Novel use of an enhanced fluoroscopic imaging device to reduce radiation exposure and operative time during intramedullary nailing of hip fractures

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Purpose of the Study:
To evaluate the effectiveness of a novel digital image enhancement (DIE) technology called LessRay in reducing the radiation exposure to both the patient and surgical staff during standard intramedullary nail placement for treatment of hip fractures. Secondarily, to evaluate whether the image quality and reproducibility of desired images can be improved with use of the LessRay Device. Finally, to evaluate whether LessRay Device reduces total operative time.

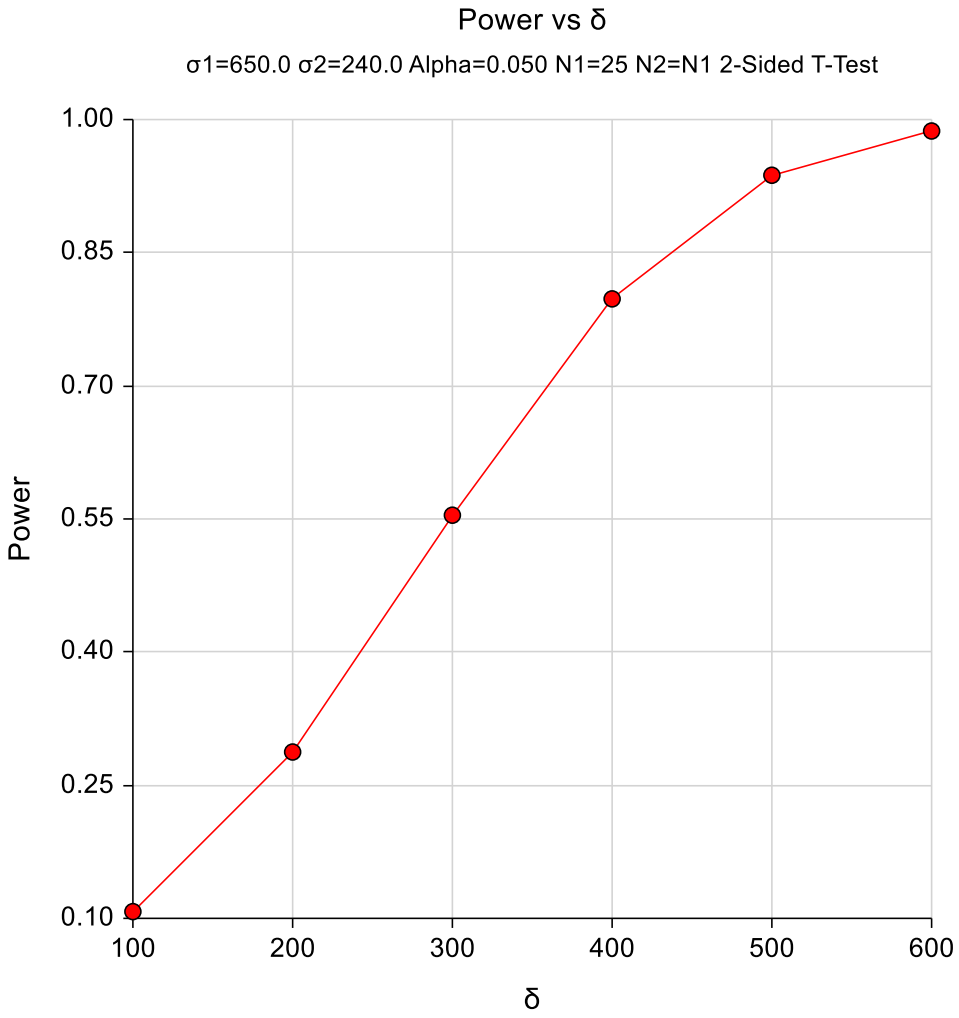
Background & Significance:
Intraoperative exposure to ionizing radiation is a growing concern for the safety of both patient and OR staff[1-12]. Several studies have shown an association between the dose of radiation the surgeon/surgical staff is exposed to and several types of cancers, including thyroid cancer[1, 3, 6, 7]. Efforts to reduce the amount of radiation during fluoroscopic procedures often result in decreased image quality (i.e. "low pulse rate" imaging). LessRay Device is able to digitally enhance images obtained from a C-arm machine using a low-dose pulse setting allowing for reduction in radiation dose while maintaining image quality. Moreover, LessRay Device allows for saving the precise location of the C-arm in space when the desired image is obtained. This allows for easy return to the exact spot where a previous image was taken, rather than taking multiple fluoroscopic images to return to the similar image. This theoretically reduces both the radiation exposure and total operative time. It also aids in evaluating and confirming reductions throughout the case as the surgeon can return to the previously obtained "perfect" or preferred AP/lateral/oblique image precisely.
The DIE system is a standalone computer display system interfaced to a fluoroscope with a video cable and combines the current image with a prior baseline image of the same anatomy. An algorithm provides for digitally enhanced images (higher resolution) using the low dose-pulse setting.
We anticipate that our results will show the LessRay Device provides a way to drastically reduce the amount of radiation exposure to both the patient and surgical staff during routine intertrochanteric hip fracture fixation. Further studies could then be performed in the hopes of reducing radiation exposure during other orthopaedic trauma cases as well. We are also hopeful that utilizing the "saved" image feature of the technology will significantly reduce overall operative time while not compromising image quality.

Design & Procedures:
This will be a prospective, randomized study. Patients presenting with closed, intertrochanteric hip fractures requiring intramedullary nail placement will be enrolled. Inclusion criteria will include adult, non-pregnant patients. Patient demographics (age, sex, BMI, any previous hip surgery), fracture type, and total radiation dose to the primary and assistant surgeon, as well as surgical tech and the patient will be documented. Primary surgeon characteristics will also be collected, i.e. post-graduate year (PGY), in

order to account for any differences in training level leading to increased OR time and/or radiation usage.
Total radiation emission as documented by the C-arm machine will be recorded. The exact radiation dose to the patient, primary and assistant surgeons, and surgical technician will also be monitored with individual dosimeter badges. Total operative time will be documented. Finally, a brief survey will be issued to the primary and assistant surgeons asking the question: "Was the image quality 'poor,' 'satisfactory,' or 'superior.'" They will also be asked to rate the image quality on a scale of 1-10. Responses to these questions for the standard of care (SOC) fluoroscopy vs. DIE will be compared.
All adult patients presenting with a closed intertrochanteric hip fracture requiring intramedullary nailing will be screened for enrollment. The only exclusion criteria for the study will be age <18 years.

Selection of Subjects:
All adult patients presenting with a closed hip fracture requiring intramedullary nailing. The only exclusion criteria for the study will be age <18 years. Consented subjects will be randomized to either standard of care (SOC) fluoroscopy use or the DIE.

A sample size of 25 per group achieves 93.7% power to reject the null hypothesis of equal means when the population mean difference is 500.0 with standard deviations of 650.0 for SOC group and 240.0 for DIE group. The significance level (alpha) of 0.050 is assumed using a two-sided two-sample unequal-variance t-test. Power calculations are based on historical data which demonstrated radiation doses of 1000 ± 650 in the SOC group and 373 ± 240 in the DIE group. The study would have approximately 80% power to show a 400 mRAD difference based on similar assumptions.



Subject Recruitment & Compensation:
Patients will be recruited from trauma population presenting to the Emergency Department who have sustained a closed hip fracture requiring intramedullary nailing.

There will be no compensation for participation in this study.

Consent Process:
Before a subject's participation in the clinical study, the investigator or study staff will be responsible for obtaining written informed consent from the subject after adequate explanation of the aims, methods, anticipated benefits, and potential hazards of the study and before any protocol-specific screening procedures or any investigational products are administered. Consent will take place in private patient rooms and patients and their families will have time to ask any questions and discuss privately. Inpatients will be given the option to keep the consent to consider participation up until their surgery is scheduled to take place.

Subject's Capacity to Give Legally Effective Consent:
Since there are no risks associated with use of the LessRay Device, LARs will be used for this study, since patients will be recruited from a trauma setting and may or may not be able to give legally effective consent.

Study Interventions:
There are no interventions performed in this study other than the normal operative fixation of the hip fracture. The LessRay Device is added to the regular C-Arm fluoroscopy machine.

Risk/Benefit Assessment:
There is no added risk to the patient. There is a theoretical benefit in less radiation exposure and decreased operative time.

Costs to the Subject:
There are no additional costs to the subjects as a result of participation in this study.

Data Analysis & Statistical Considerations:
Data will be presented using standard summary statistics including the sample size, mean, standard deviation, median, inter-quartile range and range for continuous variables and counts with percentages for categorical data.

Radiation exposure and operative time will be compared between the DIE and SOC groups using either the t-test, if normally distributed, or Wilcoxon rank-sum test otherwise. Power calculations assume that the radiation exposure data are approximately normally distributed; however, this will be tested formally using the Kolmogorov-Smirnov test before comparing groups.

Percentages will be compared using the chi-square test or Fisher's exact test (expected cell counts < 5). Analyses will be done using SAS version 9.4 or higher and a $p < 0.05$ will be considered statistically significant.

Data & Safety Monitoring:
Data monitoring will be conducted on a routine basis by the PI and study team as specified below. Since this technology does not involve any risk to the patient other than loss of confidentiality, we do not anticipate any safety issues.

This study represents minimal risk to subjects, and no adverse events are anticipated. Accordingly, safety monitoring will be conducted to the extent that it ensures privacy and confidentiality, as indicated below.

Privacy, Data Storage & Confidentiality:
Any data that is stored in electronic format will be housed in a secure server behind the Duke University Medical Center firewall. Confidentiality of subject data will be ensured by de-identification of subject data. During data collection, subject identifiers and relevant data elements (specified in Section 3) will be recorded. Then, study-specific identification numbers will be assigned to each subject. Prior to dissemination of any

information in this database beyond the DUMC's secure servers or firewall, all identifiers will be stripped from the database and data will only be referenced by the study-specific identification numbers. A master log, which links the study-specific identification number to the study subject, will be generated in Excel. The master log will be stored as stated above, and will be accessible only to study staff. The adequacy of the Research Data Security Plan will be evaluated and approved by the Orthopaedic CRU prior to protocol conduct. Any publications or presentations that result from this research will not identify any subjects individually, and will present data in aggregate form only.