Official Title:	Evaluation of the Patient Reported Outcomes After Sensor-guided Total Knee Arthroplasty Under Spinal Anesthesia With Limited Motor-block.
NCT Number:	NCT03053453
Study Number:	16-00129
Document Type:	Study Protocol
Date of the Document:	• February 2, 2021

Evaluation of the patient reported outcomes after sensor-guided total knee arthroplasty under spinal anesthesia with limited motor-block.

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Protocol Number: *S16-00129*

Initial version: November 8, 2016

I. PURPOSE OF THE STUDY AND BACKGROUND

Purpose

The purpose of this study will be to evaluate and compare patients undergoing TKA with sensor guidance versus that of a standard technique. Secondly, each patient will be assessed for the difference between passive, soft tissue controlled, pressure balance and muscle activated pressure balance.

We hypothesize that patients undergoing TKA with sensor guidance will have consistently higher satisfaction rates compared with standard technique and that muscle activated pressure balance will demonstrate a similar ratio of the medial to lateral compartment as that of the passive pressure balance.

Rationale

Total Knee Arthroplasty (TKA) is a successful and cost-effective method to relieve pain and improve function and quality of life in patients with advanced knee arthritis. Despite these reported benefits, 75-89% of patients are not satisfied with the outcome of their TKA. Thus, it behooves the surgeon to further investigate the reasons for this dissatisfaction. Besides unhappy patients and increased TKA revision rates, unsatisfactory outcomes lead to a high socio-economic burden.

The reliably of a successful total knee replacement is dependent on appropriate alignment of components, rotation congruency between components and ligamentous balance of the knee joint. The use of robotic systems and CT imaging has allowed for the surgeon to ensure correct alignment and anatomic rotation of the components but obtaining soft tissue balance remains elusive. Balance of a TKR is determined by numerous methods that are variable and highly subjective. This is dependent not only on a surgeons' experience, training and procedural volume but the patients BMI, gender and relative ligament laxity. Instability is cited in up to 22% of reported reasons for revision. In patients with instability the increased laxity in the soft tissue can cause pain, effusions, and inability to traverse curbs and inclined planes.

Reduction of these complications is essential to minimize the percentage of revision surgeries performed. Real-time data, presented intraoperatively can assist the surgeon in achieving a well-aligned and well-balanced knee. The Verasense Knee System device (OrthoSensor inc., Dania Beach, Florida) is a sterile sensor system that replaces the tibial insert trials used during surgery. The sensor contains a microprocessor and integrated nanosensor system, which wirelessly transmits real-time data to a portable graphic display unit used for read-out of the data. The sensor measures and localizes peak load at the medial and lateral tibiofemoral joint interfaces. Loading data is thereby captured intra-operatively through the full range of movement (ROM) using the sensor system.

Study Design

This is a randomized prospective study looking at the impact sensor guidance has on the outcome of patients and comparing to that of patients with a standard technique. The study is also designed to evaluate the difference between passive, soft tissue controlled, pressure balance and muscle activated pressure balance. Prior to the randomized study, there will be an observational pilot of 25 patients. These patients will not be randomized and will receive standard of care anesthesia. The reason for the 25 pilot patients is to perfect the sensor guidance so all subsequent study patients will have a streamlined, consistent measurement.

Primary Objective

The primary study objective is to evaluate patient outcomes following surgery with the use of the new Knee Society Score and the Knee Injury and Osteoarthritis Outcome Score (KOOS).

Secondary Objective

The secondary objective is to evaluate and compare the difference between passive, soft tissue controlled, pressure balance and muscle activated pressure balance at the time of surgery.

Further patient data that will be collected and evaluated will be: kinematic data including varus/valgus and anteroposterior stability, the presence of a flexion contracture or extension lag, anatomical alignment and ROM

II. CHARACTERISTICS OF THE RESEARCH POPULATION

Number of Subjects
The total number of subjects will be approximately 125. We would like to observe 25 patients as part of a pilot, preliminary study. These patients will not be randomized and will receive standard of care anesthesia. The reason for the 25 pilot patients is to perfect the sensor guidance so all subsequent study patients will have a streamlined, consistent measurement. Approximately 100 subjects will be enrolled into the randomized study.

Gender of Subjects
Men and women will be included in this study.

Age of Subjects
Subjects should be at least 50 years of age

Racial and Ethnic Origin
There are no enrollment restrictions based on race or ethnic origin.

Inclusion Criteria
Patients will be screened for eligibility based on whether they have chronic knee pain as a result of an arthritis-related condition.

- Patient with chronic knee pain who is indicated for total hip or knee replacement surgery
- Patient is at least 50 years of age
- Patient is willing to participate in pre- and postoperative surveys

Exclusion Criteria

- Failure to complete pre-operative surveys.
- Revision Total Knee Arthroplasty
- Prior ipsilateral knee surgery such as ligament reconstruction or osteotomy
- Simultaneous Contralateral Total Knee Arthroplasty
- Prior tibial plateau fracture
- Ligamentous Insufficiency
- History of fibromyalgia, chronic fatigue syndrome

Vulnerable Subjects
Although this population may include the elderly, which is a vulnerable population, we are not specifically targeting vulnerable subjects.

III. METHODS AND PROCEDURES

Methods and Procedures
After patients are enrolled in the study by meeting the inclusion criteria, subjects will participate in the study until 12 months after their knee replacement surgery. We estimate it will take 18 months to enroll all study subjects.

Visit 1: Immediate visit prior to surgery: Obtain consent and gather kinematic data including varus/valgus and anteroposterior stability, the presence of a flexion contracture or extension lag, anatomical alignment, ROM, and patient reported outcome measures, by use of the new Knee Society Score and the Knee Injury and Osteoarthritis Outcome Score KOOS

Visit 2: The day of surgery. Patients will undergo TKA performed under one of two spinal anesthesia protocols. Patients will be randomized into one of the two groups at their first visit.

- Protocol 1 – the current standard of care. Patients will be given spinal anesthesia with 2.6 mL of 0.5% isobaric bupivacaine.
- Protocol 2 – spinal anesthesia using a solution of 1ml of 0.5% isobaric bupivacaine in combination with 1.5 cc of sterile saline solution containing 7.5 micrograms of sufentanil 0.005mg/ml. Using this technique motor function of the operated leg is not inhibited during surgery. This is a sensation-only block with no added medical or pain risk to the patient. While it is true that many studies using intrathecal sufentanil use 5 mcg rather than 7.5 mcg [16], in this case, because of the reduced dose of local anesthetic, we elected to increase the dose of sufentanil to ensure that the patient would not experience pain. In our clinical experience, as well as in the published literature [17-27], especially in obstetrics, where preservation of motor function is especially important, a dose of 7.5 or 10 mcg does not seem to cause more adverse effects than 5 mcg.

During the surgery, each patient will be momentarily awakened and asked to move their leg in order to measure pressure balance and the results recorded. This poses no additional risk to the patient, who will have no conscious memory of the experience. Pressure balance and soft-tissue balancing of the knee is typically done as a standard of care for all patients, yet we hypothesize that utilizing the wakeup test in this study will improve the accuracy of soft-tissue balancing techniques. Following implantation of the final components the knee pressure will again be tested in both the passive and active state. Patients in the pilot portion (25 subjects) will only receive PROTOCOL 1. They will receive all other aspects of the study,

Visit 3: 3 months post-surgery: Re-administer Knee Society Score/KOOS and gather physical data

Visit 4: 6 months post-surgery: Re-administer Knee Society Score/KOOS and gather physical data

Visit 5: 12 months post-surgery: Re-administer Knee Society Score/KOOS and gather physical data

Data Storage and Confidentiality

All research data will be recorded into a password-protected database and stored in the offices of the investigators on a password-protected computer. After initial data collection, all private health information will be removed, and patients will be tracked with an anonymous study number. The collected data will be permanently deleted immediately after the completed study is accepted in full for publication.

Participant medical information will be stored electronically within a password protected database available only to the principal investigator, co-investigators, and research staff as necessary for data analysis. The names and medical record numbers of the study participants will be deleted from their stored medical information and replaced with a linkage code. Access to participant medical information contained within the registry will be restricted.

IV. RISK/BENEFIT ASSESSMENT

This study involves only minimal risk to the patient. There is a risk of breach of confidentiality.

Protection against Risks

All patients will be de-identified and given a code. Information linking the patient codes to the participants' names and medical record numbers will be stored in a secure location separate from the medical information. Access to the information linking the linkage codes with participant identifiers shall be restricted.

Potential Benefits to the Subjects
Benefits of the study include the possibility of improved satisfaction and knee stability. It is the hope of the research team that results of this study will benefit future patients and their physicians by allowing for improved outcomes with better knee stability during total knee arthroplasty.

V. INVESTIGATOR'S QUALIFICATIONS AND EXPERIENCE

A copy of the senior investigator's CVs is available. All investigators and research personnel have completed training in the protection of human subjects.

VI. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT

Method of Subject Identification and Recruitment
Upon IRB approval, the research assistants will begin screening patients to be seen in health clinics in the upcoming days. Appropriate patients, who meet all of the inclusion criteria and none of the exclusion criteria will be identified by the treating surgeon, and will be asked about interest in participating in the research study. If the patient has an interest, he/she will then be approached by a research assistant after leaving the surgeon's office. If the patient consents, a more complete search of each patient's medical record will then be conducted. They will note each patient's gender, age and pertinent medical history. Should a patient meet any exclusion criteria, it will be noted in the screening log and that patient will not be approached for inclusion in the study.

Process of Consent
Written consent will be obtained from subjects who are eligible candidates for the total knee replacement (as determined by their physician). The consent process will take place during an office visit at which time the investigator has determined subject's voluntary participation has been upheld. Subjects will be informed about the study and the intended purpose. They will be given the opportunity to ask questions and receive thorough explanations. They will be made aware of the possible risks and anticipated benefits. They will also be informed of alternative procedures. Subjects will then be given another opportunity to ask questions and agree or disagree to consent.

Subject Capacity
All subjects enrolled in this study will have capacity to provide informed consent.

Debriefing Procedures
Information will not be withheld from any participant, as they will be self-administering all survey items.

Consent Forms
Informed consent will be obtained from all subjects and documented with a signed, written consent form using the NYU IRB's English standard consent form.

Documentation of Consent
Documentation of consent will be maintained in the study's regulatory binder.

Costs to the Subject
Subjects will not incur any additional financial costs as a participant in this study.

Payment for Participation
No payments/reimbursements will be provided to subjects for their participation in this study.

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