A Biomechanical Cadaveric Study of a Modified U-shaped Interspinous Distraction Device

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Study Design: An experimental study.

Objective: To analyze the effects of a modified U-shape interspinous distraction device (IDD) on the stability of a destabilized lumbar spine model.

Summary of Background Data: The use of IDD for treatment of lumbar spine pathology remains a subject of debate. A modified design of an IDD consisted of a titanium (Ti) U-shape dynamic stabilizer and a Ti tensioning wire loop was biomechanically tested.

Materials and Methods: Six sets of cadaveric lumbar vertebrae levels 1–5 (L1–L5) were subjected to loads in flexion, extension, and lateral bending in the 4 following sequences: intact specimen, unilateral facetectomy and discectomy at L3–L4, insertion of the modified U-shape IDD at L3–L4, and pedicle screw fixation at L3–L4. The range of motion (ROM) of L3–L4 following modified U-shape IDD insertion was compared with that of the intact specimen. The ROM of the adjacent vertebrae (L2–L3 and L4–L5) following modified U-shape IDD insertion was compared with that after pedicle screw fixation. Statistical analysis was performed using the Wilcoxon signed-rank test.

Results: The modified U-shape IDD decreased the ROM of a destabilized L3–L4 in all testing load ($P<0.05$). The stability of L3–L4 following the modified U-shape IDD insertion was restored to that of the intact specimen ($P>0.05$). The ROM at adjacent vertebrae after the modified U-shape IDD placement was similar to the ROM obtained after pedicle screw fixation at L3–L4.

Conclusions: The modified version of a U-shape IDD is effective in stabilizing an unstable segment of the lumbar spine. The device does not create deleterious effects on the adjacent vertebrae.

Key Words: interspinous distraction device, modified U-shape device, titanium wire, tension wire loop, posterior dynamic stabilizing device, lumbar spine instability, biomechanical cadaveric study, adjacent segment instability

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Arthrodesis remains the gold standard for the treatment of many lumbar spinal pathologies[1,2]; however, the procedure delivers variable outcomes and may cause premature degeneration of adjacent vertebrae.[3,4] To avoid the long-term consequences of arthrodesis[2] including a reoperation,[5] interspinous distraction devices (IDD) have been introduced as an alternative to relieve neurological symptoms secondary to lumbar spinal deformities and to preserve the range of motion (ROM) of the lumbar spine. Theoretically, IDD should limit multiple planes of motion at the level of insertion and does not cause an excessive motion of the adjacent lumbar vertebrae to ensure a favorable outcome. IDD have evolved into various designs and are made of different materials. They are usually placed between the 2 consecutive spinous processes in a free-floating manner and function as either a static or dynamic spacer. The effect of IDD is predominantly on the extension of lumbar spines with little effect on flexion, axial rotation, and lateral bending.[1,6–9] Various materials, for example, Dacron ribbon, polyethylene ligament, and rivet, have been added to some of the current designs[6,8,10,11] to improve their functional stability although these modifications deliver variable results on the biomechanics reports.[9,12,13] In the current experiment, a tensioning titanium (Ti) (Ti 6Al/4V), wire loop is combined to a U-shaped Ti interspinous dynamic stabilizer (modified U-shaped IDD) as shown in Figure 1.

The objectives of this study are to investigate the stabilizing effect of the modified U-shaped IDD on a destabilized cadaveric lumbar spine model and to compare its effect on the ROM of adjacent vertebra with that following pedicle screw fixation. We hypothesized that the modified U-shaped IDD implantation would decrease the

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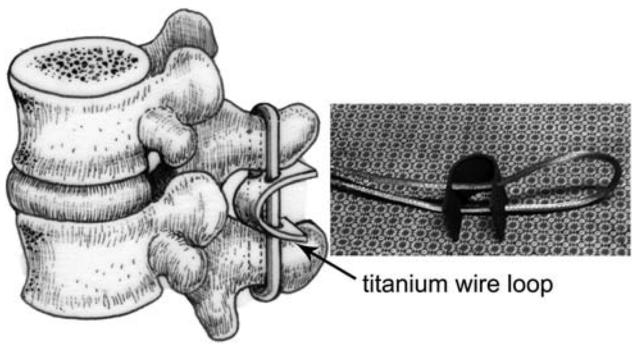

FIGURE 1. A conceptual design of the modified U-shaped interspinous distraction device. A titanium (Ti-6Al-4V) wire is incorporated to the U-shape interspinous dynamic stabilizer.

ROM of destabilized lumbar vertebrae and would not increase an abnormal motion of the adjacent vertebrae.

MATERIALS AND METHODS

Specimens and Experimental Setup

Six sets of human lumbar vertebrae at levels 1–5 (L1–L5) were retrieved from 3 male and 3 female cadavers. The mean donor age was 52 years (range, 48–58 y). The donors did not have a prior history or a radiographic sign of any metabolic bone diseases, metastatic diseases, or infections. The specimens were freshly harvested, sealed in double plastic bags, and stored at $-25^{\circ}C$ until further use. On the testing day, the specimens were thawed, dissected, and tested at the room temperature. Spinal ligaments, facet joints, intervertebral disks, and bony structures were preserved. L1 and L5 vertebra were anchored to the potting fixture using bone cement and screws which were attached to the upper and lower loading frames of the biomechanics testing apparatus (Intelligent fatigue test machine, Biomechanical Design and Manufacturing Laboratory, Bangkok, Thailand). Marker plates were fixed to the bodies of L2–L5 for ROM measurement using a digital goniometer in the coronal and sagittal planes (Fig. 2A).

Biomechanics Testing

The specimens were first preconditioned with a 300 N of the axial compression force for 30 minutes.[14,15] Subsequently, the specimens were tested in the 4 sequential steps: (1) intact; (2) L3–L4 instability; (3) with the modified U-shape IDD insertion at L3–L4; and (4) with pedicle screw fixation at L3–L4. In each step, the specimens were subjected to an axial compression force with 10-degree displacement controlled by a positioning frame at a rate of 50 Ns until 700 N was reached and the load was maintained for 5 seconds before ROM measurement was done (Fig. 2B). Mode of loading direction comprised flexion (10 degrees), extension (10 degrees), and right lateral bending (10 degrees) to simulate the lumbar spine movement previously demonstrated.[16,17]

After testing the intact specimens, a destabilization procedure was performed to test the ROM under step 2. The destabilization procedure included a nucleus pulposus removal without damaging the annulus and endplates, and right unilateral facetectomy between L3 and L4 vertebrae. Subsequently, the modified U-shaped IDD was manually inserted following the removal of the supraspinous ligament between L3 and L4 vertebrae. A Ti wire loop was passed proximally to the L3 and distally to the L4 spinous processes without damaging supraspinous ligaments of the adjacent vertebrae. The wire loop was subsequently fastened to the U-shaped Ti interspinous dynamic stabilizer with a tensioning device at 100 N[18] to assemble the modified U-shaped IDD (Fig. 3A). Then, the step 3 testing was performed. Finally, the modified U-shaped IDD was removed and pedicle screws and rods (MEGA spine system; BK Meditech, Republic of Korea) were inserted at the L3–L4 vertebrae (Fig. 3B) followed by the step 4 testing.

Statistical Analysis

Ranges of flexion, extension, right lateral bending, and flexion-extension at L3–L4 were compared among the first 3 steps of the experiment. In the final step, the ROM of the adjacent vertebrae (L2–L3 and L4–L5) following the modified U-shaped IDD insertion was compared with that following pedicle screw fixation. The Wilcoxon signed-rank test was performed using the

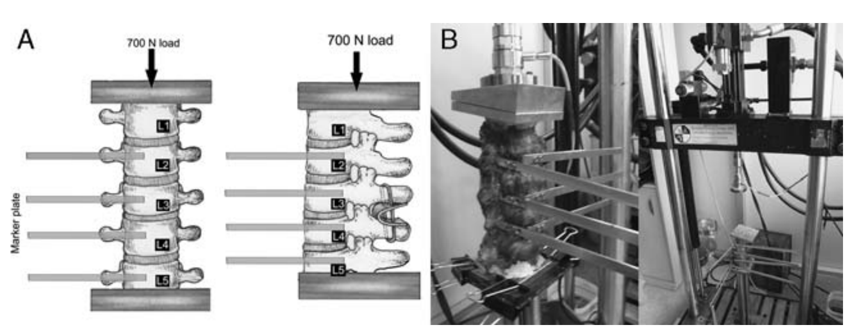

FIGURE 2. A, A frontal and lateral drawing of the conceptual design of the biomechanics test showing a marker plate attached to the vertebrae. B, A cadaveric lumbar spine was mounted on the biomechanics testing machine with a positioning frame on the most cephalad vertebral body and the loading force was axially loaded.

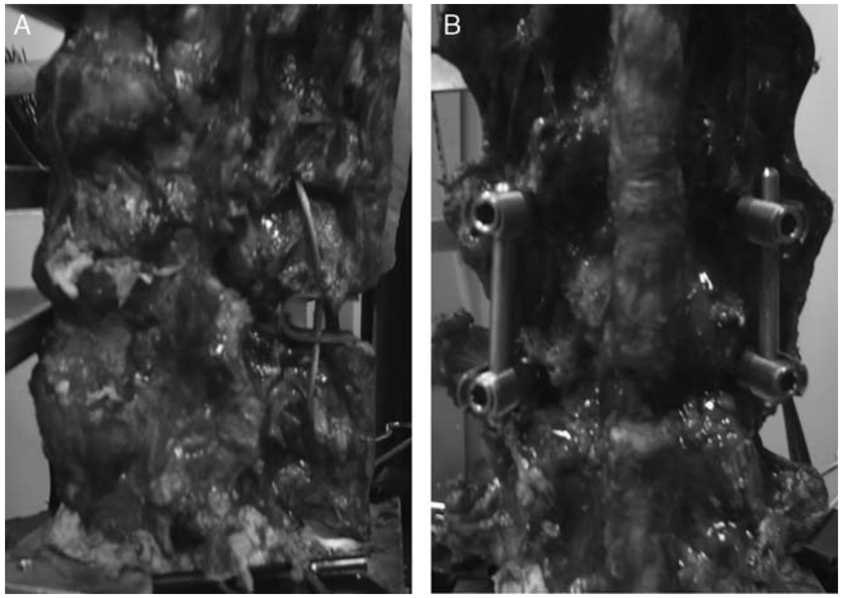

FIGURE 3. A, A modified U-shape interspinous distraction device was inserted at L3–L4. B, Pedicle screw fixation was performed at L3–L4 after the modified U-shaped interspinous distraction device was removed.

Statistical Package for Social Sciences program version 11.5 (SPSS Inc., Chicago, IL). *P* values of <0.05 were considered statistically significant.

RESULTS

The results of ROM of the 4 steps at L2–L3, L3–L4, and L4–L5 vertebrae were summarized in Figures 4 to 6, respectively. After the completion of the destabilization procedure, a model of L3–L4 instability was successfully created as evidenced by a significant increase of the ROM in every loading direction at the L3–L4 vertebrae when compared with the ROM of the intact specimens ($P<0.05$). The alteration of the ROM of L2–L3 and L4–L5 vertebrae was also demonstrated.

The Effects of the Modified U-shaped IDD on L3–L4 Stability

After the modified U-shaped IDD was implanted at the L3–L4 vertebrae, a significant reduction in the ROM was observed in every testing load when compared with the ROM measured in L3–L4 destabilized model ($P<0.05$). The modified U-shaped IDD restored the stability of L3–L4 to the level of the intact specimen in every loading direction ($P>0.05$).

The Effects of the Modified U-shaped IDD on Adjacent Spinal Segments

Following the modified U-shaped IDD insertion, the ROM of both L2–L3 and L4–L5 was comparable with that of the intact specimen. The ROM of L2–L3 had a trend toward being wider than that of L4–L5. Although the ROM of L2–L3 and L4–L5 was increased after the pedicle screw fixation when compared with that following the modified U-shape IDD insertion in all loading directions except for the right lateral bending load of L4–L5, the difference of the ROM only reached statistical significance in the flexion and flexion-extension loads of L2–L3 ($P = 0.03$).

DISCUSSION

Lumbar intervertebral disk degeneration is a pathologic process that often leads to instability and spinal canal stenosis.[19] The surgical procedures on the lumbar vertebrae which could improve segmental stability with limited deleterious effects on the mechanics of the adjacent segments would be ideal. According to Whitesides' viewpoint, the interspinous process device is a reemerging idea from the 1950s.[20] IDD, requiring a minimally invasive procedure to insert, has, again, become an attractive option as the implant provides adequate stabilization of the respective pathologic vertebral segment while allowing adjacent segments to maintain their physiological range of movement.[1,21]

In this study, a cadaveric lumbar spine model with L3–L4 instability was induced and the mechanical effect provided by the modified U-shape IDD was appraised. We confirmed the finding of Abumi et al[22] that a procedure involving a unilateral facetectomy and discectomy resulted in an increased motion of the respective spinal segment in all loading directions when compared with that of the intact specimen. In this L3–L4 instability model, the changes of the ROM of L4–L5 were more pronounce than those of L2–L3. The discrepancy in the changes of the ROM between the 2 adjacent spinal segments can be explained by the different length of the moment arms. When a constant axial loading was applied to the model, the moment arm of the caudad segment was proportionally longer than that of the cephalad segment.

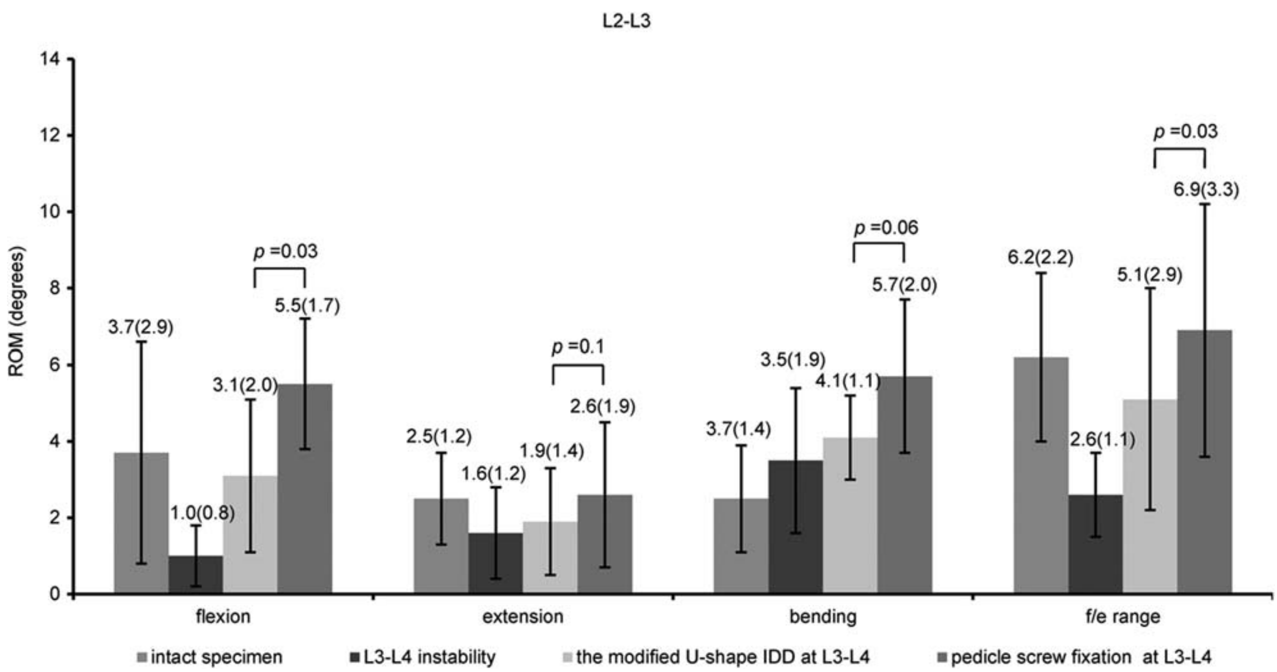

FIGURE 4. Range of motion following each testing sequence at L2–L3. Data were given as mean (SD). IDD indicates interspinous distraction device; ROM, range of motion.

The modified U-shape IDD is a prototype which combines a tensioning Ti wire loop with a U-shape posterior dynamic stabilizer. The biomechanic properties of this modified design were confirmed in vitro that the system can provide sufficient stability.[18,23] After the modified U-shape IDD was implanted, ranges of flexion, extension, and right lateral bending at L3–L4 were significantly improved compared with the ROM of L3–L4 instability model. Sagittal plane ROM at the instrumented vertebrae will be restrained by the Ti wire

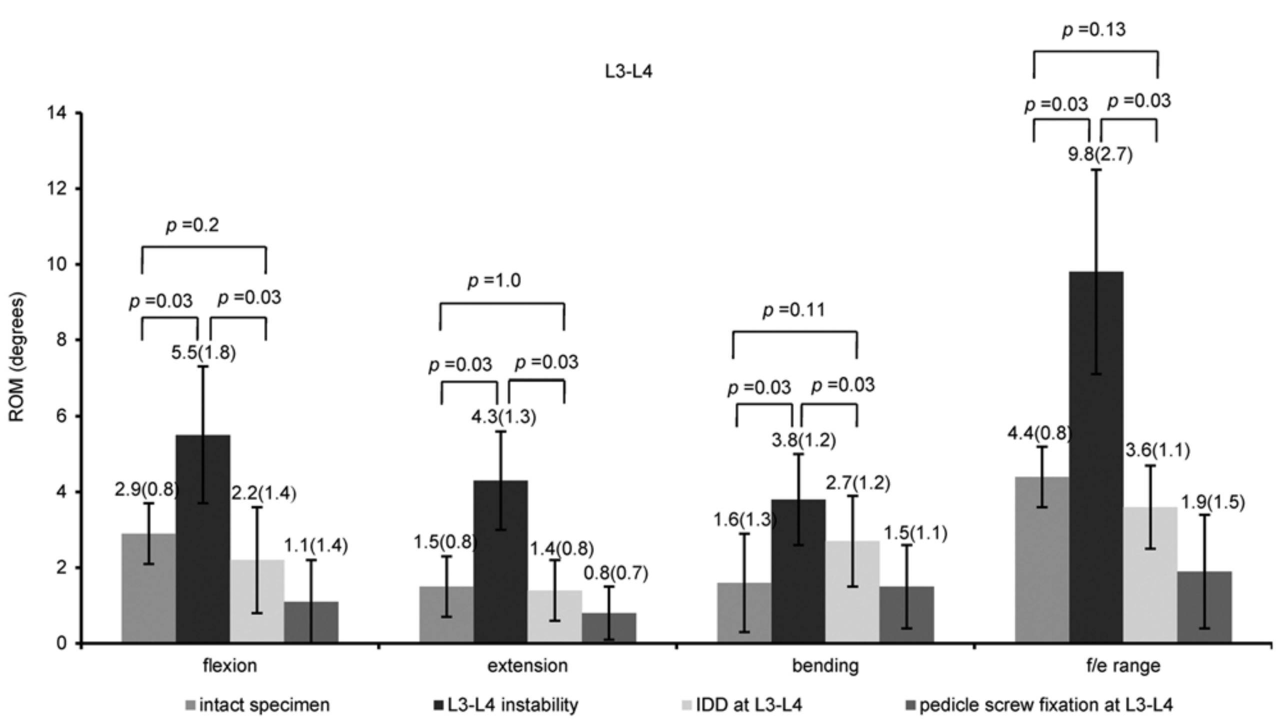

FIGURE 5. Range of motion following each testing sequence at L3–L4. Data were given as mean (SD). IDD indicates interspinous distraction device; ROM, range of motion.

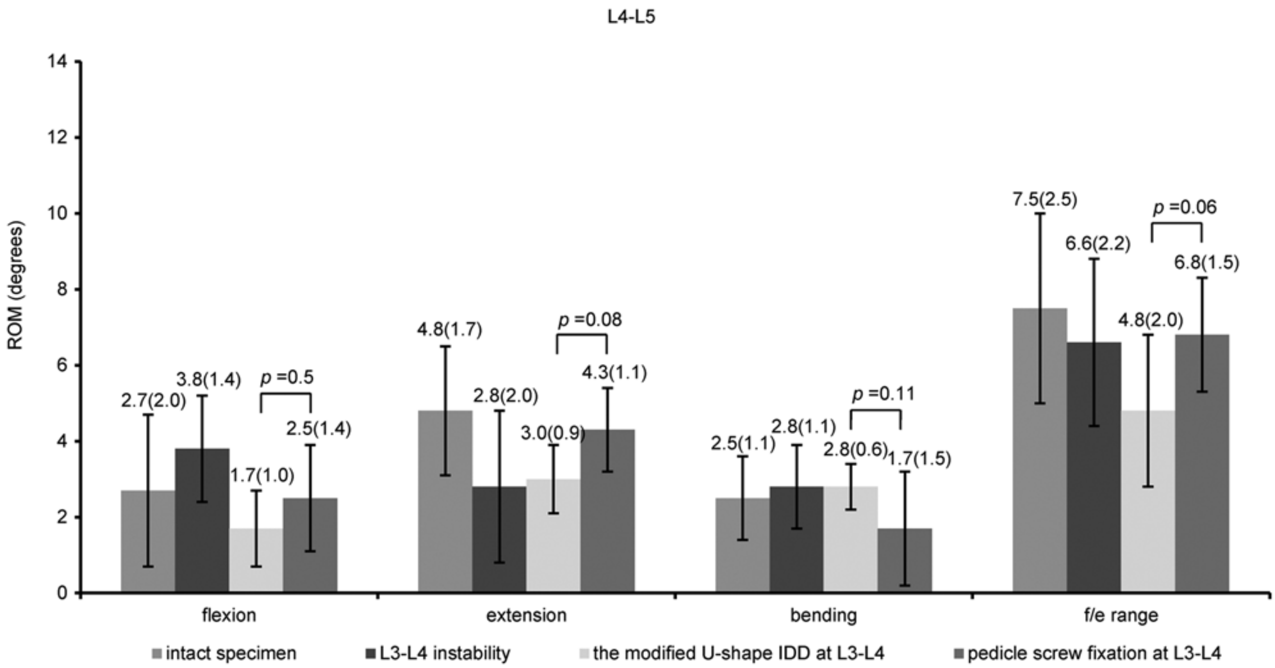

FIGURE 6. Range of motion following each testing sequence at L4–L5. Data were given as mean (SD). IDD indicates interspinous distraction device; ROM, range of motion.

which loops around supra-adjacent and subadjacent spinous processes, whereas a U-shape interspinous dynamic stabilizer should maintain the ROM in other planes. The mean flexion ROM of L3–L4 after the modified U-shape IDD being inserted was less than that of L2–L3 when the model was tested in the flexion mode. The device also limits the load transferred onto L4–L5 which resulted in a less flexion ROM at L4–L5 vertebrae when compared with that of L3–L4 vertebrae. The effect of the modified U-shape IDD on the extension mode is not as obvious as this is the function of the U-shape interspinous dynamic stabilizer which, by design, is more pliable than the Ti wire loop is. However, our results showed a higher extension ROM at L2–L3 and L4–L5 than that of L3–L4 following the modified U-shape IDD insertion. The U-shape interspinous dynamic stabilizer thus limits lumbar spine extension. The most important finding is that the proposed device restores the stability of the L3–L4 vertebrae to the level of the intact specimen. This is a supporting evidence that the modified U-shape IDD is designed to achieve the appropriate mechanical properties and does not overrigidly stabilize the respective vertebral segment. A principal design of many available implants is a free-floating apparatus that limits lumbar spine extension, maintains the area and the width between 2 lumbar vertebrae, decreases intradiscal pressure, and reduces the load transmitted via facet joints.[7,15,24] A variety of material is used including titanium, polyetheretherketone, silicone, and ceramic.[25,26] A previous study has confirmed that currently available implants without a restraining element fail to stabilize a cadaveric model in the flexion and lateral bending loads.[13] Tsai et al[9] showed that the Coflex (Paradigm Spine, New York, NY) reduced angular motion in a destabilized spinal model although the actual range of flexion or extension was not compared. Moreover, Kettler et al[12] reported that the ROM had a tendency to increase in flexion, axial rotation, and lateral bending planes after Coflex placement. Wilke and colleagues compared 4 currently available interspinous devices and demonstrated that every design except the Wallis (Zimmer Spine, Austin, TX) provided comparable stability in the extension plane only. The Wallis has been shown to preserve the stability in a flexion motion in the same degree as the intact specimen does.[13] This can be attributable to the function of the Dacron ligament supplemented to the interspinous blocker in the Wallis design.[8] These data support our idea to use a material that can resist a posterior tension force and maintain stability during the flexion motion of the lumbar vertebrae. We suggested that the Ti wire loop should be a vital component for a future design of the interspinous process device. Dacron-coated or polyethylene-coated silicone has been used in some commercially available system.[6,8,27,28] A rivet, functioning as a static bolt, was subsequently added to the Coflex-F (Paradigm Spine).[29] This rivet increases the stability governed by the Coflex-F when compared with the result after pedicle screw fixation. We propose that the Ti wire loop may serve as a better alternative than the Dacron or silicone as it has modulus of elasticity resembling to bone and does not act as a static restrictor like a bolt.

The modified U-shaped IDD could partially control the spine in the lateral bending load as evidenced by the smaller amount of changes of the right lateral bending ROM when compared with the other planes of movement. However, this alteration reached the statistical significance. This partial control of the lateral bending motion might be due to a limited contact between the width of the U-shape interspinous dynamic stabilizer and the posterior element of the spinal column. Compared with a currently available design, a flange extension in the Coflex is superior to a Ti wire loop attachment in this aspect.[30] Future modification of this device should aim to maintain a multiplane stability thus obviate the need to perform the conventional fusion procedure.

Adjacent segment instability and accelerated degeneration at adjacent vertebrae is a major drawback of a rigid spinal fixation and fusion procedure.[3] This study confirms that the modified U-shape IDD does not create a deviant ROM at adjacent vertebrae.[31] In this step of our experiment, L3–L4 was rigidly stabilized by pedicle screws, thus the applied load was transferred onto the cephalad (L2–L3) and the caudad (L4–L5) level. This resulted in an increased ROM in every loading direction at L2–L3 vertebrae and reached statistically significant difference on flexion motion. This abnormal motion at the cephalad level was not observed after L3–L4 was stabilized by the modified U-shape IDD. The ROM at L4–L5 vertebrae in the sagittal plane also had an increasing trend compare to the ROM obtained after the modified U-shape IDD but the statistically significant was not reached. This may be partially explained by the nature of the cadaveric experiment in which the applied load was absorbed by pedicle screw system at L3–L4, thus less than predicted force exerted on L4–L5. Previous data on the ROM at an adjacent segment showed conflicting outcomes. Lindsey et al[11] demonstrated that an interspinous implant diminished the ROM in the sagittal plane at the inserted level and did not produce an increased motion at adjacent segments which was similar to our finding. Wan et al[32] also showed that the motion at adjacent segments was not affected by the X-stop spacer (Medtronic Spine, Memphis, TN) implantation at 7-month follow-up. In contrast, Hartmann et al[10] reported an increased ROM especially at the cephalad level of the adjacent spines after interspinous device or pedicle screw placement.

Historically, this class of device was designed to create a flexion posture of the lumbar spine.[20] An indication approved by the US Food and Drugs administration is symptomatic 1- or 2-level lumbar spinal stenosis.[7,25] Other indications remain controversial due to the stability of the respective lumbar vertebrae created by the device.[1,2,8,21,28] Many experts recommend the use of this device as a mean of fixation in several clinical situations in which the stability of the lumbar segment may be of major concerns including patients with a large or recurrent discectomy, a degenerative disk disease adjacent to the fused level, and an isolated Modic type I disk lesion with chronic low back pain.[8,28] In contrast, segmental lumbar instability is considered to be a contraindication by others.[21] As our result shows that the modified U-shaped IDD restores the stability at destabilized lumbar vertebrae without disturbing the motion of adjacent segments, the indication of this modified U-shape IDD may extend to patients who suffer from the early stage of lumbar instability or disk problem and the modified U-shape IDD may delay the development of a more serious lumbar spinal pathology.[8,33] A cyclic loading test of the modified U-shape IDD is still required before a guideline for clinical use can be recommended. The clinical relevance of this modified U-shape IDD remains to be determined.

There are a few limitations to this study. First, decreasing in the bone mineral density of the vertebrae due to aging is likely to alter the modified U-shape IDD function and the data on bone mineral density of the specimens are lacking. Second, as facetectomy at L3–L4 results in rotational instability, a rotational test should be performed to add additional information to the biomechanics profile of the modified U-shape IDD. Third, due to L1–L5 lordotic alignment, the axial loading force applied in this experiment did not pass through an axis of rotation of each lumbar vertebra and this line of force continuously change by a 10-degree positioning frame relative to an axis of rotation. Loading the lumbar spine through different load paths would yield different results as previously demonstrated by Patwardhan et al.[34] Finally, the statistical power of this study may not be enough as the number of specimens was small.

Specific complications related to the interspinous device included device displacement, bone erosion, spinous process fracture, bursa formation, overdistraction, and neurological injury might also be a disadvantage.[2,21] Device malposition and displacement might be attributable to its free-floating design. We speculate that the rate of implant malposition or dislodgement would be less by including a tensioning wire loop to the modified U-shape IDD although the conclusion could not be drawn directly from this study.

In conclusion, this in vitro study demonstrates that the modified U-shaped IDD limits an excessive motion at destabilized lumbar vertebrae and restores the stability to the level of the intact specimen. This study supports the future clinical trial of this device especially in active adult patients with degenerative lumbar instability.

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REFERENCES

1. Christie SD, Song JK, Fessler RG. Dynamic interspinous process technology. *Spine (Phila Pa 1976)*. 2005;30:S73–S78.
2. Alfieri A, Gazzeri R, Prell J, et al. Role of lumbar interspinous distraction on the neural elements. *Neurosurg Rev*. 2012. Available at: http://www.springerlink.com/content/j552lr53u2070525/fulltext.html. Accessed September 25, 2012.

3. Disch AC, Schmoelz W, Matziolis G, et al. Higher risk of adjacent segment degeneration after floating fusions: long-term outcome after low lumbar spine fusions. *J Spinal Disord Tech*. 2008;21:79–85.
4. Lee CS, Hwang CJ, Lee SW, et al. Risk factors for adjacent segment disease after lumbar fusion. *Eur Spine J*. 2009;18:1637–1643.
5. Aiki H, Ohwada O, Kobayashi H, et al. Adjacent segment stenosis after lumbar fusion requiring second operation. *J Orthop Sci*. 2005;10:490–495.
6. Phillips FM, Voronov LI, Gaitanis IN, et al. Biomechanics of posterior dynamic stabilizing device (DIAM) after facetectomy and discectomy. *Spine J*. 2006;6:714–722.
7. Richards JC, Majumdar S, Lindsey DP, et al. The treatment mechanism of an interspinous process implant for lumbar neurogenic intermittent claudication. *Spine (Phila Pa 1976)*. 2005;30:744–749.
8. Senegas J. Mechanical supplementation by non-rigid fixation in degenerative intervertebral lumbar segments: the Wallis system. *Eur Spine J*. 2002;11(suppl 2):S164–S169.
9. Tsai KJ, Murakami H, Lowery GL, et al. A biomechanical evaluation of an interspinous device (Coflex) used to stabilize the lumbar spine. *J Surg Orthop Adv*. 2006;15:167–172.
10. Hartmann F, Dietz SO, Kuhn S, et al. Biomechanical comparison of an interspinous device and a rigid stabilization on lumbar adjacent segment range of motion. *Acta Chir Orthop Traumatol Cech*. 2011;78:404–409.
11. Lindsey DP, Swanson KE, Fuchs P, et al. The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine. *Spine (Phila Pa 1976)*. 2003;28:2192–2197.
12. Kettler A, Liakos L, Haegele B, et al. Are the spines of calf, pig and sheep suitable models for pre-clinical implant tests? *Eur Spine J*. 2007;16:2186–2192.
13. Wilke HJ, Drumm J, Haussler K, et al. Biomechanical effect of different lumbar interspinous implants on flexibility and intradiscal pressure. *Eur Spine J*. 2008;17:1049–1056.
14. Adams MA. Mechanical testing of the spine. An appraisal of methodology, results, and conclusions. *Spine (Phila Pa 1976)*. 1995;20:2151–2156.
15. Swanson KE, Lindsey DP, Hsu KY, et al. The effects of an interspinous implant on intervertebral disc pressures. *Spine (Phila Pa 1976)*. 2003;28:26–32.
16. Panjabi MM, Oxland TR, Yamamoto I, et al. Mechanical behavior of the human lumbar and lumbosacral spine as shown by three-dimensional load-displacement curves. *J Bone Joint Surg Am*. 1994;76:413–424.
17. Yamamoto I, Panjabi MM, Crisco T, et al. Three-dimensional movements of the whole lumbar spine and lumbosacral joint. *Spine (Phila Pa 1976)*. 1989;14:1256–1260.
18. Tantavisut S. *Measurement of Interspinous Distance of Thai Population in MRI and New Design Interspinous Dynamic Stabilization System of the Lumbar Spine*. Bangkok: Chulalongkorn University; 2007.
19. Kirkaldy-Willis WH, Wedge JH, Yong-Hing K, et al. Pathology and pathogenesis of lumbar spondylosis and stenosis. *Spine (Phila Pa 1976)*. 1978;3:319–328.
20. Whitesides TE Jr. The effect of an interspinous implant on intervertebral disc pressures. *Spine (Phila Pa 1976)*. 2003;28: 1906–1907; author reply 7-8.
21. Kim DH, Albert TJ. Interspinous process spacers. *J Am Acad Orthop Surg*. 2007;15:200–207.
22. Abumi K, Panjabi MM, Kramer KM, et al. Biomechanical evaluation of lumbar spinal stability after graded facetectomies. *Spine (Phila Pa 1976)*. 1990;15:1142–1147.
23. Tantavisut S, Ittiravivong P, Tangpornprasert P, et al. Magnetic resonance imaging based lumbar interspinous distance measurements in Thai subjects. *Chula Med J*. 2012;56:297–305.
24. Wiseman CM, Lindsey DP, Fredrick AD, et al. The effect of an interspinous process implant on facet loading during extension. *Spine (Phila Pa 1976)*. 2005;30:903–907.
25. Bono CM, Vaccaro AR. Interspinous process devices in the lumbar spine. *J Spinal Disord Tech*. 2007;20:255–261.
26. Yano S, Hida K, Seki T, et al. A new ceramic interspinous process spacer for lumbar spinal canal stenosis. *Neurosurgery*. 2008; 63:ONS108–ONS113; discussion ONS14.
27. Shim CS, Park SW, Lee SH, et al. Biomechanical evaluation of an interspinous stabilizing device, Locker. *Spine (Phila Pa 1976)*. 2008;33:E820–E827.
28. Singh K, Phillips FM. DIAM (device for intervertebral assisted motion) spinal stabilization system. In: Kim DH, Cammisa FP Jr, Fessler RG, eds. *Dynamic Reconstruction of the Spine*. New York: Thieme; 2006:274–283.
29. Kettler A, Drumm J, Heuer F, et al. Can a modified interspinous spacer prevent instability in axial rotation and lateral bending? A biomechanical in vitro study resulting in a new idea. *Clin Biomech (Bristol, Avon)*. 2008;23:242–247.
30. Trautwein FT, Lowery GL, Wharton ND, et al. Determination of the in vivo posterior loading environment of the Coflex interlaminar-interspinous implant. *Spine J*. 2010;10:244–251.
31. Kong DS, Kim ES, Eoh W. One-year outcome evaluation after interspinous implantation for degenerative spinal stenosis with segmental instability. *J Korean Med Sci*. 2007;22:330–335.
32. Wan Z, Wang S, Kozanek M, et al. Biomechanical evaluation of the X-Stop device for surgical treatment of lumbar spinal stenosis. *J Spinal Disord Tech*. 2012;25:374–378.
33. Villarejo F, Carceller F, de la Riva AG, et al. Experience with coflex interspinous implant. *Acta Neurochir Suppl*. 2011;108:171–175.
34. Patwardhan AG, Havey RM, Carandang G, et al. Effect of compressive follower preload on the flexion-extension response of the human lumbar spine. *J Orthop Res*. 2003;21:540–546.