Radiation exposure in spine surgery using an image-guided system based on intraoperative cone-beam computed tomography: analysis of 107 consecutive cases

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OBJECTIVE The O-arm system in spine surgery allows greater accuracy, lower rate of screw misplacement, and reduced surgical time. Some concerns have been postulated regarding the radiation doses to patients and surgeons. To the best of the authors' knowledge, most of the studies in the literature were performed with the use of phantoms. The authors present data regarding radiation exposure of the surgeon and operating room (OR) staff in a consecutive series of patients undergoing spine surgery.

METHODS Radiation exposure data were collected in a series of 107 patients who underwent spine surgery using the O-arm system. The doses received by the surgeon and the staff were collected using electronic dosimeters.

RESULTS All patients underwent 1–3 scans. The mean radiation dose to the patients was 5.15 mSv (range 1.48–7.64 mSv). The mean dose registered for the scan operator was 0.005 μ Sv (range 0.00–0.03 μ Sv) while the other members of the surgical team positioned outside the OR received 0 μ Sv.

CONCLUSIONS The O-arm system exposes patients to a higher radiation dose than standard fluoroscopy. However, considering the clear advantages of this system, this adjunctive dose can be considered acceptable. Moreover, the effective dose to the patient can be reduced using collimation or minimizing the parameters of the O-arm system used in this paper. The exposure to operators is essentially negligible when radioprotective garments and protocols are adopted as recommended by the International Commission on Radiological Protection.

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KEY WORDS O-arm system; navigation; radiation dose; spine surgery; dosimetry; technique

X-RAY fluoroscopy imaging systems were introduced widely to the operating room (OR) in the 1980s and since then the evolution of these devices has advanced continuously. In more recent years, the development of new intraoperative devices able to perform 3D imaging has become the focus of attention, especially in spine surgery. In fact, the advent of a cone beam–based imaging system (O-arm system, Medtronic, Inc.), especially when associated with an image-guided system (IGS), was seen as a revolution,¹⁷ and excellent results were reported,^{3,9,10,13,21,22,27} with accuracy in screw placement up to 98.5%.⁴ However, despite these encouraging results there is still debate regarding where and when this technology should be used. Specifically, concern exists re-

garding the overall cost of these technologies, the learning curve, and especially the radiation exposure. Because radiation exposure is a crucial aspect in spine surgery, one of the major criticisms regarding the O-arm system concerns the effective radiation dose. Furthermore, if this device leads to solving the need for real-time detailed intraoperative imaging, which can be considered similar to the images of a CT scan for bone but not for soft tissue, we must consider that a direct relationship exists between the number of scans and the possibility of developing cancer.²⁴ Therefore, as better accuracy of results is expected when using the O-arm, it is important to understand the cost in terms of radiation dosages for the patients, surgeons, and OR staff.

ABBREVIATIONS BMI = body mass index; CTDI = CT dose index; DLP = dose length product; ICRP = International Commission on Radiological Protection; IGS = image-guided system; OR = operating room.

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To date, there have been only a few reports in the literature with an analysis of radiation dose of the O-arm system: several were performed on phantoms or cadavers^{1,14,21,29} or during a balloon kyphoplasty procedure,²³ while only 2 studies analyzed radiation doses during an instrumented spinal procedure.^{5,25} For this reason, the authors are presenting data regarding the radiation exposure of the patients, surgeon, and operative team in a consecutive series of patients undergoing instrumented spine surgery.

Methods

The authors prospectively collected the data of all patients treated for spinal instrumentation with the aid of an IGS from February 2014 to April 2014. In our department, all the instrumented procedures are performed with a navigation system based on intraoperative acquisition using the O-arm system. At the end of each surgical procedure the data regarding surgery (type of surgery, levels treated, surgical times) as well as the radiation dose data were collected on a specific form.

All surgical procedures were performed with spinal navigation using a StealthStation S7 (Medtronic) with Synergy Spine software and the O-arm system. The O-arm provided a standard protocol for cervical, thoracic, and lumbar spine dose, which can be changed case by case according to necessity. In particular, it is possible to work directly modifying the parameters (for example, peak kilovoltage [kVp] and milliamperes [mA]) or using a manual collimation protocol that allows one to perform adjustment of the collimator shutters. Doses to the patients were extracted directly from the data provided by the O-arm system and comprise fluoroscopy time, kVp, mA/sec, dose area product (expressed as mGy-cm²), CT dose index (CTDI, expressed in mGy), and dose length product (DLP, expressed in computed mGy-cm). These data were considered reliable according to the results of the dosimetry report for the O-arm system (version June 2013, provided directly by the manufacturer) and by the control conducted by the health physicist of our institute annually, showing a noncorrespondence of less than 10% between the dosimetry report of the O-arm system and the data measured on a proper phantom.

The doses referring to the surgeon and the operative staff of each surgical procedure were collected using an electronic dosimeter (ThermoScientific EPD Mk2.3) attached at breast level. The surgeon performing the imaging acquisition was protected behind a 2-mm-thick mobile lead wall placed at 2.5 meters from the gantry of the O-arm, always in the same position. The rest of the operative team (second surgeon, anesthetist, and nurses) was more than 5 meters outside the OR during imaging acquisition, behind a lead-lined door (Fig. 1).

Results

From February 2014 to April 2014, data were collected from 107 consecutive patients operated on for spinal instrumentation using an IGS based on intraoperative scanning, performed with the O-arm system. The mean age of the population was 64.1 years (range 37–79 years); 62 patients (57.9%) were female and 45 (42.1%) were male.

The mean body mass index (BMI) was 25.11 (range 17.07–34.9). In all, 8 cervical procedures (7.5%), 17 thoracic procedures (15.9%), and 82 lumbar procedures (76.6%) were performed.

The intraoperative 3D scanning was conducted successfully in all patients, ranging from 1 to 3 scans per patient (mean 2.02 scans). Specifically, 1 scan was performed in 2 cases (in revision surgery as final control); in 98 cases 2 scans were performed (1 for navigation and 1 for final control); and in 7 cases 3 scans were completed. Of these scans, there was a technical problem during the scanning and the examination was aborted in 3 cases, 2 cases were cervical corpectomies, and 2 controls were performed (1 for decompression and 1 for final plate-cage construction), while in 2 cases it was necessary to replace at least 1 screw and an adjunctive control was performed. All scans were performed in standard definition, with a scanning time of 13 seconds.

The mean cervical protocol acquisition data were 120 kVp, 25 mA, 97.75 mA/sec (product of the mA delivered to the tube and the time of the x-ray pulse length), and 12.41 mGy CTDI, while the DLP ranged from 85.4 to 198.55 mGy-cm (mean 143.61 mGy-cm) according to the collimation used, which corresponds to 0.78 mSv per single scan (range 0.5–1.8 mSv) calculated using the ImPACT CT patient dosimetry calculator. The mean thoracic and lumbar protocol acquisition data were the same, and corresponded to 120 kVp, 40 mA, 156.4–195.5 mA/sec, and 14.08 mGy CTDI, while the DLP ranged from 240.15 to 720.10 mGy-cm (mean 447.67 mGy-cm), which corresponds to 2.52 mSv per single scan (range 1.42–4.28 mSv). The overall mean radiation dose received by the patients due to fluoroscopy and 3D imaging scans was 5.15 mSv (range 1.48–7.64 mSv).

The mean radiation dose received by the surgeon performing the imaging acquisition at breast level was 0.005 μ Sv (range 0.00–0.03 μ Sv). The dose outside the OR, where the other members of the team were during the imaging acquisition, was 0 (Fig. 2).

Discussion

This study attempted to estimate the real radiation dose for the surgical team and patients during posterior cervical and thoracolumbar instrumented spinal procedures using an IGS based on cone-beam imaging (such as the O-arm system) in a consecutive series of 107 patients.

To date, several papers in the literature have meticulously examined fluoroscopic radiation exposure and how to minimize dosage to operating personnel during spine surgery. However, these studies were almost all in vitro studies,^{2,8,11,16,18} and only 1 prospective in vivo study exists.¹⁹ In that study, Mulconrey analyzed the fluoroscopic radiation exposure during spinal surgery, showing how the yearly maximum number of minutes of fluoroscopic time remained below the International Commission on Radiological Protection (ICRP) guidelines.²⁸ However, the final radiation exposure results are affected by many factors, such as the number of surgical procedures, surgeon experience, and fluoroscopic technician experience.^{2,7,19}

These drawbacks appear to be overcome with a naviga-

FIG. 1. Setup of the OR and of the staff during scan acquisition with the O-arm system. The figures in *blue* represent surgeons and the anesthetist, while figures in *green* are nurses. In the center of the figure, the patient is inside the O-arm during image acquisition. The surgeon at the upper left is acquiring the intraoperative imaging using the O-arm system. The 2 machines to the right of the patient are the 2 parts of the navigation system (infrared camera above and the monitor below). The machine to the left of the patient is the central console of the O-arm system with its monitor. The numbers at the top and bottom of the figure are part of the planimetry of the OR and represent the dimensions (in meters) of the doors of the room. Figure is available in color online only.

tion system based on CT imaging or on 3D sophisticated isofluoroscopic imaging (such those created by the O-arm system), as the intraoperative fluoroscopic controls are avoided using real-time navigation imaging, as shown by Gebhard et al.⁶ The results of this study confirm that assumption. In fact, with our protocol, the dose per surgery to the operating personnel can be considered negligible: the surgeon performing the scan and fluoroscopic imaging with the O-arm system in our study received a mean dose of 0.005 μSv , while for the rest of the personnel it was 0. These doses are absolutely consistent with the ICRP recommendation for occupational radiation exposure, which proposes a limit of 2 mSv per year.¹²

While the advantage for surgeons and operating teams in reducing the effective dose using the IGS is intuitive and demonstrated, there are different considerations and

concerns regarding the radiation exposure for the patients. In fact, using a CT-based IGS, the final dose for patients is sensibly higher with respect to the conventional technique with fluoroscopy.²⁶ As stated in a previous paper,⁴ the adjunctive radiation dose of a pre- or intraoperative CT scan for patients may be criticized, but also may be regarded as acceptable considering the effectiveness of these techniques (from 96.1% to 98.5%) and the possibility of reducing or avoiding the frequency of a postoperative CT scan and a reoperation for misplaced screws. The results of this study revealed that the dose received by patients using the O-arm system was 5.15 mSv, and they are consistent with other reports performed on phantoms¹⁴ and in vivo,²³ and are lower with respect to the mean effective dose for a lumbar spine CT scan that is estimated to range between 7.5 and 10 mSv.^{12,26}

FIG. 2. Distribution and irradiation of isodoses (red lines) during scan acquisition with the O-arm system. The figures in blue represent surgeons and the anesthetist, while figures in green are nurses. Figure is available in color online only.

However, the effective dose presented in our study can be further optimized. Once the surgeon is comfortable with and can safely perform the navigation technique, he or she can reduce the number of scans (performing them only during acquisition imaging for spinal navigation). For example, we only perform the second control image acquisition in cases of doubt, or in the presence of non-convincing intraoperative anteroposterior or latero-lateral fluoroscopy. In this way, the final dose to the patient is almost halved. Moreover, the effective dose to the patient can be reduced using collimation or by minimizing the parameters of the device, as demonstrated by Su et al.,²⁵ who by changing the O-arm setting minimized the effective radiation dose to the patient (0.65 mSv vs 4.65 mSv in standard mode; $p < 0.0001$) using this device. Although a quality imaging analysis was not performed in this paper, the authors stated that it was not necessary to repeat the examination in all cases due to poor-quality imaging definition, and our experience confirmed this assumption.

During the process of optimizing the radiation dose,

the BMI of the patient must also be carefully considered. It is easily understood that the quality of the scan, as for all diagnostic procedures, depends directly on the BMI. In our series, as previously stated, we tried to define limits between optimization for radiation dose and quality of imaging to avoid having to repeat the examination scan due to poor-quality imaging definition.

It must be noted that at present, no strict guidelines have been established for reasonable effective radiation doses for patients in spine surgery. The impact of the radiation dose for patients triggers many questions and considerations, especially from an ethical point of view: it is quite difficult to define the limit between the effectiveness of this technology and the stochastic risks related to the radiation dose. However, in our opinion, the higher doses received by the patient using the O-arm system can be justified compared to the standard fluoroscopy technique in instrumented spinal surgery, considering the reduction of screw misplacement (85.48% according to the results of a meta-analysis of a fluoroscopy series²⁰) and the relative

consequences (such as postoperative CT scans, reoperations, etc.).

In general, surgeons should be aware of the radiation exposure implications to both the patient and the surgical team, and finding a balance between effectiveness of the procedure and radiation safety, with a proper minimization of its use, is a crucial point. Finally, it must be considered that there has never been a reported radiation-induced malignancy from the O-arm system, and a future study will be important to also define this aspect and to better define how and when to use this technology.

Conclusions

Given our results in this study, we believe this IGS based on intraoperative 3D imaging to be an effective and safe tool for spine surgery. The impact of the radiation dose for the operative personnel was negligible, and this is a relevant result considering the annual cumulative radiation dose for surgeons. The radiation dose received by the patient, if also considered acceptable, can be reduced using optimization of the device settings and using proper collimation, allowing final safe exposure in relation to a more effective procedure.

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Costa, Cardia. Acquisition of data: Tosi, Attuati, Ortolina. Analysis and interpretation of data: Costa, Tosi, Grimaldi. Critically revising the article: Costa, Galbusera. Reviewed submitted version of manuscript: Costa, Galbusera, Fornari. Approved the final version of the manuscript on behalf of all authors: Costa. Administrative/technical/material support: Attuati, Grimaldi. Study supervision: Costa, Fornari.

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