The Effect of Surgical Technique During Total Knee Arthroplasty on Knee Joint Stability

DISSERTATION

Presented in Partial Fulfillment of the Requirements for the Degree Doctor of Philosophy in the Graduate School of The Ohio State University

By

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2013

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Abstract

Total knee arthroplasty (TKA) is a common surgical procedure which reduces pain and restores joint function in patients with advanced knee osteoarthritis. In 2005, there were approximately 523,000 TKA surgeries performed in the US and this number is expected to increase to 3.48 million by 2030. Although TKA is an effective intervention, suboptimal outcomes do occur, causing many patients to have difficulty carrying out activities of daily living. Many of these suboptimal outcomes are believed to be the result of poor component alignment and soft tissue balancing during TKA.

While surgeons have a keen sense of what is acceptable joint stability, there is no objective definition and they do not know precisely how their actions during surgery affect postoperative stability. The goal of my dissertation research is to determine the relationship between surgical technique and knee joint stability.

A successful TKA is dependent on many factors, but component alignment has been identified as particularly important. A variety of techniques exist to establish the rotation of the tibial component and the impact of this variability is unknown. To address this void, we performed a cadaver study to determine how tibial component rotation affects knee stability. We used a surgical navigation system and a custom stability device to measure knee stability and passive kinematics on 10 specimens with the tibial component aligned to 4 commonly used axes. Our study showed that for all rotations,
TKA produces a “softer” knee, but showed little change based on the tibial alignment alone.

Knee stability during TKA is usually assessed as a surgeon manually manipulates the knee and decides if the joint has acceptable laxity and stiffness. This subjective method does not objectively quantify stability and has unknown repeatability. Using the navigation system and custom stability tool from the cadaver study, we are the first group to intra-operatively characterized knee stability during a TKA by measuring the force applied by the surgeon and the resulting knee motion on 15 patients. Results from this initial cohort demonstrate that our system is reliable and that TKA generally results in a looser knee.

In addition to subjective assessments of stability, some surgeons use the “gap technique” to achieve a balanced joint which aims to establish equal gaps in flexion and extension between the bone cuts on the femur and the tibia. However, it is not thoroughly understood how TKA component alignment affects the gaps or the frontal plane biomechanics of the knee. Using a computer simulation that accurately models the stability testing done in the OR and in the lab, we varied TKA component alignment to determine the effect on the gaps between the bone cuts and the biomechanical behavior of the joint. Our model showed that alignments that achieve balanced gaps do not necessarily result in balanced frontal plane behavior.

This dissertation advances the understanding of how TKA changes the stability of the knee. The methodology presented in this dissertation lays the groundwork for future
orthopaedic research involving the use novel measurement tools inside the OR and computer modeling.
Acknowledgments

I have been extremely fortunate to be surrounded by many bright, hard-working, and dedicated individuals who have made this project possible over the past 5 years. I am grateful for the support I received and hope they know that my gratitude extends much further than the words of acknowledgment found here.

I’d like to acknowledge the Orthopaedic Research and Education Foundation and the National Institutes of Health, both of which have provided funding for the studies presented in this dissertation. Conducting high quality research generally has a cost associated with it and I am appreciative of their financial support to make this work possible.

This dissertation would not have been possible without Rob Siston, my advisor. I am grateful to you for taking me on as your first doctoral student. You have taught me how hard work, high expectations, and critical questioning result in valuable research. I truly appreciate all the time and energy you’ve invested into helping me make this project a success. I also want to thank you for setting an excellent example for how to mentor students, both academically and personally. I will forever carry with me the lessons I learned from you about being an effective researcher, teacher, and mentor.

I’d also like to thank the rest of my committee. To John Bolte, spending time in your lab gave me the confidence to run my first cadaver study. To Ajit Chaudhari, I’d
like to thank you for always asking the tough questions and making my research better for it. To Rebecca Dupaix, I appreciate the modeling experience you shared with me and I am equally grateful for the great example of how to balance a professional life and parenthood.

I owe my gratitude to Steve Piazza at Penn State for his simulation expertise. Thank you for your collaborative efforts to develop the model used in the simulation study and making time for a weekly phone call. The simulation portion of my dissertation would not have been possible without your support.

This dissertation would not have been possible without the cooperation of several orthopaedic surgeons, including Cornel Van Gorp, Jeffrey Granger, Matthew Beal, and Andrew Glassman. Thank you for collaborating with me to perform clinically relevant studies. I’d especially like to acknowledge Jeffrey Granger and Matthew Beal for allowing me to collect data in their operating room. It was the highlight of my testing!

I’d also like to acknowledge the patients who volunteered to be part of the OR study. Regrettably, I cannot thank them by name, but I truly appreciate your willingness to participate and help future TKA patients.

I want to thank many of the staff at OSU East Hospital. The OR testing created extra work for several of the nurses and I would specifically like to acknowledge Megan Ambrus who scrubbed in on most of the study patients. I’d also like to thank the folks down in sterilization for making certain our equipment was ready to go for surgery, especially Joe Harris.
I am grateful to my NMBL labmates, past and present, especially Julie Thompson, Becky Lathrop, and Joe Ewing. Thank you for the hands-on support during testing and the moral support through the past few years.

I’d like to thank Paula Clancy, John Warren, and Beau Morrison from Zimmer Orthopaedic for their support during both cadaver and OR testing. Thank you for loaning me instrument trays and helping streamline our equipment into the OR. Your knowledge of hospital procedures, surgeon preferences, and scheduling was immensely helpful.

I’d like to acknowledge Jeff Stanley from Northern Digital, Inc. for his technical support. Creating data acquisition systems from scratch presents unique challenges and I can’t thank Jeff enough for always taking the time to help resolve issues with our camera system.

Thank you to the machinists in the ME department, past and present, including Neil Gardner, Chad Bevins, and Kevin Wolf. I appreciate the time you took to ensure that the equipment I took into the OR for use on patients was safe and functional. I did not have a strong machining background, but you were always willing to teach me what I needed to know and for that I am grateful.

I’m grateful for the support of my family. My parents and my in-laws have always wanted to see me succeed and I am thankful. I also appreciate that I could always turn to them when I was in a pinch and without fail, someone would be there. You have been a great “safety net”.

Lastly and most importantly, I’d like to thank my husband, Alex, and my son, Griffin. To Alex, I wake up each morning feeling so incredibly lucky to be married to
someone who truly only wants the best for me. Words can’t fully express the gratitude I have for all the support you have given me. To Griffin, thank you for infusing pure joy into my life for the past 4 years. You are the best reminder of what is most important in this world. I love you both with all my heart.
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Chapter 1: Introduction

Although total knee arthroplasty (TKA) is an effective intervention for the pain and disability associated with knee osteoarthritis (OA), suboptimal outcomes do occur. These outcomes range from mild anterior knee pain to failures requiring revision surgery.\textsuperscript{1,2} Several causes related to surgical technique have been identified for these suboptimal outcomes, including excessive joint laxity, malalignment, aseptic loosening, and excessive wear of the polyethylene insert.\textsuperscript{1-4} Despite the importance of surgical technique to post-operative outcome, many intra-operative practices, such as prosthetic alignment and soft tissue balancing, are highly variable making it difficult to determine precisely how actions in the operating room influence joint stability. A quantitative characterization of how surgical technique effects stability is essential to the development of more efficacious treatment plans.

Knee Stability

Stability of the knee joint can be defined by two distinct parameters, laxity and stiffness (Figure 1.1).\textsuperscript{5} Laxity, or “looseness” of the joint, is characterized by large amounts of motion when a relatively small load is applied to the joint. Conversely, stiffness is characterized by little joint motion when large loads are applied.
Currently, published research on knee stability has used various practices to evaluate the laxity and stiffness of the knee joint. The existing methods and devices suffer from numerous drawbacks including the inability to be used on patients as opposed to cadaver specimens, the inability to be used in the operating room (OR), and the inability to fully characterize the force-displacement relationship of the knee joint. Cadaver studies often use specialized test rigs that mount directly into the bones and are not suitable for use in living patients.\textsuperscript{5-7} Commercial devices, such as the Genucom Knee Analysis System, KT1000 device, KT2000 device, and the TELOS device, allow a clinician to apply a known load to the test subject’s leg and provide a single value for the translation or rotation of the knee.\textsuperscript{8-11} The commercially available devices were developed for use in a doctor’s office or a research lab, not the operating room and cannot be sterilized. Researchers performing in vivo experiments have used custom-designed devices.
constructed from dental chairs, erector sets, fiberglass casts, and goniometers.\textsuperscript{12-14} While these devices do provide more data on the load-displacement relationship of the knee than the commercially available systems, they are not able to be used in the OR because of the size and lack of sterilizability.

**Knee stability of healthy and pathologic joints**

Normal knee stability has been evaluated in multiple experiments.\textsuperscript{5,6,12-14} Markolf et al. characterized how the knee joint becomes looser with increasing joint flexion and showed that significant differences in stability are common between the left and right knees through a series of cadaver and in vivo testing.\textsuperscript{5,12} Other studies also indicate that normal knees exhibit coupled motion where, for instance, a varus-valgus moment will induce varus-valgus and internal-external motion of the knee.\textsuperscript{6,14} It has also been established that laxity decreases under weight-bearing conditions.\textsuperscript{13}

Several studies have shown osteoarthritic knee stability to be different from normal knee stability. Knees with mild to moderate OA often demonstrate an increase in varus-valgus and anterior/posterior laxity.\textsuperscript{8,10,15} It is believed that the increase is due to a loss in bone cartilage, primarily in the medial compartment of the knee, which effectively decreases the joint space and creates “slack” in the collateral ligaments.\textsuperscript{10,15} However, in the most severe cases of OA, patients often experience an increase in joint stiffness thought to be attributed to collateral ligament contracture, damage to the cruciate ligaments, and pressure on the ligaments from osteophytes.\textsuperscript{9} The current research on OA
knee stability examines knee laxity under one load, but has not focused on quantifying the stability of the joint through a comprehensive force-displacement curve.

Knee stability after TKA is an important issue given that instability is the leading cause of early clinical failure.\textsuperscript{3,16} Despite multiple cadaver, intra-operative, and prospective cohort studies that have investigated knee laxity after TKA, the effect of TKA on knee stability is not well-understood.\textsuperscript{7,11,17-23} Several studies found varus-valgus laxity decreased after TKA, while others found no difference in laxity or even an increase in laxity.\textsuperscript{7,17-19,21,24} It has been suggested that TKA does restore the varus-valgus balance of the knee by establishing varus laxity that is equal to valgus laxity after surgery.\textsuperscript{17} Bellemans et al. also suggested that laxity is transient in just the first 30 minutes after prosthesis implantation by observing increases in varus-valgus laxity in TKA patients.\textsuperscript{20}

**Achieving a stable knee during TKA**

Several surgical techniques exist to achieve a “balanced” knee that feels neither too loose nor too tight. Orthopaedic surgeons commonly use the “gap technique” which aims to establish a gap between the distal femoral bone cut and the proximal tibial cut that is rectangular in shape and equally sized when the knee is in flexion or extension (Figure 1.2).\textsuperscript{25}
Figure 1.2: Illustration of equal gaps between the distal femoral cut and proximal tibial cut in flexion and extension.

This method involves releases of the collateral ligaments in conjunction with the bone cuts to achieve a stable knee joint.\textsuperscript{26,27} It is believed that this rectangular joint space will lead to a balanced joint, assuming that the gap is proportional to the length of the ligaments, which is proportional to force.\textsuperscript{28} However, this assumption hasn’t been proven for healthy or osteoarthritic knees. Measured resection is another commonly used method, which involves measuring the thickness of the bone the is removed from the tibia and femur and sizing the TKA components to match.\textsuperscript{29,30} This is thought to restore the anatomy of a normal knee, but often involves subjective decisions by the surgeon when the knee has severely abnormal anatomy due to OA.

In addition to the gap technique and measured resection, knee stability is frequently assessed intra-operatively using the “calibrated hands” method, which is when the surgeon applies a varus-valgus load to the knee and decides if the joint feels stable.\textsuperscript{17,26} This subjective method has several downfalls and provides little insight on
how surgical technique impacts stability. First, since the success or failure of this
technique is verified once the patient returns to weight-bearing activities, the surgeon is
left with no opportunity to make changes aside from re-opening the joint. Additionally,
this method does not quantify stability with any force or displacement measurements
resulting in the inability to provide an objective definition of the joint’s pre- or post-TKA
stability. This qualitative method also has unknown patient-to-patient repeatability.
Occasionally, intra-operative evaluations of knee laxity are performed using a surgical
navigation system to record joint displacement or rotation while a surgeon applies a load
to the knee, but the magnitude and direction of the load is not known.\textsuperscript{17,18}

Implant alignment is critical to the success of TKA and is known to affect the
gaps between the bone cuts and the perceived feel of stability. Malalignment is
associated with aseptic component loosening, patellar maltracking, excessive wear, and
joint instability.\textsuperscript{1-3,31} The epicondylar axis is the most commonly used anatomical axis
for aligning the femoral component since it consistently optimizes kinematics, minimize
joint forces, and produces balanced gaps.\textsuperscript{31-34} Unlike the femoral component, a “gold
standard” for the rotational alignment of the tibial component does not exist. Currently,
there are many anatomical landmarks that surgeons use to align the tibial component,
including the transepicondylar axis, the tibial tubercle, the transverse axis of the tibia, the
malleolar axis, and the second metatarsal.\textsuperscript{35-37} Multiple studies have noted that the
rotation of both components is highly variable and the effect of this variability on post-op
knee stability is unknown.\textsuperscript{35,36,38}
Computer modeling has been used to study the effect of TKA component alignment on characteristics of the post-op joint including kinematics, joint forces, ligament/muscle forces, and implant-bone impingement. Simulation studies have demonstrated that internal rotation of the femoral component causes patellar maltracking, induces a valgus limb alignment, increases patellar forces, increases the quadriceps force, and increases the MCL force during knee flexion.\textsuperscript{39-41} Increasing posterior slope of the tibial component has been shown to increase the flexion angle at which bone-implant impingement occurs and reduce femoral roll-back in simulated flexion-extension motions.\textsuperscript{42,43} Existing models have not modeled how a TKA knee responds to an applied varus-valgus force, as is often performed in the OR to assess stability and balance, or examined the gaps between bone cuts. However, simulations offer the potential to systematically vary component alignment and predict these parameters, which may aid surgeons in the OR who desire to make a patient’s knee more tight or loose.

1.1 Focus of Dissertation

This dissertation focused on determining how TKA changes the stability of the knee. Using a custom stability testing device and a custom surgical navigation system, we determined how the rotational alignment of the tibial component in the transverse plane affected passive knee kinematics, as well as frontal plane laxity and stiffness, in a cadaver study. Once our testing method was proven on cadaver specimens, we collected intra-operative load-displacement data on an initial cohort of TKA patients before and after prosthesis implantation to quantify how TKA alters knee laxity and stiffness.
Lastly, using a subject-specific forward dynamic simulation, we determined how varying the alignment of the femoral and tibial component in the frontal, sagittal, and transverse planes changes the stability and balance of the knee.

1.2 Significance of Research

Total knee arthroplasty is a common procedure and is only expected to become more prevalent.\textsuperscript{44,45} Despite the importance of surgical technique to the success of TKA, establishing a stable joint remains a challenge that is not always achieved.\textsuperscript{25,46} The ability to quantify knee stability, as we have with our custom testing system, is an important step toward improving patient outcomes.

Proper component alignment during TKA is known to be critical to TKA outcome and rotation in the transverse plane has been shown to be particularly variable. Given that it has been suggested that the potential range of tibial component rotation may be as large as 90°, research has focused on repeatable methods of alignment using various anatomical landmarks.\textsuperscript{35,36,47,48} However, reports of significant post-op knee pain are linked to internal rotation of the tibial component as small as 6.2°.\textsuperscript{1} This suggests that tibial component rotation is a significant factor in the clinical success of TKA, but the biomechanical impact has not been closely examined. Using our custom stability device and navigation system, we performed a cadaver study that determined the relationship between rotational alignment of the tibial component and the passive kinematics and joint stability.
Once our test set-up was validated on cadavers, we moved it into the OR to quantify knee stability before and after TKA component implantation. To the best of our knowledge, we are the first group to simultaneously measure the loads applied to the patient’s limb and the resulting motion of the joint during surgery, providing a comprehensive characterization of the load-displacement relationship. While many surgeons have become skilled at developing a “feel” for acceptable laxity and stiffness, knee stability can be objectively measured in the OR with our equipment, which will allow us to assess repeatability and possibly provide a teaching tool for younger surgeons.

We also investigated the relationship between the alignment of the femoral and tibial components in the frontal, sagittal, and transverse planes and the balance of the knee using an experimentally validated subject-specific computer model. Many surgeons rely on establishing equal gaps between the bone cuts to achieve a balanced knee and it is known that gaps are affected by the surgeon’s selected component alignment.\textsuperscript{29,33,49,50} Multiple studies have noted that surgeons will vary the VV alignment of distal femoral and proximal tibial bone cuts by as much as 10.4° to achieve balanced gaps.\textsuperscript{29,49} It is also believed that component alignment affects biomechanical stability, with some studies linking malalignment of the tibial component to excessive stiffness.\textsuperscript{51,52} Additionally, Nagamine et al. suggested that external rotation of the femoral component greater than 5° has been shown to decrease VV range of motion.\textsuperscript{53} Since these studies have involved examining the alignment on actual TKA patients or cadavers, researchers did not have the capability of investigating all possible alignments and the relationship between alignment
and balance (gap or biomechanical) is not precisely understood. Additionally, it is unknown if gap balance results in biomechanical balance.

1.3 Overview of Dissertation

This dissertation contains four subsequent chapters; Chapters 2-4 are written as self-contained journal articles. Chapter 2 (published in *Clinical Orthopaedics and Related Research* in May 2013 with co-authors Jeffrey Granger, Matthew Beal, and Robert Siston) presents our results from a cadaver study that determined how knee stability and passive kinematics are affected by the tibial component rotation in the transverse plane. Chapter 3 (submitted to *Orthopedics* in October 2013 with co-authors Matthew Beal, Xueliang Pan, and Robert Siston) presents our initial experiences and results from measuring intra-operative pre- and post-implant knee stability on a cohort of TKA patients. Chapter 4 (scheduled to be submitted to *The Journal of Orthopaedic Research* by December 2013 with co-authors Joseph Ewing, Jeffrey Granger, Matthew Beal, Stephen Piazza, and Robert Siston) presents our results from a computer simulation study that investigated the relationship between component alignment, gap balance, and biomechanical stability using an experimentally validated subject-specific model. Chapter 5, the conclusion, summarizes the key contributions of this dissertation, discusses additional applications of this research, and proposes future directions of study.
Chapter 2: Effect of TKA Tibial Component Rotational Alignment on Stability and Kinematics

2.1 Abstract

Joint function after TKA depends on many factors, but component alignment is particularly important. While the transepicondylar axis is regarded as the gold standard rotationally aligning the femoral component, a variety of techniques exist for tibial component rotational alignment. The impact of this variability on joint kinematics and stability is unknown. We determined how rotationally aligning the tibial component to four different axes changes knee stability and passive tibiofemoral kinematics in a knee following TKA. Using a custom surgical navigation system and stability device to measure stability and passive tibiofemoral motion, we tested 10 cadaveric knees from 5 hemi-corpses before TKA and then with the tibial component aligned to four axes using a modified tibial tray. No changes in knee stability or passive kinematics occurred as a result of tibial rotational alignment. TKA produces a “looser” knee over the native condition by increasing mean laxity by 5.2°, decreasing mean maximum stiffness by 4.5 N·m/°, increasing mean anterior femoral translation during passive flexion by 5.4 mm, and increasing mean internal-external tibial rotation during passive flexion by 4.8°. However, no statistically or clinically significant differences exist between the 4 TKA conditions. For all tibial rotations, TKA increased laxity, decreased stiffness, and
increased tibiofemoral motion during passive flexion but showed little change based on the tibial alignment. Surgeons who align the tibial component to any of the axes we examined are expected to have results consistent with their peers who may use a different axis.

2.2 Introduction

TKA is commonly and increasingly used to treat the pain, disability, and loss of motion associated with osteoarthritis. While most patients experience relief of pain and improved function and quality of life, a variety of suboptimal outcomes do occur, ranging from mild anterior knee pain to failures requiring revision surgery. Patients with these suboptimal outcomes often report excessive joint stiffness or looseness, limited ROM, and difficulty with activities of daily living, such as climbing stairs and walking.

Joint function after TKA depends on many factors, but component alignment has been identified as particularly critical. Alignment errors compromise the stability of the joint, alter tibiofemoral kinematics, and result in patella maltracking and pain. As little as 6.2° of internal rotation of the tibial component reportedly relates to postoperative pain, while just 3° of internal rotation of the femoral component increases varus displacement of the knee.

The transepicondylar axis (TEA) of the femur is generally regarded as the gold standard axis for establishing the rotational alignment of the femoral component during TKA. This axis is believed to best approximate the flexion-extension axis of the knee.
knee and produces a balanced joint and the most normal patellar tracking and minimize patellofemoral shear forces. Rotational alignments that deviate from this axis have resulted in abnormal varus-valgus joint displacement and patellofemoral kinematics, as well as an increase in tibiofemoral wear.

Unlike the femoral component, a gold standard does not exist for the rotational alignment of the tibial component. Currently, many anatomic landmarks are used to align the tibial component, including the projected femoral TEA, the medial border of the tibial tubercle, the medial ⅓ of the tibial tubercle, the PCL attachment, the transverse axis of the tibia, the posterior condylar line of the tibia, the midsulcus of the tibial spine, the malleolar axis, the patellar tendon, and the axis of the second metatarsal. This lack of a gold standard for tibial component alignment, combined with the difficulty in identifying anatomic landmarks during surgery and variations in anatomy between knees, may lead to variations in the surgeons’ ability to locate tibial component alignment axes as large as 44° of internal rotation to 46° of external rotation. However, it is not currently understood how this variability in tibial rotational alignment impacts the stability or kinematics of the TKA knee.

We therefore determined how rotationally aligning the tibial component to four different axes changes knee stability and passive tibiofemoral kinematics in a knee following TKA.
2.3 Materials and Methods

We performed a series of experiments on five pairs of fresh-frozen cadaveric limbs (five hemicorpuses) containing all structures distal to the pelvis using a custom, image-based surgical navigation system that was created at The Ohio State University (Columbus, OH, USA) and included a Polaris® optical tracking system (Northern Digital, Waterloo, Ontario) that was controlled by LabVIEW™ (National Instruments, Austin, TX, USA) and MATLAB® (Mathworks, Natick, MA, USA) software. This system, along with previous systems created by the senior author (RAS), has been validated and successfully used previously 17,69-71. Specimens with severe osteoarthritis, prior fractures, damaged soft tissues, or other abnormalities were not included. The average age of the specimens was 71.5 years (range, 57–81 years), with eight knees being from male donors and two knees from a female donor.

We performed an a priori power analysis assuming a difference of $6^\circ$ and an SD of $2.3^\circ$, based the original Knee Society Scoring system where points are deducted for greater than $6^\circ$ of joint laxity 72 and our previous study of knee stability showing an SD of $2.3^\circ$ 17. Accounting for the six pairwise multiple comparisons among the four different tibial rotational alignment axes that would be investigated, we determined at least six specimens would be needed to achieve a power of 0.8 with an $\alpha = 0.008$. After initial testing showed the SD associated with some alignment axes was as high as $4^\circ$, we performed another power analysis and determined 10 specimens would be needed to determine a difference in joint laxity of at least $6^\circ$ between test conditions. Before kinematic and stability testing, all specimens were CT scanned using a Philips 64-slice
mobile CT system (Philips Healthcare, Andover, MA, USA) to accurately identify the axes used to align the rotation of the femoral and tibial components. Slices were made every 2 mm for the entire length of the limb to ensure adequate visualization of anatomic landmarks. The CT data were reconstructed using commercially available software (3D-Doctor; Able Software Corp, Lexington, MA, USA), and we identified the following anatomic landmarks frequently used during TKA: the prominence of the lateral femoral epicondyle $^{38}$, the sulcus (or, when absent, the prominence) of the medial femoral epicondyle $^{38}$, the most medial border of the tibial plateau $^{35}$, the most lateral border of the tibial plateau $^{35}$, the PCL attachment on the tibia by identifying the PCL in the posterior condylar notch and selecting the geometric center $^{65}$, the medial border of the tibial tubercle $^{65}$, and the medial $\frac{1}{3}$ of the tibial tubercle $^{65}$.

The points identified on the CT images were then used to define four axes commonly used to align the tibial component. Axes used in this study were selected based on what was commonly cited and ease of identification from a CT scan. The TEA was defined as the surgical epicondylar axis, the line between the points on the lateral prominence and the medial sulcus (or, when absent, the prominence) of the femoral epicondyles $^{73}$, projected onto the tibial plateau when the specimen was in full extension. The transverse axis (TA) was defined as the line between the most medial and lateral points on the tibial plateau. The medial border axis (MBA) was defined as the line between the PCL attachment and the medial border of the tibial tubercle. The medial third axis (MTA) was defined as the line between the PCL attachment and the medial $\frac{1}{3}$ of the tibial tubercle.
An experienced orthopaedic surgeon (JFG or MDB) performed a PCL-retaining TKA on each specimen by using implants from the Zimmer® Natural-Knee® II product line (Zimmer Inc, Warsaw, IN, USA). After the knee was exposed, passive optical maker arrays with four reflective spheres were attached to the femur and tibia and anatomic reference frames were established. The greater trochanter, the distal femur, the proximal tibia, and the malleoli were digitized to register the specimen to the CT data using an iterative closest-point algorithm.

With the aid of the surgical navigation system, we recorded passive kinematics and stability data for the knee at full extension before and after prosthesis implantation. The femoral component was aligned to the TEA with the aid of the surgical navigation system, while the tibial component was aligned within 1° of the four different axes (TEA, TA, MBA, and MTA). We also used the surgical navigation system to ensure the distal femoral cut and the proximal tibial cut were always within ±1° of neutral varus-valgus rotation and the anterior femoral cut was within ±1° of neutral internal-external rotation. A custom-modified tibial tray with 1° resolution was used to allow for rotation from 25° of internal rotation to 25° of external rotation and allowed us to test four different alignments on the same specimen. Three trials were recorded for each test condition.

To measure passive kinematics, the skin surrounding the knee was closed with two to three towel clips and the joint was flexed by supporting the foot with an open palm while gently lifting the thigh. The reverse procedure was used to extend the knee. During this motion, the navigation system recorded the position and orientation of the optical reference frame fixed to the femur with respect to the optical reference frame.
fixed to the tibia. The error associated with the surgical navigation system is minimal, with a linear accuracy of less than 2 mm and a worst-case angular accuracy, in the transverse plane, of about 1.25°.

To characterize joint stability in the frontal plane, we measured the force-displacement relationship of the knee in the varus-valgus direction using a custom stability device that enabled us to repeatably and accurately apply a ±20-N·m load. (Please see Appendix A for a detailed test procedure.) While the ideal loads that should be used to assess knee laxity and stiffness during a TKA are unknown, this load was chosen because it ensured we would be able to measure the terminal stiffness of the knee, encompassed a range used to biomechanically evaluate knee stability, and was the maximum load that experienced surgeons in this study felt they could use on a patient during TKA. The specimen’s foot was placed in a modified Alvarado boot while the femur was constrained by a Lane bone clamp held by the surgeon. The load was applied to the limb with an instrumented handle, which included a load cell (Model 31 precision miniature load cell; SENSOTEC, Columbus, OH, USA), while displacement of the limb was measured by the surgical navigation system. The stability device (Figure 2.1) was previously validated for both intra- and interoperator use and showed low mean ± SD moment errors of no greater than −0.11 ± 0.73 N·m, ensuring the loads measured by our device are the loads experienced at the knee.
Figure 2.1: A custom-built stability device was used during testing. The specimen’s foot was placed in a modified Alvarado boot and then placed in the device. Using the instrumented handle, a force was applied to the varus-valgus cart while a surgical navigation system tracked the motion of the tibia, femur, boot, and cart.

Similar to Markolf et al.\textsuperscript{5}, we defined laxity as the amount of motion in degrees that occurred under a given load and stiffness as the slope between two points on the force-displacement curve. Varus-valgus knee stability was analyzed by determining the stiffness at ±20 N·m and the laxity occurring under ±10 N·m and ±20 N·m varus-valgus loads (Figure 2.2).
We examined three characteristics of passive knee kinematics as a function of knee flexion: varus-valgus rotation at discrete flexion angles (5°, 10°, 15°, 20°, 25°, 30°, 60°, 90°, and 105°), the maximum anterior translation of the femur on the tibia, and the internal-external rotation of the tibia between 5° and 105° of flexion.

We performed a repeated-measures ANOVA analyses using Minitab (State College, PA, USA) to determine whether a TKA and different tibial component rotational alignments had an effect on knee stability and kinematics in our 10 specimens. Even though the 10 knees came from five donors, each specimen was analyzed separately and acted as its own control because we saw left-to-right differences in laxity and stiffness in the native condition as large as 44% and 79%, respectively, which is similar to other researchers who have noted left-right differences in the stability as large as 35% for healthy knees. We performed an additional general linear model ANOVA to
investigate the effect of both rotational alignment and knee specimen number to confirm whether having two knees from the same donor influenced our results. The specimen number and the knee treatment (native knee, TEA, TA, MBA, or MTA) were the independent variables while stiffness, laxity, anterior femoral translation, and internal-external tibial rotation were the dependent variables. Knee flexion angle was also treated as an independent variable when we analyzed varus-valgus rotation during passive flexion as the dependent variable. When a statistically significant effect (p ≤ 0.05) was present between two test conditions, Tukey’s test was used to determine the difference between the average measurements.

2.4 Results

We found that tibial rotational alignment had no effect on ±10 N·m laxity (p=0.06), ±20 N·m laxity (p=0.08), 20 N·m varus stiffness (p=0.55), and 20 N·m valgus stiffness (p=0.26). However, TKA produces a softer knee by increasing laxity (Figure 2.3) and decreasing stiffness (Figure 2.4). For both ±10- and ±20-N·m loads, TKA increased (p = 0.001 for both) the average amount of laxity over the native knee (Table 2.1) by 4.36° and 5.20°, respectively. Average varus (p = 0.001) and valgus (p = 0.05) stiffesses both decreased (Table 1) after TKA by 5.06 N·m/° and 4.50 N·m/°, respectively.
Figure 2.3: Mean values are shown for ±10 N•m and ±20 N•m varus-valgus laxity in full extension for the native knee and all 4 rotational alignments. The error bars represent one standard deviation. A statistically significant difference exists between the native.

Figure 2.4: Mean values are shown for varus and valgus stiffness at ±20-N·m load for the native knee and all four rotational alignments. The error bars represent one SD. A difference exists between the native condition and any of the four axes, but there is no difference in stiffness based on rotational alignment alone.
Table 2.1: Stability Measures for Native and TKA Knees

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Native Knee</th>
<th>TKA Knee</th>
</tr>
</thead>
<tbody>
<tr>
<td>±10 N·m laxity</td>
<td>2.74 ± 0.54°</td>
<td>7.10 ± 1.53°</td>
</tr>
<tr>
<td>±20 N·m laxity</td>
<td>4.59 ± 0.17°</td>
<td>9.79 ± 0.42°</td>
</tr>
<tr>
<td>Stiffness at 20 N·m valgus</td>
<td>9.18 ± 5.27 N·m/°</td>
<td>4.68 ± 2.63 N·m/°</td>
</tr>
<tr>
<td>Stiffness at 20 N·m varus</td>
<td>8.12 ± 4.65 N·m/°</td>
<td>3.06 ± 1.70 N·m/°</td>
</tr>
</tbody>
</table>

We found that specimen number did have an effect on ±20 N·m laxity (p < 0.001), where one specimen demonstrated a larger amount of laxity relative to all other specimens, even the contralateral limb of the same donor. The ±20 N·m laxity measurements for the remaining 9 specimens were within 6° of each other, which we did not deem to be clinically significant based on the Knee Society Scoring System.

We found that tibial rotational alignment had no effect on anterior translation of the femur (p = 0.51) or internal-external rotation of the tibia (p = 0.98) during passive flexion, but we did observe some small differences (p = 0.001) in varus-valgus position during early flexion (< 15°). Similar to the stability variables, we found that TKA produces a “looser” knee when compared to the native condition during passive flexion (Figure 2.5, Table 2.2) by increasing the average anterior translation of the femur (p = 0.008) by 5.38 mm and the average internal-external tibial rotation (p = 0.05) by 4.86°.
Figure 2.5: Mean values are shown for (A) AP translation of the femur and (B) internal-external (IE) rotation of the tibia during passive knee flexion for the native knee and all four rotational alignments. The error bars represent one SD. A difference exists between the native condition and any of the four axes, but there is no difference in these kinematics based on rotational alignment alone.

Table 2.2: Passive Kinematic Measures for Native and TKA Knees

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Native Knee</th>
<th>TKA Knee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior translation of femur</td>
<td>7.73 ± 0.48 mm</td>
<td>13.11 ± 1.78 mm</td>
</tr>
<tr>
<td>Internal-external rotation (5°-105°)</td>
<td>5.96 ± 1.61°</td>
<td>10.82 ± 1.69°</td>
</tr>
</tbody>
</table>

Varus-valgus positon during passive flexion was the only variable to be affected by tibial rotational alignment (Figure 2.6). At 5° of flexion, aligning to the MBA or TA caused the knee to be more valgus (p = 0.001) over the native condition by 3.20°. However, there was no statistical difference in varus-valgus position at 5° of flexion between the MBA and the TA (p = 0.54). Aligning to the TEA or MTA caused an even larger average valgus increase (p = 0.001) at 5° of flexion over the native knee of 4.74°. Once
again, there was no statistical difference in varus-valgus position at $5^\circ$ of flexion between the TEA and the MTA ($p = 0.77$). At $10^\circ$ of flexion, the differences in varus-valgus motion disappeared between the different alignments, but on average, the TKA knee showed $1.96^\circ$ increase ($p = 0.001$) in valgus motion over the native condition. By $15^\circ$ of flexion, varus-valgus differences between the native knee and the TKA conditions ceased to exist ($p = 0.24$).

Figure 2.6: Varus-valgus kinematics during passive flexion for a representative specimen is shown. In early flexion, all alignments show more valgus motion than the native condition, but the TA and MBA alignments minimize this.

2.5 Discussion

Joint function after TKA is dependent on many factors, but component alignment has been identified as particularly important. While the TEA is generally regarded as the
gold standard for rotational alignment of the femoral component, a variety of techniques exist to establish the rotation of the tibial component, and the biomechanical impact of this variability is unknown. We therefore examined varus-valgus laxity and stiffness, as well as tibiofemoral kinematics during passive flexion with the tibial component aligned to 4 commonly used axes to determine whether a gold standard tibial rotational alignment axis exists.

We note several limitations to our study. First, our findings reflect those obtained by only two experienced arthroplasty surgeons using one particular PCL-retaining TKA system on five pairs of cadaver limbs that did not require any ligament releases. Different surgeons with different specimens using different implants and techniques may yield different results because different implants provide different patterns of stability. Using a PCL-sacrificing implant would most likely result in even more laxity and reduced stiffness since the PCL reportedly provides some varus-valgus stabilization. Second, although all of our specimens came from elderly donors (average age: 71.5 years), the level of osteoarthritis that the surgeons found in the specimens used in this study was estimated to range from none to moderate. Since the majority of our specimens appeared to behave similarly, TKA patients, who typically have more severe osteoarthritis and soft tissue contractures, or a larger and more diverse collection of cadaveric specimens with a greater range of anatomic variation may also demonstrate different results. Third, the manual actuation of our device introduces variability, although we believe it to be small. While the surgeons performing these experiments applied loads quasistatically, ligament response is known to be dependent on the rate of
Fourth, all testing involved passive motion of cadaveric knee specimens and we would expect active load-bearing activities to demonstrate different kinematics. Lastly, even though all individual knees across all donors appeared to behave similarly, the use of pairs of knees from the same specimen is a potentially serious limitation and should be given careful consideration in future work with cadaveric specimens.

Our stability results (laxity and stiffness) for the native and TKA knees are similar to what has been noted by other researchers. One cadaver study of native knees estimated varus-valgus laxities in full extension under ±10 and ±20 N·m to be approximately 2° and 4°, respectively, which is comparable to our findings (Table 2.1). In patients with severe OA, Siston et al. noted average intraoperative measurements of pre- and postimplant varus-valgus ROM were 5.9° and 6.5°, respectively, which also overlaps with our cadaver results. However, studies on how varus-valgus laxity changes with TKA have yielded mixed results. Casino et al. found varus-valgus laxity decreased in full extension after TKA, while others found no difference in laxity. We believe these results may differ from ours (laxity increases after TKA) because previous studies used data from osteoarthritic knees, which is known to diminish varus-valgus laxity, and did not measure the load applied to the knee. In contrast to laxity, very little research exists on the effect of TKA on terminal stiffness of the knee. One cadaver study involving normal knees found the mean terminal varus and valgus stiffness to be 14.0 and 16.5 N·m/°, respectively, which is comparable to what we observed for the native knees (Table 2.1).
Our observation of passive flexion tibiofemoral kinematics of the native and TKA knees are also similar to what has been reported by other researchers. An increase in anterior femoral translation after TKA has been well-documented\textsuperscript{19,69,70,82}, with Cromie et al.\textsuperscript{69} reporting TKA knees demonstrated a mean of 16.1 mm anterior motion, which overlaps with our findings (Table 2.2). Studies on tibial internal-external rotation after TKA have shown mixed results, with some researchers noting decreases\textsuperscript{70} and others reporting no change\textsuperscript{19}. We observed an increase in tibial rotation, but our average value for the native condition is similar to what Siston et al.\textsuperscript{70} reported for osteoarthritic knees (4.9° ± 4.1°) and nearly identical to what Victor et al.\textsuperscript{83} observed nearly identical for TKA knees (10.8°).

Given that our mean values of joint laxity for the different alignment axes were within 2°, which is under the original threshold established by the Knee Society where points are deducted for greater than 6° of joint laxity, we are confident in saying the alignment axes do not yield differences in joint laxity that are either statistically different or clinically important. However, published studies on the effect of component rotational alignment on TKA kinematics have shown conflicting results. Similar to our findings, several studies have noted no difference in varus-valgus kinematics in late flexion\textsuperscript{40,70}. However, we demonstrated no change in the translation of the femur during passive kinematics based on tibial component rotation, while others have found that particular alignment to be a key factor\textsuperscript{40,84}. Thompson et al.\textsuperscript{40} reported an increase in femoral anterior translation when the tibial component was externally rotated in an Oxford rig simulation. Conversely, Mihalko et al.\textsuperscript{84} found internal rotation of the tibia caused the
greatest increase in anterior translation during a simulated lunge. Thompson et al.\(^{85}\) and Mihalko et al.\(^{84}\) measured translation at the point of contact between the tibia and femoral condyles, which is slightly different from our method that measures the motions of a tibial and a femoral reference frame with origins at the midpoint of the tibial spine and the femoral anterolateral PCL attachment, respectively\(^{70}\). However, we believe the disagreement in AP kinematic results is likely due to the fact that those previous studies simulated different weightbearing activities, while we investigated passive flexion-extension kinematics.

We did note large variability in our results across specimens, and knees from the same donor exhibited right-left differences in laxity and stiffness as large as 44% and 79%, respectively. We suspect the variability is the result of large variations in bony anatomy seen in our specimens. Across all 10 specimens in our study, the most internally and most externally rotated axes were not consistent even when comparing knees from the same donor, and the angle between these two axes ranged from 10.2° to 27.1° (Figure 2.7). This large variation among specimens agrees with what other researchers have noted regarding tibial rotational alignment. Akagi et al.\(^{36}\) found the angle between the TEA and the transmalleolar axis ranged from 8° to 49.4°. Similarly, Matziolis et al.\(^{86}\) found the angle between the TEA and an axis that aligned to the midpoint point of the tibial tubercle ranged from 0.7° to 43.4°.
Figure 2.7: We noted a high degree of variability in specimen anatomy. CT scans of the tibial plateau (most proximal CT slice of the tibia) with the most internal and external axes of two different specimens are shown. (A) For this specimen, the most internal and external axes were the MBA and TA, respectively, with 27.1° between the two. (B) For this specimen, the most internal and external axes were the TEA and MTA, respectively, with a 10.2° angle between the two.

2.6 Acknowledgements

We thank Dr. Michael Knopp for assistance with the CT images and Zimmer for loans of surgical trays. Financial support for the study was provided, in part, by the Orthopaedic Research and Education Foundation, the American Association of Hip and Knee Surgeons, and Award Number R01AR056700 from the National Institute Of Arthritis And Musculoskeletal And Skin Diseases. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute Of Arthritis And Musculoskeletal And Skin Diseases, the National Institutes of Health, or the other agencies supporting this work.
3.1 Abstract

Knee stability during total knee arthroplasty (TKA) is usually assessed as a surgeon manually manipulates the knee and decides if the joint has acceptable laxity and stiffness. This subjective method does not objectively quantify stability, has unknown repeatability, and is difficult to teach to younger surgeons. Using a novel system to measure the force applied by the surgeon and the resulting knee motion, we have comprehensively characterized knee stability for 15 patients during a TKA. Results from this initial cohort demonstrate that our system is reliable and that TKA generally results in a looser knee for this initial cohort.

3.2 Introduction

While total knee arthroplasty (TKA) is generally successful at restoring knee joint function and improving quality of life for patients with advanced osteoarthritis (OA), a significant subset of patients struggle with suboptimal outcomes including mild anterior knee pain, difficulty climbing stairs, slower walking, and failures requiring revision surgery. The success of TKA depends on many factors, but surgical technique, including establishing a stable joint, has been identified as particularly critical.
Improper intra-operative management of soft tissues due to surgical inaccuracy or prosthesis alignment can lead to post-operative complications such as instability, early loosening of the components, stiffness, limited range of motion, and excessive polyethylene wear.\(^{26,49}\)

Despite the importance of joint stability to the success of TKA, debate exists regarding how much soft tissue balancing is appropriate. In general, surgeons believe the knee should not be too tight and a little varus-valgus laxity should be achieved postoperatively with the ideal knee being looser in flexion than in extension and looser laterally (under varus stress) than medially, but little evidence supports these beliefs.\(^ {7,20,88}\) Similarly, patients have reported they are more comfortable with a lax knee than with an over-tight knee.\(^ {89}\) However, an objective definition of what constitutes clinically successful stability does not exist.

Surgeons currently use multiple techniques to aid in establishing a stable joint during a TKA. Many rely on qualitative evaluation in which the knee is manipulated to determine if it feels stable. While many surgeons have become skilled at developing a “feel” for acceptable laxity and stiffness, the qualitative evaluation lacks any objective measurements, has unknown repeatability, and is difficult to teach to younger surgeons. Surgeons also focus on proper component alignment to avoid an unbalanced knee.\(^ {34}\) However, component alignment is known to be highly variable and the relationship between alignment and knee stability is not fully known.\(^ {34,35,38,90}\) Many surgeons also use the “gap technique” which aims to establish equal rectangular gaps between the bone cuts in extension and flexion.\(^ {17,26,49,88}\) It is believed that this rectangular joint space will lead
to equal compartmental pressures and improved kinematics, but equal gaps can be
difficult to achieve and the clinical effect of imperfect gaps on joint stability is
unknown.²⁵,⁹¹

Recently, surgical navigation systems have been used to make objective
measurements in the OR in an effort to improve the existing techniques aimed at
establishing a stable TKA knee. These systems have allowed surgeons and researchers to
measure varus-valgus range-of-motion (ROM), component alignment, and verify the gap
technique at the time of surgery.¹⁷,³⁰,⁹²-⁹⁷ Several studies have indicated that the amount
of motion under a varus load is approximately equal to the amount of motion under a
valgus load.¹⁷,⁹² However, the loads applied to the patients’ legs are not measured in
these studies. Multiple studies also indicate that the use of surgical navigation systems
improves component alignment in the frontal and sagittal planes.⁹³-⁹⁶ Although
researchers generally agree that navigation reduces malaligned outliers, the clinical
benefit of navigation is heavily debated since some studies show improvements in joint
function scores with use of navigation while others show none.⁹³-⁹⁶ Several studies have
compared navigation-verified gap technique in a cohort of TKA patients to another
cohort where a measured resection technique was used and showed that the use of
navigation reduced the number of outliers that had unequal gaps (> 3mm) or whose
alignment deviated more than 3° from the mechanical axis.³⁰,⁹⁷ However, similar to
varus-valgus ROM and navigation-verified component alignment, the navigation-verified
gap technique has not been proven to produce a long-term clinically successful outcome
and does not comprehensively characterize the stability of the knee.
We believe the ability to objectively characterize intra-operative laxity and stiffness represents a key step in objectively defining acceptable joint stability and would mark a substantial improvement over the subjective or incomplete measurements currently made with existing approaches. To address that challenge, we created a novel system to allow surgeons to quantify varus-valgus (VV) and anterior-posterior (AP) laxity and stiffness of the knee during a TKA. Our system uses a custom testing device and a custom navigation system to measure the forces that the surgeon applies to the leg and the resulting motion of the knee. The objectives of the pilot study presented in this manuscript are to report our initial experiences with our system, determine if our system could be used reliably during surgery to make objective measurements of knee stability before and after prosthesis implantation, and determine if TKA altered joint stability in this small cohort of patients.

3.3 Materials and Methods

This study followed a protocol that was approved by the Institutional Review Board at The Ohio State University. Increased surgical time associated with making our measurements of knee stability was limited to 20 minutes and the surgeon (Beal) could elect to stop testing at any time. In this manuscript, we are reporting on a cohort of 15 patients, 5 males and 10 females, with an average age of 62.2 ± 4.2 years who have all had a pre-operative varus deformity. All patients provided informed written consent to participate.
Our custom surgical navigation system is comprised of a Polaris Spectra camera (Northern Digital, Inc., Waterloo, Ontario), 6 wireless optical trackers (Figure 3.1) which are seen by the camera, MATLAB software (MathWorks, Natick, MA), and LabVIEW software (National Instruments, Austin, TX).

Figure 3.1: This is an example of the optical trackers used by our custom surgical navigation system. We use a total of 6 trackers during testing.

We also used a custom sterilizable stability device (Figure 3.2) that was designed and built at Ohio State and was comprised of 6 main parts: rail, pivot, instrumented handle, modified Alvarado boot (Zimmer, Warsaw, IN), VV slider mechanism, and AP bracket.\textsuperscript{71}
Figure 3.2: This figure shows detailed parts of our stability device. The varus-valgus (VV) slider, pivot, and rail can be seen in Fig. 3.2A. The instrumented handle, modified Alvarado boot, and the anterior-posterior (AP) bracket (partially obscured by dressing on the patient’s leg) can be seen in Fig. 3.2B.

The error associated with the surgical navigation system is minimal with a linear accuracy of <2 mm and a worst-case angular accuracy, in the transverse plane, of about 1.25°. To ensure that the loads measured by our system are actually the loads experienced at the knee, we validated our system for both intra- and inter-operator use by testing a mechanical “leg” with a 6 degree of freedom load cell at the knee and showed low mean errors no greater than a -0.11±0.73 N·m moment. The small magnitude of the errors, along with the similarities between the intra-observer and inter-observer errors suggested that our system can be used by a wide variety of surgeons as a valuable tool to characterize knee stability.

To minimize increased surgical time, we set up most of our system before the patient is brought into the operating room (OR). The camera is positioned to ensure good visualization of the surgical field and the stability device is assembled as seen in Figure 3.2, since it is taken apart for sterilization. We also calibrate a stylus and attach optical
trackers to the VV slider mechanism, the modified Alvarado boot, and a custom plate probe. The stylus is then used to digitize several known points on these 3 pieces of equipment to establish reference frames needed for calculating the loads applied to the patient, the joint motions, and the orientations of the bone cuts.\textsuperscript{71}

After the patient is in the room, the knee is opened using a standard medial parapatellar arthrotomy and the surgeon places a threaded coupler that will rigidly hold an optical tracker in the tibia and femur. A 4 mm diameter 26 mm length cancellous screw (Zimmer, Warsaw, IN) is inserted through a flange in the coupler and into the bone to prevent it from rotating. To ensure that the couplers do not interfere with instrumentation needed to perform the TKA, the couplers are placed slightly medial and at the most proximal point of the incision for the femur and the most distal point of the incision for the tibia. Once trackers are attached to the patient’s tibia and femur via the couplers, both bones are digitized and reference frames are established using a previously established method.\textsuperscript{70}

The next step taken in the OR is to place the assembled stability device on the table above the sterile drapes by clamping the device rail to the table. The modified boot is then applied to the patient’s foot using Coban wrap (3M, St. Paul, MN) and the boot rod is placed in the VV slider mechanism with the leg in full extension as seen in Figure 3.2B.

For all testing, the optical tracking system records the motion of the tibia, femur, boot, and slide while the instrumented handle measures the load applied to the leg. Target loads were chosen based on what the surgeons felt were safe during a cadaver
pilot study and are similar to those used in other studies on normal knee stability.\textsuperscript{12,90,98}

We begin data collection by zeroing the load cell (Honeywell Model 31, Morristown, NJ) housed in the instrumented handle (Figure 3.2B). For varus-valgus testing, the surgeon places the instrumented handle in the VV slider (Figure 3.3A) and restrains the femur by gripping the patient’s distal thigh himself or with the help of a resident. He then applies varus-valgus load to the leg with a $\pm 15 \text{ N}\cdot\text{m}$ target for 3 trials. For anterior-posterior testing, the AP bracket is attached to the patient’s tibia using Coban (3M, St. Paul, MN). The instrumented handle is placed in the bracket and the surgeon applies an anterior-posterior load ($\pm 100 \text{ N}$ target) while restraining the femur (Figure 3.3B) for 3 trials. It is important to note that the surgeon is entirely in control of the amount of force applied to the patient and can stop at any time, thus ensuring the patient’s safety. After pre-implant data is taken, the trackers are removed from the couplers on the tibia, the femur, and the boot. The pivot and VV slider mechanism are removed from the table and the rod is removed from the boot.

Figure 3.3: Our system has been successfully used in the OR to collect stability data in A) the varus-valgus direction and B) the anterior-posterior direction.
The surgeon then performs a standard TKA, and a Zimmer NexGen LPS flex knee (Warsaw, IN) has been used in this initial cohort of patients. After the bone cuts are made, the surgeon replaces the optical trackers into the couplers on the femur and tibia and places the plate probe on the distal femur cut, the anterior femur cut, and the proximal tibia cut in order to record the orientation of the implants. In our current protocol, the surgeon is blinded to these values because we only want to record what the surgeon does and not influence the procedure. After the implants are cemented in the knee, all trackers are replaced, the device is placed back on the OR table, and the patient’s leg is put in the device again. Using the same procedure as before, varus-valgus and anterior-posterior stability data is taken. All equipment is then removed from the patient and the table and then the surgeon closes the case.

Intra-op data is used to characterized knee stability by plotting the load applied to the leg (moment for VV testing and force for AP testing) versus the displacement (degrees for VV testing and millimeters for AP testing) for each trial of the pre- and post-implant data. An idealized curve can be seen in Figure 3.4. We defined laxity as the amount of displacement that occurs under a given load and stiffness as the slope of the load-displacement curve (Figure 3.4). For the varus-valgus data, we specifically determined for every trial the laxities that occur under a +10 N·m moment (varus), a -10 N·m moment (valgus), ±10 N·m moment, maximum varus moment, maximum valgus moment, and the maximum varus-valgus moment. We also determined the stiffnesses occurring under a +10 N·m moment, a -10 N·m moment, the maximum varus moment applied, and the maximum valgus moment applied. For the anterior-posterior data, we
determined for every trial the laxities that occur under a +100 N force (anterior), a -100 N force (posterior), ±100 N force, maximum anterior force, maximum posterior force, and the maximum anterior-posterior force. We also determined the stiffnesses occurring under a +100 N force, a -100 N force, the maximum anterior force, and the maximum posterior force.

Figure 3.4: Load-Displacement curves were used to analyze knee stability. Laxity is the displacement under a given load. Stiffness is the slope of the curve.

We calculated the average pre- and post-implant laxities and stiffnesses for all subjects and performed paired t-tests to determine if TKA, on average, caused a statistically significant change in joint stability in this small cohort (p ≤ 0.05). We conducted sensitivity analyses using a mixed model for repeated measures to account for the association of measures from the same individual to confirm the conclusions. To evaluate the reliability of our system, we calculated the between subject and within
subject standard deviation for all laxities and stiffnesses. To evaluate the consistency of the surgeon’s technique, we also calculated the average maximum loads and standard deviations that the surgeon applied to the subjects both pre- and post-implant.

### 3.4 Results

We have successfully used our system in the OR to take pre- and post-implant stability data on 15 patients. There have been no intra-operative or post-operative complications and the increase in surgical time has not exceeded 20 minutes (average 14.2 ± 4.9 minutes) for any of the participating patients. We were able to apply at least a ±10 N·m varus-valgus load and a ±100 N anterior-posterior load to each patient.

Maximum loads varied based upon what the surgeon felt was safe for each individual patient and are summarized in Table 3.1. Across patients, the maximum varus moment ranged from 10.1-34.3 N·m, the maximum valgus moment ranged from 10.2-34.2 N·m, the maximum anterior force ranged from 101.4-178.8 N, and the maximum posterior force ranged from 100.3-193.3 N.
Table 3.1: Averages and Standard Deviations (SD) for Maximum Applied Loads

<table>
<thead>
<tr>
<th>Load</th>
<th>Average</th>
<th>p-value</th>
<th>Between Subjects SD</th>
<th>Within Subject SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Varus Moment (N·m)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Pre</td>
<td>19.2</td>
<td>0.022</td>
<td>6.6</td>
<td>5.3</td>
</tr>
<tr>
<td>Post</td>
<td>16.5</td>
<td></td>
<td>5.1</td>
<td>3.4</td>
</tr>
<tr>
<td>Max Valgus Moment (N·m)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>19.8</td>
<td>0.403</td>
<td>5.1</td>
<td>2.7</td>
</tr>
<tr>
<td>Post</td>
<td>21.0</td>
<td></td>
<td>5.3</td>
<td>3.3</td>
</tr>
<tr>
<td>Max Anterior Force (N)</td>
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<td></td>
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<tr>
<td>Pre</td>
<td>134.2</td>
<td>0.879</td>
<td>19.0</td>
<td>14.7</td>
</tr>
<tr>
<td>Post</td>
<td>134.8</td>
<td></td>
<td>20.5</td>
<td>16.3</td>
</tr>
<tr>
<td>Max Posterior Force (N)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>142.2</td>
<td>0.423</td>
<td>25.5</td>
<td>11.5</td>
</tr>
<tr>
<td>Post</td>
<td>137.6</td>
<td></td>
<td>20.9</td>
<td>10.9</td>
</tr>
</tbody>
</table>

The low standard deviation found within subjects and between subjects (Table 3.2 and 3.3) indicates that our system for measuring intra-operative stability is reliable. The maximum within subject standard deviations for laxity in the varus-valgus direction and the anterior-posterior direction were 1.9° and 1.9 mm, respectively, which are close to the error associated with our measurement system (1.25° and 2 mm). For all laxity and stiffness values, the between subjects standard deviation is greater than the within subject standard deviation, indicating that our system is repeatable within the same person and capable of detecting differences between patients.
Table 3.2: Averages and Standard Deviations (SD) for Varus-Valgus Measurements

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Average</th>
<th>p-value</th>
<th>Between Subjects SD</th>
<th>Within Subject SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Laxity (°)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+10 N·m (varus)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>2.1</td>
<td>&lt; 0.001</td>
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<td>0.9</td>
</tr>
<tr>
<td>Post</td>
<td>3.5</td>
<td></td>
<td>1.6</td>
<td>1.4</td>
</tr>
<tr>
<td>-10 N·m (valgus)</td>
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<td>0.006</td>
<td>1.1</td>
<td>0.6</td>
</tr>
<tr>
<td>Post</td>
<td>3.5</td>
<td></td>
<td>1.8</td>
<td>1.0</td>
</tr>
<tr>
<td>±10 N·m (varus-valgus)</td>
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<td></td>
<td></td>
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<tr>
<td>Pre</td>
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<td>0.002</td>
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<tr>
<td>Post</td>
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<td>1.3</td>
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<tr>
<td>Max Varus Laxity</td>
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</tr>
<tr>
<td>Pre</td>
<td>3.1</td>
<td>&lt; 0.001</td>
<td>1.5</td>
<td>1.2</td>
</tr>
<tr>
<td>Post</td>
<td>4.4</td>
<td></td>
<td>1.9</td>
<td>1.6</td>
</tr>
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<td>Max Valgus Laxity</td>
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<td></td>
</tr>
<tr>
<td>Pre</td>
<td>2.8</td>
<td>&lt; 0.001</td>
<td>1.5</td>
<td>0.6</td>
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<td>Post</td>
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</tr>
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<td>Max Varus-Valgus Laxity</td>
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<td>&lt; 0.001</td>
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<td>1.2</td>
</tr>
<tr>
<td>Post</td>
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<tr>
<td><strong>Stiffness (N·m/°)</strong></td>
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</tr>
<tr>
<td>+10 N·m (varus)</td>
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<tr>
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<td>2.8</td>
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<tr>
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<td>-10 N·m (valgus)</td>
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<td>&lt; 0.001</td>
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Table 3.3: Averages and Standard Deviations (SD) for Anterior-Posterior Measurements

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Average</th>
<th>p-value</th>
<th>Between Subjects SD</th>
<th>Within Subject SD</th>
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<tr>
<td><strong>Laxity (mm)</strong></td>
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<tr>
<td>+100 N (anterior)</td>
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<tr>
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<td>±100 N (anterior-posterior)</td>
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<td>1.4</td>
<td>0.3</td>
</tr>
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<td>Max Posterior Laxity</td>
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<td>0.6</td>
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<td>Max Anterior-Posterior Laxity</td>
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<tr>
<td><strong>Stiffness (N/mm)</strong></td>
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<td></td>
</tr>
<tr>
<td>+100 N (anterior)</td>
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<td></td>
</tr>
<tr>
<td>Pre</td>
<td>120.5</td>
<td>0.438</td>
<td>31.5</td>
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</tr>
<tr>
<td>Post</td>
<td>106.5</td>
<td>49.9</td>
<td>49.9</td>
<td>21.0</td>
</tr>
<tr>
<td>-100 N (posterior)</td>
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<td></td>
</tr>
<tr>
<td>Pre</td>
<td>85.5</td>
<td>0.304</td>
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<td>13.3</td>
</tr>
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<td>Post</td>
<td>74.3</td>
<td>40.4</td>
<td>40.4</td>
<td>10.8</td>
</tr>
<tr>
<td>Max Anterior Stiffness</td>
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<td></td>
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</tr>
<tr>
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</tr>
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<td>Post</td>
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<td>57.1</td>
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<td>21.0</td>
</tr>
<tr>
<td>Max Posterior Stiffness</td>
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<td></td>
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<tr>
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<td>0.096</td>
<td>95.0</td>
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</tr>
<tr>
<td>Post</td>
<td>102.7</td>
<td>40.9</td>
<td>40.9</td>
<td>20.5</td>
</tr>
</tbody>
</table>
TKA did cause changes in joint stability for the 15 patients who participated in this study. Examples of pre- and post-implant varus-valgus and anterior-posterior stability curves for 2 representative patients can be seen in Figures 3.5 and 3.6, respectively.

Figure 3.5: Representative varus-valgus stability data from two representative patients (A and B) with the knee in full extension. Mean values from three cycles of testing are plotted along with ± one standard deviation. The surgeon successfully improved the alignment on each subject by reducing the varus deformity, as seen by the frontal plane angle when the moment is zero.
In our small cohort, TKA generally results in a “looser” knee in the frontal plane (Table 3.2), but no significant changes in stability were noted in the sagittal plane (Table 3.3). Specifically, TKA has increased (p < 0.001) the average amount of varus-valgus laxity under a ±10 N·m varus-valgus load by 3.0±2.8°. Maximum varus-valgus laxity also increased (p < 0.001) by 3.3±3.0° on average. The average stiffnesses at +10 N·m and -10 N·m loads decreased (p < 0.001 for both) after TKA by 1.9 N·m/° and 1.8 N·m/°, respectively, indicating a softer knee. However, the maximum varus-valgus stiffnesses did not change (p ≥ 0.05, see Table 3.2) after prostheses implantation.

3.5 Discussion

Our system, comprised of a custom surgical navigation system and a custom-built stability device, has been successfully used in the OR to quantify knee stability before
and after the TKA components are implanted. We believe that our approach is one of the only uses of a navigation system that can provide an objective intra-operative assessment of joint stability by recording not only the displacement of the knee but also, most importantly, the applied load that induced that displacement. We have demonstrated that our system can provide repeatable measurements while detecting differences between patients and between OA and TKA conditions. Additionally, the pilot study presented here indicates that TKA causes statistically significant changes in joint laxity and stiffness.

Our novel approach is not without limitations. While we acknowledge that there is a learning curve related to tracker placement and device assembly, taking stability measurements with our system is intuitive and requires a relatively small increase in surgical time (≤ 20 minutes). Additionally, it is a somewhat large piece of equipment and the size and weight would need to decrease in order for it to be more widely used. We also recognize that, despite the leg being tightly wrapped with Coban (3M, St. Paul, MN), some slippage between the boot and the leg is inherent to the design of the device because we are not using a rigid attachment to apply loads to the limb. However, our low standard deviations and our previous study suggests that this error is minimal. It is also important to keep in mind that while we observed some statistically significant differences between pre- and post-implant stability, we only tested 15 subjects with similar pre-op deformities who all underwent TKA with the same surgeon using the same implant. A different surgeon, use of different implants, or a different cohort of patients (for instance, valgus instead of varus deformity) could demonstrate different patterns of
stability. Additionally, knees in this initial cohort were tested in full-extension and
testing in deep flexion will likely yield different results. Despite these limitations, we
believe our system provides surgeons with a more objective comprehensive
characterization of intra-operative joint stability than has historically been possible.

Despite having the same fellowship-trained surgeon perform all of the TKAs in
this study, surgical technique between the 15 patients was highly variable. The varus-
valgus loads applied to some patients were 3 times the loads that were applied to others,
while anterior-posterior loads varied by a factor as large as 1.9. Similarly, we observed
post-implant max varus-valgus laxity to vary from 3.6° to 13.3° and post-implant max
varus-valgus stiffnesses to fall between 2.3 N·m/° and 20.0 N·m/°. Some of this
variability is likely due variations in the pre-op condition of the joints (some patients had
more severe deformities and contractures). Additionally, the max load that the surgeon
felt was safe to apply to a given patient is not going to be appropriate for all patients.
However, since the surgeon was blinded to the data while in the operating room, we
believe our study suggests that large variability exists in what is considered acceptable
stability of the TKA knee and the clinical impact of this variability is not currently
known.

While some researchers have used surgical navigation systems, pressure films,
tensioners, and instrumented trial components to assess balance (ROM, compartment
pressures, or gaps), we believe our system is unique in its ability to comprehensively
characterize the load-displacement relationship of the knee.\textsuperscript{17,30,91,97,99} In addition to
quantifying pre- and post-implant stability during surgery, our system has several other
research advantages. Given that our system demonstrates a high degree of reliability, we will be able to determine how changes in surgical technique, including component alignment, insert thickness, and soft-tissue balancing, can alter the stability of the joint. Our system is also being used as part of a larger study that aims to establish the relationship between intra-operative stability measurements and post-operative outcome by performing gait testing on participating patients before surgery and at 6 months and 2 years post-op.

3.6 Conclusion

We have demonstrated on 15 patients that our system for measuring intra-operative knee stability during a TKA can be easily and safely used. It provides reliable measurements and can detect differences between patients and changes in stability that are caused by TKA. Our system replaces a subjective “feel” of knee stability with an objective definition and provides us with the capability to determine how stability is related to clinical outcome which we believe is an important step toward improving patient satisfaction.

3.7 Acknowledgements

Research reported in this publication was supported by the National Institute Of Arthritis And Musculoskeletal And Skin Diseases of the National Institutes of Health under Award Number R01AR056700. The content is solely the responsibility of the
authors and does not necessarily represent the official views of the National Institutes of Health.
4.1 Abstract

In order to achieve a successful total knee arthroplasty (TKA) outcome, surgeons strive to establish proper TKA component alignment and a balanced joint in the operating room. What constitutes a perfectly balanced knee is not well-defined and many surgeons use the gap technique and/or assess balance by feel. However, it is not precisely understood how TKA component alignment affects the gap technique and the frontal plane biomechanics of the knee. Using a subject-specific computer model that accurately predicts frontal plane kinematics resulting from an applied varus-valgus (VV) force, we varied TKA component alignment to determine the effect on the gaps between the bone cuts and the biomechanical behavior of the joint. Regression analyses showed that gaps and VV joint mechanics could be accurately predicted by component alignment ($R^2$ values between 69.0% - 96.8%). However, our model showed that alignments that achieve balanced gaps do not necessarily result in balanced VV behavior. Our findings may indicate why current intra-operative techniques for achieving balance do not result in a successful clinical outcome for all patients.
4.2 Introduction

While total knee arthroplasty (TKA) is generally successful at restoring knee joint function and improving quality of life for patients with advanced osteoarthritis (OA), a significant subset of patients struggle with suboptimal outcomes including mild anterior knee pain, difficulty climbing stairs, slower walking, and failures requiring revision surgery. The success of TKA depends on many factors, but establishing a balanced knee has been identified as particularly critical. An improperly balanced joint can lead to instability, excessive polyethylene wear, and component loosening; all which are major factors for early revision surgeries. Achieving a balanced joint, however, remains a challenge that is not always achieved.

In an effort to establish a well-balanced joint intra-operatively, surgeons typically use the gap technique and/or assess the varus-valgus (VV) range of motion. The gap technique aims to create equal rectangular gaps between the bone cuts in full extension and 90° of flexion because it is believed that equal gaps will lead to equal forces in the collateral ligaments. Many surgeons have used spacer blocks, laminar spreaders, tensioning devices, instrumented trial components, and surgical navigation systems to help achieve a balanced joint in the OR. Assessing VV motion intra-operatively is usually also done by qualitative feel (the surgeon applies a VV load and judges if the knee feels balanced), but some surgeons are using navigation systems to measure the frontal plane motion of the joint. However, it is unknown if balanced gaps result in balanced frontal plane kinematics.
Component alignment is known to be highly variable\textsuperscript{35,38} and affects both the gaps between the bone cuts and the perceived feel of stability by both the surgeon and the patient. Multiple studies have noted that surgeons will vary the VV alignment of distal femoral and proximal tibial bone cuts by as much as 10.4° to achieve balanced gaps.\textsuperscript{29,49} Debate exists on the proper internal-external (IE) rotation of the femoral component to achieve perfectly balanced gaps with some researchers claiming that aligning to the transepicondylar axis is best and others noting that femoral IE rotation that achieves perfect gaps can vary between patients by as much as 13.3°.\textsuperscript{33,50} Internal rotation of the tibial component and lack of posterior slope on the tibial cut have been linked to excessive stiffness.\textsuperscript{51,52} Conversely, external rotation of the femoral component greater than 5° has also been shown to decrease VV range of motion.\textsuperscript{53} It is unknown, though, precisely how the combined alignment of both the femoral and tibial components in the coronal, sagittal, and axial planes effects the VV motion of the joint and the gaps between the bone cuts.

Computer simulations provide a robust method to identify cause-effect relationships\textsuperscript{103}, including how TKA component alignment impacts a variety biomechanical outcomes. Studies involving forward dynamic simulations have investigated the relationship between alignment and kinematics, ligament/muscle forces, and implant-bone impingement.\textsuperscript{42,85} Thompson et al. demonstrated that internal rotation of the femoral component induced a valgus alignment, increased quadriceps force, and increased the MCL force during a simulated oxford rig squat.\textsuperscript{85} Increasing posterior slope of the tibial component has been shown to increase the flexion angle at which bone-
implant impingement occurs and reduce femoral roll-back in simulated flexion-extension motions.\textsuperscript{42,43} Existing models have not examined how TKA component alignment affects gaps between bone cuts or the VV range of motion of the knee, but simulations offer the potential to systematically vary component alignment and predict these parameters.

We have developed an experimentally validated forward dynamic model which outputs frontal plane kinematics of the TKA knee when a VV force is applied distal to the ankle. To simplify the initial analysis, we ran the simulation with the knee in full extension since gaps and VV laxity are assessed at this angle in the OR and in 20\textdegree of flexion as commonly experienced during the weight acceptance phase of gait.\textsuperscript{104} The 3 objectives of this study are to: 1) predict the medial and lateral gaps between the bone cuts with the knee in full extension based on component alignment, 2) predict VV motion of the TKA knee in 0\textdegree and 20\textdegree of flexion based on component alignment, and 3) determine if balanced gaps between the bone cuts results in balanced VV kinematic behavior.

4.3 Materials and Methods

Experimental data used to develop and validate a musculoskeletal model were collected from a fresh frozen cadaveric specimen using a custom navigation system and test fixture.\textsuperscript{71} The motions of the femur and tibia were recorded while an experienced orthopedic surgeon (J. Granger) applied a VV load using the test fixture (Please see Appendix A for a detailed test procedure). Three trials were performed with the knee in full extension and in 20\textdegree of flexion after posterior-stabilized TKA components (Zimmer
NexGen LPS Flex, Warsaw, IN) were implanted. The load range for the knee in full extension was ±40N, while the load range for the knee in 20° of flexion was ±25N. Using our navigation system, we also recorded the orientation of the femoral and tibial components.

Our musculoskeletal model included the femur as one segment and all bony structures distal to the knee as a single segment (Figure 4.1).

![Figure 4.1: Model in A) full extension and B) 20° of flexion. In both cases, the femur is constrained proximal to the epicondyles, as indicated by the red triangles, while a varus-valgus force is applied to the yellow block.](image)
The size, mass, and inertia of each segment were scaled based on subject-specific anatomical measurements. TKA component models were obtained from the manufacturer (Zimmer, Warsaw, IN) and tibio-femoral contact was modeled using a previously established method.\textsuperscript{85,105} The LCL and MCL were each represented with two fibers; the posterior capsule was represented with 4 fibers; and all soft tissues were modeled as tensile springs with quadratic force-strain relationships.\textsuperscript{106} Components were placed in the model according to the alignment measured by the navigation system. The slack length and stiffness of the ligaments were then optimized to minimize the differences between the simulated and experimental load versus displacement curves (Figure 4.2). Table 4.1 summarizes the final ligament properties that resulted in the best correlated results. Forward dynamic simulations of the VV motions under $\pm 40$N load in full extension and $\pm 25$N load for the flexed knee were created using the SIMM Dynamics Pipeline (MusculoGraphics, Inc.; Santa Rosa, CA, USA) and SD/FAST (Parametric Technologies; Needham, MA, USA).
Figure 4.2: Validation plots for A) 0° and B) 20°. The experimental curves show the mean values along with ± one standard deviation (SD). The simulation curves fall within the SD of the experimental curves.

Table 4.1: Optimized ligament properties used for the subject-specific model

<table>
<thead>
<tr>
<th>Ligament</th>
<th>Stiffness (N/mm²)</th>
<th>Slack Length (% strain)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LCL – anterior band</td>
<td>43.48</td>
<td>5.62</td>
</tr>
<tr>
<td>LCL – posterior band</td>
<td>25.92</td>
<td>5.27</td>
</tr>
<tr>
<td>MCL – anterior band</td>
<td>377.77</td>
<td>8.66</td>
</tr>
<tr>
<td>MCL – posterior band</td>
<td>815.97</td>
<td>10.43</td>
</tr>
<tr>
<td>Posterior capsule 1</td>
<td>197.79</td>
<td>10.50</td>
</tr>
<tr>
<td>Posterior capsule 2</td>
<td>166.63</td>
<td>10.82</td>
</tr>
<tr>
<td>Posterior capsule 3</td>
<td>145.08</td>
<td>9.07</td>
</tr>
<tr>
<td>Posterior capsule 4</td>
<td>179.57</td>
<td>8.92</td>
</tr>
</tbody>
</table>

We ran a total of 146 simulations (73 at both 0° and 20° of knee flexion) to investigate how the force-displacement relationship of the knee was affected by TKA component alignment. The alignment ranges were chosen based on what is commonly seen in the OR. \(^{35,38,90,107,108}\) Femoral and tibial component varus(+)/-valgus(-) alignment were varied by ±6° in 3° increments. Femoral and tibial component external(+)/-internal(-) alignment were varied by ±15° in 7.5° increments. Femoral component flexion(+)/-recurvatum(-)
and tibial slope were varied by ±10° in 5° increments. For each plane, the femoral and tibial component alignments were each varied independently and then varied together.

From each simulation, we calculated medial and lateral gaps and generated a plot of the applied load versus the VV displacement. Medial and lateral gaps (Figure 4.3) were calculated in full extension prior to the load being applied to the leg.

![Image of knee joint with medial and lateral gaps indicated]

Figure 4.3: The medial and lateral gaps are indicated by the white arrows.

The medial gap was defined as the distance between the most medial points on the distal femoral cut and the proximal tibial cut. Similarly, the lateral gap was defined as the distance between the most lateral points on the distal femoral cut and the proximal tibial cut. Gap balance was calculated by subtracting the medial gap from the lateral gap (a value of 0 indicates perfectly balanced gaps). From each load-displacement curve, we
calculated the maximum VV laxity (the total amount of motion under the maximum applied varus and valgus loads), laxity under a ±15N load, VV terminal stiffness (slope of the load-displacement curve at the maximum applied varus and valgus loads), and VV stiffness when a 15N varus load and a 15N valgus load was applied (Figure 4.4). Laxity balance was calculated by subtracting the valgus laxity from the varus laxity for the maximum loads and ±15N. Similarly, stiffness balance was calculated by subtracting the valgus stiffness from the varus stiffness for the maximum loads and ±15N. Laxity/stiffness balance values of 0 indicate perfect balance.

Figure 4.4: A) Laxity and stiffness were determined for a 15N varus load and a 15 N valgus load. B) Laxity and stiffness were determined for the max varus and max valgus loads.

The relationships between component alignment and gaps, gap balance, laxity, laxity balance, stiffness, and stiffness balance were examined using Minitab software (State College, PA) by performing regression analyses with linear, quadratic, and interaction effects. The relationships between gap balance, laxity balance, and stiffness balance were examined with linear and quadratic effects only. A total of 39 regression analyses
were performed each having up to 15 terms. Factors that had regression coefficients with p-values $\leq 0.05$ were considered significant.
4.4 Results

The equations that resulted from our regression analyses show that we can successfully predict ($R^2 \geq 90.1\%$) the medial gap, lateral gap, and gap balance for the knee in full extension based on the frontal, sagittal, and axial alignments of the femoral and tibial components (Table 4.2).
Table 4.2: $R^2$ values for all regressions performed at $0^\circ$ and $20^\circ$

<table>
<thead>
<tr>
<th>Parameter</th>
<th>$R^2$ (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$0^\circ$</td>
</tr>
<tr>
<td>Gaps based on component alignment</td>
<td></td>
</tr>
<tr>
<td>Medial Gap</td>
<td>93.0</td>
</tr>
<tr>
<td>Lateral Gap</td>
<td>90.1</td>
</tr>
<tr>
<td>Gap Balance</td>
<td>92.0</td>
</tr>
<tr>
<td>Laxity based on component alignment</td>
<td></td>
</tr>
<tr>
<td>Max Laxity ($\pm40N$ for $0^\circ$, $\pm25N$ for $20^\circ$)</td>
<td>93.8</td>
</tr>
<tr>
<td>Max Varus Laxity</td>
<td>91.8</td>
</tr>
<tr>
<td>Max Valgus Laxity</td>
<td>96.8</td>
</tr>
<tr>
<td>$\pm15N$ Laxity</td>
<td>95.1</td>
</tr>
<tr>
<td>$15N$ Varus Laxity</td>
<td>94.3</td>
</tr>
<tr>
<td>$15N$ Valgus Laxity</td>
<td>95.6</td>
</tr>
<tr>
<td>Stiffness based on component alignment</td>
<td></td>
</tr>
<tr>
<td>Terminal Varus Stiffness ($40N$ for $0^\circ$, $25N$ for $20^\circ$)</td>
<td>69.1</td>
</tr>
<tr>
<td>Terminal Valgus Stiffness ($40N$ for $0^\circ$, $25N$ for $20^\circ$)</td>
<td>74.3</td>
</tr>
<tr>
<td>$15N$ Varus Stiffness</td>
<td>71.3</td>
</tr>
<tr>
<td>$15N$ Valgus Stiffness</td>
<td>80.6</td>
</tr>
<tr>
<td>Balance based on component alignment</td>
<td></td>
</tr>
<tr>
<td>Max Laxity Balance</td>
<td>94.6</td>
</tr>
<tr>
<td>$15N$ Laxity Balance</td>
<td>94.6</td>
</tr>
<tr>
<td>Terminal Stiffness Balance</td>
<td>94.3</td>
</tr>
<tr>
<td>$15N$ Stiffness Balance</td>
<td>94.3</td>
</tr>
<tr>
<td>Balance based on gap balance</td>
<td></td>
</tr>
<tr>
<td>Max Laxity Balance</td>
<td>7.3</td>
</tr>
<tr>
<td>$15N$ Laxity Balance</td>
<td>7.3</td>
</tr>
<tr>
<td>Terminal Stiffness Balance</td>
<td>40.4</td>
</tr>
<tr>
<td>$15N$ Stiffness Balance</td>
<td>40.4</td>
</tr>
</tbody>
</table>

The frontal plane of alignment of both components, the IE alignment of the femoral component, and the tibial slope are statistically significant ($p \leq 0.05$) when predicting the medial gap. All 6 alignments are significant when predicting the lateral gap and the gap balance. The medial gap, the lateral gap, and the gap balance are most sensitive to the
femoral and tibial component varus-valgus alignment. Table 4.3 indicates the alignments that will increase the gaps and achieve gap balance.

Table 4.3: Alignments that will increase gaps and achieve gap balance. Alignments that do not contribute (p > 0.05) are blacked out, while alignments that a variable is most sensitive to are highlighted in blue.

<table>
<thead>
<tr>
<th>Alignment</th>
<th>Increase Medial Gap</th>
<th>Increase Lateral Gap</th>
<th>Achieve Gap Balance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral VV</td>
<td>Varus</td>
<td>Valgus</td>
<td>Slight Varus</td>
</tr>
<tr>
<td>Tibial VV</td>
<td>Varus</td>
<td>Valgus</td>
<td>Slight Varus</td>
</tr>
<tr>
<td>Femoral IE</td>
<td>Internal</td>
<td>Internal</td>
<td>External</td>
</tr>
<tr>
<td>Tibial IE</td>
<td>Internal</td>
<td>External</td>
<td></td>
</tr>
<tr>
<td>Femoral FR</td>
<td>Flexion</td>
<td>Recurvatum</td>
<td></td>
</tr>
<tr>
<td>Tibial Slope</td>
<td>Extension</td>
<td>Slight Flexion</td>
<td>Slight Extension</td>
</tr>
</tbody>
</table>

Based on the regression analyses, we can also accurately predict, based on component alignment, various laxities ($R^2 \geq 91.8\%$), laxity balances ($R^2 \geq 90.4\%$), stiffnesses ($R^2 \geq 69.0\%$), and stiffness balances ($R^2 \geq 88.8\%$) as summarized in Table 4.2 for the knee in $0^\circ$ and $20^\circ$ of flexion. Table 4.4 summarizes the significant alignments (p ≤ 0.05) for predicting the laxity and stiffness of this knee and those alignments that would result in a softer knee with increased laxity and decreased stiffness. In full extension, the max laxity and the ±15N laxity for this knee are most sensitive to the femoral IE alignment and tibial VV alignment, respectively. Component alignment in the sagittal plane is most critical to laxity when the knee is in $20^\circ$ of flexion, terminal varus stiffness regardless of flexion angle, and terminal valgus stiffness in $20^\circ$ of flexion. Terminal valgus stiffness for the knee in full extension is most sensitive to tibial component IE rotation.
Table 4.4: Alignments that achieve a soft knee (increased laxity and decreased stiffness). Alignments that do not contribute (p > 0.05) are blacked out, while alignments that a variable is most sensitive to are highlighted in blue.

<table>
<thead>
<tr>
<th>Alignment</th>
<th>Max Laxity</th>
<th>±15N Laxity</th>
<th>Terminal Varus Stiffness</th>
<th>Terminal Valgus Stiffness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0°</td>
<td>20°</td>
<td>0°</td>
<td>20°</td>
</tr>
<tr>
<td>Femoral VV</td>
<td>Valgus</td>
<td>Varus</td>
<td>Valgus</td>
<td>Varus</td>
</tr>
<tr>
<td>Tibial VV</td>
<td>Valgus</td>
<td>Varus</td>
<td>Valgus</td>
<td>Varus</td>
</tr>
<tr>
<td>Femoral IE</td>
<td>Slight</td>
<td>Internal</td>
<td>Neutral</td>
<td>Internal</td>
</tr>
<tr>
<td>Tibial IE</td>
<td>External</td>
<td>External</td>
<td>External</td>
<td>External</td>
</tr>
<tr>
<td>Femoral FR</td>
<td>Flexion</td>
<td>Neutral</td>
<td>Flexion</td>
<td>Flexion</td>
</tr>
<tr>
<td>Tibial Slope</td>
<td>Flexion</td>
<td>Flexion</td>
<td>Flexion</td>
<td>Flexion</td>
</tr>
</tbody>
</table>

Table 4.5 summarizes the significant alignments (p ≤ 0.05) for predicting the laxity balance and stiffness balance and indicates the alignments likely to achieve kinematic balance. Stiffness balance is most sensitive to the VV alignment of both components, while laxity balance at 0° and 20° is most dependent on femoral IE alignment and femoral VV alignment, respectively.

Table 4.5: Alignments that achieve a balanced laxity and terminal stiffness. Alignments that do not contribute (p > 0.05) are blacked out, while alignments that a variable is most sensitive to are highlighted in blue.

<table>
<thead>
<tr>
<th>Alignment</th>
<th>Laxity Balance</th>
<th>Stiffness Balance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0°</td>
<td>20°</td>
</tr>
<tr>
<td>Femoral VV</td>
<td>Varus</td>
<td>Neutral</td>
</tr>
<tr>
<td>Tibial VV</td>
<td>Slight Valgus</td>
<td>Varus</td>
</tr>
<tr>
<td>Femoral IE</td>
<td>Neutral</td>
<td>Internal</td>
</tr>
<tr>
<td>Tibial IE</td>
<td>Slight Internal</td>
<td>Neutral</td>
</tr>
<tr>
<td>Femoral FR</td>
<td>Recurvatum</td>
<td>Recurvatum</td>
</tr>
<tr>
<td>Tibial Slope</td>
<td>Extension</td>
<td>Extension</td>
</tr>
</tbody>
</table>
In contrast to our regressions based on component alignment, our results indicate that laxity balance and stiffness balance cannot be predicted by gap balance (Table 4.1, $R^2 \leq 42.9\%$) as illustrated in Figures 4.5 and 4.6. Additionally, component alignments that produce gaps that are within 1mm of each other can results in very different force vs. displacement curves (Figure 4.7).

Figure 4.5: This plot shows laxity balance vs. gap balance. Laxity balance is the max valgus laxity minus the max varus laxity. Gap balance is the lateral gap minus the medial gap. Alignments that achieve a gap balance of 2 mm or less can have a laxity balance as large as 6°. Similarly, alignments that achieve laxity balance within 1° of perfect can have a gap balance as large as 8 mm.
Figure 4.6: This plot shows stiffness balance vs. gap balance. Stiffness balance is the terminal valgus stiffness minus the terminal varus stiffness. Gap balance is the lateral gap minus the medial gap. Alignments that achieve a gap balance of 1 mm can have a stiffness balance as large as 443 N/°. Similarly, alignments that achieve near-perfect stiffness balance can have a gap balance larger than 3 mm.
Figure 4.7: This plot shows the force-displacement curves that result from TKA component alignments that achieve near equal gaps. Different amounts of laxity and stiffness are observed despite all 4 alignments achieving a gap-balance within 1mm.

4.5 Discussion

To the best of our knowledge, we are the first to develop a forward dynamic model to predict joint kinematics, gaps, and stability when a varus-valgus load is applied to a TKA knee. Using our experimentally validated subject-specific model, we are able to accurately predict how the gaps between bone cuts, varus-valgus laxity, and varus-valgus stiffness change when the alignment of the femoral and tibial components are varied. The regression analyses indicated that gaps, laxity, and stiffness can be accurately predicted by component alignment alone. However, we also demonstrated that, for this particular knee, balanced gaps are not predictive of biomechanical balance (VV laxity or stiffness).
Our biomechanical model indicates that it is possible for surgeons to “tune” the component alignments to achieve desired gaps, laxity, and/or stiffness during a TKA. It is important to note that the optimal component alignment to minimize or maximize these variables is often in the middle of the range of possible alignments used in this study, indicating that our modeling technique can elucidate a “sweet spot” for TKA component alignment. As a result, our model suggests that the alignments needed for a tight knee are not merely opposites of the alignments that would produce a loose knee. Our model also indicates that there are complex trade-offs when adjusting component alignments. For example, if a surgeon wanted a looser-feeling knee for this particular subject, increasing valgus alignment of the tibial and femoral components would result in more laxity with the knee in full extension, but less laxity in 20° of flexion.

There are some potential limitations to our model. Since it is subject-specific, the component alignments that result in a balanced knee should cautiously be generalized only to other knees with similar anatomy. Similarly, the equations that resulted from our regression analyses cannot be applied to other knees to predict gaps, laxity, and stiffness. Another limitation of this study is that it was limited to a knee in full extension and 20° of flexion. While the model was well-correlated to experimental data at 0° and 20°, we noted a high degree of variability in the experimental data collected at 90° of flexion. Future studies will involve improvements to the test set-up to minimize the variability and allow for modeling in deeper flexion.

Considerable research has been dedicated to improving TKA outcomes by improving the alignment of the TKA components. The use of surgical navigation
systems in the OR has been shown to improve frontal and sagittal plane alignment of the femoral and tibial components, as well as reduce the number of outliers.\textsuperscript{95,109-112}

However, several studies comparing navigated to conventional cohorts suggest that navigation may not have long-term clinical advantages, since functional scores, range of motion, activity, and pain scores are not statistically different between the 2 groups at 5 years post-op.\textsuperscript{95,112} More recently, patient-specific instrumentation (PSI) has been used in the OR to aid in component alignment and several studies indicate that PSI is superior to conventional instrumentation in restoring a neutral mechanical axis at the time of surgery.\textsuperscript{113-115} While both of these methods (PSI and navigation) are likely to reduce outliers, they don’t provide the surgeon with any information on the biomechanical behavior of the knee that will result from the selected component alignments unlike our model.

The clinical utility of achieving equal gaps intra-operatively is debated, with many studies recognizing that even normal knees do not exhibit equal gaps and equal gaps can be difficult to realize.\textsuperscript{25,30,116,117} Some studies have suggested that the gap technique has no long-term clinical benefit when compared to measured resection and results are similar for post-op range of motion and functional knee scores.\textsuperscript{30,116} Our study indicates that various unique component alignments can result in equal gaps and simultaneously have different biomechanical behavior, which may be a possible reason why achieving equal gaps in the OR does not always constitute a clinically successful knee.
4.6 Conclusion

Knee balance in the OR during TKA is generally established by use of the gap technique and/or surgeon feel. Our subject-specific model and subsequent regression analyses provide accurate predictions for the gaps between bone cuts, frontal plane laxity, and frontal plane stiffness based on the alignment of the femoral and tibial components. However, our model indicates that balanced gaps do not necessarily predict balanced biomechanical behavior of the knee which we believe may be more indicative of a successful functional outcome. The modeling technique and regression analyses used for this study provide a preliminary algorithm for establishing a balanced knee based on alignment and we hope this could potentially lead to a more robust algorithm that could eventually be used in the OR to aid surgeons in achieving a balanced joint and improving post-operative functional outcomes.
Chapter 5: Conclusion

Establishing a well-aligned and stable knee during TKA is important to the clinical outcome of the procedure, but is often a more of an art than a science for surgeons. In an effort to improve component alignment, surgeons have turned to surgical navigation systems, patient-specific instrumentation, and instrumented trials. Spacer blocks, tensioning devices, and laminar spreaders have also been used in the OR to evaluate the gaps between the bone cuts when trying to ensure a balanced knee. More recently, navigation systems have been used to intra-operatively verify the gaps and assess varus-valgus range of motion. However, the long-term clinical success of all these methods is debated. It is not clear how TKA changes the load-displacement relationship of the knee or what’s clinically acceptable.

We developed a custom stability device and a custom surgical navigation system that can comprehensively characterize the load-displacement relationship of the joint. We have used this system to determine if there is an optimal rotational alignment of the tibial component in the transverse plane. We also used our system inside the OR to quantify the stability of OA and TKA knees. Lastly, we developed a computer simulation, which was validated with previously collected stability data, that was used to study the relationship between component alignment, bone cut gaps, and biomechanical stability.
5.1 Contributions

The main contributions of the research presented in this dissertation are:

Implementation of our custom stability device and custom image-based navigation system for use on cadavers. While other cadaver studies have investigated the load-displacement relationship of normal knees, we are one of the first groups to examine this in TKA knees. By developing and refining our system on cadaveric specimens, we were able to transfer this capability to the OR.

TKA changes knee kinematics and stability, but there is no statistically significant difference based on tibial component rotation. The cadaver study presented in Chapter 2 suggests that TKA produces a looser knee. We observed an increase in frontal plane laxity and a decrease in terminal stiffness. The results for passive flexion kinematics also indicated that anterior translation of the femur and internal-external rotation of the tibia also increased. However, we collected data for 4 different rotational alignments of the tibial components and found no statistically significant differences. Our observations suggest surgeons who align the tibial component to any of the axes we examined are expected to have results consistent with those who may use a different axis.

Implementation of our custom stability device and custom image-free navigation system for use in the OR on TKA patients. Navigation systems have been used in the
OR to measure gaps between the bone cuts and the frontal plane motion of the knee when a surgeon applies a varus-valgus load. However, we were able to develop and use an entirely new tool to in the OR that provides a more complete picture of knee stability. To the best of our knowledge, we are the only group with a tool that is capable of measuring both the load applied to the patient’s leg and the motion of the bones in the OR. Load-displacement data has been collected on cadaver specimens and on living patients in a clinic setting, but the equipment used in these studies was not suitable for use in the OR. Our device is sterilizable and has been successfully used by 2 orthopaedic surgeons thus far. The capability afforded by our system provides a much more complete picture of joint stability during surgery than previous methods.

**Demonstrated that achieving equal gaps between bone cuts in surgery does not result in biomechanical balance in all patients.** Many surgeons utilize the gap technique in the OR due to the belief that equal gaps will result in equal forces in the collateral ligaments and ultimately, produce a balanced knee. However, this has never been proven. Our simulation study demonstrated that a variety of component alignments will result in balanced gaps, but exhibit very different biomechanical behavior including unbalanced amounts of varus-valgus laxity and terminal stiffness.

**Established a preliminary algorithm for establishing a stable joint in the OR.** Our simulation study showed that we can accurately predict bone cuts and biomechanical stability using regression equations based solely on component alignment. Currently,
establishing a stable joint in the OR is generally a subjective process and often surgeons will perform soft tissue balancing until the knee “feels right”. However, our results indicate that the surgeon could systematically tune the alignment of the components to achieve a desired tightness or looseness in the joint. In the future, the regressions could be expanded to include soft tissue balancing, providing surgeons with a comprehensive algorithm for establishing a stable joint.

5.2 Future Work

This dissertation presents the implementation of a custom stability device and a custom navigation system in a laboratory setting and in the OR. This system was subsequently used to answer clinically relevant questions about surgical technique during TKA and has laid the ground work for additional investigations.

**Determining clinically successful knee stability.** While we have shown that it is possible to characterize knee stability in the OR by measuring the load applied to the patient’s leg and the resulting motion, we don’t know what amount of laxity and stiffness will result in a clinically successful TKA outcome. In general, surgeons believe the knee should not be too tight and a little varus-valgus laxity should be achieved postoperatively with the ideal knee being looser in flexion than in extension and looser laterally (under varus stress) than medially, but little evidence supports these beliefs.\(^7,^{20,88}\) The TKA patients who elected to be part of the intra-operative study were evaluated in the OSU Movement Analysis and Performance Program Lab before surgery and are planning to...
return at 6 months and 2 years post-op. We plan to continue recruiting patients into this study in order to increase our sample size. A main goal of this larger study is to link the stability measurements made in the OR to clinical outcomes and hopefully provide surgeons with a “target” stability range.

**Measurement of load-displacement relationship of the TKA knee in flexion.** The research presented in this dissertation focuses on the evaluation of the knee in full extension. However, it is well documented that the knee becomes looser as it is flexed.\(^5\) It is not understood how TKA changes the laxity and stiffness of a flexed knee. Our system will allow for stability testing with the knee at any flexion angle between 0° and 90°, but time limitations have not allowed for additional testing in the OR. However, this is an important void to address because surgeons will frequently perform a subjective assessment of stability with the knee in 90° and many activities of daily living (walking, climbing stairs, rising from a chair) require knee flexion.\(^87,104\)

**Investigation of posterior cruciate ligament (PCL) retaining implant designs.** PCL-substituting (PS) implants were used for the initial cohort of TKA patients that participated in the OR study and will continue to be used on those who enroll in the future. However, many surgeons opt for a cruciate-retaining (CR) implant and it has been established that CR and PS designs demonstrate different kinematics. The two designs have been shown to produce different patterns of femoral roll-back during deep knee flexion.\(^118\) Additionally, patients with PS implants have demonstrated better range
of motion when compared to patients with cruciate-retaining (CR) designs.\textsuperscript{118,119} It has also been suggested that CR and PS designs also have different tension patterns in the soft tissues surrounding the knee.\textsuperscript{120} It seems reasonable that the force-displacement relationship of a knee with a CR implant may be different from those that we’ve recorded in the OR using a PS design.

**Effect of soft tissue balancing.** Debate exists regarding how much soft tissue balancing is appropriate during TKA to establish a stable knee. It has been suggested that ligament releases may not be necessary if the knee joint is properly aligned.\textsuperscript{121} Post-operative “imbalance” of the collateral ligaments can lead to early loosening and instability, but leaving the knee too tight may cause stiffness and limited motion.\textsuperscript{26,122-124} Using the custom stability device and navigation system, the effect of individual ligament releases on knee stability could be investigated on cadavers or on TKA patients in the OR. The most complete understanding of soft-tissue balancing and its relationship to stability is likely to result from a parametric study using our computer model where releases could be evaluated individually and in combination with each other.

**Predict laxity and stability in real-time during surgery.** The regression analysis performed on the results from the simulation study presented in Chapter 4 indicate that laxity and stiffness can be well-predicted by inputting component alignments into an equation. Since surgeons can measure component alignment off the bone cuts before the final implants are cemented in place, this calculation could be done quickly in the OR and
allow the surgeon to make alignment changes if the computed laxity and stiffness are not desirable.

Currently, the regression equations are specific to the cadaver specimen that we chose to model and cannot be generalized to other knees. By developing more patient-specific models, we hope to classify knees based on pre-implant stability patterns and generate regression equations for each group. This would allow a surgeon to categorize a TKA patient based on the pre-implant stability data and then calculate the post-op laxity and stiffness in the OR using the appropriate set of regression equations.

**Development of an algorithm based on pre-op condition of the knee, component alignment, and soft-tissue balancing that will predict functional outcomes after TKA.** Using the methods presented in this dissertation, we have the capability to comprehensively characterize joint stability in the OR, link OR measurements to functional activities in a gait lab (pre- and/or post-op), and create validated computer models. We believe this lays the ground work for the development of an algorithm that would take inputs like pre-implant function, pre-implant stability, component alignment, implant design, and soft-tissue releases to predict the post-implant stability of the knee. If our modeling capabilities are expanded to functional activities like walking, rising from a chair, and climbing stairs, we could potentially predict the functional outcome before the patient leaves the OR. The ability to predict post-op function while the patient is still in the OR provides the surgeon with the opportunity to make changes to many of
the algorithm inputs in an effort to ensure the best possible outcome for every TKA patient.

5.3 Additional Applications

Additional applications of the work presented in this dissertation include studies of orthopaedic surgeries other than TKA, comprehensive characterization of knee stability in a clinic setting, prosthetic design, evaluation of physical therapy protocols, and applications in veterinary medicine.

Stability during anterior cruciate ligament (ACL) reconstruction surgeries. ACL injuries requiring surgical repair are common athletic injuries and considerable research has been dedicated to post-op knee stability.\textsuperscript{125,126} Similar to TKA, ACL researchers acknowledge that what constitutes clinically successful stability is unknown. Yamamoto et al. specifically noted that new, more specific dynamic tests may be necessary to understand the relationship between surgical technique and in the patients’ perception of stability.\textsuperscript{126} Additionally, the work presented in this dissertation and the on-going TKA studies cannot be generalized to patients undergoing ACL reconstruction since the TKA population is significantly older. Considering that ACL repairs in adolescents, especially females, are increasing, understanding what is normal healthy knee stability in this younger population and how ACL-reconstructed knees differ may help orthopaedic surgeons achieve better clinical outcomes.\textsuperscript{127-129}
**Shoulder arthroplasty.** Shoulder arthroplasty has been successful in treating patients with severe rotator cuff tears and glenohumeral arthritis, both of which result in a painful, functionally limited shoulder. However, complication and revision rates are high, the procedure has an inconsistent clinical outcome, and instability after surgery has been linked to dislocations. This maybe especially problematic since some studies project that the growth rate of shoulder arthroplasty will be comparable or higher than TKA. Surgical navigation systems have been shown to improve component placement during shoulder arthroplasty, but little research exists on intra-operative kinematics or stability of the joint. The development of a tool to intra-operatively measure the load-displacement relationship of the shoulder joint, similar to the custom stability device we use on knees, would allow surgeons to understand how the shoulder arthroplasty changes stability and possibly how surgical technique affects clinical outcomes.

**Device for comprehensive characterization of knee stability in a clinic setting.** The work presented in this dissertation focused on measuring the load-displacement relationship of the knee inside the OR by attaching optical trackers directly to the tibia and femur. This is an invasive method and not appropriate for use outside of surgery. However, the ability to accurately and easily obtain a stability curve in a clinic setting may be useful before and after surgery. There are several commercially available devices that researchers and clinicians have used to evaluate knee laxity outside the OR including the Genucom Knee Analysis System, KT1000 device, KT2000 device, and the TELOS device. These devices will apply a known load to the test subject’s leg and provide a
single value for the translation or rotation of the knee, which gives only a “snapshot” of the joint’s stability. Researchers performing in vivo experiments on healthy subjects have simultaneously measured both load and joint displacement in a lab setting, but the test equipment frequently involves dental chairs, erector sets, and fiberglass casts, rendering them impractical in a medical office due to sheer size.\textsuperscript{12-14} The development of a new compact, easy-to-use device that would accurately measure the load-displacement curve of the knee in a surgeon’s office may aid in pre-op planning of the TKA and post-op assessment when sub-optimal outcomes do occur.

**Canine Total Knee Arthroplasty.** The number of TKAs performed on dogs to treat debilitating OA has been growing since 2005 when implants first became commercially available.\textsuperscript{134} Surgical technique in canine TKA currently involves “eyeballing” alignment and subjective evaluations of intra-op stability and kinematics. Research on TKA in dogs is still in the early phases and has focused mainly on proper implant fixation and restoration of the mechanical axis of the limb.\textsuperscript{135} Similar to human TKA, veterinary surgeons acknowledge that errors in component alignment and soft tissue management can result in excessive joint laxity, instability, and asymmetric loading of the implant.\textsuperscript{134} However, canine TKA poses some unique challenges not seen in human TKA including highly variability in the bony anatomy due to the range in dog sizes and the large number of breeds. Additionally, canine bones are much smaller in scale than human bones, making the procedure much more prone to errors in component alignment. Use of
surgical navigation during canine TKA, similar to our use during human TKA, may improve alignment and aid in the assessment of stability and kinematics.

**Prosthetic design for transfemoral amputees.** In 2005, there were an estimated 1.3 million individuals in the US living with the loss of a limb and this number is expected to grow to 3.6 million in 2050.\(^{136}\) Individuals who have undergone a tranfemoral amputation typically use a prosthetic leg that has a knee which is controlled mechanically or by a microprocessor.\(^{137-140}\) Patients with these types of prosthetics have been shown to walk slower, exhibit abnormal trunk kinematics, and have an altered swing phase.\(^{137,139,140}\) Many researchers believe this maybe due to sub-optimal joint stability.\(^{137,139,141}\) Lawson et al. has recently developed a new controller for a microprocessor powered knee that is intended to enhance knee stability.\(^{141}\) However, no generally accepted way of how to define or quantify stability or dynamic balance control during walking currently exists for this population.\(^{137}\) Comprehensively characterizing the load-displacement relationship of the knee joints that are part of the prosthetic limbs, similar to how we did in the OR study, may be an important step in determining what constitutes a stable and clinically successful prosthetic limb.

### 5.4 Summary

The number of patients opting for total knee arthroplasty due to debilitating osteoarthritis is increasing and generally, it is an effective procedure. However, a significant number of patients experience sub-optimal outcomes that include pain,
instability, and difficulties with activities of daily living. These outcomes are frustrating and distressing for patients and surgeons alike. The ultimate goal of the research presented in this dissertation is to improve patient satisfaction with TKA. Since knee instability has been linked to revision surgeries and is usually evaluated subjectively, fully quantifying stability and understanding the effect of TKA on knee stability was determined to be an important step in improving clinical outcomes and selected as the focus of this dissertation.

The research and methodologies presented here will hopefully lay the framework for additional orthopaedic and biomechanics studies. The use of novel equipment and surgical navigation systems to collect data in the OR presents opportunities to address research questions far beyond the scope of this project. Historically, use of navigation has focused heavily on component alignment, but this work highlights that it can be used as a powerful research tool as well.

I also hope that the research presented here will serve as a prime example of the benefits of cross-disciplinary research. Neither the cadaver study, the OR study, nor the computer simulation would have been possible without engineers, surgeons, nurses, and statisticians working together. As an engineer, I feel truly fortunate to have had the opportunity to work in such a highly integrated field. After all, replacing a joint in the human body with a mechanical system permanently interlocks the fields of medicine and mechanical engineering.
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Appendix A: Detailed Test Procedure for Use of the Custom Stability Measurement System

A custom system to measure knee stability was used for both the cadaver study and the intra-operative study presented in this dissertation. Our system is comprised of a custom surgical navigation system and a custom stability device (Figure A.1). The device measures the load that the surgeon applied to the leg and the resulting motion of the limb is recorded with the navigation system. The measurements obtained with our system comprehensively characterize the load-displacement relationship of the joint. This appendix contains a step-by-step test procedure used for cadaver and intra-operative data collection.

Figure A.1: Custom stability device used for cadaver and OR testing
1. The stylus (Figure A.2) used for digitizing points on the device and the leg is calibrated by circumducting the tool around a single point.

![Figure A.2: Stylus used for digitizing points during testing](image)

2. A tracker is attached to the modified Alvarado boot and a reference frame is established by digitizing 3 known points (Figure A.3). The position of the tracker in its holder is recorded so that it can be removed and replaced if needed throughout the test procedure. The holder has 6 discreet positions.

![Figure A.3: Digitized points on boot](image)
3. A tracker is attached to the varus-valgus slider and a reference frame is established by digitizing 3 known points (Figure A.4). The position of the slider tracker in its holder is recorded.

![Figure A.4: Digitized points on the varus-valgus slider](image)

4. A reference frame is established for a plate probe by digitizing 3 known points (Figure A.5)

![Figure A.5: Digitized points on plate probe](image)
5. The surgeon opens the knee using a standard medial parapatellar arthrotomy.

6. A tracker holder (Figure A.6) is screwed into the medial distal end of the femur and the medial proximal end of the tibia. An additional surgical screw is placed through a tab in the holder to prevent rotation. Care is taken to keep the holders away from where the bone cuts will be made.

![Tracker holders](image)

Figure A.6: Tracker holders are screwed into the femur and tibia.

7. Optical tracking arrays are placed in the holders on the tibia and the femur as seen in Figure A.7. The position of each tracker in its holder is recorded.
8. The surgeon circumducts and flexes the hip joint to calculate the center of the hip.

9. The surgeon digitizes the PCL attachment, the lateral epicondyle, and the medial epicondyle on the femur to establish a reference frame for the bone.

10. The surgeon digitizes the midpoint of the tibial spine, the most medial and lateral points on the tibial plateau, and the medial and lateral malleoli to establish a reference frame for the tibia.

11. The surgeon flexes and extends the knee 3 times while the surgical navigation system records the passive kinematics. The joint is flexed by supporting the foot with an open palm while gently lifting the thigh taking care not to apply any internal-external or varus-valgus torques on the limb. The reverse procedure is used for extended the leg.
12. The modified Alvarado boot is placed on the foot and secured with Coban™ (3M Products, St. Paul, MN).

13. The custom stability device is placed on the OR table or the lab bench.

14. The peg extending from the boot is placed in the rotating fork on the varus-valgus slider as seen in Figure A.8.

Figure A.8: The leg is placed in the stability device by placing the boot peg in the slider fork.

15. Make certain all trackers are placed in the proper positions (those used for establishing reference frames) and are easily viewed by the camera.

16. Zero the load cell in the instrumented handle.

17. The surgeon places the instrumented handle in the varus-valgus slider (Figure A.9) and applies a load of approximately ±20 N·m. The surgeon can stop applying the load at any point if s/he feels it isn’t safe. The custom surgical navigation system
simultaneously records the motion of the trackers and the load applied to the limb. Three trials are performed.

Figure A.9: The instrumented handle is placed in the slider for varus-valgus data collection.

18. The anterior-posterior (AP) bracket is attached to the leg using Coban™ (3M Products, St. Paul, MN).

19. The instrumented handle is placed in the AP bracket (Figure A.10) and the surgeon applies a ±100 N load. Three trials are performed.
Figure A.10: The instrumented load cell is placed in the AP bracket for anterior-posterior data collection.

20. The internal-external (IE) wrench is slid on to the boot peg and the instrumented handle is inserted into the wrench (Figure A.11). The surgeon applies a torque to the leg via the wrench. The target torque is ±15 N·m and 3 trials are performed.
Figure A.11: The instrumented handle is inserted into the IE wrench for internal-external data collection.

21. Once all pre-implant stability and kinematic data have been recorded, the stability device can be removed from the table and the tibial, femoral, and boot trackers can be removed from their holders. The holders should remain in the bones and the boot should remain on the limb. The AP bracket can also be removed from the leg.

22. The surgeon performs a standard TKA.

23. Replace the tibial and femoral trackers in the proper position in their holders after the surgeon has made the bone cuts, but before the final implants are in place.

24. Using the plate probe, record the orientation of the distal femoral, the anterior femoral, and the proximal tibial bone cuts (Figure A.12).
25. Remove the bone trackers from their holders and finish installing the TKA components.

26. After the final implants are in place, replace the bone trackers in their proper positions and take passive kinematic data again using the same procedure as before.

27. Replace the boot tracker in its holder and place the stability device back on the table.

28. Ensure all trackers are in their proper positions and take varus-valgus, anterior-posterior, and internal-external stability data using the same procedure followed in steps 16 – 20.

29. Once all post-implant data has been collected, remove the stability device from the table. The AP bracket, the boot, the IE wrench, and the tracker holders in the tibia and femur should also be removed.
30. Once all test equipment is out of the surgical field, the surgeon can close the case as usual.