Title:
Early outcomes of Total Knee Arthroplasty using the MAKO Surgical Robot and Triathlon Knee

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OVERVIEW

Background information:

Over 500,000 total knee arthroplasty (TKA) procedures are performed each year in the US and this number is projected to increase to 3.5 million procedures per year by 2030[1]. The vast majority of TKA involve the use manual instrumentation for bone resection, soft tissue balance and prosthesis alignment. Accuracy and precision using these traditional instruments is variable [4]. Improper component placement and instability can increase the risk of failure [5]. Additionally, manual instrumentation predispose to soft tissue damage with poorly controlled saw cuts. Soft tissue trauma may have the potential to increase pain and slow recovery. Furthermore, poorly controlled sawblades may injure critical ligamentous or neurovascular structures. Robotically assisted TKA has been shown to improve surgical accuracy and precision in bone resection, component alignment and soft tissue balance [6]. The avoidance of TKA outliers through the use of robotic assistance has the potential to improve component survivorship. Additionally, the haptic feedback of the robotic arm can prevent sawblade excursion into and damage of soft tissue structures. This may lead to an improvement on postoperative pain and recovery.

Research objectives:
The purpose of this study is to determine the early clinical and radiographic outcomes of robotically assisted total knee arthroplasty with the MAKO surgical robot using the Triathlon knee system. Mean weekly VAS pain score during the first 4 weeks is the primary end point. Results of this study will be compared to prospective cohort of patients in the IRB study 201805014 from this institution who underwent TKA using non-robotic, manual instruments

Primary Hypothesis: Patients receiving robotic TKA will have better early recovery, including lower mean weekly VAS pain score for the first 4 weeks postoperatively and higher functional outcome scores, than the manual TKA historical cohort.

Secondary Hypothesis:
Patients receiving robotic TKA will have more accurate component position and alignment than the manual TKA historical cohort.

Potential Contribution: This study would give us a better understanding of the clinical and radiographic outcomes of patients receiving robotic TKA versus manual TKA. It will identify potential advantages and disadvantages of robotic TKA using the MAKO surgical robot.

METHODS
Timeline: 2 years (12 months of prospective enrollment, 3 months and beyond of follow-up for all participants, approx 1 year of data analysis)

Inclusion/Exclusion criteria: The Principal Investigator (PI) will independently review all cases to confirm study eligibility for each patient. The following inclusion and exclusion criteria will be used to determine patient eligibility.

Inclusion criteria:

A. Planning to undergo Unilateral primary total knee arthroplasty
B. 18 and up
C. Willing to sign informed consent
D. Willing to return for all follow-up visits
E. Smartphone or tablet device capable of running the Fitbit andFocusMotion platform

Exclusion criteria:

A. BMI > 45
B. Inflammatory arthritis
C. Narcotic use greater than 5 days per week

D. Walking aid for musculoskeletal or neurologic issue other than operative joint
E. Bilateral total knee arthroplasty
F. Patient with an active infection or suspected infection in the operative joint
G. The absolute and relative contraindications stated in the FDA cleared labeling for the device

Recruitment: We will be recruiting patients from the clinical practices of Dr. Ryan Nunley and Dr. Robert Barrack.

Design: This study is a prospective cohort trial designed to evaluate the short-term outcomes of patients receiving robotic-assisted total knee arthroplasty, with comparison to a historical modern cohort of patients who received the same knee prosthesis at the same institution using manual, non-robotic instruments.

Number of participants: We propose to enroll 95 patients in this prospective cohort. A Pre-hoc power analysis for the primary outcome measure of VAS pain score was performed. The minimum clinically important difference for VAS pain in knee osteoarthritis is reported between 1.5 and 3 in the literature, with a standard deviation of 2 to 3 at one week postoperatively. A medium effect size of 0.5 was estimated using a VAS pain score difference of 1.5 with a standard deviation of 3. With power set at 0.9 and alpha 0.05, power of 0.9, and alpha error of 0.05 were used for the analysis. With these assumptions, 172 patients were required for the study, which includes 86 patients in the current cohort and 86 patients in our historical cohort (data previously collected). Therefore, assuming a 10% drop out rate, we will enroll 95 patients with a goal of achieving 86 patients to match the historical cohort.

Data collection:
Data collection will be done preoperatively, intraoperatively, 3-6 weeks postoperatively and at 12 weeks postoperatively 1 year and up to two year.The data will be analyzed by site staff. All data to be collected can be found in tables 1-7.

All procedures will be performed by two surgeons (R.B., R.N.) within a single institution at one sites (Barnes Jewish West County).

All participants will undergo standard admission and pre-operative procedure for primary total knee arthroplasty per institution protocol. Participants will be admitted to hospital on day of surgery for elective procedure. PT treatment and evaluation will take place on day of surgery and postoperative day one prior to discharge. Pain medications will be standardized during admission.

Participants will be scheduled for a standard clinical visit at 3-6weeks.

Participants will undergo final evaluation at 3 months post-operatively and beyond.

Focus Motion knee brace app

During the pre-operative arthroplasty class, participants in the sub-study will be set-up with a Fitbit wrist-based activity tracker and FocusMotion knee brace and the appropriate software. Participants will be instructed to use the device in the 2 weeks prior to undergoing surgery, to gather baseline data on narcotic use, pain, use of assistive device and sleep quality. They will continue to use the device for 3 months postoperatively. Patient will keep the software on their phone for up to 2 years.

Subject Payment

Honorarium of $100 provided at the 3-6 week post op visit and following completion of the 3 month evaluation. Honorarium of $50 will be provided once the 1 year and 2 year surveysare completed on the app. Participants in the study will be gifted the FocusMotion smart-brace and platform as well as the Fitbit device

Radiographic Analysis

One standing full length AP and lateral EOS imaging as well as anteroposterior, lateral, and sunrise view radiographs of the knee will be taken preoperatively, and one EOS at one post-op at either 3-6 week visit, or the ,3 or 12 month post-op visit in the hospital. Anteroposterior and lateral radiographs will be taken postoperatively in the hospital. The spatial relationship between the native bone and the mechanical axes will be determined and the following angles will be measured: the varus/valgus angle of the femoral component relative to the femoral mechanical axis, the varus/valgus position of the tibial component relative to the tibial mechanical axis, the varus/valgus position of the entire limb as the sum of the tibial and femoral mechanical axes, the extension/flexion of the femoral component in relation to the femoral mechanical axis, the tibial posterior slope, the rotational deviation of the femoral component from the epicondylar axis, and the rotational deviation of the tibial component from the referenced axis. All radiographs will be measured by a blinded independent examiner.

Procedures: Once the participant has signed informed consent, he or she will be setup and instructed on use of the FocusMotion platform and Fitbit device. Data collection will begin 2 weeks preoperatively and will continue for 3 months postoperatively through the focusmotion platform and up to two year. Perioperative data will be collected in the electronic medical record in the hospital. Standard of care office visits with clinical and xray evaluations will be conducted at 3-6weeks, 3 months and beyond.

Participants Lost to follow-up: Some participants will not return for follow-up at the required intervals. A member of the research team shall contact non-respondent participants using phone calls, regular mail, e-mail, certified letters, or other means to urge participants to return for clinic follow-up or ascertain if a participant has moved, died, or otherwise become lost to follow-up. The following flow chart identifies the steps for attempts to locate lost participants. These actions, along with any other options available to the site, should be followed to exhaust all reasonable means in locating lost participants. These actions should be documented in the participant's records and may be performed concurrently or in parallel.

Phone call to last known number → Contact → Follow-up with participant
↓
No Contact
↓
Phone call to other numbers (spouse, relative, etc.) → Contact → Follow-up with participant
↓
No Contact
Note: There will be a minimum of 10 calls to different numbers at different times of the day, on different days of the week, and over at least 2 weeks
↓
Mail letter to last known patient address → Contact → Follow-up with participant
↓
No Contact
↓
Mail letter to secondary addresses → Contact → Follow-up with participant
↓
No Contact
↓
Mail "certified" type of letter to last address and any secondary address → Contact → Follow-up with participant
↓
No Contact
↓
Social Security Death Index to determine if participant has died → Confirm death
↓
Not Confirmed

↓
End attempts.

INFORMED CONSENT

Written informed consent will be obtained from each participant prior to screening and enrollment. Patients who are identified by the treating surgeon during their clinical office visit as being eligible and who will be scheduling a total knee arthroplasty will be offered participation in the study. The study coordinator will review the informed consent document and study requirements with the patient and answer any questions the patient may have in a private clinic area. The patient will have the opportunity to review the consent form, discuss with family/friends, and do his/her own research on the participant if desired. Once the patient has consented and signed the informed consent, he or she will be screened for eligibility and enrolled on study if eligibility is confirmed.

PROCEDURES FOR MAINTAINING CONFIDENTIALITY

Email Security: Since we are contacting patients via email following privacy protections will be enacted for all email communications involving PHI; 1) a test email will be sent to the participant to verify their identify (confirm correct recipient) and that this email will be sent in a secure manner (i.e., [secure] in subject line); 2) The body of the email will instruct the participant to send all information as a response to this thread and to not remove the "[secure]" from the subject line; 3) document in our research records the participant's agreement to provide information over email.

Data Security: Hard copies of patient questionnaires and CRFs will be stored in individual patient binders. The binders will be kept in a locked filing cabinet in an office that has password protected access and is locked when not in use.

Data collected on questionnaires and CRFs will be entered into electronic databases for analysis and tracking. These databases are on a secure server and can only be accessed by authorized research team members. There is no intention that the electronic records will be transported. We will not use laptops/jump drives/CD/DVDs to store, analyze, or input this data.

De-identification of Data: All information will be collected by the research team in a confidential manner. PHI will be de-identified. All data will be entered into a master database that is password and security protected. Only members of the research team will be able to access information on study participants. Once all manuscript submission is complete, all study documents, including the master list, will be retained for seven years after close of the study.

ASSESSMENT OF RISKS AND BENEFITS

There is a slight risk that patients may feel a small amount of psychological discomfort answering the questionnaires.

In addition there is the risk of breach of confidentiality.

Benefits: Participants will receive no direct medical benefit from study participation. However, there is very little published in the orthopedic literature regarding the outcomes of robotic TKA as compared to manual instrument TKA, and this study would give us a better understanding of the outcomes these patients can expect as well as a better idea of what patients are best indicated for this procedure.

G1. Tables

Table 1: Pre-operative data within 4 weeks of procedure

Test	Unit	Collected by
Knee circumference	cm	Focus Moton Brace
Passive Knee ROM	degrees	Focus Motion Brace
Active Knee ROM	degrees	FocusMotion Brace
Pittsburgh Sleep Quality Index	scale	FocusMotion App Survey
Oxford knee score	scale	FocusMotion App Survey
FJS	scale	FocusMotion App Survey
Visual Analog Scale pain score thigh	scale	FocusMotion App Survey
Visual Analog Scale pain score knee	scale	FocusMotion App Survey
Visual Analog Scale pain score leg/calf	scale	FocusMotion App Survey
% normal knee	Scale	FocusMotion App Survey
Use of assistive device	incidence	FocusMotion App Survey
Narcotic requirement, daily	Daily MME/hr	FocusMotion App survey
Sleep duration	min	Fitbit
Sleep quality (REM sleep/non-REM sleep)	percentage	Fitbit
Sleep disturbances	count	Fitbit
Sleep efficiency(time asleep/time in bed)	percentage	Fitbit
Charleston Comorbidity Index	Score	EPIC CPAP documentation
PROMIS	Score	WUPRO

Table 2: Intra-operative data during procedure

Test	Unit	Collected by
Length of surgery	minutes	Surgeon

Table 3:

Table 3: Post-operative data during hospital stay

Test	Unit	Collected by
Total operative time(skin to skin)	Hours	Chart review
Tourniquet time	Minutes	Chart review
Tourniquet inflation pressures Blood loss	 mL	 Chart review
Occurrence of transfusion	Incidence	Chart review
Time to discharge	Number	Chart review
Total time in hospital	Hours	Chart Review
Pain scores in hospital	Qshift	Chart Review
Morphine equivalents in hospital	mg	Chart Review
PT eval on discharge: distance ambulated, ROM, pain score	Degrees	PT or focus motion brace

Table 4: Daily data points, from postop day 0 to 12 weeks postop

Data	Unit	Collected by
VAS pain score-location of most pain (at the month mark)	Scale	FocusMotion App Survey
Forgotten Joint Score (at the 1 month mark)	Scale	FocusMotion App Survey
% of Normal Knee (a the 1 month mark)	Scale	FocusMotion App Survey
Narcotic requirement, daily	MME/hr	FocusMotion App Survey

Sleep duration	Min	Fitbit
Sleep disturbances	Count	FItbit
Sleep efficiency (time asleep/time in bed)	percentage	Fitbit
Sleep quality (REM sleep/non-REM sleep)	Percentage	Fitbit
Step count	Count	Fitbit
Use of assistive device	Incidence	FocusMotion App Survey
Active Knee ROM	degrees	FocusMotion Brace
Passive Knee ROM	degrees	FocusMotion Brace
Compliance with home PT protocol	incidence	FocusMotion App

Table 5: Post-operative data at 3 months following procedure

Passive Knee ROM	degrees	Focus Motion Brace
Active Knee ROM	degrees	FocusMotion Brace
PSQI	scale	FocusMotion App Survey
OKS	scale	FocusMotion App Survey
Forgotten Joint Score	scale	FocusMotion App Survey
% of normal knee	Scale	Focus Motion App Survey
VAS pain score (location of most pain)	scale	FocusMotion App Survey
Use of assistive device	incidence	FocusMotion App Survey
Narcotic requirement	daily MME/hr	FocusMotion App Survey
Sleep duration	min	Fitbit
Sleep disturbances	count	Fitbit
Sleep efficiency (time asleep/time in bed)	percentage	Fitbit

Sleep quality (REM sleep/non-REM sleep)	percentage	Fitbit
Wound complications	incidence	EPIC documentation
DVT/PE	incidence	incidence
Infection	incidence	EPIC documentation
Return to OR	incidence	EPIC documentation

Table 6: Post-operative data at 12 months following procedure

PSQI	scale	FocusMotion App Survey
OKS	scale	FocusMotion App Survey
Forgotten Joint Score	scale	FocusMotion App Survey
% of normal knee	Scale	Focus Motion App Survey
VAS pain score (location with the most pain)	scale	FocusMotion App Survey

Table 7: Post-operative data at 24 months following procedure

PSQI	scale	FocusMotion App Survey
OKS	scale	FocusMotion App Survey
Forgotten Joint Score	scale	FocusMotion App Survey
% of normal knee	Scale	Focus Motion App Survey
VAS pain score (location with the most pain)	scale	FocusMotion App Survey

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