Lowering the Risk of Neurogenic Pain from Misplaced Pedicle Screw Instrumentation through Pedicle Screw Modification

Date: 01/29/2012

Authored By:

J. Scott Smith MD
drsmith.spine@gmail.com

ABSTRACT

Background
Using traditional techniques, up to 20% of pedicle screws are misplaced. Unintended breaches of the medial or inferior pedicle wall may lead to neurogenic pain and dysfunction. Although CT guidance and neuromonitoring have proven beneficial, misdirected screws continue to be a problem.

OBJECTIVE
This study was to determine if a modification to the threaded shaft of a pedicle screw could decrease these risks.

Study Design
A modified pedicle screw was designed and manufactured specifically for this purpose. The midsection of the screw contained a nonthreaded region which was adjusted to face the nerve root after insertion. Neither CT guidance nor neuromonitoring was used on any patient.

Methods
Sixty-one consecutive patients receiving 287 of the modified pedicle screws were evaluated. Postoperative CT scans were reviewed by the operating surgeon and a board certified radiologist to identify breaches in the medial or inferior wall of the pedicle. All patients were interviewed for neurogenic pain related to the pedicle screws before leaving the hospital, and at subsequent office visits.

Results
Without the modification, 37 or 13 % of the screws would have breached the pedicle wall. With the modification, only six breaches were identified for a rate of 2%. (four <2mm, one 3-4mm, and one 5-6 mm) No patient suffered neurogenic pain from the misplaced pedicle screws, and no additional procedures were performed to redirect or retrieve the misdirected screws.

Conclusions
A simple modification to the shaft of a pedicle screw can reduce the potential contact between misdirected pedicle screws, and the associated nerve roots. Minimizing this contact should reduce the incidence of neurogenic complications associated with pedicle screw instrumentation. The modification appears to be effective, without any additional financial burden.

INTRODUCTION

Pedicle screw instrumentation continues to be utilized extensively. Even in experienced hands, proper placement of pedicle screws can be challenging.[1,2] The size of the patient, the size, shape, and angulation of the pedicle, as well as the quality of the bone, may all work against attempts to properly place a pedicle screw. Traditionally, intraoperative fluoroscopy and palpation have been relied upon to properly assess the intraoperative placement of pedicle screws.[3] Unfortunately, these techniques can be falsely reassuring to the surgeon. [2,4,5,6] Indeed, it has been reported that up to 20 percent of pedicle screws are mal-positioned using standard techniques.[3,7,8] Percutaneous systems, which eliminate the ability to palpate, make the procedure even more demanding. [7,9,10] Even with the assistance of CT guidance technology and intraoperative neural-monitoring, the risk of a misdirected pedicle screw remains.[6, 8,11,13,14,15,16,17] Unintended breaches of the medial or inferior pedicle wall can be problematic.

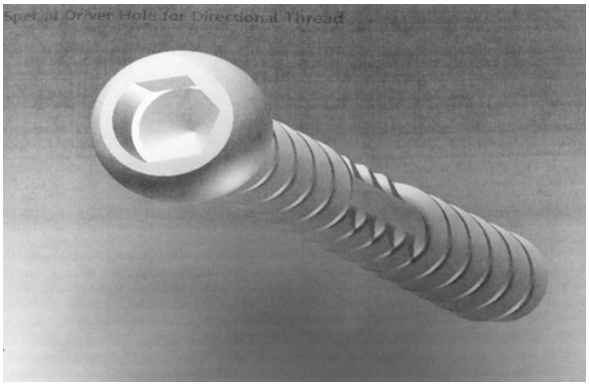
Intimately associated with each pedicle is a nerve root exiting the spinal canal. ln the lumbar spine, nerve roots exiting the thecal sac travel medial to the corresponding pedicle along the posterior wall of the vertebral body. The nerve then exits the spinal canal by wrapping itself under the pedicle before turning anterior. The nerve root remains in intimate contact with the pedicle until it exits the neuroforamina. Due to the absolute proximity of the nerve root to the pedicle, the nerve root is at risk from the placement of pedicle screws. Any breach of the medial or inferior pedicle wall by a pedicle screw may leave the threading of the screw exposed against the nerve root. This unintended interaction between the nerve root and the threaded shaft of the screw can lead to nerve irritation and potential injury.

A misplaced pedicle screw can be the source of pain and dysfunction. The patient may complain immediately after anesthesia of pain in the corresponding dermatome, or the pain may develop over the course of several days following surgery. In the author's personal experience, the pain from a misplaced pedicle screw may not present until after the patient has been discharged from the hospital; in some cases, even many months afterwards. Although misplaced pedicle screws do not generally cause permanent neurologic injury, they can be the source of neurogenic pain and other symptoms including, dysasthesias, numbness and weakness. [3,6,7,10] Persistent symptomatology may necessitate redirection or removal of the offending pedicle screw. Unfortunately, the patient must suffer through an additional operative procedure, the surgeon must accept responsibility for the situation, and additional costs are generated that that may or may not be recovered. Without this interaction between the nerve root and the threaded shaft of the pedicle screw, this neurogenic pain could be avoided.

MATERIALS AND METHODS

Pedicle screws specifically modified to reduce this risk were developed, and manufactured with appropriate 510K clearance. The modification required the removal of an area of threading along the mid-portion of the screw shank. The nonthreaded region completed 140 degrees of the shaft for a distance of 12 -15 mm. The threading was gradually brought in and out of the nonthreaded region to avoid any sharp

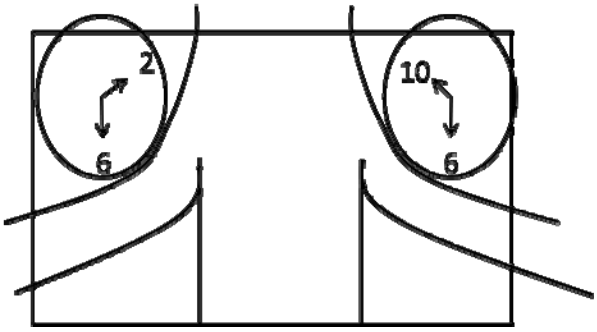
transitions. For rotational control, the head of the screw mates with its driver in a single orientation. These changes are illustrated in the figure 1 below.



The modified pedicle screw is shown. Note how the head of the screw can only accept a driver in one configuration.

A visual indicator corresponding to the nonthreaded portion of the screw is located at the opposite end of the driver. With the screw attached to the driver, this indicator provides rotational control during screw insertion. Visually, the surgeon rotates the nonthreaded portion of the screw towards the nerve root. For the right sided pedicle, the nonthreaded portion of the screw should ideally be directed from six o'clock to ten o'clock: for the left side, two o'clock to six o'clock. See Figure 2.

A



On the right, the nonthreaded portion of the screw should be directed from 6-10 O'clock. On the left, from 2-6 O'clock

A radio-opaque marker placed within the cannulation of the screw indicates the nonthreaded region providing depth control. The tantalum marker is seen under fluoroscopy due to the differing densities of the titanium screw and the tantalum marker. See Figure 3.

After insertion of the pedicle screw, the marker is removed.

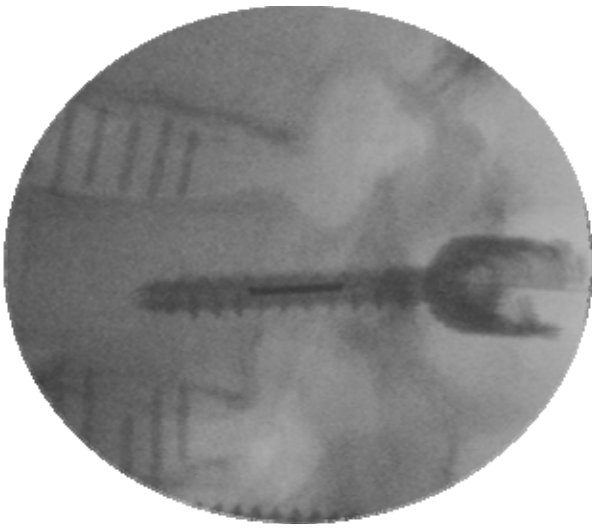


Figure 3
The tantalum marker within the pedicle screw marks the location of the nonthreaded portion of the screw.

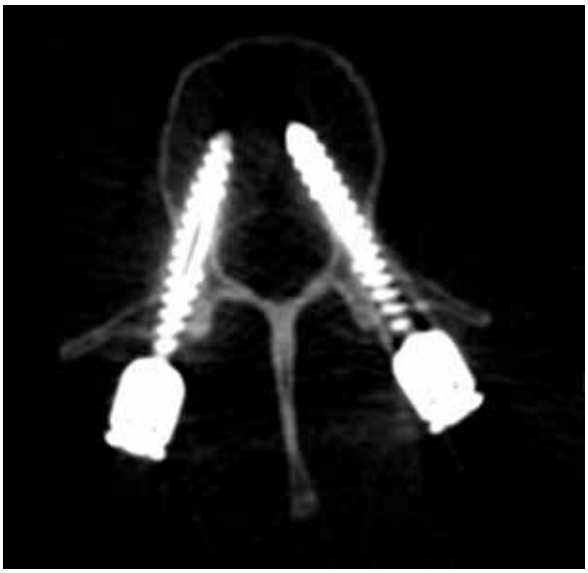


Figure 4
Axial view of a properly placed screw. The nonthreaded portion of the screw faces towards the neurological structures.

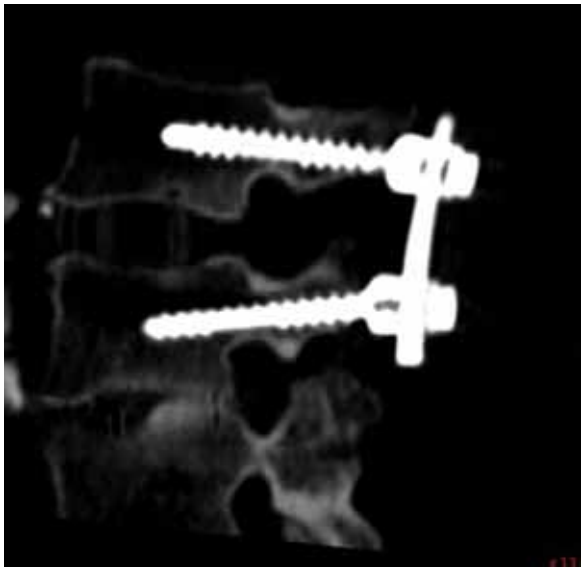


Figure 5
The nonthreaded portion of the screw spans the location of the nerve root within the neuroforamina.

Properly inserted, the unthreaded portion of the screw spans across and faces towards the associated nerve root. In this manner, the potential for irritation of the nerve root from exposed threading is minimized. In the event of a medial or inferior wall breach, the exposed portion of the pedicle screw lacks threading. This smooth portion of the screw is less likely to be problematic.

Figures 4 and 5 illustrate the proper placement of the modified pedicle screw from an axial view and sagittal view. Figure 6 shows a three dimensional view of the pedicle screw construct with the bony elements subtracted. The nonthreaded portion of the screw is directed towards the location of the nerve root. The modified pedicle screw is available as the Aversion Pedicle Screw System through Integrated Spine Concepts LLC.

The author inserted 287 of these modified pedicle screws in 61 consecutive patients using the described technique. The screws were placed using both open and minimally invasive techniques. Fluoroscopy was used for intraoperative imaging. Neither CT guidance nor neuro-monitoring was used on any patient. The patients were assessed for neurogenic pain during their hospitalization, and at each postoperative follow up visit. Neurologic examinations were performed at each follow up office visit. All patients underwent postoperative multiplanar CT scanning prior to leaving the hospital. The scans were subsequently

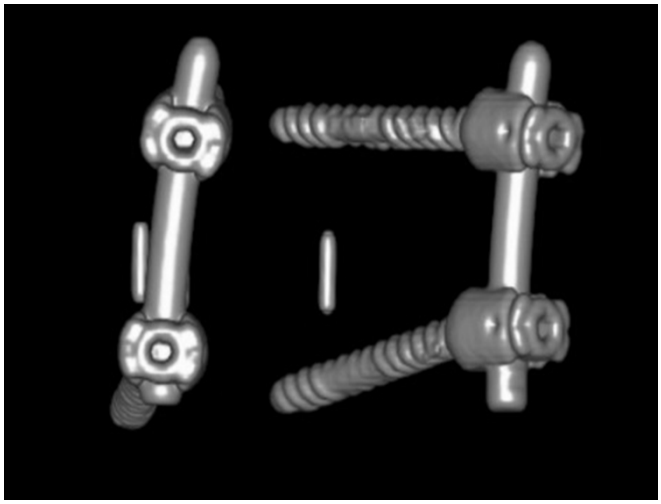


Figure 6
Three dimensional view showing the proper orientation of the nonthreaded portion of the installed pedicle screws.

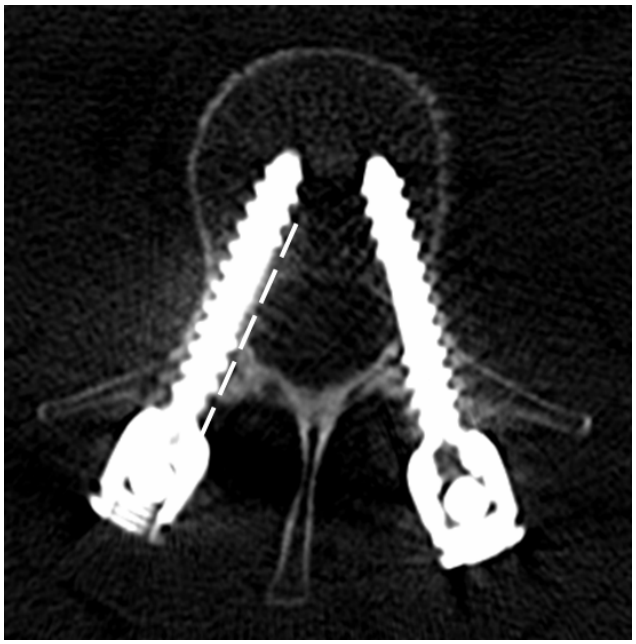


Figure 7 The screw on the right is in the pedicle. The screw on the left is also in, but *would* have been out if not for the modified shaft.

reviewed by the operating surgeon and a board certified radiologist. Breach of the inferior or medial wall of the pedicle was assessed for each pedicle screw. Agreement was reached for each screw prior to grading. Screws were graded as: I = inside the pedicle, O = outside the pedicle with cortical breach, or W = in the pedicle, but *would* have been outside the pedicle, if not for the modified shaft. In cases where cortical penetration could not be determined with certainty, the screw was graded as inside the pedicle. Screws graded as W would have been outside the pedicle by greater than 1 mm.

Figure 7 illustrates the method used to look for potential cortical breach. Axial sections along the plane of the screw were created, after which point the tips of the threading were connected with a straight line. In the example, the right sided screw appears to be inside the pedicle whereas the left sided screw would have been outside the pedicle without the modification. The height of the pedicle screw threading was .9mm for all screws.

RESULTS

The classification of the pedicle screws by level is shown in Table 1. The screws were graded as being: contained within the pedicle (I); outside the pedicle (O), with medial or inferior wall breach; and lastly, contained within the pedicle due to thread modification. (W)

Without the modification to the shaft, 37 of the 287 screws (13%) would have breached the medial wall of the pedicle potentially causing neurogenic pain. This is in agreement with previously published data. With the modified shaft, however, only six of the 287 screws (2%) were identified as outside the

Table 1

Screw Classification	L1	L2	L3	L4	L5	S1	Total
Inside-No Breach	2	17	45	73	72	41	250
Outside-Breach	0	3	0	2	1	0	6
Would have Breached	2	6	11	7	5	0	31

wall of the pedicle. This is represents a reduction of 85%.

Tables 2 and 3 illustrate the percentage of pedicle screws with the potential for neurogenic pain by level with and without the modified shaft. Pedicle screws were more likely to be misplaced as the level moved cephalad.

Six screws breached the medial or inferior wall of the pedicle wall exposing the modified titanium shaft to the nerve root. In these situations, the portion of the pedicle screw exposed to the nerve root was absent any threading. Of the six confirmed cortical breaches, four were less than 2mm, one was 3-4mm and one was 5-6 mm., as measured to the inner diameter of the shaft. Each of these malpositioned screws was placed in a different patient; therefore, six of the sixty-one patients had a definite cortical breach, for a rate near 10%. No patient experienced neurogenic pain from the pedicle screws, and no patient required additional surgery for either redirection, or pedicle screw removal.

Figure 8 is an example of a pedicle screw clearly outside of the pedicle. Two pedicle screws have been inserted at the L2 level. The screw on the right extends into the spinal canal approximately five to six millimeters. The left sided screw was scored as inside the pedicle. This patient did not experience any neurogenic pain following the surgery, or at three month follow up.

Table 2

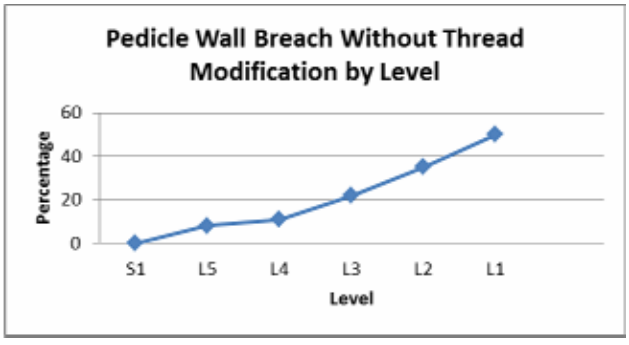
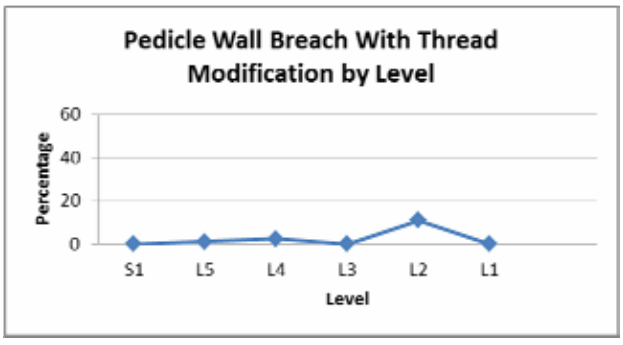


Table 3



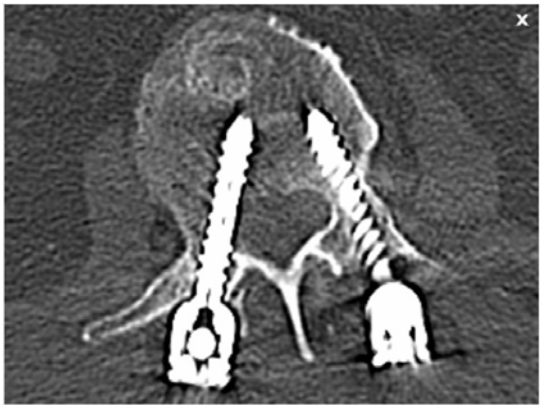


Figure 8
The screw on the right has breached the medical wall of the pedicle. The exposed region of the screw is not threaded and did not create any neurogenic pain.

DISCUSSION

The problem of medial or inferior wall breach by pedicle screws continues to be a recognized problem: a problem all currently available pedicle screw systems share. Previous attempts to address this issue have met with limited success. Although the rate of misplaced pedicle screws can be decreased through the incorporation of CT guidance technology and/or intraoperative neuro-monitoring, these technologies have limitations, and associated costs.[16] Breach of the medial or inferior wall remains a possibility, with the associated consequences. Modification to the shaft of the pedicle screw can reduce the risk of contact between exposed threading from misdirected pedicle screws, and the associated nerve roots. Minimizing this contact should help to reduce the incidence of neurogenic complications, including pain and dysfunction. The procedure appears to be safe and effective, without any additional financial burden.

REFERENCES

1. Gonzalvo, Augusto; Fitt, Gregory; Liew, Susan; et al. The Learning Curve of Pedicle Screw Placement: How Many Screws Are Enough? Spine. 34(21):E761-E765, October 1, 2009.

2. Learch, Thomas J.; Massie, Jennifer B.; Pathria, Mini N.; et al. Assessment of Pedicle Screw Placement Utilizing Conventional Radiography and Computed Tomography: A Proposed Systematic Approach to Improve Accuracy of Interpretation, Spine. 29(7):767-773, April 1, 2004.

3. Ravi, Bheeshma; Zahrai, Ali; Rampersaud, Raja. Clinical Accuracy of Computer-Assisted Two-Dimensional Fluoroscopy for the Percutaneous Placement of Lumbosacral Pedicle Screws. Spine. 36(1):84-91, January 1, 2011.

4. Sedory, David M.; Crawford, John J.; Topp, Raymond F. The Reliability of the Ball-Tipped Probe for Detecting Pedicle Screw Tract Violations Prior to Instrumenting the Thoracic and Lumbar Spine. Spine. 36(6):E447-E453, March 15, 2011.

5. Ferrick, Michael R.; Kowalski, Joseph M.; Simmons, Edward D. Jr. Reliability of Roentgenogram Evaluation of Pedicle Screw Position. Spine. 22(11):1249-1252, June 1, 1997.

6. Amiot, Louis-Philippe; Lang, Karsten; Putzier, Michael; et al. Comparative Results Between Conventional and Computer-Assisted Pedicle Screw Installation in the Thoracic, Lumbar, and Sacral Spine. Spine. 25(5):606-614, March 1, 2000.

7. Constantin, Schizas; Jacky, Michel; Kosmopoulos, Victor, et al. Computer Tomography Assessment of Pedicle Screw Insertion in Percutaneous Posterior Transpedicular Stabilization. Eur Spine J. 2007 May; 16(5): 613–617.

8. Costa, Francesco; Cardia, Andrea; Ortolina, Alessandro; et al. Spinal Navigation: Standard Preoperative Versus Intraoperative Computed Tomography Data Set Acquisition for Computer-Guidance System: Radiological and Clinical Study in 100 Consecutive Patients. Spine. 36(24):2094-2098, November 15, 2011.

9. Wiesner, Lothar; Kothe, Ralph; Rüther, Wolfgang. Anatomic Evaluation of Two Different Techniques for the Percutaneous Insertion of Pedicle Screws in the Lumbar Spine. Spine. 24(15):1599, August 1, 1999.

10. Wiesner, Lothar; Kothe, Ralph; Schulitz, Klaus-Peter; et al. Clinical Evaluation and Computed Tomography Scan Analysis of Screw Tracts After Percutaneous Insertion of Pedicle Screws in the Lumbar Spine. Spine. 25 (5):615-621, March 1, 2000.

11. Raynor, Barry L.; Lenke, Lawrence G.; Bridwell, Keith H.; et al. Correlation Between Low Triggered Electromyographic Thresholds and Lumbar Pedicle Screw Malposition: Analysis of 4857 Screws. Spine. 32 (24):2673-2678, November 15, 2007.

12. Danesh-Clough, Tony; Taylor, Peter; Hodgson, Bruce; et al. The Use of Evoked EMG in Detecting Misplaced Thoracolumbar Pedicle Screws. Spine. 26(12):1313-1316, June 15, 2001.

13. Kosmopoulos, Victor; Schizas, Constantin . Pedicle Screw Placement Accuracy: A Meta-analysis . Spine. 32 (3):E111-E120, February 1, 2007.

14. Woo-Kie Min, Hyun-Joo Lee, Won-Ju Jeong, et al. Reliability of Triggered EMG for Prediction of Safety during Pedicle Screw Placement in Adolescent Idiopathic Scoliosis Surgery. Asian Spine J. 2011 March; 5(1): 51–58.

15. Toleikis, J. Richard; Skelly, Jon P.; Carlvin, Arnold O.; et al. The Usefulness of Electrical Stimulation for Assessing Pedicle Screw Placements . Journal of Spinal Disorders. 13(4):283-289, August 2000.

16. Wood, Martin; Mannion, Richard. A Comparison of CT-based Navigation Techniques for Minimally Invasive Lumbar Pedicle Screw Placement. Journal of Spinal Disorders & Techniques. 24(1):E1-E5, February 2011.

17. Duffy, Michael F.; Phillips, Jonathan H.; Knapp, Dennis R.; et al. The Usefulness of Electromyography Compared to Computed Tomography Scans in Pedicle Screw Placement. Spine. 35(2):E43-E48, January 15, 2010.