Official Ttile: 3D X-ray Motion Analysis of Ankle-foot Motion After Total Ankle Arthroplasty

NCT Number: NCT03575975

Consent Form: Approved November 18. 2019

CONSENT FORM FOR ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology
Project Title: 3D X-ray Motion Analysis of Ankle-Foot Motion after Total Ankle Replacement with Stryker STAR Implant

Principal Investigator: Young-Hui Chang, Ph.D
Document Version: Subject Consent Form v2019.10.31

We are asking you to participate in a research study called, "3D X-ray Motion Analysis of Ankle-Foot Motion after Total Ankle Replacement with Stryker STAR Implant"

Purpose:
This research aims to study ankle-foot motion following an ankle replacement procedure. We will record high-speed, 3D X-Ray videos of your ankle and foot to measure the amount of movement within your ankle and foot.

Inclusion Criteria:

To be *included* in the mobile bearing prosthesis group, participants must exhibit all of the following:
- Be able to walk independently with STAR prosthesis at different self-selected speeds
- Have had an ankle replacement surgery with implanted STAR prosthesis at a minimum of one year prior to enrollment
- Be pain free and radiologically normal
- Be able to walk at preferred walking speed without an assistive device (cane, crutches, etc.)
- Be between 18 to 79 years of age

To be *included* in the fixed bearing prosthesis group, participants must exhibit all of the following:
- Be able to walk independently with their prosthesis at different self-selected speeds
- Have had an ankle replacement surgery with implanted INBONE II prosthesis at a minimum of one year prior to enrollment
- Be pain free and radiologically normal
- Be able to walk at preferred walking speed without an assistive device (cane, crutches, etc.)
- Be between 18 to 79 years of age

To be *included* in the control group, participants must exhibit all of the following:
- Be between 18 and 79 years old and within 3 years of one of the STAR group participants
- Be the same gender as the matched STAR participant
- Not have a history of major musculoskeletal injuries
- Not have a history of major neuromuscular injuries

Exclusion Criteria:

Participants will be *excluded* from the study if they exhibit any of the following:
- Have dementia or an inability to give informed consent
- Have significant or chronic loss of hip or knee joint motion
- Have any subtalar or hindfoot fusion
- Have a history of dizziness and/or balance problems
- Have had any additional x-ray exposures in the past year that would put them beyond the recommended annual dose as determined by Georgia Tech ORS
- Are pregnant

- For prosthesis groups: exhibit evidence of polysubsidence (implant loosening)
- For prosthesis groups: exhibit evidence of a broken implant

Procedures:
You will need to provide the research team with a lower leg CT scan from your doctor. You can provide the CT scan data on a DVD, CD, or thumb drive. If you do not have a CT scan available, we will direct you to obtain a CT scan of your lower leg at the Emory Orthopedics and Spine Center from their Department of Radiology and Imaging. The entire visit, including scan time, should take 1-2 hrs. Dr. Jason Bariteau, M.D. (Emory Orthopaedic Surgery) is an ankle surgeon who will ensure that your CT scans will not contain any personal information when delivered to the GT team.

For the testing session, you will go to the laboratory of Dr. Young-Hui Chang located at 555 14th St., Atlanta, GA 30318. We will provide you with directions prior to your visit. In the building, you will go to the Georgia Tech (GT) X-Ray Motion Analysis (XMA) Lab for a 1-2-hour session. In the lab, we will record several x-ray based videos of your lower leg in the following conditions:

1. Normal standing
2. Standing on one leg while moving your ankle
3. Walking a short distance at a comfortable speed

Risks or Discomforts:

Radiation Risk:
You will be exposed to x-rays from the CT scan and from data collection. These procedures are not necessary for your medical care and will occur because you participate in this study. The primary risk associated with x-ray dose is the possibility of developing a radiation-induced cancer later in life. But, the risk of this due to this study is minimal based on the expected dose.

You will receive x-ray exposure from the machine that images your ankle. Your leg muscles and bones will receive x-ray exposure, but the highest exposure will be to your skin. The x-ray dose to your skin will be about 1/10th of that required to cause a noticeable skin effect such as reddening, peeling or blistering.

The general x-ray dose you will receive is less than the x-ray exposure limit allowed each year for people who are exposed to radiation in their daily jobs. This includes radiology doctors, x-ray technicians, or even the researchers for this study. If you should, however, experience skin discomfort in the area that was imaged during the next month, you should report this to Dr. Chang immediately.

We will provide you with lead aprons, throat and eye shields to wear during the data collection. They will help shield your body from exposure to any scattered x-rays. Also, a railing will be in place on the walkway to make sure you maintain a safe distance from the x-ray source.

Benefits:
There are no direct benefits to you for being in this study. We will use your data to better understand how ankle motion is affected by an implant. Your data may influence future implant design and strategies for improving ankle movement after a joint replacement.

Compensation to You:
We will pay you $15 per hour for your time. If needed, you will make 1 visit to Emory Orthopedics and Spine Center for a lower leg CT scan. We will arrange for payment for all CT services related to this study. If free visitor parking is not available, we will reimburse you up to $20 for any parking expenses you

have to pay (please save your receipt). You will also make 1 visit to the XMA Lab at Georgia Tech for data collection.

Your time spent in this study should not total more than 4 hours for a maximum payment of $60 for your time. We will pay you after your data collection session is done. We will provide full payment to participants who must stop due to a physical inability to complete the study. We will provide partial payment to those who remove themselves from the study early or do not complete it for other reasons. In this case, we will prorate the payment for each block of 30 minutes completed.

U.S. Tax Law requires that a 1099-misc be issued if U.S. tax residents receive $600 or more per calendar year. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required. Your address and citizenship/visa status may be collected for payment purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.

Confidentiality:
To protect your personal information, we will keep your data private to the extent allowed by law. Your data will be kept in our lab under a coded ID number, rather than by name. Reported findings and any data outside the lab will contain no personal information about individual participants, including performance on the experiment.

X-ray images of your lower leg will be stored on password-protected lab computers and will only be accessed by study personnel. We will use these images to measure your ankle motion. Upon study completion, we may share x-ray motion videos and data with Stryker Corp. We will also archive this information in our lab at Georgia Tech.

To make sure research is being carried out properly, the Georgia Tech IRB may review study records. The Office of Human Research Protections and/or the Food and Drug Administration may also look over study records during required reviews. The sponsor of this study, Howmedica Osteonics Corp./Stryker Corp., has the right to review study records as well.

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

Costs to You:
There are no costs to you, other than your time, for being in this study.

In Case of Injury/Harm:
If you are injured as a result of being in this study, please contact Young-Hui Chang, Ph.D., via phone at (404) 894-9993. Neither the Principal Investigator nor Georgia Tech has made provision for payment of costs associated with any injury resulting from participation in this study.

Participant Rights:
Your participation in this study is voluntary. We will provide for you, any new information that may cause you to change your mind about being in this study. We will give you a copy of this consent form to keep. You do not waive any of your legal rights by signing this consent form.

Questions about the Study:

If you have any questions about the study, you may contact Dr. Young-Hui Chang at (404) 894-9993) or via email at yh.chang@ap.gatech.edu.

Questions about Your Rights as a Research Participant:
If you have any questions about your rights as a research participant, you may contact Ms. Kelly Winn, Georgia Institute of Technology Office of Research Integrity Assurance, at (404) 385- 2175.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer participant in this study.

_____
Participant Name (printed)

_____ _____
Participant Signature Date

_____ _____
Signature of Person Obtaining Consent Date