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Intraoperative anteroposterior and oblique fluoroscopic views for detection of mediolateral pedicle screw misplacement in the lumbar spine: a randomized cadaveric study

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Abstract: BACKGROUD CONTEXT Pedicle screws are commonly used for posterior fixation of the lumbar spine. Inaccuracy of screw placement can lead to disastrous complications. PURPOSE As fluoroscopic assisted pedicle screw instrumentation is the most frequently used technique, the aim of this study was to assess the specificity, sensitivity and accuracy of intraoperative fluoroscopy to detect mediolateral screw malpositioning. We also analyzed whether the addition of an oblique view could improve these parameters. STUDY DESIGN On 12 human cadavers, 138 pedicle screws were placed intentionally either with 0 to 2 mm (75 screws), with 2 to 4 mm (six medial and 12 lateral screws) and with >4 mm (22 medial and 23 lateral screws) breach of the pedicle from Th12 to L5. METHODS Three experienced spine surgeons evaluated the screw positioning in fluoroscopic AP views and 4 weeks later in AP views and additional oblique views. The surgeons' interpretation was compared with the effective screw position on postoperative CT scans. RESULTS Pedicle breaches greater than 2 mm were detected in 68% with AP views and in 67% with additional oblique views (p=.742). The specificity of AP views was 0.86 and 0.93 with additional oblique views (p=<.01). The accuracy was 0.78 with AP views and 0.81 with AP + oblique views (p=.114). There was a substantial inter-reader agreement (Fleiss's kappa: 0.632). CONCLUSIONS Fluoroscopic screening of pedicle screw misplacement has a limited sensitivity. Adding an oblique view improves specificity but not sensitivity and accuracy in detecting screw malpositions. CLINICAL SIGNIFICANCE When in doubt of a screw malpositioning, other modalities than a fluoroscopic assisted pedicle screw instrumentation such as intraoperative CT imaging or an intraoperative exploration of the screw trajectory must be evaluated.

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Basic Science

Intraoperative anteroposterior and oblique fluoroscopic views for detection of mediolateral pedicle screw misplacement in the lumbar spine: a randomized cadaveric study

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Abstract

BACKGROUD CONTEXT: Pedicle screws are commonly used for posterior fixation of the lumbar spine. Inaccuracy of screw placement can lead to disastrous complications.

PURPOSE: As fluoroscopic assisted pedicle screw instrumentation is the most frequently used technique, the aim of this study was to assess the specificity, sensitivity and accuracy of intraoperative fluoroscopy to detect mediolateral screw malpositioning. We also analyzed whether the addition of an oblique view could improve these parameters.

STUDY DESIGN: On 12 human cadavers, 138 pedicle screws were placed intentionally either with 0 to 2 mm (75 screws), with 2 to 4 mm (six medial and 12 lateral screws) and with >4 mm (22 medial and 23 lateral screws) breach of the pedicle from Th12 to L5.

METHODS: Three experienced spine surgeons evaluated the screw positioning in fluoroscopic AP views and 4 weeks later in AP views and additional oblique views. The surgeons' interpretation was compared with the effective screw position on postoperative CT scans.

RESULTS: Pedicle breaches greater than 2 mm were detected in 68% with AP views and in 67% with additional oblique views (p=.742). The specificity of AP views was 0.86 and 0.93 with additional oblique views (p=<.01). The accuracy was 0.78 with AP views and 0.81 with AP + oblique views (p=.114). There was a substantial inter-reader agreement (Fleiss's kappa: 0.632).

CONCLUSIONS: Fluoroscopic screening of pedicle screw misplacement has a limited sensitivity. Adding an oblique view improves specificity but not sensitivity and accuracy in detecting screw malpositions.

CLINICAL SIGNIFICANCE: When in doubt of a screw malpositioning, other modalities than a fluoroscopic assisted pedicle screw instrumentation such as intraoperative CT imaging or an intraoperative exploration of the screw trajectory must be evaluated.

Keywords: Anteroposterior view; Fluoroscopy; Lumbar spine; Oblique view; Pedicle screws; Screw placement

FDA device/drug status: Not applicable.

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Background

Pedicle screw fixation is commonly used in the lumbar spine for degenerative disorders, deformities, traumas, tumors, and infections.

Pedicle screw instrumentation insertion is technically demanding and screw misplacement is a major complication of the posterior fixation of the lumbar spine potentially causing injury to neurovascular structures or biomechanical compromise of the construct.

In recent years, various assisting techniques for safe screw positioning have been introduced in spine surgery such as computer-assisted navigation, intraoperative CT or C-arm [1]. Further examples are robotic-assisted navigation [2], the template-guided instrumentation [3] or augmented reality guided systems [4].

Even if the misplacement rates under navigated systems are significantly lower, the use of navigation systems is associated with high costs, increased operating time and technical difficulties [5] as well as the need for preoperative CT imaging.

Fluoroscopic-assisted pedicle screw instrumentation is therefore still one of the most frequently used techniques in spine centers over the world [6,7] and even if placed with navigation, intraoperative fluoroscopy can be used additionally and very easily to verify a screw position if in doubt.

Purpose

With this study, we aimed therefore to analyze the sensitivity, specificity and accuracy of intraoperative fluoroscopy for detecting pedicle screw malpositions in a cadaveric setting. Additionally, we investigate the diagnostic value of an oblique view in addition to the conventional anteroposterior view.

Methods

Approval by the responsible ethical committee was obtained. The authors declare that the study was performed according to the ethical principles of the Declaration of Helsinki.

Specimens

Twelve adult human cadaveric fresh-frozen spine specimens were obtained from Science Care (Arizona Headquarters, Phoenix, AZ, USA). All human body parts used originate from persons who agreed to the use of body parts before their death for medical education and research purposes.

The spine specimens were prepared to obtain a bilateral exposure of the transverse processes by removing soft tissues and paraspinal muscles. The specimens were stored at −20˚C before the instrumentation.

Preoperative planning of the screw trajectories

Computed tomography (CT) scans (SOMATOM Edge Plus, Siemens Medical Solutions, Erlangen, Germany, slice thickness 0.6 mm, filter: BR62, voltage: 90 kVp) of all specimens were acquired. The CT data was used to digitally plan the screw trajectories using the Medacta Myspine assistance software (Myspine, Medacta SA International SA, Castel San Pietro, Switzerland) to obtain individualized 3D-printed guides. Pedicle screw positions were planned in a randomized fashion either completely within the pedicle (29 screws), with 2 to 4 mm (26 medial and 27 lateral screws) and with >4 mm (27 medial and 29 lateral screws) breach of the pedicle from Th12 to L5.

The diameter of inserted screws was 6 mm in 135 screws and 5 mm in three screws (used for Th12 vertebrae) and the length was planned to reach the anterior third of the vertebral body. In this respect, the screw length ranged between 30 mm and 55 mm, depending on the size of the vertebral body.

Screw placement

The spine specimens were thawed to room temperature 24 hours before instrumentation. The vertebra-specific guides were used (Medacta MySpine guide, Medacta International SA, Castel San Pietro, Switzerland) for screw placement in order to adhere to the intended perforation extent as precisely as possible. Instrumentation was performed by two experienced spine surgeons. After the correct positioning of the 3D guides, a 2.7 mm drill was used to drill the template-guided trajectory in the pedicle. The 3D guide was removed after the insertion of a K-wire in the borehole. A cannulated tap was used to prepare the borehole before inserting the cannulated pedicle screw.

Postoperative assessment of actual screw position by CT

Three-dimensional surface models of segmented vertebrae and screws obtained from postoperative CT scans were used to determine the position of the screws relative to the respective vertebrae. This allowed computing the actual screw breach in the pedicle by computing the largest distance in radial screw direction between the perforating implant surface and the surface of the intersected pedicle (Fig. 1). The maximum value of pedicle perforation was set to the screw diameter (ie, 5 or 6 mm) and the minimum was set to zero for the case of no detectable pedicle wall breaching. Analysis was performed in MATLAB (R2020b, TheMathWorks Inc., Natick, MA, USA).

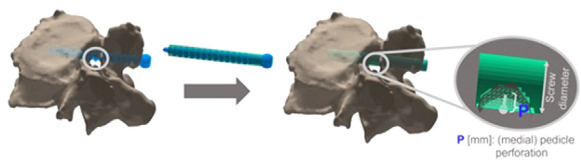

Fig. 1. Computation of the actual screw breach in the pedicle by computing the largest distance in radial screw direction between the perforating implant surface and the surface of the intersected pedicle.

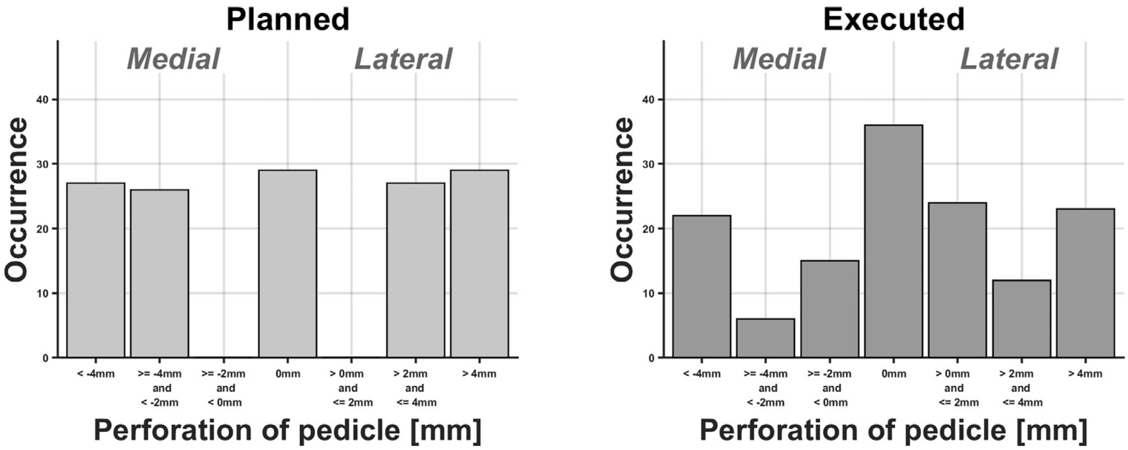

Fig. 2. Planned and executed distribution of screw placements. Adherence to a planned screw perforation of 2-4mm seemed to difficult. Most of these screws shiftet to a perforation of 0 to 2 mm.

Thus, we could confirm that 138 out of 144 pedicle screws were placed. 75 out of 138 screws were positioned either completely within the pedicle (36 screws) or within a 0 to 2 mm breach (15 lateral or 24 medial screws). Eighteen screws had a perforation of 2 to 4 mm (six medial and 12 lateral screws) and the remaining 45 screws perforated the pedicle more than 4 mm (22 medial and 23 lateral screws)(Fig. 2). Six screws had to be abandoned because the corresponding vertebra was previously injected with bone cement making them unusable for the present study as it complicates screw placement and fluoroscopic assessment.

Obtaining fluoroscopic images

Fluoroscopic anteroposterior (AP) and oblique view radiographs of the instrumented cadaveric lumbar spines were obtained. The spine specimens were placed in prone position on a radiolucent table. The C-arm was first positioned in the sagittal plane to ensure a correct AP radiograph (spinous process just between the pedicles). To account for the sagittal curve, the cranio-caudal orientation was adjusted to ensure a beam that was as orthogonal as possible to three adjacent vertebral bodies of interest. For the oblique view, the C-arm was then tilted by an experienced spine surgeon in the oblique position until a good view of the pedicle axis was achieved.

Evaluation of breach extent by fluoroscopic views

Three experienced spine surgeons interpreted the position of the screws by evaluating the fluoroscopic views (Fig. 3 A, B, C, D). Medial or lateral perforation of a screw was assessed in AP-views according to the criteria described by Kim et al. [7]. According to these criteria, a screw tip of a correctly positioned screw should be situated between the medial wall of the ipsilateral pedicle and the spinous process. In the oblique views, a perforation was supposed when the screw tip crossed the identified medial or lateral wall of the pedicle.

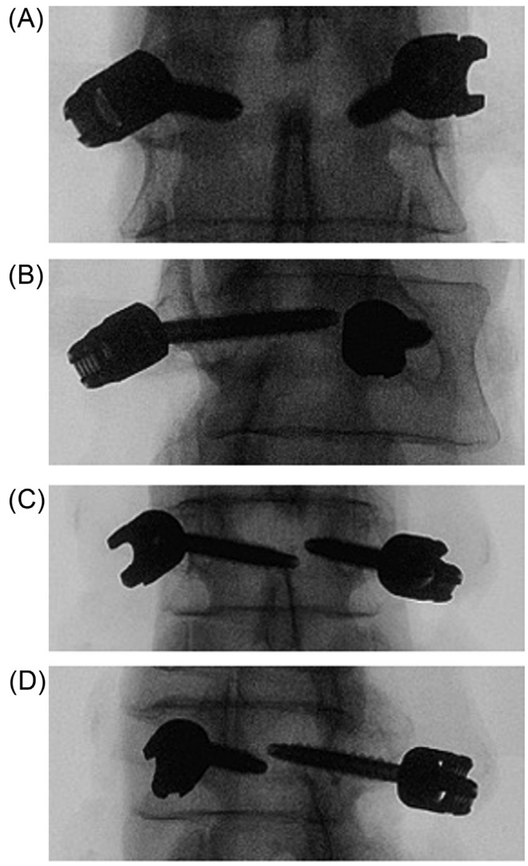

Fig. 3. A, B, C, D (A) Antero-posterior (AP) view of a correctly placed screw on both sides (Level L4, control screws). (B) Right oblique view of the same level as in 1a for evaluation of the right screw. (C) Antero-posterior view (AP) of a malpositioned screw on the left side (Level L3, >4 mm medial perforation). (D) Left oblique view of the same level as in 1c for evaluation of the left screw (>4 mm medial perforation).

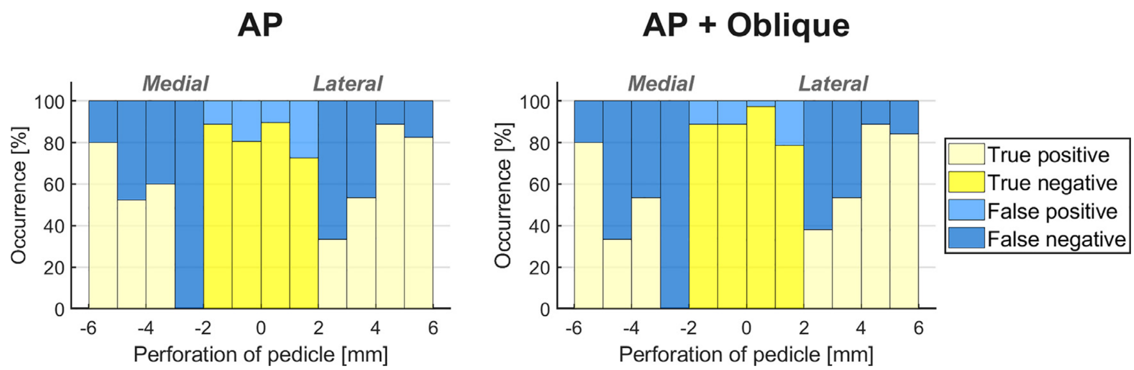

Fig. 4. Pooled analysis of distribution of true negative, true positive, false negative and false positive stratified by degree of perforation. AP compared with AP+oblique views show similar distribution patterns with lowest sensitivity at (-2)-3mm perforation.

Powerpoint (PPT)-slides were created with fluoroscopic views of all screws and delivered to the surgeons. A maximum of three screws were evaluated on one slide.

The first series of PPT-slides (Microsoft Corp., Redmond, WA, USA) contained only AP-views of all screws. Four weeks later a second series of PPT-slides containing the same AP-views and additional oblique views were delivered to the surgeons for evaluation. The four-week interval was introduced to mitigate recall bias. The surgeons defined the screw positions as control screw (no breach), <2 mm, 2 to 4 mm and >4 mm medial or lateral breach of the pedicle.

Statistics

The fluoroscopic evaluation was compared with the actual breach extent assessed by the postoperative CT.

Sensitivity, specificity, and accuracy were determined to evaluate the surgeons' ability to detect presumably relevant perforations. Relevant perforations were defined as perforations greater than 2 mm, according to Gertzbein et al. [8] and Roy-Camille et al. [9].

AP-only and AP + oblique view conditions were assessed for all three raters. Inter-rater agreement was quantified with Fleiss's κ, while McNemar's χ^2 was computed to compare the performance of the two rating approaches. Further, the level-wise accuracy values for pedicle breach detection were determined and compared with McNemar's χ^2 (comparisons between AP and AP + Oblique) and Pearson's χ^2 (comparisons between the levels) tests. Bonferroni correction for multiple testing was used. The significance level α was set to 0.05 and statistical evaluation was performed with MATLAB Matlab 2020b.

Results

There was a substantial inter-observer agreement in evaluating screw positions by fluoroscopy as Fleiss's kappa was 0.632.

The sensitivity of AP views to detect a pedicle perforation greater than 2 mm was 0.68 among the pooled readers (CI 0.63−0.73, rater 1: 0.61 (CI 0.51−0.69), rater 2: 0.77 (CI 0.68−0.83), rater 3: 0.67 (CI 0.59−0.75). The sensitivity using both AP + oblique views was 0.67 (CI: 0.62−0.71) among the pooled readers (rater 1: 0.73 (CI 0.65−0.80), rater 2: 0.72 (CI 0.63−0.79), rater 3: 0.55 (CI 0.46−0.63). There was no statistically significant difference in the sensitivity of the two methods (p= 0.742). When stratified by the degree of perforation, the larger the perforation, the better sensitivity was found, as expected (Fig. 4). Similar distribution patterns of true positives, negatives and false positives and negatives could be found when using AP views compared with AP + oblique views (Fig. 4).

The specificity of AP views was 0.86 (CI 0.82−0.89) and 0.93 (CI 0.90−0.95) when using both AP + oblique views among pooled readers. This difference was statistically significant (p=<.01).

The accuracy was calculated as 0.78 (CI 0.73−0.81) with AP views only and 0.81 (CI 0-76−0.84) using both AP + oblique views. The difference was statistically not significant (p=.114).

The accuracy for detection of screw misplacement tended to be the best at level L2 (Fig. 5).

The accuracy was 68% (AP; CI 0.55−0.79) and 73% (AP+ Oblique view; CI 0.60-0.83) for Th12, 74% (AP; CI 0.62−0.84) and 77% (AP + Oblique view; CI 0.65−0.86) for L1, 92% (AP; CI 0.82−0.97) and 95% (AP + Oblique view; CI 0.86−0.99) for L2, 76% (AP; CI 0.64−0.85) and 82% (AP + Oblique view; CI 0.71−0.90) for L3, 82% (AP; CI 0.71−0.90) and 76% (AP + oblique view; CI 0.64−0.85) for L4 and 72% (AP; CI 0.60−0.82) and 82% (AP + Oblique view; CI 0.70−0.89) for L5. There was no significant difference in accuracy when comparing AP and AP + Oblique views for each level. The accuracy at the best level (L2) differed significantly when compared with level Th12 which had the worst accuracy.

Discussion

This study investigated the ability of intraoperative fluoroscopy to identify mediolaterally misplaced pedicle screws.

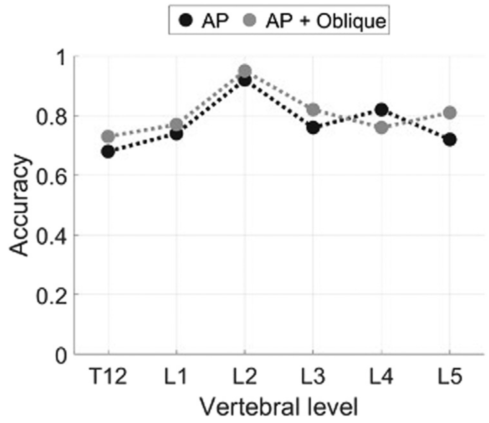

Fig. 5. Accuracy (y-axis) for detection of a pedicle wall perforation (>2 mm) depending on the level (x-axis). Best accuracy was shown on level L2.

The overall sensitivity to detect misplaced pedicle screws was 0.68. This is comparable with previous studies where a sensitivity from 0.52 to 0.83 was reported [7,10−14]. However, some of them included also craniocaudal misplacements, which makes proper comparison with our results difficult. We believe that craniocaudal malpositions are easier to detect since the craniocaudal pedicle wall is usually well recognized in a lateral view due to the strong contrast to the foraminal fat tissue and the missing overlaying bony structures.

The sensitivity certainly depends on the observers' ability and experience [12]. Kim et al. [15] tried to improve the sensitivity by developing standardized radiographic criteria to detect pedicle screw misplacements. With these criteria, he improved the sensitivity up to 87% for radiographic detection of medial pedicle wall violations. However, these excellent results could not be validated by other studies. In our study we tried to improve our sensitivity by adding an oblique view. The oblique view takes the transverse angulation of the pedicle screw trajectory and the angulation of the anatomical pedicle axis in to account. It is known, that the pedicle axis can reach a transverse angulation of up to 30° depending on the vertebral level. A few studies have analyzed the accuracy of the oblique view also called the "coaxial", "pedicle axis" or "owl's eye" view to insert lumbar pedicle screws with promising results [2,5,16]. None of them have analyzed its sensitivity to detect screw malpositioning when the screws are already in place. However, we could only improve the specificity but not reach a better sensitivity using this additional view. One reason might be that once a screw malpositioning is difficult to see due to overlaying degenerations, such as hypertrophic facet joints, the oblique view might not compensate for this obstacle.

There are some limitations of this study. First, the spine specimens did not have previous surgeries or severe deformities such as de novo scoliosis, rotatory instabilities, listhesis, hypoplastic pedicles and so on. This likely made screw placement evaluation easier than in some specific cases. Additionally, the limited sample size of twelve cadaveric specimens may affect the generalizability of our results to a larger population. Furthermore, the spine specimens were isolated from surrounding soft tissue such that the quality of fluoroscopic views in this study could be better than in real patients such as in obese patients. Our results apply therefore only for normally aged or degenerated spines. Second, we did not examine craniocaudal malpositions. We decided to do so since most of the malpositions are in the axial plane [17]. The reason for this is probably that the craniocaudal pedicle walls are usually well visualized with a lateral fluoroscopic view. Finally, the angulation of the oblique views was arbitrarily chosen according to one experienced surgeon's discretion. However, this could reduce accuracy since in a real case, surgeons are used to do several fluoroscopic views to get the optimal oblique view which might influence the accuracy as well.

Clinical relevance

If screw misplacement is suspected, we recommend checking the screw position with an additional imaging modality that allows a 3D reconstruction or checking the screw directly through a laminotomy or an internal palpation of the screw trajectory. Finally, the accuracy of placing pedicle screws using only fluoroscopy as guidance remains strongly dependent on the ability and experience of the surgeon. However, in experienced hands, this technique can reach accuracies up to 91.5% for a correct pedicle screw placement [18]. This is comparable with computed tomography-guided techniques or robot-assisted techniques with reported accuracies of 95.5% and 90.5%, respectively [18].

Conclusion

Pedicle screw placement using fluoroscopic guidance has an acceptable accuracy in experienced hands. However, when considering in isolation the ability of intraoperative fluoroscopy to detect screw malposition, we achieve only moderate sensitivity. Adding an oblique fluoroscopic view does improve the specificity but not sensitivity and accuracy.

Acknowledgments

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Ethical committee approval

Kantonale Ethikkommission Zurich had given the approval for the study. (Basec No. 2020-00453).

Declaration of Competing Interest

One or more of the authors declare financial or professional relationships on ICMJE-TSJ disclosure forms.

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