THE PROBLEM

There is an abundance of clinical experience involving pedicle screws. There are numerous published series regarding neurological complications from misplaced or malpositioned screws. The actual incidence of this complication varies by series. Some series claim misplacements rates as high as 20%.[i] [ii] [iii] Misdirected pedicle screws have the potential to create radicular pain from nerve root irritation when the medial wall of the pedicle has been breached.

RADICULAR SYMPTOMS IMPROVE WITH SCREW REMOVAL

Misplaced pedicle screws can create pain, and even neurological deficits. The greater the displacement: the greater the risk for neurologic injury. In general, the radicular symptoms and deficits resolve once the malpositioned pedicle screw is redirected or removed. The literature demonstrates that the associated clinical symptoms are, in most cases, reversible with appropriate action.[iv] [v] [vi] [vii] [viii] [ix] [x] [xi] These studies demonstrate, that passage of the screw over the nerve root during insertion is not the cause of ongoing radicular pain, but rather the continued interaction between the sensitive root and the threads of the pedicle screw. From personal experience, intraoperative redirection of a malpositioned pedicle screw does not lead to clinical symptoms postoperatively. My experience, which includes over 1500 instrumented fusions, and nearly 10,000 pedicle screw placements, has been consistent with the published literature. With the Aversion system, a misplaced screw may indeed pass the nerve root, and the threads may come into contact briefly with the nerve root; however, once the screw is fully implanted, with proper technique, there should be minimal or no thread contact between the screw and the nerve root. Any contact between the screw and the nerve root should be along the smooth portion of the shank.

ANATOMICAL CONSIDERATIONS

Exploring this idea anatomically, we should begin with an understanding of the local anatomy within this region. Several studies have been published regarding the relationships between the pedicle, the nerve roots, and the lumbar neural foramen.

Anterior Location of the Nerve Root inside the Spinal Canal

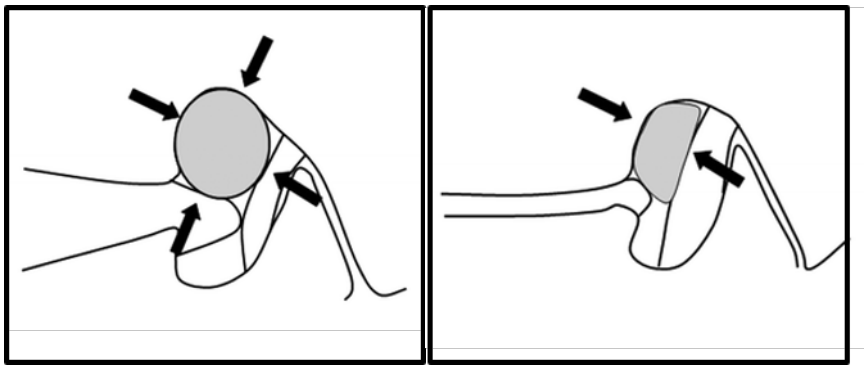
Each nerve root leaves the thecal sac from a relatively fixed point at an angle in the coronal plane. The nerve then descends on its way to exit the spinal canal. This take off angle has been documented by several authors. Cohen reported the coronal take off angle for the L1-5 nerve roots at approximately 40 degrees, and 22 degrees at S1. [xii] Wu, et. al., measured the angle to decrease from 52 degrees at T11 to

25 degrees at L5. Wu also measured the distance from the origin of the root sleeve to the posterior midline. He found the distance decreased from 10.9mm to 8.2 from L1-5.[xiii] The nerve roots, then originate from the anterior portion of the thecal sac, and remain anterior, separated from the posterior vertebral body wall only by the venous plexus as they descent and approach the pedicle.

The Nerve Root and its Pedicle: an Intimate Relationship

The nerve root must pass around the pedicle and exit through the neural foramen before it can join with the lumbar plexus. The diameter of the exiting nerve roots range from 3.8 to 4.6 mm as measured by Ebraheim, et.al. [xiv] The intimate relationship between the pedicle and the nerve root places the nerve at risk during pedicle screw insertion. Ebraheim et. al., found the mean distances from the lumbar pedicle to the dural covering of the nerve to be 1.5 mm medially, 1.5mm inferiorly, and 5.3mm superiorly. [xv] Camille reported a distance of 2mm from the pedicle cortex to the nerve root medially; whereas Maaly reports 1.4mm[xvi] [xvii] The intervening space is filled with a combination of fat and/or periosteum. Degenerative changes and stenosis may reduce this separation. Passing around the pedicle, the nerve root occupies the anterosuperior one-third of the intervertebral foramen.[xviii] [xix] Hypertrophy of the posterior structures, including the facet joints and ligamentum flavum, may force the nerve root further cephalad and forward, decreasing the available space between the nerve root, the inferior pedicle, and the posterior wall of the vertebral body. [xx] See Figure A below.

Figure A



Spinal stenosis from the posterior structures forces the nerve root against the pedicle and vertebral body wall. Further reduction in the foraminal volume will produce deformation and compression of the nerve root. The loss of space between the pedicle and the root increases the risk of nerve/screw contact.

Foraminal Dimensions – Anterior/Posterior Space for Available for the Nerve Root

The lumbar foramina have an inverted triangular shape, with the larger dimension superiorly where the nerve root is located. The sagittal view of a lumbar MRI verifies this fact. The anterior-posterior width of the neural foramen, which we are concerned with, has been measured in three separate studies. Using radiographs, Magnussen reported a mean value of 7mm; whereas, Smith reported 8mm by CT. [xxi] [xxii] Cramer measured the distance horizontally from the posterior aspect of the vertebral body to the ligamentum flavum immediately in front of the inferior articular process. This line passes directly through the location of the nerve root in the superior aspect of the foramina. In this study, the width of the lumbar foramina was similar for all levels: ranging from 9 to just over 10 mm.

Why the Modification to the Shaft of the Aversion Pedicle Screw is 12.5 mm Long

The discussed dimensions are sufficient to fully characterize the local relationships between the lumbar pedicles, the exiting nerve roots, and their location within the foramina. We now see that the 4-5 mm nerve root stays within 2mm of the pedicle medially and inferiorly as is passes through a 10 mm foraminal opening. The nerve then travels anterior to join the lumbar plexus. With the aversion screw system, the non-threaded portion of the pedicle screw is 12.5 mm in length. The 2.5mm pitch and single lead thread pattern allow for adjustments in 2.5mm increments. Adjustments require a full rotation of the screw. Insertion of the pedicle screw such that the non-threaded portion extends a full rotation past the posterior wall of the vertebral body on fluoroscopy, leaves 10mm of non-threaded shank to span the foraminal width - as measured by Cramer. Combining the largest published distance (2mm) between the posterior wall of the vertebral body, or pedicle, and the nerve root: and allowing for a 5 mm nerve root, the modified portion of the pedicle screw needs to span no more than 7mm. In degenerative conditions, the nerve root is forced both cranially and anteriorly, reducing the 2 mm space separating it from the pedicle and vertebral body. The fixed attachment to the anterior thecal sac prevents the nerve from moving posterior. The non-threaded portion of the Aversion Screw can easily accommodate this worst case scenario, with a 3mm or 30% margin of safety. This is greater than the 2.5mm thread pitch, allowing for a complete rotation of error. Thus the surgeon can be off a complete rotation either anteriorly or posteriorly without compromising the purpose of the screw modification. Figure B

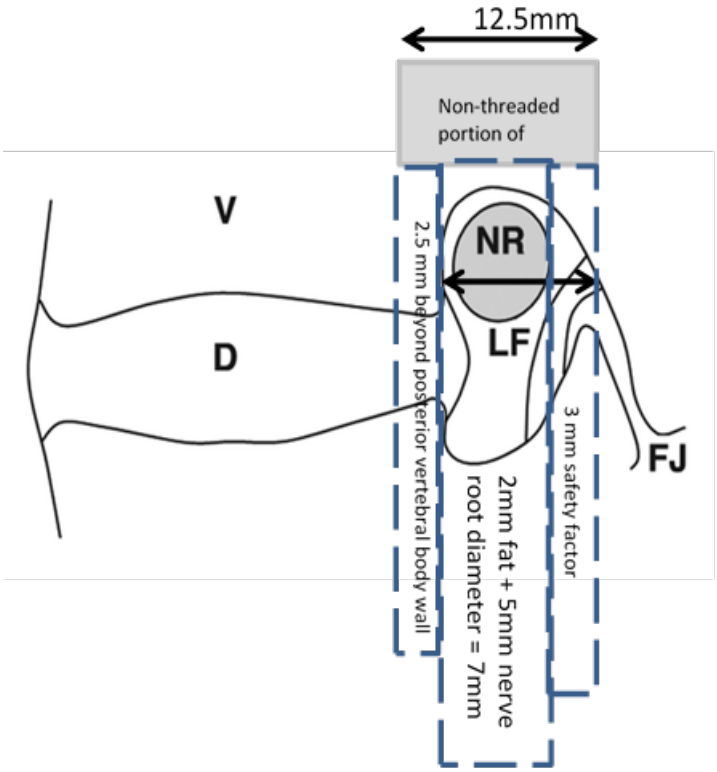


Figure B

The relationship between the nerve root, the pedicle and the foramina is shown. The drawing is to scale of all components. Note how the non-threaded portion of the screw spans the location of the nerve root within the foramina with a 30 % margin for adjustment and safety.

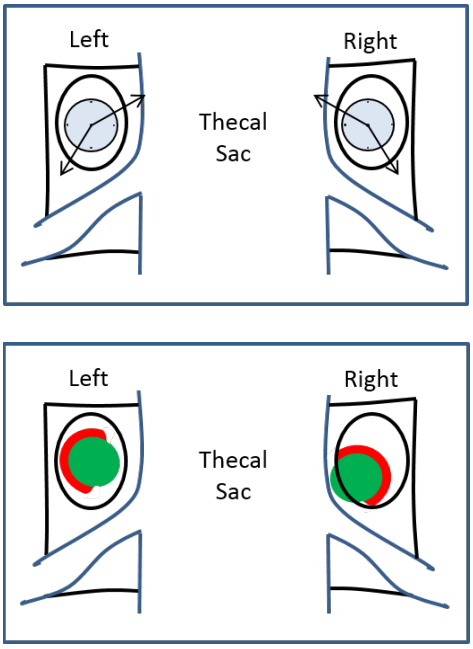
Placing the Aversion Pedicle Screw Properly – Rotational Control

With the proper pedicle screw selected and inserted to the proper depth, the non-threaded portion of the screw shaft must be rotated to face the nerve root. The nerve root approaches the pedicle at an angle previously described. For the L1-L5 nerve roots, this angle is generally between 30 and 40 degrees. [xxiv] The descending root becomes vulnerable as it passes within 2mm of the midpoint of the pedicle. [xxv] The nerve remains intimately associated with the pedicle as it completes a near 90 degree turn before leaving the neural foramen. The non-threaded portion of the Aversion pedicle screw measures 150 degrees circumferentially. The additional 60 degrees allows for a margin of safety with regard to rotation. Rotational control is essential so that the non-threaded portion of the pedicle screw is directed towards the nerve root.

Obtaining rotational control of the non-threaded portion is simple. The screw head will only accept the driver in a single orientation. The opposite end of the driver has a visual marker that corresponds to the threaded/non-threaded portions of the screw. The surgeon simply checks the visual marker on the driver to align the non-threaded portion of the screw with the axis of the patient. The 150 degrees

available to the surgeon corresponds to 5 hours on a clock. On the left side, the non-threaded portion should cover 2 o'clock to 7 o'clock. On the right side: 5 o'clock to 10 o'clock. The surgeon can easily alter this relationship as needed. Figure C.

Figure C

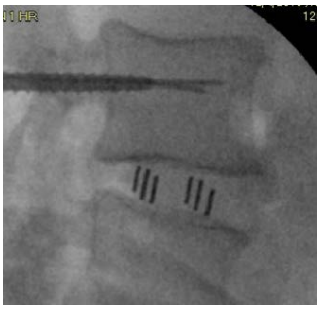


The non-threaded portion of the screw is exposed for 150 degrees. This corresponds to five hours on the clock. Ideal placement for the left is 2-7 o'clock, and 5-10 o'clock on the right.

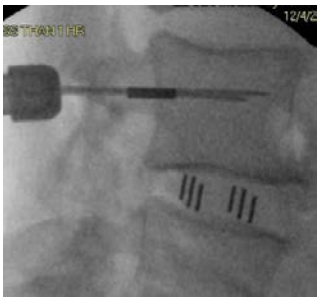
Two pedicle screws are shown in coronal section. The green circle represents the shaft of the screw, and the red corona represent the threading. The left screw is within the pedicle. The right screw has breached the medial wall with the potential to contact the nerve root. With proper rotation and depth control, the exposed shaft is absent threading. The smooth portion of the shaft is shaped more like the native pedicle than the threaded portion, and may be less likely to create nerve root irritation.

Placing the Aversion Pedicle Screw Properly – Depth Control

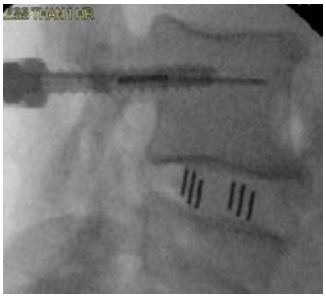
Based on the dimensions from the literature, the non-threaded portion of the Aversion pedicle screw is designed to span nerve root within the neural foramen. To be successful, the surgeon must place the screw properly with regard to both depth and rotation. Regarding depth, the surgeon has seven different screw sizes to choose from. The screws increase in size by 2.5 mm: the distance traveled by the screw after one complete rotation. A uniquely designed depth gauge has been designed to help the surgeon select the proper length screw. This is done under fluoroscopic viewing. After the screw has been placed within the pedicle, confirmation of depth is verified fluoroscopically with the help of a radiographic marker placed inside the screw. Figure D



With guide wires in place, the pedicle is tapped to allow for the depth gauge insertion. It is essential that the pedicle is tapped beyond the posterior wall of the vertebral body to allow for placement of the depth gauge.



The depth gauge is properly positioned only when the end of the gauge ocupies the desired position of the pedicle screw tulip head, and the radio-opaque marker spans the location of the nerve root. The radio-opaque marker is adjusted to span the location of the nerve root by advancing the marker just beyond the posterior wall of the vertebral body. The marker corresponds to the location of the nonthreaded portion of the pedile screw shaft. Read the gauge to select the proper pecicle screw



Once the the pedicle screw has been inserted into the pedicle, fluoroscopy is used to verify proper depth. Placement of a high density tantalum marker inside the screw cannulation confirms the relationship between the nonthreaded portion of the screw and the nerve root. The tantalum marke is easily seen through the titanium screw, even with the contralateral screw in place. Proper rotation is assured using the visual marker on the driver. The depth marker is then removed.

Clinical Application

Clinical experience has shown that with the assistance of fluoroscopy, the pedicle screw can be placed in the manner described. Fluoroscopy gives excellent visualization allowing for both proper screw selection and depth control. A depth gauge has been developed which mimics the pedicle screw head and shaft. The gauge has a tantalum marker in the end which corresponds to the non-threaded portion of the screw. After tapping the pedicle, the gauge is inserted and adjusted such that the marker spans the assumed location of the nerve root with the opposite end at the proposed location of the tulip head. This takes only a moment to accomplish. The very dense tantalum is clearly visible under

fluoroscopy: even when superimposed over another pedicle screw. The selected screw is attached to the driver such that the nonthreaded portion of the screw is aligned with the visual marker on the driver. After insertion, the depth is verified fluoroscopically using a tantalum marker passed down the screw cannulation. This marker is clearly visualized through the titanium pedicle screw -even with a contralateral screw in place. The screw is rotated to face towards the nerve root. Rotation is confirmed with the visual indicator on the river. The screw can be adjusted for depth using complete rotations as needed. Figure C demonstrates the level of contrast seen under fluoroscopy.

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