General Institutional Review Board
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December 14, 2017

Jeremy Reid, MD
Virtua Joint Replacement Institute
200 Bowman Drive, Suite E400
Voorhees, NJ 08043

Re: IRB G17022, A prospective study to examine patient satisfaction, function and limb alignment outcomes for Mako vs. Non-Mako total knee replacements

Dear Dr. Reid:

At their meeting today, the Virtua General Institutional Review Board (IRB) has reviewed and approved the protocol and consent for the above-referenced study. This approval requires that:

- Any changes in the principal investigator or co-investigators, change in the consent or protocol, must be submitted and approved by the IRB prior to implementation
- Any mortality associated with this investigation be reported to the IRB within seven days of occurrence.
- Morbidity, which is unanticipated or statistically higher than outlined in your submission, must be reported to the IRB within seven days of the occurrence.

Please note, this approval expires on December 13, 2018. You will need to update the IRB on the study's progress at their meeting at that time. The Virtua General IRB operates in accordance with the regulations required by 21 CFR Parts 50 and 56.

If you have any questions, please feel free to contact me at (856) 761-3844.

Sincerely,

Amy Glasofer, DrNP, RN, NE-BC
IRB Administrator

Protocol Title: A Prospective Study to Examine Patient Satisfaction, Function, and Limb Alignment Outcomes for Mako versus Non-Mako Total Knee Replacements

Principal Investigator: Jeremy Reid, MD
Virtua Joint Replacement Institute
200 Bowman Dr, Suite E400, Voorhees, NJ 08043
(609) 267-9400

Emergency Contact: Katy Whaley
(609) 267-9400 Ext. 6601

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not sign this form unless the study research team has answered your questions to your satisfaction and you decide that you want to be part of this study.
- Your participation in this research study is voluntary. If you do not want to participate you will still receive the standard of care that you would without your participation in this research study. Please read this consent and ask your doctor any questions you may have before deciding if you want to participate in this study.

Why am I being asked to Volunteer?

You are being invited to participate in this research study because:

- You have been diagnosed with knee osteoarthritis - a condition in which your knee joints become diseased or injured due to a loss of cartilage that acts as a protective cushion between your knee joints; and

- You are about to undergo total knee replacement surgery at the Virtua Joint Replacement Institute (Virtua JRI) to treat this problem.

What is the purpose of this research study?

At the Virtua JRI, there are two alternative surgical techniques currently used to carry out the total knee replacement procedure depending on the preference of the surgeon.

- The first technique is the traditional method where the surgeon employs mechanical guides, expert judgment, and natural hand-eye coordination in making the necessary cuts to prepare the bone for the implant as well as in placing the implant.
- In the second technique, in addition to expert judgment and hand-eye coordination, the surgeon also relies on a robot called the Mako System by Stryker Orthopaedics, in making cuts within the pre-determined diseased areas of the joints and placing the implants. This is made possible by uploading 3-dimensional (3D) images of your knee joints into the robot prior to surgery. The robot uses these 3D images to guide the surgeon during the procedure. The 3D images are obtained from a computerized tomography (CT) scan that combines a series of X-ray images taken from different angles to create cross-sectional images of the bones. All 5 surgeons at the Virtua JRI are well experienced with the robot-assisted total knee replacement surgical technique.

This study aims to see if outcomes for patients that receive the traditional total knee replacement surgical technique are different than the outcomes for patients that receive robot-assisted total knee replacement. The outcomes we will be tracking include:

1. Your self-reported awareness of your artificial joint during activities of daily living;
2. Your self-reported pain, other symptoms, function in daily living, function in sport and recreation, and knee-related quality of life;
3. Your self-reported general health perceptions, physical functioning, role limitations due to physical and emotional problems, bodily pain, energy-fatigue, social functioning and mental health;
4. The accuracy of your implant placement and limb alignment

Study outcomes 1 to 3 are termed the patient satisfaction outcomes for which surveys will be given to you to complete. Data to support study outcome 4 will be obtained through plain x-ray images and CT scans that will be taken before and after your surgery.

What am I being asked to do and how long will I be in the study?

If you choose to participate in this study, you will undergo the standard total knee replacement surgery, as well as the standard post-operative course, including all current protocols for post-operative pain control, post-operative physical therapy, post-operative restrictions, and post-operative evaluations including x-rays. The only difference is that the surgical technique you receive – traditional or robot-assisted will not depend on the surgeon's preference as is currently the case, but rather, will be left to chance, like flipping a coin. This means you will have equal chance of being assigned to either the traditional group or the robot-assisted group. You will not be told which group you were assigned to, so you will not know whether you received the traditional total knee replacement surgery or the robot-assisted total knee replacement surgery. You will receive 2-4 skin incisions above and below the knee, each ¼-inch long. This is done to blind you as to which surgical treatment you received. These skin incisions allow tracking pins to be in the leg and thigh bone during the robotic-assisted procedure.

As part of your standard pre-surgery plan of care, you will be scheduled to undergo a CT scan 2 to 3 weeks before your surgery at the Virtua Voorhees Hospital. You and/or your health insurance will be billed for the costs of your pre-surgery CT scan since you will have this CT scan performed whether or not you participate in the study. If your insurer does not reimburse for the cost of the CT scan, you may not be able to participate in the study.

Following your surgery, at a point prior to your 6-week post-surgery office visit, you will return to Virtua Voorhees Hospital to undergo a second CT scan. This CT scan will solely be used for the purpose of this research study. It will not be used for the diagnosis of any other condition and it will not be part of your medical record. The CT scan will be arranged by your surgeon at a time convenient to you and will not cost you anything. It will also be arranged, at no cost to you, for you to undergo an assessment of the mechanical alignment of your limb using plain x-ray images during your 6-week post-surgery office visit.

You will be followed for a period of 5 years during which you will be expected to complete the patient satisfaction surveys during your regularly scheduled post-surgery office visits 3 months, 6 months, 1 year, 2 years, and 5 years following your surgery. It is estimated that each patient satisfaction survey should take about 15 minutes to complete and you have the option of completing the surveys while waiting to see your surgeon at the office or have the surveys emailed to you to complete ahead of your office visit.

At the end of year 5, your participation in the study will be complete and the research team will no longer collect data from you or your medical record.

How many other people will be in the study?

There will be a total of 248 patients enrolled in this study. All patients will be followed for a period of 5 years.

What are the possible risks or discomforts?

Your surgeon will discuss with you the risks involved with any total knee replacement surgery. These risks include, but are not limited to: nerve damage, blood clots in the legs, kidney failure, loss of intestinal movement, blood loss, changes in blood pressure, stroke, pneumonia, heart attack, and death.

Implant-related risks which may lead to a revision of the implant include infection, fracture, loosening, instability, nerve damage, wear of the implant, metal sensitivity, localized progressive bone loss, and reaction to wear of the implant, also described as inflammation that can develop after long-term use of the implant causing pain, stiffness, and swelling. Knee implants may not provide the same feel or performance characteristics experienced with a normal healthy joint.

Radiation exposure from x-rays is considered small and not likely to adversely affect you or your disease. However, the effects of radiation add up over a lifetime. It is possible that having several x-rays performed may add to your risk of injury or disease. When deciding to enter this study, please think about your past and future contact with radiation. Examples include plain radiographs and radiation treatment for cancer.

Please note that this study may involve risks that are currently unforeseeable.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You may not receive any benefit from being in this study. If the study findings reveal that robot-assisted total knee replacements produce superior patient satisfaction and limb alignment outcomes, then this surgical technique may become the gold standard at the Virtua JRI and help other patients in the future.

What other choices do I have if I do not participate?

If you choose not to participate, you will still receive total knee replacement surgery by either of the two surgical techniques depending on your surgeon's preference. You will also receive the standard post-operative course, including all current protocols for post-operative pain control, post-operative physical therapy, post-operative restrictions, and post-operative evaluations including x-rays. There is no penalty if you choose not to participate and no medical care will be withheld.

Will I be paid for being in this study?

There is no compensation for participation in this study.

Will I have to pay for anything?

You and/or your health insurance will be billed for the costs of medical care during this study as these expenses would have occurred even if you were not in the study. However, your post-surgery limb alignment assessment, and post-surgery CT scan, will be free of charge to you and your insurance company.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. The only unique risk inherent to study participation beyond the risk of total knee replacement is possibly having a skin incision that was not used for pin placement become infected or have delayed healing. This risk is estimated at <1 %. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for Virtua to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the Principal Investigator (PI) in charge of the research study as soon as possible. The PI's name and phone number are listed on the first page of the consent form. The data collected up to that point will be retained by the PI.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed their 5 year post-surgery patient satisfaction surveys, and all information has been collected. Your

participation in the study ends once you complete your 5 year post-surgery patient satisfaction survey. This study may also be stopped at any time because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care. If at any time you choose to withdraw from the study, please send your withdrawal request in writing to the Principal Investigator, Jeremy Reid, MD, at the address listed on the first page of this consent form.

Who can see or use my information? How will my personal information be protected?

Results of clinical procedures and post-operative care and course will be placed in your medical record and may be accessible to employees of the health system that are not part of the research team. This information may also be viewed by your insurance company during routine audits.

We will do our best to make sure that the personal information in your medical record will be kept private, as is our standard protocol for any patient whom we treat. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

Before the data for this study is analyzed, all information such as your name, date of birth, medical record number, address, telephone number, social security number, or any other information that may identify you will be removed. Therefore, if information from this study is published in medical journals or presented at scientific meetings, your name and other personal information WILL NOT be used.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. This research has been reviewed and approved by an Institutional Review Board (IRB). An IRB reviews research projects so that steps are taken to protect the rights and welfare of human subjects taking part in the research. For questions about your rights while taking part in this study, call the Virtua Health General IRB coordinator, Eileen Morris at (856) 761-3844.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the Virtua Joint Replacement Institute to use your personal health information collected about you for research purposes within our institution.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date

APPROVED
DEC 14 2017
VIRTUA
Institutional Review Board