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Intraoperative CT-Guided Navigation for Pediatric Spine Patients Reduced Return to OR for Screw Malposition Compared to Free/ Fluoroscopic Techniques

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Abstract

Purpose: Placement of pedicle screws can be performed using freehand/fluoroscopic technique or intra-operative CT guided navigation. We sought to compare screw malposition and return to OR for pedicle screw malposition for screws placed with and without CT-guided navigation.

Methods: This study was a single center retrospective comparative study. All patients under the age of 18 with minimum 2-year follow-up who underwent pedicle screw instrumentation between 2009–2015 were included. IRB-approval was obtained and patient charts were reviewed for patient demographics and surgical outcomes. If available, incidental CTs following the index surgery were reviewed to assess screw position.

Results: 217 patients underwent spinal instrumentation. 112 patients had pedicle screws placed using fluoroscopic guidance, while 105 patients had screws placed using lowdose intraoperative CT-guided navigation (O-arm, Medtronic). Of the total cohort, 107 (49.3 %) patients had adolescent idiopathic scoliosis, and the remainder had neuromuscular, tumor, congenital, or other diagnoses. Patients in each group had a similar number of levels fused (fluoroscopic = 10.9 vs. CT navigation = 9.8, $p = 0.06$). There was no difference in total estimated blood loss (1127 vs. 1179 mL, $p = 0.63$), or in blood loss per level fused (133.7 vs. 146.6 mL, $p = 0.47$). Patients with screws placed using fluoroscopic guidance had a shorter total operative time (441 vs. 468 minutes, $p = 0.04$); however, there was no difference when controlling for number of levels fused (58.3 vs. 61.5 minutes/level, $p = 0.63$). Postoperative CTs were available in 51 patients representing 526 imaged screws, which showed a significantly higher rate of severely malpositioned (>4 mm) screws in the fluoroscopic group than the CT navigation group (3.3% vs. 1.0%, $p = 0.027$). There was a 3.6% rate of return to OR for pedicle screw malposition in the freehand/fluoroscopic group compared to 0% in the CT-guided navigation group ($p=0.048$). Including patients with less than 2-year follow

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IRB-Approved Retrospective Comparative Study

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up (169 fluoroscopy, 220 CT-guidance) also found higher rates of screw malposition (13.5% vs. 7.1%, $p = 0.004$), severe screw malposition (3.0% vs. 0.50%, $p = 0.04$) and return to OR due to screw malposition (2.4% vs. 0%, $p = 0.02$) in patients with screws placed using fluoroscopic guidance.

Conclusion: Patients with pedicle screws placed with CT-guided navigation had a lower rate of severely malpositioned screws and unplanned returns to the OR. There was no significant difference in blood loss or operative time when controlling for number of levels fused.

Significance: In the era of healthcare ‘never-events,’ return to OR for screw malposition could certainly be deemed unacceptable. Use of intraoperative CT guided navigation thus far eliminated return to OR for screw malposition in a complex cohort of pediatric spinal deformity patients, without measurable increase in operative time or blood loss.

Introduction

Posterior spinal fusion remains the primary treatment for pediatric patients with severe spinal deformity. Pedicle screws have become the mainstay for spinal instrumentation, due to improved deformity correction, lower pseudoarthrosis rates, and powerful 3-column fixation^{1,2,3}. Accurate placement of these screws is particularly challenging in pediatric deformity patients due to narrow pedicles and altered surgical anatomy^{4, 5}. In rare instances, malpositioned screws can lead to damage to surrounding neurovascular structures⁶. Freehand/fluoroscopic screw placement has a reported 10–15% rate of pedicle screw malposition^{7,8}. Return to OR due to screw malposition has been reported and intraoperative CT guided navigation has been shown to decrease the rate of pedicle screw malposition^{9,10}. However, there is little data regarding whether use of intraoperative CT navigation reduces return to surgery for screw malposition.

The purpose of this study is to identify whether intraoperative CT guidance can reduce the number of adverse outcomes caused by malpositioned screws, specifically return to OR. We sought to compare screw malposition, adverse outcomes, and return to OR for pedicle screw malposition for screws placed with freehand/ fluoroscopic technique compared to intraoperative CT-guided navigation.

Methods

This study was a single center retrospective comparative study. All patients under the age of 18 who underwent pedicle screw instrumentation at our institution between 2009–2015 were included. Only patients with a minimum of two year follow-up were included in the study. The medical records for all patient included were reviewed for patient demographics and surgical outcomes. When available, incidental CTs following the index surgery were reviewed to assess screw position, although CT scans were not routinely performed. Screw placement was classified as well positioned or mildly (0–2mm), moderately (2–4mm), or severely (>4mm) malpositioned¹¹.

Intraoperative neuromonitoring with SSEPs and MEPs was used in all cases. In the freehand/fluoroscopy group, screws were placed using freehand technique based on

anatomic landmarks, with palpation of the screw tract using a ball-tipped probe. After screws were placed but prior to rod placement, screw position was verified under fluoroscopy or intraoperative radiograph. If CT-guidance (O-arm, Medtronic) was utilized, a reference frame was clamped on the spinous process following dissection, and an intraoperative CT scan was obtained. Pedicle screws were placed at each level using anatomic landmarks to locate the starting point, and the position was verified under navigation (Stealth, Medtronic). Instruments with fiberoptic markers were used for screw placement to develop the screw tract. During the case, the accuracy of the navigated device was frequently confirmed by placing the instrument on a known anatomic landmark. The length of each pedicle was measured using the ball-tipped feeler and confirmed on CT-guided navigation. Due to concerns regarding radiation, a second intraoperative CT scan to check screw position was not routinely performed. All surgeons used both guidance methods. Initially, surgeons primarily used freehand/fluoroscopic techniques. In 2011, one surgeon switched to only CT guided navigation, and by 2014 all surgeons exclusively used CT guided navigation for all cases.

Approval from our Institutional Review Board (IRB) to conduct a retrospective review of medical records was obtained. Pearson's chi-square tests were used to compare discrete variables in the treatment groups. Pooled t-tests were used to compare continuous normally-distributed numerical values. Significance was set to a p-value less than 0.05. Holm-Bonferonni method was used to correct for family-wise error. JMP® was utilized for statistical analysis (version 9.0.1; SAS Institute Inc, SAS Campus Drive, Cary, NC, USA 27513).

Results

217 patients aged 18 or younger underwent spinal instrumentation between 2009–2015 and were followed for a minimum of two years. Mean follow-up for patients included in the study was 2.48 years. 112 patients had pedicle screws placed under fluoroscopic guidance, while 105 patients had pedicle screws placed using low-dose intraoperative CT-guided navigation. Of the total cohort 71.4% were female (67.6% in the CT-guided navigation cohort vs. 75.0% in the fluoroscopy cohort, $p = 0.23$) (Table 1). There was no significant difference in number of levels between the two groups, 9.8 in the CT-guided navigation cohort vs. 10.0 in the fluoroscopy cohort ($p = 0.062$). For the group that had pedicle screws placed using CT-guided navigation, an average of 1.8 intraoperative CT-guided navigation spins were taken (Table 2). Each CT scan will image 6 to 8 vertebral levels. In the case of longer fusions, more than one CT scan was required in order to perform intraoperative CT-guided navigation.

Operative time was shorter for patients whose screws were placed using fluoroscopic guidance than for those whose screws were placed under CT-guidance (441 vs. 468 min, $p = 0.05$), however this was not significant when controlling for the number of levels fused (58.3 vs. 61.5 min/level, $p = 0.63$). There was no difference in intraoperative blood loss (1468 mL vs. 1291 mL, $p = 0.331$) between the two groups. This trend held true when controlling for the number of levels fused (134 mL/level vs. 147 mL/level, $p = 0.47$). The two groups also did not differ in the volume of packed red blood cells patients received (143 mL vs. 195 mL,

$p = 0.13$). Of the patients included in this study, none had a demonstrated neurologic deficit within 90 days following surgery. Additionally, there were no intraoperative complications related to screw malposition. The freehand/ fluoroscopy group had a higher rate of unplanned return to OR due to malpositioned screws (3.6% vs. 0%, $p = 0.048$, Table 3). No patients with congenital deformities required a return to the OR due to screw malposition.

A total of 4 patients who were treated by 3 different surgeons underwent return to OR due to screw malposition. Diagnoses included trauma (1), severe adolescent idiopathic scoliosis (2), and syndromic scoliosis (1). One patient presented at 12 weeks postoperatively with severe headaches and new-onset Chiari malformation due to a dural leak at right T3 and has been previously reported in a multicenter case series¹². Two patients presented with diffuse back pain and malpositioned screws medially at right T12 and laterally at left T8/T9. In both cases, screw removal which was performed greater than 1 year postoperatively, and the pain resolved. The fourth patient was asymptomatic, but a lateral breach at T12 with the screw tip touching the aorta was found on an incidental CT and the surgeon recommend removal which was performed without incident at 22 months following the index surgery.

In total, incidental CT scans were available for 51 patients representing 526 screws, which were reviewed for screw position. 206 screws had been placed using CT-guided navigation and 323 were placed under fluoroscopic guidance. There were significantly more severely ($>4\text{mm}$) malpositioned screws in the freehand/fluoroscopy group than in the CT-guided navigation group (3.3% vs. 1%, $p = 0.027$). For all patients, including those with less than 2 year follow-up, there was no detected difference between the two groups in the frequency of medial vs. lateral breaches ($p = 0.06$, Table 4). Rate of malposition based on underlying diagnosis was also evaluated (Table 5).

We also re-evaluated our study population, including patients with less than two years follow-up. This expanded the cohort to a total of 369 patients (169 freehand/fluoroscopy, 220 CT guidance). There remained no difference in EBL (freehand/fluoroscopy = 1325mL vs. CT guidance = 1124 mL, $p = 0.07$), EBL/Level (130mL vs. 114 mL, $p = 0.15$), operative time (449 min vs. 467 min, $p = 0.15$), or operative time/level (56.2 min vs. 54.8 min, $p = 0.74$) between the two groups. Incidental CTs were reviewed for 75 patients (20.3%) (35 freehand/fluoroscopy, 40 CT guidance, $p = 0.53$) and 768 screws (401 freehand/fluoroscopy, 367 CT guidance). Again, there was a higher incidence of malpositioned screws (13.5% vs. 7.1%, $p = 0.004$), and severely malpositioned screws (3.0% vs. 0.50%, $p = 0.04$) in the freehand/fluoroscopy group than in the CT guidance group. Additionally, there was a higher rate of return to OR due to screw malposition (2.4% vs. 0%, $p = 0.02$) in the freehand/fluoroscopy group than in the CT guidance group.

Discussion

When using postoperative radiographs alone, reported rate of screw malposition in pediatric patients have been found to range from 1–6%¹³. A meta-analysis found on average 5% of pediatric pedicle screws are malpositioned¹⁴. Using postoperative CT to assess screws to consistently assess screw position, however, results in a higher reported malposition rate. Rajesekaran et al. found 23% of freehand screws breached the pedicle, compared to 2% in

the navigated group¹⁵. Lehman et al. found 10.5% screws placed using the freehand technique were malpositioned on CT imaging¹⁶. Baghdadi et al. found 9% of screws placed in children with freehand technique had more than a 4 mm breach, and up to 20% may have a 2 mm breach^{17,18}. Samdani et al. also found that 12% of freehand screws had a > 2 mm breach, with no statistical correlation based on surgeon experience¹⁹. Ughwanagho et al. found that 9% of non-navigated screws placed by freehand were potentially unsafe (>50% of screw breaching the pedicle), compared to only 3% of navigated screws. Thus, using postoperative CTs to evaluate screw position, rather than plain radiographs, results in higher rates of identified screw malposition, presumably due to improved visualization. Compared to fluoroscopy, CT imaging provides superior visualization, particularly we feel in the axial plane when treating scoliosis. In our series using postoperative CTs to evaluate screw position, we identified higher rates screw malposition in the freehand/fluoroscopy cohort compared to screws placed with CT-guided navigation.

The significance of malpositioned screws is unknown, and there is wide variation in surgeon opinion regarding which asymptomatic pedicle screws may be observed and which necessitate return to OR for revision or removal (Floccari et al.). Reported return to OR for screw related complications are reported at 0.66–4.3% of patients and 0.11–0.48% of screws^{6, 14, 18}. A previous study by Diab et al found the rate of neurologic complications in surgery for AIS to be 0.69% from all causes. Of these neurologic complications, 22% were caused by malpositioned screws (0.15% of all cases)¹⁹. In our study, unplanned return to OR due to screw malposition were initiated by finding on incidental CT (1), back pain (2), and headache (1). All of these occurred in screws placed by freehand/fluoroscopy.

Downsides of navigation include patient exposure to radiation. Fluoroscopy time can vary greatly between surgeons. Previous studies of fluoroscopic screw placement have found a mean fluoroscopy time of 35.3 seconds, representing essentially intraoperative imaging the screws to assess position prior to correction maneuvers^{20,21}. Other series report up longer fluoroscopy times of up to 2.8 minutes per case²². Rampersaud et al. reported 9.3 seconds of fluoroscopy exposure per screw²³. At our center, use of fluoroscopy was not used extensively during screw placement and instead reserved for checking screw position after freehand placement. Thus, the conclusions in this paper may not apply to a fluoroscopic technique using extensive intraoperative imaging. Further study is needed to compare ‘high use fluoroscopy’ with intraoperative CT guided navigation to determine if this results in fewer malpositioned screws.

Low dose intraoperative CT navigation results in increased patient radiation exposure than fluoroscopy, but similar patient radiation exposure as intraoperative radiographs. Using a low-dose technique, imparted radiation from 2-view spine x-ray is similar to that from one low dose CT-navigated spin^{20,24}. Standard manufacturer settings on the device result in a much higher level of radiation exposure for the patient.

Limitations of this study include shorter follow-up time in the CT-navigation group and problems inherent to a retrospective chart review in that surgical techniques and protocols may have changed over the study period. Additionally because this is a retrospective review, and there were no set criteria for determining when to use CT-guidance, when to obtain post-

operative CTs or when to return to the operating room it is possible that inherent differences exist between our two groups. Also, as the surgeons at our center moved towards CT-guidance over time, there is a temporal difference between the two groups with the CT-guided cohort undergoing surgery more recently than those who underwent surgery using fluoroscopic guidance. Blood loss and operative times for this review were higher than commonly reported in the literature. We attribute this to a diverse and patient population with greater than ½ the patient population representing non-idiopathic patients. Additionally, patients receiving postoperative CTs in this series may have been at higher risk for screw malposition, in that postoperative CTs were not routinely performed in all patients. Those who had postoperative CTs may have had symptoms which prompted the additional imaging. Thus, caution must be taken when using these scans as a representation of the entire cohort. Nevertheless, we found a lower rate of screw malposition in those patients who had screws placed using intraoperative CT-guided navigation.

Placement of pedicle screws remains a key technique for achieving correction in pediatric spine deformity. Pedicle screws offer lower rates of revision, decreased requirement for anterior surgical approaches, and better purchase than alternative hooks or hybrid instruments. This series found a decreased rate of severely malpositioned screws with the use of CT guided navigation compared to freehand/fluoroscopy with no increased operative time or blood loss. Further, there was a lower rate of return-to-OR for screw malposition in patients who had screws placed with intraoperative CT-guided navigation. Interestingly, to date, we have eliminated return to OR for screw malposition, which with modern technology may be a preventable problem.

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Highlights:

- Placement of pedicle screws using CT-guided navigation (O-arm) did not lengthen operative time or blood loss per level fused when compared to freehand/fluoroscopic pedicle screw placement.
- Placement of pedicle screws using CT-guided navigation reduced the rate of screw malposition when compared to freehand/fluoroscopic pedicle screw placement.
- Patients who had their pedicle screws placed under CT-guidance had a lower rate of return to OR due to screw malposition than those patients whose screws were placed freehand.

Table 1.**Patient Demographics**

	Freehand	O-Arm	p-value
Number of Patients	112	105	
Mean age at surgery	13.8	13.9	0.75
Male/Female	28/84	34/71	0.23
Time to Follow-up	3.2	2.4	<0.0001
Mean levels fused/patient	10.9	9.8	0.062
Diagnosis			
Congenital	11 (9.8%)	12 (11.4%)	
Idiopathic	65 (58.0%)	40 (38.1%)	
Neuromuscular	26 (23.2%)	30 (28.6%)	
Spondylolisthesis	3 (2.7%)	2 (1.9%)	
Syndromic	3 (2.7%)	11 (10.5%)	
Trauma	2 (1.8%)	3 (2.9%)	
Tumor	2 (1.8%)	4 (3.8%)	

Table 2.

Surgery Characteristics by Screw Placement Technique

	Fluoroscopy	CT-guidance	P-value
Cases	112	105	
Number of O-Arm Spins (mean)	--	1.8 (1–5)	
Number of levels (mean)	10.9 (1–18)	9.8 (2–18)	0.062
EBL (mean)	1127 (200–4830)	1179 (50–5900)	0.63
EBL/Level (mean)	133.7 (15–540)	146.6 (17–800)	0.47
Blood Transfusion (mean)	143 (0–1650)	195 (0–2600)	0.13
Operative time (mean)	441 (174–748)	468 (157–786)	0.05
Operative time/level (mean)	58.3 (26–371)	61.5 (28–198)	0.63

Table 3.

Surgical Outcomes by Screw Placement Technique

	Fluoroscopy	CT-guidance	P-value	Adjust- α
Rate of screws severely malpositioned (> 4mm)	3.3%	1.0%	0.027	0.05 *
Rate of return to OR for screw malposition	3.6%	0%	0.048	0.05 *

*
alpha-values adjusted using Holm-Bonferroni method

Table 4.

Malpositioned Screws by Level and Direction

Freehand					CT-guidance				
Level	Left	Right	Lateral	Medial	Level	Left	Right	Lateral	Medial
T1	0	0	0	0	T1	0	0	0	0
T2	0	1	1	0	T2	0	0	0	0
T3	0	1	0	1	T3	0	1	0	1
T4	2	0	1	1	T4	1	1	1	1
T5	2	3	2	3	T5	2	1	3	0
T6	3	3	1	5	T6	1	2	0	3
T7	1	2	1	2	T7	3	3	2	4
T8	2	4	2	4	T8	2	1	0	3
T9	2	3	2	3	T9	5	0	2	3
T10	4	3	2	5	T10	1	0	1	0
T11	6	2	3	5	T11	3	1	3	1
T12	8	4	2	10	T12	3	2	3	2
L1	3	3	2	4	L1	3	1	1	3
L2	0	3	1	2	L2	2	2	3	1
L3	1	3	2	2	L3	0	2	2	0
L4	0	0	0	0	L4	0	2	2	0
L5	1	0	1	0	L5	0	0	0	0

Table 5.

Rate of Malposition by Patient Diagnosis and Placement Technique

Diagnosis	Rate of Any Malposition (Visualized Screws)	
	Freehand/Fluoroscopy	CT-Guidance
Congenital	n/a	8/29
Idiopathic	46/167	4/18
Neuromuscular	19/122	13/70
Spondylolisthesis	0/8	0/2
Syndromic	n/a	18/57
Trauma	2/8	1/9
Tumor	2/18	2/18