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ORIGINAL ARTICLE

Radiation exposure for the surgical team in a hybrid-operating room

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Abstract
Hybrid-operating rooms enable the surgeon to acquire intraoperative high-resolution 2- and 3D images and use them for navigation. The radiation dose of the operating personal and the patient remains the major concern. In 9 months, 109 pelvic and spine cases were performed using a hybrid operating room. Radiation dose of the surgeon and the assisting nurse was recorded using real-time dosimeters. Lower radiation doses for the main surgeon in navigated dorsal instrumentations of the thoracic spine were recorded. Standing between the C-arm during screw placement increased the radiation dose sixfold. Lumbar dorsal instrumentation showed a similar radiation dose compared to the previous studies in traditional operating room settings. The use of a hybrid-operating room for dorsal spine instrumentation showed no increase in radiation dose compared to traditional settings. Intraoperative navigation can help to reduce the radiation dosage for the operating personnel.

Keywords Hybrid-OR · Radiation · Spine surgery · Iliosacral screw · Navigation

Introduction

The use of radiation is rising in all medical fields [1]. In orthopedic surgery, the major sources for radiation exposure are intraoperative fluoroscopy and 3D-scans. The orthopedic surgeon is, therefore, exposed to direct and scattered radiation [2]. Surgeries like closed locked femoral nailing expose the operating personnel to high level of scattered radiation [3, 4]. The exposure to radiation for spine surgeons may be significantly higher compared to other orthopedic specialties [5]. Pedicle screw placement in trauma patients is technical demanding and intraoperative imaging is used by many surgeons to confirm fracture reduction, screw direction, depth, and position. The delayed effects of radiation lead to increased cancer rates for orthopedic surgeons compared to non-orthopedic surgeons [6]. The upper limit of the annual effective dose for the human body was set to 20 mSv by the International Commission of Radiological Protection [7]. However, the dose limit for non-classified personnel in Germany is set to 6 mSv a year [8]. To ensure the safety of the operating personnel, these dose limits should not be exceeded.

The radiation exposure depends mainly on the surgeon's position and behavior. The role of the location of the surgeon in relation with the C-arm in traditional operating room settings was subject of the previous studies. In general, standing in larger distance and contralateral to the imaging source decreases the radiation [9–11]. Standing in a 2 m distance of the C-arm will reduce the radiation to less than 1 mSv [12]. Wearing lead aprons will reduce the radiation exposure by factor 4 in lateral and factor 16 in posterior–anterior view. The often neglected thyroid shield reduces the exposure by a factor of 2.5 [13]. The surgeon should also be familiar with the C-arm handling. It should be operated solely by adequately trained personnel. If possible the exposure time should be limited and pulse mode, which can reduce the radiation dose by about 64%, should be used [14]. In more complex operating room settings like hybrid-operating rooms with enhanced mobility of the C-arm and CT-like 3D-scan capability, these measurements should be reevaluated.

To improve screw placement and increase patient safety, surgical navigation systems have been introduced since the early 1990s. Multiple studies showed a reduction of misplaced screws in lumbar and thoracolumbar spine surgery compared to conventional techniques [15–17]. Improvements in pedicle screw placement could be seen even in

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the thoracic spine using 3D navigation compared to the free hand technique [18, 19]. A metaanalysis showed a higher accuracy for pedicle screw placement with the help of 3D navigation [20, 21]. In addition, iliosacral screws that were implanted using 3D navigation showed a higher accuracy compared to conventional implantation [22]. Furthermore, computer guidance can help to save intraoperative radiation. For spine surgery, the use of computer-assisted navigation systems can reduce the radiation exposure of the operating personnel significantly [23–26].

The authors used a hybrid-operating room equipped with a floor-based flat-panel robotic C-arm with 3D-scan capability (Artis Zeego, Siemens; Germany) combined with a navigation system (BrainLAB Curve; BrainLAB; Germany). This system was usually used as an angiography system for minimally invasive cardiac and vascular surgery. Main orthopedic indications are pelvic and spine fractures. The described setting creates superior image quality and optimal circumstances for intraoperative navigation and minimally invasive surgery [27]. These improvements raise concerns regarding the radiation doses for the patient and especially for the operating personnel in navigated and non-navigated procedures.

To minimize tissue trauma minimal-invasive surgical approaches (MIS) are becoming more popular. These approaches can increase the intraoperative radiation, because the usual orientation due to anatomic landmarks is not possible [28, 29]. Multiple studies have shown a higher effective dose in minimal-invasive techniques for the operating staff and especially for the surgeon [30].

The aim of this study was to evaluate if the use of a hybrid-operating room for pelvic and spine procedures leads to a higher radiation dose for the surgical team. The primary outcome parameters were the radiation dose of the main surgeon and the scrub nurse during navigated and non-navigated procedures and during minimal invasive and open approaches. The secondary outcome parameter was the operating time of these procedures. Furthermore, we tried to determine specific radiation safety measures in a hybrid-operating room which could help to reduce the radiation exposure.

Methods

The ethical committee approval for the use of data was obtained. For this prospective single-center cohort study, all patients treated in the hybrid operating room from August 2015 until March 2016 were included. Out of total of 109 patients, 47 navigated and 62 non-navigated surgeries were included in our study. The most common procedure was dorsal instrumentation of the spine, including 25 lumbar and 20 thoracic cases. Furthermore, 18 sacroiliac screws were implanted. Other procedures included combined operations of the pelvis and the spine and complex trauma procedures (acetabulum, femur, tibia and talus). All procedures were performed by three experienced spine and pelvic surgeons, who also controlled the robotic C-arm. In all procedures, the radiation dosage for the main surgeon and the scrub nurse was recorded using real-time dosimeters (RaySafe™ i2, Unfors Raysafe; Sweden) worn on the chest above the lead apron during the whole operation. The main surgeon recorded the surgical procedure, the approach, his position during the operation and the operating time. The data sheets were marked with the date and time of the operation to allocate the sheets and the data of the dosimeters. Data extraction from the dosimeters and sheets was always performed by the same investigator.

Hybrid-operating room

The hybrid-operating room consists of a floor-based flat-panel robotic C-arm with 3D-scan capability (Artis Zeego, Siemens; Germany) (Fig. 1). It is capable of fluoroscopic large volume 3D scans. Hereby, the C-arm rotates around the isocenter for 5–20 s and creates a CT-like 3D-scan. The 3D data set is automatically sent to the navigation system (BrainLab Curve, BrainLab; Germany). The robotic C-arm is controlled by the surgeon with a sterile draped control panel that is attached to the table. The intraoperative scans were performed by the surgeon with a foot switch. The surgeon was standing behind a radiation protection wall. Everyone except the main surgeon left the operating room during the intraoperative scans.

Real-time dosimeter

The radiation dose for the main surgeon and scrub nurse was recorded in real time using the RaySafe™ i2 system. The dosimeter was fixed above the lead apron at breast height. The recorded data were sent wireless and in real time to

Fig. 1 Hybrid-operating room. The robotic C-arm (left) is digitally linked to the operating table and navigation system (yellow-framed camera and screen)

the RaySafe™ i2 Monitor, which could not be seen by the main surgeon or the scrub nurse during surgery. Prior to its use, the system was verified at the Metrology Laboratory of Ionizing Radiation of IST-LPSR in accordance with IEC 61526:2010 to verify the technical specifications stated by the manufacturer. The manufacturer states a 5% uncertainty.

Overall radiation dose for the main surgeon and the scrub nurse

In 90 cases, the radiation dose measured was used for statistical evaluation. In 19 cases, radiation doses of the main surgeon or scrub nurse were not fully recorded or technical difficulties occurred during the operation with the RaySafe™ i2 system or the Artis Zeego. Problems involved failure of the navigation software, an intraoperative switchover to conventional screw placement and damage to the RaySafe™ i2 Monitor, which loosened and fell on the ground during operation. The radiation dose was measured in all cases in the beginning to get experience in the usage of the dosimeters. Data of combined surgeries of the spine and the pelvis was only used for the analyzation of the overall radiation dose of the main surgeon and the assisting nurse.

Positioning of the surgeon

In our hybrid-operating room setting, the head of the patient always faces the Artis zeego C-arm for spine surgery. During lumbar instrumentation, it is not difficult to stand next to the zeego C-arm. In case of thoracic instrumentation, it is very convenient to step inside the C-arm due to the kyphosis of the spine and the screw angle (Fig. 2). The position of the surgeon during the operation was recorded. After the first preliminary results, the positioning of the surgeon inside the C-arm was prohibited because of the high radiation dosage measured. Dividing the groups according to the position of the surgeon, we could analyze eight thoracic spine cases for each position. Four cases in which the position of the main surgeon changed during the operation were excluded.

Navigated versus non-navigated procedures

Overall 20 dorsal stabilizations with 112 screws were performed in the thoracic spine. 4–12 screws were implanted per operation depending on the fracture pattern of the vertebra. Without the main surgeon standing inside the C-arm ten navigated, four non-navigated dorsal instrumentations of the thoracic spine were statistical evaluated. The group allocation was done by the main surgeon depending on fracture pattern, body mass index, and personal preference.

Lumbar spine

In the lumbar spine, 25 dorsal non-navigated instrumentations were performed with placement of 4–8 pedicle screws per operation. Overall 90 screws were implanted in the lumbar spine.

Sacroiliac screws

Sacroiliac screw placement was performed 18 times with 5 screws placed unilateral and 13 screws placed transiliacal–transsacral. During all procedures, the navigation system was used.

Minimal invasive versus open approaches

39 dorsal instrumentations of the thoracic and lumbar spine were performed with a minimal invasive and ten with an open technique. After excluding cases with the main surgeon standing inside the C-arm, the radiation dose of 34 minimally invasive and 7 open cases was compared.

Fig. 2 Right picture standing inside the C-arm, left picture standing outside the C-arm during screw placement

Operating time was compared for all of the 39 minimal invasive and ten open cases. The group allocation was done by the main surgeon depending on fracture pattern, body mass index, and personal preference.

Statistical analysis

The recorded data were analyzed using the RaySafe™ i2 dose manager. Statistical analysis was performed using Microsoft Excel 2011 and SPSS V22. Radiation dosage of the main surgeon and the operating time was investigated according to the approach (minimal invasive or open surgery), the number of screws, type of operation (navigated versus non-navigated), and the position of the main surgeon in the operating room. Because of some small subgroups, group means and standard deviations were calculated as well as the medians. Differences between the groups were analyzed by the Mann–Whitney *U* test. Statistical significance of differences was accepted when $p < 0.05$.

Results

Overall radiation dose for the main surgeon and the assisting nurse

The mean radiation dose in the hybrid-operating room for the surgeon (66 ± 106 nSv; $n = 90$) was significantly higher ($p = 0.03$) compared to the assisting nurse (19 ± 45 nSv; $n = 90$) (Fig. 3).

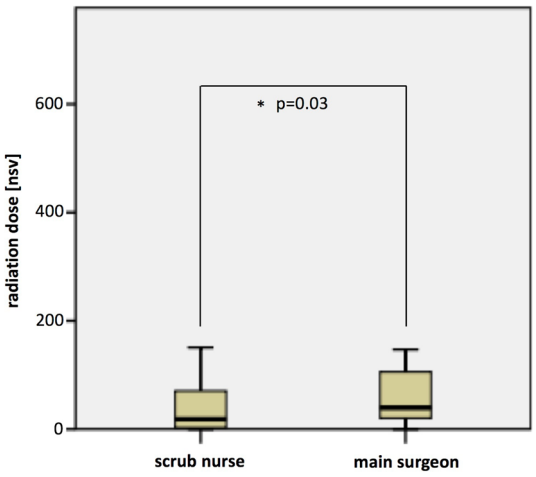

Fig. 3 Radiation dose was higher for the main surgeon than for the scrub nurse

Positioning of the surgeon

The radiation dose for the surgeon was significantly decreased ($p = 0.001$) if the surgeon stood outside the C-arm (51 ± 35 nSv; $n = 8$) during screw implantation compared to a position inside the C-arm (311 ± 187; $n = 8$) (Fig. 4).

Navigated versus non-navigated procedures

For thoracic spine procedures, the mean radiation dose for the surgeon was significantly decreased ($p = 0.002$) in navigated operations (93 ± 123 nSv; $n = 10$) compared to non-navigated operations (292 ± 46 nSv; $n = 4$) (Fig. 5). There was no difference in mean operating time between navigated (143 ± 55 min; $n = 10$) and non-navigated (142 ± 45 min;

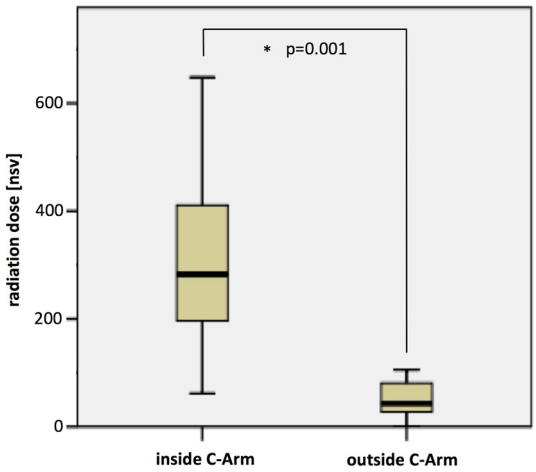

Fig. 4 Radiation dose was significantly reduced, if the surgeon was standing outside the C-arm during screw implantation

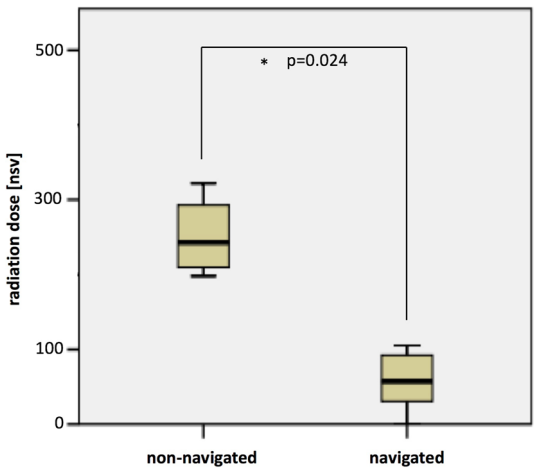

Fig. 5 Radiation dose was significantly reduced in navigated procedures of the thoracic spine

$n=4$) procedures. Statistical analysis showed no influence of the number of screws on the radiation dose.

Lumbar spine

For lumbar spine procedures (57 ± 90 nSv; $n=25$), radiation dose was significantly lower ($p=0.023$) compared to thoracic procedures (147 ± 168 nSv; $n=20$) (Fig. 6). Mean operating time in lumbar dorsal instrumentations (78 ± 39 min; $n=25$) was significantly shorter ($p=0.006$) compared to thoracic dorsal instrumentation of the spine (118 ± 49 min; $n=20$). Statistical analysis showed no influence of the number of screws on the radiation dose.

Sacroiliac screw placement

Navigation was performed for all 18 sacroiliac screw placements. There was no difference in mean radiation dose for the surgeon between sacroiliac (53 ± 41 nSv; $n=5$) and transiliac transsacral screws (40 ± 37 nSv; $n=18$). In addition, there was no statistical difference in mean operating time placing sacroiliac (64 ± 20 min; $n=5$) or transiliac transsacral (57 ± 77 min; $n=18$) sacroiliac screws.

Minimal invasive versus open approaches

39 minimal invasive and 10 open spine procedures were performed. 13 of the 39 minimal-invasive procedures were navigated. There was no difference in mean radiation dose for the surgeon between MIS (60 ± 57 nSv; $n=34$) and open techniques (65 ± 78 nSv; $n=7$). Mean operating time in MIS dorsal instrumentation of the spine (88 ± 40 min; $n=39$) was significantly shorter ($p=0.01$) compared to open dorsal instrumentation of the spine (144 ± 55 min; $n=10$).

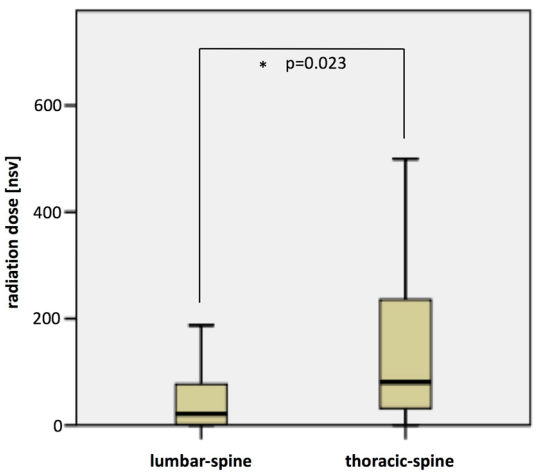

Fig. 6 Radiation dose was significantly lower during lumbar procedures

Discussion

The RaySafe™ i2 personal dosimeter system was used to record the radiation dose during navigated and non-navigated operations in our hybrid-operating room for the operating team. We analyzed the mean dose above the lead apron in front of the torso of the main surgeon and the scrub nurse. Mean radiation dose of the surgeon was 66 nSv and of the scrub nurse 16 nSv per procedure. Thus, annual cumulative radiation exposure for the surgeon in the hybrid-operating room with 300 operations per year would approach approximately 20 mSv and, therefore, would exceed the radiation exposure limit in Germany of 6 mSv per year [8]. However, this is the radiation dose recorded outside of the lead aprons which reduce the dose about 94% [13]. In a consequence, using a hybrid-operating room every day for navigated and non-navigated operations will not exceed the radiation dose limit of 6 mSv per year. Radiation dose of the scrub nurse was significantly lower than the dose of the surgeon. Assuming 300 operations a year, the scrub nurse would have an annual cumulative dose of 6 mSv. Therefore, even without the protection of the lead aprons, the scrub nurse would not exceed the annual dose limit. The scrub nurse can keep a safe distance to the Artis Zeego at all times and leaves the operating room during 3D-scan. This explains the significant lower doses compared to the surgeon.

In the first ten observed cases, we recorded higher radiation dose for the surgeon using navigation compared to non-navigated procedures. Further investigation showed that the position in relation with the C-arm of the Artis Zeego was the main variable determining the radiation dose of the surgeon. If the surgeon was standing inside the C-arm while implanting the screws under fluoroscopic control, the dosage was significantly higher. In our hybrid-operating room, the head of the patient always faces the Artis zeego C-arm for spine surgery. During lumbar instrumentation, it is not difficult to stand next to the zeego C-arm. In case of thoracic instrumentation, it is very convenient to step inside the C-arm due to the kyphosis of the spine and the screw angle. During pedicle screw insertion under fluoroscopic control, we recorded an average radiation dose of 311 nSv standing inside the C-arm. Just by stepping a few steps back outside the Artis zeego C-arm decreased the radiation for the main surgeon to an average of 51 nSv. This procedure—stepping a few steps back during fluoroscopic control—consequently became the standard procedure in our hybrid-operating room during our study. Unfortunately, this change in behavior reduced the sample size for the comparison of navigated and non-navigated spinal procedures.

During surgery, 3D-scans were activated by the main surgeon using a foot switch standing behind a radiation

protection wall. The assisting staff always left the hybrid-operating room. Meanwhile, the foot switch was changed to a wireless model. Thereby the surgeon can also leave the operating room during a 3D-scan. Due to these actions, we could reduce the radiation dose for every trauma surgeon significantly.

The hybrid-operating room in our hospital is used for other medical departments as well [22]. The department of neurosurgery and vascular surgery is now trying to achieve a reduction of radiation dose using the RaySafe™ i2 system. This study showed comparable results to former investigations, proving a distinct reduction of the radiation dose of the surgical personnel using a visual radiation dose feedback system [31–33].

A comparison of navigated and non-navigated dorsal thoracic spine instrumentation under these new circumstances showed a significant reduction of the radiation dose for the surgeon for navigated dorsal instrumentations of the thoracic spine. Lower radiation dose for navigated surgery can also be shown in kyphoplasty of osteoporotic vertebra fractures [24], cadaver studies for lumbar fusions [34], and lumbar pedicle screw placements [23, 35]. To obtain usable images in the thoracic spine, higher radiation doses have to be applied because of the shoulders and bony thorax. Navigated dorsal instrumentation was mainly performed in the thoracic spine due to the reduced fluoroscopic visibility in this area. In non-navigated procedures, the entry point and the position of the awl are usually double-checked with the image intensifier. Further images are acquired to control the screw position. The higher radiation doses needed and the additional fluoroscopic controls explain the higher radiation exposure in non-navigated procedures for the operating personnel. No differences of the operating time could be seen between both groups. In conclusion, performing navigated spine and pelvic procedures in a hybrid-operating room can reduce the radiation exposure without an increase in operating time. The sample size with only ten navigated and four non-navigated cases was low. No statistical power analysis could be performed prior to the study, because this is the first study using Raysafe i2-Dosimeters for real-time measurement of radiation exposure. Due to the high difference between the groups, statistical significance was achieved even with the small sample size.

As expected, the radiation dose for the surgeon performing dorsal instrumentation of the thoracic spine was higher than in lumbar region. The average dose of the surgeon during dorsal stabilization of the lumbar spine was 57 nSv. A former study reported an average of 43 nSv for lumbar stabilization [35]. The slightly higher dosage using a hybrid-operating room can be explained by the use of a different type of dosimeter. Furthermore, Smith et al. only did one-level spine segment instrumentation on a cadaver [35]. We also performed two- and three-level spine segment dorsal stabilization increasing the number of needed fluoroscopic controls. In conclusion, the radiation dose during lumbar spine instrumentation in a hybrid-operating room is comparable to the use of a conventional 3D-image intensifier.

The mean radiation dose of the surgeon was lower for sacroiliac screw placement than dorsal instrumentation of the lumbar and thoracic spine. Mean dosage for the surgeon over all sacroiliac screw placements was 44 nSv. Richter et al. demonstrated that accuracy of sacroiliac screws can be improved using a hybrid-operating room [22]. In our department, all sacroiliac and transiliac transsacral screw are placed using computer-assisted navigated surgery to assure optimal screw placement, which can be achieved without high radiation doses for the operating personal.

We also compared minimal invasive with open pedicle screw placement of the spine. Kulkarni et al. [36] compared minimal invasive and open transforaminal lumbar interbody fusions and reported more fluoroscopic controls and longer operating times in the minimal-invasive procedures. Bronsard et al. [30] found a higher radiation dose performing minimal-invasive techniques at the lumbar spine compared to open procedures. In comparison, we found no difference in the mean radiation dose and shorter operating times for MIS. The excellent visualization of the Artis Zeego is a major benefit for MIS screw implantation. The pedicles can be easily identified and the position of the jamshidi needle can be controlled. With a standard C-arm, only concentric collimation is possible. The flat-panel detector enables the surgeon to do an asymmetric collimation. The collimators can be controlled independently. Thereby, the image quality can be improved and the radiation dose reduced. Furthermore, the open procedure in our hospital is based on fluoroscopic images. The entry point and the position of the awl are usually double-checked with the image intensifier. Further images are acquired to control the screw position, which explains the comparable results.

Open procedure took significantly more time than the minimal-invasive technique. In comparison, Wild et al. [37] found longer operations times in dorsal instrumentations of the thoracolumbar spine performing the minimal-invasive technique. However, recent studies showed no difference in the operating time comparing MIS and open approaches [38]. One study limitation was that open approaches were mainly performed in case of thoracic pathologies. These procedures are often technical demanding due to poor fluoroscopic visibility and small pedicle diameters leading to longer operation times. In three cases, the open approach was used to perform laminectomy also prolonging the operating time. In our department, MIS is preferred because of the preservation of soft tissues [30, 38, 39] and comparable results concerning radiation.

This study has certain limitations. The RaySafe™ i2 dosimeters were only calibrated by the manufacturer and

the measurements of the dosimeters could not be verified by the authors. The comparison between the two positions of the main surgeon was not planned but necessary after high values of radiation exposure were measured during the first navigated thoracic operations. The high radiation exposure was due to the position of the main surgeon between the C-arm. This position was then avoided and the radiation exposure was reduced significantly. The cases with the main surgeon standing between the C-arm branches were than excluded from the comparison of navigated versus non-navigated thoracic spine procedures. Therefore, the sample size for the position of the surgeon and the comparison of navigated versus non-navigated procedures was low, but reached statistical significance. The radiation dose was only measured above the lead apron on the chest. The radiation exposure under the lead aprons in different regions like the thyroid gland, genitals, hands or lenses was not part of the study. In further studies, we will evaluate the exposure of different anatomical regions during navigated and non-navigated procedures.

In conclusion, using a hybrid-operating room with a floor-based flat plate robotic C-arm and a navigation interface can reduce the radiation exposure for the surgeon during navigated dorsal instrumentation of the thoracic spine compared to non-navigated procedures. The use of a hybrid-operating room did not increase the radiation dose for the surgeon performing lumbar dorsal instrumentation. Furthermore, the radiation dose for the surgeon in minimal-invasive techniques is lower compared to open techniques. Although it is convenient, the spine surgeon should avoid standing inside the C-arm while placing cervical or thoracic pedicle screws under fluoroscopic control. We found a sixfold increase of the radiation dose standing inside the C-arm during screw placement. Radiation doses of the surgeon could be reduced just by changing the position in the OR due to live dosimetry. In addition, intraoperative navigation for dorsal spine stabilization and sacroiliac screw placement can reduce the radiation dose for the operating personal in a hybrid-operating room.

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Compliance with ethical standards

Conflict of interest The authors K. Schuetze, A. Eickhoff, C. Dehner, and M. Schultheiß declare that they have no conflict of interest. P. H. Richter and F. Gebhard hold lectures for Siemens Healthcare. No company had influence in the collection of data or contributed to or had influence on the conception, design, analysis, and writing of the study. No further funding was received.

Ethical approval All procedures followed were in accordance with the ethical standards of the responsible ethics committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in this study.

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