IRB Approved at the
Protocol Level
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Kinematics in Posterior Cruciate Retaining and Bi-Cruciate Retaining Total Knee Replacements

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In vivo knee kinematics will be assessed for 80 subjects that have been implanted with either a Smith & Nephew Journey II posterior cruciate retaining (PCR) [40 subjects] or bi-cruciate retaining (BCR) [40 subjects] total knee arthroplasty (TKA) who are patients of Dr. Cates or Dr. Freeman. Enrollment and testing will be increased to 45 patients per implant model to ensure the necessary 80 usable datasets are acquired and also to account for any subjects that may drop out of the study. 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 or Dr. Mark Freeman, according to their professional opinions. 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 either a Smith & Nephew Journey II posterior cruciate retaining (PCR) [45 subjects] or bi-cruciate retaining (BCR) [45 subjects] 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. Subjects 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:
Research Foundation of Dr. Harold Cates
9330 Park West Blvd., Suite 208B
Knoxville, TN 37923
Phone: (865) 373-1811

Erlanger Orthopaedics
979 East 3rd St.
Chattanooga, TN 37403
Phone: (423) 778-4900

Fluoroscopic exams:
Tennessee Orthopaedic Clinic
9430 Park West Blvd.
Knoxville, TN 37923
Phone: (865) 690-4861

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

Recruitment
Up to forty-five patients will have been implanted with a Smith & Nephew Journey II posterior cruciate retaining (PCR) and 45 patients will have been implanted with a bi-cruciate retaining (BCR) whose post-operative conditions permit them to capably perform the study activities. Research staff from Dr. Cates' Research Foundation or Dr. Freeman's practice at Erlanger Orthopaedics will determine potential participants for the study by reviewing medical files. The surgeon's research staff will review the patient's KSS, clinical dictation, and electronic health record (EHR), and he will approve or reject the patient as a candidate for the study. During review of medical files, the research staff will utilize the CMR Recruitment/Enrollment checklist (Attachment 6) to ensure that each potential subject meets all eligibility requirements prior to being contacted. This sheet included a checklist of the inclusion criteria, as well as a field for the

research staff to include a subject identifier so the subject's eligibility can once again be confirmed on the day of data collection. Once this sheet has been completed by the staff, it will be submitted to a UT Research Coordinator, lead researcher or PI/Co-PI/Sub-I to review and authorize recruitment and enrollment. After a potentially eligible subject has been identified and authorized to be enrolled in the study, s/he will be contacted for a visit to the surgeon's office to be consented. The subject will then be consented and scheduled for fluoroscopy data collection at the Tennessee Orthopaedic Clinic in Knoxville, TN. All testing collection at Tennessee Orthopaedic Clinic will be scheduled after normal clinic hours so as not to interfere with the patient treatments occurring during the day.

Data Collection
University of Tennessee researchers with experience conducting fluoroscopic research studies, as well as either a PI/Co-PI/Sub-I 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 the Tennessee Orthopaedic Clinic will collect fluoroscopic video while subjects perform the following activities: walking up and down a ramp, deep knee bend and rising from the DKB position.

Prior to starting data collection, UT researchers will complete the second portion of the CMR Recruitment/Enrollment checklist to ensure subjects meet eligibility requirements to document inclusion criteria for compliance purposes. Age and weight will be verified at the time of fluoroscopy to ensure eligibility. 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 clinic 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.

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.

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 (0.0083 rem per min) (Verdun[1]). Mettler, et al have reported that the typical effective dose for a conventional knee procedure is 0.005 mSv (0.00005 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 (0.0027 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 less than 4 rem. 4 rem is considered "Very Low" risk. It is unlikely that anyone in this study will approach the 4 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 4.0 rems of radiation. This means that the maximum total exposure rate will be less than 4 rems per subject for the entire experiment (Attachments 3 and 4). The participant's knee joint will be fluoroscoped using minimal risk levels of radiation according to published literature (Attachment 2).

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 she/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.

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.

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:

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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

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, Tennessee Orthopaedic Foundation for Education and Research
- Clinical Research Staff, including Ms. Peggy Adams and Mr. Johnny Campbell, Tennessee Orthopaedic Foundation for Education and Research
- Radiation technician(s) will operate the fluoroscopy machine.
- Western Institutional Review Board

List of Persons Involved in Research affiliated with Erlanger Health System:

- Dr. Mark Freeman, study doctor/Sub-Investigator, Erlanger Orthopaedics
- Selected research staff, Erlanger
- University of Tennessee College of Medicine, Chattanooga IRB

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

- Richard D. Komistek, PI, UT Professor
- Michael LaCour, Ph. D., Sub-I, UT Research Assistant Professor
- William Hamel, Ph. D., Sub-I, 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.
- Rebecca Robertson, Research Coordinator, UT staff
- 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 the surgeon'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.

- 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.

The researchers have been conducting fluoroscopic exams for 25 years. In those previous studies, subjects participated and the findings from those studies have led to implant design improvements with the knee implant systems. Therefore, like those subjects who participated in previous studies, data from this study will lead to results that will continue to improve the longevity of future knee implants.

METHODS TO OBTAIN "INFORMED CONSENT" FROM PARTICIPANTS

Once a patient is identified as potentially eligible by the surgeon's staff (TOC: Ms. Smith, JJ Campbell or Peggy Adams; Erlanger Orthopaedics - TBD), the patient's KSS, clinical dictation, and EHR will be reviewed by the surgeon and he will approve or reject the patient as a candidate for the study. As indicated in the Recruitment section of this protocol, in order to ensure and document compliance of eligibility, during review of medical files, the research staff will utilize the CMR Recruitment/Enrollment checklist to ensure that each potential subject meets all eligibility requirements prior to being contacted. This sheet includes a checklist of the inclusion criteria, as well as a field for research staff to include a subject identifier so the subject's eligibility can once again be confirmed on the day of data collection. Once this sheet has been completed by the Research Foundation staff, it will be submitted to a UT Research Coordinator, lead researcher or PI/Co-PI/Sub-I to review and authorize recruitment and enrollment. After a potentially eligible subject has been identified and authorized to be enrolled in the study, the research staff will then contact the subject, and if interested, the subject will be scheduled for a meeting with the research staff at their office. After a thorough explanation of the study and the activities that the subject will be doing, making sure the subject has asked all questions and received answers, if the subject agrees to participate, s/he will sign the Informed Consent and the HIPAA release. A research staff member will then schedule the fluoroscopic testing session during after-hours at the Tennessee Orthopaedic Clinic. These consent forms will be securely transmitted and stored at the University of Tennessee, as well as the Research Foundation and Erlanger Orthopaedics and will be accessible by only the aforementioned personnel.

Dr. Cates nor Dr. Freeman will be present during the consenting process to avoid possible subject coercion to participate. Subjects may contact their 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 UT 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. Fluoroscopy on-time and any fluoroscopy unit measurements will be indicated on each subject's IC/HIPAA form.

Compensation

Since study participants who are patients of Dr. Freeman will be traveling from the Chattanooga area to Knoxville for data collection, the sponsor of the study has allocated a $100.00 stipend for these individuals. This payment will be made through the University of Tennessee. Subjects will be asked to complete necessary paperwork during their consenting visit for them to receive this payment. An invoice will be created for each subject on the day that they complete their data collection and the payment will be processed through the University's system. It could take up to two weeks for payment to be received. Local subjects of Dr. Cates did/will not receive this compensation as their travel is not as substantial.

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
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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

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* 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 grown to approximately 6,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the Department of Defense, 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.

Health Physics Society

Specialists in Radiation Safety • Founded 1956 • http://hps.org/

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Who We Are
Background
Organization
People
Affiliates
Join

Answer to Question #708 Submitted to "Ask the Experts"

Category: Medical and Dental Issues — Nuclear Medicine and PET

The following question was answered by an expert in the appropriate

field:

Q: ***Do you know a source or Web site where I can find a listing of typical whole-body doses for common nuclear medicine, radiography, CT, mammo, and fluoro exams? I'm just looking for average doses.***

A: There are numerous sources for some of this information. While that is nice for those of us who know where to look, there really isn't one source of information on doses for all types of typical exams. I've put together, in the tables below, some of the information you requested. I've also included the references I used in the event you might want to go to the library to look at them or to order a copy for yourself. Table 1 is a list of x-ray exams and I've given a single-film effective dose.

Table 1. Effective doses for single x-ray films

Single radiographs	Effective Dose (mrem)
Skull (PA or AP)[1]	3
Skull (lateral)[1]	1
Chest (PA)[1]	2
Chest (lateral)[1]	4
Chest (PA and lateral)[5]	6
Thoracic spine (AP)[1]	40
Thoracic spine (lateral)[1]	30
Lumbar spine (AP)[1]	70
Lumbar spine (lateral)[1]	30
Abdomen (AP)[1]	70
Abdomen[6]	53
Pelvis (AP)[1]	70
Pelvis or hips[6]	83
Bitewing dental film[6]	0.4
Limbs and joints[6]	6

Table 2 shows the dose an individual might receive if undergoing an entire procedure, e.g., a lumbar spine series typically consists of five films.

Table 2. Effective doses for complete x-ray procedures

Complete exams	Effective Dose (mrem)
Intravenous Pyelogram (kidneys, 6 films)[1]	250
Barium swallow (24 images, 106 sec fluoroscopy)[1]	150
Barium meal (11 images, 121 sec fluoroscopy)[1]	300
Barium follow-up (4 images, 78 sec fluoroscopy)[1]	300
Barium enema (10 images, 137 sec fluoroscopy)[1]	700
CT head[1]	200
CT chest[1]	800
CT abdomen[1]	1,000
CT pelvis[1]	1,000
CT (head or chest)[5]	1,110
PTCA (heart study)[6]	750 - 5,700
Coronary angiogram[6]	460 - 1,580
Mammogram[6]	13
Lumbar spine series[6]	180
Thoracic spine series[6]	140
Cervical spine series[6]	27

Table 3 gives examples of typical nuclear medicine procedures.

Table 3. Effective doses for routine nuclear medicine studies

Nuclear Medical Scan	Activity (mCi)	Radiopharmaceutical	Effective Dose (mrem)
Brain[2]	20	$^{99m+}$Tc DTPA	650

Brain[3]	50	^{15}O water	170
Brain[4]	20	^{99m}Tc HMPAO	690
Hepatobiliary[2]	5	^{99m}Tc SCO	370
Bone[2]	20	^{99m}Tc MDP	440
Lung Perfusion/Ventilation[2]	5 & 10	^{99m}Tc MAA & ^{133}Xe	150
Kidney[2]	20	^{99m}Tc DTPA	310
Kidney[3]	20	^{99m}Tc MAG3	520
Tumor[2]	3	^{67}Ga	1,220
Heart[3]	30	^{99m}Tc sestimibi	890
	30	^{99m}Tc pertechnetate	1,440
Heart[4]	2	^{201}Tl chloride	1,700
	30	^{99m}Tc tetrofosmin	845
Various[3]	10	^{18}F FDG	700

References:

1. Wall BF, Hart D. Revised radiation doses for typical x-ray examinations. The British Journal of Radiology 70: 437-439; 1997. (5,000 patient dose measurements from 375 hospitals)

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4. International Commission on Radiation Protection. Radiological protection in biomedical research. New York, NY: Pergamon Press; ICRP Publication 62; 1993.

5. National Council on Radiation Protection and Measurements. Sources and magnitude of occupational and public exposures from nuclear medicine procedures.

Bethesda, MD: National Council on Radiation Protection and Measurements; NCRP Report 124; 1996.

6. United Nations Scientific Committee on the Effects of Atomic Radiation. Sources and effects of ionizing radiation, Vol. 1: Sources. New York, NY: United Nations Publishing; 2000.

Kelly Classic,
Certified Medical Health Physicist

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ATTACHMENT 5

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

Date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

Name of Surgeon ☐

9- Was this a primary or revision knee replacement?

○ Primary ○ Revision

To be completed by surgeon

10- Charnley Functional Classification (Use Code Below) ☐

A Unilateral Knee Arthritis	C1 TKR, but remote arthritis affecting ambulation
B1 Unilateral TKA, opposite knee arthritic	C2 TKR, but medical condition affecting ambulation
B2 Bilateral TKA	C3 Unilateral or Bilateral TKA with Unilateral or Bilateral THR

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)

ATTACHMENT 6

The Center for Musculoskeletal Research

The University of Tennessee

Study Name: "***Kinematics in Posterior Cruciate Retaining and Bi-Cruciate Retaining Total Knee Replacements***"

Study Physician: _____

Surgeon's Office Personnel Name: _____

UT Principal Investigator Name: Richard Komistek

UT Researcher Name: _____

Patient Code (generated by surgeon's office staff): _____

Patient Recruitment and Enrollment Checklist

At time of recruitment:	To be completed by surgeon's office:	
	Yes	No
Date of contact for recruitment:		
Have required type of TKA?		
"***Smith & Nephew Journey II bi-cruciate retaining (BCR)***"		
Patient of Dr. Freeman?		
Post-operative time ≥ 3 months?		
KSS ≥ 80 (at > 3 months post-op)?		
Weigh <250 lbs (or BMI <40)?		
Age > 40?		
Can you perform?		
Walk up ramp?		
Walk down ramp?		
Deep knee bend?		

X _____

Surgeon's office personnel signature and date

1
3187FB
BCR V2.1

Are you pregnant or could you possibly be/become pregnant? (at time of recruitment)		
Prior to <u>data collection/enrollment</u>:	To be completed by UT researcher	
Date of data collection:		
Post-operative time:		
Date of surgery:		
	Yes	No
Confirmed required type of TKA?		
"***Smith & Nephew Journey II bi-cruciate retaining (BCR)***"		
Confirmed post-operative time ≥ 3 months?		
KSS ≥ 80 (at > 3 months post-op)?		
Weigh <250 lbs (or BMI <40)?		
Age > 40?		
Are you pregnant or could you possibly be/become pregnant?		
Can you perform?		
Walking up ramp?		
Walking down ramp?		
Deep knee bend?		

X

UT Researcher Signature and date

2
3187FB
BCR V2.1