Complications of Pedicle Screw Fixation in Scoliosis Surgery

A Systematic Review

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Study Design. Systematic review.

Objective. To review the published literature on the use of pedicle screws in pediatric spinal deformity to quantify the risks and complications associated with pedicle screw instrumentation, particularly in the thoracic spine.

Summary of Background Data. The use of pedicle screws in adolescent scoliosis surgery is common. Although many reports have been published regarding the use of pedicle screws in pediatric patients, there has been no systematic review on the risks of complications.

Methods. PubMed, Ovid Medline, and Cochrane databases were searched for studies reporting the use of thoracic pedicle screws in pediatric deformity. We excluded articles dealing with neuromuscular scoliosis or bone dysplasia to focus mostly on adolescent thoracic idiopathic scoliosis and the likes. We then searched for cases reports dealing with thoracic pedicle screws complications.

Results. This systematic review retrieved 21 studies with a total of 4570 pedicle screws in 1866 patients. The mean age of the patients was 17.6 years; 812 patients were women and 284 were men, and 5 studies did not identify sex. Overall, 518 (4.2%) screws were reported as malpositioned. However, in studies in which postoperative computed tomography scans were done systematically, the rate of screw malpositioning was as high as 15.7%. The reported percentage of patients with screw malpositioned is around 11%. Eleven patients underwent revision surgery for instrumentation malposition. Other complications reported include loss of curve correction, intraoperative pedicle fracture or loosening, dural laceration, deep infection, pseudarthrosis, and transient neurologic injury. There were no major vascular complications reported in these 21 studies. We could identify 9 case report articles dealing with complications of pedicle screws. Such complications were mostly either vascular (10 cases) or neurologic (4 cases), without any irreversible complications.

Conclusion. Malposition is the most commonly reported complication of thoracic pedicle screw placement, at a rate of 15.7% per screw inserted with postoperative computed tomography scans. The use of pedicle screws in the thoracic spine for the treatment of pediatric deformity has been reported to be safe despite the high rate of patients with malpositioned screws (11%). Major complications, such as neurologic or vascular injury, were almost never reported in this literature review of case series. Cases reports on the other hand have started to identify such complications.

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Posterior spinal instrumented fusion is the current gold standard in the treatment of progressive idiopathic scoliosis. The original correction with the Harrington rod system has evolved to segmental instrumentation: first with sublaminar wires according to Luque, then multiple hooks, hybrid instrumentation, and now all pedicle screw constructs. The advantage of the latter being a powerful anchor with the ability to achieve better correction.

Pedicle screw instrumentation has gained popularity over the last decade because several studies have demonstrated superior curve correction. Lenke et al claim that pedicle screw fixation is the state of the art in spinal deformity correction. Others have questioned the benefits of pedicle screw fixation in thoracic curves because of potential risks of placement in morphologically abnormal vertebral bodies or even the questionable benefits of increased curve correction. Proponents cite the ability to achieve 3-column fixation, greater ability to derotate the spine, and improved coronal balance, whereas having lower pseudarthrosis and implant failure rates.

In addition, they claim that fewer segments need to be included in the fusion construct without placing implants within the spinal canal. Other authors argue that no level-1 evidence on the superiority of pedicle screw in adolescent scoliosis has been reported. However, the greatest point of discussion in the pedicle screws debate remains related to their potential complications.

The senior author of this article has encountered or observed 7 pedicle screw complications over a 17 years experience of treating adolescent idiopathic scoliosis. Two personal misplaced pedicle screw in the thoracic spine: 1 case in which an intracanalar screw was responsible for upper thoracic pain with radiculopathy that resolved after screw removal, and 1 case in which the somatosensory-evoked potentials disappeared after screw insertion, which was fortunately reversible within 10 minutes after screw removal. Five other cases where his expertise was requested to treat the patient or give his opinion: 1 Brown Sequard syndrome that resolved after screw removal from a 4-mm intracanalar screw inserted, 2 catastrophic paraplegia where his opinion was requested as an expert, and 2 more cases where screws had
to be removed after catastrophic neurologic events because of screw malpositioning. Despite these concerns, there are only a limited number of severe complications reported in the adolescent patient resulting from the use of pedicle screws. The most severe complications of pedicle screw, such as neurologic vascular or pleuropulmonary complications, have been described in some rare case reports. However, the exact incidence and clinical relevance of screw malpositioning does not seem clearly in each case study yet numerous articles using pedicle screw have now been published. We, therefore, decided to carry out a systematic review of the literature to compile the various published complications to provide a better overall incidence and clinical consequences of complications related to pedicle screw use in adolescent scoliosis.

Materials and Methods

Inclusion Criteria

For this systematic review, our inclusion criteria were the following: articles on treatment of pediatric thoracic spinal deformities with pedicle screws and articles with an identifiable pedicle screw group in comparison studies on management of thoracic spine deformities. Only English-literature articles were selected. Case reports were analyzed separately.

We excluded the following: cadaveric studies, revision surgery, cervical kyphosis, and other spinal pathologies, such as trauma, tumors, and spondylolysis. We excluded neuromuscular scoliosis, such as spina bifida, muscular dystrophy, or other deformities with bone dysplasia or osteodystrophy to focus mostly on adolescent thoracic idiopathic scoliosis or the likes.

Search Strategy

PubMed, Cochrane database, and Ovid Medline electronic databases were queried. Search terms included scoliosis, kyphosis, pedicle screws, and complications. A total of 174 articles were identified in PubMed. In the Cochrane database, 2 articles were identified. The Ovid Medline search yielded 115 articles. The abstract and title of each article were reviewed, and the article was retrieved if the content was relevant to the inclusion criteria and study design. To ensure a thorough review, the bibliography of each included article was reviewed and relevant articles were selected for inclusion. Each article selected for inclusion was reviewed by the junior authors to ensure proper selection. In the case of controversy, the senior author arbitrated final inclusion or exclusion.

Data Collection

Data were tabulated using Microsoft Excel software. Study design, number of patients, sex of patients, number of pedicle screws, preoperative diagnosis, and all complications were compiled.

Results

Analysis of Published Articles

Study Details. Our query retrieved 21 studies that met our inclusion criteria. Only 1 study was a randomized controlled trial comparing navigation versus non-navigated pedicle screw insertion, of evidence level 1. The 20 other studies were retrospective case series of evidence level 4. Nine cases report articles dealing with complications of pedicle screws could be identified and will be addressed in the discussion.

Patients’ Demographics. These 21 studies included a total of 1666 patients; 812 patients were women and 252 were men, and 4 studies did not categorize the patients on the basis of sex. The mean age of patients was 17.6 years. The total number of pedicle screws studied was 14,570. An average of 8.75 screws per patient was placed. Seven studies did not mention the number of pedicle screws used. Average follow-up ranged from 2 to 10 years, with a mean follow-up of 3.78 years.

Pedicle Screw Insertion Technique. Since the introduction of original insertion technique by Suk et al, where the pedicle screw insertion is checked with temporary k-wires and posteroanterior flat plate radiographs, several other methods of insertion have been described. In 14 articles, the free hand pedicle screw insertion technique described by Kim et al was used. In 2 cases, a minilaminotomy technique was used. In 1 case fluoroscopic and in 1 case funnel technique were used for screw insertion. One study was a comparison study between the navigation and non-navigation group.

Loss of Curve Correction

Mean preoperative Cobb angle of the curves ranged from 44° to 100.2°, with an average of 64°. Mean percentage curve correction ranged from 52% to 77%. Loss of curve correction at the end of follow-up period ranged from 1% to 5.4%.

Screw Malposition

Overall, 518 (4.2%) of the 12,248 screws were reported as malpositioned. Only 12 studies specifically addressed pedicle screw malposition in 11,928 screws, for a rate of 4.3%. Method of surveillance of screw malpositioning varied in different studies. Only 6 studies obtained systematic postoperative computed tomography (CT) scans to evaluate screw positioning in all patients of the series. Five studies obtained a postoperative CT scan only if there was a doubt for screw malpositioning on the postoperative radiographs. In 1 study, only plain radiographs were used to assess screw positioning. In studies where CT scans were obtained on all patients, the reported rate of screw malposition was 346 (15.7%) of 2202 screws in 184 patients. Authors reported screws as malpositioned with any breach of the pedicle except Kuklo et al, who chose >2 mm of violation as a reportable breach. In this study, the accuracy (≤2 mm breach) of pedicle screw placement within the pedicle was 96.4%. In this group of 20 patients with scoliosis >90°, 10 screws were misplaced by 2 mm and 2 other screws misplaced by >4 mm. In studies where CT scans were only obtained in the case of a suspicious plain film, the reported rate of screw malposition was 169 (1.75%) of 9635 in 1199 patients. Ruf and Harms reported screw malposition by plain radiographs only in 3 (3.3%) of 91 screws in 16 patients.
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Of a total of 518 misplaced screws, 277 (53%) were lateral, 124 (24%) were medial, 75 (14%) were inferior, 30 (6%) were superior, 42 (8%) had anterior vertebral cortex perforation, and 7 (1%) had anterolateral cortical perforation. (Some screws were malpositioned in multiple zones.) Medial encroachment was divided into 3 different zones as proposed by Kim et al:0 0 to 2 mm, safe zone; 2 to 4 mm, probable safe zone; and 4 to 8 mm, questionable safe zone. Of the 4 studies with 78 medial screw misplacements, which provided the information on the perforation in relation to safe zones, 45 were in 0 to 2 mm zone, 22 were in 2 to 4 mm zone, and 11 were in 4 to 8 mm zone.

The number of patients with malpositioned screws was only reported in a limited number of studies. This varies from 1.2% to 20%. However, 3 studies report a fairly consistent rate around 11%. In a study by Di Silvestre et al using a minilaminotomy technique the incidence of patients with malpositioned screw was 11.3% for an accuracy of 98.3% per screw. In the study by Suk et al, the number of patients with malpositioned screws was 10.4% of for an accuracy per screw of 98.5% and with an average of 10 pedicle screws per patient. In the study by Smorgick et al the number of patients with malpositioned screw were 12.5%.

Revision Operation for Malpositioned Screws. In 16 studies with a total of 1436 patients, 12 (0.83%) patients had reoperation for misplaced or loose screws. Di Silvestre et al reported reoperation in 5 (4.3%) patients for malposition. Three patients had 1 screw removed each for asymptomatic intrathoracic screws, 1 patient had an intrathoracic screw removed for pleural effusion, and 1 patient had an asymptomatic, loose, laterally malpositioned screw removed. Suk et al reported removal of 1 screw for transient paraparesis because of medial breach and epidural hematoma. The screw was removed along with evacuation of the hematoma through a laminectomy, and the neurologic deficit resolved. Liljenqvist et al reported 1 reoperation for exchange of a screw that penetrated 3 mm through the anterior vertebral body without evidence of vascular injury. Kuklo et al reported the removal of 2 screws in 1 patient for significant medial breach (>4 mm) without neurologic deficit. Di Silvestre et al reported 1 reoperation for screw pullout and persistent rib hump 2.7 years after the index operation, with replacement of the screw and thoracoplasty. Smorgick et al reported 1 patient who underwent screw revision for asymptomatic aortic abutment. Ruf and Harms reported 2 reoperations; 1 for early pedicle fracture in a monosegmental construct and 1 for a malpositioned screw, which loosened at 9 months with progression of deformity.

Intraoperative Pedicle Fracture. Three studies reported intraoperative pedicle fracture. Twenty-seven pedicle fractures were noted in 5370 screws, with an incidence of 0.50% per screw inserted.

Pulmonary Complications

One pulmonary effusion was reported. It resulted from intrathoracic screw malposition and resolved after screw removal. Suk et al reported a pneumothorax, which required chest tube placement in a patient who had undergone a thoracotomy. This was unlikely related to the instrumentation.

Dural Lesion. Only 4 studies reported dural leaks during screw placement. Three studies reported the rate of durotomy to be 0.35% per screw inserted. In all cases where the location was reported, it was a concave thoracic pedicle. Di Silvestre et al advocated direct repair with no sequelae in his 2 reports, whereas Suk et al and Kim et al advocated screw repositioning without direct repair, also without negative sequelae.

Infection. Ten superficial infections were reported in 12 studies, with a total of 1045 patients. In the same 12 studies, 10 deep infections were reported.

Neurologic Complications. One temporary neurologic complication was reported of a total of 1666 patients included in the analysis. This patient had an epidural hematoma and malpositioned screw revised as described in the Revision Operation for Malpositioned Screws section. Patient recovered from his neurologic deficit. Lee et al reported a permanent paraplegia after anterior posterior kyphosis correction, which was apparently a result of manipulation, as there is no mention of errant pedicle screws.

Vascular Complications. No major vascular complication was reported. Four studies did not mention vascular complications, and 16 specifically reported no instances. Aortic abutment was noted in 6 (0.07%) of the 8147 screws in 8 studies that specifically reported this finding.

Pseudarthrosis. Only 1 case of pseudarthrosis was reported in 192 cases included in the 5 studies that reported the incidence of pseudarthrosis. The pseudarthrosis was diagnosed after implant failure with wound drainage. This patient underwent revision posterior fusion after eradication of his wound infection.

Loosening or Pullout. Loosening was observed in 38 (0.54%) of 6972 pedicle screws inserted in 8 studies. Suk et al had the highest incidence of pullout reported at 0.67%. Most occurred at the apex of the deformity during the correction maneuver.

Other. Other complications included 1 case of recurrence of deformity, 1 case each of persistent nausea and sternal chest pain, and 1 case of screw breakage.

Discussion

Despite the widespread use of pedicle screws in the surgical treatment of adolescent deformity surgery, literature on the prevalence of complications is sparse. The pedicles of the thoracic spine are smaller than those in the lumbar spine,
and there is a relative increase in the theoretical risk of injury to neurologic and vascular structures. This risk is further increased in severe deformities with dysmorphic vertebral anatomy, where the concave pedicles are thinner, more sclerotic, and dysplastic with the spinal cord in direct contact with the medial wall of the pedicle.

Most centers which have reported, as shown in our reference list, on their experience of surgical correction of thoracic scoliosis with pedicle screws come from very experienced surgeons. Therefore, this literature review may not reflect the reality of what happens in less-experienced centers or with surgeons going through their learning curve.

The most commonly reported complication was screw malposition. Twelve studies addressed pedicle screw malposition. The major determinant in the rate of malposition reported was the surveillance method. In the 5 studies in which CT scans were obtained, only if there were abnormalities on plain radiographs, the reported rate of malposition was 1.75%. In 6 studies in which CT scans were obtained in all patients, the reported rate of malposition of screws was 15.7%. In the 1 study in which plain radiography was used to assess screw position, the rate of malpositioned screws was likely underreported. Lehman et al reported the incidence of malpositioned screws was 3.3%. In studies in which plain radiographs control, navigation, or even minilaminotomy before screw insertion, the incidence of malpositioned screws was likely underestimated. Lehman et al looking specifically at the pedicle screw malpositioning in a consecutive series of 60 scoliosis patients with instrumentation from T1 to L4, found an incidence of 11.5% of screws that did not have an acceptable position (their definition of non-acceptable was that the screw axis was outside the pedicle wall). This study included instrumentation down to the lumbar spine where pedicle screws are easier to insert, and therefore, the overall incidence of misplaced thoracic screw may be higher in this study than the 11.5% reported. The true incidence of pedicle and vertebral body breeches is likely closest to 15%, represented by the studies where CT scans were universally obtained as in our literature review.

The number of patients with screw malpositioned varies depending on the study, the number of screws inserted, the surveillance method, and what is an acceptable pedicle screw breeching. We found this figure to be extremely variable between 1.2% and 20%. The reported number of patients with misplaced screws in Di Silvestre et al’s study and in Suk et al’s study is in the range of 11%, which is in keeping with their accuracy rate of 98.3% to 98.5% of screw accuracy and number of pedicle screw inserted. Statistically, if the pedicle screw accuracy is 85% (as per the surveillance with postoperative CT scan in this systematic review), one can anticipate that the chances for all the screws to be perfectly positioned in 1 patient with 8 pedicle screw inserted becomes 0.85 raised to the eighth power (0.85^8). This equals to a 27% chance for the patient to have all his screws well positioned (the chances for all the screws to be perfectly positioned can be estimated as the screw accuracy raised to the power of the number of pedicle screw inserted).

How much encroachment in the canal is acceptable? From this systematic review, it seems that most of the referenced authors agree that a 2-mm encroachment is acceptable. This corresponds also to the thickness of the blade of laminar hooks that have been inserted for years in the spine canal, with an extremely low incidence of neurologic injuries. Above 2 mm, it seems that there is disagreement as to the safety of the screw. Kim et al quote that between 2 and 4 mm it is probably a safe encroachment. Papin et al reported 2 malpositioned screws in one 16-year-old girl who underwent scoliosis correction. These 2 screws each had a 4-mm medial wall breach, resulting in epigastric pain, right foot resting tremor, and dysesthesias of her legs. Her symptoms resolved after revision surgery with the removal of the 2 malpositioned implants. This case, who had a 4-mm medial penetration breach of her pedicle, raises the question as to the relative safety often quoted of malpositioned screws between 2 and 4 mm. Obviously, the localization of the screw (concave or convex screw and the level where the screw is inserted) plays a role in the potential neurologic complication. Besides, in large and stiff curve, because the spinal cord always remains tethered on the concave side even during correction, a slightly malpositioned screw may have a catastrophic consequence on the neurologic outcome. Such event may only happen during the correction maneuver even if the motor-evoked potential were normal before just after screw insertion, as a consequence of further tethering.

This very high incidence of patients with malpositioned screw raises the following questions: Should we put so many screws in straight forward curves that will correct easily no matter what the type of instrumentation or the number of screws that will be inserted? Whether one uses a free hand technique, intraoperative markers and radiographs control, navigation, or even minilaminotomy before screw insertion, the incidence of patient with screw malpositioning will remain very high taking into account the very large numbers of screws inserted per patient: Therefore, all techniques that can help decrease screw malpositioning should be applied. This includes in our mind inserting only the number of screws necessary for a given curve at the strategic levels, use of spinal cord monitoring (motor-evoked potential) after each screw insertion, triggered electromyography of thoracic pedicle screws, intraoperative confirmation of correct screw placement with anteroposterior, obliques, and lateral fluoroscopy. We have tried ourselves to check screw placement with intraoperative axial reconstruction fluoroscopy, but we found this not to be accurate enough because of the metal scatter notwithstanding the limited visualization field, the time required, and the amount of radiation delivered by such technique. Should we have a systematic postoperative surveillance CT scan? The high radiation dose of such postoperative CT scan may not represent an issue any longer because low-radiation dose CT are now available and may be done systematically to assess screw malpositioning. With such CT scan, the amount of radiation is estimated to be 20 times lower than conventional CT scan and would allow appropriate visual-
ization of the screw placement. What is the correct attitude vis à vis of a malpositioned screw? If some spinal instrumentation systems allow very easy removal or exchange or a misplaced screws through a 3-cm-long incision, other systems require having almost a complete removal of the instrumentation to access the offending pedicle screw. Obviously, clinical judgment is most important in the case of a misplaced pedicle screw.

Despite the incidence of malpositioned screws, there were only 12 (0.6%) reoperations for device malposition reported among all 1666 patients. One study however, reported a 4.3% reoperation rate for misplaced pedicle screw.29 Most of these revision surgeries were for asymptomatic malposition. One epidural hematoma, which resulted from a medial breach, was the only major neurologic complication reported to result from these screw position aberrations. This hematoma resulted in a neurologic deficit, which resolved after evacuation and screw removal.

Dural lesions were most commonly reported in concave thoracic pedicles. This is no surprise because the thecal sac is closely apposed to the pedicles in this location. There were no persistent leaks whether the dural tear was repaired directly through a laminotomy or allowed to seal on its own by simply placing bone wax over the aberrant pedicle screw tract and repositioning the screw. In the article by Diab et al,42 looking at the 1301 cases of the pediatric spinal deformity study group, only 3 dural tears had been identified. None of them was associated with any neurologic injury and none of them required repair. It is fortunate that despite damage to the thecal sac in this worrisome location there was no reported neurologic injury. Laminectomy to expose the dural tear to repair it does not seem necessary according to Diab et al29 and Suk et al22 as opposed to Di Silvestre et al’s study.20

If we search case reports in the literature and look at other articles dealing with complications of scoliosis surgery with or without pedicle screw, further information can be gained. Alanay et al19 reported a neurologic deficit that resulted from late pullout of T2 pedicle screws in a patient with neuromuscular disease. She had undergone fusion for progressive kyphosis. Her deficit resolved after construct revision. Buchowski et al24 recently reported 2 cases of neurologic complications caused by insertion of hemostatic sealant in the pedicle screw path. Both these cases fortunately recovered after decompressive laminectomy. Overall, major and permanent catastrophic neurologic injuries have not been reported in our systematic literature review or cases series. However, careful attention to published case reports and the own experience of the senior author demonstrate that such complications do exist at a rate not reported. This lack of report may be related to medicolegal issues and the fear to report such cases or enrollment of patients in studies in a noncontiguous fashion or with selection bias.

Only 1 pulmonary complication resulting from the use of pedicle screws was reported. This pulmonary effusion resolved after revision surgery to remove the offending lateral screw.18

There were no vascular injuries reported in the included studies of our systematic review. However, of concern is the report of Kakkos and Shepard who reported 2 vascular complications after pedicle screw insertion and found 8 other cases in the literature.12–15 Wegener et al13 reported a case of adult aortic injury. Sarlak et al35 in a study of 12 patients with right thoracic curves that had preoperative MRI imaging, found that T4–T8 concave pedicle screw may pose a risk to the aorta as well as T11–T12 on the convex side.

Vaccaro et al44,45 demonstrated in the straight spine that the thoracic aorta and the esophagus were at greatest risk for injury in cases of anterior cortex penetration by the screws on the left side. On the right side in the lower thoracic spine, the azygos vein and the inferior vena cava especially were at risk. These structures were found to be within 5 mm of the anterior vertebral cortex. Despite these theoretical concerns, there were no reported events in 14,570 screws in 1666 patients. It is plausible that chronic irritation from a malpositioned screw could lead to major vascular complications beyond the 2- to 10-year follow-up included in these studies. This is a particular risk with the pulsatile aorta. Surgeons should be mindful in follow-up evaluation of these patients. Clinical judgment and thorough analysis of postoperative CT scan and or MRI or even CT angiogram become paramount in the decision to remove a screw that is threatening the vascular structures.

Pedicle fractures compromise the force available to effect curve correction. The rate of intraoperative pedicle fracture was quite low at 0.5%. Likewise, loosening and screw pullout compromise a construct. These events were also quite uncommon at 0.5% and 0.67%. Other complications, including pseudarthrosis, “add-on,” and wound problems were reported at very low rates.

**Conclusion**

From this exhaustive systematic review, it seems that the published incidence of all complications is extremely low. However, concern remains as to the very high rate of screw malpositioned if one uses CT scan as a surveillance method (15.7%). The reported percentage of patients with a misplaced pedicle screw seems to be at least 10% for an average of 8 pedicle screws. One can, however, anticipate that the true number of patients with malpositioned screw would even be higher (the percentage of patients with all the screws perfectly positioned is calculated as the accuracy per inserted screw to the exponential power of number of screws inserted). The exact clinical relevance of screw malpositioning is still not very clear because almost all are asymptomatic at least initially with a relative short follow-up. Most of the authors agree that <2 mm encroachment in the spine canal is acceptable. Such systematic review did not demonstrate any major permanent catastrophic neurologic or vascular injury caused by screw misplacement. More worrisome is that case reports on the other hand are starting to identify such complications. Clinical judgment is most important in the decision to revise a malpositioned pedicle screw taking into consideration the amount of en-
croachment, their proximity to the great vessels, and the asymptomatic nature of most of the malpositioned screws versus their possible late neurologic or vascular complication potentials.

**Key Points**

- Screw malpositioning is observed at a rate of 15.7% if one uses postoperative computed tomography scan surveillance.
- Percent of patient with screw malpositioned is reported to be around 11%.
- Reported neurologic and vascular injury are extremely rare in articles dealing with patients series.
- Vascular and neurologic complications are starting to be reported in case report.
- Clinical judgment should be used to decide the removal of asymptomatic implant to avoid late vascular or neurologic complication.

**References**