The Effects of Cement Augmentation Technique and Cement Volume on Pedicle Screw Fixation in Osteopenic Bone

INTRODUCTION Cement augmentation of pedicle screws has been shown to improve screw fixation in osteopenic spines. The use of polymethylmethacrylate cement augmentation has been documented in various studies using a number of different techniques: cement injection directly into an open pilot hole, through cannulated screws, using implanted sleeves, and using kyphoplasty techniques. Complications can arise regardless of the technique employed including extravasation into the surrounding anatomy with the risk of embolization. Entry into the spinal canal and neural foramen could cause direct neurologic compression. The use of cannulated and fenestrated screws through which cement can be injected has proven effective; however, once the cement is hardened the screws require extremely high and dangerous torques for removal in revision situations. [1]

To address these difficulties we have developed a novel cement delivery device and technique that, once removed, leaves a threaded tract for insertion of pedicle screws [1]. Unlike the cannulated screws mentioned above, this system is withdrawn prior to hardening. A separate, non-fenestrated screw can then be inserted. This eliminates the revision complications of the fenestrated screw system and decreases the extravasation possibility with the direct injection, while still improving overall fixation strength. In previous studies we have shown that resistance to toggling was significantly improved when compared to screws implanted without cement.

In this study we compared this novel technique to open pedicle injection of cement. To further investigate the use of such a device, we used two different cement volumes, 2ml and 3ml.

METHODS Lumbar spine segments (L1-L5) from six fresh frozen spines were harvested and debrided of soft tissue (average age 85.3, range:70-95). Only specimens meeting osteopenic criteria with BMD of 1.1g/cm² or less based on DEXA were selected. Twenty-one vertebral bodies met this criterion and were otherwise deemed suitable.

The novel cement delivery device, fully described in previously reported study [1], consisted of a 6.0-mm x 45-mm cannulated Viper pedicle screw (DePuy Spine, Inc., Raynham, MA) with multiple side fenestrations, each 2 mm in diameter, milled at the threads at the tip of the screw (Figure 1). The screw head was removed and threaded to allow direct attachment of a syringe to provide pressurized delivery of the cement through the screw.

Figure 1. Fenestrated screw for cement delivery.

Standard techniques were employed in the preparation of each pedicle. One pedicle of each vertebral body was designated to receive cement using the novel fenestrated screw system, the contralateral pedicle received cement through open injection. The device was removed as the cement began to warm, followed by the insertion of a standard, unaltered 6.0-mm x 45-mm Viper screw. For the contralateral pedicle, the same cement volume was injected directly into the tapped screw holes. Injection was immediately followed by the insertion of a standard, unaltered 6.0-mm x 45-mm Viper screw. Regardless of which augmentation method was used, both pedicles of each vertebral body were augmented with either 2 or 3 ml of cement. There were four groups compared in this study: fenestrated device with 2 ml cement, fenestrated device with 3 ml cement, open injection with 2 ml cement, and open injection with 3 ml cement.

Each vertebral body was potted in PMMA leaving the posterior elements exposed. The specimens were then mounted into a hydraulic materials testing machine with the anatomic plane perpendicular to the testing axis. A 5.5-mm rod was connected to the pedicle screw polyaxial head in horizontal alignment and coupled to the actuator using a custom-designed hinge fixture. The screws were loaded repetitively in a cephalocaudal direction with progressive loads of 20N, 40N, 60N, 80N, and 100N at 2,000 cycles for each load, totaling 10,000 cycles. The cephalocaudal displacement of the screw head in the cephalocaudal plane was recorded and served as the primary outcome measure. Following testing, screws were removed. The pedicle of all vertebral bodies was examined for evidence of cement extravasation into the pedicle.

The torque required to extract the screws was then determined using 8 additional vertebral body specimens. The insertion technique was identical to that previously mentioned. Potted specimens were individually mounted on a biaxial load cell, allowing measurement of applied axial load and torque upon screw removal. Maximum torques was used as the primary outcome measure. ANOVA was used to examine the data with significance at p<0.05.

RESULTS Pedicle screws augmented using the fenestrated screw technique allowed significantly greater toggling motion than did screws augmented using the open injection method (p<0.003). The variability of the displacement recorded was also significantly greater with the fenestrated screw technique. Cement volume (2ml or 3ml), however, was not found to have had a significant effect on toggling displacement (p=0.616). (See Figure 2)

Visual inspection of the pedicles following testing showed that there was one (5%) occurrence of extravasation into the pedicle of a fenestrated tap specimen; for the direct injection specimens there were a total of 18 (86%), this difference in occurrence rate was significant (p<0.001). (Table 1)

Augmentation method was found to significantly affect the maximum removal torque (p<0.001). Cement volume was not found to be significant for torque but was nearly significant (p=0.089). (Table 2)

Figure 2. Cephalocaudal screw head displacement during toggle testing. Error bars represent 95% confidence intervals.

Table 1. Cephalocaudal toggle displacement and number of occurrences of cement extravasation into the pedicle.

<table>
<thead>
<tr>
<th>Groups</th>
<th>2ml of Cement (%)</th>
<th>3ml of Cement (%)</th>
<th>Rate of Extrav.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>2.19±0.90</td>
<td>9 of 10</td>
<td>2.14±0.49</td>
</tr>
<tr>
<td>Fenestrated</td>
<td>4.17±1.46</td>
<td>1 of 10</td>
<td>5.06±3.07</td>
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</tbody>
</table>

Table 2. Maximum torque required to remove screws.

<table>
<thead>
<tr>
<th>Groups</th>
<th>2ml (Nm±SD)</th>
<th>3ml (Nm±SD)</th>
<th>All (Nm±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>841(±366)</td>
<td>1228(±270)</td>
<td>1034(±283)</td>
</tr>
<tr>
<td>Fenestrated</td>
<td>320(±54)</td>
<td>302(±156)</td>
<td>271(±113)</td>
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CONCLUSIONS These findings underscore the risks and benefits of both techniques evaluated. It is noted that the fenestrated screw group do have more toggle. The improved performance of the direct cement injection is thought to be due to the increased strength of the pedicle into which the cement extravasated. This increased strength is weighted against the possibility of complications of this extravasation including neural compression or vascular embolization. In addition, we noted the increased force for removal. The possibility of reducing complications associated with cement extravasation and screw removal makes the fenestrated technique valid option.

References

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