

Comparison of the Pedicle Screws Placement Between Electronic Conductivity Device and Normal Pedicle Finder in Posterior Surgery of Scoliosis

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Study Design: Prospective randomized clinical trial.

Objective: To compare the accuracy and time using of pedicle screw placement between electronic conductivity device (ECD) and normal pedicle finder (NPF) in posterior surgery of scoliosis, through a randomized clinical trial.

Summary of Background Data: Pedicle screw insertion for scoliosis correction can be associated with increased pedicle perforations. The malposition rates using various techniques in different region of the spine have been reported to occur with a frequency of 3.3%–43%. An ECD has been reported in spine surgeries, but its accuracy and surgical time comparing with NPF in the presence of scoliosis has not been reported.

Methods: The 42 patients of adolescent idiopathic scoliosis with average major Cobb angle of 55.3 ± 7 degrees (range, 45–78 degrees), who received posterior correction surgeries using pedicle screws system only were divided into 2 groups by random: group NPF (22 patients); and group ECD (20 patients). NPF group had 332 screws and ECD group had 362 screws. The 2 groups were compared for accuracy of screw placement, time for screw insertion, and the number of times the C-arm had to be brought into the field.

Results: There were 47 (14.2%) pedicle perforation in the NPF group as compared with only 15 (4.1%) in the ECD group ($P < 0.001$). Although in different region of the spine, screw accuracy showed discrepant statistical result, with upper (T1–T3), middle (T4–T7), and lower thoracic (T8–T10) comparison showing significant statistical difference ($P = 0.010, 0.001, \text{ and } 0.041$, respectively) and thoracolumbar (T11–L2) and lower lumbar (L3–L5) comparison showing no significant statistical difference ($P = 0.278 \text{ and } 0.292$, respectively). Average screw insertion time in the NPF group was 241 ± 61 seconds compared with

204 ± 33 seconds in the ECD group ($P = 0.009$). The C-arm had to be moved into the operation field on an average of 1.59 ± 0.67 times in the NPF group compared with 1.20 ± 0.52 in the ECD group ($P = 0.040$).

Conclusions: ECD increases pedicle screw accuracy, especially in T1–T10, and reduces insertion time and radiation in posterior adolescent idiopathic scoliosis.

Key Words: scoliosis, pedicle screws, navigation, electronic conductivity device, pedicle finder

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Pedicle screw fixation has numerous advantages over other methods of spinal fixation.¹ When used in scoliosis surgery, transpedicular screws have been reported to enhance the operative correction.² Pedicle screw placement, particularly in scoliosis surgery, can be challenging even for an experienced surgeon, due to the deformation of the anatomy and the changes in vertebral morphology. Pedicle screw perforation, with rates ranging as high as 43%,³ can further lead to complications such as dural tear, nerve root injuries, paraplegia, or vascular injury.^{4,5}

We used a recently produced wireless electronic free-hand drilling instrument based on electronic conductivity, which was first used in degenerative spine patients reported by Bolger et al⁶ in scoliosis surgery. The electronic conductivity device (ECD) (PediGuard, SpineGuard TM) (Fig. 1) is integrated into the drilling tool, and allows real-time detection of bone perforation through electronic conductivity variation. The device is designed to detect the initiation of iatrogenic breaches in the vertebral pedicle wall before screw insertion.

We presented the results of a randomized control clinical study, which compared the accuracy and time used by ECD and traditional free-hand normal pedicle finder (NPF), navigating pedicle screw fixation in thoracic and lumbar spine for correction of adolescent idiopathic scoliosis (AIS).

MATERIALS AND METHODS

Forty-two AIS patients undergoing spinal deformity correction surgeries using posterior pedicle screw

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FIGURE 1. The PediGuard—electronic conductivity device.

instrumentation formed the study group. The inclusion criteria were the scoliosis curve between 40 and 80 degrees. Patients of non-AIS, more severe deformities, or a body weight of more than 80 kg were excluded because in these condition, it would significantly alter the pedicle diameter, which could influence the pedicle screws placement accuracy and time.

Approval of the ethical committee was obtained, and patients were randomly allocated to 2 study groups using a computer-generated random number table: 20 in the ECD group and 22 in NPF group. In the ECD group, the pedicle screw trajectory was made using ECD. In the other group, the pedicle screw trajectory was made using NPF. In both groups, the pedicle screw positions were confirmed using the same C-arm. The 42 patients were all AIS, with Lenke type I 18, Lenke type II 8, Lenke type III 6, Lenke type IV 2, Lenke type V 4, and Lenke type VI 4 cases. The average age of the patients was 15 ± 6.52 years (range, 10–18 y, median 16 y), and the average major curve Cobb angle was 55.3 ± 7 degrees (range, 45–78 degrees). All patients underwent posterior spinal fusion with pedicle screw only constructs. The average number of segments instrumented was 9 ± 3 (range, 6–14) (Table 1).

Patients underwent preoperative assessment by plain radiography and magnetic resonance imaging of the whole spine. All surgeries were performed by the surgical team experienced in the treatment of deformities. The titanium implants were used routinely in all patients. The T1–T3 levels were grouped as upper thoracic vertebra (UT), T4–T7 levels as middle (MT), T8–T10 levels as lower (LT), T11–L2 levels as thoracolumbar (TL), and L3–L5 levels as lower lumbar vertebra (LL).

In the NPF group, an entry point was appropriately chosen and developed with a burr. The NPF was then used to navigate through the pedicle. The blunt probe was also intermittently used to feel for the pedicle walls so as to detect any breach at the earliest. The insertion depth of probe was then measured using a ruler. Screws of 5 in millimeter diameter were inserted uniformly into the thoracic pedicles, and 6 in millimeter diameter were inserted uniformly into the lumbar pedicles. The screw length was measured approximately up to 60%–80% of

the vertebral body.^{7,8} Multiple C-arm images usually had to be obtained to get an end-on view of the pedicle screw. The number of times the C-arm was moved into the operating field per operation and the time taken for insertion of each screw were measured.

In the ECD group, every step was the same with the former group, except for using ECD instead of NPF. The ECD is a free-hand drilling instrument, designed with an electronic conductivity sensor at its sharp tip, which can translate relative values of electronic conductivity into audible and visual signals. It works on the premise that cancellous bone within the pedicle possesses lower resistance than the cortical bone and soft tissues that surround it, and thus can provide the surgeon live feedback as to whether the trajectory has strayed from within normal intrapedicle spatial boundaries.

Screw position was evaluated 1 week after operation using an axial computed tomography (CT) scan at each screw axis. Following the scheme of Rao et al,⁹ the evaluation of screw malposition was classified as grade 0 (no apparent violation of the pedicle), grade 1 (< 2 mm perforation of the pedicle, with 1 screw thread out of the pedicle), grade 2 (between 2 and 4 mm of perforation of the pedicle, with half of the diameter of the screw outside of the pedicle), and grade 3 (> 4 mm or complete perforation of the pedicle), with grades 1, 2, and 3 representing “perforation.” On the basis of this grading system, screw misplacement rates were determined. The medial, lateral, superior, inferior, or anterior perforation of the pedicle wall was also evaluated. Interobserver and intraobserver variability between the 2 independent evaluators blinded to the study who evaluated 50 CT scans at an interval of 8 weeks showed a good rate of agreement ($k = 0.85$ for interobserver and $k = 0.83$ for intraobserver reliability).

RESULTS

Total of 694 pedicle screws were inserted. Three hundred sixty-two screws were in ECD group and 332 were in NPF group. There were 103 pedicle screws in UT (50 ECD group and 53 the other group), 185 in MT (104 ECD group and 81 the other group), 156 in LT (80 ECD group and 76 the other group), 202 in TL (103 ECD group and 99 the other group), and the rest 48 in LL (25 ECD group and 23 the other group). None of these patients had any clinical evidence of neurovascular involvement and revision surgery (Table 2). Average blood loss was 950 mL (range, 500–1800 mL) in the ECD group,

TABLE 1. Preoperative Patient and Demographic Particulars in the 2 Study Groups

Group	NPF	ECD
No. patients	22	20
No. pedicle screws	332	362
Age of patients (range), y	15.5 ± 5.6 (10–18)	16.2 ± 4.5 (11–18)
No. males	5	4
No. females	17	16

ECD indicates electronic conductivity device; NPF, normal pedicle finder.

TABLE 2. Screws Perforation Rate Results Based on Region

Group	NPF	ECD	P
Total	47/332 (14.2%)	15/362 (4.1%)	0.001
UT	11/53	2/50	0.010
MT	21/81	8/104	0.001
LT	8/76	2/80	0.041
TL	6/99	3/103	0.278
LL	1/23	0/25	0.292

ECD indicates electronic conductivity device; LL, lower lumbar vertebra; LT, lower thoracic vertebra; MT, middle thoracic vertebra; NPF, normal pedicle finder; TL, thoracolumbar vertebra; UT, upper thoracic.

whereas it was 1050 mL (range, 600–2000 mL) in the NPF group.

Accuracy

In the NPF group, there were 7 superior (2–4 mm) and 15 inferior pedicle breaches (2–4 mm). There was a total of 6 screws with medial pedicle breach, with 5 encroaching < 2 mm and 1 between 2 and 4 mm of the spinal canal. Ten screws had breached lateral pedicle cortex, with: 2 being < 2 mm; 4, 2–4 mm; and 4 > 4 mm. Nine screws had penetrated the anterior or lateral cortex of the vertebral body, of which 5 were more than 4 mm, others were 2–4 mm. In the ECD group, 2 patients had a superior pedicle breach of 2–4 mm, whereas 4 had inferior cortical breach of 2–4 mm. One patient had a medial pedicle breach of < 2 mm. Of the 3 screws breaching the lateral pedicle cortex, 2 with more than 4 mm pedicle breach. The remaining 1 screw had a lateral pedicle breach of less than 2 mm. Five screws were < 2 mm longer than the limits of the vertebral body. The rate of pedicle breach of different region of the spine and total comparison between 2 groups was made using Pearson χ^2 test (Table 2), (Fig. 2).

Screw Insertion Time

In the NPF group, average screw insertion time was 241 ± 61 seconds (range, 72–367 s). Average screw insertion time in the ECD group was 204 ± 33 seconds (range, 65–255 s) per screw (Table 3).

Movement of the C-Arm into the Operating Field

In both groups, final anterior-posterior view was obtained after all screws were put in using C-arm. If improper screws position was found, C-arm was removed, the improper screws were pulled out and the original pedicle trajectory maker (NPF or ECD) was used to re-navigate through the pedicle, then put in screws and moved C-arm into the operation field for checking position. This procedure was repeated until all screws were identified good position by surgery group. In the NPF group, the C-arm had to be moved into the operation field on an average of 1.59 ± 0.67 times per operation, with 12 screws regulation. In the ECD group, the C-arm had to be moved into the operation field on an average of 1.20 ± 0.52 times per operation, with 3 screws regulation (Table 3).

Comparison of the screw insertion time and radiation exposure rate per operation between the 2 study groups was analyzed using the independent *t* test (Table 3).

DISCUSSION

Transpedicular stabilization has become an established method for instrumentation of the thoracic and lumbar spine because of its immediate rigidity, better coronal and sagittal correction, and shorter fusion length in scoliosis surgery when compared with other instrumentation techniques.² The pedicle screw insertion in scoliosis surgery involves the increased perforation risk because of a morphologic peculiarity of scoliotic vertebra, vertebral rotations, and inaccuracy of intraoperative fluoroscopic images.^{10,11}

Classic methodologies for verification of optimal placement of pedicle screws include a free-hand technique,¹² intraoperative fluoroscopy, triggered electromyography,¹³ intraoperative image-based navigation,¹⁴ and most recently, the use of a hand-held ECD.⁶ ECD was shown to have high overall sensitivity and specificity values (98% and 99%, respectively) for detecting pedicle breaches, as well as high (> 94%) negative and positive predictive values. Betz et al¹⁵ reported that screws placed with an ECD in degenerative patients showed greater efficacy.

In our study, the ECD group showed an overall 4.1% perforation rate, which was significantly ($P < 0.001$) under 14.2% perforation fate of the NPF group. This result was comparable with the study of previous accuracy analysis of pedicle screw placement between conventional fluoroscopic and computer-assisted navigation system in posterior scoliosis surgery. The reported perforation rate using computer-assisted navigation technique was from 3.3%–14%.^{16–20} Ovadia et al²¹ most recently reported a retrospective study of using ECD, which significantly reduced intraoperative neuromonitoring alarms concomitant with screw placement occurred from 6.6% in NPF group to 3.0% in ECD group, which we believed to be only a midterm inspection of perforation before putting in screws rather than the final screws perforation rate result. Koller et al²² reported, in an in vitro study showed that the use of an ECD can be a valuable adjunct in cervical pedicle screw insertion. Zeller et al²³ reported that 30.8% of the screws were placed an average of 1.33 mm deeper than planned in pediatric patients with cervical spinal disorders using ECD. These 2 cervical screws (lateral mass, pars, laminar, and/or anterior vertebral body) studies described above were different with our thoracic and lumbar screws in scoliosis.

As we predicted, different region of spine showed varied perforation rate and statistical result. The UT, MT, and LT region showed significant statistical differences with *P* value of 0.01, 0.001, and 0.041, respectively. Nevertheless, the TL and LL region showed no statistical differences in both groups with *P* value of 0.278 and 0.292, respectively. Lonstein et al²⁴ reported in TL to sacral spine surgeries including a scoliosis, complications



FIGURE 2. A, Preoperative AP x-ray of a 12-year-old female patient with adolescent idiopathic scoliosis with a main thoracic curve of 50 degrees and a lumbar curve of 47 degrees (group electronic conductivity device). B, Her postoperative AP x-ray showing thoracic curve of 7 degrees (86% of correction) and lumbar curve of 5 degrees (85% of correction). AP indicates anteroposterior.

associated with pedicle screws in 875 patients, demonstrating the screw malposition rate of 5.1%, even mostly in LL screw insertions. Belmont et al³ reported the clinical accuracy of thoracic pedicle screws in 40 patients of scoliosis and kyphosis, demonstrating 43% of screw perforation rate at T1–T12. In our experience, it was really confident in putting lumbar and TL screws using free-hand technique, although less attention, times, and feeler was used here than in thoracic. The 7 and 3 perforated screws in normal NPF and ECD group of TL and LL region were most likely due to accidental factors in putting screws, such as the quality of bone, manual power, and so on, because all of them were just < 2 mm lateral pedicle breach and showed no statistical difference in comparing perforation rate of the 2 groups. The reason why we chose our study inclusion criteria of scoliosis curve between 40 and 80 degrees was that we believed these relatively simple curves could to the greatest extent reduce screws perforation occurred in deformity correction maneuver rather than in putting screws.

The average time required to insert the pedicle screws and average number of C-arm shot per case was significantly shorter in the ECD group in comparison with the NPF group (241 vs. 204 s and 1.59 vs. 1.20 times, with *P*-value: 0.009 and 0.040, respectively), with less screw regulation and perforation rate. We contributed the most prominent reason for considering using ECD, reduced average screw insertion time to the convenience of

finding channels and putting pedicle screws into the malformed and rotated vertebra of scoliosis. Our earlier study had shown even the computer-assisted navigation system would increase surgical time at the beginning usage and it had a relative long learning curve, although it could decrease time in the long run.¹⁸ Our present study just began 6 months after ECD implementation, therefore better result could be presumed in longer implementation. Less average number of C-arm shot in ECD group would further decrease average operation time though it was not calculated in this study.

To our knowledge, this is the first prospective clinical study comparing the screw accuracy of deferent region and time using of ECD navigated and NPF navigated pedicle screws instrumentation for AIS in the range of 40–80 degrees. However, there are certainly some limitations of this study. Firstly, our study commenced just 6 months after ECD implementation, the learning curve

TABLE 3. Average Time per Screw and Radiation Exposure per Case

Group	NPF	ECD	<i>P</i>
Average time per screw (s)	241 ± 61	204 ± 33	0.009
Average number of shot per case	1.59 ± 0.67	1.20 ± 0.52	0.040

ECD indicates electronic conductivity device; NPF, normal pedicle finder.

factor might not be eliminated, although we found it easy to grasp and no clustered data in the series at the beginning. Fortunately, the study showed a favorable result of ECD, which would be better during the following time after our study. Secondly, routine postoperative CT increased amount of ionized radiation to the patients, but it could give a definite answer for surgeons and patients to whether any screw was safe besides our study purpose.

In our experience, the use of the ECD improved pedicle screw insertion safety and saved surgical time, and this study showed it as well. The ECD would bring more benefit in UT, MT, and LT vertebra pedicle screws instrumentation in AIS.

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