Position and complications of pedicle screw insertion with or without image-navigation techniques in the thoracolumbar spine: a meta-analysis of comparative studies

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Abstract

Computer-navigated pedicle screw insertion is applied to the thoracic and lumbar spine to attain high insertion accuracy and a low rate of screw-related complications. However, some in vivo and in vitro studies have shown that no advantages are gained with the use of navigation techniques compared to conventional techniques. Additionally, inconsistent conclusions have been drawn in various studies due to different population characteristics and methods used to assess the accuracy of screw placement. Moreover, it is not clear whether pedicle screw insertion with navigation techniques decreases the incidence of screw-related complications. Therefore, this study was sought to perform a meta-analysis of all available prospective evidence regarding pedicle screw insertion with or without navigation techniques in human thoracic and lumbar spine. We considered in vivo comparative studies that assessed the results of pedicle screw placement with or without navigation techniques. PubMed, Ovid MEDLINE and EMBASE databases were searched. Three published randomized controlled trials (RCTs) and nine retrospective comparative studies met the inclusion criteria. These studies included a total of 732 patients in whom 4,953 screws were inserted. In conclusion, accuracy of the position of grade I, II, III and IV screws and complication rate related to pedicle screw placement were significantly increased when navigation techniques were used in comparison to conventional techniques. Future research in this area should include RCTs with well-planned methodology to limit bias and report on validated, patient-based outcome measures.

Keywords: meta-analysis, position, pedicle screw insertion, navigation, complication

INTRODUCTION

Pedicle screws, which perforate the pedicle cortex, increase the risk of dural tearing, neural damage and vascular or visceral complications, especially in the thoracic spine due to its complex anatomy and decreased pedicle dimensions [36,49]. Moreover, pedicle screw misplacement results in a loss of fixation, especially at the lower end of a construct, such as lumbar spine. Ideal pedicle screw should have a maximum diameter and length that do not breach the cortical layer of the pedicle or the vertebral body and should be converged. The development of methods that improves the accuracy of pedicle screw insertion is an active area of research.

Pedicle screws are often inserted using conventional techniques that are based on anatomical landmarks of the vertebrae or assisted with any intraoperative imaging fluoroscopy, which is called fluoroscopic guided technique to localize the pedicle and evaluate the position of the pedicle screw [2,4,6,15,16,20,21,29,35,36,41,42,44,45,50,53].

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With development of computer technology, image-navigated techniques now include computed tomography (CT)-based navigation and fluoroscopy-based navigation. Both provide 2- or 3-dimensional (2D or 3D) intraoperative imaging to assist screw insertion and have been applied extensively. Many studies reported that image-navigated techniques lead to a significant reduction in the rate of screw misplacement. However, in vivo and in vitro studies found no advantages to using navigation techniques compared to conventional techniques, especially in the thoracic spine. Additionally, it has been shown that experienced spine surgeons insert screws in the thoracolumbar region with a low incidence of screw misplacement using conventional techniques. Furthermore, limitations of navigation systems relate to a lengthy learning curve, calibration errors, bending of instruments, occasional blocking of the surgical field with camera, inadvertently touching or hitting reference frames, and non-rigid connection between reference base and actual surgical site.

Although a few studies reported that the accuracy of navigation techniques was comparable to that of CT navigation, differences in population characteristics and methods of assessing placement accuracy between studies have resulted in inconsistent conclusions.

The accuracy of pedicle screw insertion is determined according to the method performed to insert the pedicle and the tools (such as photography, CT, or magnetic resonance imaging (MRI)) performed to assess the position of the pedicle screw and the adoption of standard definitions of correct pedicle screw insertion. According to the relationship between the pedicle and screws, most surgeons consider pedicle violation as a safe zone of pedicle perforation smaller than 2 mm. The grade of pedicle screw violation based on this definition is classified into four groups: screws fully contained within the pedicle; perforated screws with up to 2 mm of displacement (Grade A); perforated screws with 2–4 mm of displacement (Grade B); perforated screws with greater than 4 mm of displacement (Grade C). This classification has been used in the majority of studies. In addition, medial pedicle perforation greater than 4 mm may endanger the neural elements and result in neurological deficit. However, no studies have compared all types of screw positions. The increased safety of inserting pedicle screws may be related to more accurate screw positioning and the fact that less violation of the lateral cortex is unlikely to cause neurological complications. Although serious complications such as neurological, visceral, or vascular complications are very rare, the overall incidence of complications related to screw malposition is 0%–42%. Moreover, it remains unclear whether pedicle screw insertion using navigation techniques decreases the incidence of screw-related complications.

In this study, we performed a meta-analysis to compare the positioning of pedicle screws in the human thoracic and lumbar spine, and the screw-related complications with or without the assistance of navigation techniques.

MATERIALS AND METHODS

Inclusion criteria

Studies fulfilling the following criteria were eligible for inclusion. First, the report needed to be a comparative study and included randomized controlled trials (RCTs) or prospective or retrospective comparative studies, and the methods used to insert the pedicle screws were conventional techniques or image-navigated techniques. Second, the study was performed in vivo; cadaveric and animal studies as well as studies that used spine models and morphologic articles were excluded. Third, the study was published in English. Fourth, as fixing the cervical spine using the lateral mass and not the pedicle was the main technique used for the cervical spine because of its complicated anatomy, we excluded studies on pedicle screw insertion in the cervical spine. However, we accepted studies that included pedicle screws inserted into the S1 vertebrae, and we also accepted studies where the cervical spine was involved along with the thoracic and/or lumbar spine if separate results for the thoracolumbar spine were available. Fifth, the postoperative screw position must was assessed using CT or MRI.

Search strategy

The electronic databases of PubMed, Ovid MEDLINE (1950 to February, 2013), and EMBASE (1980 to February, 2013) were searched with the following search terms: “pedicle screw with navigation” or “navigated”; “computer assisted/assistance/aided”; and “image guided/guidance”.

Screening and assessment of eligibility

Two of the authors (JT and ZZ) independently screened the titles and abstracts of the studies from the electronic search to identify all citations potentially containing the comparison of interest. They independently evaluated and identified these studies by searching references and abstracts from meetings to determine the final set of included articles. Disagreements were resolved by discussion and by further discussion with an independent colleague if necessary.
Some definitions and standardizations

Most surgeons consider a pedicle violation of less than 2 mm as a safe zone of pedicle perforation\textsuperscript{[24,38]}. Although there is no strong evidence to support post-operative assessment, this was considered a criterion for inclusion in this meta-analysis\textsuperscript{[15,37]}. The grade of pedicle screw violation was categorized into four groups (grade I, II, III and IV) based on published criteria. Grade I screws were those located inside the pedicle, which were defined as the “perfect” position for the screw; grade II screws were defined as “safe” zone screws; grade III screws were those in a “potentially hazardous” zone; and grade IV screws were defined as screws in a zone that was “absolutely hazardous”. The screw-related complications included nerve root or spinal cord injury, vascular injury, cerebrospinal fluid leak, visceral injury and pedicle fracture\textsuperscript{[13]}.

Data extraction

For each eligible study, two of the authors (JT and ZZ) extracted the relevant data independently for both the intervention and control groups. These data included demographic data (age and sex) and other types of data. The variables collected including type of study (RCT, prospective comparative study, or retrospective comparative study), anatomic level, number of patients, indications, method of insertion, method of screw position assessment, accuracy of screw placement and criteria, pedicle screw position grades (I, II, III and IV) and screw-related complications.

Statistical analysis

Data concerning each grade of screw and screw-related complications from the included studies were pooled according to whether pedicle screw insertion was performed using conventional or navigation techniques. Dichotomous variables were pooled across studies. The rate of pedicle violation and incidence of complications were summarized using odds ratios (OR) and 95% confidence intervals (CIs). $P < 0.05$ was considered statistical significant. Heterogeneity was evaluated by using the $\chi^2$ test and $I^2$-statistics. $P < 0.1$ and $I^2 > 50\%$ were considered to be significant for heterogeneity. Fixed-effect models were used unless statistical heterogeneity was significant, in which case a random-effects model or sub-group analysis was used. Publication bias was assessed by visually examining the funnel plots based on each grade of pedicle screw and screw-related complications. All analyses were carried out in Review Manager 5.1 software (Cochrane IMS).

RESULTS

Search results

Fig. 1 shows the process for identifying eligible studies. There were 187 potentially relevant papers; after screening the title as well as reading the abstract and the entire article, we identified three published RCTs\textsuperscript{[17,25,37]} and nine retrospective comparative studies\textsuperscript{[13,9,24,26,31,39,42,43]} that met all of the inclusion criteria (Fig. 1).
| Author and year | Type of study and class of evidence | Anatomic level | Patients | Indications | Methods of insertion | Tools and criteria for screw assessment |
|-----------------|------------------------------------|----------------|----------|-------------|---------------------|----------------------------------------|
| Allam/2013[1]   | Retrospective comparative study (III) | Thoracic T1-T12 | N=45 Nav n=27/Con n=18 | Post-discectomy syndrome spondylolysis/ Spondylolisthesis osteochondritis | Free-hand/generic 3D-based CT | CT 3 mm |
| Shin/2012[42]   | Retrospective comparative study (III) | Thoracolumbar T5-S1 | N=69 Nav n=24/Con n=45 | Degenerative spine diseases/metastatic spine tumors/traumas | C-arm/O-arm CT | CT 2 mm |
| Cui /2012[49]   | Retrospective comparative study (III) | Thoracolumbar | N=59 Nav n=28/Con n=31 | Scoliosis/kyphosis/scoliokyphosis | Free-hand/CT | CT 2 mm |
| Sibermann/2011[13] | Retrospective comparative study (III) | Lumbosacral L1-S1 | N=67 Nav n=37/Con n=30 | Post-discectomy syndrome/spondylolisthesis/ Spondyloarthropathy osteochondritis | Free-hand/O-arm CT | CT 3 mm |
| Han/2010[17]    | Randomized controlled trial (I)     | Thoracic T1-T12 | N=42 Nav n=20/Con n=22 | Trauma/spinal stenosis, segmental instability, metastasis/spondylolisthesis | C-arm/BD computer navigation CT | CT 2 mm |
| Sakai/2008[39]  | Retrospective comparative study (III) | Thoracolumbar | N=40 Nav n=20/Con n=20 | Scoliosis | C-arm/computer-assisted CT | CT 2 mm |
| Rajasekaran/2007[37] | Randomized controlled trial (I)   | Thoracic | N=33 Nav n=17/Con n=16 | Scoliosis/kyphosis | C-arm/Isocentric CT | CT 2 mm |
| Merloz/2007[31] | Retrospective comparative study (III) | Thoracolumbar | N=52 Nav n=26/Con n=26 | Fracture/degenerative instabilities/ Spondylolisthesis scoliosis | C-arm/Isocentric CT and X-ray | 2 mm |
| Kotani/2007[24] | Retrospective comparative study (III) | Thoracolumbar | N=45 Nav n=20/Con n=25 | Scoliosis | C-arm/Isocentric CT | CT 1/4 diameter of a screw |
| Laine/2000[25]  | Randomized controlled trial (I)     | Thoracolumbar/lumbo-sacral | N=100 Nav n=41/Con n=50 | Spinal stenosis/post-discectomy syndrome/ spondylolisthesis/ spondyloarthropathy osteochondritis | C-arm/computer-assisted CT | CT 2 mm |
| Amiot/2000[44]  | Retrospective comparative study (III) | Thoracolumbar sacral | N=150 Nav n=50/Con n=100 | Fracture/degenerative instabilities/ spondylolisthesis/failed surgery/ lumbar metastasis | C-arm/computer-assisted CT | MRI 2 mm |
| Laine/1997[26]  | Retrospective comparative study (III) | Lumbar | N=30 | Post laminectomy instability/spinal stenosis/ painful disc degeneration/spondylolisthesis/ pseudarthrosis/post-traumatic kyphosis | C-arm/computer-assisted CT | CT 2 mm |

*Nav, the navigation techniques group; Con, the conventional techniques group.
**Extraction of data**

A total of 732 patients and 4,953 screws were included in the 12 studies. There were 2,323 pedicle screws inserted using navigation techniques and 2,630 pedicle screws inserted using conventional techniques. Table 1 shows a summary of these studies. CT\(^{[3,9,25,26,39]}\) and 3D\(^{[1,17,24,31,37]}\) imaging modalities were used to insert pedicle screws in five studies. An O-arm was used in two studies\(^{[42,43]}\). Eight\(^{[1,3,25,31,37,39,42,43]}\) papers defined the number of screws in grade I, II, and III, and two papers\(^{[9,17]}\) described cases of grade I and II. One\(^{[26]}\) study defined only grade I screws, and another\(^{[24]}\) study published only grade II screws (Table 2). Eight papers\(^{[1,3,9,17,24,31,37,39,42,43]}\) used 2 mm as the criterion for pedicle screw violation, whereas two papers\(^{[1,43]}\) used 3 mm and one\(^{[24]}\) used 1/4 of the diameter of the screw as this criterion. With these different criteria, we pooled and analyzed the data according to sub-groups. One\(^{[3]}\) study assessed the position of the pedicle screw using MRI, and the others used CT. Tohtz et al.\(^{[48]}\) studied post-operative screw position using MRI or CT, and con-
Meta-analysis of each grade of pedicle screw

Eleven papers reported the number of perfect screws. The comparison of outcomes between placement with or without navigation is shown in Fig. 2. Meta-analysis revealed a significant difference between image-guided and non-image-guided placement (OR: 3.36, 95%CI: 2.37, 4.77, I² = 56%, P < 0.00001).

Eleven papers provided the number of “safe zone” screws. As the different criteria used for perforation of the pedicle screw, such as 2 mm, 3 mm and 1/4 D, sub-group analysis was used. The comparison of outcomes with or without navigation is shown in Fig. 3. Based on meta-analysis, there was a significant difference favoring procedures performed using navigation compared to those performed without navigation (OR: 4.72, 95%CI: 3.25–6.86, I² = 9%, P < 0.0001).

Seven papers provided the number of “potentially hazardous” screws. As different criteria were used for the perforation of the pedicle screws, including 2 mm and 3 mm, sub-group analysis was performed. The comparative outcomes for procedures performed with and without navigation are shown in Fig. 4. Meta-analysis favored procedures performed with navigation compared to procedures performed without navigation (OR: 0.27, 95%CI: 0.10–0.77, I² = 69%, P = 0.01).

Six papers provided the number of “absolutely hazardous” screws. As the different criteria were used for the perforation of the pedicle screw, including 2 mm and 3 mm, sub-group analysis was used. The comparison of absolutely hazardous screws between procedures with and without navigation is shown in Fig. 5. Meta-analysis favored procedures performed with navigation compared to those without navigation for absolutely hazardous screws (OR: 0.09, 95%CI: 0.03–0.26, I² = 40%, P < 0.00001).

Meta-analysis of screw-related complications

All papers included in the analysis provided rates of screw-related complications. Four papers reported no complications in two groups. The total incidence of complications was 0.22%, but only one complication occurred in the navigation group. There were 17 complications overall, including 13 neurological deficits, one cerebrospinal fluid leak, one pleural injury, one minor dura violation, and one pedicle fracture. Meta-analysis of these complications showed a significant difference favoring navigation compared to the conventional method (OR: 0.25, 95%CI: 0.09–0.70, I² = 0%, P = 0.008) (Fig. 6).

Publication bias

The funnel plot was based on each grade of pedicle screw and screw-related complications (Fig. 7). The graphical funnel plots based on screw-related complications of included studies appeared to be symmetrical, which suggested no publication bias, but the funnel plots based on each grade of pedicle screw of included studies appeared to be asymmetric, which suggested the presence of publication bias.

DISCUSSION

This meta-analysis has shown that for screws in the “perfect,” “safe,” “potentially hazardous”, and “absolutely hazardous” zones, the accuracy of pedicle screw
insertion was significantly improved with the aid of image-guided navigation. Based on the outcomes, screws inserted in the thoracic and lumbar spine with the use of navigation techniques exhibited a higher accuracy in pedicle screw placement than those placed with conventional techniques. The results are consistent with the report by Gelalis [14], who conducted a review to compare the free-hand, fluoroscopic-guided and navigation techniques, and found that the accuracy of screw positioning was improved when navigation assistance was used. However, this previous report used descriptive statistics to explain the findings. There have been four meta-analyses [23,46,47,52] published in the field of pedicle screw accuracy, and all of these reports included studies that performed retrospective analyses of screw placement and also included the cervical spine, which has a more complicated anatomy than other spinal segments. These studies also showed that insertion with navigation techniques improves the accuracy of pedicle screw insertion. Tian et al. [46] also compared pedicle screw insertion accuracy with different navigation methods and found that CT and 2D and 3D navigation techniques presented few differences. However, these studies only compared the accuracy of "safe zone" screws with or without the use of navigation techniques, whereas the present study compared all of the different screw zones in the thoracic and lumbar spine, which suggests that the current report may provide more accurate evidence.

As pedicle screws were inserted in vivo, the assessment of pedicle screw positioning post operation must be performed using plain radiography, CT, or MRI, as opposed to dissection, which may influence the accuracy of pedicle screw assessment. This is one possible reason why the accuracy of pedicle screw insertion in vitro is superior to that in vivo [23]. Assessment by plain radiography was not included in the present study due to its lower accuracy [5,54], whereas CT scans have been considered the "gold standard" for the assessment of pedicle screw placement [5,6,10,38]. The CT technique can reduce metal artifact significantly and provide 3D images that display all aspects of the position of...

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### Table: Comparison of Pedicle Screw Procedures with and without Navigation

| Study or subgroup | Nav Events | Total | Nonnav Events | Total | Weight | Odds ratio M–H, Random, 95% CI | Year | Odds ratio M–H, Random, 95% CI |
|------------------|------------|-------|---------------|-------|--------|-------------------------------|------|-------------------------------|
| Amiot 2000       | 294        | 529   | 544           | 1.7%  | 17.24 [1.03, 289.19]          | 2000 |                               |
| Laine 2000       | 217        | 266   | 277           | 5.7%  | 4.49 [0.98, 20.46]            | 2000 |                               |
| Merloz 2007      | 139        | 120   | 138           | 3.3%  | 20.85 [2.74, 158.50]          | 2007 |                               |
| Rajasekaran 2007 | 238        | 201   | 236           | 11.1% | 10.36 [3.62, 29.65]           | 2007 |                               |
| Sakai 2008       | 234        | 154   | 214           | 36.4% | 3.04 [1.87, 4.93]             | 2008 |                               |
| Han 2010         | 92         | 81    | 84            | 1.5%  | 7.94 [0.40, 156.12]           | 2010 |                               |
| Shin 2012        | 103        | 192   | 204           | 7.7%  | 2.15 [0.59, 7.78]             | 2012 |                               |
| Cui 2012         | 474        | 528   | 577           | 20.8% | 4.39 [2.38, 10.06]            | 2012 |                               |
| Subtotal (95% CI)| 1,840      | 2,274 | 98.3%         | 4.79  | [2.96, 7.75]                  |      |                               |

**Total events:** 1,791

**Heterogeneity:** Tau² = 0.12; Chi² = 9.83, df = 7 (P = 0.20); I² = 29%

**Test for overall effect:** Z = 6.37 (P < 0.00001)

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**Fig. 3** Forest plot of the comparison between “safe zone” screw procedures performed with and without navigation.
the pedicle screw. However, CT images cannot display the soft tissues clearly, especially the nerve root. In contrast, MRI provides excellent evaluation of the soft tissues, including the nerve root, although due to metal artifacts, MRI cannot display metal screws clearly. Recently, one study \[^{[48]}\] has shown that artifact-reduced

![Forest plot comparing “potentially hazardous” screws between procedures performed with and without navigation.](fig4)

![Forest plot comparing “absolutely hazardous” screws between procedures performed with and without navigation.](fig5)
MRI could be considered an alternative to the gold standard for postoperative imaging to assess the accuracy of pedicle screw insertion, as this technique can reveal the relationship of the pedicle screw to the nerve root after spinal fusion surgery. Thus, MRI will likely become a standard method to assess the position of pedicle screws in the future.

Malposition of a pedicle screw leads to many complications, such as dural lesions, nerve root irritation, vascular injury, cerebrospinal fluid leak, visceral injury and pedicle fracture. However, there are few symptomatic complications relative to the high rate of pedicle screw perforations. Reportedly, experienced surgeons could accurately place pedicle screws in 80% of cases with conventional techniques and that neurological symptoms are rarely affected by an inaccurate pedicle screw placement, even if the penetration of the pedicle wall is greater than 6 mm. Gelalis et al. showed in a review that the neurological complication rate was similar between studies using CT navigation, the free-hand technique and fluoroscopy. In our meta-analysis, pedicle screw insertion using navigational techniques led to a significantly lower incidence of screw-related complications compared to conventional methods.

The results of this meta-analysis should be interpreted with caution due to several limitations. First, only three studies were RCTs, and most data included in the present study were reported from nonrandomized, controlled trials. A meta-analysis of such data leads to less powerful results compared to those obtained purely from randomized studies. However, it is difficult to conduct a prospective randomized trial to answer these types of questions due to poor patient compliance, different patient demographic characteristics and different indications for surgery. Second, methods and tools used to assess postoperative screw position vary across studies, and these differences are usually associated with heterogeneity among studies. Furthermore, technical issues, such as differences in surgeons’ skills, varying complexity of the surgery, and screw/pedicle dimensions could be responsible for this reported heterogeneity. Other limitations

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**Fig. 6** Forest plot comparing complications between procedures performed with and without navigation.

**Fig. 7** Funnel plot checking the publication bias based on screw-related complications.
include the heterogeneity of different navigation techniques and the different spine levels instrumented. Although the outcome of the current study indicated a significant difference, the funnel plots based on each grade of screw showed obvious publication bias as authors are more likely to report positive outcomes. We also only included papers written in English.

In conclusion, our study showed that the accuracy and complication rate of pedicle screw insertion using navigation techniques was superior to those obtained using conventional techniques. Furthermore, research in this area should include RCTs with well-planned methodologies to limit bias and report on validated patient-based outcome measures.

The outcome of this meta-analysis found that the accuracy and complication rate of pedicle screw insertion using navigation techniques was superior to those obtained using conventional techniques. More RCTs of high quality are needed to strengthen the quality of evidence.

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Retraction: Physical and degradation properties of PLGA scaffolds fabricated by salt fusion technique.

The paper entitled “Physical and degradation properties of PLGA scaffolds fabricated by salt fusion technique. *J Biomed Res* 27(4), 318–325 (DOI: 10.7555/JBR.27.20130001)” has been retracted. The paper is withdrawn at the request of the editor as it contains plagiarized materials from Murphy, William L., et al. "Salt fusion: an approach to improve pore interconnectivity within tissue engineering scaffolds." *Tissue engineering* 8.1 (2002): 43-52. The Publisher apologizes for any inconvenience this may cause.