#### **ORIGINAL ARTICLE** ORIGINAL ARTICLE



# Safety and accuracy of spinal instrumentation surgery in a hybrid operating room with an intraoperative cone-beam computed tomography

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### Abstract

Although spinal instrumentation technique has undergone revolutionary progress over the past few decades, it may still carry significant surgery-related risks. The purpose of the present study was to assess the radiological accuracy of spinal screw instrumentation using a hybrid operating room (OR) and quantify the related radiation exposure. This retrospective study included 33 cases of complex spine fusion surgeries that were conducted using a hybrid OR with a flat panel detector (FPD) angiography system. Twelve cases (36.4%) were cervical, and 21 (63.6%) were thoracolumbar. The average number of spine fusion levels was 3 and 4.8, respectively, at the cervical and thoracolumbar spine levels. A FPD angiography system was used for intraoperative cone-beam computed tomography (CBCT) to obtain multi-slice spine images. All operations were conducted under optimized radiation shielding. Entrance surface doses (ESDs) and exposure times were recorded in all cases. A total of 313 screws were placed. Satisfactory screw insertion could be achieved in all cases with safe screw placement in 97.4% and acceptable placement in 2.6%. None of the cases showed any significant anatomical violation by the screws. The radiation exposure to the patients was absolutely consistent with the desired ESD value, and that to the surgeons, under the annual dose limit. These results suggest that the hybrid OR with a FPD angiography system is helpful to achieve safe and precise spinal fusion surgery, especially in complex cases.

Keywords Cone-beam CT  $\cdot$  Hybrid operating room  $\cdot$  Radiation exposure  $\cdot$  Spinal instrumentation  $\cdot$  Surgical safety

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# Introduction

Spinal instrumentation technique has undergone revolutionary progress over the past few decades. This progress has significantly changed the surgical strategy for spine disease, for not only spinal trauma but also congenital diseases, cancer, infection, and aging degeneration. Hospitalization time has been reduced, patients are mobilized more rapidly, and the overall surgical outcome has improved. On the other hand, spinal instrumentation such as pedicle screws may carry a risk of neural or vascular injury [\[1,](#page-7-0) [2](#page-7-0), [4](#page-8-0), [13](#page-8-0)]. To avoid such surgery-related complications, intraoperative image guidance using fluoroscopy or CT-based computer navigation was developed. However, technical pitfalls and the means to avoid them need to be carefully considered [\[31](#page-8-0)]. More recently, a 3D-CT-based navigation system using intraoperative conebeam computed tomography (CBCT) with a flat panel detector angiography module, also referred to as hybrid operating room (OR), has been actively developed to achieve more accurate and safe surgery [[23\]](#page-8-0). Meanwhile, the associated

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radiation exposure to the patients and surgeons remains a major concern. The purpose of the present study was to assess the radiological accuracy of spinal screw instrumentation using a hybrid OR system and quantify the related radiation exposure. The benefits and possible disadvantages of the hybrid OR system for spinal instrumentation surgery are discussed with a literature review.

# **Methods**

## Patients

This retrospective study included a total of 33 (23.2%) of 142 spine fusion surgeries in the study period from April 2014 to May 2017. The indication for use of hybrid OR with intraoperative CBCT imaging was carefully determined based on the complexity of the cases. So were indicated, cases of revision, multi-spine fusion, infectious, multi-trauma, and spinal deformity surgeries, while ordinary cases such as short fusion surgeries were usually completed using the conventional C-arm fluoroscopy. The patients included 22 men and 11 women, and their mean age at surgery was 62.8 years (range, 20–86 years). Twelve cases (36.4%) were cervical, and 21 (63.6%) were thoracolumbar. The average number of spine fusion levels was 3 and 4.8, respectively, at the cervical and thoracolumbar spine levels. Patients' characteristics are summarized in Table 1.

### Hybrid OR system

Spinal instrumentation, such as the cervical pedicle screw (CPS), cervical lateral mass screw (CLMS), cervical translaminar screw (CTL), thoracolumbar pedicle screw (TLPS), or lumbar cortical bone trajectory screw (LCBTS), was achieved using a fluoroscopy image guidance system. The initial insertion (screw or Kirschner wire) was conducted with free hands or assistance of a preoperative CT-based navigation module (Stealth Station, Medtronic, Inc., Memphis, TN, USA). A flat panel detector (FPD) angiography system AlluraClarity FD20 (Philips, Amsterdam, The Netherlands) was combined with a carbon-fiber operating table (Maquet, Germany) and used for intraoperative CBCT to obtain multi-slice spine images in the hybrid OR (Fig. [1\)](#page-2-0). The size of the FPD was maximally 19 in, with a pulsed fluoroscopy rate of 7.5 p/s. The digital subtraction angiography frame rate was 30 f/s. Multi-slice spine images were then acquired immediately after the placement of spine instrumentation screws or temporary Kirschner wires to confirm their satisfactory and safe positioning, or the need of repositioning. After the placement of all instrumentation screws, local

#### Table 1 Patients' characteristics



decompression, bilateral facet release, or interbody fusion was carried out if necessary. The rods, bent earlier according to the preoperative plan, were then applied to the screws and fully tightened. Bone grafting from local bone and beta tricalcium phosphate application were done to ensure adequate fusion.

#### Measurement of radiation exposure

All operations were conducted under optimized radiation shielding in the hybrid OR system. Entrance surface doses (ESDs) and exposure times were recorded in all cases in milliGray (mGy) and seconds, respectively, by radiological technicians. ESD can be measured at the center of the entrance surface in the X-ray beam field, and it includes backscattered radiation from the patient [[20](#page-8-0), [45](#page-9-0)]. In 23 cases, pocket radiation dosimeters (Hitachi, Tokyo, Japan) were placed inside and outside the protective suit of the principal surgeon to evaluate the radiation exposure to the surgeon during the surgery. Exposures are reported in microSievert (μSv).

## Postoperative assessment of radiological accuracy of screw placement

The radiological accuracy of spinal instrumentation screws was evaluated based on the postoperative CT scans and defined retrospectively using our proposed grading scale (Table [2](#page-3-0)). Screw positions were classified into three grades based on the potential risk of neural or vascular injury: grade

<span id="page-2-0"></span>

Fig. 1 A flat panel detector angiography system. The flat panel detector is combined with a carbon-fiber operation table and used for intraoperative cone-beam computed tomography (CBCT) in the hybrid OR system. a A

0, safe placement; grade 1, minor cortical perforation without any possible clinical risks; and grade 2, major perforation associated with possible risks.

## Statistical analysis

All data are expressed as means  $\pm$  standard deviation. Statistical analysis of correlations between two variables was performed using the Pearson correlation coefficient. JMP version 9.0 software (SAS Institute, Cary, NC) was used for all statistical analyses in the present study. Values of  $p < 0.05$ were considered significant.

# **Results**

A total of 313 screws were placed in 33 cases to stabilize the spine using the hybrid OR system during the study period. The intraoperative fluoroscopic images obtained using a FPD angiography system were of great quality, wide and long enough to cover even cases of long spine fusions (Figs. [2](#page-3-0) and [3\)](#page-4-0). The intraoperative axial reconstruction images acquired from the CBCT were comparable in terms of quality to postoperative CT images (Fig. [4](#page-4-0)). The radiological accuracy of the screws was grade 0 in 97.4% (30[5](#page-5-0) of the 313 screws) (Fig. 5a–c), grade 1 in 2.6% (8 of the 313 screws) (Fig. [4d](#page-4-0)–f), and grade 2 in 0%. No neural or vascular complications closely associated with screw placement were encountered in the present study. A total of 8 of the 313 screws were found to perforate the bone cortex, classified as grade 1 radiological accuracy. Four cervical LMS or TLS were found to outstrip by less than 2 mm, 1 thoracolumbar PS outstripped by less than 5 mm, and 3 lumbar CBTS were protruding by less than 10 mm. Fortunately, no screw of grade 2 was found in the present study. The radiological accuracy of screw placement is summarized in Table [3.](#page-5-0)

flat panel detector angiography system is introduced after covering the operative site with sterile sheets. b, c Multi-slice spine images are obtained in a smooth and quick motion

#### Radiation exposure

The radiation ESD of cervical spine cases ranged from 6.38 to 30.62 mGy, with an average of 14.11 mGy, and that of the thoracolumbar spine cases ranged from 27.15 to 381.32 mGy, with an average of 113.01 mGy. The average fluoroscopy time per surgery including CBCT was 90.3 s (22.2–277.2 s) for the cervical spine cases and 210.9 s (43.0–508.8 s) for the thoracolumbar spine cases. Radiation exposures outside the surgeon's protective suit in cervical spine cases ranged from 1.0 to 15.0  $\mu$ Sv, with an average of 4.8 μSv, and from 0 to 3.0 μSv inside the protective suit, with an average of  $0.25 \mu Sv$ . These values in the thoracolumbar spine cases ranged from 7.0 to 146.0 μSv outside the protective suit, with an average of 54.1  $\mu$ Sv, and from 0 to 18.0  $\mu$ Sv, with an average of 5.7  $\mu$ Sv, inside the surgeon's protective suit. The radiation exposure data for the patients and surgeon are summarized in Table [4.](#page-5-0) A linear regression and correlation analysis of collected data showed no significant correlation between the number of spine fusion levels and the recorded exposure time, but there was a noteworthy correlation between exposure time and ESD ( $p = 0.00005$ ;  $r = 0.64602$ ), as well as between the exposure time and doses recorded outside  $(p = 0.00003; r = 0.75411)$  and inside  $(p = 0.00003; r = 0.00003)$ 0.75689) the surgeon's protective suit (Fig. [6](#page-6-0)).

# **Discussion**

#### The latest technological advances for safe surgery

This study aimed to evaluate the benefits and possible disadvantages of a hybrid OR system, for spinal instrumentation surgery, in the context of the progressing intraoperative imaging technology. Its first benefit may be the fact that surgeons can avoid the high risk of instrumentation-related neural or <span id="page-3-0"></span>Table 2 Grading scale of the radiological accuracy of screw placement



vascular injury, using a combination of intraoperative wide fluoroscopy, CBCT, and eventually navigation. Spinal instrumentation surgery has become essential to manage spinal pathologies related to aging degeneration, trauma, inflammation, and infection. However, factors like the individual anatomical variations, surgeon's experience, or material specifications may expose patients to risks of screw misplacement and their potentially associated complications [\[1](#page-7-0), [2](#page-7-0), [4](#page-8-0), [13](#page-8-0)]. To avoid these, various protocols such as rational use, as in the present study, of pulsed fluoroscopy combined with intraoperative CBCT may help accurately reach the initially planned goals while minimizing the risks. Furthermore, the addition of

Fig. 2 Illustrative case of degenerative cervical kyphosis that was operated in the hybrid OR system. a Preoperative plain radiograph, b Intraoperative fluoroscopic image, c Postoperative plain radiograph



<span id="page-4-0"></span>Fig. 3 Illustrative case of degenerative lumbar scoliosis that was operated in the hybrid OR system. a Preoperative plain radiograph. b Intraoperative fluoroscopic image. c Postoperative plain radiograph



navigation reduces the need of extensive radiation exposure while providing extra precision [\[5](#page-8-0), [44](#page-9-0)].

The latest technological advances in imaging systems, such as 3D navigation, intraoperative O-arm, or the hybrid OR system presented here, have brought the possibility of instant visualization of anatomical structures and guidance support during surgery [[8,](#page-8-0) [23](#page-8-0), [25\]](#page-8-0). Among these options, some modalities demonstrated better surgical precision than others

Fig. 4 Comparison of axial reconstruction images. a, c Images obtained by using intraoperative CBCT. b, d Postoperative CT images

[\[35](#page-8-0)–[37\]](#page-8-0). Though, the achieved accuracy taken alone could not suffice to determine the efficiency and must be weighed against the radiation exposure that accompanies it. From recent publications focusing on the surgical safety, it has emerged that spinal navigation was quite helpful for surgeons to place screws accurately, with higher success rates than the free-hand technique or standard fluoroscopy-guided surgery [\[6](#page-8-0), [16](#page-8-0), [22](#page-8-0), [35](#page-8-0)]. Intraoperative CBCT offers helpful and reliable



<span id="page-5-0"></span>

Fig. 5 Postoperative CT axial images. a C2 translaminar screws of grade 0. b lumbar pedicle screw of grade 0. c Lumbar cortical bone trajectory screw of grade 0. d C1 lateral mass screw of grade 1. e Lumbar pedicle screw of grade 1. f Lumbar cortical bone trajectory screw of grade 1

instant CT-like images of better clarity than those of conventional fluoroscopy, with reportedly the highest accuracy at all spinal levels, where used [[19](#page-8-0)]. These images, once processed, also deliver high-quality 3D representations that are suitable for navigation during spinal surgery and indirectly help in reducing the overall radiation dose [[33,](#page-8-0) [41](#page-9-0)].

No doubt remaining about the interest of navigation, two major types of CBCT systems are being actively used now for various spinal surgeries: the hybrid OR in this series and the O-arm system. The accuracy for spinal screw placement in the present study was comparable to that obtained using the Oarm system (Table [5](#page-7-0)). Satisfactory screw insertion could be achieved in all our cases (100%), with safe screw placement (grade 0) in 97.4% and acceptable ones (grade 1) in 2.6%. None of the present cases showed any significant anatomical violation by the screws exposing the patient to neural, vascular, or any visceral injury. Our hybrid OR system modality of

Table 3 Radiological accuracy of screw placement

Grade	Type of screw	No.	Total no.	Percent
0	Cervical PS	77	305	97.4%
	Cervical LMS or TLS	62		
	Thoracolumbar PS	107		
	Lumbar CBTS	59		
1	Cervical PS	0	8	2.6%
	Cervical LMS or TLS	4		
	Thoracolumbar PS	1		
	Lumbar CBTS	3		
2	Cervical PS	0	$\Omega$	$0\%$
	Cervical LMS or TLS	0		
	Thoracolumbar PS	$\Omega$		
	Lumbar CBTS	0		
			313	$100\%$





<sup>a</sup> The Japan Association of Radiological Technologists

<sup>b</sup> International Commission Radiological Protection

<span id="page-6-0"></span>

Fig. 6 Scatter plots with regression lines for correlation analysis. a Between the entrance surface dose (ESD) to the patient and exposure time and between b the radiation exposure to the surgeon and exposure time

intraoperative wide fluoroscopy and main usage of CBCT images allowed us to confirm the correct position of spinal instrumentation and to reposition any unsatisfactorily inserted screw. In addition to the comparable achievement capabilities to the O-arm, our hybrid OR CBCT can offer a great flexibility and provide wider 3D images than the O-arm system, making it a valuable tool for multilevel spinal fusion surgery.

#### Intraoperative radiation exposure

While the use of intraoperative CBCT has become popular and no doubt remains about its efficacy, concern about the intraoperative radiation exposure to surgeons and patients remains. A previous comparative clinical study demonstrated that the use of intraoperative CBCT resulted in higher radiation exposure than standard fluoroscopy during standard posterior fusion surgery for idiopathic scoliosis, whereas in vitro studies demonstrated decreased radiation exposure to the operator specifically [\[24,](#page-8-0) [36](#page-8-0)]. The recent developments have led to more complex systems, such as the O-arm that is being actively deployed now, but evaluations regarding its efficacy and safety of use are still needed [\[23,](#page-8-0) [28](#page-8-0)]. An anthropomorphic study put forward that O-arm system may expose patients to significant radiation doses [\[30](#page-8-0)]. A comparative phantom study demonstrated higher radiation doses to the surgeon by the O-arm than the C-arm in their 2D fluoroscopy mode [[28\]](#page-8-0), partly contrasting with the results found by other authors that suggested less radiation exposure for the surgeon in one series, but similarly, higher radiation exposure to the patient with the O-arm than the C-arm in both reports [\[39](#page-9-0), [40](#page-9-0)]. Among the clinical series reported so far, Costa et al. demonstrated that the O-arm, as seen for the C-arm system, exposed patients to a higher radiation dose than standard fluoroscopy but concluded that their recorded doses were still acceptable when balancing with the advantages of the O-arm system [[3\]](#page-7-0). Another author concluded to higher radiation doses with O-arm system than those in their free-hand series, without any noticeable benefit in cases of screw placement for moderate idiopathic scoliosis [\[42](#page-9-0)]. It is well-understandable that CBCT devices may add radiation to the customary use of fluoroscopic sessions from standard fluoroscopy. The current recommendations for addressing this issue suggest a reduction of the fluoroscopic time, potentiating the use of navigation or preferring lowdose protocols [\[29](#page-8-0)]. Our series brings additional data that may help to compare the relative radiation exposure between the common CBCT devices being used currently. The radiation exposures encountered during spinal fusion surgeries with use of O-arm system in clinical series found in the literature are summarized in Table [5](#page-7-0). Notwithstanding the fact that there are some differences in operative protocols, number of spine fusion, surgeon's experience, and method of evaluation among the available data, our imaging modality demonstrated acceptable results, in comparison to the O-arm system in terms of radiation exposure.

The levels of exposure may be affected by several factors, such as the surgeon's experience and fluoroscopy technician's aptitude, the extent of spinal fusion, and the intraoperative imaging modalities, which make standardization of these studies and strict comparison difficult [[21](#page-8-0)]. Iprenburg et al., who analyzed their prospective study regarding patient radiation exposure during transforaminal lumbar endoscopic spine surgery, suggested that patients are likely to be exposed to higher doses of radiation during a surgeon's early experience [[10\]](#page-8-0). Indeed, surgeon's evaluation capacity and agility are most likely to increase with time, allowing further avoidance of needless acquisitions. Distances to the radiation source and beam path are other essential factors affecting radiation exposure to the surgeon and operating staff. In addition, better devices and optimal system configurations may lead to higher efficiency and a better balance between the benefits and risks.

<span id="page-7-0"></span>Table 5 Literature review of screw placement accuracy and radiation exposure in clinical series of spinal fusion surgery with O-arm

First author	Year	Intraoperative imaging system	Average no. of fusion levels	Screw placement			Radiation exposure (average)	
				No. of screws analyzed	$%$ of safe	$%$ of minor placement or major perforation	Patient	Surgeon
Silbermann J $[38]$		2011 O-arm		187	99	1		
Ishikawa Y [11]	2011	$O-arm$	2.1	108	88.9	11.1		
Oertel MF [26]	2011	$O-arm$		278	96.8	3.2		
Patil S [27]		2012 O-arm		116	94.8	5.2		
Houten $[8]$		2012 O-arm		205	97	3		
Van de Kelft E [43]		2012 O-arm		1881	97.5	2.5	10.6 mGy (2D) 203.1 mAs (3D)	
Ling JM $[18]$		2014 O-arm		467	95.3	4.7	—	
Kotani T [17]		2014 O-arm		416	84.4	15.6		
Shin MH [35]	2015	O-arm		124	91.9	8.1		
Smith JD [37]		2016 O-arm		30	73	27	$39.0$ mGy	
Costa $F[3]$		2016 O-arm		$\overline{\phantom{0}}$		$\overline{\phantom{0}}$	$5.15$ mS <sub>v</sub>	$0.005 \mu Sv$
Kleck CJ $[14]$		2016 O-arm		158	81	19		$\qquad \qquad -$
Shimokawa N [34]	2017	$O-arm$		310	97.1	2.9		
Safee MM [32]	2018	$O-arm$	1.38			-	$62.0$ mGy	
Kobayashi K [15]	2018	$O-arm$	11	$\overline{\phantom{0}}$	$\overline{\phantom{0}}$	$\overline{\phantom{m}}$	401 mGy	
Urbanski W [42]	2018	$O-arm$		451	96	4	1071 mGy-cm	$\overline{\phantom{m}}$
Present study		CBCT in a hybrid OR Cervical 3		313	97.4	2.6	14.11 mGy	$4.8 \mu Sv$
			Th-L 4.8				113.01 mGy	$54.1 \mu Sv$

The AlluraClarity FD20 system used in the present study comes with advantages that were described previously, among which is an improved algorithm for image noise reduction that allows higher-quality images for less acquisitions, and optimized functions that lower considerably the amount of radiation per acquisition [[7\]](#page-8-0). The frame rate acquisitions in this study allowed no image deterioration by the system, contributed to containing the overall radiation exposure to both patient and surgeon. The radiation exposure to patients in the present study was absolutely consistent with the desired ESD value of less than 2000 mGy proposed by the Japan Association of Radiological Technologists [[12\]](#page-8-0). Similarly, the radiation exposure to the surgeons stayed under the annual dose limit of 20,000 μSv recommended by the International Commission on Radiological Protection [[9\]](#page-8-0). This leads us to the conclusion that the hybrid OR system used in the present study remains safe for routine spinal instrumentation surgery.

# Conclusions

Our hybrid OR system allowed us to achieve precise surgery and was well suited for complex spinal fusion cases. Although concerns remain about the radiation exposure to both patients and surgeons, the data analyzed in the present study suggests that the hybrid OR with a FPD angiographic system is helpful to achieve safe and accurate spinal fusion surgery, especially in complex cases.

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#### Compliance with ethical standards

Conflicts of interest The authors declare that they have no conflict of interest.

Ethical approval and informed consent The authors certify that all applicable institutional and governmental regulations concerning the ethical use of clinical data were adhered to for the present study. This retrospective outcome analysis of spine surgery was approved by the ethics committee of Osaka City University Graduate School of Medicine.

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