



Accuracy of imaging grading in comparison to open laminectomy to evaluate pedicle screws positioning

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Study design: Prospective experimental study.

Objective: To compare the accuracy of O-Arm-acquired radiographic and computed tomography (CT) evaluation of thoracic pedicle screw placement with open laminectomy in a simulation laboratory.

Summary of background data: Improving surgical safety and procedural efficiency during thoracic posterior spine instrumentation is essential for decreasing complication rates and possible related risks. The most common way of verifying the position of pedicle screws during the surgical procedure and immediately postoperatively is to acquire intraoperative fluoroscopic images and plain radiographs of the spine, respectively. Laboratory simulated surgery is a valuable tool to evaluate the accuracy of those exams.

Methods: Twenty simulation models of scoliosis from T3 to T7 were instrumented by five spine fellows (total of 200 pedicle screws), followed by radiographic and CT images acquired with the assistance of the O-Arm which were evaluated by three independent raters. A fellowship-trained spine neurosurgeon performed laminectomies on the instrumented levels and assessed pedicle integrity (gold standard).

Results: Forty-eight breaches were identified in the axial direct view after laminectomy. Of those, eighteen breaches were classified as unacceptable. Regarding the sagittal direct view, four breaches were observed, three of which were classified as unacceptable. Overall, both O-arm radiographic and CT evaluations had a significantly high negative predicted value but a low positive predicted value to identify unacceptable breaches, especially in the sagittal plane. The frequency of missed breaches by all three examiners was high, particularly in the sagittal plane.

Conclusion: Postoperative evaluation of pedicle screws using O-arm-acquired radiographic or CT images may underdiagnose the presence of breaches. In our study, sagittal breaches were more difficult to diagnose than axial breaches. Although most breaches do not have clinical repercussions, this study suggests that this modality of postoperative radiographic assessment may be inaccurate.

Level of evidence: 4.

Keywords: Scoliosis, simulation, pedicle screw, navigation, O-arm, screw positioning

Introduction

The presence of misplaced pedicle screws during Posterior Spine Instrumentation (PSI) in patients with adolescent idiopathic scoliosis (AIS) has been widely reported^[1]. In a scoping literature

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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Annals of Medicine & Surgery (2024) 86:199–206

Received 22 August 2023; Accepted 5 November 2023

Published online 17 November 2023

<http://dx.doi.org/10.1097/MS9.0000000000001515>

HIGHLIGHTS

- Postoperative and intraoperative images (radiographs and computed tomography) are the most common way of verifying pedicle screws placement in spine surgeries, including scoliosis.
- This study used surgical simulation models and open laminectomy to compare the accuracy in the evaluation of screw placement via diagnostic imaging examinations in comparison to direct visualization.
- This study demonstrated that diagnostic imaging exams may underdiagnose the presence of breaches seen during pedicle screws placement in the thoracic spine.

review, the rate of screw misplacement after posterior thoracic instrumentation ranged from 5.7 to 50%^[1]. Farber *et al.*^[2] reported computed tomography (CT) scans visualizing pedicle violations ten times more frequently than radiographic assessment.

Patients should be fully aware and informed of the possible risks and complications associated with the surgical procedure,

and physicians are legally and ethically obligated to ensure an accurate informed consent process prior to any surgical procedure^[3], while also offering the best and safest procedures or techniques available for their patients^[4]. One of the main concerns resulting from screw misplacement is the risk of neurovascular complications (0-1%)^[1], which seem to arise when breaches exceed 4 mm, particularly on the medial wall^[1,5].

Several classification methods exist for grading the presence and degree of breach during pedicle screw placement. In our study, we utilize Abul-Kasim *et al.*^[11]'s classification, which is the most accurate and complete classification seen in the literature for breach evaluation.

Many instrumentation techniques have been used during PSI procedures for AIS^[6-10]. The original drilling technique was reported by Roy-Camille in 1986^[11] and has been widely substituted by the freehand pedicle probe technique over the years^[11,12]. Higher screw placement accuracy has been seen when using a guided drilling technique instead of pedicle probe procedures^[13,14]. Peiro-Garcia *et al.*^[15] reported increased accuracy and surgical safety, as well as reduced operative times and transfusion rates, when using combined CT-based navigation and a drill guide for pedicle screw insertion. Moreover, the use of intraoperative navigation has been shown to improve accuracy when placing pedicle screws in comparison to non-navigated techniques^[16-21].

Pedicle screw placement is a skill taught during residency and fellowship years for orthopaedic and neurosurgery^[22,23], with a reported "learning curve" of 60-80 screws^[24,25]. The navigated sequential drilling technique appears to have a shorter "learning curve" with increased accuracy of screw placement and high technique reproducibility among fellows^[15]. The use of surgical simulation laboratory is a valuable teaching tool for surgical procedures in orthopaedic setting^[15,26,27].

The aim of this study was to compare the radiographic and CT assessments of pedicle screw placement on AIS models on the images obtained with the O-Arm with direct visualization (gold standard).

Materials and methods

After obtaining ethical approval and informed consent, five spine fellows (three orthopaedic surgeons and two neurosurgeons) performed PSI on 20 simulation spine models (AIS TruTrainer, Artisan Medical Displays). In each model, 10 5.0 × 35 mm CD Horizon Legacy (Medtronic) pedicle screws were placed from T3 to T7. Two hundred pedicle screws were instrumented using four different surgical techniques [freehand pedicle probe (FH-P), freehand guided drilling (FH-D), navigated pedicle probe (N-P), and navigated sequential drilling (N-D)].

Prior to the experiment, all participants received detailed teaching of all four techniques through an institutional video. A questionnaire was also administered to identify the skills and training levels of all subjects (Table 1).

Operative technique

The on-site simulation laboratory was located in an operating room at our tertiary children's hospital (Figs. 1, 2, and 3). The aim of the simulation laboratory in our service is to replicate the surgical techniques used in real AIS surgeries as accurately as possible. All experiments were standardly prepared and monitored by one of the investigators, using the same equipment and setup for all participants.

Table 1

Training level of the spine fellows.

	Number, n (%)
Training	
Orthopaedic surgery	3 (60)
Neurosurgery	2 (40)
Previous experience with scoliosis surgery	
Low	1 (20)
Moderate	2 (40)
High	2 (40)
Previous experience with thoracic pedicle screw instrumentation	
Low-moderate	1 (20)
Moderate-high	4 (80)
Previous experience with guided drilling technique	
Yes	2 (40)
No	3 (60)
Previous experience with freehand technique	
Yes	4 (80)
No	1 (20)
Previous experience with navigation technique	
Yes	4 (80)
No	1 (20)

Spine models were positioned on a standard operating table (Mizuho OSI Modular Table System) using a four-square drape and two self-retaining retractors (Fig. 1). The same investigator who prepared the experiments also assisted with the passive role of handling the instruments requested by the participants.

Radiological and direct visualization evaluation

At the end of each experiment, radiographic images of the anteroposterior and lateral views as well as axial and sagittal CT were obtained using an O-arm and StealthStation S7 (O-arm O2 Imaging System with software version 4.2.x, Medtronic Navigation, CO) operated by a certified radiology technician (Fig. 2, Fig. 3). For each experiment, the equipment acquired images at 30 frames per second, capturing approximately 391 projections in high resolution.

Subsequently, a fellowship-trained spine neurosurgeon performed laminectomies in all instrumented models (Fig. 4) and graded pedicle integrity according to the Abul-Kasim *et al.* classification (Fig. 5).

Three independent senior spine surgeons (blinded to the surgical procedure and participants) used a high-definition software to review and grade all radiographic and CT images obtained after screw placement. These results were compared with the grading obtained after open laminectomy.

The Abul-Kasim and colleagues classification grades cortical perforation as partial or complete and the location as lateral, medial, anterior, cranial, or caudal margins of the pedicle (Fig. 5). Pedicle screws classified into categories C, F, G, H, I, and K were considered unacceptable.

The data obtained was analyzed using Python and IBM SPSS Statistics Version 26.

Results

In total, the participants instrumented 200 pedicles, with 48 breaches seen on direct inspection of the axial direct view. From

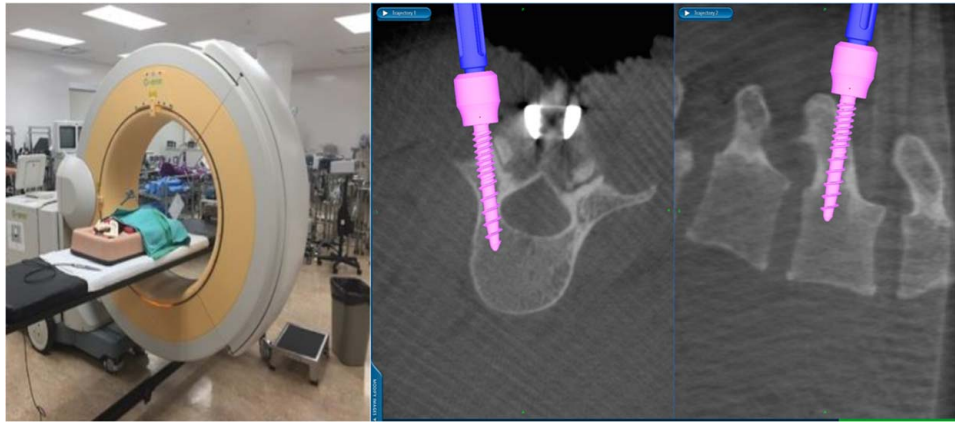


Figure 1. On-site simulation laboratory setup including model placement and O-Arm, and navigation images obtained intraoperatively.

those 48, 18 were classified as unacceptable (C, F, G, H, and I) based on the open laminectomy results. Moreover, four breaches were visualized using the sagittal direct view, three of which were classified as K (unacceptable) (Table 2). For the purposes of this study, breaches were deemed to occur if they fell into the “unacceptable” category. The frequency of missed breaches by the examiners in comparison to the gold standard is shown in Table 3. Most breaches (95%) were observed at T4 on the right side, corresponding to the apical pedicle of the proximal thoracic curve, on the concave side.

During the statistical analysis, χ^2 value was used to examine whether there were statistically significant differences between the counts of the two groups. Fisher’s exact test was used when the expected count of one or more cells was less than five. *P* value of less than 0.05 was considered statistically significant at a 95% CI.

The analysis also evaluated the accuracy, sensitivity, specificity, positive predictive value (PPV) and negative predicted value (NPV) of screw placement correct classification by the examiners.

Table 4 show the statistical metrics when comparing examiner image-based grading to the gold standard.

A significant *p* value (<0.05) was only observed when comparing Examiner 3’s grading on the AP radiographic view and Examiner 1’s grading on the CT axial view. Although a significant *p* value was presented, the 95% CI for both results was

extremely wide, demonstrating a lack of precision in these results and the need for further statistical analyses to confirm these findings.

As seen in the results presented above, the overall grading accuracy of the examiners ranged from 88 to 99% in all radiological views when compared with the open laminectomy results.

Furthermore, one of the most notable results was the sensitivity and PPV equal to zero, and the frequency of 100% missed breaches by all examiners in the O-arm-acquired radiographic lateral view and computed tomography sagittal view. Moreover, this study presented a high NPV (ranging from 0.95 to 1) and specificity (ranging from 0.91 to 0.98).

Discussion

The low sensitivity and high PPV observed in the O-arm-acquired radiographic lateral view and CT sagittal view demonstrate that all unacceptable breaches (3) in the lateral planes were missed by the examiners, independent of the diagnostic imaging technique used. When observing the grading classification, we appreciate that the axial plane is three times more specific regarding screw placement than the sagittal plane, and we believe that the examiners might have considered minor breaches in the sagittal plane acceptable during the evaluation. Moreover, we decided to



Figure 2. AP and lateral radiographic view of sawbones post instrumentation.

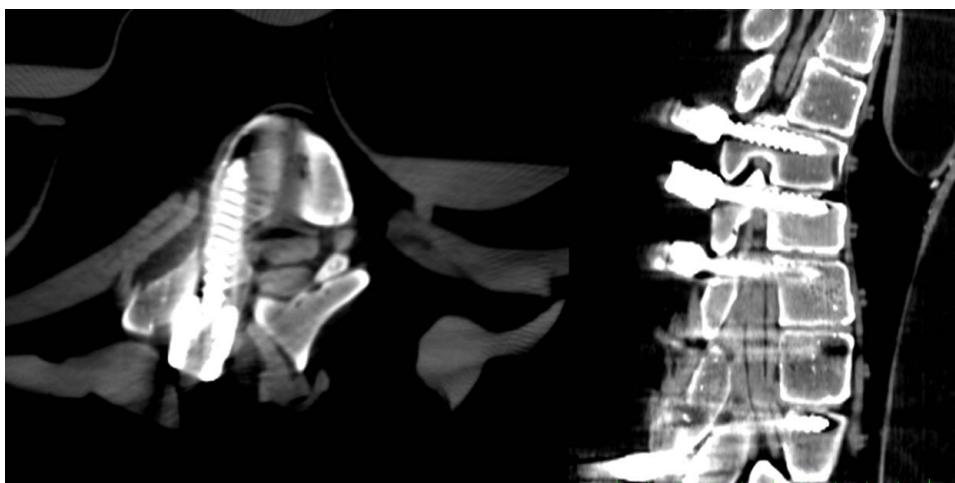


Figure 3. Axial and Sagittal view of sawbones post instrumentation.

analyze the relationship of every screw in every individual view, as performed by Abul-Kasim and colleagues in two previous studies where this grading classification was also applied^[1,28], to better visualize and describe all possible breaches in each radiographic and tomographic view.

Furthermore, the high NPV and specificity seen in our results could demonstrate either a high capacity to identify correctly placed screws by the examiners in all images and planes analyzed, or simply reflect the incidence of correct screw placement during our experiment.

Findings of this study suggest that there is no statistically significant difference between the postoperatively O-arm-acquired radiographic and CT images for the evaluation of pedicle screw placement, and both examinations can underdiagnose the presence of unacceptable breaches when compared to our gold standard. When correlating our results with previously published data, some studies described that standard CT scans might be more accurate than plain radiographs when both examinations are performed postoperatively^[28–32], which disagrees with our

findings. However, those studies were performed in live patients and used standard CT after a surgical procedure instead of O-Arm images and did not have the ability to perform an open laminectomy as the gold standard for comparison. Moreover, we should consider the possibility of different quality and resolution in the images obtained from surgical spine models compared to those obtained from real patients, including the presence of artifacts (such as surgical hardware) and possible patient mobilization during image acquisition, which would probably interfere with image resolution and the accuracy of the exam.

Pedicle screw malposition is one of the most common complications observed in the thoracic spine after surgical correction of deformities^[19,20,31], including in paediatric patients^[33].

Previous research compared the accuracy of standard CT to direct visualization in cadaveric spine specimens, stating that CT is the most accurate and valid radiological method to assess screw placement^[34], but it tends to overestimate the number of misplaced screws^[35]. This result disagrees with our findings, representing an underestimation of breaches. However, simulation

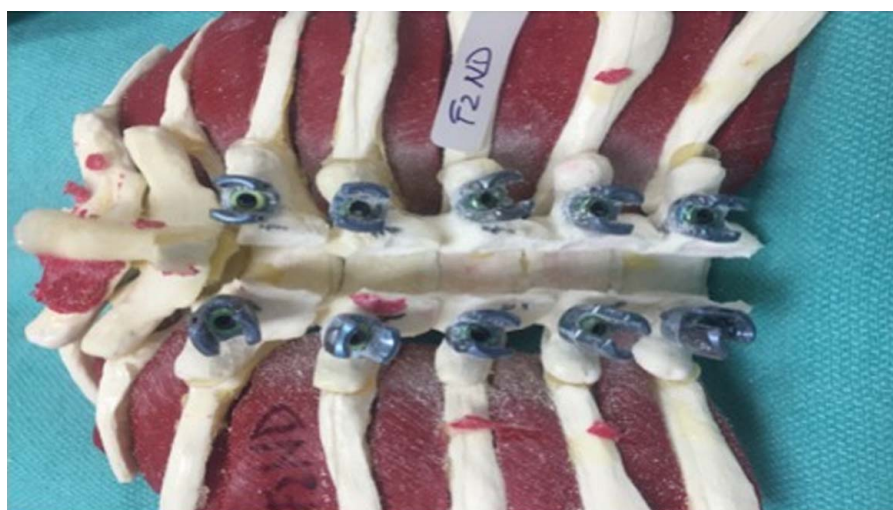


Figure 4. Spine instrumented model after the performance of open laminectomy in order to classify screw placement via direct visualization.

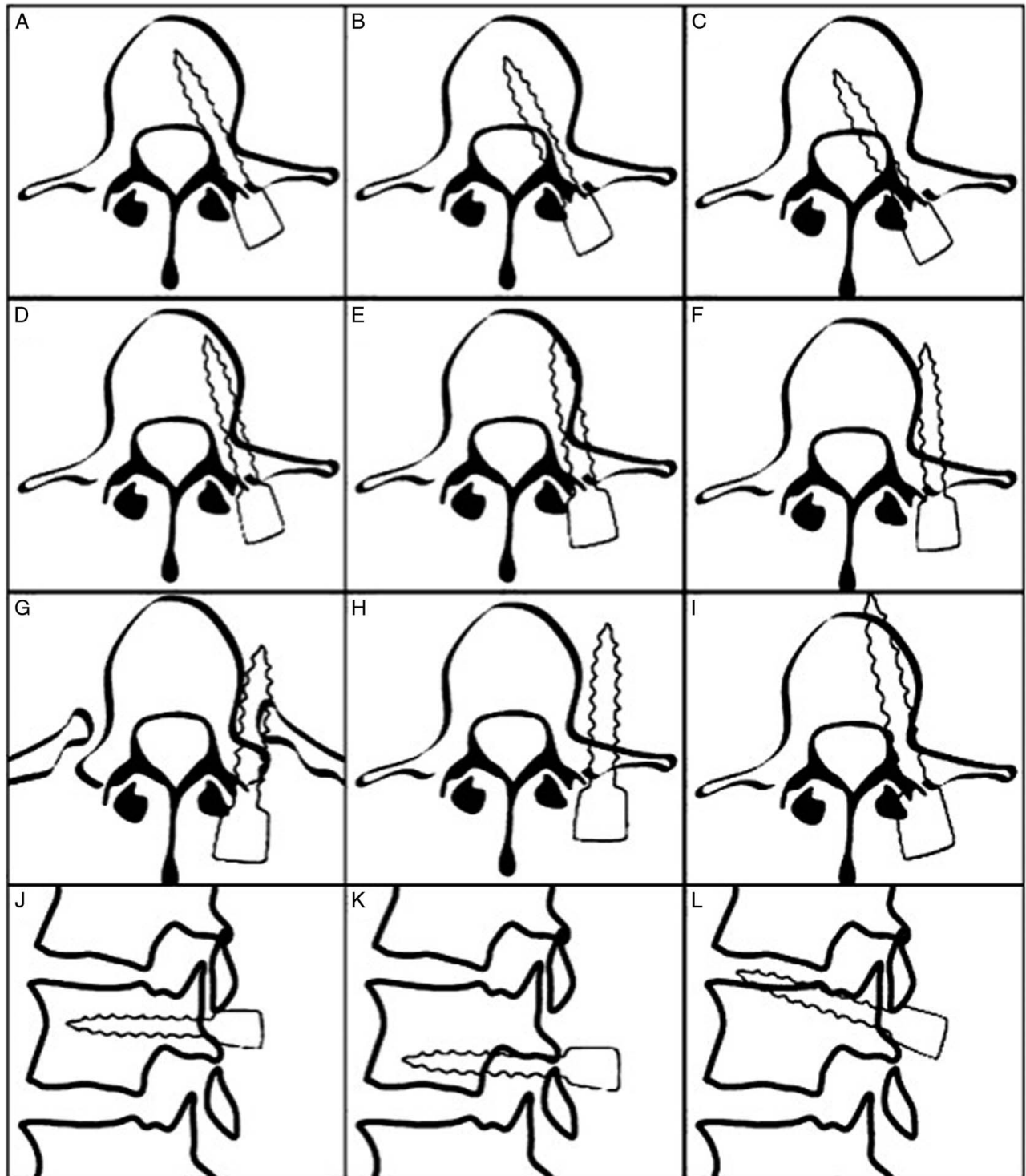


Figure 5. Abul-Kasim *et al.* classification for spine screw placement in both AP and Lateral views.

models are made of sawbones that are not capable of expanding as regular human bones, possibly influencing the number of breaches seen in our study. Moreover, spine models may not fully represent the multiple anatomical and deformity variabilities seen in patients, which might contribute to the discrepancy in findings seen between our study and the literature.

The literature illustrates the significant contribution of implementing navigated techniques in screw placement and their accuracy when compared to non-navigated techniques, especially in cases where surgical complexity increases^[16–21]. A randomized clinical study performed in humans by Rajasekaran and colleagues evaluated the placement of 478 thoracic pedicle screws in 33

Table 2**Summary of total breaches seen during visualization of gold standard.**

	Axial view	Sagittal view
Unacceptable breaches	18	3
Total breaches	48	4

Table 3**Proportion of missed breaches using diagnostic imaging as compared to visualization as gold standard.**

	Examiner 1 (%)	Examiner 2 (%)	Examiner 3 (%)
Xray AP	97.9	68.8	81.3
Xray lateral	100	100	100
CT axial	66.7	70.8	47.9
CT sagittal	100	100	100

AP, anterior to posterior radiographs; CT, computed tomography.

patients with scoliosis or kyphosis, which was performed under navigation or fluoroscopy control by an experienced surgical team. This study reported 23% of breaches in the non-navigated group using 2 mm grading postoperative CT-scan images in comparison to 2% in the navigation group. In contrast, Chan *et al.*^[32,36,37] published a systematic review and meta-analysis illustrating moderate evidence of the superiority of the CT-navigated procedure over freehand methods when observing the presence of breaches.

A meta-analysis performed by Liu *et al.*^[38] reviewed 579 patients, demonstrating that the accuracy of intraoperative image acquisition via O-Arm navigation was higher than the 2 mm grading CT-scan image criteria ($P = 0.02$). However, when comparing the difference in accuracy between these two measurement methods, no significant difference was observed when using the 0 mm CT-scan grading criteria ($P = 0.34$). Furthermore, this study described intraoperative O-arm navigation as an important tool for decreasing the incidence of pedicle perforation

during spinal surgery. The use of O-Arm navigation provides multiple benefits to patients and surgeons, including improved accuracy of hardware placement, lower radiation exposure and real-time detailed imaging.

We believe that an on-site simulation laboratory can be a valid tool for training purposes^[26,27], providing an objective way to measure procedures that cannot be performed outside a laboratory. For example, open laminectomy for the direct visualization of pedicle screw placement cannot be performed ethically anywhere else, besides on a simulation laboratory or in cadaveric specimens.

Cadaveric specimens have been used extensively for training purposes^[39]. Nowadays, the use of simulation models can provide a more robust training environment but requires convenient physical location and storage of simulation models. Peiro-Garcia *et al.*^[15] described the positive aspects of a simulation laboratory, which led to a quantifiable teaching method for residents, fellows, and even radiology technicians who operate the O-arm and navigation system.

On a reflexive account, this study raises the hypothesis that some pedicle screw violations that may not be detected with O-arm radiographic views or CT-scan images can potentially be a source of pain and discomfort to patients and may be difficult for physicians to diagnose without surgical intervention.

The difference in training between examiners was also analyzed in this study, and no significant difference was observed when comparing the grading given between all three examiners, which allowed us to conclude that the training level of examiners did not influence the results presented.

Conclusion

To the best of our knowledge, this is the first experimental study to compare high-definition O-Arm-acquired radiographic and computed tomographic images with direct visualization after open laminectomy in simulation models. The findings from our study suggest that the postoperative evaluation of pedicle screws via O-Arm radiographs and CT scans underdiagnose the

Table 4**Statistical results seen when comparing examiner image-based grading to the gold standard.**

	<i>p</i>	95% CI	Accuracy	Sensitivity	Specificity	PPV	NPV
Xray AP							
Examiner 1	1	a	0.91	0	0.91	0	1
Examiner 2	0	6.114–195.985	0.93	0.71	0.93	0.28	0.99
Examiner 3	0.001	3.467–83.823	0.92	0.57	0.93	0.22	0.98
Xray lateral							
Examiner 1	a	a	0.98	0	0.98	0	1
Examiner 2	a	0.998–1.033	0.99	0	0.98	0	0.99
Examiner 3	a	a	0.98	0	0.98	0	1
CT axial							
Examiner 1	0.026	1.365–17.694	0.88	0.29	0.92	0.22	0.95
Examiner 2	0	6.114–195.985	0.93	0.71	0.93	0.28	0.99
Examiner 3	0	7.147–110.944	0.92	0.64	0.94	0.39	0.98
CT sagittal							
Examiner 1	1	0.998–1.033	0.97	0	0.98	0	0.98
Examiner 2	1	0.998–1.033	0.98	0	0.98	0	0.99
Examiner 3	a	a	0.98	0	0.98	0	1

^aNo statistics are computed because one group has a constant value.

AP, anterior to posterior radiographs; CT, computed tomography; NPV, negative predicted value; PPV, positive predictive value.

presence of breaches, and that sagittal breaches are more difficult to diagnose than axial breaches in both radiographic and computed tomographic views. No significant difference was observed when comparing the accuracy of identifying breaches using O-arm radiographs to O-arm computed tomography.

Our study demonstrates that both O-arm-acquired radiographic methods have the same chance of missing breaches, and one does not seem to be superior to the other in both the axial and sagittal planes. However, owing to the limitations of simulators and O-Arm-acquired radiographic methods, they may not present the same results as standard radiographs or standard CT scans in humans.

We would recommend that future research in this subject should consider engaging a multidisciplinary team including not only surgeons, but perhaps other medical specialties with significant understanding of spinal procedures post-surgical examinations (such as radiologists), in the assessment of the image accuracy obtained through O-Arm during open laminectomy. This comprehensive evaluation not only strengthens the credibility of research findings but also provides valuable insight of the usability of O-arm-acquired images during surgical procedures.

Although most breaches do not have clinical repercussions for patients, this study suggests that postoperative radiographic assessments can be inaccurate, and imaging findings should always be interpreted with caution.

The main strength of our study was the comparison of images obtained with the assistance of O-Arm (plain radiographs and CT) to open laminectomy (gold standard) in simulation models and to reinforce the need for cautious analysis of postoperative images, independent of the modality of images obtained. Incorporating these discoveries into clinical and surgical practice can empower surgeons to enhance their assessment of pedicle screw placement. This can improve the correlation between imaging outcomes and the patient's clinical presentation, resulting in better standard of care for individuals undergoing spinal procedures.

Ethical approval

Ethical approval for this study (REB15-0652) was provided by the Ethical Committee CHREB of the university of Calgary, on January 19, 202.

Consent

Written informed consent was obtained from the participants for publication and any accompanying images. A copy of written consent is available for review by the Editor-in-Chief of this journal on request.

Sources of funding

The Alberta Children's Hospital Foundation donor funds were received in support of this work. Medtronic contributed to this research by loaning capital instrumentation equipment.

Author contribution

M.R.F.: data collection, analysis, and interpretation, and main responsible for writing the paper. A.P.-G.: study concept and data collection. D.L.P., K.T.: writing revision. F.F.d.B.: study concept and design, data collection and writing revision.

Conflicts of interest disclosure

The authors declare that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

Research registration unique identifying number (UIN)

Our research was done using simulation laboratory models, and not human patients. All the instrumentation and CT-based imaging was performed in laboratory models of scoliosis, and all the data used in this study came from those models. No humans/patients were the subject of our study.

Guarantor

Marina Rosa Filezio.

Data availability statement

All relevant data are within the paper and its Supporting Information files.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Acknowledgement

The authors acknowledge the statistical work of Golpira Elmi Assadzadeh in this manuscript.

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