A Two Year Multicenter Study of Robotic-Arm Assisted THA: Acetabular Cup Placement Accuracy and Clinical Outcomes (The MAKO Trial)

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1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

The incidence of dislocation following total hip arthroplasty (THA) has been reported to be from 1 percent to as much as 3.2 percent (Woo and Morrey 1982; Pellicci 1998). The demand for THA is expected to increase. Post dislocation solutions include closed reduction, open reduction, THA revision and constrained cup, conversion to hemi-arthroplasty, allograft, or girdlestone resection. These solutions are often costly, painful, and can involve substantial additional risks and complications. Acetabular cup placement is an important factor in the stability of the THA. Cup malpositioning has been associated with bearing surface wear and dislocation (Callanan, 2011). For most subjects, acceptable angles are 40 degrees of abduction ($\pm$10 degrees) and 20 degrees ($\pm$5 degrees) of version (Lewinnek 1978; Soong 2004). However, malpositioning continues to occur resulting in cup angles outside acceptable ranges which leaves subjects with an increased risk of dislocation.

1.2 Name and Description of Investigational Product or Intervention

This study will involve a quantitative assessment of prospectively collected computed tomography, radiographic, and patient reported outcomes data from multiple centers.

1.3 Compliance Statement

This study will be conducted in full accordance with all applicable West Virginia University Research Policies and Procedures and all applicable federal and state laws and regulations including 45 CFR and 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent (if applicable), and will report unanticipated problems involving risks to subjects or others in accordance with the WVU Institutional Review Board (IRB) Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

2.1 Primary Objective (or Aim)

The objective of this study is to examine the acetabular cup placement of THA subjects and compare results for subjects who undergo THA with robotic-arm assistance to those who undergo traditional THA. The central hypothesis is that robotic-arm assisted acetabular cups will have greater accuracy of placement and better long-term outcomes over those traditionally placed. To obtain the most definitive assessment of cup placement, the study will utilize a digital imaging analysis program called the Martell Hip Analysis Suite (HAS, Chicago, IL) as well as computed tomography (CT) scans. Patient reported outcomes (HOOS, PROMIS10, hip stability, and return to function) will also be collected at specified intervals. Using CT scans and HAS analysis allows for a complete description of cup

placement and better accounts for factors such as pelvic rotation and/or tilt, otherwise not accounted for in radiographic analysis (Ghelman 2009).

2.2 Secondary Objectives (or Aim)

Specific Aim #1: Determine the accuracy of placement of robotic-arm assisted acetabular cups versus manual cup placement. The working hypothesis is that robotic-arm assisted cup placement will demonstrate more accurate cup placement compared to conventional manual cup placement.

Specific Aim #2: Assess the frequency with which the robotic-arm assisted placements of acetabular cups are accurately placed compared to the surgical plan. The working hypothesis is that robotic-arm assisted THA will demonstrate greater accuracy by adhering to the surgical plan more frequently than non-robotic-arm assisted cases.

Specific Aim #3: Examine the patient reported outcomes of robotic-arm assisted THA subjects. The working hypothesis is that subjects undergoing robotic-arm assisted acetabular cup placement will report better outcomes than subjects with conventional manual cup placements.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

Subjects of eight surgeons at two institutions (Allegheny Health Network or AHN and West Virginia University or WVU) will be enrolled in the study, providing a valuable multi-center perspective and reducing the inherent bias produced from a single surgeon or single site study. This group of providers represents surgeons at varying levels of experience which are average annual volume, and robotic experience, factors found to contribute to accuracy of cup placement (Callanan 2010). Our institution will conduct this study at WVU Medicine and at two sites that are part of AHN, Allegheny General Hospital (AGH) and Forbes Regional Hospital. We will enroll a total of 192 subjects, which is 24 subjects per surgeon.

3.2 Allocation to Treatment Groups and Blinding

3.3 Duration of Study Participation

The study duration per subject will be up to 2 years ($\pm$6 months).

3.4 Total Number of Study Sites/Total Number of Subjects Projected

To achieve accuracy of cup placement within 5 degrees of the target version (40 degrees $\pm$5) and abduction (20 degrees $\pm$5) angles 90 percent of the time, we will enroll 24 subjects per provider. The study will be conducted at two investigative sites in the United States and recruitment will stop when a total of 192 subjects are enrolled at these facilities. It is expected that 120 subjects will be enrolled at WVU Medicine, 48 subjects will be enrolled at Allegheny General Hospital (AGH), and 24 subjects at Forbes Regional Hospital.

3.5 Study Population

The study population is defined in section 3.6 (inclusion criteria) and 3.7 (exclusion criteria).

3.6 Inclusion Criteria

1) Males and females age 18 years and older.

2) Subjects requiring primary total hip arthroplasty.

3) Subjects agreeable to randomization.

4) Subjects willing and able to comply with follow-up requirements.

5) Subjects willing to sign an IRB approved Informed Consent Form (ICF).

3.7 Exclusion Criteria

1) Subjects with a Body Mass Index (BMI) >40.

2) Subjects with an active infection or suspected latent infection in or about the hip joint.

3) Bone stock that is inadequate for support or fixation of the prosthesis.

4) Previous major hip surgery excluding hip arthroscopy.

5) Total hip arthroplasty using cement fixation or resurfacing.

6) Pregnant or planning on becoming pregnant within the next two years.

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

	Screening/Pre-Op (-30 days)	Visit 2/Intra-op	Visit 3/3-6 months (± 1 months)	Visit 4/1 year (± 3 months)	Visit 5/2 year (+ 6 months)
Consent	X				
Inclusion/Exclusion	X				
Demographics	X				
Medical History	X				
Surgical Details		X			
Function Evaluation/ROM	X		X	X	
HOOS	X		X	X	X
PROMIS 10	X		X	X	X
Dislocation/Ad Events			X	X	X
Radiographs	X		X	X	X
Computed Tomography	X		X		
HAS Analysis			X	X	X
Con Meds	X	X	X	X	X
Physical Exam	X				

4.1 Concomitant Medication

All prior and concomitant medications used within 30 days prior to the screening visit and through the end of the study will be recorded. The dates of administration, dosage, and reason for use will be included.

4.2 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study treatment or visit schedules or adverse events (AEs). The Investigator may also withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. It will be documented whether or not each subject completes the clinical study. If the Investigator becomes aware of any serious related adverse events, both serious and non-serious after the subject completes or withdraws from the study, they will be recorded in the source documents and on the case report form (CRF).

4.3 Early Termination Study Visit

Subjects who withdraw from the study will have all procedures enumerated for Visit 5 as the early termination visit.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Medical Record Review

- The following variables will be abstracted from the subject's electronic medical record: Preoperative Diagnosis [avascular necrosis/fracture, osteoarthritis, congenital/development dysplasia, and other (tumors, inflammatory disease, or metabolic diagnosis)].

5.2 Physical Examination

The physical examination is considered standard of care prior to surgery.

5.3 Diagnostic Tests, Scales, Measures, etc.

This study will involve a quantitative assessment of prospectively collected computed tomography, radiographic, and patient reported outcomes data. Function measures include Range of Motion (ROM) scores. Outcomes measures include the HOOS, PROMIS 10, and HAS evaluation (cup placement measurements conducted on specific MAKO software).

5.4 Safety Evaluation

Subject safety will be monitored by adverse events, physical examinations, and questionnaires.

6 STATISTICAL CONSIDERATIONS

6.1 Sample Size and Power

Patient characteristics and demographics will be analyzed using Chi-square or Fisher's exact test as appropriate for categorical variables and parametric and non-parametric hypotheses tests for continuous variables as appropriate. The central hypothesis will be evaluated using a univariate logistic regression model to determine the accuracy of cup placement using the NON-ROBOTIC ARM group as the reference. Confounding factors will be controlled for in the model and interaction between terms will also be evaluated.

Data will be analyzed by the West Virginia University biostatistics team/core; other tests may be added at the discretion of those experts.

7 SAFETY MANAGEMENT

The PI and Co-Is will be responsible for the safety management of this study. Since the study procedures are not greater than minimal risk, serious adverse events (SAEs) are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs), they will be reported to the IRB. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

7.2 Adverse Event Reporting

Unanticipated problems related to the research involving risks to subjects or others that occur during the course of this study (including SAEs) will be reported to the IRB in accordance with WVU IRB SOP: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

7.3 Definition of an Adverse Event

An adverse event is any untoward medical occurrence in a subject who has received an intervention (drug, biologic, or other intervention). The occurrence does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable or unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporarily associated with the intervention, whether or not considered related to the intervention.

All AEs (including serious AEs) will be noted in the study records and on the CRF with a full description including the nature, date and time of onset, determination of non-serious versus serious, intensity (mild, moderate, severe), duration, causality, and outcome of the event.

7.4 Definition of a Serious Adverse Event (SAE)

An SAE is any adverse experience that results in any of the following outcomes:

- Death;
- Life-threatening event (at risk of death at the time of the event);
- Inpatient hospitalization or prolongation of existing hospitalization required;
- Persistent or significant disability/incapacity; and
- Congenital anomaly/birth defect in the offspring of a subject.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

A distinction should be drawn between serious and severe AEs. A severe AE is a major event of its type. A severe AE does not necessarily need to be considered serious. For example, nausea which persists for several hours may be considered severe nausea, but would not be an SAE. On the other hand, a stroke that results in only a limited degree of disability may be considered a mild stroke, but would be an SAE.

7.5 Relationship of SAE to study drug or other intervention

The relationship of each SAE to the study intervention should be characterized using one of the following terms in accordance with WVU IRB Guidelines: definitely, probably, possibly, unlikely, or unrelated.

7.6 IRB Notification of SAEs and Other Unanticipated Problems

The Investigator will promptly notify the IRB of all on-site unanticipated, serious Adverse Events that are related to the research activity. Other unanticipated problems related to the research involving risk to subjects or others will also be reported promptly. Written reports will be filed using the IRB system and in accordance with the timeline in the IRB SOP. External SAEs that are both unexpected and related to the study intervention will be reported promptly after the investigator receives the report.

7.7 Follow-up report

If an SAE has not resolved at the time of the initial report and new information arises that changes the investigator's assessment of the event, a follow-up report including all relevant new or reassessed information (e.g., concomitant medication, medical history) should be submitted to the IRB. The investigator is responsible for ensuring that all SAEs are followed until either resolved or stable.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

The method of THA surgery (robotic-arm assisted or not) will be randomly assigned using a pre-populated randomization schedule after patient consent. Patients in the control group will undergo traditional THA surgery without robotic-arm assistance. The same variables will be collected for both study groups

8.2 Data Collection and Management

1. Confidentiality

- A master list containing personal health information (PHI) and subject identification (ID) number separate from data forms (paper and electronic) that have only a study ID number. The master list will be kept on a separate computer, removable disk drive, or in a locked file cabinet.

- Data files will be stored electronically on a WVU password protected restricted drive. Only the key study personnel associated with this study will have access to the data files.

2. Security

   The subject master list will be stored electronically on a password protected Excel spreadsheet housed on secure servers at West Virginia University. Patient binders and information will be stored in a locked cabinet in the clinical research coordinator's locked office.

3. Destruction

   All data will be retained for 10 years and be kept in a locked room. Each document will be marked with a destroy date with earliest dates at the front.

8.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and The Health Insurance Portability and Accountability Act (HIPAA) on subject privacy. The Investigator and other site personnel will not use such data and records for any purpose other than conducting the study.

The Institution owns all Study Data, excluding Site's patient medical records and Investigator's personal notes. Institution hereby grants to the Site a non-exclusive, non-transferable, non- sub-licensable right to use the Study Data solely for its own internal, non-commercial research and educational purposes.

In performance of this Study, Site shall not provide to Institution any individually identifiable health information. All Study Data provided by Site to Institution shall be de-identified. Any individually identifiable health information collected or produced by Site or Site Investigator shall be in accordance with the Protocol and only for the purpose of complying with applicable law, provided that all such uses are disclosed in the IRB-approved ICF. Institution may use information that is not identifiable under any applicable U.S. laws for any research and development purpose. Institution will not contact any Study subjects, unless permitted by the ICF.

8.4 Regulatory and Ethical Considerations

IRB approval will be obtained from the West Virginia University IRB board. The study will be conducted according to the IRB/West Virginia University policies and procedures. This study will be reviewed by the IRB on a yearly basis.

The proposed study anticipates recruiting a proportion of racial/ethnic minorities (African Americans, Asian-Americans, and Hispanics) as well as non-Hispanic and white subjects. The study will not include children or prisoners.

It is the Investigators' responsibility to conduct the protocol under the current version of Declaration of Helsinki, ICH Guidelines, Good Clinical Practice, and the rules of the West Virginia University IRB. The investigator must ensure that the patient's anonymity be maintained within the data.

All paper records will be kept in locked file cabinets in a locked office. All electronic records of study data will be stored on password protected computers in restricted drives. Clinical information will not be released without written permission of the patient, except as necessary for monitoring by the IRB. Consent procedures and forms, and the communication, transmission, and storage of patient data will comply with individual site IRB and requirements for compliance with HIPAA.

Study Discontinuation: Participants will be informed that they may discontinue the study at any time, for any reason. They will be assured that the medical care which they receive at the participating facility will not be affected should they elect to discontinue participation in the study.

8.5 Data and Safety Monitoring Plan

The PI and Co-Is will be responsible for safety management of this study. The study progress will be monitored quarterly with the study team. Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs), these will be reported to the IRB in accordance with IRB SOP: Unanticipated Problems Involving Risks to Subjects. Adverse Events that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

8.6 Risk Assessment

As a hip replacement candidate, all risks for this surgical procedure will be explained in detail to you by your surgeon prior to surgery. Some, but not all, of the risks involved with surgery are blood clots, infection, fracture, dislocation, change in leg length, and prosthesis/implant loosening.

This study requires you to undergo two CT scans of your pelvis. Exposure to radiation is associated with an increased risk of cancer. Patients will be exposed to additional radiation from the CT scan 1-2 times over the course of the study based on which TREATMENT METHOD [arm] they are randomized to. The risk of developing cancer as a result of
exposure to radiation depends on the part of the body exposed, the individual's age at exposure, and the individual's gender. For the purpose of radiation protection, a conservative approach that is generally used is to assume that the risk for adverse health effects from cancer is proportional to the amount of radiation dose absorbed and that there is no amount of radiation that is completely without risk. The possibility of fatal cancer from radiation is approximately 1 chance in 2000 for an equivalent radiation dose of 10 milliSievert. The equivalent radiation dose range for one CT scan of the hip is 0.2-25 milliSievert, depending on patient size. Therefore, the possibility of fatal cancer from radiation is approximately 1 chance in 2000, equal to the dose from one or two hip CT scans, depending upon patient height and weight.

This study may involve risks to the unborn child. For this reason, women who are pregnant will not be accepted. If you are a woman who could become pregnant, you will not be allowed to participate in the study until you have a negative pregnancy test. You must use a medically approved method of birth control while you are on this study.

8.7 Risk-Benefit Assessment

The expected outcome of this study will be to demonstrate that acetabular cups placed with robotic-arm assistance during THA are more frequently and accurately placed resulting in better patient outcomes and fewer dislocations long-term. The results of this study could benefit future hip replacement patients.

The surgical procedure being studied in this protocol, total hip arthroplasty (THA), is a standard of care procedure. Risks associated with THA (not an inclusive list) are blood clots, infection, fracture, dislocation, change in leg length, and prosthesis/implant loosening.

The minimal risk of potential breach of private health information also exists. However, there are safeguards in place by study personnel to minimize this risk. The data will be recorded in such a manner that the subjects cannot be identified directly. The electronic personal health information (EPHI) will be stored only under the individual West Virginia University's users' log-ins of the key personnel, therefore it will be password protected. It is believed that potential benefits for future patients outweigh these minimal risks.

8.8 Recruitment Strategy

The orthopaedic surgeon investigators will screen viable subjects from their pre-operative orthopaedic surgery clinic. If agreeable, subjects will consent and enroll in the study at this visit. Advertising will not be used. There will be sufficient subjects to achieve enrollment goals within the practice.

8.9 Informed Consent/Assent and HIPAA Authorization

The orthopedic surgeon investigators will screen viable subjects from their pre-operative orthopedic surgery clinic. They will be told that their care will not be affected regardless of their participation and will be advised that they can withdraw consent any time before the surgery. After full explanation of the study, informed consent will be obtained and witnessed and a signed copy of the consent given to the patient or family member. A combined consent-HIPAA authorization will be used.

8.10 Payment to Subjects/Families

The subject will be paid $50 for the 3-6 month visit and $100 for the 1 and 2 year follow-up visits for a total of $250. The subject will receive a *VISA Gift Card,* which can be used anywhere that debit Visas are accepted (including online). When the patient receives the card, they will be provided further information about the card including how to use it, confidentiality, and privacy information.

9 REFERENCES

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