In Vivo Determination of Knee Kinematics for Subjects Having a Zimmer-Biomet Persona PCR or PS TKA

PI: Richard D Komistek, PhD
University of Tennessee
1506 Middle Drive
310 Perkins Hall
Knoxville, TN 37996
Phone: (865) 974-2093
Fax: (865) 946-1787
Email: rkomiste@utk.edu

Co-I : Jean Noël Argenson, MD, PhD
The Institute for Locomotion
Aix-Marseille University, Hopital Sainte-Marguerite
270 Boulevard Sainte-Marguerite, 13009, Marseille, France
Phone: +33 491 745 011
Email: Jean-noel.ARGENSON@ap-hm.fr

Sub-I : Matthieu Ollivier, MD, PhD
The Institute for Locomotion
Aix-Marseille University, Hopital Sainte-Marguerite
270 Boulevard Sainte-Marguerite, 13009, Marseille, France
Phone: +33 491 745 011
Email: ollivier.mt@gmail.com

Sub-I : Paul Bizzozero, MD
The Institute for Locomotion
Aix-Marseille University, Hopital Sainte-Marguerite
270 Boulevard Sainte-Marguerite, 13009, Marseille, France
Phone: +33 491 745 011
Email: paulbizzozero@gmail.com

Sub-I: Adrija Sharma, PhD
University of Tennessee
1506 Middle Drive
310 Perkins Hall
Knoxville, TN 37996
Phone: (865) 974-7684
Fax: (865) 946-1787
Email: asharma1@utk.edu

Introduction:

A better understanding of knee joint kinematics is important to explain the premature polyethylene wear failures, patient dissatisfaction with function and to help design a prosthesis that most closely approximates the normal knee. Previously, most experimental studies of knee kinematics have involved cadaveric, in vitro analyses, or have not tested the knee in a weight-bearing mode. Others have used exoskeletal linkages and skin markers that permit error due to undesired motions between markers and the underlying bone. More recently, fluoroscopy has been used to assess in vivo kinematics for subjects having a TKA. These in vivo studies have defined the following abnormal kinematic patterns that exist with total knee arthroplasty (TKA), in comparison to the normal knee:

1. Most subjects having a posterior cruciate retaining PCR TKA and some having a posterior stabilized (PS) TKA experience a paradoxical translational of the femoral component relative to the tibial component
2. All TKA types experienced a significant percentage of subjects having reverse axial rotation, where the femoral component internally rotates with increasing knee flexion, opposite of the normal knee.
3. All TKA types demonstrate the occurrence of condylar lift-off, where one condyle raises off the tibial plateau.

New TKA continue to be designed and marketed to the patient and surgeon, but are these designs significantly different than those previously offered? What is the rational for those design changes and do they truly offer an advantage? More recently, Zimmer-Biomet brought a new knee implant to the orthopaedic market, called the Persona TKA. This family of TKA includes both a posterior stabilized and posterior cruciate retaining design for the surgeon to choose. More recently, surgeons have implanted both the PCR and PS Persona TKA into patients, but as of today Zimmer does not have in vivo data validating their design or have compared the kinematic results with those patients previously evaluated having either a NexGen PCR or PS TKA. Therefore, the objective for this study is to analyze the in vivo kinematics for patients implanted by two surgeons having either a Zimmer-Biomet Persona PCR or PS TKA.

Hypothesis:

1. It is hypothesized that subjects having a PS TKA will experience greater posterior femoral rollback, axial rotation and weight-bearing flexion than subjects having a PCR TKA.
2. It is hypothesized that subjects having a Persona TKA will experience better kinematic patterns than subjects previously analyzed having a NexGen TKA.

Study design: In vivo knee kinematics will be assessed for 25 subjects that have been implanted with a Zimmer-Biomet Persona fixed bearing posterior stabilizing (PS) total knee arthroplasty (TKA) by Dr. Jean Noel Argenson of the Institute for Locomotion, Aix-Marseille University, Hopital Sainte-Marguerite. The other 25 subjects with the Zimmer-Biomet Persona fixed bearing poster cruciate retaining (PCR) TKA will be provided by another surgeon at a separate site, which has yet to be determined. Dr. Ollivier and Dr. Bizzozero both of the Institute for Locomotion, Aix-Marseille University, Hopital Sainte-Marguerite will serve as Sub-Investigators. Dr. Adrija Sharma of the University of Tennessee will also serve as a Sub-Investigator. Enrollment will be increased to 28 subjects per implant type to ensure that researchers acquire the necessary 25 usable datasets for analysis for each implant type and also

to account for any subjects that may drop out of the study. All TKAs should be judged clinically successful (KSS > 75). Each subject should have a well-functioning prosthesis, be at least six months post-operative, and should have good-to-excellent post-operative passive flexion.

Deciding which subjects received which kind of implant was up to the discretion of the study surgeon, according to his professional opinion. The determination as to which type of implant subjects received is outside the scope of this particular study. Subjects will already have the knee implants and must be at least six months post-operative.

Inclusion and exclusion criteria:

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

1. Subjects will have a Zimmer Persona fixed bearing PS TKA.
2. Subjects must be at least six months post-operative.
3. Subjects will have KSS greater than 75.
4. Participants must be able to perform the required activities - stepping up and a deep knee bend.
5. Subjects must be willing to sign the Informed Consent (IC) / HIPAA form to participate in the study.
6. Bilateral subjects may be included in the subject population.

Exclusion criteria:

1. Pregnant, potentially pregnant or lactating females. 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. To ensure this, a pregnancy test will be administered to any female participants of child bearing age who have not had a hysterectomy.
2. Subjects without the required type of knee implant.
3. Subjects who are unable to perform stepping up and deep knee bend.
4. Subjects who are unwilling to sign Informed Consent/HIPAA documents.
5. Subjects who do not speak English and/or French.

Study locations

Subject Recruitment will take place at The Institute for Locomotion
Aix-Marseille University, Hopital Sainte-Marguerite
270 Boulevard Sainte-Marguerite, 13009, Marseille, France
Phone: +33 491 745 011

Fluoroscopic and range of motion exams will be performed on 28 PS TKA subjects at:
The Institute for Locomotion
Aix-Marseille University, Hopital Sainte-Marguerite
270 Boulevard Sainte-Marguerite, 13009, Marseille, France
Phone: +33 491 745 011

Analysis will take place at the University of Tennessee's Center for Musculoskeletal Research laboratories:
Science and Engineering Research Facility

1414 Circle Dr.
Knoxville, TN 37996

CMR administrative offices:
310 Perkins Hall
1506 Middle Dr.
Knoxville, TN 37996

Recruitment
Dr. Argenson will recommend eligible subjects for recruitment that have been implanted with the Zimmer Persona PS TKA whose post-operative conditions permit them to capably perform the study activities. Drs. Ollivier and Bizzezero will be responsible for reviewing those subjects' medical records to determine if they meet the remaining eligibility required for the study according to the study-specific criteria. A Request for Partial Waiver of HIPAA Authorization for the purposes of recruitment will be submitted.

During review of medical files, Drs. Ollivier and Bizzezero will ensure that each potential subject meets all eligibility requirements prior to being contacted about participation in the study. If patients meet all eligibility criteria, then Drs. Ollivier or Bizzozero will contact the patients to explain the study, using the included script, and inquire as to whether or not they are interested in participating; If a subject is agreeable to participate, Drs. Ollivier or Bizzozero will schedule a time for the patient to visit the Institute for Locomotion on the day of data collection. On this scheduled day, UT researchers will travel to the Institute for Locomotion to collect the kinematic data of participant implanted knees at least six months post-operatively under fluoroscopic surveillance using a C-arm fluoroscopic unit while subjects perform the following activities: stepping up and a deep knee bend. The fluoroscopic images will be stored on videotape and/or external hard drive for subsequent analysis.

Data Collection
On the day the fluoroscopic procedures will take place, researchers selected by Dr. Richard Komistek, student research assistants (Garett Dessinger, Jarrod Nachtrab, Manh Ta, Milad Khasian) with the Center for Musculoskeletal Research (CMR) will travel to the Institute for Locomotion to collect the data. A study Investigator will be present for the fluoroscopy procedures. Drs. Ollivier or Bizzozero will consent the participants. They will meet with each potential participant individually to make sure s/he has been properly informed of the procedures and to help with any of the IC/HIPAA form. Subjects will be informed that they do not have to participate and are free to leave if they wish and will answer any questions subjects may have about the study. Participation is entirely voluntary.

After consent has been obtained and eligibility has been confirmed, a study physician will administer the New Knee Society Score survey to all participants.

In addition to fluoroscopy video, subjects will be videotaped from the shoulders down (to maintain subject anonymity) while performing the activities (live feed perspective). During the fluoroscopy procedure, the radiation technician (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 practice portion of the data collection without radiation will not be video-recorded. The participant will be allowed to rest as necessary and be instructed to stop the activity at the first sign of pain. The speed level of each trial will be based on the comfort level of the subject. One of the researchers will be ready and in close proximity to assist each subject 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.

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.

When both the subject and study team are ready, the following activities will be performed:

1. Step up
    a) The subject will begin standing at rest with his/her knee in question slightly forward in front of a small set of portable stairs.
    b) The subject will then begin to ascend the stair case beginning with her/his lead foot, making sure that with each step, the foot is landing one step above the other.
2. Deep knee bend
    a) The subject will begin standing in a starting position in which the knee is fully extended. When ready the subject will flex the knee through its full weight bearing range of motion. Once maximum weight bearing flexion is achieved the activity is complete, and the subject can rise to a comfortable resting position.

The fluoroscopic footage for these activities will be stored on digital video files on a secure computer workstation, and participant information will be removed and replaced with identifiers by researchers selected by Dr. Komistek to lead the study, which may include any researchers that attend data collection. All researchers with access to identifiable subject data will sign statements of confidentiality. This study data will then be uploaded onto a secure server that University of Tennessee researchers will use to conduct the kinematic analysis using a 3D-to-2D image registration technique the allows researchers to determine the 3D kinematics of the tibio-femoral joint for each of the frames in question. Once each of the frames has been analyzed for a single participant, kinematic curves can be produced to describe the motions of the joint. It is not feasible for a participant to be identified merely by the components within their individual implants.

Private Health Information/Medical Record Data

The surgeon and his staff will provide subjects' clinical information from their medical records – PHI – to Dr. Komistek and his researchers to aid in the interpretation of the results and correlate clinical outcomes versus kinematic results, although only researchers present during data collection or those appointed by Dr. Komistek to lead the study will have access to PHI; they will sign confidentiality statements. 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.

The clinical/demographic information acquired from the medical records with participant authorization obtained as required by HIPAA will include:

- the range-of-motion (at least 6 months post-operative),
- DOB, body weight, Body Mass Index (BMI),
- date of surgery,
- Subjects post-operative KSS (must be >75),
- previous medical assessments that are not a part of this particular research study, that may alter the kinematic results, such as previous knee x-rays,
- post-operative time and any other conditions that may alter the kinematic results, such as back problems, ankle fusion, or contra-lateral knee problems.

The surgeon's office will also relate the implant component information and surgical technique details:

- Size of: femur, tibial plate, articular surface thickness [mm], patella
- Product/Reference # of: femur, tibial plate, polyethylene (PE) insert, patella
- Lot # of: femur, tibial plate, PE insert, patella
- Surgical operation notes
- Use (if any) and details of intraoperative surgical technologies, such as robotic assistance, subject-specific cutting guides, surgical navigation, etc.

The subject data – fluoroscopy frames, video footage and data from medical files– will be uploaded and stored on CMR's secure server for use in this and future studies (if participant permission is obtained via IC) by the researcher(s) who attend data collection or appointed by Dr. Komistek. Once data has been uploaded, the database automatically removes subject identifiers and assigns an ID for each subject. Only these files of de-identified data (no dates of birth or surgery) are now available for researchers to review and analyze. Only Dr. Adrija Sharma (Sub-I) has access to the identifiable data that was originally uploaded by the GRA, as it remains in a password-protected portion of the secure server. Only Dr. Sharma can grant access to this identifiable password-protected portion of the database by changing a user's level of authentication with different privilege levels. Researchers would like to retain this study 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. Participants will be asked if their study data may remain a part of the CMR 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 data collected from them at the point of withdrawal may be used for data analysis or if their information should be destroyed from CMR records; subjects choosing to withdraw will be asked to complete a Revocation of Consent wherein they may indicate their preference regarding the data collected from them.

On the day of data collection, the list of subject names will be given to UT researchers and the researchers will use this to generate subject-specific identifiers. A table will be generated for this study, indicating the participant's name and generated ID number; this table with subject names

and corresponding ID numbers will be provided to the surgeons' staff, so the staff will be aware of which identifier is linked with each subject. Then, study staff will upload the PHI from medical files into an excel spreadsheet created by the UT researchers present during data collection or those appointed by Dr. Komistek (who will sign statements of confidentiality) that will only have the generated ID numbers. This spreadsheet will be securely transferred to UT researchers via UT's secure email known as the Vault. See 'Computer Database' section under Participant Confidentiality for additional details regarding the actual acquisition of PHI data from the surgeon's office.

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 subject variability and differences in imagining techniques, all subjects enrolled in this study will receive fewer 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 (Attachments 3 and 4). The participant's knee joint will be fluoroscoped using negligible to low risk levels of radiation according to published literature (Attachments 2 and 3).

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.

---

[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

Researchers will be at the hospital during the fluoroscopic exams, serving as consultants to the hospital RT. They will not operate the fluoroscopy unit, but will be available to the RT and the hospital staff if questions arise. Researchers will be on hand to assist the participant at any time during the procedure. 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. If researchers and the investigator during data collection concur that a subject is at risk and the subject persists in participating, the researchers will ask the subject to discontinue the activities and not to participate in the study.

We are estimating a total maximum time of 45 minutes to permit the subject time to complete the IC/HIPAA 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 investigators will ensure subject confidentiality to the extent that is permissible by law is maintained throughout the study and after. Researchers not notated as Investigators of this study that have access to PHI will sign pledges of confidentiality. Complete confidentiality cannot be guaranteed.

Computer Database

As noted, 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; the surgeons' study staff will be provided with this list of subject names and corresponding generated identifiers that they will use to upload into an excel spreadsheet created by UT researchers. The excel spreadsheet with and transmit the document back to UT researchers via UT's secure email transmission known as the Vault, https://vault.utk.edu/.

After the study data has been entered into the spreadsheet by the surgeon's office, researchers present during data collection or appointed by Dr. Komistek 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. The personnel in the following list will have access to participant PHI:

List of Persons Involved in Research:

- Richard Komistek, PhD, PI, UT Professor, Biomedical Engineering
- Jean Noël Argenson, MD, PhD, Co-I, The Institute for Locomotion, Aix-Marseille University, Hospital Sainte-Marguerite, orthopaedic surgeon
- Matthieu Ollivier, MD, PhD, Sub-I, The Institute for Locomotion, Aix-Marseille University, Hospital Sainte-Marguerite, orthopaedic fellow
- Paul Bizzozero, MD, Sub-I, The Institute for Locomotion, Aix-Marseille University, Hospital Sainte-Marguerite, orthopaedic fellow
- Dr. Adrija Sharma, PhD, Sub-I, UT Research Assistant Professor, Biomedical Engineering
- Radiation technician(s) will operate the fluoroscopy machine
- A study investigator will be present during the fluoroscopy procedure.
- Rebecca Robertson, Research Coordinator, UT staff.
- Researchers present during data collection at the University of Tennessee and/or the lead researchers appointed by Dr. Komistek.
    - Graduate students:
        - Garett Dessinger
        - Jarrod Nachtrab
        - Milad Khasian
        - Manh Ta
    - * Undergraduate student researchers employed by CMR will be involved in analyzing the data after it has been collected and transferred to CMR's digital data collection. Since subject information will be removed and replaced with the assigned identifiers before the data is transferred to the database, it will not be possible for these undergraduate students to be able to identify subjects. They will only have access to the study data that has been uploaded onto the secure CMR digital collection. These undergraduate student researchers will not have contact with subjects, unless they are part of the data collection team.
- Institutional Review Board/Ethics Committee
    - The University of Tennessee will waive oversight to WIRB. Waiver of Oversight is forthcoming.
    - The Institute of Locomotion will waive oversight of study to WIRB. Waiver of Oversight is forthcoming.

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. If researchers see anything in the imaging that is extremely out of the ordinary (*e.g.,* floating body, severe dislocation, potential tumors [spots of incredibly dense tissue on bones and skin]), they will bring this to the attention of Drs. Argenson, Ollivier, or Bizzozero. It is not anticipated that the imaging collected during this study would potentially provide benefit to specific subjects by influencing the physician's 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.
- Information related to the data gathered may be provided to the surgeon by the researchers if something out of the ordinary is seen during the imaging. However, researchers are not radiologists and cannot interpret anything they may see. If there is something within the imaging that is obviously wrong as mentioned above, then this could result in potential modification of a subject's treatment plan if images collected as a result of this study reveal any kind of "significant problem."

METHODS TO OBTAIN "INFORMED CONSENT" FROM PARTICIPANTS
Informed consent will be obtained prior to any procedures being conducted. Subjects who are agreeable to participate will be scheduled to visit on the day that UT researchers will travel to the Institute for Locomotion for data collection. Participating physicians from the Institute will be responsible for consenting the participants, giving them ample time to review and complete the forms and assist the participants with review of the documentation, if the participants are unable to read the form on their own. Only upon signed consent will the subject be allowed to participate in the study. If the subject chooses to be removed from the study after participating, his/her video footage and any other demographical data that was collected will be managed according to the subject's response on the Revocation of Consent form. A copy of his/her Revocation of Consent will be attached to his/her IC and placed in a separate, secure file for IRB review. These consent forms will be stored at UT, Knoxville and will be accessible by only the aforementioned personnel.

Dr. Argenson will not be present during the consenting process to avoid possible subject coercion to participate. Subjects may contact the surgeon's office with any questions they may have.

From previous studies, we have determined that it takes approximately 15 minutes to consent a subject and answer any questions that s/he may have. We have also estimated approximately 30 minutes for researchers to guide the subject through the steps of the procedure, allow the subject to practice the activities and then to actually perform the activities under fluoroscopic surveillance; actual radiation exposure will be up to, but not more than two minutes. We have estimated a total time of approximately 45 minutes for each subject to be consented, complete the fluoroscopy procedure.

ATTACHMENT 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.

Table 2
Generic Dose-Area Products, Conversion Factors, and Effective Doses at Angiography in a Standard Adult Patient

Examination*	Fluoroscopy time (min)	Dose-Area Product (Gy • cm^2)	Conversion Factor (mSv/Gy • cm^2)	Effective Dose (mSv)
Cerebrum	12	75	0.04	3.0
Coronary arteries	4	75	0.20	15.0
Abdomen	8	80	0.25	20.0
Lower limbs	6	50	0.10	5.0

Source.—Adapted from reference 27.
*Including image acquisition.

Table 3
Generic Dose-Length Products, Conversion Factors, and Effective Doses at CT in a Standard Adult Patient

Examination	Dose-Length Product (mGy • cm)	Conversion Factor (mSv/mGy • cm)	Effective Dose (mSv)
Head	1000	0.0023	2.3
Neck	400	0.0054	2.2
Chest	300	0.017	5.1
Abdomen-pelvis	500	0.015	8.0
Lower limbs (excluding pelvis)	500	0.0012	0.6

Sources.—References 21 and 32.

Table 4
What to Tell Your Patients concerning Additional Risk of Death from Cancer

Effective Dose (mSv)	Risk	Quantification	Examination
<0.1	$<10^{-6}$	Negligible	Radiography of the chest (postero-anterior), extremities, or teeth
0.1–1.0	10^{-5}	Minimal or extremely low	Abdomen, lumbar spine
1.0–10	10^{-4}	Very low	CT of the brain, chest, or abdomen
10–100	10^{-3}	Low	Multiphase CT
>100	$>10^{-2}$	Moderate	Interventional procedures,* repeat CT

Sources.—References 10 and 22.
*Including the determinist effects of ionizing radiation (skin burns).

ATTACHMENT 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

Results

Representative values and ranges of effective doses reported in the literature for various examinations and procedures are presented in Tables 1–5.

In addition to effective dose, absorbed organ doses are important for some procedures that either involve high doses or include sensitive tissues in the primary radiation beam. For CT scanning, organs in the beam can receive doses that are 10–100 mGy but are usually in the range of 15–30 mGy per single CT sequence (162–169).

Doses to the lens of the eye during CT scanning of the head have been reported to be 30–50 mGy (170–174). Values depend on whether the lens is in the direct beam or out of the beam when the gantry is angled. Angulation of the gantry for head CT studies can reduce the eye dose by 90%, to about 3–4 mGy. For many new scanners, such as portable intensive care unit scanners, positron emission tomography/CT scanners, and dual-tube multidetector CT scanners, the gantry cannot be angled, which will result in higher eye doses when head CT examinations are performed.

Radiation dose to the breast tissue is of critical importance, especially in girls and young women. Chest CT scanning results in relatively high doses to breast tissue. Doses have been estimated to be 20–60 mGy for a CT examination performed for pulmonary embolism, 50–80 mGy for a CT coronary angiography examination, and even 10–20 mGy to the inferior part of the breast for an abdominal CT examination (175–177). Even though lower x-ray energies are used, as a comparison, for mammography, the American College of Radiology and the Mammography Quality Standards Act of 1992 regulations require that the mean glandular dose for a single mammogram to a normal-sized breast with 50% glandularity be less than 3 mGy.

Discussion

As mentioned earlier, effective dose is a calculated age- and sex-averaged value that is used as a robust measure to compare detriment from cancer and hereditary effects due to various procedures involving ionizing radiation. Martin (178) has pointed out a number of limitations in its use, including about ±40% uncertainty for a reference patient. Often, effective dose is calculated and expressed to a much greater precision than is warranted, and we have expressed values to only one significant digit. There clearly are additional problems in trying to apply the sex-averaged effective dose to procedures that predominantly involve one sex (such as mammography).

The sources of information reviewed were variable in quantity, qual-

Table 1

Adult Effective Doses for Various Diagnostic Radiology Procedures

Examination	Average Effective Dose (mSv)	Values Reported in Literature (mSv)
Skull	0.1	0.03–0.22
Cervical spine	0.2	0.07–0.3
Thoracic spine	1.0	0.6–1.4
Lumbar spine	1.5	0.5–1.8
Posteroanterior and lateral study of chest	0.1	0.05–0.24
Posteroanterior study of chest	0.02	0.007–0.050
Mammography	0.4	0.10–0.60
Abdomen	0.7	0.04–1.1
Pelvis	0.6	0.2–1.2
Hip	0.7	0.18–2.71
Shoulder	0.01	...
Knee	0.005	...
Other extremities	0.001	0.0002–0.1
Dual x-ray absorptiometry (without CT)	0.001	0.001–0.035
Dual x-ray absorptiometry (with CT)	0.04	0.003–0.06
Intravenous urography	3	0.7–3.7
Upper gastrointestinal series	6*	1.5–12
Small-bowel series	5	3.0–7.8
Barium enema	8*	2.0–18.0
Endoscopic retrograde cholangiopancreatography	4.0	...

* Includes fluoroscopy.

Table 2

Adult Effective Doses for Various CT Procedures

Examination	Average Effective Dose (mSv)	Values Reported in Literature (mSv)
Head	2	0.9–4.0
Neck	3	...
Chest	7	4.0–18.0
Chest for pulmonary embolism	15	13–40
Abdomen	8	3.5–25
Pelvis	6	3.3–10
Three-phase liver study	15	...
Spine	6	1.5–10
Coronary angiography	16	5.0–32
Calcium scoring	3	1.0–12
Virtual colonoscopy	10	4.0–13.2

ATTACHMENT 3

PS010-3

HEALTH PHYSICS SOCIETY

RADIATION RISK IN PERSPECTIVE

POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

Adopted: January 1996
Revised: July 2010
Further revised: May 2016

Contact: Brett Burk
Executive Director
Health Physics Society
Telephone: 703-790-1745
Fax: 703-790-2672
Email: HPS@BurkInc.com
http://www.hps.org

The Health Physics Society advises against estimating health risks to people from exposures to ionizing radiation that are near or less than natural background levels because statistical uncertainties at these low levels are great.

The average annual equivalent dose[1] from natural background radiation in the United States is about 3 mSv. A person might accumulate an equivalent dose from natural background radiation of about 50 mSv in the first 17 years of life and about 250 mSv during an average 80-year lifetime.

Substantial and convincing scientific data show evidence of health effects following high-dose exposures (many multiples of natural background). However, below levels of about 100 mSv above background from all sources combined, the observed radiation effects in people are not statistically different from zero.

Scientists evaluate and estimate radiation risk using several assumptions that, taken together, may lead to a range of hypothetical health risk estimates for any given exposure scenario.

For radiation protection purposes and for setting radiation exposure limits, current standards and practices are based on the questionable premise that any radiation dose, no matter how small, could result in detrimental

[1] Dose is a term used to express or quantify the amount of radiation a person or object has received. Equivalent dose to an organ or tissue is a quantity derived from the absorbed dose. Equivalent dose is used in radiation protection to relate absorbed dose to the probability of a stochastic radiation effect (cancer induction and hereditary changes) in that organ or tissue. The equivalent dose represents the sum of all of the contributions from radiations of different types multiplied by their respective radiation qualities.

health effects such as cancer or heritable genetic damage. Implicit in this linear no-threshold (LNT) hypothesis is the core assumption that detrimental effects occur proportionately with radiation dose received (NAS/NRC 2006). However, because of statistical uncertainties in biological response at or near background levels, the LNT hypothesis cannot provide reliable projections of future cancer incidence from low-level radiation exposures (NCRP 2001).

Molecular-level radiation effects are nonlinear

Studies show that dose-response relationships are typically nonlinear (Tubiana and Aurengo 2006; Tubiana et al. 2006). Substantial scientific data indicate that the LNT model of radiation effects oversimplifies the relationship between dose and response. Linearity at low dose may be rejected for a number of specific cancers, such as bone cancer, lymphoma, and chronic lymphocytic leukemia. Heritable genetic damage has not been observed in human studies.

Recent low-dose research indicates that biological response mechanisms such as DNA repair, bystander effects, and adaptive response modulate radiation-induced changes at the molecular level. Cellular transformation leading to carcinogenesis by mutation of genetic material appears to be a complicated, multistep process that is not reflected in the LNT model.

Radiogenic health effects have not been consistently demonstrated below 100 mSv

Due to large statistical uncertainties, epidemiological studies have not provided *consistent* estimates of radiation risk for whole-body equivalent doses less than 100 mSv. Underlying dose-response relationships at molecular levels appear mainly nonlinear. The low incidence of biological effects from exposure to radiation compared to the natural background incidence of the same effects limits the applicability of radiation risk coefficients at organ equivalent doses less than 100 mSv (NCRP 2012).

The references to 100 mSv in this position statement should not be construed as implying that health effects are well established for doses exceeding 100 mSv. Considerable uncertainties remain for stochastic effects of radiation exposure between 100 mSv and 1,000 mSv, depending upon the population exposed, the rate of exposure, the organs and tissues affected, and other variables. In addition, it is worth noting that epidemiological studies generally do not take into account the dose that occupationally or medically exposed persons incur as natural background; thus, the references to 100 mSv in this position statement should generally be interpreted as 100 mSv above natural background dose.

Dose-rate issues

Risk estimates commonly used to predict health effects in exposed individuals or populations are based primarily on epidemiological studies of Japanese atomic bomb survivors and other populations exposed to relatively high doses delivered at high dose rates. Animal, cellular, and molecular studies all demonstrate that at any level of biological organization, the responses following low-dose-rate exposure are less than observed after the same dose delivered at a high dose rate (Dauer et al. 2010). Epidemiological studies have not consistently demonstrated adverse health effects in persons exposed to small (less than 100 mSv) doses protracted over a period of many years.

Collective dose and radiation protection planning

A common approach in many circles, not recommended here, involves extrapolating the calculated risk derived at high doses to low-dose levels. Extrapolation may be convenient for setting radiation protection guidelines. However, when used prospectively to predict future risk to an exposed population, the multiplication of small risk coefficients by large population numbers leads inevitably to unsupportable claims of cancer risk from ionizing radiation (NCRP 1997, 2012).

Significant dosimetry uncertainties for individual subjects characterize most epidemiological studies. Actual doses and individual responses to radiation may be highly variable. It follows, therefore, that the collective population dose (the sum of individual whole-body equivalent doses expressed in units of person-sievert) is a highly uncertain number. Since the risk coefficient at low dose is uncertain, and the individual contributors to collective population dose are also uncertain, the resultant uncertainty is greater than each of the individual contributions—and should not be used with confidence to predict cancer incidence in an exposed population.

Equivalent dose is not defined for short-term deterministic effects

The concept of equivalent dose applies only to population group averages (reference models) for radiation protection purposes and not to biological risk for individual subjects. Since the radiation-weighting factors used to derive equivalent dose were developed only for stochastic effects, the equivalent dose is not applicable to deterministic biological effects. Therefore, equivalent dose should not be used for evaluating organ or tissue toxicity from radiation.

References

Dauer LT, Brooks AL, Hoel DG, Morgan WF, Stram D, Tran P. Review and evaluation of updated research on the health effects associated with low-dose ionising radiation. Radiat Protection Dosimetry 140:103–136; 2010.

National Academies of Science/National Research Council. BEIR VII Phase 2: Health risks from exposure to low levels of ionizing radiation. Washington, DC: National Academies Press; 2006.

National Council on Radiation Protection and Measurements. Uncertainties in fatal cancer risk estimates used in radiation protection. Bethesda, MD: National Council on Radiation Protection and Measurements; NCRP Report No. 126; 1997.

National Council on Radiation Protection and Measurements. Evaluation of the linear-nonthreshold dose-response model for ionizing radiation. Bethesda, MD: National Council on Radiation Protection and Measurements; NCRP Report No. 136; 2001.

National Council on Radiation Protection and Measurements. Uncertainties in the estimation of radiation risks and probability of disease causation. Bethesda, MD: National Council on Radiation Protection and Measurements; NCRP Report No. 171; 2012.

Tubiana M, Aurengo A. Dose-effect relationship and estimation of the carcinogenic effects of low doses of ionizing radiation: The joint report of the Académie des Sciences (Paris) and of the Académie Nationale de Médecine. Int J Low Radiat 2 (3/4); 2006.

Tubiana M, Aurengo A, Averbeck D, Masse R. Recent reports on the effect of low doses of ionizing radiation and its dose-effect relationship. Rad Environ Biophys 44(4):245–251; 2006.

*The Health Physics Society is a nonprofit scientific professional organization whose mission is excellence in the science and practice of radiation safety. Since its formation in 1956, the Society has represented the largest radiation safety society in the world, with a membership that includes scientists, safety professionals, physicists, engineers, attorneys, and other professionals from academia, industry, medical institutions, state and federal government, the national laboratories, the military, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society. The Society may be contacted at 1313 Dolley Madison Blvd., Suite 402, McLean, VA 22101; phone: 703-790-1745; fax: 703-790-2672; email: HPS@BurkInc.com.

ATTACHMENT 4

5940547318 Page 1/7

KNEE SOCIETY SCORE: POST-OP

DEMOGRAPHIC INFORMATION (To be completed by patient)

1- Today's date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

2- Date of birth ☐☐ / ☐☐ / ☐☐☐☐

3- Height (ft' in") ☐ ☐☐

4- Weight (lbs.) ☐☐☐

5- Sex
○ Male ○ Female

6- Side of this (surgically treated) knee
○ Left ○ Right
If both knees have been operated on, please use a different form for each knee

7- Ethnicity
○ Native Hawaiian or other Pacific Islander ○ American Indian or Alaska Native ○ Hispanic or Latino
○ Arab or Middle Eastern ○ African American or Black ○ Asian ○ White

8- Please indicate date and surgeon for your knee replacement operation

OBJECTIVE KNEE INDICATORS (To be completed by surgeon)

ALIGNMENT

1- Alignment: measured on AP standing Xray (Anatomic Alignment) — **25 point max**

Neutral: 2-10 degrees valgus	(25 pts)
Varus: < 2 degrees valgus	(-10 pts)
Valgus: > 10 degrees valgus	(-10 pts)

INSTABILITY

2- Medial / Lateral Instability: measured in full extension — **15 point max**

None	(15 pts)
Little or < 5 mm	(10 pts)
Moderate or 5 mm	(5 pts)
Severe or > 5 mm	(0 pts)

3- Anterior / Posterior Instability: measured at 90 degrees — **10 point max**

None	(10 pts)
Moderate < 5 mm	(5 pts)
Severe > 5 mm	(0 pts)

JOINT MOTION

4- Range of motion (1 point for each 5 degrees)

Deductions

Flexion Contracture — **Minus Points**

1-5 degrees	(-2 pts)
6-10 degrees	(-5 pts)
11-15 degrees	(-10 pts)
> 15 degrees	(-15 pts)

Extensor Lag — **Minus Points**

<10 degrees	(-5 pts)
10-20 degrees	(-10 pts)
> 20 degrees	(-15 pts)

SYMPTOMS (To be completed by patient)

1- Pain with level walking (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

2- Pain with stairs or inclines (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

3- Does this knee feel "normal" to you? (5 points)

○ Always (5 pts) ○ Sometimes (3 pts) ○ Never (0 pts)

Maximum total points (25 points)

PATIENT SATISFACTION

1- Currently, how satisfied are you with the pain level of your knee while sitting? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

2- Currently, how satisfied are you with the pain level of your knee while lying in bed? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

3- Currently, how satisfied are you with your knee function while getting out of bed? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

4- Currently, how satisfied are you with your knee function while performing light household duties? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

5- Currently, how satisfied are you with your knee function while performing leisure recreational activities? (8 points)

○ Very Satisfied (8 pts) ○ Satisfied (6 pts) ○ Neutral (4 pts) ○ Dissatisfied (2 pts) ○ Very Dissatisfied (0 pts)

Maximum total points (40 points)

PATIENT EXPECTATION (To be completed by patient)

Compared to what you expected before your knee replacement:

1- My expectations for pain relief were... **(5 points)**

- ○ Too High- "I'm a lot worse than I thought" (1 pt)
- ○ Too High- "I'm somewhat worse than I thought" (2 pts)
- ○ Just Right- "My expectations were met" (3 pts)
- ○ Too Low- "I'm somewhat better than I thought" (4 pts)
- ○ Too Low- "I'm a lot better than I thought" (5 pts)

2- My expectations for being able to do my normal activities of daily living were... **(5 points)**

- ○ Too High- "I'm a lot worse than I thought" (1 pt)
- ○ Too High- "I'm somewhat worse than I thought" (2 pts)
- ○ Just Right- "My expectations were met" (3 pts)
- ○ Too Low- "I'm somewhat better than I thought" (4 pts)
- ○ Too Low- "I'm a lot better than I thought" (5 pts)

3- My expectations for being able to do my leisure, recreational or sports activities were... **(5 points)**

- ○ Too High- "I'm a lot worse than I thought" (1 pt)
- ○ Too High- "I'm somewhat worse than I thought" (2 pts)
- ○ Just Right- "My expectations were met" (3 pts)
- ○ Too Low- "I'm somewhat better than I thought" (4 pts)
- ○ Too Low- "I'm a lot better than I thought" (5 pts)

Maximum total points (15 points) ☐

FUNCTIONAL ACTIVITIES (To be completed by patient)

WALKING AND STANDING (30 points)

1 - Can you walk without any aids (such as a cane, crutches or wheelchair)? **(0 points)**

○ Yes ○ No

2 - If no, which of the following aid(s) do you use? **(-10 points)**

○ wheelchair (-10 pts) ○ walker (-8 pts) ○ crutches (-8 pts) ○ two canes (-6 pts)

○ one crutch (-4 pts) ○ one cane (-4 pts) ○ knee sleeve / brace (-2 pts)

○ other

3 - Do you use these aid(s) because of your knees? **(0 points)**

○ Yes ○ No

4 - For how long can you stand (with or without aid) before sitting due to knee discomfort? **(15 points)**

○ cannot stand (0 pts) ○ 0-5 minutes (3 pts) ○ 6-15 minutes (6 pts)

○ 16-30 minutes (9 pts) ○ 31-60 minutes (12 pts) ○ more than an hour (15 pts)

5 - For how long can you walk (with or without aid) before stopping due to knee discomfort? **(15 points)**

○ cannot walk (0 pts) ○ 0-5 minutes (3 pts) ○ 6-15 minutes (6 pts)

○ 16-30 minutes (9 pts) ○ 31-60 minutes (12 pts) ○ more than an hour (15 pts)

Maximum points (30 points)

STANDARD ACTIVITIES (30 points)

How much does your knee bother you during each of the following activities?	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	I never do this	
1 - Walking on an uneven surface	○	○	○	○	○	○	○	
2 - Turning or pivoting on your leg	○	○	○	○	○	○	○	
3 - Climbing up or down a flight of stairs	○	○	○	○	○	○	○	
4 - Getting up from a low couch or a chair without arms	○	○	○	○	○	○	○	
5 - Getting into or out of a car	○	○	○	○	○	○	○	
6 - Moving laterally (stepping to the side)	○	○	○	○	○	○	○	

Maximum points (30 points)

ADVANCED ACTIVITIES (25 points)

1 - Climbing a ladder or step stool	○	○	○	○	○	○	○	
2 - Carrying a shopping bag for a block	○	○	○	○	○	○	○	
3 - Squatting	○	○	○	○	○	○	○	
4 - Kneeling	○	○	○	○	○	○	○	
5 - Running	○	○	○	○	○	○	○	

Maximum points (25 points)

DISCRETIONARY KNEE ACTIVITIES (15 points)

Please check 3 of the activities below that you consider *most important* to you.

(Please do not write in additional activities)

Recreational Activities

- ☐ Swimming
- ☐ Golfing (18 holes)
- ☐ Road Cycling (>30mins)
- ☐ Gardening
- ☐ Bowling
- ☐ Racquet Sports (Tennis, Racquetball, etc.)
- ☐ Distance Walking
- ☐ Dancing / Ballet
- ☐ Stretching Exercises (stretching out your muscles)

Workout and Gym Activities

- ☐ Weight-lifting
- ☐ Leg Extensions
- ☐ Stair-Climber
- ☐ Stationary Biking / Spinning
- ☐ Leg Press
- ☐ Jogging
- ☐ Elliptical Trainer
- ☐ Aerobic Exercises

Please copy all 3 checked activities into the empty boxes below.

How much does your knee bother you during each of these activities?

Activity (Please write the 3 activites from list above)	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	
1.	○	○	○	○	○	○	
2.	○	○	○	○	○	○	
3.	○	○	○	○	○	○	

Maximum points (15 points)

Maximum total points (100 points)