

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: *Total Knee Replacement Component Alignment Using Manual Versus Custom Instrumentation*

Investigator: *Dr. David W. Manning, MD*

Supported By: This research is supported by the department of Orthopaedic Surgery at Northwestern University.

Financial Interest Disclosure:

The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

Your doctor, who may also be responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

You are being asked to participate because you will be undergoing a total knee replacement as a patient of Dr. David Manning or Dr. Matthew Beal.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This study aims to compare the alignment of knee replacements performed with two different types of surgical instrumentation. The two types of instrumentation are called 1) manual instrumentation and 2) custom instrumentation. Both types of instrumentation are routinely used in knee replacement surgery. Manual instrumentation requires your surgeon to make measurements during surgery to determine the proper location to make cuts in the bone to align your knee replacement, while custom instrumentation uses guides that are made from a CT scan to determine the location of these bone cuts. While both types of instrumentation are commonly used, it is not known yet if one type works better than the other. This study aims to help answer that question.

How long will the research last and what will I need to do?

We expect that you will be in this research study for a total of 6 weeks after your surgery.

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You will be asked to undergo a standard-of-care standing X-ray and CT prior to your surgery, be randomized to one of four study arms on the day of the surgery, and thereafter undergo a standard-of-care standing X-ray 6 weeks after your surgery.

More detailed information about the study procedures can be found under the section **What happens if I say “Yes, I want to be in this research”?**

Is there any way being in this study could be bad for me?

There are several potential risks and discomforts involved in this study. The preoperative CT scan and the postoperative follow-up appointments and X-ray are the same as if you chose not to participate.

Another possible risk related to your participation in this study is the loss of privacy.

More detailed information about the risks of this study can be found under “Is there any way being in this study could be bad for me? (Detailed Risks)”

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. Taking part in this study may help future patients that undergo knee replacement surgery.

What happens if I do not want to be in this research?

You can leave the research at any time and it will not be held against you.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 312-472-6024.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 112 people here will be in this research study.

What happens if I say “Yes, I want to be in this research”?

If you consent to participate, you will be requested to undergo the following steps:

- 1) You will be randomized into one of the three groups below prior to surgery. Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in each group:

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- Knee replacement with Medacta GMK Sphere implants using manual instrumentation for both the tibia component and the femur component
OR
 - Knee replacement with Medacta GMK Sphere implants using manual instrumentation for the tibia component and custom instrumentation for the femur component
OR
 - Knee replacement with Medacta GMK Sphere implants using custom instrumentation for both the tibia component and the femur component
OR
 - Knee replacement with Medacta GMK Sphere implants using custom instrumentation for the tibia component and manual instrumentation for the femur component
- 2) You will be scheduled for a Computed Tomography Scan (CT scan) of your knee prior to surgery. Your surgeon will use this CT scan to plan the location of the cuts in your femur and tibia bones to appropriately align your knee replacement components.
- 3) You will be seen in the orthopaedic clinic for your standard postoperative visits at 3 weeks and at 6 weeks after your surgery. An x-ray of your knee will be taken at the 6 week follow-up visit.

The pre-operative and 6 week post-operative images will be sent to the manufacturer of the X-ray machine – EOS Imaging in order to record measurements. All images sent to EOS Imaging will be completely de-identified.

The total duration of follow up for this study will be 6 weeks after your surgery.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time it will not be held against you.

Detailed Risks: Is there any way being in this study could be bad for me?

There are several potential risks and discomforts involved in this study. The preoperative CT scan and the postoperative follow-up appointments and X-ray are the same as if you chose not to participate.

Another possible risk related to your participation in this study is the loss of privacy.

To reduce these risks, all of the information collected about you will be coded (you will be assigned a study number and all data will be linked to that number and not your name) and stored in a password-protected file on a password-protected computer. Additionally, some of the questions asked may be upsetting to you. If you do not wish to answer a question, you may skip it and go to the next question.

Please note that both knee instrumentation types included in this study are in common use by orthopaedic surgeons today. Both types of instrumentation are known to function very well for knee replacement surgery and have been approved for use by all relevant regulatory bodies. There is no evidence that either of these types of instrumentation works better for any particular type of patient or type of knee problem; as such, each type of instrumentation has individually been deemed a suitable choice for your knee replacement by your surgeon. Therefore, there are no additional risks involved in the use of these types of instrumentation for this study.

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This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: "What happens to the information collected for the research?"

Will it cost me anything to participate in this research study?

The cost of your conventional medical care will be billed to you or to your health insurance company in the usual way, including the prosthesis, surgery and usual clinic visits. However, some health insurance plans will not pay the costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular treatment. If your insurance does not pay, you will be responsible for the charges of your conventional medical care.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. Taking part in this study may help future patients that undergo knee replacement surgery.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires
- Records about study medication or drugs

During this study you may be coming to the Northwestern Memorial Healthcare Corporation (NMHC) entity (for example, Northwestern Memorial Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following groups of people may give the researchers information about you: All current and previous health care providers, including but not limited to the Northwestern Medical Group (NMG), and Northwestern Memorial Hospital (NMH).

Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University and its clinical partners (or affiliates) will not contain your name, address,

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telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study).
- Clinical affiliates, including but not limited to the Northwestern Medical Group (NMG), and Northwestern Memorial Hospital (NMH). Your participation in this clinical study will be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG) and Northwestern Memorial Hospital (NMH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study.
- Study monitors and auditors who make sure that the study is being done properly.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

However, Illinois law does not allow the re-release of HIV/AIDS, genetic testing, mental health and developmental disabilities information by the receivers of the information except in precise situations allowed by law.

Also, Federal Confidentiality Rules, 42 CFR Part 2, prohibit making any further disclosure of substance use disorder information unless further disclosure of this information is expressly permitted by written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Dr. David W. Manning, MD

Northwestern University Feinberg School of Medicine

676 N. St. Clair, Suite 1350

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Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Signature of participant

Date

Printed name of participant

Signature of person obtaining consent

Date

Printed name of person obtaining consent