Columbia University Human Subjects Protocol

General Information

Principal Investigator: Geller, Jeffrey
Title: Outcomes in free-hand versus sensor-guided balancing in total knee arthroplasty: a randomized controlled trial
Protocol Version #: IRB-approved version 07/14/2021 (Y05M00)
IRB-AAAR6137

Background

Total knee arthroplasty (TKA) is one of the most successful surgical procedures performed worldwide, and if conducted properly, has proven to improve pain, knee range of motion, and ultimately quality of life. Approximately 700,000 TKAs are performed annually in the United States, and this number is projected to increase to 3.48 million annually by 2030.1 Unfortunately, roughly 20% of patients who undergo TKA are dissatisfied with their outcome and this number has remained stagnant for the past decade. Patient satisfaction after TKA is predominantly driven by postoperative pain and function.2 Outcomes in TKA are influenced by multiple factors, stemming from patient-specific factors and surgically modifiable factors. Patient specific factors include body mass index (BMI), preoperative range of motion (ROM), psychological status, and other comorbidities; examples of surgically modifiable factors include the type of prosthesis utilized, posterior condylar offset, posterior tibial slope, and soft tissue balancing.3,4,5Knee arthritis is a disease not only of the condylar surfaces, but of the soft tissues as well. As such, the success of a TKA depends on the ultimate restoration of the integrity of the knee articular surfaces, necessitating two critical elements, beginning with precise osteotomies and ending with soft tissue balancing to realign the lower extremity to a neutral mechanical axis.6 In the last three decades, this first element has been addressed by major technological advances to perform precise and reproducible osteotomies, most recently with the development of computer-assisted navigation and validation techniques and modalities that allow osteotomies based on anatomical jigs created by CT imaging of the patient's knee.6 Despite these advances, little advancement has been appreciated by the second element—soft tissue balancing. While precise osteotomies are critical to the success of a TKA, they do not address ligamentous stability and balance, which if absent, leads to knee instability, stiffness, accelerated prosthetic wear, aseptic loosening, and premature implant failure.6, 7,8 Soft tissue imbalance accounts for 35% of early TKA revisions in the United States.9,10 Soft tissue balancing in TKA has traditionally been more of an art than a science, relying exclusively on the surgeon's subjective assessment based on nebulous tactile feedback after completion of the osteotomies. The diseased soft tissues (i.e. ligaments) may be lengthened, tightened, or released to achieve balance, range of motion, and functional stability.11 However, these methods are numerous, variable, and above all, highly subjective.9, 12 The individual experience of the surgeon, including fellowship training and procedural volume play a role in their ability to balance a knee properly. Typically, it is only after many years of experience does the surgeon develop the ability to accurately assess stability in varus, valgus, anterior and posterior planes. Objective balancing of soft tissues in TKA may contribute to a decrease in pain, improve function, patient satisfaction, and ultimately decrease the rate of revision.2 The need for the transformation of TKA soft tissue balancing from an art to a science has been realized by a technology that allows surgeons to objectively quantify ligament balance by offering real-time, evidence-based data during TKA. The Verasense (Orthosensor Inc., Dania, FL) is a disposable wireless device embedded with force sensors and inserted into the tibial component during the trialing phase of surgery after gross balancing, allowing real-time loading values in the medial and lateral compartments of the knee and fine-tuning of the end result by further soft tissue releases to improve balance and stability. Balance in TKA is defined as stability in the sagittal plane and less than 15 pounds difference in the medial and lateral compartments of the knee.9, 13 In a multi-center study, intraoperative sensors were utilized to define balance and to correlate it with improved clinical outcomes. TKAs that had undergone said balancing were compared to unbalanced TKAs, with results showing improved Knee Society Score (KSS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) between balanced (172, 14.5 points) and unbalanced (145.3, 23.8 points), respectively.9 The authors concluded that a well-balanced TKA was the most significant contributing factor to improved postoperative outcomes. Similarly, Chow et al. investigated six-month patient-reported outcomes in a small retrospective cohort

study with short-term follow up of six months comparing sensor-assisted to non-sensor-assisted TKA balancing. They reported that the KSS, Oxford Knee Score, and knee range of motion was significantly higher in the sensor-assisted cohort and that the rate of arthrofibrosis was lower in the sensor-assisted group, however, not statistically significant.2 Further, Geller et al. retrospectively compared the incidence of arthrofibrosis before and after the implementation of the Verasense technology to assist with ligament balancing and reported a 5% rate of arthrofibrosis prior to implementation versus 1.6% after.14 In this same report, median length of surgery was 83 minutes before implementation compared to 115 minutes after. The authors reported that while the implantation of the sensor increased operative time, this additional time does not have a clinical impact and that the benefits outweigh this potential increase in operative time.14Multiple reports in the literature have suggested that a well-balanced TKA, which leads to increased activity levels may be part of a cascade effect, which ultimately results in higher patient-reported outcome scores. Unfortunately, soft tissue balancing is one of the only remaining aspects of TKA that has not benefited from a consensus based on quantitative measures and objective data. As the economic environment changes in medicine, coupled with a five-fold increase in TKAs performed and the subsequent need for less experienced surgeons to perform TKAs, it is imperative that the traditional subjectivity once relied upon be replaced by more empirical and clinical data to construct a scientific consensus of what balance is. In so doing, clinical outcomes may be improved, with a resultant decrease in the rate of early revisions, and ultimately significant savings in healthcare expenditures. While the literature has demonstrated a clear advantage by technology like the Verasense, previous studies have predominantly been underpowered, with short-term follow up, and unstandardized TKAs, including surgical approach, prosthetic designs, manufacturer, and above all, not randomized and controlled.

References: 1. Kurtz S, Ong K, Lau E, et al. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am 2007; 89:780.2. Chow JC, Breslauer L. The use of intraoperative sensors significantly increases the patient-reported rate of improvement in primary total knee arthroplasty. Orthopedics. 2017. 40(4):648-6513. Jacobs CA, Christensen C, Karthikeyan T. Patient and intraoperative factors influencing satisfaction two to five years after primary total knee arthroplasty. J Arthroplasty 2014; 29: 1576-15794. Judge A, Arden NK, Cooper C, et al. Predictors of outcomes of total knee replacement surgery. Rheumatology 2012;51:1804.5. Kim KW, Han JW, Cho HJ, et al. Association between comorbid depression and osteoarthritis symptom severity in patients with knee osteoarthritis. J Bone Joint Surg Am 2011;93- A:556.6. Camarata D. Soft tissue balance in total knee arthroplasty with a force sensor. Orthop Clin N Am. 2014. 45:175-1847. Dennis DA, Komistek RD, Kim RH, et al. Gap balancing versus measured resection technique for total knee arthoplasty. Clin Orthop Relat Res 2010;468:102–78. Krackow KA. Instability in total knee arthroplasty: loose as a goose. J Arthroplasty 2003;18(3 Pt 2): 45–479. Gustke KA; Golladay GJ; Roche MW; Elson LC; Anderson CR. A new method for defining balance: promising short-term clinical outcomes of sensor guided TKA. J Arthroplasty 2014; 29: 955-96010. Fehring T, Odum S, Griffin W, et al. Early failures in total knee arthroplasty. Clin Orthop Relat Res 2001;392:315.11. Meneghini RM; Ziemba-Davis MM; Lovro LR; Ireland PH; Damer BM. Can intraoperative sensors determine the “target” ligament balance? Early outcomes in total knee arthroplasty. J Arthroplasty 2016; 31: 2187-2187 12. Incavo S, Wild J, Coughlin K, et al. Early revision for component malrotation in total knee arthroplasty. Clin Orthop Relat Res 2007;13:455.13. Walker P, Meere P, Bell C. Effects of surgical variables in balancing of total knee replacements using an instrumented tibial trial. The Knee. 2013.14. Geller JA, Lakra A, Murtaugh T. The use of electronic sensor device to augment ligament balancing leads to a lower rate of arthrofibrosis after total knee arthroplasty. 2017. 32: 1502-1504

Study Design

In a randomized-controlled fashion, this investigation will evaluate the use of the Verasense technology to achieve optimal TKA balance. Patients will be randomized to either: 1) undergo manual soft tissue balancing or 2) soft tissue balancing with the Verasense. The primary outcomes of interest will include patient-reported outcomes as well knee range of motion at 3 months, 6 months, 1 year, and 2 years. Secondary outcomes of interest will include pain level as assessed by the visual analogue scale (VAS) in the acute post-operative and follow up periods, ambulation distance during inpatient physical therapy postoperatively, surgical time, tourniquet time, amount of opioid consumption, length of hospital stay, incidence of arthrofibrosis and subsequent manipulation under anesthesia. We hypothesize that the use of the Verasense technology will lead to improved soft tissue balancing in TKA and ultimately result in favorable patient-reported outcomes and postoperative knee range of motion.

Statistical Procedures

Basic statistics will be done to describe the patient demographics for the overall cohort as well as the two groups. T-test and Fischer exact test will be done to compare the two groups.

Privacy & Data Security

Study data will require the use of identifiers only as long as necessary data collection is on-going. Data storage will occur only on encrypted desktop computers in the Center for Hip and Knee Replacement (PH1155) and the multi-user system ID #6692 that has been approved as a certified environment by Columbia. As soon as the required study information is collected, the patient names and MRNs will be replaced with patient numbers (patient 1,2,3,4.....). The only document linking study codes to patients will be protected by a password and safely stored on an encrypted desktop computer in a locked CUMC office as well as on the multi-user system ID #6692 that has been approved as a certified environment by Columbia.

Subjects will only be consented in private office rooms with only necessary research personnel. Research personnel and medical staff will be reminded to not discuss study participation outside closed private offices with study participants and research personnel.

Study Procedures

Patients undergoing TKA will be randomized to receive OrthoSeonsor or surgeon-guided ligamentous balancing. Patient-reported outcomes, pain levels, range of motion will be assessed at 3 month, 6 month, 1 year, and 2 year follow up visits.

No new pre, intra, or post-operation procedures will take place if you choose to take part in this study.

Before surgery, as we do with other non-study patients, you will be asked to complete several questionnaires to evaluate the function of your knee. Also as per standard of care, your knee will be evaluated by a few brief physical exams (i.e. range of motion tests, leg stability tests, neurovascular exam).

On the day of your surgery, your TKA will be performed either with or without utilization of the OrthoSensor device. This is to be decided randomly.

As a follow-up schedule, you will be seen at three months post-operation, six months post-operation, one year post-operation, and two years post-operation, where you will repeat the standard questionnaires. You will repeat the standard physical therapy exams. These visits will include the standard of care post-operative practices, exams and questionnaires.

The information recorded at the physical exams and on the questionnaires will be viewed and used by the study team to evaluate the procedure.

Study Devices

Device name: VERASENSE knee system
Device description: The device is a computer assistance device that is temporarily inserted into the tibial tray during total knee replacement. The device measures pressures and alignment in the knee intraoperatively.
Device Model/Version #: K130380
Phase of Study: Pivotal
Manufacturer Information: OrthoSensor

Recruitment and Consent

Subjects will be voluntarily recruited from the Principal Investigator or Sub-Investigator clinic population and/or referring physicians. Subjects who present with osteoarthritis or degenerative bone disease will be screened to determine if they meet all inclusion and no exclusion criteria. If all entry criteria are achieved, the subject will be eligible to participate in the study. All general and indication-specific entry criteria must be met prior to study entry. All relevant medical and non-medical conditions will be taken into consideration when determining whether a patient is suitable for participation within the study. As potential subjects will be under the clinical care of the study investigators, subjects will initially be informed of the study by each of the treating physicians. Researchers will not approach a patient for recruitment until that patient is informed of the study by the physician or PI on this study and the PI has ascertained that the patient is willing to discuss the study with the investigators. The sponsor is providing the devices in the same manner they currently provide them in the hospital.

Research Aims and Abstracts

Research Purpose:
The purpose of this study is to find out whether using a device to measure pressure inside a replacement knee can help the replacement knee work better long term.

Research Question(s)/Hypothesis(es):
Utilization of the OrthoSensor system will provide improved gap balancing and functional outcomes

Scientific Abstract:
It is thought that inter-compartmental soft tissue balance is an important factor with regards to primary TKA success rate. Until recently however, there has not been a way of quantifying this balance to rigorously check the validity of this correlation and determine whether ligamentous balancing

quantification improves surgical and patient-reported outcomes. Consenting patients (n=130) who present with an arthritic knee indicative of primary TKA will be randomized to undergo TKA either utilizing the OrthoSensor tibial trial device, which provides intra-operative compartmental pressure readings, or via the analogous standard of care TKA without the OrthoSensor device. Both groups will be evaluated both pre and post-operatively with various knee use scores (KSFS, WOMAC, and SF 12). The data will be analyzed to evaluate the efficacy of the OrthoSensor device and its effects on early clinical outcomes.

Lay Abstract:
In total knee replacements, it is thought that the tension on the medial compartment of the knee must be in balance with the tension on the lateral compartment of the knee for the replacement to work well and last. Until recently however, there has not been a way to test this claim with hard numbers. In this study, patients who have an arthritic knee, and are recommended to undergo total knee replacement surgery will either receive surgery using the OrthoSensor device, which provides real-time pressure readings on the compartments, or via the standard of care for total knee replacement, a procedure that solely relied on the surgeons experience and feel to balance the two compartments. By collecting quality of life, pain, and knee function information before and after surgery (at multiple post-surgery visits), efficacy of the OrthoSensor device and its effect on patients outcome will be compared.

Risks, Benefits and Monitoring

Loss of confidentiality is a potential risk. There are no other known risks for participating in this study beyond those described by the physician as part of the standard of care TKA procedure.

The potential benefits of this study include improved soft-tissue balancing and improved rotational congruency between the medial and lateral compartments in the knee undergoing operation. Another is improving the orthopaedic field's understanding of how medial and lateral compartment pressures, as well as rotational alignment, correlate with patient outcome. A final potential benefit is improving the standard of care for TKA, if the OrthoSensorTM device proves to be a reliable enhancer of patient outcomes and success rate.

Patients who are eligible for TKA, but do not wish to participate in the trial can decline participation and receive the treatment modality of their choice.

Patient confidentiality will be maintained through the storage of study data on encrypted, password protected devices, accessible only to approved study personnel. All non-digital information will be stored in a locked file cabinet available only to the principal investigator and key approved personnel. In the unlikely event that some potentially harmful consequence of the study occurs, medical and other professional intervention will be available and provided for the patient. Each patient enrolled will be given a study ID number, which will be used for the duration of the study instead of patient information. The match list with the study identifiers will be stored on a local, encrypted, password protected drive only to be available to key study personnel.

Study Subjects

Participation Duration: 2 years
Anticipated Number of Subjects: 130