

Accuracy Analysis of Pedicle Screw Placement in Posterior Scoliosis Surgery

Comparison Between Conventional Fluoroscopic and Computer-Assisted Technique

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Study Design. The accuracy of pedicle screw placement was evaluated in posterior scoliosis surgeries with or without the use of computer-assisted surgical techniques.

Objective. In this retrospective cohort study, the pedicle screw placement accuracy in posterior scoliosis surgery was compared between conventional fluoroscopic and computer-assisted surgical techniques.

Summary of Background Data. There has been no study systemically analyzing the perforation pattern and comparative accuracy of pedicle screw placement in posterior scoliosis surgery.

Methods. The 45 patients who received posterior correction surgeries were divided into 2 groups: Group C, manual control (25 patients); and Group N, navigation surgery (20 patients). The average Cobb angles were 73.7° and 73.1° before surgery in Group C and Group N, respectively. Using CT images, vertebral rotation, pedicle axes as measured to anteroposterior sacral axis and vertebral axis, and insertion angle error were measured. In perforation cases, the angular tendency, insertion point, and length abnormality were evaluated.

Results. The perforation was observed in 11% of Group C and 1.8% in Group N. In Group C, medial perforations of left screws were demonstrated in 8 of 9 perforated screws and 55% were distributed either in L1 or T12. The perforation consistently occurred in pedicles in which those axes approached anteroposterior sacral axis within 5°. The average insertion errors were 8.4° and 5.0° in Group C and Group N, respectively, which were significantly different ($P < 0.02$).

Conclusion. The medial perforation in Group C occurred around L1, especially when pedicle axis approached anteroposterior sacral axis. This consistent tendency was considered as the limitation of fluoroscopic screw insertion in which horizontal vertebral image was not visible. The use of surgical navigation system successfully reduced the perforation rate and insertion angle errors, demonstrating the clear advantage in safe and accurate pedicle screw placement of scoliosis surgery.

Key words: scoliosis surgery, surgical navigation, computer-assisted surgery. *Spine* 2007;32:1543-1550

The goal of scoliosis surgery was to achieve a sufficient coronal correction while maintaining or improving sagittal spinal alignment. The correction technique of scoliosis surgery has changed from Harrington principles of concave distraction to segmental realignment and stabilization.¹⁻³ The use of pedicle screw in lumbar curve was introduced to enhance the correction and stabilization and several studies reported the clinical advantage of lumbar pedicle screw over hook instrumentation in terms of curve correction, horizontalization, and translation of lowest instrumented vertebra.⁴⁻⁷ More recently, some authors reported the use of pedicle screws in thoracic spine to enhance the correction rate as well as minimizing the fusion area despite potential risks.⁸⁻¹²

In contrast to comparative efficacy of pedicle screws in scoliosis, several complications associated with pedicle screws have been reported.¹³⁻¹⁶ The reported complications included the nerve root or spinal cord compression due to screw malposition, pseudarthrosis, and major vessel injury.¹³⁻¹⁶ In scoliosis patients, several unique morphometric characteristics including pedicle dimension and vertebral rotation were pointed out.^{11,17-20} These included an intravertebral asymmetry of vertebra, smaller diameter of concave side pedicle around apex, and significant vertebral rotations, which significantly increased the insertion risk of pedicle screws. In the operative setting, the lateral fluoroscopy has conventionally been used for pedicle screw insertion; however, the decreased accuracy of fluoroscopic image in scoliosis surgery has been pointed out.¹¹ This leads to the abnormality of angle and length on the horizontal and sagittal plane.

We have used the surgical navigation system configured with originally developed screw insertion instrument for several cervical disorders and spinal deformities.²¹ This system warranted the accuracy below 0.5 mm in each step of screw insertion, while providing simultaneous and 3-dimensional instrument/screw tip information.

The objectives of this study were twofold: 1) to analyze the pedicle screw placement accuracy at lower thoracic and lumbar spine levels in posterior scoliosis surgery with conventional fluoroscopic (manual) technique and understand the possible tendency of misplacement;

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and 2) to evaluate the efficacy of the latest computer-assisted insertion technique.

Materials and Methods

Patient Demographics. The scoliosis patients who received posterior or anterior-posterior combined surgery from April 1998 to December 2004 were retrospectively reviewed. For accuracy evaluation of pedicle screws, the patients with preoperative and postoperative CT scans available were enrolled in this study. When the screw trajectory and screw perforation could not be evaluated due to metal artifacts, the patients were not included in this study. Consequently, a total of 45 patients were enrolled in this study. There were 8 males and 37 females.

Twenty-five patients received fluoroscopy-based conventional pedicle screw insertion at lower thoracic and lumbar spine levels in the earlier period of 1998 to 2001 (Group C). Twenty patients received the selective computer-assisted pedicle screw insertion with surgical navigation system (StealthStation; Medtronic SofamorDanek, Memphis, TN) and cervical/thoracic navigation instruments specially designed for cervical and thoracic pedicle screw insertion in later period of 2001 to 2004 (Group N).²¹ The average ages at operation were 16 years (range, 12–33 years) and 13 years (range, 6–18 years) in Group C and Group N, respectively. The etiology of scoliosis was mostly idiopathic; however, neuromuscular and mesenchymal etiology was identified in 5 and 2 patients of Group C, respectively. In Group N, mesenchymal and congenital etiology was identified in 2 and 1 patient, respectively. The average Cobb angles of major curve were $73.7^\circ \pm 20.9^\circ$ (range, 48° – 122°) and $73.1^\circ \pm 22.9^\circ$ (range, 40° – 113°) in Group C and Group N, respectively, and surgically corrected to $32.3^\circ \pm 13.8^\circ$ (range, 4° – 72°) and $31^\circ \pm 12^\circ$ (range, 12° – 49°), after surgery (mean \pm SD). The average numbers of instrumented spinal segments were 11.5 ± 1.6 (range, 7–13) and 10.8 ± 2.3 (range, 6–13) in Group C and Group N, respectively. In 4 cases of Group C, planned 2 stage surgeries of combined anterior and posterior correction and fusion were performed to gain a better correction and spinal balance.

Surgical Procedures. The posterior correction surgery was performed using Isola spinal system (Depuy AcroMed, Raynham, MA) with multiple claw hook formations for upper fixation anchor and sublaminar wiring with either Isola double wires or polyethylene tapes (Azwell, Co. Ltd., Osaka, Japan) under the spinal cord monitoring. The pedicle screws were inserted for lower fixation anchor at caudal 2 or 3 spinal segments with occasional use of laminar hook. The screw insertion levels were distributed from T11 to L4 overall. In Group C, the conventional fluoroscopy-based pedicle screw insertion was conducted with use of lateral fluoroscopy while assuring that bilateral pedicle images were correctly superimposed. The sequential careful surgical steps of awl, probing, tap, and screw insertion were performed following the use of pedicle sounder. When the pedicle perforation was detected before screw insertion, the screw insertion was not performed. When the screw perforation was detected with electric cautery stimulation after the screw insertion, the corresponding screw was removed. The pedicle diameters were before surgery measured with CT scans, and appropriate screw diameters of 4.75 mm, 5.5 mm, or 6.25 mm were selected intraoperatively. All pedicle screws were randomly inserted by 3 surgeons (K.A., M.I., and Y.K.) in a same manner described above. The preceding anterior correction

surgery was conducted in 7 cases using Kaneda Anterior Scoliosis System for major curve to achieve better final scoliosis correction. In Group N, pedicle screw diameters were measured with preoperative CT scans (1-mm slices) and spinal levels required for navigation system were selectively determined before surgery. Consequently, the use of navigation system was minimized to 1.5 vertebrae in average.

We used a surgical navigation system (StealthStation, SofamorDanek, Memphis, TN) combined with our unique screw insertion instruments reported previously.²¹ The navigation system consisted of a computer system and a charge-coupled device camera, allowing CT data to convert into the hard disc and to reconstruct 3-dimensional spinal image before surgery. The reference frame was attached to the spinous process of vertebra, allowing its signal to be sent to charge-coupled device camera. The subsequent registration procedures of point-merge and surface-merge produced 3-dimensional spinal images on the monitor, which were identical to the actual spines in the operative field. Instead of solely using a conventional navigation probe, our screw insertion instruments consisted of a modified awl, probe, tap, and screwdriver for cervical and thoracic pedicle screw use (Figure 1). These instruments were modified from original pedicle screw instruments; however, special considerations were required to prevent a bending of instrument during insertion as well as to attach to the image-guided awl/probe/tap driver (Figure 1). The tip configuration of these instruments was also modified to the straight shape. The pharmaceutical affairs law and new design for practical use in Japan approved this system (#3092558). Using this system, the instrument/screw tip information was 3-dimensionally identified in each step of screw insertion (Figure 2). Therefore, surgeons can assure a 3-dimensional position of instrument/screw tip in the axial, parasagittal, and coronal images during the operation procedure. In each case, lateral fluoroscopic images were simultaneously used with spinal navigation to deal with unexpected registration or computer error during surgery. However, no conversion from navigation surgery to manual insertion was demonstrated in this series of patients.

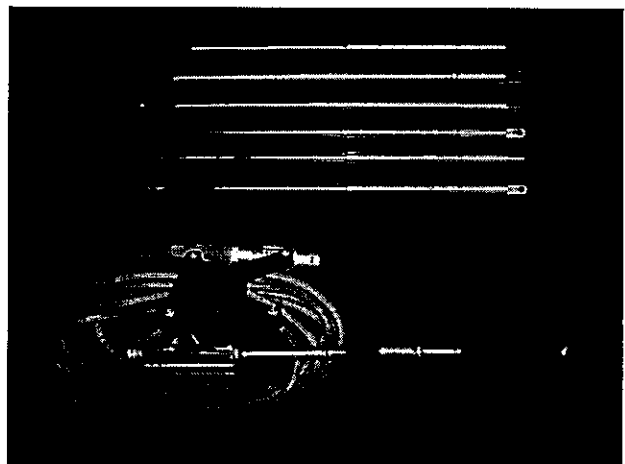


Figure 1. Screw insertion guidance system specially designed for cervical or thoracic pedicle screw insertion. The system consists of modified awl, probe, tap, and screwdriver modified from original pedicle screw instruments. Each instrument was simply attached to the image-guided awl/probe/tap driver without reregistration procedures.

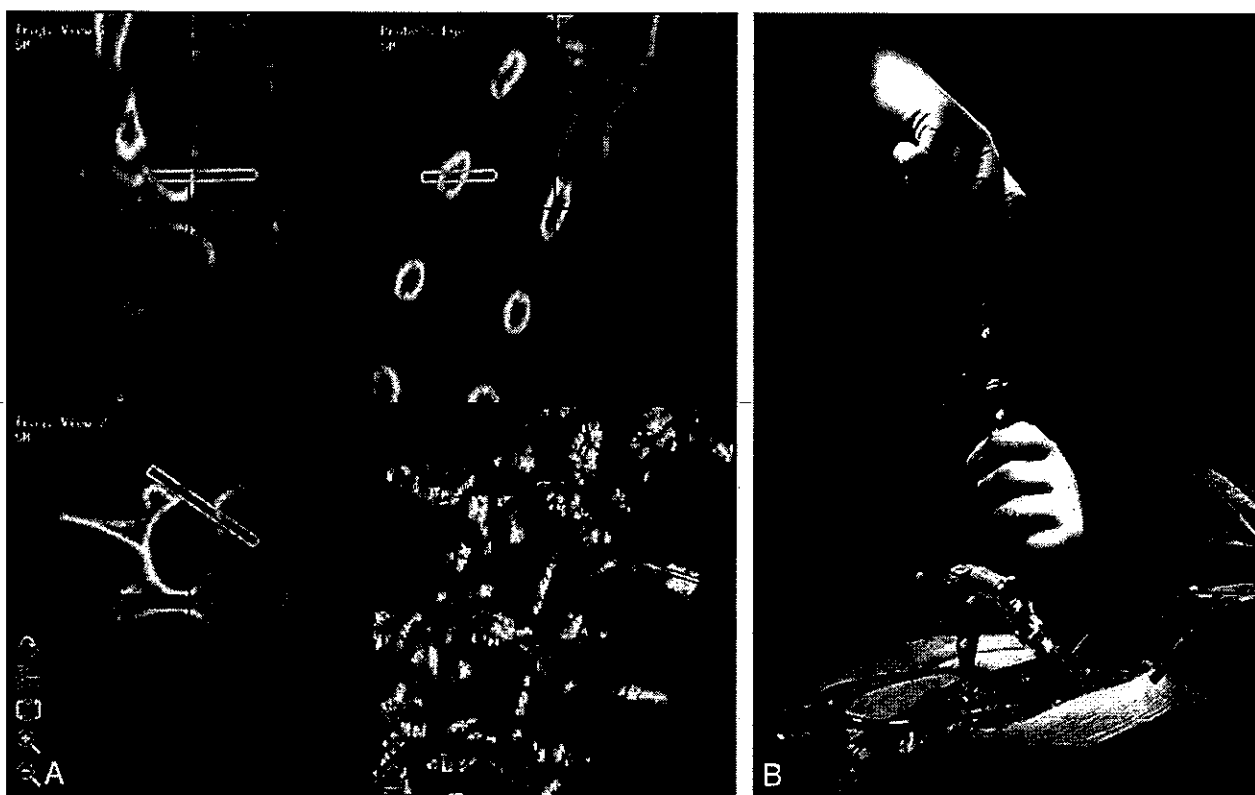


Figure 2. Navigated pedicle screw insertion in scoliosis with simultaneous and 3-dimensional instrument/screw tip data. **A**, Navigation views provide horizontal, parasagittal, and pedicle-axis images in conjunction with a planned screw and actual instrument tip images. The actual instrument tip was inserted to the middle of small pedicle at L2 with planned width of 2.5 mm in this photograph. **B**, The reference frame was attached to the spinous process of corresponding vertebrae for spinal navigation. The optical signal from the light-emitting diode on the image-guided driver was transmitted to the computer, and the instrument tip location was displayed 3-dimensionally on the monitor.

Radiologic Evaluation of Pedicle Anatomy and Screw Placement. Using preoperative CT scans, following 3 anatomic parameters were measured. Vertebral rotation (VR) was calculated as the angle between sagittal axis of corresponding vertebra and sagittal sacral axis (Figure 3A). The sagittal vertebral axis bisected vertebral body, spinal canal, and spinous process. The angle between the pedicle axis and sagittal sacral axis was measured and defined as the pedicle axis to sagittal sacral axis (PSS) (Figure 3B). The angle between pedicle axis and sagittal vertebral axis represented the anatomic pedicle angulation in each vertebra (PVS) (Figure 3C). Using postoperative CT scans, the pedicle screw error (PSER) was defined as the angle between inserted screw axis and anatomic pedicle axis (Figure 3D). The CT scans with significant metal artifacts were not used for this investigation and the patients with those CT scans were excluded from this study. All parameters described above were compared between Group C and Group N.

Screw Perforation and Correlation Analysis to Anatomic Parameters. The pedicle screw perforation was examined in terms of its frequency, and perforated spinal levels. The one-fourth of screw thread exposure out of the pedicle was defined as screw perforation and the borderline cases were comprehensively analyzed with the insertion angle and point, and magnified anteroposterior and lateral radiographs by independent 2 examiners. In perforated cases, the tendency of screw angle, insertion point, abnormality of screw length, and neurologic

disturbance were investigated. The correlation between PSER and VR, PSS, or PVS was examined to clarify whether anatomic parameters affected the misplacement of pedicle screws. These precise analyses were tried to assess the pattern of screw misplacement in posterior scoliosis surgery from a human engineering standpoint.

Statistical Analysis. The age and preoperative and postoperative Cobb angles were statistically compared using unpaired Student's *t* test between Group C and Group N. Radiologic parameters were also compared between Group C and Group N using an unpaired *t* test. The screw perforation rate was compared using a Fisher's exact probability test between Group C and Group N with a significance level set at 0.05. The correlation analysis was performed with simple linear regression and Pearson's correlation coefficient.

■ Results

There were no statistical differences in preoperative and postoperative Cobb angles between Group C and Group N. The average numbers of instrumented spinal segments were statistically equivalent between those 2 groups. In the subgroup requiring an additional anterior surgery, the average Cobb angle was 78.6°, which was not significantly different from whole Group C. In both Group C and Group N, surgical corrections were suc-

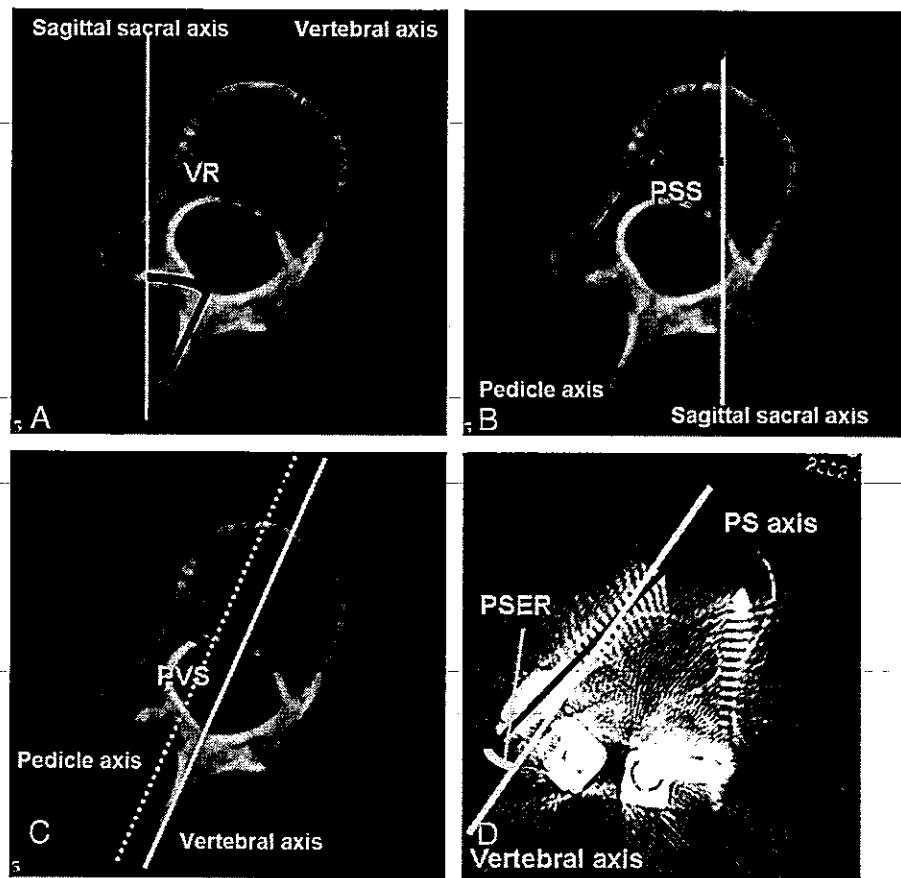


Figure 3. Calculated parameters on computed tomographic image. A, Vertebral rotation to sagittal sacral axis (VR). B, Pedicle axis to sagittal sacral axis (PSS). C, Pedicle axis to vertebral axis (PVS). D, Pedicle screw error as measured to pedicle axis (PSER).

cessfully performed without any neurologic disturbance and surgical complications except 1 case of late neurologic disturbance requiring screw removal in Group C.

Radiologic Evaluation of Pedicle Anatomy and Screw Placement

The VRs at each spinal level that required pedicle screw insertion indicated 5° to 17° in Group C, and 10° to 20° in Group N from T12 to L3 (Figure 4). There was no statistical difference in VR between 2 groups at each spinal level. The maximum VR demonstrated 38° and 28° in Group C and Group N, respectively. The PSS demonstrated an apparent contrast between right and left side at T12 to L3. The PSS on the right side demonstrated consistently higher values than that on left side and indicated 15° to 31° in average with the maximum value of 52° in both groups (Figure 5A). PSS on left indicated 4° to 14° in average and frequently approached to sagittal sacral axis (0°) (Figure 5B). On both right and left side, PSS did not demonstrated statistical differences between Group C and Group N. The PVS on right side demonstrated 8.2° to 11.7° in average in Group C, while 6.8° to 15.1° in Group N. There were no statistical differences in right PVS between Group C and Group N. The PVS on left side demonstrated 8.8° to 12.7° in average in Group C, while 9.0° to 15.1° in Group N. There were no statistical differences in left PVS between Group C and Group N. The overall PSER in 2 surgical groups were 8.4° ±

6.3° and 5.0° ± 2.9° (mean ± SD) in Group C and Group N, respectively. There was a statistical difference between 2 values at a P value of 0.02. The comparison of PSER value at each spinal level between 2 groups demonstrated the tendency of higher values in Group C at

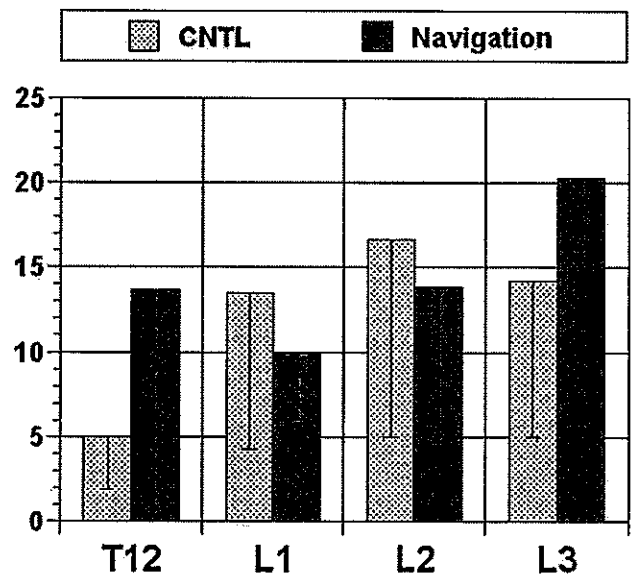
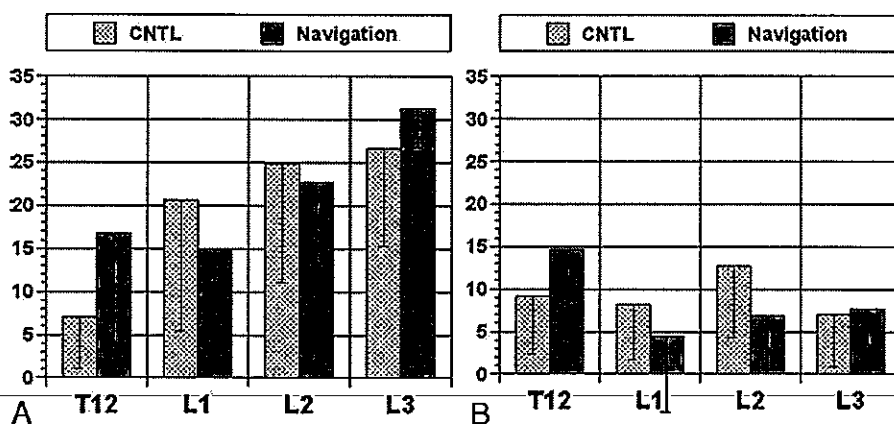


Figure 4. Vertebral rotation to sagittal sacral axis (VR) at T12 to L3 levels in control and surgical navigation groups.

Figure 5. Pedicle axis to sagittal sacral axis (PSS) at T12 to L3 levels in control and surgical navigation groups. A, PSS on right side. B, PSS on left side.



right T12 and L1. However, the statistical difference of PSER was not demonstrated at each spinal level.

Screw Perforation and Correlation Analysis to Anatomic Parameters

The overall screw perforation was demonstrated in 9 of 81 screws of Group C (11%), and in 1 of 57 screws of Group N (1.8%) ($P = 0.08$). The perforated spinal levels in Group C were 4 at L1, 2 at L3, 1 at T11, T12, and L4, respectively. The 1 case in Group N demonstrated a slight lateral perforation below 2 mm at T12; however, this did not cause any vascular and organ compression. The perforation patterns in Group C were subdivided into following 3 groups: medial perforation at the level caudal to the major curve in 5 cases, medial perforation within major curve in 3 cases, and lateral perforation within the major curve in 1 case. Specifically, the perforations occurred at end-vertebra in 4 cases, followed by 3-level distal to end vertebra in 2 cases. The precise analysis of screw perforation demonstrated that the frequency of medial perforation was high in 89% (8 of 9

cases), as well as the dominance of left side perforation in 78% (7 of 9 cases). In these medial perforations, the main cause was attributed to the insertion angle abnormality (87%) instead of medial insertion point error (14%). And importantly, the medial perforation consistently occurred in pedicles in which those axes approached anterior-posterior sacral axes. The average PSS in the perforated case demonstrated 3° (0° – 8°), while 7° to 19° in nonperforated cases. The correlation between PS error and either VR and PSS demonstrated no statistically significant difference. The use of surgical navigation system effectively reduced the screw perforation rate and improved the screw insertion accuracy.

Case Reports

Case 1

The 12-year-old girl in Group C was the only case who demonstrated late neurologic disturbance due to perforated L3 screw at 4 years after combined anterior and posterior surgeries (Figure 6). The medial perforation of

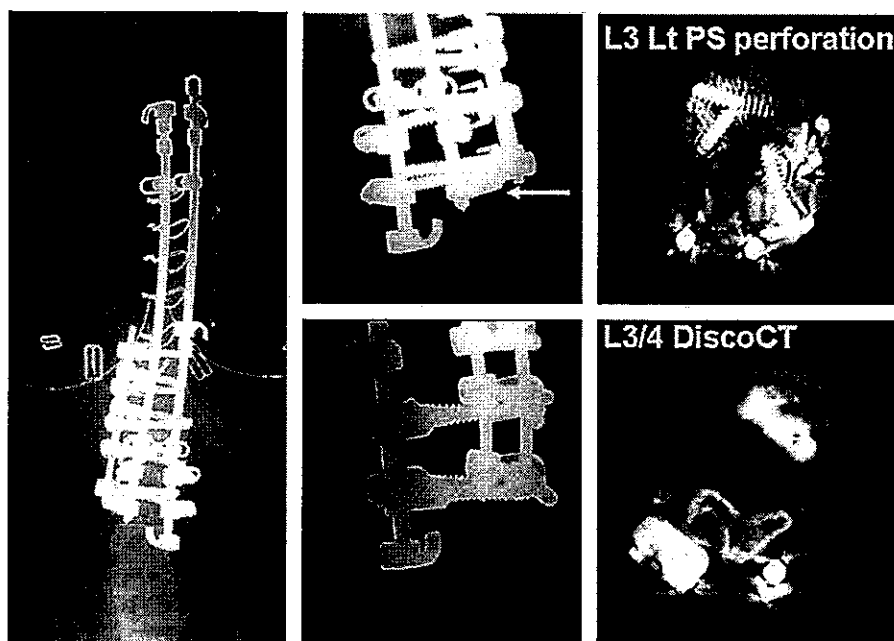


Figure 6. Late onset L3 radiculopathy by perforated pedicle screw in 16-year-old girl at 4 years after surgery (Group C). The leg pain and weakness disappeared immediately after the screw removal.

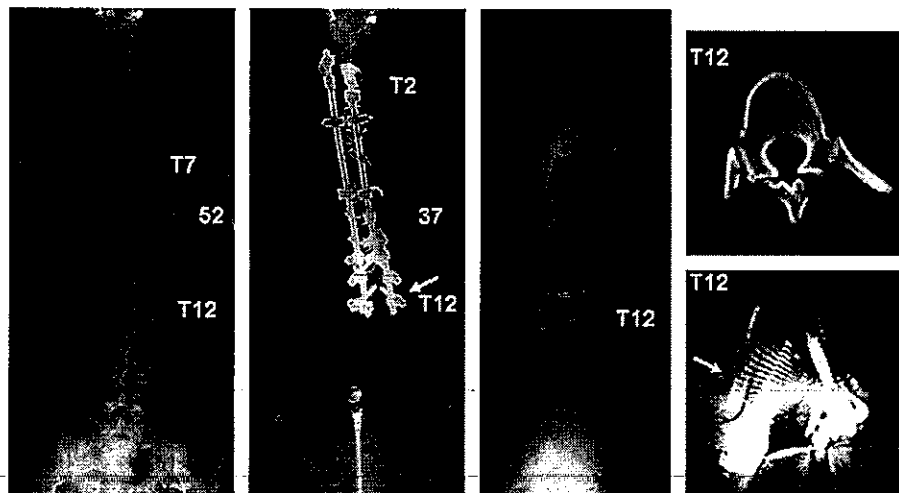


Figure 7. The asymptomatic medial screw perforation at T12 after posterior surgical correction for double thoracic curve (Group C).

left L3 pedicle screw was detected on CT scan without a lateral disc herniation on discography. The leg pain and weakness disappeared immediately after the screw removal.

Case 2

The 17-year-old girl in Group C received the posterior correction surgery using Isola system (Figure 7). The double thoracic curves were corrected, however, on post-operative CT scan, the medial perforation of right pedicle screw was demonstrated on CT scan without any neurologic disturbance.

Case 3

The 14-year-old girl in Group N received the posterior correction surgery with the assistance of surgical navigation system (Figure 8). The single thoracic curve was corrected from 65° to 36° by Cobb angle with the accurate placement of pedicle screws at small pedicles.

■ Discussion

Technical Issues of Pedicle Screw Insertion in Scoliosis Surgery

The pedicle screw insertion in scoliosis surgery involves the increased perforation risk due to a morphologic peculiarity of scoliotic vertebra, vertebral rotations, and inaccuracy of intraoperative fluoroscopic images.^{11,17-20} The screw malposition increases the risk of injury to neural, vascular, and visceral structures.¹³⁻¹⁶ Liljenqvist *et al* analyzed the scoliotic vertebrae with CT scan in 29 patients, demonstrating a significantly smaller pedicle width on the concavity of the curve as well as asymmetric shape of vertebra.¹⁷ Smith *et al* previously reported this vertebral asymmetry as a bone drift, which reflected the natural tendency to correct the deformity by counteracting the rotation.¹⁸ This affects the asymmetric pedicle screw length, thereby allowing a shorter screw on convex side. In addition to these internal anatomic hazards, vertebral rotations were significant hazards in scoliosis. In

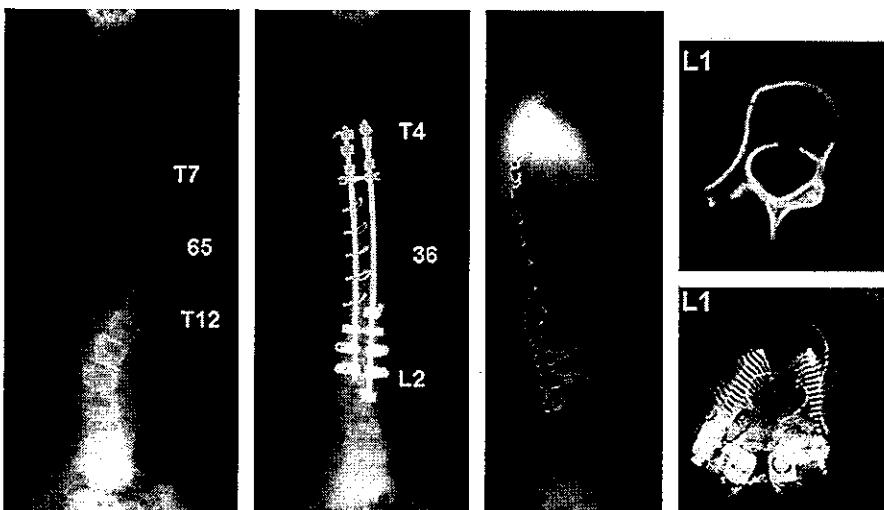


Figure 8. Accurate pedicle screw insertion and surgical correction of scoliosis with assistance of surgical navigation system (Group N).

the present study, 10° to 20° of vertebral rotations were observed in average at the thoracolumbar region, while some patients demonstrated the maximum rotation of 40°. The pedicle insertion angles measured as PSS to sagittal sacral axis were much more exaggerated between concave and convex side, leading to possible pedicle screw perforations. Other important factor during operation was the inaccuracy of fluoroscopic lateral spine images. The significant vertebral tilt in scoliosis disturbed the clear visualization of lateral vertebral images, causing the possible misdirection of screws in cephalad and caudal directions.

Previous Reports Regarding PS Perforation in Spine and Scoliosis Surgery

In thoracolumbar to sacral spine surgeries including a scoliosis, Lonstein *et al* reported complications associated with pedicle screws in 875 patients, demonstrating the screw malposition rate of 5.1% with 20.7% pseudarthrosis even mostly in lower lumbar screw insertions.¹³ Among 5.1% of malposition, 1.0% of procedures led to neural irritation, mostly caused by medial perforations. Amiot *et al* retrospectively reviewed 100 patients of thoracic and lumbar instrumentation surgeries (T5–S1), demonstrating 15% of PS malposition rate including 7% of neurologic problems. These patients consequently required reoperations. Although some authors have recently reported the thoracic PS insertion in scoliosis,^{8–10,22} there have been several controversies due to increased perforation rate and serious complications. Belmont *et al* reported the clinical accuracy of thoracic pedicle screws in 40 patients of scoliosis and kyphosis, demonstrating 43% of screw perforation rate at T1–T12.²² In this study, the medial and lateral perforation rates of 14% and 29% were demonstrated without neurologic and vascular complications; however, 2 screws were subsequently removed due to the proximity of aorta. Liljenqvist *et al* reported 33 patients of thoracic PS insertion in idiopathic scoliosis, demonstrating 25% of perforation rate without neurovascular and pulmonary complications.¹⁰ However, 1 screw was replaced due to its direct proximity of thoracic aorta. In terms of serious complications, Minor *et al* reported the iatrogenic aortic injury at T5, in which thoracic PS penetrated the descending aortic wall without hemodynamically unstable condition.¹⁴ The endovascular treatment was successfully conducted in association with simultaneous implant removal without any consequences. Papin *et al* reported a case of spinal cord complication associated with thoracic pedicle screw in posterior scoliosis surgery.¹⁵ In this case, the medially perforated screw caused persistent abdominal pain and tremor of legs, requiring a removal after 6 months.

Accuracy Analysis of Conventional Fluoroscopic PS Insertion in the Present Study

In the present study, several parameters were measured on CT scans: VR, PSS, PVS, PSER, and their correlations.

And importantly, the PS perforation patterns were analyzed to find out whether spinal levels, screw insertion point or angle were attributed to the perforation. The analyses demonstrated that there were significant variations in vertebral rotations and screw insertion directions. The maximum vertebral rotation was close to 40°. The screw insertion angles to sagittal sacral axis (PSS) were much more exaggerated and were typically larger on right side. Although the perforation rate of 11% was larger than expected, there were apparent perforation patterns detected. Typically, the medial screw perforations at the spinal levels distal to the major thoracic curve were demonstrated (55%) especially at L1, in which the pedicle direction approached to the sagittal sacral axis. The 33% of perforations were detected at the medial side within the major curve in a same manner. Specifically, PSS below 5° was the relative risk for screw perforation, meaning that in case the pedicle axis approaches anteroposterior sacral axis, medial perforation tends to occur with increased screw insertion angulations.

Pedicle Screw Insertion in Scoliosis Surgery With Computer-Assisted Technique

The recent progress of CASS has allowed the accurate screw insertion in cervical, thoracic, and spine deformity surgeries.^{21,23–27} The clinical randomized study performed by Laine *et al* in 100 patients, including small numbers of spinal deformity demonstrated that the screw perforation rate significantly decreased from 13.4% to 4.6% with use of CASS in thoracic and lumbar spine.²⁴ Amiot *et al* reported comparative results of 150 patients between conventional and computer-assisted surgeries in the traumatic, degenerative, and tumors of the thoracic and lumbar spine, demonstrating that the use of CASS significantly decreased the perforation rate from 15% to 5%.²³ Seven patients in manual insertion group required reoperations due to neurologic problems. Youkilis *et al* reported the perforation rate of 3.6% over 2 mm in thoracic pedicle screws used in 65 patients, including scoliosis surgeries, highlighting the effectiveness of surgical navigation system.²⁷ Specifically in scoliosis surgery, Merloz *et al* reported the use of navigation system in 12 patients of thoracolumbar and lumbar pedicle screw insertions, demonstrating 14% of malposition.²⁵ These previous reports indicated the increased difficulty in pedicle screw insertion of scoliosis, and even with the use of first-generation navigation system, the reported perforation rate was not below 10%.

With the use of second generation navigation instrument, we developed,²¹ the insertion accuracy below 0.5 mm was warranted in each step of probing, tapping, and screw insertion, while providing simultaneous and 3-dimensional instrument/screw tip information. This was originally developed for cervical pedicle screw insertion; however, this effectively reduced the screw perforation and surgical complication rates in posterior scoliosis surgeries. After the learning curve for registration procedure, the extension of operative time is minimized within

10 minutes. The future development of highly accurate fluoro-navigation with CT merging technology as well as intraoperative CT taking wide area of the spine will change the scoliosis surgery to safer and more accurate ones with the superior correction rate.

■ Key Points

- The pedicle screw placement accuracy in posterior scoliosis surgery was compared between conventional fluoroscopic and computer-assisted surgical techniques.
- In the fluoroscopic group, the perforation consistently occurred in pedicles in which those axes approached anteroposterior sacral axis within 5°.
- The use of a surgical navigation system successfully reduced the perforation rate and insertion angle errors, demonstrating the clear advantage in safe and accurate pedicle screw placement of scoliosis surgery.

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