11–17

# The influence of anatomy (normal versus scoliosis) on the free-hand placement of pedicle screws: Is misplacement more frequent in patients with anatomical deformity?

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Methods evaluation and class of evidence (CoE)

| | |
|---|---|
| **Methodological principle:** | |
| Study design: | |
| Prospective cohort | |
| Retrospective cohort | • |
| Case control | |
| Case series | |
| Methods | |
| Patients at similar point in course of treatment | |
| Follow-up ≥ 85% | • |
| Similarity of treatment protocols for patient groups | • |
| Patients followed for long enough for outcomes to occur | • |
| Control for extraneous risk factors | |
| **Evidence class:** | **III** |

The definiton of the different classes of evidence is available on page 73.

## ABSTRACT

***Study design:*** Retrospective prognostic study

***Objective:*** To evaluate whether patients with anatomical deformity due to scoliosis have a higher frequency of inaccurate pedicle screw insertion and related complications using the free-hand technique compared with those whose normal anatomy had been impacted by trauma.

***Methods:*** Consecutively treated trauma patients with otherwise normal anatomy (48 patients instrumented with 291 screws, group A) and scoliosis patients (24 patients instrumented with 287 screws, group B) were evaluated. Screw position on CT was evaluated using the classification by Gertzbein and Robbins with modification by Karagoz Guzey. (See web appendix at www.aospine.org/ebsj for complete classification description.) Images were examined by two fellows and one junior staff member none of whom participated in patient management. Screw position was determined by consensus.

***Results:*** In group A, five (1.7%) out of 289 screws were severely misplaced and 26 (9%) screws caused either medial (3.8%) or lateral (5.2%) cortical breeches. The other 258 (89.3%) screws were fully contained within the cortical boundaries of the pedicle. In group B, seven (2.8%) out of 256 screws were severely misplaced. Thirty-three (13%) screws caused cortical breeches, either medial (9%), lateral (2%), or anterior (2%), and 216 (84.3%) screws were fully contained within the cortical boundaries of the pedicle and the vertebra. Neurological complications were reported in one patient with scoliosis. No vascular complications were reported in either group.

***Conclusions:*** The percentage of incorrectly placed screws was similar in both groups, trauma and deformity patients. The presence of vertebral anatomical changes related to adult scoliosis was not associated with an increase in the screw-related neurological or vascular complications.

No funds were received in support of this work.

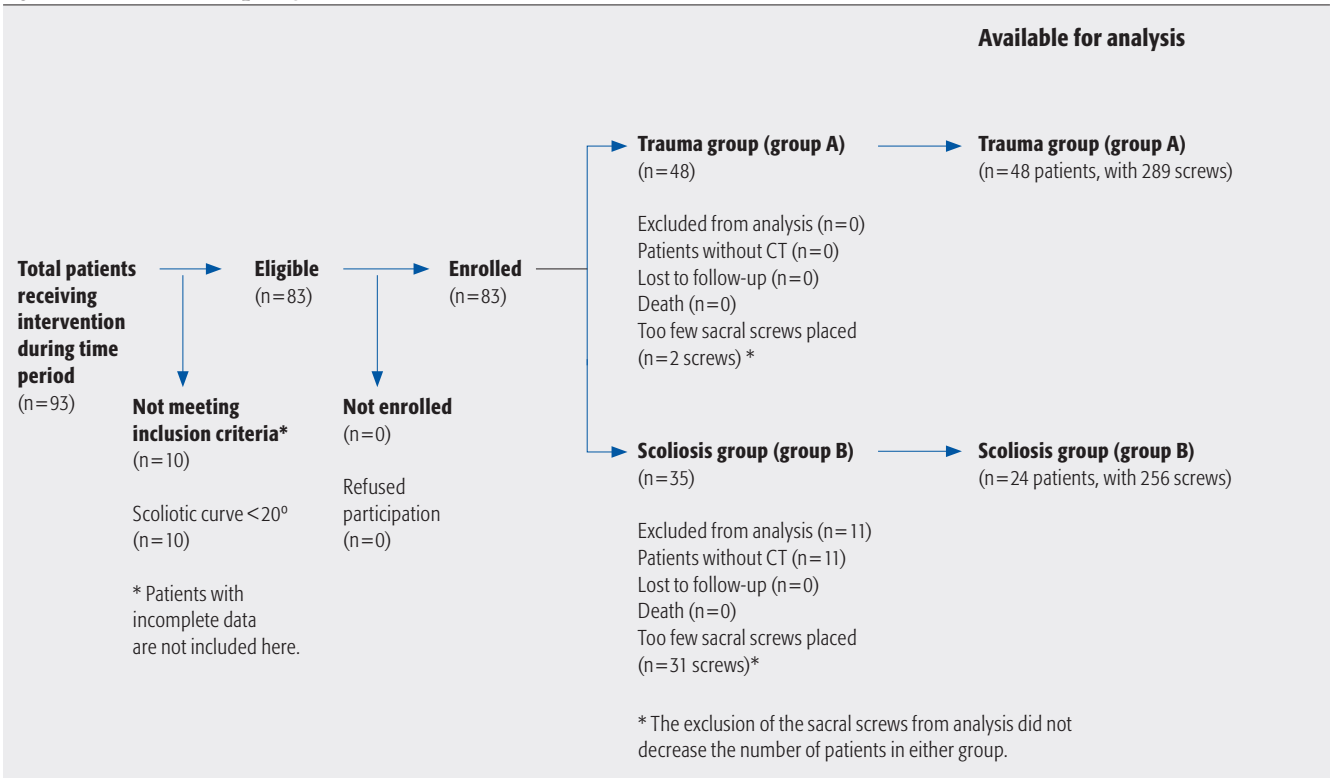
## STUDY RATIONALE AND CONTEXT

Pedicle screw fixation affords multidimensional control, greater rigidity, and may increase the fusion rates [1–5] compared with other options making it the method of choice for most surgeons. However, accurate insertion relies heavily on anatomical landmark identification. Distortion of anatomy and spatial orientation, which occurs in adult scoliosis with spondylosis for example, may make landmark identification difficult. When inserted incorrectly, pedicle screws can cause neurological or vascular injuries. Understanding which patient groups may be at higher risk for screw misplacement is therefore important.

## OBJECTIVES

To evaluate the frequency of pedicle screw misplacement and complications in patients with severe anatomical distortion (adult scoliosis) compared to those with normal anatomy (trauma patients) following posterior instrumentation using the free-hand technique. Our hypothesis was that a higher frequency of screw misplacement would occur in patients with severe anatomical distortion.

Figure 1 **Patient sampling and selection**



## METHODS

***Study design:*** Retrospective prognostic study

***Inclusion criteria:*** Consecutive patients with traumatic injury (but otherwise normal anatomy) or adult scoliosis (distorted anatomy) treated with posterior instrumentation operated between January 2004 and January 2006 were eligible.

***Exclusion criteria:*** In the scoliosis group, ten patients were excluded because the curve was less than 20°.

***Patient population and pedicle screw placement compared* (Figure 1)*:***

- All patients instrumented with pedicle screws for trauma or scoliosis (more than 20° Cobb angle) as the main diagnosis were eligible and screened for inclusion (N = 83). Data from postoperative CT scan was not available for eleven patients, leaving 72 patients available for analysis, with a follow-up rate of 86.7% .
- Two groups of consecutive patients, one with traumatic injury (n = 48) and the other with adult scoliosis with a mean deformity of 45° (n = 24), treated with posterior instrumentation using pedicle screws were available for analysis.
- In the trauma group (group A), posterior instrumentation utilizing 291 pedicle screws was done; 111 screws were placed in the thoracic spine, 178 in the lumbar spine, and two in the sacrum.
- In the adult scoliosis patients (group B) a total of 287 pedicle screws were placed; 73 placed in the thoracic spine, 183 in the lumbar spine, and 31 in the sacrum. Six patients had at least one previous surgery.
- After all the screws were placed, a fluoroscopic visualization of every screw was obtained in the frontal, lateral and oblique views to confirm their correct position, or to make the necessary corrections. In all cases a careful posterolateral arthrodesis with autologous bone grafts taken from the iliac crest was performed. Additional technical details can be found in the web appendix at www.aospine.org/ebsj.

***Outcomes and prognostic factors:***

- Screw misplacement was the primary outcome of interest **(Table 1)**. Screw position on postoperative CT (sagittal and frontal reconstruction) was defined using the classification system of Gertzbein and Robbins [3] that assigns a grade from 0–3 related to amount of pedicle perforation. The modification by Karagoz Guzey, et al [7] which includes determination of medial or lateral penetration was also used. (See web appendix for complete classification description at www.aospine.org/ebsj.) Postoperative CT was performed immediately in trauma patients and the timing was variable in patients with scoliosis.

Definitions of screw misplacement were as follows **(Table 1** and **Figures 2–5)**:

- simple cortical breeches = misplacement grades M1, L1 and A1
- true misplacements = misplacement grades M2, L2, A2, M3, L3, and A3
- severely misplaced screws = misplacement grades 2 and 3

- Vascular and neurological complications due to screw misplacement requiring a second operation were recorded.
- The prognostic factor of interest was presence of anatomical distortion.

***Analysis***

- All images were examined by two fellows and one junior staff, none of whom participated in patient management. Determination of screw position was based on consensus.
- Analysis was confined to thoracic and lumbar screws since there were too few sacral screws (ie, 2) placed in the trauma group (group A) compared with the scoliosis group (group B, 31 screws) for valid analysis.
- Relative risk (RR) estimates and 95% confidence intervals with corresponding chi-square statistics were calculated. Fisher's exact test was used when small numbers of patients (< 5) were involved.

Additional methodological and technical details are provided in the web appendix at www.aospine.org/ebsj.

## RESULTS

- Trauma patients were younger (36 years old) and predominantly male (60.4%) compared with scoliosis patients (56 years old, 12.5% male) **(Table 2)**.
- Patients with scoliosis had no increased risk of screw misplacement with respect to the total frequency of misplaced screws (ie, any screw outside the perfect position or grade 0) overall, or when cortical breeches or severely misplaced screws in general were evaluated separately **(Table 3)**. Subanalysis of patients with severely misplaced screws suggests that penetration of the anterior cortex may be more common among patients with scoliosis. (See web appendix at www.aospine.org/ebsj tables for details by level.)
- When comparing the groups with respect to screws placed in the same region, cortical breeches (M1, L1, A1) in the lumbar spine were statistically higher in patients with scoliosis ($P=.0051$), but not clinically relevant.
- Overall, there were more misplaced screws in the thoracic region compared with the lumbar region in both groups: 20% thoracic versus 5% lumbar in the trauma group ($P=.00008$) and 21% versus 14% in the scoliosis group (not significant).
- No vascular complications requiring reoperation were reported in either group and only one patient in the scoliosis group underwent screw removal for right L5 radicular pain which did not respond to conservative treatment.

Table 1 **Grading of screw misplacement**

| Gertzbein – Robbins Grade [3] | Description |
|---|---|
| Grade 0 | No pedicle perforation |
| Grade 1 | Only the threads outside the pedicle (less than 2 mm) |
| Grade 2 | Core screw diameter outside the pedicle (2–4 mm) |
| Grade 3 | Screw entirely outside the pedicle |
| **Karagoz Guzey Modification* [7]** | |
| Grade M1 | Medial penetration to pedicle wall 2 mm or below |
| Grade M2 | Medial penetration above 2 mm |
| Grade M3 | Location wholly in the spinal canal |
| Grade L1 | Lateral penetration to pedicle wall 2 mm or below |
| Grade L2 | Lateral penetration above 2 mm |
| Grade L3 | Lateral location wholly outside of the pedicle |
| **Anterior grade** | |
| Grade A1 | Anterior extension of screw length outside the cortex less than 2 mm |
| Grade A2 | Anterior extension of screw length between 2 and 4 mm |
| Grade A3 | Anterior extension of screw length more than 4 mm |

* This modification creates a medial and lateral subdivision for classifying screw placement. For screws inside the pedicle and vertebral body but long enough to protrude through the anterior wall, an anterior grading was added.

Table 2 **Characteristics of patients with traumatic pathology (group A) and adult scoliosis (group B) treated with posterior instrumentation using pedicle screws**

| Characteristic | Trauma patients group A (n=48) | Scoliosis patients group B (n=24 ) | *P*-value |
|---|---|---|---|
| Mean age, years (range) | 36 (18–80) | 56 (18–75) | .00001§ |
| Male (%) | 29 (60.4%) | 3 (12.5%) | .00001‡ |
| Total number of screws placed* | 289 | 256 | .7§ |
| Mean number of screws per patient (± sd)—thoracic | 2.3 (± 16.9) | 3 (± 8.2) | .85§ |
| Mean number of screws per patient (± sd)—lumbar | 3.7 (± 23.2) | 7.6 (± 4.8) | .42§ |

*Reflects the number of screws placed after sacral screws were excluded.
§ t-test
‡ Chi-square test

Table 3 **Risk of pedicle screw misplacement following posterior instrumentation in patients with adult scoliosis (group B) compared with patients with traumatic fractures (group A) as the reference group**

| | Trauma patients group A (n=289 screws) | Scoliosis patients group B (n=256 screws ) | Effect size RR (95% CI) | *P*-value* |
|---|---|---|---|---|
| **Total misplaced screws** | 31 (11%) | 40 (16%) | 1.5 (0.8, 2.3) | .0900 |
| Cortical breeches | 26 (9%) | 33 (13%) | 1.0 (0.8, 1.2) ‡ | .8785 |
| Severely misplaced (grades 2 and 3) | 5 (2%) | 7 (3%) | 1.1 (0.4, 3.1)‡ | .8785 |
| Penetration of anterior cortex† | 0 (0%) | 5 (2%) | incalculable | .0278 |
| **Fully contained screws** | 258 (89%) | 216 (84%) | | |
| | | | | |
| **Analysis by region** | | | | |
| Misplaced screws at thoracic spine§ | 22/111 (20%) | 15/73 (21%) | 1.0 (0.6, 1.9) | .9040 |
| Misplaced screws at lumbar spine§ | 9/178 (5%) | 25/183 (14%) | 2.7 (1.3, 5.6) | .0051 |
| Severely misplaced screws, thoracic spine | 5/22 (23%) | 4/15 (27%) | 1.1 ( 0.4, 3.7)‡ | 1.000 |
| Severely misplaced screws, lumbar spine | 0 (0%) | 3/25 (12%) | incalculable | .2368 |

RR=risk ratio with trauma patients as the referent group. RR > 1 indicates an increased of screw misplacement in patients with scoliosis, however inclusion of the value of one in the confidence interval indicates that the result is not statistically significant.
* Based on chi-square test or, if small numbers, Fisher's exact test
† This is a subset of severely displaced screws, ie, five of the seven severely misplaced screws in the scoliosis group penetrated the anterior cortex; Fisher's exact test used to compare frequency of anterior cortex penetration among those with severe displacement.
‡ Risk ratio among patients who had any screw misplacement
§ Any misplacement

Figure 2 **Grade 0—no pedicle perforation**

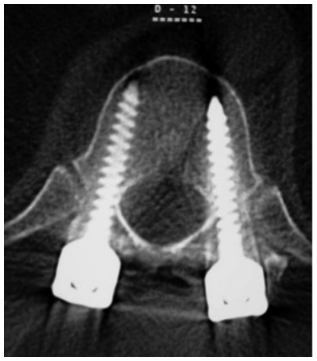


Figure 3 **Grade 1 (M1)—medial penetration to pedicle wall ≤ 2 mm**

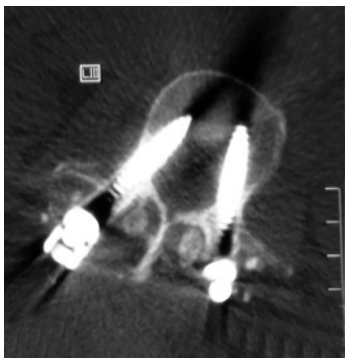


Figure 4 **Grade 2 (M2)—medial penetration of the screw > 2mm**

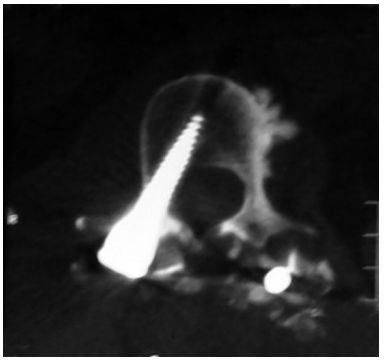
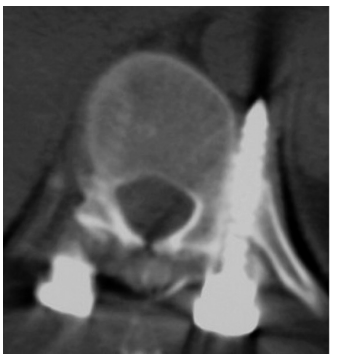


Figure 5 **Grade 3 (L3)—screw is completely outside of the pedicle (laterally) and is in contact with the aorta**



## DISCUSSION (SEE ADDITIONAL DISCUSSION IN THE WEB APPENDIX AT WWW.AOSPINE.ORG/EBSJ)

- As in many other series [3, 8, 9], most of the malpositioned screws in our study were of no clinical significance and only two of the 545 screws (0.4%) posed an indication for removal. The reported frequency of screw misplacement and related complications varies across studies [3, 10, 11]. The variation may in part be due to differences in misplacement classification, surgeon experience, and pathologies treated.
- Contrary to our hypothesis, no significant differences in the rate of misplaced screws, either simple cortical breeches or severely misplaced, between patients with severe anatomical distortion and those with normal anatomy were found.
- Failure to identify a significant difference between groups might be partially explained by technical factors that favor screw placement in scoliotic patients. Long incisions with extensive dissection may enhance a three-dimensional orientation and facilitate the introduction of the pedicle finder in the desired position. The long multisegmental instrumentation utilized in scoliosis may leave some 'difficult-to-find' pedicles with no screws. In the scoliotic thoracic spine, if the surgeon is unsure about a screw position it can be replaced by a hook. Finally, when a decompression is performed, usually at the most affected dysplastic levels of the scoliotic lumbar segments, pedicles can easily be palpated from inside the canal. Failure to detect a statistically significant difference may also in part be due to lack of power to detect differences in relatively rare events.
- Limitations include the retrospective study design that made it impossible to record screw replacement due to malposition during surgery, (as opposed to only evaluating screw position on postoperative CT) and only results from experienced surgeons were evaluated. Another limitation is that we did not consider for this study confounding factors such as osteoporosis or BMI that could influence the screw placement accuracy.
- After comparing these two different pathologies and regions we were not able to isolate a group under a higher risk for complications requiring a more accurate method for screw placement (eg, navigation systems).

## SUMMARY AND CONCLUSIONS: KEY POINTS

- The presence of vertebral anatomical changes related to adult scoliosis was not associated with an increase in the screw-related neurological or vascular complications and does not require a more accurate method for screw placement.
- Pedicle screws placed by experienced surgeons give rise to a low rate of vascular or neurological complications.

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## EDITORIAL STAFF PERSPECTIVE

*This is a class of evidence III prognostic study.*
*The idea behind this article—to compare screw placement accuracy between two different patho-entities is laudable and clever. The paper also reintroduces the readership to a more systematic form of recording pedicle screw malpositions and reviews response possibilities.*

*There were a number of questions raised which could not be readily resolved. They are listed here to promote further deliberation on the part of readers.*

*1. Selection bias? Reviewers noted a difference of the number of screws listed in the thoracic group for trauma (2.3 compared to the scoliosis group 3 and 3.7 in the lumbar group for trauma versus 7.6 in the scoliosis group. The reasons for these differences may lie in physician preferences. However, they also may reflect the influence of physician 'wisdom' or experience. What was the indication for screw placement as opposed to hooks and when and why was the decision made to not use fixation? If there are 24 patients in the scoliosis group, then if all patients had screws bilaterally, there would be a total of 48 screws listed in Table 5. A cursory review of this suggests that there are multiple uninstrumented pedicles in this series. This is discussed in the web appendix (at www.aospine.org/ebsj) to a certain extent, but there appears to be a bias as to when to use screws and when not to use screws that is not explained.*

*2. Systematic error? Although this would require quite a bit more work, it would be interesting to know the size of the pedicles instrumented and the size of screws placed in relation to pedicle size. One might suspect that the trauma group has larger 'targets' than the scoliosis group. This may be a factor to account for differences in accuracy and may also be a factor in where screws were 'avoided'.*

*3. Methods: Factors which may have influenced placement accuracy such as BMI and were not evaluated in this study. Significant differences in patient age and gender between the two groups of patients may be surrogates for factors such as osteoporosis which may influence screw placement. It is unclear whether the differential timing in performance of postoperative CT between the trauma patients (immediate) and those with scoliosis (variable timing) may influence evaluation of placement.*

*These are important considerations, which again show the limitations of retrospective studies. Despite best intentions and a creative idea for identifying a comparison group, the attempt of reinterpreting previously made clinical decisions in the context of a retrospective study is very complex and may be contaminated with wrongful assumptions.*