SAFETY AND EFFICACY OF THE SYNTHES THORACIC HOOK LOCKING SCREW

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INTRODUCTION

Posterior spinal fusion and instrumentation using rods attached to hooks, wires, or screws is commonly used to correct severe thoracic scoliosis deformities. Posterior and lateral forces are applied to the spine through an interface between the rod and the posterior vertebral elements. The advantage of pedicle hooks is the footplate’s broad surface area through which forces are applied. Hooks are relatively easy to insert compared to wires and pedicle screws, decreasing the potential for neurologic or dural injury. However, the hooks can easily dislodge during corrective maneuvers. Pedicle screws in the thoracic spine have been gaining popularity but are clearly more technically challenging to place safely.

The Universal Spine System (USS, Synthes Spine Corp., Paoli, PA) contains a locking screw that passes through the body of the hook, traversing the pedicle and into the cranial endplate of the vertebral body, creating fixation between the hook and pedicle. During placement it is possible that either the drill bit or the screw may come into contact with neural elements. We compared the safety and ease of placement of this construct with 2 separate screw lengths against thoracic pedicle screws. Our specific aims were: 1) to determine if the pedicle screw, the longer hook locking screw or the shorter hook locking screw could be consistently placed such that the screw does not impinge on the neural elements; and 2) to assess the lateral and posterior pullout strength of these three constructs.

METHODS

Three groups of implants were placed in 7 intact fresh frozen cadaveric thoracic vertebrae (T1-T12, average age 59 yrs). T12 bone mineral density (BMD) was determined for each specimen using dual energy x-ray absorptiometry (DXA) in order to normalize the pullout data for varying specimen density. The groups consisted of: 1) thoracic pedicle hooks with a 40 mm locking screw, 2) thoracic pedicle hooks with a 20 mm locking screw, or; 3) 4.2 mm standard thoracic pedicle screws. The implants were alternated by vertebral level. No real time radiographic imaging was used for placement of either implant.

Each level was then inspected to determine the anatomic proximity of the implants to the neural elements, based on the known typical location and course of nerve roots and the thecal sac. The vertebral bodies were then disarticulated and embedded in aluminum fixtures; the transverse and spinous processes and the hardware were left unembedded. The constructs were tested to failure in either a lateral or posterior direction. Only a single hook or screw at each level was tested and the side was alternated.

Maximum pullout force and stiffness data were analyzed using a multifactorial analysis of variance with specimen, screw type, and pullout direction as separate factors. If screw type and loading direction had an effect on pullout force or stiffness, we performed a Tukey Post Hoc analysis to detect group differences at p<0.05.
RESULTS

Safety: Of 37 hooks with short locking screws, 4 screws (11%) had potential neural contact medially without significant canal compromise or likely neurologic sequelae in-vivo. Three (8%) screws were misplaced laterally, which would not likely have any neural contact.

Of 38 hooks with long locking screws, 1 screw (3%) intersected the path of the nerve root as it exited the foramen, having a high possibility of encroachment or nerve root injury in-vivo. Ten (26%) of the long locking screws were misplaced laterally, which would not likely have any neural contact.

Of 42 pedicle screws inserted, 2 (4%) screws had potential neural contact. One was angled too caudally by 38°, placing the screw directly across the path of the nerve root as it exited the foramen. The second screw broke through the medial pedicle wall, mildly reduced the volume of the lateral recess and had a low probability of clinically significant neural contact.

Strength: During pullout testing, all constructs had equivalent failure load (Table 1). During posterior pullout testing, the pedicle screw was stiffer than both locking screws (p<0.0005, 95% power).

Table 1: Data (mean ± standard deviation, sample size) for the 3 screw types. "Pedicle screw stiffness in the posterior direction was significantly greater than the long or short screws.

<table>
<thead>
<tr>
<th>Screw</th>
<th>Direction</th>
<th>Stiffness (N/mm)</th>
<th>n</th>
<th>Failure Load (N)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long</td>
<td>Lateral</td>
<td>168 ± 65</td>
<td>8</td>
<td>668 ± 247</td>
<td>9</td>
</tr>
<tr>
<td>Short</td>
<td>Lateral</td>
<td>181 ± 81</td>
<td>11</td>
<td>449 ± 241</td>
<td>11</td>
</tr>
<tr>
<td>Pedicle</td>
<td>Lateral</td>
<td>229 ± 112</td>
<td>10</td>
<td>499 ± 182</td>
<td>11</td>
</tr>
<tr>
<td>Long</td>
<td>Posterior</td>
<td>423 ± 143</td>
<td>11</td>
<td>861 ± 231</td>
<td>11</td>
</tr>
<tr>
<td>Short</td>
<td>Posterior</td>
<td>593 ± 246</td>
<td>11</td>
<td>1098 ± 315</td>
<td>11</td>
</tr>
<tr>
<td>Pedicle</td>
<td>Posterior</td>
<td>1245 ± 302</td>
<td>8</td>
<td>840 ± 203</td>
<td>9</td>
</tr>
</tbody>
</table>

DISCUSSION

Of 119 implants placed, 4% of the pedicle screws and 37% of the hook locking screws missed their intended path. One long locking screw and one pedicle screw directly crossed the anatomic path of a thoracic nerve.

Four of the short locking screws and 1 long locking screw were placed against the medial wall of the pedicle in the lateral recess of the neural canal. One pedicle screw was placed slightly medial and broke the medial cortex of the pedicle decreasing the space available for the nerve root within the lateral recess. Six additional locking screws were near the nerve root but not as likely to have clinical impact as the locking screw and pedicle screw that traversed the course of the nerve roots.

Theoretically, the placement of the locked hook should be technically easier than placement of the standard pedicle screw. However, we found more variation in the anatomic placement of the hook locking screws, though this did not result in increased risk of nerve root injury. Despite an increased risk of malposition, the locked hooks had equivalent failure loads to the pedicle screws, and equivalent stiffness in the lateral direction.

While pedicle screws have gained popularity for their significant contribution to stability in spinal instrumentation, there are ongoing concerns about the safety of pedicle screw implantation. The goal of this ongoing design effort is to equal the stiffness and failure load of pedicle screw instrumentation with an implant that can be safely placed by a wide population of surgeons.

ACKNOWLEDGEMENT

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