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Study Title: Survivorship and Outcomes of Robot Assisted Medial Partial Knee Replacement.

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MAKO SURGICAL CORP.

PROTOCOL

TITLE

Survivorship and Outcomes of Robotically Assisted Medial UKA

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SITES

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BACKGROUND

Unicompartmental knee arthroplasty (UKA) is a procedure to replace only one tibiofemoral compartment of the diseased knee, most commonly the medial compartment. Overcorrection or undercorrection of limb alignment is due to malpositioning of the components or improper selection of polyethylene thickness. Malalignment of the leg is associated with increased polyethylene wear [Hernigou 2004-A], disease progression to the opposite compartment [Hernigou 2004-A; Jeer 2004; Sarangi 1994; Ridgeway 2002], and implant loosening [Koshino 1991]. In addition to limb alignment issues, malalignment and malpositioning of prosthesis components can lead to early failure [Kasodekar 2006; Barrett 1987; Emerson 1991; Herzog 1991]. Malalignment of the femoral component is known to cause femoral fracture [Sandborn 1987] and tibial component loosening [Assor 2006]. Excessive posterior slope (>7 degrees) of the tibial component is associated with tibial component loosening [Hernigou 2004-B], rupture of the ACL [Hernigou 2004-B], and increased bone stresses [Sawatari 2005]. When performed accurately, UKA performed using minimally invasive surgical (MIS) techniques has been correlated with faster rehabilitation, shorter hospital stays [Carlsson 2006], and better functional results [Muller 2004]. However, MIS UKA is a more technically demanding procedure and smaller incisions reduce visibility, increasing the risk of malalignment. Compared to conventional open UKA, MIS UKA resulted in less accurate implant positioning and limb alignment [Fisher 2003], and resulted in increased rates of revision and non-revision operations [Hamilton 2006]. Robotically guided surgery has been introduced to improve accuracy in less invasive procedures. Robotically guided surgery involves a patient specific 3D plan and accurate tactile burring of the planned implant position. When augmented with robotically guided surgery, UKA produced more accurate and reproducible alignment than with conventional UKA [Coon]. With increased pressures from patients to shorten rehabilitation time, hospital stays, and incision length, successful MIS UKA is a desirable procedure. However, MIS UKA can lead to malalignment of components and early failure. Robotically guided UKA has been shown to improve post-operative alignment. Survivorship of this novel procedure has not yet been reported. This study aims to determine a survivorship of this procedure coupled with a novel, anatomically designed UKA implant at two years post-operative.

SPECIFIC AIM

The specific aim of this study is to determine the survivorship rate of robotically guided MCK medial onlay UKA implants at a two, five, and ten year follow up. Study participants will also be asked about their level of satisfaction with their knee function following their robotically guided UKA procedure.

INCLUSION CRITERIA

All patients over 21 years of age who underwent primary robotically guided UKA and received a medial MCK onlay implant and are at least 24 months post-operative are eligible to participate in the study.

EXCLUSION CRITERIA

Patients will be excluded from participation in the study if they are cognitively unable to answer questions related to their index procedure. There are no other exclusion criteria.

STUDY ENROLLMENT PROCEDURE

Patients will be retrospectively identified and selected to participate in the study based on the following criteria: They underwent a MAKOplasty procedure by the investigating surgeon and received a medial MCK onlay implant. They must be at least 24 months post-operative at the time of the study. The sponsor will provide the study staff with relevant dates of surgery for the study.

Investigator's study staff will review past surgery schedules to identify potential subjects; charts will be pulled to confirm the type of surgery performed. Once this has been done, the study staff will mail eligible subjects a Research Subject Information Sheet to introduce the study. The subject will then be contacted by phone to review the study. The research staff will answer any questions the subject may have and then verbally consent the subject over the phone.. Once the subject has verbally consented, the research staff will continue to ask the subject the 5 research questions. The research staff will document the subject's verbal consent and collect the subject's answers over the phone.

STUDY DESIGN

The purpose of this study is to determine the survivorship and outcomes of medial MCK onlay implant initially at two years post-operative, then at five and ten years post-operative. Once eligible patients are identified, contacted, and consented, they will be asked a series of questions to determine: a) if they have had their original MAKOplasty medial MCK onlay implant revised or reoperated, and b) if they still have their original implant, how satisfied they are with their outcomes. The questions that will be asked of the patients are as follows, in this order:

- Did you have a MAKOplasty medial MCK onlay implant done by Dr. Borus on [DOS] on your [side] knee?
    - If yes, have you since had that implant/knee removed, revised, or reoperated for any reason? Response options: Yes, No, Do Not Know
        - If yes, please list the reason and the date of revision.
        - If yes, did you return to the same surgeon that performed your original MAKOplasty procedure to perform your revision procedure?
- How satisfied are you with your knee function on the MAKOplasty operative knee? Response options: Very Satisfied, Satisfied, Neutral, Dissatisfied, Very Dissatisfied.

The investigator is responsible for enrolling approximately 150 subjects. All patient responses will be reported. Patients who respond "do not know" on whether they have had a revision to their original MAKOplasty knee or patients who are lost to follow up will be included in the study for reporting reasons, however we will continue to contact patients until we have a total of at least 100 confirmed responses (yes/no) for the investigating surgeons. Three attempts will be made to contact each patient.

After the third unsuccessful attempt to contact the patient, the patient will be regarded as "Lost to Follow Up".

Basic demographic information such as gender, date of birth, and BMI at time of surgery will also be collected retrospectively from each patient.

PATIENT FOLLOW-UP

All patients who consent to participate in the study will be asked a series of questions related to their original MAKOplasty implant at two years post-operative. Patients will be contacted again with the same series of questions at five years post-operative and ten years post-operative.

RISKS/BENEFITS

This is a minimal risk study which involves collection of data. The purpose of this study is for research purposes only. There is no direct benefit to the patient to participate in this study. The results of this research study may contribute to clinical research overall and may be published.

DATA MANAGEMENT

All data will be collected and entered by approved study staff into a secured, password protected excel spreadsheet. Patients will be assigned a study ID number before being entered into the spreadsheet. A master spreadsheet correlating the patients to their study ID number will be locked and password protected, accessible only by the PI and study staff.

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