

# Kinematic Analysis: Posterior Stabilized, Fixed-Bearing TKA with Attune Knee System

University of Tennessee

Adrija Sharma, Ph D

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## **INTRODUCTION**

A better understanding of knee joint kinematics for patients implanted with total knee arthroplasties (TKAs) to help improve designs of prostheses that most closely approximates the normal knee kinematics. TKA surgery inevitably and irreparably alters the complex geometry and the soft tissue interactions occurring at the knee joint. Moreover, TKA surgery is always performed on non-normal, non-healthy knee joints. Therefore, not surprisingly, kinematic profiles observed after TKA have been reported to vary considerably than those observed in normal knees. Specifically, posterior stabilizing (PS) knees have been found to be associated with lower amounts of posterior femoral rollback, higher occurrence of reverse axial rotation and increased amount of condylar lift-off. It is important to focus on these previously reported abnormalities and design newer PS TKA which can restore kinematics (at least in nature, although not necessarily in overall magnitudes due to design constraints) closer to that observed in normal, non-implanted knees. This is would ensure optimal operating conditions for the PS TKAs while inside the body so that they can further improve function and can last a long time without the need for immediate revision.

The Attune™ PS fixed bearing knee system has incorporated subtle changes in its design to address these issues. However, in order to understand if this design is able to effectively restore kinematics in the implanted knee, further in vivo analysis is necessary. With this aim in mind, this study is designed to analyze the in vivo kinematics observed in patients implanted with the Attune™ PS TKA.

## **DESCRIPTION AND SOURCE OF RESEARCH PARTICIPANTS**

In vivo knee kinematics will be assessed for 30 subjects who have been implanted with a DePuy Attune PS TKA by Dr. Thomas Fehring, Dr. J. Bohannon Mason, or Dr. William Griffin recruited from their practices at OrthoCarolina, PA, 2001 Vail Avenue, Suite, Charlotte, NC 28207; this is the location from which all participants for this study will be recruited. Subjects will have the DePuy Attune PS fixed bearing TKA, will have a well-functioning prosthesis, and be judged clinically successful. Deciding which patients received this specific kind of implant was up to the discretion of Drs. Fehring, Mason, or Griffin, according to their professional opinions. The determination as to which type of implant each patient 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.

We will use the following criteria to recruit implanted participants for this study:

1. Subjects must be at least three (3) months post-operative with no other surgical procedures conducted within the past six months.
2. Subjects must be between 30-80 years of age.
3. Potential subjects will have a body weight of less than 280 lbs.
4. Participants must have Body Mass Index (BMI) >18.5 and <35.
5. Pregnant or potentially pregnant females will be excluded from the study. 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.
6. Must have of Knee Society score (KSS) greater than 80. [Acquired after consenting.]
7. Potential subjects should have good-to-excellent post-operative passive flexion with no ligamentous laxity or pain.
8. Participants must be able to walk on level ground without aid of any kind, perform a ramp descent, and a deep knee bend (DKB), all without assistance.
9. All potential subjects will have a DePuy Attune PS Fixed Bearing TKA.
10. Patients from the physician's list who do not meet the study requirements will not be considered.
11. Patients must be willing to sign the Informed Consent (IC) and HIPAA forms to participate in the study.

All participants will be between the ages of 30 and 80 years old, which is typical for a patient having a TKA. Since the average age of an implant patient is 70 years, it is unlikely that any female subjects will be pregnant. 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 due to the radiation exposure from use of fluoroscopy in data collection.

The U.S. Department of Health and Human Service's publication Vital and Health Statistics from May of 2013 cites the "a standard age range (often 16-49)" commonly used to define "child-bearing age" (1), so researchers will use that age range to determine whether or not any female potential participants are of "child-bearing age." If it is determined that one of the potential participants' age falls within this particular range, the female subject will be asked to submit to a

urine test or provide documentation that she cannot become pregnant. If the potential subject is pregnant or refuses the test, she is not eligible to participate in the study.

## **METHODS AND PROCEDURES**

After Dr. Thomas Fehring, Dr. J. Bohannon Mason, or Dr. William Griffin satisfactorily evaluated patients with the DePuy Attune PS TKA from their practices at OrthoCarolina PA that fulfilled the study criteria for participation, the OrthoCarolina Research Institute (OCRI) staff sent recruitment letters to eligible patients that explained the study, inviting them to participate. The recruitment letter requested that those eligible patients that wished to participate call Alexis Ready to inform her of their willingness to participate and schedule a visit to OCRI to sign the IC/HIPAA forms and demographic information forms for travel and payment. The surgeon will administer the KSS and KOOS surveys to confirm eligibility requirements.

Subjects traveled to Knoxville to undergo the fluoroscopy procedure using a fluoroscopy unit at either the University of Tennessee using a mobile fluoroscopy unit or to Abercrombie Radiology. Subjects will be asked to perform the same three activities under fluoroscopic surveillance using the fluoroscopy unit: (1) level walking, (2) ramp descent, and (3) a DKB. Subjects will be video-recorded from the waist down while performing the activities while under fluoroscopy surveillance.

The study activities are: (1) level walking (gait), (2) ramp down, and (3) a DKB.

### **1. Normal Gait**

- a) The subject will begin standing at rest with her/his knee in question slightly forward.
- b) The subject will take a lead step with her/his knee in question and proceed to walk at a comfortable pace for approximately 5 paces, or until instructed to stop.

### **2. Ramp Down**

- a) The subject will begin standing at rest with her/his knee in question slightly forward at the top of the ramp.
- b) The participant will be asked to take a lead step with her/his knee in question down the ramp until s/he reaches the bottom of the ramp (approximately 3 steps).

### **3. Deep Knee Bend**

- a) The participant will be asked to stand with his/her examined knee close to the image intensifier at full extension with his/her feet staggered (examined knee in front).
- b) The participant will flex her/his knee until it has reached maximum flexion.

These activities will be performed without the aid of handrails, as walking without aid of any kind is one of the criterion for participation in the study; however, one of the researchers will be ready and in close proximity to assist each subject during all activities in case the participant requires help. This precaution will be practiced for all participants, regardless of physical wellbeing, age or prior results; no assumptions will be made as to any participant's capabilities.

Ground reaction force (GRF) data will be acquired simultaneously by force plates embedded into the platforms on which participants perform the activities; it will be measured, captured and then used as input into a mathematical model, allowing for determination in vivo forces at the knee. The speed level of each trial will be based on the comfort level of the subject. The fluoroscopic images will be stored digitally for subsequent analysis on secure servers and workstations at UT. In vivo knee kinematics will be assessed for all 30 subjects.

There will be at least two UT researchers present, as well as the study PI, Dr. Sharma, to conduct the fluoroscopic evaluation. A Radiation Technician (RT) will perform the actual fluoroscopy procedure, following the subjects' implanted knee with the unit as the activities are performed; 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. The UT researchers, graduate research assistants (GRAs) will be present, although they will not perform the actual fluoroscopy procedure. They will be present during the fluoroscopy procedure to walk subjects through the activities, answer any questions that may arise, ensure data collection equipment is set up as needed and serve as consultants to the RT.

Subjects will have the opportunity to ask any questions they may have during the scheduled data collection visit. All subjects will be informed that they do not have to participate and are free to leave if they wish. Participation is entirely voluntary.

Participants will be asked to practice the activities to ensure they can comfortably complete them and experience no pain with the fluoroscopy machine off (no radiation). Age, weight and other eligibility requirements will be verified prior to fluoroscopy to ensure eligibility using the study's Inclusion Criteria Recruitment/Enrollment form. If a subject does not meet the inclusion criteria just prior to fluoroscopy, s/he will not be tested. The KSS score will be confirmed with subject medical data from OCRI prior to beginning the fluoroscopy procedure.

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 idle periods. On-time will be recorded on the subject's IC, as well as any output the fluoroscopy unit is able to provide.

The fluoroscopic footage for these activities will be stored on digital video files on a secure computer workstation and stored securely by UT researchers. It will then be uploaded onto the secure CMR database by these researchers. Once the data has been uploaded, identifiers are removed from the data automatically by the database, and a study and subject-specific identifier will be assigned to each subject. Data such as dates of birth and surgery are converted to number of months by the database. Only the converted data with study and subject-specific identifiers are what are available to UT researchers after the initial upload of data.

### Implanted Knee Analysis

Using a model-fitting approach, the relative pose of knee implant components will be determined in three-dimensional (3D) from a single-perspective fluoroscopic image by manipulating a computer-aided design (CAD) model in 3D space. The 3D scene of the fluoroscopic unit is virtually recreated on a computer. The scene consists of a light source (x-ray), an image plane on which to project the fluoroscopic image (image intensifier), an area to manipulate a 3D model (subject area), and a camera to view the entire scene.

Individual fluoroscopic frames at specified degrees of flexion for each activity will be digitized. The images will be projected onto the image plane and the corresponding implant models added to the scene. The operator will manipulate the models in an initial starting position, and a global optimization algorithm will determine an accurate fit. The correct fit will be achieved when the silhouettes of the femoral and tibial implant components best match the corresponding components in the fluoroscopic image. The pose of each component will be recorded and measurements of interest will be extracted using a CAD modeling program. For deep flexion activities, the process will be performed at full extension, 30° of knee flexion, 60° of knee flexion, 90° of knee flexion, and 120° of knee flexion (if subject achieves this amount). For the walking activity, the process will be performed at heel-strike, toe-off and two other instances during stance-phase. The following femoro-tibial kinematic parameters will be investigated under in vivo conditions and reported:

1. Location of the contact points
2. Amount of translation and axial rotation
3. Weight-bearing range-of-motion
4. Lift-off

## **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 ). Mettler, et al have reported that the typical effective dose for a conventional knee procedure is 0.005 mSv (0.0005 rem). 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 (0.014 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 subject variability and differences in imaging techniques, all subjects enrolled in this study will receive fewer than 2 rem. Two rem is considered "Very 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 minimal 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 1 hour 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.

## 2. Participant Confidentiality

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

### Computer Database:

On the day of data collection, the list of subject names will be given to UT researchers and researchers will use this to generate subject-specific identifiers; surgeon study staff will be provided with this list of subject names and corresponding generated identifiers. These assigned identifiers will be uploaded into an excel spreadsheet created by UT researchers. Surgeon study staff will be aware of each subject's respective identifier from the table provided to them on the day of data collection after UT researchers generate the subject-specific identifiers. They will upload the PHI from subject medical files into the excel spreadsheet and transmit the document back to UT researchers via UT's secure email transmission known as the Vault <https://vault.utk.edu/>. No names exist on the spreadsheet.

After the study data has been entered into the spreadsheet by the surgeon's office, researchers present during data collection or appointed by Dr. Sharma will upload the subject data, including PHI, fluoroscopy, and video footage, into the CMR digital data collection. Consequently, student researchers in CMR who assist in data analysis cannot access subject-specific information. All participant queries (lookups) generate the participant identification number (the ID generated by UT researchers) and no subject identifiers. No identifiable images exist in the database. This study data will be kept indefinitely on the secure CMR database for possible future research (with the permission of each participant – requested in the IC). In the case of participant withdrawal from the study, the Revocation of Consent that the participant will be asked to complete requests that the participant indicate whether or not data collected prior to withdrawal may be used for data analysis purposes, or if it should be removed from the CMR data collection completely and destroyed.

### Hard Copy

In compliance with HIPAA regulations, all participants will have their identities withheld from all public files. Individuals not indicated as Investigators below will have access to participant information and they will sign pledges of confidentiality.

### Clinical Observations



There are no clinical observations made during this data collection or from the images obtained through data collection. UT researchers do not require a report of any kind. 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 a patient’s treatment plan.

#### Protected Health Information/Medical Record Data

OCRI staff will send subjects’ clinical information from their medical records – protected health information (PHI) – to CMR researchers to aid in the interpretation of the results and correlate clinical outcomes versus kinematic results, although only researchers present during data collection, appointed student researchers chosen by Dr. Sharma to lead the study, Investigators and respective staff will have access to PHI; individuals not noted as Investigators will sign confidentiality statements. OCRI staff will send subject data (with subject-assigned IDs) to CMR researchers by inputting data into an excel spreadsheet that will be transferred back to UT researchers via UT’s secure email known as the Vault <https://vault.utk.edu/>. The clinical/demographic information acquired from the medical records with participant authorization obtained via HIPAA form will include:

- Age or date of birth
- Body weight
- Range-of-motion
- Previous medical assessments that are not a part of this particular research study
- Post-operative time and any other conditions that may alter the kinematic results, such as back problems, ankle fusion, or contra-lateral knee problems
- Pre-operative Knee Society score
- Knee implant information

This information can be used to rule out any unique kinematic patterns. This information will only be used by the UT researchers and will not be provided to any other source.

Researchers would like to retain this de-identified data in our secure database so as to continue to add relevant, current data to our digital collection to help us work with manufacturers in the future to create better implants that last longer and will not require revision surgery, as many

TKAs currently do. Participants will be asked if their de-identified data may remain a part of the CMR digital data collection for use in future studies in the IC. Likewise, should a subject choose to withdraw from the study, s/he will have the option as to whether or not de-identified data collected from them at the point of withdrawal may be used for data analysis or if their information should be provided to them and destroyed from CMR records on the Revocation of Consent form they will be asked to complete.

Two separate tables will be created for this study which will be stored securely on the CMR server, the first of which will contain the participants' names and assigned ID numbers. This table will only be accessible by Dr. Sharma after the initial study data has been uploaded onto the secure CMR database.

## **BENEFITS**

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

- Determination as to whether or not the DePuy Attune PS TKA more closely represents the natural knee.
- Future implant design improvements based on the kinematic findings.
- New and advanced surgical techniques for TKA based on the results.
- Participants will receive a set stipend agreed upon by sponsor.
- There is no intention of any direct benefit to participants of the study. They will be able to see their implant on the video monitor.

## **Remuneration**

Participants will be compensated for their participation in the amount of a \$300.00 set stipend. The \$300.00 stipend will be paid by the University of Tennessee and was included in the budget for the proposal, agreed upon by sponsor and University.

One night of lodging will be booked for each subject according to the scheduled time of their appointment. Lodging expenses will be direct billed to the University; any additional lodging will be at the expense of the participant. Participants will be reimbursed for mileage at a rate of \$.56 per mile, maximum of 550 miles/\$308.00 [roundtrip]; mileage reimbursement will be calculated by using their home address. Subjects will also receive up to \$75.00 per day for meals expenses for two days (maximum of \$150.00 for both days), although in order to acquire reimbursement, itemized receipts for the meals must be submitted to UT. No meals expenses will be processed

without itemized receipts, as this documentation is necessary in order for DePuy to reimburse UT for these costs. It is the responsibility of the subject to acquire itemized receipts. If itemized receipts are not submitted, per diem rates do not apply and will not be processed.

#### Investigator Funding

DePuy Synthes, the sponsor of this study, has approved and agreed to a specific amount of compensation for conducting this particular research study with Dr. Sharma at the University of Tennessee which has been deposited into an R' account (for research) which will be overseen by Dr. Sharma. There is a contract agreement between the University of Tennessee and OCRI for the OCRI staff's participation in this study. The first page of the IC indicates a brief allocation of funds by the sponsor to the PI.

#### **METHODS FOR OBTAINING "INFORMED CONSENT" FROM PARTICIPANTS**

After subjects were recruited and enrolled by OCRI using the approved recruitment materials and study documents, they were asked to complete the KSS and KOOS surveys and the necessary forms for their stipend to be processed for payment through UT. They were given the opportunity to ask any questions about the study.

The copies of IC/HIPAA forms completed prior to data collection will be maintained in a locked cabinet at the University of Tennessee and accessible by only approved study personnel. The forms will be securely maintained through any future use of protected data (at the very least three years) at the University of Tennessee

#### **STATISTICAL ANALYSIS PLAN**

Basic descriptive statistics (mean, standard deviation and range) would be analyzed for the condylar movement, axial rotation and maximum ground reaction forces for the all the activities.