

A Biomechanical Evaluation of an Interspinous Device (coflex™ Device) used to Stabilize the Lumbar Spine

Kai-Jow Tsai, MD ^{1,2}, Hideki Murakami, MD, PhD ^{1,3}, Gary L. Lowery, MD, PhD ⁴, William C. Hutton, DSc ¹

■ Abstract

A biomechanical study of a posterior interspinous stabilization spinal implant (coflex™ device) was carried out using eight human lumbar L4/L5 motion segments. Each motion segment was mounted in a materials testing machine and tested according to a loading sequence consisting of compression, flexion/extension, lateral bending, and axial rotation. Each motion segment was tested according to the loading sequence at five conditions: 1) intact; 2) partial destabilization (resection of all ligaments, ligamentum flavum, facet capsule, and bilateral resection of inferior facets); 3) stabilization with coflex™ device; 4) complete destabilization with total laminectomy and; 5) stabilization with pedicle screws and rods.

The results show that: 1) the motion segment after destabilization and insertion of the coflex™ device does not allow significantly more or less motion than the intact specimen in either flexion/extension or axial rotation; 2) the motion segment after coflex™ implant insertion (condition 3) allows significantly less motion in flexion/extension as compared to when the specimen was partially destabilized (condition 2) or completely destabilized (condition 4); 3) the motion segment after coflex™ implant insertion (condition 3) allows significantly less motion in axial rotation as compared to when the specimen was partially destabilized (condition 2) or completely destabilized (condition 4). Thus the coflex™ device offers non-rigid fixation and can return a partially destabilized specimen back to the intact condition in terms of motion in flexion/extension and axial rotation.

Key words: biomechanics, lumbar spine, spinal stenosis, coflex™ device, Interspinous stabilization device, pedicle screw, laminectomy.

■ Introduction

Degenerative lumbar spinal stenosis (DLSS) is a disabling disease common in the elderly, a population that has been estimated to double by 2025¹. In 1954, Verbiest² first described the symptoms of narrowing of the lumbar vertebral canal. The symptoms include bilateral radicular pain and intermittent neurogenic claudication, sensation disturbance and loss of strength in the legs. Many patients suffering from DLSS would benefit from lumbar decompressive surgery, rather than conservative management, but sometimes medical co-morbidity prohibits major surgery³.

With the introduction of pedicle screws in the 1980s and cages in the 1990s, lumbar fusion with instrumentation became a common procedure after laminectomy and decompression for DLSS⁴. The advantages of instrumentation include restoring lordosis, providing internal stability, and theoretically, facilitating fusion. Despite the use of circumferential fusion, the clinical "excellent results" are in the region of 30%⁵. However, the complications rate has been reported to be 33%⁶, with pseudarthrosis resulting in implant failure occurring in 7% to

10% of patients⁷. In addition, rigid posterior instrumentation can lead to facet arthropathy and adjacent level degeneration in the long-term⁸. Therefore, it seems clear that there is some need for less invasive strategies that provide a balance between safety and effectiveness^{9,10}.

The dynamic interspinous stabilization device (coflex™ device) was designed by Samani in 1994 to provide non-rigid fixation, and to treat different conditions affecting the degenerative lumbar spine. Using the device allows decompression that is limited to partial laminectomy and facetectomy, foraminotomy, and resection of the ligamentum flavum, supraspinous and interspinous ligaments. Preservation of the spinous processes and a major portion of the lamina provide protection to the dura. The presence of the coflex™ device helps to reduce buckling of the soft tissue, narrowing of the spinal canal and loading of the degenerated disc¹¹.

Biomechanical experiments using human cadaveric lumbar L4/L5 motion segments were carried out to test the facility of the coflex™ device. Since the device is positioned between the spinous processes, it was anticipated that it would allow less motion in flexion/extension and axial rotation, and be non-restrictive in lateral bending and to a lesser degree in compression. The goal of the experiment was to measure the ability of the coflex™ device to allow limited motion after a motion segment is destabilized.

■ Materials and Methods

Eight fresh human cadaveric lumbar spines were obtained (mean age: 73 years old, range 59-84 years, 6 female, 2 male). The specimens were examined grossly and radiographically to rule out any malignancy or fractures that might interfere with the results. The spines were separated into L4/L5 motion. Each motion segment was stripped of muscle, with care taken to preserve all ligaments, joint capsules, discs, and bone structures.

■ Biomechanical Motion Test

Each vertebral body of the L4/L5 motion segment was potted up to its midbody in a 10-cm-diameter polyvinylchloride (PVC) cup using dental cement. The specimen was mounted in a materials testing machine (MTS, Minneapolis, MN), and after a cyclic compression conditioning period (500 N ± 75 N, at 1 Hz, for 1,000 cycles) the motion segment was tested according to an eight-step loading sequence (see below). At each step, the load was applied three times and a load-deformation curve was obtained each time. The three load-deformation curves were always identical, and the first was used to calculate stiffness when appropriate (see below). A digital goniometer (accuracy of 0.1° and 1-sec dampening; Pro Smart Level, Wedge Innovations, San Jose, CA) was used to measure angular deformations in flexion/extension and lateral bending (see below). An on-board rotational transducer, incorporated into the testing machine, was used to make measurements in axial rotation (see below).

Step 1 (Establishing the center of rotation)

The center of rotation for flexion/extension and lateral bending was established in the intact motion segment using a pure compressive load of 50 N applied through a roller bearing to the top surface of the cup containing L4. The load was applied, repositioned and reapplied until no angular rotation in the coronal or sagittal planes could be detected using the digital goniometer. This was done to ensure that no

¹ Atlanta VA Medical Center and the Emory Spine Center, Department of Orthopaedic Surgery, Emory University School of Medicine, Atlanta, GA, USA.

² Department of Orthopaedic Surgery, Cathay General Hospital, Taipei, Taiwan.

³ Department of Orthopaedic Surgery, Iwate Medical University School of Medicine, Morioka, Japan.

⁴ Paradigm Spine, LLC, New York, NY, USA

bending of the specimen took place during pure compression at step 2. This spot on the cup was designated the center of rotation and was clearly marked as the reference point for all the remaining steps (steps 2 to 8).

Step 2 (Compression)

The specimen was then loaded at the center of rotation in pure compression at a displacement rate of 0.25 cm/min. Load was applied up to a maximum of 900 N. A load-deformation curve was obtained.

Step 3 (Flexion)

A 600 N load was then applied 2 cm anterior to the center of rotation, producing a bending moment of 12 Nm (i.e. 2 cm x 600 N = 12 Nm) in flexion. The extent of flexion at this bending moment was measured three times using the digital goniometer; the three measurements were all roughly the same. Load-deformation curves were also obtained.

Step 4 (Extension)

A 600 N load was then applied 2 cm posterior to the center of rotation, producing a bending moment of 12 Nm. The extent of extension at this bending moment was measured three times using the digital goniometer. Load-deformation curves were also obtained.

Step 5 (Right lateral bending)

The 600 N load was applied 2 cm to the right of the center of rotation. The extent of lateral bending was measured three times using the digital goniometer. Load-deformation curves were also obtained.

Step 6 (Left lateral bending)

The 600 N load was applied 2 cm to the left of the center of rotation. The extent of lateral bending was measured three times using the digital goniometer. Load-deformation curves were also obtained.

Step 7 (Right axial torsion)

To apply axial torsion, the specimen was first compressed to 600 N and then an axial torque was applied in a clockwise motion (about the center of rotation), to a maximum of 9 Nm. Three torque-angular deformation curves were obtained. The extent of angular rotation was measured three times using the on-board rotational transducers.

Step 8 (Left axial torsion)

The test to 9 Nm was repeated as in step 7 in a counterclockwise direction. Torque-angular curves were obtained and the extent of angular rotation was measured using the on-board rotational transducers.

■ Testing Sequence

Condition 1. Steps 1 to 8 as described above were carried out on the intact specimen.

Condition 2. The specimen was destabilized by cutting the supraspinous and interspinous ligaments, the ligamentum flavum, the facet capsules, and 50% of the inferior bony facet bilaterally. The specimen was then retested according to steps 1 to 8 above.

Condition 3. The coflex™ interspinous device was inserted (see Figure 1). The wings were opened slightly at the midportion. The laminar surfaces were contoured and the device was deeply seated using a special impaction device. The wings were then maximally crimped (using pliers) onto the spinous processes while the lordosis was preserved. The specimen was then retested according to steps 1 to 8 above.

Condition 4. The coflex™ device was removed and a complete laminectomy was carried out. The specimen was then retested according to steps 1 to 8 above.



Figure 1: coflex™ device inserted between the spinous processes after partial destabilization of the L4/L5 lumbar motion segment.

Condition 5. Pedicle screws were then inserted into L4 and L5 and rods were applied to secure the motion segment (see Figure 2). The specimen was then retested according to steps 1 to 8 above.

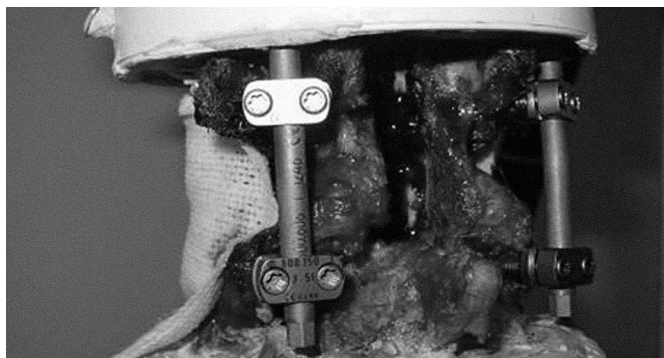


Figure 2: Pedicle screw and rod insertion after complete destabilization of the L4/L5 motion segment.

■ Statistical Analysis:

For each measurement type including compression, flexion/extension, lateral bending and axial rotation, a Friedman test was used to test whether there were any statistically significant difference between each of the five conditions (i.e. intact, destabilized, coflex™ device, laminectomy and pedicle screw). This was followed by Wilcoxon Signed Rank tests for pairwise comparisons when the overall Friedman test was statistically significant at the 0.05 levels. Multiple comparisons are based on Fisher's protected LSD method.

■ Results

The measurements made using the goniometer (i.e. those in flexion/extension and lateral bending) and the on-board transducers (i.e. those in axial rotation) were used to make our comparisons discussed below. The load/deformation and torque/angular deformation curves obtained in these planes were not used, as the direct angle measurements were more useful. For compression, we used the measurements of stiffness, derived from the slope of the load/deformation curves obtained in compression (there is no angular motion in compression).

The coflex™ device is inserted between the spinous processes and in this position it can best resist motion in flexion/extension and axial rotation, thus the more relevant measurements (to test the facility of the coflex™ device) are those in flexion/extension and axial rotation. The findings in lateral bending and compression to a lesser degree are not relevant as to the facility of the coflex™ device.

The results shown in Figures 3 and 4 have been normalized against the equivalent result for the intact specimen (condition 1). In flexion/extension (Figure 3) the partially destabilized specimen with the coflex™ device inserted (condition 2) allows: 1) less angular motion than the intact specimen (condition 1) (not significant); 2) less angular motion as compared to the specimen after partial destabilization

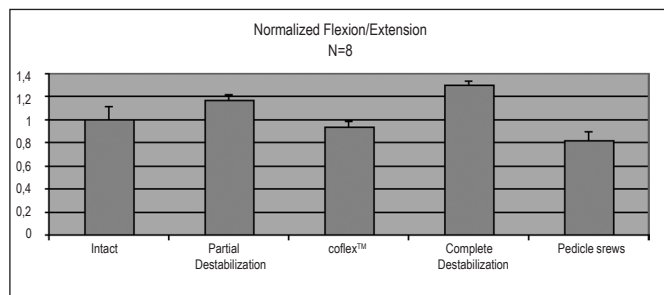


Figure 3: Normalized flexion/extension values in the 5 test conditions of the L4/L5 motion segments.

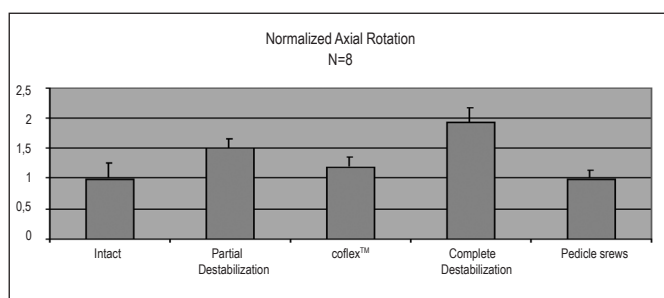


Figure 4: Normalized axial rotation values in the 5 test conditions of the L4/L5 motion segments.

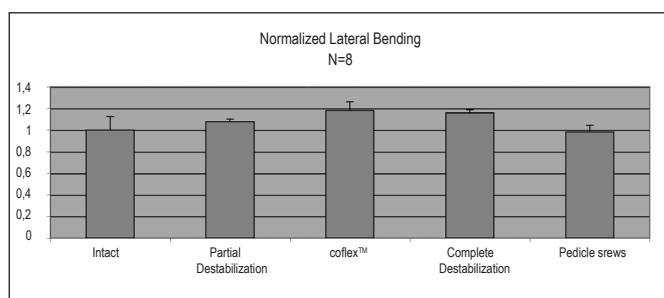


Figure 5: Normalized lateral bending values in the 5 test conditions of the L4/L5 motion segments.

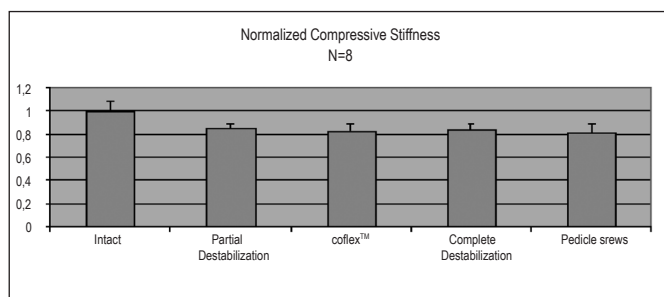


Figure 6: Normalized compressive stiffness values in the 5 test conditions of the L4/L5 motion segments.

(condition 2) ($P = 0.035$); 3) less angular motion than the specimen undergoing a complete destabilization (condition 4) ($P = 0.017$); and 4) slightly more angular motion than the specimen stabilized with pedicle screws and rods (condition 5) (not significant). None of the other pairwise comparisons for flexion/extension were relevant or statistically significant.

In axial rotation (Figure 4) the specimen with the coflex™ device inserted allows: 1) more axial rotation than the intact specimen (not significant); 2) less axial rotation than the specimen after partial destabilization ($P = 0.03$); 3) less axial rotation than the specimen after complete destabilization ($P = 0.012$); and 4) more axial rotation than the specimen stabilized with pedicle screws and rods (not significant). None of the other pairwise comparisons for axial rotation were relevant or statistically significant.

In lateral bending, the results are somewhat scattered and essentially irrelevant to a discussion on the effectiveness of the coflex™ device (Figure 5). Suffice to say, that there is no significant difference in lateral bending as measured for the intact specimen compared to that measured for the specimen with the coflex™ device inserted.

In compression, the stiffness value measured for the intact specimen is greater than the stiffness values measured for the specimens in the other four conditions (Figure 6), and there are no significant differences in the stiffness values between each of these four other conditions.

It should be noted that in the Figures showing normalized angular motion (e.g. Figures 3, 4, and 5), the greater the value shown, the greater the angular motion. For compression, however, (Figure 6), the values shown are normalized stiffness and are such, that the greater the value shown, the greater the stiffness (i.e. resistance to motion). In other words, stiffness is the converse of motion (i.e. the higher the stiffness the less the motion).

Discussion

Biomechanically, the coflex™ device aids in controlling motions in two specific planes: 1) sagittal rotation (or flexion/extension); and 2) axial rotation. Therefore, implantation of the coflex™ device after partial destabilization (resection of all posterior ligaments, the ligamentum flavum, facet capsule, and bilateral inferior facetectomy) leads to spinal restabilization in flexion/extension and axial rotation.

The results for flexion/extension and axial rotation suggest that the coflex™ device would be clinically useful in these two planes. It allows motion that is significantly less than the motion found in the partially destabilized and completely destabilized specimens and this motion is not significantly different from that shown by the intact specimens. The results in both flexion/extension and axial rotation illustrate that the device offers non-rigid fixation and has the ability to restore the destabilized specimen back to its normal motion characteristics in these two planes. Therefore clinically, one would envision a "controlled, but restricted motion" after stabilization with the coflex™ device.

The results for lateral bending are shown in Figure 5. The results are somewhat scattered and not particularly relevant since the coflex™ device spans the midline. It is positioned between the spinous processes and should not influence lateral bending.

For compression, load/deformation curves were used to measure stiffness, or resistance to compression. It is interesting to note that the compressive stiffness of the intact specimen is greater than the stiffness shown by the specimens in the other four loading modes (Figure 6). Clearly the surgical interventions applied to the specimens rendered them "softer" or more deformable, even when braced by the coflex™ device or stabilized by pedicle screws and rods.

One surprising result to emerge from the experiments (although not really relevant to a study on the coflex™ device) is the extent of motion in flexion/extension, axial rotation and lateral bending, as well as the lack of rigidity in compression shown by the specimens after the pedicle screws are inserted. One might have predicted that the pedicle screws would have made the specimens more motionless. However, in every case, the results for the specimens after pedicle screw insertion are not significantly different than the results for the intact specimens. One explanation would be that the complete laminectomy brought such instability that even the pedicle screws (with their attached rods) could not immobilize the specimens to any great degree, but could restore the completely destabilized specimen to an equivalent normal state.

In the lumbar spine, the greatest range of motion is in flexion/extension as compared to the motions in the other planes (flexion plus extension range approximately 15 degrees, unidirectional axial rotation approximately 2 degrees, and unilateral bending about 6 degrees¹²). The foraminal area, dural sac area, epidural pressure, and intradiscal pressure are influenced by the position of the spine in flexion and extension. Inufusa et al. presented data showing spinal canal changes of

11% increase in flexion and 11% decrease in extension¹³. The foraminal cross-sectional area can change depending upon on the position of the lumbar spine. Schmid et al. utilized an open-configuration MRI system to measure the change of foraminal area between flexion and extension in the upright position. They measured a 19.2% increase from upright to upright flexion, and a 23.2% decrease from upright to upright extension¹⁴. These results suggest that if normal flexion/extension motion can be recovered after a destabilizing procedure, then the patient will derive some benefit.

At present, there are some interspinous devices under clinical and biomechanical investigations^{3,15,16}. Zucherman¹⁶ et al. reported a prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X-STOP interspinous implant. This is essentially a distraction device providing indirect decompression. The device is inserted under local anesthesia. Their one-year results demonstrated a 59% satisfaction rate compared to 12% in non-operative patients. Using quality of life outcomes in neurogenic intermittent claudication patients, the X-STOP implant demonstrated immediate postoperative improvement and lasted for at least two years¹⁷.

The study presented here using the coflex™ device provides a comparison between two surgical options. The partially destabilized specimen (Condition 2) represents the model of microsurgical decompression (partial laminectomy combined with partial facetectomy) to decrease the pressure on the nerve root. The limited removal of offending tissue and bone in the distal two-thirds of upper lamina and proximal one third of lower lamina, provides limited damage and less chance of instability¹⁸. Postacchini¹⁹ et al. reported a study that compared multiple laminotomy with total laminectomy. They found the laminotomy is beneficial for preservation of vertebral stability; none of their 26 patients showed vertebral hypermobility after laminotomy, whereas three of 32 patients had resultant scoliosis and spondylosis after total laminectomy. A total laminectomy completely destabilizes the motion segment, which may then require pedicle screws with rods in a clinical setting. Therefore, if possible, it would seem reasonable to use the coflex™ interspinous device after microsurgical decompression rather than perform a total laminectomy with pedicle screw and rod fixation when spinal stabilization is deemed necessary for immediate or future instability.

■ Conclusion

The coflex™ interspinous device offers non-rigid fixation and can return a destabilized specimen back to the intact condition in terms of motion in flexion/extension and axial rotation. A partial destabilization with an interspinous coflex™ device inserted is a biomechanical alternative to a total laminectomy with pedicle screw and rod fixation.

References

- Singer BH, Manton KG. The effects of health changes on projections of health service needs for the elderly population of the United States. *Proc Natl Acad Sci U S A* 1998; 15618-22.
- Verbiest H. A radicular syndrome from developmental narrowing of the lumbar vertebral canal. *J Bone Joint Surg Br*. 1954; 230-7.
- Swanson KE, Lindsey DP, Hsu KY, et al. The effects of an interspinous implant on intervertebral disc pressures. *Spine* 2003; 26-32.
- Gibson JN, Grant IC, Waddell G. The Cochrane review of surgery for lumbar disc prolapse and degenerative lumbar spondylosis. *Spine* 1999; 1820-32.
- Mulholland RC, Sengupta DK. Rationale, principles and experimental evaluation of the concept of soft stabilization. *Eur Spine J* 2002; S198-205.
- Mayer HM, Korge A. Non-fusion technology in degenerative lumbar spinal disorders: facts, questions, challenges. *Eur Spine J* 2002; S85-91.
- Korovessis P, Papazisis Z, Koureas G, et al. semirigid versus dynamic instrumentation for degenerative lumbar spinal stenosis: a correlative radiological and clinical analysis of short-term results. *Spine* 2004; 735-42.
- Kumar MN, Baklanov A, Chopin D. Correlation between sagittal plane changes and adjacent segment degeneration following lumbar spine fusion. *Eur Spine J* 2001; 314-9.
- Gunzburg R, Szpalski M. The conservative surgical treatment of lumbar spinal stenosis in the elderly. *Eur Spine J* 2003; S176-80.
- Lee J, Hida K, Seki T, et al. An interspinous process distractor (X STOP) for lumbar spinal stenosis in elderly patients: preliminary experiences in 10 consecutive cases. *J Spinal Disord Tech* 2004; 72-7.
- Minns RJ, Walsh WK. Preliminary design and experimental studies of a novel soft implant for correcting sagittal plane instability in the lumbar spine. *Spine* 1997; 1819-25.
- White AA, 3rd, Panjabi MM. Kinematics of the spine. In: White AA, 3rd, Panjabi MM, eds. *Clinical Biomechanics of the Spine*, Second ed. Philadelphia: J.B. Lippincott, 1990:111.
- Inufusa A, An HS, Lim TH, et al. Anatomic changes of the spinal canal and intervertebral foramen associated with flexion-extension movement. *Spine* 1996; 2412-20.
- Schmid MR, Stucki G, Duetz S, et al. Changes in cross-sectional measurements of the spinal canal and intervertebral foramina as a function of body position: in vivo studies on an open-configuration MR system. *AJR Am J Roentgenol* 1999; 1095-102.
- Senegas J. Mechanical supplementation by non-rigid fixation in degenerative intervertebral lumbar segments: the Wallis system. *Eur Spine J* 2002; S164-9.
- Zucherman JF, Hsu KY, Hartjen CA, et al. A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X STOP interspinous implant: 1-year results. *Eur Spine J* 2004; 22-31.
- Skidmore G, Hsu KY, Zucherman JF, et al. The Quality of life of neurogenic intermittent claudication patients treated with interspinous process decompression. *International Society for the Study of the Lumbar Spine, 32nd Annual Meeting Abstracts*. 2005; 365.
- Rao RD, Wang M, Singhal P, et al. Intradiscal pressure and kinematic behavior of lumbar spine after bilateral laminotomy and laminectomy. *Spine J* 2002; 320-6.
- Postacchini F, Cinotti G, Perugia D, et al. The surgical treatment of central lumbar stenosis. Multiple laminotomy compared with total laminectomy. *J Bone Joint Surg Br* 1993; 386-92.

Please address all correspondence to:

Dr. William C. Hutton
The Emory Spine Center
59 Executive Park South
Atlanta, GA, 30329
Tel: 404-778-7156
Fax: 404-778-7117

Email: William_Hutton@emoryhealthcare.org