Pedicle screws are widely used in a variety of spinal fixation procedures and surgical procedures to correct adolescent idiopathic scoliosis. Inherent in any fixation procedure is the risk of slippage or failure of fixation devices. Pedicle screws fail by loosening or breakage. Failure of these screws and fixation can be problematic and may lead to complications, such as pain, neurologic injury, or loss of deformity correction.\textsuperscript{1,2} The possibility of screw failure and the associated complications led the authors to search for parameters to optimize the integrity of the fixation system and produce better outcomes. To examine the strength of the bone-screw interface, an axial pullout test is frequently used. It is a good predictor of bone-screw interface strength, even though pedicle screws in vivo rarely fail through pure axial pullout.

Surgeons who treat scoliosis have begun to use rod reduction maneuvers to reduce a deformed spine to a contoured rod. Some authors have reported that:

Effect of Pedicle Fill on Axial Pullout Strength in Spinal Fixation After Rod Reduction

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Rod reduction to pedicle screws is used for a variety of spinal fixation procedures; however, it can alter the integrity of the screw-bone interface. The authors investigated the effect of pedicle fill (ratio of pedicle screw diameter to pedicle diameter) on the strength of the screw-bone interface after simulated rod reduction on 17 vertebrae (3 thoracolumbar spine specimens). Pedicle diameter was measured with standard clinical computed tomography scan protocols. The authors determined the minimum pedicle diameter for each level. Polyaxial pedicle screws were surgically placed bilaterally with a freehand technique with standard clinical anatomic landmarks. The pedicle pairs were instrumented with pedicle screws of predetermined diameter, 1 with greater than 80% fill and 1 with less than 80% fill. A simulated reduction maneuver was performed with a 5-mm gap followed by an axial pullout test to assess screw interface strength. Comparison of insertion torque between less than 80% fill and greater than 80% fill did not show significant increases. A significant difference in pullout load ($P = .043$) occurred with greater than 80% fill (791±637 N) compared with less than 80% fill (636±492 N). No significant difference in stiffness was noted ($P = .154$) with pedicle fill of greater than 80% (427±134 N/mm) compared with less than 80% (376±178 N/mm). The current findings support the use of greater than 80% pedicle fill for optimal screw anchoring in pedicle screw-based constructs involving rod reduction. Surgeons should consider placing screws that can safely fill vertebral pedicles, especially at the apex of the curve and the proximal and distal levels of constructs, where excessive forces are imparted to the screws. [Orthopedics. 201x; xx(x):xx-xx.]

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Dr K Albanese, Mr Ordway, and Dr S A Albanese have no relevant financial relationships to disclose. Dr Lavelle has received grants from DePuy Spine, Medtronic, IntegraLife, Sigmus, Inc, Spinal Kinetics, Inc, K2M, Inc, Providence Technologies, Stryker Spine, and Vertebral Technologies, Inc.

This study was supported in part by DePuy Synthes Spine.

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Received: March 31, 2017; Accepted: August 8, 2017.

doi: 10.3928/01477447-20170925-02
these maneuvers alter the integrity of the bone-screw interface and have suggested backing out the pedicle screw to a position that more easily reduces to the rod as an alternative. However, backing out the pedicle screw reduces the strength of the bone-screw interface.

Proper screw sizing is 1 factor that affects pullout strength. Theoretically, the relationship of screw size to pullout strength is straightforward because a screw with a larger diameter has more surface area engaged with the surrounding bone and higher axial pullout strength. Pedicle morphology and its relationship to screw size are also important. Previous studies postulated that the relationship of screw diameter to minimum pedicle diameter, otherwise known as pedicle fill, is an important predictor of ultimate pullout strength. Misenhimer et al reported that screws sized with greater than 80% fill had greater pullout strength. Other studies correlated pedicle fill and insertion depth with fixation stiffness. The validity of maximizing pedicle fill and the mechanism by which this produces greater pullout strength is intensely debated.

The current study investigated whether pedicle fill of greater than 80% significantly increased pullout strength after an in vitro simulated rod reduction maneuver that is commonly used in surgery to correct spine deformity.

**Materials and Methods**

Three human cadaveric thoracolumbar spine specimens (T4-L3) were procured (age range, 48-59 years; mean height, 181±7 cm; mean weight, 101±10 kg). Lumbar dual-energy x-ray absorptiometry scans and lateral and anteroposterior radiographs were acquired to exclude specimens with significant degeneration and those that would be classified as osteoporotic. Bone mineral density as measured by dual-energy x-ray absorptiometry was 1.27±0.07 g/cm².

Specimens were evaluated with computed tomography scans according to standard lumbar clinical protocols. At each vertebral level, the pedicle axis in the sagittal plane (lateral scout image) relative to the vertebral body was determined (Figure 1). Based on this angle, coronal and transverse 1-mm slice reconstructions of each pedicle were acquired (Figure 2). Each set of reconstructions was viewed to determine which image best represented the midpedicle region. Minimum pedicle diameter was measured for this image and for both images adjacent in the sequence.

Polyaxial pedicle screws (Expedium Cortical Fix; DePuy Spine, Raynham, Massachusetts) were surgically placed bilaterally in the specimens with a freehand technique with standard clinical anatomic landmarks. Screw placement was confirmed by direct palpation of the screw path with a ball tip probe and visual inspection with a mini C-arm (Fluoroscan, Inc., Northbrook, Illinois). Screw pilot holes were tapped a size smaller than the diameter of the assigned screw. At every other level of each thoracolumbar specimen, the pair of pedicles was instrumented with a pedicle screw with a predetermined diameter: 1 with greater than 80% fill (based on the ratio of screw diameter to minimum pedicle diameter) and 1 with less than 80% fill. Screw length was selected to be approximately 80% of the depth of the insertion point to the anterior cortex (vertebral body depth). At adjacent levels, pedicle screws were placed based on 80% fill criteria. Peak insertion torque during screw placement was monitored and recorded.

After all pedicle screws were placed, a rod that spanned 2 disk levels (3 vertebrae) was instrumented and contoured to allow a 5-mm residual gap between the rod and the tulip at the midvertebra. End levels were fitted with caps (not tightened), and a rod reduction device was used to engage the rod into the pedicle screw at the midvertebra. After a 5-minute period to allow for stress relaxation of the rod-screw construct, the rods were removed. The 5-minute period was chosen to allow for sufficient and consistent
loading of the rod-reduced pedicle screw. This preparation resulted in rod-reduced pedicle screws with varying pedicle fill of either less than 80% or greater than 80%.

The spine specimen was stripped of soft tissue, but mechanically relevant ligamentous and joint capsule tissues were left intact. The thoracolumbar spine was dissected into 3 to 4 sections of vertebrae. The vertebral bodies of each section were encased in polymer (Z-Grip Lightweight Filler; Evercoat, Cincinnati, Ohio) to facilitate biomechanical testing. Testing was performed with a material testing machine (MTS 858; MTS Systems Corporation, Eden Prairie, Minnesota) with custom fixtures and a multiaxis machining vice. Each pedicle screw construct was positioned in the vice. Before each test, the longitudinal axis of the screw was aligned with the actuator axis of the MTS. A driver was placed in the tulip, and the angle of the vice was modified until the driver was aligned with the actuator axis (confirmed with vertical laser). Once the axes of the screw and the actuator were aligned and coincident, the construct was fixed in a vice to the frame of the MTS. The driver was removed, a short spinal rod and cap were attached, and a turnbuckle fixture was used to attach the actuator to the rod (Figure 3). The pedicle screw-bone construct was tested in tension at a rate of 5 mm/min. Load and displacement data were collected at 100 Hz. After each test, the construct was examined to confirm failure of the screw-bone interface.

Data Analysis

For each pedicle, the average of the transverse pedicle diameter from 3 images was compared with the average of the coronal pedicle diameter. The lesser of these 2 averages was taken as a conservative estimate of the minimum pedicle diameter. Ultimate pullout load and stiffness were determined from each pedicle pullout test based on load and displacement data. Descriptive statistics were calculated for pedicle diameter, pedicle screw insertion torque, pullout load, and stiffness. A paired Student’s t test was performed on insertion torque, pullout load, and stiffness, with pedicle fill (<80% or >80%) as the nominal variable. A significance level of alpha=0.05 was used.

RESULTS

For this data set, 17 vertebrae (34 pedicles with screws) from 3 spine specimens underwent rod reduction. Minimum pedicle diameter was 4.7 to 10.8 mm, and cortex thickness averaged approximately 1 mm (Table 1). Selected screw sizes ranged from 4.35 to 8 mm. For 4 vertebrae, pedicle diameter was either too small or too large for the available screw sizes to accommodate a paired set (<80% and >80%). Because 1 pedicle breach occurred, 12 paired pedicles were included in this data set for statistical comparison (Table 2). A comparison of insertion torque between fill of less than 80% and greater than 80% showed a nonsignificant increase in peak torque. Across all vertebral levels and screw sizes, pullout load ranged from 183 to 2095 N. A significant difference was found for pullout load (P=0.043) when greater than 80% fill (791±637 N) was compared with less than 80% fill (636±492 N). No significant difference in stiffness (P=0.154) was found based on pedicle fill of greater than 80% (427±134 N/mm) compared with less than 80% (376±178 N/mm).

DISCUSSION

This study examined pedicle screw fill in relation to rod reduction maneuvers. Rod reduction has become more common in the treatment of spine deformities. As surgeons perform more aggressive corrections with this technique, screws are stressed via axial pullout. Numerous studies have examined pedicle screw pullout in degenerative spine models; however, to the authors’ knowledge, this is the first report to examine a rod reduction model with respect to the amount of pedicle fill. Anchoring screws into the pedicle is advantageous because the pedicle is the main force-transmitting element from the posterior vertebrae to the vertebral body.11
Steffee et al\textsuperscript{11} referred to the pedicle as the “force nucleus” and maintained that pedicle fixation allowed for superior control of the spine for manipulation while minimizing the number of vertebrae that require fixation.

Numerous factors contribute to the integrity of this type of fixation. One factor is the hardware itself. Pedicle screws come in various types that differ in geometry (conical or cylindrical), thread type (single or dual lead), thread pitch, material, and head design (monoaxial or polyaxial). Many studies have examined the effects of screw thread design on pullout strength.\textsuperscript{12-15} There has also been research on the pullout strength of conical vs cylindrical screw designs.\textsuperscript{1,4,16,17} Theoretically, conical screws compact the cancellous bone surrounding the screw on insertion, resulting in greater pullout strength.\textsuperscript{14,17} However, the benefit of conical screws has been debated.\textsuperscript{4,16} Pitch and major and minor screw diameter have been shown to be important determinants of pullout strength.\textsuperscript{13} The current study did not compare screw designs and focused on pedicle fill; therefore, it is possible that different pedicle screws could affect results, but the relationships shown in the current study should be similar.

When evaluating the strength of screw-bone interaction, the bone morphology of the pedicle is important to consider. Two studies showed that the screw-bone interface in the pedicle contributes approximately 60\% to overall pullout strength compared with the component of the screw that rests in the vertebral body.\textsuperscript{18,19} Misenhimer et al\textsuperscript{7} described the pedicle as a cancellous bone core with a thin cortical shell. Hirano et al\textsuperscript{18} further broke down the bone layers into an inner trabecular layer and a denser outer subcortical layer surrounded by a thin, dense cortical layer. The trabecular and subcortical layers form the cancellous core and comprise approximately 60\% of the inner pedicle area,\textsuperscript{18} leaving an outer layer of denser cortical bone that accounts for approximately 40\% of the pedicle.

Although numerous studies have reported on screw design and the effects of pedicle fill pullout strength, most are concerned with screws designed for cancellous bone interaction. The authors believe that cortical thickness is also important. The importance of the outer layer of cortical bone for fixation stiffness has been debated. Misenhimer et al\textsuperscript{7} reported no cortical purchase for large screws of greater than 80\% of cortical diameter because of plastic deformation of the pedicle. Zdeblick et al\textsuperscript{20} refuted this point and found that the screws used in their study did visibly purchase the cortical layer. A study of bovine tibias with screws designed to engage the cortical layer found a positive correlation between pullout strength and cortical thickness.\textsuperscript{21} Another study found similar correlations for tibial screw pullout strength, but only for specimens with cortical thickness of greater than 1.5 mm.\textsuperscript{22} Zhuang et al\textsuperscript{23} reported cortical thicknesses with an upper limit of approximately 1.5 mm. In the current study, cortical thickness averaged 1 mm, so it is unclear to what extent the smaller cortical thickness seen in pedicles affects pullout strength.

The current results showed a significant increase of pullout strength with pedicle fill of greater than 80\%. This is likely a result of a complex interplay among multiple factors, most importantly, pedicle morphology and screw diameter. Although cortical thickness likely has some effect on pullout strength, the authors believe that cortical purchase is unlikely to be the major contributor to the increased pullout strength that is seen with greater than 80\% pedicle fill. The probable reason why the cortex is not a major contributing factor has to do with pedicle morphology. Unlike the screw, the pedicle is not a perfect cylindrical shape. Previous research-

### Table 1

<table>
<thead>
<tr>
<th>Spinal Level</th>
<th>No.</th>
<th>Mean±SD Minimum Pedicle Diameter, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>T4</td>
<td>4</td>
<td>5.4±0.7</td>
</tr>
<tr>
<td>T6</td>
<td>6</td>
<td>6.6±0.7</td>
</tr>
<tr>
<td>T8</td>
<td>6</td>
<td>6.7±0.5</td>
</tr>
<tr>
<td>T10</td>
<td>6</td>
<td>7.1±0.8</td>
</tr>
<tr>
<td>T12</td>
<td>6</td>
<td>9.9±0.9</td>
</tr>
<tr>
<td>L2</td>
<td>6</td>
<td>9.6±1.1</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>Pedicle Fill</th>
<th>No.</th>
<th>Pedicle Diameter, mm</th>
<th>Insertion Torque, Nm</th>
<th>Pullout Force, N\textsuperscript{a}</th>
<th>Pullout Stiffness, N/mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;80%</td>
<td>12</td>
<td>6.5±1.2</td>
<td>2.17±1.62</td>
<td>791±637</td>
<td>427±134</td>
</tr>
<tr>
<td>&lt;80%</td>
<td>12</td>
<td>7.0±0.8</td>
<td>1.80±1.28</td>
<td>636±492</td>
<td>376±178</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Significant difference (P<.05).
ers showed that pedicle diameter varies in the transverse, sagittal, and coronal planes. Zindrick et al. found minimum pedicle diameter in the transverse plane. Because of the inconsistent pedicle shape, cylindrical screws probably do not have consistent or meaningful cortical purchase throughout the length of the screw. Therefore, cortical purchase likely is not the leading contributing factor in overall pullout strength.

Screw size may be a larger contributing factor than cortical purchase. DeCoster et al. showed a linear correlation of screw diameter and pullout strength, with larger screw diameters having greater pullout strength. Other investigators confirmed this relationship. Intuitively, a larger screw core diameter increases the surface area in contact with the surrounding bone and thus increases frictional resistance to axial pullout. This is consistent with previous work by the current authors in which multiple regression analysis showed that screw diameter was a large contributor to pullout strength, independent of bone mineral density, insertion torque, and pedicle fill. Given this relationship, for maximum purchase, the largest diameter screw that can be inserted safely should be used rather than using 80% pedicle fill as a cutoff.

Fixation stiffness was another parameter tested in the current study. Brantley et al. found that, as length increases, construct stiffness increases if the screw fills the pedicle by greater than 70%, screw width increases, and penetration depth is greater than 80%. In the current study, screws were inserted to approximately 80% of the depth to the anterior cortex, so this variable was constant. The current authors tested the claim that greater than 80% fill increases fixation stiffness. However, the results showed no significant increase in fixation stiffness with greater than 80% or less than 80% fill. On the basis of the current results, it is unclear whether the relationship between pedicle fill and fixation stiffness holds true in pure axial pullout.

The current study performed direct side-to-side comparison of pedicle fixation. The thoracolumbar specimens showed a wide range of pedicle fixation strength because of variations in pedicle morphology, variations in bone mineral density between levels and specimens, and a range of sizes of pedicle screws used. Overall, this study supports the claim that increasing pedicle fill increases pullout strength and the overall integrity of the fixation system, even when rod reduction is used. The current results showed a significant difference in pullout strength when the screw was sized to fill greater than 80% of the pedicle. The authors attributed this difference mostly to screw diameter and suggested that the contribution of the cortical layer to fixation strength is likely much smaller because of varying pedicle shape throughout its length, likely leading to inconsistent cortical purchase. The authors found no significant difference in fixation stiffness between pedicles with greater than 80% or less than 80% fill. Therefore, the authors cannot affirm previous claims about the effect of pedicle fill on fixation stiffness.

**CONCLUSION**

This study supported the importance of pedicle fill for optimal screw anchoring for constructs based on pedicle screws after rod reduction for surgery to correct spine deformity. Surgeons should consider placing screws that can safely fill the vertebral pedicles, especially in constructs where the highest forces will be imparted to the screws, such as sites where a deformed spine will be pulled to a precontoured rod (the apex of a vertebra altered by scoliosis or a kyphosis construct) and the proximal and distal ends.

**REFERENCES**

North American Spine Society Meeting; October 18-21, 1995; Washington, DC.


