Pilot Study of Effect of Real-Time Dosimetry on Surgeon Radiation Exposure During Operative Repair of Femur and Pelvis Fractures

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Purpose: Intraoperative use of fluoroscopy has increased in orthopaedic surgery. Real-time dosimetry during procedures has been associated with reductions in radiation exposure during fracture surgery. The purpose of this pilot randomized trial is to estimate a sample size required to test effectiveness of real-time dosimetry in reducing surgeon radiation exposure.

Methods: We conducted a prospective randomized controlled trial of adults undergoing operative treatment of fractures of the femoral shaft, proximal femur, acetabulum, and pelvis at a Level I trauma center. Participants in this study included attending orthopaedic surgeons, fellowship orthopaedic trauma surgeons, and resident orthopaedic surgeons. The unit of randomization was the patient, with all participants randomized to either the blind group (BG), where participants were blinded to exposure levels, or the aware group (AG), where participants had visual access to exposure levels.

Results: Of the 44 eligible operations, 22 were randomized to the BG and 22 to the AG. There were no differences in average age, body mass index (BMI), or OTA fracture class between the two treatment groups. Overall mean surgeon exposure in the AG was lower than the BG (mean 88.8 μSv, SD 96.5; and mean 134.7 μSv, SD 172.7, respectively); however, mean difference did not achieve statistical significance ($P = 0.28$). Proximal femur fractures had the highest mean surgeon radiation exposure for blind group and aware group (mean 157.4 μSv, SD 211.9; and mean 101.1 μSv, SD 128.1, respectively). Additionally, there was no significant difference between the study groups when mean surgeon exposure was adjusted for patient BMI, patient radiation exposure, number of fluoroscopic images, or fluoroscopy duration. In order to achieve a false discovery rate of 5% and power of 80%, 140 subjects would need to be randomized to each treatment group in order for the mean reduction in exposure found in the AG to reach statistical significance.

Conclusion: Although our data did not demonstrate the efficacy of real-time visualization, a 34% reduction in mean exposure endorses previously reported reductions associated with this modality. Further research with a larger sample size, that we are now able to estimate with these data, will allow us to determine the true impact of knowledge of exposure levels in real time on surgeon dosing during fluoroscopy-intensive fracture surgery.

See pages 49 - 106 for financial disclosure information.

Table 1. Mean surgeon radiation exposure by fracture location and treatment group				
Femur Fracture	**Mean Radiation Exposure (µSv) Blind Group (SD)**	**Mean Radiation Exposure (µSv) Aware Group (SD)**	**Mean Difference (µSv) Blind – Aware (95% CI)**	**P**
Femur	143.0 (182.6)	96.7 (111.2)	46.2 (-56.4 - 148.9)	0.37
Pelvis	88.2 (90.7)	67.7 (35.5)	14.4 (-191.7 - 220.5)	0.81
Total	134.7 (172.7)	88.8 (96.5)	45.9 (-39.3-131.0)	0.28

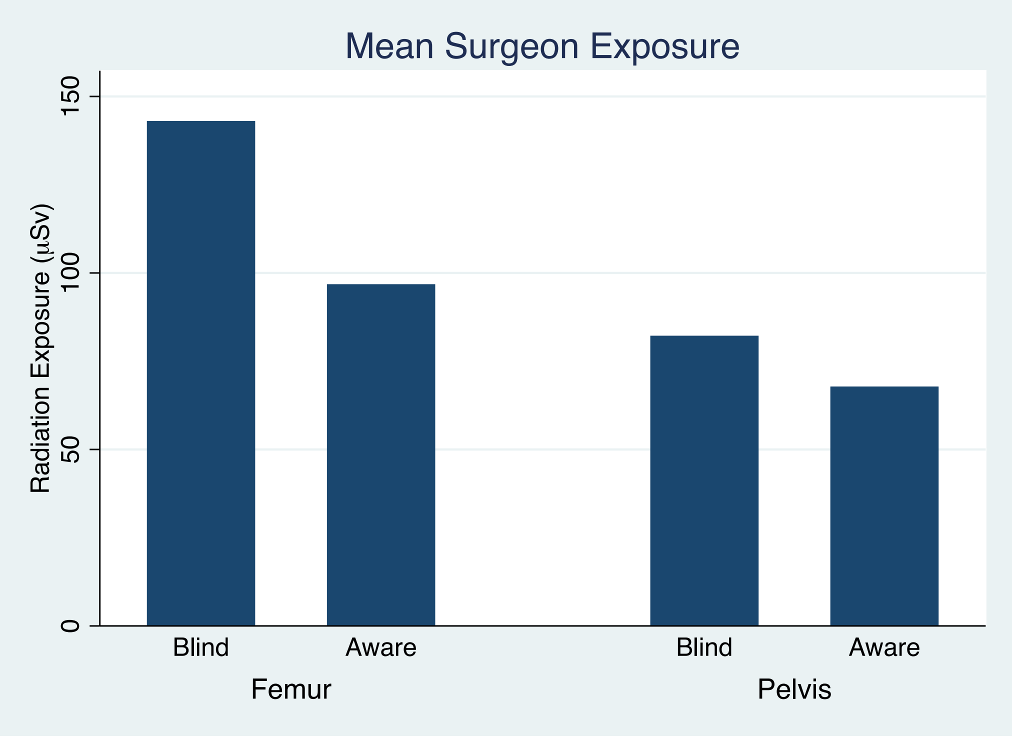

Figure 1. Mean surgeon radiation exposure for fracture location

POSTER ABSTRACTS

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.