Prospective Randomized Evaluation Of A Two And Three Piece Total Ankle Replacement

Document Date: December 15, 2016

NCT01504438

Prospective Randomized Evaluation Of A Two And Three Piece Total Ankle Replacement

Purpose of the Study – Randomized study to prospectivly compare and evaluate the functional outcome and patient satisfaction of total ankle replacements for tibio-talar osteoarthritis using either the STAR or Salto-Talaris prothesis.

Background & Significance – The primary articulation of the ankle joint is between the tibia and talus. This joint is subjected to extreme forces during daily activity and therefore is susceptible to the development of osteoarthritis. Severe osteoarthritis of the ankle is treated either by joint fusion or replacement. Traditionally, most orthopaedic surgeons have opted for joint fusion over replacement because of the high failure rates and poor technology of total ankle replacements. However, newer total ankle replacements are being introduced with better results, largely due to borrowed technology from the tried and true fields of total hip and knee replacement. Therefore, more surgeons are opting for ankle replacement to preserve ankle motion and prevent adjacent joint osteoarthritis often seen with ankle joint fusion. In the US at present time, there is a single 3 piece ankle prothesis (STAR) and several 2 piece (Salto-Talaris, InBone, Agility) approved for use. Currently there is debate in the orthopaedic community about whether a 2 piece or 3 piece ankle replacement is superior in terms of longevity, satisfaction, and function. This study will evaluate patient satisfaction and functional outcome of total ankle replacement for ankle osteoarthritis by one of two different currently available and approved ankle prothesis, the STAR and the Salto-Talaris.

Design & Procedures – Adult patients (age > 18 years) who have severe osteoarthritis of the ankle joint significant enough to be treated with a total ankle replacement as determined by Drs. Nunley, DeOrio, or Easley with the aid of the physical exam and routine radiography, treated at Duke University Medical Center will be asked to participate in this study. After routine surgical counseling by Drs. Nunley, DeOrio, Adams or Easley, those patients meeting the inclusion criteria will be asked to participate in this study by their attending physician. The consent form will be administered in the clinic. No PHI will be collected prior to consent. If a patient chooses to participate, they will be asked to sign the consent form and will be asked to complete the following patient outcome questionnaires (attached): Visual Analog Pain Scale, Short-form 36, AOFAS hind foot score, a Short Musculoskeletal Function Assessment questionnaire and FADI. Also at this time patients will be randomly assigned to receive either the STAR or Salto-Talaris ankle prosthesis at the time of their surgery. There will be 80 individual, sealed, opaque sequentially numbered envelopes containing the randomization of either ankle prosthesis (40 of each implant). The patient will then undergo surgery as scheduled at a later date. Participants will be in the study a total of ten years.

Following surgery, the patient will present for routine follow-up appointments. At the six month, one year, two year, three year visit and every year thereafter, the patients participating in the study will be asked to complete the previously mentioned outcome questionnaires. These are all normal follow-up visit time points; the patients will not be asked to return to clinic for any additional visits that would not be routine. At each visit, the patient will also receive plain x-rays. Plain x-rays are part of routine follow-up and not additional tests for this study.

The study will proceed until a minimum of ten-year follow-up is achieved for all patients. We will leave the ten year window open for all subjects until the last subject has finished their ten year time point. This will ensure that all subjects will have an appropriate time span in order to return for their standard of care visit.

All patients who receive a total ankle replacement at Duke is asked to complete a set of questionnaires (Visual Analog Scale, Short Musculoskeletal Function Assessment, Short Form-36 Health Survey, Foot and Ankle Outcome Score Questionnaire, AOFAS Ankle-Hindfoot Scale) as part of the Duke Orthopaedics Foot and Ankle physicians' standard of care. We will ask subjects permission to use these questionnaires that have been collected from them since their randomized TAR surgery. We are also asking subjects permission to release their de-identified study information to orthopaedic equipment manufacturers, and to continue their follow-up to their 10-year post-operative time point. A letter will be mailed to all subjects explaining the change. This letter is explained in the Consent Process section. Drs. DeOrio, Easley, Nunley, Adams will only be recruiting their own patients

Subject identification, recruitment, and compensation- Inclusion/ Exclusion criteria: Adult patients (age > 18 years) who will benefit from a total ankle replacement, as determined by Drs. Nunley, DeOrio, Adams or Easley, with the aid of the physical exam and routine radiography treated at Duke University Medical Center and who have no medical conditions that would represent contraindications to surgery or anesthesia will be

asked to participate in this study. The only excluded patients will be those who do not choose to participate in this study, have a weight greater than 230lbs, or do not meet the minimum age of 18 years. Drs. Nunley, DeOrio, or Easley will only be recruiting their own patients. Drs. Nunley, DeOrio, Adams or Easley will not personally obtain consent due to a conflict of interest related to their consulting relationship with Tornier Inc and SBI Inc. Approximately 100 DUHS patients will be recruited to undergo either a STAR or Salto-Talaris Total Ankle Replacement. Study enrollment will be complete once 50 of each cohort have been treated. There is no compensation associated with participation in this study.

Consent Process – Upon determination that a subject is compatible with the eligibility criteria of the protocol, the study will be explained to the subject by the investigator or his/her authorized designee. If the subject indicates interest in participating in the study, the informed consent document will be provided to the patient since these documents provide a comprehension explanation of the study in lay terms. If the subject continues to show interest, the investigator or his/her authorized designee will thoroughly explain to the subject the required elements of informed consent and all aspects of the study (i.e., inclusion/exclusion criteria, risks, benefits and alternatives to the study, etc.).
The subject will receive a copy of the study consent form and the signed and dated original copy will be retained in the subject's study file or medical record.
Dr. DeOrio has a consulting relationship with SBI and therefore is not able to sign the informed consent and will have approved IRB personnel to do so.
A letter will be mailed to all patients previously consented to this study, explaining the changes made to the study protocol. Along with this letter two consent forms, one for subjects to keep and the other to send back, will be included in this packet. If subjects return to clinic and have not yet signed and returned the consent form that was mailed we will approach them in clinic and explain the additions to the study. Patients will be given a copy of the study consent form, and the signed and dated original copy will be retained in the subject's study file or medical record.

Subject's Capacity to Give Legally Effective Consent – Only those subjects able to read and comprehend the consent form will be asked to participate in this study.

Risk/Benefit Assessment – There is a minimal risk of loss of confidentiality. If a patient chooses not to participate, they will receive the total ankle replacement as planned.

Costs to the Subject – There will be no cost to the subject associated with this study.

Data Analysis & Statistical Considerations – The data will be summarized using routine descriptive statistics. The following clinical outcome parameters will be analyzed using a series of 2X4 between subject repeated measures ANOVAs, with Tukey post hoc testing to determine statistically significant differences. The 2 X 4 ANOVA will be comparing the 2 groups (Salto Talaris and STAR implants) and the five time points of interest (pre-op, 6 months, 1 year, 2 years, and 3 years following surgery). The clinical outcome variables of interest will be the visual analog pain scale, foot and ankle disability index, the SF-36, the AOFAS hind foot score, and the short form musculoskeletal assessment. In addition, radiographic measurements will be collected on the radiographs that are available in the patients' medical record at each of the pre and post-operative time points. Monitoring of data will not be done until the final analysis after all data is collected. A p-value less than 0.05 will be used as the level of statistical significance for this study.

Data & Safety Monitoring - Monitoring data for safety is a function of the PI and study team. The PI will be responsible for review and sign off on all adverse events and/or problems as they occur and report adverse events and/or problems as required by HRPP policies to the IRB.

Data storage & confidentiality– The principal investigator and co-investigators will collect data in a computerized database using a commercially available database program. During collection, data will be indexed by the patient's medical record number. After data collection, a case number will be assigned to the data, and the medical record number (the only identifying data collected) will be stripped from the database. The code linking medical record number to case number will be kept in a locked file with access limited to the primary investigator. When the study is complete the code linking medical record numbers to case numbers will be destroyed. During data collection and review protected health information will be available only to the principal investigator and co-investigators and will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study.