The Use of an Interspinous Implant in Conjunction With a Graded Facetectomy Procedure

Paul D. Fuchs, MD,*† Derek P. Lindsey, MS,‡ Ken Y. Hsu, MD,† James F. Zucherman, MD,† and Scott A. Yerby, PhD‡§¶

Degenerative lumbar stenosis is a disabling condition associated with neurogenic claudication caused by compression of the lumbar nerve roots.14–17 If conservative treatment fails, relief from claudication symptoms can be attained from decompression of the neural elements.8,9 Surgical decompression can be associated with significant blood loss, nerve injury, instability, worsening back pain, and infection.10,11 Many of these patients are elderly and have serious concomitant medical problems, which preclude extensive surgery and general anesthesia.12

During early clinical trials, a novel implant (X STOP, St. Francis Medical Technologies, Alameda, CA) has successfully treated spinal stenosis using a minimally invasive approach without the need for general anesthesia.13 The device is comprised of an oval spacer made of titanium, which is placed between 2 adjacent lumbar spinous processes at the level of stenosis. There are 2 lateral wings that keep the implant in position and prevent lateral migration. Placing the segment in slight flexion increases the space available for the neural elements, relieving the symptoms associated with neurogenic claudication.3

In patients with severe stenosis at multiple levels who may not be candidates for the X STOP as a stand-alone device, the implant may increase the effectiveness as an adjunct when performing decompressive procedures such as unilateral medial facetectomy (UMF) and unilateral total facetectomy (UTF) for subarticular and foraminal stenosis, respectively. The implant may decompress the neural structures while allowing a minimum amount of tissue to be resected and, thus, making the procedure less invasive. While reviewing the literature, there are numerous reports describing the contribution of the lumbar facets to stability, and their role in supporting loads and restricting motion.14–25 Prasad and Kaing26 have inferred that the facets carry from 0% to 33% of the total axial load of the spine. Nachemson27,28 reported that the facets carry up to 18% of the total axial load, and Yang and King18 concluded that the facets carried up to 25% of the load, and as much as 47% if the facets were arthritic. From a functional and anatomic standpoint, Schneck29 describes “the vertebral and paired facet joints, as an asymmetric tripod load-transmission system (ATLTS) from one vertebra to the next, with the vertebral body bearing most of the load.” Numerous studies have shown that injury or surgical removal of the facet joints can negatively influence stability from a biomechanical and clinical standpoint.14–16,19,21,22,25

Abumi et al16 showed that injury to the facet joint por-
tion of the ATLTS produces instability in the vertebral complex. They showed instability in flexion after UMF and in axial rotation after bilateral total facetectomy (BTF). They concluded that if a complete unilateral facetectomy was performed, the motion segment would be unstable, and spinal fusion should be performed to maintain stability.

The purpose of this study was to investigate the effect of the X STOP on the range of motion (ROM) of the lumbar spine after sequential graded facetectomies, which included UMF, UTF, and BTF. Specifically, the authors asked if the spacer implant could restore the “tripod” load transmission and stability system ROM, and prevent the instability increased ROM seen after graded facetectomies. Based on previous findings by Lindsey et al., the investigators hypothesized that the implant would not decrease the ROM during lateral bending and axial rotation but would decrease the ROM in extension.

Materials and Methods

Seven human lumbar (L2–L5) cadaver specimens were cleaned of all muscle and adipose tissue, and the ligamentous structures were left intact. The cranial portion of L2 and caudal portion of L5 vertebrae were secured in polymethylmethacrylate, and each specimen was placed in a spinal loading frame capable of applying independent bending moments and axial loads (MTS 858, MTS Systems, Eden Prairie, MN). Individually labeled steel pins 10 cm in length were placed in each vertebra, and on the upper and lower actuators to indicate the angular position (Figure 1). Two CCD cameras were used to record the position of the pins during the testing. The first camera (Model XC-77, Sony, Tokyo, Japan) was placed perpendicular to the flexion-extension and then lateral bending planes; the images recorded during those tests were used to measure the intervertebral motion as a result of the respective movement. The second camera (Model DC-37, Sony) was placed perpendicular to the plane of axial rotation and recorded images during axial rotation testing. Three images were taken during each test cycle. During flexion-extension, images were recorded with the specimens in the flexed, neutral, and extended positions. During lateral bending, images were recorded during right bending, neutral, and left bending. Finally, during axial rotation, images were recorded during right rotation, neutral, and left rotation.

Specimens were initially tested intact by applying a \( \pm 7.5 \) Nm bending moment with a superimposed 700 N compressive load in flexion and extension, left and right axial rotation, and left and right lateral bending (Figure 1). Angle, force, and torque data were recorded for each motion at 10 Hz by the MTS. Following the intact testing, the specimens were removed from the loading frame, and an appropriately sized interspinous spacer implant (X STOP) (Figure 2) was placed between the L3–L4 spinous processes in each specimen. The specimens were returned to the loading frame, and the previously described loading regimen was applied to each specimen. The implant was then removed from the interspinous space, and UMF was performed on the left facet. After the specimen was tested once again with this treatment, the implant was placed in the interspinous space, and the specimen was tested again. This scenario was repeated after UTF to the left facet and BTF to both facets.

The initial intervertebral angle was calculated relative to the intact position before testing in flexion and extension. This value was recorded as the sum of the cephalad and caudal actuator angles before each test, subtracted from the initial position of the intact specimen. Because all facetectomy and implantation treatments were performed at the L3–L4 level, it was assumed that all changes in the initial angle were a result of the changes at the L3–L4 level and not the L2–L3 or L4–L5 levels. The angle of each pin was determined using Scion Image (Scion Corp., Frederick, MD) for all 3 images of each test cycle, and the difference between adjacent vertebrae was recorded as the ROM. Data for flexion and extension were measured inde-
pendently to measure an individual flexion and extension ROM for each intervertebral level. Data for right and left axial rotation, and right and left lateral bending were combined, respectively, to produce single axial rotation and lateral bending movements at each intervertebral level. For a given treatment and intervertebral level, mean ROM was compared between the intact and implanted specimens using a single factor analysis of variance followed by a Fisher protected least significant difference (PLSD) follow-up test with a level of significance of 0.05 (StatView 5.0.1, SAS Institute, Cary, NC). Mean ROM at each level was compared between the intact specimens and those with graded facetectomies using a single factor analysis of variance followed by a Fisher PLSD follow-up test with a level of significance of 0.05.

Results

Effect of the Implant on Intervertebral Angle
The mean initial angle of the facetectomy treated specimens ranged from 0.55° of extension to 0.33° of flexion relative to the intact specimens (Figure 3). The mean initial angle of the X STOP implanted specimens was 2.26° of flexion relative to the intact specimen, and this initial position decreased with each successive facetectomy to a point where the BTF specimens were in 0.61° of relative extension.

Flexion
At the instrumented level (L3–L4), the implant significantly decreased the mean ROM of the intact specimen, and those with UMF and BTF treatments (Figure 4, Table 1). The ROM for the UTF treatment was reduced, although not significantly (1.60° vs. 1.15°, P < 0.13). The graded facetectomies had no significant effect on mean ROM when compared to the intact specimens. At the adjacent levels, the implant significantly reduced the L2–L3 ROM following UMF and BTF treatments, and at the L4–L5 level, the intact and UMF ROM was significantly reduced following X STOP implantation (Table 1). None of the graded facetectomies without an implant had any significant effect on mean ROM at these adjacent levels when compared to the intact specimens.

Extension
At the instrumented level (L3–L4), the implant significantly decreased the mean ROM of the intact specimen, and those with UMF and BTF treatments (Figure 5, Table 1); the ROM for the UTF treatment was reduced, although not significantly (1.60° vs. 1.15°, P < 0.13). The graded facetectomies had no significant effect on mean ROM when compared to the intact specimens. At the adjacent levels, the implant significantly reduced the L2–L3 ROM following UMF and BTF treatments, and at the L4–L5 level, the intact and UMF ROM was significantly reduced following X STOP implantation (Table 1). None of the graded facetectomies without an implant had any significant effect on mean ROM at these adjacent levels when compared to the intact specimens.

Axial Rotation
At the L3–L4 level, the implant had no significant effect on the mean ROM of any of the specimens with or without facetectomy (Figure 6, Table 2). Mean ROM gradually increased with each increase in facetectomy grade in specimens without an implant, and similar to the mean ROM in flexion, BTF allowed for a statistically signifi-
Table 1. A Summary of the Flexion and Extension Mean ROM (in degrees)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Flexion</th>
<th></th>
<th>Extension</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>L2/3</td>
<td>L3/4</td>
<td>L4/5</td>
<td>L2/3</td>
</tr>
<tr>
<td>Intact</td>
<td>5.89 ± 2.02</td>
<td>6.34 ± 2.44**</td>
<td>6.96 ± 2.40</td>
<td>2.27 ± 1.10</td>
</tr>
<tr>
<td>Intact w/implant</td>
<td>6.14 ± 1.75</td>
<td>2.54 ± 1.21†</td>
<td>7.29 ± 3.12</td>
<td>2.67 ± 1.06</td>
</tr>
<tr>
<td>UMF</td>
<td>6.08 ± 1.50</td>
<td>6.50 ± 2.46†</td>
<td>6.91 ± 3.17</td>
<td>2.78 ± 1.39*</td>
</tr>
<tr>
<td>UMF w/implant</td>
<td>6.35 ± 1.87</td>
<td>3.49 ± 0.80‡</td>
<td>7.65 ± 3.12</td>
<td>1.88 ± 0.86*</td>
</tr>
<tr>
<td>UTF</td>
<td>6.06 ± 1.91</td>
<td>7.10 ± 2.54†</td>
<td>7.72 ± 3.12</td>
<td>2.49 ± 1.21</td>
</tr>
<tr>
<td>UTF w/implant</td>
<td>6.58 ± 1.92</td>
<td>4.48 ± 1.95†</td>
<td>7.36 ± 4.00</td>
<td>2.03 ± 0.86</td>
</tr>
<tr>
<td>BTF</td>
<td>5.89 ± 2.40*</td>
<td>7.77 ± 2.93**, **</td>
<td>6.75 ± 3.01</td>
<td>2.89 ± 1.85¶</td>
</tr>
<tr>
<td>BTF w/implant</td>
<td>6.84 ± 1.81*</td>
<td>5.96 ± 2.81††</td>
<td>6.60 ± 3.27</td>
<td>1.88 ± 0.97†</td>
</tr>
</tbody>
</table>

Note: Depicted values are mean ± standard deviation. Significant differences (P < 0.05) within a motion are denoted by common footnotes. All unilateral facetectomies were performed on the left side.

cient increase in mean ROM when compared to the intact condition. For a given treatment, the implant had no statistically significant effect on mean ROM at the adjacent, uninstrumented L2–L3 and L4–L5 levels (Table 2). In addition, none of the graded facetectomies without an implant had any significant effect on mean ROM at these adjacent levels when compared to the intact specimens.

Lateral Bending

At the instrumented level (L3–L4) for a given facetectomy, the implant significantly increased mean ROM (Figure 7, Table 2). However, the implant had no effect on the mean ROM of intact specimens without a facetectomy. Mean ROM did not significantly change with the graded facetectomy without an implant when compared to the intact specimens. For a given treatment, the implant had no statistically significant effect on mean ROM at the adjacent, uninstrumented L2–L3 and L4–L5 levels (Table 2). In addition, none of the graded facetectomies without an implant had any significant effect on mean ROM at these adjacent levels when compared to the intact specimens.

Discussion

There have been numerous studies documenting the role of the lumbar facets for maintaining stability. If the lumbar facets are surgically altered, there is potential for instability and poor clinical outcome.31,32 The goal of this study was to assess the influence of the X STOP implant on the motion segment stability ROM after sequential graded facetectomies.

Experimental data from this study confirm results from previous studies that show the ROM is significantly increased in flexion and axial rotation as more extensive facetectomies are performed, including UMF, UTF, and BTF. However, lateral bending and extension were not significantly affected by facetectomy. Abumi et al16 reported statistically significant increases in the flexion ROM following UMF, and in the axial rotation ROM following either UTF or BTF, depending on the rotation direction. The results of the current study reveal a progressive increase in mean flexion ROM with each facetectomy performed, and BTF destabilized the specimens to the point in which the ROM was significantly higher than that of the intact specimens (Figure 4, Table 1). In axial rotation, a similar steady increase in ROM was identified, and, again, BTF caused a significant increase in ROM compared to the intact specimens (Figure 6, Table 2). Also similar to the study of Abumi et al,16 the results of the current study show no significant changes to the extension or lateral bending ROM following graded facetectomies.

Although the results of the current study and those of Abumi et al16 are similar, they are not in total agreement. In particular, the ROM from Abumi et al is somewhat larger than those in the current study. One possible reason is that Abumi et al transected the supraspinous and interspinous ligaments before initial facetectomy was performed, and the methodology in the current study preserved the supraspinous ligament throughout testing. The supraspinous ligament is a strong stabilizing structure that restricts flexion. The findings during axial rotation were quite similar between the 2 studies; both found a significant increase in ROM after BTF was performed. With lateral bending, the 2 studies also produced similar results; there were no significant differences detected after any of the graded facetectomies. However, the intact

![Figure 5. Mean ROM during extension at the instrumented level (L3–L4) normalized to mean intact ROM. Bars with common superscripts are significantly different (P < 0.05). Error bars are ±1 standard deviation. All unilateral facetectomies were performed on the left side.](image-url)
ings in the current study, Adams and Hutton stated that the current study applied different reasons for this discrepancy may lie in the loading regimen. The current study applied a 700 N axial load, whereas Abumi et al. applied an 8.0 Nm and a 200 N axial load. The lower bending moment will obviously result in a lower bending angle, and the higher axial load will also result in a lower bending angle because of the increased stability caused by the higher axial load.

Similar to the findings of Abumi et al. and the findings in the current study, Adams and Hutton stated that the major restriction to torsion in the lumbar spine is the facet joint. Only after total bilateral facetectomy was a significant increase in axial rotation measured. In the current study, when surgery was limited to UMF or UTF, the ROM in axial rotation was not significantly different from the intact ROM, although the ROM did progressively increase. Only when complete bilateral facetectomy was performed did the ROM in axial rotation significantly increase. This progressive increase in the axial rotation ROM was likely a result of the progressive removal of the facet joint, which is the primary element that restricts axial rotation in a motion segment. Following BTF, the only elements remaining to restrict axial rotation are the anterior and posterior longitudinal ligament, intervertebral disc, and the supraspinous and interspinous ligaments, all of which are secondary elements when compared to the facets.

The current testing comparing the mean ROM of the intact motion segment with and without the implant showed no significant change in mean ROM during axial rotation or lateral bending; although the lateral bending ROM did increase 0.60°, it was not a statistically significant increase. However, a significant decrease in flexion and extension ROM was shown when the X STOP was placed in an intact segment. The decreased ROM in flexion was likely a result of the slight flexion placed on the motion segment by the implant (Figure 3), and the decreased extension ROM was a result of the extension restriction that the implant placed on the motion segment. However, the fact that there was any extension at all seems a bit contradictory and must be placed in the appropriate context. The implant places the motion segment of the intact specimen in approximately 2.26° flexion, relative to the intact specimen. During testing of the intact specimens with the implant, the extension ROM was 0.53° relative to the starting point but was still in flexion relative to the intact specimen. In other words, the motion segment remained in absolute flexion, while the remaining motion segments were placed in extension. This scenario is true for the UMF treated specimens with the implant as well. The small amount of extension that did occur was likely a result of elastic deformation of the implant as well.

ROM for each of the 3 motions in the current study was smaller than those reported by Abumi et al. A possible reason for this discrepancy may lie in the loading regimen. The current study applied ±7.5 Nm in conjunction with a 700 N axial load, whereas Abumi et al. applied ±8.0 Nm and a 200 N axial load. The lower bending moment will obviously result in a lower bending angle, and the higher axial load will also result in a lower bending angle because of the increased stability caused by the higher axial load.

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### Table 2. A Summary of the Axial Rotation and Lateral Bending Mean ROM (in degrees)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Axial Rotation</th>
<th>Lateral Bending</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>L2/3</td>
<td>L3/4</td>
</tr>
<tr>
<td>Intact</td>
<td>1.56 ± 0.84</td>
<td>1.62 ± 0.73*</td>
</tr>
<tr>
<td>Intact w/implant</td>
<td>1.66 ± 0.53</td>
<td>1.66 ± 1.27</td>
</tr>
<tr>
<td>UMF</td>
<td>1.86 ± 0.89</td>
<td>1.67 ± 0.91</td>
</tr>
<tr>
<td>UMF w/implant</td>
<td>1.76 ± 0.87</td>
<td>1.97 ± 1.15</td>
</tr>
<tr>
<td>UTF</td>
<td>1.93 ± 1.36</td>
<td>2.01 ± 1.24</td>
</tr>
<tr>
<td>UTF w/implant</td>
<td>1.71 ± 0.92</td>
<td>2.25 ± 1.15</td>
</tr>
<tr>
<td>BTF</td>
<td>2.06 ± 0.91</td>
<td>2.69 ± 1.80*</td>
</tr>
<tr>
<td>BTF w/implant</td>
<td>1.56 ± 0.74</td>
<td>4.29 ± 2.41</td>
</tr>
</tbody>
</table>

Note: Depicted values are mean ± standard deviation. Significant differences (P < 0.05) within a motion are denoted by common footnotes. All unilateral facetectomies were performed on the left side.
spinous processes during extension. The X STOP likely placed the implanted level in slight flexion and, therefore, did not allow as much flexion as in the intact case. The implant also limited extension between the adjacent vertebrae.

However, different results were observed regarding stability in axial rotation and lateral bending after facet surgeries were performed and the implant was placed. Placement of the implant significantly increased the ROM during lateral bending following the graded facetectomies. This increase in lateral bending ROM is likely a result of facet distraction caused by the implant, coupled with the removed facet capsule(s). Both of these components, which reduce the stability of the facet joints, allow for increased sliding of the facet joint and increased ROM during lateral bending. However, the implant had no significant effect on the ROM during axial rotation following the graded facetectomies.

As expected, the adjacent levels were unaffected by facetectomy or implant placement during axial rotation and lateral bending. The same bending moment and axial load were applied to each specimen with each treatment. Because no stabilizing structures at the adjacent levels were altered, there was no difference in the ROM during any of the motions for any of the treatments. However, the ROM of selected adjacent levels during flexion and extension were affected by the implant (Table 1). During flexion, mean L2–L3 ROM significantly increased by 0.95° following BTF and X STOP implantation. However, During extension, mean L2–L3 ROM significantly decreased following UMF and BTF; mean L4–L5 ROM also significantly decreased following implantation in the intact specimens and following UMF. The general decreases in the flexion ROM and increases in the extension ROM at the adjacent levels are likely a result of some compensatory lordosis at these levels. The explanation for the increase in lateral bending ROM is much better understood. It is likely that the X STOP not only prevents extension but also distracts the spine to some extent following implantation, as has been shown in recent biomechanical studies. This distraction, coupled with the removed facet capsule, reduces the stability of the facet joints and allows for increased sliding of the ROM during lateral bending.

One important finding of this study was identified while placing the implant in the interspinous space following and UTF or BTF. The X STOP implant is placed in the anterior margin of the interspinous space from a lateral direction. The implant is not permanently attached to the vertebrae, and anteroposterior migration is prevented by the laminae and supraspinous/interspinous ligamentous complex. During insertion, retaining at least a portion of the facet joint intact protects the exiting nerve root from potential injury during insertion. However, after completing UTF, the nerve root was no longer protected, and when BTF was performed, both exiting nerve roots were exposed as well as a portion of the thecal sac. Although there was no shift in the position of the implant during biomechanical testing, there is a possibility that during placement of the implant following UTF and BTF treatments, contact between the implant and nerve roots, and/or spinal cord could occur. Therefore, if the X STOP is used in conjunction with UTF or BTF, care must be taken not to allow the implant to enter the neural space during insertion.

This study shows that the implant decreases the ROM during flexion and extension, and does not alter the kinematics during axial rotation. However, the implant does increase the ROM during lateral bending by approximately 1° (approximately 0.5° in each direction). Although debatable, it is unlikely that changes in lateral bending are clinically significant. Provided that the facetectomy does not introduce a clinically unstable motion segment that would normally be fused, the results suggest that the implant may be used in conjunction with a graded facetectomy. Only the BTF seemed to introduce a significant increase in flexion and axial rotation ROM. Clinically, this procedure is typically combined with fusion. However, UMF and UTF are relatively stable, and the X STOP may be used in conjunction with these treatments. The X STOP should not, however, be used in conjunction with BTF because this procedure more than doubles the ROM in axial rotation. The implant does not provide any additional stability during axial rotation or
lateral bending. Finally, care must be taken during insertion when the X STOP is used in conjunction with UTF because the nerve root is exposed.

■ Conclusion

Testing the intact specimens revealed that the implant decreased the ROM during flexion and extension but had no stabilizing effects on axial rotation or lateral bending. The implant actually caused a slight, statistically significant increase in ROM during lateral bending after graded facetectomy. When implanted into intact specimens, the implant does significantly decrease the ROM in flexion and extension. However, these results indicate that the implant does not stabilize unstable motion segments or restore the ATLTS in axial rotation or lateral bending, and should not be used as a stabilizing device for congenital or iatrogenic instabilities. Furthermore, placing the implant in conjunction with a UTF or BTF procedure runs the risk of injuring the neural elements during insertion. In patients with severe stenosis at multiple levels who may not be candidates for the X STOP as a stand-alone device, the implant may increase the effectiveness as an adjunct when performing decompresive procedures such as UMF or UTF for subarticular and foraminal stenosis, respectively. The implant may decompress the neural structures, while allowing a minimum amount of tissue to be resected, making the procedure less invasive.

■ Key Points

- A biomechanical study investigated the influence of an interspinous spacer implant on the ROM of the lumbar spine following graded facetectomy.
- BTF caused a significant increase in ROM during flexion and axial rotation.
- Following a series of graded facetectomies, the interspinous implant tended to decrease the ROM in flexion and extension, had no effect on axial rotation, and increased the ROM in lateral bending.

Acknowledgments

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