

Permission to Take Part in a Human Research Study

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Title of research study: *A Randomized Controlled Trial Comparing Reoperation Rates and Clinical Outcomes of Rotating Hinge Versus Condylar Constrained Knee Implants in Revision Total Knee Arthroplasty*

Investigator: *Dr. Brett R. Levine, MD*

Sponsor/Funding Source or Support: *N/A*

Financial Interest Disclosure:

Dr. Brett Levine is a paid consultant for Zimmer Biomet, the manufacturer of the NexGen® Legacy® Constrained Condylar Knee and the NexGen® Rotating Hinge Knee being used in the study. However, this study is not sponsored or funded by Zimmer Biomet. The research is being conducted independently within MedStar hospitals. We do not plan to report any data, analysis, or findings to Zimmer at the close of this study. 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 is also 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 following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have decided to undergo revision total knee arthroplasty; in other words, a surgery to replace your previous total knee replacement.

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?

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Rotating Hinge Knee implants and Condylar Constrained Knee implants are both commonly used devices in revision total knee replacement surgeries. This study is being conducted to compare how these two types of implants perform in patients undergoing revision knee surgery. We aim to determine if the two implants produce similar outcomes. Your participation will help us better understand how these implants affect function, patient satisfaction, implant longevity and overall success of revision knee replacements. Both Rotating Hinge Knee implants and Condylar Constrained Knee implants are normally used for these type of surgeries and the choice between them is based purely on surgeon discretion. For the purposes of this study, the implant will be randomly chosen which is further detailed below.

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

We expect that you will be in this research study for approximately 8-10 years and follow our routine course for office visits after your procedure

If you choose to participate, you will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance, like flipping a coin. A computer program will pick a group for you. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

If you are randomized to Group 1 (also known as the Control Group):

Before surgery, you will answer routine and study-specific questions. During surgery, you will receive a Condylar Constrained Knee implant. After surgery, you will answer routine and study-specific questions at each follow-up.

If you are randomized to Group 2 (also known as the Treatment Group):

Before surgery, you will answer routine and study-specific questions. During surgery, you will receive a Rotating Hinge Knee implant. After surgery, you will answer routine and study-specific questions at each follow-up

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

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

There are inherent surgical risks associated with undergoing a revision total knee replacement. These risks are related to the procedure itself and not caused by participation in this study. More detailed information about the surgical risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

Participation in this study involves certain risks. One potential risk is the loss of confidentiality of your personal or medical information. However, every attempt will be made to protect your privacy and ensure that your information remains confidential. More detailed information about the risks related to study participation 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?

We cannot promise any benefits to you or others from your taking part in this research. We hope the information learned from this study will benefit other patients like you in the future.

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

Participation in research is completely voluntary. You can decide to participate or not to participate. You can agree to participate now and later change your mind. Your decision will not be held against you or affect your medical care in any way.

If you decide not to participate, your doctor will still perform your total knee replacement and continue with your routine care following the procedure.

Detailed Information: The following is more 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:

Name: Miles Hollimon (study coordinator)
Institution: MedStar Georgetown University Hospital
Phone: (443) 257-7634
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

Name: Joshua Lawrence (study coordinator)
Institution: MedStar Georgetown University Hospital
Phone: (240) 863-1681
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

Name: Brett R. Levine, MD
Institution: MedStar Georgetown University Hospital
Phone: (202) 444-8766
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may contact the MHRI IRB by phone at: (301) 560-2912 Or by email at:

MHRI-ORIHeldesk@medstar.net You

may choose to contact the IRB if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

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- 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 186 people here will be in this research study.

What happens if I say yes, I want to be in this research?

If you choose to join this study, you will be placed in one of the 2 groups discussed earlier. A computer program will pick a group for you. The group you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what group you get. You will have an equal chance of being given each group.

You will undergo standard procedures for the treatment of your knee. Your doctor will discuss the surgical procedures with you in detail including its risks and potential benefits. You will not know which implant you received until 6 months after your surgery, at which time you may choose to be informed if you wish. You will be asked to visit your doctor's office for standard follow-up visits before the procedure and 6 weeks, 6 months, 1 year and annually thereafter the procedure. This is the standard schedule for individuals like you who have decided to undergo this surgery. Your doctor may want to see you more often if they think it is necessary for your care.

You will receive the typical care, tests, physical exam, and x-rays at these visits that you would get if you were not in the study. You will be asked routine and study specific questions at every clinical visit before and after surgery by either your doctor or a research team member. For example, you will be asked to complete questionnaires about your health, pain, physical function and overall well-being. These are called patient reported outcome measures and they help us understand how your knee replacement affects your daily life from your perspective.

The surgery can be performed at MedStar Georgetown University Hospital or MedStar Montgomery Medical Center. The follow-up visits can be scheduled at MedStar Georgetown University Hospital or MedStar Montgomery Medical Center. If you choose to participate:

Before surgery

- Read, understand, and sign this informed consent form.
- Answer routine and study-specific questions about your knee.
- Visit hospital/clinic for routine physical exam and x-rays.

Day of surgery

- Follow all standard day of surgery procedures.
- There will be no difference in whether your surgery is performed if you choose to be in this study or not, nor the group that you are randomly placed in. The surgery will be performed under general anesthesia.

- If you are placed in Group 1 (Control group), you will be given a Condylar Constrained Knee implant.
- If you are placed in Group 2 (treatment group), you will be given a Rotating Hinge Knee implant
- Whether you are placed in Group 1 (Control group) or Group 2 (Treatment group), you will receive the standard of care anesthesia.
- We will perform all routine procedures for closing incision and recovery at the end of the surgery.

After surgery

- Return to the hospital/clinic for routine follow-ups after surgery. The post-operative follow-ups take place 6 weeks, 6 months, 1 year and annually thereafter for 8-10 years. Routine x-rays will be done 1 year after surgery and repeated 8-10 years after surgery. Your doctor will let you know if you need additional routine visits and/or imaging.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- Reading, understanding, and signing this informed consent form.
- Following the instructions of your doctor and the research staff.
- Attending all clinic visits. If you cannot make an appointment, please call your doctor's office or one of the study coordinators at (443) 257-7634 or (240) 863-1681 to reschedule as soon as possible.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. Your decision will not affect the quality of your medical care in any way.

If you decide to leave the research, we ask that you continue to keep your follow-up appointments to ensure the best outcome from your surgery.

Let your doctor or the study coordinator know that you do not wish to or are unable to continue your participation in the study. If you stop participating in the study, data that has already been collected may not be removed from the study database but will be kept confidential. You will be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

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

There are inherent surgical risks associated with undergoing a total knee replacement. These risks are related to the procedure itself and not caused by participation in this study.

Risk of study

Participation in this study involves certain risks.

- There is a chance of loss of personal and medical information collected for this study. Every attempt will be made to ensure that your information remains confidential. We will only collect data that is needed for research. All information will be stored in a secure, encrypted and password-protected MedStar databases. Only the research team will have access to your data.

You and your insurance company will be charged for the health care services that you would ordinarily have to pay for. In some cases, insurance may not pay for services ordinarily covered because these services were performed in a research study. Any expense associated with this study that is not paid by research funds or your insurance may be billed to you. MedStar will work to limit your financial responsibility when possible. This may include a review of what is typically covered by insurance or obtaining prior authorization for some coverage. However, while we will make a reasonable effort to limit your financial responsibility, we cannot guarantee insurance coverage for all procedures. You may also contact your health insurance provider directly to ensure you understand what costs your insurance may or may not cover.

If you have any questions about cost or are unsure about cost of taking part in this research, please talk with your study doctor or research staff.

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 organization.

If the research team uncovers abuse, neglect, or reportable diseases, we may have to disclose this information to appropriate authorities.

Research records will be maintained the longer of Federal regulation, state statute, sponsored contract terms, or institutional policy. Only IRB-approved research staff will have access to the research records.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, the IRB, and/or the Food and Drug Administration will be granted direct access to your medical records to conduct and/or oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential in any publication.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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Federal law provides additional protections of your medical records and related health information. These are described in an attached document. **HIPAA Authorization**

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the 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. The health information we may collect from you and use for this research includes:

- Information in your medical records necessary for this research
- 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
- Imaging results and reports
- Records about study medication or drugs
- Records about study devices

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of MedStar Health and its clinical partners (or affiliates): the MedStar Health Research Institute Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

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 MedStar Health policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the MedStar Health workforce, who may need to see your information, such as administrative staff members from the MedStar Health Research Institute, Office for Research Integrity and members of the Institutional Review Board.
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
- Other MedStar Health research centers and MedStar Health 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 people may be able to share your information with others without your separate permission.

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

This research authorization will remain in effect until the end of the study unless you revoke consent for participation in this study. If you revoke consent MedStar Health may not gather new information about you, or use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless MedStar Health obtains permission to do so from you.

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:

PI's Name: Brett R. Levine, MD
Institution: MedStar Georgetown University Hospital
Department: Knee/hip
Address: 3800 Reservoir Rd NW, Washington, DC 20007

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 allow this. 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.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Can I be removed from the research without my consent?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include

- If you do not qualify for the study based on the conditions discussed earlier.
- You fail to complete any procedures explained by the doctor or the research staff.
- Any new information becomes available that might be harmful to you. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research study.
- If you require a revision procedure following the revision total knee replacement.

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We will tell you about any new information that may affect your health, welfare, or choice to stay in the research study.

What else do I need to know?

MedStar Health has no program to pay for medical care for a research-related injury. No compensation is available for a research related injury.

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party.

If you feel that you are having a medical emergency, you should go to the emergency room right away.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

Typically, any data collected, or results obtained for research is not shared with the participants. Results can be shared with you at the end of the study once data analysis is complete. Results will not be shared unless a written request is made to:

PI’s Name: Brett R. Levine, MD
Institution: MedStar Georgetown University Hospital
Department: Knee/Hip
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject Printed name of subject	Date
Signature of person obtaining consent	Date
Printed name of person obtaining consent	