## ORIGINAL ARTICLE



# Radiation dose reduction in thoracic and lumbar spine instrumentation using navigation based on an intraoperative cone beam CT imaging system: a prospective randomized clinical trial

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### Abstract

Purpose Spine surgery still remains a challenge for every spine surgeon, aware of the potential serious outcomes of misplaced instrumentation. Though many studies have highlighted that using intraoperative cone beam CT imaging and navigation systems provides higher accuracy than conventional freehand methods for placement of pedicle screws in spine surgery, few studies are concerned about how to reduce radiation exposure for patients with the use of such technology. One of the main focuses of this study is based on the ALARA principle (as low as reasonably achievable).

Method A prospective randomized trial was conducted in the hybrid operating room between December 2015 and December 2016, including 50 patients operated on for posterior instrumented thoracic and/or lumbar spinal fusion. Patients were randomized to intraoperative 3D acquisition high-dose (standard dose) or low-dose protocol, and a total of 216 pedicle screws were analyzed in terms of

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screw position. Two different methods were used to measure ionizing radiation: the total skin dose (derived from the dose–area product) and the radiation dose evaluated by thermoluminescent dosimeters on the surgical field.

Results According to Gertzbein and Heary classifications, low-dose protocol provided a significant higher accuracy of pedicle screw placement than the high-dose protocol (96.1 versus 92%, respectively). Seven screws (3.2%), all implanted with the high-dose protocol, needed to be revised intraoperatively. The use of low-dose acquisition protocols reduced patient exposure by a factor of five.

Conclusion This study emphasizes the paramount importance of using low-dose protocols for intraoperative cone beam CT imaging coupled with the navigation system, as it at least does not affect the accuracy of pedicle screw placement and irradiates drastically less.

Keywords Cone beam CT - Intraoperative imaging - Radiation exposure - Dose reduction strategies - Pedicle screws

# Introduction

In spine surgery, a correct pedicular screw position is of paramount importance for every surgeon. A misplaced pedicle screw may lead to pain, neurological or vascular damage, and sometimes requires reinterventions [\[1](#page-8-0), [2](#page-8-0)]. Imaging technologies have improved over the years to enhance accuracy in inserting implants. One of the latest evolving technology in spinal surgery is a combination of an intraoperative three-dimension imaging system with an optokinetic navigation [\[1–3](#page-8-0)]. Hybrid operating rooms equipped with such technology offer a double advantage. The first is to provide an intraoperative CT-like data set

<span id="page-1-0"></span>which can be directly combined with optokinetic navigation station, avoiding the need of preoperative CT for the volume registration as well as the need of performing a surface matching during the surgery. The second is to perform an intraoperative CT scan after screw placement to check the implants' positions, giving the possibility to the surgeon to reposition the screw if necessary  $[1, 4-6]$  $[1, 4-6]$ . Recently, several studies using intraoperative 3D imaging and navigation have shown higher accuracy in the placement of pedicle screw than conventional freehand methods  $[7-13]$  $[7-13]$ . The main drawback of such imaging surgical systems is an additional radiation exposure compared to conventional techniques [\[5](#page-8-0), [14](#page-9-0), [15](#page-9-0)]. A new intraoperative cone beam computed tomography (CBCT) imaging device, which is a robotic interventional angiography system (Artis zeego, Siemens Healthcare, Forchheim, Germany), has been used successfully for spine surgery [\[16](#page-9-0), [17\]](#page-9-0). A recent preliminary study [[18\]](#page-9-0) assessed radiation exposure for patients during spine surgery using this technology and demonstrated a threefold dose reduction only by changing the intraoperative 3D acquisition protocol. Dose reduction is of paramount importance in spine surgery. but it remains unclear if it would have an impact on the accuracy of screw placement. In this study, we randomized patients operated on for thoracic or lumbar spinal fusion to high-dose protocol or low-dose protocol for intraoperative 3D acquisition. The first aim of this trial was to compare pedicle screw placement between the two protocols. The second purpose was to compare the radiation dose imparted to patients by varying in the acquisition protocol.

## Materials and methods

#### Study design

We designed a prospective randomized trial in the hybrid operating room at a university hospital accustomed to spine surgery between December 2015 and December 2016. The research was approved by the Hospitalo-Facultary Ethics Committee (N0. B4403201523492). All patients recruited for this study had to fulfill the following inclusion criteria: age older than 15 years, posterior thoracic and/or lumbar spinal instrumentation for degenerative, traumatic or tumoral indications, and signed an informed consent to participate in this study. All eligible patients agreed to participate. Patients with a diagnosis of scoliosis were excluded because it is required in such cases to perform multiple CBCT for navigation (one CBCT is able to cover 4–5 levels). Data collection included radiation parameters (i.e., dependent variables, Table 1) and other parameters related to the patient, the surgery and the intraoperative imaging system (i.e., independent variables, Table 2).



Table 2 List of independent variables investigated

Patient's factors
Age (years)
Sex
BMI $(kg/m^2)$
Surgery's factors
Surgical approach
Open surgery
Minimally invasive surgery
Operative time (min)
Level of instrumentation
Thoracic T1-T10
Thoracolumbar T10–L2
Lumbar
Surgical technique
Central decompression
Foraminal decompression
Durotomy
Number of pedicle screws (no.)
Surgical technique
Central decompression
Foraminal decompression
Durotomy
Fusion method: no fusion
Postero-lateral fusion (PLF)
Posterior lumbar interbody fusion (PLIF)
Transforaminal lumbar interbody fusion (TLIF)
Intraoperative imaging system parameters
Fluoroscopy time (min)
Scan protocol
6sDCT body (high dose)
5sDR body (low dose)
Number of CT scans during surgery (no.)
6sDCT body (high dose)
5sDR body (low dose)

Patients were randomized to intraoperative 3D acquisition high-dose or low-dose protocol. The randomization scheme was generated by using Statistical Package for the Social Sciences (SPSS) version 20 software package. Three experienced orthopedic spine surgeons performed the procedures.

# CBCT imaging technique

The intraoperative CBCT imaging system is a floormounted multi-axis robotic C-arm system (Artis zeego, Siemens Healthcare, Forchheim, Germany), rotating around the target spinal region and acquiring repeated images during the orbital scan around the isocenter [[6\]](#page-8-0) (Fig. [1](#page-3-0)). Numerous 2D fluoroscopy images are reconstructed into a 3D volume of the spine, thereby creating a CT-like data set available for the navigation system [[6,](#page-8-0) [19\]](#page-9-0). Patients were randomized in terms of 3D volume registration between a protocol that acquires 397 projection images during 6 s (high dose) and a protocol that acquires 133 projection images during 5 s (low dose). All patients were positioned prone on a spinal surgery foam cradle throughout the surgical intervention. Patient and C-arm were covered with custom-fit sterile drapes. Four thermoluminescent dosimeters (TLD, type TLD 100, Harshaw/Bicron, OH, USA) (Fig. [2](#page-3-0)) were sterilely packed and positioned on the patient at a specific location: one TLD (left TLD) on the left lateral side of the patient and another (right TLD) on the right lateral side at the level of the operation wound, one TLD (posterior TLD) on the back of the patient nearest the surgical wound and another (anterior TLD) which was fixed below the operating table at the anterior projection of the wound level. A fifth TLD (control TLD) was placed outside the operating room to account for the background radiation. The 3D data set was automatically transferred to the workstation (Syngo X Workplace, Siemens Healthcare, Forchheim, Germany) and displayed in the form of multiplanar reconstructions. After implant positioning, all TLDs were removed outside the operating room, so they measured only radiation from the low- or highdose protocols for 3D acquisition, regardless of radiation from control CBCT. All patients underwent a final control intraoperative CBCT scan with high-dose protocol before wound closure to evaluate pedicle screw positioning. Each screw was analyzed in the axial, coronal and sagittal views by scrolling over the screen. If a screw was misplaced and needed to be revised, a third 3D CT-like scan was performed to confirm the final intraoperative implant position.

#### Assessment of pedicle screw placement

Primary end point of this study was to compare pedicle screw placement by varying the 3D acquisition protocol. Three orthopedic surgeons independently assessed the placement of pedicle screw, according to the Gertzbein and the Heary classifications [\[20](#page-9-0), [21\]](#page-9-0). The final implant position was defined as an agreement between at least two of the three judges. In case of complete disagreement, screws were reviewed and their final screw positions were determined by consensus between the three judges. Both classifications were complementary and are summarized in Tables [3](#page-4-0) and [4.](#page-4-0) The Gertzbein scale grades cortical breaches by the extent of extracortical screw violation. The grade 0 defines cases in which a screw was perfectly located in the pedicle without cortical breach, whereas higher grades are assigned in breach distances of multiples of 2 mm, where distance is measured from the medial border of the pedicle [[20,](#page-9-0) [22](#page-9-0)]. The main drawback of this grading system is that it only assesses the degree of medial spinal encroachment, as lateral, superior and inferior breaches are not included in the classification. This is why we used the Heary classification that takes into account medial, lateral, anterior and inferior breaches [[21\]](#page-9-0).

#### Intraoperative radiation measurement

Concerning dependent variables (Table [1\)](#page-1-0), two radiation parameters were used: the total skin dose (SD) and the radiation dose evaluated by four TLD positioned on the patient. The peak skin dose (PSD) estimates the probability of occurrence of deterministic effect. The deterministic effect is defined as a cause and effect relationship between radiation and some side effects that appear beyond a certain threshold (e.g., risk to skin). The PSD is the highest dose at any portion of patient's skin during a procedure. The PSD takes into consideration both the primary X-ray beam and the scatter radiation, and is measured in mGy [\[23](#page-9-0), [24](#page-9-0)]. Unfortunately, there is no currently available method to measure or calculate PSD in real time and this parameter must be estimated. SD is the dose at a defined reference point, which is located along the central axis of the X-ray beam at a distance of 15 cm from the isocenter toward the source. Its value is derived from the dose–area product which is measured at the level of the tube diaphragms by an ionization chamber. The SD, measured in mGy, is usually an estimation of the PSD, but it does not account for beam motion, patient size and position and the backscatter. TLDs are another estimation of the radiation dose applied to the patient since they are placed on the patient's skin at four specific locations. They are measured in mGy. They

<span id="page-3-0"></span>

Fig. 1 The intraoperative CBCT imaging system Artis zeego



Fig. 2 Intraoperative images: a the reference arc of the navigation was attached to the spinous process. The desired entry point was punctured with an awl. The arrow indicates the TLD positioned on

provide an accurate measurement of the skin dose at the locations that they are positioned, taking into account the anatomy of the patient and the backscatter. TLDs generally underestimate PSD as they cover only four reference points, so it would be unlikely for a single TLD to be placed in the area with the highest dose of radiation. Concerning independent variables, we registered many radiation parameters (Table [2\)](#page-1-0). The fluoroscopy time (FT)

the left side of the patient. b Image of TLD before being sterilely packed and positioned on the patient

is defined as the total time of fluoroscopy used during the procedure and is measured in minutes [[23\]](#page-9-0). These data were collected from the ''Exam Protocol'', which is an excerpt of X-ray Radiation Dose Structured Report. Surgical interventions were performed with significantly reduced or even absent radiation exposure to the surgeon and operating room personnel, since all medical staff went out of the operating room during 3D acquisitions.

<span id="page-4-0"></span>Table 3 Gertzbein classification

Grade	Breach distance
$\Omega$	$0 \text{ mm}$ (no breach)
	$<$ 2 mm
$\overline{2}$	$2-4$ mm
3	$>4$ mm
	$>6$ mm or other breach

Table 4 Heary classification



## Statistical analysis

A priori sample size determination was performed using G\*Power (v 3.0.10, Erdfelder, Faul, & Buchner, 2008) given  $\alpha = 0.05$ ,  $\beta = 0.2$  and a small effect size ( $w = 0.2$ ). Post hoc test was performed to compute the achieved power of the study. To explore the data, we performed a univariate and bivariate analysis and then focused on inference and modeling. For continuous variables, their normal distribution was tested using a Kolmogorov– Smirnov test and consequently presented in terms of mean (standard deviation) or median (25th–75th percentile). The effect of randomization of the independent variables was tested to ensure group equivalency using Student's  $t$  and Chi-squared tests. For implants positions, reliability analysis of the inter-rater agreement was performed using intraclass correlation. Contingency tables were constructed to account for implants positions in the two groups. Independence between variables was assessed by Fisher's exact test, as the assumption of the number of cases per cell in the contingency tables was not fulfilled. The statistical modeling for radiation dose was based on a linear regression model with forward stepwise method which met conditions of the absence of multicollinearity and independence of errors and approached a studentized distribution of residues. All statistics were performed using SPSS software (v.20, SPSS, Inc., Chicago, IL, USA).

# Results

Within 13 months, a total of 216 pedicle screws were implanted in 50 patients who underwent posterior thoracic and/or lumbar spine navigated instrumentation with the



Table 5 Study parameters

Bold for a non gaussian distribution according to Kolmogorov– Smirnov test

CBCT intraoperative imaging system. The underlying pathologies were degenerative disease  $(n = 43)$ , trauma  $(n = 6)$  and malignancy  $(n = 1)$ . Patient data are summarized in Table 5. Due to randomization, no significant differences were found between the two groups (low and high dose) in terms of patient's factors (age, sex, body mass index) and operative factors (surgical approach, operative time, surgical technique) (Table [6\)](#page-5-0). There were no significant differences of the instrumented thoracic, lumbar or sacral levels between both protocols, which were from T1 to S1 ( $p = 0.894$ ). Concerning the surgical procedure, there were 33 (66%) central decompressions, 21 (42%) foraminal decompressions and 3 (6%) incidental durotomies.

## Assessment of placement of pedicle screw

The inter-rater reliability was adequate with an intraclass correlation of 0.869 and 0.850 for the Gertzbein and Heary classifications, respectively, translating into an excellent agreement between the three orthopedic spine surgeons. Of

<span id="page-5-0"></span>Table 6 Comparison of parameters between the two protocols

	Low-dose protocol $(n = 23)$	High-dose protocol $(n = 27)$	$\boldsymbol{p}$
Age (mean, years)	61.9	59.1	0.522
Sex (male/female)	10/13	12/15	0.945
BMI (median, $\text{kg/m}^2$ )	26.73	28.18	0.252
Surgical approach (no.)			
Open surgery	22	26	0.908
Minimally invasive surgery	1	1	
OT (mean, min)	199.5	219.9	0.142
Level of instrumentation (no.)			
Thoracic	1	2	0.894
Thoracolumbar	$\overline{c}$	2	
Lumbar	20	23	
Surgical technique (no.)			
Central decompression	14	19	0.557
Foraminal decompression	7	14	0.158
Durotomy	$\Omega$	3	0.240
Fusion method	5	5	0.111
No fusion	8	3	
PLF	7	9	
PLIF	3	10	
TLIF			

216 pedicle screws placed, 199 (92%) were found in a correct position, namely grade 0 of the Gertzbein classification and grade 1 of the Heary classification (Table [7\)](#page-6-0). An inaccurate position of the screw was determined by either a grade  $>0$  in the Gertzbein classification or a grade  $>1$  in the Heary classification. There was a significant difference for the accuracy in pedicle screw placement between the two protocols ( $p = 0.046$ ). Of 216 implanted screws, 102 were placed with the low-dose protocol. 98 screws (96.1%) were in a correct position and 4 (3.9%) were in an inaccurate position (Table [8](#page-6-0)). 114 screws were inserted with the highdose protocol (101 screws (88.6%) were in a correct position and 13 (11.4%) were in an inaccurate position). Seven screws (3.2%), all implanted with the high-dose protocol, needed to be revised intraoperatively (Table [9](#page-6-0)). Thoracic level was the most frequent location of inaccurate screw placement (20%) followed by sacral (5.6%) and lumbar levels (5.1%), respectively. There was no association between screw placement and side (left or right) of screws implanted ( $p = 1.00$ ) as well as between screw placement and spine surgeon ( $p = 0.732$ ).

#### Intraoperative radiation measurement

If in our findings, low-dose protocol did not increase the risk of misplaced pedicle screw, how much reduction in the radiation dose imparted to patients can the surgeons expect? There is consistency between the two measures (SD and TLD) in estimating the radiation dose, as a regression highlighted the linear association between them with an *R*-square of 0.863. Considering that TLD may underestimate the effective radiation exposure dose while the SD may overestimate it, there is an interval in which the effective radiation dose imparted to patients is approximated. Even if SD and TLD are two estimations of the PSD, their linear association makes comparison between two protocols in terms of radiation exposure possible. Discrepancy between the two measures could be explained as the imaging system rotates around the isocenter for the acquisition of the frames, following an orbital range of the gantry of 178°, so the left TLD received the maximum exposure during the beam motion, followed by the anterior TLD. Taking into account SD or TLD, we found a fivefold dose reduction with the use of the lowdose protocol. Considering the surgeon's point of view, we created a regression model predicting SD by using all patients and surgery-related factors ( $R^2 = 0.818$ ). Two main parameters accounted for most of the variance explained by the model: the protocol and the BMI. These findings impressively underline the paramount importance of using low-dose protocols since BMI cannot be changed.

# **Discussion**

Each spine surgeon recognized the importance of accuracy of pedicle screw placement and the potential serious outcomes of misplaced instrumentation of the spine. Imaging

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

Gertzbein						
	No breach	$<$ 2 mm	$2-4$ mm	$>4$ mm	Extrapedicular or other breach $>6$ mm	
Heary						
No breach	199	0	0	$_{0}$	0	
In out in	$_{0}$	$\theta$	0	0		
Ant or lat in vertebral body		$\theta$	0	$\theta$		
Inf or med pedicular breach	0			$_{0}$		
Needing immediate removal			$\Omega$			

Table 8 Low-dose protocol: pedicle screw placement according to Gertzbein and Heary classifications (% of screws)

Gertzbein							
	No breach	$<$ 2 mm	$2-4$ mm	$>4$ mm	Extrapedicular or other breach $>6$ mm		
Heary							
No breach	96.1%	$0\%$	$0\%$	$0\%$	$0\%$		
In out in	$0\%$	$0\%$	$0\%$	$0\%$	$0\%$		
Ant or lat in vertebral body	$1\%$	$0\%$	$0\%$	$0\%$	$0\%$		
Inf or med pedicular breach	$\theta$	$0.9\%$	$0\%$	$0\%$	$0\%$		
Needing immediate removal	$0\%$	$0\%$	$0\%$	$0\%$	$0\%$		

Table 9 High-dose protocol: pedicle screw placement according to Gertzbein and Heary classifications (% of screws)



technologies have improved over the years to enhance accuracy in inserting implants, most recently with the use of an intraoperative three-dimension imaging systems with an optokinetic navigation. Even if many studies [[4,](#page-8-0) [7–12\]](#page-8-0) have emphasized such technologies, showing higher accuracy in the placement of pedicle screw than conventional freehand methods, only one recent study [[18\]](#page-9-0) assessed radiation exposure to the patient with the Artis Zeego technology during spine surgery. In our prospective randomized trial, two purposes were followed, always bearing in mind the attempt to decrease radiation exposure. Due to randomization of 50 patients operated on for thoracic or lumbar spinal fusion in two groups (low-dose and high-dose protocols for 3D acquisition), we could compare pedicle screw placement between both protocols, which consisted in the first aim of our study. Even if there has been an amount of published data regarding how best to interpret pedicle screw cortical breaches, it is important to point out that the evaluation of accuracy of the pedicle screw still remains difficult due to differing interpretations

<span id="page-7-0"></span>





Fig. 3 Axial reconstructions of 3D volume acquisition. a High-dose protocol, b low-dose protocol

of misplacement or breach, combined with different evaluation methods (radiograph or CT scan) [\[4](#page-8-0), [11](#page-8-0), [22](#page-9-0), [25–27](#page-9-0)]. Therefore, we used two grading scales (Gertzbein and Heary classifications), complementary and currently used, to assess pedicle screw placement [\[20](#page-9-0), [21](#page-9-0)]. Each screw was verified with an intraoperative 3D CBCT with high-dose protocol. Considering that a correct position is a grade 0 of the Gertzbein classification and a grade 1 of the Heary classification, 92% of screws were correctly positioned in our study. Costa et al. [[4\]](#page-8-0) in a retrospective study compared preoperative CT scan with intraoperative O-arm CT scan in terms of pedicular screw placement. They found, after the analysis of 11,144 screws, an accuracy of 96.1 and 98.5%, respectively. Because screws with a cortical violation less than 2 mm were thought to have neither clinical nor mechanical differences with a screw without perforation, the accuracy was defined by a Gertzbein grade 0 OR grade 1. Using both classifications, we considered more screws as misplaced than some previous studies using only one classification [\[1](#page-8-0), [2](#page-8-0), [4,](#page-8-0) [7,](#page-8-0) [10,](#page-8-0) [28–31\]](#page-9-0). However, our results were consistent with the literature (Table 10). We could find an agreement with Parker et al. [[32\]](#page-9-0) who demonstrated that breach occurred more frequently in the thoracic than the lumbar spine (2.5 and 0.9%, respectively;  $p \lt 0.0001$ ), most likely because lumbar vertebrae have much larger pedicles than thoracic vertebrae. This last ascertainment

<span id="page-8-0"></span>illustrates the added difficulty in comparing previous studies on the accuracy rates of pedicle screws, as results are influenced by the relative proportions of instrumented levels [4, [22\]](#page-9-0).

Surprisingly, while it is obvious for surgeons that the 3D volume obtained with the low-dose protocol is of lower quality than the images acquired with the high-dose protocol (133 projection images for the low dose versus 397 projection images for the high dose) (Fig. [3\)](#page-7-0), we found that the low-dose protocol provided a significant higher accuracy of pedicle screw placement than the high-dose protocol. After a thorough analysis of possible biases, it was not possible to find, at this stage, any explanation for this discrepancy. The study design was made with the intention of comparing two acquisition protocols but it remains a non-inferiority study. In keeping with this finding, the lowdose protocol is, if not better, as good as the high-dose protocol.

The second aim of our study was to estimate radiation exposure for patients. On the first hand, we used two different methods measuring ionizing radiation (SD and TLD), and the collected data could barely approximate the proper radiation imparted to the patients. On the other hand, data could be used to produce reliable analysis in terms of inter-group comparison (low- versus high-dose protocols). Gebhard et al. [[33\]](#page-9-0) used TLD and showed a clear reduction of intraoperative radiation by using CT or C-arm-based computer-assisted surgery compared to the standard procedure. The same conclusion was made by Villard et al. in their prospective study comparing navigation versus image-guided procedures [\[13](#page-9-0)]. Previous studies [[18,](#page-9-0) [34\]](#page-9-0) emphasized the paramount importance of choice of the scan protocol, allowing a reduction of radiation exposure by a factor of 3–13. In our study, we demonstrated fivefold dose reduction by comparing only low- and high-dose protocols for 3D acquisition, regardless of the total radiation exposure (with a final CBCT control). Our data are therefore consistent with the literature, highlighting the importance of using a low-dose protocol for posterior thoracolumbar spinal surgeries.

## Conclusion

In spine surgery, the use of intraoperative CBCT and navigation systems improves the accuracy of pedicle screw placement, but increases patients' radiation exposure in return. One of the main focuses of this study is based on the ALARA principle (as low as reasonably achievable). We recommend the use of low-dose protocol for intraoperative 3D acquisition, as it does not affect the accuracy of pedicle screw placement and because it is able to drastically decrease the radiation dose imparted to the patients. In keeping with this finding, it might be suggested to perform a final intraoperative 3D CT scan with the low-dose protocol (and not with the high dose as currently performed) to evaluate the final implant position.

#### Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

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