

Official Title: 3D X-ray Motion Analysis of Ankle-foot Motion After Total Ankle  
Replacement With Stryker STAR Implant

NCT Number: has not been assigned yet

Protocol: approved January 3, 2018

## **Study Protocol with Statistical Analysis Plan**

### **Title: 3D X-Ray Motion Analysis of Ankle-Foot Motion After Total Ankle Arthroplasty**

#### **Objectives:**

- Quantify *in vivo* 3D ankle-foot kinematics through direct imaging of skeletal elements using high-speed dual-plane radiographic measurement using the Georgia Tech 3D X-ray Motion Analysis (XMA) system.
- Determine motion patterns of prosthetic components during clinically-relevant motions
- Evaluate extent that mobile bearing prostheses restore normal ankle motion in TAA patients
- Evaluate extent that fixed bearing prostheses restore normal ankle motion in TAA patients

#### **Design and Methods**

Quantifying motion within the ankle and foot is extremely challenging due to the inability to use external markers on the skin to accurately track the different bones and complex organization of joints. A high-speed biplanar X-Ray Motion Analysis (XMA) system (Imaging Systems & Service, Inc.) provides a direct method to obtain 3D radiographic images of skeletal motion. The XMA system includes two 45KW x-ray generators (EMD technologies), two 400KHU x-ray tubes (Varian), two 12" image intensifier tubes (Thales) and two XC-2M high-speed digital cameras (Xcitex). This system synchronizes the two x-ray beams with the opening and closing of the camera shutters to minimize radiation exposure and beam interference. Validated of the GT XMA System using phantom objects of known dimensions moving within the capture volume yielded an average measurement accuracy of 87 microns and an average measurement precision (reproducibility) was 73 microns.

Each participant will provide informed consent prior to enrolling in this study that is approved by the Georgia Tech Institutional Review Board (IRB). Each participant will undergo a CT scan to obtain a 3D digital model of their lower foot and ankle bones. In addition, they will participate in one data collection session to obtain X-Ray Motion Analysis (XMA) data.

The XMA system will be positioned around a walkway. Radiographic images will be gathered for each patient at 100 images per second and at a x-ray source to skin distance (SSD) greater than 100cm. The x-ray technique proposed for this study has already been verified and approved by the Georgia Tech Office of Radiological Safety (ORS) to generate effective radiation doses within allowable, safe limits for live human studies. During the XMA session, participants will be imaged in three conditions:

1. Assuming a neutral standing position to establish reference coordinate axes
2. Rotating their ankle in a non-weight-bearing position to obtain active range of motion measurements
3. Walking at a preferred speed to obtain ankle-foot kinematics during gait

Parameters for each procedure include:

- Each patient will maintain an SSD of at least 100cm from the x-ray emitter.
- Duration of each trial will not exceed 6 seconds, at 100 frames per second.
- Multiple trials may be performed to ensure the patient's ankle joint is recorded within the video capture volume.
- Multiple trials/condition will be used for analysis, not to exceed 30 trials in total
- Patient radiation exposure will <30 rem (10% of exposure required for any skin irritation)

The motion analysis procedure is marked by patient data collection, tracking, and reanimation for joint kinematics. In post-processing, sagittal, coronal, and axial plane motion of the implanted ankle prosthesis will be tracked using x-ray motion analysis software (XROMM Autoscooper, Providence RI) for all components of the total ankle replacement. Once CT scan data are obtained for each enrolled study participant, 3D bone surface models will be generated (3D Slicer) for all participants. These bone surface models will be used along with the x-ray video data to calculate joint angle trajectories and joint ranges of motion during plantar/dorsiflexion, internal/external rotation, and inversion/eversion of the foot-ankle complex using 3D animation software (Maya, Autodesk).

#### Statistical Analysis Plan

We will use a repeated measure design to test against the null hypothesis that participants that have a particular prosthetic ankle implant do not exhibit a difference in ankle joint range of motion compared to healthy, age- and gender-matched controls. Participants will be enrolled into a group that have experienced total ankle arthroplasty and currently have a mobile bearing (Stryker STAR) prosthetic implant. Age- and gender-matched participants that have experienced total ankle arthroplasty and currently have a fixed bearing 2-component implant (INBONE 2 Total Ankle System) will be enrolled into another group. Healthy, age- and gender-matched participants with intact ankle joints will be recruited into a control group. A comparison will be made between the mobile bearing implant group and the matched control group using a paired, one-tailed t-test. A second comparison will be made between the fixed bearing implant group and the matched control group using a paired, one-tailed t-test. Available x-ray-based gait kinematics data on intact subjects (Wang et al. 2015) were used to perform a power analysis (G\*Power statistical software) to determine that a sample size of 5 participants per group is needed to distinguish differences between group means with a Bonferroni-corrected alpha level of 0.025 and a power of 0.95.

Reference: Wang, B., Roach, K.E., et al., Accuracy and feasibility of high-speed dual fluoroscopy and model-based tracking to measure in vivo ankle arthrokinematics. *Gait & Posture*. 41(2015) p. 888-893.