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Misdirection- What The Eyes See and The Ears Hear, The Mind Believes- A Retrospective Study of Misdirected Pedicle Screw Fixations in Thoracolumbar Spine

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Abstract: *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 when compared to the other instrumentation techniques. Pedicle screw insertion resulting in neurologic deficit is rare, but may be due to faulty placement of the screw, with perforation of the cortex and impingement on adjacent neural structures. Despite improvements in the design of the instruments and attention to insertion techniques, cortical perforation does occur. Because many transgressions are asymptomatic, the true incidence is not known. Roy-Camille et al report in their experience 10% of screws were not completely in the pedicle. A retrospective study was done to determine the incidence of screw misplacement and complications in 120 transpedicular screws (30 patients) in the thoracolumbar spine with conventional open technique and intraoperative fluoroscopy. Outcome measures were: Accuracy of screw placement was evaluated by postoperative CT scan. Screw position was classified as 1.correct when the screw was completely surrounded by the pedicle cortex, 2. cortical breach and as 3. frank penetration when the screw was outside the pedicular boundaries. Frank penetration was further subdivided as grade A (up to 2.0 mm), grade B(2.1–4 mm), and grade C(> 4 mm).Results- In our study we found out that only 56 screws were in the category of correct, while a total of 40 pedicle screws had Frank penetration, mostly medially(followed by laterally and anteriorly) with a grade B penetration (followed by grade A and grade C) with 8 complications attributable to this misdirections, of which, 4 each had medial and lateral breech, all of which thankfully completely resolved with time at subsequent follow up.*

Keywords: *Accuracy, Misplacement, Pedicle screw, Fluoroscopy, Spinal stabilization, Intraoperative imaging*

I. Introduction

Given our nation's military's ability to target smart missiles from hundreds of miles away, there is no reason that we should not have a convenient, accurate, safe and easy to use targeting system in the operating room.

The use of pedicle screw instrumentation was described by Boucher in 1950s and was popularized by Roy-Camille et al in 1960s. The initial use of pedicle screws began in the lumbar spine and as surgeons became more comfortable with the complex anatomy required for accurate screw placement, they evolved the use of pedicle instrumentation in thoracolumbar and thoracic spine.Transpedicular screw fixation has many advantages over other spinal instrumentations such as Harrington rod fixation, Luque's instrumentation, etc., in various pathologies. Pedicle screws also prevent the need to place instrumentation within the spinal canal like sublaminar wiring, which creates the risk of neurological injury.

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 when compared to the other instrumentation techniques. Comparing pedicle screws, wires, and hooks, the highest incidence of symptomatic impingement occurs with pedicle screws, with nerve root injury or irritation occurring in a reported 3.2% of cases. Pedicle screw insertion resulting in neurologic deficit is rare, but may be due to faulty placement of the screw, with perforation of the cortex and impingement on adjacent neural structures. Despite improvements in the design of the instruments and attention to insertion techniques, cortical perforation does occur. Because many transgressions are asymptomatic, the true incidence is not known. Roy-Camille et al report in their experience 10% of screws were not completely in the pedicle.

Ideally, the pedicle screw is completely contained within the pedicle, and the spinal canal is not violated. Pedicle screws that violate the pedicle cortex increase the risk of neurologic injury; however, minor violations of the cortex are not uncommon and may be asymptomatic. In these cases, the screw position may be acceptable. Ultimately, patient symptomatology is probably the most important factor in determining acceptable positioning of the screw.

The advances of technology in terms of imaging have widened the field of image guidance in several surgical techniques. It is well established that image-guidance techniques have improved the clinical results in various fields such as knee, hip and spine surgery. Classic free-hand technique for screw positioning is based on vertebral bone landmarks for screw insertion without the assistance of any intraoperative imaging. Fluoroscopic guided technique uses a C-arm for screw insertion and positioning evaluation. Newer techniques such as computed tomography and fluoroscopy-based navigation are also being used with improved accuracy.

AIM- To determine the incidence of screw misplacement and complications in 120 transpedicular screws (30 patients) in the thoracolumbar spine with conventional open technique and intraoperative fluoroscopy.

II. Material and Methods

Because of close proximity to spinal canal and surrounding vessels, misplacement of pedicle screw can lead to disastrous complications, thus accurate and safe placement of the screw within the pedicle is a crucial step during surgery.

A retrospective study of 30 consecutive case records (120 screws) of posterior spinal fixation done using transpedicular screw in the thoracic and lumbosacral spine with conventional open technique and intraoperative fluoroscopy to find out the percentage of misdirected screws and complications arising thereof. Surgery was performed in all cases by the same surgeon's team, using the same implant, and all results were assessed by means of postoperative CT scan. The screw position was assessed by the authors. A review of the relevant literature was also done.

Inclusion criteria- All adults patients who underwent posterior spinal fixation at thoracolumbar spine regardless of the etiology for surgery.

Exclusion criteria –

- Cases not having a postoperative CT evaluation of pedicle screw placement with a detailed description of the grade of screw perforation.
- Scoliosis cases
- pedicle screw placement at the cervical spine were also excluded, due to differences in cervical spine anatomy and the fact that mainly lateral mass and not pedicle screws are inserted in this area.

Outcome measures : Accuracy of screw placement was evaluated by postoperative CT scan. Screw position was classified as 1.correct when the screw was completely surrounded by the pedicle cortex, 2. cortical breach and as 3. frank penetration when the screw was outside the pedicular boundaries. Frank penetration was further subdivided as grade A (up to 2.0 mm), grade B(2.1–4 mm), and grade C(> 4 mm). Indications for surgery were varied, trauma, spondylolisthesis, degenerative, tumour.

The risk of neurologic injury following cortical perforation by a pedicle screw is due to the pedicle's proximity to the neural elements. Medially, the pedicle cortex is separated from the dural sac by a thin layer of epidural fat, which is typically 2 mm in thickness.The pedicle is also intimately related to the nerve root of the corresponding vertebra. The spinal nerve root occupies the anterosuperior one-third of the intervertebral foramen. The exiting position of the root passes immediately below the inferomedial pedicle cortex. Perforation of the pedicle inferiorly can result in radicular symptoms and signs. The spinal nerves immediately lateral to the neuroforamen are adjacent to the lateral edge of the caudal pedicle. Because of this regional anatomy, the safest placement of pedicle screws is within the cephalad portion of the pedicle. If the superior cortex is violated, there is surrounding fat separating the pedicle from the exiting nerve root of the vertebra above.

III. Results

Indications for surgery were varied, mostly trauma(12),followed by spondylolisthesis (7), degenerative disease (5) and tumor (2)

In our study we found out that only 56 screws were in the category of correct, while a total of 40 pedicle screws had Frank penetration, mostly medially(followed by laterally and anteriorly) with a grade B penetration (followed by grade A and grade C) with 8 complications attributable to this misdirections, of which, 4 each had medial and lateral breech, all of which thankfully completely resolved with time at subsequent follow up.

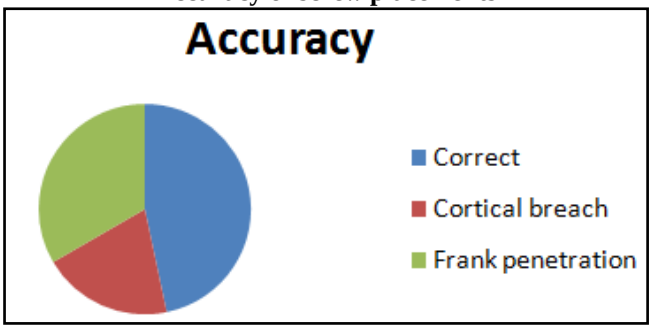
Distribution of cases based on indication for fixation

Indication	Number
Trauma	12
Spondylolisthesis	7
Degenerative	5
Tumour	2

Accuracy of screw placements

Accuracy	Number
Correct	56
Cortical breach	24
Frank penetration	40

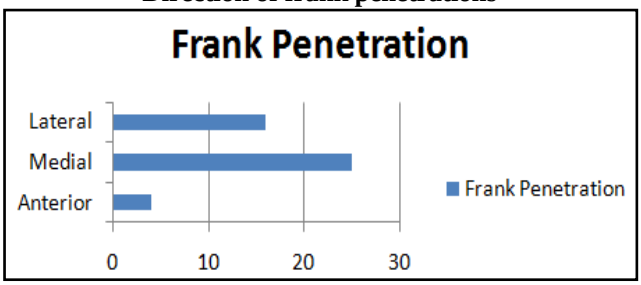
Accuracy of screw placements



Direction of frank penetrations

Frank penetration	Number
Anterior	4
Medial	25
Lateral	16

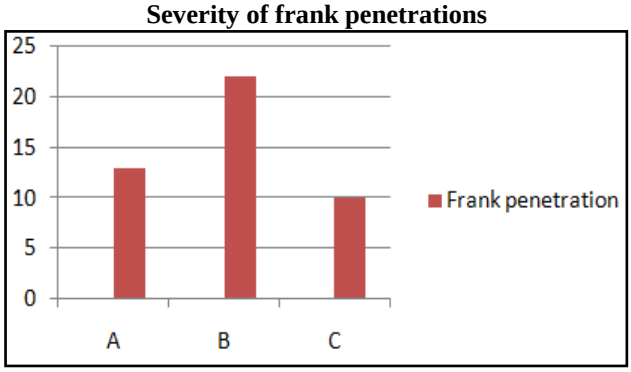
Direction of frank penetrations



Severity of frank penetrations

Frank penetration	Number
A	13
B	22
C	10

Severity of frank penetrations



Complications attributable to the misdirected screws

Attributable complications	Number
L5 irritation	5
Paraesthesia	3
Requiring surgery	0

IV. Conclusion

Fast is fine but accuracy is the key. Pedicle screw fixation is a tricky surgery as far as the correct positioning of the screws is concerned and we should always be very careful in preventing the misdirection of screws.

Misdirection- What the eyes see and the ears hear, the mind believes

Limitations of the study – This being a retrospective study is limited by the heterogeneity of the study population, the indication of surgery and the different spine levels instrumented.

Review of Literature

Weinstein et al evaluated the accuracy of pedicle screw placement using fluoroscopic guidance and postoperative AP and lateral radiographs following placement of 124 screws into 8 cadaver thoracolumbar spines. Following instrumentation, the spines were transected, and pedicle screw placement was determined by visual and tactile inspection. The overall rate of incorrect screw placement with cortical perforation in their series was 21%, of which 92% of the errant screws entered the spinal canal. An interobserver agreement rate of 74% for the radiographic assessment of placement was obtained, which is low considering that the rating was a 2-point scale of success or failure. In their study, the sensitivity of the radiographic evaluation for screw perforation was only 31%, whereas the specificity was 90%. The authors state that the low sensitivity of radiographs for determining screw perforation is unacceptable because the majority of failed screw placements were classified as correctly placed on the basis of conventional radiographic assessment. Weinsteinet al did not discuss the criteria used for determining the adequacy of screw placement on the radiograph and did not suggest any method by which to improve on the accuracy of the radiologic interpretation.

Ferrick et al reported accuracy rates of 73% to 83% in the radiographic evaluation of pedicle screw placement in human cadaver lumbar spines. Posteroanterior and lateral radiographs were used to grade screws as in or out. If out, screws were graded medial, lateral, superior, and inferior misplaced. Misplaced screws that were incorrectly labeled as correct were usually medially misplaced.Farber et al inserted 74 pedicle screws in 16 patients and evaluated the sensitivity of radiographic assessment of cortical perforation, using CT as the gold standard. In their study, 21/74 (28%) of pedicle screws violated the medial pedicle cortex on CT imaging, despite the performance of a midline laminectomy to palpate the pedicle during screw insertion. Despite the high rate of cortical perforation, none of the patients in this series developed a neurologic deficit. Screws were graded as being entirely within the pedicle, as definitely perforating the pedicle cortex, or as questionable on the basis of the radiographs. In their series, radiographs showed 42 instances of definite or questionable perforation, compared with 64 shown by CT. The discrepancy between radiographs and CT was most striking with medial misplaced screw, where CT depicted 10 times as many definite or questionable violations of the pedicle cortex than did conventional radiographs.

Laine et al studied pedicle screw placement in 30 low back pain patients with radiographs and CT. A total of 32/152 (21%) of screws perforated the pedicle cortex as judged by CT imaging. Radiographs diagnosed only four of these perforations. Gertzbein and Robbins studied 167 thoracolumbar pedicle screws placed in 40 consecutive patients with postoperative CT. Medial cortical perforation with 2 mm or more of screw encroachment into the spinal canal was identified in 15% of screw placements. Lateral perforation occurred in 4% of screw placements, but did not produce symptoms in this series.Yoo et al reported accuracy rates of 68 to 87% in the CT evaluation of pedicle screw placement in cadaver scans using in/out criteria. Increased accuracy occurred with titanium *versus* cobalt chrome screws, thought to be due to less CT scanning artifacts.Intrestingly, in this study, there was no identifiable correlation between years in clinical practice and accuracy, suggesting that greater experience does not lead to improved accuracy.

Multiple studies have reported varying results in radiographic and CT evaluation of pedicle screw placement. None of these studies described methods to improve interpretation of these imaging methods.

An analysis of 26 prospective clinical studies including in total 1,105 patients in which 6,617 screws were inserted it was found that in the studies using free-hand technique, the percentage of the screws fully contained in the pedicle ranged from 69 to 94%, with the aid of fluoroscopy from 28 to 85%, using CT navigation from 89 to 100% and using fluoroscopy-based navigation from 81 to 92%. The screws positioned with free-hand technique tended to perforate the cortex medially, whereas the screws placed with CT navigation guidance seemed to perforate more often laterally.It concluded that navigation does indeed exhibit higher accuracy and increased safety in pedicle screw placement than free-hand technique and use of fluoroscopy.

In vitro and in vivo studies in which conventional surgical techniques were used, have reported pedicle screw misplacement rates from 5 to 41% for the lumbar spine and 3–55% for thoracic spine.It is also believed that the extent of misplacement could be related to damage of the nervous elements. Even experienced surgeons misdirect the screws medially in 5% and inferolaterally in 15% of the cases when using standard fluoroscopic imaging. It has been shown that medial pedicle perforation more than 4 mm may endanger the neural elements presenting neurological deficits. Although there is not strong evidence in the literature ensuring that pedicle

violation less than 2 mm is safe, most surgeons consider it as safe zone of pedicle perforation.Therefore, the importance of accuracy in screw placement meaning that the screw is fully included in the pedicle and there is no cortex violation has been recognized early.

Computed tomography-based navigation and fluoroscopic-based navigation with its two and three-dimensional options are the most popular spine navigation systems. These image-guided modalities have increased the pedicle screw placement accuracy and reduced the imaging intra-operative time and radiation exposure. Recently, a trend of better accuracy in the thoracic spinal level with the assistance of computed tomography compared to the 2D fluoroscopy-based navigation has been reported.

When evaluating the position of perforation, literature shows that in the studies using free-hand technique, a range from 32 to 87% was found for medial perforation compared to 12–67% for lateral perforation and when fluoroscopy was used, the pedicles were perforated medially in a percentage ranged from 14 to 100% and laterally from 16 to 79%. In patients where CT navigation was used the proportion of screws medially perforated was significantly increased ranging from 8 to 29%, compared to the percentage of screws with lateral perforation with a range from 29 to 80%. In the studies evaluating fluoroscopy-based navigation, there was no difference between medial and lateral perforation proportion with medial ranging from 37 to 80% while lateral ranged from 20 to 63%.In relation to the grade of perforation, when free-hand technique was used, most of the screws were grade A (range 7–71%). The percentage of screws with grade B perforation ranged from 15 to 46%, while grade C perforated screws ranged from 12 to 46%. In studies where CT navigation was used, there was a 42–100% range of grade A violation, 12–57% grade B violation and 12–31% grade C violation. When the screws were instrumented with the use of fluoroscopy technique screws with grade A perforation represented the largest proportion with a range from 25 to 100%. Grade B ranged from 10 to 53% and grade C ranged from 2 to 40%. In studies evaluating fluoroscopy-based navigation, most of the perforated screws were grade A (range 60–85%), as grade B and grade C screws were significantly less with a range from 13 to 40% and 2 to 10%, respectively.

When assessing the number of screws exceeding 4 mm violation (Grade C), it was interesting that in studies using navigation, the percentage ranged from 0 to 3.3% for CT navigation and 0 to 2% for fluoroscopy-based navigation. In contrast, the percentage of grade C screws in studies without navigation systems ranged from 1 to 6.5%, while in studies using fluoroscopy the range was 0–40%. Furthermore, the percentage of screws that were fully included in the pedicle plus these that had less than 2 mm cortex violation ranged from 80 to 97% for free-hand technique, 93–100% for CT navigation, 71–100% for fluoroscopy technique and 95–97% for fluoroscopy-based navigation.

One important finding seen in literature was that the screws positioned with free-hand technique tend to perforate the cortex medially, whereas the screws placed with CT navigation guidance seem to perforate more often laterally.Normally if the unintended perforations using CT navigation would be the result of the inherent inaccuracy of the navigation system, the perforations should be randomly distributed medially and laterally. The explanation for a preponderance of lateral perforations in CT-based navigation could be the difference between the longitudinal midline axis of the pedicle (ideal screw trajectory) and the anatomically feasible axis. To avoid too close contact to the facet joint, the surgeon accepts in some cases a lateral perforation, i.e. those are intended perforations. This is unavoidable especially, in cases where the screw diameter is very close or even bigger than the diameter of the isthmus of the pedicle. In certain studies, a correlation between medially malpositioned screws and neurological complications has been proposed. Therefore, the increased safety proven when navigation techniques are used could be related not only to the more accurate screw positioning, but also to the lateral cortex violation is related with less neurological complications. The increased safety due to the usage of the navigation systems is attributed not only to the aforementioned more accurate screw positioning, but also to lateral cortex violation, that is related with less neurological complications.

The neurological complication rate in many studies was found to be similar in some studies using CT navigation, free-hand technique and fluoroscopy. This adds to the point of the literature that the use of navigation systems has not proved yet to decrease the neurological complication rate. Some studies suggest an association between the degree of spinal canal penetration and the frequency of neurological symptoms.

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