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Original Article

Reduced radiation exposure during O-arm navigation in degenerative lumbar spine surgery

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ABSTRACT

Objectives: We aimed to compare the amount of radiation exposure that was produced during computed tomography (CT)-control versus O-arm control of pedicle screw placement during degenerative lumbar spine surgery.

Patients and methods: Between November 2013 and August 2021, 358 patients (O-arm + neuronavigation) group (154 males, 204 females; mean age: 61.4±12.3 years; range, 40 to 84 years) who underwent spinal surgery were included in the study. All patients in this group underwent surgery with intraoperative O-arm CT and neuronavigation assistance. The control (fluroscopy + CT-control) group consisted of 124 patients (50 males, 74 females; mean age: 63.9±11.9 years; range, 49 to 72 years) who underwent lumbar spinal stabilization surgery for adult degenerative lumbar disease under fluoroscopy and postoperative CT-control. All data were collected retrospectively. Kolmogorov-Smirnov test was employed to test whether radiation dose values exerted an equal distribution. Following the detection that these values did not distribute equally, a Mann-Whitney test was used to test the significance.

Results: Patients operated with intraoperative O-arm CT and neuronavigation assistance did not require any revision surgery. Median radiation exposure per patient was calculated as 1108.4 and 838 mGycm for control (CT-control) and study (O-arm) groups, respectively. Mann-Whitney test revealed a significant difference in reduced radiation exposure with O-arm (z: −6.056, asymptotic significance (2-tailed) $p<0.0001$). We detected reduced levels with O-arm surgery in terms of cumulative radiation exposure.

Conclusion: We advocate the routine use of intraoperative O-arm imaging and neuronavigation particularly in degenerative spinal surgery due to both reduced radiation exposure and providing more precise screw placement.

Keywords: Imaging in surgery, O-arm, radiation dose, spine surgery.

Lumbar disc degenerative disease is a condition in which wear and tear on a vertebral disc causes pain in low back region. It is a chronic degenerative process of the lumbar spine that involves the intervertebral discs and vertebral bodies of the low back. As the water content in discs decreases, they start to shrink, and bone spurs frequently form as osteoarthritis progresses. Although symptoms can vary, most lumbar degenerative disc disease patients suffer from low-grade, yet continuous back pain that may intensify for a couple of days or more. In the surgical treatment of degenerative lumbar spine disease, the O-arm™ (Breakaway Imaging, LLC, Littleton, MA, USA) 3-dimensional (3D) scan enables increased imaging data, evaluation of the position of pedicle screws, and kyphoplasty procedures, etc., in comparison to traditional fluoroscopy or radiographs alone. The O-arm™ is a cone-beam imaging mobile system that merges a computed tomography (CT) scanner in 3D scan acquisition mode and conventional C-arm fluoroscope in 2-dimensional (2D) scan acquisition mode. By employing a gantry that can be closed or opened and a flat panel detector, the O-arm™ imaging can function as either a CT system obtaining 3D volumetric imaging data or as a 2D fluoroscopy device.[1]

Several investigations report the utility of CT-guided O-arm placement of lateral

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mass/pedicle screws with documented several pros and a few cons for the employment of the O-arm in spine surgery.[2] As cons, increased radiation exposure with O-arm is mentioned in certain studies, yet results are conflicting.[2,3] Moreover, O-arm is reported to possess several advantages in other orthopedic surgical operations which may be also relevant for spine surgery; for instance, in percutaneous placement of pedicle screws into neurologically-intact thoracolumbar fractures, O-arm increases accuracy and decreases functional and serious perforations in comparison to conventional fluoroscopy. Moreover, it minimizes violations of the facet joints and hinders degeneration of adjacent segments.[4] The employment of pedicle screws necessitates precise placement to hinder damage to the large vessels in front of the spine and the spinal cord; hence, to ensure the proper placement of pedicle screws, radiological imaging is necessary. Some surgeons prefer freehand techniques relying solely on anatomical landmarks. The number of misplaced screws in degenerative adult lumbar spines using freehand techniques is significantly greater than the number of misplaced screws placed following a 3D scan with subsequent navigation.[5] A considerable amount of pedicle screws are misplaced when navigation is not employed.

In an adult patient population, Balling[6] performed a single-center prospective cohort study to define radiation dose and additional time requirements in O-arm-navigated pedicle screw thoracolumbosacral spine instrumentations. The investigator compared O-arm with non-navigated spinal procedures employing a single C-arm or postoperative CT scan for checking pedicle screw positions. The researcher evaluated 306 posterior instrumentations in vertebral levels T10-S1 using O-arm for insertion of pedicle screws. Following sufficient procedural experience, navigated operations can be made with an additional time requirement of 13.0 minutes compared to non-navigated spinal procedures, and with a total dose-length product (DLP) slightly below that of a diagnostic lumbar CT scan. In an elderly patient population, Ricciardi et al.[7] compared the radiation exposure with the conventional C-arm versus O-arm for screwing the odontoid fractures and demonstrated significantly lesser exposure to radiation with O-arm. Petersen et al.[5] reported that for the first 30 children for whom the screws were positioned under fluoroscopic navigation and then position-checked with volumetric imaging demonstrated that about 8% of a total of 424 screws were misplaced (regarding the Ohlin classification) and 1% of screws had to be positioned again or removed.

In our view, imaging of the patient shall be planned such that a revision would be made peroperatively without the need for a second surgery if required. In our case series, we did not encounter any occasion where we had to reposition or remove the screws during the placement of a total of 2,706 screws. For many years, fluoroscopy was the only available intraoperative imaging modality. Intraoperative cone-beam flat-detector X-ray applications advanced spinal surgical approaches and are fastly and globally being implemented. These modalities provide both 3D and 2D fluoroscopic images and significantly improve surgical outcomes. Using such a system, the registration interval is swift and navigation can be implemented in four to six vertebrae before a new 3D scan is needed. The key issue of the image guidance during insertion of pedicle screws is the ability to precisely determine the cortex relative to the pedicle screw.

Similar to any other imaging technique employing ionizing radiation, medical staff, and patients exposed during a procedure are faced with a risk of radiation-induced injuries including germinal cell mutations and malignant disorders. Hence, defining, controlling, and optimizing exposure to radiation is crucial for alleviating health hazards.[8] Since the O-arm's introduction first in 2006, questions have arisen regarding the risks to patients and operators from scattered radiation, especially during its acquisition mode in 3D. To evaluate these concerns, Zhang et al.[1] analyzed scattered radiation from an O-arm™ and compared these results to those obtained from a Siemens Sensation 64-slice scanner. They also assessed the image quality of the O-arm™ system using a Catphan phantom. Their findings demonstrated that under the same radiographic techniques (mAs, kVp, etc.) and with identical scan length, the O-arm™ in 3D-scan acquisition mode delivers about half the radiation dose of a 64-slice CT scanner. As mentioned, there exist few yet conflicting studies on whether O-arm poses an increased or decreased risk of radiation exposure. For instance, literature exists on the superiority of employing O-arm regarding exposure to radiation, with some citing prominent radiation exposure to the patient while others declaring minimal surgeons' exposure.[3] Hence, in this study, we aimed to compare the radiation doses of screw positioning control with perioperative O-arm versus perioperative fluoroscopy plus postoperative CT imaging in adult patients with degenerative lumbar spine disease.

PATIENTS AND METHODS

Study design and population

Demographical characteristics of the patients are demonstrated in Table 1. In this comparative, retrospective, nonrandomized study, 358 consecutive patients (154 males, 204 females; mean age: 61.4±12.3 years; range, 40 to 84 years) who underwent O-arm (StealthStation S7, Medtronic, Minneapolis, MN, USA) navigation-guided lumbar stabilization surgery for adult degenerative lumbar disease between November 2013 and August 2021 in Elmacı Neurosurgery Clinic were included in this study. Trauma, tumor, and scoliosis patients and the patients who were operated on over 5 segments were excluded. The reason for excluding patients operated over 5 segments is that the precise O-arm gantry capacity is limited to 5 levels. The patients who were operated for 2 to 5 segments were included. The control (fluroscopy + CT-control) group consisted of 124 patients (50 males, 74 females; mean age: 63.9±11.9 years; range, 49 to 72 years) who underwent lumbar spinal stabilization surgery for adult degenerative lumbar disease under fluoroscopy and postoperative CT-control. In the study (O-arm + neuronavigation) group, O-arm images were acquisitioned before and after screw placement. The irradiation dose documentation of radiation hazard, which was obligatory and collected automatically, was obtained from each device just after the operation. The radiation reports of the routine operations were reviewed; hence, patient consent, and Ethics Committee/Institutional Review Board approval were not required. The study was conducted in accordance with the principles of the Declaration of Helsinki. A written informed consent was obtained from each patient.

Surgical procedure and radiation exposure

All the surgical procedures were performed by the same surgical team. After general anesthesia induction, the patients were placed prone on a radiolucent spine operational table. In the control group, under fluoroscopy guidance,

Table 1. Demographical characteristics of patients

	O-arm group (n=358)			CT group (n=124)		
	n	Mean±SD	Median	n	Mean±SD	Median
Age (year)			61.4			63.9
Sex						
Male	154			50		
Female	204			74		
Region: Lumbar						
2 Segments	37			12		
3 Segments	65			32		
4 Segments	132			42		
5 Segments	112			38		
Average number of stabilized segments			3.9			-
Total number of screws	2706			-		
Radiation total dosage (mGycm)		687±353	838		863±507	1108.4
Prescrewing	440			440		
Postscrewing	450			810		

CT: Computed tomography; SD: Standard deviation.

a serial dilator was positioned and docked on the facet via a skin incision in the paramedian direction, and the tubular retractor was put in. After viewing the facet joints, pedicle screws were inserted under fluoroscopy guidance, and anteroposterior and lateral imaging was obtained during the placement of screws. Following the operation, the positioning of the screws was controlled with lumbar CT. In the study group, the same surgical procedure was performed but the screws were placed under the guidance of O-arm with navigation system. In both the control and the study groups, under microscopical guidance, total laminectomy, facetectomy, and ligamentum flavum removal were made with Kerrison rongeurs and a high-speed drill. All roots were observed to be decompressioned in the surgical area. Rods were placed to ensure lumbar alignment. Thereafter, local autologous bone grafts, obtained during decompression were placed into the transverse process. In the control group, subsequent tapping, insertion of screws, and rod setups were performed under image confirmation using lateral fluoroscopy. In the control group, the entry point and trajectory were determined in real-time, as affirmed by the anterior-posterior (AP) fluoroscopy, while the needle depth was affirmed by the lateral fluoroscopy. In the study group, first, an O-arm CT was employed and following this surgical approach, the neuronavigation setup was finished. Then the screws were placed under the navigation. During the interval of fluoroscopy, the staff and operators stayed behind a lead panel, and during the O-arm CT, the staff and operators left the surgical theater during image acquisition. After affirming the quality of the images, the total procedure of pedicle screw placement was made under navigation. After the insertion of each pedicle screw, fluoroscopic images were not needed for affirming the positions of screws and the proper assembly of the rod and screw construct in O-arm-guided surgery. In the study group, we controlled all of the screw placement using O-arm CT.

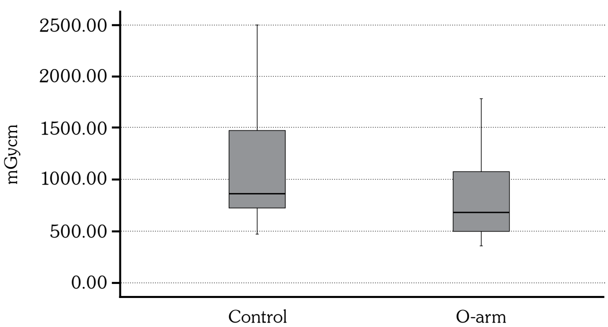

Figure 1. Exposed levels of radiation (mGycm) in control (fluoroscopy + CT) versus O-arm groups.
CT: Computed tomography.

Quantification and comparison of radiation exposure

During this investigation, intraoperative acquisition of images was obtained by the O-arm coupled with the StealthStation navigation system (Medtronic, Minneapolis, MN, USA) or by OEC Fluorostar 7900 digital mobile C-arm (GE Healthcare, Chicago, IL, USA). Both types of equipment included a built-in dosimeter that was regularly maintained and calibrated. The DLP of the O-arm and the dose area product (DAP) of the C-arm were obtained from each device. The DLP and DAP values were further converted to determine the effective dose in cGy values. The effective doses were calculated and compared between the study and control groups.

Statistical analysis

First, the Kolmogorov-Smirnov test was used to test whether radiation dose values exerted an equal distribution. Following the detection that these values did not distribute equally, a Mann-Whitney test was employed to analyze the significance of the difference between groups.

RESULTS

In the study group, the surgery was 2 levels in 37 patients, 3 levels in 77 patients, 4 levels in 132 patients, and 5 levels in 112 patients. In the control group, 12 patients had 1-level, 32 had 2-level, 42 had 3-level, and 38 had 4-level interbody fusion. Radiation dosage levels in both groups did not exert equal distributions. This is likely due to the different body sizes of the investigated patients. In the control group, the mean level of total radiation exposure is 1108.4 mGycm with a mean of 863±507 mGycm. In the control group, the median level of total radiation exposure is 838 mGycm with a mean of 687±353 mGycm. According to the mean radiation exposure levels, a 32.3% decrease in irradiation occurred in the O-arm group in comparison to the conventional CT control. The difference between these groups was found to be significant and the Mann-Whitney test revealed that O-arm poses a lower risk of radiation exposure (z:−6.056, asymptotic significance (2-tailed) $p<0.0001$), as shown in Figure 1. We did not calculate radiation dosage per screw level as the image acquisitions both in O-arm and conventional CT imaging modalities are performed independently of the screwing levels.

DISCUSSION

We believe that controlling screw position and malposition with postoperative CT is necessary for patients undergoing spine surgery and we perform this in our daily practice. Surgeons prefer conservative approaches to perform the operation with fluoroscopy and make their control with postoperative X-ray. In our clinical practice, we encounter pain problems that do not cause neurological deficits but are difficult to control. Screw malposition could be seen during CT imaging. That's why we've been getting post-screw CT imaging for a long time. It is necessary to analyze the amount of radiation exposure in different imaging modalities due to the carcinogenic risks of radiation. A 10 mSv radiation dose poses a 0.1% risk of cancer development, and the pediatric population is at increased risk. The harmful biological effects heighten with the applied dose of radiation and are again more prominent in children. A dose-response association between exposure to CT and enhanced risk of malignancy is demonstrated in a population-based study. Those who were examined with CT scans had a 24% higher risk of developing a malignancy in comparison to the unexposed cohort, and the incidence ratio was even higher at younger ages of exposure and enhanced by 0.16 for each additional examination with CT.[9]

In this study, we compared our previous surgical experience using fluoroscopy+CT with the O-arm and neuronavigation-guided surgeries we have performed for the last nine years. O-arm provides real-time 3D spine images during surgery. Simultaneously, with the navigation set-up, screws can be placed in the correct position even in spondylolisthesis (Grade-3) and advanced degenerative cases. However, screw positions are confirmed with the control O-arm following screw insertion. In our practice, no screw malposition occurred with the O-arm and neuronavigation system. During the O-arm, the surgical team is protected from radiation by waiting outside the operating room during the shooting. The surgeon's comfort is high as he does not wear lead clothes. Using fluoroscopy during surgery provides a two-dimensional image. Sometimes, screws protruding from the median wall of the peduncle cannot be distinguished by fluoroscopy. While it is easy to understand lateral and advanced medial malpositions with fluoroscopy, it is difficult to understand lateral recess malpositions. In our study, repeat surgery was required in three patients (4 screws in total) due to malposition in the group for whom the screw placement was controlled with conventional CT. Patients who required re-surgery did not have neurologic deficits but had radicular pain. While the total mean dose was 687±353 mGycm with O-arm before and after the screw, the total dose was 863±507 mGycm in fluoroscopy+postoperative CT. The total radiation exposure was significantly less in the O-arm group. No postoperative revision was required in the O-arm group. In the beginning, the surgical time of the O-arm-guided operations was generally longer due to a learning curve that declined thereafter. Besides combining the technical features of conventional fluoroscope and cone beam CT scan, the O-arm system is also able to memorize the surgical trajectories in the differing spatial localization, which can be fastly and automatically shifted during the operational procedure.[7] O-arm has more accuracy and resolution than conventional navigation and C-arm and is particularly beneficial for screw insertion during spine surgery.[9] O-arm images obtained intraoperatively can precisely detect pedicle screw violations in the lumbosacral and thoracic spine. O-arm is helpful for exact pedicle screw placement in scoliosis patients and employment of O-arm lowers the screw malpositioning rates from 5-15 to 1-3%.

The dose difference between the CT scanner and the O-arm^{TM} in 3D scan mode was attributed to a couple of factors. For instance, the difference in dose may be due to the employment of different fan-beam angles. The O-arm's fan beam is about 20 degrees, while the CT's fan beam angle is about 45 degrees. As mentioned, in the study of Zhang et al.,[1] it was revealed that at the same radiation dose, the high contrast resolution of the O-armTM is similar to that of the CT system. Nonetheless, as we do not employ the same radiation dosage in the O-arm, the resolution quality is less than in conventional CT. However, the O-arm's image resolution is sufficient enough for precise surgical planning. In our study, high dose O-arm was used since the patients suffered from degenerative spine disease. Even considering this fact, the radiation dose exposure was found to be significantly lower in the O-arm group in comparison to the conventional CT-control despite two O-arm CTs being performed before and after screw placement. Zhang et al.[1] also concluded that the O-arm is more advantageous than a CT scanner due to its reduced patient dose (under the same setups), acceptable image qualities, and wide coverage. Kobayashi et al.[9] reported that O-arm causes more radiation exposure than C-arm, but less than conventional CT.

As briefly cited above, Ricciardi et al.[7] studied the feasibility of employing the O-arm for screwing the odontoid and compared the radiation exposure to the conventional C-arm. In their study, patients with odontoid type 2 fractures underwent surgery employing either O-arm or C-arm-assisted procedures. They evaluated the duration of surgery, acquisition numbers, global exposure to X-rays for the patients and staff, and accuracy of screw placement. There were no differences in patients' demographical features and duration of surgery. They found that the acquisition numbers, intraoperative global X-ray dose, for the patients and staff, was lower in O-arm-assisted procedures while all the screws were well positioned. The author concluded that, at the end of the surgical procedure, O-arm can be employed for checking the position of instrumentation via its cone beam CT with 3D reconstructions, thus hindering the requirement for postoperative CT scan, longer stay in hospital, and even reinterventions. Additionally, the standard CT scan poses a higher dose of radiation to the patients than the cone beam CT-scan. Hence, the global patients' exposure to X-rays was found to be lower when employing the O-arm.

Araiza et al.[3] compared the efficacy, radiation exposure to patient and surgeon, and accuracy of O-arm versus C-arm with navigation in the insertion of iliosacral and transiliac-transsacral screws by an orthopedist fellow in early surgical practice. They studied on 12 frozen cadavers. They reviewed preoperative CT-scans to evaluate for secure corridors in the S1 and S2 segments. In dysmorphic pelvises, they assigned iliosacral screws to the S1 segment and randomized screws to laterality and modality and recorded radiation exposure to the surgeon and cadaver and time of surgical exposure. Screw placement with C-arm exposed the surgeon to a higher level of radiation while the O-arm exposed the cadaver to a higher level of radiation. The authors concluded that a significant increase in surgeons' exposure to radiation employing C-arm may be clinically significant throughout a career and thus, the decision between employing these two modalities will differ based on hospital resources and on surgeons' preference. Using the O-arm, the minimal surgeon's radiation exposure and an increased exposure to the patient were attributed largely to the distance of the surgeon from the O-arm gantry and the surgeons' protection behind the X-ray mobile barrier during the operation and immediately after the postoperative CT-scan. In our study, the surgeon was not exposed to radiation during O-arm as the surgical team stayed outside the surgical theater during image acquisition. Costa et al.[10] collected radiation exposure data in 107 patients who were treated with spinal surgery employing the O-arm system. Electronic dosimeters measured and collected the doses received by the staff and surgeon. The authors reported that the O-arm system exposed patients to increased radiation levels than the conditional fluoroscopy, yet considering the significant advantages of this modality, this adjunctive dose can be regarded as acceptable.

Radiation exposure to the patient would have decreased by foregoing a confirmatory spin. C-arm afforded increased radiation exposure to the surgeon but decreased exposure to the patient when compared with O-arm. This can be attributed to the surgeon's close proximity to the image intensifier throughout the case and the requirement of multiple fluoroscopic images intraoperatively. The surgeon held the guide pin and pin driver to make immediate adjustments after each fluoroscopic image as is common practice for surgeons who perform this procedure using C-arm. Increasing the distance from the surgeon to the C-arm has a logarithmic decrease in radiation up to 2 meters; however, removing the pin driver from the field for each image may decrease the accuracy of correction after each image.[3] Members of the surgical staff staying outside the surgical theater received 0 μSv,[10] which was also the case in our surgical practice. There are several techniques used to minimize radiation exposure.[3] As we have mentioned, certain surgical ecoles finish the operations with C-arm and make their postoperative control with direct X-rays. However, to our review, it is necessary to perform postoperative CT-controls with C-arm; and our study design was planned accordingly. It is evident that the C-arm poses a lower radiation dose than the O-arm. On the other hand, when postoperative CT control is performed, the patient's radiation exposure in O-arm-guided surgeries is either equal or lower.

There are some limitations to our study. In this study, there was no significant obstacle to the use of the O-arm system in the patient group. However, patients with multiple trauma, patients who are difficult to position and/or have external fixators, patients who do not fit into the O-arm gantry width, and surgical tables that are not X-ray-proof are restrictive in the use of this system.

In conclusion, in our current study analyzing a high number of patients, we have revealed that patients were exposed to notably lower levels of radiation when screw placement was controlled with perioperative O-arm in comparison to conventional postoperative CT imaging. Considering the mean level of radiation exposure, the O-arm poses about 270 mGycm lesser radiation dose which corresponds to a 32.3% decrease in comparison to the conventional CT control. This is not a negligible difference. As patients exposed to imaging-related radiation have an increased risk of radiation-induced germinal cell mutations and cancer; our findings are of clinical importance. Our study was conducted in an adult patient population, yet we believe that these results may also be extrapolated to pediatric patients. As outlined, just a 10 mSv radiation dose poses a 0.1% risk of cancer development with increased risk to the pediatric population. Since children are more prone to radiation hazards (due to higher rates of cellular proliferation and vulnerability to DNA damage), and due to the likely necessity of consequent and frequent radiological imaging, these results are even more important for the spine surgery of the pediatric population. Such concerns are also highly relevant for the adult patient population. Those who underwent CT scans had a 24% elevated risk of cancer development in comparison to the unexposed cohort which increased by 0.16 for each additional examination with CT. Therefore, it is important to demonstrate that O-arm-controlling of screw malposition poses a reduced risk of radiation exposure. Due to these facts, we strongly advocate to employ O-arm imaging to control screw placement in spine stabilization surgery.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, design, writing the article, analysis: R.S.; Control/supervision: Ö.B.; Data collection, literature review: E.B.K.Ö.; Critical review: İ.E.

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