In Vivo Kinematics for Subjects With Smith & Nephew Journey II BCS TKA, Journey II CR TKA, Or Journey II XR TKA

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In vivo knee kinematics will be assessed for 50 subjects that have been implanted with either a Smith & Nephew BCS, XR, or CR TKA. All TKAs should be judged clinically successful (KSS > 80). A KSS score of greater than 90 is deemed to be excellent by the Knee Society. Each subject should have a well-functioning prosthesis, be at least three months post-operative, and should have good-to-excellent post-operative passive flexion.

Deciding which patients received which kind of implant was up to the discretion of Dr. Harold Cates, according to his professional opinion. The determination as to which type of implant patients received is outside the scope of this particular study. Subjects will already have the knee implants and must be at least three months post-operative. Bilateral subjects will not be included in the study populations.

Inclusion criteria:

1. Subjects will have required type of TKA.
2. Patients must be at least three months post-operative.
3. Participants must be judged clinically successful with their most recent new Knee Society score equal to or greater than 80.
4. Weigh < 250
5. BMI < 40
6. Must be >40 years of age
7. Participants must be able to perform the required activities without concern.
8. Patients must be willing to sign the Informed Consent (IC) form to participate in the study.

Exclusion criteria:

1. Pregnant, potentially pregnant, lactating females or of childbearing age. To satisfy radiation protocol, each female subject will be asked if she is pregnant, or possibly could be pregnant. A pregnant person will not be allowed to participate in the study.
2. Subjects without the required type of knee implant.
3. Cannot not have pain in other parts of the body that would prohibit the patient from performing the activities
4. Cannot have ligamentous pain and/or laxity.
5. Unwilling to sign IC form.

6. Does not speak English.

Study locations
Subject Recruitment will take place at the Research Foundation of Dr. Harold Cates:
9330 Park West Blvd., Suite 208B
Knoxville, TN 37923
Phone: (865) 373-1811

Fluoroscopic exams will be performed on all subjects at:
Tennessee Orthopaedic Clinic
9430 Park West Blvd.
Knoxville, TN 37923

Study data analysis:
Science and Engineering Research Facility
1414 Circle Dr.
Knoxville, TN 37996

CMR Administrative offices:
310 Perkins Hall
1506 Middle Dr.
Knoxville, TN 37996
(865) 974-2093

Data Collection
University of Tennessee researchers with experience conducting fluoroscopic research studies, as well as either a PI or Co-PI for the study, and possibly Dr. Cates' staff will be present during the fluoroscopy procedure to walk subjects through the activities. A radiation technician (RT) employed by Parkwest Medical Center will collect fluoroscopic video while subjects perform the following activities: deep knee bend. For the DKB activity, the subjects were instructed to begin at full extension on a raised platform and take a step back while flexing their knee as far as they could, in order to obtain a maximum flexion value for each subject. For this activity, images were taken at 30° increments from full extension (0°) to maximum flexion (MAX) for the entire flexion/extension cycle. Patients were examined while performing these activities using a C-Arm type fluoroscopic unit. The fluoroscopic videos were captured digitally and transferred to a secure lab network for subsequent analysis.

If a subject does not meet the inclusion criteria, s/he will not be tested. If the participant still meets all study criteria, s/he will be asked to practice the activities to ensure s/he can comfortably complete them and experience no pain with the hospital fluoroscopy machine off (no radiation). The practice portion of the data collection without radiation will not be video-recorded. During the fluoroscopy procedure, the RT will follow the motion of the implanted knee with the fluoroscopy machine; only the knee joint (from the fluoroscopy machine) will be recorded on the fluoroscopy footage. The participant will be allowed to rest as necessary and be instructed to stop the activity at the first sign of pain.

Multiple trials of each activity may be conducted to ensure usable images have been acquired to complete the study. Radiation time will be kept as low as reasonably achievable (ALARA) and will not exceed two minutes. The RT will start the fluoroscope just prior to the subject beginning each activity trial and will stop the fluoroscope immediately after the subject completes each activity trial to ensure that the subject is not exposed during idol periods. Fluoroscopy on-time will be recorded on each subject's IC.

The fluoroscopic footage for these activities will be stored on digital video files on a secure computer workstation, uploaded onto the secure CMR database by the UT researcher that attended data collection, where identifiable data will be removed and substituted for data that cannot identify the subject (e.g., dates of birth will be removed and replaced with number of months the individual has been alive). Subjects will be assigned study and subject-specific identifiers which is how the system will distinguish the datasets.

DATA ANALYSIS

The kinematic variables of interest included the femoral and tibial 3D rotational and translational kinematics. The relative motion of the femoral component and tibial component were calculated based on the transformation matrices of each rigid body. This information was then used to extract anterior/posterior low points and contact points as well as internal/external rotation of the femoral component with respect to the tibial component.

Once the subjects have completed the activity, the fluoroscopic videos will be stored digitally and specific frames of interest will be captured from the video and exported into the preprocessing software. The specific frames of interested will be full extension, maximum knee flexion (both inclusive), and 30º knee flexion increments during the complete flexion cycle.

Our 3D to 2D registration technique will be used to overlay the 3D models of the implanted components on their projection in the 2D fluoroscopic image. The fluoroscopic video would be digitized into frames and corrected for distortion. From here, the distortion-free images would be used with the 3D to 2D registration technique to extract in vivo patient femorotibial kinematics, which involves overlaying the 3D models of the components on their projection in the 2D fluoroscopic image.

Statistical analysis of the data will be carried out to analyze the two cohorts. All variables, except for lift-off and VAG, will be denoted as continuous. The data will be first checked for normality using the Shapiro-Wilk test. Only when the data is found to be normally distributed will parametric tests be used; otherwise, non-parametric tests will be used. The data will also be tested for equality of variance using the Barlett's test and Levene's test. The final selection criterion for the type of test to conduct will be based on the check for normality, as well as the check for equal variance. Therefore, for all the continuous variables, the following tests will be used:

1. Student's t-test (when the data is normally distributed and has equal variance).
2. Welch Anova test (when the data is normally distributed but has unequal variance).

3. Wilcoxon Mann Whitney U-test (when the data is not normally distributed).

Lift-off, as applicable, will be treated as a categorical variable in this study and a contingency analysis using the Fisher's exact test will be carried out. All statistical tests will be carried out at 95% confidence level (α=0.05) and will be performed using JMP® Statistical DiscoveryTM (SAS Institute Inc., Cary, NC) software.

SPECIFIC RISKS AND PROTECTION MEASURES

1. Fluoroscopic Procedures

As with every clinical study, there may be some risks. However, doses of radiation exposure received will be much lower than those known to produce detectable health effects. Previously reported literature shows that fluoroscopy-based procedure (angiography) on the lower limb result in a typical effective dose of 0.83 mSv per min (0.083 rem per min) (Verdun[1]). Mettler, et al have reported that the typical effective dose for a conventional knee procedure is 0.005 mSv (0.0005 rem)[2]. According to either estimate, the additional risk of a fluoroscopic procedure involving the knee ranges between "Negligible" to "Low" for a 2 minute exam (Verdun). A previous fluoroscopy TKA study conducted at another hospital with a 2 minute on-time limit shows that the average effective dose was 0.14 mSv (0.0014 rem) with a maximum dose of 0.27 mSv (0.027 rem). The additional risk for all subjects in this previous study would be considered "Negligible". To account for patient variability and differences in imagining techniques, all subjects enrolled in this study will receive less than 2 rem. 2 rem is considered "Low" risk. It is unlikely that anyone in this study will approach the 2 rem limit. Since the fluoroscopy data will be collected in one session, there will only be one day in which the participants will be exposed to this amount of radiation.

In conclusion, a participant who will be fluoroscoped for less than two minutes will be exposed to a *maximum* amount of only 2.0 rems of radiation. This means that the maximum total exposure rate will be less than 2 rems per subject for the entire experiment. The participant's knee joint will be fluoroscoped using negligible to low risk levels of radiation according to published literature.

The participant has the right to stop the procedure at any time; researchers or the RT can end the procedures at any time if they feel the participant is at risk, but the participant can choose to remain in the study if s/he feels that there is no risk to her/his surgical procedure or recuperation.

We are estimating a total maximum time of 45 minutes to permit the subject time to complete the IC form, ask any questions s/he may have, practice the activities or repeat any activities that could not be completed, and collect all necessary fluoroscopy data from each subject.

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[1] Verdun FR, Bochud F, Gundinchet F, Aroua A, Schnyder P, Meuli R. Quality Initiatives Radiation Risk: What You Should Know to Tell Your Patient 1. *Radiographics* 2008 Nov 28(7):1807-16.
[2] Mettler, et al. "Effective Doses in Radiology and Diagnostic Nuclear Medicine." *Radiology* 248.1 (2008): 254-263. http://radiology.rsna.org/content/248/1/254.full.pdf+html

2. **Participant Confidentiality**

The investigator will ensure patient confidentiality to the extent that is permissible by law is maintained throughout the study and after. Complete confidentiality cannot be guaranteed.

Hard Copy

In compliance with HIPAA regulations, all participants will have their identities withheld from all public files. The personnel in the following list will have access to participant PHI for the purposes of recruitment or compliance and/or may have contact with patients:

List of Persons Involved in Research affiliated with Covenant Health:

- Dr. Harold Cates, Study Doctor/Co-PI, Tennessee Orthopaedic Clinics
- Ms. Jane Smith, Research Director, TOFER
- Clinical Research Staff
- Radiation technician(s) will operate the fluoroscopy machine.
- Institutional Review Board of Covenant Health

List of Persons Involved in Research affiliated with the University of Tennessee:

- Richard D. Komistek, PI, UT Professor
- Researchers present during data collection at the University of Tennessee and/or the lead graduate student(s) appointed by Dr. Komistek.
- * Undergraduate student researchers employed by the Center for Musculoskeletal Research (CMR) will be involved in analyzing the data after it has been collected, transferred to a computer workstation and stored in CMR's digital data collection. Since participant information will be removed and replaced with identifiers (a code that is assigned to each individual research subject) before the data is transferred to the secure server, it will not be possible for these undergraduate students to be able to identify subjects. These student researchers will never have contact with subjects, unless they are part of the data collection team.
- Institutional Review Board of the University of Tennessee

Clinical Observations:

There are no clinical observations made during this data collection or from the images obtained through data collection. There will be no radiology report generated for this procedure conducted as a result of this study. Therefore, no RT will review such a report for the procedures, which would be the only way such a "significant problem" would be determined. It is not anticipated that the imaging collected during this study would potentially provide benefit to specific subjects by influencing Cr. Cates' treatment plan.

BENEFITS

The potential benefits from this study include, but are not limited to:

- Better understanding of the joints analyzed with the same technique in the past.
- Future implant design improvements based on the kinematic findings.
- New and advanced surgical techniques for TKA based on the results.

- There is no intention of any direct benefit to participants of the study accept they will be able to see their implant on the video monitor and the fluoroscopic video will be assessed by the research team.