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ORIGINAL ARTICLE

The effect of a new universal laser aiming device in C-arm fluoroscopy on the technician's accuracy

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Orthopedic surgeons are major users of C-arm fluoroscopic systems, and their use is becoming increasingly common in fracture reduction and internal fixation as well as in minimally invasive surgical techniques.^[1-3] Minimizing fluoroscopy time is one of the most effective and recommended ways to reduce radiation exposure to patients and staff during operations to eliminate possible side effects.^[4,5]

Users without much experience with fluoroscopic systems may require multiple images to be taken to achieve a well-aligned image. The use of additional apparatus, such as laser aiming devices (LADs), has the potential to reduce the total fluoroscopy time by helping to center the desired surgical area on the image with fewer shots.^[5,6] While there are several LADs available on the market, their brand- and model-specific compatibility and development limit their use among different systems. In addition, many institutions working with a tight budget may not have access to them due to their high cost.

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ABSTRACT

Objectives: This study aims to introduce a new low-cost universal laser aiming device (LAD) that can be used in existing C-arm fluoroscopy devices, independent of brand and model, and to determine whether this new universal LAD improves technician accuracy in locating the desired region at the midpoint of the fluoroscopic image.

Materials and methods: A low-priced universal LAD that is compatible with existing 12-inch C-arm fluoroscopy devices was designed. Eight radiology technicians with varied levels of experience in C-arm fluoroscopy participated in the study. A 12 mm cortical screw with a diameter of 3.5 mm was placed on proximal, diaphyseal, and distal points of femur, tibia, and humerus bones in the anteroposterior plane on L3 vertebrae and the left pubis arm in the pelvis bone model. Technicians were asked to align each screw in the image center 10 times from a distance of 30 cm in the anterolateral plane, first without the LAD and then with the LAD. The distance of the screw head to the center point was measured from the 3,520 images with the help of medical viewer software based on the X- and Y-axis.

Results: Each fluoroscopic image was divided into 48 equal parts and the length of a part was taken as one unit for distance measurements. The compliance between technicians without the LAD was 0.347 (95% confidence interval [CI]: 0.208-0.47, p=0.001) and with the LAD was 0.687 (95% CI: 0.621-0.741, p=0.001). The distance between the screw head and the center of the image without the LAD was 19.0±9.8 for technicians with more than 10 years of experience and 28.0 ± 12.9 for those with less than 10 years of experience. This difference was statistically significant (p=0.001). When the LAD was used, the difference between the less experienced (3.1±1.5) and more experienced (3.3±2.0) technicians was statistically reduced, along with the distance (p=0.033).

Conclusion: The use of the LAD with C-arm fluoroscopy appears to be successful in helping technicians capture the desired point in the center of the fluoroscopic image. The use of the LAD reduces the experience gap between technicians.

Keywords: C-arm fluoroscopy, laser aimer, radiation, radiology technicians.

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Laser aiming devices are one of the only existing tools that can help technicians reduce the number of shots, thus minimizing the total fluoroscopy time and the amount of radiation that the patient and operating room personnel are exposed to. In this study, we aimed to introduce a new low-cost universal LAD that can be used in existing C-arm fluoroscopy devices, independent of brand and model, and to determine whether this new universal LAD improves technician accuracy in locating the desired region at the midpoint of the fluoroscopic image.^[7]

MATERIALS AND METHODS

This study was conducted at Başkent University Adana Dr. Turgut Noyan Research and Application Center between July 2018 and December 2018. We designed and developed a universal LAD using light sources and electronic components that can be purchased almost anywhere in the world. Other simple parts such as holders and frames were manufactured in an ordinary machine shop. The total cost of the device was under US\$500. The study protocol was approved by the Başkent University School of Medicine Ethics Committee (application number KA18/265). The study was conducted in accordance with the principles of the Declaration of Helsinki.

In the LAD, three Class 3A line lasers (Class 3A laser with a power of 5 mW does not present a risk of burning to skin or materials) were placed at 90 degree intervals on a 12 inch metal ring that can fit tubes of

the most commonly used C-arm fluoroscopy devices in orthopedic surgery. The inner side of the ring was wrapped with a foam tape so that any changes in thickness due to coatings on the surface of the tube were tolerated. The planes created by two red lasers (632 nm) were intersected to form a crosshair pattern on the center axis of the tube. A green laser (532 nm) positioned at an angle of 90 degrees from one of three lasers was used to determine the distance of the tube from the surface. The rotation axes and positions of the lasers were adjusted using a specially designed holder. With proper alignment of the lasers, the center of the crosshair deviated only 0.5 mm from the center for the tube-to-surface distance range of 15 mm to 150 mm. A 3.7 V 3400 mAh rechargeable battery was used as a power source and provided at least seven hours of continuous use. Once placed in the fluoroscopy tube, the LAD was secured with a screw at the open end of the ring to prevent movement during operation (Figure 1).

C-arm technicians registered with the Turkish Registry of Radiologic Technologists participated in the study. The eight technicians had various levels of experience (average 8.5 years; range, 3.5 to 16 years). They were informed about the harmful effects of radiation, the As Low As Reasonably Achievable (ALARA) principle, and the work. The uses of lead aprons, thyroid shields, protective glasses, and personal dosimetry were required in the operating room. A calibrated OEC 9900 Elite C-arm (GE Healthcare, Salt Lake City, UT, USA) was used for

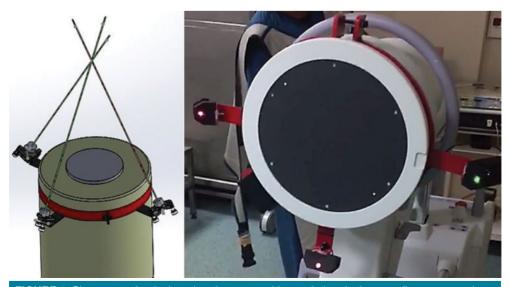


FIGURE 1. Placement of a designed and prototyped laser aiming device on a fluoroscopy tube.

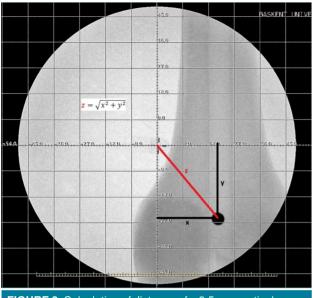


FIGURE 2. Calculation of distance of a 3.5 mm cortical screw head from center with Pythagorean theorem. Length of each 48 equal parts of fluoroscopic image was taken as one unit.

live fluoroscopic image acquisition, and all shootings were performed by using a remote control at a distance of 2 meters from the device.

Cortical screws with a width of 3.5 mm and length of 12 mm (DePuy Synthes, Massachusetts, USA) were placed in the proximal, diaphyseal, and distal of femur, tibia, and humerus model bones in a lumbar vertebrae (L3) model bone (Sawbone Europe AB, Malmö, Sweden) and left pubis of a pelvis model. The bones were arranged 20 cm apart on a radiolucent operating table (Maquet, Rastatt, Germany). The table was fixed to a height of 90 cm from the floor and the distance of the fluoroscope tube to the table was 30 cm. Thus, the Z-axis was kept constant and the technicians were given freedom of movement in the X- and Y-axes.

Technicians were asked to align the C-arm without the LAD so that each screw was positioned at the midpoint of the fluoroscopic image. The shots were taken in a mixed sequence and after each shot, the technicians moved 1 meter away from the table and brought the machine to its starting position. Each technician performed 10 repetitive shots at the anteroposterior and lateral position for each of the 11 screws in five different bone models. A total of 1,760 shots were obtained from eight individuals. They then repeated the same experiments with the LAD installed in the tube. A total of 3,520 (1,760 without the LAD, and 1,760 with the LAD) images were recorded and transferred to the computer using a General Electric Medical Viewer (General Electric, Salt Lake City, UT, USA). Each image was divided into 48 equal parts on the X- and Y-axes to create a grid. The image center was considered as the origin (X=0, Y=0), and the length of a part was taken as one unit. The distance of the screw to the origin $(\sqrt{x^2+y^2})$ was calculated from the X and Y coordinates of the screw head (Figure 2). When there was no screw in the image, the maximum distance available in the grid (48 units) was assigned.

Statistical analysis

The normality of distribution of continuous variables was tested using the Shapiro-Wilk test. The Mann-Whitney U test was used to compare two independent groups and the Wilcoxon test to compare two dependent measurements for

TABLE I Distance of screw heads from center for technicians					
	Without LAD (n=220)	With LAD (n=220)			
Technicians (experiences)	Mean±SD	Mean±SD	p		
T1 (16 year 1 month)	18.5±9.6	3.9±1.9	0.001*		
T2 (14 year 6 month)	19.3±8.6	2.5±1.2	0.001*		
T3 (13 year 4 month)	19.1±11.1	3.0±1.0	0.001*		
T4 (6 year 9 month)	30.7±12.8	3.6±2.1	0.001*		
T5 (5 year 6 month)	26.7±12.7	3.5±2.0	0.001*		
T6 (5 year 1 month)	26.6±13.2	3.6±1.8	0.001*		
T7 (4 year 5 month)	24.5±12.7	3.2±2.4	0.001*		
T8 (3 year 6 month)	27.3±12.0	2.7±1.4	0.001*		
LAD: Laser aiming device; * Significant at 0.05 level; Wilcoxon test.					

		TABLE II				
Dist	Distance of screw heads from center for different bone locations					
		Without LAD (n=160)	With LAD (n=160)			
Bone	Place	Mean±SD	Mean±SD	p		
	Proximal	27.1±12.8	2.6±2.7	0.001*		
Femur	Diaphysis	24.5±11.9	2.5±1.5	0.001*		
	Distal	27.2±12.7	2.4±1.6	0.001*		
	Proximal	24.4±14.6	2.5±1.4	0.001*		
Tibia	Diaphysis	27.1±12.5	2.5±1.4	0.001*		
	Distal	25.4±12.7	3.8±1.8	0.001*		
	Proximal	25.8±13.1	3.9±1.3	0.001*		
Humerus	Diaphysis	24.1±12.0	4.0±1.6	0.001*		
	Distal	23.4±9.9	4.5±1.8	0.001*		
Pelvis		21.7±11.6	3.9±1.7	0.001*		
Vertebra		20.1±12.7	3.2±1.3	0.001*		
LAD: Laser aiming device; * Significant at 0.05 level; Wilcoxon test.						

TABLE III					
Distance of screw heads from center for imaging directions					
	Without LAD (n=880)	With LAD (n=880)			
Side	Mean±SD	Mean±SD	p		
Anteroposterior	25.2±12.6	3.0±1.7	0.001*		
Lateral	24.0±12.6	3.5±1.9	0.001*		
LAD: Laser aiming device; * Significant at 0.05 level; Wilcoxon test.					

non-normal data. Mean \pm standard deviations were given as descriptive statistics. Statistical analysis was performed using the IBM SPSS for Windows version 24.0 software (IBM Corp., Armonk, NY, USA) and a p value of less than 0.05 was accepted as statistically significant.

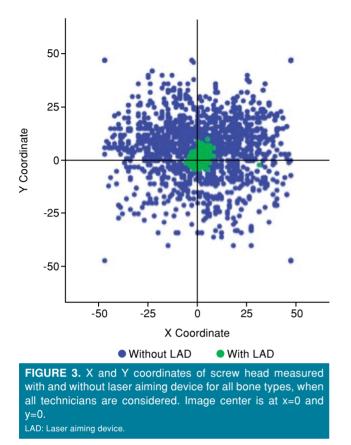
RESULTS

Five of the eight radiology technicians involved in the study had less than 10 years of experience and three had more than 10 years of practice. The average experience was 8.64 years (range, 3.5 to 16.08 years). The use of LAD was successful in imaging the midpoint of the screw for all radiology technicians (p=0.001) (Table I). The LAD was effective in centering the screw regardless of bone type (p=0.001) and imaging direction (p=0.001) (Tables II, III). X and Y coordinates of the screws head were measured with and without the LAD for all bone types, when all technicians are considered (Figure 3). The compliance between technicians without the LAD was 0.347 (95% confidence interval [CI]: 0.208-0.47, p=0.001) and with the LAD was 0.687 (95% CI: 0.621-0.741, p=0.001). Without employing the LAD, the distance

between the screw head and the center of the image for technicians with more than 10 years of experience was 19.0 ± 9.8 and for those with less than 10 years of experience was 28.0 ± 12.9 . This difference was statistically significant (p=0.001). When the LAD was used, the difference between the less experienced (3.1 ± 1.5) and more experienced (3.3 ± 2.0) technicians was statistically reduced, along with the distance (p=0.033). The inexperienced technicians had better aiming results with LAD than the experienced ones without using LAD.

DISCUSSION

The use of C-arm fluoroscope in orthopedic surgery contributes to shortened surgical time and decreased morbidity. During fluoroscopic imaging, the operating room personnel and the patient are exposed to ionizing radiation. Studies have shown that the cumulative radiation dose to which surgeons are exposed is below world standards.^[8,9] However, the consequences of long-term exposure to low-dose ionizing radiation remain unclear.^[4,5] Furthermore, surgeons in training are exposed to four times more radiation than senior surgeons and they often do not have enough knowledge



about the negative effects of radiation and protection methods.^[10-12] This exposure may lead to potential risk of thyroid cancer, hematological malignancies, eve damage, and skin/bone tumors. Personal protection equipment decreases an individual's exposure to radiation. For instance, the use of lead glasses (0.75 mm lead-equivalent) and thyroid shields reduces radiation exposure to the surgeon's eye by 90% and the thyroid by at least 85%.^[13,14] Moreover, wearing a lead apron (0.25 mm thickness) attenuates 90% of radiation.^[8] Protective accessories are heavy due to lead content; therefore, they may cause serious problems for staff in long-term surgery. There is a significant reduction in radiation exposure, particularly at a distance of 91.4 cm from fluoroscopic devices, but this is not always possible during surgery.^[15] The best method to protect the patient and staff is to reduce the number of unnecessary shots taken during the procedure.

C-arm fluoroscopy, which was previously used only in intramedullary nailing operations, has begun to be employed in orthopedic procedures in parallel with developments in minimally invasive techniques. In a study using an intramedullary nail distal locking model, Williams et al.^[16] found that the number of shots taken is reduced significantly when using C-arm as the primary surgeon and radiology technicians speak the same terminology in the operating room. Conn and Hallett^[6] demonstrated that a simple laser pointer in a fluoroscope provides a 50% reduction in screening time in patients undergoing surgery for hip fracture. In their study, the best location for imaging was marked with a pen, and the number of shots was reduced by matching the point with the developed laser. In our study, technicians were able to see the imaging region clearly. However, during surgery, they may not see the area at all times and shoot as directed. Using both the LAD and physically marking the region of interest would provide more accurate shots.

Shuler et al.^[17] suggested that the experience of the radiologist does not cause a statistically significant difference in the centering of the desired point. Our study showed that, with or without the LAD, experienced technicians were able to bring the screw closer to the center than inexperienced ones. However, the difference was significantly reduced when the LAD was employed. Thus, we believe that the LAD would make a positive impact on unnecessary shooting and exposure time when the possibility of working with experienced technicians is less likely during off-hours and over-night surgeries. The same study also stated that while the use of a laser marker does not cause a difference in the visualization of the hip joint in obese cadavers, it decreases total fluoroscopy time by 29% at the knee joint and 39% at the ankle. In our study, the LAD achieved similar success rates in all bone models. We believe that this may be related to the ability of the technician to see the area in which the image is taken.

In a randomized prospective clinical study, Harris et al.^[18] observed no significant reduction in the number of shots with the use of a laser marker during fluoroscopy. In the same study, both the number of exposures and the exposure time were increased during wrist examination when the aiming guide was used. They attributed this to bias during patient selection and that surgeons may have disregarded randomization protocol and not used the device for simple cases. In addition, this was explained by the surgeon's desire to center the laser beam on the body part to gain a perfectly aligned image.

Our LAD, unlike the existing devices available in the market, can be attached to all C-arm fluoroscopes with a 12-inch cylindrical tube without interfering with the normal functioning of the unit. It is simple and inexpensive. The additional third line laser in the device allows the images to be taken from the same height at the same magnification when the C-arm needs to be moved during the operation. In this study, the success of our LAD may be attributed to the ability of radiology technicians to see the imaging field with their own eyes. However, this may not be always possible during operations, particularly in minimally invasive surgery. In addition, it is sometimes sufficient for the surgeon to see the desired region on the screen without perfect image alignment. We believe that the LAD would be more successful in repetitive shooting of the same points. For this purpose, placing a physical mark that the technicians can see in the imaging region can significantly contribute to obtaining the same image.

This study was performed only on bone models. Systematic clinical studies with patients or cadavers are needed to demonstrate the true effect of LAD on the number of shots and total fluoroscopy time.

In conclusion, the LAD developed for this study has been successful in helping technicians to place the desired point in the center of the fluoroscopic image, independent of the bone model, viewing point, and the technician who takes the image. In addition, the LAD has reduced the experience gap between radiology technicians. We believe that further multicentric studies should be performed on the clinical effect of the LAD.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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