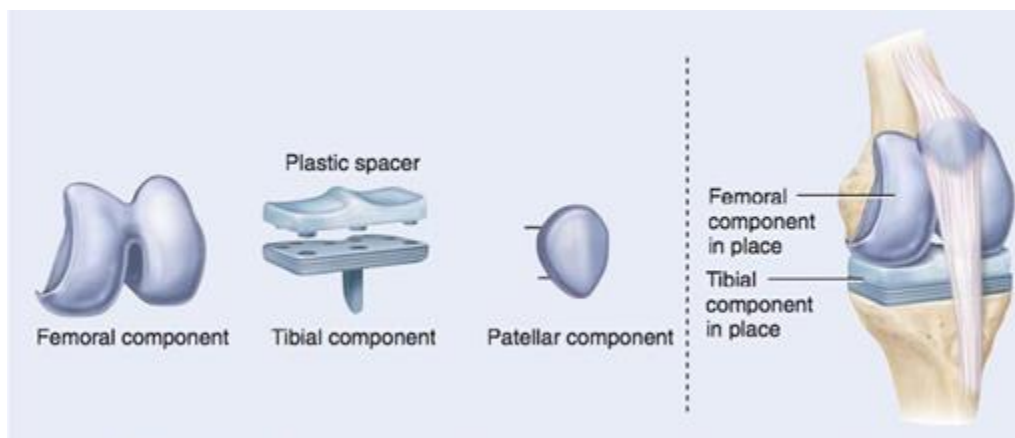


Figure 1: Components of a total knee arthroplasty.

Reproduced from Tortora GJ, Nielsen MT. *Principles of Human Anatomy*. Vol 12th ed. (Roesch B, ed.). Jefferson City: John Wiley & Sons, Inc.; 2012⁷⁰, reprinted with permission from Wiley (Appendix D).

Neutral alignment is achieved by a combination of bony resections (BRs) and soft tissue releases (STRs). BRs on the femur are based on preoperative templating using the intramedullary axis and zero degrees from the mechanical axis on the tibia in the coronal plane^{6,45}. In the sagittal plane, the distal femoral cut should be 90° to the intramedullary canal. The tibial cut is made depending on the knee replacement system and design as well as the patient's anatomy, but in general the surgical objective is about a three degree posterior slope⁶. These cuts begin the correction of alignment towards neutral as well as account for proper flexion and extension gaps that will be important later in the surgery.

Depending on the patients' preoperative alignment, the series of STRs can vary. In addition to the initial incision to allow for exposure to the joint to make the surgery possible, additional soft tissues on the medial side may be released to create a balanced knee after the BRs in a patient with varus medial arthropathy. The deep medial collateral ligament (DMCL) is generally the first soft tissue released^{11,46-48}. The DMCL lies directly underneath the superficial medial collateral ligament (SMCL) which both originate on the posterior aspect of the medial femoral condyle. The DMCL inserts onto the edge of the medial tibial plateau and medial meniscus⁴⁹. The DMCL is a secondary stabilizer of the knee from valgus forces when the knee is in extension⁵⁰. Approximately 50% of it is released to the mid-coronal plane as part of the standard exposure⁵¹. If

further correction is needed, the complete DMCL is released. Generally these two releases are completed first to correct mild varus alignment, but for more severe alignment, further releases must be performed^{11,46-48}. Although the order in which these releases are done are not standard across all surgeons, in general, most surgeons follow general guidelines which fit most patient profiles as described as follows:

Following the release of the DMCL, the medial posterior capsule is the next structure that is targeted to correct alignment⁵². The joint capsule acts to seal the joint space, passively stabilize the joint in multiple directions, as well as provide joint position feedback through proprioceptive receptors⁵³. The joint capsule is the deepest layer surrounding the knee and has posterior attachment points on the femur and tibia, several centimetres superior and inferior to the joint space, respectively^{53,54}. Since the joint capsule is the deepest layer surrounding the knee, the release is approached intra-articularly through the joint space.

Semimembranosus and the posterior oblique ligament (POL) are generally the next soft tissues releases, if needed¹⁵. Semimembranosus is a long muscle that runs down the posterior side of the leg, originating from the ischial tuberosity on the pelvis and inserting on the capsule as well as the posterior aspect of the medial condyle of the tibia^{49,55}(Figure 2 and Figure 3). Semimembranosus helps to flex the knee and extend the hip, as well as provide medial rotation to the knee. It is also known to contribute to medial stability especially when the knee is flexed⁵⁶.

The POL consists of three arms: superficial, central, and capsular (Figure 2 and Figure 3). These three arms branch off the distal tendon of semimembranosus posteromedially and inferiorly to the knee articulation^{49,57}. The general course for the POL is from the adductor tubercle of the femur, continuing distally to the tibia and semimembranosus tendon⁵⁷. The primary function of the POL is to prevent medial rotation of the knee while the knee is extended, as well as resist valgus forces while the knee is being extended⁵⁷. Both the semimembranosus and POL are in close proximity with the posterior capsule, so in order to achieve releases of these two ligaments, the release of the posterior capsule is continued posteriorly.

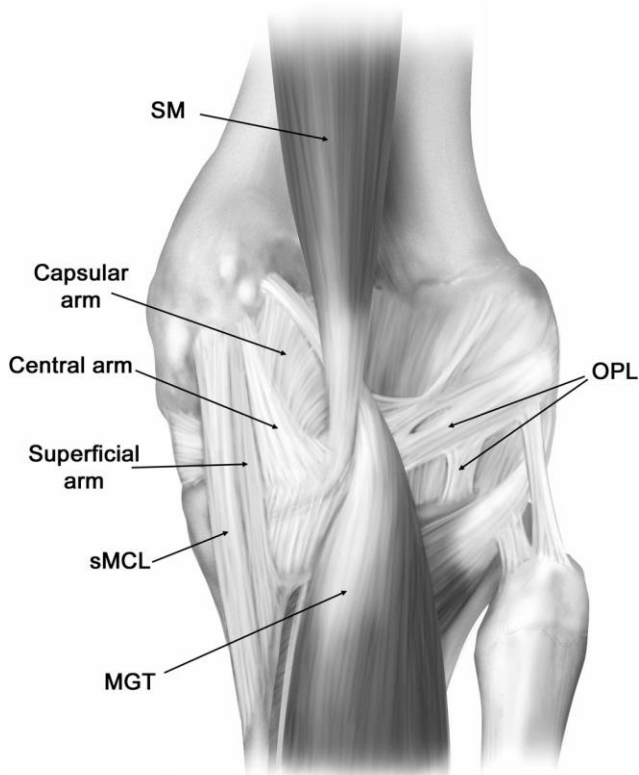


Figure 2: Illustration of the three arms of the posterior oblique ligament and surrounding structures of the posteromedial knee (posteromedial aspect, right knee).

sMCL = superficial medial collateral ligament, SM = semimembranosus muscle, MGT = medial gastrocnemius tendon, and OPL = oblique popliteal ligament.

Reproduced from LaPrade RF *et al.* The anatomy of the medial part of the knee. *J Bone Joint Surg Am.* 2007;89(9):2000-2010. doi: 10.2106/JBJS.F.01176.⁴⁹, reprinted with permission from The Journal of Bone and Joint Surgery (Appendix D).

Lastly, the SMCL is released to complete the correction of varus alignment. The SMCL is the largest ligament on the medial knee spanning from the medial femoral epicondyle to two attachments proximally and distally to the medial condyle of the tibia (Figure 2 and Figure 3). The proximal attachment is primarily soft tissue rather than bone, where it converges with the tendon of semimembranosus, while the distal attachment is located on the posteromedial crest of the tibia⁴⁹. The SMCL acts as the primary restrictor of valgus forces in the knee⁵⁸. Two approaches can be used to release the SMCL. The first option is a more conservative method which releases the ligament gradually and is referred to as

the “pie crust” method. To accomplish this, small horizontal cuts using a small scalpel or perforations using a large bore needle are made throughout the ligament to slowly increase laxity. The other method is referred to as the “deep” or distal release which involves a full release of the distal SMCL using a blunt instrument to sweep the SMCL off the tibia⁴⁸.

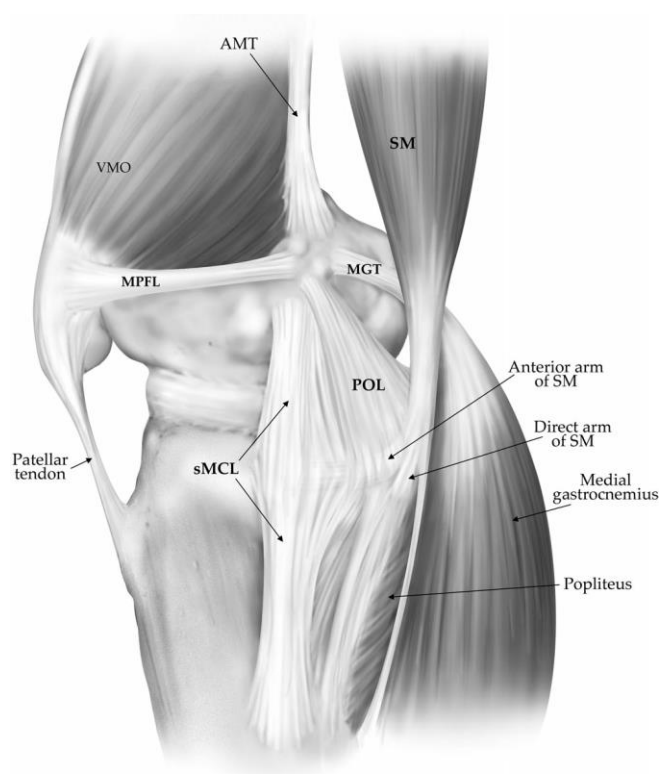


Figure 3: Illustration of the medial knee tendons and ligaments (medial aspect, right knee).

VMO = vastus medialis obliquus muscle, MPFL = medial patellofemoral ligament, POL = posterior oblique ligament, sMCL = superficial medial collateral ligament, SM = semimembranosus muscle

Reproduced from LaPrade RF *et al.* The anatomy of the medial part of the knee. *J Bone Joint Surg Am.* 2007;89(9):2000-2010. doi: 10.2106/JBJS.F.01176.⁴⁹, reprinted with permission from The Journal of Bone and Joint Surgery (Appendix D).

Osteophytes are removed throughout the procedure as well which allow for a smooth distal femur and proximal tibia to ensure correct balancing and prevent soft tissue impingement^{46,48}. Bony resections such as tibial reduction osteotomy as well as medial

epicondyle osteotomy can be performed as well if the patients' knee is severely malaligned^{13,59}. Tibial reduction osteotomy involves removing a portion of the posteromedial tibia that flares out. This decreases the distance that the surrounding ligaments have to travel, resulting in increased joint space⁵⁹. Medial epicondyle osteotomy accomplishes increased joint space as well. The osteotomy allows the mobilization of the epicondyle with all the soft tissues attach to the epicondyle, including the superficial MCL. This allows the joint space to open by allowing the epicondyle to move distally, decreasing the tension on the medial soft tissues⁶⁰.

The tibial component is installed by drilling a hole down the intramedullary axis of the tibia as well as creating space for the medial and lateral metal flares on the tibial component⁶. After the bone is cleaned, cement is applied to both the bone and prosthetic component and the component is impacted into place. Similar steps are taken for the femoral component, but without drilling into the bone since the femoral component fits directly over the existing femoral condyles. All excess cement is removed at this time, and a trial tibial polyethylene implant can be inserted onto the tibial component⁶. Extending the leg will compress the components further into place. From here, the surgeon can determine whether further steps are required to balance the knee.

Flexion and extension gaps are measured through the entire procedure to ensure a properly balanced knee⁵¹. These gaps refer to the joint space between the femur and tibia in flexion and extension when viewed anteriorly. If a gap is symmetrically too tight, it can cause limitations in ROM, while if the gap is too loose, it will cause hyperextension or instability in the joint resulting in poor functionality of the joint and poor longevity of the implant⁴⁷. These gaps can be measured by using the trial tibial polyethylene implant⁴⁷. If the gaps are found to be too tight or too loose, then appropriate STRs or BRs may be necessary to fix the issue. Proper shape of the gap is also ensured by performing the necessary releases. Ideally the gap space should be rectangular, having equal spacing on the medial and lateral sides, which ensures even wear on the implant. If there is asymmetry of the gap space in extension or flexion, the patient can perceive instability. Since instability is one of the most common reasons of revision⁶¹, the success of the surgery is partially dependent on the ability to balance the joint. The gap space can

be tested by using a laminar spreader, static spacer blocks, or by digital imaging⁴⁷.

Asymmetry can be determined from these tools and further releases can be performed to balance the joint. Once the surgeon believes the knee is properly balanced, the trial tibial component can be removed and the permanent polyethylene component can be inserted and snapped into the locking mechanism of the tibial component, completing the procedure.

2.4 Summary

Osteoarthritis is a severely debilitating disease that primarily affects load bearing joints such as the knee. Progression of this disease leads to severe pain and mechanical issues, causing a severe burden on the person affected. Medial tibiofemoral compartment OA is the most common form of knee OA seen, and is associated with varus alignment. After exhaustion of conservative treatment options, TKA is the gold standard for treating OA of the knee, which involves replacing the articular surface within the knee to return functionality and relieve pain.

Currently no literature exists that links the variability of releases within the TKA procedure with patient pain and satisfaction postoperatively. If intraoperative releases and cuts can be quantified and related to postoperative pain, this information can be used to improve patient satisfaction towards 100% by informing patients on realistic expectations following their surgery.

Chapter 3

3 Objectives

3.1 Primary Objective

Our primary objective was to evaluate whether there is any relationship between soft tissue releases and bony resections performed during a total knee replacement to achieve neutral lower limb alignment and the patients' pain and satisfaction throughout the postoperative timeline.

We hypothesized that the number of soft tissue releases and bony resections performed during a total knee arthroscopy will not have any association with patients' satisfaction or pain at three months post-surgery.

Chapter 4

4 Materials and Methods

4.1 Setting

The prospective cohort study took place in London, Ontario at the Rorabeck Bourne Joint Replacement Clinic at the London Health Sciences Centre's (LHSC) University Hospital. The clinic serves seven orthopaedic surgeons specializing in total knee and total hip arthroplasty, four of whom participated in this study. The three surgeons who were not part of the study were excluded because two of them used patellar resurfacing, while the other used a cruciate retaining implant. Patients who participated read the Letter of Information, signed the Consent form (Appendix B) and completed questionnaires before surgery, one- and two- days post-surgery, two weeks, six weeks, three months, and 12 months post-surgery. Following surgery, the consulting surgeon completed a form detailing the specifics of the surgery.

4.2 Ethics Approval

We obtained approval from the University of Western Ontario's Health Sciences Research Ethics Board (Appendix A).

4.3 Eligibility Requirements

Eligible patients were those older than 18 years of age who were receiving a primary TKA for OA. We excluded patients if any of the following were present: (1) rheumatoid arthritis; (2) valgus alignment; (3) prior femoral or tibial osteotomy/ trauma; (4) Charcot joint; (5) prior knee infection; (6) patellar resurfacing; (7) cruciate retaining implant; (8) inability to speak, understand, or read English; (9) cognitive impairment or psychiatric illness that precludes informed consent or renders patient unable to complete questionnaires; (10) no fixed address and no means of contact; (11) did not consent.

4.4 Outcome Measures

We administered all outcome measures preoperatively, day one and two post-surgery, two weeks, six weeks, three months and 12 months post-surgery. For the purpose of this thesis, we reported the results up to three months post-surgery.

4.4.1 Primary Outcome Measure

The primary outcome measure is the Knee Society Score (KSS). KSS consists of patient reported and clinician reported sections. The patient reported questionnaire consists of three sections: expectations (15 points), satisfaction (40 points), and function (100 points). These sections can be combined for a total score. The clinician reported form consists of five sections: pain (50 points), alignment (25 points), stability (25 points), range of motion (25 plus bonus points) and deductions for flexion contracture and extensor lag (up to -30 points). These sections can be combined for a total score. There are two versions of this form; one to record pre-surgery scores, and the other to record post-surgery scores. A higher total indicates a better outcome. KSS is a widely used outcome measure that has been proved to have good validity and reliability⁶²⁻⁶⁴, specifically for use with TKA.

4.4.2 Secondary Outcome Measures

4.4.2.1 SF-12 Health Survey (SF-12)

SF-12 is a condensed version of the SF-36 questionnaire designed to assess functional health and well-being. It is a patient reported outcome measure that consists of 12 questions regarding both physical and mental health on a three to five point ordinal scale. The physical and mental components are scored on the population normalized scale. A lower score indicates reduced functional health and well-being.

The SF-12 survey has been extensively used in research, and has proved to be a valid, reliable, and responsive outcome measure. It has also been shown that it maintains these qualities when used in orthopaedic studies⁶⁵.

4.4.2.2 Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

The WOMAC was designed to assess pain, stiffness and physical function in patients with hip and/or knee arthritis. The WOMAC is a patient-completed questionnaire which consists of 24 items that are divided into three sections. The three sections include: pain (five items), stiffness (two items), and physical function (17 items). There are two different versions of the WOMAC which are the Likert Scale or the 100mm Visual Analog. For the purposes of this study we will be using the Likert Scale. For each item in the WOMAC there are five descriptors: none, mild, moderate, severe, and extreme. Each of these descriptors corresponds to a nominal scale of zero to four. For each section, the answers are given a numerical representation and the sum of the responses include possible ranges of zero to 20 (pain), zero to eight (stiffness), and zero to 68 (physical function). All three sectional scores are added together at the end and the summed amount indicates the severity of the patients' pain, stiffness, and physical function. The higher the WOMAC score, the worse the pain, stiffness, and physical functionality. The method that we used to calculate the score inverts the WOMAC score, indicating that a higher WOMAC score means less pain, less stiffness, and increased functionality.

In a systematic review completed by McConnell et al., the WOMAC was found to be valid, reliable, and sensitive for use in TKA studies¹⁸. They also found consistent responsiveness for all three WOMAC subsections within knee arthroplasty studies (pain 1.14 (0.8 ± 0.7), stiffness 0.88 (0.7 ± 0.8), physical function 1.14 (0.8 ± 0.7)). Internal consistency has been shown to be high for all sections, while test-retest reliability is high for the physical function and pain sections¹⁸.

4.4.2.3 Numeric Pain Rating Scale (NPRS)

The numeric pain rating scale (NPRS) is a patient reported measure for pain consisting of an interval scale from zero to ten; zero indicating no pain, and ten indicating the worst pain imaginable. Patients were asked to record their average pain for day one and day

two after surgery, as well as at two weeks, six weeks, three months, and 12 months postoperatively.

Williamson *et al.* found that the NPRS is valid and reliable, as well as has high sensitivity in clinical settings¹⁹. NPRS has also been shown to be the simplest and most efficient way of collecting pain intensity postoperatively¹⁹.

4.4.2.4 Surgical Information Form

Preoperatively, the clinician indicated their predictions of which STRs and BRs that would be required to achieve neutral alignment for each patient based on viewing only the radiographs. Postoperatively, the clinician recorded the soft tissue releases (STRs) and bony resections (BRs) actually performed during each TKA. The form consists of seven STRs and three BRs commonly used during a TKA (Appendix C). The clinician also reported any laxity in the knee immediately post-surgery. Laxity was recorded in millimetres from zero to greater than three while the patient was in extension and with 30 degrees of flexion at the knee.

4.5 Sample Size

The sample size needed for this study was estimated using the rule of thumb suggested in a book by Harrell⁶⁶. He suggested that for every independent variable in a linear regression model, you need to have a minimum of 10 to 15 observations. In our case we wanted to use six independent variables: STRs and BRs performed during TKA, preoperative alignment, preoperative NPRS, preoperative WOMAC function, previous TKA, and BMI. In order to use six independent variables, we would need a minimum sample size of 60 to 90. We hoped to enroll 300 to 400 patients to have a sufficient number of patients who fall into each category of releases. For the purpose of this thesis, we conducted an interim analysis on 100 patients.

4.6 Plan For Analysis

We used SPSS version 22.0 to perform the analysis of the data. We used descriptive statistics to present the demographic characteristics of the study participants using means

and standard deviations for continuous variables (age, BMI) and proportions for nominal variables (sex, operative knee, previous TKA, number of releases performed).

We used a Pearson's product-moment correlation coefficient (Pearson's r) to determine whether there was a correlation between the preoperative alignment and the STRs and BRs performed during the surgery.

We used paired sample t-tests to compare the means of the pre-surgery and post-surgery outcome measures to determine whether patients were improving after their TKA. We reported the means at each time point with the standard errors, as well as the mean difference and the confidence intervals surrounding them.

To address our primary objective, we used linear regression to determine the magnitude of the association between the STRs and BRs performed during the TKA procedure, and the patients' satisfaction at three months. The same analysis was done comparing the STRs and BRs with pain at three months. The regression model was reported with the corresponding F statistic and degrees of freedom, and associated p-value.

To visualize the relationship, we used boxplots of the satisfaction scores against the number of STRs and BRs performed. A boxplot was also used to visualize the pain score. Boxplots were shown with 95% confidence intervals. If the linear regression did not support a linear relationship then we planned to explore whether other relationships (for example, quadratic) might fit better.

We performed diagnostics for our regression model to test for assumptions associated with regression modeling. To test for normal distribution of residuals, we visually analyzed a distribution graph of the standardized regression residuals fit with a distribution curve. Further to that, we also visually analyzed a normal probability plot of the standardized regression residuals. To test for heteroscedasticity, we visually analyzed a scatter plot of the standardized residuals versus the predicted values. Finally, to test for any collinearity between our independent variables we performed a variance inflation factor (VIF) diagnostic test.

Chapter 5

5 Result

5.1 Participant Flow

The flow of patients through each stage of the study is outlined in Figure 4. We screened 607 patients from July 2014 to July 2015. Of these, 273 did not meet the eligibility criteria and 29 refused to participate.

We excluded patients if they had a Charcot joint (n=1), had cognitive issues (n=5), if a language barrier existed (n=17), had suffered a prior femoral fracture (n=9), had a prior HTO (n=13), had prior open knee surgery (n=20), was receiving a revision TKA (n=5), had rheumatoid arthritis (n=9), had suffered a prior tibial fracture (n=17), were in valgus alignment (n=118).

Patients were also excluded for a variety of unforeseen issues such as: bilateral TKAs simultaneously (n=2), had a lower limb amputation (n=2), had chronic referred pain syndrome (CRPS) (n=1), if they were physically unable to complete the forms (n=1), or had cancelled their surgery (n=8).

Initially we excluded patients who had already experienced a TKA in the other knee (n=25), but this was later amended since we were looking to capture a large sample size and we felt that it would have no impact on the outcome measures.

Two hundred and twelve eligible patients gave consent to participate in the study. Twenty patients were excluded after surgery because they received patellar resurfacing making them ineligible. Twenty three patients were excluded after surgery because the operative data was missing. Three patients were withdrawn from the study at the three month follow-up; two because they refused to complete the forms, and one because they were lost-to-follow up.

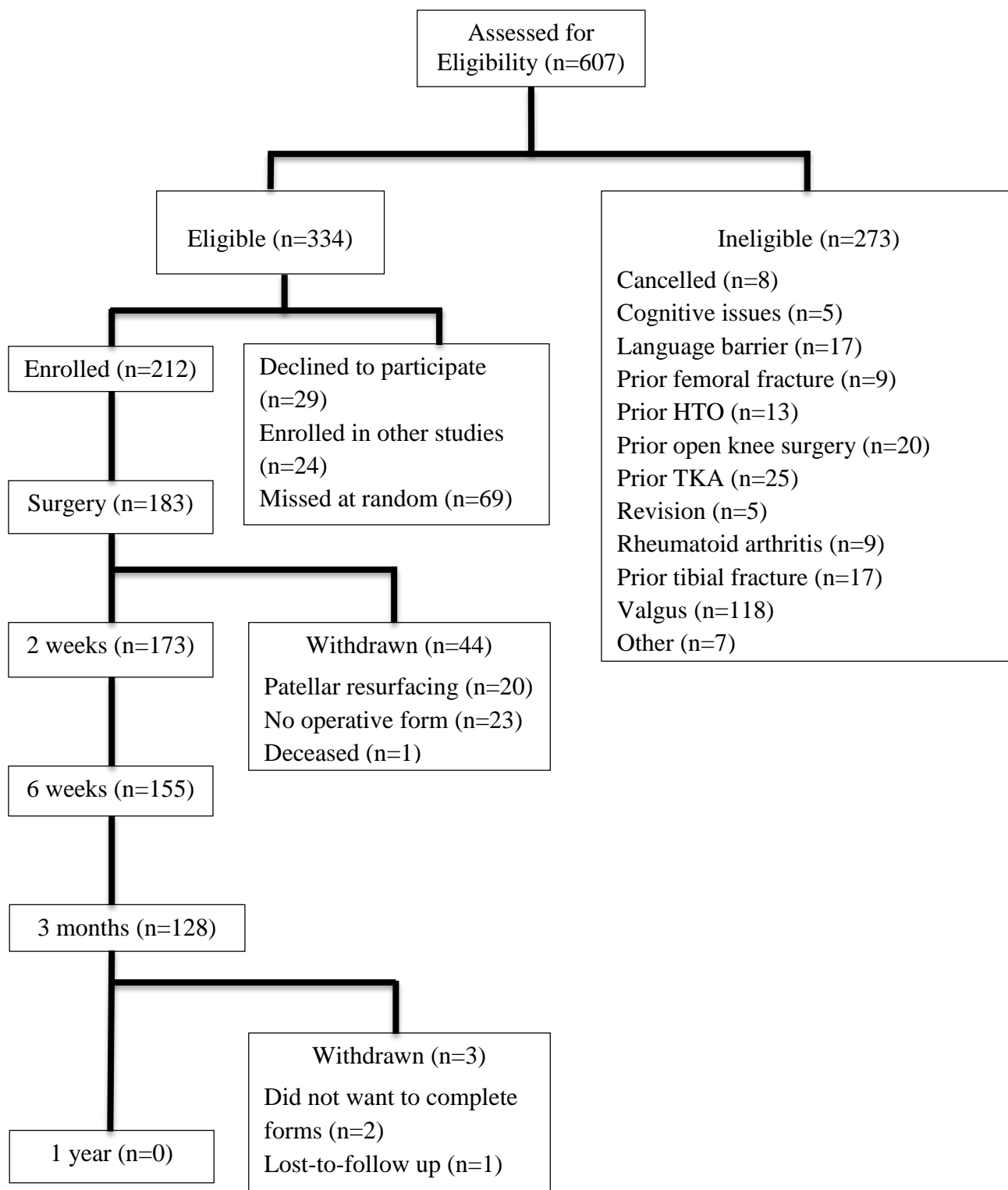


Figure 4: Participant flow through the study

5.2 Demographic Information

At the time of analysis, 100 patients had completed three month follow-up visits. Patient demographic characteristics are shown in Table 1. Mean age and BMI were similar to a typical TKA study cohort^{15,20,23}.

Table 1: Baseline Demographics

Characteristic	Value (n=100)
Sex, n (%)	
Male	47 (47)
Mean age \pm SD, y	70 \pm 9.08
BMI \pm SD, kg/m ²	32.76 \pm 7.52
Affected knee, n (%)	
Left	45 (45)
Previous TKA, n (%)	34 (34)

Abbreviations. BMI= body mass index; SD= standard deviation; TKA= total knee arthroplasty

Frequencies of the number of soft tissue releases and bony resections performed during total knee arthroplasty are given in Table 2. The majority of patients (66%) received two or three releases during surgery.

Table 2: Frequencies of the number of soft tissue releases and bony resections performed during total knee arthroplasty.

Number of STRs/ BRs	Frequency
1	4
2	28
3	38
4	6
5	12
6	6
7	4
8	2

Abbreviations. STRs- soft tissue releases; BRs= bony resections

5.3 Preoperative vs. Postoperative Outcome Measures

All outcome measures were compared between the preoperative assessment and three month follow-up (Table 2). All patient-reported and surgeon-reported outcomes showed a statistically significant improvement between pre-surgery and three months post-surgery, except for the mental component of the SF-12 survey ($p=0.24$), and the expectations component of the patient reported KSS, which queries the degree that expectations are met or not met, at three months ($p<0.001$).

Preoperative alignment was correlated with the number of releases performed during the TKA, $r=0.30$, $p=0.002$, which was expected.

Table 3: Preoperative vs. Postoperative Outcome Measure Scores Using Paired Sample t-Test

Outcome Measure	Baseline (mean \pm SE)	Three Months (mean \pm SE)	Mean Difference (95% CI)	p-value
WOMAC				
Pain	45.4 \pm 1.6	75.48 \pm 1.6	30.1 (26.0 to 34.2)	<0.001
Stiffness	40.6 \pm 1.9	66.26 \pm 1.9	25.7 (20.8 to 30.5)	<0.001
Function	46.6 \pm 1.6	76.06 \pm 1.6	29.4 (25.6 to 33.3)	<0.001
Total	44.8 \pm 83	73.76 \pm 1.4	28.9 (25.3 to 32.6)	<0.001
KSS (patient)				
Satisfaction	12.5 \pm 0.7	30.4 \pm 0.8	17.9 (16.0 to 19.8)	<0.001
Expectations	13.4 \pm 0.2	9.7 \pm 0.3	N/A	N/A
Function	56.0 \pm 2.6	101.7 \pm 2.9	45.7 (39.2 to 52.3)	<0.001
Total	81.9 \pm 3.0	141.9 \pm 3.4	60.0 (52.3 to 67.6)	<0.001
SF-12				
PC	29.2 \pm 0.8	41.2 \pm 0.94	12.1 (10.1 to 14.1)	<0.001
MC	55.7 \pm 1.2	54.4 \pm 0.95	-1.3 (-3.5 to 0.9)	0.24
NPRS	6.1 \pm 0.2	2.1 \pm 0.17	-4.0 (-4.4 to -3.5)	<0.001
KSS (surgeon)				
Pain	15.9 \pm 1.0	39.1 \pm 0.9	23.2 (20.9 to 25.5)	<0.001
Alignment	-10.0 \pm 0.0	23.0 \pm 0.8	32.9 (31.2 to 34.6)	<0.001
Stability	11.3 \pm 0.5	15.0 \pm 0.1	3.7 (2.7 to 4.6)	<0.001
Motion	10.6 \pm 0.6	16.1 \pm 0.2	5.5 (4.3 to 6.6)	<0.001
Total	27.5 \pm 1.4	92.8 \pm 1.3	65.3 (62.0 to 68.5)	<0.001

Abbreviations: SE= standard error; CI= confidence interval; WOMAC= Western Ontario and McMaster Universities Osteoarthritis Index; KSS= Knee Society Score; SF-12=

Short Form 12 questionnaire; PC= physical component; MC= mental component; NPRS= Numeric Pain Rating Scale.

5.4 Primary Outcome

The number of soft tissue releases (STRs) and bony resections (BRs) performed during a TKA was not associated with satisfaction scores from the KSS ($F(5, 87) = 1.77, p=0.13$), with an R^2 of 0.09, and adjusted R^2 of 0.04.

Since the data seemed to suggest a potential relationship between the number of releases and satisfaction from zero to four releases (linear) and five to eight releases (quadratic), we tested for the presence of an interaction term but found no significant interaction (Figure 5).

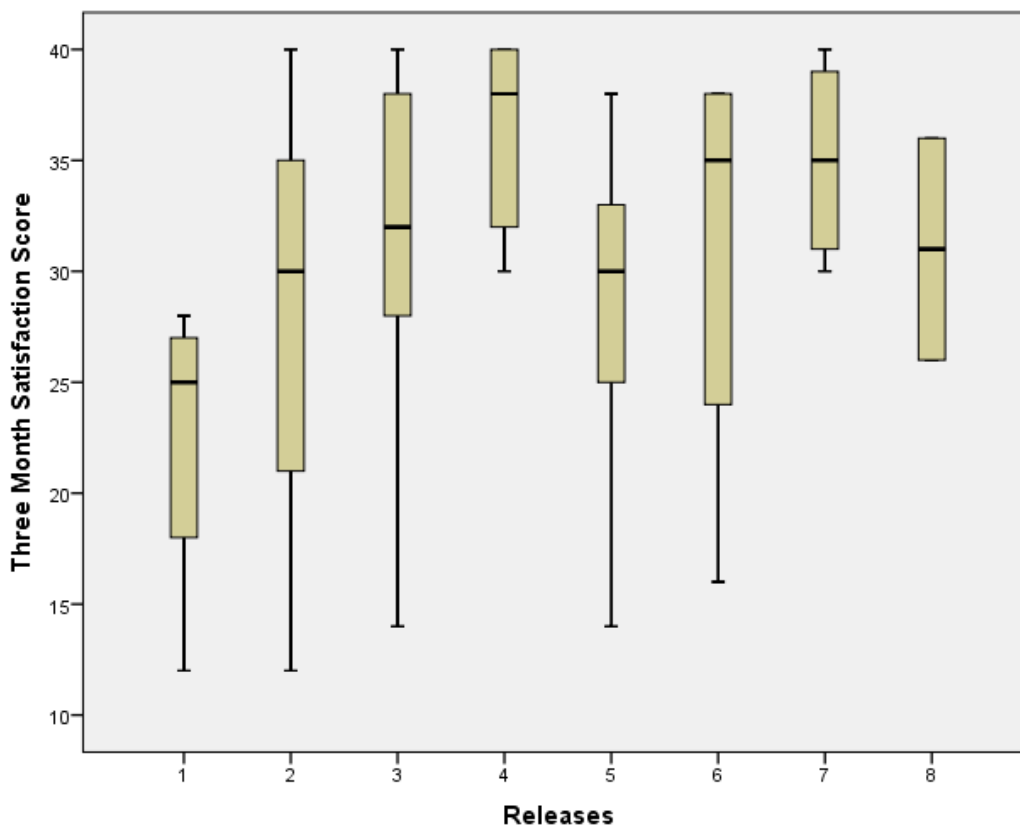


Figure 5: Boxplot of Three Month Satisfaction Score Versus Number of Soft Tissue Releases and Bony Resections Performed During Total Knee Arthroplasty

Next, we used a quadratic nonlinear regression model to test the association between satisfaction score from KSS based on the number of STRs and BRs performed during a TKA. We found a significant relationship ($F(2, 97) = 3.416, p = 0.037$), with an R^2 of 0.07 and an adjusted R^2 of 0.05. We then reran the model with all of our independent variables included and found no significant association ($F(7, 85) = 1.67, p=0.13$), with an R^2 of 0.12 and an adjusted R^2 of 0.05.

Next, since the boxplot suggested a linear relationship for the first four releases and a quadratic relationship for five to eight releases we tested whether the association was best described by splitting the data into two datasets (0-4 releases; and 5-8 releases). The linear model using only the patients who underwent 0-4 releases showed a significant association with satisfaction ($F(1, 74) = 14.698, p<0.001$), with an R^2 of 0.17 and an adjusted R^2 of 0.15. The quadratic model using only the patient who underwent 5-8 releases did not show a significant association with satisfaction ($F(2, 21) = 0.99, p=0.39$), with an R^2 of 0.09.

Finally, we categorized patients into 0-3 or 4 or more releases, conducted a linear regression and found a significant relationship between number of releases and satisfaction ($F(1, 98) = 7.03, p = 0.01$), with an R^2 of 0.07 and an adjusted R^2 of 0.06.

In terms of diagnostic tests, our standardized residuals and our normal probability plot confirmed that our data was approximately normally distributed (Figure 6 and Figure 7). Next, our standardized residuals versus our standardized predicted values from our regression model (Figure 8) showed a symmetrical ‘cloud-like’ shape, indicating no heteroscedasticity. To ensure that we did not have significant multi collinearity, we calculated the variance inflation factors (VIF). Each independent variable showed a VIF value of less than 1.5, which indicates low collinearity.

To reinforce that our quadratic nonlinear model is the best fit for our data, we compared the diagnostic tests from our linear model to our quadratic nonlinear diagnostic tests. The linear model showed negative skewness of residuals and therefore a less normal distribution, as well as greater deviance from the normal probability plot.

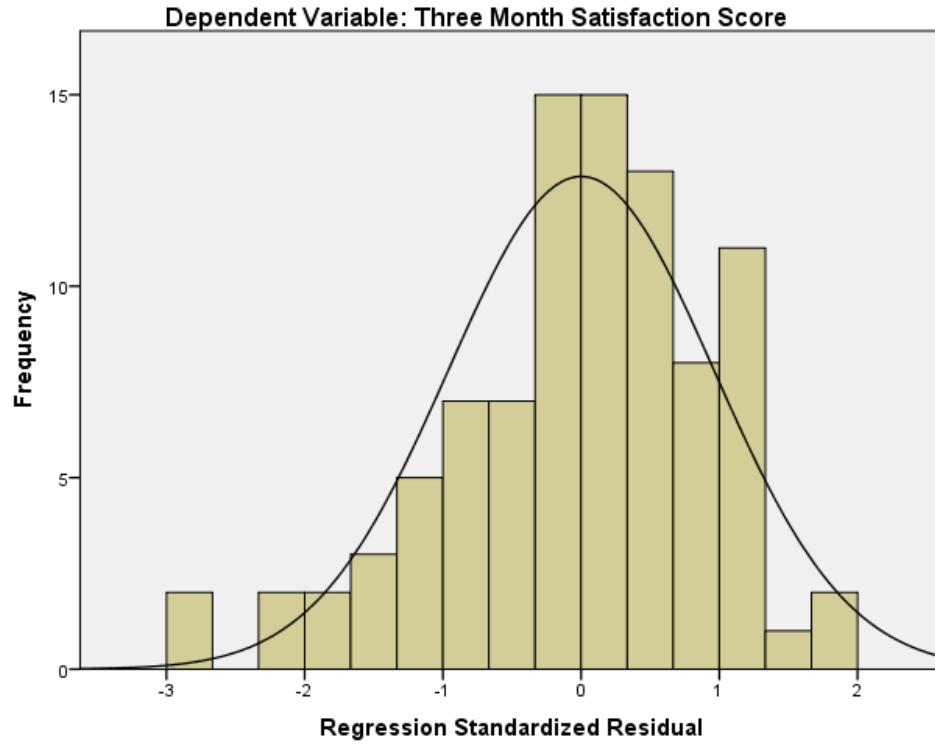


Figure 6: Histogram of the Frequency of Standardized Regression Residuals Fitted with a Distribution Curve

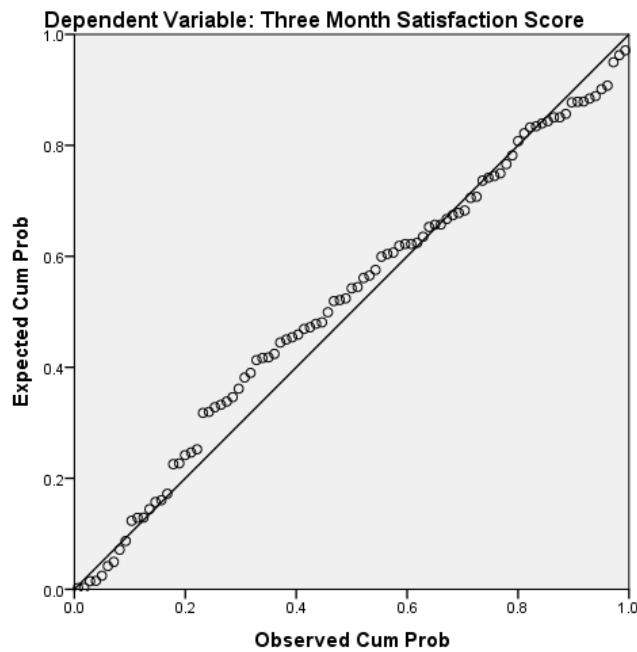


Figure 7: Normal Probability Plot of Standardized Residuals of the Regression Model

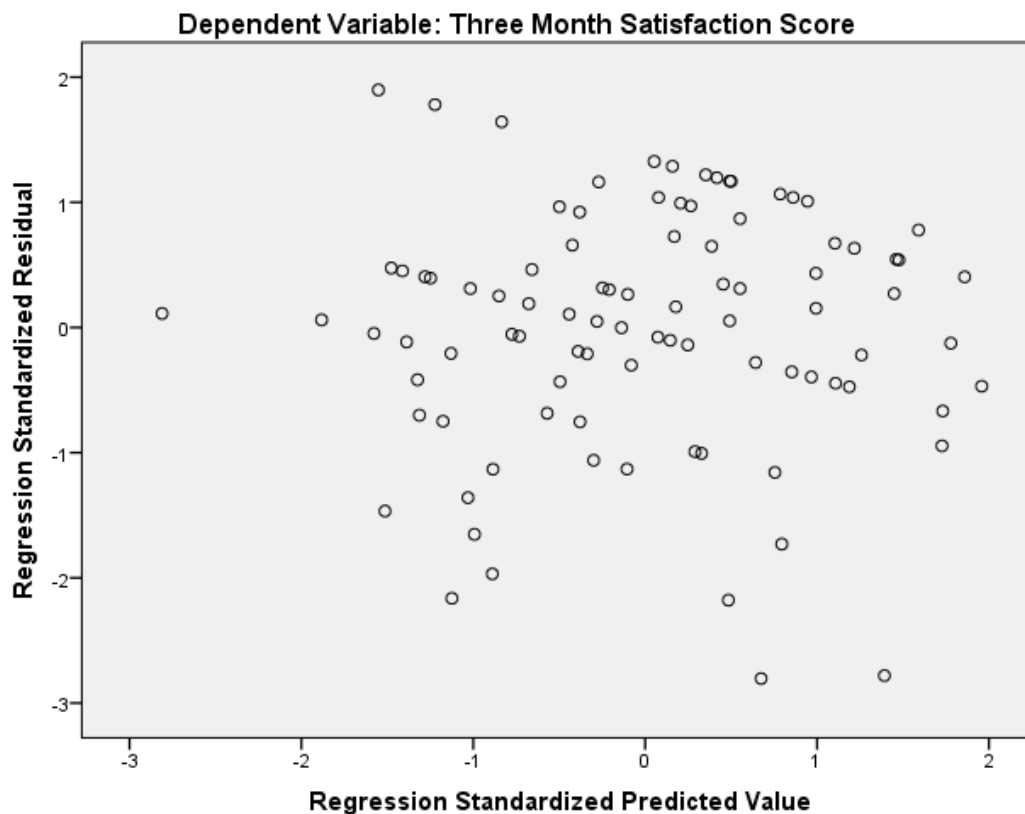


Figure 8: Scatterplot of Standardized Residuals Versus Standardized Predicted Values of the Regression Model

5.5 Secondary Outcome

There was no significant association between NPRS score and the number of STRs and BRs performed during a TKA ($F(1, 98) = 3.10, p=0.08$), with an R^2 of 0.03, and adjusted R^2 of 0.02. The boxplot further confirmed no relationship (Figure 9).

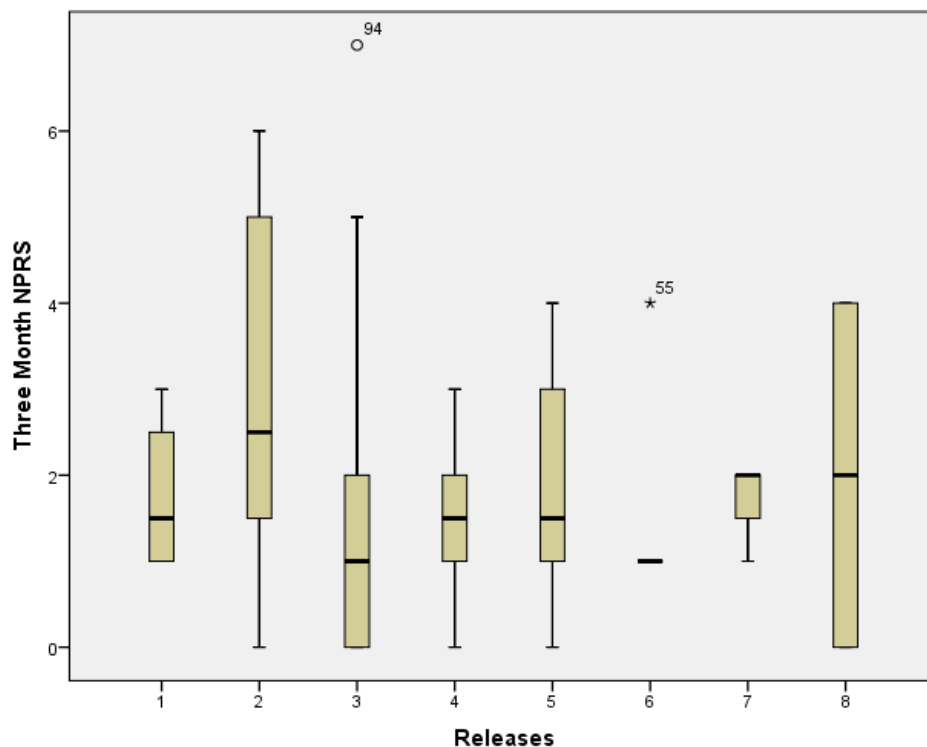


Figure 9: Boxplot of Three Month Numeric Pain Rating Scale Versus Number of Soft Tissue Releases and Bony Resections Performed During Total Knee Arthroplasty

5.6 Adverse Events

Thirteen patients in our analysis experienced adverse events between their surgery and the three month follow-up. Six patients suffered a fall between their two week and three month follow-ups. Five of the patients did not experience any increased pain or injury associated with the fall. The sixth experienced a medial femoral condyle avulsion which required no additional intervention. One patient suffered from a pulmonary embolism while recovering at the hospital after their surgery. This was treated with anticoagulation medications for three months and is expected to resolve without further intervention. Two patients experience stiffness in the knee, which required manipulation. Both patients improved from manipulation and continued with regular rehabilitation to fully resolve the issue. Two patients suffered from numbness around their knee which was

followed up with by an anesthesiologist and is expected to resolve. One patient suffered from a superficial infection that was fully resolved following a course of Keflex. Finally, one patient experienced anterior knee pain secondary to a gait abnormality. The patient was educated about adherence to physiotherapy instructions and focusing on their gait. We expected the pain to resolve within a few months.

Chapter 6

6 Discussion

As expected, all patient reported outcome measure scores improved from pre-surgery to post-surgery following TKA. We aimed to assess the relationship between patients' satisfaction and pain postoperatively and the number of soft tissue releases (STRs) and bony resections (BRs) performed during a total knee arthroplasty (TKA).

Sixty-six out of the 100 patients had two or three releases performed during their surgery which was related to their preoperative alignment. We collected preoperative alignment and we found a correlation between preoperative alignment and number of releases, which was expected. A patient with greater malalignment would require a greater number of releases.

Our boxplots suggested that patients receiving more STRs and BRs were more satisfied with their TKA. This may be contrary to what the majority of people would expect since more STRs and BRs during surgery would indicate more trauma to the knee and subsequently more pain and therefore less satisfaction. This is most likely not the case because by the time patients reach the three month follow-up, the incision site and the majority of the structures around the knee have healed such that the differences in pain scores are indiscernible between people with different number of releases. This can be seen by a boxplot of NPRS versus number of STRs and BRs (Figure 9). This boxplot shows that pain levels across every release group are similar, which would enforce that in our study pain does not have an impact on satisfaction at three months.

The second possible explanation for greater satisfaction with more releases could be explained by the patients' change in alignment from pre-surgery to post-surgery. Patients who are receiving a greater number of releases are the patients who are more severely varus to begin with and by correcting their alignment towards neutral, the varus forces acting on the knee are reduced more considerably than a patient with less severe varus alignment. Varus thrust is a main contributor to the varus forces which is visualized during gait as the worsening of varus alignment as the limb becomes weight bearing⁶⁹.

The reduction in forces on the knee is larger in patients with more severe varus alignment preoperatively which could be related to greater satisfaction. This will have to be explored further once radiographs are taken at one year.

Because of the exploratory nature of this study, we tested different regression models to see whether there was any association between satisfaction and the STRs and BRs performed. Our analysis did not support a linear relationship unless we restricted the analysis to patients who underwent 0-4 releases or if we included patients who received greater than 3 releases as one group. It may be that once four or more releases are performed, the outcomes for satisfaction plateau. Due to our small sample size, it is unclear whether this association will remain once recruitment is complete. We found no significance when we ran a quadratic nonlinear model though the association did improve over the linear model, which suggests that it may still be a viable option for exploring the relationship once all of the data is collected.

There may be several different explanations for why we did not observe a significant association. One possible reason is that we are looking at three month data which may be too early to identify patients who are satisfied or dissatisfied. It may be that three months is not a sufficient amount of time for patients to have been living with their new knee to fully gauge whether or not they are satisfied. It may turn out that at one year post-surgery is when the patient no longer considers themselves as still recovering and our distribution of satisfaction scores reflects a wider distribution of scores. In addition, we had very few patients who were dissatisfied (21%), making it difficult to identify common elements among them to precisely define a relationship.

Patient expectations may be a better proxy for reporting patient satisfaction rather than a satisfaction scale. Patient expectations could capture patient specific goals with the use of a goal attainment scale, which could be determined a priori. Determining whether patients' expectations have been met based on which activities they would like to returning to could be more indicative of a satisfied patient. The use of these outcome measures along with satisfaction scale could potentially provide more detailed measure of overall satisfaction with their knee replacement.

Finally, the lack of significant association may be explained by our small sample size. Specifically, we only had four patients who received one release, and twelve patients who received six, seven, and eight releases, cumulatively. To properly evaluate whether a relationship exists between satisfaction score and releases, we need to recruit a larger frequency of patients receiving different numbers of releases.

6.1 Limitations

The most prevalent limitation to this study was our small sample size. However, this was an interim analysis of the first 100 patients to complete their three month follow-up. A larger sample size would provide greater certainty in the outcome measures.

Our follow up time could also be a limitation since three months is very soon after surgery to be determining whether a patient is satisfied or not. Satisfaction may be more reliable at six or twelve months.

Another limitation to our study was that we did not collect the angle that the tibia was resected at which impacts the number of STRs and BRs. By increasing the angle that the tibia is resected at, this can correct the degree of alignment which in turn would lead to fewer STRs and BRs needed to be performed.

The last limitation would be that our outcome measure may not be an appropriate proxy for patient satisfaction. The use of a different outcome measure such as patient expectations, or a combination of outcome measures could be a better indicator of patient satisfaction.

Chapter 7

7 Conclusion

We found that there is preliminary evidence that the number of releases is associated to satisfaction but not to pain at three months post-surgery. These results are preliminary, so more definitive conclusions will be made after full completion of the study.

7.1 Directions of Future Research

In the future, we will complete data collection to include 400 patients in the study which will strengthen our conclusions. With the use of radiographs we plan to retrospectively determine the angle that the tibia was resected at to determine how it may affect the number of STRs and BRs performed. We will also explore our two secondary objectives which include:

- To evaluate the direction and magnitude of association between the degree of correction (or by proxy the number of soft tissue or bony releases) and pain and satisfaction.
- To determine the agreement between the clinician's preoperative prediction of soft tissue release and/or bony resection using plain radiographs and actual procedures performed.

Future research in this area should include a validation study to validate the satisfaction assessment. An improvement on the study would be to create a follow-up at the six month time frame in order to gauge if or when satisfaction scores and other outcome measures differ based on the number of releases performed during surgery.

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Appendices

Appendix A: Ethics Approval



**Western
Research**

Research Ethics

**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/Surgery, London Health Sciences Centre

HSREB File Number: 105204
Study Title: The correlation between soft tissue releases and bony resections performed in total knee arthroplasty and patient pain and satisfaction post-operatively.
Sponsor:

HSREB Initial Approval Date: June 20, 2014
HSREB Expiry Date: September 30, 2018

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Letter of Information & Consent	Letter of information and consent	2014/03/27
Instruments	Visual analogue scale for pain (VAS)	2014/03/25
Instruments	Western Ontario and McMaster Universities Arthritis Index (WOMAC)	2014/03/11
Other	Withdrawal form	2014/03/11
Instruments	SF-12 short form health survey	2014/03/11
Instruments	Pre-surgery surgical procedural form	2014/03/11
Instruments	Patient reported knee society score- Post-operative	2014/03/11
Other	Adverse events reporting form	2014/03/11
Other	Notification of adverse events	2014/03/11
Other	Follow-up form for adverse events	2014/03/11
Western University Protocol	Western Protocol revisions clean pdf	2014/05/26

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. If an Updated Approval Notice is required prior to the HSREB Expiry Date, the Principal Investigator is responsible for completing and submitting an HSREB Updated Approval Form in a timely fashion.

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.



Ethics Officer to Contact for Further Information



This is an official document. Please retain the original in your files.

Appendix B: Letter of Information and Consent Form



Title of Research: The correlation between soft tissue releases and bony resections performed in total knee arthroplasty and patient pain and satisfaction post-operatively.

Principal Investigators:

Dr. Brent Lanting [REDACTED]

Co-investigators:

Dr. James Howard [REDACTED]

Dr. Steven MacDonald [REDACTED]

Dr. Douglas Naudie [REDACTED]

Dr. Ted Vasarhelyi [REDACTED]

Purpose:

The purpose of this letter is to provide you with the information you require to make an informed decision about participating in this research.

You are being invited to participate in a study to investigate the correlation between soft tissue releases (STRs) and bony resections (BRs) performed in total knee arthroplasty (TKA) and patient pain and satisfaction post-operatively. STRs and BRs are part of standard surgical procedure during a TKA. STRs involve cutting fibres of the surrounding knee ligaments and tendons. BRs involve cutting away a small portion of bone on the tibia. Both of these procedures allow for the surgeon to provide a properly balanced and functional knee for the patient. We are asking you to take part because you are receiving a TKA resulting from osteoarthritis and have varus knee alignment.

Procedures:

If you agree to participate, you will be asked to complete a paper or online survey (of your choice) detailing information about yourself, including demographics, psychological health, lifestyle, pain, activity level, various knee-related self-report measures, and pain medication history. Your personal identifying information (name, mailing address, email address, phone number, hospital identification number and your date of birth) will also be taken for clerical purposes and kept separately from data collection. This questionnaire is expected to take 20 minutes of your time. You will be asked to complete these questionnaires at all of your regularly scheduled follow ups with your clinician. A surgical procedure form, completed by your surgeon, will also be filled out during surgery detailing the specifics of your surgery.

Your answers to the questionnaire will go into a database. The confidentiality and security of this database is discussed below.

Version date: 7/17/2015

1 of 4

Initials _____

Participant Exclusion Criteria:

If you have had previous high tibial osteotomy, if you have rheumatoid arthritis, if you have had prior femoral or tibial osteotomy/ trauma, if you have a Charcot joint, if you have had a prior knee infection, if you have any cognitive impairment, if you are younger than 18 years old, or if a language barrier exists you are not eligible to participate in this study.

Estimate of participant's time and number of participants:

Each questionnaire will be administered at the time of the patients' regularly scheduled follow up. The questionnaire is expected to take about 20 minutes at each visit. The entire research project is expected to have about 400 subjects.

Risks:

There are no known risks to your participation in this study.

Benefits: There are no known benefits to you for participating in this study; however, participation may benefit society as our results could explain differences in patient pain and satisfaction after receiving a TKA.

Voluntary Participation:

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or discontinue the survey at any time with no effect on your future care. Should you choose to discontinue the survey, we will keep the data you have contributed to that point. If you choose not to participate, you will receive the usual care provided by your current health care provider at LHSC.

Confidentiality:

All information will be kept confidential to the best of our ability. The company that takes care of the research database is EmPower Health Research. Your identifying information (name, mailing address, phone number, email address, date of birth) is being collected as part of your participation in this study. Your data is protected by a username and password. It travels in a scrambled format to a server (storage computer) that is located in Montreal, Quebec, Canada. The company that houses the server is a professional company (Netelligent) with extremely high standards of physical and virtual security. We want to let you know however, that even with this high level of security, there is always a remote chance that your information could be accessed or "hacked" by someone who is not supposed to have your information. The chance that this information will be accidentally released is small. In any publication, presentation or report, your name will not be used and any information that discloses your identity will not be released or published. Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

Compensation:

There are no costs to participating in this study.

Consent form:

You do not waive any legal rights by signing the consent form. You will be provided with a copy of this letter of information and the consent form.

If you have any questions about your surgery, please contact your orthopaedic surgeon. If you have any questions about this research, please contact the research assistant Matt Carter at [REDACTED], or the principal investigator Dr. Brent Lanting at [REDACTED] or [REDACTED].

If you have any questions about your rights as a study participant, please contact Dr. David Hill, Scientific Director, Lawson Health Research Institute at [REDACTED].

Sincerely,

Dr. Brent Lanting, MD, FRCSC
Dr. James Howard, MD, MSc, FRCSC
Dr. Steven MacDonald, MD, FRCSC
Dr. Douglas Naudie, MD, FRCSC
Dr. Edward Vasarhelyi, MD, FRCSC
Matt Carter, MSc Candidate

Version date:7/17/2015

Initials_____

3 of 4



Caring for You. Innovating for the World.®

The correlation between soft tissue releases and bony resections performed in total knee arthroplasty and patient pain and satisfaction post-operatively.

Informed Consent Form

I have read the Letter of Information regarding this study and give my informed consent to participate.

Printed Name of Participant

Signature of Participant

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

Appendix C: Total Knee Arthroplasty Operative Recording Form

Surgeon: _____

Date: _____

Patient: _____

Total Knee Arthroplasty Procedure Recording Form

Check all that apply:

Soft tissue release/ bone modification		Completed
50% Deep MCL (Mid-coronal plane)		<input type="checkbox"/>
Osteophytes (<u>Tibial</u> and femoral)		<input type="checkbox"/>
Complete deep MCL		<input type="checkbox"/>
Posterior capsule		<input type="checkbox"/>
SM/ POL		<input type="checkbox"/>
<u>Tibial</u> reduction osteotomy		<input type="checkbox"/>
Superficial MCL	Pie crust	<input type="checkbox"/>
	Deep release	<input type="checkbox"/>
Medial epicondyle osteotomy		<input type="checkbox"/>

Laxity (mm)

Circle one (1) for each direction:

Extension:

Medial 0 1 2 3 >3

Lateral 0 1 2 3 >3

30° Flexion:

Medial 0 1 2 3 >3

Lateral 0 1 2 3 >3

Additional comments: _____

If completing prior to surgery please indicate who is completing form:

Surgeon _____

Fellow _____

Resident _____

Appendix D: Image Permissions

From: Matthew Carter [REDACTED]
Sent: Wednesday, June 10, 2015 10:50 AM
To: [REDACTED]
Subject: Image Permission

I am a graduate student at Western University in Ontario, Canada. For my Master's thesis I am conducting a study entitled: The correlation between soft tissue releases and bony resections performed during total knee arthroplasty and patients' pain and satisfaction post-operatively. I was wondering if I could use Figure 3 (Illustration of the main medial knee structures (right knee)) and Figure 6 (Illustration of the three arms of the posterior oblique ligament (posteromedial aspect, right knee)) from "The Anatomy of the Medial Part of the Knee" printed in The Journal of Bone and Joint Surgery 2007, vol. 89-A, number 9, pp. 2000-2010? Usage would be in the literature review section of my thesis, and full credit would be cited.

Thank you very much,
 Matt

PERMISSION LICENSE AGREEMENT

P6773.JBJSInc.JBJS Am.LaPrade.881.Western University.Carter

JBJSInc.JBJS Am.LaPrade.881

6/11/2015

Mr. Matthew Carter
 M.Sc. Candidate
 Western University
 Kinesiology

**INVOICE
 ATTACHED**

Dear Mr. Carter,

Thank you for your interest in JBJS [Am] material. Please note: This permission does not apply to any figure or other material that is credited to any source other than JBJS. It is your responsibility to validate that the material is in fact owned by JBJS. If material within JBJS material is credited to another source (in a figure legend, for example) then any permission extended by JBJS is invalid. We encourage you to view the actual material at www.ejbs.org or a library or other source. Information provided by third parties as to credits that may or may not be associated with the material may be unreliable.

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PERMISSION IS VALID FOR THE FOLLOWING MATERIAL ONLY:

Figure 3 and Figure 6

Journal of Bone and Joint Surgery American, September, 2007, 89, 9, The anatomy of the medial part of the knee.1, LaPrade, 2000-2010

IN THE FOLLOWING WORK ONLY:

electronic and/or print copies of study entitled: The correlation between soft tissue releases and bony resections performed during total knee arthroplasty and patients' pain and satisfaction post-operatively, thesis, Western University, not used for any commercial purpose, and not sold or leased.

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Please contact Beth Ann Rocheleau at [REDACTED] with questions.

← Reply ← Reply all → Forward ...

MC Matthew Carter [REDACTED]
Thu 6/25/2015 10:51 AM
Sent

Mark as unread

To: Wiley Global Permissions [REDACTED]

- To help protect your privacy, some content in this message has been blocked. To re-enable the blocked features, [click here](#).
- To always show content from this sender, [click here](#).

I am a graduate student at Western University in Ontario, Canada. For my Master's thesis I am conducting a study entitled: The correlation between soft tissue releases and bony resections performed during total knee arthroplasty and patients' pain and satisfaction post-operatively. I was wondering if I could use image "E" on page 299, of the components of a knee replacement for illustrative purposes in my literature review section. Full credit would be cited and would it would not be used in any publications.

Matt

WG Wiley Global Permissions [REDACTED]
Thu 6/25/2015 3:04 PM

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Dear Mr. Carter:

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Sincerely,

Sheik Safdar
Permissions Coordinator
Wiley

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

Appendix E: Curriculum Vitae

MATTHEW CARTER

EDUCATION

Master of Science

Kinesiology
Western University, London ON
September 2013 - August 2015

Bachelor of Science

Human Kinetics maj.
Nutrition and Nutraceutical Sciences min.
University of Guelph, Guelph ON
September 2008 – April 2012

RESEARCH EXPERIENCE

Western University
London, ON
Thesis Project
2013 - Present

University Hospital
Under the supervision of Dr. Dianne Bryant and co-advisory of Dr. Lyndsay Somerville and orthopaedic surgeon Dr. Brent Lanting
A prospective cohort study investigating the relationship between soft tissue releases and bony resections performed during total knee arthroplasty and patient pain and satisfaction postoperatively. Responsible for patient recruitment, follow up and scheduling, data collection and entry, statistical analysis, manuscript writing

Western University
London, ON
Student Research Asst.
2013 - Present

University Hospital
Assisting Bryn Zomar in her thesis project under supervision of Dr. Dianne Bryant
A quasi- randomized trial comparing gait measurements of patients receiving either direct anterior or lateral total hip arthroplasty. Responsible for patient follow up and data collection.

Western University
London, ON
Student Research Asst.
2013 – Present

University Hospital
Assisting Olawale Sogbein in his thesis project under supervision of Dr. Dianne Bryant
A randomized controlled trial investigating motor sparing knee blocks for postoperative analgesia following total knee arthroplasty. Responsible for patient follow up and data collection.

University of Guelph
Guelph, ON
Student Volunteer
2012

Exercise Nutrition Lab
Assisting Dr. Nicolette Bradley in her thesis project under supervision of Dr. Lawrence Spriet
A study researching the effects of training on fat transporter protein content in skeletal muscle, mitochondria, and blood plasma during exercise. Responsible for managing exercise protocol for subjects as well as operating the “Lode” exercise bikes and recording various measurements at specific time intervals.

University of Guelph
Guelph, ON
Student Volunteer
2011

Exercise Nutrition Lab
Assisting Dr. Matt Palmer in his thesis project under supervision of Dr. Lawrence Spriet
A study researching the effects of dehydration on skeletal muscle metabolism and sprint performance. Responsible for performing study protocol as well as learning how to use associated equipment, and blood and muscle biopsy techniques.

CONFERENCES

Toronto, ON
Presenter
May 2015

Bodies of Knowledge
Presented interim data analysis of thesis work regarding the soft tissue releases and resections performed during total knee arthroplasty and patients’ pain and satisfaction postoperatively

Toronto, ON
Presenter
May 2014

Bodies of Knowledge
Presented protocol of thesis work regarding the soft tissue releases and resections performed during total knee arthroplasty and patients’ pain and satisfaction postoperatively

TEACHING EXPERIENCE

Western University
London, ON
Teaching Assistant
Sept 2013 – April 2014

A Systemic Approach to Functional Human Anatomy
Health Science 2300/ Kinesiology 2222

Western University
London, ON
Teaching Assistant
Sept 2014 – April 2015

A Systemic Approach to Functional Human Anatomy
Health Science 2300/ Kinesiology 2222

AWARDS AND CERTIFICATIONS

2013 – 2015

Western Graduate Research Scholarship

2014, 2015

Faculty of Health Science Travel Award