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# Intraoperative CT Scan Verification of Pedicle Screw Placement in AIS to Prevent Malpositioned Screws: Safety Benefit and Cost

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## Abstract

**Study Design:** Prospective database review.
**Objectives:** Determine if use of intraoperative 3D imaging of pedicle screw position provides clinical and cost benefit.
**Summary of Background:** Injury or reoperation from malpositioned pedicle screws in adolescent idiopathic scoliosis (AIS) surgery occurs but is increasingly considered to be a never-event. To avoid complications, intraoperative 3D imaging of screw position may be obtained.
**Methods:** A prospective, consecutive AIS database at a high-volume pediatric spine center was examined three years before and after implementation of an intraoperative low-dose computed tomographic (CT) scan protocol. All screws were placed via freehand technique and corrected if found to be outside optimal trajectory on the postplacement CT scan. Demographic and outcome data were compared between cohorts, along with number, location, and reason for screw change. Cost analysis was based on the average cost of revision surgery for screw malposition versus intraoperative CT use.
**Results:** There were 153 patients in the pre-CT and 153 in the post-CT cohorts with a minimum 2-year follow-up. Two reoperations were needed for revision of improper screw placement in the pre-CT group and none in the post-CT group. Number of patients needed to harm was 76 (absolute risk increase = 1.31% [−0.49%, 3.11%]). Of those who had intraoperative CT scans, 80 (52.3%) needed on average 1.75 screw trajectories/lengths changed. Forty-three percent were medial breaches; of these, 39% were in the concavity. There were no differences between patients who did and did not need screw repositioning with regard to body mass index (BMI), age, curve size, surgeon/trainee side, screw density, or preoperative and one-year postoperative Scoliosis Research Society−22 patient questionnaire (SRS-22) scores. The average cost of reoperation for malposition was $4,900, whereas the cost of a single intraoperative CT was $232.
**Conclusion:** Intraoperative CT is an effective tool to prevent reoperation in AIS surgery for incorrect screw placement. Despite high volume, experience, and specialty training, incorrect trajectories occur and systems should be in place for preventable error.
**Level of Evidence:** Level II.


*Keywords:* Adolescent idiopathic scoliosis; Pedicle screw; Screw safety; Intra-operative CT; Oarm

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## Introduction

Pedicle screws have become common in the surgical treatment for adolescent idiopathic scoliosis (AIS) because of the ability to facilitate three-column deformity correction. Pedicle screws, particularly in the thoracic spine, have been the subject of much attention with regard to placement technique and technology, learning curve, complications, and accuracy.

The rate and significance of malpositioned screws may be underestimated [1]. Malpositioned screws can lead to reoperation for a number of complications including neurologic, vascular, pulmonary, or dural injury [2-11]. These complications may not become evident until the surgery is complete, after patients have left the operating suite with malpositioned screws. Moreover, postoperative radiographs may only be 68% accurate at identifying screw misplacements [12].

There have been a large number of studies that focus on pedicle screw accuracy, as measured often by millimeters of pedicle breach [13-16], and comparing accuracy between various placement techniques [13,16-23]. This paper instead focused on the clinical and cost significance of malpositioned pedicle screws to determine the benefit of a prospectively implemented intraoperative computed tomographic (CT) scan protocol after pedicle screw placement in AIS with regard to complications, reoperation, and cost.

## Materials and Methods

With institutional review board approval and without funding source, a prospective, consecutive AIS database at a single high-volume pediatric spine center was examined three years immediately before and after (2009−2014) implementation of an intraoperative low-dose CT scan protocol to evaluate pedicle screw placement. The two attending surgeons were fellowship trained with at least seven years' pediatric spine subspecialization experience each. All pedicle screws were placed by the freehand technique, included a surgeon in training (resident or fellow) placing screws on one side of the patient, and used single-shot fluoroscopy assistance on difficult pedicles at the attending surgeon's discretion. After screw placement but before rod placement and correction maneuvers, all screw locations were evaluated on imaging. The screws in the pre-CT cohort were checked for radiographic accuracy with fluoroscopic C-arm images using Kim and colleagues' [24] radiographic criteria. Screws were removed or redirected at surgeon's discretion with particular attention to screw tips that crossed the vertebral body midline, and those outside the normal cascade of screws. The screws in the CT protocol cohort were checked by CT O-arm scan (Medtronic, Minneapolis, MN). Screws that were directly threatening a vascular or neurologic structure, including four or more threads into the spinal canal per the CT accuracy findings of Yoo et al [25], those that had no purchase of the screw tip in the vertebral body, or those that were not centered down the pedicle were redirected or removed. Screws that were too long and protruded past the anterior vertebral body cortex were backed out by one-half to two turns as needed. In this manner, the threshold for redirecting screws was lower than would have been if using the criteria as with the prior fluoroscopy cohort. Redirected screws were confirmed on fluoroscopy and recorded in the operative note.

Data were prospectively recorded for patient demographics, Lenke curve type classification, major Cobb angle, number of levels fused, and reoperation rate at final follow-up. In the CT cohort, the number, location, and reason for screw exchange post-scan was recorded. For those who had a reoperation for a malpositioned screw, an average cost analysis of their readmission was performed and compared against the cost of the addition of an intraoperative O-arm scan as determined from the second cohort.

Results were compared between the two groups using the unpaired Student *t* test for continuous data and Fisher two-tailed exact test for categorical data. Analysis of variance was used when comparing multiple categorical groups between the two such as Lenke classification type. An absolute risk assessment, or number need to harm, was made for malpositioned screw reoperation. All p values were considered significant if $<0.05$.

## Results

In this six-year review of our prospectively collected idiopathic scoliosis database, there were 153 patients in the pre-CT cohort and 153 in the post-CT cohort, all with at least two-year follow-up. There were no significant differences between the two cohorts with respect to age, gender, weight, or body mass index (Table 1); the post-CT cohort was significantly taller (164 vs. 161 cm; p = 0.007). Average major Cobb angle did not vary between cohorts, nor did Lenke curve type, number of levels fused, or attending surgeon case inclusion (Table 2).

Of those who had intraoperative CT scans, 80 (52.3%) had an average 1.75 screw trajectories or lengths changed. Of these, 43% were medial breaches, 39% of which were in the concavity of the curve. Thirty-five

Table 1
Demographic comparison between Pre-CT and Post-CT protocol cohorts.

| Cohort demographics | | | |
|---|---|---|---|
| Characteristic | Pre-CT cohort | Post-CT cohort | p value |
| Gender, n (%) | | | .49 |
| Male | 31 (20.3) | 37 (24.4) | |
| Female | 122 (79.7) | 116 (24.2) | |
| Age at surgery, years, mean | 14.3 | 14.7 | .081 |
| Weight at surgery, kg, mean | 56.0 | 57.0 | .53 |
| Height at surgery, cm, mean | 161.1 | 163.9 | .007 |
| Body mass index, mean | 21.5 | 21.1 | .43 |

CT, computed tomography.

Table 2
Scoliosis comparisons between Pre-CT and Post-CT protocol cohorts.

Curve characteristics of cohorts

| Characteristic | Pre-CT cohort | Post-CT cohort | p value |
|---|---|---|---|
| Average preoperative major curve Cobb angle (range) | 53.96° (40° -80°) | 54.83° (40° -120°) | .47 |
| Fusion levels, mean (range) | 9.7 (4-14) | 10.1 (4-14) | .15 |
| Lenke curve type, no. of patients | | | .77 |
| 1 | 48 | 61 | |
| 2 | 41 | 41 | |
| 3 | 7 | 10 | |
| 4 | 4 | 2 | |
| 5 | 21 | 28 | |
| 6 | 11 | 11 | |
| Lenke lumbar modifier, no. of patients | | | .68 |
| A | 53 | 61 | |
| B | 24 | 25 | |
| C | 54 | 67 | |
| Surgeon A, no. of patients | 96 | 107 | |
| Surgeon B, no. of patients | 57 | 46 | .22 |

CT, computed tomography.

percent were lateral, 19% anterior (long), and 1% superior (Fig. 1). The anterior breaches were corrected by backing out the screw one-half to two screw turns, as appropriate; none needed a screw exchange. Fifty-one percent of screws were on the patient's right side and 49% from the left. Eleven percent were lumbar screws and 89% were thoracic. There were no statistical differences between those who did and did not need screw repositioning with regard to BMI, age, curve size, screw density (0.87 vs. 0.90, p = 0.11), or preoperative and one-year postoperative Scoliosis Research Society–22 patient questionnaire scores (p = 0.43, p = 0.27 respectively).

Two reoperations were performed for revision of improper screw placement in the pre-CT group (1.31%) and none in the post-CT group (0%). The number of patients needed to harm by not performing an intraoperative CT was therefore 76 (absolute risk increase = 1.31% [−0.49%, 3.11%]). There was no difference in the total average preoperative Scoliosis Research Society–22 patient questionnaire scores between the two reoperations and the entire pre-CT group (3.8 vs. 4.0; p = 0.58), but there was a significant decrease in the reoperation group at one year

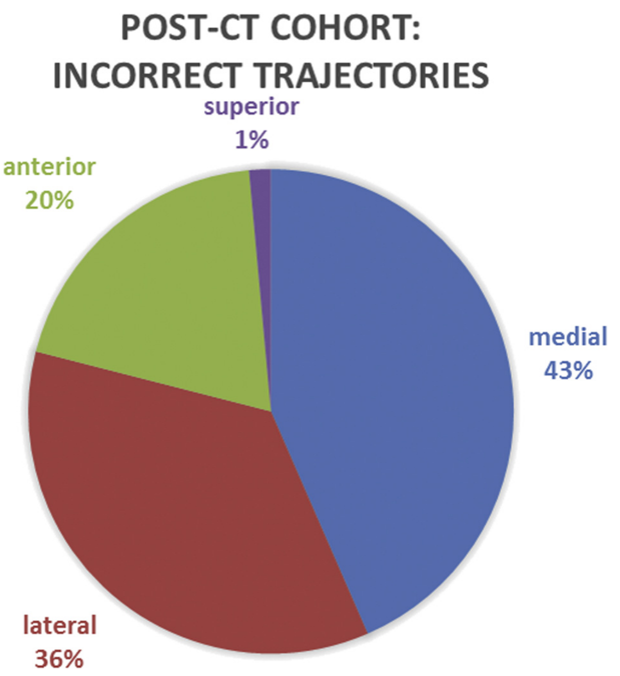


Fig. 1. Distribution of incorrect trajectories of screws changed intraoperatively after intraoperative computed tomography.

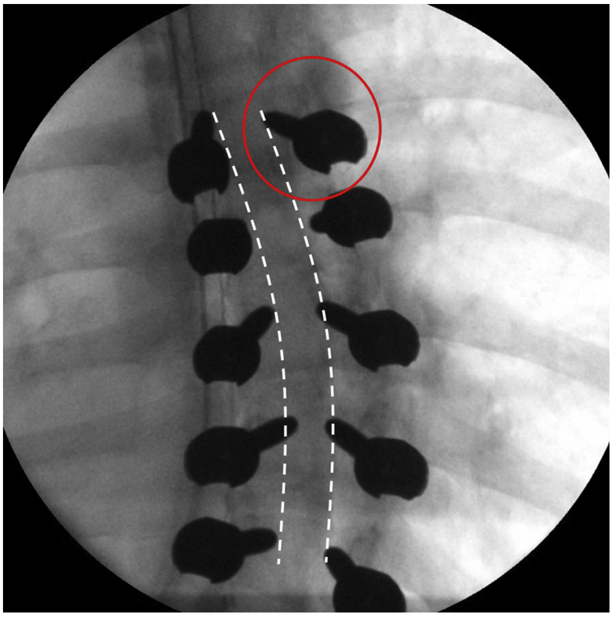

Fig. 2. Malpositioned screw circled at right upper instrumented vertebra position. Dashed lines indicate smooth contour of screw tips along rotated curve, thus intraoperative assumption of acceptable screw position.

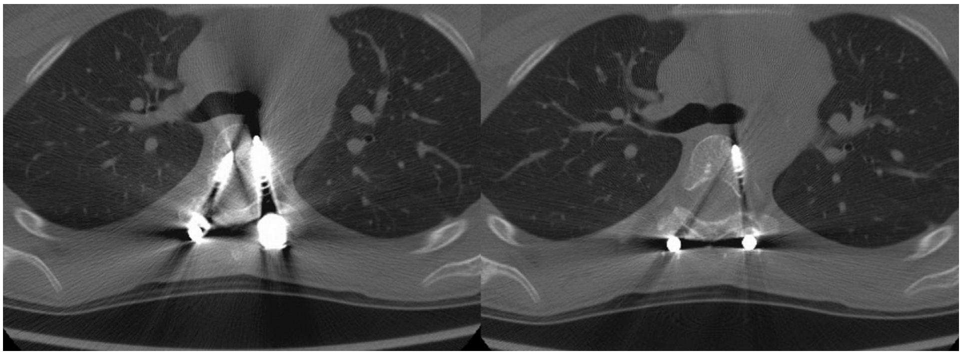

Fig. 3. Two consecutive images from the postoperative computed tomographic scan obtained due to radicular symptoms correlating to malpositioned right upper instrumented vertebra screw, medially breaching the pedicle cortex.

postoperatively (3.9 vs. 4.6; p = 0.0016). One reoperation was indicated due to persistent dermatomal radicular pain five months postoperatively. The screw was at the upper instrumented vertebra on the convexity on the right. Although it appeared to be in acceptable position on intraoperative fluoroscopy (Fig. 2), investigative CT and subsequent palpation on reoperation indicated a medial breach (Fig. 3). At three years postoperatively from her revision, the patient's nerve pain had completely resolved but a dermatomal stripe of numbness remained. The other malpositioned screw was found incidentally on an abdominal CT scan 16 months postoperatively. The screw was again at the upper instrumented vertebra on the convexity, at T11 on the left in a selective lumbar fusion, and was found to have an anterolateral breach in the vicinity of the aorta (Fig. 4). Although there was no frank impingement, an informed decision-making process led to screw removal without sequela.

Fig. 4. Malpositioned screw causing reoperation. Left screw placed lateral of the pedicle, resulting in screw tip proximity to the aorta.

A cost analysis of reoperation and the associated care involved, done by averaging the costs for the two patients revised as above, found a $4,900 cost per reoperation. A single use of the O-arm at our institution, taking into account operating room time spent during the case, proportional cost of the machine, technical support, and radiologist charges, costs $232. In comparison, at our institution the cost of a single O-arm Stealth (Medtronic) navigated case, which includes setup, disposable equipment, and representative support costs $6,200.

## Discussion

Intraoperative CT scan to evaluate screw placement demonstrates an advantage over fluoroscopic methods. Compared to radiographs and fluoroscopy, CT evaluation detects as much as 10 times more pedicle perforations [26,27]. Completing the CT evaluations after the screws have been placed removes the possible error of navigation that may be inherent to a system of individually mobile vertebra using a single immobile fiducial. It also ensures detecting a screw that took a different path than a previously fluoroscopy-verified pedicle marker. Although Miller et al demonstrated only a two-degree difference between pedicle finder and subsequent screw tracks [28], at least one study had a complication from a screw placed outside of the originally made track as evidenced on CT [26]. Moreover, screws are at risk of moving during the correction itself, which is after the O-arm evaluation. However, knowing that the screw is well placed via CT allows the surgeon to be confident in the force they apply to the screw, as those at risk for pulling out or loosening and suboptimally placed. Final fluoroscopy shots are traditionally obtained to ensure T1, upper instrumented vertebra, and pelvic balance and these can be scrutinized for aberrant screws potentially moved during reduction.

Although a large number of studies have reported on screw accuracy, comparing them can be difficult. Each study has the inherent biases of the experience and innate skill of the surgeons involved. Prior studies have noted a learning curve in screw placement, particularly with regard to a surgeon's first 60−80 screws [29,30], 30 cases [31], and avoidance of a medial pedicle wall breach [32]. These differences between individual surgeons, as well as the universal improved comfort level with pedicle screws over the last decade, also make studies that use prior published data as the control comparison group difficult to interpret. This study benefits from using the same surgeons pre- and postprotocol change, with the same proportion of cases included by each, as well as starting data collection well into each of their subspecialized pediatric spine careers and pedicle screw experience. In our group, there was a near equal number of screws changed on the left—typically the primary surgeon's side—and on the right—usually the assistant or learner's side. This echoes the findings of Hoashi et al of no increased risk in pedicle screw complications when looking at surgical trainees in July [33].

Although CT improves accuracy, no intraoperative screw evaluation technique is completely reliable. When compared to direct cadaver inspection, evaluation of screws by plain radiograph produces up to 8% false positives and 14.5% false negatives for pedicle violation [34]. CT scan compared to direct cadaver inspection is only up to 87% accurate [25,35]. Inter- and intraobserver reliability of the CT scans on pedicle breach beyond 2 mm have been reported by several studies to be below a 0.5 kappa value [36,37], with greater scatter in stainless steel and cobalt chrome than titanium. At least one study found no benefit to navigation in the thoracic spine [19], yet several others support CT navigation [22,23,38]. A study by Cui et al [39] compared a CT-navigated cohort to a nonnavigated cohort, and both then underwent intraoperative postscrew CTs. Even in the navigation cohort, there was a 5.2% breach rate, needing 2% screw repositioning, which compared to 5% screw repositioning in the nonnavigated group. Here, as in many studies however, repositioning was based on >2 mm pedicle breach, yet Castro et al found nerve root damage only once a screw deviated from the pedicle cortex by >6 mm on CT [15]. Anterior breaches have also been found to be clinically significant only if >4 mm by CT and cadaveric study [12]. These inconsistencies in measurement accuracy suggest that most pedicle breaches reported in prior studies may not have a clinical significance, but it also highlights the potential error within navigation systems.

The advantage of accuracy to avoid reoperation must be balanced with the financial cost, as well as radiation risk to the patients. In our cohort, the average cost of reoperation for screw malposition was more than 20 times higher than the cost of a single intraoperative CT scan. Because one in every 20 cases without an O-arm evaluation did not result in reoperation, one could point out that this does not result in cost savings. However, we believe that the overall value judgment of avoiding what we feel is a never-event in AIS balanced against the cost makes this a cost-effective tool. Moreover, this CT protocol avoids costs associated with navigational systems and support that is almost 30 times as costly. We recognize that with experience, many centers have removed the representative support for navigation systems, therefore making them more cost effective. Our calculations did not include the distribution of the initial O-arm purchase cost, as it is used for multiple applications within the hospital. For smaller institutions that may purchase an O-arm for only this purpose, however, the upfront cost is of interest. Although the price varies, our initial purchase cost was $750,000 and we anticipate 10 years of use. If the O-arm were used for only the 306 cases included in this study over the six years, that would be an additional cost of $1,470 per case. Prior to purchasing an O-arm for this purpose, institutions may consider that newer safe screw placement technologies may also be forthcoming that could supplant the current O-arm system. Another technology aimed at safer pedicle screw placement is a single-use electrical conductivity pedicle finder. Studies have shown its ability to detect pedicle breach, resulting in screw placement with reduced fluoroscopy, intraoperative monitoring alarms, and pedicle perforation (4.1% in one study) [40-43]. At the cost of $690 per probe each case some institutions may find this to be another safety option instead of or in addition to O-arm. However, the same questions highlighted above of ensuring the tap and screw follow this pathway, as well as the inaccuracy of evaluating the screw placement on fluoroscopy remain. The technology may not applicable in solid cortical pedicles or in-out-in trajectories sometimes encountered in large deformity.

With respect to radiation, the definition of freehand technique, as reported in prior studies, varies from zero fluoroscopy shots up to an average of six shots per screw [23], which has obvious implications on radiation exposure comparison. In fact, one study comparing radiation between intraoperative CT and fluoroscopy reported at least one patient subjected to an effective dose of 0.64 mSv by fluoroscopy, nearly equaling the O-arm CT dose of 0.65 mSv (Su). Another provided data from a pilot study that showed their O-arm spins equal to 20−40 C-arm fluoroscopy shots, with their surgeons taking 40−70 fluoroscopy shots per case. Fluoroscopy-based navigation using multiple references also demonstrated higher radiation exposure than CT-based navigation [16]. For our patients, low-dose CT was used for all. A weakness of the study is that we did not investigate the fluoroscopy dose used during our freehand technique both before and after the O-arm protocol, partly because of the variation of use between surgeons. Although we anecdotally had a much lower reliance on fluoroscopy with the O-arm protocol, we did use it to assess the starting point when unable to place a pedicle screw.

The reported AIS reoperation rate is 2.4% to 7.1% [44-46], but revision for malpositioned screws has been reported at an incidence as high at 5.4% [5,9]. Misplaced screws lead to a number of complications. When causing neurologic symptoms, they can necessitate a 50% reoperation rate [3]. Vascular structures at risk, particularly near the concavity of a typical apex-right thoracic curve, include the aorta, azygous vein, and iliac veins in the lumbosacral region [4,6,7]. When causing vascular encroachment, which occurs in 0.22% of pedicle screws, 13% undergo revision despite being asymptomatic [4]. Up to a 12.1% dural tear rate per patient was also reported from misplaced screws [8,9]. In addition to the risk of complications, malpositioned screws also have decreased pullout strength and greater likelihood of loosening [26,42]. Revision surgery itself has been shown to carry higher risks of complications compared to primary cases, including implant-related complications [2].

A weakness of this study is that there was no uniform protocol for screw exchange in the retrospective cohort, nor data recorded on the number of screws changed based on fluoroscopy alone. Although there were basic guidelines for exchange in the CT protocol cohort, much is left to the individual surgeon's clinical decision making. Given the relative ease of screw exchange intraoperatively after the CT before multisegment rod reduction, a large number of screws were likely exchanged because of the abundance of caution. There may have been more screws malpositioned in the pre-CT cohort but were never discovered. A third patient cohort that included screws placed by the same surgeons under CT navigation would have added further comparison; however, because these patients would need a second CT to evaluate screw positions for the comparison, this was not deemed a worthwhile risk of extra radiation to our patients given the number of prior similar studies.

Despite high volume, experience, and specialty training, malpositioned pedicle screw trajectories in AIS surgery can occur. Intraoperative CT scan to evaluate screw placement prevents reoperation for malpositioned pedicle screws in AIS surgery, thereby increasing safety, in a cost-effective manner.

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