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PATELLA RESECTION IN TOTAL KNEE ARTHROPLASTY: AN ANALYTICAL COMPARISON OF THREE TECHNIQUES

by Kelsey Cushway

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Medical Engineering Western Michigan University Homer Stryker M.D. School of Medicine 2021

Thesis Committee: Keith Kenter, M.D., Chair Peter Gustafson, Ph.D. Steven Butt, Ph.D. Nicholas Miladore, M.D. © 2021 Kelsey Cushway

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ABSTRACT

Patella resection, as a routine component of TKA, can be both difficult to plan and difficult to execute. The primary purpose of this study was to evaluate the repeatability of three unique patellar resection techniques used in total knee arthroplasty. The secondary purpose of this study was to establish whether different surgical techniques were able to reproduce preoperative plans made by each surgeon. We used radiographic measurements to evaluate patellar thickness and patellar cut angle preoperatively and postoperatively. Three techniques and significant quantitative differences between average patellar thickness and tilt values. No one technique was found to accurately execute the preoperative plans, and all resections were completed at a more conservative thickness than was pre-planned by the surgeons. Our results reflect conclusions in the literature, finding no significance in the ability to pre-plan patellar resections.

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ABBREVIATIONS

Abbreviation	Definition
ADI	Analyzing Digital Images
АКР	Anterior Knee Pain
AP	Anterior-Posterior
BMI	Body Mass Index
CITI	Collaborative Institutional Training Initiative
СТ	Computed Tomography
IRB	Institutional Review Board
OR	Operating Room
PFA	Patellofemoral Arthroplasty
PFJ	Patellofemoral Joint
PFOA	Patellofemoral Osteoarthritis
TJA	Total Joint Arthroplasty
TJR	Total Joint Replacement
TKA	Total Knee Arthroplasty
WMed	Western Michigan University Homer Stryker M.D. School of Medicine
X-RAY	Energetic High-Frequency Electromagnetic Radiation

CHAPTER I: INTRODUCTION

Total Knee Replacement

Knee replacement surgery, or total knee arthroplasty (TKA), can help relieve pain and restore function in damaged and diseased knee joints. With more than 1 million total knee replacement procedures completed in the United States annually, TKAs are one of the most durable and effective orthopaedic surgeries¹. A study completed in 2015 found total knee replacements were completed in the adult U.S. population at a rate of 1.52%, with prevalence among adults fifty years of age or older even higher at 4.55%². This coincides with higher rates of diagnosis and treatment of arthritis in aging populations, as well as the desire for greater mobility and increased quality of life following advancements in treatment³. It is likely that the incidence of total joint procedures, specifically TKAs, will continue to rise with increased demand and confidence in surgical advancements. Further, continued developments in navigated surgery, wear-resistant bearing surfaces, and overall implant design promise a continual evolution of the TKA procedure⁴.

Total knee replacements are the leading solution for patients experiencing pain and loss of function as a result of severe osteoarthritis in the knee. TKAs involve the removal of damaged native tissue within the knee joint and subsequent replacement with 4 artificial components: (i) femoral component, (ii) tibial component, (iii) polyethylene liner, and an optional (iv) patella component (Figure 1). Patellar replacement is however considered to be routine in the U.S. and will be referred to from here forward as a standard component of this procedure. Routine patellar replacement will therefore be the focus for this manuscript.

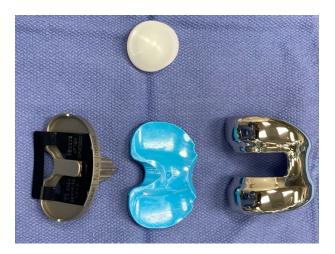


Figure 1. Example of the 4 components of TKA: tibial component, trail polyethylene spacer, femoral component, and (top) patellar component.

Patellar Replacement

Patellar replacement, or patellar resurfacing, involves the removal of the (often osteoarthritic) posterior aspect of the patella, followed by the placement of a patellar implant. The implant, often metal-backed or made entirely of polyethylene, is secured to the remaining native bone using fixation pegs and/or cement.

Employing appropriate surgical techniques in combination with an ideal implant design will result in optimal outcomes, in both situations of patellar resurfacing and patellar preservation⁵. The selection of a suitable patellar component size, implant design, and placement of the component, combined with the completion of necessary releases and/or removal of osteophytes should be carefully weighed when performing patellar resurfacing during TKA^{5,6}.

Resurface or Retain Native Tissue?

Early TKAs did not include patellar resurfacing, and many patients reported anterior knee pain^{5,7,8}. As a result, patellar resurfacing was incorporated into the procedure. Resurfacing, combined with component placement, creates a surface on the posterior side of the patella for the femoral and tibial components to articulate against while the knee is in motion. Despite a reduction in anterior knee pain, a number of complications associated with patellar resection

have emerged: component failure, instability, patellar fracture, patellofemoral tendon rupture, soft tissue impingement, asymmetric resection, aseptic loosening, infection, and malalignment^{5,9,10,11}.

The question of whether or not to resurface the patella has thus proven to be a controversial topic, with the risk of severe complications discouraging some surgeons from routinely resurfacing the patella during TKA¹². This risk of complication has resulted in a division of opinion; some surgeons recommend routine resurfacing, another group does not recommend resurfacing under any circumstances, and a third party utilizes selective resurfacing⁵.

While routine resurfacing or retention of the native knee offer a clear-cut approach to the topic, selective resurfacing involves the replacement of the patella only when the indications for doing so are present, i.e. when the patella has noticeable arthritic tissue, the articular surface is eburnated, or there is evidence of patellofemoral maltracking⁵. If the bone is not healthy enough to articulate against the femoral and tibial implant surfaces, significant anterior knee pain is likely to follow, and revision may be necessary. Preservation of the patella is recommended when the patella is too small to be a good candidate for resurfacing, or when the patella has both a normal articular surface and standard patellar tracking is observed.

The selection of a suitable patellar component size, implant design, and placement of the component, combined with the completion of necessary releases and/or removal of osteophytes should be followed when performing patellar resurfacing during TKA; adherence to these guidelines should result in a successful TKA with patellar resurfacing⁵.

Indications For/Against Resurfacing

Indications for resurfacing include both the routine replacement of a patella during TKA and partial/bilateral knee arthroplasty, as well as the presence of patellar arthritis and osteoarthritis. Contraindications for resurfacing include significant amounts of unhealthy patellar tissue or significant levels of wear that would not support a patellar implant, significantly small patient anatomy, and patellar fracture^{13,14}. Patients with small, delicate patellae may not have

enough tissue to suggest resurfacing of the patella, as the average thickness to remove is usually 12-15mm, dependent upon which implant system is being used^{15,16}.

In cases where there is little-to-no arthritis present in the patellofemoral compartment, the normal patellar cartilage can be retained or replaced, dependent upon the preference of the surgeon; strong outcomes have been recorded for both instances¹².

Patellar Resurfacing Procedure

Patellar replacement involves the resurfacing of the posterior aspect of the patella, and is completed in total knee arthroplasty, bicompartmental knee arthroplasty, and isolated patellofemoral arthroplasty (PFA)¹⁷. The patellar implant component serves to provide a new articulation surface for the posterior patella and replace diseased tissue associated with patellofemoral osteoarthritis (PFOA), which is symptomatic in greater than 10% of individuals (8% of women and 2% of men) who are older than 55 years of age¹⁸. PFA completed using a number of implant types results in good clinical outcomes and survivorship, but still remains controversial due to high revision rates^{12,15}. According to various literature sources, requirements for successful PFA involve patient selection, intra-operative techniques, implant selection, optimized extensor mechanism function, an avoidance of 'overstuffing' of the PFJ, and medialization of the implant^{10,17,5,19}. Despite strong clinical evidence that these factors lead to good outcomes, these factors are occasionally overlooked in TKA due to the lack of precision necessary during the procedure, in contrast to PFA. Clinical outcome trial data has been reported concluding that there is a 5mm allowance in the thickness of the remaining native patella during TKA, provided that the cut is made at the proper angle^{20,21}.

The technical goal for patellar resection is to restore the native thickness of the patella using an implant, resulting in equal distances from the resection surface to the anterior surface across the length of the patella^{11,16}. This produces a flat resection plane upon which the patellar implant is affixed. Patient-reported anterior knee pain (AKP) can occur in cases of asymmetric resection, where a tilted resection results from unequal thicknesses being removed from either

side of the patella ^{22,14,23}. A minimum of 15mm should remain following patellar resection, to avoid significant weakening of the retained native bone which could lead to fracture ^{24,5}.

Approaches for Patellar Resection

The two most common approaches for patellar resection are: (i) completing a cut parallel to the anterior surface of the patella, and (ii) completing a cut from the medial to the lateral extents of the patella^{11,20}. Both approaches offer a level of subjectivity due primarily to the sheer variability of patient patellae. Thus, it can be difficult to define landmarks with which to complete a cut that would be repeatable and accurate in all cases. It can be even more difficult to establish the estimated thickness of the patella when the bone has been reduced by wearing of the joint¹⁶. While a formal written preplan for patellar resection is not completed in standard practice, cuts are mentally planned by each surgeon using the available pre-operative X-rays combined with intraoperative examination of the patella. While the symmetry of the cut itself may be confirmed by calipers, many surgeons measure by feel, grasping the patella between their thumb and forefinger which is subjective and lacks precision but is convenient. A study by DeOrio and Peden confirmed that assessing the cut in this manner, without visualization, resulted in a significant underestimation of asymmetry²². To limit this subjectivity, some surgeons will utilize interoperative aids in addition to the guides available through major orthopaedic manufacturers. Certain methods involve the use of calipers to measure thickness before and after resection (Figure 2), while others draw a line or ring at the level of resection directly onto the patella using a cauterizing tool. As with most surgical techniques, attention to detail during the patella resection portion of the procedure is especially important in order to minimize patellarelated complications.



Figure 2. Example of a caliper (and trial patellae) used to measure the restored thickness of the patella.

Patellar Implant Design

The patella handles an extreme amount of stress, and the mechanical environment of the patellofemoral joint can be difficult to design for. Establishing the appropriate size of the patellar implant is one of the most important steps made in an effort to ensure the functional success of total knee arthroplasty¹⁶. There are a number of patellar implant designs with a variety of purposes, from anatomic models that are meant to replace a damaged or diseased patella in the native knee joint, to dome and cylindrical patellae implants that are meant to articulate against an artificial joint following unilateral, bilateral, or total knee arthroplasty (Figure 3).

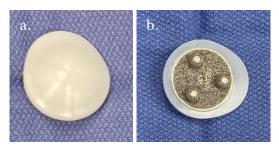


Figure 3. Example of a metal-backed patella implant used in TKA; anterior (a.) and posterior (b.) view.

Patellar tracking and contact area differ between native and artificial knees, with artificial knees altering the tracking of the patellofemoral joint along with the joint anatomy. There is no consensus on an ideal design, and surgeons use different patellar implants based on the patient

anatomy, type of implant system, and the quality of the patella. The shape of the patellar implant is therefore based entirely on the surface geometry of the femoral component.

The fixation pegs on the back of the patella are often placed in a grouping of three peripherally rather than earlier designs which included a central peg (shown in Figure 2, image b). This helps to distribute the force acting on the patella and reduces the risk of patellar fracture²⁵. A patella jig (Figure 4) is used to drill the holes in an equidistant spacing, forming 3 holes in a triangular grouping.



Figure 4. Example of the jig (and drill bit) used as a guide for placing patellar implant peg holes.

The majority of currently available patella implant components are dome shaped or modified dome shaped and entirely made of polyethylene. Metal-backed patellar components may also be used, depending on the reason for revision, duration of implantation, and fixation²⁶.

Assistive Devices for Patellar Resection

There are multiple assistive devices available for the completion of the patellar resection procedure, the most notable of which are the cutting guide and the reamer²⁰. The cutting guide

clamps onto the posterior surface of the patella and offers a slot for an oscillating saw to articulate through. The guide provides constraints for the resection, ensuring that the cut is completed in the intended plane. However, these cutting guides do present notable limitations: the guides are often cumbersome, they may detach from the patella and alter the plane of the cut, and they limit both the tactile feel and viewing plane of the patella for the surgeon.

The second commonly used assistive device is known as a reamer. This device allows the surgeon to ream off the posterior aspect of the patella to a pre-set target depth that is dependent upon the thickness of the incoming implant, leaving a perfectly flat surface to accept the artificial patella. This method is the easiest to apply and execute, but takes additional time, can result in the incorrect depth of resection, and can be tilted without the user's knowledge²⁰. For these reasons, neither of these devices have gained widespread acceptance due to their various shortcomings.

On top of these difficulties associated with assistive devices, the accurate resection of the patella itself is made more difficult by the small size of the patella, the soft tissues often covering key landmarks on the bone surface, and the hard nature of the bone itself relative the tibia and femur¹¹. Patellar resurfacing is thus said to be more of an art than a science, with many surgeons completing the cut using freehand techniques and little consensus regarding which landmarks to base the cut on^{11,20}.

Variability of the Patella

The patella is the largest sesamoid bone in the human body, triangular in shape, with an anterior-facing apex and posterior-facing base. The lateral facet of the patella is larger than the medial, with the apex shifted medially in the knee. Thickness varies based on age, gender, presence of disease, wear, and surgical intervention²⁷.

The Wiberg classification system is used to describe the shape of the patella²⁸; it is based upon the asymmetry between the medial and lateral facets of the patella from an axial view, with increasing number corresponding to a larger measure of asymmetry²⁹. Type I patellae are described by symmetrical facets that are concave and roughly equal in size. Type II patellae are described by a smaller, flatter medial facet. Type III patellae are described by a markedly smaller medial facet with a near 90-degree angle observed between the medial and lateral facets. A fourth type was later described by Baumgartl, signified by a patella with no medial facet and consequently no median ridge^{30,31}.

When considering vertical alignment, patella alta refers to a patella that is aligned superiorly, or high-riding, while patella baja refers to a low-riding patella³². These classifications are determined using the Insall-Salvati index ratio, measured on lateral view X-rays and considered to be the most reliable method for measuring patellar height³³. The length of the patellar tendon and the longest sagittal diameter of the patella are determined, and a ratio is created where a value of 1 is considered normal; a ratio smaller than .8 would indicate patella baja, and greater than 1.2 patella alta.

There is a large amount of variation present in samples of patellae, with a variety of conclusions drawn in the literature. For example, a study completed in 2009 by Anglin et al., found female patellae and deformed patellae to have greater asymmetry¹¹. Additional studies have aimed to quantify the clinical effects of this variability; a study completed in 2011 determined that patellar shape can be a predisposing factor in patellar instability²⁷.

Complications Related to the Patella

Patellofemoral complications are reported to occur in up to 10% of TKAs and remain the most common reason for revision procedures^{6,26}. These complications include, but are not limited to: patellar and soft tissue impingement, patellar fracture, aseptic loosening, anterior knee pain, patellar component wear, extensor mechanism ruptures, malalignment, and patellofemoral instability^{9,10,32,34–38}.

It is important for clinicians to understand the intricacies of the combined anatomy, biomechanics, and kinematics of the knee and patellofemoral joint (PFJ) when considering treatments to understand the consequences of changes to the mechanical environment of the knee³⁹. Surgical treatment can have a significant impact on the performance and function of the knee, altering the biomechanics of the knee altogether. Regarding the PFJ, small changes to patellar tracking or quadriceps stabilization and contraction can result in noticeable changes to a patient's knee utility.

The PFJ serves as the main extensor mechanism in the knee, contracting in conjunction with the quadriceps muscle to extend the lower leg and foot. The patella is generally out of contact with the trochlear groove while the knee is fully extended, but in flexion the rounded posterior aspect of the patella slots naturally into the trochlear groove; this allows extension/flexion of the knee to track along the midline of the joint. This contact area can extend from the far medial margin of the patella to the lateral margin of the patella, depending on the motion of the knee and the variable anatomy of the knee joint. The patella itself serves as a fulcrum, stabilizing the knee both medially and laterally while increasing the moment arm of the quadriceps muscle and enhancing the extension force of the leg⁴⁰.

Ideal Resection Plane

There has been little consensus regarding an ideal resection plane in TKAs, specifically with respect to desired landmarks for use in resection planning¹¹. Anglin et al. noted that patellar resection is often completed freehand and there has been little-to-no quantitative comparison of available resection definitions. The study analyzed the currently accepted methods for resection and proposed two additional definitions based on radiographic analysis. An inherent variability in drawing the intended resection plane was noted, resulting in a recommendation to clinicians to draw their lines several times and average the results when comparing patellar tilt.

Patellar Thickness

As stated previously, a minimum of 15mm should remain following patellar resection, to avoid weakening of the retained native bone which could lead to fracture ^{24,5}. Patellar resection should restore the native thickness of the patella while maintaining equal distances from the resection surface to the anterior surface across the length of the patella¹¹. This lends to the idea of

patellar symmetry, meaning that the goal is to make a symmetric cut along the length of the patella, removing the same amount of tissue from each side to reduce the risk of fracture.

Thickness and tilt are therefore the main metrics used to quantitatively describe patellar resection, making them the obvious point of reference in the case of procedural planning. Preplanning for patellar resection would therefore involve the designation of the start and end of a resection cut based on a series of anatomical reference points; surgeons would attempt to plan a cut that would achieve both optimal thickness and optimal resection angle.

Patellar Tilt

Patellar tilt was introduced as a form of malalignment in 1978 by Laurin et al. This was the first time a measure of "lateral patellofemoral angle," or so-called patellar tilt, was used to describe tilt rather than displacement of the patella.

Patellar tilt has not been well-defined from a radiological perspective. A study completed by Grelsamer et al. in 1993 involved the radiographic analysis of patellar tilt, determining an angle for patellar tilt and relating it to malalignment of the extensor mechanism of the knee⁴¹. Tilt angle was defined as the angle made between the resection plane and the horizontal in the sunrise type film. This is an inherent limitation in the study, as it assumes that each film was taken perfectly. This measure assumes that the horizontal plane of the X-ray viewing screen translates directly to a true horizonal line. This may not be the case due to several factors, including the variability in distance and distortion of leg rotation associated with taking an X-ray in sunrise view as well as a lack of consistency in the individual administering the X-ray. It is therefore assumed that these assumptions for the designation of patellar tilt are flawed.

Although this approach served to describe patellar tilt compared to the horizontal, this study proposes a new methodology for determining patellar tilt angle that looks at the tilt dependent upon the apex of the patella itself. This may be more clinically relevant when describing the tilt of the resection, as it describes the tilt with respect to the patella directly rather than the tilt related to the joint or the ground. The patella is often some degree "off-parallel" to

the ground, so this kind of measure may tell us more about the tilt of the patella resection with respect to the femoral trochlear groove.

Other literature has looked at the patellofemoral angle (slope of the lateral patellar facet) established by Laurin et al.⁴²; Laurin's patellofemoral angle is based on the shape of the lateral facet of the patella, which may vary between patients independently of the degree of tilt and can be difficult to measure repeatedly on sunrise-type X-rays. This is especially notable in cases involving diseased or arthritic patellae. Although Grelsamer accommodated for the clinical assessment of tilt based on palpation of the edges of the patella, their reference of tilt (to the horizontal) would be less clinically relevant than comparing the plane of resection to the trochlear groove or the patella. The biomechanics of the patellofemoral joint (PFJ) result in the patella lining up with the trochlear groove through which it articulates, rather than a line parallel to the floor. Although these planes may align in some cases, it cannot be assumed that they are the same.

This study thus proposes a methodology for determining patellar tilt angle that looks at the tilt dependent upon the apex of the patella itself. This may be more clinically relevant, as it describes the tilt with respect to the bone itself, rather than the tilt related to the ground. Further, the use of a line drawn from the lateral edge of the patella to the medial edge is advantageous because it is drawn independently of patellar morphology and corresponds most closely to the clinical evaluation of patellar tilt.

Patellar Resection Today

Advances in medical technologies and robotic-assisted surgery techniques have resulted in the development and implementation of robot-assisted TKA procedures, which allow for improved surgical precision and detailed surgical pre-planning^{43,44}. Despite these advancements, patellar resurfacing, patellar bone preparation, and component positioning are still completed without the assistance of a robot⁷. Standard protocol in the U.S. allows for these resection procedures to be completed using a freehanded technique, often with the aid of a commercially available cutting guide. Previous literature has investigated the clinical and radiological outcomes of patellar resection techniques used during TKA, specifically comparing the use of a cutting guide to freehanded cutting techniques⁴⁵. To this point however, there has not been any research examining the variation in cuts produced by distinctly different freehand techniques. Further, little has been done to qualify or quantify the differences between these freehand techniques. This presents the need for descriptive research to develop an understanding of this delicate balance between science and art in orthopaedic surgery.

Thickness and tilt are important quantitative metrics for patient outcomes, but the qualitative aspect of differing techniques has yet to be investigated. Thus, as the technique differs, it was in our interest to investigate the effects of the different techniques on the reproducibility of a preplan, measured by the difference in thickness and tilt between the preplan and execution.

Purpose

The primary goal of this work is to provide metrics for establishing the difference between unique resection techniques for surgeons to reduce variation between patellar resections in total knee arthroplasty due to technique. Further, we present a simple and easily reproducible measure for patellar tilt based on AP axial radiographs of the knee.

Objectives

Objective 1: Define qualitative descriptions of each unique resection technique.

H₁: There will be no qualitative differences between each resection technique.

Objective 2: Determine whether there are quantitative differences between each resection technique.

H₂: There will be no difference between the preoperative plans and postoperative resections completed using each individual technique.

Objective 3: Determine the ability of each technique to reproduce the pre-operative plan with the postoperative patellar resection.

H₃: There will be no differences between the pre-operative plan and the executed cuts completed using each technique.

CHAPTER II: METHODS

Participants

Surgeons were selected from the orthopaedic surgery group at Ascension Borgess Hospital. The surgeons participating in this study each agreed to participate by virtue of collaborating on the study procedures and were able to opt out at any time for any reason. Cases that did not support indications for resurfacing were not included in the study. Patients were selected in consecutive order by each surgeon within a specific timeframe, until the goal of 15 cases was met by each surgeon. This retrospective study was deemed exempt and approved by the WMed IRB (WMed-2021-0712) in February of 2021 (Appendix E).

The research took place at Ascension Borgess Hospital in Kalamazoo, MI. All data was gathered in patient rooms, radiology exam rooms, and orthopaedic operating rooms. Patient radiographs were obtained by each patient's surgeon and securely uploaded for the investigator's viewing. The surgeries were performed by three surgeons experienced in TKAs. The investigators had successfully completed the CITI program training and the participating clinicians had all previously participated in research at Ascension Borgess. The research timeframe set for this study was 4 months.

Measures

Patient Demographics

The following patient demographic data was collected and recorded from chart review after the procedure and post-op appointment had taken place: age (years), gender, weight (kilograms), BMI, height (centimeters), and operative side. The chart review was completed by a medical student at WMed with access to patient information. Patient data was deidentified, and a patient key was created to correlate with pre-operative and post-operative X-rays.

Patient X-rays

Patient X-rays were reviewed following standard protocol, between 3 and 9 weeks retroactively, dependent upon how far out each participating physician scheduled their post-op appointments. Sunrise view radiographs of the knee were required (Figure 5), providing an AP view of the knee.



Figure 5. Visual depictions of sunrise view images for radiographic analyses for ambulatory patients (a-b) and non-ambulatory patients (c-d).

Sunrise-type radiographs were taken following the clinical standard with the knee flexed and the midfoot kept parallel to the edges of the table wherever possible to avoid rotation of the knee.

Participating surgeons were instructed to mark their intended resection plane on the preoperative X-ray of each participating patient case following an adaptation of the methodologies of Anglin et al. (2019). This involved drawing a superimposed line onto the

surface of the X-ray, extending the line from the lateral side of the patella to the medial side of the patella (Figure 6).



Figure 6. Pre-planned patellar cut

This resection plane was considered their goal for the procedure. The patella was then surgically resected using one of three indicated techniques with no change to normal procedure. All surgeries were performed by one of three orthopaedic surgeons experienced in TKAs, each using their preferred patellar resection technique.

Patient postoperative X-rays were then gathered according to standard procedure at the scheduled post-op appointment. These films were accessed remotely by a WMed medical student and uploaded to a secure REDCap database for analysis.

Measurement Collection

Two observers independently measured each subject's patellar thickness and patellar tilt angle (via sunrise view) using a picture archiving and communication system (PACS version 11.0; Carestream Healthcare, Rochester, NY, USA) and a third-party measurement software (Analyzing Digital Images version Xojo; 2016). The protocol for these measurements can be found in Appendix A. Each measurement was repeated 2 times by each observer; the interval between measurements was 3 days. This methodology allows for the measure of both intra- and interobserver reliability between measurements. Measurements were calibrated based on the ruler present in the X-ray (present in Figure 6), determined by the PACS system and accurate to 1 mm. After calibrating the image within the Analyzing Digital Images (ADI) software, measurements were completed with the patella filling the entire viewing screen to optimize measurement precision.

Two observers were trained in these measurements by an orthopaedic surgeon experienced in reading and interpreting knee X-rays; the surgeon was approached if there was any uncertainty or discrepancies in measurement for determination of the apex of the patella or the resection plane. Measurements were taken by both observers and then repeated 3 days later. Intra- and inter-observer reliability was calculated using interclass correlation coefficients (ICC).

The complete dataset included both pre-planned and post-resection thickness of the patella, and pre-planned and post-resection patellar tilt angle for all patients. Surgical data was also recorded, noting the resection technique used and implant type.

Measurement of Patellar Thickness

Patellar thickness was measured for both pre-op and post-op X-rays, and was defined as the length of the line between the thickest portion of the patella along its midline, down to the resection plane. Measurements were all completed in the AP plane. This thickness was measured perpendicular to the preoperative planned resection plane or postoperative resection. The image below shows one such thickness measurement on a pre-op X-ray. If there were two thicker points along the patella, the thickness nearest the center of the trochlear groove was chosen for measurement (shown in Figure 7 below).

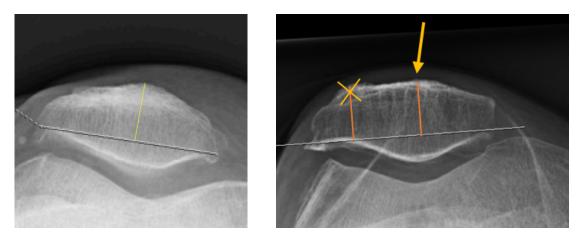


Figure 7. Patellar thickness measurements taken at midline.

Measurement of Patellar Tilt Angle

Patellar tilt was also measured for each pre-op and post-op X-ray. Patellar tilt was defined and recorded as the included angle (in the anterior to posterior plane) between the resection plane and a line drawn between the apex of the patella and the intersection of the resection with the lateral edge of the patella. For pre-operative X-rays, this meant using the planned resection plane as the first leg of the angle. For post-operative X-rays, the plane of the resection that was completed was used. The apex of the patella was defined as the thickest portion of the patella along its midline, or most centrally located over the trochlear groove. The images below show patellar tilt angle measurement on both a pre-op X-ray and post-op X-ray (Figure 8).

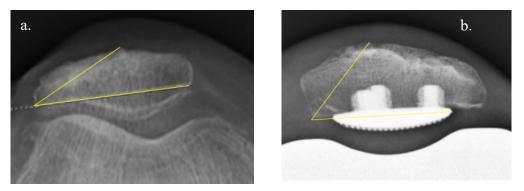


Figure 8. Patellar tilt measurement for both pre (a) and post-op (b) x-rays

Description of Resection Techniques

Each surgeon was approached and asked to develop a written description of their unique patellar resection technique, including (i) the landmarks that they use to define their resection cut, (ii) their initial insertion point with the oscillating saw, (iii) their management of the soft tissue surrounding the patella, and (iv) criteria for the completion of the resection procedure. The surgical techniques were written independently by each participating surgeon, working off a standard resection technique description.

Cutting Guide Technique A

The surgeon places the jig (example shown in Figure 9 below) at the level of the quadriceps, patellar tendon and capsular insertion points, removing any bone and/or cartilage that protrudes beyond that level. Rarely, if ever, will the surgeon resect at a deeper level than the capsular insertion. The cut is made through the resection guide and inspected using the fingers as calipers to be sure the residual thickness is sufficient. This is based on the surgeon's gestalt after having done about 5-6,000 procedures. If more resection is needed, the surgeon will move the jig and re-cut or peel back some of the capsule in order to re-position the jig. Using their fingers only without the aid of additional tools, the surgeon inserts the cemented components in order to minimize the chance of iatrogenic fracture and uses the clamp on the press fit components since these patients have better bone quality. After patellar insertion, the surgeon will rongeur off as much lateral bone overhang as possible to avoid impingement and if the patella will not track without holding it in place, an inside-out lateral release is completed before medial closure.



Figure 9. Example of a cutting guide used in patellar resurfacing

Freehand Technique B

The surgeon places two short kochers (Rochester-Ochsner forceps) on the medial patella, just inside the superior and inferior poles of the patella. The surgeon holds the kochers so the index finger is able to support the patella and the thumb is over the top to allow for eversion of the patella and stabilization of the saw blade. The patella is everted 90 degrees. Manual palpation of the posterior surface of the patella is completed to determine the cutting plane. The surgeon gauges overall patellar thickness: if there is extensive wear present, a full cm will not be resected. Expected resection thickness for the procedure is based on analysis of the preoperative X-ray(s) and CT scan. The cut originates on the subchondral surface of the medial facet, using an oscillating saw. The surgeon makes an initial cut to insert the blade a quarter of an inch into the bone to stabilize the saw blade before determining the cut plane. The cut exits the patella on the chondral surface at the end of the lateral facet. The first pass is conservative, cutting off additional bone when desired. Multiple passes may follow to ensure a flat, level surface. The procedure is complete when a resection plane with symmetric poles (both medially/laterally and superiorly/inferiorly) has been achieved. The goal is to resect 10-11mm, based on incoming patellar implant thickness.

Freehand Technique C

The patella is everted and the fat pad as well as surrounding synovial tissue is excised. The under surface is examined and deemed appropriate for patella resurfacing. X-rays are referenced in the operating room. The medial facet thickness is felt between the index and thumb. A medial start point is picked based on thickness of lateral facet, thickness of medial facet and the remaining bone planned. A wide oscillating saw is then used to complete the cut. Multiple passes may be made to ensure a flat, level surface. Once the cut exits just below the lateral facet cartilage, the cut is complete.

Statistical Methods

Quantitative data was reported as mean and standard deviation (SD). Descriptive statistics for each case were provided, listing maximum, minimum, median, and range for measurements. Both intra- and interobserver reliability of thickness measurements was analyzed using the intraclass correlation coefficient (ICC). An ICC less than .40 was considered to be poor, between .40 and .50 fair, between .50 and .75 good, and an ICC > .75 and above was considered to be excellent. A scaled reliability analysis was used to calculate the ICC values.

The resection thickness and patellar tilt angle values for each technique were compared using a paired-samples t test. This allowed for the realization of potential difference(s) present between planned resection planes and the resections completed for each case. Quantitative measurements for the three treatment groups were then compared using an analysis of variance (ANOVA). This was done to determine whether the change in thickness was due to the surgeon and/or technique associated with the case.

Linear regression analysis was completed to determine the proportion of variation in post-op thickness/tilt that would be accounted for by the model. This was done in an effort to measure how well pre-op planned thickness and tilt measurements would serve as a predictor for post-operative thickness and tilt.

Significance was assessed at α =0.05. All statistical analysis were performed through a combination of Microsoft Excel and MiniTab (Version 19).

Prior to enrollment in the study, an *a priori* power analysis was conducted using radiographic data from a study completed by Camp et al. in 2015⁴⁵. Assuming that similar variability in resection asymmetry and cut thickness would be observed in this study, a sample of 54 repeated measures would provide 95% power to detect a difference in mean cut thickness of at least 0.61 mm (alpha=.05, two-sided test). The sample size calculation was performed using G*Power 3 (version 3.1.9.6).

CHAPTER III: RESULTS

Patient Demographic Summary

Of the 60 patients enrolled in the study, data was recorded and reported for 45; one set of 15 patients was removed due to incomplete data collection. The distribution of gender for included patients was 19 (42.2%) male patients and 26 (57.8%) female patients. There were 21 left knees (10 male and 11 female) and 24 right knees (9 male and 15 female). Table 1 summarized the demographics for the patients.

	Age (yrs)	Height (cm)	Weight (kg)	BMI (kg/m ²)
Average	64.22	167.86	97.65	34.66
St Dev	10.36	11.79	23.22	7.35
Median	65	165.62	98.2	34.1
Max	85	189.59	153.4	48.8
Min	43	140.73	56.05	20
Range	42	48.86	97.35	28.8

Table 1. Patient demographic descriptive statistics

Inter- and Intra-Class Correlation (ICC)

The resulting ICC values are shown below in Table 2. The 2 repetitions completed by Observer 1 were found to have an ICC value of .98 for patellar thickness and .97 for patellar tilt. The 2 repetitions completed by Observer 2 were found to have an ICC value of .99 for patellar thickness and .94 for patellar tilt. These repetitions were then averaged to create a dataset including one average thickness value and one average tilt value for each observer. These values resulted in ICC values of .98 for patellar thickness and .81 for patellar tilt, measures of interobserver reliability.

Table 2. Intraclass correlation coefficients for observers 1 and 2

	PATELLAR THICKNESS (cm)	PATELLAR TILT (deg)
ICC Observer 1	0.984	0.973
ICC Observer 2	0.992	0.949
ICC between Observers	0.983	0.815

Pearson's Correlation

Pearson's correlation values were calculated to establish the correlation between individual repetitions both within and between observers. Obs 1 Rep 1 refers to the first repetition completed by observer 1, and Obs 2 Rep 1 refers to the first repetition completed by observer 2 respectively.

	Obs 1 Rep 1	Obs 1 Rep 2	Obs 2 Rep 1	Obs 2 Rep 2
Obs 1 Rep 1	1			
Obs 1 Rep 2	0.985	1		
Obs 2 Rep 1	0.986	0.987	1	
Obs 2 Rep 2	0.982	0.985	0.992	1

Table 3. Pearson's correlation for patellar thickness

Table 4. Pearson's correlation for patellar tilt

	Obs 1 Rep 1	Obs 1 Rep 2	Obs 2 Rep 1	Obs 2 Rep 2
Obs 1 Rep 1	1			
Obs 1 Rep 2	0.972	1		
Obs 2 Rep 1	0.769	0.835	1	
Obs 2 Rep 2	0.773	0.829	0.948	1

Students T-Test Results

Comparisons were made between the pre-operative plans and post-operative resections made by each individual surgeon. This data is shown in tables 5, 6, and 7 below.

	THICKNESS (cm)	TILT (deg)
Average	-0.335	-5.85
St Dev	0.256	3.307
T-Stat	-12.410	-16.781
P-Value	<0.001	<0.001
Alpha	0.05	0.05

Table 5. T-test comparison of pre-op and post-op measures: Surgeon A

Table 6. T-test comparison of pre-op and post-op measures: Surgeon B

	THICKNESS (cm)	TILT (deg)
Average	-0.373	-4.812
St Dev	0.135	3.557
T-Stat	-26.219	-12.832
P-Value	<0.001	<0.001
Alpha	0.05	0.05

Table 7. T-test comparison of pre-op and post-op measures: Surgeon C

	THICKNESS (cm)	TILT (deg)
Average	-0.376	-5.93
St Dev	0.281	4.844
T-Stat	-12.680	-11.614
P-Value	<0.001	<0.001
Alpha	0.05	0.05

Box-plots were generated to offer a visual representation of the data spread found in these analyses. Outliers were defined as anything beyond 1.5 IQR, and denoted as an asterisk. These are displayed in Figures 10 through 12 below.

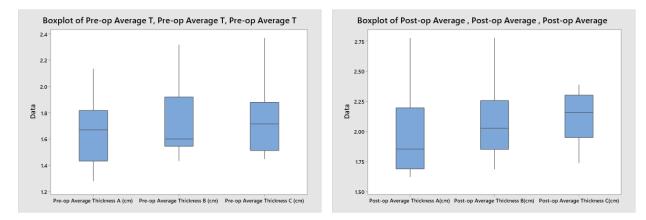


Figure 10. Preoperative and postoperative patellar resection thickness box plots for all surgeons

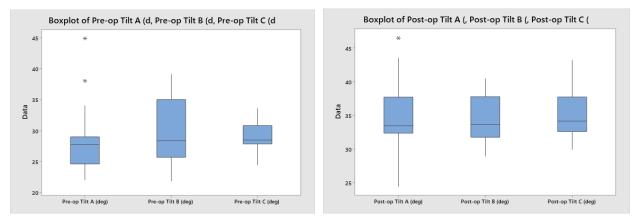


Figure 11. Preoperative and postoperative patellar tilt angle for all surgeons

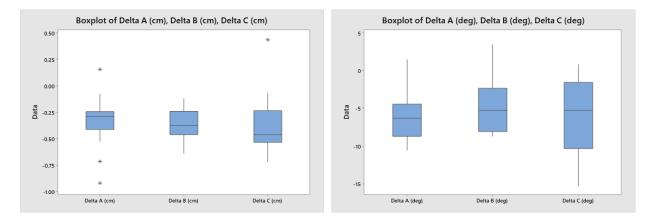


Figure 12. Difference in thickness and tilt angle from pre-op to post-op for all surgeons

One measurement (patellar tilt associated with Surgeon A) did not meet the assumption for normality, and a nonparametric Wilcoxon test was run to confirm the significance of the findings.

Table 8. Difference in tilt angle from pre-op to post-op for Surgeon A

	Patellar Tilt (deg)
Wilcoxon Statistic	3.000
Median value	-6.35
P-Value	0.001

Regression Analysis

Simple linear regression was run on the patellar thickness and patellar tilt data. The sample size included 15 patients each for the individual surgeons. Analyses were run on each surgeon individually, to determine the ability to predict post-op effective cut thickness and tilt from pre-operative plans as above. This data is shown for each of the 3 participating surgeons in Table 9 below.

Surgeon A	Thickness (cm)	Tilt (deg)
R2	0.452	0.711
Coefficient	0.929	0.786
P-Value	0.006	<0.001
Surgeon B	Thickness (cm)	Tilt (deg)
R2	0.813 0.	557
Coefficient	1.044 0.	518
P-Value	<0.001 0.	001
Surgeon C	Thickness (cm)	Tilt (deg)
R2	0.027	0.006
Coefficient	0.129	-0.111
P-Value	0.555	0.784

Table 9. Regression outputs for Surgeons A, B, and C

Scatterplots for each regression equation are located in Appendix B. Scatterplots referencing the raw data with preoperative planned thickness plotted (x-axis) vs. post-operative resection thickness (y-axis) can be found in Appendix D.

ANOVA Analysis

A one-way ANOVA was run on both thickness and tilt measurements for each surgeon pre-operative and post-operative measures. The p-values are reported below in Table 10.

Table 10. ANOVA p-values for thickness and tilt values

	P-VALUE (sig. < .05)
Delta Thickness (cm)	0.87
Delta Tilt (deg)	0.69

CHAPTER IV: DISCUSSION

The major findings of this study indicate that there were qualitatively defined differences between the three unique resection techniques included in this study. As all measures recorded excellent ICC values, we were able to determine that there were statistically significant differences between the average patellar thickness and patellar tilt values recorded for cases completed by each surgeon. Additionally, no one technique was found to accurately and repeatedly execute the pre-operative plans created by each participating surgeon. This resulted in all resections being completed at a more conservative level than was pre-planned by the surgeons.

Patient demographic means and standard deviations closely aligned with those presented in the literature, providing an accurate sampling of the demographics operated on during TKA. There was adequate representation of both right and left knees within both gender groupings. Median values for all patient demographic indicators were nearly identical to the mean of the set, suggesting that there was minimal skewing of the sampled population.

A total of 45 patients were included in this study with 15 cases provided by each participating surgeon. This resulted in a total of 90 X-rays for measurement, including the determination of both patellar thickness and patellar tilt for each preoperative and postoperative X-ray (180 measures completed). These measurements were repeated twice by each observer, resulting in a grand total of 360 measurements (180 measures in duplicate).

Intraclass Correlation Coefficient (ICC) values were calculated to determine the interand intra-observer bias for each measurement. ICC is commonly used to assess the reliability of ratings within observer repetitions and between different observers. The variability of different ratings of the same subject is compared to the total variation across all ratings and all subjects. Put simply, the ICC value shows the degree of agreement between observers. All ICC values found by comparisons within and between observers were greater than or equal to .75, resulting in excellent ratings in all cases. The 2 repetitions completed by Observer 1 were found to have an ICC value of .98 for patellar thickness and .97 for patellar tilt. The 2 repetitions completed by Observer 2 were found to have an ICC value of .99 for patellar thickness and .94 for patellar tilt. Both values were > .75 and therefore represented an excellent intra-observer ICC rating. These repetitions were then averaged to create a dataset including one average thickness value and one average tilt value for each observer. These averaged values resulted in ICC values of .98 for patellar thickness and .81 for patellar tilt. Falling in the excellent range (> .75), these values showed that the observations were reliable both between repetitions for the same observer, and between observers. These strong reliability metrics offer support for the consistency in the methodology, despite measures that involved subjective decision-making, suggesting that the measurement protocol put forth was repeatable. Thus, as the measures were considered both repeatable and precise, the values for thickness and tilt were averaged together to create one dataset upon which to run the remainder of the statistics.

Pearson's correlation was also run to better understand the relationship between individual repetitions completed by the 2 observers. This measure was able to provide more insight into the relationship between each observer's individual measures, specifically between measures of patellar tilt which reported slightly lower ICC values.

All values presented for measures of thickness were higher than .98, providing further evidence of a strong relationship between observer repetitions and inter-observer comparisons. The values for patellar tilt showed more variation, with individual correlation between observations coming in at .97 for observer 1 and .95 for observer 2. Despite the strong correlations within observers, the correlation values calculated between observers were lower. For patellar tilt, correlations between the first and second observer's measurements ranged from .77 between the first set of measurements, to .83 between the second set of measurements. This shows that although their individual accuracy between measurement repetitions was high, the measurements performed by each observer showed slight, but clinically insignificant, differences. This may result from a subjective decision regarding (i) which point to consider as the apex of the patella, (ii) designation of the lateral periphery of the patella, and/or (iii) determination of the plane of resection shown in the post-operative X-rays. Paired Student T-Tests were run alongside the ICC measurements to determine whether measurements made by each observer were statistically different from each other. The results from the observer repetition T-test mirrored that of the ICC and Pearson correlation conclusions, reporting p-values of .2-.9 for measures of thickness and tilt. All measurements failed to reject the null hypothesis that there is a significant difference between the means of each repetition for each observer.

Paired T-tests were also run to discover if there was a difference between the preplanned thickness and tilt values and the respective postoperative resection values. The p-values for each measure were significant, with values reported well below the cutoff of $\alpha =0.05$. Strong rejection of the null hypotheses provided evidence for a significant difference in pre- and post-operative thickness and patellar tilt values. This suggests that planning the patellar resection procedure using the methodology proposed by this work may not relate to post-operative resection as closely as was hypothesized. Given the significant difference, it may be beneficial to investigate different methods for preplanning. This could involve additional X-ray views of the knee, and/or a 3-D rendering of the knee via CT scans to more accurately pre-plan the resection.

The box-plots generated for these T-tests provided additional visual representations of the distributions. Notable observations were found in the range provided in the plots. While in some cases the medians were similar, the range differed greatly. When examined visually, this suggests that there is a difference in precision between techniques used. For example, the boxplot representing post-operative thickness showed Surgeon A reporting the smallest medial thickness with a wide range in values, Surgeon B showing a slightly higher median and comparable range, and Surgeon C reporting the thickest median patellar measurement with a small range in values. This suggests that Surgeon C's completed resection thicknesses were most uniform, though this would be dependent upon the patient anatomies Surgeon C encountered. In addition, the boxplot representing post-operative patellar tilt maintained nearly identical minimum (Q1), median, (Q2), and maximum (Q3) values, while range varied across surgeons. Patellar tilt values mirrored the ranges reported by thickness, exhibiting the relationship between patellar thickness and tilt based on the measurements put forth by this study.

Also of note, are the negative values reported for all thickness and patellar tilt averages and T-stat values. These negative values tell us that all of the surgeons completed resections in which the native thickness retained was greater than the pre-operative plan. In the same manner, the postoperative tilt angles achieved by each surgeon were all significantly greater than the planned resection angle, which agrees with the above statement regarding increased thickness of retained native patellar bone. Clinically, surgeons are more likely to leave a thicker native patella due to the decreased risk for patellar complications. Removing too much patellar bone could result in a number of undesirable effects, ultimately including patellar fracture, which would be detrimental to the patellofemoral joint. While the risk of patellar overstuffing must also be considered, these findings reflect the conservative nature of the cuts made by the surgeons when compared to their pre-plans.

All measures for comparison were assumed to be normal. However, the p-values calculated for the Anderson-Darling test suggest that the measurements for patellar tilt associated with one surgeon were not from a random normal distribution. This subset could appear to be non-normal for several reasons, including subjectivity in measures as previously stated, as well as atypical patient anatomies. It is therefore necessary to exercise caution when interpreting the results generated from these measures, as the assumption for normality was not met for all cases. However, a nonparametric test was run, producing a similarly significant result (p-value from Wilcoxon test: .001).

The results of the regression analysis describe the degree to which pre-operative patellar thickness could be used to predict post-operative patellar thickness, and the degree to which pre-operative patellar tilt could be used to predict post-operative patellar tilt. Simple linear regression was run to determine the strength of association between preoperative planned resections and postoperative completed resections. At a significance level of $\alpha = 0.05$, the predictive variables for patellar thickness and tilt were statistically significant for the surgical techniques used by surgeons A and B. This postulates a relationship between pre-planned and post-operative patellar thickness/tilt data for the techniques used by surgeons A and B. It is worth noting that it would be expected that if there is a relationship found between thickness measures, there should also be

a relationship found between tilt measures as tilt is inherently dependent upon thickness of the patella.

In the confines of this study, when examining whether it is possible to predict the postoperative thickness or tilt metrics, we see that some surgeon's preplans are better predictors than others. Surgeon B's thickness R² value was .813, resulting in the interpretation that 81.3% of the post-op thickness could be explained by pre-op thickness. Likewise, Surgeon A's R² value for patellar tilt was .711, allowing us to conclude that 71.1% of the post-op tilt could be explained by pre-op tilt. Conversely, both patellar thickness and tilt R² values reported for Surgeon C were miniscule, with non-significant p-values, accounting for the negligible relationship between preoperative and post-operative values. It is important to note that in an ideal situation, the p-values for all measures would be significant, and the regression coefficients for each metric would be approaching a value of 1. This would mean that for every one unit increase associated with planned patellar thickness/tilt, there would be a corresponding unit increase in patellar resection thickness/tilt, suggesting that the patellar resection measurements for pre-op planning and postop resections were the same.

One-way ANOVA was used as an additional method to determine whether there was a significant difference between pre-operative plans and post-operative completed resections Metrics for delta thickness and delta tilt were used because the delta values block for the variation due to individual patient anatomy. Both cases reported p-values that were well above the value for significance, resulting in a failure to reject the null hypothesis that all means were equal and acceptance of the alternate hypothesis that at least 2 groups were different. This means that there was no significant difference in accuracy of pre-plan execution between the surgeons, suggesting that technique alone does not impact the ability to reproduce a pre-plan, and resections completed using a freehand technique vs. cutting guide are not statistically different.

Means and standard deviations were reported for each surgical technique: i.) difference in thickness between pre-op and post-op, and ii.) differences in tilt between pre-op and post-op. These values mirrored the discussion posed from the reported means and SDs in the paired T-test, concluding that more native bone was retained than planned for in the pre-op X-rays.

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It is important to note that this study is measuring the differences achieved by the techniques utilized by each surgeon, rather than the surgeons themselves. There will always be variation due to surgeon individuality, which highlights the artistic component within the science of surgery.

When comparing the techniques qualitatively, the following findings were realized. Across surgeons, some of the notable similarities were: (i) mental pre-planning for the expected resection plane was based on review of the X-rays, (ii) intended resection thickness was determined intraoperatively, using the finger and thumb as calipers to ensure residual thickness would be sufficient, and (iii) the goal for the resection plane was an even, flat surface to affix the patellar implant to.

Notable differences were found between the technique employing the use of a cutting guide and the two freehand techniques; the surgeon using the cutting guide reported establishing the thickness and plane of the cut, then replacing the jig only if more resection was necessary. The surgeons completing the cut using a freehand technique both mentioned completing a conservative cut or "first pass" before shaving off more material to ensure a flat, level surface at the determined thickness. This may be due to the time associated with removing and replacing the jig compared to the ease of completing consecutive cuts with a freehanded approach; the cutting guide placement was meant to achieve the intended cut in one-go, while the freehanded techniques involved intentionally gradual removal of tissue.

Between the freehand techniques, the surgeons noted different definitions for the entry point of the oscillating saw on the patella but referred to the same metrics for determination of completion of the cut. This highlights the variability in freehand resection, while also solidifying similar clinical (tracking, alignment, thickness, angle, etc.) goals for patellar resection.

These results may differ with the inclusion of a larger sample, examining the preplanning techniques of additional surgeons on a significantly larger sample of patients. Although the 15 cases that we included were representative of a random sampling of TKA patients, it is likely that a larger sample would strengthen (or potentially refute) the findings and reveal additional considerations.

Despite the inclusion of three unique patellar resection techniques in this study, no one technique was found to accurately reproduce the pre-operative plans made by the surgeons. This discrepancy could lie with the surgeons due to the difficulty in noting an intended resection plane for a bone of variable anatomy on a 2D X-ray, or due to the subjective nature of the measures. In addition, there was no significant difference between freehand and cutting guide techniques as was the focus of our objective. Neither tilt nor thickness showed anything to suggest that one technique could more accurately execute a preplan.

The measurement of patellar tilt was dependent on the establishment and repeated consideration of the apex of the patella. This point can be subjective, with some patient patellae showing few landmarks on an axial view X-ray. Further, patellar tilt is measured as a function of the width of the patella: in cases where the apex has been shifted, the angle would be significantly larger (if shifted laterally) or smaller (if shifted medially). This method for assessing patellar tilt can however be easily and inexpensively used in routine clinical investigation to better understand the tilt of the patella based on an internal reference point: the apex of the patella.

A number of factors may influence the technique that a surgeon utilizes in the operating room. It is likely that surgeons choose a technique that is both comfortable and allows them to maintain control of the patella and oscillating saw throughout the procedure. This choice may be influenced by their unique hand dimensions, stature, and other anthropometric factors. For example, the wrist biomechanics may change based on the height of the surgeon, the height of their workspace (operating table), and the distance from their workspace. These factors are also dependent on the anthropometries of the rest of the surgical staff; some shorter statured surgeons or first-assists may use stools to keep everyone involved in the procedure at a comfortable working height. This height, and the wrist biomechanics in turn, may change throughout the total knee procedure as the task needs alternate between physically demanding (i.e. reaming and pounding with a mallet) and precision (i.e. removal of the fat pad, closing the incision) tasks. The

majority of the patella resection component of TKA involves precision tasks, meaning that ideal biomechanical conditions for the surgeon would include operating on a patella that is just above elbow height and within the normal reach envelope of the surgeon, maintaining neutral wrist postures. This would therefore look different for surgeons of different heights in different operating environments and may lead to some of the variation we see between techniques.

It has also been suggested that surgeons prefer to use the technique(s) that they were trained with, making small adjustments along the way as they transition into their own practices. During residency, surgeons-in-training are taught by their attending physicians, who likely pass on the technique that they have found most accurate and repeatable throughout their years of experience completing this short, but highly technical procedure. All of these influences factor into the technique that a surgeon uses to complete patella resections.

The assessments made by this study for patellar thickness and tilt are not part of the standard procedural protocol for TKAs; the addition of these metrics would provide clinical applications that would both benefit surgeons and provide teaching opportunities for medical students and residents. Surgeons would be able to refer to their quantitative results in an effort to determine how near their resections were to their planned resection planes, noting any differences and potentially using the feedback to make changes to their pre-operative planning or techniques as a result. Additionally, developing descriptions for unique techniques using detailed qualitative language could result in definitions that could be sorted and published for resident training purposes. These written descriptions of techniques could be read and referenced by surgeons-in-training, looking for slight changes in technique that would be helpful in their own development. Feedback on patellar thickness and patellar tilt achieved would also allow for the retrospective study of any outliers or complications on a case-by-case basis. This would allow surgeons and residents alike to refer back to their plans and resections to determine whether any discrepancies could have factored into patella-related complications post-TKA.

Limitations

The main limitation in this study is the lack of patient outcome data. Although we are able to speak to the repeatability and predictability of three separate techniques, these conclusions lack clinical significance that would be drawn with correlated outcome data. Due to time constraints, this information was not gathered within the scope of this project, but a secondary retrospective study could be completed to correlate these case measures to patient outcome in the future.

General observations regarding difficult associated with measurements were recorded by the observers. It was particularly difficult to take measurements on the post-operative X-rays of knees that received all-polyethylene implants in comparison to metal-backed patellae which had a defined posterior resection plane. The poly implant materials do not show up on the film, resulting in undefined edges of the patella where the implant would be located (Figure 13). This likely introduced a small degree of error to the measurements of both patellar thickness and tilt for the 8 patients (represented in each of the surgeon's datasets) receiving these implants and increased the potential for subjectivity of the measure in these cases. Based on the measurement protocol found in Appendix A, observers were instructed to complete post-operative measurements for both thickness and tilt based on a line that intersects the lateral-most and medial-most edges of the patellar implant (along the anterior surface of the implant). This may have resulted in measurements that were 1-2mms too thick, adding to the conservative findings of the completed resections

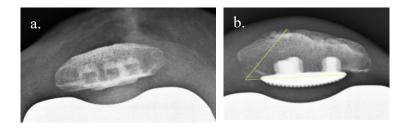


Figure 13. There was a noticeable difference in the ability to determine patellar thickness between all-polyethylene implants (a) and metal-backed implants (b).

Further, many of the patellae measured would fall into Wiberg classifications of 2 or 3. Due to the greater degree of patellar asymmetry, it was more difficult to establish a reproducible thickness measure that spanned from a centrally located apex (defined within the context of our study as the thickest point near the midline of the patella) to an intended or completed resection plane.

An additional limitation may be found in our measure of patellar tilt, since the tilt angle was inherently dependent upon width of the patella, rather than an independent reference point. It was also assumed that the apex found in the preoperative X-rays would be differentiable in the post-operative X-rays and used for the consideration of patellar tilt angle. Some measurement limitations associated with this study would stem from the inability to ensure that the same view of the apex of the patella could be found in both pre-operative X-rays and post-operative X-rays. It is likely that slight discrepancies in sunrise view technique would result in skewed images.

It was later identified after the conclusion of the study that there may have been surgical residents completing some of the resections included and measured for Surgeon A; these resections would all have been completed using a standard cutting guide, but variability may have been introduced by an additional user with less experience.

Future Directions

First and foremost, we would like to follow up with all of the included patients, gathering post-operative knee scores, outcome information, and recording any adverse outcomes related to the patellofemoral joint. Basic patient outcome data for each of these procedures will be gathered in the year to follow, allowing for further analysis including the relative success of the procedures. The occurrence of any complications will be noted and those concerning the patella will be discussed in a secondary work.

It is suggested that developments in pre-planning utilizing the three-dimensional view of a CT scan would offer significant advantages to the definition of resection planes by way of radiographic analysis. The additional views and diagnostic quality provided by a 3D image would eliminate a majority of the difficulties brought to light through our measurement of the planned and executed resection plane, allowing surgeons to view multiple visualizations and planes of the knee. The rising prevalence of robot-assisted procedures for the completion of TKA should make a study of this nature possible, with required pre-operative CT scans readily available as a necessary preparatory step in the standard operating procedure. Approval, consent, and funding would have to be secured before considering taking additional post-operative CTs for a comparison mirroring our methodology. The higher fidelity images in the patient CT scans may also increase the accuracy and repeatability of both the thickness and patellar tilt angle measurements.

A larger sample size would also be beneficial, taking into account a greater variety of techniques used by orthopaedic surgeons; clinicians using unique freehand techniques, as well as those utilizing a cutting guide or reamer could be included, recording a larger number of cases for each resection type. The study could also be re-worked to follow a case-controlled matched design, in which surgeons would include patellae with similar anatomies and thicknesses that had been pre-screened by the investigators. This would allow for a study design in which surgeons would operate on a set number of Wiberg type I, II, III, and Baumgartl (type IV) patellae to look at the differences in technique achieved by surgeons operating on similar sized/shaped patellae. This kind of study could also be simulated, using high-fidelity models to show the results in the case of surgeons operating on the same patellae using their unique techniques.

CHAPTER V: CONCLUSIONS

It has been established that patellar resection is considered one of the most challenging parts of the total knee arthroplasty procedure, due to the variety of biomechanical and technical needs that must be identified and balanced intraoperatively. For this reason, significant clinical consequences can result from small changes to thickness or patellar tilt during the procedure. This cut is both difficult to plan, and difficult to execute. Our results reflect this notion within the literature, finding no significance in the ability to effectively pre-plan patellar resections using three unique approaches.

Clinically, a method for accurately reproducing pre-operative plans has not been established. Our study thus attempted to use a combination of radiological assessment tools to identify the differences between pre-operative plans completed by surgeons and their surgical outcome. Assuming that the methodologies for determining patellar thickness and an internallyreferenced metric for patellar tilt produced accurate values, our study highlighted key similarities and differences between pre-operative plans and completed resections. In actuality, we are limited to concluding that our measurements were merely accurate and precise, independent of their true clinical relevance or patient outcome. Further work will be done to establish their relevance based on clinical definitions for patellar thickness and tilt and propose modifications to increase the clinical applications.

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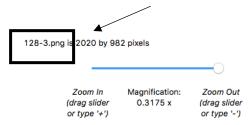
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APPENDIX A.

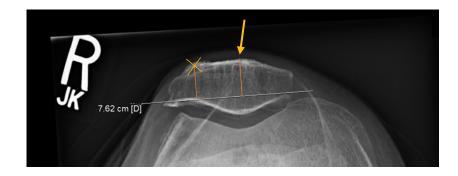
Measurement Protocol

Tips and Design of Experiments

- 1. It may be best to work on two screens if you have the option: one for the excel sheet, and one for the ADI measurement software (split-screen may work just as well it doesn't work on my Mac).
- 2. Save the folder containing all of the pre/post-op files to your desktop or your documents on your computer. It will be easier to import the photos into ADI.
- 3. Your list of X-rays for measurements are ordered randomly, which is reflected in your individual spreadsheet. Make sure that the file numbers and Excel spreadsheet match up before entering measurement data.
 - a. if you need to check which file you are looking at, you will find the file name right above the magnification toggle near the bottom of the screen (below)



- 4. Save your excel spreadsheet intermittently; we don't want to have to repeat any measurements.
- 5. If ADI prompts you to decide whether to "trim" the photo you are importing, select No.
- 6. If ADI asks if the image is part of a time series, select **Reset Settings**.
- 7. Pan around the image by using the arrow keys or holding the SHIFT key and clicking and dragging the image.
- 8. If you have to decide between two "thickest points" choose the one that is most centered on the patella as a whole.



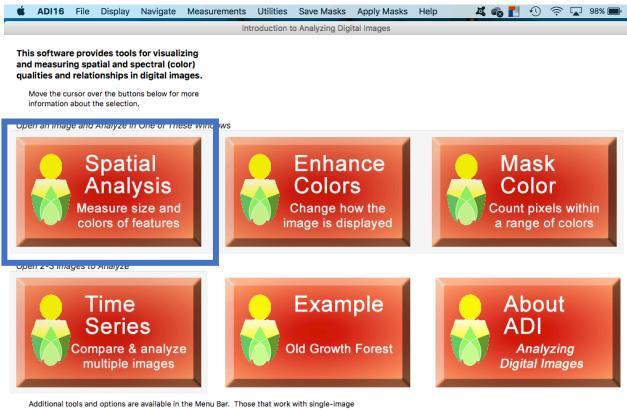
- 9. Measure to the lateral edge of the patella
 - a. left-hand corner on R knees
 - b. right-hand corner on L knees

Opening Files and Preparing for Measurements:

- 1. Open the excel file entitled "YOUR LAST NAME_Radiographic Analysis_Measurements.xlsx" that was shared via OneDrive or flashdrive.
- 2. Open the folder entitled "YOUR LAST NAME_Radiographic Analysis_Files"
 - a. Your files will be randomly ordered, in a range from 01-60.

Preop files will be designated as P01, P02, P03,..., P60 Postop files will be designated as 01, 02, 03,..., 60

- 3. Open ADI application in second screen.
 - a. Download ADI version XOJO (2016) from https://www.umassk12.net/adi/
 - b. Save to your desktop
 - i. if having trouble opening the software on a Mac: find the application in Finder, right-click and select "open" and it should run
 - c. Open ADI16 (shown below)



Additional tools and options are available in the Menu Bar. Those that work with single-image analysis (Spatial Analysis, Enhance Colors, and Mask Colors) are marked with an icon of a single image. Those that work with the time series of images are marked with an icon of multiple images. Some options work with both single and multime images and so are indicated by having both icons.

If you select a menu option that doesn't work for your type of analysis, nothing will happen.

- d. Select "Spatial Analysis" boxed above (double-click)
- e. It will automatically open your documents so that you can select an image to open
 - i. choose the first one in the folder and hit "open"
- 4. Calibrating your file
 - a. a box "select method of pixel size calibration" will pop up, and you should select the option "scale present in image". This will allow you to calibrate the measurement tools based on the ruler in the X-ray files.

Select Method to Calibrate the Pixel Size
Click if you know the size of the pixels, which is common for orthophotographs from aerial reconnaissance and satellite imagery.
Click if there is a linear scale located in the image. This includes photographed objects of known length (ruler, penny, clipboard, etc.) or a distance scale on digital maps or satellite imagery.
Click if there is no way to know the size of the pixels in the image.

- b. The x-ray file will open. Make sure to select "hide line circles" as these can impede your view of a clean end of the line you are using to calibrate the photos.
- c. Zoom in as far as you can while comfortably viewing the ruler (there are instructions on screen for how to zoom/pan)
- d. You can now click and drag to create a line (yellow) that goes from one end of the ruler to the other
 - i. enter a value for "length of line drawn": 10
 - ii. enter a value for "unit of length": cm

you may have to use less of the ruler, as some of the ruler was cut off in a few of the images; if you can only see 9 tick marks, type in 9cm instead

iii. click "done" and your image will be calibrated for measurement.



Pre-Op X-Ray: THICKNESS

- 1. Now that you have calibrated your file, you are ready to take the necessary measurements
 - a. select "line tool" from the "select measurement tool dropdown"
 - b. zoom in until the patella takes up the whole screen
 - c. click and drag to take a measurement
 - i. take a measurement for the thickest point at the center of the dome enter length of line value in excel on second screen

Ex: measuring thickest point at center of dome with arrow pointing to measurement readout

	Spatial tools measure the color and size of features in digital images.	Spatial Analysis 🔓 Enhance Colors 🔓 Mask Colors Time Series
	Color enhancement to use - Change in Display Menu	
	Original Image	. · · · · · · · · · · · · · · · · · · ·
	Line Tool	
	Click and drag to create a line. Use the blue and red arrows below to move the corresponding end one pixel, or click and drag either end.	m [D]
	Select Measurement Number 1 3	
	Hide Tool	
	Select Color Erase Tool	
	Show Tool Circles	
	Pixel Position Adjust	
enter this	X Y Start Point 352 299	
value in exce	l Stop Point 344 345	
	Number of Pixels 47 Length of Line 1.7 cm Color Intensity (%)	
	Average Red 57.431	130-1.pdf is 792 by 612 pixels
	Average Green 57.431	
	Average Blue 57.414	When zoomed in, pan around the image by using the arrow keys or
	Average Color 57.425	Zoom In Magnification: Zoom Out holding the SHIFT key and clicking
	Intensities of colors range from 0%, meaning none of the color is present, to 100%, when maximum color is present.	(drag slider 2.5000 x (drag slider and dragging the image. or type '+') or type '-')

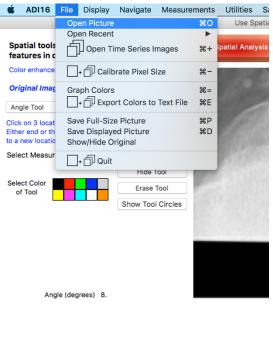
ANGLE

- 2. When you have finished the thickness measurement, you are ready to take an angle measurement (shown on next page)
 - a. select "angle tool" from the "select measurement tool dropdown"
 - b. zoom in and move the photo until it is in an optimal view
 - i. click along the top periphery of the patella, where your thickest point/apex would be found, and drag your cursor to the bottom lateral side of the patella where the planned resection line intersects, drawing the first leg of the angle
 - a. click at the intersection point and drag along the planned resection to draw the second leg of the angle in line with the drawn resection plane enter angle value (boxed in blue) in excel on second screen

make sure that you are measuring lateral side on both R and L knees



3. Move onto the next image by selecting "File" in the top left-hand corner of your computer, then "Open Picture" and selecting your next image.



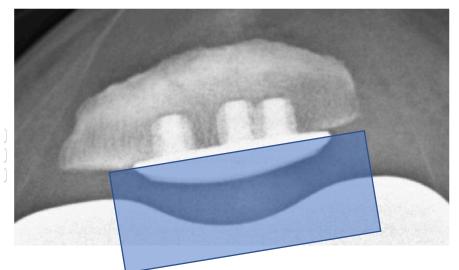
130-1.pdf is 792 by 61



Post-Op X-Ray:

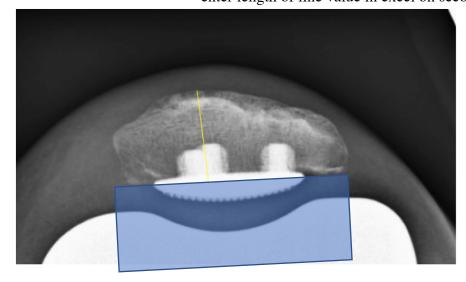
1. Repeat measurements with slight alterations, using a sticky note on your screen to establish the resection line.

place the sticky note between the edges of the patellar implant, lining the ends up with the widest point of the implant (shown below with a partially transparent "sticky note" for reference)



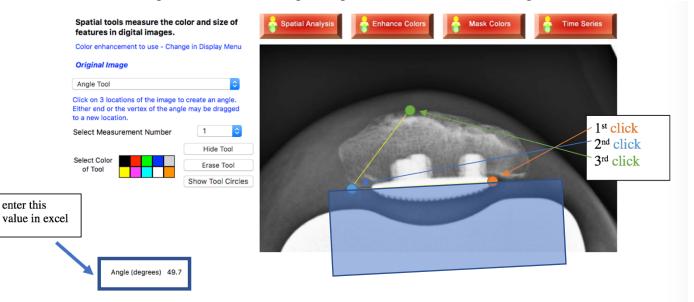
Thickness Measurement:

- 1. Calibrate your file based on the 10cm ruler
 - a. select "line tool" from the "select measurement tool dropdown"
 - b. zoom in until the patella takes up the whole screen
 - c. click and drag to take a measurement
 - i. take a measurement from the <u>thickest point at the center of the dome</u> to the top of the sticky note (even with the widest point of the implant) enter length of line value in excel on second screen

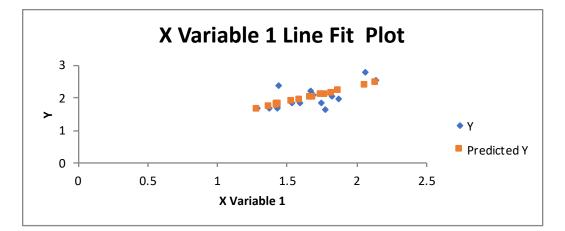


Angle Measurement:

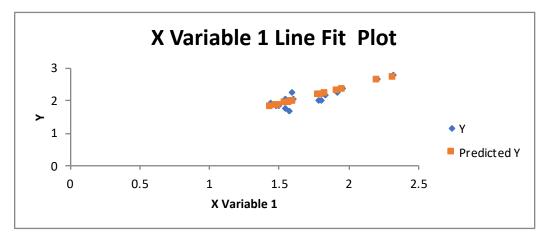
- 1. When you have finished the thickness measurement, you are ready to take an angle measurement (shown below)
 - a. select "angle tool" from the "select measurement tool dropdown"
 - b. zoom in and move the photo until it is in an optimal view
 - i. draw the first leg of the angle by clicking on the right-hand side of the implant at its widest point, dragging the cursor through the left-hand side of the patella and extending the line through until it is even with the edge of the left side of the patella
 - ii. click and drag the second leg of the angle up to the top periphery of the patella at the thickest point/apex and click to finish the angle measurement

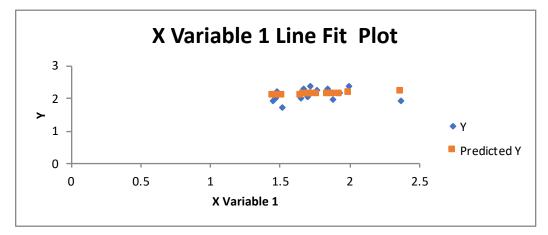


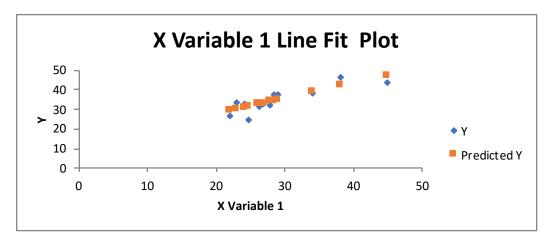
APPENDIX B



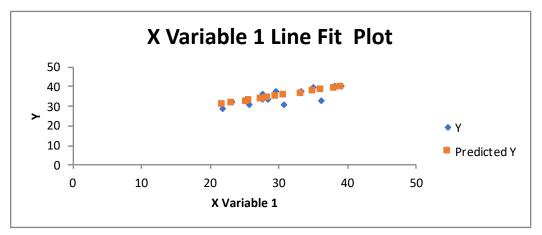
Regression Scatterplots: Thickness by Individual Surgeon

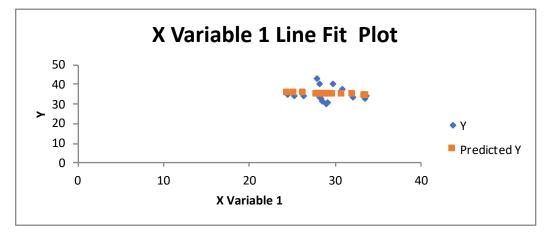






Regression Scatterplots: Patellar Tilt by Individual Surgeon

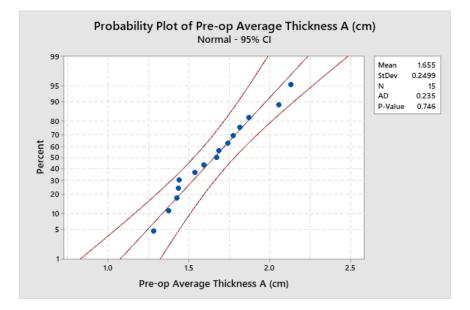




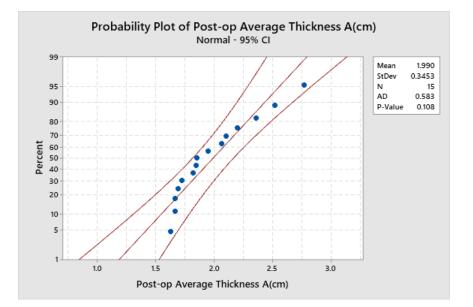
APPENDIX C

Probability Plots: Surgeon A

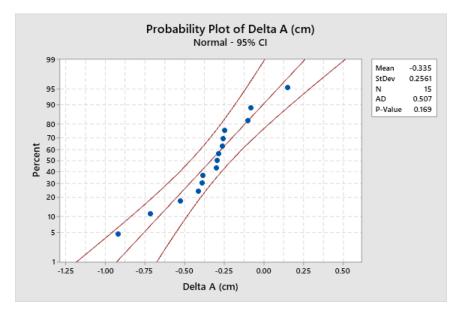
Pre-operative Average Thickness



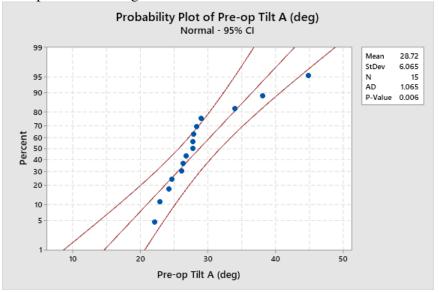
Post-operative Average Thickness



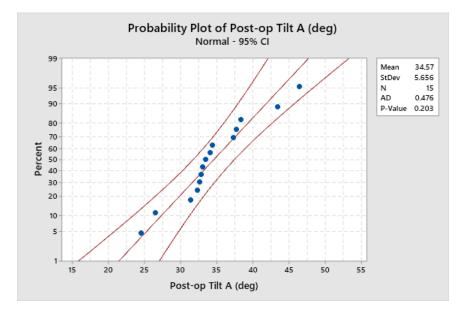
Delta Thickness



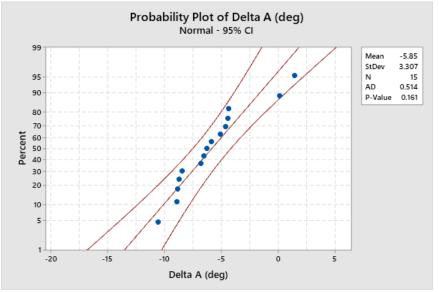
Pre-operative Average Tilt



Post-op Average Thickness

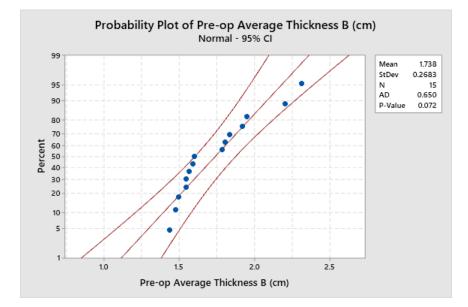




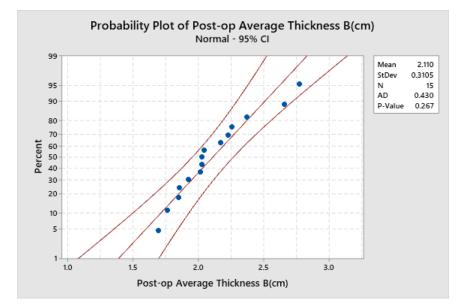


Probability Plots: Surgeon B

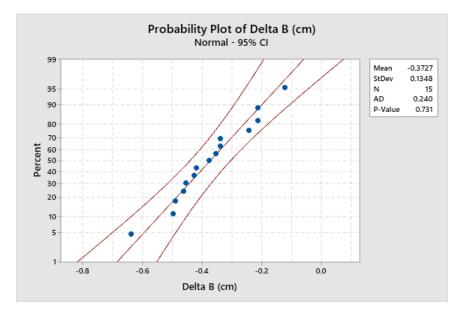
Pre-operative Average Thickness



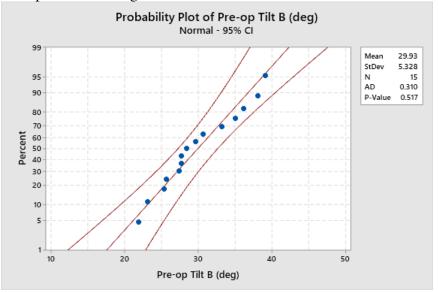
Post-Operative Average Thickness

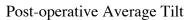


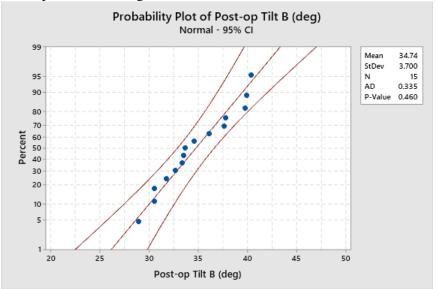
Delta Thickness



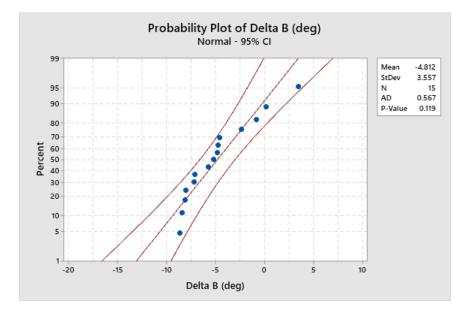
Pre-operative Average Tilt





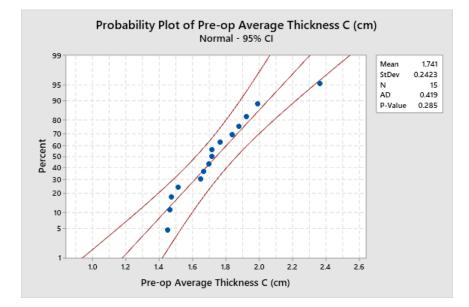




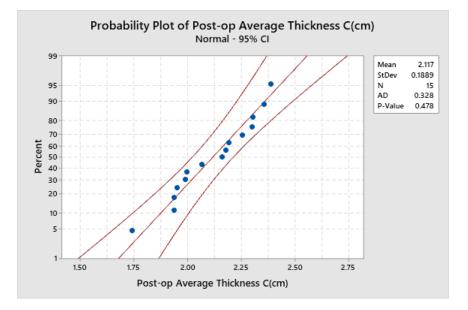


Probability Plots: Surgeon C

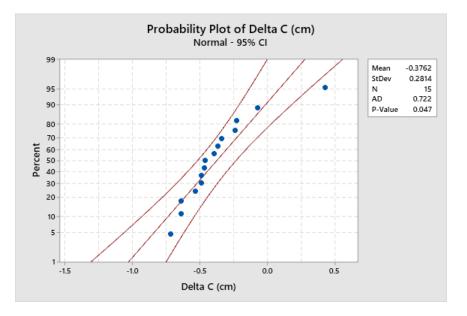
Pre-operative Average Thickness



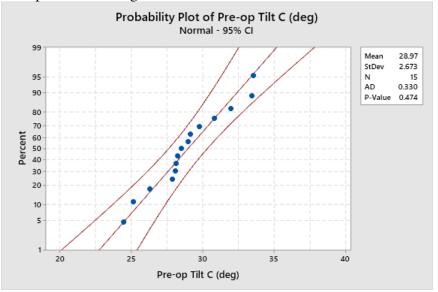
Post-operative Average Thickness



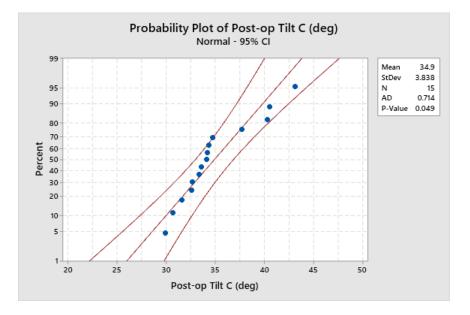
Delta Thickness



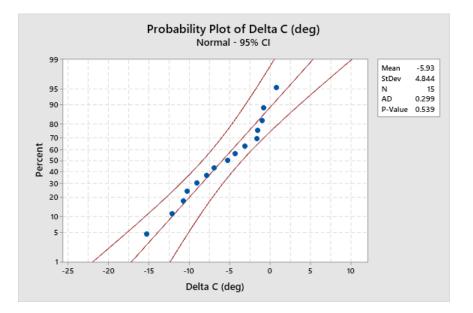
Pre-operative Average Tilt



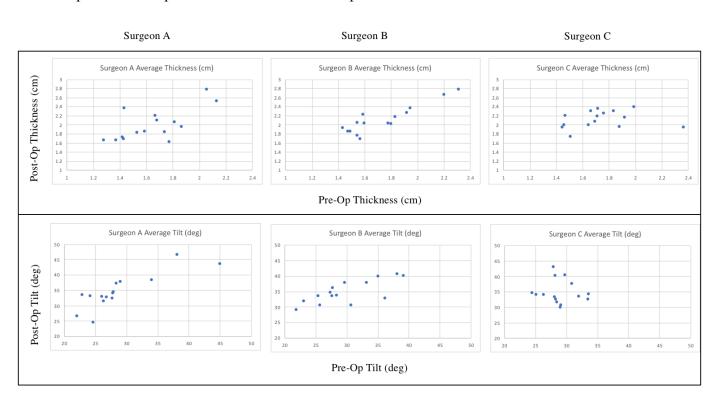
Post-operative Average Tilt



Delta Tilt



APPENDIX D



Scatterplots of Pro-operative Plan Data vs. Post-operative Resection Data

APPENDIX E

IRB Determination





EXEMPT DETERMINATION

February 08, 2021

Keith Kenter, M.D. Western Michigan University Homer Stryker M.D. School of Medicine Department of Orthopaedic Surgery 1000 Oakland Drive Kalamazoo, MI 49008

IRB#: WMed-2021-0712 (please reference this number in all correspondence with the IRB)

PROTOCOL TITLE: Radiographic Analysis and Comparison of Four Unique Patellar Resection Techniques

Dear Dr. Kenter:

The above referenced protocol and associated materials were reviewed on 01/27/2021 and it has been determined that it meets the criteria for exempt status as described in 45 CFR Part 46.104 (d):

 Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

The IRB reviewed the following documents related to the determination:

- Application for Initial Review Form Submitted 01/22/2021
- Study protocol version dated 01/21/2021

Although your research involves human subjects, it is not subject to the regulations requiring IRB continuing review and approval. However, it is important to understand that an exemption from IRB review and approval is not equal to an exemption from the investigator responsibilities and institutional policies governing human subjects research at WMU Homer Stryker M.D. School of Medicine. This information can be accessed on the medical school <u>website</u>.

In order to capitalize on the spirit of exempt research, submit any changes to the IRB only if it no longer meets the criteria for exemption and/or the conditions of the waiver of HIPAA authorization outlined above. If you are not sure, please contact the IRB office at the contact information below.

Please note changes to your IRB application related to key research personnel must be reported





to the IRB via a Personnel Change Form which can be accessed in the electronic system. Keep in mind only individual(s) accessing identifiable data and/or interacting with research subjects should be added. The IRB will acknowledge these addition(s) or removal(s).

If you have any questions, please contact the WMed IRB office at 269-337-4345 or email <u>irb@med.wmich.edu</u>.

Sincerely,

Perto Goto

Parker Crutchfield, PhD IRB Chair Western Michigan University Homer Stryker M.D. School of Medicine 1000 Oakland Drive Kalamazoo, MI 49008-8012

cc: Kelsey Cushway